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A Comparative Study of Cervical Length Measurement by Ultrasound Versus Digital Examination for Predicting Preterm Labor in Low-Risk Population

Dr. Lata K Mankani[1], Dr. Santosh S Ankalagi[2]

[1]Assistant Professor, Department of OBG, KLE Jagadguru Gangadhar Mahaswamigalu Moorusavirmath Medical College and Hospital, Hubli, KLE Academy of Higher Education and Research, Deemed to be University, Belagavi, Karnataka, India – 590010

Email ID: latakmankani@gmail.com

[2]Assistant Professor, Department of OBG, KLE Jagadguru Gangadhar Mahaswamigalu Moorusavirmath Medical College and Hospital, Hubli, KLE Academy of Higher Education and Research, Deemed to be University, Belagavi, Karnataka, India – 590010

Email ID: ankalagis7@gmail.com

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ABSTRACT

Background: Preterm birth remains a significant cause of neonatal morbidity and mortality worldwide. Early identification of women at risk for preterm labor is crucial for timely intervention. This study aimed to compare the accuracy of cervical length measurement by transvaginal ultrasound versus digital examination in predicting preterm labor in a low-risk population.

Methods: This prospective cohort study included 240 pregnant women with singleton pregnancies between 20-24 weeks of gestation without prior history of preterm birth. Cervical length was assessed by both transvaginal ultrasound and digital examination at enrollment and at 28 weeks. Participants were followed until delivery, with preterm birth (delivery before 37 completed weeks) as the primary outcome. Sensitivity, specificity, positive and negative predictive values were calculated for both methods. Receiver operating characteristic (ROC) curves were constructed to determine optimal cut-off values.

Results: The overall preterm birth rate was 8.75% (21/240). The mean cervical length by ultrasound was significantly shorter in women who delivered preterm compared to those who delivered at term (28.3±4.2 mm vs. 36.5±3.9 mm, $p<0.001$). Digital examination had lower accuracy in estimating cervical length compared to ultrasound ($r=0.42$, $p<0.001$). For prediction of preterm birth, a cervical length <30 mm by ultrasound at 20-24 weeks had a sensitivity of 76.2%, specificity of 82.4%, positive predictive value of 29.1%, and negative predictive value of 97.3%. In contrast, digital examination had a sensitivity of 38.1%, specificity of 68.4%, positive predictive value of 10.4%, and negative predictive value of 92.1%.

Conclusion: Transvaginal ultrasound measurement of cervical length is superior to digital examination for predicting preterm labor in low-risk women. A cervical length <30 mm at 20-24 weeks gestation can effectively identify women at risk for preterm birth, allowing for closer surveillance and timely interventions.

Keywords: *APH, Maternal outcomes, Fetal outcomes*

1. INTRODUCTION

Preterm birth, defined as delivery before 37 completed weeks of gestation, remains one of the most significant challenges in obstetric care and a leading cause of neonatal morbidity and mortality worldwide. According to global estimates, approximately 15 million babies are born preterm annually, representing about 11% of all live births, with rates varying from 5% to 18% across different regions.1 In India, the reported prevalence of preterm birth ranges from 10% to 15%, contributing significantly to the burden of infant mortality.2 Despite advances in perinatal care, the rate of preterm birth has not decreased significantly over the past few decades, emphasizing the need for effective prediction and prevention strategies.

The etiology of preterm birth is multifactorial and complex, involving genetic, environmental, socioeconomic, and medical factors. Common risk factors include history of previous preterm birth, multiple gestation, uterine anomalies, cervical insufficiency, maternal infections, and medical disorders such as hypertension and diabetes.3 However, a substantial proportion of preterm births occur in women without identifiable risk factors, making prediction challenging, particularly in low-risk populations.

Early identification of women at risk for preterm birth is crucial for implementing timely interventions, such as administration of corticosteroids for fetal lung maturation, tocolytic therapy, and referral to tertiary care centers with appropriate neonatal facilities. This approach has been shown to significantly improve neonatal outcomes.4 Therefore, developing reliable methods for predicting preterm birth has been a focus of research in recent years.

The cervix plays a critical role in maintaining pregnancy, acting as a mechanical barrier between the vagina and the uterine cavity. Cervical remodeling, including shortening and softening, is one of the early changes that precede preterm labor, often occurring weeks before the onset of clinical symptoms.5 Assessment of cervical length and integrity has emerged as a promising approach for predicting preterm birth.

Traditionally, digital examination has been the standard method for assessing cervical status in clinical practice. This method involves the assessment of cervical length, position, consistency, and dilation through vaginal examination. However, digital examination is subjective, with significant inter-observer variability, and may not accurately assess the entire cervical length, particularly the supravaginal portion.6 Additionally, digital examination involves manipulation of the cervix, which may potentially increase the risk of infection or precipitate preterm labor.

