Experimental
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Cerclage Area: A Postoperative Ultrasonographic Parameter for Predicting Preterm Birth

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ABSTRACT

OBJECTIVE: This study evaluated the link between postoperative cervical ultrasonographic measurements in women who underwent transvaginal cerclage for cervical insufficiency and preterm birth, focusing on the potential of the new parameter, cerclage area (CA), to predict preterm birth.

STUDY DESIGN: This prospective observational study at a tertiary care center (January 2022–June 2024) included 45 pregnant women who underwent McDonald transvaginal cerclage per ACOG guidelines. Postoperative transvaginal ultrasonography assessed cervical wall thickness, suture depth, cervical length above and below the cerclage, and cerclage area. Participants were followed to delivery; obstetric and neonatal outcomes were recorded.

RESULTS: In the assessments conducted, 48.9% of the cases were preterm, whereas 51.1% were term deliveries. Classical parameters and CA did not differ significantly between the preterm and term groups ($p>0.05$). However, the CA was significantly correlated with the depths of both the anterior and posterior sutures, and with the thickness of the posterior cervical wall ($p<0.05$).

CONCLUSION: Although the cerclage area does not significantly predict preterm birth, it may be a useful quantitative tool for assessing cervical structure after cerclage placement. Larger, multicenter studies are needed to clarify the clinical value of this metric.

Keywords: Cerclage area; Cervical insufficiency; Preterm birth; Transvaginal cerclage; Ultrasonography

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Introduction

Cervical insufficiency is marked by painless cervical dilatation and repeated second-trimester pregnancy losses, which can lead to severe obstetric consequences (1). Cervical cerclage is used to prevent preterm birth by providing mechanical support to the cervix (2,3). Previous studies have shown that transvaginal cerclage can reduce premature birth in high-risk pregnancies. Many factors can affect the efficacy of cerclage. These include gestational age at cerclage, cervical length, funneling observations, and intraamniotic inflammation (4-5). However, few studies have examined the link between structural or quantitative ultrasound data obtained after cerclage and the timing of delivery (6-8). Recently, ultrasound assessment of cervical morphology following cerclage has become more important (6-8). Evaluating parameters such as anterior and posterior suture depth, cervical wall thickness, and cervical length above and below the cerclage may help predict surgical success and obstetric outcomes (9,10). In this study, we developed a new measurement unit, cerclage area (CA), along with conventional postoperative ultrasound parameters, in pregnant women who underwent cerclage. We investigated the potential of CA to predict preterm birth and assessed the correlation between CA-a metric not previously defined in the literature-and preterm birth risk.

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Material and Method

This research is a prospective observational study conducted from January 2022 to June 2024 at the perinatology clinic of a tertiary educational and research facility. The study included 45 singleton pregnancies at risk of preterm birth who received transvaginal cerclage in accordance with ACOG (American College of Obstetricians and Gynecologists) guidelines.

Throughout the study period, ultrasound assessments were conducted after cerclage. Pregnant women were monitored until delivery, and their obstetric and neonatal outcomes were documented. Cerclage is recommended by ACOG Practice Bulletin No. 142 in three clinical settings. One indication is for women with two or more second-trimester losses or preterm births resulting in painless cervical dilatation (11,12). Ultrasound-indicated cerclage is recommended for asymptomatic women with a cervical length of ≤25 mm before 24 weeks of gestation, especially if they have a history of preterm birth. Physical examination indicates that cerclage is used before 24 weeks for women with cervical dilatation greater than 1 cm and membranes in the vaginal canal, requiring immediate cerclage. Inclusion criteria were transvaginal cerclage between 13 and 25 weeks of gestation, singleton pregnancy, post-cerclage ultrasound assessments by our team after enrolment, and follow-up until delivery with comprehensive obstetric data. Exclusion criteria included multiple gestation, uterine anomalies or prior cervical surgeries, preterm premature rupture of membranes (PPROM), active hemorrhage, infection, loss to follow-up or incomplete follow-up after cerclage, and use of a vaginal pessary or other cervical support techniques.

