



Effects of cerclage suture type on pregnancy and neonatal results: Mersilene suture & prolene suture

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Abstract

Aim: The aim of this study is to compare pregnancy and neonatal results with regards to the thickness of the suture material used in the transvaginal cerclage operation.

Materials and Methods: Patients who were subject to transvaginal cervical cerclage due to cervical insufficiency were evaluated in a secondary care center between 2103 and 2021 retrospectively. The demographic data, cerclage indications (ultrasound induced, prophylactic, or physical examination induced), number of pregnancy weeks at cerclage, type of cerclage suture (prolene, mersilene), type of cerclage (McDonald, Shirodkar), total pregnancy weeks, delivery method (cesarean (C/S), normal spontaneous vaginal delivery) of each patient were recorded. Additionally, 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 with regard to the type of cerclage suture (mersilene or prolene) and maternal, neonatal and pregnancy results were compared between these groups.

Results: The study included 151 patients in total. Prolene sutures were used for 69 of the patients (45.7%) and mersilene sutures for 82 patients (54.3%) Cerclage was applied for 18 patients (11.9%) depending on the ultrasound findings, 121 patients (80.1%) depending on emergency and 12 patients (7.9%) depending on history. Gravida increased significantly in the prolene suture group ($p=0.021$). Pregnancy week was found to be significantly lower in the mersilene suture group [32.5 w (15-40)] compared to the prolene suture group [37.0 w (15-41)] [37.0 w (15-41)] ($p<0.001$). Ratios of birthing below 34 weeks and 37 weeks for the mersilene suture group were found as 57.3% and 80.5%, and for the prolene suture group 11.6% and 40.6% respectively, and a statistically significant difference was observed ($p<0.001$). Fetal weight, 1st and 5th minute APGAR scores in the mersilene suture group were significantly lower ($p<0.05$). Ratios of newborn intensive care requirements and preterm premature rupture of membranes (PPROM) in the mersilene suture group were found to be significantly higher compared to the prolene suture group ($p=0.016$, $p<0.001$ respectively).

Conclusion: Although mersilene suture is more preferred, its supply is not always possible in emergency situations. Therefore, the prolene suture should be kept in mind as an even stronger cerclage suture option.



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Introduction

Preterm birth (PTB) is a significant factor increasing neonatal morbidity and mortality [1]. Although there are many underlying causes of preterm birth, one of the important in etiology is cervical insufficiency [1]. One of the major obstetric interventions for preventing (PTB) in women with cervical insufficiency is the cervical cerclage [2]. Cerclage was found to be beneficial in women with histories

of physical examination differences, sonography findings demonstrating cervical insufficiency, and second trimester miscarriage [3]. While many variables are evaluated with regard to cerclage success, there are a limited number of studies evaluating the effect of cerclage suture material on the efficiency of cerclage in preventing preterm birth, with these offering differing results. While it was reported that using different suture types showed no differences with regard to extending the period of gestation [4], it was also reported that the braided polyester thread (MersileneR)

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suture type was more effective for extending the period of gestation compared to other suture types in emergency or physical examination induced cerclages [5]. However in certain animal and wound site studies, based on the hypothesis that bacteria would increase more in multifilament sutures and would lead to an ascendant infection risk, it was asserted that monofilament sutures would be less correlated with infection compared to mersilene [6-8]. Surgical sutures differ from each other and in transvaginal cerclage procedures, a 5 mm thick braided polyester fiber tape (mersilene tape), polyester thread (Ethibond), and polypropylene non-braided monofilament (prolene) type suture may be used [3]. Although these are nonabsorbable sutures, their success rate in effecting the pregnancy period is still not precisely known. Certain studies in literature have argued that thicker sutures provide more force and larger tension and consequently better pregnancy results [4,9]. Contrarily, certain authors have argued that thicker and braided sutures increase the risk of infection more, could lead to changes in vaginal flora, and preterm birth, and consequently increase negative neonatal results [10]. The aim of this study is to compare the effectiveness of monofilament sutures (Prolene™) and braided polyester thread (Mersilene™) sutures used in transvaginal cerclage and to evaluate the pregnancy and neonatal results of these suture materials used for transvaginal cerclage with regard to thickness.

