

A COMPARATIVE STUDY OF INTRATHECAL ROPIVACAINE-FENTANYL AND BUPIVACAINE-FENTANYL FOR LOWER LIMB ORTHOPAEDIC SURGERIES

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ABSTRACT

BACKGROUND

The aim of the study was to compare the efficacy and safety of intrathecal ropivacaine-fentanyl (RF) with bupivacaine-fentanyl (BF) for lower limb orthopaedic surgeries.

METHODS AND MATERIALS

In this Single Centred, Prospective, Randomised, Parallel group, Double-Blind study, sixty patients were randomly allocated to receive either intrathecal 15 mg of 0.5% ropivacaine (isobaric) with 25 mcg fentanyl (Group RF) or 15 mg of 0.5% bupivacaine (isobaric) 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 and Sigma Stat 3.5 version (2012).

RESULTS

Time to reach highest sensory level, complete motor block and two segment sensory regression time is also 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 than RF.

CONCLUSION

Intrathecal RF provided satisfactory anaesthesia with haemodynamic stability for lower limb orthopaedic surgeries. It provides a lesser sensory and a shorter duration of motor block compared to BF, which is a desirable feature for early ambulation, voiding and physiotherapy.

KEYWORDS

Ropivacaine, Bupivacaine, Fentanyl, Intrathecal, Orthopaedic Surgery.

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BACKGROUND

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 bupivacaine is widely used in spinal anaesthesia over a long period of time.

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 cardiotoxic potential. Though ropivacaine is being used frequently, in epidural and nerve blocks, the literature regarding its use in intrathecal route is sparse.

Aim of the Study

The aim of study is to compare the efficacy and safety of intrathecal Ropivacaine-Fentanyl and Bupivacaine-Fentanyl for lower limb Orthopaedic surgeries with respect to

1. Primary Outcome- Spinal block characteristics.
2. Secondary Outcome- Haemodynamic effects and side effects.

MATERIALS AND METHODS

It is a single centred, prospective, randomised, parallel group, double-blind study. This study was done in Government Chengalpattu Medical College Hospital at Department of Anaesthesiology during the period June 2016 to August 2016.

After obtaining institutional ethical committee approval, 60 patients between the age group of 18-60, who were posted for elective lower limb orthopaedic surgeries were recruited for the study. These 60 patients were randomised using a computer generated table, into two groups of 30 patients each as follows-

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

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

Inclusion Criteria

- ASA physical status I & II.
- Age 18-60 years.
- Both genders.
- Lower limb orthopaedic surgery.

Exclusion Criteria

- Known hypersensitivity to any of the test drugs.
- Any contraindication to spinal anaesthesia.
- Cardiac arrhythmias.

Financial or Other, Competing Interest: None.

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Procedure/Masking

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 in 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 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 were 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 IV ephedrine 6 mg and bradycardia (Heart rate <50/min.) incidents were treated with IV atropine 0.6 mg increments.

Parameters Observed/Primary

Spinal Block Characteristics

- Time to reach peak sensory level - Pinprick test.
- Time to reach peak motor block - Bromage scale grade 3.
- Two segment sensory regression time.
- Time to motor regression to Bromage scale grade 1.
- Duration of analgesia.

Post-Operative Period

- Time to first analgesic demand (VAS > 4)

Secondary

- Heart Rate (< 50/min.-Bradycardia).
- Blood Pressure (> 20% fall from baseline SBP-Hypotension).
- Oxygen Saturation.
- Pruritus.
- Nausea.
- Vomiting.
- Shivering.

Score	Response
0	Normal Sensation
1	Loss of Pinprick Sensation -Analgesia
2	Loss of Touch Sensation - Anaesthesia

Table I. Sensory Score

Grade	Response	Degree of Motor Block
0	No Motor Block	Nil (0%)
1	Unable to Raise the Straight Leg	Partial (33%)
2	Unable to Flex the Knee Against Resistance	Almost Complete (66%)
3	Unable to Flex the Ankle	Complete

Table II. Bromage Motor Scale

Time of Onset of Sensory Block

The time interval between end of anaesthetic injection and appearance of cutaneous analgesia in the dermatomes assessed by the pinprick 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 anaesthetic and the attainment of grade 0 in Bromage motor scale.

