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# Unilateral Spinal Anaesthesia for Lower Limb Orthopaedic Surgery Using Low Dose Bupivacaine with Fentanyl or Clonidine: A Randomised Control Study

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### **Abstract**

**Background and objective:** Providing a spinal block with preferential distribution to operative side is a useful technique. This study aimed to determine the incidence and suitability of unilateral spinal block, hypotension and recovery profile by 7.5 mg of 0.5% hyperbaric bupivacaine alone or with fentanyl/clonidine for knee or below knee orthopaedic surgery of moderate duration.

**Methods:** 120 patients undergoing orthopaedic surgery of lower limb received 7.5 mg of 0.5% hyperbaric bupivacaine intrathecally with 25  $\mu$ g of fentanyl (Group BF), 25 Regularg of clonidine (Group BC) or 0.5 ml of saline (Group BS). Block characteristics, unilaterality, haemodynamic changes and recovery profile was noted.

**Results:** Unilateral block was seen in more than 70% of patients in all the groups (p=0.057). Time of regression of sensory block to L2 level (133  $\pm$  18, 187  $\pm$  19, 182  $\pm$  18 mins respectively in groups BS, BF and BC) and time of first postoperative analgesia (245  $\pm$  27, 324  $\pm$  24, 318  $\pm$  22 mins respectively in groups BS, BF,BC, p<0.001) was prolonged in groups BF and BC. Motor block was prolonged in group BC only. Cardiovascular parameters were stable throughout, in all the groups.

**Conclusion:** 7.5 mg of hyperbaric bupivacaine alone or with fentanyl or clonidine produced predominantly unilateral spinal anaesthesia in more than 70% patients in the entire group with stable cardiovascular parameters. Addition of fentanyl or clonidine did not influence unilaterality or block characteristics but prolonged postoperative analgesia. Unilateral spinal block is suitable for moderate duration orthopaedic surgery of knee or below knee.

**Keywords:** Unilateral spinal anaesthesia; 0.5% hyperbaric bupivacaine; Fentanyl; Clonidine; Orthopaedic surgery

## Introduction

The term unilateral spinal anaesthesia is used when block is of operative side only with absence of block on non-operative side [1]. When surgery involves only one lower limb, such block is advantageous as it minimizes cardiovascular effects, avoids motor block of nonoperative limb and facilitates early discharge [2,3]. Although unilateral spinal is often practiced, but the potential to control the spread of intrathecal drugs, there by restricting the distribution of spinal block to the operative side, remains controversial and frequently debated [4,5]. It has been extensively studied for short duration outpatient arthroscopic surgeries of knee with favorable results [2,3,6-8], the studies involving moderate duration orthopaedic surgery are very few [9]. We hypothesized that 7.5 mg of hyperbaric bupivacaine would produce strictly unilateral block of sufficient duration for such surgeries. The purpose of this study was to determine the incidence of unilateral block, frequency of hypotension and suitability of this block for such surgeries using 7.5 mg of 0.5% hyperbaric bupivacaine. In addition we also sought to investigate if addition of clonidine or fentanyl to bupivacaine would affect unilaterality, block characteristics and recovery profile.

## Methods

The study was conducted on adult patients of either sex in the age group of 23-65 years with ASA grade I-II scheduled for elective knee and below knee orthopaedic surgery expected to last for 90-120 minutes, after approval from institutional review board. Patients with painful traumatic fractures, spinal deformity, diabetes, significant systemic disease and neuropathy were excluded from the study. Written and informed consent was obtained from each patient. The

patients were randomly allocated into one of three treatment groups by using computer-generated random numbers, inserted into sealed envelopes marked -120. All patients received subarachnoid block with 7.5 mg of 0.5% hyperbaric bupivacaine. In group BF 25  $\mu$ g of fentanyl, in group BC 25  $\mu$ g of clonidine and in group BS 0.5 ml of N Saline was added to bupivacaine. The spinal solution was prepared immediately before injection by a nurse not involved in anaesthetic care of patient and the volume was kept similar (2 ml) for each group.