Materials and Methods

The hospital records and surgical operation reports of patients subject to transvaginal cervical cerclage in a secondary center between 2013 and 2021 from the hospital archive and the system were examined retrospectively. Prior to the study, approval was obtained from the local ethics committee (ethics committee date and no: 30.04.2021-003). Pregnant women without a congenital anomaly and with transvaginal cervical cerclage were included in the study, regardless of cerclage indication. Patients whose demographic data, cerclage (suture and indication), or neonatal information could not be obtained were excluded from the study. From the patient surgical operation reports and files examined, the demographic data (age, gravida, parity), cerclage indications (ultrasound indication, prophylactic or physical examination indication), cerclage weeks, cerclage suture type (prolene, mersilene), cerclage route of administration (McDonald, Shirodkar), birth weeks, and delivery method (C/S, normal spontaneous vaginal delivery) were recorded for each patient included in the study. In addition, birth weights, 1st and 5th minute APGAR scores, and NICU requirements of the newborns were recorded. Since the selection of the suture type is at discretion of the gynecologist as per hospital policy, no record was kept. Regardless of the suture type, all cerclage procedures were performed at 12-3-6-9 hours, respectively. Under regional anesthesia, the patient is placed in the dorsal lithotomy position and prepped with a vaginal 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 had been identified. Just anterior to this junction, a non-

absorbable suture is inserted into the cervix in a purse-string manner, taking caution to avoid the paracervical vessels. The suture is then tied down with a surgeon knot, either anterior or posterior. History induced cerclage (prophylactic) was defined as a cerclage procedure conducted in the absence of labor and placenta decollement, in one or more second trimester pregnancy losses related to painless dilatation, or in previous pregnancies due to painless dilatation in the second trimester of the previous pregnancies. Physical examination induced cerclage (emergency or salvage cerclage) was defined as second trimester painless cervical dilatation (minimum 1 cm). Ultrasound finding based cerclage was defined as spontaneous (PTB) history and short CL (less than 25 mm) ultrasound finding in the current pregnancy. All patients were administered 7 Hydroxyprogesterone caproate (17-OHP) after the cerclage. Progesterone 2*200 mg daily for the first week was continued orally and then intravaginally. Progesterone support was continued until the cerclage suture was removed. Patients were divided into two groups depending on the type of suture used: mersilene and prolene. Computer-assisted randomization method was used when patients were randomized. Blinding was done with a single-blind experimental setup. Simple random sampling method was used. The maternal, neonatal, and pregnancy results of the groups were compared.

Statistical analysis

Continuous variables were represented by the median (minimum-maximum), while categorical data were represented by numbers and percentages. The Kolmogorov-Smirnov Goodness of Fit Test was used to analyze the normality of continuous variables. Continuous variables were compared by Independent Samples T Test where they were consistent with the normal distribution, and Mann Whitney U Test was used where they were incoherent with the normal distribution. Risk factors and odds ratio values with regard to mersilene use were determined by Logistic Regression Analysis (Backward:LR). Variables that were found to be significant both clinically and as the result of the univariate analysis were selected and evaluated by the Multivariable Logistic Regression Model. The model fitness was evaluated by the Hosmer-Lemeshow test. Comparison of the categorical data was made by Chi-square Test (where necessary Fisher's Exact Test). According to previous study results, sample size of the study population was calculated to be 150 patients ($\alpha=0.05$ and the study power=80%). The IBM SPSS Package Program version 22.0 was used for the analyses (IBM Corporation, Armonk, NY, USA). Statistical significance level was taken as $p<0.05$.

