European Journal of Molecular & Clinical Medicine

ISSN 2515-8260 Volume 09, Issue 04, 2022

Original Research Article

Efficacy and reliability of 0.5% hyperbaric Bupivacaine and 0.75% isobaric Ropivacaine for intra-thecal use in patients undergoing lower abdominal and lower limb surgeries

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Abstract

Bupivacaine is three to four times more potent than lignocaine[4] and has a longer duration of action. Bupivacaine is an amide group of drug that is most frequently used for spinal anaesthesia. Both hyperbaric and isobaric forms are available. Hyperbaric solutions produce a more predictable extension of sensory block, short duration of block and faster recovery than isobaric solutions. The study was undertaken after obtaining ethical committee clearance as well as informed consent from all the patients. One hundred and twenty six patients in the age group between 20 years and 60 years of either sex belonging to ASA I and II posted for elective lower abdominal surgeries were grouped randomly into two groups (n=63). The mean time taken for attaining the maximum sensory blockade is 8.62±2.08 minutes in Group 1 and in Group 2 it is 8.71±2.59 minutes. Statistically there is no significance between the groups ($p>0.05$). The mean time taken to achieve maximum motor blockade in Group 1 is 7.03±2.24 minutes and in Group 2 it is 8.56±2.49 minutes, which is statistically significant between the groups ($p<0.001$).

Keywords: Hyperbaric bupivacaine, isobaric ropivacaine, lower abdominal and lower limb surgeries

Introduction

Spinal anaesthesia is preferred technique for lower abdominal and lower limb surgeries. It is simple to perform and requires small dose of drug with rapid onset of action and reliable anaesthesia. It avoids polypharmacy, allows the surgical incision to be made earlier and also provides post-operative analgesia.

ISSN 2515-8260 Volume 09, Issue 04, 2022

It is associated with a variable degree of haemodynamic changes. Hence there is a search for drugs which don't cause such changes and also produces reliable anaesthesia [1].
Spinal anaesthesia with cocaine was initially produced inadvertently by Leonard J Corning in 1885, and first used deliberately by August Bier in 1898. For decades lignocaine had been the local anaesthetic of choice for spinal anaesthesia. Its advantages are rapid onset of action and good motor blockade, manifested as good muscle relaxation. Its use is limited by its short duration of action and has been implicated in transient neurological symptoms and cauda equina syndrome following intra thecal injection [2].
Bupivacaine is three to four times more potent than lignocaine4 and has a longer duration of action. Bupivacaine is an amide group of drug that is most frequently used for spinal anaesthesia. Both hyperbaric and isobaric forms are available. Hyperbaric solutions produce a more predictable extension of sensory block, short duration of block and faster recovery than isobaric solutions. It is associated with hypotension & bradycardia of variable degree [3].
Ropivacaine is new long acting S-enantiomer amide local anaesthetic, with high pka and low lipid solubility, approved for intra-thecal use in 2004. It blocks pain transmitting nerves more readily than motor nerves. This property is advantageous for early ambulation. The drug is less cardiotoxic than equivalent concentrations of racemic Bupivacaine *in vitro* and has significantly higher threshold for central nervous system toxicity than racemic Bupivacaine [4].
We have undertaken this study to compare efficacy and reliability of 0.5% hyperbaric Bupivacaine and 0.75% isobaric Ropivacaine for intra-thecal use in patients undergoing lower abdominal and lower limb surgeries.

Methodology

The study was undertaken after obtaining ethical committee clearance as well as informed consent from all the patients. One hundred and twenty six patients in the age group between 20 years and 60 years of either sex belonging to ASA I and II posted for elective lower abdominal surgeries were grouped randomly into two groups (n=63). Randomization was done using the numbers generated by computer.
Group 1: Received 15mg of 0.5% hyperbaric Bupivacaine (0.5%, 3ml)
Group 2: Received 22.5mg of 0.75% isobaric Ropivacaine (0.75%, 3ml)

Inclusion criteria

- Age: 20-60 years
- ASA I&II
- Patients posted for elective lower abdominal and lower limb surgeries.

Exclusion criteria

- Age <20yrs and >60yrs
- ASA III, IV, V & emergency cases
- Contraindications to spinal anesthesia
- Pregnant patients

Preoperative assessment was done for each patient and written informed consent was taken. Patients were kept nil per oral for solids 6 hrs and clear fluids 2 hrs before surgery. Patients were premedicated on the night before surgery with tablet Pantoprazole 40mg and tablet Alprazolam 0.5mg.

