



Original Article

Comparison Of Analgesic Efficacy of Ultrasound Guided Bilateral Erector Spinae Plane Block Versus Conventional Intravenous Patient Controlled Analgesia in Patients Undergoing Cardiac Surgery with Midline Sternotomy: An Open Label Randomised Controlled Trial

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ABSTRACT

Background and aims: The effective analgesia following cardiac surgery with minimum opioid usage prevent post-operative pulmonary complications. The study aimed to assess the analgesic efficacy and safety of Ultrasound guided single shot bilateral Erector spinae plane (ESP) block compared to conventional intravenous patient controlled opioid analgesia in patients undergoing cardiac surgeries with midline sternotomy.

Methods: 102 patients belonging to ASA status II and III, aged between 18 to 70 years, scheduled for elective cardiac surgery with midline sternotomy were enrolled and randomly allocated into two groups. The patients in group 1 received ESP block (n=51) with 0.3 ml/kg of 0.5% ropivacaine under ultrasound guidance before anaesthesia induction at T5 spinous level, while patients in group 2 did not receive any block. After surgical procedures, patients were sent to the intensive care unit and extubated in accordance with protocol. Post-surgery, patients were taken to the ICU and extubated per protocol. Pain levels were assessed using the Visual Analogue Scale (VAS) for 24 hours. Both groups were provided intravenous fentanyl through a Patient Controlled Analgesia (PCA) pump. The primary objective was on comparing post-operative fentanyl consumption within the first 24 hours of ICU stay after extubation. Data collected were analysed using the Chi-square test or Students' t-test with the help of SPSS 22.0.

Results and Conclusion: The median fentanyl (IQR)(range) consumed (in µg) in first 24 h of ICU stay was significantly lower in ESP block group [160 (71.50). (10-420)] compared to IV PCA fentanyl group [380 (132.50) (130-600)] (P value <0.001). Use of bilateral ESP block provides effective analgesia promoting early extubation of patients, and also reduces post-operative opioid consumption and its associated side effect with better patient's satisfaction in relieving acute postoperative pain after cardiac surgery.

Keywords: elective adult cardiac surgery, sternotomy, postoperative pain. erector spinae plane block, patient-controlled analgesia, Opioids, Visual analogue scale.

INTRODUCTION

Patients undergoing cardiac surgery experience moderate to severe pain in the postoperative period and the intensity of pain is maximum in the initial 72 hours.^[1] Multiple factors, including tissue damage, intercostal nerve injury, sternotomy, stainless-steel wire sutures, and costo-chondral separation contribute to pain following sternotomy. Inadequate pain management following cardiac surgeries promotes the development of postoperative pulmonary complications (PPC) like pulmonary atelectasis, pneumonia etc., and can also lead to the development of chronic pain.^[2]

For acute pain following cardiac surgery, short-acting intravenous (IV) opioids are routinely used.^[3, 4] However, their use is associated with side effects and the quality of analgesia provided doesn't match with that provided by regional anesthesia techniques.^[5] Use of anticoagulation during cardiac surgery makes the central neuraxial analgesia techniques relatively contraindicated however, the fascial plane blocks have been used successfully.^[6] The erector spinae plane (ESP) block is one of the fascial plane block technique first described by Forero et al. for thoracic and abdominal neuropathic pain.^[11] The local anaesthetics are deposited between the erector spinae muscle and the transverse process of the vertebrae. By blocking dorsal and ventral rami of spinal nerves, it provides excellent analgesic coverage over the thorax at the targeted dermatome, including the midline sternotomy site when administered at the level of the T4 transverse process. The target site is relatively superficial, distant from the pleura and major vessels, nerves, and the spinal cord, which reduces the risk of complications.^[12]

Although, few RCTs established the efficacy of ESP block for acute pain management after cardiac surgery by comparing pain scores of the patients but literature is scanty regarding its postoperative analgesic efficacy in reducing opioid consumption and its safety in administering to cardiac surgery patients. Hence, we hypothesized that ESP block significantly reduces the postoperative opioid consumption in cardiac surgery patients. The other aims were to compare the VAS score during postoperative period, time to extubation, peak inspiratory flow rate, number of rescue analgesics, postoperative pulmonary complications, patient satisfaction and side effects of both the techniques.

