Prevention of preterm birth among singleton pregnant women with an obtuse uterocervical angle: a quasi-experimental study on the value of cervical pessary combined with progesterone

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Abstract

Background: Micronized progesterone is an effective preterm birth prophylactic intervention in singleton pregnancies with short cervical length measured via transvaginal ultrasound in the second trimester. The use of cervical pessary as a preventive method for preterm birth has controversial findings when compared to progesterone-combining pessary, with the hypothesis that it narrows the uterocervical angle and reduces the risk of preterm birth. This study aimed to evaluate the value of cervical pessary combined with progesterone in the prevention of preterm birth among singleton pregnant women with a short cervix having uterocervical angles ≥ 95°. **Methods:** A quasi-experimental study with a nonequivalent-group design was conducted on 225 singleton pregnant women with a gestational age of 16^{+0} to 23^{+6} weeks, who had a cervical length of < 25 mm. Participants were assigned to two groups: prophylactic treatment with progesterone alone or progesterone combined with a cervical pessary. The association between cervical length, uterocervical angle (≥ 95° or ≥ 105°), and preterm birth outcomes (< 37 weeks or < 34 weeks) was assessed using a multivariable binary regression model. The difference was statistically significant ($p < 0.05$). **Results:** The probability of preterm birth (< 37 weeks) in the group of pregnant women with a uterocervical angle ≥ 95° treated with progesterone plus cervical pessary decreased compared to the progesterone-alone group, with an OR (95% CI) of 0.34 (0.15 - 0.8). In the group of pregnant women with a uterocervical angle ≥ 105°, the treatment by a cervical pessary plus progesterone yielded a lower rate of preterm birth < 37 weeks and < 34 weeks, with an OR (95% CI) of 0.03 (0.01 - 0.13) and 0.08 (0.02 - 0.35), respectively. **Conclusions:** The results of this study suggested that a cervical pessary has an added effect combined with progesterone in preventing preterm birth among singleton pregnant women with obtuse uterocervical angles. The preventive effect is stronger if the uterocervical angle measurement is ≥ 105°.

Keywords: *uterocervical angle, preterm birth, singleton pregnancy, cervical pessary.*

1. INTRODUCTION

The World Health Organization defines a preterm birth (PTB) as a live birth that takes place between 20^{+0} and 36^{+6} gestational weeks. An estimated 15 million babies are born prematurely each year worldwide, more than 60% of which occur in Africa and South Asia. According to UNICEF (2014), Vietnam's PTB rate was 9%, placing it 21st globally. Although research efforts on PTB have been ongoing, PTB rates have remained unchanged over the past decade in every region of the world [1]. Two-thirds of PTBs are due to spontaneous preterm labor, which is still a challenge in obstetric care. This is a significant contributor to neonatal morbidity and death, primarily because of immature respiratory systems, brain bleeding, and infection. These conditions can result in long-term neurological abnormalities such as intellectual disability, cerebral palsy, chronic lung disease, deafness, and blindness [2]. Therefore, the effect and safe application of PTB preventive measures are clinically essential.

Until now, the cervical length (CL) measurement via transvaginal ultrasound (TVS) in the second trimester has been consistently shown to be a recommended strategy for predicting PTB, with recommendations to use micronized progesterone in patients with a short cervix for the prevention of PTB [3]. Prophylaxis of PTB with micronized progesterone was associated with an approximately 40% reduction in the risk of PTB in singleton pregnancies in mothers with a short cervix [4]. In recent years, the uterocervical angle (UCA) has been proposed as a potential predictor of PTB [5]. The more obtuse the UCA, the greater the gravitational effect from the uterus and the fetus on the internal os tends to be along the length of the cervical canal, which can result in a shortened

