Original article:

A comparative study of Ropivacaine and Bupivacaine in combined spinal epidural anaesthesia and Post- operative analgesia

Dr. K. Hemnath Babu [1], Dr. Shashikanth G. Somani [2], Dr. (Col) Venugopalan VM [3]

[1] Assistant Professor, Department of Anaesthesiology, Osmania Medical College, Hyderabad, Telangana

[2]Assistant Professor, Department of Anaesthesiology, Kamineni Institutes of Medical Sciences, Narketpally, Nalgonda, Telangana

[3] Professor, Department of Anaesthesiology , Kamineni Institutes of Medical Sciences, Narketpally Nalgonda, Telangana

Corresponding author: Dr. Shashikant G. Somani

Abstract:

Objective: To compare the efficacy and safety of Ropivacaine with Bupivacaine in providing anaesthesia and post operative analgesia in lower abdominal and lower limb surgeries in terms of, onset & duration of anaesthesia, hemodynamic stability & post operative analgesia.

Study Design: Prospective observational study.

Materials and Methods: Present study was conducted in 60 patients undergoing lower abdominal and lower limb surgeries. They were randomly allocated into two groups of 30 each. Combined spinal epidural anaesthesia was standardized. Haemodynamic parameters, onset and duration of sensory and motor blockade, level achieved, regression and side effects & post operative analgesia were compared between the two groups. Data was analysed statistically using student unpaired t test.

Results: The two segment regression time, mean duration of sensory blockade & motor blockade was decreased in ropivacaine group which was statistically significant $p<0.5$. Duration of motor blockade was significantly shorter in ropivacaine group. Excellent analgesia, with minor side effects and stable haemodynamics was noted in ropivacaine group.

Conclusion: We conclude that use of ropivacaine for Combined spinal epidural anesthesia in the lower abdominal and lower limb surgeries provided an adequate level of block for the surgery with faster onset of sensory and motor blockade, lesser duration of motor blockade with good analgesia and stable hemodynamics. There is no distinct advantage of ropivacaine over bupivacaine in postoperative analgesia.

Keywords: Bupivacaine , Combined spinal epidural anaesthesia, Post- operative analgesia, Ropivacaine

Introduction:

Surgical procedures are associated with a number of responses in the human body, the most important being pain & pain relief during and after surgical procedures continues to be a major challenge. Post operative analgesia not only is desirable for humanitarian reasons, but also essential to reduce post operative morbidity and mortality along with rapid recovery to normal life.

Combined spinal epidural anaesthesia has opened a new era of anaesthetic quality and cost effectiveness. Various local anaesthetics available for spinal and epidural anaesthesia are lidocaine, bupivacaine, levobupivacaine and recently introduced ropivacaine [1].

The transient neurologic symptoms (TNS) is more with lidocaine. Hence there is a need for local anaesthetics with less incidence of TNS and long duration of action and ropivacaine scores in terms

of lesser incidence of TNS than bupivacaine [2-4].

In 2009, Ropivacaine, an amide local anaesthetic has been introduced in our country. It has a structure, pharmacology, mechanism of action and physiochemical properties similar to bupvacaine, but it is less toxic to the cardiovascular and central nervous systems.[5-8].

Aim & Objectives:

To compare the efficacy and safety of Ropivacaine with Bupivacaine in providing anaesthesia and post operative analgesia in lower abdominal and lower limb surgeries in terms of, onset & duration of anaesthesia, hemodynamic stability & post operative analgesia.

Material & Methods:

After approval from institutional ethical committee , Present prospective study was conducted in Department of Anaesthesiology, Kamineni Institute of Medical Sciences, during October 2009 to September 2011 in 60 patients undergoing lower abdominal and lower limb surgeries.

Inclusion Criteria: 1. ASA grade I and II

2. Age between 18 and 60 years of either gender.

Exclusion Criteria: 1. ASA grade III and above

2. Emergency surgeries

3. Patients allergic to study drugs

4. Contraindications to regional anaesthesia

5.Refusal for participation

After a thorough pre-anaesthetic evaluation of all patients, a written and informed consent was obtained, both for conduct of study as well as administration of combined spinal epidural anaesthesia.

They were kept nil by mouth for eight hours before surgery .

Intravenous access was established with a 18G Intravenous cannula and preloading was done with 15 ml/kg Lactated Ringer's solution. Anaesthesia machine, accessories, monitors & drugs were checked.

All patients were randomly allocated into two groups using computer generated randomization technique.

- Group R (Ropivacaine group) (n=30)
- Group B (Bupivacaine group) (n=30)

Under strict aseptic conditions, in lateral position, epidural catheter was then inserted at L2-L3 level. Then, subarachnoid block was performed at L3-L4 intervertebral space with a 23G spinal needle and Group R patients received 3 ml of 0.5% ropivacaine heavy and Group B patients received 3ml of 0.5% bupivacaine heavy. Hyperbaric ropivacaine solutions was made with 4ml of 0.75% ropivacaine and 2ml of 20% dextrose, which was equivalent to 5mg/ml of 0.5% hyperbaric ropivacaine [9].

