European Journal of Molecular & Clinical Medicine

ISSN 2515-8260 Volume 09, Issue 02, 2022

Original Research Article

Comparison of changes in Heart rate and MAP between Intrathecal 0.75% ropivacaine with fentanyl and 0.5% bupivacaine with fentanyl for lower limb surgeries

[1]Dr. Arjun Nair, [2]Dr. Pramod Kohli, [3]Dr. Rohit Balyan, [4]Dr. Sachin Kumar, [5]Dr. Maitree Pandey, [6]Dr. Prashantha Kumar

[1,3]Assistant Professor, Department of Anesthesia, Maulana Azad Medical College, New Delhi, India
[2]Retd. Professor, Department of Anesthesia, Lady Hardinge Medical College, New Delhi, India
[4]Assistant Professor, Department of anesthesia, AIIMS, New Delhi, India
[5]HOD, Department of Anesthesia, Lady Hardinge Medical College, New Delhi, India
[6]Assistant Professor, Department of Anesthesia, The Oxford Medical College, Bangalore, Karnataka, India

Corresponding Author:
Dr. Maitree Pandey

Abstract

Ropivacaine reversibly interferes with the entry of sodium into the nerve cell membranes, leading to decreased membrane permeability to sodium and raises the threshold for electrical excitability. It blocks the generation and the conduction of nerve impulses, presumably by increasing the threshold for electrical excitation in the nerve, by slowing the propagation of the nerve impulse, and by reducing the rate of rise of the action potential. 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. The difference in the fall of heart rate from baseline in both the groups was clinically comparable. Only two (5% in group B) had an episode of bradycardia between 6-9 min after the sub-arachnoid block which resolved after a single dose of 0.6 mg of atropine in both the cases.

Keywords: Heart rate, MAP, intrathecal 0.75% ropivacaine

Introduction

Ropivacaine hydrochloride is a relatively newer long acting local anaesthetic belonging to the amino amide group and belongs to the same group as that of bupivacaine and mepivacaine, pipecoloxylidides local anaesthetics ropivacaine was introduced to clinical practice in 1996. Historically Bupivacaine was used because of its long duration of action, but subsequently it was found that "propyl derivatives" of pipecoloxylidides were less toxic than 'butyl derivatives' (bupivacaine). Thus, Ropivacaine was developed after bupivacaine was noted to be associated with significant number of cardiac arrests. Despite being in the market for close to three decades internationally, it was only introduced into the Indian market very recently [1, 2].

ISSN 2515-8260 Volume 09, Issue 02, 2022

It is the first local anaesthetic to be presented as an almost S-enantiomer (> 99% pure. It is used as local anaesthetic including infiltration, nerve block, epidural and of late for intrathecal anaesthesia in adults and children over 12 years of age. It is also used for peripheral nerve blocks and caudal epidural in children 1-12 years of age for surgical pain relief [3].

Ropivacaine reversibly interferes with the entry of sodium into the nerve cell membranes, leading to decreased membrane permeability to sodium and raises the threshold for electrical excitability. It blocks the generation and the conduction of nerve impulses, presumably by increasing the threshold for electrical excitation in the nerve, by slowing the propagation of the nerve impulse, and by reducing the rate of rise of the action potential [4].

Bupivacaine is a chiral drug because the molecule possesses an asymmetric carbon atom. The commercially available form is a racemic mixture (50:50) of the R and S configurations. It is a very stable liquid with a specific gravity of 1.005 at 20 ˚C and 0.997 at 37 ˚C. It is decomposed by boiling in either acid or alkali or with repeated autoclaving.

The lipophilic unionized form of bupivacaine enters the nerve at the nodes of ranvier and is ionized inside the axon. It is this, ionized form, which binds to the ion selective sodium channels in the nerve membranes and inhibits the passage of sodium ions through them. Failure of sodium ion channel permeability to increase slows the rate of depolarization such that threshold potential is not reached and thus an action potential is not generated [5].

Bupivacaine is a weak base with a pKa value of 8.2. Less than 50% exists in a lipid soluble non-ionized form at physiological ph. It is 94% plasma protein (alpha acid glycoprotein) bound [35]. Bupivacaine, like all other amide local anaesthetics, undergoes metabolism in liver by aromatic hydroxylation, N-dealkylation, amide hydrolysis and conjugation. A small amount is excreted unchanged in the urine [6].

