# EFFICACY OF CONTINUOUS ERECTOR SPINAE PLANE BLOCK VERSUS INTRAVENOUS PATIENT CONTROLLED ANALGESIA FOLLOWING SPINE SURGERY: AN OPEN LABEL RCT

**THESIS**

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## DOCTOR OF MEDICINE (MD)

## ANAESTHESIOLOGY AND CRITICAL CARE

**JUNE, 2022** **DR PRIYADARSAN A M**

**AIIMS, JODHPUR**

# DECLARATION

I hereby declare that the thesis titled **"Efficacy of continuous erector spinae plane block versus intravenous patient-controlled analgesia following spine surgery: An open label RCT"** 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 **"Efficacy of continuous erector spinae plane block versus intravenous patient-controlled analgesia following spine surgery: An open label RCT"** is the bonafide work of **DR PRIYADARSAN A M** 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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# CERTIFICATE

This is to certify that the thesis titled **"Efficacy of continuous erector spinae plane block versus intravenous patient-controlled analgesia following spine surgery: An open label RCT"** is the bonafide work of **Dr Priyadarsan A M** carried out at Department of Anaesthesiology and Critical Care, All India Institute of Medical Sciences, Jodhpur.

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"*The ignorant work for their own profit, the wise work for the welfare of the world, without thought for themselves"*

(*Bhagavad Gita)*

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**Dr Priyadarsan A M**

*Dedicated to my Patients,*

*Parents, Teachers*

*&*

*my Family…*

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# LIST OF ABBREVIATIONS

| Abbreviation | Full Form |
|---|---|
| ASA | American Society of Anesthesiologists |
| BMI | Body Mass Index |
| ESP | Erector Spinae Plane |
| ERAS | Enhanced Recovery After Surgery |
| GA | General Anaesthesia |
| HR | Heart Rate |
| IV | Intravenous |
| IQR | InterQuartile Range |
| LOS | Length of in Hospital Stay |
| MEC | Minimum Effective Concentration |
| PCA | Patient controlled analgesia |
| PACU | Post Anaesthesia Care Unit |
| RA | Regional Anaesthesia |
| SD | Standard Deviation |
| ugm | Microgram |
| VRS | Verbal rating scale |
| VAS | Visual Analog Scale |

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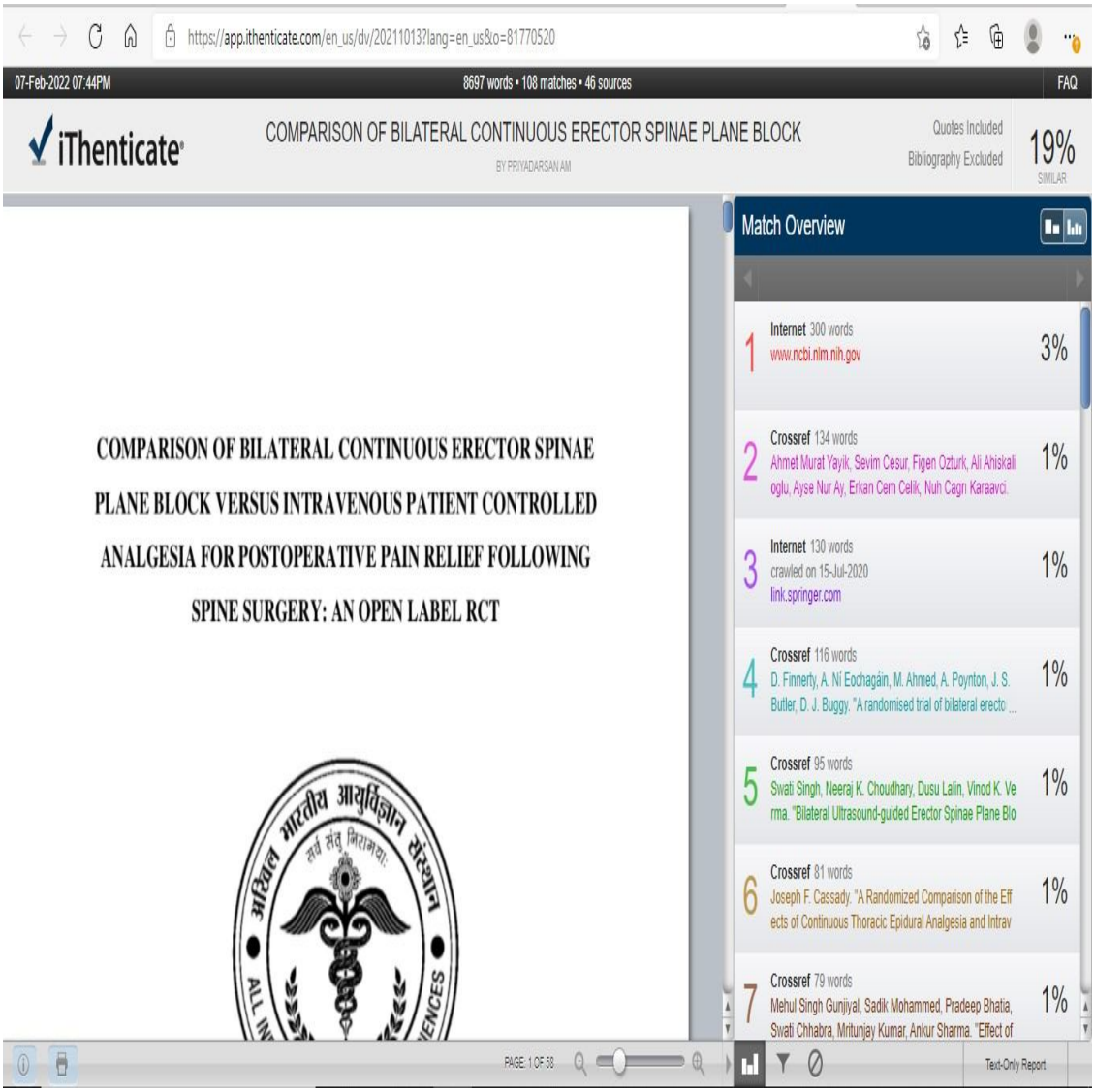
# PLAGIARISM CHECK CERTIFICATE

Plagiarism check was done on ithenticate. All the sections except references and review of literature were checked for plagiarism.



# SUMMARY

**Background:** Patients undergoing spine surgery experience intense and severe pain in the postoperative period. Multimodal pain management protocols including the available pharmacological options have demonstrated improved pain control with less reliance on opioids. Use of regional anaesthesia (RA) techniques as a component of multimodal pain protocol could replace opioid-based analgesia and is one of the cornerstones of the Enhanced Recovery After Surgery (ERAS). Recently, the erector spinae plane (ESP) block has been introduced in clinical practice as part of a multimodal pain strategy. The present study was carried out to compare ESP block and opioid based Intravenous (IV) patient-controlled analgesia (PCA) following multilevel spine surgery.

**Material and Methods:** A total 54 patients of either sex, aged between 18-65 years, belonging to American Society of Anesthesiologists (ASA) physical status I or II and scheduled for elective multiple level spine surgery were enrolled. Using a computer-generated random number table, patients were randomly allocated to either group ESP (n=27) or group PCA (n=27). Allocation concealment was done using sequentially numbered coded sealed opaque envelopes that were opened on the day of surgery. After completion of the surgery, while the patient was still in the prone position, ultrasound guided bilateral continuous ESP block was performed in patients who were allocated to group ESP. In the Post Anaesthesia Care Unit (PACU), all patients were given fentanyl based IV PCA pumps. For patients in group PCA, the background infusion rate was kept at 1 µg/kg/hr with a bolus dose of 0.5 µg/kg and lockout interval of 30 min. In Group ESP, a bolus dose of 0.5 µg/kg with a lockout interval of 30 min was set without background infusion. In both the group visual analogue scale

(VAS) scores were recorded at every hour in the PACU and then at every 3 h till 24 h in the ward. Rescue analgesia IV Diclofenac 75 mg was administered on patient demand or whenever VAS ≥ 4 were recorded. The primary outcome of the study was comparison of VAS between the groups. The secondary outcomes were comparison of total opioid consumption, number of rescue analgesics used and satisfaction score.

**Results:** The VAS scores at rest and during movement were significantly better in group ESP compared to group PCA both during PACU stay as well as in the ward at all predefined time points. The median (IQR) (range) total opioid [fentanyl (µg)] consumed over 24 h was significantly lower in patients receiving ESP block [48 (0, 80) (0 – 170)] compared to those maintained on IV PCA [1750 (1375, 1990) (80 – 2240)]. Twenty (74.07%) patients in group ESP did not require rescue analgesia while in group PCA, 14 (51.85%) required rescue analgesia in the form of diclofenac 75 mg. The total rescue analgesia doses consumed in group ESP was eight while group PCA it was twenty-six. None of the patients in the group ESP had block related adverse events while a significant proportion of patients in the group PCA experienced opioid related side effects.

**Conclusion:** Continuous ESP block is a safer and more effective alternative to opioid based analgesia as a component of multimodal pain management for patients undergoing multilevel spine surgery.

# INTRODUCTION

Pain from the back originates from different tissues such as vertebrae, intervertebral discs, ligaments, dura, nerve root sleeves, facet joint capsules, fascia, and muscles. Innervation of these structures is via the posterior rami of spinal nerves connected to sympathetic and parasympathetic nerves. The ventral motor root and the dorsal sensory root unite to form the spinal nerve that subdivides as it exits the intervertebral canal, into anterior primary ramus and posterior primary ramus. The posterior ramus runs around the facet joints and gives branches supplying ligaments, joints, and all the segmental spinal muscles in addition to providing for the cutaneous supply over the back from the vertex to the coccyx.[1]

Many surgical procedures on the spine are often associated with intense pain in the immediate and early postoperative period. Current treatment modalities rely heavily on opioid analgesics with all the inherent limitations and side effects. While current best practice focuses on a 'multimodal approach' (i.e. using multiple drugs and techniques to control pain after surgery), there is no consensus regarding which components of this multimodal therapy provide optimal analgesia.[2]

Regional anaesthesia (RA) techniques which include both neuraxial and peripheral nerve block can play a significant role in multimodal analgesia.[3,4] Although use of both neuraxial techniques (epidural and intrathecal) have been described with promising results, the descriptions of use of peripheral nerve block in spine surgery are sparse.[5-7] The erector spinae plane (ESP) block technique was first described for thoracic and abdominal analgesia via its action on the ventral rami of spinal nerves.[8,9] There is increasing evidence that it also anesthetizes the dorsal rami, which innervate the paraspinal muscles and vertebrae.[10] In this study, we planned to evaluate the efficacy of ESP block for decreasing postoperative opioid consumption after multilevel thoracolumbar spine surgery. We hypothesized that bilateral continuous ESP blocks would be a safer and effective alternative to opioid based IV PCA for postoperative pain control in patients undergoing multilevel spine surgery.

# AIMS AND OBJECTIVES

The aim of our study was to determine the safety and efficacy of ESP block for providing postoperative analgesia after multilevel thoracolumbar spine surgery as compared to IV fentanyl based PCA.

*Primary outcome measure*

- To compare postoperative Visual Analog Scale (VAS) pain score during the first 24-h after spine surgery.

*Secondary outcome measure*

- To compare total opioid consumed during the first 24-h after spine surgery.
- To compare postoperative total rescue analgesia consumed during the first 24-h after spine surgery.
- To compare the side effects of both techniques.
- To compare patient satisfaction scores of both techniques.

# REVIEW OF LITERATURE

Major spine surgery is acknowledged to be associated with moderate to severe postoperative pain. A prospective cohort study of patients undergoing spinal surgery reported median verbal response scale (VRS) pain scores ranging from 5 to 7 on the first postoperative day.[11] Severe postoperative pain is associated with considerable morbidity, prolonged length of in-hospital stays (LOS), increased opiate requirements and prolonged time to mobilisation.

Currently, opiate therapy is the primary treatment option for patients suffering acute postoperative pain after major spine surgery. Adverse events associated with high opioid requirements postoperatively are well documented and include nausea, constipation, respiratory depression, lower respiratory tract infections and drug dependency. Multimodal pain regimens, such as described by Dietz et al. in their guidelines of enhanced recovery after surgery in spine surgery, are based on different pathways to reduce pain.[12] Length of stay for lumbar spine fusion surgery has been reduced dramatically by enhanced recovery after surgery (ERAS)-protocols in the last decade. A retrospective study found a reduction from 6.7 days in 2012–2013 to 4.8 days in 2016–2017 for posterior lumbar spine fusion.[13] Furthermore, compliance to early mobilization protocols is hampered by uncontrolled pain.[14] By optimizing our pain protocol, we have significantly reduced the LOS. In addition to the improvement of patient care, this also results in reduced hospital costs and higher hospital bed capacity.

Pain from the back originates from different tissues such as vertebrae, intervertebral discs, ligaments, dura, nerve root sleeves, facet joint capsules, fascia, and muscles. Innervation of these structures is via the posterior rami of spinal nerves connected to sympathetic and parasympathetic nerves. The ventral motor root and the dorsal sensory root unite to form the spinal nerve that subdivides as it exits the intervertebral canal, into anterior primary ramus and posterior primary ramus (Figure-1). The posterior ramus runs around the facet joints and gives branches supplying ligaments, joints, and all the segmental spinal muscles in addition to providing for the cutaneous supply over the back from the vertex to the coccyx.

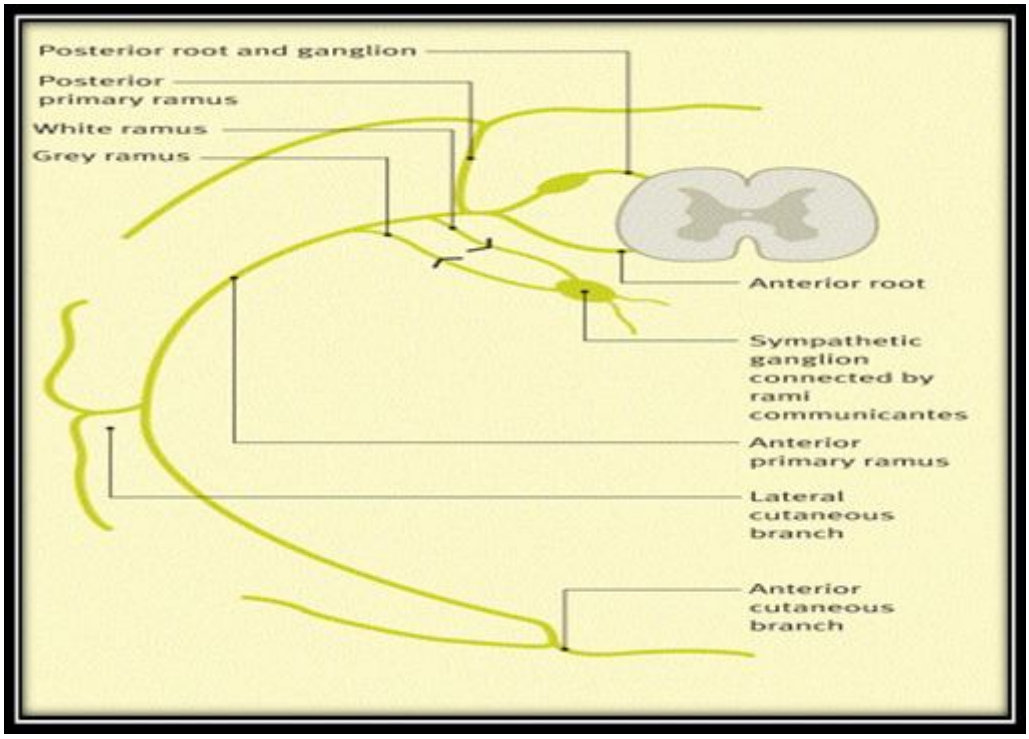



**Figure-1:** The arrangement of a typical spinal nerve.

The ESP block, first described by Forero in 2016 for the treatment of thoracic neuropathic pain, involves depositing local anaesthesia under ultrasound guidance on the transverse process of the thoracic vertebrae, deep to the erector spinae muscle complex.[15] Cadaveric and MRI studies suggest that ESP can block the posterior rami of the spinal nerves in addition to the anterior spinal nerve rami to the paravertebral and epidural spaces, although this seems less consistent (Figure-2).[16-18] The posterior ramus of the spinal nerves provides sensory innervation of the paraspinal muscles, soft tissue and skin at the level at which it emerges.[19] This is of particular relevance in spinal surgery, because these structures must be incised and retracted in order to gain appropriate surgical exposure. Recent case reports suggest a positive effect of an ESP block on pain for multiple indications including vertebral metastases, lumbar transverse process fractures or following lumbar spine fusion and scoliosis surgery.[20-23] Available evidence to date suggests the ESP block may have opioid-sparing properties.[10,24,25] making it an attractive option in spine surgery that merits further investigation.

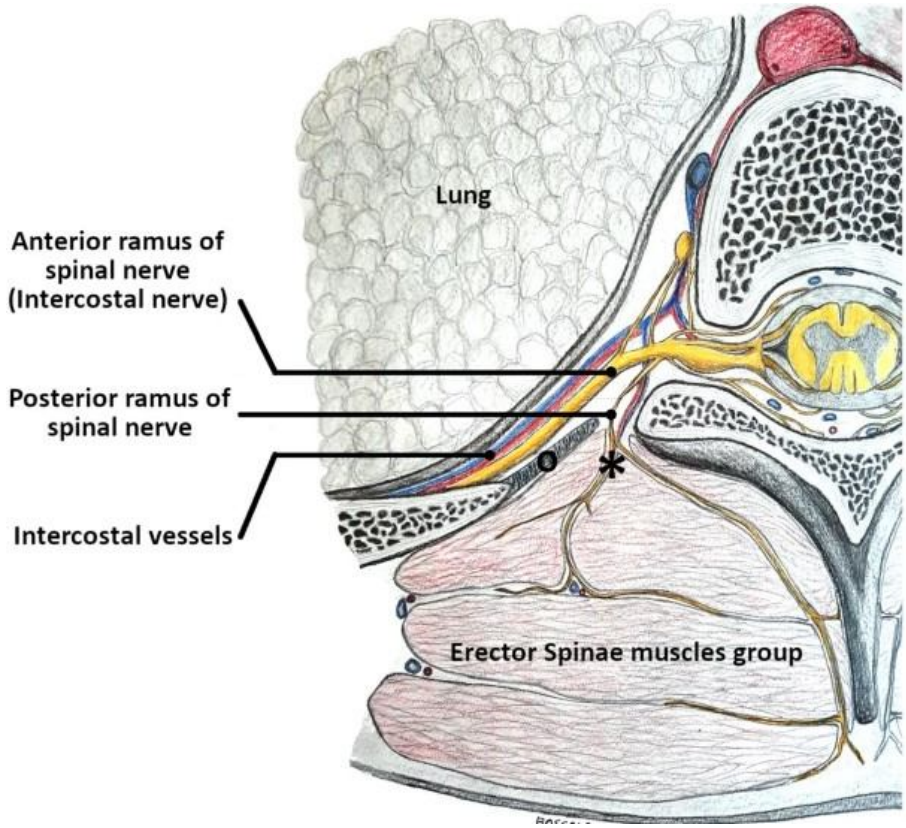



**Figure-2:** Anatomical basis for ESP block.

An ESP block has a very low risk of complications, as sonoanatomy is easily recognizable and there are no structures in close proximity at risk of needle injury.[26] The transverse process acts as an anatomical barrier and avoids needle insertion into the pleura or vessels, thus preventing a pneumothorax or hematoma. Moreover, the needle is relatively far from the vertebral canal, which means the risk of spinal cord injury is very low. An ESP block preserves bladder function and motor neuron function enabling early mobilization. Since motor function is unaltered, immediate postoperative neurological evaluation of spinal cord function is possible.

**Patient controlled analgesia**

Patient-Controlled Analgesia (PCA) has been utilized to optimize pain relief since 1971, with the first commercially available PCA pump appearing in 1976. The goal of PCA is to efficiently deliver pain relief at a patient's preferred dose and schedule by allowing them to administer a predetermined bolus dose of medication on-demand at the press of a button. Each bolus can be administered alone or coupled with a background infusion of medication. PCA is used to treat acute, chronic,

postoperative, and labour pain.[27] These medications can be administered intravenously, epidurally, through a peripheral nerve catheter, or transdermally.[28,29] Drugs commonly administered are opioids and local anaesthetics, but dissociatives or other analgesics are also options. PCA has proven to be more effective at pain control than non-patient opioid injections and results in higher patient satisfaction.[30]

Modalities for PCA administration include intravenous lines, central lines, epidural catheters, peripheral nerve catheters, or transdermal delivery systems. Any peripheral vein can be used to insert a catheter and begin the administration of PCA. Central lines placed in the internal jugular, subclavian, or femoral veins.[31]

The administration of PCA requires the selection of route, medication, and type of pump to be used:

*Routes*

The route for PCA administration can be through an intravenous catheter, epidural catheter, indwelling nerve catheter, or an iontophoretic transdermal system. The equipment and procedure for the placement of these devices appear in the articles for those specific modalities.

