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Evaluation of impact of epidural volume extension on the quality of spinal anaesthesia in patients undergoing proximal femoral nailing surgeries – randomized controlled study

Vikram Bedi, Sanghamitra Debbarma, Sandeep Sharma, Rajeev Navaria, Anchal Jhawer, Santosh Choudhary

Rabindranath Tagore Medical College, Udaipur, India

Abstract

Background: Epidural volume extension is technique aiming to mitigate spinal anaesthesia induced hypotension, by reducing the dose of local anaesthetics. The present study was executed to determine the effect of epidural volume extension subarachnoid block with 0.5% hyperbaric bupivacaine in patients undergoing proximal femoral nailing (PFN) regarding characteristics of sensory-motor block and postoperative analgesia.

Methods: In this prospective, double-blind trial conducted from October 2021 to April 2022, 105 adult patients scheduled to undergo PFN were randomised into groups: control (C), 10 mL NS (E1), and 20 mL NS (E2), to receive 10 mg hyperbaric bupivacaine intrathecally plus additional epidural volume extension with 10 and 20 mL normal saline in groups E1 and E2, respectively. The primary outcome measured was the duration of postoperative analgesia. The secondary outcomes measured included onset of sensory-motor block and duration of sensory block. $P < 0.05$ was considered statistically significant.

Result: A significantly longer duration of postoperative analgesia was noted in patients receiving 10 and 20 mL epidural volume extension (365.09 ± 101.83 and 330.06 ± 35.22 vs. 265.77 ± 38.01 min in the control group, $P < 0.01$). Patients who received any epidural volume extension with either 10 or 20 mL had significantly quicker onset of sensory and motor block as well as prolonged duration of sensory block. No significant difference in duration of postoperative analgesia, and onset and duration of block was observed between patients receiving either 10 or 20 mL epidural volume extension.

Conclusions: Epidural volume extension significantly shortened the onset of sensory-motor block and increased the duration of sensory block and postoperative analgesia in patients undergoing PFN under subarachnoid block; however, no such difference was observed between 10 and 20 mL epidural volume extension.

Key words: epidural anaesthesia, epidural volume extension, subarachnoid block, hyperbaric bupivacaine.

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CORRESPONDING AUTHOR:

Rajeev Navaria, Rabindranath Tagore Medical College, Udaipur, India, e-mail: drrajeevnavaria@gmail.com

Proximal femoral fractures are common causes of hospitalisation in elderly patients [1]. Among the various surgical modalities available for these fractures, proximal femoral nailing (PFN) is a commonly used technique.

The goal of the anaesthetic technique to be used for PFN is to provide optimum operating conditions with good anaesthesia as well as postoperative analgesia, resulting in early recovery, better mobilisation, and short duration of hospital stay. Various anaesthetic techniques are used to carry out PFN surgery. These include spinal anaesthesia, epidural anaesthesia, general anaesthesia, combined spinal-epidural anaesthesia, etc. Administration of spinal or epidural anaesthesia during major hip surgeries is associated with reduced risk of perioperative complications such as deep vein thrombosis, decreased blood loss, early ambulation, and greater patient satisfaction.

Spinal anaesthesia is often accompanied by concomitant hypotension. To mitigate this, attempts have been made to reduce the dose of local anaesthetics by adding adjuvants intrathecally, such as opiates, and non-opiates, such as α_2 adrenoceptor

agonists, neostigmine, ketorolac, magnesium, adenosine, and midazolam [2].

A newer modality that has been tried is epidural volume extension, which is a modification of the combined spinal epidural technique, wherein the level of sensory analgesia after subarachnoid block is increased by injecting normal saline into the epidural space [3]. The most common explanation for the success of this technique relies on thecal compression due to the volume effect on the consequent epidural injection of fluid.

Epidural volume extension combines 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 postoperative analgesia [4].

