

Comparison of postoperative analgesia and opioid requirement with thoracic epidural vs. continuous rectus sheath infusion in midline incision laparotomies under general anaesthesia - A prospective randomised controlled study

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ABSTRACT

Background and Aims: To assess and compare the effect of bilateral continuous rectus sheath infusion (CRSB) for postoperative analgesia with continuous thoracic epidural infusion (TEA) in patients undergoing midline incision laparotomies. **Methods:** A prospective, randomised study involving sixty patients with Indian Society of Anesthesiologists (ASA) grade I to III, planned for elective laparotomy were enrolled for the study. Patients were randomly allocated into two groups. In the TEA group, an epidural was sited before induction of general anaesthesia (GA), whereas in the CRSB group, bilateral ultrasound-guided RSB catheters were placed at the end of the surgical procedure, before extubation. Both groups received continuous 0.2% Ropivacaine infusion for postoperative analgesia. They were followed for two post-operative days (POD), for the opioid requirement and post-operative pain at rest, coughing, and moving. Age and body mass index (BMI) were compared using independent t-test and visual analogue scale (VAS) scores were compared by the Mann–Whitney test between the two groups. Opioid consumption, gender, and type of surgery were compared using the Chi-Square test. Statistical analysis was done using Statistical Package for Social Sciences (SPSS 21.0). **Results:** Opioid consumption in both groups was comparable, for the first two post-operative days with no statistically significant difference. Pain scores were comparable among the groups at all times except postoperative day (POD) 0 (4 h and 12 h postop) and POD 2 (8 AM and 12 PM), where lower pain scores were observed in CRSB Group. **Conclusions:** As a part of the multimodal analgesia technique, CRSB offers a reliable, safe, and effective alternative to TEA.

Key words: Analgesia, epidural analgesia, laparotomy, pain, post-operative, rectus sheath block

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INTRODUCTION

The use of thoracic epidural analgesia (TEA), as a part of post-operative multimodal analgesia, has become standard practice after abdominal surgeries in comparison to high doses of systemic opioids.^[1]

For rectus sheath block (RSB), a local anaesthetic (LA) is deposited bilaterally between the rectus muscle and posterior rectus sheath. The use of ultrasound for the insertion of an infusion catheter can prolong the analgesic effect by continuous infusion of local anaesthetic (LA).^[2]

The existing literature related to the use of RSB is limited to single-shot technique. Only a few studies are there, which utilize rectus sheath catheters,

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but these too have used intermittent boluses of LA only.^[1]

In our study, the primary aim was to compare opioid consumption between the TEA group and the continuous rectus sheath block (CRSB) group. Our secondary aims were to assess the quality of post-operative analgesia using Visual Analogue Scale (VAS) score and time to first top-up of local anaesthetic/opioid between TEA and CRSB group.

METHODS

After obtaining approval by the institutional Ethics Committee, all patients with American Society of Anesthesiologists (ASA) physical status I to III between 18 and 75 years of age, scheduled for elective midline incision laparotomies under general anaesthesia from March 2016 to November 2016, were included in the study. Patients with drug addiction, peripheral neuropathies, contraindication to regional anaesthesia (allergic to LA, coagulopathy), previous laparotomy scar were excluded.

After obtaining written informed consent, patients were randomly allocated into two groups (30 each) - TEA group and CRSB group, using computer-generated random numbers. All patients enrolled for the study, received premedication with tablet alprazolam 0.25 mg and tablet ranitidine 150 mg, the night before surgery, and 2 h before surgery with a sip of water. Both the groups received general anaesthesia with fentanyl 2 $\mu\text{g kg}^{-1}$, propofol 2 mg kg^{-1} , and rocuronium 1 mg kg^{-1} . The airway was secured with an appropriate size endotracheal tube. Morphine (0.1 mg kg^{-1}) was given just before incision. Anaesthesia was maintained with isoflurane (0.8%–2%) in 50:50 mixture of air and oxygen with positive pressure ventilation. Intermittent boluses of fentanyl 0.5 mg kg^{-1} and rocuronium were given. During the closure of the surgical incision, injection paracetamol 1 gm (iv infusion) was given over 20 min.

