Comparison of efficacy of Interathecal 0.5\% Isobaric Levobupivacaine With Fentanyl Versus 0.5\% Isobaric Bupivacaine with Fentanyl for Inguinal Hernia Repair

Charuta Gadkari\(^1\), Prakash Singh\(^2\), Rishihesh Jirapure\(^3\), Anjali Bhure\(^4\)

**ABSTRACT**

**Introduction:** As practice of medicine focuses increasingly on outpatient care, spinal anaesthetics should provide short acting and adequate anaesthesia without compromising early ambulation and discharge from day care surgery unit. Both clinical and preclinical trials have demonstrated a better safety profile for Levobupivacaine than for Bupivacaine. In this study we proposed to compare a combination of low dose Levobupivacaine with Fentanyl to low dose isobaric racemic Bupivacaine with Fentanyl for the characteristics of spinal blockade with respect to onset and duration.

**Material and Methods:** The present study was conducted among 70 patients who were classified as American Society of Anaesthesiologists (ASA) physical status I or II, undergoing elective inguinal hernia repair surgeries under spinal anaesthesia divided into two groups of 35 each. Patients in Group LB were given Levobupivacaine 0.5\% isobaric 5 mg (1ml) + Inj. Fentanyl 25 µg (0.5ml) and Group B were given Bupivacaine 0.5\% isobaric 5 mg (1ml) + Inj. Fentanyl 25 µg (0.5ml). The onset of motor blockade (Time taken for motor blockade to reach Modified Bromage Scale 1) and duration of motor blockade (Regression of motor blockade to Modified Bromage scale 0) were noted. Sensory and motor blocks were assessed at the start of surgery and at the end of surgery for comparison between groups.

**Results:** Intrathecal 0.5\% isobaric Levobupivacaine with Fentanyl combination has slower onset of sensory blockade and motor blockade, slower time for achieving peak sensory levels when compared to 0.5\% isobaric bupivacaine with Fentanyl combination. But, intrathecal 0.5\% isobaric Levobupivacaine has a faster onset of two segment regression, faster S2 regression and faster regression of motor block when compared to 0.5\% isobaric bupivacaine with Fentanyl combination. Similarly, the time to ambulation and time to urination are also early with intrathecal 0.5\% isobaric Levobupivacaine.

**Conclusion:** Intrathecal 0.5\% isobaric Levobupivacaine offers an advantage for the patient for faster discharge hence can be suitable for day care surgeries.

**Keywords:** Intrathecal; Levobupivacaine; Spinal Anaesthesia

**INTRODUCTION**

Spinal anaesthesia is popular and commonly used worldwide. The advantages of an awake patient, minimal drug costs and rapid patient turnover have made this the method of choice for many surgical procedures.\(^1\) As practice of medicine focuses increasingly on outpatient care, spinal anaesthetics should provide short acting and adequate anaesthesia without compromising early ambulation and discharge from day care surgery unit.\(^3\) Levobupivacaine is an interesting alternative to Bupivacaine for spinal anaesthesia. It produces sub arachnoid block with similar sensory and motor characteristics and recovery like Bupivacaine. Intrathecal administrations of 15 mg of Levobupivacaine provide an adequate sensory and motor block lasting for approximately 6.5 hours. Smaller doses (i.e. 5-10mg) have been used in day-case surgeries.\(^4\) Both clinical and preclinical trials have demonstrated a better safety profile for Levobupivacaine than for Bupivacaine. Preclinical studies with the two enantiomer of B support the idea that the lower cardiac toxicity of LB in humans is due to its lower direct effect on the heart, although other external factors should not be disregarded. The lower cardiac toxicity, along with the equivalent anaesthetic potency, suggests that LB is a safer anaesthetic than the racemic form of B.\(^5\)\(^6\)

The addition of opioids to LA spinal anaesthesia increases anaesthesia quality and ensures effective analgesia during intraoperative and early postoperative periods. For this reason, the strongly lipophilic drugs sufentanil and Fentanyl are preferred.\(^7\)

In this study we proposed to compare a combination of low dose Levobupivacaine with Fentanyl to low dose isobaric racemic Bupivacaine with Fentanyl for the characteristics of spinal blockade with respect to onset and duration to assess suitability for ambulatory anaesthesia application.

