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Clinical Utility of Epidural Volume Extension Following Reduced Intrathecal Doses: A Randomized Controlled Trial

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Abstract

Overview

The study aimed to investigate the impact of Epidural Volume Extension (EVE) on sensory block height following intrathecal injections with reduced doses of bupivacaine. It was designed as a randomized, controlled, double-blind trial involving 80 adult male patients with ASA status I or II scheduled for orthopedic lower limb surgery under combined spinal epidural anaesthesia. Patients were randomly assigned to receive either a reduced intrathecal dose of bupivacaine (5 or 8 mg) with or without EVE, based on group allocation. The study aimed to compare the maximum sensory level (Smax) achieved with and without EVE application across the two different intrathecal doses. Further research is warranted to better understand the relationship between intrathecal dose and EVE efficacy, considering various factors such as instillation technique, timing, and patient characteristics.

Results: The study revealed that applying Epidural Volume Extension (EVE) alongside a 5 mg intrathecal bupivacaine dose significantly decreased the maximum sensory block height (Smax) compared to not using EVE However, there was no significant difference in Smax when EVE was applied alongside an 8 mg intrathecal bupivacaine dose compared to without it.

Conclusion: Avoiding the application of Epidural Volume Extension (EVE) to 5 mg plain bupivacaine during a combined spinal epidural block in patients undergoing lower limb orthopedic surgery is advisable. This caution stems from the observation that implementing EVE alongside this particular dosage of bupivacaine could lead to a reduction in the maximum sensory level.

Keywords: Epidural Volume Extension (EVE), Sensory, Oximetry, (Smax).

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INTRODUCTION

The method of epidural volume extension (EVE) involves injecting 0.9% saline into the epidural space shortly after administering an intrathecal injection to enhance the sensory block achieved by the intrathecal drug. While some studies have cast doubt on EVE's effectiveness in increasing sensory block levels, a conclusive determination remains elusive due to insufficient data. Various factors may influence its success, with the intrathecal dose of local anesthetic emerging as a significant determinant.

In regional anesthesia, the intrathecal dose plays a pivotal role in determining the sensory block level following a spinal block. Therefore, understanding its impact on the efficacy of EVE is imperative.

Previous research on EVE has employed differing intrathecal doses. Enhancement of sensory block levels has been well-documented with intrathecal bupivacaine doses of 8 mg or higher, across diverse patient populations. However, studies investigating EVE with lower intrathecal doses, particularly below 8 mg, are limited, especially in obstetric patients, and have yielded varied outcomes.

Despite these findings, reports exist of successful EVE utilization even with intentionally reduced intrathecal doses, sometimes as low as 3 mg. Initially, reducing the intrathecal dose was perceived as advantageous, with EVE compensating for the lower local anesthetic dose.

In light of this, researchers sought to evaluate the influence of intrathecal dose on EVE efficacy, particularly when applied to reduced intrathecal doses. They conducted a study comparing EVE application to 5 mg and 8 mg intrathecal bupivacaine doses in non-obstetric patients, with each dose having a control group without EVE application.

METHODS

This prospective, randomized, controlled trial was conducted after receiving approval from the Institutional Ethical Committee and obtaining written informed consent from all participants. A total of 84 adult male patients with ASA status I or II, weighing between 50-70 kg and with a height ranging from 150-180 cm, scheduled for lower limb orthopaedic surgery like tibia nail, tibia plating, ankle arthrodesis, femur plating or nailing under combined spinal epidural anesthesia were included. Patients with contraindications to combined spinal epidural anesthesia, such as a history of spinal disease, hypersensitivity to local anaesthetics, coagulation abnormalities, skin infection at the injection site, or previous block failure, were excluded.

Using computer generated random number tables, patients were assigned to one of four groups based on the intrathecal bupivacaine dose and whether epidural volume extension was performed: groups A and A1 received 5 mg intrathecal bupivacaine without and with epidural volume extension, respectively, while groups B and B1 received 8 mg intrathecal bupivacaine without and with epidural volume extension, respectively. Plain bupivacaine was chosen over hyperbaric bupivacaine due to previous data supporting the success of epidural volume extension with plain bupivacaine.

