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ORIGINAL RESEARCH

Clinical Equivalence of Polyglycolic Acid Suture and Polyglactin 910 Suture for Subcutaneous Tissue Closure After Cesarean Delivery: A Single-Blind Randomized Study

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Purpose: The global rise in frequency of cesarean delivery raises the concern to minimize the post-operative complications, in order to improve the maternal and neonatal health. Closure of subcutaneous tissue following cesarean section closes dead space, hence reduces the wound complications. No previous study has compared the clinical equivalence of polyglycolic acid suture with polyglactin 910 suture for subcutaneous tissue closure following cesarean section. Therefore, this study compared the incidence of subcutaneous abdominal wound disruptions within the first 6 weeks of subcutaneous tissue closure with either of the sutures.

Patients and Methods: A single-blind, prospective, randomized study was conducted in two centres between February and November, 2021. Primiparous or multiparous women (18–40 years) with a singleton pregnancy requiring cesarean section were randomized to polyglycolic acid suture (Truglyde®) (n=54) and polyglactin 910 suture (Vicryl®) (n=54) group. The primary endpoint, incidence of subcutaneous abdominal wound disruptions within 6 weeks of cesarean delivery was evaluated. In addition, the secondary endpoints, incidence of post-operative subcutaneous abdominal wound disruptions for the study period, skin disruption, surgical site infection (SSI), seroma, hematoma, intraoperative handling, operative time, hospital stay, suture removal, microbial deposits on sutures, pain, time taken to resume normal activities, and adverse events were recorded.

Results: Non-significant difference in the incidence of subcutaneous abdominal wound disruptions, skin disruption, SSI, seroma, hematoma, intraoperative handling characteristics, operative time, pain, duration of hospital stay, suture removal, microbial deposits, time taken to return to day-to-day activities, and adverse events were observed between the two treatment groups.

Conclusion: Following cesarean section, subcutaneous tissue closure using polyglycolic acid suture or polyglactin 910 suture was not associated with incidence of subcutaneous abdominal wound disruptions. Additionally, non-significant differences regarding secondary endpoints between the groups suggested the clinical equivalence of the sutures.

CTRI Registration Number: CTRI/2020/12/029737; Registration date: 11/12/2020.

Keywords: abdominal wound disruption, cesarean delivery, polyglactin 910 sutures, polyglycolic acid sutures

Introduction

Cesarean section (CS) was documented in AD 1020 for the first time, and since then, it is evolving remarkably.[1] National Family Health Survey (NFHS) of India recorded a rise in CS from approximately 9% (NFHS-3) in 2005 to approximately 17% (NFHS-4) in 2016.[2] Recent data of NFHS-5 (2019–2020) reported 60.7% CS delivery, with higher prevalence recorded across the southern states of India.[3] Existing literature suggested post-cesarean development of wound complications, viz. hematoma, seroma, and surgical site infection (SSI), that impaired maternal recovery by

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causing morbidity and mortality.[4–6] Subcutaneous tissue suturing was reported to reduce the risk of wound complications.[7]

An ideal suture is characterized by sterility, non-allergenic, good handling, adequate tensile strength, and the ability to eliminate dead space. Polyglycolic acid sutures are considered experimentally suitable and resistant to infections, with 50% tensile strength support for 25 days. On the other hand, polyglactin 910 suture retains 75% of its tensile strength till 14 days and 50% till 21 days.[8] However, no randomized clinical study has compared the clinical equivalence of polyglycolic acid suture with polyglactin 910 suture in subcutaneous tissue closure. Therefore, the present study attempts to compare the rate of subcutaneous abdominal wound disruptions after subcutaneous tissue closure with either polyglycolic acid suture or polyglactin 910 suture in women, who underwent CS.

Materials and Methods

Study Design

Between February and November 2021, a single-blind, prospective, randomized study was conducted in two centres. The primary objective was the comparison of polyglycolic acid suture with polyglactin 910 suture for subcutaneous abdominal wound disruptions within the first 6 weeks following cesarean delivery. The secondary objectives were to compare subcutaneous abdominal wound disruptions, tissue reaction, SSI, seroma and hematoma, intraoperative handling, time taken to return to normal activities, other adverse events, post-operative pain, and bacterial growth on the two suture materials (in case of infection/suture removal) between the polyglycolic acid and polyglactin 910 suture groups.

