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Original Research Article

Intrathecal 0.75% ropivacaine with fentanyl and 0.5% bupivacaine with fentanyl for lower limb surgeries: Changes in blood pressure

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Abstract

Intrathecal hyperbaric bupivacaine for orthopedic surgeries has faster onset but episodes of hypotension, nausea, vomiting is more than intrathecal isobaric ropivacaine. Maximum level of sensory block height is higher with intrathecal bupivacaine compared to ropivacaine in equipotent doses. To detect a significant difference in mean duration of sensory block between groups B (Bupivacaine with fentanyl) and group R (Ropivacaine with fentanyl) with $\alpha = 0.05$ & power = 80% the minimum number of 40 cases was required in each group. Randomization was done using a random number table generated from computer software and divided into 2 groups of 40 each. The mean of mean blood pressure showed a significant and consistent fall from the baseline after the sub arachnoid block. This fall was seen in both the groups and was statistically highly significant but was clinically within normal physiological limits. Similarly, the difference in the mean of mean blood pressure between the groups were statistically highly significant but were clinically comparable.

Keywords: Ropivacaine, Fentanyl, Bupivacaine

Introduction

Bupivacaine has been used as a standard local anaesthetic for intrathecal use in orthopedic procedures and surgeries. Now ropivacaine is gaining popularity due to its low grade cardiovascular and neurotoxic potential. Its pharmacokinetic and pharmacodynamic properties are similar to that of bupivacaine. Its tolerability and low toxic potential provide better safety profile over other local anaesthetics [1].

Intrathecal hyperbaric bupivacaine for orthopedic surgeries has faster onset but episodes of hypotension, nausea, vomiting is more than intrathecal isobaric ropivacaine. Maximum level of sensory block height is higher with intrathecal bupivacaine compared to ropivacaine in

equipotent doses. Hence ropivacaine may be preferred over bupivacaine because of shorter duration of motor block with less hemodynamic changes. It is also accepted that best concentration of ropivacaine for intrathecal route is 0.75% and anaesthetic and analgesic effects are dose dependent. The higher concentration and doses result in more intense motor block.

Ropivacaine injection is preservative-free and is available as single dose ampoules in concentrations of 0.2%, 0.5%, 0.75% and 1%. The specific gravity of ropivacaine injection solutions ranges from 1.002 to 1.005 at 25 °C. There is an experimental evidence of lesser effect on the cardiac conduction system than occurs with bupivacaine. Evidence also supports the concept that ropivacaine has lesser impact on cardiac conduction and the frequency of arrhythmias that local anaesthetics have at blood levels producing systemic toxicity [2, 3].

In 1999, Gautier PE [4] *et al*. evaluated intrathecal ropivacaine for ambulatory surgery. 150 patients with ASA physical status 1 scheduled for knee arthroscopy were randomly assigned to receive 4 ml of one of five isobaric intrathecal solutions. Patients in group 1 received 8 mg of bupivacaine; patients in group 2 received 8 mg ropivacaine; patients in group 3 received 10 mg ropivacaine; patients in group 4 received 12 mg ropivacaine; and patients in group 5 received 14 mg ropivacaine. The level and duration of sensory anaesthesia were recorded along with the intensity and duration of motor block. Intrathecal ropivacaine 10 mg produced shorter sensory anaesthesia and motor blockade than bupivacaine 8mg (152 ± 44 min & 135 ± 41 min vs. 181 ± 44 min & 169 ± 52 min, mean ± SD; $p < 0.05$). However, the quality of intraoperative analgesia was significantly lower in the 10 mg ropivacaine group ($P < 0.05$). Ropivacaine 12 mg produced sensory and motor block almost comparable to bupivacaine 8 mg. Ropivacaine 14 mg produced sensory and motor block comparable to ropivacaine 12 mg but significantly increased the time to void. Intrathecal ropivacaine 12 mg is approximately equivalent to bupivacaine 8 mg. At this dose, ropivacaine offers no significant advantage compared with bupivacaine.

Jean-Marc Malinovsky *et al*. [5] in 2000 a randomized double blind study on intrathecal ropivacaine and bupivacaine in 100 patients scheduled for transurethral resection of bladder or prostate. Doses of ropivacaine and bupivacaine were chosen according to a 3:2 ratio found to be equipotent in orthopedic surgery. Patients were randomly assigned to receive either 10 mg of 0.2% isobaric bupivacaine or 15 mg of isobaric 0.3% ropivacaine. Onset and offset times for sensory & motor blockades, mean arterial blood pressure and pain at surgical site requiring supplemental analgesics were recorded. Cephalad spread of sensory block was significantly higher with bupivacaine (median level for cold T_4 and pinprick T_7) than with ropivacaine (cold T_6 and pinprick T_9) ($p < 0.001$). Onset time of T_{10} anaesthesia and offset time at L_2 were 11 ± 7 min & 127 ± 41 min in bupivacaine group and 13 ± 8 min & 105 ± 29 min in ropivacaine group. No statistically significant difference was found between onset, duration and the intensity of motor block between the 2 groups. Haemodynamic effects were similar in both the groups. They concluded that 15 mg of intrathecal ropivacaine provided similar motor and haemodynamic effects but less potent anesthesia than 10 mg of bupivacaine for endoscopic urological surgery [6].

