

Effectiveness of Cervical Cerclage on Pregnancy Outcomes in Pregnant Women with the History of Preterm Labor

Hengameh Mohamadkhani Shahri^{1*}, Fakhrolmolouk Yassae², Leila Mohamadkhani Shahri³, Vahideh Hafezi⁴

1. Obstetric & Gynecologist, Imam Khomeini Hospital, Pol-e Dokhtar, Iran.
2. Obstetric & Gynecologist, Tale Ghani Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran.
3. PhD Candidate of Reproductive Health, Department of Midwifery, Karaj Branch, Islamic Azad University, Iran.
4. Guilan University of Medical Sciences, Rasht, Iran.

ABSTRACT

Background and Aim: We aimed to investigate the effectiveness of Cerclage in the pregnancy outcome based on the obstetric history and find out how the timing of the cerclage insertion could improve the pregnancy outcomes.

Methods: We conducted a retrospective descriptive study that enrolled 210 women who underwent history - indicated Cerclage. In all the women, McDonald's method was performed. Demographic data and delivery history were retrieved from the informative hospital system (HIS). The pregnancies were divided into two groups, low-risk group defined as pregnant women with a history of preterm labor (PTL) or second-trimester loss (STL) ≤ 2 , and a high - risk group referred to patients with a history of preterm labor or second - trimester loss (STL) ≥ 3 , to compare the efficacy and timing of the Cerclage in both groups. The Pearson Chi - squared test, student t-test, and ANOVA test were performed by SPSS 26.0. P-value < 0.05 was statistically significant

Results: of 210 women enrolled in the study, 158 were low - risk. Our results show that the obstetric history and cerclage - related factors shortened the gestational age at cerclage insertion and delivery (P-value < 0.05). Earlier cerclage insertion prevented preterm labor and improved neonatal outcomes. However, the time of cerclage insertion was later in the low - risk group, and the gestational age of the low-risk group was statistically significantly longer than the high-risk group (36.61 ± 2 weeks in the low - risk group versus 35 ± 2.14 weeks' gestation in the high - risk group) (P-value < 0.001). Women in the high - risk group were significantly more likely to deliver a newborn with low birth weight or be admitted to the NICU ward.

Conclusion: Cerclage improved pregnancy and neonatal outcomes. The elective Cerclage was more effective in the low - risk group than the high - risk group.

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*CORRESPONDING AUTHOR

Hengameh Mohamadkhani Shahri

Email: Hengameh_3mk@yahoo.com

0000-0002-9666-4383

INTRODUCTION

Preterm labor is the most common cause of newborn death, estimated at up to 35% (1, 2). South Asia and Sub Sahar Africa account for 60% prevalence of preterm birth in a total prevalence of 5% - 18% globally. Preterm labor is associated with newborn morbidity and mortality. Indeed, preterm birth complications are not limited to short - term morbidities such as respiratory distress syndrome, necrotizing enterocolitis, and intraventricular hemorrhage, but also exceeded developmental disabilities (1, 3, 4). Although the etiology of

preterm labor is unknown, it is considered a multifactorial condition; one of these risk factors is cervical insufficiency, which is described as a painless dilation and shortening of the cervix without uterine contraction (5).

The literature has investigated Cerclage and progesterone as the therapeutic options for cervical insufficiency regarding the setting of cost - effectiveness, adverse effects, and the patient preference because the equal effectiveness of Cerclage and progesterone in singleton pregnancies with a previous second - trimester sonographic short cervix and



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spontaneous preterm labor has been evidenced and both interventions efficiently prevent preterm labor, low birth weight, and respiratory distress syndrome (RDS) (4-7).

Cerclage's effectiveness was well established for extending the pregnancy and depleting the incidence of recurrent preterm labor in emergent or prophylactic subjects (8). In contrast, the application of Cerclage in patients with a different obstetric history or the timing of Cerclage to yield the optimal beneficial effects without threatening complications such as chorioamnionitis and maternal infection is controversial (9-12). We aimed to describe the efficacy of cerclage insertion based on the demographical data, obstetric history, cerclage factors, and neonatal outcomes; and find out how the timing of the cerclage insertion could improve pregnancy outcomes.

