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Cervical length, cervical dilation, and gestational age at cerclage placement and the risk of preterm birth in women undergoing ultrasound or exam indicated Shirodkar cerclage

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ABSTRACT

Background: Preterm birth is a major cause of neonatal morbidity and mortality in the USA. In many patients at risk for preterm birth, cervical length (CL) screening is used to guide decisions regarding cerclage placement. Quality evidence shows that cerclage prolongs pregnancy in high-risk women with a short CL in women with a history of preterm birth and in women with painless cervical dilation in the second trimester, though the degree of cervical shortening, dilation, or gestational age at cerclage placement are not consistently associated with the subsequent rate of preterm birth. Our objective was to determine if cervical length (CL), cervical dilation or gestational age (GA) at the time of cerclage placement are associated with preterm birth among women undergoing ultrasound-indicated or exam-indicated cerclage.

Study design: This was a retrospective cohort study of all patients with a singleton pregnancy who underwent ultrasound-indicated or exam-indicated Shirodkar cerclage placement at a single maternal-fetal medicine practice in New York City between November 2005 and May 2017. All patients included in the study had previously undergone CL screening for an increased risk of preterm birth (for example, prior spontaneous preterm birth or mid-trimester loss, prior cervical excision). The cervical length or dilation and GA at the time of cerclage placement were collected, as were demographic and obstetric outcome data for the current pregnancy. The primary outcome was delivery <36 or ≥ 36 weeks. Planned subgroup analyses of the primary outcome were performed based on CL at the time of ultrasound-indicated cerclage (0–9 mm, 10–19 mm, ≥ 20 mm), cervical dilation at the time of physical exam-indicated cerclage (<2 cm vs. ≥ 2 cm), and gestational age at cerclage placement (<20 weeks vs. ≥ 20 weeks). Data were analyzed using the Student's *t*-test and chi-square test for trend.

Results: There were 123 and 39 patients in the ultrasound- and exam-indicated cerclage groups, respectively. Twenty six (21.2%) patients in the ultrasound-indicated subgroup and 24 patients (61.5%) in the exam-indicated subgroup delivered <36 weeks. CL (16.4 versus 17.6 mm, $p = .28$) and GA (19.7 versus 20.0 weeks, $p = .58$) at the time of ultrasound-indicated cerclage placement were not significantly different in patients who delivered <36 and ≥ 36 weeks' gestation, respectively. Women with cervical dilation ≥ 2 cm prior to exam-indicated cerclage placement were significantly more likely to deliver <36 weeks when compared to women with cervical dilation <2 cm (77.8 versus 47.6%, $p = .05$); however, there were no significant differences in rates of preterm birth <28 and <32 weeks between these two groups (38.9 versus 23.8%, $p = .31$ and 50.0% versus 28.6%, $p = .17$, respectively).

Conclusions: Cervical length and GA at the time of ultrasound-indicated Shirodkar cerclage placement do not appear to impact the likelihood of preterm birth <36 weeks, while cervical dilation ≥ 2 cm at the time of exam-indicated Shirodkar cerclage is associated with an increased rate of preterm birth <36 weeks, but not earlier gestational ages at delivery.

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Introduction

Preterm birth is a major cause of neonatal morbidity and mortality in the USA, where 9.6% of pregnancies end in preterm birth <37 weeks' gestation [1]. In many patients at risk for preterm birth, cervical length

(CL) screening is used to guide decisions regarding cerclage placement [2]. Cerclage has been shown to prolong pregnancy in women with a short cervix who have a history of preterm birth [3]. Women with mid-trimester cervical dilation are particularly at high risk,

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Table 1. Demographic information of patients undergoing exam- or ultrasound-indicated cerclage placement.

