

# Journal Pre-proof



## PREDICTING CESAREAN DELIVERY FOR FAILURE TO PROGRESS AS AN OUTCOME OF LABOR INDUCTION IN TERM SINGLETON PREGNANCY

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1 **PREDICTING CESAREAN DELIVERY FOR FAILURE TO PROGRESS AS AN**  
2 **OUTCOME OF LABOR INDUCTION IN TERM SINGLETON PREGNANCY**

3

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25

26 **Condensation:**

27

28 To develop and validate an objective and easily applicable model to predict  
29 successful induction of labor.

30

31 **Short title:** Prediction model for induction of labor outcome

32

33 **AJOG at a glance:**

34 **A. Why was this study conducted?**

35 To develop a reliable model for prediction of cesarean delivery for failure to  
36 progress as an outcome of labor induction in term singleton pregnancies.

37

38 **B. What are the key findings?**

39 A predictive model comprising maternal age, cervical length, angle of progression  
40 at rest and fetal occiput posterior position provided accurate prediction of  
41 successful induction of labor (area under the receiver operating characteristic  
42 curve (AUC 0.79, 95% confidence interval 0.71-0.87). There was also a good  
43 performance in validation of the model with AUC of 0.88, 95% confidence interval  
44 0.79-0.97).

45

46 **C. What does this study add to what is already known?**

47 A model for prediction of the success of induction of labor, focusing on objective,  
48 accessible and acceptable predictors.

49

50 **ABSTRACT:**51 ***Background:***

52 Induction of labor is one of the most common interventions in modern obstetrics  
53 and its frequency is expected to continue to increase. There is inconsistency as to  
54 how failed induction of labor is defined, however, the majority of studies, define  
55 success as the achievement of vaginal delivery. Induction of labor in nulliparous  
56 women poses an additional challenge with a 15-20% incidence of failure, ending in  
57 emergency operative deliveries. The Bishop score has been traditionally used  
58 before decisions for induction of labor. Nonetheless, it is subjective and prone to  
59 significant inter-observer variation. Several studies have been conducted to find  
60 alternative predictors, yet, a reliable, objective method still remains to be  
61 introduced and validated. Hence, there is still a need for the development of new  
62 predictive tools to facilitate informed decision making, optimization of resources,  
63 and minimization of potential risks of failure. Furthermore, peripartum transperineal  
64 ultrasound scan has been proven to provide objective, non-invasive assessment of  
65 labor.

66 ***Objectives:***

67 To assess the feasibility of developing and validating an objective and reproducible  
68 model for the prediction of cesarean delivery for failure to progress as an outcome  
69 of labor induction in term singleton pregnancies.

70 ***Study Design:***

71 This was a prospective observational cohort study conducted in Cairo University  
72 Hospitals and University of Bologna Hospitals between November 2018 and

73 November 2019. We recruited 382, primigravidae, with singleton term pregnancies  
74 in cephalic presentation. All patients had baseline Bishop scoring together with  
75 various transabdominal and transperineal ultrasound assessments of the fetus,  
76 maternal cervix and pelvic floor. The managing obstetricians were blinded to the  
77 ultrasound scan findings. The method and indication of induction of labor, the total  
78 duration of stages of labor, mode of birth, and neonatal outcomes were all  
79 recorded. Women who had operative delivery for fetal distress or indications other  
80 than failure to progress in labor were excluded from the final analysis leaving a  
81 total of 344 participants who were randomly divided into 243 and 101 pregnancies  
82 that constituted the model development and cross-validation groups, respectively.

### 83 **Results:**

84 It was possible to perform transabdominal and transperineal scans and assess all  
85 the required parameters on all study participants. Univariate and multivariate  
86 analyses were used for selection of potential predictors and model fitting. The  
87 independent predictive variables for cesarean delivery included maternal age (OR  
88 1.12,  $P = 0.003$ ), cervical length (OR 1.08,  $P = 0.04$ ), angle of progression at rest  
89 (OR 0.9,  $P = 0.001$ ), occiput posterior position (OR 5.7,  $P = 0.006$ ). We tested the  
90 performance of the prediction model on our cross-validation group. The calculated  
91 areas under the curve for the ability of the model to predict cesarean delivery were  
92 0.7969 (95% confidence interval 0.71-0.87) and 0.88 (95% confidence interval  
93 0.79-0.97) for the developed and validated models, respectively.

### 94 **Conclusions:**

95 Maternal age and sonographic fetal occiput position angle of progression at rest  
96 and cervical length prior to labor induction are very good predictors of induction  
97 outcome in nulliparous women at term.

98

99 **Keywords:**

100 Angle of progression; biomarkers; cervical length; cesarean delivery; maternal age;  
101 occiput posterior position; parturition; prediction; replication; successful induction of  
102 labor; transperineal ultrasound; ultrasound in labor; vaginal birth.

