Low Dose Bupivacaine - Fentanyl Vs. Conventional Dose Of Bupivacaine In Spinal Anesthesia For Orthopaedic Procedures In Elderly Patients

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Abstract: Background: Maintenance of the body physiology as near normal as possible during spinal anesthesia is one of the primary goals of the anaesthesiologist. As we know, marked hemodynamic derangements are often seen following subarachnoid block especially in trauma and elderly patients. Neuraxial opioids are not associated with sympathetic nervous system denervation, skeletal muscle weakness or loss of propioception. They predominantly act at the μ receptors present in the substantia gelatinosa of the spinal cord to exert its synergistic analgesic effect more specifically for visceral pain. . Studies have established that opioids and local anesthetics administered together intrathecally have a potent synergistic analgesic effect. *Objectives* This study was conducted for evaluate the efficacy of low dose hyperbaric bupivacaine plus fentanyl for spinal anaesthesia in the elderly and study the incidence of hypotension in the compared groups.[1] Methods: This was prospective study carried out on 60 patient posted for elective lower limb orthopedic surgeries during the period 2010-2011 at civil hospital gandhinagar.The study population was randomly allocated to two groups; Group A - 15mg of 0.5% bupivacaine & Group B - 10mg of 0.5% bupivacaine and 25μg of fentanyl. Results: After analyzing the results of our study we find that systolic B.P. decreased in both the groups, maximum fall occurredat 15 to 20 min in both the groups: decreases were more severe in group A than in group B,(P<0.O5).heart rates were better maintained in group B than in group A. thus group B showed better hemodynamic stability. group b had lesser duration of motor blockage without significantly compromising the duration of sensory block or the operative conditions. none of the patients required intraop anesthetic supplementation. 3 patients in group B had pruritus while none of the patients developed respiratory depression. Conclusion: subarachnoid block with 2cc bupivacaine 0.5% and 25μg fentanyl is a safer and better option, both in terms of maintaining hemodynamic stability and lower incidence of complications without compromising the surgical conditions, for elderly patients undergoing lower limb surgeries. [Halvadia S et al NJIRM 2013; 4(1) : 49-55]

Key Words: bupivacaine, fentanyl, spinal anesthesia, elderly patients, orthopedic lower limb surgery

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Introduction: The undertaking of complex and major surgical procedures on frail elderly patients with multiple disorders has always been and still remains a controversial and enigmatic issue. At the same time, in an increasingly ageing society, the need for such procedures will extend and the patients will expect a more favorable outcome. Surgery in old age will, therefore, pose an ongoing challenge. Elderly surgical patients undergo approximately 20% or more of all surgical procedures in acute care hospitals across the country. The presence of age-related systemic changes and multiple co-morbid conditions often limits their functional capacity and recovery and increase the risk of peri-operative morbidity and mortality. It is universally agreed that the anaesthesia of choice for lower limb surgeries is subarachnoid block. Regional anaesthesia is generally well tolerated by the elderly patients, producing less postoperative confusion and delirium than general anaesthesia. It is also associated with lesser incidence of post-op thromboembolism. However subarachnoid block has got its own inherent complications, especially related to cardiovascular stability. Studies have shown that spinal anaesthesia for a surgical repair of lower limb fracture in the elderly is associated with a high incidence of hypotension. Peri-operative hypotension may affect post-operative recovery and also the high incidence of coronary disease in this population increases the risk of ischemia secondary to the hypotension.[2]There is considerable controversy over the use of vasopressor and intravenous fluids to treat or prevent the hypotension of spinal anaesthesia. Unfortunately, none of these methods is without

potential ill effect. Another approach has been to minimize hypotension by using very small or titrated doses of local anaesthetic. However, though low dosage local anaesthetic for spinal blockade may limit hypotension, it may not provide acceptable anaesthesia for sufficient duration.[3] Intrathecal opioids enhance analgesia from sub-therapeutic doses of local anaesthetics and make it possible to achieve successful spinal anaesthesia using otherwise inadequate doses of local anaesthetics. Using opioids it is possible to enhance the sensory blockade without altering the degree of sympathetic blockade ensuring better hemodynamic stability[3].