*Pumps*

There are a variety of PCA pumps in the market, and all contain the essential components of a locking device, medication chamber, programming screen, and patient button. A provider inserts a syringe of medication into the pump and programs the pump to the prescribed initial loading dose, PCA dose, lockout interval, continuous infusion rate, and one and four-hour limits. For intravenous PCA, the medication line then gets connected to a fluid infusion line. Opioid medications include pure Mu opioid receptor agonists (morphine, fentanyl, hydromorphone, meperidine, sufentanil, alfentanil, and remifentanil) Mu opioid receptor agonist-antagonists (butorphanol, nalbuphine, pentazocine) and partial Mu opioid receptor agonists (buprenorphine, dezocine). Despite a variety of medication options, morphine remains the gold standard medication for intravenous PCA. [32,33]

Local anaesthetics are primarily used for epidural catheter and indwelling nerve catheter PCA. They include the sodium channel blockers (bupivacaine, levobupivacaine, and ropivacaine).

**Technique:**

PCA dosing contains a variety of variables, including the initial loading dose, bolus or demand dose, lockout interval, continuous infusion rate, and one and four-hour limits. The initial loading dose can be titrated by a nurse to reach the minimum effective concentration (MEC) of the desired medication. The bolus or demand dose is the dose of medication delivered each time the patient presses the button. A lockout interval is the time after a demand dose in which a dose of medication will not get administered even if the patient presses the button; this is done to prevent overdosing. A continuous infusion rate can be used in the background of PCA dosing to maintain the MEC of the medication independent of patient demands. One and four-hour limits put a cap on the maximum allowed amount of medication to be administered within those time periods and are usually less than the dose given if the patient were to press the dosing button at every possible interval. This mechanism allows for an added safety benefit and can notify the nurse and provider that the patient's pain is not under adequate control with the prescribed medication and dosing parameters.

Complications of epidural and indwelling nerve catheter PCA include infection, catheter dislodgement, medication leakage, skin irritation, allergic reaction, and short and long term nerve damage. [34,35] They can also include complications resulting from incorrect placement of the catheter such as intravascular, intrapleural, intraneural, and intrathecal placement.

Side effects of PCA administration can be related to the medications or the delivery device used and include nausea and vomiting, constipation, urinary retention, pruritus, respiratory depression, and local anesthetic toxicity.[36,37]

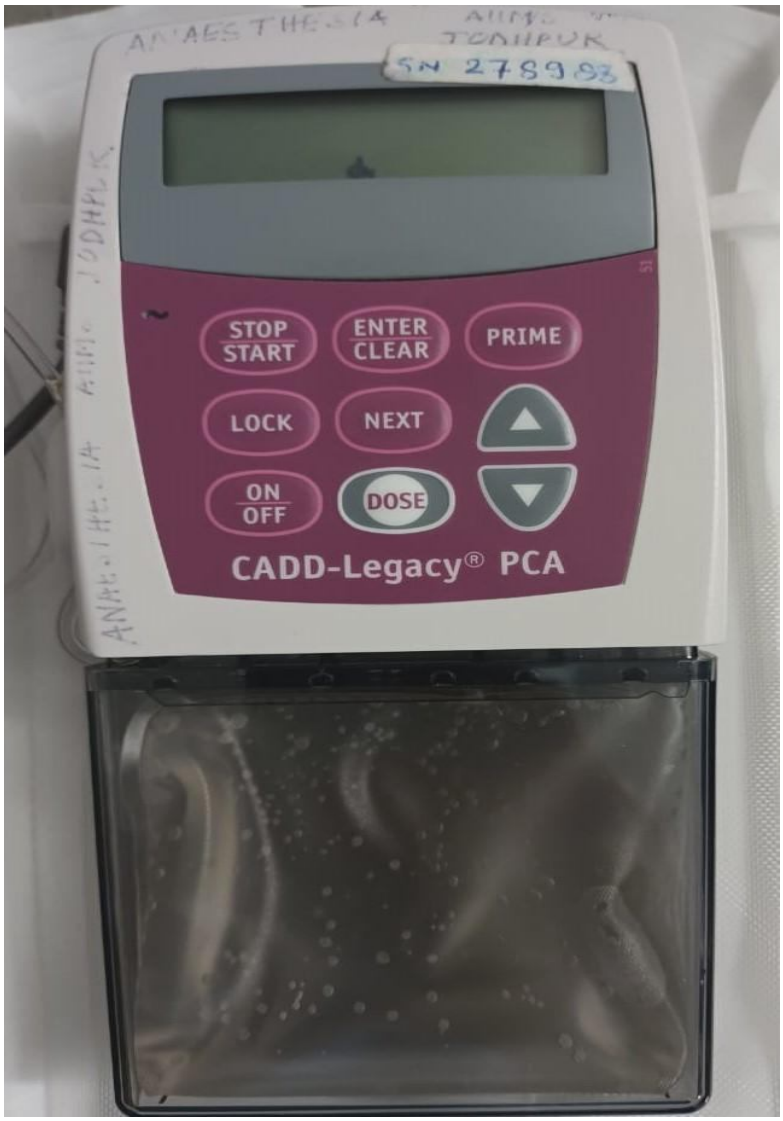



**Figure-3:** Image showing CADD pump (Patient-controlled analgesia)

**Vipin Kumar Goel** et al.[38] assessed the efficacy of ultrasound guided ESP block with conventional (opioid based) multimodal for postoperative analgesia in 100 patients undergoing single level lumbar spinal fusion surgery. The Numerical Rating Scale (NRS) pain score was used for assessing pain in the postoperative period until 24-h. Their results showed that total opioid consumption for 24-h following induction and intraoperative blood loss was significantly lower in the block group ($p<0.001$). The NRS pain score in the control group was higher in the first 48-h following surgery. The satisfaction score was significantly higher in the block group (<0.001). They conclude that US-ESP block for single-level lumbar fusion surgery is an effective component of multimodal analgesia for reducing blood loss, total opioid

consumption and related side effects with a significant reduction of postoperative pain and higher patient satisfaction.

**Qingfen Zhang** et al.[39] conducted a randomised study to assess whether bilateral ultrasound- guided ESP block could alleviate postoperative pain in patients undergoing lumbar spinal fusion in 60 patients. The primary outcome was pain intensity at rest within 12-h postoperatively using the NRS. Their results showed significantly lower pain scores at rest at 4-h after surgery (95% confidence interval [CI] -2.4 to -0.8, $p<0.001$), at 8-h (95%CI -1.9 to – 0.6), $p<0.001$) and at 12-h (95%CI -1.3 to -0.1, $p=0.023$). The ESP block group also showed significantly lower pain scores on movement at 4-h after surgery (95% CI –2.5 to -0.6). A significantly smaller proportion of patients required sufentanil within 12-h following surgery ($p = 0.020$) in the block group and they concluded that bilateral US-ESP block improves postoperative analgesia in patients undergoing lumbar spinal fusion.

**Swati Singh** et al.[24] conducted a study to compare the effect of US-ESP on 24-h postoperative cumulative opioid requirements with standard (opioid based) analgesia. Both groups received standard general anaesthesia during surgery. The primary outcome was the 24-h postoperative cumulative opioid requirements. Postoperative morphine consumption was significantly lower in patients in the ESP group ($p<0.001$). All patients in the control group required supplemental morphine compared with only 9 (45%) in the ESP block group ($P=0.002$). They concluded that US-guided ESP block reduces postoperative opioid requirement and improves patient satisfaction compared with standard analgesia in lumbar spine surgery patients.

**Jing- Jing Zhang** et al.[40] conducted a randomised controlled study to assess whether bilateral ultrasound- guided ESP block at a lower thoracic level could improve pain control and quality of recovery in 60 patients undergoing lumbar spine surgery. Their results showed in ESP block group, the duration to the first PCIA bolus was significantly longer than that in the control group [8.0 (4.5, 17) vs 1 (0.5, 6), $p<0.01$], resting and coughing NRS scores at 48-h post operative were significantly lower than those in the control group ($p<0.05$) while Sufentanil consumption during operation was significantly lower in the ESP block group than in the control group ($p<0.01$), while there was no significant difference between the two groups regarding morphine consumption at 24-h or 48-h post operative. They concluded that ultrasound

guided ESPB at a lower thoracic level improves the analgesic effect, reduces opioid consumption and improves postoperative recovery in patients undergoing lumbar spine surgery.

**Ahmed Murat yayik** et al.[41] conducted a randomised study to investigate the effect of the ESP block on postoperative opioid consumption and pain scores in 60 patients undergoing open lumbar decompression surgery. The primary outcome was the VAS at various time points until the 24-h postoperative period. The results showed that the VAS scores were statistically lower in the ESP group during all measurements of time, both at rest and active movement ($P < 0.05$). Tramadol consumption was lower in the ESP group compared with the control group at all the time periods ($p<0.05$) and the difference was 28%. The time to first analgesic requirement was significantly longer in the ESP group than in the control group. They concluded that ESP block can be used in multimodal analgesia practice to reduce opioid consumption and relieve acute postoperative pain in patients undergoing open lumbar decompression surgery.

**Yanwu jin** et al.[42] conducted a study to investigate the analgesic effects of ESP block in lumbar laminoplasty. In a randomised double blinded study 62 patients were enrolled. Of these, 32 received only general anaesthesia [G group], whereas the other 18 patients received the ESP block in addition to general anaesthesia (E group). The primary outcome was postoperative pain scores for the first 48-h after surgery. Their results showed significant differences in pain scores over time were found between the two groups ($p=0.010$) with group E patients having significantly lower pain scores than group G during the first six h ($p=0.000$). The opioid consumption in group G was significantly lower than in group E both intraoperatively ($p=0.000$) and postoperatively (0.005). Group E patients had lower intraoperative sevoflurane requirement, improved satisfaction with pain management and earlier return of bowel function than Group G patients. They concluded that ESP block is effective in reducing postoperative pain scores and lowering opioid utilisation (both intraoperatively and postoperatively), resulting in improved patient satisfaction for pain management in lumbar laminoplasty.

**Yulong yu** et al.[43] conducted a randomised study to investigate the postoperative analgesic efficacy of ultrasound-guided lumbar ESP blocks in 80

patients undergoing posterior lumbar spinal surgery for lumbar spinal fractures. Their results showed that NRS at rest and during movement at 6, 12 and 24 h was lower in the ESP-PCA group ($p<0.001$, $p<0.001$, $p=0.0016$ at rest; all $p<0.001$ during movement). Lumbar ESP blocks diminished accumulative bolus presses of PCA at 6,12,24 and 48 h postoperatively. The incidence of postoperative nausea and vomiting in the ESP-PCA group was lower than that in the PCA group. They concluded that PCA combined with Lumbar ESP blocks provided superior postoperative analgesia for patients with lumbar spinal fractures treated with posterior internal fixation and also, they concluded that Lumbar ESP blocks decreased postoperative opioid consumption and incidence of postoperative nausea and vomiting.

**Renee j c van de Broek** et al.[44] conducted a retrospective case-control study in 40 patients undergoing posterior lumbar interbody fusion surgery. Postoperative pain scores in the PACU were lower in patients who received an ESP block ($p = 0.041$). Opioid consumption during surgery and in the PACU was not significantly different. Need for patient-controlled analgesia postoperatively was significantly lower in the group receiving an ESP block ($p = 0.010$). Length of stay in hospital was reduced from 3.23 days (IQR 1.1) in the control group to 2.74 days (IQR 1.6) in the study group ($p = 0.012$). They conclude that the ESP blocks reduces analgesic consumption in posterior lumbar interbody fusion surgery.

**Hadi Ufuk Yorukoglu** et al.[45] conducted a study to determine the effect of ESP block on postoperative analgesia in 54 patients who underwent elective lumbar disc herniation repair surgeries. All the patients were provided with IV-PCA devices containing morphine. The primary outcome was total opioid consumption. Total morphine consumption at 24-h after surgery decreased by 57% ($11.3 \pm 9.5$ mg in the ESP group and $27 \pm 16.7$ mg in the control group). They concluded that ESP block provided effective analgesia in patients who underwent lumbar disc herniation surgery.

**Teng Jiao Zhang** et al.[46] conducted a randomised study in 60 patients to determine the effectiveness of pre-operative ESP block in enhancing recovery of posterior lumbar surgery. MOAA/S scores at 10 minutes after extubation were 4.2 (95% CI, 4.0 to 4.4), and 3.4 (95% CI, 3.2 to 3.6) ($P <0.001$) respectively. They

concluded that bilateral ESP block at T12 can enhance recovery after posterior lumbar surgery and reduce perioperative opioid consumption.

**D Finnerty** et al.[47] conducted a study to test the efficacy and safety of bilateral ESP block on quality of recovery and pain after thoracolumbar decompression in 60 patients. ESP block reduced mean (SD) area under the curve pain during the first 24 postoperative h: at rest, from 78 (49) to 50 (39), p = 0.018; and on sitting, from 125 (51) to 91 (50), p = 0.009. The cumulative mean (SD) oxycodone consumption to 24-h was 27 (18) mg in the control group and 19 (26) mg after block, p = 0.20. They concluded that ESP block improved recovery and provided analgesia for 24-h after thoracolumbar decompression surgery.

# MATERIAL AND METHODS

The present study was carried out in the department of Anaesthesiology and Critical Care at AIIMS, Jodhpur after getting approval from institutional ethics committee [Institutional Ethics Committee, All India Institute of Medical Sciences, Jodhpur 342005 (Raj.); Certificate Reference Number: AIIMS/IEC/2019-20/998 dated 01/01/2020; approved by Dr Parveen Sharma] and informed written consent from patients. We registered the study prospectively at the clinical trial registry of India (CTRI: www.ctri.nic.in) (Ref. No. CTRI/2020/01/030711, Date of Registration: 15/01/2020, Patient Enrolment date: 01/02/2020).

A total 54 patients of either sex, aged between 18-65years, belonging to American Society of Anesthesiologists (ASA) physical status I or II and scheduled for elective multiple level thoracolumbar spine surgery were enrolled. Patients who refused to participate, pregnant females, patients with baseline cognitive deficits sufficient to make objective pain assessment unreliable, coagulopathy, liver and renal dysfunction, preoperative neurological deficits, opium addict and allergy to amide LAs or opioids were excluded.

During preoperative visit, patient's particulars and baseline vital parameters were recorded. Detailed history, general physical and systemic examinations were done. Routine laboratory investigations such as haemoglobin, bleeding time, and clotting time were carried out for all patients. All patients were kept fasting as per institutional protocol (2 h for clear liquid and 6 h for semisolid and solid). All patients were prescribed tablet alprazolam 0.25 mg PO night before and in the morning of surgery.

Using a computer-generated random number table, patients were randomly allocated to either group ESP (n=27) or group PCA (n=27). Allocation concealment was done using sequentially numbered coded sealed opaque envelopes that were opened on the day of surgery. Blinding of the patients, investigator and observer was not possible because of the intervention selected.

On arrival of patients in the operation room, ASA standard monitors were attached and baseline parameters including heart rate (HR), blood pressure (BP), peripheral oxygen saturation ($SpO_2$), and respiratory rate (RR) were recorded.

Intravenous (IV) line was secured with 18 or 20 G cannula and maintenance IV fluid (Ringer Lactate) was started at the rate of 10ml/kg/hr. Premedication with IV midazolam 0.03 mg/kg and IV fentanyl 2 µg/kg was administered 10 min before induction. Induction was performed using standard technique in all the patients with IV propofol 2-2.5 mg/kg. After abolition of eyelash reflex tracheal intubation was facilitated using IV rocuronium 0.6 mg/kg. Anaesthesia was maintained with inhaled isoflurane (1 to 2 vol%) in oxygen and air mixture. Intraoperative analgesia was maintained by intermittent boluses of IV fentanyl 1 µg/kg repeated every hour and IV paracetamol 1gm (30 min prior to end of surgery). After completion of the surgery, while the patient was still in the prone position, ultrasound guided bilateral continuous ESP block was performed in patients who were allocated to group ESP. The level at which the block was performed was either one vertebral segment above or below the surgical incision. After securing the catheter patients were made supine and the trachea was extubated after complete recovery from anaesthesia. All the blocks were performed by a single experienced anaesthetist having more than five-year experience in the field of regional anaesthesia.

***ESP block technique***

Portable ultrasound device ("LOGIQ e", GE Healthcare, Chicago, United States) fitted with a linear high frequency (13-8 MHz) probe was used for performing ultrasound guided bilateral ESP block using the technique by Mauricio Forero and colleagues.[8] While the patient was in prone position, ultrasound transducer was placed in a longitudinal orientation on the spinous process one vertebral level above or below the surgical incision. The transducer then slowly moved to the lateral direction and all muscles were identified superficial to the hyperechoic transverse process shadow. A 10 cm, 22- gauge block needle (Stimuplex; B Braun Medical, Bethlehem, Pa) was inserted in the direction of incision until the tip crosses the interfascial plane between muscles, and reached the transverse process, evidenced by visible linear spread of fluid between transverse process and muscle upon injection. A total of 0.4 ml/kg of 0.2% ropivacaine was injected, followed by catheter insertion 4 cm distal to needle tip. After bilateral catheter insertion, infusion (0.2% ropivacaine) at 5 ml/h on both sides using separate infusion pumps was continued in the post-operative period for the next 24-h.

In the PACU, VAS score was recorded and all patients were given fentanyl IV PCA pumps (CADD-Legacy® PCA, Model 6300, Smith Medical ASD, Inc., St. Paul, MN 55112, USA). For patients in group PCA, the background infusion rate was kept at 1 µg/kg/h with a bolus dose of 0.5 µg/kg and lockout interval of 30 min. In Group ESP, there was no background infusion and a bolus dose of 0.5 µg/kg with a lockout interval of 30 min was set. All patients in both groups received IV paracetamol 1 gm every 6-h. In both the groups, VAS scores were recorded at every hour in the PACU and then at every 3-h till 24-h in the ward. Rescue analgesia IV Diclofenac 75 mg was administered on patient demand or whenever VAS $\geq$ 4 were recorded. At the end of the observation period the total opioid consumed and the total rescue analgesia required was recorded. Side effects during the observation period like drowsiness, respiratory depression, postoperative nausea vomiting, itching, urinary retention etc. were recorded. Patient satisfaction was recorded on a four-point Likert scale as 1- excellent; 2- good; 3- fair and 4- poor.

***Statistical analysis***

A non-blinded randomized study was designed to compare ESP and IV PCA. Our primary outcome was to compare analgesic effectiveness i.e. differences in mean VAS pain scores, upon which the sample size calculation was based. Data from previous studies indicate that a reasonable assumption for the standard deviation of VAS pain scores is 1.93 cm. Based on a 2-tailed analysis, it is estimated that 27 patients per treatment group would be required to provide 80% power of detecting a statistically significant difference ($P < .05$), assuming that a clinically important treatment difference between VAS scores is 1.5 cm.

Data collected during the study was compiled using Microsoft Excel spreadsheets. 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 (IQR) (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 analyse continuous and categorical data respectively. Quantitative variables with non-normal distribution and ordinal variables were analysed using Mann-Whitney test. P value <0.05 was considered as significant.

# RESULTS

Total seventy-two patients were assessed for eligibility out of them eighteen were excluded (11 not meeting inclusion criteria and 07 refused to participate) and remaining fifty-four patients were randomised into two groups based on computer generated randomization sequence. Twenty-seven patients were enrolled in group 'ESP' and the remaining twenty-seven patients in group 'PCA'. There was no loss to follow up and data from all the patients randomized were analyzed (Figure-4)

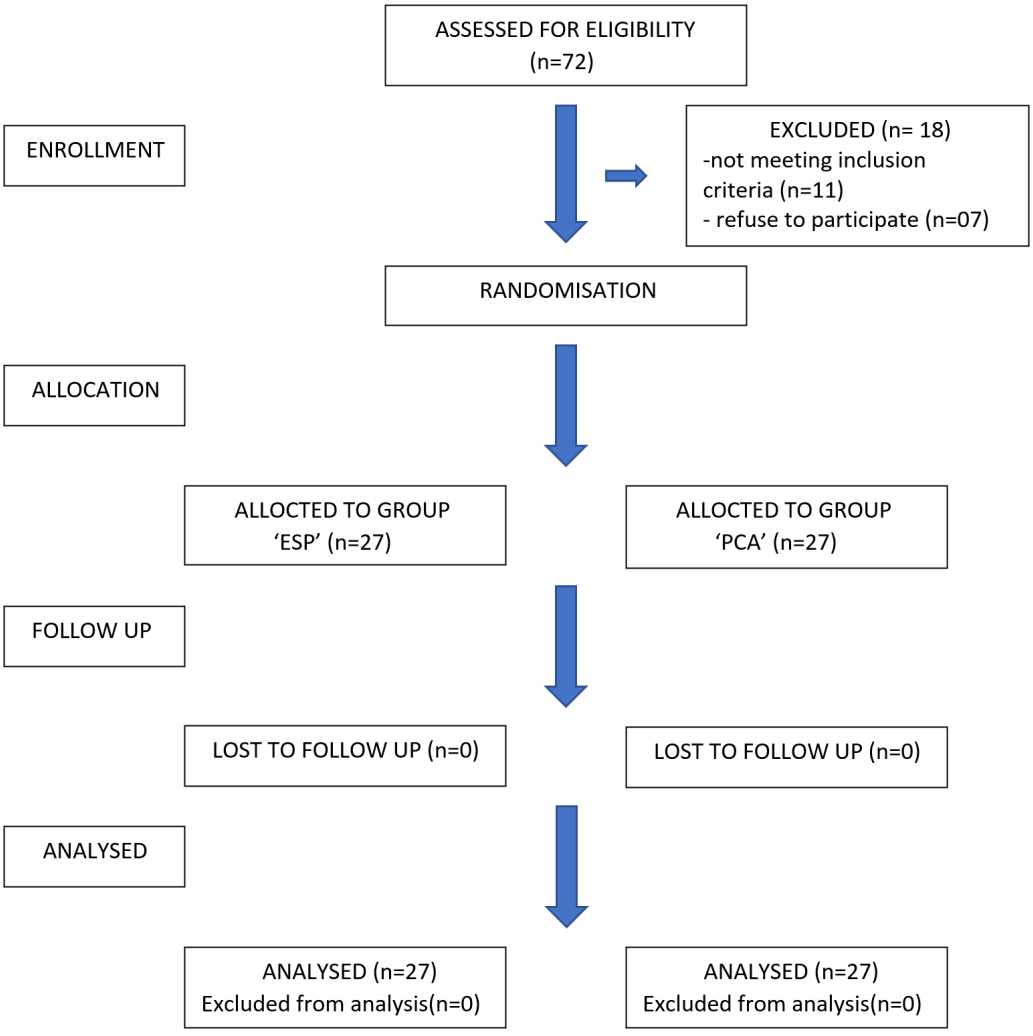



**Figure-4**: Consort Flow Diagram

**TABLE 1:** Distribution of patients in different age groups and comparison of mean age between the study groups.

| Age (yrs) | Group ESP N (%) | Group PCA N (%) | Mean Difference (95% CI) | p-value |
|---|---|---|---|---|
| 21-30 | 2 (7.41) | 6 (22.22) | - | - |
| 31-40 | 11 (40.74) | 8 (29.63) | | |
| 41-50 | 4 (14.81) | 6 (22.22) | | |
| 51-60 | 7 (25.93) | 7 (25.93) | | |
| ≥61 | 3 (11.11) | 0 (0) | | |
| Mean±SD | 44.77±11.11 | 40.11±10.84 | 4.67 (-1.33 to 10.66) | 0.12 |

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 both groups were belonging to the age group 31 to 40 years. The mean±SD of age in group ESP and group PCA was 44.77±11.11 and 40.11±10.84 respectively. The unpaired Student's t-test was used to compare the age between the study groups which showed a mean difference (95% CI) of 4.67 (-1.33 to 10.66) between groups with corresponding p-value of 0.12 which was statistically non-significant i.e. both the study groups were comparable with respect to the age.

