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Original Research Article

A prospective, randomized, single blind study comparing polyglactin-910 fast suture and chromic catgut suture in episiotomy repair

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ABSTRACT

Background: Episiotomy is a standard surgical procedure performed during childbirth to enlarge the vaginal opening and facilitate baby delivery. Effective suturing techniques promote optimal wound healing, minimize complications, and enhance postpartum recovery for women undergoing episiotomy repair. This study aims to compare the effect of two different suture materials- chromic catgut and fast absorbable polyglactin-910 in the repair of episiotomy and its complications.
Methods: A prospective, randomized, single blinded study was conducted at the department of obstetrics and gynecology, in a tertiary care hospital in India, between April 2021 and September 2022. Women aged 18-35 years with a singleton pregnancy undergoing vaginal delivery with episiotomy were included after giving informed written consent and fulfilling inclusion and exclusion criteria. Either chromic catgut (n=58) or polyglactin-910 fast (n=58) suture was used in episiotomy repair. The primary endpoint was to assess perineal pain following episiotomy repair using (VAS) visual analogue scale. The secondary endpoints were to assess wound healing using the REEDA scale, short term complications (hematoma, swelling, puerperal fever, dehiscence, wound healing and re-suturing), long term complications (feeling of slight stitches, dyspareunia and suture granuloma), intraoperative suture parameters, and any adverse events were noted.
Results: Perineal pain, analgesic requirement, a feeling of slight stitches, and swelling were significantly more in the chromic catgut suture group compared to the polyglactin-910 fast absorbable suture group.
Conclusions: The study concluded that polyglactin-910 fast absorbable suture is superior to chromic catgut suture and recommended its use over chromic catgut suture.

Keywords: Chromic catgut, Episiotomy, Perineal pain, Polyglactin-910 fast, Vaginal delivery

INTRODUCTION

The word “episiotomy” originates from the Greek word “episton,” which refers to the pubic region, and “tomy,” which means to cut. It refers to an incision made over the pudendum, while perineotomy refers to an incision made over the perineum. In our practice, both terms, episiotomy and perineotomy, are often used synonymously. Episiotomy incisions can be either median or mediolateral, with the mediolateral technique being the most commonly employed.[1]

Episiotomy is a surgical procedure commonly performed during childbirth to facilitate the delivery of the baby and prevent severe perineal tears. However, this perineal incision can lead to extensive tissue damage, necessitating meticulous repair to promote optimal healing and reduce postoperative complications. It is notable that a majority of women experience short-term discomfort following an episiotomy, while approximately 20% experience long-term complications like dyspareunia.[2,3] The repair of episiotomy plays a critical role in reducing maternal morbidity, which encompasses physical, psychological,

and social challenges. To mitigate these adverse outcomes, effective episiotomy repair necessitates the expertise of skilled and trained medical professionals, along with the utilization of high-quality suture materials.

The choice of suture material plays a crucial role in the success of episiotomy repair, as it directly influences wound healing, tensile strength, and the overall recovery process. The primary function of suture material is to approximate the incised tissue without tension to facilitate healing via primary intention, control bleeding and to minimize the chances of infection.[4]

An ideal suture material should cause the least tissue reaction and be absorbed maximally during the healing process.[5] Well-aligned perineal wounds heal by primary intention with minimal complications within two weeks of suturing.

Historically, chromic catgut suture has been widely used in episiotomy repair due to its absorbable nature and long-standing familiarity in surgical practice. Derived from the submucosal layer of sheep or goat intestines, chromic catgut suture provides various benefits, including biocompatibility and ease of handling. However, concerns have been raised regarding its tensile strength and potential to induce inflammatory reactions, which could potentially impede wound healing and increase the risk of infection.[6]

The emergence of synthetic absorbable sutures has introduced a viable alternative to chromic catgut sutures. Polyglactin-910 fast absorbable suture, a synthetic copolymer of glycolide and lactide, exhibits improved tensile strength and reduced tissue reactivity compared to chromic catgut. These characteristics make polyglactin-910 fast absorbable suture an attractive choice for episiotomy repair, potentially leading to enhanced wound healing, decreased postoperative discomfort, and improved patient outcomes.[7,8]

Despite the growing popularity of polyglactin-910 fast sutures, there is a paucity of comparative studies directly assessing their efficacy and safety in episiotomy repair. As healthcare professionals strive to provide evidence-based care, it is imperative to comprehensively evaluate the benefits and drawbacks of chromic catgut and polyglactin-910 fast sutures. By examining factors such as wound healing rates, patient comfort, short term and long term complications, we can gain valuable insights into the optimal choice of suture material for episiotomy repair. This study compares chromic catgut suture and polyglactin-910 fast absorbable suture in episiotomy repair.

