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Predictive model for spontaneous preterm labor among pregnant women with contractions and intact amniotic membranes

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Abstract
Purpose To determine a predictive model for supporting decisions relating to the prognosis for women presenting with preterm labor and intact membranes.
Method We conducted a prospective observational cohort study on 70 pregnant women at between 22 and 34 weeks of gestation. Transvaginal sonographic evaluation on the cervix was performed once on women who had completed a course of parenteral tocolysis. The sonographic parameters of cervical length measurement and presence of cervical glandular area were obtained. The outcome variable was occurrences of preterm delivery (<35 weeks). Using a univariate logistic regression model, the coefficients of each independent variable were first estimated. To construct the predictive model, multivariate logistic regression containing all the selected variables that might be related to preterm delivery was used as the starting point. Accuracy, sensitivity, specificity and predictive values were used to measure associations of predicted probabilities and to check the ability of the model to predict outcomes. The predictive analyses were based on logistic regression models, with calculation of odds ratios and 95 % confidence intervals.
Results The incidence of preterm delivery was 32.80 % (23/70). After validation, the predictive model proposed showed accuracy of 87.88 %, sensitivity of 78.26 % and specificity of 93.02 %.
Conclusion The model presented good accuracy with correspondence between predictions and observations, and has the capacity to become a useful tool for management of pregnant women with preterm labor and intact amniotic membranes.

Keywords Prediction · Preterm delivery · Pregnant women · Transvaginal ultrasound

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Introduction

The prevalence of births before the 37th week of pregnancy has remained unchanged over the last 50 years, even with advances in knowledge of risk factors and mechanisms relating to preterm delivery [1]. The prematurity rate varies between different countries due to population characteristics and the risk factors present. In Europe and other developed countries, it varies from 6 to 10 %. In the United States, the rate rose from 9.5 % in 1981 to 12–13 % in 2005, thus contributing towards one of the highest rates in two decades [1–3]. Preterm delivery is associated with approximately 75 % of the cases of perinatal mortality, 85 % of the main neonatal morbidities and over half of the long-term morbidities [4].

Preterm delivery is diagnosed based on the presence of persistent uterine contractions and cervical modifications (effacement and/or dilatation) evaluated by palpation [5]. However, this method presents poor inter-observer correlation, sensitivity and positive predictive value [3]. It is often hard to establish a direct relationship between

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possible risk factors and spontaneous preterm delivery. The multifactorial nature of preterm delivery, the fact that many preterm births occur among women without clinical risk factors and the lack of any adequate animal model for testing preterm delivery make it impossible to use these predictive factors successfully for delivery prediction [6].

Because of the limitations on evaluation of the uterine cervix by palpation, and because serial exams do not reduce the preterm delivery rate, viewing uterine cervix modification via transvaginal ultrasound has achieved importance over the last few years as an indicator of the risk of spontaneous prematurity, although it is incapable of evaluating the softening, position and distension of the endocervical canal [3, 7, 8]. There is an inverse correlation between the cervical length seen on ultrasound and occurrences of preterm delivery [8]. Among symptomatic women, because of the high negative predictive value, it contributes towards minimizing possible hospitalization [9].

The limit below which the risk of preterm labor becomes significant is still undefined, and it varies between different studies. The criteria that define abnormal results are controversial. Different cutoff points have been found and many criteria have been used to define dilatation of the internal orifice in different studies [8, 10]. According to Berghella et al. [11], there is not enough evidence so far for implementing routine monitoring among symptomatic or asymptomatic women using the cervical length seen on ultrasound. However, although there is no significant association between cervical length seen on ultrasound and low incidence of preterm delivery among symptomatic women, new studies need to be conducted with the aim of defining a protocol for management of these women based on cervical length results obtained from ultrasound, which would be easy to perform and reproduce.

Different cutoffs to the measurement of cervical length has been proposed in the literature as 18 and 30 mm with sensitivity and specificity reaching values between 44 and 97 % and between 68 and 100 %, respectively [8, 10]. The cervical gland area (CGA) corresponds to the sonographic marker of endocervical glands. In a pioneer study, Sekiya et al. [12] obtained detection tax of CGA of 100 % until 27 weeks of gestation, and 93 % between 28 and 31 weeks. The absence of CGA is an important marker to the prediction of preterm delivery in symptomatic pregnant women.