Previously, the epidural volume extension technique has been used to reduce the dose of bupivacaine used in subarachnoid block using different volumes in either caesarean section patients [5] or infra-umbilical surgeries [6]. But there is a lack of availability of studies on the use of epidural volume extension in orthopaedic patients for PFN, which are also prone to hypotension and other complication related to spinal anaesthesia. To the best of our knowledge, there is no study available that compares different volumes of epidural volume extension in orthopaedic patients. Thus, we decided to conduct a study to compare the effect of epidural volume extension with 2 different volumes of normal saline, i.e. 10 mL and 20 mL with 10 mg of 0.5% heavy bupivacaine intrathecally in patients undergoing PFN surgeries with the primary objective of duration of postoperative analgesia and the secondary objective of block characteristics.

METHODS

After approval from Institutional Ethics Committee (RNT/Stat./IEC/2020/02) and registration in Clinical Trials Registry India (CTRI/2021/09/036769, dated 23/09/2021), this prospective, double-blind, randomised, controlled trial was conducted following principles of Declaration of Helsinki in a tertiary care hospital over a period of 6 months, from October 2021 to April 2022. A total of 105 patients with American Society of Anaesthesiologists (ASA) physical status I, II or III, of either gender, aged between 18 and 65 years, scheduled to undergo PFN were enrolled for the study.

Patients having absolute contraindications for spinal anaesthesia, body mass index > 30 kg m^{-2}, severe comorbid diseases like cardiovascular, neurological, psychiatric illness, and hypersensitivity to local anaesthetic agents were excluded from the study.

After obtaining written informed consent, patients were allocated into 3 groups: control (C), 10 mL NS (E1), and 20 mL NS (E2), by using a table of computer-generated random numbers in opaque sealed envelopes. The group C received 10 mg of 0.5% hyperbaric bupivacaine intrathecally; the E1 group received 10 mg 0.5% hyperbaric bupivacaine intrathecally with 10 mL normal saline in the epidural space; and the E2 group received 10 mg of 0.5% hyperbaric bupivacaine intrathecally plus 20 mL normal saline in the epidural space.

Blinding was ensured by keeping the patients unaware of the group allocation. The block with or without epidural volume extension as designated was done by an anaesthesiologist who did not participate further in the study.

Patients were fasting for 6 hrs and not consuming clear fluids for 2 hours before surgery. All the patients received 0.5 mg alprazolam *p.o*. the night before surgery and 20 mg omeprazole *p.o*. on the morning of surgery (with sip of water). Intravenous access was obtained with 20 G cannula and preloading was done with ringer lactate 10 mL kg^{-1} half an hour before anaesthesia. Monitoring was done by using a multiparameter monitor having pulse oximetry, electrocardiography and non-invasive blood pressure and baseline vital signs were recorded.

After positioning the patients in the sitting position, an 18 G epidural needle (EPI KIT Romsons Scientific & Surgical Industries Pvt Ltd, India) was introduced in the L3–L4 interspace under all aseptic precautions. The epidural space was identified by loss of resistance to saline. Keeping the needle bevel facing cephalad, an epidural catheter was passed through it, up to 5 cm into the epidural space. A 25 G spinal needle (Pricon Spinal anaesthesia needle, Iscon Surgicals Ltd, India) was introduced through the L4–L5 interspace, and a subarachnoid block was performed with 2 mL of 0.5% hyperbaric bupivacaine. Then either 10 mL, 20 mL, or no normal saline was injected epidurally as per group allocation. Then patients were placed in a supine position. The level of sensory and motor block was assessed every 1 min by using a cold cotton swab and modified Bromage scale, respectively. The Modified Bromage scale is as follows: 0 = no motor block, able to flex hips/knees, ankles; 1 = able to move knees and ankle, unable to flex hip, i.e. unable to raise extended legs (partial motor block); 2 = able to flex ankles, unable to flex hip/knee (almost complete motor block); and 3 = unable to move any part of the lower limb (complete motor block). Once the desired block level was achieved, surgery was allowed to proceed.

