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A Comparative Randomized Control Study of Continuous Spinal Anaesthesia with Continuous Epidural Anaesthesia in Elderly Patients Undergoing Dynamic Hip Screw Surgeries

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ABSTRACT

Background: Hip fractures in elderly patients is common and occurs with trivial fall. Continuous epidural anesthesia (CEA) and Continuous spinal anesthesia (CSA) are available modalities for lower extremities surgeries. This study was done to compare the effectiveness of CEA and CSA.

Methods: A prospective open-label randomized control trial was carried out in the Department of Anaesthesiology and Critical care at GMC, Kadapa, from January 2019 to July 2020. One hundred patients were enrolled and divided into Group A and B, with 50 participants in each group. Group A received continuous spinal anesthesia, and Group B was given continuous epidural anesthesia. VAS score, Onset of sensory block, the Onset of motor block and no. of rescue analgesia, etc., were considered as the primary outcome variable. coGuide statistical software was used for analysis.

Results: There was a statistically significant difference between the study groups (Group A vs. Group B) in the Onset of sensory block (7.6 ± 1.6 min, 17.5 ± 1.62 min), the start of motor block (10.1 ± 1.11 min,20.28 ± 1.36 min), duration of sensory block (108.7 ± 16.84 min, 147.4 ± 20.39 min), duration of motor block (175.8 ± 12.47 min, 219.4 ± 18.56 min) and analgesia duration (199.2 ± 11.92 min, 327.6 ± 18.8 min) respectively. The Difference in the number of rescue analgesia in 24 hrs between the study group was significant with a P-value of <0.001.

Conclusion: The current study revealed that CSA is more effective than CEA in Hip surgeries.

The incidence of hip fractures is alarming and has emerged as a significant public health issue [1]. The elderly population is prone to hip fractures due to fragile bone density causing mortality, disability, and decreased quality of life [2-4]. Hip fractures are becoming a matter of concern in Asia, mainly because of a 2–3 times increase in their incidence in almost every country in the continent [5-6]. In India annual incidence of hip fracture is estimated to be over 120 fractures per 100,000 persons above the age of 50 years, with higher rates in females. As per the 2011 census population of India over 50 years was near about 170 million, which means 0.2 million hip fractures a year [7-8].

In elderly patients with osteoporotic bones, the intertrochanteric fracture is the most frequent hip fracture as it can be caused by simple falls and other low-energy traumas [9]. In a large population-based study with eight cohorts of older people from Europe and the USA, it was found that the hip fracture was associated with excess short- and long-term all-cause mortality in both genders [10]. For such intertrochanteric fractures, Clawson's dynamic hip screw (DHS), introduced in 1964, is majorly used as an implant of choice [11].

Continuous spinal anesthesia (CSA) is a technique of anesthesia that is considered optimal for surgical procedures of the perineum, lower extremities, and lower

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abdomen. CSA can be beneficial in patients with complex heart disease and severe aortic stenosis undergoing lower extremity surgery [12-13]. Andrew Emyedu et al., in their case report, concluded that using Continuous spinal anesthesia will avoid the complications related to general anesthesia while maximizing the benefits of both epidural and single-shot spinal anesthesia like the fast Onset of anesthesia and ability to prolong the duration of anesthesia, for long surgeries [14]. However, the extensive use of CSA is not much appreciated as it causes a high risk for post-dural puncture headache (PDPH) associated with epidural needles and catheters [15]. Other similar complications associated with CSA are brutal catheter insertion, breakage, poor anesthesia, and infrequency development of cauda equina syndrome [16]. Epidural anesthesia, unlike spinal anesthesia, is technically more complex, less reliable, and needs a higher pharmacological dose of local anesthetics [17].

Epidural anesthesia definitely decreases chances of perioperative morbidity after major orthopedic procedures, and postoperative epidural analgesia may reduce myocardial ischemia after hip fracture surgery [18-19]. Another case report suggested that CSA with minimally invasive hemodynamic monitoring was a suitable alternative to epidural or general anesthesia in two patients with severe aortic stenosis who had undergone lower limb surgery [20].

Both the methods have their advantages and disadvantages. Elfeky AM et al. [17] studies on high-risk elderly undergoing major lower limb surgeries showed that CSA was an effective and safe choice. Another study by Lux AE et al. [21] did a retrospective analysis of 1212 cases undergoing lower limb surgeries with CSA; the results proved no significant complications, and the patient satisfaction was also reasonable. However, there is a lack of studies on Comparison between CSA and CEA on hemodynamic parameters (Heart rate, Systolic blood pressure, Diastolic blood pressure, mean arterial pressure) and the Onset and duration of the sensory and motor block, the need for rescue analgesia and adverse effects in both the groups. Hence, this study compared CEA and CSA based on these parameters.

