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## Title

Contribution of ultrasonography to the prediction of the induction-delivery interval:  
The ECOLDIA prospective multicenter cohort study.

## Authors

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1 **Highlights:**

- 2 • Previous studies reported contradictory results that might be explained  
3 by heterogeneous populations
- 4 • We sought to evaluate a large population of women homogeneous for  
5 cervical status using a robust methodology. Thus, bishop score was an  
6 original inclusion criterion when selecting a population to study the  
7 prediction of induction-delivery interval.
- 8 • It is the largest cohort of women to evaluate the induction-delivery  
9 interval.
- 10 • Moreover, women undergoing induction of labor with a harmonized  
11 single-agent protocol in order to reduce heterogeneity of study  
12 population.
- 13 • Transvaginal ultrasound cervical length can significantly predict  
14 induction-delivery interval with parity.

15

16 **ABSTRACT**

17 Introduction: To evaluate the ability of preinduction ultrasonographic cervical  
18 length to predict the interval between induction and delivery in women at term  
19 with a Bishop score of 4 to 6 at induction.

20 Study design: This multicenter prospective observational cohort recruited 334  
21 women from April 2010 to March 2014. Inclusion criteria were women with  
22 singleton pregnancies at a gestational age  $\geq 37$  weeks, with no previous  
23 caesarean, a medical indication for induction of labor, and a Bishop score of 4,  
24 5, or 6. All women underwent cervical assessment by both transvaginal

25 ultrasound and digital examination (Bishop score). The induction protocol was  
26 standardized. The primary outcome measure was the induction-delivery interval.  
27 Hazard ratios (HR) and their 95% confidence intervals (95% CI) were used to  
28 assess potential predictors.

29 Results: Mean gestational age at induction was 40.1 weeks, 60.8% of the  
30 women were nulliparous, and the cesarean rate was 13.4%. The mean  
31 induction-delivery interval was 20.8 h ( $\pm$  10.6). Delivery occurred within 24 h for  
32 56.9% (n=190) of the women. An ultrasonographic cervical length measurement  
33 less than 25 mm (HR=1.50, 95% CI 1.18–1.91, P<0.01) and parity (HR=1.41,  
34 95% CI 1.21–1.65, P<0.01) appeared to predict induction-delivery interval. The  
35 cervical length cutoff to reduce the induction-delivery interval was 25 mm.

36 Conclusion: A cervical length cutoff of 25 mm was associated with shorter  
37 induction-delivery interval in women at term with a Bishop score of 4 to 6.

38

### 39 **Abbreviations**

40 TVUS: transvaginal ultrasonography

41

### 42 **INTRODUCTION**

43 Induction of labor occurs in nearly 22% of pregnancies (1). An important  
44 challenge in induction of labor is predicting which patients will have vaginal  
45 deliveries and the time interval from induction to delivery. We believe that  
46 information about delay is an important clinical feature that can affect women's  
47 information and satisfaction when inducing labor. For this reason, we were  
48 focused on delay rather than outcome of the delivery. The Bishop score is

49 currently the standard method for evaluating local cervical ripening before  
50 induction (2). A Bishop score of six or more is considered favorable for induction  
51 of labor, so that oxytocin can be recommended to start induction (3). An  
52 intermediate Bishop score is interpreted to mean that the cervix is unfavorable,  
53 in which case it is recommended that women undergo cervical ripening before  
54 oxytocin administration. Their management thus relies on digital cervical  
55 examination, known to have a subjective measurement with high inter- and  
56 intra-observer variability and a poor predictive value for delivery outcome (4). It  
57 may thus be of limited value, especially in women with intermediate Bishop  
58 scores (4 to 6). Accordingly, other types of preinduction cervical evaluations  
59 have been suggested, such as ultrasound assessment, because they might be  
60 reproducible and more objective as well as more acceptable to women (5). In  
61 women with a low Bishop score, it could also be a useful tool for predicting time  
62 to delivery.

