CLINICAL RESEARCH

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Predictive Value of Cervical Length Measurement Combined With Shear Wave Elastography Parameters for Preterm Birth: A Retrospective Cohort Study

Authors' Contribution:
Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
Funds Collection G

ABCDEFG 1 Dongxiang Zhang
ABCDEFG 2 Yiling Kang
ABCDEFG 3 Lingling Zhu

1 Department of Gynecology, Affiliated Maternity and Child Health Care Hospital of Nantong University, Nantong, Jiangsu, PR China
2 Department of Ultrasound, Affiliated Maternity and Child Health Care Hospital of Nantong University, Nantong, Jiangsu, PR China
3 Department of Obstetrics, Affiliated Maternity and Child Health Care Hospital of Nantong University, Nantong, Jiangsu, PR China

Corresponding Author: Lingling Zhu, Department of Obstetrics, Affiliated Maternity and Child Health Care Hospital of Nantong University, Nantong, Jiangsu 226000, China, Phone: +86-15006289820, e-mail: zhulingling_edu@163.com

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Background: Spontaneous preterm birth is a major cause of neonatal morbidity and mortality, yet predicting it in women who are asymptomatic and at low risk is challenging. Cervical length (CL) has limited sensitivity. Shear wave elastography (SWE) quantifies tissue stiffness and may capture premature cervical remodeling. This study aimed to combine SWE parameters with CL to predict spontaneous preterm birth.

Material/Methods: We retrospectively analyzed 100 asymptomatic women with low risk of preterm birth (singleton, 18-24 weeks) undergoing routine transvaginal ultrasound. The primary outcome was spontaneous preterm birth (<37 weeks). CL and SWE parameters (internal os stiffness [IOS], external os stiffness [EOS], elasticity contrast index [ECI], hardness ratio [HR]) were measured. Multivariable logistic regression and ROC analysis assessed predictive performance, with bootstrap internal validation.

Results: Twenty-three women (23%) delivered preterm, including 18 spontaneous and 5 iatrogenic cases; sensitivity analysis excluding iatrogenic cases yielded similar results. The preterm group had shorter CL, higher IOS, EOS, and ECI, and lower HR (all $P<0.05$). Independent predictors were CL (aOR=0.90), IOS (aOR=1.10), and ECI (aOR=1.28). The combined model (CL+IOS+ECI) achieved an AUC of 0.889 (95% CI: 0.791-0.985), sensitivity of 82.6%, and specificity of 87.0%, which was significantly better than that of CL alone (AUC=0.709, $P=0.01$). Optimism-corrected AUC was 0.881.

Conclusions: Combining CL with SWE parameters (IOS and ECI) significantly improved spontaneous preterm birth prediction over CL alone in women who are asymptomatic and at low risk. External validation is needed before clinical use.

Keywords: Cervical Length • Obstetrics • Predictive Value of Tests • Preterm Birth • Shear Wave Elastography • Ultrasonography

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Introduction

Preterm birth, defined as delivery before 37 weeks of gestation, remains a leading cause of perinatal morbidity and mortality worldwide [1]. Most cases are spontaneous preterm births [2], the pathogenesis of which is multifactorial and incompletely understood, involving genetic predisposition and immune-mediated inflammation [3]. Beyond its immediate effect on infant survival, preterm birth is associated with long-term neurodevelopmental and health complications [4]. According to statistics, the global incidence rate of preterm birth ranges from 5% to 8%, while in China, the incidence rate of preterm birth is as high as 15% [5]. The World Health Organization and the United Nations have both listed the prevention of preterm birth as one of the strategic goals for improving global newborn health and reducing newborn mortality rates [6]. Preventing preterm birth, reducing the incidence of preterm birth, and improving the survival rate of preterm infants are the urgent tasks currently faced by obstetricians and gynecologists in China [7]. Early prediction of preterm birth and the implementation of early intervention measures can significantly reduce the incidence of preterm birth and improve the survival rate of preterm infants.

At present, the clinical prediction of preterm birth mainly relies on clinical symptoms, medical history, Bishop score, biochemical examination, and ultrasound examination of cervical length (CL) [8]. The first 3 detection methods are subjective, while the biochemical test has many influencing factors [9]. Due to the advantages of ultrasound, such as the absence of radiation, simple operation, easy re-examination, and quantification, its role in predicting preterm birth is becoming increasingly important [10]. Numerous studies conducted in China and other countries have shown that premature cervical remodeling is closely related to the occurrence of preterm birth [11]. From a physiological perspective, cervical remodeling refers to the deformation of the cervix, and the degree of cervical deformation depends on the balance between the stiffness and load of the cervix [12]. Specifically, normal cervical ripening involves progressive disorganization and reduction of collagen cross-linking, leading to decreased tissue stiffness. Premature onset of these biomechanical changes, such as collagen degradation and increased hydration, may precede morphological shortening and can be detected by elastography. CL measurement is widely used in clinical practice; however, it provides only morphological information and does not capture the biomechanical properties of cervical tissue, such as stiffness or elasticity, which are known to change during cervical remodeling. Consequently, CL measurement alone may have limited predictive value, as it cannot fully reflect the complex physiological processes leading to preterm cervical ripening [13].

Shear wave elastography (SWE) is an advanced ultrasound technique that generates shear waves using acoustic radiation force. By quantifying shear wave velocity, SWE provides an objective and reproducible measure of tissue stiffness, expressed as Young's modulus in kilopascals (kPa) [14]. Studies have confirmed that the smaller the SWV, the softer the cervical tissue, and the greater the risk of preterm birth [15]. It has been reported that SWE is helpful in accurately predicting pregnancy outcomes in clinical settings [16]. Despite these promising findings, several key knowledge gaps remain. First, most existing studies have focused on either CL or SWE parameters in isolation, and it is unclear whether combining these 2 modalities could provide incremental predictive value over either alone. Second, the optimal combination of SWE parameters, such as stiffness at the internal os and tissue heterogeneity indices, for predicting spontaneous preterm birth has not been established. Third, the predictive performance of such combined models in asymptomatic women during the mid-trimester, a critical window for potential intervention, remains poorly characterized. Moreover, the biological rationale for using SWE in this context is based on the known pathophysiology of cervical remodeling: premature ripening is associated with degradation and reorganization of collagen fibers, leading to a measurable decrease in tissue stiffness and increased heterogeneity. SWE provides a direct, quantitative assessment of these biomechanical alterations, complementing the purely morphological information provided by CL.

