Evidence-based Medicine in Obstetric Ultrasonography

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Summary

The purpose of the Evidence-based Medicine is to promote clinical decision-making based on scientific research. This means not applying to clinical practice what research has shown to do harm and applying what research has demonstrated as beneficial. Taking the routine ultrasonography examination for prenatal care as a case study, a disagreement can be found between medical research findings and common clinical practice. Although there is no evidence supporting a screening for Down syndrome using the nuchal fold thickness as a marker, or supporting routine ultrasound scans during pregnancy, several clinical practice guidelines are recommending so.

Introduction

In 1992 a scientific and professional working group published an article about a new "paradigm" for the practice in medicine: Evidence-Based Medicine (EBM), which de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research [1]. The EBM Working Group stated that physicians require having new skills to properly synthesize the scientific literature. In fact, the EBM methods are necessary because of the overwhelming amount of scientific information we are facing (in 1940 there were 2,300 biomedical publications and today there are more than 25,000). Indeed, problems arise when information sources suggest different approaches to the same patient care situation. Then, it is essential to critically assess all that information.

In 1993 the so-called EBM Working Group started a series of articles dealing with the critical appraisal of the medical literature. These articles are guides

to assess not only therapy studies, but also diagnosis, harm prognosis, and even overviews, clinical practice guidelines, economic analysis, and qualitative research in health care. Last one appeared in 2000, and it was the 25th of this series.

The methodology of EBM is not new. Meta-analysis, one of the main techniques used to quantitatively synthesize scientific literature, had been used for years in psychology. Epidemiologists and public health researchers had always been used to critically review and synthesize the medical literature; but what the EBM has brought up is the relevance of applying this systematic approach to any level of clinical decision making. However, there is still a gap between the results of medical research and clinical practice.

The first objective of the presentation is to illustrate the usefulness of meta-analysis in diagnostic tests. The thickened nuchal fold in the second-trimester as a marker to detect fetuses with Down syndrome has been selected as a case study. The second objective is to compare systematic reviews and meta-analyses compiling medical research, with recommendations and guidelines specifically designed for clinical practice. The ultrasound imaging for routine prenatal care has been selected as case study.

Material and Methods

1) Meta-analysis of nuchal fold thickness as a second-trimester marker for Down syndrome (study carried out in 1998)

The studies to be included in the meta-analysis were identified through several bibliographic search strategies at the MEDLINE, HealthStar and The Cochrane Library databases, and also a careful checking of the references of selected studies was made to identify additional missing studies. Studies were selected according to a minimal set of quality criteria [2]. Overall pooled sensitivity and specificity values of the combination of all studies were estimated by means of a random-effects model.

2) Comparison between systematic reviews of scientific evidence and clinical practice guidelines

Clinical practice guidelines and clinical recommendations for routine ultrasound in pregnancy were searched through specific databases like the National Guideline Clearinghouse or obstetric societies and networks' web sites. Additionally, documents from health departments were obtained. On the other hand, meta-analyses and systematic reviews were searched at MEDLINE and The Cochrane Library databases.

The National Guideline Clearinghouse is a comprehensive database of evidence-based clinical practice guidelines and related documents produced by the US Agency for Healthcare Research and Quality (AHRQ), in partnership with the American Medical Association (AMA) and the American Association of Health Plans (AAHP). This database is available at www.guideline.gov.

Results

1) Meta-analysis of nuchal fold as a second-trimester marker for Down syndrome (study carried out in 1998)

Twenty-six studies were identified that met the quality criteria for inclusion in the meta-analysis. The overall diagnostic accuracy of thickened nuchal fold as a marker for Down syndrome in the second trimester of pregnancy showed a pooled sensitivity value of 33% with a 95% confidence interval (95% CI) of 26% to 41%, and a pooled specificity value of 99% (95%CI: 99-100%) [Figure 1].

