

Comparative Study of Effect of Monofilament Prolene Suture with Braided Silk Suture in Patients with Cervical Insufficiency Undergoing Cervical Cerclage for Prevention of Pre-Term Labour

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ABSTRACT

Introduction: Cervical insufficiency affects approximately 1% of pregnancies and is responsible for up to 15% of recurrent second-trimester losses. Cervical cerclage has become the standard therapeutic intervention, but the optimal suture material remains debated. This study compared the clinical outcomes of monofilament prolene versus braided silk sutures in cervical cerclage procedures.

Methods: This prospective randomized controlled study included 30 women with cervical insufficiency requiring cerclage between 14-20 weeks gestation. Participants were randomly allocated to monofilament prolene (Group 1, n=15) or braided silk suture (Group 2, n=15) groups. Primary outcomes included ease of performance, procedure time, postoperative complications, and pregnancy outcomes. Data were analyzed using SPSS version 21 with p-value <0.05 considered significant.

Results: Both groups had comparable baseline characteristics including age (27.5±3.96 vs 29.13±3.98 years, p=0.260) and BMI (25.63±3.09 vs 27.61±3.84, p=0.133). Prolene sutures showed significantly higher ease of performance scores (4.60±0.51 vs 3.73±0.70, p=0.001) but caused more foreign body sensation (33.3% vs 0%, p=0.014). Procedure time and intraoperative bleeding were similar between groups. Mean gestational age at delivery was higher in the prolene group (36.13±3.10 vs 34.87±2.85 weeks, p=0.238), with 60% reaching term compared to 26.7% in the silk group. PROM rates were comparable (13.3% vs 20%, p=0.624).

Conclusion: While prolene sutures offer technical advantages during placement with trends toward better pregnancy outcomes, they cause more patient discomfort. Both materials demonstrate comparable safety profiles, suggesting that material selection should be individualized based on clinical scenarios and patient factors.

Keywords: Cervical cerclage, cervical insufficiency, prolene suture, silk suture, preterm birth, pregnancy outcomes

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I. INTRODUCTION

Preterm birth, defined as delivery before 37 completed weeks of gestation, remains one of the most significant challenges in obstetric care and a leading cause of perinatal morbidity and mortality worldwide.¹ Cervical insufficiency, characterized by painless cervical dilation leading to recurrent second-trimester pregnancy losses or early preterm births, is an important contributory factor to this global health concern.² The condition affects approximately 1% of all pregnancies and is implicated in up to 15% of recurrent second-trimester losses.³

Cervical cerclage, first described by Shirodkar in 1955 and later modified by McDonald in 1957, has become a standard therapeutic intervention for managing cervical insufficiency.⁴ This surgical procedure involves placing a purse-string suture around the cervix to provide mechanical support and maintain cervical length throughout pregnancy. The primary goal is to prevent premature cervical dilation and effacement, thereby reducing the risk of preterm birth and its associated complications.⁵ The success of cervical cerclage depends not only on appropriate patient selection and timing but also on technical factors including the choice of surgical technique and suture material.

The choice of suture material for cervical cerclage has been a subject of ongoing debate in obstetric practice. Traditionally, braided silk sutures have been widely used due to their handling characteristics and long-standing familiarity among surgeons. However, these multifilament sutures have been associated with

increased bacterial colonization and potential inflammatory responses due to their braided nature.⁶ Monofilament Prolene sutures, composed of polypropylene, offer several theoretical advantages including reduced bacterial adherence and tissue reaction, potentially decreasing the risk of infection and inflammatory complications.⁷ Despite these theoretical benefits, comparative data on the clinical outcomes of different suture materials in cervical cerclage remains limited, highlighting the need for more comprehensive research to guide evidence-based selection of suture materials.⁸

II. METHODOLOGY

This prospective randomized comparative study was conducted in the Department of Obstetrics and Gynecology at MGM Institute of Health Sciences, Navi Mumbai, from January 2023 to June 2024. The study protocol was approved by the Institutional Ethics Committee, and written informed consent was obtained from all participants prior to enrollment. Women between 14-20 weeks of gestation with diagnosed cervical insufficiency based on previous obstetric history, clinical examination, and transvaginal ultrasonographic findings were screened for eligibility. Inclusion criteria included women aged 18 years and above with singleton pregnancy requiring cervical cerclage based on three or more previous midterm losses, previous cerclage history, or shortened cervix (<25 mm) by ultrasound. Women with multiple pregnancies, active vaginal infection, rupture of membranes, active uterine contractions, or major fetal anomalies were excluded.

