

Comparative Evaluation of Intrathecal Isobaric Levobupivacaine 0.5% and Isobaric Ropivacaine 0.5% in Transurethral Resection of Prostate Surgeries- An Observational Study

Swati Bhau¹, Tanveer Rasool², Ayesha Naaz³, Deepak Kumar⁴, Tabasum Shebnum⁵, Showkat Ahmad Gurcoo⁶, Zaid Bin Muneer⁷, Beenish Mehraj⁸

¹Senior resident, Department of Anaesthesiology, VMMC, Delhi, India.

²Consultant Anesthesia, Capitol Multi-speciality Hospital, Jalandhar, Punjab, India

³Resident Radiology, department of Radiology and Imaging, SKIMS, Srinagar, India

⁴Consultant Anesthesia, Sarvodaya Hospital, Greater Noida, Uttar Pradesh, India

⁵Assistant Professor Anaesthesia and Critical care, Department of Anesthesia and Critical care, SKIMS, Srinagar, India.

⁶Professor and Head of the Department Anesthesia and Critical care, SKIMS, Srinagar, India

⁷Consultant Anaesthesia, KD Super speciality Hospital Jammu, India.

⁸Senior resident, Department of Anaesthesiology and Critical Care, SKIMS, Srinagar, India.

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Corresponding author: Dr. Deepak Kumar

Conflict of interest: Nil

Abstract

Background: Spinal anaesthesia (SA) is technique of choice for TURP which besides providing surgical anaesthesia and postoperative analgesia, has added advantage of preserving cerebral function which in turn allows earliest recognition of unique complication related to TURP.

Aim: To compare the onset and duration of sensory and motor block, hemodynamic stability and any side effect among the study population.

Methods: The present study was conducted in the department of Anaesthesiology and Critical Care, SKIMS, Soura, Srinagar to compare the efficacy of intrathecal isobaric levobupivacaine 0.5% and isobaric ropivacaine 0.5% in patients undergoing transurethral resection of prostate under spinal anaesthesia. This prospective, observational study was conducted over a period of 18 months. 100 male patients having BPH of ASA I and II scheduled for transurethral resection under spinal anaesthesia were assigned to two groups of 50 each. Group I received 2.5ml [12.5mgs] of isobaric ropivacaine [0.5%] with 0.5ml [25ug] of fentanyl and group II received 2.5ml [12.5mgs] of isobaric ropivacaine [0.5%] with 0.5ml [25ug] of fentanyl. All the statistical analysis was done by using SPSS software. All the categorical variables were presented in the form of frequency and percentage. All the continuous variables were analysed by using proper statistical test by checking the normality of the distribution. All the results were discussed at 5 level of significance.

Results: There was a statistically significant difference ($p < 0.05$) in highest sensory level achieved between the two groups, with more number of patients in levobupivacaine group (group II) achieving a highest sensory level (T8 and above) as compared to ropivacaine group (group I). Onset of sensory and motor block was earlier with isobaric levobupivacaine on comparison to isobaric ropivacaine ($p < 0.05$). Duration of sensory and motor block was also significantly longer with isobaric levobupivacaine as compared to isobaric ropivacaine as measured by the time taken for regression of sensory and motor blockade ($p < 0.05$). time from injection of drug to first supplemental analgesia was longer in levobupivacaine group as compared to ropivacaine indicating longer duration of post-operative analgesia with levobupivacaine ($p < 0.05$).

Conclusion: We conclude that 0.5% isobaric ropivacaine with fentanyl and 0.5% isobaric levobupivacaine with fentanyl provide adequate spinal block for transurethral resection of prostate. Ropivacaine can be used for day care surgeries with early ambulation and faster home discharges, levobupivacaine is better for surgeries who need prolonged duration of spinal anaesthesia.

Keywords: Spinal anaesthesia, Levobupivacaine, Ropivacaine, TURP, Hemodynamic, Sensory and Motor block.

