

Comparison of the Efficacy and Safety of Intrathecal Fentanyl 20 µg vs Sufentanil 5 µg as Adjuvant to Bupivacaine 0.5% (12.5 mg) using Combined Spinal Epidural Technique for Lower Limb Orthopedic Surgeries

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ABSTRACT

Aim: To compare the efficacy and safety of intrathecal fentanyl 20 µg vs sufentanil 5 µg as adjuvant to bupivacaine 0.5% (12.5 mg) using combined spinal epidural (CSE) technique for lower limb orthopedic surgeries.

Background: Use of local anesthetics along with opioids intrathecally has been widely reported. We aimed to compare two commonly used opioids as adjuvants to local anesthetic agents in combined spinal epidural techniques.

Materials and methods: A total of 60 patients were recruited in this prospective, randomized, double-blind study to receive either intrathecal sufentanil 5 µg (Group S) or fentanyl 20 µg (Group F) as adjuvants to 12.5 mg of 0.5% hyperbaric bupivacaine. The onset and duration of sensory and motor block and the pain scores were assessed perioperatively. Duration of analgesia was recorded. The incidence of side effects such as nausea, vomiting, pruritus, shivering, and postdural puncture headache (PDPH) were recorded.

Results: Demographic data and hemodynamic and respiratory parameters were comparable in both the groups. Onset of analgesia—time to reach highest level of analgesia—was faster in the sufentanil group. Sufentanil group patients had higher grade of motor block. Patients in fentanyl group had higher score of sedation than those of sufentanil group. None of the patients in any group had nausea, vomiting, or pruritus.

Conclusion: Addition of either fentanyl or sufentanil to intrathecal bupivacaine as an adjuvant in CSE technique enhances the quality of analgesia and motor block with minimal side effects. Hence, this is useful in orthopedic patients, especially in the geriatric age group.

Keywords: Combined spinal epidural technique, Fentanyl, Intrathecal adjuvant, Lower limb surgeries, Sufentanil.

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INTRODUCTION

The use of intrathecal opioids for acute and chronic pain relief for orthopedic surgeries has been reported in various clinical studies.^{1,3} Local anesthetic and opioids are commonly used either alone or in combination for centri-neuraxial blockade.⁴ These drugs appear to enhance the effects of each other when used together. These are particularly helpful in elderly patients where low-dosage local anesthetics are used intrathecally to avoid hemodynamic consequences. Sufentanil and fentanyl are pure opioid agonists acting on mu receptor having high lipid solubility, faster onset, and shorter duration of action with lesser cardiovascular depressive effects.^{5,6}

We compared intrathecal fentanyl 20 µg vs sufentanil 5 µg with 0.5% bupivacaine 12.5 mg in combined spinal epidural (CSE) technique for lower limb orthopedic surgeries lasting more than 3 hours.

AIMS AND OBJECTIVES

The aims and objectives are to compare

Onset and duration, level and quality of analgesia in intrathecal fentanyl 20 µg vs sufentanil 5 µg as adjuvant to bupivacaine 0.5% (12.5 mg).

Onset and quality of motor block.

Time at first epidural top up required for continuing analgesia.

Side effects like hypotension, nausea, vomiting, pruritus, and respiratory depression.

MATERIALS AND METHODS

After obtaining clearance from the institutional ethical committee, double-blind randomized prospective study was done using a sealed envelope technique; patients were randomly allocated to one of two groups (S, F), each

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comprising 30 patients undergoing lower limb orthopedic surgeries lasting more than 3 hours.

No. of patients: 60

Group F: 30 patients (fentanyl group)

Group S: 30 patients (sufentanil group)

After informed consent all patients were given spinal anesthesia with bupivacaine 12.5 mg (0.5%) with either fentanyl 20 µg or sufentanil 5 µg, and epidural catheter was passed in all the patients using needle through needle technique using CSE set. Epidural top ups were given with 3 cc increments of bupivacaine 0.5% as and when required. All patients were monitored for the parameters to be compared every 15 minutes throughout the surgery and 2 hours postoperatively.

Statistical Analysis

Continuous data were analyzed by using one-way analysis of variance. Mann-Whitney U test was used for comparison between two groups. Pearson chi-square and Fisher’s exact test were used to evaluate the significant difference of categorical variables. A p value of less than 0.05 was taken as the level of significance. Data were analyzed by using SPSS version 12.0.

