



RESEARCH ARTICLE

REVISED Clinical equivalence of Trusynth fast[®] and Vicryl rapide[®] polyglactin 910 fast absorbing sutures on maternal morbidity experienced by women following episiotomy repair: a single-blind, randomized study [version 2; peer review: 2 approved]

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V2 First published: 17 Oct 2022, 11:1179
<https://doi.org/10.12688/f1000research.126555.1>
 Latest published: 23 Jun 2023, 11:1179
<https://doi.org/10.12688/f1000research.126555.2>

Abstract

Background: Episiotomy procedure enlarges the vaginal outlet to facilitate childbirth. Polyglactin 910 fast-absorbing sutures are widely used for the repair of episiotomy because of their rapid absorption and less inflammatory response. This study was designed for subjective assessment of perineal pain post-episiotomy repair, with Trusynth Fast[®] and Vicryl Rapide[®] polyglactin 910 fast-absorbing sutures.

Method: This was a single-blind, randomized, prospective study conducted between January 7, 2021 and July 14, 2021 across two centers in India. Primiparous or multiparous women (18–40 years), who required episiotomy during vaginal delivery were included, and either Trusynth Fast[®] (n=47) or Vicryl Rapide[®] (n=49) suture was used for their episiotomy repair. The primary endpoint, perineal pain was assessed with visual analogue scale at all follow-up visits. The secondary endpoints, quantity of local anesthesia, number of sutures used, time to repair episiotomy, intraoperative suture handling, analgesics used, early and late wound complications, wound re-suturing, time to complete healing, presence of residual sutures, return to sexual activity, dyspareunia, and adverse events were also recorded.

Results: The study showed no significant difference in perineal pain between the two groups at any visit. A statistically significant difference ($p < 0.05$) in total score of episiotomy healing scale on day 2 (0.13 ± 0.34 versus 0.35 ± 0.56) and swelling on day 2 (8.51 versus

Open Peer Review

Approval Status

	1	2
version 2 (revision) 23 Jun 2023	 view	 view
version 1 17 Oct 2022	 view	 view

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28.57%) was noted between Trusynth Fast[®] and Vicryl Rapide[®] group. Non-significant difference was observed between the groups regarding anesthesia, number of sutures, time to repair episiotomy, intraoperative suture handling, analgesics, puerperal fever, wound infection, dehiscence, hematoma, urinary incontinence, re-suturing, time to complete healing, return to sexual activity and dyspareunia.

Conclusion: Trusynth Fast[®] suture is clinically equivalent to Vicryl Rapide[®] suture and can be used for episiotomy repair with minimal risk of perineal pain and wound complications.

Clinical Trials Registry of India Registration: CTRI/2020/12/029925;
Registered on December 18, 2020

Keywords

Episiotomy healing scale, Episiotomy repair, Perineal pain, Polyglactin 910 fast absorbable suture, Vaginal delivery, Wound complications

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Competing interests: Authors AKM and DTS are the employees of Healthium Medtech Limited, India who are manufacturers of Trusynth fast suture. Author DHD, CB, PD and MBB declares no conflict of interest.

Grant information: The study is funded by Healthium Medtech Limited.

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How to cite this article: Hemalatha Devi D, Bolanthakodi C, D'Cunha P *et al.* **Clinical equivalence of Trusynth fast[®] and Vicryl rapide[®] polyglactin 910 fast absorbing sutures on maternal morbidity experienced by women following episiotomy repair: a single-blind, randomized study [version 2; peer review: 2 approved]** F1000Research 2023, 11:1179

<https://doi.org/10.12688/f1000research.126555.2>

First published: 17 Oct 2022, 11:1179 <https://doi.org/10.12688/f1000research.126555.1>

REVISED Amendments from Version 1

The sequence of appearance of Figures 2 and 3 in version 1 has been interchanged as per the reviewer's comments. In addition, SD values have been updated in Figure 2.

Any further responses from the reviewers can be found at the end of the article

Introduction

Episiotomy, the most frequently performed operative procedure enlarges the vaginal outlet in order to facilitate childbirth. It is performed by applying an incision on the perineum. In India, episiotomy is performed in approximately 63% of women during vaginal delivery.¹ Generally, episiotomy is associated with wound infection, wound dehiscence, perineal pain and discomfort.² About 46% of mothers in lower income countries experience some degree of trauma to the perineal area during vaginal delivery.³

After performing episiotomy, the incised tissue has to be approximated, which is significantly impacted by the suture material used for tissue approximation, as it may affect perineal pain, discomfort and episiotomy healing.⁴ Although chromic catgut suture material was most commonly used for episiotomy repair, a higher incidence of short-term morbidity was found after using it in comparison to absorbable synthetic material.⁵ Furthermore, in comparison to chromic catgut sutures, use of polyglactin 910 sutures reported lower cases of morbidity and perineal pain.⁶ The fast-absorbing polyglactin 910 sutures accelerate hydrolysis and take 42 days to be absorbed.⁷ Previous studies compared synthetic absorbable suture materials (both polyglactin-910 and fast-absorbing polyglactin 910) with catgut sutures for episiotomy repair,^{5,8,9} but comparison between Trusynth Fast[®] and Vicryl Rapide[®] fast-absorbing polyglactin 910 sutures for episiotomy repair has not been done yet. Therefore, this study was designed to compare Trusynth Fast[®] and Vicryl Rapide[®] fast-absorbing polyglactin 910 sutures for evaluating maternal morbidity experienced by women following episiotomy repair.

Methods**Study design**

This was a single-blind, randomized, prospective study conducted between January 7, 2021 and July 14, 2021 across two centers in India. The primary objective was subjective assessment of perineal pain post-episiotomy repair, with Trusynth Fast[®] and Vicryl Rapide[®] suture. The secondary objectives included assessment of overall intraoperative handling, use of analgesics, wound healing, resumption of sexual activity and dyspareunia, number of sutures utilized and residual suture removal and maternal morbidities post-episiotomy in Trusynth Fast[®] and Vicryl Rapide[®] suture groups.

