Original Investigation

Retrospective evaluation of transvaginal cervical cerclage cases in a tertiary reference center: comparison of indications and suture materials

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Abstract

Objective: To compare history-indicated cervical cerclage (HICC), ultrasound-indicated CC (UICC) and physical examination-indicated CC (PEICC) in terms of obstetric outcomes and to compare the outcomes related to braided and non-braided suture materials (Prolene suture vs. Mersilene tape).

Material and Methods: We retrospectively evaluated 173 transvaginal CC procedures performed in a single center. Cases were classified based on procedure indications and the type of suture material used.

Results: Of the 173 cases reviewed, 103 (59.5%), 45 (26.0%) and 25 (14.4%) cases were in the HICC, UICC and PEICC groups, respectively. Patients in the PEICC group underwent cerclage at significantly later gestational weeks, had higher hospitalization rates, longer hospital stays following the procedure, a shorter interval between cerclage and delivery, and a higher rate of procedure-related pregnancy loss compared to the other groups ($p<0.05$ for all). Both the gestational age at delivery and the take-home baby rate were lower in this group compared to the other groups ($p<0.05$ for both). There were no significant differences identified in terms of suture materials used. Subgroup analyses revealed similar obstetric outcomes between different suture materials.

Conclusion: PEICC had worse perinatal outcomes compared to HICC and UICC procedures. CC indication was the major determinant of perinatal outcome in this cohort while suture material had no significant effect on perinatal outcomes. [J Turk Ger Gynecol Assoc.]

Keywords: Cervical cerclage, indication, mersilene suture, prolene suture, suture material

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Introduction

Cervical cerclage (CC) is a procedure performed to reinforce the cervix in certain circumstances. Transvaginal CC was first described by Shirodkar and modified by McDonald to its most widely used technique (1,2). Several surgical techniques have been described, such as a transabdominal or laparoscopic approach, especially in cases with previous transvaginal CC failure (3,4).

The indications for the cerclage procedure are mainly categorized into three groups; history-indicated CC (HICC), ultrasound-indicated CC (UICC) and physical examination-indicated CC (PEICC) (5). The patient selection for the procedure must also be within the defined indications as

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the procedure has also some important complications that may even result in pregnancy loss. Membrane rupture, intra-amniotic infection or suture migration are the most commonly reported complications of cerclage procedure. The rate of complications has been reported to increase with maternal age and advanced cervical dilatation (6). However, there are also numerous studies showing similar results between different group of patients, including UICC and PEICC, in terms of procedure related complications (7).

Success of a cerclage procedure strictly depends on the indication for the procedure as well as the used surgical technique and surgical materials. Despite transabdominal or laparoscopic routes for CC being associated with higher morbidity, these procedures may be preferred for patients with a prior transvaginal CC failure (8). Furthermore, placement of suture material and the remaining intact cervical height have been associated with greater success of the procedure (9).

Beyond surgical techniques, the association between suture material type and pregnancy outcomes has been widely studied. Braided suture materials, such as Mersilene tape, are the most widely used material for this procedure (10). However, there are numerous studies evaluating the appropriateness of non-braided, non-absorbable sutures, such as Prolene, for CC. This question has been investigated in a multicenter randomized trial and the authors found no differences between braided and non-braided suture materials (11). However, due to lack of further randomized studies confirming these results, we believe that additional data may be helpful.

The aim of this study was to evaluate the obstetric and neonatal outcomes in pregnancies with CC according to cerclage indication and suture materials used.

Material and Methods

All CC procedures were performed between January 1, 2004 and December 31, 2023 in the Department of Obstetrics and Gynecology, Division of Maternal Fetal Medicine, were evaluated in this retrospective cohort study. Study data were extracted from the electronic database of Hacettepe University. Singleton pregnancies undergoing CC procedure were included. All the procedures were performed by maternal fetal medicine specialists. Multiple pregnancies and pregnancies with transabdominal cerclage procedures were excluded from the study. Patients who were lost to follow-up were also excluded. The study was performed in accordance with the Declaration of Helsinki. This study was approved by the Hacettepe University Health Sciences Research Ethics Committee (approval number: 2023/03-08, date: 19.09.2023).

