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Efficacy and Safety of Cervical Pessary in Decreasing the Preterm Labor in Symptomatic Pregnant Women: A Randomized Clinical Trial

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ABSTRACT

Background & Objective: Pessary is a silicone, rubber or plastic device, available in different shapes and sizes, which may prevent preterm labor in some pregnant women.

Materials & Methods: We enrolled >18-year-old women with gestational age between 24 weeks and 0 days to 34 weeks and 0 days, admitted to hospital with signs/symptoms of preterm labor (threatened preterm labor) and shortened cervical length (<25 mm in ultrasound measurement). Included subjects were randomly allocated to 2 groups. In first group a cervical pessary was placed for patient in lithotomy position. In second group no pessary was inserted and patients received only the routine standard institutional treatments.

Results: Demographic characteristics, Body Mass Index, mean cervical length, parity status, fertilization type (natural, assisted) and route of delivery had no statistically significant difference in 2 studied groups. Although gestational age at which patient had experienced her first preterm labor episode was similar in 2 groups, gestational age at delivery was higher in pessary group compared with expectant management group (38.64 weeks versus 35.80 weeks which was statistically significant). Neonatal outcome measures (like rate of respiratory distress, orotracheal intubation, low birth weight, NICU admission, fetal death, etc.) were better (statistically significant) in pessary group.

Conclusion: Using cervical pessary after successful control of a threatened preterm labor episode in women with short cervix can postpone the labor significantly, leading to increased gestational age and improved neonatal outcome.

Keywords: Cervical pessary, Efficacy, Preterm labor, Safety



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Introduction

Birth before 37 completed weeks of gestation (259 days), defined as preterm birth, is seen in about 5%-10% of all pregnancies and impose a substantial risk of neonatal mortality and morbidity, permanent life-long disabilities (like cerebral palsy) and considerable economic cost to health system (1-3).

Although about half of preterm births and two thirds of extreme preterm births (birth before 28 weeks) occur spontaneously (4,5), there are some well-defined maternal/fetal risk factors which can put the fetus in the way of preterm labor. Cervical incompetence usually

presented as a short cervix (cervical length \leq 25 mm in second trimester of pregnancy measured by transvaginal ultrasound scan) is a major risk factor for preterm birth and can predict the probability of preterm labor onset in apparently normal singleton pregnancies and is a cause of about 20% of premature deliveries (6,7).

Both surgical (cerclage) and medical methods (bed rest, tocolytics and/or hormone administration) are used to manage the cervical incompetency. Pessary is a silicone, rubber or plastic device, available in

different shapes and sizes, which prevents preterm labor in some patients by different mechanisms like closing the internal cervical ostium (by bending the cervix posteriorly), compressing the cervical canal, protecting the cervical mucus plug, maintaining the immuno-microbiological barrier between the chorio-amnion membrane and extraovular space. Pessary insertion is a simple, relatively non-invasive procedure requiring no anesthesia or sedation (8).

Although mechanical devices (like pessary, rings, balloons, etc.) have been used to close the cervix from 50 years ago (9), their efficacy in prevention of preterm labor is not so clear yet. Some studies have shown a significant reduction in preterm labor rate after placing the pessary in cervix but other studies have found no efficacy.

This randomized clinical trial evaluates the beneficial effects of cervical pessary in decreasing the rate of preterm labor in women with singleton pregnancy and shortened cervix.

Materials and Methods

Setting and Design

This prospective open-labeled randomized clinical trial was performed in a referral teaching hospital with annual census of 40,000. Cases were included conveniently between May 2018 and December 2019 in accordance with the Declaration of Helsinki (1989) after obtaining the informed written consent from the patients. Institutional ethics committee approved our study (Code: IR.SBMU.RETECH.REC.1396.460). We have registered our study in IRCT.ir with the registration code of IRCT20180819040830N3 in 2020-04-29 (link: https://irct.ir/user/trial/45855/view).

Participants

All >18-year-old women with singleton pregnancy admitted in hospital with diagnosis of preterm labor were assessed for eligibility. Preterm labor was defined as the presence of regular painful uterine contractions documented on fetal heart monitoring with frequency of 3 or more contractions in every 20 minutes leading to cervical changes (dilatation, effacement and shortening in ultrasound study measurement).

We enrolled patients with gestational age between 24 weeks and 0 days to 34 weeks and 0 days and shortened cervical length. Gestational age was calculated using the date of the first day of last menstrual period (confirmed by measuring the crown-rump length of fetus in first-trimester ultrasound scan). Shortened cervical length was defined as cervical length ≤25 mm measured by transvaginal ultrasound scan in supine position using vaginal probe and calculating the distance between internal os and external os with straight and/or curve line.