Therefore, to address these knowledge gaps, we aimed to evaluate the predictive value of CL measurement combined with multiple SWE parameters for spontaneous preterm birth in a low-risk, asymptomatic population of pregnant women who underwent routine mid-trimester ultrasound screening (18-24 weeks of gestation) at our institution, without any specific clinical suspicion of preterm birth. We sought to determine whether this combined approach offers superior predictive performance compared with CL alone in this specific cohort.

Material and Methods

Study Design and Population

We conducted a retrospective analysis of data from women who delivered at our hospital between January 2023 and December 2024. Data were retrieved from the hospital's electronic medical record system (version 5.2) and cross-referenced with the obstetric ultrasound database and delivery room records to ensure completeness of clinical and outcome data.

This study specifically targeted women who were asymptomatic and at low risk for spontaneous preterm birth. All participants were recruited from a routine universal transvaginal ultrasound screening program at 18 to 24 weeks of gestation, not on the basis of any specific clinical symptoms or risk factors. To achieve

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this, we applied strict exclusion criteria that removed women with known risk factors for iatrogenic or indicated preterm birth, including multiple gestation, infections, cervical insufficiency, previous cervical surgery, and serious pregnancy complications. Consequently, our cohort was a relatively homogeneous population of women with low baseline risk for preterm birth, reducing the potential for confounding by these factors but also limiting the generalizability of our findings to higher-risk populations.

We initially reviewed the medical records of all pregnant women who underwent transvaginal ultrasound examination between 18 and 24 weeks of gestation during the study period. From this initial pool, we consecutively enrolled all women who met the inclusion criteria and had complete outcome data. Given the retrospective and exploratory nature of this study, a formal sample size calculation was not performed a priori. The sample size was determined by the number of eligible women with complete datasets during the study period, which yielded a final cohort of 100 participants. A flow chart depicting the study process is presented in **Figure 1**.

A total of 118 pregnant women who met the inclusion criteria were initially identified from the hospital's obstetric database between January 2023 and December 2024. After reviewing medical records, 18 women were excluded due to missing ultrasound data (n=7), loss to follow-up (n=6), or incomplete delivery outcome records (n=5). Only women with complete data for all variables of interest were included in the final analysis (complete-case analysis). Consequently, a final cohort of 100 women with complete datasets was included in this retrospective analysis. All eligible women meeting the inclusion criteria during the study period were consecutively included. This consecutive sampling method ensured that all eligible cases during the study period were considered.

This study was approved by the Ethics Committee of Affiliated Maternity and Child Health Care Hospital of Nantong University (approval Number: Y2022028). All participants provided written informed consent at the time of ultrasound examination, which included permission for their anonymized data to be used for future research purposes.

Due to the retrospective design, ultrasound operators were not blinded to patient characteristics at the time of examination, as this reflects real-world clinical practice. However, to minimize bias in the analysis phase, the researchers performing the statistical analysis were blinded to group allocation (preterm vs full-term) until after the predictive models were finalized.

Inclusion and Exclusion Criteria

The inclusion criteria were as follows: (1) The pregnancy period was confirmed by ultrasound to be between 18 and 24 weeks; (2) age of participant was between 20 and 40 years old; and (3) transvaginal SWE was performed, and there was no spontaneous membrane rupture upon admission.

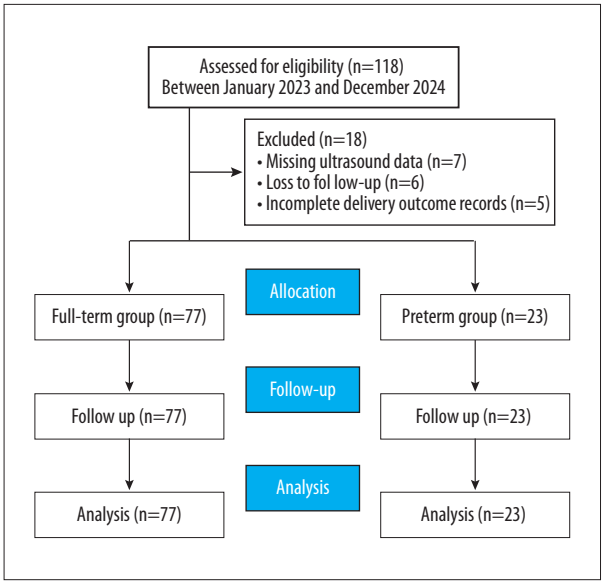

Figure 1. Flow chart.

The exclusion criteria were as follows: (1) previous cervical surgery; (2) serious pregnancy complications or comorbidities; (3) placental abruption, elective termination of pregnancy, or early pregnancy loss; (4) presence of high-risk factors for iatrogenic preterm birth, such as multiple gestation, infections, or cervical insufficiency; (5) known genetic history; and (6) missing data.

Patient Recruitment and Admission Details

The recruitment of pregnant women was based on the data retrieved from the obstetric outpatient medical record system. All eligible women meeting the inclusion criteria were consecutively included. These women were then admitted to the hospital for delivery at their respective gestational ages, and their data were collected for retrospective analysis.

Transvaginal Ultrasound Examination Method

All ultrasound examinations were performed by one of two experienced sonographers, each with more than 5 years of experience in obstetric ultrasound and specialized training in SWE techniques. Daily quality control checks of the Voluson E9 system were performed according to the manufacturer's specifications, to ensure consistent performance and calibration.

All examinations were performed using the Voluson E9 ultrasound system equipped with the SWE advanced package (software version 4.0.3; General Electric Co, USA) with a

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Table 1. Definition and measurement protocol for cervical length and shear wave elastography (SWE) parameters.

Parameter	Full name	Definition	Unit	ROI location	ROI size	Measurements	Quality control
CL	Cervical length	Linear distance between the internal os and external os along the endocervical canal	mm	Along the endocervical canal	N/A	3 times, mean recorded	Clear visualization of entire cervix in sagittal plane
IOS	Internal os stiffness	Young's modulus value at the internal os of the cervix	kPa	Internal os	Fixed 2 mm circle	3 times, mean recorded	Stable SWE signal for ≥4 s; no probe pressure
EOS	External os stiffness	Young's modulus value at the external os of the cervix	kPa	External os	Fixed 2 mm circle	3 times, mean recorded	Stable SWE signal for ≥4 s; no probe pressure
ECI	Elasticity contrast Index	A measure of tissue heterogeneity, calculated as the ratio of the standard deviation to the mean elasticity within the ROI	(unitless)	Full thickness of anterior cervical lip, including internal and external os	Variable, encompassing cervical stroma	3 times, mean recorded	Pressure indicator maintained at 3-4 for ≥5 s during strain elastography
HR	Hardness ratio	Ratio of stiffness in a harder reference area to a softer reference area within the cervix	(unitless)	Full thickness of anterior cervical lip, including internal and external os	Variable, encompassing cervical stroma	3 times, mean recorded	Pressure indicator maintained at 3-4 for ≥5 s during strain elastography

transvaginal probe (frequency: 4.0-9.0 MHz). Pregnant women were instructed to empty their bladder and were placed in the lithotomy position. The probe was covered with a sterile condom and inserted into the vagina, ensuring gentle contact with the external cervical os without applying pressure.