CC procedures were performed according to McDonald's technique based on three main indications: 1) HICC which was based on a prior history of one or more second-trimester losses associated with painless cervical dilation (12); 2) UICC defined as singleton pregnancy, prior preterm birth or a second-trimester loss, and a short cervical length (≤25 mm) on transvaginal ultrasound examination at 16 to 23 weeks of gestation; and 3) PEICC which was performed in cases of cervical insufficiency based on a dilated cervix on a digital or speculum examination at 16 to 23 weeks of gestation (5).

Patients were evaluated in terms of obstetric histories, antenatal risk factors and cervical assessment before the operation. Fetal anomalies incompatible with life, intrauterine infection, active vaginal bleeding, active preterm labor, preterm premature rupture of membranes (PPROM) and fetal demise were considered as contraindications for the CC procedure (12). Cerclage procedures included in the cohort were primarily performed at or before 24 weeks of gestation. In five cases (four PEICC, one UICC), the procedure was performed beyond 24 weeks (25-26 weeks) following detailed counseling with the patient and family regarding potential risks and benefits. A comprehensive informed consent was provided for all patients including estimated success rates, procedure related complications and possible neonatal adverse outcomes. After obtaining required written permissions, the patients were placed in lithotomic position, the operation field was cleansed with aseptic solutions, surgical drapes were placed and sedoanalgesia was administered in the operating room. All patients received a single prophylactic dose of 2 g intravenous cefazolin prior to the procedure, following institutional standard protocol. The anterior and posterior lips of the cervix were grasped by two ring forceps. Then sutures (either Prolene or Mersilene tape) were inserted at 12, 3, 6 and 9 o'clock positions circumferentially around the entire cervix as high as safely possible, avoiding the bladder, rectum, and uterine vessels (9, 12). The lateral positions (3 and 9 o'clock) were approached with particular caution to avoid uterine artery injury, and the suture pathway was adjusted according to the cervical anatomy (5). Either outpatient approach or hospitalization was chosen according to individual patient clinical picture. Mersilene tape (5-0 Mersilene™ white 1X18" S-14 double armed, Ethicon, Johnson & Johnson, New Jersey, USA) or Prolene suture (Prolene™ #1, polypropylene suture, Ethicon, Johnson & Johnson, New Jersey, USA) were used in all cases. Pregnancies were closely followed-up at the division of perinatology until delivery.

Pregnancies included in the study were divided into three groups based on CC indications: 1) HICC group; 2) UICC group; and 3) PEICC group. Maternal age, gravidity, parity, previous miscarriage, number of living children, multiparity, gestational week of cerclage procedure, suture material, hospitalization rate, duration of hospitalization after the cerclage procedure, procedure related pregnancy loss (pregnancy losses that occurred within a week after the CC procedure), preterm labor/PPROM rate, rates of deliveries at $<34^{th}$, 34^{th}-$<37^{th}$, and $\geq 37^{th}$ weeks of gestation, duration between cerclage procedure

and delivery, birth weight, route of delivery, rate of any Apgar score less than 7 in the first ten minutes, admission to neonatal intensive care unit (NICU), neonatal infection rate (presence of neonatal sepsis and/or congenital pneumonia) and take-home baby rates were compared between the groups. Thereafter, pregnancies were divided into groups based on suture material, either 1) Prolene suture group and 2) Mersilene tape group. The same set of variables were compared between the groups. Preterm birth rate was considered the primary outcome of the study. Other outcomes, including gestational age at delivery, birthweight, NICU admission, take-home baby rate, perinatal mortality, and procedure-related pregnancy loss, were evaluated as secondary outcomes.