## 103 INTRODUCTION

104 Induction of labor (IOL), is one of the most common exercised and studied  
105 interventions in obstetrics. Its frequency has been increasing, with reports of 1 in 5  
106 pregnant women undergoing IOL<sup>1,2</sup> and is expected to continue to rise given the  
107 increase in the evidence-based, recommended indications for IOL, whether for  
108 obstetric, fetal, maternal, or medical reasons.<sup>3-5</sup> There is inconsistency in defining  
109 failed IOL: some authors define failure of IOL based on the duration of the latent  
110 phase, using 15 hours as a cut-off value<sup>6</sup> and others consider an inability to  
111 achieve cervical dilatation > 4 cm within 12 hours of oxytocin administration as an  
112 indicator of failed IOL.<sup>7</sup> Another study suggested that the simple achievement of  
113 active labor should be considered a measure of successful IOL.<sup>8</sup> Nonetheless, the  
114 majority of authors, find it pertinent to consider the outcome, rather than the  
115 process, and propose vaginal delivery as the main IOL outcome. After all, for the  
116 expectant woman, when embarking on IOL, the outcome sought is vaginal delivery;  
117 otherwise she would opt for cesarean delivery from the start. Induction of labor in  
118 nulliparous women at term does not always lead to a normal spontaneous vaginal  
119 delivery; some cases, especially primigravidae of advanced age, need assistance  
120 with an instrumental delivery or require cesarean delivery.<sup>5,9</sup> It is estimated that 15-  
121 20% of IOLs fail to result in vaginal birth, ending in intrapartum operative  
122 deliveries.<sup>10</sup>

123 Numerous investigators have evaluated several clinical and  
124 ultrasonographic parameters as predictors of IOL outcome and reported varying  
125 results.<sup>11-18</sup> The Bishop score has traditionally been used as the standard test prior

126 to IOL determination. Nonetheless, it is a subjective assessment associated with  
127 poor predictive value, reproducibility and high degrees of inter- and intra-observer  
128 disagreement.<sup>18-20</sup> Moreover, studies that compared the predictive value of  
129 ultrasonographic indices to the Bishop score have generated contradictory  
130 results.<sup>21-23</sup> The negative impacts of failed IOL range from the stress of enduring a  
131 futile, prolonged trial of labor; an increased economic burden and misuse of  
132 healthcare resources due to prolonged hospital stay; excessive use of medications;  
133 vigilant maternal/fetal monitoring; and an increased rate of interventions to the  
134 increased prevalence of maternal, fetal, and neonatal complications of an  
135 emergency cesarean delivery.<sup>24</sup> Therefore, to enable obstetricians to individualize  
136 the care offered to patients, it is important to identify women at high risk of IOL  
137 failure, improve clinical outcomes, and optimize the cost-effectiveness of  
138 healthcare interventions. In an attempt to identify methods of assessment more  
139 objective than digital examination, ultrasound has been shown to be suitable to  
140 assess labor progression. Transabdominal and transperineal ultrasound have been  
141 shown to provide reproducible, objective and non-invasive assessment of labor  
142 progression.<sup>16,25-32</sup> Nevertheless, a reliable, objective method to predict the  
143 likelihood of vaginal delivery still remains to be introduced and validated. This calls  
144 for the development of new predictive tools for the success of IOL to allow for  
145 informed decision making, optimization of resources, and minimization of potential  
146 risks of failure. The objective of this study was to assess the feasibility of  
147 developing and validating an objective and reproducible model for the prediction of  
148 cesarean delivery for failure to progress as an outcome of labor induction in term  
149 singleton pregnancies.



150

151 **METHODS**152 **Design and setting**

153 This was a prospective observational cohort study conducted between November  
154 2018 and November 2019 in two tertiary-level university-affiliated maternity units:  
155 Kasr Al-Ainy University Hospital, Cairo University, Egypt, and Sant'Orsola Malpighi  
156 University Hospital, University of Bologna, Bologna, Italy. The local research ethics  
157 committees of both participating units approved the study protocol prior to study  
158 commencement (Kasr Al-Ainy University Hospital reference number O18005 and  
159 Sant'Orsola Malpighi University Hospital, reference number 139/2016/U/Oss). All  
160 study participants provided written informed consent prior to enrollment.

161 **Participants**

162 Women were considered eligible for inclusion in this study if they met the following  
163 requirements:  $\geq 18$  years of age, nulliparous, singleton, term pregnancy (37-42  
164 weeks of gestation) planned for induction of labor for any indication, and a fetus in  
165 a cephalic presentation. Women presenting in labor or with a history of uterine  
166 surgery or scarring were excluded from the study. Recruitment into the study was  
167 non-consecutive, depending on the availability of a member of the study team  
168 trained to undertake the *a priori* set of ultrasound parameters under consideration.

169 A total of 382 nulliparous women were enrolled into the study, including 268  
170 of a total of 1440 (18.6%) pregnancies during the study period at Kasr Al-Ainy  
171 University Hospital and 114 of a total of 983 (11.6%) at Sant'Orsola Malpighi

172 University Hospital. All participants had a baseline clinical cervical assessment  
173 using the modified Bishop score<sup>33</sup>; the attending obstetricians managed the labor in  
174 line with the unit's protocol and were blinded to the ultrasound scan findings  
175 (supplementary appendix). In addition to demographic details, data were collected  
176 as follows: the method and indication of induction of labor, the total duration of  
177 labor (onset of induction to delivery), duration of first and second stages including  
178 length of the pushing phase, mode of birth, and neonatal outcomes. As the aim of  
179 our study was to develop and validate a prediction model for successful induction  
180 of labor, women who had a cesarean delivery for fetal distress or indications other  
181 than failure to progress in labor were excluded from the final analysis.

