

# Comparison of Two Different Volumes of Epidural Normal Saline for Enhancing the Effects of Spinal Anesthesia in Adult Patients Undergoing Elective Lower Limb Surgeries: A Prospective Randomized Study

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## ABSTRACT

**Background:** The combined spinal-epidural (CSE) anesthesia technique gives a reliable subarachnoid block as well as the flexible epidural block. One of the modified technique of CSE is epidural volume expansion (EVE) in which normal saline or local anesthetic (LA) is instilled through epidural catheter leading to increase in level of sensory blockade. Aim of the study was to compare two different volumes of normal saline for enhancing the effects of spinal anaesthesia in adult patients undergoing elective lower limb surgeries.

**Methods:** 90 patients were randomly divided into two group. Group A - 45 patients who were received intrathecal 2.0ml of 0.5% hyperbaric bupivacaine and epidural 10ml of 0.9% normal saline for EVE using CSE technique. Group B - 45 patients who were received intrathecal 2.0ml of 0.5% hyperbaric bupivacaine and epidural 15ml of 0.9% normal saline for EVE using CSE technique.

**Results:** The demographic data were comparable in both groups. Significant difference was seen in total duration of sensory blockade between group A (192.11±9.80) and group B (Mean ± SD 215.33±17.57minutes) (p<0.0001). Total duration of motor blockade was longer in group B (Mean± SD: 181.91± 16.42) as compared to group A (Mean ± SD: 162.48 ± 9.35 minutes) (p<0.0001).

**Conclusion:** We conclude that epidural volume expansion (EVE) with 15 ml epidural normal saline was associated with faster onset, higher level and early achieve maximum level of sensory blockade, longer two segment regression time, early onset and longer duration of motor blockade as compared to EVE with 10 ml epidural normal saline.

## Introduction

Combined spinal epidural (CSE) has been an effective and a reliable method of postoperative analgesia especially in infraumbilical surgeries [1-2]. The combined spinal-epidural anesthesia technique gives a reliable subarachnoid block as well as the flexible epidural block [3]. It is defined as an instillation of drug

into the intrathecal space and placing the catheter in the epidural space, the intervertebral space used for both the technique is same [4]. The control of postoperative pain by Combined spinal epidural(CSE) is advantageous over the systemic opioids when used alone [5-6]. Various explanations were put forward through different studies to describe the increase in level of sensory block through epidural expansion technique which includes 'effect of volume', 'effect of drug' [7].

The authors declare no conflicts of interest.

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The most common technique of epidural volume expansion is by 'volume effect.' Normal saline undergoes a cephalad shift in CSF due to thecal compression on instilling normal saline through the epidural catheter. EVE makes the subarachnoid block rapid, dense, reliable and helps in controlling the duration of anesthesia [5].

Limited studies have been done involving the use of various volumes of normal saline in EVE's technique and there is no consensus regarding the use of a particular volume of normal saline which increases the sensory as well as motor blockade following spinal anesthesia. Thus, this study was conducted to compare the effects of two different volumes (10 ml and 15 ml) of normal saline for epidural volume expansion on spinal block characteristics.

We hypothesise that higher volume (15 ml) of epidural normal saline provides better enhancement of effects of spinal anesthesia compared to lower volume (10 ml) of epidural normal saline in adult patients undergoing elective lower limb surgeries. Aim of the study was to compare two different volumes of normal saline for enhancing the effects of spinal anaesthesia in adult patients undergoing elective lower limb surgeries.

## Methods

Following approval from the institutional ethics committee (IEC/PGIMER/RMLH/835/18), this prospective randomized comparative study was initiated. Ninety patients, ASA class I and II, age between 18 to 60 years, either sex, BMI < 30 kg/m<sup>2</sup>, height of patients between 150 cm - 170 cm, posted for elective lower limb surgeries were included in this study. Patients with any allergy to local anaesthetic drugs, coagulopathy and bleeding disorder, local site infection, preexisting neuromuscular disorders, congenital anomalies of lower back, raised intracranial pressure, severe hypovolemia, patients with spine pathology were excluded.

