



COMPARISON OF ANAESTHETIC POTENCY OF INTRATHECAL ISOBARIC ROPIVACAINE WITH AND WITHOUT FENTANYL FOR LOWER ABDOMINAL AND LOWER LIMB SURGERIES

Anaesthesiology

Jasleen Kaur

Associate Professor, Department of Anaesthesia and Intensive Care, MMIMSR, Mullana, Ambala, India

Kirti Rishi

Senior Resident 33, Officer's Enclave, Phase – 1, Patiala, Punjab, India - Corresponding

ABSTRACT

Background: The addition of intrathecal opioids to local anaesthetics have been shown to enhance the sensory blockade and improve the quality of subarachnoid block. **Material and Methods:** This prospective, double-blind randomized controlled study was conducted in 60 patients in the age group of 20 – 60 yrs, belonging to American Society of Anaesthesiologists (ASA) physical status I and II scheduled for lower abdominal and lower limb surgeries under subarachnoid block. Patients were randomly allocated into two groups to receive either intrathecal 3.5ml of isobaric ropivacaine 0.75% (Group R) or 3ml of isobaric ropivacaine 0.75% with 0.5ml (25mcg) fentanyl (Group RF). Demographic data, hemodynamic profile, sensory and motor block characteristics, complications and time to first postoperative analgesic requirement were compared in the two groups. **Results:** The onset of sensory blockade was faster in Group RF (4.56 ± 1.36 min) as compared to Group R (6.7 ± 1.08 min). Time to reach T10 dermatome and the maximum level of sensory block attained were comparable. Regression of sensory blockade to S2 dermatome was 306.5 ± 39.25 min in Group RF and 230.05 ± 17.05 min in Group R ($P < 0.05$). Onset of motor blockade was earlier and regression was delayed in Group R as compared to Group RF. Time to first post-operative analgesic requirement was significantly prolonged in Group RF (222.25 ± 48.05 min) than Group R (195.9 ± 31.60 min). Hemodynamic parameters and complications were comparable. **Conclusion:** The addition of intrathecal fentanyl to ropivacaine enhances the onset of sensory blockade and prolongs the postoperative analgesia with stable hemodynamics and minimal side effects

KEYWORDS:

fentanyl, intrathecal, lower abdominal, lower limb surgeries, ropivacaine.

I. INTRODUCTION

Spinal anaesthesia is a widely practiced anaesthetic technique with a high success rate. It offers the advantage of reduced intra-operative stress response and improved early post-operative pain relief as compared to general anaesthesia. Various local anaesthetics with and without the use of adjuvants have been used for subarachnoid block. The observation of transient neurological symptoms with lignocaine led to the withdrawal of the drug.^[1] Intrathecal bupivacaine provides profound and prolonged motor blockade delaying the discharge of the patient after ambulatory surgery. Ropivacaine, an amide local anaesthetic has been shown to provide similar sensory block to bupivacaine at equipotent doses with early motor recovery.^[2] It has a better safety profile and has less neurotoxic and cardiotoxic potential as compared to bupivacaine.^[1,3]

Intrathecal opioids act synergistically with local anaesthetics and improve the quality of spinal anaesthesia with a lower dose of local anaesthetic.^[4,5] This prospective, double-blind randomized trial was undertaken to compare isobaric ropivacaine and fentanyl versus ropivacaine alone in subarachnoid block for lower abdominal and lower limb surgeries.

II. MATERIAL AND METHODS

After the ethics committee approval and a written informed consent from the patients, this study was undertaken in 60 patients belonging to ASA I or II in the age group of 20-60 yrs scheduled for lower abdominal and lower limb surgeries under subarachnoid block. Exclusion criteria included patient's refusal, history of allergy to amide local anaesthetics, abnormality of spine, any skin infection or local lesions, coagulation defects, severe cardiac or respiratory disease and any neurological disorders.

Patients were randomized by a computer generated randomization table into two groups: Group R (n=30) received 3.5 ml (26.25mg) of isobaric ropivacaine 0.75% and Group RF (n=30) received 3 ml (22.5mg) of isobaric ropivacaine 0.75% with 0.5 ml (25 mcg) fentanyl. All patients underwent preanaesthetic evaluation a day before the surgery and were familiarized with the Visual Analogue Scale (VAS). Patients were kept nil per oral overnight. Premedication included tablet alprazolam 0.25 mg and tablet ranitidine 150 mg PO at night and 2 h before surgery in the morning. After arrival in the operation theatre, standard monitors including electrocardiography, non invasive blood pressure (NIBP) and pulse oximeter were connected to the patient and

baseline parameters recorded. A good intravenous access was established and preloading was done with 20ml/kg of Ringer Lactate. Under all sterile precautions subarachnoid block was performed in L3-4 intervertebral space using 25 Gauge Quinke needle and the patient received one of the two study drugs. The anaesthesiologist who administered the intrathecal drugs and carried out the observations was blinded to the drug administered. The drug solutions were prepared by a second anaesthesiologist.