Ethical Approval

Clinical Trials Registry of India (CTRI) registration was done on 11/12/2020 with registration number CTRI/2020/12/029737. Approval was obtained from both the Institutional Ethics Committees of the participating sites: 1) KIMS Ethics Committee, Telangana, India and 2) Institutional Ethics Committee, IPGME&R, West Bengal, India. This study complies with the Declaration of Helsinki and is presented as per Consolidated Standards of Reporting Trials (CONSORT).

Study Participants

Primiparous or multiparous women, aged 18–40 years with a singleton pregnancy, good systemic and mental health, requiring cesarean delivery (Pfannenstiel incision) with Centers for Disease Control and Prevention (CDC) surgical wound classification class I were included after receiving written informed consent.

Women with low hemoglobin (<7 g/dl), urogenital tract infection within 2 weeks of delivery, bleeding disorders, allergy to the suture materials, stillbirth, surgical plan for vertical skin incision, and a history of similar surgical procedure or used an investigational device or drug within 3 months of becoming pregnant, who did not require subcutaneous suturing were excluded. Participation in another clinical study or unlikeliness of compliance to study procedure as per investigators opinion was also considered for exclusion.

Study Settings

Department of Obstetrics and Gynaecology, KIMS Hospital, Telangana, India, and Institute of Post Graduate Medical Education and Research and SSKM Hospital, West Bengal, India.

Interventions

Truglyde® (Healthium Medtech Limited) polyglycolic acid suture is a sterile, synthetic, absorbable, braided, and coated suture composed of homopolymers of glycolide (100%). Absorption of polyglycolic acid suture is completed within 90 days. Vicryl® (Ethicon, Johnson & Johnson) polyglactin 910 suture is a sterile, synthetic, absorbable, braided, and coated suture composed of a copolymer made from 90% glycolide and 10% L-lactide. Absorption of polyglactin 910 suture is essentially completed within 56–70 days. Both the sutures get absorbed at the site of implantation that begins with loss of its tensile strength, followed by mass, through the process of hydrolysis. Both the sutures are indicated for use in soft tissue approximation and/or ligation.

Randomization and Blinding

The participants were randomized using a computer-generated randomization sequence with varied block sizes of four, six, and eight. A sequentially numbered opaque sealed envelope technique was used for the randomization of the participants. A total of 109 eligible subjects were randomized to either the polyglycolic acid suture (n=54) or polyglactin 910 suture (n=55) group. The subjects were unaware of the allocation status in this study.

Closure of Subcutaneous Tissue

The subjects underwent CS at the baseline appointment if they met the inclusion criteria during the screening visit (Day 0). Pre-, intra-, and postoperatively, all customary aseptic precautions were taken per the established norms. Following fascial closure, the depth of the subcutaneous adipose tissue was determined and sutured with polyglycolic acid suture or polyglactin 910 suture. The skin was re-approximated in accordance with the standard operating procedure for surgical procedures at the institution, and dressed as per the standard of care. The participants were contacted again on visit 2 (Day 3), visit 3 (Day 4–7), visit 4 (Week 6), and visit 5 (Week 12) for follow-up.

Demographic Characteristics

Age, ethnicity, weight, height, vital signs, alcohol consumption and smoking history, ante- and post-partum profile along with medical/surgical history were recorded for both treatment arms.

Study Outcomes

Primary Endpoint

The primary endpoint was incidence of subcutaneous abdominal wound disruptions (infection in the tissue between rectus fascia and skin, hematoma, and seroma) within 6 weeks of CS.

Secondary Endpoints

The secondary endpoints, subcutaneous abdominal wound disruptions during the study period, skin disruption (~1 cm width separation of the wound), SSI (according to CDC guidelines, SSI occurring within 30 days, or up to 90 days after the surgery is superficial or deep SSI, respectively), seroma and hematoma (collection of blood or serous fluid surrounding the wound), intraoperative handling, duration of surgery (skin incision to closure) and hospital stay, time taken to resume normal activities, post-operative pain, adverse events, suture removal, and microbial deposits on sutures (in case of suture removal due to infection), were measured.

Suture handling characteristics, viz. memory, stretch capacity, ease of tissue passage, suture fraying, knot holding, security of knot, and knot tie-down smoothness, were rated on a five-point scale (5, 4, 3, 2 and 1 for excellent, very good, good, fair and poor, respectively). Visual analogue scale (VAS) was used to grade the pain after surgery (0–4 no pain, 5–44 mild pain, 45–74 moderate pain, and 75–100 severe pain). Any unexpected symptoms or clinical events during the study period were collected as adverse events.

