Original Article

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A Prospective Randomized Study of Erector Spinae Plane Block Combined with General Anaesthesia Versus General Anaesthesia in Lumbar Spine Surgery

Vikram Reddy. V[1], Rama Krishna. S[2], Dr. Prudhvi. G[3], Lakshmi Pushpa. S[4]

[1]Senior Consultant, Department of Anaesthesia, YASHODA HOSPITAL, Malakpet Branch, Hyderabad, Telangana, India.

[2]HOD, Senior Consultant, Department of Anaesthesia, Yashoda Hospital, Malakpet Branch, Hyderabad, Telangana, India.

[3]Senior Resident, Department of Anaesthesia, Yashoda Hospital, Malakpet Branch, Hyderabad, Telangana, India.

[4]Senior Consultant, Department of Anaesthesia, Yashoda Hospital, Malakpet Branch, Hyderabad, Telangana, India.

Abstract

Background: By causing total muscular relaxation, preserving stable intraoperative hemodynamics, and offering prolonged analgesia in the immediate aftermath of surgery, they produce close to perfect operating conditions. [4] We anticipated that ESP block can be utilised well as a lumbar surgery analgesic since LA broadly extends cranially and caudally when conducted. **Aim:** To determine the superiority of ESP block as a mode of postoperative analgesia compared to multimodal analgesia in lumbar spine surgeries. **Subjects and Methods:** A prospective, randomized, comparative study. Study area: Department of Anaesthesia, at YASHODA HOSPITAL, Malakpet branch, Hyderabad, Telangana. Study Period: 1 year. Study population: ASA physical grade I, II, patients, satisfying the inclusion criteria, undergoing lumbar spine surgeries were included. Sample size: 60 patients were divided into two groups of 30 each. All the patients have undergone thorough pre anaesthetic evaluation on the day prior to surgery. Investigations were done depending on the age & associated co-morbidities. All system were examined including airway and surface anatomy where the block was given and the procedure to be carried out was explained to the patients. Patients were reassured to alleviate their anxieties. All the patients were kept nil per oral as per the fasting guidelines. Written informed consent was taken. **Results:** Total dose of analgesic required in first 24 hours in ESP group is 41.67±58.844, without ESP group 105±80.247 with p value 0.001 which is clinically significant. Mean duration for which the block acted effectively was 983.50±89.019 mins. It is taken from time of block given. Occurrence of nausea in ESP block was 4 out of 30(13.33%), without ESP block 5 out 0f 30(16.67%), with p value 0.718 which is clinically insignificant. **Conclusion:** Based on the results, we conclude that ESP block decreases the post-operative pain scores and opioid requirements and can be used as excellent component of multimodal analgesia, which is safe and easily performed with no major complications.

Keywords: Erector spinae plane block, post-operative pain scores, intraoperative hemodynamics.

Corresponding Author: Dr. Lakshmi Pushpa. S, Senior Consultant, Department of Anaesthesia, YASHODA HOSPITAL, Malakpet Branch, Hyderabad, Telangana, India.
Email: lkshm.pushpa@gmail.com
ORCID ID: 0009-0002-5197-6890

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Introduction

Pain is "a disagreeable sensory and emotional experience linked with, or approximating that associated with, existing or potential tissue injury," according to the International Association for the Study of Pain.[1] "Practice guidelines for acute pain management in the perioperative context" published by the ASA.[2] emphasises the use of multimodal therapy, which combines two or more analgesics or analgesic modalities for the management of postoperative pain.

Due to improvements in real-time imaging techniques, which have increased patient safety and success rates, regional anaesthetic has dramatically increased during the past ten years. Precision in needle placement, increased block success, and a decreased risk of complications are all aided by ultrasound assistance.

When LA travels via the paravertebral region, it is believed that ESP block will have an analgesic effect on somatic and visceral pain by affecting the ventral rami and rami communicans, which include sympathetic nerve fibres.[3]

By causing total muscular relaxation, preserving stable intraoperative hemodynamics, and offering prolonged analgesia in the immediate aftermath of surgery, they produce close to perfect operating conditions.[4] We anticipated that ESP block can be utilised well as a lumbar surgery analgesic since LA broadly extends cranially and caudally when conducted.[4] Multimodal regimes that combine paracetamol, NSAIDs, and opioids may be utilised to treat postoperative analgesia.[5] When compared to

multimodal analgesia with IV analgesics, regional anaesthesia techniques like ESP block may be thought to offer the most effective analgesia. Hence the present study was undertaken to determine the superiority of ESP block as a mode of postoperative analgesia compared to multimodal analgesia in lumbar spine surgeries.

