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 RANDOMIZED CONTROL TRIAL

THESIS

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Dr. MANISH MOHAN

DECLARATION

I hereby declare that the thesis titled **"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 RANDOMIZED CONTROL TRIAL"** embodies the original work carried out by me at All India Institute of Medical Sciences, Jodhpur.

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CERTIFICATE

This is to certify that the thesis titled **"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 RANDOMIZED CONTROL TRIAL"** is the bonafide work of **DR MANISH MOHAN** carried out under our guidance and supervision, at Department of Anaesthesiology and Critical Care, All India Institute of Medical Sciences, Jodhpur.

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"Gratitude can transform common days into thanks giving, turn routine jobs into joy, and ordinary opportunities into blessings"

- **William Arthur Ward**

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Dr. MANISH MOHAN

Dedicated to my patients,
teachers, my family and friends...

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

ASA : American Society of Anesthesiologists

B/L : Bilateral

US : Ultrasound

USG : Ultrasonography

ESP : Erector Spinae Plane

GA : General Anaesthesia

RA : Regional Anaesthesia

LA : Local Anesthetic

NSAID : Non Steroidal Anti-Inflammatory Drug

ICU : Intensive Care Unit

T4 : Transverse process of Fourth thoracic vertebra

T5 : Transverse process of Fifth thoracic vertebra

ESPB : Erector Spinae Plane Block

TPVB : Thoracic Para Vertebral Block

TAP : Transversus Abdominis Plane

ITM : Intra Thecal morphine

VAS : Visual Analog Scale

NRS : Numerical Rating Scale

VRS : Verbal Rating Scale

RCT : Randomized Controlled Trail

FLACC : Face, Leg, Activity, Cry, Consolability

TEA : Thoracic Epidural Analgesia

BMI : Body Mass Index

LVEF: Left Ventricular Ejection Fraction

HR : Heart Rate

BP: Blood Pressure

SPO2 : Oxygen Saturation

IV : Intravenous

CBC: Complete Blood Count

RFT: Renal Function Test

LFT: Liver Function Test

PO : Per Oral

BIS : Bispectral Index

IQR : Interquartile Range

PCA : Patient Controlled Analgesia

SD : Standard Deviation

mcg : Microgram

mcg/kg : Microgram per kilogram

mcg/kg/hr : Microgram per kilogram per hour

L2-L3: Second and third Lumbar vertebrae

PONV: Post Operative Nausea Vomiting

CONSORT : Consolidated Standards of Reporting Trials

mm: Millimeter

cm : Centimeter

yrs : Years

bpm : Beats per minute

hrs : Hours

cc : Centimeter cube

vs : versus

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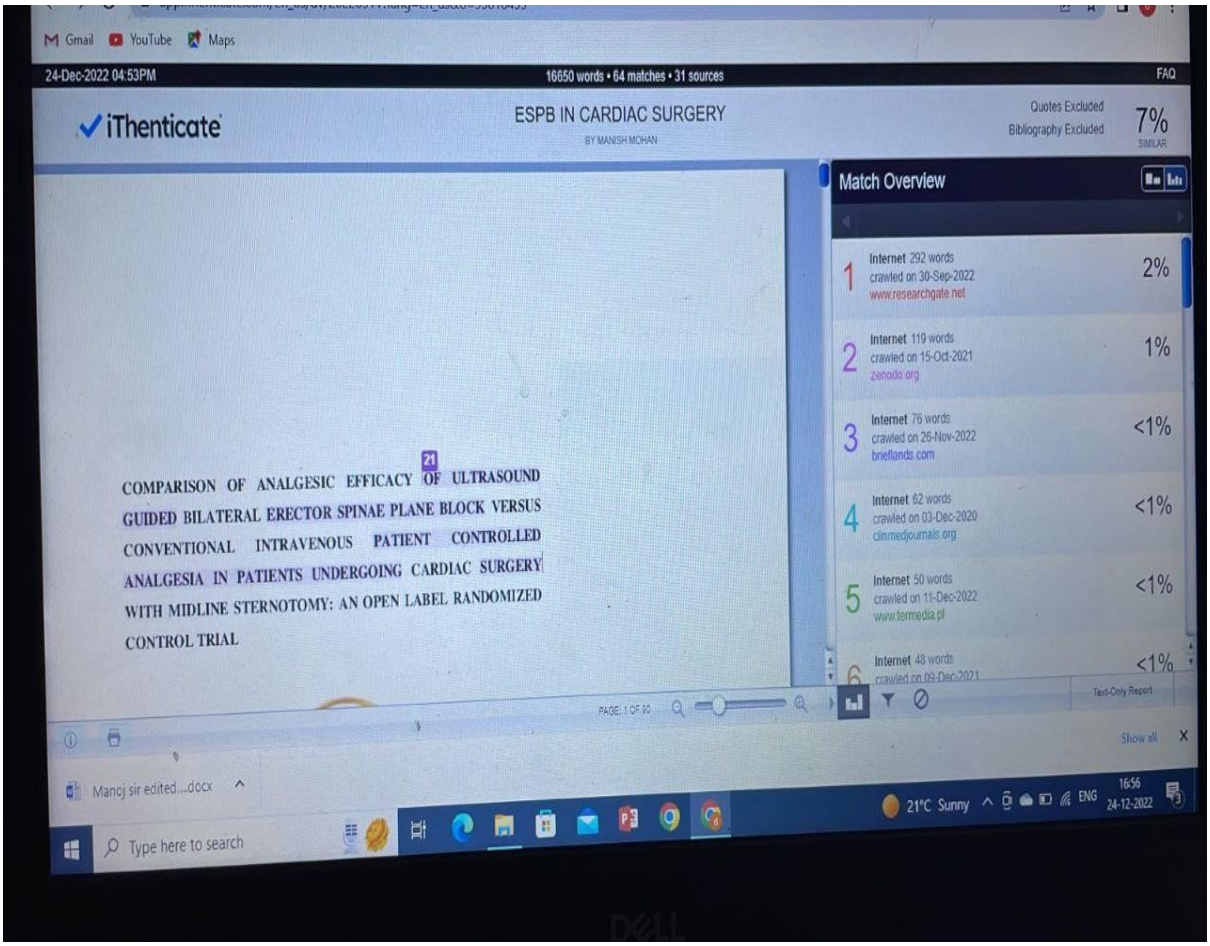
PLAGIARISM CHECK CERTIFICATE

Plagiarism check was done on i-thenticate. All the sections except references andreview of literature were checked for plagiarism.



SUMMARY

SUMMARY

Background: Sternotomy pain in cardiac surgery is often intense and undertreated. Adequate postoperative pain management without significant sedation and side effects are crucial for early recovery and to reduce postoperative cardiovascular and respiratory complications. With all of their inherent drawbacks and adverse effects, opioid analgesics form the foundation of the current therapeutic approaches. The use of regional anaesthesia (RA) procedures and multimodal pain treatment protocols, which include a variety of pharmacological choices, has reduced the need for opioids. The superior analgesic cover of the erector spinae plane (ESP) block has been identified as spanning the entire thorax, including the midline and upper abdomen. The present study was carried out to compare the analgesic efficacy of ESP block over conventional opioid based patient-controlled analgesia (PCA) in patients undergoing cardiac surgeries with midline sternotomy.

Material and Methods: After obtaining informed consent, a total of 120 patients of either sex, between the ages of 18 and 70, with ASA physical status II or III who were scheduledfor elective cardiac surgery with a midline sternotomy were enrolled. A software-generated random number table was used to allocate patients at random to either group PCA (n=51) or ESP (n=51). Utilizing serially numbered sealed opaque paper packets that were revealed on the day of operation, allocation concealment was carried out. The surgical procedure was carried out under general anaesthesia. The bilateral (B/L) single shot ESP block was performed at T5 level, who were allocated to group ESP by using 0.3 ml/kg of 0.5% ropivacaine under ultrasound (US) guidance. Incidence of procedure related complications were noted. After surgical procedures, patients were sent to the intensive care unit (ICU) and extubated in accordance with protocol. After extubation, pain was measured using visual analogue scale (VAS). With a bolus dose of 0.5 mcg/kg and a lockout interval of 30 minutes, PCA pump was used to provide intravenous fentanyl to the patients in both groups. Diclofenac 75 mg was administered as rescue analgesic on patient demand. The primary outcome of the study was to compare post-operative fentanyl consumption during first 24 hoursof ICU stay after extubation. The secondary outcomes were to compare postoperative VAS atrest and on cough during first 24 hours, time to extubation, peak inspiratory flow rate, number of rescue analgesics, post operative pulmonary complications, patient satisfaction score and side effects of both the techniques.

Results: The median fentanyl consumption(mcg) after extubation was significantly lower in patients received ESP block [160(71.50)] compared to conventional opioid based patient-controlled analgesia (PCA)[380(132.50)]. At all predefined time points of the ICU stay, the group ESP's VAS scores at rest were considerably lower than those of the group PCA. However, the VAS scores on cough was notably lower in ESP group up to first 20 hours and was similar at 24 hours compared to the control group. The respiratory effort assessed by peak inspiratory flow rate was clinically and statistically much better in patients who received B/L ESP block when compared to the control group at all predefined time points except at the time of extubation and 8^{TH} hour of extubation. The median time for extubation was considerably shorter in ESP group (3.25 hours) when compared to that in the control group (5.50 hours)(P <0.001). The median (IQR)(range) number of rescue analgesia requiredpostoperatively in group ESP [0(1)(0-2)] was significantly lower when compared to PCA group[2(1)(0-4)].Neither of the patients in the ESP block group had block related adverse events while a significant proportion of patients (49%) in the PCA group experienced opioid related side effects in which sedation was the most common adverse effect. Also, none of the patients in either group had any postoperative pulmonary complications associated the technique involved in them. The degree of comfort and satisfaction was significantly better ingroup ESP compared to group PCA(P = 0.0002).

Conclusion: Preoperative US guided bilateral ESP block provides a safer and more effective alternative to opioid based analgesia as a component of multimodal pain management for adult patients undergoing cardiac surgery involving midline sternotomy, thereby facilitating early extubation, minimizing opioid-related adverse effects while promoting patient comfort and satisfaction.

INTRODUCTION

INTRODUCTION

Patients who undergo cardiac surgeries experiences moderate to severe pain in the post-operative period and the intensity of pain is maximum on the initial post-operative days. Multiple factors, including as tissue damage, intercostal nerve injury, scarring, fractured ribs, sternal infection, stainless-steel wire sutures, and costochondral separation, might contribute to prolonged pain following sternotomy. [1] It is the responsibility of every anaesthesiologist to provide post-operative analgesia to cardiac surgery patients. Inappropriate pain management following cardiac surgeries is responsible for reduced vital capacity (VC) and functional residual capacity (FRC) of lungs, which result in complications like pulmonary atelectasis, pneumonia, stasis of bronchial secretion, increased oxygen consumption, and can lead to chronic pain. [2] In order to reduce, pulmonary function disorder, the minimum requirement is to eliminate pain which is the main cause of this post-operative respiratory depression. [3]

The American Society of Anesthesiologists (ASA) recommends the use of multimodal techniques of pain management including regional anaesthesia (RA), intravenous analgesia, neuropathic medications, oral drugs like opioids and NSAIDS. Pain control is crucial in enhanced recovery after cardiac surgeries program. Traditionally, the acute pain was managed by short acting intravenous opioid analgesics in cardiac surgeries to facilitate early extubation and short stay in ICU. [4] However, opioid use can cause nausea, vomiting, pruritis and respiratory depression when used solely for analgesia and it also don't match the quality of analgesia provided by regional anesthesia. [5]

The regional analgesic techniques are less frequently practiced in cardiac surgeries due to risk of complications in anticoagulated patients**.** The anticoagulation is a relative contraindication to regional blocks. [6]

In cardiac surgeries major concern in using neuraxial technique is the incidence of epidural hematoma. It has been shown that the chance of developing an epidural hematoma with thoracic epidural analgesia (TEA) is 1 in 12,000 and that the risk from catheter use is 1 in 5493. [7] Moreover, the sympathetic block caused by a neuraxial technique is more likely to result in systemic hypotension, which can be challenging to treat. [8]

Fascial plane blocks are frequently used method by an anesthesiologists who used USG for regional anaesthesia. These blocks are effective enough to provide appropriate postoperative analgesia, enabling early extubation, movement, and critical care unit discharge. [9] The US guidance provide reliable, accurate block with less complications specially with superficial truncal block. The ESP block is a new fascial plane block, which was initially described for thoracic and abdominal analgesia, as it acts via the dorsal and ventral rami of spinal nerves. [10] The drug is deposited between erector spinae muscle and the ends of the spinal transverse processes. The substantial volume (0.3 ml/kg) of local anaesthetic (LA) spreads in the caudocranial direction for 3-6 vertebral levels and relieves pain in the somatic and visceral organs in the area supplied by the congruent spinal nerves. [11] A multi-dermatomal sensory block of the anterior, posterior, and lateral thoracic and abdominal walls is made possible by this blockage of the dorsal and ventral rami of the spinal nerves. Excellent analgesic coverage is provided over the entire thorax at the targeted dermatome, including the midline sternotomy site, by bilateral ESP block when administered at the level of the T4 transverse process. [12]

Due to risks associated with employing paravertebral and neuraxial methods on anticoagulated patients, the role of regional anaesthesia in cardiac surgery has remainedsomewhat limited. ESP block is performed in the myofascial plane deep to the erector spinae muscle; this site is relatively superficial, distant from the pleura and major vessels, nerves, and the spinal cord, which reduces the risk of complications associated with its application and may be taken into consideration in patients undergoing cardiac surgery who have coagulopathy. [13]

Regional anaesthesia, however, may be able to be securely implemented into enhanced recovery pathways for cardiac surgery patients and reduce the need for opioids for analgesia in the post-operative period, thereby reducing its associated side effects. This has been accomplished by the latest advancement of the ultrasound guided ESP block. [14] Therefore, we planned a study to evaluate the efficacy and safety of ESP Block in cardiac surgery patients compared to conventional intravenous patient controlled opioid analgesia. We hypothesize that US guided single shot bilateral ESP block is a safe technique of providing regional analgesia and it significantly reduces the post-operative opioid consumption in cardiac surgery patients.

AIM & OBJECTIVES

AIM AND OBJECTIVES

Aim: The aim of our study was to compare the analgesic efficacy and safety of US guided single shot bilateral ESP block versus conventional intravenous patient controlled opioid analgesia in patients undergoing cardiac surgeries with midline sternotomy.

Objectives:

Primary objective:

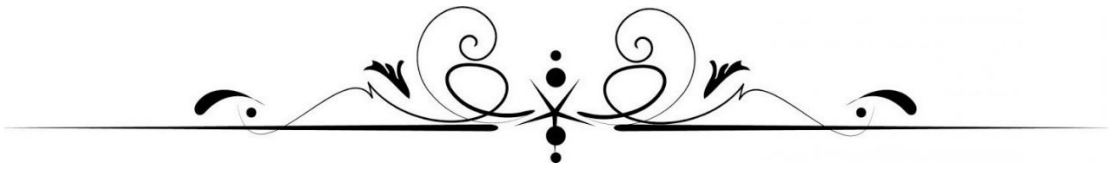
- To compare post-operative fentanyl consumption during first 24 hours of ICU stay

Secondary objectives:

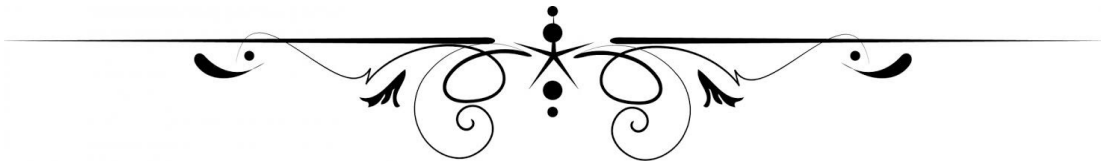
- To compare postoperative Visual Analog Scale pain score at rest and on cough during first 24 hours.
- To compare the time to extubation in both the groups.
- To compare the peak inspiratory flow rate during first 24 hours.
- To compare the number of rescue analgesia required postoperatively in both the groups.
- To compare the post-operative pulmonary complications like atelectasis, acute bronchitis, ARDS, Respiratory failure, aspiration pneumonia etc in both techniques.
- To compare patient satisfaction score.
- To compare the adverse effects of both the techniques.

Hypothesis:

US guided single shot bilateral ESP block is a safe technique of providing regional analgesia and it significantly reduces the post-operative opioid consumption in cardiac surgery patients.



REVIEW OF LITERATURE



REVIEW OF LITERATURE

As per literature, many patients report substantially more discomfort than anticipated following sternotomy. Usually, acute pain at the location of the surgical incision is worst on the first postoperative day. The worst discomfort is typically felt when moving or coughing.[15] Earlier, large doses of opioids were traditionally used during open heart surgeries to maintain hemodynamic stability during surgery and to relieve pain afterwards. The opioids' analgesic effect makes them comfortable, but it is not devoid of complications. The opioid use is linked to side effects that can harm patients and raise the cost of care and duration of stay.[16]

The routine administration of anticoagulants and antiplatelet agents in cardiac surgery during the perioperative period, as well as the invasive and complex nature of the procedures, the role of central neuraxial analgesia and regional analgesic techniques like thoracic epidural, thoracic paravertebral block, and intercostal nerve block are controversial.[17]

The ESP block, a new myofascial plane block, offers comprehensive multi-dermatomalsensory block. Both the dorsal and ventral rami of spinal neurons, including the sympathetic chain, are blocked in a bilateral ESP block at the T5 spinous process, which produces analgesia from the T2 to T9 sensory level and analgesia for both the somatic and visceral body. The T2 to T6 nerves comprise the majority of the sternal area's nerve supply, this blockmight be able to adequately anaesthetize a median sternotomy. The ease of recognition of sonoanatomy and the absence of any nearby structures that could be injured by a needle, an ESP block has a very minimal risk of consequences. The transverse process, which serves as an anatomical barrier and protects the pleura and blood vessels from needle entry, hence less incidence of pneumothorax or hematoma. The danger of spinal cord injury is also quite minimal because the needle is comparatively far from the vertebral canal. [10] Thus in this study, we studied the analgesic efficacy of ESP block and its effect on reducing opioid based patient controlled analgesic consumption following cardiac surgery involving midline sternotomy.