Ethical approval

This trial was registered at Clinical Trials Registry of India (CTRI Reg. No: CTRI/2020/12/029925; December 18, 2020) and the Institutional ethics committee of both participating sites approved the study protocol. Government Victoria Hospital-King George hospital ethics committee, approved the study on 4th December 2020, and Father Muller Institutional ethics committee approved the study on 15th December 2020 with registration number FMIEC/CCM/693/2020. The study is reported as per Consolidated Standards of Reporting Trials (CONSORT), and details regarding the CONSORT check list is present in data availability section.

Informed consent

Written informed consent was obtained from all participants for participation in the study as well as for publication of their clinical data.

Study participants

Primiparous or multiparous women aged 18 to 40 years, with a singleton pregnancy, gestational age of >34 weeks, and good systemic/mental health, who required episiotomy during the course of vaginal delivery, who visited the Department of Obstetrics & Gynecology of both the centers were invited to participate in this research. They were included in this study after obtaining informed consent.

Women were excluded if they had intrapartum fever, tears (perineal, cervical or vaginal) or extension of the episiotomies, HIV or hepatitis B infection, stillbirth, known allergy to the suture materials and a history of bleeding/coagulation disorders or perineal surgery other than the primary repair after childbirth.

The women were also excluded if the investigator felt it would be difficult to follow the study procedure and follow-up.

Study settings

The study was conducted at two sites: (i) Department of Obstetrics & Gynecology, Government Victoria Hospital, Visakhapatnam-530001, Andhra Pradesh, India, and (ii) Department of Obstetrics & Gynecology, Father Muller Medical College, Mangalore-575002, Karnataka, India.

Intervention

The two studied interventions were Trusynth Fast[®] (Healthium Medtech Limited) and Vicryl Rapide[®] (Ethicon, Johnson and Johnson) sutures. Both sutures are coated, braided, absorbable sterile polyglactin 910 fast absorbable sutures and indicated for use in soft tissue approximation, where only short-term wound support is required, and rapid absorption of the suture can be beneficial.

Study procedure

On the day of delivery (Baseline visit or day 0), the episiotomies were repaired as per standard institutional protocol with either Trusynth Fast[®] or Vicryl Rapide[®] sutures. The time between giving of the episiotomy and the time of start and completion of suturing was noted. The subjects were followed on day 2 (In-patient visit while in the hospital), day 11 (In-clinic/Telephonic visit), week 6 (In-clinic visit) and week 12 (Telephonic visit).

Demographics

Baseline demographics including age, ethnicity, smoking and alcohol consumption history, weight, height, vital signs along with period of gestation, parity, history of previous episiotomy, fetal presentation in utero and medical/surgical history were recorded.

Study outcomes

Primary outcome

The primary outcome, perineal pain following repair of episiotomy at 2 hours, 4 hours, 6 hours, and 12 hours after surgery, and on the day 2, day 11, week 6, and week 12 were noted using the visual analogue scale (VAS). VAS of 0–4 was graded as no pain, 5–44 as mild pain, 45–74 as moderate pain and 75–100 as severe pain.

Secondary outcome

The secondary endpoints, quantity of local anesthesia, number of sutures used, time to repair episiotomy, intraoperative suture handling, post-episiotomy number and dosage of analgesics, early and late wound complications, *viz.* puerperal fever (fever caused by uterine infection), swelling, infection (mild to severe discharge requiring treatment), hematoma (wound swelling >1 cm with changing color of skin), wound gaping, disruption or dehiscence (separation of wound edges of ≥ 1 cm) and urinary incontinence (involuntary loss of urine with coughing, sneezing, laughing, or running), time to complete healing, presence of residual sutures, frequency of wound re-suturing, return to sexual activity, dyspareunia and adverse events were evaluated.

The intraoperative suture handling was assessed using parameters like ease of passage through tissue, first-throw knot holding, knot tie-down smoothness, knot security, stretch capacity, memory, suture fraying on a five-point scale: 1 poor; 2 fair; 3 good; 4 very good; and 5 excellent. Wound healing was assessed by the standardized and valid REEDA (redness, edema, ecchymosis, discharge, and approximation) scoring scale, with scores ranging from 0 to 15. A lower score indicates better healing at the episiotomy site and higher score shows poor healing processes. Any unanticipated clinical signs, medical condition, disease or injury during the study period, which were already captured as study endpoints were not labeled and reported as adverse events.

Other standard details about the duration of second stage of labor, length of incision, number of layers closed, suture related challenges, perioperative complications, postpartum hemorrhage, outcome of surgery, length of hospital stay, antibiotic prophylaxis, suture loosening, feeling of slight stitches, and suture sent for culture were also recorded. In addition, the prescribed/concomitant medications during the study period were also noted.

Sample size

The data from a previous study found that one out of 50 (2%) women in Vicryl Rapide[®] group had mild discomfort in sitting posture at six weeks, and 98% had no discomfort or pain.⁹ Following the findings of this study, the proportion of patients experiencing no perineal pain, post-episiotomy repair, in the standard Vicryl Rapide[®] arm was assumed to be 98% i.e., $\pi_1=98\%$. Assuming type I error as 5% ($\alpha=0.05$), power as 80% ($1-\beta=0.8$) and a difference to be detected as 1% for the proportion of patients experiencing no perineal pain in the Trusynth Fast[®] arm ($\pi_2=97\%$) with a margin of non-inferiority as 10% of the difference (δ), a minimum sample size was determined approximately as 38 in each arm. Further,

considering a drop out of 20% and post-randomization exclusion of 10%, the required sample size was increased to 50 in each arm. So, a total of 100 subjects participated in this trial.

Sample size calculation formula:

$$\text{Two-sample Parallel Non-inferiority } \pi_1 - \pi_2 \geq \delta \quad n_i = \frac{(z_\alpha + z_\beta)^2 (\pi_1(1 - \pi_2) + \pi_2(1 - \pi_1))}{(\pi_1 - \pi_2 - \delta)^2}$$

n_i : sample size required in each group; Z_α : conventional multiplier for alpha; Z_β : conventional multiplier for power; π_1 : proportion of patients experiencing no perineal pain in the Vicryl Rapide® arm; π_2 : proportion of patients experiencing no perineal pain in the Trusynth Fast® arm; δ : margin of non-inferiority difference; $\pi_1 - \pi_2$: size of difference of clinical importance.