63 Previous studies comparing the Bishop score with transvaginal ultrasonography  
64 (TVUS) of the cervix to predict time to delivery or delivery outcome have  
65 reported contradictory results (6-17). Their differences might be explained by  
66 small samples (between 43 to 266 women included) and heterogeneous  
67 populations that further differ for their Bishop scores at inclusion, gestational  
68 age at induction, and main outcome. Moreover, induction methods were not  
69 standardized within studies and differed between them. Similarly,  
70 ultrasonographic measurements were not homogeneous and various  
71 parameters were evaluated: cervical length, width, dilatation, posterior cervical  
72 angle, and lower segment thickness. We sought to evaluate a large population

73 of women homogeneous for cervical status and undergoing induction of labor  
74 with a harmonized single-agent protocol.

75 Accordingly, the aim of this study was to evaluate if preinduction  
76 ultrasonographic cervical measurements is associated with the induction-  
77 delivery interval in women at term.

78

## 79 **MATERIALS AND METHODS**

80 The prospective multicenter cohort study ECOLDIA (Echographie du COL dans  
81 l'évaluation du Délai Induction Accouchement) took place from April 2010  
82 through March 2014, in three tertiary hospital centers in France. Screening took  
83 place among all women for who induction of delivery was indicated whatever  
84 the indication. The inclusion criteria required that women be pregnant with a  
85 singleton live fetus in cephalic presentation at 37 to 42 weeks of gestation, and  
86 have a medical indication for labor induction, a Bishop score of 4 to 6 during the  
87 hour before induction, and no contraindication for dinoprostone. The Bishop  
88 score was assessed by digital examination by a midwife and was calculated  
89 according to the position, consistency, shortening and dilation of the maternal  
90 cervix and the station of the fetal presenting part (2). The exclusion criteria  
91 were: a previous cesarean delivery, any indication for an elective cesarean,  
92 cervical cerclage for this pregnancy, congenital uterine malformation, a history  
93 of uterine surgery, fetal abnormality, or an age younger than 18 years.

94 The studied factor was the ultrasonographic cervical length assessed one hour  
95 before induction. TVUS was performed in all cases by an obstetrician blinded to  
96 the results of the clinical examination. All participants were blinded to the

97 cervical length. A junior or senior ultrasound certified obstetrician used a 5–9  
98 MHz transvaginal probe and a Voluson E8 (GE Healthcare, Milwaukee, WI,  
99 USA) for the TVUS. A standardized procedure was used for cervical  
100 measurement: the woman had to have an empty bladder and was placed in a  
101 supine position with legs abducted. The operator placed the probe in the  
102 anterior vaginal fornix to obtain a sagittal view of the cervix, avoiding undue  
103 pressure on it to avoid false elongation of the images. He or she then identified  
104 the internal and external os, using the endocervical mucosa to define the level  
105 of the internal os, and checked for and noted any funneling at the internal os.  
106 The cervical canal was magnified to obtain at least 75% of the image. Three  
107 measurements of the distance between the internal and external os were taken  
108 over a period of about 3 minutes, and the shortest measurement of the cervical  
109 length was recorded. Width and dilatation of internal os were also evaluated.  
110 The following data were also collected: age, body mass index, parity, term of  
111 pregnancy, weight gain, indication for induction, analgesia during labor,  
112 oxytocin, mode of delivery and, if a cesarean was performed, its indication,  
113 interval from the start of induction to delivery, Apgar score, arterial pH, and  
114 neonatal hospitalization in the intensive care unit.

115 Cervical ripening for all women was performed with the vaginal prostaglandin  
116 E2 slow-release system (Propess® 10 mg, Ferring, Gentilly, France), which  
117 releases the medication at 0.3 mg/h, for 24 hours. If labor had not started 24  
118 hours after cervical ripening began, it was induced by artificial rupture of  
119 membranes and oxytocin administration, in accordance with French guidelines  
120 (18).

121 The primary outcome was the induction-delivery interval, defined as the period  
122 from the start of cervical ripening to delivery in hours.