All cerclage procedures were performed by skilled perinatologists from the same surgical team using the McDonald technique. Before the procedure, sterilization, antibiotic prophylaxis (2 g cefazolin IV), and tocolysis were provided as necessary. A non-absorbable polyester suture, specifically Mersilene suture (Ethicon, Johnson & Johnson), was used. All ultrasonographic assessments were conducted systematically between days 7 and 14 following cerclage.

This schedule was established to align with the standard postoperative evaluations and fetal assessments conducted at our facility.

The following parameters were evaluated: AUWIOA (°), angle of the anterior uterine wall internal os; AUWEOA (°), angle of the anterior uterine wall external os; ACWW (mm), anterior cervical wall thickness; PCWW (mm), posterior cervical wall thickness; ASD (mm), anterior suture depth; PSD (mm), posterior suture depth; CLAC (mm), cervical length above the cerclage; CLBC (mm), cervical length below the cerclage. The cerclage area (CA, mm²) was calculated using the triangular formula ($CA = ½ \times ASD \times PSD \times \sin\theta$). This formula uses anterior and posterior suture depths (ASD, PSD) with the fixed angle parameter (θ) set by the device. The Voluson E8 (GE Healthcare, USA) ultrasound system generated the calculation using its built-in software. Researchers did not calculate it manually. The CA value appeared on the device screen and was recorded during the examination. Measurement samples are shown in Figure 1. Pregnant women were monitored until delivery. Obstetric and neonatal data, including preterm birth (<37 weeks), birth weight (grams), and 1- and 5-minute APGAR scores, were obtained from postnatal records.

Ethical approval was obtained by the institutional review board from Etlik Zubeyde Hanim Women's Health Care, Training and Research Hospital on 22.12.2021# 2021/132. The study complied with the ethical principles for medical research of the Declaration of Helsinki.

Statistical analysis

Normality of continuous variables was assessed using the Shapiro–Wilk test. Statistical analyses were performed using nonparametric tests because the data were not normally distributed. Continuous variables were expressed as median (minimum–maximum) and compared between groups using the Mann–Whitney U test. Categorical variables were represented as numerical values and percentages (%), with the chi-square test or Fisher's exact test used for comparison when ap-

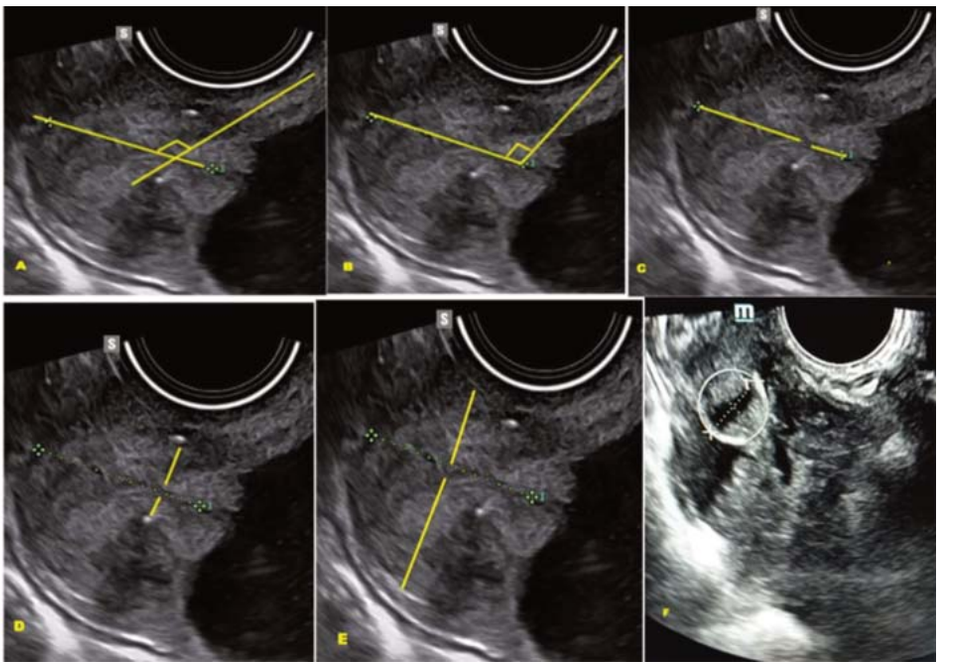

Figure 1A: *Anterior uterine wall external os angle,* ***B****: Anterior uterine wall internal os angle,* ***C:*** *Cervical length above the cerclage, Cervical length below the cerclage,* ***D:*** *Anterior suture depth, Posterior suture depth,* ***E****: Anterior cervical wall width, Posterior cervical wall width* ***F****: Cerclage Area*

