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Research Article

A STUDY TO ASSESS THE EFFICACY OF ANATOMICAL LANDMARK GUIDED ERECTOR SPINAE PLANE BLOCK IN PATIENTS UNDERGOING ABDOMINAL HYSTERECTOMY UNDER GENERAL ANESTHESIA- A RANDOMIZED CONTROLLED STUDY

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A B S T R A C T

Context: Total abdominal hysterectomy causes significant postoperative pain. The Erector spinae plane block (ESPB) is an emerging component of multimodal pain alleviation regimen as it gives both visceral and somatic analgesia.[1]

Aims: To compare the frequency and number of rescue analgesia required during first 36 hours postoperatively and the modified defense and veterans pain rating scale [2]scores in the two groups.

Settings and Design: Hospital based, randomized controlled trial.

Methods and Material: Seventy female patients aged 35 to 60 years, physical status I and II undergoing abdominal hysterectomy were enrolled. Group ESPB(n=35) received General anesthesia +ESPB using 0.25% Ropivacaine hydrochloride 15ml bilaterally while Group GA (n=35) received only General Anesthesia. Post Operative 36 hours follow up. Statistical analysis used: Independent-samples Student t-test.

Results: All 35 patients of GA group required tramadol whereas in group ESPB only 3 out of 35 patients. Tramadol consumption in milligrams was significantly higher in group GA (491±28) mg than Group ESPB (133±57)mg, ($P <$ 0.0001). The Pain scores for group ESPB; @0 hour (2.2±0.75), @8h (2.42±0.69), @16h (1.94±0.48), @24h (1.45±0.56), @36h (1.08±0.44) were significantly lower than group GA; @0hour (5.2±0.65), @8 h (4.7±0.42), @16h (4.1±0.58), @24h (3.4±0.49), @36h (2.6±0.49), (P<0.0001). Similarly, Score for other components of Modified defense and veterans pain rating scale: sleep, activity, mood, stress were also lower for ESPB group.

Conclusions: Our results suggest that a landmark guided ESPB performed at T10 level provides good pain relief to the patients after abdominal hysterectomy under GA.

INTRODUCTION

An effective analgesia can significantly reduce patient's postoperative discomfort after Total Abdominal Hysterectomy that causes significant moderate to severe pain. Erector spinae plane block (ESP) is finding important place in multimodal analgesia regimens as no nerve or vascular structure needs to be identified for local anesthetic injection but the spread occurs in a muscle plane and will reach the nerves of interest. The injection is far off from the neuraxis, pleura, and vessels, thus lower incidences of complications.[3]

We have studied anatomical landmark-guided technique of ESPB using Injection Ropivacaine 0.25% in patients of Abdominal Hysterectomy under general anesthesia.

Subjects and Methods

With due approval of Institutional Ethical Committee, a prospective, hospital based, single blinded, randomized controlled, comparative study was done on **70** female patients, age between 35-60 years, weighing 30-80 kg, ASA I or II who were posted for abdominal hysterectomy.

The patients not giving consent, with history of drug allergy to any of our study drugs, history of significant respiratory, cardiac, hepatic, renal, neurological, psychiatric, or neuromuscular disease, bleeding disorder, local pathology at injection site or disability limiting the performance of block, were excluded.

The patients were assigned into two groups by computer generated system. We used sequentially numbered, closed, opaque, sealed envelope technique for allocation concealment. ***Group ESPB (n=35)*** *received GA+Erector spinae plane block using 0.75% Ropivacaine hydrochloride 10 ml diluted to total volume 30ml using 0.9% NaCl given 15 ml bilaterally and* ***Group GA(n=35)*** *Turn off cases were given only GA without erector spinae plane block. The investigator* who monitored the patients in postoperative 36 hours was unaware of the group allocation thus we maintained single blinding.