	Ultrasound-indicated cerclage ^a N = 123	Exam-indicated cerclage ^a N = 39
Maternal age (years)	33.6 ± 5.7	34.1 ± 6.1
GA at cerclage placement (weeks)	19.9 ± 2.3	20.2 ± 2.5
CL (mm) at time of cerclage placement	17.4 ± 6.0	
Cervical dilation (cm) at time of cerclage placement		1.9 ± 1.2
Prior PTB (n, %)	80 (65)	12 (30.8)
Prior second trimester loss (n, %)	61 (49.6)	8 (20.5)
Prior cervical excision procedure (n, %)	16 (13.0)	3 (7.7)
Prior cerclage (n, %)	30 (24.4)	4 (10.3)
GA at delivery (weeks)	37.0 ± 3.3	32.1 ± 6.8
Delivery <36 weeks (n, %)	26 (21.2)	24 (61.5)
Birthweight (g)	2383 ± 713	2039 ± 1030

PTB defined as spontaneous delivery between 24.0/7 and 36.6/7 weeks' gestation in a prior pregnancy due to premature labor or preterm premature rupture of membranes.

Second trimester loss defined as spontaneous pregnancy loss between 14.0/7 and 24.0/7 weeks' gestation in a prior pregnancy due to advanced cervical dilation or preterm labor with neonatal demise.

GA = gestational age; CL = cervical length; PTB = preterm birth.

^aAll values are mean ± standard deviation unless otherwise indicated.

as more than 90% of women with mid-trimester cervical dilation will deliver prematurely [4]. For patients with painless cervical dilation less than 24 weeks' gestational age, a cerclage may be offered for the prevention of preterm birth [4,5]. However, the literature is mixed as to whether the degree of cervical shortening, cervical dilation, or gestational age (GA) at the time of cerclage placement are associated with rates of subsequent preterm birth.

The objective of this study was to determine if CL and GA at the time of ultrasound-indicated cerclage placement were associated with spontaneous preterm birth. Additionally, we sought to determine if cervical dilation and GA at the time of exam-indicated cerclage placement were associated with spontaneous preterm birth (PTB).

Materials and methods

This was a retrospective cohort study of all patients with a singleton pregnancy who underwent ultrasound-indicated or exam-indicated cerclage placement at a single maternal-fetal medicine practice in New York City between November 2005 and May 2017. Patients were identified from a pre-existing database. In our practice, women at increased risk for preterm birth undergo serial cervical length screening every 2 weeks with endovaginal ultrasound (for example, those with a history of prior spontaneous preterm birth due to preterm labor or preterm premature rupture of membranes, prior mid-trimester loss due to cervical insufficiency or preterm labor, or prior excisional cervical procedures). RDMS-certified sonographers perform all sonograms in our practice, with images reviewed and interpreted by Maternal-Fetal Medicine attendings. In those women with a short

cervix, ultrasound-indicated cerclage is offered in patients less than 24-weeks gestation when the sonographic cervical length is 25 mm or less. Patients with a short cervical length are examined for cervical dilation and amniocentesis is performed on a case-by-case basis to rule out intrauterine infection. In patients with asymptomatic cervical dilation in the mid-trimester and no evidence of labor or infection, exam-indicated cerclage is offered. All cerclage placements were performed by Maternal-Fetal Medicine attendings and were modified Shirodkar type, following the previously-described technique [6,7]. Patients with multiple gestations were excluded from this analysis.

Patient demographic data including age, race, insurance status, obstetric history, risk factors for preterm birth, and number of prior preterm births were extracted from a pre-existing database for all patients. Preoperative cervical length (for ultrasound-indicated cerclage), preoperative cervical dilation (for exam-indicated cerclage), gestational age (GA) at time of cerclage placement, and obstetric outcomes for the current pregnancy were collected. The primary outcome was spontaneous delivery <36 weeks, as our practice typically recommends cerclage removal between 36 and 37 weeks. Secondary outcomes studied were spontaneous delivery <28 weeks, delivery <32 weeks, and birth weight. Planned subgroup analyses were performed based on CL at the time of ultrasound-indicated cerclage (0–9 mm, 10–19 mm, 20–25 mm), cervical dilation at the time of physical exam-indicated cerclage (<2 cm vs. ≥2 cm), and gestational age at cerclage placement (<20 weeks vs. ≥20 weeks). Data were analyzed using the Student *t*-test and chi-square test (IBM SPSS for Windows 22.0, Armonk, NY, 2013). Kaplan–Meier curves were created using Stata/IC 15. The log-rank test was used to

