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Prediction of an effective cervical ripenning in the induction of labour using vaginal dinoprostone

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To develop a predictive model for successful cervical ripening in women that undergo induction of labour by means of a vaginal prostaglandin slow-release delivery system (Propess®). Prospective observational study on 204 women that required induction of labour between February 2019 and May 2020 at "La Mancha Centro" hospital in Alcázar de San Juan, Spain. The main variable studied was effective cervical ripening (Bishop score > 6). Using multivariate analysis and binary logistic regression, we created three initial predictive models (model A: Bishop Score + Ultrasound cervical length + clinical variables (estimated fetal weight, premature rupture of membranes and body mass index)); model B: Ultrasound cervical lenght + clinical variables; and model C: Bishop score + clinical variables) to predict effective cervical ripening. All three predictive models obtained (A, B and C) presented good predictive capabilities, with an area under the ROC curve ≥ 0.76. Predictive model C, composed of the variables: gestational age (OR 1.55, 95% CI 1.18–2.03, *p* = 0.002), premature rupture of membranes (OR 3.21 95% CI 1.34–7.70, *p* = 0.09) body mass index (OR 0.93, 95% CI 0.87–0.98, *p* = 0.012), estimated fetal weight (OR 0.99, 95% CI 0.99–1.00, *p* = 0.068) and Bishop score (OR 1.49 95% CI 1.18–1.81, *p* = 0.001), is presented as the model of choice with an area under the ROC curve of 0.76 (95% CI 0.70–0.83, *p* < 0.001). A predictive model composed of the variables: gestational age, premature rupture of membranes, body mass index, estimated fetal weight and Bishop score upon admission presents good capabilities in predicting successful cervical ripening following administration of prostaglandins. This tool could be useful in making clinical decisions with regard to induction of labour.

Cervical ripening is required in patients who present unfavourable cervical conditions prior to undergoing induction of labour (IoL), with the aim of increasing the probability of vaginal birth and reducing induction time[1]. This process can be done using pharmacological methods, such as the use of prostaglandins, or mechanical methods, such as insertion of balloon catheters[2].

So far, no cervical ripening method has been demonstrated to be clearly superior to another in terms of cervical ripening, labour induction or reducing the risk of caesarean[1–3]. In the meta-analysis published by Chen W et al.[2] in 2016, the use of vaginal misoprostol was demonstrated to be the most effective method for achieving vaginal birth in 24 h, in comparison with the use of vaginal dinoprostone or balloon catheters, and was associated with a lower rate of caesareans in IoL. However, this method presented a higher rate of uterine hyperstimulation with changes in fetal heart rate in comparison to other methods.

The use of vaginal dinoprostone (PGE2) is one of the most commonly used methods to achieve cervical ripening[4]. Many studies have been published in relation to its use, but few have aimed to determine which factors predict successful cervical ripening when dinoprostone is administered by means of the vaginal delivery system Propess® (Ferring Pharmaceutical, Saint-Prex, Switzerland)[5–7]. Additionally, there is high heterogeneity in these studies' final results, as no specific distinction is made between the cervical ripening process and induction

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of labour, and different definitions of successful induction of labour are used[8,9], making it difficult to compare results and draw definitive conclusions.

Knowing the factors associated with the cervical ripening process will allow us to improve success rates in this procedure and select the right pre-induction method for each patient. The objective of this study is therefore to create a model to predict which patients that undergo induction of labour will present successful cervical ripening, defined as a Bishop score (BS) > 6, through use of the vaginal prostaglandin delivery system (Propess®), independently of the final birth outcome.

Methods

Design and selection of subjects. We conducted a prospective observational study. A total of 223 women took part in the study between February 2019 and May 2020 at "La Mancha Centro" hospital in Alcázar de San Juan, Spain. Before collecting the data, we obtained written informed consent from the patients and approval from the hospital's clinical research ethics committee (CEIC), with protocol number 102-C. This study follows the principles of the Hensilki declaration.