Objectives

To compare the hemodynamic parameters (heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure), Onset and duration of the sensory and motor block, the need for rescue analgesia, and adverse effects in both the groups (CEA vs. CSA).

Methods

The present study was a prospective, open-label, randomized control study carried out in the Department of Anaesthesiology and Critical care at GMC, Kadapa. The study duration was from January 2019 to July 2020. After obtaining ethical committee clearance from the institutional ethical committee, the study was undertaken. Data confidentiality was maintained.

The required sample size was 50 in each group (based on the mean duration of analgesia in CEA as 89.92 vs. CSA as 93.7 as per a study by Mohamad A. Elfeky et al [17].

$\mu1, \mu0$ =Difference between the means ($\mu1$=89.92 and $\mu0$=93.7)

$\sigma1, \sigma0$ =Standard deviations ($\sigma1$=6 and $\sigma0$ =6)

u=0.84

V= 1.960

The sample size was calculated using the below formula by Daniel WW et al. [22].

$$N = \frac{(u+v)^2(\sigma_1^2+\sigma_0^2)}{(\mu_1-\mu_0)^2}$$

The study consisted of a total of 100 patients of both genders. Participants were divided into two groups containing 50 participants, each based on computer-generated random numbers. Group A consisted of the continuous spinal anesthesia (CSA) group, which received fentanyl 5mcg with Isobaric Ropivacaine 0.75% in 0.5ml boluses. Group B was given continuous epidural anesthesia (CEA) fentanyl 50mcg with Isobaric Ropivacaine 0.75% in 5ml boluses. Patients above 60 years of ASA physical status II and III were included in the study. Those with coagulopathies, bleeding diathesis, pre-operative hypovolemia, known hypersensitivity to study drugs, a significant cognitive and psychiatric history, pre-existing neurological diseases, and patients whose sensory blockade did not reach T10 level within 15 min were excluded from the study. Written informed consent was obtained from the patients before participation in the study. Hypotension was defined as systolic blood pressure falling more than 20 % from the pre-operative level. The Onset of motor block was considered with Initiation of the league until attaining a complete motor block, i.e., grade 3 of the modified Bromage scale. The start of the sensory block was considered with the Initiation of partnership till the development of the first signs of sensory block at the T10 sensory level. Duration of analgesia is the duration from Initiation of block till the patient complains of pain with VAS ≥3. The course of sensory block- Is from the attainment of T10 sensory level to two-segment regression. Duration of motor block- Is from the achievement of Modified Bromage score 3 to the return of modified Bromage grade 1/0.

In Group A, 22G Sprotte spinal needle (Intra Long, Pajunk, Germany) was introduced in the L3-L4 space a 27 G catheter was introduced 3cms into subarachnoid space spinal needle was removed. The catheter was secured at an appropriate length on the back of the patient. In Group B, 18G Tuohy needle (B Braun, Melsungen, Germany) was introduced & advanced gradually till the epidural space was identified with the Loss of Resistance to air technique. 20G epidural catheter was introduced 3cms into the epidural space, and the epidural needle was removed. The catheter was secured at an appropriate length on the back of the patient. Group A received 0.5 ml (3.75mg) of isobaric Ropivacaine (0.75%) together with fentanyl 5µgm injected through the catheter at a rate of 0.2 ml/15 sec. Group B received 5 ml of isobaric Ropivacaine (0.75%) and fentanyl 50 µ g via the catheter. Additional boluses of 5 ml of Ropivacaine 0.75% were injected epidurally every 10 min until the level of T10 was achieved. The Onset of the sensory block, the start of the motor block, and hemodynamic parameters were monitored intraoperatively. No analgesics were administered throughout the intraoperative period. Hemodynamic parameters were assessed.

Statistical analysis: VAS score, Onset of sensory block, Onset of motor block and no. of rescue analgesia, etc., were considered as the primary outcome variable. The study group (Group A vs. Group B) was regarded as the primary explanatory variable. All Quantitative variables were checked for normal distribution. For non-normally-distributed Quantitative parameters, Medians and Interquartile range (IQR) were compared between study groups using Mann Whitney u test (2 groups). Continuous variables were analyzed by Independent-samples T-tests and expressed as the mean and standard deviation. And the count variables were analyzed by the Chi-square test, speaking as a number. A statistically significant difference was set at $P < 0.05$. Data were analyzed by using coGuide software, V.1.03 [23].

Results

A total of 100 subjects were included in the final analysis.

There was statistically not significant difference between the study group in age group (in years) (P value 0.698), gender (p value 0.677), height (in cm) (P value 1.000), weight (in cm) (p value 1.000), ASA grade (p value 1.000), diagnosis (P value 1.000) and duration of surgery (p value 0.650). There was statistically significant Difference between the study group in Onset of sensory block, onset of motor block, duration of sensory block, duration of motor block and anal duration (p value <0.05) (Table 1).

