

Research Article

Comparative study of 0.5% hyperbaric bupivacaine with sufentanil (5µg) and 0.5% hyperbaric bupivacaine for spinal anesthesia

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ABSTRACT

Background: In the present day practice of Anesthesiology, bupivacaine is the most commonly used drug for spinal anesthesia. To improve the quality of analgesia and prolong the duration of its action, many adjuvants have been tried. Intrathecal opioids have been found to fulfil both these objectives. This study was done to evaluate the effects of adding sufentanil to bupivacaine for spinal anesthesia.

Methods: 100 ASA grade I/II patients aged between 20 – 60 years undergoing elective lower abdominal, urologic, lower limb surgeries were selected and divided into two groups of 50 each. Group A received 2.5 ml of heavy Bupivacaine, whereas the second group B received 2.5 ml of heavy Bupivacaine with 5 µg Sufentanil. Parameters - Onset and duration of sensory block and motor block, time for two dermatomal segments regression, duration of analgesia, vitals and side effects were assessed.

Results: There was no variation in onset of sensory blockade and motor blockade. The time to achieve peak sensory level was 3 minutes earlier in group B. The time for two segment regression and the time to full sensory and motor recovery were prolonged in Group B. Duration of complete and effective analgesia prolonged by 40-60 minutes and the time for first request of analgesic postoperatively was delayed by 70 - 80 minutes in group B. The quality of analgesia was better in group B. Pruritus was the common side effect in group B.

Conclusions: Sufentanil potentiates bupivacaine spinal anesthesia by increasing the duration and improving the quality of analgesia with minimal side effects.

Keywords: Spinal anesthesia, Sufentanil, Bupivacaine, Visual analogue scale, Complete and effective analgesia

INTRODUCTION

The duration of surgery nowadays are getting prolonged either because the surgeons are in the beginning of their learning curve or because of the complex nature of the surgery itself. One of the major disadvantages of spinal anaesthesia using hyperbaric bupivacaine alone is the relatively shorter duration of action. Among the augmentation strategies available to prolong intrathecal analgesia, the intrathecal opioids administration is undoubtedly among the most popular, commonly combined with local anaesthetics to improve the onset time of block, duration and quality of analgesia both

intraoperatively and post operatively. The opioids act by having synergistic effects at opioid receptors present in the spinal cord. Addition of morphine, fentanyl have been used regularly. Sufentanil, a synthetic congener of Fentanyl, 1000 times more potent than morphine and highly lipid soluble has been one of the latest tools for present day anaesthesiologists¹. Hence this study was done to evaluate the effectiveness of adding Sufentanil to Bupivacaine for spinal anaesthesia and to compare its use to that of Bupivacaine alone.

METHODS

This study was conducted over a period of 12 months from August 2014 after obtaining approval from the ethical clearance committee of the college and written informed consent by the patients. 100 patients fulfilling the inclusion and exclusion criteria were included in the study.

Patients between 20 - 60 years of age, belonging to ASA grade I & II, undergoing elective surgeries of lower abdomen, urological, and lower extremities under spinal anaesthesia were included. Exclusion criteria were patient refusal, patients belonging to ASA grade III or more, infection at site of injection, coagulation abnormalities, hypersensitivity to local anaesthetic or sufentanil, neurological or neuromuscular disease and pregnant patients. In this prospective randomised control study, patients were allocated into two groups viz, Bupivacaine group – Group A: 50 patients received intrathecal bupivacaine 0.5% heavy 12.5 mg (2.5ml), Sufentanil group - Group B: 50 patients receiving intrathecal sufentanil 5µg with intrathecal bupivacaine 0.5% heavy 12.5 mg (2.5ml). Under strict aseptic precautions, lumbar puncture was performed in left lateral position by midline approach by using disposable Quincke spinal needle (25 G) at L₃-L₄ intervertebral space. After spinal anaesthesia, Oxygen (5L/min) by facemask was given. Fluid therapy was maintained with lactated Ringer's solution (10mL/kg/hr). The following parameters were observed and recorded: patient demographic data, heart rate, blood pressure, oxygen saturation, time of onset of both sensory and motor block, time for two dermatomal segments regression, duration of both sensory and motor block, duration and quality of complete analgesia and side effects.

