Xie et al. BMC Pregnancy and Childbirth (2024) 24:716
https://doi.org/10.1186/s12884-024-06779-3

BMC Pregnancy and Childbirth

RESEARCH

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Use of uterine electromyography in the prediction of preterm birth after transvaginal cervical cerclage

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Abstract

Background Preterm birth (PTB), complications of which account for approximately 35% of deaths among neonates, remains a crucial issue. Cervical insufficiency (CI) is defined as the inability of the utrine cervix to retain a pregnancy, leading to PTB. Cervical cerclage is an efficient surgery for CI patients by preventing the cervix from being further mechanically shortened. Unfortunately, a certain number of patients who had cerclage still delivered prematurely, raising the urgent need to accurately assess the risk of PTB in patients with cerclage. Uterine electromyography (uEMG) is an emerging technology that characterizes uterine contractions by describing the actual evolution process of uterine activity and has been used to predict PTB in recent years.

Method In this single-center retrospective case-control study, singleton pregnancy women who received cervical cerclage and uEMG assessment between January 2018 and January 2022 at the Sun Yat-sen Memorial Hospital of Sun Yat-sen University were enrolled.

Results 32 PTBs were observed of the 69 women who underwent assessment. Based on multivariate logistic regression analysis, PTB after cerclage was significantly associated with previous PTB history or mid-trimester pregnancy loss (OR: 2.87, 95%CI: 1.49–5.54) and contraction frequency detected by uEMG (OR: 2.24, 95%CI: 1.44–3.49). The AUC of contraction frequency (0.766, $P<0.001$) was observed, and the optimal cut-off value suggested by Youden Index was 1.75 times per hour. Combined with previous preterm history and cervical length, the AUC of contraction frequency reached 0.858. After stratification by contraction frequency, the median duration was 11 weeks in the high frequency group (> 1.75 times per hour) and 15 weeks in the low frequency group (≤ 1.75 times per hour) ($P<0.001$).

Conclusions The uEMG effectively predicts PTB after transvaginal cervical cerclage and provides a new method for clinicians to evaluate the pregnancy outcome of CI patients.

Keywords Uterine electromyography, Cervical cerclage, Spontaneous preterm birth

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Background

Preterm birth (PTB), complications of which account for approximately 35% of deaths among neonates, remains a crucial issue [1]. Growing evidence suggests that individuals born preterm are at greater risk of both short-term and long-term complications, including respiratory infection, neurodevelopmental deficits, retinopathy, adulthood hypertension, heart failure, and diabetes [2–7]. Hospital readmission increases the financial burden on the health system and brings enormous psychological difficulties to the families [8, 9]. Owing to the awareness of PTB as a global public health issue, early identification of high-risk populations and extension of the gestational week via effective treatment becomes the critical link.

The maintenance of pregnancy requires proper cervical function. As one of the important causes of PTB, cervical insufficiency (CI) is defined as the inability of the utrine cervix to retain a pregnancy in the absence of symptoms of uterine contraction. Globally, the incidence rate of CI reaches approximately 1% of the obstetric population [10]. Recent research has established that cervical cerclage is an efficient surgery for prolonging gestational age and decreasing the occurrence of early PTB by preventing the cervix from being further shortened mechanically [11]. However, as the pathological mechanism is incompletely understood, about 46–54% of women still deliver prematurely after vaginal cerclage [12, 13]. Thus, accurate evaluation of the women who will have spontaneous PTB continues to be a main obstacle.

Uterine contraction is generated by spontaneous electrical activity in the form of the action potential at the myometrium, which is composed of smooth muscle cells [14]. Uterine electromyography (uEMG) is an emerging technology that characterizes uterine contractions by describing the actual evolution process of uterine activity. When the action potential generates, it will be detected by the recording electrode placed on the abdominal surface. The dense sequence of spikes will be recognized as the burst, which corresponds to the contraction of the uterus [15]. Compared with the tocodynamometer (TOCO), uEMG correlates better with the gold-standard invasive intrauterine pressure catheter (IUPC) and provides a reliable noninvasive alternative regardless of obesity [16]. Another advantage of the uEMG is the improved sensitivity to reflect the frequency and intensity of uterine contraction in the second trimester of gestation [17]. As the maintenance of pregnancy requires quiescence of myometrium, uterine contractions presenting in the second and third trimesters can be the threat of full-term delivery. Existing research confirmed the critical role played by uEMG focused on PTB prediction in symptomatic women [18–20]. A recent study observed a specific frequency of myometrial electromyography signals in second-trimester women with short cervical lengths by uEMG, which provides a plausible biophysiological explanation of the link between abnormal myometrial activation and painless cervical shortening [21]. However, the predictive effectiveness of uEMG for subsequent PTB among women who had cervical cerclage remains undefined.

