Original Article

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Comparison of Efficacy and Safety of Sequential Combined Spinal Epidural Technique and Spinal Block for Lower Abdominal Surgeries: A Randomized Controlled Trial

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Abstract

Background: Even though, spinal and epidural anesthesia (SA and EA) are still the two most popular regional anesthetic techniques, with proven efficacy in a variety of surgical procedures across the globe, they are fraught with few disadvantages. The combined spinal epidural (CSE) technique has been claimed to overcome the shortcomings of both SA and EA by achieving rapid onset and profound blockade with the facility to modify or prolong the block. Studies comparing the efficacy and safety of spinal and CSE techniques in lower abdominal studies are very scarce.

Objective: The objective was to compare the efficacy and safety of sequential CSE technique and spinal block for lower abdominal surgeries.

Materials and Methods: The study was a randomized, single-blind controlled study, conducted in a tertiary care teaching hospital in South India. Fifty subjects undergoing lower abdominal surgeries were randomized to either SA or combined spinal and epidural anesthesia (CSEA).

Results: The time taken for onset of anesthesia was 5.48 min in spinal anesthesia group, compared to 7.40 min in CSEA group (mean difference of 1.92, 95% confidence interval [CI]: 0.78-3.05, *P*-value 0.001). The duration of analgesia was 115.6 min in spinal, compared to 124.5 in CSE (mean difference of 8.92, 95% CI: 0.87-18.71, *P*-value 0.07). The proportion of subjects who achieved the excellent quality of surgical analgesia was 92% in Group A compared to 88% Group B.

Conclusions: The CSE has got the following advantages over spinal anesthesia: (1) Better hemodynamic stability is seen, such as pulse rate (PR) and blood pressure (BP). (2) The advantage of prolongation and extension of the block when compared to the spinal anesthesia. (3) The provision of post-operative analgesia. (4) The quality of analgesia and onset of action are almost similar in both groups. However, muscle relaxation is comparatively less in CSE technique.

Key words: Combined spinal epidural, Efficacy, Safety, Spinal block

INTRODUCTION

In recent times, the use of regional anesthesia techniques is increasing worldwide. Spinal anesthesia (SA) and epidural anesthesia (EA) are still the two most popular regional anesthetic techniques, with proven efficacy in a variety of surgical procedures across the globe.[1] However, both these techniques are fraught with few disadvantages. Precipitous hypotension and difficulty in controlling the level of analgesia are major disadvantages of spinal block.[2] Apart from epidural block with the catheter technique gives a better control of the level of analgesia and can be used for providing post-operative pain relief by opioids or local anesthetic agents. However, it still has its drawbacks such as the slower onset of action, patchy anesthesia, more doses of local anesthetics, and hazard of cardiovascular and neurotoxicity.[3]

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The combined spinal epidural (CSE) technique, which was introduced by Soresi in 1937, using "single needle – single interspace" technique aims to address these problems. Different methods and techniques of came into use since its inception, each one having its own advantages and disadvantages.[2,4-7]

As the CSE, technique provides the benefits of spinal block with the flexibility of an indwelling epidural catheter to extend the duration of analgesia into the post-operative period.[8] Hence, it has gained increasing popularity for patients undergoing various major surgical procedures below the umbilical level. The procedures include orthopedic surgeries, lower abdominal gynecological surgeries, and lower extremity procedures, etc. The technique is particularly popular in obstetric anesthesia and analgesia.[9-16]

Even though the spinal and CSE techniques are in practice for the last few decades, the studies comparing the efficacy and safety of these two techniques in lower abdominal studies are very scarce from India. The current study was undertaken with the aim of filling this crucial gap in the knowledge, which can aid the clinicians and patients in taking informed decisions about the choice of the anesthetic technique.

Objective

The aim of this study was to compare the efficacy and safety of sequential CSE technique and spinal block for lower abdominal surgeries.

MATERIALS AND METHODS

Study Design

The study was a randomized, single-blind controlled trial involving two intervention groups:

a. Group A: SA
b. Group B: Combined spinal and epidural anesthesia (CSEA)

Study Setting

The study was conducted in a tertiary care teaching hospital in South India (Govt. General Hospital, Kurnool.)

Sample Size

Time for the onset of analgesia was the primary outcome parameter used for sample size calculation. Assuming the mean time for onset of anesthesia in control group as 6 min, to detect 1 unit difference, with 90% power of study and alpha error of 0.05, 23 subjects are needed in each of the treatment groups. To account for refusals, it was decided to include 25 subjects in each group.