Statistical analysis

Statistical analyses were performed using the Statistical Package for the Social Sciences version 22 (IBM Inc., Armonk, NY, USA). Variables were investigated using visual and analytical methods to determine whether they were normally distributed. Descriptive analyses are presented as medians and interquartile range for non-normally distributed variables. As continuous variables were not normally distributed, Kruskal-Wallis or Mann-Whitney U tests were performed to compare the median values between the groups. A p value of <0.05 was used to infer statistical significance. Categorical variables were defined based on numbers and percentages. Categorical variables were compared with Fisher's exact or chi-square test as appropriate. Pairwise compasions were performed by Mann-Whitney U test for continuous variables and post-hoc analyses were performed for significantly different categoric variables.

Results

A total of 173 transvaginal CC procedures were performed during the study period, including 103 (59.5%) in the HICC group, 45 (26.0%) in the UICC group, and 25 (14.4%) in the PEICC group. Significant differences were found for gravidity, number of previous miscarriages, gestational week of cerclage procedure, hospitalization after CC rate, duration of hospitalization after the cerclage procedure, procedure related pregnancy loss, pregnancy outcome, preterm labor rate, PPROM rate, gestational week at delivery subgroups, gestational week at delivery, duration between cerclage procedure and delivery, birth weight, admission rate to NICU and take-home baby rate ($p<0.05$ for all) (Table 1). Although the median number of previous miscarriages was zero in the UICC group, all patients had qualifying risk factors, such as prior spontaneous preterm birth or second-trimester loss, consistent with guideline-based indications for UICC. Median values for gestational week of CC procedure were 13, 20 and 21 weeks for HICC, UICC and PEICC groups, respectively ($p<0.001$). Hospitalization rates after cerclage procedures were 29.1%, 51.1% and 92% for HICC, UICC and PEICC groups, respectively ($p<0.001$). Duration of hospitalization after CC was significantly different between all groups ($p<0.001$). The procedure-related pregnancy loss rate was significantly higher in the PEICC group (40%) compared to HICC (1.9%) and UICC groups (6.6%, $p<0.001$ for both). Pregnancy outcomes differed among groups as to whether they ended in miscarriage or delivery. Miscarriage rates were 8.7%, 6.6% and 36% for HICC, UICC and PEICC groups, respectively. Preterm labor rate was higher in the PEICC and UICC group

Table 1. Characteristics of the patient groups based on cervical cerclage indications

Variables	History indicated cerclage group (n=103)	Ultrasound indicated cerclage group (n=45)	Physical examination indicated cerclage group (n=25)	p values
Maternal age (median, p25-p75)	32 (29-35)	33.5 (30-37.5)	33 (28.5-34.5)	0.309
Gravidity (median, p25-p75)	3.5 (3-5)	2 (1-3)	2 (2-4)	**<0.001**[a]
Parity (median, p25-p75)	1 (0-2)	1 (0-1)	0 (0-1)	0.050
Previous miscarriage (median, p25-p75)	1 (1-2)	0 (0-1)	1 (0-2)	**0.009**[b]
Living child (median, p25-p75)	0 (0-1)	0 (0-1)	0 (0-1)	0.411
Multiparous n, (%)	67 (65.1)	23 (51.1)	11 (44)	0.083
Gestational week of cerclage procedure (median, p25-p75)	13 (12-14)	20 (17.5-22)	21 (19-24)	**<0.001**[c]
Suture material n (%)				0.867
Prolene	63 (61.1)	26 (57.7)	16 (64)	
Mersilene tape	40 (38.9)	19 (42.3)	9 (36)	

p25-p75: 25th and 75th percentiles, NICU: Neonatal intensive care unit, PPROM: Preterm prelabor rupture of membranes
Pairwise comparison revealed significant differences between;
[a]Ultrasound indicated and history indicated groups
[b]Ultrasound indicated and other two groups
[c]History indicated and other two groups

compared to HICC group (p=0.005). Median gestational week at delivery was lowest in the PEICC group (34) and this value was significantly lower than the HICC (37) and UICC (36) groups (p=0.025). Median duration between the CC procedure and delivery was longest in the HICC (24) group and shortest in the PEICC group (11). This difference was significant between all groups by pairwise analyses (p<0.001 for both). Median birth weight was 3050 g, 2850 g and 2340 g for HICC, UICC and PEICC groups, respectively, with a significant difference between HICC and PEICC groups. Rate of any first ten minute Apgar score <7 was similar between groups (p=0.420). Admission rates to NICU were highest for the PEICC group (56.2%) in comparison with HICC (20.2%) and UICC (30.9%) (p=0.008). Take-home baby rate was significantly lower in the PEICC group (64%) in comparison with the HICC (91.2%) and UICC (88.8%) groups (p=0.001).