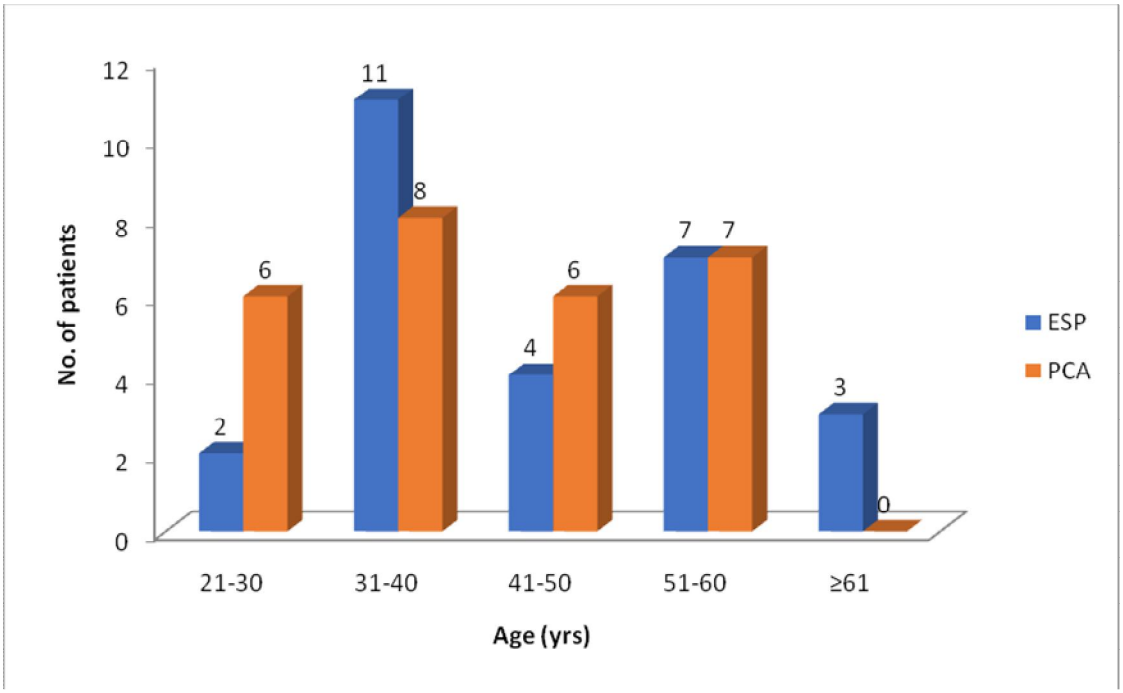



**Figure-5:** Distribution of patients in different age groups.

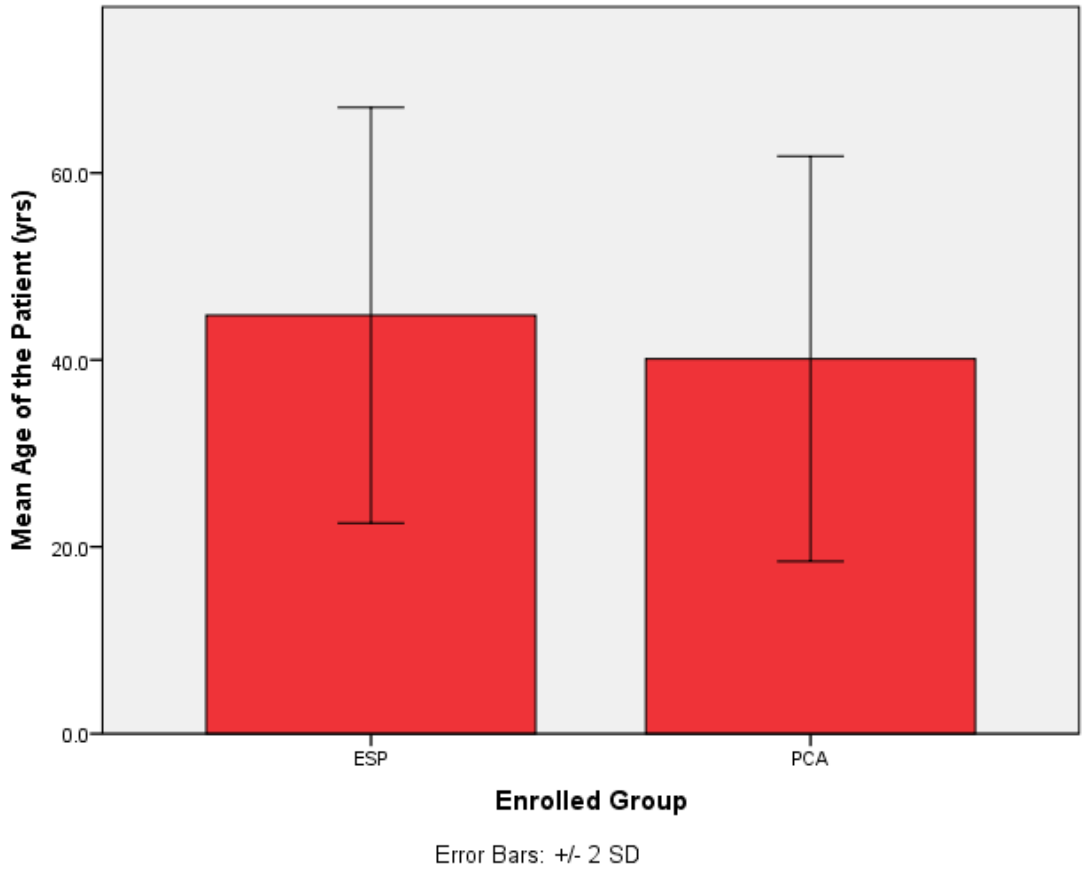



**Figure-6:** Comparison of mean±SD age between the study groups.

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

| Gender | Group ESP N (%) | Group PCA N (%) | $\chi^2$; p-value |
|---|---|---|---|
| Male | 15 (55.56) | 17 (62.96) | 0.307; 0.58 |
| Female | 12 (44.44) | 10 (37.04) | |
| Total | 27 (100) | 27 (100) | |

The above table shows the distribution of patients according to gender between the study groups. Total 32 patients belonged to Male gender, out of them 15 patients were randomly allocated in group ESP and 17 patients in group PCA. Remaining 22 patients belonged to Female gender, out of which, 12 patients were randomly enrolled in group ESP and 10 patients in group PCA. The chi-square statistic was applied to compare gender between the study groups which showed a $\chi^2$ value of 0.307. The corresponding p-value was 0.58 considered to be non- significant i.e. both the study groups were comparable with respect to the gender of the patients.

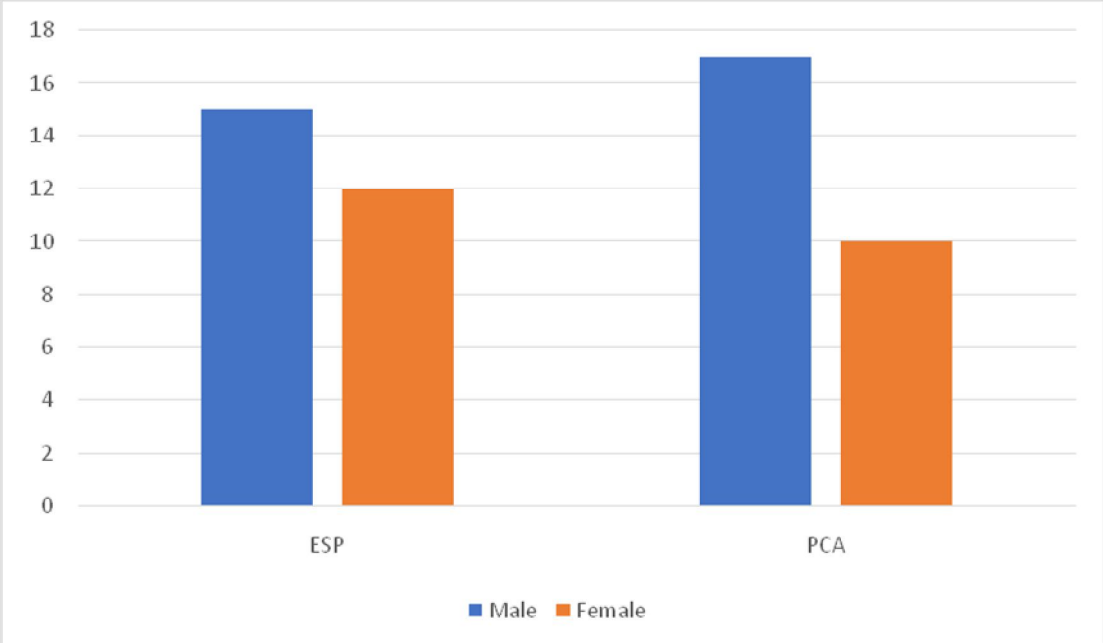



**Figure-7:** Distribution of patients according to gender between the study groups.

**TABLE 3:** Distribution of patients in different height groups and comparison of mean height between the study groups.

| Height (cm) | Group ESP N (%) | Group PCA N (%) | Mean Difference (95% CI) | p-value |
|---|---|---|---|---|
| 150-160 | 8 (29.63) | 8 (29.63) | - | - |
| 161-170 | 12 (44.44) | 12 (44.44) | | |
| ≥171 | 7 (25.93) | 7 (25.93) | | |
| Mean± SD | 164.59±7.86 | 165.37±6.85 | -0.8 (-4.8 To 3.2) | 0.70 |

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 group ESP and group PCA was 164.59±7.86 and 165.37±6.85 respectively. The unpaired Student's t-test was used to compare the height between the study groups which showed a mean difference (95% CI) of -0.8 (-4.8 to 3.2) between groups with corresponding p value of 0.70 which was statistically non-significant i.e. both the study groups were comparable with respect to the height.

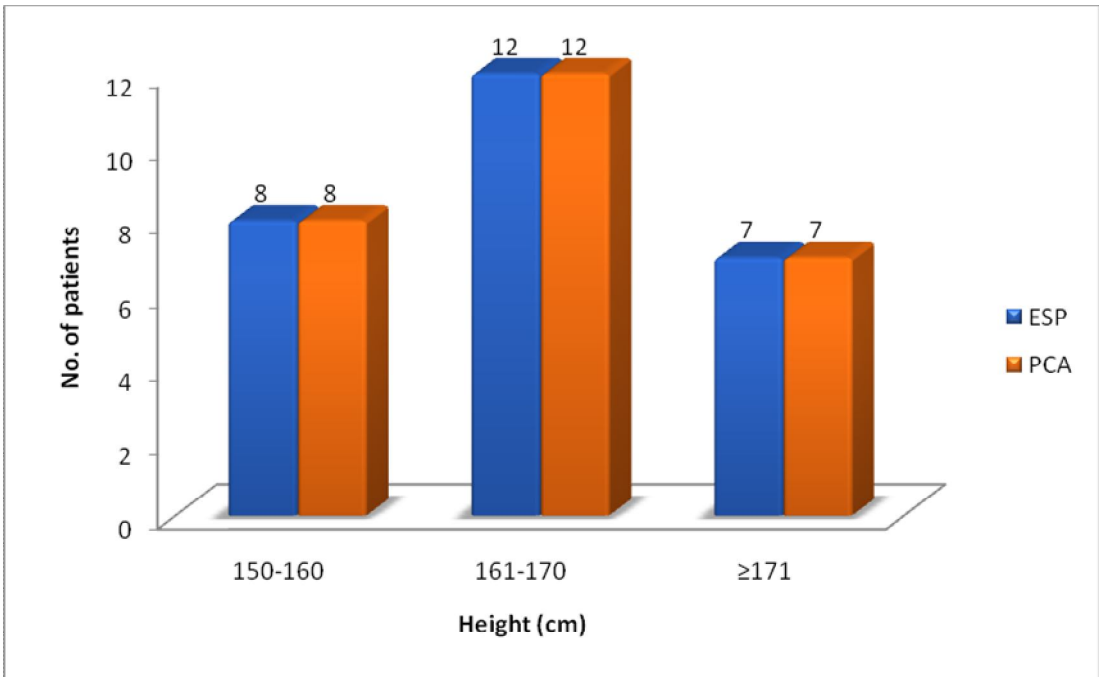



**Figure-8:** Distribution of patients in different height groups.

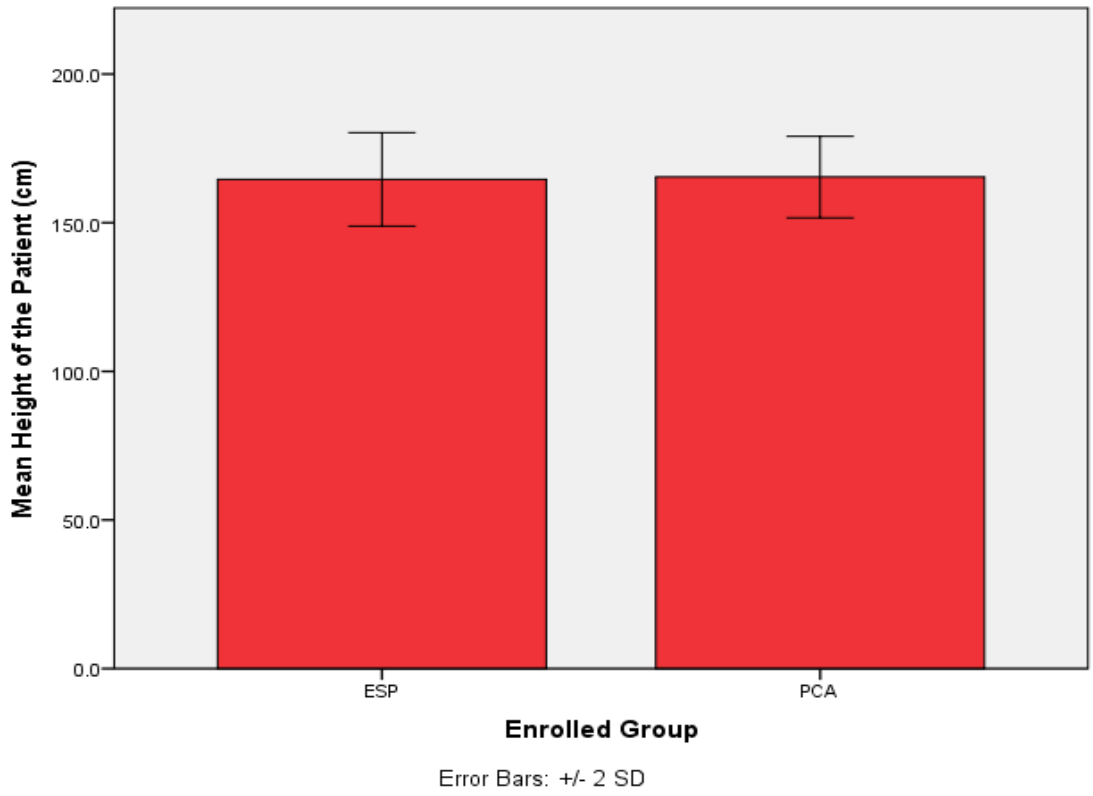



**Figure-9:** Comparison of mean±SD height between the study groups.

**TABLE 4:** Distribution of patients in different weight groups and comparison of weight between the study groups.

| Weight (kg) | Group ESP N (%) | Group PCA N (%) | Mean Difference (95% CI) | p-value |
|---|---|---|---|---|
| 48-60 | 9 (33.33) | 11 (40.74) | - | - |
| 61-70 | 8 (29.63) | 4 (14.81) | | |
| 71-80 | 7 (25.93) | 10 (37.04) | | |
| ≥81 | 3 (11.11) | 2 (7.41) | | |
| Mean±SD | 67.44±11.00 | 65.40±11.48 | 2.03 (-4.1 To 8.1) | 0.51 |

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 48 to 60 kg weight group. The mean±SD of weight in group ESP and group PCA was 67.44±11.0 and 65.40±11.48 respectively. The unpaired Student's t-test was used to compare the height between the study groups which showed a mean difference (95% CI) of 2.03 (-4.1 to 8.1) between groups with corresponding p value of 0.51 which was statistically non-significant i.e. both the study groups were comparable with respect to the weight.

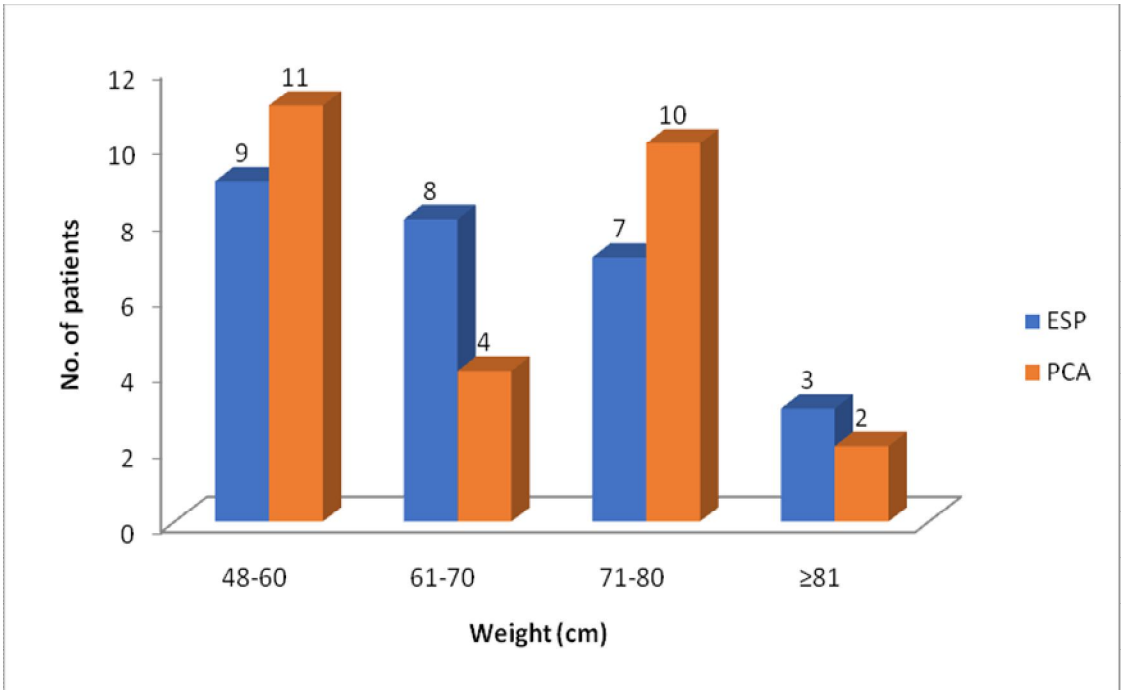



**Figure-10:** Distribution of patients in different Weight groups.

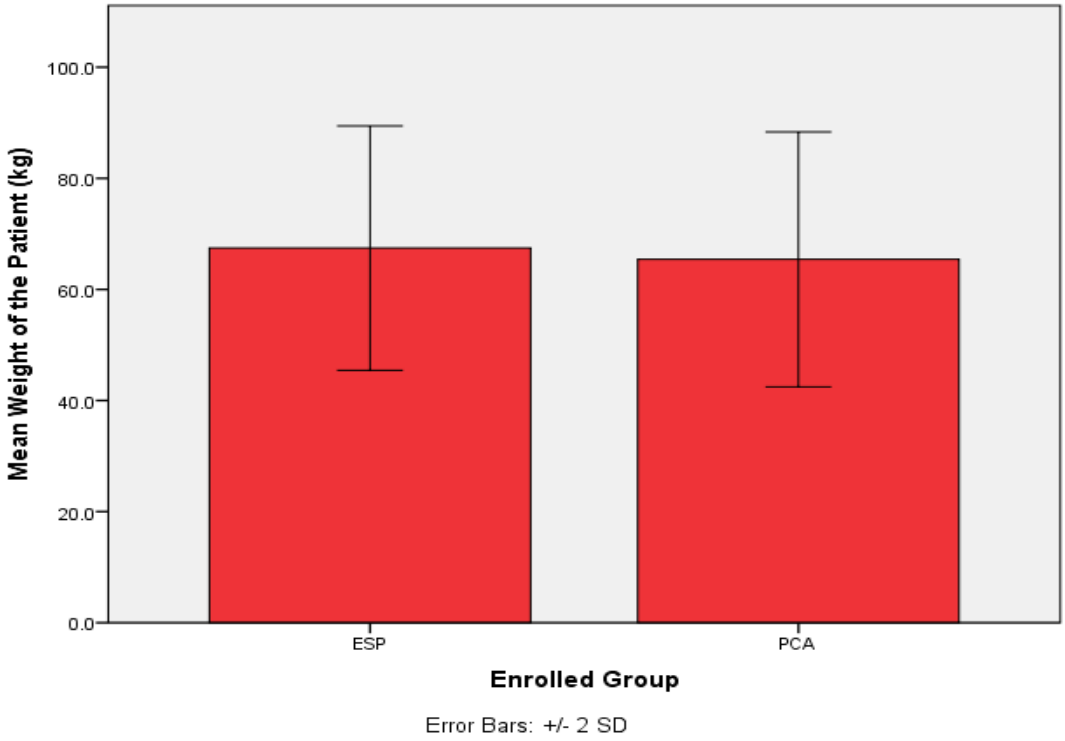



**Figure-11:** Comparison of mean±SD Weight between the study groups.

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

| BMI ($kg/m^2$) | Group ESP N (%) | Group PCA N (%) | Mean Difference (95% CI) | p-value |
|---|---|---|---|---|
| <18.5 | 0 (0.00) | 1 (3.70) | - | - |
| 18.5-24.9 | 14 (51.85) | 14 (51.85) | | |
| 25-29.9 | 12 (44.44) | 12 (44.44) | | |
| ≥30 | 1 (3.70) | 0 (0.00) | | |
| Mean±SD | 24.77±2.76 | 23.80±3.15 | 0.97 (-0.65 to 2.59) | 0.235 |

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 group i.e. BMI between 18.5 to 24.99. The mean±SD of BMI in group ESP and group PCA was 24.77±2.76 and 23.80±3.15 respectively. The Student's t-test was used to compare BMI between groups which showed a mean difference (95% CI) 0.97 (-0.65 to 2.59) with corresponding p value of 0.235 which was statistically significant i.e. both the study groups were not comparable with respect to the BMI.

