Original Article

Comparison between Subcuticular Skin Closure by Different Suture Materials in Cesarean Delivery: An Interventional Randomized Controlled Clinical Trial

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ABSTRACT

Background: Although several studies compared absorbable and nonabsorbable suture, only one of these studies has found an increase in wound complications for nonabsorbable suture.

Objective: The objective is to compare the rate of wound complications among women who will undergo cesarean delivery through a Pfannenstiel skin incision followed by subcuticular closure with either polyglactin 910 sutures (VICRYL RAPIDE®; Ethicon), (DemeCRYL®; DemeTECH) or polypropylene (DemeLENE®; DemeTECH).

Materials and Methods: The prospective randomized controlled clinical trial conducted of 90 pregnant women scheduled for elective caesarean section and subdivided into 3 groups; group A: (30) women with subcuticular suture, synthetic, absorbable, coated, polyglactin 910, braided, undyed, 2-0, 75 cm, 26mm reverse cutting needle (VICRYL RAPIDE®; Ethicon), group B: (30) women with subcuticular suture, synthetic, absorbable, coated, polyglactin 910, braided, violet, 2-0, 75 cm, 36mm reverse cutting needle (DemeCRYL®; DemeTECH) and group C: (30) women with subcuticular suture, synthetic, non-absorbable, uncoated, polypropylene, monofilament, blue, 2-0, 100 cm, 40mm curved cutting needle (DemeLENE®; DemeTECH).

Results: This study found no statistically significant difference between study groups as regard wound complication including infection, hematoma, discharge and seroma. Also, the present study showed that there was no statistically significant difference between study groups as regard pain degree and scar complication included scar dehiscence, hypertrophic, hyper-pigmented, depressed and itching. Finally, the current study showed no statistically significant differences between 3 groups regarding to hospital stay and occurrence of allergy.

Conclusion: This study concluded that surgical site infections and other wound complications in skin closures with vicryl were similar to those identified with demecryl and polypropylene.

Key Words: Cesarean Delivery, Subcuticular Skin Closure; Suture Materials.

Received: 27 August 2022, **Accepted:** 27 August 2022

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ISSN: 2090-7265, February 2023, Vol.13, No. 1

INTRODUCTION

In the United States, the cesarean delivery rate in 2014 was 32.2%[1]. The incidence of wound complications after cesarean delivery has been reported from 3% to 30%[2].

Wound complications can include surgical site infection, hematoma, seroma, and wound separation[3]. Additional medical costs to treat a surgical site infection alone after cesarean delivery can be as high as $3,529 per case[4].

Although several studies compared absorbable and nonabsorbable suture, only one of these studies has found an increase in wound complications for nonabsorbable suture[5].

These studies had suboptimal designs to evaluate which suture material resulted in fewer cesarean wound complications. Physiologic wound healing involves five steps: inflammation, granulation, epithelialization, wound contraction, and scar maturation[6].

Suture materials differ in structural profiles and have different effects on these biological healing processes. The most widely used sutures for low-transverse cesarean skin incision closure in are polyglactin 910 and polypropylene[7].

Prolene is a synthetic, monofilament, nonabsorbable polypropylene suture. Its advantages include minimal tissue reactivity, durability and less infection. Disadvantages include fragility, high plasticity and high expense. Vicryl (polyglactin 910) is an absorbable, synthetic, usually

DOI:10.21608/ebwhj.2022.158890.1195

braided suture. Its advantages include strength and more cosmoses. Disadvantages include slow absorption by hydrolysis with more tissue reactivity and infection[8].

Vicryl Rapide suture has advantages such as avoidance of pain associated with suture removal and tissue damage, reduce burden on medical staff, and reduce time required for outpatient examinations, also support the usefulness of Vicryl Rapide in skin suture during surgery[9].

PATIENTS AND METHODS

This prospective interventional randomized controlled clinical trial was carried out on 90 pregnant women scheduled for elective caesarean section at operative theater of Ain Shams University Maternity Hospital from February till August 2021.

Inclusion criteria

Primigravida or not more than previous 1 cesarean section women aged 18-35 years old with viable fetus, no history of medical comorbidities, body mass index (BMI) ranged between 18.5 29.9 kg/m^2, hemoglobin (Hb) ≥ 10 gm/dl and underwent elective lower segment cesarean section were enrolled.