METHODS

Study design

This prospective, comparative, randomized (1:1), single-blinded study compared the chromic catgut suture and polyglactin-910 fast absorbable suture in the episiotomy repair. This study was conducted from April 2021 to September 2022. The study's primary objective was to assess perineal pain following episiotomy repair. The secondary objective of the study was to evaluate tissue reaction, wound healing, suture parameters, and dyspareunia in both the groups.

This study was conducted at department of obstetrics and gynaecology, in a tertiary care hospital in India. The ethics approval was obtained from Institutional Ethical Committee. The study was conducted and reported in compliance with the principles of Good Clinical Practice guidelines and the Declaration of Helsinki. Written informed consent was obtained from each patient before their enrolment in the study. The study was prospectively registered in Clinical trial registry of India. The clinical trial was reported in accordance with 2010 Consolidated Standards of Reporting Trials (CONSORT) guidelines (CTRI/2021/04/033103).

Study participants

Based on inclusion and exclusion criteria, women aged between 18-35 years, with a singleton pregnancy undergoing vaginal delivery with episiotomy and were willing to provide informed consent for participating in the study procedures were included, and women administered with epidural labour analgesia, whose membranes had ruptured for >24hrs, having perineal tears, cervical tears, vaginal tears, an extension of the episiotomies, previous history of perineal surgery other than the primary repair post-delivery, women having AIDS, hepatitis-B, chronic disease, local vaginal or vulval infection, bleeding/coagulation disorders/intrapartum fever, severe anaemia, uncontrolled diabetes, BMI >35kg/m^2 and <18kg/m^2, who have delivered a dead foetus, and with positive RT-PCR test for COVID 19 infection were excluded from the study.

Interventions

The women who were scheduled for episiotomy repair following vaginal delivery were randomized into two groups to receive either of the two sutures, i.e. chromic catgut suture (Trugut, Healthium Medtech Limited): It is a natural absorbable, monofilament suture material (number 1 size with round bodied ½ circle needle). Polyglactin-910 fast absorbable suture (Trusynth fast, Healthium Medtech Limited): It is a synthetic absorbable multifilament suture material (number 1 size, with round bodied ½ circle needle).

Study procedure

During the study, all participants underwent a right mediolateral episiotomy, and the subsequent closure of the episiotomy involved three layers, including the mucosa, muscle, and skin. The progress and recovery of the

participants were assessed through four follow-up visits, during which various factors were observed and recorded.

At each visit, the participants' level of perineal pain was evaluated using the Visual Analog Scale (VAS) score. The VAS score is a numerical value ranging from 0 to 100, with higher scores indicating greater pain intensity. Analgesics were administered as needed based on the reported pain levels. This subjective assessment of pain intensity helps quantify the participants' pain experience and is commonly used in clinical settings and research studies.[9]

The healing progress of the episiotomy wound was assessed using the REEDA score at visit 2 and visit 3. The REEDA score is a clinical assessment tool that evaluates the healing process of perineal wounds, including episiotomies. It stands for redness, edema (swelling), ecchymosis (bruising), discharge, and approximation. Each component is individually evaluated and assigned a numerical rating. The ratings are then summed to provide an overall REEDA score. A lower REEDA score indicates better healing progress, while a higher score may suggest inflammation, infection, or delayed wound healing. The interpretation of the total score on the REEDA scale reveals healed: 0; moderately healed: 1 to 5; mildly healed: 6 to 10; and not healed: 11 to 15, allowing healthcare professionals to monitor the wound healing process and determine if further evaluation or intervention is necessary.[10]

Short-term and long-term complications were documented in the data sheet after each visit. Short-term complications included hematoma, swelling, puerperal fever, dehiscence and re-suturing. Long-term complications included feeling of slight stitches, dyspareunia and suture granuloma.

The women were followed up for a total of 5 visits, which included visit 1 (Day of episiotomy), visit 2 (day 2), visit 3 (day 11+/- 3), visit 4 (6 weeks) and visit 5 (24 weeks). At screening visit, participants age, height, weight, BMI, and parity was recorded.

