



Original Research Article

A prospective randomized trial of evaluation of post-operative analgesia of erector spinae plane block in patients undergoing laparotomy

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ABSTRACT

Background: The erector spinae plane block (ESPB) can be used to reduce pain and opioid requirements after abdominal surgery. The study was undertaken to assess post-operative analgesia of ESPB in patients undergoing laparotomy under general anaesthesia.

Materials and Methods: A total 34 patients of either sex, age between 20-60 years, ASA status 1 and 2 undergoing exploratory laparotomy were included and equally randomised into two study groups of 17 each. Group A received ESPB with 0.25% inj. bupivacaine 20ml on each side (Total 40ml 0.25% inj. Bupivacaine) and group B with no intervention.

Results: The mean VAS Score was <4cm till 1½ hr in both the groups. Henceforth, mean VAS scores were observed to be <1cm in all the patients of Group A till 24hr whereas VAS Scores were >4cm all intervals till 24hr in Group B. Thus, quality of analgesia was better in Group A. In Group B, 10 (58.82%) out of 17 patients required first dose of tramadol at 1½ hr as compared to none in Group A. At 24hr, all patients in Group B received tramadol as rescue analgesic compared to only 3 (17.64%) in Group A. The cumulative tramadol consumption was significantly low in Group A (5.88±13.71mg) than Group B (191.76±40.65mg). Complications like nausea, vomiting was more in Group B because of increased tramadol consumption.

Conclusion: ESPB is a simple, easy, convenient option, when utilized as a component of multi-modal analgesia for pain relief in abdominal surgery.

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1. Introduction

Laparotomies are common procedures generally performed under general surgery. They cause significant postoperative pain and discomfort to the patient, which induces profound physiological changes in the perioperative period by increasing sympatho-adrenal and other neuro-endocrinal activity and cytokines production. The management of postoperative pain due to laparotomy usually includes combination of parenteral drugs paracetamol, NSAIDs,

opioids and regional interventions. Parenteral agents like paracetamol, NSAIDs have to be supplemented with opioids for management of pain. However, opioids are associated with side effects such as sedation, respiratory depression, constipation, delayed patient mobilization which have led to a decrease in their use.¹ A multimodal postoperative analgesia regime, i.e., a combination will help reduce complications and prevent chronic pain development and also promote smooth recovery together with minimal surgical morbidity and shorter hospitalization.²

Forero et al. in 2016 described the erector spinae plane block (ESPB), an inter-fascial plane block. It

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was observed to be safer, less invasive, and technically less demanding alternative to conventional thoracic epidural anaesthetic techniques.³ In comparison to commonly utilised techniques such as thoracic epidural and paravertebral injections, the ESPB targets a plane remote from central neural elements.^{4,5} When performing ESPB, the local anaesthetic is injected into fascial plane that is deep to erector spinae muscle group, which spreads cranio-caudally thus providing anaesthesia to majority of thoracic cavity and abdominal wall.⁶

The ESPB is a novel technique that has been extensively utilized for superficial surgeries of thorax e.g., breast surgeries. There are however limited evidence-based studies available regarding post-operative analgesia after ESPB following laparotomy procedures. Hence, the present study was conducted with the aim of understanding the efficacy of post-operative analgesia achieved by means of pre-operative institution of ESPB, in terms of opioid consumption, pain scores, incidence of complications as well as intra-operative sevoflurane consumption and fentanyl requirement in patients undergoing elective and emergency laparotomies.