Table 2. Rates of preterm birth following ultrasound-indicated cerclage stratified by cervical length at time of placement ($N = 123$).

	CL 0–9 mm $N = 16$	CL 10–19 mm $N = 55$	CL 20–25 mm $N = 52$	p value
Delivery <28 w	0 (0%)	4 (7.3%)	1 (1.9%)	.76
Delivery <32 w	0 (0%)	5 (9.1%)	2 (3.8%)	.98
Delivery <36 w	3 (18.8%)	14 (25.5%)	9 (17.3%)	.60

CL = cervical length.

perform survival analysis. A p value of $\leq .05$ was considered significant. The study was approved by the Biomedical Research Alliance of New York Institutional Review Board.

Results

There were 123 patients identified who underwent ultrasound-indicated cerclage and 39 patients who underwent exam-indicated cerclage. Baseline demographic data are depicted in Table 1. In those patients undergoing ultrasound-indicated cerclage, 65% had a prior PTB, 49.6% experienced prior second-trimester loss, 13% had a prior cervical excision, and 24.4% had a cerclage placed in a prior pregnancy. In the exam-indicated cohort, 30.8% experienced a prior PTB, 20.5% a prior mid-trimester loss, 7.7% prior cervical excision and 10.3% had a cerclage in a prior pregnancy (Table 1). The mean cervical length prior to ultrasound-indicated cerclage was 17.4 mm (SD 6.0 mm) and the mean dilation prior to physical exam-indicated cerclage was 1.9 cm (SD 1.2 cm). All patients with cervical dilation had visible membranes prolapsed to the level of the external os, which was assessed with sterile speculum examination.

In the ultrasound-indicated subgroup, 26 patients (21.2%) delivered <36 weeks. Cervical length (16.4 versus 17.6 mm, $p = .28$) and GA (19.7 versus 20.0 weeks, $p = .58$) at the time of ultrasound-indicated cerclage placement were similar in patients who delivered <36 and ≥ 36 weeks' gestation, respectively. When stratified by CL prior to ultrasound-indicated cerclage placement, there were no significant differences in rates of preterm birth <28, <32, and <36 weeks (Table 2) or overall time to delivery using survival analysis (Figure 1). Ultrasound-indicated cerclage placement <20 weeks' vs. ≥ 20 weeks' gestation also did not significantly impact the rate of PTB <36 weeks (25.0 versus 17.9%, $p = .34$).

In the exam-indicated subgroup, 24 (61.5%) patients delivered <36 weeks. The median GA at delivery was 33.6/7 week (range 16.3/7 – 41.0/7). Cervical dilation at the time of exam-indicated cerclage placement was significantly higher in patients

who delivered <36 weeks compared to ≥ 36 weeks' gestation (2.2 versus 1.5 cm, $p = .05$), though the gestational age at the time of exam-indicated cerclage placement was not different between these groups (20.1 versus 20.5 weeks, $p = .55$). When stratified by cervical dilation <2 cm versus ≥ 2 cm prior to exam-indicated cerclage placement, there was no significant difference in rates of PTB <28 and <32 weeks, though there was a significant difference between rates of PTB <36 weeks (47.6 versus 77.8%, $p = .05$) (Table 3). In survival analysis, cervical dilation >2 cm was associated with a significantly shorter prolongation of pregnancy (Figure 2, $p = .03$). There were no differences in rates of PTB <36 weeks when an exam-indicated cerclage was placed <20 versus ≥ 20 weeks (75.0 versus 55.6%, $p = .25$), or <22 versus ≥ 22 weeks (61.5 versus 61.5%, $p = 1.0$).