Prolene suture and Mersilene tape was used in 105 (60.7%) and 68 (39.3%) cases, respectively. Both groups were comparable in terms of study parameters. CC indications were similar between groups. We could not demonstrate any significant difference regarding neonatal and perinatal outcomes (Table 2).

We performed further statistical analyses regarding the suture

Table 2. Clinical outcomes of the patient groups based on cervical cerclage indications

Variables	History indicated cerclage group (n=103)	Ultrasound indicated cerclage group (n=45)	Physical examination indicated cerclage group (n=25)	p values
Hospitalization after cerclage, n (%)	30 (29.1)	23 (51.1)	23 (92)	**<0.001**[a]
Duration of hospitalization after the cerclage procedure (days) median, (p25-p75)	0 (0-1)	0.5 (0-1)	3 (1-7.5)	**<0.001**[a]
Procedure related pregnancy loss n (%)	2 (1.9)	3 (6.6)	10 (40)	**<0.001**[b]
Pregnancy outcome, n (%) Miscarriage Delivery	 9 (8.7) 94 (91.3)	 3 (6.6) 42 (93.4)	 9 (36) 16 (64)	**0.001**[b]
Preterm labor[¥]	27 (28.7)	23 (54.7)	9 (56.2)	**0.005**[c]
PPROM (n, %)	10 (10.6)	9 (21.4)	7 (43.7)	**0.003**[b]
Gestational week at delivery subgroups, n (%)[¥]				**0.003**[c]
<34th weeks	10 (10.6)	11 (26.1)	7(43.7)	
34th-<37th weeks	17 (18.1)	12 (28.5)	2(12.5)	
≥37th weeks	67 (71.3)	19 (45.4)	7(43.7)	
Gestational week at delivery median, (p25-p75)[¥]	37 (36-38)	36 (31.5-38)	34 (20.5-37)	**0.025**[b]
Duration between cerclage procedure and delivery (weeks) median, (p25-p75)[¥]	24 (20-25)	16 (10.5-19.5)	4 (0.5-12)	**<0.001**[a]
Birth weight (g), median (p25-p75)[¥]	3050 (2715 - 3295)	2850 (2335-3255)	2340 (987.5-2955)	**0.005**[d]
Route of delivery, n (%)[¥]				
Spontaneous vaginal delivery	24 (25.5)	14 (33.3)	8 (50)	0.126
Cesarean section	70 (74.5)	28 (66.7)	8 (50)	
5th minute Apgar <7 n (%)[¥]	15 (15.9)	10 (23.8)	2 (12.5)	0.420
Admission to NICU, n (%)[¥]	19 (20.)	13 (30.9)	9 (56.2)	**0.008**[d]
Neonatal infection, n (%)[¥]	6 (6.3)	6 (14.2)	3 (18.7)	0.163
Take-home baby rate, n (%)	94 (91.2)	40 (88.8)	16 (64)	**0.001**[b]

p25-p75: 25th and 75th percentiles, NICU: Neonatal intensive care unit, PPROM: Preterm prelabor rupture of membranes
[¥]Analyses were performed after exclusion of cases with abortion
Pairwise comparison revealed significant differences between;
[a]All groups
[b]Physical examination indicated group and others
[c]History indicated and other two groups
[d]Physical examination indicated and history indicated groups

material in each indication group (Table 3). There were no significant differences in obstetric and neonatal outcomes between suture material groups by indication group. However, the take-home baby rate was slightly higher for the Prolene group compared to the Mersilene group in PEICC, although this difference was not significant (75% vs. 44.4%; p=0.127) (Table 4).