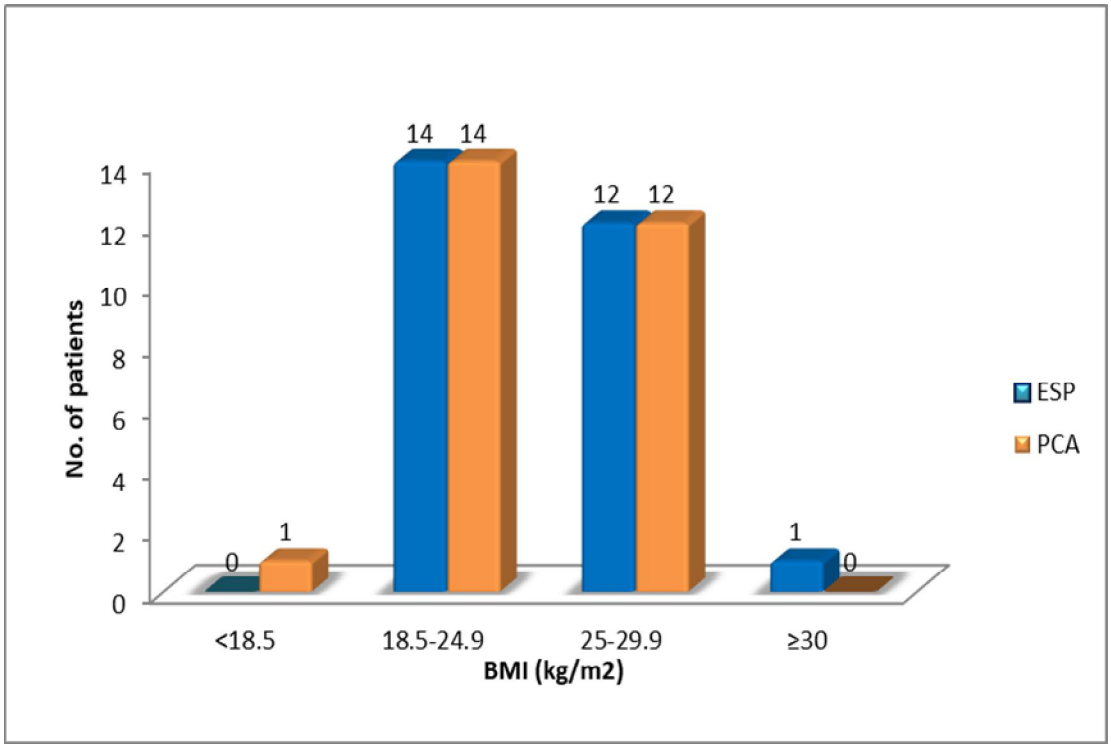



**Figure-12:** Distribution of patients in different BMI groups.

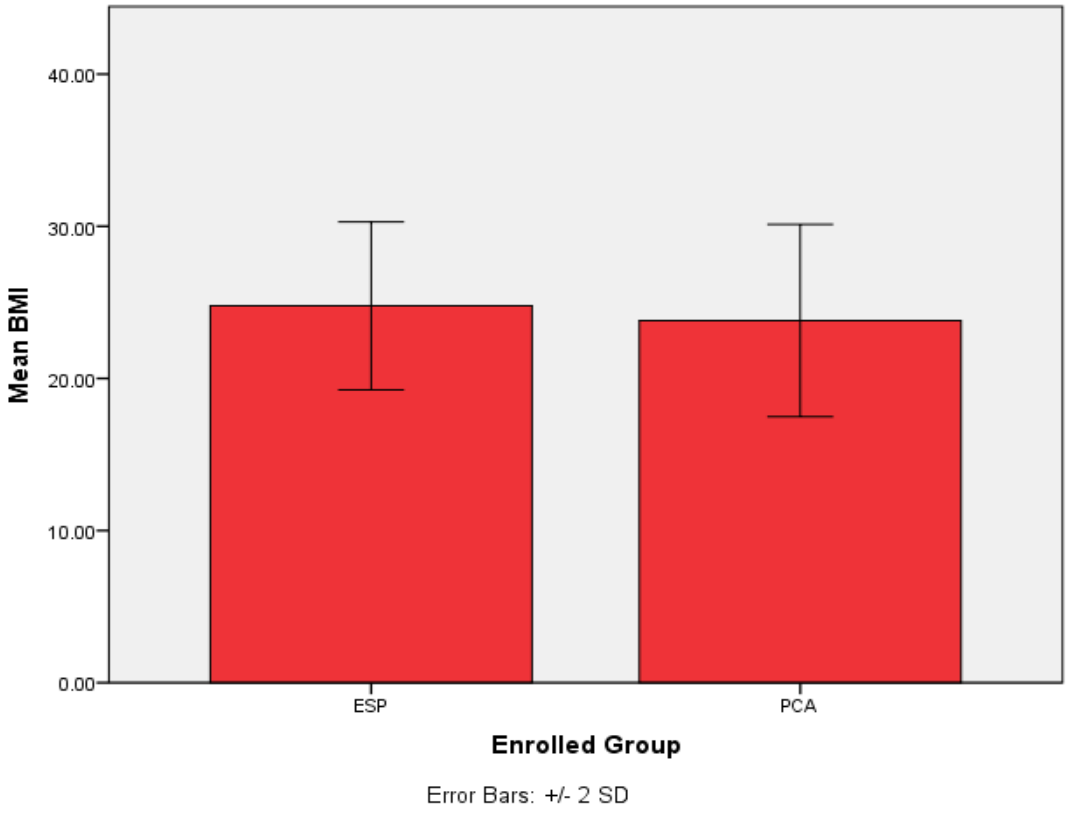



**Figure-13:** Comparison of mean±SD BMI between the study groups.

**TABLE 6:** Distribution of patients in different ASA groups and comparison of ASA grades between the study groups.

| ASA | Group ESP N (%) | Group PCA N (%) | p-value |
|---|---|---|---|
| I | 23 (85.19) | 24 (88.89) | 0.69 |
| II | 4 (14.81) | 3 (11.11) | |
| Total | 27 (100) | 27 (100) | |

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 I or II. Total 47 patients belonged to class I, out of which, 23 patients were randomly enrolled in group ESP and 24 patients in group PCA. Seven patients belonged to class II, out of them, 4 patients were randomly enrolled in group ESP and 3 patients in group PCA. The Mann-Whitney U test was used to compare the ASA physical status between groups which showed a statistical value of 351 with a corresponding p value of 0.69 which was statistically non-significant i.e. both the study groups were comparable with respect to the ASA physical status class.

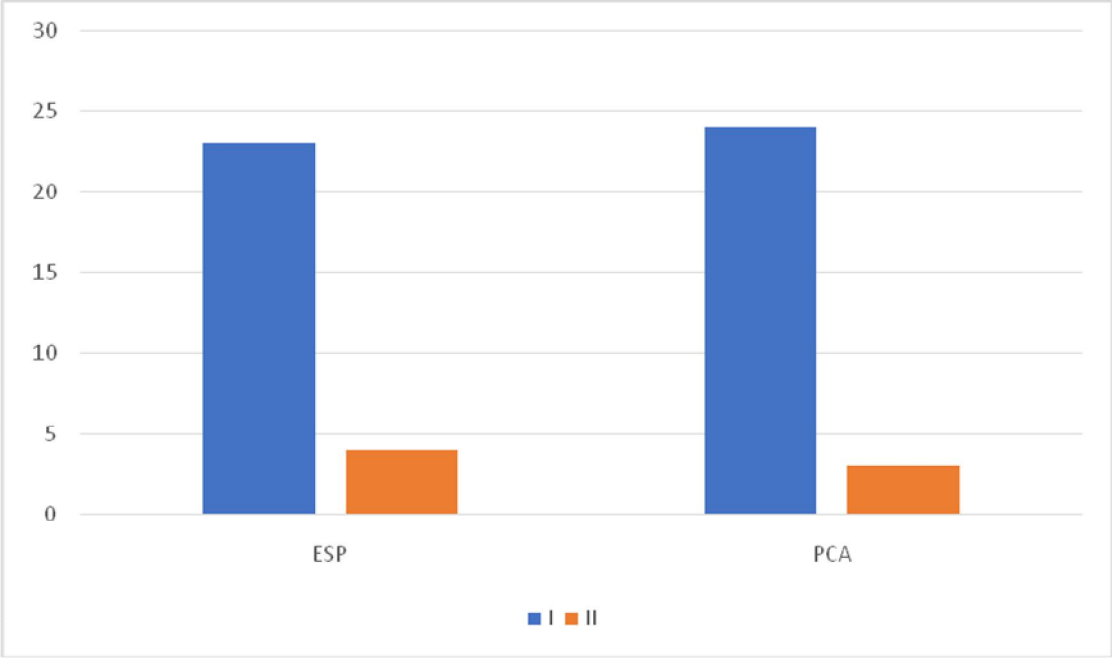



**Figure-14:** Distribution of patients in different ASA physical status classes.

**TABLE 7:** Distribution of patients according to different surgical duration and comparison of mean duration of surgery between the study groups.

| Duration of surgery (hrs) | Group ESP N (%) | Group PCA N (%) | Difference (95% CI) | p-value |
|---|---|---|---|---|
| ≤3 | 1 (3.70) | 2 (7.41) | - | - |
| 4-5 | 21 (77.78) | 15 (55.56) | | |
| 6-7 | 5 (18.52) | 10 (37.04) | | |
| Median (IQR) (range) | 5 (4, 5) (3-7) | 5 (4, 6) (3-7) | 0 (-0.7 to 0.4) | 0.5 |

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 4-5 h in both the groups. The median (IQR) (range) duration of surgery (h) in group ESP and group PCA was 5 (4, 5) (3–7) and 5 (4, 6) (3–7) respectively. The Mann-Whitney U test was used to compare the duration of surgery between the study groups which showed a statistical value of 327 with a corresponding p- value of 0.5, which was statistically non-significant, i.e. both the study groups were comparable with respect to the duration of surgery.

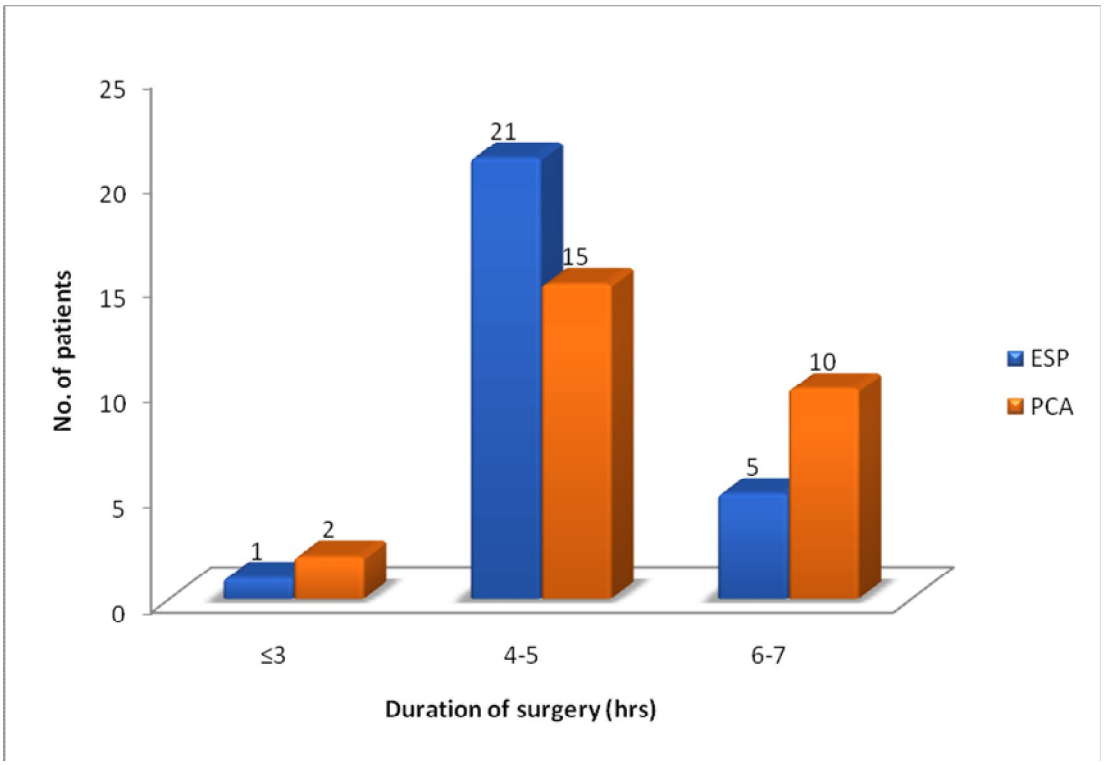



**Figure-15:** Distribution of patients in different groups based on surgical duration.

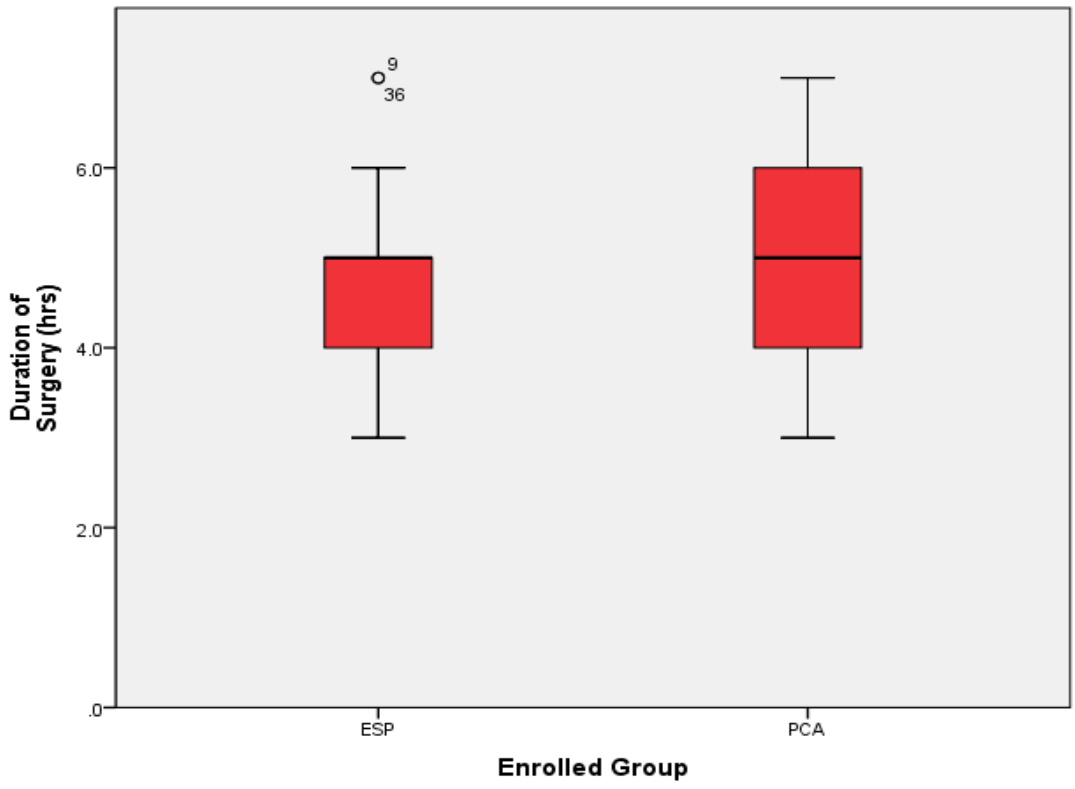



**Figure-16:** Box plot for comparison of duration of surgery between the study groups.

**TABLE 8:** Comparison of Region of surgery, surgical procedure and vertebral level involved between the study groups.

| Surgical Characteristics | | Group ESP N (%) | Group PCA N (%) | p-value |
|---|---|---|---|---|
| Region of Surgery | Lumbar region surgery | 15 (55.55) | 10 (37.04) | 0.17 |
| | Thoracic region surgery | 12 (44.45) | 17 (62.96) | |
| Surgical Procedure | Laminectomy with screw fixation | 13 (48.15) | 15 (55.56) | 0.59 |
| | Laminectomy without screw fixation | 14 (51.85) | 12 (44.44) | |
| Vertebral Level involved | 2 vertebral level | 12 (44.44) | 13 (48.15) | 0.54 |
| | >2 vertebral | 18 (66.67) | 14 (51.85) | |

The above table shows comparison of surgical procedure characteristics (region of the spine involved, vertebral level involved and procedure performed) between the study groups. The chi square test was applied for comparison which showed a p value of 0.17, 0.59 and 0.54 respectively which were statistically non-significant, i.e. both the study groups were comparable with respect to the surgical procedure characteristics.