Intravenous line was secured in forearm with 18G intravenous cannula and monitoring of non-invasive blood pressure,  $\mathrm{SpO}_2$  and ECG were established. All the patients were hydrated with 500 ml of lactated Ringer's solution before the spinal block. Patients were placed in the lateral decubitus position with the limb to be operated in the dependent position. The vertebral column position was accurately visualized before dural puncture and was maintained as horizontal as possible by tilting the operatingtable or by putting a pillow under the patient's shoulder. With strict aseptic precautions the 25 G Quincke spinal needle was inserted into L3-4interspace using a midline

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approach. The spinal solution was injected slowly without barbotage or aspiration after turning the needle orifice towards the dependent side. The patients were maintained in the lateral position for 20 minutes before turning supine. The patients were transferred to main OR after adequate anaesthesia of operative limb.

An observer, blinded to group allocation, recorded evolution and regression of block. The level of sensory and motor block was determined on both dependent and nondependent sides. Assessments were done immediately after spinal injection and at 5 minutes interval for 20 minutes and every 15 minutes until end of surgery and regression of block to L2 level. Time of complete motor recovery was also recorded. Sensory testing was done from caudal to cephalad and analgesic level was defined as the cephalad most dermatome at which the patient had decreased sharp sensation. Motor blockade was assessed according to modified Bromage scale (0-no block, 1-hip blocked, 2-hip and knee blocked, 3- hip, knee and ankle blocked). Haemodynamic parameters were recorded immediately before spinal, every 5 minute for first 30 minutes and every 15 minutes till completion of surgery. Hypotension was labeled as significant if fall was more than 30% from baseline and bradycardia if heart rate decreased below 50 bpm. Hypotension was treated with IV fluids and ephedrine and bradycardia by atropine. Further BP and heart rate were recorded at the time of assessment of sensory and motor block.

The spinal anaesthesia was termed as unilateral when the sensory block was upto or above T12 level and modified Bromage score for motor block was >2 on the operative limb and no detectable sensory and motor block on the other limb. Adequacy of surgical anaesthesia was judged according to need for supplementary analgesics or anaesthetics; adequate if none needed, inadequate if only analgesic (fentanyl) needed and failed if general anaesthetic drugs needed to start or complete the surgery. After completion of surgery the patients were shifted to PACU. They were observed for side effects such as nausea, vomiting, pruritus, pain and retention of urine. The patients were discharged from PACU after complete resolution of spinal block, with stable vital signs and spontaneous urination. The time of first request for analgesic was also noted.

The sample size was calculated using a G Power analysis programme. Using a prior power analysis with a accuracy mode calculation, and assuming a two-tailed type I error protection of 0.05, a power of 0.8 and an effect size convention of 0.3, a sample size of 40 patients in each group was required to accept the alternative hypothesis i.e. 25% difference in the time for complete recovery of spinal block. Statistical analysis was conducted using SAS V9.1.2 for windows. Patient characteristics were analyzed with Kruskal-Wallis test. Hemodynamic changes from baseline values were analyzed by ANOVA with Tukey-Kraemer corrections. The characteristics of sensory and motor blockade were analyzed by two way analysis of variance for repeated measures with Tukey-Kraemer test for multiple comparisons. Chi-square test with appropriate correction was used to analyze dichotomous variables. Continuous variables are presented as mean  $\pm$  SD. Ordinal data are presented as median (range) or as count (percentage).

## **Results**

No difference in age, weight, height, female to male ratio, distribution and duration of surgery was observed between the groups (Table 1). In most of the patients surgery could be completed without analgesic/anesthetic supplementation. One patient in groups BF and BS required supplementation with propofol and fentanyl due to inadequate block and two patients in group BS required fentanyl

towards end of surgery.

Sensory and motor block assessments are summarized in Table 2. Sensory level was significantly higher and motor block was more intense (Bromge scale >2) in operative limb compared to non-operative limb in all the groups (p=0.000). Highest sensory level in operative limb ranged between T6 to T10 level in groups BS and BC whereas highest level in group F ranged between T7-T11, mode being T10 in all the groups (p>0.05). Time to reach highest level and time to reach T12 level was also not different among the groups (p>0.05). Time for regression of sensory block to the level of L2 was significantly prolonged in study groups BF and BC compared to group BS (p<0.001). Motor block was more intense in operative limb, being Bromage scale 3, in majority of the patients in all three groups, (p>0.05). Time of complete recovery of motor block (Bromage scale 0) was significantly prolonged in group BC compared to other two groups (p<0.001) (Table 2). Strictly unilateral block was present in 73, 75 and 73% of patients in groups BS, BF and BC respectively (p=0.203) (Table 2). However, when the patients were turned supine after 20 minutes, unilateral block reduced to 65% (Group BS) 70% (Group BF) and 68% in group BC. Time of first analgesic request was significantly prolonged in groups BF and BC in relation to group BS (p<0.001) but on comparison between study groups BF and BC it was not significant (p=0.32). Haemodynamic variables (Mean and SEM) are shown in Figures 1-3. None of the patients in any group had bradycardia (heart rate<50) or hypotension (fall >30% of baseline). Although on inter group comparison systolic and diastolic BP remained slightly lower in groups BC and BS compared to groups BF, the difference was not significant (p>0.05). Maximum fall in BP ranged between 4-11% from baseline in all the groups. No patient required vasopressors. Mean time of spontaneous urination was similar in each group. Urinary retentions were noted in 2 patients one each in group F and S. Three patients of group BF complained of pruritus. PDPH was reported by 5, 3 and 7 patients in groups BS, BF and BC respectively. Neurological symptoms were not seen in any patient.