In recent decades, transvaginal ultrasonography has gained popularity as an objective and reproducible method for assessing cervical length. This technique allows visualization of the entire cervix, including the internal os, external os, and cervical canal, providing a more accurate measurement of cervical length.7 Numerous studies have demonstrated an inverse relationship between cervical length measured by transvaginal ultrasound and the risk of preterm birth, with shorter cervical lengths associated with higher risks.8,9

While the utility of cervical length measurement in high-risk populations, such as women with a history of preterm birth or cervical insufficiency, is well-established, its role in low-risk populations remains a subject of debate. Some studies suggest that universal cervical length screening may be beneficial in identifying women at risk for preterm birth who would otherwise be missed by risk-based screening.10 However, concerns about cost-effectiveness, availability of resources, and potential for unnecessary interventions have limited the widespread adoption of universal screening.

Furthermore, most studies comparing ultrasound and digital examination for cervical assessment have focused on high-risk populations or women presenting with symptoms of preterm labor. There is limited data on the comparative accuracy of these methods in low-risk, asymptomatic women, particularly in the Indian context where resource constraints may influence the choice of screening methods.

Therefore, this study aimed to compare the accuracy of cervical length measurement by transvaginal ultrasound versus digital examination in predicting preterm labor in a low-risk population without prior history of preterm birth. We hypothesized that transvaginal ultrasound would provide a more accurate assessment of cervical length and better prediction of preterm birth compared to digital examination. Additionally, we sought to determine the optimal cut-off value of cervical length for predicting preterm birth in our population.

The findings of this study will contribute to the ongoing debate on universal versus risk-based cervical length screening and help in developing evidence-based protocols for preterm birth prediction in low-resource settings. By identifying a simple, cost-effective, and reliable method for predicting preterm birth, we aim to facilitate early intervention and ultimately improve maternal and neonatal outcomes.

2. AIMS AND OBJECTIVES

Primary Objectives

The primary objectives of this study were:

1. To compare the sensitivity and specificity of cervical length measurement by transvaginal ultrasound versus digital examination in predicting preterm labor in a low-risk population.
2. To determine the positive predictive value and negative predictive value of both methods for predicting preterm birth.
3. To establish the optimal cut-off value of cervical length for predicting preterm birth in our population.
4. To evaluate the effectiveness of different assessment methods (digital examination alone, transvaginal ultrasound alone, or both methods combined) in predicting preterm labor.
5. To assess the correlation between cervical length measurements obtained by the two methods.

Secondary Objectives

The secondary objectives were:

1. To evaluate the association between progressive changes in cervical length and the risk of preterm birth.
2. To identify other potential risk factors that may enhance the predictive value of cervical length measurement.
3. To assess the feasibility and acceptability of different cervical assessment methods in clinical practice.

3. MATERIALS AND METHODS

Study Design and Setting

This prospective cohort study was conducted at the Department of Obstetrics and Gynecology, KLE Jagadguru Gangadhar Mahaswamigalu Moorusavirmath Medical College and Hospital, Hubli, KLE Academy of Higher Education and Research, Deemed to be University, Belagavi, Karnataka, India – 590010, and its affiliated hospitals (KLE'S Suchirayu Hospital Hubballi & KLE'S Hubballi Co-operative Hospital Hubballi) from January 2023 to December 2023. The study protocol was approved by the Institutional Ethics Committee, and written informed consent was obtained from all participants.

Sample Size Calculation

The sample size was calculated based on the estimated prevalence of preterm birth in the low-risk population (10%) and the expected sensitivity of transvaginal ultrasound for predicting preterm birth (70%). Using a confidence level of 95% and a margin of error of 5%, the minimum required sample size was 218. Considering a potential dropout rate of 10%, we enrolled 240 participants.

Study Population

Pregnant women attending the antenatal clinics of our institution and affiliated hospitals were screened for eligibility. The inclusion criteria were: (1) singleton pregnancy, (2) gestational age between 20-24 weeks confirmed by first-trimester ultrasound, (3) no history of preterm birth, and (4) absence of known risk factors for preterm birth such as uterine anomalies, cervical insufficiency, or medical disorders. The exclusion criteria were: (1) multiple gestation, (2) history of preterm birth or second-trimester miscarriage, (3) known uterine anomalies or cervical surgery, (4) placenta previa, (5) ruptured membranes, (6) active vaginal bleeding, and (7) medical disorders such as pre-eclampsia, diabetes, or systemic infections.

Study Procedures

At enrollment, detailed demographic and obstetric information was collected from all participants, including age, parity, socioeconomic status, education level, and occupation. A thorough medical and obstetric history was obtained, and a general physical and obstetric examination was performed.

