

A prospective randomised comparative study between 10 ml and 15 ml of normal saline for epidural volume expansion on 10mg of 0.5% hyperbaric bupivacaine spinal anesthesia for elective infraumbilical surgeries in adult patients

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Abstract

Introduction: The technique of combined spinal epidural (CSE) anaesthesia has become popular for patients undergoing elective infraumbilical surgeries where intraoperative prolonged and effective post-operative analgesia is required. CSE has the reliability of subarachnoid block as well as the flexibility of epidural block. The epidural volume expansion (EVE) technique is a modification of CSE in which the level of sensory analgesia obtained by subarachnoid block is increased by saline administered through the epidural catheter.

Aims and Objectives: The present study was designed to compare different volumes of normal saline (10ml and 15ml) for epidural volume expansion on spinal anaesthesia with 10 mg (2 ml) of 0.5% hyperbaric bupivacaine for elective infraumbilical surgeries in adult patients with respect to sensory and motor block characteristics and haemodynamic stability.

Materials and Methods: In this randomized, double blind, prospective study, ninety patients of ASA I and II of age group 18 – 59 years undergoing elective infraumbilical surgeries were randomly assigned into three groups namely group 0, group 10 and group 15. Combined Spinal Epidural technique was performed using double segment technique in lateral position in all the patients. Group 0 received 10 mg of 0.5% hyperbaric Bupivacaine intrathecally without EVE, group 10 received 10mg of 0.5% hyperbaric Bupivacaine followed by EVE with 10 ml of normal saline, group 15 received 10mg of 0.5% hyperbaric Bupivacaine followed by EVE with 15 ml of normal saline.

Results: There were no statistically significant difference in the demographic data among the studied groups. Regarding block profile, the time of onset of sensory block was found to be statistically insignificant whereas a significant difference was noted among the three groups regarding maximum level of sensory blockade. Time to achieve maximum level of sensory blockade was observed to be longest in group 15 (mean \pm SD: 4.76 \pm 0.72 minutes) as compared to group 10 (mean \pm SD: 4.60 \pm 0.56 minutes) which was longer when compared to group 0 (4.26 \pm 0.90 minutes) and was statistically significant ($p=0.035$). Time for two segment regression, time for complete sensory regression(s1) and total duration of analgesia were longest in group 10 (120 \pm 21.21minutes, 204.50 \pm 32.35 minutes, 218.50 \pm 34.94 minutes respectively) as compared to group 15 (99.00 \pm 17.43 minutes, 181.50 \pm 19.43 minutes, 209.00 \pm 18.02 minutes respectively) which was longer than group 0 (79 \pm 14.81 minutes, 116.50 \pm 22.17 minutes, 125.50 \pm 24.11 minutes respectively). The parameters were statistically significant ($p=0.000$) among the groups. No statistically significant difference among the groups were observed with respect to time of onset of motor block and maximum motor blockade. The total duration of motor blockade was longer in group 10 (193.00 \pm 32.65 minutes) as compared to group 15 (162.00 \pm 15.45 minutes) and group 0 (106.00 \pm 18.02 minutes). Hemodynamic stability was better in group 0 and group 10 when compared to group 15.

Conclusion: Epidural volume expansion (EVE) has definite advantages over subarachnoid block alone. EVE of 10 ml of saline with intrathecal 0.5% Bupivacaine is better when compared to EVE of 15 ml of saline with regard to sensory and motor block characteristics while maintaining the hemodynamic stability.

Keywords: Combined spinal epidural, Epidural volume expansion, Intrathecal bupivacaine.

Introduction

The technique of combined spinal epidural (CSE) anaesthesia has become popular for patients undergoing infraumbilical surgeries who require prolonged and effective intra operative and post operative analgesia.¹ CSE technique reduces or eliminates some of the disadvantages of spinal anaesthesia while preserving their advantages.² One of the modifications of CSE technique is the Epidural volume expansion (EVE), wherein the level of sensory analgesia after subarachnoid block is increased by administering normal saline or local anaesthetic through the epidural catheter.³

The singularity in EVE lies in its ability to combine the rapidity, density and reliability of subarachnoid block with the flexibility of continuous epidural block to titrate a

desired sensory level, vary the intensity of block, control the duration of anaesthesia and deliver post-operative analgesia.⁴ Among various mechanisms described, the most commonly extended explanation is the thecal compression due to the 'volume effect' on the consequent epidural injection of fluid.⁵

Various volumes of normal saline (5ml, 10ml, 15ml and 20mL) have been used for EVE technique but there is no consensus regarding the effective volume of normal saline for epidural volume expansion on the sensory and motor block characteristics of spinal anaesthesia.

