

Double-blind Randomized Controlled Trial Comparing the Effect of Closure vs Nonclosure of Peritoneum during Cesarean Section on Postoperative Pain

Suman Poddar¹, Saikat Tripathy²

ABSTRACT

Background: Postoperative pain is one of the major discomforts interfering with baby-care after cesarean section. In our resource-poor hospital setup, we have addressed the issue of impact on postoperative pain, with peritoneal suturing keeping a standardized anesthetic and surgical technique; and postoperative conditions.

Aim: To compare postoperative pain intensity after peritoneal closure vs nonclosure during cesarean section.

Materials and methods: All total of 140 eligible subjects were allocated over one year into two equal groups as per the randomization list. In the control group, both visceral and parietal peritoneum was closed using absorbable suture; whereas in the study group, both peritoneal layers were left un-sutured. All patients received similar anesthetic and surgical techniques. Postoperative pain assessment was done at regular intervals by a 100 mm visual analog scale (VAS) at rest and on movement. Patient satisfaction was assessed by verbal rating scale (VRS). Per rectal diclofenac was given as an on-demand analgesic and recorded with dose. Both subjects and outcome assessors were blinded in the study.

Results: Two groups were found to be matched with respect to basic characteristics, i.e., age, body mass index (BMI), gestational age, gravida, and surgical skill. Operative time was significantly ($p < 0.00001$) shorter in a nonclosure group. There was no significant difference found in the VAS score for postoperative pain (both at rest and on movement) observed at regular intervals (6/12/24/48 hours) between the two groups. Patient satisfaction level was also not significantly different, as demonstrated with a VRS score after 24 hours and 48 hours ($p = 0.5776$ and 0.2354 , respectively). Postoperative on-demand analgesic dose was found significantly higher in closure group during the first 24 hours and later ($p < 0.00001$ and 0.00034 , respectively).

Conclusion: Peritoneum suturing can safely be avoided during the cesarean section. This would be significantly cost-effective with adequate patient satisfaction.

Keywords: Peritoneal suturing, Postoperative pain, Verbal rating scale, Visual analog scale.

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INTRODUCTION

Standard surgical practice traditionally includes the closure of peritoneum during any abdominal surgery with an aim to restore anatomy, re-approximate the tissues, and reduce infection, and adhesion by forming an anatomical barrier.¹ On the contrary, both clinical and animal studies²⁻⁴ have shown many advantages of leaving the peritoneum open after abdominal surgery. Potential advantages claimed after nonclosure of the peritoneum include shorter surgical time, lesser postoperative pain and infection rate, shorter hospital stay, and thus more cost-effective.⁵⁻¹⁰

Postoperative pain is one of the major discomforts which often interfere with mother-baby interaction after cesarean section (CS). Pain perspective with peritoneal suturing has been vastly studied over the globe, but mixed results were found simply because very few published studies¹¹⁻¹⁹ to date were specifically designed to assess postoperative pain. In our resource-poor hospital setup, we have addressed this issue; visual analog scale (VAS) for pain intensity assessment and per rectal route for on-demand postoperative analgesia have been used keeping other standardized anesthetic and surgical techniques at per. Our aim was to compare postoperative pain intensity between peritoneal closure and nonclosure group during CS.

MATERIALS AND METHODS

The study was a double-blind randomized controlled trial (RCT) conducted over one-year (January to December 2017) in the

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Department of Obstetrics and Gynaecology, RG Kar Medical College and Hospital, tertiary-care teaching center situated at North Kolkata, West Bengal, India. The study was approved by the Hospital Ethical Committee.

The randomization sequence was generated by computer generated random numbers using WinPepi software Version 10.1 (2000). Simple balanced allocation of a total of 140 eligible women to group I and group II (relative size 1:1) was done. In the group I (control group), both the visceral and parietal peritoneum were closed using absorbable suture, and in group II (study group), both peritoneal layers were left unsutured. Allocation concealment of the randomization sequence was done with the use of opaque sealed sequentially numbered envelopes.