The study included all women with single-gestation pregnancy that required IoL with cervical ripening through use of 10 mg vaginal prostaglandin (Propess®). Single-gestation pregnancies between weeks 34 and 41 with unfavourable cervix were included in this study. Multiple births, non-cephalic presentation, fetal malformations and inductions due to antepartum fetal death were excluded for ethical reasons. Cases in which the medication was removed due to changes in fetal heart rate during the cardiotocography (CTG) or in which there was secondary uterine hyperstimulation were also excluded from the study.

Procedure. Induction of labour in patients with an unfavourable cervix (Bishop ≤ 6) is done following the medical indications described by the Spanish Society of Obstetrics and Gynaecology (SEGO)[10], which involves placing the slow-release delivery system (Propess®) in the posterior vaginal fornix. The device contains 10 mg prostaglandin, which is released at a rate of 0.3 mg/h in 24 h. Once the device has been placed, CTG is performed on the patient over a period of 2 h. If, after insertion, fetal heart rate falls into categories II or III (according to the system proposed by the National Institute of Child Health and Human Development—NICHD[11]) or a uterine tachysystole is observed (defined as more than five contractions in 10 min), the device is removed immediately. If no changes occur, a CTG is performed at 12 h and at 24 h and the device is removed either when the patient achieves favourable cervical ripening (Bishop > 6) and dilation of 3–4 cm with regular uterine contractions; or after 24 h, regardless of Bishop score. After the cervical ripening process, in cases in which it is required, induction of labour continues with intravenous administration of oxytocin in order to regulate uterine dynamics and move forward in the labour process. Artificial rupture of membranes is performed in women with intact membranes and who, after 24 h of cervical ripening, have not started the active phase of labor, if technically possible.

Information sources and study variables. To collect the information, a specific record was created including variables from the digitised hospital medical histories, additional information obtained from personal interviews, and clinical assessments in the form of the Bishop score and cervical length measured by ultrasound. The independent variables were sociodemographic, obstetric and neonatal in nature (Table 1). The main variable result was effective cervical ripening (BS > 6) obtained following application of vaginal dinoprostone, regardless of the final outcome of the birth (spontaneous, instrumental or caesarean). The Bishop score prior to IoL (BS) and the cervical length (CL) measured by ultrasound were collected by the gynaecologist in charge of the delivery room on the day of the IoL. To measure CL, the guidelines proposed by the International Society of Ultrasound in Obstetrics and Gynecology (ISUOG)[12] and the Fetal Medicine Foundation (FMF) were followed[13].

Statistical analysis. Firstly, descriptive analysis was conducted with absolute and relative frequencies for categorical variables and mean with standard deviation (SD) for the quantitative variables.

We then conducted bivariate analysis with all potential variables associated with cervical ripening (Table 2) and we pre-selected those with a P value < 0.25 (Lemeshow test[14]), using either the Pearson chi-squared or the Student-Fisher t-test, depending on whether the independent variable was qualitative or quantitative. The next step was to perform multivariate analysis through binary logistic regression using the backward stepwise method in SPSS (Stadistical Package for the Social Sciences) to create three predictive models (Table 3), in which odds ratios (OR) were obtained with respective confidence intervals of 95% (CI).

Model (A) was composed of pre-selected variables plus BS and CL, model (B) was composed of pre-selected variables plus CL, and model (C) was made up of pre-selected variables plus BS.

The reason that we initially created three predictive models was to be able to compare their predictive capability and to identify which variable is a better predictor of response to cervical ripening with dinoprostone: Bishop score, cervical length, or a combination of both.

The predictive capability was determined using the area under the ROC curve, with respective confidence intervals of 95%. The final model was selected based on three criteria: clinical plausibility, predictive capability, and principle of parsimony (least number of variables). All calculations were done using the program SPSS v24.0.

Ethical approval. Ethical approval for this study was granted in February 2019 by the hospital's clinical research ethics committee (CEIC) in Ciudad Real (Spain), with protocol number 102-C.

Informed consent. Written informed consent was obtained from all women included in the study before collecting the data.