Following parameters were recorded:

- Time of onset of analgesia, maximum level of analgesia and two segment regression.
- Onset , level, intensity & regression of motor blockade (by modified Bromage scale)
- Heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP) and mean arterial pressure (MAP) were monitored at 2 minute intervals for 10 minutes, then at 5 minute intervals for next 30 minutes and at 15 minute intervals until 2 hours after giving study drug.
- ECG and SpO2 were monitored continuously.

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- Total RL administered to patients were recorded.
- Post operative complications (shivering, vomiting and urinary retention) if any were noted.

Duration of sensory block was taken from the time of intrathecal injection to Visual Analogue Scale (VAS) > 2, at which point the patient received the test solution through the epidural catheter. Test solution 6 ml of 0.125% ropivacaine for Group R patients and 6 ml of 0.125% bupivacaine for Group B patients was given. Postoperatively, patients were monitored for pain using VAS for 24 hours along with vital parameters every 6 hours.

All data was analysed statistically using student unpaired t test. p value <0.05 was considered significant.

Results:

Demographic profile was comparable in both the groups (p-value > 0.05) (Table-1)

Table-1 Distribution according to Demographic profile (N=60)

S.No	Parameters	Group-R (n=30) (Mean ± SD)	Group-B(n=30) (Mean ± SD)	p value
1	Age (year)	41.00±15.69	39.46±13.50	>0.05
2	Height (cm)	158.70±4.41	160.40±3.88	>0.05
3	Weight (kg)	53.63±7.95	54.96±7.30	>0.05
4	Gender (M:F)	17:13	16:14	-

SD – standard deviation, M = Male; F = Female

Table-2 Comparison of study parameters in both groups) (N=60)

S.NO	Parameters	Group-R (n=30) (Mean ± SD)	Group-B (n=30) (Mean ± SD)	P value
1	Baseline HR (bears per min)	85.80±8.80	84.90±10.73	>0.05
2	Baseline SBP (mmHg)	125±6.82	124.97±10.90	>0.05
3	Baseline DBP (mmHg)	78.10±11.88	79.2±8.63	>0.05
4	Baseline mean arterial pressure(mmHg)	93.73±6.56	94.45±6.14	>0.05
5	Mean onset time of analgesia(Min)	3.36±1.30	2.81±1.61	>0.05
6	Mean two segment regression time(Min)	68±36.40	72.4±26.81	**<0.05**
7	Mean duration of sensory blockade (Min)	174±36.36	200.7±36.40	**<0.05**
8	Mean onset time of motor blockade (Min)	6.3+3.70	5.8+4.21	>0.05
9	Mean duration of motor blockade(Min)	103.4±23.70	162.4±18.21	**<0.05**

p-value <0.05 is taken as significant

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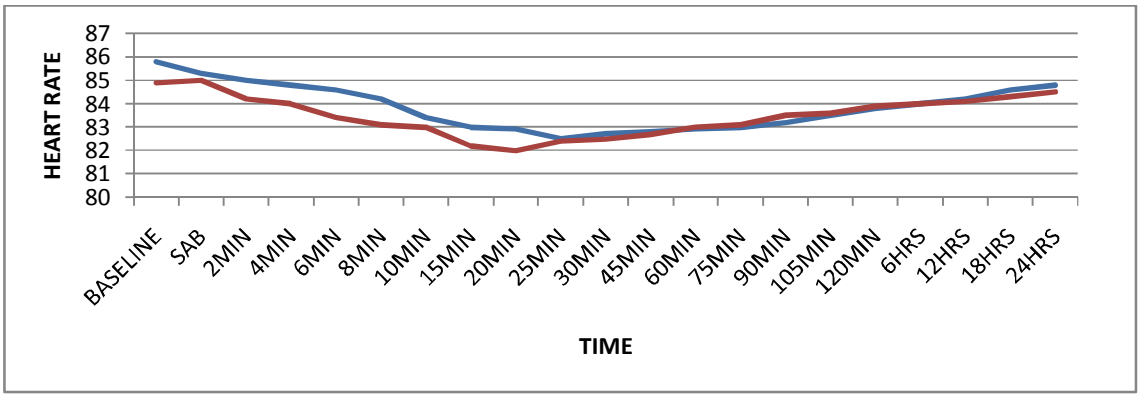