Aim

To determine the superiority of ESP block as a mode of postoperative analgesia compared to multimodal analgesia in lumbar spine surgeries.

Objectives

1. To assess the duration of ESP block as a post-operative analgesic technique by VAS score.
2. Total Dose of rescue analgesic (Tramadol) required.
3. Time of First dose of rescue analgesic required.
4. Duration of analgesia.
5. Complications

Subjects and Methods

Study Design

A prospective, randomized, comparative study.

Study Area

Department of Anaesthesia, at YASHODA HOSPITAL, Malakpet branch, Hyderabad, Telangana.

Study Period

1 year.

Study Population

ASA physical grade I, II, patients, satisfying the inclusion criteria, undergoing lumbar spine surgeries were included.

Sample Size

60 patients were divided into two groups of 30 each.
sample size was decided by consultation with a statistician and based on study done by Vipin goel et al.[6]
N= 2*(Zalpha + Zbeta)2 (standard deviation)2/ D2
Alpha (α) Type 1 error rate
Beta (β) Type 2 error rate
D difference of means
A=Error is taken as 5%, Power =80%, n=sample size with a power of 80% at the 5% significance level.
Group 1= group received bilateral ESP block prior to surgery after induction
Group2 = Conventional general anaesthesia receiving multimodal analgesia (MMA)

Sampling Method

Simple random method.

Inclusion Criteria

1. Patients belonging to age group 18-60 years with
2. ASA grade I and grade II
3. Elective lumbar spine surgeries
4. Weight 55kg to 75kg

Exclusion Criteria

1. Patients who refuse.
2. Patients with history of bleeding disorders.
3. Patients with local infection at the site of block.
4. Patients with documented neuromuscular disorders.
5. Patients with respiratory compromise/post pneumonectomy having one functional lung.
6. Patients with known allergy to local anesthetic drugs.

Ethical consideration: Institutional Ethical committee permission was taken prior to the commencement of the study.

Study tools and Data collection procedure

PREANAESTHETIC EVALUATION

All the patients have undergone thorough pre anaesthetic evaluation on the day prior to surgery. Investigations were done depending on the age & associated co-morbidities. All system were examined including airway and surface anatomy where the block was given and the procedure to be carried out was explained to the patients. Patients were reassured to alleviate their anxieties. All the patients were kept nil per oral as per the fasting guidelines. Written informed consent was taken.

Preliminaries

- Written informed consent
- Patient will be kept nil by mouth for at least 6 hours prior to surgery.
- Intravenous access – starting of an intravenous line with 20GIVcannula on the upper limb under aseptic techniques.
- On arrival of the patient in the operation theatre all standard ASA monitors pulse oximetry, ECG and NIBP are connected.
- Baseline pulse rate, saturation and blood pressure were recorded. Inj. glycopyrrolate 0.2 mg, Inj. midazolam 1mg, Inj. zofer 4mg, Inj. fentanyl 100mcg were given.
- Preoxygenated for 3 min after induction with Inj. Propofol 2-2.5mg/kg and Inj. cis-atracurium 10mg given then under direct laryngoscopy intubation was done.
- Patient was kept in prone position with pressure points taken care of.

Equipment

IV canula and IV fluids, Sterile tray, Quincke Babcock spinal needle (23G), 4 Sterile syringe 10 cc to give drug ropivacaine (0.375%)

Drugs

A. Study agent: Inj. Ropivacaine 0.75% 20ml ampoule, Inj . dexamethasone 8mg
B. Emergency drugs: Inj. Adrenaline, Inj. Atropine, Inj. Ephedrine, Inj.Phentermine, Inj. Dopamine, Inj. Dobutamine, Inj. Thiopentone,
C. Others: Ultrasound machine.