Eligible participants were randomly allocated into two groups using computer-generated random numbers with concealed allocation using sequentially numbered, opaque, sealed envelopes. Group A received monofilament prolene suture while Group B received braided silk suture for cervical cerclage. All cerclage procedures were performed under regional anesthesia using the McDonald technique by experienced obstetric surgeons following standard aseptic precautions. The suture was placed circumferentially around the cervix at the cervicovaginal junction, approximately 2 cm from the external os, with the knot tied anteriorly.

Detailed records were maintained for each participant including demographic data, obstetric history, and procedural details. The ease of performing cerclage was assessed using a standardized scoring system (1-5 scale, with 5 being easiest), and procedure duration was recorded. Participants were monitored for immediate post-operative complications including bleeding and fever, followed up weekly for the first month, then fortnightly until 28 weeks, and weekly thereafter until delivery. Primary outcomes measured included ease of performing cerclage, procedure duration, perioperative bleeding, post-operative fever within 48 hours, vaginal discharge within the first week, occurrence of PROM, ease of suture removal, and evidence of cervical injuries. Secondary outcomes included gestational age at delivery and mode of delivery. Data were analyzed using SPSS version 21 with appropriate statistical tests, and p-value <0.05 was considered statistically significant.

III. RESULTS

This comparative study evaluated 30 women with cervical insufficiency who underwent cervical cerclage using either monofilament prolene (n=15) or braided silk sutures (n=15). Data collection included baseline demographics, intraoperative measures, postoperative outcomes, and pregnancy/delivery outcomes. Statistical analysis was performed using Student's t-test for continuous variables and chi-square test for categorical variables, with significance set at p<0.05.

Table 1: Baseline Characteristics and Obstetric History

Variable	Group 1 (Prolene) n=15	Group 2 (Silk) n=15	P-value
Demographics			
Age (years)	27.5 ± 3.96	29.13 ± 3.98	0.260
BMI	25.63 ± 3.09	27.61 ± 3.84	0.133
Obstetric Parameters			
GA at cerclage (weeks)	16.20 ± 1.52	15.53 ± 1.51	0.238
Cervical length (mm)	19.67 ± 2.94	19.13 ± 3.07	0.631
Previous Pregnancy Losses			
3 losses	11 (73.3%)	9 (60%)	0.706
4 losses	2 (13.3%)	3 (20%)	
5 losses	2 (13.3%)	2 (13.3%)	
6 losses	0	1 (6.7%)	

No significant differences were observed in baseline characteristics between groups, indicating successful randomization.

Table 2: Intraoperative and Immediate Postoperative Outcomes

Variable	Group 1 (Prolene) n=15	Group 2 (Silk) n=15	P-value
Intraoperative Measures			
Ease of performance score (1-5)	4.60 ± 0.51	3.73 ± 0.70	0.001*
Procedure time (minutes)	22.53 ± 3.85	24.60 ± 4.12	0.169
Bleeding during procedure (ml)	23.87 ± 7.46	27.53 ± 8.21	0.198
Postoperative Complications			
Post-op vaginal discharge (days)	2.33 ± 1.63	3.80 ± 2.76	0.090
Foreign body sensation	5 (33.3%)	0 (0.0%)	0.014*
Post-operative fever	1 (6.7%)	3 (20%)	0.283

Prolene sutures demonstrated significantly easier placement but caused more foreign body sensation.

Table 3: Pregnancy Complications and Cerclage Removal Outcomes

Variable	Group 1 (Prolene) n=15	Group 2 (Silk) n=15	P-value
Pregnancy Complications			
PROM occurred	2 (13.3%)	3 (20%)	0.624
Cerclage Removal			
Ease of removal score (1-5)	3.87 ± 0.834	4.2 ± 0.676	0.239
Easy removal	11 (73.3%)	13 (86.7%)	0.36
Difficult removal	4 (26.7%)	2 (13.3%)	
Cervical injuries	3 (20.0%)	2 (13.3%)	0.624

No significant differences were observed in pregnancy complications or cerclage removal outcomes.

