

EVALUATION OF POSTOPERATIVE ANALGESIC EFFECT OF ULTRASOUND GUIDED ERECTOR SPINAE PLANE BLOCK FOR PATIENTS UNDERGOING PERCUTANEOUS NEPHROLITHOTOMY SURGERY: A RANDOMIZED CONTROLLED TRIAL

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Abstract

Background: Erector spinae plane block was recently introduced as an alternative to postoperative analgesia in surgical procedures including percutaneous nephrolithotomy, thoracoscopy, mastectomy and cholecystectomy. This study was conducted to assess its efficacy in patients undergoing elective PCNL surgeries under general anaesthesia with respect to postoperative analgesia. **Materials and Methods:** Randomized controlled study was conducted in 44 patients of either sex aged 18-65 years of ASA (I-III) undergoing elective unilateral PCNL surgery. Patients were randomly allocated into two groups of 22 each, Group A patients received general anesthesia alone and Group B patients received ultrasound guided ESPB using 20 ml of 0.5% bupivacaine before general anesthesia. **Result:** The demographic parameters were similar in both groups. The total tramadol consumption in Group A was 166.55 ± 45.441 mg and in Group B it was 58.57 ± 36.951 mg p = 0.000. The mean duration of postoperative analgesia in Group A was 27.27 ± 34.52 minutes and in Group B it was 440.95 ± 374.138 minutes p = 0.000 **Conclusion:** ESPB reduces the cumulative consumption of tramadol, prolongs the duration of analgesia, lowers the pain score compared with conventional analgesia.

INTRODUCTION

Percutaneous nephrolithotomy (PCNL) in patients with renal stones is an effective, minimally invasive endourological surgical procedure.^[1] It is usually accompanied by severe pain and chest discomfort peri-operatively. The main source of acute pain after PCNL are visceral pain originating from the kidneys and ureters (T10-L2) due to dilatation of the renal capsule and the parenchymal tract and somatic pain from the incision of skin, subcutaneous tissue and muscle layer, the presence of nephrostomy tube (T8-T12).^[1,2]

The regime for providing post-operative analgesia includes several systemic analgesics [opioids, non-steroidal anti-inflammatory drugs (NSAIDs)], paracetamol, and regional techniques (subcutaneous infiltration, peritubal infiltration, intercostal nerve block (ICNB), paravertebral block (PVB), epidural analgesia³ Managing this pain with opioids can lead

to sedation, nausea, vomiting, and constipation, which defeat the purpose of this minimally invasive procedure.^[3,4]

NSAIDs can have potential systemic side effects (e.g., gastritis) in these patients with possible kidney injury.

Regional analgesia is an important modality in perioperative care of these patients. The use of ultrasound has further increased the safety of various regional anaesthetic techniques.

Erector spinae plane block is a new interfascial block that has been proven to block somatic and visceral nerves to provide analgesia. It was first introduced by Forero et al in 2016 as a mode of analgesia in patients with thoracic neuropathic pain.^[5] Local anaesthetic injected in the plane between the erector spinae muscle and the transverse process, exerts its effect by diffusing into the paravertebral space through spaces between two vertebrae. The anaesthetic then acts both on the

dorsal and ventral branches of thoracic and lumbar spinal nerves.^[6]

The indications for the block then extended from thoracic surgeries to upper abdominal surgeries. This block is easy to perform, has a high success rate, and carries minimal complications when performed by an anaesthesiologist skilled in ultrasound-guided blocks.

The plane block usage is increasing in popularity as it decreases pain as estimated by numeric rating pain scores postoperatively and decreases the need for postoperative narcotic analgesic usage thereby reducing opioid and NSAIDs induced complications. They also shorten Post-Anaesthesia Care Unit stay time and increases patient satisfaction by causing less interference with the physiology of our body.

The use of ultrasound guidance for performance of the block increases the success rate, reduces block performance times, improves quality of block, reduces the local anaesthetic doses needed and reduces the chance of complications.

Despite these advantages there are only few clinical trials and case reports available regarding efficacy of ESPB in PCNL surgeries. Hence the aim of this study is to evaluate the efficacy of ESPB in post-operative analgesia in patients undergoing elective PCNL surgeries under general anaesthesia.