METHODOLOGY

The present prospective, randomised, single-blind, comparative study was conducted after obtaining informed and written consent from patients and approval from the Institutional Ethics Committee (IEC Reg No. AIIMS/IEC/2021/3316, dated 12/03/2021; approved by Dr. Parveen Sharma). The study was prospectively registered at Clinical Trial Registry-India (CTRI Reg. No. CTRI/2021/04/042455 dated 26/04/2021; Patient enrolment date-03/05/2021). All the procedures were followed in accordance with the ethical standards of the local institutional committee on human experimentation and with the Helsinki Declaration of 1975. A total of 102 patients of either sex, aged between 18-70 years, belonging to ASA physical status II or III, scheduled for elective cardiac surgery with midline sternotomy were enrolled. Patients undergoing emergency surgery, redo surgery, low ejection fraction, refusal for block and patients with cognitive deficits were excluded. Following screening, patients were randomised with computer generated random number table into two groups (n=51). The group allocated was sealed in opaque envelope which was opened on day of operation. The group 1 patients received ultrasound guided bilateral ESP block which was performed at T5 level with 0.3 ml/kg of 0.5% ropivacaine on either side, while patients in group 2 did not receive any block.

Preoperative Evaluation: All patients underwent a thorough pre-anaesthetic evaluation and they were taught how to use the PCA pump and how to express the severity of their postoperative pain using a visual analogue scale with a score ranging from 0 to 10 (0 = no pain to 10 = the worst pain experience). According to institutional protocol, all patients were kept nil per oral (2 h for clear liquid and 6 h for semisolid and solids). Tablet alprazolam 0.25 mg and tablet ranitidine 150 mg was prescribed night before the surgery and the morning of the surgery.

Day of Surgery, Operating Room: After application of standard American Society of Anesthesiologists (ASA) monitors like electrocardiogram (ECG), non-invasive blood pressure (NIBP), and pulse oximetry were attached. A 16-gauge peripheral intravenous cannula and 20-gauge right radial arterial catheter were secured under local anaesthesia.

ESP Block Group: Patients belonging to group 1, received bilateral ESP block using portable ultrasound device ("Philips Epiq 7CUS machine" Chicago, United States) in sitting position with the help of linear high frequency (13-8 MHz) probe. The ultrasound transducer was placed at T5 spinous process. The transducer then slowly moved to the lateral direction and all the three muscles (erector spinae, rhomboid major and trapezius) were identified superficial to the hyperechoic transverse process shadow. A 5 cm, 22-gauge block needle (Stimuplex; B Braun Medical, Bethlehem, Pa) was inserted in the plane of transducer at an angle of 30 degree to the skin in a caudal to cranial direction until the tip crosses the inter fascial plane between muscles and the transverse process. The needle tip position was confirmed by visible linear spread of fluid between transverse process and muscle upon injection of normal saline. A total of 0.3 ml/kg of 0.5% ropivacaine was injected on that side after negative aspiration for blood under US guidance. The same procedure was attempted on the other side.

Anesthetic Management: The fentanyl 5 µg/kg and propofol 1-2 mg/kg were administered till BIS in the range of 40-60 than rocuronium 1mg/kg was administered and airway was secured with appropriate size endotracheal tube. Anaesthesia was maintained with oxygen and air mixture (50:50) and isoflurane. The muscle relaxant and fentanyl were administered intraoperatively as per discretion of consultant. Intraoperative BIS was maintained in the range of 40-60.

The last dose of rocuronium and fentanyl was given at the time of sternal closure. After completion of the surgical procedure patients were shifted to ICU and extubation was carried out according to standard institutional protocol. The paracetamol 1 gm was prescribed to all patients every 6 hourly. The time to extubation was recorded in both groups and it was defined as from shifting of patient in the ICU to the extubation.

After extubation, VAS score was recorded and patients in both the groups were received fentanyl IV PCA pump (CADD-Legacy® PCA, Model 6300, Smith Medical ASD, Inc., St. Paul, MN 55112, USA). For PCA pump, bolus dose of 0.5 mcg/kg and lockout interval of 30 minutes were set. Diclofenac 75 mg was administered as rescue analgesic on patient demand.

