

Effectiveness of Double Cervical Cerclage in Women with at Least One Previous Pregnancy Loss in the Second Trimester

Original
Article

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ABSTRACT

Background: Recurrent pregnancy failure in second trimester is defined as three or more losses although most authors consider clinical treatment with 2 consecutive miscarriages at 14-18 weeks of gestation. Preterm births are more likely to occur in future pregnancies for women who have previously experienced cervical incompetence.

Objective: The study's objective was to determine whether double cervical cerclage had any impact on perinatal outcomes and preterm delivery prevention in women who had experienced second-trimester foetal loss.

Materials and Methods: This interventional prospective randomized controlled study included patients who attended the Outpatient Clinic with suspected cervical incompetence either by previous obstetric history or by ultrasound examination with gestational age between 14 and 18 weeks. The patients were randomly allocated into 2 groups; group 1 included 20 patients who had traditional modified MacDonal operation using a 5 mm mersilene tape in the middle third of the cervix and group 2 included 20 matched patients who had double cervical cerclage with two purse-string sutures using two 5 mm mersilene tapes; in the upper and lower third of the cervix.

Results: There was no significant difference between the double cervical and single cervical group regarding weight of the baby at birth, GA at delivery, abortion, mode of delivery and admission of baby to NICU. There was no significant difference between both groups regarding hematuria, hospital stay (hours) and neonatal death after operation ($p > 0.05$).

Conclusion: Women with cervical incompetence who undergo double cervical cerclage do not experience better perinatal or maternal outcomes.

Key Words: Cerclage, fetal, preterm.

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INTRODUCTION

Three consecutive miscarriages or more are considered to be recurrent pregnancy losses, which affect 0.5–1% of women. With significant debate surrounding the diagnosis and therapy, the etiology is frequently murky and may be complicated. Reasonably accepted etiologic factors include genetics, anatomical, endocrine, placental, hormonal, infections, smoking and alcohol use, exposure to environmental risk factors, psychological trauma and stressful life events, certain coagulation and immunoregulatory protein defects, and infections^[1].

The term "cervical incompetence" refers to recurrent second-trimester pregnancy losses that are brought on by an inherent or acquired weakness in the tissue integrity of the cervical region, resulting in the cervix going through painless effacement and dilation. It might appear as a predisposition to preterm labour, preterm premature rupture of the membranes (PPROM), or traditionally

defined recurrent pregnancy loss in the second trimester without labour. It can also manifest as an abnormally shortened cervix. 8% of women who experience repeated mid-trimester losses have cervical incompetence, which affects 1% of pregnancies^[2].

The phrase "cervical insufficiency," formerly known as "cervical incompetence," refers to an underlying structural abnormality of the cervical region that increases the risk of an otherwise healthy pregnancy ending prematurely^[3].

Based on historical data, a traditional diagnosis of cervical insufficiency is given when cervical dilatation occurs without contractions in one or more pregnancies. Most frequently, this results in birth during the second trimester of pregnancy^[3]. Activity restriction or cervical cerclage surgery are two options for treating cervical insufficiency. Limited information is also known regarding the use of vaginal pessaries and progesterone therapy in the treatment of specific patients^[4].

The purpose of the work:

Is to assess how double cervical cerclage affects perinatal outcomes and preterm delivery prevention in women who have experienced second-trimester foetal loss.

PATIENTS AND METHODS

It is an interventional prospective randomized controlled study including 40 women who attend the Outpatient Clinic with suspected cervical incompetence which is defined as an initial painless and progressive-dilation of the uterine cervix under which circumstance preterm delivery seems inevitable if there is no interference either by previous obstetric history or by ultrasound examination with gestational age between 14 and 18 weeks.

The patients gave informed and signed consent before entering the study. They were randomly allocated into 2 groups:

Group 1 included 20 patients who had traditional modified MacDonal operation using a 5 mm mersilene tape in the middle third of the cervix.