Methodology

To detect a significant difference in mean duration of sensory block between groups B (Bupivacaine with fentanyl) and group R (Ropivacaine with fentanyl) with $\alpha = 0.05$ & power = 80% the minimum number of 40 cases was required in each group. Randomization was done using a random number table generated from computer software and divided into 2 groups of 40 each.

Group B: 2.5 ml of 0.5% hyperbaric bupivacaine with 25 µg fentanyl.

Group R: 2.5 ml of 0.75% isobaric ropivacaine with 25 µg fentanyl.

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Study population

Adult patients scheduled for lower limb surgeries.

Inclusion criteria

- Age 20-65 years of both sexes.
- ASA grade 1 and 2.
- Patients scheduled for lower limb surgeries.

Exclusion criteria

- Patients with ASA grade 3 and 4.
- History of known hypersensitivity to any drugs being used.
- Mental disturbances.
- Contraindications to neuraxial blockade.
- BMI ≥ 40 kg/m^2.
- Surgery lasting for > 2hours.

After a detailed pre-anaesthetic checkup, informed written consent was taken.
The patients were kept fasting for 8 hours before the surgery.
On arrival in the OT following baseline observations were recorded-

- Heart rate, blood pressure, SpO_2, ECG.
- They were co-loaded with 10-12 ml/kg ringer lactate solution IV.
- All patients in the sitting position received a combined spinal epidural anaesthesia by a needle through needle technique using a 18 gauge Tuohy's needle through which a 27 gauge pencil point spinal needle was introduced in the sub-arachnoid space at L_3-L_4 level or one space below.
- The study drug was injected as per the group designated.

Group B: 2.5 ml of 0.5% hyperbaric bupivacaine with 25 µg fentanyl.
Group R: 2.5 ml of 0.75% isobaric ropivacaine with 25 µg fentanyl.

- The study drug was given after which the spinal needle was withdrawn, epidural catheter was put through the Tuohy's needle and the patient was made to lie supine on the operating table.
- Surgery was allowed after level of block reaches T_{10} dermatome.

Intra-operative observations

All times were recorded considering the time to give spinal in CSE as time 0. Following parameters were recorded intra-operatively.

Primary outcome parameters

- Sensory block was assessed by using pin prick sensation with 23 gauge hypodermic needle in mid-clavicular line bilaterally.
- Time to reach T_{10} dermatome (by Hollmen scale).
- Time to achieve highest sensory level (by Hollmen scale).
- Time of onset of motor block (in minutes; to reach modified bromage scale 1&3).

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Secondary outcome parameters

- Heart rate, mean blood pressure were recorded every 3 minute for 15 minutes and thereafter every 10 min till end of surgery.
- ECG and SpO_2 were monitored continuously.
- Side effects.

Results

Table 1: Mean of mean blood pressure (mm Hg)

Group	Group B		Group R		p-values
Time (In min)	Mean BP	p-value	Mean BP	p-value	(gpB vs. gpR)
0	95.45 ± 6.88	-	90.38 ± 4.83	-	S***
3	92.93 ± 6.24	S**	89.53 ± 5.09	0.053	S**
6	80.2 ± 7.16	S***	85.45 ± 4.86	S***	S***
9	75.3 ± 10.01	S***	83.78 ± 5.35	S***	S***
12	75.73 ± 10.65	S***	83.63 ± 7.69	S***	S***
15	78.2 ± 8.67	S***	83.9 ± 5.84	S***	S***
25	78.5 ± 7.93	S***	83.15 ± 4.5	S***	**S****
35	76.18 ± 8.72	S***	82.75 ± 4.54	S***	S***
45	77.93 ± 8.52	S***	83.5 ± 5.45	S***	S***
55	77.4 ± 8.27	S***	83.73 ± 4.39	S***	S***
65	76.78 ± 6.76	S***	83.75 ± 4.75	S***	S***
75	78.23 ± 5.72	S***	83.68 ± 5.16	S***	S***
85	78.8 ± 6.73	S***	83.05 ± 5.09	S***	**S****
95	77.53 ± 7.53	S***	82.45 ± 4.57	S***	S***
105	75.83 ± 6.56	S***	82.4 ± 4.97	S***	S***
120	74.68 ± 6.4	S***	82 ± 4.18	S***	S***
150	73.98 ± 6.75	S***	82.15 ± 4.1	S***	S***
180	72.25 ± 6.14	S***	81.44 ± 4.44	S***	S***
210	71.96 ± 6.21	S***	81.27 ± 4.73	S***	S***
240	70.91 ± 6.56	S***	78.89 ± 4.28	S***	**S****

(NS): $p > 0.05$-Non-significant, (S)*: $p \leq 0.05$-Significant, (S)**: $p \leq 0.01$-Highly significant, (S)***: $p \leq 0.001$- Very highly significant.

