Ultrasound screening in pregnancy: a systematic review of the clinical effectiveness, cost-effectiveness and women's views

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Authors' objectives
The authors had several objectives, only one of which is considered in this abstract: to review the use of routine ultrasound during pregnancy for the detection of foetal abnormalities.

Searching
MEDLINE was searched from 1995 onwards; the search terms were provided. Citation searching, using the Science Citation Index, was performed to identify papers cited by a previous literature review (see Other Publications of Related Interest no.1). The authors also reviewed studies identified from the search for a related cost-effectiveness review for additional clinical studies.

Study selection

Population-based studies were eligible for inclusion. The included studies were prospective and retrospective.

Specific interventions included in the review
Studies of routine ultrasound screening during the first, second, or third trimester of pregnancy for the detection of foetal abnormalities were eligible for inclusion. The studies were required to fully describe the ultrasound intervention and the definition of anomalies sought. The description of the intervention should include gestation at the time of ultrasound, diagnostic approach, quality control, operator(s), and skills, and equipment used. In the included studies, ultrasound was mainly performed by radiographers, sonographers, or obstetricians in district general hospitals or tertiary care centres.

Reference standard test against which the new test was compared
The reference standard used was postnatal ascertainment. To be eligible for inclusion, the studies had to report the method of postnatal ascertainment, including false-positives and false-negatives; neonatal examination of all live-born babies; the examination of stillborn babies, babies who died during the neonatal period and foetuses that were aborted after the first trimester; and post-delivery follow-up of all abnormalities.

Participants included in the review
Studies of low-risk or unselected pregnant women were eligible for inclusion.

Outcomes assessed in the review
Studies were eligible for inclusion if they reported false-positives and false-negatives. The outcomes reported in the included studies were the detection rates of anomalies in each trimester, sensitivity, specificity, the prevalence of anomalous foetuses and anomalies (including false-positives), and termination of the pregnancy.

How were decisions on the relevance of primary studies made?
The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
The authors reported that a minimum quality threshold had to be attained for a study to be eligible for inclusion. The criteria appear to relate to the quality of reporting of the following parameters: population-based study using an unselected or low-risk population; clear definitions of study aim(s); setting; participants; duration of the study, ultrasound intervention, including gestation at the time of ultrasound, diagnostic approach, quality control, operator and skills, and equipment used; and the specific anomalies sought. In addition, each study had to report a method of postnatal ascertainment (including false-positives and false-negatives) of all abnormalities, and details of anomalies.
detected per foetus.

The authors did not state how the papers were assessed for quality, or how many reviewers performed the quality assessment.

**Data extraction**

The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction. Data were extracted on the detection rate in each trimester (including the sensitivity and specificity), the overall detection rates, the prevalence of anomalous foetuses and anomalies (including false-positives), and termination of the pregnancy.

**Methods of synthesis**

How were the studies combined?

The results of each included study were tabulated and combined in a narrative discussion.

How were differences between studies investigated?

Differences between the studies were assessed narratively according to the trimester of pregnancy, the study design used, the method of reporting and defining the outcome, and the setting and individual performing the scan.

**Results of the review**

Eleven studies (96,633 foetuses, including multiple pregnancies) were included in the review: 1 randomised controlled trial (7,575 foetuses), 4 prospective studies (35,710 foetuses) and 6 retrospective studies (53,348 foetuses).

Number of false-positives.

A total of 52 false-positives were reported in the included studies. None of the false-positives were associated with lethal anomalies; 19 were associated with possible survival and long-term morbidity; 2 were amenable to intrauterine therapy; 18 were associated with possible short-term or immediate morbidity; 10 were associated with either long-term or short-term morbidity; a further 3 could not be classified.

Detection of anomalies.

First trimester (less than 15 weeks): none of the included studies reported the detection of anomalies during the first trimester.

