The test accuracy of antenatal ultrasound definitions of fetal macrosomia to predict birth injury: a systematic review

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ABSTRACT

Objectives

To determine which ultrasound measurement for predicted fetal macrosomia most accurately predicts adverse delivery and neonatal outcomes.

Study Design

Four biomedical databases searched for studies published after 1966.

Randomised trials or observational studies of women with singleton pregnancies, resulting in a term birth who have undergone an index test of interest measured and recorded as predicted fetal macrosomia ≥28 weeks.

Adverse outcomes of interest included shoulder dystocia, brachial plexus injury (BPI) and Caesarean section.

Results

Twenty-five observational studies (13,285 participants) were included. For BPI, the only significant positive association was found for Abdominal Circumference (AC) to Head Circumference (HC) difference > 50 mm (OR 7.2, 95% CI 1.8 to 29). Shoulder dystocia was significantly associated with abdominal diameter (AD) minus biparietal diameter (BPD) ≥ 2.6 cm (OR 4.2, 95% CI 2.3 to 7.5, PPV 11%) and AC > 90th centile (OR 2.3, 95% CI 1.3 to 4.0, PPV 8.6%) and an estimated fetal weight (EFW) > 4000 g (OR 2.1 95%CI 1.0 to 4.1, PPV 7.2%).

Conclusions

Estimated fetal weight is the most widely used ultrasound marker to predict fetal macrosomia in the UK. This study suggests other markers have a higher positive predictive value for adverse outcomes associated with fetal macrosomia.

Keywords

Fetal macrosomia; shoulder dystocia; ultrasound markers

INTRODUCTION

Fetal macrosomia refers to a bigger than average baby in utero or at the time of birth. Women with big babies tend to have longer labours and higher risk of operative delivery, perineal injury or shoulder dystocia. Shoulder dystocia may cause birth injury, including brachial plexus injury (2-16%), bony fractures or birth asphyxia with risk of neurological damage or death [1].

Macrosomia generally refers to a neonate with a birthweight > 4000 g regardless of gestational age. Predicted fetal macrosomia refers to a fetus with an ultrasonic estimated fetal weight (EFW) of > 4000 g. Many institutions use 4 kg as the definition but currently, an estimated weight of > 4.5 kg is more widely used as a threshold to define fetal macrosomia [2-4]. Babies that weigh ≥ 4.5 kg have an increased risk of adverse maternal and perinatal outcomes [5, 6]. Approximately 10% of all pregnancies result in fetal macrosomia but this estimate ranges from 3-15% [3, 7].

Antenatal detection of fetal macrosomia by ultrasound is notoriously poor. Evidence has shown that the accuracy of ultrasound in estimating the weight of large babies has approximately 45-56% sensitivity for an EFW > 4000 g [8, 9] and 80% sensitivity for an abdominal circumference > 35cm [9].

A number of factors limit the accuracy of sonography which include: inaccuracy of the biometry measurements [10]; inexperienced operators; the equipment quality; oligohydramnios; maternal obesity and the inaccuracy of the formulae for EFW used [11].

Consensus has not yet been reached on the measurement definition of fetal macrosomia. A multitude of imaging measurement definitions to predict fetal macrosomia exist worldwide. Many studies have been published testing the diagnostic accuracy of antenatal prediction of fetal macrosomia in comparison to absolute birth weights. It is also known from a very large observational study what level of absolute birth weight is associated with complications [12]. These studies are only useful for retrospective analysis and do not help to guide clinical management. What we do not know is if any of these antenatal imaging predictions are (more or less) associated with adverse maternal and neonatal outcomes.

The antenatal prediction of fetal macrosomia is particularly pertinent now. The 2015 Supreme Court ruling, Montgomery v Lanarkshire has highlighted the importance of counselling women with suspected fetal macrosomia. A recent Cochrane review (4 trials, 1190 women) found that induction of labour at 37-40 weeks for suspected fetal macrosomia reduced birthweight, fractures and shoulder dystocia [13]. Given that we have an effective intervention for suspected fetal macrosomia, trying to improve the accuracy of our prediction of fetal macrosomia has never been more important.