Table 3. Demographic features and clinical characteristics of the patient groups based on suture material

Variables	Prolene suture group (n=105)	Mersilene tape group (n=68)	p value
Maternal age, median (p25-p75)	32 (26-36)	33 (30-35.5)	0.559
Gravidity, median (p25-p75)	3 (2-4)	3 (2-4)	0.489
Parity, median (p25-p75)	1 (0-2)	0 (0-1)	0.614
Previous miscarriage, median (p25-p75)	1 (0-2)	1 (0-3)	**0.115**
Number of living children, median (p25-p75)	0 (0-1)	0 (0-1)	0.270
Multiparous, n (%)	69 (67.6)	32 (47.1)	0.015
Gestational week of cerclage procedure, median (p25-p75)	14 (13-20)	15 (13-20)	0.439
Cerclage indication, n (%)			0.867
History indicated	63 (60)	40 (58.8)	
Ultrasound indicated	23 (21.9)	19 (27.9)	
Physical examination indicated	16 (18.1)	9 (13.2)	
Hospitalization after cerclage, n (%)	48 (45.7)	28 (41.1)	0.557
Duration of hospitalization after the cerclage procedure (days), median (p25-p75)	0 (0-1)	0 (0-1)	0.667
Procedure related pregnancy loss, n (%)	9 (8.8)	6 (8.8)	0.954
Pregnancy outcome, n (%) Miscarriage Delivery	 12 (11.4) 93 (88.6)	 9 (13.2) 59 (86.8)	0.772
Preterm labor¥	40 (43)	19 (32.2)	0.183
PPROM, n (%)¥	18 (19.3)	8 (13.5)	0.355
Gestational week at delivery groups¥, n (%)			0.234
<34th weeks	17 (18.2)	11 (18.6)	
34th-<37th weeks	23 (24.7)	8 (13.5)	
≥37th weeks	53 (56.9)	40 (67.9)	
Gestational week at delivery, median (p25-p75)¥	37 (32-38)	37 (33-38)	0.912
Duration between cerclage procedure and delivery (weeks), median (p25-p75)¥	21 (13-24)	19.5 (13-24)	0.872
Birthweight (g), median (p25-p75)¥	2910 (2430-3270)	3000 (2590-3250)	0.739
Route of delivery, n (%)¥			0.958
Spontaneous vaginal delivery	28 (30.1)	18 (30.5)	
Caesarean section	65 (69.9)	41 (69.5)	
5th minute Apgar <7 n (%)¥	14 (15.1)	13 (22.0)	0.273
Admission to NICU, n (%)¥	25 (26.8)	16 (27.1)	0.925
Neonatal infection, n (%)¥	11 (11.8)	4 (6.7)	0.309
Take-home baby rate, n (%)	91 (86.6)	59 (86.7)	0.985

p25-p75: 25th and 75th percentiles, NICU: Neonatal intensive care unit, PPROM: Preterm prelabor rupture of membranes
¥Analyses were performed after exclusion of cases with abortion

Table 4. Comparison of obstetric and neonatal outcomes according to the suture materials and indications

