

Trends in cerclage use

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Key words

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Conflict of interest

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

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Abstract

Introduction. The indications of placement of cerclage have recently changed, and so it is important to evaluate how many women are undergoing this procedure. With the recent completion of clinical trials, it is plausible that obstetricians and perinatologists may have become more selective in terms of the best candidates for cerclage. **Material and methods.** We conducted a retrospective cohort study of women who underwent cerclage for prevention of preterm birth in the Division of Maternal and Fetal Medicine of Thomas Jefferson University Hospital (Philadelphia, USA) over a 16-year period, from 1998 to 2013. We included women with singleton gestations who had a history-indicated (HIC) or ultrasound-indicated cerclage (UIC). Physical examination-indicated cerclage and transabdominal cerclage were excluded. We planned to compare data before and after 2005. **Results.** From 1998 to 2013, there were 33 353 deliveries, of which 16 871 occurred from 1998 to 2005 and 16 482 from 2006 to 2013. Of all deliveries, 328 women (1.0%) received HIC or UIC, and were therefore included in the analysis. Between 1998–2005 and 2006–2013 there were significant decreases in the overall rate of cerclage (1.4% to 0.6%; $p < 0.001$), as well as the rate of HIC (0.8% to 0.2%; $p < 0.001$) and UIC (0.6% to 0.3%; $p < 0.001$). **Conclusions.** During the last 16 years, the overall rate of HIC and UIC cerclage at Thomas Jefferson University Hospital significantly declined from 1.4% to 0.6%; significant decreases were seen for both HIC and UIC. The reason for the lower rate of cerclages may be the recently published evidence.

Abbreviations: CL, cervical length; HIC, history-indicated cerclage; PTB, preterm birth; RCT, randomized controlled trial; sPTB, spontaneous preterm birth; TVU, transvaginal ultrasound; UIC, ultrasound-indicated cerclage.

Introduction

Cervical cerclage was devised in the 1950s for women with previous early preterm births (PTB) who developed a dilated cervix detected by manual examination in the second trimester (1,2). In contemporary practice, there are three possible indications for cerclage. History-indicated cerclage (HIC) is defined as a cerclage placed usually between 12 and 15 weeks of gestation based solely on

poor previous obstetrical history, e.g. multiple second-trimester losses due to painless dilatation. Ultrasound-indicated cerclage (UIC) is defined as a cerclage placed usually

Key Message

During the last 16 years, the overall rate of cerclage has significantly declined.

between 16 and 23 weeks for transvaginal ultrasound (TVU) cervical length (CL) <25 mm in a woman with a previous spontaneous PTB. Physical-examination-indicated is defined as a cerclage placed usually between 16 and 23 weeks because of cervical dilatation of ≥ 1 cm detected on physical (manual) examination.

Randomized trials and meta-analysis of these have shown that UIC is associated with significant reduction in PTB and improved neonatal outcome (3), whereas evidence of efficacy for HIC and physical-examination-indicated cerclage is limited (4,5). In the USA, the national data show that the rate of cerclage has decreased in the last few years (6). Indications for placement of cerclage have recently changed, so it is important to evaluate how many women are undergoing this procedure. With the recent completion of clinical trials, it is plausible that obstetricians and perinatologists may have become more selective in terms of the best candidates for cerclage (7).

Our objective was to evaluate the trends in rate of cerclage by its indications at our institution over the last few years.

Material and methods

We conducted a retrospective cohort study of women who underwent cerclage for prevention of PTB in the Division of Maternal and Fetal Medicine, Department of Obstetrics and Gynecology, of Thomas Jefferson University Hospital (Philadelphia, PA, USA) over a 16-year period, from 1998 to 2013. Women who received a cervical cerclage were identified through our prematurity database, medical records, and billing records. The prematurity database at our institution is a prospectively maintained database, in which demographics, obstetric history, cerclage, and perinatal outcome data on women with risk factors for PTB were systematically collected. The accuracy of information in the database was verified against outpatient and hospital records.

All singleton gestations with HIC and UIC performed during the study period were included. We excluded physical-examination-indicated and abdominal cerclages, as these are uncommonly performed in clinical practice; and multiple gestations. HIC was defined as a cerclage placed between 12 and 15 weeks based solely on poor previous obstetrical history, e.g. multiple second-trimester loss due to painless dilatation. UIC was defined as a cerclage placed between 16 and 23 weeks for TVU CL <25 mm in a woman with a previous spontaneous PTB. Data were stratified by year of cerclage in two groups: 1998–2005 and 2006–2013. This was done because the first meta-analysis showing some evidence for effectiveness of UIC was published in 2005 (8), and it represented a convenient mid-point in our study period. After 2005,

we placed HIC only in women with multiple second-trimester losses, and routinely performed CL screening for women with previous PTB or just one second-trimester loss from 16 to 23^{6/7} weeks, using CL <25 mm (rarely just for funnelling >25% before 2005) as an indication for UIC placement.

