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REPORT

USE OF  
ULTRASOUND IN  
ANTENATAL AND  
PRIMARY CARE

HEALTH TECHNOLOGY ASSESSMENT UNIT  
MEDICAL DEVELOPMENT DIVISION  
MINISTRY OF HEALTH MALAYSIA  
MOH/PAK/88.04(TR)

## EXECUTIVE SUMMARY

### INTRODUCTION

Ultrasound has been used for diagnostic purposes for more than 20 years in almost all branches of medicine. Ultrasonography has been widely accepted due to its clinical usefulness, convenience and non-invasiveness, as well as fetal biometry and detection of fetal anomalies. In addition, the newer ultrasound techniques like Doppler waveforms are used for fetal echography, uterine and fetal blood flow. The use of ultrasound as an effective diagnostic modality therefore continues to increase worldwide. Improvements in resolution and image quality, and in grey scale, have further enhanced its usefulness, while the advent of endo-vaginal and trans-rectal ultrasound examinations, allow direct access to anatomical structures without interference from overlying abdominal organs that occur in trans-abdominal ultrasound.

### OBJECTIVES

To assess the safety, effectiveness, cost effectiveness of the use of ultrasound in antenatal care and in primary care.

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### RESULTS

#### Safety

There is no scientific evidence on adverse effects of ultrasound, although there is some evidence of a statistically significant association between ultrasound and left handedness among males baby.

#### Effectiveness

##### *Use of ultrasound in antenatal care*

There is sufficient evidence that ultrasound is effective in dating pregnancy, assessing the viability of foetus, diagnosing twin pregnancy, diagnosing intrauterine growth retardation, diagnosis of placenta praevia, and detection of congenital abnormalities. There is also evidence of effectiveness of trans-vaginal ultrasound in detection of congenital abnormalities, retained products of conception, and predicting pre-term labour. There is sufficient evidence that routine ultrasound in antenatal care or ultrasound examination in low-risk population does not improve the outcome of pregnancy.

##### *Use of ultrasound in Gynaecology*

There is sufficient evidence that ultrasound is effective in detecting ectopic pregnancy, screening for ovarian cancer, and detecting uterine abnormalities.

##### *Use of Ultrasound in Surgery*

There is sufficient evidence that ultrasound is effective in diagnosing abdominal trauma, appendicitis, breast lesions, and gall bladder lesions like stones and tumours.

#### Training

There is sufficient evidence that the quality of ultrasound is determined by the level of training and experience of operators, and that appropriate training should be provided to those carrying out ultrasonography.

**Cost implications**

For antenatal screening, there is sufficient evidence that routine ultrasound screening for low-risk population is not cost-effective.

**Ethical implications**

There are ethical issues that need to be considered in providing ultrasonography services.

**Legal Aspects of Ultrasound**

There are legal issues to be considered in carrying out ultrasonography.

**RECOMMENDATIONS**

There is sufficient evidence to recommend that routine antenatal screening not be carried out in the low risk population. However, ultrasound screening should be carried out for high risk mothers. In addition, it should be used for diagnosis of various conditions in pregnancy or to rule out these conditions. Ultrasound is also recommended in secondary and tertiary care for diagnosis of gynaecological and surgical conditions.

Training has to be provided for all those involved in providing ultrasonography services.

Ethical and legal implications need to be considered.

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# 1. BACKGROUND

Ultrasound has been used for diagnostic purposes for more than 20 years, in almost all branches of medicine. Ultrasonography has been widely accepted due to its clinical usefulness, convenience and non-invasiveness, as well as fetal biometry and detection of fetal anomalies. In addition, the newer ultrasound techniques like Doppler waveforms are used for fetal echography, uterine and fetal blood flow (Reece et al, 1990). The use of ultrasound as an effective diagnostic modality therefore continues to increase worldwide. Improvements in resolution and image quality, and in grey scale, have further enhanced its usefulness, while the advent of endovaginal and transrectal ultrasound examinations; allow direct access to anatomical structures without interference from overlying abdominal organs that occur in trans-abdominal ultrasound.

In addition, the development of specialised applications like color flow monitoring has the potential to increase the diagnostic effectiveness of ultrasound. However, it has become evident that there has been an associated trend toward the use of equipment or machines with greater power outputs. Modern ultrasound equipment is capable of emitting acoustic power at levels that are sufficient to produce measurable effects in biological tissue (Barnett et al, 1994). In recent years there have been serious concerns that diagnostic applications of ultrasound may produce significant biological effects. The most sensitive target for ultrasound induced biological effects is the central nervous system of the developing embryo and foetus. As the bone develops so does the extent of ultrasound induced heating and tissues adjacent to the heated bone may be damaged (Barnett et al, 1994).

Ultrasound is also widely used in the investigation of abdominal symptoms. Its increasing popularity may lead to pressure on radiological services and diagnostic delays. Ultrasound is not radiological, since obstetricians and sonographers perform much of the obstetric ultrasound. Although obstetricians were among the first non-radiologists to perform and interpret ultrasound examinations, other specialists quickly recognized the relevance of this modality to their practice.

# 2. INTRODUCTION

## 2.1 Use of ultrasound in antenatal care

The Malaysian Society of Ultrasound and Obstetrics and Gynaecological Society of Malaysia have recommended that all pregnancies should have an ultrasound examination carried out at 20 weeks gestation. This in the Malaysian context has been said to be due to the higher preponderance of pregnant women being of dates, besides ensuring fetal well being, detecting fetal anomaly, multiple pregnancy, abnormal placental sites, and detecting pelvic masses, It has also been suggested, that prior to an ultrasound examination patients should be informed of the clinical indication, the benefits and limitations of the ultrasound examination (Malaysian Society of Ultrasound & Obstetrics and Gynaecological Society of Malaysia, 1995).

An ultrasound examination has been said to be cheap and safe, providing useful information during pregnancy, like gestational age, number and viability of fetus, and placental position (Shirley, 1991). It has been estimated that about 2% newborn infants have congenital or genetically determined abnormalities, and hence, prenatal ultrasound, especially in the first

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trimester is commonly used to detect such fetal structural abnormalities (Sherer, 1998). The diagnostic results have been said to have a profound effects on parental counselling, fetal outcome and perinatal management ( Phelps et al, 1996). In addition, twin pregnancies are associated with a three-fold increase in perinatal mortality due primarily to respiratory distress syndrome, and are also at increased risk of cerebral hemorrhage, asphyxia, anoxia and congenital abnormality (Hughes, 1985). In addition, monochorionic twins have a higher prevalence of antenatal and perinatal complications, and thus a diagnosis of chorionicity is important in managing twin pregnancies (Sepulveda, 1996; Wood, 1996; Sherer, 1998).

## 2.2 Use of Ultrasound in Gynaecological Care

Ultrasound evaluation of the female pelvis has been dramatically improved in recent years by the introduction of the endovaginal probe. This new approach allows closer proximity of the probe to the structure of interest and improves resolution. Ultrasound evaluation is also required to exclude retained products of conception, associated with miscarriage causing persistent bleeding (Dillon et al, 1993).

## 2.3 Use of Ultrasound in Surgical Settings

The use of ultrasound is expanding rapidly into all areas of surgical practice. Amongst the advantages of this diagnostic modality are that it is portable, non-invasive, diagnosis can be made expeditiously and can be repeated at any time, can be used to guide biopsy and is cost effective. With proper training, surgeons can accurately perform and interpret focused ultrasound examinations.

## 3. OBJECTIVE

To assess the safety, effectiveness, cost effectiveness of the use of ultrasound in antenatal care and in primary care.

## 4. METHODOLOGY

A literature search was carried out, the details of which are indicated in Appendix 1.

## 5. TECHNICAL FEATURES

Ultrasound or ultrasonography is a medical imaging technique that uses high frequency waves and their echoes. The technique is similar to the echolocation used by bats, whales, dolphins, as well as Sonar used by submarines.

The ultrasound machine transmits high-frequency (1-5 MHz) sound pulses through the body via a probe. These sound waves travel in the body and when they hit a boundary between tissues, some of the sound waves get reflected back to the probe, while some travel on further to reach another boundary and get reflected. These reflected waves are picked up by the probe and relayed to the machine. It calculates the distance from the probe to the tissue or organ (boundary using the speed of sound in tissue is either 5,005 ft/s or 1,540m/s) and the time of the each return (usually on the order of millionths of a second). The distances and intensities of the echoes will be displayed on the screen. In a typical ultrasound, millions of pulses and echoes are sent and received each second. The probe can be moved along the surface of the body and angled to obtain various views.

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There are different types of ultrasound like two-dimensional images, or “slices” of three-dimensional objects (fetus, organs), but the two types of ultrasound currently in use are 3D ultrasound imaging and Doppler ultrasound.

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### 5.1 3D Ultrasound Imaging

In these machines, several two-dimensional images are acquired by moving the probes across the body surface or rotating inserted probes. The two dimensional scans are combined by specialized computer software to form 3D images. 3D imaging allows a better view of the organ being examined and is best used for early detection of cancerous and benign tumors like examining the prostate gland for early detection of tumor, looking for masses in the colon and rectum, detecting breast lesions for possible biopsies. It also used for visualizing a fetus to assess its development, especially for observing abnormal development of the face and limbs and visualizing blood flow in various organs or a fetus.

### 5.2 Doppler Ultrasound

Doppler ultrasound is based upon the Doppler Effect, when the object reflecting the ultrasound waves is moving; it changes the frequency of the echoes, creating a higher frequency if it is moving toward the probe and a lower frequency if it is moving away from the probe. The frequency changed depends upon how fast the object is moving. Doppler ultrasound has been used mostly to measure the rate of blood flow through the major arteries of the heart.

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## 6. RESULTS AND DISCUSSION

### 6.1 Safety

Routine ultrasound scan may have significant psychological effects on pre-natal attitudes towards each other and the fetus (Zlotogorski et al, 1997). Another study shows that a suspected fetal malformation results in psychological stress with anxiety and depression levels significantly higher than in normal samples (Gotzmann et al, 2002).

Studies have not shown any effects on birth weight, growth during childhood, neurological development, language development, or the prevalence of dyslexia of routine ultrasound and there is no scientific evidence to support a relationship between ultrasound exposure to the fetus and cancer during childhood (Vogel, 1996; SBU, 1998; Kieler et al, 1998; Naumburg et al, 2000; Salvesen, 2002). Another review found that there is insufficient evidence to draw meaningful conclusions regarding safety of prenatal and postnatal use of Doppler or of ultrasound contrast agents used, and the developing central nervous system. However, if a standardized examination is instituted following appropriate patient handling guidelines, the risk of adverse outcomes associated with neurosonography is minimized (Barr, 2001). A Cochrane review also found that there is lack of data on the effect on both short and long term neonatal and childhood outcome (Bricker & Neilson, 2000). However, statistically significant association between ultrasound and left handedness among males has been found, although there is still need for more research (Salvesen, 2002; Marinac-Dabic, Krulewitch & Moore, 2002; Ziskin, 1999; Kieler et al, 1998). Another study found that more babies of low birth-weight were born in the ultrasound study group (Geerts, Brand & Theron, 1996). A review also found that there are some reports of a possible relation between prenatal ultrasound exposure and adverse effects like growth restriction, delayed speech, dyslexia (Marinac-Dabic, Krulewitch & Moore, 2002).

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A review found that focused ultrasound examination at the trauma suite can be as safe and accurately performed by surgery residents as by radiologists and radiology residents and should be a routine part of the initial trauma evaluation process (Buzzas et al., 1998).

## 6.2 Effectiveness

### 6.2.1 Use of ultrasound in antenatal care

#### Dating of pregnancy

Early ultrasound helps date a pregnancy, and this has been reported to be useful in the literature. The ultrasound determination of fetal crown rump length (CRL) in the first trimester has been shown to be an accurate measurement for gestation age (Pedersen, 1982).

Early pregnancy dating has led to high pre-term delivery and an increased estimate of term delivery, but lower estimate of post-term delivery (Reuss, Hatch & Susser 1995). Another prospective study revealed that antenatal dating of pregnancy was always superior to post natal estimation of gestational age (Wariyar, Tin & Hay, 1997). It was also found in a prospective observational study that 20% women who were screened had altered dates of delivery made by ultrasound compared to their last menstrual period. It was also found that ultrasound reduces the incidence of induction, and caesarean section rates, as well as reducing the incidence of post-term pregnancy (Belfrage, Fernstr & Hallenberg, 1987). In addition, it was found that accurate dating of pregnancy resulted in improvement of the obstetric management of pregnancy by lowering the incidence of delivery of small for gestation infants (Rasmussen et al, 1990).

#### Viability of foetus

A prospective observational study found that ultrasound correctly diagnosed 2.1% of non-viable pregnancies (Bahmaie & Edmonds, 1996). Another study showed that ultrasound scan at 10-13 weeks was able to diagnose about 3% of early pregnancy failure (Pandya et al., 1996). It has also been shown that Doppler velocimetry of the umbilical vessels may be useful in the assessment of viable fetuses with a sonographic diagnosis of a nuchal cord (Pilu et al., 1998). A single transvaginal sonography was found to be a reliable test to diagnose non-viable pregnancy in case the mean sac diameter is  $\geq 16$  mm or in case the crown rump length is  $> 5$  mm, since the combination of absence of cardiac activity and the absence of a yolk sac virtually rules out the possibility of a viable pregnancy in these patients (Schouwink et al., 2000).

#### Multiple pregnancies

The use of ultrasound at 10-14 weeks of gestation using the lambda sign is a good way of diagnosing chorionicity in twin pregnancy (Sepulveda et al., 1996). The ultrasound assessment of chorionicity using the twin peak has a sensitivity of 94% and specificity of 88% (Wood et al., 1996). It has been noted that there is a three-fold increase in perinatal mortality with twin pregnancies, primarily due to respiratory distress syndrome, but in part to an increased risk of cerebral hemorrhage, asphyxia, anoxia and congenital anomalies, and hence ultrasound identification and correct dating is essential. A significant improvement in perinatal outcome has been shown in routinely scanned patients (Hughey & Olive, 1985).

A study found that the sonographic identification of yolk sacs in multiple pregnancies allows an early and efficient recognition of presence and chorionicity of twin pregnancy, both intra and

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Use of ultrasound to diagnose ectopic pregnancy¶  
The sensitivity and specificity of transvaginal ultrasonography for predicting ectopic pregnancy was ranged from 87% to 99% and 84% to 100% respectively (Chechia et al., 2000; Shalev et al., 1998; Durham et al., 1997; Turan et al., 1996; Hopp et al., 1995; Sadek Al. & Schiotz, 1995; Achiron et al., 1994; Braffman et al., 1994; Hernadi et al., 1992; Bocciolone et al., 1991; Aleem et al., 1990). There were definite role on diagnosing ectopic pregnancy (Sadek, & Schiotz, 1995; Athey et al., 1991). However, combination with beta-hCG assay increases diagnostic accurac (... [9])

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extra-uterine, while identification of abnormal yolk sac or yolk sacs suggests death of one or all embryos (Malinowski, 1998). A review also found that dichorionic pregnancy foetal death of one twin does not entail any great risk of damage to the survivor; in such a pregnancy single foetal death in a premature phase may be accepted and the pregnancy may be continued. Sonographic determination of the chorionicity in multiple pregnancy at an early stage is essential because it also determines the policy if foetal problems occur (van Heteren et al, 1999).

### Detection of intrauterine growth restriction

When fetal growth is decreased, intrauterine growth restriction (IUGR) presents, and this is associated with increased risk of antenatal fetal death, intrapartum fetal distress and post natal developmental disorder. Sonography by being able to directly assess the fetus is more helpful in detecting IUGR than clinical or biochemical techniques. The detection of IUGR permits close surveillance of the affected pregnancy and early intervention for the compromised fetus. IUGR babies require close monitoring with ultrasound, fetal movement and fetal heart variation (Vindla et al, 1997). Fetal growth, measured by change in abdominal circumference examination, also shows promise for diagnosis of IUGR but is dependent on serial examinations (Craig et al, 1994). The estimated fetal weight at the time of the ultrasound examination has been used to predict actual birth weight and at delivery. The percent difference between the projected and actual birth weights used to define whether an infant was small, appropriate, or large for gestational age. This method appeared to be accurate and showed identical relationships to the presence of abnormal fetal heart rate patterns in growth-retarded infants as did the traditional birth-weight-for-gestational-age method of defining intrauterine growth retardation (Ott, 1990).

It has been found that Doppler is good in detecting IUGR babies (Arbeille et al, 1988), while it has also been said to be the best mode of investigation to detect adverse fetal outcome and growth restriction in multiple pregnancies (Joerhn et al, 1997). In Europe, a meta-analysis showed that pregnancies with hypertension complicated with IUGR had a higher risk of developing absence of reversed end diastolic velocity waveforms on Doppler examination (Karsdorp et al, 1994). It has been found that the cerebral umbilical ratio shows a sensitivity of 90% compared with 78% of middle cerebral artery and 83% for umbilical artery indices when used as a predictor of poor perinatal outcome in this growth restricted fetuses. It was also found that absent end diastolic flow is associated with severe IUGR and hypoxia and poor fetal outcome (Arbeille, 1997).

The Swedish Council on Technology Assessment in Health Care (SBU) found that ultrasound examination aimed at determining fetal weight is the best method for diagnosing intrauterine growth retardation, although the evidence does not show any favorable effect from this ultrasound examination (Hagenfeldt et al, 1998).

### Location of placenta

Ultrasound has been said to be a good predictor of placental location (Zelop et al, 1994). It has also been found to be a good tool in the diagnosis of placenta praevia from the first trimester (Hill, 1995), as well as at term (Lauria et al, 1996). SBU found that routine ultrasound examination during the first half of pregnancy would predict most cases of placenta previa even if the method is often over-diagnosed. Thus, the substantial risk for over-diagnosing the condition during the first half of pregnancy makes it doubtful whether assessing the position of

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¶ Use of Doppler ultrasonography examinations in singleton pregnancies with increased risk of or signs of IUGR is estimated to be about 5000 per annual (Westergaard, & Langhoff-Roos, 2002).
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the placenta should be included in routine, prenatal ultrasound examination, particularly since this condition is rare (Hagenfeldt et al, 1998).

Colour Doppler flow has also been found to be useful in diagnosis of placenta accrete. However, trans-vaginal ultrasound has been said to be superior to trans-abdominal ultrasound in the diagnosis of placenta praevia (Tan et al, 1995).

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The use of trans-vaginal sonographic and color Doppler in women with risk of vasa previa may help to reduce the mortality from these conditions (Oyelese et al, 1998). A prospective study shows that the specificity sonographic diagnosis of vasa previa was 91%, so that antenatal diagnosis prevented the catastrophic outcomes commonly associated with vasa previa (Catanzarite et al, 2001).

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## **Congenital abnormalities**

### *Sensitivity and specificity of ultrasound screening*

The sensitivity of routine ultrasound screening for fetal abnormality in low risk population less than 24 weeks gestation ranges from 19 - 99.9% (Grandjean Larroque & Levi, 1999; VanDorsten, 1998; Magriples & Copel, 1998; Sakri et al, 1998; Lee et al, 1998; Aymerich, Almazan & Jovell, 1997; Skupski et al, 1996; Shirley, 1992; Chitty et al, 1991), while the specificity ranges from 99.4 - 99.9% (Magriples & Copel, 1998; Lee et al, 1998; Aymerich, Almazan & Jovell, 1997; Skupski et al, 1996). Ultrasound has been found to be highly sensitive (89.7%) and specific (99.7%) among patients with risks, and the accuracy of anomaly detection is high, even in low risk patients (VanDorsten et al, 1998). In Korea, the sensitivity of ultrasound test was found to be 78.7% for abnormal fetus and 58% for anomalies with a specificity of 99.9% (Lee et al, 1998). However, a review found that the sensitivity of routine prenatal ultrasound for detection of chromosomal abnormalities is low (Stoll et al, 1993).

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### *Use of ultrasound to detect major and minor abnormalities*

While ultrasound examination could diagnose approximately 50% of major abnormalities, the effect of perinatal outcome in low risk pregnancies has not been established, and therefore the role of routine ultrasound scanning remains controversial. However, in high risk population the accuracy in diagnosing congenital abnormalities is more than 90% (Garmel & D'Alton, 1994). Skupski et al, (1996), found that the sensitivity and specificity to detect major abnormalities was 30% and 100% respectively, with the sensitivity rising to 75% if only major anomalies are included. Routine obstetric ultrasonographic screening in low risk population at 18 - 20 weeks gestation was able to detect 5.35% anomalies, with 1.16% major anomalies and 4.19% minor anomalies (Skupski et al, 1996). Similarly, routine ultrasound was found to detect major and less severe congenital abnormalities in low risk population. In addition, there were undetected major abnormalities during selective ultrasound, which could potentially be detected by routine anomaly scanning. However, there may be a high false positive scan in routine scanning (Long & Sprigg, 1998). While ultrasound is a useful tool to identify various congenital abnormalities, it is more accurate for the detection of major abnormalities with a detection sensitivity of 73.7% compared to 45.7% for minor abnormalities (Gradjen, Larroque & Levi, 1998; 1999).

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*Use of ultrasound in detection of cardiac anomalies*

Ultrasound does not detect cardiac anomalies as efficiently as it does other abnormalities (Busken et al, 1996). The sensitivity of ultrasound to detect serious cardiac anomaly was found to be 0% in first trimester, 10 - 25% in second trimester, and 50% for third trimester (Roberts et al, 1998).

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*Use of ultrasound in detection of CNS abnormalities*

Ultrasound has a sensitivity of 100% in detecting anencephaly even in the low risk population and is thus a good tool for screening for neural tube defects, but is more effective with an existing alpha fetoprotein level (Chan et al, 1995). In Scandinavia, the detection rate of neural tube defects was 79.4% by second trimester ultrasound screening in the low risk population (Jorgesen et al., 1999). Another study in Europe showed that 96% of anencephaly was correctly identified prenatally (Boyd et al, 2000). The Health Council of Netherlands (2001) found that there is no hard evidence to support the use of ultrasound screening for structural abnormalities other than neural tube defects. Another review found a similar finding that fetal ultrasonography while effective in identifying neural tube defects, the accuracy of detection of other CNS malformations remain unclear (Pilu & Hobbins, 2002).

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*Use of ultrasound in detection of Down's Syndrome*

A review found that the sensitivity of using nuchal translucency as ultrasound marker to detect Down's Syndrome is approximately 70 - 80% with 5% false positive rate (Souter & Nyberg, 2001). Another study showed that about 75% of trisomic pregnancies can be identified using nuchal translucency thickness at 11 - 14 weeks scan combined with maternal age (Nocolaides, Heath & Liao, 2000). In Scandinavia, it was found that the detection of Down's Syndrome was 6.3% using ultrasound screening at second trimester for low risk population (Jorgensen et al, 1999). The Catalanian Agency for Health Technology Assessment found that using nuchal fold and length of femur as ultrasound markers for detection of Down's Syndrome, the sensitivity ranged from 32% - 65% and specificity was 99% (Aymerich et al, 1997).

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Benn et al, (1997) found that use of ultrasonography to measure gestation age could be reduced if amniocentesis was performed to detect Down's Syndrome. Abnormal ultrasonographic results have been found more likely to be associated with Down's Syndrome than normal results (Nyberg et al, 1995). It was found that about half of the fetuses with trisomy 21 had abnormal sonographic finding in second trimester scan (Tongong et al, 2001).

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*Use of ultrasound for detection of abdominal wall defects*

The Euroscan Study Group found that the sensitivity of antenatal ultrasound examination in detecting omphalocele was 75% and that of gastroschisis was 83% (Barisic et al, 2001). In Scandinavia, the detection of abdominal wall defects was 85.7% using ultrasound screening at second trimester for low risk population (Jorgensen et al, 1999). Another study found that the detection of anterior abdominal wall defects in an unselected population between 16 - 22 weeks gestation was 60% with false positive rate of 5.3% (Walkinshaw et al, 1992).

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*Use of ultrasound for detection of other abnormalities*

Prenatal ultrasound had an influence on the incidence of newborns with anomalies, by decreasing from 1.95 - 1.34%, subsequently increasing the termination of pregnancy from 0.35 - 0.83%

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because of fetal anomalies, while the detection of malformations increased from 53.9 - 79.6 % (Zimmer et al, 1997). The National Coordinating Council for Health Technology Assessment in the UK found that the detection rate of fetal abnormalities by ultrasound scan varies with the organ affected, with a variation also seen at second and third trimester examination (NCCHTA, 2000). Genetic ultrasonography used in a community based practice is highly effective in identifying chromosomal abnormal fetuses (Wax et al, 2000). The risk of fetal chromosomal abnormalities reduces 2 to 3 fold when ultrasound examination is normal, whereas, the presence of any major ultrasonographic abnormality or certain minor abnormalities significantly increases the risk. However, the application of these results to low risk patients is still premature (Ott & Taysi, 2001).

The detection of anomalous fetuses using ultrasound was significantly better in the indicated group compared to screening group (VanDorsten et al, 1998). There was a high detection rate of abnormalities of the CNS and low for rates for skeletal and cardiac abnormalities (Bricker et al, 2000; Grandjen, Larroque & Levis, 1999). Ultrasound is also less reliable in detecting hindgut abnormalities and best for detection duodenal obstruction (Phelps et al, 1991). Urinary tract abnormalities were diagnosed in 0.18% of the pregnancies, and of these 61.7% were found at the second routine ultrasound scanning (Fugelseth et al, 1994). Antenatal ultrasound able to detect 93% of cleft lip and palate, 22% of isolated cleft palate and the overall detection rate was 65% (Cash, Set & Coleman, 2001). The sensitivity of detection of esophageal atresia was 80% (Shulman et al, 2002).

### Use of trans-vaginal ultrasound in antenatal care

#### Use of trans-vaginal ultrasound in detection of abnormalities

High-resolution trans-vaginal ultrasound has been found to be useful for the early screening of chromosomopathies, however it was felt that further studies are necessary (Felicetti et al, 2001). It has been shown that trans-vaginal ultrasound was able to detect 51.6% of anomaly in early pregnancy, and if combined with second trimester trans-abdominal ultrasound the detection rate was 84.4%. Hence, trans-vaginal ultrasound appears to be effective in identifying many congenital fetal abnormalities like cystic hygroma and fetal hydrops, although other abnormalities, particularly heart defects, are associated with lower rates (Guariglia & Rosati, 2000). However, Yagel et al, (1995) found that 17.4% of birth defects were not detected by early second trimester vaginal scan, and thus it has been recommended that the vaginal ultrasonographic examination should be followed by trans-abdominal scan.

#### Use of trans-vaginal ultrasound in detection of retained products of conception

Trans-vaginal sonography has been found to be a useful supplement to clinical assessment in women who experience a spontaneous first-trimester abortion (Wong, Lam & Ho, 2002; Carlan, 1994). It was also found that the use of trans-vaginal sonography reduces unnecessary general anesthesia and uterine curettage (Wong, Lum & Ho, 2002; Chung et al, 1998; Haines, 1991). The use of color ultrasound has been found effective for this purpose as well (Dillon et al, 1993).

#### Use of trans-vaginal ultrasound in improving perinatal outcome

A number of systematic reviews and health technology assessments found that there is sufficient evidence that routine/screening ultrasound does not improve the outcome of pregnancy by an increased number of live births or of reduced perinatal morbidity (Aymerich, Almazan & Jovell,

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 ¶ NCCHTA (2000) found that the detection rate of fetal abnormalities by ultrasound scan was varying with the organ affected. There were also a variation seen at second and third trimester examination, and there is lacking of data for first trimester scanning.¶  
 ¶ Genetic ultrasonography use in community base practice is highly effective in identifying chromosomal abnormal fetuses. (Wax et al., 2000)¶  
 ¶ The risk of fetal chromosomal reduces by 2 to 3 fold when ultrasound examination is normal, whereas, the presence of any major ultrasonographic abnormality or certain minor abnormalities significantly increases the risk. However, the application of these results to low risk patients is still premature (Ott, & Taysi, 2001)¶  
 ¶ Ultrasound is less reliable in detecting hindgut abnormalities and best for detection duodenal obstruction (Phelps, 1991).¶  
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 ¶ Antenatal ultrasound able to detect 93% of cleft lip and palate, and the detection rate of isolated cleft palate was 22%, hence the overall detection rate was 65% (Cash et al., 2001)¶  
 ¶ The sensitivity of detection of esophageal atresia was 80% (Shulman et al., 2002).¶  
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Deleted: The sensitivity and specificity of cervical status for detecting retained products of conception were 65% and 56%, respectively, whereas the overall sensitivity and specificity of transvaginal sonographic examination (bilayer endometrial thickness 8 mm or less) were 44% to 100% and 80% to 92% respectively. Thus, t...is ...SJ.....CJ ...studied ...an [30]

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1999; Hagenfeldt et al, 1998; Neilson, & Neilson, 2001; Bricker & Neilson, 2001; Garmel & Alton, 1994; Bucher & Schmidt, 1993; Ewigman et al, 1993). Another Cochrane review found that based on the existing evidence, routine Doppler ultrasound examination in low risk or unselected populations did not result in increased antenatal, obstetric and neonatal interventions, and no overall differences were detected for substantive short term clinical outcomes such as perinatal mortality (Bricker & Neilson, 2001).

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However, another review found a significant decrease of 50% in perinatal mortality and in stillbirth of anatomically normal fetuses, with no increase in neonatal or maternal mortality associated with the use of Doppler ultrasound, and delay in timing fetal death not contributing to the reduction in perinatal mortality (Gonser & Vetter, 1995). Other studies also found that ultrasound screening significantly lowers perinatal mortality rate in the routinely screened population compared to the control group (Saari-Kemppainen et al, 1990, 1994; Bucher et al, 1993). However, there was no difference found in perinatal morbidity between women with routine ultrasound scanning and selective ultrasound screening (Greet, Brand & Theron, 1996).

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... [33]

*Use of trans-vaginal ultrasound in prediction of preterm delivery*

Trans-vaginal ultrasound assessment of endo-cervical length has been found to be superior to funnelling and digital examination in predicting preterm delivery in patients who present with suspected preterm labor, and is a better predictor in singletons than in twins between 23 and 33 weeks' gestation (Crane et al, 1997). Another study stated that cervical canal length less than or equal to 28 mm measured by trans-perineal sonography had the highest diagnostic performance with a sensitivity of 78.1% and specificity of 82.7% compared with digital examination, cervical dilatation and effacement and is thus more accurate than digital examination for prediction of preterm delivery in patients presenting with preterm labor. However, trans-perineal ultrasonographic examination of cervix is invaluable in the prediction of preterm delivery where trans-vaginal transducers are lacking or skilled staffs are unavailable (Onderoglu, 1997).

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... [34]

It has been found that a single trans-vaginal sonographic measurement of cervical length at 28-30 gestational weeks can be used to predict the risk of preterm delivery, but its cost-effectiveness needs to be assessed further (Tongsong et al, 1995). It was also found that trans-vaginal ultrasonography of the cervix between 14 and 24 week's gestation is a good predictor of preterm delivery in high-risk pregnancies (Berghella et al, 1999). Another study showed that trans-vaginal ultrasonography, in addition to routine trans-abdominal ultrasonography at 18 to 22 weeks, helps to identify many patients at significant risk for prematurity; however, low sensitivity and low positive predictive value limit its usefulness in screening low-risk obstetric populations (Taipale & Hiilesmaa, 1998).

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Cervical length has been found to be a more significant predictor of preterm premature rupture of membranes (PPROM) compared with preterm labour (PTL), while socio demographic factors were more predictive of PTL (Odibo, Talucci, & Berghella, 2002). Another study found that the shortening of the functional canal length (< or = 20 mm) is predictive of impending preterm delivery and the functional canal length of more than 31 mm is an indicator of the absence of labor. Thus, cervical sonography can be a valuable adjunct to the clinical assessment of patients with signs and symptoms of preterm labor (Hincz et al, 2001). It was also found by a meta-analysis and a review that the best cut-off for cervical length was 18 to 30 mm, with sensitivity

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... [36]



for predicting preterm birth ranging from 68 - 100%, and specificity from 30 - 79% (Vendittelli & Volumenie, 2000; Leitich et al, 1999). For cervical lengths of 25 and 35 mm or 25 and 39 mm, the sensitivity to predict preterm delivery was 33 - 54%, or 63 - 76% and specificity 95 - 99% or 92% respectively (Leitich et al, 1999). In patients at high risk for preterm delivery because of obstetric history, trans-vaginal sonographic cervical length < 25 mm, a cervical length < 10 mm and cervical funneling > 75% were the most predictive of PPROM and a major contributor to preterm delivery in these patients (Odibo et al, 2001). Another study found that both cervical length < or = 30 mm and cervical funneling in twin pregnancies under 26 weeks' gestation are independently and strongly associated with high risk for preterm births. However, a long cervix, more than 35 mm long, is associated with very low risk (4%) of preterm birth (Yang et al, 2000). It was also found that in high-risk singleton gestations cervical length was comparable to other sonographic cervical parameters in its ability to predict spontaneous preterm birth and was better for the prediction of earlier periods of prematurity. However, the optimal cervical lengths and their performance for predicting prematurity may be influenced by obstetric risk factors (Guzman et al, 2001). It was found that the sonographic findings of premature dilatation of the internal os prolapse of the membranes into the endo-cervical canal and shortening of the distal cervix are associated with a high rate of delivery at less than 34 weeks (51%) and neonatal death (27%) (Benham et al, 2002). A study found that a short cervix seen on second-trimester sonogram was a powerful predictor of early spontaneous preterm delivery (Hassan et al, 2000).

Serial sonography up to 28 weeks' gestation is useful in identifying patients at higher risk for premature rupture of the membranes and preterm delivery (O'Brien, Hill & Barton 2002). The use of trans-vaginal ultrasonography for cervical length measurement during preterm premature rupture of membranes may predict early delivery, but cannot anticipate the risk of chorioamnionitis or neonatal sepsis (Gire et al, 2002).

Ultrasound-guided management despite cervical shortening does not result in unfavorable pregnancy outcome, and a significant number of patients can avoid operative procedures (Kassanos et al, 2001).

### 6.2.2 Use of ultrasound in Gynaecology

#### Ectopic pregnancy

Ultrasound has also a role in diagnosing ectopic pregnancy (Sadek & Schiotz, 1995; Athey et al, 1991). Patients whose ultrasound showed an empty uterus had the highest frequency of ectopic pregnancy (Dart et al, 2002). It was found that the best criterion to use for the diagnosis of ectopic pregnancy is a non-cystic adnexal mass (Brown & Doubilet, 1994). Sub-classification of indeterminate ultrasound readings identifies patients at high, intermediate, or low risk for ectopic pregnancy may improve the diagnostic accuracy of ultrasonography in patients at risk for ectopic pregnancy (Dart & Howard, 1998). It was found by Burry et al, (1993) that the halo sign in ultrasonography is presumptive evidence of a living ectopic pregnancy, and when identified may allow earlier diagnosis and intervention. Another study also found that ultrasound has been found to be a promising modality in the confirmatory diagnosis of ectopic pregnancy, especially when a strong suspicion was established by history clinical examination and pregnancy test (Iloabachie & Mgbor, 1991).

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In a study by Ehsan & Mohamood (1998), the diagnosis of ectopic pregnancy could be made clinically (80%), by culdocentesis (90%), by ultrasound (90%) and confirmed by laparoscopy (100%) However, ultrasound in combination with beta-hCG assay has been found to increase diagnostic accuracy (Chechia et al, 2000; Turan et al, 1996; Bocciolone et al, 1991; Aleem, DeFazio & Gibtautas, 1990). It was also found ultrasound correctly identified 69.6% of ectopic pregnancy, although subsequently the true positive rate increased to 78.3%, and the false negative rate decreased to 8.8% (Dallas, West & Mullings, 1994).

Durston et al. (2000) found that the specificity of Emergency Department Sonography in ruling an intra-uterine pregnancy (IUP) was 100%. Another study found that trans-abdominal ultrasound performed in the emergency department is useful in screening for early pregnancy complications, with ectopic pregnancy being suspected when no IUP is found on preliminary scanning (Wong et al, 1998). Emergency physician ultrasonographic diagnoses included definite IUP 59%, probable abnormal IUP 11%, definite ectopic pregnancy 2%, and no definite IUP 28% (Mateer et al, 1995).

With the advent of vaginal ultrasound, early diagnosis of ectopic pregnancy can be made and hence conservative tubal surgery can be performed, so that there is improved outcome with the use of ultrasound in the diagnosis of ectopic pregnancy (Abound, 1997). A review indicated that the most common endo-vaginal sonographic finding of ectopic pregnancy is an extra-ovarian, round or elongated, solid tubal mass, or alternatively a tubal ring (Atri et al, 1996).

The sensitivity and specificity of trans-vaginal ultrasonography for predicting ectopic pregnancy ranges from 87% - 99% and 84% - 100% respectively (Chechia et al, 2000; Shalev et al, 1998; Durham et al, 1997; Turan et al, 1996; Hopp et al, 1995; Sadek Al. & Schiotz, 1995; Achiron et al, 1994; Braffman et al, 1994; Hernadi et al, 1992; Bocciolone et al, 1991; Aleem et al, 1990). A prospective study found that transvaginal sonography enabled detection of hemoperitoneum with a sensitivity of 91%, so that a tubal pregnancy can be predicted reliably on the basis of trans-vaginal sonographic findings (Cacciatore, 1990). The sensitivity and specificity of echogenic fluid for establishing hemoperitoneum were both 100%, compared with 66% and 80% respectively for culdocentesis. Thus, sonography is more sensitive than culdocentesis in the detection of hemoperitoneum (Chen et al, 1998).

It was also found that the use of trans-vaginal B mode imaging alone in the diagnosis of ectopic pregnancy achieved a sensitivity of 98% (Chew et al, 1996). Trans-vaginal sonography (TVS) has been found to be superior, offer an earlier, clearer and more exact diagnosis of ectopic pregnancy than transabdominal scan (TAS) (Luo et al, 2002; Hanchate et al, 2002; Gramith et al, 1991; Valenzano et al, 1991; Thorsen et al, 1990). It is suggested that TVS is best used when TAS is not conclusive, or when immediate confirmation of an intrauterine pregnancy is desired (Gramith et al, 1991).

Color Doppler techniques can also complement endovaginal sonographic findings (Atri et al, 1996). The capacities of color Doppler further enhance the diagnostic sensitivity of trans-vaginal ultrasound for the early recognition of abnormal and normal intrauterine pregnancy, and small extrauterine masses (Goes, Breueq & Osteaux, 1998). However, the use of trans-vaginal color flow imaging has also been shown not to increase detection rates of ectopic pregnancy, having

failed to improve on the results of trans-vaginal B mode sonography in the detection of ectopic pregnancy (Chew et al, 1996).

A retrospective study found that endovaginal scanning does not permit a confident diagnosis of ectopic pregnancy in many cases (Russell, Filly & Damato, 1993). Another study suggests that trans-vaginal Doppler ultrasound has significant lower sensitivity and does not provide more useful diagnostic information than 2-D imaging alone for stable patients with suspected ectopic pregnancies (Achiron et al, 1994).

### Ovarian cancer

A health technology assessment found that ultrasound screening can detect a higher proportion of ovarian cancers at Stage I (Bell et al, 1998). Another study found that 77.3% of the primary ovarian carcinomas found during screening were in curable Stage I, and thus increased use of trans-vaginal sonography screening for ovarian carcinoma may increase the chance for early diagnosis and decrease the mortality of the disease (Sato et al, 2000; Fleischer et al, 1996). Similarly, another study showed that women that had morphologically normal ovaries on ultrasound examination and non-suspicious on color Doppler analysis, were also negative on histopathological analysis, indicating that color Doppler ultrasonography to be a valid first level screening method (Rampone et al, 2001). About 9.6% of the ovarian tumors detected by ultrasound were diagnosed as malignant (Osmers et al, 1998).

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### Endometrial polyps

A prospective study shows that using trans-vaginal sonography low levels of endometrial thickness reduced the possibility of abnormalities such as polyps and hyperplasia, but did not exclude them, nor increase the diagnostic performance in those with normal sonograms (Dueholm et al, 2001).

### Uterine abnormalities

Sonohysterography has been found to provide additional information over trans-vaginal sonography alone in symptomatic women with known or suspected myomas, particularly before surgical or medical therapy (Becker et al, 2002). Another study had shown trans-vaginal – color Doppler ultrasound may be more useful in differentiating between endometrial hyperplasia and endometrial carcinoma than measuring endometrial thickness by trans-vaginal grey-scale sonography (Emoto et al, 2002). The diagnostic accuracy of saline infusion sonography has been found to be higher than that of TVS for endometrial thickness measurement and is the optimal method for reducing the hysteroscopy rate (Dijkhuizen et al, 2000). Another study also found that TVS allows the detection of an endometrial pathology in the vast majority of patients with postmenopausal bleedings (Gerber et al, 1999). The accuracy of TVS was found to be comparable with that of hysteroscopy in detecting cervical involvement in endometrial cancers (Gabielli et al, 1996).

However, another study stated that while TVS has a very high sensitivity for the detection of early endometrial carcinoma, but the specificity remains low, and Doppler sonography does not improve the detection of pre-malignant and malignant endometrial lesions compared to normal ultrasound (Vuento et al, 1999). Similarly, it has been found that the use of color velocity

imaging and pulsed Doppler does not improve the diagnostic accuracy of trans-vaginal ultrasonography alone in the diagnosis of ovarian endometrioma (Alcazar et al, 1997).

### Adnexal masses

Color Doppler ultrasound has been found to have a better diagnostic performance as compared with CA-125, being significantly more specific (Alcazar et al, 1999). Another study stated that the present technique of Doppler ultrasound examination is helpful only in the differential diagnosis of multilocular cysts with solid parts (Valentin, 1997).

### 6.2.3. Use of Ultrasound in Surgery,

#### Use of Ultrasound in Abdominal Trauma

The evaluation of the patient with potential intra-abdominal injury continues to challenge trauma and emergency doctors. Although there is no substitute for an accurate history and physical examination, trauma patients may present with altered mental status due to head injury, polytrauma or homodynamic instability, alcohol or drug intoxication, rendering clinical evaluation difficult. The low sensitivity of physical examination has encouraged clinicians to rely various on objective diagnostic modalities for the detection of intra-abdominal injury like the ultrasound.

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Sonography as the primary diagnostic tool has been said to provide accurate, fast, cost-effective, and non-invasive initial management of patients with blunt abdominal trauma. It has also been shown to be an excellent indicator of the need for emergency laparotomy, and proved to be of high value in revealing relevant injury (Bode et al, 1999). The sensitivity of ultrasound in blunt abdominal trauma ranges from 69 – 96% and specificity from 95 – 100%, with accuracy ranging from 96.1 - 99% (Pear & Todd, 1996; Kern et al, 1997; McKenney et al, 1998; Rozycki et al, 1998; Bode et al, 1999; Fernandez Cordoba et al, 2001). It was also found that the use of ultrasound detection of free intra-peritoneal fluid alone regardless of associated injuries showed a sensitivity of 75 - 98% in detecting free intra-peritoneal fluid and specificity of 95 - 100% (Rathaus et al, 2001; Holmes et al, 2001; Corbett et al, 2000; Pear & Todd, 1996). Another study found that the sensitivity and specificity of ultrasound in determining the need for emergency laparotomy ranged from 84 – 93% and 88 - 100% respectively, and the effectiveness of ultrasound localization of injured organs had a sensitivity ranging from 20 - 80% depending upon the organ injured (Pear & Todd, 1996). However, in comparing with diagnostic peritoneal lavage and Computed Tomography, sonography is less sensitive for identifying intra-peritoneal injuries (Pear, & Todd, 1996). Another study found that ultrasound was most sensitive and specific for the evaluation of patients with pre-cordial or trans-thoracic wounds (sensitivity 100%, specificity 99.3%) and hypotensive patients with blunt abdominal trauma (sensitivity 100%, specificity 100%), suggesting that it should be the initial diagnostic modality for the evaluation of these patients and immediate surgical intervention is justified when those patients have positive results (Rozycki et al, 1998).

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ranged from 69 - 91.7% and specificity  
ranging from 86- 94.7%, while DPL had  
sensitivity of 100% and specificity of 86-  
94.7%, CT had sensitivity ranging from  
75%-97% and specificity ranging from  
95-100%. Thus, evidence indicates that  
than DPL and CT ..., but has value in  
identifying patient for laparotomy...US  
were... US ...with precordial wounds  
and blunt truncal injuries because it is  
rapid and accurate. Because of the high  
sensitivity and specificity of US in the  
evaluation of patients with precordial  
wounds and hypotensive patients with  
blunt torso trauma, ...a ...US  
examination.... [43]

A study found that blunt abdominal trauma is often associated with acute injuries of the kidney with significant splenic, hepatic, or bowel trauma, and while, sonography may be used in the triage of patients with blunt abdominal trauma and possible renal injury, a negative ultrasonogram does not exclude renal injury (McGahan et a 1999). A retrospective review found that a normal ultrasound examination or the presence of pelvic fluid would indicate that organ

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injury is unlikely, the probability of an organ injury is very high with peritoneal fluid outside the pelvis (Rathaus et al, 2001).

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For intra-abdominal injuries in the emergency department, it has been found that although sonography to evaluate patients for injury caused by blunt trauma is highly accurate and specific sonographic detection of free fluid is only moderately sensitive for diagnosis (Richards et al, 2002). There were similar findings in another study that emergency abdominal ultrasound scan used solely for the detection of intra-peritoneal fluid in pediatric blunt trauma patients has a modest accuracy, best results being obtained in those children who are hypotensive (Holmes et al, 2001). Another study found that ultrasonography is a reliable and rapid method uses for screening traumatized children for free fluid in the peritoneum even in the hands of novice sonographers in the emergency department (Corbett et al, 2000). A review found that emergency sonography is sensitive for the detection of grade III or higher liver injuries resulting from blunt abdominal trauma (Richards et al, 1999).

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The sensitivity of Focused Abdominal Sonogram for Trauma (FAST) ranges from 30 - 68% and specificity 95 - 100% (Frezza, Ferone & Martin, 1999; Patel & Tepas, 1999; Mutabagani et al, 1999; Boulanger et al, 2001; Udobi et al, 2001). A study found that FAST is an invaluable diagnostic tool in the primary survey of trauma victims (Frezza, Ferone & Martin, 1999). FAST when compared to diagnostic peritoneal lavage, CT scan, operative findings, serial examination and/or post-mortem findings had an overall sensitivity of 67% and specificity of 97%, and it was thus concluded that the FAST examination is feasible and should be used in the initial assessment of trauma (Yeo, Wong & Soo, 1999). FAST in evaluation of pediatric blunt trauma patients performed by surgical residents and attending in the emergency department has been found to rapidly and accurately predict the presence or absence of intra-peritoneal fluid, and indicates that it is a potentially valuable tool to rapidly prioritize the need for laparotomy in the child with multiple injuries and extra-abdominal sources of bleeding (Thourani et al, 1998). A study suggests that FAST can be a useful initial diagnostic study after penetrating abdominal trauma, a positive FAST being a strong predictor of injury, so that patients should proceed directly to laparotomy. If negative, additional diagnostic studies should be performed to rule out occult injury (Udobi et al, 2001). It was also found that while the routine use of sonography in penetrating torso injury is beneficial and the detection of pericardial or peritoneal fluid is clinically useful, a negative FAST examination does not exclude abdominal injury, such as a diaphragm or hollow viscus wound, and further investigation or close follow-up is required (Boulanger et al, 2001). It has also been suggested that FAST should be expanded to include the thorax especially in diagnoses of pneumothorax (Dulchavsky et al, 2001).

However, a prospective study found that FAST missed injuries like liver laceration, adrenal hematoma, renal laceration, small bowel injury and splenic laceration, and concluded that FAST alone is not a useful screening test in the evaluation of children with suspected intra-abdominal injury (Mutabagani et al, 1999). Another study also found that FAST could not reliably exclude intestinal injury in patients with seat belt marks (Stassen et al, 2002).

A study found that computed tomography is the imaging modality of choice in children with severe abdominal trauma but ultrasonography is a reasonable technique to arouse diagnostic suspicion that can avoid additional tomographic studies. Abdominal computed tomography must

be reserved for the hemodynamically stable children with abnormal ultrasonographic findings or with suspected injuries by a clinical evaluation that gone unnoticed (Fernandez Cordoba et al, 2001).

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### Use of Ultrasound in Appendicitis

The sensitivity, specificity and accuracy of ultrasound in diagnosing appendicitis in various studies ranged from 21.5 - 99.3%, 68.1 - 97% and 86.8 - 96% respectively (Fa & Cronan, 1989; Orr et al, 1995; Zoller, Kellner & Schwerk, 1996; Ramachandran et al, 1996; Chen et al, 1998; Hahn et al, 1998; Marusch, Allecke & Gastinger, 1998; Simonovsky, 2000; Soda et al, 2001).

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It has been reported that the efficacy of ultrasonography using simple criteria was superior to the initial clinical impressions (Soda et al, 2001). Among patients with acute abdomen, the sensitivity and specificity of ultrasound scan was found to be 81% and 86% with a prevalence of appendicitis of 83%. with 50% of misdiagnosed patients discharged without ultrasound and 100% of those discharged after a false negative ultrasound returning with ruptured appendicitis (Axelrod et al, 2000). In an East German study, it was found that 90% of those with a positive sonogram result shows were confirmed intra-operatively, indicating that if clinical examination showed a presumptive diagnosis of acute appendicitis, a negative sonogram should not prevent the surgeon from performing an operative intervention (Marusch et al, 1998). Another study suggests that ultrasound should not be used to exclude appendicitis for patients with classic signs of the illness due to the high false-negative rate, while a positive result indicates the necessity of an operation, or extended observation in patients with intermediate signs of appendicitis; ultrasound screening is not recommended for those patients with a low probability of appendicitis due to the high false-positive rate (Orr et al, 1995). However, another study found that appendiceal ultrasonographic examination is a reliable ancillary technique in diagnosing or excluding appendicitis, with a maximal appendiceal diameter of more than 6 millimeters (Fa & Cronan, 1989).

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A prospective study suggests that patients with clinically diagnosed or suspected acute appendicitis should routinely undergo abdominal sonography examination performed by an experienced surgeon, which would decrease the negative appendectomy rates (Chen et al, 1998). Another study found a similar finding that a sonographic examination by an experienced examiner could decrease the rate of negative laparotomies to 7%, while possible differential diagnoses could be either confirmed or ruled out by using ultrasound technique (Zoller, Kellner & Schwerk, 1996).

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In children with acute appendicitis, although the use of ultrasound for diagnosis had excellent results, the decision for surgery remains a clinical one because of the continuing false-negative and false-positive results from sonography (Hahn et al, 1998). Another prospective study reported that graded compression sonography with adjuvant use of a posterior manual compression technique seems to be useful for detecting the vermiform appendix and for diagnosing acute appendicitis (Lee et al, 2002).

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However, another study found that helical CT has a significantly higher sensitivity and accuracy than graded compression sonography for the diagnosis of appendicitis in a pediatric and young adult population, particularly in children more than 10 years old (Sivit et al, 2000).

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Patients undergoing sonography before appendectomy have a longer delay before operation, a higher rate of misdiagnosis, and more postoperative complications. Thus, it has been recommended that limiting sonography to truly equivocal cases and using it early in the diagnostic workup may improve outcomes in this group of patients (Emil et al, 2001).

