

# Routine ultrasound examination during pregnancy

## SBU Summary and Conclusions

### Introduction

Ultrasound examination during pregnancy was introduced nearly 25 years ago. At the outset, this technology was used mainly in cases of suspected morbidity or fetal malformation. As ultrasound technology has advanced, the indications for this type of examination have also expanded, and all pregnant women are now offered an ultrasound examination at least once during their pregnancy. In Sweden, an average of slightly more than two ultrasound examinations are performed per pregnant woman, including examinations performed on medical indications. More than 95% of women who deliver have undergone routine ultrasound examination.

The intent of routine ultrasound examination during pregnancy is to determine the gestational age, whether there is more than one fetus, and the position of the placenta. Depending on when the examination is performed, it can also provide information concerning the gender of the fetus. Ultrasound also provides an opportunity to check the anatomy of the fetus.

Whether or not a more thorough examination of the anatomy of the fetus is conducted, routine ultrasound examination does detect some cases of fetal malformation. The parents are then faced with the ethical dilemma of whether to terminate the pregnancy or continue it with the knowledge that the child may be born with a severe disability. The ethical dilemma is amplified due to the fact that ultrasound examination does not always provide 100% certainty concerning the situation. However, some studies have shown that the vast majority of expectant parents in Sweden want to have information concerning possible defects in the fetus. Routine ultrasound examination during pregnancy is standard procedure in 22 of 25 western countries. In the United States, Canada, Australia, and in all European countries except Sweden and Denmark, examination of fetal anatomy is an obligatory aspect of routine ultrasound examination during pregnancy. Nevertheless, in Sweden, the anatomy of the fetus is examined in 80% of all ultrasound examinations given to pregnant women.

The Swedish government has charged SBU with reviewing the scientific evidence concerning the medical benefits and the potential risks of routine ultrasound examination for the mother and the child, as well as its social, economic, and ethical consequences.

### Effects and Potential Risks of Ultrasound Examination

Despite several large comparative studies, routine ultrasound examination has not been shown to reduce mortality or morbidity in relation to delivery or during the perinatal period, nor does it reduce the risk for delivering a child having a growth disorder. On the other hand, there is some evidence to show that fewer newborns require care in intensive care units.

To study the potential relationship between ultrasound examination and the possible negative consequences for the fetus, several randomized, controlled studies have been conducted. These studies 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.

### **Assessment of Gestational Age**

To establish an accurate diagnosis concerning premature delivery or prolonged pregnancy it is necessary to know the exact gestational age. Knowledge about the gestational age may also be of critical importance in managing other prenatal complications.

There is scientific evidence to show that assessing the gestational age by ultrasound examination during the first half of the pregnancy predicts the delivery date with greater precision than does information concerning the last menstruation. This also applies to women who report menstrual regularity and who are certain about the first day of the last menstruation.

It has been clearly shown that routine ultrasound examination as a means of determining the gestational age leads to fewer post-term pregnancies and hence fewer induced births due to prolonged pregnancy. Isolated studies also show that fewer women are treated with drugs that prevent preterm labor and that more births are induced because of suspicions that the fetus is not growing normally. Furthermore, a decline has been shown in the number visits to specialists.

Nevertheless, it is unclear whether the number of children born with lower birth-weights than expected has declined because of routine ultrasound examination. Likewise, it has not been shown whether or not routine ultrasound examinations affect the load on hospital birthing units.

### **Diagnosis of Multiple Pregnancies (Twins)**

A pregnancy involving twins is associated with a greater risk for complications than a pregnancy involving a single birth. Hence, theoretically, early diagnosis of twins should lead to better outcomes of pregnancy. Ultrasound examination can determine the number of fetuses with relatively high certainty.

Several controlled studies show that routine ultrasound examination leads to earlier diagnosis of multiple pregnancies. However, there is no undisputed evidence to show better outcomes for twins whose mothers undergo routine ultrasound examination.

The current monitoring and treatment methods are, however, probably superior to those used in the studies upon which this report is based.

### **Diagnosis of Placenta Previa**

Placenta previa means that the placenta develops abnormally low in the uterus. This condition occurs in approximately two cases per 1000 deliveries in Sweden. The condition is life threatening for both the mother and the fetus. Routine ultrasound examination during pregnancy can, in theory, lead to diagnosing all cases before the onset of labor. This facilitates the planning of necessary cesarean procedures, whereby it should be possible to reduce morbidity and mortality in both mothers and children.