Exclusion criteria

Women with history of urogenital tract infection within 2 weeks before cesarean delivery, clinical signs of infection at the time of delivery including PPROM and intra-amniotic infection, medical comorbidities as hypertension, diabetes, etc., hypersensitivity to any of the suture materials, abnormal placentation as placental abruption or placenta previa, history of systemic corticosteroids intake during their pregnancy for 2 weeks or more, history of previous surgical site infection were excluded. Also immune compromised women and woman who refused to participate in the study or write consent were excluded.

Sampling Method

A randomization table for a convenience sample of cesarean section candidate

Sample size

- A total of 90 patients who were subdivided into 3 groups;

- Group A: (30) women with subcuticular suture, synthetic, absorbable, coated, polyglactin 910, braided, undyed, 2-0, 75 cm, 26mm reverse cutting needle (VICRYL RAPIDE®; Ethicon) was used in subcuticular skin closure.

- Group B: (30) women with subcuticular suture, synthetic, absorbable, coated, polyglactin 910, braided, violet, 2-0, 75 cm, 36mm reverse cutting needle (DemeCRYL®; DemeTECH) was used in subcuticular skin closure.

- Group C: (30) women with subcuticular suture, synthetic, non-absorbable, uncoated, polypropylene, monofilament, blue, 2-0, 100 cm, 40mm curved cutting needle (DemeLENE®; DemeTECH) was used in subcuticular skin closure.

- Sample size was inflated by 15% drop ratio, so the total sample size was 105.

Randomization

Patients were randomized using sequentially sealed opaque envelope method into three groups each including (30) patients, to ensure that every patient fulfilling the inclusion criteria had the same chance of participating in this study, randomization was guided by a table of random members by a computer-based program (using www.randomization.com).

Allocation and concealment

Women participating in the study were randomized by a computer-generated randomization sheet using MedCalc version 13. A total of 30 envelopes were numbered serially and, in each envelope, the corresponding letter which denotes the allocated group was put according to randomization table. Then all envelopes were closed and put in one box. When the first patient arrived, the first envelope was opened by whom, and the patient was allocated according to the letter inside and so on.

Study procedures

Pregnant women planning to undergo elective lower CS were counseled to be enrolled in the study.

After enrollment in the study, an informed written consent was taken from all participants before recruitment in the study and after explaining the purpose, possible risks and complications e.g., wound dehiscence and blood transfusion. All participants will be subjected to:

Complete history taking

- Personal history (age, duration of marriage, occupation),

- History of present illness (any current medical or surgical diseases and any current medication),

- Past history (any chronic medical disease or surgical procedures, known allergy, blood transfusions),

- Obstetric history (parity, gestational age, obstetric complications),

- Contraception and menstrual history.

Clinical Examination

- General examination was done for assessment of the patients vital data, general condition, weight, height, body mass index, pallor in anemic patients, cardiac and chest auscultation and lower limb assessment.

- Abdominal examination was done for assessment of fundal level, fetal lie, presentation, liquor volume and previous abdominal scar.

- Vaginal examination was done to exclude cervical changes, rupture of membranes and cervical polyp or fibroids.

Investigations

- **Labs:** CBC, coagulation profile, RH, blood group, viral markers, liver and kidney function tests, random blood sugar test.

- **Basic ultrasound examination** was done for all participants to assess (fetal life, fetal parameters, amniotic fluid and placental location).

All Caesarean deliveries were performed by a senior registrar capable of performing elective caesarean delivery.

All patients received prophylactic intravenous antibiotic (1st generation Cephalosporins e.g., Cefazoline® 2 gm) 30: 60 minutes before skin incision to be repeated if the operation lasts for more than 3 hours or blood loss is more than 1000 cc.

Cephalosporins were replaced by Ampicillin/Sulbactam in case of Cephalosporins hypersensitivity.

Patients were recruited consecutively 1-3 days prior to an elective (pre-labor, scheduled) CS during the routine preoperative assessment.

All patients were scheduled for an elective CS for various indications who agreed to participate in the study were included and provided signed informed consent.

Specific precautions

It was a routine lower segment caesarean section with the following precautions:

- All operations were performed under regional spinal anesthesia.

- Pfannenstiel skin incision was performed and lower transverse uterine incision and delivery of the baby followed by complete delivery of the placenta by controlled cord traction.

- The skin was closed either in group A running subcuticular suture, synthetic, absorbable, coated, polyglactin 910, braided, undyed, 2-0, 75 cm, 26mm reverse cutting needle (VICRYL RAPIDE®; Ethicon), group B by running subcuticular suture, coated, synthetic, absorbable, polyglactin 910, braided, 2-0, dyed, 75 cm, cutting needle (Vicryl®; Ethicon) and group C by running subcuticular suture, synthetic, non-absorbable, polypropylene, 2-0, blue, 75 cm, cutting needle (PROLENE®; Ethicon).