Yapici et al [18] evaluated the effect of 7 mcg/kg intrathecal morphine in RCT for post-operative analgesia in coronary bypass surgery in post-operative period. The VAS scores of the patients who had all received intrathecal morphine were lower, required less pethidine, extubated earlier and shorter hospital stay than those of the control group. Theyconcluded that the Intrathecal morphine provided effective analgesia, earlier tracheal extubation and less ICU length stay after on-pump coronary bypass surgery.

Chin et al [19] conducted a study to ascertain whether ESP block had any analgesic effects on patients scheduled for ventral hernia operations. In patients undergoing laparoscopic ventral hernia repair, they administered pre-operative bilateral ESP blocks with 20–30 ml ropivacaine 0.5% at the level of the T7 transverse process. Opioid usage over a 24-hour period was 18.7 mg (0.0-43.0 mg) on average. On an 11-point numerical rating scale, the highest and lowest median (range) pain scores over the first 24 hours were 3.5 (3.0-5.0) and
2.5 (0.0-3.0). Additionally, they carried out the block on a fresh corpse and used computerized tomography to determine how far the injections had travelled. There wasradiological proof of spread that went caudally as far as the L2-L3 transverse processes and cranially as far as the upper thoracic levels. They came to the conclusion that the ESP block, when applied at the level of the T7 transverse process, is a promising regional anaesthetic approach for laparoscopic ventral hernia repair and other abdominal surgery. Its benefits include its relative simplicity and the ability to block both supra-umbilical and infra- umbilical dermatomes with a single level injection.

Nagaraja et al [20] compared the efficacy of continuous thoracic epidural analgesia (TEA) with erector spinae plane (ESP) block for the perioperative pain management in 50 patients undergoing cardiac surgery for the quality of analgesia, incentive spirometry, ventilator duration, and ICU duration. Comparable VAS scores were found in both groups at 0 h, 3 h, 6 h, and 12 h during coughing and at rest ($P > 0.05$). At 24 h, 36 h, and 48 h, Group TEA exhibited a statistically significant VAS score advantage over Group ESP (P 0.05), but the mean VAS in each Group was 4 both at rest and while coughing. There were seven breakthrough pain events in Group ESP and nine total breakthrough pain episodes in Group TEA, both of which required analgesics during the postoperative period. They concluded that ESP block and TEA had a comparable pain scores and hence it could be an effectivealternative to TEA and reduce the risk of epidural hematoma in anticoagulated cardiacsurgery patients.

Gurkan et al [21] did RCT in 50 patients scheduled for elective breast cancer surgery to determine the analgesic effect of US guided ESP block. Patients were randomized into two groups, ESP and control. Single-shot ultrasound (US)-guided ESP block with 20 ml 0.25% bupivacaine at the T4 vertebral level was performed preoperatively to all patients in the ESP group. The control group received no intervention. All patients in both groups received intravenous PCA devices containing morphine. The mean morphine intake was 5.76 3.8 mg in the ESP group and 16.6 6.92 mg in the control group at 24 hours postoperatively. Postoperative nausea and vomiting were not significantly different across the groups. They concluded that ESP block provided sufficient analgesia and considerably decreased opioid usage in individuals who had breast surgery.

Swati Singh et al [22] compared the effect of US guided ESP block on 24 h postoperative cumulative opioid requirements with standard (opioid based) analgesia. While, patients in Group 2 (ESP group) received a unilateral US-guided ESP block preoperatively (20 mL 0.5% bupivacaine to the operating side) followed by GA, patients in Group 1 (GA group) only received general anaesthesia (GA) and were treated for pain postoperatively in accordance with standard protocol. The main finding was that patients receiving US guided ESP blocks consumed much less postoperative morphine than the control group (9.3 2.36 mg required in the control group vs. 1.95 2.01 mg required in the ESP group, P value = 0.01), which was the primary endpoint. Only two patients in the US guided ESP block group needed additional morphine after surgery, compared to all patients in the control group (P 0.01). They concluded that ultrasound-guided ESP block appears to be an effective block for postoperative analgesia and in decreasing postoperative morphine requirement in breast cancer surgery.

Fang et al [23] compared the analgesic effect of ESP block and TPVB block in 90 patients scheduled for thoracotomy lung surgeries. Both blocks were given in preoperative period under sterile precautions. After the surgery patients in both groups were provided with an intravenous patient-controlled analgesia (PCA) device containing sufentanil. At 1, 6, 12, and 24 hours postoperatively, pain levels on the visual analogue scale (VAS) were collected while the patient was coughing and at rest. They found no differences between the ESPB and TPVB groups in terms of pain levels and sufentanil requirement when resting or coughing in either of the first two days following surgery. The ESPB group had significantly reducedrates of hypotension (6.7% vs. 21.7%, P=0.04), bradycardia (0 vs. 8.7%, P=0.04), and

hematoma (0 vs. 10.9%, P=0.02) as well as a higher success rate with one puncture (82.2 vs. 54.3%, P0.001). With this study they concluded that, when compared to TPVB, preoperative single-injection ESPB with postoperative sufentanil PCA offered comparable pain relief for patients undergoing thoracotomy. However, ESPB has the advantage of a decreased incidence of side effects.

Adhikary et al [24] did retrospective cohort study to ascertain the efficacy of ESP block in enhancing respiratory and analgesic outcomes in patients with traumatic rib fractures hospitalized to a level-one trauma center. They looked at the 12-hour opioid consumption, maximum numerical rating scale static pain scores, and incentive spirometry volume before and up to 72 hours after erector spinae plane blocking. In the 79 patients who were a part of the trial, 77% had continuous erector spinae plane block for a median (SD) of 3.7 (1.9) days. Following erector spinae plane blocking, incentive spirometry volumes increased within the first 24 hours from 784 (694) to 1375 (667) ml (p 0.01). In the first three hours, pain scores dropped from 7.7 (2.5) to 4.7 (3.2). Although there were decreases in opioid consumption, it was not statistically significant. Erector spinae plane blocks, in the aftermath of rib fracture, were linked to better inspiratory capacity and analgesic results without causing haemodynamic instability. They suggested that when other localized analgesic treatments are not practical, ESP block should be explored as a possible substitute.

Krishna et al [25] did RCT in106 patients who were scheduled for elective heart bypass surgery. Before inducing anaesthesia at the T6 transverse process level, group ESP (n=53)got a 3 mg/kg of 0.375% ropivacaine-guided B/L ESP block under US guidance. In the post- operative period, patients in group 2 received intravenous tramadol 50 mg every eight hours and paracetamol 1 gm every six hours. The main goal of the study was to assess resting pain using an 11-point Numeric Rating Scale (NRS). The median pain score at rest in group ESP was 0/10 for the first six hours, 3/10 at eight hours, and 4/10 at ten and twelve hours after extubation. In comparison to group 2, these were significantly lower (p 0.0001). Patients in group 1 experienced analgesia for a substantially longer amount of time on average (8.980.14hours), with an NRS of 4/10, than patients in group 2 (4.600.12 hours) (p0.0001). They concluded that ESP block offer superior pain relief at rest for a longer duration.

Hameed et al [26] concluded that ESPB provides effective postoperative analgesic effect and reduce the need of opioids in pregnant women having elective caesarean deliveriesafter RCT in 140 parturients. The ESPB-group received 20 mL of 0.5% bupivacaineimmediately after the procedure at T9 level. They also received 10 mg of hyperbaric bupivacaine intrathecally through spinal anaesthesia. The ITM-group underwent spinal anaesthesia with 10 mg of hyperbaric bupivacaine and 100 mcg of morphine beforereceiving a sham block at the conclusion of the procedure. The total amount of opioids consumed, the period before the first analgesic request, and the visual analogue scale (VAS) score for pain at various postoperative time points were all assessed. The VAS scores (at rest) in the ITM group were, on average, 0.25 units higher in the post-operative period (0-24 hours). The ITM group consumed considerably more tramadol overall in the first 24 hours than the ESPB group (101.71 25.67 mg vs. 44 16.71 mg, respectively). In theITM group, it took 4.930.82 hours, while it took 122.81 hours in the ESPB group beforethe first analgesic request was made.

Gado et al [27] studied the efficacy and safety of bilateral ESP blocks in 98 children scheduled for cardiac surgery through a median sternotomy. Children were divided randomly into 2 groups: the ESP group (n = 50) who received bilateral ultrasound-guided ESP blocks, and the N group (n = 48) who received no block. The findings revealed that the N group consumed significantly more intraoperative fentanyl (6.7 3 vs 4.3 1.9 g.kg-1) and postoperative morphine (0.5 0.2 vs 0.4 0.2 mg.kg-1) than the ESP group (P 0.001). In the first24 hours following surgery, FLACC pain score values were considerably greater in the N group than in the ESP group. They concluded that ESP block could reduce perioperative painkiller usage by using bilateral ultrasound-guided ESP blocks. Additionally, it can be usedto speed up early extubation and reduce postoperative pain scores.

Malawat et al [28] established that ESP block can provide complete surgical anaesthesia on ipsilateral side after their study in thirty patients undergoing modified radical mastectomy (MRM) surgery. The addition of dexamethasone 8 mg with 25 ml of 0.5% bupivacaine provides long-lasting postoperative analgesia for an average of 41.73 hours, and they all underwent complete surgical anaesthesia with an ultrasound-guided single-shot ESP block in an average of 31.50 minutes. All 30 patients had significantly low VAS scores duringassessments, both while they were at rest and when moving the ipsilateral arm.

Teng Jiao Zhang et al [29] established the effectiveness of pre-operative ESP block in enhancing recovery of posterior lumbar surgery in 60 patients. MOAA/S ratings were 4.2 (95% CI, 4.0 to 4.4) and 3.4 (95% CI, 3.2 to 3.6) after 10 minutes following extubation, respectively (P>0.001). They came to the conclusion that a bilateral ESP block at T12 can improve healing following posterior lumbar surgery and lower perioperative opioid use.

Borys et al [30] established the efficacy of the ESP block in patients undergoing right mini-thoracotomy. The single shot ESP block was given before induction of anaesthesia. After being extubated for postoperative analgesia, PCA was begun with oxycodone in the ESP group and with morphine in the control group. The first postoperative day saw an average oxycodone consumption in the ESP group of 18.26 (95% CI: 15.55-20.98) mg and an averagemorphine consumption in the control group of 12.64 (11.92-13.36) mg. The ESP group'smean mechanical ventilation time (0.6 (0.4-1.1) h) was considerably lower than the control group's (10 (8-17) h, p=0.00001) mechanical ventilation time. Patients in the ESP group also spent less time in the intensive care unit (ICU) (1 (1-1)) than those in the control group (2 (2- 2), with a p value of 0.0001. They concluded that ESP block reduced the amount of postoperative opioids used by patients undergoing right mini-thoracotomy for mitral/tricuspidvalve surgery.

Ciftci et al [31] investigated the analgesic efficacy of erector spinae plane block (ESPB) in 60 patients undergoing video assisted thoracic surgery. The 30 patients were received a single-shot ultrasound-guided ESPB with 20 ml of 0.25% bupivacaine was administered preoperatively at the T5 vertebral level while another 30 patients behave as control group. Patients of both groups received intravenous patient-controlled postoperative analgesia. They were assessed using visual analogue scale (VAS) scores, opioid consumption, and adverse events. In the ESPB group, the active and passive VAS scores at 0, 2, 4, 8, 16, and 24 hours, as well as the opioid intake at 1, 2, 4, 8, and 16 hours were all statistically lower than in the control group at all of the time points (p 0.05). There were higher incidences of nausea and itching in the control group, but no intergroup differences in terms of other negative effects. They concluded that the patients who underwent VATS lobectomies, single-shot ESPB produced good analgesia, reduced opioid usage, and decreased VAS scores over the first 24 hours.

Kamel et al [32] compared ultrasound-guided bilateral ESP block versus bilateral TAP block on postoperative analgesia after open total abdominal hysterectomy in 48 patients. When compared to the TA group, the Visual Analog Scale scores at 30 minutes, 2, 4, 6, 8, 12, 16, and 24 hours were statistically substantially lower in the ES group. When compared to theTA group (10.58 2.35 hours), the time for the first morphine requirement was statistically substantially longer in the ES group (14.81 3.52 hours). In the ES group, the total amount of morphine consumed throughout the course of the first 24 postoperative hours was statistically significantly lower; P = 0.01. They concluded that bilateral ultrasound-guided ESP block provides more potent and longer postoperative analgesia with less morphine consumption than TAP block after open total abdominal hysterectomy.

Finnerty et al [33] compared ESP block with serratus anterior plane (SAP) among 60 patients undergoing minimally invasive thoracic surgery. In ESP group, the mean (SD) area under the deep inspiration curve was 107 mm h1 (32) as opposed to 129 (32) in SAP (P140.01). Opioid consumption was 29 (31) in the ESP group at 24 hours postoperatively compared to39 (34) (P140.37) in the SAP group. At 24 hours, the median (25e75% range) of VRS painon movement was 4 (2e4) in ESP and SAP, and it was 5 (3e6) (P140.04), respectively. They concluded that ESP block gives greater quality analgesia and reduced postoperative problems at 24 hours compared to SAP block.

Vaughan et al [34] also established that continuous erector spinae plane blocks in open cardiac surgical operations decreased opioid use, delay to extubation, and length of overall hospital stay in patients undergoing open cardiac surgeries. Patients in the block group got a preoperative 0.5% ropivacaine bolus followed by a postoperative 0.2% ropivacaine infusion. The patients who received blocks took less opioids both during surgery (34 mg vs. 224 mg) and while they were in the hospital (224 mg vs. 461 mg). Patients who received blocks experienced shorter times to extubation (126 min vs 257 min), shorter stays in the intensive care unit (35 min vs 58 min), and shorter stays in the hospital (5.6 min vs 7.7 min).

MATERIALS & METHODS

MATERIAL AND METHODS

Study setting: Department of Anaesthesiology and Critical Care, All India Institute of Medical Sciences (AIIMS), Jodhpur

Study design: Single center, open label, randomized controlled trial.

Study period: From March 2021 to September 2022.

The study was conducted after approval from the Institutional Ethics Committee (IEC Reg No. AIIMS/IEC/2021/3316, dated 12/03/2021: approved by Dr. Parveen Sharma) and by informed written consent from patients. The study was registered with Clinical Trial Registry – India (CTRI Reg. No. CTRI/2021/04/042455 dated 26/04/2021).

Inclusion criteria: Patients aged between 18 to 70 years, belonging to ASA-II or III scheduled for elective cardiac surgery with midline sternotomy.

Exclusion criteria:

- Emergency Surgery
- Patient in whom fast tracking could not be possible e.g requiring postoperative elective ventilatory support for more than 12 hours.
- Patient with allergy to fentanyl.
- Patient with cognitive deficits making them inefficient to use of IV PCA pump
- Patient with any contraindications for fascial plane block
- Patient with LVEF < 40%
- Patient with liver and renal dysfunction

Sampling and sample size calculation:

The sample size calculation was based on study done by Gurbet et al. [35] based on the observation of a 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.

The formula for sample size calculation of non inferiority trail is as follows

$$\text{Sample Size (n)} = \frac{[Z(1-\alpha) + Z(1-\beta)]2\ 2\ Sp2}{\mu 2}$$

Sp = Pooled Variance, μd = Mean Difference between two groups;

Z (1-β) = 1.28 as Power is 80%.

Z (1-α) = 1.96 as the significance level of 95%

N = 51 per treatment group.

A total 120 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 who refused to participate included women who were pregnant, patients with cognitive deficits that made objective pain assessment unreliable at baseline, patients with coagulopathy, liver and renal dysfunction, preoperative neurological deficits, opium addicts, low ejection fraction (40%), and allergy to amide LAs or opioids were excluded (n=18).

Prior to the surgical procedure, all patients underwent a thorough pre-anaesthetic evaluation. Patients 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). The patient's particulars and baseline vital parameters were noted during the preoperative visit. The patient underwent thorough systemic, general, and physical tests. All patients had standard laboratory testing, including complete blood count (CBC), renal function teat (RFT), liver function test (LFT), bleeding time, and clotting time. According to institutional protocol, all patients were maintained on fast (2 h for clear liquid and 6 h for semisolid and solids). Alprazolam 0.25 mg PO tablets were prescribed to the patients the night before and the morning of the surgery.

A software-generated random number table was used to allocate patients at random to either group PCA (n=51) or ESP (n=51). On the day of operation, opaque envelopes with sequentially numbered codes were opened to reveal the locations of the allocations. Because of the intervention selected, blinding of the patients, investigator, and observer was not possible.

In the Operation theatre, standard ASA monitors like electrocardiogram, non- invasive blood pressure, and pulse oximetry were attached. A 16-gauge peripheral intravenous canula and 20-gauge right radial arterial catheter were secured under local anaesthesia. Patients belonging to ESP group, received the block in sitting position under all aseptic precaution. Ultrasound guided bilateral single shot ESP block was performed at T5 level with 0.3 ml/kg of 0.5% ropivacaine on either side, with the help of high frequency linear probe.

ESP block technique

After taking the patient inside operation theater, ASA standard monitors were attached. The bilateral ESP block was performed by portable ultrasound device ("Philips Epiq 7C US machine" Chicago, United States) 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 spiane, 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.