### Discussion

The results of this prospective double blind randomized study demonstrated that 7.5 mg of hyperbaric bupivacaine produced a spinal block relatively restricted to operative limb in more than 70% of patients with minimal changes in cardiovascular parameters. Upper sensory level, time to achieve this level, degree of motor block and unilaterality were not affected by addition of fentanyl or clonidine to bupivacaine. However, addition of fentanyl and clonidine delayed the regression of sensory block and extended postoperative analgesia. Clonidine also significantly prolonged the recovery of motor block.

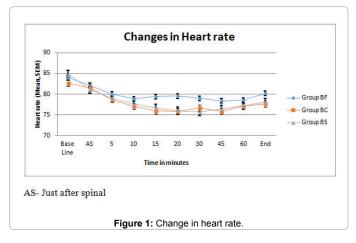
There was significant difference in spread of anaesthesia between operative and contralateral limb. Sensory levels were much higher and

	O DO (40)	O DE (40)	O DO (40)
	Group BS (n=40)	Group BF (n=40)	Group BC (n=40)
Age (yrs)	46 ± 12	45 ± 14	43 ± 11
Height (cm)	162 ± 5	161 ± 6	163 ± 6
Weight (kg)	64 ± 11	67 ± 14	65 ± 12
Gender (M/F)	26/14	31/9	29/11
Type of surgery			
Knee	14	17	15
Below Knee	26	23	25
Duration of surgery (Mins)	98 ± 23	98 ± 20	101 ± 23

**Table 1:** Patient characteristics (data are Mean  $\pm$  SD or number)

	Group BS	Group BF	Group BC
Sensory block	9.5 ± 1.84	9.8 ± 1.84	10.0 ± 1.60
· Time to reach T12(mins)			
· Highest Block			
Operative limb	T10 (T6-11)	T10 (T7-12)	T10 (T6-11)
Non operative limb	L3 (T12-S3)	L3 (T12-S1)	L2 (T12-S1)
· Time to regress to L2 level (mins)			
	133 ± 18.03	187 ± 14.39	181.6 ± 17.57
Motor block (bromage scale)			
0/1/2/3			
Operative limb     Non operative limb	1/0/5/34	0/1/3/36	1/2/0/37
	30/5/4/1	32/4/2/2	30/6/2/2
Time of complete recovery of motor block (min)	186.88 ± 10.97	198.03 ± 12.59	250.00 ± 28.77
Unilateral Block			
At 20 mins	29 (73%)	30 (75%)	29 (73%)
At 40 mins	26 (65%)	28 (70%)	27 (68%)
Surgical anaesthesia (Adequate/			
Inadequate/failed)	37/2/1	38/2/0	36/3/1
Time of lst analgesic need (mins)	245.35 ± 26.60	324.45 ± 23.57	318 ± 22.29
Time of spontaneous urination (mins)	398.35 ± 16.60	408.43 ± 18.00	1.36 ± 16.69

Table 2: Block characteristics and other data (data are expressed as Mean ± SD, Median (range) or Number (%)



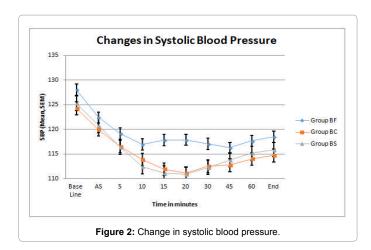
motor block was denser in operative limb in relation to non-operative limb. Unilateral spinal anaesthesia was achieved in 73% of patients each in groups BS and BC and in 75% in group BF patients. Unilateral block ranging between 73-86% has been reported by previous investigators using hyperbaric bupivacaine [3,8,10-13]. This is due to higher anaesthetic concentration achieved near the nerve roots of operative limb. When the patients were turned supine, unilateral anaesthesia decreased to 65%, 70% and 68% in groups BS, BF and BC respectively. This can be explained due to diffusion of free local anaesthetic on attaining supine position [12,13]. But this portion of drug is too small to block nerve roots to a clinically significant level.