	History indicated cerclage group		
Variables	**Prolene suture group (n=63)**	**Mersilene tape group (n=40)**	**p value**
Gestational week of cerclage procedure, median (p25-p75)	13 (12-14)	14 (13-14)	0.027
Hospitalization after cerclage, n (%)	20 (31.7)	10 (25)	0.463
Duration of hospitalization after the cerclage procedure (days), median (p25-p75)	0 (0-1)	0 (0-0.5)	0.263
Procedure related pregnancy loss, n (%)	2 (3.1)	0 (0)	0.255
Pregnancy outcome, n (%) Miscarriage Delivery	 6 (9.5) 57 (90.5)	 3 (7.5) 37 (92.5)	0.723
Preterm labor, n (%)¥	20 (35.1)	7 (18.9)	0.091
PPROM, n (%)¥	7 (12.2)	3 (8.1)	0.522
Gestational week at delivery groups, n (%)¥			0.226
<34th weeks	7 (12.2)	3 (8.1)	
34th-<37th weeks	13 (22.8)	4 (10.8)	
≥37th weeks	37 (64.9)	30 (81.1)	
Gestational week at delivery, median (p25-p75)¥	37 (36-38)	37 (37-38)	0.646
Duration between cerclage procedure and delivery (weeks), median (p25-p75)¥	24 (22-25)	23 (21-25)	0.152
Birthweight (g), median (p25-p75)¥	3015 (2657.5-3285)	3100 (2797.5-3300)	0.673
Route of delivery, n (%)¥			0.452
Spontaneous vaginal delivery	13 (22.8)	11 (29.7)	
Cesarean section	44 (77.2)	26 (70.3)	
5th minute Apgar <7, n (%)¥	9 (15.7)	6 (16.2)	0.956
Admission to NICU, n (%)¥	12 (21)	7 (18.9)	0.801
Neonatal infection, n (%)¥	5 (8.7)	1 (2.7)	0.240
Take-home baby rate, n (%)	57 (90.5)	37 (92.5)	0.723
	Ultrasound indicated cerclage group		
	Prolene suture group (n=26)	**Mersilene tape group (n=19)**	**p value**
Gestational week of cerclage procedure, median (p25-p75)	20 (18-22)	20 (17-22)	0.951
Hospitalization after cerclage, n (%)	13 (50)	10 (52.6)	0.862
Duration of hospitalization after the cerclage procedure (days), median (p25-p75)	0.5 (0-1.25)	1 (0-1)	0.488
Procedure related pregnancy loss, n (%)	2 (7.6)	1 (5.2)	0.747
Pregnancy outcome, n (%) Miscarriage Delivery	 2 (7.6) 24 (92.4)	 1 (5.2) 18 (94.7)	
Preterm labor¥	14 (58.3)	9 (50)	0.551
PPROM, n (%)¥	5 (20.8)	4 (22.2)	0.914
Gestational week at delivery groups, n (%)¥			0.729
<34th weeks	6 (25)	5 (27.7)	
34th-<37th weeks	8 (33.3)	4 (22.3)	
≥37th weeks	10 (42.6)	9 (50)	

Table 4. Continued

	History indicated cerclage group		
Variables	**Prolene suture group (n=63)**	**Mersilene tape group (n=40)**	**p value**
Gestational week at delivery, median (p25-p75)¥	36 (31.25-37.75)	36.5 (33-38)	0.823
Duration between cerclage procedure and delivery (weeks), median (p25-p75)¥	15.5 (10.75-19.5)	16 (12.75-20)	0.899
Birthweight (g), median (p25-p75)¥	2910 (1757.5-3295)	2845 (2402.5-3209)	0.755
Route of delivery, n (%)¥			0.508
Spontaneous vaginal delivery	9	5	
Cesarean section	15	13	
5th minute Apgar <7 n (%)¥	4 (16.6)	6 (33.3)	0.209
Admission to NICU, n (%)¥	7 (29.1)	6 (33.3)	0.773
Neonatal infection, n (%)¥	4 (16.6)	2 (11.1)	0.611
Take-home baby rate, n (%)	22 (84.6)	18 (94.7)	0.286
	Physical examination indicated cerclage group		
	Prolene suture group (n=16)	**Mersilene tape group (n=9)**	
Gestational week of cerclage procedure, median (p25-p75)	23.5 (19.25-24.75)	20 (18.5-22.5)	0.417
Hospitalization after cerclage, n (%)	15 (93.7)	8 (88.8)	0.667
Duration of hospitalization after the cerclage procedure (days), median (p25-p75)	3 (1-7)	4 (2-12)	0.397
Procedure related pregnancy loss, n (%)	5 (31.2)	5 (55.5)	0.234
Pregnancy outcome, n (%) Miscarriage Delivery	 4 (25) 12 (75)	 5 (55.5) 4 (44.4)	0.127
Preterm labor, n (%)¥	6 (50)	3 (75)	0.383
PPROM, n (%)¥	6 (50)	1 (25)	0.383
Gestational week at delivery groups, n (%)¥			0.319
<34th weeks	4 (33.3)	3 (75)	
34th-<37th weeks	2 (16.6)	0	
≥37th weeks	6 (50)	1 (25)	
Gestational week at delivery, median (p25-p75)¥	35.5 (27-37)	31.5 (27-36)	0.585
Duration between cerclage procedure and delivery (weeks), median (p25-p75)¥	11 (2.5-16)	10 (6.25-12.25)	0.569
Birthweight (g), median (p25-p75)¥	2515 (987-3030)	1810 (1047-2715)	0.569
Route of delivery, n (%)¥			1.000
Spontaneous vaginal delivery	6 (50)	2 (50)	
Cesarean section	6 (50)	2 (50)	
5th minute Apgar <7, n (%)¥	1 (8.3)	1 (25)	0.383
Admission to NICU, n (%)¥	6 (50)	3 (75)	0.383
Neonatal infection, n (%)¥	2 (16.6)	1 (25)	0.712
Take-home baby rate, n (%)	12 (75)	4 (44.4)	0.127

