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Effect of cerclage suture type on pregnancy and newborn results: mersylene suture versus prolene suture

Serklaj sütür tipinin gebelik ve yenidoğan sonuçları üzerine etkisi: mersilen sütüre ve prolen sütür karşılaştırılması

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ABSTRACT

Aim: The aim of this study is to compare pregnancy and neonatal outcomes according to the type of the suture material used in the transvaginal cerclage operation.

Materials and Methods: Demographic data regarding cerclage indications, number of weeks of gestation in cerclage, cerclage suture type (prolene, mersilene), gestational week at cerclage insertion and delivery, routes of delivery were recorded. In addition, birth weight, 1st and 5th minute APGAR scores, and neonatal intensive care unit (NICU) requirements were recorded as neonatal parameters. Patients were divided into two groups according to cerclage suture type (group 1 mersilene (n=40) or group 2 prolene (n=39)) and maternal, newborn and pregnancy outcomes were compared between these groups.

Results: Comparison of the groups in terms of age, gravidity, parity, number of miscarriages and BMI revealed significantly higher mean gravidity in group 1 compared to group 2 (P<0.05), while groups were found to be similar in terms of age, parity, number of miscarriages and BMI (P>0.05). Cesarean delivery rate was 40 % in group 1 while it was 43.6 % in groups 2, no statistical difference was determined in terms of rate of cesarean delivery (p>0.05). Similar number of newborns needed NICU admission between the two groups following delivery (17.5% versus 17.9 %p>0.05). Mean APGAR scores at 1st (6.8 versus 7.4) and 5 th (7.8 versus 8.3) min were comparable between the groups (p>0.05)

Conclusion: Although mersilene stitch is commonly preferred, data analysis revealed similar results with prolene stitch in terms of maternal and neonatal outcomes.

Keywords: Mersilene,prolene, cerclage, cervical cerclage, neonatal outcome

ÖZ

Amaç: Bu çalışmanın amacı transvajinal serklaj operasyonunda kullanılan sütür materyalinin tipine göre gebelik ve neonatal sonuçları karşılaştırmaktır.

Gereçler ve Yöntem: Serklaj endikasyonları, serklajdaki gebelik haftası, serklaj sütür tipi (prolen, mersilen), serklajın uygulandığı ve doğumdaki gebelik haftası, doğum şekli ile ilgili demografik veriler kaydedildi. Ayrıca doğum ağırlığı, 1. ve 5. dakika APGAR skorları ve yenidoğan yoğun bakım ünitesi (YYBÜ) gereksinimleri yenidoğan parametreleri kaydedildi. Hastalar serklaj sütür tipine göre iki gruba ayrıldı (grup 1 mersilen (n=40) veya grup 2 prolen (n=39)) ve bu gruplar arasında maternal, yenidoğan ve gebelik sonuçları karşılaştırıldı.

Bulgular: Gruplar yaş, gravite, parite, düşük sayısı ve VKİ açısından karşılaştırıldığında, grup 1'de ortalama gravitenin grup 2'ye göre anlamlı olarak daha yüksek olduğu (P<0.05), yaş, parite, düşük sayısı ve VKİ açısından ise grupların benzer olduğu saptanmıştır (P>0.05). Sezaryenle doğum oranı grup 1'de %40 iken grup 2'de %43.6'dır, sezaryenle doğum oranı açısından istatistiksel fark saptanmamıştır (p>0.05). Doğumu takiben iki grup arasında benzer oranda yenidoğanın YYBÜ'ye yatırılması ihtiyacı olmuştur (%17,5'e karşı %17,9 p>0,05). Ortalama APGAR skorları 1. (6.8'e karşı 7.4) ve 5. (7.8'e karşı 8.3) dakikalarda gruplar arasında benzer bulunmuştur (p>0.05)

Sonuç: Mersilen sütür yaygın olarak tercih edilmesine rağmen, veri analizi sonucu maternal ve neonatal sonuçlar açısından prolen sütür ile benzer sonuçlar elde edilmiştir.