The primary and secondary objectives :

The primary outcome of this study was the total requirement of intravenous PCA fentanyl in first 24 hours. Secondary outcomes measured were post-operative VAS score, peak inspiratory flow rate by using incentive spirometry at extubation and then every 4 hours till 24 hours. The time to extubation, number of rescue analgesia, patient satisfaction score and adverse effects were recorded. Side effects during the observation period like drowsiness, respiratory depression, postoperative nausea vomiting, itching, and post-operative pulmonary complications were also noted.

The sample size was calculated on the basis of previous study by Gurbet et al.^[13]. The standard deviation of 5.84 in the IV PCA group with non-inferiority limit of 5, significance level of 5 % and power of study 80%; the sample size calculated was 51 per group. Considering a 20% contingency, we decided to include 51 patients in each group.

Statistical analysis: The data was entered in Microsoft Excel spreadsheet and the final analysis was done with the use of statistical Package for Social Sciences software (SPSS). Normality of data was tested with Kolmogorov– Smirnov one-sample test. Data were presented as mean ± standard deviation (SD) for normally distributed quantitative variables and as median (range) for ordinal variables and quantitative variables with non-normal distribution. Categorical variables were presented as absolute numbers or percentages. Student's t test and χ^2 test were used to analyze continuous and categorical data respectively. Quantitative variables with non-normal distribution and ordinal variables were analyzed with Mann-Whitney test. P value <0.05 were considered significant.

RESULTS

Total 120 patients were enrolled in the study, but 18 patients were excluded from the study (10: not meeting the inclusion criteria and 8: refuse to participate). Remaining 102 patients were randomized equally into two groups of 51 each. There was no lost to follow up in either of the group.

There were no statistically significant difference between group with respect age, gender, weight, height and BMI (table 1). The total postoperative fentanyl consumed in ESP group, bolus dose attempted and bolus dose administered was 160(71.50)(10-420), 8(3.5)(5-18) and 6(2.5)(2-14), while in PCA group was 380(132.50) (130-600), 15(3) (7-20) and 14(3) (6-16), ($P < 0.001$) (Table 2). The median time to extubation was shorter in group ESP compared to PCA group ($P < 0.001$) (Table 3).

ESP had significantly lower VAS score at rest compared to group PCA during first 24 hours ICU stay. The VAS Score on cough was significantly lower in group ESP upto 20 hours of ICU stay (Table 5). The peak inspiratory flow rate during ICU stay at pre-defined interval were statistically significant except at time of extubation and at 8th hour of extubation.

The median number of rescue analgesia was lower in group ESP compared to group PCA [0(0,1)(0-2); 2(1)(0-4) respectively, ($P < 0.001$) (Table 3). The median patient satisfaction score in group ESP was 2 (2,2) (1-3) and while in group PCA it was 2(2,3) (2-4) respectively (Table 3).

No patients in group ESP, while twenty-five (49%) patients in groups PCA had at least one adverse event. Sedation was the most adverse event followed by nausea/vomiting and pruritus. None of the patients in either group had any post operative pulmonary complications in relation with the technique involved. Patients in group ESP had significantly lower adverse effects for the technique compared to the patients in group PCA ($P < 0.001$) (Table 4).

Table 1: Demographic data & Variables.

Characteristics	ESP group	PCA group	P value
Sex distribution			
Male	21	30	0.113
Female	30	21	
Surgical procedure			

Single valve surgery	26	28	0.843
Dual valve surgery	10	15	0.357
Other(ASD,VSD..)	15	8	0.155
Variables	Mean ± SE or Median(IQR)(Range) (95% CI)	Mean ± SE or Median(IQR)(Range) (95% CI)	p value
Age (y)	34.37±11.89	35.29±12.30	0.701
Weight(kg)	53.12±12.74	57.08±12.29	0.113
Height(cm)	165.67±6.96	165.35±6.81	0.818
BMI	20.52±3.61	22.31±3.52	0.307
ASA(II/III)	19/32 5.5(1)(3-8)	18/33 6.5(2)(4-8)	1.00 0.009
Duration of surgery (in hours)			
HR(bpm) (mean ± SD)	77.65 ± 9.56	76.39 ± 10.30	0.525
MAP(mm Hg) (mean ± SD)	70.44 ± 7.17	73.39 ± 8.30	0.426
Spo2(%) median(IQR)(range)	99(1)(98-100)	99(1)(98-100)	0.211
RR(per min) median(IQR)(range)	14(2.5)(12-18)	14(3)(12-17)	0.754