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### Use of Ultrasound in Breast

Ultrasonography has been reported to be a useful adjunct to clinical and mammographic evaluation of breast diseases like cysts, aids in differentiating benign from malignant lesions, and facilitates office needle biopsy of non-palpable abnormalities, permitting timely and cost-effective patient care (Hieken & Velasco, 1998). Studies have shown that the sensitivity and specificity of ultrasound alone in detecting breast lesion ranges from 55 - 100% (Moon, Noh & Im, 2002; Kaiser et al, 2002; Hou et al, 2002; Satake et al, 2000; Buchberger et al, 2000; 1999), and 31 - 96% respectively (Moon, Noh & Im, 2002; Kaiser et al, 2002; Satake et al, 2000; Buchberger et al, 2000; 1999; Georgian-Smith et al, 2000). The sensitivity of ultrasound is inversely related to age and directly related with fattiness of breast (Saarenmaa et al, 2001). A Health Technology Assessment by New Zealand (1999) also found that ultrasound is very sensitive in the investigation of breast lesions among younger women (below 35 years) and recommended it as the first radiology investigation for these women. Another study done in Taiwan had shown that sonography is a more accurate and superior screening tool than mammography and physical examination for breast cancer in the high risk group (Hou et al, 2002). It was also found that ultrasound has a high sensitivity for detection of small invasive lobular carcinoma (Evans & Lynos, 2000; Chapellier et al, 2000).

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It has been shown that the addition of ultrasound to mammography increased the specificity from 51.4 - 66.45% at a prevalence of 31.3% malignancy, and significantly improved the performance over mammography alone in women, as well as masses both more and less than 1 cm. It was thus concluded that the addition of ultrasound to mammography could substantially reduce the number of breast biopsies for benign disease (Taylor et al, 2002). The addition of sonography to mammography was found to increase diagnostic confidence in suspicious lesions (Partik et al, 2001). It has also been shown that the combination of mammography and ultrasonography is effective in detecting a greater number of occult breast cancers and recommend ultrasonography not only for evaluation of a mass detected by mammography but also in radiographically dense non-radiolucent breast lesions (Jacob et al, 1997). While mammography detected 94.5% of breast carcinomas, breast sonography 91% and palpation 87%, a combination of mammography and sonography or mammography and palpation detected 99% of carcinomas and sonography and palpation 95% of carcinomas (Meden et al, 1995). The addition of ultrasound to mammography in screening has been shown to significantly increase detection of small cancers and detect significantly more cancers and at smaller size and lower stage than does physical examination (Kolb, Lichy & Newhouse, 2002).

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Apart from this, it has been found that sonography is a valuable and efficient diagnostic modality in detecting internal mammary lymph node metastases (Michigishi et al, 1992). It has been suggested that sonography is very sensitive in patients with extensive nodal involvement who may have had negative results in the sentinel node procedure (Rizzato, 2001). For detecting lymph node metastases ultrasonography was found to have high specificity, although

microscopic and small lymph node metastases are missed by ultrasound. However, sonography is better than axillary palpation (Hergan et al, 1996).

Another study suggests that sonography is useful for pre-surgical assessment of tumor size in patients with breast cancer, especially for single lesions of 20 mm or less and without an extensive intra-ductal component (Tresserra et al, 1999).

A study showed that while ductal carcinoma in-situ may appear on sonography as calcifications, masses or focally dilated ducts. Lesions associated with masses or dilated ducts on sonography were found more likely to be high-grade histological specimens (Hashimoto, Kramer & Picozzi, 2001). Another retrospective review found that changes in carcinomas seen on ultrasound included skin thickening (96%), parenchymal echogenicity changes (73%), dilated lymphatic channels (68%), solid mass (80%), pectoral muscle invasion (10%), focal areas of parenchymal acoustic shadowing (37%) and axillary lymphadenopathy (3%). Thus, ultrasound is helpful not only in depiction of masses masked by the edema pattern but also in demonstration of skin and pectoral muscle invasion, as well as axillary involvement (Gunnhan-Bilgen, Ustun & Memis, 2002).

It has also been reported that the use of high resolution sonography as an adjunct to mammography in women with dense breasts may lead to detection of a significant number of otherwise occult malignancies. It was also shows that classification of these lesions based on sonographic characteristics results in a significant reduction in number of unnecessary biopsies performed (Buchberger et al, 1999). Similarly, another retrospective study stated that breast biopsy may be avoided in women with palpable abnormalities when both ultrasound and mammography depict normal tissue at the lump site (Dennis et al, 2001). Ultrasound was found to be better than or equivalent to mammography in determining tumor size, while it was better for T1 and T2 tumours, thus suggesting that ultrasound is more accurate than mammography in assessing breast cancer size (Hieken et al, 2001). It has also been suggested that whole-breast ultrasound when performed in patients with dense breast tissue (BI RADS category 3 or 4 density), is useful in detecting breast cancer not discovered with mammography or clinical breast examination (Kaplan, 2001). While mammography was more sensitive than clinical examination or ultrasound in detecting contra-lateral breast cancer, ultrasound provided complementary information about palpable masses in 50% of the cases in which the mammographic finding was difficult to interpret (Rissanen et al, 1995).

In comedo intra-ductal cancer, ultrasound has been found to have a tendency to underestimate it, compared with mammography and Magnetic Resonance Imaging (Satake et al, 2000). In a case series too, ultrasound was found to underestimate the pathologic tumor size (Finlayson & MacDermott, 2000). However, while a combination of ultrasound and mammography showed significantly higher performance than mammography alone, the accuracy of ultrasound may be influenced by breast parenchyma density (Skaane, 1999).

A major limitation of ultrasonography is its inability to visualize micro-calcifications, so that while it is important in the diagnosis and therapeutic decision of cystic and fibrocystic masses, it cannot substitute mammography in early detection of breast carcinoma (Rosner & Blair, 1985).

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Ultrasound with fine needle aspiration biopsy has been shown to be a useful tool in diagnosing non-palpable breast nodes (Sieluzycska et al, 2000). It was also found that ultrasound-guided fine needle aspiration biopsy provided an accurate adjunct to clinical examination and mammography for diagnosing and excluding breast cancer recurrence after mastectomy (Rissanen et al, 1997). Sonographic fine needle aspirations or microbiopsy under ultrasonographic control has been shown to allow modification of mammographic and clinical diagnostic errors, and thus, this method appears important in diagnosis of infiltrating lobular carcinoma (Escolano et al, 1997).

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### Use of Ultrasound in Gall bladder

Sonography has been found to be highly accurate for detecting mass lesions, gallstones, liver infiltration, metastasis and ascites, although, visualization of lymph nodes, common bile duct infiltration and peritoneal dissemination was poor. Sonography was found to be a good diagnostic tool for diagnosis of carcinoma of the gallbladder, although its sensitivity was poor for staging nodal spread of the disease (Pandey et al, 2000). It has been found to be reliable in the detection of a primary gallbladder mass, or of local extension of the tumor into the liver. However, sonographic findings do not accurately reflect the full extent of disease, and sonography is particularly limited in the diagnoses of metastases to the peritoneum and lymph nodes (Bach et al, 1998).

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For gall bladder stones, it was found that stones of a uniform size were recognized correctly in 92% of cases, but stones of two different sizes were correctly identified only 30% of cases, the second, smaller stones were missed in 79% of cases (Brink et al, 1989).

For acute cholecystitis, ultrasound had a sensitivity of 48%, and hence it has been suggested that ultrasound be used to confirm the presence of gallbladder stones rather than to diagnose acute cholecystitis (Kalimi et al, 2001).

For the local assessment of periampullary tumors, endoscopic sonography has been found to be superior to transabdominal sonography and computed tomography, although the staging accuracy is minimally affected by the presence of an endobiliary stent (Chen et al, 2001).

For carcinoma of the gallbladder, sonography was found to be a good diagnostic tool, but its sensitivity was poor for staging nodal spread of the disease (Pandey et al, 2000).

Ultrasound-guided fine needle aspiration biopsy has been shown to be a safe and accurate technique to diagnose gall bladder malignancy, with a repeat aspiration or surgical biopsy being recommended when there is a high suspicion of malignancy, and the initial aspiration biopsy is negative (Venkataramu et al, 1999).

In measuring the common bile duct diameter, both ultrasonography and endoscopic retrograde cholangiopancreatography provide reliable readings, though the average diameter is significantly less by sonography than by endoscopic retrograde cholangiopancreatography. Ultrasonography is said to be the technique of choice in the initial investigation of patients with biliary acute pancreatitis (Pezzilli et al, 1999).

### Use of Ultrasound in Thyroid

Color Flow Doppler Sonography has been found to have a useful role in the assessment of thyroid nodules and it may provide information highly predictive for malignancy (Summaria et al, 2001).

### Use of Ultrasound in Urology

In testicular torsion, Doppler sonography can be used to reliably rule it out, so that routine scrotal exploration in cases of acute scrotum may no longer be necessary. Thus, by reducing the number of emergency operations and hospitalization days, color Doppler sonography can cut down the total cost of managing acute painful scrotum in boys (Weber et al. 2000).

For penile tumours, sonography has been shown to give a more accurate estimate of tumor extent than does physical examination, so that routine use of sonography for such measurements may enable preservation of more of the penis (Agrawal et al, 2000). With respect to the prostate, trans-rectal ultrasonographic guidance has been found to be useful in the diagnosis of prostatic abscess as well as in the guidance for aspiration and the drainage of such abscesses. Trans-rectal ultrasonographically guided needle aspiration could be an effective method for treating prostatic abscess (Lim et al, 2000).

### Use of Ultrasound in Orthopaedics

In the Achilles tendon, sonography can be used to differentiate full-form partial-thickness tears or tendinosis with 92% accuracy (Hartgerink et al, 2001).

Although for visualization of partial finger extensor tendon tears in rheumatoid arthritis patients, sonography as found to perform slightly better than MRI, both techniques are not sensitive enough to be used in daily practice (Swen et al, 2000). A prospective study also found that ultrasonography was able to identify tendon tears with an accuracy of 93%, a sensitivity of 100%, and a specificity of 88% (Waitches et al, 1998). It has also been found that ultrasonography demonstrated 82% of the subscapularis tendon tears, 86% of the full-thickness tears and 67% of the partial-thickness tears, this showing that sonography can diagnose and show the size of subscapularis tendon tears reliably (Farin & Jaroma, 1996).

### Use of Ultrasound in Congenital Hip Dysplasia

In Norway it was found that the sensitivity and specificity of ultrasonographic screening for all live births would result in the avoidance of 2 cases per 1,000 live births per annum of late-detected congenital dysplasia of the hip (CDH). Thus, by introducing an ultrasonographic screening programme an estimated 2.6 cases of late-discovered CDH per annum would be avoided (Geitung, Rosendahl, & Sudmann, 1996). Another study found that sonographic helped to identify hip instability that was missed on initial clinical examination (Rosenberg & Bialik, 2002).

### Use of Ultrasound in Diagnosis of Intussusception

A review found that sonographically guided hydrostatic reduction of intussusception is safe and effective, and recommended that this approach be attempted before surgery is considered, even in cases where the intussusception contains entrapped fluid or is located in the left side of the abdomen. However, the level of experience of the radiologist who performs the reduction

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sonography is reliable in the detection of a primary gallbladder mass or of local extension of tumor into the liver. However, sonographic findings do not accurately reflect the full extent of disease, and sonography is particularly limited in the diagnoses of metastases to the peritoneum and lymph nodes (Bach et al., 1998)¶

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Symptomatic cholelithiasis rank among the most common conditions seen in surgical practice. Surgeon-performed gallbladder US offers several benefits. It acts as an extension of the physical examination allowing prompt physical clinical decision making by the surgeon who knows the anatomy, the pathology, and the options for further investigation and treatment. ( ). In this study, the authors examine the use of surge (... [82])

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significantly affects the results of this procedure and should be taken into consideration, particularly where initial sonography reveals the presence of risk factors (Crystal et al, 2002).

### 6.3 Training

The quality of ultrasound has been said to be determined by the level of training and experience of operators (Hahn et al, 1988; Wells, 1986; Chitty et al, 1991; Rustico et al, 1995; Skupski et al, 1996; Levi, 1998).

It has been shown that a highly specialized centre with properly trained personnel in obstetric ultrasonography has better quality ultrasonography as determined by a higher detection rate, there being a three-fold difference in the detection of anomalies between tertiary centers and private doctors' offices. A review concluded that a simple training programme for obstetric ultrasonography increased their ability to detect serious congenital heart disease at a routine 18-20 weeks anomaly scan (Hunter et al, 2000). The Royal College of Obstetrics and Gynaecologists in the UK state that while there is no statutory requirement for ultrasound practitioners to receive accredited training, suggested that medical staff who undertake ultrasound scanning for foetal abnormality should ideally hold a advanced Certificate of Ultrasound Training, issued following a 300 hours course in centres recognized by the College of Obstetrics and Gynaecologists /Royal College of Radiology . Skills should be maintained by performing detailed scans 1-2 sessions a week. In Alberta, College of Physicians and Surgeons requirements are that they must have completed a minimum of 6 months' full time training in ultrasonography in a teaching program accredited by the Royal College of Physicians and Surgeons in Canada. Training is to be in a large accredited service providing all aspects of obstetrical and gynaecological care, with the trainee having to participate in 100 gynaecologic and early pregnancy scans, 200 obstetrical scans, and must perform 170 ultrasound procedures annually at each obstetric or focused obstetrical and/or gynaecological site. According to the guidelines on the use of Ultrasound in Pregnancy by the Perinatal Society of Malaysia, the level of expertise required in ultrasound scanning is divided into basic, intermediate and advanced levels, with differing training requirements (Malaysian Society of Ultrasound in Medicine Guidelines, 1996).

A senior surgical resident has been shown to be capable of performing focused ultrasound examination for trauma with a high level of skill after a concise introductory course (Smith et al, 1998). It has also been found that the accuracy of FAST for inexperienced sonographers, particularly in diagnosing smaller volumes, can be improved significantly by including positive studies in training and exposure to positive FAST examination (Gracias et al, 2002). A review showed that most FAST educators agreed that education should consist of didactic, practical and experiential phases (Saleh & Melanson & Heller, 2000). Another study found that a cadaver laboratory training program is an important adjunct to improve the skills of residents in performing and reading FAST (Frezza et al, 1999). It was also found that focused trauma workshops can significantly improve the skills of non-radiologists in sonographic identification of pericardial and intra-peritoneal fluid and should therefore be considered an essential component of ultrasound training for trauma physicians (Ali et al, 1996). A study found that after a month of intensive training, general practitioners were able to rule out or exclude fluid collections, aortic aneurysms and common gallbladder disease (Suroma et al, 2002). It was also found that a simulator is a convenient and objective method of introducing ultrasound to surgery

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Cost Implications¶

Antenatal care¶

Routine antenatal ultrasound screening for low-risk population is cost-effective, if all significant cost is taken into account, which, strongly dependent on the rates of malformation detected, and subsequent pregnancy termination (Perrson, 1983; Wells, 1986; James, 1989; Lachlan et al., 1989; Saari-Kempainen et al., 1990; Isabel, 1990; Gregory, 1991; Lyn S Chitty, 1991; Temmerman, 1991; Luck, 1992 [94]

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[residents and compares favorably with the experience gained with traditional hands-on patient models \(Knudson & Sisley, 2000\).](#)

[However, a study found that an involvement in 200 or fewer cases during the training period is not sufficient for doctors to develop an acceptable level of competence in sonography \(Hertzberg et al, 2000\).](#)

[The American Registry of Diagnostic Medical Sonographers has no specific recommendation for training and continuous medical education for those individuals performing ultrasound. However, the doctor responsible for the care of the patient should have completed ultrasound training in residency or completed a postgraduate course in ultrasound for limited ultrasound evaluation, while for complete ultrasound evaluation, 100 supervised scans must have been carried out as part of training.](#)

## [6.4 Cost implications](#)

### [6.4.1 Antenatal screening](#)

[With respect to cost implications of antenatal screening, routine antenatal ultrasound screening for low-risk population has been found to be cost-effective, provided all significant costs are taken into account, which depends heavily on the rates of malformation detected, and subsequent termination of pregnancy \(Perrson & Kullanders, 1983; Wells, 1986; deCresoigny, Warren & Buttery, 1989; Saari-Kemppainen et al, 1990; Shirley, Bottomley & Robinson, 1992; Chitty, 1991; Temmerman & Buckens, 1991; Luck, 1992; Brand et al, 1994; Saari-Kemppainen, 1994; Rustico et al, 1995; Chitty, 1995; Muller et al, 1996; Leivo et al, 1996; Viljoen et al, 1996; Long & Spriggs, 1998; van Dorsten et al, 1998; Vintzileos et al, 1998; Long & Spriggs, 1998; Romano & Waitzman, 1998; Waitzman & Romano, 1998\). The costs included the cost of maintenance of a severely crippled infant for about 40 years as well as cost of termination of pregnancy \(Luck, 1992; Leivo et al, 1996\). Other factors that need to be considered in cost-benefit ratio calculation include unnecessary antenatal visits and postnatal investigations, unnecessary induction for misdiagnosed intrauterine growth retardation and post-maturity that was reduced by routine screening \(Bucher et al, 1993\), as well as decrease of perinatal morbidity and mortality with routine scanning \(Leivo et al, 1996\). The costs also depend on the expertise in doing the scanning, techniques used and its referral systems. However, numerous studies found that routine antenatal ultrasound screening for low-risk population is not cost saving, since they compare ultrasound screening between low-risk and high-risk population, the detection rate of congenital anomalies and perinatal outcome, without considering total cost incurred in maintaining severely crippled infants and other consequences \(Temmerman & Buckens, 1991; Busken et al, 1996; Geert, Brand & Theron, 1996; Long & Spriggs, 1996; Robert, Mugford & Piercy, 1998\). Others found that is not cost-effective due to the low sensitivity of detection of congenital anomalies in low-risk population resulting from the use of inadequately qualified operators \(Levi, 1998; Stoll, Atembik & Dott, 1993\).](#)

[Other health care benefits of screening which indirectly affect the costs of routine ultrasound include fewer unnecessary antenatal services \(Geert, Brand & Theron, 1996; Leivo et al, 1996\), smaller number of ultrasound screening, less antenatal admissions \(Saari-Kemppainen et al, 1990\) reduced number of postnatal investigations \(Luck, 1992\), and reduced rate of induction \(Wadernstrom et al, 1988\).](#)

**Deleted:** A study found that after 1 month of intensive training (about 100 examinations), general practitioner was able to rule out or exclude fluid collections, aortic aneurysms and common gallbladder disease (Suroma et al., 2002). It was also found that a training consist of didactic session followed by 1 hour for each student of hands on training on medical models/medical patients or by training on the ultrasound simulator found that all residents show significant improvement in their pretest and posttest scores in both their knowledge of ultrasound physics and in their interpretation of ultrasound images presented on videotapes. The use of a simulator is a convenient and objective method of introducing ultrasound to surgery residents and compares favorably with the experience gained with traditional hand-on patient models (Knudson, & Sisley, 2000). A review found that a simple training programme for obstetric ultrasonography increased their ability to detect serious congenital heart disease at a routine 18-20 weeks anomaly scan (Hunter et al., 2000).

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**Deleted:** Royal College of Obstetrics and Gynaecologist stated that there is no statutory requirement for ultrasound practitioner to receive accredited training. It was also suggested that medical staff who undertake ultrasound scanning for foetal abnormality should ideally hold a advanced Certificate of Ultrasound Training which is issued following a 300 hours course centres recognized by the RCOG/RCR skill should be maintained by performing detailed scan one and preferably two sessions a weeks and should not undertake scans of any sort if they have not been specifically trained. ¶ In Alberta, College of Physician and Surgeon stated that they must have completed a minimum of 6 months full time training in ultrasonography in a teaching program accredited by Royal College of Physician and Surgeon in Canada. This policy had been approved by the Diagnostic Imaging Committee of Society of Obstetrician and ... [99]

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The total health care benefit cost calculated per ultrasound screening was two thirds lower, which was accounted for by the lower inpatient cost (Leivo et al, 1996). The number of induced labour in the ultrasound group was significantly lower as a result of the more accurate dating of the gestational age (Walderstrom, 1988), though there was no effect on the number or duration of hospital admissions. Various studies justify systematic one-stage ultrasound screening of all pregnancies for the detection of major congenital anomalies under circumstances in which their elimination by induced abortion is acceptable, as being cost-effective (Wells, 1986; Saari-Kempainen 1990; Luck, 1992; Bucher & Schmidt, 1993; Brand et al, 1994; Viljoen et al, 1996; Long & Sprigg, 1998). In addition, routine screening during pregnancy for low-risk population was also found to be cost-effective considering the benefits of avoiding one perinatal death, and reduced health care costs for late-pregnancy outpatient and inpatient visits, as well as delivery (Saari - Kempainen, 1990; Bucher, & Schmidt 1993; Greets, Brand & Theron, 1996; Leivo et al, 1996).

#### 6.4.2 Trauma

It has been estimated in the US, that hospital saving can be projected to exceed \$ 662 for each trauma patient screened by FAST before CT, especially as it has been found that FAST as performed by surgical residents is more cost-effective than that performed by ultrasound technicians (Frezza, Ferrone & Martin et al, 1999). It has also been calculated that the annualized cost savings with the use of ultrasound evaluation versus standard diagnostic evaluation would amount to over \$100,000.00 (Thomas et al, 1997).

#### 6.4.3 Acute abdomen

Routine use of ultrasonography in the acute abdomen population resulted in an additional cost of \$ 234 per patient when compared with immediate operation. The use of ultrasonography can be recommended for children with suspected appendicitis and equivocal examinations who are discharged from the emergency room after a negative examination result (Axelrod et al, 2000).

#### 6.4.4 Congenital dislocation of hip

It has been found that ultrasonographic screening would result in fewer cases of late-detected congenital dislocation of hip (CDH), so that a general screening programme applied to the total population of new-born infant was not cost effective. However, screening for those identified as being at greater risk (traumatic birth and family history of CDH) may bring additional benefits and be cost effective. Moreover, if the screening programme adopted only ultrasonographic testing and the clinical examinations were eliminated the programme would be cost-effective (Geitung, Rosendahl & Sudmann, 1996).

### 6.5 Ethical implications

#### 6.5.1 Competence and referral

In performing an ultrasound examination, there is an ethical obligation to provide a competent examination so as to provide the most accurate and reliable information. This would require adequate training with regular update courses.

The doctor who receives patients for second opinion has an ethical obligation to encourage the referring doctor to maintain standards of general competence, as well as disclosing to the patient any avoidable diagnostic errors by the colleague who made the referral.

**Deleted:** According to the guidelines on the use of Ultrasound in Pregnancy Perinatal Society of Malaysia recommended that the level of expertise required in ultrasound scanning can be divided into 3 levels. There are level 1 (Basic) in which it required to attend one basic course and the remainder in an accredited hospital by member of a board run by Obstetric & Gynaecological Society or Ultrasound in Medicine or Perinatal Society of Malaysia or senior members of the obstetric department of the accredited hospital and performing 100 ultrasound scans under supervision. For level 2 (Intermittent) the requirement are attended accredited in intermediate and /or advance course, 1 year experience after basic level accreditation and incorporation into postgraduate training programmes like master in Obstetric & Gynaecology and post MRCOG in accredited hospitals. While level 3 (Advance) must had attended accredited coursed eg. RCOG/RCR in foetal Medicine for 1 year or accredited local course, and scholarship in recognized Foetal Medicine training centre abroad such as DDU (Australia)< RCOG?RCR course accreditation or Mmed (Foetal Medicine) Birmingham. (Malaysia Society of ultrasound in Medicine Guidelines, 1996)¶

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Often important ethical dimensions are neglected in clinical practice.¶  
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### 6.5.2 Disclosure

The patient needs to be informed of the limitations of the scan, so that a pregnant woman is aware of the possibility of having to terminate a pregnancy in which an anomaly is detected. It has been said that there is an apparent bonding of some pregnant women to their fetuses occurring when the women see the ultrasound images, which can complicate ethical decisions made in relation to the fetus. Any uncertainty about diagnosis, management and prognosis of the pregnancy should be disclosed to the patient. Similarly, with respect to gender identification, patients need to be informed about the uncertainties of gender identification and its lack of clinical relevance, unless there are doubts about sex-linked disorders.

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Deleted: Several ethical issues arise concerning the disclosure of results of ultrasound examination: ¶  
 ¶ re must be an adequate process of informing the ... s ... It is important for the ... to be ... potential for confronting the unanticipated ... ing ... A ... can occur s ... This ... that affects clinical judgment . The other issue is about .... There should be frank discussion .... It is not ly ... t ... is (... [102])

### 6.5.3 Confidentiality

Ultrasound findings should only be disclosed to the third parties such as the spouse, family and in-laws only with the permission of the pregnant women (Chervenak, 1989).

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### 6.5.4 Routine screening

For routine screening, competent ultrasonographers and the facilities for scanning all pregnant women in the country would need to be provided. While staff training is very important for a screening programme to be successful, it is often neglected (Chervenak, 1991). In Malaysia, there is currently no routine screening, patients being scanned based on clinical needs.

Deleted: This is not a practice in Malaysia. Patients are scanned on a 'need to' basis based on clinical needs. If ... is a practice...then there will be need to provide ... is...S...the...cornerstone of a screening program. Yet this is one of the more ... aspects of running a screening program ... FA (... [104])

## 6.6 Legal Aspects of Ultrasound

### 6.6.1 Source of litigation

Under the law of tort followed in Malaysia, damages are awarded for negligence under the following conditions:

1. The examination or invasive procedure is carried out in a manner less than expected from a competent practitioner.
2. The mother or the fetus was harmed.
3. On the balance of probabilities, the negligent examination or procedure caused the damage.

Deleted: 2...O...The introduction of ultrasound has revolutionized the management of pregnancy and it is common for a woman in Malaysia to have had at least one scan in the course of her pregnancy. Ultrasound is unique as an imaging modality in at least three aspects. ¶  
 ¶ Ultrasound may be performed by obstetricians, radiologists, and radiographers and midwives with varying grades of expertise and qualification. It may be both a diagnostic and screening test depending upon the level of (... [105])

Ultrasound during pregnancy is not offered as a routine test in Malaysia. The termination of pregnancy in Malaysia may be legal under the Abortion Act 1989 if it is necessary to save the life of the mother to prevent grave permanent injury to her mental or physical health.

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The following could be possible grounds for litigation;

1. Failure to offer routine screening.
2. Screening too late in pregnancy to allow termination.
3. Failure to act on abnormal or suspicious ultrasound findings.
4. Failure to warn the patient that the ultrasound examination could detect an abnormality.
5. Failure to use ultrasound to suggest other screening tests such as maternal serum alpha-fetoprotein or the triple test.
6. Failure to detect multiple pregnancies.

### 6.6.2 *Safe practice*

It is suggested that pregnant women be provided written information at the time of the booking visit on the purpose of the ultrasound examination, so that it gives a chance for the parent to opt out of an ultrasound examination.

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### 6.6.3 *Departmental protocols*

It is suggested also that each department have a written protocol that details its practice of ultrasound in pregnant women. If an ultrasound examination is incomplete, as it will be in some women because of maternal obesity, then it should be clearly stated and the woman asked to return for a repeat examination 1 to 2 weeks later.

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### 6.6.4 *Interpretation of measurements*

The measurement of the bi-parietal diameter, head as well as abdominal circumference and femur length should be plotted on appropriate charts. These can be done on local charts available in the home-based antenatal card used in Malaysia.

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### 6.6.5 *Suspected abnormalities*

If an abnormality is suspected on scanning, the women should be referred for detailed anomaly scanning.

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### 6.6.6 *Diagnostic ultrasound*

Litigation has arisen from the use of ultrasound as a diagnostic test under the following circumstances:

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1. Failure to give advice.
2. Giving the wrong advice.
3. Failure to explain the hazards of an invasive test.
4. Failure to warn the patient of the possibility of not being able to make a diagnosis.
5. Failure to warn the patient of possible errors in diagnosis.

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## 7. CONCLUSION

### 7.1 Safety

There is no scientific evidence on adverse effects of ultrasound, although there is some evidence of a statistically significant association between ultrasound and left handedness among males.

### 7.2 Effectiveness

#### 7.2.1 Use of ultrasound in antenatal care

There is sufficient evidence that ultrasound is effective in dating pregnancy, assessing the viability of foetus, diagnosing twin pregnancy, diagnosing intrauterine growth retardation, diagnosis of placenta praevia, and detection of congenital abnormalities. There is also evidence of effectiveness of trans-vaginal ultrasound in detection of congenital abnormalities, retained products of conception, and predicting pre-term labour.

There is sufficient evidence that routine ultrasound in antenatal care or ultrasound examination in low-risk population does not improve the outcome of pregnancy.

7.2.2 Use of ultrasound in Gynaecology

There is sufficient evidence that ultrasound is effective in detecting ectopic pregnancy, screening for ovarian cancer, and detecting uterine abnormalities.

7.2.3 Use of ultrasound in Surgery

There is sufficient evidence that ultrasound is effective in diagnosing abdominal trauma, appendicitis, breast lesions, and gall bladder lesions like stones and tumours.

**7.3 Training**

There is sufficient evidence to show that the quality of ultrasound is determined by the level of training and experience of operators, and that appropriate training should be provided to those carrying out ultrasonography.

**7.4 Cost implications**

For antenatal screening, there is sufficient evidence that routine ultrasound screening for low-risk population is not cost-effective.

**7.5 Ethical implications**

There are ethical issues that need to be considered in providing ultrasonography services.

**7.6 Legal Aspects of Ultrasound**

There are legal issues to be considered in carrying out ultrasonography.

**8. RECOMMENDATIONS**

There is sufficient evidence to recommend that routine antenatal screening not be carried out in the low risk population. However, ultrasound screening should be carried out for high risk mothers. In addition, it should be used for diagnosis of various conditions in pregnancy or to rule out these conditions.

Ultrasound is also recommended in secondary and tertiary care for diagnosis of gynaecological and surgical conditions.

Training has to be provided for all those involved in providing ultrasonography services.

Ethical and legal implications need to be considered.

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(a) Amniocentesis¶  
The risk of having a normal pregnancy is about 1:200 pregnancies. The risk of failed cell culture is about 0-1-0.2 % and the risk of a wrong result because of cultured maternal cells is about 0.1 % .  
(Pearce 1994).¶  
¶  
(b) Chorionic villus biopsy¶  
There is an overall risk of pregnancy loss of about 4°16. An adequate sample may not be obtained in 1°16 of cases and may need to be rejected. Placental mosaics may result in an uninterpretable result in 1.5-°16 cases. Amniocentesis may be required later in such pregnancies.  
(Pearce 1994).¶  
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(c) Fetal blood sampling¶  
Losses may range from 1-25% of the pregnancies within two weeks of the procedures (Maxwell1991).¶  
¶  
(d) Fetal reduction, selective feticide and late termination¶  
These are fraught with legal and ethical issues and should not be considered in Malaysia.¶  
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(a) Amniocentesis¶  
The risk of having a normal pregnancy is about 1:200 pregnancies. The risk of failed cell culture is about 0-1-0.2 % and the risk of a wrong result because of cultured maternal cells is about 0.1 % .  
(Pearce 1994).¶  
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(b) Chorionic villus biopsy¶  
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**EVIDENCE TABLE :- USE OF ULTRASOUND AND SAFETY**

No	Author, title, Journal, Year, Vol, page	Study design, sample size, follow up	Outcomes & Characteristic	Grade & Comments
1	<p>Zlotogorski Z, Tadmor O, Rabinovitz R, Diamant Y (1997)</p> <p>Parental attitudes toward obstetric ultrasound examination</p> <p><i>J Obstet Gynaecolo Res</i> 23(1), Feb, pp25-8</p>	<p>N= 1089</p>	<p>Routine ultrasound scan may have significant psychological effects on prenatal attitudes towards each other and the fetus</p>	<p>Poor</p>
2	<p>Geerts LT, Brand EJ, Theron GB (1996)</p> <p>Routine obstetric ultrasound examinations in South Africa: Cost and effect on perinatal outcome:- a prospective randomized controlled trial</p> <p><i>Br J Obstetric Gynaecolo,</i> 103(6), Jun, pp 501-7</p>	<p>Randomised controlled trial</p> <p>N= pregnant patient without risk factors for congenital anomalies refer for ultrasonography bet 18 and 24 weeks</p>	<p>More babies of low birthweight were born in the study group</p>	<p>Good</p>
3	<p>Vogel E (1996)</p> <p>A Review of epidemiologic studies on ultrasound during pregnancy</p> <p><i>Ultraschall Med,</i> 17 (1), Feb, pp 2-6</p>	<p>Review</p>	<p>Routine sonography is of great value, no negative effects on birth weight, neural development, and cancer incidence among the child have been found</p>	<p>Good</p>

No	Author, title, Journal, Year, Vol, page	Study design, sample size, follow up	Outcomes & Characteristic	Grade & Comments
4	<p>Gotzmann L, Schonholzer SM, Kolbe N, Klaghofer R, Scheuer E, Zimmermann R, huch R, Buddeberg C (2002)</p> <p>Suspected fetal malformation in ultrasound examination: effects on the psychological well-being of pregnant women</p> <p><i>Ultraschall Med</i>; 23 (1), Feb, pp 33-40</p>	N= 86 pregnant women	A suspected fetal malformation results in psychological stress with anxiety and depression level significantly higher than in normal samples.	Poor
5	<p>Barr LL (2001)</p> <p>Clinical concerns in the ultrasound exposure of the developing central nervous systems</p> <p><i>Ultrasound Med Biol</i>; 27(7), Jun, pp 889-92</p>	Review	<p>Prenatal and postnatal use of Doppler or of ultrasound contrast agent use and the developing central nervous system are insufficient to draw meaningful conclusion regarding safety.</p> <p>By instituting a standardized examination and following appropriate patient handling guidelines, the risk of an adverse outcomes associated with neurosonography is minimized.</p>	Good
6	<p>Ziskin MC (1999)</p> <p>Intrauterine effects of ultrasound: human epidemiology</p> <p><i>Teratology</i>; 59 (4), Apr, pp 252-60</p>	Review	There is no verified document evidence of adverse effects in patients caused by exposure to diagnostic ultrasound. However there is some bioeffect was identified such as low birth weight, delay speech or increased incidence of left-handedness.	Good

No	Author, title, Journal, Year, Vol, page	Study design, sample size, follow up	Outcomes & Characteristic	Grade & Comments
7	Kieler H, Ahlsten G, Haglund B, Salvesen K, Axelsson O (1998)  Routine ultrasound screening in pregnancy and the children's subsequent neurologic development  <i>Obstet Gynaecol</i> , 91(5 pt1), May, pp750-6	Randomised controlled trial  N= 4637 eligible singleton  F/up: 1985-87	Delay speech development was reported by 2.9% in the screening group compared with 2.4% in the nonscreening group.. similarly prevalence was found when analysis was according to ultrasound exposure. Delay motor development was reported y 7.6% in screening group compared to 7.4% in non screening group. There also were no significant differences in behavioral disorder between screen and non screen or between exposure or non exposure children respectively No significant difference in impaired neurologic development between ultrasound exposure and unexposure children.	Good
8	Kieler H, Axelsson O, Haglund B, Nilsson S, Salvesen KA (1998) Routine ultrasound screening in pregnancy and the children's subsequent handedness  <i>Early hum Dev</i> , 50(2), Jan 9, pp 233-45	Rnandomised controlled trial  N= Follow up o 8-9 year old children to women who participant on ultrasound screening during 1985-87	No difference was found in non-right handedness between children in the screening and non-screening group. In separate analyses on ultrasound exposure and non-right handedness among boys a significant differences was found	Good
9	SBU Health technology Assessment 1998  <i>Routine ultrasound examination during pregnancy</i>  SBU Health technology Assessment	HTA	Have not shown any effects on birth weight, growth during childhood, neurological development, language development, or the prevalence of dyslexia. Likewise there is no scientific evidence to support a relationship between ultrasound exposure to the fetus and cancer during childhood.	Good

No	Author, title, Journal, Year, Vol, page	Study design, sample size, follow up	Outcomes & Characteristic	Grade & Comments
10	Naumburg E, Bellocco R, Cnattingius S, Hall P, Ekblom A (2000)  Prenatal ultrasound examination and risk of childhood leukaemia: case control study  <i>BMJ</i> , 320, Jan 29, pp282-283	Case control study  N=752  F/up: 1973-1989	Single or repeated intrauterine exposure to ultrasound, early of late in pregnancy, does not influence the risk of subsequently development of lymphatic or myeloid childhood leukaemia.	Poor
11	Salvesen KA (2002)  EFSUMB: safety tutorial. Epidemiology of diagnostic ultrasound exposure during pregnancy _ European committee for medical ultrasound safety (ECMUS)  <i>Eur J Ultrasound</i> , 15(3), Oct, pp 165-71	Tutorial	The epidemiological evidence does not indicate any association between diagnostic ultrasound exposure during pregnancy and reduce birth weight, childhood malignancies or neurological development. However, statistically significant association between ultrasound and left handedness among males has been found. There is still need for more research.	Poor
12	Marinac-Dabic D, Krulewitch CJ, Moore RM Jr (2002)  The safety of prenatal ultrasound exposure in human studies  <i>Epidemiology</i> , 13 (3 supp) May, pp S19-22	Review	A majority of epidemiology studies tends to support the safety of diagnostic ultrasound use during pregnancy. However, there have been some reports that there may be a relation between prenatal ultrasound exposure and adverse outcome. Like growth retraction, delayed speech, dyslexia and non-right handedness association with ultrasound exposure.. Continue research needed to evaluate the potential adverse effects of ultrasound exposure during pregnancy	Good

No	Author, title, Journal, Year, Vol, page	Study design, sample size, follow up	Outcomes & Characteristic	Grade & Comments
13	Buzzas GR, Kern SJ, Smith RS, Harrison PB, Helmer SD, Reed JA.(1998)  A comparison of sonographic examinations for trauma performed by surgeons and radiologists.  <i>J Trauma</i> ,44(4), Apr, pp 604-6; discussion 607-8	Retrospective review of medical records of all trauma patients who received focused ultrasound examinations  F/up:January 1, 1995, through June 30, 1996	Patient populations at the two centers were similar except that the mean Injury Severity Score at TCB was higher than at TCA (11.74 vs. 9.6). Sensitivity, specificity, accuracy, or negative predictive value were not significantly different between the two cohorts. A significantly lower positive predictive value for examinations performed by surgery residents was noted and attributed to a lower threshold of the surgery residents to confirm their findings by computed tomography	
14	Bricker L, Neilson JP (2000)  Routine ultrasound in late pregnancy (after 24 weeks gestation).  <i>Cochrane Database Syst Rev.</i> (2):CD001451.	Systematic Review	There is a lack of data about the potential psychological effects of routine ultrasound in late pregnancy, and the effects on both short and long term neonatal and childhood outcome.	Good

### ET- DATING OF PREGNANCY

No	Author, title, Journal, Year, Vol, page	Study design, sample size, follow up	Outcomes & Characteristic	Grade & Comments
1	Reuss MC, Hatch MC, Susser M (1995)  Early ultrasound dating of pregnancy. Selection and measurement biases <i>J Clin Epidemiol</i> , 48(5), May, pp 667-74	Prospective observation study  N= 764	Ultrasound dating of pregnancy led to a higher estimate of preterm delivery (10 vs 7.6%), a higher estimate of term delivery (87.2% vs 82.7%) and a lower estimate of post term delivery (2.8 vs 9.7) then dating by menstrual history	Fair

No	Author, title, Journal, Year, Vol, page	Study design, sample size, follow up	Outcomes & Characteristic	Grade & Comments
2	Belfrage P, Fernström I, Hallenberg G (1987)  Routine or selective ultrasound examination in early pregnancy  <i>Obstet Gynaecol</i> , 69(5), May, pp 747-50	Prospective observational study  N= 2054	Neonatal outcome was similar. Frequency of induction was reduced in the group with routine early ultrasound screening and so was the caesarean section rate. 20% of the patients had altered dates of delivery in the screened group which shows that ultrasound is better than LMP	Fair
3	Pedersen JF (1982)  Fetal crown-rump length measurement by ultrasound in normal pregnancy  <i>Br J Obstet Gynaecol</i> , 89(11),Nov, pp 926-30	Prospective observation study  N= 105	The longitudinally collected observations showed that CRL in female fetuses was significantly smaller compared with male fetuses. Measurement of CRL enables assessment of gestation age to within +/- 4-6 days with greatest precision of CRL at 31-40 mm. The discrepancy of ultrasound age and menstrual age may be variable of prognostic significance in threatened abortion and maternal diabetes	Fair
4	Rasmussen S, Dalaker K, Nordboerge L, Lundgren R (1990)  One stage ultrasound screening in pregnancy. An evaluation  <i>Acta Obstet Gynaecol Scand</i> , 69 (7-8), pp 581-8	Prospective observation study  N=2766	Among women who did not have a 2 <sup>nd</sup> trimester ultrasound examination, labour was induced for presumed post term pregnancy in 4% vs 1.5% of pregnancies in the screening group. In the group with 2 <sup>nd</sup> trimester ultrasound scanning other than screening the frequency was 3.2%. Of women with spontaneous labour or who was induced for presumed post-term pregnancy. 3.8% in a screening group and 8% in a group with other 2 <sup>nd</sup> trimester ultrasound examination were post-term according to the BPD measurements. In screening group, 6.2% of liveborn singletons were small for gestation age (< 10 <sup>th</sup> percentile) compared with 8.5% in the non screening group. According to LMP and ultrasound examination. 7.4% & 3.8% of these were post term respectively	Good

No	Author, title, Journal, Year, Vol, page	Study design, sample size, follow up	Outcomes & Characteristic	Grade & Comments
5	Wariyar U, Tin W, Hay E (1997)  Gestation assessment assessed  <i>Arch Dis Child Fetal Neonatal Ed</i> , 77(3), pp F216-20	Prospective study  N= 452	The best techniques of estimating gestation immediately after birth were only half as accurate as estimates based on antenatal ultrasound at 15-19 weeks gestation. Assessments that relied on tone, posture and appearance of the baby at birth were less reliable and tended to overestimate the gestation age	Fair

### ET - FETAL VIABILITY

No	Author, title, Journal, Year, Vol, page	Study design, sample size, follow up	Outcomes & Characteristic	Grade & Comments
1	Schouwink MH, Fong BF, Mol BW, van der Veen F. (2000)  Ultrasonographic criteria for non-viability of first trimester intra-uterine pregnancy.  <i>Early Pregnancy</i> 4(3), Jul, pp 203-13	prospective cohort study  N= 372 pregnancies  May 1995 and March 1996	Among 372 pregnancies, there were 92 (25%) non-viable. The combination of absence of cardiac activity and absence of a yolk sac appeared to be a highly specific criterion whenever the mean sac diameter was $\geq 16$ mm or whenever a crown rump length was $> 5$ mm. We conclude that single transvaginal sonography is a reliable test to diagnose non-viable pregnancy in case the MSD is $\geq 16$ mm or in case the crown rump length is $> 5$ mm. The combination of absence of cardiac activity and absence of a yolk sac virtually rules out the possibility of a viable pregnancy in these patients.	Poor
2	Pilu G, Falco P, Guazzarini M, Sandri F, Bovicelli L. (1998)  Sonographic demonstration of nuchal cord and abnormal umbilical artery waveform heralding fetal distress.  <i>Ultrasound Obstet Gynecol</i> , 12(2), Aug, pp 125-7	Case study	Doppler velocimetry of the umbilical vessels may be useful in the assessment of viable fetuses with a sonographic diagnosis of a nuchal cord. Conversely, a nuchal cord should be considered as part of the differential diagnosis of abnormal Doppler velocimetry of the umbilical vessels.	Poor



No	Author, title, Journal, Year, Vol, page	Study design, sample size, follow up	Outcomes & Characteristic	Grade & Comments
3	<p>Bahmaie A, Edmonds DK (1996)</p> <p>Booking ultrasound examinations performed by obstetric senior house officers – time to reevaluate</p> <p><i>Aust NZ J Obstet Gynaecol</i>, 36(4), Nov, pp 389-91</p>	<p>Prospective observation study</p> <p>N= 336 pregnant women who had booking scans and detail anomaly scans at 18-20 weeks</p>	<p>7(2.1) had a non- viable pregnancy at booking scan 7 pairs of twins were correctly diagnosed. 89.4% of scans done by senior house officers were correct when compared with the details of anomaly scans. No anomalies were detected in this study group</p>	Fair
4	<p>Pandy PP, Snijders RJ, Psara N, Hilbert L, Nicolaidis KH (1996)</p> <p>The prevalence of non-viable pregnancy at 10 -13 weeks of gestations</p> <p><i>Ultrasound Obstet Gynaecol</i>, 7(3), Mar, pp 170-3</p>	<p>Prospective observation study</p> <p>N= 17 870 pregnant women at 10-13 weeks gestation had an ultrasound</p>	<p>The prevalence rate of early pregnancy failure was 2.8% (501) including 313(62.5%) missed abortions and 188 (37.5%) anembryonic pregnancies. Lower gestation and higher maternal age were associated with a higher prevalence (chi 2 = 143.5; p&lt; 0.001 and chi 2 = 53.3; p ,0.0001 respectively). The prevalence was higher in women with a history of vaginal bleeding (chi 2 = 141.5; p , 0.0001). there was no significant association with previous pregnancy losses (chi 2= 2.8), parity (chi 2= 0.6) or cigarette smoking (chi 2= 0.0)</p> <p>The early ultrasound diagnoses early pregnancy loss earlier and evacuation can be planned better and safer, making it an important investigation</p>	Fair

### ET - MULTIPLE PREGNANCIES

No	Author, title, Journal, Year, Vol. Page	Study design. Sample size & follow up	Outcomes & Characteristic	Grade & comment
1	Malinowski W. (1998)  Yolk sacs in twin pregnancy.  <i>Acta Genet Med Gemellol</i> , 47(3-4), pp 177-81	N= 38 twin pregnancy	In five cases, one of yolk sac was abnormally large (> 8 mm) and had thin wall. Four of the five mothers spontaneously aborted during the next 2-3 weeks. In one case of monochorionic twin ectopic pregnancy two yolk sacs were seen normally. CONCLUSION: The sonographic identification of yolk sacs in multiple pregnancies allows an early and efficient recognition of presence and chorionicity of twin pregnancy, both in intra- and extrauterine. Identification of abnormal yolk sac or yolk sacs suggests death of one or all embryos.	Poor
2	van Heteren CF, Nijhuis JG, Semmekrot BA, Merkus JM. (1999)  [Discordant fetal growth in multiple pregnancy: intervention should be based on chorionicity]  <i>Ned Tijdschr Geneesk</i> ,15; 143(20), May, pp1017-21	Review	dichorionic pregnancy foetal death of one twin does not entail any great risk of damage to the survivor; in such a pregnancy single foetal death in a premature phase may be accepted and the pregnancy may be continued. Sonographic determination of the chorionicity in multiple pregnancy at an early stage is essential because it also determines the policy if foetal problems occur.	Fair
3	Sepulveda W, Sebire NJ, Hughes K, Odibo A, Nicolaides KH (1996)  The lambda sign at 10-14 weeks of gestation as a predictor of chorionicity in twin pregnancies  <i>Ultrasoun Obstet Gynecol</i> , 7(6), Jun, pp 421-3	Prospective study  N= 369 twin pregnancies till delivery	Ultrasound at 10-14 weeks of gestation looking for the lambda sign at the inter-twin membrane-placental junction. In 81(22%) monochorionic twin diagnosis ended in all same sex deliveries. In all dichorionic twin diagnosis there were different sex twins delivered	Fair

No	Author, title, Journal, Year, Vol. Page	Study design. Sample size & follow up	Outcomes & Characteristic	Grade & comment
4	Wood SI, St Onge R, Connors g, Elliot PD (1996)  Evaluation of the twin peak or lambda sign in determining chorionicity in multiple pregnancy  <i>Obstet Gynaecol</i> , 88(1), Jul, pp 6-9	Prospective study  N= 55 cases of multiple pregnancy cases were assessed	Real-time ultrasound scans of the origin of the inte twin membrance for the presence or absence of the twin peak/lambda sign. Chorionicity was determined by the placental pathological analysis. The ultrasound correctly predicted chorionicity in 34 of 36 dichorionic and 7 of 8 monochorionic twin pregnancies. Sensitivity of dichorionicity 94% specificity 88%, positive predictive value 97% an negative predictive value 78%	Fair
5	Hughey MJ, Olive DI (1985)  Routine ultrasound scanning for the detection and management of twin pregnancies  <i>J Reprod Med</i> , 30(5), May, pp 427-30	Prospective observation study  N=1551 pregnancies in the study with 5950 in the control group till delivery	A significantl difference could be shown in the early detection of twin pregnancies i.e. 94% were detected in the study group while only 68% in the control (p=0.03). a singnificant improvement was also noted in the study group. The unfavourable outcome was reduced from 60% in control compared with 25% in the study group (p=0.0007). this reduction was due to a reduced incidence of low birth weight, smallness for gestation age, prematuriy, depressed. APGAR scores and stillbirths. When twins in both groups were diagnosed before 25 weeks gestation the outcomes were similar	Fair

**ET –DETECTION OF INTRAUTERINE GROWTH RETRICTION**

No	Author, Title, Journal, Year, Vol page	Study design, sample size, follow up	Outcomes & Characteristic	Grade & comment
1	Hagenfeldt K, Alton Lundberg V, Axelsson O, Blennow M, Boj F, Bygdemann M et al (1998)  Routine ultrasound in pregnancy  <i>The Swedish Council on Technology Assessment in Health Care (SBU), PP 263</i>	HTA	Ultrasound examination aimed at determining fetal weight is the best method for diagnosing intrauterine growth retardation, the evidence does not show a favorable effect from ultrasound examination in this respect.	Good
2	Ott WJ. (1990)  Defining altered fetal growth by second-trimester sonography.  <i>Obstet Gynecol,75(6),Jun, pp 1053-9</i>	N=315 obstetric patient	Estimated fetal weight at the time of the ultrasound examination was used to predict actual birth weight. At delivery, the percent difference between the projected and actual birth weights was then used to define whether an infant was small, appropriate, or large for gestational age. This method appeared to be accurate and showed identical relationships to the presence of abnormal fetal heart rate patterns in growth-retarded infants as did the traditional birth-weight-for-gestational-age method of defining intrauterine growth retardation	poor
3	Arbeille P, Body G, Saliba E, Tranquart F, Berson M, Roncin A, Pourcelot L. (1988)  Fetal cerebral circulation assessment by Doppler ultrasound in the normal and pathological pregnancies.  <i>Eur J Obstet Gynecol Reprod Biol, 29 (4), Dec, pp 261-73,.</i>	Prospective study 40 pregnancies	In normal pregnancies the cerebral index (Rc) is always higher than the placental index (Rp) and the cerebra/placental ratio (Rc/Rp) greater than 1..of 29 pregnant women with hypertension, 17 delivered normally (Rc,Rp and Rc/Rp was normal), 14 delivered an hydrotropic fetus. In 12 of the 14 pregnancies one of the 2 indices was abnormal and Rc/Rp ratio was always less or equal to 1. Rc/Rp ratio sensitivity was 86% and specivicity was 100%. In 11 pregnancies with idiopathic IUGR, the Rc?Rp ratio was less or equal to 1 in 8 cases (73%) and greater than 1 in 3 cases (3 false negative results).	Fair  Rc?Rp ratio has a good specificity and sensitivity to detect a hydrotropic fetus.

