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Original Article

Anaesthesia Section

Comparison of Efficacy and Safety of Unilateral Spinal Anaesthesia with Sequential Combined Spinal Epidural Anaesthesia for Lower Limb Orthopaedic Surgery

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ABSTRACT

Introduction: Orthopaedic anaesthesia plan requires customization as per patient's need for safe outcome. Sequential Combined Spinal Epidural Anaesthesia (Sequential CSEA) and Unilateral Single Shot Spinal anaesthesia (Unilateral SA), both have advantages over conventional spinal anaesthesia that they provide longer lasting block with less hypotension.

Aim: To compare safety and efficacy of unilateral spinal anaesthesia with sequential combined spinal epidural anaesthesia for lower limb orthopaedic surgery.

Materials and Methods: This prospective randomized study was conducted on sixty ASA I-III patients aged 18- 65 years undergoing lower limb orthopaedic surgeries of approximately two hours duration. Sequential CSE group received spinal with 5 mg of 0.5 hyperbaric bupivacaine followed by incremental epidural top up of 2 cc of 0.5% isobaric bupivacaine to achieve and maintain T10 level. In unilateral SA group, unilateral spinal anaesthesia was given with 10 mg of 0.5% hyperbaric bupivacaine. Haemodynamic parameter, anaesthesia readiness time and block characteristics were recorded and results were analysed using unpaired Student's t-test.

Results: There was no failure of block, surgical anaesthesia with T10 sensory level and bromage score three motor block was achieved by all patients in both groups. Anaesthesia readiness time was less in unilateral SA ($p<0.001$) Incidences of hypotension (p-value 0.0059) and mean ephedrine dose were significantly less in sequential CSEA. Five patients of unilateral SA required supplementation with general anaesthesia.

Conclusion: Thus, our study concludes that unilateral SA is a cost-effective and rapidly performed anaesthetic technique. Unilateral SA with 10 mg bupivacaine and sequential CSEA with 5 mg spinal and incremental epidural top up, both provide good quality sensory and motor block for lower limb orthopaedic surgery but sequential CSEA provides significantly more stable haemodynamics with feasibility to prolong block. Thus sequential CSEA should be preferred over unilateral SA in high risk patients especially for major lower limb orthopaedic surgeries.

Keywords: Block characteristics, Haemodynamics, Sequential combined spinal epidural, Unilateral spinal

INTRODUCTION

Regional anaesthesia is preferred over general anaesthesia for lower limb orthopaedic surgery and spinal anaesthesia is often a choice [1]. Spinal anaesthesia is a simple and quick technique but it has risk of severe hypotension. Even though spinal anaesthesia provides intense and reliable block, it has risk of limited duration of action. Compared to conventional spinal anaesthesia, unilateral Spinal Anaesthesia (unilateral SA) provides more dense and longer lasting block with less hypotension and prolonged analgesia with faster onset of action and lower incidence of failure [2,3]. A more improved method called sequential Combined Spinal Epidural Anaesthesia (sequential CSEA) in which a dose intended to be inadequate for surgery is used in an attempt to reduce hypotension and the block is then deliberately extended to the desired level with the epidural drug. This technique is becoming increasingly popular because of various benefits mainly stable haemodynamic status and feasibility to prolong block for anaesthesia and analgesia [4]. The sequential CSEA is now used in elderly high risk patients for orthopaedic surgeries with encouraging results [5,6]. In our institution, we routinely use both unilateral SA as well as sequential CSEA for lower limb orthopaedic surgeries even in high risk elderly patients.

Thus, to compare their efficacy and safety, we conducted this prospective randomized study between sequential CSEA verses unilateral SA. Our primary outcome were anaesthesia readiness time, characteristics of block, incidences of haemodynamic adverse events, supplementation of general anaesthesia and secondary outcome were bupivacaine dose, duration of analgesia, cost effectiveness.

MATERIALS AND METHODS

This was single center, randomised, prospective comparative study, conducted between January 2008 – January 2010. The study was approved by the Local Institutional Ethical Committee and written, informed consent was obtained from all patients before surgery. Sample size calculation was based on previous study and the pilot study considering difference of 30% in episodes of clinically significant hypotension between the two groups [5]. With α error of 0.05 and power of study 80%, sample size came to 27 per group. We decided to study 60 patients to account for possible dropouts.

