Original Research Paper

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A COMPARATIVE STUDY: TO STUDY THE EFFECTIVENESS OF ERECTOR SPINAE BLOCK VERSUS INTRA-VENOUS ANALGESIA FOR POST OPERATIVE PAIN MANAGEMENT IN PATIENTS UNDERGOING SPINE SURGERIES

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ABSTRACT Spine surgeries are generally associated with intense pain in the postoperative period, especially for the initial few days. Adequate pain management in this period has been seen to correlate well with improved functional outcome, early ambulation, early discharge, and preventing the development of chronic pain. The aim of our study is to study the effectiveness of erector spinae block versus intravenous analgesia for postoperative pain management in patients undergoing spine surgeries. This randomized controlled study included 60 ASA grade I, II, III patients between the ages of 18 and 80 who underwent elective spine surgeries. After obtaining consent, the patients were randomly allocated into two groups of 30 each by a computer-generated random table to receive erector spinae block with 20ml 0.375% ropivacaine along with intravenous fentanyl infusion 0.5 microgram/kg/hour in Group A and only intravenous fentanyl infusion at 0.5 microgram/kg/hour in Group B. In both groups, intravenous fentanyl was started immediately post-surgery and bolus doses were adjusted according to pain scores till 24 hours after surgery. The primary outcome measurement was the numerical rating scale (NRS) pain score (a scale of 0 to 10, where 0 = no pain & 10 = worst pain) at various time points until the end of 24 hours. Each patient's pain level was measured at 0, 2, 4, 6, 8, 12, 18 and 24 hours post operatively. The secondary outcome measures were the amount intravenous fentanyl during the first 24 hours after surgery, patient satisfaction according to likerts scale and the number of patients who reported complications such as nausea and vomiting. Patients who reported nausea and vomiting were injected with 10 mg of intravenous metoclopramide. The NRS score and the amount of fentanyl required for analgesia was significantly lower in the study group (erector spinae group) compared to the control group. Patient satisfaction was significantly higher in the erector spinae group compared to the study group. The I.V. fentanyl dose requirement was also significantly reduced in the erector spinae group. However, there was no significant difference in the incidence of complications like nausea, vomiting and pruritis between the two groups.

KEYWORDS : Lumbar Spine Surgeries, Erector Spinae Block, Fentanyl

INTRODUCTION

Spine surgeries are generally associated with intense pain in the postoperative period. Adequate pain management in this period has been seen to correlate well with improved functional outcome. Erector Spinae block is a regional anesthesia technique in which local anesthetic (LA) is injected between the erector spinae muscle and transverse process under ultrasound guidance[1]. The first description of the erector spinae plane (ESP) block was by Forero et al1 in 2016 for 2 cases of severe thoracic neuropathic pain. Being a relatively new block, previous studies indicated a need for more randomized clinical trials to confirm the efficacy of the block and the optimum volume and doses of the local anesthetic necessary[1].

AIM

To study the effectiveness of erector spinae block versus intravenous analgesia for postoperative pain management in patients undergoing spine surgeries.

Primary Objectives

a) Assessment of pain using NRS score 0-10 at 0, 2, 4, 6, 8, 12 ,16 and 24 hours postoperatively (0: no pain and 10: severe pain).
b) Measurement of hemodynamic parameters (heart rate, systolic and diastolic blood pressure) post-operatively at 0, 2, 4, 6, 12, 16 and 24 hours

Secondary Objectives

c) Measure the total amount of intravenous fentanyl used during study period.
d) Measure the satisfaction of the patients. Measures of satisfaction were noted on a 5-point scale according to Likert's scale.
e) Evaluate incidence of complications like nausea, vomiting and pruritis postoperatively.

METHODS

Study Design

A comparative prospective randomized controlled trial.

Study Duration

12 months. {August 2019-August 2020}.

Study Population

After getting approval from the ethical committee and the institutional review board and obtaining a well-informed consent, sixty patients undergoing lumbar spine surgeries were chosen. The patients were randomized into two groups using computer generated random number tables.

Sample Size Determination

As per the study by Ueshima et al., the amount of fentanyl bolus administration varies from median:40 [IQR:40–60] μg to median:100 [IQR: 80–100] μg across the two groups. Hence assuming mean as 40 and 100 with SD as 20, the required sample size is estimated as 30 at each group (Total 60) at 80% power and 5% level of significance. The following formula is used to determine the sample size:

$$n = \frac{2\left(Z_{1-\alpha/2} + Z_{1-\beta}\right)^2 \sigma^2}{d^2}$$

Where,
σ : Pooled standard deviation
d : Difference between two group means
$Z_{1-\beta}$: Z value for corresponding power
$Z_{1-\alpha/2}$- Two-sided Z value for corresponding a

Inclusion Criteria

- Age: 16 years to 75 years
- ASA: I, II, III
- Patients undergoing lumbar spine surgeries
- BMI : < 35

Exclusion Criteria

- Patient refusal to the study
- Age: <16 years or >75 years
- ASA: > III
- BMI: > 35
- Patients with infections at site of administration of block
- Patients with coagulation disorders

Patient Preparation

Complete preoperative evaluation and the appropriate investigations done. On the day of the surgery, injection pantoprazole 40 mg IV,

Ondansetron 4mg IV & test dose for local anaesthesia was given.