Second trimester (less than 24 weeks): the overall sensitivity of second trimester scanning was 41.3% (range: 13.5 to 85.3). The sensitivity was lower in studies where the gestational age range at scanning was less than 18 weeks (5 studies; overall sensitivity 21.5%, range: 16.6 to 71.4) than in those where the gestational age was greater than 18 weeks (6 studies; overall sensitivity 51%, range: 13.5 to 85.3). The overall specificity was 99.94% (range: 99.4 to 100), based on 10 studies.

The detection rates for anomalies at different anatomical systems were: 76.4% for the central nervous system (CNS), 67.3% for the urinary tract, 50% for pulmonary, 41.9% for gastrointestinal, 23.8% for skeletal and 17.4% for cardiac. The detection rate for chromosomal abnormalities was 18.8%. Third trimester (greater than 24 weeks): the overall sensitivity of third trimester scanning was 18.6% (range: 18.2 to 40.4), based on 4 studies. Specificity was 100% (1 study).

The detection rates for anomalies at different anatomical systems were: 71% for the CNS, 69.7% for the urinary tract, 50% for gastrointestinal, 44.4% for pulmonary, 26.1% for skeletal and 26.1% for cardiac. The detection rate for chromosomal abnormalities was 10.4%.

Termination of the pregnancy.
The overall rate of pregnancy termination in the included studies was 0.41% (range: 0.09 to 0.67).

Differences between the studies.

Study design: there was no difference in the incidence of abnormalities or the detection rates, according to the type of study.

Reporting of anomalies: studies that reported data by the number of anomalies had a higher sensitivity than those that reported the number of anomalous foetuses. Some studies reported an overall detection rate per foetus, but reported per anomaly for anatomical data. The authors stated that this may lead to an overestimation of the sensitivity. There was variation in the definition of major and minor anomalies and postnatal ascertainment of anomalies, which may have affected the overall detection rate.

Setting and delivery of ultrasound: there was no effect on the performance of routine ultrasound according to the setting, the expertise of the individual performing the scan, or the equipment used.

Cost information
None. However, the authors stated that the data were managed and used to populate a decision model, to determine the cost-effectiveness of ultrasound screening in pregnancy.

Authors' conclusions
The detection rates of foetal abnormalities varied according to the anatomical site affected during anomaly scanning at both the second and third trimester: there were high rates of abnormalities of the CNS and low rates for skeletal and cardiac abnormalities. There was no evidence on the effectiveness of anomaly scanning during the first trimester.

CRD commentary
The review lacked explicit inclusion criteria with regards to the participants, intervention and outcomes, but instead applied stringent inclusion criteria to identify studies with a minimum level of reporting of these parameters. There was no assessment of quality in terms of study design. However, the authors provided a comprehensive list of studies that did not meet the threshold with reasons for their exclusion. It was unclear whether the authors used procedures to minimise bias in the study selection, quality assessment and data extraction processes. Therefore, the possibility for systematic bias in the review methodology cannot be ruled out. The search was limited to one electronic database and citation searching using a previous review. It is therefore possible that not all available studies were identified. Publication bias was not assessed.

The characteristics and results of each included study were presented in detail. The studies were combined in a narrative discussion, which appears to have been appropriate given the differences between each included study. The authors also provided a detailed discussion of the components of each included study that may impact on observed differences. The evidence presented in this review supports the authors' conclusions and recommendations for further research. However, it should be noted that some relevant studies might not have been identified for inclusion in the review.

Implications of the review for practice and research
Practice: The authors stated that the Royal College of Obstetricians and Gynaecologists Working Party's recommendations seem appropriate, in that routine ultrasound should be conducted by trained personnel with equipment no more than 5 years old. Quality control mechanisms should be implemented to audit performance. The reporting of suspected anomalies to regional foetal anomaly registers should be encouraged, where possible (see Other Publications of Related Interest no.2). However, these guidelines have not been appraised and should only be viewed as the authors' implications.

Research: The authors stated that further research is required to assess the effect of detection of foetal abnormalities on substantive outcomes with regards to short- and long-term morbidity and mortality for the mother and child. Further
research into the efficacy of routine ultrasound screening for foetal abnormalities should include a comprehensive postnatal ascertainment.

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