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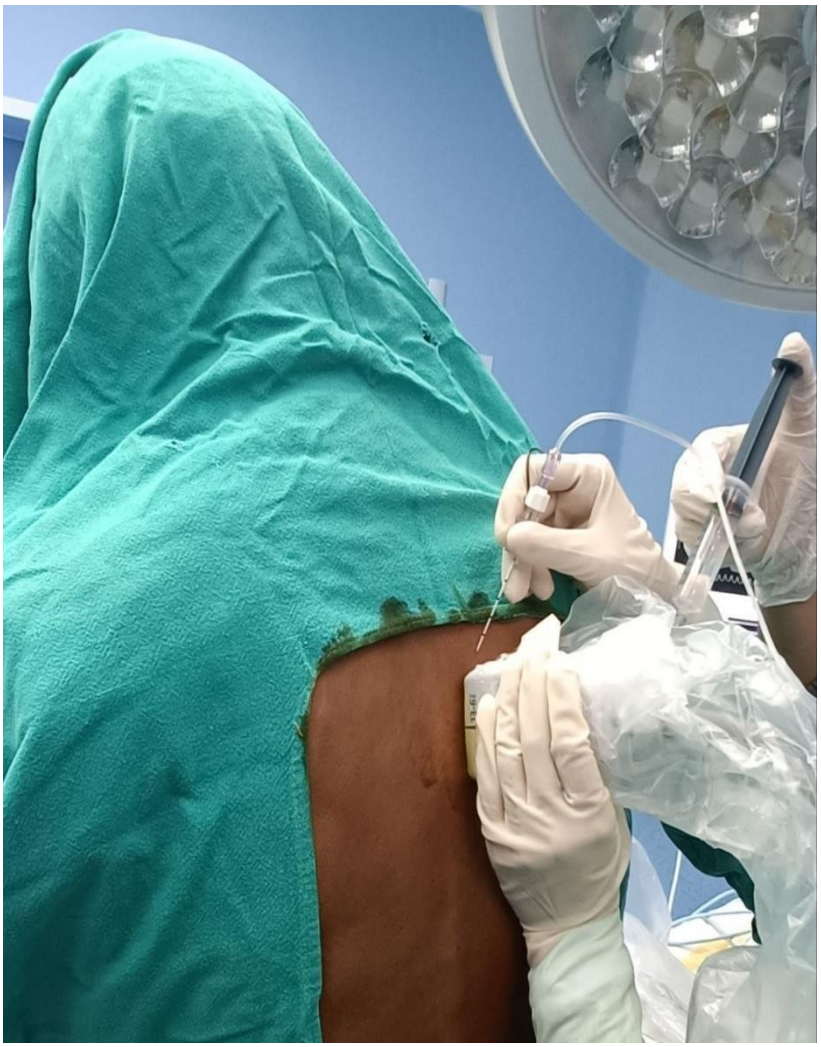


Figure 1: USG guided ESP block being performed under aseptic conditions at T5 vertebral level with in-plane technique using a high frequency linear probe (8-13MHz). A22-gauge 50 mm block needle was inserted in a cephalad to caudal direction.

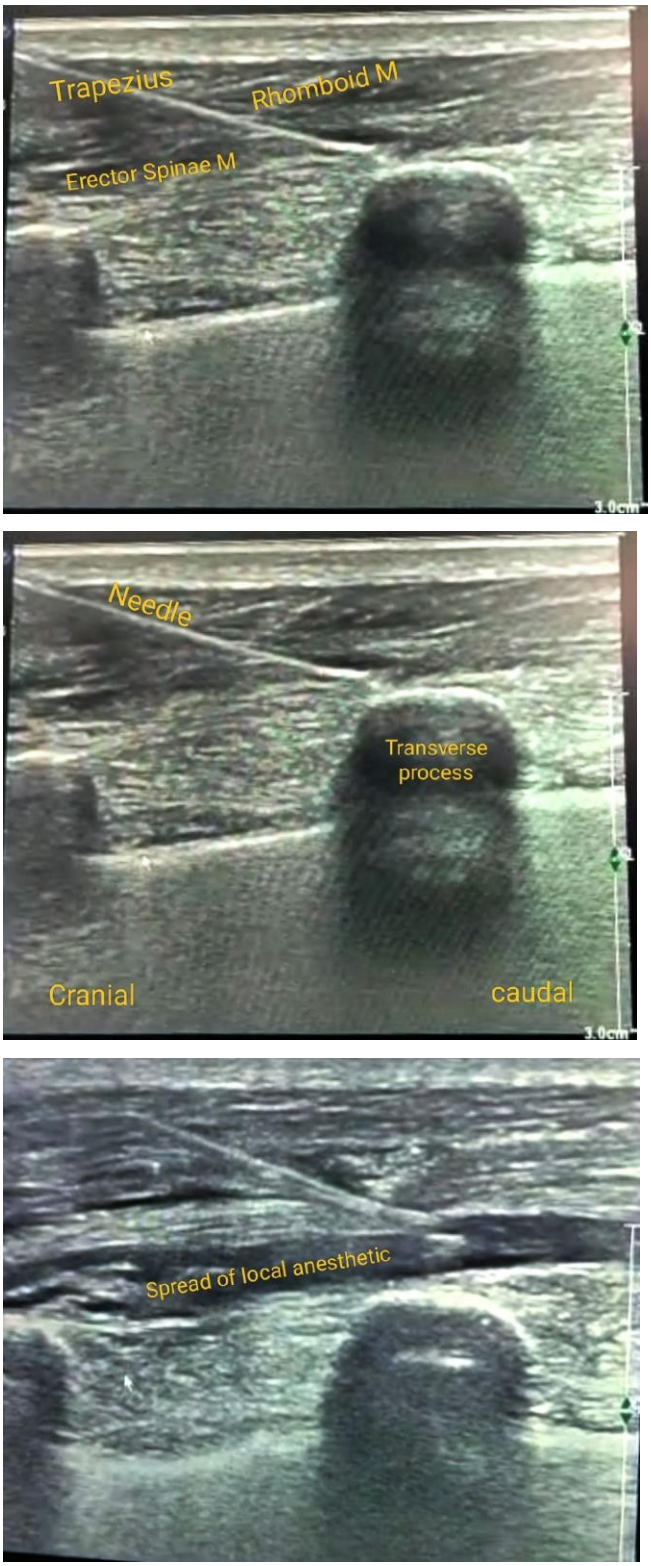


Figure 2: Craniocaudal spread of local anesthetic in erector spinae plane.

Anaesthetic management: Patients were induced with fentanyl 5 mcg/kg and Propofol 1-2 mg/kg till BIS was achieved in the range of 40-60. The airway was secured with appropriate size endotracheal tube after administration of rocuronium 1 mg/kg. The 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 between 40-60.

The last dose of rocuronium 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 institute protocol. The time to extubation was recorded in bothgroups and it was defined as from shifting of patient in the ICU to the extubation of patient.

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 min were set.

The VAS and peak inspiratory flow rate using incentive spirometry was recorded at extubation and then at every 4 hours till 24 hours in all patients. At the end of the observation period (first 24 hours) the total requirement of IV fentanyl was recorded. Side effects during the observation period like drowsiness, respiratory depression, postoperative nausea vomiting, itching, etc. were recorded. Post-operative pulmonary complications in both the group were also noted. Patients satisfaction was recorded on a four-point Likert scale as 1-excellent; 2- good; 3- fair and 4- poor.

Statistical analysis

This open label randomized study was designed to compare the analgesic efficacy of ESP and conventional intravenous patient controlled opioid analgesia. Our primary objective was to compare the postoperative opioid requirement in first 24 hours of ICU stay.

The data was entered in Microsoft Excel spreadsheet and the final analysis was done with the use of statistical Package for Social Science software. 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 $\chi 2$ 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 as significant.

RESULTS

RESULTS

Total one hundred and twenty patients were assessed for eligibility. Eighteen patients (10 not meeting inclusion criteria and 08 due to refusal to participate) were excluded from the study. The remaining one hundred and two patients were randomized into two groups based on computer generated randomization sequence. Fifty-one patients were enrolled in group 'ESP' and the remaining fifty-one patients in group 'PCA'. There was no loss to follow up, and data from all the patients randomized were analyzed.

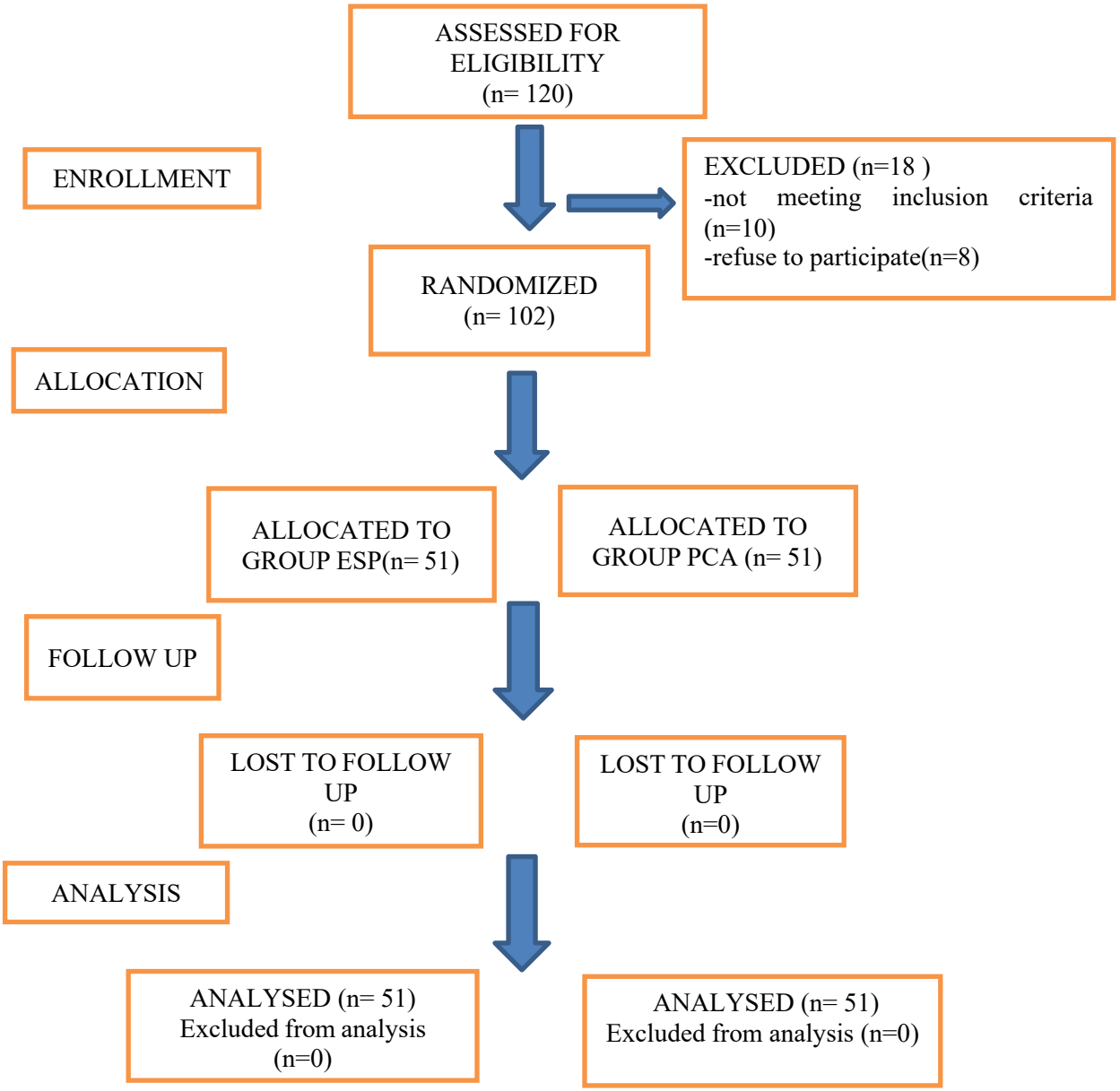


Figure 3: CONSORT flow diagram

Table 1: Distribution of patients in different age groups and comparison of mean agebetween the study groups

Age (year)	Group ESP		Group PCA		*P* value
	No.	%	No.	%	
18-30 yrs	25	49.01	27	52.94	
31-40 yrs	10	19.60	11	21.56	
>40 yrs	16	31.37	13	25.49	
Total	51	100.00	51	100.00	
Mean ± SD	34.37 ± 11.89		35.29 ± 12.30		0.701

The above table shows the distribution of patients in different age groups and comparison of mean ± SD age between group ESP and group PCA. Most of the patients in ESP group and PCA group were belonging to the age group 18 to 30 years. The mean ± SDof age in group ESP and group PCA was 34.37 ± 11.89 and 35.29 ± 12.30 respectively. The Chi square test was used to compare the age between the study groups which showed a *P* value of 0.701 which was statistically non-significant i.e. both the study groups were comparable with respect to the age.

Figure 4: Distribution of patients in different age groups

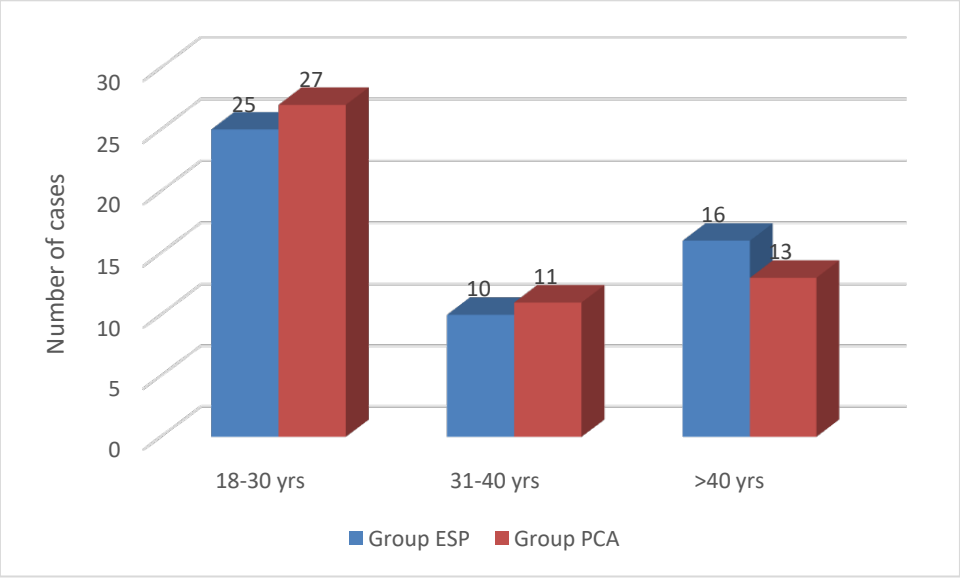


Table 2: Gender distribution and comparison of gender between the study groups.

Gender	Group ESP		Group PCA		*P* value
	No.	%	No.	%	
Male	21	41.18	30	58.82	
Female	30	58.82	21	41.18	0.113
Total	51	100.00	51	100.00	

The above table shows the distribution of patients according to gender between the study groups. Total 51 patients belonged to male gender, out of them 21 patients were randomly allocated in group ESP and 30 patients in group PCA. Remaining 51 patients belonged to Female gender, out of which, 30 patients were randomly enrolled in group ESP and 21 patients in group PCA. The chi-square statistic was applied to compare gender between the study groups which showed a *P* value of 0.113, which was statistically non-significant i.e. both the study groups were comparable with respect to the gender of the patients.

Figure 5: Gender Distribution and comparison of gender between the study groups.

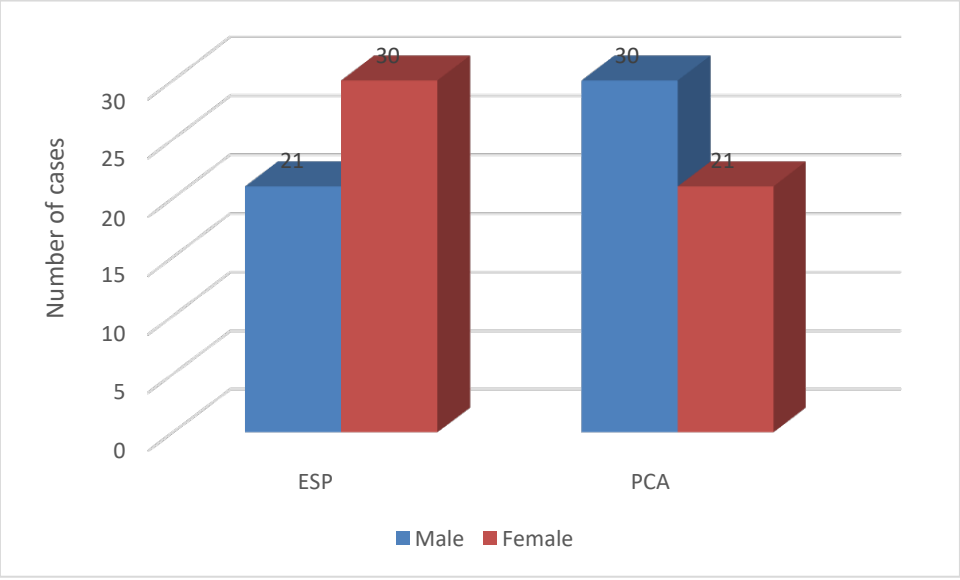


Table 3: Distribution of patients in different weight groups and comparison of weight between the study groups.

Weight (kg)	**Group ESP**		**Group PCA**	
	No.	%	No.	%
≤60	39	76.47	28	54.90
61-70	7	13.73	16	31.37
>70	5	9.80	7	13.73
Total	51	100.00	51	100.00
Mean ± SD	53.12 ± 12.74		57.08 ± 12.29	
***P* value**	0.113			

The above table shows the distribution of patients in different weight groups and comparison of mean ± SD of weight between group ESP and group PCA. Most of the patients belonged to the less than 60 kg weight group. The mean ± SD of weight in group ESP and group PCA was 53.12 ± 12.74 and 57.08 ± 12.29 respectively. The unpaired student's t-test was used to compare the weight between the study groups which showed p value of 0.113, which was statistically non-significant i.e. both the study groups were comparable with respect to the weight.

