

A Randomized Trial Comparing Skin Closure in Cesarean Section: Interrupted Suture with Nylon vs Subcuticular Suture with No '1' Polyfilament

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ABSTRACT

Background: Cesarean section is one of the most commonly performed operations in most countries of the world including Nepal. Hence there is a load on the financial resources of healthcare system. The rationale of this study was to utilize the remaining No '1' polyfilament after closing rectus sheath to stitch skin. So, the primary objective was to determine the wound complication rates for subcuticular suture with No '1' petcryl (polyfilamentpolyglycolic acid) Vs intermittent suture with nylon 2-0 for skin closure at cesarean delivery and secondary objective was to compare postoperative pain and patient satisfaction about the scar.

Methods: One hundred and thirty eight women undergoing cesarean section at Chitwan Medical College was randomized to either intermittent skin suture with nylon 2-0 or subcuticular with polyfilament No '1' (remaining suture after closing rectus sheath). Evidence of wound infection, pain and overall satisfaction were assessed postoperatively.

Results: The overall wound complications rate in subcuticular stitch with No '1' polyfilament suture were similar as in intermittent mattress stitch with nylon 2-0 (15.9% vs. 14.49%). Pain on postoperative third day and six weeks and overall satisfaction about wound were similar in both groups. Only prolonged rupture of membrane >18 hours was found to be a significant risk factor of wound infection (OR: 3.4; p=0.04).

Conclusions: The remaining no '1' polyfilament suture (petcryl) after suturing rectus sheath can be safely used to close skin suture in cesarean section.

Keywords: cesarean section; skin closure; subcuticular sutures.

INTRODUCTION

A variety of technique and materials are used in skin closure after Cesarean Section (CS) and largely relies on surgeon's preference.¹ In 2012, the Cochrane database concluded that there are insufficient data to recommend one method for skin closure.²

Most CS are performed with Pfannensteil incision and rectus sheath is closed with No '1' polyfilament 90 cm (vicryl, petcryl) where only half (45cm) suture is usually used and rest is discarded. Thus the rationale of this study is to use same remaining No '1' polyfilament to close skin because subcuticular suture are better as shown in

literature.³ Since very high number of CS is performed, even small differences may be important for the cost of health services or population health.^{4,5}

So, the objectives of the study were to compare the wound complication rate, postoperative pain and overall patient satisfaction between subcuticular suture with No '1' petcryl Vs intermittent with nylon 2-0 for skin closure.

METHODS

A randomized prospective clinical trial was conducted at Department of Obstetrics and Gynaecology in Chitwan

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Medical College from 2nd May 2012 to 7th October 2012. The study was done after taking ethical approval from IRC-CMC and written consent was taken from the women before the surgery. Inclusion criteria were women of age ≥ 18 years old who underwent caesarean delivery with pfannenstiel incision in our hospital. Exclusion criteria were women having bleeding disorders, septicaemia, chorioamnionitis, extreme obesity (BMI > 35). After informed consent, eligible women were allocated randomly to two groups: group A (intermittent suture) or Group B (subcuticular stitch) on the operation table just before CS by a preformed computer-generator randomization sequence placed in operation theatre. Demographic data, obstetric history, delivery data, and risk factors were collected in preformed proforma. Cesarean sections were performed as surgeon's preference up to the closure of rectus sheath.

For Group A: Skin was closed with intermittent mattress stitch, using No. 2-0 nylon with cutting needle. For Group B: skin was closed with subcuticular stitch using same remaining No '1' polyfilament (petcryl, 90 cm) after closing rectus sheath but knot was placed outside the skin because knot from No'1' would be big and took time to absorb. All surgeries were performed by MD, Gynaecologist at least having one year experience and were done under spinal analgesia.

Antibiotics prophylaxis and analgesics were given as protocol of this hospital. On postoperative day (POD) three, wound was opened and dressing done. Patients were asked to rate the pain at wound site using 10- point VAS (visual analogue scale, with '0' representing no pain and '10' worst pain). Knot or stitch was cut on POD five and discharged if no complications. Both groups of women were asked to come for follow-up after one week to evaluate the evidence of wound infection. After six weeks, telephone interview was done for any discharge from wound or presence of persistent pain at wound site, and patient overall satisfaction regarding scar in terms of redness, thickness, itching, and regularity using Likert scale (1-5, with 5 representing very satisfied and 1 very dissatisfied) which was pre-informed before discharge from the hospital. Details regarding wound complication and management were noted in preformed proforma.