#### 182 **Ultrasound parameters**

183 Once enrolled, study participants underwent a transabdominal scan to evaluate  
184 fetal biometry and fetal occiput position, and a transperineal ultrasound  
185 examination was conducted to measure the cervical length, angle of progression  
186 (AoP), antero-posterior diameter of the levator hiatus, head-to-perineum distance,  
187 and head-to-symphysis distance; the last four parameters were assessed both at  
188 rest and at maximum Valsalva<sup>34</sup> (**Figures 1 and 2**). Scans were performed using a  
189 convex 3.5-5 MHz transducer (Voluson 730 Expert, Voluson P8 or Voluson E10,  
190 GE Medical Systems, Zipf, Austria) by one of two operators with more than three  
191 years of experience in obstetric and transperineal ultrasound (R.K. and A.Y.) who  
192 were blind to clinical examination findings. Fetal biometry was conducted in  
193 accordance with published ISUOG guidelines.<sup>35</sup> Occiput position determination  
194 was made by transabdominal ultrasound as previously published.<sup>36-38</sup> This was

195 performed by looking for the following landmarks: the fetal occiput, the fetal orbits,  
196 the midline of the fetal brain, and cerebellum. According to these landmarks, the  
197 fetal occiput position was described in relation to a clockface.<sup>39</sup> Occiput position  
198 was described as anterior if the occiput was between 09:30 and 02:30 h,  
199 transverse (OT) if between 02:30 and 03:30 h, or 08:30 and 09:30 h, and posterior  
200 (OP) if between 03:30 and 08:30 h.

201 For transperineal ultrasound examination, the transducer was covered with a  
202 sterile surgical glove. The transducer was placed between the labia majora in a  
203 mid-sagittal plane, aligning the acquisition plane with the long axis of the pubic  
204 symphysis. Cervical length was measured along the length of the endocervical  
205 canal with simultaneous visualization of the internal os and external os, using a  
206 straight line drawn between internal os and external os for the measurement.  
207 Transvaginal ultrasound was used in cases of non-optimal visualization with care  
208 not to compress and distort the cervix by the probe.<sup>40</sup> The antero-posterior  
209 diameter of the levator hiatus was measured in mid-sagittal view as the distance  
210 between the inferior border of the symphysis pubis to the anterior border of the  
211 puborectalis muscle.<sup>41</sup> The AoP was measured as the angle between a line  
212 running along the long axis of the pubic symphysis and another line extending from  
213 the most inferior portion of the pubic symphysis tangentially to the fetal skull  
214 contour.<sup>16</sup> Head-symphysis distance is the distance along the infrapubic line  
215 between the caudal end of the pubic symphysis and the fetal skull.<sup>42</sup> For head-to-  
216 perineum distance, the transducer was rotated into a transperineal transverse  
217 plane at the level of the posterior commissure and pressed against the pubic

218 rami.<sup>43</sup> Head- perineum distance is defined as the shortest distance between the  
219 perineum and the outer-most part of the bony skull.

## 220 **Statistical analysis**

221 Simulation studies examining predictor variables for inclusion in logistic regression  
222 models suggest that 5 - 10 events are necessary for each candidate predictor to  
223 avoid overfitting.<sup>44-46</sup> Based on 7 events per predictor and the assumption that we  
224 will examine 10 candidate predictors, it was estimated that 70 women with the  
225 primary outcome of interest (cesarean delivery following IOL due to failure to  
226 progress ) would be required. Based on a cesarean delivery rate of 22% following  
227 IOL a sample size of 318 women would be required. Applying the methodology  
228 proposed by Riley et al, a global shrinkage factor and adjusted  $R^2$  ( $R^2_{\text{adjust}}$ ) are  
229 required to estimate the minimum number of events per predictor.<sup>47</sup> In view of the  
230 absence of any information regarding these two parameters we assumed that  
231 ( $R^2_{\text{adjust}}$ ) and shrinkage factor values would be 0.25 and 0.9, respectively. To  
232 develop our logistic regression model based on up to 10 predictors and assuming a  
233 cesarean delivery rate of 22%<sup>10</sup> a sample size of 307 would be needed and the  
234 events per predictor would be 7 per predictor (supplementary appendix).

235 The study sample ( $n = 344$ ) was randomly divided into 243 and 101  
236 pregnancies that constituted the model development and cross-validation groups,  
237 respectively. For model development, the differences of the maternal and  
238 ultrasonographic data between the vaginal delivery and cesarean delivery groups  
239 were calculated by a Student's t-test (for continuous variables) and the  $\chi^2$  test (for  
240 categorical variables). All variables in the bivariate analysis with  $P < 0.2$  were

241 evaluated further using multiple logistic regression analysis by computing odds  
242 ratios (OR) and their 95% confidence intervals (CI). Variables with a P value > 0.2  
243 were removed from the model. The reduced model was then successively refitted,  
244 and the model with the lowest Akaike's information criteria value was considered  
245 the best. Akaike's information criteria represents the ratio between the number of  
246 parameters in the numerator and log likelihood in the denominator (supplementary  
247 appendix). Akaike's information criteria score of the model will increase in  
248 proportion to the growth in the value of the numerator, which contains the number of  
249 parameters in the model (i.e. a measure of model complexity). And the Akaike's  
250 information criteria score will decrease in proportion to the growth in the  
251 denominator which contains the maximized log likelihood. Thus, Lower value of  
252 Akaike's information criteria suggests "better" model.<sup>48</sup>

253 Only significant objective variables that predicted the risk of cesarean  
254 delivery after IOL were included in the final model. We constructed a receiver  
255 operating characteristic (ROC) curve to assess the prognostic accuracy of the  
256 devised model. The predicted probability of cesarean delivery was used as the  
257 predictive variable with the actual occurrence of cesarean delivery as the tested  
258 outcome. The area under the ROC curve (AUC), expressing the prognostic  
259 performance of the model, was calculated and compared for statistically significant  
260 differences.