- Wound was covered by a sterile pad for 1 week postoperative and the patient wasgiven instructions regarding postoperative wound care (always keep the wound dry and clean)

Post-operative wound care

- All patients received non-steroidal anti-inflammatory drugs in form of (Diclofenac Sodium) 75 mg IM (one ampule) immediately post-operative then one ampule 12 hours postoperative.

- All patients were informed about warning symptoms which raise suspicion for any wound complications e.g., wound dehiscence and wound sepsis.

- Patients attended outpatient clinic 1-week post-operative to observe pain, infection and seroma.

- Women were instructed for postoperative wound care e.g., to always keep wound dressing dry and clean and in case it gets wet, it is to be dressed in an aseptic non-touch technique, using sterile gloves, sterile field, sterile equipment, solutions and disinfection wipes.

- Patient informed that the wound should be covered with dressing for at least 24-48 hours, dry wound area carefully following the shower, avoid touching the wound (unless it is necessary to), ensure that the patient regularly wash her hands especially before and after using the toilet and wearing comfortable cloths.

The appearance of the scars was evaluated one week after the CS by both the patient and the physician. For scar evaluation pain, infection and seroma.

Patient Scale

The Patient Scale contained six questions applying to pain, itching, colour, pliability, thickness and relief. Because it is too difficult for patients to make the distinction between pigmentation and vascularity, both characteristics were captured in one item i.e. colour.

Evaluation of the complications as

- Surgical site infection (SSI) (manifested by e.g., serous discharge, pus and/or erythema) were assessed by Southampton wound scoring system.

- Wound disruption and/or wound dehiscence (hematoma or seroma).

- Surgical site allergy to suture materials.

- Duration of surgery measured in minutes from closure of the subcutaneous fat layer to closure of the skin.

- Hospital stays measured in days after the CS (decision of discharge of patient from hospital is based on patients vital data, bowel motility and wound quiescence).

Post-Operative Pain Scale

The intensity of the pain indicated by the woman on a Post-Operative Pain Scale graded from 0 to 10, zero representing no pain at all, and 10 the worst possible pain imaginable.

Elimination of bias

- All cesarean deliveries were performed by an obstetric team having the same level of surgical skills.

- The observer of the cesarean deliveries scar was same for all patients using the same assessment scale.

STATISTICAL ANALYSIS

Statistical analyses were conducted using SAS version 9.1 (SAS Institute, Inc., Cary, NC). The randomization code was kept confidential by a single statistician until the end of study after the database had been cleaned and locked for data analysis. At this time the code was imported into the database. The chi-square test of association and Fisher's exact test was used for analysis of categorical data. The Pearson's chi-square test was used where applicable. Where assumptions for this procedure werent met, Fisher's exact test was used. Quantitative measures were analyzed using the two-tailed unpaired Student t-test and the Wilcoxon rank sum test. Statistical significance was defined as $P \leq 0.05$ without adjustments for multiple comparisons. The analysis, while occurring earlier than originally planned, was the final planned analysis. Hence, no adjustments were made to preserve alpha for subsequent analyses. Relative risks and 95% confidence intervals were presented for primary and secondary outcomes. All analyses were by intent-to-treat.

RESULTS

There was no statistically significant difference between study groups as regard age with *P value 0.507*, BMI with *P value 0.104*, GA with *P value 0.523*, gravidity with P value 0.226 and Parity with *P value 0.788* (Table 1).

Table 1: Demographic characteristics of study groups

Variable	Vicryl Group	Demecryl Group	Polypropylene Group	P value
Age (yrs)[1]	26.5±4.13	25.2±4.84	25.3±4.97	0.507[a]
BMI (kg/m^2)[2]	24.4±3.05	23.9±3.08	25.6±3.24	0.104[a]
GA (wks)[3]	39.7±1.14	39.5±1.16	39.4±1.1	0.523[a]
Gravidity[4]	2.7±1.53	2.9±1.6	3.4±1.6	0.226[a]
Parity[5]	1.2±1.04	1.36±1.21	1.43±1.16	0.788[a]

There was no statistically significant difference between study groups as regard operative time with *P value 0.560* and time of skin closure with *P value 0.356* (Table 2).