Randomization and blinding

Before initiation of the study, a computer-based, automated randomization number was generated by using version 1.0 of Random Allocation Software, using block sizes of 4, 6 or 8 by an independent programmer. The randomization concealment was done by sequentially numbered opaque sealed envelopes (SNOSE) technique. The subjects were allocated randomly in a 1:1 ratio to Trusynth Fast® (n=50) or Vicryl Rapide® (n=50) suture group. This was a single-blind study and the subjects were kept blinded to the device allocation status.

Statistical analysis

The per-protocol or PP analysis set was used for statistical analysis using the SPSS version 25.0 (SPSS, Chicago, Illinois, USA). The PP set includes all subjects, who have complete data on the primary effectiveness parameter during 12 weeks follow-up. All continuous variables were expressed as mean±SD (standard deviation) and compared using the t-test for normally distributed data or Mann-Whitney U test for distribution-free data. All qualitative variables were expressed as proportions/percentages, and compared using Chi-squared test or Fisher's Exact test. A p value of < 0.05 was considered statistically significant.

Results

A total of 100 women were screened for eligibility between January 7, 2021 and April 21, 2021 and follow-up of the last subject was completed on July 14, 2021. However, four subjects met the exclusion criteria and did not receive the intervention. Therefore, the PP set consisted of 96 subjects, who received the allocated intervention (Trusynth Fast®, n=47; Vicryl Rapide®, n=49) for episiotomy repair and completed the study (Figure 1).

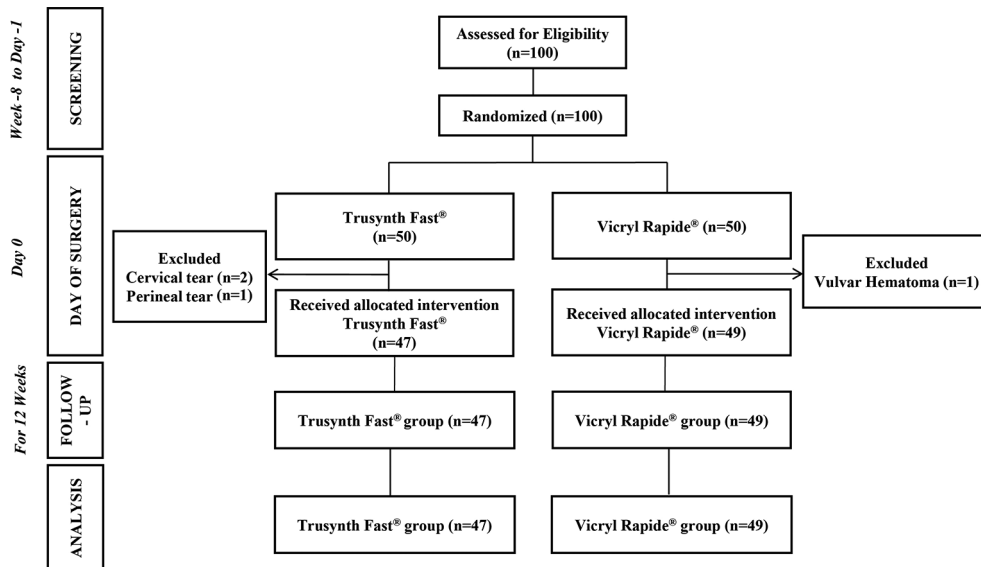


Figure 1. CONSORT flow diagram of the study participants and the study design.

Table 1. Baseline demographics and other relevant characteristics of the study participants.

Parameters	Trusynth Fast® (n=47)	Vicryl Rapide® (n=49)	p-value
Age (years), Mean±SD	25.54±4.29	25.46±4.55	0.63
Weight (kilogram), Mean±SD	61.36±10.77	59.39±8.66	0.16
Height (centimeter), Mean±SD	154.68±7.56	153.89±6.75	0.30
BMI (kilogram/meter ²), Mean±SD	25.58±3.57	25.11±3.34	0.86
Gestation period (weeks), Mean±SD	38.31±1.54	38.47±1.16	0.42
Parity number, n (%)			
0	20 (42.55)	24 (48.98)	0.88
1	23 (48.94)	20 (40.82)	
2	3 (6.38)	4 (8.16)	
3	1 (2.13)	1 (2.04)	
History of previous episiotomy, n (%)	19 (40.43)	18 (36.75)	0.71
Medical/surgical history, n (%)	8 (17.02)	11 (22.45)	0.45
Pulse rate (beats/minute), Mean±SD	82.66±6.23	83.12±4.42	0.68
Respiratory rate (breaths/minute), Mean±SD	17.11±1.77	16.80±1.59	0.37
Systolic blood pressure (mmHg), Mean±SD	118.30±12.04	119.18±11.15	0.71
Diastolic blood pressure (mmHg), Mean±SD	77.66±7.29	78.57±6.46	0.52

BMI=body mass index, SD=standard deviation, mmHg=millimeters of mercury.

Baseline demographics

Baseline demographics, vital signs and other relevant characteristics were comparable between the two treatment arms (Table 1). All the subjects who participated in the study were Indians and none of them had a history of alcohol consumption or smoking. The fetus of all the studied women was in vertex position.

Primary endpoint analysis

The perineal pain was assessed using VAS scale at 2 hours, 4 hours, 6 hours and 12 hours after childbirth and on all follow-up visits. No significant difference in perineal pain was observed, between the two groups at any time point. The intensity of pain was gradually decreased in subsequent follow-up visits (Figure 2a and b).

Secondary endpoint analysis

Intraoperative profile

All subjects received 10 mL of local anesthesia (lignocaine) and antibiotic prophylaxis. In all subjects, normal delivery was done with no requirement for instrument use. All the episiotomies were right mediolateral incisions and three layers were closed in both groups. The results relative to the intraoperative handling characteristics are shown in Figure 3. “Excellent” score was higher for ease of passage, first-throw knot holding, knot security, stretch capacity, memory, and degree of fraying in Trusynth Fast® group, and for knot tie-down in Vicryl Rapide® group. Moreover, good outcome of surgery was noted in all subjects, as well as no suture-related challenges and perioperative complications were noted in both groups. The other intraoperative characteristics are summarized in Table 2.