propriate. The Spearman rank correlation coefficient (ρ) was employed to assess the association between the CA and several ultrasonographic parameters. Effect sizes (Cliff's delta for group comparisons and Spearman's r for correlations) together with 95% confidence intervals were calculated. The threshold for statistical significance was set at $p<0.05$, and p-values were reported to 3 decimal places; values <0.001 were reported as <0.001.

Since the sample size was determined by available cases, a post-hoc power analysis was performed. With 22 cases in the preterm group and 23 in the term group (total n=45), the study had 80% power at $\alpha=0.05$ to detect a large between-group effect (Cohen's $d\approx0.85$). For correlation analyses, the sample size provided 80% power to detect $r\geq0.40$. Thus, the study was sufficiently powered to detect moderate-to-strong associations, although smaller effects may not have been reliably evaluated.

Results

The study involved 45 pregnant women who received cerclage. Among these, 22 (48.9%) experienced preterm deliveries (<37 weeks of gestation), whereas 23 (51.1%) had term births (≥37 weeks of gestation). No statistically significant differences were observed between the preterm and term delivery groups regarding maternal age, body mass index (BMI), smoking status, gravidity, parity, presence of intraamniotic sludge, funneling findings, and timing of cerclage application ($p>0.05$, Table I).

Upon examination of neonatal outcomes, the preterm group had a significantly lower birth weight (2378 (590–2990), $p<0.001$). Furthermore, 1-minute APGAR scores were markedly lower in the preterm cohort ($p=0.034$). Nonetheless, the 5-minute APGAR scores exhibited no statistically significant difference between the groups ($p=0.123$, Table I).

Ultrasound measurements following cerclage, including anterior uterine wall internal and external os angles (AUWIOA, AUWEOA), anterior and posterior cervical wall thicknesses (ACWW, PCWW), anterior and posterior suture depths (ASD, PSD), and cervical lengths above and below the cerclage (CLAC, CLBC), along with CA, a new parameter assessed in this study, were compared between preterm and term groups. No statistically significant differences were observed between the groups for any of these parameters ($p>0.05$, Table II). Correlation analysis revealed a significant positive correlation between CA and posterior suture depth (PSD) ($\rho=0.574$,

Table I: *Comparison of sociodemographic and obstetric characteristics according to gestational age at delivery*

	Preterm <37 weeks (n=22)	Term ≥37 weeks (n=23)	p
Maternal age (years) Median (min-max)	31 (19-37)	32 (21-38)	0.665[a]
BMI (kg/m²) Median (min-max)	25.5 (19-39)	27 (18-32)	0.123[a]
Smoking, n (%)	2 (9.1)	1 (4.3)	0.483[b]
Gravidity Median (min-max)	3 (1-10)	4 (1-7)	0.517[a]
Parity Median (min-max)	1 (0-4)	1 (0-4)	0.933[a]
Intraamniotic sludge, n (%)	4 (18.2)	3 (13)	0.530[b]
Funneling sign, n (%)	7 (31.8)	8 (34.8)	0.542[b]
GW at cerclage Median (min-max)	17 (13-25.4)	19.2 (13.5-25.2)	0.223[a]
Birth weight(gram) Median (min-max)	2378 (590-2990)	3000 (2765-3480)	**<0.001**[a]
APGAR 1st minute Median (min-max)	9 (4-9)	9 (8-9)	**0.034**[a]
APGAR 5th minute Median (min-max)	10 (0-10)	10 (9-10)	0.123[a]

BMI: Body mass index, GW: Gestational week, a: Mann-Whitney U test, b: Chi-square, Fisher-Exact test

