

A HOSPITAL BASED PROSPECTIVE STUDY TO COMPARE THE EFFICACY AND SAFETY OF ROPIVACAINE FENTANYL AND BUPIVACAINE FENTANYL USING INTRATHECAL IN LOWER LIMB ORTHOPEDIC SURGERIES

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Abstract

Background: Spinal Anaesthesia is the widely used method for lower limb orthopaedic surgeries, providing a faster onset and effective motor and sensory blockade. The aim of study is to compare the efficacy and safety of intra thecal Ropivacaine- Fentanyl and Bupivacaine-Fentanyl for lower limb Orthopaedic surgeries. **Materials and Methods:** A hospital based prospective randomized double-blind study done on 40 patients between the age group of 18-60 were posted for elective lower limb orthopaedic surgeries were recruited for the study. Forty patients were randomly allocated to receive either intrathecal 15 mg of 0.5% ropivacaine with 25 mcg fentanyl (Group RF) or 15 mg of 0.5% bupivacaine with 25 mcg fentanyl (Group BF). The onset, duration, spread of sensory and motor block, haemodynamic parameters and side effects were recorded. Data analysis was done by using SPSS software 22.0 v. **Result:** Time to reach highest sensory level, complete motor block and two segment sensory regression times were comparable. The motor recovery to Bromage scale 1 was faster in Group RF. The haemodynamic stability was better in Group RF. Time duration of analgesia was prolonged in Group BF. **Conclusion:** Intrathecal RF provided satisfactory anaesthesia with Haemodynamic stability for lower limb orthopaedic surgeries. It provided a similar sensory, but a shorter duration of motor block compared to BF, which is a desirable feature for early ambulation, voiding and physiotherapy.

INTRODUCTION

Spinal anaesthesia is the most convenient anaesthetic technique that offers many advantages over general anaesthesia, including reduced stress response and improved post-operative pain relief.^[1] Spinal Anaesthesia is the widely used method for lower limb orthopaedic surgeries, providing a faster onset and effective motor and sensory blockade. It is simple, easy to perform and has got a definite endpoint.

Intrathecal opioids are synergistic with local anaesthetics and intensify the sensory block without increasing the sympathetic block while achieving satisfactory quality of spinal anaesthesia at a much lower dose of local anaesthetic.^[2,3] Intrathecal bupivacaine is widely used in spinal anaesthesia over a long period of time.

However, spinal bupivacaine induces profound motor block of longer duration and delays home discharge after ambulatory surgery.^[4] Ropivacaine, an amide local anaesthetic, has been introduced

recently and used successfully to provide epidural analgesia for labouring women, caesarean delivery

and post-operative analgesia.^[5] Intrathecally, it has been used for day care procedures as it provides adequate sensory block with early motor recovery.^[6] In this setting, a newer drug Ropivacaine has emerged, which is being widely used for epidural blocks and nerve plexus blocks. Ropivacaine has an improved safety profile over bupivacaine with respect to central nervous system and cardio toxic potential. Though ropivacaine is being used frequently, in epidural and nerve blocks, the literature regarding its use in intrathecal route is sparse.^[1] The aim of study is to compare the efficacy and safety of intra thecal Ropivacaine- Fentanyl and Bupivacaine-Fentanyl for lower limb Orthopaedic surgeries.

MATERIALS AND METHODS

A hospital based prospective randomized double-blind study done on 40 patients between the age

group of 18-60 were posted for elective lower limb orthopaedic surgeries were recruited for the study. These 40 patients were randomized using a computer-generated table, into two groups of 20 patients each as follows-

Group RF - 15 mg of 0.5% Ropivacaine (3.0 ml) + 25 mcg Fentanyl (0.5 ml)

Group BF - 15 mg of 0.5% Bupivacaine (3.0 ml) + 25 mcg Fentanyl (0.5 ml)

Inclusion Criteria

- ASA physical status 1 & 2
- Age 18 – 60 years
- Both genders
- Lower limb orthopaedic surgery

Exclusion Criteria

- Known hypersensitivity to any of the test drugs
- Any contra – indication to spinal anaesthesia
- Cardiac arrhythmias