Statistical analysis: Assuming 15% wound complication as shown in literature and α error = 0.05, a sample size of 69 cases in each arm was calculated. Data were recorded in pre-designed proforma, entered into Epi-info 7 program and analysis was done with both Epi-info and SPSS software. Mean values were compared with one-way Anova and categorical variables compared with Chi-Sq or Fisher's exact test as appropriate. The odds ratio (OR) and their corresponding 95% confidence interval (CI) were calculated using unconditional multiple logistic regression analysis for the predictors of wound infections.

RESULTS

One hundred and thirty eight women undergoing cesarean section were assigned randomly into two groups, 69 in each. Baseline characteristics were almost similar in both groups except mean gestational age at delivery which was lower in group B. The surgical risk factors (e.g. diabetes, prolong rupture of membrane, preeclampsia, emergency CS, repeat CS) were also similar between the two groups (Table 1). Almost 50% of the women were primigravida in both groups. Most patients had singleton gestation at full term.

Table 1. Baseline maternal characteristics.

Characteristics	Group A(n=69)	Group B(n=69)	P-value
Age	24.4 \pm 4.1	24.3 \pm 4.01	0.9
Gestational age(week)	39.2 \pm 2.05	38.3 \pm 2.4	0.01
Gravida	1.7 \pm 1.3	1.7 \pm 0.9	0.7
Para	0.4 \pm 0.7	0.5 \pm 0.7	0.8
BMI	24.8 \pm 4.5	24.8 \pm 3.4	0.9
Hemoglobin	11.1 \pm 1.2	10.9 \pm 1.3	0.2
Diabetes mellitus, n(%)	1(1.45%)	3(4.3%)	0.3
Preeclampsia, n(%)	3(4.3%)	5(7.2%)	0.3
PROM* > 18hrs, n(%)	5(7.2%)	8(11.5%)	0.2
Repeat CS†, n(%)	6(8.7%)	8(11.5%)	0.2
Emergency CS, n(%)	48(69.5%)	44(63.7%)	0.2
Subcutaneous fat > 2cm, n(%)	9(13%)	11(15.9%)	0.3
Duration > 60 mins, n(%)	2(2.9%)	0	0.2

Data are presented as mean (SD) or percent.

*PROM: prolong rupture of membrane, †CS: cesarean section

The overall wound complications and wound separation rate for the entire cohort were 15.2% (21/138) and 0.02% (3/138) respectively. Wound complication rate were almost similar (15.9% vs. 14.49%) in both group (Table 2). Only one woman in group A had wound dehiscence >2cm due to hematoma who needed re-suturing. Two women, one from each group, had wound dehiscence <2cm which healed with secondary intention without packing. All other wound complications were minor and superficial which required only few dressings and oral Cloxacillin antibiotic.

Table 2. Wound complications by skin closure.

Wound status	Group A (n=69)	Group B (n=69)	p-value
Healthy wound	58 (84.06%)	59 (85.5%)	
Overall wound complication	11 (15.9%)	10 (14.49%)	0.4
Redness and edema	6	5	
Seroma	2	0	
Hematoma	1	0	
Blackish (superficial necrosis)	2	4	
Purulent	0	1	
Wound dehiscence			
<2cm	1 (1.45%)	1 (1.45%)	0.3
>2cm	1 (1.45%)	0	

Pain on third postoperative day was similar in both groups. Overall, 97% of the women were either very satisfied or satisfied with their wound closure. No significant difference was noted for overall satisfaction of women or persistent pain at six weeks postoperatively (Table 3).

Table 3. Postoperative pain and women's satisfactions.

	Group A (n=69)	Group B (n=69)	p-value
Pain POD*3	2.5±1.1	2.1±0.8	0.06
Pain POD* 6weeks, n(%)	22 (31.8%)	24 (34.7%)	0.3
Overall satisfaction (POD* 6weeks), n(%)			
Strongly satisfied	12 (17.3%)	19 (27.5%)	
satisfied	54 (78.2%)	49 (71.02%)	
Don't know	3 (4.3%)	1 (1.45%)	0.3

*POD: postoperative day

Multiple logistic regression analysis with predictors of wound infections was done. Only prolong rupture of membrane (PROM) >18 hours was found to be a significant risk factors of wound infection, with an odds ratio of 3.4, p= 0.04 (Table 4).