Heart Rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), respiratory rate (RR) and oxygen saturation (SpO₂) were monitored throughout the study. Blood pressure and heart rate were recorded every 5 minutes for 30 minutes after the intrathecal injection and then every 10 minutes for the rest of the surgery. A fall in BP more than 25% from the baseline was taken as hypotension and treated with intravenous fluids and ephedrine. Pulse rate < 50 /min was considered as bradycardia and treated with atropine 0.6mg intravenously.

The level of sensory block and motor block was assessed every two minutes for the first 15 minutes and every 15 minutes thereafter till 6h. The sensory block was evaluated using 23 Gauge hypodermic needle using pin-prick method along mid-clavicular line bilaterally. Onset of sensory block, time required to reach T10 dermatome, maximum level of sensory blockade and regression to S2 dermatome were recorded. Motor block was assessed according to Bromage Scale (0-no motor block ; 1-inability to raise extended leg, able to bend knee; 2- inability to bend the knee, can flex ankle; and 3- no movement). Time for onset of motor block and complete regression was noted.

Any complications like nausea, vomiting, bradycardia, hypotension, shivering, pruritis and respiratory depression were observed, treated and recorded. The time to first analgesic requirement in the post-operative period when VAS was more than 3 was noted and injection diclofenac 75 mg intravenously administered.

Statistical analysis was performed using SPSS version 20 with paired and unpaired t-test and ANOVA. Categorical data were analysed using Chi-square test. Data are presented as mean \pm standard deviation and $P < 0.05$ was considered statistically significant.

III. RESULTS

The demographic data including age, gender, height, weight and duration of surgery was comparable in both the groups "Table 1"

Table 1: Demographic data

| Parameters | Group R (n=30) | Group RF (n=30) |
|---------------------------|----------------|-----------------|
| Age (years) | 40 ± 13.90 | 35.75 ± 12.69 |
| Weight (kg) | 55.67 ± 4.95 | 57.33 ± 4.58 |
| Height (cm) | 155.45 ± 8.24 | 156.24 ± 7.80 |
| Gender (male/female) | 27/3 | 29/1 |
| Duration of surgery (min) | 101 ± 32.59 | 104 ± 30.16 |

Values are in mean ± Standard deviation

There was no significant difference in the HR, SBP, DBP, RR and SpO₂ between the two groups at baseline and post subarachnoid block at all intervals measured. The onset of sensory block was significantly faster in RF group (4.56 ± 1.36 min) than group R (6.7 ± 1.08 min). The time of sensory block to reach T10 dermatome was 9.95 ± 1.57 min with ropivacaine alone and 9.99 ± 0.91 min in the fentanyl group. The highest sensory level achieved was comparable at T4 dermatome. Regression of sensory block to S2 dermatome was delayed in Group RF (306.5 ± 39.25 min) as compared to Group R (230.05 ± 17.05 min). The mean time of onset of motor block was 6.8 ± 1.39 min in Group R and 8.8 ± 1.39 min in Group RF. The time for complete regression of motor block was significantly longer in Group R (328.05 ± 28.23 min) as compared to Group RF (231.04 ± 29.69 min). The mean time duration for first post-operative analgesic requirement was 195.9 ± 31.60 min with ropivacaine alone and 222.5 ± 48.05 min with ropivacaine and fentanyl and this difference was statistically significant (P < 0.05).

