Study and Compare the Efficacy of 2 Suture Materials: Poliglecaprone 25, Polyglactin 910 as Subcuticular Skin Stitches in Women Undergoing Elective Cesarean Section

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Abstract

Objectives: To compare the efficacy of two suture materials, that is, poliglecaprone 25 and polyglactin 910 as subcuticular skin stitches in post-cesarean women.

Study Design: This study was a prospective comparative study.

Study Setting and Study Duration: This study was conducted in the Department of Obstetrics and Gynaecology, Indira Gandhi Government Medical College, Nagpur, a Tertiary Care Center in Central India, for 2 years after approval from the Institutional Ethical Committee.

Inclusion Criteria: All pregnant women undergoing elective cesarean section for the first time with hemoglobin more than 10 g % done in same operation theater using same technique of cesarean section as per the hospital standard protocol and by qualified obstetrician, using Pfannenstiel incision. The participants were then assessed for the following parameters - pain, tenderness, swelling, induration, discharge from wound, dehiscence, wound healing, and cosmesis on day 4, day 8, day 15, day 30, and day 45. Participants with healthy wound after removal of sutures were discharged on the 8th post-operative day and followed up in outpatient department on day 15, day 30, and day 45. Pain and tenderness were assessed on the basis of visual analog scale. All data were analyzed for categorical and continuous variables such as age, properties of suture materials, and post-operative wound complications, especially in relation to type of suture materials used for subcuticular skin incision closure.

Result: Poliglecaprone 25 is the most efficacious, with least wound complications, provides better cosmetic outcome compared to polyglactin 910 in cesarean skin closure but little costlier than poliglecaprone 25.

Key words: Cesarean section, Elecive, Poliglecaparone 25, Polyglactin 910, Suture materials

INTRODUCTION

Cesarean section is one of the most commonly performed abdominal operations on women worldwide. Its rate has

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increased markedly in recent years and is about 20-25% of all childbirths in most developed countries.¹

Wound infection can cause serious complications such as necrotizing fasciitis, rupture of the fascia, or dehiscence of the wound. The infection occurs in about 3-6% of women who undergo cesarean delivery. These women translate into a substantial portion of the population, and hence there is a load on the financial resources of health-care system. The use of sutures for tissue approximation is the oldest and still the most common form of wound closure. The oldest known suturing material used on

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humans dates back to 1100 BC, and the oldest known suturing material used on live human tissue dates back to 600 BC. These ancient sutures comprised of natural material such as linen, human hair, cotton, and flax and did not change until the 1800's. Through the 18th century into the 19th century, rapid improvement occurred and new materials were introduced into the field of sutures. By 1901, sutures could be found in the form of catgut and kangaroo gut kept in sterile glass tubes, gold and silver wire, silkworm gut, silk, cotton, linen, tendon, and intestinal tissue from many forms of animals.⁴

In modern times, a variety of surgical techniques and suture materials for all elements of the cesarean section operation are in use.⁵ Staples, adhesives, tape, and sutures are commonly used for skin closure in cesarean section. However, there is no enough evidence to say whether any particular technique for closing the abdominal wall during cesarean section is better than the others. Many of these have not yet been rigorously evaluated in randomized controlled trials (RCTs), and it is not known whether or not they are associated with better outcomes.

Most of the times in surgeries, the choice of suture material has been largely surgeon's choice depending on the availability of suture material. Subcuticular stitches have been used for the closure of surgical wounds with good cosmetic results. Such stitches have now been proven to offer a great advantage in terms of proper healing and cosmetics.

Ideally, a wound closure material and method should be cost-effective, time-efficient, easy to perform, and produce the optimal cosmetic result. The primary goals of treating wounds in general and skin incisions, in particular, are rapid closure with the creation of a functional and esthetic scar.⁶

Although sutures are used frequently in surgery, there are few reviews available in the literature that compare or review the attributes and qualities of sutures.⁷

As there is a lack of enough evidence regarding the best suture materials for cesarean skin closure, our aim is "to study and compare the efficacy of 2 suture materials poliglecaprone 25, polyglactin 910 as subcuticular skin stitches in women undergoing elective cesarean section." The ultimate aim is to choose the suture material which is cheap, cost-effective, and with least complications.