This study aims to investigate whether uEMG as a prognostic factor could predict the pregnancy outcome of cervical insufficiency in women who received cervical cerclage.

Methods

Design and setting

This retrospective study reported adhering to the Standards for Reporting Diagnostic Accuracy Studies (STARD) reporting guideline. The protocol was approved by the medical ethical committee of the Sun Yat-sen Memorial Hospital of Sun Yat-sen University(Approval No. SYSKY-2022-077-01, Approval Date May 30, 2022). Singleton pregnancy women with valid delivery information received cervical cerclage and underwent uEMG assessment between January 2018 and January 2022 and were enrolled at the Sun Yat-sen Memorial Hospital of Sun Yat-sen University, Guangzhou, China. Inclusion criteria: (i) Singleton pregnancy women; (ii) Received cervical cerclage; (iii) Received uterine uEMG assessment. Exclusion criteria: (i) Severe complication, such as severe preeclampsia and severe prenatal bleeding; (ii) Termination of pregnancy due to fetal factors, such as fetal distress, fetal abnormality; (iii) congenital uterine malformation.

Criteria for the indication of surgery

All of the surgical indications are according to *ACOG Practice Bulletin No.142* [22]. History-indicated cerclage is performed as a prophylactic surgery in asymptomatic women, usually between 14 and 16 weeks of gestation, based on prior obstetrical history, including prior cerclage due to painless cervical dilation in the second-trimester and second-trimester pregnancy losses due to painless cervical dilatation. Ultrasound-indicated cerclage is usually placed between 16 and 24 weeks of gestation for cervix length less than 25 mm on transvaginal ultrasound with prior spontaneous early PTB and short cervical length (less than 25 mm) before 24 weeks of gestation. Physical exam-indication is cervical dilatation of one or more centimeters detected by physical examination. The measurement of cervical length was done before cerclage.

Clinical management and uEMG assessment

All surgeons applied McDonald cerclage and procedures are applied vaginally. McDonald procedure is a relatively minimally invasive technique performed transvaginally.

The technique is simpler and less dependent on the skill of the surgeon compared to the Schillocker technique. The operation was performed by experienced senior doctors only if there were no signs of inflammation and no contractions observed by manual measurement. The test of biochemical indicators such as white blood cell count, C-reactive protein, and vaginal cultures before surgery was applied to exclude uncontrolled infection. Amniocentesis was not routinely performed. To manage surgical incision contamination and reduce complications [23, 24], all women received prophylactic antibiotics in the perioperative period, and the use of tocolytic agents in the postoperative period was decided by clinicians. All patients initially received ritodrine (5 mL: 50 mg; Taiwan Biotech Co, Ltd, Taiwan). Initially administered intravenously, followed by oral maintenance therapy, closely monitoring adverse reactions to determine the individual optimal dosage. Intravenous infusion: Dilute 0.2 mg/mL of solution and maintain a left side position during intravenous infusion to reduce the risk of hypotension. Pay close attention to the infusion rate and use a controllable infusion device. Initially, control the infusion rate to a dose of 5 drops per minute, increasing it by 5 drops per minute every 10 min until the effect is achieved, usually maintained at 15–35 drops per minute. Wait until uterine contractions stop and continue infusion for at least 12–18 h. When the maximum dose of ritodrine cannot control uterine contractions or patients experienced clinical symptoms such as palpitations or heart rate>120 bpm, which means they cannot tolerate ritodrine, the tocolytic agent was changed to atosiban (5 mL: 37.5 mg; Ferring GmbH, Switzerland). The dosage of Atosiban is follows on the drug instructions provided by pharmaceutical company. Activity restriction, instead of absolute bed rest, was recommended regularly. PTB was used to describe delivery before 37+0 completed weeks of gestation. [25]

The uEMG data were collected for a minimum of 60 min using the Monica AN 24 (Monica Healthcare Co, UK) on the first to second postoperative day. The electrode placement and operation were performed according to the operator manual from the manufacturer. The uterine contraction is extracted from the slow wave. Technical details of the uEMG procedure: After cleaning the abdomen, ensure that the electrode placement area is dry. Choose intact skin and avoid areas with body hair (if hair cannot be avoided, shaving the body hair at the electrode placement location). Place the electrodes according to the Fig. 1.