No	Author, Title, Journal, Year, Vol page	Study design, sample size, follow up	Outcomes & Characteristic	Grade & comment
4	Joerhn H, Schroeder W, Sassen R, Rath W (1997)  Predictive value of a single CTG, ultrasound and Doppler examination to diagnosis acute and chronic placental insufficiencies in multiple pregnancies  <i>J Perinat Med</i> , 25 (4), pp 325-32	Prospective observational study  N= 130 pregnancies	A non- stress test, ultrasound biometry (BPD & abd diameter) and a Doppler sonography blood flow measurement (fetal descending aorta, umbilical artery and fetal middle cerebral artery) were done in the third trimester. Prognostic value for growth retardation (81 from 263 children defined as bt wt < 10 <sup>th</sup> percentile), and a “ pathological fetal ourcome. (76 of 236 children defined as 5 min Apgar <8, Umbilical artery PH < 7.20 and transfer to neonatal intensive care unit). Fetal growth retardation was best predicted by Doppler results of all three vessels (sensitivity 75.9%) . it also showed the bestresult in predicting a “ pathological fetal outcomes” (sensitivity 60.3%)	Fair
5	Karsdorp VH, Van Vugt JM, Van Geijn Hp, Kostense PJ, Arduini D, Montenegro N, Todros T (1994)  Clinical significance of absent or reversed end diastolic velocity waveforms in umbilical artery  <i>Lancet</i> , 344(8938), Dec 17, pp 1664-8	Meta analysis  N= 459 patients	Logistic regression showed that compared with pregnancies with hypertension only, pregnancies complicated by IUGR had a higher risk of developing absent or reversed end diastolic velocity wavforms (ARED). ARED flow in the umbilical artery(OR= 3.1). Pregnancies complicated by both IUGR and hypertension had an even higher risk. Maternal age and smoking habits did nor influence the risk of developing ARED flow. The overall perinatal mortality rate was 28%. More neonates in the ARED flow group needed admittance to the neonatal intensive care unit (positive end diastolic floe (PED) 60% absent end diastolic flow (AED) 96% and reversed end diastolic velocities (RED) (98%). The OR for perinatal mortality in pregnancies complicated by AED flow was 4 and in RED flow was 10.6 compared with PED flow, een after adjustment for menstrual age. ARED flow significantly influence the risk of cerebral haemorrhage, anaemia or hypoglycaemia	Good

No	Author, Title, Journal, Year, Vol page	Study design, sample size, follow up	Outcomes & Characteristic	Grade & comment
6	Vindla S, James DK, Sahota DS, Coppens M (1997)  Computerised analysis of behaviour in normal and growth retarded fetuses  <i>Eur J Obstet Gynaecol Reprod Biol</i> , 75(2), Dec, pp 169-175	Prospective study  N= 27 normally grown fetuses and 18 fetuses complicated by IUGR were monitored using an ultrasound & analysed by computer	The IUGR fetuses had a significantly lower fetal movement (FA) rate than normally grown fetuses at all gestations. They also spent a significantly lower proportion of time exhibiting high fetal heart rate (FHR) variation at 28-31 weeks. Only 2 of 18 IUGR fetuses had abnormal biophysical profile scores (BPS) yet all but one of them had either FHR or FA patterns that were outside the 10 <sup>th</sup> - 90 <sup>th</sup> percentile range for the normally grown fetuses suggesting that FHR & FA abnormalities predated BPS changes. More of the IUGR fetuses had abnormalities of FA than FHR. IUGR fetuses with small head circumference (< 3 <sup>rd</sup> percentile) had lower FA rates during period of both low & high FHR variation, though this was only statistically significant for periods of low FHR variation (p.0.05)	Fair
7	Arbeille P (1997)  Fetal arterial Doppler – IUGR & hypoxia  <i>Eur J Obstet Gynaecol Reprod Biol</i> , 75(1), Dec, pp 51-3	Retrospective study	The umbilical resistance indices, when greater than the upper limit of the normal range (> 2sd) are frequently associated with IUGR (sensitivity 65 to 70%). Absent end diastolic flow is associated with severe IUGR and hypoxia and poor fetal outcome. A fairly good correlation was found between the existence of significantly decreased (<2 sd) cerebral resistance and the development of post asphyxial encephalopathy in the neonates (specificity 75% , sensitivity 87%) . the earliest detectors of IUGR & hypoxia are the cerebral-umbilical cerebral carotid or cerebral aortic ratios (sensitivity 85% sepecificity 90%). When used as a predictor of poor perinatal outcome in the growth retarded fetuses, the cerebral umbilical ratio shows a sensitivity of 90% compared with 78% of the middle cerebral artery and 83% for umbilical artery indices. Changes in the ratio are well correlated with fetal pO2 changes. The sensitivity in predicting IUGR was for the aortic PI: 41% & for the aortic BFC (Blood flow classes) 57%. In predicting delivery for fetal distress, the corresponding values were 76 & 87 % respectively	Poor

No	Author, Title, Journal, Year, Vol page	Study design, sample size, follow up	Outcomes & Characteristic	Grade & comment
8	<p>Craig SD, Beach ML, Harvey-Wilkes KB, D'Alton ME (1996)</p> <p>Ultrasound predictors of neonatal outcome in intrauterine growth restriction.</p> <p><i>Am J Perinatol.</i> 13(8), Nov, pp 465-71.</p>	N=127 patients	Estimated weight percentile, amniotic fluid volume, umbilical artery Doppler velocimetry, and head circumference/abdominal circumference ratio were compared with neonatal outcome.	

#### ET – LOCATION OF PLACENTA

No	Author, title, Journal, Year, Vol, Page No	Study Design, Sample size, Follow up	Outcome & Characteristic	Grade & Comment
1	<p>Hagenfeldt K, Alton Lundberg V, Axelsson O, Blennow M, Boj F, Bygdemann M et al (1998)</p> <p>Routine ultrasound in pregnancy</p> <p><i>The Swedish Council on Technology Assessment in Health Care (SBU)</i> pp 263</p>	HTA	<p>Routine ultrasound examination during the first half of pregnancy would predict most cases of placenta previa even if the method is often over-diagnosed.</p> <p>The substantial risk for over-diagnosing the condition during the first half of pregnancy makes it doubtful whether assessing the position of the placenta should be included in routine, prenatal ultrasound examination, particularly since this condition is rare</p>	Good

No	Author, title, Journal, Year, Vol, Page No	Study Design, Sample size, Follow up	Outcome & Characteristic	Grade & Comment
2	Catanzarite V., Maida C Thomas W, Mendoza A. Stanco L, Piacquadio KM (2001)  Prenatal sonographic diagnosis of vasa previa: ultrasound findings and obstetric outcomes in ten cases  <i>Ultrasound Obstet Gynecol</i> , 18(2), Aug, pp 109015	Prospective  N= 33 208  F/up: 8 years	11 cases of vasa previa without placenta previa were diagnoses of 33 208 women over 8 years 10 had confirmation of the diagnoses by the delivering obstetrician and or placenta examination, giving specificity diagnosis of 91% Conclusion the specificity sonographic diagnosis of vasa previa was 91%. Antenatal diagnosis permitted us to prevent the catastrophic outcomes commonly associated with vasa previa.	Fair
3	Oyelese KO, Schwarzler P, Coates S, Sanusi FA, Hamid R, Campbell S. (1998)  A strategy for reducing the mortality rate from vasa previa using transvaginal sonography with color Doppler.  <i>Ultrasound Obstet Gynecol</i> , 12(6), Dec, pp 434-8	Case studies	We present the last three cases of vasa previa to have occurred in our institution, two of which were diagnosed antenatally using TVS and color Doppler. In all three cases, routine 20-week obstetric sonography revealed low-lying placentas; in only one of these did the placenta remain low at term. A low-lying placenta at 20 weeks may be a risk factor for vasa previa; we suggest that further studies be carried out to ascertain this. Judicious use of TVS and color Doppler in women considered at risk of vasa previa may help to reduce the mortality from this condition.	Poor
4	Zelop CC, Bromley B, Frigoletto FD, Benacerraf BR (1994)  Second trimester sonographically diagnosed placenta praevia; prediction of persistent praevia at birth  <i>Int J Gynaecol Obstet</i> , 44(3), Mar, pp 207 -10	Prospective study  N=925	267 of the 925 underwent cesarean delivery, 43 of which had placenta praevia (4.6%). 22 of the 43 were asymptomatic without antepartum bleeding, Symmetry of the placenta with respect to the internal os at 2 <sup>nd</sup> trimester scan had a sensitivity of 49% for prediction of placenta praevia at birth. The degree of placental symmetry with respect to the internal os during the 2 <sup>nd</sup> trimester successfully predicted the praevias most likely to persist at delivery with a sensitivity of 49% and specificity of 93%	Fair



No	Author, title, Journal, Year, Vol, Page No	Study Design, Sample size, Follow up	Outcome & Characteristic	Grade & Comment
5	Lauria MR, Smith RS, Treadwell MC, Comstock CH, Kirk JS, Lee W, Bottoms SF (1996)  The use of second trimester transvaginal sonography to predict placenta praevia  <i>Ultrasound Obstet Gynaecol</i> , 8(5), Nov, pp 337-40	Prospective study	The incidence of placenta praevia diagnosed by TVS at 15 -20 weeks was 1.1%, 14% persisted until delivery. Between 15 & 24 weeks gestation, placenta overlapping the internal os by > or = 10 mm identified patients at risk of placenta praevia at delivery with 100% sensitivity and 85% specificity	Fair
6	Tan NH, Abu M, Woo JI, Tahir HM (1995)  The role of transvaginal sonography in the diagnosis of placenta praevia  <i>Aust NZ Obstet Gynaecolo</i> , 35(1), Feb, pp 42-5	Prospective study  N= 70 patients	49 cases (70%) were correctly diagnosed to have placenta praevia by both scans. Transvaginal ultrasonography ruled out placenta praevia in 12 cases (17%) though to be placenta praevia by transabdominal ultrasound. Both diagnosed placental migration in 4 cases (6%). 5 patients (7%) were wrongly diagnosed to be placenta praevia by both techniques. The diagnostic accuracy of transvaginal ultrasonography was 92.8 % compared with 75.7 % for transabdominal ultrasonography	Fair
7	Hill LM, DiNofrio DM, Chenevey P. (1995)  Transvaginal sonographic evaluation of first-trimester placenta previa.  <i>Ultrasound Obstet Gynecol.</i> , 5(5), May, pp 301-3.	N=1252	A total of 77 out of 1252 (6.2%) patients had a first-trimester placenta previa; four cases persisted until term. There were no false-negative diagnoses. Our conclusion is that approximately 6.2% of patients will have a placenta previa in the first trimester. Transvaginal sonography can exclude a diagnosis of placenta previa after 9 weeks' gestation. The likelihood that a placenta previa will persist until term increases if the placenta covers the internal cervical os by > or = 1.6 cm.	Poor

**EVIDENCE TABLE : CONENITAL ABNORMALITIES**

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
1	<p>Aymerich M, Almazan C, Jovell AJ (1997)</p> <p>Assessment of obstetric ultrasonogahy for the control of normal pregnancies in primary care</p> <p><i>Catalan Agency for Health Technology Assessment (CAHTA) 1997</i></p>	HTA	<p>The diagnostic of accuracy in the detection of congenital malformations in the general population of pregnant women has only analysed in specialized obstetric centres. The value of the resulting specificity of each was high (99.9%) while the range of the sensitivity values is quite broad in the different studies from 20% to 96%</p> <p>The diagnostic accuracy to detect Downs Syndrome using nuchal fold and length of femur or combination of both as ultrasonographic marker shown that the sensitivity value ranging from 32% ( length of femur at second trimester pregnancy ) to 65% (nuchal hold at first trimester) and the specificity ranging from 92% (length of femur at second trimester) and 99% (nuchal fold at second trimester)</p>	Good
2	<p>Long G, Sprigg A (1998)</p> <p>A comparative study of routine versus selective fetal anomaly ultrasound scanning</p> <p><i>Journal of Medical Screening, 5(1), pp 6-10</i></p>	<p>Non randomised trial with Historical control</p> <p>3826 pregnancies - selective group</p> <p>3798 – routine group</p> <p>1077 second trimester ultrasound scan were performed in selective group and 3775 in the routine group</p> <p>Follow up- 24 months after delivery</p>	<p>56 significant abnormalities occurred in the selective group and 54 in the routine group. The routine ultrasound detected 11 major and 18 less severe congenital abnormalities in low risk pregnancies. Major congenital abnormalities undetected antenatally during 12 month of selective ultrasound ( and potentially detectable by routine anomaly scanning) occurred in 10 cases. 12 significant abnormalities were missed (false negative scans) in the routine group and 25 false positive scans were given in the routine ultrasound group.</p>	Poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
3	<p>VanDorsten JP, Hulsy TC, Newman RB, Menard MK (1998)</p> <p>Fetal anomaly detection by second trimester ultrasonography in tertiary centre</p> <p><i>American Journal of Obstetrics &amp; Gynecology</i>, 178(4), pp 742-749</p>	<p>Prospective cohort study</p> <p>Ultrasonographic scan between 15 – 22 weeks</p> <p>2031 pregnant women</p> <p>1611 –routine scan 420 – specific indications that placed the fetus at risk of anomalies</p>	<p>A combination of ultrasonographically detected and delivery detected anomalies yielded an overall major anomaly prevalence of 2.95% in the indicated group and 1.3% in the screening group</p> <p>The sensitivity is significantly higher in the indicate group (89.7%) than the screening group (47.6%)</p> <p>Specificity were more than 99% in both group</p> <p>Detection was significantly higher in the indicated group (93.1%) compared with the screening group (65.5%)</p> <p>Conclusion</p> <p>Detection of anomalous fetuses was significantly better in the indicated group compared with the screening group</p>	Poor
4	<p>Bricker L, Garcia J, Henderson J, Mugford M, Neilson J, Robert T, Martin MA (2000)</p> <p>Ultrasound screening in pregnancy: a systematic review of the clinical effectiveness, cost effectiveness and women's view</p> <p><i>National Coordinating Centre for Health Technology Assessment</i>, 4(16) ,pp 193</p>	HTA	The effectiveness of anomaly detection has highlighted substantial variation in , and limits to, detection rates of certain structural abnormalities.	Good

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
5	<p>Roberts T, Mugford M, Piercy J (1998)</p> <p>Choosing option for ultrasound screening in pregnancy and comparing cost effectiveness a decision analysis approach</p> <p><i>British Journal of Obstetric &amp; Gynecology</i>, 105(9), pp 960-70</p>		<p>The estimate /assumed sensitivity of each of the four types of scan for serious cardiac anomaly were 0% for first trimester dating scan (T1d), 0% for first trimester anomaly scan (T1- including nuchal translucency examination, usually 10-14 weeks) 10-25% for second trimester scan (usually carried out at 18-20 weeks gestation) and 50% (clinical hunch) for third trimester scan (28-40 weeks).</p>	
6	<p>Health Council of the Netherlands (2001)</p> <p>Prenatal Screening : Downs Syndrome, Neural tube defect , routine ultrasound</p> <p><i>Health Council of the Netherlands 2001</i></p>	HTA	<p>The scientific evidence does not provide hard evidence to support the use of the ultrasound screening for structural abnormalities other than neural tube defects</p>	Good
7	<p>Skupski DW, Newman S, Edersheim T, Hutson JM, Udom-Rice I Chervenak FA, McCullough LB (1996)</p> <p>Fetus-Placenta-Newborn: The impact of routine obstetric ultrasonographic screening in a low risk population</p> <p><i>American Journal of Obstetrics and Gynecolog</i>, 175(5), Nov, pp 1142-1145</p>	<p>Retrospective chart review</p> <p>1990-1994</p> <p>860 fetuses in 854 pregnancies all underwent ultrasonographic examination at 18 to 20 weeks gestation</p>	<p>Structural anomalies were found in 5.35% (46/860) of fetuses, with major anomalies in 1.16% (10/860) of fetuses and minor anomalies in 4.19% (36/860) of fetuses.</p> <p>Routine second trimester ultrasonography for the detection of all fetal anomalies resulted in sensitivity, specificity, and positive and negative predictive values of 8.7%, 99.9%, 80% and 95.7% respectively</p> <p>For major anomalies the sensitivity, specificity and positive and negative predictive values were 30%, 100%, 100% and 99.2% respectively. If only major anomalies detectable by ultrasonography are included, this sensitivity rises to 75% and the specificity and positive and negative predictive values are 100%,100% and 99.9% respectively</p>	Fair

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
8	<p>Nyberg DA; Luthy DA, Cheng EY; Sheley RC; Resta RG; William MA (1995)</p> <p>Role of prenatal ultrasonography I women with positive screen for Down Syndrome on the basis of maternal serum markers</p> <p><i>American Journal of Obstetrics and Gynecology</i>; 173(4), Oct, pp 1030-1035</p>	<p>395 – 374 had normal karyotype by genetic amniocentesis (n=232) or postnatal follow up(n=142)</p> <p>F/up: Jan 1 1990 – Aug 15 1991</p>	<p>Down syndrome was found in nine of 36 (25%) fetuses with one or more ultrasonographic abnormalities compared with nine of 359 fetuses with normal results. Hence abnormal results increased the risk of Down Syndrome by 5.6 fold and results reduced the risk by 45%.</p> <p>An abnormal ultrasonography results was 10 times more likely to be associated with Down Syndrome than a normal result (25% vs 2.5%)</p> <p>Negative result reduced the risk by 56%</p> <p>Conclusion</p> <p>Ultrasonographic finding can be used to modify the estimate risk of fetal Down Syndrome in women with a positive triple screen. Correction of menstrual dates reduces the rate of false positive screen and unnecessary amniocentesis. Abnormal findings further increase the risk of Down Syndrome. However a normal ultrasonography is less predictive, reducing the risk for Down Syndrome by approximately half</p>	Poor
9	<p>Magriples U. Copel JA (1998)</p> <p>Accurate detection of anomalies by routine ultrasonography in an indigent clinic population</p> <p><i>American Journal of Obstetric &amp; Gynecology</i>, 179(4), Oct, pp978-981</p>	<p>Retrospective Study</p> <p>N=901 women undergoing obstetric ultrasonography between 15 &amp; 26 weeks</p> <p>F/up: 18 month period</p>	<p>81 patients (8.9%) were referred for repeated screening ultrasonography for inadequately visualized anatomy. 39 of these had their gestational age recalculated</p> <p>42 patients (4.7%) were therefore referred for repeated ultrasonography for anatomic survey alone.</p> <p>21% of patients in this study group were referred for comprehensive ultrasonography; in half of these patients the referral was based on the results of the screening sonogram alone. There were a total of 28 anomalies (3.1%), 20 of which were detected by screening ultrasonography. These were 5 fetuses with false-positive diagnosis, 4 of which had a normal targeted sonogram and were subsequently normal at birth.</p> <p>The sensitivity, specificity and positive and negative values of screening ultrasonography were 71.4%; 99.4%, 80% and 99.1% respectively.</p>	Fair

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
10	Souter VL, Nyberg DA (2001)  Sonographic screening for fetal aneuloidy: first trimester  <i>J Ultrasound Med</i> , 20(7), Jul , pp 775-90	Review literature since 1995	Although early studies showed wide variation in detection of fetal Down syndrome when using nuchal translucency, more recent studies showed sensitivities of approximately 70% to 80%, for a 5% false-positive rate. Increased nuchal translucency has also been found to be a marker for other aneuploidies, including trisomy 18, trisomy 13, and Turner syndrome.	Poor
11	Wax JR, Guilbert J, Mather J, Chen C, Royer D, Steinfeld JD, Ingardia CJ (2000)  Efficacy of community-based second trimester genetic ultrasonography in detecting the chromosomally abnormal fetus.  <i>J Ultrasound Med</i> ,19(10), Oct, pp 689-94	Prospectively Evaluation study  All women had a targeted ultrasonographic examination between April 1997 and June 1999 and were offered fetal chromosomal analysis. Markers of aneuploidy and pregnancy outcomes were recorded prospectively.	Of the 1030 fetuses seen during the study, 789 had outcome data available and constituted the study group. In this group, 694 (87.9%) ultrasonograms were normal, 73 (9.2%) had one marker present, 17 (2.2%) had two markers present, and 5 (0.6%) had three or more markers present. Fourteen of 17 (82.3%) aneuploid fetuses had an abnormal ultrasonogram (one or more markers present), including 5 of 7 (71.4%) with Down syndrome. Logistic regression showed abnormal four-chamber view, structural anomaly, and intracardiac echogenic focus to be significant aneuploidy markers. The amniocentesis rate was 334 of 1030 (32.4%), and it increased with the number of sonographic markers noted (0 = 29.9%, 1 = 60.2%, 2 = 70.6%, 3 or more = 80%). Genetic ultrasonography is highly effective in identifying chromosomally abnormal fetuses in a community-based practice.	Fair
12	Nicolaidis KH, Heath V, Liao AW. (2000)  The 11-14 week scan.  <i>Baillieres Best Pract Res Clin Obstet Gynaecol</i> , 14(4), aug, pp 581-94	Review	Fetal nuchal translucency thickness (NT) at the 11-14 week scan has been combined with maternal age to provide an effective method of screening for trisomy 21; for an invasive testing rate of 5%, about 75% of trisomic pregnancies can be identified. Other benefits of the 11-14 week scan include early diagnosis of major fetal defects and the detection of multiple pregnancies, as well as reliable identification of chorionicity.	Fair

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
13	<p>Ott WJ, Taysi K (2001)</p> <p>Obstetric ultrasonographic findings and fetal chromosomal abnormalities: refining the association</p> <p><i>Am J Obstet Gynecol</i>, 184(7), Jun, pp1414-20</p>	Retrospective Review	<p>A normal ultrasonographic examination result in patients who are at increased risk for fetal chromosomal abnormalities reduces the risk 2 to 3 fold, whereas the presence of any major ultrasonographic abnormality or certain minor abnormalities significantly increase the risk.</p> <p>The application of these results to low risk patients is still premature</p>	Fair
14	<p>Grandjean H, Larroque D, Levi S. (1999)</p> <p>The performance of routine ultrasonographic screening of pregnancies in the Eurofetus Study.</p> <p><i>Am J Obstet Gynecol</i>, 181(2), aug, pp 446-54</p>	<p>All ultrasonographic diagnoses of malformations and the outcomes of the fetuses were prospectively recorded in 61 European obstetric units</p> <p>F/up: over a 3-year period (1990-1993).</p>	<p>Of 3685 malformed fetuses, 2262 had received diagnoses during pregnancy (sensitivity, 61.4%). Of a total number of 4615 malformations, 2593 were detected (sensitivity, 56.2%). The detection sensitivity was higher for the major than for the minor abnormalities (73.7% vs 45.7%), and the diagnosis was made earlier in the pregnancy (24.2 weeks vs 27.6, P &lt; .01). Overall, 55% of the major abnormalities were detected within 24 gestational weeks. Within each severity group the accuracy of detection depended on the system. For the major abnormalities it was better for the central nervous system (88.3%) and urinary tract (84.8%) but lower for the heart and great vessels (38.8%). Detection of minor abnormalities was also effective for the urinary tract (89.1%) but not for the heart and great vessels (20.8%) or the musculoskeletal system (18%). The rate of live births for the mothers in whom no abnormalities were detected, mainly because of the higher rate of elective terminations of pregnancy in the former group. Conclusion Systematic ultrasonographic screening during pregnancy can now detect a large proportion of fetal malformations, although some still escape detection</p>	Fair

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
15	<p>Jorgensen FS, Valentin L, Salvesen KA, Jorgensen C, Jensen FR, Bang J, Eik-Nes SH, Madsen M, Marsal K, Persson PH, Philip J, Bogstad JW, Norgaard-Pedersen B. (1999)</p> <p>MULTISCAN--a Scandinavian multicenter second trimester obstetric ultrasound and serum screening study.</p> <p><i>Acta Obstet Gynecol Scand</i>, 78(6), Jul, pp 501-10</p>	<p>Prospective multicenter study</p> <p>N= 27,844 low-risk women at 18-34 years of age who had a second trimester ultrasound screening examination. Of these, 10,264 also had a serum test</p> <p>F/up: 1/1/1989-31/12/1991..</p>	<p>The detection rates, (% with 95% confidence interval) for ultrasound screening were: NTD: 79.4 (62.1-91.3); AWD: 85.7 (42.1-99.6); DS: 6.3 (0.8-20.8). In the subgroup of women who had both tests, the detection rates for ultrasound screening vs double test were: NTD: 62.5 (24.5-91.5) vs 75.0 (34.9-96.8); AWD: 66.7 (9.4-99.2) vs 100 (29.2-100.0); DS: 7.7 (0.2-36.0) vs 46.2 (19.2-74.9). The false positive rates (%) for ultrasound screening vs double test were: NTD: 0.01/3.3; AWD: 0.01/3.3; DS: 0.1/4.0.</p> <p>CONCLUSION: Second trimester ultrasound screening in a low risk population gave a low detection rate for fetal DS (6.3%) and an acceptable detection rate for NTD (79.4%) and AWD (85.7%). In the subgroup of women who had both tests, serum screening performed better than ultrasound as applied in the present study, especially regarding DS</p>	Fair
16	<p>Skupski DW, Newman S, Edersheim T, Hutson JM, Udom-Rice I, Chervenak FA, McCullough LB. (1996)</p> <p>The impact of routine obstetric ultrasonographic screening in a low-risk population.</p> <p><i>Am J Obstet Gynecol</i>, 175(5), Nov, pp 1142-5</p>	<p>Retrospective chart review</p> <p>N= 860 fetuses in 854 pregnancies – routine ultrasound at 18-20 weeks gestation</p>	<p>Anomalies were present in 5.35% (46/860); these were major anomalies in 1.16% (10/860) and minor anomalies in 4.19% (36/860). The sensitivity, specificity, and positive and negative predictive values for the diagnosis of all anomalies were 8.7%, 99.9%, 80%, and 95.7%, respectively. However, if only major anomalies detectable by ultrasonography are included, these values become 75%, 100%, 100%, and 99.9%, respectively. There was one false-positive diagnosis not affecting outcome, a small ventriculoseptal cardiac defect. Postnatal ascertainment of anomalies was excellent, as determined by an incidence of ventriculoseptal defects of 1 in 120</p> <p>CONCLUSION: Distinguishing between major and minor anomalies and between ultrasonographically detectable versus nondetectable anomalies is essential in the evaluation of the diagnostic accuracy of screening ultrasonography. Any comparisons of studies examining the effectiveness of prenatal screening for congenital anomalies with ultrasonography should use the same outcome: major anomalies identifiable by ultrasonography</p>	Fair



No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
17	Fugelseth D, Lindemann R, Sande HA, Refsum S, Nordshus T. (1994)  Prenatal diagnosis of urinary tract anomalies. The value of two ultrasound examinations.  <i>Acta Obstet Gynecol Scand</i> , 73(4), Apr, pp 290-3	retrospective study  N= 47 cases where fetal urinary tract malformations were diagnosed in a two-stage screening program (17th and 32nd week of gestation) covering 22,310 women  F/up: ten years, 1982-91	Urinary tract anomalies were diagnosed in 0.18% of the pregnancies. Of these, 61.7% were found at the second routine ultrasound screening CONCLUSION. If only one ultrasound scanning had been performed in the 17th week, approximately two-thirds of the cases would not have been detected. Early intervention and follow-up after delivery would only have been performed if the infants had developed symptoms or complications related to the urinary tract anomalies.	fair
18	Walkinshaw SA, Renwick M, Hebisch G, Hey EN. (1992)  How good is ultrasound in the detection and evaluation of anterior abdominal wall defects?  <i>Br J Radiol</i> , 65(772), Apr, pp 298-301		The ability of routine obstetric ultrasound to detect and accurately describe fetuses with anterior abdominal wall defects has been examined in an unselected population using data from a regional abnormality survey. Examination between 16 and 22 weeks gestation detected 60% of defects with a false positive rate of 5.3%. Fetuses with gastroschisis were incorrectly assigned as exomphalos in 14.7% of cases recognized before 22 weeks gestation. The diagnosis, including description of associated detectable anomalies, was completely accurate in 71.6% of cases. Some of the problems of diagnostic accuracy need to be considered when counselling couples with a fetal anomaly. Cross-referral between obstetric ultrasound units should be encouraged to improve diagnostic accuracy.	
19	Shulman A, Mazkereth R, Zalel Y, Kuint J, Lipitz S, Avigad I, Achiron R (2002)  Prenatal identification of esophageal atresia: The role of ultrasonography for evaluation of functional anatomy  <i>Prenat Diagn</i> , 22(8), Aug, pp 669-74	N= 25 pregnant patients	The positive predictive value for prenatal ultrasound for detecting esophageal atresia is 100% with a sensitivity of 80%.	Poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
20	<p>Pilu G, Hobbins JC (2002)</p> <p>Sonography of fetal cerebrospinal anomalies</p> <p><i>Prenat Dian</i>, 22(4), Apr, pp 321-30</p>	<p>Review</p>	<p>Fetal sonography is effective in identifying neural tube defects, although alpha-fetoprotein screening seems to give a greater sensitivity. The accuracy of ultrasound in the identification of CVS malformations other than neural tube defects remain unclear because of the ascertainment biases of the few large prospective studies that have been conducted to date</p>	Poor
21	<p>Cash C, Set P, Coleman N (2001)</p> <p>The accuracy of antenatal ultrasound in the detection of facial clefts in a low risk screening population</p> <p><i>Ultrasound Obstet Gynecol</i>, 18(5), Nov, pp 432-6</p>	<p>Retrospective review</p> <p>F/Up 5 years</p>	<p>Out of 23, 577 live and still births, 30 had facial clefts, four were excluded from the study. Of the remaining 26 cases, 10 had associated major anomalies. There were 19 live births and seven terminations, 6 of the 7 terminations had other major abnormalities. The detection rate for cleft lip and palate was 93% and the detection rate for isolated cleft palate was 22%. Isolated cleft lip was detected in 67% of cases. The overall detection rate for facial clefts was 65%</p>	fair
22	<p>Barisic I, Clementi M, Hausler M, Gjergja R, Kern J, Stoll C, The Euroscan Study Group (2001)</p> <p>Evaluation of prenatal ultrasound diagnosis of fetal abdominal wall defects by 19 European registries</p> <p><i>Ultrasound Obstet Gynecol</i>, 18(4), Oct, pp 309-16</p>	<p>Multicenter Study, Evaluation Studies</p> <p>N= 690, 123</p> <p>Study period 30 months (July 1996 – Dec 1998)</p>	<p>The sensitivity of antenatal ultrasound examination in detecting omphalocele was 75% (103/137). The overall prenatal detection rate for gastroschisis was 83% (8/106). Detection rate varied between registries from 25 to 100% for omphalcele and from 18 to 100% for gastroschisis</p>	Poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
23	Tongong T, Wanapirak C, Sirichotiyakul S, Sirivatanapa P. (2001)  Prenatal Sonographic markers of trisomy 21  <i>J Med Asso Thai</i> , 84(2), feb, pp 274-80	Prospective descriptive analysis  N= Pregnancies at risk of trisomy 21 between 14-27 weeks gestation	36 fetuses with subsequently proven trisomy 21 were prenatally evaluated by ultrasound in the second trimester. About half of the fetuses with trisomy 21 had abnormal sonographic findings in the second trimester.	Fair
24	Boyd PA, Wellesley DG, De Walle HE, Tenconi R, Garcia-Minaur S, Zandwijken GR, Stoll C, Clementi M (2000)  Evaluation of the prenatal diagnosis of neural tube defects by fetal ultrasonographic examination in different centres across Europe  <i>J Med Screen</i> ; 7 (4), pp 169-74	Evaluation Study Multicenter Study  N= 670 766  F/up: 30 months	542 case of neural tube defect was diagnosed at delivery. 166 anencephaly, 252 spina bifida, 35 encephalocele was isolated. Of 166 isolated cases with anencephaly 96% were correctly identified prenatally one was missed on scan, two were wrongly diagnosed, and four were not scanned, sensitivity 98%, 86% of isolated anencephalic pregnancies were terminated. Of the 252 cases of isolated spina bifida, 171 (68%) were correctly identified prenatally, the diagnosis was missed on scan in 66 cases and 21 were not scanned, sensitivity 75%	Poor
25	Skari H, Bjornland K, Bjornstad-Ostensen A, Haugen G, Emblem R (1998)  Consequences of prenatal ultrasound diagnosis: a preliminary report on neonates with congenital malformations  <i>Acta Obstet Gynecol Scand</i> , 77(6), Jul, pp 635-42	N= 36 consecutive neonates with congenital diaphragmatic hernia, abdominal wall defects, bladder exstrophy and meningomyelocele	The sensitivity of prenatal ultrasound for diagnosis of the congenital malformations was 7/36 at 17-18 <sup>th</sup> week of gestation, and overall 13/36. Conclusion The sensitivity of prenatal ultrasound in diagnosing the congenital malformations under study in low risk population was 19% at 17-18 <sup>th</sup> week of gestation and 36% throughout the pregnancy	Poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
26	Zimmer EZ, Avaraham Z, Sujoy P, Goldstein I, Bronshtein M (1997)  The Influence of prenatal ultrasound on the prevalence of congenital anomalies at birth <i>Prenat Diagn</i> , 17(7), Jul, pp 623-8	N= 23 439, All birth and stillbirth with congenital defects, and all terminations of pregnancy for fetal anomalies in the Rambam Medical Center  F/up: 5 year (1989 -1993)	The incidence of newborns with anomalies decreased from 1.95 to 1.34%. The incidence of termination of pregnancy because of fetal anomalies increased from 0.35 to 0.83 %. The detection rate of malformations increased from 53.94% to 79.60%. The termination of pregnancy after ultrasound detection of fetal anomalies had an impact on the prevalence of anomalies in newborns There was also continuing significant improvement in the detection rate o ultrasound examinations	poor
27	Buskens E, Grobbee DE, Frohn-Mulder IM, Stewart PA, Jutmann RE, Wladimiroff JW, Hess J (1996)  Efficacy of routine fetal ultrasound screening for congenital heart disease in normal pregnancy  <i>Circulation</i> ; 94(1), Jul 1, pp 67-72	Prospective  N= 6922 scanned fetuses	80 cases of congenital malformation were diagnosed during the study: 44 cases of congenital heart disease, 40 cases of noncardiac malformations, and a combination of the two in 4 cases. The fetal four chamber view examination had sensitivity of 4.5%. Sensitivity for noncardiac anomalies was 30%. Overall sensitivity of ultrasound examination was 16.3%. Specificity and negative predictive value were high > 98%. The positive value was low with wide CIs. Conclusion Routine prenatal ultrasound screening for congenital malformations is inefficient, particularly for cardiac anomalies	Fair
28	Stoll C, Dott B, Alembik Y Roth MP (1993)  Evaluation of routine prenatal ultrasound examination in detecting fetal chromosomal abnormalities in low risk population  <i>Hum Genet</i> , 91(1), Mar, pp 37-41	N= 119 099 consecutive pregnancies  F/up: 1980 to 1987	At least one ultrasonographic examination seeking congenital malformations was performed in more than 95% of the pregnant women studied. The total number of chromosomal anomalies during the study period was 199. 123 of these being Down Syndrome. only 41 of the 119 fetuses with chromosomal abnormalities and congenital malformation examined had been found to have a malformation at ultrasound examination this low sensitivity is not the result of the quality of the ultrasound equipment, it may explained by the inadequate qualification of some operators and bu the insufficient duration of the routine examination. <b>Conclusion</b> the sensitivity of the detection of chromosomal abnormalities by routine prenatal ultrasound screening is low. Other screening methods are need	poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
29	<p>Lee K, Kim SY, Choi SM, Kim JS, Lee BS, Seo K, Lee YH, Kim DK. (1998)</p> <p>Effectiveness of prenatal ultrasonography in detecting fetal anomalies and perinatal outcome of anomalous fetuses.</p> <p><i>Yonsei Med J</i>, 39(4), Aug, pp 372-82</p> <p>Koreo</p>	<p>Retrospective</p> <p>N=</p> <p>F/up: 5 year</p>	<p>From a total of 5544 singletons, 4819 had at least one ultrasound scan (87%), of which 3004 at low risk and 1815 (38%) at high risk for anomalies had routine screening (RS) and indicated scanning (IS), respectively. A total of 136 fetuses were structurally abnormal (2.82%, RS and IS: 0.77% and 6.23%) and 200 major anomalies (RS and IS: 37 and 163) were recorded. The overall sensitivity of the ultrasound test was 78.7% (RS and IS: 34.8% and 87.6%, <math>P &lt; 0.01</math>) for abnormal fetuses and 58.0% (RS and IS: 29.7% and 64.4%, <math>P &lt; 0.01</math>) for anomalies. The overall specificity was 99.9% and the positive and negative predictive values were 97.3% and 99.4%, respectively; these values did not differ significantly between the two groups. The sensitivity of ultrasound for the detection of abnormal fetuses before 24 weeks was 22.8% (RS and IS: 13.0% and 24.8%) which was associated with a 61% (25/41) termination rate (RS and IS: 25% and 75.9%, <math>P &lt; 0.01</math>) and a 24.4% (10/41) postnatal survival rate (RS and IS: 41.7% and 17.2%). The overall survival rate following pre- and postnatal correction of anomalies was 44.9% (RS and IS: 60.9% and 41.6%). For the detection of fetal anomalies anatomic ultrasound scanning is necessary during pregnancy, irrespective of pregnancy condition. Early detection of fetal anomalies could offer the option of pregnancy termination.</p>	Good to fair
30	<p>Grandjean H, Larroque D, Levi S. (1998)</p> <p>Sensitivity of routine ultrasound screening of pregnancies in the Eurofetus database. The Eurofetus Team.</p> <p><i>Ann N Y Acad Sci</i>, 847, pp 118-24</p>	<p>Prospective study</p> <p>N=3,685 fetuses with congenital structural abnormalities from an unselected population of women who underwent routine ultrasound examinations during their pregnancies.</p>	<p>Overall, 2,262 fetuses were diagnosed as being abnormal before birth (sensitivity = 61.4%). The total number of abnormalities was 4,615, of which 1,733 (37.5%) were major abnormalities. The overall number of detected abnormalities was 2,593 (sensitivity = 56.2%). If only major abnormalities were considered, the sensitivity rose to 73.7%, compared to only 45.7% for the minor abnormalities. Within each severity group, the accuracy of detection varied across systems. For the major abnormalities, it was higher for the central nervous system (88.3%) and urinary tract (84.8%), but lower for heart and great vessels (38.8%). Detection of minor abnormalities was also effective for the urinary tract (89.1%), but not for the heart and great vessels (20.8%) and the musculoskeletal system (18%).</p>	Fair

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
31	<p>VanDorsten JP, Hulsey TC, Newman RB, Menard MK (1998)</p> <p>Fetal anomaly detection by second-trimester ultrasonography in a tertiary center.</p> <p><i>Am J Obstet Gynecol</i>, 178(4), apr, pp 742-9.</p>	<p>Prospectively</p> <p>N= 2031 pregnant women</p> <p>F/up: July 1, 1993, and June 30, 1996. was</p>	<p>Forty-seven fetuses (2.3%) were diagnosed by ultrasonography as having a major anomaly: 8.6% in the indicated group and 0.68% in the screening group. The sensitivity for detecting the anomalous fetus was 75.0% overall: 89.7% in the indicated group and 47.6% in the screening group. Of the 47 patients diagnosed with fetal anomalies, 11 (23.4%) chose pregnancy termination; of the 35 (74.5%) live-born anomalous infants, 29 (82.9%) were discharged alive. Projected newborn cost savings offset the cost of routine midtrimester screening. CONCLUSIONS: Detection of anomalous fetuses was significantly better in the indicated compared with the screening group. Nevertheless, routine ultrasonographic screening appeared cost-effective in our population.</p>	Fair
32	<p>Chitty LS, Hunt GH, Moore J, Lobb MO. (1991)</p> <p>Effectiveness of routine ultrasonography in detecting fetal structural abnormalities in a low risk population.</p> <p><i>BMJ</i>, 303(6811), Nov 9, pp 1165-9</p>	<p>Retrospective study</p> <p>N=8785 fetuses.</p> <p>1988-9</p>	<p>8432 (95%) of the fetuses were examined by ultrasonography in the second trimester. 130 fetuses (1.5%) were found to have an abnormality at birth or after termination of pregnancy, 125 of which had been examined in the second trimester. In 93 cases the abnormality was detected before 24 weeks (sensitivity 74.4%, Two false positive diagnoses occurred, in both cases the pregnancies were not terminated and apparently normal infants were born. This gives a specificity of 99.98%. The positive predictive value of ultrasonography in the second trimester was 97.9% (92.6% to 99.7%). Of the 125 abnormalities, 87 were lethal or severely disabling; 72 of the 87 were detected by the routine screening programme (sensitivity 82.8%, 73.2% to 90.0%). CONCLUSION-- Routine fetal examination by ultrasonography in a low risk population detects many fetal structural abnormalities but can present several dilemmas in counseling</p>	Fair

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
33	<p>Chan A, Robertson EF, Haan EA, Raneira E, Keane RJ (1995)</p> <p>The sensitivity of ultrasound and serum alpha- fetoprotein in population based antenatal screening for neural tube defect South Australia 1968-91</p> <p><i>Br J Obstet Gynaecoll</i>, 102 (5), May, pp 370-6</p>	<p>Retrospective studyd</p> <p>N= 243</p>	<p>For pregnancies with neural tube defect screened by any method (serum alph-protein, ultrasound or amniocentesis)86% sensitivity was achieved. Ultrasound screening for anencephaly achieved 100% sensitivity even in low risk pregnancies, compared with 92% for serum alpha – fetoprotein screening (64%); for spina bifid, the sensitivity of ultrasound of screening increased with the level of risk of pregnancy: it was 60% in low risk pregnancies which was equivalent to that of serum alpha-fetoprotein screening (64%), 89% in high risk pregnancies and 100% for women referred for confirmation of suspected spina bifida by another ultrasonography. Ultrasound screening in high risk pregnancies for spina bifida achieved higher sensitivity in teaching hospitals compared with other ultrasound services in the State (97% vs65%) but the sensitivity was equivalent for low risk pregnancies. Had the screening programme not been in place, the level of sensitivity achieved for spina bifida by ultrasound and amniocentesis would have been 62% compared with the actual situation of 76% with the programme in existence, a difference of nearly 15%</p>	Poor
34	<p>Phelps S, Fischer R, Partington A, Dykes E (1997)</p> <p>Prenatal ultrasound diagnosis of gastrointestinal malformations</p> <p><i>J Pediatr Surg</i>, 32(3), Mar , pp 438-40</p>	<p>Prospective study</p> <p>N=156, 000</p>	<p>294 gastrointestinal malformations (GIM) were identified and reviewed. 220 cases of confirmed GIM only (35 (16%) had been correctly identified prenatally. Of the 84 prenatal diagnosis of GIM, only 25(42%) were confirmed postnatally. Prenatal ultrasound was most reliable in the detection of duodenal obstruction (55% confirmed cases identified prenatally) and least reliable in malformations of the hindgut. Of 44 cases of nonspecific sonographic bowel abnormality. Only 12 (27%) had confirmed GIM after delivery</p>	Good

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
35	Garmel SH, D'Alton ME.(1994)  Diagnostic ultrasound in pregnancy: an overview.  <i>Semin Perinatol</i> , 18(3), Jun, pp 117-32	Review	ultrasound examination can diagnose in approximately 50% of major anomalies. The accuracy of anomaly detection improves with increasing operator experience and advances in equipment resolution of the fetal image. The effect of routine sonography on perinatal outcome in low-risk pregnancies has not been established. Therefore, the role of ultrasound in routine screening remains controversial. However, in high-risk populations the accuracy of ultrasound in diagnosing congenital anomalies is well over 90%. The prenatal detection of abnormalities often influences obstetrical management and optimizes care of the fetus and newborn. The ability of ultrasound examination to determine gestational age, detect multiple gestations, and assess fetal well-being by diagnosing growth and fluid abnormalities has changed the practice of obstetrics more than any other technology in recent years.	Fair
36	BennPA; Borgida A; Horne DBSW,m Briganti S BS Collins RBS, Rodis JF  Down Syndrome and neural tube defect screening : The value of using gestational age by ultrasonography  American Journal of Obstetrics & Gynecology 1997 May; 176(5):1056-1061	F/up: April 15 1992-may 31 1995  N= 24,313 women at 15 to 21.9 weeks gestation : 14245 women based on ultrasonographic evaluation of gestation age and LMP dating was 10,068	Both initial and revised screen-positive rates for Down Syndrome were significantly lower than when ultrasonographic data were used compared with last menstrual period dating,  The detection rate for Down Syndrome appeared to be higher with ultrasonographic dating (approximately 76% vs 60% for the last menstrual period dating) Down Syndrome fetuses had a significantly shorter gestational age when evaluated by ultrasonography (relative to last menstrual period dating), but a similar trend was also seen in control pregnancies. Initial and revised screen-positive rates for open neural tube defects were higher for women who had received an ultrasonographic examination compared with the rates for those women referred with only last menstrual period data. The detection rates for open neural tube defects were similar for both methods of pregnancy dating. Conclusion Use of ultrasonographic measurement of gestation age, the number of amniocentesis performed to detect Down Syndrome can be substantially reduced while detection rates are maintained or improved	



**EVIDENCE TABLE : USE OF TRANSVAGINAL ULTRASOUND IN ANTENATAL CARE**

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
1	<p>Hagenfeldt K, Alton Lundberg V, Axelsson O, Blennow M, Boj F, Bygdemann M et al (1998)</p> <p>Routine ultrasound in pregnancy</p> <p><i>The Swedish Council on Technology Assessment in Health Care (SBU), pp 263</i></p>	HTA	<p>Ultrasound examination is the method which can be used to detect most congenital malformations, but all severe deformities cannot be identified by ultrasound. Although uncommon, false-positive findings of congenital deformity do occur in routine ultrasound examination. Hence there are special informational need prior to such an investigation. In Sweden , routine ultrasound examination is not used specifically to search for indications of chromosomal anomaly in the fetus. Routine prenatal ultrasound examination increase the detection rate of the congenitally malformed fetus</p>	Good
2	<p>Yagel; Simcha; Achiron, Reuven; Ron; Moshe; Revel; Ariel; Anteby; Eyal (1995)</p> <p>Obstetrics: Transvaginal Ultrasonography at early pregnancy cannot be used alone for targeted organ ultrasonographic examination in a high risk population</p> <p><i>American Journal of Obstetric &amp; Gynecology , 172(3), Mar, pp 971-975</i></p>	<p>N=563 pregnant women at high risk for birth defects were examined by transvaginal ultrasonography at 13 – 16 weeks gestation follow by transabdominal scan at 18 to 20 weeks of pregnancy</p> <p>F/up: April 1989 and December 1991</p>	<p>Transvaginal ultrasonography performed at 13 to 16 weeks gestation identified 42 structural anomalies. 17 fetuses and the rest of the population underwent a second transabdominal survey at 18 to 20 weeks gestation, which identified eight structural anomalies that were not diagnosed by the previous examination. In five cases the diagnosed anomaly disappeared. Together, the scans brought about the detection of 41 of 46 abnormal fetuses (89%).</p> <p>Conclusion A significant number of birth defect (17.4%) was not detected by early second trimester vaginal scan,, we recommended whenever early transvaginal ultrasonographic examination is performed it should be followed by a transabdominal scan at the most advanced stage of pregnancy at which an abortion is still feasible</p>	Poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
3	Guariglia L, Rosati P (2000)  Transvaginal sonographic detection of embryonic-fetal abnormalities in early pregnancy..  <i>Obstet Gynecol</i> , 96(3), Sep, pp 328-32	Prospectively analyzed records of 3592 sequential pregnant women at 10-16 weeks' (singleton) gestation (mean 13 weeks and 2 days).  N=3478 women.	The anomaly detection rate by transvaginal ultrasound was 51.6% (33 of 64; 95% confidence interval [CI] 38.7, 64.2) in early pregnancy, and the detection rate by transvaginal ultrasound combined with second-trimester transabdominal ultrasound was 84.4% (54 of 64; 95% CI 73.1, 92.2). Cystic hygroma and fetal hydrops were the anomalies detected most frequently by transvaginal ultrasound. Low detection rates for abnormalities of the face and of the cardiac, skeletal, and urinary systems were found even when both methods were used. CONCLUSION: Transvaginal sonography appears to be an effective way to identify many congenital fetal anomalies in early pregnancy. There is a good probability of diagnosing cystic hygroma and fetal hydrops, although other abnormalities, particularly heart defects, are associated with lower detection rates	Fair
4	Garmel SH, D'Alton ME. (1994)  Diagnostic ultrasound in pregnancy: an overview.  <i>Semin Perinatol</i> , ;18(3), Jun, pp 117-32	Review	The safety of ultrasonography in pregnancy is well documented. In screening populations, with the exception of the RADIUS trial, ultrasound examination can diagnose in approximately 50% of major anomalies. The effect of routine sonography on perinatal outcome in low-risk pregnancies has not been established. Therefore, the role of ultrasound in routine screening remains controversial. However, in high-risk populations the accuracy of ultrasound in diagnosing congenital anomalies is well over 90% of obstetrics more than any other technology in recent years.	Fair
5	Felicetti M, Domenico AD, Salzano P, Borrelli P, Labocetta A, Borrelli AL. (2001)  The importance of high resolution transvaginal sonography in early screening of fetal chromosomal pathology.  <i>Clin Exp Obstet Gynecol</i> ,28(1), pp 53-4	N= 650 pregnant women at risk of congenital anomalies at 10 <sup>th</sup> and 14th weeks	Sonographic fetal anomalies were seen in 61 cases (9.3%). The incidence of fetal anomalies in these cases was 52.5%. Trisomies and number of sexual chromosome anomalies were seen, especially, in the cases of cystic septated hygroma and fetal nuchal translucency > or = 3 mm which are the most frequent sonographic markers of chromosomopathies. CONCLUSIONS: Although further studies are necessary, these findings suggest the usefulness of high resolution transvaginal sonography for the early screening of chromosomopathies.	Poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
6	Ewigman BG, Crane JP, Frigoletto FD, LeFerve ML, Bain RP, McNellis D (1993)  Effect of prenatal ultrasound screening on perinatal outcome RADIUS study Group  <i>N Engl J Med</i> , 329(12), Sep 16, pp 821-7	Randomised control trial  N=15151 pregnant women	Screening ultrasonography did not improve perinatal outcome as compared with the selected use of ultrasonography on the basis of clinical judgement	Good
7	Gonser M, Vetter K (1995)  Diagnostic and clinical value of Doppler ultrasound in obstetric  <i>Geburtshilfe Frauenheilkd</i> , 55 (11), Nov, pp 605-15	Review	There is significantly decrease of 50% in perinatal mortality and in stillbirth of anatomically normal fetuses. It is important to note that there was no increase in neonatal or maternal mortality associated with the use of Doppler ultrasound, and the reduction in perinatal mortality was not the result of a delay in timing fetal death.	Good
8	Bucher HC, Schmidt JG (1993)  Does routine ultrasound scanning improve outcome in pregnancy? Meta analysis of various outcome measure  <i>BMJ</i> , 307 (6895), Jul 3, pp13-7	Meta analysis	Routine ultrasound scanning does not improve the outcome of pregnancy in terms of an increased number of live births or of reduced perinatal morbidity. Routine ultrasound scanning may be effective and useful as a screening for malformation. Its use for this purpose, however, should be made explicit and take into account the risk of false positive diagnosis in addition to ethical issue.	Good

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
9	Aymerich M, Almazan C, Jovell AJ, (1999)  Evaluation of obstetrical ultrasound examination in the monitoring of normal pregnancy in primary health care  <i>Catalan Agency for Health Technology Assessment (CAHTA) pp 8</i>	HTA report	There is sufficient evidence to conclude that routine or screening ultrasound versus selective ultrasound does not improve perinatal mortality.	Good
10	Bricker L, Neilson JP (2001)  Routine ultrasound in late pregnancy (after 24 weeks gestation)  <i>The Cochrane Library, Issue 4</i>	Cochrane Review	There was no difference in antenatal, obstetric and neonatal intervention or morbidity versus control groups. Routine late pregnancy ultrasound was not associated with improvements in overall perinatal mortality.	Good
11	Bricker L, Neilson JP (2001) Routine Doppler ultrasound in pregnancy  <i>The Cochrane Library, Issue 4</i>	Cochrane Review	Based on the existing evidence routine Doppler ultrasound examination in low risk or unselected populations did not result in increase antenatal, obstetric and neonatal inventions. And no overall differences were detected for substantive short term clinical outcomes such as perinatal mortality. There is no available evidence to assess maternal outcomes, particularly psychological effect.	Good
12	Neilson JP, Neilson JP (2001)  Ultrasound for fetal assessment in early pregnancy  <i>The Cochrane Library, Issue 4</i>	Cochrane Review	There were no differences detected for substantive clinical outcomes such as perinatal mortality	Good