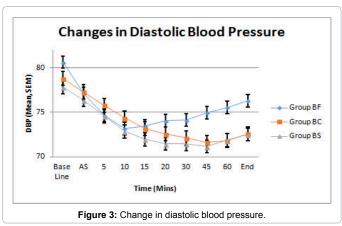
Co-administration of fentanyl and clonidine with bupivacaine prolonged the time of demand of first postoperative analgesic in our patients. Our study confirmed previous reports of prolongation of postoperative analgesia by addition of fentanyl [8,11,14] and clonidine [7,15,16] to spinal local anaesthetic. This can be explained due to synergistic effect of fentanyl with local anesthetic. The mechanism of clonidine induced prolongation of analgesia is said to be mediated by action on presynaptic and postsynaptic alpha-2 adrenergic receptors in dorsal horn [17].

In addition, there was some prolongation of motor block in patients receiving intrathecal clonidine. These findings concur with previous reports [7,8,18]. The mechanism of prolongation of motor block by clonidine remains speculative [7] and can be due to direct inhibition of impulse conduction in motor nerve fibres [19].

One of the main advantage of unilateral block is more stable haemodynamic status [20]. In agreement with previous investigators [5,9,11,12] no significant fall in BP and heart rate was noted in any patient. Mean fall in BP was % from baseline values. Less hypotension is due to lower dose of anaesthetic and slow ascent of block [9]. This allows patients to activate homeostatic vascular mechanism more efficiently [2,9,21].

The simultaneous factors for unilateral spinal block are: lateral decubitus position during and subsequently after intrathecal injection, low dose of local anesthetic and slow speed of injection [2,9,20]. Position of patient (lateral decubitus) with respect to baricity of local anaesthetic [22] and duration of lateral position after intrathecal injection are main determinants of distribution of spinal block to one side. The optimum





duration of lateral position is difficult to define [10] as it is also related to local anaesthetic dose. When 5-8 mg of hyperbaric bupivacaine is used, maintaining lateral position for 15-20 minutes is enough to prevent anaesthetic migration to other side when the patients are turned supine [3,23,24]. As we used hyperbaric bupivacaine we positioned the patients in lateral position with operative side in dependent position and maintained this position for 20 minutes after spinal injection. Slow speed of injection minimizes mixing of local anaesthetic with CSF and thus facilitates unilateral block [9,10].

Reduction of local anaesthetic dose is crucial for unilaterality of block [23,25]. However, too small dose can increase failure rate of spinal [6,10] and shorten the duration of block [16]. We used intermediate dose of 7.5 mg of bupivacaine which probably reduced the rate of unilateral block compared to other studies [3,10,23] but allowed surgery without need of supplementary analgesia in more than 97% of patients. Further, we also used adjuvants to reduce risk of failed block and enhance postoperative analgesia [16,18].

There may be several potential benefits to the daily practicing of unilateral spinal anaesthesia but there are also shortcomings that leave us wondering whether this is a technique worth pursuing. Placing the patients in lateral position for 20 minutes may be time consuming for a busy OR. For this we performed spinal block in a room adjacent to OR well in advance and shifted to main OR after adequate surgical anaesthesia. Lying on operative side with painful fractures is impossible. Although use of hypobaric or plain solutions may increase patient acceptability in such situations, hyperbaric solutions are better for producing unilateral block [3]. We excluded patients with fractures

from the study and used hyperbaric solution.

## Conclusion

7.5 mg of hyperbaric bupivacaine alone or with fentanyl or clonidine produced unilateral spinal anaesthesia of sufficient duration with cardiovascular stability in majority of patients making the block suitable for patients undergoing planned knee or below knee surgery of moderate duration. Fentanyl or clonidine extended early postoperative analgesia without influencing spread or unilaterality of block. Clonidine, however also prolonged motor block.

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