We excluded cases with major fetal abnormalities, fever or any other clinical findings in favor of chorioamnionitis and placenta previa as well as women with normal cervical length and women who had not responded to the routine standard treatments of preterm labor and were experiencing continued signs and symptoms of preterm labor after 48 hours of admission. We also excluded women with vaginal bleeding or signs of ruptured membranes.

Interventions and Measurements

The patients were admitted and treated with bed rest, hydration, tocolytics, corticosteroids and/or magnesium sulfate (if indicated), antibiotics for vaginal infection (is suspected), etc. All of them were followed up during their hospital admission. If the signs and symptoms of preterm labor were alleviated after at least 48 hours of admission and patients were scheduled for discharge, they were included in study and randomly allocated to 2 groups after obtaining the informed written consent and verifying that the cervical length is <25 mm yet (by repeated ultrasound measurement). Included patients with gestational age between 24 weeks and 0 days to 34 weeks and 0 days and shortened cervical length were randomized to 2 groups. Randomization was based on the discharge sequence and we used block randomization with computer generated blocks of 4.

In first group (pessary group), a cervical pessary (Milex® Pessary, CooperSurgical co, NewYork, USA) with proper size was placed for the patient in lithotomy position. In second group (control group), no pessary was inserted and patients received only the routine standard institutional treatments prescribed for women with preterm labor.

All patients received routine standard care for preterm labor prevention and our study didn't affect the routine prenatal care provided for patients with history of treated threatened preterm labor. Demographic characteristics and data about the parity, baseline and delivery time gestational age, method of fertilization, route of delivery and patient's drug history were collected and compared in 2 groups.

Outcome Measures

Primary outcome was giving birth after 37 weeks of gestation. Possible side effects of pessary (including vaginal discharge, pessary descent, urinary tract infection, sepsis, cervical necrosis, severe pelvic pain or discomfort) and spontaneous preterm birth before 34 weeks were considered as secondary outcomes. Fetal outcomes including neonatal birth weight, rate of fetal death, orotracheal intubation, respiratory distress, NICU admission, intra-ventricular hemorrhage, necrotizing enterocolitis and retinopathy of prematurity were also considered as secondary outcome measures.

Data Analysis

Descriptive statistics were presented as minimum, maximum, mean and standard deviation. Student t-test

and Chi-square were used to compare means. We considered P-value<0.05 as significant. Statistical analysis was performed on intention-to-treat basis. All analyses were performed using SPSS, version 18 (SPSS, Inc., Chicago, IL., USA).

Results

A total of 159 subjects, admitted to hospital with signs and symptoms of preterm labor, were assessed for eligibility while 18 of them refused to participate in the study and 41 cases were excluded. Finally 100 women were included and randomized. CONSORT diagram showing the participants flow in the study is illustrated in Figure 1.

Of the subjects, 38 in pessary group and 36 in control group were nulliparous. There was no statistically significant difference between 2 groups in terms of parity status (P=0.60). Of the 50 women in pessary group, 47 and of the 50 women enrolled into the control group, 48 had natural fertilization. In pessary group and control group, 3 and 2 women respectively had

received assisted reproductive treatments (P=0.98). Route of delivery had no statistically significant difference in both studied groups (P=0.06) as 40 women in pessary group and 46 women in control group had natural vaginal delivery. Demographic data and basic characteristics were similar in both studied groups (Table 1).

Gestational age at delivery time was $38.64 (\pm 1.01)$ in pessary group and $35.80 (\pm 1.89)$ in control group with expectant management which shows a statistically significant difference (P=0.00). Although minimum baseline gestational age (gestational age at which patient had experienced her first preterm labor episode and was enrolled in study) was similar in both groups; gestational age at delivery was higher in pessary group than expectant management group (38.64 weeks versus 35.80 weeks, which was statistically significant) (Table 2). Mean time between enrolling in study (time of controlling the episode of preterm labor) and delivery was higher in pessary group than control group (9.14 versus 6.38 weeks which also was statistically significant) (Table 1).