Study outcomes

Primary endpoint was subjective assessment of perineal pain following episiotomy repair at visit 1, visit 2, visit 3, visit 4 and visit 5 using (VAS) visual analogue scale. Secondary endpoints were to assess wound healing using the REEDA scale, short term complications (hematoma, swelling, puerperal fever, dehiscence, wound healing and re-suturing) were noted on visit 2 (day 2) and visit 3 (day 11 +/-3), long term complications (feeling of slight stitches, dyspareunia and suture granuloma) at visit 4 (6 weeks) and visit 5 (24 weeks), intraoperative suture parameters, and any adverse events.

Sample size

The sample size has been calculated as

$$N = \frac{\alpha\,[Z\,\alpha/2 + Z\beta]\,*\,P(1-P)}{(P1-P2)^2}$$

Where, α =allowable error; n = sample size; p = prevalence.

Considering the values, sample size was estimated to be 53.1. After adding 10 percent dropout, the final sample size was 58 per group, attributing to a total of 116 patients.

Randomization

Randomization was performed by the use of sealed codes with unique randomization subject number in a ratio of 1:1 to ensure an unbiased and balanced allocation of interventions. A computer generated block randomization sequence list was generated for the same. Each randomization number with the allocated treatment information was sealed in a serially numbered opaque sealed envelopes.

Statistical analysis

The data was analysed using SPSS for Windows [SPSS version 22.0, IBM Corp, Armonk]. The continuous data was presented in form of mean±SD. The t-test was used to analyse normally distributed data. The categorical data was analysed using Chi-Square test or Fishers exact test. The primary endpoint was analysed using Fishers exact test. Secondary endpoints were analysed using Chi-Square test or Fishers exact test. The p-value ($P<0.05$) was considered as statistically significant.

RESULTS

A total 116 women were enrolled in our study. This study was conducted from April 2021 to September 2022; two women were excluded in view of lost to follow up during week 6 (Visit 4). The CONSORT flow chart of the study participants is shown in (Figure 1).

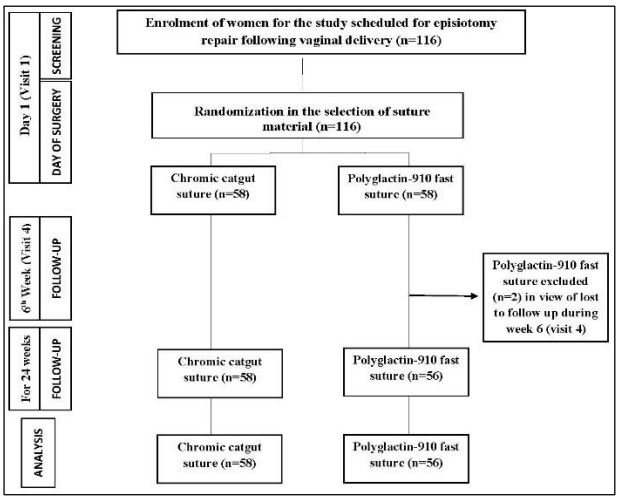

Figure 1: Consort flow diagram of participants.

Baseline demographics

The groups were comparable with respect to baseline demographics presented in (Table 1) and there were no significant differences according to randomization group for age, height, weight and BMI. In terms of parity, 58.6% of women were multiparous and 41.4% were primiparous (Figure 2).

Assessment of pain

The assessment of pain was done as per VAS score in both the groups at all the 5 visits. A significantly higher proportion of women in the chromic catgut suture group experienced severe pain compared to the polyglactin-910 fast suture group at the first visit (96.6% vs. 22.4%, respectively), which was statistically significant at 24 hours. There was gradual decrease in intensity of pain with each follow up visit, and at 24 weeks' follow-up none of the women in both groups reported pain (Table 2).

Analgesic requirement

During the immediate post-partum period, women in both the chromic catgut and polyglactin-910 fast suture groups required analgesics for pain management. In first 24 hours, a higher proportion of women in the chromic catgut suture group received analgesics thrice a day compared to the polyglactin-910 fast suture group (Figure 3). None of the women in either groups required analgesics after visit 2.

Table 1: Baseline demographics.