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All patients had undergone a detailed preanesthetic checkup including history, physical examination, and routine investigations. A written informed consent was ensured from the patients before the procedure after explaining the anesthetic technique and the five component Defense and veterans pain rating scale (our tool of assessment in postoperative period). All the drugs and equipment necessary for general anesthesia and resuscitation were kept ready. All the Standard ASA monitoring including noninvasive blood pressure (NIBP), pulse oximetry (SpO2), and electrocardiogram (ECG) was done and a good intravenous (IV) access was secured. The baseline values of systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), heart rate (HR), respiratory rate (RR), oxygen saturation were recorded.

Patient was made to sit comfortably. T10 spinous process was identified and marked. Under all aseptic precautions, a 22 G, spinal needle was introduced at a right Angle to the skin at a point which is 3cm sidewards to spinous process hitting the transverse process of the thoracic vertebra. This bony hit feel comes at a varying depth of 2–4 cm into the skin and thus depth of needle insertion must be gentle keeping in mind the patient's build. Once the needle came in contact with the transverse process, a volume of 15 ml of 0.25% ropivacaine was injected on both sides in 3–5 ml aliquots after negative aspiration. The general anesthesia was administered with injection fentanyl 1mcg/kg and propofol. Anesthesia was maintained using oxygen+ nitrous oxide+ inhalational agent and atracurium as muscle relaxant. Intraoperatively injection paracetamol 1g infusion was given around 30 minutes before closure. Blood loss assessment was done and fluids were administered as per the loss. Duration of surgery was noted.

Neuromuscular block reversal was done and patient was extubated when fully conscious, with stable vital parameters. Patient was shifted to post anesthesia care unit(PACU) and monitored for adequacy of muscular power, respiration, circulation and oxygen saturation.

In the postoperative period patients were assessed for hemodynamic parameters and modified defense veterans pain rating scale[2] at 0hr, 8 hr, 16 hr, 24hr and 36 hrs.

Statistical analysis

The sample size was calculated using following formulae:

$$n = \frac{(\sigma_1^2 + \sigma_2^2) \times [Z_{1-\alpha/2} + Z_{1-\beta}]^2}{(\mu_1 - \mu_2)^2}$$

where n = sample size,

For 90% power, $Z_{1-\beta}$=1.28,

For 0.05 significance level, Z_{α}=1.96,

σ_1 (SD1)[1] = 20.39, σ_2(SD2)[1] = 67.49,

μ_1 (mean 1)[1] = 485, μ_2 (mean 2)[1] = 445

$$N = \frac{(415.75 + 4554.9) \times (1.96 + 1.28)^2}{(485-445)^2}$$

N ≈ 33 rounded off to 35. So, we enrolled 35 subjects per group i.e. a total of 70 subjects as per the reference article[3]. Data was entered in Microsoft Excel sheets and Statistical analysis was done using IBM SPSS statistical package for windows. Normally distributed numerical data was presented as mean (standard deviation) and between-groups differences were compared working the independent-samples Student t-test.

Categorical data was presented as ratio and inter-group comparison was performed using the Pearson Chi-square test.

RESULTS

The demographic data including mean age, weight, ASA physical status classification and duration of surgery were comparable in both the groups (Table 1).

Table 1 Demographic profile

Parameter	Group ESPB (n=35)	Group GA (n=35)	*P* value
Age	45.82 ± 7.6	46.51± 6.1	0.707 (NS)
ASA PS (I/II)	32/3	33/2	0.10 (NS)
Weight (kg)	52.91 ± 7.7	52.48 ± 5.9	0.793 (NS)

The mean modified defense and veterans pain rating scale scores for pain (Table2), sleep (Table3), activity (Table4), mood (Table5), stress (Table6) were significantly lower in group ESPB than group GA for first 36 hours postoperatively. These differences in the two groups were found to be statistically significant (*P<0.0001)*.

Table 2 Comparison of mean modified Defense and veterans pain rating scale (DVPRS) score (PAIN) in two groups.