Eligible participants were randomly allocated into three groups:

- Group A: Cervical assessment by digital examination only
- Group B: Cervical assessment by transvaginal ultrasound only
- Group C: Cervical assessment by both digital examination and transvaginal ultrasound

Cervical assessment was performed at enrollment (20-24 weeks) and at 28 weeks. All examinations were performed by experienced obstetricians who had undergone standardized training for cervical length assessment. In Group C, the obstetricians performing the digital examination were blinded to the ultrasound findings and vice versa.

Transvaginal Ultrasound Examination

Transvaginal ultrasound was performed using a Siemens Acuson X300 ultrasound machine with a 5-8 MHz transvaginal probe. The examination was performed with the patient in the dorsal lithotomy position with an empty bladder. The probe was inserted into the vagina and placed in the anterior fornix. The sagittal view of the cervix was obtained, visualizing the internal os, external os, and cervical canal. The cervical length was measured from the internal os to the external os along the endocervical canal. Three measurements were taken, and the shortest was recorded. The presence of funneling (dilatation of the internal os) or sludge (particulate matter in the amniotic fluid near the internal os) was noted.

Digital Examination

Digital examination was performed with the patient in the dorsal lithotomy position. The examiner inserted two fingers into the vagina and assessed the cervical length by estimating the distance from the external os to the cervicovaginal junction. The cervical position, consistency, and dilatation were also noted. The Bishop score was calculated based on these parameters.

Follow-up and Outcome Assessment

All participants were followed up regularly at the antenatal clinic until delivery. Additional cervical assessments were performed if clinically indicated, such as in case of symptoms of preterm labor. Information on the gestational age at delivery, mode of delivery, birth weight, Apgar scores, and neonatal outcomes was collected.

The primary outcome was preterm birth, defined as delivery before 37 completed weeks of gestation. Secondary outcomes included early preterm birth (delivery before 34 weeks), very early preterm birth (delivery before 32 weeks), birth weight, Apgar scores, neonatal intensive care unit admission, and perinatal mortality.

Statistical Analysis

Data were analyzed using SPSS version 25.0. Continuous variables were expressed as mean ± standard deviation or median with interquartile range, depending on the distribution. Categorical variables were expressed as frequencies and percentages. The comparison of continuous variables between groups was performed using the one-way ANOVA or Kruskal-Wallis test, as appropriate. Post-hoc analysis was performed for significant results. Categorical variables were compared using the chi-square test or Fisher's exact test.

The correlation between cervical length measurements obtained by transvaginal ultrasound and digital examination in Group C was assessed using Pearson's correlation coefficient. The agreement between the two methods was evaluated using the Bland-Altman plot.

The sensitivity, specificity, positive predictive value, and negative predictive value of each assessment method (digital examination alone, transvaginal ultrasound alone, or both methods combined) for predicting preterm birth were calculated. Receiver operating characteristic (ROC) curves were constructed to determine the optimal cut-off values of cervical length for predicting preterm birth. The area under the ROC curve (AUC) was calculated to assess the overall predictive performance of each method.

Univariate and multivariate logistic regression analyses were performed to identify independent predictors of preterm birth. Variables with a p-value < 0.1 in the univariate analysis were included in the multivariate model. A p-value < 0.05 was considered statistically significant for all analyses.

4. RESULTS

Demographic and Baseline Characteristics

A total of 300 pregnant women were enrolled in the study (100 in each group), of whom 285 (95%) completed the follow-up and were included in the final analysis (Group A: n=94, Group B: n=96, Group C: n=95). The mean age of the participants was 26.4 ± 4.2 years, and the mean gestational age at enrollment was 22.1 ± 1.3 weeks. The majority of the participants (65.6%) were nulliparous. The baseline characteristics of the study population are presented in Table 1.

Table 1: Baseline Characteristics of the Study Population

Characteristic	Group A (n=94)	Group B (n=96)	Group C (n=95)	p-value
Age (years), mean ± SD	26.2 ± 4.3	26.5 ± 4.1	26.6 ± 4.2	0.78
Gestational age at enrollment (weeks), mean ± SD	22.0 ± 1.4	22.2 ± 1.2	22.1 ± 1.3	0.54
Parity, n (%)				0.82
Nulliparous	63 (67.0%)	61 (63.5%)	63 (66.3%)	
Multiparous	31 (33.0%)	35 (36.5%)	32 (33.7%)	
Socioeconomic status, n (%)				0.93
Low	22 (23.4%)	24 (25.0%)	21 (22.1%)	
Middle	52 (55.3%)	53 (55.2%)	54 (56.8%)	
High	20 (21.3%)	19 (19.8%)	20 (21.1%)	
Education level, n (%)				0.89
Primary	18 (19.1%)	17 (17.7%)	16 (16.8%)	
Secondary	39 (41.5%)	42 (43.8%)	40 (42.1%)	

Characteristic	Group A (n=94)	Group B (n=96)	Group C (n=95)	p-value
Higher	37 (39.4%)	37 (38.5%)	39 (41.1%)	
Occupation, n (%)				0.76
Housewife	69 (73.4%)	72 (75.0%)	68 (71.6%)	
Employed	25 (26.6%)	24 (25.0%)	27 (28.4%)	

There were no significant differences in the baseline characteristics among the three groups, indicating successful randomization.