Suture type		N	Mean	Std. deviation	T-test P-value
Age	Chromic catgut suture	58	25.84	3.30	0.978
	Polyglactin-910 fast suture	58	25.83	3.47	
Height	Chromic catgut suture	58	153.34	7.20	0.399
	Polyglactin-910 fast suture	58	154.45	6.83	
Weight	Chromic catgut suture	58	54.97	6.19	0.821
	Polyglactin-910 fast suture	58	54.71	6.06	
BMI	Chromic catgut suture	58	23.53	3.50	0.339
	Polyglactin-910 fast suture	58	22.98	2.55	

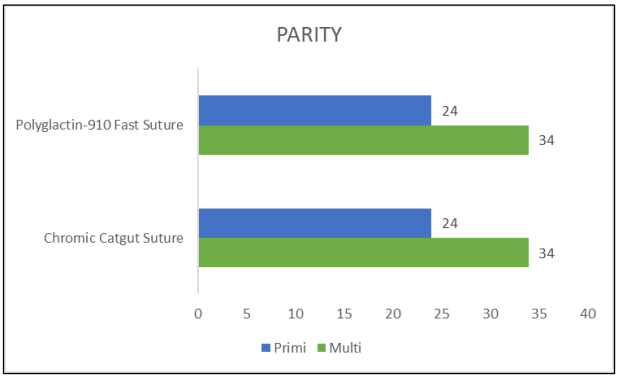

Figure 2: Comparison of parity between polyglactin-910 fast suture and chromic catgut suture.

Assessment of wound complications

Women in both the groups were observed for short term complications and post episiotomy healing as per REEDA score on visit 2 and visit 3, and long term complications on visit 4 and visit 5 are presented in (Table 3).

During visit 2, none of the participants in either group had hematoma. Swelling was observed in 12.1% women in the chromic catgut suture group and 3.4% women in the polyglactin-910 fast suture group. Puerperal fever was observed in 5.2% women in the chromic catgut suture group and 1.7% woman in the polyglactin-910 fast suture group. Dehiscence occurred in 3.4% women in the chromic catgut suture group, while none of the women in polyglactin-910 fast suture group experienced dehiscence. Only 1.7% woman in the chromic catgut group required re-suturing, while none of the women in polyglactin-910 fast required re-suturing.

Table 2: Comparison between polyglactin-910 fast suture and chromic catgut suture with VAS Score and sutures used.

		Suture type Chromic catgut suture N (%)	Polyglactin-910 fast suture N (%)	P-value
VAS (Day 1: day of episiotomy)	No pain	0 (0.0)	0 (0.0)	0.000*
	Mild	0 (0.0)	2 (3.4)	
	Moderate	2 (3.4)	43 (74.1)	
	Severe	56 (96.6)	13 (22.4)	

Continued.

		Suture type Chromic catgut suture N (%)	Polyglactin-910 fast suture N (%)	P-value
	Total	58 (100.0)	58 (100.0)	
VAS (Day 2)	No pain	0 (0.0)	0 (0.0)	0.000*
	Mild	32 (55.2)	56 (96.6)	
	Moderate	26 (44.8)	2 (3.4)	
	Severe	0 (0.0)	0 (0.0)	
	Total	58 (100.0)	58 (100.0)	
VAS (Day 11+/- 3)	No pain	6 (10.3)	50 (86.2)	0.000*
	Mild	52 (89.7)	8 (13.8)	
	Moderate	0 (0.0)	0 (0.0)	
	Severe	0 (0.0)	0 (0.0)	
	Total	58 (100.0)	58 (100.0)	
VAS (6 weeks)	No pain	54 (93.1)	55 (98.2)	0.183
	Mild	4 (6.9)	1 (1.8)	
	Moderate	0 (0.0)	0 (0.0)	
	Severe	0 (0.0)	0 (0.0)	
	Total	58 (100.0)	56 (100.0)	
VAS (24 weeks)	No pain	58 (100.0)	56 (100.0)	1.000
	Mild	0 (0.0)	0 (0.0)	
	Moderate	0 (0.0)	0 (0.0)	
	Severe	0 (0.0)	0 (0.0)	
	Total	58 (100.0)	56 (100.0)	
VAS : Visual Analogue Score, N= number of subjects, * statistically significant at P<0.05				

Post episiotomy healing was assessed for signs of healing. During visit 3, 91.4% women had complete wound healing, 1.7% wounds were moderately healed, 5.2% wounds were mildly healed, and 1.7% wound were not healed. In the polyglactin-910 fast suture group, 98.2% women had complete wound healing and 1.8% had mildly healed wound.