After detailed preoperative assessment, sixty patients, aged 18 to 65 years of both sexes, ASA I – III undergoing unilateral lower limb orthopaedic surgery predicted to last approximately two hours were randomly allocated into two equal groups of 30 each according to computer-generated list compiled before the start of the study as Group Unilateral SA and Group sequential CSEA. Exclusion criteria were hypersensitivity to local anaesthetic agents, any contraindication to central neuraxial blockade and patients who

were not able to give lateral position for spinal anaesthesia due to pain.

In the operative room, routine noninvasive monitoring, electrocardiogram, Heart Rate (HR), SpO_2, Noninvasive Arterial Blood Pressure (NIBP) and nasal capnometer was used. All patients were premedicated with alprazolam 0.25 mg at night before the day of operation as routine protocol. All patients were preloaded with 500 ml of Ringer lactate solution before the start of surgery. Nature of intervention did not allow the blinding of investigator except for noninvasive haemodynamic variables which was recorded by blinded investigator who was not a part of anaesthesia team.

In sequential CSEA group, sequential combined spinal epidural anaesthesia was given in sitting position under strict aseptic precautions after local infiltration with 2 cc of 2% lignocaine in L2- L3 interspace. Epidural catheter was inserted after identifying epidural space with loss of resistance technique using 18 G Tuohy needle (Portex) facing cranially. The 3 cc of 1.5% lignocaine hydrochloride and adrenaline was given through epidural catheter as a test dose to rule out intravascular or subarachnoid catheter placement. Spinal anaesthesia was given with 1 cc (5 mg) of 0.5% hyperbaric bupivacaine over 30 seconds by midline approach in L3-L4 interspace using a 25 gauge Quincke point needle (Spinocan, Braun Melsungen, Germany). Patients were then placed in supine position immediately after fixing epidural catheter in position. If the desired spinal level of T10 was not achieved after 10 minutes of subarachnoid block, then incremental epidural top up dose with isobaric 0.5% bupivacaine 2 cc for every unblocked segment was given through epidural catheter till T10 level was achieved. Intraoperative if spinal level receded to T12 level, then again incremental epidural top up with isobaric 0.5% bupivacaine was given to maintain sensory block at T10 level.

In unilateral SA group, patient were placed in lateral decubitus position with the limb to be operated in the dependent position. Under strict aseptic precautions subarachnoid block was given in L3- L4 space using 25 gauge Quincke point spinal needle with (Spinocan, Braun Melsungen, Germany) with midline approach. After noting free and clear flow of CSF, needle's bevel was turned towards dependent side and 2 cc (10 mg) of 0.5% hyperbaric bupivacaine was injected over two minutes without further aspiration of CSF. Patient was kept in this lateral position for 15 minutes and then made supine.

Sensory block was assessed by pin prick method on operated limb side. Dermatome level tested every five minutes till thirty minutes, then every fifteen minutes until the point of regression of sensory level reached to L3 on the operated limb. At the end of 15 minutes if sensory block failed to reach T10 level or if patient had pain due to inadequate block, it was considered as failed block and general anaesthesia was given and these patient were excluded from further statistical analysis.

We recorded various variable like anaesthesia readiness time as time from the end of injection of spinal drug to the time sensory block reached T10 level and patient anaesthesia wise ready to be handed over to surgeon for surgery, degree of motor block on operated limb was evaluated using a Modified Bromage scale when patient was anaesthesia wise ready for surgery (Bromage O: Free movement of limb at hip, knee and ankle joint. Bromage 1: Free movement of limb at knee and ankle joint. Bromage 2: Free movement limb at ankle joint. Bromage 3: No movement of limb at hip, knee and ankle joint). Duration of motor block noted as time from the onset of grade 3 motor block to complete resolution of motor block.

Time to regression of sensory block to T12 noted as time from the onset of T10 sensory block to regression of sensory level to T12. If due to regression of spinal block and inability to maintain surgical anaesthesia during surgery in any group and if general anaesthesia was supplemented intraoperative then it was noted as supplementation of general anaesthesia. Initial and total dose bupivacaine required to establish and maintain block to T10 level also noted down.