METHODS

Study Design

We conducted a retrospective descriptive study of 210 pregnant women with a history of cervical Cerclage at hospitals under Shahid Beheshti University of Medical Sciences in Tehran, Iran, between 2011 and 2019.

Cervical and vaginal infectious were treated before the McDonald's surgery, a cerclage procedure with a 5 mm mersilene fiber suture, which was considered the preferred method in this study. All the pregnancies underwent spinal anesthesia to perform McDonald's surgery according to the protocols; then, the patients were monitored in the hospital for 24 hours. The existence of preterm labor history or second - trimester loss was the inclusion criteria. Exclusion criteria were severe preeclampsia or maternal diseases, placenta previa, twin - to - twin transfusion syndrome (TTTS), twin reversed arterial perfusion (TRAP), incomplete history of the patient, and congenital or chromosomal fetus abnormality. Demographic data, including age, BMI, smoking history, and the risk factors for the adverse pregnancy outcomes, including gravidity, parity, a history of conization, uterine abnormality, history of the previous Cerclage, were retrieved from the hospital informational system (HIS). Delivery outcomes including gestational age at

labor, cerclage insertion and removal, vaginal or cesarian delivery; birth weight; neonatal hospitalization in NICU; and adverse pregnancy complications were extracted to determine the effectiveness of Cerclage.

Pregnancies were divided into two groups: low - risk group defined as pregnant women with a history of preterm labor (PTL) or second-trimester loss (STL) ≤ 2 , and a high - risk group referred to patients with a history of preterm labor or second - trimester loss (STL) three or more times. We described the outcomes in both groups and investigate the association of gestational age at cerclage insertion with demographic data and adverse effects. Preterm labor refers to delivery < 37 weeks of gestational age and second-trimester loss, which is defined as the abortion of a fetus between 14 and 27 weeks of gestation.

Ethical Consideration

The Institutional ethics review board approved the study (ethic code: IR.SBMU.MSP.REC.1398.309). Confidentiality of patients' data was concerned.

Statistical Analysis

The Statistical Package for the Social Sciences SPSS version 24.0 was applied for Statistical analysis. Chi - square or Fisher's exact tests analyzed categorical variables, and continuous variables were analyzed by Student t-test or ANOVA. The findings were presented as mean $\pm$ standard deviation or frequency (%). The significance level was considered as $p < 0.05$.

RESULTS

In this study, 210 women who underwent cerclage insertion were included. The low - risk group consisted of 158 participants who had a history of preterm delivery or second - trimester loss (STL) two times or less. The mean age of participants was 28.7 ± 4.75 years which ranged from 20 to 40 years. A mean BMI was 29.9 ± 4 kg/m² with a minimum of 20.1 kg/m² to a maximum of 39.2 kg/m². Table 1 presents the demographic data.

Table 1. Description of Cerclage and delivery timing based on the demographical data

Demographical data	Group	Frequency	Time of Cerclage (gestational week)	P-value	Time of Delivery (gestational week)	P-value
Age	20-25	73(34.7%)				
	26-30	56(26.7%)		0.623		0.007
	31-35	64(30.5%)		($r = 0.068$)		($r = -0.184$)
	36-40	17(8.1%)				
BMI	20-25	21(10%)				
	26-30	85(40.5%)		0.151		0.039
	31-35	79(37.6%)		(0.099)		($r = -0.142$)
	36-40	25(11.9%)				

Smoking	Yes	24(11.4%)	14.6 ± 1.68	0.14	36.2 ± 2.18	0.84
	No	186(88.6%)	14.8 ± 1.3		36.2 ± 2.27	