Results

During the study, 176 patients in our clinic were subject to a cerclage procedure. Since 25 of these patients did not meet the requirements for being included in the study, they were excluded, and 151 patients were accepted in the study. Prolene was used in 69 (45.7%) of these patients, and mersilene was used in 82 (54.3%). All cerclage procedures were the McDonald cerclage. The clinical and demographic features of the patients are listed in Table-1.

Table 1. Comparison of the groups in terms of some negative pregnancy outcomes.

	Prolene (n=69)	Mersilene tape (n=82)	p
Mother's age (year) (Ave±Sd)	30.57±5.12	31.89±6.07	0.158*
Gravida [median (min-max)]	1 (1-3)	1 (1-3)	0.021**
Parity [median (min-max)]	0 (0-6)	0 (0-6)	0.171**
Cerclage indication (n,%)			0.178***
Ultrasound induced cerclage	9 (13.04%)	9 (10.9%)	
Physical examination induced cerclage	53 (76.8%)	68 (82.9%)	
History induced cerclage	5 (7.2%)	7 (8.5%)	
Cerclage week [median (min-max)]	17 (11)	17 (12-26)	0.074**
Cerclage patency [median (min-max)]	2 (0-5)	3 (0-6)	0.053**
***[median (min-max)]	37.0 (15-41)	32.5 (15-40)	<0.001*
Birth Week (n,%)			
<34 wk	8 (11.6%)	47 (57.3%)	<0.001*
≥34 wk	61 (88.4%)	35 (42.7%)	
Birth Week (n,%)			
<37 wk	28 (40.6%)	66 (80.5%)	<0.001*
≥37 wk	41 (59.4%)	16 (19.5%)	
Fetal weight [median (min-max)]	3220 (560-4800)	2150 (400-5290)	<0.001*
APGAR 1[median (min-max)]	6 (4)	0 (0-6)	<0.001*
***[median (min-max)]	10 (6)	0 (0-6)	<0.001*
Cervical length (cm) [median (min-max)]	6 (4)	3 (3-8)	0.011
Type of childbirth (n,%)			0.010****a
C/S	43 (64.2%)	59 (71.9%)	
NSVD	22 (32.8%)	28 (15.9%)	
Medical evacuation	2 (3.0%)	10 (12.2%)	
Twin pregnancy (n,%)			0.016****a
No	65 (94.2%)	66 (80.5%)	
Yes	4 (5.8%)	16 (19.5%)	
NICU Requirement (n,%)			<0.001****a
No	52 (81.3%)	26 (36.1%)	
Yes	12 (18.8%)	46 (63.9%)	
Servikal effacement (n,%)			0.263***
40	5 (7.2%)	8 (9.8%)	
50	38 (55.1%)	32 (39.0%)	
60	5 (21.7%)	79 (35.4%)	
70	9 (13.0%)	9 (11.0%)	
80	2 (2.9%)	4 (4.9%)	
PPROM (n,%)			<0.001****a
No	50 (72.5%)	6 (7.3%)	
Yes	19 (27.5%)	76 (92.7%)	

*Independent samples t test *Mann Whitney u test *** Chi-square Test (aFisher's Exact Test) Min: Minimum, Max: Maximum, Wk: Week, C/S: Cesarean, NSVD: Normal spontaneous vaginal delivery, NICU: neonatal intensive care unit, PPRM: preterm premature rupture of membranes.

Table 2. Multivariable regression analysis for the determination of the risk factors with regard to mersilene suture usage.

	B	SE	OR	95% CI	p
Age	0.127	0.050	1.135	1.029-1.252	0.012*
Fetal weight	-0.001	0.000*	0.999	0.999-1.000	0.017*
Twin pregnancy (yes)	2.813	1.036	16.660	2.185-127.022	0.002*
PPROM (yes)	2.684	0.638	14.650	4.192-51.204	<0.001*
Constant	-3.343	1.879	0.035		0.075*

* Binary Logistic Regression (Enter method) (Omnibus Tests of Model Coefficients <0.001, Nagelkerke R Square=0.603, Hosmer and Lemeshow Test=0.703) ** SE=Standard error, OR=Odds Ratio, GA=Confidence Interval In the multivariable logistic regression model; age, gravida, birth week, fetal weight, Apgar 1, Apgar 5, NICU requirement, cervical length, twin pregnancy and PPRM variables were included.