Inclusion Criteria

1. American Society of Anesthesiologists (ASA) physical status I and II
2. Aged between 20-50 years
3. Both genders
4. Patients undergoing lower abdominal surgeries.

Exclusion Criteria

1. Critically ill patients (ASA physical status criteria III and above)
2. Patients having neurological, cardiovascular and respiratory, coagulation disorders, other system disorders, emotional instability, unwillingness to participate, and any anticipated difficulty in regional anesthesia were excluded.

Random Allocation

The participants were randomly allocated using computer generated random number sequence, maintained independently by statistician.

Blinding

Since the nature of intervention did not allow the blinding of investigator, the participants were blinded about the nature of intervention.

Ethical Approval

Approval of Institutional Human Ethics Committee was obtained. The procedure, risks, and benefits of the procedure were thoroughly explained to the patient, and informed written consent was sought from them. Only the participants willing to sign the informed written consent were included in the study. Confidentiality, the participants were maintained through the study.

Study Procedure

The pre-anesthetic evaluation of all the participants was done as per the established protocol. All relevant hemodynamic parameters were recorded just before the anesthesia. All patients were pre-meditated with Midazolam l mg IV. The blocks were given in lateral position in both the groups under all aseptic conditions.

a. Group A: Spinal needle 24G is introduced into the subarachnoid space at L_3 L_4 interspace and 3cc of Bupivacaine heavy 05% is injected, spinal needle is withdrawn and the drug is allowed to fix.
b. Group B: Patient was positioned laterally held by the operation theater (OT) assistant skin on the back was cleaned with savlon and spirit in sequence. The cleaned area was draped with a spinal towel. The L_3 L_4 space was identified, and a skin weal was raised with 1% lignocaine solution. The 18G Tuohy needle was introduced into the epidural space using loss of resistance technique by air filled syringe. Four

quadrant aspiration and loss of resistance were done to locate an epidural space. A sterile epidural catheter was introduced through the epidural needle until 3-4 cm of catheter is in epidural space, it is secured and patency checked by aspiration for the absence of cerebrospinal fluid and blood and the catheter is fixed. Now 24G Quinckebabcock spinal needle was taken, and subarachnoid anesthesia is given by injecting 1.5cc of 0.5% hyperbaric bupivacaine with the aim of achieving S_5-T_8 block. The spinal needle was withdrawn and after the subarachnoid drug was fixed (i.e., 15 min). The level of the block was extended to T_6 by injecting the fractioned dose (1.5-2 ml per unblocked segment) of 0.5% bupivacaine into epidural catheter depending on the need. Loss of sensation was tested by pinprick method at 5 min intervals till the maximum level of the block was achieved and thereafter every 15 min; the following observation were made.

Primary Outcome Parameters

1. Time of onset of analgesia as the time taken for analgesia to make its firstobjective appearance.
2. The time taken for analgesia: It is the time taken for the complete spread of analgesia to its upper limit.
3. Duration of sensory blockade: Regression of the upper two dermatomes. It is the time interval between the time of spread of analgesia to the time of regression in upper two dermatomes.

Secondary Outcome Measures

1. The quality of surgical analgesia was assessed and graded as: Excellent - if no supplementary drug required; Good - if one analgesic required; Fair - if more than one analgesic required; and Poor - if general anesthesia is required.
2. The degree of the motor blockade of the lower limb was assessed according to the modified Bromage Scale.
3. Hemodynamic parameters such as PR and BP were monitored at 5 min intervals for 1 h and thereafter every 15 min.
4. Any complication reported or observed was also documented.

Statistical Analysis

The baseline characteristics were compared between the two study groups. Categorical variables were presented as frequency and percentage; quantitative variables were presented as mean and standard deviation. All the primary and secondary outcome variables listed above were compared between the two study groups by estimating appropriate parameters. The statistical significance of the parameters was tested by independent sample *t*-test or Chi-square test, as appropriate. IBM SPSS Statistics, version 21 and Microsoft Excel were used for statistical analysis.

OBSERVATION AND RESULTS

A total of 50 participants, 25 in each of the treatment groups were included in the final analysis. The baseline characteristics are compared between the two study groups. There was no significant difference in the mean age and weight of the patients between the two study groups. The male to female ratio was slightly higher in Group B. The proportion of general surgical procedures was high in Group A, whereas in Group B more gynecological surgeries were performed (Table 1).