Time in hours postoperative period	Modified DVPRS (Pain)		*P* value
	Group GA, n=35	Group ESPB, n=35	
0 h	5.2±0.65	2.2±0.75	<.0001 (S)
8h	4.7±0.42	2.42±0.69	<.0001 (S)
16h	4.1±0.58	1.94±0.48	<.0001 (S)
24h	3.4±0.49	1.45±0.56	<.0001 (S)
36h	2.6±0.49	1.08±0.44	<.0001 (S)

Table 3 Comparison of mean modified Defense and veterans pain rating scale (DVPRS) score (Sleep) in two groups.

Time in hours postoperative period	Modified DVPRS (Sleep)		*P* value
	Group GA, n=35	Group ESPB, n=35	
0	4.6±0.5	3.57±0.5	<.0001 (S)
8	4.2±0.6	3.05±0.6	<.0001 (S)
16	3.9±0.7	2.6±0.7	<.0001 (S)
24	3.7±0.5	2.25±1.0	<.0001 (S)
36	3.5±0.5	1.77±1.1	<.0001 (S)

Table 4 Comparison of mean modified Defense and veterans pain rating scale (DVPRS) score (Activity) in two groups.

Time in hours postoperative period	MODIFIED DVPRS (Activity)		*P* value
	Group GA, n=35	Group ESPB, n=35	
0	4.9±0.6	2.9 ±0.8	<.0001 (S)
8	4.3±0.7	2.6±0.6	<.0001 (S)
16	4.05±0.6	2.0±0.8	<.0001 (S)
24	3.8±0.7	1.6±0.8	<.0001 (S)
36	3.5±0.5	0.8±0.9	<.0001 (S)

Table 5 Comparison of mean modified Defense and veterans pain rating scale (DVPRS) score (Mood) in two groups.

Time in hours postoperative period	Modified DVPRS (Mood)		*P* value
	Group GA, n=35	Group ESPB, n=35	
0	4.6±0.5	2.7±0.6	<.0001 (S)
8	4.0±0.5	1.9±0.7	<.0001 (S)
16	3.8±0.5	1.5±0.6	<.0001 (S)
24	3.5±0.5	1.1±0.6	<.0001 (S)
36	3.3±0.4	1.0±0.5	<.0001 (S)

The rescue analgesia requirement (injection tramadol consumption in mg) was significantly higher in group GA

(491±28) than Group ESPB (133±57), (Table8). The mean analgesia requirement in ESPB group was injection paracetamol 1.37±0.4 g and inj. tramadol 133±57 mg. The mean analgesics consumed in GA group were inj. paracetamol 1.2 ±0.4g and injection tramadol 491±28 mg in the first 36 hours postoperative period. These results were found to be statistically significant (*P<0.0001).* The number of patients prescribed injection tramadol was significantly high for group GA (i.e. all 35 patients) as compared to group ESPB (only 3 out of 35 patients) during first 36 hours of postoperative period, (Table 7).

Table 6 Comparison of mean modified Defense and veterans pain rating scale (DVPRS) score (Stress) in two groups.

Time in hours postoperative period	Modified DVPRS (Stress)		*P* value
	Group GA, n=35	Group ESPB, n=35	
0	4.8±0.5	2.2±0.9	<.0001 (S)
8	4.1±0.5	1.8±0.6	<.0001 (S)
16	3.9±0.6	1.4±0.9	<.0001 (S)
24	3.6±0.5	0.6±0.7	<.0001 (S)
36	3.3±0.5	0.2±0.6	<.0001 (S)

Table 7 Comparison of number of patients consuming tramadol in two groups.