Statistical analysis

The normality of the sample data for continuous variables was determined using the Shapiro-Wilk test for normality. If the data did not follow a normal distribution, it was represented by the median (25th percentile, 75th percentile), and comparisons between two groups were made using the Wilcoxon rank-sum test. If the data followed a normal distribution, it was expressed as the mean ± standard deviation, and comparisons between two groups were made using an independent sample t-test. Categorical variables were statistically described using frequencies (percentages), and comparisons between groups were made using the Chi-square test or Fisher's exact test. Most of the analyses were performed using IBM SPSS Version 25 (SPSS Statistics V25, IBM Corporation, Somers, New York). Univariate logistic regression analysis and multivariate logistic regression were performed to analyze the risk factors of PTB. The parameters with

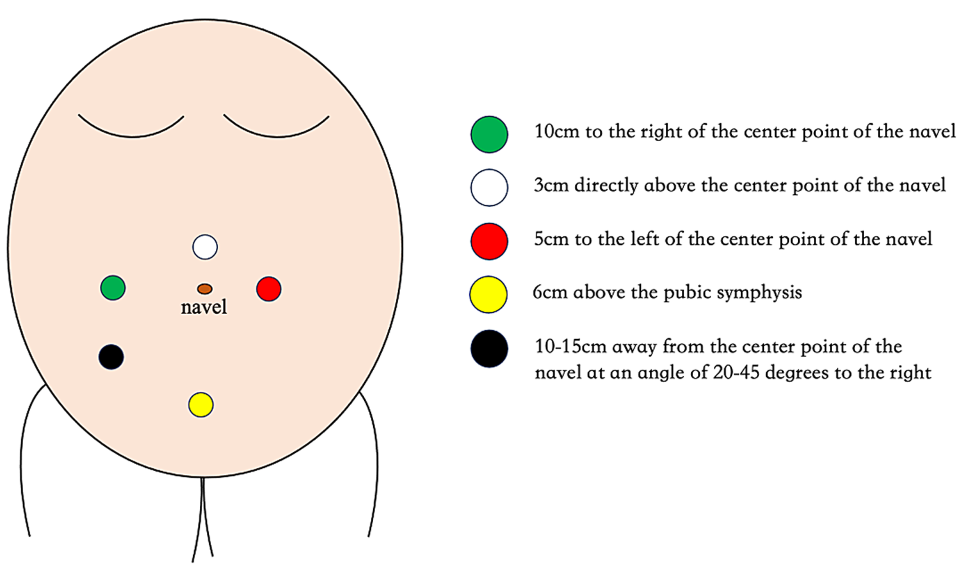


Fig. 1 Placement diagram of uterine electromyography electrodes

$p<0.05$ in the results of univariate logistic regression analysis and parameters with clinical value reported in previous studies were included in the multivariate analysis. The nomogram, the Kaplan-Meier curve and receiver operating characteristic (ROC) analysis was constructed with Statistical Package R(R4.2.1). Receiver operating characteristic (ROC) analysis and area under curve (AUC) were applied to assess the predictive effectiveness and the discriminatory ability of uEMG, respectively. Delong test was used to compare different ROC curves. The Kaplan-Meier curve and log-rank test were performed to evaluate the interval to delivery and gestational age at delivery stratified by contraction frequency, using GraphPad Prism version 8.0.0 for Windows (GraphPad Software, San Diego, California, USA). Statistical significance was assumed at P values less than 0.05. In addition, calibration curves and clinical decision curves were generated, and applies 10-fold cross-validation for internal validation, and draws a nomogram.

Results

Between January 2018 and January 2022, we enrolled and followed up with 199 women according to protocol, and 122 women did not deliver at the researchers' hospital (Fig. 2). Of the remaining 77 women, eight individuals with severe complications, fetal distress, or uterine malformation were excluded, leaving 69 women for analysis. Of these, 17 cases were history-indicated cerclage, 40 were ultrasound-indicated cerclage, and 12 were physical examination-indicated cerclage.

A total of 32 PTBs were observed in the overall cohort. Table 1 demonstrates the univariate logistic regression