The time taken for the onset of anesthesia was shorter in SA group compared to CSEA group. The time taken for onset of anesthesia was 5.48 min in SA group compared to 7.40 min in CSEA group, with a mean difference of 1.92 min (95% CI: 0.78-3.05, *P*-value 0.001). The duration of analgesia was 115.6 min in Group A compared to 124.5 in Group B, with a mean difference of 8.92 min (95% CI: 0.87-18.71, *P*-value 0.07) (Table 2).

The proportion of subjects who achieved the excellent quality of surgical analgesia was 92% in Group A compared to 88% in Group B. The remaining 8% and 12% of the subjects the quality of the anesthesia was good. None of the patients had either fair or value poor quality analgesia. The mild differences in the quality of anesthesia were statistically not significant (Chi-square value 0.22 and *P*- value 0.637).

All the 25 subjects in SA group have achieved grade III muscle relaxation, according to the Bromage Scale. In

Table 1: Comparison of baseline characteristics of two study groups

Parameter	*N*=25		*P* value
	Group A	Group B	
Age (mean±SD)	35.46±8.95395	35.36±9.95774	0.976
Male:Female	0.78:1	1.27:1	0.396
Weight (mean±SD)	53.4±5.05799	51.08±4.97426	0.109
Surgery/gynecology	15/10 (60:40)	10/15 (40:60)	0.257

SD: Standard deviation

Table 2: Comparison of primary outcome parameters in two study groups (unpaired *t*-test)

Parameter	Mean	Mean difference	*P* value	95% CI	
				Lower	Upper
Onset of action					
Group A	5.48	1.920	0.001	0.788	3.052
Group B	7.40				
Duration of analgesia					
Group A	115.60	8.920	0.073	–0.877	18.717
Group B	124.52				

the CSE group, 4 (16%) of the subjects have achieved grade II, 20 (80%) have achieved grade III, and remaining 1 (4%) person has achieved grade V muscle relaxation. The differences in grade of motor blockade were statistically not significant (Table 3).

Hemodynamically, the incidence of hypotension and bradycardia was more in case of SA compared to CSE. In my study, 80% of patients CSE group had only <10% fall in PR compared to only 12% in case of SA. Where 76% of patients had shown fall in PR of 10-30% to the previous value (Chi-square value 22.52, $P < 0.001$). The number of subjects with fall in systolic BP of more than 20 mm of Hg was 11 (44%) in Group A, whereas this number was 1 (4%) in Group B (Chi-square: 21.52, $P < 0.001$) (Table 4).

The proportion of subjects reporting apprehension, nausea and vomiting was more in Group A and 4 (16%) subjects reported backache in Group B against 1 (4%) in Group A. However, these minor differences in the adverse events were not statistically significant (*P* value 0.273) (Table 5).

Table 3: Comparison of hemodynamic parameters in two study groups

Parameter	*N*=25 (%)		Chi square value	*P* value
	Group A	Group B		
Quality of surgical analgesia			0.222	0.637
Excellent	23 (92.0)	22 (88.0)		
Good	2 (8.0)	3 (12.0)		
Fair	0 (0.0)	0 (0.0)		
Poor	0 (0.0)	0 (0.0)		
Muscle relaxation grading (motor block) grade (Bromage scale)			5.556	0.062
0	0 (0.0)	0 (0.0)		
1	0 (0.0)	0 (0.0)		
2	0 (0.0)	4 (16.0)		
3	25 (100)	20 (80.0)		
5	0 (0.0)	1 (4.0)		

Table 4: Comparison of hemodynamic parameters in two study groups

Parameter	*N*=25 (%)		Chi square value	*P* value
	Group A	Group B		
Fall in PR			22.52	<0.001
<10	3 (12.0)	20 (80.0)		
10-20	10 (40.0)	4 (16.0)		
20-30	9 (36.0)	1 (4.0)		
>30	3 (12.0)	0 (0)		
Fall in systolic BP (mmHg)			21.52	<0.001
<10	2 (8.0)	18 (72.0.0)		
10-20	12 (48.0)	6 (24.0)		
20-30	9 (36.0)	1 (4.0)		
>30	2 (8.0)	0 (0.0)		

BP: Blood pressure, PR: Pulse rate

Table 5: Comparison of adverse effects in two study groups

Parameter	*N*=25 (%)		Chi square value	*P* value
	Group A	Group B		
Adverse effects				
Nausea and vomiting	2 (8.0)	0 (0.0)	3.891	0.273
Apprehension	6 (24.0)	5 (20.0)		
Backache	1 (4.0)	4 (16.0)		
PDPH	0 (0.0)	0 (0.0s)		
Seizures	0 (0.0)	0 (0.0)		
Total spinal	0 (0.0)	0 (0.0)		
High spinal	0 (0.0)	0 (0.0)		
Respiratory depression	0 (0.0)	0 (0.0)		

DISCUSSION

The CSE technique has been claimed to overcome the shortcomings of both SA and EA by achieving rapid onset and profound blockade with the facility to modify or prolong the block.[9]

The influence of age, sex, and weight is likely to be very minimal in the study as their distribution was almost similar in both study groups, without any statistically significant difference.