For all patients in the TEA group, an epidural was sited at T8 to T10 level before the induction of general anaesthesia (GA). Using standard aseptic insertion technique, epidural was placed in a sitting position with Tuohy 18G needle (Epidural minipack: Portex®, US), using a loss of resistance to saline technique. After the identification of epidural space, the catheter was threaded 5 cm in the epidural space. A test dose of 3 mL of lignocaine 2% with adrenaline (1:200,000)

was given after negative aspiration for blood and cerebrospinal fluid (CSF), to rule out intravascular placement.^[3] The catheter was then secured with Lockit Plus™ 18G (Smith medical, Keene, USA) and transparent dressing. Before the reversal of anaesthesia, epidural bolus was given with 10 mL of 0.2% ropivacaine after negative aspiration for blood and CSF.

In the CRSB group, under all aseptic precautions, bilateral rectus sheath block (RSB) catheters were placed after surgical procedure and before extubation. An HFL38x (6-13 MHz) linear ultrasound probe (Sonosite M-Turbo, Bothell, WA, USA) was used, with an imaging depth of 4–6 cm. Rectus sheath was approached with Tuohy 18G needle (Epidural minipack: Portex®, US) by in-plane technique just below the costal margin. 5 mL saline bolus was used for hydro-dissection to confirm the needle placement in the posterior rectus sheath compartment. Subsequently, after careful aspiration, a 20 mL bolus dose of 0.2% inj. ropivacaine was injected in 5 mL aliquots. Nearly 8 cm epidural catheter length was inserted in the potential space and secured to the skin at 12–15 cm length with Lockit Plus™ 18G (Smith medical, Keene, USA) and transparent dressing. The same procedure was repeated on the opposite side and a 20 mL bolus of 0.2% ropivacaine was deposited on that side also, using the Tuohy 18G needle (Epidural minipack: Portex®, US).^[4]

After completion of the surgical procedure, neuromuscular blockade was reversed, and patients were extubated and shifted to post-anaesthesia care unit (PACU)/intensive care unit (ICU).

In the postoperative period, epidural infusion in TEA group and bilateral rectus sheath infusion in CRSB group were started with inj. ropivacaine 0.2% at 5-8 mL/hr (LA infusion rate through CRSB was based on our pilot study, as we did not have a previous study of CRSB infusion in laparotomies). Also, all patients received inj. paracetamol 1 gm i.v. 6 hourly and inj. diclofenac 75 mg i.v. 12 hourly.

Patients were assessed for pain score using VAS, ranging from 0 (no pain) to 10 (worst pain). VAS score assessment was done for two consecutive post-operative days (POD). VAS was assessed at rest, coughing (patient was asked to cough once), and moving (supine to sitting position in bed) at 2 h intervals on POD-0, 4 h intervals on POD-1 and

two readings at 6 h interval on POD-2. Ropivacaine infusion in both groups was discontinued on POD-2. Epidural catheter (in TEA group) and bilateral RSB catheters (in the CRSB group) were removed after the second reading on POD-2.

If VAS ≥ 3 at rest and/or VAS ≥ 6 on coughing/moving, top-up was given with inj. ropivacaine 0.2% 5 mL through the epidural catheter (in TEA group) and 10 mL was given bilaterally through rectus sheath catheters (in CRSB group). VAS was reassessed after 15 min. If still, VAS was high, inj. morphine 0.05 mg kg⁻¹ was given intravenously and repeated after 15 min if required (maximum dose of 0.2 mg kg⁻¹ iv).

The total amount of opioids consumption (mg) and VAS (at rest, on coughing, and on moving) at 2 h intervals on POD-0, 4 h intervals on POD-1, and two readings at 6 h interval, on POD-2 was assessed.