Pregnancy Outcomes

The overall preterm birth rate in our study population was 9.12% (26/285), with 5.26% (15/285) delivering between 34-37 weeks, 2.81% (8/285) between 32-34 weeks, and 1.05% (3/285) before 32 weeks. The mean gestational age at delivery was 38.3 ± 2.1 weeks. The pregnancy outcomes by group are summarized in Table 2.

Table 2: Pregnancy Outcomes by Group

Outcome	Group A (n=94)	Group B (n=96)	Group C (n=95)	p-value
Gestational age at delivery (weeks), mean ± SD	38.1 ± 2.4	38.4 ± 2.0	38.3 ± 2.0	0.62
Preterm birth (<37 weeks), n (%)	9 (9.57%)	8 (8.33%)	9 (9.47%)	0.94
34-37 weeks	5 (5.32%)	5 (5.21%)	5 (5.26%)	0.99
32-34 weeks	3 (3.19%)	2 (2.08%)	3 (3.16%)	0.84
<32 weeks	1 (1.06%)	1 (1.04%)	1 (1.05%)	0.99
Mode of delivery, n (%)				0.78
Vaginal delivery	63 (67.0%)	67 (69.8%)	68 (71.6%)	
Cesarean section	31 (33.0%)	29 (30.2%)	27 (28.4%)	
Birth weight (g), mean ± SD	2965 ± 470	2998 ± 455	2990 ± 461	0.87
Low birth weight (<2500 g), n (%)	14 (14.9%)	12 (12.5%)	13 (13.7%)	0.88
Apgar score at 5 minutes, median (IQR)	9 (8-9)	9 (8-9)	9 (8-9)	0.94
NICU admission, n (%)	11 (11.7%)	9 (9.4%)	10 (10.5%)	0.87
Perinatal mortality, n (%)	1 (1.1%)	1 (1.0%)	1 (1.1%)	0.99

There were no significant differences in pregnancy outcomes among the three groups.

Cervical Length Measurements and Comparison Between Groups

Group A: Digital Examination Only

In Group A, the mean cervical length measured by digital examination at enrollment (20-24 weeks) was 32.6 ± 5.1 mm. Women who subsequently delivered preterm had significantly shorter cervical lengths compared to those who delivered at term (28.4 ± 4.9 mm vs. 33.0 ± 4.8 mm, p=0.009). At 28 weeks, the mean cervical length was 30.2 ± 5.6 mm, with significantly shorter lengths in the preterm group (25.6 ± 5.7 mm vs. 30.7 ± 5.3 mm, p=0.005).

Group B: Transvaginal Ultrasound Only

In Group B, the mean cervical length measured by transvaginal ultrasound at enrollment was 35.8 ± 4.7 mm. Women who delivered preterm had significantly shorter cervical lengths compared to those who delivered at term (27.9 ± 4.5 mm vs. 36.7 ± 3.9 mm, p<0.001). At 28 weeks, the mean cervical length was 33.4 ± 5.0 mm, with significantly shorter lengths in the preterm group (24.2 ± 4.6 mm vs. 34.3 ± 4.2 mm, p<0.001).

Group C: Both Methods Combined

In Group C, both methods were performed on each participant. The mean cervical length measured by transvaginal ultrasound at enrollment was 35.7 ± 4.6 mm, while the mean cervical length estimated by digital examination was 32.9 ± 5.0 mm, which was significantly lower (p<0.001). The correlation between the two methods was moderate (r=0.43, p<0.001), with digital examination consistently underestimating the cervical length compared to ultrasound. The Bland-Altman plot showed a mean difference of 2.8 mm (95% CI: 1.9-3.7 mm) between the two methods.

For women who delivered preterm in Group C, both transvaginal ultrasound and digital examination detected significantly shorter cervical lengths compared to those who delivered at term (TVS: 28.5 ± 4.1 mm vs. 36.5 ± 3.8 mm, p<0.001; DE: 29.6 ± 5.2 mm vs. 33.2 ± 4.9 mm, p=0.03).

The cervical length measurements by group and method are presented in Table 3.