As per ASA standards intraoperative monitoring such as ECG, Non-Invasive Blood Pressure (NIBP) monitoring, oxygen saturation via pulseoxymetry, end tidal CO2 was applied.

Machine was checked and drugs were loaded. A Mayo trolley with syringes, bowl with 10% povidone iodine solution, sponge holding forceps, short beveled insulated needle 22G, 10cms in length, 2% Lignocaine, 0.75% Ropivacaine and USG machine was kept ready.

Technique

Figure 1: (A) Performance of the erector spinae plane (ESP) block in the right lateral decubitus position. Red lines mark the spinous process and yellow arrow marks 3 cm laterally where is the target point above the transverse process. (B) The ESP catheter is inserted and secured close to the posterior midline. The needle is oriented in a cephalad-to-caudal direction[8]

All the patients were administered with general anesthesia using appropriate drugs and then turned prone. A low frequency curvilinear ultrasound transducer was placed sagittally against the target vertebrae in the prone position, the spinous process was identified and moved 3-cm lateral to the midline in longitudinal position. The transverse process was identified as a hyperechoic curvilinear structure with pronounced finger-like acoustic shadowing beneath (trident sign). The transducer was fixed over the targeted transverse process and a needle inserted along the long axis 1–2 cm away from the probe and advanced at a 30–45-degree angle till the targeted transverse process was reached. Local anesthetic was injected in the fascial plane below the erector spinae muscle, with alternating aspiration. Anechoic fluid was seen separating the erector spinae muscle from the transverse process.
At the end of the surgical procedure, patients in both groups were extubated awake in the supine position. 1 gram paracetamol was given for both the groups just prior to extubation. For both groups, infusion fentanyl 0.5 mcg/kg/hour was started immediately after extubation in the Post Anesthesia Care Unit (PACU). Rescue analgesic injection of fentanyl was administered according to the NRS scores as per the following table. Parameters such as HR, SBP, DBP, MAP, fentanyl infusion, NRS score, nausea, vomiting, pruritis and satisfaction scores were measured at 0 , 2 ,4 , 6, 8, 12, 16, 18 and 24 hrs. Injection prantoprazole 40 mg I.V. and injection ondansetron 4 mg I.V. was given 12th hourly.

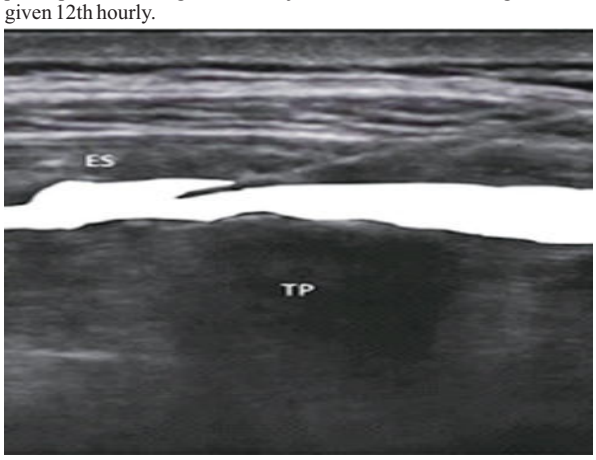


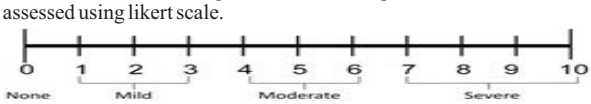
Figure 2: Ultrasound image of local anesthetic (white frame) after erector spinae plane block. Local anesthetic spread to the deep surface of the erector plane muscle (ES). TP, transverse process; ES, erector spinae.2

In the PACU, patients who presented with breakthrough pain received IV fentanyl boluses as per NRS scale.

NRS	Quantity of Fentanyl Administered
>=6	30 micrograms
4 to 5	20 micrograms
3	10 micrograms
< 3	No boluses

Pain & Patient Satisfaction Assessment

Pain was assessed using NRS scale and patient satisfaction was assessed using likert scale.