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Introduction

Spinal anaesthesia has been widely used for urologic operations because it permits early recognition of symptoms caused by over-hydration, transurethral resection of prostate (TURP) syndrome, and bladder perforation. In addition, short acting spinal anaesthesia may help to prevent complications associated with delayed immobilization. [1]

Spinal anaesthesia may offer several advantages over general anaesthesia. [2] It is particularly useful for patients with significant respiratory disease. It confers good postoperative analgesia and may reduce the stress response to surgery. More importantly, spinal anaesthesia allows the anaesthetist to monitor the patient's level of consciousness, which makes it easier to detect the early signs of TURP syndrome. Early recognition of capsular tears and bladder perforation is also possible as the patient complains of periumbilical or shoulder pain provided the spinal level is limited to T10.[2]

Spinal administration of local anaesthetics during transurethral resection of prostate (TURP) produce analgesia, anaesthesia and motor block, depending on the volume, concentration and doses of drug used. For the local anaesthetics selection, it is known that the agent's onset and duration of action, sensory block level to motor block level and cardiac toxicity should be considered. [3-7] The control of the spread of the drug in the cerebrospinal fluid that produces predictable levels of sensorimotor blockade without any major complication is the prime challenge in spinal anaesthesia. [8]

Local anaesthetic and opioid combination techniques have been studied in the surgical population. The local anaesthetic works at nerve axons while the opioid works at the receptacle site in the spinal cord. Fentanyl acts primarily as agonist at μ -

opioid receptors to enhance spinal analgesia.[9,10] Intrathecal opioids added to local anaesthetics enhance analgesia without intensifying motor and sympathetic block, and make it possible to achieve successful anaesthesia in spite of the use of a low dose local anaesthetic [11,1,12] and resulting in lower incidence of hypotension, early recovery and mobilization. [13]

Methods

This study entitled "Comparative evaluation of intrathecal isobaric levobupivacaine 0.5% and isobaric ropivacaine 0.5% in Transurethral resection of prostate surgeries - An observational study" was undertaken in the Department of Anaesthesiology & Critical Care, SKIMS, Soura

Srinagar, India, over a period of 18 months from 2017-2019. After Institutional Ethical Committee approval, 100 patients of ASA grade I and II males age above 60 years undergoing transurethral resection of prostate (TURP) were allocated to two groups of 50 patients each. A proper informed written consent was taken from all patients participating in the study.

The study population of 100 patients was divided into two groups of 50 patients each.

Group I included 50 patients and received 2.5ml [12.5mgs] of isobaric ropivacaine [0.5%] with 0.5ml [25ug] of fentanyl making a total of 3ml.

Group II included 50 patients and received 2.5ml [12.5mgs] of isobaric levobupivacaine [0.5%] with 0.5ml [25ug] of fentanyl making a total of 3ml.

No premedication was given to patients. In the operation theatre, intravenous line with 18 gauge cannula was secured and after routine monitoring, each patient in the study received infusion of 20 ml/kg of Ringer's lactate fluid. The baseline hemodynamic values were recorded and then spinal anaesthesia was performed in sitting position after proper preparation of the area with antiseptic solution, using a 26G Quincke needle at the L3-4 interspace and a midline approach.

The direction of the needle was kept cranial during the injection. After free flow of CSF verified, anaesthetic solution was given in 15 seconds without barbotage or aspiration. Immediately after the injection of the drug, the patients were placed in supine position. Heart rate, mean arterial pressure, systolic blood pressure, diastolic blood pressure and oxygen saturation were recorded every 2 minutes for 15 minutes after intrathecal injection and every 5 minutes thereafter.

A 20% decrease from baseline SBP or SBP <90 mm Hg or a decrease of mean arterial BP of < 65 mmHg, defined as Hypotension and treated with intravenous boluses of ephedrine 5 mg and bradycardia [Heart rate < 60] associated with hypotension was treated with i.v atropine 0.5 mg. Supplemental oxygen at 4 litres/min was given to all patients via nasal cannula.

Sensory and motor block were assessed every 2 minutes for 15 minutes after intrathecal injection and every 5 minutes thereafter until the sensory block regressed to S1. Anaesthesia was considered adequate for surgery when pain sensation as assessed by principle method was lost at T10 level. Patients were then placed in lithotomy position and surgery started. The time to achieve sensory block to T10, highest level of sensory block and time to regression of sensory block to S1 were recorded.

VAS SCORE was monitored hourly in postoperative period after completion of surgery till 6th hour, subsequently 2 hourly till 12th hour then 3 hourly till completion of 24 hours. In the postoperative period, the time to first analgesic demand was noted and injection paracetamol 1gm was administered in patients with VAS > 3.

