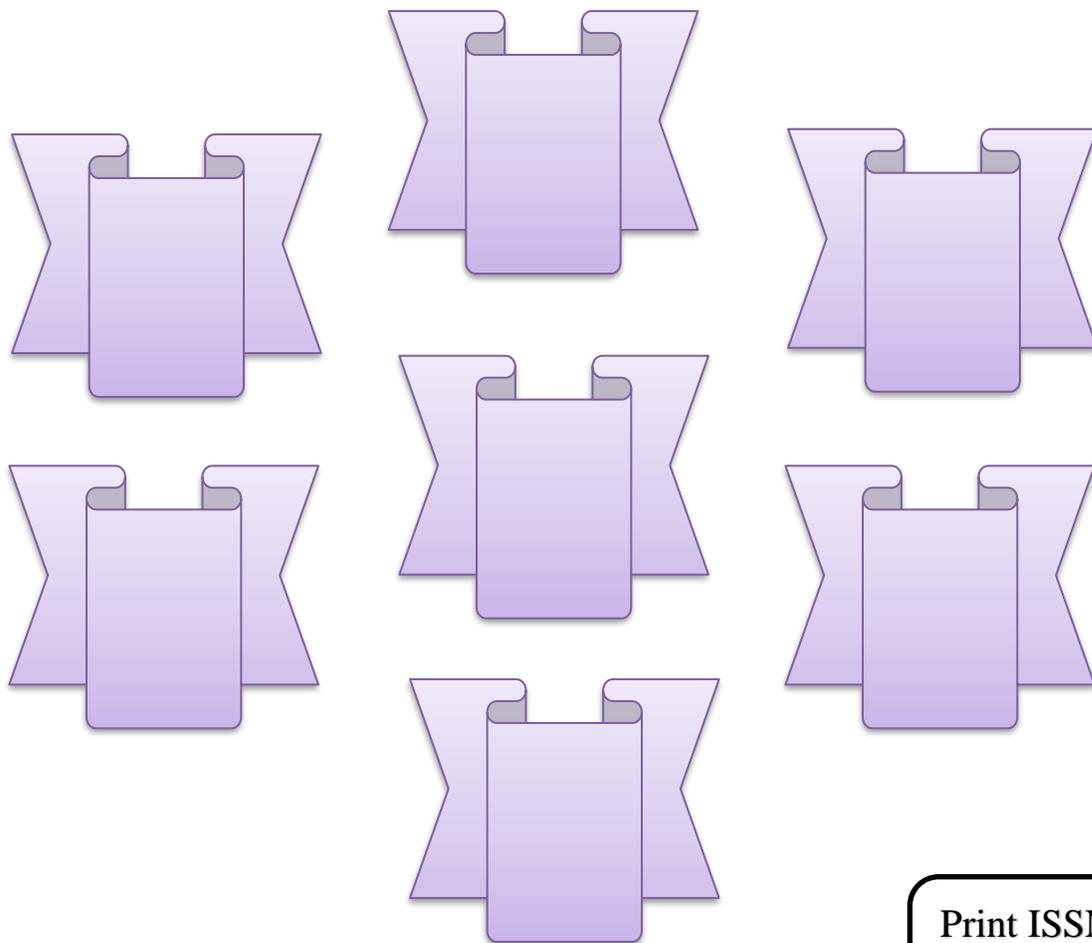


INTERNATIONAL JOURNAL OF MEDICAL ARTS



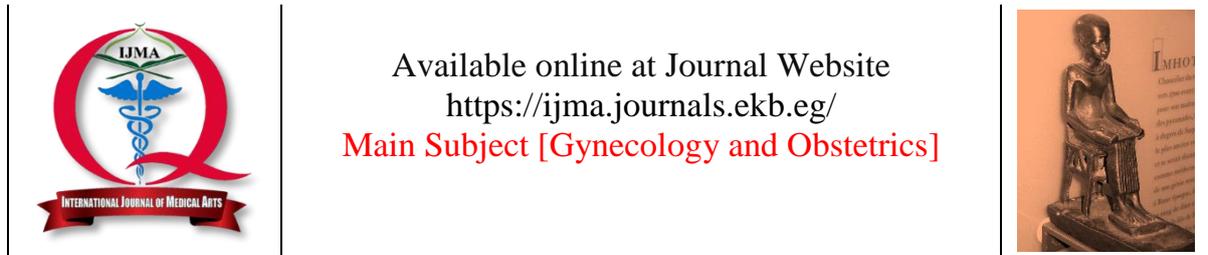
Volume 5, Issue 7, July 2023

<https://ijma.journals.ekb.eg/>



Print ISSN: 2636-4174

Online ISSN: 2682-3780



Available online at Journal Website
<https://ijma.journals.ekb.eg/>
 Main Subject [Gynecology and Obstetrics]



Original Article

Comparing the Effect of Monofilament and Braided Suture on Pregnancy Loss Rates in Women Requiring Vaginal Cervical Cerclage

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ABSTRACT

Article information

Received: 23-05-2023

Accepted: 29-07-2023

DOI:
10.21608/IJMA.2023.212954.1693.

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Citation: Marai A. Comparing the Effect of Monofilament and Braided Suture on Pregnancy Loss Rates in Women Requiring Vaginal Cervical Cerclage. IJMA 2023 July; 5 [7]: 3404-3411. doi: 10.21608/IJMA.2023.212954.1693.

Background: Preterm birth affects 11% of pregnancies and can result in serious complications. Cervical insufficiency is a frequent reason for preterm birth and also can be treated with vaginal cervical cerclage using different types of sutures. Observational studies suggest that monofilament sutures may decrease pregnancy loss compared to braided sutures, but randomized controlled studies are needed to confirm this finding.

Aim of the work: The research aims to assess the efficacy of monofilament versus braided sutures in preventing miscarriage for women undergoing vaginal cervical cerclage.

Patients and Methods: This trial was done in Obstetrics and Gynecology Department, El-Hussein University Hospital, from January 2020 to November 2022. There were 201 participants in the study. Individuals were monitored in the obstetrics and gynecological clinics at El-Hussein University Hospital, Faculty of Medicine, Al-Azhar University. Females with a singleton pregnancy and a cervical cerclage indicator were split evenly amongst receiving a monofilament or braided suture. Pregnancy loss was the fundamental result; secondary outcomes included maternal and neonatal outcomes. Surgeons were permitted to employ any method they found most effective.