The onset of sensory block was tested by pin-prick method using a hypodermic needle. The time for two dermatomal segments regression of sensory level was noted. The duration of sensory blockade was taken as time from onset to time of return of pinprick sensation to S1 (heel) dermatomal area. Motor block was assessed by Bromage scale. The time interval between injections of drug into subarachnoid space, to the patient's inability to lift the straight extended leg was taken as onset time. The duration of motor block was taken from time of injection to complete regression of motor block (ability to lift the extended leg). Pain was assessed by Visual Analogue Score (VAS). Duration of complete analgesia was defined as the time from the intrathecal injection to VAS >0 to <4. Analgesics and opioids were avoided until demanded by the patient and the time taken for the first pain medication was also noted (i.e. when VAS > 6). VAS was also recorded 3, 6, 12 hours postoperatively. The side effects of intrathecal bupivacaine and sufentanil like nausea, vomiting, pruritus, shivering, respiratory depression (respiratory rate <10/ min, arterial oxygen desaturation: SpO₂ <90%) drowsiness, hypotension, euphoria, chest tightness and urinary retention were noted

down. Hypotension was defined as a decrease in systolic blood pressure more than 20% of the baseline value and was treated with Inj. Ephedrine 6 mg intravenous increments and bradycardia as pulse rate <60/ min was treated by atropine 0.6 mg intravenous.

The demographic data were analysed using either Student's t-test or Chi-square test. Quantitative data was analysed by student's t' test and qualitative data was analysed by Chi-square test. All values were expressed as mean ± standard deviation. P <0.05 was considered statistically significant.

RESULTS

A total of 100 patients belonging to ASA grade I and II posted for lower abdominal and lower limb surgeries were randomly selected. Fifty of them (Group A) received 0.5% hyperbaric Bupivacaine 12.5 mg (2.5 ml) and Other 50 (Group B) received 0.5% hyperbaric Bupivacaine 12.5mg (2.5 ml) + 5µg Sufentanil for spinal anaesthesia.

Table 1: Demographic profile.

Parameter	Group A	Group B	p value
Age (in years)	43.12 ± 10	39.56 ± 11.9	0.120
Sex (male: female)	29: 21	26: 24	0.44
Height (in feet)	5.42 ± 0.32	5.39 ± 0.23	0.596
Weight (in Kg)	57.28 ± 8.5	57.8 ± 8.051	0.990

There was no statistically significant difference between the two groups with regard to age, sex, height and weight (Table 1). The onset of sensory block and motor block in group A was delayed by only few second than group B (p >0.05), so the difference was statistically insignificant (Table 2).

Table 2: Onset of sensory & motor block.

	Group A	Group B	P value
Sensory block (in seconds)	135.49±13.3	135.12±7.5	0.705
Motor block (in seconds)	228.9±21.1	219.18±11.3	0.055

The time for 2 segment regression was considerably slower in Group B 135.5±14.2 minutes when compared to Group A 86.89±17.9 minutes. This difference was statistically significant (p < 0.001). The mean duration of motor block in sufentanil group B was 203.5±12.9 minutes and that in bupivacaine group A was 193.7±13 minutes. There was statistically significant difference in duration of motor block between groups (p < 0.001). The

duration of sensory block (time for complete sensory recovery) was significantly longer in sufentanil group than in bupivacaine group ($p < 0.001$) (Table 3).

Table 3: Recovery parameters.

Recovery parameters	Group A	Group B	p value
Time to 2 segment regression (in minutes)	86.9 ± 17.9	135.5 ± 14.2	< 0.001
Time to complete sensory recovery (in minutes)	213.4 ± 14	245.4 ± 13	< 0.001
Time to complete motor recovery (in minutes)	193.7 ± 13	203.5 ± 12.9	< 0.001

The mean duration of complete analgesia in group A was 170.04±33.2 and in group B was 209.8±18.8, which was statistically highly significant ($p < 0.001$). The time for first request of analgesics postoperatively in group A was 243.7±23.8 minutes and in group B was 320.86 ± 24.4 minutes. The need for analgesic postoperatively was delayed by about 60 minutes. This was statistically highly significant (Table 4).

Table 4: Duration of analgesia.