2. Materials and Methods

After obtaining Institutional Ethical Committee approval and written informed consent from all the patients, this single blinded, randomized control study was conducted in the Department of Anaesthesiology, at a Tertiary Care Hospital in Central India during a period of 18 months from July 2021 to December 2022. A total 34 patients of either sex, age between 20–60-year, ASA status 1 and 2 undergoing exploratory laparotomy in surgery indoor patient department were included in the study. Patients with body mass index (BMI) >30, coagulation disorders and thrombocytopenia with platelet count less than 150,000 mm³, infection at the site of injection and insertion of needle, allergy to local anaesthetics, use of opioids (except for tramadol) or alpha-2 agonists for sedation, premedication, or postoperative analgesia and patient refusal for ESP placement were excluded from the study. In patients in whom surgery lasted more than 150min i.e., 2½ hr, patients becoming uncooperative or suffering from any adverse event intra-operatively necessitating post-operative ventilator support or patients requiring re-exploration were to be withdrawn from the study.

Data related to demographic, history, general examination were recorded for all patients. Pre-anaesthetic check-up was done a day prior. Minimum mandatory investigations like CBC, INR, ECG, X-ray Chest PA view were carried out. Additional specialized investigations like USG abdomen, CT scan as per history and necessity were done. In the pre-operative room, intravenous access was secured and Ringer's Lactate Solution 2ml/kg/hr was started. In the operating room, standard monitors were attached. Baseline parameters were recorded, pulse rate,

systolic blood pressure, diastolic blood pressure, mean arterial blood pressure, SpO₂, ECG and temperature.

Reviewing the literature and based on the study by Peker et al, evaluating the efficacy of erector spinae plane (ESP) block in consumption of tramadol for postoperative analgesia, as a component of multimodal analgesia, sample size has been calculated. A Power analysis using total amount of tramadol consumed in the post-operative period as the primary outcome variable [68.42 ± 47.10 mg and 129.07 ± 61.95 mg] with a type-1 and -2 error probability of 5% and 20% (power of 80%), respectively and a between group mean difference in tramadol consumption of 50 mg, a sample size calculated is of 14 patients per Group. Assuming a drop-out rate of 20%, a final sample size of 34 patients (17 per Group) has been calculated. Patients were equally randomised into two study groups of 17 each, using a predetermined computer-generated random number allocation plan. Group A - Patients received ESP block with 0.25% inj. bupivacaine 20ml on each side (Total 40ml 0.25% inj. Bupivacaine). Group B - Patients had no intervention done.

The erector spinae plane block procedure was explained to the patients randomly allotted to Group A and performed in sitting position. The spinous process of the T9 vertebra were identified and a point 3 cm lateral was identified. A sonosite edge II linear probe HFL38x1 (6-13 MHz) (Fujifilm Sonosite, USA), was placed vertically and the back muscles, the trapezius, the rhomboidus major and erector spinae muscle from skin inwards was identified. The transverse process and the pleura was also identified. 2 ml of 2% lidocaine was infiltrated with hypodermic needle at the point of entry, i.e., caudal to the probe. A 22G spinal needle (Spinocan, B. Braun Melsungen AG, Germany) was inserted inplane in the cranial direction. Needle was visualized through the entire length. The transverse process was contacted and local anaesthetic (total 20ml of 0.25% bupivacaine) was injected slowly after confirmation of spread between the bone shadow and transverse process in the muscle plane. The same procedure was repeated on the opposite side. A volume of 40 ml of 0.25% bupivacaine (20 ml of 0.25% bupivacaine on either side) were injected in the patients of Group A. After performing the block, the patient was positioned in the supine position. Twenty minutes later, general anaesthesia was induced for the surgical procedure of exploratory laparotomy.

All the patients (Group A and B) were premedicated with inj glycopyrrolate 0.05 mg/kg. Anaesthesia was induced with 0.04 mg/kg midazolam, 2 mcg/kg fentanyl, and titrated doses of propofol. Endotracheal intubation was facilitated with 0.1 mg/kg of vecuronium bromide after confirmation by mask ventilation and mechanical ventilation was commenced with the tidal volume of 8ml/kg and frequency adjusted to achieve end tidal carbon dioxide of 35–40 mmHg. Sevoflurane 1-2%, in a mixture

of oxygen and nitrous oxide, was used for anaesthetic maintenance. Twenty minutes before the completion of surgery, all the patients received intravenous paracetamol 1 g, ondansetron 0.1 mg/kg and a loading dose of tramadol 1mg/kg. Patients were extubated at the discretion of the attending anaesthesiologist and the patients were transferred to the Post Anaesthesia Care Unit.

