

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

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21

22 **ABSTRACT**

23 **Objectives**

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

26 **Study Design**

27 Four biomedical databases searched for studies published after 1966.

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

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

33 **Results**

34 Twenty-five observational studies (13,285 participants) were included. For BPI, the only significant
35 positive association was found for Abdominal Circumference (AC) to Head Circumference (HC)
36 difference > 50 mm (OR 7.2, 95% CI 1.8 to 29). Shoulder dystocia was significantly associated with
37 abdominal diameter (AD) minus biparietal diameter (BPD) ≥ 2.6 cm (OR 4.2, 95% CI 2.3 to 7.5, PPV
38 11%) and AC > 90 th centile (OR 2.3, 95% CI 1.3 to 4.0, PPV 8.6%) and an estimated fetal weight (EFW)
39 > 4000 g (OR 2.1 95%CI 1.0 to 4.1, PPV 7.2%).

40 **Conclusions**

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

44 **Keywords**

45 Fetal macrosomia; shoulder dystocia; ultrasound markers

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53 **INTRODUCTION**

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

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

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

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

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

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

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

86 **MATERIALS AND METHODS**

87 The study was prospectively registered (CRD42016046850).

88 **Study objective**

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

91 **Eligibility criteria**

92 Types of studies

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

99 Participants

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

104 Index test

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

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

119 **Primary analysis**

120 Search strategy

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

125 Study selection

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

130 Data extraction and quality assessment

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

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

138 The quality of included studies was assessed by a structured assessment completed independently by
139 two reviewers (RCR and VAW). The STARD and QUADAS-2 published checklists are both validated
140 methods for the study of methodological quality in the reporting of diagnostic test accuracy studies.
141 [16, 17]. From within these validated tools, we selected the elements that best represented the
142 methodical quality for systematic reviews that assess the association between prognostic tests and
143 outcome. We used the same approach that has been used successfully by other similar, published
144 systematic reviews and meta-analyses [18, 19].

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

147 Data analysis

148 We used aggregate data to quantitatively synthesise odds ratios (ORs) and 95% confidence intervals
149 (95% CIs) for each index test-outcome pair. The results were pooled for each index test using a random
150 effect meta-analysis to provide the summary estimate of prognostic association with outcome. If a
151 strong and statistically significant prognostic association was identified between a test and an
152 outcome measure, we calculated sensitivity, specificity and likelihood ratios from the 2x2 tables and
153 then used a bivariate random-effects meta-analysis model to assess the predictive ability of the test.

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

162 All analyses were performed in Stata (version 15).

163 **RESULTS**

164 **Study selection**

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

169 **Quality assessment**

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

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

174

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

179 Eighteen studies [10, 22-37] (11447 women test/outcome data sets) reported shoulder dystocia as an
180 outcome. Three studies [26-28] reported on AC > 90th centile and shoulder dystocia.

181 Three studies [23, 28, 29] reported on abdominal diameter minus biparietal diameter \geq 2.6 cm. Four
182 studies reported on estimated fetal weight > 4000 g [11, 28, 35, 38]. The summary prevalence
183 (calculated from these ten studies included in the meta-analysis) for shoulder dystocia was 4.9% (95%
184 CI 2.1 to 11%) (Table 5).

185 Meta-analysis revealed shoulder dystocia was associated with: abdominal diameter (AD) minus
186 biparietal diameter (BPD) \geq 2.6 cm (OR 4.2, 95% CI 2.3 to 7.5, PPV 11%) and AC > 90th centile (OR 2.3,

187 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,
188 PPV 7.2%) (Table 3). PPVs were predicted for a new population with a prevalence of 4.9% for shoulder
189 dystocia. Full results are shown in Table 3.

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

198

199 **DISCUSSION**

200 **Principal findings**

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

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

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

212 **Strengths and weaknesses**

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

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

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

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

232 **Comparison to other studies**

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

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

247 **CONCLUSION**

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

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

255

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