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
13	Geerts LT, Brand EJ, Theron GB.(1996)  Routine obstetric ultrasound examinations in South Africa : cost and effect on perinatal outcome - a prospective randomised controlled trial.  <i>Br J Obstet Gynaecol.</i> 103(6), Jun, pp 501-7	Prospective RCT, 988 respondents (496 routine ultrasound group & 492 selective ultrasound group.).  Duration of study 10 months.	1. The groups did not defer significantly in their use of antenatal and neonatal services except for a greater number of ultrasound scans in the study group. 2. The incidence of overall or major adverse perinatal outcome was comparable. 3. Routine ultrasonography was accompanied by a considerable increase in costs. Selective use of obstetric ultrasonography did not increase the use of antenatal and neonatal services. Not routinely performing ultrasonography has led to considerable Health Service savings without increasing the risk for adverse perinatal outcome. It saved 75% of selected patients a referral to an ultrasound unit.	Good to Fair
14	Saari-Kemppainen A, Karjalainen O, Ylostalo P, Heinonen OP (1994)  Fetal anomalies in a controlled one-stage ultrasound screening trial. A report from the Helsinki Trial  <i>Perinatal Medicine.</i> ; 22(4) pp, 279-89	RCT Screening gp 4691 Control gp 4619	- Screening gp – 40% of major FA were detected and 11 cases abortion were induced because the malformation was either lethal which severely handicapping. - Control gp- 77% of participants had ultrasound examination any time during pregnancies, 13 (27%) major FA were detected only 2 of these before the 21st weeks of gestation - Prenatal mortality rate was 4.2/1000 in the screening and 8.4/1000 in the control gp (p=0.013) Conclusion: The detection of major FA in ultrasound screening can reduce perinatal mortality rate A systematic search for FA should be included in the ultrasound screening of all pregnancies. -	Good Big sample

**EVIDENCE TABLE – USE OF ULTRASOUND - GYNEACOLOGY– RETAINED PRODUCTS OF CONCEPTION**

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
1	<p>Wong SF, Lam MH, Ho LC.(2002)</p> <p>Transvaginal sonography in the detection of retained products of conception after first-trimester spontaneous abortion.</p> <p><i>J Clin Ultrasound</i>, 30(7), Sep, pp 428-32</p>	<p>N= 113 women with clinically incomplete abortion</p>	<p>Among 52 women with a clinically incomplete abortion, only 50% had retained products of conception. The use of transvaginal sonography resulted in a 29% (15/52) reduction of surgical intervention in these women. On the other hand, 30% (14/47) of women with a clinical diagnosis of complete abortion had retained products of conception. The sensitivity and specificity of cervical status for detecting retained products of conception were 65% and 56%, respectively, whereas the overall sensitivity and specificity of transvaginal sonographic examination (bilayer endometrial thickness 8 mm or less) were 100% and 80%, respectively.</p> <p>CONCLUSIONS: Transvaginal sonography is a useful supplement to clinical assessment in women who experience a spontaneous first-trimester abortion. If this modality is used to assess the uterine cavity, the cervical status can be ignored. Use of transvaginal sonography should reduce unnecessary general anesthesia and uterine curettage.</p>	<p>Poor</p>
2	<p>Chung TK, Cheung LP, Sahota DS, Haines CJ, Chang AM (1998)</p> <p>Evaluation of the accuracy of transvaginal sonography for the assessment of retained products of conception after spontaneous abortion.</p> <p><i>Gynecol Obstet Invest</i>,45(3), pp 190-3</p>	<p>N=100</p>	<p>TVS assessments were correlated with findings at subsequent evacuation of retained products of conception (ERPC). There was a strong correlation between the weight of the surgical specimen at ERPC with both the sagittal (<math>r = 0.76</math>; <math>p &lt; 0.05</math>) and transverse (<math>r = 0.73</math>; <math>p &lt; 0.05</math>) plane area measurements of the uterine cavity. Combining the 2 sonographic measurements increased the correlation to <math>r = 0.81</math> (<math>p &lt; 0.05</math>). Fifteen of 25 subjects who had been categorised to have an 'empty' uterus had less than 5 g of tissue removed and the other 10 subjects less than 10 g of tissue. In 20 of these 25 cases, the surgeon described the amount of curettings as 'small or non-significant'. TVS can accurately identify those women who do not have a significant amount of residual uterine tissue following spontaneous abortion.</p>	<p>Poor</p>

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
3	Dillon EH, Case CQ, Ramos IM, Holland CK, Taylor KJ (1993)  Endovaginal US and Doppler findings after 1 <sup>st</sup> trimester abortion  <i>Radiology</i> , 186(1), Jan, pp 87-91	Prospective study  N=19 patients	13 of the 22 (59%) examination revealed different amounts of intrauterine material of varying echogenicity. 7 of the 22 (32%) showed a thick endometrium stripe & only 2 showed a normal stripe. Color flow Doppler demonstrated typical peritrophoblastic flow in 4 of 8 patients on the 2 <sup>nd</sup> & 3 <sup>rd</sup> days after abortions were performed. After the 3 <sup>rd</sup> day flow was observed only in 2 of 11 patients and intrauterine material was also seen. Intrauterine material and low impedance flows are frequently observed after an abortion and do not indicate clinically important retained products of conception . Ultrasound and color Doppler could be used to reduce unnecessary ERPOC in patients suspected with spontaneous abortions	Fair
4	Haines CJ, Chung T, Leung DY (1991)  Trnasvaginal ultrasonography and the conservative management of spontaneous abortion  <i>Gyneacol Obstet Invest</i> , 37(1), pp 14-7	Prospective study  N=50 patients	32 patients were chosen for non-operative management based upon their uterine cavity measurements. In all cases bleeding stopped within 2 weeks. Ultrasound can be used as a tool to predict the cases where conservative or non-operative management can be employed in cases of spontaneous abortions	Fair

**EVIDENCE TABLE – USE OF TRANVAGINAL ULTRASOUND IN ANTE NATAL CARE – PRETERM DELIVERY**

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
1	<p>Crane JM, Van den Hof M, Armson BA, Liston R.(1997)</p> <p>Transvaginal ultrasound in the prediction of preterm delivery: singleton and twin gestations.</p> <p><i>Obstet Gynecol</i>, 90(3), Sep, pp 357-63</p>	<p>Clinical Trial</p> <p>N=One hundred sixty-two subjects were recruited (136 singletons and 26 twin pregnancies),</p>	<p>The best cutoff points were 30 mm for endocervical length at ultrasound, 50% for effacement, and 1.5 cm for dilatation. Of these, the best predictor was endocervical length, which was a better predictor in singleton than in twin pregnancies. Of the potential predictors, including endocervical length, funneling, dilatation, and effacement, only endocervical length was an independent predictor of preterm delivery at less than 34 weeks' gestation for both singletons and twins by multiple logistic regression. When analyzed for delivery at less than 37 weeks' gestation, this relation held true for singletons but not twins. Endocervical length less than 30 mm had a sensitivity of 81% and 75%, specificity of 65% and 30%, positive predictive value of 46% and 63%, and negative predictive value of 90% and 43% for singleton and twin pregnancies, respectively, in predicting spontaneous birth at less than 37 weeks' gestation. Between 23 and 33 weeks' gestation, transvaginal ultrasound assessment of endocervical length is superior to funneling and digital examination in predicting preterm delivery in patients who present with suspected preterm labor, and is a better predictor in singletons than in twins.</p>	<p>Poor</p>
2	<p>Tongsong T, Kamprapanth P, Srisomboon J, Wanapirak C, Piyamongkol W, Sirichotiyakul S. (1995)</p> <p>Single transvaginal sonographic measurement of cervical length early in the third trimester as a predictor of preterm delivery.</p> <p><i>Obstet Gynecol</i>,86(2), Aug, pp 184-7</p>	<p>N= 771 women attending the antenatal clinic at the Maharaj Nakorn Chiang Mai Hospital</p> <p>F/up: January 1, 1990, and November 30, 1993, with singleton gestations, cervical competence, accurate dates of last menstrual period, and gestational ages between 28-30 weeks,</p>	<p>Ninety-one (12.5%) women ended with preterm births and the remaining 639 (87.5%) delivered at term. The mean cervical lengths of the term and preterm groups were statistically significantly different at 37 +/- 5 and 34 +/- 6 mm, respectively (P &lt; .001). The appropriate cutoff point based on the receiver operating characteristic curve (35 mm) was associated with a significantly increased likelihood of preterm delivery (20 versus 7%) and was detected in two-thirds of preterm births. This cutoff point gave a sensitivity and specificity of 65.9 +/- 5.1% and 62.4 +/- 5.2%, respectively. A single transvaginal sonographic measurement of cervical length at 28-30 gestational weeks can be used to predict the risk of preterm delivery, using a cutoff point of 35 mm, but its cost-effectiveness should be assessed further.</p>	<p>Poor</p>



No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
3	<p>Kassanos D, Salamalekis E, Vitoratos N, Panayotopoulos N, Loghis C, Creatsas C. (2001)</p> <p>The value of transvaginal ultrasonography in diagnosis and management of cervical incompetence.</p> <p><i>Clin Exp Obstet Gynecol</i>, 28(4), pp266-8</p>	<p>Randomised Controlled Trial</p> <p>N= 55 patient</p> <ul style="list-style-type: none"> <li>- group I (n=27) elective cerclage was applied during the 14th week.</li> <li>- group II (n=28) were subjected to serial weekly evaluations of the cervix by transvaginal ultrasonograms</li> </ul>	<p>In group I, labor started before the 33rd week in two cases (7.4%), between 33 and 37 weeks in nine (33.3%) and after the 37th week in 16 cases (59.2%). Out of the 18 patients in group II who had cervical cerclage after ultrasonographic evaluation, four (22.2%) delivered before the 33rd week, three (16.6%) between 33 and 37 weeks and 11 (61.1%) after the 37th week. No statistical difference was noted between the two groups referring to pregnancy outcome (<math>p &lt; 0.1</math>). We concluded that ultrasound-guided management despite cervical shortening, does not result in unfavorable pregnancy outcome. A significant number of patients can avoid the operation.</p>	Good to Fair
4	<p>O'Brien JM, Hill AL, Barton JR (2002)</p> <p>Funneling to the stitch: an informative ultrasonographic finding after cervical cerclage.</p> <p><i>Ultrasound Obstet Gynecol</i>, 20(3), Sep, pp 252-5</p>	Prospective	<p>Cervical cerclage resulted in a significant increase in cervical length from 2.1 +/- 1.2 cm to 2.9 +/- 0.8 cm after the procedure,; however, this measure was not correlated with gestational age at delivery. Funneling to the level of the cerclage was associated with an earlier gestational age at delivery 31.3 +/- 5.6 weeks vs. 36.8 +/- 2.8 weeks for those cases without this finding.. A statistically significant association between funneling to the cerclage and preterm delivery was identified irrespective of the indication (prophylactic or emergency) for the procedure. When descent of the membranes to the level of the cerclage was noted, it occurred by 28 weeks' gestation in all patients studied .The incidence of premature rupture of the membranes was also significantly greater postcerclage in women with descent of the membranes to the cerclage (52%) compared to those without this finding (9%). CONCLUSIONS: Funneling to the cerclage is significantly associated with earlier preterm delivery in patients who have undergone cervical cerclage. Serial sonography up to 28 weeks' gestation is useful in identifying patients at higher risk for premature rupture of the membranes and preterm delivery.</p>	Poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
5	<p>Odibo AO, Talucci M, Berghella V. (2002)</p> <p>Prediction of preterm premature rupture of membranes by transvaginal ultrasound features and risk factors in a high-risk population.</p> <p><i>Ultrasound Obstet Gynecol</i> 20(3), Sep, pp 245-51</p>	<p>Prospectively</p> <p>N= 321 patients with singleton gestations at high-risk for preterm delivery were screened with transvaginal ultrasound between 14 and 24 weeks</p>	<p>The sensitivity, specificity and positive and negative predictive values of Cervical Length (CL) &lt; 25 mm for preterm premature rupture of membrane (PPROM) at &lt; 35 weeks were 73%, 69%, 25% and 95%, respectively; for preterm labor (PTL) at &lt; 35 weeks they were 58%, 66%, 15% and 94%; for PPROM at &lt; 32 weeks they were 85%, 68%, 20%, and 98%; for PTL at &lt; 32 weeks they were 70%, 66%, 12% and 97%. CONCLUSION: There are differences in both transvaginal ultrasound findings and risk factors that predict PPROM or PTL. Of the pathways leading to PTD, CL was a more significant predictor of PPROM compared with PTL, while socio demographic factors were more predictive of PTL.</p>	Fair
6	<p>Gire C, Faggianelli P, Nicaise C, Shojai R, Fiori A, Chau C, Boubli L, D'Ercole C (2002)</p> <p>Ultrasonographic evaluation of cervical length in pregnancies complicated by preterm premature rupture of membranes.</p> <p><i>Ultrasound Obstet Gynecol</i> , 19(6), Jun, pp 565-9 .</p>	<p>Prospective Study</p> <p>N= 101 singleton pregnancies with PPROM</p> <p>F/up = 3 years</p>	<p>A cervical length of less than 20 mm was associated with a significant risk of early delivery (mean latency period was 59.44 +/- 159.93 h vs. 240.94 +/- 364.67; P &lt; 0.05). There was no relation between cervical length and occurrence of chorioamnionitis or neonatal sepsis. CONCLUSIONS: These data suggest that the use of transvaginal ultrasonography for cervical length measurement during preterm premature rupture of membranes may predict an early delivery but cannot anticipate the risk of chorioamnionitis or neonatal sepsis.</p>	Fair

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
7	<p>Benham BN, Balducci J, Atlas RO, Rust OA. (2002)</p> <p>Risk factors for preterm delivery in patients demonstrating sonographic evidence of premature dilation of the internal os, prolapse of the membranes in the endocervical canal and shortening of the distal cervical segment by second trimester ultrasound.</p> <p><i>Aust N Z J Obstet Gynaecol</i>, 42(1), feb, pp46-50</p>	<p>Retrospective chart review</p> <p>N=37 patients</p>	<p>The sonographic findings of premature dilatation of the internal os, prolapse of the membranes into the endocervical canal and shortening of the distal cervix are associated with a high rate of delivery &lt; 34 weeks (51%) and neonatal death (27%).</p>	Poor
8	<p>Hincz P, Wilczynski J, Kozarzewski M, Szaflik K. (2001)</p> <p>[Transvaginal sonography in prediction of preterm delivery in patients presenting with signs and symptoms of preterm labor]</p> <p><i>Ginekol Pol</i>, 72(10), Oct, pp 778-82</p>	<p>Prospective</p> <p>N= 82 patients</p>	<p>The shortening of the functional canal length (&lt; or = 20 mm) is predictive of impending preterm delivery and the functional canal length &gt; 31 mm is the indicator of the absence of labor. 2. Cervical sonography can be a valuable adjunct to the clinical assessment of patients with signs and symptoms of preterm labor.</p>	Fair

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
9	<p>Odibo AO, Berghella V, Reddy U, Tolosa JE, Wapner RJ. (2001)</p> <p>Does transvaginal ultrasound of the cervix predict preterm premature rupture of membranes in a high-risk population?</p> <p><i>Ultrasound Obstet Gynecol</i> 18(3), Sep, pp 223-7</p>	<p>Retrospective</p> <p>N= 69 patients</p>	<p>Of 69 patients identified to have a cervical length &lt; 25 mm, 27 (39%) had PPROM, and 42 (61%) did not. Mean +/- standard deviation (SD) cervical length was 12.7 +/- 8.7 mm and 17.0 +/- 7.6 mm in the two groups, respectively (P = 0.04). Mean +/- SD cervical funneling was 57.4 +/- 31.4% and 40.0 +/- 28.1%, respectively (P = 0.01). The characteristics most predictive of PPROM were: cervical length of &lt; 10 mm (sensitivity, specificity, positive and negative predictive values of 33, 90, 69, and 68%, respectively; odds ratio, 4.8; 95% confidence interval, 1.3-17.5) and cervical funneling &gt; 75% (sensitivity, specificity, positive and negative predictive values of 33, 93, 75 and 68%, respectively; odds ratio, 6.5; 95% confidence interval, 1.6-26.9). Stepwise logistic regression revealed cervical length to be a significant predictor of PPROM (odds ratio, 4.0; 95% confidence interval, 1.1-14.2). CONCLUSION: In patients at high risk for preterm delivery because of obstetric history and transvaginal sonographic cervical length &lt; 25 mm, a cervical length &lt; 10 mm and cervical funneling &gt; 75% were most predictive of PPROM. PPROM was the major contributor to preterm delivery in these patients.</p>	Poor
10	<p>Guzman ER, Walters C, Ananth CV, O'Reilly-Green C, Benito CW, Palermo A, Vintzileos AM. (2001)</p> <p>A comparison of sonographic cervical parameters in predicting spontaneous preterm birth in high-risk singleton gestations.</p> <p><i>Ultrasound Obstet Gynecol</i> 18(3), Sep, pp 204-10</p>	<p>Prospective cohort</p> <p>N= 469 high-risk gestations</p>	<p>In high-risk singleton gestations a cervical length of &lt; or = 2.5 cm was equal to other sonographic cervical parameters in its ability to predict spontaneous preterm birth and was better for the prediction of earlier forms of prematurity (at &lt; 28 and &lt; 30 weeks) than later forms (at &lt; 32 and &lt; 34 weeks). The optimal cervical lengths and their performance for predicting prematurity may be influenced by obstetric risk factors</p>	Poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
11	<p>Yang JH, Kuhlman K, Daly S, Berghella V. (2000)</p> <p>Prediction of preterm birth by second trimester cervical sonography in twin pregnancies.</p> <p><i>Ultrasound Obstet Gynecol</i>,15(4) Apr, pp 288-91</p>	<p>Prospective</p> <p>N= 65 twin pregnancies</p>	<p>Sixty-five twin pregnancies were analyzed, of which 23% (15/65) delivered preterm. Cervical ultrasound examination was performed by 22 weeks' gestation in 75% and by 24 weeks' gestation in 91% of women. Cervical length <math>\leq</math> 25 mm and <math>\leq</math> 30 mm was associated with sensitivities of 27% and 53%, respectively, and with 67% and 62% rates of PTD, respectively. A cervical length <math>&gt;</math> 35 mm was associated with only a 4% rate of Preterm delivery (PTD). Of 10 women (15%) with any cervical funneling, 70% delivered preterm, all under 32 weeks' gestation. By logistic regression analysis, both short cervix <math>\leq</math> 30 mm and any funneling were strongly predictive of PTD.</p> <p>CONCLUSIONS: Both cervical length <math>\leq</math> 30 mm and cervical funneling in twin pregnancies under 26 weeks' gestation are independently and strongly associated with high risk for preterm birth. A long cervix, of length <math>&gt;</math> 35 mm, is associated with very low risk (4%) for preterm birth.</p>	Poor
12	<p>Hassan SS, Romero R, Berry SM, Dang K, Blackwell SC, Treadwell MC, Wolfe HM (2000)</p> <p>Patients with an ultrasonographic cervical length <math>\leq</math> 15 mm have nearly a 50% risk of early spontaneous preterm delivery.</p> <p><i>Am J Obstet Gynecol</i>, 182(6), Jun,pp 1458-67</p>	<p>Retrospective</p> <p>N=6877 patients</p>	<p>For early preterm delivery a cervical length of <math>\leq</math> 15 mm had a positive predictive value of 47.6%, a negative predictive value of 96.7%, a sensitivity of 8.2%, and a specificity of 99.7%.</p> <p>CONCLUSIONS: A short cervix seen on a second-trimester sonogram was a powerful predictor of early spontaneous preterm delivery (<math>\leq</math> 32 weeks' gestation). Nearly 50% of patients with a cervical length <math>\leq</math> 15 mm had an early spontaneous preterm delivery, which suggests that clinical trials of interventions (eg, cerclage) in this population are urgently needed</p>	Fair

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
13	Vendittelli F, Volumenie J. (2000)  Transvaginal ultrasonography examination of the uterine cervix in hospitalized women undergoing preterm labour.  <i>Eur J Obstet Gynecol Reprod Biol</i> , 90(1), May, pp 3-11	Meta- analysis	The best cut-off for cervical length varies from 18 to 30 mm. The sensitivity for predicting preterm birth ranges from 68 to 100%, and the specificity ranges from 30 to 78%. Cervical wedging has a sensitivity varying from 23 to 100%, and a specificity ranging from 54 to 90%. CONCLUSION: Ultrasonography of the cervix is an interesting technology as it is cheap and easy to use. However this technique remains to be assessed before implementing it in daily clinical practice. Finally, studies incorporating transvaginal ultrasonography into interventional trials are needed to determine the efficacy of measuring cervical length in the prevention of preterm birth.	Good
14	Leitich H, Brunbauer M, Kaider A, Egarter C, Husslein P. (1999)  Cervical length and dilatation of the internal cervical os detected by vaginal ultrasonography as markers for preterm delivery: A systematic review.  <i>Am J Obstet Gynecol</i> , 181(6), Dec, pp1465-72	Review N=3 subgroups of studies including patients with preterm labor or low-risk, symptom-free patients with early (20-24 weeks) or late (27-32 weeks) ultrasonographic examination, optimal cutoff values for cervical lengths ranged between 18 and 30, 25 and 35, or 25 and 39 mm.	At these cutoff values, sensitivity rates were between 68% and 100%, 33% and 54%, or 63% and 76%, and specificity rates were between 44% and 79%, 73% and 91%, or 59% and 69%, respectively. Sensitivity rates for dilatation of the internal cervical os were 70% to 100%, 16% to 25%, or 33%, and specificity rates were 54% to 75%, 95% to 99%, or 92%, respectively. CONCLUSION: In patients with symptoms of preterm labor, endovaginal cervical ultrasonography appears to be an effective predictor of preterm delivery.	Good
15	Taipale P, Hiilesmaa V. (1998)  Sonographic measurement of uterine cervix at 18-22 weeks' gestation and the risk of preterm delivery.  <i>Obstet Gynecol</i> ,;92(6), Dec, pp 902-7	Clinical trial  N= 3694	Transvaginal ultrasonography performed as an addition to routine transabdominal ultrasonography at 18 to 22 weeks helps to identify many patients at significant risk for prematurity; however, low sensitivity and low positive predictive value limit its usefulness in screening low-risk obstetric populations.	Fair

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
16	Onderoglu LS. (1997)  Digital examination and transperineal ultrasonographic measurement of cervicallength to assess risk of preterm delivery.  <i>Int J Gynaecol Obstet</i> , 59(3), Dec, pp 223-8	N= 32 patients	Receiver operative characteristic curve analysis revealed that cervical canal length < or = 28 mm measured by transperineal sonography had the highest diagnostic performance with a sensitivity of 78.1% and specificity of 82.7%. The sensitivity and specificity of digital examination were found to be 65.5%, 72.4% and 62.5%, 68.9% for the cervical dilatation > 2 cm and effacement > or = 40%, respectively. CONCLUSION: Transperineal ultrasonographic examination for cervical length is more accurate than digital examination for prediction of preterm delivery in patients presenting with preterm labor. Transperineal ultrasonographic examination of cervix is invaluable in the prediction of preterm delivery where transvaginal transducers are lacking or skilled staff are unavailable.	Poor
17	Berghella V, Daly SF, Tolosa JE, DiVito MM, Chalmers R, Garg N, Bhullar A, Wapner RJ. (1999)  Prediction of preterm delivery with transvaginal ultrasonography of the cervix in patients with high-risk pregnancies: does cerclage prevent prematurity?  <i>Am J Obstet Gynecol</i> , 181(4), Oct, pp 809-15	Prospective  N= 168 women	CONCLUSIONS: Transvaginal ultrasonography of the cervix between 14 and 24 weeks' gestation is a good predictor of preterm delivery in high-risk pregnancies. Cerclage may not prevent preterm delivery in patients identified to be at high risk for this outcome by transvaginal ultrasonography.	Poor

## EVIDENCE TABLE – USE OF ULTRASOUND IN GYAENECOLOGY

### ET- ECTOPIC PREGNANCY

No	Author, Title , Journal	Study design, Sample size, follow up	Outcomes & Characteristic	Grade & Comment
1	<p>Luo GX, Wang SS, Zhang H, Liu SL. (2002)</p> <p>Transvaginal sonography and transabdominal sonography in the diagnosis of ectopic pregnancy in the fallopian tubal: a comparative study in 38 cases.</p> <p><i>Di Yi Jun Yi Da Xue Xue Bao</i>,22(11), pp1046-50</p>	<p>Comparative Study</p> <p>N= Thirty-eight patients with ectopic pregnancy in the fallopian tube were examined by TAS with moderately filled bladder, followed by reexamination with TVS with the bladder emptied. The manifestations in the 2 imaging examinations were compared</p>	<p>Trans Vaginal Sonography showed masses in 38, gestations in 23, heart beat in 10, pelvis fluid in 16 and circular blood signal in 25 cases respectively, while Trans Abdominal Sonography identified masses in 30, gestations in 13, heart beat in 5, pelvis fluid in 14 and circular blood flow signal in 13 cases. CONCLUSION: TVS may offer an earlier, clearer and more exact diagnosis of ectopic pragnacy in the fallopian tube than TAS is capable of.</p>	Poor
2	<p>Chechia A, Koubaa A, Terras K, Bahri N, Makhlouf T.(2000)</p> <p>[Ultrasonographic diagnosis of ectopic pregnancies. A report of 109 cases]</p> <p><i>Tunis Med</i>,78(10), Oct, pp 589-94</p>	<p>Retrospective study</p> <p>N=109 patients</p> <p>F/up: January 1997 and December 1998.</p>	<p>All patients had a transvaginal sonography. Of these, 15 had a transabdominal sonography. Ultrasonographic findings of the 109 ectopic pregnancies were an extrauterine gestational sac in 10 cases (9.17%), an adnexel mass clearly separated from uterus and ovary in 87 cases (79.81%), a pelvic fluid in 90 cases (82.56%) and pseudogestational sac in 6 cases. Ultrasonography established the diagnosis of ectopic pregnancy in 89% of cases. Serum B HCG level was needed for diagnosis in 12 cases (11%). CONCLUSION: Transvaginal sonography is the method of choice for the evaluation of women with a suspected ectopic pregnancy. However, serum B HCG levels are useful for diagnosis in 11% of cases</p>	Fair



No	Author, Title , Journal	Study design, Sample size, follow up	Outcomes & Characteristic	Grade & Comment
3	Durston WE, Carl ML, Guerra W, Eaton A, Ackerson LM. (2000)  Ultrasound availability in the evaluation of ectopic pregnancy in the ED: comparison of quality and cost-effectiveness with different approaches.  <i>Am J Emerg Med</i> ,18(4), Jul, pp408-17	Retrospectively  N= 120 cases of ectopic pregnancy  F/up: 6 years	The specificity of ED Sono in ruling in an IUP was 100% , but analysis of secondary quality indicators reflecting times from first ED visit to treatment in Epoch 3 raised the possibility that an adnexal mass or signs of tubal rupture may have been missed on some ED Sonos. We conclude that increased availability of ultrasonography leads to improved quality in the detection of ectopic pregnancy in the ED, but at the expense of a disproportionate increase in the number of ultrasound studies done per ectopic pregnancy detected. Our study suggests that the most cost-effective strategy is for emergency physicians to screen all patients with first trimester cramping and bleeding with ED Sonos, and to obtain MI Sonos at the time of the initial ED visit in all cases in which the ED Sono is indeterminate or shows no IUP.	Fair
4	Wong TW, Lau CC, Yeung A, Lo L, Tai CM. (1998)  Efficacy of transabdominal ultrasound examination in the diagnosis of early pregnancy complications in an emergency department.  <i>J Accid Emerg Med</i> , 15(3), May, pp155-8	Clinical trial  N=151 cases  F/up: four month	For evaluating the presence or absence of IUP, sensitivity of the initial scan was 82% (95% confidence interval 76% to 88%) and specificity 92% (88% to 96%).  The diagnoses made in the emergency department were thought to be compatible with the final assessments by gynaecologist in 72% (65% to 79%). Using either no definite IUP or other findings as a positive screening test for ectopic pregnancy, the sensitivity, specificity, positive predictive value, and negative predictive value were 80%, 78%, 12% and 99% respectively. CONCLUSIONS: Transabdominal ultrasound performed in the emergency department is useful in screening for early pregnancy complications. Ectopic pregnancy should be suspected when no IUP is found on preliminary scanning	Poor
5	Goes E, Breucq C, Osteaux M.(1998)  Ultrasound studies in ectopic pregnancies.  <i>J Belge Radiol</i> , 81(1), feb, pp14-6	Review	Transvaginal ultrasound has proven to be an essential tool in the early diagnosis of ectopic pregnancy. Colour Doppler capacities further enhance the diagnostic sensitivity of transvaginal ultrasound for the early recognition of abnormal and normal intrauterine pregnancy, and small extrauterine masses. The aim of this paper is to provide an overview of the major sonographic signs and pitfalls in the ultrasound diagnosis of ectopic pregnancy.	Poor

No	Author, Title , Journal	Study design, Sample size, follow up	Outcomes & Characteristic	Grade & Comment
6	Dart R, Howard K. (1998)  Subclassification of indeterminate pelvic ultrasonograms: stratifying the risk of ectopic pregnancy.  <i>Acad Emerg Med</i> ,5(4), Apr, pp313-9	Retrospective review  N=248  F/up:August 1991 to December 1994	Patients with an empty uterus [25/94 = 27% ] had the highest frequency of ectopic pregnancy. Patients with nonspecific intrauterine fluid collections [4/30 = 13% ] had the next highest frequency of ectopic pregnancy. Patients with intrauterine echogenic debris [2/39 = 5% ], abnormal sacs [1/36 = 3% ], or normal-appearing sacs [0/29 = 0% ] had low frequencies of ectopic pregnancy. CONCLUSION: Subclassification of indeterminate ultrasound readings identifies patients at high, intermediate, or low risk for ectopic pregnancy and should improve the diagnostic accuracy of ultrasonography in patients at risk for ectopic pregnancy.	Poor
7	Shalev E, Yarom I, Bustan M, Weiner E, Ben-Shlomo I. (1998)  Transvaginal sonography as the ultimate diagnostic tool for the management of ectopic pregnancy: experience with 840 cases.  <i>Fertil Steril</i> ,69(1), Jan, pp 62-5	Prospective  N= Eight hundred forty women  F/up: January 1988 through December 1995.	Overall, 380 patients were found to have EP. Of these, 331 were identified positively by transvaginal sonography and 49 were not. In 27 of 358 laparoscopies, no EP was found. The sensitivity of transvaginal sonography for the prediction of EP was 87% and the specificity was 94%. The positive and negative predictive values were 92.5% and 90%, respectively.	Poor
8	Durham B, Lane B, Burbridge L, Balasubramaniam S.(1997)  Pelvic ultrasound performed by emergency physicians for the detection of ectopic pregnancy in complicated first-trimester pregnancies.  <i>Ann Emerg Med</i> ,29(3), Mar, pp 338-47	N=125	ED ultrasound accurately identified 87 pregnancies with intrauterine embryonic structures, including 5 patients with fetal demise Diagnosis of pregnancy location in these 87 patients effectively ruled out EP, with a negative predictive value of 100%. The sensitivity and specificity of ED ultrasound in the detection of EP were 90% and 88%, respectively. CONCLUSION: Pelvic ultrasonography performed by emergency physicians can be used to rule out EP and make an accurate diagnosis in most patients with complicated first-trimester pregnancies during the initial ED visit. The remaining patients at risk can be identified and a diagnosis made by means of follow-up ultrasound and serial hCG determinations.	Poor

No	Author, Title , Journal	Study design, Sample size, follow up	Outcomes & Characteristic	Grade & Comment
9	<p>Chew S, Anandakumar C, Vanaja K, Wong YC, Chia D, Ratnam SS. (1996)</p> <p>The role of transvaginal ultrasonography and colour Doppler imaging in the detection of ectopic pregnancy.</p> <p><i>J Obstet Gynaecol Res</i>,22(5), Oct, pp 455-60</p>	N=71 patients	<p>The use of transvaginal B mode imaging alone in the diagnosis of ectopic pregnancy achieved a sensitivity of 98% and a positive predictive value of 86%. The mean gestational age at time of diagnosis was 6 weeks 5 days (range 4 weeks to 13 weeks 2 days). The use of transvaginal colour flow imaging did not increase detection rates of ectopic pregnancy. The mean RI values for patients with or without ectopic pregnancy were almost identical. CONCLUSION: Colour Doppler imaging failed to improve on the results of transvaginal B mode sonography in the detection of ectopic pregnancy.</p>	Poor
10	<p>Turan C, Ugur M, Dogan M, Ekici E, Vicdan K, Gokmen O.(1996)</p> <p>Transvaginal sonographic findings of chronic ectopic pregnancy.</p> <p><i>Eur J Obstet Gynecol Reprod Biol</i>,67(2), Aug, pp 115-9</p>	<p>Retrospective</p> <p>N=55 cases</p>	<p>chronic ectopic pregnancy is not a rare clinical entity and should be considered in differential diagnosis among patients presenting with an adnexal mass and an overt clinical picture. Transvaginal sonography is sensitive in diagnosing chronic ectopic pregnancy, but not specific. The combined use of transvaginal ultrasonography and beta-hCG assay increases diagnostic accuracy. However, it should be kept in mind that a negative beta-hCG value does not rule out chronic ectopic pregnancy.</p>	Poor

No	Author, Title , Journal	Study design, Sample size, follow up	Outcomes & Characteristic	Grade & Comment
11	<p>Atri M, Leduc C, Gillett P, Bret PM, Reinhold C, Kintzen G, Aldis AE, Thibodeau M. (1996)</p> <p>Role of endovaginal sonography in the diagnosis and management of ectopic pregnancy.</p> <p><i>Radiographics</i>, 16(4), Jul, pp 755-74; discussion 775</p>	Review	<p>The most common endovaginal sonographic finding of EP (89%-100% of cases) is an extraovarian, round or elongated, solid tubal mass. A tubal ring (an extrauterine saclike structure) is the second most common finding (40%-68% of cases). Pelvic fluid may be present, but it is a nonspecific finding. An EP may have a pseudosac, which can be distinguished sonographically from the true gestational sac of an intrauterine pregnancy. Color Doppler techniques can complement endovaginal sonographic findings, but they should be performed only after a thorough real-time evaluation of the adnexal region. Current therapeutic options for EP include expectant management (ie, close follow-up), medical treatment (usually injections of methotrexate), and surgery. Accurate diagnosis with endovaginal sonography is the prerequisite to nonsurgical management, since surgery is the logical treatment if laparoscopy is used for diagnosis.</p>	Fair
12	<p>Hopp H, Schaar P, Entezami M, Ebert A, Hundertmark S, Vollert W, Weitzel H. (1995)</p> <p>[Diagnostic reliability of vaginal ultrasound in ectopic pregnancy]</p> <p><i>Geburtshilfe Frauenheilkd</i>, 55(12),Dec, pp 666-70in</p>	N=184 patients	<p>In 103 cases suspicion of EP was confirmed, in 81 cases it was ruled out. All cases were evaluated by laparoscopy, D&amp;C, serial HCG determinations or sonographic follow-up in case of an intrauterine pregnancy. Sensitivity of TVS in the diagnosis of EP was 96%, specificity 88%, the positive predictive value was 89%, the negative predictive value was 95%. Four cases with a false negative result at TVS were very early in pregnancy and were subjected to laparoscopy because of persistent high HCG values without demonstration of an intrauterine pregnancy. Five cases of sonographically confirmed ectopic pregnancies were missed by the first laparoscopy. These cases required intervention because of clinical symptoms and had low levels of HCG. TVS has a high diagnostic accuracy in the diagnosis of ectopic pregnancy.</p>	Poor

No	Author, Title , Journal	Study design, Sample size, follow up	Outcomes & Characteristic	Grade & Comment
13	<p>Mateer JR, Aiman EJ, Brown MH, Olson DW. (1995)</p> <p>Ultrasonographic examination by emergency physicians of patients at risk for ectopic pregnancy.</p> <p><i>Acad Emerg Med</i>,2(10), Oct, pp 867-73</p>	<p>Prospective study,</p> <p>N=pregnant patients &gt; or = 18 years old and at risk for ectopic pregnancy were assessed</p>	<p>Emergency physician ultrasonographic diagnoses included: definite IUP, 87/148 (59%); probable abnormal IUP, 17/148 (11%); definite ectopic pregnancy, 3/148 (2%); and no definite IUP, 41/148 (28%). The gynecologist agreed with 93% of the initial interpretations. Twelve of 16 patients who had the final diagnosis of ectopic pregnancy were admitted from the ED with this diagnosis. The ultrasonographic diagnosis of the other four was no definite IUP, and no mass or free fluid. For the latter four patients, the presenting serum beta hCG level was &lt; 2,000 mIU/mL (First International Reference Preparation). They were diagnosed as having ectopic pregnancy after serial outpatient EVS and beta hCG measurements.</p> <p>CONCLUSIONS: The application of EVS to emergency practice appears promising. Emergency physicians trained in its use and who apply this diagnostic tool in conjunction with a defined protocol can stratify the risk of patients who have the potential for ectopic pregnancy.</p>	Poor
14	<p>Sadek AL, Schiotz HA (1995)</p> <p>Transvaginal sonography in the management of ectopic pregnancy.</p> <p><i>Acta Obstet Gynecol Scand</i>,74(4), Apr, pp 293-6</p>	<p>Clinical trial</p> <p>N= 57</p> <p>F/up: 3 Years</p>	<p>The diagnostic sensitivity and specificity of vaginal sonography for ectopic pregnancy was 96.2% and 99.4%, respectively, for the finding of free pelvic fluid, and 81.1% and 99.6% for a tubal mass. All patients with ectopic pregnancy were correctly selected for laparoscopic management. Transvaginal sonography is a valuable tool in the early diagnosis of ectopic pregnancy.</p>	

No	Author, Title , Journal	Study design, Sample size, follow up	Outcomes & Characteristic	Grade & Comment
15	<p>Achiron R, Goldenberg M, Lipitz S, Mashiach S, Oelsner G (1994)</p> <p>Transvaginal Doppler sonography for detecting ectopic pregnancy: is it really necessary.</p> <p><i>Isr J Med Sci</i>,30(11), Nov, pp 820-5.</p>	<p>Clinical Trial</p> <p>N= 76 stable patient with Serum BhCG &gt;1000 mIU/ml</p>	<p>Ectopic pregnancies were verified in 42 patients (60%), intrauterine pregnancies (normal and abnormal) in 19 (27%), and possible complete abortions, either intrauterine or extrauterine, in 9 patients (13%). Based on 2-D imaging alone, the appearance of an adnexal mass separated from the ovaries, and a lack of clear intrauterine gestational sac indicated ectopic pregnancy with a sensitivity of 95%. Intrauterine sac-like structures and absence of adnexal masses excluded ectopic pregnancies with a specificity of 89%. High velocity systolic flow, and low impedance diastolic flow which characterizes trophoblastic tissue when detected outside the uterus, had a sensitivity of 48%, while the presence of trophoblastic signals in the uterus or their absence outside the uterus excluded ectopic pregnancies with a specificity of 89%. The positive predictive values were 91% for Doppler and 95% for 2-D imaging, while the negative predictive values were 89% for imaging alone and 44% for Doppler. These data suggest that transvaginal Doppler ultrasound has significant lower sensitivity and negative predictive value and does not provide more useful diagnostic information than 2-D imaging alone for stable patients with suspected ectopic pregnancies.</p>	Poor
16	<p>Dallas J, West W, Mullings A. (1994)</p> <p>Evaluation of transabdominal ultrasonography for ectopic pregnancy.</p> <p><i>West Indian Med J</i> , 43(1), Mar, pp 20-2</p>	<p>Case study</p> <p>N= 66 patients</p>	<p>23 women who had the diagnosis confirmed at laparotomy, 16 (69.6%) were correctly identified on ultrasound, 4 were reported as unlikely ectopic pregnancies and 3 were undetermined. Two patients with false negative ultrasound reports had positive findings on ultrasound, but the findings were misinterpreted. Correct identification of these would have increased the true positive rate to 78.3% and decreased the false negative rate to 8.8%. There were 5 false positive reports due to ovarian cysts.</p>	

No	Author, Title , Journal	Study design, Sample size, follow up	Outcomes & Characteristic	Grade & Comment
17	<p>Braffman BH, Coleman BG, Ramchandani P, Arger PH, Nodine CF, Dinsmore BJ, Louie A, Betsch SE. (1994)</p> <p>Emergency department screening for ectopic pregnancy: a prospective US study.</p> <p><i>Radiology</i>,190(3), Mar, pp 797-802</p>	<p>Prospectively</p> <p>N= 1,427 consecutive patients with a serum level of the beta subunit of human chorionic gonadotropin of over 1,500 IU/L.</p>	<p>Sonograms were diagnostic in 1,158 patients and indeterminate in 269. When indeterminate studies were considered falsely negative, the diagnostic accuracy was 81%. Twenty-four percent of patients with indeterminate studies were subsequently proved to have ectopic pregnancy. In ectopic pregnancy (n = 103), the most common finding was a complex adnexal mass (specificity = 92% [P &lt; .001]). The sensitivity and specificity of screening sonography for ectopic pregnancy were 99% and 84%, respectively. CONCLUSION: Pelvic sonography is an effective screening test for ectopic pregnancy. Having a one in four chance of harboring an ectopic pregnancy, patients with indeterminate studies require close follow-up. The presence of a complex adnexal mass is a strong predictor of ectopic pregnancy.</p>	Fair
18	<p>Burry KA, Thurmond AS, Suby-Long TD, Patton PE, Rose PM, Jones MK, Choffel JK, Nelson DW. (1993)</p> <p>Transvaginal ultrasonographic findings in surgically verified ectopic pregnancy.</p> <p><i>Am J Obstet Gynecol</i>,168(6 Pt 1), jun, pp1796-800; discussion 1800-2</p>	<p>Retrospectively</p> <p>N=Eighty-nine patients admitted with an ectopic pregnancy</p> <p>F/up: September 1987 through September 1989</p>	<p>Ultrasonography revealed adnexal masses in 54 patients (78%). Thirty-six masses had an appearance consistent with an adnexal ring. Twenty-four adnexal rings demonstrated a thin sonolucent area surrounding the ring, a "halo sign" (67%). A control group of 116 intrauterine pregnancies were evaluated by ultrasonography. Forty-one women had adnexal cysts. Twenty-seven of these had an adnexal ring; only two of these had halos. CONCLUSION: The halo sign is presumptive evidence of a living ectopic pregnancy and, when identified, may allow earlier diagnosis and intervention.</p>	Fair

No	Author, Title , Journal	Study design, Sample size, follow up	Outcomes & Characteristic	Grade & Comment
19	Russell SA, Filly RA, Damato N. (1993)  Sonographic diagnosis of ectopic pregnancy with endovaginal probes: what really has changed  <i>J Ultrasound Med</i> ,12(3), Mar, pp 145-51	Retrospective  N=123 at risk patients F/up: 2 years	Of these 123 women, 19 (15.4%) had a surgically proved ectopic pregnancy, only three (15.8%) of which were visualized directly at sonography. A confident diagnosis of an intrauterine pregnancy (IUP) was made at the initial scan in 74%, which contrasts with 58% diagnosed at the first transabdominal (TA) scan in an earlier study from this laboratory, thus confirming an improvement in diagnostic ability with EV transducers. This study has failed to confirm some findings of other workers, particularly that adnexal ring-like structures are visualized frequently in the presence of an ectopic pregnancy. No adnexal rings were observed in our 19 cases. The combination of an adnexal mass and free pelvic fluid was found to correlate best with the presence of an ectopic pregnancy. This study further emphasizes that a significant proportion (26.3%) of ectopic pregnancies have a normal EV sonogram at presentation. The group failing to demonstrate an IUP and showing no evidence of an adnexal mass or pelvic fluid (i.e., a normal pelvic sonogram) carried a 1:3 risk for the presence of an ectopic pregnancy, a result that is very similar to our data published before the introduction of EV technology. We conclude that, although it provides a significant improvement and refinement in the recognition of intrauterine pregnancies, EV scanning does not permit a confident diagnosis of ectopic pregnancy in many cases.	
20	Hernadi L, Torocsik M, Playerne Dorko A. (1992)  [The value of transvaginal sonography combined with qualitative human chorionic gonadotropin determination in suspected extrauterine pregnancy] <i>Orv Hetil</i> ,133(19), May, pp 1173-7	Review  N= 225 patients	In 144 patients a correct diagnosis was made during the first scan; 19 patients were rescanned for the final diagnosis. Ectopic pregnancy was successfully ruled out by transvaginal scanning in 115 patients by diagnosing an intrauterine pregnancy and 41 ectopic pregnancies were found, 33 by TVS and only 8 cases by transabdominal scanning. Two false- negative identification occurred. The sensitivity, the specificity, the positive and negative predictive value of diagnosing ectopic pregnancy by TVS were 94.3%, 100%, 98.3% and 100%, respectively. The number of unruptured tubal pregnancies in this series was 64.5%. These results show that transvaginal ultrasonography is a sensitive method for diagnosing or excluding ectopic pregnancy	Fair



No	Author, Title , Journal	Study design, Sample size, follow up	Outcomes & Characteristic	Grade & Comment
21	<p>Athey PA, Lamki N, Matyas MA, Watson AB Jr. (1991)</p> <p>Comparison of transvaginal and transabdominal ultrasonography in ectopic pregnancy.</p> <p><i>Can Assoc Radiol J</i>,42(5), Oct, pp 349-52</p>	<p>Retrospective Review</p> <p>N= 45 consecutive cases</p>	<p>TV ultrasonography was superior to TA ultrasonography in 22 cases (49%) and inferior in 3 (7%). In the remaining 20 cases (44%) the two methods yielded similar information. For cases in which TV ultrasonography was superior, this method provided clear evidence of ectopic pregnancy in 11 cases in which TA ultrasonography demonstrated nonspecific masses or normal adnexa; in the other 11 cases both methods led to the correct diagnosis, but TV ultrasonography provided additional useful information. The authors conclude that TV ultrasonography has a definite role in improving the diagnosis of ectopic pregnancy.</p>	Fair
22	<p>Bocciolone L, Vercellini P, Villa L, Rognoni MT, Dorta M, Fedele L. (1991)</p> <p>Early detection of ectopic pregnancy. Use of a sensitive urine pregnancy test and transvaginal ultrasonography.</p> <p><i>J Reprod Med</i>,36(7), Jul, pp 496-9</p>	<p>N= 116 women with subacute pelvic pain</p>	<p>The diagnosis of tubal pregnancy was confirmed with laparoscopy in 100 of the 103 women with positive sensitive urine pregnancy tests and no intrauterine gestational sac at transvaginal ultrasonography. Laparoscopy revealed a hemorrhagic corpus luteum in four of the eight subjects with negative monoclonal antibody pregnancy tests and no intrauterine gestational sac, an ovarian cyst in three and a normal pelvis in one. Of the five women with a positive pregnancy test and an intrauterine gestational sac, two had a hemorrhagic corpus luteum, two a normal pelvis and one a tubal pregnancy at laparoscopy. The sensitivity of a monoclonal antibody urine pregnancy test and transvaginal ultrasonography combined for the diagnosis of ectopic pregnancy was 99%, and the specificity was 80%, with positive and negative predictive values of 97% and 92%, respectively</p>	Poor
23	<p>Iloabachie GO, Mgbor S. (1991)</p> <p>The diagnosis of ectopic pregnancy by real-time ultrasonography.</p> <p><i>West Afr J Med</i>, 10(1), Jan – Mar, pp 361-70</p>	<p>N=102 doubtful ectopic pregnancies had ultrasonic evaluation after initial clinical work up.</p>	<p>52 (76.5%) patients out of 68 who had ectopic pregnancy were diagnosed at the first scan. There were 16 (23.5%) false negatives. Twenty-eight (82.4%) patients out of 34 patients who never had ectopic pregnancy were cleared at the first scan. There were 6 (17.6%) false positives who had laparotomy performed. Fetal pulsations were seen as early as 6 weeks in 11.8% of the ectopic pregnancies. This sign was considered diagnostic. Ultrasound was found promising in the confirmatory diagnosis of ectopic pregnancy especially when a strong suspicion was established by history clinical examination and pregnancy test.</p>	

No	Author, Title , Journal	Study design, Sample size, follow up	Outcomes & Characteristic	Grade & Comment
24	<p>Valenzano M, Anserini P, Remorgida V, Brasca A, Centonze A, Costantini S. (1991)</p> <p>Transabdominal and transvaginal ultrasonographic diagnosis of ectopic pregnancy: clinical implications.</p> <p><i>Gynecol Obstet Invest</i>,31(1), pp 8-11</p>	<p>N=35 patients attending an emergency room with a positive pregnancy test and suspected ectopic pregnancy underwent an ultrasonographic examination with both the transabdominal and the transvaginal techniques</p>	<p>Twenty-four out of 26 ectopic pregnancies were correctly diagnosed on admission, combining results of the two techniques, the sensitivity of the two techniques used separately being 88.4% (transvaginal) and 76.9% (transabdominal). In our unselected symptomatic patients, the transvaginal technique showed to be advantageous but not essential in the management of ectopic pregnancy. The surgical outcome of these patients suggested that a prompt diagnosis of ectopic pregnancy did not warrant a conservative treatment.</p>	Poor
25	<p>Gramith F, Sirr S, Hollerman J, Hawks L. (1991)</p> <p>Transvaginal versus transabdominal sonography in patients suspected of having ectopic pregnancy.</p> <p><i>Minn Med</i>,74(1), Jan, pp 27-31</p>	<p>Retrospectively studied</p> <p>N= 47 pregnant patients in whom both conventional transabdominal sonography (TAS) and transvaginal sonography (TVS) had been performed.</p>	<p>sonographic findings of early pregnancy are more likely to be seen transvaginally than transabdominally. In 23% of the patients, only TVS provided the findings for diagnosis of the location and status of the pregnancy. In another 22%, the information gathered through TVS allowed increased confidence in the diagnostic accuracy of the TAS findings by providing additional findings. Therefore, in 45% of the cases, TVS influenced clinical decision-making. In no case was TVS less informative than TAS. These results support the claim that TVS contributes to diagnostic accuracy in early pregnancy. TVS should usually be used in conjunction with, and not as a substitute for, TAS. TVS is best used when TAS is not conclusive, or when immediate confirmation of an intrauterine pregnancy is desired.</p>	Fair

No	Author, Title , Journal	Study design, Sample size, follow up	Outcomes & Characteristic	Grade & Comment
26	<p>Cacciatore B. (1990)</p> <p>Can the status of tubal pregnancy be predicted with transvaginal sonography? A prospective comparison of sonographic, surgical, and serum hCG findings.</p> <p><i>Radiology</i>, 177(2), Nov, pp 481-4</p>	<p>Prospectively</p> <p>N=120 women</p>	<p>The most common sonographic finding was a saclike adnexal ring, which was seen in 74 of the women (61.7%). This finding was strongly associated with functioning trophoblasts and with an intact fallopian tube. In 39 of the women (32.5%) an adnexal mass with a complex texture was found. Of these 39 women, 20 had a tubal hematoma and six had a ruptured fallopian tube. The size of the tubal mass created by ectopic pregnancy was predicted precisely (<math>r = .91</math>, <math>P</math> less than .001), and transvaginal sonography enabled detection of hemoperitoneum with a sensitivity of 91% (68 of 75 women). This study suggests that the status of a tubal pregnancy can be predicted reliably on the basis of transvaginal sonographic findings.</p>	Fair
27	<p>Aleem FA, DeFazio M, Gintautas J. (1990)</p> <p>Endovaginal sonography for the early diagnosis of intrauterine and ectopic pregnancies.</p> <p><i>Hum Reprod</i>, 5(6), Aug, pp 755-8</p>	N=58 patients	<p>The detection of ectopic versus intrauterine gestation showed a high sensitivity of 95%, a specificity of 100%, a positive predictability of 100% and a negative predictability of 97%. The data confirm the value and reliability of endovaginal and cul-de-sac sonography, combined with measurement of the beta-HCG level in the early diagnosis of ectopic pregnancy. This combined approach not only makes the differentiation between normal and extrauterine gestation more accurate but also helps to avoid unnecessary diagnostic laparoscopy and hospitalization.</p>	