Table 3: Cervical Length Measurements by Group and Method

Parameter	**Group A: Digital Examination**	**Group B: Transvaginal Ultrasound**	**Group C: Both Methods**
At 20-24 weeks			
All participants, mean ± SD	32.6 ± 5.1 mm	35.8 ± 4.7 mm	TVS: 35.7 ± 4.6 mm DE: 32.9 ± 5.0 mm
Preterm birth, mean ± SD	28.4 ± 4.9 mm	27.9 ± 4.5 mm	TVS: 28.5 ± 4.1 mm DE: 29.6 ± 5.2 mm
Term birth, mean ± SD	33.0 ± 4.8 mm	36.7 ± 3.9 mm	TVS: 36.5 ± 3.8 mm DE: 33.2 ± 4.9 mm
p-value (preterm vs. term)	0.009	<0.001	TVS: <0.001 DE: 0.03
At 28 weeks			
All participants, mean ± SD	30.2 ± 5.6 mm	33.4 ± 5.0 mm	TVS: 33.3 ± 5.1 mm DE: 30.7 ± 5.5 mm
Preterm birth, mean ± SD	25.6 ± 5.7 mm	24.2 ± 4.6 mm	TVS: 24.8 ± 4.7 mm DE: 26.2 ± 5.9 mm
Term birth, mean ± SD	30.7 ± 5.3 mm	34.3 ± 4.2 mm	TVS: 34.2 ± 4.3 mm DE: 31.2 ± 5.3 mm
p-value (preterm vs. term)	0.005	<0.001	TVS: <0.001 DE: 0.009

TVS: Transvaginal ultrasound; DE: Digital examination

In Group C, the presence of funneling was detected by transvaginal ultrasound in 7.4% (7/95) of participants at enrollment, with a significantly higher proportion in the preterm group compared to the term group (55.6% vs. 2.3%, p<0.001).mm) (95% CI) | 2.8 (1.9-3.7) | 1.8 (0.2-3.4) | 3.4 (2.3-4.5) | - |

Predictive Performance for Preterm Birth

The ROC curve analysis for predicting preterm birth using cervical length measurements at 20-24 weeks was performed for each group. In Group A (digital examination only), the area under the curve (AUC) was 0.65 (95% CI: 0.52-0.78). In Group B (transvaginal ultrasound only), the AUC was 0.87 (95% CI: 0.79-0.95), which was significantly higher than Group A (p<0.001). In Group C, the AUC for transvaginal ultrasound was 0.86 (95% CI: 0.77-0.95), which was significantly higher than the AUC for digital examination (0.64, 95% CI: 0.53-0.75, p<0.001). However, when both methods were used together in Group C, the AUC increased to 0.89 (95% CI: 0.82-0.96), although this was not statistically significantly higher than transvaginal ultrasound alone (p=0.12).

The optimal cut-off values for predicting preterm birth were determined to be 28 mm for digital examination and 30 mm for transvaginal ultrasound. Using these cut-offs, the sensitivity, specificity, positive predictive value, and negative predictive value were calculated for each group and are presented in Table 4.

Table 4: Predictive Performance of Cervical Length Measurement for Preterm Birth

Parameter	**Group A: Digital Examination (<28 mm)**	**Group B: Transvaginal Ultrasound (<30 mm)**	**Group C: Both Methods**	**p-value**
Sensitivity (%)	44.4	75.0	77.8	<0.001
Specificity (%)	74.1	81.8	86.0	0.04
Positive predictive value (%)	15.4	28.6	36.8	0.03
Negative predictive value (%)	92.6	97.1	97.4	0.08
Positive likelihood ratio	1.71	4.12	5.56	<0.001
Negative likelihood ratio	0.75	0.31	0.26	<0.001
Accuracy (%)	71.3	81.3	85.3	<0.001

Transvaginal ultrasound (Group B) demonstrated superior performance in all predictive parameters compared to digital examination (Group A). The combination of both methods (Group C) showed slightly better performance than transvaginal ultrasound alone, particularly in terms of specificity and positive predictive value, although the differences were modest.

Progressive Cervical Length Changes

The change in cervical length between 20-24 weeks and 28 weeks was also evaluated as a predictor of preterm birth in each group. In Group A (digital examination), women who delivered preterm had a significantly greater decrease in cervical length compared to those who delivered at term (2.8 ± 1.4 mm vs. 2.3 ± 1.1 mm, p=0.04). In Group B (transvaginal ultrasound), the difference was more pronounced (3.7 ± 1.5 mm vs. 2.4 ± 1.1 mm, p<0.001). Similar findings were observed in Group C (transvaginal ultrasound: 3.7 ± 1.7 mm vs. 2.3 ± 1.2 mm, p<0.001; digital examination: 3.4 ± 1.5 mm vs. 2.0 ± 1.1 mm, p<0.001).

A decrease in cervical length of ≥3 mm between the two examinations had a sensitivity of 56.3% and a specificity of 72.8% for predicting preterm birth across all groups. When stratified by assessment method, transvaginal ultrasound showed better predictive performance for cervical length changes compared to digital examination.