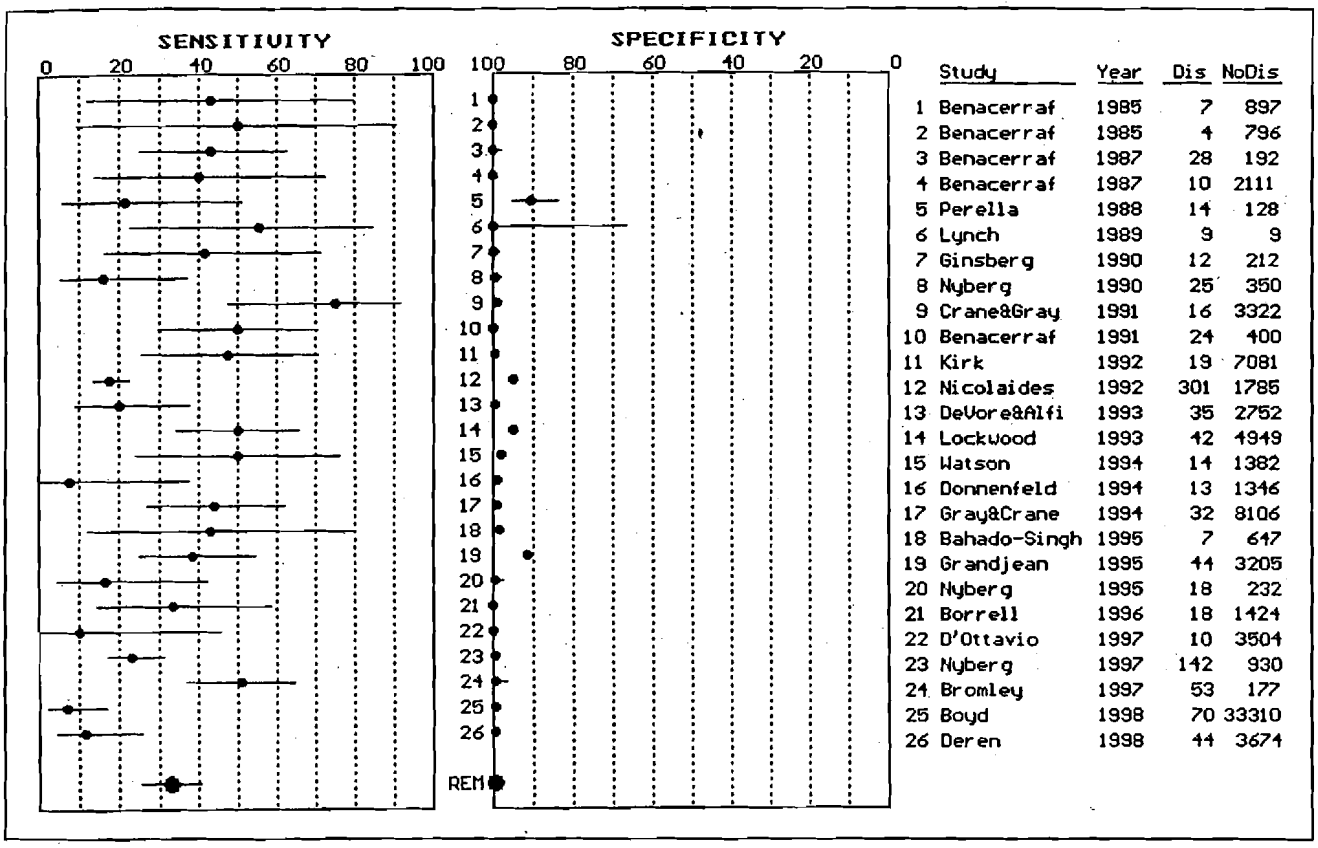

Figure 1. Meta-analysis of the thickened nuchal fold as a second-trimester marker for Down syndrome

2) Comparison between systematic reviews of scientific evidence and clinical practice guidelines of ultrasound imaging for routine prenatal care

There is evidence that routine ultrasound before 24 weeks of gestation provides better gestational age assessment and earlier detection of multiple pregnancies, but neither of these effects has been shown to improve fetal outcome [3]. Regarding routine ultrasound after 24 weeks, the existing evidence does not confer benefit on mother or baby [4] (Table 1).

Some clinical practice guidelines for routine ultrasound imaging in prenatal care recommend three ultrasound scans during pregnancy, some others only

Table 1: The reduced incidence of induction of labour for apparent post-term pregnancy presumably results from better gestational "dating" [3].