Group 2 included 20 matched patients who had Two 5 mm mersilene tapes are used to create a double cervical cerclage with two purse-string sutures placed in the top and lower thirds of the cervix, respectively.

General anaesthesia was used for double or single cervical cerclage surgeries. Usually between 14 and 18 weeks of gestation, the cervical cerclage is inserted. If the cervical length is insufficient to execute a double cerclage, the bladder was dissected from the uterus. In the operating room and for several hours following the procedure, prophylactic intravenous broad-spectrum antibiotics were given. The length of the process, including cerclage, was timed throughout surgery.

Inclusion criteria:

- suspected cervical incompetence which is defined as an initial painless and progressive-dilation of the uterine cervix
- previous obstetric history
- gestational age between 14 and 18 weeks.

Exclusion criteria:

- Patients with no obstetric history of pregnancy loss in the second trimester.
- Patients with prolapsed and ballooning of the membrane into the vagina.
- Patients with multiple pregnancy.

Methods:

Each case in the study was subjected to the following:

- 1- Explanation of the procedure.
- 2- Verbral consent was taken.
- 3- Detailed obstetric and gynaecological history was fulfilled.
- 4- Clinical examination was done.
- 5- Ultrasound examination.

Outcome measurements:

- Mean operative time.
- Need of postoperative analgesia.
- Postoperative complications.
- The pregnancy outcome regarding to gestational age at delivery.

Following the procedure, the patient was instructed to spend the next 24 hours in bed and then move around for one day before being allowed to leave the hospital. If after surgery there was abdominal pain, vaginal bleeding, or fever, patients were allowed to stay in the hospital for a longer period of time. The duration of the hospital stay was measured in days. When necessary for postoperative tocolysis, patients were given -mimetic medications. In cases where the urine had a typical yellow hue, the Foley catheter was taken out. If hematuria was discovered during surgery or if bladder dissection was done in order to execute a cervical cerclage, the Foley catheter was kept in place for longer than one day.

One week prior to the operation and one week following it, transvaginal ultrasonography was used to measure the cervical length. We measured the centimeters of total cervical length from the external os to the internal os.

In the event of preterm labour or an early rupture of the membranes, women were readmitted to the hospital. Patients at risk of an early birth received betamethasone treatment at around 34 weeks' gestation. A single or double cerclage was removed from the cervix at 37 weeks of pregnancy or whenever labour broke out. Caesarean sections were only carried out when absolutely necessary for obstetrical reasons. Comparisons were made between the effects of single and double cerclage sutures on pregnancy length, perinatal outcomes, maternal hospital stay, neonatal death, and admission of newborns to intensive care units (NICU).

Statistical analysis:

Data were checked, entered and analyzed by using SPSS version 20.

RESULTS

Age, parity, nulliparity, and multiple foetal losses during the second trimester did not differ significantly from one another ($p > 0.05$). Nine women had single cervical cerclage and fifteen under double cervical cerclage; both groups of women were nulliparous. Twenty women in the double cervical cerclage group and eighteen in the single cervical cerclage group experienced multiple foetal losses during the second trimester of pregnancy. (Table 1). Regarding cervical dilatation (cm), removal of suture at and before labour, PROM, and chorioamnionitis, there was no statistically significant difference between the two groups. At labour, twelve women in the single group and fifteen women with double cervical cerclages had the sutures removed. There were 13 women; five in the double cervical cerclage group removing suture before labour and eight in single cervical cerclage before labour. There were ten women having PROM; six in the double cervical group and four in the single cervical group. There were 7 women having chorioamnionitis; three in the double cervical cerclage group and four in the single cervical cerclage