Figure 6: Distribution of patients in different Weight groups

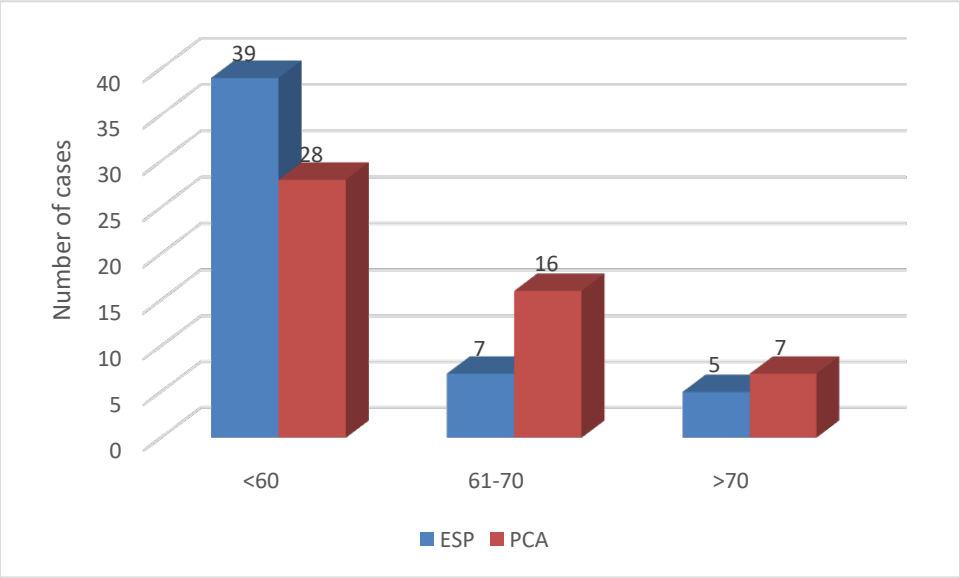


Figure 7: Box plot for comparison of weight between the study groups

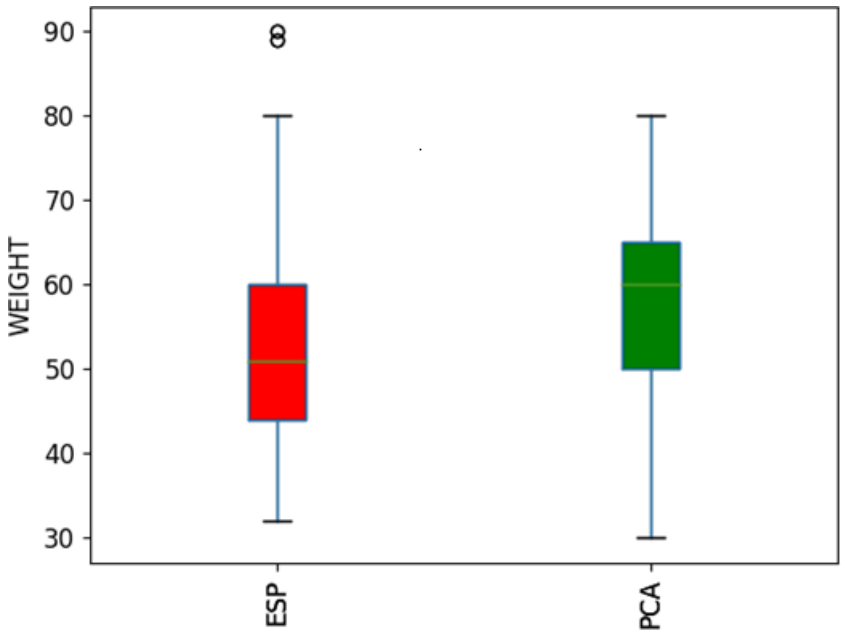


Table 4: Distribution of patients in different height groups and comparison of mean height between the study groups.

Height (cm)	**Group ESP**		**Group PCA**	
	No.	%	No.	%
150-160	13	25.49	16	31.37
161-170	28	54.90	25	49.02
≥171	10	19.61	10	19.61
Total	51	100.00	51	100.00
Mean ± SD	165.67 ± 6.96		165.35 ± 6.81	
***P* value**	0.818			

The above table shows the distribution of patients in different height groups and comparison of mean ± SD of height between group ESP and group PCA. Most of the patients belonged to the height group 161 to 170 cm. The mean ± SD of height in groupESP and group PCA was 165.67 ± 6.96 and 165.35 ± 6.81 respectively. The unpaired Student's t-test was used to compare the height between the study groups which showed *P* value of 0.818 which was statistically non-significant i.e. both the study groups were comparable with respect to the height.

Figure 8: Distribution of patients in different height groups

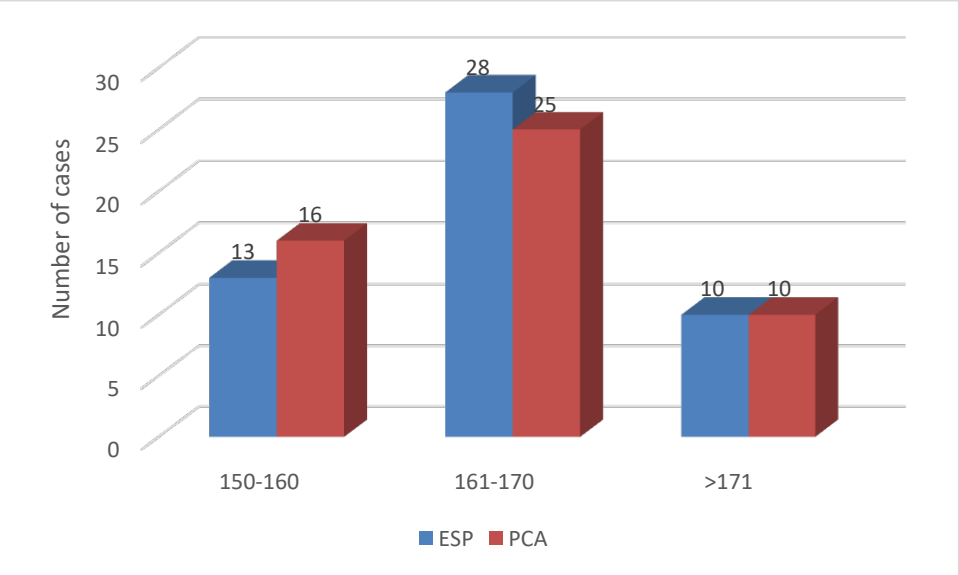


Figure 9: Box plot for comparison of height between the study groups

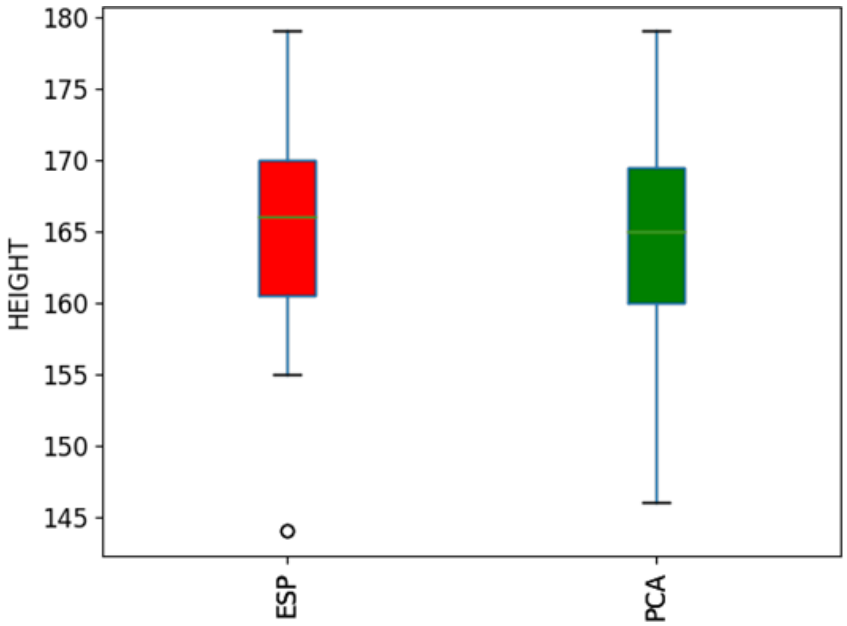


Table 5: Distribution of patients in different BMI groups and comparison of BMI grades between the study groups.

BMI (kg/m^2)	**Group ESP**		**Group PCA**	
	No.	%	No.	%
<18.5	14	27.45	7	13.73
18.5-24.9	31	60.78	33	64.71
25-29.9	4	7.84	9	17.65
≥30	2	3.92	2	3.92
Total	51	100.00	51	100.00
Mean ± SD	20.52 ± 3.61		22.31 ± 3.52	
***P* value**	0.307			

The above table shows the distribution of patients in different BMI groups and comparison of mean ± SD of BMI between group ESP and group PCA. Most of the patients belonged to the normal BMI between 18.5 to 24.99. The mean ± SD of BMI in group ESP and group PCA was 20.52±3.61 and 22.31 ± 3.52 respectively. The unpaired Student's t-test was used to compare the BMI between the study groups which showed *P* value of 0.307 which was statistically non-significant i.e. both the study groups were comparable with respect to the BMI.

Figure 10: Distribution of patients in different BMI groups

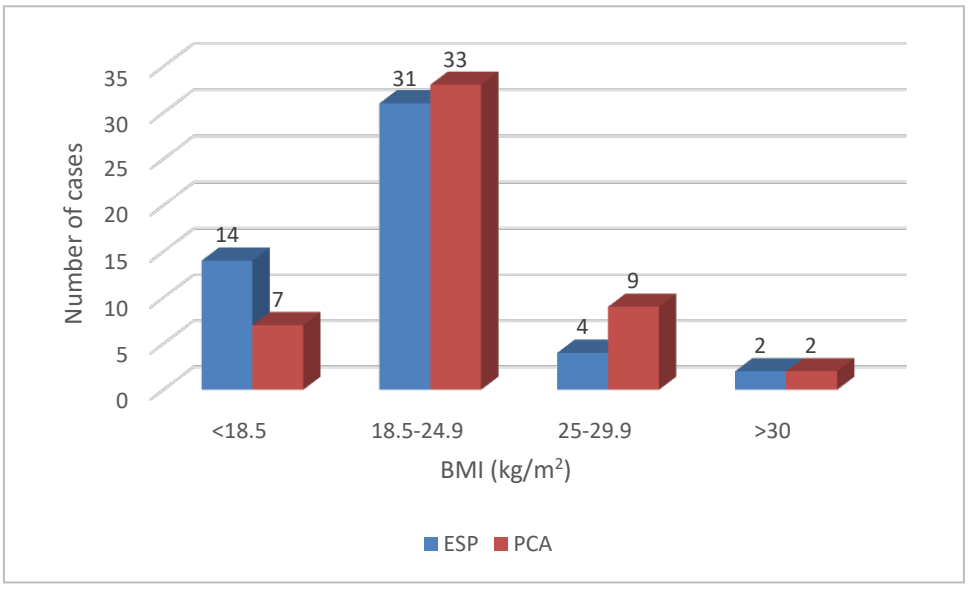


Table 6: Distribution of patients in different ASA groups and comparison of ASA status between the study groups.

	Group ESP		**Group PCA**	
ASA	No.	%	No.	%
II	19	37.25	18	35.29
III	32	62.75	33	64.71
Total	51	100.00	51	100.00
***P* value**	1.00			

The above table shows the distribution of patients according to ASA physical status class between the study groups. All patients enrolled were belonging to either ASA physical status II or III. Total 37 patients belonged to class II, out of which, 19 patients were randomly enrolled in group ESP and 18 patients in group PCA. 65 patients belonged to class III, out of them, 32 patients were randomly enrolled in group ESP and 33 patients in group PCA. The Chi-square test was used to compare the ASA physical status between groups which showedp value of 1.00 which was statistically non-significant i.e. both the study groups were comparable with respect to the ASA physical status class.

Figure 11: Distribution of patients in different ASA physical status classes

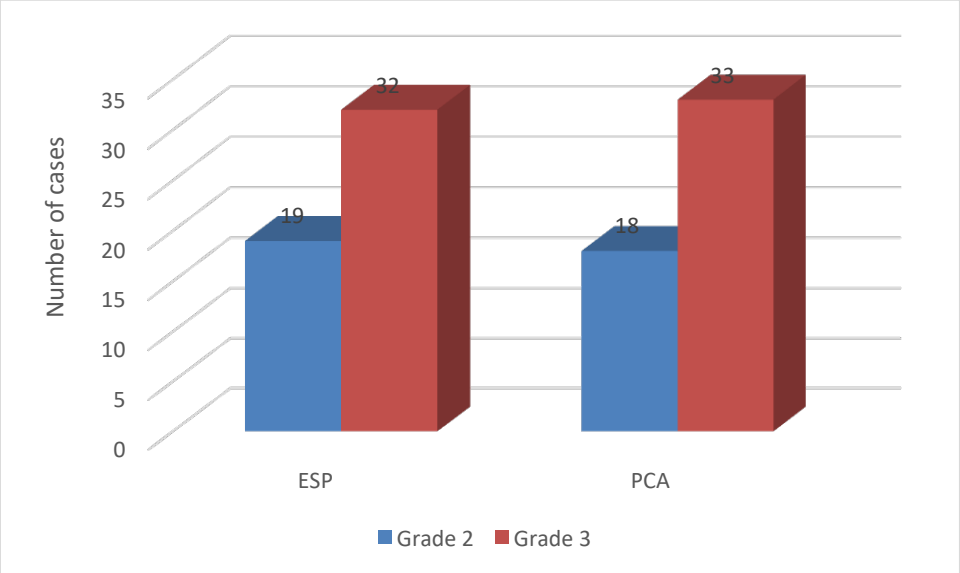


Table 7: Distribution of patients according to different surgical duration and its comparison between the study groups.

Duration of surgery (hrs)	**Group ESP**		**Group PCA**	
	No.	%	No.	%
≤3	1	1.96	0	0.00
4-5	18	35.29	14	27.45
6-7	32	62.75	37	72.55
Total	51	100.00	51	100.00
Median (IQR) (range)	5.5 (1) (3-8)		6.5 (2) (4-8)	
***P* value**	0.009			

The above table shows the distribution of patients according to duration of surgery between the study groups. In most of the patients the surgical duration was 6-7 h in both the groups. The median (IQR) (range) duration of surgery (h) in group ESP and group PCA was 5.5 (1) (3-8) and 6.5 (2) (4-8) respectively. The Mann-Whitney U test was used to compare the duration of surgery between the study groups which showed *P* value of 0.009, that is there was a difference in duration of surgery between the groups which was statistically significant.

Figure 12: Distribution of patients in different groups based on surgical duration.

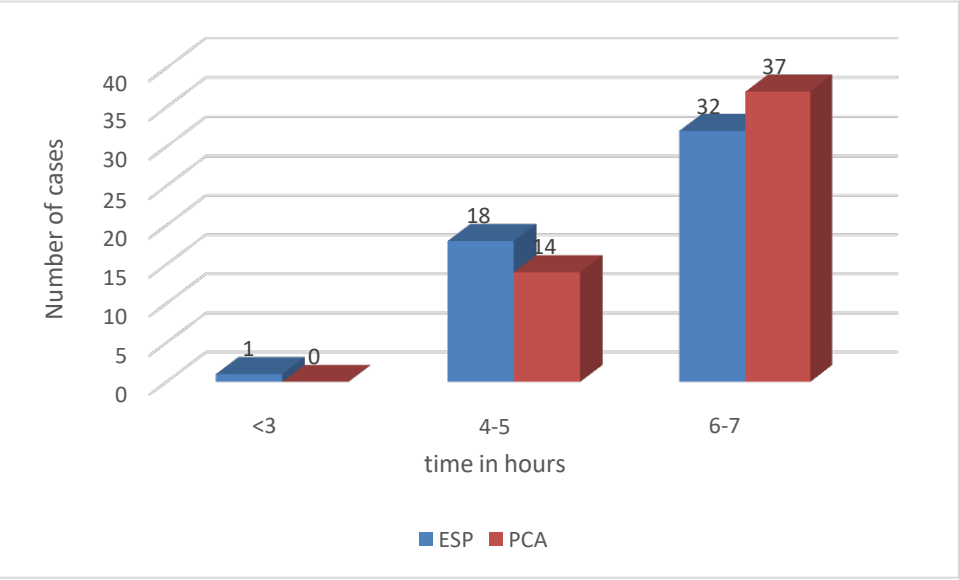


Figure 13: Box plot for comparison of duration of surgery between the study groups.

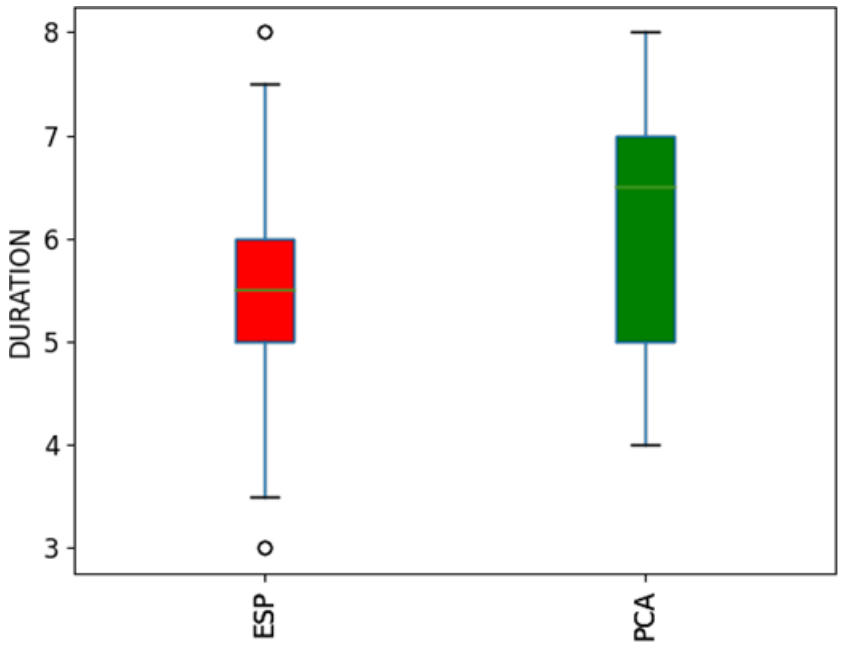


Table 8: Comparison of type of surgery between the study groups.

	Group ESP		**Group PCA**		***P* value**
	No.	%	No.	%	
Single valve surgery	26	50.98	28	54.90	0.843
Dual valve surgery	10	19.61	15	29.41	0.357
Other surgeries with sternotomy (ASD, VSD etc.)	15	29.41	8	15.69	0.155
Total	51		51		

The above table shows comparison of type of surgical procedure (single valve surgery, dual valve surgery, and other surgeries with midline sternotomy performed) between the study groups. The chi square test was applied for comparison which showed a p value of 0.843, 0.357, and 0.155 respectively which were statistically non- significant, i.e. both the study groups were comparable with respect to the surgical procedure characteristics.