After positioning the patient on the operating table, standard monitoring including blood pressure, electrocardiography, and pulse oximetry was applied. Intravenous access was established, and Ringer's lactate solution was infused as a preload. Under aseptic conditions, combined spinal epidural anesthesia was performed in sitting at the L4-5 intervertebral space using a needle through needle technique. The epidural space was identified with an 18G Tuohy needle using loss of resistance to air, limiting the volume of air to less than 2 mL. Subarachnoid space was identified using a 25G Quincke needle and free flow of cerebrospinal fluid was confirmed. The intrathecal solution corresponding to the group allocation was injected, and the time of removal of the spinal needle marked the completion of intrathecal block. Following removal of the spinal needle, the epidural catheter was inserted and normal saline was injected through it in patients of the A1 and B1 groups. Oxygen was administered via facemask, and sensory and motor blockade were assessed every 3 minutes until a maximum level was achieved.

Heart rate and mean arterial pressure were also monitored, and episodes of hypotension were recorded and treated accordingly. Incidence of intraoperative nausea, vomiting, and pruritus were noted, and epidural top-ups were administered if necessary. Postoperative analgesia was provided through the epidural catheter. Demographic data and procedural times were recorded.

RESULTS

The statistical analysis comprised intergroup comparisons of maximum sensory block levels using unpaired t-tests and Analysis of Variance (ANOVA) for normally distributed demographic variables. The sample size was calculated to detect a difference in sensory block level following epidural volume extension with 80% power and a 5% error rate, with adjustments made for possible withdrawals.

Initially, 21 patients were assigned to each of the four groups. However, the protocol was completed in 20 patients each for groups A, B, and B1, and 19 patients in group A1. Baseline characteristics, including demographic parameters, hemodynamic variables, and surgery duration, were compared as shown in the table.

The primary outcome measure, Smax, was found to be significantly lower in group A1 compared to group A, but similar between groups B and B1. Similarly, the maximum motor blockade and the time to maximum sensory and motor block following intrathecal injection, assessed prior to epidural top-up, showed no significant differences between groups A and A1, as well as groups B and B1.

The time required to position the patient supine after completion of intrathecal block was comparable between groups A and A1, but longer for group B1 compared to group B. However time taken for positioning was not statistically significant between group B & B1.

The incidence of intraoperative hypotension, pruritus, nausea, and vomiting were similar between groups A and A1, as well as between groups B and B1. The number of patients requiring intraoperative epidural top-up was similar between these groups.

Table 1: Characteristics of intrathecal block

	Group A (n = 20)	Group A1 (n = 19)	p- value	Group B (n = 20)	Group B1 (n = 20)	p-value
S_{max}	$T_{6.4}$±1.9	$T_{8.9}$±4.3	0.030	$T_{6.4}$±2.2	$T_{5.8}$±1.8	0.324
Time to maximum sensory level (min)	8.2±2.7	6.7±3.2	0.108	9.2±3.4	8.7±3.0	0.623
Maximum motor block (Bromage score)	3.6±0.7	3.6±1.5	0.961	3.2±0.7	2.8±0.9	0.170
Time to maximum motor blockade (min)	6.9±2.6	7.0±3.2	0.974	9.0±3.9	9.1±2.9	0.930
Time to position the patient supine (min)	3.4±1.0	4.0±1.4	0.171	3.7±0.9	4.3±1.0	0.029

Values are presented as mean ± SD.

– Group A: 5 mg intrathecal plain bupivacaine

– Group A1: 5 mg intrathecal plain bupivacaine with epidural volume extension

– Group B: 8 mg intrathecal plain bupivacaine

– Group B1: 8 mg intrathecal plain bupivacaine with epidural volume extension

Inter-group comparisons were made between group A and A1, as well as between groups B and B1.

Table 2: Intraoperative adverse events.