The sample size calculation was based on a study conducted by Doganci N et al [8]. The study observed that mean values of duration of sensory block in 10ml and 15 ml was 260.1 ± 80.1 and 303.8 ± 59.6 respectively. Taking these values as reference, the study sample size of 82 individuals (41 in each of the two study groups) to achieve an 80% power level and maintain a 5% level of significance. Therefore, sample size taken for the study is 90 (45 patients per group).

Formula used for comparing mean of two groups: -

$$N \geq 2 \frac{(\text{standard deviation})^2 (\alpha + \beta)^2}{(\text{mean difference})^2}$$

Where  $\alpha$  is value of Z at two sided alpha error of 5% and  $\beta$  is value of Z at power of 80% and mean difference is difference in mean values of two groups.

$$N \geq \frac{(2 * 70.60 * 70.60 * (1.96 + .84)^2)}{(303.8 - 260.1)^2} = 40.9 = 41 (\text{approx.})$$

Written informed consent was taken from all the patients. After careful pre-anaesthetic examination and investigation, patients meeting the inclusion criteria were

taken for the study. 90 patients were randomly divided into two groups of 45 patients each by computer generated random number. Group A - 45 patients who were received intrathecal 2.0ml of 0.5% hyperbaric bupivacaine and epidural 10ml of 0.9% normal saline for epidural volume expansion using CSE technique. Group B - 45 patients who were received intrathecal 2.0ml of 0.5% hyperbaric bupivacaine and epidural 15ml of 0.9% normal saline for epidural volume expansion using CSE technique.

Patients underwent a 6-hour fasting period for solids and a 2-hour fasting period for clear liquids prior to surgery. As part of routine pre-operative care, patients were administered Tab Ranitidine 150 mg the night before the scheduled surgery. Upon arrival in the operating room, essential pre-operative baseline parameters, such as ECG, heart rate (HR), blood pressure (BP) measured via NIBP technique (including systolic, diastolic, and mean values), and oxygen saturation (SpO<sub>2</sub>), were recorded. Intravenous line was secured in Operation theatre with 18G intravenous cannula and co-loading was done with Ringer Lactate. Patient was placed in sitting position. Under aseptic precautions combined spinal epidural blockade using CSE technique was performed. 18G Tuohy's epidural needle was introduced at L3-L4 interspace through loss of resistance (LOR) technique using 2ml of air. Subarachnoid block was performed at L3-L4 (same space in which epidural needle is inserted) through a midline approach using 26G spinal needle of CSE set and 0.5% hyperbaric bupivacaine 2.0 ml was injected at rate of 0.2 ml/second with operating table kept flat. Epidural catheter was inserted through Tuohy's epidural needle and fixed 3cm inside the epidural space. Patient was turned to supine posture immediately. 10ml and 15 ml of Normal Saline was injected in group A and group B respectively through the epidural catheter after negative aspiration.

The following parameters were observed and recorded. Onset of sensory blockade was defined as time taken from the completion of the injection of the intrathecal bupivacaine till the subject did not feel the pin prick at T10 level. Onset of motor blockade was defined as the time taken from the completion of injection of intrathecal bupivacaine till the patient developed Bromage scale -1 (Table 1). Maximum sensory blockade was defined as the time from the completion of the injection of intrathecal bupivacaine to the maximum sensory blockade attained. Sensory blockade was tested using pinprick method with a blunt 27G hypodermic needle every 30 seconds for first 2 minutes, every minute for next 5 minutes and every 10 minutes for next 30 minutes and every 15 minutes till the end of surgery and then after 30 minutes until sensory block was resolved. Time taken for maximum motor blockade was defined as the time from the completion of the injection of intrathecal bupivacaine to the maximum motor blockade attained (Bromage scale - 4). Duration of sensory blockade was the time taken from the time of injection till the subject did not feel sensation at S1. Duration of motor blockade was the time taken from the

time of injection till the subject attained complete motor recovery (Bromage scale - 0).

**Table 1- Quality of motor blockade was assessed by modified Bromage scale**

Bromage 0	No motor block
Bromage 1	Inability to raise extended leg; able to move knees and feet
Bromage 2	Inability to raise extended leg and move knee; able to move feet
Bromage 3	Complete block of motor limb

Time for sensory regression to L1 was defined as the time taken from the maximum level of sensory block attained till the sensation had regressed to L1 segment. Duration of analgesia was defined as the time from spinal injection to the first request of analgesics (VAS > 4) which consisted of intramuscular injection Diclofenac Sodium (NSAIDs) 75mg. Hemodynamic monitoring was done till end of the surgery employing multi parameter monitor which displayed heart rate, systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), ECG and SpO<sub>2</sub> hourly.