Material and Methods: This study was conducted at civil hospital, GMERS Medical College, Gandhinagar. Approval of the college ethics committee and written informed consent from all the patients were obtained. It was a prospective study where 60 selected patients who were posted for lower limb surgeries were randomly divided into two groups. First group received bupivacaine alone and the second group a combination of bupivacaine and fentanyl. Patients satisfying the inclusion criteria were randomly divided into groups of 30 each. Both the patient and the principle investigator were blinded for the drug, which was being administered during the period of observation.

Inclusion criteria

- ASA I,II & III
- Age >50 yrs
- Height 155-175
- Patients posted for lower limb surgeries

Exclusion criteria

- History of allergy to local anaesthetics
- Patients with severe cardiac or respiratory disease eg. Cardiac arrhythmia, abnormal cardiac anatomy or congestive cardiac failure,
- Patients with psychiatric illness, mental retardation, clinical evidence of significant dehydration
- Hemoglobin concentration less than 8g/dl
- Patients with uncontrolled hypertension, taking medications such as digoxin.

Patients were classified as hypertensive if they had a baseline SAP of > 150 mm Hg or if they were receiving regular treatment for hypertension. Antihypertensive medications were noted and continued pre-operatively. Routine investigations in the form of Hb, blood sugar, urea, Rh typing, X-ray, ECG were carried out. Any specific investigations, if required according to the individual cases were also done. The patients who were selected and posted for lower limb surgeries were scrutinized as per criteria mentioned above. They were randomly divided into the bupivacaine and fentanyl group using the random number chart. Both the groups were comparable with respect to age, height, cardiac risk index and pre-anaesthetic arterial pressure.

All the patients were fasted overnight for 8 to 10 hrs. No intravenous fluid was given till arrival to operating theatre. Patients received no premedication before arrival in the operating theatre. Psychological preparation was done and the procedure explained to all the patients in advance. On arrival in the operating room an IV access was secured using an 18G cannula under local anesthesia in the left forearm vein. Before spinal block, each patient received a fast infusion of 8 ml/kg of lactated Ringer's solution. Standard monitoring included continuous electrocardiogram, pulse oximetry, non-invasive automated blood pressure measurements and visual assessment of respiration.

In all the patients, under strict aseptic and antiseptic precautions, lumbar puncture was performed in the sitting position, after giving local anesthesia with a 26G needle, using a 23-gauge Quincke point needle positioned midline at the L3-L4 interspace. Group A received 3ml 0f 15 mg hyperbaric bupivacaine 0.5% (Astra, Sodertalje, Sweden); and Group B 10 mg (2 ml) of hyperbaric bupivacaine 0.5% plus 25 µg (1ml) fentanyl (prepared by withdrawing 100 µg fentanyl diluted to 4ml with saline). Injectate volume for both groups was 3 ml. Injections were made over 10-15sec. After completion of injections the patients were immediately returned to the supine position. Sensory level of T6-8 was achieved. Throughout

the procedure patients received an oxygen supplementation of 4L/min via oxygen mask. The syringe was prepared by one researcher and administered by a second who remained blinded to its contents. Patient assessment and care were conducted and study data were recorded by the second researcher.

Pulse rate, blood pressure and Spo_2 were checked every 2 min for the first 10 minutes and every 5 min for the next 30 min and every 15 min thereafter till 1hour post operatively. They were followed up-to 12 hours after surgery and thereafter with routine post-op care in the post-surgical wards. For the purpose of the study hypotension was defined as a systolic blood pressure of < 90 mmHg or a decrease of more than 30% from the baseline mean arterial pressure. Reaching either criterion was considered hypotension and was treated with an incremental intravenous bolus of mephentermine 6 mg. Bradycardia (defined as heart rate <60bpm) was treated with IV atropine, if it was associated with hypotension.

In addition to the loading dose of intravenous fluids, patients received a maintenance infusion of lactated Ringer's solution as calculated according to the conventional formulae. Intra-op blood loss was replaced as indicated. No additional sedative medications were given during the operation. Inadequate anaesthesia (patient complaint of pain) was to be treated with an additional bolus of intravenous fentanyl 1 mug/kg, with a second bolus allowable. The protocol allowed for conversion to general anesthesia as deemed necessary by the blinded anesthesiologist.

