Original Article

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Comparison of Hypobaric Bupivacaine, With and Without Fentanyl for Patients Undergoing Surgeries around Hip: A Randomized Double Blind Study from North India

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Abstract

Background: Hip surgeries are frequently performed using single shot spinal anesthesia with 15-17.5 mg plain bupivacaine 0.5% which provides surgical anesthesia for 3-4 hours but is difficult to make the patients with hip fractures to lie in lateral decubitus position with the operating side dependent and to make them sit also. Using hypobaric local anesthetic for surgeries around hip, preparation time may be reduced for performing spinal anesthesia and surgery in the same position without waiting for establishment of spinal anesthesia in the supine position. Furthermore, hypobaric local anesthetics can produce more selective block on the operating side and avoid unnecessary paralysis of the nonoperating side potentially resulting in hemodynamic stability and better mobilization of patients during recovery period. **Subjects and Methods:** In the present study, we compared the anesthetic and hemodynamic effects of hypobaric bupivacaine with and without fentanyl in 100 ASA physical status I and II patients undergoing surgeries around hip. Patients received spinal injection of either 2.5ml (12.5mg) of isobaric bupivacaine with 1.5ml of distilled water (total 4ml) making it hypobaric or 2.5 ml (12.5mg) of isobaric bupivacaine with 1ml of distilled water and 0.5ml(25 µg) of fentanyl (total 4ml) with operative side up, in a double blinded manner. Sensory level and motor block were evaluated on the operative and non-operative sides until regression to L2 and full motor recovery. Hemodynamic changes after spinal injection and the first analgesic request for VAS >3 were noted. **Results:** Demographic characteristics of both the groups were comparable. Time to maximal fall in MAP and patients requiring vasopressor were similar in both the groups. None of the patients in any of the two group required atropine for bradycardia. Co-administration of fentanyl in hypobaric bupivacaine hastened the onset of sensory block (12±3 vs. 20±9.0, p value <0.001) and the time required was less on the operative side than on the contralateral (non-operative) side in both the groups. The median upper level of block was higher on the operative than on the contralateral side in both the groups. Co-administration of fentanyl in hypobaric bupivacaine prolonged the sensory regression to L2 (298±40 vs. 256±35, p value <0.001). Co-administration of fentanyl had no effect on the time to complete motor recovery as at the end of surgery, all the patients had complete motor recovery on the contralateral (non-operative) side, while none of the patient in any of the two groups had complete motor recovery on the operative side. Time to first analgesic requirement was significantly higher (318±27 vs. 288±28, p value <0.001) with the addition of fentanyl to the hypobaric bupivacaine. **Conclusion:** So we conclude that the use of hypobaric bupivacaine produces spinal anesthesia with a faster sensory motor recovery on the contralateral (non-operative) side. Co-administration of fentanyl further prolongs the sensory block on the operative side without significantly affecting the motor block, so delays the use of first analgesic without further compromising the systemic hemodynamics.

Keywords: Hypobaric Bupivacaine, Spinal Anaesthesia, Hip Surgeries.

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Introduction

Hip surgeries are frequently performed using single shot spinal anesthesia with 15-17.5 mg plain bupivacaine 0.5% which provides surgical anesthesia for 3-4 hours. Many factors influence the distribution of local anesthetic solution within the subarachnoid space. Out of the various factors specific gravity of the local anesthetic solution relative to that of the CSF and the patient position during and after injection are recognized as perhaps the two most important variables influencing segmental spread of spinal anesthesia.[1] Patient positioning significantly affect the hemodynamic variables during hypobaric spinal anesthesia.[2] It is also very difficult to make the patients with hip fractures to lie in lateral decubitus position with the operating side

dependent and to make them sit also. Using hypobaric local anesthetic for surgeries around hip, preparation time may be reduced for performing spinal anesthesia and surgery in the same position without waiting for establishment of spinal anesthesia in the supine position. Furthermore, hypobaric local anesthetics can produce more selective block on the operating side and avoid unnecessary paralysis of the nonoperating side potentially resulting in hemodynamic stability and better mobilization of patients during recovery period.