The onset time for sensory analgesia is slightly higher in CSE group, but it was achieved with a considerably lower dose of anesthetic in the subarachnoid space. The duration of analgesia, as measured by two segment regression was found to be longer in case of CSE compared to SA group. This was attributable to prolongation of anesthesia by epidural catheter in few necessary cases, which would not be possible with SA. The quality of surgical analgesia and muscle relaxation following spinal block was slightly superior over CSE. However, there was no significant difference between the two groups and no surgeon had complained or raised the problem of inadequate relaxation or surgical analgesia during the procedure of CSE compared to SA.

Almost all the studies published on the subject have either compared CSE with epidural or compared two different techniques of CSE. Even though many studies documented the clear superiority of the CSE, recent systematic reviews are of the conclusion that the clear superiority of CSE needs to further proved by large scale, well-controlled randomized controlled trials.

Priya *et al.* in their study on 40 patients, undergoing gynecological and orthopedic surgeries, the surgical analgesia and motor blockade occurred significantly early

in CSE group compared to epidural group. Duration of analgesia was significantly shorter in CSE (81.75 ± 11.09 min) as compared to epidural group (120.75 ± 7.56 min). The authors have concluded that sequential CSE is a superior alternative to epidural block.[9]

Gallinger *et al.*, in 88 anesthesia's in patients operated on the lower limb vessels have reported that in comparison to CSEA was characterized by a shorter latent period (12.9 ± 1.3 min vs. 24.7 ± 3.4 min, $P < 0.05$), a lower dose of bupivacaine (lidocaine: 735 ± 89 mg in CSEA and 848 ± 92 mg in EA; bupivacaine: 28.3 ± 7.2 mg in CSEA and 92.6 ± 8.5 mg in EA, $P < 0.01$), and a higher reliability. Hence, recommended CSEA over prolonged EA in operations on the lower limb vessels.[12] In a retrospective analysis of 525 women undergoing cesarean section, Ranasinghe *et al.* have concluded that CSE anesthesia is better than either SA or EA.[17]

Heesen *et al.*, have conducted a systematic review of 10 randomized controlled trials comparing CSE and EA in 1722 women in labor. The authors concluded that a consistent benefit of CSE over EA cannot be demonstrated on the basis of current best evidence and recommended large randomized controlled trials with adequate power.[18]

Hemodynamically, the incidence of hypotension and bradycardia was more in case of SA compared to CSE. Though the bupivacaine is said to produce less hemodynamic changes, gross fall in BP following SA was observed in some cases and in two patients of SA, BP had fallen more than 30% than the previous value, which was due to excessive intraoperative blood loss.

Although the spinal block is given in initially in case of CSE significant hemodynamic changes are not observed because of less extensive spinal block (T8-T9) due to sequential CSE technique combined with the slower onset of epidural block. This allows more time for the compensatory mechanisms to be effective.

Even though, the proportion of subjects reporting apprehension, nausea and vomiting were more in Group A and back ache was more in Group B, there was no statistically significant difference in the proportion of various adverse effects between spinal and CSE group.

Holloway *et al.*, in order to address the concern spinal blockade may have resulted in an increase in frequency of neurological sequel, a questionnaire-based assessment of 222 obstetric units across UK found, no obvious difference in incidence of problems associated with CSE versus the single-shot spinal technique (odds ratio: 1.14, CI: 0.53-2.46).[19]

In the current study, double space technique was used for giving CSE, as it appears to be more convenient to the anesthetist. In case of double space technique we need not to be in a hurry of introducing the epidural catheter following SA and this technique is also economical compared to single space technique as the equipment set of CSE anesthesia is very costly. Moreover, there is likely chance of unilateral anesthesia in case of xylocaine usage for spinal block in single space CSE where there is a delay in passing the epidural catheter.

CONCLUSIONS

The following conclusions can be derived from the current study of comparison between SA and sequential CSEA for lower abdominal surgeries. The CSE has got the following advantages over SA.

