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Indications for Cervical Cerclage in Pregnant Women: Obstetric and Perinatal Outcomes in a Tertiary Public Hospital

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Authors' contributions

This work was carried out in collaboration between both authors. Author JMU wrote and prepared the original draft. Author TFK designed the study and performed the statistical analysis. Both authors read and approved the final manuscript.

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ABSTRACT

Aims: This study aims to assess the impact of cervical cerclage on gestational and perinatal outcomes at a tertiary hospital, considering various surgical indications. Preterm labor (PTL) is a major cause of neonatal and perinatal morbidity and mortality, affecting about 15 million newborns globally each year. Cervical insufficiency (CI) contributes significantly to PTL, particularly in women with a history of spontaneous preterm births or second-trimester losses. This research examines how cervical cerclage, a standard treatment for CI, influences these outcomes.
Study Design: This is an observational, analytical, retrospective cohort study based on documentary research.

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Place and Duration of Study: The study was conducted at a tertiary public hospital in Cascavel, Paraná, Brazil, from January 1, 2020, to March 20, 2024.
Methodology: A database review was performed for pregnant women who received cervical cerclage using the McDonald technique. Participants were divided into three groups based on the indication for the procedure: obstetric history only, ultrasound only, and both. The study analyzed gestational and perinatal outcomes. Comparisons were made using ANOVA, Kruskal-Wallis, and Chi-square tests, with $P < 0.05$ considered significant.
Results: Out of 41 women studied, 19 (46.3%) had cervical cerclage based solely on obstetric history, 16 (39.0%) based on a combination of obstetric history and ultrasound, and 6 (14.6%) based only on ultrasound. Significant differences were noted in maternal age, history of premature births and miscarriages, cervical length, and nulliparity. Despite these differences, no statistically significant variations were observed in obstetric and perinatal outcomes, including gestational age at cerclage removal and delivery, delivery type, neonatal weight, APGAR score, NICU admission, and neonatal morbidity and mortality. Notably, 76.3% of births occurred at term (> 37 weeks), and the average pregnancy length post-cerclage was 21 weeks (IQR: 5.00). Additionally, 90.3% of neonatal outcomes were favorable.
Conclusion: All three indications for cervical cerclage were associated with extended gestation, increased rates of full-term births, and favorable neonatal outcomes.

Keywords: Cervical cerclage; cervical incompetence; preterm labor; ultrasound diagnosis; prenatal care.

1. INTRODUCTION

Preterm labor (PTL) is one of the main causes of neonatal and perinatal morbidity and mortality [1–4], with around 15 million neonates born prematurely each year and responsible for approximately 1 million infant deaths due to complications related to preterm birth [5]. In 2020, the prevalence of preterm births worldwide was 9.9% of 13.4 million births, but rates vary according to each region [6]. Faced with this worrying reality, the prevention and treatment of preterm births stand out as fundamental elements in reducing neonatal mortality rates [1,4,7].

The etiology of PTL remains inconclusive, however, it has known risk factors [8–11]. In this sense, cervical insufficiency (CI) stands out as one of the main determinants of PTL, especially when there is a previous history of spontaneous premature births or spontaneous loss in the second trimester, as proven by a wide compilation of data [11–13]. Although it does not have a universally accepted definition, it is commonly described as the dilation and shortening of the cervix before the 37th week of pregnancy, without the presence of PTL, and which can result in membrane prolapse, premature rupture of the membranes, gestational loss or PTL [8,9,14] and has an incidence of 1% in the obstetric population worldwide and 8% in women who have suffered a gestational loss in the second trimester [4,9,15].

Despite the lack of a definitive diagnostic test, it is essential to carry out screening to predict the chance of CI occurring. This process is based on obstetric history (OH), physical examination, and ultrasound screening of the cervix. Through the OH, the main risk factors are previous gestational loss in the second trimester or a PTL before 34 weeks of gestation [8]. In this context, transvaginal ultrasound (US) has stood out in clinical practice as a reliable and reproducible method for assessing the condition of the uterus of the cervix [9], where cervical shortening of less than 25.0 mm in the second trimester is already associated with an increased risk of PTL [9,16].

Cervical cerclage (CC) is the surgical procedure of choice for treating CI [10,16]. The Royal College of Obstetricians and Gynaecologists (RCOG) [11], the Society of Obstetricians and Gynaecologists of Canada (SOGC) [9], and the American College of Obstetricians and Gynecologists (ACOG) [8] have defined its three indications: by OH, US and physical examination (emergency or rescue cerclage).