The parameters were assessed and compared are time for adequate level of analgesia (T10, assessed with pinprick), peak sensory level reached (assessed with pinprick), time for motor block to recede to L3-4 level, ability to flex knee.(modified bromage scale), duration of sensory block, incidence of complications including –respiratory depression, hypotension, bradycardia, nausea and vomiting, pruritus, sedation, shivering and mandatory bladder catheterization within 12 hours.

The motor block was assessed using a modified bromage scale.

0- No paresis – full movement of lower limb
1 - Partial paresis - Flex knees and ankles
2- Partial paresis - Flex ankles
3 - Partial paresis - Flex toes only
4 - Full paresis - No movements

Sedation status was assessed using

	Score
Awake & alert	1
Response to voice	2
Response to touch	3
Response to pain	4
No response	5

Results: The observations made were tabulated and analyzed using appropriate statistical tools. The patients in both the groups were comparable with respect to their age, height and duration of surgery. (Mean ± SD) The average duration of surgery in both the groups was 120 to 150 minutes. The study shows equal distribution of males and females in both groups. This study shows that majority of patients of both the groups are of ASA grade II. The time of onset of adequate level of sensory block (T10) was longer for group B than group A. Time for onset of adequate block T-10 (sec) was 95 ± 10.32(sec) in Group A & 128 ± 8.3(sec) in Group B. This delay in onset of block for group B was found to be statistically significant.

The motor block assessment is presented in table 1 & graph 1.

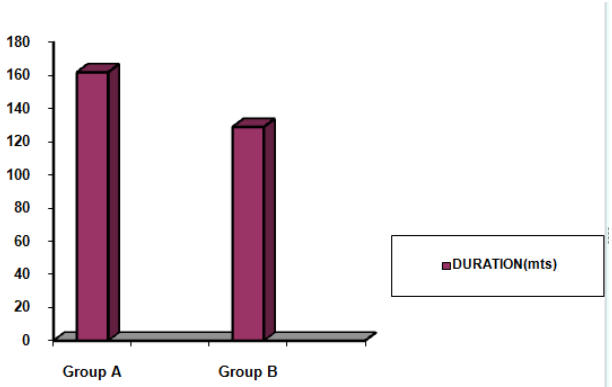
Duration of motor block is longer in group A as compared to group B and it was statistically significant (P value <0.05). None of the patients needed supplementation of analgesia during operation and surgeons were satisfied with the intensity of sensory and motor block in both the groups. In our study we assessed the motor block using modified bromage scale which showed maximum scoring for group A and the combination group shows a slight decline in score which is statistically insignificant. However none of the

patients, in either group, had a bromage score of less than 3. For lower limb orthopaedic procedures a bromage score of 3 is considered to be satisfactory.

Table 1: Intensity of motor block

Bromage Scale	Group A	%	Group B	%
1	0	0	0	0
2	0	0	0	0
3	7	23.3	13	43.3
4	23	76.6	17	56.6

Graph 1: Duration of motor block (min.)



Duration of motor block is longer in group A (162.5 ± 7.5 minutes) as compared to group B (129.4 ± 9.9 minutes) and it was statistically significant (P value <0.05). The table 2 shows lower pulse rates for the fentanyl group but within acceptable limits.

Table 2: Comparison of pulse rate (average) at different time

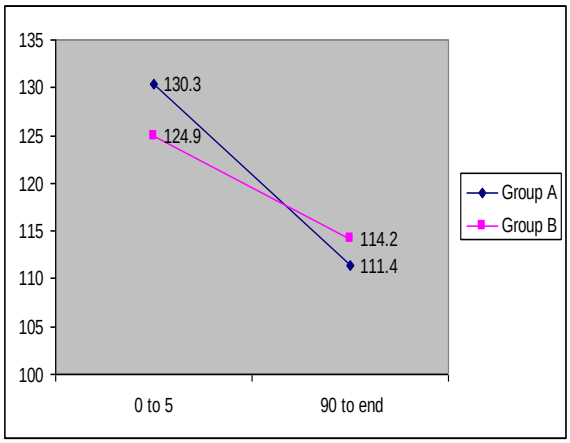
Time(min)	Group A	Group B
Base line	81.3	76.8
0 to 5	81.6	76.2
5 to 10	81.1	76.2
10 to 15	80.6	76.06
15 to20	78.9	74.8
20 to 30	77.6	73.4
30 to 45	77.0	72.6
45 to 60	77.2	71.7
60 to75	77.0	71.0
75 to 90	77.6	70.6
90 to end	77.2	70.3