- Better hemodynamic stability is seen, such as PR and BP.
- The advantage of prolongation and extension of block when compared to the SA.
- Provision of post-operative analgesia.
- The quality of analgesia and onset of action is almost similar in both groups.

However, muscle relaxation is comparatively less in CSE technique.

Limitations

1. The confounding effect of various other potential confounding factors such as body mass index, other medical conditions present in the patients, type and severity of surgeries could not be evaluated because of lower effective sample size. However, randomization would have ensured minimizing this effect.

Recommendations

1. Further large-scale, well-controlled randomized studies comparing spinal and CSE techniques are needed to guide the clinicians on the choice of regional anesthesia n lower abdominal surgeries.

REFERENCES

1. Gizzo S, Noventa M, Fagherazzi S, Lamparelli L, Ancona E, Di Gangi S, *et al.* Update on best available options in obstetrics anaesthesia: Perinatal outcomes, side effects and maternal satisfaction. Fifteen years systematic literature review. Arch Gynecol Obstet 2014;290:21-34.
2. Datta S, Alper MH, Ostheimer GW, Weiss JB. Method of ephedrine administration and nausea and hypotension during spinal anesthesia for cesarean section. Anesthesiology 1982;56:68-70.
3. Thorburn J. Bupivacaine toxicity in association with extradural analgesia for caesarean section. Br J Anaesth 1984;56:551-3.
4. Backe SK, Sheikh Z, Wilson R, Lyons GR. Combined epidural/spinal

anaesthesia: Needle-through-needle or separate spaces? Eur J Anaesthesiol 2004;21:854-7.
5. Burke D, McLeod G. Combined spinal epidural anaesthesia: Question of technique. Int J Obstet Anesth 1999;8:219.
6. Juelsgaard P, Felsby S. Combined spinal and epidural anesthesia. A review of the method. Ugeskr Laeger 1993;155:2192-6.
7. Lew E, Yeo SW, Thomas E. Combined spinal-epidural anesthesia using epidural volume extension leads to faster motor recovery after elective cesarean delivery: A prospective, randomized, double-blind study. Anesth Analg 2004;98:810-4.
8. Soresi AS. Episubdural anesthesia. Anesth Analg 1937;16:306-10.
9. Priya G, Dua CK, Verma UC, Saxena KN, Chakraborty I. Sequential combined spinal epidural versus epidural anaesthesia in orthopaedic and gynaecological surgery: A comparative evaluation. Indian J Anaesth 2002;46:453-6.
10. Rawal N. Combined spinal-epidural anaesthesia. Curr Opin Anaesthesiol 2005;18:518-21.
11. Bai NY, Guo QL, Liu Y. Comparison of continuous spinal and combined spinal-epidural anesthesia in patients for uterectomy. Hunan Yi Ke Da Xue Xue Bao 2002;27:539-41.
12. Gallinger EIu, Seleznev MN, Babalian GV, Zolicheva NIu, Kriukov SP. Combined spinal-epidural and epidural anesthesia in operations on the vessels of the lower extremities. Anesteziol Reanimatol 1999;5:44-8.
13. Lee JS. Combined spinal epidural anaesthesia is better than spinal or epidural alone. Br J Anaesth 2004;92:295.
14. Simmons SW, Taghizadeh N, Dennis AT, Hughes D, Cyna AM. Combined spinal-epidural versus epidural analgesia in labour. Cochrane Database Syst Rev 2012;10:CD003401.
15. Williams RK, McBride WJ, Abajian JC. Combined spinal and epidural anaesthesia for major abdominal surgery in infants. Can J Anaesth 1997;44:511-4.
16. Yun MJ, Kwon MY, Kim do H, Lee JW. Combined spinal-epidural anesthesia using a reduced-dose of spinal bupivacaine and epidural top up leads to faster motor recovery after lower extremity surgeries. Korean J Anesthesiol 2014;66:28-33.
17. Ranasinghe JS, Steadman J, Toyama T, Lai M. Combined spinal epidural anaesthesia is better than spinal or epidural alone for Caesarean delivery. Br J Anaesth 2003;91:299-300.
18. Heesen M, Van de Velde M, Klöhr S, Lehberger J, Rossaint R, Straube S. Meta-analysis of the success of block following combined spinal-epidural vs epidural analgesia during labour. Anaesthesia 2014;69:64-71.
19. Holloway J, Seed PT, O'Sullivan G, Reynolds F. Paraesthesiae and nerve damage following combined spinal epidural and spinal anaesthesia: A pilot survey. Int J Obstet Anesth 2000;9:151-5.

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