MATERIALS AND METHODS

This study Prospective randomized controlled trial was done on admitted at Major OT Complex, Dept. of Anesthesiology, VIMS, Ballari. Forty-four patients of either sex in the age group of 18-65years of ASA (I - III) posted for elective percutaneous nephrolithotomy surgery. Duration of study period was one year (from November 2020 to November 2021). Ethical clearance was obtained from the institutional ethical committee for the present study. Informed consent was taken from the parents study subjects. This study was conducted after registration under Clinical Trials Registry of India (CTRI/2021/02/031402). The patients were included in the study by applying the inclusion and exclusion criteria.

Methods of Collection of Data

After thorough pre-anesthetic evaluation and overnight fasting, patients shifted to operation theatre and following monitors are connected. (Pulse oximeter, electrocardiogram, capnograph and noninvasive Blood pressure).

All patients were premedicated with Inj Midazolam 0.03 mg/kg and Inj Fentanyl 1µg/kg. Patients were randomly allocated into 2 groups (Group A and Group B) as per computer generated randomization table.

Allocation concealment was done using sequentially numbered, opaque sealed Envelope (SNOSE) technique.

Group A - Patients received general anaesthesia alone

Group B - Patients received ultrasound guided erector spinae plane block (ESPB) using 20 ml of 0.5% bupivacaine prior to general anaesthesia.

Group A patients were directly shifted to operation theatre from premedication room and patients assigned to group B were shifted to procedure room for the block.

Ultrasound guided Erector spinae plane block was performed with patients lying in prone position with the arm and elbow flexed. The location of tenth rib was found using a counting down approach from the first rib under ultrasonography and marked on the skin. Under aseptic precautions, high frequency(6-13MHz) 38mm linear array probe (Micromax Sonosite™, US) placed in parallel to the vertebral axis at the level of the tenth rib, the probe then moved from the lateral side to medial side transversely to identify any change in shape that transited the rib and transverse process (TP).

When the round shadow of the rib shifted into the rectangular shape of the TP, an 18 G Tuohy needle was inserted toward the trapezius, erector spinae and the Transverse Process of T10 using in-plane technique in a cephalad to caudal direction.

Once the needle made contact with the transverse process, the fascial plane was well confirmed by injecting 2ml of normal saline. A total of 20 ml of 0.5% bupivacaine was injected through the needle under ultrasound guidance.

After administering the block, the sensory level was assessed by a blinded observer with pinprick sensation every 5 min in each dermatomal distribution from T7 to L2. If the pinprick sensation did not decrease in any segment up to 30 min, it was considered as a block failure.

Basal recordings of hemodynamic parameters such as HR, SBP, DBP, MAP was observed and recorded just before the administration of block, every 5 minutes after administration till 30 minutes, at the time of skin incision and every 10 minutes intraoperatively following induction of general anaesthesia till extubation and postoperatively at 0 min, 20 min, 40 min, 60min, then hourly for first 2 hours and at 4,6,12,24 hrs after extubation.

Following the block procedure, induction of general anesthesia was performed using IV propofol (2–3mg/kg) and fentanyl (1.5 µg/kg). Then, tracheal intubation was performed after administration of vecuronium 0.1mg/kg. Anesthesia was maintained with a isoflurane 0.8-1% with oxygen-nitrous oxide mixture at a ratio of 1:1 which is adjusted to maintain SpO₂ >97% while minute ventilation was adjusted to maintain the end-tidal CO₂ in the range of 34–38mm Hg. Intermittent boluses of fentanyl 0.5 µg/kg were used to achieve adequate depth of anesthesia, which maintain heart rate and systolic blood pressure at not more than 20% of the baseline readings.

Monitoring during maintenance included pulse oximetry, an electrocardiogram, non-invasive blood pressure (NIBP) and end-tidal carbon dioxide.

All the patients were administered inj.paracetamol 1g iv 8th hourly in PACU for postoperative analgesia. Postoperative nausea and vomiting were recorded and treated with inj.ondansetron 8 mg if they occurred.

Post-operative pain was assessed at at 0 min, 10 min, 30min, then hourly for first 2 hours and at 4,6,12,24 hrs after extubation using Numeric rating scale (NRS).

Inj.tramadol 1 mg/kg IV is used as rescue analgesic when NRS score is ≥ 4 .

In this study, pain was assessed using Numerical rating scale (NRS) postoperatively.

NRS for pain is a uni-dimensional measure of pain intensity and is simple, adaptable to wide range of population.