Within this context, the objective of this study was to determine a predictive model based on demographic, obstetric outcome and uterine cervix ultrasonographic data that would be capable of identifying symptomatic women with intact amniotic membranes with higher likelihood of evolving to preterm delivery, and which would serve to support clinical decision-making.

Methods

We conducted a prospective observational cohort study on women undergoing specialized treatment in the Obstetrics Clinic of the Obstetrics and Gynecology Service of the University Hospital of the Federal University of Maranhão (UFMA), from August 2005 to August 2010. This study was approved by the Research Ethics Committee of UFMA and the patients who participated signed a consent statement. This study is in accordance with the Helsinki Declaration of 1975, which was revised in 1983.

Patients admitted to hospital because they presented symptoms and clinical signs of preterm labor, and who met the inclusion criteria, became part of the cohort study after they had completed at least the first cycle of intravenous tocolysis with intravenous terbutaline. The inclusion criteria were: pregnancy with a single live fetus; gestational age between 22 and 34 weeks, confirmed by first-trimester ultrasonography; signs and symptoms of preterm labor (two or more contractions lasting for at least 40 s in 10 min associated with cervix changes). The exclusion criteria were: cervical dilatation $\geq$3.0 cm found through vaginal palpation; delivery occurring within the first 48 h at the hospital; vaginal bleeding; preterm premature membrane rupture; polyhydramnios; fetal malformation; uterine Müllerian anomaly; previous cerclage; clinical chorioamnionitis; or intrauterine growth restriction.

The uterine cervix was evaluated through a single transvaginal ultrasound examination, around 48 h after admission of the patient. In this manner, we sought to intentionally exclude women in advanced preterm labor. The examinations were filed in electronic form for review purposes. They were performed using the Logic 400 Pro and Voluson 730 Pro devices (General Electric Medical Systems, Zipf, Austria). The ultrasound examination on the uterine cervix was performed vaginally, after complete emptying of the bladder. The patient was placed in the gynecological position, in dorsal decubitus, with the legs abducted. The transducer, which was covered with a non-lubricated sterile condom, was inserted slowly and carefully as far as the anterior vaginal fornix and was kept in the external third of the vaginal canal, taking the necessary care not to put pressure on it and thereby stretch it. Using 75 % magnification, a sagittal cross-section through the cervix was obtained, with well-shown endocervical mucosa along the cervical canal, limited by the external and internal orifices. If the internal orifice was found to be closed, the linear length measurement was made from the triangular area of the internal orifice to the V-shaped notch of the external orifice. If the internal orifice was found to be open, with narrowing, the occluded portion was measured such that the apex of the narrowing was taken to be the beginning of the portion that remained closed and the end

was taken to be the external orifice, carefully done so as not to include the vaginal walls. Three measurements were made, without dynamic cervical changes, and the smallest of these length measurements was registered in millimeters. If a dynamic change was noted during the examination, three more measurements were performed after it ended, and the smallest measurement was registered [13, 14]. The endocervical glandular area (defined as an area of solid isoechoic or hypoechoic texture surrounding the endocervical canal) was then observed with the objective of identifying its presence or absence. The duration of the cervical ultrasound examination ranged from 5 to 7 min.

Demographic, socioeconomic and obstetric variables

The demographic data included name, age, skin color and origin. Age was registered in years. The variable "skin color" was chosen instead of "race" because of the difficulty in visually defining the latter in the state of Maranhão, which is characterized by great miscegenation. Maternal schooling was evaluated according to educational level: none; incomplete elementary school and complete elementary school (which corresponds to approximately eight years of formal education); incomplete high school and complete high school (which corresponds to approximately 11–14 years of formal education). To evaluate the family income variable, the number of minimum salaries was used, based on the Brazilian minimum salary at the time of inclusion in the study (between 176.00 and 264.00 US dollars). Time spent working was categorized as the number of hours worked per day (4, 6, 12 or 14 h) and, in the case of housework, whether there was any help. In the clinical evaluation, data relating to the last menstrual period, number of gestations, number of term deliveries, number of preterm deliveries and number of late abortions were registered. Data relating to gestation age at the first ultrasonography of the current pregnancy were also registered.