### 123 ***Statistical analyses***

124 It was difficult to formulate a quantitative hypothesis regarding the association  
125 between ultrasound variables and induction-delivery time because there were  
126 no data available in the literature. Based upon the rates of induction in the  
127 participating units, our aim was to include 400 women to be able to conduct the  
128 study with sufficient power and reasonable precision.

129 Continuous data are presented as medians with their interquartile ranges (1st  
130 quartile-3rd quartile) or means and their standard deviations, and categorical  
131 data as counts and percentages (normal distribution was verified by histograms).  
132 Receiver operating characteristic (ROC) curves were generated to identify the  
133 best cutoff values with maximum efficiency for TVUS cervical length as  
134 categorical predictors of the induction-delivery interval. To construct the ROC  
135 curve, the binary outcome was the delivery within 24 hours. We conducted  
136 survival analysis of the data with the Kaplan–Meier method and the log rank  
137 test.

138 Then, to take into account the competing risks between vaginal delivery and  
139 cesarean delivery occurs during labor, we used a Fine and Gray regression  
140 model. Indeed, a woman who had a C-section because she fails to progress at  
141 6cm for example will delivery faster than a woman who starts labor quickly and  
142 had a vaginal delivery. The associations between the ultrasound measurement  
143 (functional cervical length and funnel width), parity, maternal age, gestational  
144 age at induction, BMI, indication for induction (PPROM versus other indications)

145 and induction-delivery interval are presented with hazard ratios (HR) and 95%  
146 confidence intervals (95% CI).

147 Analyses were conducted with R version 3.1.3. Differences were defined as  
148 significant when  $P < 0.05$ .

149

### 150 ***Ethical approval***

151 Written informed consent was obtained from all participants. The ethics  
152 committee approved this study. This clinical trial was registered as  
153 NCT02570620. The study follows the STROBE statement guidelines for  
154 reporting observational studies (19).

155

### 156 **RESULTS**

157 This study included 342 women and analyzed 334 (Figure 1); their  
158 characteristics and outcomes are shown in Table 1. Regarding neonatal  
159 outcomes, the median Apgar score was 9.7 ( $\pm 0.7$ ), the arterial pH was 7.2 ( $\pm$   
160 0.08), and the venous pH was 7.3 ( $\pm 0.07$ ). There was no difference in perinatal  
161 outcomes between women who delivered before or after 24 hours ( $p=0.846$ ).

162 Among primiparous women, 43.8% ( $n=89$ ) gave birth within 24 hours. The  
163 average functional cervical length before induction was 18 mm ( $\pm 11$  mm) for  
164 women who delivered before 24 hours and 24 mm ( $\pm 12$  mm) for those who  
165 delivered with an interval of more than 24 hours. The results of ultrasound  
166 cervical length measurement compared with clinical assessment are shown in  
167 Table 2. There was a good correlation between the two measurements. Among  
168 women who gave birth within  $>24$  hours, 96.5% received oxytocine after

169 dinoprostone. The mean induction-delivery interval for the entire population was  
170 20.8 hours ( $\pm 10.6$ ). Delivery occurred within 24 hours for 56.9% of the women  
171 (n=190) with a mean induction-delivery interval of 13.3 hours. For the remaining  
172 43.1% of women (n=144) who gave birth more than 24 hours after induction  
173 began, the mean induction-delivery interval was 31.2 ( $\pm 7.6$ ) hours. This mean  
174 interval was 20.5 hours ( $\pm 10.6$ ) for women who had a vaginal delivery, 25.4  
175 hours ( $\pm 10.2$ ) for those with a cesarean delivery (P=0.004; reference group  
176 "vaginal delivery"), and 31.2 hours ( $\pm 8.9$ ) for the cesareans indicated for "failure  
177 to progress" or "failed induction".