Patients were observed for any discomfort, nausea, vomiting, shivering, pruritis, bradycardia, and any

other side effects. All patients were observed in the post anaesthesia care unit [PACU] and later in the ward.

Results: Both the groups were comparable in terms of Age and ASA class and no statistically significant difference was found ($P > 0.05$) [Table 1].

Table 1: Comparison of demographic profile

Variables	Group I	Group II	P value
Age (years)	69.0 ±3.45	69.44±3.96	0.883
ASA I/II	25/25	22/28	0.384

Onset of sensory and motor block was earlier with isobaric levobupivacaine on comparison to isobaric ropivacaine ($p < 0.05$) [Table 2]. Duration of sensory and motor block was also significantly longer with isobaric levobupivacaine as compared to isobaric ropivacaine as measured by the time taken for

regression of sensory and motor blockade ($p < 0.05$) [Table 2]. Time from injection of drug to first supplemental analgesia was longer in levobupivacaine group as compared to ropivacaine indicating longer duration of post-operative analgesia with levobupivacaine ($p < 0.05$) [Table 2].

Table 2: Comparison of Block characteristics and duration of analgesia.

Variables	Group I	Group II	P value
Time from injection to highest sensory level achieved	9.4340±4.66	6.8080±1.92	*0.000
Time from injection to grade 1 motor block	5.12±2.29	3.68±1.32	*0.000
Time from injection to grade 3 motor block	8.19±3.20	5.15±1.64	*0.002
Sensory regression to S1	286.56±43.05	383.14±16.14	*0.001
Motor regression to grade 1	224.32±39.20	331.92±47.59	*0.034
First Supplemental Analgesia	373.32± 29.37	435.32± 27.601	*0.001

There was no significant difference in baseline heart values (p value = 0.396). Mean heart rate was comparable after injection of drug (p value = 0.197). But significant differences in mean heart rate were observed between the two groups at 5 minutes after spinal anaesthesia, with lower mean heart rate in group II (Group I : 79.06±14.14 vs Group II: 73.52±8.51) with a p value = 0.020 [Fig 1].

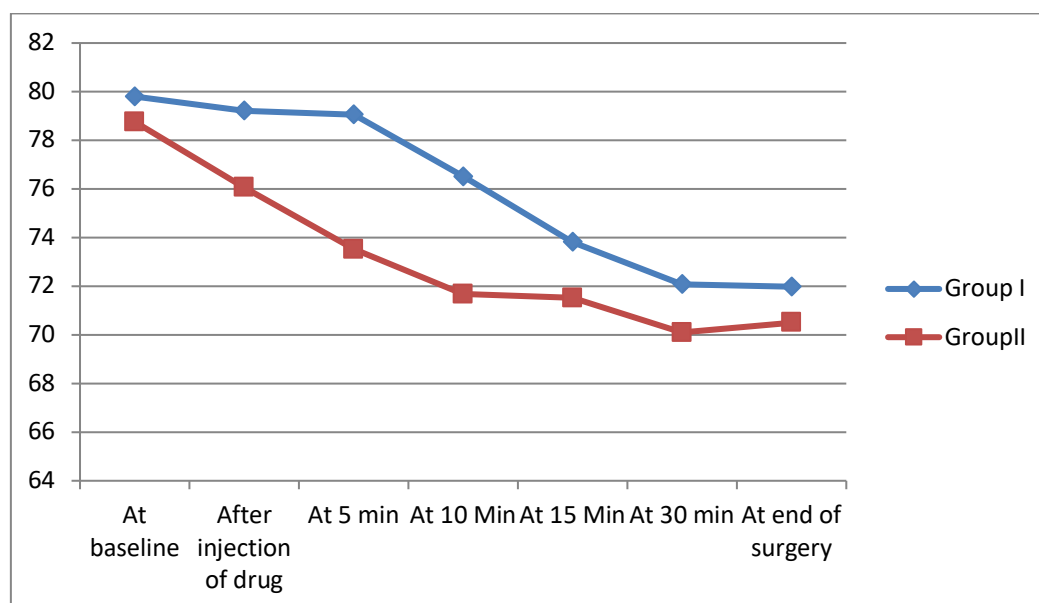


Figure 1:

There was statistical insignificant difference in baseline mean systolic blood pressure between the two groups (p value = 0.239). Significant difference in mean systolic blood pressure was observed between two groups at 5min ($p < 0.05$) with mean systolic blood pressure in group II remained lower than group I [Fig 2].