Past obstetric history showed that the mean gravidity of the patients was 3.33 ± 1.34 , range 2-7, and more frequency, 126 cases (60%), was observed in women with 2 or 3 prior pregnancies. The parity range was 0-5 in the participants, among whom 126 cases had one or two previous labors. Most of the participants, 118 women (56.2%), had no history of cerclage insertion, and 56 had 1 or 2 times failed cerclage

placements in their history. Four patients of the study (9.1%) had a history of a cone biopsy (Table 2). Of 150 women with 1 to 4 previous preterm births, two-third of the patients had only one record. Among the 50 remaining women, 24 women had two histories, and 22 had three histories of preterm delivery. One or two prior STL in 95 out of 102 women with an STL history was noted (table 3).

Table 2. Description of Cerclage and delivery timing based on the obstetric history

Obstetric history	Group	Frequency	Time of Cerclage (gestational week)	P-value	Time of Delivery (gestational week)	P-value
Gravidity	2-3	126(60%)		-0.222 (r = 0.001)		0.003 (r = -0.204)
	4-5	62(29.5%)				
	6-7	22(10.5%)				
Parity	0	44(21%)		-0.213 (r = 0.002)		0.005 (r = -0.37)
	1-2	126(60%)				
	>2	40(19%)				
Prior cerclage	No history	118(56.2%)	15.2 ± 1.5	0.0001	15.2 ± 1.5	0.001
	Failed	56(26.7%)	14.6 ± 1.3		14.6 ± 1.3	
	Successful	36(17.1%)	14.7 ± 1.3		14.7 ± 1.3	

Table 3. Description of Cerclage and delivery timing based on the cerclage factors

Cerclage factors	Group	Frequency	Time of Cerclage (Gestational week)	P-value	Time of Delivery (Gestational week)	P-value
prior PTL	No	150(71.4%)	15 ± 0.82	0.024	37.3 ± 1.2	0.0001
	Yes	60(28.6%)	14.9 ± 1.49		35.4 ± 2.6	
prior STL	No	108(51.4%)	15.1 ± 2.1	0.001	36.7 ± 1.8	0.011
	Yes	102(48.6%)	14.9 ± 1.1		36 ± 2.68	
Timing of cerclage insertion	<13weeks	22(10.5%)		0.374 (r = -0.062)		0.0001 (r = -0.531)
	13-15weeks	88(41.9%)				
	15-17weeks	90(42.9%)				
	17-19weeks	10(4.7%)				
Timing of cerclage removal	<30weeks	12(5.7%)		0.002 (r = -0.256)		
	30-34weeks	8(3.8%)				
	34-37weeks	99(47.1%)				
	>37weeks	91(43.4%)				
Timing of delivery	30-34	26(12.4%)		0.002 (r = -0.256)		
	34-37	68(32.4%)				
	<37	116(55.2%)				
Type of delivery	Vaginal	136(64.8%)	14.8 ± 1.38	0.645	35.8 ± 2.4	0.055
	Cesarean	74(35.2%)	15 ± 1.3		36.6 ± 2	

The average gestational age at cerclage placement was 14.8 ± 1.35 weeks, which varies from 12 to 19 weeks and

35.4 ± 2.7 weeks, was the mean gestation of cerclage removal ranged between 20 and 39 weeks. Labor at

36.2 ± 2.17 weeks' gestation was the median with the range of 30-39 weeks. Most of the pregnancies carried out vaginal delivery with a frequency of 136 (64.8%) (Table 3). The birth weight of 152 newborns (72.4%) was 2.500 g or greater.

Newborns hospitalized in NICU had 52 frequencies (24.8%) (Table 4).