For CL measurement, a sagittal view of the entire cervix was obtained, clearly visualizing the internal and external os. CL was measured as the linear distance between the internal and external os along the endocervical canal. The measurement was repeated 3 times, and the mean value was recorded.

For SWE acquisition, in the same sagittal plane, the SWE mode was activated. The probe was held stationary for at least 4 seconds to allow for stable shear wave propagation. A region of interest was placed over the full thickness of the anterior cervical lip, including both the internal and external os. The system automatically calculated the Young's modulus (kPa) values. For quantitative analysis, a fixed 2-mm circular region of interest was placed at the internal os and external os to measure stiffness at these specific anatomical locations. The following SWE parameters were defined: internal os stiffness (IOS, kPa; representing Young's modulus at the internal os), external os stiffness (EOS, kPa; Young's modulus at the external os), elasticity contrast index (ECI, dimensionless), and hardness ratio (HR, dimensionless). All SWE measurements were performed without any external probe pressure. Each parameter was measured 3 times, and the mean value was used for analysis.

Strain elastography was performed to assess ECI and HR. The operator applied mild, repetitive pressure with the transvaginal probe, guided by the built-in pressure indicator scale (range 1-7) on the Voluson E9 system. Pressure was maintained consistently within the optimal range of 3 to 4 on this scale for at least 5 seconds to ensure reproducible tissue displacement. The ECI and HR were automatically calculated by the system. Each measurement was repeated 3 times, and the mean value was recorded.

The definition and measurement protocol for CL and SWE parameters are shown in **Table 1**.

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Observation Indicators

CL and elastography parameters, including IOS (kPa), EOS (kPa), ECI (dimensionless), and HR (dimensionless), were compared between women who delivered preterm and those who delivered at term.

Binary logistic regression analysis was used to assess the independent association of each parameter with the risk of spontaneous preterm birth. To develop a robust predictive model, multicollinearity among predictors was assessed using the variance inflation factor (VIF). A reduced multivariable model was then constructed based on clinical relevance and univariate analysis results, to identify independent predictors.

The predictive accuracy of individual cervical parameters and the combined multivariable model for spontaneous preterm birth was assessed using receiver operating characteristic (ROC) curve analysis. The area under the ROC curve (AUC), sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and positive and negative likelihood ratios (LR+, LR-) were calculated to quantify predictive performance and clinical utility.

Statistical Analysis

Due to the exploratory nature of this retrospective study, a formal sample size calculation was not performed; the sample size was determined by the number of eligible women with complete datasets during the study period.

All statistical analyses were conducted using GraphPad Prism 10.0.2 (GraphPad Software, Boston, MA, USA). Normality of continuous variables was assessed using the Shapiro-Wilk test. Data following a normal distribution were presented as mean±standard deviation (SD) and compared using the *t* test; non-normally distributed data were compared using the Mann-Whitney U test. Categorical variables were presented as counts and percentages and compared using the χ^2 test.

Intraobserver and interobserver reliability of SWE measurements were evaluated using the intraclass correlation coefficient (ICC) in 20 randomly selected patients. For intraobserver reliability, the same operator performed 1 sets of measurements 1 hour apart. For interobserver reliability, 2 independent operators, blinded to each other's results, performed measurements on the same patients. ICC values >0.75 were considered indicative of good reliability.

Binary logistic regression analysis was used to evaluate the association between cervical parameters and preterm birth risk. ROC curves were constructed to assess predictive performance, with AUCs and 95% CIs calculated. The DeLong test was used to compare AUCs between individual and combined models.

Given the limited number of preterm events (n=23), special attention was paid to avoid overfitting. The events-per-variable ratio for our final model (23 events/3 predictors) was approximately 7.7, which is below the recommended threshold of 10 to 20 for robust prediction model development. Therefore, our findings should be considered exploratory and hypothesis-generating, requiring external validation in larger cohorts. Multicollinearity among predictors was assessed using the VIF, with VIF greater than 5 as an indicator of concerning collinearity. Variable selection was performed based on clinical relevance and univariate analysis results to maintain an events-per-variable ratio above 5. Internal validation was performed using bootstrap resampling with 1000 repetitions to obtain optimism-corrected estimates of model performance (AUC and calibration metrics). Model calibration was assessed using the Hosmer-Lemeshow goodness-of-fit test and calibration plot, and overall performance was quantified using the Brier score.

Baseline characteristics were compared between the 2 groups. No significant differences were observed; thus, they were not included as covariates. In addition to the primary model, a sensitivity analysis was performed adjusting for clinically relevant covariates (parity and history of prior preterm birth). Variables with $P<0.10$ in univariate analysis or established clinical importance were considered for inclusion.

A P value <0.05 was considered statistically significant.

Results

General Data Between the 2 Groups

As shown in **Table 2**, there were no significant differences in maternal age, gestational age at ultrasound examination, body mass index, parity, history of prior preterm birth, smoking status, or in vitro fertilization conception between the preterm and full-term groups (all $P>0.05$). These findings indicated that the 2 groups were well-balanced with respect to these potential confounding variables, supporting the validity of subsequent comparisons of cervical parameters.

Among the 23 preterm births, 18 (78.3%) were classified as spontaneous preterm birth, and 5 (21.7%) were classified as iatrogenic preterm births. The indications for iatrogenic preterm delivery included severe preeclampsia (n=3) and placental abruption (n=2). Given that our study specifically targeted spontaneous preterm birth, the inclusion of a small number of iatrogenic cases (which were identified after delivery) represents a limitation, and a sensitivity analysis excluding these cases was performed (see below).

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Table 2. General data of the 2 groups of pregnant women during gestational weeks 16 to 35.

