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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 Trail

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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 theanalgesicefficacyandsafetyof Ultrasound guided singleshotbilateralErector spinae plane (ESP)block compared to conventionalintravenouspatientcontrolledopioid analgesia inpatients undergoingcardiac surgeries withmidline 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 contributeto pain following sternotomy.Inadequatepainmanagement following cardiac surgeries promotes the development of postoperative pulmonary complications (PPC) like pulmonaryatelectasis, pneumonia etc., and can also leadto the development of chronicpain.[2]

For acutepainfollowingcardiac surgery,short-acting intravenous (IV) opioids are routinely used.[3, 4]However, their use is associated with side effectsand the quality of analgesia provided don't match with thatprovided byregional 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]Theerector spinae plane (ESP)blockis one of the fascial plane block technique first described by Forero et al.forthoracicand abdominalneuropathic pain.[11]The local anaesthetics are deposited between the erectorspinaemuscle and the transverse process of the vertebrae. By blockingdorsalandventralramiofspinal nerves,it provides excellentanalgesiccoverageoverthethoraxatthetargeteddermatome,includingthemidlinesternotomysitewhenadministere datthelevelofT4transverseprocess.The targetsite 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 tocardiac surgery patients.Hence,wehypothesized that ESP block significantly reduces the post operative opioid consumption in cardiac surgery patients.The other aims were to compare the VAS score during post operative period,time to extubation,peak inspiratory flow rate ,number of rescue analgesics,post operative 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 form patientsand approval from the Institutional Ethics Committee (IEC RegNo. AIIMS/IEC/2021/3316, dated 12/03/2021: approved by Dr. Parveen Sharma). The study wasprospectivelyregisteredatClinicalTrialRegistry–India(CTRIReg.No.CTRI/2021/04/042455dated 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 envelop 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 theirpostoperative pain using a visual analogue scale with a score ranging from 0 to 10 (0 = nopainto10=theworstpainexperience).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 andthe morning ofthe surgery.

Day of Surgery,Operating Room: After application of standard American Society of Anesthesiologists (ASA) monitors like electrocardiogram (ECG), non- invasiveblood pressure (NIBP), and pulseoximetry wereattached. A 16-gauge peripheralintravenouscanula 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 thenslowly moved to the lateral direction and all the three muscles (erector spinae, rhomboidmajor and trapezius) were identified superficial to the hyperechoic transverse processshadow. A 5 cm, 22- gauge block needle (Stimuplex; B Braun Medical, Bethlehem, Pa) wasinserted in the plane of transducer at an angle of 30 degree to the skin in a caudal tocranial direction until the tip crosses the inter fascial plane between muscles and thetransverse process. The needle tip position was confirmed by visible linear spread offluidbetweentransverseprocessandmuscleuponinjectionofnormalsaline.Atotalof 0.3ml/kgof0.5%ropivacainewasinjectedonthatsideafternegativeaspirationfor blood underUSguidance. The sameprocedure

was attempted on the otherside.

Anesthetic Management: The fentanyl 5 µg/kg and propofol1-2 mg/kg were administered till BIS in the range of 40-60 than rocuronium1mg/kg was administered and airway was secured withappropriatesizeendotrachealtube. Anaesthesia was maintained with oxygen and air mixture (50:50) and isoflurane. Themuscle relaxant and fentanyl were administered intraoperatively as per discretion ofconsultant.Intraoperative BISwasmaintained in the range of 40-60.

The last dose of rocuronium and fentanylwas given at the time of sternal closure. After completion ofthesurgicalprocedurepatientswereshiftedtoICUandextubationwascarriedoutaccordingtostandardinstitutional protocol.The paracetamol 1 gm was prescribed to all patients every 6 hourly. Thetimetoextubationwasrecordedinboth groups and it was defined as from shifting of patient inthe ICU to the extubation.