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DOI: 10.34071/jmp.2025.4.18

Received: 12/04/2025; Accepted: 05/08/2025; Published: 30/08/2025

cervix [6]. A study by Dziadosz et al. found that UCA thresholds ≥ 95 ° and ≥ 105° have a sensitivity of 80% and 81%, respectively, compared to a sensitivity of 62% and 60% of CL ≤ 25 mm in predicting PTB < 37 weeks and < 34 weeks [7]. A recent study by Singh et al. showed a higher risk of PTB in pregnant women with a UCA ≥ 95° and CL ≤ 25 mm, with a sensitivity and specificity of 86.7%, 93%, 31.1%, and 95.6%, respectively [8]. Another non-invasive method of preventing PTB is using a cervical pessary, with the hypothesis that it narrows the UCA, which disperses the impact force from the uterus and the fetus down to the cervix. However, the results of these studies are controversial [9]. A meta-analysis of eight studies in singleton pregnancies with short cervixes found that a cervical pessary was not effective in reducing the risk of PTB at < 34 weeks (RR = 0.73), < 37 weeks (RR = 0.69) [10]. Studies published during the 2018 - 2022 period about the combination of progesterone with a cervical pessary confirmed the effects of this therapy on pregnancy and neonatal outcomes [11-14]. Some studies have shown that combined therapy reduces the rate of PTB compared with progesterone alone [15], while other studies have reported no effect [16, 17]. Due to the discrepancy in the results of the studies above and the hypothesis that a biochemical treatment (progesterone) in combination with a mechanical treatment (cervical pessary) would be additionally effective in reducing the incidence of PTB in the group of women with an obtuse UCA, this study aimed to evaluate the value of cervical pessary combined with progesterone in the prevention of PTB among singleton pregnant women with a short cervix and obtuse UCAs measured in the second trimester of pregnancy.

2. MATERIAL AND METHODS

2.1. Study population

All singleton pregnant women aged 18 - 40 years old with a live fetus at the age of 16^{+0} - 23^{+6} weeks with TVS CL measurements ≤ 25 mm managed at the Haiphong Hospital of Obstetrics and Gynecology, Vietnam, from September 2020 to September 2022 were enrolled in the study.

Gestational age was estimated by the last menstrual period and confirmed by the fetal crown-rump length via ultrasound in the first trimester.

The following were the exclusion criteria: (1) history of PTB or miscarriage in the 2nd trimester; (2) history of cervical intervention (conization and loop electrosurgical excision procedure (LEEP)), (3) pregnant women with signs of threatened miscarriage, miscarriage, threatened PTB, or PTB; (4) PTB by medical indication; (5) pregnant women with a cervical cerclage; (6) non-adherence to progesterone treatment; (7) congenital malformations; and (8) loss to follow-up.

2.2. Methods

Study design

This was an open-label, quasi-experimental study with a nonequivalent group design. All participants received PTB prophylaxis with vaginal progesterone following recommendations. The choice of combination with a cervical pessary depended on the mother's decision after consultation with a senior obstetrician. Mothers who do not want to make their own decisions could completely follow the opinion of the treating doctor, based on the doctor's clinical experience with the mother's written consent.

Sample size calculation

The following formula was used to calculate the sample size for this study:

$$n = \frac{[P_S \text{ x } (1 - P_S)] \text{ x } [P_N \text{ x } (1 - P_N)]}{(P_N - P_S)^2} \text{ x f } (\alpha, \beta)$$

n: number of subjects for each group.

α: significance level.

1 – β: the power of the test.

f (α, ß): reliability. If α = 0.05 and ß = 0.1, then f (α, ß) = 10.5.

Ps (P standard): The success rate of the old method, taking Ps = 85.4% based on the PTB rate in the group of pregnant women with a CL ≤ 25 mm without cervical pessary insertion, is 14.6%, according to a study by Saccone et al. [16].

P_N (P new): The intended success rate of the new method, taking P_N = 89.4% based on the PTB rate in the group of pregnant women with a CL ≤ 25 mm and pessary application, is 10.6%, according to a study by Saccone et al. [16].

The minimum calculated sample size for each group is 62 patients.

We scheduled the recruitment of at least 87 patients to each group, with an estimated 40% of patients lost to follow-up.

Research variables

Maternal characteristics; ultrasonographic characteristics; gestational age at birth; PTB rates < 34 weeks or < 37 weeks of gestation; neonatal characteristics and outcomes, including mean birth weight, Apgar score, neonatal intensive care unit admission, death, and adverse neonatal outcome were recorded. Pregnant women giving birth at other hospitals were contacted by phone to collect information about the birth, maternal, and neonatal outcomes.