Table II: *Comparison of post-cerclage ultrasound measurements and treatment*

	Preterm <37 weeks (n=22)	Term ≥37 weeks (n=23)	p
AUWIOA (°)	128 (44.5-143)	125 (51-157)	0.946[a]
AUWEOA (°)	100 (70-135)	100 (49-148)	0.517[a]
ACWW (mm)	13.0 (4.4-24.0)	10.0 (1.2-14.8)	0.25[a]
PCWW (mm)	13.0 (6.0-21.0)	11.0 (1.0-19.0)	0.12[a]
ASD (mm)	7.4 (2.5-8.9)	7.6 (2.7-11.6)	0.510[a]
PSD (mm)	7.1 (2.1-9.8)	5.8 (2.8-8.9)	0.134[a]
CLAC (mm)	17.0 (4.3-36.0)	15.0 (8.3-47.5)	0.946[a]
CLBC (mm)	13.0 (4.3-17.0)	15.0 (6.1-20.0)	0.982[a]
CA, mm²	260 (89-673)	230 (138-448)	0.633[a]
Post-cerclage treatment, n (%)			
Yes	13 (59.1)	12 (52.2)	
No	9 (40.9)	11 (47.8)	0.434

AUWIOA: Anterior uterine wall internal os angle, AUWEOA: Anterior uterine wall external os angle, ACWW: Anterior cervical wall thickness, PCWW: Posterior cervical wall thickness, ASD: Anterior suture depth, PSD: Posterior suture depth, CLAC: Cervical length above the cerclage, CLBC: Cervical length below the cerclage, CA: Cerclage Area, mm: millimeter, °: angle a: Mann-Whitney U test, b: Chi-square,Fisher-Exact test

p<0.001). A significant positive correlations were also observed with anterior suture depth (ρ=0.351, p=0.018) and posterior cervical wall thickness (ρ=0.298, p=0.047, Table III). Meanwhile, no statistically significant correlation was observed between the CA and factors, including maternal age, body mass index (BMI), or the gestational week at which the cerclage was administered (p>0.05).

Table III: *Correlation of cerclage area with ultrasound Parameters*

	ρ (rho)	p
AUWIOA (°)	0.038	0.802
AUWEOA (°)	-0.101	0.509
ACWW (mm)	0.229	0.130
PCWW (mm)	0.298	0.047
ASD (mm)	0.351	**0.018**
PSD (mm)	0.574	**<0.001**
CLAC (mm)	0.273	0.069
CLBC (mm)	0.155	0.311

AUWIOA: Anterior uterine wall internal os angle, AUWEOA: Anterior uterine wall external os angle, ACWW: Anterior cervical wall thickness, PCWW: Posterior cervical wall thickness, ASD: Anterior suture depth, PSD: Posterior suture depth, CLAC: Cervical length above the cerclage, CLBC: Cervical length below the cerclage, mm: millimeter, °: angle

Discussion

This study evaluated the association between postoperative ultrasonographic findings and pregnancy outcomes in women who underwent transvaginal cerclage for cervical insufficiency, with particular focus on the relationship between the newly introduced parameter, the CA, and the risk of preterm birth. Our results demonstrated that neither conventional ultrasonographic parameters assessed post-cerclage nor the CA showed significant predictive value for preterm birth. Significant positive associations were identified between the cerclage region and specific structural parameters, notably suture depths and posterior cervical wall thickness. These findings suggest that the morphological evaluation of the cervical structure post-cerclage may primarily reflect the surgical technique and its anatomical consequences, rather than serving as a reliable predictor of delivery timing. The literature indicates that the correlation between ultrasound-measured characteristics following cerclage (such as suture depth, cervical length, and the presence of funneling) and premature birth remains ambiguous (6-8). Our research corroborates this perspective.

The CA is a metric calculated from the suture depths and their angular configuration, designed to quantitatively reflect the extent of the surgical intervention. The notable positive associations observed between CA and ASD, PSD, and PCWW indicate that this metric reflects the effect of surgical intervention on cervical structures. However, in our study, CA was not significantly associated with preterm birth and thus cannot yet be considered a clinically useful prognostic tool. Further multicenter investigations with larger populations are needed to clarify its potential role.