Other standard details about antibiotic prophylaxis, number and size of sutures, subcutaneous tissue depth, perioperative complications, outcome of surgery, birth weight, and number of analgesics were captured.

Sample Size

A previous study reported 3% wound gaping, post-subcutaneous closure with polyglactin 910 suture, 6 weeks after cesarean delivery.[9] Based on this evidence, the proportion of subjects having subcutaneous abdominal wound disruptions within 6 weeks of CS in the standard polyglactin 910 suture arm was assumed to be 3%. Assuming a power of 80%, type I error of 5%, and a difference of 0.3% for the proportion of subjects having subcutaneous abdominal wound disruptions in the polyglycolic acid suture arm with a margin of non-inferiority (10% of the difference), sample size was determined as 48 in each arm. Further, considering 20% post-randomization exclusion and dropout, sample size was calculated as 58 in each group. So, a total of 116 subjects were screened for the study. Following the exclusion criteria, 54 subjects were randomized to polyglycolic acid suture group and 55 subjects to polyglactin 910 suture group.

Statistical Analysis

Version 28.0 of SPSS was used for all statistical calculations (SPSS, Chicago, Illinois, USA). Subjects having data on primary endpoint at the 12-week follow-up period were included in the per-protocol (PP) analysis. The *t*-test (for data that were normally distributed) or Mann–Whitney *U*-test (distribution-free data) was used to compare all continuous variables. The Chi-square test or Fisher's Exact test was used to compare all qualitative variables, which were all reported as percentages or proportions. The Chi-square test was used to compare the primary endpoint, which was the proportion or percentage of participants with wound disruptions. Depending on the variable's qualitative or quantitative nature, the secondary endpoints were reported as proportions/percentages or as mean + SD. Statistical significance was considered when the p-value was less than 0.05.

Results

Between February and August 2021, 116 women were screened and last subject's follow-up was completed in November 2021. A total of 7 subjects met exclusion criteria and 1 subject was lost to follow-up (Figure 1); therefore, the PP set consisted of 108 subjects [polyglycolic acid suture (n=54) and polyglactin 910 suture (n=54)], who received the allocated intervention and completed the study.

Baseline Demographics and Other Relevant Characteristics

All study participants were Indians, with no smoking or alcohol history. Baseline demographics, vital signs, and obstetric details were also comparable between the groups (Table 1). In both groups, 25 (46.29%) subjects had a medical/surgical history (p=1.00).