The sample size was estimated based on a pilot study where the mean difference in morphine requirement in TEA and CRSB groups was 2 mg with a standard deviation (SD) of 2.1.

For comparing the mean of two groups

$$N \geq \frac{(\text{standard deviation})^2}{(\text{mean difference})^2} \times (Z_{\alpha} + Z_{\beta})^2$$

Where Z_{α} = value of Z at the two-sided alpha error of 5%

Z_{β} = value of Z at the power of 80%

Mean difference = difference in post-intervention mean values of the two groups.

$$\text{Calculations: } - \frac{N \geq 2 * (2.1 * 2.1) * (1.96 + 0.84)^2}{(2 * 2)}$$

Z_{α} = 1.96 at 5%

Z_{β} = 0.84 at 80% power of study

$N \geq 17.287$

$N \geq 18$

A sample size of 18 subjects in each was calculated at a power of 80% and a confidence interval of 95%. For possible dropouts, 30 patients were included in each group.

Statistical Package for Social Sciences (SPSS 21.0) was used for statistical analysis. $P < 0.05$ was taken as statistically significant value. The normality of data was tested using the Kolmogorov–Smirnov test. The parametric test was applied for data that were normally distributed. Age and body mass index (BMI) were compared using independent t-test and VAS scores were compared by the Mann–Whitney Test (as the data sets were not normally distributed) between the two groups. Opioid consumption, gender, and type of surgery were compared using the Chi-Square test.

RESULTS

Sixty patients (30 in each group) participated in the study [Figure 1]. Age, gender, BMI, and type of surgeries were comparable between the groups [Table 1].

No statistically significant difference was found in post-operative opioid consumption ($P = 0.389$) among TEA (6.66% patients required opioid) and CRSB group (3.33% patients required opioid) on POD 0. There was no opioid requirement in either group on POD 1 and POD 2 [Figure 2].

The difference in VAS between the two groups was found to be significant on POD-0 (at 4 hours and 12 hours post-operatively) and POD-1 (at 8 AM and 12 PM). At all other times, VAS was comparable between the two groups [Figures 3-5].

On POD 0 in TEA group, the mean VAS at 4 hours post-operatively was found to be higher on coughing (3.3 ± 1.18) and moving (3.47 ± 1.25) than CRSB group on coughing (2.6 ± 0.77) and moving (2.63 ± 0.72), respectively. This was statistically significant with a P value of 0.012 and 0.003, on coughing and moving, respectively. At 12 hours post-operatively, mean VAS in TEA group was found to be higher at rest (1.57 ± 0.5), coughing (3.03 ± 1.19), and moving (3.03 ± 1.17), respectively than CRSB group at rest (1.2 ± 0.41), coughing (2.4 ± 0.62), and moving (2.47 ± 0.68), respectively. The difference was

Table 1: Patient data

	TEA	RSB	P
Age in years (Mean \pm SD)	56.07 \pm 12.94	55.37 \pm 12.36	0.831
Sex (M:F)	17:13	13:17	0.302
BMI (Mean \pm SD)	26.99 \pm 2.21	26.04 \pm 2.28	0.934
Type of surgery (U:GI:Gy)	6:18:6	1:20:9	0.118

U=Urological surgeries, GI=Gastrointestinal surgeries, Gy=Gynaecological surgeries, BMI=Body mass index,SD=Standard deviation