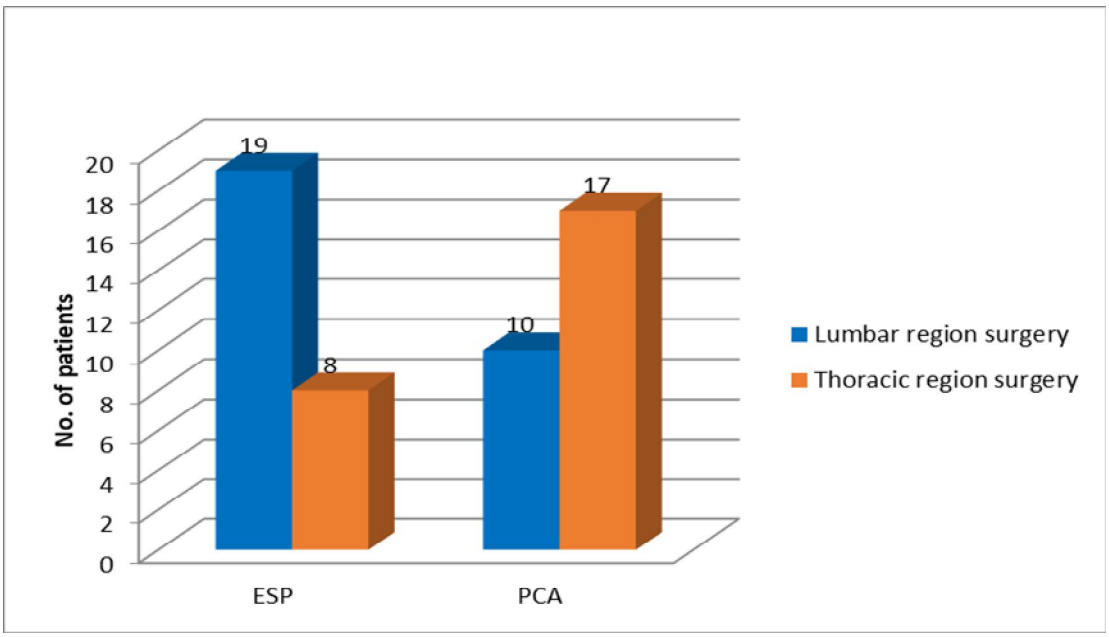



**Figure-17:** Distribution of patients in different study groups based on region of surgery

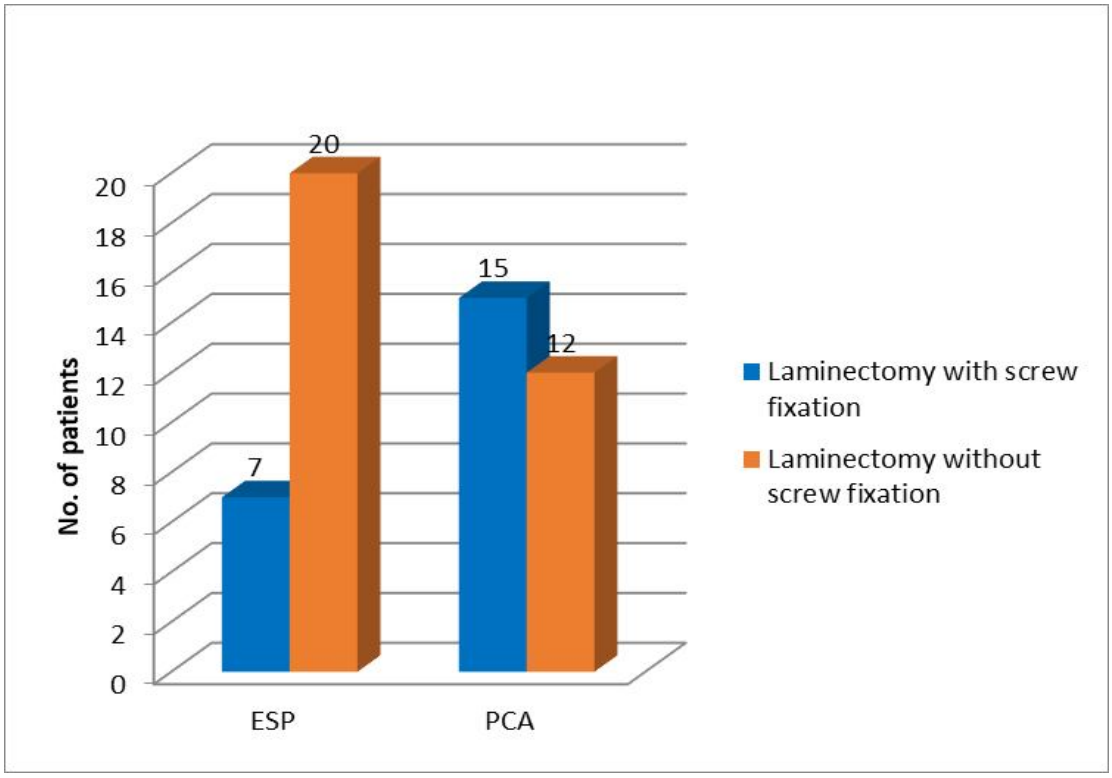



**Figure-18:** Distribution of patients in different study groups based on surgical procedure.

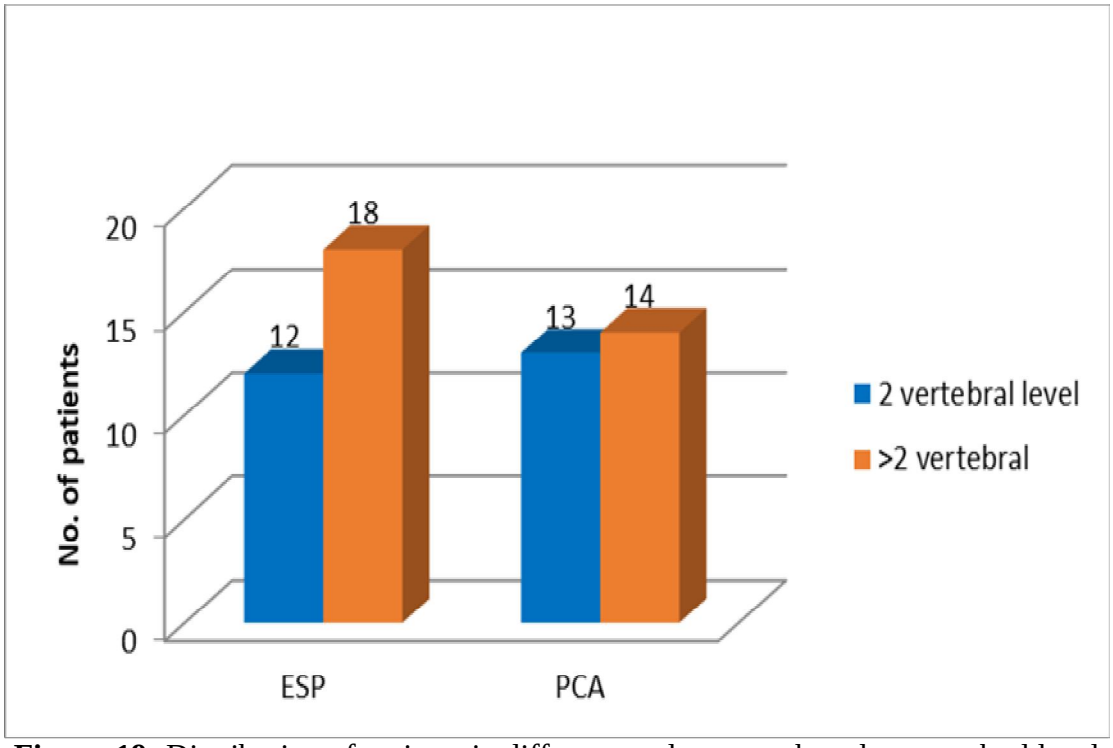



**Figure-19:** Distribution of patients in different study groups based on vertebral level involved

**TABLE 9:** Comparison of Baseline vitals heart rate, mean arterial pressure, oxygen saturation, respiratory rate between the study groups

| Baseline vitals | Group ESP | Group PCA | Difference (95% (CI) | p-value |
|---|---|---|---|---|
| HR (bpm) (Mean±SD) | 78.30±7.04 | 80.40±10.41 | -1.709 (-6.5 to 3.1) | 0.48 |
| MAP (mmHg) (Mean±SD) | 91.44±8.18 | 89.33±9.28 | 2.11 (-2.67 to 6.89) | 0.38 |
| $SpO_2$ (%) [Median (IQR) (Range)] | 100 (99, 100) (98-100) | 100 (99, 100) (99-100) | 0 (-0.28 to 0.28) | 0.85 |
| RR (per minute) [Median (IQR) (Range)] | 15 (14, 16) (13-18) | 15 (15, 16) (13-18) | 0 (-0.8 to 0.5) | 0.7 |

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 78.30±7.04 and 91.44±8.18 and group PCA was 80.40±10.41 and 89.33±9.28 respectively. The Student's t-test was used to compare the mean HR and MAP between the study groups which showed a p value of 0.48 and 0.38 respectively. The [median (IQR) (range)] of $SpO_2$ and RR in group ESP was 100 (99, 100) (98 -100) and 15 (14, 16) (13–18) and group PCA was 100 (99, 100) (99-100) and 15 (15, 16) (13–18) respectively. The Mann Whitney U test was used to compare the $SpO_2$ and RR between the study group which showed a p value of 0.85 and 0.7 respectively which was statistically non-significant.

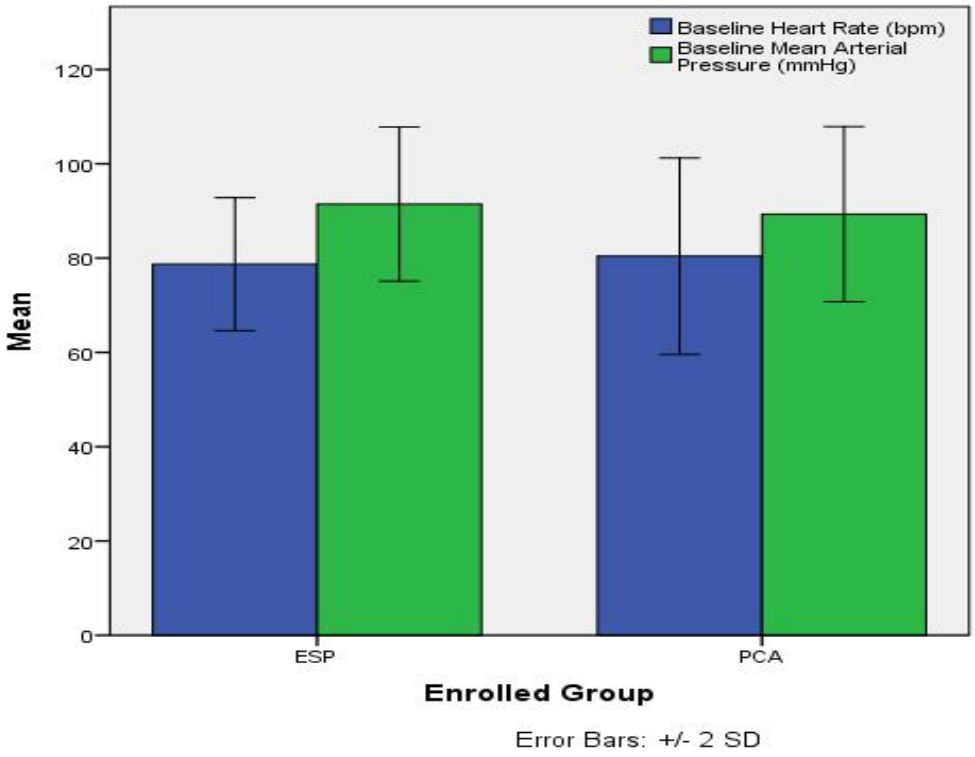



**Figure-20:** Comparison of mean (SD) baseline HR and MAP between the study groups.

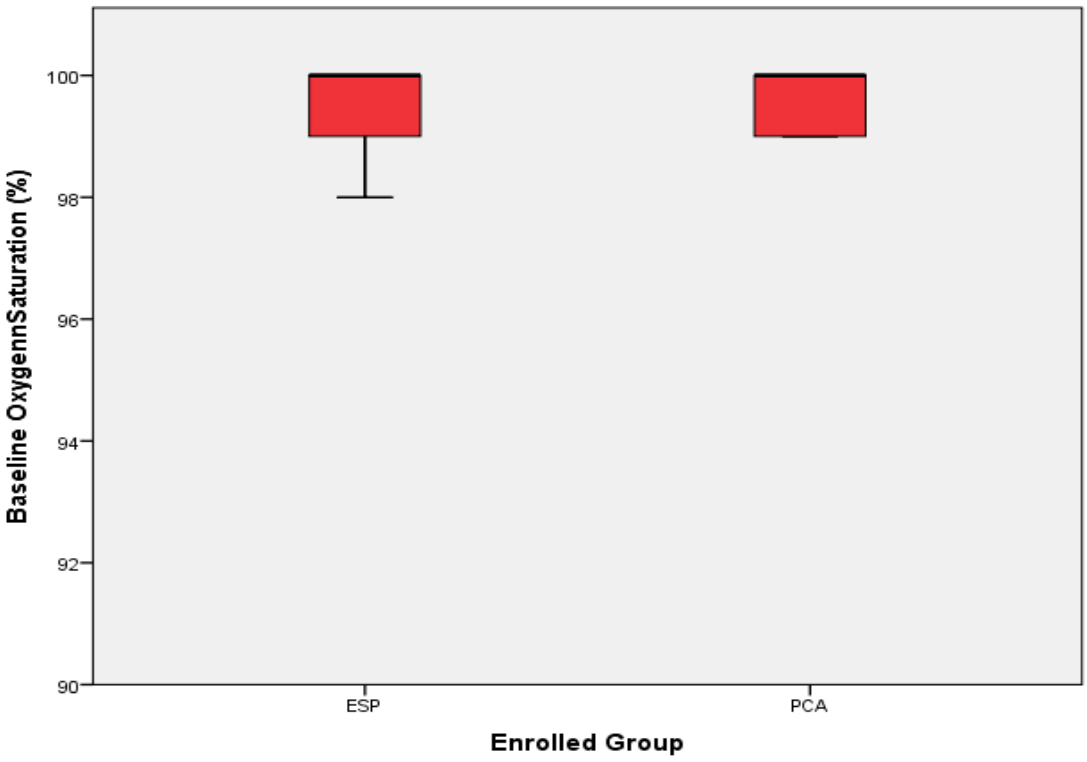



**Figure-21:** Comparison of median (IQR) (range) baseline $SpO_2$ between the study groups.

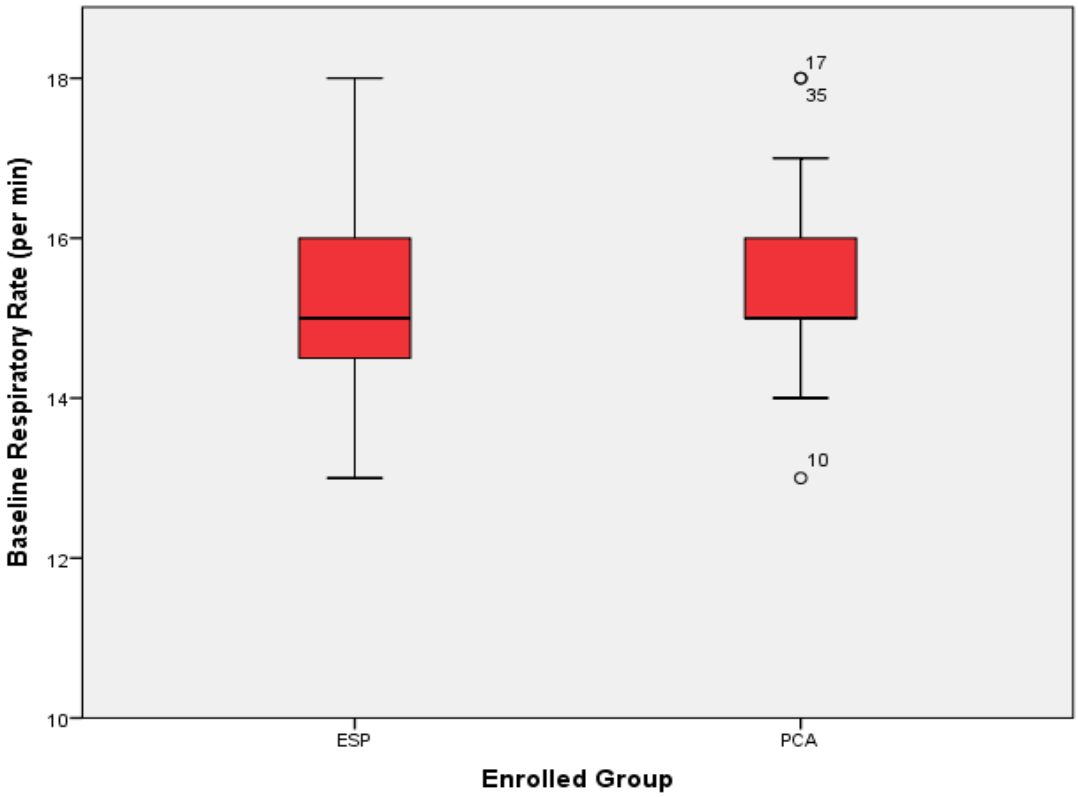



**Figure-22:** Comparison of median (IQR) (range) baseline RR between the study groups.

**TABLE 10:** Comparison of VAS score at rest during PACU stay between the study groups.

| Time | VAS score PACU rest [Median (IQR) (Range)] | | Median Difference (95% CI) | p-value |
|---|---|---|---|---|
| | Group ESP | Group PCA | | |
| 1 h | 3 (2, 3) (1 - 4) | 3 (3, 4) (2 - 5) | 0 (-1.01 to -0.25) | 0.001 |
| 2 h | 2 (2, 3) (1 - 4) | 3 (3, 3) (2 - 4) | 1 (-1.19 to -0.43) | <0.0001 |
| 3 h | 2 (1, 2) (1 - 3) | 2 (2, 2) (2 - 4) | 0 (-1.11 to -0.45) | <0.0001 |
| 4 h | 2 (1, 2) (1 - 3) | 2 (2, 2) (1 - 3) | 0 (-0.82 to -0.21) | 0.001 |
| Shifting | 1 (1, 2) (1 - 2) | 2 (2, 2) (1 - 3) | 1 (-0.91 to -0.35) | <0.0001 |

The above table shows median (IQR) (range) VAS Score at rest during PACU stay (1 h, 2 h ,3 h, and 4 h) and while shifting from PACU in the study groups and their comparison. In group ESP, the VAS Score at rest during PACU stay (1 h, 2 h ,3 h, and 4 h) was 3 (2, 3) (1–4), 2 (2, 3) (1–4), 2 (1, 2) (1–3), and 2 (1, 2) (1–3) respectively, while during shifting it was 1 (1, 2) (1–2). In group PCA, the VAS score during PACU stay was 3 (3, 4) (2–5), 3 (3, 3) (2–4), 2 (2, 2) (2–4), and 2 (2, 2) (1–3) respectively, while during shifting it was 2 (2, 2) (1–3). The Mann-Whitney U test was used to compare the VAS Score at rest during PACU stay (1 h, 2 h ,3 h, and 4 h) and during shifting showed a p-value of <0.0001 (0.001, <0.0001, <0.0001, and 0.001 respectively) and <0.0001, which was statistically significant. Group ESP had significantly lower VAS score at rest compared to group PCA during PACU stay as well as during shifting.

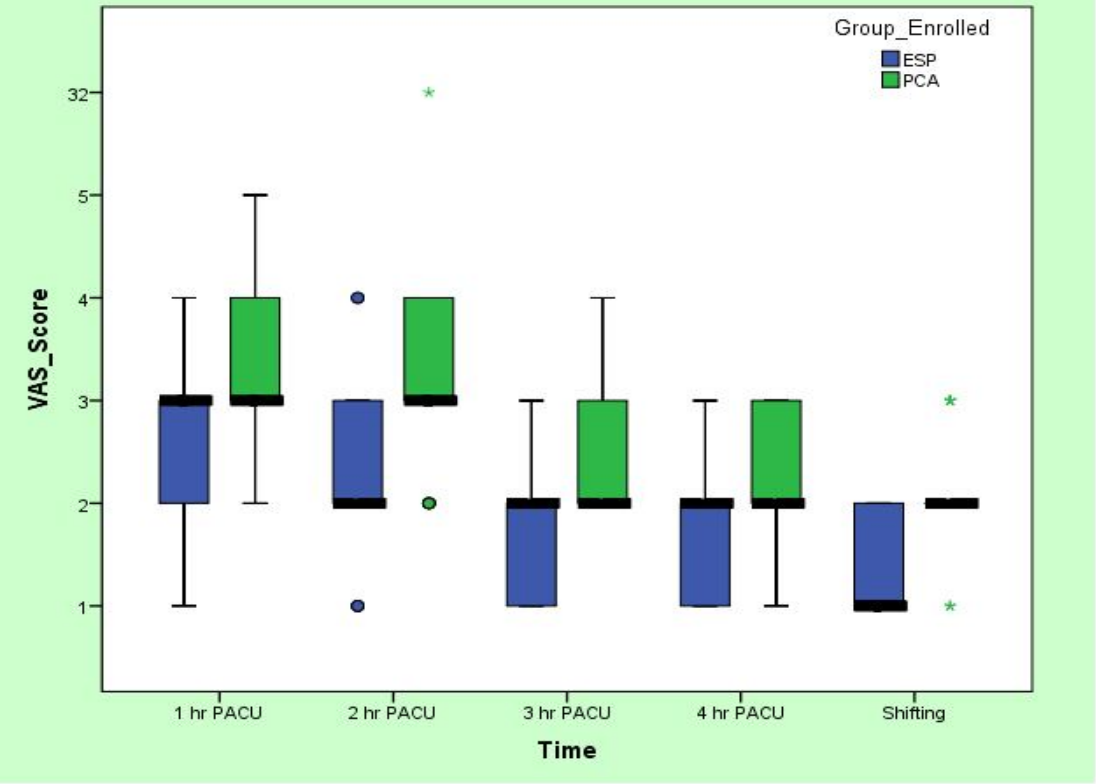



**Figure-23:** Comparison of median (IQR) (range) of VAS Scores at rest during PACU stay and while shifting from PACU between the study groups.