Index	Preterm group (n=23)	Full-term group (n=77)	t value	P value
Age (years)	29.15±4.57	29.48±4.62	0.30	0.76
Gestational age (weeks)	22.32±1.83	22.15±1.94	0.45	0.65
BMI (kg/m^2)	21.20±2.36	21.23±2.32	0.05	0.95
Parity (nulliparous), n (%)	14 (60.9)	48 (62.3)	0.02	0.90
Prior preterm birth, n (%)	2 (8.7)	5 (6.5)	0.13	0.72
Smoking during pregnancy, n (%)	1 (4.3)	3 (3.9)	0.01	0.92
IVF conception, n (%)	2 (8.7)	6 (7.8)	0.02	0.89

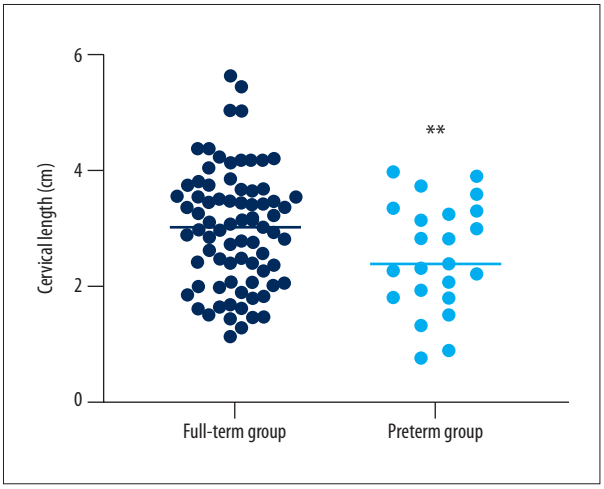

Figure 2. Comparison of cervical length (CL) between the 2 groups. ** *P*<0.01.

Reproducibility of SWE Measurements

The intraobserver and interobserver reproducibility for SWE parameters were excellent. The ICC values for intraobserver reliability were 0.92 (95% CI: 0.88-0.95) for IOS, 0.90 (95% CI: 0.85-0.94) for EOS, 0.89 (95% CI: 0.84-0.93) for ECI, and 0.91 (95% CI: 0.87-0.94) for HR. For interobserver reliability, the ICC values were 0.88 (95% CI: 0.82-0.92) for IOS, 0.86 (95% CI: 0.80-0.91) for EOS, 0.85 (95% CI: 0.78-0.90) for ECI, and 0.87 (95% CI: 0.81-0.92) for HR. These high ICC values (>0.85) indicate that the SWE measurements were highly consistent and reliable, supporting the robustness of subsequent analyses.

Comparison of Cervical Parameters Between the 2 Groups

Compared with the full-term group, the preterm group exhibited significantly shorter CL (*P*<0.01, **Figure 2**). For SWE parameters, the preterm group demonstrated lower HR and higher ECI, IOS, and EOS (all *P*<0.05, **Figure 3**). These findings suggest that, as early as 18 to 24 weeks of gestation, women who subsequently delivered preterm had not only a shorter cervix but also distinct biomechanical properties: softer cervical tissue (lower HR), increased stiffness at both the internal and external os, and greater tissue heterogeneity (higher ECI).

Multicollinearity Assessment and Variable Selection

Before constructing multivariable models, we assessed multicollinearity among the 5 candidate predictors. The VIF values were CL, 1.32; ECI, 4.87; HR, 5.23; IOS, 4.56; and EOS, 4.92. The VIF exceeding 5 for HR indicated concerning multicollinearity among the elastography parameters, supporting the need for variable reduction to ensure model stability. Based on clinical relevance and univariate significance, we selected 3 key predictors for the final multivariable model: CL (representing cervical morphology), IOS (representing SWE-based stiffness), and ECI (representing strain elastography-based tissue heterogeneity).

Association of Cervical Parameters With Preterm Birth Risk

In univariate logistic regression analysis, all 5 cervical parameters were significantly associated with preterm birth risk: shorter CL (OR: 0.89, 95% CI: 0.82-0.95; *P*<0.01), lower HR (OR: 0.78, 95% CI: 0.68-0.89; *P*<0.01), higher ECI (OR: 1.45, 95% CI: 1.18-1.79; *P*<0.01), higher IOS (OR: 1.12, 95% CI: 1.05-1.20; *P*<0.01), and higher EOS (OR: 1.15, 95% CI: 1.07-1.24; *P*<0.01).

In the reduced multivariable model (including CL, IOS, and ECI), all 3 parameters remained independent predictors of preterm birth: CL (aOR: 0.90, 95% CI: 0.83-0.97; *P*<0.01), IOS (aOR: 1.10, 95% CI: 1.03-1.18; *P*<0.01), and ECI (aOR: 1.28, 95% CI: 1.06-1.55; *P*=0.01). These adjusted odds ratios indicate that even after accounting for the other cervical parameters, each variable contributed independently to the prediction of preterm birth. Specifically, for every 1-mm decrease in CL, the odds of preterm birth increased by approximately 11%; for every 1-kPa increase in IOS, the odds increased by 10%; and for every 0.1-unit increase in ECI, the odds increased by 28%.

