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Original Article

Intrathecal Chloroprocaine Plus Fentanyl and Levobupivacaine Plus Fentanyl in Infraumbilical Surgeries in Adults

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Abstract

Background: The changing trend from an inpatient to outpatient has urged us to use short-acting local anesthetic with adjuvants such as opioids to intensify sensory block without affecting sympathetic blockade in spinal anesthesia. This study was designed to compare the safety and efficacy of 25 μg fentanyl as an adjuvant to either 10 mg levobupivacaine or 40 mg chloroprocaine intrathecally.

Materials and Methods: In this prospective, randomized, clinical trial, 60 patients of 18–60 years were randomly divided into two groups of 30 each, to receive either 4 ml of 1% chloroprocaine (40 mg) plus 25 μg fentanyl (Group C) or 2 ml of 0.5% isobaric levobupivacaine (10 mg) plus 25 μg fentanyl (Group L) intrathecally. Patients were monitored for 24 h for sensory and motor block characteristics as a primary outcome and post-operative analgesia, hemodynamics, and side effects as a secondary outcome.

Results: Onset of sensory block and time to maximum sensory block were rapid in Group C (2.53 ± 1.20 min and 4.40 ± 1.45 min) as compared to Group L (4.43 ± 1.12 min and 8.10 ± 0.83 min) ($P < 0.001$). The maximum sensory block was T4 in Group C and T6 in Group L. Maximum Bromage score was 2 in both groups but achieved earlier in Group C as compared to Group L ($P < 0.001$). Duration of sensory and motor block was significantly prolonged in Group L (264.47 ± 29.97 min and 173.80 ± 31.47 min) as compared to Group C (101.50 ± 10.30 min and 75.93 ± 10.41 min). The total duration of analgesia was also prolonged in Group L (259.83 ± 29.60 min) as compared to Group C (96.50 ± 9.84 min). Patients remained hemodynamically stable and no significant side effects and complications were noted.

Conclusion: Chloroprocaine provides adequate duration and depth of surgical anesthesia for short procedures with the advantages of faster block resolution.

Key words: Chloroprocaine, Fentanyl, Infraumbilical surgeries, Spinal anesthesia

INTRODUCTION

The trend of ambulatory surgery is rapidly growing worldwide. The primary goal of ambulatory surgery is a rapid onset and offset of anesthesia, fast patient recovery, and rapid patient discharge.[1] Spinal anesthesia is a suitable option for infraumbilical surgeries and as the shift toward ambulatory surgery continues, search for short-acting local anesthetics with rapid onset, adequate potency, predictable duration of action with decreased toxicity profile continues.

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Levobupivacaine, a pure S-enantiomer of bupivacaine, is an amide local anesthetic[2] which provides differential sensory and motor block, that is, rapid onset and longer duration of sensory block with short duration of motor block and less cardiac toxicity.[3,4] Chloroprocaine is an amino-ester local anesthetic with a very short half-life which has been successfully used for spinal anesthesia for short surgical procedures. Recently, the preservative-free formulation of 2-chloroprocaine has been extensively evaluated with a favorable profile in terms of both safety and efficacy.[5] It provides faster offset times and quicker patient discharge from the hospital. To prolong the effect of low dose local

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anesthetics, adjuvants such as opioids are added, which produce a synergistic effect by acting directly on opioid receptors in the spinal cord. Fentanyl, a short-acting lipophilic opioid which stimulates μ1 and μ2 receptors, potentiates the sensory blockade without intensifying the motor block, thus providing good quality of intraoperative and post-operative analgesia, hemodynamic stability with minimal side effects.[6]

Until date, scant literature is available where low doses of chloroprocaine and levobupivacaine, with fentanyl as an adjuvant, were compared for block characteristics in short surgical procedures. Hence, the present study was designed to compare the safety and efficacy of 25 μg fentanyl as an adjuvant to either 10 mg levobupivacaine or 40 mg chloroprocaine intrathecally in patients undergoing infraumbilical surgeries, in terms of onset and duration of sensory and motor blockade as a primary outcome and post-operative analgesia, hemodynamic parameters, side effects, and complications as a secondary outcome.

MATERIALS AND METHODS

In this perspective, randomized, clinical trial, 60 patients of American Society of Anesthesiologists grades I and II of either sex, in the age group of 18–60 years scheduled for elective infraumbilical surgeries under spinal anesthesia were included after approval from the Institutional Ethics Committee and CTRI registration (CTRI/2018/05/013565). Patients with unwillingness for the procedure, coagulation or neurological disorders, deformity, or previous surgery of spine, pregnancy, and allergy to the study drug were excluded from the study. A day before surgery, a detailed pre-anesthetic check-up was done. A general physical examination along with systemic examination, assessment of airway, and local examination of the lumbar spine was done. Relevant investigations were reviewed. Visual analog scale (VAS) was explained to the patients to determine the level of analgesia in the post-operative period. It was carried out with a 0–10 cm line. The first end mark "0" means "no pain" and the end marked "10" means "severe pain." Informed consent was taken from all the patients.