We evaluated the association and test accuracy of ultrasound definitions of fetal macrosomia for the prediction of adverse maternal and neonatal outcomes.

MATERIALS AND METHODS

The study was prospectively registered (CRD42016046850).

Study objective

Which measurement definition of predicted fetal macrosomia most accurately predicts adverse maternal and neonatal outcomes?

Eligibility criteria

Types of studies

Randomised controlled trials or observational studies that allowed the generation of a 2x2 table to include true positives, false positives, false negative and true negatives. Any studies with ≤10 participants were excluded due to the unreliability of a small sample [14]. Case control studies, when participants are selected for inclusion on the basis of the presence of their adverse outcome, are known to be prone to spectrum bias [15]. This fact was accounted for in the scoring system used in the quality assessment.

Participants

The population for inclusion were pregnant women with singleton pregnancies that resulted in a term birth (≥37 weeks). These pregnant women must have had an index test of interest measured and recorded as predicted fetal macrosomia ≥28 weeks. Studies including multiple pregnancies and premature deliveries were excluded.

Index test

~~All measurements and thresholds that have been described as methods to predict fetal macrosomia were included as index tests for the initial scoping searches. Including all modalities (2D or 3D ultrasound (US) and magnetic resonance image (MRI).~~ All measurements and thresholds that have been described as methods to predict fetal macrosomia were included as index tests for the initial scoping searches, including all modalities (2D or 3D ultrasound (US) and magnetic resonance image (MRI). Scoping searches were performed to determine whether there was available primary data for these measurement prediction parameters combined with the outcomes of interest. These initial searches revealed that for 3D US and MRI studies no clinical outcome data was recorded. Therefore, the index tests included in the review consisted of 2D ultrasound data only.

Ultrasound measurement defined as predicted fetal macrosomia included: EFW (>4k g, 4-4.5 kg, >4.5 kg, >90th centile, >95th centile); abdominal circumference (AC) (>35 cm, >36 cm, >75th centile, >90th centile, > 95th centile); ratios of measurements and novel distances (e.g. abdominal diameter/biparietal diameter, femur length/abdominal circumference, cheek to cheek, humeral soft tissue thickness). These ultrasound markers were pre-defined.

Primary analysis

Search strategy

The search was undertaken in May 2018 through the following electronic bibliographic databases (Medline, Embase, PubMed, and the Cochrane Library), sources of 'grey' literature (OpenGrey, Web of Science) and citation tracking on relevant studies. There was no language restriction. The search strategy is shown in Appendix 1.

Study selection

The abstracts of potentially relevant studies were identified and screened by RCR, 10% were screened by VAW and no new papers were identified. Relevant full-text studies were retrieved and assessed for eligibility by RCR and VAW. Any disagreements were resolved by consultation with NWJ.

Data extraction and quality assessment

Data was extracted using a standardised form independently by VAW and RCR, from the included studies, for assessment of study quality and evidence synthesis. Each study had data extracted twice independently. The extracted information included the methodology and timing of the index tests as well as the outcomes, allowing the generation of 2 x 2 tables to calculate estimates of the association between the ultrasound marker and outcomes.

The authors of included studies were contacted directly to request data if the manuscript did not provide enough information to populate the 2x2 tables.

The quality of included studies was assessed by a structured assessment completed independently by two reviewers (RCR and VAW). The STARD and QUADAS-2 published checklists are both validated methods for the study of methodological quality in the reporting of diagnostic test accuracy studies. [16, 17]. From within these validated tools, we selected the elements that best represented the methodical quality for systematic reviews that assess the association between prognostic tests and outcome. We used the same approach that has been used successfully by other similar, published systematic reviews and meta-analyses [18, 19].