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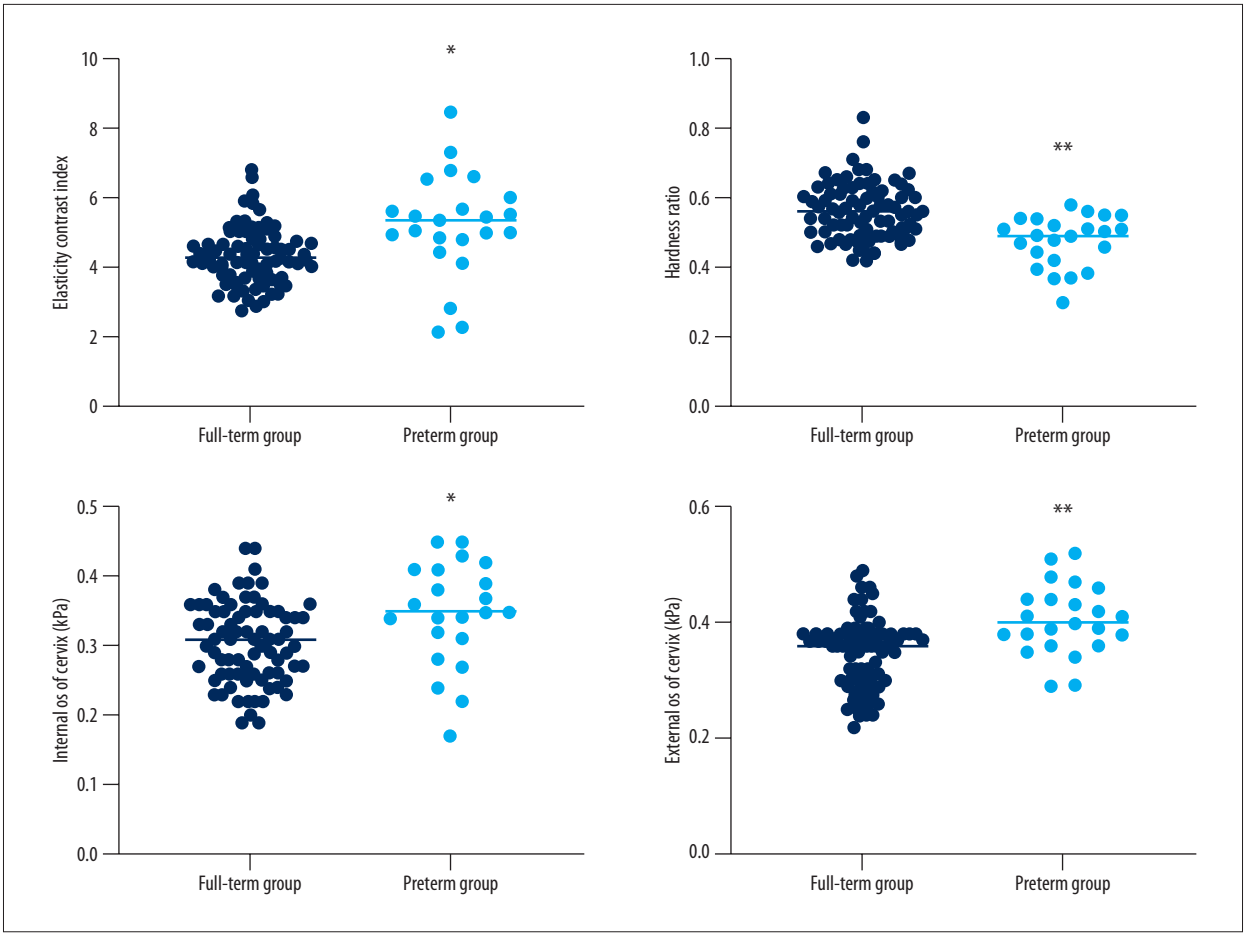

Figure 3. Comparison of shear wave elastography (SWE) parameters between the 2 groups. ** *P*<0.01.

Exploratory Analysis of Correlations With Gestational Age at Delivery

As a secondary analysis, we examined correlations between cervical parameters measured at 18 to 24 weeks and the eventual gestational age at delivery. As shown in **Figures 4 and 5**, CL was positively correlated with gestational age at delivery (r=0.31, *P*<0.01), while ECI (r=-0.34), IOS (r=-0.26), and EOS (r=-0.40) were negatively correlated with gestational age at delivery (all *P*<0.05). HR was positively correlated with the gestational age at the time of delivery (r=0.25, *P*=0.01). These correlations, although modest, are consistent with the expected physiological trend: women with a shorter, softer, and stiffer os cervix at mid-gestation tended to deliver earlier. However, these findings are exploratory and should be interpreted with caution, as correlation with continuous gestational age does not directly equate to prediction of the binary outcome of preterm birth.

Predictive Performance of Individual Parameters

ROC curve analysis was performed to evaluate the predictive value of each parameter for preterm birth. CL alone achieved an AUC of 0.709 (95% CI: 0.558-0.861), with a sensitivity of 47.8% and specificity of 91.3% at the optimal cut-off (**Table 3 and Figure 6**). This indicates that while CL is highly specific, its low sensitivity limits its utility as a standalone screening tool.

Among individual SWE parameters, EOS showed the highest AUC (0.866, 95% CI: 0.762-0.971), followed by HR (0.857, 95% CI: 0.749-0.964), IOS (0.844, 95% CI: 0.727-0.960), and ECI (0.762: 95% CI: 0.612-0.913) (all *P*<0.01, **Table 3 and Figure 7**). The high AUC values for EOS, HR, and IOS suggest that cervical stiffness parameters, particularly at the external os, have strong predictive potential individually.

Predictive Performance of the Combined Model

The reduced combined model (CL+IOS+ECI) demonstrated excellent predictive performance, with an AUC of 0.889 (95% CI: 0.791-0.985), a sensitivity of 82.6%, and a specificity of 87.0% at the optimal cut-off (*P*<0.01, **Table 3 and Figure 8**). This AUC was significantly higher than that of CL alone (*P*=0.01, DeLong test), indicating that adding SWE parameters to CL provided substantial incremental predictive value.

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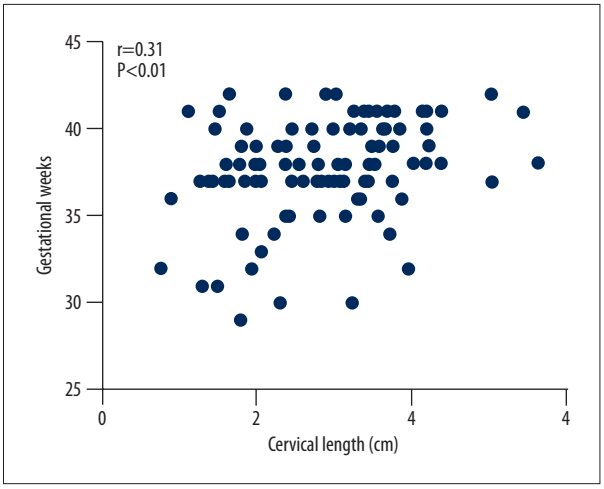

Figure 4. Correlation between cervical length (CL) and preterm birth.

Clinical Utility Metrics

To enhance the clinical applicability of our findings, we calculated additional performance metrics for each parameter and the combined model based on the optimal cut-off values determined by the Youden index. These metrics included PPV, NPV, LR+, and LR-, which are presented in **Table 4**.

For CL alone, at a cut-off of 26.9 mm, the PPV was 58.3% and NPV was 86.4%, with an LR+ of 5.49 and LR- of 0.57. This indicates that a short cervix (<26.9 mm) increases the probability of preterm birth approximately 5.5-fold, while a normal cervix reduces the probability by approximately 43%.