ISSN 2515-8260 Volume 09, Issue 04, 2022

In the operation theatre intravenous line was obtained with 18 guage cannula and patient was preloaded with Ringer lactate 500ml before anaesthesia. Monitoring was done using multi-parameter monitor having pulse oximetry, ECG and NIBP. Patients were placed in flexed lateral position. Under aseptic precautions subarachnoid block was performed at level of L3-L4 through a midline approach using 25G Quincke spinal needle and study drug was injected with operative table kept flat. Patient was turned to supine posture immediately and supplemental oxygen given.
The test drugs were prepared by the senior anaesthesiologist who was not involved in the study, i.e. Bupivacaine (5 mg/ml) and Ropivacaine (7.5mg/ml). The observer and the patient were blinded for the study drug.

Results

Table 1: Sensory onset in two groups of patients studied

Sensory onset(min)	Group 1		Group 2	
	No	%	No	%
1-5	0	0.0	11	17.5
6-10	40	63.5	28	44.4
11-15	23	36.5	24	38.1
Total	63	100.0	63	100.0
Mean ± SD	9.25±2.02		8.75±2.91	

P=0.257, Not significant, Student t test

The mean time of onset of sensory blockade in Group 1 is 9.25±2.02 minutes and in Group 2 it is 8.75±2.91 minutes. Statistically there is no significant difference between the groups.

Table 2: Maximum sensory level in two groups of patients studied

Maximum Sensory Level	Group 1		Group 2	
	No	%	No	%
T4	30	47.6	27	42.9
T6	33	52.4	36	57.1
Total	63	100.0	63	100.0

P=0.591, Not significant, Chi-Square test

30 out of 63 patients in Group 1 and 27 out of 63 patients in Group 2 achieved T4 level of sensory blockade. 33 out of 63 patients in Group 1, 36 out of 63 patients in Group 2 achieved T6 level of sensory blockade. Statistically there is no significant difference between the groups ($p>0.05$).

Table 3: Maximum sensory blockade (minutes) in two groups of patients studied

Maximum sensory blockade (min)	Group 1		Group 2	
	No	%	No	%
<5	0	0.0	4	6.3
5-10	48	76.2	40	63.5
>10	15	23.8	19	30.2
Total	63	100.0	63	100.0
Mean ± SD	8.62±2.08		8.71±2.59	

P=0.821, Not significant, Student t test

The mean time taken for attaining the maximum sensory blockade is 8.62±2.08 minutes in Group 1 and in Group 2 it is 8.71±2.59 minutes. Statistically there is no significance between

ISSN 2515-8260 Volume 09, Issue 04, 2022

the groups (p>0.05)**.**

Table 4: Motor onset (minutes) in two groups of patients studied

Motor onset (min)	Group 1		Group 2	
	No	%	No	%
<5	63	100.0	0	0.0
5-10	0	0.0	51	81.0
>10	0	0.0	12	19.0
Total	63	100.0	63	100.0
Mean ± SD	1.97±0.88		8.14±2.22	

P<0.001**, significant, Student t test

The mean time taken for the onset of motor blockade is1.97±0.88 minutes in Group 1 and it is 8.14±2.22 minutes in Group 2, which is statistically significant (p<0.001).

Table 5: Grade of motor block in two groups of patients studied

Grade of motor block	Group 1		Group 2	
	No	%	No	%
2	0	0.0	3	4.8
3	63	100.0	60	95.2
Total	63	100.0	63	100.0

P=0.244, Not significant, Fisher Exact test

63 out of 63 patients in Group 1 and 60 out of 63 patients in Group 2 achieved grade III motor blockade. Statistically there is no significant difference in the intensity of motor blockade achieved (p>0.05).

Table 6: Maximum motor blockade (minutes) in two groups of patients studied

Maximum motor blockade (min)	Group 1		Group 2	
	No	%	No	
<5	13	20.6	0	0.0
5-10	50	79.4	43	68.3
>10	0	0.0	20	31.7
Total	63	100.0	63	100.0
Mean ± SD	7.03±2.24		8.56±2.49	

P<0.001**, significant, Student t test

The mean time taken to achieve maximum motor blockade in Group 1 is 7.03±2.24 minutes and in Group 2 it is 8.56±2.49 minutes, which is statistically significant between the groups (p<0.001).

