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EFFICACY OF ULTRASOUND GUIDED ERECTOR SPINAE PLANE BLOCK FOR POST-OPERATIVE PAIN RELIEF IN HIP JOINT AND PROXIMAL FEMUR SURGERIES- A RANDOMIZED CONTROLLED STUDY.

Anaesthesiology

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ABSTRACT

Background & Aims: Erector Spinae Plane Block (ESPB), an interfascial technique, blocks dorsal and ventral rami of the spinal nerves. Primary aim of our study was to evaluate the efficacy of ultrasound guided lumbar ESPB in hip joint and proximal femur surgeries for post-operative pain relief in terms of duration of analgesia through Visual Analogue Scale (VAS) score. **Material & Methods:** After approval from institutional ethics committee for biomedical and health research, this randomized controlled study was carried out in 86 patients of 18-70 years of age. Patients were randomized into two groups using sealed opaque envelope method. All surgeries were conducted under spinal anaesthesia. At the end of surgery, Group E patients were given ultrasound guided ESPB at L4 transverse process level using an out of plane approach with 30 ml 0.25% Bupivacaine and Group S received Tramadol 1.5 mg/kg intravenously. Post-operative pain was assessed by VAS Score with duration of analgesia as our primary objective and number of rescue analgesic doses required in 24 hours being secondary objective. Significance of student 't' test was judged by P value< 0.05 as significant with parametric data presented as Mean ± SD form. **Results:** The duration of analgesia was 23.2±1.1 hours in Group E which was longer compared to 6.7±0.7 hours in Group S (P<0.0001). Mean number of rescue analgesic doses required in 24 hours was 0.4±0.5 in Group E which was much less compared to 2.4±0.5 in Group S (P<0.0001). **Conclusion:** Erector spinae plane block with 0.25% bupivacaine provides prolonged post-operative analgesia reducing requirements of post-operative opioids and other systemic analgesics in hip joint and proximal femur surgeries.

KEYWORDS

Ultrasound, Erector Spinae Plane Block, Post-operative Pain, Hip, and Proximal Femur Surgeries.

INTRODUCTION:

Orthopaedic operations like Total Hip Replacement (THR), Proximal Femur Nail (PFN) and Dynamic Hip Screw (DHS) can lead to significant post-operative pain. Appropriate analgesia not only reduce pain but also fasten recovery and shorten hospital stay.

Efforts have been made for regional analgesic strategies for reducing opioid consumption and consecutively, opioid related adverse effects. [1] Non-opioid analgesia techniques are important in aging populations when comorbidities are considered. [2] Side effects of opioids have led to increased use of novel analgesic techniques. [3] Erector Spinae Plane Block (ESPB) is such an inter-fascial plane block where injectant will spread to both dorsal and ventral rami of the spinal nerves, leading to blockage of both somatic and visceral pain producing effect like epidural analgesia. [4]

In ESPB, local anaesthetic injection is given between the erector spinae muscle and transverse process of the vertebra into tissue plane which is distant from major blood vessels, nerves, and pleura, so there is decreased potential of risk in giving peri-operative analgesia through ESPB. [5] Spread of the drug occurs cephalad, caudally and through the paravertebral space. [2] The advantages of ESPB are its simplicity, minimal risk for serious complications and easily identifiable ultrasonographic landmarks. Ultrasound guided techniques shorten the block performance and onset time significantly. [6]

Erector spinae plane block was first described by Forero et al in 2016 as an effective treatment method for thoracic neuropathic pain. [7] As part of a multimodal analgesia, ESPB has been found to be an effective and safe inter-fascial plane block with a large range of indications according to Serkan Tulgar et al in 2019. [8]

Thus, aim of our study was to assess the efficacy of ultrasound guided erector spinae plane block for post-operative pain relief in hip joint and proximal femur surgeries. Our primary objective was to estimate duration of analgesia and secondary objectives were to estimate number of rescue analgesic doses within 24 hours and assess vital parameters and complications if any.