Discussion

Cerclage placement for women with a clinically significant risk of preterm birth is an important obstetric intervention to reduce the rate of preterm birth and thus potentially improve neonatal outcomes [8]. Cervical length screening with endovaginal ultrasound is an effective tool to identify women at high risk for PTB, both in women with a history of prior PTB and in patients who experience mid-trimester painless cervical dilation without an antecedent history of PTB whose short cervical length at the time of routine screening in the mid-trimester may prompt a physical exam [5,9].

Ultrasound-indicated cerclage placement for women with cervical shortening and a history of PTB prolongs pregnancy [3]. In our cohort of Shirodkar cerclage placement, we found that the cervical length at the time of ultrasound-indicated cerclage does not significantly impact the rate of PTB <36 weeks, similar to the findings of Berghella and colleagues in their 2010 meta-analysis [10]. This finding is distinct from that of most other groups, which have demonstrated a shorter prolongation of pregnancy with very short cervical length, particularly when the preoperative cervical length is <15 mm [11–14]. However, unlike our practice which exclusively used the Shirodkar approach, the majority of other studies of ultrasound-indicated cerclage utilized the McDonald technique. The use of Shirodkar cerclage in our practice may better reconstitute the internal os, thereby increasing the residual cervical length, which has been shown by Cook and colleagues to lead to a decreased risk of subsequent preterm birth <37 weeks [13]. A 2012

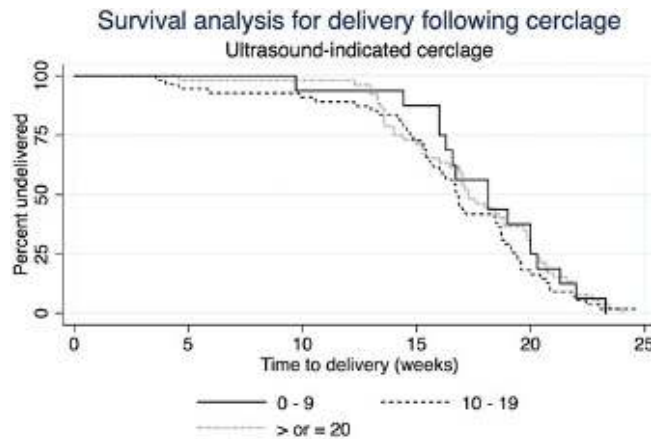


Figure 1. Time to delivery in the ultrasound-indicated cerclage cohort stratified by cervical length at time of cerclage placement 0–9 mm, 10–19 mm, or ≥ 20 mm (p value = .53).

Table 3. Rates of preterm birth following exam-indicated cerclage stratified by cervical dilation at time of placement ($N = 39$).

	Dilation <2 cm $N = 21$	Dilation ≥ 2 cm $N = 18$	p value
Delivery <28 w	5 (23.8%)	7 (38.9%)	.31
Delivery <32 w	6 (28.6%)	9 (50.0%)	.17
Delivery <36 w	10 (47.6%)	14 (77.8%)	.05

study by Hume and colleagues demonstrated decreased rates of preterm birth and preterm premature rupture of membranes when comparing an ultrasound-indicated Shirodkar cerclage to ultrasound-indicated McDonald cerclage [7]. This theoretical benefit of Shirodkar cerclage on cervical reconstitution has not been proven, and therefore the Society for Maternal-Fetal Medicine supports the use of either Shirodkar or McDonald cerclage for the prevention of preterm birth, though we propose this possible mechanism to explain the efficacy of Shirodkar cerclage in our population. This hypothesis would best be tested with direct comparison of cerclage techniques in patients with very short cervical length. The gestational age at the time of ultrasound-indicated cerclage placement did not impact the rates of preterm birth in our cohort, which is consistent with the findings by Berghella and colleagues in their meta-analysis in 2011, demonstrating cerclage placement at a cervical length of <25 mm significantly decreased subsequent preterm birth <35 weeks, regardless of timing of cerclage placement [3].