NRS score is a reliable tool to assess pain intensity and to determine the effectiveness of pain treatments, and the need to change in the post-surgical patient.

In this scale of 0 to 10 patient state the number that best shows how bad his or her pain with 0 being no pain and 10 being severe pain.

Statistical Analysis: Data was analyzed with SPSS@ Version 26.0 (IBM SPSS statistics for Windows, Armonk, NY: IBM Corp; 2011) software. The relationship between variables was analyzed using ANOVA, Pearson correlation coefficient, Students T test and Chi Square test. P value <0.05 was considered statistically significant.

RESULTS

44 patients of ASA I - III undergoing elective unilateral percutaneous nephrolithotomy surgery under general anaesthesia in two groups were assessed postoperatively for pain using NRS. The mean age of patients in group A was 42.41 ± 11.048 and in group B it was 39.19 ± 14.79 , with p value of 0.422. Age in both the groups were comparable.

There was no statistical difference in age and sex distribution among both groups.

Mean weight in group A was 60.07 ± 12.42 and group B was 57.67 ± 9.23 with p value of 0.478. Weight in both the groups were comparable. Mean height in group A was 1.53 ± 0.097 and in group B it was 1.54 ± 0.094 with a p value of 0.704. Height in both the groups were comparable. Mean BMI in group L was 25.52 ± 4.93 and in group B was 24.09 ± 3.76 with p value of 0.292. BMI in both groups were comparable.

All patients posted for elective PCNL surgery belonged to ASA PS I -III. Out of 44 patients 19 were ASA PS I of which 10 and 9 were in group A and B respectively. Of the 20 belonging to ASA PS II 9 were in Group A and 11 were in group B. Of the 4 patients belonging to ASA PS III 3 were in group A and 1 were in group B with no statistically significant differences between two groups.

The mean duration of surgery in group A was 123.64 ± 20.77 minutes and group B it was 138.57 ± 25.33 minutes and there was statistically significant difference between the groups.

NRS scores were compared postoperatively at 0 min, 10 min, 30 min, 1hr, 2hr, 4hr, 6hr, 12hr and 24hr. At $NRS \geq 4$, rescue analgesia was given. The median NRS score in Group B patients were significantly lower for 6 hours postoperatively compared to Group A.

The mean duration of analgesia in group A was 27.27 ± 34.52 min and group B it was 440.95 ± 374.13 min. The p value was 0.000 which is statistically significant. The duration of analgesia in Group B is significantly more than Group A.

The mean dose of inj Tramadol in group A was 166.55 ± 45.44 and in group B it was 58.57 ± 36.95 , with p value of 0.000 which is significant statistically. The dose of rescue analgesia required in Group A is significantly higher than that of Group B.

Hemodynamic variables such as HR, SBP, DBP, MAP, SpO2 were measured. Basal parameters in both the groups were comparable and were not significant statistically.

Table 1: Postoperative NRS scores of patients in group A and group B at various time interval

Group	Time interval	Median	Minimum	Maximum	Interquartile value
Group A	0 min	3.00	0.00	8.00	5.25
	10 min	2.00	0.00	8.00	4.00
	30 min	3.00	0.00	6.00	2.00
	1hr	3.00	0.00	7.00	2.00
	2hr	4.00	2.00	6.00	3.25
	4hr	3.00	2.00	6.00	2.00
	6hr	3.00	2.00	6.00	2.25
	12hr	2.00	0.00	4.00	2.00
	24hr	1.00	0.00	2.00	2.00
Group B	0 min	0.00	0.00	3.00	2.00
	10 min	0.00	0.00	3.00	2.00
	30 min	1.00	0.00	3.00	2.00
	1hr	2.00	0.00	3.00	1.00
	2hr	2.00	0.00	3.00	2.50
	4hr	2.00	0.00	4.00	3.50
	6hr	3.00	0.00	5.00	2.00
	12hr	3.00	0.00	4.00	2.00
	24hr	1.00	0.00	2.00	2.00

Table 2: Comparison of baseline vital parameters between the two groups.