Figure 14: Distribution of patients in different study groups based on type of surgery

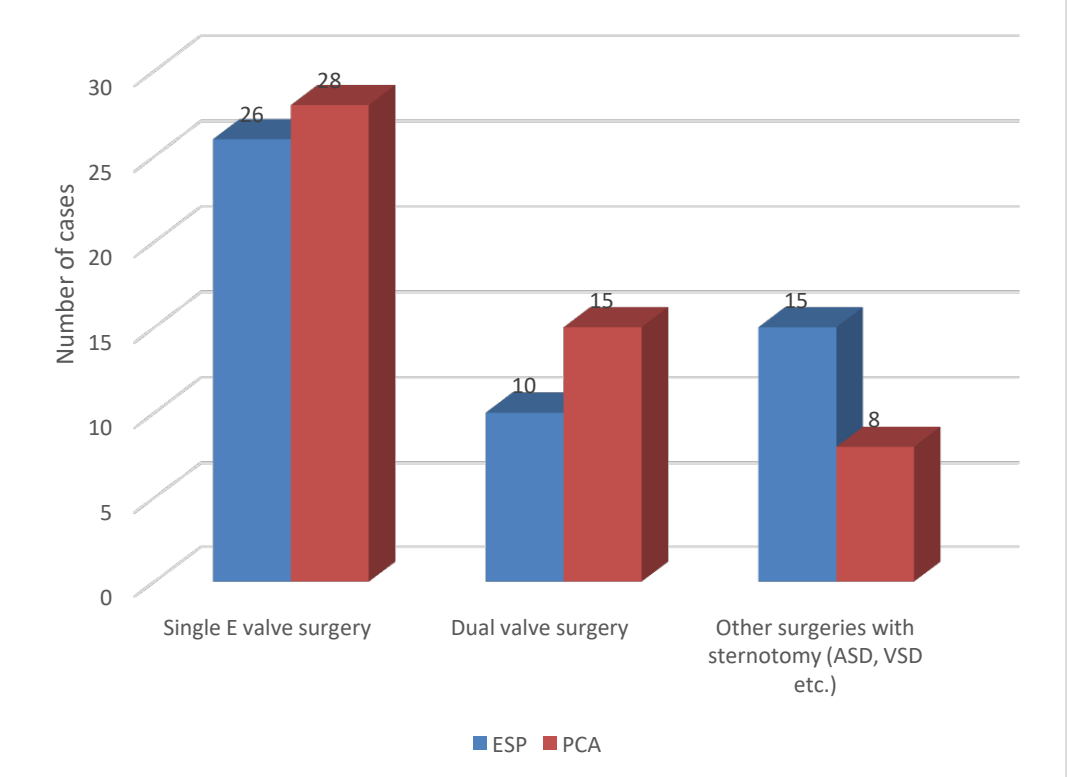


Table 9: Comparison of Baseline vitals heart rate, mean arterial pressure, oxygensaturation, respiratory rate between the study groups

Baseline vitals	**Group ESP**	**Group PCA**	***P* value**
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 minute) [Median (IQR) (Range)]	14 (2.5) (12-18)	14 (3) (12-17)	0.754

The above table shows preoperative heart rate, mean arterial pressure, oxygen saturation and respiratory rate in both the study groups and their comparison. The mean ± SD of HR, MAP in group ESP was 77.65 ± 9.56 and 70.44 ± 7.17 and group PCA was 76.39 ± 10.30 and 73.39 ± 8.30 respectively. The Student's t-test was used to compare the mean HR and MAP between the study groups which showed p value of 0.525 and 0.426 respectively. The[median (IQR) (range)] of SpO2 and RR in group ESP was 99 (1) (98-100) and 14 (2.5) (12- 18) and group PCA was 99 (1) (98-100) and 14 (3) (12-17) respectively. The Mann Whitney U test was used to compare the SpO2 and RR between the study group which showed a p value of 0.211 and 0.754 respectively which was statistically non-significant.

Figure 15: Distribution of patients in different study groups based on baseline vitals.

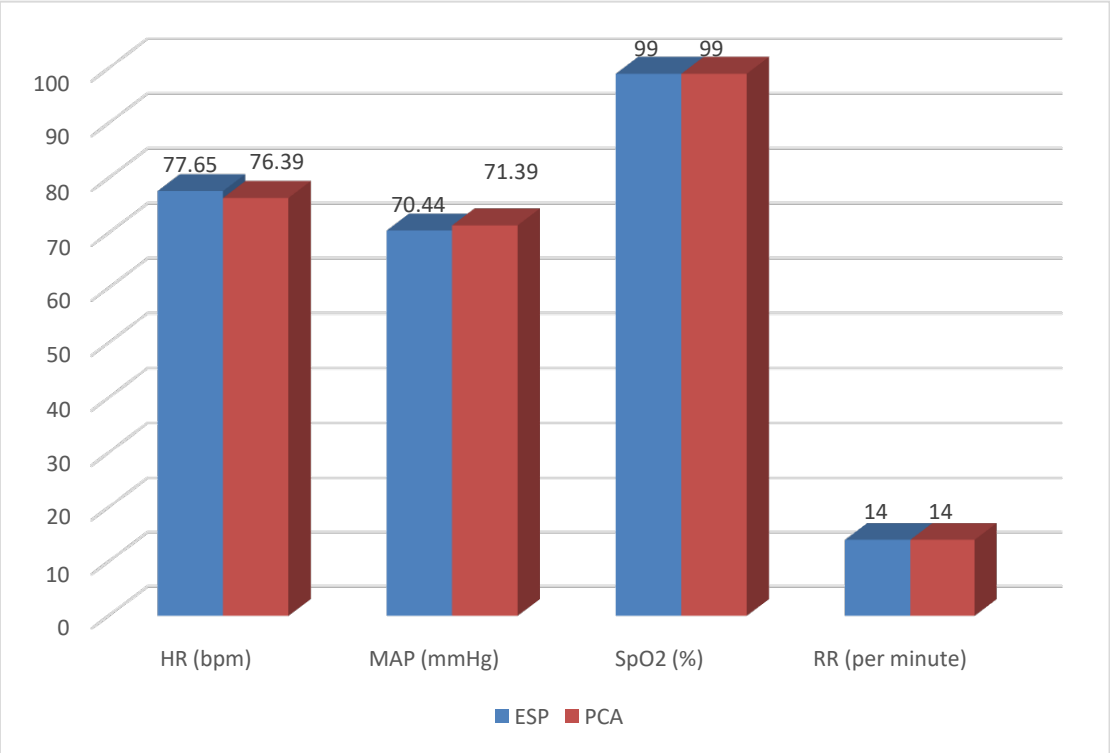


Table 10: Comparison of Intraoperative analgesia (total opioids-fentanyl) consumed between the study groups

Intraoperative opioid	**Group ESP**		**Group PCA**	
	Mean	SD	Mean	SD
fentanyl (mcg/kg/hr)	1.54	0.45	2.17	0.74
Median(IQR)	1.50(1.24-1.83)		2.02(1.66-2.50)	
***P* value**	<0.001			

The above table shows the total opioid (fentanyl in mcg) consumed intraoperatively for analgesia in both the study groups and their comparison. The median(IQR) of total opioid consumed (mcg/kg/hr) in group ESP was 1.50(1.24-1.83) while in group PCA it was 2.02(1.66-2.50) respectively. The unpaired student's t-test was used for comparison between the study groups which showed a *P* value of <0.001 which was considered significant, that is patients in ESP group had significantly lower opioid requirement intraoperatively for analgesia as compared to that in group PCA.

Figure 16: Distribution of patients in different groups based on Intraoperative opioid (fentanyl in mcg/kg/hr) consumed.

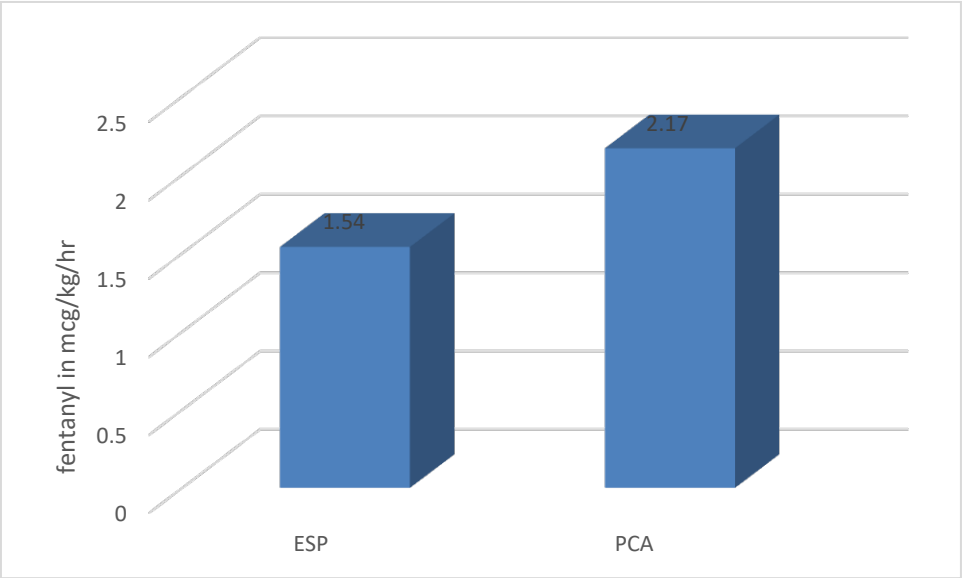


Figure 17: Box plot for comparison of intraoperative opioid consumed between the study groups.

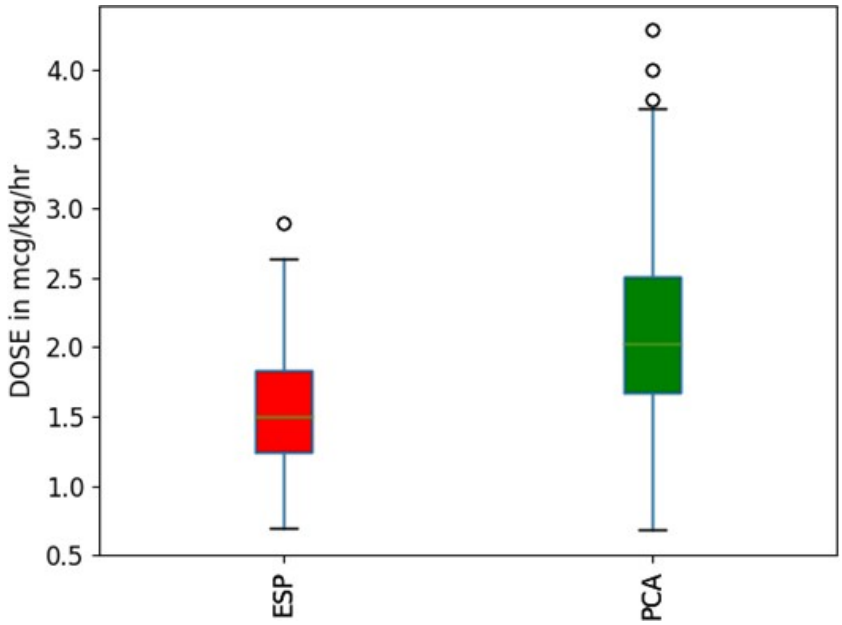


Table 11: Comparison of time to extubation (hrs) between the study groups

Time for extubation (hrs)	**Group ESP**		**Group PCA**	
	Mean	SD	Mean	SD
	3.52	1.08	5.48	1.03
Median(IQR)	3.25(3-4)		5.50(5-6.25)	
***P* value**	<0.001			

The above table shows the time to extubation in both the study groups and their comparison. The median(IQR) of time to extubation in group ESP was 3.25(3-4) while in group PCA it was 5.50(5-6.25) respectively. The unpaired student's t-test was used for comparison between the study groups which showed a p-value of <0.001 which was considered significant, i.e. patients in ESP group had significantly lower time to extubation as compared to that in group PCA.

Figure 18: Distribution of patients in different study groups based on mean time (in hours) to extubation.

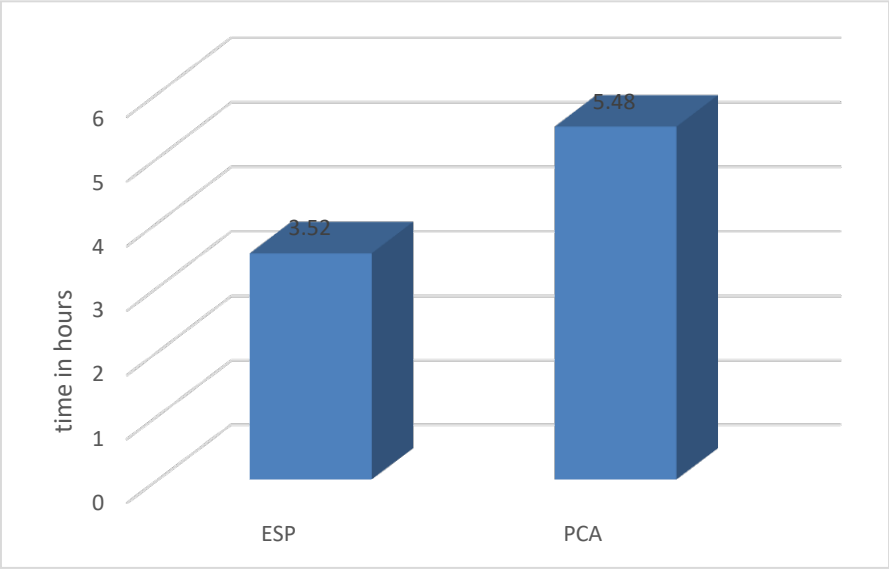


Figure 19: Box plot for comparison of time to extubation between the study groups

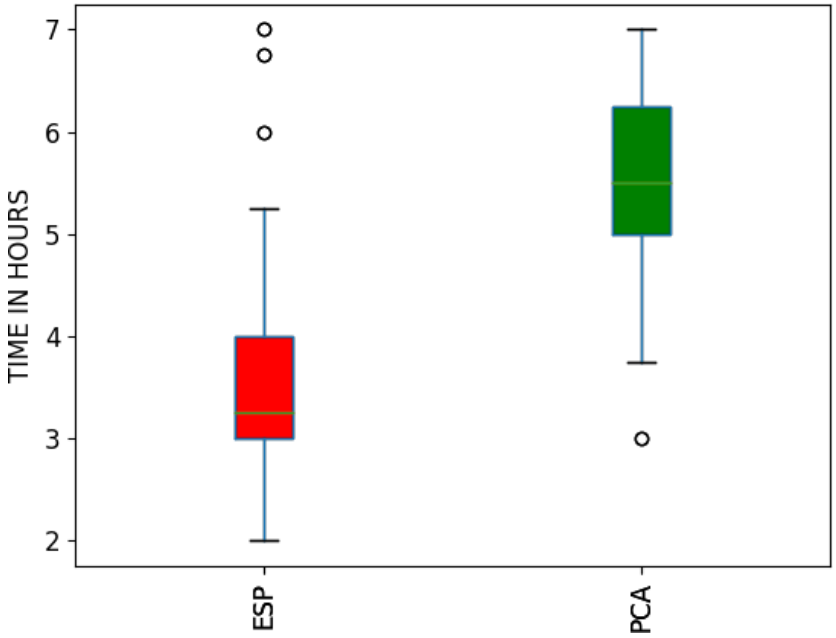


Table 12: Comparison of VAS score at rest during ICU stay between the studygroups.

Time	**Group ESP** [Median(IQR) (range)]	**Group PCA** [Median(IQR) (range)]	***P* value**
On extubation	5 (5,5) (4-6)	6 (5,6) (4-7)	<0.001
4 hrs	4 (4,5) (3-6)	5 (5,6) (3-6)	<0.001
8 hrs	4 (4,5) (3-5)	5 (4,5) (3-6)	0.0006
12 hrs	4 (4,4) (3-5)	4 (4,5) (3-6)	0.0041
16 hrs	4 (3,4) (2-5)	4 (3,4) (3-5)	0.023
20 hrs	3 (3,4) (2-4)	4 (3,4) (2-5)	0.012
24 hrs	3 (3,4) (2-4)	4 (3,4) (1-5)	0.018

The above table shows comparison of median (IQR) VAS Score at rest during ICU stay (on extubation, 4h, 8h, 12h, 16h, 20h and 24 h) in both the groups. In group ESP, the VAS score at rest (on extubation, 4h, 8h, 12h, 16h, 20h and 24h) was 5 (5,5) (4-6), 4 (4,5) (3-6), 4 (4,5) (3-5), 4 (4,4) (3-5), 4 (3,4) (2-5), 3 (3,4) (2-4) and 3 (3,4) (2-4) respectively. In group PCA, the VAS score during PACU stay was 6 (5,6) (4-7), 5 (5,6) (3-6), 5 (4,5) (3-6), 4 (4,5) (3-6), 4 (3,4) (3-5), 4 (3,4) (2-5) and 4 (3,4) (1-5) respectively. The Mann-Whitney U test was used to compare the VAS Score at rest during PACU stay (on extubation, 4h,8h,12h,16h,20h and 24 h) in both the groups showed a p-value of <0.001, <0.001, 0.0006, 0.0041, 0.023, 0.012 and 0.018 respectively, which was statistically significant. Group ESP had significantly lowerVAS score at rest compared to group PCA during ICU stay.

Figure 20: Box plot for comparison of VAS Scores at rest between the study groups during ICU stay.

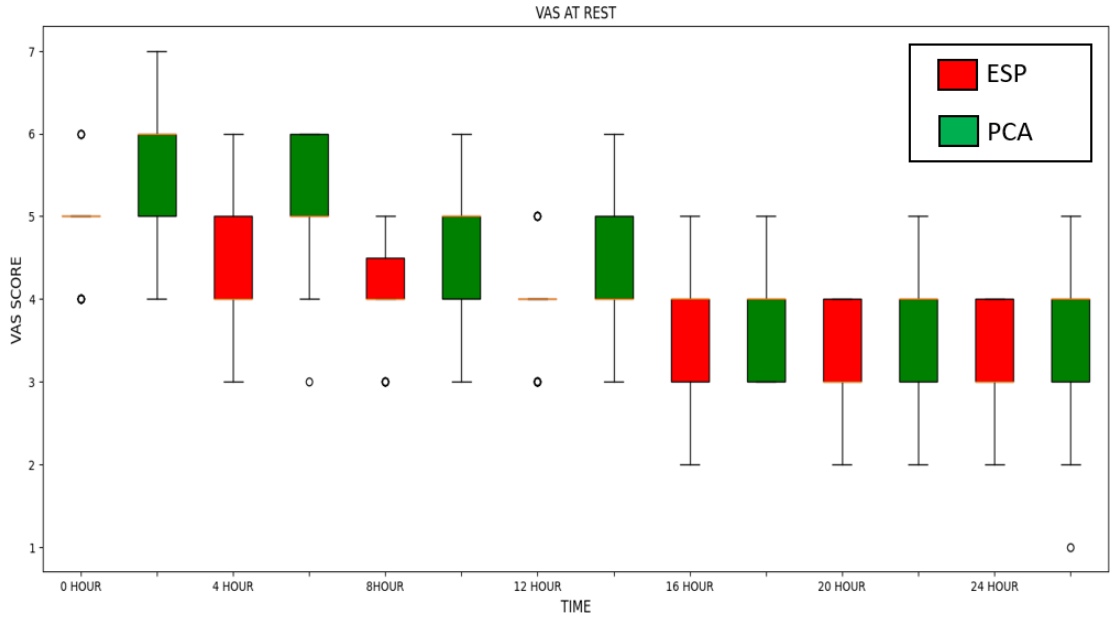


Table 13: Comparison of VAS score at cough during ICU stay between the studygroups.