	Group GA(n=35)	Group ESPB(n=35)	*P* value
No. of patients required injection Tramadol(100mg)	35	3	<.0001 (S)

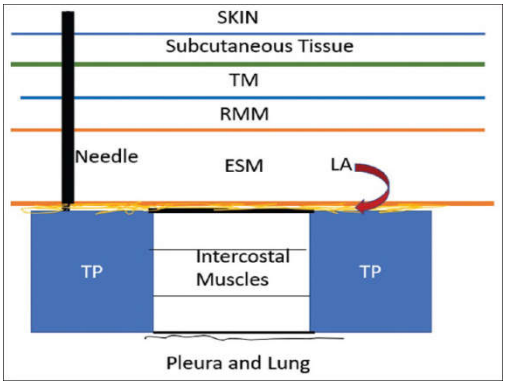
Table 8 Comparison of mean tramadol consumption in two groups (expressed as milligrams of tramadol used)

	Group GA (n=35)	Group ESPB (n=35)	*P* value
Total inj. Tramadol (mg) consumption	491±28	133±57	<.0001 (S)

No significant hemodynamic changes (HR, SBP, DBP, MAP) were noted in both groups both intraoperatively and postoperatively. No adverse effect or complications were noted in any of the patients.

DISCUSSION

Literature has revealed that ESP block is being widely used for different indications and also provides a variable duration of postoperative analgesia. The main purpose of our study was not only to assess the efficacy of erector spinae plane block but also to emphasize the importance and ease of the anatomical landmark guided technique to perform this block . Our study did not mandate availability of setup equipped with ultrasonography which is a common situation of developing countries. So this technique can be used not only at tertiary care hospitals but also at secondary care level where there is non availability of ultrasonography.



Schematic diagram of landmark guided Erector Spinae Plane Block adapted from article by Vadera and Mistry.[18] TM-Trapezius Muscle, RMM-Rhomboid Muscle, ESM-Erector Spinae Muscle, TP-Transverse Process of vertebra, LA-Local Anesthetic.

We enrolled patients being taken for abdominal hysterectomy into two groups for comparison, with 35 patients in each group. One group patients received low thoracic ESPB injection and then general anaesthesia. The other group did not receive the block and taken under general anaesthesia. Both the groups were followed for 36 hours postoperative period. Chin *et al*[4] suggests to give the ESP block at the spinal level complementary to the midpoint of the expected analgesia field. A drawback of the method is the obligation to perform injections bilaterally for the surgeries that cut across midline.[4] We gave bilateral injections at T10 level.

Table 9 Modified Defense and Veterans Pain Rating Scale [2] (Reference)

Circle the one number that describes how pain has interfered your usual activity										
0 Does not interfere	1	2	3	4	5	6	7	8	9	10 Completely interferes
Circle the one number that describes how pain has interfered your sleep										
0 Does not interfere	1	2	3	4	5	6	7	8	9	10 Completely interferes
Circle the one number that describes how pain has affected your mood										
0 Does not interfere	1	2	3	4	5	6	7	8	9	10 Completely affects
Circle the one number that describes how pain has contributed to your stress										
0 Does not interfere	1	2	3	4	5	6	7	8	9	10 Contributes a great deal
Circle the one number that describes your pain intensity										
0 No pain	1	2	3	4	5	6	7	8	9	10 Maximum pain

We used a 0.25% injection Ropivacaine 10 ml diluted to total volume of 30 ml in this study which is also in concurrence with the volumes and concentrations used in ultrasound-guided ESPB in all 12 RCTs of the meta-analysis reported by Huang and Lio i.e. 20 and 30 ml : 0.25% bupivacaine or 0.5% ropivacaine and 10-20 ml : 0.25–0.5% bupivacaine.[5]

We decided to give injection paracetamol 1g at 8 hours post surgery to all patients of both the groups (as premptive analgesia), and further 8 hourly on demand.

The total number and frequency of rescue analgesia requirement in addition to this 1g Paracetamol at 8th hour, were noted for both the groups and compared. NRS pain scores at rest were lower in group ESPB than in GA group as observed in the first 36 postoperative hours. The total tramadol consumed during this period was also lower in the ESPB group.