Basal Parameters	Group	N	Mean	Std. Deviation	P Value
HR (bpm)	Group A	22	85.41	13.841	0.328
	Group B	21	90.05	16.812	
SBP (mm hg)	Group A	22	124.18	14.325	0.563
	Group B	21	127.24	19.743	
DBP (mm hg)	Group A	22	80.45	9.298	0.609
	Group B	21	78.76	12.124	
MAP (mm hg)	Group A	22	93.77	9.670	0.681
	Group B	21	92.29	13.620	
SPO2(%)	Group A	22	98.82	0.733	0.466
	Group B	21	98.62	1.024	

Table 3: Comparison of intubation parameters between the two groups

Intubation Parameters	Group	N	Mean	Std. Deviation	P Value
HR (bpm)	Group A	22	88.45	13.588	0.444
	Group B	21	83.67	25.494	
SBP (mm hg)	Group A	22	122.55	15.358	0.586
	Group B	21	119.90	16.180	
DBP (mm hg)	Group A	22	78.95	11.713	0.531
	Group B	21	76.62	12.516	
MAP (mm hg)	Group A	22	92.73	12.792	0.470
	Group B	21	89.90	12.554	
SPO2(%)	Group A	22	99.32	0.646	0.756
	Group B	21	99.38	0.669	

Intubation and skin incision parameters in both the groups were comparable and were not significant statistically. Intubation and skin incision parameters in both the groups were comparable and were not significant statistically.

Table 4: Comparison of skin incision parameters between the two groups.

Skin incision Parameters	Group	N	Mean	Std. Deviation	P Value
HR (bpm)	Group A	22	84.55	12.805	0.803
	Group B	21	83.48	15.108	
SBP (mm hg)	Group A	22	117.86	14.393	0.243
	Group B	21	113.19	11.197	
DBP (mm hg)	Group A	22	76.73	8.686	0.159
	Group B	21	73.05	8.121	
MAP (mm hg)	Group A	22	89.73	10.714	0.174
	Group B	21	85.57	8.818	
SPO2(%)	Group A	22	99.50	0.598	0.055
	Group B	21	99.05	0.740	

The mean HR, Blood pressure, Spo2 were assessed at various intervals intraoperatively and were comparable between two groups.

Table 5: Comparison of intraoperative pulse rate between the two groups

Time interval	Group	N	Mean(bpm)	Std. Deviation	P Value
0	Group A	22	118.27	13.159	0.537
	Group B	21	113.43	10.962	
20 min	Group A	22	117.00	12.107	0.562
	Group B	21	115.48	12.139	
40 min	Group A	22	116.86	10.320	0.477
	Group B	21	114.95	12.627	
60 min	Group A	22	117.09	12.471	0.456
	Group B	21	119.53	12.756	
80 min	Group A	22	114.91	9.749	0.895
	Group B	21	118.26	12.431	
100 min	Group A	21	115.62	10.893	0.863
	Group B	21	118.80	18.159	
120 min	Group A	16	116.25	13.675	0.907
	Group B	21	119.23	20.425	
140 min	Group A	10	115.60	13.624	0.077
	Group B	21	134.00	15.875	
160 min	Group A	2	116.00	14.142	0.821
	Group B	21	113.00	0.000	

Table 6: Comparison of intraoperative mean arterial pressures between the two groups.

Time interval	Group	N	Mean (mm hg)	Std. Deviation	P Value
0 min	Group A	22	90.41	11.354	0.078
	Group B	19	84.71	9.095	
20 min	Group A	22	87.45	20.738	0.842
	Group B	19	88.43	8.370	
40 min	Group A	22	90.73	8.982	0.268
	Group B	15	87.57	9.432	
60 min	Group A	22	90.82	10.751	0.873
	Group B	13	90.32	9.019	
80 min	Group A	22	89.41	7.744	0.617
	Group B	3	88.16	8.126	
100 min	Group A	21	89.62	7.972	0.750
	Group B	1	90.60	10.377	
120 min	Group A	16	88.31	9.624	0.366
	Group B	21	92.00	11.091	
140 min	Group A	10	90.10	10.546	0.232
	Group B	21	98.67	9.074	
160 min	Group A	2	92.50	19.092	0.905
	Group B	21	89.00	0.000	