Aims and Objectives

1. To study the efficacy of two suture materials in terms of pain, tenderness, swelling, induration, discharge, wound healing, and cosmesis, that is, poliglecaprone 25, polyglactin 910 in wound healing.

- 2. To compare the efficacy of these suture materials.
- 3. To search the suture material which is cheap, costeffective, and with least complications.

MATERIALS AND METHODS

This was a prospective, observational study conducted in the Department of Obstetrics and Gynaecology, in a tertiary care center in Central India, for 2 years after approval from the Institutional Ethical Committee.

Inclusion Criteria

- 1. Participants undergoing elective cesarean section for the first time.
- 2. Hemoglobin more than 10 g %.

Exclusion Criteria

Were previous abdominal surgeries including previous cesarean section, medical illness - pulmonary Koch's, bronchial asthma, diabetes, hypertension, hematological disorders, skin infections, and emergency obstetrics indications.

Methods

A total of 240 women fulfilling inclusion and exclusion criteria as above were enrolled for the present study. They were divided into 2 groups of 120 each by systematic sampling technique.

- In Group 1: Poliglecaprone 25 (2-0) (monocryl, centisynth) was used as subcuticular stitch for skin closure.
- In Group 2: Polyglactin 910 (2-0) (vicryl, centicryl, and trusorb) was used.

Elective cesarean section was done in the same operation theater for various indications in both the groups by using pfannenstiel incision using same operative technique and respective suture material was used for skin closure as per the group to which the study participant belonged (i.e., Group 1 poliglecaparone 25, polyglactin 910). All cesarean sections were done by qualified obstetricians as per the standard hospital protocols. Both groups primarily received the same form of treatment including antibiotics and analgesics. The participants were then assessed for the following parameters - pain, tenderness, swelling, induration, discharge from wound, dehiscence, wound healing, and cosmesis on day 4, day 8, day 15, day 30, and day 45. Participants with healthy wound after removal of sutures were discharged on the 8th post-operative day and followed up in outpatient department on day 15, day 30, and day 45. Pain and tenderness were assessed on the basis of visual analog scale. It has rating of no pain at one end and unbearable pain at another end with gradings of mild, moderate, and severe. The rest of the parameters were assessed as follows: Swelling and induration assessed in form of erythema, edema, and localized hardening of tissue; discharge from the wound described as serous, serosanguinous, or purulent, wound dehiscence as superficial or deep; and wound healing and cosmesis by the Modified Hollender Cosmesis Scale, which was composed of six components:

- 1. Step-off borders (0 for yes, 1 for no).
- 2. Contour irregularity puckering.
- 3. Scar width <2 mm.
- 4. Edge inversion sinking, curling.
- 5. Inflammation redness, discharge.
- 6. Overall cosmes is (0 = poor, 1 = acceptable).

The wound score addresses 6 clinical variables: Absence of step-off, contour irregularities, wound margin separation >2 mm, edge inversion, excessive distortion, and overall cosmetic appearance. Each of these categories is graded on a 0-or 1-point scale. A total cosmetic score is derived by the addition of the scores of the 6 categorical variables. A score of 6 is considered optimal, while a score of <5 suboptimal. All data were analyzed for categorical and continuous variables such as age, properties of suture materials, and post-operative wound complications, especially in relation to type of suture materials used for subcuticular skin incision closure. The information regarding the various parameters was then filled in the pro forma of the respective patient. Statistical tests were applied and P value was calculated using Chi-square test and Fischer's exact test. Data obtained were evaluated with the help of relevant statistical analysis using Epi Info Software to compare two groups.

OBSERVATION AND RESULTS

From Table 1, it is obvious that there is statistically significant difference related to post-operative wound complication parameters between Group 1 and Group 2.