Results: No significant variances were present in baseline characteristics, pregnancy and maternal outcomes, and neonatal outcomes between the two study groups. However, the Monofilament suture group had significantly more complications with cerclage removal.

Conclusion: Both monofilament and braided sutures are effective and safe procedures with minimal side effects and complications. Although monofilament suture may cause more difficult removal and removal complications, it remains a viable option for treating cervical insufficiency.

Keywords: Monofilament suture; Braided suture; Maternofetal outcomes; Vaginal cervical cerclage.



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INTRODUCTION

Premature birth is a serious issue worldwide, with approximately 11% of pregnancies are complicated by preterm delivery [1]. The clinical repercussions of premature birth can be significant, including the death of some infants born too early to survive and permanent difficulties in those who survive, such as cerebral palsy [2]. Therefore, it is crucial to identify the causes and risk factors connected with preterm birth and find effective treatments for reducing the rate of premature delivery [3].

Preterm birth is a complex and multifactorial issue that can arise for various reasons [4]. One of the possible causes of preterm delivery can be caused by cervical insufficiency, which occurs in 0.5-1 percent of pregnant ladies and can be managed with the insertion of a vaginal cervical cerclage. Cervical cerclage may be performed if a woman has experienced a second-trimester miscarriage or early delivery, has had cervical surgery, or has a transvaginal ultrasound that reveals a short cervical length [5]. However, the decision to carry out a cervical cerclage is a clinical one that should be made after considering various factors, including the individual patient's medical history and risk factors [6].

