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A Comparative Study of Intrathecal Isobaric 0.5% Ropivacaine with Isobaric 0.5% Bupivacaine in Elective Lower Abdominal and Lower Limb Surgeries

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Abstract

Ropivacaine has a lower and different toxicity profile compared to Bupivacaine. It is a new long-acting, enantiomerically pure (S-enantiomers), amide local anaesthetic with a high pKa and low lipid solubility. T. Ropivacaine has a greater degree of motor sensory differentiation, which could be useful when motor blockade is undesirable. The reduced lipophilicity is also associated with decreased potential for central nervous system toxicity and cardio toxicity. Ropivacaine should be a favorable local anesthetic for day-case surgery and could be associated with earlier postoperative mobilization than Bupivacaine. *Objective of Study*: To compare the effects of intrathecal hyperbaric 4 ml of 0.5% Ropivacaine with 4 ml of hyperbaric 0.5% Bupivacaine in a ratio of 1:1 by volume (Ropivacaine 16.5 mg and Bupivacaine 11 mg) for lower abdominal/lower limb orthopedic surgeries with regard to: Onset and duration of sensory block, motor block. Maximum height of sensory block. Quality of anesthesia and Adverse reactions if any after taking written informed consent. *Observations:* Onset of motor blockade was slower and duration of motor blockade was shorter with Ropivacaine compared to Bupivacaine. However, all the patients in either groups attained complete motor blockade. With respect to hemodynamic parameters intrathecal Ropivacaine provided a higher Degree of cardiovascular stability with a lesser incidence of hypotension and bradycardia was observed. *Result:* There is delayed onset of motor block and shorter duration of motor block with Ropivacaine compared to Bupivacaine. Cardiovascular stability is better than Bupivacaine. Hence, Ropivacaine can be used successfully for lower limb/abdominal surgeries where early recovery is well appreciated by the patients

Keywords: Ropivacaine; Buphivacaine; Lower Limb Surgeries.

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Introduction

Bupivacaine rapidly gained popularity for surgeries of longer duration. Although it has slow onset of action, it produces good muscle relaxation, prolonged sensory and motor blockade. Duration and quality of motor and sensory blockade is dose dependant [1]. But increasing the doses of this hyperbaric Bupivacaine leads to increased cephalad spread of drug which accounts for more incidences of hypotension, bradycardia and in some cases, respiratory difficulty and cardio-respiratory arrest. Prolonged motor weakness associated with use of Bupivacaine is also a limiting factor for its use especially when used for surgeries of short duration as it delays the ambulation. It is also associated with side effects including cardiovascular and central nervous system toxicity. In cases of inadvertent intravascular injection of Bupivacaine, it was often

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fatal and responded poorly to conventional resuscitation methods [2]. The selective cardio toxicity of Bupivacaine is attributed to the "R enantiomers in its racemic mixture. This triggered pharmacological research that emphasized the selective behavior of the two enantiomers of racemic Bupivacaine, i.e. S-Bupivacaine and R Bupivacaine. Levo-enantiomer appeared to have a safer pharmacological profile than its dextro-partner [15].

Ropivacaine, a pure S-enantiomers, synthesized in the 1950s, but not introduced clinically until 1996 [3], was the 3rd in the Mepivacaine, Bupivacaine series. It has a similar onset of action as Bupivacaine, but is less potent requiring concentrations of up to 1%. As it is less liphophilic, the preservation of motor function is appealing in areas where early ambulation is desirable, such as in the labour ward or following ambulatory surgery. Ropivacaine being comparatively less cardio toxic also produces minimal motor blockade of shorter duration [17] which also relieves the psychological distress of being immobile for a longer period of time after surgery compared to intrathecal Bupivacaine during lower abdomen and lower limb surgeries [4]. Extensive clinical data have shown that ropivacaine is effective and safe for regional anaesthetic techniques such as epidural and brachial plexus block. However, experience of intrathecal anaesthesia with ropivacaine is not as well documented [5].

Aims and Objectives

To compare the effects of intrathecal isobaric 0.5% Ropivacaine with isobaric 0.5%. Bupivacaine in a ratio of 1:1 by volume (Ropivacaine 20 mg and Bupivacaine 20 mg) for lower abdominal and lower limb surgeries with regard to:

1. Onset and duration of sensory block
2. Onset and duration of motor block.
3. Maximum height of sensory block.
4. Post operative spinal level regression
5. Haemodynamic effect
6. Quality of anesthesia
7. Adverse reactions if any.