Two Segment Sensory Regression Time

The time taken for the sensory block to regress two segment 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 anaesthetic and the disappearance of cutaneous level of sensation at each dermatomal level.

Post-Op Analgesia Duration

The time between the administration of anaesthetic and time of analgesic requirement (Visual analogue scale > 4) in PACU.

1	2	3	4	5	6	7	8	9	10
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Visual Analogue Scale

RESULTS

Statistical Analysis

The information which was collected regarding all the selected cases were recorded in a master chart. Data analysis was done with the help of computer by using SPSS software and Sigma Stat 3.5 version (2012). 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.

After an initial moderate fall produced by the sympathetic blockade in both groups, the systolic BP got stabilised after 90 min. in RF group, indicated by the recovery of BP to a higher level comparing to BF group, This reflects the better haemodynamic stability in RF group.

There is a statistically significant difference among the two groups with respect to systolic blood pressure.

This also coincides with the early recovery of motor power in RF group, when compared to the BF group.

Systolic BP	Group RF	Group BF	SD	SD	P
Min. 0	124.6	121.5	3.73	2.45	<0.001
3	122.4	118.5	4.79	4.52	0.002
5	121.2	116.5	3.52	4.31	<0.001
15	116.9	115.3	2.55	1.91	0.006
30	109.3	111.8	2.02	2.76	<0.001
60	107.6	108.5	2.88	3.98	0.333
90	108.0	106.7	2.70	3.15	0.021
120	113.2	107.8	2.24	1.06	<0.001
150	114.2	109.9	2.49	0.96	<0.001
180	118.7	111.0	1.51	1.47	<0.001
210	119.1	111.8	1.76	1.16	<0.001
240	118.8	111.9	3.24	1.88	<0.001
270	119.0	114.3	2.44	2.20	<0.001
300	118.5	116.0	2.79	1.88	<0.001
Min. 330	119.1	116.0	0.83	1.68	<0.001

Table III. Systolic Blood Pressure

There was statistically significant difference in the systolic blood pressure between the two groups from 120 to 240 minutes. i.e. $p<0.05$. There is early stabilisation of systolic BP in group RF.

Duration of Motor Block/Ropivacaine
Duration of motor block in minutes.

0	5	10	30	60	90	120	150	180	210	240	270	300	330
Table IV													

0	2	3	3	3	3	3	3	2	2	2	2	1	1	1
0	3	3	3	3	3	3	3	3	3	3	3	2	1	1
0	3	3	3	3	3	3	3	3	2	2	2	2	1	1
0	3	3	3	3	3	3	3	2	2	2	2	2	1	0
0	3	3	3	3	3	3	3	3	3	3	1	0	0	0
0	3	3	3	3	3	3	3	3	3	3	3	2	1	0
0	2	3	3	3	3	3	3	3	2	2	2	2	1	1
0	3	3	3	3	3	3	3	1	1	1	1	0	0	0
0	3	3	3	3	3	3	3	3	2	2	1	1	1	0
0	3	3	3	3	3	3	3	3	2	2	2	1	1	0
0	3	3	3	3	3	3	3	2	2	1	1	0	1	0
0	2	3	3	3	3	3	3	3	2	2	2	1	1	0
0	3	3	3	3	3	3	3	3	2	2	1	1	0	0
0	3	3	3	3	3	3	3	3	3	3	3	2	1	1
0	3	3	3	3	3	3	3	2	2	2	1	1	0	0
0	3	3	3	3	3	3	3	3	2	1	1	0	0	0
0	2	3	3	3	3	3	3	3	3	2	1	1	0	0
0	3	3	3	3	3	3	3	3	3	3	1	1	1	1
0	3	3	3	3	3	3	3	2	2	1	1	0	0	0
0	3	3	3	3	3	3	3	3	3	2	1	1	1	0
0	3	3	3	3	3	3	3	3	3	2	1	1	1	0
0	2	3	3	3	3	3	3	3	3	3	1	1	0	0
0	3	3	3	3	3	3	3	2	2	1	1	0	0	0
0	3	3	3	3	3	3	3	3	3	1	1	1	1	0
0	3	3	3	3	3	3	3	3	3	1	1	1	1	0
0	3	3	3	3	3	3	3	3	3	1	1	1	0	0
0	3	3	3	3	3	3	3	3	2	1	1	1	1	1
0	2	3	3	3	3	3	3	3	3	1	1	1	0	0
0	3	3	3	3	3	3	3	3	3	1	1	1	0	0
0	3	3	3	3	3	3	3	3	3	1	1	1	1	1