Variable	N (%)	Mean (SD)
Maternal age		32.8 (5.03)
≤ 35 years	140 (68.6)	
> 35	64 (31.4)	
Weeks of gestation		
< 37	6 (3)	
37–41	147 (72.6)	
≥ 41	50 (24.5)	
Nationality		
Spanish	171 (83.8)	
Other	33 (16.2)	
Body mass index (BMI)		24.97 (4.67)
Number of previous pregnancies		
1	96 (47.1)	
2	56 (27.5)	
≥ 3	52 (25.6)	
Number of vaginal births		
None	131 (64.2)	
1	53 (26)	
2	15 (7.4)	
≥ 3	5 (2.5)	
Previous caesarean		
Yes	23 (11.3)	
No	180 (88.2)	
Missing values	1	
Reason for previous caesarean		
Failure to progress (FTP)	5 (2.5)	
Failed Induction (FI)	3 (1.5)	
Cephalopelvic disproportion (CPD)	4 (2)	
Non-reassuring fetal heart rate (NRFHR)	6 (2.9)	
Podalic presentation	2 (1)	
Maternal illness	2 (1)	
Fetal sex		
Male	108 (52.9)	
Female	96 (47.1)	
Diabetes		
No	186 (91.2)	
Pregestational	3 (1.5)	
Gestational insulin dependent	13 (6.4)	
Gestational non-insulin dependent	2 (1)	
Intrauterine growth restriction (IUGR)		
No	193 (94.6)	
Yes	11 (5.4)	
Hypothyroidism		
No	174 (85.3)	
Pregestational	16 (7.8)	
Gestational	14 (6.9)	
Hypertensive states in pregnancy		
No	188 (92.2)	
Chronic HTN	4 (2)	
Gestational HTN	8 (3.9)	
Pre-eclampsia	4 (2)	
Prepartum estimated fetal weight (EFW)		3179.87 (621.76)
Prepartum amniotic fluid index (AFI)		
< 5	24 (11.8)	
5—25	165 (81.3)	
> 25	14 (6.9)	
Continued		

Variable	N (%)	Mean (SD)
Cervical length prior to induction (CL)		24.48 (9.14)
Funnelling		
Yes	21 (10.3)	
No	183 (89.7)	
Bishop score upon admission		2.78 (1.37)
0–1	46 (8.8)	
2–4	140 (68.6)	
5–≤ 6	28 (8.9)	
Reason for induction		
Post-term pregnancy	67 (32.8)	
Premature rupture of membranes (PROM)	39 (19.1)	
Gestational diabetes	15 (7.4)	
Maternal illness	11 (5.4)	
Hypertensive states in pregnancy	20 (9.8)	
Hydramnios	14 (6.9)	
Oligohydramnios	12 (5.9)	
Intrauterine growth restriction (IUGR)	14 (6.9)	
Non-reassuring status	1 (0.5)	
Macrosomia	1 (0.5)	
SGA	10 (4.9)	
Bishop score in dilation		6.28 (1.89)
Duration of dilation		288.80 (231.34)
Duration of second stage		83.28 (81.03)
Type of birth		
Spontaneous	113 (55.4)	
Vacuum	17 (8.3)	
Spatula	11 85.4)	
Forceps	6 (2.9)	
Caesarean	57 (27.9)	
Indication for instrumental delivery		
Shorten second stage	21 (61.76)	
Non-reassuring fetal heart rate (NRFHR)	9 (26.47)	
Maternal illness	1 (2.94)	
Inadequate progress	3 (8.82)	
Indication for caesarean		
Failure to progress (FTP)	20 (12)	
Failed induction (FI)	9 (5.4)	
Cephalopelvic disproportion (CPD)	7 (4.2)	
Non-reassuring fetal heart rate (NRFHR)	20 (12)	
Weight of newborn		3201.68 (504.7)
APGAR 1 minute		
>7	189 (92.6)	
<7	15(7.4)	
APGAR 5 minutes		
>7	202 (99)	
<7	2 (1)	
Level of resuscitation		
No resuscitation	161 (68.9)	
Type I	38 (18.6)	
Type II	1 (0.5)	
Type III	4 (2)	
Arterial PH		7.27 (0.06)
Venous pH		7.32 (0.05)

Table 1. Sociodemographic and obstetric variables studied.