Among individual SWE parameters, EOS demonstrated the highest PPV (78.9%) and LR+ (13.82) at a cut-off of 0.38 kPa, indicating that increased stiffness at the external os is a strong

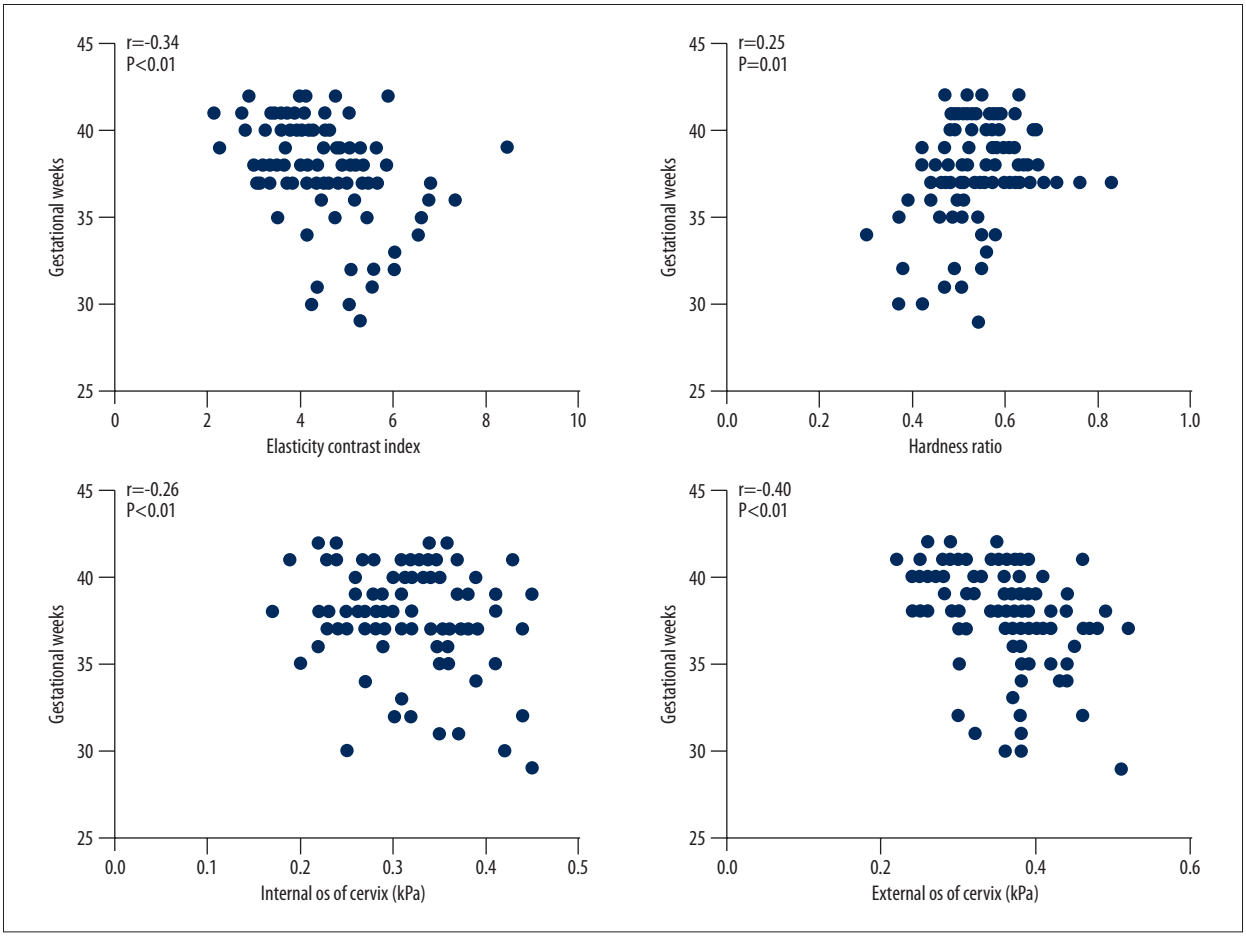

Figure 5. Correlation between shear wave elastography (SWE) parameters and preterm birth.

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Table 3. Sensitivity, specificity, and Youden Index of cervical length (CL) and shear wave elastography (SWE) parameters in predicting preterm birth.

Variable	AUC (95% CI)	Sensitivity	Specificity	Cut-off value	Youden Index	P value
CL	0.709 (0.558-0.861)	0.478	0.913	26.9 (mm)	0.391	<0.01
ECI	0.762 (0.612-0.913)	0.782	0.782	4.65	0.565	<0.01
HR	0.857 (0.749-0.964)	0.739	0.739	0.42	0.478	<0.01
IOS	0.844 (0.727-0.960)	0.772	0.782	0.30 (kPa)	0.555	<0.01
EOS	0.866 (0.762-0.971)	0.608	0.956	0.38 (kPa)	0.565	<0.01
CL+IOS+ECI	0.889 (0.791-0.985)	0.826	0.870	0.52	0.696	<0.01

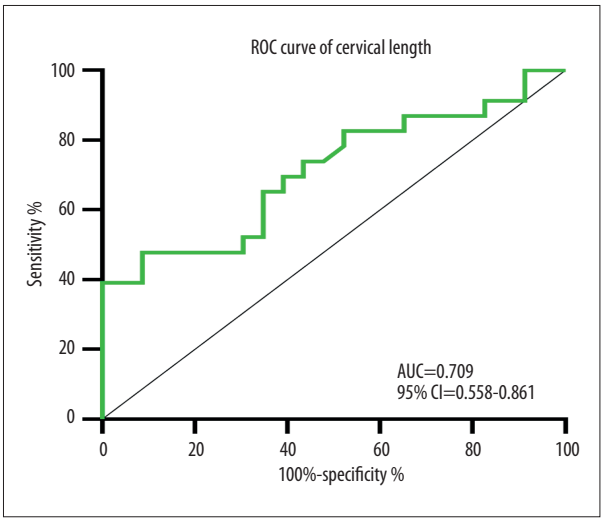

Figure 6. ROC curve analysis of cervical length (CL) in predicting preterm birth.

clinical predictor. The combined model (CL+IOS+ECI) achieved the best overall performance, with a PPV of 76.0%, NPV of 91.8%, LR+ of 6.66, and LR- of 0.20 at a cut-off of 0.52. The high NPV (91.8%) suggests that this model is particularly effective at ruling out preterm birth, which is clinically valuable for avoiding unnecessary interventions in women at low risk.

Internal Validation and Model Calibration

Bootstrap validation with 1000 resamples yielded an optimism-corrected AUC of 0.881 (95% CI: 0.792-0.958) for the combined model. The minimal shrinkage from 0.889 to 0.881 suggests that overfitting was not a major concern despite the modest sample size. The Hosmer-Lemeshow test (χ^2=6.24, P=0.62) indicated good calibration, and the Brier score of 0.11 confirmed excellent overall model performance. These internal validation results support the robustness and stability of the combined predictive model.