Technique

After selecting the L1 transverse process for the ESP block, placed the curvilinear transducer in a paramedian sagittal orientation, approximately 2cm away from the midline

(spinous processes), transverse process is visualised. The transverse process will be more superficial and wider, while the rib will be deeper and thinner. Erector spinae muscle (ESM) should be identified superficial to the transverse process. 23G QB needle was inserted superior to the ultrasound probe using an in-plane approach in the cephalad to caudal direction. The bevel of the QB needle is pointed posteriorly and inferiorly, and advance under ultrasound guidance through the trapezius muscle, and erector spinae muscle and towards the transverse process; once the needle tip is below the erector spinae muscle, a small bolus of local anaesthetic should be given through the QB needle. The erector spinae muscle was visualized, separating from the transverse process. This separation from the transverse process confirms the proper needle position. The local anaesthetic is then injected in 5 ml increments, with aspiration after every 5 ml to prevent intravascular injection. 20 ml of 0.375% ropivacaine is used on each side.

The following parameters were observed

- Duration of analgesia.
- Vitals like blood pressure and heart rate in both groups, in both intraoperative and postoperative period.
- Postoperative complications in both groups like nausea and vomiting.
- First time of rescue analgesic given.
- Total rescue analgesic requirement in both groups.
- VAS score in postoperative period.
- Complications of block like pruritis.

Duration of Analgesia

(Till appearance of pain requiring analgesia).

In both the groups, postoperative rescue analgesia was provided with intravenous tramadol 50-100 mg boluses upto a maximum of 400 mg per day was given when the VAS score was >4.

Hemodynamic parameters

Heart Rate, systolic BP(SBP), diastolic BP(DBP) were monitored continuously. Initial bolus dose timing was assumed to be the baseline time. Post-operatively vital parameters were recorded at every 30 minutes till the regression of the block. The anaesthesia record was maintained and changes in heart rate, blood pressure were noted.

Analgesia

The findings suggested that VAS ratings of 0 to 3 can be considered no pain; 4 to 6 mild pain; and 7 to 10, severe pain.

Statistical Methods

The following methods of statistical analysis have been used in this study. The statistical analysis was performed by a statistician using SPSSv25. Categorical data was represented as frequencies and percentages. Continuous data was represented as mean and standard deviation. Chi square test was used as test of significance for categorical data. Unpaired t – test was used as test of significance for continuous data. P value < 0.05 is considered as statistically significant.

Results

Table 1: Number of people in each group according to age

Age (Years)	Group		Total
	With ESP	Without ESP	
<=30	8	8	16
31 - 45	10	14	24
46 & Above	12	8	20
Total	30	30	60

Chi square test, P value – 0.48

In our study, age group of 18-60 years were taken into consideration. After calculating by chi-square test p value was 0.48 which was not statistically significant.

Table 2: Comparison of Sex Groups in Each Group

SEX	GROUP				
	WITH ESP		WITHOUT ESP		
MALE	13	43.33%	15	50%	28
FEMALE	17	56%	15	50%	32
TOTAL	30		30		60

Chi square test, p value 0.605

In our study 60 patients were taken in both genders. Among them 28 females and 32 males are present in total which is statistically not significant. (p =0.605).

Table 3: Comparison of ASA Groups Between Two Groups

ASA	GROUP				TOTAL
	WITH ESP		WITHOUT ESP		
1	19	63.33%	19	63.33%	38
2	11	36.33%	11	36.33%	22
TOTAL	30	100%	30	100%	60

Chi square test p value 1

In our study 60 patients were taken out of which 38 patients in ASA 1 group and 22 patients in ASA 2 group. P value 1 which is insignificant.

Table 4: Comparison of Heart Rate in Both Groups

HR	Group		P Value
	With ESP	Without ESP	
Baseline	79 ± 9.752	77.5 ± 9.916	0.557
After Induction	80.9 ± 8.466	73.97 ± 6.73	0.001
After Incision	73.6 ± 6.621	76.87 ± 7.59	0.081
10 Mins	72.03 ± 5.58	77.83 ± 7.26	0.001
20 Mins	71.53 ± 5.419	76.4 ± 6.162	0.002
30 Mins	71.27 ± 5.051	74.17 ± 6.56	0.06
1 Hr	70.9 ± 5.261	73.07 ± 5.45	0.123
1.5 Hrs	70.83 ± 5.299	71.77 ± 5.21	0.494
2 Hrs	70.53 ± 4.833	69.9 ± 4.483	0.601
2.5 Hrs	70.6 ± 4.215	69.6 ± 3.829	0.34
Post-Op 1 Hr	71.17 ± 6.204	69.57 ± 3.79	0.233
Post-Op 2 Hrs	70.97 ± 5.678	85.53 ± 7.25	<0.001
Post-Op 4 Hrs	73.17 ± 5.24	86.97 ± 5.70	<0.001
Post-Op 8 Hr	74.87 ± 4.424	88.57 ± 5.09	<0.001
Post-Op 16 Hrs	77.53 ± 4.24	87.23 ± 5.84	<0.001
Post-Op 24 Hrs	79.8 ± 3.21	84.97 ± 4.97	<0.001

NS- Not Significant (p>0.05), *-Statistically significant (p<0.05), **-Highly significant (p<0.001).