Anahtar Kelimeler: Mersilen, prolen, servikal serklaj, neonatal sonuçlar

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INTRODUCTION

Preterm birth (PTB) is an important factor that increases neonatal morbidity and mortality. Although there are many underlying causes of preterm birth, one of the important ones in its etiology is cervical insufficiency (1). One of the main obstetric interventions for prevention in women with cervical insufficiency is cervical cerclage (2). Cerclage has been found to be beneficial in women with a history of differences in physical examination, sonography findings indicating cervical insufficiency, and a history of second trimester miscarriage (3). While many variables are evaluated in terms of cerclage success, there are a limited number of studies that evaluate the effect of cerclage suture material on the effectiveness of cerclage in preventing premature birth and provide different results. While it has been reported that the use of different suture types does not differ in terms of prolonging the pregnancy period (4), it has also been reported that the braided polyester thread (MersileneR) suture type is more effective in prolonging the pregnancy period than other suture types (5). However, some animal and wound site studies are based on the hypothesis that bacteria will multiply more in multifilament sutures and cause infection.

It has been suggested that monofilament sutures would be less associated with infection than mersilene due to suture risk (6-8). Although these are non-absorbable stitches, their success in affecting the pregnancy period is still not known for sure. Some studies in the literature argue that thicker sutures provide greater force and greater tension, thus providing better pregnancy outcomes (9). In order to increase suture power, previous study sought to determine whether routine placement of a second suture during cervical cerclage increases its effectiveness. Analysis of the data revealed that the two-stitch approach to cervical cerclage increases cerclage height but may not increase effectiveness. (10). Some other studies aimed to determine the efficacy of different techniques, Shirodkar cerclage was compared with that of the McDonald procedure for the prevention of PTB in women with a short cervix. Authors concluded that In women with short cervical length randomly assigned to receiving cerclage, no significant difference in prevention of PTB was observed using Shirodkar or McDonald's procedures (11). On the contrary, some authors have suggested that thicker and braided sutures increase the risk of infection, may lead to changes in vaginal flora and premature birth, and therefore may increase negative neonatal outcomes (12).

The aim of this study is to compare the effectiveness of monofilament sutures (Proline™) and braided polyester thread (Mersilene™) sutures used in transvaginal cerclage and to evaluate the pregnancy and neonatal outcomes of these suture materials used in transvaginal cerclage in terms of thickness.

MATERIALS AND METHODS

Hospital records and surgical operation reports of patients who underwent transvaginal cervical cerclage in a tertiary center between 2020 and 2024 were retrospectively examined from the hospital archive and system. Eskişehir Şehir Hastanesi Etik Kurulu approval was obtained before the study (22/02/2024-ESH/GOEK 2024/86). Regardless of the indication for cerclage, pregnant women who did not have congenital anomalies and underwent transvaginal cervical cerclage were included in the study. Patients whose demographic data, cerclage (suture and indication) or newborn information could not be obtained were excluded from the study. By examining the patient's surgical operation reports and files, demographic data (age, gravida, parity), cerclage indications (ultrasound indication, prophylactic or physical examination indication), cerclage weeks, cerclage suture type (prolene, mersilene), method of cerclage application were determined. Each patient included in the study was evaluated. (McDonald, Shirodkar), weeks of birth and mode of delivery (C/S, normal spontaneous vaginal birth) were recorded. In addition, newborns' birth weights, 1st and 5th minute APGAR scores, and NICU requirements were recorded. Since the choice of stitch type was at the discretion of the gynecologist as per hospital policy, no records were kept. Regardless of the stitch type, all cerclage procedures were performed in 12-3-6-9 hours, respectively. Under regional anesthesia, the patient is placed in the dorsal lithotomy position and the vagina is prepared with betadine solution. A speculum or right-angle retractors are used to adequately visualize the cervix. The anterior lip of the cervix was gently grasped using ring polyp forceps and the vesicocervical junction was identified. Immediately anterior to this junction, a nonabsorbable suture is placed in a gathered fashion across the cervix, taking care to avoid the paracervical vessels. The stitch is then tied with a surgeon's knot in the front or back. History-based cerclage (prophylactic) was defined as cerclage performed in the absence of labor and placental abruption, in one or more second trimester pregnancy losses due to painless dilatation, or in previous pregnancies due to painless dilatation in the second trimester of the previous trimester. Cerclage based on physical examination (emergency or rescue cerclage) was defined as painless cervical dilation (minimum 1 cm) in the second trimester. Cerclage based on ultrasound finding was defined as history of spontaneous (PTB) in the current pregnancy and ultrasound finding of short CL (less than 25 mm). For the first week, 2x200 mg daily progesterone treatment was continued orally and then intravaginally. Progesterone support was continued until the cerclage stitch was removed. The patients were divided into two groups, mersilene (group 1) and prolene (group 2), according to the type of suture used. Maternal, newborn and pregnancy outcomes of the groups were compared.