Blinded observer noted down haemodynamic variables such as systolic arterial blood pressure and heart rate before administering anaesthesia and throughout intraoperative period. Clinically significant hypotension was defined as decrease in systolic arterial pressure by 30% or more from baseline values or <90 mm Hg. It was treated with IV ephedrine 5 mg incremental boluses dosages and the total amount of ephedrine required was noted. Clinically significant bradycardia was defined as a heart rate less than 50 beats per min and it was treated with IV atropine 0.5 mg boluses. Incidences of clinically significant hypotension and bradycardia were noted as incidence of haemodynamic adverse event.

After surgery epidural catheter was kept in situ for pain relief if patient demands it in sequential CSEA. All the patients were monitored in post anaesthesia care unit till they were shifted to general ward after they fulfilled PACU discharge criteria. Time to demand first rescue analgesia after completion of surgery from the onset of T10 sensory level was noted as duration of analgesia. Rescue analgesia was provided by epidural 8 cc of 0.1% bupivacaine with 1mg/Kg preservative free tramadol in sequential CSEA and with IV tramadol 1-2 mg/Kg in unilateral SA.

STATISTICAL ANALYSIS

The results were expressed as mean±standard deviation for continuous variables while ordinal data as frequency and percentage. Continuous variables were analysed using unpaired two-tailed Student's t-test. Ordinal data were analysed using Chi-square test. The $p<0.05$ was considered as statistically significant. All statistical calculation were performed using SYSTAT package 7.0 (SPSS Inc. Chicago IL, USA) and Microsoft Excel were used for statistical analysis.

RESULTS

A total of 60 patients randomly divided into two groups of 30 each, were studied. No patient in either group had failed block. Both groups were comparable with regard to age, height, gender ratio, ASA grade physical status and duration of surgery [Table/Fig-1].

Anaesthesia readiness time was significantly longer in sequential CSEA (p-value<0.001) [Table/Fig-2].

On comparing characteristics of block, all patients in both group achieved sensory level T10 and grade 3 Bromage score in operated limb. In unilateral SA group only one patient achieved T5 peak sensory level while 12 patients achieved T10 level thus, median was T10 with max -min range was T5 to T10 while in sequential CSEA group only six patients achieved T9 level rest 24 patients achieved T10 level thus median was T10 with max -min range was T9 to T10. Thus, the peak sensory level achieved was significantly higher in unilateral SA.

Variables	Group unilateral SA	Group sequential CSEA	p-value
Age (years) Mean±SD	40.4±9.70	43.5±10.18	0.230
Height (cm) Mean±SD	163.47±4.49	163±3.76	0.660
Weight (kg) Mean±SD	60.43±4.92	59.57±4.01	0.460
Gender (M/F) N {%}	21(70%)/9(30%)	19(66.7%)/11(36.7%)	0.580
ASA Grade I/II/III N {%}	14/10/6 46.7%/33.3%/20%	14/9/7 46.7%/30%/23.3%	0.940
Duration of surgery (min) Mean ± SD	131.5±14.57	135±10.75	0.290

[Table/Fig-1]: Demographic characteristics of the patients, duration of surgery.
p<0.05- Significant data are expressed as mean±SD and N [%] - numbers (percentage)
Unilateral SA – unilateral spinal anaesthesia
sequential CSEA – sequential combined spinal epidural anaesthesia

Variables	Group Unilateral SA	Group Sequential CSEA	p-value
Anaesthesia readiness time (Mean±SD)min	15.93±1.98	19.13 ± 2.87	<0.001
Peak sensory level Median (Max-Min)	T10 {T5 – T10}	T10 {T9 – T10}	0.004
Degree of motor block Grade 0/1/2/3	0/0/0/3	0/0/0/3	1.0
Time to regression of sensory block to T12 (Mean±SD) min	137.67±13.50	110.33±6.29	<0.001
Duration of motor block (Mean±SD) min	155.33±17.27	170.83±10.59	<0.001
Duration of analgesia (Mean±SD) min	172.67±22.27	223.67±17.12	<0.001
Supplementation with general anaesthesia N (%)	5(16.66 %)	0(0%)	0.02
Total bupivacaine consumption (mg)	10.00±0.00	41.66±6.37	<0.001