261 We applied bootstrap resampling methodology of AUC as previously  
262 described.<sup>49</sup> This method was used to implement 10-fold cross-validation for the  
263 AUC for a dependent variable after fitting a logistic regression model and provides

264 the cross-validated fitted probabilities for the dependent variable. Then bootstrap  
265 resampling for AUC and 95% CI were generated. Bootstrap resampling  
266 methodology was done using Stata Corp. 2013 (Stata Statistical Software Release  
267 13. College station, TX: StataCorp LP) with the command of CVAUROC

268 The final model was then applied to the cross-validation group by using the  
269 holdout sample validation method, and a ROC curve was constructed to assess  
270 the accuracy of the cross-validated model.

271 We conducted all data analyses by using statistical software programs  
272 (MedCalc version 12.1.4.0 (MedCalc Software byba, Mariakerke, Belgium) SPSS  
273 for Windows version 21.0 (SPSS Inc., Chicago, IL, USA).

274

## 275 **RESULTS**

276 A total of 382 women who fulfilled the inclusion criteria were enrolled into the study.  
277 Of these participants, 38 women underwent a cesarean delivery for unpredictable  
278 indications (e.g. fetal distress) and were excluded from the study herein, leaving a  
279 total of 344 pregnancies contributing to the analysis (**Figure 3**). It was possible to  
280 perform ultrasound scans and assess all the required parameters on all study  
281 participants who found it quite acceptable. The characteristics of the study  
282 population are shown in **Table 1**.

283 We aimed to study variables that are objective, easily assessed, and  
284 reproducible to minimize inter- and intra-observer variability and to establish a  
285 reliable model Multivariate logistic regression analysis (**Table 2**) revealed the

286 independent predictive variables for cesarean delivery to be maternal age (OR  
 287 1.12, 95% CI 1.03-1.2; P value = 0.003), cervical length (OR 1.08, 95% CI 1.002-  
 288 1.17; P = 0.04), AoP at rest (OR 0.9, CI 0.85-0.96; P = 0.001), occiput posterior  
 289 (OP) position, where OA is the reference position, (OR 5.7, 95% 1.6-19; P =  
 290 0.006).

291 The following equation can calculate the probability of cesarean delivery:

292  $P(CS) =$

$$293 \frac{e^{1.62+0.11Xage+0.08Xcervical\ length-0.09XAOP_{rest}+0.009XHSD-val+(0[OA]|-0.28[OT]|+1.75[OP]}}{1+e^{1.62+0.11Xage+0.08Xcervical\ length-0.09XAOP_{rest}+0.009XHSD-val+(0[OA]|-0.28[OT]|+1.75[OP]}}$$

294 The calculated AUC for the ability of the model to predict cesarean delivery was  
 295 0.79 (95%CI 0.71-0.87).

296 Applying bootstrap resampling methodology, the AUC calculated using CVAUROC  
 297 was 0.73 (95%CI 0.58-0.78)

298 We internally validated our model where it was applied to the cross-  
 299 validation group by using the holdout sample validation method, and a ROC curve  
 300 was constructed to assess the accuracy of the cross-validated model. **Table 3**  
 301 shows the characteristics of the cross -validation group. The calculated AUC for  
 302 the model to predict cesarean delivery as an outcome of IOL in the validation  
 303 cohort was 0.88 (95%CI 0.79-0.97) (**Figure 4**).

304 We aimed to assess the prediction model on a clean sample of women who  
 305 failed to progress in labor without diluting the sample with women who had  
 306 cesarean delivery for fetal distress since this can result from other factors such as

307 placental insufficiency and oligohydramnios induced cord compression,  
308 nonetheless we appreciate the possible overlap between various causes.  
309 Therefore, we calculated the AUC including women who had cesarean delivery for  
310 fetal distress for, both, model development and validation cohorts and these were  
311 0.73(95%CI 0.65-0.81) and 0.87(95% CI 0.79-0.96) respectively.

312

## 313 **DISCUSSION**

### 314 ***Principal findings of the study***

315 A prediction model was devised utilizing a combination of patient characteristics  
316 and pre-induction clinical and ultrasonographic variables; maternal age, cervical  
317 length, AoP at rest and fetal occiput position. We provided a calculator for the  
318 probability of cesarean delivery. Based on the calculated AUC of 0.79, this model  
319 performed well as a predictor of women whose IOL failed and who required  
320 cesarean delivery. This finding was also confirmed when the model was tested on  
321 our validation cohort with an AUC of 0.88.

322

### 323 ***Results in the context of what is known***

324 Several groups have attempted to predict IOL outcome and it is anticipated that  
325 these attempts will continue due to the increasing prevalence of IOL and hence the  
326 need to alleviate maternal, fetal and neonatal complications as well as optimise the  
327 cost effectiveness of the procedure. A predictive model proposed by Kawakita *et*  
328 *al.*, reported independent significant predictors for successful vaginal delivery in  
329 nulliparous women who underwent IOL: maternal age, gestational age at delivery,



330 race, maternal height, pre-pregnancy weight, gestational weight gain, cervical  
331 examination on admission (dilation, effacement, and station), chronic hypertension,  
332 gestational diabetes, pre-gestational diabetes, and abruption.<sup>50</sup> Their study, a  
333 retrospective analysis, included a large number of patients (10591), yet the  
334 predictors it introduced are largely demographic and rely on clinical assessment of  
335 the cervix, which is subjective.