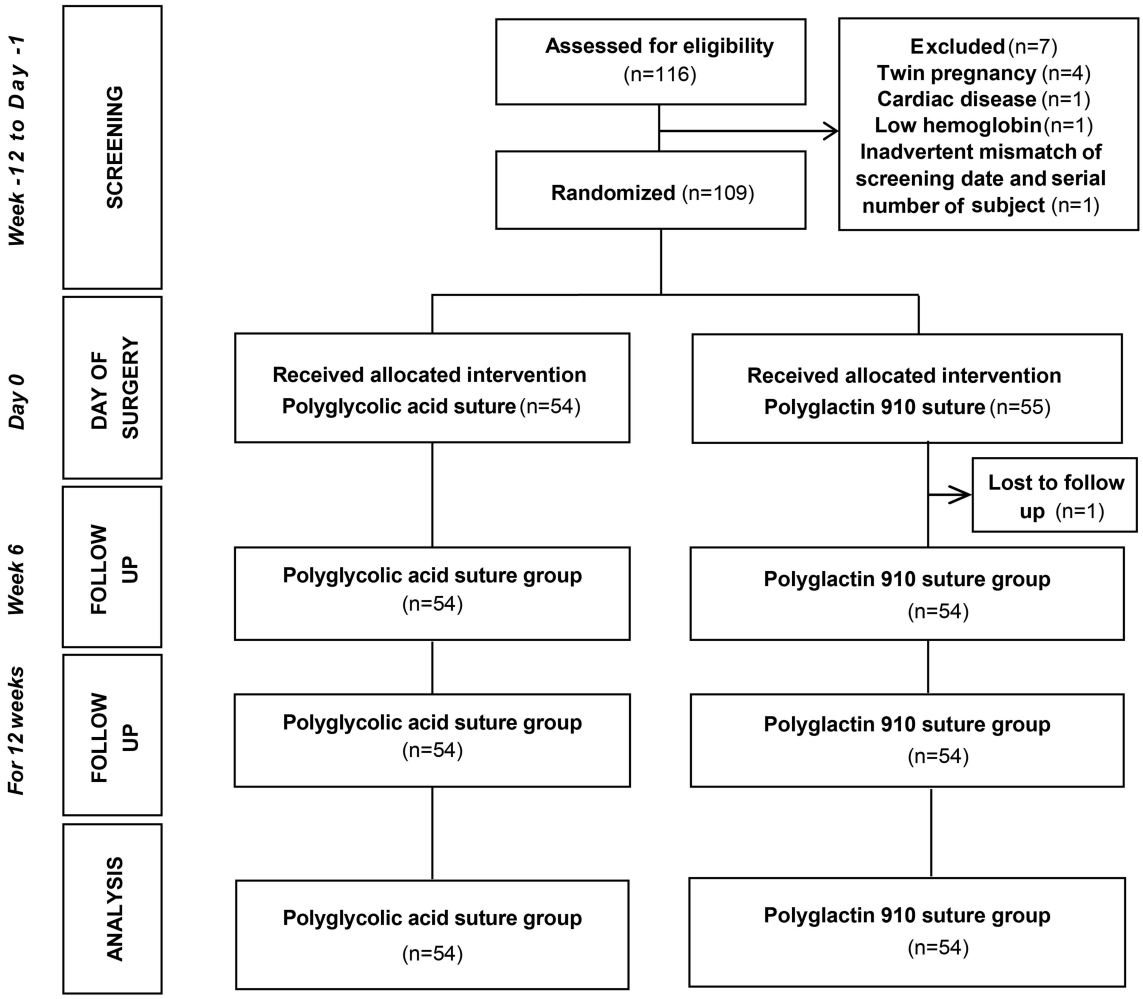

Figure 1 CONSORT flow chart of study design.

Table 1 Baseline Characteristics of the Study Participants

Characteristics		Polyglycolic Acid Suture (n=54)	Polyglactin 910 Suture (n=54)	p value
Demographics				
Age (years), Mean±SD		26.92±5.37	27.67±4.99	0.45
Weight (kg), Mean±SD		73.68±8.07	73.28±9.88	0.82
Height (cm), Mean±SD		157.25±6.38	158.25±9.50	0.52
BMI (kg/m^2), Mean±SD		29.88±3.68	29.35±3.96	0.47
Vital signs				
Pulse rate (beats/minute), Mean±SD		84.72±10.38	84.48±12.00	0.91
Respiratory rate (breaths/minute), Mean±SD		19.24±2.14	18.87±2.59	0.42
Systolic blood pressure (mmHg), Mean±SD		117.76±14.73	119.06±17.08	0.67
Diastolic blood Pressure (mmHg), Mean±SD		77.02±8.04	78.24±8.70	0.45
Obstetric details				
Gestation period (weeks), Mean±SD		37.16±3.16	38.10±2.16	0.07
Parity, n (%)	0	42 (77.78)	47 (87.04)	0.42
	1	11 (20.37)	6 (11.11)	
	2	1 (1.85)	1(1.85)	
	≥3	0	0	
Gravida, n (%)	1	33 (61.11)	40 (74.07)	0.32
	2	15 (27.78)	9 (16.67)	
	≥3	6 (11.11)	5 (9.26)	
Fetal presentation in utero, n (%)	Breech	4 (7.41)	4 (7.41)	0.60
	Cephalic	50 (92.59)	49 (90.74)	
	Transverse	0	1 (1.85)	
Reason for cesarean section, n (%)	Fetal Distress	35 (64.82)	39 (72.22)	0.25
	Gestational Hypertension	1 (1.85)	1 (1.85)	
	Gestational/Uncontrolled Diabetes Mellitus	3 (5.56)	0	
	Intrauterine Growth Retardation	9 (16.67)	8 (14.82)	
	Maternal Request	1 (1.85)	1 (1.85)	
	Post-myomectomy	1 (1.85)	0	
	Septate Uterus	1 (1.85)	1 (1.85)	
	IUI and IVF Conception	3 (5.56)	4 (7.41)	
Birth weight of infant (Kg), Mean±SD		2.63±0.72	2.78±0.55	0.24

Abbreviations: SD, standard deviation; BMI, body mass index; IUI, intrauterine insemination; IVF, in vitro fertilization.

Primary Endpoint Analysis

The subjects of both groups experienced no incidence of subcutaneous abdominal wound disruptions within 6 weeks of CS.