Assessment of CL and UCA

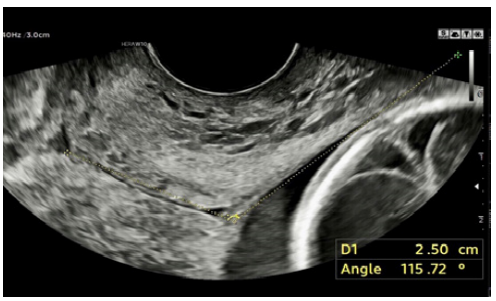
Each patient had their CL and UCA measured once at enrollment and was followed up until delivery. The CL and UCA measurements were performed by a certified sonographer, who was monitored by the Maternal Fetal Medicine Foundation.

The transvaginal probe (frequency 4.0 - 9.0 MHz) was used with the GE Voluson E6 (GE Healthcare Korea) ultrasound machines for measurements.

Following the Fetal Medicine Foundation's recommendation, CL measurements were made by drawing a single, straight line from the internal to the external os.

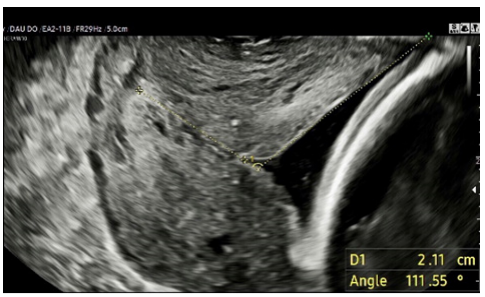
The UCA was measured using the method described by Dziadosz et al. [7]. The angle between the two lines was used to determine the UCA. Between the internal and exterior ostium, the first line was drawn. The internal os was the intersection of the first and second lines, which were drawn 3cm apart and parallel to the lower aspect of the anterior inner uterine wall (Figure 1a). To lessen measurement bias, three images from each subject were measured, and the most obtuse UCA from the three images was utilized. Pregnant women with a UCA of ≥ 95º or ≥ 105º were considered at risk for spontaneous PTB, according to previous studies [7, 8].

In the case of a funnel-shaped internal os, the UCA's first line was placed to measure CL, and the second line was drawn from the innermost part of the cervix that can be measured and extended tangentially to the lower anterior inner uterine (Figure 1b).



a. GA 19^{+4} weeks, UCA 115.7°

Figure 1a. Transvaginal sonographic images showing the measurement technique of UCA at 19^{+4} weeks of gestation with a CL of 25 mm and UCA of 115.7°



b. GA 23^{+4} weeks, UCA 111.6°.

Figure 1b. 23^{+4} weeks pregnant with a V-shaped internal os, CL of 21.1 mm, and UCA of 111.6 °.

Cervical pessary

The cervical pessary used in our study was Arabin (Dr Arabin GmbH & Co, Witten, Germany), which consists of flexible, comfortable silicone with an outer diameter of 65 mm (for nulliparous women) or 70 mm (for multiparous women), an inner diameter of 32 mm, and a height of 25 mm. Before inserting the Arabin pessary, patients had a gynecological examination and screening for vaginal infection. A senior physician placed the cervical pessary in the manner described by Arabin et al. (18). The Arabin is folded and inserted vertically into the vagina, applying pressure along the posterior vaginal wall to the posterior vaginal fornix; the inner diameter is directed upwards, and the participant does not feel pain. The pessary is released into the vagina, and the inner diameter is applied directly to the cervix. It is essential to make sure the entire cervix is located within the inner diameter by moving the index and middle fingers around the cervix. Press the back edge of the pessary up to the back to help the cervix fold backward. Place the speculum to check again: the pessary's inner diameter should completely cover the cervix, and the participant should not feel pain.

The Arabin pessary was withdrawn at 37 weeks or more in asymptomatic patients or cases of (1) PTB (uterine contractions unresponsive to tocolytics), (2) labor, (3) heavy vaginal bleeding, (4) leaking amniotic fluid/rupture of membranes, (5) feeling of pain or discomfort, or (6) where the patients required it.

Micronized progesterone

Both groups of pregnant women were supported with vaginal progesterone (Cyclogest, Actavis UK Limited) at a dose of 200 mg/day every night to the end of 36 gestational weeks or at the onset of labor. Medication adherence was recorded at each routine antenatal visit. In the case of pregnant women with symptoms of threatened PTB during

pregnancy, they were managed according to the protocol.