Post-operative profile

The subjects of Vicryl Rapide® group took comparatively longer time for complete healing after episiotomy repair than Trusynth Fast® group, but the difference was not statistically significant (Table 2). None of the subjects in any group required analgesic during week 6 and week 12 of delivery. A significantly higher ($p<0.05$) mean score of total episiotomy healing scale at day 2 in Vicryl Rapide® group indicated good healing in Trusynth Fast® group (Figure 2c). At day 2, more subjects with score 0 for REEDA scale were found in Trusynth Fast® group, compared to Vicryl Rapide® group (Figure 2d). The feeling of slight stitches was registered in both Trusynth Fast® and Vicryl Rapide® group at day 2 (mild, 2.13 versus 2.04%; moderate, 40.43 versus 40.82%, $p=0.98$), day 11 (mild, 31.92 versus 14.29%; moderate, 6.38 versus

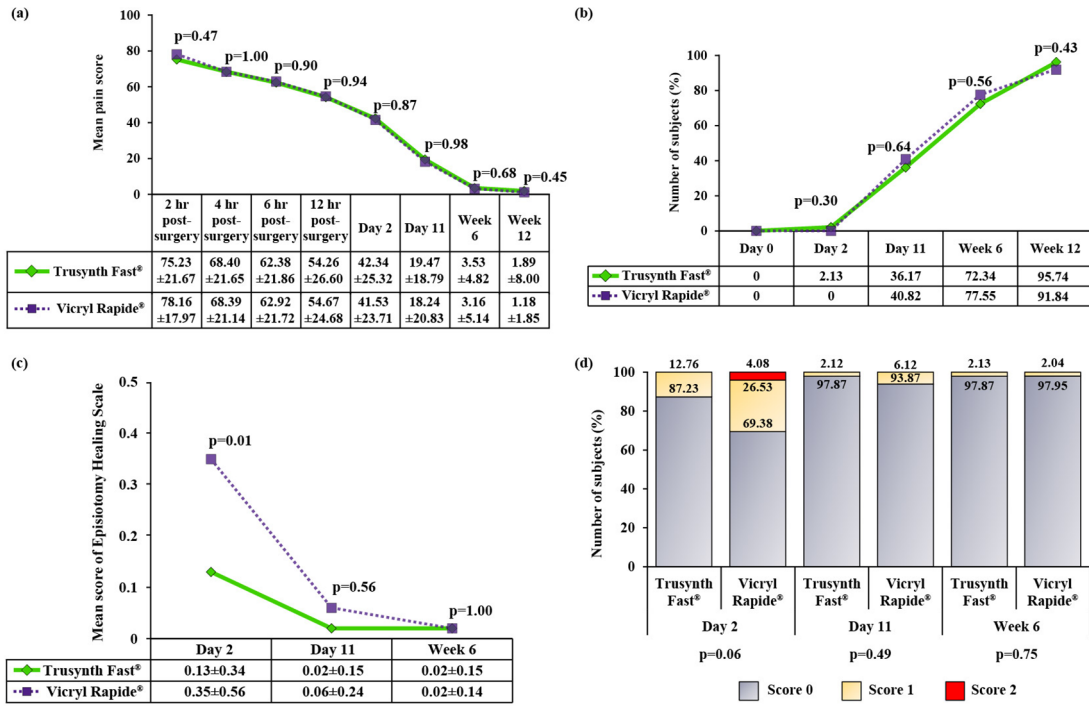


Figure 2. Post-operative profile of the subjects randomized to Trusynth Fast® (n=47) and Vicryl Rapide® (n=49) groups: (a) Mean pain score was evaluated using visual analogue scale (VAS) scale, (b) Frequency of subjects with no pain, (c) Mean total score of episiotomy healing scale, and (d) Percentage of score of Episiotomy Healing Scale or REEDA scale. hr: Hours, p<0.05 is statistically significant.