There was statistically no significant difference between the study group in vas score (3hrs (p value 0.144),6hrs (p value 0.308),12 hrs (p value 0.242) and 24 hrs (p value 0.646.). The Difference in no of rescue analgesia in 24 hrs between the study group is found to be significant with a P- value of <0.001, with majority of 38 (76%) 4th rescue analgesia participants were in Group A. The pulse rate was monitored at baseline, 0 min, 1min, 3min, 5min, 7min, 9min, 11min, 13min, 15min, 20min, 25min, 30min, 60min, 90 min, 120min,150min,180min and 210min. There were no significant changes in the pulse rate in both groups (p value >0.05) (Table 2).

Majority of the mean arterial pressure at 60 min was 92.56 ± 6.21 min in group A and in group B was 92.52 ± 6.22min. The mean arterial pressure was monitored at baseline, 0 min, 1min, 3min, 5min, 7min, 9min, 11min, 13min, 15min, 20min, 25min, 30min, 90 min, and end of the surgery. There were no significant changes in the mean arterial pressure in both groups (p value >0.05) (Table 3).

Table 1- Comparison of baseline parameter between study group(N=100)

Parameter	Study group		P value
	Group A(N=50)	Group B(N=50)	
Age (in years)			
60 to 65years	18 (36%)	20 (40%)	0.698*
66 to 70years	19 (38%)	15 (30%)	
71years and above	13 (26%)	15 (30%)	
Gender			
Male	33 (66%)	31 (62%)	0.677*
Female	17 (34%)	19 (38%)	
Height (in cm)	158.4 ± 6.95	158.4 ± 6.95	1.000†
Weight (in kg)	59.86 ± 9.35	59.86 ± 9.35	1.000†
ASA grade			
Grade II	29 (58%)	29 (58%)	1.000*
Grade III	21 (42%)	21 (42%)	
Diagnosis			
EC # Femur left	13 (26%)	13 (26%)	1.000*
EC # Femur right	15 (30%)	15 (30%)	
IT # Femur left	11 (22%)	11 (22%)	
IT# Femur right	11 (22%)	11 (22%)	
Duration of surgery (in Minutes)	99.9 ± 12.84	98.7 ± 13.51	0.650†
Onset of sensory block (in Minutes)	7.6 ± 1.6	17.5 ± 1.62	<0.001†
Onset of motor block (in Minutes)	10.1 ± 1.11	20.28 ± 1.36	<0.001†

Duration of sensory block (in Minutes)	108.7 ± 16.84	147.4 ± 20.39	<0.001†
Duration of motor block (in Minutes)	175.8 ± 12.47	219.4 ± 18.56	<0.001†
Anal duration (in Minutes)	199.2 ± 11.92	327.6 ± 18.8	<0.001†

*****Chi square test †Independent sample T test

Table 2- Comparison of vas score and pulse rate at different time periods between study group(N=100)

Parameter	Study Group		P value
	Group A	Group B	
VAS score			
3hrs	2 (2,3)	2 (2,2)	0.144*
6hrs	2 (2,3)	2 (2,2)	0.308*
12hrs	2 (2,2)	2 (2,3)	0.242*
24hrs	2 (2,3)	2 (2,3)	0.646*
No. of rescue analgesia in 24 hrs			
3	12 (24%)	36 (72%)	<0.001†
4	38 (76%)	14 (28%)	
Pulse rate			
Baseline	72.7 ± 5.95	72.68 ± 6.1	0.987‡
0 min	72.7 ± 6.24	72.68 ± 6.3	0.987
1 min	72.14 ± 6.4	72.1 ± 6.44	0.975
3 min	73.58 ± 6.27	73.7 ± 6.27	0.924
5 min	73.72 ± 6.44	73.86 ± 6.32	0.913
7 min	73.22 ± 5.46	73.32 ± 5.22	0.926
9 min	73.1 ± 6.69	73.32 ± 6.63	0.869
11 min	72.2 ± 6.22	72.16 ± 6.26	0.974
13 min	73.52 ± 7.26	73.46 ± 7.44	0.968
15 min	73.42 ± 5.71	72.98 ± 6.05	0.709
20 min	74.3 ± 6.79	74.3 ± 6.94	1.000
25 min	74.24 ± 6.6	74.3 ± 6.48	0.964
30 min	73.92 ± 7.24	74.04 ± 7.13	0.934
60 min	73.74 ± 6.46	73.8 ± 6.35	0.963
90 min	72.92 ± 6.41	72.76 ± 6.33	0.900
120 min	73.62 ± 5.42	73.56 ± 5.44	0.956
150 min	75.12 ± 4.51	74.9 ± 4.38	0.805
180 min	77.5 ± 5.65	77.12 ± 5.5	0.734
210 min	80.34 ± 5.45	80.12 ± 5.25	0.838