Cases were selected by the attending consultants/residents. Pregnant women undergoing primary and prelabor cesarean sections were only included. Written informed consent was obtained when posted for CS after discussing study aims, the use of intravenous/per rectal analgesics and the use of visual analog scale (VAS)/verbal rating scale (VRS). Cases unable to understand VAS/VRS were excluded from the study.

The envelopes were opened in sequence by on-duty OT sister just before surgery, and the note was shown to the surgeon whether to leave the peritoneum open or to close it. Name of the eligible patient and hospital registration number along with allocated case number were informed to one researcher who was keeping all the records. Rest assessed the outcomes. Thus, both patients and outcome assessors were blinded in the study.

All patients received spinal anesthesia using a 25G Quincke needle, and 2 mL of 0.5% bupivacaine heavy was injected in a sitting position to achieve a good sensory block to at least T5. No intrathecal opioid was used.

Cesarean section was done with low transverse incision on skin, rectus muscle separating approach for entry further, transverse uterine incision in lower segment, two-layered uterine wound closure after delivery of baby and afterbirths, peritoneal closure done according to allocation, rectus sheath sutured continuously with delayed absorbable suture and skin by interrupted mattress stitch using nonabsorbable suture. Total operative time (skin—incision-to-closure) was recorded.

All patients received intraoperative fluid loading. Intravenous antibiotic (ceftriaxone 1 g) and 10 IU oxytocin IM was given immediately after the delivery of the baby. The end of surgery was taken as zero hour. Postoperatively, all patients received two further doses of intravenous antibiotics at 12 hours interval and intravenous fluid 6 hourly till bowel sounds audible. 10 IU oxytocin was charged in the first two infusion bottle. For the first 24 hours, paracetamol IV infusion 1 g 8 hourly was scheduled for all cases.

Primary outcome measure was postoperative pain intensity assessed at 6, 12, 24, and 48 hours after CS by 100 mm VAS (0 mm = no pain, 100 mm = unbearable pain) at rest and on movement.

Secondary outcome measures were postoperative patient satisfaction and analgesic requirement. Patient satisfaction was assessed by VRS (0 = poor, 1 = fair, 2 = adequate, 3 = good, 4 = very good, and 5 = excellent) at 24 hours and 48 hours after surgery. Postoperative analgesic requirement (per rectal diclofenac was chosen as an on-demand analgesic as easily available hospital supply) for the first 48 hours with dose has been recorded for study.

Sample size was calculated using nMaster 2.0 software on the basis of pain intensity (as assessed by 100 mm VAS) as the primary outcome measure. It was estimated that 67 subjects would be required for each group in order to detect a difference of 10 mm in this parameter with 80% power and 5% probability of type I error. This calculation assumed a standard deviation of 20 mm in both study groups. Adjusting for possible 10% dropout, finally, 70 subjects were considered eligible for each group.

Assessment of distribution pattern of the observations belonging to two groups was done by the Kolmogorov–Smirnov test. Values were expressed in median (with interquartile range) or mean [with standard deviation] following distribution pattern as applicable. Mann–Whitney *U* test and *t* test have been used for comparison where appropriate. Chi-square test was applied for comparison where data was presented in number (%). Data analysis was done with the help of IBM statistical package for the social

sciences (IBM SPSS 64 version 20). $p < 0.05$ has been considered significant.

RESULTS

One hundred and forty eligible subjects were allocated to group I (closure group) and group II (nonclosure group) (relative size 1:1) over one year as per the randomization list. Three subjects from closure group and one subject from nonclosure group were considered as dropped out cases for obvious reasons. Thus, analysis was done with 67 subjects in the closure group and 69 subjects in the nonclosure group (Flowchart 1).

Two groups were found to be matched with respect to basic characteristics, i.e., age, BMI, gestational age, gravida, (Table 1) and surgical skill applied (Table 2).

Operative time was significantly ($p < 0.00001$) shorter (40 minutes) in the nonclosure group as compared with the closure group (49 minutes) (Table 2).