Sensitivity Analysis Excluding Iatrogenic Preterm Births

To assess the potential effect of including iatrogenic preterm births (n=5), we performed a sensitivity analysis excluding these cases, leaving 18 spontaneous preterm births and 77 full-term births. The combined model (CL+IOS+ECI) remained a strong predictor, with an AUC of 0.882 (95% CI: 0.798-0.966), sensitivity of 83.3%, and specificity of 87.0%. These results were similar to that of the primary analysis, suggesting that the inclusion of a small number of iatrogenic cases did not materially bias our findings.

To further assess the robustness of our findings, we performed a multivariable logistic regression analysis adjusting for parity and history of prior preterm birth in addition to CL, IOS, and ECI. After adjustment for these clinical covariates, the combined model remained a significant predictor of spontaneous preterm birth (adjusted OR for the model score: 1.15 per 0.1-unit increase, 95% CI: 1.08-1.23; P<0.01). The AUC of the model after adjusting for clinical covariates was 0.892 (95% CI: 0.818-0.966), similar to the unadjusted model (0.889), indicating that the predictive value of the cervical parameters was independent of these clinical risk factors.

Discussion

In this retrospective study of 100 asymptomatic pregnant women at low risk of preterm birth who were examined at 18 to 24 weeks of gestation, we found that combining CL with SWE parameters demonstrated promising predictive performance for spontaneous preterm birth. Specifically, our reduced multivariable model incorporating CL, IOS, and ECI achieved an AUC of 0.889, with good calibration and internal validation. These findings suggest that integrating biomechanical cervical assessment with conventional morphological evaluation could potentially enhance early risk stratification for preterm birth in low-risk populations, although these results should be considered preliminary.

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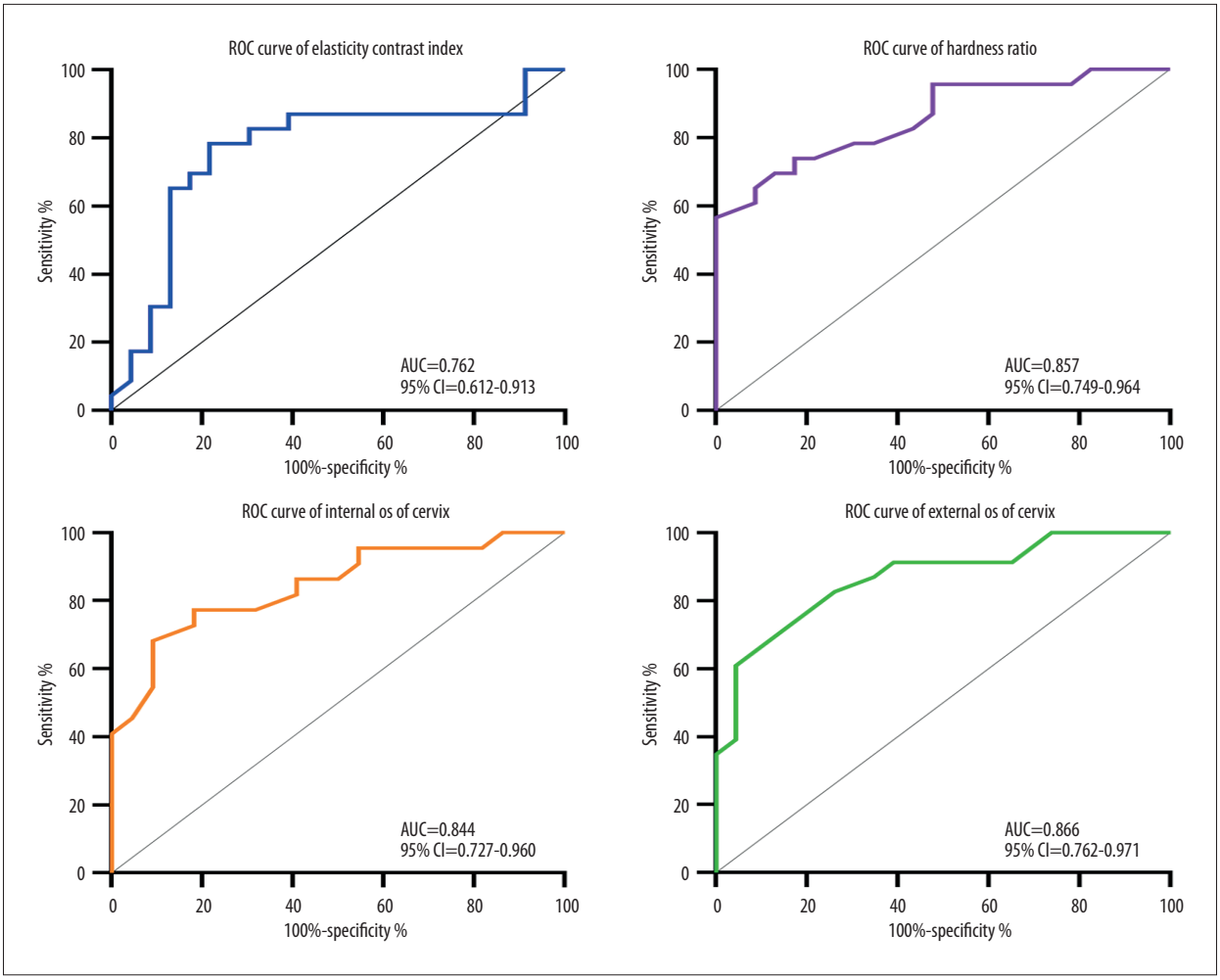

Figure 7. ROC curve analysis of shear wave elastography (SWE) parameters in predicting preterm birth.

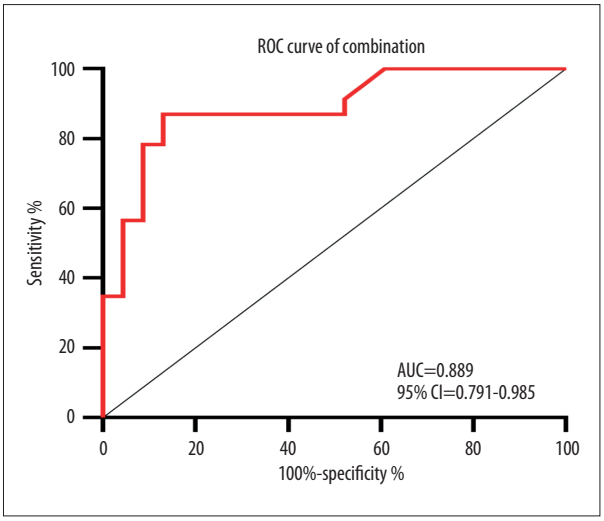

Figure 8. ROC curve analysis of cervical length (CL) combined with shear wave elastography (SWE) parameters in predicting preterm birth.