MATERIAL & METHODS:

This prospective, randomized controlled study was carried out in total 86 patients in the Department of Anaesthesiology, at a tertiary care teaching hospital from April 2021 to October 2021. The study protocol was approved by the Institutional Ethics Committee for Biomedical and Health Research, on 03/02/2021 (IECBHR/21-2021). Clinical Trials Registry – India (CTRI) Registration Number is CTRI/2021/04/032741 (12/04/2021). We have used the CONSORT reporting guidelines. [9]

Considering number of rescue analgesic requirement doses in first 12 hours- 7 and 2 in control- Standard analgesia protocol group and case- Lumbar Erector spinae plane block group respectively, in parent reference, with 80% Power and 95% Confidence interval (CI), sample size was determined to be 43 in each group according to OpenEpi software. [2] Parent reference was "Comparison of ultrasound-guided lumbar erector spinae plane block and trans-muscular quadratus lumborum block for postoperative analgesia in hip and proximal femur surgery: A prospective randomized feasibility study."

Inclusion criteria included ASA I / II / III patients of either sex with age between 18-70 years, posted for hip joint and proximal femur surgeries. Patients who were able to give verbal and informed consent and understand VAS score were included.

Patients not willing, having allergy to local anaesthetics, having contraindication of spinal or regional anaesthesia, patients with

coagulopathy, local infection, pre-existing neurological deficits, history of drug or alcohol abuse, psychiatric illness, pelvic fracture were excluded. Surgeries lasted for more than 120 minutes were also excluded.

Patients suffering from moderate to severe arthritis of the hip posted for total hip replacement and patients with intertrochanteric and subtrochanteric femur fractures posted for proximal femur nailing were taken in our study. Random number sequence generation was computer software based (Randomiser.org). They were randomized into two groups with parallel group study design comprising of 43 patients in each group. Sequentially numbered, opaque, sealed envelope method was used for allocation. Consultant generated the allocation sequence by opaque, sequentially numbered envelopes. I as a trainee, enrolled participants, and assigned each participant to intervention as per the allocated envelope.

All patients underwent a thorough pre-anaesthetic check-up which included detailed history with general and systemic examination. Routine and specific investigations were advised as required. Patients were thoroughly explained about the procedure with its benefits and side-effects. VAS score was also explained. On the day of operation, after confirming nil by mouth status, written informed consent was taken. In operation theatre, we secured 18 G intravenous (IV) cannula and started ringer lactate drip. Vital parameters- systolic and diastolic blood pressure, pulse rate and oxygen saturation were recorded. Premedication IV injection Ondansetron 4 mg, Glycopyrrolate 0.2 mg (5 min before spinal anaesthesia), Midazolam 1 mg (5 min after spinal anaesthesia) were given.

In this study, a total of 86 patients undergoing hip joint and proximal femur surgeries were given spinal anaesthesia under all aseptic and antiseptic precautions in sitting position, at the level of L3-L4 or L4-L5 space using 23-gauge spinal needle with 3ml of hyperbaric bupivacaine 0.5%.

At the end of surgery after closure of the wound, In Group E (Spinal+ ESPB) (n=43), patients were given ultrasound guided erector spinae plane block with 30 ml inj. bupivacaine 0.25%.

In Group S (Spinal) (n=43), patients were given inj. tramadol 1.5 mg/kg IV in 100 ml normal saline as infusion.

In group E, ultrasound guided erector spinae plane block was given in lateral position after surgery done under spinal anaesthesia. Surgical side leg was kept in the nondependent position (Fig.1). Post-operatively in THR patient, surgical side leg was already kept in non-dependent position; wherein PFN patient, patient was given lateral position from supine with due care for the purpose of administering block.

After all aseptic precautions, a convex ultrasound transducer [10] was placed in a longitudinal parasagittal orientation 4-6 cm lateral to desired spinous process (Fig.1). The erector spinae muscle was identified superficial to the tip of L4 transverse process on the nondependent side (Fig.2). [11]

Figure 1: Position of the patient, placement of transducer probe and needle. (Original)

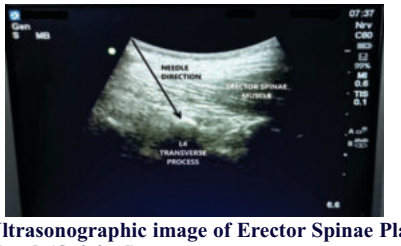

Figure 2: Ultrasonographic image of Erector Spinae Plane block at Lumbar level. (Original)

(Image shows transverse processes of L3, L4, L5 vertebrae as white hyperechoic lines and below black acoustic shadows.)