CC indicated by the OH is recommended electively in early pregnancy, between 12 and 14 weeks, for asymptomatic women with a single pregnancy, based on a previous history of premature births or gestational losses in the second trimester [8,9,11]. About the number of pregnancy losses, while the ACOG [8] mentions one or more pregnancy losses in the second trimester as a criterion for CC, the RCOG [11],

and the SOGC [9] specifies that three or more pregnancy losses in the second trimester or premature births are necessary to consider CC.

CC indicated by the US is performed in women with a single pregnancy, a history of one or more spontaneous losses in the second trimester or premature births, and a cervical length equal to or less than 25.0 mm before 24 weeks of gestation. The transvaginal US is recommended to assess cervical length between 14 and 24 weeks of gestation, with ultrasound surveillance starting at 16 weeks and continuing until 24 weeks of gestation [8,9,11]. The RCOG11 and the SOGC [9] do not recommend the insertion of a CC in pregnant women without other risk factors for PTL when a short cervix is identified on the US performed at the end of the second trimester.

The efficacy of CC for PTL prevention varies according to the type of indication (OH, US, and physical examination) [17]. Recently, the use of CC in cases of high-risk PTL has been suggested, supported by evidence such as the 2014 American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin, which affirms its effectiveness in patients with a history of CI and cervical length of less than 20 mm by the 24th week of gestation [8]. In addition, the Cochrane review in 2017 highlighted that CC in high-risk situations could reduce PTL rates compared to groups not undergoing the procedure [14]. Therefore, the effectiveness of CC in various clinical scenarios and at different stages of pregnancy remains a subject of discussion and research.

This study aimed to evaluate the obstetric and perinatal outcomes in patients who underwent CC with an indication only for OH, only for the endovaginal US to measure the length of the cervix and a combination of both.

2. MATERIALS AND METHODS

This is an observational, analytical, retrospective cohort study based on documentary research conducted at a tertiary public hospital in Cascavel, Paraná, Brazil, from January 1, 2020, to March 20, 2024.

The study included patients with singleton pregnancies diagnosed with or at risk of CI, who underwent CC using the McDonald technique based on ultrasound indications of cervical measurement and/or OH. Women with multiple pregnancies and those who underwent emergency or rescue cerclage indicated by physical examination were excluded from the study.

A non-random sampling approach was employed to review all available case files. The patients' medical information was retrospectively analyzed using the hospital center's data network (TASY® system), following approval from the ethics committee. The following clinical information was collected from the study population: maternal age, history of premature birth, spontaneous abortions in the second trimester, history of conization, and maternal comorbidities such as gestational diabetes, hypothyroidism, psychological conditions (anxiety, depression, and bipolar disorder), gestational hypertension, grade II and III obesity, leiomyoma, endometriosis, asthma, syphilis, arrhythmia, cervical cancer, polycystic ovary syndrome, type 2 diabetes, trachelectomy, epilepsy, cysticercosis, thrombosis, polyhydramnios and supraventricular tachycardia. In addition, gestational age at CC, cervical length, and the finding of "sludge" on endovaginal ultrasound were recorded. Gestational outcomes were also analyzed: duration of CC, gestational age at delivery, the occurrence of preterm delivery, full-term delivery, miscarriage, type of delivery (vaginal or cesarean section), medications in use, and neonatal outcomes (birth weight, APGAR score, admission to the Neonatal Intensive Care Unit - NICU and neonatal mortality).

Indications for CC were categorized into three groups: CC indicated only by OH, CC indicated only by US measurement of the cervix, and CC indicated by a combination of both indications. Obstetric history refers to a history of one or more previous premature births or gestational losses in the second trimester related to painless cervical dilation or a history of cervical conization. US measurement of the cervix was applied to women whose transvaginal ultrasound revealed a short cervical length (less than 25.0 mm) in pregnancies of less than 24 weeks, without associated cervical dilation. CC examinations and procedures were conducted by experienced clinicians from the mentioned hospital center, and the three study groups were compared regarding clinical characteristics, pregnancy outcomes, and neonatal outcomes.

In this study, the crucial measure evaluated was the CC success rate, determined by the

percentage of pregnancies that resulted in delivery after 37 weeks of gestation, with no immediate surgical complications related to CC. This measure essentially reflected the effectiveness of this intervention in preventing preterm births and their complications. For a more detailed analysis, pregnancy outcomes were categorized into different groups: miscarriage/fetal death before 22 weeks, extremely preterm birth before 28 weeks, very preterm birth between 28 and 31 weeks, moderate preterm birth between 32 and 36 weeks, and full-term birth from 37 weeks [18].