The primary outcome included the rate of cerclage. We defined rate of cerclage as the number of cerclages placed annually divided by total number of annual deliveries at our institution. Secondary outcomes included gestational age at delivery, spontaneous PTB (sPTB) <37 weeks, sPTB <35 weeks, sPTB <32 weeks, sPTB <28 weeks, sPTB <24 weeks, and neonatal outcomes including birthweight, admission to neonatal intensive care unit, and perinatal death.

Statistical analysis was performed using SPSS v 19.0 (IBM Inc., Armonk, NY, USA). Differences between groups were analyzed using chi-squared test and Fisher's exact test for categorical variables and Student's *t* test or Mann–Whitney *U* test for normally and non-normally distributed continuous variables, respectively. To test for the trend over time, we used the chi-squared test for trend. A two-tailed *p* value of 0.05 or less was considered significant.

Results

From 1998 to 2013, there were 33 353 deliveries, of which 16 871 (50.5%) were from 1998 to 2005, and 16,482 (49.5%) were from 2006 to 2013. Of all deliveries, 328 women (1.0%) received either HIC or UIC, and were therefore included in the analysis. Table 1 shows the characteristics of the included women. Of the 328 women, 168 (51%) received HIC and 160 (49%) received UIC. All women received McDonald cerclage.

Figure 1 shows the rate of cervical cerclage from 1998 to 2013 at Thomas Jefferson University Hospital. Between 1998–2005 and 2006–2013, there were significant decreases in the overall rate of cerclage from 1.4% (237 cerclages/16 871 deliveries) to 0.6% (91 cerclages/16 482 deliveries) ($p < 0.001$) (Figure 1). The rate of HIC decreased from 0.8% (133/16 871) to 0.2% (35/16 482) ($p < 0.001$, Figure 2), and that of UIC from 0.6% (104/16 871) to 0.3% (56/16 482) ($p < 0.001$, Figure 2) in 1998–2005 compared with 2006–2013, respectively. Chi-squared test for trend suggested a significant linear decrease of cervical cerclage rate across the whole time from 1998 to 2013 ($p < 0.0001$). However, a significant increase from 2006 to 2013 in the UIC rate at our institution was found by using chi-squared test for trend ($p < 0.0001$), whereas the HIC rate and the overall cerclage rate did not increase ($p = 0.52$ and $p = 0.25$, respectively) (Figures 1 and 2).

Table 2 shows maternal characteristics stratified by indication for cerclage. BMI and the incidence of dilatation and curettage were higher after 2005 in both HIC and UIC groups; there were no other differences among groups. Table 3 shows obstetric and neonatal outcomes stratified by indication for cerclage. There were no significant differences in any of the outcomes except for PTB

<35 weeks, which was lower in the 2006–2013 period compared with the 1996–2005 period for the HIC group, and birthweight, which was higher in the 1998–2005 period compared with the 2006–2013 period for the UIC group. After we adjusted for statistically proven confounders, we found no difference in the incidence of PTB < 35 weeks in the HIC group (adjusted odds ratio 1.96, 95% confidence interval 0.84 to 4.57). Moreover, no statistically significant differences were found in any outcomes in the UIC group after adjusting for statistically proven confounders.

Table 1. Characteristics of the included women

	All women with HIC or UIC (n = 328)
Age	
Mean ± SD	30.7 ± 5.8
>35 years, n (%)	77 (23)
<20 years	13 (4)
Race	
African-American	184 (56)
Caucasian	108 (33)
Others ^a	36 (11)
Smoking	43 (13)
Body mass index	
Mean ± SD	25.1 ± 14.9
<19 kg/m ²	63 (19)
>30 kg/m ²	126 (38)
Gravidity	
mean ± SD	4.2 ± 2.1
Gestational age at cerclage placement	
Mean ± SD	16.3 ± 4.2
Indication for cerclage	
HIC	168 (51)
UIC	160 (49)

HIC, history-indicated cerclage; UIC, ultrasound-indicated cerclage; SD, standard deviation.

Data presented as n (%) or mean ± SD.

^aOthers, included Hispanic and Asian.