336 Tolcher *et al.*, devised a nomogram for predicting cesarean delivery after  
337 IOL in nulliparous women.<sup>12</sup> This nomogram identified advanced maternal age,  
338 short maternal stature, high body mass index, increased weight gain during  
339 pregnancy, advanced gestational age, hypertension, diabetes mellitus, and initial  
340 cervical dilatation < 3 cm as independent risk factors associated with an increased  
341 risk for cesarean delivery. This study also included a relatively large number of  
342 patients (785), and introduced parameters representing subjective assessment of  
343 the cervix as well as maternal medical and demographic factors.

344 Our findings are concordant with these two studies in that maternal age is a  
345 strong predictor of successful IOL, with advanced maternal age increasing the  
346 likelihood of cesarean delivery; nonetheless, we opted to use cervical length  
347 assessed by ultrasound rather than clinically assessed cervical dilatation, used in  
348 the two studies cited above, to provide a more objective, reproducible means of  
349 assessment. Cervical length was mostly assessed transperineally, not  
350 transvaginally, as there were other transperineal parameters to measure. We found  
351 that this method avoids risk of cervical distortion due to pressure by the  
352 transvaginal probe, and is more acceptable to patients.

353 Previously Rane *et al.*, and Peregrine *et al.*, also found cervical  
354 assessments to be highly predictive and incorporated this in their IOL outcome  
355 predictive models. The model of Peregrine *et al.*, included body mass index and  
356 height, both parameters were not identified as significant enough to be selected  
357 during our model development.<sup>51</sup> Rane *et al.*, added posterior cervical angle  
358 measurement and occiput position to the cervical length measurement.<sup>52</sup> We also  
359 added the occiput position as a significant predictor in our model, which is of  
360 interest as in a previous study conducted by our group, we found that pre-induction  
361 assessment of the fetal occiput and spinal position did not associate well with the  
362 likelihood of cesarean delivery in 136 nulliparous women undergoing IOL at term.<sup>53</sup>  
363 The difference in the number of the study population might account for this  
364 discrepancy. It has been previously suggested that the exclusion of estimated fetal  
365 weight or information on maternal pelvic adequacy was a shortcoming of a web-  
366 based calculator devised for the prediction of success of IOL.<sup>54,55</sup> In our study, both  
367 parameters were identified as strong predictors of IOL outcome, but more so when  
368 combined, because the process of labor involves the synergistic relationship  
369 between these two factors, which was represented in our study by the AoP, but not  
370 as single isolated parameters. AoP has been previously identified as a useful  
371 sonographic predictor for successful vaginal delivery among nulliparous women at  
372 term undergoing IOL.<sup>56</sup> Levy *et al.*, found that a narrow AoP in nulliparous women,  
373 not in labor at term is associated with a high rate of CS.<sup>57</sup> We found that the AoP  
374 was a strong predictor for cesarean delivery as an outcome for IOL in nulliparous  
375 women, and its inclusion improved the performance of our model.

376 In contrast, Pereira *et al.*, when attempting to include the AoP in a predictive  
377 model with cervical elastography and pre-induction cervical length in women  
378 undergoing IOL found that the AoP and an internal os elastographic score were  
379 unlikely to be useful.<sup>58</sup> The variation between the findings of Pereira *et al* and ours  
380 could be due to our larger sample size (344 vs 99) or the non-inclusion of cervical  
381 elastography in our pre-IOL variables, given its limited availability in regular  
382 ultrasound machines commonly used in labor units.

383 In the present study, we measured indices of the fetal head descent and the  
384 anteroposterior diameter of the levator ani muscle hiatus at rest and under  
385 Valsalva. There is growing evidence on the relationship between the pelvic floor  
386 and labor outcome. Some authors suggested that larger anteroposterior diameters  
387 measured before the onset of labor were associated with an increased likelihood of  
388 vaginal delivery and with lower fetal head descent in the birth canal, whereas  
389 others found an association exclusively with the duration of the second stage of  
390 labor.<sup>41,59-63</sup> In the present study we did not demonstrate an association between  
391 anteroposterior diameters and Cesarean delivery. However, some studies  
392 demonstrated an association between the angle of progression under Valsalva and  
393 the mode of delivery.<sup>64</sup> Although this was confirmed in the present study, the angle  
394 of progression under Valsalva did not add any predictive value to our model,  
395 reflecting a more important role to the static rather than the dynamic ultrasound  
396 indices of the fetal head descent in the birth canal in the prediction of Cesarean  
397 delivery.