	Group A	Group B	p value
Duration of complete analgesia (in minutes)	170.04 ± 33.2	209.8 ± 18.8	< 0.001
Duration of effective analgesia (in minutes)	227.1 ± 30.1	283.1 ± 22.9	< 0.001
Time to first pain medication (in minutes)	243.71 ± 23.8	320.86 ± 24.4	< 0.001

The mean VAS intraoperatively in group A was 0.54 ± 0.5, and in group B was 0.28±0.5, which was statistically insignificant. ($p = 0.036$). VAS at the end of three hours were 0.9±0.78 and 0.5±0.6 respectively in group A and group B. VAS at the end of six hours were 3.62±1.2 and 1.76±0.8 respectively in group A and group B. VAS at the end of twelve hours were 4.12±1.4 and 2.88±1.39 respectively in group A and group B. VAS were statistically significant at 6 and 12 hours implying Patients in sufentanil group had better pain relief (lower VAS) in the postoperative period than in bupivacaine group (Table 5).

Table 5: Visual analogue scale (vas) scores.

Time	Group A	Group B	p value
Intraoperative	0.54 ± 0.5	0.28 ± 0.5	0.036
3 hours	0.9 ± 0.78	0.5 ± 0.6	0.006
6 hours	3.62 ± 1.1	1.76 ± 0.8	< 0.001
12 hours	4.12 ± 1.4	2.88 ± 1.39	< 0.001

The two groups did not differ significantly with respect to heart rate at any interval ($p > 0.05$), the fluctuations in the heart rate was less in group B patients when compared

with group A though negligible. There was no incidence of bradycardia in any patients of either group. The changes in mean systolic and diastolic blood pressures at any time interval are statistically and clinically insignificant between both the groups (Table 6).

Table 6: Heart rate.

Time interval (minutes)	Group A	Group B	p value
Baseline	79.3 ± 8.6	79.74 ± 9.8	0.813
05	79.84 ± 8.2	79.88 ± 10.1	0.983
10	80.1 ± 8.2	79.18 ± 11.5	0.648
20	80.58 ± 7.9	78.96 ± 11.6	0.390
30	81.34 ± 8.1	77.96 ± 10.9	0.084
60	81.30 ± 8.2	78.2 ± 10.3	0.101
120	81.54 ± 8.6	78.5 ± 9.4	0.105
150	80.82 ± 7.7	78.8 ± 9.5	0.258

In sufentanil group, 30% patients experienced pruritus, 12% nausea, vomiting, 12% hypotension, 8% drowsiness. Whereas bupivacaine group, none had Pruritus, 8% nausea and vomiting, 8% hypotension, 8% shivering. There was no significant difference among other side effects like bradycardia, chest tightness (Table 7).

Table 7: Adverse effects.

Adverse Effects	Group A	Group B
Nausea/Vomiting	4 (8%)	6 (12%)
Pruritus	0 (0%)	15 (30%)
Shivering	4 (8%)	0 (0%)
Bradycardia	0 (0%)	0 (0%)
Hypotension	4 (8%)	6 (12%)
Drowsiness	2 (4%)	4 (8%)
Chest tightness	0 (0%)	0 (0%)

DISCUSSION

Among all the various population groups studied type II Spinal anesthesia consists of the temporary interruption of nerve transmission within the subarachnoid space produced by injection of a local anesthetic solution into cerebrospinal fluid. Spinal anesthesia with hyperbaric bupivacaine 0.5% is a popular method. The duration of spinal analgesia can be prolonged by the adjuvants like vasoconstrictors, opioids, neostigmine, ketamine, midazolam etc. Vasoconstrictors (epinephrine, ephedrine, and phenylephrine) prolong the duration of action of the local anesthetic by decreasing systemic absorption but have been found to induce neurological signs and symptoms due to reduced blood supply to the spinal cord. Intrathecal ketamine results in psychomotor symptoms and intrathecal neostigmine causes excessive nausea and vomiting.²⁻⁴

Opioid added to local anaesthetic for spinal anesthesia

was first introduced into clinical practice in 1979 with Morphine as a forerunner. Fentanyl, a lipophilic opioid, has rapid onset of action following intrathecal administration. It does not tend to migrate into the fourth ventricle in sufficient concentration to cause delayed respiratory depression when administered intrathecally.⁵ Sufentanil, a newer lipophilic opioid is more potent than Fentanyl and significantly prolongs the duration of sensory analgesia with minimal side effects. Opioids administered together with local anaesthetics intrathecally, reduce the requirement of local anesthetic, resulting in shorter duration of motor block as well as significantly extended postoperative analgesia without prolonging the recovery and producing minimal side effects.