Discussion

The overall rate of cerclage at our institution significantly declined from 1.4% to 0.6% from 1998 to 2013. The overall decline was observed regardless of whether the indication was obstetrical history (HIC) or short CL (UIC). There was an increase in the second time period, from 2006 to 2013, in the UIC rate. HIC was the more commonly performed cerclage in the first period (1998–2005); however, we noted that HIC was much less common in the second period compared with UIC (Figure 2). In the more recent period, 2006–2013, only two patients per 1000 deliveries received a HIC, and 3 per 1000 deliveries received a UIC at Thomas Jefferson University Hospital, despite this being a referral institution. HIC used to be more commonly performed, but is now less common than UIC. Despite a non-significantly lower rate of cerclage placement from 2006 to 2013, the rate of PTB and perinatal mortality remained low (was even lower in several analyses) in both HIC and UIC groups.

We acknowledge that our study has limitations of a retrospective study design. Due to the retrospective nature

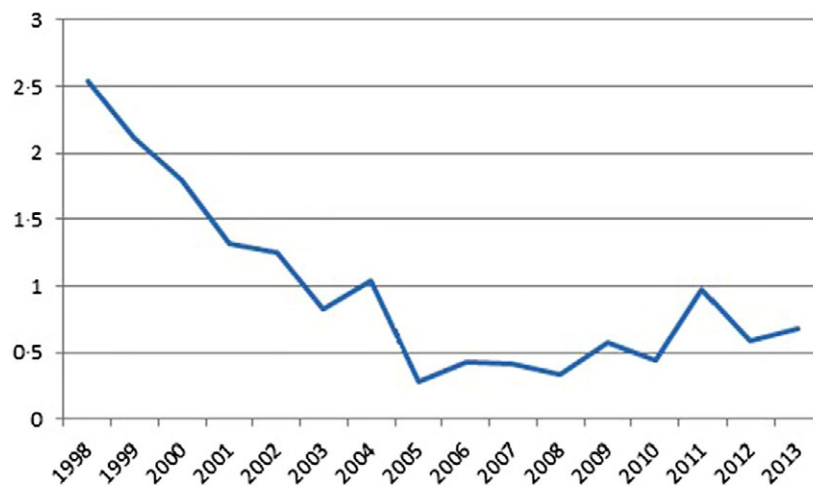


Figure 1. Overall cerclage rate at Thomas Jefferson University Hospital.

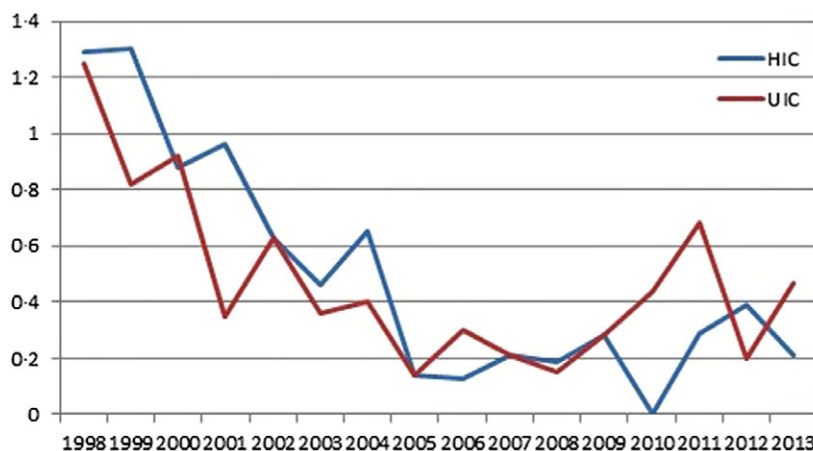


Figure 2. Rate of cerclage based on indication [History-indicated cerclage (HIC) and ultrasound-indicated cerclage (UIC)] at Thomas Jefferson University Hospital.