There was no significant difference found in the VAS score for postoperative pain (both at rest and on movement) observed at regular intervals (6/12/24/48 hours) between the two groups (Table 3).

Patient satisfaction level was similar as demonstrated with the VRS score after 24 and 48 hours ($p = 0.5776$ and 0.2354 , respectively) between two groups (Table 4).

Postoperative on-demand analgesic requirement was found to be significantly higher in closure group during first 24 hours ($Z = -8.28773$, $p < 0.00001$); and later ($Z = -3.58$, $p = 0.00034$) (Table 5).

DISCUSSION

Peritoneum, having a mesothelial origin, heals differently to epithelial tissue. New mesothelium arises by metaplasia of the sub-peritoneal perivascular connective tissue cells; not by a process of centripetal growth from the wound margins as in the repair of epithelial surfaces. Moreover, mesothelial cells spontaneously initiate multiple sites of repair within 48–72 hours with complete healing in 5–6 days, even if large peritoneal defects left un-sutured.²⁰

On the contrary, an approximation of the peritoneal layers by suture actually hampers wound healing by tissue ischemia. As perivascular tissue fails to proliferate at the ischemic margin, definitive mesothelial cells would not appear or slow to appear. Absent or fewer definitive mesothelial cells with their associated fibrinolytic activity actually facilitate adhesion in the long run.^{3,21,22} Moreover, tissue ischemia and stretched peritoneal nerve endings along with foreign body reaction to suture material, produce cumbersome early postoperative morbidities (that is pain, infection, etc.) often leading to a longer hospital stay.

Our study compared different observations between two groups importantly found to be matched with respect to basic characteristics, i.e., age, BMI, gestational age, gravida, and surgical skill applied, similar to other published studies.^{13,17,19,23}

A systematic review²⁴ by Bambigboye and Hofmeyer revealed that not stitching the peritoneum after CS took less theatre time, and therefore less costly. In our trial, operative time was also found to be significantly shorter in the nonclosure group as compared with the closure group. A series of other published studies^{13,14,17,19,25–39} supported our findings. In two published studies,^{12,40} by contrast, no significant difference was revealed in the duration of surgery.

Flowchart 1: Participants in the study

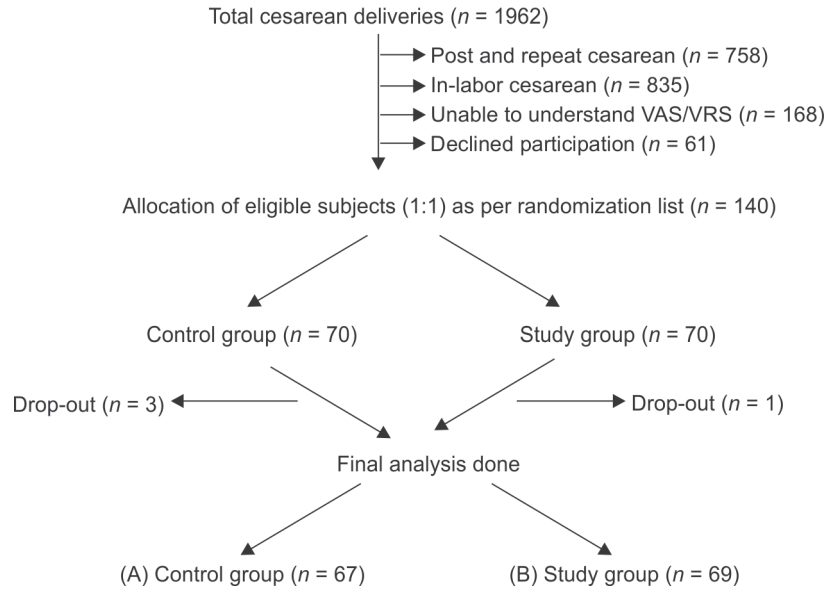


Table 1: Patient characteristics: values are in median (interquartile range) or mean [standard deviation]

| | Closure group (n = 67) | Nonclosure group (n = 69) | p value |
|-------------------------|------------------------|---------------------------|---------|
| Age (years) | 23.0 (4) | 23.0 (5) | 0.882 |
| BMI | 24.1 (3) | 24.8 (2.7) | 0.062 |
| Gestational age (weeks) | 38.29 [1.6] | 38.23 [1.5] | 0.833 |
| Gravida | 1.0 (0) | 1.0 (1) | 0.084 |