Methods

Pre-filled labelled syringes loaded with the drugs were prepared by an anaesthesiologist not participating in the study. The anaesthesiologist who did the intervention and observation was unaware of the contents of the syringes and the group allocation. When the patient arrived the operation room, IV access was established, and 500 ml of RL was started. Multipara monitor attached, and baseline parameters - EGG, NIBP, SPO2, respiratory rate were recorded. After skin infiltration with 2% lidocaine, 25G Quincke's needle was inserted through L3-4 interspace in the midline, with the patient in sitting position. Correct placement of the needle was identified by free flow of cerebrospinal fluid and 3.5 ml of the study drug was injected over 10 seconds, and the patient was then placed supine.

Standard monitoring was used throughout the surgical procedure. ECG and pulse– oximetry was continuously monitored, while NIBP was measured at 5-min intervals. Heart rate and NIBP were recorded before intrathecal injection, 3, 5, 15, 30 minutes after the intrathecal drug administration, and thereafter every 30 minutes till the end of the surgery and one hour after the end of the surgery, at the ward. Any hypotension (systolic blood pressure lower than 20% from the baseline) was treated with i.v ephedrine 6 mg and bradycardia (heart rate < 50/min) incidents were treated i.v atropine 0.6 mg increments.

Time of Onset of Sensory Block

The time interval between end of anesthetic injection and appearance of cutaneous analgesia in the

dermatomes assessed by the pin prick test using 20 G hypodermic needle in T-12, T-10, T-8, T-6 or higher levels (T-4)

Motor Block Duration

It is the time taken between administration of anesthetic and the attainment of grade 0 in Bromage motor scale.

Two Segment Sensory Regression Time

The time taken for the sensory block to regress to two segments down from the maximum level of blockade is defined as the two-segment regression time

Duration of Analgesia

It is the time of administration of anesthetic and the disappearance of cutaneous level of sensation, at each dermatomal level.

Post-Op Analgesia Duration

The time between the administration of anesthetic and time of analgesic requirement (visual analog scale > 4) in PACU.

Statistical Analysis

Data analysis was done with the help of computer by using SPSS software 22.0v. Using this software, percentage, mean, standard deviation and 'p' value were calculated through one way ANOVA, and Chi square test and a P value of < 0.05 was taken as significant.

RESULTS

The demographic data in both the groups were comparable in terms of age, gender, height, weight and duration of surgery [Table 1]. The peak sensory levels attained between the two groups were comparable (Group RF was 4.33±0.78 & Group BF was 4.68±0.83, P>0.05 NS). The time to reach peak sensory level between the two groups is statistically not significant (Group RF was 6.15±0.93 & Group BF was 6.14±0.86, P=1.00 NS). The two-segment sensory regression time between the two groups was comparable. i.e statistically not significant (Group RF was 64.76±3.24 & Group BF was 66.13±3.77, P>0.05 NS). There is a statistical significance in the difference between the two groups RF and BF (Group RF was 243.53±13.73 & Group BF was 291.24±15.48, P<0.001***), the duration of analgesia is more in BF group [Table 2]. The most commonly occurring adverse effect was the hypotension, experienced in 2 (10%) patients in group RF & 6 (30%) patients in group BF [Table 3].

Table 1: Demographic data

Demographic profile	Group RF	Group BF	P-value
Mean Age (yrs)	41.37±11.28	43.74±12.36	>0.05
Weight (kg)	68.56±8.12	70.22±6.78	>0.05
Height (in cm)	168.79±8.16	165.99±7.65	>0.05
Gender (Male/Female)	15/5	15/5	1.00
Duration of surgery	125.45±57.64	125.24±58.45	1.00

Table 2: Spinal block Characteristics

Spinal block Characteristics	Group RF	Group BF	P-value
Peak sensory level (Thoracic)	4.33±0.78	4.68±0.83	>0.05
Time to reach peak sensory level (Min.)	6.15±0.93	6.14±0.86	1.00

Two segment sensory regression time	64.76±3.24	66.13±3.77	>0.05
Duration of analgesia (Min.)	243.53±13.73	291.24±15.48	<0.001***

Table 3: Complications

Complications	Group RF	Group BF
Hypotension	2	6
Bradycardia	1	1
Nausea-vomiting	0	1
Shivering	1	1

DISCUSSION

Ropivacaine is a long acting, enantiomerically pure (S-enantiomer) amide local anaesthetic, and with a low lipid solubility. The low lipid solubility of ropivacaine relates the lesser duration of analgesia comparing to Bupivacaine. Intrathecal ropivacaine, in animal studies has shown to produce effective sensory block, but the duration of motor block is shorter than intrathecal bupivacaine, with no signs of neurological side effects.