A 22G, 10 cm needle was inserted using an out-plane superior to inferior approach until contact made with the L4 transverse process. After that, needle was withdrawn for 1-2 mm and needle tip location was confirmed by injecting 0.5 -1 ml distilled water and seeing the fluid lifting the erector spinae muscle off the bony shadow of the transverse process. A total volume of 30 ml 0.25% inj. bupivacaine was injected. [12] Drug was injected deep to the erector spinae muscle for more dynamic and extensive spread. [13]

In group S, inj. tramadol 1.5 mg/kg IV in 100 ml normal saline as infusion was given to the patients at the end of surgery.

Post-operatively, patients were shifted to High Dependency Unit (HDU) for at least 2 hours under observation. Patients were evaluated for duration of analgesia using VAS score, number of rescue analgesic doses required in 24 hours, vital parameters and complications if any. Rescue analgesia was given in the form of inj. paracetamol 15 mg/kg IV at VAS score≥4.

Duration of analgesia is the time interval from end of injection of drug to first rescue analgesic drug required. Total number of rescue analgesic doses required in 24 hours is evaluated as number of doses of inj. paracetamol consumption 15 mg/kg IV in first and second 12 hours. Pain was assessed using 10-point VAS score. Patients were explained about this scoring system and were asked to mark a vertical mark on the scale which would reflect the intensity of pain, which they would experience at that time. VAS score was assessed every one hour for first six hours, every six hours for next 24 hours. Post-operative vital parameters like mean pulse rate, mean systolic blood pressure, mean diastolic blood pressure, mean SpO2 (oxygen saturation) were assessed at intervals in both the groups.

Statistical analysis was done using MedCalc statistical software. Data was presented in Mean ± SD form. Parametric data was analyzed by student 't' test & non-parametric data by Chi square test in both groups. Significance of student 't' test was judged by P value. P> 0.05 was considered not significant, P< 0.05 significant.

Complications either due to procedure or drugs used were observed during post-operative period and treated as per need. Immediate complications like bradycardia, hypotension, nausea, vomiting, arrhythmias, systemic local anesthetic toxicity, allergic reaction or rarely anaphylaxis and delayed complications like infection, backache-headache due to spinal anaesthesia were observed and treated accordingly.

RESULTS:

This study was carried out in total 86 patients undergoing hip joint and proximal femur surgeries as shown in Consort diagram (Fig.3).

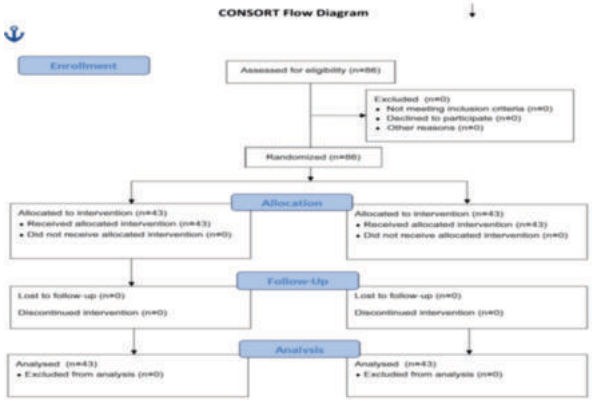

Figure 3: Consort Diagram (Original)

Demographic data is shown in the table 1. The age range was 18-70 years in both groups.

Table 1: Demographic Data And Type Of Surgeries:

PARAMETERS	GROUP E	GROUP S
AGE (in years) Mean ± SD*	49.35±16.55	50.63±13.80

SEX (Male: Female) (%)	29:14 (67%:33%)	27:16 (63%:37%)
ASA Grade (I II III)	8:25:10 (19%:58%:23%)	7:27:9 (16%:63%:21%)
TYPE OF SURGERIES - PFN: THR (Proximal Femur Nail: Total Hip Replacement)	24:19 (56%:44%)	26:17 (60%:40%)

***** Standard Deviation

Post-operative analgesia was assessed in the form of VAS score and total number of rescue analgesic doses requirement within 24 hours post-operatively as described in figure 4 and table 2 respectively.

Duration of analgesia in group E was 23.2 ± 1.1 hrs. and in group S was 6.7 ± 0.7 hrs. which was suggestive of prolonged postoperative analgesia in group E. It was statistically significant with 95% Confidence Interval: 22.9-23.5; p<0.0001. Standardized effect size was 23.57 and Cohen's term d was ≥0.8 (14.8) (large effect size index).