group. (Table 2) there is significant data between two groups in GA at surgery and foley's catheterization due to dissection (Table 3). There was no significant difference between the double cervical and single cervical group ($p > 0.05$) regarding weight of the baby at birth, GA at delivery, abortion, mode of delivery and admission of baby to NICU. There was only one missed abortion at 19-20 weeks on the double cervical cerclage group. There were 15 babies born by NVD in double group and 17 babies born by NVD in single group. But, there were 4 babies born by CS in the double cervical group and 3 babies born by CS in the single cervical cerclage group. There were 6 babies entering NICU in double cervical cerclage group and 7 in the single cervical cerclage group. (Table 4). There was no significant difference between both groups regarding hematuria, hospital stay (hours) and neonatal death after operation ($p > 0.05$). There were eight women having hematuria; six in the double cervical cerclage group and zero in the single cervical cerclage group. There were twelve women having fetal death due to complications and decreased Apgar score; five in the double cervical cerclage group and seven in the single cervical cerclage group. There was no significant difference between hospital stay from 24-72 hours in the double cervical cerclage group and from 24-48 hours in the single cervical cerclage group. (Table 5).

Table 1: Demographic data

	Double (n = 20)	Single (n = 20)	t	p
Age (years)				
Mean \pm SD	28.3 \pm 3.1	28.2 \pm 3.6	0.09	0.92
Range	22-35	20-35		
Parity				
Mean \pm SD	3.7 \pm 1.3	4.45 \pm 1.2	1.99	0.06
Range	2-7	2-6		
Nullipara	15 (75%)	9 (45%)	$X^2 = 4.64$	0.19
More than one fetal loss at 2 nd trimester	20 (100%)	18 (90%)	$X^2 = 0.53$	0.46

Table 2: Perinatal outcome

	Double	Single	X^2	p
Cervical dilatation (cm)				
Mean \pm SD	3.3 \pm 0.57	3.2 \pm 0.55	0.28	0.77
Range	2-4	2-4		
Removal of suture				
At labour	15 (75%)	12 (60%)	$X^2 = 1.03$	0.31
Before	5 (25%)	8 (40%)		
PROM	6 (30%)	4 (20%)	0.53	0.46
Chorioamnitis	3 (15%)	4 (20%)	0	1

PROM = Premature Rupture of Membrane

Table 3: Operative data

	Double	Single	t	p
GA at surgery (weeks)				
Mean ± SD	15.4 ± 1.1	14.75 ± 1.4	1.69	0.09
Range	14-18	12-18		
Foley catheterization due to dissection	6 (30%)	0 (0%)	4.9	0.02

GA = Gestational Age

Table 4: Fetal outcome

	Double (n = 20)	Single (n = 20)	T	p
Weight (kg)				
Mean ± SD	2.3 ± 1.1	2.15 ± 1.29	0.46	0.64
Range	0.1-3.5	0.015-3.5		
Gestational Age (GA) at delivery				
Mean ± SD	31.9 ± 7.5	31.8 ± 8	0.04	0.96
Range	18-39	19-39		
Abortion	1 (5%)	0 (0%)		
Mode of delivery				
NVD	15 (75%)	17 (85%)	X ² = 1.27	0.53
CS	4 (20%)	3 (15%)		
Admission to NICU	6 (30%)	7 (35%)	0	1

Table 5: Postoperative complications

	Double		Single		X ²	P
	No	%	No	%		
Haematuria	6	30	0	0	4.9	0.02
Hospital stay (hours)	26.8 ± 7.3 (24-72)		26.9 ± 10.7 (24-48)		0.16	0.68
Neonatal death	5	25	7	35	0.34	0.55

DISCUSSION

Weak understanding exists of the factors that contribute to impaired fetomaternal tolerance leading to pregnancy loss. Although there was statistical significance, the preterm delivery rate at 28 weeks of gestation in the conventional single cervical cerclage group was greater at 29.4% than in the double cerclage cervical group (5.9%). Although no statistically significant difference was discovered, it is likely because of the limited sample size that the double cervical cerclage group's infant survival rate was greater^[5].