Table 1. Comparison of basic data in 2 groups

Variable	Pessary group (n=50)			Control group (n=50)			. P-
	Minimum	Maximum	Mean (SD)	Minimum	Maximum	Mean (SD)	value*
Age, years old	18	38	28.14 (4.72)	18	39	27.02(5.03)	0.56
Body Mass Index, kg/m2	18.23	30.12	25.90 (2.52)	19.43	30.98	25.14 (3.21)	0.04
Cervical length, mm	8	24	18.36 (4.3)	6	24	18.83 (4.4)	0.32
Baseline gestational age, weeks	25	33	29.64 (2.66)	24	33	29.46(2.83)	0.23
Gestational age at delivery, weeks	32	39	38.64 (1.01)	28	40	35.80 (1.89)	0.00
Time between study inclusion and delivery, n (%)	6	12	9.14 (2.54)	1	14	6.38 (5.84)	0.00
Fetal birth weight (g)	1850	3700	3102.00 (325.13)	660	3600	2663.30 (723.50)	0.04

^{*}Student's t-test, P<0.05 is significant

Table 2. Comparison of Pessary complications

		Pessary group (n=50)	Control group (n=50)	P-value*	
Adverse effects of pessary	Vaginal discharge, n (%)	18 (36)	6 (12)		
	Itching/burning sensation	0 (0)	0 (0)	0.02	
	Smelling odor	0 (0)	0 (0)		
	Vaginal discomfort or pain, n (%) 1(2) 3 (6) Urinary/vaginal infection, n (%) 1(2) 2 (4)		3 (6)	0.02	
			2 (4)		
	Pessary descent, n (%)	0 (0)	0 (0)		
Neonatal outcome	Respiratory distress, n (%)	1(2)	22 (44)		
	Orotracheal intubation, n (%)	0 (0)	14 (28)		
	Low birth weight, n (%) 1(2)		11(22)	0.00	
	Birth before 34 weeks	1(2)	8 (16)		

	Pessary group (n=50)	Control group (n=50)	P-value*
NICU admission, n (%)	1(2)	4 (8)	
Intra-ventricular hemorrhage, n (%)	0 (0)	3 (6)	
Fetal death, n (%)	0 (0)	3 (6)	
Necrotizing enterocolitis, n (%)	0 (0)	2 94)	

^{*}Chi-Square test, P<0.05 is significant

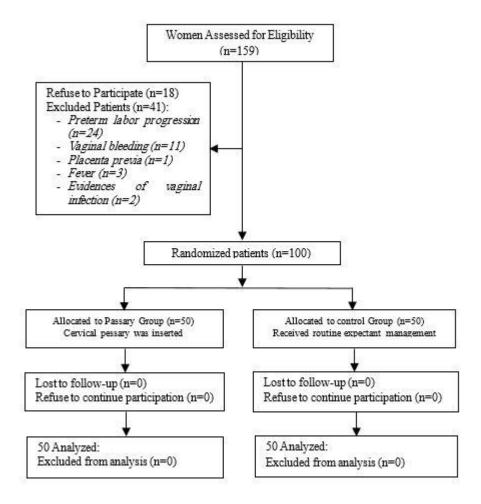


Figure 1. CONSORT diagram showing participants flow in study

Discussion

According to recent studies, making efforts to find safe and effective medical or surgical intervention to decrease the rate of preterm birth is an "urgent need", especially in low-income countries. Multi-country analyses have shown that if all currently available diagnostic and therapeutic modalities be implemented properly in women at risk of preterm labor (including the women with short cervical length), rate of preterm birth will decrease just as 5% (10). Effective therapeutic interventions are even more limited in primigravid women with gestational age >24 weeks experiencing a threatened preterm labor (as even the cerclage is usually used in women with repeated abortion and suspected or documented cervical incompetence in gestational age <24 weeks).

Our study showed that using cervical pessary after successful control of a threatened preterm labor episode in women with short cervix can postponed the labor significantly (leading to increased gestational age and improved neonatal outcome). Mean time between controlling the "threatened preterm labor" and "delivery" was about 3 weeks longer in patients with pessary than patients with control (9.14 versus 6.38 weeks). These 3 weeks of gestational age prolongation is very crucial for fetal growth and developmental processes and decreases the mortality and morbidity rate in neonates.

While most of available studies have focused on cases with repeated preterm labor/abortion, we studied the cases with treated first episode of threatened preterm labor. There are very limited number of studies in this

subgroup of patients. An important recent study regarding this case is the study by Pratcorona et al., where 357 pregnant women with gestational age between 24 weeks and 0 day and 33 weeks and 6 days and controlled threatened preterm labor (not delivered 48 hours after beginning the signs and symptoms) who had also a short cervix were randomly allocated to cervical pessary or routine management groups. Spontaneous birth rate <28 weeks, <34 weeks and <37 weeks and neonatal outcome were compared and it was reported that spontaneous birth rate in gestational age of <34 weeks was similar in pessary and routine management groups but spontaneous birth in <37 weeks was less (statistically significant) in pessary group than the routine management group (14.7% versus 25.1%) (P=0.01). Threatened preterm labor recurrence, and the preterm premature rupture of membranes rate were also lower (statistically significant) in pessary carriers. The most common adverse reaction of pessary insertion was vaginal discharge seen in 36% of our patients which was similar to the findings of Pratcorona et al. who reported having moderate amount of white inodorous vaginal discharge as the most common complication in pessary group followed by "feeling the pessary inside the vagina" (seen in about 20% of patients) (11). Other studies have also shown that increased vaginal discharge (mainly due to foreign body irritation of vaginal mucosa and not an infection) is seen in about 50% of pessary users (12-13). No cases of pessary descent were seen in our study and the study by Pratcorona and "tolerability" was not an issue in both studies. We did not evaluate the patient satisfaction but Pratcorona et al. reported that the majority of studied women would recommend using this intervention to prevent the preterm labor to the other patients.