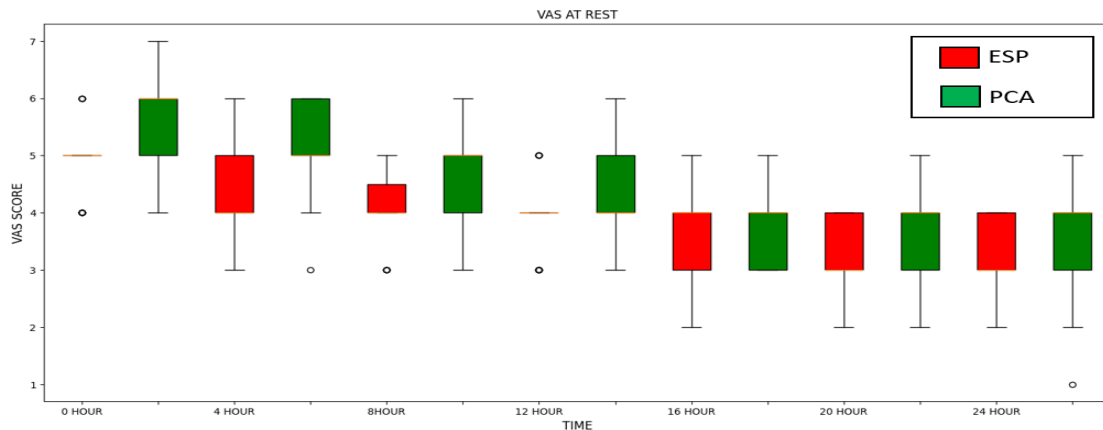


Figure 3: Box plot for comparison of VAS Scores at rest between the study groups during ICU stay

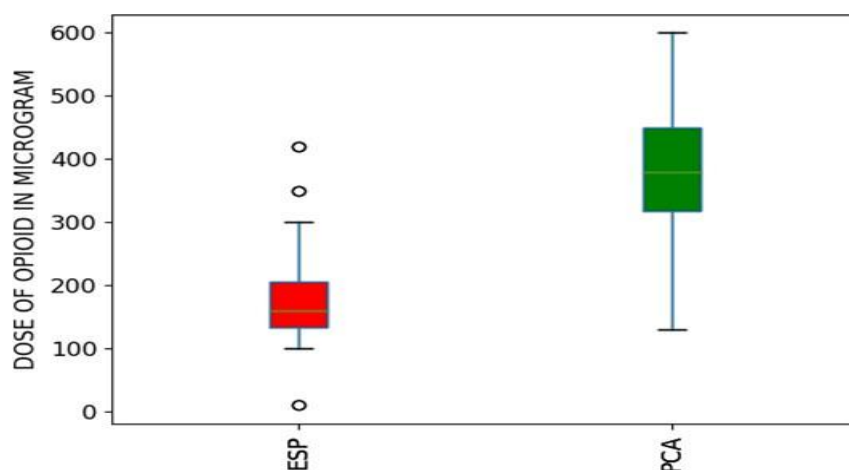


Figure 4: Box plot for comparison of total postoperative opioid consumed between the study groups during ICU stay.

Table 2: Comparison of Postoperative Total opioid consumed, PCA bolus dose attempted

and administered between the study groups during ICU stay

	Group ESP [Median (IQR)(range)]	Group PCA [Median (IQR)(range)]	P value
Total opioid consumed (µg) [Median (IQR)(range)]	160 (71.50) (10-420)	380 (132.50) (130-600)	<0.001
Bolus dose attempted [Median (IQR)(range)]	8 (3.5) (5-18)	15 (3) (7-20)	<0.001
Bolus dose administered [Median (IQR)(range)]	6 (2.5) (2-14)	14 (3) (6-16)	<0.001