**TABLE 11:** Comparison of VAS score on movement during PACU stay between the study groups.

| Time | VAS score PACU Movement [Median (IQR) (Range)] | | Median Difference (95% CI) | p-value |
|---|---|---|---|---|
| | Group ESP | Group PCA | | |
| 1 h | 4 (3, 4) ( 2 - 5) | 4 (4, 5) (3 -7) | 0 (-0.97 to -0.13) | 0.010 |
| 2 h | 3 (3, 4) (2 - 5) | 4 (4, 4) (3 - 5) | 1 (-1.16 to -0.39) | 0.0002 |
| 3 h | 3 (2, 3) (2 - 4) | 3 (3, 4) (3 - 5) | 0 (-1.16 to -0.46) | <0.0001 |
| 4 h | 3 (2, 3) (2 - 4) | 3 (3, 4) (2 - 4) | 0 (-0.82 to -0.21) | 0.001 |
| Shifting | 2 (2, 3) (2 - 3) | 3 (3, 3) (2 - 4) | 1 (-0.95 to -0.38) | <0.0001 |

The above table shows median (IQR) (range) VAS Score on movement during PACU stay (1 h, 2 h ,3 h, and 4 h) and while shifting from PACU in the study groups and their comparison. In group ESP, the VAS Score on movement during PACU stay (1 h, 2 h, 3 h, and 4 h) was 4 (3, 4) (2–5), 3 (3, 4) (2–5), 3 (2, 3) (2–4), and 3 (2, 3) (2–4) respectively, while during shifting it was 2 (2, 3) (2-3). In group PCA, the VAS score during PACU stay was 4 (4, 5) (3–7), 4 (4, 4) (3–5), 3 (3, 4) (3–5), and 3 (3, 3) (2–4) respectively, while during shifting it was 3 (3, 3) (2–4). The Mann-Whitney U test was used to compare the VAS Score on movement during PACU stay (1 h, 2 h ,3 h, and 4 h) and during shifting showed a p-value of <0.05 (0.001, <0.0001, <0.0001, and 0.001 respectively) and <0.0001, which was statistically significant. Group ESP had significantly lower VAS score on movement compared to group PCA during PACU stay as well as during shifting.

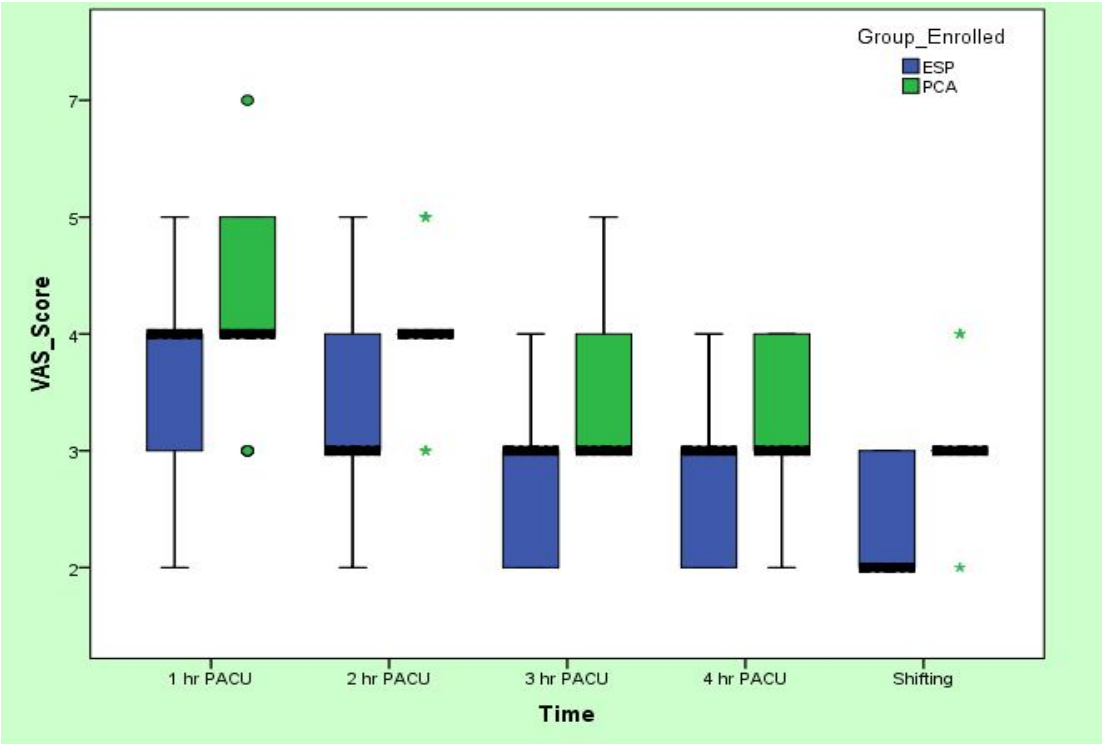



**Figure- 24:** Comparison of median (IQR) (range) VAS Scores on movement during PACU stay and while shifting from PACU between the study groups.

**TABLE 12:** Comparison of VAS score at rest in ward between the study groups.

| Time | VAS score ward rest [Median (IQR) (Range)] | | Median Difference (95% CI) | p-value |
|---|---|---|---|---|
| | Group ESP | Group PCA | | |
| 1 h | 1 (1, 2) (1 - 2) | 2 (2, 2) (1 - 4) | 1 (-0.93 to – 0.32) | 0.0001 |
| 3 h | 1 (1, 1) (0 - 2) | 2 (2, 2) (1 - 3) | 1 (-1.15 to -0.55) | <0.0001 |
| 6 h | 1 (0, 1) (0 - 2) | 2 (1, 2) (1 - 3) | 1 (-1.25 to -0.60) | <0.0001 |
| 12 h | 1 (0, 1) (0 - 2) | 1 (1, 2) (1 - 2) | 0 (-1.20 to -0.57) | <0.0001 |
| 18 h | 0 (0, 1) (0 - 2) | 1 (1, 2) (0 - 2) | 1 (-0.98 to – 0.35) | <0.0001 |
| 24 h | 0 (0, 1) (0 - 1) | 1 (1, 1) (0 - 2) | 1 (-0.74 to – 0.22) | 0.0005 |

The above table shows VAS score at rest in ward at different time (1 h, 3 h ,6 h, 12 h, 18 h and 24 h) in both the study groups and their comparison. The median (IQR) (Range) VAS Score at rest in ward rest at (1 h, 3 h ,6 h, 12 h, 18 h and 24 h) in group ESP was 1 (1, 2) (1 – 2), 1 (1, 1) (0 – 2), 1 (0, 1) (0 – 2), 1 (0, 1) (0 – 2), 0 (0, 1) (0 – 2), and 0 (0, 1) (0 – 1) respectively while in group PCA it was 2 (2, 2) (1 – 3), 2 (1, 2) (1 – 3), 1 (1, 2) (1 – 2), 1 (1, 2) (0 – 2), and 1 (1, 1) (0 – 2) respectively. The Mann-Whitney U test was used to compare the VAS Score at rest in ward at (1 h, 3 h ,6 h, 12 h, 18 h and 24 h) between the study groups showed a p-value of 0.0001, <0.0001, <0.0001, <0.0001, <0.0001 and 0.0005 respectively, which was statistically significant, i.e. patients in group ESP had significantly lower VAS score at rest in ward at all-time point of observation.

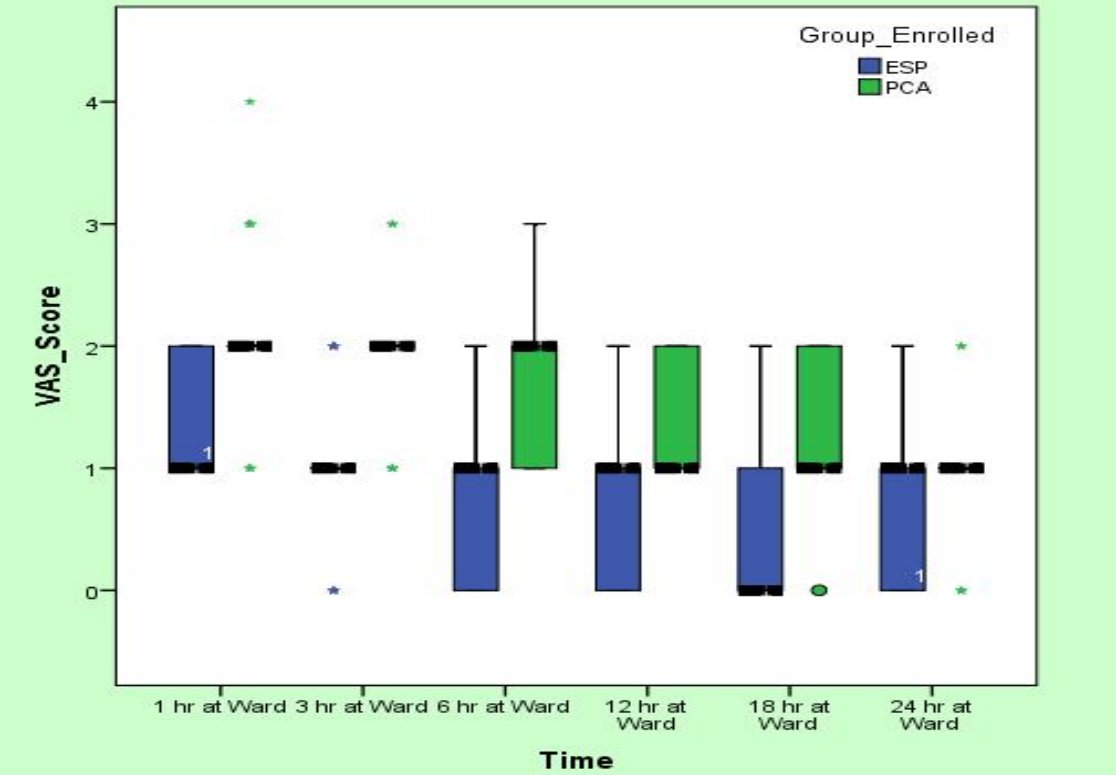



**Figure- 25:** Comparison of median (IQR) (range) of VAS Scores at rest in ward at different time points between the study groups.

**TABLE 13:** Comparison of VAS score on movement in ward between the study groups.

| Time | VAS score ward movement [Median (IQR) (Range)] | | Median Difference (95% CI) | p-value |
|---|---|---|---|---|
| | Group ESP | Group PCA | | |
| 1 h | 2 (2, 3) (2 - 3) | 3 (3, 3) (2 - 4) | 1 (-0.82 to – 0.29) | 0.0001 |
| 3 h | 2 (2, 2) (1 - 3) | 3 (3, 3) (2 - 4) | 1 (- 1.05 to – 0.50) | <0.0001 |
| 6 h | 2 (1, 2) (1 - 3) | 3 (2, 3) (2 - 4) | 1 (-1.16 to – 0.53) | <0.0001 |
| 12 h | 2 (1, 2) (1 - 3) | 2 (2, 3) (2 - 3) | 1 (-1.20 to – 0.57) | <0.0001 |
| 18 h | 1 (1, 2) (0 - 3) | 2 (2, 3) (1 - 3) | 1 (-1.03 to -0.37) | <0.0001 |
| 24 h | 1 (1, 2) (0 - 3) | 2 (2, 2) (1 - 3) | 1 (-0.94 to – 0.31) | 0.0002 |

The above table shows VAS score on movement in ward at different time (1 h, 3 h ,6 h, 12 h, 18 h and 24 h) in both the study groups and their comparison. The median (IQR) (Range) VAS score on movement in ward at (1 h, 3 h ,6 h, 12 h, 18 h and 24 h) in group ESP was 2 (2, 3) (2 – 3), 2 (2, 2) (1 – 3), 2 (1, 2) (1 – 3), 2 (1, 2) (1 – 3), 1 (1, 2) (0 – 3) and 1 (1, 2) (0 – 3) respectively while in group PCA it was 3 (3, 3) (2 – 4), 3 (3, 3) (2 - 4), 3 (2, 3) (2 - 4), 2 (2, 3) (2 – 3), 2 (2, 3) (1 – 3), and 2 (2, 2) (1 – 3) respectively. The Mann-Whitney U test was used to compare the VAS Score on movement in ward at (1 h, 3 h ,6 h, 12 h, 18 h and 24 h) between the study groups showed a p-value of 0.0001, <0.0001, <0.0001, <0.0001, <0.0001 and 0.0002 respectively, which was statistically significant, i.e. patients in group ESP had significantly lower VAS score on movement in ward at all-time point of observation.

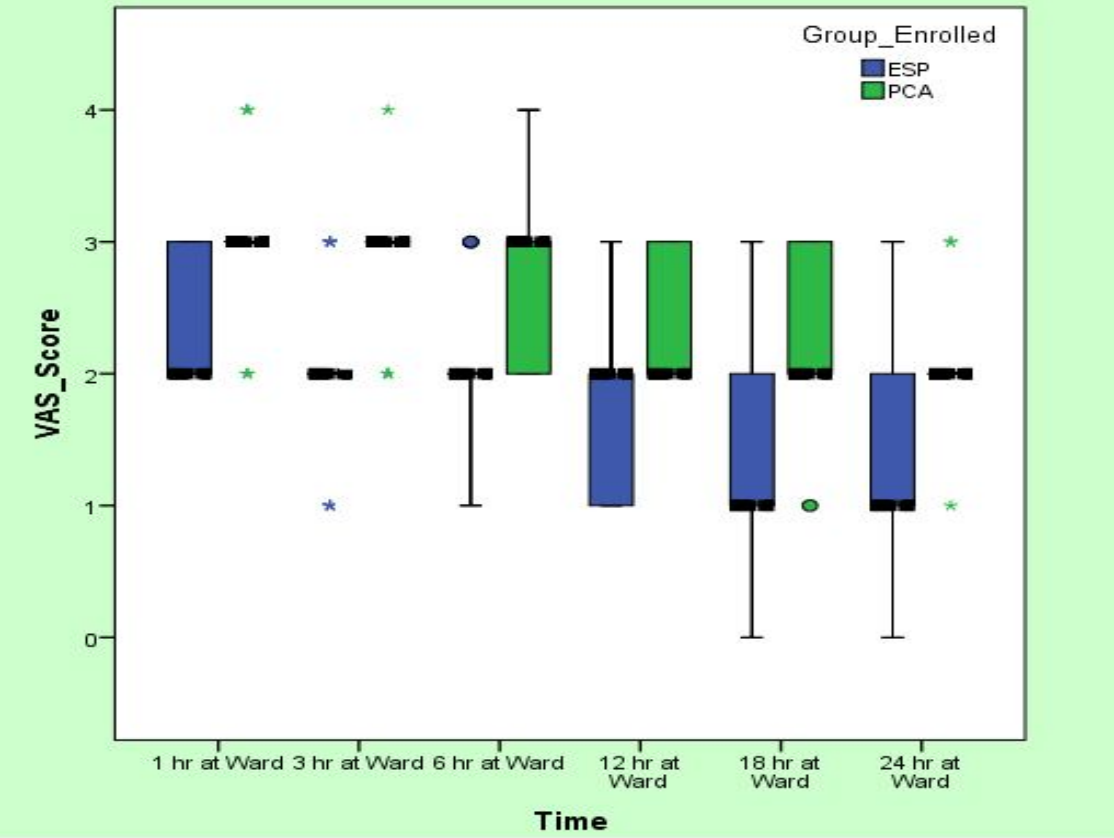



**Figure- 26:** Comparison of median (IQR) (range) of VAS Scores on movement in ward at different time points between the study groups.

**TABLE 14:** Comparison of Total opioid consumed, Bolus dose attempted and administered between the study groups

| Parameter | Group ESP | Group PCA | Median Difference (95% CI) | p-value |
|---|---|---|---|---|
| Opioid consumed (µg) [Median (IQR) (range)] | 48 (0, 80) (0 – 170) | 1750 (1375, 1990) (80 – 2240) | 1702 (-1764.8 to -1415.7) | <0.0001 |
| Number of Bolus attempted [Median (IQR) (range)] | 3 (0, 6) (0 – 10) | 6 (5, 8) (3 – 14) | 3 (-4.5 to -1.4) | 0.001 |
| Number of Bolus administered [Median (IQR) (range)] | 2 (0, 3) (0 – 5) | 3 (2, 4) (2 – 7) | 1 (-2.3 to -0.7) | <0.0001 |

The above table shows the total (µg) opioid (fentanyl) consumed along with the patient controlled analgesia (PCA) bolus dose attempted and administered 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 48 (0, 80) (0 – 170), 3 (0, 6) (0 – 10) and 2 (0, 3) (0 – 5) respectively while in group PCA it was 1750 (1375, 1990) (80 – 2240), 6 (5, 8) (3 – 14) and 3 (2, 4) (2 – 7) respectively. The Mann-Whitney U test was used for comparison between the study groups which showed a p-value of <0.0001, 0.001 and <0.001 respectively which was considered significant, i.e. patients in ESP group had significantly lower opioid requirement, lesser number of PCA dose attempted and administered compared to group PCA.