Risk Factors for Preterm Birth

Univariate and multivariate logistic regression analyses were performed to identify independent predictors of preterm birth. In the univariate analysis, short cervical length by transvaginal ultrasound (<30 mm), short cervical length by digital examination (<28 mm), presence of funneling, decrease in cervical length ≥3 mm, and low socioeconomic status were significantly associated with preterm birth. In the multivariate analysis, only cervical length <30 mm by transvaginal ultrasound (OR 13.8, 95% CI: 5.1-37.4, p<0.001), presence of funneling (OR 5.3, 95% CI: 1.7-16.9, p=0.004), and decrease in cervical length ≥3 mm (OR 3.6, 95% CI: 1.3-9.8, p=0.01) remained independent predictors of preterm birth.

Table 5: Univariate and Multivariate Logistic Regression Analysis for Predictors of Preterm Birth

Notably, when both transvaginal ultrasound and digital examination results were combined in a predictive model, the odds ratio for preterm birth prediction increased to 16.5 (95% CI: 5.8-46.9, p<0.001), suggesting a potential benefit of using both methods together.

5. DISCUSSION

This prospective cohort study compared the accuracy of cervical length measurement by transvaginal ultrasound versus digital examination in predicting preterm labor in a low-risk population, with participants randomly allocated to three assessment groups. Our findings demonstrate that transvaginal ultrasound is superior to digital examination in predicting preterm birth, with higher sensitivity, specificity, and overall accuracy. A cervical length <30 mm measured by transvaginal ultrasound at 20-24 weeks gestation was identified as the optimal cut-off for predicting preterm birth in our population. Interestingly, the combination of both methods showed slightly better predictive performance than either method alone, particularly in terms of specificity and positive predictive value.

The preterm birth rate in our study was 9.12%, which is slightly lower than the reported national average but consistent with rates reported in low-risk populations. This relatively low rate underscores the challenge of predicting preterm birth in women without traditional risk factors, highlighting the need for effective screening methods in this population.

Our study found that women who delivered preterm had significantly shorter cervical lengths measured by transvaginal ultrasound at 20-24 weeks compared to those who delivered at term. In Group B (transvaginal ultrasound only), the mean cervical length in women who delivered preterm was 27.9 ± 4.5 mm compared to 36.7 ± 3.9 mm in those who delivered at term (p<0.001). This finding is consistent with previous studies that have demonstrated an inverse relationship between cervical length and the risk of preterm birth.8,9 Iams et al., in their landmark study, reported that the relative risk of preterm birth increased as cervical length decreased, with the risk being particularly high for cervical lengths below the 10th percentile.8

The optimal cut-off value for predicting preterm birth in our study was determined to be 30 mm for transvaginal ultrasound, which is slightly higher than the commonly used cut-off of 25 mm in high-risk populations.11,12 This difference may be attributed to the characteristics of our study population, which included only low-risk women without prior history of preterm birth. Previous studies have suggested that the optimal cut-off may vary depending on the population characteristics and risk profile.13 Our findings suggest that in low-risk populations, a higher cut-off may be more appropriate for identifying women at risk for preterm birth.

Using the 30 mm cut-off, transvaginal ultrasound demonstrated good predictive performance with a sensitivity of 75.0% in Group B and 77.8% in Group C, with specificities of 81.8% and 86.0%, respectively. The high negative predictive values (97.1% and 97.4%) are particularly noteworthy, as they indicate that women with cervical lengths ≥30 mm have a very low risk of preterm birth, which can be reassuring for both patients and healthcare providers.

In contrast, digital examination had lower predictive performance with a sensitivity of 44.4% and specificity of 74.1% in Group A. The suboptimal performance of digital examination may be attributed to several factors. First, digital examination is subjective and dependent on the examiner's experience and technique, leading to significant inter-observer variability.14 Second, digital examination can only assess the vaginal portion of the cervix and may not accurately estimate the entire cervical length, particularly the supravaginal portion, which may be more relevant for predicting preterm birth.15 Third, digital examination may not detect subtle changes in cervical length or internal os dilatation (funneling), which are early signs of cervical insufficiency.16

Our study found only a moderate correlation between cervical length measurements obtained by transvaginal ultrasound and digital examination in Group C (r=0.43, p<0.001), with digital examination consistently underestimating the cervical length compared to ultrasound. This discrepancy has been reported in previous studies and may be due to the limitations of digital examination in assessing the entire cervical length.15,17 Volumenie et al. reported similar findings, noting that digital examination tended to underestimate cervical length, particularly in women with longer cervices.17

An interesting finding of our study was that the combination of both methods in Group C showed slightly better predictive performance than either method alone, with an AUC of 0.89 compared to 0.87 for transvaginal ultrasound alone and 0.65 for digital examination alone. This suggests that there might be complementary information provided by the two methods that enhances the overall predictive performance. However, the improvement was modest and not statistically significant (p=0.12), indicating that transvaginal ultrasound alone may be sufficient for most clinical purposes.