Table 2. Maternal characteristics stratify by indication for cerclage

Variable	HIC (n = 168; 51%)		p-value	UIC (n = 160; 49%)		p-value
	1998–2005 (n = 133)	2006–2013 (n = 35)		1998–2005 (n = 104)	2006–2013 (n = 56)	
Age						
mean ± SD	31.5 ± 5.2	31.6 ± 5.3	0.87	29.9 ± 6.5	29.2 ± 5	0.49
>35 years	37 (28)	8 (23)	0.69	24 (23)	8 (14)	0.21
<20 years	3 (2)	0 (0)	0.85	7 (6)	3 (2)	0.98
Race						
African-American	75 (56)	20 (57)	0.87	61 (58)	28 (51)	0.32
Caucasian	43 (33)	12 (34)		34 (35)	19 (29)	
Others ^a	15 (11)	3 (9)		9 (7)	9 (20)	
Smoking	12 (11)	9 (15)	0.62	17 (16)	5 (9)	0.23
Body mass index						
mean ± SD	24.1 ± 14	31.4 ± 12	0.001	19.4 ± 17	30.2 ± 98	<0.001
<19 kg/m ²	30 (22)	1 (3)	0.006	32 (30)	0 (0)	<0.001
>30 kg/m ²	45 (33)	21 (60)	0.006	38 (37)	22 (39)	0.73
Gravidity						
mean ± SD	3.2 ± 1.4	2.9 ± 1.9	0.48	3.5 ± 1.1	2.7 ± 1.8	0.13
median (range)	5 (1–11)	5.5 (1–15)		6 (1–15)	4.5 (1–10)	
GA of cerclage placement, mean ± SD	13.3 ± 4.1	12.4 ± 3.7	0.64	20.8 ± 2.4	21.7 ± 3.3	0.78
CL (in mm), mean ± SD	–	–	–	12.8 ± 1.7	11.3 ± 2	0.01
Cervical surgery, n (%)	20 (15)	3 (8)	0.41	10 (10)	6 (11)	0.79
D&C, n (%)	4 (3)	10 (29)	0.001	13 (13)	17 (30)	0.01
Müllerian anomalies, n (%)	2 (2)	0 (0)	0.97	1 (1)	0 (0)	0.97
Prior cerclage, n (%)	72 (54)	18 (51)	0.85	13 (13)	2 (4)	0.08

D&C, dilatation and curettage; GA, gestational age; HIC, history-indicated cerclage; SD, standard deviation; UIC, ultrasound-indicated cerclage. Data presented as n (%) or mean ± SD.

^aOthers, included Hispanic and Asian.

of the study, we were not able to assess the number of cerclages performed against the number of cerclages that were truly indicated at the time based on evidence-based guidelines. Other factors may have influenced the inci-

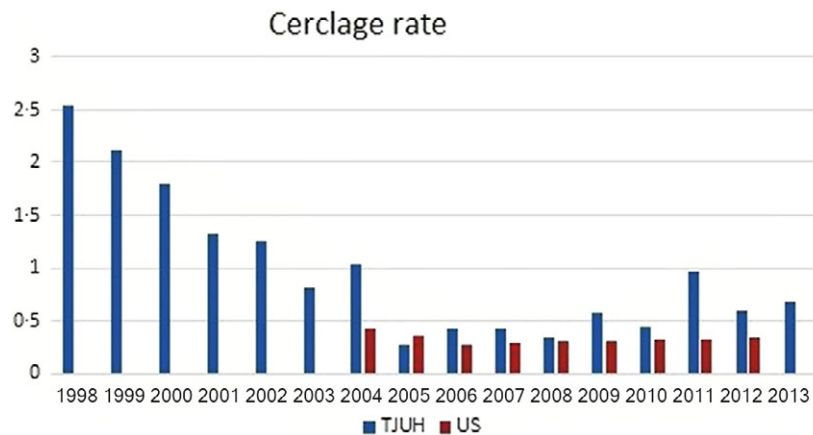
dence of cerclage at our institution. Improvements in ultrasound equipment may have led to a better assessment of TVU CL. We had no major changes in insurance coverage or referrals during the study period. We cannot

Table 3. Secondary outcomes stratified by indication for cerclage

Variable	HIC (n = 168; 51%)			UIC (n = 160; 49%)		
	1998–2005 (n = 133)	2006–2013 (n = 35)	p-value	1995–2005 (n = 104)	2006–2013 (n = 56)	p-value
GA at delivery, mean ± SD	33.9 ± 7.5	36.2 ± 7.3	0.12	32.9 ± 7.6	31.2 ± 7.1	0.27
PTB < 37 weeks, n (%)	72 (54)	12 (34)	0.05	54 (52)	27 (48)	0.74
PTB < 35 weeks, n (%)	47 (35)	5 (14)	0.02	40 (39)	23 (41)	0.86
PTB < 32 weeks, n (%)	32 (24)	4 (11)	0.16	30 (29)	18 (32)	0.71
PTB < 28 weeks, n (%)	26 (19)	2 (6)	0.07	26 (25)	15 (27)	0.85
PTB < 24 weeks, n (%)	20 (15)	2 (6)	0.17	19 (18)	9 (16)	0.82
NICU, n (%)	12 (9)	5 (14)	0.35	12 (12)	12 (21)	0.10
Birthweight (g), mean ± SD	2775 ± 1166	2610 ± 1154	0.41	2477 ± 1244	1869 ± 1332	0.01
Perinatal death, n (%)	12 (9)	0 (0)	0.07	11 (11)	6 (11)	0.97

GA, gestational age; HIC, history-indicated cerclage; NICU, neonatal intensive care unit; PTB, spontaneous preterm birth; SD, standard deviation; UIC, ultrasound-indicated cerclage.