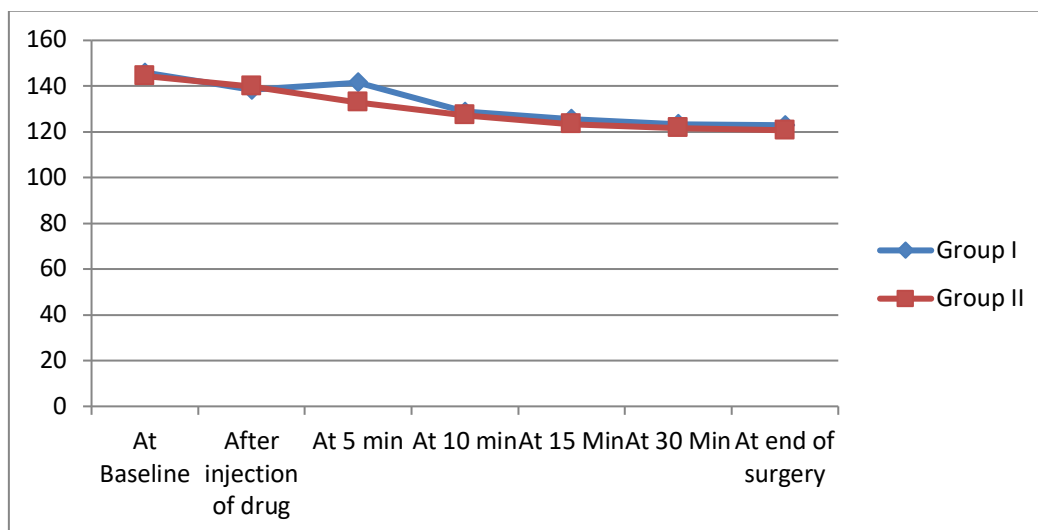


Figure 2:

There was no statistically significant difference in baseline diastolic blood pressure values in both groups (p value=0.766). There was no statistically significant difference in mean diastolic blood pressure at subsequent stages of study (p value > 0.05) [Fig 3].

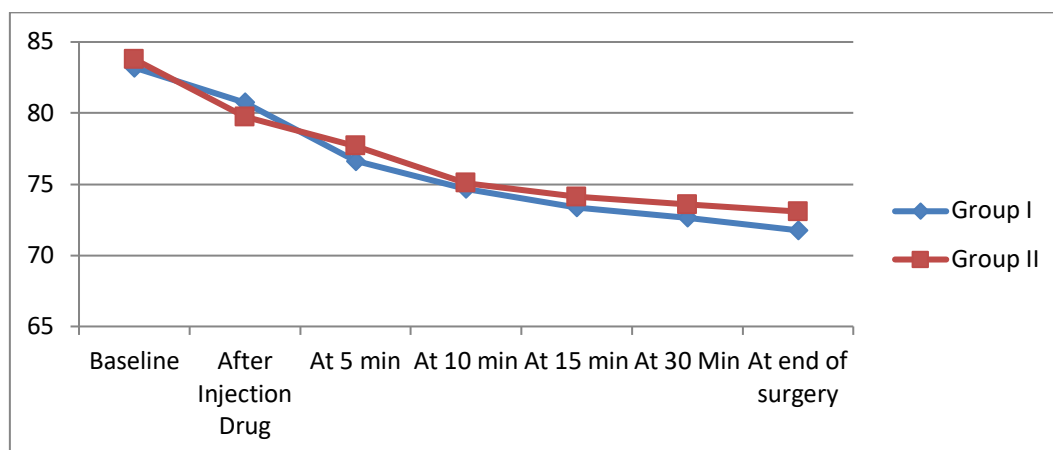


Figure 3:

There was statistically insignificant difference in baseline mean MAP between the two groups ($p = 0.342$). Significant difference in mean MAP was observed between two groups at 5 min ($p < 0.05$) with mean MAP in group II remained lower than group I [Fig 4].