The onset time of sensory block (time between completion of subarachnoid local anaesthetic injection and achievement of the sensory blockade at T8 level), onset time of motor block (time taken to achieve Modified Bromage Score of 3), duration of sensory block (time interval between onset of the sensory block and regression of the sensory block to S1), and duration of analgesia (time from onset of sensory block to time of administration of rescue analgesia at the request of the patient after surgery) were recorded. Rescue analgesia was provided by injecting 0.125% bupivacaine 10 mL with 1 μg mL^{-1} fentanyl epidurally.

Intraoperative complications such as hypotension, bradycardia, nausea, vomiting, and shivering were noted. Hypotension was defined as fall in MAP of > 20% from baseline value and treated with intravenous mephentermine (6 mg), titrated till desired effect was achieved. Bradycardia was defined as a fall in HR < 60/min and treated with intravenous atropine (0.3 mg), titrated till desired effect was achieved. Any requirement of vasopressor (number of doses and amount) was recorded in each case.

After carrying out a pilot study on 15 patients, the mean duration (standard deviation) of postoperative analgesia in the control group was found to be 338.8 (58.7) min. The sample size was calculated by using OpenEpi (Open Source Epidemiologic Statistics for Public Health) software based on an expected mean increase in duration of the postoperative analgesia of 40 min or more. The type I error and power of the study were kept at < 0.05 and 80%, respectively.

The primary outcome measured was the duration of postoperative analgesia. The secondary outcomes measured included the onset of sensory block, onset of motor block, and duration of sensory block.

Statistical analysis

Statistical analysis was conducted with OpenEpi. Continuous variables are presented as mean (standard deviation), and categorical variables are presented as absolute numbers and percentage. The comparison of normally distributed continuous variables between the groups was performed using ANOVA. Post hoc analysis with Bonferroni correction was used. Nominal categorical data between the groups were compared using the χ^2 test. $P < 0.05$ was considered statistically significant.

RESULTS

In total 112 patients were assessed for eligibility, of whom 7 were excluded (5 due to patient refusal and 2 due to not meeting of inclusion criteria). Finally, 105 patients were enrolled for study (Figure 1). As per the calculation, the sample size of control and experimental groups were 34 in each group. Each group included 35 patients to compensate for possible dropouts. All the 3 groups were comparable