Time	**Group ESP** [Median(IQR) (range)]	**Group PCA** [Median(IQR) (range)]	***P* value**
On extubation	6 (6,6) (5-6)	6 (6,7) (5-7)	0.0003
4 hrs	5 (5,6) (4-6)	6 (6,6) (5-6)	0.003
8 hrs	5 (5,6) (4-6)	6 (5,6) (5-6)	0.0001
12 hrs	5 (4,5) (3-6)	6 (5,5) (4-6)	0.0002
16 hrs	4 (4,5) (3-5)	5 (5,5) (4-6)	0.0004
20 hrs	4 (4,5) (3-5)	5 (4,5) (3-6)	0.012
24 hrs	4 (4,4) (3-5)	4 (4,5) (2-5)	0.083

The above table shows VAS score on cough in ICU stay (on extubation, 4h, 8h, 12h, 16h, 20h and 24h) in both the groups and their comparison. The median (IQR) (Range) VAS score on cough at (on extubation, 4h, 8h, 12h, 16h, 20h and 24h) in group ESP was 6 (6,6) (5-6), 5 (5,6) (4-6), 5 (5,6) (4-6), 5 (4,5) (3-6), 4 (4,5) (3-5), 4 (4,5) (3-5) and 4 (4,4) (3-5) respectively while in group PCA it was 6 (6,7) (5-7), 6 (6,6) (5-6), 6 (5,6) (5-6), 6 (5,5) (4-6), 5 (5,5) (4-6), 5 (4,5) (3-6) and 4 (4,5) (2-5) respectively. The Mann-Whitney U test was used to compare the VAS Score on cough in ICU (on extubation, 4h, 8h, 12h, 16h, 20h and 24h)between the study groups and showed a *P* value of 0.0003, 0.003, 0.0001, 0.0002, 0.0004, 0.012 and 0.083 respectively, which was statistically significant at all point of times except at 24 hours i.e. patients in group ESP had significantly lower VAS score on cough upto 20 hours of ICU stay and had no difference in VAS score on cough at 24 hours of time.

Figure 21: Box plot for comparison of VAS Scores at cough between the study groups during ICU stay.

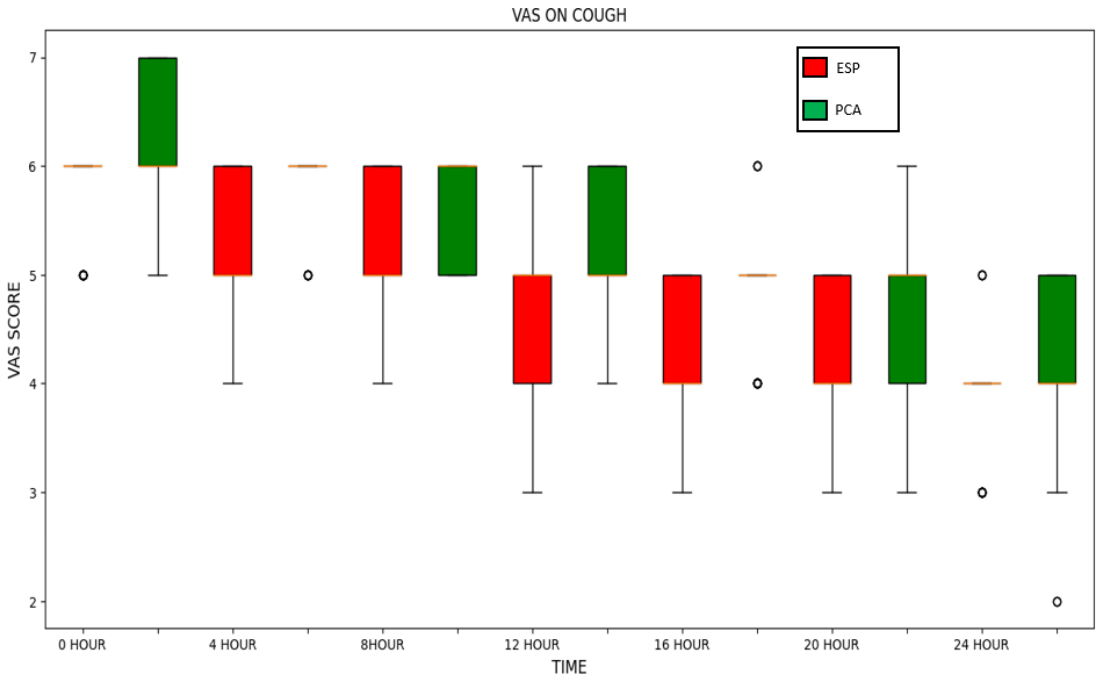


Table 14: Comparison of peak inspiratory flow rate during ICU stay between the study groups.

	Group ESP [Median(IQR) (range)]	**Group PCA** [Median(IQR) (range)]	***P* value**
On Extubation	300 (300,300) (200-500)	300 (300,300) (300-400)	0.417
4 hrs	400 (300,500) (300-800)	300 (300,400) (300-700)	0.031
8 hrs	500 (400,600) (300-800)	500 (300,600) (300-900)	0.094
12 hrs	600 (550,600) (300-900)	600 (500,600) (300-900)	0.012
16 hrs	700 (600,900) (500-900)	600 (600,700) (500-900)	0.0006
20 hrs	900 (800,900) (600-900)	800 (600,900) (500-900)	0.003
24 hrs	900 (900,900) (700-900)	800 (700,900) (600-1000)	0.0007

The above table shows the peak inspiratory flow rate during ICU stay at (pre-defined interval) between the study groups and their comparison. The median (IQR) (Range) Peak inspiratory flow rate (on extubation, 4h,8h,12h,16h,20h and 24 h) in group ESP was 300 (300,300) (200-500), 400 (300,500) (300-800), 500 (400,600) (300-800), 600 (550,600) (300-900), 700 (600,900) (500-900), 900 (800,900) (600-900) and 900 (900,900) (700-900) respectively, while in group PCA it was 300 (300,300) (300-400), 300 (300,400) (300-700), 500 (300,600) (300-900), 600 (500,600) (300-900), 600 (600,700) (500-900), 800 (600,900) (500-900) and 800 (700,900) (600-1000) respectively. The Mann-Whitney U test was used to compare the peak inspiratory flow rate and showed a p-value of 0.417, 0.031, 0.094, 0.012, 0.001, 0.003 and 0.0007 respectively, which was statistically significant except at time of extubation and at 8th hour of extubation, i.e. patients in group ESP had higher peak inspiratory flow rates than group PCA during ICU stay.

Figure 22: Box plot for comparison of peak inspiratory flow rate between the study groups during ICU stay

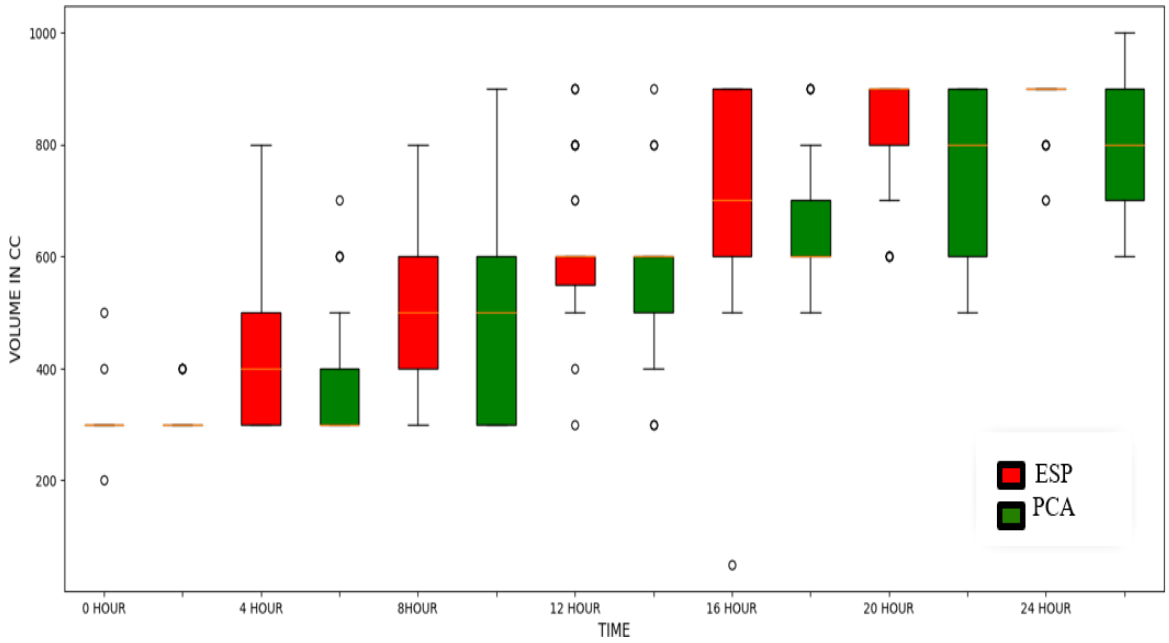


Table 15: Comparison of Total opioid consumed, PCA bolus dose attempted and administered between the study groups during ICU stay.

	Group ESP [Median (IQR) (range)]	**Group PCA** [Median (IQR) (range)]	***P* value**
Total opioid consumed (mcg) [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

The above table shows the total opioid (fentanyl) consumed (mcg) in PCA pump in postoperative period after extubation along with the bolus dose attempted and administered dose in both the study groups and their comparison. The median (IQR) (range) of total opioid consumed, bolus dose attempted and bolus dose administered in group ESP was 160(71.50) (10-420), 8(3.5) (5-18) and 6(2.5) (2-14) respectively, while in group PCA it was 380(132.50) (130-600), 15(3) (7-20) and 14(3) (6-16) respectively. The unpaired student's t-test was used for comparison between the study groups which showed a p-value of <0.001 in terms of total opioid consumed, bolus dose attempted and bolus dose administered which was considered significant, i.e. patients in ESP group had significantly lower opioid requirement, lesser number of PCA dose attempted and administered as compared to group PCA.

Figure 23: Distribution of patients in different study groups based on total opioids consumed, PCA bolus dose of opioid attempted and administered during ICU stay.

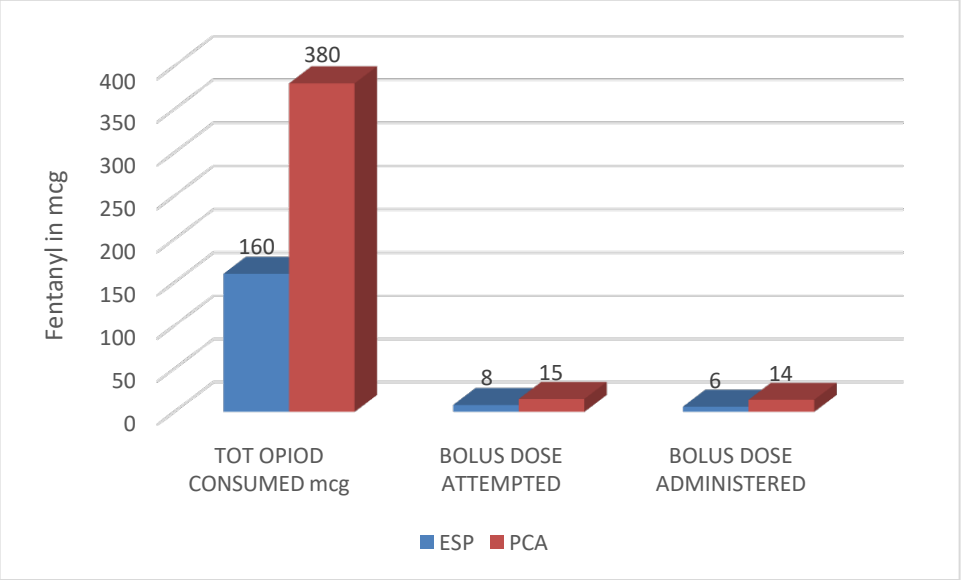


Figure 24: Box plot for comparison of total opioid consumed between the study groups during ICU stay

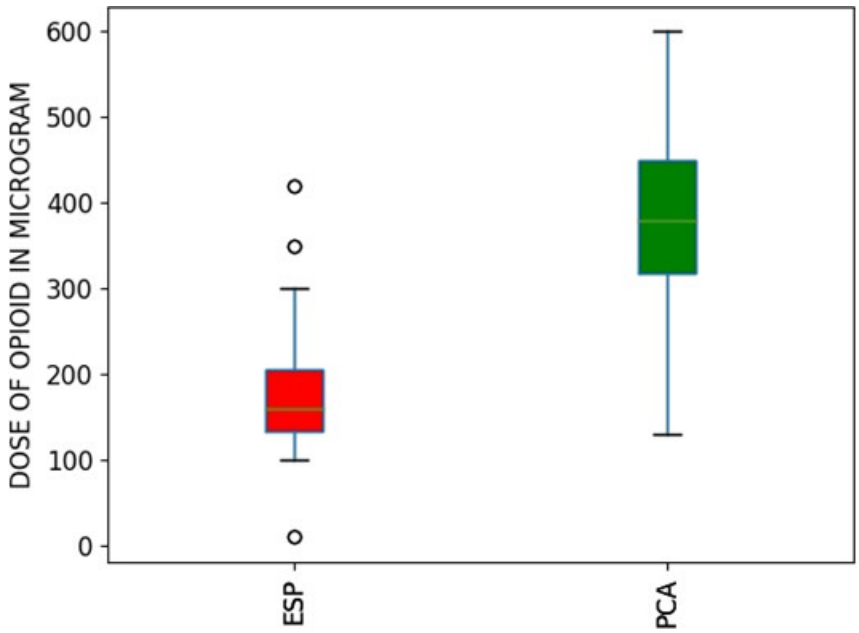


Figure 25: Box plot for comparison of PCA bolus doses attempted between the study groups during ICU stay.

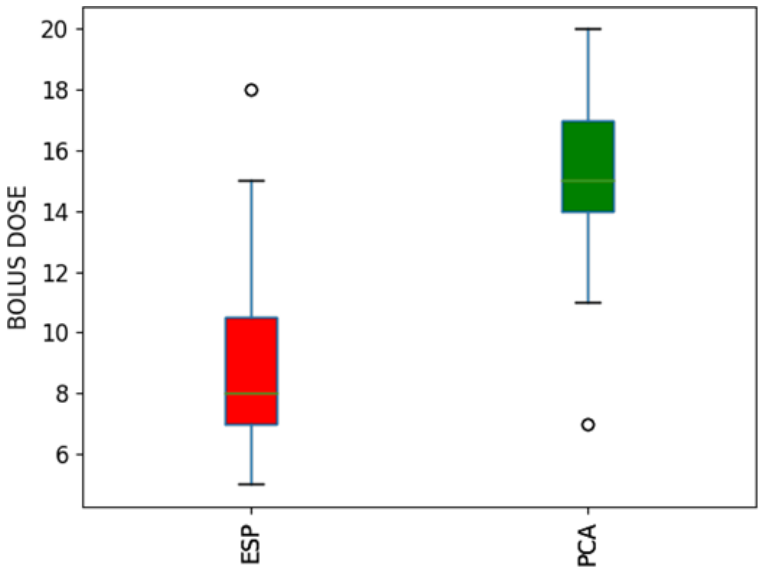


Figure 26: Box plot for comparison of PCA bolus doses at administered between the study groups during ICU stay.

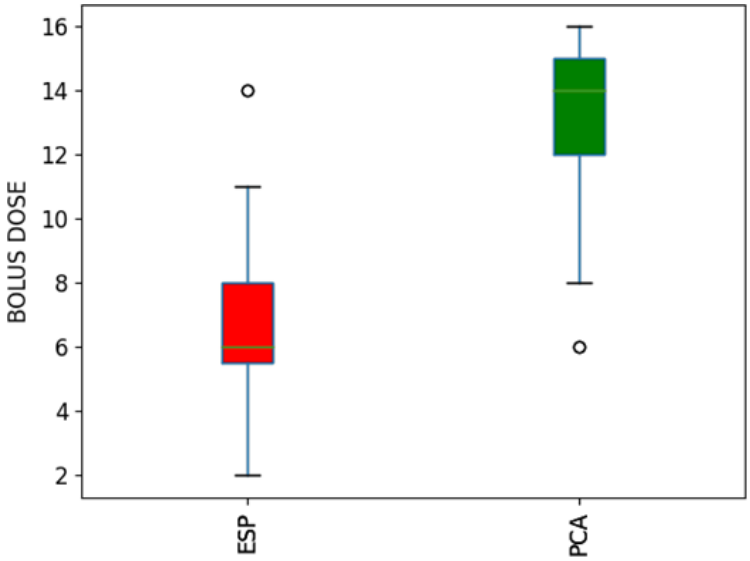


Table 16: Comparison of number of doses of rescue analgesia required postoperatively between the study groups

	Group ESP		**Group PCA**	
	No.	%	No.	%
0	26	50.98	6	11.76
1	24	47.06	12	23.53
2	1	1.96	21	41.18
3	0	0.00	10	19.61
4	0	0.00	2	3.92
Total	51	100.00	51	100.00
Median (IQR) (range)	0 (1) (0-2)		2 (1) (0-4)	
***P* value**	<0.001			

The above table shows the number of rescue analgesia required in both the study groups and their comparison. The median (IQR) (range) number of rescue analgesia required in group ESP was 0 (0, 1) (0 – 2), and while in group PCA was2 (1) (0-4) respectively. Chi-squaretest was used for comparison between the study groups which showed a *P* value of <0.001 which was statistically significant, i.e. patients in group ESP required significantly lesser number of rescue analgesia compared to group PCA.