Patients were randomly divided into two groups of 30 each, using a computer generated table of random numbers. Group C (n = 30) received 4 ml of 1% 2-chloroprocaine (40 mg) plus 0.5 ml fentanyl (25 μg) and Group L (n = 30) received 2 ml of 0.5% isobaric levobupivacaine (10 mg) plus 0.5 ml fentanyl (25 μg). The volume of drugs was different in both groups to meet the requirement of equipotent doses. To prevent bias, one anesthesiologist performed the subarachnoid block and another anesthesiologist blinded to the study drug was assigned to monitor the block characteristics, hemodynamics, and side effects.

All patients were given tablets alprazolam 0.25 mg and tablet ranitidine 150 mg orally a night before surgery and at 6:00 am on the day of surgery. Patients were asked to orally restrict solids for 6 h and clear fluids for 2 h before surgery. After shifting to the operation theatre, multipara monitor was attached and baseline respiratory rate (RR), heart rate (HR), noninvasive systolic blood pressure (SBP) and diastolic blood pressure (DBP), peripheral oxygen saturation (SpO_2), and electrocardiography (ECG) were recorded and continuous monitoring was started. An intravenous line was secured and injection midazolam 1 mg and injection butorphanol 1 mg was given intravenously 3–6 min before the start of the surgery.

Patients were preloaded with 10 ml/kg body weight of ringer lactate solution. Under all aseptic precautions, spinal anesthesia was given in L3-L4 space with 25 gauge or 26 gauge Quincke spinal needle through the midline approach in lateral decubitus position. On the free flow of cerebrospinal fluid, the study drug was injected intrathecally. Patients were immediately turned to a supine position and oxygen was started at the rate of 6 L/min. All parameters were noted by taking the time of giving the study drug intrathecally as time 0. Continuous monitoring of RR, HR, noninvasive SBP and DBP, SpO_2, and ECG was done intra-operatively every 2 min for the first 10 min, thereafter every 5 min until 30 min and then every 15 min until the end of surgery in both the groups. Postoperatively readings were recorded every 30 min until 180 minutes of surgery, then one hourly until 12 h and then every three hourly until 24 h of study. Bradycardia (HR below 60 beats per minute) was treated with injection atropine sulfate 0.6 mg IV. Hypotension (defined as fall in blood pressure more than 20% below the baseline) was treated with IV fluids and injection ephedrine 5 mg boluses titrated according to blood pressure.

Sensory blockade was assessed by loss of sensation to pinprick in the midline using a 22 gauge blunt hypodermic needle every 3 min for the first 15 min, then every 5 min for the next 15 min, then every 15 min until 180 min of surgery thereafter, postoperatively sensory blockade was checked one hourly for the next 12 h and then three hourly until 24 h of the study period. The onset of sensory block (when patient does not feel pinprick at T10 level), the highest level of sensory block achieved, time to maximum sensory block, regression of sensory block to L5, and total duration of sensory block (regression to S1 dermatome) were noted. Post-operative pain was monitored using VAS score every 15 min until 180 min, then one hourly until 12 h and every three hourly until 24 h and rescue analgesia was given when the VAS was >3 in both the groups. Inj. diclofenac 75 mg

intramuscularly was given as rescue analgesia and if needed, inj. tramadol 50 mg intramuscularly was given. Time to first rescue analgesia (total duration of analgesia) and total number of doses of rescue analgesia was also noted.

Motor blockade was checked every 3 min for the first 15 min, then every 5 min for the next 15 min, then every 15 min until 180 min of surgery Thereafter, postoperatively motor blockade was checked one hourly for the next 12 h and then three hourly until 24 h of study period according to modified Bromage scale:- Grade 0: No motor block, Grade 1: Inability to raise extended leg; able to move knees and feet, Grade 2: Inability to raise the extended leg and move knee; able to move feet, and Grade 3: Complete block of lower limb. Maximum motor block achieved, time to the maximum motor block, and total duration of motor block (motor recovery to Bromage 0) were noted. When the motor block was totally resolved, patients were allowed to ambulate. Surgery was allowed to start when sensory block to T10 dermatome was achieved. The quality of surgical analgesia was assessed and graded as excellent – no supplementary drugs required, good – analgesic required, fair – more than one analgesic required, and poor – general anesthesia required. Patients were monitored for any side effects or complications such as hypotension, bradycardia, nausea, vomiting, sedation, urinary retention, pruritus, headache, backache, and neurological changes for 24 h.