Demographic profile and baseline parameters: The differences in the demographic profile i.e. mean age, weight, ASA physical status (Table-1) between the two groups of our study was not found to be statistically significant (P>0.05), which provided us the uniform platform to evenly compare the results obtained. Our study mostly included patients of ASA PS –I and II**.**

Hamed *et al*[3] conducted a similar study with total 60 female patients 30 in each group undergoing abdominal hysterectomy, ASA physical status I-III. Women were 40–70 years old and weighing 50– 90 kg. They gave 20 ml: 0.5% bupivacaine as USG guided ESPBat ninth thoracic vertebrae level and the control group was given 20 ml saline as placebo injection.

In our study we did not give any sham injection to avoid unnecessary needle pricking to the control group. Although they must have done the sham block in order to maintain blinding.

The primary objective in our research study was to estimate and compare the number and frequency of rescue analgesia required in both the groups for first 36 hours post operatively. Secondarily, we tried to assess the *effective analgesia* by scoring the modified Defense and Veterans Pain Rating Scale (mDVPRS).

Rescue analgesia requirement: The number of rescue analgesia requirement was significantly higher in group GA(all 35 patients) than group ESPB(only 3 out of 35 patients) . The frequency of rescue analgesia requirement (injection tramadol consumption in mg) was significantly higher in group GA (491±28) than Group ESPB (133±57). So the total analgesia required in ESPB group was injection paracetamol 1.37±0.4 g and inj. tramadol 133±57 mg. The total analgesics consumed in GA group were inj. paracetamol 1.2 ±0.4g and injection tramadol 491±28 mg in the first 36 hours postoperative period. These results were in concurrence with the study by Gürkan *et al*.[6] They reported a decrease in morphine consumption after single ESPB shot using 20 ml of Local anesthestic at T4 level .The mean morphine consumption was 5.76 mg far less than 16.6 mg of control group at postoperative 24 hour. This was a statistically significant decrease of 65%. In our study there was 70% decrease which is statistically and clinically significant.

Tulgar *et al* [7] did a retrospective evaluation of 182 patients from their medical records who had ESPB in a year. Thirteen different combinations and levels were evaluated, which included thoracic: nine, lumbar: two and bilevel: two. They analyzed postoperative 24-hour analgesia consumed and found that 23% = 41 patients needed rescue analgesia, 9%= 15 out of 41 required rescue within the first 12 hours. The mean paracetamol + tramadol used per patient was 2.33 g [0-3 g] + 99.33 [0-300] mg. The mean NRS score of first 24 hours was 1.86 (average range remained 0-4.75).

Modified defense and veterans pain rating scale. The two groups were compared for effective postoperative analgesia using a multiparameter scoring system i.e. modified Defense and Veterans Pain Rating Scale (mDVPRS).The components of mDVPRS are Activity, Sleep, Mood, Stress and Pain.

The Pain scores for group ESPB were significantly lower than group GA. Similarly Yamak *et al*[8] documented extended analgesia in a patient after lower segment caesarean section who were given single injection of bilateral ESP block and reported NRS scores of 1–3 in the first 24 hours. Tulgar *et al* reported 3 patients subjected to different abdominal surgeries who were given single ESP block. Analgesia durations of 13, 16and 17 hours were observed.[9] Moreover, Hamed *et al*[3] observed more than 12 hours of the analgesia in ESP block group of women undergoing abdominal hysterectomy. Our results also matched well with the results of Chin *et al*[4] where an ESPB at D7 transverse process level (local anesthetic volume 20 -30 ml) resulted in pain scores ranging 0 to 5 with minimal use of intra-operative opioid. The average opioid consumption was found to be 18.7 mg in 24 hours.[4]

The Activity scores for group ESPB were significantly lower than group GA. Results could not be compared because of paucity of a similar study for same parameter, however we used the reference article Khan *et al* [2] to rate the activity scores related to pain in our patients.