Vital parameters like pulse rate, SBP, DBP, MAP, SpO₂ were noted preoperatively, every five minutes after performing the ESPB, after pre-medication, at induction, at intubation, post intubation and then every 10 minutes till end of surgery, after reversal and after extubation, and then every half an hour for 2 hr and then at 4, 6, 12, 18, 24 hr in the recovery room. Intra-operative sevoflurane dial concentration and fresh gas flow and additional doses of fentanyl administered was also noted intra-operatively. The severity of pain at rest was assessed using a 10 cm visual analogue scale (VAS). VAS were noted at the beginning of surgery and then postoperatively at the same intervals in the recovery room. A standard post-operative analgesia regimen consisting of IV paracetamol 1g, 8 hourly was followed. If patient complained of pain (VAS Scores > 4 cm) then, IV tramadol analgesia with a demand dose of 20 mg, maximum dose of 100mg, and a lockout interval of 10 minutes were followed in all patients. Number of boluses of tramadol, cumulative tramadol consumption for 24 hr were noted.

The incidence of nausea, vomiting, sedation, respiratory depression and pruritus were assessed at same above-mentioned intervals post operatively. Rescue antiemetic ondansetron 0.1 mg/kg was given when a patient complained of nausea or vomiting. Sedation was assessed using the Ramsay sedation scoring system (1=patient anxious or agitated or both, 2= patient cooperative, oriented, 3= patient responds to commands only, 4= a brisk response to light glabellar tap, 5= a sluggish response to a light glabellar tap, 6= no response). Respiratory depression was noted as respiratory rate <8 per minute or SpO₂ < 90% on air. This was to be treated by giving supplementary oxygen and ventilator support if required. Any other complication or adverse effects such as block failure, bleeding, accidental epidural injection, local anaesthetic toxicity, pneumothorax, wound infection were noted and treated accordingly. Patients were followed till discharge and duration of hospital stay to be noted. The above parameters were assessed by the attending anaesthesiologist blinded to group allocation.

2.1. Statistical analysis

Statistical analysis was carried out with the help of Statistical Package for the Social Sciences (SPSS) Statistics for Windows [version 24.0, Professional] (IBM Corp., Armonk, N.Y., USA). Quantitative data were expressed as means +/- SD while qualitative data were expressed as numbers and percentages (%). One-way analysis of variance

(ANOVA) or t-test was used to test significance of difference for quantitative variables that follow Chi squared (X²), or Mann Whitney test was used to test significance of difference for qualitative variables. A probability value (p-value) <0.05 was considered statistically significant.

3. Observations and Results

A total of 34 patients were included in the study and randomly divided into two groups of 17 patients in each group. All the patients of either of the groups completed the study. Both the groups were comparable with respect to demographic profile of the patients and duration of surgery as shown in Table 1.

The baseline characteristics like heart rate, SBP, DBP, MAP, respiratory rate, and oxygen saturation were comparable with no significant difference between the two groups. The mean pulse rate in Group A was significantly less than Group B after premedication, after induction-intubation and at all intervals throughout the surgery. Post-operatively, the mean pulse rate was observed to be significantly less in Group A than in Group B with no incidence of bradycardia in any patient (Figure 1).