Uterine cervical variables evaluated using transvaginal ultrasonography

We evaluated the cervical length quantitatively, in mm, and the cervical glandular area as a dichotomous qualitative variable. The length of the uterine cervix was defined as the linear distance between the internal and external orifices. If the opening of the internal orifice was larger than 5.0 mm, the functional cervix length (defined as the distance of the residual occluded portion) was measured without any fundal or suprapubic compression maneuver. The cutoff point for cervical length was taken to be 20 mm, based on a previous study conducted in our clinic [15]. The cervical glandular area was dichotomized as present when it could be viewed, or absent when it could not be viewed.

Outcome variable

The study outcome was gestational age at the time of delivery. Because of the high morbidity observed with gestation ages lower than 35 weeks, and to facilitate comparison with other studies that also used this threshold [10, 16, 17], the outcome was categorized as delivery earlier than a gestational age of 35 weeks and delivery at a gestation age greater than or equal to 35 weeks.

Statistical analysis

For statistical analysis, we used the STATA software, version 10.0 (Stata Corp., College Station, TX, USA), with a significance level of 5 %. Descriptive statistics was performed, presented as frequency tables, with the objective of characterizing the sample studied. Initially, to identify which study factors were associated with preterm labor, we used a univariate logistic regression model [18], in which the variable of interest was defined as follows:

$$y_i = \begin{cases} 1, & \text{occurrence of preterm delivery} \\ 0, & \text{without occurrence of preterm delivery} \end{cases}$$

Let $\pi_i = P(y_i = 1)$, such that $0 < \pi_i < 1$, be the probability that a pregnant woman i will have a preterm delivery. Thus, assuming that the pregnant women are independent, it is natural to model y_i by means of Bernoulli distribution with π_i probability. This way, the probability π_i that the woman i will have a preterm delivery is related to the explanatory variables $x_{i1}, x_{i2}, \ldots, x_{ip}$ through the following logistic model [18]: $\log \frac{\pi_i}{1-\pi_i} = \beta_0 + \beta_1 x_i + \cdots + \beta_p x_p$, where $\beta_0, \beta_1, \ldots, \beta_p$ are unknown parameters that therefore need to be estimated.

Multivariate models were generated such that variables with p values lower than 20 % in the univariate analysis were retained and variables with clinical importance were added. A more liberal significance value was used to select variables for multivariate logistic regression models because it was possible that some predictive variables might be directly related to the outcome through correlations with other variables. Some variables might also present weak associations with the outcome, but combinations of them could have significant predictive power. Many multivariate regression models were developed, thereby hoping to obtain a parsimonious model with good generalization. Once the final multiple logistic regression models had been chosen, the bootstrap technique was used, with 2,000 replications to validate it [19]. For this, the model was adjusted in each bootstrap sample, with the same number of variables. The bootstrap sample was

obtained by randomly resampling n times, with replacement of the observations of the original sample, thereby obtaining 2,000 replications. After model validation, we calculated sensitivity, specificity and accuracy (number of observations that were correctly classified), and also the receiver operating characteristic (ROC) curve, in order to evaluate the area under the ROC curve, which corresponded to the predictive capacity or discriminatory power of the model [19].

Results

Initially, 82 pregnant women presenting persistent uterine contractions and intact amniotic membranes were included, but 12 women were subsequently excluded. Four women did not return to our clinic to have their deliveries; one reported using abortion medication one week after hospitalization; and two had not delivered by the end of the data gathering period. All pregnant women invited to participate of this study agreed and signed a consent statement. Therefore, for the final statistical analysis, 70 pregnant women were taken into consideration. Relative to demographic and socioeconomic characteristics, we observed predominance of women of mixed skin color [49 (70.00 %)]; aged between 20 and 30 years [37 (52.86 %)]; living with a partner [52 (74.29 %)]; with schooling up to high school level [43 (61.43 %)], thus totaling 11–14 years of formal education; and with a precarious economic situation [55 (78.57 %)], with family income of up to two Brazilian minimum salaries.

Relative to obstetric history at the time of hospitalization, we found predominance of women with less than 27 weeks of gestation [50 (71.4 %)], with one or more previous pregnancies [56 (80.0 %)] and without previous preterm delivery history [56 (80.0 %)]. When considering gestational age at birth (preterm or term), we did not observe any significant differences between the clinical characteristics of the groups. Statistical significance was observed in relation to gestational age at the time of delivery, which was already expected because of the outcome.