The feeling of slight stitches was reported by 81% women in the chromic catgut suture group and 36.2% women in the polyglactin-910 fast suture group. Neither group showed cases of suture granuloma. Dyspareunia was observed in 20.7% women in the chromic catgut suture group, while 7.1% women in the polyglactin-910 fast suture group (Table 3).

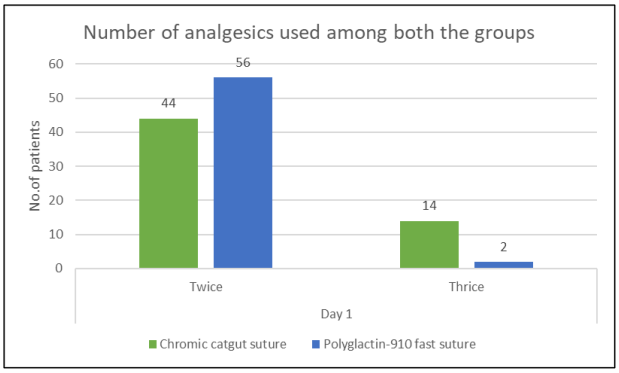

Figure 3: Number of analgesics used among both the groups.

Table 3: Short term complications, long term complications and REEDA scores between two groups.

		Suture type chromic catgut suture N (%)	Polyglactin-910 fast suture N (%)	P-value
Hematoma-visit 2 (day 2)	No	58 (100.0)	58 (100.0)	
Swelling-visit 2 (day 2)	No	51 (87.9)	56 (96.6)	0.083
	Yes	7 (12.1)	2 (3.4)	
Swelling-visit 3 (day 11+/- 3)	No	57 (98.3)	58 (100.0)	0.315
	Yes	1 (1.7)	0 (0.0)	
Puerperal fever-visit 2 (day 2)	No	55 (94.8)	57 (98.3)	0.309
	Yes	3 (5.2)	1 (1.7)	

Continued.

		Suture type		
		chromic catgut suture N (%)	Polyglactin-910 fast suture N (%)	P-value
Puerperal fever -visit 3 (day 11+/- 3)	No	58 (100.0)	58 (100.0)	1.000
Dehiscence -visit 2 (day 2)	No	56 (96.6)	58 (100.0)	0.154
	Yes	2 (3.4)	0 (0.0)	
Dehiscence-visit 3 (day 11+/- 3)	No	52 (89.7)	54 (96.4)	0.157
	Yes	6 (10.3)	2 (3.6)	
Dehiscence-visit 4 (6 weeks)	No	56 (96.6)	56 (100.0)	0.161
	Yes	2 (3.4)	0 (0.0)	
Resuturing-visit 2 (day 2)	No	57 (98.3)	58 (100.0)	0.315
	Yes	1 (1.7)	0 (0.0)	
Resuturing-visit 3 (day 11+/- 3)	No	54 (93.1)	57 (98.3)	0.170
	Yes	4 (6.9)	1 (1.7)	
Feeling of slight stitches-visit 2 (day 2)	No	11 (19.0)	37 (63.8)	1.000
	Yes	47 (81.0)	21 (36.2)	
Epi healing assessment-visit 2 (day 2) wound appearance	Healed	58 (100.0)	58 (100.0)	1.000
Epi healing assessment-visit 3 (day 11+/- 3) wound appearance	Healed	53 (91.4)	55 (98.2)	0.549
	Moderately healed	1 (1.7)	0 (0.0)	
	Mild healed	3 (5.2)	1 (1.8)	
	Not healed	1 (1.7)	0 (0.0)	
Feeling of slight stitches-visit 4 (6 weeks)	No	47 (81.0)	47 (83.9)	0.685
	Yes	11 (19.0)	9 (16.1)	
Feeling of slight stitches-visit 5 (24 weeks)	No	57 (98.3)	56 (100.0)	0.324
	Yes	1 (1.7)	0 (0.0)	
Suture granuloma -visit 4 (6 weeks)	No	58 (100.0)	56 (100.0)	1.000
Suture granuloma -visit 5 (24 weeks)	No	58 (100.0)	56 (100.0)	1.000
Dyspareunia-visit 4 (6 weeks)	No	26 (44.8)	38 (67.9)	0.026*
	Yes	12 (20.7)	4 (7.1)	
	NR	20 (34.5)	14 (25.0)	
Dyspareunia-visit 5 (24 weeks)	No	52 (89.7)	55 (98.2)	0.146
	Yes	2 (3.4)	0 (0.0)	
	NR	4 (6.9)	1 (1.8)	

N= number of subjects, NR: Not resumed, * Statistically significant at P<0.05

Intraoperative suture handling characteristics

No suture related challenges or complications were noted in both the groups.