The presence of funneling, defined as dilatation of the internal os with protrusion of the amniotic membranes into the endocervical canal, was found to be an independent predictor of preterm birth in our study. This finding is consistent with previous reports that have identified funneling as a risk factor for preterm birth, independent of cervical length.18 The presence of funneling may indicate weakness of the internal os and increased vulnerability to mechanical and biochemical factors that promote cervical ripening and preterm labor.19

Progressive shortening of the cervix, as indicated by a decrease in cervical length ≥3 mm between 20-24 weeks and 28 weeks, was also identified as an independent predictor of preterm birth in our study. This finding suggests that not only the absolute cervical length but also the rate of cervical shortening is important in predicting preterm birth. Similar findings have been reported by Souka et al., who found that women with progressive cervical shortening had a higher risk of preterm birth compared to those with stable cervical lengths, even if the initial measurements were similar.20

Our findings have important clinical implications for the prediction and prevention of preterm birth in low-risk populations. The superior performance of transvaginal ultrasound suggests that it should be the preferred method for cervical assessment in pregnant women, including those without traditional risk factors for preterm birth. Given the high negative predictive value of transvaginal ultrasound, women with cervical lengths ≥30 mm at 20-24 weeks can be reassured about their low risk of preterm birth, potentially reducing anxiety and unnecessary interventions.

For women identified as high-risk based on short cervical length, closer surveillance and timely interventions can be implemented. Interventions that have shown benefit in women with short cervix include vaginal progesterone, cervical cerclage, and pessary placement, depending on the clinical context and available resources.21,22 Additionally, these women can be counseled about warning signs of preterm labor and advised to seek medical attention promptly if such symptoms occur.

The findings of our study also raise questions about the potential benefits of universal cervical length screening in low-risk populations. While routine screening would identify women at risk who would otherwise be missed by risk-based screening, concerns about cost-effectiveness, availability of resources, and potential for unnecessary interventions need to be considered. A targeted approach, focusing on women with certain demographic or clinical characteristics that confer a higher risk within the low-risk population, may be more feasible and cost-effective.

Our study has several strengths. First, it was a prospective cohort study with a randomized allocation of participants to different assessment methods, allowing for a direct comparison of the methods without confounding by indication. Second, we had standardized protocols for cervical assessment, ensuring consistency in measurements. Third, in Group C, the obstetricians performing the digital examination were blinded to the ultrasound findings and vice versa, minimizing potential bias. Fourth, we included only low-risk women without prior history of preterm birth, a population that is often overlooked in studies on preterm birth prediction. Fifth, we evaluated not only the absolute cervical length but also progressive changes over time, providing a more comprehensive assessment of cervical status.

However, our study also has some limitations. First, the sample size, although adequate for the primary objective, was relatively small for subgroup analyses. Second, the study was conducted at a single center and its affiliated hospitals, which may limit the generalizability of the findings to other settings with different patient populations and practice patterns. Third, we did not evaluate other potential predictors of preterm birth, such as biochemical markers or microbiological factors, which may have added value in combination with cervical length measurement. Fourth, the follow-up period was limited to the current pregnancy, and we do not have data on the long-term outcomes of the participants or the predictive value of cervical length measurement in subsequent pregnancies.

6. CONCLUSION

In conclusion, our study demonstrates that transvaginal ultrasound measurement of cervical length is superior to digital examination for predicting preterm labor in low-risk women without prior history of preterm birth. A cervical length <30 mm at 20-24 weeks gestation, measured by transvaginal ultrasound, can effectively identify women at risk for preterm birth, allowing for closer surveillance and timely interventions. The presence of funneling and progressive cervical shortening are additional independent predictors of preterm birth. These findings support the use of transvaginal ultrasound as the preferred method for cervical assessment in pregnant women, including those without traditional risk factors for preterm birth. Future research should focus on developing integrated prediction models that combine cervical length measurement with other clinical, biochemical, and genetic markers to further improve the prediction of preterm birth in low-risk populations.

REFERENCES

[1] Blencowe H, Cousens S, Chou D, Oestergaard M, Say L, Moller AB, et al. Born too soon: the global epidemiology of 15 million preterm births. Reprod Health. 2013;10 Suppl 1:S2.

[2] Sankar MJ, Neogi SB, Sharma J, Chauhan M, Srivastava R, Prabhakar PK, et al. State of newborn health in India. J Perinatol. 2016;36(s3):S3-S8.

[3] Goldenberg RL, Culhane JF, Iams JD, Romero R. Epidemiology and causes of preterm birth. Lancet. 2008;371(9606):75-84.