Statistical analyses were conducted using Jamovi software (Jamovi, Version 2.3, Computer Software, https://www.jamovi.org). Initially, the data underwent descriptive analysis, followed by categorization into frequency of occurrence. The Shapiro-Wilk test was used to assess the normality of the quantitative variables. When the data exhibited a normal distribution, a one-way ANOVA test was conducted, followed by Tukey's post hoc test. If the data did not follow a normal distribution, the Kruskal-Wallis test was used to identify potential significant differences between the groups. In addition, this analysis was complemented by the Dwass-Steel-Critchlow-Fligner (DSCF) test to carry out multiple comparisons.

The dichotomous data was converted into several observations (n) and frequency (%) to assess the distribution in each group. Subsequently, these data were subjected to the Chi-square test to explore significant associations between the variables of interest. All these tests, ANOVA, Kruskal-Wallis, and Chi-Square, were used to examine the relationship between the indication for CC and the different pregnancy outcomes. To assess survival over time, Kaplan-Meier methods were used to estimate the survival function, and the Log-Rank test was used to compare the survival curves between the groups. These methods provided a detailed understanding of survival dynamics in the study. A *P*-value < 0.05 was considered significant in all analyses.

3. RESULTS

The study included 41 pregnant women who had undergone the CC. There were no immediate post-operative complications associated with the procedure, including rupture of membranes or spontaneous abortion within one week of surgery. Among these 41 patients, 9.7% (4) resulted in spontaneous pregnancy loss or neonatal mortality, and 76.3% (29) delivered after 37 weeks of gestation. The median gestational age at delivery was 37.5 weeks (IQR:1.75), with a median birth weight of 3155g (IQR:575). The median gestational length after CC was 21 weeks (IQR:5.00). Of the patients who delivered after 24 weeks gestation, 65.8% had a vaginal delivery and 34.2 had a cesarean section. The indication for CC was based on OH in 19 patients (46.3%), on the combination of unfavorable OH and cervical measurement on ultrasound in 16 patients (39.0%), and exclusively by US in 6 patients (14.6%). Unfortunately, premature births occurred in 9 cases (23.7%). However, the study had a favorable neonatal outcome, with a success rate of 90.3% (Table 1) and the clinical characteristics of the study groups are shown in Table 2.

Table 1. Indication for CC and obstetric outcomes in pregnant women who underwent the procedure at the University Hospital of Western Paraná, from January 2020 to March 2024

	Number of cases (n)	Rate (%)
Indication:		
• OH	19	46.3%
• OH + US	16	39.0%
• US	6	14.6%
Spontaneous abortion/fetal death	4	9.7%
Premature birth (< 37 weeks gestation)	9	23.7%
• Extreme premature birth (< 28 weeks)	1	2.6%
• Very premature birth (between 28 and 31 weeks)	0	0.0%
• Moderate preterm birth (between 32 and 36 weeks)	8	21.1%

	Number of cases (n)	Rate (%)
Full-term birth (≥ 37 weeks gestation)	29	76.3%
Gestational age at delivery (median)	41	37.5 weeks (IQR:1.75)
Birth weight (median)	41	3155 grams (IQR:575)
Duration of CC	41	21 weeks (IQR:5.00)
Vaginal delivery	25	65.8%
Cesarean section	13	34.2%

Table 2. Clinical and ultrasound characteristics of the study population

	CC indicated by OH (n=19)	CC indicated by OH + US (n=16)	CC indicated by US (n=6)	*P*-value (<.05)
Number of patients	19 (46.3%)	16 (39.0%)	6 (14.6%)	<.001***
Maternal age (average in years)	31.5 (±5.38)[a]	29.9 (±6.37)[c]	21.0 (±3.52)[ac]	<.001*
Parity	1.00 (IQR:1.00)	1.00 (IQR:2.00)	0,00 (IQR:0.00)	.070**
• Nulliparous	4 (9.8%)	5 (12.2%)	5 (12.5%)	.019***
• Multiparous	7 (17.1%)	5 (12.2%)	1 (2.4%)	.651***
History of premature birth or miscarriage in the second half of life quarter	18 (43.9%)	12 (29.3%)	0 (0.0%)	<.001***
Maternal comorbidities	12 (31.6%)	11 (28.9%)	2 (5.3%)	.424***
Gestational age at CC (weeks)	15.0 (IQR: 5.00)	15.0 (IQR:3.00)	19.5 (IQR: 1.75)	.162**
History of conization	2 (4.9%)	6 (14.6%)	0 (0.0%%)	.057***
Cervical length (average in mm)	33.0 (±7.55)[ab]	22.7 (±4.08)[b]	22.4 (±3.85)[a]	.002*
"Sludge" in ultrasound	0 (0.0%)	2 (4.9%)	0 (0.0%)	.193***