After extubation, VAS score was recorded and patients in both the groups were receivedfentanyl 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 30minutes wereset.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 VASscore, peakinspiratoryflowrateby usingincentivespirometryat extubationandthenevery4hourstill24hours.The time to extubation,number of rescue analgesia,patient satisfaction score and adverse effects were recorded. Sideeffects during the observation period like drowsiness, respiratory depression, postoperativenausea 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 of5, significance level of 5 % and power of study 80%; the sample size calculated was 51 pergroup.Considering a20% contingency,we decidedto include51 patientsin each group.

Statistical analysis: The data was entered in Microsoft Excel spreadsheet and the final analysis was done withthe use of statistical Package for Social Sciencesoftware (SPSS). Normality of data was testedwith Kolmogorov– Smirnov one-sample test. Data were presented as mean ± standarddeviation (SD) for normally distributed quantitative variables and as median (range) forordinalvariablesandquantitativevariableswithnon-normaldistribution.Categoricalvariables were presented as absolute numbers or percentages. Student's t test and $\chi 2$ testwere used to analyze continuous and categorical data respectively. Quantitative variableswith 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 fentanylconsumed in ESP group, bolus dose attempted and bolus dose administered was160(71.50)(10-420),8(3.5)(5-18)and6(2.5)(2-14),whileinPCA group was 380(132.50) (130-600), 15(3) (7-20) and 14(3) (6-16), (P<0.001)(Table 2).The mediantime to extubation was shorter in group ESP compared to PCA group (P<0.001)(Table 3).

ESP had significantly lowerVASscore at rest compared to groupPCA during first 24 hours ICUstay.The VAS Score on coughwas significantly lower in group ESP upto20 hoursofICUstay(Table 5).The peakinspiratoryflowrateduringICUstayat pre-definedinterval were statistically significant except attime of extubation and at 8th hour of extubation.
The median number of rescue analgesia was lower in groupESPcompared to group PCA [0(0,1)(0–2); 2(1)(0-4)respectively, (P<0.001)(Table 3). Themedianpatient satisfactionscorein groupESPwas2 (2,2) (1-3) and while in group PCA it was 2(2,3) (2-4) respectively(Table 3).
Nopatients in group ESP, while twenty-five (49%) patientsin groups PCA had at least one adverse event. Sedation was the most adverse event followedby nausea/vomiting and pruritus. None of the patients in either group had any post operativepulmonary complications in relation with the technique involved. Patients in group ESP had significantly lower adverse effects forthetechnique comparedto the patientsingroupPCA (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**
	19/32	18/33	**1.00**
ASA(II/III)	5.5(1)(3-8)	6.5(2)(4-8)	**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**

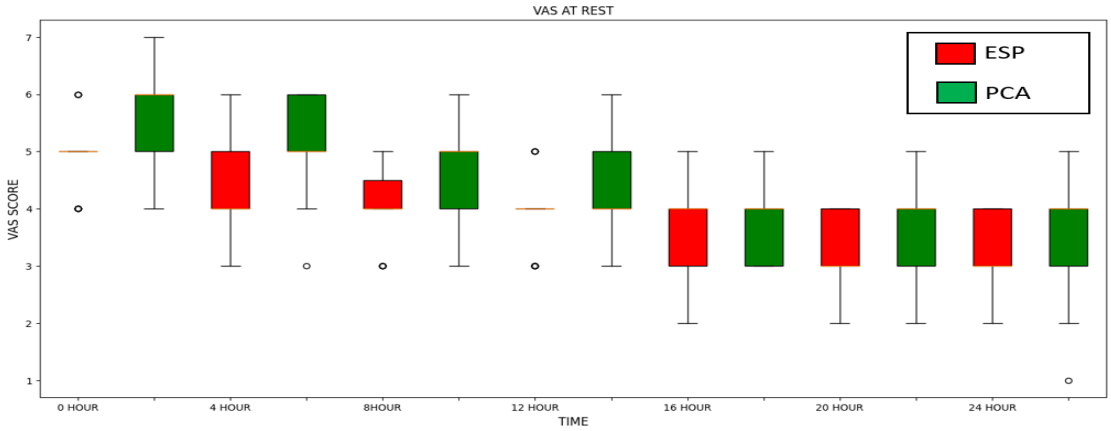


Figure 3: Box plot for comparison of VAS Scores at rest between the study groups duringICU stay