Hypotension was defined as decrement of Systolic Blood Pressure (SBP) more than 20% below baseline or fall in SBP less than 90 mm of Hg, and it was treated with increased rate of intravenous (IV) fluids and if needed injection Mephenteramine Sulfate 3mg IV increments was given. Bradycardia was defined as heart rate less than 60 beats/minute and was treated with injection Atropine 20ug/kg IV.

Patients were monitored during the post-operative period for analgesia, and side effects if any like hypotension, bradycardia were observed and noted. Postoperative pain was assessed using Visual analogue scale (0 – 10) at 30 minutes, and time to first rescue analgesic request was recorded.

Primary objective of the study was duration of sensory block. Secondary objectives of the study were enhancement of motor blockade effects of spinal anaesthesia, hemodynamic parameters, including heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP), were recorded during the study.

### Statistical Analysis

In statistical analysis Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean  $\pm$  SD. Normality of data was tested by Kolmogorov-Smirnov test. If the normality was rejected, then non parametric test was used. Quantitative variables were compared using Unpaired t-test/Mann-Whitney Test (when the data sets were not normally distributed) between the two groups. Qualitative variables were compared using Chi-Square test /Fisher's exact test. A p value of <0.05 was considered statistically significant. The data was then entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0.

## Results

90 patients were included in the study. No significant difference was seen in age (years) between group A (Mean  $\pm$  SD 42.066 $\pm$ 9.99) and group B (Mean  $\pm$  SD 45.4 $\pm$ 7.882) (p value 0.0823). There was no statistically significant difference in the weight of patients among the two groups (p>0.05). There was no statistically significant difference in height of the patients among the two groups (p>0.0001). No significant difference was seen in BMI (kg/m<sup>2</sup>) between group A (Mean  $\pm$  SD 23.8  $\pm$  2.58) and group B (Mean  $\pm$  SD 24.1  $\pm$  2.18) (p>0.05). The difference in the duration of surgery among the two groups was statistically not significant (p >0.05) (Table 2).

Significant difference was seen in time of onset of sensory block between group A (Mean  $\pm$  SD 6.84  $\pm$  2.62) and group B (Mean  $\pm$  SD 3.34  $\pm$  1.69) in group B (p<0.05). In group B two patients (4.44%) showed the maximum sensory blockade up to T4 whereas 16 patients of group A (35.56%) showed the maximum sensory blockade level up to T6. Hence, there was statistically significant difference among the 2 groups (p=0.018). Time required to achieve the maximum level of sensory blockade was longer in group A (mean  $\pm$  SD: 9.44  $\pm$  2.52 minutes) as compared to group B (mean  $\pm$  SD: 5.24  $\pm$  1.67 minutes). Both the groups showed that there was significant difference statistically (p<0.0001). Time for two segment regression was longer in group B (mean  $\pm$  SD: 98.17  $\pm$  17.79) as compared to group A (mean  $\pm$  SD: 69.46  $\pm$  15.07). (p<0.0001). Time for complete sensory regression was observed to be longer in group B (mean  $\pm$  SD: 196.97 $\pm$ 17.78) as compared to group A (mean  $\pm$  SD: 181.53  $\pm$  9.85) (p<0.0001). Total duration of sensory blockade was longest in group B (Mean  $\pm$  SD 215.33 $\pm$ 17.57 minutes) as compared to group A (192.11 $\pm$ 9.80 minutes), which was statistically significant (p<0.0001). Significant difference was seen in time of onset of motor block between group A (Mean  $\pm$  SD 9.17  $\pm$  2.92) and group B (Mean  $\pm$  SD 5.4  $\pm$  1.64) in group B (p<0.0001). Significant difference was seen in time of maximum motor blockade between group A (Mean  $\pm$  SD 11.06  $\pm$  2.91) and group B (Mean  $\pm$  SD 7.33  $\pm$  1.88) in group B (p<0.0001). Total duration of motor blockade was longer in group B (Mean  $\pm$  SD: 181.91 $\pm$  16.42 minutes) as compared to group A (Mean  $\pm$  SD: 162.48  $\pm$  9.35 minutes) (p<0.0001) (Table 3).