DISCUSSION

The choice of suture material is crucial in episiotomy repair as it can significantly impact patient outcomes and the occurrence of complications. In this study, we compared the effects of two different suture materials, chromic catgut and polyglactin-910 fast absorbable, in the repair of episiotomy and their associated complications.

The age characteristics of the participants in our study were consistent with those reported in a prospective study by Gowda et al. Both studies showed a similar distribution of women across different age groups, with a majority falling in the 21-30 years' age range. Additionally, the proportion of multiparous and primiparous women in our study was comparable to the findings of the previous study. These similarities in age and parity characteristics between the two studies contribute to the generalizability and reliability of our results.[11]

Our findings revealed that the severity of pain differed significantly between the two groups at multiple time points, including day 1, day 2, day 11+/-3, 6 weeks, and 24 weeks post episiotomy repair. The polyglactin-910 fast suture group experienced significantly lower pain levels compared to the chromic catgut suture group. This is consistent with previous studies by Gowda et al, Shahgheibi et al, Gupta et al, and Abdullah et al, which also reported reduced pain levels in the polyglactin-910

fast suture group compared to the chromic catgut suture group. These findings highlight the importance of suture material selection in minimizing postoperative pain in episiotomy repair.[11-14]

Analgesic requirements during the immediate postpartum period were also assessed, and it was observed that a significantly higher proportion of women in the chromic catgut suture group required analgesics compared to the polyglactin-910 fast suture group. Bharathi et al reported similar findings, with a lower proportion of women requiring analgesics in the polyglactin-910 fast suture group compared to the chromic catgut suture group. This suggests that the use of polyglactin-910 fast suture may lead to better pain management and reduced reliance on analgesic medication.[15]

In terms of complications, the polyglactin-910 fast suture group demonstrated favourable outcomes compared to the chromic catgut suture group. The incidence of swelling (13.8% vs. 3.4%) was significantly lower in the polyglactin-910 fast suture group at visit 2, consistent with the findings of Kalita et al, swelling was observed to be (27% vs. 13%) at 24-48 hours.[16] Furthermore, the occurrence of dehiscence was completely absent in the polyglactin-910 fast suture group, while a small percentage of women experienced dehiscence in the chromic catgut suture group. These results align with the study by Gupta et al, which also reported a significantly lower incidence of dehiscence in the polyglactin-910 fast suture group. The need for re-suturing was limited to the chromic catgut suture group in our study, which is consistent with Gupta K et al.'s findings.[13]

Regarding patient comfort, the polyglactin-910 fast suture group exhibited better outcomes. The feeling of slight stitches was significantly lower in this group compared to the chromic catgut suture group. Gupta et al also reported a higher number of uncomfortable sutures in the chromic catgut suture group.[17] Dyspareunia, a potential complication affecting sexual intercourse, was more prevalent in the chromic catgut suture group, whereas the polyglactin-910 fast suture group demonstrated a lower incidence. These findings align with the prospective study of Singh et al that highlighted the reduced risk of dyspareunia associated with polyglactin-910 fast sutures.[18-19]

However, it is important to acknowledge several limitations of this study. First, the sample size was relatively small, which may limit the generalizability of the findings. A larger sample size would provide more statistical power and enhance the reliability of the results. Additionally, the study was conducted in a single-centre setting, which could introduce potential biases and limit the external validity of the findings. Further, multi-centre studies are needed to validate these results across diverse populations and settings.

CONCLUSION

In conclusion, the study provides valuable insights into the use of chromic catgut suture and polyglactin-910 fast absorbable suture in episiotomy repair. It was found that polyglactin-910 fast absorbable suture outperformed chromic catgut suture in several aspects. The chromic catgut suture group experienced more perineal pain, increased analgesic requirement, a sensation of slight stitches, and swelling compared to the polyglactin-910 fast absorbable suture group. Furthermore, polyglactin-910 fast absorbable suture significantly reduced pain. Although polyglactin-910 fast absorbable suture was slightly more expensive, it demonstrated better quality, efficacy, and fewer post-procedure complications. As a result, we conclude that polyglactin-910 fast absorbable suture is superior to chromic catgut suture and recommended its use over chromic catgut suture.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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