Bromage Scale

There is an early recovery of motor block in ropivacaine-fentanyl group when compared to bupivacaine-fentanyl group. Most patients had full motor recovery by 300 minutes.

0	5	10	30	60	90	120	150	180	210	240	270	300	330
Table V. Bupivacaine- Duration of Motor Block in Minutes													

0	3	3	3	3	3	3	3	3	3	3	3	2	2	1	1
0	3	3	3	3	3	3	3	3	3	3	2	2	2	1	1
0	3	3	3	3	3	3	3	3	3	3	2	2	2	1	1
0	3	3	3	3	3	3	3	3	3	3	2	1	1	1	0
0	3	3	3	3	3	3	3	3	3	3	3	2	2	2	1
0	3	3	3	3	3	3	3	3	3	3	2	2	2	1	1
0	2	3	3	3	3	3	3	3	3	3	2	1	1	1	1
0	3	3	3	3	3	3	3	3	3	3	2	2	2	2	1
0	3	3	3	3	3	3	3	3	3	3	3	2	1	1	1
0	3	3	3	3	3	3	3	3	3	3	2	2	2	2	1
0	3	3	3	3	3	3	3	3	3	2	1	1	1	1	1
0	2	3	3	3	3	3	3	3	3	3	3	2	2	1	1
0	3	3	3	3	3	3	3	3	3	2	2	1	1	1	1
0	2	3	3	3	3	3	3	3	3	3	2	2	2	2	1
0	3	3	3	3	3	3	3	3	3	2	2	1	1	1	1
0	3	3	3	3	3	3	3	3	3	3	2	2	2	2	1
0	3	3	3	3	3	3	3	3	3	3	3	2	2	2	1
0	3	3	3	3	3	3	3	3	3	3	3	2	1	1	0
0	3	3	3	3	3	3	3	3	3	2	1	1	1	1	1
0	3	3	3	3	3	3	3	3	3	3	2	1	1	1	1
0	3	3	3	3	3	3	3	3	3	2	1	1	1	1	1
0	3	3	3	3	3	3	3	3	3	3	2	2	1	1	1
0	3	3	3	3	3	3	3	3	3	3	2	1	1	1	1
0	3	3	3	3	3	3	3	3	3	3	2	2	2	2	1
0	3	3	3	3	3	3	3	3	3	3	2	2	1	1	0
0	3	3	3	3	3	3	3	3	3	2	1	1	1	1	1
0	3	3	3	3	3	3	3	3	3	2	1	1	1	1	1
0	3	3	3	3	3	3	3	3	3	3	3	2	1	1	1
0	3	3	3	3	3	3	3	3	3	2	2	2	2	1	1
0	3	3	3	3	3	3	3	3	3	2	2	2	1	1	1
0	3	3	3	3	3	3	3	3	3	2	2	2	1	1	1
0	3	3	3	3	3	3	3	3	3	3	1	1	1	1	1

The duration of motor block was prolonged in BF group as evidenced by more patients in Bromage scale 3 even in 180 minutes.

Duration of Analgesia (min.)	Group RF	Group BF
Mean	242.27	289.2
SD	12.81	16.38
p value	< 0.001 Significant	

Table VI. Duration of Analgesia

There is a statistical significance in the difference between the two groups RF and BF, p value <0.001 i.e., the duration of analgesia is more in BF group.