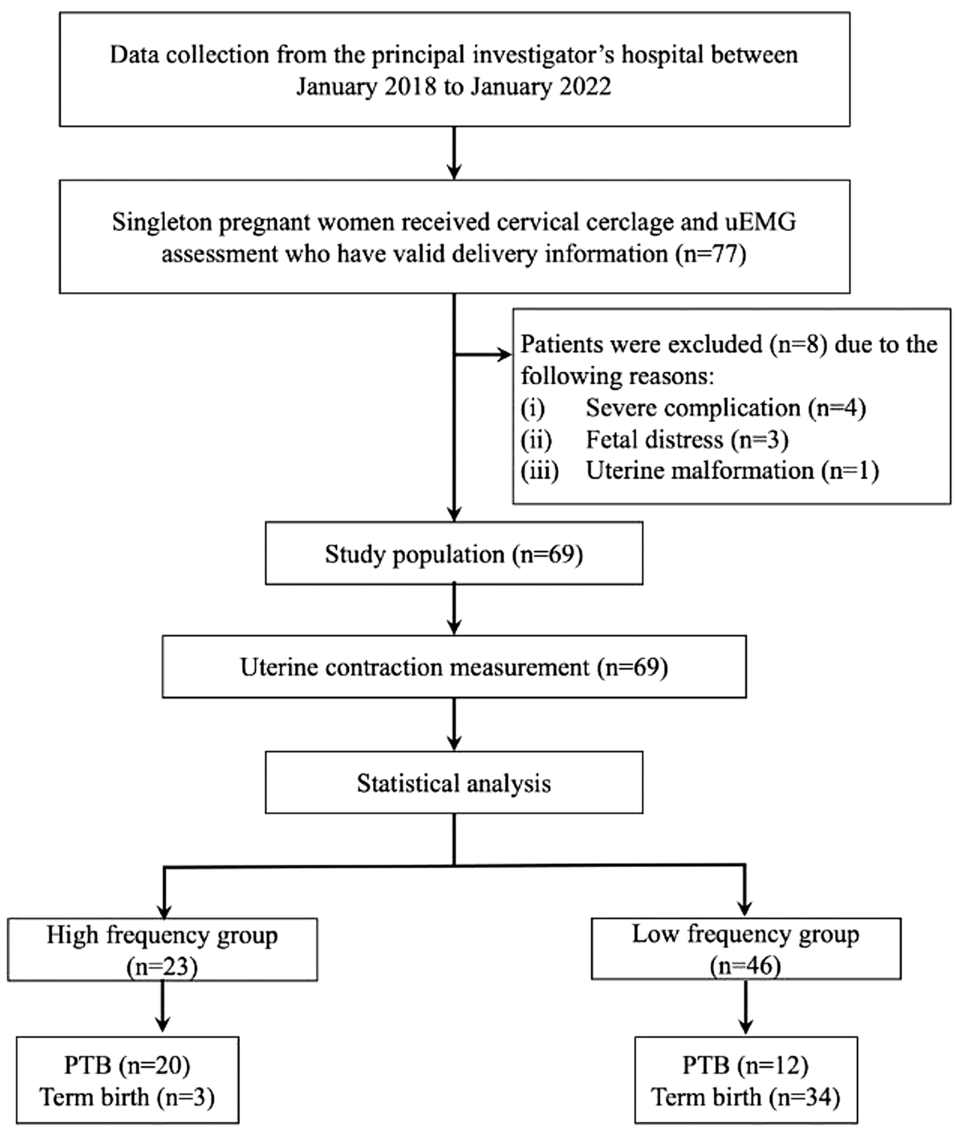


Fig. 2 Flowchart depicting participants' inclusion. PTB: Preterm birth

Table 1 Univariate logistic regression analysis of risk factors associated with PTB

Variables	Sum (*n* = 69)	PTB (*n* = 32)	Term birth (*n* = 37)	*P* value
Maternal age (years)	33.73 (32.58, 34.89)	33.59 (31.94, 35.24)	33.86 (32.18, 35.55)	0.817
ART pregnancy	19 (27.5%)	9 (28.1%)	10 (27%)	0.919
BMI	22.79 (22.02, 23.56)	23.75 (22.41, 25.09)	22.16 (21.24, 23.07)	0.041
Gravidity	4 (3, 4)	3 (3, 4)	4 (3, 5)	0.965
Previous PTB or mid-trimester pregnancy loss	0 (0, 1)	1 (0, 2)	0 (0, 1)	0.001
Gestational age at cerclage	22 (18, 24)	22 (14.5, 23)	23 (18, 24)	0.098
Cerclage indication				0.001
History-indicated	17 (24.64%)	11 (34.375%)	6 (16.21%)	
Ultrasound-indicated	40 (57.97%)	11 (34.375%)	29 (78.38%)	
Emergency	12 (17.39%)	10 (31.25%)	2 (5.41%)	
Cervical length	13 (5, 22.5)	10.5 (0, 29)	14 (9.5, 21)	0.239
Contraction frequency	0.7 (0, 2.6)	2.5 (0.4, 3.6)	0 (0, 1)	< 0.001

ART: Assisted reproductive technology, BMI: Body mass index, PTB: Preterm birth

Table 2 Univariate and multivariate logistic regression analysis of risk factors associated with PTB and the receiver-operating characteristic curves results

Variables	AUC	OR (95%CI)	*P* value	Cut-off value
Univariable Model				
Contraction frequency	0.766	2.24 (1.44–3.49)	<0.001	1.75
Previous PTB or mid-trimester pregnancy loss	0.716	2.87 (1.49–5.54)	0.002	0.5
Cervical length	0.576	0.99 (0.95–1.03)	0.576	6.5
Multivariate Model 1	0.754			
Previous PTB or mid-trimester. pregnancy loss		3.79 (1.74–8.22)	<0.001	
Cervical length		0.91 (0.91–1.004)	0.070	
Multivariate Model 2	0.836			
Contraction frequency		3.15 (1.49–6.66)	0.003	
Previous PTB or mid-trimester pregnancy loss		2.38 (1.44–3.96)	<0.001	
Multivariate Model 3	0.858			
Contraction frequency		4.24 (1.69–10.64)	0.002	
Previous PTB or mid-trimester pregnancy loss		0.95 (0.89–1.01)	0.101	
Cervical length		2.39 (1.43–3.99)	<0.001	