A study was rated as high quality (met at least four criteria), medium quality (three) and low (two or less).

Data analysis

We used aggregate data to quantitatively synthesise odds ratios (ORs) and 95% confidence intervals (95% CIs) for each index test-outcome pair. The results were pooled for each index test using a random effect meta-analysis to provide the summary estimate of prognostic association with outcome. If a strong and statistically significant prognostic association was identified between a test and an outcome measure, we calculated sensitivity, specificity and likelihood ratios from the 2x2 tables and then used a bivariate random-effects meta-analysis model to assess the predictive ability of the test.

The prevalence was pooled for each outcome using a random-effects meta-analysis model and the exact binomial method. Sensitivity and specificity were pooled for each index test using a bivariate random-effects meta-analysis model. If the bivariate model could not be estimated or there were estimation concerns (e.g. for the correlation parameter), then univariate models were used to pool sensitivity and specificity separately, as recommended by Takwoingi *et al* [20]. The positive predictive value (PPV) for a new population was derived using the formula of Riley *et al* [21] which uses the summary sensitivity, specificity and prevalence (Table 2). The PPV is dependent on the prevalence used to calculate it and would change if the prevalence changed.

All analyses were performed in Stata (version 15).

RESULTS

Study selection

Twenty-five observational studies (13,285 participants) were included (Figure 1). Three of these were included after further data was provided by the authors. Details of the included studies are shown in Table 1. In total, 23 articles were excluded due to inadequate data for creation of the 2x2 tables or clarification of the population resulted in exclusion.

Quality assessment

Of the studies, 24 studies were classed as high (96%) and one was moderate quality (4%). All studies were observational studies. Majority were cohort designs (84%) and retrospective (80%). The remaining studies were four prospective cohort studies and one prospective case control study.

Accuracy of antenatal ultrasound definitions of fetal macrosomia to predict adverse outcomes

Four studies [22-25] (31 - 362 women) reported brachial plexus injury as an outcome (Table 2). For BPI, the only positive association was found for Abdominal Circumference (AC) to Head Circumference (HC) difference > 50 mm (OR 7.2, 95% CI 1.8 to 29) from a single study [31]. The PPV calculated for this test from that single study was 18%.

Eighteen studies [10, 22-37] (11447 women test/outcome data sets) reported shoulder dystocia as an outcome. Three studies [26-28] reported on AC > 90th centile and shoulder dystocia.
Three studies [23, 28, 29] reported on abdominal diameter minus biparietal diameter ≥ 2.6 cm. Four studies reported on estimated fetal weight > 4000 g [11, 28, 35, 38]. The summary prevalence (calculated from these ten studies included in the meta-analysis) for shoulder dystocia was 4.9% (95% CI 2.1 to 11%) (Table 5).
Meta-analysis revealed shoulder dystocia was associated with: abdominal diameter (AD) minus biparietal diameter (BPD) ≥ 2.6 cm (OR 4.2, 95% CI 2.3 to 7.5, PPV 11%) and AC > 90th centile (OR 2.3,

95% CI 1.3 to 4.0, PPV 8.6%) and an estimated fetal weight (EFW) > 4000 g (OR 2.1 95% CI 1.0 to 4.1, PPV 7.2%) (Table 3). PPVs were predicted for a new population with a prevalence of 4.9% for shoulder dystocia. Full results are shown in Table 3.

Fifteen studies [10, 24, 27, 32, 34-36, 38-45] (11630 women test/outcome data sets) reported caesarean section (CS) as an outcome. The summary prevalence for CS in the studies was 36% (95% CI 23 to 51 %) (Table 5). Five studies reported on CS and EFW > 4000 g [10, 32, 38, 43, 45]. For CS, the only positive association was found for EFW > 4000 g. Meta-analysis demonstrated CS was associated with an EFW > 4000 g (OR 2.6, 95% CI 1.6 to 4.2, PPV 62%) (Tables 3). Full results are shown in Table 4. For those ultrasound measurements with a positive association between the measurement and an adverse outcome, the positive predictive values for each adverse outcome by ultrasound measurements are shown in Table 6.