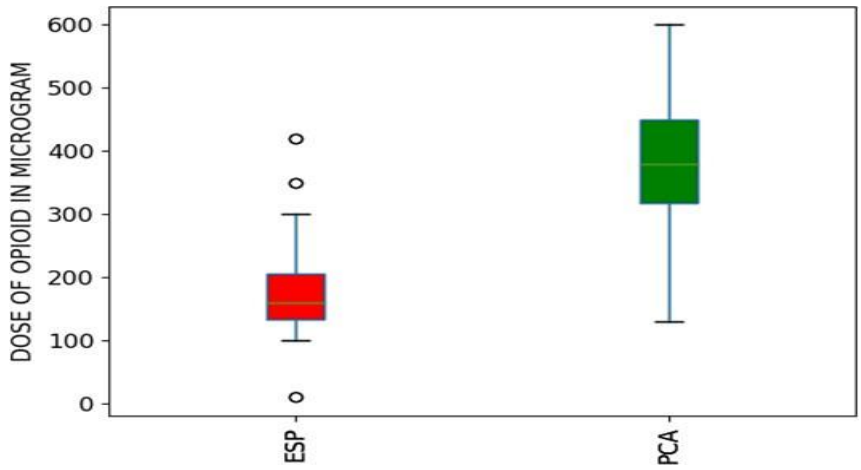


Figure 4: Box plot for comparison of total postoperative opioid consumed between the study groups during ICU stay.

Table 2: Comparison of Postoperative Total opioid consumed, PCA bolus dose attempted andadministeredbetween the study groups during ICUstay

	GroupESP [Median (IQR)(range)]	**GroupPCA** [Median (IQR)(range)]	P value
Totalopioidconsumed(µg)[Median(IQR)(range)]	160 (71.50) (10-420)	380 (132.50) (130-600)	<0.001
Bolus dose attempted[Median(IQR)(ra nge)]	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

Table4: Comparison of Side Effects between the study groups

Adverse Effects	**GroupESP**		**GroupPCA**	
	No.	%	No.	%
Sedation	0	0.00	15	29.41
Nausea&vomiting	0	0.00	8	15.68
Pruritis	0	0.00	2	3.92
Nosideeffects	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 midlinesternotomy,especiallyintheinitialfewdays.Adequateanalgesiaenhancesfunctionaloutcomes,encouraging

earlyambulationandhospitaldischarge,and preventtheonsetofchronicpain.Conventionally the postoperativepainfollowingcardiacsurgery 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 sideeffects such as nausea,urinaryretention, delayed extubation.

With introduction of ultrasound, the fascial plane blocks are performed with precisely. The drug is deposited under vision and these block demonstratedimproved paincontrolwithlessrelianceonopioids. [15]Variousblockslikeparavertebralblock,ESPblock,SAPblock,parasternalblocksareusedinpatientsundergoingcardiacsurgery.

The ESP block has demonstrated extensive craniocaudal spread of local anesthetic when given deep toESPmuscleatthelevelT5transverseprocess.Astheinjectionsiteisfarfromthecentralneural axis and major vascular structures as well as simple to visualize also, hence ESPblockisasimpleandsafe and can be used asreplacementtothoracicparavertebralandepiduralblock.Additionally,thetransverseprocessis helpfulasastopperandbackstopfor 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 cardiacsurgery patients with a reasonable margin of safety and trust.[10]