178 First, we evaluated the parity and TVUS cervical length to predict the induction-  
179 delivery interval. Cutoff values for cervical length were obtained from the ROC  
180 curve (Figure 2). The AUC of the ROC curve was 0.65 for predicting induction-  
181 delivery interval based on functional cervical length. We found no difference  
182 between a Bishop score of 4, 5, or 6 and the induction-delivery interval  
183 (P=0.119). This result confirms the homogeneity of the study population. A  
184 cervical length less than 25 mm at induction was associated with a shorter  
185 induction-delivery interval (Log rank test, P<0.001) (Figure 3). We evaluated  
186 some others ultrasonographic measurements such as width and dilatation of  
187 internal os. Multiparity was also associated with a shorter induction-delivery  
188 interval (Figure 4).

189 Second, we evaluated the induction-delivery interval in a multivariable  
190 regression model, taking cesarean delivery into account as a competing risk,  
191 adjusted for TVUS cervical length, funnel width, parity, maternal age,  
192 gestational age at induction, BMI and indication for induction (PPROM versus

193 other indications). The cervical length and funnel width as measured by  
194 ultrasonographically, parity and induction for PPROM were the factors that were  
195 significant predictors of the induction-delivery interval (respectively, HR=1.32,  
196 95% CI 1.03–1.69, P=0.03; 1.02 [1.01;1.04] p=0.01; HR=1.50, 95% CI 1.27–  
197 1.77, P<0.01; 2.02 [1.43;2.86] p<0.01) (Table 3).

198

### 199 **COMMENT**

200 Our results showed that measuring cervical length by ultrasound before  
201 induction improved the prediction of the induction-delivery interval in a large  
202 prospective cohort of women at term with a Bishop score of 4–6. The cervical  
203 length cutoff associated with a shorter induction-delivery interval was 25 mm.  
204 Funnel length was also associated with a reduced delay. Multiparity and  
205 PPROM were also predictive of a shorter induction-delivery interval.

206 These results are consistent with data from the literature, which find a  
207 significant association between the ultrasonographic measurement of the cervix  
208 and the induction-delivery interval, or the success of labor induction (6–12).  
209 Other studies, however, have not found that cervical ultrasound is more useful  
210 than the Bishop score for predicting time to delivery (13–17). Conflicting data  
211 from the literature can be explained by numerous biases in the studies.

212 First, the numbers included are generally small. Among the seven studies that  
213 calculated the required sample size and included more than 100 women, three  
214 showed that the Bishop score was more useful than TVUS. The main outcome  
215 criteria differed and were difficult to compare. Few studies considered the  
216 Bishop score (which was not initially created to predict issues of induction) as

217 an inclusion criterion, as we did. In addition, the populations are heterogeneous  
218 for gestational age, parity, and method of induction. All of this could lead to an  
219 underestimation of the value of TVUS in decisions about labor induction.

220 A meta-analysis including two small randomized controlled trials of 234 women  
221 that compared the Bishop score and TVUS for assessing preinduction cervical  
222 ripening (20) did not demonstrate that either method was superior to the other  
223 for determining the induction-delivery interval. In the first trial, this interval was  
224 11.2 hours (IQR 7.8 to 15.9) for the Bishop score arm versus 9.5 hours (IQR 5.6  
225 to 14.7) in the TVUS arm (21). In the second randomized controlled trial, the  
226 median induction-delivery interval reported was 10.3 hours (95% CI 7.0–13.5) in  
227 the Bishop score group, and 10.9 hours (95% CI 9.4–12.3) in the TVUS group  
228 (22). These differences were not significant. The median interval in the two  
229 randomized controlled trials was half of our interval (i.e., a mean induction-  
230 delivery interval of 20.5 hours (SD 10.6)), likely explained by the heterogeneous  
231 populations in those trials; 20% of the women had a Bishop score greater than  
232 6. Our study included only women with a Bishop score of 4, 5, or 6; they were  
233 both nulliparous and parous, and received prostaglandins for no more than 24  
234 hours before oxytocin infusion.