Table 3: Comparison of blood pressure (average)

Time (min)	Group A	Group B
Base line	133.46	127.2
0 to 5	130.3	124.9
5 to 10	124.06	122.4
10 to 15	115.86	119.6
15 to20	109.4	116.8
20 to 30	107.4	115.06
30 to 45	107.2	114.0
45 to 60	107.6	113.9
60 to75	108.4	112.3
75 to 90	109.8	113.6
90 to end	111.4	114.2

The above table shows systolic B.P. at different time intervals, with maximum fall occurring at 15 min. after giving spinal anesthesia in both the groups. Fall in blood pressure in group A was significantly more as compared to group B; thus there is better hemodynamic stability in group B.

Graph 2: Degree of BP fall



This graph shows lesser degree of B.P. fall for Group B.

This study shows that the incidence of hypotension and thus vasopressor use was much higher in group A(12 patient, 40%) than group B(3 patient, 10%). This difference was found to be statistically significant (P value <0.05) The total duration of sensory block was slightly more for Group A (227.6±9.8 minutes)than in Group B (211.5± 14.2

minutes), but this was not found to be statistically significant.

Table 4: The incidence of intra-operative complications

	Group A	Group B
Hypotension	12 (40%)	3 (10%)
Bradycardia	1 (3.3%)	2 (6.6%)
Pruritus	0	3 (10%)
Nausea &Vomiting	0	0
Sedation	0	0
Shivering	3 (10%)	0
Respiratory depression	0	0

The incidence of hypotension and shivering was significantly higher in group A as compared to group B. The incidence of bradycardia is higher in group B; but is within acceptable limits. Pruritus was the most common adverse effect in patients who received intrathecal fentanyl (Group B) but none of the patients needed treatment for the same. No patients suffered from nausea and vomiting in both the groups. None of the patients in either group developed respiratory depression.

Discussion: The recommended level of regional anaesthesia for lower limb surgeries is T10. The standard recommended dose for this using hyperbaric bupivacaine 0.5% is 3cc or 15mg. In the pilot study done by us earlier, it was found that 2.5 cc or 2cc of hyperbaric bupivacaine 0.5% given intrathecally was often insufficient to produce the desired block for sufficient duration, when given alone.

In our present study we have added 25µg of fentanyl, a highly lipophilic opioid to lower the doses (10mg) of hyperbaric bupivacaine 0.5% and compared the hemodynamic parameters – blood pressure and heart rate changes as well as various known side effects of fentanyl, and the sensory, motor profiles of the block. Ben-David, Frankel et al[4]studied the effect of minidose bupivacaine (4mg) and fentanyl (20µg) in spinal anesthesia for surgical repair of hip fracture in the aged and compared it to 10mg of bupivacaine alone. The average duration of surgery in their study was 90 minutes. In our institute the conventional dose of hyperbaric bupivacaine used for lower limb surgeries is 15mg and since the average duration of surgery is significantly more than that in the reference study, we selected a higher dose of bupivacaine.

The prime objective of the study was to compare the hemodynamic stability of hyperbaric bupivacaine alone and its combination with fentanyl. In our study 12 patients with bupivacaine alone developed hypotension of which 10 patients needed one dose of vasopressor and 2 required 2 doses. Whereas only 3 from the fentanyl group experienced hypotension. Our study also revealed that the degree of blood pressure fall among bupivacaine alone group was higher amounting to 18.9 mm of Hg and among the combination group was 10.7mm of Hg from their initial systolic blood pressure values. These findings are in agreement with findings of Ben-David et al[4], Ben-David, Frankel et al[5]and Matyr et al[6] who did similar studies among elderly subjects undergoing hip/femur surgeries and concluded that combination with fentanyl could dramatically lessen the incidence of hypotension and nearly eliminate the need for vasopressor support of blood pressure when compared to use of bupivacaine alone.