Variable	Cervical ripening			
	Bishop score ≤ 6	Score bishop > 6	OR CI	*P* value
Maternal Age	33.5 (5.10)	32.6 (5.24)	0.97 (0.92–1.02)	0.239
Weeks of gestation	39.3 (1.47)	39.7 (1.32)	**1.24 (1.01–1.52)**	**0.037**
Body mass index (BMI)	27.0 (5.39)	24.7 (5.14)	**0.91 (0.86- 0.96)**	**0.001**
Parity				0.378
Primiparous	71 (54.2)	60 (45.8)	1	
Secundiparous	28 (52.8)	25 (47.2)	1.06 (0.56–2.00)	0.866
Terciparous or more	14 (70.0)	6 (30.0)	0.51 (0.18–1.40)	0.190
Previous caesarean				0.330
No	98 (54.4)	82 (45.6)	1	
Yes	15 (65.2)	8 (34.8)	0.64 (0.26–1.58)	
Fertility treatment				
None	102 (54.5)	85 (45.5)	1	
Insemination	1 (100.0)	0 (0.0)	NC	1.000
In vitro fertilisation	9 (64.3)	5 (35.7)	0.68 (0.22–2.07)	0.482
Fetal sex				**0.028**
Female	61 (63.5)	35 (36.5)	1	
Male	52 (48.1)	56 (51.9)	**1.88 (1.07–3.29)**	
Diabetes				0.055
No	99 (53.2)	87 (46.8)	1	**0.045**
Yes	14 (77.8)	4 (22.2)	0.33 (0.10–1.03)	
Intrauterine growth restriction (IUGR)				
Yes	7 (63.6)	4 (36.4)	1	
No	106 (54.9)	87 (45.1)	0.70 (0.20–2.46)	
Hypothyroidism				0.879
No	96 (55.2)	78 (44.8)	1	
Yes	17 (56.7)	13 (43.3)	0.94 (0.43–2.06)	
Hypertensive states in pregnancy				0.111
No	101 (53.7)	87 (46.3)	1	
Yes	12 (75.0)	4 (25.0)	0.39 (0.12–1.24)	
Prepartum estimated fetal weight (EFW)	3245.2 (57.73)	3187.8 (45.38)	1.00 (0.99–1.00)	0.470
Cervical length (CL) before induction	28.79 (9.57)	23.59 (9.02)	0.93 (0.90–0.96)	**< 0.001**
Funnelling				0.865
No	101 (55.2)	82 (44.8)	1	
Yes	12 (57.1)	9 (42.9)	1.08 (0.44–2.70	
Prepartum amniotic fluid index (AFI)				
< 5	13 (54.2)	11 (45.8)	1	
≥ 5—25	90 (54.5)	75 (45.5)	1.02 (.43–2.40)	0.972
> 25	10 (71.4)	4 (28.6)	0.48 (0.15–1.59)	0.230
Bishop score upon admission	2.16 (1.41)	3.04 (1.35)	1.58 (1.28—1.96)	**< 0.001**
Premature rupture of membranes (PROM)				**0.001**
No	101 (61.2)	64 (38.8)	1	
Yes	12 (30.8)	27 (69.2)	**3.55 (1.68—7.50)**	
Hours between rupture of membranes and induction	7.6 (6.00)	13.3 (18.16)	1.05 (0.95–1.16)	0.164
Time with Propess*	14.5 (7.27)	9.3 (5.31)	**0.88 (0.84- 0.93)**	**< 0.001**

Table 2. Bivariate analysis of the obstetric characteristics and effective cervical ripening. Significant values are in [bold].

Results

The total number of patients attended to during the period of study was 1061. Of the 223 inductions, 204 (91.47%) met the inclusion criteria, while 19 (8.52%) women were excluded from the study. Following insertion of the PROPESS, 91 (44.6%) patients achieved successful cervical ripening, while 113 (55.4%) presented a Bishop score < 6. The patient selection process is shown in Fig. 1.