No	Author, Title , Journal	Study design, Sample size, follow up	Outcomes & Characteristic	Grade & Comment
28	Chen PC, Sickler GK, Dubinsky TJ, Maklad N, Jacobi RL, Weaver JE (1998)  Sonographic detection of echogenic fluid and correlation with culdocentesis in the evaluation of ectopic pregnancy  <i>AJR Am J Roentgenol</i> ,170(5): May, pp 1299-302	N=40	In 40 of 46 patients with ectopic pregnancy, the sensitivity and specificity of echogenic fluid for establishing hemoperitoneum were 100% and 100%, respectively, compared with 66% and 80%, respectively, for culdocentesis. More important, the negative predictive value of a nondiagnostic culdocentesis was 25% compared with 100% for echogenic fluid in the ectopic subgroup of patients. In two patients with incomplete abortions, sonography failed to detect small amounts of hemoperitoneum at surgery performed 4 hr and 7 days after sonography. CONCLUSION: Sonography is more sensitive than culdocentesis in the detection of hemoperitoneum. Culdocentesis is invasive, and nondiagnostic results cannot be used to exclude hemoperitoneum. Culdocentesis should play no role in the evaluation of ectopic pregnancy except in the unusual circumstance in which high-resolution sonography cannot be readily performed.	Poor
29	Brown DL, Doubilet PM (1994)  Transvaginal sonography of diagnosing ectopic pregnancy: positively criteria and performance characteristic  <i>J Ultrasound Med</i> , 13(4), Apr, pp 259-66	Metaanalysis  N= 2216	4 different criteria were used . criterion A, Living extrauterine pregnancy; criterion B, extrauterine gestational sac containing yolk sac or embryo; criterion C, empty : tubal ring” or extrauterine gest sac containing yolk sac or embryo, and criterio D, any adnexal mass other than a simple cysts. Criteria A, B, and C all have high specificity (99.5%-100%) and positive predictive values (97.8 -100%) but low sensitivities (20.1 -64.6%) and mediocre negative predictive values (78.5-89.1%). Criterion D, has the best characteristic, with only slightlylower specific (98.9%) and positive predictive value (96.3%) but considerably higher sensitivity (84.4%) and negative predictive value (94.8%)	Good
30	Ehsan N, Mehmood A (1998)  Ectopic pregnancy: an analysis of 62 cases  <i>J Pak Med Assoc</i> , 48(2), Feb, pp 26-9	Prospective observational study  N=62	An incidence of 1: 174 births or 5.7 per 1000 births. In 48.3% cases the cause was unknown, 16.1% followed by pelvic inflammatory disease, 16.1% had history of D&C for abortion. 6.4% had history of pelvic surgery, 4.8% had IUCD in situ and 1.6% had recurrent EP. Diagnosis had been clinically in 80.6% of cases. Culdocentesis was performed and was diagnostic in 90.1% of cases. Ultrasound showed positive results in 90.1% of cases. Laparoscopi had 100% accurate results	Fair

No	Author, Title , Journal	Study design, Sample size, follow up	Outcomes & Characteristic	Grade & Comment
31	<p>Aboud E (1997)</p> <p>A 5 year review of ectopic pregnancy</p> <p>Clin Exp Obstet Gynaecol, 24 (3), pp 127-9</p>	<p>Retrospective study</p> <p>N= 98</p>	<p>The commonest presenting symptom was abdominal pain (97%) &amp; vagina bleeding (79%). 4 were asymptomatic &amp; were diagnosed by ultrasound. History of infertility (15%), use of IUCD (14%) &amp; previous EP (11%) were elicited. 5 patients had a false negative UPT. Vaginal ultrasound have made early diagnosis possible, allowing conservative tubal surgery</p>	Fair
32	<p>Hanchate V, Garg A, Sheth R, Rao J, Jadhav PJ, Karayil D. (2002)</p> <p>Transvaginal sonographic diagnosis of live monochorionic twin ectopic pregnancy.</p> <p><i>J Clin Ultrasound</i>, 30(1), Jan, pp 52-6.</p>	Case report	<p>With transabdominal sonography, we initially diagnosed a single ectopic pregnancy, visualized as an ill-defined mass in the left adnexa. However, with transvaginal sonography, we determined the left adnexal mass to contain a single monochorionic gestational sac with 2 embryos, each with cardiac motion. These findings were confirmed with color Doppler sonography and at laparotomy. The introduction of high-resolution transvaginal sonography has resulted in the earlier diagnosis of ectopic pregnancy and has contributed to a recent decrease in the maternal mortality and morbidity associated with this condition</p>	Poor
33	<p>Thorsen MK, Lawson TL, Aiman EJ, Miller DP, McAsey ME, Erickson SJ, Quiroz F, Perret RS.(1990)</p> <p>Diagnosis of ectopic pregnancy: endovaginal vs transabdominal sonography.</p> <p><i>AJR Am J Roentgeno</i>, 155(2), Aug, pp 307-10</p>	N=193 patients	<p>Endovaginal sonography was superior to transabdominal sonography in the evaluation of suspected ectopic pregnancies. Overall, endovaginal sonography was diagnostic in 113 patients, whereas transabdominal sonography was diagnostic in 52 patients. The finding of an extrauterine fetal pole or embryo was diagnostic for an ectopic pregnancy. Pelvic fluid, the appearance of the endometrium, and a single positive serum HCG determination were not helpful in making the diagnosis of ectopic pregnancy.</p>	Poor

No	Author, Title, Journal	Study design, Sample size, follow up	Outcomes & Characteristic	Grade & Comment
34	Dart RG, Burke G, Dart L. (2002)  Subclassification of indeterminate pelvic ultrasonography: prospective evaluation of the risk of ectopic pregnancy.  <i>Ann Emerg Med.</i> ;39(4), Apr, pp382-8.	prospective observational  F/up January 1, 1995, to August 31, 2000,	Seven hundred eighty patients with indeterminate ultrasonographic examinations were identified. One hundred forty-five were lost to follow-up, and therefore, 635 were enrolled. The frequency of ectopic pregnancy for each subclass is as follows: empty uterus, 36 of 259 (13.9%; 95% CI 10.1% to 18.5%); nonspecific fluid, 6 of 127 (4.7%; 95% CI 1.9% to 9.6%); echogenic material, 4 of 93 (4.3%; 95% CI 1.4% to 10.5%); abnormal sac, 0 of 103 (0%; 95% CI 0.0% to 2.9%); and normal sac, 0 of 53 (0%; 95% CI 0.0% to 5.5%). The relative risk of ectopic pregnancy in patients with an empty uterus versus in those without an empty uterus was 5.2 (95% CI 2.6 to 10.2). CONCLUSION: In our sample, patients with an empty uterus at ultrasonography had the highest frequency of ectopic pregnancy, with a relative risk of ectopic pregnancy 5 times greater than that of the other 4 subclasses.	Poor

#### ET - OVARIAN CANCER

No	Author, Title, Journal, Year	Study design, Sample size, Follow up	Characteristic & Outcome	Grade
1	Bell R, Petticrew M, Luengo S, Sheldon TA (1998)  Screening for Ovarian cancer: systematic Review  <i>Health Technology Assessment</i> ,2(2) pp 84	HTA report Systematic Review	Ultrasound screening can detect a higher proportion of ovarian cancers at stage 1 about 75% in ultrasound screening studies Annual screening with ultrasound appear to have a sensitivity or detection rate close to 100% The false positive result rate is about 1.2-2.5% for women screened by ultrasound About 0.5-1% of women will suffer a significant complications due to surgery and most of those who do not have ovarian cancer will have a benign gynecological condition About 3-12% of screened women are recalled for further testing and assessment, resulting in potential distress and anxiety to otherwise healthy women	Good small number of ovarian cancer

No	Author, Title, Journal, Year	Study design, Sample size, Follow up	Characteristic & Outcome	Grade
2	Fleischer AC, Cullinan JA, Peey CV, Jones HW (1996) Early detection of ovarian carcinoma with transvaginal color Doppler ultrasonography  <i>American Journal of Obstetric &amp; gynecology</i> , 174(1), Jan, pp101-106	Retrospective  N=206 – 54 % premenopausal or perimenopausal 45% were postmenopausal	Overall positive predictive value of transvaginal color Doppler ultrasonography was 86% and the negative predictive value was 98% with a specificity of 86% and a sensitivity of 92% If further analyse according to pre menopausal and postmenopausal status, the positive predictive value was 98% and the negative predictive value was 99% in postmenopausal women and 90% and 88% in premenopausal women respectively Transvaginal colorcan detect early-stage ovarian cancer. In fact, in three of 17 stage I tumour, the color Doppler ultrasonography findings were highly suggestive of ovarian cancer	Fair
3	Rampone B, Rampone A, Tirabasso S, Panariello S, Rampone N (2001)  Ovarian cancer screening by transvaginal color Doppler ultrasonography  <i>Minerva Ginecol</i> , 53 (1 supp 1), Feb, pp 125 -8	N= 60 women  F/up: Jan 1997 and Dec 1998	Sonographicmorphology evaluation and color dropler were suspicious in 11 cases and 9 of these were positive on histopathological analisis (true- positive = 15%, false positive=5%). All women that had morphologically normal ovaries observed on ultrasound examination and were not suspicious on color dropler analisis, were also negative on histopathological analisis (true negative =80%) Conclusion The color Doppler ultrasonography revealed a decidedly valid method of screening of the first level.	Poor
4	Sato S, Yokoyama Y, Sakamoto T, Futagami M, Saito Y.(2000)  Usefulness of mass screening for ovarian carcinoma using transvaginal ultrasonography.  <i>Cancer</i> ,89(3), Aug 1, pp 582-8	N= 183,034 women who participated in primary screening. - 51,550 were undergoing screening for the first time. - - 5309 participants (10.3%) --surgery was performed on 324 participants	Twenty-two primary tumors and 2 metastatic tumors were detected for a diagnostic rate of 0.047%. Of the 22 primary tumors, 17 (77.3%) were classified as Stage I carcinoma, with tumor markers positive only for 5 (29.4%). The percentage of the total number of Stage I ovarian carcinoma cases increased after the induction of screening from 29.7% to 58.8%. CONCLUSIONS: These results are significant in that 77.3% of the primary ovarian carcinomas found during the current screening were of curable Stage I. Increased use of TVS screening for ovarian carcinoma may increase the chance for early diagnosis and decrease the mortality of the disease	Poor

No	Author, Title, Journal, Year	Study design, Sample size, Follow up	Characteristic & Outcome	Grade
5	Osmer RG, Osmer M, von Maydell B, Wagner B, Kuhn W. (1998)  Evaluation of ovarian tumors in postmenopausal women by transvaginal sonography.  <i>Eur J Obstet Gynecol Reprod Biol</i> , 77(1), Mar, pp 81-8	Postmenopausal women (> or =1 year of secondary amenorrhea) with ovarian tumors (n=378; tumors > or =3 cm and <3 cm but with solid parts) were examined in a prospective study by transvaginal sonography  F/up:1987 and 1993.	Of all ovarian tumors in postmenopausal women, 6.3% were functional cysts (follicular or corpus luteum cysts). Almost all of them were detected within the first 5 years of postmenopause. The other ovarian tumors were diagnosed as retention cysts (17.5%), benign neoplasms (39.4%), and malignant tumors (36.8%). Simple ovarian cysts (monolocular, smooth inner wall) represented sonomorphologically the second most frequent type of ovarian tumors in postmenopausal women (35.7%). Of these tumors, 9.6% were diagnosed as malignant. CONCLUSIONS: Simple reproducible sonomorphological criteria proved to be a useful clinical parameter in the preoperative evaluation of ovarian tumors.	Poor

#### EVIDENCE TABLE –ENDOMETRIAL POLYS

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
1	Dueholm M, Jensen ML, Laursen H, Kracht P. (2001)  Can the endometrial thickness as measured by trans-vaginal sonography be used to exclude polyps or hyperplasia in pre-menopausal patients with abnormal uterine bleeding?  <i>Acta Obstet Gynecol Scand</i> , 80(7), Jul, pp 645-51	Prospective study  N=355 pre-menopausal women	The mean endometrial thickness was significantly different in patients with hyperplasia 11.5 mm, polyps 11.8 mm, sub-mucous myomas 7.1 mm and in patients without these abnormalities 8.37. Hyperplasia and/or polyps were present in 20% of all patients, and in 8% of 143 patients with an endometrial thickness of < or =7 mm. This proportion did not decrease with lower cut-off levels for endometrial thickness. Receiver operating characteristic (ROC) curves were not optimal for excluding hyperplasia or polyps by endometrial thickness. In 173 cases with a distinct, regular midline echo without echo-dense foci in TVS the proportion of patients with abnormalities was 16% (11-23). This proportion did not decrease with cut-off levels for endometrial thickness. CONCLUSIONS: Using TVS, low levels of endometrial thickness reduced the possibility of abnormalities such as polyps and hyperplasia, but did not exclude them. Low cut-off levels for endometrial thickness did not increase the diagnostic performance in cases with normal sonograms.	Fair



**EVIDENCE TABLE – USE OF ULTRASOUND – UETERINE ABNORMALIITES**

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
1	<p>Becker E Jr, Lev-Toaff AS, Kaufman EP, Halpern EJ, Edelweiss MI, Kurtz AB. (2002)</p> <p>The added value of transvaginal sonohysterography over transvaginal sonography alone in women with known or suspected leiomyoma.</p> <p><i>J Ultrasound Med.</i>;21(3), Mar, pp 237-47</p>	<p>N= 72 women</p>	<p>The added information provided by sonohysterography resulted in improved diagnostic confidence for most parameters. Interobserver agreement was markedly improved for the diagnosis and location of submucous myomas and focal endometrial lesions. Sensitivity values for submucous myomas and focal endometrial lesions were 100% and 90% for transvaginal sonography and sonohysterography together and 100% and 70% for transvaginal sonography alone. CONCLUSIONS: We found that sonohysterography does provide additional information over transvaginal sonography alone and is an important adjunct to transvaginal sonography in symptomatic women with known or suspected myomas, particularly before surgical or medical therapy.</p>	<p>Poor</p>
2	<p>Emoto M, Tamura R, Shiota K, Hachisuga T, Kawarabayashi T.(2002)</p> <p>Clinical usefulness of color Doppler ultrasound in patients with endometrial hyperplasia and carcinoma</p> <p><i>Cancer</i>, 94(3), Feb, pp 1700-6</p>	<p>Clinical trial</p> <p>N= 71 postmenopausal patients</p>	<p>Transvaginal –Color Doppler Ultrasound may be more useful in differentiating between Endometrial Hyperplasia(EH) and Endometrial Carcinoma (EC) than measuring endometrial thickness by transvaginal gray-scale sonography. For patients with EC, the detection of intratumoral blood flow may be helpful in distinguishing between low-grade and high-grade tumors and predicting myometrial invasion. However, intratumoral blood flow analysis using resistance index, Pulsatility Index, or Peak Systolic Velocity may not be useful for predicting tumor spread before surgery.</p>	<p>Good to Fair</p>

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
3	Dijkhuizen FP, De Vries LD, Mol BW, Brolmann HA, Peters HM, Moret E, Heintz AP. (2000)  Comparison of transvaginal ultrasonography and saline infusion sonography for the detection of intracavitary abnormalities in premenopausal women.  <i>Ultrasound Obstet Gynecol</i> , 15(5), May, pp 372-6	N= 50	The sensitivity of TVS in directly visualizing intracavitary abnormalities was 61% for a specificity of 96%. The likelihood ratio of presence of an intracavitary abnormality was 16 and the likelihood ratio of absence of such a finding was 0.41. When defining abnormality at TVS as direct visualization of an intracavitary abnormality or an increased endometrial thickness (cut-off level 5 mm), the sensitivity of TVS was 87% for a specificity of 56%, with corresponding likelihood ratios of 2 and 0.23, respectively. The sensitivity and specificity of SIS was 100% and 85% with likelihood ratios of 6 and 0.0, respectively. No intracavitary abnormality was missed by SIS. CONCLUSION: The diagnostic accuracy of SIS is higher than the accuracy of TVS. A combined approach using endometrial thickness measurement by TVS and, reserving SIS for patients with increased (> 5 mm) endometrial thickness, or endometrium inadequately visualized on TVS, is the optimal method of reducing the hysteroscopy rate.	Poor
4	Gerber B, Krause A, Kuelz T, Quasmeh A, Reimer T, Friese K (1999)  [Rating of transvaginal sonography in the evaluation of postmenopausal bleeding]  <i>Zentralbl Gynakol</i> , 121(3), pp143-8	N=1198 postmenopausal patients with vaginal bleedings  F/up: January 1990 and December 1996,	Atrophy was found in 46.3%, endometrial polyps in 19.8%, endometrial cancer in 17.5%, and hyperplasia in 6.7%. An endometrial thickness of lower than 5 mm ( $p < 0.0001$ ) was shown in TVS patients with atrophy in 71%, with endometrial polyps in 10.9%, with endometrial cancer in 3.9% and hyperplasia in 6.8%. In 55.2% of these cases with endometrial cancer the preoperatively estimated thickness was 10 mm or more. The additionally morphologic examination in cases with an endometrium smaller than 5 mm was false positive in 75% (9/12). Thus an endometrial thickness of > 5 mm had a sensitivity of 92.5%, specificity of 71.0%, positive and negative predictive value of 75.6, respectively 90.9% for the detection of endometrial pathology. CONCLUSIONS: TVS allows the detection of an endometrial pathology in the vast majority of patients with postmenopausal bleedings. In cases with a single postmenopausal bleeding and an endometrium smaller than 5 mm we recommend expectative procedures with repeated ultrasound examination of the endometrium.	Poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
5	<p>Alcazar JL, Laparte C, Jurado M, Lopez-Garcia G (1997)</p> <p>The role of transvaginal ultrasonography combined with color velocity imaging and pulsed Doppler in the diagnosis of endometrioma.</p> <p><i>Fertil Steril</i>.;67(3), Mar, pp 487-91</p>	<p>Prospective study</p> <p>N= 78 consecutive pts</p> <p>F/up: Jan 1995 – March 1996</p>	<p>Twenty-seven (32.9%) of the 82 masses were proven to be ovarian endometriomas. Morphological assessment diagnosed correctly 24 (88.9%) of 27 endometriomas (false-positive rate: 9%). Typical flow pattern was present in 90.5% of endometriomas (false-positive rate: 80). The sensitivity, specificity, and positive and negative predictive values of transvaginal ultrasonography alone and combined with color velocity imaging and pulsed Doppler were 88.9%, 91%, 84.2%, and 94.5%, and 76.2%, 88.9%, 82.4%, and 82.4%, respectively. The use of color velocity imaging and pulsed Doppler does not improve the diagnostic accuracy of transvaginal ultrasonography alone in the diagnosis of ovarian endometrioma.</p>	Fair
6	<p>Gabrielli S, Marabini A, Bevini M, Linsalata I, Falco P, Milano V, Zantedeschi B, Bovicelli A, Stagnozzi R, Cacciatore B, Gubbini G, Bovicelli L. (1996)</p> <p>Transvaginal sonography vs. hysteroscopy in the preoperative staging of endometrial carcinoma.</p> <p><i>Ultrasound Obstet Gynecol</i>, 7(6), Jun, pp 443-6</p>	<p>67 women with histologically proven endometrial carcinoma.</p>	<p>Transvaginal sonographic examination `was initially directed at assessing myometrial invasion, which was correctly predicted in 52/67 (78%) women. Transvaginal sonography demonstrated a sensitivity of 88% (23/26) and a specificity of 71% (29/41) for deep invasion, with a positive predictive value (PPV) of 66% (23/35) and a negative predictive value (NPV) of 91% (29/32). The accuracy of transvaginal sonography in detecting cervical involvement was 82% (55/67), and that of hysteroscopy was 72% (48/67): transvaginal sonography was slightly less sensitive (54% vs. 64%), but more specific (87% vs. 73%) than hysteroscopy. When cervical invasion was present, the PPVs of transvaginal sonography and hysteroscopy were 46% (6/13) and 32% (7/22), respectively, while the NPV was 91% for both techniques (49/54; 41/45). Our data show that the accuracy of transvaginal sonography was comparable with that of hysteroscopy in detecting cervical involvement.</p>	Poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
7	Vuento MH, Pirhonen JP, Makinen JI, Tyrkko JE, Laippala PJ, Gronroos M, Salmi TA. (1999)  Screening for endometrial cancer in asymptomatic postmenopausal women with conventional and colour Doppler sonography.  <i>Br J Obstet Gynaecol.</i> ,106(1), Jan, pp 14-20	Clinical Controlled Trial	Transvaginal sonography is confirmed to have a very high sensitivity for the detection of early endometrial carcinoma, but the specificity remains low. If endometrial cancer is to be detected at an early stage, further examinations should be carried out when the endometrial thickness is > or = 4.0 mm, especially when the woman has risk factors such as obesity, late menopause or current use of hormonal replacement therapy. Doppler sonography does not improve the detection of premalignant and malignant endometrial lesions compared with normal ultrasound.	Fair

#### EVIDENCE TABLE — ADNEXAL MASSES

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
1	Alcazar JL, Errasti T, Zornoza A, Minguez JA, Galan MJ. (1999)  Transvaginal color Doppler ultrasonography and CA-125 in suspicious adnexal masses.  <i>Int J Gynaecol Obstet</i> ,66(3), Sep pp 255-61	Review  N= 94 patients - 52 premenopausal - 42 postmenopausal	Fifty-six (59.6%) tumors were found to be malignant and 38 (40.4%) benign. Sensitivity, specificity, PPV and NPV for Doppler sonography (CD) were 87.5% , 84.2%, 89.1% and 82.1%, respectively. Sensitivity, specificity, PPV and NPV for CA-125 were 83.9% , 68.4%, 79.7% and 74.3%, respectively. Sensitivity, PPV and NPV were not statistically different. CD had higher specificity (P = 0.01). AUC curve for Doppler (0.75) was significantly higher than for CA-125 (0.61) (P = 0.0002). CONCLUSIONS: Our results indicate that color Doppler ultrasound has a better diagnostic performance as compared with CA-125, being significantly more specific.	Fair

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
2	<p>Valentin L. (1997)</p> <p>Gray scale sonography, subjective evaluation of the color Doppler image and measurement of blood flow velocity for distinguishing benign and malignant tumors of suspected adnexal</p> <p><i>Eur J Obstet Gynecol Reprod Biol.</i>;72(1), Mar, pp 63-72</p>	N=151	<p>Ultrasound morphology correctly identified all the malignant tumors, with a false-positive rate of 61%; none of the 49 unilocular or multilocular cysts without solid parts was malignant, whereas 24% (24/102) of the tumors with solid components were. Among multilocular cysts with solid parts, both tumor color scores and time average maximum blood flow velocities were significantly higher in malignant than in benign tumors, but among solid tumors there was complete overlap in Doppler results between the malignant and benign subgroups. Using Doppler examination to discriminate between benign and malignant multilocular cysts with solid parts and ultrasound morphology for differentiation of the remaining tumors, all the malignancies in the study were detected with a false-positive rate of 32 or 38% depending on which Doppler variable was used. CONCLUSION: The present technique of Doppler ultrasound examination is helpful only in the differential diagnosis of multilocular cysts with solid parts. Therefore, the degree to which Doppler examination can contribute to the differential diagnosis of pelvic tumors will depend on the proportion of multilocular cysts with solid parts in the population studied: the greater this proportion, the greater the potential of the Doppler examination to improve diagnostic accuracy.</p>	Poor

**EVIDENCE TABLE – USE OF ULTRASOUND IN SURGERY**

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
1	<p>Pear WS, Todd KH, (1996)</p> <p>Ultrasonography for the initial Evaluation of Blunt Abdominal Trauma: A Reviews of Prospective Trials <i>Annals of Emergency Medicine</i>; 27(3), March, pp 353-361</p>	<p>Reviews of prospective trials</p> <p>11 studies</p> <p>N- 200 participants</p>	<p>4 studies reported results for ultrasound detection of free intraperitoneal fluid alone regardless of associated injuries showing the sensitivity of detecting free intraperitoneal fluid ranging from 87-98% and specificity ranging from 99% to 100%. Ultrasound as a screening test, the sensitivity was range from 69 – 96% and specificity from 95 – 100%. The effectiveness of ultrasound in determining the need for emergency laparotomy, reporting the sensitivities ranging from 84 – 93% and specificity ranging from 88 -100%. The effectiveness of ultrasound localization of injured organs with the sensitivity ranging from 20-80% depending upon the organ injured. In comparing with diagnostic peritoneal lavage and Computed Tomography, ultrasound had sensitivity from 69 – 91.7% and specificity ranging from 86- 94.7%, while DPL had sensitivity of 100% and specificity of 86-94.7%, CT had sensitivity ranging from 75%-97% and specificity ranging from 95-100%. All studies concluded that ultrasound was of value as a complementary study. Evidence indicates that sonography is less sensitive than DPL and CT for identifying intra-peritoneal injuries, but has value in identifying patient for laparotomy.</p>	2
2	<p>Frezza EE, Ferone T, Martin M(1999)</p> <p>Surgical residents and ultrasound technician accuracy and cost-effectiveness of ultrasound in trauma</p> <p><i>American Surgeon</i>, 65(3), pp 289-91</p>	<p>Retrospective study</p> <p>N=697 Trauma patient</p> <p>650 - Focused Abdominal Sonogram for Trauma (FAST) (502 adult trauma &amp; 148 paediatric trauma patients)</p> <p>F/up July 1996 – June 1997</p>	<p>FAST is an invaluable diagnostic tool in the primary survey of trauma victims, Furthermore, FAST as performed by surgical residents is an accurate method of evaluating the trauma patient.</p>	

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
3	<p>McGahan JP, Richards JR, Jones CD, Gerscovich EO. (1999)</p> <p>Use of ultrasonography in the patient with acute renal trauma.</p> <p><i>J Ultrasound Med</i>,18(3), Mar, pp 207-13; quiz 215-6</p>	<p>Prospective</p> <p>N= 32 patients</p> <p>F/up:3 year period</p>	<p>Free fluid in the abdomen was identified in 19 of 32 patients (59%). However, 12 of these 19 patients had concomitant injury, such as splenic rupture requiring splenectomy, severe liver lacerations, or bowel lacerations requiring repair, that were possible causes of the free fluid. Eliminating these patients, only seven of 20 patients with isolated renal injuries had free fluid in the abdomen (35%), whereas 13 of 20 patients (65%) had no evidence of free fluid. All seven patients with free fluid had moderate or severe renal injuries. Renal parenchymal abnormalities were identified on ultrasonograms in eight of 37 (22%) of injured kidneys. The abnormalities were detected more commonly in cases of severe injury (60%). In conclusion, acute injuries of the kidney from blunt abdominal trauma often are associated with significant splenic, hepatic, or bowel trauma. Isolated renal injuries frequently occur without the presence of free fluid in the abdomen. Furthermore, the ultrasonogram of the kidney often is normal with acute renal injuries, but it is more likely to be abnormal with severe (grade II or greater) renal injuries. Sonography may be used in the triage of patients with blunt abdominal trauma and possible renal injury. However, a negative ultrasonogram does not exclude renal injury, and, depending on clinical and laboratory findings, other imaging</p>	Fair
4	<p>Patel JC, Tepas JJ 3<sup>rd</sup> (1999)</p> <p>The efficacy of focused abdominal sonography for trauma (FAST) as a screening tool in the assessment of injured children.</p> <p><i>J Pediatr Surg</i>, 34(1), Jan, pp 44-7; discussion 52-4</p> <p>.</p>	N= 94 cases	<p>From the practical perspective of indicating need for operative intervention in BTT, FAST has a high specificity (95%); however, it is not particularly sensitive (33%). This excellent specificity in combination with clinical examination underscores FAST utility by avoiding unnecessary diagnostic intervention in 72% of the patients in this study.</p>	Poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
5	<p>Mutabagani KH, Coley BD, Zumberge N, McCarthy DW, Besner GE, Caniano DA, Cooney DR. (1999)</p> <p>Preliminary experience with focused abdominal sonography for trauma (FAST) in children: is it useful?</p> <p><i>J Pediatr Surg</i>,34(1), pp 48-52; discussion 52-4</p>	<p>Prospectively</p> <p>N= 64 patients</p>	<p>FAST identified four children with positive findings (free intraperitoneal fluid), whereas CT showed 13 children with injuries (nine with associated free intraperitoneal fluid and four with only solid organ injury and no associated intraperitoneal fluid). There were nine false-negative and no false-positive FAST scans. The sensitivity of FAST was 0.3 and the specificity was 1.0. Injuries missed by FAST included liver laceration, adrenal hematoma, renal laceration, small bowel injury and splenic laceration. CONCLUSION: Preliminary results suggest that FAST alone is not a useful screening test in the evaluation of children with suspected intraabdominal injury.</p>	Fair
6	<p>Stassen NA, Lukan JK, Carrillo EH, Spain DA, Richardson JD.(2002)</p> <p>Abdominal seat belt marks in the era of focused abdominal sonography for trauma.</p> <p><i>Arch Surg</i> ,137(6), Jun, pp718-22; discussion 722-3</p>	<p>Retrospective</p> <p>N= 23</p> <p>F/up: 3 years</p>	<p>Eighteen patients (78%) had either negative or equivocal FAST results when significant intestinal injury was present. All 23 patients had CT scan findings suggestive of bowel or mesenteric injury. Moderate-to-large free intraperitoneal fluid without solid organ injury was the most common finding (n = 21, 91%). Operative findings included small-bowel perforation (n = 18, 78%), colonic perforation (n = 7, 30%), bowel deserosalization (n = 8, 35%), and isolated mesenteric injury (n = 5, 22%). Sixteen patients (70%) had multiple intra-abdominal injuries. All patients were taken directly from the emergency department to the operating room. Seventeen percent of operative explorations (4/23) were nontherapeutic (no repairs required). CONCLUSION: This study confirms that FAST cannot reliably exclude intestinal injury in patients with seat belt marks.</p>	Fair



No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
7	Richards JR, Schleper NH, Woo BD, Bohnen PA, McGahan JP.(2002)  Sonographic assessment of blunt abdominal trauma: a 4-year prospective study.  <i>J Clin Ultrasound</i> , 30(2), Feb, pp 59-67	N= 3264  F/up:Jan 1995 – Oct 1998	Three hundred ninety-six (12%) of the 3,264 patients had IAIs. Sonography detected free fluid presumed to represent hemoperitoneum in 288 patients (9%). The sonographic detection of free fluid alone had a 60% sensitivity, 98% specificity, 82% positive predictive value, and 95% negative predictive value for diagnosing IAI. The accuracy was 94%. Seventy patients (2%) had parenchymal abnormalities identified with sonography that corresponded to actual organ injuries. The sensitivity of the sonographic detection of free fluid and/or parenchymal abnormalities in diagnosing IAI was 67%. CONCLUSIONS: Emergency sonography to evaluate patients for injury caused by blunt trauma is highly accurate and specific. The sonographic detection of free fluid is only moderately sensitive for diagnosing IAI, but the combination of free fluid and/or a parenchymal abnormality is more sensitive.	Poor
8	Rathaus V, Zissin R, Werner M, Erez I, Shapiro M, Grunebaum M, Konen O. (2001)  Minimal pelvic fluid in blunt abdominal trauma in children: the significance of this sonographic finding.  <i>J Pediatr Surg</i> , 36(9), Sep, pp1387-9	Retrospective Review  N= 183 children - group A, N=87 - normal examination; - group B N=57, pelvic fluid only; - group C N=39, peritoneal fluid outside the pelvis	Four abdominal organ injuries were missed by the ultrasound examination. The sensitivity and specificity of the ultrasound examinations to predict organ injury in presence of peritoneal fluid outside the pelvis were, respectively, 89.5% and 96.6%; the positive and negative predictive value were 87.2% and 97.3%. No statistically significant difference was seen between group A and group B, whereas the presence of peritoneal fluid outside the pelvic cavity (group C) was associated strongly with an organ injury (P <.001). CONCLUSIONS: A normal ultrasound examination or the presence of pelvic fluid are associated with a low probability of an organ injury. In the presence of peritoneal fluid outside the pelvis, the probability of an organ injury is very high	Fair

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
9	Boulanger BR, Kearney PA, Tsuei B, Ochoa JB. (2001)  The routine use of sonography in penetrating torso injury is beneficial.  <i>J Trauma</i> , 51(2), Aug, pp 320-5	N= 238  F/up: Jan 1999 – Jan 2000	The sensitivity of FAST alone for abdominal injury was 67%, specificity was 98%, positive predictive value was 92%, and negative predictive value was 89%. Pericardial fluid was seen in 3 of 34 patients; one had a heart wound and two had negative pericardial windows. All 31 patients without pericardial fluid recovered without surgery. CONCLUSION: The routine use of sonography in penetrating torso injury is beneficial. The detection of pericardial or peritoneal fluid is clinically useful. However, a negative FAST examination does not exclude abdominal injury, such as a diaphragm or hollow viscus wound, and further investigation or close follow-up is required.	Poor
10	Kern SJ, Smith RS, Fry WR, Helmer SD, Reed JA, Chang FC.(1997)  Sonographic examination of abdominal trauma by senior surgical residents  <i>Am Surg</i> , 63(8), Aug, pp669-74.	Prospective study  N= 518 patients  F/up: 1995-1996	Mechanism of injury was blunt in 92% of patients . there were 22 true positive,12 false negative, 8 false negative and 476 true negative. Five of the eight false negatives were secondary to limited hollow viscous injuries with minimal associated intraperitoneal fluid. Sensitivity, specificity, accuracy, positive predictive value and negative predictive value were 73.3, 97.5, 96.1, 64.7 and 98.3% respectively.	Poor
11	Holmes JF, Brant WE, Bond WF, Sokolove PE, Kuppermann N.(2001)  Emergency department ultrasonography in the evaluation of hypotensive and normotensive children with blunt abdominal trauma.  <i>Pediatr Surg</i> , 36(7), Jul, pp 968-73	Prospective, observation study  N= 224 peadiatric blunt trauma patients  F/up: 29 Months	The accuracy of abdominal ultrasound for detecting intraperitoneal fluid associated with IAI was sensitivity, 82%; specificity, 95%; positive predictive value, 73%; and negative predictive value, 97%. In the 13 patients who were hypotensive, ultrasound scan correctly identified intraperitoneal fluid in all 7 patients (sensitivity 100%) with IAI, and hemoperitoneum and was negative in all 6 patients (specificity 100%) who did not have hemoperitoneum. Nine patients had IAI without intraperitoneal fluid, and ultrasound scan result was negative for fluid in all 9.ED abdominal ultrasound scan used solely for the detection of intraperitoneal fluid in pediatric blunt trauma patients has a modest accuracy. Ultrasonography has the best test performance in those children who are hypotensive and should be obtained early in the ED evaluation of these patients.	Fair

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
12	<p>Fernandez Cordoba MS, Gonzalez Pinera J, Puertas Hernandez F, Marco Macian A (2001)</p> <p>[Usefulness of ultrasonography in the initial assessment of blunt abdominal trauma in children]</p> <p><i>Cir Pediatr</i>, 14(1), Jan, pp :9-13</p>	<p>Review</p> <p>N= 22 children</p> <p>F/up: 1991-1999</p>	<p>The accuracy of the abdominal ultrasound in the diagnosis of intra-abdominal injury was 77.27%, with a 82.35% sensitivity, 60% specificity, 87.5% positive predictive value, and 50% negative predictive value. The accuracy of the compute tomography ( TAC) in the diagnosis was 93.75%. The sensitivity, specificity, positive predictive value, and negative predictive value of the TAC were 92.85%, 100%, 100%, and 66% respectively. We conclude that TAC is the imaging modality of choice in children with severe abdominal trauma but ultrasonography is a reasonable technique to arouse diagnostic suspicion, that can avoid additional tomographic studies. Abdominal computed tomography must be reserved for the hemodynamically stable children with anormal ultrasonographic findings or with suspected injuries by a clinical evolution that gone unnoticed in the previous study.</p>	Fair
13	<p>Udobi KF, Rodriguez A, Chiu WC, Scalea TM. (2001)</p> <p>Role of ultrasonography in penetrating abdominal trauma: a prospective clinical study.</p> <p><i>J Trauma</i>,50(3), Mar, pp 475-9</p>	<p>Validation Study</p> <p>N= 75 consecutive patients</p> <p>F/up: Dec 1998- Jun 1999</p>	<p>41 had proven abdominal injury and 34 had no injury; and 21 patients had a positive FAST. Nineteen had peritoneal blood and injuries requiring repair at the time of laparotomy. There were two false-positive studies. Fifty-four patients had a negative FAST. In 32 patients, this was a true-negative study. Thirteen patients had a false-negative FAST and had peritoneal blood and significant injury on further evaluation. Nine patients had a negative FAST and no peritoneal blood but still had abdominal injuries requiring operative repair, including liver (four), small bowel (four), diaphragm (three), colon (three), and stomach (one). The overall sensitivity of FAST was 46% and the specificity was 94%. The positive predictive value was 90%, and the negative predictive value was 60%. CONCLUSION: FAST can be a useful initial diagnostic study after penetrating abdominal trauma. A positive FAST is a strong predictor of injury, and patients should proceed directly to laparotomy. If negative, additional diagnostic studies should be performed to rule out occult injury.</p>	Fair

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
14	Corbett SW, Andrews HG, Baker EM, Jones WG. (2000)  ED evaluation of the pediatric trauma patient by ultrasonography.  <i>Am J Emerg Med</i> , 18(3), May, pp 244-9	Prospective  N= 47 children	Sensitivity, specificity, and accuracy of the ultrasound examination for the detection of free fluid in the abdominal cavity was 75% (95% confidence interval [CI] 36% to 95%), 97% (95% CI 81% to 100%), and 92% (95% CI 77% to 98%). Positive and negative predictive values were 90% (95% CI 46% to 100%) and 92% (95% CI 74% to 99%), respectively. Ultrasound examinations took an average of 7 minutes and 36 seconds, although this did not take into consideration delays created by interruptions for other diagnostic tests or procedures. An emergency physician and radiologist agreed on blinded interpretations of 83% of the examinations (kappa = 0.56). Bedside ultrasonography is a reliable and rapid method for screening traumatized children for the presence or absence of free fluid in the peritoneum even in the hands of novice sonographers.	Fair
15	Yeo A, Wong CY, Soo KC. (1999)  Focused abdominal sonography for trauma (FAST).  <i>Ann Acad Med Singapore</i> , 28(6), Nov, pp 805-9	N=27 patient  F/up: Jan 1997 – July 1998	The results of the examination were compared to diagnostic peritoneal lavage, CT scan, operative findings, serial examination and/or post-mortem findings. Overall sensitivity was 67% and specificity 97%. Although the FAST examination missed the small amount of free fluid seen in the CT scan of 2 patients, these patients did not have to undergo laparotomy as their abdominal examination was normal. We conclude that the FAST examination is feasible and should be part of a general surgeon's armamentarium in the initial assessment of trauma.	
16	Richards JR, McGahan JP, Pali MJ, Bohnen PA. (1999)  Sonographic detection of blunt hepatic trauma: hemoperitoneum and parenchymal patterns of injury.  <i>J Trauma</i> , 47(6), Dec, pp:1092-7	Review  N= 2622 emergency sonogram were performed  F/up: Jan 1995 – Dec 1998	Emergency sonography is sensitive for the detection of grade III or higher liver injuries resulting from blunt abdominal trauma. Sonography may also reveal BHI on the basis of parenchymal abnormality, with a discrete hyperechoic area the most commonly encountered pattern.	Fair

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
17	<p>Bode PJ, Edwards MJ, Kruit MC, van Vugt AB.(1999)</p> <p>Sonography in a clinical algorithm for early evaluation of 1671 patients with blunt abdominal trauma.</p> <p><i>AJR Am J Roentgenol</i>,172(4), Apr, pp 905-11</p>	<p>Prospective study</p> <p>N=1671 consecutive patients</p>	<p>Sonography correctly identified all patients requiring emergency laparotomy. No inconclusive laparotomies were performed in this group. The sensitivity of sonography for revealing intraabdominal injury was 88%, the specificity was 100%, and the accuracy was 99%. In 132 patients (8%), abdominal CT was performed. CT revealed relevant posttraumatic abnormalities in 61% of all patients. Four hundred seventy patients with negative sonographic findings were discharged approximately 12 hr after admission; two of these patients (0.4%) were mistakenly discharged. Trauma scores did not influence the efficacy of sonography.</p> <p>CONCLUSION: Our algorithm that uses sonography as the primary diagnostic tool provides accurate, fast, cost-effective, and noninvasive initial management of patients with blunt abdominal trauma. Our test characteristics were excellent indicators of the need for emergency laparotomy. Sonography also achieves high values in revealing relevant injury. Our algorithm produced medically satisfactory and economically prudent management of patients with blunt abdominal trauma.</p>	Fair

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
18	<p>Rozycki GS, Ballard RB, Feliciano DV, Schmidt JA, Pennington SD.(1998)</p> <p>Surgeon-performed ultrasound for the assessment of truncal injuries: lessons learned from 1540 patients.</p> <p><i>Ann Surg</i>, 228(4), Oct, pp 557-67</p>	<p>Clinical Trial</p> <p>N= FAST examinations were performed in 1540 patients (1227 with blunt injuries, 313 with penetrating injuries)</p> <p>F/up: 3 years</p>	<p>There were 1440 true-negative results, 80 true-positive results, 16 false-negative results, and 4 false-positive results; the sensitivity was 83.3%, the specificity 99.7%. US was most sensitive and specific for the evaluation of patients with precordial or transthoracic wounds (sensitivity 100%, specificity 99.3%) and hypotensive patients with blunt abdominal trauma (sensitivity 100%, specificity 100%). CONCLUSIONS: US should be the initial diagnostic modality for the evaluation of patients with precordial wounds and blunt truncal injuries because it is rapid and accurate. Because of the high sensitivity and specificity of US in the evaluation of patients with precordial wounds and hypotensive patients with blunt torso trauma, immediate surgical intervention is justified when those patients have a positive US examination.</p>	Fair
19	<p>McKenney KL, Nunez DB Jr, McKenney MG, Asher J, Zelnick K, Shipshak D (1998)</p> <p>Sonography as the primary screening technique for blunt abdominal trauma: experience with 899 patients.</p> <p><i>AJR Am J Roentgenol</i>,170(4), Apr, pp 979-85</p>	<p>N=899</p> <p>F/up: Dec 1994 – Dec 1995</p>	<p>f the 899 sonograms obtained for blunt abdominal trauma, the findings of 783 were negative, 101 were positive, and 15 were indeterminate. Of the 783 sonograms with negative findings, 768 (98%) were confirmed by CT, surgery, or clinical follow-up. Similarly, of the 101 sonograms with positive findings, 95 (94%) were confirmed. Interpretations resulted in 15 false-negative and five false-positive examinations. For all sonograms, we calculated a sensitivity of 86%, a specificity of 99%, and an accuracy of 98%. CONCLUSION: Sonography can be used effectively as the primary screening technique for blunt abdominal trauma.</p>	Poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
20	<p>Thourani VH, Pettitt BJ, Schmidt JA, Cooper WA, Rozycki GS. (1998)</p> <p>Validation of surgeon-performed emergency abdominal ultrasonography in pediatric trauma patients.</p> <p><i>J Pediatr Surg</i>,33(2), Feb, pp 322-8</p>	<p>Controlled clinical trial</p> <p>N=192 children</p>	<p>The focused assessment for the sonographic evaluation of pediatric blunt trauma patients performed by surgical residents and attendings in the ED rapidly and accurately predicted the presence or absence of intraperitoneal fluid. The FAST is a potentially valuable tool to rapidly prioritize the need for laparotomy in the child with multiple injuries and extraabdominal sources of bleeding.</p>	Fair
21	<p>Dulchavsky SA, Schwarz KL, Kirkpatrick AW, Billica RD, Williams DR, Diebel LN, Campbell MR, Sargysan AE, Hamilton DR. (2001)</p> <p>Prospective evaluation of thoracic ultrasound in the detection of pneumothorax.</p> <p><i>J Trauma</i>, 50(2), Feb, pp 201-5.</p>	<p>Prospective study</p>	<p>There were 382 patients enrolled; the cause of injury was blunt (281 of 382), gunshot wound (22 of 382), stab wound (61 of 382), and spontaneous (18 of 382). Pneumothorax was demonstrated on chest radiograph in 39 patients and confirmed by ultrasound in 37 of 39 patients (95% sensitivity); two pneumothoraces could not be diagnosed because of subcutaneous air; the true-negative rate was 100%. CONCLUSION: Thoracic ultrasound reliably diagnoses pneumothorax. Expansion of the focused abdominal sonography for trauma (FAST) examination to include the thorax should be investigated for terrestrial and space medical applications</p>	Fair

**EVIDENCE TABLE – USE OF ULTRASOUND APPENDICITIS**

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
1	<p>Orr RK, Porter D., Hartman D (1995)</p> <p>Ultrasonography to evaluate adults for appendicitis decision making based on meta-analysis and probabilistic reasoning</p> <p><i>Academic Emergency Medicine</i>, 2(7), pp 644- - 650</p>	<p>Reviews ( Case series)</p>	<p>US poole sensitivity was 84.7% and specificity 92.1%. accuracy of diagnosis was calculated to occur in 85.9, 88.9 and 91.8% of cases in group 1., 2 and 3 patient respectively. A positive predicted value was calculated for each risk group: group 1- 97.6%, group 2 - 87.3% and group3 – 19.8%. a negative predicted value was calculated for each risk group : group 1 59.5%, group2 – 89.9% and group 3- 99.7%. US should not be used to excluded appendicitis for patients with classic sign of the illness (group 1) due to the high false-negative rate. In patients with intermediate signs of appendicitis (group 2) a positive US result should indicate the necessity of an operation, or extended observation</p> <p>The high false-positive rate I those patients who have a low probability of appendicitis (group 3) suggests that US screening is not to be recommended.</p>	<p>Poor</p>
2	<p>Axelrod DA, Sonnad SS, Hirschl RB (2000)</p> <p>An economic evaluation of sonographic examination of children suspected appendicitis</p> <p><i>Journal of Pediatric Surgery</i>; 35(8), pp1236-1241</p>		<p>In the acute abdomen population, the prevalence of appendicitis was 83%. The sensitivity and specificity of ultrasound scan were 81% and 86%. In the equivalent examination population, the prevalence of appendicitis was 28.4% , the sensitivity and specificity of ultrasound scan were 93% and 93% respectively. 50% of misdiagnosed patients discharged without ultrasound would return with ruptured appendicitis. 100% of those discharge after a false negative ultrasound would return with ruptured appendicitis.</p>	
3	<p>Fa EM, Cronan JJ. (1989)</p> <p>Compression ultrasonography as an aid in the differential diagnosis of appendicitis.</p> <p><i>Surg Gynecol Obstet</i>,169(4), Oct, pp 290-8</p>	<p>Retrospective</p> <p>N=all patients who underwent abdominal or pelvic compression</p> <p>F/up: 15 month</p>	<p>Ultrasonography was found to be 66.7 per cent sensitive, 90.6 per cent specific and 86.8 per cent accurate in the diagnosis of appendicitis, with a positive predictive value of 57.1 per cent and a negative predictive value of 93.5 per cent. a maximal appendiceal diameter of greater than 6 millimeters. Ultrasonography was shown to be 80.0 per cent sensitive, 95.0 per cent specific and 92.9 per cent accurate in diagnosing appendicitis, with a positive predictive value of 72.7 per cent and a negative predictive value of 96.6 per cent. appendiceal ultrasonographic examination is a reliable ancillary technique in diagnosing or excluding appendicitis</p>	<p>Fair</p>



No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
4	<p>Marusch F, Allecke K, Gastinger I. (1998)</p> <p>[Value of ultrasound in diagnosis of appendicitis. Results of the East German Multicenter Study. East German Working Group "Outcome Assessment and Quality Assurance in Surgery" of the CAQ of the German Society of Surgery]</p> <p><i>Zentralbl Chir</i>,123, Suppl 4 , pp29-31</p>	<p>prospective trial</p> <p>N=3924 patients</p> <p>F/up: one year at 34 East German hospitals.</p>	<p>The correlation of sonogram and intraoperative macroscopic findings showed a high rate (68.2%) of acute inflamed appendices in cases with negative ultrasound results. A positive sonogram with an inflamed appendix was confirmed in 90% of the cases intraoperatively. In our study the routine use of ultrasonography for the diagnosis of acute appendicitis shows a sensitivity of 21.5% and a specificity of 80.1%. The positive predictive value is 95.6% and the predictive value for negative results is 9.8%. In conclusion, if clinical examination shows the presumptive diagnosis of acute appendicitis, a negative sonogram should not withhold the surgeon to perform an operative intervention.</p>	Fair
5	<p>Soda K, Nemoto K, Yoshizawa S, Hibiki T, Shizuya K, Konishi F (2001)</p> <p>Detection of pinpoint tenderness on the appendix under ultrasonography is useful to confirm acute appendicitis.</p> <p><i>Arch Surg</i>,136(10), Oct, pp1136-40</p> <p>.</p>	<p>Prospective clinical trial.</p> <p>N=Eighty-nine patients</p> <p>F/up: March 1998 and November 2000.</p>	<p>The diagnosis of appendicitis had a sensitivity of 86.7%, a specificity of 89.7%, a positive predictive value of 94.5%, a negative predictive value of 76.5%, and overall accuracy of 87.6%. All 50 patients with pinpoint tenderness noted on the appendix had appendicitis. The surgeon's initial clinical impression had a sensitivity of 83.3%, a specificity of 44.8%, a positive predictive value of 75.8%, a negative predictive value of 56.5%, and overall accuracy of 70.8%. CONCLUSIONS: The efficacy of ultrasonography using the simple criteria was superior to that of the surgeon's initial clinical impression (P&lt;.001). Our ultrasonographic criteria for the diagnosis of appendicitis are simple to use and efficient.</p>	Fair