Baseline Heart rate in ESP group was (79±9.752) and

without ESP group was (77±9.916) and p value 0.557 which is statistically not significant. The heart rate was monitored intraoperatively in both groups, after induction, after incision, at 10, 20, 30 mins, 1, 1.5, 2, 2.5 hours, there was not statistically difference in mean heart rate in both groups at majority of the points. The heart rate was monitored post operatively in both groups at 1,2,4,8,16,24 hours, in which (p value <0.001) clinically significant.

Mean Baseline systolic bp in ESP group was 127± 12.028 and without ESP group was 129.37± 9.3 with (p value 0.445) which is clinically insignificant. The systolic BP was monitored intraoperatively in both groups, after induction, after incision, at 10, 20, 30 mins, 1, 1.5, 2, 2.5 hours, there was statistically difference in systolic BP in both groups Which was clinically significant at majority of points. The systolic BP was monitored post operatively in both groups at 1,2,4,8,16,24 hours, in which (p value <0.001) clinically highly significant.

Diastolic BP in both the groups baseline and intraoperatively monitored at after induction, after incision, at 10, 20, 30 mins, 1, 1.5, 2, 2.5hours, there was statistically difference in systolic BP in both groups Which was clinically significant at majority of the points. The diastolic BP was monitored post operatively in both groups at 1,2,4,8,16,24 hours, in which (p value <0.001) clinically highly significant.

Table 5: Comparison of VAS Score in Both Groups

VAS	Group		P Value
	With ESP	Without ESP	
Post-Op 1 Hr	1.03 ±0.183	2.33 ±1.269	<0.001
Post-Op 2 Hrs	1.23 ±0.43	2.83 ±0.874	<0.001
Post-Op 4 Hrs	1.33 ±0.547	3.3 ±0.877	<0.001
Post-Op 8 Hr	1.43 ±0.568	3.3 ±0.702	<0.001
Post-Op 16 Hrs	2.7 ±0.75	3.63 ±0.89	<0.001
Post-Op 24 Hrs	3.37 ±0.615	3.73 ±0.944	0.08

VAS score at 1,2,4,8,16 hours postoperatively (p value <0.001) which was clinically highly significant and at 24 hours p value was 0.08 which was clinically insignificant.

Table 6: Comparison Between Both Groups in Time of First Rescue Analgesic Given

Group	Time of First Resque Analgesic Given (Mins)			P Value (t-test)
	N	Mean	Std. Deviation	
With ESP	12	900.00	135.378	0.002
Without ESP	23	476.74	417.606	

Table 7: Comparison Between Both Groups in Total Dose of Analgesic Requirement

Group	Total Dose of Resque Analgesic Requi		P Value (t-test)
	Mean	Std. Deviatic	
With ESP	41.67	58.844	0.001
Without ESP	105.00	80.247	

Total dose of analgesic required in first 24 hours in ESP group is 41.67±58.844, without ESP group 105±80.247 with p value 0.001 which is clinically significant.

Mean duration for which the block acted effectively was 983.50±89.019 mins. It is taken from time of block given.

Occurrence of nausea in ESP block was 4 out of 30(13.33%), without ESP block 5 out 0f 30(16.67%), with p value 0.718 which is clinically insignificant.

Occurrence of vomiting in ESP block group was 6.67%, whereas in without ESP group was 10% with p value 0.64 which is clinically insignificant.

PRURITIS

Out of 30 patients in ESP block only 2 patients were observed to have pruritis. No pruritis in without ESP block was observed.

HAEMORRHAGE

There was no haemorrhage observed in both the groups.

Discussion

After lumbar spine surgeries, ESP block has been shown to lower postoperative pain scores and opioid consumption, enabling earlier discharge. Managing pain following spine surgery is challenging. The analgesic regimen should be effective, safe and devoid of side effects.