Figure 1: Comparision of Mean Heart Rate

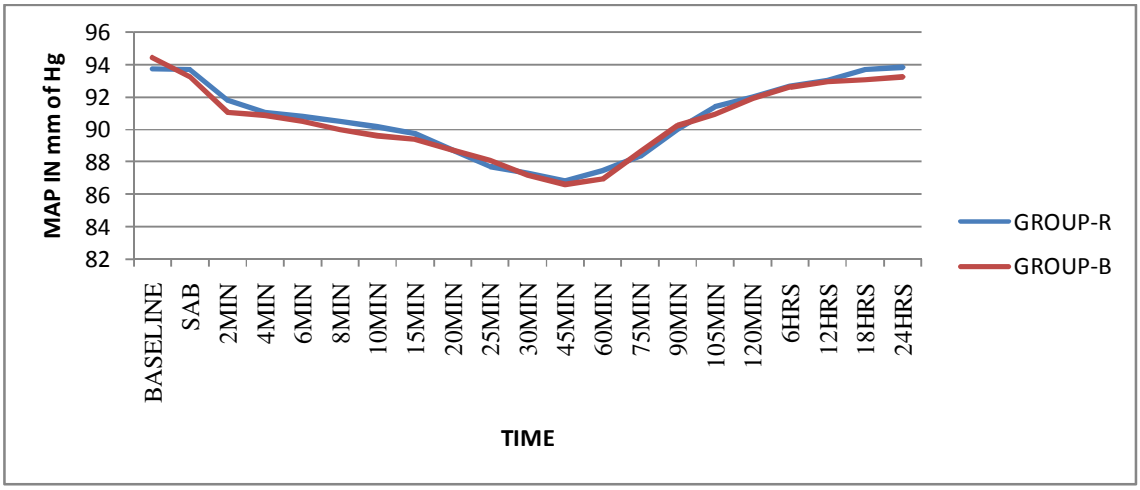

Figure 2: Comparision of mean arterial pressure

Baseline hemodynamic parameters (Figure1 & 2), mean onset time of analgesia & mean onset time of motor blockade are comparable between both the groups. The two segment regression time, mean duration of sensory blockade & motor blockade was decreased in ropivacaine group and statistically significant.

Table-3 Comparison of Number of Epidural Top up Dose (N=60)

	Group-R (n=30)	**Group-B(n=30)**
Number of Epidural Top Up Doses	4	3

Table-4 Comparison of Incidence of Postoperative Complications (N=60)

S.NO	**Complication**	**Group-R (n=30)**	**Group-B(n=30)**
1	Nausea	1(3.33%)	2(6.66%)
2	Vomiting	Nil	1(33.3%)

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Discussion:

Ropivacaine is a long-acting local amide anesthetic with similarities in structure, pharmacology and pharmacokinetics to that of bupivacaine but it is a pure (S-isomer) enantiomer. It has efficacy similar to bupivacaine with regard to pain relief but causes less motor blockade at low concentrations. It may be a preferred option because of its reduced CNS and cardiotoxic potential and its lower propensity for motor block [10,11]. Increasing doses of ropivacaine were associated with an increased clinical effect [12]. The wide safety margin of ropivacaine allows the use of higher concentrations and doses compared with bupivacaine with less risk of systemic toxicity, ensuring better surgical anesthesia [13].

The demographic profile was comparable with those of Chan-Jong Chung et al [9]. Hemodynamic parameters were comparable in both the groups which is consistent with others study[9,10]. In both groups initial slight fall in arterial pressure is in accordance with the expected sympathetic block produced by spinal anaesthesia. ECG monitoring did not show any abnormalities.

We observed, onset of sensory block for ropivacaine was 3.36 min and for bupivacaine was 2.81 min showing early onset of sensory blockade with bupivacaine, even though it is not statistically significant ($p>0.05$) ,this is consistent with prior study [9]. Intrathecal administration of both the drugs was well tolerated and adequate block was achieved in all patients.

We observed patients in ropivacaine group had a slower onset, shorter duration of motor block and a faster recovery from sensory block compared to bupivacaine group. The duration of analgesia was longer in bupivacaine group. Shorter duration of sensory and motor blockade with ropivacaine, has advantage of early ambulation of patients.

We observed the incidence of adverse effects like nausea was 1(3.33%) case in the ropivacaine group and 2(6.66%) and vomiting in 1(3.33%) case in bupivacaine group. M Mantonvalon et al[14] also noticed nausea in 5% cases in ropivacaine group and 7.5% of nausea and 2.5% vomiting in bupivacaine group. There were no incidence of urinary retention which was consistent with prior study [14].

Post operative analgesia was given by epidural route & monitored using VAS Score. Mean requirement of top ups in 24hrs was 4 doses in Ropivacaine and 3 doses in bupivacaine group patients. There is no significant differences in VAS and amount of local anaesthetics requried. This is in aggrement with the study done by Meister et al [11] .

Conclusion:

We concluded that, the mean duration of sensory and motor blockade was shorter for ropivacaine, which has advantage of early ambulation of patients. Excellent analgesia, with minor side effects and stable haemodynamics was noted in ropivacaine group. There is no distinct advantage of ropivacaine over bupivacaine in postoperative analgesia.

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