2.4. Statistical analysis

Categorical variables were denoted by frequencies (n) and percentages (%), while continuous variables were expressed as mean and standard deviation. The Kolmogorov-Smirnov and Shapiro-Wilk tests were used to assess the normality of variables. The characteristic differences between the group of patients treated with progesterone alone and the group in combination with a cervical pessary were evaluated using the Chi-square test and Fisher's exact test for categorical variables, and the T-test and Mann–Whitney U test for continuous variables with normal distribution and non-normal distribution data, respectively. We determined the correlation between CL, UCA, and gestational age at birth and calculated the OR (95% CI) to determine the association between the output variable and the independent variables. A multivariable binary regression model was used to assess the association between CL, UCA, and PTB outcomes. Participants were divided into two groups according to UCA values ≥ 95° or ≥ 105 for analysis. The role of the cervical pessary on the PTB outcome with different UCA measurements was assessed according to the UCA group. The significance level was set to 0.05. The software SPSS version 26.0 (SPSS, Inc., Chicago, IL) was used for all analyses.

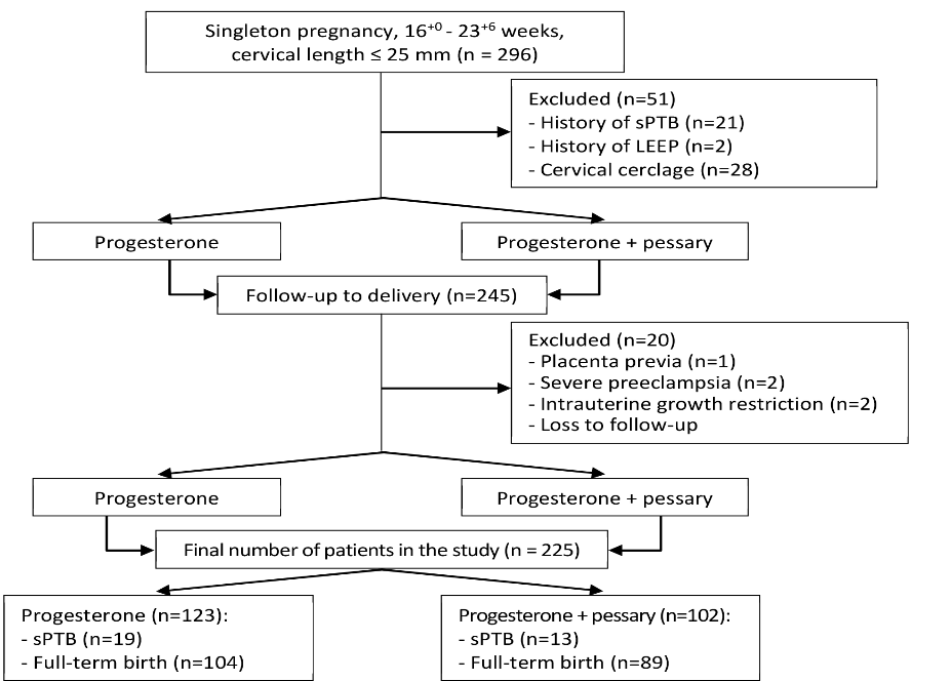


Figure 2. Study diagram

2.5. Research ethics

The research protocol was approved by the Ethics Committee for Biomedical Research of Hue University of Medicine and Pharmacy, Vietnam (IDH 2020/035), and the Scientific Council of Hai Phong Obstetrics and Gynecology Hospital, Vietnam (IEC, 1186/QD-BVPSHP). All pregnant women voluntarily participated in the study and signed written consent after receiving a full explanation of the research objectives and procedures.

3. RESULTS

A total of 296 singleton pregnant women with a gestational age of 16^{+0} to 23^{+6} weeks and a CL of ≤ 25 mm via TVS participated in the study. After excluding 71 cases with other high-risk factors for PTB or loss to follow-up, 225 women remained for the final analysis. These women were divided into two groups: one treated with progesterone alone (123 women) and the other treated with progesterone combined with a cervical pessary (102 women).