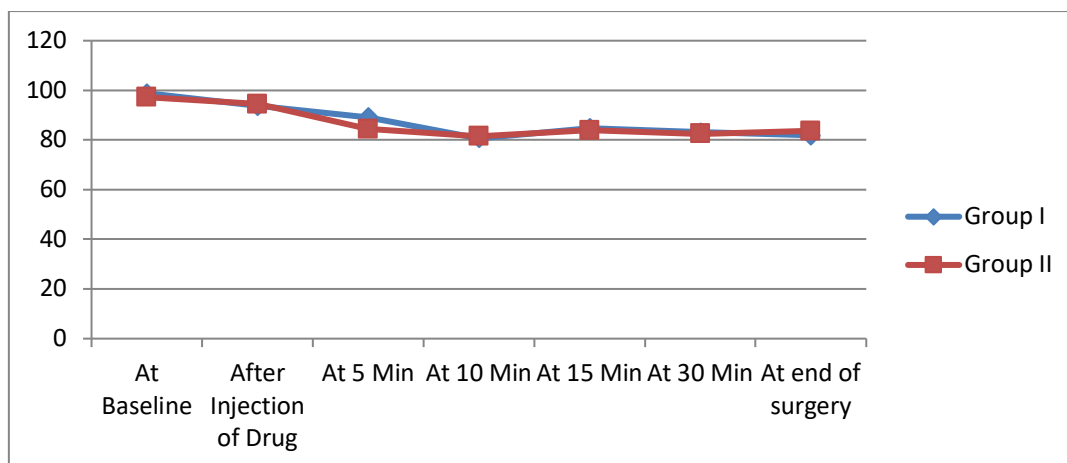


Figure 4:

With respect to bradycardia, number of patients experiencing bradycardia were less with isobaric levobupivacaine as compared to isobaric ropivacaine ($p < 0.05$).

With respect to hypotension, nausea and vomiting, a slightly more number of patients experienced these side effects with isobaric levobupivacaine as compared to isobaric ropivacaine but the results

were statistically insignificant ($p > 0.05$). A slightly more number of patients experienced shivering with isobaric ropivacaine as compared to isobaric levobupivacaine but the difference was statistically insignificant ($p > 0.05$).

None of our patients in either of the study group experienced respiratory depression in our study [Fig 5].

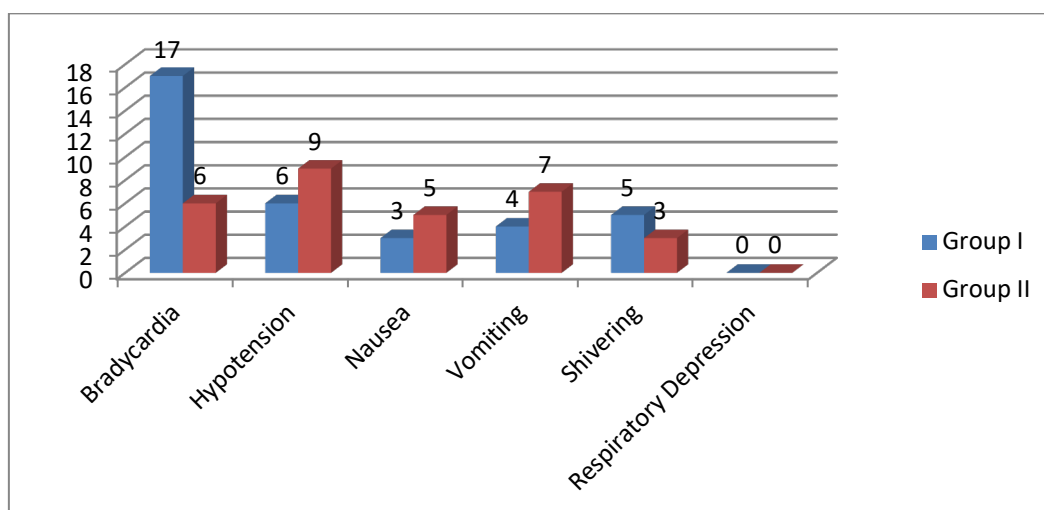


Figure 5:

Discussion

Spinal anaesthesia began to develop towards the late nineteenth century as an effective mode of providing regional anaesthesia.³ Neuraxial anaesthesia methods are preferred for transurethral procedures due to advantages such as reduced postoperative pain, less nausea and vomiting, early patient mobilization and shorter hospital stay. [14]