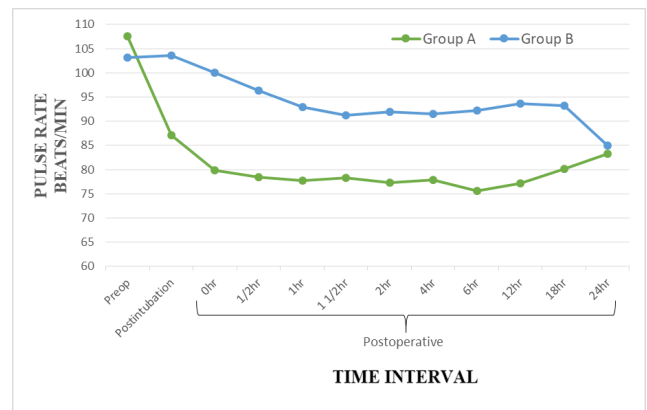


Fig. 1: Heart rate changes between 2 Groups

The mean of MAP of two groups, was comparable at all intervals intraoperatively and postoperatively except at induction, where mean MAP was less in Group A compared to Group B, due to the effect of propofol compounded by effect of block (Figure 2).

The mean of respiratory rate of Group A significantly less than Group B at all intervals post-operatively. No patient depicted respiratory rate less than 10 breaths/min (Figure 3). Similarly, there was no significant difference noted in SpO₂ in between the groups postoperatively except at 1/2, 6 and 18 hr (97-98%), hence clinically insignificant.

In the postoperative period, VAS score in Group A was significantly less at all intervals postoperatively than Group B (Figure 4). Mean VAS Scores were observed to be continuously rising from 0 hr (immediate postoperative

Table 1: Demographic profile of the patients and duration of surgery

Demographic data		Group A	Group B	P value
Age (years)	Mean	44.41±10.45	43.76±10.60	0.863
Weight (kg)	Mean	64.47±6.46	61.94±5.84	0.240
Gender	Male	09 (52.94%)	10 (58.82%)	0.730
	Female	08 (47.06%)	07 (41.18%)	
Duration of surgery (min)	Mean	116.47 ± 38.06	111.17 ± 34.79	0.6750
P Value > 0.05 - Not significant				

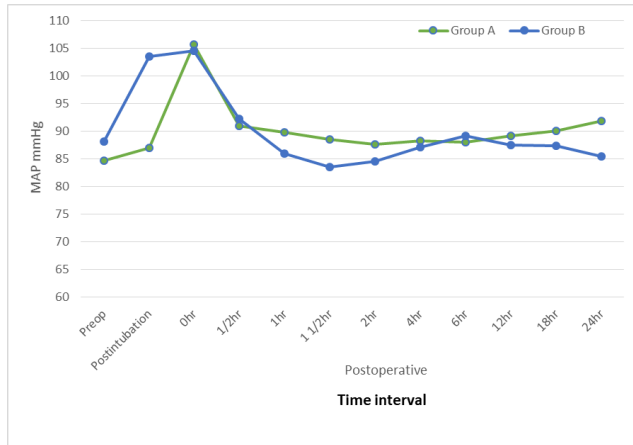


Fig. 2: Mean arterial pressure changes between 2 groups

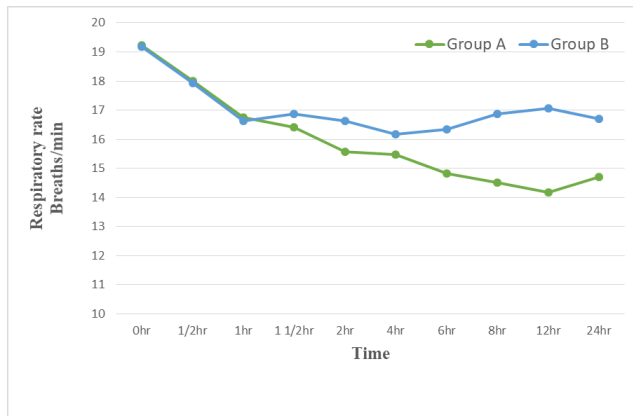


Fig. 3: Post operative respiratory rate changes between 2 groups

period) throughout the postoperative period in Group B patients. 10, 12, 15, 14 and 17 patients at 2 hr, 4 hr, 6 hr, 12 hr and 24 hr respectively, in Group B had a VAS Score of > 4 cm whereas they were found to be <1 cm in most of the patients of Group A for the above-mentioned intervals postoperatively.