Materials and Methods

Source of Data

A prospective randomized comparative study was conducted on 80 patients undergoing elective lower abdominal/limb surgery under subarachnoid block at a tertiary care centre during the period from November 2014 to October 2016.

Inclusion Criteria

All patients of ASA grade I and II., undergoing elective surgeries.

Exclusion Criteria

Patients having deformities of spine and infection at the site of insertion of spinal needle. Patients having bleeding disorders/coagulation abnormalities/ raised intra cranial pressure. Patients who fail to achieve desired sensory and motor blockade were excluded from the study.

The study protocol was approved by Hospital Ethics committee and Ethical Clearance was obtained from the institution for the study. Written informed consent was obtained. Preoperative preparation and optimization of the patients were done as per protocol.

Method

Eighty patients were randomly divided into two groups of forty each.

Group B - Forty patients receiving 4 ml of injection 0.5% isobaric Bupivacaine intrathecally.

Group R - Forty patients receiving 4 ml of 0.5% isobaric Ropivacaine intrathecally.

After shifting the patient to operation theatre, IV access was obtained on the forearm with 18 Gauge IV canula and IV infusion started with Ringer Lactate. Patients were monitored for heart rate (HR), non invasive blood pressure (NIBP), percentage oxygen saturation (SpO_2). Under all aseptic precautions spinal anesthesia was performed with the patient in the lateral position using a 25 gauge Quincke's needle at the L_{3-4} interspaces. The study solution (4ml) was administered over 30 sec. Patient was turned gently and placed supine without elevation of extremities and tested every 5 minutes until maximal spread of sensory blockade, then every 15 and 30 minutes thereafter during the operation.

Parameters Evaluated

1. Sensory Block: Assessed using pin-prick test on each side and patients asked about the sensation. Onset time and duration of Sensory block was noted

2. Motor block: Motor block was assessed using "Modified Bromage Scale. This was performed

every minute until complete motor blockade and then every fifteen minute until return of normal motor function.

3. Vital Parameters: were recorded every 5 minute for the first fifteen minutes and then every 15 mins throughout the surgery.

Hypotension and Bradycardia

Patients were considered hypotensive when their mean arterial pressure decreased to less than 25% from baseline and were treated with injection mephenteramine 6 mg intravenously, dose titrated according to response. A decrease in the heart rate to less than 50 beats per minute was considered as bradycardia and treated with injection atropine 0.02 mg/kg intravenously.

4. Highest level of sensory and motor block with the Onset and offset time for both blockades was recorded during perioperative period.

Complications such as nausea, vomiting and shivering as well as the treatment given were noted down. At the end of surgery the quality of analgesia was judged according to patient's description, as follows: Excellent- No discomfort or pain

Good -Mild pain / discomfort, no need for additional analgesics.

Poor -Moderate to severe pain that required additional analgesics. All the patients were observed during the post operative period for 2 hours and later 6th hourly to know the duration, quality and intensity of pain. The patients were also observed for the development of PDPH and were followed up for 3-4 days.

Observations and Results

A total of 80 patients aged 18 to 60 years belonging to ASA–I and II posted for Elective lower abdomen and lower limbs surgeries were randomly selected. 40 of them belonging to Group B received 4.0 ml of 0.5% isobaric injection. Bupivacaine (20 mg) intrathecally and other 40 patients belonging to Group R received 4.0 ml of 0.5% isobaric injection Ropivacaine (20 mg) intrathecally.

After data collection, data entry was done in Excel. Data analysis was done with the help of SPSS Software Ver. 15 and Sigma - plot Ver. 11. Quantitative data is presented with the help of Mean, Standard deviation, Median and IQR.

Comparison between groups was done with the help of Unpaired T test or Mann–Whitney test as per results of Normality test. *Qualitative data* is presented with the help of Frequency and Percentage table. Association among study and control group is assessed with the help of Chi–Square test.

p value less than 0.05 is taken as significant level. Data is expressed as Mean±Std. Dev.

Age of the patients in both the groups studied varies in between 28 to 60 years of age. Both the study groups B and R are comparable in terms of age with mean age 41.30±9.45 and 40.10±10.67 years respectively. This was statistically insignificant as $p > 0.05$.

Both the study groups are comparable in terms of gender with male gender comprising the whole bulk of the population studied.

Height of the patients in both the study groups varies from 156 to 170 cms. The mean height in group B and R are 164.75±4.50 cms and 165.65±5.66 cms respectively with $p > 0.05$ which was statistically not significant.