Neuraxial anaesthesia can be performed with local anaesthetics at different doses and bariicity. Local anaesthetics can be combined with opioids, and the addition of opioids allows for the use of a lower dose of local anaesthetic, which results in more stable hemodynamics. The low-dose local

anaesthetic may reduce the extent of the spinal block and may also provide a favourable profile for the resolution of the spinal block, which can be useful in the ambulatory setting. [15-17]

It has been found that isobaric local anaesthetics are ideal for surgeries below T10 level of block and high volumes are required for surgeries above T10. In our study, we selected patients posted for transurethral resection of prostate requiring a blockade below T10. All the patients in our study were given spinal anaesthesia in sitting position considering patient comfort and a fact that level of sensory block after intrathecal administration of isobaric local anaesthetics is unaffected by the patient position. [18,19] Baseline heart rate was

comparable between the two groups ($p>0.05$). After spinal anaesthesia decrease in mean HR was observed in both the groups. At most of the study stages comparison of mean HR between the two groups did not show any statistically significant difference ($p>0.05$) except at 5 min and at 10 min interval ($p<0.05$). These findings were in concordance with the study conducted by Athar M, et al. (2016) [20] who compared levobupivacaine and ropivacaine at equipotent doses in patients undergoing spinal anaesthesia for lower limb surgery in a prospective, randomised double blind controlled trial and observed a comparable intraoperative mean HR between the two groups.

Baseline DBP was comparable between the two groups ($p>0.05$). Intraoperative DBP was also comparable between the two groups at all the study stages with no statistically significant difference ($p>0.05$). There was a slight decrease in DBP after anaesthesia in each study group which however was not associated with any significant intergroup differences. Baseline MAP between the two study groups was comparable ($p>0.05$). After anaesthesia, there was a slight decrease in MAP in each study group but was not associated with significant intergroup difference ($p>0.05$) at most of the study stages (except at 5 min). Our results were in concordance with the study conducted by Athar M, et al. (2016) [20] who also in their study found no comparative intraoperative difference in hemodynamics ($p>0.05$). These findings in hemodynamics were also in concordance with the study conducted by Mehta A, et al. (2007) [21] who in their study of comparative evaluation of intrathecal administration of newer local anaesthetic agents ropivacaine and levobupivacaine with bupivacaine in patients undergoing lower limb surgery, found no significant difference between intraoperative mean SBP, mean DBP, mean MAP between the two groups.

In our study, more patients in group II receiving isobaric levobupivacaine achieved a sensory level of T8 and above as compared to those in group I receiving isobaric ropivacaine. Singh G, et al. (2017) [22] in their study compared isobaric levobupivacaine 0.5% and isobaric ropivacaine 0.5% for spinal anaesthesia in lower limb surgeries in patients belonging to age group of 18-65 years. Our results were in concordance with this study which also observed more patients receiving intrathecal levobupivacaine achieved a highest sensory level of T6 ($n=18$) as compared to those receiving ropivacaine ($n=8$). Athar M, et al. (2016) [20] in their study observed the median maximum height achieved in terms of dermatomes in both study groups receiving intrathecal ropivacaine and levobupivacaine was T7. Athar M, et al. did not use fentanyl as additive in their study and even the age

group in their study was different (18-60years) as compared to our study (>65 years).

Onset of sensory block (as measured by time taken to achieve highest sensory level) was earlier in group II receiving levobupivacaine as compared to group I receiving ropivacaine. Onset of sensory block defined as time taken to achieve T10 level was 9.43 ± 4.66 min in group I receiving ropivacaine and 6.80 ± 1.92 min in group II receiving levobupivacaine. This difference in the onset of sensory block was statistically highly significant ($p=0.000$). Onset of motor block (as measured by time taken to achieve grade 1 and grade 3 motor block) was also earlier in group II receiving levobupivacaine when compared with group I receiving ropivacaine and the difference was also statistically significant between the two groups ($p<0.05$). The mean time from injection of drug to grade I motor block was 5.12 ± 2.29 min in group I and 3.68 ± 1.32 min in group II. The difference was statistically highly significant ($p=0.000$).