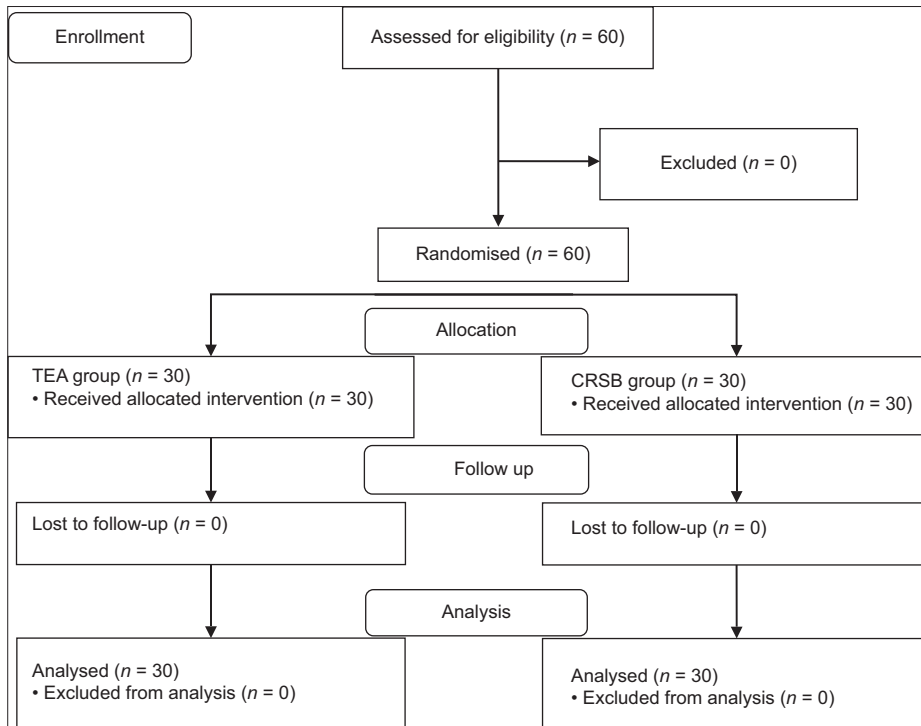


Figure 1: Consort flow diagram

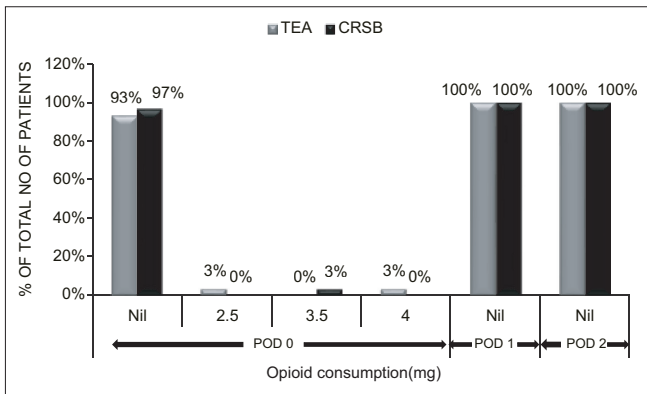


Figure 2: Comparison of opioid consumption (mg) on postoperative days (POD)- 0, 1, 2