Table 1. General characteristics of study subjects (n = 225)

Maternal characteristics		Progesterone (n = 123)	Progesterone + pessary (n = 102)	P value*
Maternal age (X ± SD) (years)		27.5 ± 5.4	28.2 ± 5.5	0.404
BMI (X ± SD) (kg/m^2)		24.0 ± 2.8	23.5 ± 2.4	0.140
Obstetric history	Nulliparous	67 (54.5)	54 (52.9)	0.819
	Multiparous	56 (45.5)	48 (47.1)	
Gestational age at ultrasound (X ± SD) (weeks)		20.49 ± 2.4	20.9 ± 2.3	0.187
Cervical internal os shape at ultrasound	Closed	79 (64.2)	71 (69.6)	0.776
	Y-shaped	17 (13.8)	11 (10.8)	
	V-shaped	14 (11.4)	12 (11.8)	
	U-shaped	13 (10.6)	8 (7.8)	
Cervical length at ultrasound (X ± SD) (mm)		23.8 ± 2.9	22.9 ± 2.9	0.020
Uterocervical angle at ultrasound (X ± SD) (degrees)		88.8 ± 21.5	111.1 ± 17.5	< 0.001

**P values were obtained by the Chi-square test for categorical variables and the T-test for continuous variables. BMI: body mass index; SD: standard deviation.*

There were no statistically significant differences in maternal age, maternal BMI, CL, and cervical internal os shape between the two groups. However, the mean UCA at ultrasound was significantly larger in the group of patients with combined treatment than in the group of patients with progesterone alone (p <0.001).

Table 2. Pregnancy outcomes of study subjects (n = 225)

Outcomes / Prophylactic Treatment	Preterm birth < 37 weeks				Preterm birth < 34 weeks			
	Yes n (%)	No n (%)	OR (95%CI)	p	Yes n (%)	No n (%)	OR (95%CI)	p
Progesterone + pessary	13 (12.7)	89 (87.3)	0.80 (0.37 - 1.71)	0.563	5 (4.9)	97 (95.1)	0.65 (0.21 - 2.01)	0.455
Progesterone	19 (15.4)	104 (84.6)			9 (7.3)	114 (92.7)		

There was no statistically significant difference in PTB rates between the two groups, specifically for those occurring at < 37 weeks and < 34 weeks.

Table 3. Neonatal characteristics and outcomes of study subjects (n = 225)

Neonatal Characteristics and Outcomes		Progesterone (n = 123)	Progesterone + pessary (n = 102)	p
Gestational age at birth (X ± SD) (weeks)		37.7 ± 2.0	37.9 ± 1.6	0.654
Birthweight (grams)	< 1500	2 (1.6%)	2 (2.0%)	0.627
	1500 - 2499	19 (15.4%)	17 (16.7%)	
	2500 - 3999	100 (81.3%)	83 (81.4%)	
	≥ 4000	2 (1.6%)	0 (0%)	
	X ± SD	2886.6 ± 523.2	2845.6 ± 504.5	0.553
Apgar scores	≥ 7	121 (98.4%)	102 (100%)	0.502
	< 7	2 (1.6%)	0	
Neonatal Intensive Care Unit admission		6 (4.9%)	5 (4.9%)	1.000

There was no statistically significant difference in neonatal outcomes between the two groups (p > 0.05).

Table 4. Multivariable binary regression model to assess the association between cervical length, uterocervical angle, and preterm birth outcomes < 37 weeks**

Prophylactic treatment		Beta	OR	95% CI	p
Progesterone (n = 123)	CL	-0.57	0.57	0.32 - 1.01	0.055
	UCA	0.18	1.20	1.07 - 1.33	0.001
	Maternal age	0.23	1.26	1.05 - 1.51	0.015
	Treatment of threatened preterm labor	-2,48	0,08	0,01 - 0,76	0,027
	Gestational age at ultrasound	-0.27	0.77	0.50 - 1.18	0.223
	Previous cesarean	-0.60	0.55	0.07 - 4.16	0.563
	Cervical internal os shape	-0.21	0.81	0.37 - 1.77	0.599
Progesterone + cervical pessary (n = 102)	CL	-0.20	0.83	0.65 - 1.06	0.133
	UCA	0.05	1.05	0.10 - 1.12	0.053
	Maternal age	0.11	1.12	0.10 - 1.30	0.153
	Treatment of threatened preterm labor	-2.28	1.10	0.02 - 0.49	0.004
	Gestational age at ultrasound	-0.27	0.77	0.52 - 1.12	0.169
	Previous cesarean	-0.07	0.93	0.14 - 6.04	0.942
	Cervical internal os shape	0.37	1.45	0.74 - 2.86	0.282