Multivariate Model 1: Combined previous PTB or mid-trimester pregnancy loss and cervical length. Multivariate Model 2: Combined previous PTB or mid-trimester pregnancy loss and contraction frequency. Multivariate Model 3: Combined previous PTB or mid-trimester pregnancy loss, cervical length and contraction frequency. PTB: Preterm birth

analysis of risk factors associated with PTB. No significant difference was found between participants with term birth and PTB in maternal age, gravidity, gestational age at cerclage, or cervical length. However, compared with participants with term birth, participants with PTB were more likely to have previous PTB or mid-trimester pregnancy loss, higher body mass index(BMI), emergency cerclage, and higher contraction frequency. Some studies have confirmed that pre pregnancy being underweight and overweight were risk factors for PTB [26, 27]. However, the association between overweight and PTB is still controversial. Some studies found that pre pregnancy overweight could reduce the risk of PTB [28, 29]. Some studies found no association between pre pregnancy overweight and the risk of PTB [30, 31]. Because this is a retrospective study, there are 9 out of 69 patients with missing BMI, and 8 of them were in 32 PTBs. Therefore, BMI were not included in the regression model. No significant association of PTB after cerclage with cervical length was observed. In clinical practice, there is a correlation between cervical length and cerclage indications, and some guidelines indicate that cervical length is associated with preterm birth. Therefore, this study included cervical length in the logistic regression analysis model. The logistic regression analysis showed that PTB after cerclage was significantly associated with previous PTB history or mid-trimester pregnancy loss (OR: 2.87, 95%CI: 1.40-10.89, P=0.009) and contraction frequency (OR: 2.24, 95%CI: 1.44–3.49, P<0.001) (Table 2).

The ROC of the related factors is shown in Fig. 3, and the AUC is listed in Table 2. The AUC of contraction frequency (0.766, P<0.001) was observed, and the optimal cut-off value suggested by Youden Index was 1.75 times per hour. Combining previous PTB or mid-trimester pregnancy loss and contraction frequency as model 1, the AUC reached 0.754. Combining previous PTB or

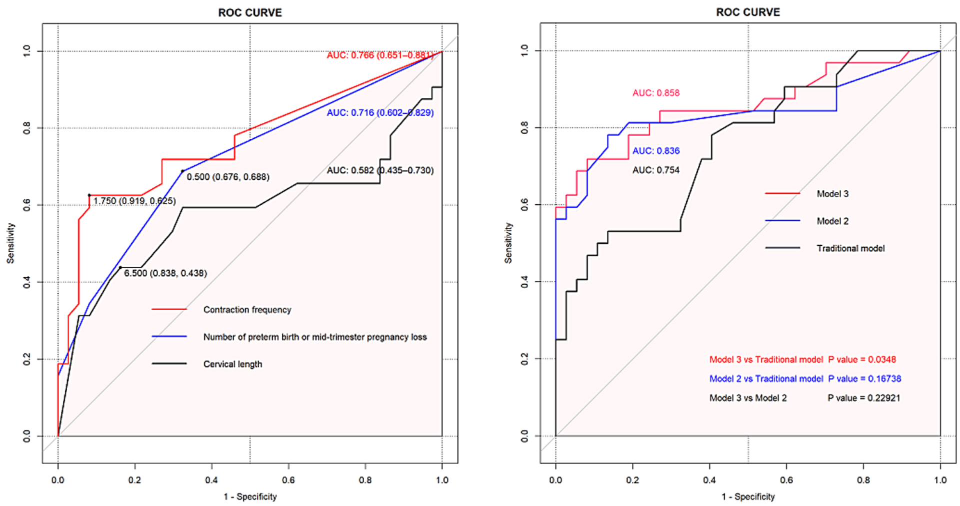


Fig. 3 The receiver-operating characteristic curves of risk factors of PTB. PTB: Preterm birth. Traditional model: Preterm birth or mid-trimester pregnancy loss + Cervical length. Model 2: Preterm birth or mid-trimester pregnancy loss + Contraction frequency. Model 3: Preterm birth or mid-trimester pregnancy loss + Cervical length + Contraction frequency

Table 3 10-fold cross-validation over 10 times of AUC

AUC	R^2	Discrimination index
0.83	0.52	0.34
1.00	−2.13	−1.05
0.83	0.52	0.34
1.00	0.12	−0.08
1.00	0.70	0.60
0.67	0.24	0.07
0.67	0.19	0.02
1.00	0.66	0.47
0.93	0.66	0.54
1.00	0.24	−0.01

mid-trimester pregnancy loss and contraction frequency as model 2, the AUC was 0.836. Combining previous PTB or mid-trimester pregnancy loss, contraction frequency and cervical length as model 3, the AUC was 0.858. We test model 3 in a repeated 10-fold cross-validation over 10 times. When applied to internal validation, the score revealed good discrimination with internal ten fold cross-validation, we obtained average AUCs of 0.863 (Table 3). On the basis of multivariable logistic regression analysis, we established the nomogram for predicting the risk of PTB after cerclage, including previous PTB history and contraction frequency (Fig. 4). Calibration curves and clinical decision curves (Fig. 5) indicate that within the risk threshold range of 0.2–0.8, the clinical decision to treat premature birth based on model 3 is more advantageous than treating all patients or not treating them at all.