[Table/Fig-2]: Block characteristics and total bupivacaine consumption of the groups.
p<0.05- Significant, **p<0.01-Highly significant
Data are expressed as mean±SD and N (%) – numbers (percentage)
Unilateral SA – unilateral spinal anaesthesia
Sequential CSEA – sequential combined spinal epidural anaesthesia

Variables	Group Unilateral SA (n=30)	Group Sequential CSEA (n =30)	p-value
Number of patients developed clinically significant hypotension Number (percentage)	9(30%)	1(3.3%)	0.0059
Number of patients developed clinically significant bradycardia Number (percentage)	6(20%)	1(3.3%)	0.040
Mean ephedrine requirement (Mean±SD) mg	1.83±3.07	0.17±0.91	0.0062

[Table/Fig-3]: Incidence of hypotension and bradycardia.
p<0.05- Significant, **p<0.01-Highly significant
Data are expressed as mean±SD and N (%)–numbers (percentage)
Unilateral SA – unilateral spinal anaesthesia
Sequential CSEA – sequential combined spinal epidural anaesthesia

Regression of sensory block to T12 was faster in sequential CSEA. Duration of motor block in operated limb and duration of analgesia was longer in sequential CSEA. Total bupivacaine consumption was more in sequential CSEA. On comparing haemodynamics [Table/Fig-3] nine patients (30%) in unilateral SA and one patients 1 (3.3%) in sequential CSEA had episode of clinically significant hypotension (p-value=0.0059). The mean dose of ephedrine required was higher in unilateral SA (1.83±3.07) as compared to sequential CSEA (0.17±0.91 mg) (p=0.0062). One patient (3.3%) in sequential CSEA and 6 (20%) patient in unilateral SA required atropine for bradycardia (p-value=0.040).

DISCUSSION

The results from this study indicate that sequential CSEA and unilateral SA both provided good quality block with T10 sensory level and motor block of modified Bromage score 3 for lower limb orthopaedic surgery with no failed block. Sequential CSEA required extra anaesthesia readiness time but had significantly less haemodynamic adverse events and less ephedrine dose requirement and due to its feasibility to extend block, avoided need to supplement general anaesthesia and provided longer analgesia. There are multiple studies comparing sequential CSEA as well as unilateral SA with conventional spinal anaesthesia and continuous spinal anaesthesia. Both, sequential CSEA as well as unilateral SA have proven to be superior to conventional spinal anaesthesia especially in terms of duration of block and haemodynamic stability [5-8]. Though continuous spinal anaesthesia is a technique with definite end point for successful anaesthesia, technical difficulty in spinal catheters insertion and due to the possibility of complication like Caudal Equina syndrome and Post Dural Puncture Headache (PDPH), it has a very limited use [9,10]. We did not find any randomized studies in the literature comparing sequential CSEA with unilateral SA for lower limb orthopaedic surgery.

Unilateral SA is given with aim to limit distribution of spinal block only to the operated side for operations involving only one lower limb. It is achieved by giving minimal required dose of intrathecal agent so that only nerve roots supplying specific area and only the modalities that require to be anaesthetized are affected. Unilateral SA has low rate of cardiovascular complication due to its low degree of sympathetic block than bilateral spinal anaesthesia [8,11,12]. It has been suggested that a unilateral distribution of spinal anaesthesia can be attempted using the lateral decubitus position with small doses of not isobaric spinal anaesthetic solution, small gauge directional pencil point needles, injecting the drug slowly over long time and maintaining the lateral decubitus position for 15 to 20 minutes [2,3]. An injection of 10 mg (2 ml) hyperbaric bupivacaine 0.5% is recommended to provide block of duration approximately two to three hours for operations above the knee [13,14]. Thus, we used 10 mg of 0.5 % hyperbaric bupivacaine for unilateral SA for the block to last approximately two hour in our study.

