Original Research Article

A prospective study evaluating the effectiveness of epidural volume extension with normal saline in combined spinal epidural anesthesia for lower limb orthopedic surgeries using low dose intrathecal hyperbaric bupivacaine

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	International Archives of Integrated Med	dicine, Vol. 4, Issue 11, November, 2017.	
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	Available online at <u>http://iaimjournal.com/</u>		
Jacob Contraction	ISSN: 2394-0026 (P)	ISSN: 2394-0034 (O)	
IAIM	Received on: 15-10-2017	Accepted on: 24-10-2017	
	Source of support: Nil	Conflict of interest: None declared.	

How to cite this article: S. Sudhakaran, S. Ashwini. A prospective study evaluating the effectiveness of epidural volume extension with normal saline in combined spinal epidural anesthesia for lower limb orthopedic surgeries using low dose intrathecal hyperbaric bupivacaine. IAIM, 2017; 4(11): 52-60.

Abstract

Background: Combined spinal-epidural anesthesia technique for providing pain relief for orthopedic procedures has gained popularity. It combines the advantages of rapid onset and the reliability of blockade obtained spinally along with the flexibility given by epidural catheter avoiding the disadvantages of either technique used alone. Spinal anesthesia provides dense neural blockade of finite duration while epidural is more titratable producing less hemodynamic swings and postoperative analgesia. The epidural volume extension adds color to combined spinal-epidural anesthesia technique where the onset and the level of blockade obtained spinally are enhanced by administering saline or local anesthetic via the epidural catheter. The ideology behind this is the volume effect accomplished by injecting saline epidurally which would result in intrathecal compression and cephalad migration of spinal local anesthetic.

Aim of the study: To identify the effectiveness of block profile provided by extending the epidural volume with normal saline for lower limb orthopedic surgeries using a low dose intrathecal hyperbaric bupivacaine without causing hemodynamic changes.

Materials and methods: A prospective randomised controlled study involving 80 patients posted for elective lower limb orthopedic surgeries were divided into two groups of 40 each. Group A received combined spinal-epidural anesthesia with 10 mg of 0.5% bupivacaine with epidural volume extension of 10 ml normal saline. Group B received combined spinal-epidural anesthesia alone. The blood pressure and heart rate changes were observed at the 5th, 10th, 15th, 20th min and then every fifteen minutes.

Results: Low dose of intrathecal hyperbaric bupivacaine (10 mg) with 25 micrograms of fentanyl with epidural volume extension (10ml normal saline) is associated with early onset of sensory and motor blockade, high level of sensory block, shorter time of two segment regression.

Conclusion: In this study we can safely conclude that combination of spinal epidural with epidural volume extension with normal saline achieves an effective and shorter block time as evident by significantly lower maximum motor block time providing prolonged analgesia by requiring less top-up dose of bupivacaine with higher level of sensory block at the tenth minute with shorter mean maximum sensory block time.

Key words

Combined Spinal Epidural, Epidural Saline Expansion, Intrathecal Bupivacaine.

Introduction

The combined spinal-epidural anesthesia technique was first reported in cesarean section in 1984, has recently gained popularity. Spinal anesthesia has a very rapid onset of action providing a dense neural blockade of finite duration [1]. Epidural anesthesia is more titratable producing less hemodynamic swings and can also provide postoperative analgesia. Combined spinal-epidural anesthesia technique provides the advantages of both subarachnoid and extradural anesthesia thus decreasing their failure rates when used alone [2]. The epidural volume extension (EVE) adds color to combined spinal-epidural anesthesia technique where the onset and the level of blockade obtained spinally are enhanced by administering saline or local anesthetic via the epidural, catheter. The ideology behind this is the volume effect accomplished by injecting saline epidurally which would result in intrathecal compression and cephalad migration of spinal local anesthetic [3]. The majority of lower extremity orthopedic surgery patients are old age and have multiple coexisting medical problems. Ensuring