Statistical Analysis

Continuous variables were represented by median (minimum-maximum), while categorical data were represented by number and percentage. Kolmogorov-Smirnov Goodness of Fit Test was used to analyze normality of continuous variables. Continuous variables were compared with the Independent Samples T Test when they had a normal distribution, and with the Mann Whitney U Test when they did not have a normal distribution. Risk factors and odds ratio values related to Mersilene use were determined by Logistic Regression Analysis (Backward: LR). Variables that were found to be significant as a result of both clinical and univariate analysis were selected and evaluated with the Multivariate Logistic Regression Model. Model fit was evaluated with the Hosmer-Lemeshow test. Comparison of categorical data was made with Chi-square Test (Fisher's Exact Test when necessary). According to previous study results, the sample size of the study population was calculated as 150 patients (α = 0.05 and study power = 80%). IBM SPSS Package Program version 22.0 was used for analyzes (IBM Corporation, Armonk, NY, USA). Statistical significance level was taken as $p<0.05$.

RESULTS

Comparison of the groups in terms of age, gravidity, parity, number of miscarriages and BMI revealed significantly higher mean gravidity in group 1 compared to group 2 ($P<0.05$), while groups were found to be similar in terms of age, parity, number of miscarriages and BMI ($P>0.05$, Table 1). No difference was determined with regard to gestational week at cerclage application, cervical length, cervical dilatation just before cerclage insertion, gestational age at cerclage removal and delivery and birth weight ($p>0.05$, Table 2). Groups were

Table 1. Demographic data of the patients.

	Cerclage type	N	Mean	Std. Deviation	P value
Age (years)	Mersylene Suture	40	31.83	6.460	
	Prolene Suture	39	29.69	5.979	0.1
Gravidity	Mersylene Suture	40	3.68	2.005	
	Prolene Suture	39	2.74	1.332	<0.05
Parity	Mersylene Suture	40	1.20	1.363	
	Prolene Suture	39	.74	1.019	0.09
Miscarriages	Mersylene Suture	40	1.45	1.648	
	Prolene Suture	39	1.00	.761	0.1
BMI (kg/m2)	Mersylene Suture	40	26.7053	3.80000	
	Prolene Suture	39	27.1457	5.54794	0.7

Table 2. The outcomes for patients according to cerclage type.

	Cerclage type	N	Mean	Std. Deviation	P Value
Gestational age at cerclage application (weeks)	Mersylene Suture	40	17.93	4.079	
	Prolene Suture	39	16.33	3.003	0.05
Cervical Length (mm)	Mersylene Suture	40	22.95	13.843	
	Prolene Suture	39	27.67	12.995	0.1
Cervical Dilatation (mm)	Mersylene Suture	40	1.05	1.584	
	Prolene Suture	39	.51	1.048	0.08
Gestational age at removal (weeks)	Mersylene Suture	40	34.63	5.021	
	Prolene Suture	39	35.46	3.776	0.4
Gestational age at delivery (weeks)	Mersylene Suture	40	34.90	5.098	
	Prolene Suture	39	35.85	3.997	0.4
Birth Weigth (gr)	Mersylene Suture	40	2545.00	905.575	
	Prolene Suture	39	2765.38	794.023	0.3

comparable in terms of subgroups established according to their number of previous deliveries (p>0.05). Groups were comparable in terms of indications for cerclage insertion (History based (23 vs. 28), emergency (13 vs. 5), ultrasound indicated (4 vs. 6), p>0.05). Cesarean delivery rate was 40 % in group 1 while it was 43.6 % in groups 2, no statistical difference was determined in terms of rate of cesarean delivery (p>0.05). Similar number of newborns needed NICU admission between the two groups following delivery (17.5% versus 17.9 %p>0.05). Mean APGAR scores at 1st (6.8 versus 7.4) and 5 th (7.8 versus 8.3) min were comparable between the groups (p>0.05)