Tables 1, 2 and 3 show the univariate analysis on the demographic, obstetric and uterine cervix characteristics, respectively. In relation to demographic characteristics, educational level was the independent variable that correlated with preterm delivery with statistical significance: complete elementary school (95 % CI = 0.00–0.96) and complete high school (95 % CI = 0.05–0.94). Gestational age between 31 and 35 weeks, at the time of cervical ultrasonography, showed a significant association with preterm delivery (95 % CI = 0.09–1.44). Among the ultrasound variables, cervical length less than 20.0 mm (95 % CI = 2.39–24.62) and lack of cervical glandular

Table 1 Univariate analysis on demographic characteristics of symptomatic women with intact amniotic membranes

Demographic and socioeconomic characteristics	Delivery <35 weeks		Delivery ≥35 weeks		*p*
	N	%	*N*	%	
Age (years)					
<20	7	30.4	16	69.5	–
20–30	11	29.7	26	70.2	0.95
>30	5	50.0	5	50.0	0.28
Color					
Mixed	17	34.6	32	65.3	–
White	4	30.7	9	69.2	0.79
Black	2	25.0	6	75.0	0.59
Educational level					
None	0	0	0	0	
Incomplete elementary school	1	11.1	8	88.8	–
Complete elementary school	5	22.7	17	77.2	0.04
Incomplete high school	1	25.0	3	75.0	0.27
Complete high school	5	22.7	17	77.2	0.04
Incomplete university-level education	1	25.0	3	75.0	0.27
Family income (minimum salaries)					
<1	7	38.8	11	61.1	–
1–2	12	32.4	25	67.5	0.63
3–4	3	25.0	9	75.0	0.43
≥5	1	33.3	2	66.6	0.85

Table 2 Univariate analysis on the obstetric history of symptomatic women with intact amniotic membranes

Obstetric history	Delivery <35 weeks		Delivery ≥35 weeks		*p*
	N	%	*N*	%	
Number of preterm deliveries					
None	19	33.9	37	66.0	–
1	3	37.5	5	62.5	0.84
2	0	0	4	100.0	
≥3	1	50.0	1	50.0	0.64
Gestational age at the examination (weeks)					
<27	5	45.4	6	54.5	–
27–31	8	50.0	8	50.0	0.81
31–35	10	23.2	33	76.7	0.15
Parity					
Nulliparous	5	35.7	9	64.2	–
One or more deliveries	18	32.1	38	67.8	0.79

Table 3 Univariate analysis on uterine cervix characteristics seen on transvaginal ultrasonography on symptomatic women with intact amniotic membranes

Uterine cervix characteristics	Delivery <35 weeks		Delivery ≥35 weeks		*p*
	N	%	*N*	%	
Cervical length < 20.0 mm					0.001
Present	18	54.5	15	45.4	
Absent	5	13.5	32	86.4	
Cervical glandular area					0.15
Present	9	25.0	27	75.0	
Absent	14	41.1	20	58.8	

area (95 % CI = 0.17–1.31) presented associations with preterm delivery.

Variables with statistical significance in univariate analyses ($p < 0.20$) and variables with clinical and epidemiological relevance were kept in the multivariate logistic model. The final model was defined as the one that included the variables presented in Table 4. The predictive model proposed here presented accuracy of 87.8 %, sensitivity of 78.2 % and specificity of 93.0 %. Its post-test results were 85.7 % for positive predictive value and 88.8 % for negative predictive value. The model was validated using the bootstrap method, which presented diagnostic rates compatible with the evaluated model, with the exception of sensitivity (Table 5). Figure 1 represents the ROC curve of the proposed model, with an area of 0.9050 under the curve, thus showing that the model had good discriminatory power. The area under the ROC curve of the bootstrap model corresponded to the same area in the final multivariate model.

Discussion

In clinical practice, the accuracy of preterm labor diagnosis is only greater at more advanced stages, when tertiary preventive measures do not have the expected effect [20]. On the other hand, some pregnant women with signs and symptoms suggestive of preterm labor will not evolve to delivery [21]. In this context, a multivariate problem takes shape, in which there is a set of independent variables for predicting one dependent variable, i.e. preterm delivery.