	Group A (n = 20)	Group A1 (n = 19)	p-value	Group B (n = 20)	Group B1 (n = 20)	p-value
Hypotension	5 (25)	8 (42)	0.365	8 (40)	7 (35)	0.799
Nausea and/or vomiting	1 (5)	1 (5)	0.989	0 (0)	1 (5)	0.799
Pruritus	0 (0)	0 (0)	1.000	0 (0)	0 (0)	1.000

Values are presented as the number of patients (%).

– Group A: 5 mg intrathecal plain bupivacaine

– Group A1: 5 mg intrathecal plain bupivacaine with epidural volume extension

– Group B: 8 mg intrathecal plain bupivacaine

– Group B1: 8 mg intrathecal plain bupivacaine with epidural volume extension

Inter-group comparisons were made between group A and A1, as well as between groups B and B1.

Table 3: Characteristics of first intraoperative epidural top-up.

Group A (n = 20)	Group A1 (n = 19)	p- value[a]	Group B (n = 20)	Group B1 (n = 20)	p- value[b]
Frequency of intraoperative epidural top-up 17 (85)	18 (95)	0.607	18 (90)	17 (85)	0.799
Indicated due to inadequate intrathecal block 1 (5)	5 (26)	0.247	1 (5)	0 (0)	0.799
Time to first epidural top-up (min) 75.8 ± 29.2	53.9 ± 33.2	0.034	90.0 ± 32.3	104.3 ± 34.2	0.184

Data are number of patients (%).

Certainly, here are the intergroup comparisons between the specified groups:

Group A vs. Group A1 (5 mg intrathecal plain bupivacaine vs. 5 mg intrathecal plain bupivacaine with epidural volume extension)

Group B vs. Group B1 (8 mg intrathecal plain bupivacaine vs. 8 mg intrathecal plain bupivacaine with epidural volume extension)

DISCUSSION

The present study aimed to investigate whether the outcomes of epidural volume extension (EVE) depend on the amount of intrathecal local anesthetic when used in reduced doses. Our primary focus was on Smax (maximum sensory block level) achieved with or without EVE following intrathecal bupivacaine doses of 5 mg and 8 mg.

We deliberately chose reduced intrathecal doses to mimic clinical practice where EVE is utilized. The 8 mg dose was selected as it's documented as the ED50 for lower limb surgeries, justifying the need for sensory block augmentation in about 50% of patients. The 5 mg dose was chosen because it's commonly and successfully used with EVE in clinical settings.

Our study was adequately powered to detect even a single dermatome change in sensory block level after applying EVE. However, we observed a significant but paradoxical decrease in Smax when EVE was applied to the 5 mg dose, along with an insignificant increase in the need for epidural supplementation to initiate surgery. No such clinical or statistical changes were noted with the 8 mg dose.

Contrasting earlier studies showing success with EVE following doses of 8 mg or less, our findings of failed sensory block augmentation with both intrathecal doses raise questions. Previous successful evidence mainly pertains to obstetric patients, while our study focused on non-obstetric patients. It's known that intrathecal drug spread and block characteristics differ between these populations, which might explain the discrepancy.

Despite inconclusive evidence on EVE's utility, clinical reports of its successful use, especially in high-risk parturients with extremely reduced intrathecal doses, add complexity to the situation. This phenomenon's dependence on various variables, including intrathecal dose and pregnancy status, is evident.

One limitation of our study is its focus solely on Smax, and we couldn't ascertain the reason for the detrimental effect of EVE on the 5 mg dose. Nevertheless, our observations suggest that intrathecal dose influences EVE efficacy. These findings have implications for clinical EVE application, particularly in scenarios requiring intrathecal dose reduction while ensuring adequate Smax.

CONCLUSION

In conclusion, applying EVE to the smaller intrathecal dose of 5 mg plain bupivacaine during lower limb orthopedic surgery may decrease the maximum sensory level. While EVE can be applied without adverse effects with an 8 mg intrathecal bupivacaine dose, it doesn't offer beneficial sensory block augmentation. Further investigations are warranted to determine the lowest effective dose for both obstetric and non-obstetric patients.

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