**One-way ANOVA test and Tukey's post hoc test*
***Kruskal-Wallis test*
****Chi-square test*
CC: cervical cerclage; OH: obstetric history; US: ultrasound.
Data are presented as mean and standard deviation, median and interquartile range (IQR), or n (%). a - P < 0.05, group indicated by history versus group indicated by ultrasound. b- P < 0.05, group indicated by history versus group indicated by history plus ultrasound. c - P < 0.05, group indicated by history plus ultrasound versus group indicated by ultrasound.

No statistically significant differences or associations were found between the three groups about parity, maternal comorbidities, gestational age at CC, history of conization, and sludge on ultrasound. However, of the two cases of sludge observed, one resulted in miscarriage in the second trimester (18 weeks) and the other in full-term delivery. Both cases belonged to the group with CC indicated by the combination of OH and US.

The factors that proved statistically significant or showed relevant associations include maternal age, nulliparity, history of premature births or spontaneous losses in the second trimester, and cervical length. In the group where CC was indicated only by echographic measurement, maternal age was statistically lower compared to the other two groups. On the other hand, cervical length was statistically higher in the group where CC was indicated only by OH. In addition, a significant association was observed between indications for CC and a history of premature birth or spontaneous loss in the second trimester. This association was stronger in the group where CC was indicated by OR alone and in the group

where a combination of this history and cervical ultrasound measurement indicated CC. Additionally, nulliparity showed a significant association, particularly in cases where the US was the indication.

The pregnancy outcomes of the cases evaluated, as shown in Table 3, did not demonstrate statistically significant differences or associations across all the parameters assessed. These parameters include gestational age at miscarriage, gestational age at CC removal, gestational age at delivery (in weeks), duration of CC until delivery (in weeks), miscarriage/fetal death (< 22 weeks), extremely preterm birth (< 28 weeks), moderate preterm birth (between 32 and 36 weeks), preterm birth (≤ 37 weeks), term birth (≥ 37 weeks), type of birth (vaginal birth or cesarean section) and the measurement in use at delivery. In addition, there was no record of the incidence of very preterm birth (between 28 and 31 weeks). When compared using the Kaplan-Meier survival curve, the groups showed no significant difference (p=0.09) in the duration of CC until delivery (Fig. 1).

Table 3. Pregnancy outcomes of the study population according to CC indications

	CC indicated by OH (n=19)	**CC indicated by OH US (n=16)**	**CC indicated by US (n=6)**	***P*-value (<.05)**
Gestational age in spontaneous abortion	19 (IQR:0,00	19 (IQR:1.00)	NaN	1.000*
Gestational age at the removal of CC (weeks)	36.0 (IQR:1.00)	37.0 (IQR:1.00)	36.5 (IQR:1.00)	.761*
Gestational age at delivery (weeks)	37.0 (IQR:1.75)	38.0 (IQR:1.00)	38.5 (IQR:2.50)	.664*
Duration of CC until delivery (weeks)	21.0 (IQR:5.75)	22.0 (IQR:1.75)	17.0 (IQR:2.00)	.143*
Fetal death (< 22 weeks)	1.0 (2.4%)	2.0 (4.9%)	0.0 (0.0%)	.542**
Extreme premature birth (< 28 weeks)	1.0 (2.6%)	0.0 (0.0%)	0.0 (0.0%)	.565**
Very premature birth (between 28 and 31 weeks)	0.0 (0.0%)	0.0 (0.0%)	0.0 (0.0%)	NaN
Moderate preterm birth (between 32 and 36 weeks)	3.0 (7.9%)	3.0 (7.9%)	2.0 (5.3%)	.686**
Premature birth (< 37 weeks)	4 (10.5%)	3 (7.9%)	2 (5.3%)	.831**
Full-term birth (≥ 37 weeks)	14 (36.8%)	11 (28.9%)	4 (10.5%)	.831**
Type of delivery				
• Vaginal delivery	11 (28.9%)	10 (26.3%)	4 (10.5%)	.829**
• Caesarean section	7 (18.4%)	4 (10.5%)	2 (5.3%)	.829**
Medication in use during childbirth	14 (35.9%)	15 (38.5%)	4 (10.3%)	.276**

**Kruskal-Wallis test*
***Chi-Square test*
CC: cervical cerclage; OH: obstetric history; US: ultrasound. Data is presented as median and interquartile range (IQR) or n (%).

