The Association between Shirodkar Cerclage and Preterm Premature Rupture of Membranes in Singleton Pregnancies

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Abstract

Objective The aim of this study was to estimate if preterm premature rupture of membranes in women with cerclage is due to the cerclage itself or rather the underlying risk factors for preterm birth in this population.

Study Design This was a retrospective cohort study of singleton pregnancies who underwent Shirodkar cerclage by a single maternal–fetal medicine practice between 2005 and 2019. The control group was an equal number of randomly selected women with a singleton gestation who had a prior preterm birth and were treated with 17-OH-progesterone but no cerclage. Patients with major uterine anomalies or fetal anomalies were excluded. The primary outcome was preterm premature rupture of membranes prior to 34 weeks. Chi-square and logistic regression were used.

Results A total of 350 women with cerclage (154 [44%] history-indicated, 137 [39%] ultrasound-indicated, and 59 [17%] exam-indicated) and 350 controls were included. Preterm premature rupture of membranes prior to 34 weeks did not differ between the groups (8.9% in cerclage vs. 6.0% in controls, $p = 0.149$, adjusted odds ratio 0.62, 95% confidence interval: 0.24–1.64) nor between the different cerclage indications (9.1% of history-indicated, 7.3% of ultrasound-indicated, and 11.9% of exam-indicated, $p = 0.582$). This study had 80% power with an α error of 0.05 to detect an increase in preterm premature rupture of membranes prior to 34 weeks from 6.0% in the control group to 12.0% in the cerclage group.

Conclusion Cerclage does not increase the risk of preterm premature rupture of membranes prior to 34 weeks compared with other women at increased risk of preterm birth. The observed association between cerclage and preterm premature rupture of membranes is likely due to underlying risk factors and not the cerclage itself. The risk of preterm premature rupture of membranes prior to 34 weeks in women with cerclage is 10% or less and does not appear to differ based on cerclage indication.

Keywords

- cerclage
- preterm premature rupture of membrane
- premature rupture of membranes
- preterm birth

Key Points

- Cerclage does not increase the risk of PPROM.
- Risk of PPROM with cerclage is approximately 10%.
- Risk does not appear to vary by indication.

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Preterm birth is defined as delivery prior to 37 weeks of gestation, which in 2018 accounted for 1 in 10 births in the United States.[1] Preterm delivery has been widely associated with increased neonatal morbidity and is a leading cause of neonatal mortality worldwide.[2] An important obstetrical intervention, which has been shown to prolong pregnancy in certain high-risk women, is cerclage.[3,4] Indications for cerclage include a prior history of unexplained second-trimester losses or preterm births (history-indicated), a short cervical length on transvaginal ultrasound (ultrasound-indicated), or second trimester cervical dilation in the absence of labor or ruptured membranes (exam-indicated).[5] Although data continue to evolve, there does appear to be a role for cerclage for all three indications in well-selected women.

One risk commonly quoted for cerclage is preterm premature rupture of membranes (PPROM), potentially due to the introduction of pathogens into the cervix through an exogenous source or an indwelling foreign body.[6–8] However, when selected in accordance to current evidence-based criteria, women who receive cerclage are already at an increased risk of PPROM due to a poor obstetric history, short cervical length, or dilated cervix. Therefore, it is unclear whether cerclage itself increases the risk of PPROM above the baseline in high-risk women.

The objective of this study was to estimate whether cerclage increases the risk of PPROM above the baseline risk for women already at increased risk for preterm birth.

Materials and Methods

After Biomedical Research Alliance of New York institutional review board approval was obtained, we reviewed the records of all patients with a singleton pregnancy who underwent a Shirodkar cerclage placement by a single maternal–fetal medicine practice between November 2005 and February 2019. We included women with history-indicated, ultrasound-indicated, and physical exam-indicated cerclage. All Shirodkar cerclage placements were performed following previously described techniques using a 5-mm Mersilene suture.[9,10] For a control group, we sought to identify another cohort of women at increased risk of PPROM and preterm birth who did not have a cerclage. Therefore, we randomly selected an equal number of women with singleton pregnancies delivered by the same maternal–fetal medicine practice who had no cerclage and received 17-OH-progesterone for the indication of a prior preterm birth. In both groups, we excluded women with major fetal anomalies discovered before or after birth, as well as women with bicornuate, unicornuate, or didelphys uterus.

Baseline data collected for analysis from the electronic medical record included age, race, prior obstetric history, history of prior cerclage, prior cervical excision procedure, and any progesterone use beyond the first trimester. For the cerclage group, we also noted gestational age at cerclage placement as well as cerclage indication. Cerclage indications were: (1) history-indicated, defined as a cerclage placed solely due to the patient's prior obstetrical history; (2) ultrasound-indicated, defined as a cerclage placed after a transvaginal ultrasound diagnosis of a short cervical length (2.5 mm or less); and (3) exam-indicated, defined as a cerclage placed due to a dilated cervix seen on speculum examination with membranes at or beyond the external cervical os. If a patient was scheduled to have a history- or ultrasound-indicated cerclage, but at the time of surgery was noted to have a dilated cervix as described above, she was considered part of the exam-indicated group. Indications for transvaginal cervical lengths varied and included prior preterm birth, prior second trimester loss, prior cervical excision procedure, and suspected cervical shortening on routine transabdominal imaging. Several patients had more than one of these indications.