Hence the study was undertaken to compare the effects of two different volumes (10 ml and 15ml) of normal saline for epidural volume expansion on sensory, motor and

haemodynamic characteristics after subarachnoid block as well as for post operative analgesia.

Materials and Methods

Institutional ethical committee approval was obtained and 90 patients in the age group between 18 to 59 years of American Society of Anaesthesiologists (ASA) class I and II undergoing elective infra umbilical surgery were selected for the study. It was a randomized, double blind, prospective study, undertaken at Krishnarajendra Hospital attached to Mysore Medical College and Research Institute, Mysore between November 2014 to July 2016.

Patients with body mass index > 30 kg/ m², patients having any absolute contraindications for spinal anaesthesia like severe hypovolemia, raised intracranial pressure, bleeding diathesis, local infection and patients with severe co morbid diseases like diabetes, hypertension, cardiovascular diseases, psychiatric and neurologic diseases were excluded from the study.

The study population was randomly divided into 3 groups of 30 patients each, using shuffled closed opaque envelope method.

Group 0: received 10mg (2ml) of 0.5% Hyperbaric Bupivacaine intrathecally and did not receive any epidural volume expansion. (n=30)

Group 10: received 10mg (2ml) of 0.5% Hyperbaric Bupivacaine intrathecally and 10ml of 0.9% Normal Saline for epidural volume expansion. (n=30)

Group 15: received 10mg (2ml) of 0.5% Hyperbaric Bupivacaine intrathecally and 15ml of 0.9% Normal Saline for epidural volume expansion. (n=30)

Preoperative assessment was done in detail and informed written consent was taken.

Patients were kept nil per oral, 8 hrs for solids and 2 hrs for clear fluids before surgery. All the patients received tablet ranitidine 150mg and tablet alprazolam 0.5mg the night before surgery. Intravenous line was obtained with 18G cannula and preloaded with Ringer Lactate 10mL/kg half an hour before anaesthesia. Monitoring was done using multiparameter monitor (Edan iM80) having Pulse oximetry, Electrocardiography (ECG), and Non-Invasive Blood Pressure (NIBP). Under aseptic precautions, combined spinal epidural blockade was performed in lateral flexed position using double segment technique at either L2-L3 or at L3-L4 interspace through loss of resistance (LOR) to air technique. After placing the epidural catheter, spinal block was performed at either at L3- L4 or at L4-L5 intervertebral space through a midline approach using 25 gauge Quincke spinal needle and after confirming free and clear flow of CSF, 0.5% hyperbaric bupivacaine 10 mg (2ml) was injected at rate of 0.2 ml/second with operative table kept horizontal. The epidural catheter was secured and patients were turned to supine posture immediately. This combined spinal epidural technique was done by the same anaesthesiologist who was also the observer for the study population. Immediately after turning the patient to supine position, epidural volume expansion was done with either 10 ml or 15 ml normal saline by an anaesthesiologist who

was involved with the randomisation but, not involved further in the study. Thus, both the observer and the subjects were blinded.

The following parameters were observed and recorded, Onset of sensory block at T 10 and motor blockade (Modified Bromage 1), Maximum level of sensory blockade attained and the time taken for the same was noted. Two segments sensory regression time (defined as recovery of sensory blockade by two segments from the highest level of sensory block achieved), total duration of sensory blockade (time of injection till the subject feels sensation at S1) and total duration of analgesia (time for spinal injection and first request for analgesics) were noted. Maximum motor blockade attained and the total duration of motor blockade (attainment of modified Bromage score of 0) were noted. Quality of sensory blockade was tested using pinprick method with a blunt 27G hypodermic needle. Quality of motor blockade was assessed by modified Bromage scale. (0 = no paralysis; 1 = unable to raise extended leg; 2 = unable to flex knee; 3 = unable to flex ankle).

Haemodynamic monitoring for heart rate, systolic, diastolic and mean arterial pressure, ECG and SPO₂ blood pressure (SBP), was done every minute for first 5minutes, every 5 minutes till the end of surgery. Patient was monitored during the postoperative period for the duration of analgesia and side effects like hypotension and bradycardia and respiratory depression. Hypotension was defined as reduction of systolic blood pressure (SBP) more than 30% below baseline or fall in SBP less than 90 mm of Hg, and it was treated with IV fluid bolus and if needed increment of injection Mephentermine 6mg IV. Bradycardia was defined as heart rate less than 60 beats/minute and was treated with injection Atropine 0.6mg IV.