Sequential CSEA technique is a significant advance in regional blockade [4]. Sequential CSEA involves intentional subarachnoid blockade with low dose of local anaesthetic and titration of the epidural top up dose according to surgical needs to restrict acute high sympathetic blockade and thereby reducing the chances of hypotension. This has also gained popularity because of the short onset time of spinal anaesthesia, while the catheter provides flexibility to allow the blockade to be extended when needed [5,6].

As safety of both these techniques is reported in elderly as well as in ASA grade III patients, we included them in our study [5,10]. We were technically able to give the block and could achieve successful surgical anaesthesia in all patient in both group. This may be because unilateral SA is a simple technique with very high success rate and because in sequential CSEA we used double segment CSE technique. Double segment CSE technique has 100% frequency of successful block compared to single segment needle-through-needle CSE technique with similar anaesthetic characteristics and time required to give the block [10,15]. Double segment CSE technique was also used to avoid delay in giving supine position after injecting spinal drug if there is difficulty in passing epidural catheter to obtain optimal effect of initial low dose spinal drug.

In sequential CSEA with intentional low dose spinal with 5 mg of 0.5% hyperbaric bupivacaine, sensory block up to T11 to L1 level and motor block of Bromage score grade 3 was achieved till the end of ten minutes which was then extended to T10 sensory level with incremental epidural top up with 2 ml of 0.5% isobaric bupivacaine per missed segment. Thus, with this technique advantage of good motor block achieved with spinal is preserved while the disadvantage of inadequate motor block due to epidural is eliminated. As epidural top up was required in all patients to achieve T10 level, anaesthesia readiness time was significantly longer (p <0.001). Result of our studies are comparable to the other studies when comparable dosages of bupivacaine were used for unilateral SA and sequential CSEA [5,6,13,14]. Faster onset and higher level of block are reported in the studies in which higher bupivacaine dosages were used for spinal anaesthesia or when epidural top up were not given in increment [14,16,17].

As the dose of spinal drug determine duration of spinal anaesthesia and because unilateral technique further prolongs duration of spinal anaesthesia, regression of block to T12 level was faster in sequential CSEA as compared to unilateral SA. Similar results are reported in other studies [18,19]. Recovery of motor block on operated limb

was delayed in sequential CSEA due to epidural top up given with 0.5% bupivacaine to maintain surgical anaesthesia. Intraoperative supplementation of general anaesthesia due to unpredicted delay in surgery time was required in unilateral SA due to lack of feasibility to prolong block with epidural top up. Duration of analgesia was also longer in sequential CSEA due to epidural supplementation given. On comparing haemodynamics, as compared to sequential CSEA, more patients with unilateral SA required treatment of bradycardia and hypotension. This difference was due to difference in acute sympathetic block due to lower dose of spinal drug used and incremental epidural top up allowing time for compensatory mechanism to be effective in sequential CSEA. Our results are comparable to other studies which suggest that dose of spinal drug and thus extend of block is responsible for haemodynamic stability [5,6,13,14,17].

Mean ephedrine dose required in our study in unilateral SA as well as sequential CSEA was very less compared to dose of ephedrine required in study by Yun MJ as level of block was higher as epidural dose was not titrated as per level [19].

The main advantage of sequential CSEA that initial dose of spinal anaesthesia can be titrated as per patient's cardiovascular status but still required level of block for surgery can be achieved with titration of epidural top up. In unilateral SA haemodynamic stability can be improved by reducing dose of spinal drug but we should keep in mind that spinal drug dose decides the level and duration of spinal block needed.

Unilateral SA is cost-effective as sequential CSEA requires extra cost of epidural set and extra drug. Possible limitation of study is that we did not do this study selectively in elderly high risk patients or selectively in major orthopaedic surgeries in elderly patients.

CONCLUSION

Unilateral SA is a cost-effective and rapidly performed anaesthetic technique. Unilateral SA and sequential CSEA technique both provide sufficient sensory and motor block for lower limb orthopaedic surgery but sequential CSEA provides significantly more stable haemodynamics with feasibility to prolong anaesthesia thus avoids general anaesthesia. Thus, sequential CSEA should be preferred over unilateral SA in high risk elderly patient for major lower limb orthopaedic surgeries.

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