The efficacy and safety of ESPblock was established in noncardiac cardiac surgeries.[16]Although,ESPblockwasstudiedincardiacsurgicalpopulation,butlimitedliteratureisavailable 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 studyconducted 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 beexplainedby the singleshot ESPblock withropivacaine andits expectedduration ofaction. [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 intern lead to lesser post-operative pulmonary complications. In our study non-significancein 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 the median (IQR) (range) satisfaction score of group ESP was 2 (2,2) (1 – 3)(good),andwhileingroupPCAwas2(2,3)(2–4)(goodtofair)(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 trail 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 basedanalgesia as a component of multimodal pain managementin patients undergoing cardiacsurgery involving midline sternotomy. Use of bilateral ESP blockprovides effective analgesiapromoting early extubation of patients, and also reduces post-operative opioidconsumptionand its associated side effect with better patient's satisfactionin relieving acute postoperativepain 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.

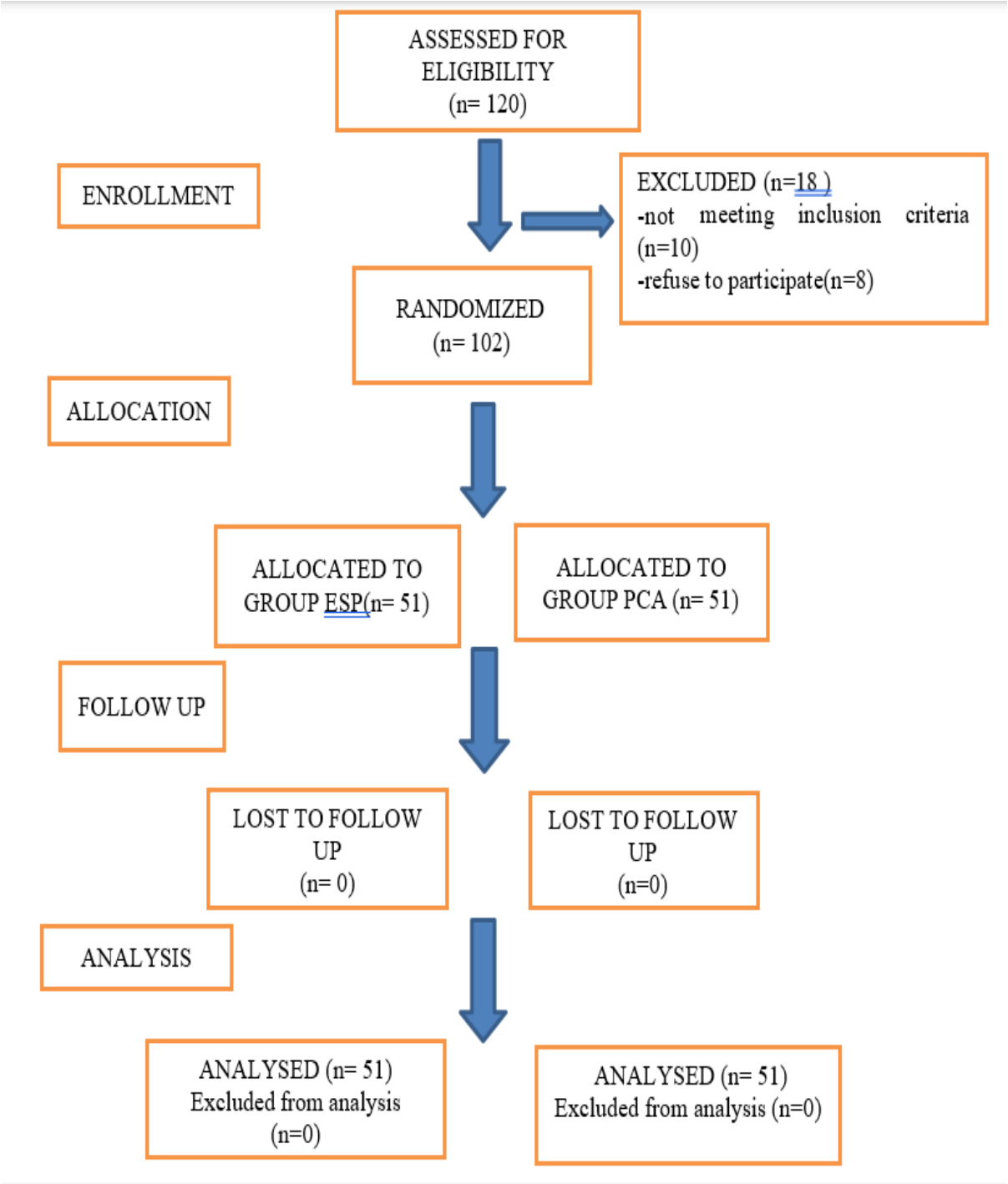


Fig 1. CONSORT flow chart

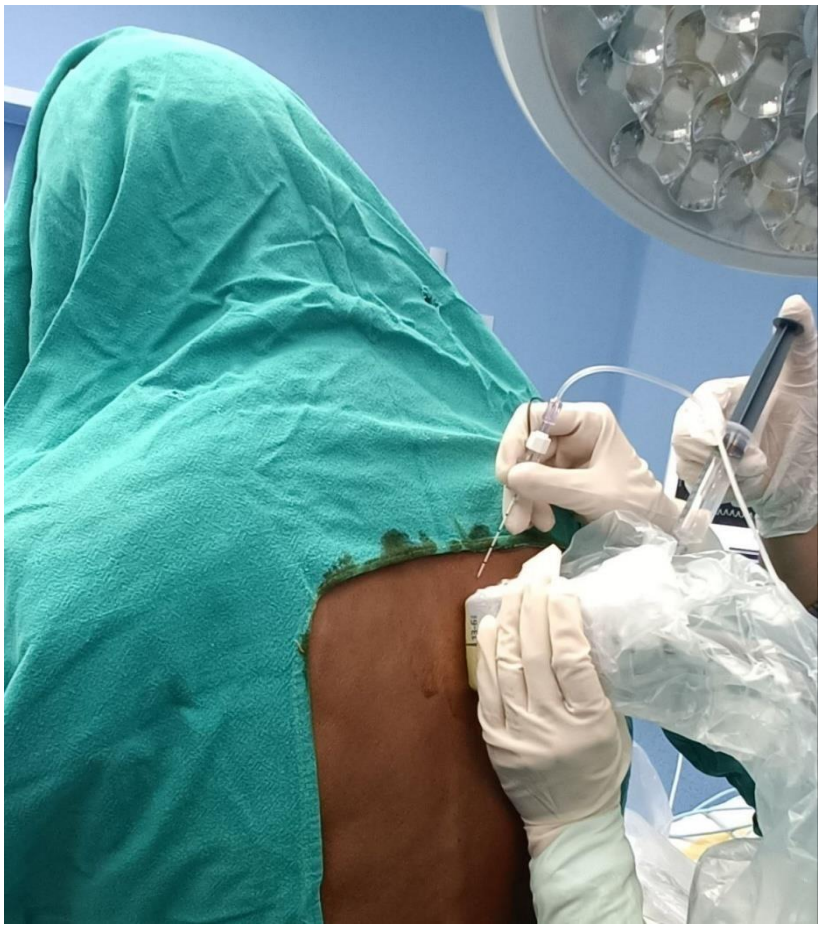
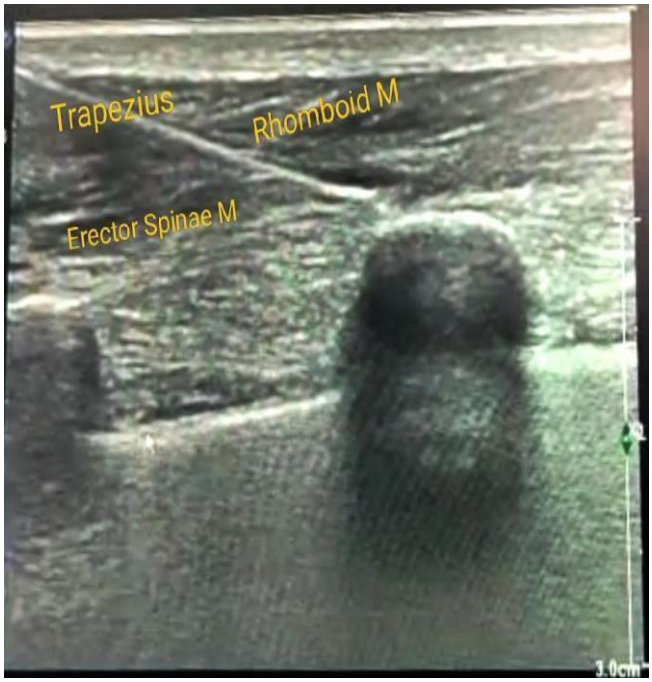