Table 1 contains all of the obstetric and socioeconomic variables analysed. The main reason for induction was post-term pregnancy (67, 32.8%) followed by premature rupture of membranes (PROM) (39, 19.1%) and

Variables	Coef B	aOR IC95%	*P* value	ROC– AUC
Model A				
Gestational age	0.463	1.58 (1.20–2.09)	0.001	0.77 (0.71–0.84)
PROM	1.080	2.95 (1.21–7.15)	0.017	
BMI	−0.066	0.93 (0.88–0.99)	0.035	
Estimated fetal weight	−0.001	0.99 (0.99–1.00)	0.044	
Bishop score upon admission	0.296	1.34 (1.04–1.73)	0.023	
Cervical length (TVS)	−0.042	0.95 (0.92–0.99)	0.036	
Model B				
Gestational age	0.475	1.61 (1.22–2.11)	0.001	0.76 (0.69–0.82)
PROM	1.269	3.56 (1.50–8.41)	0.004	
BMI	−0.058	0.94 (0.88–1.00)	0.060	
Estimated fetal weight	−0.001	0.99 (0.99–1.00)	0.035	
Cervical length (TVS)	−0.060	0.94 (0.91–0.97)	0.001	
Model C				
Gestational age	0.437	1.55 (1.18–2.03)	0.002	0.76 (0.70–0.83)
PROM	1.168	3.21 (1.34–7.70)	0.009	
BMI	−0.078	0.93 (0.87–0.98)	0.012	
Estimated fetal weight	−0.001	0.99 (0.99–1.00)	0.068	
Bishop score upon admission	0.404	1.49 (1.18–1.81)	0.001	

Table 3. Predictive models for cervical ripening. Multivariable analysis.

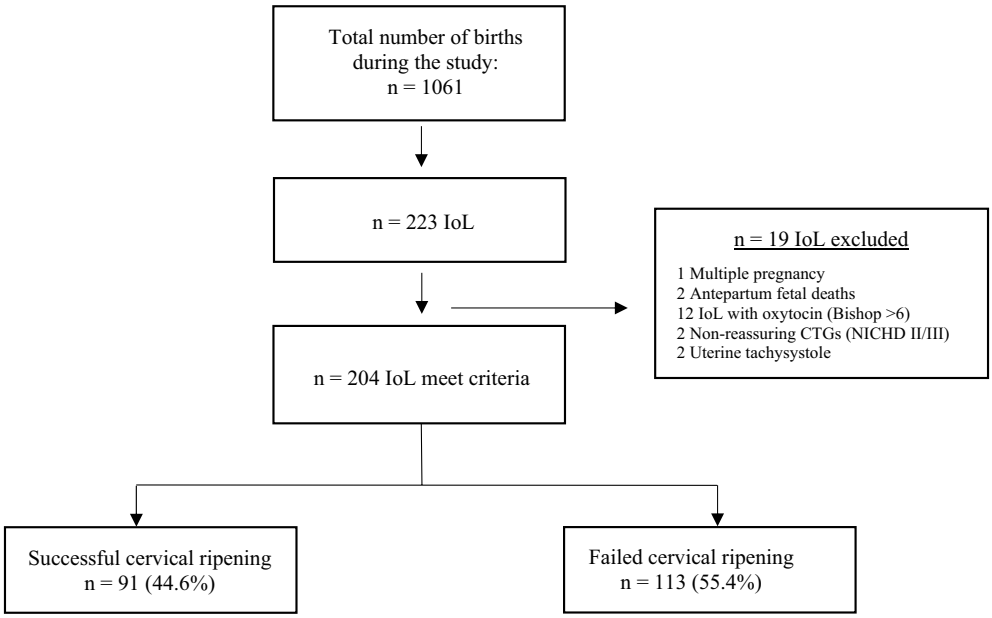

Figure 1. Flow chart of patient selection process.

diabetes (15, 7.4%). The mean Bishop score (BS) was 2.78 (SD = 1.37) and the mean cervical length (CL) measured by ultrasound prior to IoL was 24.48 mm (SD = 9.14).