No significant difference was observed in mean heart rate among the two groups (p>0.05). No significant difference was observed in mean systolic blood pressure among the two groups (p>0.05). No significant difference was observed in mean diastolic blood pressure among the two groups (p>0.05). No significant difference was observed in mean blood pressure among the two groups (p>0.05). 11 patients had hypotension in group B and in group A only 2 patients showed hypotension within 10 minutes of EVE. 14 patients had bradycardia in group B as compared to group A where only 2 patients had bradycardia.

**Table 2- Comparison of demographic characteristics**

Parameters	Group A	Group B	P value
Mean Age (years)	42.066±9.99	45.4±7.88	0.0823
Mean Height (cms)	158.06 ± 5.45	159.06 ± 5.07	0.31
Mean Weight (kg)	159.06 ± 5.07	61.22± 7.35	0.369
Mean BMI (kg/m <sup>2</sup> )	23.8 ± 2.58	24.1 ± 2.18	0.5
Duration of surgery (min)	99.24 ± 18.63	98.82 ± 18.52	0.91

**Table 3- Comparison of different parameters related to sensory blockage and motor blockage between group A and group B**

Parameters	Group A	Group B	P value
Time of onset of sensory blockade (min)	6.84 ± 2.62	3.34 ± 1.69	<0.0001
Maximum level of sensory blockade	T6	T4	0.018
Time to achieve maximum level of sensory blockade (min)	9.44 ± 2.52	5.24 ± 1.67	<0.0001
Time for two segment regression (min)	69.46 ± 15.07	98.17 ± 17.79	<0.0001
Time for complete sensory regression (min)	181.53 ± 9.85	196.97±17.78	<0.0001
Total duration of sensory blockade (min)	192.11±9.80	215.33±17.57	<0.0001
Time of onset of motor blockade (min)	9.17 ± 2.92	5.4 ± 1.64	<0.0001
Maximum motor blockade (min)	11.06 ± 2.91	7.33 ± 1.88	<0.0001
Total duration of motor blockade (min)	162.48 ± 9.35	181.91± 16.42	<0.0001

## Discussion

Epidural volume expansion (EVE) is a technique of administering normal saline or any local anesthetic drug through epidural route after the intrathecal injection of drug enhancing the effects of spinal anesthesia.

Blumgart et al [9] stated that the increase of the sensory blockade is possible by the volume effect. Injection of normal saline epidurally leads to dural sac compression causing the local anesthetic to travel cephalad. Higuchi et al [10] designed a study where a magnetic resonance imaging (MRI) was used to find the effect of injection of different volumes (5ml, 10ml, and 15ml) of epidural saline on the CSF volume. He recorded the waveform of the velocity induced by normal saline injections. Dural compression lasted for 30 minutes after the instillation of the saline. Hence, clinical and imaging studies showed that augmentation of the block with EVE is caused by volume effect.

In spite of various studies on EVE's technique, there is wide variations in results regarding the extent of epidural saline-induced spinal anaesthesia because of difference in methods adopted among the studies. These factors include mainly the injection of local anaesthetics for spinal anesthesia and the timing of the saline injection. On Generalizing the results of these studies, the ability to increase dermatomal spread by incremental epidural volume seems to be time dependent [11-12].

In our study, the time of onset of sensory blockade was statistically significant between both the groups. Result of our study correlates with the study done by Okasha et

al [5] which showed earlier onset of sensory blockade in EVE group in comparison to a group without EVE in hip screw surgery.

In our study, group B, two patients (4.44%) showed the maximum level of sensory blockade up to T4 whereas 16 patients of group A (35.56%) showed the maximum level of sensory blockade up to T6. Hence, there was statistically significant difference among the 2 groups (p=0.018) regarding the maximum level of sensory blockade. Our study showed results similar to study done by Okasha et al [5] study, where the maximum level of sensory blockade achieved was higher in EVE group as compared to group without EVE. Chiraynth J et al [13] study also showed that, there was an extension of level of sensory blockade was higher in Group EVE when normal saline was administered epidurally as compared to the group which had not received the normal saline. They attributed the cause for the higher level of the subarachnoid block partly due to the effect of the volume of the local anesthetic in epidural space and partly due to the local anesthetic effect.