Assuncao Braga et al evaluated the effect of Sufentanil with three different doses of Bupivacaine and found that the onset of action was clinically and statistically insignificant among the groups. Ngiam SKK et al in their study showed that there was no significant difference in the onset of sensory block when 15 g of Fentanyl, 10 g of Sufentanil added to 7.5mg of Bupivacaine.^{6,7} Our results corroborates with the above-mentioned study. Hence we conclude that addition of Sufentanil has no variation in the onset of sensory and motor blockade.

In a study by Dahlgren G et al the duration of sensory block was significantly longer in sufentanil and post-operative analgesia in sufentanil group was significantly longer.⁸ The mechanism for the longer duration of the sensory blockade in the Sufentanil groups compared with control group may be an example of synergism between Sufentanil and the local anesthetic. Hence we conclude that use of sufentanil intrathecally results in increased intensity and prolonged sensory and motor blockade. Lin BC et al reported that the addition of intrathecal Sufentanil 10 micrograms to 12.5 mg of bupivacaine 0.5% improved patient comfort and significantly reduced the demand of postoperative analgesia.⁹ In a study conducted by Courtney MA et al the duration of complete analgesia and duration of effective analgesia were significantly prolonged in all patient groups receiving Sufentanil as compared to control groups receiving no narcotic.¹⁰ Our results were similar to the above studies. Hence we infer that addition of sufentanil to bupivacaine intrathecally results in significantly prolonged duration of complete analgesia and the time to first pain medication is longer with improved quality of analgesia and reduced requirements of analgesics postoperatively.

Olofsson C et al concluded that a reduced dose (7.5 mg) of hyperbaric bupivacaine in combination with Sufentanil (5 µg) provides reliable spinal anesthesia for the repair of hip fracture in aged patients with few events of hypotension and little need for vasopressor support of blood pressure.¹¹ The cardiovascular profile of our patients was found to be remarkably stable throughout the intraoperative period in both the groups.

Respiratory depression is one of the major side effects of intrathecal opioids. None of our patient's experienced respiratory depression and the mean respiratory rate between both the groups was statistically not significant. Safety doses of sufentanil 5µg corroborates with the other study conducted by Assuncao Braga et al, S K K Nigam et al, Gunnar Dahlgren et al, where they have used doses of sufentanil 5.0 µg, 7.5 µg, 10 µg and even up to 12.5 µg and found no respiratory depressant effects.⁶⁻⁸

In our study group B, 30% patients experienced pruritus, 12% nausea/vomiting, 8% drowsiness whereas in control group A, none of the patients experienced pruritus, 8% nausea/vomiting, 8% shivering. The incidence of other side effects like chest tightness, bradycardia was similar among the two groups. The incidence of urinary retention is known to be higher with use of intrathecal opioids. In our study we could not assess this parameter as most of our patients who underwent hysterectomies and urologic surgeries were electively catheterized. Assuncao Braga et al in their study found that pruritus was of higher incidence when sufentanil 7.5 g was used. Ngiam SKK et al found in their study the incidence of pruritus was 35.0% with sufentanil and 27.8 % with fentanyl as against 0% with bupivacaine alone. Courtney MA et al in their study experienced significant increase in pruritus in patients receiving subarachnoid Sufentanil.^{6,7,10}

With the above considerations, we can conclude that the addition of Sufentanil with hyperbaric Bupivacaine for subarachnoid block proved advantageous, in being able to attain higher levels of sensory blockade. It provides good quality of analgesia and prolongs the duration of analgesia with minimal adverse effects.

CONCLUSION

Based on the present clinical comparative study, we can conclude that the addition of 5 µg Sufentanil to 0.5% hyperbaric Bupivacaine 12.5 mg (2.5ml) in spinal anesthesia prolongs the duration of sensory and motor blockade. It also increases the duration and improves the quality of analgesia, with better hemodynamic stability. However, the incidence of pruritus is higher.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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