Next, the relationship between effective cervical ripening and the independent variables was studied by means of bivariate analysis, observing statistical relationships with gestational age ($p = 0.037$), body mass index (BMI) ($p = 0.001$), fetal sex ($p = 0.028$), CL measured by ultrasound prior to IoL ($p < 0.001$), BS upon admission ($p = 0.001$), PROM ($p = 0.001$) and time with Propess® ($p < 0.001$). Table 2 shows the bivariate analysis.

Finally, the multivariate analysis was conducted, obtaining three initial predictive models (Table 3) composed of the following variables: gestational age, premature rupture of membranes (PROM), body mass index (BMI), Estimated fetal weight (EFW), Bishop score (BS) upon admission and cervical lenght (CL) measured by ultrasound.

Model A presented an area under the ROC curve of 0.77 (95% CI 0.71–0.84, $p < 0.001$). Model B presented a ROC-AUC of 0.76 (95% CI 0.69–0.82, $p < 0.001$). Model C also presented a ROC-AUC of 0.76 (95% CI 0.70–0.83,

$p < 0.001$). All three models presented good predictive capabilities, with an area under the ROC curve ≥ 0.76. Figure 2 shows the ROC curves for each model and compares them.

Predictive model C was chosen based on the criteria of clinical plausibility, predictive capability, and parsimony. It was composed of the variables: gestational age (odds ratio [OR]1.55, 95% confidence interval [CI] 1.18–2.03, $p = 0.002$), premature rupture of membranes (PROM) (OR 3.21 95% CI 1.34–7.70, $p = 0.09$) body mass index (BMI) (OR 0.93, 95% CI 0.87–0.98, $p = 0.012$), estimated fetal weight (EFW) (OR 0.99, 95% CI 0.99–1.00, $p = 0.068$) and BS (OR 1.49 95% CI 1.18–1.81, $p = 0.001$).

Discussion

The variables associated with successful cervical ripening (Bishop score > 6) were: gestational age, PROM and Bishop score upon admission. These results coincide with those reported in the literature in relation to the labour induction process overall[15]. Obesity and estimated fetal weight (EFW), factors widely known to be predictors of failure in IoL[8,16], were also risk factors for failure in cervical ripening. In contrast, estimated fetal weight (EFW) is not reported to be a predictor of cervical ripening failure in studies conducted by Daykan[6] and Hiersch[5].

We did not find any association between successful cervical ripening and maternal age, parity, reason for induction, number of hours between rupture of membranes and placement of vaginal dinoprostone, or neonatal factors.

We only identified two studies in the literature that present models that predict success in the cervical ripening process with vaginal dinoprostone slow-release devices. Hiersch et al.[5] presented an initial predictive model composed of parity, cervical dilation at admission and gestational age, with a ROC-AUC of 0.79 (95% CI 0.74–0.84) and a second, more complex, model composed of maternal age, BMI, parity, cervical dilation, effacement, indication for induction, gestational age and neonatal weight, with a ROC-AUC of 0.80 (95% CI 0.75–0.85). Melamed et al.[7] identified maternal age > 30 years, nulliparity, BMI ≥ 25, cervical dilation < 1 cm, effacement ≤ 50% and gestational age > 37 weeks as predictors of failure of cervical ripening, and created a logistic regression model that can predict ≈50% of all cases of failed ripening ($R^2 = O.47$).

However, we agree with the conclusions of Melamed et al.[7] and must be cautious when interpreting results reported in the literature. Most studies analyse successful induction of labour, defined as vaginal birth within 24 h[8,9,17], as the final result, without distinguishing induction from the prior cervical ripening process, so it is not possible to correctly evaluate cervical response to the action of vaginal dinoprostone without this result being affected by additional intrapartum factors.