**MATERIAL AND METHODS**

The present Prospective Double Blind Randomized Trial was conducted among 70 patients (35 in each group) undergoing inguinal hernia repair under subarachnoid block in a tertiary care hospital. The study was approved by the institutional ethics committee. The study was conducted among 35 patients from each group undergoing inguinal hernia repair under spinal anaesthesia. The study was approved by the institutional ethics committee. The study was conducted among 35 patients (35 in each group) undergoing inguinal hernia repair under spinal anaesthesia. The study was approved by the institutional ethics committee. The study was conducted among 35 patients (35 in each group) undergoing inguinal hernia repair under spinal anaesthesia. The study was approved by the institutional ethics committee. The study was conducted among 35 patients (35 in each group) undergoing inguinal hernia repair under spinal anaesthesia. The study was approved by the institutional ethics committee.

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\(^1\)Professor, Department of Anaesthesiology, NKPSIMS and RC, Nagpur, \(^2\)Senior Resident, Department of Anaesthesiology, NKPSIMS and RC, Nagpur, \(^3\)Junior Resident, Department of Anaesthesiology, NKPSIMS and RC, Nagpur, \(^4\)Professor and Head, Department of Anaesthesiology, NKPSIMS and RC, Nagpur, Maharashtra, India

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ethics committee (IEC). Subjects were enrolled after obtaining written informed consent for participation in the study. Inclusion Criteria consisted of 50-70 years aged with 160-180 cm height and 50-70 Kg weight fulfilling criteria of American Society of Anesthesiologist (ASA) Physical Status: I, II. Patients with infection at the intended site of spinal needle insertion, history of hypersensitivity to study drugs, severe cardiac disease, abnormal coagulation status and pre-existing neurological and musculoskeletal disease were excluded from the study. A pilot study was conducted initially on 10 subjects in each group and then the minimum sample size was calculated with 95% confidence interval and 95% power to be 33 in each group. A thorough preanaesthetic examination of the patient was done. Investigations were done as per individual patient assessment and requirement. Patients were also explained about Visual analogue scale (VAS).

The study population consisted of seventy patients undergoing elective inguinal hernia repair surgeries under spinal anaesthesia divided into two groups of 35 each. Patients in Group LB were given Levobupivacaine 0.5% isobaric 5 mg (1ml) + Inj. Fentanyl 25 µg (0.5ml) and Group B were given Bupivacaine 0.5% isobaric 5 mg (1ml) + Inj. Fentanyl 25 µg (0.5ml). Preparation of patients included overnight fasting and the patients were pre-medicated. Monitoring included three lead ECG in Standard lead II, Non-invasive Blood pressure, Respiratory rate, Pulse oximetry, (SpO2), Capnography (Et-CO2).

The onset of sensory anaesthesia was tested by pinprick bilaterally in the mid clavicular line. Sensory anaesthesia was defined as the loss of sharp sensation to pinprick test. The onset of sensory block was defined as loss of pinprick sensation at L1. Peak sensory level was defined as the sensory level which remained same for consecutive three assessments. Peak sensory level and time to achieve peak sensory level was recorded. Sensory blockade was assessed every minute for first 10 minutes, every 2 minutes till 20 minutes, thereafter, every 10 min during surgery till end of surgery and every 15 min postoperatively to note 2 segment regression and S2 segment regression. The time for total duration of surgery was calculated. All durations were calculated considering the time of spinal injection as time 0. Motor blockade was determined using Modified Bromage scale. Motor blockade was assessed at same points. The onset of motor blockade (Time taken for motor blockade to reach Modified Bromage Scale 1) and duration of motor blockade (Regression of motor blockade to Modified Bromage scale 0) were noted. Sensory and motor blocks were assessed at the start of surgery and at the end of surgery for comparison between groups.