In this study, six babies entered NICU in double cervical cerclage group because they were preterm and seven in the single cervical cerclage entered NICU. But, only one had IUFD in double cerclage group due to chorioamnitis. In our study, we found that double cervical cerclage may be effective in preventing preterm delivery and improving perinatal outcome in cervical incompetence. This comes in agreement with the results of the study of Althuisius *et al.*

(2019) they stated that cerclage suture placement close to the internal os will lead to better perinatal outcomes than cerclage suture placement in the middle or lower part of the cervix.^[6]

However, the increased cervical length following cerclage therapy was not a reliable indicator of preterm delivery, according to Drakeley *et al.*'s (2020) report. Prophylactic cerclage may increase cervical length. Our research did not find a significant difference between women who had double cerclage and those who had a conventional single cervical cerclage in terms of cervical status, perinatal outcome, or maternal and maternal outcome following surgery. This discrepancy could have been caused by a number of circumstances.^[7]

In contrast to earlier research, ours used a different patient selection process and different cervical cerclage techniques. In women who had suffered at least one previous second-trimester premature foetal loss, we conducted

double or single cervical cerclage. Due to cervical incompetence, these women were highly susceptible to recurrent foetal loss. Comparing a single cervical cerclage to a double cervical cerclage, the cervical length for cervical incompetence rose considerably. Additionally, it has been proposed that the second suture's placement closer to the internal os is one reason for the superior perinatal result. Due to this, double cerclage is superior to single cerclage in terms of preventing premature birth.

There were 15 babies born by NVD in double group and 17 babies born by NVD in single group. But, there were 4 babies born by CS in the double cervical group and 3 babies born by CS in the single cervical cerclage group. There were 6 babies Entering NICU in double cervical cerclage group and 7 in the single cervical cerclage group.

The double cervical cerclage did not result in many complications. There were no difficulties during surgery for 14 patients in the double cervical cerclage group and none for the group with a single cervical cerclage, even though a longer time frame is required to fully understand the long-term consequences associated with cervical cerclage. Furthermore, regardless of whether there was a double or single cervical suture, there was statistical significance in removing the suture at term or whenever labour began, however there were 6 individuals who sustained bladder injuries as a result of the bladder dissection surgery. due to the second suture in the group with double cervical cerclages having an inadequate length cervical.

(Rand *et al.*, 2018; Kurup and Goldkrand, 2019; Sakai *et al.*, 2021) have proposed the effects of complications from hematuria and/or chorioamnionitis on the results after cervical cerclage.^[8,9,10]

In 33.3% of asymptomatic patients with cervical shortening who had cervical cerclage, Rizzo *et al.* (2018) reported, postoperative chorioamnionitis was discovered.^[8]

Additionally, Kwak, and Goldkrand (2019) found that chorioamnionitis and microbial invasion of the amniotic cavity were highly likely when elevated IL-8 concentrations in cervical mucus and a short cervix coexisted.^[9]

In this study, three patients suffered from chorioamnionitis in double cerclage group and four patients suffered from chorioamnionitis in single cerclage group which is also due to PROM. There were ten women having PROM; six in the double cervical group and four in the single cervical group.

Scheib *et al.* (2021) discovered that patients who underwent cerclage and had a short cervix and high levels of IL-8 in their cervical mucus were more likely to give birth preterm.^[10]

According to our study, it is challenging to increase the cervical length and power with just one cerclage suture, regardless of where the cerclage is positioned in the cervix. This could be the reason why there is no discernible difference between bed rest alone and therapeutic cervical cerclage in the prevention of premature delivery. Double cervical cerclage in the upper and lower cervixes could theoretically address these issues.

The prevention of preterm birth, as well as perinatal and maternal outcomes in women who had at least one prior pregnancy loss in the second trimester, were investigated, and it was shown that double cervical cerclage may considerably improve perinatal outcomes.^[11]

CONCLUSION

The findings of this study led to the conclusion that in women with cervical incompetence, double cervical cerclage did not improve perinatal and maternal outcomes. However, a larger investigation is required to confirm this.

CONFLICT OF INTEREST

There are no conflicts of interests.

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