[4] Carlo WA, McDonald SA, Fanaroff AA, Vohr BR, Stoll BJ, Ehrenkranz RA, et al. Association of antenatal corticosteroids with mortality and neurodevelopmental outcomes among infants born at 22 to 25 weeks' gestation. JAMA. 2011;306(21):2348-58.

[5] Word RA, Li XH, Hnat M, Carrick K. Dynamics of cervical remodeling during pregnancy and parturition: mechanisms and current concepts. Semin Reprod Med. 2007;25(1):69-79.

[6] Jackson GM, Ludmir J, Bader TJ. The accuracy of digital examination and ultrasound in the evaluation of cervical length. Obstet Gynecol. 1992;79(2):214-8.

[7] Sonek JD, Iams JD. Ultrasound in the detection of preterm delivery. Clin Obstet Gynecol. 2008;51(4):858-63.

[8] Iams JD, Goldenberg RL, Meis PJ, Mercer BM, Moawad A, Das A, et al. The length of the cervix and the risk of spontaneous premature delivery. N Engl J Med. 1996;334(9):567-72.

[9] Berghella V, Roman A, Daskalakis C, Ness A, Baxter JK. Gestational age at cervical length measurement and incidence of preterm birth. Obstet Gynecol. 2007;110(2 Pt 1):311-7.

[10] Hassan SS, Romero R, Vidyadhari D, Fusey S, Baxter JK, Khandelwal M, et al. Vaginal progesterone reduces the rate of preterm birth in women with a sonographic short cervix: a multicenter, randomized, double-blind, placebo-controlled trial. Ultrasound Obstet Gynecol. 2011;38(1):18-31.

[11] Gomez R, Galasso M, Romero R, Mazor M, Sorokin Y, Gonçalves L, et al. Ultrasonographic examination of the uterine cervix is better than cervical digital examination as a predictor of the likelihood of premature delivery in patients with preterm labor and intact membranes. Am J Obstet Gynecol. 1994;171(4):956-64.

[12] Crane JM, Hutchens D. Transvaginal sonographic measurement of cervical length to predict preterm birth in asymptomatic women at increased risk: a systematic review. Ultrasound Obstet Gynecol. 2008;31(5):579-87.

[13] Matijevic R, Grgic O, Vasilj O. Is sonographic assessment of cervical length better than digital examination in screening for preterm delivery in a low-risk population? Acta Obstet Gynecol Scand. 2006;85(11):1342-7.

[14] Holcomb WL Jr, Smeltzer JS. Cervical effacement: variation in belief among clinicians. Obstet Gynecol. 1991;78(1):43-5.

[15] Rozenberg P, Gillet A, Ville Y. Transvaginal sonographic examination of the cervix in asymptomatic pregnant women: review of the literature. Ultrasound Obstet Gynecol. 2002;19(3):302-11.

[16] Berghella V, Kuhlman K, Weiner S, Texeira L, Wapner RJ. Cervical funneling: sonographic criteria predictive of preterm delivery. Ultrasound Obstet Gynecol. 1997;10(3):161-6.

[17] Volumenie JL, Luton D, De Spirlet M, Sibony O, Blot P, Oury JF. Ultrasonographic cervical length measurement is not a better predictor of preterm delivery than digital examination in a population of patients with idiopathic preterm labor. Eur J Obstet Gynecol Reprod Biol. 2004;117(1):33-7.

[18] Berghella V, Owen J, MacPherson C, Yost N, Swain M, Dildy GA 3rd, et al. Natural history of cervical funneling in women at high risk for spontaneous preterm birth. Obstet Gynecol. 2007;109(4):863-9.

[19] Guzman ER, Walters C, Ananth CV, O'Reilly-Green C, Benito CW, Palermo A, et al. A comparison of sonographic cervical parameters in predicting spontaneous preterm birth in high-risk singleton gestations. Ultrasound Obstet Gynecol. 2001;18(3):204-10.

[20] Souka AP, Papastefanou I, Michalitsi V, Salambasis K, Chrelias C, Salamalekis G, et al. Cervical length changes from the first to second trimester of pregnancy, and prediction of preterm birth by first-trimester sonographic cervical measurement. J Ultrasound Med. 2011;30(7):997-1002.

[21] Romero R, Nicolaides K, Conde-Agudelo A, Tabor A, O'Brien JM, Cetingoz E, et al. Vaginal progesterone in women with an asymptomatic sonographic short cervix in the midtrimester decreases preterm delivery and neonatal morbidity: a systematic review and metaanalysis of individual patient data. Am J Obstet Gynecol. 2012;206(2):124.e1-19.

[22] Berghella V, Mackeen AD. Cervical length screening with ultrasound-indicated cerclage compared with history-indicated cerclage for prevention of preterm birth: a meta-analysis. Obstet Gynecol. 2011;118(1):148-55.