Accuracy of fetal echocardiography in the routine detection of congenital heart disease among unselected and low risk populations: a systematic review

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CRD summary
This review determined the accuracy of foetal echocardiography during the second trimester for the detection of congenital heart disease among unselected and low-risk populations. While the high specificities and reasonably high sensitivities, at least for the detection of major defects and arrhythmias, appear promising, the small number of studies included and the questionable quality of the primary studies limit interpretation of the results and justify a conclusion that further research is needed.

Authors' objectives
To determine the accuracy of foetal echocardiography during the second trimester for the detection of congenital heart disease among unselected and low-risk populations.

Searching
MEDLINE, EMBASE, the Science Citation Index, the Cochrane Library, National Research Register, MRC Research Register, the HTA Projects Database, the National Co-ordinating Centre for Health Technology Assessment, HSTAT, TRIP, SIGLE and PsycINFO were searched from 1990 to July 2002. A diagnostic search filter combined with subject area terms were used to search for studies. Reports, discussion papers, dissertations and theses, and conference proceedings were searched for grey literature. The reference lists of primary studies and relevant reviews were screened and experts in the area were contacted.

Study selection
Study designs of evaluations included in the review
No inclusion criteria relating to study design were reported.

Specific interventions included in the review
Studies of foetal echocardiography were eligible for inclusion. Only studies in which all patients received foetal echocardiography were eligible for inclusion. Studies that did not fully describe the ultrasound technique (scanning regime, gestation at scanning and equipment used) were excluded. The included studies assessed:

- routine foetal echocardiography (four-chamber view + outflow tracts),
- routine followed by extended foetal echocardiography on suspicion of congenital heart disease (four-chamber view + outflow tracts + Doppler colour-flow mapping in selected patients), or
- routine extended foetal echocardiography (four-chamber view + outflow tracts + Doppler colour-flow mapping).

Ultrasound operators in the included studies included experienced trained specialists, experienced trained non-specialists, and experienced and inexperienced non-trained non-specialists. The ultrasound transducer frequency ranged from 3.5 to 5 MHz.

Reference standard test against which the new test was compared
Studies that included a postnatal reference standard were eligible for inclusion. The reference standards reported in the included studies were neonatal examination, neonatal echocardiography, autopsy, and electrocardiogram at birth and at 6 and 24 months’ follow-up.

Participants included in the review
Studies of low-risk women in their second trimester, or in general unselected obstetric populations of second trimester
women, were eligible for inclusion. Studies restricted to high-risk pregnant women were excluded. Gestation at scanning ranged from 20 to 34 weeks.

Outcomes assessed in the review
The studies had to report sufficient data to construct a 2x2 table of test performance to be included in the review. Estimates of accuracy were presented separately for major defects, minor defects, non-structural defects or arrhythmias, and all defects.

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 studies were assessed for methodological quality using a checklist that the authors devised for this review. The items assessed included selection bias, appropriate choice and application of the reference standard, and blinding in the interpretation of scan defects. The studies were assigned a quality score, but the authors did not report how this was calculated or the exact items assessed.

One reviewer assessed quality, cross-checking with a second reviewer when necessary.

Data extraction
One reviewer extracted the data, cross-checking with a second reviewer when necessary. Accuracy data were extracted as 2x2 tables of test performance. The sensitivity and specificity were calculated with 95% confidence interval using the Exact (Clopper-Pearson) method.

Methods of synthesis
How were the studies combined?
A qualitative synthesis of the studies was undertaken.

How were differences between studies investigated?
Differences between the studies were discussed in the body of the text.

Results of the review
Five studies (n=60,901) were included. Four studies included a low-risk population; the other study included unselected women. Four studies were prospective in design and one was retrospective.

The studies suffered from methodological limitations in terms of choice and application of the reference standard and selection bias.

Specificity for the detection of major defects, minor defects, non-structural defects or arrhythmias, and all defects was greater than 99.6% in all studies. Sensitivity was less high and showed greater variations between studies. The sensitivity ranged from 84.6 to 94% for the detection of major defects (4 studies), from 23.1 to 82.1% for the detection of minor defects (4 studies), from 83.3 to 95.2% for the detection of non-structural defects or arrhythmias (3 studies), and from 35.4 to 86.1% (5 studies) for the detection of all defects.

Authors' conclusions
The evidence from this review does not support the routine use of foetal echocardiography among unselected and low-risk populations during the second trimester to detect congenital heart disease.

CRD commentary
The review addressed a clear objective and was supported by well-defined inclusion criteria. Extensive literature
searches, which included attempts to locate unpublished studies, were carried out. The authors referred to the use of diagnostic filters, which are known to have limited sensitivity, thus their use might have led to reduced retrieval of the available literature. Very few details of the review process were reported and those that were did not include appropriate steps to minimise reviewer error or bias. A quality assessment was conducted but insufficient details were reported; the authors did not clearly define individual assessment criteria and quality scores were presented with no details of how they were calculated. This is of particular significance since the reviewers discussed the importance of variations in quality on the results of the review.

While the high specificities and reasonably high sensitivities, at least for the detection of major defects and arrhythmias, appear promising, the small number of studies included and the questionable quality of the primary studies limit the interpretation of the results and justify a conclusion that further research is needed.

**Implications of the review for practice and research**

**Practice:** The authors stated that the evidence was not sufficient to support the routine use of foetal echocardiography among unselected and low-risk populations during the second trimester to detect congenital heart disease.

**Research:** The authors stated that future research needs to consider the broader consequences of using foetal echocardiography, such as health outcomes and associated costs, among unselected and low-risk populations during the second trimester. In addition, the authors stated that future research should address the methodological limitations highlighted by this review.

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