Taking into consideration the benefits of hypobaric bupivacaine, this randomized double blind study was conducted to evaluate the effectiveness of hypobaric bupivacaine with or without fentanyl in patients undergoing surgeries around hip.

Subjects and Methods

After obtaining the approval from the institutional ethical board a written informed consent from all the patients aged 20- 75 years of ASA physical status I and II and of either sex, with ± 20% of ideal body weight and height, scheduled for surgeries around hip, were included for this study. Exclusion criteria were coagulation disorders, local infection, obvious spinal deformity, previous spinal surgery, back pain, neurological abnormalities of leg, peripheral neuropathy, obesity (body mass index >30) and patients unable to comprehend the basic aspects of study.

Soon after the arrival of patients in the operation theater, 500 ml of Ringer lactate was rapidly infused over 10-15 minutes before the induction of spinal anesthesia. Patients were monitored with automated BP cuff at 5 minutes interval, three lead electrocardiography and pulse oxymetry. All patients were given 1 mg midazolam IV 10 minutes before the lumbar puncture as premedication. Patients were placed in lateral decubitus position with operating side up. Patients were randomly allocated into one of the following groups using a computer generated table of random numbers. Isobaric bupivacaine Solutions were made hypobaric by adding 1.5 ml of distilled water to 2.5 ml (12.5 mg) isobaric bupivacaine in group I (4 ml volume) and 1 ml of distilled water and 0.5 ml (25µg) fentanyl to 2.5 ml (12.5 mg) isobaric bupivacaine in group II (4 ml volume). Lumbar puncture was performed at L2-L3 or L3-L4 interspace using midline approach with 25G pencil point spinal needle and after confirming the free flow of CSF and no abnormal sensation, the solution was injected slowly at the rate of 0.5 ml/second according to the group.

Group I Patients received 2.5 ml (12.5 mg) isobaric bupivacaine with 1.5 ml distilled water i.e. 4 ml of hypobaric solution.

Group II Patients received 12.5 mg isobaric bupivacaine with 1 ml distilled water and 0.5 ml (25µg) fentanyl i.e. 4 ml of hypobaric solution.

The following variables were measured throughout the study by an anesthetist who was blind to the treatment groups.

Maximum upper sensory block level by pin prick test (24 gauge needle), its onset time and time of regression to L2 (level of surgical incision) on both the sides was recorded.

Maximal degree of motor block, using a modified Bromage scale ranging from 0 to 4 (0= able to move hip, knee, ankle and toes; 4 = unable to move hip, knee, ankle and toes) on both the limbs every 5 minutes during the first 45 minutes, its onset time, and the time to total motor recovery of both limbs was recorded.

Heart rate and mean arterial blood pressure was recorded every 5 minutes during surgery and then every 15 min. in the recovery room until the study termination (defined as the sensory regression to L2 on both the sides). Ephedrine 5-10 mg IV was given if mean arterial blood pressure (MAP) decreased >20% from the baseline value or if the systolic pressure decreased to <90 mmHg. Atropine 0.6 mg IV was given if the heart rate (HR) decreased to <45 bpm.

Duration of anesthesia was defined as the time between spinal injection and the end of surgery. While the duration of surgical analgesia (defined as the time between spinal injection and the first analgesic requirement for a pain score at the operative site >3 on VAS scale ranging from 0 to 10) was noted and 75 mg IM diclofenac sodium was given.

All the above variables were determined in the operation theater and recovery room by anesthesia trainees who were blind to the group allocation. Discomfort related to lateral position during surgery was treated with fentanyl 1 micrograms/kg IV (maximal 2 doses) and anxiety with midazolam 1 mg IV.