*Mann Whitney U test †chi square test ‡Independent sample T test

Table 3- Comparison of MAP at different time periods between study group(N=100)

MAP	Study group		P value*
	Group A (N=50)	Group B (N=50)	
Base line	89.5 ± 7.13	89.5 ± 7.13	1.000
0Min	91.02 ± 6.53	91.08 ± 6.49	0.963
1Min	89.6 ± 6.36	89.58 ± 6.35	0.987
3Min	89.08 ± 7.36	89.28 ± 7.44	0.893
5 Min	88.34 ± 7.04	88.58 ± 7	0.865
7 Min	88.82 ± 7.24	88.88 ± 7.25	0.967
9 Min	88.74 ± 7.25	89.14 ± 7.2	0.783
11 Min	89.24 ± 7.29	89.32 ± 7.27	0.956
13 Min	89.54 ± 6.58	90.04 ± 6.51	0.703
15 Min	90.18 ± 6.16	90.26 ± 6.12	0.948
20 Min	90.42 ± 6.32	90.58 ± 6.31	0.899
25 Min	91.04 ± 5.88	91.24 ± 5.93	0.866
30 Min	91.72 ± 5.82	91.82 ± 5.8	0.932
60 Min	92.56 ± 6.21	92.52 ± 6.22	0.974
90 Min	91.22 ± 6.24	92.32 ± 5.65	0.358
END of the surgery	91.38 ± 5.44	92.1 ± 5.59	0.516

*Independent sample T test

Discussion

The occurrence of hip fracture and growing age are seen to have a close association and are showing an increase in upcoming years [24-25]. In previous literature, none of the studies have shown to have anyone single anaestaetic technique or agent to have all-inclusive benefits for the geriatric population undergoing surgery with regard to survival. General and regional anesthesia both have side effects in elderly patients [18,26].

In the current study, we found that there was statistical significance among the primary outcome variables in both groups. The Onset of sensory block and Onset of motor block was rapid in group A when compared to group B. Also, we found that the duration of sensory block and motor block was less in the CSA group and analgesia duration was faster in the CSA group than CEA group. Rescue analgesia in 24 hrs was administered less in the CSA group than CEA group. This indicates that analgesia effect efficient in the CEA group. There were no adverse effects observed in both groups.

Our results were harmonious with a study by Mohamad A Elfeky et al., which concluded that the Onset of sensory and motor block was rapid in patients with the CSA group compared to patients in CEA group [17]. In another study done by Imbelloni et al., it was found that the CSA group had rapid Onset of the sensory block with better hemodynamic stability compared to the combined spinal-epidural anesthesia group [27]. Continuous Spinal anesthesia is known to allow opioids and individualized titration of a local intrathecal anesthetic to control the level of the sensory and motor blockade as per the need of the surgery, and it maintains hemodynamic stability necessary for cardiomyopathy patients [28]. Similar results were shown by a study that compared CSA and CEA in lower limb surgeries. They found that CSA is an easy technique, better Onset & quality, it decreases the risk of systemic toxicity when compared to CEA in lower limb surgery [29]. In a retrospective study conducted on 1212 patients who underwent surgery of the lower extremities with continuous spinal anesthesia, it was found that CSA was a feasible and advantageous technique for elderly patients undergoing lower limb surgery [30]. Other literature results are similar to the current study where the study found that Continuous spinal anesthesia had a more rapid onset of action, produced more effective sensory and motor blockade, and had a shorter recovery period [31]. Our results were similar to the previously conducted review, which stated Continuous spinal anesthesia is a well-established technique and has clear advantages over epidural and single-shot spinal anesthesia, especially in elderly or high-risk patients [32].

The strength of the current study is this was a prospective study; hence occurrence of failures because of technical issues and postoperative complications or adverse effects were taken into account. This increased the reliability of the results. Limitations of this study are this was an open-label trial, only femur fracture was considered in the study. We recommend future studies should be carried out, including all lower extremity fractures and a large sample size.

Conclusion

Our study results suggest that continuous spinal anesthesia and continuous epidural anesthesia both techniques are effective and advisable for elderly patients undergoing dynamic hip screw surgeries. On comparing both the techniques, CSA was more effective in terms of sensory and motor block. Onset duration of sensory. Pain management was better in the CSA group. Hence, we conclude that CSA is more effective in maintaining hemodynamics intraoperatively with rapid Onset and recovery of sensory and motor blocks.

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