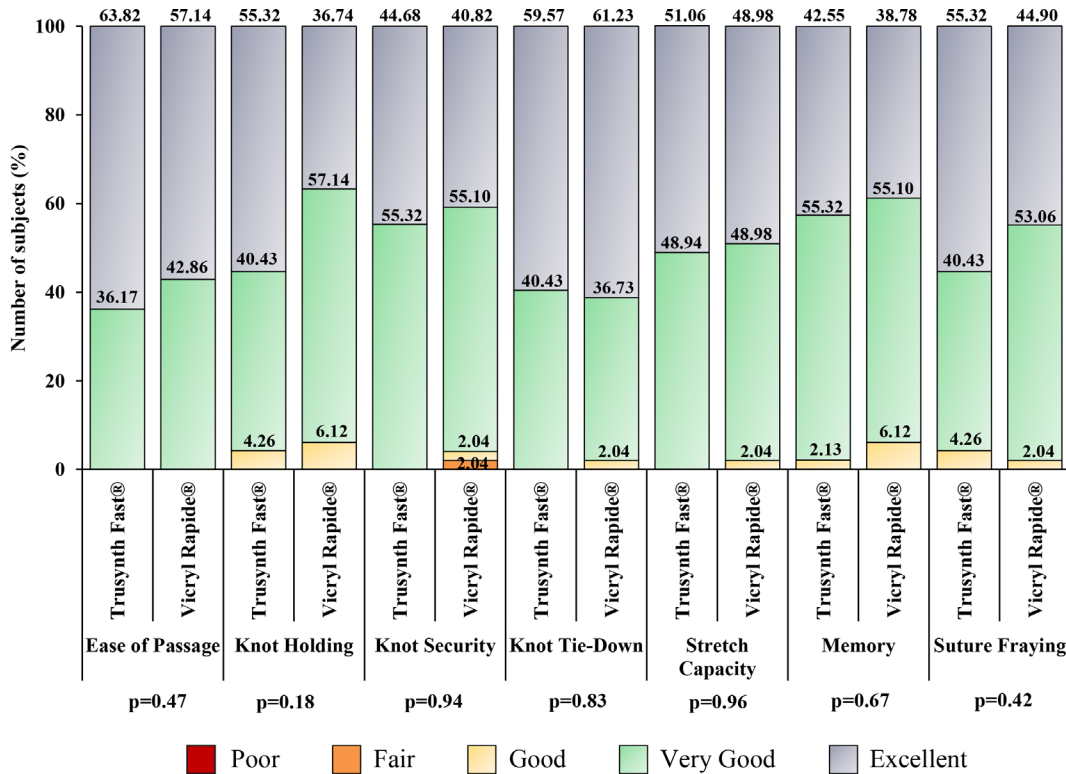


Figure 3. Intraoperative suture handling characteristics in subjects randomized to Trusynth Fast® (n=47) and Vicryl Rapide® (n=49) groups: Percentage scores for “excellent”, “very good”, “good” and “fair” are shown in one bar for different suture handling characteristics. None of the characteristics had “poor” score.

Table 2. Intraoperative and post-operative profile of the study participants.

Parameters	Trusynth Fast [®] (n=47)	Vicryl Rapide [®] (n=49)	p-value
<i>Intraoperative profile</i>			
Duration of second stage of labor (hours), Mean±SD	0.70±0.43	0.68±0.47	0.86
Number of suture used, Mean±SD	1.43±0.54	1.49±0.51	0.58
Number of sutures used, n (%)			
1	28 (59.57)	25 (51.02)	0.29
2	18 (38.29)	24 (48.97)	
3	1 (2.13)	0	
Length of incision (centimeter), Mean±SD	4.30±0.83	4.14±0.68	0.30
Total time spent with repair of episiotomy (minutes), Mean±SD	15.26±4.43	13.98±3.85	0.13
Time of giving episiotomy to time of completion of suturing (minutes), Mean±SD	30.40±6.87	31.20±8.37	0.61
Mild atonic postpartum hemorrhage, n (%)	1 (2.13)	3 (6.12)	0.22
<i>Post-operative profile</i>			
Birth weight of infant (Kilogram), Mean±SD	2.92±0.29	2.83±0.44	0.24
Length of hospital stay (days), Mean±SD	4.15±1.14	3.92±1.10	0.32
Number of analgesics prescribed, Mean±SD			
Day 0	1.04 ± 0.29	1.04 ± 0.41	1.00
Day 2	0.98 ± 0.15	0.96 ± 0.20	0.58
Day 11	0.23 ± 0.43	0.33 ± 0.47	0.41
Week 6	0	0	-
Week 12	0	0	-
Swelling, n (%)			
Day 2	4 (8.51)	14 (28.57)	0.01*
Day 11	1 (2.13)	1 (2.04)	0.98
Week 6	0	0	-
Week 12	0	0	-
Time to complete healing (days), Mean±SD	3.19±3.18	6.96±11.12	0.18

SD=standard deviation.

*p<0.05.

8.16%, p=0.09) and week 6 (mild, 17.02 versus 14.29%, moderate 0 versus 0, p=0.71). At week 12, no subjects had the feeling of slight stitches.

None of the subjects were readmitted to the hospital during any follow-up visits. Incidence of suture loosening, residual suture removal and sent for culture were not recorded during entire study period. The incidence of swelling was observed in subjects of both Trusynth Fast[®] and Vicryl Rapide[®] groups at day 2 (8.51 versus 28.57%, p<0.05), that improved at day 11 (2.13 versus 2.04%, p=0.98), and became nil at week 6 and 12. No other wound complications (wound infection, wound dehiscence, hematoma, wound re-suturing, puerperal fever and urinary incontinence) were noted at any follow-up visits. After 6 weeks of delivery, 6 (12.77%) women in the Trusynth Fast[®] group and 6 (12.24%) women in the Vicryl Rapide[®] group were able to resume sexual activity (p=0.94). After 12 weeks of surgery, 21 (44.68%) women in Trusynth Fast[®] group and 17 (34.69%) women in the Vicryl Rapide[®] group resumed sexual activity (p=0.32). Furthermore, the women who resumed sexual activity did not report incidence of dyspareunia. Other post-operative characteristics are presented in Table 2.

Non-serious adverse events were observed, viz. drug allergy in one (2.13%) subject, mild vaginal discharge in one (2.13%) subject, and fever in 3 (6.38%) subjects of Trusynth Fast[®] group. In the Vicryl Rapide[®] group, one (2.04%)

Table 3. Concomitant or prescribed medication during the study period.

Medications	Trusynth Fast® (n=47)	Vicryl Rapide® (n=49)
Analgesics, n (%)		
Diclofenac	32 (68.09)	29 (59.18)
Paracetamol	15 (31.91)	18 (36.73)
Antibiotics, n (%)		
Amoxicillin	42 (89.36)	42 (85.71)
Metronidazole	19 (40.43)	20 (40.82)

subject had general body pains along with vomiting and headache, one (2.04%) subject had fever, one (2.04%) subject had general body pains, and one (2.04%) subject had vomiting. The adverse events were mild in severity and not related to the study device. The prescribed/concomitant medications used during the study period are given in Table 3.

Discussion

In India, more than 60% of women undergo episiotomy during vaginal delivery.¹ Post-episiotomy development of swelling, hemorrhage, hematoma, wound dehiscence and infection along with prolonged hospital stay, perineal pain and delayed resumption of sexual activity is already reported.² The repair technique and the type of suture material used have a major influence on the outcome of episiotomy repair. According to NICE guidelines, rapidly absorbable synthetic suture is the optimal material for perineal repair.¹⁰ Existing literature demonstrated the beneficial effect of synthetic suture over chronic catgut suture material regarding post-episiotomy complications, perineal pain and discomfort.^{5,6,8,9} However, the comparison of two polyglactin 910 fast absorbing suture brands for episiotomy repair post-vaginal delivery is still not established. Therefore, this study compared Trusynth Fast® and Vicryl Rapide® fast-absorbing polyglactin 910 sutures for evaluating maternal morbidity experienced by women following episiotomy repair.