Table 3: Post operative Variables

Variables	Group ESP	Group PCA	P value
Time to extubate	3.25(3-4)	5.50(5-6.25)	<0.001
Intraoperative Fentanyl (µg/kg/h)	1.50(1.24-1.83)	2.02(1.66-2.50)	<0.001
No. Rescue analgesia required	0(1)(0-2)	2(1) (0-4)	<0.001
Patient Satisfaction Score	2(2,2)(1-3)	2(2,3)(2-4)	0.0002

Table 4: Comparison of Side Effects between the study groups

Adverse Effects	Group ESP		Group PCA	
	No.	%	No.	%
Sedation	0	0.00	15	29.41
Nausea & vomiting	0	0.00	8	15.68
Pruritis	0	0.00	2	3.92
No side effects	51	100.00	26	50.98
Total	51	100.00	51	100.00
P value	<0.001			

Table 5: Comparison of VAS scores at rest and cough between study groups. Values are presented as median (IQR)(range).

Time (h)	VAS at Rest		P value	VAS at cough		P value
	ESP (n=51)	PCA (n=51)		ESP (n=51)	PCA (n=51)	
On extubation	5(5,5)(4-6)	6(5,6)(4-7)	<0.001	6(6,6)(5-6)	6(6,7)(5-7)	0.0003
4	4(4,5)(3-6)	5(5,6)(3-6)	<0.001	5(5,6)(4-6)	6(6,6)(5-6)	0.003
8	4(4,5)(3-5)	5(4,5)(3-6)	0.0006	5(5,6)(4-6)	6(5,6)(5-6)	0.0001
12	4(4,4)(3-5)	4(4,5)(3-6)	0.0041	5(4,5)(3-6)	6(5,5)(4-6)	0.0002
16	4(3,4)(2-5)	4(3,4)(3-5)	0.023	4(4,5)(3-5)	5(5,5)(4-6)	0.0004
20	3(3,4)(2-4)	4(3,4)(2-5)	0.012	4(4,5)(3-5)	5(4,5)(3-6)	0.012
24	3(3,4)(2-4)	4(3,4)(1-5)	0.018	4(4,4)(3-5)	4(4,5)(2-5)	0.083

DISCUSSION

This study was designed to investigate the efficacy of US guided bilateral ESP block for post-operative analgesia management after midline sternotomy in cardiac surgical patients. The results demonstrated that the bilateral single shot ESP block provided a good quality of analgesia, reduces the opioid consumption, lower VAS scores during the first 24 hours in the patients who underwent midline sternotomy. Additionally, patients received ESP block required fewer rescue analgesics, fewer PCA bolus doses (attempted and administered), extubated earlier and less respiratory complications. The patients in ESP group had less opioid related side effects and had higher patient satisfaction.

Intense discomfort is frequently experienced in patients undergoing midline sternotomy, especially in the initial few days. Adequate analgesia enhances functional outcomes, encouraging early ambulation and hospital discharge, and prevent the onset of chronic pain. Conventionally the

postoperative pain following cardiac surgery was managed with intravenous administration of opioids, PCM, NSAIDs, gabapentinoids, acetaminophen, etc.^[14]

Due to risk of epidural hematoma in anticoagulated patients the neuraxial analgesia (epidural or intrathecal) and paravertebral block are not popular technique.^[6] The pain in cardiac surgical patients is usually managed by intravenous opioid, but it is not devoid of side effects such as nausea, urinary retention, delayed extubation.

With introduction of ultrasound, the fascial plane blocks are performed with precisely. The drug is deposited under vision and these block demonstrated improved pain control with less reliance on opioids.^[15] Various blocks like paravertebral block, ESP block, SAP block, parasternal blocks are used in patients undergoing cardiac surgery.

The ESP block has demonstrated extensive craniocaudal spread of local anesthetic when given deep to ESP muscle at the level T5 transverse process. As the injection site is far from the central neural axis and major vascular structures as well as simple to visualize also, hence ESP block is a simple and safe and can be used as replacement to thoracic paravertebral and epidural block. Additionally, the transverse process is helpful as a stopper and backstop for needle progress, enhancing the comfort and the block's safety in preventing pleural puncture. These safety aspects of the ESP block allow one to perform the block on anticoagulated cardiac surgery patients with a reasonable margin of safety and trust.^[10]