hemodynamic stability in these patients requires selection of appropriate techniques of regional anesthesia, focussing on maintaining a safe and desirable level of the blockade and limiting extensive sympathectomy. EVE is a unique technique for regional anesthesia which offers reliability and rapidity of spinal anesthesia along with the flexibility of epidural anesthesia [4]. The desired degree of surgical anesthesia is achieved with a small dose of local anesthetic which prevents adverse hemodynamic effects seen with the conventional doses. It avoids the disadvantages of general anesthesia in patients with high cardiac risk by avoiding the cardio depressant drugs [5]. A maximum proportion of the patients coming for orthopedic surgeries are middle-aged and elderly. As the age advances, there is a constant deterioration in the functional reserve thus not sparing any organ system. Accordingly, the response of the elderly people to surgery and anaesthesia are varied [6]. The response of the geriatric patients to stress and illness is unpredictable due to the coexistence of numerous major medical conditions. These patients present commonly with alterations in the respiratory mechanics with the impaired

efficiency of gas exchange. Structural alterations in the upper and lower airways occur [7]. Cardiovascular and autonomic aging leads to an unstable blood pressure and hypokinesia with lower ejection fraction. Diabetes mellitus, coronary artery disease. ischemic cardiomyopathy, moderate left ventricular dysfunction, severe right ventricular dysfunction, severe pulmonary artery hypertension are presented the commonly to orthopedic department following trauma. The options that could be pondered broadly include spinal or general anesthesia. EVE has emerged as a resolving technique for all undesirable elderly changes [8]. It has significant dose sparing effect providing the required level of anesthesia and analgesia without compromising the hemodynamic profile of the patient. It has offered the advantage of regional and general anesthesia at the same time avoiding the undesirable side effects of both the techniques [9]. It also provides a backup in case spinal anesthesia fails. It offers a clear edge over general anesthesia eliminating airwav manipulation and the accompanying stress response which would adversely affect the patient's cardiovascular status. It alleviates the negative inotropic effects of anesthetic agents and the adverse effects on the venous return due to positive pressure ventilation. The mild vasodilatation achieved by subarachnoid block by EVE's technique is found to be advantageous in patients with isolated left ventricular dysfunction [10].

Materials and methods

After getting approval from the Institutional Ethics Committee in Govt. Kilpauk Medical College and written informed consent from patients/relatives, 80 patients of ASA 1 and 2 who underwent elective lower limb orthopedic surgeries in supine position at Govt. Kilpauk Medical College Hospital and Govt. Royapettah Hospital was enrolled in this study group.

Inclusion criteria

• Age above 40 years and below 70 years.

- Height > 150 cm and < 170 cm.
- Weight 40 75 kg.
- Males and females.
- ASA physical status 1 and 2.
- Patients undergoing elective lower limb orthopedic surgeries in the supine position.

Exclusion criteria

- ASA physical status 3 and 4.
- Patients who refuse regional anaesthesia.
- Patients with an increase in intracranial pressure.
- Intrinsic or idiopathic coagulopathy
- Skin or soft tissue infection at the proposed site of needle insertion.
- Severe hypovolemia.
- A pre-existing neurological disease like lower extremity peripheral neuropathy.
- Emergency orthopedic surgeries.
- Orthopaedic surgeries not done in supine posture.
- Surgeries lasting for more than 3 hrs.
- Patients with known allergy to study drugs.

Totally 80 patients were selected in the study. They were divided into two groups of 40 each Group A and Group B.Group A: Combined spinal-epidural anesthesia with epidural volume extension of saline (CSE-EVE). Group B: Combined spinal-epidural anesthesia alone (CSE).After preparation of all requirements of both regional and general anesthesia, CSE was performed under strict aseptic precautions with the patient in sitting position at $L_2 - L_3$ or $L_3 - L_3$ L4 interspace using low dose intrathecal hyperbaric bupivacaine 10 mg (2 ml of 0.5% bupivacaine) and 25 micrograms (0.5 ml) of fentanyl. Epidural was first performed using 16 G or 18 G Tuohy needle by the loss of resistance to air technique and 18 G or 20 G epidural catheter was inserted in a cephalad direction 4 - 6 cm into epidural space and secured. Spinal anesthesia was then performed using 25 G or 23 G Quincke's needle in a different interspace.