235 On the other hand, these two trials reported that cervical length cutoff values of  
236 30 mm (21) and 28 mm by TVUS could reduce the need for intracervical  
237 prostaglandin treatment by 35% and 50% respectively, without affecting the  
238 success rate for induction. Thus, TVUS might change practices by identifying  
239 women who despite an intermediate cervix can undergo oxytocin administration  
240 to avoid unnecessary exposure to cervical ripening by prostaglandins. That is

241 the reason why the trial was designed to evaluate the delay and none the  
242 success of the delivery as a primary outcome. In our population, the cutoff to  
243 predict a shorter induction-delivery interval was 25 mm. Our results were  
244 consistent those of with other studies: Gabriel et al. found that women with an  
245 unfavorable Bishop score had a shorter duration of labor when their cervical  
246 length was less than 26 mm (8). A cutoff value at 28 or 30 mm may more  
247 precisely define a Bishop score less than 4 (21,22). The transvaginal cervical  
248 length measurement may be superior to the Bishop score in evaluating the  
249 ripened cervix. Several parameters TVUS could thus be useful supplementary  
250 information for obstetricians to evaluate the benefit of cervical ripening.

251 One strength of this study is its homogeneous population, defined by an  
252 inclusion criterion based on the Bishop score, intended to limit selection bias.  
253 Another is the standardization of the induction protocol for all women, and the  
254 large size of the cohort. The study's principal limitation is its observational  
255 nature. The cutoff value of sonographically measured cervical length to  
256 determine the value of cervical ripening must be validated.

257

## 258 **CONCLUSION**

259 A cervical length cutoff of 25 mm may help clinicians to predict the induction-  
260 delivery interval in women with an unripe cervix. We postulate that knowledge of  
261 this interval is a useful tool for clinicians to allow them to adapt management to  
262 the degree of urgency in obstetric care and to economic considerations. Further  
263 studies are needed to assess whether cervical ripening is necessary in this  
264 population.

265 **Conflicts of interest**

266 None

267

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270 Hospitalier de Recherche Clinique Interrégional 2009).

271

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275

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352

353

354

355

### 356 **Legends of figures and tables**

357 Figure 1: Flow chart of the study

358 Figure 2: ROC curve of cervical length as a function of induction-delivery  
359 interval (< or >24h).

360 Figure 3: Kaplan-Meier survival curves of induction-delivery interval according  
361 to TVUS cervical length measurement before induction. The solid line  
362 represents a cervical length < 25 mm. The dotted line represents a cervical  
363 length ≥ 25 mm. Log rank test  $p < 0.01$ .

364 Figure 4: Kaplan-Meier survival curves of induction-delivery interval according  
365 to TVUS cervical length measurement before induction. The solid line  
366 represents nulliparous women. The dotted line represents parous women. Log  
367 rank test  $p < 0.01$ .

368

369

370 Table 1: Characteristics of 334 women analyzed.

371 Table 2: Clinical cervical length in comparison to the cervical length measured  
372 by transvaginal ultrasound without and with uterus pressure.

373 Table 3: Evaluation of induction-delivery interval in multivariable regression  
374 model taking cesarean delivery into account as a competing risk, adjusted for  
375 Bishop score, ultrasound cervical length, and parity