Table 4: Delivery Outcomes

Variable	Group 1 (Prolene) n=15	Group 2 (Silk) n=15	P-value
Gestational Age at Delivery			
Mean GA at delivery (weeks)	36.13 ± 3.10	34.87 ± 2.85	0.238
Term delivery (37-40 weeks)	9 (60.0%)	4 (26.7%)	0.416
Preterm delivery (33-36 weeks)	3 (20.0%)	6 (40%)	
Early preterm (<33 weeks)	3 (20.0%)	5 (33.3%)	
Mode of Birth and Delivery			
Spontaneous labor initiation	12 (80%)	12 (80%)	1.0
Normal vaginal delivery	8 (53.3%)	10 (66.7%)	0.459
Cesarean section	6 (40.0%)	3 (20.0%)	
Instrumental delivery	1 (6.7%)	2 (13.3%)	

Though not statistically significant, prolene group showed trends toward longer pregnancy duration and higher term delivery rates.

IV. DISCUSSION

Our study demonstrated several significant differences between monofilament prolene and braided silk sutures in cervical cerclage procedures. The significantly higher ease of performance score for prolene (4.60±0.51 vs 3.73±0.70, p=0.001) suggests important technical advantages during placement, consistent with findings from Kindinger et al., who reported that monofilament sutures were technically easier to place with less tissue resistance.⁹ This improved handling likely stems from prolene's smooth surface creating less friction compared to braided silk's rougher texture. However, this technical advantage was counterbalanced by significantly higher rates of foreign body sensation in the prolene group (33.3% vs 0%, p=0.014), which may be attributed to prolene's greater rigidity exerting more localized pressure on surrounding tissues. The trend toward higher post-operative fever rates in the silk group (20% vs 6.7%), while not statistically significant, aligns with literature suggesting braided sutures' propensity to harbor bacteria within their interstices, as demonstrated by Batterbee and colleagues who found thicker braided sutures associated with higher chorioamnionitis rates.¹⁰

The pregnancy outcomes revealed clinically important trends favoring prolene sutures, with higher mean gestational age at delivery (36.13±3.10 vs 34.87±2.85 weeks) and greater proportion reaching term (60% vs 26.7%), though statistical significance was not achieved due to our limited sample size. These findings align with emerging evidence from Kindinger et al., who reported significantly lower preterm birth rates with monofilament versus braided sutures (17% vs 28%, p=0.0006) in their larger cohort of 678 women.¹¹ The

comparable PROM rates between groups (13.3% vs 20%, $p=0.624$) suggest that suture material does not significantly influence this critical complication, though the numerical difference warrants consideration given PROM's association with adverse outcomes. The mechanisms underlying observed differences likely relate to the distinct physical and biological properties of these materials - prolene's biocompatibility and resistance to bacterial colonization may explain the trend toward longer pregnancy duration, while its rigidity accounts for increased patient discomfort.¹²

While our study provides valuable insights, several limitations warrant consideration. The relatively small sample size (15 patients per group) limited statistical power to detect small but clinically meaningful differences, particularly for rare outcomes. The single-center design and subjective nature of some measures like ease of performance introduce potential bias, though significant p -values suggest real differences despite these limitations. Our findings have important clinical implications: the superior ease of placement with prolene may benefit less experienced operators, but the increased foreign body sensation requires consideration for patient comfort and compliance. The trend toward better pregnancy outcomes with prolene, while requiring confirmation in larger studies, suggests potential advantages in the primary objective of preventing preterm birth. Future research should focus on larger multicenter trials with adequate power to detect clinically meaningful differences, incorporation of objective inflammatory markers, and long-term follow-up to assess effects on subsequent pregnancies.¹³

V. CONCLUSION

This comparative study demonstrates that both monofilament prolene and braided silk sutures represent viable options for cervical cerclage, each with distinct advantages and limitations. Prolene sutures offer significant technical advantages during placement with easier handling characteristics and show promising trends toward longer pregnancy duration and higher term delivery rates. However, these benefits must be weighed against the significantly higher incidence of foreign body sensation that may impact patient comfort and satisfaction. Both materials demonstrate comparable safety profiles regarding procedure time, bleeding, and major complications.

The choice of suture material should be individualized based on specific clinical scenarios, considering factors such as operator experience, patient risk profile for infectious complications, and individual patient tolerance. While the trends toward improved pregnancy outcomes with prolene are encouraging, larger multicenter studies are needed to confirm these benefits and establish definitive recommendations for optimal suture material selection in cervical cerclage procedures.

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