Table 1: Comparison of post-operative wound complications parameters on day 4 between suture materials

Post-operative wound complications	Group 1 poliglecaprone 25 n=120 (%)	Group 2 polyglactin 910 <i>n</i> =120 (%)	P value Chi-square test
Pain	28 (23.3)	56 (46.7)	0.0001 significant
Tenderness	27 (22.5)	54 (45.0)	0.0001 significant
Swelling	12 (10.0)	43 (35.8)	0.0001 significant
Discharge	0 (0.0)	14 (11.7)	0.0001 significant
Induration	12 (10.0)	42 (35.0)	0.0001 significant
Dehiscence	0	0	

From Table 2, it is obvious that there is statistically significant difference related to post-operative wound complication parameters between Group 1 and Group 2.

From Table 3, it is obvious that there is no statistically significant difference related to post-operative wound complication parameters between Group 1 versus Group 2.

- Out of total 240 participants, 191 (79.58%) were discharged on the day 8, 29 (12.08%) participants required admission beyond 8 days up to 15 days, 42 (17.50%) required admission for more than 15 days.
- In Group 1, 95.83% participants were discharged on day 8, 0.83% required admission beyond 8 days up to 15 days, 3.33% required admission for more than 15 days.
- In Group 2, 63.66% participants were discharged on day 8, 12.5% required admission beyond 8 days up to 15 days, and 24.16% required admission for more than 15 days.

From the Table 4, it is clear that the number of participants with severe pain was maximum in Group 2, that is, 25.0% on day 4, 22.5% on day 8, and 20.8% on day 15.

On day 30, 1 (0.8%) participant had moderate and 3 (2.5%) had mild pain in Group 2, whereas there was no complain of pain in Group 1.

On day 45, 1 (0.8%) patient had mild pain in Group 2, whereas there was no complain of pain in Group 1

The wound healing and cosmesis were assessed on day 30 and day 45 by Modified Hollander's Scale where wound evaluation score (WES) of 6/6 was graded as "excellent."

Maximum number of participants, that is, 112 (93.3%) and 115 (95.8%) from Group 1 showed excellent wound healing at day 30 and day 45 of caesarean section as compared to 74 (61.66%) and 80 (66.6%) from Group 2.

DISCUSSION

Tables 1-7 shows the comparison of post-operative wound complications between the three suture materials on days 4, 8, 15, 30, and 45 of cesarean section.

Pain

In our study, pain and tenderness were significantly less with poliglecaprone 25 as compared to polyglactin 910 similar findings were noted in a study by Regan and Lawrence.⁹ at the Center of Dermatologic Surgery at Cooper University Hospital. This study was conducted on 140 patients to compare poliglecaprone 25 and polyglactin 910 in

Table 2: Comparison of post-operative wound complications parameters on the day 15 between both groups among each other

Post-operative wound complications	Group 1 poliglecaprone 25 n=120 (%)	Group 2 Polyglactin 910 <i>n</i> =120 (%)	Total <i>n</i> =240 (%)	P value Group (1 vs. 2)
Pain	20 (16.7)	45 (37.5)	65 (26.7)	0.001 significant
Tenderness	21 (17.5)	44 (36.7)	65 (26.9)	0.001 significant
Swelling	9 (7.5)	33 (27.5)	42 (17.5)	0.0001 significant
Discharge	4 (3.3)	29 (24.2)	33 (11.7)	0.0001 significant
Induration	9 (7.5)	32 (26.7)	41 (17.2)	0.0001 significant
Dehiscence	0 (0.0)	7 (5.8)	7 (2.2)	0.014 significant

Table 3: Comparison of post-operative wound complications parameters on day 30 between two groups among each other

Post-operative wound complications	Group 1 poliglecaprone 25 n=120 (%)	Group 2 Polyglactin 910 n=120 (%)	Total <i>n</i> =240 (%)	P value group (1 vs. 2)
Pain	0 (0.0)	4 (3.3)	4 (1.1)	0.122 not significant
Tenderness	0 (0.0)	4 (3.3)	4 (1.1)	0.122 not significant
Swelling	0 (0.0)	2 (1.7)	3 (0.8)	0.498 not significant
Discharge	0 (0.0)	4 (3.3)	4 (1.1)	0.122 not significant
Induration	0 (0.0)	2 (1.7)	3 (0.8)	0.498 not significant
Dehiscence	0 (0.0)	4 (3.3)	4 (1.1)	0.122 not significant

Table 4: Distribution of participants according to severity of pain by VAS on post-operative days 4, 8, 15, 30, and 45