***Adjusted with CL, UCA, maternal age, treatment of threatened preterm labor, gestational age at ultrasound, previous cesarean, and cervical internal os shape.*

There was a statistically significant relationship between the UCA at ultrasound and outcomes of PTB < 37 weeks in the group treated with progesterone alone, with an OR (95% CI) of 1.12 (1.07 - 1.33). Meanwhile, in the group in combination with a cervical pessary, no statistically significant relationship was found between CL, UCA, and outcomes of PTB < 37 weeks (p > 0.05).

Table 5. The pregnancy outcomes in the UCA ≥ 95° subgroup (n = 134).

Outcomes Prophylactic treatment	PTB < 37 weeks				PTB < 34 weeks			
	Yes n (%)	No n (%)	OR (95% CI)	p	Yes n (%)	No n (%)	OR (95% CI)	p
Progesterone	16 (34.8)	30 (65.2)	0.34 (0.15 - 0.8)	0.011	8 (17.4)	38 (82.6)	0.30 (0.09 - 0.99)	0.063
Progesterone + pessary	13 (15.5)	71 (84.5)			5 (6.0)	79 (94.0)		

There was a statistically significant relationship between the prophylaxis treatments and PTB < 37 weeks in the subgroup of pregnant women with UCA ≥ 95°. The probability of PTB < 37 weeks in the group treated with progesterone combined with a cervical pessary decreased, with an OR (95% CI) of 0.34 (0.15 - 0.80), in comparison to the progesterone-alone group. However, no statistically significant association was found between PTB prophylaxis treatments and outcomes of PTB < 34 weeks.

Table 6. The pregnancy outcomes in the UCA ≥ 105° subgroup (n = 81)

Outcomes Prophylactic treatment	PTB < 37 weeks				PTB < 34 weeks			
	Yes n (%)	No n (%)	OR (95% CI)	p	Yes n (%)	No n (%)	OR (95% CI)	p
Progesterone	14 (87.5)	2 (12.5)	0.03 (0.01 - 0.13)	< 0.001	7 (43.8)	9 (56.2)	0.08 (0.02 - 0.35)	0.001
Progesterone + cervical pessary	10 (15.4)	55 (84.6)			4 (6.2)	61 (93.8)		

In the subgroup of pregnant women with UCA ≥ 105° there was a significant association between the group treated with progesterone combined with a cervical pessary, with a lower rate of PTB < 37 weeks, with OR (95% CI) of 0.03 (0.01 - 0.13). Besides that, the patients with combined therapy were significantly associated with a decrease in PTB < 34 weeks, with an OR (95% CI) of 0.08 (0.02 - 0.35).

4. DISCUSSION

Our results on 225 singleton pregnant women at 16^{+0} - 23^{+6} weeks gestation with a short CL found that the added effect of the cervical pessary combined with progesterone in the PTB reduction rate was clearly shown in the group of pregnant women with a UCA ≥ 105°.

A possible explanation is that if the UCA is obtuse, the gravitational pull of the uterus and fetus on the internal os tends towards the direction of the cervix, which might shorten it and be one of the causes of PTB. Therefore, a cervical pessary based on this mechanism serves to modify the UCA from obtuse to acute, moving the force of the uterus to the posterior vaginal fornix to prevent shortening of the cervix in addition to supporting the cervix and distributing the uterine force uniformly. A study by Cannie et al. [6] revealed that in the high-risk PTB group, the mean UCA value in patients who gave birth after 34 weeks was significantly lower than before the insertion of the Arabin pessary (132° vs. 146°, p = 0.01). Still, it did not change in patients who gave birth < 34 weeks (143° vs. 152°, p > 0.05).

As shown in Tables 2 and 3, the combination of progesterone and cervical pessary did not significantly reduce the probability of PTB < 37 weeks (OR = 0,80, 95% CI: 0.374 - 1.710) and < 34 weeks (OR = 0.653, 95% CI: 0.212 - 2.014) compared with progesterone alone. The two groups also had no statistically significant difference in neonatal outcomes.