Table 1: Comparison of age between the study groups (group B and R)

Study Parameters	Bupivacaine	Ropivacaine	P value
Age (in years)	41.30 ± 9.45	40.10 ± 10.67	0.264

Table 2: Gender distribution amongst the study groups

Gender		Study group		Total
		Bupivacaine	Ropivacaine	
Male	No.	40	40	80
	%	100.0%	100.0%	100.0%
Total	No.	40	40	80
	%	100.0%	100.0%	100.0%

Table 3: Comparison of height (in cm) between the study groups

Study Parameters	Bupivacaine	Ropivacaine	P value
Height (in cm)	164.75 ± 4.50	165.65 ± 5.66	0.141

Table 4: Comparison of weight (in kg) between the study groups

Study Parameters	Bupivacaine	Ropivacaine	P value
Weight (in kg)	76.38 ± 5.36	74.50 ± 5.07	0.087

Weight of the patients in both the groups varies from 60 to 82 kgs. with mean weight in Group B and R respectively as 76.38±5.36 kgs and 74.50±5.07 kgs. Both groups were Comparable in terms of weight of the population studied with statistically insignificant p value > 0.05.

Onset of sensory block at the level of L_1 is comparable in both the groups with mean time of 1.61±0.46 and 1.60±0.50 mins in group B and R respectively. This is statistically not significant with p > 0.05.

Table 6: Onset of sensory block

0nset of sensory block (in mins)	Bupivacaine	Ropivacaine	P value
	1.61 ± 0.46	1.60 ± 0.50	1.000

Table 7: Bromage scale grading amongst the study groups

Modified Bromage Scale in	Bupivacaine	Ropivacaine	P value
5 mins	3.00	2.00	0.000
10 mins	3.00	2.00	0.000
15 mins	3.00	3.00	1.000
30 mins	3.00	3.00	1.000
45 mins	3.00	3.00	1.000
1 hour	3.00	3.00	1.000
1 hour 30 mins	3.00	3.00	1.000
2 hours	3.00	3.00	1.000

Onset for motor blockage was determined with the help of modified Bromage scale, patient was examined every 5 minute till complete onset and thereafter every 15 mins. Time for the Onset of motor block (modified Bromage scale 3) was longer in group R (15 mins) than in group B (5 mins). This was clinically and statistically significant with p < 0.05 in the first 5 and 10 mins duration.

Significant fall in heart rate were observed in both the groups studied after administering of the intrathecal drugs during the 5th to 15th mins. with maximum fall at the 5th min. This fall in heart rate was clinically and statistically significant in both the groups studied.

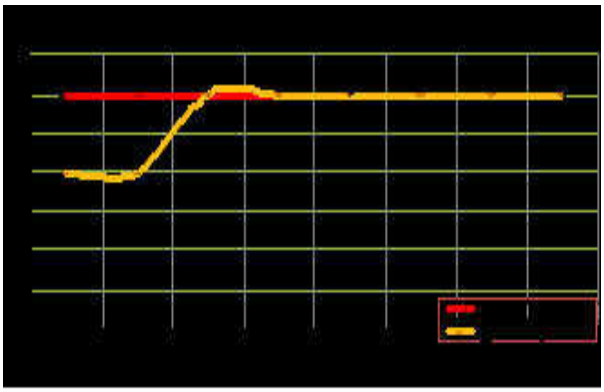

Fig. 7: Graph showing modified Bromage scale grading at various intervals

Table 8: Pulse rate changes at various intervals

Pulse (in mins)	Bupivacaine (mean ± SD)	Ropivacaine (mean ±SD)	P value
Baseline	75.35 ± 6.83	71.35 ± 5.65	0.003
5 mins	73.25 ± 7.56	66.65 ± 5.27	0.000
10 mins	70.45 ± 8.75	65.85 ± 4.72	0.004
15 mins	68.70 ± 8.84	65.65 ± 5.45	0.047
30 mins	67.15 ± 9.40	64.65 ± 4.93	0.140
45 mins	67.40 ± 5.86	64.15 ± 5.52	0.051
1 hour	66.13 ± 7.07	64.15 ± 5.59	0.170
1 hour 30 mins	66.48 ± 6.55	63.90 ± 5.64	0.063
2 hours	65.75 ± 5.86	63.90 ± 5.47	0.148