There are two methods for performing a vaginal cervical cerclage, the modified Shirodkar cerclage and the McDonald cerclage [7]. Sutures are placed around the supravaginal cervix & the suture thread is buried as part of a modified Shirodkar cerclage, which also involves a bladder dissection. In contrast, the McDonald's cerclage calls for wrapping a purse string around the cervical apex as high as feasible. The choice of suture thread is a perioperative decision that can influence the efficacy of the treatment [8]. While both monofilament and multifilament [braided] threads can be utilized for cerclage, a prior UK study found that 87 percent of physicians favored using a braided thread, with 13 percent of clinicians opting for monofilament. The preference for braided sutures was mainly attributed to the convenience of treatment and anxieties about monofilament sutures getting inserted in the cervix and becoming hard to eliminate [9].

According to **Kindinger et al.** [10], a non-randomized systematic review revealed that using monofilament sutures in vaginal cervical cerclage was related to a lower risk of a miscarriage [7.0 percent vs 18.9 percent]. The

danger ratio was 0.34, with a 95% confidence interval of 0.18–0.63. This finding is consistent with additional research that suggests that monofilament sutures may be superior to braided suture threads in this context. One possible reason for this is that braided threads can act as a reservoir for pathogenic bacteria, leading to vaginal dysbiosis and an increased risk of pregnancy loss. In contrast, monofilament sutures have been revealed to minimize vaginal dysbiosis and prevent a microbiome shift to harmful bacteria, thereby enhancing maternal then newborn outcomes through infection prevention. Despite this observational indication, there is currently no data from randomized controlled studies to guide the choice of suture thread for vaginal cervical cerclage to avoid pregnancy loss [7].

This trial seeks to fill this knowledge gap by contrasting the outcomes of vaginal cervical cerclages using monofilament versus braided sutures regarding pregnancy loss. By doing so, this study may provide valuable insights into the optimal choice of suture thread in this context, thereby improving outcomes for mothers and their babies.

PATIENTS AND METHODS

This research was conducted at El-Hussein University Hospital's Obstetrics and Gynecology Department between January 2020 and November 2022. The study involved 201 participants. All were monitored at the obstetrics and gynecology departments at El-Hussein University Hospital, Al-Azhar University's faculty of medicine.

Participants: The study enrolled women who required a vaginal cervical cerclage as part of their routine care. For women to be considered for participation, they needed to be at least 18 years old, pregnant with a single baby, and have a medical reason for undergoing cervical cerclage. Indications for cerclage entailed a history of no fewer than three previous mid-term stillbirths or premature births [≤ 28 weeks], insertion of cervical sutures in previous pregnancies, a history of mid-trimester loss or premature birth, as well as a shortened cervix [≤ 25 millimeters] in the current pregnancy, or a clinician who was concerned about the possibility of preterm birth based on the history or ultrasound results. Women who required immediate suture insertion desired an emergency or rescue cerclage, or had ruptured or visible

membranes were not allowed to participate in the study. In addition, ladies in whom a cerclage was to be inserted by an abdominal route or any other route apart from the vaginal one was not eligible for the procedure. No restrictions on gestational age were applied to collecting informed consent, allocating participants, or implantation of the cervical cerclage.

Randomization and masking: Cervical cerclages were placed in research subjects using a monofilament or braided suture at a 1:1 ratio. The randomization was carried out using a secure online system that employed minimization to ensure balance between trial groups based on several factors, Evidence of a preexisting condition, such as having three or more miscarriages or deliveries before their due date [≤ 28 weeks], suturing of the cervical opening throughout one's prior pregnancies, a previous miscarriage or premature birth in conjunction with an already shortened cervix [≤ 25 millimeters], or concern on the part of the doctor regarding the potential for an early delivery, either as a result of the person's medical history or the findings of a multiparity evaluation. The Birmingham Clinical Trials Unit provided the randomization system centrally. Clinicians inserting the vaginal cervical cerclage were not blinded to the suture thread, and the surgical record included specifics on the specific kind of cerclage utilized & the specific operations that were performed. Treatment allocation was concealed from women and other study participants whenever possible. This included microbiologists and outcome evaluators.