Methodology

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.

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 > 2 hours.

ISSN 2515-8260 Volume 09, Issue 02, 2022

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).

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: Distribution of Patients According to Type of Surgery

Surgery	Group B (n=40)		Group R (n=40)	
	No.	%	No.	%
Amputation	2	5	1	2.5
Tibial interlocking nail	2	5	3	7.5
Arthrotomy	2	5	2	5
Distal femoral locked plating	1	2.5	2	5
Femoral interlocking nail	2	5	3	7.5
Dynamic hip screw	5	12.5	4	10
Excision	1	2.5	1	2.5

ISSN 2515-8260 Volume 09, Issue 02, 2022

Debridement	1	2.5	2	5
Dynamic condylar screw	3	7.5	1	2.5
Total hip replacement	3	7.5	-	-
K wiring	3	7.5	4	10
Cannulated cancellous screw	1	2.5	1	2.5
Patellectomy	2	5	2	5
Percutaneous femoral nailing	1	3	3	7.5
Hemiarthroplasty	2	5	3	7.5
Tension band wiring	3	7.5	2	5
External fixator	2	5	3	7.5
Proximal tibial lock compression plate	2	5	2	5
Non-corticocancellous screw with plating	2	5	1	2.5

n = number of patients

Table 2: Mean Heart Rate (bpm)

Group	**Group B**		**Group R**		**p-values**
Time (in min)	**Mean ± SD**	**p-value**	**Mean ± SD**	**p-value**	**(gpB vs. gpR)**
0	103.9 ± 19.46	-	100.45 ± 19.49	-	NS
3	100.78 ± 17	S*	99 ± 17.95	NS	NS
6	99.78 ± 14.68	NS	97.73 ± 15.02	NS	NS
9	98.1 ± 17.84	S*	94.2 ± 16.07	S*	NS
12	99.63 ± 18.41	NS	94.48 ± 17.3	S*	NS
15	96.9 ± 17.45	S*	90.28 ± 15.7	S***	S*
25	97.23 ± 15.67	S*	90.4 ± 16.72	S***	S*
35	99.05 ± 14.84	NS	92.03 ± 17.19	S**	S*
45	99.55 ± 22.19	NS	92.73 ± 18.5	S**	NS
55	99.48 ± 17.65	NS	93.15 ± 19.02	S*	NS
65	99.2 ± 16.49	NS	91.88 ± 17.37	S**	S*
75	97.55 ± 15.66	NS	90.25 ± 14.42	S**	S*
85	93.4 ± 13.94	S**	88.93 ± 12.4	S***	NS
95	92.35 ± 12.93	S**	87.18 ± 11.03	S***	S*
105	91.73 ± 14.74	S**	87.23 ± 11.15	S***	NS
120	88.8 ± 14.59	S***	87.18 ± 10.8	S***	NS
150	86.5 ± 14.33	S***	86.6 ± 11.2	S***	NS
180	85.49 ± 14.43	S***	84.39 ± 10.45	S***	NS
210	85.4 ± 14.22	S***	83.65 ±11.39	S**	NS
240	85.09 ± 11.17	S**	82.4 ±7.86	NS	NS

(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 baseline heart rate was comparable in both the groups with no significant difference. There was a slight fall in heart rate in both the groups after the sub-arachnoid block was given. Although the fall in heart rate from baseline was statistically significant at 9 min, 15 min, 25 min & 85 min onwards in group B and 15 min onwards in group R, but it was within normal physiological range in both the groups.

The difference in the fall of heart rate from baseline in both the groups was clinically comparable. Only two (5% in group B) had an episode of bradycardia between 6-9 min after the sub-arachnoid block which resolved after a single dose of 0.6 mg of atropine in both the cases.

Discussion

The baseline heart rate was comparable in both the groups with no significant difference

between the two groups. There was a slight fall in heart rate in both the groups after the spinal block was given. Although the fall in heart rate from baseline was statistically significant at 9, 15, 25 min and 85 min onwards in group B and 15 min onwards in group R, but, it was within normal physiological range in both the groups. The difference in the fall of heart rate from baseline in both the groups was clinically comparable.