The Sleep scores for group ESPB were significantly lower than group GA . We could not compare the results because of paucity of a similar study for same parameter , however we used the reference article Khan *et al*[2] to rate the sleep scores related to pain in our patients.

The Mood scores for group ESPB were significantly lower than group GA. We could not compare these results because of paucity of a similar study for same parameter, however we used the reference article Khan *et al*[2] to rate the mood scores related to pain in our patients.

The Stress scores for group were significantly lower than group GA. Results could not be compared because of paucity of a similar study for same parameter, however we used the reference article Khan *et al*[2] to rate the stress related to pain in our patients.

From these low scores of ESPB group, better patient satisfaction can be inferred as compared to GA group.

Hemodynamic parameters: The two groups were compared for intraoperative mean HR, MAP. The intraoperative mean arterial pressure ranged from 92.7±3.4 mmHg to 94.3±9.3 in GA group and from 93.4±5.8 to 99±9.4 mmHg in ESPB group. The mean heart rate ranged from 80.8±6.4 to84.7±8.5 beats /min in GA group and 81.2±7.8 to 86.4±9.9 beats / min. These differences were not found to be statistically significant (p>0.05). These findings were similar to the study by Raghunath P *et al*[10] with Tranversus abdominis plane block .
One of the commonly held operative interventions in gynecology is abdominal hysterectomy. Pain following abdominal hysterectomy owns both visceral and somatic components. The ESPB serves extensive and potent analgesia which is bilateral. The local anesthetic injected beneath the erector spinae muscle ,above the transverse process; diffuses into the paravertebral space through the spaces betwixt nearby vertebrae and acts by inhibiting both the ventral and dorsal rami of the spinal nerves[11,12]

The last 10-20 years have promoted multimodal opioid-sparing analgesia as a victorious alternative to long established opioid

centred analgesia.[13] The peripheral regional nerve blocks and truncal blocks have become indistinct parts of these multimodal plans.[14]

The mechanism of action of ESBP using dye-dissection study of cadavers found that 20 ml of dye infused in the plane between erector spinae and the fifth thoracic transverse process resulted in considerable cephalad spread to T6 and laterally to the lateral attachments of iliocostalis.[15] The lateral cutaneous branches of the intercostal nerves sideward to the ribs' angle were stained.[15] They found dye on the ventral ramus in one injection (5%), and in two of the injections (10%), the dorsal root ganglia were stained through the costotransverse foramen. Adhikary *et al*. [16] used magnetic resonance imaging (MRI) for contrast diffusion study after performing ESP in cadavers and showed a paravertebral diffusion that further spanned into the epidural space. The study suggested an extensive blockade of the dorsal ramus of the spinal nerves but not involving the ventral ramus.

The thoracolumbar fascia, a complex structure containing a thick web of nerves with sympathetic fibres,[17] could explain the modulation in somatic pain after ESPB. [16]

Some of the limitations in our study were that the patients were not entirely blinded to the study. Patients knew whether they had an injection for ESPB or not. It might be better to give a bogus block using normal saline to the GA group so as to observe and compare the placebo effect but giving unnecessary needle prick was our concern. We could delineate the sensory component of block area. Chosing anatomical landmark guided technique for performing the block, in itself was a limitation as it increased the chances of missing the target plane of injecting local anaesthestic, and greater chances of block failure. There were limited result comparisons because of limited studies. We could study differences in postoperative durations of hospital stay in the two groups. In spite of these inadequacies, our findings that ESPB decreases the pain scores and opioid consumption are worth considering ESPB as an important part of multimodal analgesia protocol.
During our study, none the patients had any side effects or complications. There is a reported complication of lower extremity motor weakness after ESP block in a patient after caesarean section .[8]

CONCLUSION

Bilateral landmark guided ESPB provided effective postoperative analgesia and remarkably decreased opioid consumption for first 36 hours of postoperative period in patients of Total Abdominal Hysterectomy.

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