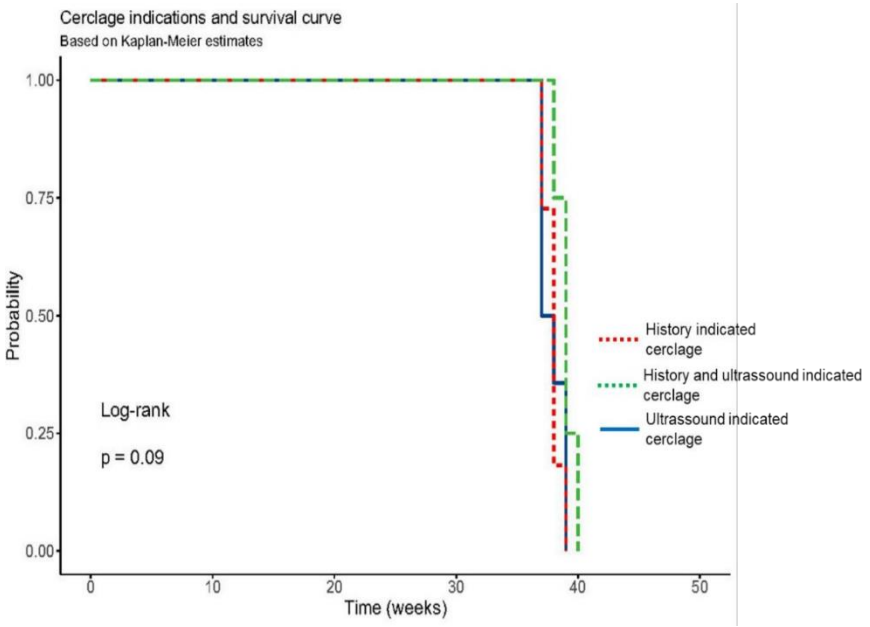

Fig. 1. Kaplan-Meyer survival curve of gestational age at delivery, comparing patients with different indications

Table 4. Perinatal outcomes of newborns according to CC indications

	CC indicated by OH (n=18)	CC indicated by OH + US (n=14)	CC indicated by US (n=6)	*P*-value (<.05)
Birth weight (g)	3105(IQR:605)	3215(IQR:471)	2985 (IQR:478)	.389*
LBW (< 2500 g)	2.0 (5.4%)	2.0 (5.4%)	2.0 (5.4%)	.454**
APGAR < 7 on the 1st minute	2.0 (5.4%)	3.0 (8.1%)	0.0 (0.0%)	.421**
APGAR < 7 on the 5th minute	0.0 (0.0%)	1.0 (2.7%)	0.0 (0.0%)	.430**
Admission to the NICU	0.0 (0.0%)	2.0 (0.0%)	0.0 (0.0%)	.176**
Perinatal mortality	1.0 (2.6%)	0.0 (0.0%)	0.0 (0.0%)	.565**

**Kruskal-Wallis test*
***Chi-Square test*
CC: cervical cerclage; OH: obstetric history; US: ultrasound.
Data are presented as median and interquartile range (IQR) or n (%). Low birth weight (LBW), Neonatal Intensive Care Unit (NICU).

The neonatal outcomes of the study groups, detailed in Table 4, revealed no statistically significant differences or associations in all the parameters evaluated. These parameters include birth weight, neonatal birth weight less than 2500g, APGAR scores less than 7 at the first and fifth minutes, the need for NICU admission, and neonatal mortality.

However, there were cases of spontaneous loss before the 22nd week of pregnancy in some groups. Specifically, one patient (2.4%) from the group indicated by OH and two (4.9%) from the group indicated by the combination of OH and US. As these events occurred before the 22nd week, the results of these patients were not included in the statistical analysis of perinatal outcomes.

4. DISCUSSION

This study broadened the understanding of the results of CC, highlighting the indications for its performance. It found that gestational and perinatal outcomes after CC showed no statistically significant differences, regardless of the indication used, whether based on unfavorable obstetric history, ultrasound

measurement of the cervix below 25.0 mm in the second trimester, or the combination of both. These results corroborate the findings of Golbasi et al [7] and Ikechebelu et al [4] and reinforce the consistency of the evidence regarding the efficacy of CC, regardless of the indication criteria used.