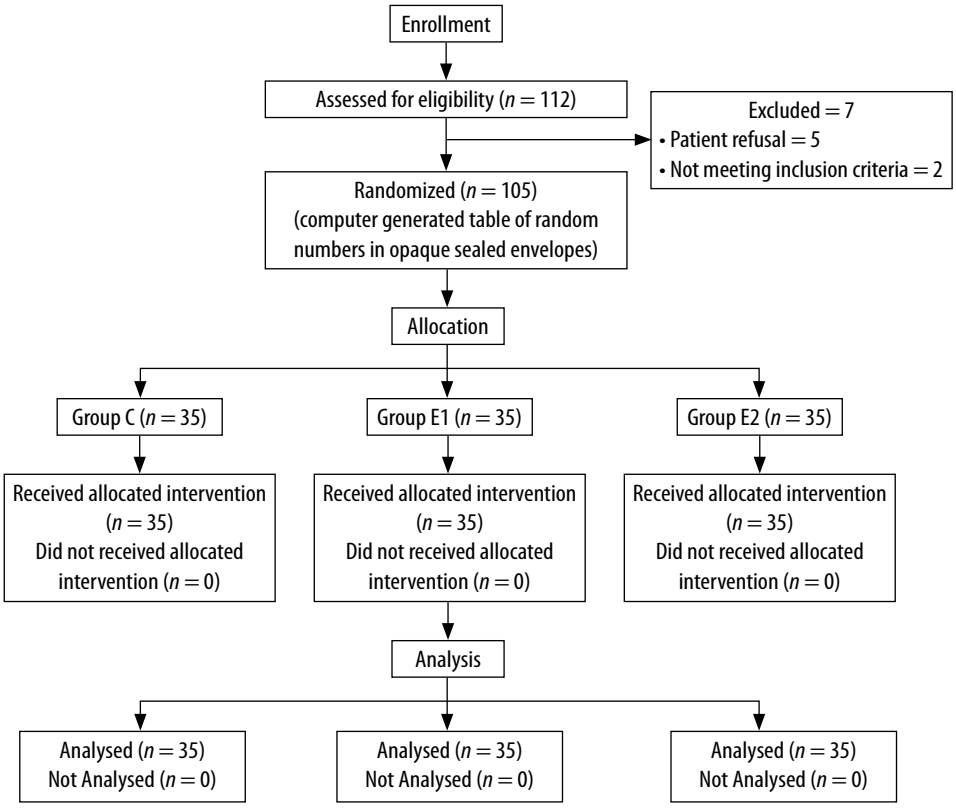

FIGURE 1. Participants flow for the study

TABLE 1. Demographic characteristics of the study population

Factor	Group E1	Group E2	Group C	*P*-value
Age group (years), *n* (%)				
≤ 50	18 (51.4)	16 (45.7)	14 (40.0)	0.631
> 50	17 (48.5)	19 (54.2)	21 (60.0)	
Total	35 (100.0)	35 (100.0)	35 (100.0)	
Gender, *n* (%)				
Male	24 (68.5)	22 (62.8)	21 (60.0)	0.749
Female	11 (31.4)	13 (37.1)	14 (40.0)	
Total	35 (100.0)	35 (100.0)	35 (100.0)	
ASA grade, *n* (%)				
I	14 (40.0)	10 (28.5)	8 (22.8)	0.537
II	20 (57.1)	22 (62.8)	25 (71.4)	
III	1 (02.8)	3 (08.5)	2 (05.7)	
IV	0 (0)	0 (0)	0 (0)	
Total	35 (100.0)	35 (100.0)	35 (100.0)	

TABLE 2. Time of onset of sensory and motor block

	Group E1 ($n = 35$)	Group E2 ($n = 35$)	Group C ($n = 35$)	*P*-value
Sensory block (min)				
Mean ± SD	5.0 ± 1.64	5.68 ± 1.58	8.51 ± 2.09	0.000
Motor block (min)				
Mean ± SD	6.71 ± 2.06	6.85 ± 1.11	9.62 ± 1.83	0.000

TABLE 3. Duration of sensory block and analgesia

	Group E1 ($n = 35$)	Group E2 ($n = 35$)	Group C ($n = 35$)	*P*-value
Sensory block (min)				
Mean duration (mean ± SD)	354.00 ± 102.59	322.00 ± 35.09	256.26 ± 39.02	0.000
Mean duration of analgesia (min)				
Mean duration (mean ± SD)	365.09 ± 101.83	330.06 ± 35.22	265.77 ± 38.01	0.000

with respect to age, gender, weight, and ASA physical status, $P > 0.05$ (Table 1).

All the patients in the study attained sensory block of dermatome T8 or higher. Patients who received epidural volume extension with either 10 or 20 mL of normal saline had quicker onset of sensory block (5.0 ± 1.64 min, 5.68 ± 1.58 min, and 8.51 ± 2.09 min for E1, E2, and C, respectively, $P < 0.001$) and motor block (6.71 ± 2.06 min, 6.85 ± 1.11 min, and 9.62 ± 1.83 min for E1, E2, and C, respectively, $P < 0.001$) as compared to the control group (Table 2). No such difference was observed between both of the experimental groups.

A prolonged duration of sensory block and postoperative analgesia were recorded in patients receiving epidural volume extension with 10 and 20 mL normal saline (Table 3). Analogously, no difference in duration of sensory block and postoperative analgesia was observed between 10 mL and 20 mL group.

DISCUSSION

The present study aimed to evaluate the characteristics of subarachnoid block with 0.5% hyperbaric bupivacaine without and with 2 different volumes of normal saline were injected epidurally along with the intrathecal block in patients undergoing proximal femoral nailing.

We found that epidural volume extension with both 10 mL or 20 mL of normal saline led to a faster onset and prolonged duration of subarachnoid block when compared to intrathecal injection alone. The time to onset of block was shortened by almost 30% and, more importantly, the duration of postoperative analgesia was prolonged by about 100 minutes in patients who received epidural volume extension. However, there was no difference between patients who received different volumes (10 mL or 20 mL) of epidural saline. The results of our study suggest that the addition of 10 mL epidural normal saline sufficiently alters the pressure

dynamics between the epidural and intrathecal components to enable a quicker and longer lasting block. Increasing the epidural dose to 20 mL normal saline does not seem to significantly influence the block and may be therefore redundant.