Cerclage was performed on 18 patients (11.9%) based on ultrasound findings, 121 patients (80.1%) based on emergency, and 12 patients (7.9%) based on history. The average age of patients where prolene and mersilene sutures were used were 30.57 ± 5.12 and 31.89 ± 6.07 , respectively, and no statistically significant difference between these values was observed ($p=0.158$). While gravida was significantly higher in the prolene suture group, no significant difference was observed in parity numbers ($p=0.021$ and $p=0.171$, respectively). Although the week of cerclage and cerclage cervical dilatation values were higher in the mersilene suture group, these differences were not statistically significant ($p=0.074$ and $p=0.053$, respectively). Birth week was found to be significantly lower in the mersilene suture group [32.5 w (15-40)] compared to the prolene suture group [37.0 w (15-41)] ($p<0.001$). While the rates of birthing below 34 weeks and 37 weeks in the mersilene suture group were found to be 57.3% and 80.5%, respectively, the prolene suture group rates were determined as 11.6% and 40.6%, with a statistically significant difference ($p<0.001$). Fetal weight, APGAR 1, APGAR 5, and cervical length values were significantly lower in the mersilene suture group ($p<0.05$). While the C/S and medical evacuation rates were higher in the mersilene suture group, NSVD rates were higher in the prolene suture group ($p=0.010$). Twin pregnancy, NICU requirements, and preterm PPRM rates in the mersilene suture group (19.5%, 63.9% and 92.7%, respectively) were found to be significantly high compared to the prolene suture group (5.8% and 18.8%, respectively) ($p=0.016$, $p<0.001$ and 27.5%, respectively). In the multivariable logistic regression analysis (Table-2) aiming to determine the possible risk factors increasing mersilene suture usage; age, gravida, birth week, fetal weight, 1st minute APGAR, 5th minute APGAR, NICU requirements, cervical length, twin pregnancy and PPRM variables were included. In this analysis, fetal weight, twin pregnancy, and PPRM existence remained significant. Accordingly, 1 unit of increase in age increases the probability of mersilene suture application by 1.13 times, existence of twin pregnancy by 16.66 times, and PPRM by 14.65 (Table 2).

Discussion

The aim of this study was to compare the effectiveness of monofilament sutures (Ex.Prolene™) and braided polyester thread (Mersilene™) sutures in transvaginal cerclage and to evaluate the pregnancy and neonatal results with regard to the thickness of these materials. At the end of the study, it was observed that the prolene suture was applied to pregnant women with higher gravida, that the final pregnancy week was significantly higher in the prolene suture group, and cervical lengths were lower in the mersilene suture group. In addition, 1st and 5th minute APGAR scores were significantly higher in the prolene group. Furthermore, when the risk factors for mersilene suture usage were examined, it was found that 1 unit of increase in age increased the probability of mersilene suture application by 1.13 times, existence of twin pregnancy by 16.66 times, and PPRM by 14.65. Since the McDonald cervical cerclage was first defined as a technique to stabilize the cervix and prevent (PTB) 60 years ago, many gynecologists have