Comparisons between cervical cerclage and expectant management have been explored in several studies, including randomized clinical trials (RCTs) and cohort studies, focusing on women presenting with cervical dilatation between 14 and 27 weeks of gestation [9, 11]. Expectant management may be appropriate in some cases of cervical dilatation, but the decision to proceed with expectant management or cervical cerclage should be made individually [9]. The comparison between cervical cerclage and vaginal progesterone has also been addressed, but few studies perform a direct comparison between these approaches. One RCT showed that combining progesterone with cervical cerclage resulted in a prolongation of pregnancy compared to cerclage alone [11]. However, current guidelines do not recommend administering progesterone after cervical cerclage [11]. A meta-analysis revealed that vaginal progesterone is more effective in preventing preterm birth in women with a short cervix. Still, the comparative effectiveness of progesterone and the Arabin pessary to cervical cerclage has yet to be established [11].

There are different types of cervical cerclage. Transvaginal cerclage includes the McDonald method, which inserts a point close to the junction of the cervix and the vagina [9]. It is indicated for women with a history of spontaneous premature birth or gestational loss in the second trimester [11]. The Shirodkar method involves inserting a point subepithelial above the junction of the cervix [9], allowing for a higher placement. The choice between the McDonald and Shirodkar methods depends on the surgeon's experience and preference [9, 11]. Transabdominal cerclage can be performed laparoscopically, through small cuts in the abdomen, or by laparotomy, which involves a larger abdominal incision [1]. Laparotomy is recommended in cases such as previous failure of transvaginal cerclage, trachelectomy, absence of a vaginal cervix, or major loss of cervical tissue [1, 9].

The role of cervical cerclage in cases of multiple previous failures is controversial [11]. A retrospective cohort study suggested that repeated suture insertion in women with cerclage indicated by history and subsequent shortening of the cervix was associated with a lower gestational age at birth and a higher rate of second-trimester losses [11]. However, the study has limitations, such as the small number of participants and the lack of well-defined criteria [11]. Transabdominal cerclage may be an option for these cases, especially when vaginal cerclage fails. The decision on the type of cerclage should be individualized, considering the risks and benefits [11].

In this study, 9.7% of pregnant women had miscarriages or perinatal mortality. Notably, the CC indicated by OH and US had a slightly higher incidence of miscarriage, at 4.9% compared to 2.4% by OH alone and 0.0% by US alone; different from perinatal mortality, with 2.6% by OH compared to 0.0% by the other groups. Berghella & Mackeen [20] observed a higher perinatal mortality rate (5% versus 3%) in pregnant women undergoing CC indicated by the US compared to those indicated only by OH.

The rates of preterm birth (< 37 weeks) were similar between the groups, totaling 23.7% overall, with rates of 10.5%, 5.3%, and 7.9% in the CC groups indicated solely by OH, US alone, or a combination of both, respectively. These numbers highlight the effectiveness of CC in improving maternal and neonatal health [4,7], showing more promising results than those found in the meta-analysis by Berghella & Mackeen [20]. In their analysis, which compared the outcomes of single pregnancies with a history of previous preterm birth, the pregnant women were submitted to CC by echographic indication in cases of short cervical length or CC indicated only by obstetric history. The indication of CC due to the presence of short cervical length had similar incidences of preterm birth before 37 weeks (31% compared to 32%) compared to CC indicated by obstetric history alone. Although CC is an effective intervention, it is crucial to maintain continuous surveillance and close prenatal follow-up in these high-risk pregnancies [11].

No statistically significant association was found between the different indications for CC and favorable pregnancy outcomes. However, the indication for CC by combining OH and US of the cervix allows for a more personalized and targeted intervention.

The benefits of CC based on OH and US on perinatal and neonatal outcomes have been demonstrated in previous studies [7,21,22], corroborating the findings of this study. For example, Golbasi et al [7] and Krispin et al [22] found that, when examining the perinatal outcomes of CC, those obtained from the physical examination were inferior compared to the methods of indication by obstetric history and ultrasound, although no statistically significant difference was found between the results of the latter two methods. In addition, Korb et al [23] demonstrated a reduction in the rate of births before 24 weeks and in neonatal mortality in cases with cervical shortening, identified both in the US and in the history of preterm birth. In addition, the meta-analysis carried out by Alfirevic Z [14] showed the positive effect of CC indicated by the US on pregnancy outcomes.