Different aspects of intraoperative suture handling characteristics studied in this study were comparable between the suture groups. Ease of passage, knot security, knot tie-down and stretch capacity were graded as either “very good” or “excellent” in all subjects of Trusynth Fast® group, while only ease of passage was graded either “very good” or “excellent” in all subjects of Vicryl Rapide® group. None of the suture handling characteristics was graded “fair” or “poor” in Trusynth Fast® group, and “poor” in Vicryl Rapide® group. Furthermore, good outcome of surgery along with no suture related challenges indicates the clinical equivalence of both sutures.

Perineal pain for ≥ 72 hours of episiotomy is the common morbidity in women, for which analgesia can be continued for ≥ 10 days after delivery.² Use of a rapidly absorbable form of polyglactin 910 for the repair of perineal trauma offers a significant reduction in pain and analgesic number, when compared to standard absorbable synthetic material.¹¹ Polyglactin 910 elicits minimal tissue reaction as compared to catgut, and is associated with less pain.⁶ A decrease in perineal pain and analgesic requirement with the use of a rapidly absorbable synthetic suture material was reported in previous studies.^{9,11} Withstanding the findings of these studies, subjects of present study also showed reduction in perineal pain, from day 2 onwards after using Trusynth Fast® and Vicryl Rapide® fast-absorbing polyglactin 910 suture for episiotomy repair. In both suture arms, similar improvement in pain was evident, with no significant difference at any follow-up visit. In addition, the mean analgesics prescribed were also decreased with each passing visit in both groups, and not required by any subjects at 6–12 weeks.

Postpartum infection is a major cause of maternal mortality and also associated with maternal anxiety and postpartum depression.¹² Similarly, wound dehiscence is one of the important causes of re-suturing, and requires hospital re-admissions in the postpartum period, leading to physical and psychological problems.¹³ The results of the present study depicted no wound infection, wound dehiscence, hematoma, puerperal fever or urinary incontinence. Moreover, re-suturing was not required in any of the subjects. However, a significantly higher incidence of swelling was observed in the Vicryl Rapide® group on day 2, which decreased eventually (within 11 days post-delivery), and no significant differences were found in the subsequent visits. A previous study reported that routine episiotomy resulted in inflammation along with hematoma, infection and dehiscence, pain, extension of the episiotomy incision, and sexual dysfunction.¹⁴ However, in this study, comparable number of subjects in both groups resumed sexual activity by week 6 and 12, with no complaint of dyspareunia.

Perineal wound heals by primary closure, with least possible complications within 14 days of suturing.¹¹ Episiotomy repair with polyglactin 910 suture results in more satisfactory wound healing as compared to chromic catgut suture.⁸ A non-significant, but faster wound healing was noted in Trusynth Fast[®] group as compared to Vicryl Rapide[®] group. In addition, no incidence of any suture-related adverse event was observed in this study.

This study is methodologically robust and appropriately powered to detect a difference in the primary and secondary outcomes; hence the findings of this study can be generalized to the wider population. The clinical equivalence of these two sutures regarding efficacy and safety indicates that Trusynth Fast[®] suture can be used in all surgeries indicated for Vicryl Rapide[®] suture. The limitation of the present study is that the surgeons who assessed the intraoperative suture handling characteristics were not blinded, and therefore, a potential bias might have occurred if they favored one suture over the other.

Conclusion

The findings demonstrated clinical equivalence of Trusynth Fast[®] suture to Vicryl Rapide[®] suture in terms of non-significant differences in primary and secondary endpoints (except swelling and mean score of episiotomy healing scale on day 2). Both the sutures can be used for episiotomy repair with minimal risk for maternal morbidity, *viz.* perineal pain, early and late wound complications, and re-suturing.

Data availability

Underlying data

Figshare. Trusynth fast suture study Dataset, <https://doi.org/10.6084/m9.figshare.21184411.v1>.¹⁵

This project contains the underlying data related to all the data points mentioned below:

- Demographic data, primary and secondary endpoints

Data are available under the terms of the [Creative Commons Attribution 4.0 International license](#) (CC-BY 4.0).

Reporting guidelines

Figshare: Trusynth fast study CONSORT checklist, <https://doi.org/10.6084/m9.figshare.21184420.v1>.¹⁶

Data are available under the terms of the [Creative Commons Attribution 4.0 International license](#) (CC-BY 4.0).

Acknowledgements

The authors are grateful to WorkSure[®] India for providing clinical research support.

References

1. Singh S, Thakur T, Chandhok N, *et al.*: **Pattern of episiotomy use & its immediate complications among vaginal deliveries in 18 tertiary care hospitals in India.** *Indian J. Med. Res.* 2016; **143**: 474–480.
[PubMed Abstract](#) | [Publisher Full Text](#)
2. Ononuju C, Ogu R, Nyengidiki T, *et al.*: **Review of episiotomy and the effect of its risk factors on postepisiotomy complications at the University of Port Harcourt Teaching Hospital.** *Niger Med. J.* 2020; **61**: 96–101.
[PubMed Abstract](#) | [Publisher Full Text](#)
3. Aguiar M, Farley A, Hope L, *et al.*: **Birth-Related Perineal Trauma in Low- and Middle-Income Countries: A Systematic Review and Meta-analysis.** *Matern. Child Health J.* 2019; **23**: 1048–1070.
[PubMed Abstract](#) | [Publisher Full Text](#)
4. Thukral P, Mendiratta S, Bhola G: **A comparative study of subcuticular and interrupted stitches for episiotomy.** *Int. J. Reprod. Contraception, Obstet. Gynecol.* 2018; **7**(5107): 5107.
[Publisher Full Text](#)
5. Perumal D, Selvaraju D: **Comparative study of episiotomy repair: absorbable synthetic versus chromic catgut suture material.** *Int. J. Reprod. Contraception, Obstet. Gynecol.* 2017; **6**: 2186.
[Publisher Full Text](#)
6. Gupta K, Gupta T, Dalmia K, *et al.*: **Section: Obstetrics and Gynaecology "A Comparative Study of Vicryl Rapide Versus Chromic Catgut for Episiotomy Repair".** 2021; **8**: 1–5.
7. Susmitha DJ, Bidri DSR: **A comparative study between fast absorbing polyglactin 910 vs chromic catgut in episiotomy wound repair.** *Int. J. Clin. Obstet. Gynaecol.* 2021; **5**: 287–291.
[Publisher Full Text](#)
8. Howells IE, Abasi IJ: **Episiotomy Repair in Poor Resource Settings, is It Justifiable to Recommend the Fast Absorbing Polyglactin 910 Suture (Vicryl Rapide) as the Suture of Choice ? – A Randomized Controlled Trial.** 2020; **4**: 30–42.
9. Samant M, Bose E, Ghosh A, *et al.*: **Comparison of impact of polyglactin 910 (Vicryl rapide) and chromic catgut sutures on perineal pain following episiotomy wound repair in eastern Indian patients.** *J. Sci. Soc.* 2013; **40**: 95.
[Publisher Full Text](#)
10. National Institute for Health and Clinical Excellence: **Intrapartum care for healthy women and babies.** *Nice.* 2014; 33–54.
11. Kettle C, Rk H, Kmk I: **Second degree tears (Review).** 2007.
[Publisher Full Text](#)
12. Boushra M, Rahman O: **Postpartum Infection Pathophysiology.** 2013; 1–8.