Conversely, we found that cervical dilation at the time of exam-indicated cerclage placement for mid-trimester painless cervical dilation was associated with a statistically significantly increased risk of subsequent PTB <36 weeks. This is consistent with the findings of other groups in the literature [9,15–18], though our

cohort did not have significantly higher rates of PTB <28 and <32 weeks' gestation. However, when evaluated as a continuous variable, cervical dilation >2 cm was associated with a higher rate of preterm birth at all gestational ages. This may be related to small sample size and the overall low numbers of women delivering at these gestational ages in our cohort. The gestational age at the time of exam-indicated cerclage placement did not change rates of spontaneous preterm birth even when stratified to <22 and ≥ 22 weeks, despite prior studies suggesting decreased rates of preterm birth when exam-indicated cerclage is placed <22 weeks [19].

There are strengths and limitations to our study. This is a cohort of patients evaluated from a high-volume high-risk practice with consistent clinical management across providers over the time period studied. Additionally, our practice universally places Shirodkar-type cerclages with a uniform technique among all surgeons in our practice. Because of this, there is unlikely to be significant variation in management or operative technique which may impact the clinical outcomes of these patients at high risk for preterm birth. Due to the retrospective nature of this study, there is a risk of selection bias as many patients are referred to our practice for cerclage placement only and deliver at other hospitals. Our small study size limits the ability to assess for the interaction of confounding variables in the two cohorts of interest. We acknowledge that certain demographic variables or obstetric factors may bias the results obtained in this retrospective study. Additionally, we may be limited by small sample size overall and therefore underpowered to show a statistically significant difference in all outcomes. This may be particularly true for patients with very short cervical length undergoing ultrasound-

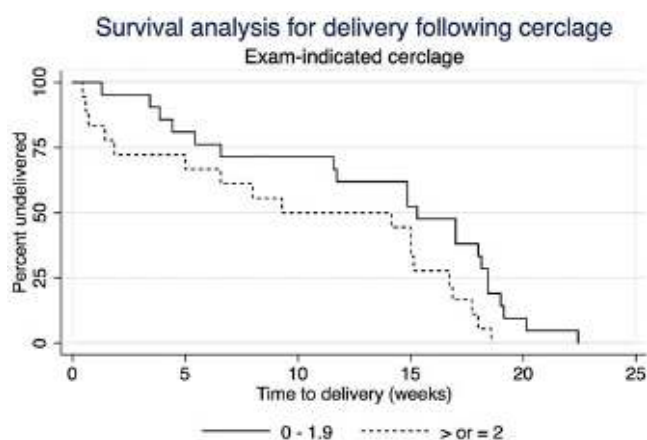


Figure 2. Time to delivery in the exam-indicated cerclage cohort stratified by dilation at time of cerclage placement < 2 or ≥ 2 cm (p value = .03).

indicated cerclage, as this has been consistently shown to correlate with rates of preterm birth in other studies, though this finding could also be related to our exclusive use of the Shirodkar technique [7]. We would recommend further study to better clarify differences in rates of preterm birth for women with very short cervical length randomized to either Shirodkar or McDonald techniques.

In conclusion, cervical length and gestational age at the time of ultrasound-indicated Shirodkar cerclage placement do not appear to impact the likelihood of preterm birth < 36 weeks, while cervical dilation ≥ 2 cm at the time of exam-indicated Shirodkar cerclage is associated with an increased rate of preterm birth < 36 weeks. This may be helpful when counseling patients about placing a clinically-indicated cerclage and to manage expectations for outcomes following Shirodkar cerclage placement.

Disclosure statement

No potential conflict of interest was reported by the authors.

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