RESULTS

The mean time for onset of sensory blockade was higher in case of Group LB (2.50 ± 0.51 minutes) when compared to Group B (1.67 ± 0.37 minutes) and the difference was statistically significant (p value <0.0001). The mean time for onset of motor blockade was higher in case of Group LB (3.34 ± 0.25 minutes) when compared to Group B (2.46 ± 0.24) and the difference was statistically significant (table 1). The mean time for peak sensory level was higher in case of Group LB (8.49 ± 0.59 minutes) when compared to Group B (7.53 ± 0.35 minutes) and the difference was statistically significant (table 1). The maximum sensory level was at T5 in Group LB and T4 in case of Group B. This was significant with p value <0.05 (table 1). The comparison of the sensory blockade at the start of surgery for the two groups showed that in Group LB, 17.14% had T4, 25.71% had T4-T6 and 57.14% had T6-T8 level at the start of surgery. In Group B, 51.43% had T4, 11.43% had T4-T6 and 37.14% had T6-T8 level at the start of surgery. There was a significant difference between the T4 levels of the two groups (p value= 0.002). The comparison of the sensory blockade at the end of surgery for the two groups showed that in Group LB, 17.14% had T4, 20.00% had T4-T6 and 62.86% had T6-T8 level at the start of surgery. In Group B, 40.00% had T4, 17.14% had T4-T6 and 42.86% had T6-T8 level at the start of surgery. There was a significant difference between the T4 levels of the two groups (p value=0.03) (table 2).

Table 3 shows the comparison of the Bromage motor blockade scores at the start and end of surgery for the two groups. In Group LB, 94.29% had Grade 2 and 5.71% had Grade 3 score at the start of surgery. In Group B, 77.14% had Grade 2 and 22.86% had Grade 3 score at the start of surgery. There was no significant difference between the Bromage scores of the two groups (P value=0.08). The comparison of the Bromage motor blockade scores at the end of surgery for the two groups showed that in Group LB, 57.14% had Grade 1, 42.86% had Grade 2 and none had Grade 3 score at the end of surgery. In Group B, 20.00% had Grade 1, 57.14% had Grade 2 and 22.86% had Grade 3 score at the end of surgery. There was no significant difference between two groups for Score 2 (p=0.2319). But, there was a significant difference between the two groups for Grade 1 (p=0.001) and Grade 3 (p=0.004). Table 5 shows comparison of regression of block between two groups. The mean time for two segment regression was lower in case of Group LB (66.11 ± 2.78 minutes) when compared to Group B (71.40 ± 5.35 minutes) and the difference was statistically significant (p value <0.001). The mean time for S2 segment regression was lower in case of Group LB (166.89 ± 4.25 minutes) when compared to Group B (171.48 ± 6.19 minutes) and the difference was statistically significant (p value <0.001) (table 4).

Table 5 shows the comparison of time to ambulation between two groups. The mean time for ambulation was less in case of Group LB (215.80 ± 14.96 minutes) when compared to Group B.
Parameters | Groups (Mean ± SD) | P-value*
---|---|---
Time for onset of sensory blockade in min | LB (n=35) | B (n=35) | <0.0001
2.50 ± 0.51 | 1.67 ± 0.37
Time for onset of Motor blockade in min | LB (n=35) | B (n=35) | <0.0001
3.34 ± 0.25 | 2.46 ± 0.24
Time for peak sensory levels in min | LB (n=35) | B (n=35) | <0.0001
8.49 ± 0.59 | 7.53 ± 0.35
Maximum sensory level (Median) | LB (n=35) | B (n=35) | <0.05
T5 | T4

Table-1: Comparison of characteristics of sensory and motor blockade in two groups

Parameters | Groups N (%) | P-value*
---|---|---
Sensory blockade at the start of surgery | LB (n=35) | B (n=35) | 0.002
T4 | 6(17.14) | 18 (51.43)
T4-T6 | 9(25.71) | 4(11.43)
T6-T8 | 20(57.14) | 13(37.14)
Sensory blockade at the end of surgery | LB (n=35) | B (n=35) | 0.0542
T4 | 6(17.14) | 14(40.00)
T4-T6 | 7(20.00) | 6(17.14)
T6-T8 | 22(62.86) | 15(42.86)

Table-2: Comparison of the Sensory blockade at the start and end of surgery for the two groups

Parameters | Groups N (%) | P-value*
---|---|---
Bromage motor blockade scores at the start of surgery | LB (n=35) | B (n=35) | 0.08
Score 1 | 0(0) | 0(0)
Score 2 | 33(94.29) | 27(77.14)
Score 3 | 2(5.71) | 8(22.86)
Bromage motor blockade scores at the end of surgery | LB (n=35) | B (n=35) | 0.2319
Score 1 | 20(57.14) | 7(20.00)
Score 2 | 15(42.86) | 20 (57.14)
Score 3 | 0(0) | 8(22.86)

Table-3: Comparison of the Bromage motor blockade scores at the start and end of surgery for the two groups