Secondary Endpoint Analysis

Intraoperative Profile

All the subjects received spinal anesthesia and antibiotic prophylaxis intraoperatively (p=1.00). One suture of size 1–0 or 2–0 was used in majority of study participants (105/108) for subcutaneous tissue closure, using either continuous or interrupted technique. A "fair" or "poor" rating was not provided to any of the suture handling parameters. Higher "excellent" scores were noted for ease of passage, memory, knot security, and knot tie-down in polyglycolic acid suture

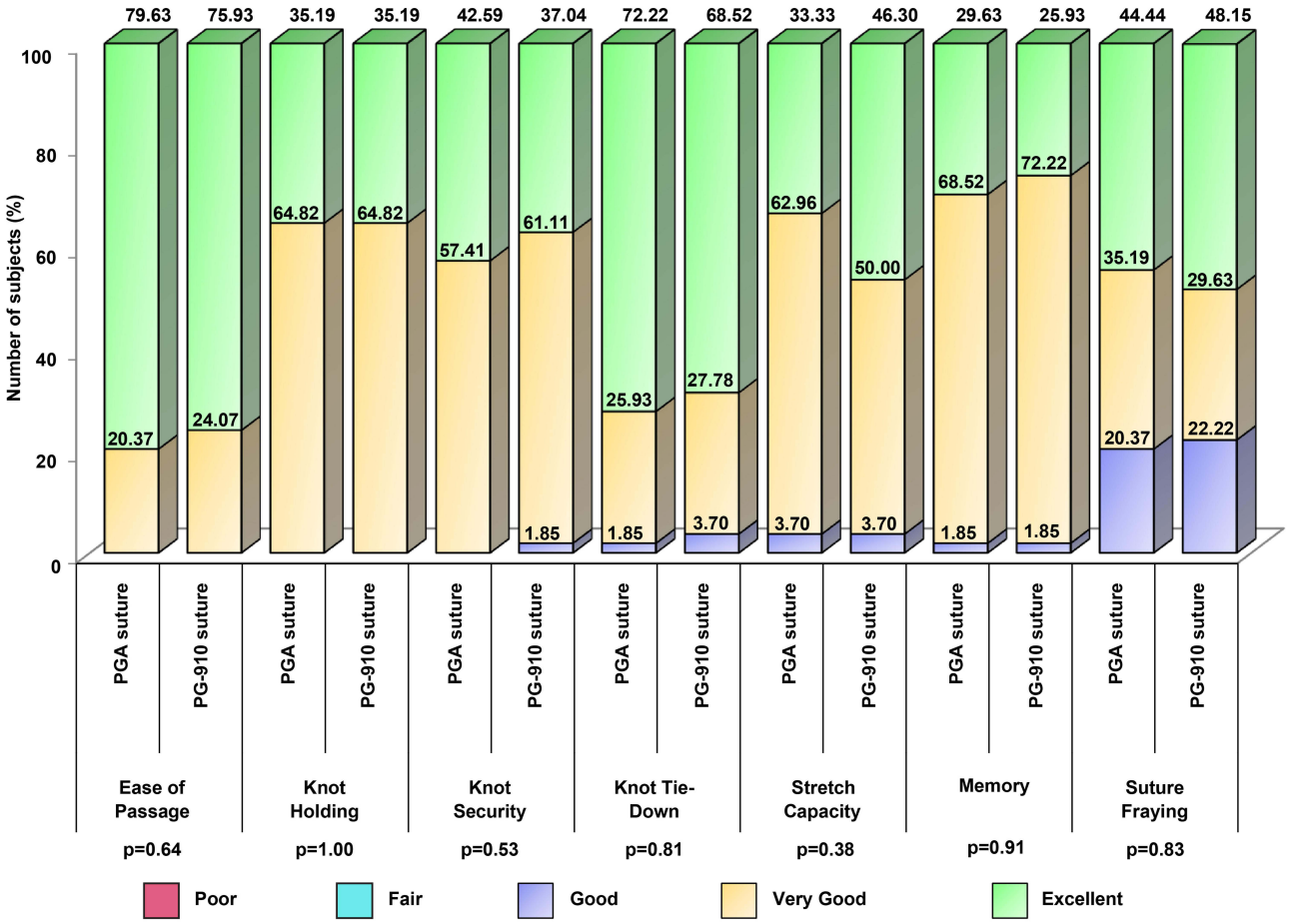

Figure 2 Intraoperative suture handling parameters [polyglycolic acid suture (PGA) (n=54) and polyglactin 910 suture (PG-910) (n=54)].

group and for stretch capacity and suture fraying in polyglactin 910 suture group, but all these parameters were comparable (Figure 2). Additionally, no suture-related challenges and perioperative complications were noted in any group. The outcome of surgery was marked as good in all subjects of both groups. Other intraoperative subject profile is summarized in Table 2.