Table 2: Operative data

Variable	Vicryl group	Demecryl group	Polypropylene group	P value
Operative time (min)	40.43±5.59	40.96±6.67	39.26±6.37	0.560
Time of skin closure (min)	6.23±1.58	6.43±1.63	5.9±1.01	0.356

There was no statistically significant difference between study groups as regard wound complication (SSI, Wound dehiscence and allergy according to observer assessment scale (Table 3).

Table 3: Wound complication (Observer scale)

Variable	VICRYL group	Demecryl group	Polypropylene group	P value
Surgical site infection	4 (13.3%)	4 (13.3%)	3 (10%)	0798[a]
Wound dehiscence (hematoma or seroma)	4 (13.3%)	5 (16.8%)	3 (10%)	
Allergy to suture material	0 (0.0%)	0 (0.0%)	0 (0.0%)	Not applicable

There was no statistically significant difference between study groups as regard scar complication according to patients assessment scale (Table 4).

Table 4: Patient scale

Variable	VICRYL group	Demecryl group	Polypropylene group	P value
Painful scar	7 (23.3%)	8 (26.6%)	5 (16.6%)	0.627*
Scar stiffness	2 (6.6%)	1 (3.34%)	1 (3.34%)	
Hypertrophic scar (thickness)	6 (20%)	11 (36.6%)	7 (23.3%)	
pigmented scar	4 (13.3%)	12 (40%)	6 (20%)	
Depressed scar (irregularity)	2 (6.6%)	1 (3.34%)	1 (3.34%)	
Itching scar	3 (10%)	3 (10%)	1 (3.34%)	

There was no statistically significant difference between study groups as regard Pain degree with P value 0.484 (Table 5).

Table 5: Severity of pain (subjective to patients)

Variable	VICRYL group	Demecryl group	Polypropylene group	P value
Pain				
- No Pain (0)	25 (83.3%)	26 (86.6%)	28 (93.3%)	0.484
- Mild (1-3)	5 (16.7%)	4 (13.4%)	2 (6.7%)	
- Moderate (4-6)	0	0	0	
- Severe (7-10)	0	0	0	

There was no statistically significant difference between study groups as regard hospital stay with P value 0.511 (Table 6).

Table 6: Hospital stay

Variable	Vicryl group	Demecryl group	Polypropylene group	P value
Hospital stay (hr)	17±2.59	16±5.67	16±2.36	0.511

DISCUSSION

In our study there was no statistically significant difference between study groups as regard age, BMI, GA, gravidity and Parity which came in agreement with studies by (Matsumine and Takeuchi, 2013, Tuuli *et al*., 2016, Vats and Suchitra, 2014)[9, 10, 11].

Also, the current study showed no statistically significant difference between study groups as regard preoperative Hb, preoperative Htc, postoperative Hb, postoperative Htc, estimated blood loss and operative time.

These findings were consistent with the findings of a study by (Koroglu *et al*., 2022) which enrolled 220 women who had undergone caesarean delivery to compare the rates of surgical wound infection in women who had undergone caesarean delivery with subcuticular skin closure with polyglactin 910 or polypropylene and found no statistically significant difference between study groups regarding demographic characteristics and perioperative and postoperative Hb and Htc in addition estimated blood loss and operative time[12].

In addition, our study found no statistically significant difference between study groups as regard wound complication including infection, hematoma, discharge and seroma. These agreed with results by (Hasdemir *et al*., 2015) which included 250 consecutive women undergoing cesarean section to Compare the rate of wound complications based on used subcuticular suture material and found Wound complication rates were similar in absorbable polyglactin and nonabsorbable polypropylene. Skin closure time is longer in nonabsorbable suture material group in both primary and repeat cesarean groups. There was no difference between groups in wound complication and itching at the scar. Although the cosmetic results tended to be better in the nonabsorbable group in primary surgery patients[5].

In addition, the same study showed There was no difference between groups in terms of postoperative pain, need for additional analgesic use, late phase pain and there was no significant difference in the visual satisfaction of the patients.

As well as, (Hasdemir *et al*., 2015) study showed Skin closure time is longer in non-absorbable suture material group in both primary and repeat cesarean groups[5].

This came in disagreement with the result of our study and with (Koroglu *et al*., 2022) study which showed no statistically significant difference between study groups as regard operative time and time of skin closure[12].

However, (Koroglu *et al*., 2022) found no statistically significant difference was observed between the groups in terms of wound complications or superficial site infections (8.3% in the polypropylene group versus 10.6% in the polyglactin 910 group, *p= .642*). Similarly, no difference was observed between the groups in terms of other wound complications[12].