Five minutes after performing the block, 10 ml of sterile preservative-free 0.9 % normal saline was injected into the epidural space. In the second group, patients were anesthetized using combined spinal-epidural without epidural volume extension using the same technique and the same dose of intrathecal hyperbaric bupivacaine and fentanyl. An effective dose is defined as one that resulted in a sensory block T 10 level within 20 minutes of height of intrathecal injection with no epidural top up. Any episodes of hypotension (systolic blood pressure < 20% from baseline) was treated by administering a titrated intravenous bolus of ephedrine 6 mg and intravenous fluids. Bradycardia (Heart rate < 25% from baseline) was treated with an intravenous bolus of atropine 0.6 mg. When an ineffective blockade occurred during the study, surgery was carried out subsequently with epidural top up or converted to general anesthesia. Postoperatively patients were observed for any complications like postural puncture headache, urinary retention, and infections for 48 hours. The epidural catheter was removed thereafter. Pulse rate, non-invasive blood pressure, pulse oximetry (SPO2), ECG, was recorded throughout the surgery. The level of the maximum sensory blockade, time to reach maximum sensory blockade (min) and two segment regression time was determined by pinprick test. The time to reach maximum motor blockade (Bromage 3) and the time to recover from motor blockade (min) was also recorded. Motor blockade was assessed by Modified Bromage Scale.

- Scale 0 able to move the hip, knee and ankle.
- Scale 1 unable to move the hip, able to move the knee and ankle.
- Scale 2 unable to move the hip and knee, able to move the ankle.
- Scale 3 unable to move the hip, knee, and ankle.

Statistics analysis

Descriptive statistics were done for all data and were reported in terms of mean values and

percentages. Suitable statistical tests of comparison were done. Continuous variables were analyzed with the unpaired t-test. Categorical variables were analyzed with the Chi-Square Test and Fisher Exact Test. Statistical significance was taken as P < 0.05. The data were analyzed using SPSS version 16 and Microsoft Excel 2007. Assuming that 80 percent of the power of the study, the minimum sample size required for the study was calculated to be 70. In our study 80 subjects were chosen.

Results

Among the patients undergoing lower limb orthopedic surgeries using a low dose of intrathecal hyperbaric bupivacaine, there was no statistically significant difference in relation to age distribution between group CSE - EVE (mean=53.13, SD=8.09) and group CSE (mean=53.15, SD=7.24) with a p-value of >0.05 as per unpaired t-test. Therefore we fail to reject the null hypothesis that there was no difference in age distribution between the intervention groups (**Table – 1**).

Among the patients undergoing lower limb orthopedic surgeries using a low dose of intrathecal hyperbaric bupivacaine, there was no statistically significant difference in relation to weight distribution between group CSE - EVE (mean=62.75, SD=5.65) and group CSE (mean=61.25, SD=5.36) with a p-value of >0.05 as per unpaired t-test. Therefore we fail to reject the null hypothesis that there was no difference in weight distribution between the intervention groups (**Table – 2**).

Among the patients undergoing lower limb orthopaedic surgeries using low dose of intrathecal hyperbaric bupivacaine, there was a statistically significant difference in relation to sensory loss at 10^{th} minute between group CSE -EVE (majority at T5 level-70.00% followed by T6 level-30.00%) and group CSE (majority at T10 level-92.50% followed by T8 level-7.50%) with a p-value of <0.05 as per Fishers exact test. Therefore we reject the null hypothesis that there

was no difference in a sensory loss at 10^{th} -minute status between the intervention groups (**Table** – **3**).

Among the patients undergoing lower limb orthopaedic surgeries using low dose of intrathecal hyperbaric bupivacaine, there was a statistically significant difference in relation to two segment regression time of sensory block between group CSE - EVE (mean – 70.00, SD -4.64) and group CSE (mean – 55.90, SD – 3.58) with a p-value of <0.05 as per unpaired t-test. Therefore we reject the null hypothesis that there was no difference in two segment regression time of sensory block between the intervention groups (**Table – 4**).