In our study, time taken for maximum level of sensory blockade was longer in group A as compared to group B. There was statistically significant difference between both the groups (p0.0001). Hence, the time taken to achieve the maximum level was slightly longer in group A when compared to group B. In support of our above study, Okasha et al [5] noticed there was a statistical significant difference between the two groups in terms of the time required to achieve the maximum sensory block level, which was faster in group I (CSE with EVE group- 10.7 ± 1.7 minutes) and longer in group II (CSE without



EVE-13.4 ± 2.4 minutes). In contrast to our study, Choi et al [14] study which showed that time taken to achieve maximum height of sensory block was longest in EVE with saline group (14.5±3.1 minutes) as compared to EVE with bupivacaine group (12.2 ± 3.6 minutes) which was longer when compared to group without EVE (8.9 ± 3.1 minutes).

Time for two segment regression was longer in group B (98.17 ± 17.79 minutes) as compared to group A (69.46 ± 15.07minutes) which was statistically significant (p<.0001) Faster regression of sensory blockade in group A when compared to group B could be due to greater spread of drug, and a shorter duration of action. Our study is similar to Okasha et al [5] study, which showed longer time for two segment regression in group I (CSE with EVE-81 ± 7.3 minutes) as compared to group II (CSE without EVE-67.9 ± 5.1 minutes). Results from Salman et al [15] were also comparable to our study and showed longer time for two segment regression in EVE group than in group without EVE.

Our study showed time for complete sensory regression to L1 was longer in group B as compared to group A ranging from 181.53 ± 9.85minutes in group 15, and 196.97±17.78 minutes in group 15, which was statistically significant (p<0.0001). Our results were consistent with the study done by Doganci et al [8] who noticed that time for sensory regression to L1 level was significantly longer in patients who received 15ml EVE as compared to 5ml, 10 ml and 20 ml of saline for EVE with intrathecal 10 mg of 0.5% plain bupivacaine. Result of our study is similar to study done by Salman et al [15], who had noticed that time for sensory block regression was longer in EVE group (158.66 ± 15.52 minutes) as compared to spinal group (131.27 ± 16.98 minutes) i.e. without EVE.

In our study, time of onset of motor blockade (Bromage– 1) was statistically significant between the two groups (p<0.0001). Our study showed faster onset of motor blockade in group B (5.4 ± 1.64 minutes) as compared to group A (9.17 ± 2.92). Our results compared with those obtained by Salman et al [15] who showed faster onset of motor blockade in EVE group (1.00 ± 0.00 minutes) as compared to spinal group (1.20 ± 0.61 minutes) in full term pregnancy of 37 – 42 weeks who were scheduled for caesarian delivery.

In our study, time taken to reach maximum motor blockade was more in group B as compared to group A which were statistically significant (p<0.0001). In contrast to our study Loubert C et al [16] study showed lower Bromage score in EVE group as compared to Group without EVE. Due to volume effect, on injecting epidural saline there is acceleration of the spread of a fraction of the spinal Bupivacaine towards the sacral segments.

Duration of motor blockade was longest in group B (181.91± 16.42 minutes) as compared to group A (162.48

± 9.35 minutes). There was significant difference in both the group (p <0.0001). This result of our study is consistent with Salman et al [15] where they also noticed, longer duration of motor blockade in EVE group as compared to group without EVE. Even the results were similar in study done by Goy RWL et al [17] study in which they demonstrated that the duration of motor block was longer in CSE group as compared to single shot spinal group.

The incidence of hypotension and bradycardia was less in group A when compared to group B. Regarding hypotension, our study result correlates with study done by Sherin M A et al [18] which also noticed frequent incidence of hypotension in EVE15 group (90%) when compared to EVE10 group (20%).

Our study has few limitations; the study had a small sample size. The study was accompanied in a single center. A multi-centered study may be more explanatory.

## Conclusion

We conclude that epidural volume expansion (EVE) with 15 ml epidural normal saline was associated with faster onset, higher level and early achieve maximum level of sensory blockade, longer two segment regression time, early onset and longer duration of motor blockade as compared to epidural volume expansion (EVE) with 10 ml epidural normal saline.

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