Only 2 cases (5%) in group B had an episode of bradycardia between 6-9 min after the sub arachnoid block which resolved after a single dose of 0.6 mg of atropine.

Singh *et al*. [7] did not observe any clinically significant fall in mean heart rate after the sub arachnoid block in both bupivacaine and ropivacaine groups.

Kallio *et al*. [8], Danelli *et al*. [9], Luck *et al*. [10] and Bigat *et al*. [11] found changes in intra-operative and post-operative heart rate to be unremarkable in their study. However, Luck *et al*. and Bigat *et al*. used hyperbaric solutions in both the groups, while Kallio *et al*. and Danelli *et al*. had used isobaric preparations of the drugs.

Contrary to our study Mantouvalou *et al*. [12] reported significant fall in mean heart rate after sub arachnoid block with 15 mg each of isobaric bupivacaine and ropivacaine. However, the difference was comparable between the two groups.

Conclusion

There was a slight fall in heart rate in both the groups after the spinal block was given. Although the fall in heart rate from baseline was statistically significant at 9, 15, 25 min and 85 min onwards in group B and 15 min onwards in group R, but, it was within normal physiological range in both the groups. The difference in the fall of heart rate from baseline in both the groups was clinically comparable.

References

1. Dernedde M, Furlan D, Verbesselt R, Gepts E, Boogaerts JG. Grand mal convulsion after an accidental intravenous injection of ropivacaine. Anesth Analg. 2004 Feb;98(2):521-3.
2. Buckenmaier CC, Bleckner LL. Anaesthetic agents for advanced regional anaesthesia: a North American perspective. Drugs. 2005;65(6):745-59.
3. Tucker GT, Mather LE. Pharmacology of local anaesthetic agents. Pharmacokinetics of local anaesthetic agents. Br J Anaesth. 1975 Feb;47:213-24.
4. Boyes RN. A review of the metabolism of amide local anaesthetic agents. Br J Anaesth. 1975 Feb;47:225-30.
5. Gautier PE, De Kock M, Van Steenberge A, Poth N, Lahaye-Goffart B, Fanard L, *et al*. Intrathecal ropivacaine for ambulatory surgery. Anesthesiology. 1999 Nov;91(5):1239-45.
6. Chung CJ, Choi SR, Yeo KH, Park HS, Lee SI, Chin YJ. Hyperbaric spinal ropivacaine for cesarean delivery: a comparison to hyperbaric bupivacaine. Anesth Analg. 2001 Jul;93(1):157-61.
7. Surjit Singh, Singh VP, Manish Jain. Intra thecal 0.75% isobaric ropivacaine versus 0.5% heavy bupivacaine for elective caesarean delivery, A Randomized control trial. Journal Pakistan medical student. 2012;2(2):75-80.
8. Kallio H, Snäll E-VT, Tuomas CA, Rosenberg PH. Comparison of hyperbaric and plain ropivacaine 15 mg in spinal anaesthesia for lower limb surgery. Br J Anaesth. 2004 Nov;93(5):664-9.
9. Danelli G, Fanelli G, Berti M, Cornini A, Lacava L, Nuzzi M, *et al*. Spinal ropivacaine or bupivacaine for cesarean delivery: a prospective, randomized, double-blind comparison. Reg Anesth Pain Med. 2004 Jun;29(3):221-6.
10. Luck JF, Fettes PDW, Wildsmith JA. W. Spinal anaesthesia for elective surgery: a comparison of hyperbaric solutions of racemic bupivacaine, levobupivacaine and ropivacaine. Br J Anaesth. 2008 Nov;101(5):705-10.

ISSN 2515-8260 Volume 09, Issue 02, 2022

11. Bigat Z, Boztug N, Karsli B, Cete N, Ertok E. Comparison of hyperbaric ropivacaine and hyperbaric bupivacaine in unilateral spinal anaesthesia. Clin Drug Investig. 2006;26(1):35-41.
12. Mantouvalou M, Ralli S, Arnaoutoglou H, Tziris G, Papadopoulos G. Spinal anesthesia: comparison of plain ropivacaine, bupivacaine and levobupivacaine for lower abdominal surgery. Acta Anaesthesiol Belg. 2008;59(2):65-71.

Accepted on 24/05/2022