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
6	<p>Lee JH, Jeong YK, Hwang JC, Ham SY, Yang SO. (2002)</p> <p>Graded compression sonography with adjuvant use of a posterior manual compression technique in the sonographic diagnosis of acute appendicitis.</p> <p><i>AJR Am J Roentgenol</i>,178(4), Apr, pp 863-8</p>	<p>Prospectively</p> <p>N= 570 consecutive patients referred for suspected acute appendicitis were examined by original, graded compression sonography</p>	<p>Graded compression sonography enabled visualization of the vermiform appendix in 485 (85%) of 570 patients. After the adjuvant use of a posterior manual compression technique, the vermiform appendix was found in an additional 57 of 85 patients, with the number of identified vermiform appendices increasing to 542 (95%) of 570 patients. The 57 patients with an additionally found appendix included 11 patients with acute appendicitis. The sonographic diagnosis of acute appendicitis was determined in 312 of 542 patients. Acute appendicitis was proven by surgery in 311 of 332 patients. Sonography was used to establish the diagnosis in 302 of the 311 patients with proven appendicitis; there were 10 false-positive diagnoses and nine false-negative diagnoses. One false-positive diagnosis was acquired after use of the posterior manual compression technique. These results showed more improvement than those of the probabilities for acute appendicitis with single use of graded compression sonography.</p> <p>CONCLUSION: Graded compression sonography with adjuvant use of a posterior manual compression technique seems to be useful for detecting the vermiform appendix and for diagnosing acute appendicitis.</p>	Fair
7	<p>Emil S, Mikhail P, Laberge JM, Flageole H, Nguyen LT, Shaw KS, Baican L, Oudjhane K. (2001)</p> <p>Clinical versus sonographic evaluation of acute appendicitis in children: a comparison of patient characteristics and outcomes.</p> <p><i>J Pediatr Surg</i>, 36(5), May, pp 780-3</p>	<p>Retrospective Study</p> <p>N= 454 consecutive patients - N=191 ultrasound group</p> <p>F/up: Jan 1998 – Dec 1999</p>	<p>When compared with the clinical group, longer symptom duration (2.2 +/- 2.5 v 1.6 +/- 1.6 days; P =.003), higher incidence of preoperative in-patient observation (19% v 4%; P &lt;.001), longer duration between evaluation and operation (8.0 +/- 3.9 v 4.9 +/- 2.9 hours; P &lt;.001), higher incidence of normal appendices on pathologic examination (13% v 6%; P =.006), and higher incidence of postoperative abscesses or phlegmons (4.4% v 1.2%; P =.04). The groups did not differ significantly in age, hospital stay, incidence of complicated appendicitis, or incidence of wound infection. CONCLUSIONS: Patients undergoing sonography before appendectomy have a longer delay before operation, a higher rate of misdiagnosis, and more postoperative complications. Limiting sonography to truly equivocal cases and using it early in the diagnostic workup may improve outcomes in this group of patients.</p>	Fair

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
8	<p>Sivit CJ, Applegate KE, Stallion A, Dudgeon DL, Salvator A, Schluchter M, Berlin SC, Myers MT, Borisa VJ, Weinert DM, Morrison SC, Grisoni ER. (2000)</p> <p>Imaging evaluation of suspected appendicitis in a pediatric population: effectiveness of sonography versus CT.</p> <p><i>AJR Am J Roentgenol</i>,175(4), Oct, pp 977-80</p>	<p>N= 386 pediatric and young adult patients</p> <ul style="list-style-type: none"> <li>- 233 underwent sonography only</li> <li>- 71 underwent CT only,</li> <li>- 82 underwent sonography and CT</li> </ul> <p>F/up: Jun 1996 –April 1999</p>	<p>Helical CT had a significantly higher sensitivity (95% versus 78%, p = 0.009) and accuracy (94% versus 89%, p = 0.05) than graded compression sonography for the diagnosis of appendicitis in children, adolescents, and young adults. The specificity of both techniques was 93%. Twenty of 82 patients who underwent both sonography and CT had discordance between the findings of the two examinations. The CT results were correct in a significantly greater number of patients with discordant examinations (17/20 patients [85%]). CONCLUSION. Helical CT has a significantly higher sensitivity and accuracy than graded compression sonography for the diagnosis of appendicitis in a pediatric and young adult population, particularly in children more than 10 years old.</p>	Poor
9	<p>Simonovsky V (2000)</p> <p>[Detection of acute appendicitis using ultrasonography]</p> <p><i>Rozhl Chir</i>,79(5), May, pp 215-20</p> <p>.</p>	<p>N= 1318 -1199 sonographic examination</p>	<p>Appendicitis was diagnosed if the appendiceal maximal mural thickness was 3 mm or more, or the appendices presented with luminal dilatation due to a large appendicolith or non-expressible fluid. In patients with verified appendicitis (n = 176) sonographic findings on a visualized appendix were correlated with surgical and histopathological findings. In patients who did not have surgery the reference standard was the clinical consensus based follow-up. A pathological appendix was detected in 165 cases of 176 surgically verified ones. The sensitivity of US in detecting appendicitis was 93.7%, the specificity 95.5% and the accuracy 95.2%.</p>	Poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
10	<p>Chen SC, Chen KM, Wang SM, Chang KJ. (1998)</p> <p>Abdominal sonography screening of clinically diagnosed or suspected appendicitis before surgery.</p> <p><i>World J Surg</i>,22(5), May, pp 449-52</p>	<p>Prospective Study</p> <p>N=191 patients</p>	<p>A total of 158 patients (82.7%) with positive findings of appendicitis proceeded to surgery; 18 patients (9.4%) were found to have other diseases, and they were treated for their conditions; and 15 patients (7.9%) with normal screening were discharged from the hospital and were reevaluated 2 weeks later. Only one patient had a false-negative finding. Of the 158 patients undergoing operation, 143 (90.5%) were proved to have appendicitis by the pathologic reports. A total of 32 negative appendectomies (16.8%) were prevented after sonographic examination. Abdominal sonography for detecting acute appendicitis had a sensitivity of 99.3%, a specificity of 68.1%, an accuracy of 91.6%, a positive predictive value of 90.5%, and a negative predictive value of 97.0%. The value of meticulous history-taking, physical examination, and laboratory tests cannot be overemphasized. Our experience suggests that patients with clinically diagnosed or suspected acute appendicitis should routinely undergo abdominal sonography examination, performed by an experienced surgeon, to further decrease the negative appendectomy rates.</p>	Fair
11	<p>Hahn HB, Hoepner FU, Kalle T, Macdonald EB, Prantl F, Spitzer IM, Faerber DR (1998)</p> <p>Sonography of acute appendicitis in children: 7 years experience.</p> <p><i>Pediatr Radiol</i>,28(3), Mar, pp147-51</p>	<p>N= 3859 children</p> <p>F/up: 7-year period (</p>	<p>High-resolution sonography was performed in 3859 children. Of the 610 patients who underwent a laparotomy, 494 had histologically proven acute or perforated appendicitis (prevalence 13%). In these children, sensitivity, specificity and overall accuracy of sonography were 90%, 97% and 96%, respectively. The reasons for false-negative and false-positive results are discussed. CONCLUSION: Although the use of ultrasound to diagnose acute appendicitis in children has excellent results, the decision for surgery remains a clinical one because of the continuing false-negative and false-positive results from sonography.</p>	Poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
12	Zoller WG, Kellner H, Schwerk WB. (1996)  [Value of ultrasound in diagnosis of acute appendicitis]  <i>Bildgebung</i> ,63(2), Jun, pp 78-82	Review  N=13 studies including more than 5,000 patients have been published	showing a sensitivity of 85% and a specificity of 96% if the sonographic examination was performed by an experienced examiner. The rate of negative laparotomies could be decreased to 7%, and possible differential diagnoses could be either confirmed or ruled out by using ultrasound technique. Based on the current literature, real-time sonography plays a major part in the diagnosis of acute appendicitis.	Fair
13	Ramachandran P, Sivit CJ, Newman KD, Schwartz MZ. (1996)  Ultrasonography as an adjunct in the diagnosis of acute appendicitis: a 4-year experience.  <i>J Pediatr Surg</i> , 31(1), jan, pp164-7; discussion 167-9	N=452 children  F/up: Aug 1991-July 1994	The sonographic data were correlated with surgical and pathological findings. Appendicitis was confirmed in 112 of the 452 cases. In 17 of these, the appendix was perforated. In the overall group of 452 children, abdominal ultrasonography had a sensitivity of 90%, specificity of 96%, and accuracy of 95%. There was no significant morbidity in the 11 patients with a false-negative study result. All 11 patients had an uncomplicated appendectomy. There were 11 false-positive results; 10 of these patients had a negative laparotomy result (negative laparotomy rate, 8.9%). For the two groups, the sensitivity and specificity of ultrasonography in the diagnosis of appendicitis were equivalent (group 1: 88% sensitivity, 96% specificity; group 2: 92% sensitivity, 97% specificity). On the basis of the high sensitivity and specificity rates, ultrasonography of the appendix can be a useful adjunct to standard examination in the diagnosis of acute appendicitis.	Poor

**EVIDENCE TABLE – USE OF ULTRASOUND DIAGNOSIS BREAST CANCER – EFFECTIVENESS**

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
1	<p>The early detection and diagnosis of breast cancer: a literature review – an update</p> <p>New Zealand Health Technology Assessment 1999; 2(2)</p>	HTA Report	Ultrasound is very sensitive in the investigation of breast lesions among younger women (under 35 years) and is recommended as the first radiology investigation for these women	Good
2	<p>Moon WK, Noh DY, Im JG (2002)</p> <p>Multifocal, multicentric and contralateral breast cancers: bilateral whole-breast US in the preoperative evaluation of patients</p> <p><i>Radiology</i>, 224(2), Aug, pp 569-76</p>	N= 201 patients	<p>In ipsilateral breast, US depicted 194 of 201 foci of invasive cancer and 52 of 69 foci of ductal carcinoma in situ (DCIS), whereas mammography and physical examination depicted 173 foci of invasive cancer and 56 foci of ductal carcinoma in situ (DCIS)</p> <p>In contralateral breast US depicted 11 of 12 foci of invasive cancer and 4 of 7 foci of DCIS whereas mammographically and physical examination depicted 6 foci of invasive and 5 foci of DCIS</p> <p>The sensitivity and specificity of prospective classification of 77 solid lesion detected at US alone were 100% and 51% respectively.</p>	Poor
3	<p>Hou MF, Chuang HY, Ou-Yang F, Wang CY, Huang CL, Fan HM, Chuang CH, Wang JY, Hsieh JS, Liu GC, Huang TJ (2002)</p> <p>Comparison of breast mammography, sonography and physical examination for screening women at high risk of breast cancer in Taiwan</p> <p><i>Ultrasound Med Biol</i>, 28(4), Apr, pp 415-20</p>	N= 935 women over 35 years old, who were relatives of breast cancer patients	<p>Of the cancers, 18 including 16 invasive cancers and 3 noninvasive cancers were detected by sonography. In contrast, only 11 invasive cancers, were detected by mammography and 7 by physical examination.</p> <p>There were only 14 cancers detected by a combination of mammography and physical examination. 7 additional cancers were detected when sonography was added.</p> <p>The sensitivity of sonography was 90.4%, which was higher than mammography (52.4%) and physical examination (33.3%)</p> <p>This indicates that sonography is a more accurate screening tool for breast cancer in the high risk group. It is superior to mammography and physical examination for the screening of Taiwanese high risk female relatives of breast cancer index cases.</p>	Poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
4	Kaiser JS, Helvie MA, Blacklaw RL, Roubidoux MA (2002)  Palpable breast thickening : role of mammography and US in cancer detection  <i>Radiology</i> , 223(3), Jun, pp 839-44	N= 123 consecutive cases of breast thickening  F/up: 1 years period	Mammography sensitivity for invasive cancer detection was 60% (3/5), specificity WAS 94% (102/108) Sensitivity of us alone was 100% (2/2 Cases), Specificity was 96% (65/68 Cases)	Poor
5	Gunnhan-Bilgen I, Ustun EE, Memis A (2002)  Inflammatory breast carcinoma: mamograhic, ultrasonographic, clinical, and pathologic findings in 142 cases  <i>Radiology</i> ,223(3), Jun, pp 829-38	Retrospective review  N=2,733 women  F/up: Jan 1998-May 2000	US showed changes in carcinomas: skin thickening, 96% (n=136), parenchymal echogenicity changes, 73% (n= 104); dilated lymphatic channels 68% (n=96) solid mass 80% (n=114), pectoral muscle invasion, 10% (n=14), focal areas of parenchymal acoustic shadowing, 37% (n=52) and axillary lymphadenopathy 3%(n=104) US is helpful not only in depiction of masses masked by the edema pattern but also in demonstration of skin and pectoral muscle invasion and axillary involvement	Fair
6	Taylor KJ, Merrit C, Piccoli C, Schmidt R, Rouse G, Fornage B, rubin E, Georgian-Smith D, Winsberg F, Goldberg B, Medelson E (2002)  Ultrasound as a complement to mammography and breast examination to characterize breast masses  <i>Ultrasound Med Biol</i> , 28(1), Jan, pp 19-26	Multicenter Study	The addition of US increased the specificity from 51.4% to 66.45 at a prevalence of 31.3% malignancy And significantly improved the performance over mammography alone in women < 55 year old,(p=0.049), > 55 year (p=0.029), masses <1 cm (p=0.016) and masses > 1 cm (p=0.016). These result show that the addition of US to mammography alone could substantially reduce the number of breast biopsies for benign disease.	Poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
7	Dennis MA, Parker SH, Klaus AJ, Stavros AT, Kaske TI, Clrk SB (2001)  Breast biopsy avoidance; the value of normal mammograms and normal sonograms in the setting of a palpable lump  <i>Radiology</i> ,219(1), Apr, pp 186-91	Retrospective study  N= 600 lump in 486 women with no focal ultrasonographic mass or mammography finding in the area of clinical concern  F/up: 2 years	Breast biopsy may be avoided in women with palpable abnormalities when both US and mammography depict normal tissue at the lump site.	Poor
8	Satake H, Shimamoto K, Sawaki A, Niimi R, Ando Y, Ishiguchi T, Ishigaki T, Funahasi H (2000)  Role of ultrasonography in the detection of intraductal spread of breast cancer: correlation with pathologic findings, mammography and MR imaging  <i>Eur Radio</i> , 10(11), pp1726-32	N= 46 patient	The sensitivity, specificity and accuracy rates in detection of in detection of intraductal spread were 55, 100 and 72% respectively. In comedo type, MMG could diagnoses the extent of intraductal spread more accurately compared with US examination.  Current US examination is useful in depicting the intraductal spread of breast cancer, however, US has a tendency to underestimate intraductal component of comedo type compared with MMG and MRI	Poor
9	Buchberger W, Niehoff A, Obrist P, DeKoekkoek-Doll P, Dunser M (2000)  Clinically and mammographically occult breast lesions: detection and classification with high-resolution sonography <i>Semin Ultrasound CT MR</i> , Aug; 21(4), pp 325-36	N= 8970 women	The overall prevalence of cancers detected with screening sonography was 0.41% and the proportion of sonographically detected cancers to the total number of nonpalpable cancers was 22%. The mean size of invasive cancers detected only by sonography was 9.1 mm, and was not statistically different from the mean size of invasive cancer detected by mammography. The sensitivity of prospective sonographic classification for malignancy was 100% and the specificity was 31%. The use of high resolution sonography as an adjunct to mammography in women with dense breasts may lead to detected cancer	Poor



No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
10	<p>Sieluzicka J, Twarkowski P, Trawinski J, Skawina W, Zabkowska K, Gornasiowa M, Nowicki G (2000)</p> <p>Ultrasonographic assessment in differential diagnosis of non-palpable tumors</p> <p><i>Pol Merkuriusz Lek</i>,8(45), Mar, pp 133-5</p>	<p>N= 121 women with non-palpable breast nodules (NPBN)</p>	<p>Based on the US examination findings, the disease was diagnosed as malignant in 6 cases, as benign in 90 and in 28 cases it was unclassified.</p> <p>15 patients underwent surgery.</p> <p>In 8 the disease was histopathologically confirmed s carcinoma, 7 were benign lesions</p>	Poor
11	<p>Georgian-Smith D, Taylor KJ, Madjar H, Goldberg B, Merritt CR, Bokobsa J, Rubin E, Mendelson EB, Fornage BD, Rouse G, Wadden NA, Dewbury KC, Cosgrove DO, Schimidt R (2000)</p> <p>Sonography of palpable breast cancer</p> <p><i>J Clin Ultrasound</i>, 28(5), Jun, pp 211-6</p>	<p>Retrospectively</p> <p>N=1,346 masses</p>	<p>Sonography detected all 293 palpable malignant lesion (95% confidence interval for sensitivity 99-100%)</p> <p>Eighteen lesions were mammographically occult</p> <p>The median lesion size as determined by sonography was 1.8 cm, for the lesions that were mammographically occult, the median size was 1.6 cm</p> <p>All palpable malignant breast lesions were visible by sonography in patients in whom a biopsy was recommended.</p> <p>The false-negative rate of sonography for equivocal palpable abnormalities is determined prospectively, sonography cannot be accurately applied to rule out malignancy in this setting.</p>	Fair
12	<p>Evans N, Lynos K (2000)</p> <p>The use of ultrasound in the diagnosis of invasive lobular carcinoma of the breast less than 10 mm in size</p> <p><i>Clin Radiol</i>, 55(4), Apr, pp 261-3</p>	<p>Retrospective</p> <p>F/up: 9 years</p>	<p>16 cases of pure small invasive lobular carcinoma (ILC) were diagnosed during the study period.</p> <p>14 of the 15 patient who underwent an ultrasound examination had abnormal findings</p> <p>high sensitivity for ultrasound in the detection of small ILC</p>	Fair

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
13	<p>Finlayson CA, MacDermott TA (2000)</p> <p>Ultrasound can estimate the pathologic size of infiltrating ductal carcinoma</p> <p><i>Arch Surg</i>, 135(2), Feb , pp158-9</p>	<p>Retrospective case series</p> <p>N=35</p>	<p>Size measured by US ranged from 0.5 to 5 cm. the mean difference of size measured by US vs pathologic size was 0.4 cm (<math>p=.01</math>). When only tumor with invasive ductal histology are evaluated, the mean difference in size is 0.33 cm (<math>P=0.008</math>). the range of difference was -1.6 cm to + 0.42 cm..17% of invasive ductal tumor were underestimated by &gt; than 1 cm, none were underestimated by &gt; than 2 cm. US tends to underestimate the pathologic tumor size, 83% of invasive ductal tumor fall within a 1 cm and 100% fall within a 2 cm extension of the US measured tumor size. Therefore, it is possible to use US to monitor the extent of treatment size when developing very localized therapeutic tools.</p>	Fair
14	<p>Tresserra F, Feu J, Grases PJ, Navarro B, Alegret X, Fernandez-Cid A (1999)</p> <p>Assessment of breast cancer size: sonographic and pathologic correlation</p> <p><i>J Clin Ultrasound</i>, 27(9), Nov-Dec, pp 485-91</p>	<p>Retrospective</p> <p>N=174 cases</p>	<p>Sonographic measurement of tumor size correlated well with size measured after surgery (<math>r=0.72</math>; 96% confidence interval, 0.64-0.78).The correlation was higher for lesions of 20 mm or less in their longest diameter than for larger lesions.He intramodal size correlation was lower for tumors with extensive intraductal component than for tumors without an extensive intraductal component. The sonographic versus pathologic correlation of tumors size was less accurate when several lesions were present. Sonography is useful for presurgical assessment of tumor size in patients with breast cancer, especially for single lesions of 20 mm or less and without an extensive intraductal component.</p>	Fair
15	<p>Buchberger W, Dekoekkoek-Doll P, Springer P, Obrist P, Dunser M (1999)</p> <p>Incidental findings on sonography of the breast: clinical significance and diagnostic workup</p> <p><i>AJR Am J Roentgenol</i>,173(4), Oct, pp 921-7</p>	<p>Prospective study</p> <p>N= 6133 asymptomatic women</p>	<p>The use of high resolution sonography as an adjunct to mammography in women with dense breasts may lead to detection of a significant number of otherwise occult malignancies that are no different in size from nonpalpable mamographically detected lesions. Prospective classification of these lesions based on sonographic characteristics results in a significant reduction in number of unnecessary biopsies perform</p>	Fair

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
16	<p>Kaplan SS (2001)</p> <p>Clinical utility of bilateral whole-breast US in the evaluation of women with dense breast tissue</p> <p><i>Radiology</i>, 221(3), Dec, pp 641-9</p>	<p>N= 1862 patients</p> <p>F/up: July 1998 &amp; April 2000</p>	<p>Bilatera; whole-breast US, when performed in patients with dense (BI-RADS category 3 or 4 density) breast tissue, is useful in detecting breast cancer not discovered with mammography or clinical breast examination.</p> <p>The 0.3% cancer detection rate compares favorably with that of screening mammography and with that in previously published studies involving bilateral whole-breast US</p>	Poor
17	<p>Rissanen TJ, Makarainen HP, Apaja-Sarkkinen MA, Lindholm EL (1995)</p> <p>Mammography and ultrasound in the diagnosis of contralateral breast cancer</p> <p><i>Acta Radiol</i>, 36(4), Jul, pp 358-66</p>	<p>N=31 patients</p>	<p>Mammography was more sensitivity than clinical examination or US in detecting contralateral breast cancer, the sensitivity of mammography being 81%.</p> <p>39% of the contralateral cancers were nonpalpable, and all were first detected at mammography. No cancer were depicted by US alone.</p> <p>US provided complementary information about palpable masses in 50% of the cases in which the mammographic finding was difficult to interpret.</p>	Poor
18	<p>Meden H, Neues KP, Roben-Kampken S, Kuhn W (1995)</p> <p>A clinical mammographic, sonographic and histologic evaluation of breast cancer</p> <p><i>Int J Gynaecol Obstet</i>, 48(2), Feb, pp 193-9</p>	<p>Clinical trial</p> <p>N= 160 patients with breast carcinoma</p>	<p>The average tumor diameter determined by mammography, sonography and palpation was 23.8, 26.1 and 30.6 mm respectively</p> <p>Mammography was capable for detecting 94.5% of breast carcinomas, breast sonography 91% and palpation 87.5.</p> <p>The combination of mammography and sonography or mammography and palpation detected 99% of carcinomas and sonography and palpation 95 % of carcinomas</p>	Poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
19	<p>Michigishi T, Nakajima K, Shuke N, Miyauchi T, Kuji I, Aburano T, Tanami N, Hisada K, Noguchi M, Mizukami Y (1992)</p> <p>Evaluation of the internal mammary nodes by lymphoscintigraphy and ultrasonography in patients with breast cancer</p> <p><i>Nippon Igaku Hoshasen Gakkai Zasshi</i>,52 (6), Jun, 25737-43</p>	<p>Histological examination</p> <p>N=10 patients had metastases (positive group), 47 did not (negative group)</p>	<p>On sonography, the thickness of the affected sonolucent internal mammary area was measured. The thickness of the affected side was 6 mm or more in two patients of the positive group and only one of the negative group. The difference in thickness of the between the affected side and the healthy side was 3 mm or more in 4 patients of the positive group. And was less than 3 mm in all of the negative group. A difference in thickness of more than 3 mm between the two sides was extremely significant. Sonography is valuable in detecting internal mammary lymph node metastases, sonography as an efficient diagnostic modality for IMN metastases</p>	Poor
20	<p>Rosner D, Blair D (1985)</p> <p>What ultrasonography can tell in breast masses that mammography and physical examination cannot</p> <p><i>J Sur Oncol</i>, 28(4), Apr, pp308-13</p>	<p>Prospective study</p> <p>N= 400 patients</p>	<p>The high resolution and accuracy of ultrasonography vs mammography in the diagnosis of cystic masses was 96% vs 42% and fibrocystic masses 84% vs 74%. Led to a substantial reduction of surgical biopsies in favor of aspiration or follow up policy, particularly when physical examination and mammography were inconclusive. Breast cancers were accurately diagnosed in 73% by sonography and 84% by mammography. The major limitation of ultrasonography was noticed in the diagnosis of minimal breast cancer due to its inability to visualize microcalcifications. The importance of ultrasonography in the diagnosis and therapeutic decision of cystic and fibrocystic masses but cannot substitute mammography in early detection of breast carcinoma.</p>	Poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
21	<p>Hieken TJ, Harrison J, Herreros J, Velasco JM (2001)</p> <p>Correlating sonography, mammography, and pathology in the assessment of breast cancer size</p> <p><i>Am J Surg</i>, 182(4), Oct, pp 351-4</p>	<p>Prospective</p> <p>N= 180 invasive breast cancer patients examined by mammography &amp; ultrasonography. 146 eligible patients had tumors visualized by both modalities</p>	<p>69% cases, US was better than or equivalent t mammography in determining tumor size, Both underestimated tumor size; mean underestimation was 3.8 +/- 0.7 mm by US and 3.5 +/- 0.9 mm (1.7 mm) by .Mammography..Maximal tumor dimension was accurate within 5 mm in 65% of cases by mammography and 57% of cases by US For mammography determined size (versus pathologic size) correlation, r, was 0.4 ad for US it was 0.63 and improved for only T1 and T2 tumors .US is more accurate than mammography in assessing breast cancer size</p>	Fair
22	<p>Kolb TM, Lichy J, Newhouse JH. (2002)</p> <p>Comparison of the performance of screening mammography, physical examination, and breast US and evaluation of factors that influence them: an analysis of 27,825 patient evaluations.</p> <p><i>Radiology</i>, 225(1), Oct, pp 165-75</p>	<p>N=11, 130 asymptomatic women underwent 27,825 screening sessions</p>	<p>Screening breast US increased the number of women diagnosed with nonpalpable invasive cancer by 42%. Mammography sensitivity declined significantly with increasing breast density and in younger women with dense breasts. Mammography and US together had significantly higher sensitivity (97%) than did mammography and physical examination (PE)74%</p> <p>Tumors detected at mammography and or US were significantly smaller and of lower stage than those detected at PE</p> <p>Conclusion</p> <p>Mammography sensitivity for breast cancer declines significantly with increasing breast density and is independently higher in older women with dense breasts. Addition of screening US significantly increases detection of small cancers and depicts significantly more cancers and at smaller size and lower stage than does PE</p>	Poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
23	<p>Saarenmaa I, Salminen T, Geiger U, Heikkinen P, Hyvarinen S, Isola J, Kataja V, Kokko ML, Kokko R, Kumpulainen E, Karkkainen A, Pakkanen J, Peltonen P, Piironen A, Salo A, Talviala ML, Haka M. (2001)</p> <p>The effect of age and density of the breast on the sensitivity of breast cancer diagnostic by mammography and ultasonography.</p> <p><i>Breast Cancer Res Treat</i>, 67(2), May, pp 117-23</p>	<p>Evaluation Studies</p> <p>572 consecutive histological and 5 cytologically verified breast cancer cases</p>	<p>Sensitivity of mammography increased by age (density-adjusted OR = 0.2, 95%, CI 0.1-0.5) in age group 26-49 compared to age group 60-92) and with fattiness of the breast (age-adjusted OR= 0.4, 95%, CI 0.1-1.0 for dense breast parenchyma in tumour area compared to fatty breast). Sensitivity of US was inversely related to age (density-adjusted OR = 2.3, 95%, CI 1.0-5.2 in age group 26-49 compared to age group 60-92) and directly related with fattiness of breast (age-adjusted OR = 0.5, 95%, CI 0.2-0.9 by dense breast parenchyma in tumour area compared to fatty breast). Density in the tumour area compared to total breast density was related only marginally better sensitivity both of mammography (0.4 vs. 0.6) and of US (0.5 vs. 0.6). CONCLUSION: Sensitivity of both mammography and sensitivity of US are independently related both to the age of the patient and to the density of the breast. The effect of age is inverse and that of density parallel between mammography and US on sensitivity. The effect of overall breast density was close to the effect of density at the site of the tumour on the sensitivity of both mammography and US.</p>	Poor
24	<p>Rizzatto GJ (2000)</p> <p>Towards a more sophisticated use of breast ultrasound.</p> <p><i>Eur Radiol</i>, 11(12), pp 2425-35</p>	<p>Review</p>	<p>Many factors are now in favor of targeted US screening in dense and complex breasts and in high-risk patients. Screening sensitivity is significantly increased. Most of these US-detected tumors are small enough to be curable. Mammography and sonography together are a unique problem-solving and cost-effective tool. They can easily guide fine aspirations or larger biopsies reducing the cost of unnecessary surgical procedures. Accurate US investigations facilitate the surgical approach to a very conservative and cosmetic operation. High-resolution sonography can demonstrate the intraductal spread of tumors and their multiple foci more easily than mammography, but US diagnosis is less sensitive than magnetic resonance mammography in the evaluation of the real tumoral extent. Sonography can easily explore the different nodal chains. US assessment is also important as sonography is very sensitive in patients with extensive nodal involvement that might result negative at the sentinel node procedure.</p>	Poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
25	Partik B, Mallek R, Rudas M, Pokieser P, Wunderbaldinger P, Helbich TH (2001)  Malignant and benign disease of the breast in 41 male patients: Mammography, sonography and pathohistological correlations  <i>Rofo Fortschr Geb Rontgenstr Neuen Bildgeb Verfahr</i> ; 173 (11), Nov, pp 1012-8	Retrospectively Evaluation study  N=41 male patients  F/up: 6 year period	The sensitivity, specificity and accuracy of mammography in differentiation of benign versus malignant disease were 92%, 89% and 90% respectively. Additional sonography did not change these results. However sonography increased diagnostic confidence in 18.2% of suspicious lesions	Poor
26	Chapellier C, Balu-Maestro C, Bleuse A, Ettore F, Bruneton JN (2000)  Ultrasonography of invasive lobular carcinoma of the breast: sonographic patterns and diagnostic value: report of 102 cases  <i>Clin Imaging</i> ; 24(6), Nov-Dec, pp 333-6	Retrospective evaluation study  N=102 patients affected by documented invasive lobular carcinoma (ILC)	At US, 5 proven tumors were not visualized (sensitivity 95%) while the remaining 97 showed sonographic images that are considered typically malignant. There were 16 subclinical tumors, and in 2 of the four in which mammography showed an indeterminate lesion, US demonstrated a malignant pattern. All the palpable tumors that were not detected mammographically were demonstrated by US. In 13 of the 102 patient (12.7%), the correct diagnosis of malignancy was established by US. Conclusion US play a very important role in the diagnosis of ILC, whenever in a patients with positive clinical findings, the mammography is negative or the mammographic features are equivocal.	Poor
27	Hashimoto BE, Kramer DJ, Picozzi VJ (2001) High detection rate of breast ductal carcinoma in situ calcifications on mammographically directed high-resolution sonography  <i>J Ultrasound Med</i> , 20(5), May, pp 501-8	Retrospective review  N= 18 patients	the calcifications were associated with sonographically detected malignant masses, and in 3 of the 18 patients the calcifications were within focally dilated ducts. Lesions that had masses or dilated ducts visible on sonography presented 9 of 11 of the grade 3 neoplasmas and only 2 of 7 of the grade 1 and 2 tumors. This difference was statistically significant ductal carcinoma in situ may appear on sonography as calcifications, masses or focally dilated ducts. Those lesions that were associated with masses, or dilated ducts on sonography were more likely high-grade histologic specimens	Poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
28	<p>Rissanen TJ, Apaja-Sarkkinen MA, Makarainen HP, Heikkinen MI (1997)</p> <p>Ultrasound-guided fine needle aspiration biopsy in the diagnosis of breast cancer recurrence after mastectomy.</p> <p><i>Acta Radiol</i>, 38(2). Mar, pp 232-9</p>	<p>N= 98</p>	<p>FNAB yielded a representative aspirate in 92.6% of cases. The sensitivity, specificity and overall accuracy of FNAB cytology were 96.1%, 89.8% and 92.6% respectively. US and FNAB cytology were complementary methods in recurrent cancer diagnosis. The cytologic examination increased the specificity of US. The only recurrent tumor which appeared benign both sonographically and cytologically was removed because of a suspicious finding at palpation. FNAB cytologic diagnosis was found to have a clinical impact in 92.2% of the recurrent cases. CONCLUSION: US-guided FNAB provided an accurate adjunct to clinical examination and mammography for diagnosing and excluding breast cancer recurrence after mastectomy.</p>	Poor
29	<p>Jacob D, Brombart JC, Muller C, Lefebvre C, Massa F, Depoerck A. (1997)</p> <p>[Analysis of the results of 137 subclinical breast lesions excisions. Value of ultrasonography in the early diagnosis of breast cancer]</p> <p><i>J Gynecol Obstet Biol Reprod (Paris)</i>, 26(1), pp 27-31</p>	<p>N= 8,489 individual screening mammographies. Ultrasonography was routinely performed for characterization of a mass detected by mammography and also in normal breast with dense, non-radiolucent tissue.</p> <p>F/up: 1991 to 1994</p>	<p>The histopathologic findings were as follow: invasive ductal carcinoma (IDC) 40 cases (59%), invasive lobular carcinoma (ILC) 7 cases (10%), ductal carcinoma in situ 21 cases (31%). Infraclinic cancer was identified by mammography alone in 45% of cases, by mammography and sonography in 43.2% of cases, by sonography alone in 11.8% of cases. About 31% of infraclinic cancer occur prior to the age of 50 (age range: 29-72, mean: 54). Cancer less than 10 mm in diameter were found in 57.5% of lesions. Axillary dissection was performed in 46 cases of invasive cancer, with a incidence of axillary node metastases of 15%. CONCLUSION: The combination of mammography and ultrasonography is effective to detect a greater number of occult breast cancers and we recommend ultrasonography not only for evaluation of a mass detected by mammography but also in radiographically dense non-radiolucent breast lesions.</p>	Poor



No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
30	Escolano E, Tournegros JM, Le Marc'Hadour F, Bernard P. (1997)  [Diagnostic difficulties in infiltrating lobular breast cancer: value of ultrasonography. 33 cases]  <i>J Gynecol Obstet Biol Reprod (Paris)</i> , 26(8), pp 781-8.	N=33	Ultrasonography disclosed only 12% of false negatives. Sonographic appearance, especially fine needle aspirations or microbiopsy under ultrasonographic control, allows modification of mammographic and clinical diagnosis errors. Thus, this method appears of importance in diagnosis of ILC.	Poor
31	Skaane P. (1999)  Ultrasonography as adjunct to mammography in the evaluation of breast tumors.  <i>Acta Radiol Suppl.</i> , 420, pp 1-47	Prospective	The impact of US in mixed cancer populations is limited. US is, however, a valuable adjunct to mammography in patients with nonconclusive mammographic findings. Negative predictive values on US approaching 100% may be achieved using strict criteria for a benign diagnosis. A considerable interobserver variation in the US interpretation is a limiting factor for the potential of breast US in the differentiation of benign and malignant breast tumors.	Fair
32	Hergan K, Haid A, Zimmermann G, Oser W. (1996)  [Preoperative axillary ultrasound in breast carcinoma: value of the method in routine clinical practice]  <i>Ultraschall Med.</i> , 17(1), Feb, pp 14-7.	N=191	For detecting lymph node metastases sensitivity was 68.2% in all T-stages and 50% in T1-stages with a specificity of 100%. Classification of the axillary status (positive or negative for lymph node metastases) is possible in 90.5% for all T-stages and 94.9% for T1-stages. Microscopic and small lymph node metastases are missed by ultrasound. Compared to axillary palpation, sonography is better. CONCLUSION: Preoperative axillary sonography is an useful diagnostic method even when done routinely. If further criteria are considered, axillary dissection could be avoided in some patients	Poor
33	Hieken TJ, Velasco JM. (1998)  A prospective analysis of office-based breast ultrasound.  <i>Arch Surg.</i> , 133(5), May, 504-7;	N=653	These data suggest that ultrasonography is a useful adjunct to clinical and mammographic evaluation of breast disease. Breast ultrasound identifies cysts, aids in differentiating benign from malignant lesions, and facilitates office needle biopsy of nonpalpable abnormalities, permitting timely and cost-effective patient care.	Poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
34	Satake H, Shimamoto K, Sawaki A, Niimi R, Ando Y, Ishiguchi T, Ishigaki T, Yamakawa K, Nagasaka T, Funahashi H. (2000)  Role of ultrasonography in the detection of intraductal spread of breast cancer: correlation with pathologic findings, mammography and MR imaging.  <i>Eur Radiol.</i> , 10(11), pp1726-32.	N=46	In comedo type, MMG could diagnose the extent of intraductal spread more accurately compared with US examination. Magnetic resonance imaging comparison was available in 25 cases. Magnetic resonance imaging depicted intraductal extension as an enhanced area during the early phase of a contrast enhancement study with a sensitivity of 93%. Ultrasound and MRI were closely related in terms of morphologic characteristics: the ductal type of US image correlated well with linear enhancement on MRI, whereas the distorted type correlated with regional or segmental enhancement. Current US examination is useful in depicting the intraductal spread of breast cancer; however, US has a tendency to underestimate intraductal component of comedo type compared with MMG and MRI.	Poor

#### EVIDENCE TABLE -- GALLBLADDER

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
1	Pandey M, Sood BP, Shukla RC, Aryya NC, Singh S, Shukla VK (2000)  Carcinoma of the gallbladder: role of sonography in diagnosis and staging  <i>J Clin Ultrasound</i> , 28(5), Jun, pp 227-32	Retrospective  N=203 cases	A mass in the gallbladder and gallbladder wall thickening (>12 mm) were cardinal sonographic finding of carcinoma. Sonography was highly accurate for detecting mass lesions, gallstones, liver infiltration, metastasis and ascites. However, visualization of lymph nodes, common bile duct infiltration and peritoneal dissemination was poor. Sonography was found to be a good diagnostic toll for carcinoma of the gallbladder; however, its sensitivity was poor for staging nodal spread of the disease.	Fair

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
2	<p>Brink JA, Simeone JF, Mueller PR, Saini S, Tung GA, Spell NO, Ferrucci JT (1989)</p> <p>Routine sonographic technique fail to quantify gallstone size and number : a retrospective study of 111 surgically proved cases</p> <p><i>AJR Am J Roentgenol</i> , 153(3), Sep, pp 503-6</p>	<p>Retrospective</p> <p>N=111</p>	<p>The number and size of stones found on pathologic examination were correlated with the results of image analysis. In patients with more than one stone, observable size differences were recorded if the smallest stone diameter was less than 50% of the largest stone diameter. Estimates of gallstones size and number from preoperative sonograms were correct in only 23(21%) of 111 cases. Stone size and number were overestimated as often as they were underestimated. Stones of a uniform size were recognized correctly in 59(92%) of 64 cases. Stone of two different sizes were correctly identified only 14(30%) of 47 cases , the second, smaller stones were missed in 26 (79%) of 33 cases</p>	Fair
3	<p>Kalimi R, Gecelter GR, Caplin D, Brickman M, Tronco GT, Love C, Yao J, Simms HH, Marini CP. (2001)</p> <p>Diagnosis of acute cholecystitis: sensitivity of sonography, cholescintigraphy, and combined sonography-cholescintigraphy.</p> <p><i>J Am Coll Surg</i>, 193(6), Dec, pp 609-13</p>	<p>Retrospective review</p> <p>N= 132 patients: Group 1 (Gp1, n = 50) US alone, group 2 (Gp2, n = 28) Cholecystoscintigraphy (HIDA) scan alone, and group 3 (Gp3, n = 54) both US and HIDA.</p>	<p>The sensitivity of US, HIDA, and combined US/HIDA as diagnostic modalities for acute cholecystitis was referenced to histopathologic confirmation. Sensitivity was 24 of 50 (48%), 24 of 28 (86%), and 49 of 54 (90%) for US, HIDA, and the combination of US/HIDA, respectively. CONCLUSIONS: HIDA scan is a more sensitive test than US in diagnosing patients with AC. Based on the results of this study, we recommend that HIDA scan should be used as the first diagnostic modality in patients with suspected acute cholecystitis; US should be used to confirm the presence of gallbladder stones rather than to diagnose AC.</p>	Fair

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
4	Chen CH, Tseng LJ, Yang CC, Yeh YH. (2001)  Preoperative evaluation of periampullary tumors by endoscopic sonography, transabdominal sonography, and computed tomography.  <i>J Clin Ultrasound</i> , 29(6), July-Aug, pp 313-21	Evaluation Studies  N=Seventy-four consecutive patients with presumed periampullary tumors were evaluated by EUS, US, and CT  F/up: 3.25-year period	EUS was the most sensitive modality in the detection (EUS, 97%; US, 24%; and CT, 39%; $p < 0.001$ for EUS versus US or CT) and T classification (EUS, 72%; US, 11%; CT, 22%; $p < 0.001$ for EUS versus US or CT) of periampullary tumors. EUS also had better sensitivity than US in detecting lymph node metastasis from periampullary cancers (EUS, 47%; US, 7%; and CT, 33%; $p = 0.02$ for EUS versus US; $p = 0.7$ for EUS versus CT). The accuracy of EUS in determining the T classification (without stent, 81%; with stent, 65%) and N classification (without stent, 80%; with stent, 70%) tended to decrease in the presence of an endobiliary stent, but the differences were not significant. EUS was the most sensitive modality in demonstrating vascular involvement (EUS, 100%; US, 0%; and CT, 33%; $p = 0.002$ for EUS versus US; $p = 0.03$ for EUS versus CT) but was not significantly different in detecting distant metastasis (EUS, 11%; US, 44%; and CT, 44%). CONCLUSIONS: EUS is superior to US and CT in the local assessment of periampullary tumors. The staging accuracy of EUS is minimally but not significantly affected by the presence of an endobiliary stent	Poor
5	Venkataramu NK, Sood BP, Gupta S, Gulati M, Khandelwal N, Suri S. (1999)  Ultrasound-guided fine needle aspiration biopsy of gall bladder malignancies.  <i>Acta Radiol</i> , 40(4), Jul, pp 436-9	N=142 patients suspected to have gall bladder malignancies underwent FNAB under real-time US guidance.	On initial FNAB, 115 patients were diagnosed to have malignancy. In the remaining 27 patients, aspirates on first FNAB showed either inflammatory pathology (n=14) or the sample was suspicious of malignancy (n=7), or the aspirates were non-representative (n=6). Of these 27 patients, 13 underwent repeat FNAB because of the high suspicion of malignancy and 12 of them showed malignancy. The FNAB diagnosis of inflammatory disease of 7 patients was confirmed on subsequent surgery and 8 patients were lost to follow-up. Thus, a total of 127/142 were diagnosed to have gall bladder malignancy. Adenocarcinoma was the most common malignancy (89.76%). No procedure-related complications were encountered. CONCLUSION: US-guided FNAB is a safe and accurate technique to diagnose gall bladder malignancy. Either a repeat FNAB or surgical biopsy is recommended when the suspicion of malignancy is high and the initial FNAB is negative.	Poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
6	<p>Pezzilli R, Billi P, Barakat B, D'Imperio N, Miglio F (1999)</p> <p>Ultrasonographic evaluation of the common bile duct in biliary acute pancreatitis patients: comparison with endoscopic retrograde cholangiopancreatography.</p> <p><i>J Ultrasound Med</i>, 18(6), Jun pp 391-4</p>	N=45 patients	<p>Ultrasonography showed gallstones in 33 patients and sludge of the gallbladder in seven patients. In the common bile duct, lithiasis was found in two patients and sludge in 25. Endoscopic retrograde cholangiopancreatography showed choledocolithiasis in eight patients and sludge of the common bile duct in 32. In 27 cases (60%) concordance occurred between ultrasonographic and endoscopic retrograde cholangiopancreatographic detection of lithiasis or sludge of the common bile duct. The average diameter of the common bile duct determined by sonography was significantly smaller than that obtained by endoscopic retrograde cholangiopancreatography. The evaluation of this parameter indicated that a good correlation existed between the values obtained with the two techniques. Both ultrasonography and endoscopic retrograde cholangiopancreatography can provide reliable measurements of the common bile duct diameter. Ultrasonography is the technique of choice in the initial investigation of patients with biliary acute pancreatitis.</p>	Poor
7	<p>Bach AM, Loring LA, Hann LE, Illescas FF, Fong Y, Blumgart LH. (1998)</p> <p>Gallbladder cancer: can ultrasonography evaluate extent of disease?</p> <p><i>J Ultrasound Med</i>, 17(5), May, pp303-9</p>	N=35	<p>Masses in the gallbladder or gallbladder fossa were present at surgery in 26 patients; 22 of these masses were shown by sonography. Sonography identified six of nine cases of pathologically confirmed liver metastases, 11 of 14 cases of bile duct involvement, and two of three cases of portal venous involvement by tumor. Sonography revealed lymph node metastases in only five of 14 patients. None of the 12 cases with peritoneal metastases was identified sonographically. Sonography correctly identified 15 of 16 patients with potentially resectable disease and seven of 19 patients with advanced disease. Twelve patients with advanced disease were under-staged: nine had peritoneal metastases, two had liver metastases, and one had celiac adenopathy, which was not shown by sonography. In conclusion, sonography is reliable in the detection of a primary gallbladder mass or of local extension of tumor into the liver. However, sonographic findings do not accurately reflect the full extent of disease, and sonography is particularly limited in the diagnoses of metastases to the peritoneum and lymph nodes.</p>	Poor

**EVIDENCE TABLE - THYROID**

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
1	Summaria V, Mirk P, Costantini AM, Maresca G, Ardito G, Bellantone R, Marano P. (2001)  [Role of Doppler color ultrasonography in the diagnosis of thyroid carcinoma]  <i>Ann Ital Chir</i> ,72(3), May -Jun , pp 277-82	N=78 patients	Color Flow Doppler Sonography has an useful role in the assessment of thyroid nodules and it may provide information highly predictive for malignancy, above all when multiple, sonographic and vascular patterns are contemporaneously present in a thyroid nodule.	Poor

**EVIDENCE TABLE – USE OF ULTRASOUND IN UROLOGY**

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
1	Weber DM, Rosslein R, Fliegel C. (2000)  Color Doppler sonography in the diagnosis of acute scrotum in boys.  <i>Eur J Pediatr Surg</i> ;10(4), Aug, pp 235-41	Review  N= 65 consecutive patients	Sonography and color Doppler sonography helped to differentiate epididymitis and torsion of a testicular appendage as a basis for further investigations and correct conservative therapy. In detecting a testicular torsion, color Doppler sonography yielded a positive predictive value of 73%, a sensitivity of 100% and a negative predictive value of 100%. We therefore conclude, that Doppler sonography can reliably rule out testicular torsion so that routine scrotal exploration in cases of acute scrotum is no longer necessary. By reducing the number of emergency operations and hospitalization days, color Doppler sonography can cut down the total cost of managing acute painful scrotum in boys.	Fair

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
2	<p data-bbox="237 264 552 345">Agrawal A, Pai D, Ananthakrishnan N, Smile SR, Ratnakar C. (2000)</p> <p data-bbox="237 370 552 451">Clinical and sonographic findings in carcinoma of the penis.</p> <p data-bbox="237 475 552 532"><i>J Clin Ultrasound</i>,28(8), Oct, pp 399-406</p>	<p data-bbox="573 264 819 289">Clinical Trial</p> <p data-bbox="573 313 819 370">N=59 patient with penis carcinoma</p>	<p data-bbox="861 264 1482 761">The overall mean difference +/- standard deviation in the tumor extent between clinical and gross pathologic evaluation was 3.9 +/- 5.3 mm (range, 1-9 mm), whereas the overall mean difference between sonographic and gross pathologic evaluation was 1.2 +/- 1.7 mm (range, 1-7 mm). As determined with reference to the gross pathologic extent, the error in measuring the extent on clinical examination was significantly greater than the error on sonography (p &lt; 0.001). Lesions involving the glans alone were more often underestimated by clinical examination than were lesions involving the shaft (with or without glanular involvement). The error in measuring the extent of tumor by sonography was not related to the site of the tumor. The tumor was hyperechoic in 21 cases (36%), hypoechoic in 28 cases (47%), and of mixed echogenicity in 10 cases (17%). There was no significant association between echogenicity and tumor morphology or grade. CONCLUSIONS: Sonography gives a more accurate estimate of penile tumor extent than does physical examination. Routine use of sonography for such measurements should enable preservation of more of the penis.</p>	<p data-bbox="1503 264 1556 289">Poor</p>

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
3	<p>Lim JW, Ko YT, Lee DH, Park SJ, Oh JH, Yoon Y, Chang SG (2000)</p> <p>Treatment of prostatic abscess: value of transrectal ultrasonographically guided needle aspiration.</p> <p><i>J Ultrasound Med</i>,19(9), Sep, pp 609-17</p> <p>.</p>	N= 14 patients	<p>The margins of the hypochoic area were well defined and thick in 11 patients (79.0%) and poorly defined in 3 patients (21.0%). The estimated volume of the prostatic abscess ranged between 2 and 28 ml (mean, 12.0 ml). The presence of a pus collection within the prostate was confirmed by transrectal ultrasonographically guided aspiration in all patients. However, successful treatment of prostatic abscess with transrectal needle aspiration was done in 12 (86.0%) of 14 patients; the treatment failed in 2 (14.0%) of 14 patients. One patient was treated with perineal incision and drainage and the other with transurethral resection. The amount of pus drained ranged between 1 and 39 ml (mean, 12.0 ml). On follow-up transrectal ultrasonographic examination, no remaining abscess pocket was found within the prostate in any of the cases. One year later, the prostatic abscess recurred in one case. In conclusion, transrectal ultrasonographic guidance is useful in the diagnosis of prostatic abscess as well as in the guidance for aspiration and the drainage of such abscesses. Transrectal ultrasonographically guided needle aspiration could be an effective method for treating prostatic abscess.</p>	Poor



**EVIDENCE TABLE – USE OF ULTRASOUND IN ORTHOPEADIC**

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
1	<p>Hartgerink P, Fessell DP, Jacobson JA, van Holsbeeck MT. (2001)</p> <p>Full- versus partial-thickness Achilles tendon tears: sonographic accuracy and characterization in 26 cases with surgical correlation.</p> <p><i>Radiology</i>,220(2), Aug, pp 406-12</p>	<p>In part A, sonographic findings (based on reports) in 26 consecutive cases of tears of the Achilles tendon were compared with surgical findings. In part B, the sonograms were blindly and retrospectively evaluated with respect to six sonographic characteristics possibly related to pathologic findings in the tendon, and the characteristics were correlated with surgical findings</p>	<p>In part A, statistical data regarding the use of sonographic findings to distinguish full- from partial-thickness tears were as follows: sensitivity, 100%; specificity, 83%; accuracy, 92%; positive predictive value, 88%; and negative predictive value, 100%. In part B, tendon thickness (P &lt;.001), posterior acoustic shadowing (P =.007), and tendon retraction (P &lt;.001) were correlated with full-thickness tears. Visualization of fat herniation (P =.051) and of the plantaris tendon (P =.098) demonstrated marginal correlation with full-thickness tears. Echogenicity at the site of the pathologic finding in the tendon showed no significant correlation. CONCLUSION: Sonography can be used to differentiate full- from partial-thickness tears or tendinosis of the Achilles tendon with 92% accuracy. Undetectable tendon at the site of injury, tendon retraction, and posterior acoustic shadowing demonstrate statistically significant correlation with full-thickness tears.</p>	Fair
2	<p>Swen WA, Jacobs JW, Hubach PC, Klasens JH, Algra PR, Bijlsma JW. (2000)</p> <p>Comparison of sonography and magnetic resonance imaging for the diagnosis of partial tears of finger extensor tendons in rheumatoid arthritis.</p> <p><i>Rheumatology</i> (Oxford),39(1): Jan, pp 55-62</p>	<p>N= Twenty-one RA patients with finger extensor tenosynovitis for more than 12 months underwent SG, MRI and surgical inspection</p>	<p>For partial tears, sensitivity and specificity were 0.27 and 0.83 for MRI, and 0.33 and 0.89 for SG, respectively. Positive and negative predictive values were 0.35 and 0.78 for MRI, and 0.50 and 0.80 for SG, respectively. Accuracy was 0.69 for MRI and 0.75 for SG. CONCLUSION: For visualization of partial finger extensor tendon tears in RA patients, SG performs slightly better than MRI, but both techniques are at present not sensitive enough to be used in daily practice.</p>	Poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
3	<p>Waitches GM, Rockett M, Brage M, Sudakoff G. (1998)</p> <p>Ultrasonographic-surgical correlation of ankle tendon tears.</p> <p><i>J Ultrasound Med</i>, 17(4), Apr, pp249-56</p>	<p>Prospective Study</p> <p>N=33 patients – 68 tendons evaluate by sonographic</p>	<p>Five patients had a final diagnosis based on clinical findings, and two were lost to follow-up. Of the 68 tendons evaluated sonographically, 54 were directly inspected at surgery; 20 were found to be torn and 34 were intact. Ultrasonography was able to identify all tears correctly with an accuracy of 93%, a sensitivity of 100%, and a specificity of 88%. The positive and negative predictive values were 83% and 100%, respectively. The combined accuracy, sensitivity, and specificity of ultrasonography in detecting tendon tears in all patients evaluated both surgically and by clinical follow-up were 94%, 100%, and 90%, respectively.</p>	Fair
4	<p>Farin P, Jaroma H (1996)</p> <p>Sonographic detection of tears of the anterior portion of the rotator cuff (subscapularis tendon tears).</p> <p><i>J Ultrasound Med</i>, 15(3), mar, pp 221-5</p>	<p>N= 1640 patients</p>	<p>Ultrasonography demonstrated 82% (14 of 17) of the subscapularis tendon tears; 86% (12 of 14) of the full-thickness tears and 67% (2 of 3) of the partial-thickness tears were correctly diagnosed with ultrasonography. Sonography can diagnose and show the size of subscapularis tendon tears reliably, but it necessitates that the arm can be externally rotated to the maximum extent when performing the study.</p>	Poor