The mean time from injection of drug to grade III motor block was 8.19 ± 3.20 min in group I and 5.15 ± 1.64 min in group II. The difference was statistically significant with p value of 0.002. These findings were similar to study conducted by Mehta A, et al. (2007) [21] who in their study compared isobaric ropivacaine and isobaric levobupivacaine with isobaric bupivacaine in patients undergoing lower limb surgery and observed a significantly earlier onset of sensory and motor block with levobupivacaine as compared to ropivacaine. Our results were also in concordance with study conducted by Das A, et al. (2015) [23] in which they compared the effects of intrathecal isobaric solutions of bupivacaine, levobupivacaine and ropivacaine in lower abdominal surgery in a double blinded, randomised controlled trial. They also observed a significantly earlier onset of sensory and motorblock in group receiving levobupivacaine when compared with the group receiving ropivacaine.

In our study, duration of sensory block as measured by sensory regression to S1, was longer in the group that received levobupivacaine as compared to group receiving ropivacaine. The results were statistically significant ($p<0.05$) between the two groups with mean $\pm$ SD of 286.56 ± 43.05 min in ropivacaine group and 383.14 ± 16.14 min in levobupivacaine group. Duration of motor block as measured by motor regression to grade 1, was also longer in the group that received levobupivacaine as compared to group receiving ropivacaine. The results were statistically significant ($p<0.05$) with mean $\pm$ SD of 224.32 ± 39.20 min in group I receiving ropivacaine and 331.92 ± 47.59 min in group II receiving levobupivacaine.

These findings were similar to the study conducted by Das A, et al. (2015) [23] in which the duration of sensory and motor block was longer in the group receiving levobupivacaine as compared to the group that received ropivacaine with statistically significant difference ($p < 0.05$). In a study conducted by Singh G, et al. (2017) [22], similar results were found. The duration of sensory and motor block was longer in the group receiving levobupivacaine as compared to the group receiving ropivacaine with highly significant result ($p < 0.05$).

The time of establishment of spinal anaesthesia to time for first supplemental analgesia was observed in our study and it was observed that the time for first supplemental analgesia was longer in group receiving levobupivacaine as compared to group receiving ropivacaine with mean $\pm$ SD of 373.32 ± 29.37 min in group I receiving ropivacaine and 43 ± 27.60 min in group II receiving levobupivacaine. The difference between the two groups was statistically significant ($p = 0.001$). These results were consistent with those found by Das A, et al. (2015)[23], who in their study compared duration of analgesia of intrathecal 3ml of 0.5% bupivacaine, 3ml of 0.5% levobupivacaine and 0.75% ropivacaine in lower abdominal surgeries. It was found that duration of analgesia was more in patients who received levobupivacaine as compared to ropivacaine which was similar to that found in our study. In the study conducted by Mantouvalou M, et al. (2008)[24] comparing plain bupivacaine, ropivacaine and levobupivacaine in patients undergoing spinal anaesthesia for lower abdominal surgery found similar results as observed in our study with a prolonged duration of analgesia with levobupivacaine as compared to ropivacaine.

With respect to hypotension, similar findings were observed in the study conducted by Singh G, et al. (2017)[22] with a slight more number of patients in group levobupivacaine experiencing hypotension as compared to group receiving ropivacaine but the difference was statistically insignificant ($p > 0.05$). With respect to hypotension, our results were also similar to those observed by Das A, et al. (2015)[23] who found no statistically significant difference between the groups receiving ropivacaine and levobupivacaine ($p > 0.05$).

In our study, there was insignificant difference between the two groups with respect to nausea and vomiting ($p > 0.05$) with a slightly higher number of patients in group receiving levobupivacaine experiencing nausea and vomiting as compared to ropivacaine. With respect to nausea and vomiting, the results in our study were consistent with the study conducted by Mehta A, et al. (2007)[22] with statistically insignificant difference ($p > 0.05$). Athar M, et al. (2016)[21] in their study, with respect to

nausea, our results were similar to their study with slightly more number of patients in group levobupivacaine experiencing nausea as compared to patients in group ropivacaine. However the results were statistically insignificant ($p > 0.05$).

In our study, with respect to shivering the difference was statistically insignificant ($p > 0.05$) with slightly more patients in levobupivacaine group ($n=5$) experiencing shivering as compared to patients receiving ropivacaine ($n=3$). However, with respect to shivering the results were not similar to the study done by Athar M, et al. (2016). [21] In their study, more number of patients in ropivacaine group experienced shivering as compared to levobupivacaine but the results were statistically insignificant ($p > 0.05$) like the one observed in our study. With respect to respiratory depression, no patient in either of the group experienced respiratory depression.

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