DISCUSSION

Gaurav Kuthiala and Geeta Chaudhary et al^[1] described that the lipophilicity of ropivacaine is less when compared to bupivacaine, and so is less likely to penetrate the large myelinated motor fibres; and so it has selective action on A δ and C nerves which were transmitting pain, comparing to A β fibres, which are involved in the motor function.

Luck et al^[2] used equal doses of hyperbaric bupivacaine, ropivacaine and levobupivacaine (15 mg) intrathecally for elective surgery, and found that ropivacaine provided spinal anaesthesia of shorter duration when compared to levobupivacaine and bupivacaine, and they concluded that the recovery profile of ropivacaine is useful, where early mobilisation is required. e.g. orthopaedic surgeries for early physiotherapy.

Koltka et al^[3] compared doses of equal potency of the isobaric bupivacaine- 13 mg and ropivacaine-19.5 mg and,

both with fentanyl- 20 mcg for the sub-arachnoid block in lower abdominal surgery. They found that the RF had a lower level of sensory block with a shorter duration of motor block, when compared to BF.

In a study by Lee et al^[4], equal doses of intrathecal ropivacaine and bupivacaine (10 mg) with 15 mcg fentanyl were used for urology surgeries, and they reported that ropivacaine provided a similar level of sensory anaesthesia, but a shorter duration of motor block, in comparison to bupivacaine.

Chung CJ, Park JS, Yun SH, Hwang GB, Chin YJ^[5] found in their study that adding fentanyl 10 mcg with hyperbaric ropivacaine 18 mg in spinal anaesthesia for caesarean section improves the quality of intraoperative anaesthesia and significantly increases the quality of analgesia in early postoperative period.

Graf BM^[6] and his colleagues hypothesised that the isomers of ropivacaine had lesser cardio depressant effects compared to isomers of bupivacaine because of the replacement of butyl group by a propyl-terminal group.

Sangeeta Varun et al^[7] study has a similar results of Luck et al study.

A Yegin et al,^[8] Prashanth K Gupta^[9] & Singh^[10] and his colleagues found in their study that adding fentanyl 25 micrograms intrathecally will improve the quality of analgesia significantly, and prolong the duration of intraoperative & postoperative analgesia, without causing a substantial increase in the major side effects and reducing post-operative analgesic requirement.

Chaudhary et al^[11] had conducted a study and showed that the addition of intrathecal fentanyl to ropivacaine may offer the advantage of haemodynamic stability, shorter duration of

complete motor blockade, and without any increase in the frequency of major side effects.

Malinovsky JM^[12] and his colleagues compared intrathecal use of ropivacaine to bupivacaine in patients scheduled for TURP. They concluded that using 15 mg of intrathecal ropivacaine provides a similar motor and haemodynamic effects, but less potent anaesthesia when compared to 10 mg of bupivacaine for endoscopic urological surgery.

D. Hughes et al^[13] conducted a study aimed to reduce the incidence of motor blockade in combined spinal and epidural technique in labour analgesia. They compared the intrathecal use of bupivacaine 2.5 mg with ropivacaine 2.5 mg, both with fentanyl 25 micrograms. They came to a conclusion that ropivacaine 2.5 mg, when used intrathecally in combination with fentanyl 25 micrograms, as part of a CSE technique had provided a safe and rapid onset of analgesia for labour, but with a lesser motor blockade when compared to a same dose of bupivacaine.

Anita R Chhabra et al^[14] had compared the efficacies of intrathecal adjuvants with isobaric ropivacaine for major lower limb surgeries and observed that clonidine, when used as an adjuvant intrathecally, provided a denser and longer duration of motor blockade, prolonged duration of sensory blockade, and a longer duration of post-operative analgesia when compared to fentanyl.

Wahedi W et al^[15] in their randomised, double-blind study, administered intrathecally two different doses of ropivacaine 5 mg/mL and 7.5 mg/mL. A volume of 3 mL was injected intrathecally to forty patients and they recorded the spinal block characteristics. They concluded that ropivacaine results in long-lasting spinal anaesthesia at concentrations of 0.5% (5 mg/mL) and 0.75% (7.5 mg/mL).