Post-operative days	Severity of pain by VAS	Suture m	Total n=240 (%)	
		Poliglecaprone 25 n=120 (%)	Polyglactin 910 <i>n</i> =120 (%)	
Day 4	Mild	12 (10.0)	8 (6.7)	20 (8.33)
-	Moderate	13 (10.8)	18 (15.0)	31 (12.92)
	Severe	3 (2.5)	30 (25.0)	32 (13.33)
Day 8	Mild	12 (10)	12 (10)	24 (10.00)
	Moderate	12 (10)	17 (14.2)	29 (12.08)
	Severe	3 (2.5)	27 (22.5)	30 (12.5)
Day 15	Mild	15 (12.5)	11 (9.1)	26 (10.83)
•	Moderate	3 (2.5)	9 (7.5)	12 (5.0)
	Severe	2 (1.7)	25 (20.8)	26 (10.83)
Day 30	Mild	0	3 (2.5)	3 (1.25)
·	Moderate	0	1 (0.8)	1 (0.41)
Day 45	Mild	0	1 (0.8)	1 (0.41)

VAS: Visual analog scale

Table 5: Comparison of post-operative wound complications parameters on day 8 between two groups among each other

Post-operative wound complications	Group 1 poliglecaprone 25 n=120 (%)	Group 2 polyglactin 910 <i>n</i> =120 (%)	Total <i>n</i> =240 (%)	P value group (1 vs. 2)
Pain	27 (22.5)	55 (45.8)	82 (34.16)	0.0001 significant
Tenderness	27 (22.5)	54 (45.0)	81 (33.75)	0.0001 significant
Swelling	12 (10.0)	37 (30.8)	49 (20.41)	0.0001 significant
Discharge	2 (1.7)	34 (28.3)	36 (15)	0.0001 significant
Induration	12 (10.0)	37 (30.8)	49 (20.41)	0.0001 significant
Dehiscence	0 (0.0)	2 (1.7)	2 (0.83)	0.498 not significant

cutaneous surgery and it was found that poliglecaprone 25 was less painful than polyglactin 910 as it resulted in significantly less extruded sutures than did polyglactin 910 (3.1% vs. 11.4%). Similarly, Vats and Pandit Suchitra. Did to the control of the contr

conducted a randomized clinical trial on 90 patients at LTMMC, Sion Mumbai, to compare the suture materials in cesarean section and showed that poliglecaprone 25 absorbable suture is associated with significantly less pain

and tenderness at the suture site (P < 0.05) as compared to polyglactin 910.

Swelling and Induration

Our study showed that the number of participants with swelling and induration was significantly more in participants with polyglactin 910 as compared to poliglecaprone 25. Similar results were demonstrated in a study by Vats and Pandit Suchitra, which showed that incidence of swelling and induration is significantly (P < 0.05) less with poliglecaprone (monofilament suture) as compared to the multifilament polyglactin suture.

Discharge

Our study showed that the number of participants with discharge was significantly more with polyglactin 910 as compared to poliglecaprone (Table 8). Similar findings were noted in a study by Regan and Lawrence, which demonstrated that poliglecaprone 25 (3.1%) resulted in significantly less extruded sutures than did polyglactin

Table 6: Distribution of study participants according to hospital stay

Duration of hospital stay	Total number of participants n=240 (%)	Group 1 poliglecaprone 25 n=120 (%)	Group 2 polyglactin 910 <i>n</i> =120 (%)
8 days	191 (79.58)	115 (95.83)	76 (63.33)
8-15 days	29 (12.08)	1 (0.83)	15 (12.5)
>15 days	42 (17.50)	4 (3.33)	29 (24.16)
Total	360	120	120

Table 7: Comparison of wound healing and cosmesis between two suture materials

Groups	Excellent wound healing with WES (6/6)	
	At 30 days	At 45 days
Group 1 poliglecaprone 25 <i>n</i> =120 (%) Group 2 polyglactin 910 <i>n</i> =120 (%) Pearson Chi-square test value <i>P</i> value	112 (93.3) 74 (61.66) 39.42 0.0001	115 (95.8) 80 (66.6) 40.18 0.0001
	(significant)	(significant)