Table 4. Description of Cerclage and delivery timing based on the neonatal outcome

Neonatal outcome	Group	Frequency	Time of Cerclage insertion (Gestational week)	P-value	Time of Delivery (Gestational week)	P-value
Birthweight	< 2.500g	58(27.6%)	15 ± 0.83	0.001	34.5 ± 2.81	0.001
	≥ 2.500g	152(72.4%)	14.8 ± 1.5		36.87 ± 1.45	
NICU admission	No	158(75.2%)	14.8 ± 1.5	0.1	36.7 ± 1.4	0.001
	Yes	52(24.8%)	14.9 ± 0.98		34.5 ± 3	

None of the demographic data correlated with the gestation at the cerclage insertion (P-value > 0.05), but evaluation of the association between the gestational age at delivery and demographic data revealed that the gestational age had a significant negative correlation with maternal age and BMI. However, smoking did not statistically correlate (Table 1)

The result of our study revealed that the parity and gravidity negatively correlated with the gestational age at cerclage placement and delivery (P-value < 0.05): the higher parity and gravidity was reported, the earlier gestational age at Cerclage and delivery was expected (Table 2). Gestational age at cerclage insertion and delivery were significantly (P-value < 0.05) earlier in women with the previous cerclage procedure, even much earlier in women who had a history of failed cerclage insertion. Also, Gestational age at Cerclage and delivery was significantly lower in women with prior preterm labor or mid - trimester loss history, but no association was found between gestational age at cerclage insertion and removal. The significant inverse correlation between the pregnancy period and gestational age at cerclage removal (P-value < 0.05) implied that the earlier cerclage removal would prevent the preterm labor, thus reducing the

preterm labor outcome rate. Indeed, earlier cerclage removal and insertion statistically prolonged pregnancy (P-value < 0.05) (Table 3).

Cerclage insertion at the later gestational age, as expected, by shortening the pregnancy increased the rate of low birth weight (< 2.500g) significantly. Although the significant rise in NICU admission was detected in women with shorter gestational age, no correlation was found between gestational age at cerclage insertion and the rate of NICU admission (Table 4).

Comparing the low - risk and high - risk group demonstrated prolonged gestational age of 36.61 ± 2 weeks in the low - risk group versus 35 ± 2.14 weeks' gestation in the high - risk group, which was statistically significant (P-value < 0.001). The gestational age at cerclage insertion was significantly longer in the low-risk group than in the high - risk group (P-value < 0.001), 15.1 ± 1.71 weeks in the low - risk group versus 14.7 ± 1.2 weeks in the high - risk group. Women in the high - risk group were significantly more likely to deliver a newborn with low birth weight or be admitted to the NICU ward (Table 5).

Table 5. Timing and outcome of Cerclage among low-risk and high-risk pregnancies

Groups	Frequency (prevalence %)	Time of cerclage insertion (weeks)	Time of delivery (weeks)	NICU admission (n)	Low birth weight (< 2.500g) (n)
Low - risk group	158 (75.2%)	15.1 ± 1.71	36.61 ± 2	33/158 (20.9%)	26/52 (50%)
High - risk group	52 (24.8%)	14.7 ± 1.2	35 ± 2.14	18/52(6.34%)	32/158 (20.3%)
P-value		0.001	0.0001	0.01	0.0001

DISCUSSION

The results of our study show the efficacy of Cerclage to improve pregnancy outcomes and reduce neonatal mortality and morbidity. The timing of Cerclage also contributed to

neonatal morbidity by prolonging the pregnancy in which the earlier placement of the Cerclage extended the gestational age, and interestingly earlier removal of Cerclage had the same result; this finding may be the result of inflammatory

responses provoked by the Cerclage at the specific period of pregnancy. However, the cerclage placement in the low - risk group was at a greater gestational age; its efficacy in the low - risk group was much higher than in the high - risk group.

Alfirevic¹ et al. reviewed 15 trials including 3490 women, and they concluded that the cervical Cerclage reduced the preterm labor and prenatal death in high - risk women for preterm delivery (5). Our results indicate similar findings which show the efficacy of cerclage insertion to reduce preterm delivery in both groups, but higher efficacy was observed in the low - risk group. Also, younger gestational age in women with a history of preterm labor, 35.4 ± 2.6 weeks' gestation in women with a previous history of preterm labor compared to 37.3 ± 1.2 weeks' gestation in women without the previous history, indicated the efficacy of Cerclage based on the obstetric history. However, Alfirevic¹ et al. stated that no evidence supported obstetric history's effect on different pregnancy outcomes followed by cerclage (5).