Age Distribution	Group CSE - EVE	%	Group CSE	%
\leq 40 Years	1	2.50	0	0.00
41-50 Years	17	42.50	18	45.00
51-60 Years	14	35.00	14	35.00
61-70 Years	8	20.00	8	20.00
Total	40	100	40	100

<u>**Table – 1**</u>: The age group of patients of CSE and EVE.

<u>**Table – 2**</u>: The weight of patients of CSE and EVE.

Weight Distribution	Group CSE - EVE	%	Group CSE	%
\leq 50 kg	0	0.00	2	5.00
51-60 kg	17	42.50	17	42.50
61-70 kg	20	50.00	21	52.50
71-80 kg	3	7.50	0	0.00
Total	40	100	40	100

<u>**Table – 3**</u>: Sensory loss at tenth minute.

Sensory Loss at 10th Minute	Group CSE - EVE	%	Group CSE	%
T5 Level	28	70.00	0	0.00
T6 Level	12	30.00	0	0.00
T8 Level	0	0.00	3	7.50
T10 Level	0	0.00	37	92.50
Total	40	100	40	100
P value Fishers Exact Test	< 0.0001			

<u>**Table** -4</u>: The two segment regression time.

Two Segment Regression Time	Group CSE - EVE	%	Group CSE	%
\leq 60 min	1	2.50	36	90.00
61-70 min	20	50.00	4	10.00
71-80 min	18	45.00	0	0.00
> 80 min	1	2.50	0	0.00
Total	40	100	40	100

Among the patients undergoing lower limb orthopaedic surgeries using low dose of intrathecal hyperbaric bupivacaine, there was a statistically significant difference in relation to maximum sensory block time between group CSE - EVE (mean -10.63, SD -0.87) and group CSE (mean -13.48, SD -1.11) with a p-value of <0.05 as per unpaired t-test. Therefore we reject

the null hypothesis that there was no difference in maximum sensory block time between the intervention groups (**Table** - 5).

Among the patients undergoing lower limb orthopedic surgeries using low dose of intrathecal hyperbaric bupivacaine, there was a statistically significant difference in relation to maximum motor block time between group CSE - EVE (mean – 4.00, SD – 0.75) and group CSE (mean – 6., SD – 0.64) with a p-value of <0.05 as per unpaired t-test. Therefore we reject the null hypothesis that there was no difference in maximum motor block time between the intervention groups (**Table – 6**).

Time for Maximum Sensory Block	Group CSE – EVE	%	Group CSE	%
$\leq 10 \min$	19	47.50	0	0.00
11-12 min	21	52.50	6	15.00
13-14 min	0	0.00	25	62.50
> 14 min	0	0.00	9	22.50
Total	40	100	40	100

Table – 5	: Time	for	maximum	sensory	block.
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<u>Table – 6</u> :	Time for	maximum	motor block.
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Time for Maximum Motor Block	Group CSE - EVE	%	Group CSE	%
\leq 3 min	11	27.50	0	0.00
4-5 min	29	72.50	1	2.50
6-7 min	0	0.00	37	92.50
> 7 min	0	0.00	2	5.00
Total	40	100	40	100

<u>**Table – 7:**</u> Top up dose of bupivacaine.

Top up Dose of Bupivacaine	Group CSE - EVE	%	Group CSE	%
Yes	1	2.50	26	65.00
No	39	97.50	14	35.00
Total	40	100	40	100
P value Fishers Exact Test	< 0.0001			

Among the patients undergoing lower limb orthopaedic surgeries using low dose of intrathecal hyperbaric bupivacaine, there was a statistically significant difference in relation to top-up dose of bupivacaine required between group CSE - EVE (majority at T5 level-2.50%) and group CSE (65.00%) with a p-value of <0.05 as per Fishers exact test. Therefore we reject the null hypothesis that there was no difference in top-up dose of bupivacaine required status between the intervention groups (**Table – 7**).