The requirement of injection Tramadol was significantly reduced in Group A than in Group B at all intervals postoperatively. The mean of total tramadol doses required in 24 hr and consumption of mean of total tramadol in 24 hr in statistically significantly lower in Group A than in Group

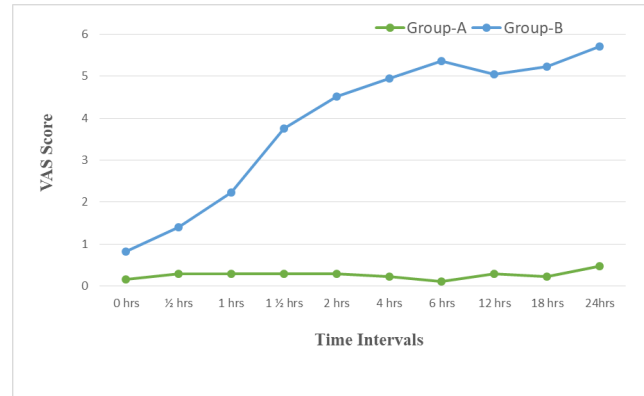


Fig. 4: Comparison of mean VAS score at different time points between 2 Groups

B (Table 3). Ten patients in Group B received tramadol as a rescue analgesic as early as 1 1/2 hr postoperatively while no patients in Group A demanded any. In Group A, only 1 patient at 2 hr and 1 at 4 hr received tramadol as a rescue analgesic. At 2 hr, 4 hr, 6 hr, 12 hr, and 24 hr 7, 5, 4, 5 and 5 patients received a single dose for pain relief, whereas 8, 12, 13, 8 and 12 patients received two bolus doses respectively (Table 2).

The mean sedation score at 0 hr (immediate postoperative period) was between RSS- 3 and RSS- 4 in all the patients due to the residual effect of anaesthesia. Hence, no difference in mean sedation scores between the groups. The mean sedation scores were more in group B than in group A at all intervals henceforth but statistically significant at 12hr and 18hr. Higher sedation scores as observed in group B could be attributed to increased consumption of tramadol (Figure 4).

The sevoflurane consumption was found to be significantly reduced in Group A than in Group B. The mean of total sevoflurane consumption during surgery in Group A was 1.96 ± 0.22 ml/min and in Group B, it was 2.98 ± 0.31ml/min with p<0.0001. The total fentanyl consumed intraoperatively in Group A was 2.01 ± 0.048 mcg/kg which was also significantly less compared to Group B i.e., 2.25 ± 0.34 mcg/kg.

A total 8 (47%) patients complained about nausea, 5 (29.4%) patients had vomiting and 17 (100%) were sedated (RSS > 3) in Group B as compared to 10 (58.82%)

Table 2: Comparison of mean Tramadol requirement at different time points between 2 groups

Time	Group-A		Group-B		P value
	Mean	SD	Mean	SD	
0 hr	0	0	0	0	–
½ hr	0	0	0	0	–
1 hr	0	0	0	0	–
1 ½ hr	0	0	11.76	10.14	0.0001
2 hr	1.17	4.85	27.05	14.03	0.0001
4 hr	1.17	4.85	34.11	9.39	0.0001
6 hr	0	0	35.29	8.74	0.0001
12 hr	0	0	24.70	16.62	0.0001
18 hr	0	0	24.70	15.04	0.0001
24hr	3.52	7.85	34.11	9.39	0.0001

P Value < 0.05, significant

Table 3: Comparison of total dose and total tramadol consumption in 24 hr between 2 groups