The surgical technique used in cerclage and the anatomical positioning of the suture significantly influence the effectiveness of the procedure. Previous research has demonstrated that higher placement of cervical sutures is associated with prolonged gestational duration (13). The data indicate that the effect of the suture on cervical anatomy may relate to cervical length, suture depth, and angular dispersion. In this context, it can be inferred that quantitative metrics, such as CA measurement, may more objectively represent these anatomical impacts.

The similarity in established risk factors, such as cerclage week, maternal age, BMI, funneling, and sludge, between preterm and term birth cohorts indicates that the study used a homogeneous sample and successfully excluded potential confounding variables. This facilitates a more reliable assessment of the acquired results.

It has been emphasized that a single ultrasonographic assessment performed soon after cerclage may be insufficient to capture the dynamic nature of cervical changes. Cervical length and funneling may exhibit considerable temporal variability, and these changes are more accurately monitored through serial ultrasonographic assessments (14,15). Consequently, although the assessments performed between 7 and 14 days in our study establish a specific temporal reference, they do not provide comprehensive insights into the cervical remodeling process. This may lead to overlooking the temporal variability of the findings.

Infection and inflammation are recognized as significant factors in the etiology of preterm birth (16). Mönckeberg et al. indicated that the efficacy of cerclage was markedly diminished in the context of intraamniotic infection, a result that did not consistently align with ultrasonography observations (17,18). In our investigation, infection markers were not routinely assessed; this may account for the low efficacy of morphological assessments, such as CA, in predicting clinical outcomes.

This study's merits encompass its prospective design, the uniformity of surgical procedures conducted by the same team, and the adherence to a singular protocol for ultrasound measures. The introduction of a new parameter (CA), not previously documented in the literature, and the examination of its correlation with measurements enhance the originality of this study. Nonetheless, the results should be interpreted cautiously, as CA did not show significant predictive ability for preterm birth in our analysis.

While there is presently inadequate data to endorse the direct incorporation of CA measurement into clinical decision-making, this technique may facilitate the standardization of cerclage efficacy in the future. Specifically, it may enable surgical trainees to quantitatively evaluate their technical proficiency. Moreover, the use of sophisticated artificial intelli-

gence and automated image processing systems may enhance the objectivity and reproducibility of such measures (19).

Limitations and Strengths of the Study: This study's limitations encompass a very small sample size and its execution at a single center. This study did not assess genetic, environmental, or biochemical variables that may affect birth outcomes. The ultrasound measurements were obtained only once, within postoperative days 7 and 14, and dynamic changes over time could not be evaluated. Infection markers such as C-reactive protein (CRP) or interleukin (IL) levels were not assessed, which may have provided additional clinical insight. Furthermore, detailed information on adjuvant therapies following cerclage, including the use of progesterone, was limited. As the sample size was determined by available cases rather than a priori calculation, the power analysis was performed post hoc; therefore, the study may not have been sufficiently powered to detect small effect sizes or subtle associations. Given these constraints, the clinical predictive value of the CA must be evaluated across diverse and larger populations.

Conclusion

This study illustrates that postoperative ultrasonographic assessments in pregnant women who received transvaginal cerclage, especially when including innovative measures such as CA, have minimal effectiveness in predicting delivery dates. Nevertheless, the CA may serve as a quantitative measure of surgical effectiveness, and its therapeutic utilization may be broadened through more extensive research in the future.

Declarations

Ethics Committee Approval

Ethical approval was obtained by the institutional review board from Etlik Zubeyde Hanim Women's Health Care, Training and Research Hospital on 22.12.2021# 2021/132. The study complied with the ethical principles for medical research of the Declaration of Helsinki.

Informed consent: A verbal and written informed consent was obtained from all participants.

Conflict of Interest: The authors declare no conflict of interest.

Availability of Data and Materials: The datasets generated and/or analyzed during the current study are available from the corresponding author upon reasonable request.

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Authors' Contributions: Conceptualization was performed by NCK, SC, ATC, and YEU. Methodology was developed by NCK, GAY, OYC, and BTC. An investigation was conducted by NCK, GAY, OYC, BTC, and OA. Formal analysis was carried out by NCK. The original draft of the manuscript was written by NCK, while review and editing were performed by YEU, SC, and ATC. Supervision was provided by YEU and SC. All authors have read and approved the final version of the manuscript.

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