Statistics

Determination of sample size was done using Anova. Thirty patients were included in each group. The data obtained was analysed using Cramer's V test, Independent T test and Anova. Data were entered into Microsoft Excel and all the statistical methods were carried out through the SPSS for Windows (version 23.0). p value of < 0.05 was considered significant.

Results

The demographic data i.e; age, sex, weight (kg), Height (cm) and BMI showed no significant changes and were comparable between the three group.

Table 1: Demographic data

Parameters	Group 0	Group 10	Group 15	P value
Age in yrs (mean±SD)	36.36 ± 10.76	35.73 ± 11.88	36.66 ± 11.51	0.949 Insignificant
SEX male/female	21/9	19/11	20/10	0.861 Insignificant
WEIGHT in Kgs (mean±SD)	61.86 ± 7.81	62.10 ± 6.92	63.80 ± 6.71	0.524 Insignificant
HEIGHT in Cms (mean±SD)	164.56 ± 7.24	165.03 ± 8.89	165.10 ± 8.03	0.962 Insignificant
BMI	22.72 ± 1.71	22.76 ± 2.03	23.32 ± 1.60	0.345 Insignificant

Group 0: No EVE group, Group 10: 10 ml of EVE group, Group 15: 15 ml of EVE group, SD: Standard Deviation

Table 2: Sensory block characteristics

Parameters		Group 0	Group10	Group 15	P value
Onset of sensory block at T10(in minutes)		2.17 ± 0.37	2.17 ± 0.37	2.27 ± 0.44	0.544 Insignificant
Maximum level of sensory blockade	T2	0	3	13	0.000 Significant
	T4	0	26	17	
	T6	2	1	0	
	T8	9	0	0	
	T10	13	0	0	
	T12	6	0	0	
Time required to achieve the maximum level of sensory blockade (in min)		4.26 ± 0.90	4.60 ± 0.56	4.76 ± 0.72	0.035 Significant
Time for two segment regression (in min)		79.50 ± 14.81	120.00 ± 21.21	99.00 ± 17.43	0.000 Significant
Time for complete sensory regression (in min)		116.50 ± 22.17	204.50 ± 32.35	204.50 ± 32.35	0.000 Significant
Total duration of anaesthesia (in min)		125.50 ± 24.11	218.50 ± 34.94	209.00 ± 18.02	0.000 Significant
Time for first Rescue Analgesia (in min)		126.00 ± 24.47	219.50 ± 35.11	211.50 ± 15.43	0.000 Significant

Table 3: Motor block characteristics

Parameters	Group 0	Group 10	Group 15	P value
Time of onset of motor blockade (in min)	2.60 ± 0.67	2.33 ± 0.46	2.30 ± 0.62	0.154 Insignificant
Maximum motor blockade (in min)	2.83 ± 0.38	2.93 ± 0.25	3.00 ± 0.00	0.053 Insignificant
Total duration of motor blockade (in min)	106.00 ± 18.02	193.00 ± 32.65	162.00 ± 15.45	0.000 Significant

Discussion

In the last decade or so, central neuraxial blockade has undergone significant modification of the techniques, as well as the drugs available for neuraxial injection. Subarachnoid and epidural block can be performed as either a single shot or continuous technique, while a combination of both is practiced as the popular combined spinal epidural (CSE) block.

Epidural volume expansion (EVE) is a modification of CSE technique, wherein the level of sensory analgesia after

subarachnoid block is increased by normal saline or local anaesthetic administered through the epidural catheter.³ More recently in clinical practice, EVE has come to imply the injection of normal saline only.

The advantage in EVE lies in its ability to combine the rapidity, density, and reliability of the subarachnoid block with the flexibility of continuous epidural block to titrate a desired sensory level, vary the intensity of the block, control the duration of anaesthesia and deliver postoperative analgesia.⁵

But regarding the disadvantage of EVE, Meta-regression showed a significant result, increase in volumes of epidural volume extension leading to higher maximum sensory spread and a higher number of patients becoming hypotensive.⁶

Various mechanisms have been described to explain the rapid extension of sensory block that occurs with EVE include a 'volume effect', 'drug effect' and augmentation of a pre-existing area of subclinical analgesia. The most commonly extended explanation for EVE is the thecal compression due to the "volume effect" on consequent epidural injection of fluid. This thecal compression causes cephalad shift of local anaesthetic within the cerebrospinal fluid, raising the level of sensory block. Imaging studies documented thecal compression following EVE and several studies demonstrate an increase in post spinal sensory block following epidural injection of normal saline.⁵

Hence the study was undertaken to compare the effects of two different volumes (10 ml and 15ml) of normal saline for epidural volume expansion on spinal block characteristics.