Procedures: The pragmatic design of the trial allowed surgeons to use their desired surgical method during the vaginal cervical cerclage. At the same time, only the type of suture material was prespecified according to the randomized allocation. The enrolled study participants inserted the cervical cerclage during a gestational age ranging between 12 and 14 weeks. The surgeon was given complete autonomy over the perioperative procedure. When possible, braided sutures should be made from Mersilene [a non-absorbable suture made of polyethylene terephthalate], and monofilament sutures should be made from Ethilon [Ethicon], a non-absorbable suture made of long-chain aliphatic polymers of nylon. Women were watched for 28 days after giving birth or until they were allowed to return home, whichever came first. Those preterm newborns [gestational age 37 weeks] who made it until delivery or

home discharge were tracked until that time. Babies delivered on time were monitored for 28 days after birth or until they were sent home from the hospital.

Outcomes

Perinatal mortality, which includes stillbirth and neonatal death in the 1st week of life, along with the loss of pregnancy termination, was the primary endpoint, and additional results were derived from the preterm birth core outcome set [11].

Among the secondary outcomes, an important one was the duration from conception to the end of pregnancy for any reason. Additional maternal as well as the results of pregnancy included miscarriage besides pre-viable neonatal mortality [described as having a delivery before the completion of twenty-four weeks], stillbirth [death that occurs within the uterus after 24 weeks of pregnancy], length from the beginning of pregnancy until the beginning of spontaneous vaginal birth [in live births that occur after 24 weeks], gestation at delivery [including less than 28, 32 & 37 weeks in live births after twenty-four weeks], sepsis [at any point during pregnancy or up to seven days postnatally] defined as infection and at least two systemic signs of infection such as fever [≥ 38 °C] or hypothermia [< 36 °C], tachycardia [heart rate above 90 beats per minute], tachypnea [a breathing rate that is greater than twenty times per minute], preterm prelabor rupture of membranes, method of labor initiation [spontaneous or induced], way of labor [operative vaginal, cervical bleeding, vaginal, or cesarean], cerclage placement complications [cervical laceration, ruptured membranes, or bladder injury], cerclage removal complications [anesthesia requirement, cervical tears, or suture removal difficulty] In addition to pregnancy-related issues [such as vaginal hemorrhage, steroid use, chorioamnionitis, maternal pyrexia also postpartum admission to a hospital's intensive care unit [ICU]].

Secondary neonatal results comprised early neonatal death [referred to as passing away within the first week after giving birth], late neonatal birthweight centile adjusted for gestational age along with sex, small for gestational age and sex [$< 10^{\text{th}}$ centile], extra care considerations [admission to special care baby unit, resuscitation at birth, neonatal ICU, high dependency unit, or transitional care] besides

duration of additional care, antibiotics administered during the first three days, sepsis [clinically diagnosed or microbiologically proven], morbidity during the initial neuro-developmental stages [severe abnormalities discovered on cranial ultrasound scan], respiratory assistance, & duration of respiratory support were found to be significant predictors of mortality, requires for supplemental oxygen beginning at thirty-six weeks postmenstrual age, necrotizing enterocolitis [Bell's stage 2 or 3], retinopathy of prematurity requiring laser treatment, impairments and also congenital defects. During the trial, serious adverse events were tracked and monitored for both the mother's health and the babies.

Ethical Approval: The University's Ethics Review Board green-lit the study, and participants signed informed permission forms. The Declaration of Helsinki, a global standard for ethical medical research involving human participants, has been followed throughout this project.

Statistical Analysis: Version 24 of IBM-SPSS was utilized for the analysis of the data. [May 2016]. The significance of the statistical

test was calculated via the Kruskal-Wallis test, the Wilcoxon test, a Spearman correlation, and logistic regression. Each variable was analyzed based on the data it included [parametric or not]. When the P-values were under 0.05 [5 %], we considered the results statistically significant.

RESULTS

There was no significant alteration amongst both study groups concerning the baseline characteristics of participants [table 1].

There were no significant alterations & in both study groups regarding pregnancy besides maternal outcomes [table 2].

There was no significant variance amongst both study groups as regards neonatal outcomes [table 3].