As well as study by (Tuuli *et al*., 2016) which included 1082 patients who had follow-up after discharge, 871 had subcuticular suture; 180 with 4-0 Vicryl and 691 with 4-0 Monocryl. There was no significant difference in the risk of surgical site infection in women closed with Vicryl compared with Monocryl (11 [6.1%] vs 35 [5.1%], *P=0.58*). Rates of other wound complications were also not significantly different. Risks of surgical site infection were similar with Vicryl and Monocryl closure in all subgroups assessed[10].

In addition, study by (Vats and Suchitra, 2014) which enrolled 90 women undergoing emergency cesarean

section to compare the efficacy of three suture materials, i.e., poliglecaprone 25, polyglactin 910, and polyamide, as subcuticular skin stitches in post-cesarean women demonstrated that Wound dehiscence was present in 3.3 % patients in group 1, 26.6 % in group 2, and 6.6 % in group 3 which not statistically significant $p=0.42$[11].

In contrast, study by (Ikeako *et al*., 2016) which recruited 220 for elective and emergency caesarean section to compare the outcome of surgical metallic staples versus absorbable subcuticular suture for skin closure at cesarean delivery, demonstrated that composite wound complications, (11.9%) vs (3.8%) $p=0.041$, mean operation time (minutes), (50.7±6.88) vs (69.5±5.71) $p<0.001$, mean post operation pain, (1.8±1.18) vs (1.1±0.99) $p<0.001$, and maternal satisfaction (8.05±0.54) vs (9.5±0.75) $p=0.011$[13].

(Buresch *et al*., 2017) which enrolled 550 women undergoing nonemergent cesarean delivery to compare the rate of wound complications among women who underwent cesarean delivery through a Pfannenstiel skin incision followed by subcuticular closure with either poliglecaprone 25 suture or polyglactin 910 suture, showed that Poliglecaprone 25 was associated with a significantly decreased rate of overall wound complications when compared with polyglactin 910, 8.8% compared with 14.4% ($P=.04$)[14].

The present study showed there was no statistically significant difference between study groups as regard pain degree and scar complication included scar dehiscence, hypertrophic, hyper-pigmented, depressed and itching. This came in agreement with (Hasdemir *et al*., 2015) study which showed non statistically significant difference between absorbable and nonabsorbable suture in primary and repeated cesarean section regarding to scar dehiscence[5].

(Vats and Suchitra, 2014) disagree with our findings were found Wound dehiscence and requirement of resuturing are significantly ($P<0.05$) less with poliglecaprone as compared to the polyglactin suture. The polyamide suture has shown results almost similar to poliglecaprone. Poliglecaprone absorbable suture is associated with significantly less discomfort at the suture site ($P\backslash 0.05$) as compared to non-absorbable polyamide suture. The difference due to large sample size in Vats and suchitra study which included 112 patients underwent emergency cesarean section and difference in skin integrity between Indian women which recruited in this study and Egyptian women in our study[11].

The current study showed no statistically significant differences between 3 groups regarding to hospital stay and occurrence of allergy. Patient Scale: The Patient Scale contains six questions applying to pain, itching, color, pliability, thickness, and relief. Because it is too difficult for patients to make the distinction between pigmentation and vascularity, both characteristics are captured in one item: color.

Observer scale included Surgical site infection (SSI) (manifested by e.g., serous discharge, pus and/or erythema), wound disruption and/or wound dehiscence (hematoma or seroma), allergy to suture materials, duration of surgery measured in minutes from closure of the subcutaneous fat layer to closure of the skin and hospital stays measured in days after the CS (decision of discharge of patient from hospital is based on patient's vital data, bowel motility and wound quiescence).

The intensity of the pain indicated by the woman on a Post-Operative Pain Scale graded from 0 to 10, "zero" representing no pain at all, and "10" the worst possible pain imaginable

Finally, our results suggest that surgical site infections and other wound complications in skin closures with vicryl are similar to those identified with demecryl and polypropylene. Polyglactin 910 is preferable because it is not required to be removed and less in price than demecryl and polypropylene.

CONCOLUSION

This study concluded that surgical site infections and other wound complications in skin closures with vicryl were similar to those identified with demecryl and polypropylene.

ACKNOWLEDGEMENTS

Authors would like to thanks to Ain Shams University and the patients recruited in the study.

CONFLICT OF INTEREST

There are no conflicts of interests.

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