Block Profile

Sensory Block Characteristics

In our study, the time of onset of sensory blockade was similar (2.17 minutes– 2.27 minutes) among the three groups. This result of our study correlates with other studies (Doganci et al, Lew et al and Salman et al) which showed no difference in time of onset of sensory blockade when different volumes of EVES were used in lower limb surgeries.^{7,8,3} Result of our study do not correlate with Okasha et al which showed early onset of sensory blockade in EVE group as compared to group without EVE in hip screw surgery.⁹ This could be due to the addition of adjuvant fentanyl to local anaesthetic.

In current study there was a statistically significant difference between the groups regarding level of maximum sensory blockade (T2), it was 43.3% of patients in group 15 and 10% of patients in group 10, which is consistent with Okasha et al study Chiraynth J et al.^{9,10}

Time for two segment regression was longest in group 10 (120.00 ± 21.21 minutes) as compared to group 15 (99.00 ± 17.43 minutes) which was longer when compared to group 0 (79.50 ± 14.81 minutes). Faster regression of sensory blockade in group 15 when compared to group 10 could be due to greater spread of drug, exposing the drug to a larger area for vascular absorption and thus a shorter duration of action.¹¹ This finding is consistent with Okasha et al study and Salman et al.^{9,3} The time for complete sensory regression was longest in group 10(204.50 ± 32.35 minutes) as compared to group 15 (181.50 ± 19.43 minutes) which was longer than group 0 (116.50 ± 22.17 minutes). Hence, early epidural catheter activation was required in the control group as compared to EVE groups. Result of our study correlates with Salman et al.⁹

Time for request of rescue analgesia was longer in group 10 as compared to group 15 and group 0. Our study is consistent with Choi et al which also showed that time for

first request of rescue analgesia was longer in EVE groups as compared to group without EVE.¹²

Motor Blockade Characteristics

In our study, time of onset of motor blockade and maximum motor blockade were similar among the three groups which correlates with Doganci et al study.⁷ Result of our study correlates with Sherin M A et al study which also showed similar Bromage scores among the groups.¹³

Duration of motor blockade was longest in group 10 (193.00 ± 32.65minutes) as compared to group 15 (162.00 ± 15.45 minutes) which was still longer as compared to group 0 (106.00 ± 18.02 minutes). This result is consistent with Salman et al and Goy RWL et al study.^{3,14}

Haemodynamic Effects

When comparing the intraoperative heart rate and mean arterial pressure between the groups, both the EVE groups (10 ml and 15 ml) showed fall in heart rate and mean arterial pressure below the basal values at various time intervals. This difference was statistically significant after 10 minutes of EVE.

Incidence of bradycardia was higher in group 15 as compared to group 10. The incidence of bradycardia was still less in group 0 when compared to EVE groups (10ml, 15ml). Regarding mean arterial pressure, fall in MAP was more in group 15 as compared to group 10 which was less in group 0 as compared to EVE groups.

Adverse Effects

When comparing adverse effects among study groups, 11 patients had hypotension in group 15 whereas only 2 patients had hypotension in group 10 after 10 minutes of EVE. Even in group 0, two patients had hypotension after 10 minutes of spinal block. Hence the incidence of hypotension was significantly high in group 15 when compared to group 10. Our study result correlates with Sherin M A et al study.¹³

Bradycardia was also seen in the study groups. 12 patients had bradycardia in group 15 as compared to group 10 where only 3 patients had bradycardia after 10 minutes of EVE and only one patient in group 0 had bradycardia after 10 minutes of spinal blockade. Hence the incidence of bradycardia was significantly high in group 15 when compared to group 10.

Conclusion

It can be concluded that epidural volume expansion of 10ml of saline with 10mg of intrathecal 0.5% hyperbaric bupivacaine is better when compared to epidural volume expansion of 15ml of saline with regard to maximum level of sensory block, total duration of sensory blockade, time for two segment regression and duration of motor blockade while maintaining haemodynamic stability.

Conflict of Interest: None.

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