376

**n = 342**  
women included

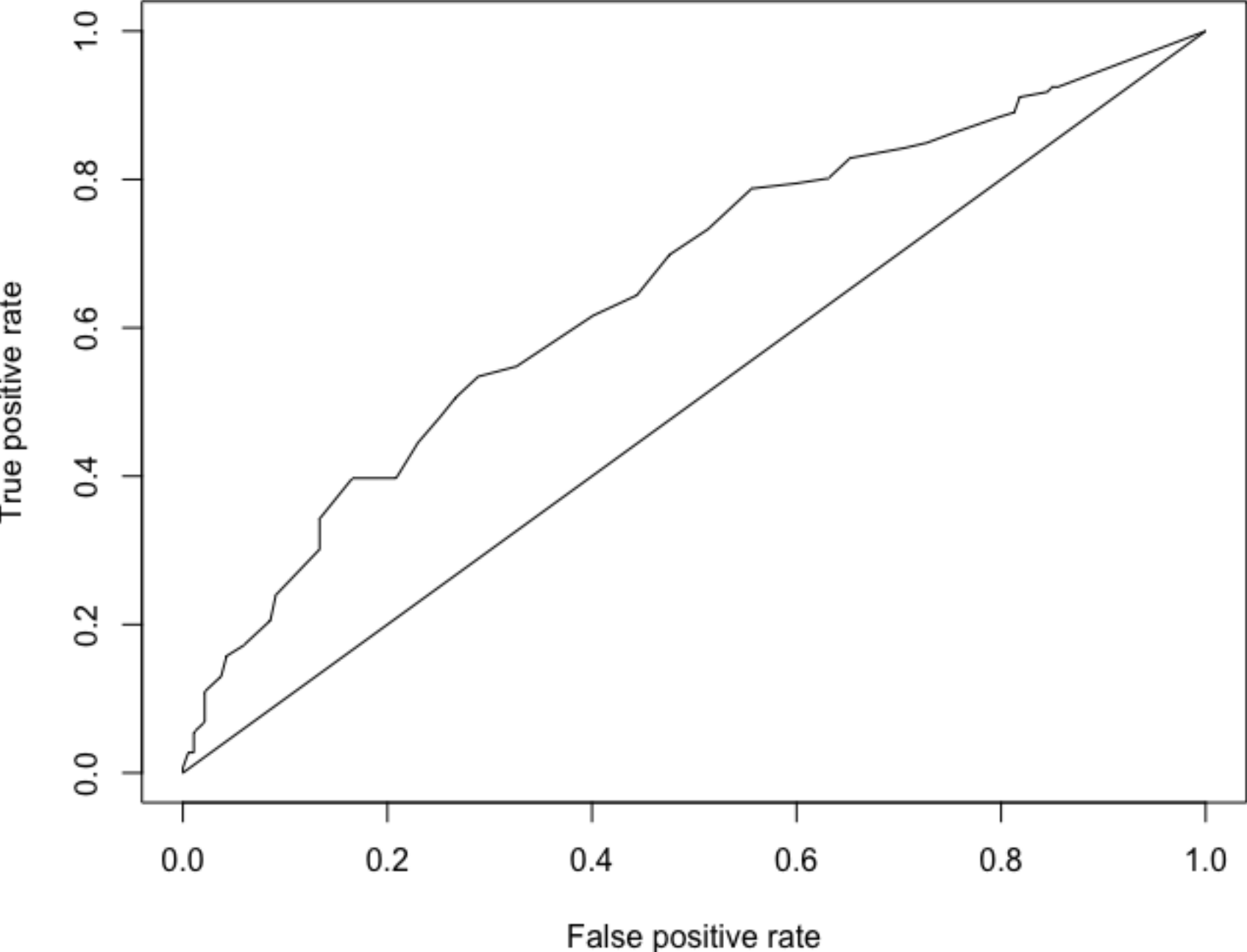
**n = 7** wrongly included

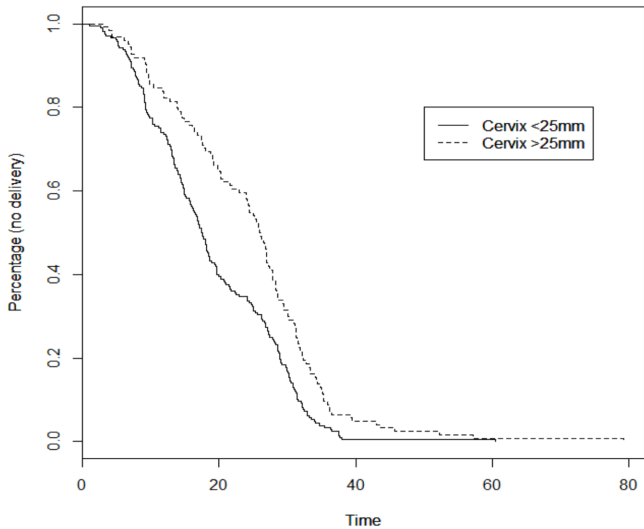
- Bishop score < 4 (*n* = 3)
- Parity > 3 (*n* = 1)
- Uterine surgery (*n* = 1)
- Cervical stitch (cerclage) (*n* = 1)
- Fetal abnormality (*n* = 1)