The early motor recovery of ropivacaine is due to the blockade of nerve fibers involved in transmission of pain (A δ and C fibers) to a greater degree, comparing to controlling of motor functions (A β fibers). This feature favors its use where early ambulation is needed as in orthopaedic surgeries, for starting physiotherapy. This feature also allows for the detection of any neurological side-effects, if any, occurred.^[1]

The present study has demonstrated that using either ropivacaine or bupivacaine intrathecally, with fentanyl as an adjuvant has provided satisfactory anesthetic conditions for lower limb ortho surgeries. Most of the sub-arachnoid block characteristics were similar. There was a significant early motor recovery in RF group with haemodynamic stability, but BF provided a prolonged duration of post-operative analgesia.

McNamee et al. studied the efficacy and safety of two concentrations of intrathecal ropivacaine –7.5 mg/ml (18.75 mg) and 10 mg/ml (25 mg) for total hip arthroplasty where they found satisfactory anaesthetic conditions in terms of sensory and motor block.^[7]

A dose response study done by Lee et al. provided a useful guide for clinicians to choose optimal dose of the spinal ropivacaine under different clinical situations. They observed that the ED50 and ED95 for the spinal ropivacaine in lower limb surgery of 50 min or less were 7.6 mg and 11.4 mg respectively.^[8] Malinovsky et al. compared intrathecal ropivacaine to bupivacaine in patients scheduled for trans-urethral resection of prostate.^[9] They found that 15 mg of intrathecal ropivacaine provided similar motor and haemodynamic effects but less potent anaesthesia than 10 mg bupivacaine for endoscopic urological surgery. Luck et al. used equal doses of hyperbaric ropivacaine, bupivacaine and levobupivacaine (15 mg) intrathecally for elective surgery and found that ropivacaine provided reliable spinal anaesthesia of shorter duration than

bupivacaine and levobupivacaine and concluded that the recovery profile of ropivacaine may be useful where prompt mobilisation is required.^[10] The efficacy of ropivacaine for major orthopaedic surgeries as an alternative to bupivacaine, using equimilligram dose (15 mg) as used by Luck et al.^[10] While maintaining the advantage of low dose local anaesthetic intrathecally, the use of analgesic adjuvants can improve the quality of intra-operative anaesthesia. Lipid soluble opioids such as sufentanil and fentanyl are the most commonly used adjuvants. Studies have shown that intrathecal opioids can enhance greatly the duration of analgesia of sub-therapeutic doses of local anaesthetics. Fentanyl added to local anaesthetic agent intrathecally seems to be the most frequently used combination in spinal anaesthesia, to enhance and increase the duration of sensory block, without intensifying the duration of motor blockade or prolonging the recovery from spinal anaesthesia.

Both intrathecal RF and BF produced an initial moderate fall in blood pressure in keeping with the expected sympathetic blockade produced by the spinal anaesthesia. Although the Systolic BP stabilized after 30 min, there was a statistically significant difference among the two groups from 120 to 240 minutes, where the systolic BP comes near the baseline values in RF group. This recovery profile of systolic blood pressure in the ropivacaine-fentanyl group more or less coincides with the recovery of motor block.

CONCLUSION

Intrathecal ropivacaine-fentanyl provides a satisfactory anaesthesia and has a better hemodynamic stability for lower limb orthopaedic surgeries. The shorter duration of motor block compared to intrathecal Bupivacaine– Fentanyl is helpful in terms of early ambulation, voiding and for starting physiotherapy earlier.

Although certain trends could be established in this study with encouraging results, further studies with larger sample sizes are needed to form a definitive opinion regarding the application of intrathecal Ropivacaine.

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