The occurrences of postoperative headache, backache, pain and/or dysesthesia in the buttocks, thighs or lower limbs, pruritus, urinary retention, nausea, vomiting, respiratory depression and sedation, were evaluated.

Sample size estimation was based on the assumption to detect a difference of at least 25% in the mean duration of analgesia between the two groups at α=0.05 and β=0.8 and 43 patients in each group were determined. We recruited 50 patients in each group to increase the power of our study.

Statistical analysis was performed with ANOVA and p values <0.05 were considered significant. Data is being presented as mean ± SD, proportion or n(%). Analysis of variance and chi-square test were used to check that the study groups were matched in terms of demographic data. The chi square and Fisher's exact test were used to compare the adverse events. For the comparison of the relevant variables (heart rate, blood pressure), and reported measures, analysis of variance test was performed. For VAS, the Kruskal-Wasel test was used.

Results

Fifty patients were allocated to each group. Patient characteristics were comparable in the two study groups [Table 1].

Table 1: Patient Characteristics in Two Groups

	Group I (n=50)	Group II (n=50)
Age (in years)	55±17	54±26
Sex (M:F)	28:22	24:26
ASA Class (I:II)	18:32	20:30
Height (in cm)	160±10	158±10
Weight (in Kg)	76±12	72±14
Duration of anesthesia (In min.)	186±35	192±40

[Table 1] shows non- significant difference between the groups regarding patient characteristics.

Median upper sensory levels are comparable between corresponding sides(up to T4 level on operative side & T6 level on nonoperative side) in the two groups but it differs significantly between operative and nonoperative side (T4 vs. T6) of the same group. Time to maximum level of sensory block is significantly higher in group I than in group II on both operative & non-operative side [Figure 1]. When comparing the sensory regression times to L2, between the groups and between the operative and nonoperative sides of the same group we find that the time to L2 regression is significantly higher in group II than in group I, on both operative (256±35 vs298±40 p<0.001) & non-operative sides (238±25 vs266±32 p<0.001) and within the group comparison show a significantly higher time to L2 regression on operative side than non-operative side in both the groups. [Figure 2].

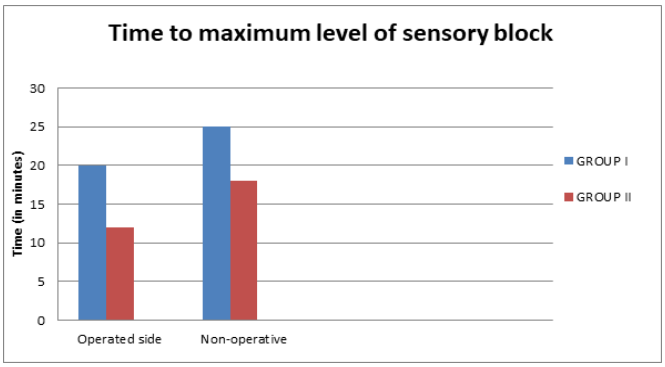

Figure 1: Shows, time to maximum level of sensory block is significantly higher in group I than in group II on both operative & non-operative side.

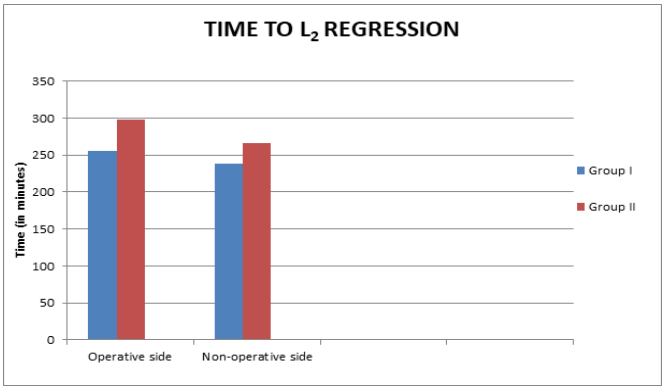

Figure 2: Shows time to L2 regression is significantly higher in group II than in group I, on both operative & non-operative sides and within the group comparison show a significantly higher time to L2 regression on operative side than non-operative side in both the groups.