Demographic Data

There was no statistical significance between age and height between the two groups (Table 1): Male/female: 16/14 group F, 25/5 group S.

Table 1: Demographic data

	Group F (30)	Group S (30)	p-value significance
Age (years)	46.3±2.73 SD	40.37±12.73 SD	0.073 NS
Sex (M/F)	16/14	25/5	
Height (cm)	159.70±9.73 SD	163.53±7.48	0.094 NS

F: Fentanyl; S: Sufentanil; NS: Not significant

RESULTS

- Onset of analgesia—time to reach highest level of analgesia—was faster in the sufentanil group (Tables 2 and 3).

Table 2: Results

	Group I (F)	Group II (S)	p-value significance
Onset of analgesia (sec)	62.67±38.68 SD	17.07±11.67 SD	6.87E-08 NS
Time for highest level (sec)	13.63±6.13 SD	12.43±6.36 SD	0.45 NS
Time for two-segment regression	115.53±30.17 SD	90.37±13.53 SD	0.0001 HS
Duration of surgery (min)	262±54.55 SD	287±85.83 SD	0.18 NS

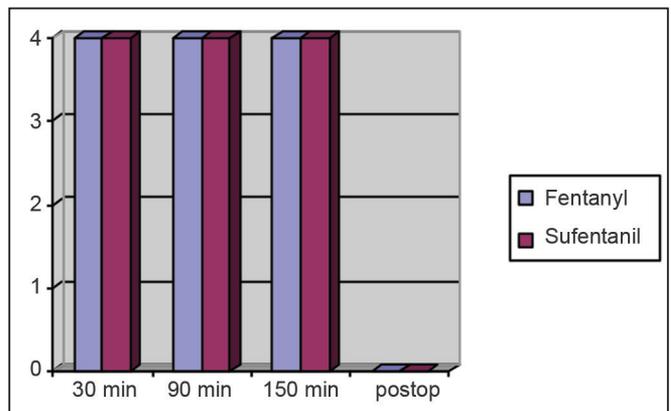
F: Fentanyl; S: Sufentanil; NS: Not significant; HS: Highly significant

Table 3: Level of analgesia

Level	Group I (F) = 30 patients (%)	Group II (S) = 30 patients (%)
T ₄	1 (3.33%)	0 (0.0%)
T ₆	12 (40%)	4 (13.2%)
T ₇	1 (3.3%)	1 (3.3%)
T ₈	10 (30.33%)	12 (40%)
T ₉	2 (6.66%)	1 (3.3%)
T ₁₀	4 (13.2%)	10 (30.33%)
T ₁₁	0 (0.0%)	1 (3.33%)

F: Fentanyl; S: Sufentanil

- Both group patients had higher grade of motor block (Bromage scale, Graph 1 and Tables 4 and 5).



Graph 1: Bromage score: motor block

Table 4: Sedation score: Ramsay sedation scale

Sedation scale	Group I (F) = 30 patients (%)	Group II (S) = 30 patients (%)
1	19	29
2	8	1
3	3	0
4	0	0

F: Fentanyl; S: Sufentanil

Table 5: Motor block

Motor block	Group I (F)	Group II (S)
I	0	0
II	0	0
III	6	0
IV	24	30

F: Fentanyl; S: Sufentanil

- Time for two-segment regression was shorter in the sufentanil group and was highly significant (p-value 0.0001).
- Pulse, blood pressure, respiratory rate, oxygen saturation, side effects were clinically not significant between the two groups.
- Patients in the fentanyl group had higher score of sedation than those in the sufentanil group.
- None of the patients in any group had nausea, vomiting, or pruritus.

DISCUSSION

Majority of the orthopedic lower limb surgeries are conducted under central neuraxial blockade of which spinal anesthesia is being widely used. Significant population undergoing lower limb surgeries is of geriatric age group, who have higher incidence of morbidity and mortality compared with young population because of reduced cardiorespiratory reserve and concomitant diseases like ischemic heart disease, diabetes mellitus, and rheumatoid arthritis.^{7,8}

Major surgeries like total knee replacement and total hip replacement offer a multitude of challenges for the anesthesiologist and perioperative physician. The choice of anesthetic has important implications, not only for the intraoperative course, but also for the postoperative outcome. Intraoperatively, optimal surgical conditions must be balanced with maintaining a stable physiologic state. The choice of anesthetic and analgesic techniques will affect not only the short-term success of postoperative analgesia, but also the ability to achieve physical therapy.^{9,10} This, in turn, may influence the overall functional outcome.