13. Dudley L, Kettle C, Waterfield J, *et al.*: **Perineal resuturing versus expectant management following vaginal delivery complicated by a dehisced wound (PREVIEW): A nested qualitative study.** *BMJ Open.* 2017; **7**: e013008–e013010.
[PubMed Abstract](#) | [Publisher Full Text](#)
14. Gün İ, Doğan B, Özdamar Ö: **Long- and short-term complications of episiotomy.** *Turkish J. Obstet. Gynecol.* 2016; **13**: 144–148.
[PubMed Abstract](#) | [Publisher Full Text](#)
15. Devi DH, Bolanthakodi C, D'Cunha P, *et al.*: **Trusynth fast suture study [DATASET].** *figshare.* 2022 [cited 2022Sep22].
[Reference Source](#)
16. Devi DH, Bolanthakodi C, D'Cunha P, *et al.*: **Trusynth fast study CONSORT checklist.** *figshare.* 2022 [cited 2022Sep22].
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Reviewer Report 27 June 2023

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Shraddha Shetty K

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No further comments to make. Article is approved.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: High risk obstetrics and adolescent gynecology

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 27 June 2023

<https://doi.org/10.5256/f1000research.151757.r181233>

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Geetika Kaur 

Wayne State University, Detroit, Michigan, USA

The article is scientifically valid in its current form.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Immunology, Cell and Molecular Biology, Angiogenesis, Pathology, Anatomy

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Reviewer Report 12 June 2023

<https://doi.org/10.5256/f1000research.138979.r163358>

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**Shraddha Shetty K**

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Brief description of the article:

This article aims at describing the type of suture material that can be used to repair the episiotomy. Benefits and complications of using Trusynth Fast and Vicryl Rapide polygactin 910 fast absorbing sutures. Primary outcome analysed was subjective post episiotomy perineal pain with the type of suture material used. Secondary outcomes analysed were quantity of local anesthesia, number of sutures used, time to repair episiotomy, intraoperative suture handling, analgesics used, early and late wound complications, wound re-suturing, time to complete healing, presence of residual sutures, return to sexual activity and dyspareunia. They concluded that Trusynth Fast® suture is clinically equivalent to Vicryl Rapide® suture and can be used for episiotomy repair with minimal risk of perineal pain and wound complications.

Relevance: Studying the type of suture material used for episiotomy and assessing the complications and side effects will help the clinicians in deciding the type of suture material to be used for episiotomy.

Comments: Dear authors, I read with great interest, which falls within the aim of this journal. In my honest opinion, the topic is of great interest to attract the readers' attention.

Major:

- Aims and objectives have been mentioned clearly.
- Review of literature is appropriate for the study.
- Materials & Methods have been explained in brief.
- The study area has been defined clearly.
- Data collection technique is appropriate for the study.
- Data analysis technique is described in detail.

- Results have been described and analysed in detail.
- The discussion has been described clearly and results have been compared with other studies and analysed.

Minor:

- Introduction to the topic has been mentioned in detail.
- Conclusions and the summary of the study have been defined which is appropriate.

Is the work clearly and accurately presented and does it cite the current literature?

Yes

Is the study design appropriate and is the work technically sound?

Yes

Are sufficient details of methods and analysis provided to allow replication by others?

Yes

If applicable, is the statistical analysis and its interpretation appropriate?

Yes

Are all the source data underlying the results available to ensure full reproducibility?

Yes

Are the conclusions drawn adequately supported by the results?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: High risk obstetrics and adolescent gynecology

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 02 June 2023

<https://doi.org/10.5256/f1000research.138979.r171249>

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Geetika Kaur 

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The manuscript entitled "Clinical equivalence of Trusynth fast® and Vicryl rapide® polyglactin 910

fast absorbing sutures on maternal morbidity experienced by women following episiotomy repair: a single-blind, randomized study" by Devi *et al.* is quite interesting. The manuscript is well-written and provides additional evidence in the literature on the safe usage of polyglactin sutures. Detailed methodology and results have been provided. However, minor changes are required to improve the manuscript.

Additional comments:

1. In the introduction section, provide characteristic features of Trusynth Fast sutures, if any previous studies have been conducted using it; they need not to be randomised but any general studies, suggesting the qualities of the suture.
2. In the methodology section, provide IEC no. of Government Victoria Hospital-King George hospital also, if any, similar to other institute's registration number.
3. As mentioned in the result section, 100 females were screened and 4 were excluded. Were 100 consecutive women screened for eligibility? If yes, why were further patients not screened or recruited when four patients met exclusion criteria?
4. The study was conducted at two sites. How many patients were recruited from each site?
5. Figure numbers are not consecutive. Figure 1, 3 and then figure 2. Kindly rectify this.
6. In Figure 3, it would be better to mention SD along with mean values of pain score and mean healing score. It is not required to be mentioned for frequency of subjects.
7. In the post-operative profile of secondary endpoint analysis, the authors have mentioned that "The subjects of Vicryl Rapide® group took comparatively longer time for complete healing after episiotomy repair than Trusynth Fast® group, but the difference was not statistically significant (Table 2)."
On applying two tailed t-test, the difference is found to be statistically significant with p value= 0.026.
I would like to know which statistical test was applied to compare the mean values?
8. How many in clinic and telephonic follow up visits were conducted on Day 11, as mentioned in methodology? How did you verify the adverse events on telephonic follow-up?
9. In the discussion section, I would suggest to add a few studies from the literature to discuss the findings of this study.