**n = 1** secondary refusal of ultrasonographic examination

**n = 334** women with ultrasonographic  
measurement of cervical length and  
dinoprostone induction of labor

**Cervical length as a function of induction-delivery interval (< or >24h)**





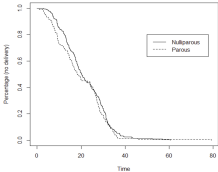


Table 1: Means prenatal characteristics of 334 women analyzed.

	Women (n=334)
Age (years)	29.0 ( $\pm$ 5.5)
Gestation at delivery (weeks' gestation)	40.1 ( $\pm$ 1.5)
BMI	25.5 ( $\pm$ 6.3)
<b>BMI &gt;30</b>	<b>37 (11.1)</b>
<b>BMI &gt;35</b>	<b>29 (8.7)</b>
Weight gain (kg)	13.7 ( $\pm$ 5.6)
Parity	
Nulliparous	203 (60.8)
Parous	131 (39.2)
Indication for induction of labor	
Prolonged pregnancy	87 (26)
Premature rupture of membranes	69 (20.6)
Gestational diabetes mellitus	44 (13.2)
Oligoamnios	37 (11)
Polyhydramnios	7 (2.1)
Decreased fetal movement activity	19 (5.6)
Maternal indication*	26 (7.8)
Fetal indication**	13 (3.9)
Hypertensive disease in pregnancy, preeclampsia, or IUGR	33 (9.9)
Bishop score	
4	133 (39.8)
5	146 (43.7)
6	55 (16.5)
Mode of delivery	
Spontaneous vaginal delivery	220 (65.9)
Instrumental delivery	59 (17.7)
Cesarean delivery	55 (16.5)
<b>Ultrasonography</b>	
<b>Functional cervical length</b>	<b>20.4 (<math>\pm</math> 12.3)</b>
<b>Funnel length</b>	<b>4.7 (<math>\pm</math> 7.5)</b>

**Table 2:** Clinical cervical length in comparison to the cervical length measured by transvaginal ultrasound without and with uterus pressure.

Bishop score	Cervical length measurement (in mm), without uterus pressure	Cervical length measurement (in mm), with uterus pressure
Long	32 ( $\pm$ 8.5) [20-52]	30.9 ( $\pm$ 8.8) [21-53]
Half-long	29.3 ( $\pm$ 8.7) [9-54]	26.7 ( $\pm$ 8.5) [7-52]
short	23.3 ( $\pm$ 8.1) [8-45]	21.1 ( $\pm$ 7.6) [7-41]
Wipe out	19.5 ( $\pm$ 4.9) [14-25]	17.5 ( $\pm$ 3.1) [13-20]

*Mean  $\pm$  standard-deviation [min-max]*

Table 3: Evaluation of induction-delivery interval in multivariable regression model taking cesarean delivery into account as a competing risk, **adjusted for ultrasound measurement of cervical length and funnel width, and clinical characteristics that have been identified as potentially modifying the time to delivery.**

<i>Outcome</i>	<i>induction-delivery interval HR (95% IC)</i>	<b>P value</b>
Functional cervical length	1.32 [1.03;1.69]	<b>0.03</b>
Funnel length	1.02 [1.01;1.04]	<b>0.01</b>
Parity	1.50 [1.27;1.77]	<b>&lt;0.01</b>
Maternal age	0.98 [0.96;1.01]	0.35
Gestational age at induction	1.05 [0.96;1.14]	0.25
BMI	0.98 [0.96;1]	0.14
Indication for induction PPROM or other	2.02 [1.43;2.86]	<b>&lt;0.01</b>