The primary outcome of this study was PPROM <34 weeks. We chose <34 weeks because it is a clinically relevant outcome and also because cerclage removals are usually scheduled at 36 to 38 weeks. Secondary outcomes were PPROM <24 weeks, any preterm birth <34 weeks, and any preterm birth <24 weeks. We compared outcomes between the cerclage group and the control group, as well as across the three cerclage indication groups (history-, ultrasound-, exam-indicated). Data were first analyzed using the Chi-square test, Student's *t*-test, and one-way ANOVA, as appropriate (IBM SPSS for Windows 22.0, IBM Corp, Armonk, NY). Logistic regression was then performed to control for differences at baseline at the $p < 0.05$ level. The regression was done in a backward stepwise fashion controlling for maternal age, prior preterm birth, prior term birth, prior cervical excision procedure, prior cerclage, maternal race, and progesterone use. There was no funding for this study.

Results

Over the course of the study period, there were 350 women who met inclusion criteria and underwent Shirodkar cerclage placement. An equal number of women were identified for the control group. Baseline demographics for the two groups are shown in ►Table 1. Patients who had undergone a cerclage were older and were more likely to have a prior cerclage, a prior cervical excision procedure, and a prior term birth. Women in the control group were more likely to have a prior preterm birth and take progesterone (both of these were expected given the selection criteria for the control group), and were more likely to be of white race.

When subdividing patients by cerclage indication, 154 (44%) were history-indicated, 137 (39%) were ultrasound-indicated, and 59 (17%) were exam-indicated. Baseline demographics for these groups are shown in ►Table 2.

Outcomes in the cerclage and control groups are shown in ►Table 3. Patients with cerclage were at no greater risk of PPROM prior to 34 weeks as compared with controls (8.9 vs. 6.0%, adjusted odds ratio = 0.62, 95% confidence interval: 0.24–1.64). Cerclage patients were also at no greater risk of any preterm birth prior to 34 weeks, PPROM prior to 24 weeks, or any preterm birth prior to 24 weeks. *Post hoc* power analysis was performed. This study has 80% power with an α error of 0.05 to detect an increase in PPROM prior to 34 weeks from 6.0% in the control group to 12.0% in the cerclage group. We did not perform a regression analysis on the outcomes of PPROM

Table 1 Baseline characteristics between combined cerclage and control groups

	Control $n = 350$	Cerclage $n = 350$	p-Value[a]
Maternal age (y)	32.3 ± 6.8	34.0 ± 5.5	<0.001
Any prior preterm birth	350 (100%)	264 (75.4%)	<0.001
Any prior term birth	95 (27.1%)	184 (52.6%)	<0.001
Any prior cerclage	8 (2.3%)	153 (43.7%)	<0.001
Prior cervical excision procedure	16 (4.6%)	31 (8.9%)	0.023
White race	304 (86.9%)	264 (75.4%)	<0.001
Progesterone use beyond the first trimester	350 (100%)	207 (59.1%)	<0.001

[a]Student's *t*-test and Chi square.

Table 2 Baseline characteristics based on cerclage indication

	History-indicated $n = 154$	Ultrasound-indicated $n = 137$	Physical exam-indicated $n = 59$	p-Value[a]
Maternal age	33.8 ± 5.3	33.8 ± 5.7	35.2 ± 5.5	0.200
Any prior preterm birth	132 (85.7%)	113 (82.5%)	19 (32.2%)	<0.001
Any prior term birth	104 (67.5%)	64 (46.7%)	16 (27.1%)	<0.001
Any prior cerclage	119 (77.3%)	31 (22.6%)	3 (5.1%)	<0.001
Prior cervical excision procedure	8 (5.2%)	19 (13.9%)	4 (6.8%)	0.028
White race	125 (81.2%)	103 (75.2%)	36 (61.0%)	0.009
Progesterone use beyond the first trimester	79 (51.3%)	95 (69.3%)	33 (55.9%)	0.006
Gestational age at cerclage placement	14.7 ± 1.8	19.9 ± 2.4	20.5 ± 2.3	<0.001
Cervical length at cerclage placement (mm)		17 ± 6		NA
Cervical dilation at cerclage placement (cm)			1 cm: 32 (54.2%) 2 cm: 10 (17.0%) 3 cm: 17 (28.8%)	

[a]One-way ANOVA and Chi square.