398

399 **Clinical Implications**

400 Prediction models and calculators are means of providing patients with an  
401 individualized risk assessment to help them decide their management. IOL is one  
402 of the most common interventions in current obstetric practice. However, at  
403 present, women make decisions about IOL based on a non-specific background  
404 risk of cesarean delivery. Upon external validation, this prediction model has the  
405 potential to be a useful tool for clinicians and women to make management plans  
406 and informed healthcare choices by providing them with the individualized risk of  
407 cesarean delivery. Moreover, it will be helpful to transfer this model to a user-  
408 friendly platform e.g., a computer software or a mobile application. An additional  
409 benefit is perhaps the possibility of optimizing the timing of IOL till a more favorable  
410 failure risk assessment is achieved, given that some of the parameters assessed  
411 are dynamic. This is particularly relevant to the increasing indications for early IOL  
412 to improve maternal and fetal outcomes.<sup>65</sup>

413

#### 414 **Research Implications**

415 We were able to develop and validate our prediction model on two different cohorts  
416 which increases the internal validity of our work. Further external validation of our  
417 findings by in larger unselected population will be useful to substantiate their  
418 generalizability, particularly in view of our higher than previously reported cesarean  
419 delivery rates. Based on the methodology previously proposed by Riley et al,<sup>47</sup> a  
420 shrinkage factor of 0.9,  $R^2_{\text{adjust}}$  of 0.05 and a cesarean delivery incidence of 29%  
421 as calculated from our model development cohort, the total number of patients  
422 required for external validation is 1050 and the number of events per predictor is  
423 50 (supplementary appendix).

424

425 **Strengths and limitations**

426 Strengths of the study include: first, relatively large sample size, second,  
427 prospective enrolment of women, third, random stratification of the study cohort  
428 into model development and model validation groups, fourth, the managing  
429 obstetricians were blinded to the pre-induction assessment and ultrasound  
430 parameters. This study provides an applicable, objective prediction model for the  
431 success of IOL in nulliparous women, thus providing patients with useful  
432 information that can empower them to make informed choices about their  
433 respective birth plans. The model performed well upon cross validation, adding to  
434 the overall strength of this study.

435 The limitations of the study include: first, ultrasound measurements were  
436 obtained by experienced maternal-fetal medical consultants. This issue can  
437 potentially have implications on the external validity of our findings. Nonetheless,  
438 transperineal measurements are expected to be performed at the time of  
439 counselling about IOL rather than as an “out of hours” procedure. Hence, it is  
440 feasible that such assessment could be conducted by a clinician trained in  
441 performing transperineal scans. Second, we factored in a model validation  
442 component within our study on a cohort different from our model development  
443 group; however, these groups were recruited from our unit at the same time. It  
444 would be prudent to validate our model on independent cohorts to further test its  
445 predictive performance.

446

447 **Conclusions**

448 Maternal age, ultrasound assessments of occiput position, angle of progression at  
449 rest and cervical length prior to labor induction are good predictors of induction  
450 outcome in nulliparous women at term.

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656 **FIGURE LEGENDS**

657 Figure 1: Transabdominal ultrasound assessment of the fetal occiput position.

658 Figure 2: Transperineal ultrasound assessment of cervical length, head to symphysis  
659 distance and angle of progression.

660 Figure 3: Flowchart of the study participants.

661 Figure 4: Calculated area under the curve for the ability of the model to predict cesarean  
662 delivery (left) and results from the validation cohort (right).

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**Table 1:** Variables studied for the development of the prediction model grouped by mode of birth.

Variable	Vaginal delivery (n=172)	Cesarean delivery (n=71)	P value
Age (yrs)	26.6 (6)	28.5 (6.4)	0.02
Body mass index (kg/m <sup>2</sup> )	29 (4)	31 (5.8)	0.001
Gestational age (weeks)	39 (1.5)	39 (1.5)	0.80
Tobacco use	1 (0.5)	3 (4)	0.04
Fetal sex: Male	85 (49)	38 (53)	0.30
Epidural	30 (18)	15 (23)	0.30
Prepidil®Dinoprostone gel	17 (9.9)	10 (14)	0.416
Propess®Dinoprostone vaginal insert	27 (15.7)	14 (20)	
Misoprostol	128 (74.4)	47 (66)	
Occiput anterior	48 (28)	15 (21)	0.30
Occiput transverse	93 (54)	39 (55)	
Occiput posterior	31 (18)	17 (24)	
Head circumference (mm)	333(15)	334(15)	0.40
Biparietal diameter (mm)	92(4)	93 (4)	0.27
Femur length (mm)	72(4)	72 (4)	0.34
Abdominal circumference (mm)	337(21)	344 (22)	0.017
Estimated fetal weight (gm)	3244(447)	3405 (503)	0.01
Angle of progression at rest (degrees)	92.7(10.8)	86 (10.7)	<0.0001
Angle of progression at Valsalva (degrees)	100.8 (12.2)	95.6 (11.4)	0.002
Head-to-symphysis distance at rest (mm)	46.3 (9.8)	50.6 (11)	0.015
Head-to-symphysis distance at Valsalva (mm)	38.4 (9.8)	43.2 (11.9)	0.006
Head-to-perineum distance at rest (mm)	51.1(8.5)	55.7 (10.6)	0.02
Head-to-perineum distance at Valsalva (mm)	45.3 (7.9)	49.8 (9.5)	0.0003
Antero-posterior diameter of the levator hiatus at rest (mm)	53.8 (8.7)	54.9 (8.7)	0.39
Antero-posterior diameter of the levator hiatus at Valsalva (mm)	59.5 (10.4)	59.6 (11)	0.90
Cervical length (mm)	27.7 (5)	29.9 (6.8)	0.016
Bishop score	3.6 (1.7)	3.4 (1.4)	0.25

Values are mean (standard deviation) or n (%)

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**Table 2:** Antepartum independent variables significantly associated with cesarean delivery as an outcome of induction of labor.