The maximal degree of motor block by modified Bromage scale were same i.e 4 in both groups on operative as well as and nonoperative side. While the time to maximum degree of motor block is significantly higher in group I than in group II on both operative (13±3 vs. 9±2 p<0.001) and non-operative side (15±4 vs. 12±5 p<0.001) and within the group it was significantly higher on non-operative side than on operative side (Figure-3). At the end of the surgery all patients had complete motor recovery on the non-operative side while none of the patients in any of the two groups had complete motor recovery on operative side.

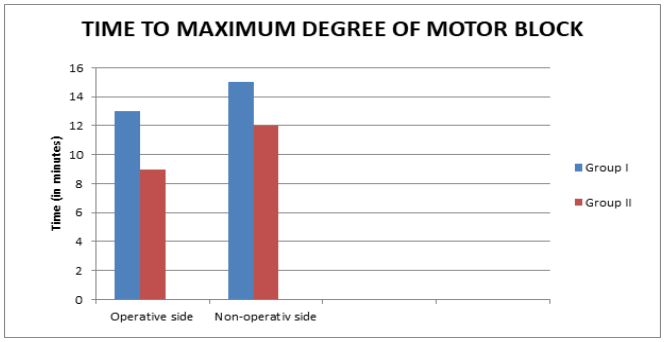

Figure 3: Shows time to maximum degree of motor block is significantly higher in group I than in group II on both operative and non-operative side but within the group comparison shows a significantly higher time to maximal degree of motor block on non-operative side than on operative side.

As the sensory regression time to L2, was longer in group II, the time to first analgesic requirement is significantly higher (318±27 vs. 288±28 p<0.001) in group II than in group I [Table 2].

Table 2: Time to First Analgesic Requirement

	Group I (n=50)	Group II (n=50)	P value
Time (in min)	288±28	318±27	p <0.001

[Table 2] shows that time to first analgesic requirement is significantly higher in group II than in group I.

Hemodynamic variables like heart rate (HR) and mean arterial blood pressure (MAP) changes during surgery and in recovery period were comparable in both the groups. Similarly no significant difference is detected in time to maximal fall in MAP (18±6.0 vs. 16±5) and the requirement of vasopressor for fall in MAP (8(16%) vs. 10 (20%)) between the two groups. No patient in either group required atropine for bradycardia.

Table 3: Hemodynamic Changes

	Group I (n=50)	Group II (n=50)	'p' value
Time to maximal fall in MAP (in min)	18±6.0	16±5	0.10
Patient requiring vasopressor (n%)	8(16%)	10(20%)	0.60

[Table 3] shows no significant difference is detected in time to maximal fall in MAP and the requirement of vasopressors for fall in MAP, between the two groups.

As far as complications are concerned no significant difference is found between two groups regarding backache, urinary retention & nausea and vomiting but significantly higher number of patient had pruritus and sedation in group II than in group I (Table-10). No patient in either group had headache, dysesthesias or respiratory depression.

Table 4: Adverse Events

	Group I (n=50) n%	Group II (n=50) n%	'p'value
Backache	2(4%)	1(2%)	0.56
Urinary Retention	6(12%)	5(10%)	0.75
Nausea/Vomiting	1(2%)	4(8%)	0.17

Pruritus	- (0%)	4(8%)	0.04
Sedation	-	6(12%)	0.012

[Table 4] shows no significant difference is found between two groups regarding backache, urinary retention & nausea and vomiting but significantly higher number of patient had pruritus and sedation in group II than in group I.