DISCUSSION

Principal findings

This study shows that the ultrasound marker of fetal macrosomia most associated with prediction of shoulder dystocia is a difference in the abdominal diameter to the biparietal diameter of ≥ 2.6 cm. If this marker is positive then approximately 1 in 10 women will subsequently experience a shoulder dystocia. The more widely used estimated fetal weight > 4 kg has more uncertainty as a predictor of subsequent shoulder dystocia with only 7 in 100 women subsequently experiencing a shoulder dystocia.

The ultrasound marker of fetal macrosomia most associated with brachial plexus injury is an abdominal circumference to head circumference difference of > 50 mm.

The ultrasound marker of fetal macrosomia most associated with caesarean delivery is an estimated fetal weight > 4 kg. If this marker is positive then approximately 1 in 2 women will subsequently have a caesarean delivery.

Strengths and weaknesses

The study followed a prospectively registered protocol, using detailed methodology, large patient populations and up to date statistical techniques for the meta-analysis (22, 23). We demonstrated both the prognostic association of ultrasound markers with adverse outcome (odds ratio) and their predictive ability (positive predictive value).

The small studies and smaller number of studies for a certain ultrasound marker may be associated with more uncertain results. This is somewhat adjusted for by the meta-analysis process and the resultant 95% confidence intervals of the odds ratios.

A comparison of the accuracy of different tests using studies that did not compare the tests within the same study population could be prone to confounding. Only four of the included studies compared multiple measures of suspected fetal macrosomia (EFW, AC, AD-BPD, and HC) within the same population. All four of these studies recorded outcome data for shoulder dystocia and just one of these studies recorded outcome data for BPI. In the case of the outcome shoulder dystocia, the individual study results proved consistent with the meta-analysis findings that used all of the available studies to compare the multiple tests, suggesting reliability. For the outcome of BPI there were significantly less studies and therefore no meta-analysis was possible. The individual study results compared different populations and thus the results we have presented for BPI are at a higher risk of confounding.

One weakness of the study is that the data on CS did not differentiate between elective and emergency CS and therefore did not account for 'treatment paradox'.

Comparison to other studies

Previous studies have focused on the diagnostic accuracy of antenatal prediction of fetal macrosomia in comparison to absolute birth weights. Currently there are no studies that have systematically reviewed our index tests in relation to delivery and neonatal outcomes. A Cochrane review published in 2016 (24) asked a similar question. Culliney *et al*, focused on the benefits and harms associated with different combinations of surveillance methods for the suspected LGA fetus but they found no RCTs that assessed the effect of the antenatal fetal surveillance regimens on important health outcomes for the mother and baby. The absence of randomised controlled trials revealed an area where research is needed. Our study relied on observational data in the form of cohort and case-control studies. Observational data is prone to bias. In the absence of RCT data, systematic review and meta-analysis of the observational trials became the best option to get data on this question.

This is the first study to our knowledge to examine which antenatal imaging measures of fetal macrosomia best predict adverse maternal and neonatal outcomes. No other review has attempted to compare different definitions of suspected fetal macrosomia to inform clinical practice. This is more useful information for clinicians needing to counsel women with suspected fetal macrosomia.

CONCLUSION

Estimated fetal weight is the most widely used ultrasound marker to predict fetal macrosomia in the UK. However, this study suggests that other markers have a higher positive predictive value for adverse outcomes associated with fetal macrosomia.

When counselling women with suspected fetal macrosomia and offering interventions to reduce shoulder dystocia, clinicians should be aware that this research would suggest that ultrasound markers which look at the difference between the size of the fetal abdomen and head or the size of the fetal abdomen alone can more accurately predict shoulder dystocia than estimated fetal weight.

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