<b>Variable</b>	<b>Odds Ratio</b>	<b>95% CI</b>	<b>P value</b>
Age	1.12	1.03-1.20	0.003
Cervical length	1.08	1.002-1.17	0.04
Angle of progression at rest	0.9	0.85-0.96	0.001
Head -to -symphysis distance at Valsalva	1.009	0.96-1.05	0.60
Occiput position			
Occiput anterior (ref)			
Occiput transverse.	0.7	0.2-2	0.60
Occiput posterior	5.7	1.6-19	0.006

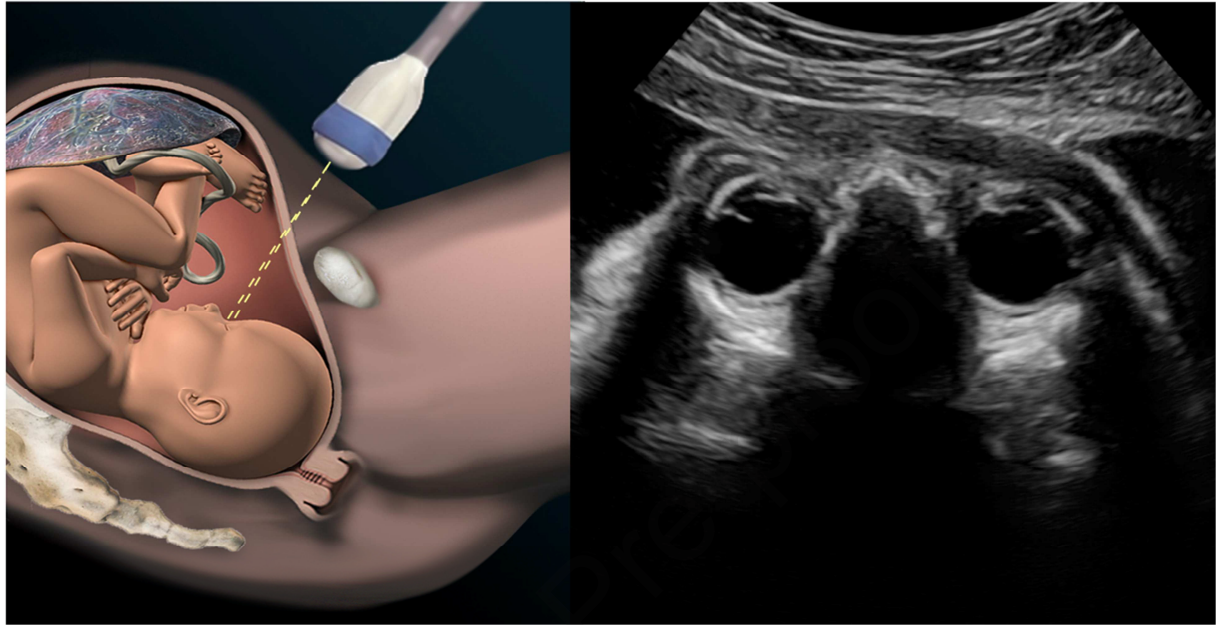
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**Table 3.** Characteristics of the cross-validation group.

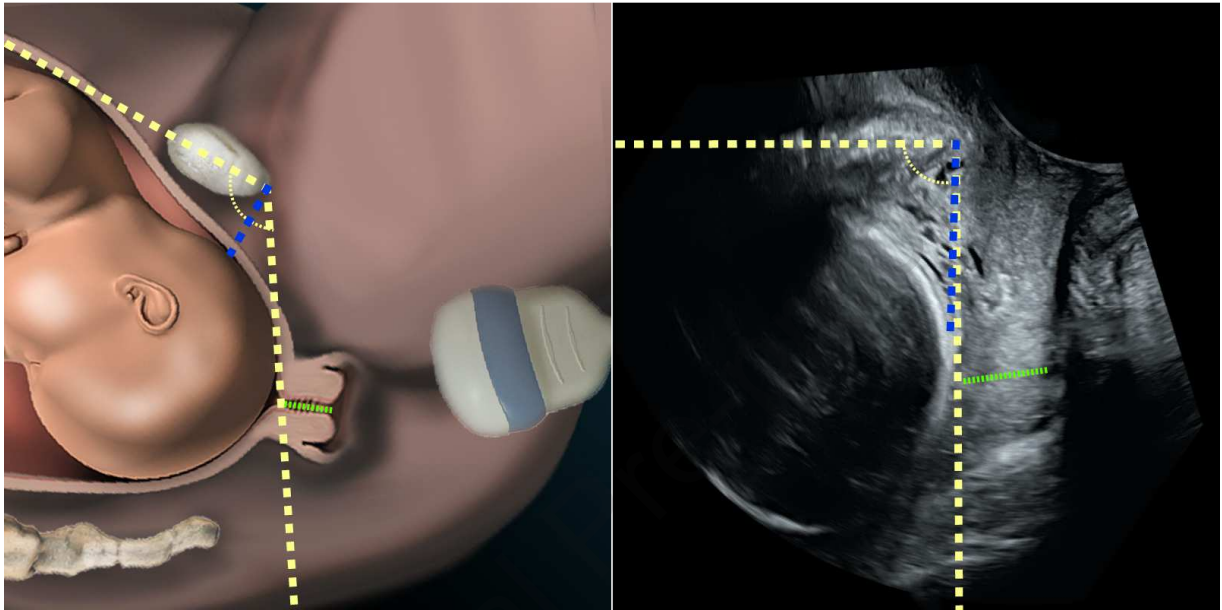
<b>Variable</b>	<b>Mean (SD) or n (%)</b>
Age (yrs)	24.8 (5.2)
Body mass index (Kg/m <sup>2</sup> )	28.5 (3.4)
Gestational age (weeks)	38.9 (1.5)
Head circumference (mm)	330.8 (28.2)
Biparietal diameter (mm)	93.0 (4.2)
Femur length (mm)	70.6 (9.8)
Abdominal circumference (mm)	335.7 (37.1)
Estimated fetal weight (gm)	3267 (499)
Angle of progression at rest (degrees)	91.3 (11.5)
Angle of progression at Valsalva (degrees)	98.5 (12.7)
Head-to-symphysis distance at rest (mm)	41.7 (9.7)
Head-to-symphysis distance at Valsalva (mm)	39.9 (9.0)
Head-to-perineum distance at rest (mm)	55.8 (6.7)
Head-to-perineum distance at Valsalva (mm)	52.4 (7.7)
Antero-posterior diameter of the levator hiatus at rest (mm)	52.1 (5.6)
Antero-posterior diameter of the levator hiatus at Valsalva (mm)	56.3 (7.1)
Cervical length (mm)	25.3 (4.1)
Occiput anterior	38 (37)
Occiput transverse	47 (46)
Occiput posterior	16 (15.7)