Postoperative pain following lumbar spine procedures is related to activation of several mechanisms, which include nociceptive, neuropathic, inflammatory. The number of vertebrae involved in the surgery directly correlates with the severity of postoperative pain. Peripheral and Central sensitization contributes to increased pain. The region of surgery does not seem to have bearing on pain severity, and it is similar in surgeries of cervical, thoracic, or lumbar spine.

Different modalities have been described to provide postoperative analgesia in patients undergoing lumbar spine surgeries. The choice of technique will of course vary depending on practitioners' and patients' preferences, comorbidity and type of surgery.

Patients in group ESP and without ESP (MMA) group in the age group <= 30 years was 26.33%, between 31 and 45 was 33.33% and 46.67%, and above 45 years was 40 and 26.67% with p value 0.48 which signifies that the two groups were comparable with regards to Age.

The percentage of males in ESP group was 43.33% and females 56.67%. The percentage of males in without ESP(MMA) group was 50% and females 50%. The P value is 0.605 which was not significant showing that the groups were comparable with regards to sex.

The percentage of ASA Grade 1 patients in group ESP was 63.33%, ASA 2 was 33.37%. The percentage of ASA Grade 1 patients in group ESP was 63.33%, ASA 2 was 33.37%. The P value is 1 which was not significant showing that the groups are comparable with regards to ASA Grade.

The age, sex and ASA grade of the patients in both groups were comparable which shows that the patients of equal age, sex and ASA grade were enrolled in the study. The patients in both groups in the present study compare favourably with those of other studies. The demographic data such as age, sex and ASA grade and were comparable in both groups and seems to have no influence on outcome of the study.

Thus, in both groups demographic data was statistically comparable and non-significant which was similar to Vipin goel et al.[6] conducted a study which found that there was

no statistically significant correlation between age, sex and ASA grading of the patients in the two groups.

The Baseline Mean Heart Rate in Group ESP was 79±9.752 BPM and in Group MMA was 77±9.916 BPM, (p =0.557) which is statistically not significant. The heart rate was monitored intraoperatively in both groups, after induction, after incision, at 10, 20, 30 mins, 1, 1.5, 2, 2.5 hours, there was not statistically difference in mean heart rate in both groups at majority of the points. The heart rate was monitored post operatively in both groups at 1,2,4,8,16,24 hours, in which (p value <0.001) clinically significant.

Similar results were obtained in the study conducted by EZZZT et al.[7] for group I (ESP), the mean heart rate values were 79.20 ± 12.46 and 74.0 ± 8.79 beats/min after stimulus and first-time interval respectively, while for group II (MMA), the mean heart rate values were 88.07 ± 10.22, 81.00 ± 8.03 beats/min at the same time intervals. So, there were statistically significant differences between the two groups after stimulus and at the first-time interval (p values 0.042, 0.031) respectively.

Baseline systolic bp in ESP group was 127±12.028 and without ESP group was 129.37±9.3 with (p value 0.445) which is clinically insignificant. The systolic BP was monitored intraoperatively in both groups, after induction, after incision, at 10, 20, 30 mins, 1, 1.5, 2, 2.5 hours, there was statistically difference in systolic BP in both groups Which was clinically significant at majority of points. The systolic BP was monitored post operatively in both groups at 1,2,4,8,16,24 hours, in which (p value <0.001) clinically highly significant.

Diastolic BP in the group ESP baseline76.57± 10.887 and in MMA group 73.83± 7.94 with p value 0.271 intraoperatively monitored at after induction, after incision, at 10, 20, 30 mins, 1, 1.5, 2, 2.5hours, there was statistically difference in systolic BP in both groups Which was clinically significant at majority of the points. The diastolic BP was monitored post operatively in both groups at 1,2,4,8,16,24 hours, in which (p value <0.001) clinically highly significant.

VAS score at 1,2,4,8,16 hours postoperatively (p value <0.001) which was clinically highly significant and at 24 hours p value was 0.08 which was clinically insignificant. Similar results were obtained in the study conducted by Gurkan et al.[8] postoperative NRS scores were assessed post operatively after breast surgery. Scores were significantly lower in the ESP Group than in the Control Group at all-time intervals (P < 0.05). VAS score at 1,2,4,8,16, 24 hours postoperatively in ESP group was 1.03±0.183, 1.23± 0.43, 1.33± 0.547, 1.43± 0.568, 2.7± 0.75, 3.37± 0.615 respectively. VAS score at 1,2,4,8,16,24 hours postoperatively in without ESP(MMA) group was 2.33± 1.269, 2.83± 0.874, 3.3± 0.877, 3.3± 0.702, 3.63± 0.89, 3.73± 0.944 respectively.