Numerical Rating Scale for Pain Assessment

Likert Scale for Patient Satisfaction Assessment

SATISFACTION LEVEL	SCORE
Very much satisfied	5
Somewhat satisfied	4
Undecided	3
Not really satisfied	2
Not at all satisfied	1

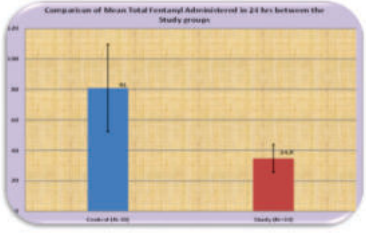
Statistical Analysis

The Tools used were Microsoft Excel + Statistical Package for Social Science (SPSS). Proportions were compared using Chi-square test of significance. Numerical measures were compared using Student's t-test. A p-value less than 0.05 was considered to be statistically significant.

RESULTS

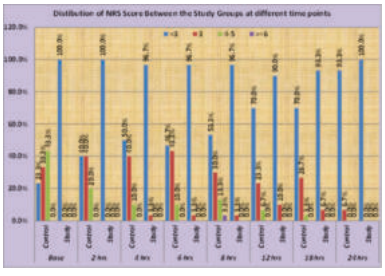
There was no significant difference between the study and control groups with respect to age, gender, ASA grading and weight. Significant difference in the heart rate between the groups with the values being lower in the erector spinae group. Significant difference in the systolic blood pressure (SBP) between the groups till 8 hrs. SBP was much lower in the study group. Significant difference in mean DBP and MAP between the groups being lesser in the study group for all time points except 12 hrs.

Significant difference in the total volume of Fentanyl in 24 hours was lower in study group as in the graph shown

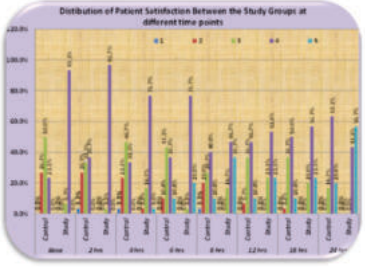


OBSERVATIONS

Chi Square test shows **significant difference** in the **NRS scores** between the groups for all time points upto 8 hrs being lesser in the study group.



Chi Square test shows **significant difference** in the **Patient Satisfaction scores** between the groups for all time points except 12 hrs & 18 hrs. Overall satisfaction was much better in the study group.



DISCUSSIONS

Various other studies were conducted using levobupivacaine, bupivacaine and ropivacaine. In our study we used 0.375% ropivacaine 20 ml on each side.

Study	Drugs Used	Volume of the Drug
Hironobu Ueshima, Mayumi Inagaki, Tomoaki Toyone, Hiroshi Otake2	0.375% levobupivacaine	20 ml on each side
Mauricio Forero, MD, FIPP, Sanjib D. Adhikary, MD, Hector Lopez, MD, Calvin Tsui, BMSc, Ki Jinn Chin, MBBS (Hons), MMed, FRCPC1	0.5% bupivacaine (Case 1) 0.5% ropivacaine (Case 2) 0.5% ropivacaine + 2% lignocaine, 1:1 mixture (Case 3) 0.5% ropivacaine (Case 4)	20 ml on each side
K. J. Chin, S. Adhikary, N. Sarwani and M. Forero3	0.5% ropivacaine + epinephrine 5mcg/ml (Case 1) 0.5% ropivacaine + preservative-free dexamethasone 4 mg (Case 2) 0.5% ropivacaine + preservative-free dexamethasone 4 mg (Case 3) 0.5% ropivacaine + preservative-free dexamethasone 4 mg (Case 4)	20 ml on each side (Case 1) 30 ml on each side (Case 2) 20 ml on each side (Case 3) 20 ml on each side (Case 4)
Swati Singh, Rahul Ranjan, and Dusu Lalin4	0.25% bupivacaine	20 ml on affected side
Present Study	0.375% ropivacaine	20 ml on each side

Most of the other studies also deposited the drug deep to the erector spinae muscle. Similarly in our study we injected the drug deep to the erector spinae muscle.

Study	Plane of Injection
Hironobu Ueshima, Mayumi Inagaki, Tomoaki Toyone, Hiroshi Otake2	Deep to erector spinae muscle
Mauricio Forero, MD, FIPP, Sanjib D. Adhikary, MD, Hector Lopez, MD, Calvin Tsui, BMSc, Ki Jinn Chin, MBBS (Hons), MMed, FRCPC1	Deep to erector spinae muscle (Case 1) Between rhomboid major and erector spinae muscle (Case 2) Deep to erector spinae muscle (Case 3) Deep to erector spinae muscle (Case 4)
K. J. Chin, S. Adhikary, N. Sarwani and M. Forero3	Deep to erector spinae muscle (Case 1) Deep to erector spinae muscle (Case 2) Deep to erector spinae muscle (Case 3) Deep to erector spinae muscle (Case 4)
Swati Singh, Rahul Ranjan, and Dusu Lalin4	Deep to erector spinae muscle
Present Study	Deep to erector spinae muscle

In the below table we have compared NRS score at various time interval between other studies and our study.

