IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

IQWiG Reports - Commission No. S05-03

Ultrasound screening in pregnancy: test accuracy with regard to detection rates of foetal abnormalities[1]

Executive Summary

[1] Translation of the executive summary of the final report "Ultraschallscreening in der Schwangerschaft: Testgüte hinsichtlich der Entdeckungsrate fetaler Anomalien" (Version 1.0; Status: 21.04.2008). Publication date of translation: 23.06.08. Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

Publishing details

Publisher:
Institute for Quality and Efficiency in Health Care

Topic:

Ultrasound screening in pregnancy: test accuracy with regard to detection rates of foetal abnormalities

Contracting agency:
Federal Joint Committee

Commission awarded on:
20.09.2005

Internal Commission No.:
S05-03

Publisher's address:

Institute for Quality and Efficiency in Health Care
Dillenburger Str. 27
51105 Cologne
Germany

Tel: ++49 (0)221/35685-0
Fax: ++49 (0)221/35685-1
E-mail: berichte@iqwig.de
Homepage: www.iqwig.de

Executive summary

Research question

The aim of this review was to determine the test accuracy of ultrasound screening in pregnancy with regard to the detection of serious foetal abnormalities, depending on examiner qualifications and device quality. Nuchal translucency measurement (NTM) was to be given particular consideration.

Methods

On the basis of a systematic literature search, randomised controlled as well as single-arm diagnostic studies on the research question outlined above were identified for the assessment. A comprehensive search in databases was conducted (MEDLINE, EMBASE, CENTRAL, CINAHL), and reference lists of relevant secondary publications (systematic reviews, HTA reports) were screened. In addition, manufacturers of ultrasound devices were asked to provide relevant published or unpublished studies. IQWiG's preliminary report was published on the IQWiG website and interested persons and parties were invited to submit comments. The final report was subsequently published.

Results

Of the 6704 abstracts retrieved in the literature search, 60 studies were identified that fulfilled the inclusion criteria and where none of the exclusion criteria applied. The studies were summarised in 11 groups according to the time of the ultrasound scan (trimester) and the abnormality investigated. In 7 of these groups, associations between examiner qualifications or device quality and detection rates were determined in sensitivity analyses (indirect comparisons between studies within one group). Overall, with regard to diagnostic accuracy, a great heterogeneity of results and wide ranges were shown.

In summary, positive associations between examiner qualifications or device quality (measured by means of grey scale values and listing on DEGUM's device list[2]) and detection rates could be inferred from indirect comparisons. These associations were also found in studies investigating the diagnostic accuracy of NTMs.

None of the studies included described detection rates in a multi-level concept as established in Germany; nor did they report detection rates when only 'foetal neck oedema' was documented.[3]

[2] Deutsche Gesellschaft für Ultraschall in der Medizin (German Society for Ultrasound in Medicine)

[3] This method, i.e. the assessment of nuchal transparency by visual judgement and documentation in the maternity log, is applied in Germany.

Conclusion

This report indicates that in ultrasound screening in pregnancy, higher qualifications or greater experience of examiners and superior device quality are associated with higher detection rates for foetal abnormalities. However, these indirect comparisons refer mainly to health care levels II (e.g. specialist practices with long-term experience or general hospitals with certified examiners) and III (mainly university clinics). On the basis of the studies included, the question cannot be answered as to which minimum preconditions have to be fulfilled to achieve sufficient detection rates (e.g. sensitivity ≥ 75 % with specificity ≥ 95 %).

Only a few studies on the multi-level screening concept as established in Germany or on comparable screening programmes studies could be identified. None of these studies fulfilled the inclusion criteria of the report. However, the detection rates achieved in these studies were low and challenge the concept of a multi-level screening programme with an initial screening on level I.

The documentation of foetal neck oedema in the maternity log is another characteristic of the German screening programme, and was not investigated in any of the studies found. It is unclear which detection rates are achieved with this method. Therefore, either an NTM following internationally established methods should be conducted or this documentation in the maternity log should be dispensed with.

In the planning of studies urgently required in the German health care setting, examiner qualifications and device quality should be considered as important influencing factors. In this context, general methodological standards for diagnostic studies should be maintained. It would also appear meaningful to link these studies to perinatal registers in order to ensure as complete a follow-up as possible of foetuses showing abnormal screening results and diagnosed as having abnormalities (“tracking”), as well as to ensure the identification of all children with congenital defects (including those with negative screening results or those unscreened).

Each screening procedure should essentially be preceded by the detailed, evidence-based, and easily comprehensible counselling of affected women or couples. In addition to information on detection rates of various risk evaluation and diagnostic procedures, this counselling should also include information on potential risks and harms.

Keywords

Prenatal diagnosis; ultrasonography; prenatal; nuchal translucency measurement; fetal diseases (fetal diseases/diagnosis); technology assessment, biomedical; review