The difference in the VAS scores of both the groups at 1 hour, 2 hours, 4 hours, 8 hours and 16 hours was statistically highly significant with p <0.001. The patients in Group MMA (without ESP) showed higher pain scores compared to Group ESP. At 24 hours p value was 0.08 which is >0.05, clinically insignificant.

This study was similar to study conducted by Yayik.A.M et al.[7] average VAS score at 2,4,8,12,24 hours at rest with ESP block was 1.10± 1.03, 1.63 ± 1.07, 1.5± 0.97, 1.93± 0.87, 2.40 ± 0.89, 2.00± 1.36 and after movement was 1.53 ± 1.04 , 2.00 ± 0.87, , 1.97 ± 0.89, 2.3± 0.6, 2.63± 0.56, 2.30± 1.56 respectively. In control group at 2,4,8,12,24 hours at rest 3.70 ± 1.60, 4.03±0.85, 3.63± 1.13, 3.83± 1.18, 3.37± 1.35, 2.83± 1.51, and at movement 4.20±1.4, 4.57± 0.82, 4.23± 0.94, 4.63± 1.1, 3.77± 0.82, 3.23± 0.77 respectively, with p value <0.001(<0.05) at all points which is clinically highly significant.

This result was similar to Yayik.A.M et al.[9] study where average VAS score at 8 hours for ESP block was 1.33± 0.547, and control group was 3.3±0.877. with p value<0.05 which is clinically significant.

First time rescue analgesic given in ESP group was 900±135.378 minutes in which only 12 members out of 30 required analgesic in first 24 hours. In MMA group it was 476.74± 417.606 minutes in which 23 out of 30 members required analgesic in first 24 hours. With p value of 0.002 which is clinically significant. This study is similar to study done by Swathi singh et al.[4] first dose of rescue analgesia after 5.8± 0.75 hours compared with 2.42± 0.59 hours in the control group (P=0.003) which was clinically significant. Similar to study conducted by Yayik.A.M et al.[9] Time to first analgesic requirement was significantly longer in the ESP Group than in the Control Group (325.17 ±22.82 minutes and 174.17 ±22.82 minutes, respectively; P < 0.001).

In our study, majority of the Group ESP patients 40% only and 76.6% of Group MMA needed rescue analgesia by the end of 4 hours This difference in analgesic requirement was statistically significant with p value 0.001. This is similar to the study done by Vipin goel et al.[6] The block group, as compared to the control group, had a significantly lower Total Opioid Consumption (TOC) (fentanyl) in the first 24 hours following induction (105.0 ± 15.15 vs 158.00 ±23.38 mcg; p < .001).

In our study we took Tramadol as rescue analgesic. Tramadol requirement in first 24 hours in ESP group was 41.67±58.844 mg, in MMA group was 105±80.247 mg, with p value 0.001 which is clinically significant. In our study we observed that nausea among ESP block was 13.33% and in MMA group was 16.67% with p value 0.718, which is statistically insignificant.

Post-operative vomiting's in ESP group was 6.67% and MMA group was 10% with p value 0.64, which is statistically not significant. It was similar to the study done by Gülçin Hacıbeyoğlu et al.[10] that PONV present in all patients in the control group, and it was severe in 40%. wheareas, 24% of the patients in the ESP group did not have nausea-vomiting.

In study conducted by Fu, Junbao et al.[11] ponv in patients undergoing hepatectomy surgeries 2 out of 30 (6.7%) in ESP group experienced PONV and 8out of 30(26.7%) in non-block group experienced PONV. Only 2 out of 30 patients was observed to have pruritis and surgical site bleeding has not occurred in any patient. In study conducted by Fu, Junbao et al.[11] 10% of ESP group patients, 13.3% in no intervention group experienced pruritis

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Conclusion

Based on the results, we conclude that ESP block decreases the post-operative pain scores and opioid requirements and can be used as excellent component of multimodal analgesia, which is safe and easily performed with no major complications.

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