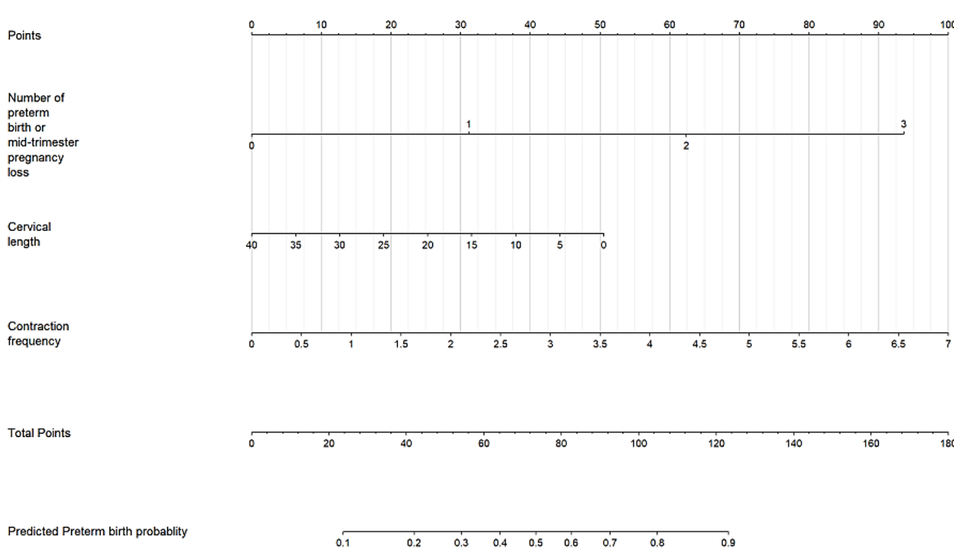
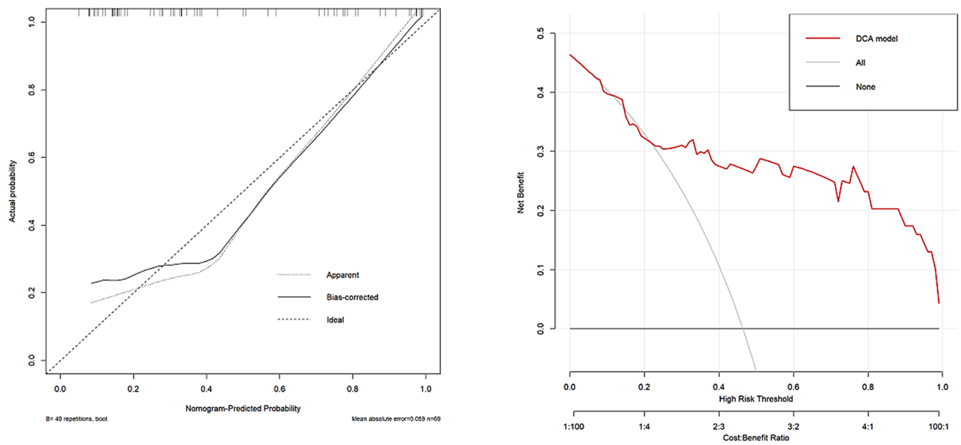


Fig. 4 Nomogram for predicting PTB. PTB: Preterm birth



A B

Fig. 5 Calibration (**A**) and Decision curve analysis (**B**) of Model 3 to predict Preterm birth. Model 3: Preterm birth or mid-trimester pregnancy loss + Cervical length + Contraction frequency

Table 4 Interval to delivery and gestational age at delivery stratified by contraction frequency

Time	Low frequency group (*N* = 46) (week)	High frequency group (*N* = 23)(week)	*P* value
GA at cerclage	23 (18, 24)	21 (16, 23)	0.214
Median duration of interval to delivery	15 (13, 18)	11 (5, 15)	0.002
Median week of GA at delivery	38 (35, 38)	32 (25, 35)	<0.001