DISCUSSION

The aim of this study is to compare the effectiveness of monofilament sutures (Proline™) and braided polyester thread (Mersilene™) in transvaginal cerclage and to evaluate pregnancy and newborn outcomes according to the thickness of these materials. In our study, comparison of the groups in terms of age, gravidity, parity, number of miscarriages and BMI revealed significantly higher mean gravidity in group 1 compared to group 2, while groups were found to be similar in terms of age, parity, number of miscarriages and BMI. No difference was determined with regard to gestational week at cerclage application, cervical length, cervical dilatation just before cerclage insertion, gestational age at cerclage removal and delivery and birth weight. Similar number of newborns needed NICU admission between the two groups following delivery. Mean APGAR scores at 1st and 5 th min were comparable between the groups.

Since McDonald cervical cerclage was first described 60 years ago as a technique to stabilize and prevent (PTB) the cervical insuffieciency, many gynecologists frequently use nonabsorbable sutures; however, there is not enough data to compare this suture type with others (13,14). Various materials have been used for cerclage. These materials include human fascia lata, Mersilene™ (Ethicon, NJ), Prolene™ (Ethicon, NJ), Tevdek™ (Teleflex, PA), and metal wires (15,16). The most commonly used are nonabsorbable monofilaments such as Mersilene™ (Thicon RS-21 or D-8113; Ethicon, NJ) (17) and prolene (18). Pregnancy outcomes of 109 pregnant women were presented according to the type of cerclage suture used, no difference was found between the pregnancy outcomes of the two groups (19).

Similar to our study, prevous study aimed to compare the effectiveness of monofilament suture (Proline™) and braided polyester thread (Mersilene™) sutures in transvaginal cerclage and to evaluate the pregnancy and neonatal results. Analysis of the data revealed that the prolene suture was applied to pregnant women with higher gravida, that the gestational age at delivery was significantly higher in the prolene suture group, and cervical lengths were lower in the mersilene suture group (20).

Another study comparing effectiveness of Mersilene tape versus alternative suture types in prolonging singleton pregnancies as well as other pregnancy and neonatal outcomes showed that Mersilene tape does not reduce the risk of preterm birth before 37, 28 or 24 weeks. Data showed that higher risk of preterm birth between 34 and 37 weeks with Mersilene tape but lower incidence before 34 weeks, higher neonatal morbidity and mortality (21).

Another data of 64 patients on this issue indicated that Mersilene, compared to Prolene, was associated with significantly lower rates of pretrm delivery at less than 24 weeks and less than 26 weeks (22).

Although mersilen sutures have traditionally been the material of choice for cerclage, prolene sutures appear to be associated with reduced PTB and improved neonatal outcomes. Although more comprehensive randomized clinical trials are needed to determine possible relationships between suture material and cerclage outcomes, prolene sutures continue to offer an option to traditional mersilene sutures (23).

Thick suture has been associated with a later gestational age at birth and a lower risk of birth and premature birth less than 34 weeks' gestation without significant increase in maternal or neonatal morbidity. In fact, thick cerclage suture was associated with lower odds of adverse maternal and neonatal outcomes, including chorioamnionitis and neonatal intensive care unit admission, compared to thin suture (24).

Monofilament suture did not reduce the rate of pregnancy loss compared with braided suture. Authors indicated that, clinicians should use the results of this trial to facilitate discussions regarding suture selection to optimize outcomes (25).

In conclusion, although mersilene stitch is commonly preferred based on previously published studies, according to our data analysis revealed similar results with prolene stitch in terms of maternal and neonatal outcomes.

Ethics Committee Approval:
Eskişehir Şehir Hastanesi Etik Kurulu approval was obtained before the study (22/02/2024-ESH/GOEK 2024/86).

Peer-review:
Externally peer-reviewed.

Author Contributions:
Z.B., M.K., M.Ş. conceived the study. and M.Ş., M.K. searched the literature and collected the data. M.K., Z.B. and M.Ş. performed the statistical analysis. Z.B., M.K., M.Ş. drafted the manuscript. Z.B., M.Ş., M.K. reviewed the manuscript. Both authors contributed to editorial changes in the manuscript. Both authors have read and approved the final paper. Both authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work. retrospective study, patient consent was not a requisite component.

Conflict of Interest:
The authors declared that there is no conflict of interest.

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None

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