Table 3 Pregnancy outcomes based on cerclage

	Control $n = 350$	Cerclage $n = 350$	RR (95% CI)[a]	aOR (95% CI)[b]
PPROM <34 weeks	21 (6.0%)	31 (8.9%)	1.52 (0.86–2.71)	0.62 (0.24–1.64)
PPROM <24 weeks	5 (1.4%)	10 (2.9%)	2.03 (0.69–6.00)	NA
Any preterm birth <34 weeks	26 (7.4%)	49 (14.0%)	2.03 (1.23–3.35)	0.61 (0.29–1.30)
Any preterm birth <24 weeks	6 (1.7%)	13 (3.7%)	2.21 (0.83–5.89)	NA

Abbreviations: aOR, adjusted odds ratio; CI, confidence interval; PPROM, preterm premature rupture of membrane; RR, risk ratio.
[a]Chi square.
[b]Logistic backward step-wise regression adjusting for maternal age, prior preterm birth, prior term birth, prior loop electrosurgical excision procedure, prior cerclage, race, and progesterone use.

prior to 24 weeks and any preterm birth prior to 24 weeks as controlling for several variables in these rare outcomes would likely result in an overfitted model.

Outcomes across the cerclage indications are shown in ►Table 4. The risk of PPROM prior to 34 weeks did not appear to differ based on the cerclage indication (9.1% of history-indicated, 7.3% of ultrasound-indicated, and 11.9% of exam-indicated; $p = 0.582$). Secondary outcomes also did not appear to differ based on cerclage indication.

Conclusion

Our study found that cerclage placement did not increase the risk of PPROM <34 weeks as compared with a control group of women also at increased risk for preterm birth. The risk of PPROM with cerclage is approximately 10% or less and does not appear to vary by the indication for cerclage placement.

In recent years, cerclage placement has become more selective and nearly all women who meet evidence-based

Table 4 Pregnancy outcomes based on cerclage indication

	History-indicated $n = 154$	Ultrasound-indicated $n = 137$	Physical Exam-indicated $n = 59$	*p*-Value[a]
PPROM <34 weeks	14 (9.1%)	10 (7.3%)	7 (11.9%)	0.582
PPROM <24 weeks	5 (3.2%)	2 (1.5%)	3 (5.1%)	0.349
Any preterm birth <34 weeks	12 (13.6%)	20 (14.6%)	7 (11.9%)	0.967
Any preterm birth <24 weeks	4 (2.6%)	5 (3.6%)	4 (6.8%)	0.352

[a]Chi square.

criteria have a significant baseline risk for preterm birth due to prior history of PPROM, prior history of spontaneous preterm birth or second trimester loss, prior cerclage, short cervix on ultrasound, or dilated cervix on exam. These are all risk factors that have been previously been associated with higher rates of PPROM.[8] Therefore, the higher rates of PPROM previously reported among cerclage patients could be attributed to the high-risk nature of this population. Our results differ from prior studies, which have reported higher PPROM rates associated with cerclage ranging from 8 to 38%.[11,12] The differences seen could be related to different populations or potentially different surgical technique. With the current evidence-based guidelines, our study is focused on high-risk women with a significant baseline risk of PPROM. Therefore, we chose to compare PPROM rates with a control group of similarly high-risk women. In contrast, a study by Nelson et al retrospectively studied a group of 133 women treated with cerclage between 1998 and 2002 and reported a higher rate of PPROM following exam-indicated cerclage (64.7%, $n = 11$) when compared with history-indicated (19.3%, $n = 17$) and ultrasound-indicated (38.5%, $n = 10$).[13] They acknowledge that many elective cerclages were placed unnecessarily, and their results reflect PPROM at any point following cerclage placement. Our study focused on PPROM <34 weeks given its clinical significance and because most cerclages are scheduled for removal at 36 to 38 weeks.

Strengths of our study include a large sample size, which allowed us to have enough power to detect a doubling of the incidence of PPROM <34 weeks (from 6–12%). Also, patients were managed by a single maternal–fetal medicine practice with established treatment protocols across clinicians, and all patients underwent Shirodkar-type cerclage with a uniform surgical technique across surgeons. These reduce the likelihood that variation in clinical management and surgical technique impacted our results. Our large sample size allowed us to power our primary outcome, but we were underpowered for rarer outcomes or for differences smaller than our *post hoc* power analysis. We are also limited by the retrospective nature of our study and the possibility of selection bias. Our results are specific to Shirodkar-type cerclage, which has been correlated with lower rates of PPROM compared with the McDonald-type.[10] Lastly, we were limited by our lack of an ideal control group of women who met the clinical criteria for cerclage but did not receive one. This is an unavoidable limitation given the retrospective nature of the study.

Placement of Shirodkar cerclage does not increase the risk of PPROM <34 weeks. The risk of PPROM in this setting is approximately 10% or less regardless of indication for cerclage placement. This information may be helpful when counseling high-risk patients about cerclage and to reassure them of the relatively low risks of PPROM associated with the procedure.

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None.

Conflict of Interest
None declared.

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