Post-Operative Profile

The pain started after 3.02 and 3.53 hours of surgery in subjects randomized to polyglycolic acid suture and polyglactin 910 suture groups, respectively (Table 2). With each passing visit, the pain gradually decreased in intensity in both studied groups (Figure 3A and B). Similarly, the mean number of analgesics also declined (Table 2).

Incidence of subcutaneous abdominal wound disruptions was not observed at any follow-up visit. There was also no incidence of skin disruption, deep SSI, hematoma and seroma, suture extrusion, and residual suture removal in both the groups. On day 4, one (1.85%) subject in the polyglycolic acid suture group had superficial SSI, characterized by pus on stitch line and a gaping of 0.5–0.6 cm, which was resutured with one knot. However, the gaping did not meet the criteria of skin disruption of at least 1 cm in width. During Week 6, two (3.70%) subjects in the polyglycolic acid suture group had superficial SSI. One subject had serous discharge from the scar line and a gaping of <0.5 cm, which did not require skin resuturing. The other subject had slight pus on stitch line. None of the occurrences were device-related. Following treatment, all three subjects recovered and continued with the study. None of the subjects in any group required readmission to hospital. Non-serious, non-device-related adverse events, viz. COVID-19 infection (1.85%), constipation (1.85%), upper respiratory tract infection (URTI) (3.70%), headache (3.70%), fever (7.41%) and cold (1.85%) in polyglycolic acid suture group, while nausea (1.85%), URTI (1.85%), fever (1.85%) and hyperprolactinemia (1.85%)

Table 2 Intraoperative and Post-Operative Characteristics of the Study Participants

Characteristics		Polyglycolic Acid Suture (n=54)	Polyglactin 910 Suture (n=54)	p value
Intraoperative profile				
Total operative time (minutes), Mean±SD		39.94±17.15	42.22±20.67	0.53
Number of sutures used, Mean±SD		1.04±0.19	1.02±0.14	0.55
Number of sutures used, n (%)	1 suture 2 sutures	52 (96.30) 2 (3.70)	53 (98.15) 1 (1.85)	0.62
Size of sutures used, n (%)	Size 1–0 suture Size 2–0 suture	29 (53.70) 25 (46.30)	28 (51.85) 26 (48.15)	0.85
Thickness of subcutaneous tissue, n (%)	2 cm 3 cm 4 cm	11 (20.37) 14 (25.93) 29 (53.70)	9 (16.67) 18 (33.33) 27 (50.00)	0.68
Technique for closure of subcutaneous tissue, n (%)	Continuous Interrupted	29 (53.70) 25 (46.30)	28 (51.85) 26 (48.15)	0.33
Post-operative profile				
Time of onset of pain after surgery (hours), Mean±SD		3.02±2.34	3.53±2.86	0.22
Number of analgesics prescribed, Mean±SD	Day 0 Day 3 Day 4–7 Week 6 Week 12	1.85 ± 0.41 1.52 ± 0.57 1.39±0.49 0 0	1.83 ± 0.38 1.61 ± 0.53 1.48 ± 0.54 0.02 ± 0.14 0.02 ± 0.14	0.81 0.39 0.35 0.32 0.34
Hospital stay (days), Mean±SD		4.96±1.32	5.00±1.29	0.88
Return to normal day to day activity (days), Mean±SD		26.26±18.20	25.59±15.84	0.88

Abbreviation: SD, standard deviation.

in polyglactin 910 suture group were recorded. The prescribed/concomitant medications during the study period are shown in Table 3.