The efficacy and safety of ESP block was established in noncardiac cardiac surgeries.^[16] Although, ESP block was studied in cardiac surgical population, but limited literature is available so far. The local anesthetic deposited posterior to ESP muscle diffuses to paravertebral space and block the ventral and dorsal rami of spinal nerve. This study demonstrated that ESP block minimizes the post-operative fentanyl consumption. The similar finding was observed in other studies.^[17-19]

Our study demonstrated the lower fentanyl consumption in ESP group compared to PCA group. Our results were in accordance with the study conducted by Ciftci et al^[17] and Ali Gado et al.^[18] The ESP block also provide pain related to chest drain. The VAS scores at rest were significantly lower till 24 hours of ICU stay, while VAS scores at cough were lower for up to 20 hours in ESP group. This could be explained by the single shot ESP block with ropivacaine and its expected duration of action.^[20] Not only better control of pain, the patients received ESP block were extubated earlier than their control group. This finding was substantiated by other studies.^[19,21] The better control of pain improves the peak inspiratory flow rate, which in turn lead to lesser post-operative pulmonary complications. In our study non-significance in peak inspiratory flow rate at extubation and at the 8th hour after extubation might be due to wear of effect of intraoperative opioids and inhalational agents.

Singh et al^[22] stated that patients who underwent ESP block were more satisfied than the control group ($P < 0.001$). Our study observed that the median (IQR) (range) satisfaction score of group ESP was 2 (2,2) (1 – 3) (good), and while in group PCA was 2 (2,3) (2–4) (good to fair) (p value = 0.0002).

There was no complications related to bleeding or hematoma formation in ESP group. However, there was a significant proportion of patients in PCA group that experienced opioid related side effects among which sedation was the most common, followed by nausea, vomiting and pruritis. Apart from our secondary objectives, we found a significant reduction in intraoperative opioid in the ESP group versus the PCA group ($P < 0.001$).

Strength of our study were that one anaesthesiologist performed all of the blocks using ultrasound guidance during the course of the study. Also randomization and allocation concealment was strictly followed throughout the study.

The **limitation** of the study was that it was an open labelled trial as blinding was not possible for the selected intervention and also ESP block was carried out using a single shot method rather than a continuous analgesic method, which would have further prolonged the analgesic duration. Also due to anatomical limitations, we were unable to gauge the precise local anaesthetic spread following the ESP block.

CONCLUSION

The ultrasound guided single shot bilateral ESP block is a safer alternative to opioid based analgesia as a component of multimodal pain management in patients undergoing cardiac surgery involving midline sternotomy. Use of bilateral ESP block provides effective analgesia promoting early extubation of patients, and also reduces post-operative opioid consumption and its associated side effect with better patient's satisfaction in relieving acute postoperative pain after cardiac surgery.

Recommendation:

Bilateral erector spinae plane block is a safer alternative to opioid based analgesia for acute post-surgical pain in patients undergoing cardiac surgery with midline sternotomy.