Outcome measure	Endresults comparing routine versus selected ultrasonography
Before 24 weeks [3]	
Detection of multiple pregnancies	OR = 0.08 (95% CI: 0.04 – 0.16)
	Earlier detection in routine
Induction of labour for post-term pregnancy	OR = 0.61 (95% CI: 0.52 – 0.72)
	Reduction of induction in routine*
Perinatal mortality	OR = 0.86 (95% CI: 0.67 – 1.12)
	No statistically significant differences
After 24 weeks [4]	
Antenatal admissions or other tests of fetal wellbeing	OR = 1.03 (95% CI: 0.90 – 1.17)
	No statistically significant differences
Obstetric interventions	No statistically significant differences
Induction of labour	OR = 1.03 (95% CI: 0.88 – 1.21)
Caesarean section	OR = 0.86 (95% CI: 0.72 – 1.04)
Post-term delivery	OR = 0.69 (95% CI: 0.58 – 0.81)
(> 42 weeks)	Reduction of post-term deliveries in routine
Low birthweight	OR = 1.15 (95% CI: 0.84 – 1.56)
(< 2.5 Kg)	No statistically significant differences
Perinatal mortality	OR = 0.60 (95% CI: 0.31 – 1.16)
	No statistically significant differences

one carried out at the second trimester, and some recommend no routine ultrasound examinations (Table 2). Therefore, after comparing these guidelines to the previous systematic reviews and meta-analyses, scientific evidence and routine ultrasonography recommendations were found not to agree in each and all cases.

Conclusions

The meta-analysis of the thickened nuchal fold as a second-trimester marker to detect fetuses with Down syndrome showed this marker is very specific but not very sensitive. This means that in spite of the low probability of finding a thickened nuchal fold in those fetuses without Down syndrome, there is a considerable probability of a false negative result. Thus, a normal nuchal fold might make mothers think they have a fetus without Down syndrome, which could be erroneous. Therefore, the nuchal fold thickness cannot be used as a single marker to detect Down syndrome fetuses. There is a need to use other

Table 2.

Guideline	Number and timing of ultrasound scans
Health and Social Security Department, Catalonia, 1998 [5]	Three at 8-12 weeks, 18-21 weeks, and 34-36 weeks
European Association of Perinatal Medicine, 1993 [6]	Three at 8-12 weeks, 18-21 weeks, and 34-36 weeks
American Institute of Ultrasound in Medicine, 1991 [7]	Three at first, second and third trimester
Society of Obstetricians and Gynaecologists of Canada, 1999 [8]	One at 18-19 weeks
US Preventive Task Force, 1996 [9]	One at second trimester
Canadian Task Force on Periodic Health Examination, 1994 [10]	One at second trimester
American College of Obstetricians and Gynecologists, 1997 [11]	None. Only for specific medical indications.
Saskatchewan Health Services Utilization and Research Commission, Canada, 1996 [12]	None. Only for specific medical indications.
National Institutes of Health Consensus Development Conference, USA, 1984 [13]	None. Only for specific medical indications.

tests, non-invasive such as biochemical tests, or invasive -but confirmatory- such as amniocentesis.

This is consistent with another meta-analysis which concluded that although only the thickened nuchal fold may be useful at distinguishing between unaffected and affected fetuses, this marker shows poor accuracy [14]. Despite this low sensitivity it is common practice among obstetricians to routinely scan for the thickened nuchal fold as a marker for Down syndrome. This gap between medical literature and clinical practice can be also shown comparing systematic reviews and some clinical practice guidelines regarding routine ultrasound examinations for fetal assessment. This illustrates either a delay translating the obstetric ultrasound research findings into clinical practice, not enough knowledge about what accuracy of a diagnostic test means, or a lack of research showing the effects of performing ultrasound scans in routine prenatal care.

Although parents can be attracted by ultrasound imaging (its attraction may increase with the spread of the 3D imaging), they have to be aware of the poor accuracy of ultrasound examination as a screening test. The security of a screening test is not only related to the test itself, but also to the consequences of test results: the problems of false negatives or the risks associated with invasive tests.

Finally, further research is needed to test the overall accuracy of different ultrasound markers, and combined with biochemical markers. A great effort must be put on translating these future results into clinical practice.

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