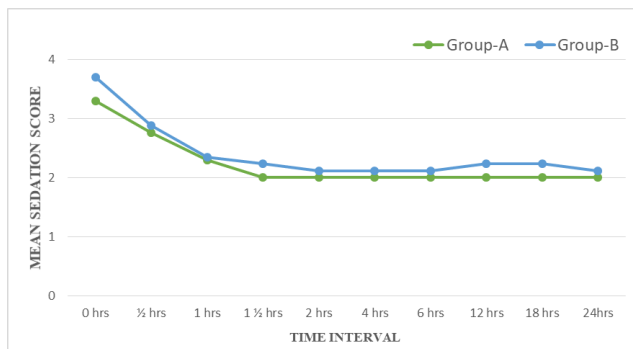
Tramadol consumption	Group-A		Group-B		p-value
	Mean	SD	Mean	SD	
Total doses	0.29	0.68	6.05	0.68	0.0001
Total Tramadol consumption in 24hr	5.88	13.71	191.76	40.65	0.0001

P Value < 0.05, significant

Table 4: Comparison of complications between 2 groups

Complication	Group-A		Group-B		P-value
	N	%	N	%	
Nausea	-	-	8	47.06	0.003
Vomiting	-	-	5	29.41	0.044
Sedation (RSS>3)	10	58.82	17	100	0.0008

P Value < 0.05 - Significant

**Fig. 5:** Comparison of sedation score between 2 groups

patients in Group A who were found sedated (RSS > 3). Hypotension, bradycardia, respiratory depression, itching, pain at site of injection, dryness of mouth was not observed in any patient. Complications due to procedure like bleeding, accidental epidural injection, local anaesthetic toxicity, pneumothorax was also not observed in group A.

4. Discussion

Visceral pain after laparotomy is generally of a short duration, lasting for 24-36 hr but intense in character and somatic pain, being the major component lasts for almost 72 hr.⁷ Opioids effectively block visceral pain compared to the somatic element of pain. Hence, only opioid analgesia may be inadequate and also give rise to opioid related side effects. The ultrasound-guided fascial plane block techniques are safer, better and simpler alternatives available that provide excellent analgesia when used as a part of multi-modal analgesia. The ESPB is a technically easier alternative to conventional methods like thoracic epidural, provides regional analgesia of the thoracic cavity and abdominal wall,^{4,5} though the drug has been injected away from neuro-axial structures. The local anaesthetic is injected into the fascial plane which lies just below the erector spinae muscle group, spreads cranially and caudally to provide analgesia.⁶

In a recent meta-analysis by Gao et al,⁸ on the post-operative efficacy of ESPB in adult abdominal surgeries, performed at levels, T7-T9 provided better analgesic profile compared to TAPB (Transverse abdominis plane block). Moreover, Kamal et al concluded that ESPB at T9 provides

more potent analgesia and less opioid consumption after open total abdominal hysterectomy. To study the efficacy of bilateral ESPB at T9 on quality of analgesia and tramadol consumption after laparotomy, 17 patients out of 34, were randomly allotted to receive bilateral ultrasound guided ESPB with 0.25% bupivacaine 40ml (20ml each side).

In the present study, both the groups were comparable and found no significant difference with respect to demographic profile of the patients and duration of surgery. The institution of ESP block produced no significant variation in the vital parameters (heart rate, SBP, DBP, MAP, respiratory rate, and oxygen saturation) and the ESP block was well tolerated and accepted.

Post-operatively, the mean VAS scores were observed to be significantly more in Group B compared to mean VAS scores in Group A at all intervals ($p=0.0001$ to 0.0198). At $\frac{1}{2}$ hr and 1 hr, VAS Scores were <4 cm in all patients, due to the analgesic effect of Inj Paracetamol and Inj Tramadol administered in the post-operative period. Though mean VAS Score in Group B was <4 cm, they were however, significantly more than that in Group A. Thus, quality of analgesia was better in group A than in group B. At 4 hr postoperatively, in Group B, all 17 patients had depicted a VAS score of > 4 cm and were administered the first dose of tramadol as a rescue analgesic. Thus, pre-operative institution of ESPB helped in maintaining VAS scores < 1 cm till 24 hr postoperatively after undergoing laparotomy procedures, conferring better quality of analgesia. These findings of present study coincided with findings observed in previous studies.^{4,8–10}