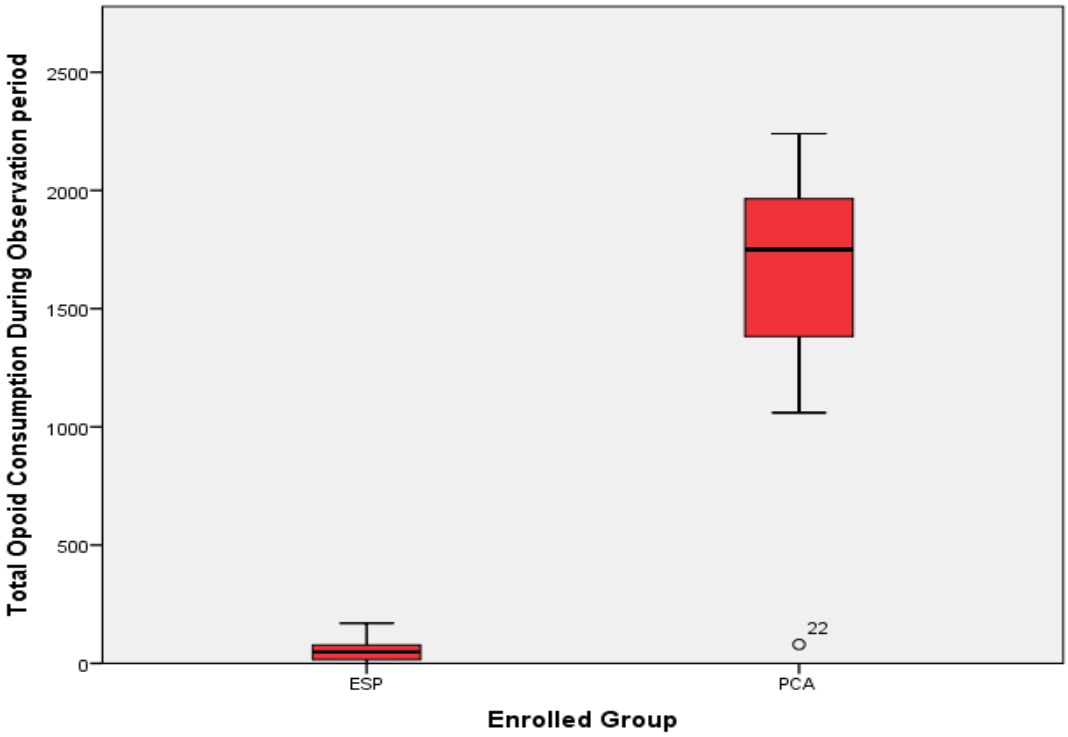



**Figure-27:** Comparison of median (IQR) (range) total (µg) opioid (fentanyl) consumed between the study groups.

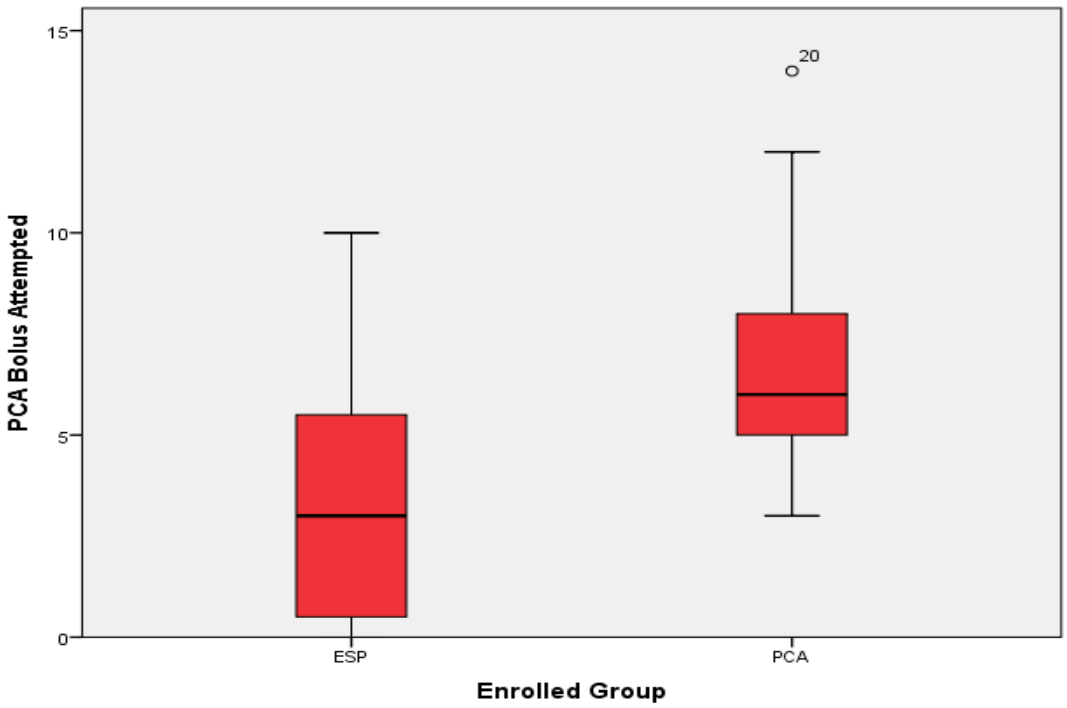



**Figure-28:** Comparison of median (IQR) (range) PCA bolus dose attempted between the study groups.

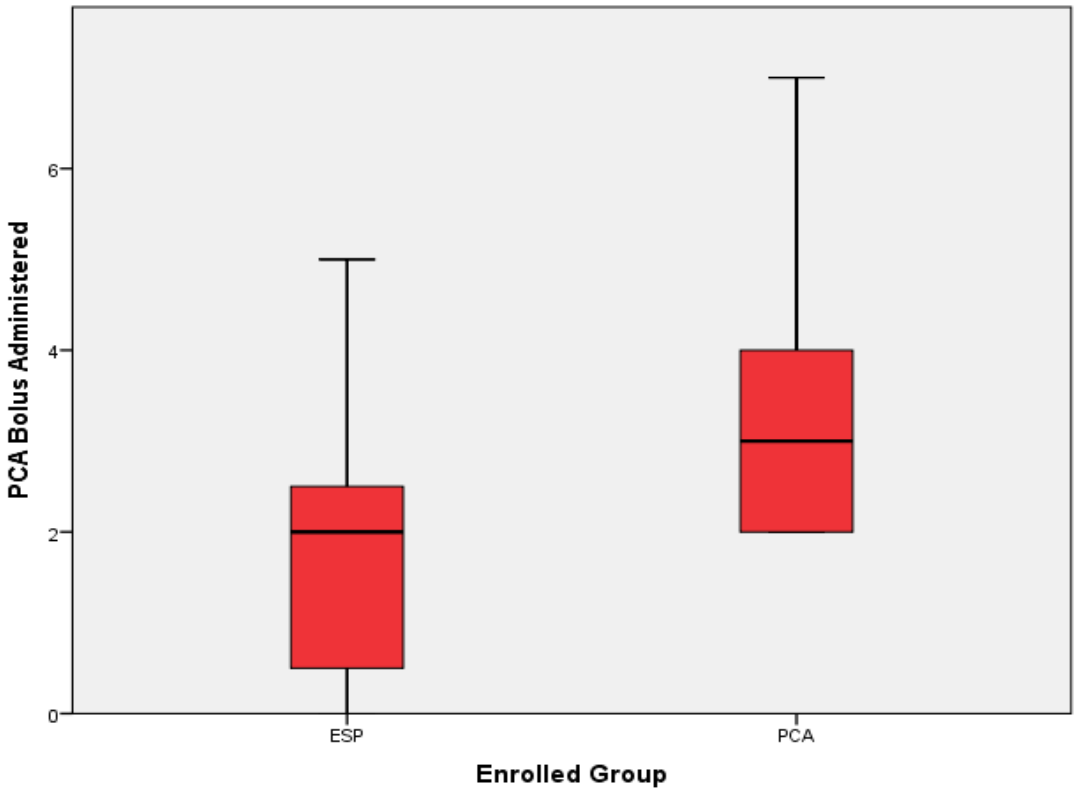



**Figure-29:** Comparison of median (IQR) (range) PCA bolus dose administered between the study groups.

**TABLE 15:** Comparison of number of rescue analgesia between the study groups

| No. of Rescue Analgesia Required | Group ESP N (%) | Group PCA N (%) | Median Difference (95% CI) | p-value |
|---|---|---|---|---|
| No requirement | 20 (74.07) | 13 (48.15) | - | - |
| Required Once | 6 (22.22) | 4 (14.81) | | |
| Required Twice | 1 (3.70) | 8 (29.63) | | |
| Required Thrice | 0 (0.00) | 2 (7.41) | | |
| Median (IQR) (range) | 0 (0, 1) (0 – 2) | 1 (0, 2) (0 – 3) | 1 (-1.12 to -0.21) | 0.014 |

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 was 1 (0, 2) (0 – 3) respectively. The Mann-Whitney U test was used for comparison between the study groups which showed a p-value of 0.014 which was statistically significant, i.e. patients in group ESP required significantly lesser number of rescue analgesia compared to group PCA.

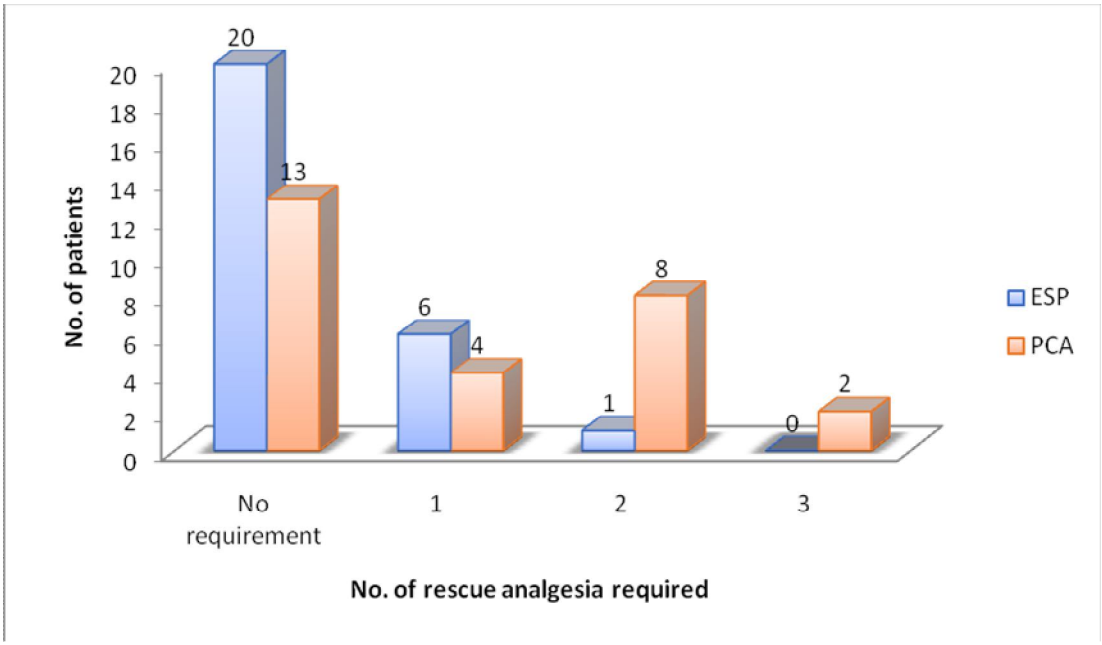



**Figure-30:** Comparison of number of rescue analgesia required between the study groups.

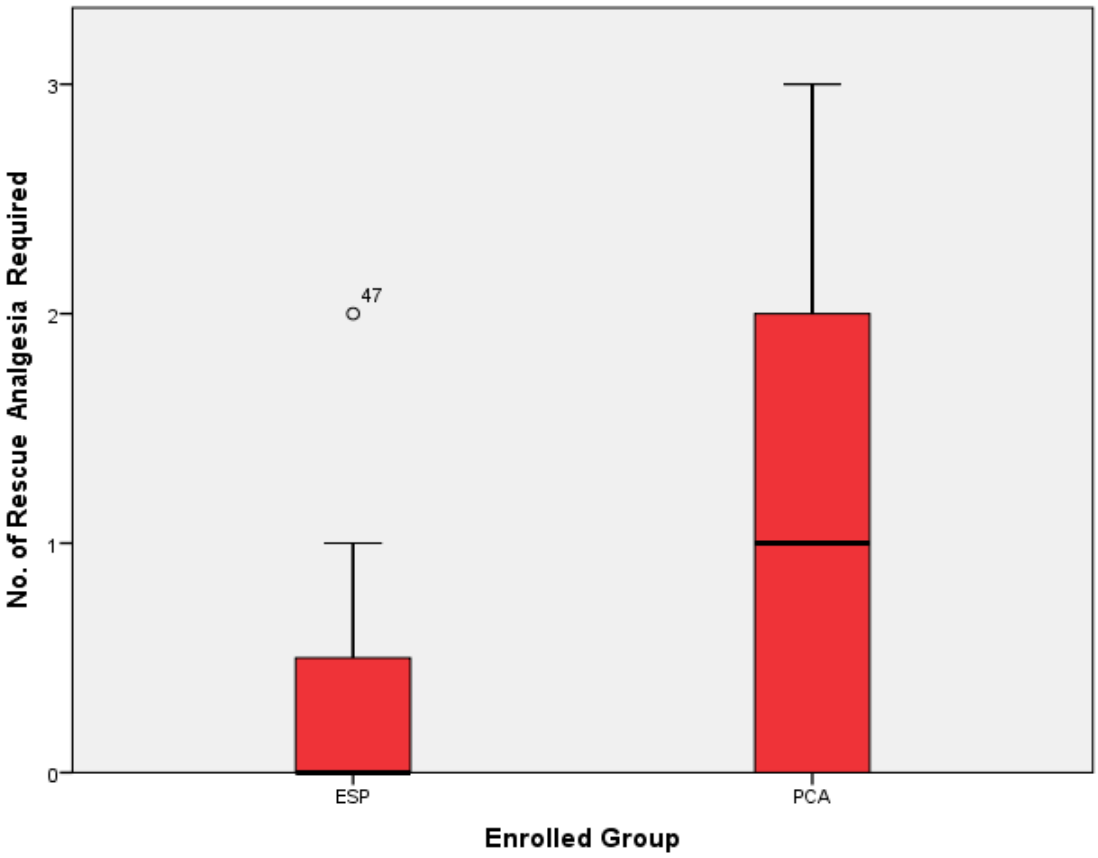



**Figure-31:** Comparison of median (IQR) (range) number of rescue analgesia required between the study groups.

**TABLE 16:** Comparison of Satisfaction scores between the study groups.

| Satisfaction score | Group ESP N (%) | Group PCA N (%) | Median Difference (95% CI) | p-value |
|---|---|---|---|---|
| 1 (Excellent) | 18 (66.67) | 1 (3.70) | - | - |
| 2 (Good) | 8 (29.63) | 12 (44.44) | | |
| 3 (Fair) | 1 (3.70) | 14 (51.85) | | |
| 4 (Poor) | 0 (0) | 0 (0) | | |
| Median (IQR) (range) | 1 (1, 2) (1 – 3) | 3 (2, 3) (1 – 3) | 2 (-1.42 to -0.8) | <0.0001 |

The above table shows the satisfaction score (Excellent, Good and Fair) in both the study groups and their comparison. The median (IQR) (range) satisfaction score of group ESP was 1 (1, 2) (1 – 3) and while in group PCA it was 3 (2, 3) (1 – 3) respectively. The Mann-Whitney U test used for comparison between the study groups which showed a p-value of <0.0001 which was statistically significant, i.e. patients in group ESP had significantly higher satisfaction for the techniques compared to patients in group PCA.

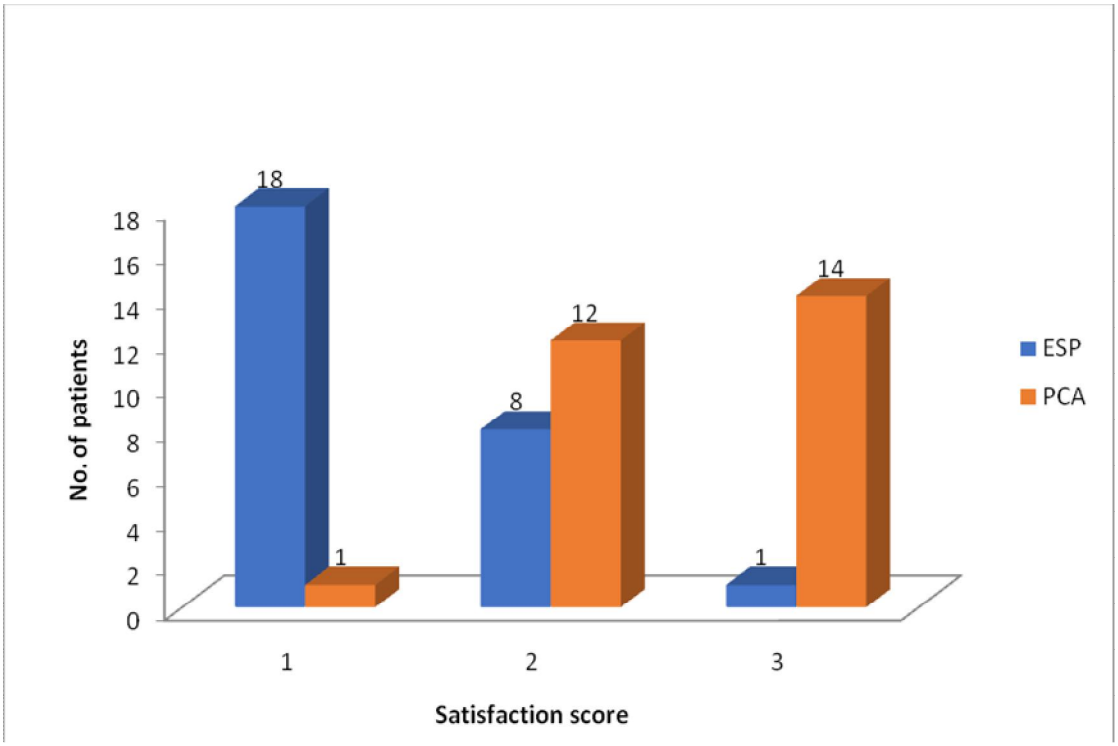



**Figure-32:** Comparison of number of patients with different satisfaction score between the study groups.

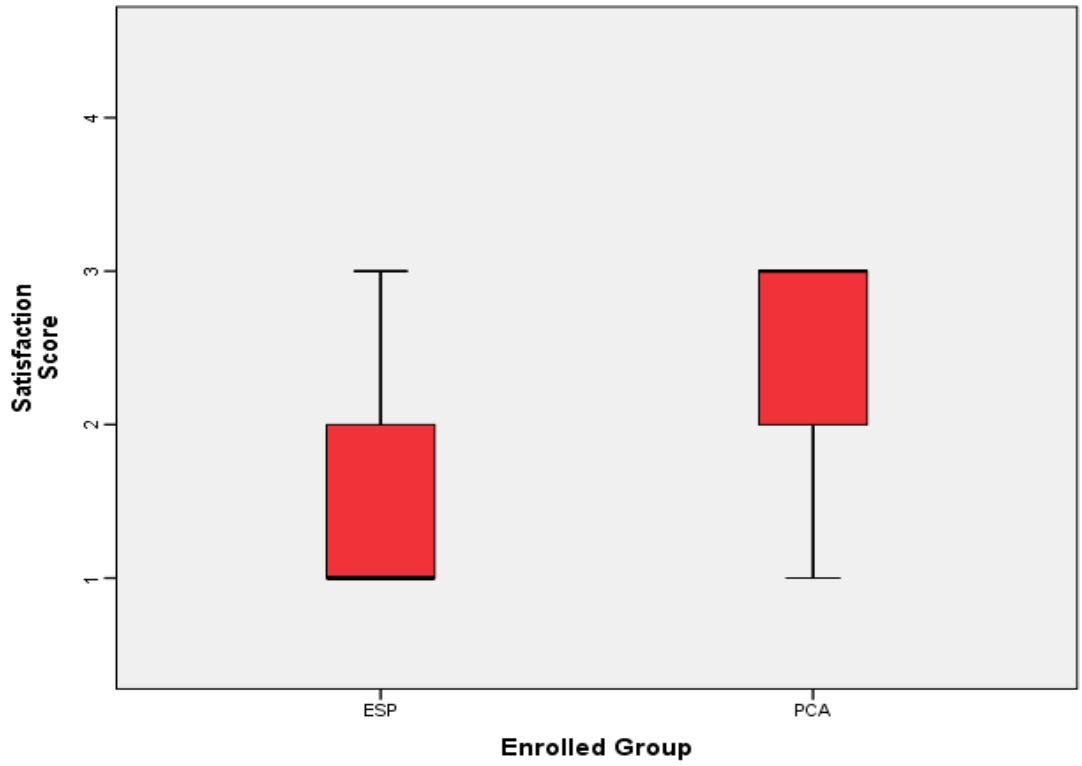



**Figure-33:** Comparison of median (IQR) (range) of Satisfaction score between the study groups.

**TABLE 17:** Comparison of Side Effects between the study groups.

| Side effect of opioids | Group ESP N (%) | Group PCA N (%) |
|---|---|---|
| Sedation | 0 (0.00) | 10 (37) |
| Nausea and vomiting | 0 (0.00) | 5 (18.5) |
| Pruritus | 0 (0.00) | 2 (7.4) |
| No side effects | 27 (100.00) | 10 (37) |
| Total | 27 (100.00) | 27 (100.00) |

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 seventeen (63%) patients in groups PCA had at least one adverse event. Sedation was the most adverse event followed by nausea/vomiting and pruritus.

# DISCUSSION

The present study demonstrated that in patients undergoing multilevel spine surgery, bilateral continuous ESP block provides better postoperative analgesia compared to IV fentanyl based PCA in terms of improved VAS score recorded at predefined time intervals and significantly reduced 24-h opioid consumption. Also, significantly less number of rescue analgesia and PCA bolus doses (attempted and administered) were required in patients receiving bilateral ESP block with lesser opioid associated side effects and significantly better patient satisfaction.

Surgical procedures on the spine are generally associated with intense pain in the postoperative period, especially for the initial few days. Providing adequate analgesia for acute postoperative pain could improve functional outcome leading to early ambulation and early discharge from the hospital as well as prevent development of chronic pain. A diverse array of IV and oral pharmacological options including opioids, nonsteroidal anti-inflammatory drugs (NSAIDs), gabapentinoids, acetaminophen etc. exists for the effective amelioration of acute postoperative pain after spine surgery. Each of these drugs possesses inherent advantages and disadvantages which restricts their universal applicability. Multimodal pain management protocols including the available pharmacological options have demonstrated improved pain control with less reliance on opioids.[48,49]

Central neuraxial blockade (epidural and intrathecal) have been used for perioperative pain management in patients undergoing surgical procedures on spine. Although these techniques provide good postoperative analgesia with reduced opioid consumption, there is an increased rate of urinary catheterization[50 ]as well as risk of dislocation of epidural catheter into a recently operated area in the vertebral column with continuous infusion of LAs may lead to unpredictable absorption of the drug and motor blockade.[51,52] A recent systematic review on pain management after complex spine surgery found that preoperative and intra-operative interventions that improved postoperative pain were paracetamol, cyclo-oxygenase (COX)-2 specific-inhibitors or NSAIDs, IV ketamine infusion and regional analgesia techniques including epidural analgesia using LAs with or without opioids. However, the evidence was limited for local wound infiltration, intrathecal and epidural opioids, thoracolumbar interfascial plane block, ESP block, intravenous lidocaine, dexmedetomidine and gabapentin.[53]

Introduction of ESP block by Forero in 2016 aroused the interest of many nerve block experts.[54] It has been found to be effective in various type of surgeries,[55] including thoracolumbar spine surgery for providing postoperative analgesia.[24,25,41,44,47] A few systematic reviews and metaanalysis have also been published evaluating role of ESP block after spine surgery and concluded that ESP block is safe and can provide effective postoperative analgesia after lumbar spinal surgery.[56,57] However, these reviews were limited by inclusion of small number of eligible studies therefore, further studies are still required to make recommendation for use of ESP block in patients undergoing spine surgeries. Hence, we planned a study to compare the ultrasound guided bilateral continuous ESP and fentanyl based IV PCA for postoperative analgesia after multilevel spine surgery.

The present study enrolled fifty-four patients of either sex, aged between 18 to 65 years, belonging to ASA physical status class I or II and scheduled for elective multilevel thoracolumber spine surgery. Our aim was to compare analgesic efficacy of bilateral continuous ESP and IV PCA following spine surgery. The primary objective was to compare postoperative VAS pain score during the first 24 h following surgery. Secondary objectives included comparison of total opioid and total rescue analgesia consumed during the first 24 h, side effects and patient's satisfaction for both the techniques.

Twenty-seven patients were enrolled in each group (group ESP and group PCA). All the patients received the allocated intervention and followed up to 24-h. There was no lost to follow up and all the patient's data were analysed as per the randomized group.

**Demographic profile:**

***Age*:**

In our study, the mean±SD of age in group ESP and group PCA was 44.77±11.11 and 40.11±10.84 respectively. Both groups were similar with respect to age. Similar studies enrolling patients aged more than 18 years or less than 65 years found similar results to that of our study. Singh et al[24] enrolled comparatively younger patients (34.9±10.1 and 35.4±8.3) while Zhang et al[25] (60.0±9.6 and 59.5±11.5), Finnerty et al[47] (59.8±15.5 and 59.2±16.5) and van den Broek et al[44]

(62.9±10.9 and 61.6±9.5) 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 (15/12) and in group PCA (17/10). Both the groups were similar with respect to the gender distribution. Finnerty et al[47] (17/13 control group and 12/18 ESP group) and van den Broek et al[44] (7/13 control group and 11/9 ESP group) also had similar gender distribution in their study. However, Singh et al[24] had comparatively more male patients (18/2 control group and 17/3 ESP group) while Zhang et al[25] had comparatively more female patients (9/21 control group and 6/24 ESP group) in their study compared to our study population. 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 164.59±7.86, 165.37±6.85 and 24.77±2.76 while in group PCA it was 67.44±11.00, 65.40±11.48 and 23.80±3.16 respectively. Both the groups were comparable with respect to height, weight and BMI. Similar to our study, in the study conducted by Singh et al[24] and Zhang et al[25], the BMI was 24.7±1.6 and 25.1±1.8 (control and ESP groups) and 24.7±2.9 and 25.4±3.2 (control and ESP groups) respectively. While Finnerty et al[47] (28.4±5.4 and 27.2±4.1 in control and ESP groups) and van den Broek et al[44] (27.0±4.0 and 26.7±4.6 in control and ESP groups) enrolled patients with higher BMI compared to our study population. Between group differences in the BMI was statistically non-significant in all the quoted studies.