p25-p75: 25th and 75th percentiles, NICU: Neonatal intensive care unit, PPROM: Preterm prelabor rupture of membranes
¥Analyses were performed after exclusion of cases with abortion

Table 5. Comparison of take home baby rates based on suture materials in each indication group

	History indicated cerclage group (n=103)	Ultrasound indicated cerclage group (n=43)	Physical examination indicated group (n=25)
Prolene suture Mersilene suture	57/63 (90.5) 37/40 (92.5) p=0.723	22/26 (84.6 %) 18/19 (94.7 %) p=0.286	12/16 (75) 4/9 (44.4) p=0.127

Discussion

Cervical insufficiency is a devastating complication which leads to second trimester pregnancy loss (12). Making the correct diagnosis for cervical insufficiency is crucial for deciding if CC surgery would be appropriate. Choosing the appropriate candidates for CC is the key element for achieving favorable obstetric outcomes (13). However, there have been ongoing debates on the optimal technique, suture material, patient selection criteria and gestational week for CC in order to get better results (7,14-16). For these reasons, experiences of tertiary reference centers may be important to enhance knowledge in this field.

In the present study, the obstetric outcomes were significantly affected by cerclage indications. PEICC had worse outcomes compared to HICC and UICC groups for most of the study parameters. In the pregnant women who underwent PEICC, the CC procedures were performed at later gestational weeks, almost all of the patients were hospitalized after the procedure, procedure related pregnancy loss rate was significantly higher, premature delivery and PPROM rate and admission rate to NICU were significantly higher, the duration between CC procedure and delivery was shorter and take-home baby rate was lower. These findings are largely consistent with the current literature. One significant concern related to PEICC cases is the lack of knowledge about the effect of duration of amniotic membrane exposure to the vaginal environment. This duration may lead to increased rates of infection and inflammation and may be a major contributor to adverse outcomes in this indication group. Despite the known risks and relatively high complication rates, the overall take-home baby rate of 64% in this high-risk cohort supports the continued use of cerclage in selected patients with cervical dilatation, suggesting that the potential benefits may outweigh the risks in appropriately counseled cases. We observed that previous studies reported similar perinatal and obstetric outcomes for HICC and UICC groups (17,18). Moreover, Drassinower et al. (19) reported similar rates of perioperative complications for HICC (n=198) and UICC (n=89) in their retrospective observational study. These results were also confirmed by meta-analysis by Chen et al. (20). Our findings were also consistent with Chen et al. (20). However, despite significantly worse results in PEICC group, CC has also been associated with favorable outcomes without increasing maternal morbidity compared to expectant management in this group of patients (21). Thus, despite having significantly worse results than other indications, PEICC still improves perinatal and neonatal outcomes compared to expectant management.

The threshold for HICC varies between major international guidelines and highlights the lack of global consensus on cervical insufficiency diagnosis and management (12,14,22). The definition used in the present study was based on American College of Obstetricians and Gynecologists and Society of Obstetricians and Gynaecologists of Canada criteria, which allow for consideration of cerclage after a single characteristic second-trimester loss.