This study showed a higher prevalence of CC based on OH and the OH-US combination, compared to the indication by the US alone, with no statistically significant difference between these groups. This finding is in line with previous studies, which have also found a higher frequency of CC indicated by history than other indications [4,7,10]. This scenario can be explained by the fact that pregnant women with a history of miscarriage in the second trimester, premature birth, or multiparous women tend to seek treatment earlier than nulliparous women7, which may have led to an increase in the number of women seeking treatment incidence of this form of indication [4]. This early search results in a significantly higher average maternal age among patients with CC indicated by history and in combination with ultrasound, compared to those whose indication was by ultrasound alone. The latter are usually primigravidas, reflecting a younger maternal age.

With technological advances and improvements in first-trimester ultrasound examination, the frequency of ultrasound-indicated CC is expected to increase. Currently, it is recommended that all obstetric patients have a routine transvaginal ultrasound in the first trimester, to ensure an early diagnosis or to direct their serial follow-up until the period of greatest sensitivity of the test (from 22 to 24 weeks), to facilitate surgical indication and the prevention of premature birth [4].

In addition, the group for whom CC was indicated by history alone had a significantly longer average cervical length before the procedure, with an average of 33.0 mm (±7.55) compared to those who received CC indicated by the history-echography combination and those indicated by ultrasound alone, whose averages were 22.7 mm (±4.08) and 22.4 mm (±3.85), respectively. These findings are in line with the recommendations of international societies such as the American College of Obstetricians and Gynecologists (ACOG) [8], the Royal College of Obstetricians and Gynaecologists (RCOG) [11], and the Society of Obstetricians and Gynecologists of Canada (SOGC) [9]. These organizations have established specific guidelines for the practice of CC, emphasizing its importance when indicated by cervical measurement in women with a history of spontaneous preterm labor and a cervical length of less than 25.0 mm in the second trimester [8,9,11].

Cervical length is recognized as one of the best predictors of preterm birth. As cervical length decreases, the estimated risk of preterm birth increases exponentially: from approximately 0.2% at 60 mm to 0.8% at 30 mm, 4.0% at 15 mm, and 78% at 5 mm [24]. In addition, it was observed that the risk of spontaneous preterm birth before 35 weeks decreased by approximately 6% for each additional millimeter of cervical length [25]. Patients with a cervical length of 15 mm have almost a 50% risk of early preterm birth, and CC in these cases was associated with a 10-fold reduction in the rate of preterm birth [26].

This study found that CC was performed earlier in the group indicated by obstetric history and short cervix on ultrasound (15 weeks), compared to the group indicated only by cervical measurement (19.5 weeks), although this difference was not statistically significant. According to Golbasi et al [7], this situation can be explained by the fact that in the group indicated by obstetric history and its association with cervical measurement, the risk of preterm delivery was reinforced by the patients' unfavorable history, leading them to undergo CC before significant cervical changes occurred. This may have contributed to the favorable outcome of these pregnancies. On the other hand, in the group with an indication based solely on cervical measurement, CC was only performed after cervical alterations had been detected, which could limit its effectiveness [7].

Therefore, it is possible that the timing of CC plays a crucial role in satisfactory pregnancy

outcomes, indicating that early intervention, preferably at the end of the first trimester or the beginning of the second (12 to 14 weeks of gestation), regardless of the type of indication, can improve the outcomes of pregnant women with CI, especially in terms of full-term deliveries [4,7,9,11,27].

This finding underscores the importance of thoroughly evaluating all pregnant women for CI during the first or early second trimester of pregnancy [7]. When patients with a history of CI are identified, CC can be performed early based on the clinical history. This procedure is in line with previous studies, which also highlighted that the groups indicated by cervical ultrasound measurement and obstetric history had better gestational outcomes, such as gestational age at delivery, APGAR scores, and fetal survival rate, compared to the group indicated by physical examination [7,28].

In terms of miscarriage (p = 0.542) and preterm birth (p = 0.831), no statistically significant difference was found between the three groups in this study, a result consistent with the observations of Golbasi et al [7] and Ikechebelu et al [4]. This result can be attributed to the similar average gestational age at which CC was performed in the three groups [4].

When analyzing gestational age at the time of delivery, the group that underwent CC based on obstetric history alone had a slightly lower gestational age, with a median of 37.0 weeks (IQR: 1.75, p=0.664). However, this difference was not statistically significant, as the group who underwent CC according to the other criteria had a gestational age at delivery that was only one and a half weeks longer. These findings, which may initially appear contradictory, are consistent with previous studies [7]. This highlights the complexity and need for ongoing research in this area since preterm birth is a multifaceted syndrome, where several causes can interact for its occurrence [29].