Figure2:USGguidedESPblockbeingperformedunderasepticconditionsatT5verte ral level with in-plane technique using a high frequency linear probe (8 13MHz). A22-gauge 50 mmblock needle wasinsertedin a cephaladto caudal direction.



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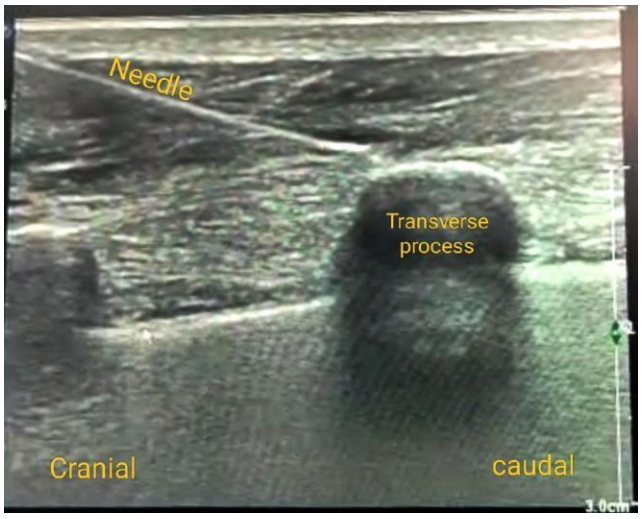

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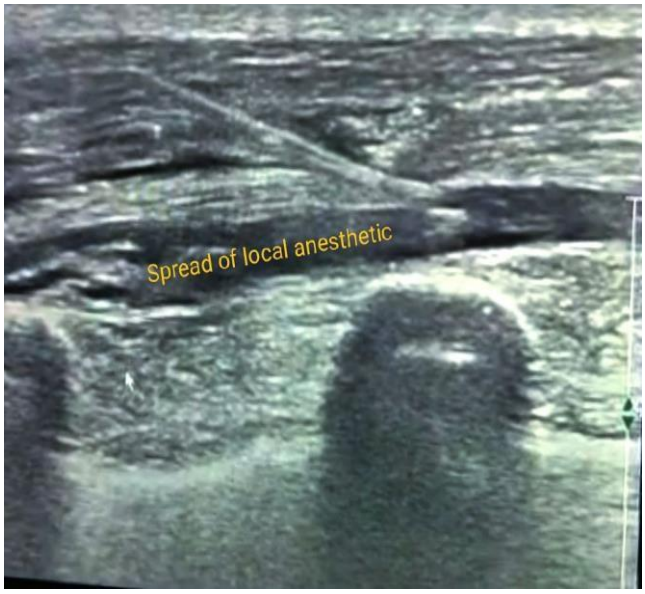

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Figure3: Craniocaudalspread of localanesthetic in erectorspinaeplane.(A) Anatomy explaining the relationship between erector spinae muscle and transverse process (TP).(B)ESP block performed at the level of T5 transverse process.(C)Local Anesthetic 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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