Regression of block | Groups (Mean ± SD) | P-value*
---|---|---
LB (n=35) | B (n=35) | <0.001
Two segment regression (min) | 66.11 ± 2.78 | 71.40 ± 5.35
Time to S2 Regression (min) | 166.89 ± 4.25 | 171.48 ± 6.19
Time to bromage score zero | 154.94 ± 8.40 | 182.40 ± 5.00

Table-4: Comparison of regression of sensory and motor blocks between two groups

Time to ambulation (min) | Groups (Mean ± SD) | P-value*
---|---|---
LB (n=35) | B (n=35) | <0.001
195.87 ± 15.56 | 219.98 ± 12.93

Table-5: Comparison of Time to ambulation between two groups

Time to urination (min) | Groups (Mean ± SD) | P-value*
---|---|---
LB (n=35) | B (n=35) | <0.001
215.80 ± 14.96 | 239.64 ± 11.91

Table-6: Comparison of Time to urination between two groups

DISCUSSION

Spinal anesthesia is an important tool for anesthesiologist and has been under trial to improve the technique since a decade. Characteristics of the spinal block, including latency and duration of anesthesia, and differential blockade, are influenced by choice of local anesthetic, baricity, and adjuvants. Manipulating these variables, as well as patient position and other technique variables, may help the anesthesiologist tailor the desired anesthesia to the specific surgical procedure and patient. Studies reported that addition of 25μg fentanyl to LA improves anaesthesia quality and prolongs postoperative analgesia without prolonging the time to void. This is a prospective randomised double blind study. Subjects were randomly allocated into different groups using computer generated randomisation table. Person who prepared the study drugs was not involved in conduct of study and observer and patient were blinded to group allocation. Levobupivacaine is available as isobaric drug for intrathecal administration. Since isobaric bupivacaine is also available, we have chosen to compare isobaric form of both the drugs. Based on the study by Girgin et al and results of our pilot study...
study, we decided to use 5 mg (1ml) of local anaesthetic drug in our study. When sub arachnoid block is given with low dose local anaesthetic, additives to improve quality of block are added so we chose lipophilic drug fentanyl as additive.

In present study, the mean time for onset of sensory block was more in case of Group LB (2.50 ± 0.51) minutes when compared to Group B (1.67 ± 0.37) minutes and the difference was statistically significant. Erdil et al\textsuperscript{8} compared intrathecal (IT) 1.5 ml plain (LB) Levobupivacaine + 15 µg Fentanyl and 1.5 plain (B) Bupivacaine + 15 µg Fentanyl in TURP procedures. They have compared time to reach T10 in both the groups and found that this time is shorter in B group compared to LB; which is similar to our results. We have compared time to L1 block (As onset of block) and found that B is fast to produce sensory block compared to LB. Akcaboy E Y et al\textsuperscript{9} have compared Levobupivacaine LB (5mg) + 15 µg Fentanyl to Bupivacaine B + 15 µg Fentanyl in TURP surgeries. They have compared onset of sensory block (time to achieve T10) between the groups. The difference is not statistically significant. Similar results are reported by Patil GA et al\textsuperscript{10} and Celik F et al\textsuperscript{11} who have comparable results between groups when time to reach T10 is the parameter used. In their study, Goyal A et al\textsuperscript{12} compared isobaric Levobupivacaine 10 mg with Fentanyl 25µg (LB) and hyperbaric Bupivacaine 10 mg with Fentanyl 25µg (B) in elective cesarean sections. The onset of sensory block was faster in case of BF group (1.7 ± 23) minutes when compared to L group (2.10 ± 0.15) minutes, however the difference was not statistically significant. Our findings do not match these results.