When comparing the monofilament suture group and the other two groups for serious adverse events, complications during cerclage implantation, & complications during cerclage removal, only the complications during removal were substantially higher [table 4].

Table [1]: Baseline characteristics of included subjects

	Monofilament suture [N = 101]	Braided suture [N = 100]	P Value
Gestational age at randomization, weeks	32.3 ± 4.8	33.2 ± 5.4	0.21
Maternal age, years	58 [57.43%]	56 [56%]	0.83
BMI at booking appointment, kg/m²	27.3 ± 6.5	28.3 ± 6.4	0.27
Gravida	2.35 ± 2.13	2.33 ± 2.23	0.95
Clinical characteristics			
A cervical-length ultrasound scan performed	69 [68.32%]	70 [70%]	0.80
Shortest cervical length before cerclage, mm	23.4 ± 9.7	23.2 ± 9.1	0.88
Cervical funneling	34 [33.66%]	35 [35%]	0.84
The primary rationale for cerclage is a history or an ultrasound indicating the risk of premature birth	61 [60.4%]	61 [61%]	0.93
Insertion of cervical sutures in previous pregnancies	21 [20.79%]	22 [22%]	0.83
A history of miscarriage during the second trimester or early birth with a shorter cervix	16 [15.84%]	16 [16%]	0.97
A history of at least three previous miscarriages, stillbirths, or premature deliveries	2 [1.98%]	2 [2%]	0.99
The planned cerclage technique includes bladder dissection	17 [16.83%]	17 [17%]	0.97
Intention to commence on progesterone	41 [40.59%]	41 [41%]	0.95
Previous cervical surgery	26 [25.74%]	28 [28%]	0.72
Data missing	2 [1.98%]	3 [3%]	0.64
Type of previous cervical surgery			
One previous large loop excision of the transformation zone	48 [47.52%]	47 [47%]	0.94
Two antecedent extensive loop excisions of the transformation area	18 [17.82%]	19 [19%]	0.83
Knife cone biopsy	11 [10.89%]	11 [11%]	0.98
Others	24 [23.76%]	23 [23%]	0.90
Prophylactic antibiotics at cerclage insertion	49 [48.51%]	48 [48%]	0.94

Table [2]: Pregnancy and maternal results of included subjects

	Monofilament suture [n = 101]	Braided suture [n = 100]	P Value	
Pregnancy loss	8 [7.92%]	8 [8%]	0.98	
The median number of weeks from conception to delivery	37.53 ± 2.6	37.5 ± 2.75	0.94	
Miscarriage or pre-viable neonatal death	6 [5.94%]	5 [5%]	0.77	
Stillbirth	1 [0.99%]	1 [1%]	0.99	
Mean gestational age at delivery, weeks	37.3 ± 3.4	37.4 ± 3.5	0.84	
The median time between conception as well as spontaneous vaginal delivery, weeks	37.63 ± 2.82	37.77 ± 2.9	0.73	
Maternal sepsis	4 [3.96%]	7 [7%]	0.34	
Preterm prelabour membrane rupture	20 [19.8%]	20 [20%]	0.97	
Mode of initiation of birth	Spontaneous	58 [57.43%]	54 [54%]	0.62
	Induced	43 [42.57%]	46 [46%]	
Mode of delivery	Vaginal	52 [51.49%]	54 [54%]	0.72
	Operative vaginal	12 [11.88%]	9 [9%]	0.50
	Caesarean delivery	37 [36.63%]	37 [37%]	0.96
Vaginal bleeding	14 [13.86%]	16 [16%]	0.67	
Steroid use	29 [28.71%]	31 [31%]	0.72	
Chorioamnionitis	3 [2.97%]	6 [6%]	0.3	
Maternal pyrexia [intrapartum]	2 [1.98%]	4 [4%]	0.4	
Maternal pyrexia [postnatal]	4 [3.96%]	5 [5%]	0.72	
Admission to high dependency unit [pre-delivery]	2 [1.98%]	2 [2%]	0.99	
Admission to ICU [pre-delivery]	0	1 [1%]	0.98	
Admittance to a high dependency ward after giving birth.	5 [4.95%]	5 [5%]	0.99	
Admission to ICU [post-delivery]	1 [0.99%]	1 [1%]	0.99	