Combined spinal epidural needle through needle technique is gaining popularity in modern anesthesia practice. Kim et al² observed that fentanyl beyond 25 µg intrathecally produced no benefit in regard to the duration of analgesia. However, fentanyl 25 µg intrathecally with low-dose bupivacaine improves postoperative analgesia and hemodynamic stability.² At the same time, fentanyl 20 µg with bupivacaine 4 mg intrathecally provides spinal anesthesia with less hypotension.^{1,2}

Many reports over the past two decades have attempted to compare risks and benefits of regional and general anesthesia in different patient populations.¹⁰ Rodgers et al¹³ performed a meta-analysis on studies comparing neuraxial *vs* general anesthesia with regard to postoperative mortality and morbidity. These authors concluded that neuraxial blockade reduces major postoperative complications in a wide variety of surgical patients, with the greatest reductions seen in the orthopedic population. These complications included deep venous thrombosis, pulmonary embolism, blood transfusion requirements, pneumonia, and respiratory depression.

Advantages of CSE Technique over only Spinal or Epidural Anesthesia

Several studies have shown that analgesia levels obtained after subarachnoid injection of same volume of hyperbaric local anesthesia solution are approximately three to four spinal segments higher in the elderly compared with young adults.¹⁵ Precipitous arterial hypotension due to high levels of sympathetic block remains a common

and acute problem associated with spinal anesthesia in geriatric patients. Despite prophylactic measures such as fluid preload and prophylactic vasopressors, it may be difficult to maintain a near-normal blood pressure in these patients.^{12,16} With only epidural anesthesia, hypotension may be gradual, but there are chances of patchy anesthesia with lesser degree of motor blockade due to fibrous bands. However, with sequential spinal-epidural technique, all such problems are overcome. So the practical and clinical advantages of CSE are as follows:

- Single wider space is enough to perform sequential CSE technique which is really helpful in geriatric patients in whom calcification and sclerosis can cause difficulty in yielding two different spaces.
- Initial epidural needle placement allows spinal needle to be guided over dura.
- Lower local anesthetic blood levels as initial spinal anesthesia is used for most duration of surgery and epidural local anesthetic drug for postoperative analgesia.
- Opioids along with local anesthetic reduce the dose of latter, hence reducing the toxicity.
- Reduction of blood loss and reduction in chances of deep vein thrombosis and thromboembolism
- More prompt return of preoperative mental state.

Our experience in using CSE for orthopedic surgeries reveals that this technique is extremely helpful, particularly in orthopedic geriatric patients. This allows us to use lower doses of local anesthetic drug along with smaller equipotent doses of opioid in spinal anesthesia with prolongation of anesthesia with epidural catheter and hence postoperative analgesia. Also better achievement of hemodynamic stability and less chances of respiratory depression are other advantages that we observed in our patients. In our study at our institute, we compared intrathecal fentanyl (20 µg) *vs* sufentanil (5 µg) with 0.5% bupivacaine 12.5 mg.

We studied and compared the groups for the following:

- Time of onset, level of sensory block, duration of analgesia, onset and level of motor blockade by Bromage scale, time taken for two-segment regression
- 1st epidural top-up at two-segment regression
- Level of sedation
- Side effects: hypotension, nausea, vomiting, respiratory depression, and pruritus.

Results showed that the time of two-segment regressions, which determined the duration of blockade, was significantly prolonged in the fentanyl group (115.53 ± 30.17 min) than in the sufentanil group (90.37 ± 13.53 min) ($p=0.0001$). The onset of analgesia, time to reach highest level of analgesia, was faster in sufentanil group, but the results were not statistically significant. Motor block was

better with fentanyl group, but the result was not statistically significant. Grade of sedation was more in fentanyl group, but was not statistically significant. Vital parameters were stable in both groups. None of the patients in any group had nausea, vomiting, or pruritus.

CONCLUSION

We conclude that addition of either fentanyl or sufentanil to intrathecal bupivacaine as an adjuvant in CSE technique enhances the quality of analgesia and motor block with minimal side effects. Hence it is useful in orthopedic patients, especially in the geriatric age group.

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