Micronized progesterone applications have been shown to effectively reduce the risk of PTB and improve neonatal outcomes in singleton pregnancies with short CL measured via TVS in the second trimester [19] [20]. Micronized progesterone is also the best PTB prophylactic intervention in singleton pregnancies with a high risk of PTB [21]. Progesterone is known for its immunomodulatory plus anti-inflammatory effects, which inhibit uterine contractions and prostaglandin production, which are potent uterotonics and promoters of cervical ripening [22]. Micronized progesterone administration acts on the immune system by increasing the CD4+ ratio, which determines T-cell regulation [23].

In some pregnancies, micronized progesterone administration alone has likely been shown to effectively reduce the risk of PTB, so that any additional benefits of other preventive interventions, such as a pessary, are barely noticeable. Recent studies comparing the use of progesterone alone versus the combination with a cervical pessary in preventing PTB in singleton pregnancies with a short CL showed opposite results. A meta-analysis of five RCTs found that this combination treatment did not reduce the risk of PTB < 34 weeks (RR = 0.78, 95% CI: 0.46 - 1.34) and < 37 weeks (RR = 1.09, 95% CI: 0.52 - 2.27) in comparison with progesterone alone. There was also no difference in neonatal outcomes between the two groups [24].

In contrast, a meta-analysis of three non-RCT studies showed that the combined treatment was effective in reducing the incidence of PTB < 34 weeks (RR = 0.41, 95% CI: 0.24-0.70). However, the CI's range indicated that no definitive conclusions could be drawn from the results of the above meta-analyses [24].

A meta-analysis of all RCTs and non-RCTs revealed that there was a marginally significant reduction in the incidence of PTB < 34 weeks of gestation in the group receiving combined therapy compared to progesterone alone (RR = 0.63, 95% CI: 0.39 - 1.01). The CI's range indicated insufficient evidence to confirm this conclusion [24].

The multivariable binary regression model assessing the association between CL, UCA at ultrasound, and outcomes of PTB < 37 weeks illustrated that there was a statistically significant relationship between the UCA at ultrasound and outcomes of PTB < 37 weeks in the group treated with progesterone alone, with OR (95% CI) of 1.195 (1.072 - 1.332). We did not find a statistically significant relationship between CL, UCA, and outcomes of PTB < 37 weeks in the group of patients treated with progesterone combined with a cervical pessary. The difference in results between the two groups may be that the cervical pessary has partly played a role in narrowing the UCA, thereby reducing the rate of PTB in this group of patients.

In recent years, many studies have evaluated UCA, measured in the second trimester of pregnancy while measuring CL via TVS, as a potential ultrasound parameter predicting PTB [25, 26]. Although there are many complex mechanisms

leading to PTB, cervical histological and anatomical variations play a key role in the pathogenesis of preterm birth labor [27]. The pressure from nearby organs and, more importantly, the growing pregnant uterus can impact the cervical internal os and alter cervical function [28]. It seems that an obtuse UCA is associated with a direct force from the pregnant uterus to the cervical internal os. At the same time, it is hypothesized that an acute UCA is associated with less direct force action on this os, which plays a supportive role in maintaining integrity as well as preventing the expansion of the internal os [18, 29]. In other words, it is hypothesized that the acute UCA acts as a barrier to the progression of labor [30].

This study had two main advantages. First, the quasi-experimental study has a sample size for each group. The analytical group was specifically calculated to ensure the representativeness and validity of the research results. Additionally, all uterocervical angles were measured by a single obstetrician to minimize interobserver variability. However, we acknowledge several limitations that are important for interpreting the findings. First, in this quasi-experimental study with non-randomized sampling, the decision to use a cervical pessary was influenced by patient selection, which may introduce classification bias. Second, although multiple variables were used to adjust the association between UCA and CL with PTB, the study still lacks information on other factors such as smoking, type of conception, and more.

5. CONCLUSIONS

The results of this study suggested that a cervical pessary has an added effect combined with progesterone in preventing preterm birth among singleton pregnant women with obtuse uterocervical angles. The preventive effect is stronger if the uterocervical angle measurement is ≥ 105°. Further randomized studies on pregnant women with obtuse uterocervical angles will be needed to clarify the role of a cervical pessary in preventing preterm birth.

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