Figure 27: Comparison of number of rescue analgesia required postoperatively between the study groups

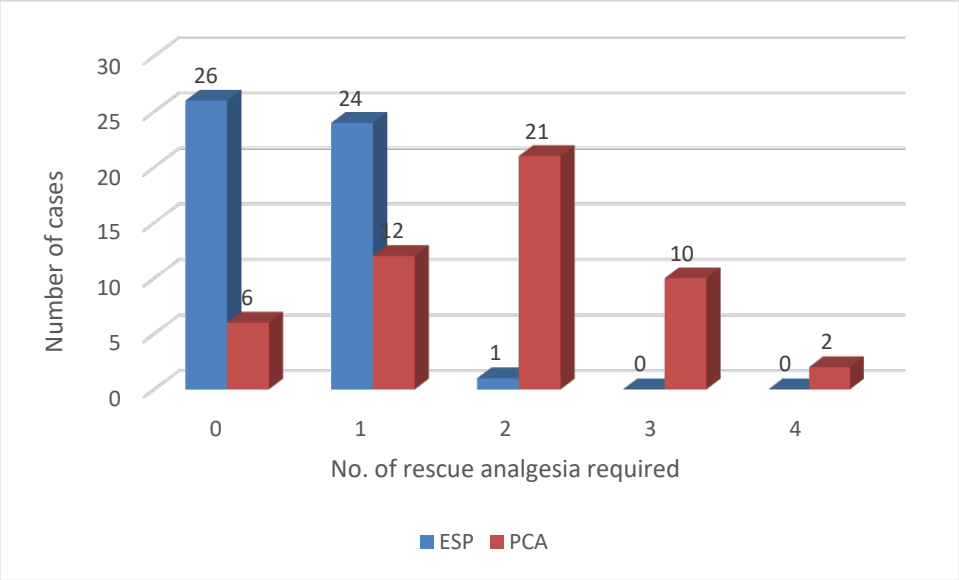


Figure 28: Box plot for comparison of number of rescue analgesia required postoperatively between the study groups.

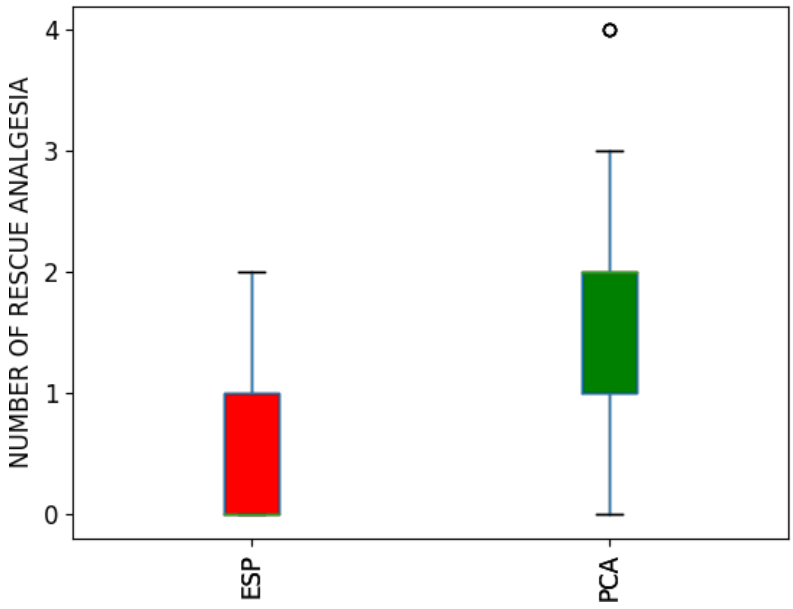


Table 17: Comparison of patient's satisfaction scores between the study groups.

Patient satisfaction Score	**Group ESP**		**Group PCA**	
	No.	%	No.	%
1	6	11.76	0	0.00
2	42	82.35	30	58.82
3	3	5.88	20	39.22
4	0	0.00	1	1.96
Total	51	100.00	51	100.00
Median(IQR) (range)	2 (2,2) (1-3)		2 (2,3) (2-4)	
***P* value**	0.0002			

The above table shows the satisfaction score (excellent, good, fair and poor) in both the study groups and their comparison. The median (IQR) (range) satisfaction score of group ESP was 2 (2,2) (1-3) and while in group PCA it was 2(2,3) (2-4) respectively. The Mann-Whitney U test used for comparison between the study groups which showed a *P* value of 0.0002, which was statistically significant, i.e. patients in group ESP had significantly higher satisfaction for the techniques compared to patients in group PCA.

Figure 29: Comparison of number of patients with different satisfaction score between the study groups

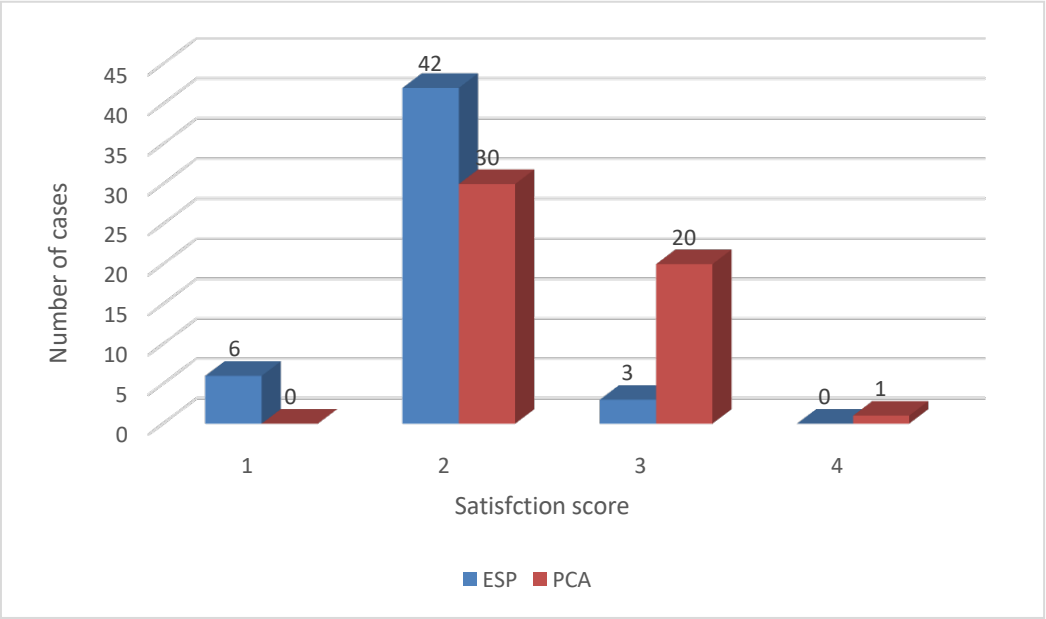


Figure 30: Box plot for comparison of satisfaction score between the study groups.

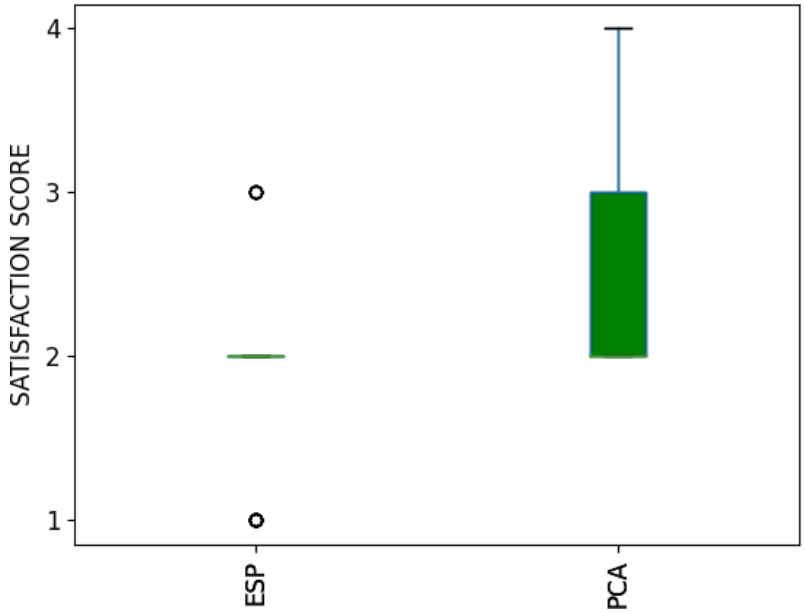
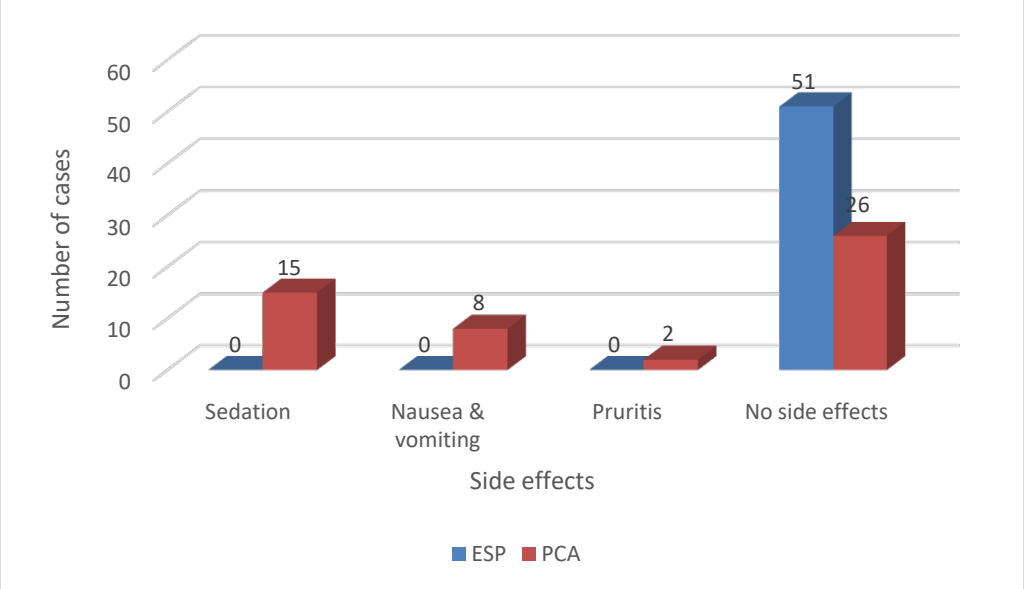


Table 18: Comparison of Side Effects between the study groups.

	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			

The above table shows comparison of adverse events between the study groups. None of the patients in group ESP were having any adverse event, while total 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. The Chi-square test was used for comparison between the study groups which showed a *P* value of <0.001which was statistically significant, i.e. patients in group ESP had significantly lower adverse effects for the technique compared to the patients in group PCA.

Figure 31: Comparison of Side Effects between the study groups.



DISCUSSION

DISCUSSION

The present study demonstrated that the bilateral single shot ESP block provide better postoperative analgesia in terms of lesser opioid consumption and improved VAS score compared to fentanyl based IV PCA in patients undergoing cardiac surgery with midline sternotomy. Additionally, patients received bilateral ESP block required fewer rescue analgesics, fewer PCA bolus doses (attempted and administered), extubated earlier, less respiratory complications. The patients in ESP group had less opioid-related side effects and higher patient satisfaction.

Intense discomfort is frequently experienced following cardiac procedures involving 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. For the efficient relief of postoperative pain following cardiac surgery, a varietyof analgesic agents, including IV and oral pharmacological agents such opioids, PCM, NSAIDs, gabapentinoids, acetaminophen, etc., are available. [36] In majority of cases, theanalgesia is managed by opioids with PCM IV, intermittently or by continuous infusion.

IV opioid PCA for pain management is associated with side effects like nausea, urinaryretention, respiratory complications and delayed extubation. The Enhanced Recovery After Surgery (ERAS) in cardiac surgical patients and advent of ultrasound in regional anaesthesia, the fascial plane blocks are becoming popular method of analgesia as a part of multimodal pain management. Various blocks like paravertebral block, ESP block, SAP block, parasternalblocks are used in patients undergoing cardiac surgery. These blocks have demonstrated improved pain control with less reliance on opioids. [37]

Patients undergoing cardiac surgery had managed for postoperative pain using central neuraxial analgesia (epidural or intrathecal) and regional anaesthetic techniques. Although, these methods lessen the need for opioids and provide effective postoperative analgesia, but there is an increased risk of epidural hematoma, pneumothorax and spinal cord injury because of intraoperative anticoagulation. [6] In order to avoid all of these issues, researchers are still looking for the best analgesic technique that also has opioid sparing properties.

The introduction of ESP block by **Forero** in 2016 aroused the interest of many nerve block experts. The ESP block demonstrated extensive craniocaudal spread of LA 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 and the sonographic focus is simple to visualize, ESP block is a simpler and safer replacement to thoracic paravertebral and epidural blocks. Additionally, the transverse processes function as a 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 ESP block has advantage of blocking of dorsal rami of sympathetic chain, which provide visceral analgesia, hence this block provides good analgesia. A meta-analysis has been published evaluating role of ESP block in adults undergoing various types of general anesthesia surgeries, concluding that ESP block is safe and can provide effective postoperative analgesia in terms of reduced opioid consumption after surgery. [38]

Although, ESP block was studied in cardiac surgical population, but limited literature isavailable so far. Hence, we planned a study to compare the efficacy of ultrasound guided singleshot bilateral ESP block and fentanyl based IV PCA for postoperative analgesia in patients undergoing midline sternotomy in adults.

The present study enrolled one hundred and twenty patients of either sex, aged between 18 to 70 years, belonging to ASA physical status class II and III scheduled for elective cardiac surgery with midline sternotomy. The study aimed to compare analgesic efficacy of single shot bilateral ESP block and IV PCA following cardiac surgery. The primary objective was to compare postoperative fentanyl consumption during first 24 hours of ICU stay. The secondary objectives were comparison of postoperative VAS pain score at rest and on cough, comparison of peak inspiratory flow rate during first 24 hours of ICU stay, time for extubation, respiratory complications if any, total rescue analgesia consumed during the first 24 hours, side effects and patient’s satisfaction for both the techniques.

Fifty-one patients were enrolled in each group (group ESP and group PCA). All the patients received the allocated intervention and followed up to 24 hours. There was no lost to follow up and all the patient’s data were analyzed as per the randomized group.

Demographic profile:

Age:

In our study, the mean ± SD of age in group ESP and group PCA was 34.37 ± 11.89 and 35.29 ± 12.30 respectively. Age-wise, the two groups were comparable. Similar studies enrolling patients aged more than 18 years or less than 70 years found similar results to that of our study. **Krishna et al** [25] and **Gurkan et al** [21] enrolled comparatively younger patients (48.321 ± 1.7 and 49.62 ± 1.51) and (49.56 ± 10.96 and 49.8 ± 10.49) respectively. While **Finnerty et al** [33] (58.8. ± 15.5 and 53.1 ± 16.5) and Fu et al [39] (55.4 ± 7.0 and 53.2 ± 7.1) enrolled comparatively older patients compared to our study population. All these studies reported no significant difference in age between control and ESP block groups.

Gender:

In our study, there was a uniform gender distribution (male/female) in group ESP (21/30) and in group PCA (30/21). The gender distribution among both groups was comparable.

Finnerty et al [33] (19/11 ESP group and 18/12 Control group), **Krishna et al** [25] (31/20 ESP group and 30/23 control group) and **Ciftci et al** [31] (16/14 ESP group and 15/15 Control group) also had similar gender distribution in their study. All these studies reported no significant difference in gender distribution between control and ESP block groups.

Height, Weight & BMI:

In our study, the mean ± SD height, weight and BMI of patients in group ESP was 165.67 ± 6.96, 53.12 ± 12.74 and 20.52 ± 3.61 while in group PCA it was 165.35 ± 6.81, 57.08 ± 12.29 and 22.31 ± 3.52 respectively. Height, weight, and BMI were comparable between the two groups.

In the studies of **Ciftci et al** [31] and **Krishna et al** [25] distribution of height and weight of the patients were comparable to our study groups. While in the study of **Fu et al** [39] had a BMI distribution similar to our study groups. In all the research cited and in our study, the BMI difference between the groups was statistically insignificant.

ASA physical status:

In our study population, most of the patients belonged to ASA physical status III. The ASA distribution (II/III) in group ESP was 19/32 and in group PCA was 18/33 respectively. **Ali Gado et al** [27] had ASA distribution (II/III) in group ESP which was 31/19 and in controlgroup it was 27/21, while **Fu et al** [39] had ASA distribution (I/II) in group ESP which was 12/18 and in PCA group it was 14/16. In terms of ASA physical status class distribution between groups, there was no statistically significant variation.

Duration of surgery:

In our study, the median (IQR) (range) of duration of surgery (hours) in group ESP and group PCA was 5.5 (1) (3-8) and 6.5 (2) (4-8) respectively, which was statistically significant.

Fu et al [39] reported mean ± SD duration of surgery in control group was 3.51± 0.50 and in ESP group 3.61±0.46 hours respectively, while in study by **Vaughan et al** [34] 3.91 ± 0.75 hours in control group and 3.91 ± 0.68 hours in ESP block group and by **Ciftci et al** [31] it was 175 ± 21 min in control group and 185 ± 34 min in ESP block group. In all the quoted studies, both the groups were having lesser duration of surgery compared with our study groups. In our study both the groups were having a difference in duration of surgery.

Surgical Procedure Characteristics:

In our study, the type of surgical procedure (hours) (single valve surgery, dual valve surgery and other surgeries for ASD, VSD etc) was compared between both study groups which came as 26/10/15 in ESP group and 28/15/8 in control group.

Krishna et al [25] included CABG, ASD repair, single valve surgery, which in control group was 27/11/15 and 26/13/14 in ESP group. which was comparable to our study population.

Ali Gado et al [27] compared surgical procedures (valve repair, septal defect repair and other surgeries) it was 3/43/2 in control group and 0/46/4 in ESP block group which was different from our study population.

Primary outcome:

Post-operative Opioid Consumption:

In our study, the median fentanyl (IQR)(range) consumed (in mcg) in first 24 h of ICU stay was significantly lower in ESP block g r o u p [160 (71.50). (10-420)] compared to IV PCA fentanyl group [380 (132.50) (130-600)]. The ESP group patients had lower number of bolus doses attempted and bolus doses administered compared with that in the control group ($p<0.001$).