Table II: Spinal block characteristics

| Parameters | Group R | Group RF | P value |
|---|----------------|----------------|---------|
| Time of onset of sensory block (min) | 6.76 ± 1.08 | 4.56 ± 1.36 | < 0.05* |
| Time to reach T10 dermatome (min) | 9.95 ± 1.57 | 9.9 ± 0.91 | > 0.05 |
| Highest sensory level (range) | T4 – T8 | T4 – T8 | |
| Time of regression of sensory block (min) | 230.05 ± 17.05 | 306.5 ± 39.25 | < 0.05* |
| Time of onset of motor block (min) | 6.8 ± 1.39 | 8.8 ± 1.39 | < 0.05* |
| Time of regression of motor block (min) | 231.4 ± 29.69 | 328.05 ± 28.23 | < 0.05* |
| Time of first analgesic requirement | 195.9 ± 31.60 | 222.25 ± 48.05 | < 0.05* |

Values are in mean ± Standard deviation; * P < 0.05 –statistically significant

There was no significant difference in the complications observed in the two groups. Two patients had bradycardia and 3 patients had hypotension in Group RF which responded to atropine and ephedrine respectively. Nausea, vomiting, shivering, pruritis or respiratory depression were not observed in any patient in either group.

IV. DISCUSSION

Spinal anaesthesia is a popular anaesthesia technique because of its technical ease and high success rate. Except for a few undesirable features like intra-operative hypotension and residual motor blockade, it has a good safety profile. Bupivacaine is the most widely long acting amide local anaesthetic. It has a high cardiotoxic and neurotoxic potential and produces prolonged motor blockade in the post operative period. Ropivacaine, the pure S enantiomer of bupivacaine has emerged as a drug with a better safety profile and short duration of motor block. Various adjuvants have been used with ropivacaine to improve the quality and duration of sensory block.[7,8] We proposed to study the efficacy of intrathecal isobaric ropivacaine with or without fentanyl for lower abdominal and lower limb surgeries.

The demographic profile including age, sex, height, weight, ASA physical status and duration of surgery was comparable in both the groups. Hemodynamic changes, sensory and motor block characteristics, any complications and time to first postoperative analgesic requirement were noted and compared in the two groups. Mean HR, SBP, DBP at baseline were 83.4 ± 10.73 bpm, 131.7 ± 6.15 mm Hg and 81.10 ± 5.04 mmHg in Group R and 84.40 ± 9.72 bpm, 128.4 ± 5.93 mm Hg and 81.55 ± 3.41 mm Hg in Group RF.

Hemodynamic changes following subarachnoid block in both the groups were comparable and statistically insignificant. Bradycardia was observed in 2 patients and hypotension in 3 patients in Group RF which responded to atropine and ephedrine respectively. This incidence was statistically insignificant. Koltka et al compared 2.6 ml (19.5 mg) ropivacaine 0.75% with 20 mcg fentanyl and 2.6 ml of bupivacaine with 20 mcg fentanyl for subarachnoid block in lower abdominal surgeries.[8] They observed similar hemodynamic changes as in our study.

The onset of sensory block was significantly earlier with the addition of fentanyl to ropivacaine (Group RF vs Group R, 4.56 ± 1.36 min vs 6.7 ± 1.08 min) "Table 2". However, the time of the sensory block to reach T10 dermatome was comparable at 9.95 ± 1.57 min in Group R and 9.99 ± 0.91 min in Group RF, consistent with other studies by Koltka et al, Seetharam and Bhatt, Sanli et al and Boztug et al.[2,8-10] The highest sensory dermatome achieved in both the groups was comparable at T4. The time taken for regression of sensory block to S2 dermatome was significantly prolonged in Group RF (306 ± 39.25 min) as compared to 230.05 ± 17.05 min in Group R. The addition of fentanyl to intrathecal local anaesthetics has been shown to enhance and prolong the duration of sensory block.[11,12]

The mean time of onset of motor block was 6.8 ± 1.39 min in Group R and 8.8 ± 1.39 min in Group RF. The time to complete regression of motor block was delayed in Group R (328.05 ± 28.23 min) as compared to 231.4 ± 29.69 min in Group RF. The difference in the onset as well as regression between the two groups was statistically significant and might be explained to the use of a higher dose of ropivacaine in Group R (26.25 mg) versus 22.5 mg in Group RF. Fentanyl does not seem to intensify the motor blockade or prolong recovery from anaesthesia.[11,12]

The time to first request of analgesia post-operatively was significantly prolonged with the addition of fentanyl (Group R vs Group RF, 195.9 ± 31.60 min vs 222.5 ± 48.05 min). The results of our study are consistent with the studies by Sanli et al and Seetharam and Bhatt.[9,10] Nausea, vomiting, pruritis, shivering or respiratory depression were not observed in any patient in either group.

V. CONCLUSION

The addition of 25 mcg fentanyl to isobaric ropivacaine 0.75% in subarachnoid block enhances the sensory block and prolongs the duration of post-operative analgesia with stable hemodynamics and minimal side effects.

VI. REFERENCES

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