WES: Wound evaluation score

910 (11.4%), and hence found to be less inflammatory or infectious, less pustular, or papular. Similarly, Vats and Pandit Suchitra.¹⁰ showed that wound discharge is significantly (P < 0.05) less with poliglecaprone as compared to multifilament polyglactin suture. Molea et al.11 compared the biocompatibility and absorption times of three absorbable monofilament suture materials (polydioxanone, poliglecaprone 25, and glycomer 631) and showed near-total absence of acute inflammatory cells at 1 month and "extremely low-tissue reaction values with poliglecaprone 25." Similarly, LaBagnara¹² noted that poliglecaprone 25 was "nearly non-reactive in tissue and no cases of stitch abscess or excessive wound inflammation were found which also corresponds with our study. This could be explained by the fact that Islam and Ehsan¹³ conducted this study at Military Hospital, Rawalpindi, Pakistan, on a large sample size of two thousand patients.

Wound Dehiscence

In our study, wound dehiscence was significantly more in polyglactin 910 compared to poliglecaprone 25. It is in compliance with the study by Vats and Pandit Suchitra, 10 which showed that wound dehiscence and requirement of resuturing are significantly (P < 0.05) less with poliglecaprone as compared to the polyglactin suture. However, Sajid *et al.* 14 reported a systematic review of published RCTs and demonstrated that absorbable sutures do not increase the risk of skin wound dehiscence, rather lead to a reduced risk of wound dehiscence compared to non-absorbables which could be explained by the fact that non-absorbable sutures need to be removed manually, and if inadvertently removed in improperly healed wound, it may result in wound dehiscence.

Table 7 shows the comparison of excellent wound healing between suture materials assessed on the day 30 and day 45 of cesarean section.

The current study found that poliglecaprone 25 has excellent wound healing properties compared to polyglactin 910. Similar findings were found in a study by Niessen *et al.*, ¹⁵ which demonstrated that poliglecaprone 25 resulted

Table 8: Comparison of post-operative wound complications parameters among our study and Pandit Suchitra study

Post-operative n wound complications	Day 4		Day 8		Day 30	
	Pandit Suchitra study <i>P</i> value	Our study P value	Pandit Suchitra study P value	Our study	Pandit Suchitra study <i>P</i> value	Our study P value
Pain	No difference	0.0001 significant	No difference	0.0001 significant	No difference	0.122 not significant
Tenderness	>0.05 not significant	0.0001 significant	>0.05	0.0001 significant	Test invalid	0.122 not significant
Swelling	<0.05 significant	0.0001 significant	>0.05	0.0001 significant	Test invalid	0.498 not significant
Discharge	<0.05 significant	0.0001 significant	< 0.05	0.0001 significant	No difference	0.122 not significant
Induration	<0.05 significant	0.0001 significant	< 0.05	0.0001 significant	Test invalid	0.498 not significant
Dehiscence	>0.05 not significant		<0.05		Test invalid	0.122 not significant

in significantly less hypertrophic scars than polyglactin 910. Vats and Pandit Suchitra. Who showed that wound healing is excellent with poliglecaprone and polypropylene. However, Meiring et al. However, deiring et al. However, deference in wound cosmesis (P = 0.08 for incisions with "excellent" cosmetic result). Wounds were evaluated at 6 weeks post-operatively by a plastic surgeon blinded to the repair material and were assessed on a scale of excellent, good, fair, or poor. Our study shows that poliglecaprone 25 is superior over polyglactin 910 and polypropylene for subcuticular skin stitches in cesarean section.

Bezwada et al.17 published a paper on "monocryl suture, a new ultra-pliable absorbable monofilament suture" and showed that monocryl sutures display excellent handling properties, minimal resistance during passage through tissue, and excellent tensile properties. These sutures provide an in vivo breaking strength retention of approximately 20-30% after 2 weeks, considered by many to be the critical wound healing period and produces slight or minimal tissue reaction. Yag-Howard and Lavallee, 18 in their study showed that the absorbable monofilament poliglecaprone 25 can serve as the sole suture material in closing deep surgical defects involving subcutaneous and epidermal tissue with the benefits of providing esthetically pleasing outcomes, possibly due to the material's low tissue reactivity and clear colorless appearance, and cost-effectiveness. Additional advantages include increased versatility, ease of handling, and convenience. Some disadvantages include a slight stiffness of the suture material, which may require a surgeon to make minor adjustments to his/her knot tying technique, as well as a transparent appearance that may make suture removal more challenging when using the undyed version o suture material. However, the many benefits of using poliglecaprone 25 for closure of surgical defects outweigh the few disadvantages.