Discussion

Present study was undertaken to evaluate Ropivacaine as a means of providing less motor block, early ambulation and less toxicity as compared to Bupivacaine. This study shows that intrathecal administration of either 22.5mg (0.75%, 3ml) Ropivacaine or 15mg (0.5%, 3ml) Bupivacaine was well tolerated and adequate block for lower limb and lower abdominal surgery was achieved in all patients. Ropivacaine has been shown to be effective in providing intrathecal anaesthesia for patients undergoing THR, TURP and lower abdominal and lower limb surgery. The efficacy and safety of two solutions, Ropivacaine and Bupivacaine were assessed [5, 6].

The pKa of Bupivacaine and Ropivacaine are identical but Ropivacaine is less lipid soluble, and hence Ropivacaine blocks alpha fibres more slowly than Bupivacaine. Thus Ropivacaine would cause less motor block than Bupivacaine, which is confirmed in this study. This evidence suggests that there is greater degree of sensory – motor separation when using Ropivacaine [7].

In present study, most of the patients had pre-operative pulse rate between 70 and 90 per minute. During intra–operative and post-operative period pulse rate change was mostly between 0-20 in Bupivacaine group and it was between 0-10/min in Ropivacaine group. Mean arterial blood pressure change from pre-operative value was more in Bupivacaine group when compared to Ropivacaine group. There was initial fall in arterial pressure in majority of patients. Mehta, V. Gupta, R. Wakhloo, *et al.* [8] compared intrathecal administration of isobaric Bupivacaine 15 mg (group1) and Ropivacaine 15 mg (Group 2) undergoing lower limb surgery. They found that, there was slight decrease in mean heart rate and arterial blood pressure over 30 minutes after anaesthesia which was statistically non-significant. Mean time of onset of sensory block up to T10 was less in group 1 than group 2, but statistically non- significant.

Mac Namee, McClelland, S. Scott *et al.* [9] studied isobaric Ropivacaine 5mg/ml (3.5ml) and isobaric Bupivacaine 5 mg/ml (3.5 ml) for major orthopaedic surgery. No statistically significant difference found in median time of onset of sensory block which was 2 minutes (range2-5 min) in Ropivacaine group and 2 min (range 2-9 min) in Bupivacaine group. As compared to our study, this difference could be due to different volume and concentration of drug used. Helena Kallio, Eljas-Veli T, *et al.* [10] used intrathecal isobaric solution (2ml) containing Ropivacaine 20 mg (1%) or 15 mg (0.75%) (group1) versus Bupivacaine 10mg (0.5%) (group2). Median onset of analgesia to T10 was 10 minutes in all groups. Difference could be due to difference in concentration.

Onset of motor blockade at grade -I in Group 1 and Group 2 was 3.8 ± 0.948 and 3.94 ± 0.913 minutes respectively, which is statistically non- significant. Mac Namee, McClelland, S. Scott *et al*.9 found that there was rapid onset in both groups with median time of onset 2 min to achieve a Bromage motor score of 1 for both groups. This difference was not statistically significant. Difference could be due to different concentration and volume of drug used. M. Mantouvalou, S. Rally, H. Arnaoutoglou *et al.* [11] found that onset of motor blockade at grade ―I was 2 ± 1 min in Bupivacaine group, 3 ± 1 min in Ropivacaine group, and 2 ± 1 min in Levobupivacaine group. These differences were not significant. This slight difference could be due to different concentration of drug used. Onset of maximum motor blockade (Grade III) in minutes in Group 1 and Group 2 was 6.66 ± 1.6856 and 7.44 ±1.473 respectively, which is statistically highly significant. Onset of maximum motor blockade was achieved up to grade III in all patients, except three patients in Ropivacaine group achieved up to grade II motor blockade [12].

Conclusion

From our study on 126 patients undergoing lower abdominal and lower limb surgeries, we found that use of sub arachnoid isobaric Ropivacaine (0.75%) has distinct advantages over hyperbaric Bupivacaine (0.5%). There was good pain relief because duration of analgesia was comparable.

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Accepted on 16/06/2022