As shown in figure 4, VAS score at 1st, 2nd, 3rd, 4th, 5th, 6th, 12th, 18th hour postoperatively was significantly low in group E as compared to group S. (P <0.0001: significant). At 24th hour, VAS score was comparable in both the groups. In group S, rescue analgesics were required frequently (at VAS score≥4) and those were around 6th, 18th and 24th hour as compared to once around 21st to 24th hours or not required in 24 hours in group E.

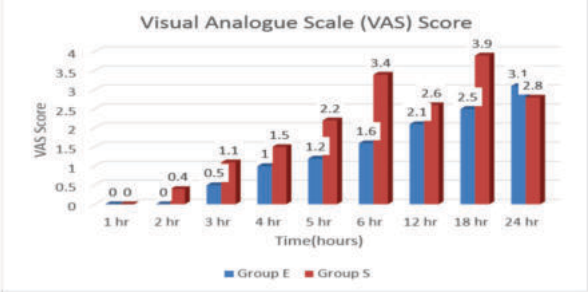

Figure 4: Graph of VAS score at different time intervals (Mean value) (Original)

On applying repeated measures ANOVA for correction of multiple comparisons for VAS score taken at multiple time points, we obtained F statistics 269.94 and p value of <0.001, which means that at all time points, VAS score of group E was better as compared to group S and it was statistically significant.

In group S, 17 (40%) patients required three doses of rescue analgesics and 26 (60%) patients required two doses of rescue analgesics within 24 hours postoperatively. In group E, 26 (60%) patients did not require any rescue analgesic whereas 17 (40%) patients required only one dose of rescue analgesic. Total number of rescue analgesic doses requirement in 24 hours was statistically significantly higher in Group S (Mean 2.4) as compared to Group E (Mean 0.4) as shown in table 2.

Table 2: Total Number Of Rescue Analgesic Doses Requirement Within 24 Hours:

Total number of rescue analgesic requirement	Group E (Mean ± SD*)	Group S (Mean ± SD*)	'p' value
First 12 hours	0 ± 0	1 ± 0	<0.0001 (significant)
Second 12 hours	0.4 ± 0.5	1.4 ± 0.5	<0.0001 (significant)
Total	0.4 ± 0.5	2.4 ± 0.5	<0.0001 (significant)

*Standard Deviation

Inter-group comparison showed no significant change statistically in mean oxygen saturation (SpO2) in both the groups (p>0.05). On applying repeated measures ANOVA for correction of multiple comparisons taken at multiple time points for Systolic Blood Pressure (SBP), we obtained F statistics 0.63 and p value 0.47. Same applied to Diastolic Blood Pressure (DBP), F statistics and p value obtained were 2.13 and 0.129. And for pulse rate, F statistics and p value were 0.16 and 0.76. These values mean that at all time points, there were no significant difference between two groups for SBP, DBP and pulse rate respectively.

Patients were observed for possible peri-operative complications either due to the procedure or the drugs used. In group E, two patients (4.65%) developed severe hypotension, which was treated with intravenous fluids, vasopressors. Nausea was observed in 3 (7%) patients of group S as they were given tramadol injection post-operatively. It was managed with inj. metoclopramide. No other complications were noted in both groups.

DISCUSSION:

Erector spinae plane block is an inter-fascial plane block where injectant spread to both the dorsal and ventral ramus of the spinal nerves, leading to blockage of both somatic and visceral pain producing similar effect like epidural analgesia. [4] Its mechanism of action is likely linked to the transforaminal and epidural spread, which may be a potential advantage over other interfascial plane blocks. Erector spinae plane block has been given similarly like ultrasound guided paravertebral block and has similar mechanism of action also because it is gaining indirect access to the paravertebral space but with less complications. [1]

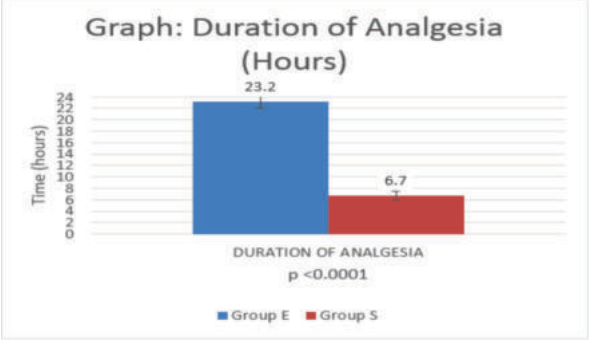

Figure 5: Graph of duration of analgesia (Mean time) (Original)