Routine ultrasound examination during the first half of pregnancy would predict most cases of placenta previa even if the method is often overdiagnosed, ie, more than the actual number of women with placenta previa are diagnosed as having the condition.

In the controlled studies thus far, the number of pregnant women is too small to reliably determine whether pregnancy outcomes in placenta previa are better among women who have undergone routine ultrasound examination than among women who were examined on clinical suspicion alone.

The substantial risk for overdiagnosing 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.

### **Diagnosis of Fetal Growth Retardation**

Intrauterine growth retardation means that the fetus does not develop its genetic growth potential. Hence, it runs the risk of dying or surviving with damage of the nerves system.

A Norwegian-Swedish study reported that repeated ultrasound examinations aimed at determining fetal weight is the best method for diagnosing intrauterine growth retardation. In six controlled studies, researchers investigated the effects of repeat ultrasound examination in children born with growth retardation. In none of these six studies were the authors able to show a favorable effect from ultrasound examination in this respect. However, the methodology of several of the studies is uncertain, and further studies are required to determine the value of ultrasound examination for this purpose.

### **Diagnosing Fetal Malformation**

Two to three percent of all children born suffer from severe deformity. Most types of congenital malformation reveal no symptoms during pregnancy. Detection of a congenital malformation may encourage the expectant mother to terminate the pregnancy. In cases where it is possible to treat the disorder, it becomes possible to plan an optimal strategy of care for the child and mother in conjunction with delivery. Some deformations can be treated in the uterus. Currently, it is unclear whether such interventions reduce mortality or morbidity in the child.

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 is a special informational need prior to such an investigation.

In two controlled studies where researchers studied the anatomy of the fetus to detect possible malformation, as an aspect of routine ultrasound examination, more congenital deformities were discovered than in the control group where women were examined on clinical suspicion. In one of the studies, birth-related mortality was lower in the ultrasound group since the discovery of severe deformity led to more cases where pregnancy was terminated.

Being informed that the fetus is malformed may traumatize the parents. Hence, psychological care is particularly important, and medical and social follow-up is critical.

There is some scientific evidence to show that false-negative results of ultrasound examination, ie, where the child is born deformed or with other diseases even though ultrasound examination did not reveal this, may have negative long-term psychological effects on the mother. The corresponding psychological effects of false-positive findings of ultrasound examination, where the child is born healthy, even though deformity was suspected after ultrasound examination, appears to have a less negative effect than false-

negative findings. The psychological effect of false-positive ultrasound findings, where the fetus is aborted on false grounds, is not addressed in the literature. For the vast majority of pregnant women, the psychological effects of routine ultrasound examination are predominantly positive.

### **Diagnosing Chromosomal Anomalies**

As the age of the mother increases, so increases the risk for having a child with chromosome anomalies, where-of the most common diagnosis is Down's Syndrome. In Sweden, pregnant women are informed of this risk, and women 35 years of age and older are generally offered amniocentesis to determine potential chromosomal anomalies in the fetus. If all women 35 years of age or older would accept such an examination, approximately one third of all Down's Syndrome fetuses would be detected prior to birth. However, the risk of this test is not negligible. For each case of Down's Syndrome detected, two women with healthy fetuses would miscarry because of the examination.

Many fetuses with chromosomal anomalies also have anatomic problems which can be identified by ultrasound. This examination can reduce the number of miscarriages since amniocentesis would be performed only on mothers where ultrasound examination raised the suspicion of chromosomal anomaly. However, there is no scientific evidence to show which method is best – from a medical, psychological, and economic perspective – to identify the fetus at increased risk for chromosomal anomaly. An adequate study to compare different methods for identifying groups at risk for chromosomal anomalies in the fetus would be of value, but would require substantial economic and administrative resources.

In Sweden, routine ultrasound examination is not used specifically to search for indications of chromosomal anomaly in the fetus.

### **Ethical Aspects**

The four main ethical principles are: the principle of doing good, the principle of doing no harm, the principle of justice, and the principle of autonomy. These principles can be applied to issues related to prenatal ultrasound examination.

When routine ultrasound examination is offered, it should maintain the same high level of quality throughout the country in order to fulfill both the principle of doing good and the principle of justice. It is uncertain whether this is the case, and therefore levels of competence, educational needs, and organization should be reviewed.

