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ORIGINAL ARTICLE

Comparison of mean duration of two-segment regression time in patients undergoing lower limb surgery treated with combined spinal-epidural anaesthesia vs. Combined spinal-epidural anaesthesia plus epidural volume extension with saline

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ABSTRACT

Background: Combined spinal-epidural (CSE) anesthesia is a novel technique that decreases the amount of anesthetic required yet with greater anesthetic effect compared to spinal or epidural anesthesia alone. Recent studies showed that epidural volume extension (EVE) with saline further increased the anesthetic effect of this combined approach resulting in longer two-segment regression time. However, literature was scarce in the local context that provides the basis of the present study.
Aim: The study focuses on the comparison between the mean duration of two-segment regression time in patients who underwent lower limb surgery treated with CSE and CSE plus EVE with saline.
Methods: It was a randomized controlled trial and included 60 patients of both genders who range between 20-60 years. They belong to ASA class I and II and underwent lower limb trauma surgery with CSE anesthesia which were further randomly divided into two treatments groups. The patients of Group-A received EVE in addition to standard CSE while Group-B received standard CSE alone. The outcome variable was the mean two-segment regression time which was compared in these two groups.
Results: Mean age of selected patients was 35.75±10.60 years. Study included 35 (58.3%) male and 25 (41.7%) female patients. The mean duration of surgery was 79.65±12.92 minutes while the mean BMI was 27.78±3.25 Kg/m^2. Nineteen (31.7%) patients were from ASA Class-I and 41 (68.3%) patients associated with ASA Class-II. The mean two-segment regression time was substantially longer in the CSE plus EVE group as compared to the group receiving CSE alone (83.77±7.56 vs. 59.97±6.22 minutes; p-value<0.001). In these two groups, a statistically important difference was also noted across subgroups based on the age of the patient, gender, BMI, duration of surgery, history of diabetes and ASA status.
Conclusion: CSE anesthesia with EVE proved its superiority over the conventional practice of CSE alone in terms of longer mean two-segment regression time in patients with lower limb trauma surgery.
Keywords: Combined Spinal-Epidural Anesthesia, Epidural Volume Extension, Two-segment Regression Time

INTRODUCTION

Epidural anesthesia is a type of neuraxial blockade technique that introduces the injection of a local anesthetic into the epidural space, which blocks the painful impulses generated from the nerves [1, 2]. This blockage can be associated with enhanced recovery and became a popular concept for surgery patients in recent times. Its fundamental purpose is to reduce the time of inpatient hospitalization, early mobilization and its associated decrease in thromboembolic events [3, 4]. Consequently, it reduces the risk of hospital-acquired infections and hospital costs which is always a desirable condition for practitioners. Recent literature has demonstrated that epidural anesthesia has shown an improvement in surgical outcome through beneficial effects on perioperative pulmonary function, soothing the surgical stress response and improved analgesia[5]. Keeping in view the fact that the right choice of perioperative analgesia is very important as it preserves lung functions, reduces trauma, blunts stress-related body response[3-6]. These factors contribute to reduce the mortality and morbidity associated with the pain during the surgery and resultantly early mobility and discharge from the hospital.

The abovementioned benefits are desirable for patients with orthopedic surgeries especially, with lower limb surgery that usually involves severe pain and mobility issues. Generally, the combined spinal-epidural (CSE) anaesthetic technique is the preferred and commonly used method for lower limb orthopedic surgeries[7]. In continuation, another technique, epidural volume extension (EVE) which is considered a modified form of CSE in which the onset and level of a block acquired by the subarachnoid block that is slightly increased in volume of saline or local anesthetic choose the epidural catheter for its performance[8]. Several mechanisms were reported to explain the efficacy of EVE with saline in the improvement of spinal block, including the effect of volume in which it is compressed by injected epidural saline, which results in squeezing of cerebrospinal fluid and increased cephalic spread of subarachnoid local anesthetic[9].

Recent studies showed that this EVE combination increased the anesthetic effect of CSE anesthesia resulting in longer two-segment regression time (time taken for recovery of sensory loss over two spinal segments) and advocated it in future practice particularly when a lengthy surgical procedure was anticipated[7,9,10]. However, as per our knowledge, there is no available local literature that justifies the need for the current study. Therefore, this study has the main focus on the assessment of the mean duration of two-segment regression times in CSE alone (as a conventional technique) and CSE with EVE. We hypothesize that the addition of EVE with CSE would possibly increase the mean duration of two-segment regression time in the patients as compared to CSE alone technique. If the result of the study shows that the mean duration is longer in patients with EVE, it will enable better anesthetic and analgesic care in future practices.

The objective of the study was to focuses on the comparison between the mean duration of two-segment regression time in patients who underwent lower limb surgery treated with CSE and CSE plus EVE with saline.