Table 4. Predictors of wound infections.

Predictors	OR(95% CI)	p-value
BMI* >30	0.6 (0.05-7.6)	0.7
PROM † >18 hours	3.5 (1-12.5)	0.04
Repeat cesarean	0.00	0.9
Preeclampsia	0.00	0.9
Diabetes mellitus	0.00	0.9
Operation time >60mins	0.00	0.9
Subcutaneous fat >2cm	1.1 (0.2-5.8)	0.8

Multiple logistic regression analysis

*BMI: Body mass index, †PROM: Prolong rupture of membrane

DISCUSSION

The overall wound complications and wound separation rate in subcuticular stitch with No '1' polyfilament suture (petcryl) was similar as in intermittent mattress stitch with nylon 2-0. Thus the remaining No '1' polyfilament (petcryl) used to stitch rectus sheath can be safely used to stitch skin subcuticularly. This 15% wound complication rates compares with rates between 6.3% to 15.1% quoted in other recent studies of cesarean section.⁶⁻⁸ This wide range is due to various definition of wound separation and wound infection quoted in different studies.

Cochrane Database Syst Rev 2012 concluded that there is currently no conclusive evidence about the techniques and materials for skin closure in caesarean section.²

The cost of nylon 2-0 is NRs 180 and vicryl 2-0 is NRs 470. Thus by utilizing the remaining No '1' polyfilament to stitch skin, load of financial burden can be reduced to the patient and the healthcare system of Nepal as Government of Nepal is providing free caesarean section service under 'Aama Suraksha Karyakram'. The wound complication rate is on the higher side in our study. This is likely due to broad inclusion criteria with high rate of co-morbidities. Still most of these wound infections are minor and superficial which needed only extra few dressings without prolongation of hospital stay. Moreover our wound separation rate is markedly less (0.02%) as compared with Basha's study (10.3%).⁶ They have shown that wound separation rate was more often with use of staples. Islam A et al also found no difference in the rates of wound infection and formation of scar tissue while using left over No '1' vicryl and prolene 2 for subcuticular stitch in the skin. In that study, vicryl No 1 thread used in stitching of the rectus sheath was continued into the skin with application of subcuticular stitches, after securing the edges with a knot.⁹

A systemic review and meta analysis concluded that subcuticular suture is associated with lesser risk of wound complication in CS compared to staples suture (13.4% vs. 6%, pooled OR 2.06, 95% CI 1.43-2.98).³ Even though in all these studies 4-0 monocril or 3-0 vicryl is used, wound complication rate, post operative pain and women's satisfactions were comparable with our study using No '1' petcryl.

Pain on third and six postoperative days and patient satisfaction were similar in both groups. Consistent findings are reported in different studies.^{6,10,11} But Rousseau et al reported significantly less pain at six weeks postoperatively in the staple group.³ In a multiple logistic regression analysis with predictors of wound infection, only PROM >18 hours was found statistically significant (OR: 3.7, p=0.04). Marten et al determined that

emergency cesarean delivery was a risk factor for wound infection but such finding is not obtained in this study.¹² Even Johansson et al shows the higher rate of wound infections with women of BMI >30 kg/m² (OR: 2.13, 95% CI 1.08-4.18) and CS done under general anesthesia.¹³ The incidences of other risk factors are very less in our study to reach any conclusion.

Literature shows that subcutaneous space closure with vicryl no 3-0 in women having subcutaneous fat >2cm is associated with a significant decrease in wound disruption (RR 0.66).¹⁴ In this study, subcuticular suture with No '1' petcryl is directly applied without closing subcutaneous space even if >2cm. None of them had wound infections or separation.

The strength of our study is that it is a randomized study having broad inclusion criteria and is very cost effective as cesarean delivery is one of the most commonly performed surgical procedure and is especially useful in developing countries like ours. The limitation of this study is that follow up was done only up to six weeks and the scar assessment was only subjective. There is a need of randomized trial to compare the scar assessment at least after one year of surgery with objective assessment score.

CONCLUSIONS

With the rising cost of health care, the financial aspect is important when choosing between materials that provide a similar outcome. Thus the remaining No '1' polyfilament (petcryl) can safely be used to close skin suture in cesarean section.

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