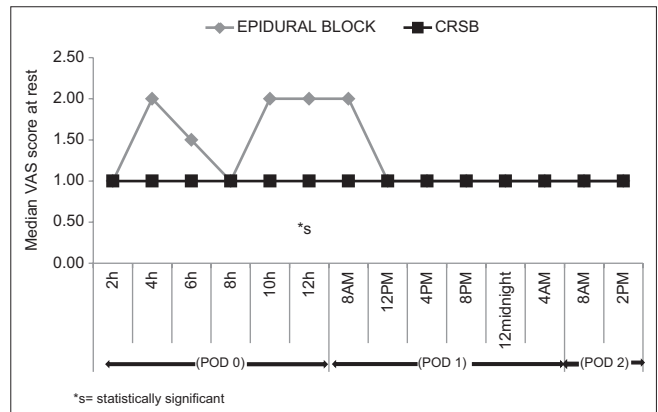


Figure 3: Comparison of median VAS Scores at rest on POD- 0, 1, 2

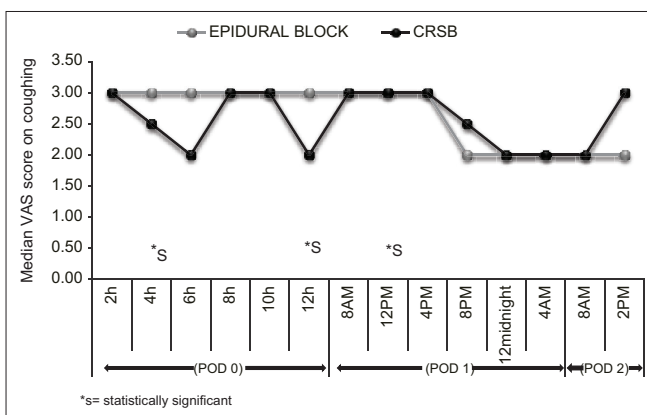


Figure 4: Comparison of median VAS Score on coughing on POD- 0, 1, 2

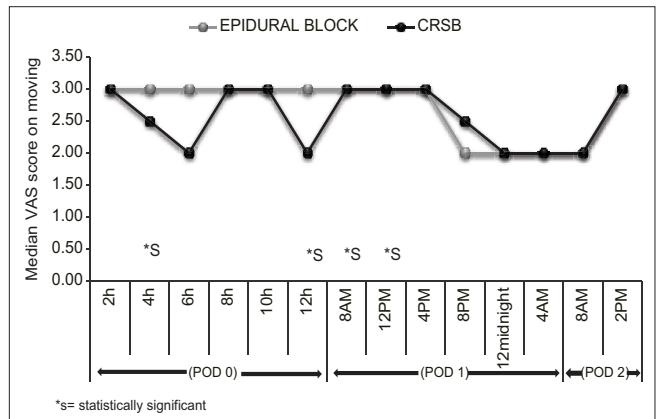


Figure 5: Comparison of Median VAS Score on Moving on POD- 0, 1, 2 in both Groups

statistically significant with $P = 0.004$ at rest, 0.015 on coughing, and 0.021 on moving, respectively.

On POD 1, mean VAS was significantly higher ($P = 0.033$) in the TEA group (3.3 ± 1.34) on moving than in the CRSB group at 8 AM (2.73 ± 0.87). At 12 PM, mean VAS of TEA group was found to be higher on coughing (3.3 ± 1.34) and moving (3.43 ± 1.34) than CRSB group on coughing (2.57 ± 0.57) and moving (2.67 ± 0.61). The difference was statistically significant on coughing ($P = 0.019$) and moving ($P = 0.010$), respectively.

The time to rescue analgesia administration and mean length of stay ($P = 0.558$) were comparable between the two groups.

No complications were noted with either of the regional techniques (haematoma, abscess, or visceral injury).

DISCUSSION

With the availability of portable ultrasound machines, long-acting LA, and small caliber infusion catheters, continuous rectus sheath infusion has emerged, as a safe and effective technique for post-operative analgesia after midline incision laparotomies.^[5]

In our study, opioid consumption in TEA and CRSB groups was comparable for two consecutive post-operative days. Pain assessment scores were also comparable between the groups at all times except on POD-0 (4 h and 12 h post-operatively) and POD-1 (8 AM and 12 PM), where lower pain scores were observed in CRSB Group.

Similarly, Parsons and colleagues reported comparable post-operative pain scores between intermittent boluses in RSB group and continuous epidural infusion in the first 72 hrs, following major urological pelvic surgeries involving lower midline abdominal incision.^[6] Also, Dutton *et al.* reported sufficient post-operative analgesia with intermittent boluses of LA through bilateral rectus sheath catheters following major urological pelvic surgeries involving lower midline abdominal incision.^[7] Their findings were confirmed by Bashandy and Elkholy who compared adult patients of RSB group with placebo group who underwent cancer surgery. They found a significantly lower pain score and opioid consumption in RSB Group