Study	NRS Pain Score
Hironobu Ueshima, Mayumi Inagaki, Tomoaki Toyone, Hiroshi Otake2	The NRS pain scores in the study group were lower at 1, 2, 4, 6, 12, and 24 hours as compared with those in the control group (comparisons at all measured time points were $p<0.05$
Mauricio Forero, MD, FIPP, Sanjib D. Adhikary, MD, Hector Lopez, MD, Calvin Tsui, BMSc, Ki Jinn Chin, MBBS (Hons), MMed, FRCPC1	NRS was significantly diminished in severity till 12 hrs (Case 1) NRS was significantly diminished in severity till 12 hrs (Case 2) Pain was significantly diminished post-op hours not documented (Case 3) Pain was significantly diminished post-op hours not documented (Case 4)
K. J. Chin, S. Adhikary, N. Sarwani and M. Forero3	The highest and lowest median (range) pain scores in the first 24 h were 3.5 (3.0–5.0) and 2.5 (0.0–3.0) on an 11-point numerical rating scale.
S. D. Adhikary, W. M. Liu, E. Fuller, H. Cruz-Eng and K. J. Chin5	Pain scores were reduced from 7.7 (2.5) to 4.7 (3.2) in the first three hours ($p < 0.01$). The study indicates that erector spinae plane blockade is effective in improving inspiratory capacity following rib fracture, and that this is associated with a modest reduction in pain scores.
Present Study	Chi Square test shows significant difference in the NRS scores between the study group and the control at time points 2, 4, 6, 8 hours.

In the following table we have compared the amount of fentanyl used in the study period.

Study	Opioid Consumption
Hironobu Ueshima, Mayumi Inagaki, Tomoaki Toyone, Hiroshi Otake2	The amount of fentanyl bolus administration in the study group was lower than that in the control group during the first 24 hours postoperatively ($p<0.05$).
K. J. Chin, S. Adhikary, N. Sarwani and M. Forero3	Median (range) 24-h opioid consumption was 18.7 mg (0.0–43.0 mg) oral morphine.
S. D. Adhikary, W. M. Liu, E. Fuller, H. Cruz-Eng and K. J. Chin5	Reductions in opioid consumption were observed but did not achieve statistical significance. These improvements were largely sustained for up to 72 hours.
Swati Singh, Gunjan Kumar, Akhileshwar6	Postoperative morphine consumption was significantly less in patients receiving US-guided erector spinae block compared to control group (1.95 ± 2.01 mg required in ESP group vs 9.3 ± 2.36 mg required in control group, P value = 0.01)).
Present Study	Chi Square test shows significant difference in the dosage of fentanyl administered between the groups for all time points except 12 hrs.

In the following table we have compared the amount of fentanyl used in the study period.

Study	Incidence of Nausea and Vomiting
Hironobu Ueshima, Mayumi Inagaki, Tomoaki Toyone, Hiroshi Otake2	The two groups did not exhibit significant differences in the incidence of complications such as nausea and vomiting.
Present Study	Chi Square test showed no significant difference in the occurrences of Nausea and Vomiting between the groups for all time points.
Study	Incidence of Pruritis

Beverly Waxler, M.D. Zerin P. Dadabhoy, M.D., Ljuba Stojiljkovic, M.D., Ph.D., Sara F. Rabito, M.D., F.A.H.A., David C. Warltier, M.D., Ph.D.7	Systemic administration of opioids may stimulate opioid receptors in the skin. Both systemic and regional opioids can cause itching by their actions on centrally located receptors.
Present Study	No significant difference in the incidence of pruritis despite the differences in the amount of i.v fentanyl administered.

Limitations

Duration of surgical procedure might have acted as a confounding variable as some surgeries were of long duration and Surgical procedure and **extent of tissue damage** was different in each surgery which might have had some influence on the amount of pain.

Also, study of **chronic pain** could not be done as study period was limited to 24 hours.

Future Scope Of The Study

In the future, more cadaveric dye studies should be done to confirm the spread of the drug with respect to the volume of LA used. We also observed that erector spinae block prior to the surgery resulted in **stable intra operative hemodyanamics** along with post operative analgesia. Evaluating the cause of this was beyond the scope of this study and needs to be further studied. The need and **safety of multiple level injections** for bigger incisions should be studied.

CONCLUSION

Erector Spinae Block for patients undergoing lumbar spine surgeries **provides analgesia and patient satisfaction for 24 hours** after the procedure. The **i.v fentanyl dose** requirement was also significantly **reduced**. There was no significant difference in the incidence of complications like nausea, vomiting and pruritis.

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