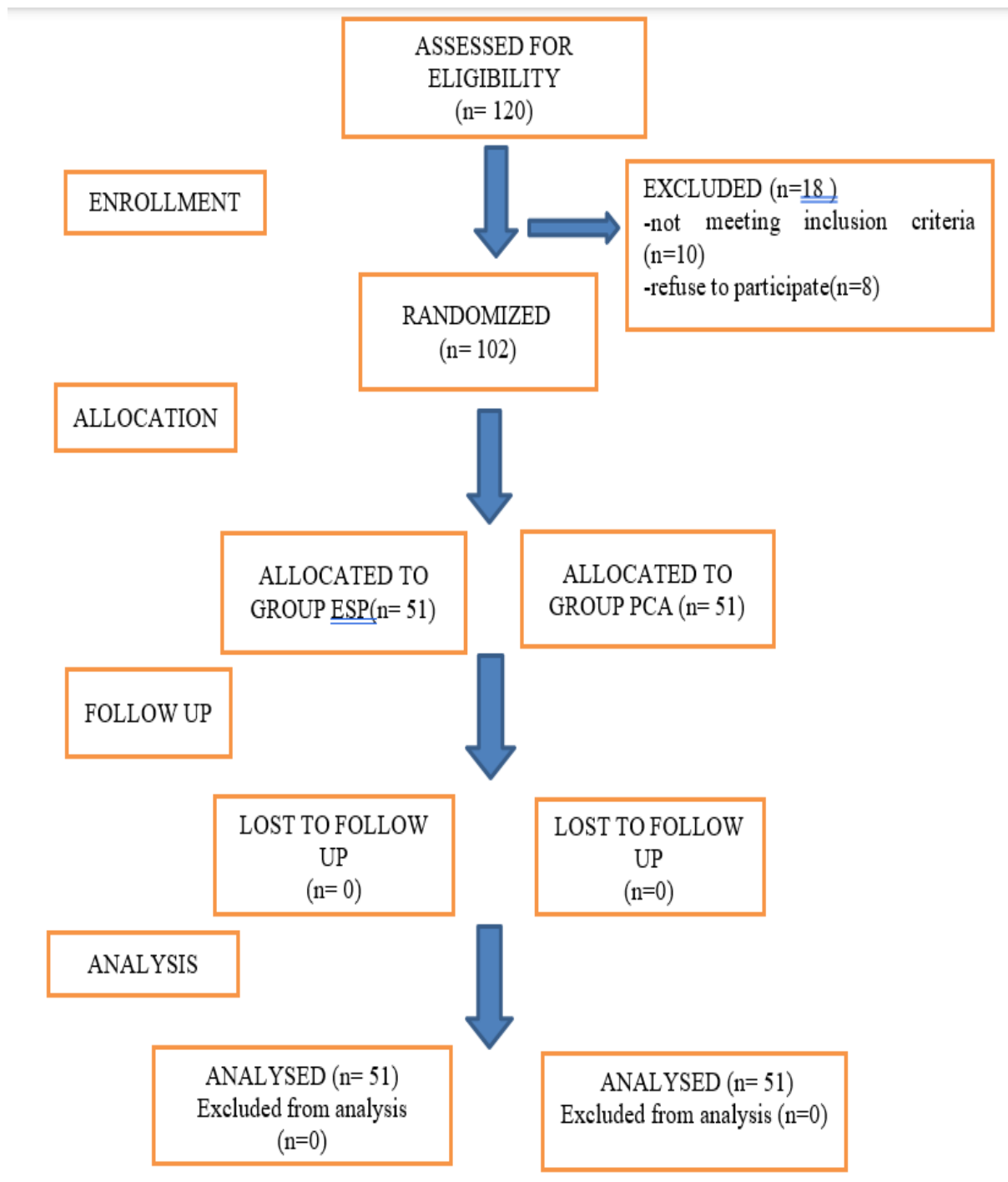


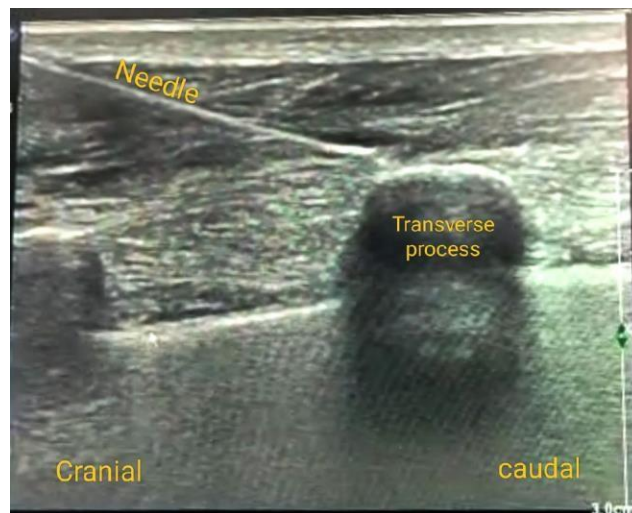
Fig 1. CONSORT flow chart



Figure 2: USG guided ESP block being performed under aseptic conditions at T5 vertebral level with in-plane technique using a high frequency linear probe (8 13MHz). A 22-gauge 50 mm block needle was inserted in a cephalad to caudal direction.



A



B



C

Figure3: Craniocaudal spread of local anesthetic in erector spinae plane. (A) Anatomy explaining the relationship between erector spinae muscle and transverse process (TP). (B) ESP block performed at the level of T5 transverse process. (C) Local Anesthetic drug injected under the ES muscle separating the fascia from T5 transverse process resulting in extensive linear spread of the drug in cranio-caudal direction.

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