Table [3]: Neonatal results of included subjects

	Monofilament suture [n = 101]	Braided suture [n = 100]	P Value
Early neonatal death [<7 days]	1 [0.99%]	1 [1%]	0.99
Late neonatal death [≥ to 7 to below 28 days]	1 [0.99%]	0	0.98
Mean birthweight centile [SD]	41.0 [29.2]	42.4 [28.8]	0.79
Small for gestational age [< 10th centile on population chart]	16 [15.84%]	15 [15%]	0.87
Resuscitation at birth	7 [6.93%]	7 [7%]	0.98
Additional care	29 [28.71%]	29 [29%]	0.96
The median length of stay in additional care, days	6.33 ± 11.14	6.67 ± 11.88	0.83
Antibiotics within 72 h after birth	26 [25.74%]	28 [28%]	0.72
Sepsis [clinically diagnosed]	11 [10.89%]	13 [13%]	0.64
Sepsis [microbiologically confirmed]	2 [1.98%]	2 [2%]	0.99
Early neurodevelopmental morbidity	1 [0.99%]	2 [2%]	0.55
Respiratory support	14 [13.86%]	16 [16%]	0.67
Median time on respiratory support, days	11.33 ± 20.05	10.67 ± 19.3	0.81
Supplementary oxygen requirements	3 [2.97%]	3 [3%]	0.99
Necrotizing enterocolitis [Bell's stage 2 or 3]	1 [0.99%]	1 [1%]	0.99
Retinopathy of prematurity requiring laser treatment	1 [0.99%]	1 [1%]	0.99
Disabilities	1 [0.99%]	1 [1%]	0.99
Congenital anomalies	2 [1.98%]	2 [2%]	0.99

Table [4]: Serious adverse events and cerclage placement also elimination complications of included subjects

	Monofilament suture [n = 101]	Braided suture [n = 100]	P Value
Cerclage complications			
Cerclage placement complication	4 [3.96%]	3 [3%]	0.71
Details of cerclage placement complications			
Cervical laceration	1 [0.99%]	1 [1%]	0.99
Bleeding from cervix	3 [2.97%]	2 [2%]	0.66
Ruptured membranes	1 [0.99%]	0	0.98
Bladder injury	0	0	-
Cerclage removal complication	57 [56.44%]	42 [42%]	0.04*
Details of cerclage removal complications			
Cervical tears	0	0	-
Difficulty in removal	31 [30.69%]	15 [15%]	0.008*
Need for anesthetic	41 [40.59%]	32 [32%]	0.21
Adverse events			
Number of women with serious adverse events	11 [10.89%]	10 [10%]	0.84
Maternal serious adverse events	14 [13.86%]	13 [13%]	0.86
Number of neonates with serious adverse events	1 [0.99%]	2 [2%]	0.55
Neonatal serious adverse events	2 [1.98%]	3 [3%]	0.64
Number of female patients who experienced an unanticipated significant adverse event related to the research	1 [0.99%]	1 [1%]	0.99
the number of unexpected major adverse outcomes that were linked to maternal causes	1 [0.99%]	0	0.98
Number of neonates with a related unexpected serious adverse event	1 [0.99%]	0	0.98
Number of neonatal-related unexpected serious adverse events	0	0	-

DISCUSSION

In terms of the secondary outcomes, close to our findings [7] reported a reduced probability of maternal sepsis in the monofilament suture group [4 percent], equated to the braided suture group [7 percent], in addition to a lower risk of clinical chorioamnionitis in the monofilament suture group [3%] compared to the braided suture group [6%]; however, the trial was not powered to detect those variations. The discovery that the infection rate was lower in the monofilament suture group lends credence to the theory that braided sutures serve as reservoirs for germs that can make patients more vulnerable to sickness [10].