Our finding that CL was significantly shorter in the preterm group (AUC 0.709) is consistent with established evidence. The modest sensitivity of CL alone (47.8%) underscores its limitation as a standalone screening tool [17], supporting the need for complementary biomarkers.

Regarding SWE parameters, our observation that women with preterm birth had higher IOS and EOS (indicating increased stiffness at the cervical os) and lower HR (indicating overall softening) aligns with the known pathophysiology of premature cervical remodeling [18,19]. Similar findings have been reported in twin and singleton pregnancies [20,21], and our AUC values for individual SWE parameters (0.762-0.866) are comparable to those of Yang et al [22], who found that adding cervical stiffness to CL improved predictive performance. The discrepancy with a prior negative study [23] likely reflects differences in SWE acquisition protocols and population characteristics, highlighting the need for standardized methodology.

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Table 4. Clinical utility metrics for cervical parameters in predicting preterm birth.

Variable	Cut-off value	PPV (%)	NPV (%)	LR+	LR-
CL	26.9 (mm)	58.3	86.4	5.49	0.57
ECI	4.65	47.4	93.8	3.59	0.28
HR	0.42	44.7	91.9	2.83	0.35
IOS	0.30 (kPa)	47.2	93.8	3.55	0.29
EOS	0.38 (kPa)	78.9	88.0	13.82	0.41
CL+IOS+ECI	0.52	76.0	91.8	6.66	0.20

Given the modest sample size and the events-per-variable ratio of approximately 7.7—which is below the recommended threshold of 10 to 20 for robust prediction model development—our findings should be interpreted as exploratory and hypothesis-generating. The model's representativeness is limited to our specific low-risk cohort, and the reported predictive performance (AUC 0.889) may be optimistic. Therefore, prospective external validation in larger, more diverse populations is mandatory before any clinical application can be considered.

Clinical Implications

If validated in prospective studies, the superior predictive performance of the combined model (CL+IOS+ECI) has several potential clinical implications. First, pending external validation, this approach could be integrated into routine mid-trimester ultrasound screening to identify asymptomatic women at increased risk for spontaneous preterm birth. Currently, risk stratification relies heavily on CL measurement alone, which misses a substantial proportion of women who will subsequently deliver preterm (sensitivity <50% in our cohort). Adding SWE parameters could improve risk detection, enabling targeted interventions such as enhanced surveillance, progesterone administration, or cervical cerclage in appropriately selected candidates.

Second, the independent contribution of IOS and ECI suggests that different aspects of cervical remodeling, namely stiffness at the internal os and tissue heterogeneity, capture distinct pathological processes. This may inform future research into the underlying mechanisms of preterm birth and guide the development of targeted preventive strategies.

Third, the noninvasive nature, rapid acquisition (approximately 2-3 minutes added to standard ultrasound), and excellent reproducibility (ICC >0.85) of the SWE measurement support its potential feasibility for clinical implementation. However, cost-effectiveness analyses and demonstration of improved pregnancy outcomes in prospective trials would be necessary before widespread adoption.

Fourth, the clinical utility metrics presented in **Table 4** further support the potential value of this combined approach. The high NPV of 91.8% suggests that the combined model could be particularly useful for ruling out preterm birth in asymptomatic women, while the PPV of 76.0% indicates that approximately 3 out of 4 women identified as being at high risk would indeed deliver preterm. These metrics, along with likelihood ratios (LR+ 6.66, LR- 0.20), compare favorably with established clinical tests and support the potential integration of this approach.

Strengths and Limitations

This study has several strengths, including the use of a standardized SWE protocol with strict quality control, assessment of multiple complementary elastography parameters, demonstration of excellent measurement reproducibility, and rigorous statistical approaches to address overfitting (variable reduction, bootstrap validation, calibration assessment).

However, several limitations must be acknowledged. First, the modest sample size (n=100) and limited number of preterm events (n=23) restricted our ability to develop more complex models or conduct subgroup analyses. Although we mitigated overfitting through variable selection and bootstrap validation, our events-per-variable ratio of approximately 7.7 remains below the recommended threshold of 10 to 20 for robust prediction model development. Consequently, our findings should be considered exploratory and require external validation in larger, independent cohorts before any clinical adoption. Second, the single-center retrospective design may limit generalizability. Whether these findings apply to other populations, gestational windows, or clinical settings remains unknown. Third, despite our efforts to exclude iatrogenic preterm births through strict criteria, 5 such cases were identified post hoc. While sensitivity analysis excluding these cases yielded similar results (AUC 0.882), the inability to completely separate spontaneous from indicated preterm birth in a retrospective design may introduce some residual confounding.

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Future Research Directions

Most importantly, external validation in independent cohorts is essential before any clinical application can be considered. Prospective multicenter studies with larger sample sizes are urgently needed to externally validate our combined model and establish normative values for SWE parameters across gestation. Such studies should also evaluate whether implementing SWE-based risk stratification improves clinical outcomes, such as reduced preterm birth rates through targeted interventions. Additionally, head-to-head comparisons with existing biomarkers (eg, fetal fibronectin) and cost-effectiveness analyses would inform optimal integration into clinical practice. Finally, efforts to standardize SWE acquisition protocols across devices and centers are essential to facilitate broader clinical adoption and comparability of research findings.

Conclusions

This preliminary study suggests that combining CL measurement with SWE parameters—specifically IOS and ECI—may provide superior predictive accuracy for spontaneous preterm birth compared with CL alone in women who are asymptomatic and at low risk. By capturing cervical morphology and biomechanical properties during the mid-trimester, this integrated, noninvasive approach could potentially enhance early identification of women at risk for preterm birth in this specific population. However, these findings require external validation in larger, more diverse cohorts and prospective studies demonstrating improved clinical outcomes before any consideration for routine clinical use.

Department and Institution Where Work Was Done

Affiliated Maternity and Child Health Care Hospital of Nantong University, Nantong, Jiangsu, PR China.

Patient Permission/Consent Declaration

This study was approved by the Ethics Committee of the Affiliated Maternity and Child Health Care Hospital of Nantong University. Written informed consent was obtained from all participants and their families.

Declaration of Figures' Authenticity

All figures submitted have been created by the authors who confirm that the images are original with no duplication and have not been previously published in whole or in part.

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