The mean of mean blood pressure showed a significant and consistent fall from the baseline after the sub arachnoid block. This fall was seen in both the groups and was statistically highly significant but was clinically within normal physiological limits.
Similarly, the difference in the mean of mean blood pressure between the groups were statistically highly significant but were clinically comparable.

Table 2: Side effects

Side effect	Group B No. of Patients (%)	Group R No. of Patients (%)	p- value
Hypotension	6(15)	1(2.5)	(NS)
Bradycardia	2(5)	0(0)	(NS)
Nausea	7(18.0)	1(3.0)	(S)*
Vomiting	2(5.0)	0(0)	(NS)
ECG changes	Nil	Nil	Nil
Paraesthesia, TNS[#]	Nil	Nil	Nil
Pruritis	Nil	Nil	Nil
PDPH	Nil	Nil	Nil

TNS[#]-transient neurologic syndrome.
(NS): $p > 0.05$-Non-significant, (S)*: $p \leq 0.05$-Significant, (S)**: $p \leq 0.01$-Highly significant, (S)***: $p \leq 0.001$-Very highly significant.

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The incidence of hypotension was higher in the group B (15%) compared to group R (2.5%). This is statistically insignificant. Only 2 patients in group B had an episode of intra operative bradycardia while it was not observed in group R. The difference between the two groups is not statistically significant.
The number of patients having nausea was significantly higher in group B (18%) than in group R (3%) which is statistically significant ($p < 0.05$). 5% of patients in group B had an episode of vomiting, whereas none of the patients of group R complained of the same. The difference was statistically insignificant.
None of the patients in both groups had any ECG changes, paraesthesias, pruritus or post dural puncture headache throughout the procedure and post operatively.

Discussion

In the present study the mean of mean blood pressure showed a significant and consistent fall from the baseline after the sub arachnoid block in both the groups and was statistically highly significant but was clinically within normal physiological limits. The intergroup comparison of mean blood pressure between group B and group R was statistically very highly significant at all time intervals but clinically was within normal physiological range.
Ogun *et al*. [6] and Mantouvalou *et al*. [7] reported significant fall in mean heart rate after sub arachnoid block with isobaric preparations of bupivacaine and ropivacaine, but the fall was more significantly seen in bupivacaine group in both the studies, although the finding was clinically comparable.
Kallio *et al*. [8] and Luck *et al*. [9] in their respective studies found the changes in mean blood pressure to be unremarkable and statistically insignificant.
The incidence of hypotension was higher in the group B (15%) compared to group R (2.5%). This is statistically insignificant. Only 2 patients in group B had an episode of intra operative bradycardia while it was not observed in group R. The difference between the two groups is not statistically significant.
Similarly, a higher incidence of hypotension with bupivacaine as compared to ropivacaine has been reported by McNamee *et al*. [10] (26% vs. 12%) and Pala *et al*. [11] (40% vs. 22.5%), which is in concordance with our study.
The present study had 2 cases of bradycardia in the group B(5%) and none in group R. Studies by Ogun *et al*. [6] (0% vs. 0%), Mantouvalou *et al*. (12.5% vs. 5%) and Pala *et al*. (30% vs. 6.45%) report higher incidence of bradycardia in the bupivacaine group.
In contrast to our study Mc Namee *et al*. and Chung *et al*. reported higher incidence of intraoperative bradycardia in ropivacaine group as compared to bupivacaine group (6.3% vs. 0% and 10% vs. 3.3%).
In the present study, the number of patients having nausea was significantly higher in group B (18%) than in group R (3%) which is statistically significant ($p < 0.05$).
Similar to our study, Osama *et al*. observed a highly significant incidence of nausea with bupivacaine group as compared to ropivacaine group (61% vs. 33%).
In contrast to our study the incidence of nausea was statistically insignificant between the two groups in Mc Namee *et al*., Mantouvalou *et al*. (7.5% vs. 5%) and Pala *et al*. (21% vs. 10%).
There was no complaint of side effects like pruritus, paraesthesias, transient neurological syndrome and post spinal headache in any of the groups in our study but a very high incidence of pruritus was observed by Ogun *et al*. and Danelli *et al*. [12] in both the groups (64% vs. 72% and 65% vs. 23% in group B and R respectively).
No incidence of post dural puncture headache, transient neurological syndrome and backache was seen in our study. This is in agreement with studies by Ogun *et al*. and Danelli *et al*.

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Conclusion

- Both drugs are associated with normal and stable perioperative haemodynamics.
- Side effects are comparable with both drugs with nausea being significantly more common with bupivacaine.

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