Discussion

As per World Health Organization (WHO), the current global prevalence of CS is 21% that may rise to 29% by 2030.[10] Mirroring the global rise, India too has witnessed a steady increase in the prevalence of CS, as sixfold rise in CS rate is recorded in the last two decades.[11] Despite its effectiveness in saving maternal and neonatal life, CS can cause remarkable complications in the settings of unsafe surgery.[10] Since CS is commonly performed, it is necessary to propose safe intervention and evidence-based approaches to reduce the CS-associated post-operative complications. Closure of the subcutaneous tissue after rectus sheath closure has been associated with a reduction in wound complications.[7] The use of ideal suture material for subcutaneous tissue closure is needed to be established in the current clinical practice to enhance the surgical outcome. Polyglycolic acid and polyglactin 910 sutures are indicated for soft tissue approximation with adequate tensile strength,[8] but not compared with each other for post-cesarean subcutaneous tissue closure. The present study is the first in its kind, comparing polyglycolic acid suture with polyglactin 910 suture for subcutaneous tissue closure following CS in homogenous populations (in terms of ethnicity, demographic, vital signs, and obstetric details).

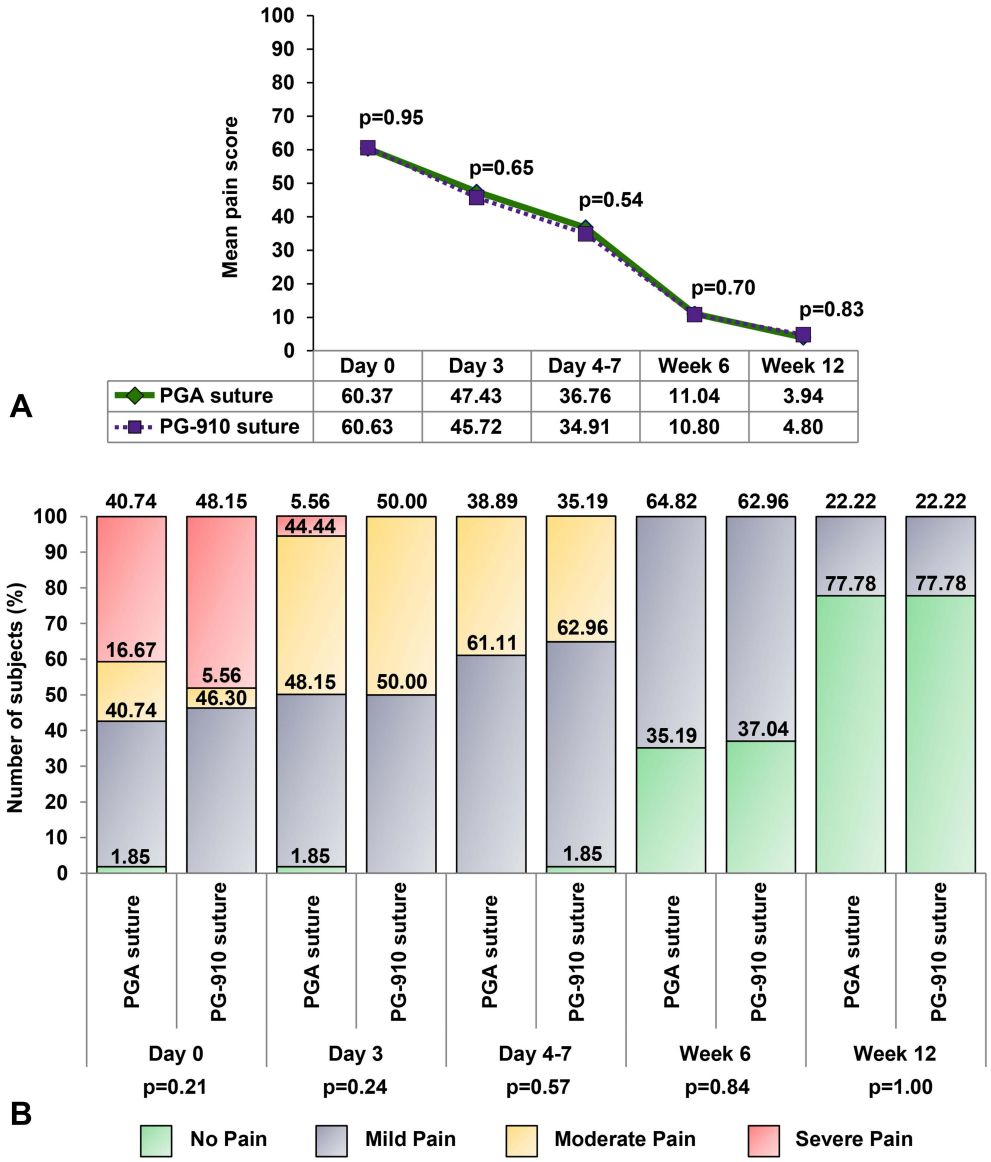

Figure 3 Change in (**A**) mean pain and (**B**) grade of pain across follow-up visits [polyglycolic acid suture (PGA) (n=54) and polyglactin 910 suture (PG-910) (n=54)].