In our study, we put forward a predictive model for preterm delivery that was based on socioeconomic and obstetric variables that are easily identifiable during consultations, have low cost and are within obstetricians' routine knowledge. Two ultrasound variables were added, and although these do not have low cost, they are easily accessible because of ultrasound apparatus availability in obstetric clinics. Although the predictive variables of maternal age, skin color, family income, number of previous preterm deliveries and parity did not fulfill the entry criteria for the multivariate model, they were nonetheless included because they are characteristics that are easy to measure at the time of admission of the pregnant women, without imposing any additional burden or problem for the logistic model. Therefore, significant variables in univariate analysis (p value < 0.20) and the variables with epidemiological and clinical relevance remained in multivariate logistic model. We added the epidemiological and clinical variables in the multivariate model; despite the fact these

Table 4 Final multivariate logistic model

Variable	Delivery <35 weeks		Delivery ≥35 weeks		*p*
	N	%	*N*	%	
Age (years)					
20–30	11	29.7	26	70.2	0.51
≥30	5	50.0	5	50.0	0.10
Color					
White	4	30.7	9	69.2	0.30
Mixed	17	34.6	32	65.3	0.67
Educational level					
Complete elementary school	5	22.7	17	77.2	0.05
Incomplete high school	1	25.0	3	75.0	0.81
Complete high school	5	22.7	17	77.2	0.10
Incomplete university-level education	1	25.0	3	75.0	0.18
Family income (minimum salaries)					
1–2	12	32.4	25	67.5	0.73
3–4	3	25.0	9	75.0	0.17
>5	1	33.3	2	66.6	0.81
Parity					
One or more deliveries	18	32.1	38	67.8	0.93
Number of preterm deliveries					
1	3	37.5	5	62.5	0.27
≥3	1	50.0	1	50.0	0.70
Gestational age at the examination (weeks)					
27–31	8	50.0	8	50.0	0.36
31–35	10	23.2	33	76.7	0.03
Cervical length < 20.0 mm					
Present	18	54.5	15	45.4	0.007
Cervical glandular area					
Present	9	25.0	27	75.0	0.68

variables were not significant, because they are easily obtained and perhaps can improve the multivariate model.

The use of skin color was used because of the great difficulty to define race in a country with great miscegenation [22]. I think to be important this classification because in Brazil the population is heterogeneous. Usually, a great majority of Brazilian population has parentage of black, white and indigenous races. It is not possible to divide the population in two groups "black and no-black", because in these groups exist the presence of other races. We think it important to divide the groups by skin color, because this classification is more appropriate to the reality of Brazilian population as well as other countries of Latin America.

Although some studies have pointed out that preterm delivery occurs in less than 15 % of the cases of symptomatic women with intact amniotic membranes [23], the incidence of preterm delivery in our sample was 32.8 %, which was also found by Gomez et al. [24] who included women with 20–35 weeks of pregnancy in their samples. Crane et al. [25] obtained similar incidence with a mixed sample of single and twin pregnancies. According to Kramer et al. [26], socioeconomic factors may not be an independent determinant for preterm delivery but, instead, may be a direct consequence of psychosocial stress due to this condition of life. Although socioeconomic condition is associated with preterm delivery, it is difficult to isolate specific risk factors, as demonstrated by Creasy et al. [27] who, in establishing a score system including predictive factors such as socioeconomics, obstetric history, living habits and evolution of the current gestation in order to evaluate the risk of prematurity, obtained low sensitivity and positive predictive values.

Previous preterm deliveries are a risk factor for preterm delivery in the current pregnancy, and this has already been pointed out in many studies on asymptomatic women [28]. After spontaneous preterm delivery, the risk of repetition ranges from 14 to 22 %. It rises from 28 to 42 % after two preterm deliveries, possibly reaching up to 67 % after three premature deliveries [29]. In our study, we did not observe

Table 5 Diagnostic rates and prediction values of the final model and validation test

	Final model (%)	Bootstrap method (%)	*p*
Accuracy	87.8	84.8	0.48
Sensitivity	78.2	65.2	0.02
Specificity	93.0	95.3	0.36
Positive predictive value	85.7	88.2	0.93
Negative predictive value	88.8	83.6	0.24