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**Figure 1:** Illustrated figure (left) with the corresponding ultrasound image (right) demonstrating the transabdominal ultrasound assessment of the fetal posterior occiput position



**Figure 2:** Illustrated figure (left) with the corresponding ultrasound image (right) for transperineal assessment of angle of progression ( yellow dotted line ) , head to symphysis distance (blue dotted line ) and cervical length ( green dotted line )

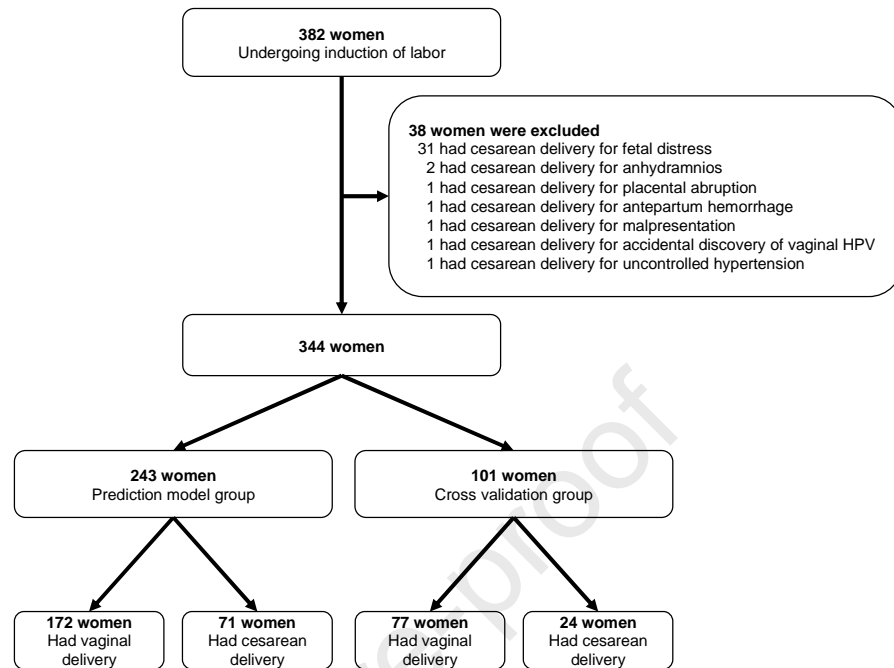


Figure 3

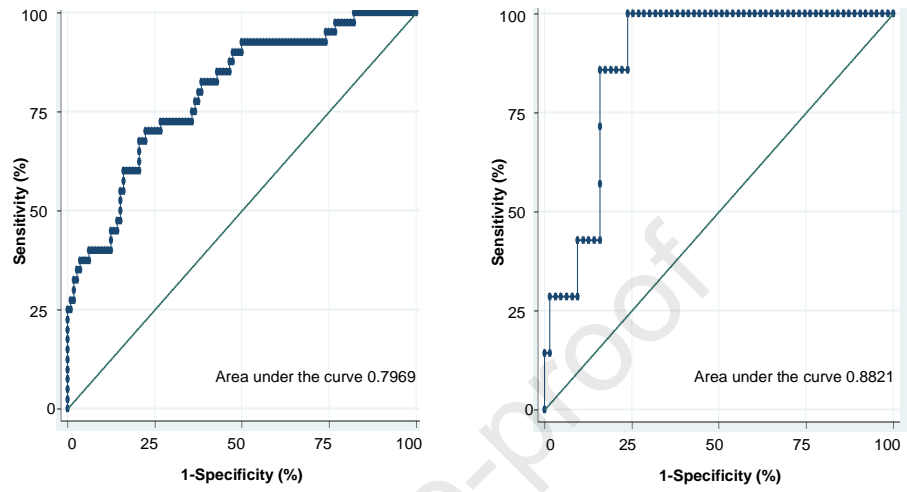


Figure 4