**EVIDENCE TABLE – USE OF ULTRASOUND CONGENITAL HIP DYSPLASIA**

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
1	<p>Geitung JT, Rosendahl K. Sudmann E (1996)</p> <p>Cost-effectiveness of ultrasonographic screening for congenital hip dysplasia in newborns</p> <p><i>Skelatal Radiology</i>, 25(3), pp 251-254</p>	Cohort	<p>The sensitivity and specificity of current screening practice resulted in an incidence of late- detected CDH of 2.6 cases in 5,000 live births</p> <p>The number of late-discovered cases of CDH was higher in ultrasonographic versus clinical screening. The ultrasonographic screening would have produced 57.5 false-positive diagnoses</p> <p>The sensitivity and specificity of ultrasonographics screening for all live births in Norway would result in the avoidance of 2 cases of late-detected CDH per annum over 1,000 live births.</p> <p>By introducing an ultrasonographic screening programme an estimated 2.6 cases of late-discovered CDH per annum would be avoided</p>	Poor
2	<p>Rosenberg N, Bialik V. (2002)</p> <p>The effectiveness of combined clinical-sonographic screening in the treatment of neonatal hip instability.</p> <p><i>Eur J Ultrasound</i>, 15(1-2) Jun , pp 55-60</p>	N= 9030 hip	<p>Instability was diagnosed in 1.4% of all hips, but only 63% of unstable hips were diagnosed on the initial clinical examination. In the remainder, the clinical pathology was established on clinical re-examination after the sonographic abnormality was recognized. Similarly, but to a much lesser extent, sonographic pathology was detected only on the re-examination in 5% of the clinically unstable hips. Although the overall initial under-diagnosis rate of hip instability was 0.6% of all hips, the rate for treated hips was 0.1%. CONCLUSION: These data should be taken into consideration in planning an efficient DDH screening policy.</p>	Poor

**EVIDENCE TABLE – USE OF ULTRASOUND INTUSSUSCEPTION – EFFECTIVENESS**

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
1	<p>Crystal P, Hertzanu Y, Farber B, Shabshin N, Barki Y. (2002)</p> <p>Sonographically guided hydrostatic reduction of intussusception in children.</p> <p><i>J Clin Ultrasound</i>, 30(6): Jul-Aug, pp 343-8</p>	<p>Review</p> <p>N=83 consecutive children sonographically diagnosed with 101 cases of intussusception</p> <p>F/up: over a 40-month period.</p>	<p>In 88 (89%) of the 99 cases, hydrostatic reduction was successful. No complications during or after hydrostatic enema were noted. The success rate was significantly lower among patients whose intussusception was located in the left side of the abdomen or contained entrapped fluid or those in whom hydrostatic reduction was not performed by an experienced sinologist. The presence of free peritoneal fluid was not a predictor of outcome. No complications during or after hydrostatic enema were noted. CONCLUSIONS: Sonographically guided hydrostatic reduction of intussusception is safe and effective. We recommend that this method be attempted before surgery is considered, even in cases in which the intussusception contains entrapped fluid or is located in the left side of the abdomen. The level of experience of the radiologist who performs the reduction significantly affects the results of this procedure and should be carefully considered, particularly in cases in which initial sonography reveals the presence of risk factors</p>	Fair

**EVIDENCE TABLE – TRAINING –EFFECTIVENESS**

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
1	<p>Smith RS, Kern SJ, Fry WR, Helmer SD (1998)</p> <p>Institutional learning curve of surgeon-performed trauma ultrasound.</p> <p><i>Arch Surg</i>;133(5), May, pp 530-5; discussion 535-6</p>	<p>Before the initiation of a program of surgeon-performed trauma ultrasound, senior surgical residents (postgraduate years 4 and 5) received 11.5 hours of hands-on and didactic instruction in the focused ultrasound examination for trauma. This examination then became a standard component of the evaluation of injured patients. Subsequent groups of senior residents received 8 hours of instruction at the onset of new academic years, 6 and 18 months, respectively, after the initial course</p>	<p>During the 24-month study period, 902 sonographic examinations were performed. No statistically significant differences were noted in sensitivity, specificity, accuracy, positive predictive value, or negative predictive value for any 6-month period of study when compared with the other 6-month periods or with the values calculated for the entire study period. CONCLUSIONS: Senior surgical residents are capable of performing the focused ultrasound examination for trauma with a high level of skill after a concise introductory course. A learning curve was not apparent in our series. Criteria for being permitted to perform trauma sonography that include the requirement of a large number of examinations or extensive proctoring should be reassessed.</p>	
2	<p>Gracias Vh, Frankel H, Gupta R, Reilly PM, Gracias F, Klein W, Nisenbaum H, Schwab CW (2002)</p> <p>The role of positive examinations in training for the focused assessment sonogram in trauma (FAST) examination</p> <p><i>Am Surg</i>, 68(11), Nov, pp 1008-11,</p>	<p>Prospective double blind design</p> <p>N= 9 patients</p>	<p>The participants has 6 PRE &amp; 5 POST course were compared as to their ability to detect and quantify intraperitoneal fluid.Sensitivity of inexperienced clinician for detecting <math>\leq 750\text{cm}^3</math> was 45% PRE and 87%POST. Accuracy in quantifying volume within 250 <math>\text{cm}^3</math> was 38% PRE and 44% POST (not significant)</p> <p>FAST accuracy for inexperienced conogrpher particularly in dignosing smaller volumes can be improved significantly by including positive studies in training. Exposure to positive FAST examination during training improves the learning curve. With the growing dependency on FAST to accurately triage blunt abdominal trauma safe and effective FAST training should consist of didactic education and a practical portion that includes positive studies.</p>	Poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
3	<p>Suroma I, Merikanto J, Paivansalo M, Reinikainen H, Rissanen T, Takalo R (2002)</p> <p>General practitioner's skills to perform limited goal-oriented abdominal US examinations after one month of intensive training</p> <p><i>Eur J Ultrasound</i>, 15 (3), Oct, pp 133-8</p>	Not stated	After 1 month of intensive training (about 100 examinations), 4 test subjects succeeded in technically performing examinations in 4 patients out of 5 patients, and were able to rule out or exclude fluid collections, aortic aneurysms and common gallbladder disease.	Poor
4	<p>Hertzberg BS, Kliewer MA, Bowie JD, Carroll BA, DeLong Dh, Nelson RC (2000)</p> <p>Physician training requirements in sonography: how many cases are needed for competence</p> <p><i>AJR Am J Roentgenol</i>, 174(5), May, pp 1221-7</p>	Sonographic competence tests were administered to 10 first year diagnostic radiology residents after their involvement in increments of 50 cases, up to total of 200 cases (four competency test).	Involvement in 200 or fewer cases during the training period is not sufficient for physicians to develop an acceptable level of competence in sonography	Poor
5	<p>Knudson MM, Sisley AC (2000)</p> <p>Training residents using simulation technology: experience with ultrasound for trauma</p> <p><i>J Trauma</i>, 48(4), Apr, pp 659-65</p>	<p>Prospective, cohort study</p> <p>N= 74 residents</p> <p>Group I: didactic session was followed by 1 hour for each student of hands on training on medical models/medical patients</p> <p>Group II: by training on the ultrasound simulator.</p>	<p>All residents show significant improvement in their pretest and posttest scores in both their knowledge of ultrasound physics and in their interpretation of ultrasound images presented on videotapes.</p> <p>The use of a simulator is a convenient and objective method of introducing ultrasound to surgery residents and compares favorably with the experience gained with traditional hand-on patient models</p>	Poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
6	<p>Salen PN, Melanson SW, Heller MB (2000)</p> <p>The focused abdominal sonography for trauma (FAST) examination: considerations and recommendations for training physicians in the use of a new clinical tool</p> <p><i>Acad Emerg Med</i>, 7(2), Feb, pp 162-8</p>	Review	Most FAST educators agreed that FAST education should consist of three phases: didactic, practical and experiential.	Poor
7	<p>Frezza EE, Solis RL, Silich RJ, Spence RK, Martin M (1999)</p> <p>Competency-based instruction to improve the surgical resident technique and accuracy of the trauma ultrasound</p> <p><i>Am Surg</i>, 65, Sep, pp 884-8</p>	<p>Controlled clinical trial- Single blind study</p> <p>N= 9 surgical residents</p> <p>Group 1; performed the test only.</p> <p>Group 2 performed training twice.</p> <p>Group 3-senior ultrasound technician, whose readings served as "gold standard"</p>	<p>Surgical residents have ability to detect fluid in the abdomen, there exists a fast learning curve, and the minimum detection level of fluid was between 200 and 400 cc in the peritoneal cavity in the laboratory. Surgical residents were able to detect intra-abdominal fluid in the trauma situation, as shown by the 92% accuracy of the FAST in the emergency situation.</p> <p>a cadaver laboratory training program is an important adjunct to improve the skills of the resident in performing and reading FAST.</p>	<p>Good</p> <p>Small samples</p>
8	<p>Ali J, Rozycki GS, Campbell JP, Boulager BR, Waddell Jp, Gana TJ (1996)</p> <p>Trauma ultrasound workshop improves physician detection of peritoneal and pericardial fluid</p> <p><i>J Surg Res</i>, 63(1), Jun, pp 275-9</p>	<p>Clinical trial</p> <p>N= 30 physicians</p>	This workshop can significantly improve the skills of nonradiologist in sonographic identification of pericardial and intraperitoneal fluid and should therefore be considered an essential component of ultrasound training for trauma physicians	Good to poor

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
9	<p>Hunter S, Heads A, Wyllie J, Robson S (2000)</p> <p>Prenatal diagnosis of congenital heart disease in the northern region of England: benefits of a training program for obstetric ultrasonography</p> <p><i>Heart</i>, 84(3), Sep, pp 294-8</p>	Review	A simple training programme for obstetric ultrasonography increased their ability to detect serious congenital heart disease at a routine 18-20 weeks anomaly scan	Poor
10	<p>Rustico MA, Benettoni A, D'Ottavio G, Maieron A, Fischer-Tamaro I, Conoscenti G, Meir Y, Monstesono M, Cattaneo A, Mandruzzato G (1995)</p> <p>Fetal Heart screening in low risk pregnancies</p> <p><i>Ultrasound Obstet Gynaecol</i>, 6(5), Nov, pp 313-9</p>	<p>N=7024</p> <p>F/up : 2 year</p>	<p>The accuracy in two distinct periods was estimated because the level of experience of the operators was different; sensitivity – 45.2% in period (1986-88) (77.8% for major defects) and 26.5% in period 2 (1989-92) (52.9% for major defects).</p> <p>A crucial factor is the level of training and experience of the operators, who need specific teaching support</p>	Good



No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
11	<p>Hahn RG, Roi LD, Ornstein SM, Rodney WM, Garr DR, Davies TC, Morgan W, O'Brien JM, McLeary RD, Peggs JF, et al. (1988)</p> <p>Obstetric ultrasound training for family physicians. Results from a multi-site study.</p> <p><i>J Fam Pract.</i>;26(5), May, pp 553-8.</p>		<p>At the conclusion of the training program, the physicians took a combined practical and written proficiency examination administered by an independent sonographer. Eight physicians completed the training, performing during the preceptorship an average of 78 examinations. The rated performance of the physicians improved markedly over the course of the preceptorship. During the last segment of the preceptorship the radiologist preceptors rated 94 percent of the ultrasound studies as acceptable, compared with 79 percent rated acceptable at the beginning of the preceptorship. Seven of the eight physicians completing the protocol took the proficiency examination: all passed. This study can provide a blueprint for an individual family physician to design his own training, or it can guide an academic department of family medicine in developing and evaluating ultrasound training programs for residents and practicing physicians</p>	Poor
12	<p><i>Guidelines on the use of ultrasound in pregnancy</i></p> <p>Malaysian Society of Ultrasound in Medicine (1996)</p>	Guidelines	<p>The level of expertise required in ultrasound scanning is divided into basic, intermediate and advanced level with differing training requirement</p>	Fair

## EVIDENCE TABLE – COST IMPLICATION

### ANTENATAL SCREENING

No.	Title, Author, Journal and Year	Study Type., Sample Size and Follow-up	Characteristic & Outcome	Grade Comments
1	<p>Busken E, Grobbee DE, Frohn-Mulder IM, Stewart PA, Juttman RE, Wladimiroff JW, Hess J (1996)</p> <p>Efficacy of fetal ultrasound screening for congenital heart diseases in normal pregnancy</p> <p><i>Circulation</i>, 94 (1), Jul 1, pp 67 - 72</p>	<p>Prospective follow-up study on 6922 scanned fetuses was performed</p>	<p>6 months postpartum follow-up in 5660(81.8%), of whom 5319 fulfilled all eligibility criteria. By comparing the prenatal diagnosis to the postnatal diagnosis, sensitivity, specificity and positive and negative predictive value of : Overall 16.3%(95% CI, 2.09% to 48.8%). Fetal 4 chamber view examination 4.5% (95% CI, 0.6% - 15%). Noncardiac anomalies 30% (95%CI. 16.6% to 46.5%). Specificity and negative predictive value were high (&gt;98%). The positive predictive value was low with wide CIs. 80 cases of congenital malformation were diagnosed, 44 of congenital heart disease, 40 cases of noncardiac malformations and a combination of the two in 4 cases.</p> <p>Conclusion: These results suggest that the current mode of routine prenatal ultrasound screening for congenital malformations is inefficient, particularly for cardiac anomalies.</p>	<p>Poor</p> <p>No full article</p>
2	<p>Brand IR, Kaminopetros P, Care M, Irving HC, Lilford RJ. (1994)</p> <p>Specificity of antenatal ultrasonography in the Yorkshire Region: A prospective study of 2261 ultrasound detected anomalies.</p> <p>Br J Obstet Gynaecol. ,101(5), May, pp 392-7.</p>	<p>Prospective , 3 ½ years</p> <p>2261 pregnancies</p>	<ul style="list-style-type: none"> <li>- 369 out of 2261 were diagnosed as fetal anomalies.</li> <li>- 16% were terminated and 57 (97%) were followed by postmortem examination.</li> <li>- Ultrasound findings exactly matched those of the postmortem or were accompanied by additional anomalies in 325 cases (91%)</li> <li>- 32 cases ultrasound findings were not confirmed by postmortem but in 30 of these the decision to offer TOP remained justified because the correct diagnosis was judged equally or more serious.</li> <li>- Ultrasound significantly over or under diagnosed a major FA in 27 of the 1139 (2.4%)</li> </ul> <p>TOP was based on the correct prognosis in over 99.5% of cases. This does not obviate the need for pathological examination of the fetus which changed or refined the diagnosis in 35% of cases</p>	<p>Good</p> <p>Big sample, prospective</p>

No.	Title, Author, Journal and Year	Study Type., Sample Size and Follow-up	Characteristic & Outcome	Grade Comments
3	Chitty LS (1995)  Ultrasound screening for fetal anomalies  Prenat Diagn, 15(13), Dec, pp 1241-57	Discussions on reports of routine ultrasound scan are reviewed and advantages and disadvantages are discussed.	Majority of routine anomaly screening is done in the 2 <sup>nd</sup> trimester	Poor  No full article
4	Skupsi DW, Newman S, Edersheim T, Hutson JM, Udom-Rice I, Chersvenak FA., McCullough LB (1996)  The impact of routine obstetric ultrasonographic screening in a low-risk population  Am. J Obstet Gynecol May 1996	Retrospective chart review was performed for all low-risk pregnancies from a single obstetric practice during 1990 – 1994.  All patients (860 fetus; 854 pregnancies) underwent routine ultrasound examination at 18 – 20 weeks gestation at the obstetric ultrasonography Unit at the New York Hospital	Routine 2 <sup>nd</sup> trimester ultrasonography for the detection of all fetal anomalies sensitivity 8.7%, specificity 99.9%, positive and negative predictive value 80% and 95.7% respectively. For major anomalies, sensitivity 30%, specificity 100%, positive and negative predictive value 100% and 99.2% respectively. For anomalies detectable by ultrasound this study showed a sensitivity of 75%. There was a 3-fold difference in the detection of anomalies between the tertiary centers and the private physicians' offices in the RADIUS study. This difference suggests that a center that specializes in obstetric ultrasonography have better quality ultrasonography as determined by a higher detection rate. Routine ultrasonography should be done in such specialized centers for the benefits to be fully realized. The incidence rate of major fetal anomalies detectable by ultrasonography in this was 0.5%. This is similar to the rate of chromosomal abnormalities for which amniocentesis, an invasive test is routinely offered. Two of 3 major malformation opted for termination	Fair Small sample
5	Viljoen D., Oosthuizen C. Van Der Westhuizen S (1996)  Patient attitudes to prenatal screening and termination of pregnancy at Groote Schuur Hospital: A two-year prospective study.  East Afr Med J, 73(5), May, pp :327-9.	Prospective study from April 1992 to May 1994.  Pregnant mother referred to counseling clinic at Groote Schuur Hospital.  A total of 466 women assessed.	An overall amniocentesis acceptance rate of 75.9%, this figure compares favorably with First World findings. No significant difference between factors such as ethnicity, education, income, and reason for referral. The overall acceptance for TOP rate was 76.3%, while those women with Muslim affiliations were 1.33 times more likely to accept TOP than persons from other religious persuasions. No significant differences were evident between the different age groups or ethnic populations for TOP. The study conclusively confirms that prenatal screening for congenital and genetic anomaly was widely accepted by the patients seen at the prenatal counseling clinic at Groote Schuur Hospital.	Fair Small sample.

No.	Title, Author, Journal and Year	Study Type., Sample Size and Follow-up	Characteristic & Outcome	Grade Comments
6	<p>Geert LT, Brand EJ, Theron GP (1996)</p> <p>Routine obstetric ultrasound examination in South Africa: Cost and effect on perinatal outcome: a prospective randomized control trial.</p> <p>Br. J. Obstet Gynecol , 103(6), June, pp 501 - 7</p>	<p>Prospective randomised controlled trial.</p> <p>Pregnant patients without risk factors for congenital anomalies referred for ultrasound between 18 – 24 weeks.</p>	<ul style="list-style-type: none"> <li>- The group did not differ significantly in their use of antenatal and neonatal services, except for a greater number of ultrasound scans in the study group. More suspected postdate pregnancies occurred in control patients, as well as more amniocentesis for confirmation of lung maturity. More babies of low birth weight were born in the study group. The incidence of overall or major adverse perinatal outcome was comparable. Routine ultrasound was accompanied by a considerable increase in costs.</li> <li>- Conclusion: Selective use of obstetric ultrasound did not increase the use of antenatal and neonatal services. Not routinely performing ultrasound has led to considerable health services savings, without increasing the risk of adverse perinatal outcome. It saved 75% of selected patients a referral to an ultrasound unit. Specific problems related to inaccurate gestational age determination need not be addressed.</li> </ul>	Good
7	<p>Bucher HC, Schmidt JG. (1993)</p> <p>Does routine ultrasound scanning improve outcome in pregnancy? Meta-analysis of various outcome measures.</p> <p><i>BMJ</i>,307(6895), Jul, pp 13-7.</p>	<p>RCT, 15,135 respondents (7992 routine ultrasound scanning group &amp; 7943 in control with selective scanning group.).</p> <p>The trials conducted in Helsinki and Trondheim randomised all women on the diagnosis of pregnancy, whereas in the Stockholm and Missouri studies only those pregnant women who had no clinical indication for ultrasound scanning at their first antenatal visit or at 12 weeks' gestation were included.</p>	<p>Conclusion:</p> <ul style="list-style-type: none"> <li>◆ This meta-analysis of RCT shows that routine ultrasound scanning does not improve the outcome of pregnancy in terms of live birth rate and Apgar score.</li> <li>◆ Routine ultrasound scanning in pregnancy is effective in detecting fetal growth retardation, multiple pregnancies and severe malformations.</li> <li>◆ PMR is reduced because fetuses with severe malformations are aborted in an early stage of pregnancy rather than dying perinatally.</li> </ul> <p>Routine ultrasound scanning in pregnancy is indicated only if explicitly performed to exclude congenital malformations.</p>	Good

No.	Title, Author, Journal and Year	Study Type., Sample Size and Follow-up	Characteristic & Outcome	Grade Comments
8	Isabel M Shirley, Fiona Bottomley and Victor P Robinson  Routine radiographer screening for fetal abnormalities by ultrasound in an unselected low risk population  <i>The British Journal of Radiology</i>	A combined prospective and retrospective study of the ultrasound findings and outcome of all pregnancies from July 1986 to 1990.	This study had shown the routine ultrasound screening by radiographers at 19 weeks gestation of women at normal risk of fetal abnormality has a sensitivity of 60.7% in detecting all abnormal fetuses, including those with abnormalities at the more minor end of the spectrum and those with abnormal karyotype without structural abnormality. Sensitivity of detecting of lethal or major handicapping abnormalities was 73%, specificity was 99.98%.	Fair To Good  Prospective combined with retrospective, Long follow up, big sample
9	de Crespigny LC, Warren P, Buttery B. (1989)  Should all pregnant women be offered an ultrasound examination  <i>Med J Aust</i> , 151(11-12), Dec 4-18, pp613-5.	Review of literatures.	<ul style="list-style-type: none"> <li>- If all pregnant women are to be offered an ultrasound examination, the optimal time is at 18 – 20 weeks' gestation. Good fetal visualization is possible while maintaining sufficient accuracy in the dating of the pregnancy. A scan earlier is less likely to detect an abnormality.</li> <li>- It is necessary to have intensive training courses to develop expertise, particularly in the difficult task of the diagnosis of subtle fetal anomalies. This development will help to ensure that the maximal possible information is obtained from each ultrasound examination, while at the same time will minimize the risk of over diagnosis.</li> </ul>	Poor
10	Leivo T; Tuominen R; Saari – Kempainen A; Ylostalo P; Karjalainen O; Heininen OP. (1996)  Cost effectiveness of one-stage ultrasound screening in pregnancy: a report from Helsinki ultrasound trial.  <i>Ultrasound Obstet. Gynecol</i> , 7(5), May, pp 309 - 14	CCT  9310 randomly selected for	<ol style="list-style-type: none"> <li>1. The cost of each avoided perinatal death was FIM 84,378 (\$21,938), while the net overall estimate combining all positive and negative costs showed a cost saving of FIM 65,680 (\$17,077).</li> <li>2. The total positive unit cost of ultrasound screening was FIM 393 (\$102).</li> <li>3. Longer ultrasound examination time and more numerous advanced examinations were rewarded by clearly fewer perinatal deaths and a better cost-effectiveness ratio.</li> </ol> <p>Conclusion: One-stage second-trimester ultrasound screening is cost-effective when all significant costs and effects are taken into account.</p>	<b>Good</b>

No.	Title, Author, Journal and Year	Study Type., Sample Size and Follow-up	Characteristic & Outcome	Grade Comments
11.	<p>Levi S (1998)</p> <p>Routine ultrasound screening of congenital anomalies. An overview of the European experience</p> <p><i>Ann N Y Acad Sci</i>, 18; (847) Junm pp 86 -98</p>	Review	<p>Fetal anomalies screening require higher education and qualification than ordinary obstetrical ultrasound.</p> <p>The health insurance system supports ultrasound screening and allows its spread in most European countries. Approximately 98% of pregnant women are examined by ultrasound and frequently 2 to 3 times (usually once per trimester).</p> <p>Detection rate of congenital anomalies is about 28% in geographical area (private practice and hospital), 60 – 80% in obstetric and gynecology ultrasound lab.</p> <p>Routine ultrasound screening policy has not proved to result in an immoderate use of ultrasound, on the contrary, chaotic use of routine ultrasound can lead to an unproductive and excessive number of scan.</p> <p>New trends in FAS, such as the early detection of fetal defects and chronic anomaly, bring more arguments for routine screening. Effectiveness should increase by enhancing education and training and the systematic referral for FAS to accredited lab.</p>	Poor
12.	<p>Long G, Sprigg A (1998)</p> <p>A comparative study of routine versus selective fetal anomaly ultrasound scanning.</p> <p><i>J Med Screen</i>, 5(1), pp 6-10</p>	Prospective study of the 12 months before and after introduction of routine second trimester ultrasound for fetal anomaly in the institution.:	<p>Routine ultrasound was the sole method of detection 11 major and 18 less severe congenital abnormalities found in low risk pregnancies which would not previously have qualified for high risk ultrasound. Seven of the above cases the parents opted for termination of pregnancy, with estimated savings on treatment and long term care of 1,015,546 pounds. The financial cost of providing the ultrasound screening service\ at that hospital for 12 months was calculated at 57,573 pounds and the resulting financial benefit for the year was estimated at 957,973 pounds.</p> <p><b>Conclusion:</b> Although it is recognised that many of the emotional and psychological costs and benefits of the service are difficult to evaluate, routine fetal anomaly ultrasound would seem to be economically justifiable. The financial savings achieved at our hospital would translate into a potential annual saving for the National Health Service of nearly 170 million pounds if screening were offered in all hospitals in England and Wales.</p>	Good

No.	Title, Author, Journal and Year	Study Type., Sample Size and Follow-up	Characteristic & Outcome	Grade Comments
13.	Chitty LS, Hunt GH, Moore J, Lobb MO (1991).  Effectiveness of routine ultrasonography in detecting fetal structural abnormalities in a low risk population.  <i>BMJ</i> , 303 Nov. 1991	Retrospective study of the ultrasonographic findings and outcome of all pregnancies in women scanned in 1988 to 1989.  N= 8785 fetuses	<ul style="list-style-type: none"> <li>- 8733 babies were born during 1988 – 9, 52 pregnancies were terminated after a fetal malformation was identified.</li> <li>- 8432 (95%) of the fetuses were examined by ultrasonography in the 2<sup>nd</sup> trimester.</li> <li>- 130 fetuses (1.5%) were found to have abnormality at birth or after termination of pregnancy, 125 of which had been examined in the second trimester.</li> <li>- In 93 cases the abnormality was detected before 24 weeks (sensitivity 74.4%, 95% confidence interval to 66.7% to 82.1%)</li> <li>- Two false positive diagnosis occurred, in both cases the pregnancies were not terminated and apparently normal infant were born.</li> <li>- Specificity of ultrasonography was 99.98%.</li> <li>- The positive predictive value of ultrasonography in the 2<sup>nd</sup> trimester was 97.9%</li> <li>- Of the 125 abnormalities, 87 were lethal or severely disabling, 72 of the 87 were detected by the routine screening program (sensitivity 82.8%, 73.2% to 90%)</li> </ul> <p>Conclusion: Routine fetal examination by ultrasonography in a low risk population detects many fetal structural abnormalities, but can present several dilemmas in counseling.</p>	Good To Fair  Big sample and retrospective
14	Muller RJ, Asseryanis E, Wieser F, Schurz B (1996)  Reliability of ultrasound pregnancy screening.  <i>Ultraschall Med</i> , 17(4), Aug, pp 163-6	1505 screening examination of pregnant women who underwent routine checks were compared with the anomalies diagnosed in the newborn of the same collective	<ul style="list-style-type: none"> <li>- 28 malformations found in screening cases</li> <li>- 5 malformations not diagnosed in ultrasound screening</li> <li>- 23 newborn had minor malformation</li> </ul> <p>Conclusion:High accuracy of the sonographic screening examination, with the exception of the median facial region and the large vessels of the base of heart.</p>	Poor

No.	Title, Author, Journal and Year	Study Type., Sample Size and Follow-up	Characteristic & Outcome	Grade Comments
15	<p>Temmerman M . Buekens P (1991)</p> <p>Cost-effectiveness of routine ultrasound examination in first trimester of pregnancy.</p> <p><i>Euro J Obstet Gynecol Reprod Biol</i>, 39(1), Mar 21, pp 3-6</p>	<p>Prospective study from 1 Jan. 1986 until 31 December 1986.</p> <p>N= 1011 samples (695 grp 1; 316 grp 2)</p>	<p>If one were to limit the 1<sup>st</sup> trimester scan to very specific indications. (uncertain LMP irregular cycle, induction of ovulation, clinical signs and symptoms), 56 out of 838 pts (6.7%) would have had their gestational age corrected at a later stage of pregnancy; 10 multiple pregnancies, 6 missed abortion, 1 congenital malformation and tubal pregnancies would have been detected later. The cost of one ultrasound examination comes to 30 USD. Therefore, performing first trimester ultrasounds only when indicated could save 22,000 USD per 1000 patients. Routine ultrasound during the 1<sup>st</sup> trimester has a low cost-effectiveness. On the contrary, the performance of a thorough examination at about 20 weeks gestation should be mandatory, when circumstances permit.</p>	<p>Fair</p> <p>Not RCT Big sample</p>
16	<p>Perrson PH, Kullander S (1983)</p> <p>Long term experience of general ultrasound screening in pregnancy.</p> <p><i>An J Obstet Gynecol</i>, 146(8) Aug 15, pp 942-7</p>	<p>N=22,400 pregnant women 43,000 ultrasound since Jan 1974</p>	<p>15% of all pregnancies, ultrasound corrected gestational age by more than 14 days. Ultrasound appeared to be superior to the clinical assessment in 88% of these discrepant pregnancies in predicting date of delivery. 0.4% malformed detected Conclusion: A cost-benefit analysis suggested that large economical gains are to be realized by screening. However, organizational and educational problems must be properly solved before general screening is offered to a healthy pregnant population.</p>	<p>Poor</p>



No.	Title, Author, Journal and Year	Study Type., Sample Size and Follow-up	Characteristic & Outcome	Grade Comments
17	<p>Wells PNT (1986)</p> <p>The prudent use of diagnostic ultrasound</p> <p><i>The British Journal of Radiology</i>, 59, pp 1143-1151</p>	Review	<p>One of the most important risks is that of inappropriate termination of pregnancy and, in this connection, it is important to remember that recent advances in neonatal surgery are potentially able to treat many urinary tract abnormalities, gastroschisis, isolated exomphalos, diaphragmatic hernia and gastrointestinal anomalies. The controlled trial limited to 1533 single pregnancies failed to demonstrate any benefit, in terms of management or outcome, from applying the two-stage ultrasound schedule to low-risk pregnancies. This results however strengthened the arguments for having a routine scan of every pregnancy before 16 weeks, for not only can fetal abnormalities be detected then an appropriate action taken, but also the determination of gestational age can be a great help in the subsequent management of difficult pregnancies. In an evaluation of the cost-benefit of carrying out a scan at about 16 weeks for all pregnancies and using his own financial estimates, showed that routine scan detected 50 abnormalities in 14,622 deliveries; 8 abnormalities had remained undetected and there had been one false positive scan. Of those detected , 7 abnormalities would have been predicted to result in severe handicap such that the cost of caring for the handicapped individuals over 40 years of life would have been more than   2.5 million The total costs of the single routine scans were calculated to be about   150,000. Therefore the profit due to routine scans were calculated to be about 1500%.</p>	Poor
18.	<p>Romano PS, Waitzman NJ (1998)</p> <p>Can decision analysis help us decide whether ultrasound screening for fetal anomalies is worth it?</p> <p><i>Ann N Y Acad Sci</i>, 847, Jun 18, pp 154 -72</p>	<p>Review</p> <p>Exploratory decision analysis of routine 2<sup>nd</sup> trimester ultrasound to detect fetal anomalies, focusing on the assumption that could have the greatest impact.</p>	<p>Routine ultrasound appears to be the preferred strategy for most women. This choice is sensitive primarily to the specificity of ultrasound and women's willingness-to-pay for the reassurance of a normal ultrasound.</p>	Poor

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19	<p>Rustico MA, Benettoni A, D'Ottavio G, Maieron A, Fischer-Tamaro I, Conoscenti G, Meir Y, Monstesano M, Cattaneo A, Mandruzzato G. (1995)</p> <p>Fetal Heart screening in low-risk pregnancies.</p> <p><i>Ultrasound Obstet. Gynecol</i>, 6(5), Nov, pp 313-9</p>	<p>Fetal heart was evaluated in 7024 pregnant women at 20 –22 weeks, and evaluation was repeated at a more advanced gestational age in 9% of cases. Cardiological follow-up was continued postnatally until 2 years of age.</p>	<p>The overall prevalence cardiac anomaly 0.93%, incidence of major defects – 0.44%; minor defects – 0.48%. They were 23 true +ve – 0.33%, in 20 cases the diagnosis was made in the 2<sup>nd</sup> trimester, 13 women (65%) chose termination of pregnancy. 17 of the 20 cases identified in the 2<sup>nd</sup> trimester were serious malformations. 42 false negatives – 0.6%, of these 12 had signs of cardiac dysfunction at birth or within the 1<sup>st</sup> month of life, 3 died of cardiac anomaly. 8 false positive – 0.11%, all of a minor type. Five of the 42 newborns in the false-negative group had trisomy 21. The overall sensitivity was 35.4%, and 61.3% for major defects. The accuracy in two distinct periods was estimated because the level of experience of the operators was different; sensitivity - 45.2% in period I (1986 – 88) (77.8% for major defects) and 26.5% in period 2 (1989 – 92) (52.9% for major defects).</p> <p>Conclusions: Fetal heart screening program in the obstetric population is justified. It defines a high-risk group for karyotyping, allows planning of delivery in a tertiary centre or the choice of terminating the pregnancy for the parents and appears to have a positive cost-benefit ratio.</p> <p>A crucial factor is the level of training and experience of the operators, who need specific teaching support.</p>	Good
20	<p>Robert T, Mugford M, Piercy J. (1998)</p> <p>Choosing options for ultrasound screening in pregnancy &amp; comparing cost effectiveness --a decision analysis approach.</p> <p><i>British J. Obstet. Gynaecol.</i>, 105(9), pp 960 - 70</p>	<p>Decision analysis based on the best data currently available, including expert opinion from the Royal College of Obstetricians and Gynecologists, Working Party and secondary data from the literature review to predict the likely outcomes in terms of malformations detected by each screening programs.</p>	<p>The results suggested that the overall allocation of resources for routine ultrasound screening in the UK is not currently economically efficient, but that certain scenarios for ultrasound screening are potentially within the range of cost effectiveness reached by other, possibly competing, screening programmes. The model highlighted the weakness of available evidence and demonstrated the need for more information both about current practice and costs.</p>	Fair To Good

No.	Title, Author, Journal and Year	Study Type., Sample Size and Follow-up	Characteristic & Outcome	Grade Comments
21	<p>Saari-Kemppainen A, Karjalainen O, Ylostalo P, Heinonen OP (1994)</p> <p>Fetal anomalies in a controlled one-stage ultrasound screening trial. A report from the Helsinki Trial</p> <p><i>Perinatal Medicin</i>, 22(4), pp 279-89</p>	<p>RCT</p> <p>Screening gp 4691 Control gp 4619</p>	<p>Screening grp – 40% of major FA were detected and 11 cases abortion were induced because the malformation was either lethal which severely handicapping. Control grp- 77% of participants had ultrasound examination any time during pregnancies, 13 (27%) major FA were detected only 2 of these before the 21<sup>st</sup> weeks of gestation. Prenatal mortality rate was 4.2/1000 in the screening and 8.4/1000 in the control grp (p=0.013)</p> <p>Conclusion: The detection of major FA in ultrasound screening can reduce perinatal mortality rate A systematic search for FA should be included in the ultrasound screening of all pregnancies</p>	<p>Good</p> <p>RCT Big sample</p>
22.	<p>Waldenstrom U, Nilsson S, Fall O, Axelsson O, Eklund G, Lindeberg S, Sjodin Y (1988)</p> <p>Effect of routine one- stage ultrasound screening in pregnancy: A randomised controlled trial.</p> <p><i>Lancet</i>, 2(8611), Sept10, pp 585-8. 1988.</p>	<p>RCT, 7354 pregnant women, 2482 screening group, 2511 in the non-screening group.</p> <p>October 1985 to March 1987.</p> <p>Screening group had an ultrasound scan at about 15 weeks (13-19wk). Control (non-screening) group did not have a scan before 19 weeks.</p>	<p>Screening reduces the rate of induction. Labour was induced because the pregnancy was believed to be post-term in 41(1.7%) in screening group vs 88(3.7%) in non-screening group (p&lt; 0.0001). Labour induced for other reasons in 99(4.2%) in screened group vs 130(5.4%) in non-screening group (p&lt; 0.052). Overall the rate of induced labours was reduced among screened women, 5.9% vs 9.1% (p&lt; 0.0001). Mean Apgar scores and frequency of score &lt; 7 at one and five minutes were the same in both groups. By comparing with the non-screening group, 231 babies were admitted to a neonatal ward vs 275 (p &lt;0.060), 8 vs 12 died in the perinatal period. Mean birth weight of babies born to nonsmoking mothers was 3570 in screened group vs 3544g. (p&lt;0.160) in a non-screening group. By comparison with the non-screening group, LBW (&lt;2500g.) was less common 59(2.5%) vs 95(4.0%), p&lt;0.005, 22 vs 43 babies in this category were born after spontaneous onset of labour (p 0.010). This study did not confirm the suggestion that screening at 15 weeks would reduce the total number of scans done during pregnancy, screened women were on average scanned more than twice as many times as unscreened. One-stage screening had no effect on the number or duration of hospital admissions</p>	<p>Good</p>

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23.	VanDorsten JP, Hulsey TC, Newman RB, Menard MK. (1998)  Fetal anomaly detection by second trimester ultrasonography in a tertiary center.  <i>Am J Obstet Gynecol</i> 178(4), Apr, pp 742 -9	2031 pregnant women with singleton gestations who prospectively underwent ultrasonographic scanning between 15 and 22 weeks and received complete obstetric care between July	47 fetuses were diagnosed by ultrasonography as having a major anomaly; 8.6% in the indicated group and 0.68% in the screening group. The sensitivity for detecting the anomalous fetus was 75% overall: 89.7% in the indicated group and 47.6% in the screening group. 47 patients diagnosed with fetal anomalies, 11 chose pregnancy termination; of the 35 live-born anomalous infants, 29 were discharged alive. Projected newborn cost savings offset the cost of routine midtrimester screening. Conclusion: Detection of anomalous fetuses was significantly better in the indicated compared with the screening group. Nevertheless, routine ultrasonographic screening appeared cost-effective in our populations.	Good
24.	Vintzileos AM, Ananth CV, Fisher AJ; Smulian JC; Day-Salvatore D; Beazoglou T. (1998)  An economic evaluation of first-trimester genetic sonography for prenatal detection of Down Syndrome.  <i>Obstet Gynecol</i> , 91(4), Apr, pp 535-9.	Unable to get original article yet	The benefits of 1 <sup>st</sup> -trimester genetic ultrasound depend on its diagnostic accuracy. First-trimester genetic sonography has the potential for annual savings of 22 million dollars in the United States.	Good To Fair
25	Waitzman NJ, Romano PS (1998)  Reduced costs of congenital anomalies for fetal ultrasound : are they sufficient to justify routine screening in the United State  <i>Ann. N Y Acad Sci</i> , Jun 18, 847pp141-53	Preliminary benefit to cost analysis drawing upon previous research on the cost of birth defects in the US and upon the literature regarding :	Benefit-to-cost ratio ranged from 0.33 to 3 suggesting that a routine screening policy for fetal anomalies be of uncertain net societal benefit. Routine screening may be justified, however, based on standards that elude the methods for establishing societal benefits adopted in this analysis.	Poor

No.	Title, Author, Journal and Year	Study Type., Sample Size and Follow-up	Characteristic & Outcome	Grade Comments
26	Luck CA. (1992)  Value of routine ultrasound scanning at 19 weeks: a four year study of 8849 deliveries.  <i>BMJ.</i> 304(6840),Jun 6, pp 1474-8.	N=8523	166 fetal anomalies occurred; 140 were detected at 19 weeks (sensitivity 85%; specificity 99.9%). In 27 cases fetuses were shown to have severely crippling or lethal abnormalities; termination of pregnancy was requested in 25. Early diagnosis influenced timing and place of delivery in babies with severe cardiac or gastrointestinal anomalies. CONCLUSION--Scanning at 19 weeks with availability of termination can reduce perinatal morbidity and mortality. Scanning can be performed in a general ultrasound department with adequate counselling facilities and close cooperation between radiographers, midwives, obstetricians, paediatricians, and the radiologist.	Poor
27	Geerts LT, Brand EJ, Theron GB. (1996)  Routine obstetric ultrasound examinations in South Africa: cost and effect on perinatal outcome--a prospective randomised controlled trial.  <i>Br J Obstet Gynaecol.</i> ,103(6), Jun , pp 501-7.	Clinical trial	Selective use of obstetric ultrasonography did not increase the use of antenatal and neonatal services. Not routinely performing ultrasonography has led to considerable Health Service savings without increasing the risk for adverse perinatal outcome. It saved 75% of selected patients a referral to an ultrasound unit. Specific problems related to inaccurate gestational age determination need to be addressed.	Poor
28	Routine radiographer screening for fetal abnormalities by ultrasound in an unselected low risk population.  Shirley IM, Bottomley F, Robinson VP (1992)  <i>Br J Radiol.</i> 65(775), July, pp :564-9.	combined prospective and retrospective study	6412 babies were born during this period, of whom 6183 (96%) were examined by ultrasound in the second trimester; 29 pregnancies were terminated for fetal abnormality. Of the 89 fetuses who were abnormal at birth or at induced termination of the pregnancy (1.4%), 84 were scanned in the second trimester. In 51 cases the abnormality was detected before 22 weeks gestation (sensitivity, 60.7%). 56 of these 84 abnormal fetuses scanned had potentially lethal or major handicapping abnormalities of which 41 were detected by ultrasound before 22 weeks gestation (sensitivity, 73%). There was one false positive diagnosis of abnormality which did not affect outcome. 6352 babies were normal at delivery or on discharge from hospital (specificity, 99.98%).	Poor

### EVIDENCE TABLE – TRAUMA

No	Author, Title, Journal	Study design, Study sample, Follow up	Outcomes & Characteristics	Grade & comment
1	<p>Frezza EE, Ferone T, Martin M (1999)</p> <p>Surgical residents and ultrasound technician accuracy and cost-effectiveness of ultrasound in trauma</p> <p><i>American Surgeon</i>, 65(3), pp : 289-91</p>	<p>Retrospective study</p> <p>N=697 Trauma patient</p> <p>F/up July 1996 – June 1997</p>	<p>FAST as performed y residents incurred a single fee of \$88 for radiological readings as compared with \$274 for a US technician fee plus the radiological reading fee of \$ 88. The cost of CAT scan was \$ 750. with the use of the US, the hospital saving can be projected to exceed \$ 662 for each trauma patient screen before CAT scan testing. With the use of FAST in the present study, only 64 from 650 patients required further testing amounting to a total saving of \$ 387,932.:FAST as performed by surgical residents is more cost-effective than FAST as performed by US technician.</p>	Fair
2	<p>Thomas B, Falcone RE, Vasquez D, Santanello S, Townsend M, Hockenberry S, Innes J, Wanamaker S (1997)</p> <p>Ultrasound evaluation of blunt abdominal trauma: program implementation, initial experience, and learning curve.</p> <p><i>J Trauma</i>;;42(3), Mar, pp 384-8</p>	<p>Prospective Study clinical trial</p> <p>N= 300 patients</p> <p>F/up: 4 month</p>	<p>Annualized cost savings with the use of US evaluation versus standard diagnostic evaluation would amount to over \$100,000.00</p>	Fair

### ACUTE ABDOMEN

No	Author, Title, Journal	Study design, Study sample, Follow up	Outcomes & Characteristics	Grade & comment
1	<p>Axelrod DA, Sonnad SS, Hirschl RB.(2000)</p> <p>An economic evaluation of sonographic examination of children with suspected appendicitis.</p> <p><i>J Pediatr Surg</i> ;,35(8), Aug, pp 1236-41</p>	Review	<p>The use of ultrasonography in patients with "an acute abdomen" is not cost efficient and results in average additional cost of \$234 per patient. In patients with equivocal diagnoses who are discharged from the emergency room after a negative ultrasound examination finding results in an average cost savings of \$260 when compared with admission and observation. Patients who are discharged without examination incur an average additional cost of \$373 as a result of the high cost of a missed diagnosis resulting in a perforated appendix. CONCLUSION: The use of ultrasonography can be recommended for children with suspected appendicitis and equivocal examinations who are discharged from the emergency room after a negative examination result.</p>	

**CONGENITAL DISCLOCATION OF HIP**

No	Author, Title, Journal	Study design, sample size & Follow up	Outcomes & Characteristic	Comment & Grade
1	<p>Geitung JT, Rosendahl K. Sudmann E (1996)</p> <p>Cost-effectiveness of ultrasonographic screening for congenital hip dysplasia in new-borns</p> <p>Skeletal Radiology; 25(3), pp 251-254</p>	Cohort	<p>The cost avoided for 2.6 cases of late-discovered CDH was Norwegian Kroner (NOK) was 315,562. The total average cost of treatment per case of late-detected CDH was NOK 121,370. The extra cost of exchanging one clinical examination for one ultrasound examination was NOK 60. The total cost of screening plus one clinical examination was estimated to be NOK 1,650,000 and the cost of false positive over treatment was estimated to be NOK 40,000 for total cost of OK 1,690,000. If the clinical examination were eliminated the extra cost of ultrasound would be NOK 285,000. Discounting was not applied. The total cost of ultrasonographic screening was NOK 1,375,438 ( 1,690,000-315,562, the cost avoided for 2.6 fewer cases of late-discovered CDH) The net cost of detecting 2.6 cases of late-detected CDH would be NOK 275 per new-born baby. Ultrasonographic screening would result in fewer cases o late-detected CDH, a general screening programme applied to the total population of new-born infant was not cost effective. However, screening for those identified as being at greater risk (traumatic birth and family history of CDH) may bring additional benefits and be cost effective. Moreover, if the screening programme adopted only ultrasonographic testing and the clinical examinations were eliminated the programme would be cost-effective</p>	Fair



**EVIDENCE TABLE I ETICAL IMPLICATION**

No	Author, Title , Journal	Study design, sample size, follow up	Outcomes & characteristic	Grade & comments
1	<p>Chervenak FA, McCullough LB. Ethics in obstetric ultrasound.(1989)</p> <p>Ethics in obstetric ultrasound.</p> <p><i>J Ultrasound Med</i>, 8(9), Sep, pp 493-7.</p>	No state	<p>An ethical framework is developed using the beneficence and autonomy models of moral responsibility in obstetric care. In terms of this framework, four ethical issues common to all ultrasound examinations are examined: (1) competence to perform obstetric ultrasound and referral to specialists, (2) routine ultrasound screening, (3) disclosure of results, and (4) confidentiality</p>	Poor
2	<p>Chervenak FA, McCullough LB. (1991)</p> <p>Ethics, an emerging subdiscipline of obstetric ultrasound, and its relevance to the routine obstetric scan.</p> <p><i>Ultrasound Obstet Gynecol</i>, 1(1), Jan 1, pp18-20</p>		<p>Ethics is an emerging subdiscipline of obstetric ultrasound because there are clinical dimensions of obstetric ultrasound that only ethics can identify and address. These dimensions concern the ethical obligations of physicians to their patients. Ethics is defined as the disciplined study of morality. Two fundamental principles of ethics are described, beneficence and respect for autonomy. How ethics can bring to light clinical dimensions of obstetric ultrasound that are insufficiently appreciated is illustrated with the example of the routine use of obstetric ultrasound in the second trimester. The authors conclude that prenatal informed consent for sonogram should be an integral part of obstetric care in countries, such as the United States, in which routine ultrasound is not endorsed</p>	

**DETAILS OF LITERATURE SEARCH**

**Ultrasound and Safety**

An electronic literature search using PUBMED database, and HTA web sites was carried out from 1997 - 2003 using the following keywords *Ultrasound; diagnostic, exposure, side effect, biological effect, effect, safe\** either singly or in combination.

**Ultrasound in Antenatal Care**

An electronic literature search using PUBMED database, Medscape was carried out from 1990-2002 , using the following keywords *ultraso\* , sonog\* , effect\*; pregnan\*; prenatal\*; screening; dat\*; confirmation of pregnancy; dating of pregnan; fetal viability; fetal well-being; placental location; placenta praevia; retained products of conception; fetal anomaly; congenital abnormality; intrauterine growth restriction or retardation, ectopic pregnancy; pregnancy ultrasound; ultrasonography screenin; in Obstetric care; legal aspects and ethical aspects* either singly or in combination. In addition, all health technology report was search. All relevant articles were then graded and appraised.

**Use of Ultrasound in Primary Care**

An electronic literature search using database PUBMED, MEDLINE was carried out from 1986 -2002 and limit to English and human. The various key words were used for search *Ultraso\* , sonog\*; surg\* , screening, breast, appendicitis, blunt trauma, primary care, abdomen ultrasound, surgeon and non-radiologist* either singly or in combination. The bibliographies of articles retrieved from the database were also reviewed to identify additional titles. Reference papers and cross-references were accessed where applicable.

**Cost effectiveness**

An electronic literature search using database PUBMED, MEDLINE was carried out from 1986 -2002. The various key words were used for search *Ultraso\* , sonog\*; surg\* , screening, breas; Cost-effectiveness, cost-benefit antenatal, blunt trauma, primary care, abdomen ultrasound, surgeon and non-radiologist* either singly or in combination. The bibliographies of articles retrieved from the database were also reviewed to identify additional titles. Reference papers and cross-references were accessed where applicable. Problems encountered in the literature search were due to lack of evidence on cost-effectiveness and cost-benefit analysis. Most of the literature was not able to state the total cost and unit cost incurred.

**Ultrasound Training for Non-radiologist**

Literature searches were conducted for the year 1997 to 2003 using PUBMED database. The following search terms was used *Ultrasound, training, non-radiologists, Physicians,* either singly or in combination.

## APPENDIX 2

### LEVEL OF EVIDENCE SCALE

Level	Strength of evidence	Study design
1	Good	Meta-analysis of RCT, Systematic Review
2	Good	Large sample RCT
3	Good to Fair	Small sample RCT
4		Non-randomised controlled prospective trial
5	Fair	Non-randomised controlled prospective trial with historical control
6	Fair	Cohort studies
7	Fair	Case control studies
8	Poor	Non-controlled clinical series, descriptive studies, multi-center
9	Poor	Expert committees, consensus, case reports, anecdotes

*(Adapted from Catalanian Agency of Health Technology Assessment & Research)*

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potential for associated developing brain is the biological effects.

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and thus the most susceptible tissue ultrasound induced heating

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. Radiologists did not develop it and it is not performed uniquely by radiologists (2).

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If pregnant women were to receive ultrasound examinations it is estimated that at least 70% of women would receive at least one scan and therefore it seems inappropriate that the remaining 30% should be denied of an ultrasound examination

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The committee has also agreed

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, subsequently to determine ultrasound training for non-radiologist.

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#### **4.1 Ultrasound and Safety**

An electronic literature search using database PUBMED, HTA web site was carried out from 1997 - 2003 using the following keywords *Ultrasound; diagnostic, exposure, side effect, biological effect, effect, safe\** either singly or in combination.