***ASA physical status*:**

In our study population, most of the patients belonged to ASA physical status I and the ASA distribution (I/II) in group ESP was 23/4 and in group PCA was 24/3 respectively. Singh et al[24] and Yayik A et al[41] also had more number of ASA I patients (control group/ESP group) 10/12 and 13/12 respectively. While van den Broek et al[44] and Zhang et al[25] had more number of ASA II (control group/ESP group) 14/11 and 23/22 patients respectively and Finnerty et al[47] had more number of

ASA III (22 control group/23 ESP group) patients. There was no statistically significant difference in distribution of ASA physical status class between groups.

***Duration of surgery*:**

In our study, the median (IQR) (range) of duration of surgery (hour) in group ESP and group PCA was 5 (4, 5) (3-7) and 5 (4, 6) (3-7) respectively. Swati Singh et al[24] reported mean±SD duration of surgery (min) and the values were 145.2±8.0 in control group and 149.3±6.3 in ESP group while in study by Finnerty et al[47] it was 3.2±1.2 h in control group and 3.4±1.2 h in ESP block group and by van den Broek et al[44] it was 247±26 min in control group and 228±29 min in ESP block group. Both the groups were having statistically similar duration of surgery.

***Surgical Procedure Characteristics*:**

In our study, the region of surgery (lumbar or thoracic), surgical procedure (Laminectomy with or without screw fixation) and vertebral level operated (2 or >2) were comparable between both study groups. Swati Singh et al[24] reported vertebral levels (I/II/III) 10/5/5 in control group and 12/5/3 in ESP group while in study by Zhang et al[25] it was 9/11/10 in control group and 4/12/14 in ESP block group and by van den Broek et al[44] it was uniform distribution 14/6 (I/II) in control group and 14/6 in ESP block group which were compared to our study population.

**Primary outcome:**

***VAS Score at rest and during movement***

In our study, the VAS scores at rest and during movement were significantly better in group ESP compared to group PCA both during PACU stay as well as in the ward at all predefined time points. Singh et al[24] found that NRS pain scores were significantly better at 0, 6, 8 and 10 h after surgery in patients receiving ESP block compared to the control group. After 10 h there was no difference in the pain scores between both groups. They performed a single shot bilateral ESP block in the preoperative period with 20 ml 0.5% bupivacaine on each side that may explain their finding of no significant difference in pain score after 10 h in the postoperative period.

Zhang et al[25] in their study also performed preoperative bilateral single shot ESP block with 20 ml 0.4% ropivacaine in the intervention group and bilateral Sham

block with 1% lidocaine in the control group. They recorded NRS pain scores at rest and during movement for 12 h after surgery. They found significantly lower NRS scores at rest in the ESP block group than the control group at all three time points (at 4, 8 and 12 h) and the estimated mean difference (95% CI, p-value) was −1.6 (-2.4 to −0.8, < 0.001), −1.3 (-1.9 to −0.6, < 0.001) and −0.7 (-1.3 to −0.1, = 0.023) at the corresponding time points respectively. The pain scores at rest were similar after 12 h (at 24 and 48 h) in both groups. During movement, NRS score was significantly lower at 4 h [−1.5 (-2.5 to −0.6)], however, the pain scores were similar at 8 h [− 0.5 (-1.2 to 0.3)] and at 12 h [−0.1 (-0.7 to 0.5)]. Similar pain scores between groups after 12 h could be explained by single shot ESP block and use of lower concentration of LA.

Finnerty et al[47] performed a preoperative ESP block with 40 ml 0.25% levobupivacaine at the midpoint of the planned incision after induction of anaesthesia. They recorded verbal response scale (0–10) to measure pain at rest and on sitting in the PACU and 12 h and 24 h later. They found significantly lower mean pain scores PACU and 12 h postoperative both at rest (3.9±2.3 vs. 2.1±2.0, p = 0.0021 and 3.5±2.6 vs. 2.1±1.9, p = 0.021 respectively) and on sitting (5.4±2.6 vs. 3.5±2.4, p = 0.0047 and 5.6±2.5 vs. 2.5±3.8, p < 0.001 respectively) in patients receiving ESP block while at 24 postoperative h there was no difference in mean pain scores both during rest (2.6±1.9 vs. 2.5±2.2, p = 0.85) and on sitting (5.1±2.3 vs. 4.5±2.7, p = 0.36) between control and block participants.

van den Broek et al[44] enrolled 40 patients undergoing posterior lumbar interbody fusion and performed preoperative bilateral single shot ESP block with 20 ml ropivacaine on either side. They recorded NRS pain scores in the PACU at 6, 12 and 24 h and found that pain scores in the PACU were lower in patients who received an ESP block [median (IQR) no block: 5 (6.0); ESP block: 2 (5.0); $p = 0.040$] while in the ward, NRS pain scores were comparable between the 2 groups at 6 h [no block: 3 (5.0); ESP block: 2 (2.0); $p = 0.800$], at 12 h [no block: 3 (2.0); ESP block: 3 (2.0); $p = 0.458$], and at 24 h [no block: 3 (3.0); ESP block: 3 (5.0); $p = 0.444$]. Their finding of similar pain scores between groups after 6 h could be explained by expected duration of single shot ESP block.

Yayik et al[41] enrolled 66 patients scheduled for 1- or 2-level open lumbar decompression surgery and performed preoperative single shot ESP block with 20 ml 0.25% bupivacaine in the intervention group. Postoperative pain was assessed at 1, 2, 4, 8, 12, and 24-h using VAS scores at rest and with active movement. The recorded VAS scores were significantly lower in patients receiving ESP block compared to the control group at all-time points of observation.

All of the studies quoted have reported significantly lower pain scores in patients receiving ESP block up to 12 h in the postoperative period. The continuous bilateral ESP block in our study provided significantly lower pain scores up to 24 postoperative h.

**Secondary outcome:**

***Total Opioid Consumption:***

In our study, the median (IQR) (range) total opioid [fentanyl (µg)] consumed over 24 h was significantly lower in patients receiving ESP block [48 (0, 80) (0 – 170)] compared to those maintained on IV (fentanyl) PCA [1750 (1375, 1990) (80 – 2240)]. The corresponding IV morphine (mg) equivalent in group ESP was 0.48 (0, 0.8) (0-1.7) and in group ESP was 17.5 (13.75, 19.9) (0.8-22.4). Zhang et al[25] also found that the median (IQR) cumulative PCA sufentanil (µg) consumption was significantly lower in the ESP block group than the control group at 4 h [0 (0–0) vs. 0 (0–5.0); p = 0.004], at 8 h [3.8 (0–8.1) vs. 10.0 (4.4–13.1); p = 0.004] and at 12 h [6.3 (0–15.0) 10.0 (5.0–22.5); p = 0.042] postoperatively, but it was similar between the two groups at 24 h [10.0 (5.0–21.3) vs. 15.0 (7.5–30.0); p=0.174] and at 48 h [22.5 (10.0–40.6) vs. 23.3 (20.0–63.8); p=0.269]. The cumulative opioid consumption during first 24 h was significantly less in ESP group [20.1 (5.0-44.4)] compared to control group [35.0 (16.9-70.6)]. The continuous ESP block in our study provided longer analgesia leading to lesser opioid requirements up to 24 h. Singh et al[24] also reported significantly lower mean±SD opioid [morphine (mg)] requirement in ESP group (1.4±1.5) compared to control group (7.2±2.0). Yayik et al[41] in their study provided PCA devices prepared with tramadol to all patients after surgery in the postoperative recovery room. These were set to a concentration of 5 mg/mL, loading dose of 100 mg, lockout interval of 15 minutes, and 15 mg bolus, without basal infusion, maintained for 24 h. They also reported that 24-h opioid consumption in the

control group was significantly higher compared with the ESP group (370.33±73.27 mg and 268.33±71.44 mg, P < 0.001, respectively), and the difference was 28%.

In our study, continuous ESP block provided longer lasting analgesia leading to significantly lesser opioid consumption during 24-h.

***Total rescue analgesia:***

In our study, 20 (74.07%) patients in group ESP did not require rescue analgesia while in group PCA, 14 (51.85%) required rescue analgesia in the form of diclofenac 75 mg. The total rescue analgesia doses consumed in group ESP was eight while in group PCA it was twenty-six. The median (IQR) (range) number of rescue analgesia required in Group ESP was [0 (0, 1) (0 – 2)] significantly less compared to group PCA [1 (0, 2) (0 – 3)] with a median difference (95% CI) 1 (-1.12 to -0.21) (p=0.014). Yayik et al[41] also found that additional analgesic requirements (25 mg pethidine) was significantly less (10 patients in the control group and 3 patients in the ESP group) (p = 0.028) in patients receiving ESP block. Swati Singh et al[24] in their study also found that all 20 patients in the control group required morphine for rescue analgesia, compared with only 9 (45%) in the ESP block group (P=0.002).

***Adverse Events*:**

In our study, none of the patients in the ESP block group had block related adverse events while a significant proportion of patients in the PCA group experienced opioid related side effects. In group PCA, 10 patients had sedation, 5 had nausea vomiting and 2 had pruritus. Finnerty et al[47] also reported significantly less nausea vomiting in patients receiving ESP block. Other studies[24,25,41] have also reported patients receiving ESP block had less chances of nausea and vomiting compared to the control group.

***Satisfaction score*:**

In our study, the median (IQR) (range) satisfaction score of group ESP was 1 (1, 2) (1 – 3) (excellent) and while in group PCA was 3 (2, 3) (1 – 3) (fair). Finnerty et al[47] measured the quality of recovery-15 (QoR-15) score which is composed of 15 questions (scored 0–10) about pain, physical comfort, physical independence, psychological state and emotional state. They found that ESP block increased the

QoR-15 score (95%CI) at 24 postoperative h by 13 (4–22), p = 0.0041. Singh et al[24] also found that patients in the ESP block group were more satisfied than those in the control group; the mean (median deviation) satisfaction scores were 5.5 (0.74) and 7.7 (0.45) in the control and ESP block groups, respectively (P<0.0001).

**Strengths of our study:**

1. All the blocks were performed by a single anaesthesiologist throughout the study period.
2. All the blocks were performed using ultrasound guidance.
3. Randomization and allocation concealment was strictly followed throughout the study.
4. We used continuous catheter technique for ESP block with continuous infusion of local anaesthetic in the postoperative period which provided long lasting analgesia.

**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. Anatomically we could not measure the exact local anaesthetic spread after injection and did not assess the dermatomal coverage post block placement either.
4. 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

The ultrasound guided bilateral continuous ESP block is a safe and more effective alternative to opioid based analgesia as a component of multimodal pain management for patients undergoing multilevel spine surgery. Use of ESP block reduces opioid consumption and its associated side effect with better patient's satisfaction in relieving acute postoperative pain after multilevel spine surgery.

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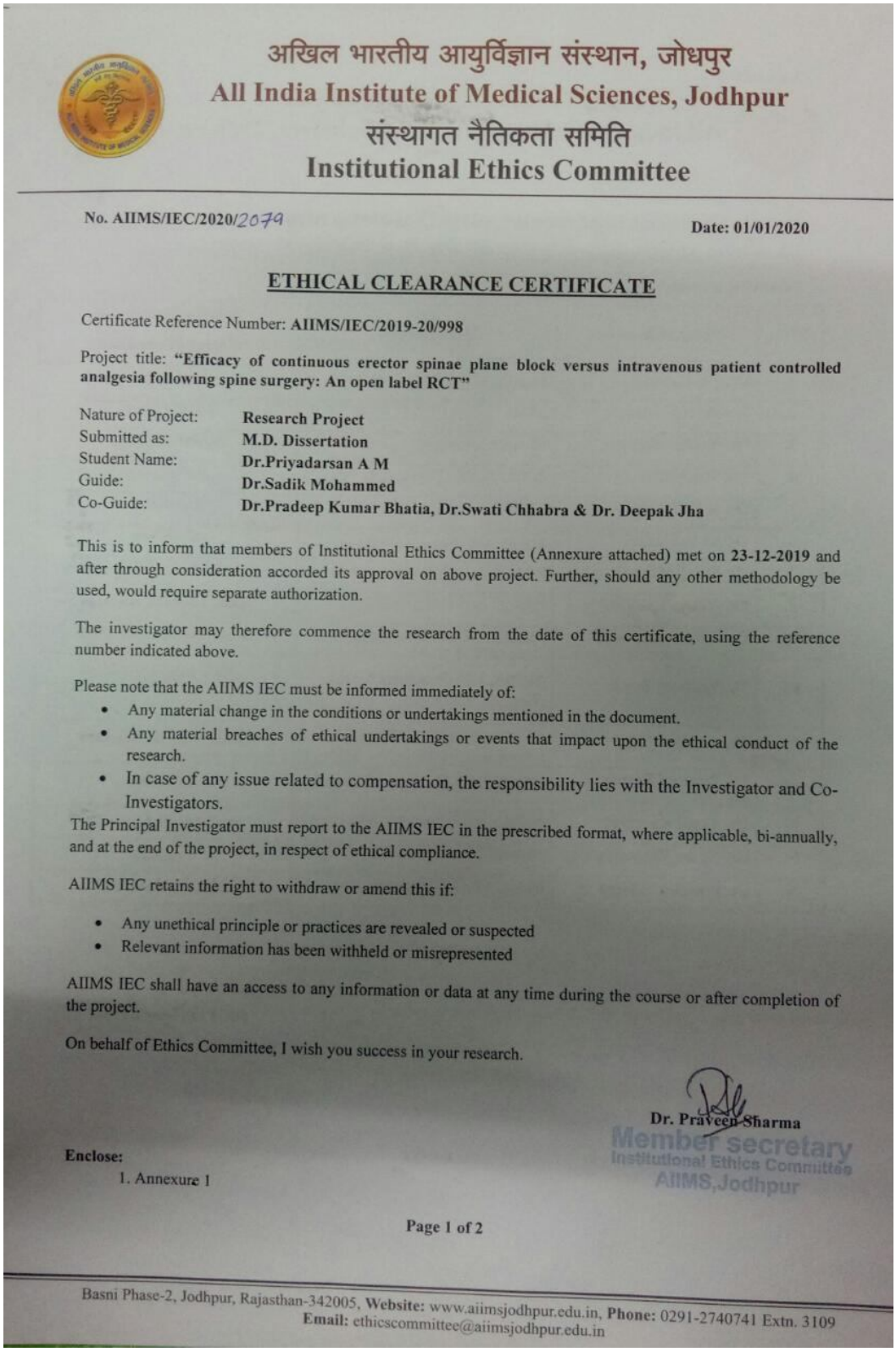
# ANNEXURES

## 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/2020/2079 Date: 01/01/2020

**ETHICAL CLEARANCE CERTIFICATE**

Certificate Reference Number: **AIIMS/IEC/2019-20/998**

Project title: **"Efficacy of continuous erector spinae plane block versus intravenous patient controlled analgesia following spine surgery: An open label RCT"**

| | |
|---|---|
| Nature of Project: | **Research Project** |
| Submitted as: | **M.D. Dissertation** |
| Student Name: | **Dr.Priyadarsan A M** |
| Guide: | **Dr.Sadik Mohammed** |
| Co-Guide: | **Dr.Pradeep Kumar Bhatia, Dr.Swati Chhabra & Dr. Deepak Jha** |

This is to inform that members of Institutional Ethics Committee (Annexure attached) met on **23-12-2019** and after through consideration accorded its approval on above project. Further, should any other methodology be used, would require separate authorization.

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.

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

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

**Enclose:**
1. Annexure 1

Page 1 of 2

Basni Phase-2, Jodhpur, Rajasthan-342005, **Website:** www.aiimsjodhpur.edu.in, **Phone:** 0291-2740741 Extn. 3109
**Email:** ethicscommittee@aiimsjodhpur.edu.in

**All India Institute of Medical Sciences,**

**Jodhpur, Rajasthan**

**INFORMED CONSENT FORM**

Title of the project: **Efficacy of continuous erector spinae plane block versus intravenous patient-controlled analgesia following spine surgery: An open label RCT**

Name of the Principal Investigator: Dr. Priyadarsan A M Tel. No. 9578680541

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: _____

**All India Institute of Medical Sciences**
**Jodhpur, Rajasthan**

# सूचित सहमति प्रपत्र

थीसिस / निबंध का शीर्षक: **स्पाइन सर्जरी के बाद लगातार इरेक्टर स्पिना प्लेन ब्लॉक और**

**अंतःशिरा रोगी नियंत्रित एनाल्जेसिया की प्रभावकारिता**

पीजी छात्र का नाम: डॉ प्रियदर्शन ए एम टेल न: 9578680541

रोगी / स्वयंसेवक पहचान संख्या: _____

मैं, _____ पुत्र / पुत्री _____

पता_____

अध्ययन "_____ " का एक भाग

बनने के लिए मेरी पूर्ण, स्वतंत्र, स्वैच्छिक सहमति दें, जिसकी प्रक्रिया और प्रकृति मुझे अपनी पूरी संतुष्टि के लिए अपनी भाषा में समझाई गई है। मैं पुष्टि करता हूं कि मुझे प्रश्न पूछने का अवसर मिला है।

मैं समझता हूं कि मेरी भागीदारी स्वैच्छिक है और मुझे किसी भी कारण दिए बिना किसी भी समय अध्ययन से बाहर निकलने के मेरे अधिकार की जानकारी है।

मैं समझता हूं कि मेरे और मेरे मेडिकल रिकॉर्ड के बारे में एकत्रित की गई जानकारी को _____ (कंपनी नाम) या विनियामक प्राधिकरणों से जिम्मेदार व्यक्ति द्वारा देखा जा सकता है। मैं इन व्यक्तियों को अपने अभिलेखों तक पहुंच के लिए अनुमति देता हूं I

तारीख: _____ _____

जगह: _____ हस्ताक्षर / बाएं अंगूठे का छाप

यह प्रमाणित करने के लिए कि मेरी उपस्थिति में उपरोक्त सहमति प्राप्त की गई हैI

तारीख: _____ _____

जगह: _____ पीजी छात्र के हस्ताक्षर

| गवाह 1 | गवाह 2 |
|---|---|
| _____ | _____ |
| हस्ताक्षर | हस्ताक्षर |
| नाम_____ | नाम_____ |
| पता_____ | पता_____ |

# PATIENT INFORMATION SHEET

1. Risks to the patients: No interventions or life-threatening procedures 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 individuals 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 पत्रक

1. रोगियों के लिए जोखिम: कोई हस्तक्षेप या जीवन-धमकी प्रक्रिया नहीं की जाएगी।
2. गोपनीयता: आपकी भागीदारी को गोपनीय रखा जाएगा। आपके मेडिकल रिकॉर्ड को गोपनीयता के साथ इलाज किया जाएगा और केवल इस अध्ययन में शामिल डॉक्टरों / वैज्ञानिकों को पता चलेगा। इस अध्ययन के परिणाम एक वैज्ञानिक पत्रिका में प्रकाशित हो सकते हैं, लेकिन आपको नाम से पहचाना नहीं जाएगा।
3. अनुसंधान संबंधी चोट के लिए नि: शुल्क उपचार की व्यवस्था। लागू नहीं।
4. ऐसी चोट से उत्पन्न विकलांगता या मृत्युके लिए विषयों का मुआवजा: लागू नहीं है
5. किसी भी समय दंड या लाभों के नुकसान के बिना किसी भी समय भाग लेने के लिए व्यक्ति को स्वतंत्रता लेने और अनुसंधान से वापस लेने के लिए स्वतंत्रता, जिसके तहत विषय अन्यथा हकदार होगा
6. आपको जुर्माना या लाभ के नुकसान के बिना किसी भी समय भाग लेने और अनुसंधान से वापस लेने की पूरी आजादी है, जिस पर आप अन्यथा हकदार होंगे।
7. अध्ययन में आपकी भागीदारी वैकल्पिक और स्वैच्छिक है।
8. प्रदर्शन की जांच की परिणामों की प्रति आपके रिकॉर्ड के लिए आपको उपलब्ध कराई जाएगी।
9. आप किसी भी समय परियोजना से वापस ले सकते हैं, और यह आपके बाद के चिकित्सा उपचार या
10. उपचार चिकित्सक के साथ संबंध को प्रभावित नहीं करेगा।
11. परियोजना के लिए कोई भी अतिरिक्त व्यय, आपके नियमित खर्चों के अलावा, आपसे शुल्क नहीं लिया जाएगा।

# 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:** _____

**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)

**VAS Score at PACU: Rest-**_____; **Movement-**_____

| | **1HR** | **2HR** | **3HR** | **4 HR** | **Shifting** |
|---|---|---|---|---|---|
| **VAS Score at rest** | | | | | |
| **VAS Score at Movement** | | | | | |

**VAS SCORE at Ward**

| | **1HR** | **3HR** | **6HR** | **12HR** | **18HR** | **24HR** |
|---|---|---|---|---|---|---|
| **VAS Score at rest** | | | | | | |
| **VAS Score at Movement** | | | | | | |

**PCA pump: Total opioid consumed:**

**Bolus doses: Attempted: _____ Administered:_____**

**Number of Rescue Analgesia required:**

**SATISFACTION SCORE (at 24 hours postoperatively)**

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

**Side Effects (Y/N)**

Drowsiness_____; PONV_____; Respiratory Depression_____;

Itching_____; Urinary retention_____; Any other_____