Group E patients had significantly longer duration of postoperative analgesia and the requirement of rescue analgesic doses been also significantly reduced. (p<0.0001: significant). This is due to the anatomical relation of the erector spinae muscle relative to the vertebra and neuroforamen enabling the clinician to target a wide dermatomal distribution with a single site of injection and due to its indirect access into the paravertebral space. [1]

Tramadol is synthetic, centrally acting opioid. It is a weak μ agonist and it causes inhibition of reuptake of serotonin and noradrenaline. Compared to Morphine, it causes less respiratory depression, less urinary retention, and has minimal hemodynamic effects. Here in our study, as per our institution's protocol, we had given inj. Tramadol post-operatively as a part of standard intravenous analgesia regimen. We noted side effect nausea in 7% patients requiring inj. Metoclopramide. None of the patient receiving tramadol developed headache.

A systematic review and meta-analysis by Bo Jiao et al (2022) [15] also suggested opioid-sparing effect and effective analgesia of ultrasound-guided ESPB.

Our study was in consonance with the **study of Serkan Tulgar et al (2018)** [2]. It demonstrated that number of rescue analgesic doses requirement in first 12 hours were 7, 2, 2 respectively in control group with IV tramadol and paracetamol injections, lumbar erector spinae plane block group, trans-muscular quadratus lumborum block group for post-operative analgesia in hip and proximal femur surgery. They noted number of patients required rescue analgesic doses in 24 hours were significantly higher in the control group compared to both block groups. According to study, Lumbar ESPB improve analgesia quality in patients undergoing hip and proximal femoral surgery when compared to standard intravenous analgesia regimen.

Results were in consonance with **meta-analysis of Jiao Huang et al (2020)** [16] aimed to determine the clinical efficacy of ultrasound-guided ESPB in adults undergoing general anaesthesia (GA) surgeries. It showed a reduction of IV opioid consumption 24 h after surgery (p<0.00001). It reduced the number of patients who required

postoperative analgesia and prolonged time to first rescue analgesia.

We have used 0.25% inj. Bupivacaine, an amide local anaesthetic for ESPB as it provides prolonged duration of analgesia. [14] We can say that patient is benefited by satisfactory pain relief of prolonged duration after major orthopaedic operation. Due to ESPB, opioid consumption will be less and thereby side effects of opioid and hospital stay, costs will be less. ESPB helps in development of opioid-free anaesthesia. There are no controversies raised by our study.

Strength is that ESPB is a safe and effective post-operative analgesic approach for hip joint and proximal femur surgeries. Chosen objectives were easily assessable. Position of the patient post-operatively for block was not problematic for fracture and non-interfering to operated site. Ultrasound guidance led to easy needle insertion and drug deposition under vision.

Limitation includes lack of blinding. The Investigator was researcher and data-analyzer, so blinding was not done as observer. Patient blinding was not done due to different techniques involved as one group was given block and other group was given intravenous injection. Scanning at lumbar level requires curvilinear probe as compared to thoracic level. So, in plane insertion of needle requires more practice. In our study, we have used out of plane technique for needle insertion.

In group E, two patients (4.65%) developed severe hypotension, which was treated well with intravenous fluids, vasopressors. Drug deposition directly into paravertebral space may be the likely cause for sudden hypotension. It was a complication requiring immediate intervention with IV fluids and inj. ephedrine. Patients were observed for 2 hours in HDU. Once stabilized, patients were observed for further 6 hours in ward for hypotension. One should be cautious while injecting drug in erector spinae plane and needle should not go beyond transverse process of vertebra. Frequent aspiration should be done while injecting drug.

Multi-centric studies can be done using other local anaesthetic agents, with other additives and comparing with other blocks like paravertebral block. Future studies are required for evaluating onset of analgesia, motor, and sensory blockade after ESPB and in plane method of needle insertion technique. Systematic review of Randomized Controlled Trials (RCTs) of lumbar ESPB for hip joint and femur surgeries should be the next step which can include this RCT.

CONCLUSION:

We can conclude that Ultrasound guided Erector spinae plane block provides prolonged post-operative analgesia with minimal complications reducing requirements of post-operative opioids and other systemic analgesics in hip joint and proximal femur surgeries.

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Conflicts Of Interest: None.

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Clinical Trial Registration Number: CTRI/2021/04/032741

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