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METHODS

A randomized controlled trial was followed in this study. This study was executed at the Department of Anesthesiology Lahore General Hospital, Lahore. The study duration was 6 months (from 25/10/2019 to 24/04/2020) after its approval. A sample of 60 cases (30 cases in each group of study) was estimated with 80% power of the test and 95% confidence interval. It was considered by taking the expected mean two-segment regression time in patients who underwent lower limb surgery under CSE anesthesia plus EVE (Group-A) with saline vs CSE alone (Group-B). Consecutive sampling, a type of non-probability sampling, was adopted to choose the sample.

Inclusion Criteria: Patients with ages in the range of 20-60 years undergoing lower limb surgery for fracture (as per X-ray) would be the part of the study. Further, the American Society of Anesthesiology (ASA) Grade I and II patients were considered. As per operational definition, the first type includes a normal healthy patient and the second type focuses on a patient with a mild systematic disease.

Exclusion Criteria

1. Patients who refused regional anesthesia.
2. Patients with the following issues; local sepsis at the site of injection, spinal deformity, raised ICP (>21mmHg), coagulopathy (INR>2), severe hypovolemia (SBP<60 mmHg), fixed cardiac output lesion and major hepatic, renal (serum creatinine >1.3mg/dl) and CVS dysfunction.
3. Patients who failed to attain sensory block 10 minutes after the CSE anesthesia.

Data collection procedure: The approval was also sought from the ethical review committee of the hospital, 60 patients (30 patients in each group) who presented in the operation room of Lahore General Hospital. These patients have also fulfilled the abovementioned inclusion criteria and were further counselled about the details of the study. A detailed history was taken from each selected patient after their written informed consent. A random approach (lottery method) was adopted to divide the patients into the following two groups.

1. Group A (CSE with EVE): combined spinal-epidural anesthesia plus epidural volume extension with saline.
2. Group B (CSE alone or without EVE): combined spinal-epidural anesthesia alone.

All patients were monitored using standard methods of monitoring (standard I and II) with ECG, pulse oximetry, non-invasive blood pressure, temperature, end-tidal carbon dioxide probe. After establishing intravenous access (18 G), a preload of 500 ml of a crystalloid (lactated ringer) was given before anesthesia. Combined epidural and spinal anesthesia was performed under complete aseptic conditions while patients were in the sitting position (patient was made comfortable 1st by keeping him/her pain-free in sitting position using ketamine or midazolam) at interspace L3-L4 or L4-L5 using a low dose of intrathecal hyperbaric bupivacaine 0.75% (10 mg). Using CSE set epidural was performed using 18-G Tuohy needle using the loss-of-resistance technique to air, a 27-G pencil-point spinal needle was then introduced through Tuohy needle into subarachnoid space. After confirming the free flow of CSF 10mg of hyperbaric bupivacaine was injected. An epidural catheter was inserted in a cephalad direction into the epidural space after removing the spinal needle. Five minutes after performing the block, 10 ml sterile preservative-free 0.9% normal saline was injected into the epidural space (this step was not performed in no EVE group). 10 minutes after that the sensory loss and extent of the dermatome having sensory loss were confirmed. Two-segment regression was noted as per operational definition and duration was noted down. All the data was observed and noted in the pre-defined performa along with the demographics of the patient. All the spinal and epidural anesthesia were given by the same person to eradicate bias. Further, a well-defined exclusion criterion was followed to control the possible confounding variables. Data analysis procedure: After data collection, it was stored in SPSS version 21.0 for appropriate statistical analysis.

Quantitative variables like age, body mass index (BMI), duration of surgery and two-segment regression time have been reported by mean ± SD. For comparison of mean two-segment regression time between the predefined two groups, two independent samples t-test was used. Further, p-value ≤ 0.05 was considered as a significant difference. Categorical or qualitative variables like gender, ASA class and history of diabetes have been reported in terms of frequency and their percentage. Data has been further stratified for age, gender, BMI, duration of surgery, history of diabetes and ASA class to deal with possible effect modifiers. For this purpose, two independent samples t-test has also been applied and tested at 5% level of significance.

RESULTS

The age of the selected patients (n=60) ranged from 20 years to 60 years with a mean of 35.75±10.60 years. Out of the total patients, 37(61.7%) were from 20-39 years age group. There were 35 (58.3%) male and 25(41.7%) female patients. The range of BMI was laying between 21.91 Kg/m2 to 33.60Kg/m^2 with a mean of 27.78±3.25 Kg/m^2. Further, 13(21.7%) patients were classified as obese and 11(18.3%) patients had a history of diabetes. As per ASA status, 19(31.7%) patients were from ASA class-I and 41 (68.3%) patients from ASA Class-II. The duration of surgery ranged from 60 minutes to 100 minutes with a mean of 79.65±12.92 minutes (Table 1).