Discussion

Combination of spinal with epidural anesthesia is the most often chosen and widely used method for lower limb orthopedic surgeries. The epidural volume extension technique is a one step ahead technique which offers a good block profile [11]. It is associated with less degree of sympathectomy that accompanies spinal anesthesia when used alone, as the dose of hyperbaric bupivacaine used is low and hence the severity of hemodynamic compromise is also less [12]. The current study evaluated the effectiveness of epidural volume extension in combined spinal-epidural anesthesia to perform adequate neuroaxial blockade by a low dose of

intrathecal hyperbaric bupivacaine (10 mg) through epidural volume extension by 10 ml of 0.9% normal saline that was injected 5 minutes after performing the block. Frequent failure was reported if administration of epidural saline was delayed beyond 10 minutes and the same was also proven by Mardirosoff and coworkers who showed that for epidural volume extension to be effective, the patient should be laid supine within 5 minutes of completing intrathecal injection [13]. Trautman, et al. showed it to be ineffective when performed 20 minutes after intrathecal injection. Hence we waited for a time that was long enough to justify the use of rescue strategy for block augmentation and yet short enough for a successful epidural volume extension [14]. In this study we can safely conclude that combination of spinal and epidural with epidural volume extension with normal saline produces faster, higher and effective sensory block compared to combined spinal-epidural alone as evident by the significantly higher incidence of sensory loss at 10th minute achieved up to T5 level [15]. The mean two segment regression time of sensory block was significantly higher in group CSE - EVE compared to group CSE by a mean difference of 14.10 minutes (20% higher). This difference is significant with a p-value of <0.0001 as per unpaired t-test. In this study we can safely conclude that combination of spinal epidural with epidural volume extension with saline achieves an effective normal and prolonged anaesthesia as evident by significantly higher two segment regression time of sensory block achieved [16]. The mean maximum sensory block time achieved was significantly lower in group CSE - EVE compared to group CSE by a mean difference of 2.85 minutes (21% lower). This difference is significant with a pvalue of <0.0001 as per unpaired t-test. In this study, we can safely conclude that combination of spinal and epidural anesthesia with epidural volume extension with normal saline achieves effective and shorter sensory block as evident by significantly lower maximum sensory block time achieved [17]. The mean maximum motor block time achieved was significantly lower in group CSE - EVE compared to group CSE by a mean difference of 2.43 minutes (38% lower). This difference is significant with a p-value of <0.0001 as per unpaired t-test. In this study, we can safely conclude that combination of spinal epidural with epidural volume extension with normal saline achieves an effective and shorter block time as evident by significantly lower maximum motor block time achieved. The incidence of top-up dose of bupivacaine required was significantly lower in group CSE - EVE compared to group CSE by a percentage difference of 62.50 scoring points (96% lower) [18]. This difference is significant with a p-value of <0.0001 as per Fisher's exact test. In this study, we can safely conclude that combination of spinal epidural with epidural volume extension with normal saline provides prolonged analgesia by requiring less top-up dose of bupivacaine as evident by the significantly lower incidence of top-up dose of bupivacaine required. With respect to the hemodynamic state, the systolic blood pressure and heart rate showed no significant changes between the two groups, which emphasized the safety of epidural volume extension technique [19]. About 1.5 and 3 ml of the epidural dose per neural segment is required to extend the subarachnoid block, which is relatively smaller than the conventional epidural dose. Blumgart, et al. put forth his study on the mechanism of extension of sensory blockade to T2-T4 level following extradural injection. He divided his study population into three groups who received an intrathecal injection of 1.6 - 1.8 ml of hyperbaric bupivacaine followed by 10ml of epidural saline in the first group, 10ml of epidural bupivacaine in the second group and finally the third sample did not receive any injection. He supplementary observed a significant and similar block profile in the first two groups. The authors concluded that the dural sac compression caused block extension [20].

Conclusion

We observed that epidural volume extension with normal saline with low dose intrathecal hyperbaric bupivacaine 10 mg attained a higher

sensory level of T5 dermatomal level. Epidural volume extension with normal saline achieved a faster two segment regression time with a mean value of 70 minutes leading to a quicker attainment of maximum sensory blockade with a mean duration of 10.63 minutes. It can be concluded that low dose of intrathecal hyperbaric bupivacaine (10 mg) with 25 micrograms of fentanyl with epidural volume extension (10 ml normal saline) is associated with early onset of sensory block, shorter time of two segment regression while maintaining the hemodynamic stability.

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