A previous study by Tyagi *et al*. [7] that evaluated the effect of epidural volume extension of intrathecal isobaric and hyperbaric bupivacaine in patients undergoing lower limb orthopaedic surgery found that epidural volume extension reduced the dose of intrathecal isobaric bupivacaine but did not affect the required dose of hyperbaric bupivacaine. The discrepancy between this result and our findings can, at least partially, be attributable to difference on methods. The authors assessed only for the adequacy of block as defined by a threshold value.. Any extension of the block beyond this threshold value was not recorded by them whereas we noted the time taken to reach a dermatomal level at T8 or modified Bromage score of 3. Secondly, their study was powered to detect the local minimal anaesthetic dose whereas our study was powered to detect the duration of postoperative analgesia.

Hakim *et al*. [8] in their study noted that the onset of sensory-motor block was earlier in patients who were given epidural volume extension. Results similar to our study have been reported by other authors as well. The use of 10 mL or 20 mL of epidurally injected normal saline has been shown to shorten the time to onset of sensory and motor blocks [9, 10], achieve a higher level of block [10], and result in a shorter time to 2-segment regression [10] while maintaining stable haemodynamics.

While the concept of augmentation of subarachnoid sensory-motor block by epidural volume extension has been well researched, most of the studies have been carried out in the obstetric population. The physiologically increased intra-abdominal pressure in pregnancy and the subsequent increase in the vertebral venous pressure causes a reduction in the epidural space. Therefore, the injection of normal saline or any other fluid results in a cephalad spread of intrathecally injected local anaesthetic and therefore causes a quicker and longer block with the same dose of intrathecal drug [11, 12]. The theory that a change in epidural volume extension may affect the rostral spread of intrathecal local anaesthetics is further supported by the work of Xiao *et al.* [13]. They demonstrated that prophylactic phenylephrine infusion increased the ED50 and ED95 of intrathecal bupivacaine in patients undergoing lower segment caesarean section. This is possibly due to the phenylephrine-induced constriction of epidural veins, which leads to an expansion of the epidural space thereby necessitating augmented doses of intrathecal local anaesthetic for adequate rostral spread. However, data on whether epidural volume extension amongst the non-pregnant patients would also enhance the characteristics of spinal block is sparse.

We decided to include only the patients undergoing open reduction and internal fixation of proximal femoral fracture in our study because most proximal femoral fractures occur in elderly patients, many of whom have several co-morbidities, thus making them a high-risk surgical group. Therefore, any intervention that will possibly lead to a reduction in dose of local anaesthetic injected intrathecally is expected to benefit this group in particular.

Our study has some limitations. Firstly, we did not observe the duration of motor block, which could potentially affect postoperative mobilisation. Further, we did not measure height of patients, which has an effect on the maximum level of neuraxial block achieved. Moreover, both genders were enrolled in the study, and thus the differences in the effect of epidural volume extension on male and female population could not be ascertained. A post hoc subgroup analysis according to genders may be helpful to generate a hypothesis for future research. Further studies are also warranted to ascertain the possibilities of a reduction of the dose of intrathecal local anaesthetics and/or an opioid sparing effect of epidural volume extension added to subarachnoid block.

CONCLUSIONS

We conclude that in patients undergoing PFN, epidural volume extension with either 10 mL or 20 mL of normal saline significantly shortened the onset of sensory-motor block and increased the duration of sensory block and postoperative analgesia when compared to patients who received intrathecal hyperbaric bupivacaine alone. We did not find any significant difference between 10 mL and 20 mL of epidural volume extension in terms of the characteristics of sensory-motor block and postoperative analgesia. Hence, the authors feel that epidural volume extension with 10 mL of normal saline may provide an effective modality of improvement in subarachnoid block in this patient population.

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