With CS, risk of maternal infections, haemorrhage, transfusion, thromboembolism, anaesthetic complications, and other organ injuries persists.[1] After undergoing CS, up to 11% of the women were reported to develop wound complications; obese women were especially at higher risk.[12] Incomplete wound healing leads to wound disruption or wound separation that generally occurs within 5–8 days of surgery.[13] The closure of the lower part of the subcutaneous tissue (if thickness is >2 cm) reduces wound disruption rate by decreasing the rate of seroma.[14] This is because subcutaneous tissue closure eliminates the dead space and reduces tension on the skin layer, thereby lowering wound complications and improving cosmetic outcomes.[7,15] Majority of the subjects in the present study had a subcutaneous thickness of 4 cm. However, no post-operative incidence of subcutaneous abdominal wound disruptions was recorded even after 12 weeks of subcutaneous closure with either polyglycolic acid or polyglactin 910 sutures.

A meta-analysis of 10 studies, which have included a total of 3696 women undergoing CS, found that subcutaneous tissue closure reduced the frequency of seroma and wound infection, though the incidence of hematoma remained unaltered.[7] In another study, 34% reduction in wound complications was also recorded after subcutaneous tissue suturing.[12] A previous study reported a significantly higher incidence of hematoma and non-significant, but a higher incidence of SSI in women, who did not have subcutaneous closure after CS.[15] Another study demonstrated no effect of

Table 3 Details of Concomitant or Prescribed Medications

Prescribed Medications	Polyglycolic Acid Suture (n=54)	Polyglactin 910 Suture (n=54)
***Analgesics*, n (%)**		
Paracetamol	54 (100.00)	53 (98.15)
Tramadol	52 (96.30)	54 (100.00)
***Antibiotics*, n (%)**		
Ceftriaxone	54 (100.00)	53 (98.15)
Metronidazole	25 (46.30)	18 (32.33)
Cefuroxime	19 (35.19)	14 (25.93)
Gentamycin	21 (38.89)	16 (29.63)
Amoxycillin	20 (37.04)	17 (31.48)
Clavulanic acid	19 (35.19)	16 (29.63)
Mupirocin	19 (35.19)	17 (31.48)
***Delivery medications*, n (%)**		
Tranexamic acid	22 (40.74)	18 (33.33)

subcutaneous closure on hematoma and wound infection.[7] In the present study, incidence of skin disruption, deep SSI, seroma and hematoma did not occur in any study participant. However, incidents of superficial SSI were noted in the polyglycolic acid suture group. The infections were not suture related as they took place on the cutaneous stitch line, where a different suture was used. Re-hospitalization of the subjects due to post-operative complications was not required during the entire study duration. Moreover, all the subjects indicated recovery and wound healing by means of reduction in post-operative pain and analgesic number with each follow-up visit. The subjects of both groups resumed their regular day-to-day activities at a similar time (~26 days). In addition, there were no device-related adverse events in the study.

Primary and secondary outcomes of this study can be generalized and validated to be incorporated into clinical practices. Equivalent results of both sutures indicated the use of polyglycolic acid suture for not only post-cesarean subcutaneous tissue closure but also for all other surgeries indicated for polyglactin 910 suture. Limitation of the present study includes 1) given that the study's investigators were not blinded, there could be a bias favoring one suture over the other and 2) the risk of overall wound complications are lesser in this patient population as these were clean surgeries.

Conclusion

In summary, we found that subcutaneous tissue closure after CS using either Truglyde® polyglycolic acid suture or Vicryl® polyglactin 910 suture was not associated with incidence of subcutaneous abdominal wound disruptions. Additionally, non-significant differences regarding tissue reaction, SSI, seroma and hematoma, intraoperative handling, time taken to return to normal activities, and post-operative pain between the groups suggested the clinical equivalence of the sutures.

Data Sharing Statement

The data of this study are available at https://doi.org/10.6084/m9.figshare.20353428/1.[16]

Informed Consent

Written informed consent from all subjects was obtained before recruitment in the study.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

AKM and DTS work for Healthium Medtech Limited, which manufactures Truglyde® polyglycolic acid suture. CRVD, RR, and SK report no conflicts of interest in this work.

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