We have also compared the obstetric outcomes according to the suture material used and found no significant difference between groups. The selection criteria for the appropriate suture material seem to be operative dependent and the optimal material remains a matter of debate. Braided sutures are favored by physicians mostly due to their physical strength, while non-braided sutures are preferred due to a theoretical decreased surgical infection risk (23,24). More recent studies about this topic have also reported conflicting results. Stafford et al. (16) reported similar outcomes for different suture materials (monofilament, braided, or 5 mm tape cerclages) in their retrospective study consisted of 109 CC procedures. In contrast, Daigle et al. (25) evaluated the outcomes of 34 CC procedures according to suture materials (16 braided, 12 monofilament and 6 5-mm tape sutures). They found that the gestational week at delivery was higher in patients operated with monofilament sutures and concluded that this material was superior to braided sutures. However Sweeney et al. (26) found that the rate of spontaneous preterm delivery was significantly higher in patients managed with monofilament sutures in HICC group. Although there is lack of consensus between retrospective studies, the randomized C-STICH trial concluded that monofilament suture materials did not improve obstetric outcomes (11). This study's conclusion is significant as it is the only randomized trial in the literature with a large number of patients. Our results were consistent with those of the C-STICH trial and we believe that choice of suture material does not significantly change the obstetric outcome. It should be noted that the C-STICH trial consisted of HICC and UICC

patients, but not PEICC patients. Our study uniquely contributes to the literature by providing one of the most comprehensive single-center comparisons of CC outcomes across all indication groups and suture types, including detailed subgroup analyses that highlight nuanced outcome patterns.

Study limitations

The main strengths of this study were relatively high number of cases included, high number of variables and the opportunity to make the comparison of two different suture materials in terms of perinatal outcomes. In addition, subgroup analyses were conducted to compare suture materials across all indication subgroups for more comprehensive results. However, it is important to note that the study was limited by its retrospective design and single-center experience. As this was a retrospective analysis of all eligible cases over two decades, no a priori power calculation was performed. However, the sample size was sufficient to detect significant differences across key variables, as demonstrated in our statistical analysis. Another limitation is the long study period of nearly 20 years, during which clinical practices and patient characteristics might have evolved. However, all procedures were conducted at a single tertiary center by the same specialist team following consistent protocols, which we believe minimized temporal variability. No adjustment for multiple comparisons was performed, which may increase the risk of type-I error. However, results were interpreted cautiously and supported by clinical consistency. Multivariate analysis was not performed, which may limit confounder control; however, groups were based on clear clinical indications and had comparable baseline characteristics. Furthermore, potential confounding variables were not adjusted for using multivariate models, which is a notable limitation. While our subgroup comparisons were based on predefined clinical indications and groups were generally similar in baseline characteristics, we acknowledge that residual confounding may still be present. Future studies with prospective designs and multivariate modeling are warranted to strengthen the findings.

Conclusion

Perinatal outcomes, with preterm birth rate as the primary outcome, significantly varied depending on the indication for CC. The PEICC group had the highest rate of preterm birth and the poorest perinatal outcomes overall. Conversely, the type of suture material (braided or monofilament) did not significantly affect obstetric or neonatal outcomes, and the choice was left to the discretion of the operating surgeon. These findings emphasize that the indication for cerclage is a more critical determinant of perinatal prognosis than the suture material used.

Ethic

Ethics Committee Approval: *This study was approved by the Hacettepe University Health Sciences Research Ethics Committee (approval number: 2023/03-08, date: 19.09.2023).*

Informed Consent: *A comprehensive informed consent was provided for all patients including estimated success rates, procedure related complications and possible neonatal adverse outcomes.*

Footnotes

Author Contributions: *Surgical and Medical Practices: U.K., E.F., Ö.D., Concept: U.K., E.F., Ö.D., Design: U.K., E.F., Ö.D., Data Collection or Processing: U.K., E.F., A.Ç.B., İ.A., E.A.K., Ö.D., Analysis or Interpretation: U.K., İ.A., E.A.K., Literature Search: E.F., A.Ç.B., Ö.D., Writing: U.K., E.F., Ö.D.*

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