There was no discernible change in the outcomes for the neonates among the 2 groups. The newborn results that were obtained in this research are unusual neonatal consequences that are largely associated with being born prematurely, and the trial did not have enough participants for it to be able to find alterations amongst both groups for these consequences. Maternal chorioamnionitis is connected with an enlarged threat of simultaneous early and late-onset neonatal sepsis [12, 13].

Despite this, there was no significant variance in the occurrence of newborn sepsis that was clinically observed between the groups who received monofilament and braided sutures. There was no discernible dissimilarity between the 2 groups regarding the proportion of neonates diagnosed with neonatal sepsis. That was a very significant proportion of neonates in both groups who required antibiotic therapy, suggesting that there was no change amongst each subset. Some research indicates a higher probability of unfavorable neonatal problems due to chorioamnionitis, while other research reveals no association; some trials only discover a correlation between histologically established chorioamnionitis and worsening infant neurodevelopmental results, although this is not conclusive [14, 15].

There is some indication that chorioamnionitis, combined with premature birth, confers a larger risk of cerebral palsy and worse neurodevelopmental results. This is particularly vital for mothers who need a cervical cerclage to deliver their babies [15]. Moreover, maternal chorioamnionitis is linked to a larger frequency of bad outcomes among women. These consequences include an increased risk of

hemorrhage, the need for blood transfusions, and increased risks of cesarean section and intensive care unit problems [16].

In 2019, **Perry *et al.*** reported that the high infection rate that we observed in our experiment could have been attributable, at least in part, to bias. Because the intervention could not be disguised, the individuals responsible for evaluating the study results may have been aware of the kind of suture material utilized. There may have been a bias toward diagnosing infection in the group who received braided sutures, given the known concern that they may lead to a subjective nature of some of the results and an elevated infection rate. This is because braided sutures are more difficult to remove than standard sutures. This possibility of bias may become more apparent when one considers the absence of data suggesting that any known infection effects, either for the mother or the infant, were significantly elevated in the group who had braided sutures. This is because braided sutures are more difficult to remove than other sutures. While we can state unequivocally that the primary result of pregnancy loss is not related to detection bias, it is still possible that some of the secondary outcomes were susceptible to this form of bias [16].

There was a perception that the problems of removing a monofilament suture had increased, and our results revealed that an additional need for anesthetic was essential throughout the removal process [7]. This should also be understood with the understanding that, in contrast to the insertion of cerclages, the removal of cerclages is often conducted by a wide variety of doctors. This is in contrast to the introduction of cerclages, which experts achieve. These doctors may have less expertise in removing monofilament sutures than braided ones. This is because monofilament sutures are not utilized as often as braided sutures. Moreover, there is a potential that the finding was also influenced by detection bias, which would make the previous point moot.

Limitations of the study: The study has several limitations that should be considered when interpreting the results. First, the study was not blinded. Second, the study was conducted at a single center, which may limit the generalizability of the findings to other settings. Third, the study did not assess long-term outcomes, such as neurodevelopmental outcome in children, which may be affected by maternal

chorioamnionitis and other complications. Finally, the study did not collect data on patient preferences or satisfaction with the procedure, which may influence the choice of suture material.

Conclusion

Monofilament and braided sutures are effective procedures with minimal side effects and complications. However, monofilament sutures may cause more difficult removal and removal complications.

Conflict of interest: The authors declare no conflict of interest.

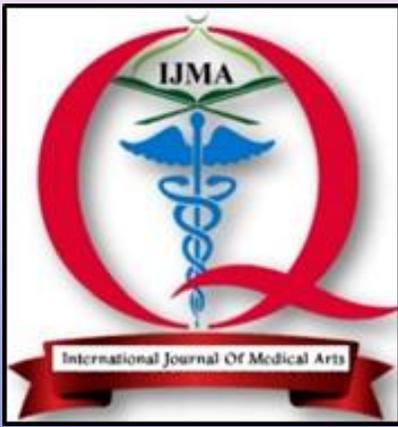
Sources of funding: This research did not receive any specific grant from public, commercial, or not-for-profit funding agencies.

Author contribution: Authors contributed equally to the study.

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Print ISSN: 2636-4174

Online ISSN: 2682-3780

of Medical Arts