for the first two post-operative days.^[8] The findings of Bakshi S, *et al.* were not different, who reported RSB with catheter using intermittent boluses of LA, as an effective pain management technique for midline laparotomies.^[1] Furthermore, work by Elbahrawy K, *et al.* and Khalil MMH established RSB technique for both intra-operative and post-operative analgesia. They reported lower opioid consumption (both intra-operative and post-operative) and lower pain scores in patients who received single-shot RSB than those with general anaesthesia alone for abdominal surgeries, in adults and children, respectively.^[2,9] A meta-analysis further supported and established RSB to be an effective analgesic technique in terms of reduced opioid requirement and pain scores in paediatric population.^[10]

Unlike the previously mentioned studies,^[1,2,5-10] we have compared two continuous infusion groups CRSB and TEA for post-operative analgesia in adults, following midline laparotomies utilising lower/upper + lower abdominal incisions.

On the contrary, Yassin HM, *et al.* compared the effect of continuous thoracic epidural analgesia (TEA) and intermittent boluses of rectus sheath block (RSB) catheters for 72 h post-operatively following midline abdominal surgeries. They reported significantly higher opioid consumption in the RSB group with comparable VAS scores in both groups.^[11] The use of more concentrated bupivacaine (0.25%) for TEA could be the cause of dissimilarity between our results because the total hourly bupivacaine dose determines analgesia quality as well as side effects during continuous TEA. Moreover, not using continuous infusion of RSB might have further contributed to their findings. We have used 0.2% ropivacaine in our study keeping in mind its better safety profile over bupivacaine.

No complications were noted with either of the regional techniques in our study, whereas Doctor JR, *et al.* reported knotting of RSB catheter in the post-operative period requiring surgical removal.^[12]

The use of multimodal analgesia has gained importance over the years for superior pain relief with the lesser individual drug (analgesic medications)-related side effects. The use of real-time ultrasound-guided regional analgesic blocks (with catheters) has further added to the safety and quality of analgesia. Based on our results, as a part of multimodal analgesia regimen, continuous rectus sheath block (CRSB) provides equivalent

post-operative analgesia compared to thoracic epidural analgesia after midline incision laparotomies. Therefore, CRSB stands as an alternative to TEA in scenarios like patient refusal for an epidural. RSB can be given after induction of general anaesthesia and this makes it preferable to awake insertions of epidural catheters.

With the increasing use of antiplatelet medications (like clopidogrel, dabigatran) by patient population, CRSB remains a safer choice over TEA, as a rectus sheath haematoma is less worrisome than an epidural haematoma. For the same reason, CRSB can be preferred in patients with coagulopathy, concomitant antiplatelet therapy, and emergency surgeries where coagulation status maybe not known.

Being a non-neuraxial block, RSB is devoid of complications like hypotension thereby making it safer for patients with shock related to hypovolemia, sepsis, or excessive blood loss. Moreover, CRSB provides comparable analgesia to EA without motor blockade thereby allowing early mobilisation. This is beneficial for an enhanced recovery program.

This study has a few limitations. First, the use of subjective VAS scales for the assessment of post-operative analgesia. Second, we did not perform a sensory assessment of the patient to confirm block onset or offset. Third, we have assessed CRSB as a part of multimodal analgesia (along with other weaker analgesics like paracetamol and diclofenac) and not as sole analgesia technique to assess the quality of post-operative pain relief. Considering all these limitations, further multi-centric studies can be undertaken to increase the power of the study to firmly claim that CRSB is at par with TEA for postoperative analgesia.

CONCLUSIONS

Ultrasound-guided continuous rectus sheath block has emerged as an easy and effective regional analgesia technique after midline incision laparotomies. Continuous rectus sheath block is a useful regional analgesia technique for laparotomies, especially when epidural block and catheter placement is contraindicated. We conclude that as a part of the multimodal analgesia technique, CRSB may offer a reliable, safe, and effective alternative to TEA.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the

patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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