Summary

A prospective study was carried out in the Department of Obstetrics and Gynaecology in a Tertiary Care Center of Central India from October 2014 to September 2016.

This analysis was to study and compare the efficacy of two suture materials, that is, poliglecaprone 25, polyglactin 910 in subcuticular skin stitches in women undergoing elective cesarean section to establish the more efficacious and cost-effective suture material with least complications. A total number of 240 pregnant women undergoing elective cesarean section were divided in two groups by systematic sampling technique. Group 1 was given to poliglecaprone 25, Group 2 was given to polyglactin 910 for subcuticular skin closure. Both groups were followed up in post-operative period on days 4, 8, 15, 30, and 45 to assess the post-operative wound complication parameters such as

pain, tenderness, swelling, induration, wound discharge, dehiscence, wound healing, and cosmesis. Data thus obtained from all three groups were evaluated and compared with each other with the help of relevant statistical tests. The results of our study can be summarized as follows.

- 1. Out of total 240 study participants participated in the study,
 - (a) Maximum number of participants, that is, 124 (51.66%) belonged to the age group of 21-25 years. (b) Most of them, that is, 144 (60.0%) were primigravida. (c) Maximum number of participants, that is, 84 (35.0%) belonged to upper-lower class. (d) 60 (25%) were under the category of normal body mass index of 18.5-25. (e) 186 (77.5%) were booked, whereas 52 (22.5%) were unbooked cases. (f) Overall, the most common indication of cesrean section was breech (26.4%), followed by cephalopelvic disproportion (26.11%) and transverse lie (23.3%).
- 2. There was a statistically significant difference (P < 0.05) between Group 1 (poliglecaprone 25) and Group 2 (polyglactin 910) with respect to post-operative wound complications parameters, that is, pain, tenderness, swelling, discharge, and in duration as assessed on post-operative days 4, 8, and 15.
- 3. On a post-operative day 30, there were no wound-related complications with Group 1 (poliglecaprone 25), whereas 10 participants in Group 2 (polyglactin 910) had post-operative wound complications out of which 4 (3.3%) participants had pain, 4 (3.3%) had tenderness, 2 (1.7%) had swelling, 4 (3.3%) had discharge, 2 (1.7%) had induration, and 4 (3.3%) had dehiscence.
- 4. Severity of pain by VAS was significantly more with polyglactin 910 as compared to poliglecaprone 25 on the post-operative days 4, 8, and 15.
- 5. There was no complain of pain with poliglecaprone 25 and polyglactin 910 on day 30 and day 45 whereas with polyglactin 910; 1 (0.8%) participants had moderate and 3 (2.5%) had mild pain on day 30 and 1 (0.8%) had mild pain on day 45.
- 6. Overall, 42 (11.66%) women required prolonged hospital stay for more than 15 days out of which maximum 29 (24.16%) belonged to Group 2 (polyglactin 910) and minimum 4 (3.33%) belonged to Group 1 (poliglecaprone 25).
- 7. 93.3% participants in poliglecaprone 25 group, 61.66% in polyglactin 910 group had "excellent" wound healing and cosmesis as per Modified Hollander's scale on day 30 and the difference was statistically significant.
- 8. 95.8% of participants in poliglecaprone 25 group, 66.6% in polyglactin 910 group had "excellent" wound healing and cosmesis as per Modified Hollander's scale on day 45 and the difference was statistically significant.

CONCLUSION

Thus, from the present study, we can summarize that poliglecaprone 25 is the most efficacious, with least wound complications, provides better cosmetic outcome compared to polyglactin 910 in cesarean skin closure but little costlier than poliglecaprone 25.

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