Buckenmaier CC, Nielsen KC, Pietrobon R, Klein SM, Martin AH, Greengrass RA, and Steele SM^[16] had compared the efficacy of ropivacaine as an alternative to lidocaine, in patients undergoing anorectal procedures as outpatient basis.

They compared intrathecal administration of hyperbaric lidocaine 25 mg with fentanyl 20 micrograms with hyperbaric ropivacaine 4 mg with fentanyl 20 micrograms. They concluded that intrathecal hyperbaric small-dose of ropivacaine with fentanyl is an acceptable anaesthetic for anorectal surgeries.

Venkata HG^[17] and his colleagues compared the duration of analgesia and haemodynamics using a low dose (7.5 mg) bupivacaine- fentanyl mixture with a conventional dose (10 mg) of hyperbaric bupivacaine for cesarean section. They compared between 10 mg of hyperbaric bupivacaine, and a drug combination containing 25 micrograms fentanyl and 7.5 mg of hyperbaric bupivacaine, posted for elective caesarean section. They concluded that in caesarean section, the combination of low dose bupivacaine 7.5 mg and fentanyl 25 micrograms is haemodynamically stable, and has a prolonged duration of analgesia when compared to bupivacaine alone.

Bogra J et al^[18] compared different doses of intrathecal bupivacaine alone and in combination with fentanyl, for caesarean section. The patient received one of the following dose i.e. 8 mg, 10 mg, 12.5 mg of bupivacaine alone, or in combination with 12.5 micrograms of fentanyl. They concluded fentanyl is able to reduce the dose of bupivacaine, due to its synergistic effect on bupivacaine, and therefore reducing its harmful effects.

Van Kleef JW et al^[19] aimed to determine the safety and clinical efficacy of ropivacaine, as a local anaesthetic for spinal anaesthesia. They studied by using either 3 mL of isobaric solution containing 0.5% (15 mg), or 0.75% (22.5 mg) ropivacaine. They concluded that subarachnoid injection of isobaric ropivacaine solutions results in a variable analgesic spread, and mostly accompanied by a good quality of motor block, in particular with the 0.75% solution.

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 fibres involved in transmission of pain (A δ and C fibres) to a greater degree, comparing to controlling of motor functions (A β fibres). This feature favours 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.

The present study has demonstrated that using either ropivacaine or bupivacaine intrathecally, with fentanyl as an adjuvant has provided satisfactory anaesthetic conditions for lower limb ortho surgeries. Most of the subarachnoid 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.

We proposed to study the efficacy of ropivacaine for major orthopaedic surgeries as an alternative to bupivacaine, using equimilligram dose (15 mg) as used by Luck et al. While maintaining the advantage of low dose local anaesthetic intrathecally, the use of analgesic adjuvants can improve the quality of intraoperative 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 subtherapeutic 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 stabilised 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.

Our results are consistent with Lee et al as we observed comparable levels of highest dermatome block, the time taken to reach the peak sensory and motor level and the two segment sensory regression time. The motor block was significantly shorter with Group RF, although it outlasted the duration of surgery.

This feature is desirable as it encourages early ambulation, voiding and physiotherapy. Neurological side effects, if any,

can also be detected early. The mean time duration of analgesia is significantly prolonged in Group BF when compared to Group RF.

No patient in either group required intraoperative analgesia, since the duration of surgery is within the duration of sensory block in both groups.

Intraoperative hypotension requiring treatment with ephedrine occurred in 3 patients in Group RF as compared to 8 patients in Group BF. One patient in each group was also treated with 0.6 mg IV atropine for bradycardia. The most common adverse effect noted was nausea and vomiting, experienced in both the groups. Shivering also occurred in both the groups.

CONCLUSIONS

Intrathecal Ropivacaine-Fentanyl provides a satisfactory anaesthesia and has a better haemodynamic 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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