Table 2: Surgical details: values are in median (interquartile range) or number [%]

| | Closure group (n = 67) | Nonclosure group (n = 69) | p value |
|-----------------------------------|------------------------|---------------------------|----------|
| Operative time (minutes) | 49 (4) | 40 (2.5) | <0.00001 |
| Grade of surgeon | | | |
| Visiting surgeon (VS) | 6 [9] | 5 [7.2] | 0.900737 |
| Senior resident (SR) | 32 [47.7] | 32 [46.4] | |
| Junior resident (JR) (supervised) | 29 [43.3] | 32 [46.4] | |

Table 3: Visual analogue scale score for postoperative pain: data are in median (interquartile range)

| | Closure group (n = 67) | Nonclosure group (n = 69) | p value |
|----------------------|------------------------|---------------------------|---------|
| VAS at rest (mm) | | | |
| 6 hours | 80 (10) | 80 (10) | 0.105 |
| 12 hours | 60 (20) | 60 (15) | 0.562 |
| 24 hours | 50 (20) | 50 (10) | 0.123 |
| 48 hours | 40 (20) | 40 (20) | 0.504 |
| VAS on movement (mm) | | | |
| 6 hours | 90 (10) | 90 (10) | 0.473 |
| 12 hours | 70 (20) | 70 (20) | 0.356 |
| 24 hours | 60 (20) | 50 (10) | 0.066 |
| 48 hours | 50 (10) | 50 (10) | 0.922 |

Table 4: Verbal rating scale score for patient satisfaction: data are presented as number of patients (%)

| | Closure group (n = 67) | Nonclosure group (n = 69) | p value |
|--------------------|------------------------|---------------------------|---------|
| VRS after 24 hours | | | |
| 0 (poor) | 9 (13.4) | 6 (8.7) | 0.5776 |
| 1 (fair) | 22 (32.8) | 18 (26.1) | |
| 2 (adequate) | 29 (43.3) | 36 (52.2) | |
| 3 (good) | 7 (10.5) | 9 (13) | |
| 4 (very good) | 0 | 0 | |
| 5 (excellent) | 0 | 0 | |
| VRS after 24 hours | | | |
| 0 (poor) | 0 | 0 | 0.2354 |
| 1 (fair) | 7 (10.5) | 8 (11.6) | |
| 2 (adequate) | 24 (35.8) | 17 (24.6) | |
| 3 (good) | 27 (40.3) | 26 (37.7) | |
| 4 (very good) | 9 (13.4) | 18 (26.1) | |
| 5 (excellent) | 0 | 0 | |

Table 5: Postoperative on-demand analgesia (per rectal diclofenac—dose in mg): values are in median (interquartile range)

| | Closure group (n = 67) | Nonclosure group (n = 69) | p value |
|-------------------------|------------------------|---------------------------|----------|
| First 24 hours: (day-0) | 300 (200–300) | 200 (100–200) | <0.00001 |
| Next 24 hours: (day-1) | 300 (200–300) | 200 (200–300) | 0.00034 |

No statistically significant difference was found in the VAS score for postoperative pain (both at rest and on movement) observed at regular intervals (6/12/24/48 hours) between the two groups in our trial.