The maximum sensory level was at T5 in Group LB and T4 in case of Group B. The difference was significant with p value <0.05. We allowed surgery to begin when sensory block reached T8, however our assessment continued to detect peak sensory level, which is important to achieve to allow patient comfort during surgery. We also compared sensory block because the adequacy of sensory level throughout the procedure is important. More number of patients had T4 block at the end of surgery in B group (p value = 0.03). With dose of 5mg local anaesthetic + 25µg Fentanyl, the surgery could be completed without any need for supplementation with any sedation. None of our patients complained any pain intra-operatively. Misirlioglu et al\textsuperscript{13} who compared Levobupivacaine (7mg) + Fentanyl 25µg (group L) and Bupivacaine (7mg) + Fentanyl 25µg (group B) for caesarean section. They have discussed the sensory block at start and end of surgery between the study groups. Sensory blocks are comparable for peak level achieved at start and end of surgery. Patil GA et al\textsuperscript{14} compared Levobupivacaine (12mg) + Fentanyl 25µg (group L) and Bupivacaine (12mg) + Fentanyl 25µg (group B) for infraumbilical surgeries. The maximum spread of sensory block was T9 in Group Levobupivacaine and T8 in group which received Bupivacaine. There was no statistical difference between the two groups with respect to peak sensory levels (p=0.05). Our results are different from these results. Akcaboy Z N et al\textsuperscript{15} have compared 5mg Bupivacaine with 25 µg Fentanyl (B) to 5 mg Prilocaine with 25µg Fentanyl (P) in TURP procedures. In B group, peak level achieved with 5mg local anaesthetic is T10. In our study, in group B, level achieved at beginning of surgery was T4 in 40% patients, T6 in 17.14% patients, and T8 42.86% patients. Though their groups are different from ours, we look at Bupivacaine group because they have used similar doses as ours. However, we have got higher peak sensory level in bupivacaine group with similar dose. Girgin NK et al\textsuperscript{16} studied the combination of Low-dose Levobupivacaine (5 mg) and Fentanyl 25µg (group LB) v/s Levobupivacaine 7.5 mg (group L) for spinal anaesthesia in ambulatory inguinal herniorrhaphy. The highest sensory block levels achieved were T7 (range T5 – T9) and T6 (range T4 – T9) in groups LF and L, respectively however there was no statistically significant difference between the two groups. Fentanyl allows comparable sensory block at lower dose of LA. They had highest level at T7 with a combination of local anaesthetic 5mg plus Fentanyl 25µg, whereas we had T5 with same dose.

We have assessed motor block with modified bromage score and compared scores at beginning and at end of surgery. In Group LB, 94.29% had Grade 2 and 5.71% had Grade 3 score at the start of surgery. In Group B, 77.14% had Grade 2 and 22.86% had Grade 3 score. There was no significant difference between the Bromage scores of the two groups (P value=0.08). At the start surgery, in the both groups, motor blockade was comparable. In Group LB, 57.14% had Grade 1, 42.86% had Grade 2 and none had Grade 3 score at the end of surgery. In Group B, 20.00% had Grade 1, 57.14% had Grade 2 and 22.86% had Grade 3 score at the end of surgery. There was no significant difference between the Bromage scores of the two groups (P value=0.08). Throughout the surgery, in the both groups, motor blockade was comparable. These results of motor blockade at beginning and end of surgery indicates that motor block was adequate throughout the surgery. None of the surgeons had any adverse comment on degree of relaxation intra-operative. In their study, Erdid et al\textsuperscript{17} compared intrathecal (IT) 1.5 ml plain (LB) Levobupivacaine + 15 µg Fentanyl and 1.5 plain (B) Bupivacaine + 15 µg Fentanyl in TURP procedures. The maximum motor block with bromage score 3 was in 36 out of 40 patients in LB group and 40 out of 40 in case of B group however this difference was statically insignificant. This is similar to our results of motor blockade between the two groups. Misirlioglu et al\textsuperscript{18} compared Levobupivacaine (7mg) + Fentanyl 25µg (group L) and Bupivacaine (7mg) + Fentanyl 25µg (group B) for caesarean section. At the start of surgery, 10 patients in group B and 3 patients in group L had a Bromage score of 3. At the end of surgery, 6 patients in group B had a Bromage score of 3, but none of the patients had a Bromage score of 3 in group L. These differences were significant (p=0.032 and p=0.014), respectively, meaning that significantly more patients had complete motor blockade in group B than in group LB. We also had more number of patients in with bromage score 3 in B versus LB but the difference was not statically significant. Patil GA et al\textsuperscript{19} compared Levobupivacaine (12mg) + Fentanyl 25µg...
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...have compared intrathecal (IT) 1.5 ml plain 1
...compared intrathecal 5 mg 0.5% Levobupivacaine + 25µg Fentanyl, and in Bupivacaine group (B) received intrathecal 5 mg 0.5% Bupivacaine + 25µg Fentanyl at an injection rate of 120 sec. At the beginning of the operation, 3 patients in B group had Bromage score of 3, but none of the patients had Bromage score of 3 in L group. This difference was found statistically significant (p = 0.042) as against ours. Bromage scores at the end of the surgery were comparable in groups, which is similar to our results.