In the study by **Krishna et al.** [25] , the ESP block group's overall opioid consumption in the first 24 hours was considerably lower than that of the control group. (231.42 ±. 6.95 mcg, vs 935.66 ± 21.99 (mcg).

Fu et al [39] also reported significantly lower mean opioid requirements in ESP group (103.1 ± 11.4 mcg) compared to control group (149.0 ± 6.0 mcg) within 48 hours postoperatively (P <0.05). Further, they observed that when compared to the ESP group(100 mcg), the control group's average 48-hour opioid intake (155 mcg) was markedly higher. These results showed that preoperative ESP block can significantly reduce the consumption of postoperative opioid analgesia and its associated side effects. In our study, B/L ESP block provided longer lasting analgesia leading to significantly lesser opioid consumption during 24 hours postoperatively.

Ciftci et al [31] also found significantly lesser consumption of fentanyl postoperatively in study groups and proved that opioid requirement at 1,2,4,8,16 and 24 hours was considerably lower in ESP group when compared with the control group. The mean ± SD of total opioid consumed postoperatively in ESP group and control group was 176.66 ± 88.83 mcg and 717.33 ± 133.98 mcg respectively. The results showed that preemptive single shot ESP block provided better analgesic quality and reduced the opioid consumption in their patients. The B/L ESP block in our study also demonstrated better quality of analgesia leading to significantly lesser opioid consumption during 24 hours postoperatively.

Ali Gado et al [27] compared the intraoperative fentanyl and postoperative morphine requirement between the study groups and they reported that there were considerably higher levels of intraoperative fentanyl administration and postoperative morphine requirement in the control group than in the ESP group (P <0.001). They also proved that ESP block reduces intraoperative and postoperative opioid consumption.

All of the above studies have reported significantly lower post-operative opioid consumption in patients receiving B/L single shot ESP block, which was similar to our study.

Secondary outcome:

VAS Score at rest and during cough

In our study, the VAS scores at rest was better in group ESP compared to group PCA during ICU stay at all predefined time points. However, the VAS scores on cough was significantly lower only up to first 20 hours in ESP group compared to the control group. This could be explained by the single shot ESP block with ropivacaine and its expected duration of action.

Ciftci et al [31] performed B/L single shot ultrasound guided ESP block with 20 ml of 0.25% bupivacaine, preoperatively in intervention group. They recorded active and passive VAS scores for 24 hours after surgery. They found that active and passive VAS scores were also significantly lesser (P <0.001) at 0, 2, 4, 8, 16 and 24 hours after surgery in patients receiving ESP block compared to the control group.

Krishna et al [25] also performed B/L single shot ESP block at T6 transverse process level preoperatively with 3 ml/kg of 0.375% ropivacaine. In the postoperative period beginning right after extubation, they compared the trend of NRS scores in the two groups to assess pain. The median NRS scores were compared at 0, 2, 4, 6, 8, 10 and 12 hours after extubation between the study groups. They reported that the NRS scores at rest were significantly lesser (P < 0.0001) at each point of time assessed in ESP group compared to the control group. They also reported that the average duration of analgesia was significantly longer in ESP group comparedwith control group (P = 0.0001)

Fu et al [39] performed single shot B/L ESP block in intervention group with 20 ml of 0.5% ropivacaine on each side preoperatively. The VAS scores on movement and at rest were used to determine postoperative pain.. The VAS scores were considerably lower in ESP group as compared to control group at 2,4,8 and 24 hours after surgery. They reported that there was no significant difference in VAS score at 48 h rest and movement after surgery (P >0.05). Their result proved that ESP block significantly lower pain scores and provide adequate quality of analgesia.

Ali Gado et al [27] in their study among performed B/L ESP block after anaesthetic induction in intervention group with 0.4 ml/kg of 0.25% of bupivacaine. The pain was assessed by using FLACC pain score. They reported significantly higher FLACC scores in the control group than in the ESP group till first 24 hours postoperatively.

Yayik et al [41] performed preoperative single shot ESP block with 20 ml 0.25% bupivacaine in the intervention group posted for open lumbar decompression surgery for 1 or 2-level. At 1, 2, 4, 8, 12, and 24 hours after surgery, postoperative pain was measured using VAS scores both at rest and during active movement. At all time points of observation, patients undergoing ESP block had reported VAS scores that were considerably lower than those in the control group.

All of the studies quoted have reported significantly lower pain scores in patients receiving ESP block up to 24 hours in the postoperative period. The ultrasound guided single shot bilateral ESP block in our study also provided significantly lower pain scores up to 24 hours postoperative.

Time to extubation:

In our study, the median time to extubation in ESP group was 3.25 hours, while it was 5.50 hours in control group, which was statistically significant. According to **Krishna et al.** [25] , patients in the ESP group were extubated markedly earlier than those in the control group. (*P* <0.0001). In their study, **Guven et al.** [42] also observed that the ESP group's length ofmechanical ventilation and time before mobilization in the ICU was significantly shorter than that of the control group. Thus, our study also provides evidence for early extubation in patients receiving B/L single shot ESP block.

Peak inspiratory flow rate

In our study, the median (IQR)(Range) peak inspiratory flow rate was significantly higher in ESP group compared to the control group (at all pre-defined time intervals 4h, 8h, 12h, 16h,20h and 24h) except on extubation and at 8th hour after extubation. The non-significance inpeak inspiratory flow rate at extubation and at the 8th hour after extubation in both groups could be explained by the residual effect of anaesthetic drugs (intraoperative opioids and inhalational agents), which impaired their respiratory efforts in performing active spirometry. The peak inspiratory flow rate was assessed by bedside incentive spirometry. Thus, our study proves that the respiratory effort assessed by peak inspiratory flow rate was clinically and statistically better in patients receiving B/L ESP block.

Adverse Events & Postoperative pulmonary complications

In our study, none of the patients in the ESP block group had block related adverse events, while a significant proportion of patients (49%) in the PCA group experienced opioid related side effects. The sedation was the most common adverse effect. In group PCA, 15 patients had sedation and 8 had nausea/vomiting and 2 had pruritus. **Fu et al** [39] and **Ciftci et al** [31] also reported significantly lesser nausea, vomiting and itching in patients who all received ESP block compared to control group.

In our study none of the patients in both the groups reported any postoperative pulmonary complication associated with the techniques involved in them. Also, our study proves that ESP block was effective and could be used as a part of opioid sparing multimodal analgesia in managing postoperative sternotomy pain in adults.

Patient's Satisfaction score

In our study, 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). As per **Singh et al.**[22],patients who underwent US-guided ESP blocks were more satisfied than the control group (satisfaction score, median (interquartile range IQR), 8.00 (0), 6.00 (1) for control and ESP group respectively, P< 0.001). Thus, in our study also, the B/L single shot US guided ESP block had improved the level of comfort and satisfaction of adult patients who all underwent cardiac surgery.

Intraoperative opioid consumption

Apart from our secondary objectives, we also compared the intraoperative consumption of opioids between the study groups. In our study, the median of total opioid consumed in group ESP was 1.50 mcg/kg/hr, while in group PCA it was 2.02 mcg/kg/hr. **Krishna et al** [25] in their study also proved that the total intraoperative fentanyl consumption was notably lower in ESP group when compared with the control group (p = 0.0001). **Ali Gado et al** [27] in their study also reported statistically higher levels of intraoperative consumption of fentanyl in the control group compared with the ESP group ($P < 0.001$).

Thus, our study also provide evidence for analgesia efficacy of B/L ESP block in reducing intraoperative opioid requirement in adult patients posted for cardiac surgery with midline sternotomy.

Strength of our study:

1. One anesthesiologist handled all of the blocks during the course of the investigation.
2. All the blocks were performed using USG guidance.
3. Randomization and allocation concealment was strictly followed throughout the study.
4. We use US guided technique for the single shot B/L ESP block using 0.5% of ropivacaine as local anesthetic which is a novel long acting aminoamide local anesthetic with low systemic toxicity.

Limitations of our study:

1. It was an open label trial as the blinding was not possible for the selected intervention. The bias associated with the open label nature of the trial could not be ruled out.
2. We could not assess the other benefits of adequate pain control (functional outcome, early ambulation, early discharge, and development of chronic pain).
3. ESP block was carried out using a single shot method rather than a continuous analgesic method, which would have further prolonged the analgesia.
4. Due to anatomical limitations, we were unable to gauge the precise local anaesthetic spread following the ESP block or evaluate the dermatomal coverage following block administration.
5. Although sample size calculation was based on the data from the published literature and clinically important reasonable assumption, we believe that further studies with multicentric design and large sample size are required to reciprocate the findings of our study.

CONCLUSION

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 B/L 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.

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BIBLIOGRAPHY

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ANNEXURES

ANNEXURES

INSTITUTE'S ETHICAL COMMITTEE APPROVAL CERTIFICATE

अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर
All India Institute of Medical Sciences, Jodhpur
संस्थागत नैतिकता समिति
Institutional Ethics Committee

No. AIIMS/IEC/2021/3481 **Date: 12/03/2021**

ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: **AIIMS/IEC/2021/3316**

Project title: **"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 Randomized Control trial"**

Nature of Project:	**Research Project Submitted for Expedited Review**
Submitted as:	**M.D. Dissertation**
Student Name:	**Dr. Manish Mohan**
Guide:	**Dr. Manoj Kamal**
Co-Guide:	**Dr. Pradeep Bhatia, Dr. Sadik Mohammed, Dr. Alok Sharma & Dr. Surendra Patel**

Institutional Ethics Committee after thorough consideration accorded its approval on above project.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.
- In case of any issue related to compensation, the responsibility lies with the Investigator and Co-Investigators.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- Any unethical principle or practices are revealed or suspected
- Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

Please Note that this approval will be rectified whenever it is possible to hold a meeting in person of the Institutional Ethics Committee. It is possible that the PI may be asked to give more clarifications or the Institutional Ethics Committee may withhold the project. The Institutional Ethics Committee is adopting this procedure due to COVID-19 (Corona Virus) situation. If the Institutional Ethics Committee does not get back to you, this means your project has been cleared by the IEC.

On behalf of Ethics Committee, I wish you success in your research.

Dr. Praveen Sharma
Member Secretary
Member secretary
Institutional Ethics Committee
AIIMS,Jodhpur

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E-mail : ethicscommittee@aiimsjodhpur.edu.in; ethicscommitteeaiimsjdh@gmail.com

All India Institute of Medical Sciences Jodhpur, Rajasthan

Informed Consent Form

Title of the project: **COMPARISON OF ANALGESIC EFFICACY OF ULTRASOUND GUIDED BILATERAL ERECTOR SPINAE PLANE BLOCK VERSUS CONVENTIONAL INTRAVENOUS PATIENT CONTROLLED ANALGESIA INPATIENTS UNDERGOING CARDIAC SURGERY WITH MIDLINE STERNOTOMY: AN OPEN LABEL RANDOMIZED CONTROL TRIAL**

Name of the Principal Investigator: **DR MANISH MOHAN** Tel. No. 9496081960

Patient/Volunteer Identification No. :_____ I,_____

S/o or D/o_____ R/o_____ give my full, free, voluntary consent to be a part of the study "_____", the procedure and nature of which has been explained to me in my own language to my full satisfaction. I confirm that I have had the opportunity to ask questions.

I understand that my participation is voluntary and am aware of my right to opt out of the study at any time without giving any reason.

I understand that the information collected about me and any of my medical records may be looked at by responsible individual from (Company Name) or from regulatory authorities. I give permission for these individuals to have access to my records.

Date: _____ ____

Place:_____ Signature/Left thumb impression

This to certify that the above consent has been obtained in my presence.

Date: _____ _____

Place:_____ Signature of Principal Investigator

Witness 1 2. Witness 2

_____ _____

Signature Signature

Name:_____ Name:_____ Address:

Address: _____ _____

अखिऱ भारतीय आयुर्विज्ञान संस्थान जोधनुर,
राजस्थान सूचित सहमचत प्रनत्र

नररयोजना का शीषक: अल्ट्रासाउंड चनदेचशत द्विनीय इरेक्टर स्पाइना प्ऱेन ब्ऱॉक की एनाल्जेचसक प्रभावकाररता की तुऱना बनाम नारंनररक इंरावेनस मरीज चनयंत्रत मध्य-रेखिका स्टनोटॉमी के साथ काद्दडियक सजरी के रोचियों में एनाल्जेचसया: एक द्विगुण ऱेबऱ रैंडम कंरोऱ रायऱ

प्रधान अन्वेषक का नाम: डी.आर मनीष मोहन तेऱ। नंबर- 9496081960
रोिी / स्वयंसेवक नहिान संख्या:..
मैं.., एस /ओ या डी/ओ ....
आर / ओ..

अध्ययन का हिस्सा बनने के चऱए मेरी नूर्ण, स्वतंत्र, स्वैच्छिक सहमचत देें "
", खजस प्रक्रिया और प्रकृचत से मुझे अननी भाषा में अननी नूर्ण संतुष्टि के चऱए समझाया िया है। मैं नुष्टि करता हूं कि मुझे सवाऱ नूछने का अवसर चमऱा है।
मैं समझता हूं कि मेरी भािीदारी स्वैच्छिक है और बिना किसी कारण के किसी भी समय अध्ययन से बाहर चनकऱने के मेरे अचधकार से अवित हूं।

मैं समझता हूं कि मेरे और मेरे किसी भी मेडिकऱ ररकॉडि के बारे में एकत्रत जानकारी को (कंननी का नाम) या चनयामक अचधकाररयों के खजम्मेदार व्यक्ति द्वारा देखा जा सकता है। मैं इन व्यक्तियों को अनने ररकॉडि तक नहुंचने की अनुमचत देता हूं।
तारीख:

जिह: हस्ताक्षर / बाएं अंिूठे का चनशान

यह प्रमाखणत करने के चऱए कि मेरी उनखस्थचत में उनरोक्त सहमचत

प्राप्त हुई है। तारीख:

स्थान: प्रधान अन्वेषक का हस्ताक्षर

साक्षी 1 िवाह 2

हस्ताक्षर हस्ताक्षर

नाम नता: नाम नता:

PATIENT INFORMATION SHEET

1. Risks to the patients: No interventions or life-threatening procedure will be done.
2. Confidentiality: Your participation will be kept confidential. Your medical records will be treated with confidentiality and will be revealed only to doctors/ scientists involved in this study. The results of this study may be published in a scientific journal, but you will not be identified by name.
3. Provision of free treatment for research related injury. Not applicable.
4. Compensation of subjects for disability or death resulting from such injury: Not Applicable
5. Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would otherwise be entitled.
6. You have complete freedom to participate and to withdraw from research at any time without penalty or loss of benefits to which you would otherwise be entitled.
7. Your participation in the study is optional and voluntary.
8. The copy of the results of the investigations performed will be provided to you for your record.
9. You can withdraw from the project at any time, and this will not affect your subsequent medical treatment or relationship with the treating physician.
10. Any additional expense for the project, other than your regular expenses, will not be charged from you.

रोगी सूचना पत्र

1. रोगियों को जोखिम: कोई हस्तक्षेप या जीवन-धमकी की प्रक्रिया नहीं की जाएगी।

2. गोपनीयता: आपकी भागीदारी को गोपनीय रखा जाएगा। आपके मेडिकल रिकॉर्ड को गोपनीयता के साथ माना जाएगा और इस अध्ययन में शामिल डॉक्टरों / वैज्ञानिकों के लिए ही पता लिखेगा। इस अध्ययन के परिणाम एक वैज्ञानिक पत्रिका में प्रकाशित हो सकते हैं, लेकिन आपको नाम से नहीं पहिचाना जाएगा।

3. अनुसंधान से संबंधित चोट के लिए मुफ्त उपचार का प्रावधान। लागू नहीं।

4. ऐसी चोट के परिणामस्वरूप दुर्घटनाग्रस्त या मृत्यु के लिए विषयों का मुआवजा: लागू नहीं

5. भाग लेने या लाभ के नुकसान के बिना किसी भी समय अनुसंधान से बाहर हटने की स्वतंत्रता, खासकर वर्तमान अन्यथा हकदार होगा।

6. आपको किसी भी समय दंड या लाभ के नुकसान के बिना भाग लेने और अनुसंधान से बाहर हटने की पूरी स्वतंत्रता है, जिसके आप अन्यथा हकदार होंगे।

7. अध्ययन में आपकी भागीदारी वैकल्पिक और स्वैच्छिक है।

8. आपके द्वारा दर्ज की गई जांच के परिणामों की प्रतिलिपि आपको प्रदान की जाएगी।

9. आप किसी भी समय परियोजना से हट सकते हैं, और यह आपके बाद के चिकित्सा उपचार या उपचार चिकित्सक के साथ संबंध को प्रभावित नहीं करेगा।

10. परियोजना के लिए कोई अतिरिक्त शुल्क आपके द्वारा किए गए अध्ययन के अलावा, आपसे कोई शुल्क नहीं

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CASE RECORD FORM

Name:_____ **Age:**_____years **Sex:** M/F

Height:_____cm **Weight:**_____kg **ASA Status:** I / II / III

Registration No: AIIMS/JDH/_____ **Date of Admission:** _____

Diagnosis:_____ **Date of Operation:** _____

Patient group:_____

Surgical Procedure:__ **Duration of Surgery:**_____

Baseline Vitals: HR-_____bpm; **MAP-**_____mmHg SpO_2-____% **RR-**____/min

Intraoperative Analgesic: Fentanyl-_____mcg; **Paracetamol**-_____gm Time to perform block (from beginning of scanning)

Time for extubation :_____**hrs**

	Vas score at rest	**Vas score on cough**	**Peak inspiratory flow rate(cc)**
On extubation			
4 hr			
8 hr			
12 hr			
16 hr			
20 hr			
24 hr			

PCA pump: Total opioid consumed:

Bolus doses: Attempted:_____ Administered:_____

Number of Rescue Analgesia required (Diclofenac):

SATISFACTION SCORE (at 24 hours post operatively)

1-Excellent 2-Good 3-Fair 4-Poor

Side Effects (Y/N)

Drowsiness :_____ PONV:_____Itching:_____

Respiratory Depression:_____

procedure related
complication ,if any:_____

Post operative pulmonary complications:_____