There are similar studies showing the efficacy and safety of pessary insertion in postponing the labor in women with a singleton pregnancy and short cervical length. For example, in the study of Goya *et al.* which was carried out in 5 hospitals in Spain on singleton pregnant women with cervical length of \leq 25 mm, cervical pessary insertion was compared with expectant management and it was shown that pessary can significantly reduce the rate of spontaneous delivery before 34 weeks (6% versus 27%) with no adverse effect (14).

There are also some studies showing no beneficial effect of pessary insertion in decreasing the preterm labor rate. For example, in a clinical randomized trial on 935 women with a singleton pregnancy and shortened cervix, Nicolaides *et al.* showed that cervical pessary insertion and expectant management have similar effect of preterm prevention and pessary cannot reduce the preterm birth rates before 34 weeks (12% of premature parturition with pessary use, and 10.8% without any intervention) (15). In another study on 108 Chinese women with singleton pregnancy and a cervical length less than 25 mm at 20-24 weeks of gestation it was also shown that 9.4% of women in pessary group and 5.5% of women in expectant management group gave birth to

their neonates before 34 weeks of gestational age which demonstrated no statistically significant difference (16). These results were confirmed by a multicenter openlabel clinical trial in Netherlands, in which 166 pregnant women with gestational age between 24 and 34 weeks and an arrested episode of threatened preterm labor who had documented and short cervix in their ultrasound scan assessments, were randomized to pessary and control groups. It was shown that pessary insertion could not decrease the rate of preterm birth (<37 weeks) significantly (17).

Our study was done on singleton pregnancies. Data on twin pregnancies is also conflicting. For example, in a randomized clinical trial on 132 pregnant women with a short cervix and twin pregnancy who had not delivered 48 hours after a threatened preterm labor episode onset with primary outcome of decreasing the rate of spontaneous birth before 28, 34 and 37 weeks, it was expressed that spontaneous preterm birth before 34 weeks was lower (statistically significant) in pessary group compared with the routine management group (16.4% versus 32.3%). Low birth weight was also less (statistically significant) in neonates of women in pessary group. In this study there was no statistically significant difference in preterm birth rate <28 weeks or between 34-37 weeks between the 2 groups (18). Another clinical trial on 137 pregnant women with twin pregnancy and a sonographic cervical length ≤25 mm also showed that using pessary can significantly decr-ease the <34 weeks birth rate (19). The recent trial by Nicolaides et al., in which 1180 women with a twin pregnancy without a specific cervical length cut-off were allocated to a pessary or expectant management gr-oup, found no effect of a cervical pessary on preterm birth rates <34 weeks = and adverse neonatal outcome (20).

We evaluated the symptomatic women who had experienced one episode of threatened preterm labor but there are some other studies of asymptomatic women. As Saccone et al. evaluated the role of pessary in decreasing the preterm birth in <34 weeks on 300 asymptomatic women with singleton pregnancies, no preterm birth history and cervical lengths of ≤25 mm and reported that use of a cervical pessary could decrease the rate of spontaneous preterm birth at <34 weeks of gestation (21). While in another study on asymptomatic women with short cervical length, <u>Dugoff</u> et al. studied 121 women randomized to 2 groups (pessary, nopessary) and showed no statistically significant difference between the 2 groups in preterm birth in <37 weeks, <34 weeks and <28 weeks and also in gestational age at delivery, fetal birth weight and adverse neonatal outcome (22).

Limitations

We studied singleton symptomatic women. Other studies on asymptomatic women or women with multiple pregnancies may be beneficial. The conflicting results on the efficacy of cervical pessary insertion in decreasing the rate of preterm birth in different studies showed that other complementary studies are needed to more precisely evaluate the role of pessary in different subgroups of pregnant women.

Conclusion

Using cervical pessary after successful control of a threatened preterm labor episode in women with short cervix can postpone the labor significantly (leading to increased gestational age and improved neonatal outcome).

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Conflict of Interest

The authors declared no conflict of interests.

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