Table 1: Baseline Characteristics of Study Sample

Characteristics	Participants n=60
Age (years)	35.75±10.60
• 20-39 years	37 (61.7%)
• 40-60 years	23 (38.3%)
Gender	
• Male	35 (58.3%)
• Female	25 (41.7%)
BMI (Kg/m^2)	27.78±3.25
• Non-Obese	47 (78.3%)
• Obese	13 (21.7%)
Duration of Surgery (minutes)	79.65±12.92
• 60-79 minutes	31 (51.7%)
• 80-100 minutes	29 (48.3%)
History of Diabetes	
• Yes	11 (18.3%)
• No	49 (81.7%)
ASA Status	
• Class-I	19 (31.7%)
• Class-II	41 (68.3%)

Table 2: Baseline Characteristics of Study Groups (n=60)

Characteristics	CSE + EVE	CSE	P-value
Age (years)	35.73±8.97	35.77±12.17	0.990
• 20-39 years	19 (63.3%)	18 (60.0%)	0.791
• 40-60 years	11 (36.7%)	12 (40.0%)	
Gender			
• Male	18 (60.0%)	17 (56.7%)	0.793
• Female	12 (40.0%)	13 (43.3%)	
BMI (Kg/m^2)	27.68±3.62	27.89±2.89	0.807
• Non-Obese	23 (76.7%)	24 (80.0%)	0.754
• Obese	7 (23.3%)	6 (20.0%)	
Duration of Surgery (minutes)	79.83±13.00	79.47±13.06	0.914
• 60-79 minutes	16 (53.3%)	15 (50.0%)	0.796
• 80-100 minutes	14 (46.7%)	15 (50.0%)	
History of Diabetes			
• Yes	6 (20.0%)	5 (16.7%)	0.739
• No	24 (80.0%)	25 (83.3%)	
ASA Status			
• Class-I	9 (30.0%)	10 (33.3%)	0.781
• Class-II	21 (70.0%)	20 (66.7%)	

Chi-square and two independent sample t-test were used to examine the difference.

Table 3: Comparison of Mean Two-segment Regression Time (Minutes) between the Study Groups()=60

	CSE + EVE	CSE	P-value
Two-segment regression time (mean±SD)	83.77±7.56	59.97±6.22	<0.001*

Baseline quantitaive characteristics of both groups were also compared and tested through t-test. Mean age (p-value=0.990), BMI (p-value=0.807) and mean duration of surgery (p-value= 0.914) were found statistically insignificant in these two groups. Further, the distribution of categorical variables in both groups was also compared. However, insignificant differences were found in these groups and tested through the chi-square test. These subgroups were based on age (p-value = 0.791), gender (p-value = 0.793), BMI (p-value=0.754), diabetes (p-value =0.739), duration of surgery (p-value =0.796) and ASA-Class (p-value =0.781) as shown in Table 2.

The mean two-segment regression time was substantially longer in the CSE with EVE group as compared to other group receiving CSE alone (83.77±7.56 vs. 59.97±6.22 minutes; p-value<0.001) as shown in Table 3. Similarly, statistically significant differences were observed with respect to two-segment regression time between these two groups across various subgroups like patient's age groups, gender, categories of BMI, duration of surgery, history of diabetes and ASA status (Table 4).

Two independent sample t-test is used, * observed difference was statistically significant

Table 4: Comparison of Mean Two-segment Regression Time (Minutes) between the Study Groups across various Subgroups (n=60)

Subgroups	Two-segment Regression Time (mean±SD)		P-value
	CSE + EVE	CSE	
Age (years)			
• 20-39 years	83.79±6.10	60.00±6.65	<0.001*
• 40-60 years	83.73±9.95	59.92±5.79	<0.001*
Gender			
• Male	84.11±6.54	60.47±6.30	<0.001*
• Female	83.25±9.18	59.31±6.30	<0.001*
BMI (Kg/m^2)			
• Non-Obese	84.22±7.82	60.17±6.33	<0.001*
• Obese	82.29±6.99	59.17±6.24	<0.001*
Duration of Surgery			
• 60-79 minutes	83.63±8.66	60.53±6.29	<0.001*
• 80-100 minutes	83.93±6.40	59.40±6.31	<0.001*
History of Diabetes			
• Yes	82.67±6.06	59.80±5.50	<0.001*
• No	84.04±7.99	60.00±6.46	<0.001*
ASA Status			
• Class-I	84.00±6.06	60.20±6.63	<0.001*
• Class-II	83.67±8.26	59.85±6.18	<0.001*

Two independent sample t-test, * observed difference was statistically significant

DISCUSSION

The appropriate choice of anesthesia technique is an important concern of practitioners. A suitable technique can increase the recovery rate of patients and reduce the length of stay at the hospital. Therefore, anaesthetists always try to find the best-customized technique for patients. It is observed that regional anesthesia has multiple advantages over general anesthesia. The prior one is a simple, economical, safe and effective block with a small dose of local anesthetics. It can also provide extended postoperative pain management which is an advantageous feature over systematic opioids alone[11]. A piece of recent evidence has shown its superiority in terms of less complications even in very old patients (over 70 years) [12]. In regional anesthsisa multiple combinations and mechanisms have been tested and established for various types of surgeries. This study found that CSE with the combination of EVE can increase the mean two-segment regression time as compared to CSE alone in lower limb surgery patients.