been frequently using non-absorbable sutures; however, there is insufficient data for comparing this suture type with others [11,12]. Various materials have been used for cerclage. Among these materials, human fascia lata, Mersilene™ (Ethicon, NJ), Prolene™ (Ethicon, NJ), Tevdek™ (Teleflex, PA), and metal wires can be mentioned [13,14]. The most commonly used ones today are non-absorbable monofilaments such as Mersilene™ (Thicon RS-21 or D-8113; Ethicon, NJ) [15] and prolene [16]. In one study, cerclage was applied to 138 ultrasound induced pregnant women with short CL, and it was found that suture type had no effect on delivery below 35 weeks or the age of pregnancy [1]. In another study comparing the pregnancy results of 108 pregnant women with regard to the cerclage suture type used, no difference was determined between the pregnancy results of the two groups. However, there may be a difference due to the sample size of the present study being small and the cerclage indications not being precise [17]. Contrary to these, in a retrospective cohort study by Kindinger et. al. conducted in England where ultrasound induced cerclage was applied to 678 women, the efficiency of mersilene and prolene sutures was compared and it was observed that the mersilene suture group had higher (PTB) rates and earlier birth weeks [10]. In another prospective study, the same authors applied ultrasound induced cervical cerclage to 49 patients and compared the mersilene and prolene suture usage. As a result, it was reported that the vaginal microbiome was corrupted in the mersilene suture group and that the pregnancy results were related to the corruption of the vaginal microbiome rather than the suture type [10]. In the present study, it was observed that the birth week of the mersilene suture group was lower and that birth rate below 34 weeks was higher compared to the prolene group. This result was consistent with the cohort study conducted by Kindinger et. al. on 678 women. However, no evaluation was made in this study with regard to the vaginal microbiome. Yet, certain animal and wound site studies reported that monofilament sutures led to fewer infections [6,8]. Based on this hypothesis, it can be argued that mersilene sutures might result in vaginal microbiome defects and consequently, and increase in preterm birth. However, more detailed studies should be carried out to better understand this relationship. The differences in the demographic data of Kindinger et. al's study (mother's age, race, etc.) might have contributed to differences in the vaginal microbiome. In the present study, fetal weight and 1st and 5th minute APGAR scores were found to be lower, whereas the NICU requirement was found as higher. This result was not surprising since negative neonatal results were expected due to the fact that the birth week was found to be lower in the mersilene suture group. Our study may be regarded as reliable due to the fact that there was no difference between the two groups with regard to cervical dilatation and cerclage weeks. In addition, medical evacuation in the mersilene group was significantly higher, and the PPRM rate was found to be 92.7%. The results of this study indicate that the use of prolene sutures is recommended for better neonatal results and positive pregnancy results. There are certain limitations of this study. Firstly, it was comprised of a comparatively smaller sampling size that limited the

demonstration of the true efficiency of the suture material, and the difference it might make. Secondly, the vaginal microbiome situation mentioned by many authors in the literature was not examined. Finally, the procedures were not conducted by a single surgeon due to the study not being mono-central and retrospective. Hence, technical differences might have affected the pregnancy results and neonatal results. Due to these reasons, randomized control studies are needed in order to evaluate the effectiveness of different suture types and to determine whether the results vary according to the cerclage suture types. However, although the superiority of one suture materials over the other was not proven, the findings support the use of a thinner suture in women with ultrasound, history, and examination induced cerclage, since thin sutures are correlated with lower preterm probability. In addition, it was observed that thinner sutures led to better neonatal results. Another issue that will negatively affect the results of the study is Most of the patients in this study were emergency cerclage patients. We attribute this to the fact that patients visit several centers before coming to our hospital and apply at the last moment. The strength of the present study is that there is limited data in the literature examining the effect of suture types on pregnancy and neonatal results, and that patients having all of the 3 indications were included in this study.

Conclusion

Although mersilene sutures have been preferred by doctors for many years, prolene sutures were found to be more effective in the amelioration of pregnancy and neonatal results. If we start from this result; Although mersilene suture is more preferred, its supply is not always possible in emergency situations. Therefore, the prolene suture should be kept in mind as an even stronger cerclage suture option. Nevertheless, future research comprising other variables that may affect the success rates of cerclage sutures shall be helpful in determining the superiority of the suture type used in cerclage procedures in induced pregnant women.

Ethics approval

Prior to the study, approval was obtained from the local ethics committee (Istanbul Gelisim University Ethics Committee. Date and No: 30.04.2021-003).

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