For the assessment of total tramadol consumption for pain relief in the postoperative period, injection tramadol was given according to VAS score in intermittent bolus doses. Ten patients in Group B received tramadol as a rescue analgesic as early as $1\frac{1}{2}$ hr in postoperative period while no patients in Group A demanded any. In Group A, only 1 patient at 2 hr and 1 at 4 hr received tramadol as a rescue analgesic and henceforth none till 24 hr. Tramadol requirement was however, observed to be more with increasing time interval. The cumulative tramadol consumption was hence, found to be significantly low in Group A (5.88 ± 13.71 mg) than Group B (191.76 ± 40.65 mg).

In Group B, at $1\frac{1}{2}$ hr, 10 patients requiring rescue analgesic, received only single bolus dose of tramadol. In Group B, all the patients received multiple doses of single or double bolus doses of tramadol throughout the study. At 24 hr, the 3 patients in Group A, requiring rescue analgesic received only a single bolus dose of 20 mg of tramadol. Thus, number of doses of Inj Tramadol was also significantly lower in Group A than in Group B. Similar findings are reported in study conducted by Gao et al⁸ and Kamel AAF et al.⁹

Sedation score was assessed with the help of Ramsay Sedation Scoring (RSS) System. Immediately postoperative period till $\frac{1}{2}$ hr, sedation score was found to be comparable between both the groups (RSS- 3 and RSS-4). The mean sedation scores were more in group B than in group A at all intervals henceforth but statistically significant at 12hr and 18hr. However, no patient in Group B depicted an RSS-4 or 5 and above. It can be inferred that the consumption of comparatively higher amount of tramadol could have led to the higher sedation score as observed in Group B. These findings are in accordance with the study done by Subedi et al¹¹ and Koncz et al.¹²

The mean of respiratory rate of Group A significantly less than Group B at all intervals post-operatively, due to the increased use of tramadol. No patient depicted respiratory rate less than 10 breaths/min. Patients of either group were hemodynamically stable throughout the study. The incidence of nausea was 47.06% and vomiting was 29.41% in Group B and 0% nausea and vomiting in Group A. The significantly increased incidence observed in Group B could be attributed to the increased consumption of tramadol. Similar findings are reported in other studies.^{8–10,13,14}

Similarly, ESPB instituted preoperatively, helps in attenuating pressor response to intubation with no effect on hemodynamic intra-operatively. These findings are coincided with the findings observed in other studies.^{4–7}

As an integral part of balanced anaesthesia, both sevoflurane, as inhalational anaesthetic agent and fentanyl opioid analgesia was used. The consumption of inhalational agent, sevoflurane and intraoperative fentanyl consumption was statistically significantly less in patients receiving ESPB, which could help in reducing costs. Findings coincide study conducted by Peker et al.⁴

There are some limitations of the study which includes- It was a single blinded study; blood level of local anaesthetics could not be measured; hence systemic effects could not be measured; Continuous ESPB was not studied.

5. Conclusion

Exploratory laparotomy with large midline incision and bowel handling for prolonged time causes severe postoperative somatic as well as visceral pain which may hamper outcome by delaying early ambulation and increasing hospital stay. The pre-operative institution of ESP block, as a part of multimodal analgesia decreases tramadol consumption till 24 hr in postoperative period by decreasing pain intensity and providing adequate analgesia. It maintains hemodynamic stability throughout the intraoperative and postoperative period. Patients are less sedated due to decreased need for tramadol and hence also reduces postoperative complications like nausea, vomiting, sedation, shivering, hypotension, respiratory depression. Thus, the study concludes that the ESPB is a simple, easy, convenient option, when utilized as a component of

multi-modal analgesia for pain relief in abdominal surgery.

Continuous ESPB with catheter and proportionate relationship between the volume injected and the extent of analgesia should be studied.

6. Source of Funding

None.

7. Conflict of Interest

None

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