GA: Gestational age, PTB: Preterm birth

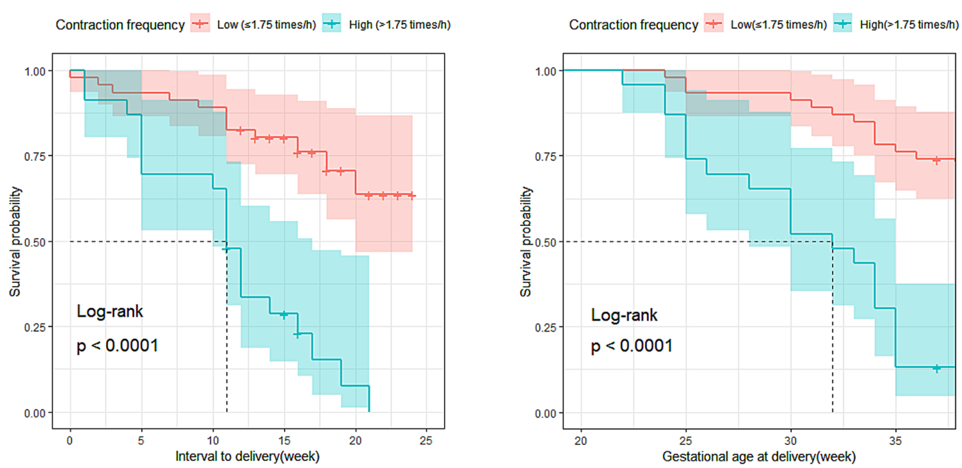


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Fig. 6 The Kaplan-Meier curve of interval to delivery and gestational age at delivery stratified by contraction frequency. (**A**) Interval to delivery of the two groups. (**B**) Gestational age at delivery of the two groups

As shown in Table 4, gestational age at the cerclage of the two groups shows no significant differences (low frequency group 23 weeks vs. high frequency group 21 weeks, $P = 0.214$). However, the median duration to delivery was 11 weeks in high frequency group and 15 weeks in low frequency group ($P = 0.002$). The median gestational age in high frequency group was 32 weeks, and 38 weeks in low frequency group ($P < 0.001$). The Kaplan-Meier curve estimated the interval to delivery and gestational age at delivery stratified by contraction frequency, where high frequency was defined as >1.75 times per hour and low frequency was defined as ≤1.75 times per hour (Fig. 6).

Discussion

Main findings

We investigated the predictive effectiveness of contraction frequency detected by uEMG for the ultimate gestational outcome of cervical cerclage. The AUC of contraction frequency was 0.766 with a 1.75 times/h cut-off value. Combined with previous preterm or mid-trimester pregnancy loss history, the AUC of contraction frequency reached 0.836. Among patients with cervical cerclage, high contraction frequency is associated with earlier delivery compared with low contraction frequency, suggesting that the high frequency of uterine contraction after cerclage is a reliable risk factor for PTB in CI patients, and the uEMG signal is an ideal predictor of PTB in CI patients after cerclage.

Results in the context of what is known

The prevalence of PTB after cerclage was 46.38% in this study, which was in line with the previous literature review [23, 24]. This study set out with the aim of assessing the utility of uEMG in the prediction of PTB in patients who received transvaginal cerclage. The myometrial electromyogram detected by surface electrodes represents the summation of cellular activities, which generates a much lower frequency band than abdominal muscles so that the distinction between different muscles can be made [32]. It was reported that Alvarez waves, also named uterine irritability, present earliest at the 9th week of gestation. These imperceptible contractions represent unsynchronized local uterine activity [17]. In our study, the population was second-trimester women, and electrical signals were detectable. uEMG was first used to monitor uterine contraction during delivery and has been used to predict PTB in recent years. There is a gradual rise in the level of electrical activity with the gestational period. Owing to the excitation-contraction coupling process, the uEMG signal's availability opens a new direction for the prediction of PTB [33].

However, there is a lack of uEMG data in women with CI. As mentioned in the literature review, the occurrence of PTB is considered to be associated with uterine contractions and cervical ripening [34, 35]. Because of the absence of abdominal pain symptoms and its relation with mechanical injury caused by surgery or birth injury, it is believed that degradation of collagen and increase in collagenase activity result in CI in the past [22, 36]. However, the results of Oxlund et al. did not support this notion. They found that low collagen concentration or collagen of inferior mechanical quality was not related to the onset of CI by investigating these factors in cervical biopsies [37]. Researchers began to ascertain the relationship between uterine contractions and cervical dilation. As the premature cervical dilation starts with the internal os, further evidence showed the area of the internal os contained 50–60% cervical smooth muscle cells while the external os is predominantly collagen. Moreover, cervical tissue which expressed oxytocin receptors contracted in response to oxytocin, and cervical contractility showed regional dependency [38]. These implicated the possibility of painless uterine contractions inducing the opening of internal os as a potential mechanisms of CI, which seems to be consistent with our research. As showed in Kaplan-Meier curve, women with more uterine contractions maintained shorter pregnancy latency.