With regard to the cervical ripening process, we must clarify that there is no universally accepted threshold score to define a favourable or unfavourable cervix that tells us how to begin an induction. High Bishop scores have traditionally been associated with higher vaginal birth success rates[18,19]. However, there are studies that question the reliability of Bishop scores in predicting the final birth outcome[20]. In our study, we considered the cervical ripening process to be successful after obtaining a BS > 6 with administration of vaginal dinoprostone, basing ourselves on the results obtained in the majority of randomised studies and in clinical guidelines for induction of labour[21,22].

As for the selection of the most adequate predictive model, many studies have compared the predictive capability of cervical length (CL) measured by ultrasound versus Bishop score on induction of labour outcomes, with conflicting results[23–26]. A systematic review conducted by Cochrane in 2015[27] did not find significant differences between both methods (CL vs BS) in terms of rates of vaginal births, caesareans and admission into NICU, and concluded that there is not enough evidence to recommend the use of CL over the standard digital examination in assessing cervical ripening.

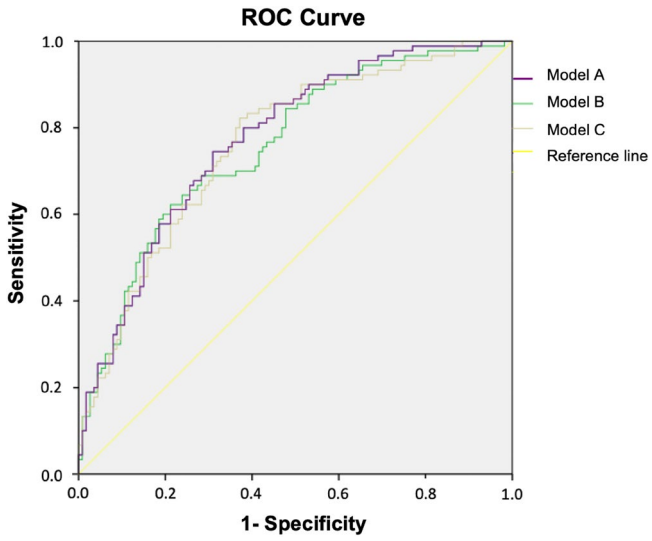

Figure 2. ROC curves for predictive models A, B and C.

As well as cervical length (CL) measured by ultrasound, fetal fibronectin has also been studied in assessing cervical ripening, but it has not been found to be superior to the Bishop score[15]. Considering the evidence from the published data and the ease of reproducing it, model C, in which the only added variable was the Bishop score, was our chosen model.

The main limitations of this study are related to the sample size, which is relatively small in comparison to other studies[5,8]. Also, our predictive model is created based on the sociodemographic and obstetric characteristics of a Caucasian/Hispanic population, so it must be validated externally in another type of population before being used.

Additionally, this study only analyses the obstetric and sociodemographic characteristics that have traditionally been associated with success in the labour induction process[15,28]. However, these data must be interpreted with caution, as there is still a certain lack of understanding of the physiological phenomena involved in the onset of labour and cervical ripening, and there is wide biological variation among mothers in the normal labour process[29].

As far as strong points, we can mention its prospective observational design, making the collection of variables more exhaustive and complete. What's more, all patients included in the study are treated based on a homogeneous labour indication protocol with clear indications on the end of the same, reducing possible biases related to its use.

Conclusion

In conclusion, successful cervical ripening through the administration of the vaginal prostaglandin slow-release delivery system (Propess®) can be predicted from specific variables: gestational age, BMI, PROM, EFW and BS upon admission, through the use of this predictive model (C). Including this predictive model in hospital labor induction protocols could help in decision-making regarding the indication of this procedure by using the variables that best predict the success of cervical ripening with this induction method.

Data availability

The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

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Validation, R.H.P. and V.R.-Á.; formal analysis, A.H.-M.; investigation, N.L.-J.; resources, A.P.-P. andM.M.-C.; writing—original draft preparation, N.L.-J. and A.H.-M.; writing—review and editing,A.P.-P. and M.M.-C.; visualization, M.M.-A.; supervision, A.P.-P. and M.M.-C.; project administration,M.M.-A. All authors have read and agreed to the published version of the manuscript.

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Additional information

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