Data presented as n (%) or mean ± SD.

**Figure 3.** Rate of cerclage at Thomas Jefferson University Hospital (blue bar) and in USA (red bar).

fully explain why the incidence of PTB <35 weeks was lower in the second epoch in the HIC group (Table 3), but higher progesterone use could be a factor. The lower birthweight in the UIC group for the second epoch could be secondary to higher incidence of previous dilatation and curettage (Table 2). From 1998 to 2013, new data on cerclage effectiveness have been published. Between 2001 and 2004, four randomized controlled trials (RCTs) on UIC vs. no UIC in women with a short CL were published, with mixed results (9–12). They showed no significant benefit in women without previous PTB (11), and possible effectiveness by meta-analysis (in 2005) in women with previous PTB (8). The benefit in women with singleton gestations, previous spontaneous PTB, and a short TVU CL before 24 weeks was confirmed by the largest RCT on this subject, published in 2009 (13), and the subsequent 2011 meta-analysis (3). In 2011, a meta-analysis comparing HIC to TVU CL screening with UIC as necessary in 467 women revealed similar PTB and peri-

natal outcomes, with only 42% of the women in the TVU CL screening group developing a short CL and therefore receiving a UIC (14).

Why is the overall rate of cerclage, and in particular HIC, decreasing? The most plausible reason is that there has been a shift in the evidence for the indications. Currently, the strongest evidence for effectiveness is for placing a cerclage in a singleton gestation with a previous spontaneous PTB who develops a TVU CL < 25 mm before 24 weeks (i.e. UIC). This is associated, in over 500 women randomized, with a significant 30% decrease in PTB, and a significant 36% decrease in perinatal morbidity and mortality (3). Instead, the evidence for efficacy of HIC is limited, with benefit shown only in a subgroup of 107 women, those with three or more previous second-trimester losses or PTBs (4). The other RCTs on HIC on singleton gestations have not shown benefit (15,16). The limited data on HIC and much stronger data on UIC have probably caused practitioners to offer TVU CL to

women with previous PTBs or even second-trimester losses, forgoing HIC. Women who were once automatically given HIC are now being followed by TVU CL and only some (about 42%) of these women develop a short CL and need cerclage (14). This is probably the main cause for the overall decrease in the rate of cerclage, and for the specific decrease in HIC.

The decrease in the rate of UIC was somewhat surprising, but there are a few potential reasons for this decline. UIC for women with a short TVU CL before 24 weeks of gestation has been proposed since the mid- to late-1990s (17). Without much evidence of effectiveness, some practitioners began offering this procedure. The first reason for the decrease in the rate of UIC is that in 2004, an RCT on singletons without previous PTB showed no benefit for UIC (11). Singletons without previous PTB usually represent at least 90% of the pregnant population. At our institution, UIC is performed only under the following circumstance: a woman with a singleton gestation, previous sPTB, and a short CL <24 weeks (3). A second reason for the decrease in UIC is that the incidence of short CL in singletons with previous PTB may be decreasing. Since 2003, based on a large RCT (18), the American Congress of Obstetricians and Gynecologists has recommended to start progesterone at 16–20 weeks in women with previous spontaneous PTB (19). There is some evidence that vaginal progesterone supplementation prevents the development of short CL (20), which would in turn decrease the rate of UIC.

We could not identify any other studies reporting specifically on the rate of cerclage. Some US national data are available on the rate of cerclage (Figure 3). The decrease in overall cerclage rate seen at Jefferson is similar to the limited US national data (Figure 3) (6). The rate of cerclage at our institution was expected to be higher (0.60% overall in 2006–2013) compared with national data (0.32% in 2006–2012), because we are a referral institution. Moreover, we can attest that the data in our institution are complete, as we checked multiple reliable sources. The national data instead come from birth record data, and may be incomplete (6).

Conclusion

In summary, the rate of cerclage use has decreased at Jefferson – and nationally – in the last few years. The recent decrease in the incidence of PTB may be in part related to both performing cerclage only for proper indications (e.g. UIC in women with singletons, previous spontaneous PTB, and short TVU CL < 25 mm before 24 weeks of gestation), and also an overall decrease of cerclage in women who do not have an evidence-based indication for this procedure.

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