Is the work clearly and accurately presented and does it cite the current literature?

Yes

Is the study design appropriate and is the work technically sound?

Yes

Are sufficient details of methods and analysis provided to allow replication by others?

Yes

If applicable, is the statistical analysis and its interpretation appropriate?

Partly

Are all the source data underlying the results available to ensure full reproducibility?

Yes

Are the conclusions drawn adequately supported by the results?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Immunology, Cell and Molecular Biology, Angiogenesis, Pathology, Anatomy

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 19 Jun 2023

Chethana Bolanthakodi

The manuscript entitled "Clinical equivalence of Trusynth fast[®] and Vicryl rapide[®] polyglactin 910 fast absorbing sutures on maternal morbidity experienced by women following episiotomy repair: a single-blind, randomized study" by Devi *et al.* is quite interesting. The manuscript is well-written and provides additional evidence in the literature on the safe usage of polyglactin sutures. Detailed methodology and results have been provided. However, minor changes are required to improve the manuscript.

Authors' response: We appreciate your valuable time and efforts invested in reviewing this manuscript.

Additional comments

1. **Comment:** In the introduction section, provide characteristic features of Trusynth Fast sutures, if any previous studies have been conducted using it; they need not to be randomised but any general studies, suggesting the qualities of the suture.

Response: It is to bring to your attention that no studies are available in the literature on Trusynth Fast[®] suture. However, we have added studies related to fast-absorbing polyglactin 910 sutures in the introduction. [Page 4].

Further, the characteristic features of both Trusynth Fast[®] and Vicryl Rapide[®] sutures are included in the Methodology section [Intervention; Page 6].

2. **Comment:** In the methodology section, provide IEC no. of Government Victoria Hospital-King George hospital also, if any, similar to other institute's registration number.

Response: No IEC number was provided on the ethical approval letter of King George Hospital. Therefore, it has not been mentioned in the manuscript.

3. **Comment:** As mentioned in the result section, 100 females were screened and 4 were excluded. Were 100 consecutive women screened for eligibility? If yes, why were further patients not screened or recruited when four patients met exclusion criteria?

Response: Female patients were recruited on the basis of inclusion and exclusion criteria rather than consecutive recruitments. The four females were excluded after randomization and during surgery due to cervical tear, perineal tear, and vulvar hematoma, as shown in the CONSORT flow diagram.

As mentioned in the sample size calculation, 76 females were to be included to attain significance. Thus, further recruitments were not conducted.

4. **Comment:** The study was conducted at two sites. How many patients were recruited from each site?

Response: Both sites recruited an equal number of patients i.e., 50 females at each site.

5. **Comment:** Figure numbers are not consecutive. Figure 1, 3, and then figure 2. Kindly rectify this.

Response: As per your suggestion, we have now rectified the same.

6. **Comment:** In Figure 3, it would be better to mention SD along with mean values of pain score and mean healing score. It is not required to be mentioned for the frequency of subjects.

Response: We have now mentioned the same.

7. **Comment:** In the post-operative profile of secondary endpoint analysis, the authors have mentioned that "The subjects of Vicryl Rapide® group took comparatively longer time for complete healing after episiotomy repair than Trusynth Fast® group, but the difference was not statistically significant (Table 2)."

Response: On applying a two-tailed t-test, the difference is found to be statistically significant with p value= 0.026.

I would like to know which statistical test was applied to compare the mean values?

Primarily, KS test was done to check the normality. The data was not found to be normally distributed thus, non-parametric approach, Mann-Whitney U test was used which resulted in p-value of 0.175. The difference was found to be statistically non-significant.

8. **Comment:** How many in clinic and telephonic follow up visits were conducted on Day 11, as mentioned in methodology? How did you verify the adverse events on telephonic follow-up?

Response: Equivalent numbers of in-clinic and telephonic follow-ups were conducted on Day 11.

During telephonic follow-up, the subjects were asked for the occurrence of any disease, injury, or any other signs for assessment of adverse events. In case of severe problems, the patients were asked for in-clinic visit.

However, adverse events such as vaginal discharge, fever, general body pains, vomiting, and headache were reported.

9. **Comment:** In the discussion section, I would suggest to add a few studies from the literature to discuss the findings of this study.

Response: Limited studies are available related to complications of episiotomy and post-episiotomy healing with polyglactin 910 sutures. We have included published articles as recent as possible to discuss the findings of the present study as described below:

- Improvement in perineal pain and a decrease in a number of analgesics with the use of polyglactin 910 suture has been discussed with respect to previous studies by Ononuju et al., 2020; Gupta et al., 2021; Samant et al., 2013 and Kettle et al., 2007 (Reference 2, 6, 9 and 11).
- Postpartum complications like infection, wound dehiscence and re-suturing, and requirement for hospital re-admissions have been discussed with respect to studies by Boushra and Rahman, 2013, and Dudley et al., 2017 (Reference 12 and 13). In addition, post-episiotomy inflammation, hematoma, infection and dehiscence, pain, extension of the episiotomy incision, and dyspareunia have been discussed after referencing the study of Gun et al., 2016 (Reference 14).
- Wound healing after episiotomy repair with Trusynth Fast® and Vicryl Rapide® group polyglactin 910 fast-absorbing sutures has been discussed with respect to studies by Howells and Abasi, 2020 and Kettle et al., 2007 (Reference 8 and 11).

Competing Interests: No competing interests were disclosed.

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