A large study on 1292 singleton pregnancies analyzed the beneficial effect of Cerclage by dividing the population into six subgroups based on their risk factors for adverse pregnancy outcomes; in contrast to our results, they found that only the singleton pregnancies with three or more mid-trimester loss or preterm labor, but without conization or cervical biopsy had a significant reduction in the rate of preterm delivery and improvement in the neonatal outcomes (13). Further studies on the women with the associated cervical insufficiency risk factors or high - risk pregnancies have proposed the Cerclage as a therapeutic option (11, 14-16). However, the evidence has not recommended the cerclage insertion in multiple pregnancies, which may worsen the pregnancy outcomes, and they suggested the expectant management approach (15, 17). Furthermore, a retrospective study on 1075 women with a previous history of conization represented the increased risk of preterm labor and preterm premature rupture of membranes in women undergoing cerclage procedures (9). These findings suggest that the Cerclage should be applied to selective patients, not to all.

In a descriptive cross - sectional study, cerclage application improved neonatal survival, and 64% of neonates had ≥ 2.500 g birth weight (16). Our results are consistent with this finding and demonstrate that the cerclage insertion at the earlier gestational age increased the birth weight of neonates but did not decline the rate of NICU admission despite a significant rise of NICU admission in the high - risk group in comparison to the low - risk group. Altogether, cerclage insertion reduced the rate of NICU admission; however, no

association was found between the timing of cerclage insertion and the rate of NICU admission.

The cerclage insertion at a higher gestational age was accompanied by earlier delivery, suggesting the superiority of the elective Cerclage to the emergency cerclage. A meta - analysis compared the pregnancy outcome of emergency cerclage to elective Cerclage reported that the pregnancy period and birthweight in the emergency cerclage group was lower than in the elective group (11). Although we assessed the association between the gestational age at cerclage insertion and prolongation of the pregnancy in the low-risk and the high - risk group, there was a trend toward prolongation of the pregnancy by applying the earlier cerclage placement. A retrospective study by comparing the pregnancy outcomes between the elective and emergency group over two years revealed that the pregnancy prolongation and birth weight was higher in the elective cerclage group than in the emergency group, which outlined the preference of elective Cerclage, but did not consider the emergency cerclage an ineffective therapeutic option (18). Existence studies supported the beneficial effect of emergency cerclage to prolong the pregnancy and improve the neonatal outcomes in the absence of advanced (> 5 cm) cervical dilation (19, 20).

The strength of this study was the application of the McDonald's technique in all patients and the removal of the confounding factors, including abortion in the first trimester and induced preterm labor. A relatively small sample size and retrospective study design were the limitations of our study. Further prospective studies should be conducted to confirm our results and construct a proper guideline for clinical practice as the cerclage insertion has been extensively applied.

Our results indicate the effectiveness of cerclage insertion, which was well established in the current studies. Later cerclage insertion in the low-risk group and earlier cerclage removal in both groups improved the pregnancy and neonatal outcomes. Therefore, no certain gestational age at which the Cerclage was inserted; should be assumed in all the patients. The pregnancies should be divided into several subgroups based on the previous history of associated cervical insufficiency risk factors and the demographic data to decide their cerclage timing.

CONCLUSION

Cerclage insertion prolonged the pregnancy period and improved neonatal outcomes. The better outcomes were observed when the earlier cerclage insertion was placed, although the low-risk pregnancies underwent Cerclage in their late gestational age. Therefore, cerclage insertion should be individualized based on the obstetric history and

evaluation of the associated cervical insufficiency risk factors.

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CONFLICT OF INTEREST

All authors declare no conflicts of interest.

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