Discussion

The result demonstrate that hypobaric spinal anaesthesia in lateral position can be a better option for for fractures around hip and with addition of fentanyl would be more advantageous. In our study, the dural puncture was performed with 25G pencil point needle and hypobaric solution was injected at a fast rate (0.5 ml/sec; 8 sec) and the mean duration of analgesia was of considerable clinical relevance, for the surgical repair of hip fractures as shown by Atchinson et al in their study.[3]

The hypobaric bupivacaine (0.32%, 12.5mg) was injected in lateral decubitus position with the operative side up and the mean highest sensory level was T4 and T6, on operative and non-operative sides, respectively ($p < 0.001$) and the duration of analgesia was also significantly higher i.e. 256 ± 35 min. This is in contrast with the study done by Van Gessel et al and the difference may attributed to higher dose and volume of the drug used by us.[4] The motor blockade was satisfactory in almost all the patients and only 16% of the patients had decrease in the mean arterial pressure requiring vasopressor. The lower incidence of hypotension in our study could be due to the larger sample size.

Taivanen et al used 8ml of 0.19% hypobaric bupivacaine in patients undergoing orthopedic surgeries of limb.[5] The solution was injected in sitting position at L3-L4 interspace in 40 sec, and patients were kept in this position for 2 minutes. The mean maximal cephalad spread was to T1 segment. The study was interrupted after observing the sensory block to C2 segment within 5 min of injection and it was associated with marked hypotension. Keeping in mind the adverse effects of the author's study we have used only 4ml of 0.32% hypobaric bupivacaine in our study and the solution was injected in L3-L4 interspace in 8 sec with the operative side up and the patients were kept in this position for 20 min. The mean maximal cephalad spread was T3 and T5 on operative and non-operative sides respectively. None of the patients in our study had sensory block of cervical segments. This difference is due to the lesser volume of drug and relatively less hypobaric solution given in lateral decubitus position in our study.

We have used 4ml of 0.32% hypobaric bupivacaine (12.5mg), injected in lateral decubitus position with the operative side up and the highest level of sensory block was T4 with the range T3-T5 on the operative side. All the patients had satisfactory motor blockade with 16% incidence of significant hypotension. While Van Gessel et al used 3ml of hypobaric bupivacaine (7.5mg) through a spinal catheter in horizontal supine position in elderly patients undergoing hip surgery.[6] The highest sensory level obtained was, T4 [(median L1); range T4-L3]. The satisfactory motor blockade was obtained only in 8 out of 15 patients. The significant decrease in MAP was seen in 13% of patients. The failure to achieve satisfactory motor blockade in author's study may be attributed to injection of the solution in horizontal supine position, with lesser volume and dose of the drug. With these findings, we infer that the surgical level of sensori-motor blockade with hypobaric solutions is better achieved with the operative side non-dependent in lower limb orthopedic surgeries.

We have injected 0.32% hypobaric solution at fast rate (0.5 ml/sec). Although the highest level of sensory block on operative side was up to T4 segment, with 16% significant hypotension, but it was transient and none of the patient had involvement of cardio-accelerator fibres, requiring atropine for bradycardia. This is in accordance with inference that fast injection of 0.3% bupivacaine solution results in higher maximum sensory level than slow injection by Horlocker et al.[7]

Keeping in mind the influence of posture during intrathecal injection on the extent of sensory block, all the patients in our study received intrathecal injection in the lateral decubitus position with the operative side uppermost as depicted by Richardson et al by using 0.25% bupivacaine with fentanyl 0.005% either in sitting or lateral decubitus position in parturients for labour analgesia and found that the mean cephalad spread of the block was greater in the sitting position while the extent of block was greater on the non-dependent side in the lateral decubitus position.[8]

As concluded by Kuusneimi et al that 30 minutes spent in lateral position did not provide benefits over 20 minutes to achieve unilateral spinal anesthesia, we maintained the lateral decubitus position till 20 minutes after intrathecal injection and on both operative and non-operative sides, the motor block was similar but recovery was faster on the non-operative side.[9] To achieve satisfactory reduction of hip fractures, the motor block is also quiet often required to give traction with minimum patient discomfort.