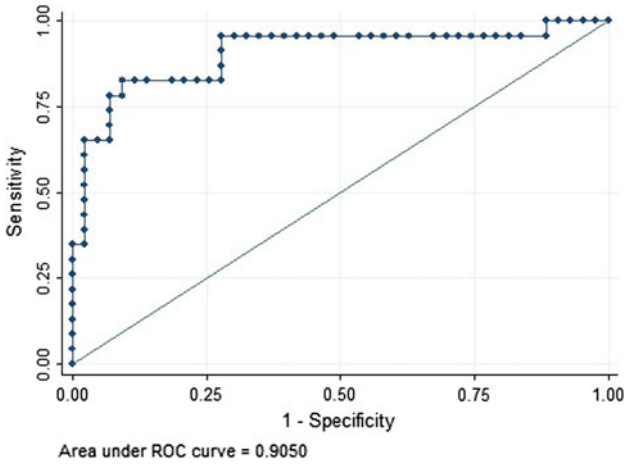

Fig. 1 Receiver operating characteristic (ROC) curve for the final multivariate logistic model

this association, probably because the sample was constituted of a small number cases. The cervical length seen on ultrasound was significantly associated with preterm delivery in the univariate and multivariate analyses of our study. We selected the length of 20.0 mm as the cutoff point, which was the same length used in a previous study conducted in our clinic [15] and in a study by Iams et al. [9]. In our previous study, using the sample of 45 pregnant symptomatic women, the cervical length had sensitivity, specificity, positive predictive value and negative predictive value of 86.9, 81.8, 83.3 and 85.75 %, respectively to prediction of preterm delivery [15]. This study could better the actual model, because we used the previous sample (45 cases), and the other 25 cases had similar demographic, obstetric outcome and uterine cervix sonographic data. However, Crane et al. [25] did not use this criterion because they prioritized a high negative predictive value, thus raising the cutoff point.

In our study, we did not include women who gave birth within the first 24–48 h in the hospital, in accordance with most other studies on symptomatic women, which have excluded cases of advanced preterm labor. Through this approach, the objective was to identify doubtful cases or cases in the initial stages, in which cervical ultrasound findings can be used as a differential for reducing the false positive rate [24, 25].

In most studies on symptomatic pregnant women, ultrasound evaluation of the uterine cervix was performed before administering tocolytic medication [16, 23]. We chose to perform the ultrasound examination after completing at least the first cycle of tocolysis. This method was also used in a previous study [24], considering that in a paired study by Rozenberg et al. [2], the uterine cervix was measured before and after tocolysis, and it was shown that there was no statistically significant difference in relation to measuring the cervical length as seen on ultrasound.

Sekiya et al. [12] showed that it was possible to detect the CGA (the likely histological glandular region) using ultrasound, and emphasized that failure to identify it using ultrasound would translate as cervical ripening. During this process, aqueous content accumulates in the connective tissue and biochemical modifications take place causing disarrangement of the cervical mucosal invaginations within the stroma, thus giving the invaginated glandular layer echogenicity similar to the adjacent stromal tissue, even though they are histologically different regions. Therefore, non-identification of the cervical glandular area on ultrasound is due to absence of acoustic impedance between the cervical glandular layer and the adjacent stromal tissue [15]. In our study, univariate analysis did not show any association between absence of the cervical glandular area and preterm delivery, contrary to other authors' findings [15, 30]. We believe that the advent of new image enhancement software such as image composition and harmonic imaging have made it possible to view cervical glandular areas better.

In a previous study realized by our group with 45 symptomatic pregnant women [15], the isolated cervical length (univariate model) using the cutoff of 20 mm had sensitivity of 81.8 % and specificity of 83.3 % to prediction of preterm delivery and the actual multivariate model had 78.2 and 93.0 %, respectively. In other words, the use of demographics and obstetric outcomes did not increase the sensitivity to the prediction of preterm delivery, but these data increased the specificity. These results confirm that the isolated use of cervical length still is a good parameter to the prediction of preterm delivery.

In summary, taking the patients' socioeconomic, obstetric and ultrasound profile into account, the model in this study achieved specificity of 93.02 %, thus showing that it is a useful tool for management of symptomatic women with intact amniotic membranes. By calculating the likelihood of preterm delivery for a given patient, it is possible to select patients who present low likelihood of preterm delivery and, thus, not expose them to the undesirable effects of tocolysis, as well as decreasing the hospitalization costs.

Conflict of interest None.

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