Table 9: SBP (mm Hg) at various intervals

SBP(mm hg)	Bupivacaine	Ropivacaine	P value
Baseline	126.30 ± 4.83	125.30 ± 4.76	0.385
5 mins	113.25 ± 5.08	116.00 ± 4.98	0.004
10 mins	110.25 ± 5.75	113.50 ± 4.24	0.005
15 mins	108.95 ± 6.81	111.70 ± 4.91	0.052
30 mins	107.85 ± 7.89	110.00 ± 4.10	0.130
45 mins	106.95 ± 7.46	108.75 ± 3.03	0.161
1 hour	108.10 ± 8.44	107.70 ± 3.28	0.781
1 hour 30 mins	107.65 ± 7.64	107.80 ± 3.38	0.910
2 hours	108.30 ± 6.86	106.60 ± 4.67	0.199

Fall in the systolic blood pressure was observed in both the groups after subarachnoid block with more pronounced fall with group B. Significant fall were observed during the 5th to 15th min in both the groups with major changes during the 5 th minute. This fall in the systolic blood pressure was clinically and statistically significant in both the groups studied.

Fall in the diastolic blood pressure was observed in both the groups after subarachnoid block, with more pronounced fall with group B. Significant fall were observed during the 5th to 15th mins in both the groups with major fall during the 5thmin. This fall in diastolic blood pressure was clinically and statistically significant in both the groups studied

In concurrence with the fall in systolic and diastolic blood pressure, the Mean arterial pressure (MAP) also shows corresponding fall in values between the 5th to 15 th mins of duration with maximal fall in the 5th min. This corresponding fall in the mean arterial pressure is clinically and statistically significant in both the groups studied.

Table 12 and its corresponding graph shows comparison of the two study group population in terms of various parameters. The two groups were found comparable in terms of maximum level of sensory block achieved, post operative spinal segment level regression at T_{12} and L_4 level. The two groups were found to be significantly different in respect to duration of motor block where group R has a significantly shorter duration of motor blockage with mean duration of 149.2±7.15 mins compared to 221.3±13.48 mins for those in group B. This was significant clinically and statistically with $p < 0.05$.

Table 10:

DBP(mm hg)	Bupivacaine	Ropivacaine	P value
Baseline	77.05 ± 4.90	77.35 ± 4.04	0.735
5 mins	65.80 ± 5.58	69.55 ± 3.34	0.000
10 mins	65.25 ± 5.58	67.70 ± 3.55	0.022
15 mins	65.90 ± 7.50	67.65 ± 3.21	0.563
30 mins	65.55 ± 4.14	65.55 ± 3.28	1.000
45 mins	65.80 ± 6.54	65.10 ± 3.81	0.561
1 hour	66.65 ± 6.36	64.35 ± 3.97	0.056
1 hour 30 mins	65.20 ± 6.19	63.25 ± 4.12	0.101
2 hours	64.70 ± 5.68	62.65 ± 3.97	0.065

Table 11:

MAP (mm hg)	Bupivacaine	Ropivacaine	P value
Baseline	93.55 ± 4.34	93.40 ± 3.75	0.911
5 mins	81.62 ± 4.76	85.03 ± 3.23	0.000
10 mins	80.25 ± 4.91	82.97 ± 2.96	0.004
15 mins	80.25 ± 6.62	81.67 ± 2.90	0.049
30 mins	79.65 ± 8.22	80.37 ± 2.71	0.602
45 mins	79.52 ± 6.20	79.65 ± 2.75	0.901
1 hour	80.47 ± 6.40	78.80 ± 2.88	0.137
1 hour 30 mins	79.35 ± 6.02	78.10 ± 3.39	0.256
2 hours	79.23 ± 5.50	77.30 ± 3.55	0.066

Table 12:

Study Parameters	Bupivacaine (Mean ± SD)	Ropivacaine (Mean± SD)	P value
Duration of maximum sensory block (min)	190.88 ± 18.18	197.88 ± 10.68	0.148
Duration of motor block (min)	221.25 ± 13.48	149.13 ± 7.15	0.000
Post operative spinal level T 8 (min)	190.88 ± 18.18	197.88 ± 10.68	0.148
Post operative spinal level T 12 (min)	212.38 ± 14.41	214.75 ± 10.56	0.721
Post operative spinal level L 4 (min)	231.38 ± 10.68	230.25 ± 10.50	0.576

Table 13: Comparison of side effects amongst the study groups

Side Effects	Bupivacaine	Ropivacaine	Percentage(%)
Brady/Hypotension	5	0	6.3
Hypotension	1	0	1.3
Bradycardia	0	0	0
Nil	34	40	92.5
Total	40	40	100