Although the degree of motor block achieved was similar on both the sides, 100% patients had complete motor recovery on the non-operative side at the end of surgery. So, from the point of view of unnecessary paralysis of the non-operative side after surgery, our technique was also like unilateral spinal anesthesia with the use of 25G pencil point spinal needle without postdural puncture headache as also concluded by Imbelloni et al.[10]

In our study, addition of 25µg fentanyl to 4 ml 0.32% hypobaric bupivacaine resulted in superior analgesia with significantly higher time to first analgesic requirement as seen in study done by Atallah et al.[11] Only 4% patients had pruritus which is statistically non-significant.

Our findings of prolonged time to sensory regression to L2 on the operative side and prolonged time to first analgesic requirement are also in accordance with the findings of Faust et al.[12]

Kaya et al evaluated the effect of 4.2 ml hypobaric bupivacaine (0.18%). The drug was administered at L3-L4 interspace with the patient kept in lateral position for 15 minutes. Unilateral spinal anesthesia was observed in 76% of patients. However, 15 minutes after when the patients were turned supine, unilateral spinal anesthesia decreased to 24% of patients. In contrast to the author's study, we have used 4 ml of 0.32% bupivacaine in lateral decubitus position, and the patients were kept in lateral position for 20 minutes. The highest level of sensory block differed between operative and

non-operative sides significantly. 100% patients had complete motor recovery on the non-operative side at the end of surgery, while none of the patient had complete motor recovery on the operative side.[13]

Our study showed a non-significant difference for incidence of hypotension between the two groups while Martyr et al found lower incidence of hypotension with the addition of fentanyl when compared to plain bupivacaine group.[14]

Hallworth et al studied the effect of posture and baricity during the induction of spinal anesthesia with intrathecal drugs in determining the spread within the CSF and found that the hypobaric sitting group had the most frequent incidence of hypotension (76%) as well as cervical blocks (24%).[15] In view of these findings, to use hypobaric solutions in our study, and to achieve maximal benefits with minimum side effects, we injected the hypobaric solution in lateral decubitus position with the operative side uppermost and operating table in the horizontal position. Thus, the incidence of significant hypotension was 16-20% and no patient had the involvement of cervical segments.

Predescu et al found that the orthopedic patients receiving hypobaric bupivacaine in lateral decubitus position, maintaining surgical side upwards for 15 minutes post injection were more satisfied with the position during anesthetic procedure.[16] We have also taken the advantage of the author's study in our patients i.e. the intrathecal injection was made in the lateral decubitus position with the operative side uppermost.

The patients in the study of Hamdani et al received 7.5mg hypobaric bupivacaine in lateral position and remained in this position for 15 minutes. Unilateral restriction of block was observed in 73.3% of patients.[17] However, in our study, we did not observe unilateral restriction of block. But the patients had the advantage of not lying on the operative side as it is painful to perform unilateral block with hyperbaric solution.

We therefore administered spinal anesthesia with hypobaric solution, as patients have to lie on the non-operative side, dependent.

Conclusion

Hence, we conclude that the use of hypobaric bupivacaine in lateral decubitus position produces unilateral spinal anesthesia with a faster sensory motor recovery on the contralateral (non-operative) side. It facilitates patient's comfort because the deep and prolonged motor block may be inconvenient for the patients. Co-administration of fentanyl further prolongs the sensory block on the operative side without significantly affecting the motor block, so delays the use of first analgesic without further compromising the systemic hemodynamics or increase in the adverse events. Fentanyl in hypobaric bupivacaine prolongs the sensory regression to L2 for about 45 minutes, which is a clinically significant finding and it further increases the reliability of hypobaric bupivacaine spinal anesthesia for patients undergoing hip surgeries.

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