In this study, similar to others [7,27], pregnant women with CC indicated by obstetric history had a higher rate of full-term deliveries, although without statistical significance ($P > 0.05$). On the other hand, an opposite result was found by Ikechebelu et al [4], where transvaginal ultrasound was performed in the first trimester, allowing for an early diagnosis of CI and an earlier CC intervention in the second trimester. The application of CC at this early stage may have contributed to a higher success rate of CC indicated by cervical measurement [4].

An encouraging aspect was the lack of statistically significant differences in perinatal outcomes among the various study groups. This suggests that the indication for CC did not significantly impact perinatal outcomes, including birth weight, APGAR scores, NICU admission, and neonatal mortality. Similar results were found by Ikechebelu et al [4], who recommended that, whenever necessary, CC should be performed to treat CI, to achieve better neonatal outcomes [4].

The median birth weight of the newborns in the group indicated by history and history-ultrasound was higher than in the group indicated by ultrasound (3105g, IQR: 605g vs. 3215g, IQR: 471g vs. 2985g, IQR: 478g). However, this difference was not statistically significant. These results differ from the study by Golbasi et al [7], which reported average weights of 2.500g ± 0.967g (OH) vs. 2.645g ± 0.814g (US), also without finding a significant difference. It is worth noting that, in the previous study, gestational age at delivery was lower than in this study, with averages of 34.9 ± 5.3 weeks and 36.1 ± 4.2 weeks, respectively, compared to the medians of 37.0 weeks (IQR: 1.00), 38.0 weeks (IQR: 2.50) and 38.5 weeks (IQR: 2.50) in this one. The more premature the birth, the lower the weight of the newborn, increasing the risks associated with prematurity. This reinforces the importance of early diagnosis of CI and the application of CC to improve pregnancy outcomes and ensure a more favorable outcome for both mother and newborn [4,28].

The main limitations of this study include its retrospective nature, the relatively small sample size, and the absence of a control group, which may compromise the reliability of the results. The use of a survival curve as a statistical estimate may not accurately reflect the real probability of survival. In addition, it was not possible to measure some known confounding factors for preterm birth, such as ethnicity, socioeconomic status, body mass index, uterine anomalies, medication use, and maternal systemic morbidities. However, it is important to note that two-thirds of preterm births occur in women without identifiable risk factors, which makes it difficult to establish causality and effective interventions7. Despite these limitations, the study groups had similar baseline characteristics, reducing the impact of these factors on the study.

Positive aspects include consistent management of all patients under the same treatment protocols at a single tertiary hospital. In addition, the direct collection of detailed information on pregnancy losses and preterm births from hospital records ensured reliable data. Carrying out the study retrospectively, without the need for prior consent from the participants, made it possible to include all the cases identified, eliminating selection bias and enabling a thorough analysis of each case. This provided the opportunity to analyze each case in detail.

Thus, the indication for OH is important for pregnant women who have a history of more than one second-trimester pregnancy loss or premature birth, US for measuring the cervix is particularly relevant for nulliparous patients. The indication that combines both is also advantageous for pregnant women who have a history of one second-trimester pregnancy loss or premature birth, allowing for a more personalized and targeted intervention with closer monitoring. Therefore, CC, when performed early, regardless of the indication, can be an effective strategy for preventing premature births and improving perinatal outcomes. This suggests the importance of performing CC electively, before the onset of PTL and at the onset of cervical changes, rather than when CI is already advanced, reinforcing the relevance of CC in obstetric practice.

5. CONCLUSION

In this study, the efficacy and results of CC were compared based on the indication, whether it was OH, US of cervical measurement, or both. All indications proved to be effective in reducing the risk of preterm birth. The results revealed that there were no statistically significant differences in gestational and perinatal outcomes among the different indications. It is recommended to consider early application of CC before cervical changes associated with CI occur. It is also suggested that all pregnant women undergo a standardized and early transvaginal US examination to identify those who may require CC. In addition, for a more comprehensive assessment, it is recommended that a large prospective, randomized, controlled clinical trial before generalizing these results.

DISCLAIMER (ARTIFICIAL INTELLIGENCE)

Author(s) hereby declare that NO generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc) and text-to-image generators have been used during writing or editing of manuscripts.

ETHICAL APPROVAL

The study was submitted to the Ethics Committee for Research with Human Subjects (CEP) of the Western Paraná State University – UNIOESTE (Cascavel, Paraná, Brazil), and its approval was obtained under protocol number 6.544.745/CAAE 75724923.5.0000.0107.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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