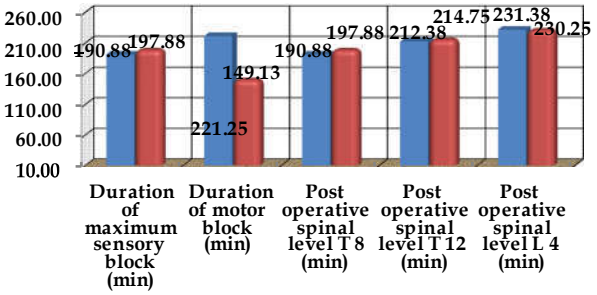

Fig. 2: Graph comparing various parameters between the two study groups

Comparison between Bupivacaine and Ropivacaine

Patients receiving Ropivacaine intrathecally were found to be more haemodynamically stable than those receiving intrathecal Bupivacaine as 5 patients presented with bradycardia and hypotension combined and one with only hypotension. They were managed accordingly with inj.mephentermine in graded doses. No significant haemodynamic changes were observed with patients of group R.

Discussion

Subarachnoid block is a commonly employed anaesthetic technique for performing lower limb/ abdominal surgeries. It is a safe, inexpensive and easy-to- administer technique which also offers a high level of post–anesthesia satisfaction for patients. The technique is simple, has rapid onset and is reliable. The risk of general Anesthesia, including mishaps due to airway management, aspiration and Polypharmacy are avoided by this technique. Bupivacaine is the local anaesthetic used routinely for lower limb/abdominal surgeries because of its high potency and minimal neurological symptoms. Though cardio toxicity is not a concern in subarachnoid block, the quality of sensory blockade, motor blockade, hemodynamic changes and side effect profile are some considerations in selecting drug for spinal anaesthesia. Ropivacaine, s-enantiomers [6] of Bupivacaine is being increasingly used for spinal anaesthesia in caesarean section, lower abdominal and perineal surgeries including lower limb surgeries. Advantages claimed are shorter duration of motor block [7] with similar sensory block properties compared to Bupivacaine (Mc Donnald SB) [8]. Thus it minimizes the psychological discomfort of being immobile for long time. Also its major advantage is lesser cardiotoxic property compared to Bupivacaine hence this study was conducted to assess the sensory and motor characteristics of ropivacaine for spinal anaesthesia in lower limb/abdominal surgeries. A prospective, randomized study was done at a Tertiary care hospital amongst 80 patients belonging to ASA I and II who underwent lower limb/abdominal surgeries under sub arachnoids block. In our study we have used a ratio of 1:1 by volume of Isobaric 0.5% Ropivacaine 20 mg and Isobaric 0.5% Bupivacaine 20 mg was used. Eighty patients were randomly divided into two groups of forty each.

Group B – Forty patients received 4 ml of 0.5% isobaric Bupivacaine intrathecally.

Group R Forty patients receiving 4 ml of 0.5% isobaric Ropivacaine intrathecally. Demographic data were comparable in the two groups. ($p>0.05$) Spinal block characteristics, haemodynamic effects and side effects were observed. Analysis of above mentioned parameters were as follows:

Demographic data: The demographic data with respect to gender, age, weight, height and type and duration of surgery were comparable in two groups. The mean age, weight and height of patients in Group B and Group R were compared and the difference was not statistically significant. The groups are comparable and by applying unpaired T test, the difference was not significant.

Sensory block at L1- All patients receiving either drug achieved adequate level of anaesthesia. We considered a block up to L_1 for onset of sensory block. Mantouvalou et al. [9] did a comparative study of plain Ropivacaine, Bupivacaine and Levobupivacaine for Lower abdominal surgeries and found that the time to achieve surgical analgesia up to T_8 dermatome was 13±2 mins for Bupivacaine group, 12±7 mins for Ropivacaine group. In our study we observe that both Ropivacaine and Bupivacaine takes almost the same time to achieve a surgical anaesthesia at the level of L_1 with mean time of onset at L_1 of 1.61±0.46 mins and 1.60±0.50 mins in Group B and R respectively.

Maximum level of sensory block: M. Mantouvalou et al. [9] noted that the cephalic spread of sensory block was similar in all groups. MC Namee et al. compared 17.5mg of plain Ropivacaine with 17.5mg of plain Bupivacaine in patients undergoing total hip arthroplasty under spinal anaesthesia. There were no significant differences in the upper extent of sensory block. In agreement to the above studies a level of T8 was attained in both the groups in our study.