#### **4.2 Ultrasound in Antenatal Care**

An electronic literature search using database PUBMED, Medscape was carried out from 1990-2002 , using the following keywords *ultroso\* , sonog\* , effect\*; pregnan\*; prenatal\*; screening; dat\*; confirmation of pregnancy, dating of pregnan;; fetal viability; fetal well-being; placental location; placenta praevia; retained products of conception; fetal anomaly; congenital abnormality; intrauterine growth restriction or retardation, ectopic pregnancy; pregnancy ultrasound; ultrasonography screenin; in Obstetric care; legal aspects and ethical aspects* either singly or in combination. In addition, all health technology report was search. All relevant articles were then graded and appraised.

#### **4.3 Use of Ultrasound in Primary Care**

An electronic literature search using database PUBMED, MEDLINE were carried out from 1986 -2002 and limit to English and human. The various key words were used for search *Ultroso\*, sonog\*; surg\*, screening, breast appendicitis, blunt trauma, primary care, abdomen ultrasound, surgeon and non-radiologist* either singly or in combination. The bibliographies of articles retrieved from the database were also reviewed to identify additional titles. Reference papers and cross-references were accessed where applicable.

#### **4.4 Cost effectiveness**

An electronic literature search using database PUBMED, MEDLINE were carried out from 1986 -2002. The various key words were used for search *Ultroso\*, sonog\*; surg\*, screening, breas;, Cost-effectiveness, cost-benefit antenatal, blunt trauma, primary care, abdomen ultrasound, surgeon and non-radiologist* either singly or in combination. The bibliographies of articles retrieved from the database were also reviewed to identify

additional titles. Reference papers and cross-references were accessed where applicable. Problems encountered in the literature search were due to lack of evidence on cost-effective and cost-benefit analysis. Majority of literatures was not able to conclude the total cost and unit cost incurred.

#### 4.5 Ultrasound Training for Non-radiologist

Literature searches were conducted for the year 1997 to 2003 using PUBMED database. The following search terms was used *Ultrasound, training; non-radiologists,Physicians*, either singly or in combination.

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A basic ultrasound machine consist the following parts:

- **Transducer probe** - probe that sends and receives the sound waves, it comes in many shapes and sizes, the shape of the probe determines its field of view, and the frequency of emitted sound waves determine deep the sound waves penetrate and the resolution of the image.
- **Central processing unit (CPU)** – computer that does all of the calculations and contains the electrical power supplier for itself and the transducer probe.
- **Display**- displays the image from the ultrasound data processed by the CPU, either black- and- white or color, depending upon the model of the ultrasound machine.
- **Keyboard/cursor** – inputs data and takes measurements from the displays
- **Disk storage devices** - the processed data and /or acquires image can be stored on disk, these disks can be hard disk, floppy disk, compacts discs (CDs) or digital video discs (DVDs)
- **Printer**- prints the image from the displayed data

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#### Use of ultrasound to diagnose ectopic pregnancy

The sensitivity and specificity of transvaginal ultrasonography for predicting ectopic pregnancy was ranged from 87% to 99% and 84% to 100% respectively (Chechia et al., 2000; Shalev et al., 1998; Durham et al., 1997; Turan et al., 1996; Hopp et al., 1995; Sadek Al, & Schiotz, 1995; Achiron et al., 1994; Braffman et al., 1994; Hernadi et al., 1992; Bocciolone et al., 1991; Aleem et al., 1990). There were definite role on diagnosing ectopic pregnancy (Sadek, & Schiotz, 1995; Athey et al., 1991). However, combination with beta-hCG assay increases diagnostic accuracy (Chechia et al 2000; Turan et al., 1996; Bocciolone et al., 1991; Aleem et al., 1990). It was also found that pelvic fluid may be present, but it is a nonspecific finding. Color Doppler techniques can complement endovaginal sonographic findings, but they should be performed only after a thorough real-time evaluation of the adnexal region (Atri et al., 1996).

In the study done by Ehsan et al., (1998) the diagnosis of ectopic pregnancy was made by clinically (80%), by culdocentesis (90%), by ultrasound (90%) and confirmed by laparoscopy (100%). Another prospective study found that transvaginal sonography enabled detection of hemoperitoneum with a sensitivity of 91%. Thus, a tubal pregnancy can be predicted reliably on the basis of transvaginal sonographic findings (Cacciatore B, 1990). However, another retrospective study found that endovaginal scanning does not permit a confident diagnosis of ectopic pregnancy in many cases (Russell et al., 1993).

The capacities of colour Doppler further enhance the diagnostic sensitivity of transvaginal ultrasound for the early recognition of abnormal and normal intrauterine pregnancy, and small extrauterine masses (Goes et al., 1998). It was also found that the use of transvaginal B mode imaging alone in the diagnosis of ectopic pregnancy achieved a sensitivity of 98%. However, the use of transvaginal colour flow imaging did not increase detection rates of ectopic pregnancy. Thus colour Doppler imaging failed to improve on the results of transvaginal B mode sonography in the detection of ectopic pregnancy (Chew et al., 1996). However, another study found that high velocity systolic flow, and low impedance diastolic flow which characterizes trophoblastic tissue when detected outside the uterus, had a sensitivity of 48%, while the presence of trophoblastic signals in the uterus or their absence outside the uterus excluded ectopic pregnancies with a specificity of 89%. These data suggest that transvaginal Doppler ultrasound has significant lower sensitivity and does not provide more useful diagnostic information than 2-D imaging alone for stable patients with suspected ectopic pregnancies (Achiron et al., 1994). It was also found ultrasound correctly identified 69.6% of ectopic pregnancy. Subsequently increased the true positive rate to 78.3% and decreased the false negative rate to 8.8%. However, there were 5 false positive reports due to ovarian cysts. (Dallas et al., 1994)

Studies found that transvaginal sonography (TVS) was superior, offer an earlier, clearer and more exact diagnosis of ectopic pregnancy than transabdominal scan (TAS) (Luo et al., 2002; Hanchate et al., 2002; Gramith et al., 1991; Valenzano et al., 1991; Thorsen, 1990). It was also found that transabdominal sonography result shows single ectopic pregnancy and an ill defined mass in the left adnexa, subsequently it was determined by transvaginal sonography that the left adnexal mass contain a single monochorionic gestation sac with 2 embryos, then, it was further confirm by color Doppler sonography and laparotomy (Hanchate et al., 2002). It was found that TVS is best used when TAS is not conclusive, or when immediate confirmation of an intrauterine pregnancy is desired (Gramith et al., 1991).

With the advent of vaginal ultrasound, early diagnosis of ectopic pregnancy can be made and hence conservative tubal surgery can be performed. Hence it can be concluded that there is an improved outcome with the use of ultrasound in the diagnosis of ectopic pregnancy (Abound E, 1994).

A review indicated that the most common endovaginal sonographic finding of EP is an extraovarian, round or elongated, solid tubal mass. A tubal ring (an extrauterine sac like structure) is the second most common finding (Atri et al., 1996).

A study found that the ultrasound result shows patients with an empty uterus had the highest frequency of ectopic pregnancy, with a relative risk of ectopic pregnancy 5 times greater than that of the other 4 subclasses (Dart et al. 2002). It was found that the best criterion to use for the diagnosis of ectopic pregnancy is a non-cystic adnexal mass (Brown DL., 1994).

A prospective observational study found that serum progesterone cannot reliably discriminate ectopic pregnancy vs spontaneous abortion in pregnant patients with no definite IUP on endovaginal US (Valley et al., 1998)

Durston et al., (2000) found that the specificity of Emergency Department Sonography in ruling an intra uterine pregnancy (IUP) was 100%. However, times from first ED visit to treatment in Epoch 3 raised the possibility that an adnexal mass or signs of tubal rupture may have been missed on some ED Sonos. Another study found that transabdominal ultrasound performed in the emergency department is useful in screening for early pregnancy complications. Ectopic pregnancy should be suspected when no IUP is found on preliminary scanning (Wong et al., 1998). Emergency physician ultrasonographic diagnoses included definite IUP 59%, probable abnormal IUP 11%, definite ectopic pregnancy 2%, and no definite IUP 28%. It was found in a study that the gynecologist agreed with 93% of the initial interpretations by ED sonograph (Mateer et al., 1995)

Subclassification of indeterminate ultrasound readings identifies patients at high, intermediate, or low risk for ectopic pregnancy and should improve the diagnostic accuracy of ultrasonography in patients at risk for ectopic pregnancy (Dart, & Howard, 1998). It was found by Burry et al., (1993) that the halo sign shows in ultrasonography is presumptive evidence of a living ectopic pregnancy, and when identified may allow earlier diagnosis and intervention. Another study also found that ultrasound was found promising in the confirmatory diagnosis of ectopic pregnancy especially when a strong suspicion was established by history clinical examination and pregnancy test (Iloabachie, & Mgbor, 1991)

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**The sensitivity and specificity of echogenic fluid for establishing hemoperitoneum were 100% and 100%, respectively, compared with 66% and 80% respectively for culdocentesis. Thus, sonography is more sensitive than culdocentesis in the detection of hemoperitoneum. However, culdocentesis should play no role in the evaluation of ectopic pregnancy except in the unusual circumstance in which, high-resolution sonography cannot be readily performed (Chen et al., 1998).**

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Twin pregnancy presents considerable risk to the well being of both infants that can be traced to either related maternal or intrinsic fetoplacental factors. Ultrasound identification and correct dating is essential. Twin pregnancy has

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Another study found that use of ultrasound at 10-14 weeks of gestation using lambda sign is a good way of diagnosing chorionicity in twin pregnancy (Sepulveda et al 1996). It was also shows that ultrasound assessment of chorionicity using the twin peak has a sensitivity of 94% and specificity of 88% (Wood et al., 1996).

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Umbilical artery Doppler velocimetry is a good tool to predict outcome in pregnancies complicated by hypertension (Tomes PJ., 1995).

IUGR babies require close monitoring with ultrasound, fetal movement and fetal heart variation (Vindla et al., 1997). An

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Another study also found that estimated fetal weight at the time of the ultrasound examination was used to predict actual birth weight. Then, at delivery, the percent difference between the projected and actual birth weights was then used to define whether an infant was small, appropriate, or large for gestational age. This method appeared to be accurate and showed identical relationships to the presence of abnormal fetal heart rate patterns in growth-retarded infants as did the traditional birth-weight-for-gestational-age method of defining intrauterine growth retardation (Ott, WJ, 1990)

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The placenta was first described sonographically by Gottesfield in 1966 but it was almost a decade later with advent of gray-scale real time ultrasound that major advances in placentograph occurred. Today, evaluation of placental position and grade is part of a basic ante-partum obstetrical ultrasound examination that can be performed in the obstetrician's office. Clinicians faced with a problem involving the placenta can rapidly reach a diagnosis in the office or emergency room and avoid hospitalization of patients for diagnostic purposes. This has resulted in major economic savings to the patient and improved hospital bed utilization.

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and used to predict placenta praevia

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A prospective study shows that the specificity sonographic diagnosis of vasa previa was 91%. Hence, antenatal diagnosis permitted to prevent the catastrophic outcomes commonly associated with vasa previa. (Catanzarite et al., 2001).

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It was also found that the detection sensitivity of major abnormalities was 73.7% compare to 45.7% for minor abnormalities (Gradjen et al., 1999).

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Routine prenatal ultrasound screening for cardiac anomaly is inefficient (Buskens et al., 1996). Another study shows that

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the detection rate of neural tube defects was 79.4%

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increased the risk of Downs Syndrome by 5.6 fold and reduce the risk by 45% and 10 time more

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It was also found that the detection rate varies between registries from 25 to 100% for Omphalocele and 18 to 100% for gastroschisis

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for detection of anomalous fetuses

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NCCHTA (2000) found that the detection rate of fetal abnormalities by ultrasound scan was varying with the organ affected. There were also a variation seen at second and third trimester examination, and there is lacking of data for first trimester scanning.

Genetic ultrasonography use in community base practice is highly effective in identifying chromosomal abnormal fetuses. (Wax et al., 2000)

The risk of fetal chromosomal reduces by 2 to 3 fold when ultrasound examination is normal, whereas, the presence of any major ultrasonographic abnormality or certain minor abnormalities significantly increases the risk. However, the application of these results to low risk patients is still premature (Ott, & Taysi, 2001)

Ultrasound is less reliable in detecting hindgut abnormalities and best for detection duodenal obstruction (Phelps, 1991).

A study found that

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in early pregnancy. There is good probability of diagnosing

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The sensitivity and specificity of cervical status for detecting retained products of conception were 65% and 56%, respectively, whereas the overall sensitivity and specificity of transvaginal sonographic examination (bilayer endometrial thickness 8 mm or less) were 44% to 100% and 80% to 92% respectively. Thus, t

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and is effective

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Radius study,

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versus selective ultrasound

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in terms of

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(CAHTA),

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(SBU),

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, (Cochrane Review)

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on routine Doppler ultrasound in pregnancy

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based on

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It was also found that there is no available evidence to assess maternal outcomes, particularly psychological effect

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stated that there is

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. It is important to note that there was

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was not the result of a delay in timing fetal death

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Numerous

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the effect of

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as estimated by the proportion of Apgar score < 7 at 1 minute was no different

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of 65.5%, 72.4%

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and 62.5%, 68.9% for the

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> 2 cm

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> or = 40%, respectively

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, transperineal ultrasonographic examination for cervical length is

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using a cutoff point of 35 mm,

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should

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. Thus, Cerclage may not prevent preterm delivery in patients identified to be at high risk for this outcome by transvaginal ultrasonography

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The sensitivity and specificity of cervical length (CL) < 25 mm for preterm premature rupture of membrane (PPROM) at < 35 weeks were 73% and 69% respectively; as for preterm labor (PTL) were 58% and 66. While for PPRM at < 32 weeks they were 85% and 68%, and for PTL were 70% and 66. Thus,

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CL was

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PPROM

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A study found that for early preterm delivery with cervical length of < or =15 mm had a sensitivity of 82%, and a specificity of 99.7%. thus, a short cervix seen on second-trimester sonogram was a powerful predictor of early spontaneous preterm delivery (< or =32 weeks' gestation). Nearly 50% of patients with a cervical length < or =15 mm had an early spontaneous preterm delivery, which suggests that clinical trials of interventions (eg, cerclage) in this population are urgently needed (Hassan et al., 2000). It was also found by a meta- analysis and review that the best cut-off for cervical length was 18 to 30 mm. The sensitivity for predicting preterm birth ranges from 68 to 100%, and the specificity ranges from 30 to 79% (Vendittelli, & Volumenie, 2000; Leitich et al., 1999 ). While the sensitivity to predict preterm delivery were 33 – 54%, or 63- 76% and

specificity were 95-99% or 92% for cutoff cervical length of 25 and 35 mm or 25 and 39 mm respectively (Leitich et al., 1999)

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The median (range) gestational age at delivery (37 (15-41) versus 37 (17-41) weeks), the number of early (< 25 weeks) losses (9.9% versus 8.8%), and preterm deliveries (< 37 weeks) (35.8% versus 36.8%) were similar in the elective and ultrasound-indicated cerclage patients, respectively. In patients at risk for pregnancy loss, placement of cervical cerclages in response to ultrasonographically detected shortening of the endocervical canal length is a medically acceptable alternative to the use of elective cerclage (Guzman et al., 1998)

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**Blunt**

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physicians

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frequently

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head injury, polytrauma or hemodynamic instability

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*Effectiveness*

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ranges from 75-98%

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ranging from

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ultrasound had sensitivity ranged from 69 – 91.7% and specificity ranging from 86-94.7%, while DPL had sensitivity of 100% and specificity of 86-94.7%, CT had sensitivity ranging from 75%-97% and specificity ranging from 95-100%. Thus, evidence indicates that

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than DPL and CT

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, but has value in identifying patient for laporatomy

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with precordial wounds and blunt truncal injuries because it is rapid and accurate. Because of the high sensitivity and specificity of US in the evaluation of patients with precordial wounds and hypotensive patients with blunt torso trauma,

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US examination

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from blunt abdominal trauma often are associated

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. Isolated renal injuries frequently occur without the presence of free fluid in the abdomen. Furthermore, the ultrasonogram of the kidney often is normal with acute renal injuries, but it is more likely to be abnormal with severe (grade II or greater) renal injuries

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, and, depending on clinical and laboratory findings, other imaging

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A study found that FAST can be a useful initial diagnostic study after penetrating abdominal trauma, and a positive FAST is a strong predictor of injury, and patients should proceed directly to laparotomy. If negative, additional diagnostic studies should be performed to rule out occult injury (Udobi et al., 2001). It was also found that the routine use of sonography in penetrating torso injury is beneficial and the detection of pericardial or peritoneal fluid is clinically useful. However, a negative FAST examination does not exclude abdominal injury, such as a diaphragm or hollow viscus wound, and further investigation or close follow-up is required (Boulangier et al., 2001). The focused assessment for the sonographic evaluation of pediatric blunt trauma patients performed by surgical residents and attending in the emergency department (ED) rapidly and accurately predicted the presence or absence of intraperitoneal fluid. The FAST is a potentially valuable tool to rapidly prioritize the need for laparotomy in the child with multiple injuries and extraabdominal sources of bleeding (Thourani et al., 1998).

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Prospective Study found that thoracic ultrasound reliably in diagnoses of pneumothorax. It has also been suggested that FAST should be eExpandedsion of the focused abdominal sonography for trauma (FAST) examination to include the thorax especially in diagnoses of pneumothorax should be investigated for terrestrial and space medical applications. (Dulchavsky et al., 2001).

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Emergency sonography to evaluate patients for injury caused by blunt trauma is highly accurate and specific. However, the sonographic detection of free fluid is only moderately sensitive for diagnosing intra abdominal injuries, if combination of free fluid and/or a parenchymal abnormality is more sensitive (Richards et al., 2002). Another study also found the similar findings that ED abdominal ultrasound scan used solely for the detection of intraperitoneal fluid in pediatric blunt trauma patients has a modest accuracy. Ultrasonography has the best test performance in those children who are hypotensive and should be obtained early in the ED evaluation of these patients. (Holmes et al., 2001). A study found that ultrasonography is a reliable and rapid method for screening traumatized children for the presence or absence of free fluid in the peritoneum even in the hands of novice sonographers in emergency department. (Corbett et al., 2000). A review found that emergency sonography is sensitive for the detection of grade III or higher liver injuries resulting from blunt abdominal trauma. Sonography may also reveal blunt hepatic injury on the basis of parenchymal abnormality, with a discrete hyperechoic area the most commonly encountered pattern. (Richards et al., 1999)

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in the previous study

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Fernandez

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*Surgical Setting*

*Appendicitis Ultrasound*

*Effectiveness*

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study found that in the

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population

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While, in the equivalent examination population, with the prevalence of appendicitis of 28.4%, the sensitivity and specificity of ultrasound scan were 93% and 93% respectively.

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However,

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would return with ruptured appendicitis while,

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that

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also would

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the correlation of sonogram and intra-operative microscopic findings showed that 68.2% cases had acute inflamed appendices with negative ultrasound result. While, if

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positive result there

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90% of an inflamed appendix was

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found that the accuracy of US in diagnosis appendicitis was 85.9% in patients with definite signs of appendicitis requiring urgent surgery; 88.9% in patients with intermediate signs requiring serial observation and 91.8% for patients with a low probability of appendicitis respectively, Thus,

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A study reported that the efficacy of ultrasonography using the simple criteria was superior to the surgeon's initial clinical impression (Soda et al., 2001).

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acute appendicitis in children

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that are no different in size from non-palpable mamographically detected lesions

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mammography could diagnose the extent of intra-ductal spread more accurately compared with US examination. Current US examination is useful in depicting the intra-ductal spread of breast cancer, however US

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intra-ductal component of comedo type

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The mean size of invasive cancers detected by sonography was 9.1 mm, and was not statistically different from the mean size of invasive cancer detected by mammography. Thus, the use of high resolution sonography as an adjunct to mammography in women with dense breasts may lead to detected cancer (Buchberger et al., 2000). Another study stated that sonography is useful for pre-surgical assessment of tumor size in patients with breast cancer, especially for single lesions of 20 mm or less and without an extensive intra-ductal component (Tresserra et al., 1999).

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there were 83% of invasive ductal tumor fall within 1 cm and 100% fall within 2 cm extension of the US measured tumor size. Therefore, it is possible to use US to monitor the extent of treatment size when developing varies localized therapeutic tools

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It was found that US was better than or equivalent to mammography in determining tumor size, and improved for only T1 and T2 tumors, thus US is more accurate than mammography in assessing breast cancer size (Hieken et al., 2001). Similarly, US revealed significantly higher diagnostic performance than mammography for tumors larger than 2 cm.

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It was also found that

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except for tumor smaller than 2 cm and the accuracy of US in patients with palpable mammographically noncalcified and not obviously malignant breast tumors is lower than reported for mixed sample population. However,

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A study stated that whole-breast US, when performed in patients with dense (BI\_RADS category 3 or 4 density) breast tissue, is useful in detecting breast cancer not discovered with mammography or clinical breast examination. There were 30% cancer detection rate compares favorable with that of screening mammography and previously published studies involving bilateral whole-breast US (Kaplan, 2001)

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Mammography was more sensitivity than clinical examination or US in detecting contra-lateral breast cancer, the sensitivity of mammography being 81%. 39% of the contra-lateral cancers were non-palpable, and all were first detected at mammography. Therefore no cancer was depicted by US alone. However, US provided complementary information about palpable masses in 50% of the cases in which the mammographic finding was difficult to interpret (Rissanen et al., 1995)

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Mammography was capable for detecting 94.5% of breast carcinomas, breast sonography 91% and palpation 87%. Whereby, the combination of mammography and sonography or mammography and palpation detected 99% of carcinomas and sonography and palpation 95 % of carcinomas (Meden et al., 1995). Another study stated that the high resolution and accuracy of ultrasonography vs mammography in the diagnosis of cystic masses was 96% versus 42% and fibrocystic masses 84% versus 74%. Whilebreast cancers were accurately diagnosed in 73% by sonography and 84% by mammography. However the

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was noticed in the diagnosis of minimal breast cancer due to

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of ultrasonography

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Sensitivity of mammography increased by age and with fattiness of the breast. However, the sensitivity of US was inversely related to age and directly related with fattiness of breast. Density in the tumour area compared to total breast density was related only marginally better sensitivity both of mammography and of US. Thus, sensitivity of mammography and US are independently related to the age of the patient and the density of the breast. The effect of age is inverse and that of density parallel between mammography and US on sensitivity. The effect of overall breast density was close to the effect of density at the site of the tumour on the sensitivity of both mammography and US (Saarenmaa et al., 2001)

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It was also found that the sensitivity, specificity and accuracy of mammography in differentiation of benign versus malignant disease were 92%, 89% and 90% respectively. However, additional sonography did not change these results. However, it increased diagnostic confidence in 18.2% of suspicious lesions (Partik et al., 2001). Another study found that mammography sensitivity for breast cancer declines significantly with increasing breast density and is independently higher in older women with dense breasts. Addition of screening US significantly increases detection of small cancers and depict significantly more cancers and at smaller size and lower stage than does physical examination (Kolb et al., 2002)

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The US role in screening might be now revised. Many factors are now in favor of targeted US screening in dense and complex breasts and in high-risk patients. Screening sensitivity is significantly increased. Most of these US-detected tumors are small enough to be curable. Mammography and sonography together is a unique problem-solving and cost-effective tool. They can easily guide fine aspirations or larger biopsies reducing the cost of unnecessary surgical procedures. Accurate US investigations facilitate the surgical approach to a very conservative and cosmetic operation

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High-resolution sonography can demonstrate the intraductal spread of tumors and their multiple foci more easily than mammography, but US diagnosis is less sensitive than magnetic resonance mammography in the evaluation of the real tumoral extent. Ductal branching has a complex pattern; therefore, intraductal spread and multifocal nodes are better demonstrated by multiplanar analysis of 3D ultrasound data volumes. Sonography can easily explore the different nodal chains.

US assessment is also important as sonography is very sensitive in patients with extensive nodal involvement that might result negative at the sentinel node procedure (Rizzato GJ 2001)

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is an accurate technique for distinguishing between benign and malignant NPBN observable sonographically

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Another study reported that ultrasonography is a useful adjunct to clinical and mammographic evaluation of breast disease like cysts, aids in differentiating benign from malignant lesions, and facilitates office needle biopsy of non-palpable abnormalities, permitting timely and cost-effective patient care (Hieken, & Velasco, 1998).

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Sonographic fine needle aspirations or micro biopsy under ultrasonographic control has been shown to allow modification of mammographic and clinical diagnostic errors, and thus, this method appears important in diagnosis of infiltrating lobular carcinoma (Escolano et al., 1997).

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**The type of tumor proliferation and the absence of microcalcifications within the invasive tissue led to 15% of false negative responses in the mammographic analysis. Ultrasonography disclosed only 12% of false negatives**

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**Sonographic appearance, especially fine needle aspirations or micro biopsy under ultrasonographic control, allows modification of mammographic and clinical diagnosis errors. Thus, this method appears of importance in diagnosis of infiltrating lobular carcinoma (Escolano et al., 1997)**

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**For detecting lymph node metastases sensitivity was 68.2% in all T-stages and 50% in T1-stages with a specificity of 100%. Classification of the axillary status (positive or negative for lymph node metastases) is possible in 90.5% for all T-stages and 94.9% for T1-stages. Microscopic and small lymph node metastases are missed by ultrasound. Compared to axillary palpation, sonography is better (Hergan et al., 1996)**

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**The use of ultrasound to evaluate non-palpable, mammographically detected masses has increased rather dramatically in recent years. Although in the United State breast ultrasound has been used to distinguish between solid and cystic lesions( its application in Europe has been considerably more broad. Recent advancement**

in ultrasound technology has broadened the actual and potential applications of ultrasound in breast disease.

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The availability of some of these technical advances have allowed for better delineation of various descriptive characteristics of breast masses. Alone or in combination, these characteristics may be helpful in predicting benign or malignant potential lesion. On the basis of such categorization and relative risk for malignancy, determination of the need for and guidance of fine -needle or core-needle biopsy can be made.

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Ultrasound is the diagnostic modality of choice for pregnant women with breast masses as well as for younger women prior to mammographic age. Ultrasound of the breast is particularly effective in evaluating an acute mastitis so as to look for abscess.( ).

Several studies have demonstrated that the accuracy of ultrasound guided needle aspiration and/ or cone biopsy is comparable to the "gold standard" of mammographic needle localization followed by open biopsy. Edgar D.S found no false positive and no false negative needle biopsy pathologies among those patients undergoing ultrasound guided aspiration cone biopsy.

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As was the case study done by Edgar D.S, occasionally lesions identified on mammography may be missed on ultrasound examination. In his study 11 of 150 patients diagnostic ultrasound failed to identify the mammographically identified lesion. In keeping with other reports suggesting a decreases in accuracy of breast ultrasound to lesions under 0.6-0.7cm.( )

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Office-based ultrasound of the breast performed by surgeons can accurately diagnose non-palpable simple cyst and can accurately guide needle aspiration and/or biopsy suspicious masses for diagnosis of cystic, benign solid or malignant lesions. Although it usefulness as a screening examinations of the breast is still somewhat limited it is extremely effective diagnostic tool when used in conjunction with physical and mammographic examination.

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## **Ultrasound**

### ***Effectiveness***

A mass in the gallbladder and gallbladder wall thickening (>12 mm) were cardinal sonographic finding of carcinoma.

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A retrospective study found that the number and size of stones found on pathologic examination were correlated with the results of image analysis. In patients with more than one stone, observable size differences were recorded if the smallest stone diameter was less than 50% of the largest stone diameter. Estimates of gallstones size and number from preoperative sonograms were correct in only 21%. Stone size and number were overestimated as often as they were underestimated.

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, 86% and 90% for US

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Cholecystoscintigraphy (HIDA), and the combination of US/HIDA, respectively. HIDA scan is a more sensitive test than US in diagnosing patients with acute cholecystitis. It was recommended that HIDA scan should be used as the first diagnostic modality in patients with suspected acute cholecystitis;

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of EUS

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for carcinoma of the gallbladder; however,

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sonography is reliable in the detection of a primary gallbladder mass or of local extension of tumor into the liver. However, sonographic findings do not accurately reflect the full extent of disease, and sonography is particularly limited in the diagnoses of metastases to the peritoneum and lymph nodes (Bach et al., 1998)

Symptomatic cholelithiasis rank among the most common conditions seen in surgical practice. Surgeon-performed gallbladder US offers several benefits. It acts as an extension of the physical examination allowing prompt physical clinical decision making by the surgeon who knows the anatomy, the pathology, and the options for further investigation and treatment.( ). In this study, the authors examine the use of surgeon-performed gallbladder ultrasound in patients suspected of having symptomatic cholelithiasis. Seventy-five patients in the study group underwent a total of 122 surgeon-performed ultrasound examinations, or 1.6 examinations per patient. In 9 of these 75 patients, no surgeon interpretation was obtained. All of the patients in the study also underwent a radiologist performed ultrasound diagnosis in 88% of patients studied as opposed to radiologist performed ultrasound diagnosis in 99% of the patients. This



preliminary study shows that general surgeons with limited ultrasound can performed gallbladder US to detect Cholelithiasis with a high degree of accuracy.

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### *Effectiveness*

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, above all when multiple, sonographic and vascular patterns are contemporaneously present in a thyroid nodule

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### *Setting*

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Doppler sonography can reliably rule out testicular torsion so that routine scrotal exploration in cases of acute scrotum is no longer necessary. By reducing the number of emergency operations and hospitalization days, color Doppler sonography can cut down the total cost of managing acute painful scrotum in boys (Weber et al., 2000)

### *Penis ultrasound*

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### Prostatic Ultrasound

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The presence of a pus collection within the prostate was confirmed by transrectal ultrasonographically guided aspiration in all patients. However, successful treatment of prostatic abscess with transrectal needle aspiration was 86.0%; while there is 14.0% treatment failed rate. On follow-up transrectal ultrasonographic examination, no

remaining abscess pocket was found within the prostate in any of the cases. One year later, the prostatic abscess recurred in one case

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Thus, transrectal ultrasonographic guidance is useful in the diagnosis of prostatic abscess as well as in the guidance for aspiration and the drainage of such abscesses. Transrectal ultrasonographically guided needle aspiration could be an effective method for treating prostatic abscess (Lim et al., 2000)

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**Ultrasonography scanning plays an important part in the diagnosis of urological problem, since almost all of the organs of the genito-urinary tract can readily visualized by this non-invasive investigation it is not surprising that urologist make considerable use of it in their daily practice. Ultrasound scanning at the time of the initial outpatient assessment by a person skilled in the procedure would theoretically be most productive by allowing a more speedy and accurate diagnosis. On the spot scanning would avoid unnecessary return visits and this would result in reduced transport costs and inconvenience to the patient. S.G.Vesey et al have assessed the value of ultrasound scanning in the urological out patient clinic by using such a machine and monitored the accuracy of the ultrasound when performed by urologist. The indications for scanning were bladder outflow symptoms in 55 patients (53.9%), haematuria in 8 (7.8%), loin pain in 15(14.7%), scrotal pathology in 7(6.9%) and miscellaneous in 17(16.7%).**

**Of 102 patients scanned, estimations of residual urine were made in 72(70.6%) and it was felt that further confirmation of these findings by radiologist ultrasound was unnecessary. The urologist in 19 of the patients referred and 11 negative scans made positive pathological findings. Radiologist further confirmed the above findings. Study by Reisman.E. M.et al of 171 patients hospitalized for prostatectomy, urologist-performed sonography was as accurate as an IVP in identifying the presence of upper tract malignancy. They also demonstrate the efficacy of urologist-performed sonography in the evaluation of patients with prostatism and clearly demonstrate its accuracy as compared to an IVP.**

**The result of these studies demonstrates that ultrasound scans of the genito-urinary tract performed by urologist can be accurate and reliable in clinical practice but appropriate training and experience in renal sonography is necessary. When there is a suspicious of upper tract pathology or when imaging of the kidneys is difficult, appropriate consultation must be sought with the radiologist to proceed with more definitive imaging modalities.**

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**Effectiveness**

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## *Achilles Tendon Tears*

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of the Achilles tendon

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Undetectable tendon at the site of injury, tendon retraction, and posterior acoustic shadowing demonstrate statically significant correlation with full- thickness tears

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nother study shows that for partial tears, sensitivity and specificity were 27% and 83% used of magnetic resonance imaging and 33% and 89% for sonography respectively. Accuracy was 69% for MRI and 75% for sonography. Thus,

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, However, at present

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all

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correctly

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The combined accuracy, sensitivity, and specificity of ultrasonography in detecting tendon tears in all patients evaluated both surgically and by clinical follow-up were 94%, 100%, and 90%, respectively

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Subsequently, a study

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were correctly diagnosed with ultrasonography

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, However, it need the arm can be externally rotated to the maximum extent when performing the study

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## *Use of ultrasound in Gynaecology setting*

### **Effectiveness**

#### ***Ovarian cancer***

HTA report found that Ultrasound screening can detect 75% of a higher proportion of ovarian cancers at stage 1 (Bell et al., 1998). Another study found that there were significant in 77.3% of the primary ovarian carcinomas found during the current screening were of curable Stage I. thus, increased use of Transvaginal sonography screening for ovarian carcinoma may increase the chance for early diagnosis and decrease the mortality of the disease (Sato et al., 2000). Similarly, another study also shows all women that had morphologically normal ovaries observed on ultrasound examination and were not suspicious on color Doppler analysis, were also negative on histopathological analysis (true negative = 80%) thus, the color Doppler ultrasonography revealed a valid first level screening method (Rampone et al., 2001). It was also found that overall sensitivity and specificity of transvaginal color Doppler ultrasonography in detecting early stage ovarian cancer was 92% and 86% respectively. If further analyse according to premenopausal and postmenopausal status, the positive predictive value was 98% and the negative predictive value was 99% in postmenopausal women and 90% and 88% in premenopausal women respectively. Therefore, transvaginal color can detect early-stage ovarian cancer, in fact, the findings were highly suggestive of ovarian cancer (Fleischer et al., 1996).

A HTA report shows annual screening with ultrasound appear to have a sensitivity or detection rate close to 100%, the false positive result rate is about 1.2-2.5% for women screened by ultrasound, there were about 0.5-1% of women will suffer a significant complications due to surgery and most of those who do not have ovarian cancer will have a benign gynaecological condition and about 3-12% of screened women are recalled for further testing and assessment, resulting in potential distress and anxiety to otherwise healthy women (Bell et al., 1998). Another prospective study found that ovarian tumors detected in postmenopausal women, includes 6.3% were functional cysts (follicular or corpus luteum cysts), and almost all of them were detected within the first 5 years of postmenopause. Others ovarian tumors were diagnosed as retention cysts (17.5%), benign neoplasms (39.4%), and malignant tumors (36.8%). Simple ovarian cysts (monolocular, smooth inner wall) represented sonomorphologically the second most frequent type of ovarian tumors in postmenopausal women (35.7%). Of these tumors, 9.6% were diagnosed as malignant (Osmers et a., 1998).

Ultrasound-guided fine needle aspiration was safely performed as an alternative treatment to surgery when persistent monolateral and unilocular ovarian cysts with regular borders and completely anechoic structure are detected during pregnancy (Guariglia et al., 1999)

#### ***Polyps***

A prospective study shows that using transvaginal sonography low levels of endometrial thickness reduced the possibility of abnormalities such as polyps and hyperplasia, but did

not exclude them. However, low cut-off levels for endometrial thickness did not increase the diagnostic performance in cases with normal sonograms (Dueholm et al., 2001)

### *Uterus*

A study reported that the sensitivity of combination of transvaginal sonography and sonohysterography in detecting submucous myomas and focal endometrial lesions were 100% and 90%, if transvaginal sonography alone the sensitivity was 100% and 70%. Thus, sonohysterography does provide additional information over transvaginal sonography alone and is an important adjunct to transvaginal sonography in symptomatic women with known or suspected myomas, particularly before surgical or medical therapy (Becker et al 2002). Another study had shown transvaginal – Color Doppler Ultrasound may be more useful in differentiating between Endometrial Hyperplasia (EH) and Endometrial Carcinoma (EC) than measuring endometrial thickness by transvaginal gray-scale sonography. For patients with EC, the detection of intratumoral blood flow may be helpful in distinguishing between low-grade and high-grade tumors and predicting myometrial invasion. However, intratumoral blood flow analysis using resistance index, Pulsatility Index, or Peak Systolic Velocity may not be useful for predicting tumor spread before surgery (Emoto et al 2002). It was also found that the sensitivity of Transvaginal Sonography (TVS) in directly visualizing intra-cavitary abnormalities was 61% and 96% for specificity. However, the sensitivity of TVS was 87% and specificity of 56%, if TVS as direct visualization of an intracavitary abnormality or an increased endometrial thickness with cut-off level of 5 mm. While, the sensitivity and specificity of saline infusion sonography was 100% and 85% and no intra-cavitary abnormality was missed by saline infusion sonography. Thus, the diagnostic accuracy of saline infusion sonography is higher than the accuracy of TVS. A combined approach using endometrial thickness measurement by TVS and, reserving saline infusion sonography for patients with increased (> 5 mm) endometrial thickness, or endometrium inadequately visualized on TVS, is the optimal method of reducing the hysteroscopy rate (Dijkhuizen et al., 2000). Another study also found that an endometrial thickness of > 5 mm had a sensitivity of 92.5%, specificity of 71.0%, respectively. TVS allows the detection of an endometrial pathology in the vast majority of patients with postmenopausal bleedings. In cases with a single postmenopausal bleeding and an endometrium smaller than 5 mm we recommend expectative procedures with repeated ultrasound examination of the endometrium (Gerber et al., 1999). However, another study stated that transvaginal sonography is confirmed to have a very high sensitivity for the detection of early endometrial carcinoma, but the specificity remains low. However, Doppler sonography does not improve the detection of premalignant and malignant endometrial lesions compared with normal ultrasound (Vuento et al., 1999). It was also reported by a study that the sensitivity and specificity of transvaginal ultrasonography alone and combined with color velocity imaging and pulsed Doppler were 88.9% and 91%; and 76.2% and 88.9%, respectively. Thus, the use of color velocity imaging and pulsed Doppler does not improve the diagnostic accuracy of transvaginal ultrasonography alone in the diagnosis of ovarian endometrioma (Alcazar et al., 1997)

A study found that transvaginal sonography demonstrated a sensitivity of 88% and a specificity of 71% for deep invasion. The accuracy of transvaginal sonography in detecting cervical involvement was 82% compare to hysteroscopy was 72%. transvaginal sonography was slightly less sensitive (54% vs. 64%), but more specific (87% vs. 73%) than hysteroscopy. The accuracy of transvaginal sonography was comparable with that of hysteroscopy in detecting cervical involvement (Gabrielli et al., 1996)

***Adnexal masses***

The sensitivity and specificity of Doppler sonography (CD) were 87.5% and 84.2%, respectively. While, for CA-125 were 83.9% and 68.4respectively. Color Doppler ultrasound has a better diagnostic performance as compared with CA-125, being significantly more specific (Alcazar et al., 1999). Another study stated that the present technique of Doppler ultrasound examination is helpful only in the differential diagnosis of multilocular cysts with solid parts. Therefore, the degree to which Doppler examination can contribute to the differential diagnosis of pelvic tumors will depend on the proportion of multilocular cysts with solid parts in the population studied, therefore the greater this proportion, the greater the potential of the Doppler examination to improve diagnostic accuracy (Valentin, 1997)

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**Effectiveness**

A Cohort study found that the number of late-discovered cases of congenital dysplasia hip (CDH) was higher in ultrasonographic versus clinical screening. There were 57.5 false-positive diagnoses. However

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CDH per annum over 1,000 live births

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the instability was diagnosed in 1.4% of all hips, but only 63% of unstable hips were diagnosed on the

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In the remainder, the clinical pathology was established on clinical re-examination after the sonographic abnormality was recognized. Similarly, but to a much lesser extent, sonographic pathology was detected only on the re-examination in 5% of the clinically unstable hips. Although the overall initial under-diagnosis rate of hip instability was 0.6% of all hips, the rate for treated hips was 0.1%

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in which

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## CONCLUSION

### Cost Implications

#### *Antenatal care*

Routine antenatal ultrasound screening for low-risk population is cost-effective, if all significant cost is taken into account, which, strongly dependent on the rates of malformation detected, and subsequent pregnancy termination (Perrson, 1983; Wells, 1986; James, 1989; Lachlan et al., 1989; Saari-Kemppainen et al., 1990; Isabel, 1990; Gregory, 1991; Lyn S Chitty, 1991; Temmerman, 1991; Luck, 1992; Heiner, 1993; Brand, 1994; Saari-Kemppainen, 1994; Rustico et al., 1995; Chitty, 1995; John, 1996; Muller et al., 1996; Carole, Leivo, 1996; Leivo et al, 1996; Daniel et al., 1996; Viljoen et al., 1996; Long, 1998; van Dorsten et al., 1998; Vintzileos et al., 1998; Long G, 1998; Romano, 1998; Waitzman, 1998). The cost calculated included the cost for maintenance severely crippled infant for about 40 years as well as cost of pregnancy termination (Luck, 1992; Leivo, 1996).). However the followings are other factors considered in cost-benefit ratio calculation: - Unnecessary antenatal visit and postnatal investigation; Unnecessary induction for misdiagnosed intrauterine growth retardation and post; maturity which was reduced by routine screening (Heiner, et al., 1993); Perinatal morbidity and

mortality decreased with routine scanning (James, 1989; Alike, 1990; Heiner, 1993; Leivo, 1996; Lout, 1996); Cost implication related to the expertise who is doing the scanning, techniques used and its referral systems (James,1989). However, numerous studies found that it is not cost savings, which, only comparing ultrasound screening between low-risk and high-risk population on the detection rate of congenital anomalies and perinatal outcome, without considering total cost incurred in maintaining severely crippled infants and other consequences (Temmerman, 1991; Heiner et al., 1993; Busken, 1996; Geert et al., 1996; Long, 1996; Robert et al., 1998). Others found that is not cost-effective due to the low sensitivity on detection of congenital anomalies in low-risk population resulted from inadequate qualification of operators (Levi, 1998; Stoll et al., 1993)

Other health care benefits of screening which affects the cost for routine ultrasound indirectly includes, fewer unnecessary antenatal services (Geert et al., 1996; Leivo et al., 1996), fewer number of ultrasound screened, less number of antenatal admission (Saari-Kemppainen et al., 1990), reduce number of postnatal investigation (Luck, 1992). and reduce rate of induction (Urban Wadernstrom et al, 1988).

The total health care benefit cost calculated per screening ultrasound examination was two thirds lower, which was accounted for by the lower inpatient cost (Leivo et al., 1996). The number of induced labour in the ultrasound group was significantly lower as a result of the more accurate dating of the gestational age. (Walderstrom, 1988) however showed that no effect on the number or duration of hospital admission.

Cost of one ultrasound examination should include physician training expenses, professional fees, personnel, equipment and maintenance costs, costs for exams repeated due to technical error, and costs for additional consultation to a radiologist. If all exams were referred to other consultants, the charges were higher (Hahn, 1988).

#### *Blunt abdomen trauma*

FAST as performed by residents incurred a single fee of \$88 for radiological readings as compared with \$274 for a US technician fee plus the radiological reading fee of \$ 88. while, the cost of Computerized Axial Tomography scan was \$ 750. Therefore, with the use of the US, the hospital saving can be projected to exceed \$ 662 for each trauma patient screen before Computerized Axial Tomography scan testing. While, the use of FAST in the present study, only 64 from 650 patients required further testing amounting to a total saving of \$ 387,932.Thus, FAST as performed by surgical residents is more cost-effective than FAST as performed by US technician (Frezza et al 1999).

Billing data revealed that the average charge for trauma sonography by radiologists was \$406.30 in one centre. While in another center, trauma sonography did not generate a specific charge; however, a \$20.00 sum was added to the trauma



activation fee to cover ultrasound machine maintenance and supplies (Buzzas et al 1998).

Annualized cost savings with the use of US evaluation versus standard diagnostic evaluation would amount to over \$100,000.00 (Thomas et al 1997).

### *Appendicitis*

In the acute abdomen population, the routine use of ultrasonography resulted in an additional cost of \$ 234 per patient when compared with immediate operation. If patients were inappropriately discharge after all negative studies, on average the cost of managing a case of appendicitis would be increased by \$ 1.114. However, in the equivocal examination model, the management with ultrasound scans and subsequent discharge resulted in expected savings of \$373 per patient when compared with immediate discharge and \$ 260 per patient when compared to admission and observation. If patient with negative scan findings were admitted subsequently, the ultrasound scan added \$ 245 to the cost per patient when compared with admission and observation only. This analysis was sensitive to variation in the percentage of patients who returned with rupture appendicitis after immediate discharge. The use of ultrasonography can be recommended for children with suspected appendicitis and equivocal examinations who are discharged from the emergency room after a negative examination result (Axelrod et al 2000)

### *Congenital Dysplasia Hip (CDH)*

A study shows that the cost avoided for 2.6 cases of late-discovered CDH was 315,562 Norwegian Kroner (NOK) and the total average cost of treatment per case of late-detected CDH was 121,370 NOK. The extra cost of exchanging one clinical examination for one ultrasound examination was 60 NOK. The total cost of screening plus one clinical examination was estimated to be NOK 1,650,000 and the cost of false positive over treatment was estimated to be NOK 40,000 for total cost of NOK 1,690,000. If the clinical examination were eliminated the extra cost of ultrasound would be NOK 285,000. Discounting was not applied. The total cost of ultrasonographic screening was NOK 1,375,438 (1,690,000- 315,562, the cost avoided for 2.6 fewer cases of late-discovered CDH). The net cost of detecting 2.6 cases of late-detected CDH would be NOK 275 per new-born baby. Thus ultrasonographic screening would result in fewer cases of late-detected CDH, a general screening programme applied to the total population of new-born infant was not cost effective. However, screening for those identified as being at greater risk (traumatic birth and family history of CDH) may bring additional benefits and be cost effective. Moreover, if the screening programme adopted only ultrasonographic testing and the clinical examinations were eliminated the programme would be cost-effective (Geitung, Rosendahl, & Sudmann, 1996)

## **CONCLUSION**

**Various studies justify systematic one-stage ultrasound screening of all pregnancies for the detection of major congenital anomalies under circumstances in which their elimination by induced abortion is acceptable, is cost-effective. (PNT Wells 1986;**

**Aulikki Saari, 1990; Carole A Luck 1992; Heiner C. Bucher 1993; Johannes G. Schmidt 1993; Brand IR et al 1994; Chamber Se et al 1995; D. Viljoen et al 1996; Long G. Sprigg A 1998;).**

**In addition, routine screening during pregnancy for low-risk population is also cost-effective considering the benefits of avoiding one perinatal deaths, and reduced health care costs for late-pregnancy outpatient and inpatient visits, as well as delivery (James P. Youngblood 1989; Auliki Saari and Kempainen 1990; Heiner C Bucher 1993 and Lut TGM et al 1996; Laevo T et al 1996;). However, it should be performed by trained, experienced ultrasonographers in the right environment. (PNT Wells 1986; Hahn RG et al 1988; Lyn S Chitty et al 1991; Gregory R. DeVore 1991; Vintzileos et al, 1992; Rustico et al, 1995; Rustino MA et al 1995; Daniel W Skupsi et al 1996; Daniel, 1996; John W Seeds 1996, Levis 1998).**

**Ultrasound operators need specific teaching support and referral system to maintain the quality of anomaly detection (Hahn RG et al 1988; Aulikki Saari 1990; Lyn S Chitty et al 1991; Rustino et al 1995; John W Seeds 1996; Daniel et al 1996; Levi S 1998).**

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Another study done on the participants has 6 PRE & 5 POST course were compared as to their ability to detect and quantify intraperitoneal fluid. Found that sensitivity of inexperienced clinician for detecting  $< \text{or} = 750 \text{ cm}^3$  was 45% PRE and 87% POST. However, there is no significant of accuracy in quantifying volume within  $250 \text{ cm}^3$  was 38% PRE and 44% POST.

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during training improves the learning curve. Hence, with the growing dependency on FAST to accurately triage blunt abdominal trauma safe and effective FAST training should consist of didactic education and a practical portion that includes positive studies

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surgical residents have ability to detect fluid in the abdomen, there exists a fast learning curve, and the minimum detection level of fluid was between 200 and 400 cc in the peritoneal cavity in the laboratory. Surgical residents were able to detect intra-abdominal fluid in the trauma situation, as shown by the 92% accuracy of the FAST in the emergency situation. Thus,

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workshop consisting discussion of ultrasound physics, demonstration of instrumentation, review of pertinent literature, videotaped demonstration, and hand-on teaching of the skill utilizing live patient models, result s shows that This

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Royal College of Obstetrics and Gynaecologist stated that there is no statutory requirement for ultrasound practitioner to receive accredited training. It was also suggested that medical staff who undertake ultrasound scanning for foetal abnormality should ideally hold a advanced Certificate of Ultrasound Training which is issued following a 300 hours course centres recognized by the RCOG/RCR skill should be

maintained by performing detailed scan one and preferably two sessions a weeks and should not undertake scans of any sort if they have not been specifically trained.

In Alberta, College of Physician and Surgeon stated that they must have completed a minimum of 6 months full time training in ultrasonography in a teaching program accredited by Royal College of Physician and Surgeon in Canada. This policy had been approved by the Diagnostic Imaging Committee of Society of Obstetrician and Gynaecologist of Canada. Training should be carried out in a large accredited service which provides all aspects of obstetrical and gynaecological care and interaction should be with trained supervisors on a one to one basis, the expertise must be achieved in 6 months dedicated training period. This mean that trainee have to participate in 100 gynaecologic and early pregnancy scans and have to participate in at least 200 obstetrical scans covering the full spectrum of obstetrics conditions and must perform 170 ultrasound procedures annually at each obstetric or focused obstetrical and/or gynaecological sites.

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### 6.1 Ethical Issues in Ultrasonography

*Often important ethical dimensions are neglected in clinical practice.*

#### 6.1.1

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confronts two main ethical concerns:

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Several ethical issues arise concerning the disclosure of results of ultrasound examination:

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re must be an adequate process of informing the

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potential for confronting the unanticipated

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. There should be frank discussion		
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the condition that		
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give permission to do so		
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This is not a practice in Malaysia. Patients are scanned on a 'need to' basis based on clinical needs. If		
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then there will be need to provide		
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cornerstone of a

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screening program. Yet this is one of the more

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aspects of running a screening program

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The introduction of ultrasound has revolutionized the management of pregnancy and it is common for a woman in Malaysia to have had at least one scan in the course of her pregnancy. Ultrasound is unique as an imaging modality in at least three aspects.

Ultrasound may be performed by obstetricians, radiologists, and radiographers and midwives with varying grades of expertise and qualification. It may be both a diagnostic and screening test depending upon the level of competence of the individual performing the test. It provides guidance for new techniques that invade the uterus.

There are no uniform method or authorities for certifying training for competence in performing ultrasound in Malaysia.

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during pregnancy

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could probably arise from;

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6.2.7 Invasive procedure

(a) Amniocentesis

The risk of having a normal pregnancy is about 1:200 pregnancies. The risk of failed cell culture is about 0.1-0.2 % and the risk of a wrong result because of cultured maternal cells is about 0.1 %. (Pearce 1994).

(b) Chorionic villus biopsy

There is an overall risk of pregnancy loss of about  $4 \times 10^{-6}$ . An adequate sample may not be obtained in  $1 \times 10^{-6}$  of cases and may need to be rejected. Placental mosaics may result in an uninterpretable result in  $1.5 \times 10^{-6}$  cases. Amniocentesis may be required later in such pregnancies. (Pearce 1994).

(c) Fetal blood sampling

Losses may range from 1-25% of the pregnancies within two weeks of the procedures (Maxwell1991).

(d) Fetal reduction, selective feticide and late termination

These are fraught with legal and ethical issues and should not be considered in Malaysia.

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