Hojberg et al.¹¹ in a RCT of 40 cases, Chanrachakul et al.¹² in a double-blind RCT of 60 cases, Rafique et al.¹³ in a double-blind RCT of 100 cases, Sood²³ in a prospective RCT with 149 cases, Tuncer et al.¹⁴ in a randomized trial of 80 cases, Huchon et al.²⁵

in a prospective RCT of 170 cases, and Atabekoglu et al.¹⁶ in a comparative study of 94 cases showed similar result. Importantly, only elective cases were included in most of the studies. Most studies involved primary cases, whereas Chanrachakul et al.,¹² in their RCT, took only repeat cesarean cases. Postoperative pain was evaluated by VAS score by all; VRS scoring was also done for pain assessment in two studies.^{13,16} Not always pain was assessed at a regular interval; in Sood study,²³ it was assessed once at 24 hours after surgery. Intravenous patient-controlled analgesia (PCA) pump was used by only two studies;^{13,16} but importantly in most studies, standardization was lacking regarding route and type of other analgesics used. Even, in Rafique et al. study,¹³ a number of data was missing in the VAS/VRS score, which could affect the result.

In more recent studies,^{15,17-19,26-30,41} mainly published in last one decade, significantly less pain score was found in the non-closure group. Here, almost all studies included elective as well as emergency cases. Cheema et al.¹⁸ and Tabasi et al.⁴¹ study, all cases were done by the same surgeon; technically eliminated skill difference. Postoperative pain was evaluated by VAS score in all studies except that numeric pain intensity scale (NPIS) was used by Deshpande et al.¹⁷ study, and VRS scoring was done in Nasir et al. study.²⁶ Pain was not assessed at regular intervals, by all; often^{15,18,26,29,30} at the specified timing, it was evaluated. Analgesics were used by different routes, often in the mixture. Sharma et al.,¹⁹ in a recent trial, did a correlation study, though no positive correlation of pain score with age and BMI was found. Importantly, no information was given in the same study regarding postoperative analgesia, which could affect the standardization of postoperative conditions.

One interesting aspect, we assessed, was patient satisfaction, which could be a reflection of effective postoperative management for early morbidities. Single published study¹³ showed significantly increased patient satisfaction in the nonclosure group at 24 hours postoperatively. But in our study, patient satisfaction level was not significantly different, as demonstrated with the VRS score after 24 hours and 48 hours between two groups.

Published study done with per rectal on-demand analgesia like ours is lacking. Even, in most studies, standardization was not done regarding route and type of other analgesics used, making direct comparison between two groups difficult. In our trial, analgesic requirement was found to be significantly higher in closure group. Many studies^{11,16,18,26,29,36,41} have supported our view, but no significant impact has also been shown by few others.^{12,23,42}

Strengths of our study are as follows—to remove potential confounding factors regarding pain perception, we included primary (not post or repeat cesarean cases); and pre-labor (elective or emergency where labor pain has not yet started) cesarean cases (not only elective or only emergency cases). Postoperative pain was assessed with 100 mm VAS at regular intervals, not on a single occasion. Assessment was done by one assessor as another person was involved in all record-keeping, but not done by other health staff. Double blinding was done (both assessor and subject were unaware of the status of peritoneal suturing) to remove bias in outcome documentation. For on-demand analgesia, per rectal route has been only used for all patients, not a variable mixture of on-demand oral, intravenous and/or per rectal analgesia.

Limitations of our study are as follows—cases were done by different surgeons; not possible to arrange for the same surgeon in our hospital set-up. Gold standard intravenous PCA pump could not be used. Review of the results indirectly points out that actually, closure group perceived higher degree pain and that was why they

required more analgesic dose; but during VAS/VRS assessment, we had similar pain score and satisfaction level simply because we have not assessed pain intensity every time before taking on-demand analgesia—inherent limitation in methodology. Studies including our trial were all small RCTs focusing on early postoperative morbidities, large trials for long-term morbidities including impact on adhesion after peritoneal suturing are needed.

CONCLUSION

Peritoneal suturing can safely be avoided during CS, provided hemostasis is secured. It would result in less operating time leading to less operative burden, less pain perception leading to less analgesic requirement, quicker recovery leading to less hospital stay, moreover, cost-effective and beneficial step with adequate patient satisfaction.

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