4. Time for onset of motor block- M. Mantouvalou et al. [9] compared the effects of plain Ropivacaine,

Bupivacaine, LevoBupivacaine for lower abdominal surgeries and found that the mean time for onset of motor block(G3) was significantly faster in the Bupivacaine group (8± 5mins) compared with (12± 5) min in the Ropivacaine group. D.A. Mc Namee and colleagues [10] also found that the median time to achieve the Bromage score of 3 was 10 mins in the Ropivacaine group and 8mins in the Bupivacaine group. In our study, patients receiving Ropivacaine had delayed onset of motor blockade compared to Bupivacaine, this is in agreement with the above mentioned study and also study conducted by Ogun [11] and others. In our study, group B attained complete motor blockade (modified Bromage scale grade 3) within 5 mins whereas in group R it took 15 mins for complete motor blockade.

Duration of motor block- D.A. McNamee et al. [10] found that the median duration of complete motor block. Modified Bromage scale 3 was significantly shorter in the Ropivacaine group compared with Bupivacaine group. M. Mantouvalou et al observed a shorter duration of motor block among the Ropivacaine group when compared with Bupivacaine group. The duration of motor block was 269±20 mins and 278±70 mins respectively for Ropivacaine and Bupivacaine. We observed the same results with mean duration of motor block of 149.13± 7.15 mins and 221.25±13.48 mins, for Ropivacaine and Bupivacaine groups respectively.

Degree of motor blockade- Chan Jong Chung and colleagues[12] observed complete motor block in all patients receiving either Bupivacaine or Ropivacaine for caesarean section. Neval Boztug [13] and others observed complete motor blockade in 88% of patients receiving Ropivacaine and 100% patients receiving Bupivacaine when administered for knee arthroscopy. All patients in our study receiving either Ropivacaine or Bupivacaine developed complete motor block and is in agreement with above mentioned studies.

Regression of sensory block to L4 – In our study mean time taken for the regression of post-operative spinal level to L4 was 231.38±10.68 mins and 230.25±10.50 mins respectively in group B and R.

Request for rescue analgesia – No patients required supplemental analgesia intra operatively. Adequate analgesia achieved in both the groups.

Quality of anaesthesia- The anaesthesia was well accepted by all patients belonging to both groups. Majority of patients opined that the quality of anaesthesia is good to excellent with both the drugs.

Hemodynamic parameters –Neval Boztug and his colleagues [13] observed that 8.8% of patients in Bupivacaine group received inj. Ephedrine for treatment of hypotension, whereas only 2 patients received in Ropivacaine group. One in group B received i.v Atropine for bradycardia but none in group R. D.A. McNamee [19] observed in their study that intra-operative hypotension requiring treatment with inj. Ephedrine occurred in 12% of patients in R group and in 26% of patients in B group. M. Mantouvalou et al found in their study that intra-operative hypotension requiring treatment with.

Inj. Mephenteramine occurred more often in the B group than in R group. Bradycardia was also more common in group B than in group R. In our study 5 patients in group B required treatment for intra-operative Hypotension and bradycardia, 1 patient required treatment or hypotension alone but there was no incidence of intra- operative hypotension or bradycardia requiring treatment in group R.

Summary and Conclusion

Demographic parameters in both the groups were comparable. Onset of sensory block was comparable in both the groups. Level of maximum sensory block and duration of sensory block tested at the level of L4 regression was also comparable.

Onset of motor blockade was slower and duration of motor blockade was shorter with Ropivacaine compared to Bupivacaine. However, all the patients in either groups attained complete motor blockade.

With respect to hemodynamic parameters intrathecal Ropivacaine provided a higher Degree of cardiovascular stability with a lesser incidence of hypotension and bradycardia. There was no incidence of side effects like Nausea, vomiting, Shivering or PDPH in Either groups.

Our study reveals that 20 mg of isobaric Ropivacaine (4 ml of 0.5%) when administered intrathecally provides adequate anesthesia for lower limb/abdominal surgeries. It has the same onset of sensory block at the level of L_1 as well as same level of maximum sensory block attained. The duration of analgesia at L_4, (L_4 regression) was significantly same with Bupivacaine. But there is delayed onset of motor block and shorter duration of motor block with Ropivacaine compared to Bupivacaine. Cardiovascular stability is better than Bupivacaine. Hence, Ropivacaine can be used successfully for

lower limb/abdominal surgeries where early recovery is well appreciated by the patients.

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