The selection of patients having lower extremity orthopedic surgery is very important. Because these patients are generally old age and might have multiple comorbidities. Therefore, hemodynamic stability in these patients is important and needs an appropriate technique of regional anesthesia that focuses on the desired characteristics[3]. CSE anesthesia is the widely used and preferred technique for lower limb orthopedic surgeries [7]. However, the main aim of the present study is to assess the mean duration of two-segment regression time of two anesthetic techniques which are CSE and CSE with EVE in patients who underwent lower limb surgery.

The current study findings reported the superiority of CSE with EVE on CSE alone in terms of two-segment regression time in the chosen patients. The mean difference was statistically significant (83.77±7.56 vs. 59.97±6.22 minutes; p-value<0.001). Further, approximately the same significance was observed in these two anesthetic techniques in various subgroups of study; patients age, BMI, gender, duration of surgery, history of diabetes and ASA status. Current study findings are consistent with various researchers who worked in different regions of the world. Okasha et al. (2013) conducted a study on Egyptian orthopedic patients who underwent lower limb trauma surgery [10]. They reported a statistically significant difference between means of two-segment regression time of two selected anesthetic techniques (CSE with EVE and CSE alone). They reported a longer mean two-segment regression time of CSE with EVE as compared to CSE alone (81.0±7.3 vs. 67.9±5.1 minutes; p-value<0.001).

Similarly, Bhatia et al. (2018) conducted a study on Indian patients who underwent hip surgery and found similar findings as discussed by Okasha et al. (2013) [7]. They found a mean of two-segment regression time in CSE with EVE (89.67±8.19 minutes) higher than CSE alone (60.0±6.30 minutes) with a significant statistical difference at 1% level of significance. Another Indian study conducted by Sudhakaran et al. (2017) compared CSE with EVE versus without volume extension in patients undergoing lower limb trauma surgery and found significantly better findings for CSE with EVE combination [13]. The mean two-segment regression time difference in two techniques was (CSE with EVE: 70.0±4.6 vs. CSE alone 55.9±3.6 minutes; p-value≤0.05). It was found that the anesthetic technique (CSE with EVE) has been found better in various types of surgeries. A study executed by Salman et al. (2013) on Turkish women who underwent cesarean section found higher mean two-segment regression time as compared to other conventional techniques[9]. Similarly, another study concluded that CSE with EVE created sufficient surgical analgesia even in cesarean section patients. Further, this technique has a significantly shorter time of recovery as compared to other groups[14].

This study is a first of its nature in the local context, however, it adds its value to the existing literature. This Pakistani sample-based evidence expanded the application of this anesthetic technique in the local context as well. The superiority of CSE with EVE on conventional practice (CSE alone) in lower limb trauma surgery in terms of longer mean two-segment regression time is desirable due to its urgency and nature of surgery. This evidence would guide the practitioners to apply this anesthetic technique to patients with a variety of surgeries. Further, this study also enhanced its impact by testing the efficacy of CSE with EVE on CSE alone in various subgroups of the population. It augments the generalizability of this superior anesthetic technique in all components of selected patients.

Like every study, this study has also multiple strengths. This study provides evidence on a relatively large sample size of 60 patients who were allotted anesthetic technique through randomization. This randomization would possibly reduce the selection bias and enhance the generalizability of findings. Further, the superiority of CSE with EVE on conventional technique is also tested and proven in various subgroups (potential effect modifiers) like age, gender, BMI, history of diabetes, ASA class and duration of surgery. However, in addition to its strengths, it has a few limitations like considering of side effects of the novel EVE. Further, we did not consider post-operative analgesia and opioid requirement in such patients which could have highlighted the safety as well as a possibly beneficial effect on postoperative pain control and patient mobilization. Overall, this type of study can become an important piece of evidence of detailed guidelines for future researchers.

CONCLUSION

In patients who underwent lower limb trauma surgery, CSE anesthesia with EVE was found superior to the conventional practice of CSE anesthesia alone in terms of longer mean two-segment regression time which is desirable in such patients and therefore advocates the preferred use of this novel approach in future anesthetic practice.

Conflict of interest: Nil

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