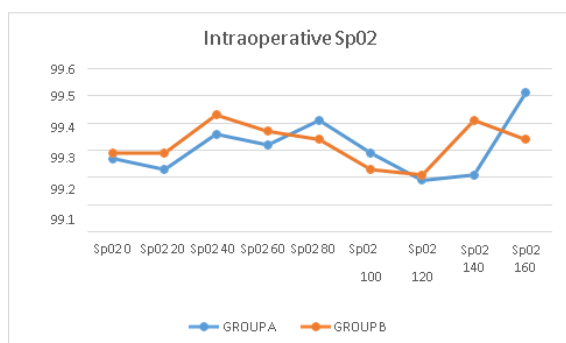


Figure 1: Comparison of intraoperative spo2

DISCUSSION

This RCT was conducted in forty-four ASA I-III patients aged 18–65 years, who underwent percutaneous nephrolithotomy (PCNL). Group A received only GA and Group B received Ultrasound guided ESPB before induction of GA. Important findings of our study were significantly lower cumulative consumption of tramadol, prolonged duration of analgesia and significantly lower NRS scores in ESPB group.

In our study we found a 35% (166.55 mg vs 58.57 mg) decrease in total tramadol consumption over 24 hr postoperatively which is comparable favorably with the study conducted by Gultekin MH et al.^[2] In a RCT they compared the analgesic efficacy of US guided ESPB using 20 ml of 0.5% bupivacaine with conventional IV analgesia in patients undergoing PCNL under GA and found 50% reduction in tramadol consumption in ESPB group.

In a study by Ibrahim et al.^[8] the efficacy of ESPB for intraoperative and postoperative analgesia for PCNL was evaluated with placebo group. The block was performed preoperatively at the level of T11 with linear US, and 30 ml of 0.5% bupivacaine was injected. Their postoperative analgesic regimen included iv paracetamol 1g 8th hourly and morphine 1 mg bolus with 10 mg basal infusion via attached PCA device. They observed a reduction in total morphine consumption by 4% (21.9 mg in block

group vs 28.4 mg in placebo group). The use of patient controlled analgesia and comparatively more potent morphine may explain the difference in comparison to our study. Wherein a study conducted by Bryniarski et al.^[9] a randomized controlled trial compared the efficacy and safety of ESPB for perioperative analgesia after PCNL with standard general anesthesia, the results were different from our study. In this study the intervention group received single shot US guided ESPB, 20 ml of 0.5% bupivacaine at T7 level preoperatively and dexamethasone 0.1mg/kg iv. Intraoperatively remifentanyl (0.08 - 2 µg/kg/min) were used for analgesia. They reported that the average nalbuphine consumption were similar in both the groups and explained that patients had most intense pain in 1st postoperative hours following discontinuation of remifentanyl infusion which let them use maximal acceptable dose in PCA. In our study, the patients who received ESPB had increased duration of analgesia (7 hours) than control group (27.27 minutes).

Mehmet et al.^[7] in their RCT compared the efficacy of ESP block with conventional analgesia in pain management after PCNL. The analgesic regimen included single shot US guided ESPB using 20 ml of 0.5% bupivacaine at T8 level after induction of GA and iv tramadol when VAS > 4 postoperatively. They found the duration of analgesia in ESPB group is 3 hours longer compared to control group.

These results could probably be attributed to difference in the level at which block is performed (T8) compared to T10 in our study to provide complete analgesia (T7-L2) in PCNL surgery and the different scoring system (VAS) adopted to evaluate pain in the study.

Ibrahim et al⁸ conducted a RCT comparing the analgesic efficacy of ESPB in patients undergoing PCNL with placebo group. Their findings in patients who received single shot US guided ESP block using 30 ml of 0.25% bupivacaine is 2.5 hours longer time to first use of PCA and reduced postoperative NRS score compared to placebo

group. The lower concentration of bupivacaine used could probably be the reason for minimal increase in duration of analgesia.

Similar studies by Bryniarski et al,^[9] and Prasad et al,^[10] found no statistically significant differences between 2 groups with regard to heart rate and mean arterial pressure during the peri-operative period. Hemodynamic stability is an added advantage of ESP block when compared to paravertebral and central neuraxial blockade.

CONCLUSION

The patients who received Erector spinae plane block had a 35% reduced tramadol consumption at 24 hr post-operatively, prolonged duration of analgesia for 6-7 hours and had higher satisfaction scores compared to control group patients. Intraoperative hemodynamics such as heart rate, SBP, DBP, MAP, SpO2 and capnogram was monitored in all patients. It was found that heart rate and mean arterial pressure were relatively lower and steadier in ESPB group compared to control group.

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