The autonomy principle requires that all pregnant women should be sufficiently informed about the advantages and disadvantages of ultrasound. In most Swedish studies, pregnant women report receiving inadequate information prior to ultrasound examination, or that they experienced ultrasound examination as an obligatory routine. This is in conflict with the autonomy principle. According to a questionnaire answered by several departments, the information given to women has improved in recent years.

The ethical dilemma, however, remains and arises from performing an examination essentially intended to answer certain obstetrical questions, but which, intentionally or unintentionally, can detect fetal malformation in some cases.

At most departments of obstetrics/gynecology in Sweden, routine ultrasound examination is used to study fetal anatomy. Since it is already possible for these examinations to reveal fetal

deformity, services should be organized to promote routine control of fetal anatomy aimed at detecting deformity. This requires certain organizational changes and further development of skills. Such a decision to organize services must be followed by a well-planned and executed informational campaign addressing the ethical dilemma involved in detecting malformation in the fetus. This will become increasingly necessary since technical advancements will enhance the precision of prenatal ultrasound examinations.

This ethical dilemma must be discussed publicly in conjunction with making definitive decisions concerning how this activity should be managed. Substantial involvement is required to initiate such a discussion which, to some extent, has already started. The present report offers one – but not the only – basis for such a discussion.

### **Economics**

Organized ultrasound services must, under any circumstances, be available for examinations that need to be performed on medical indications. The costs for routine prenatal ultrasound examinations should therefore be viewed as an extra cost. The magnitude of this cost depends on the number of ultrasound examinations performed on medical indications.

The results of two randomized controlled trials provide an estimate of a maximum and minimum alternative. In the former, a small number of examinations on clinical indications were performed, whereby the extra costs were high for routine examinations. In the minimum alternative, a large number of examinations were performed on clinical indications and subsequently the extra cost was low. The total socioeconomic extra cost per year for routine ultrasound examination in Sweden can, based on the assumptions given, be estimated to vary between 6 and 16 million SEK.

Two randomized Nordic studies suggest that routine prenatal ultrasound examination leads to benefits in terms of reduced costs in delivery and in prenatal and perinatal care. It has not been possible to estimate the magnitude of these benefits.

### **Conclusions**

- Routine ultrasound examination is offered at all departments of obstetrics/gynecology in Sweden. In nearly 80% of the examinations, the anatomy of the fetus is analyzed to detect potential malformations, whereby the gender of the fetus can also be determined. Approximately 95% of all pregnant women undergo at least one ultrasound examination.
- There is no scientific evidence to show that routine ultrasound examination creates a biological risk for the mother or the fetus.
- It has not been proven that routine ultrasound examination during pregnancy reduces perinatal mortality or reduces morbidity among newborns.
- Prenatal ultrasound examination influences the management of the pregnancy and the planning prior to delivery in a positive way. For example, since ultrasound is a superior method for showing whether more than one fetus is present, it can determine the position of the placenta, and assess the gestational age with certainty. The latter leads to fewer induced deliveries due to post-term pregnancies.
- Routine prenatal ultrasound examination increases the detection rate of the congenitally malformed fetus.

- In Sweden, fetal diagnostics in conjunction with routine ultrasound examination is – in contrast to the situation in nearly all European countries – not an expressed purpose of this examination. The scientific evidence suggests that fetal diagnostics should be routinely offered as a part of screening. The ethical, organization, and educational consequences in this context should be investigated.
- Routine ultrasound examination is voluntary, but perceived by many expectant mothers to be an obligatory aspect of maternal health care. Information to expectant parents concerning the consequences of the examination - and the opportunity to refuse the exam - should be improved, particularly when fetal anatomy is studied. This information can be based on the facts presented in this report.
- In Sweden, education in obstetrical ultrasound examination for physicians and midwives is organized by professional organizations. There is a need for continuing medical education for health services' staff in obstetrical ultrasound and in the area of psychological support when fetal malformation is suspected.
- The organizational issues concern questions of competence, access to specialized knowledge, and the potential need to centralize fetal diagnostics. Further investigations of these issues should follow this report.
- Although prenatal ultrasound examination has been used for many years, the scientific evidence is, in some respects, insufficient. This report exemplifies several areas where research is urgently needed, eg, at present there is no scientific evidence to suggest that more than one routine ultrasound examination during pregnancy is of value.