There was statistically significant increase in the time for onset of adequate block among the combination group B with 128 ± 8.3 secs, while Group A which contains 3cc of bupivacaine alone showed only 95 ± 10.32 secs. However the clinical significance of this observation in an elective surgery may be neglected, but the time parameters shows significant differences.

Addition of fentanyl reduces the pH of hyperbaric bupivacaine. This may be the reason for an observed delay in the onset of adequate block. The total duration of sensory block for Group A was 227.6±9.8min while Group B which contains 25µ gm of fentanyl had 211.5± 14.2 min. This difference between the two groups was

statistically insignificant. Addition of fentanyl enhances the duration of sensory block as concluded in the studies done by Boucher et al[7]. But in both these studies the dose of bupivacaine was same in the comparison groups, were as in our study the dose of bupivacaine in the fentanyl group is much lower which can explain the reason for slightly lower duration of sensory block in fentanyl group. Even more relevant may be the findings of of Obara et al(2003) and Goel et al (2003) that intrathecal fentanyl improves the quality and reliability of the subarachnoid block. It could be the short acting but potent analgesic action, which is producing such an effect.

Postoperative period is usually associated with less ambulance and therefore chance of stagnation of blood is more. This increases the risk of venous thromboembolism. This risk is even higher among the orthopaedic procedures and elderly. One significant and interesting finding we got was the lesser degree of motor blockade in the combination group when compared to the bupivacaine alone group. The duration of motor blockade was also higher for Group A than Group B. However the surgical conditions were found to be satisfactory in both the groups and none of the patients required any supplementary anaesthetic interventions during the surgery. Again the selective action of neuraxial opioids on pain pathways could be the possible reason for this observation. These findings are similar to that obtained by Goel.S. et al[8]and Bruce, Ben-David, Eric Solomon et al[9]who concluded that intrathecal fentanyl with small dose bupivacaine provided better anaesthesia without prolonging recovery.
There was no incidence of sedation or respiratory depression among the two groups. Fentanyl is a very potent, yet a relatively short acting drug compared to the gold standard drug morphine. Because of its lipophilicity it is rapidly absorbed into the spinal cord and epidural fat. This decreases its concentration in CSF rapidly and hence the risk of rostral spread is reduced. It has also been found that the vascular absorption after intrathecal administration of opioids is clinically insignificant. This could explain the reduced incidence of respiratory depression. Diana Fernander, Montserrat Rue et al[10] and Gurkan et al[11] had also concluded that elderly patients did not show an increased “sensitivity” to spinal fentanyl.

It is thought that fentanyl abolishes shivering by central mechanisms. In our study 3 patients in group A developed shivering compared to none in fentanyl group. This finding correlates with that of Chow et al[12]who suggested that there was significant reduction in shivering among the combination groups compared to the local anaesthetic alone group.

Pruritus is considered as the most common side effect of intrathecal opioids. Mulroy et al[13] has noted a reduced incidence of pruritus when fentanyl is combined with bupivacaine than when combined with lignocaine. Pruritus is thought to be mediated through the μ receptors present centrally. Workers have found ondansetron to be significantly useful for the treatment of this pruritus. In our study 3 among the thirty in the fentanyl group had pruritus. No one from the other group experienced pruritus which is consistent with the above mentioned studies.

The incidence of nausea and vomiting were not seen in any of these groups. Cooper et al[14] has reported statistically significant reduction in intra-operative nausea and vomiting. Again Mannulang et al[15]in a double blinded randomized study has reported that intrathecal fentanyl is superior to ondansetron for prevention of peri-operative nausea and vomiting during caesarean section under spinal anaesthesia.

Conclusion: spinal anesthesia for elderly patients undergoing lower limb surgeries with 2cc bupivacaine 0.5% and 25 μg fentanyl is a safer and better option, both in terms of maintaining hemodynamic stability and lower incidence of complications without compromising the surgical conditions. Intrathecal opioids enhance analgesia from sub-therapeutic doses of local anaesthetics and make it possible to achieve successful spinal anaesthesia using otherwise inadequate doses of local anaesthetics.

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Conflict of interest: None
Funding: None