Previous research has shown that second-trimester cervical length is predictive of PTB among patients with prophylactic cerclage [39]. However, no significant association between cervical length and PTB was observed in our study. In the beginning, we inferred it could be because the gestational age measurement in prophylactic cerclage group was earlier in our study. Dereje et al. reported that the median cervical length remained unchanged in the first 20 weeks of gestation [40]. Thus, it is possible to hypothesize that the predictive accuracy of cervical length in prophylactic cerclage group is better than the other two indication groups.

Previous studies have shown that ART singleton women have a significantly higher risk of PTB than natural pregnant women [40, 41]. As polycystic ovary syndrome [42], ovarian stimulation [43], and repeated intrauterine operation [44] are risk factors for CI, it is suggested that CI may be one of the fundamental reasons for late abortion and early premature delivery in ART pregnancy patients. Our research showed that patients with ART pregnancy account for 27.5% of the study population, and ART is not a risk factor for premature delivery after cerclage. Therefore, The monitoring of cervical function of women received ART during pregnancy should be enhanced to help reducing the occurrence of midterm pregnancy fetal loss and early PTB.

Strengths and limitations

The study preliminarily investigated the predictive effectiveness of contraction frequency detected by uEMG for the ultimate gestational outcome of cervical cerclage. We combined previous PTB or mid-trimester pregnancy loss, cervical length and contraction frequency to establish a new PTB prediction model and validated its effectiveness. Despite promising results, there were some limitations in our study. Firstly, this study is a retrospective study and lack of serial uEMG assessments. We will improve this issue in subsequent comparative studies. Secondly, participants were mixed with different cerclage indications. Though we tried to calculate the AUC of contraction frequency separately, the cut-off value was 1.75 times per hour regardless of cerclage indications, indicating poor model performance due to the small sample size. Therefore, further studies stratified by different cerclage indications will be necessary. Thirdly, this is a retrospective study with a limited sample size from a single center. A more extensive database of patients with CI from multiple centers is still needed to further validate the predictive performance of uEMG signals for PTB. Fourthly, uEMG was assessed only once in this study. Data reflecting their changes over time are missing. Further studies could compare contraction frequency before and after cerclage and investigate the values of serial uEMG assessments after cerclage.

Conclusion

This is a new finding that differs from the conventional understanding of the pathology in cervical incompetence. Our study implicated the possibility of painless uterine contractions inducing the shortening and opening of the cervix as a potential mechanisms of CI. Even if uterine contractions do not appear to be externally present, women with more uterine contractions maintained shorter pregnancy latency. Nevertheless, relying solely on the retrospective study is not sufficient to draw definitive conclusions, and additional validation is required. Should this hypothesis prove to be accurate, it has the potential to be a significant discovery that would enhance our comprehension of the pathogenesis of cervical incompetence and ultimately result in improving treatment options.

The uEMG shows effectiveness in predicting PTB after transvaginal cervical cerclage and provides a new method for clinicians to evaluate the pregnancy outcome of those women. Compared to traditional predictive models, the new model has better discrimination and calibration. Future rigorous randomized controlled trials of adequate power will be required to confirm the significance of this finding.

Acknowledgements

The authors thank the medical, nursing, and other staff of the Department of Obstetrics and Gynecology, Sun Yat-sen Memorial Hospital of Sun Yat-sen University, Guangzhou, China.

Author contributions

Haitian Xie and Menglan Zhu designed the project, wrote the manuscript and submitted the article. Kewen Deng revised it for important intellectual content. Hui Chen and Nengyong Ouyang obtained funding and supervised the study. Xiaohui Ji provided statistical advisory and performed the statistical analysis. Jinling Yi, Liqiong Zhu, Jianping Tan, Phei Er Saw and Chunwei Cao contributed to the plan analysis and interpretation of the results. All authors provided feedback on the manuscript and reviewed the final manuscript.

Funding

National Key Research and Development Program of China, Grant/Award Number: 2019YFA0801403; National Natural Science Foundation of China, Grant/Award Number: 32170612; Beijing Health Promotion Association 2022 Young and Middle-aged Doctors Research, Grant/Award Number: BJHPA-2022-SHZHYXZHQNYJ-LCH-011; Natural Science Foindation of Guangdong Province, Grant/Award.

Data availability

Data that support the findings of this study have been deposited in the digital medical record system of Sun Yat-sen Memorial Hospital of Sun Yat-sen University, Guangdong province, China.

Declarations

Ethics approval and consent to participate

The study was approved by the Medical Ethics Committee of Sun Yat-sen Memorial Hospital affiliated to Sun Yat-sen University on May 30, 2022(Approval No. SYSKY-2022-077-01). This retrospective study reported adhering to the Standards for Reporting Diagnostic Accuracy Studies (STARD) reporting guideline. All participants completed a written informed consent document.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Received: 29 February 2024 / Accepted: 23 August 2024
Published online: 30 October 2024

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