In present study, the mean time for two segment regression was lesser in case of Group LB (66.11 ± 2.78) minutes when compared to Group B (71.40 ± 5.35) minutes and the difference was statistically significant (p value <0.001). Our findings are in line with, Goyal A et al 2 who compared isobaric Levobupivacaine 10 mg with Fentanyl 25µg (LB) and hyperbaric Bupivacaine 10 mg with Fentanyl 25µg (B) in elective cesarean sections. Time to regression by two dermatomes was 79.34 ± 13.86 minutes in Group LF and 86.35 ± 16.72 min.in Group BF. This difference was statistically significant. Girgin NK et al 3 studied the combination of Low-dose Levobupivacaine (5 mg) and Fentanyl 25µg (group LB) v/s Levobupivacaine 7.5 mg (group L) for Spinal Anaesthesia in Ambulatory Inguinal Herniorrhaphy. The mean time for two segment regression was higher in case of Group LF (61 ± 12) min. and the difference was statistically significant (p value <0.05). When compared to values of LB group in our study, time to 2 segment regression was (66.11 ± 2.78) minutes in group LB. Our findings however were not in line with Erdil et al 4 who compared isobaric bupivacaine with Fentanyl combination. Similarly, from our study we conclude that intrathecal 0.5% isobaric Levobupivacaine + Fentanyl which is similar to our LB+F group. Time to S2 segment regression in their LB+F group was (188 ± 51) minutes and corresponding group in our study had (166.89 ± 4.25) minutes as time to S2 segment regression. Our findings however were not in line with the study carried by Misirlioglu et al 5 who compared Levobupivacaine (7mg) + Fentanyl 25µg (group L) and Bupivacaine (7mg) + Fentanyl 25µg (group B) for cesarean section. Time to regression to S2 was 69.05 ± 4.61 minutes in Group L and 66.69 ± 5.48 minutes in Group B. This difference was statistically not significant.

In present study, the mean time to Bromage score zero was less in case of Group LB (154.94 ± 8.40) min. when compared to Group B (182.40 ± 5.00) min. and the difference was statistically significant (p value <0.001). Wearing off of motor block is significantly faster in LB compared to B group. Our findings are in line with those of Celik F et al 6 however are not in line with the study carried by Erdil et al 7. With use of low dose spinal anaesthesia, it is expected that block will regress faster and ability to ambulate the patient is better and faster. We have assessed the time to ambulation by making the patient stand unassisted. In the present study, the mean time for ambulation was less in case of Group LB (195.87 ± 15.56) minutes when compared to Group B (219.98 ± 12.93) minutes and the difference was statistically significant (p value <0.001). Girgin NK et al 3 have compared Levobupivacaine 7.5 mg with Levobupivacaine 5mg + 25µg Fentanyl. We looked at the corresponding values in the group Levobupivacaine + Fentanyl which is similar to our LB. Time to ambulation in Group LB (201 ± 51) minutes and corresponding group in our study had (195.87 ± 15.56) minutes.

Urinary retention is a common problem associated with spinal anaesthesia as well as use of intrathecal opioids. Hence it is important to assess time to first spontaneous urination by patients. In the present study, the mean time for urination was less in case of Group LB (215.80 ± 14.96) minutes when compared to Group B (239.64 ± 11.91) and the difference was statistically significant (p value <0.001). We looked at the corresponding values in Girgin NK et al 3 study in the Levobupivacaine + Fentanyl group which is similar to our LB group. Time to Uirnation in Group LF (221 ± 58) minutes and corresponding group in our study had (215.80 ± 14.96) minutes, as time to urination. We have also analysed haemodynamic parameters between groups throughout the surgeries and the groups have been comparable with stable haemodynamic parameters.

CONCLUSION

From our study we conclude that intrathecal 0.5% isobaric Levobupivacaine with Fentanyl combination has slower onset of sensory blockade and motor blockade, slower time for achieving peak sensory levels when compared to 0.5% isobaric bupivacaine with Fentanyl combination. But, intrathecal 0.5% isobaric levobupivacaine has a faster onset of two segment regression, faster S2 regression and faster regression of motor block when compared to 0.5% isobaric bupivacaine with Fentanyl combination. Similarly,
the time to ambulation and time to urination are also early with intrathecal 0.5% isobaric Levobupivacaine. This is an advantage for the patient for faster discharge hence can be suitable for day care inguinal hernia surgeries.

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