Statistical Analysis

Power analysis was done. Effective size/power of the study was determined by taking in to account the mean onset of sensory block, mean duration of sensory block, and total duration of analgesia. The power was well above 90% by taking α error 0.05. The sample size was calculated as per formula with a conventional multiplier for alpha = 0.05

Conventional multiplier for power (b) = 0.8

$$n = 2[(a+b)^2\sigma^2]/(\mu1-\mu2)^2$$

where n = Sample size in each of the group
$\mu1$ = Population mean in treatment Group I
$\mu2$ = Population mean in treatment Group II.

Hence, 30 patients were included in each group for power analysis of 80% and were divided in open-label fashion, according to computer-generated randomization.

The data from the present study were systematically collected, compiled, and statistically analyzed using software IBM SPSS 22 to draw relevant conclusions. Data were expressed as means, standard deviation, number, and percentages. The patient characteristics (nonparametric data) were analyzed using the "Chi-Square tests" and the inter-group comparison of the parametric data was done using the "Unpaired *t*-test." *P*-value was determined to finally evaluate the levels of significance. $P < 0.05$ was considered as statistically significant.

RESULTS

In the present study, both groups were comparable with respect to demographic characteristics and duration of surgery [Table 1]. The mean time taken for onset of sensory block and the time to maximum sensory block was significantly more in Group L ($P = 0.000$). The median maximum sensory level reached was higher in Group C (T4 in Group C and T6 in Group L). The median maximum motor block achieved in both the groups was Bromage 2, but the meantime taken for achieving it was significantly more in Group L ($P = 0.000$). Regression of sensory block to L5 dermatome was significantly prolonged in Group L ($P = 0.000$). The total duration of sensory and motor block was also significantly more in Group L as compared to Group C ($P = 0.000$). The time taken for unassisted ambulation was significantly more in Group L as compared to Group C ($P = 0.00$). Time for micturition was also significantly delayed in Group L as compared to Group C ($P = 0.00$). Motor and sensory block parameters are shown in Table 2.

VAS was 0 at 75 min of the study period, then it started increasing in both the groups. VAS was on higher side in Group C as compared to Group L until 180 min. ($P = 0.000$) and patients demanded the first dose of rescue analgesia at 105 min. After this interval, VAS was on the significantly higher side in Group L ($P = 0.000$) and the

Table 1: Demographic profile of patients in Group L and Group LF

Parameter	Group C (*n*=30)	Group L (*n*=30)	*P*-value
Mean age in years	37.80±13.05	38.59±11.84	0.370
Sex ratio (%)			
Male	23 (76.67)	20 (66.67)	0.390
Female	7 (23.33)	10 (33.33)	
Mean weight in kilograms	64.40±8.03	67.80±7.34	0.060
ASA grade %			
Grade I	26 (86.67%)	27 (90%)	0.688
Grade II	4 (13.33%)	3(10%)	
Mean duration of surgery in minutes	40.13±6.18	41.83±8.71	0.521

patient demanded the first dose of rescue analgesia at 4th h of the study period, as shown in Figure 1. Hence, the duration of analgesia was significantly prolonged in Group L (259.83 ± 29.60 min) as compared to Group C (96.50 ± 9.84 min) ($P = 0.000$). The total number of doses of rescue analgesia required in 24 h was also significantly less in Group L as compared to Group C ($P = 0.03$) [Table 2]. The quality of surgical analgesia was excellent in both groups as none of the patient required supplementary analgesia intraoperatively.

Hemodynamic parameters remained stable and comparable throughout the study period, as shown in Figures 2-4. Four (13.33%) patients in Group C and three (10%) patients in Group L had bradycardia, which was corrected with Injection atropine sulfate and was comparable in both the groups ($P > 0.05$). Six (20%) patients in Group C and four (13.33%) patients in Group L had a fall in blood pressure intraoperatively, which was managed with IV fluids and intermittent boluses of injection ephedrine. The incidence of hypotension was comparable in both groups ($P > 0.05$). RR and SpO_2 remained stable and comparable at all measured intervals. Patients were monitored for side effects and complications for 24 h [Table 3]. The incidence of pruritis was comparable, that is, four (13.33%) patients in both groups. None

Table 2: Sensory and motor block characteristics in Group C and Group L

Parameters in minutes	Group C (*n*=30)	Group L (*n*=30)	*P*-value
Onset of sensory block to T10 dermatome	2.53±1.20	4.43±1.12	0.00
Median maximum sensory level	T4	T6	0.00
Time to maximum sensory level	4.40±1.45	8.10±0.83	0.00
Time for regression to L5 dermatome	90.10±10.53	212.70±29.05	0.00
Total duration of sensory block	101.50±10.32	264.47±29.97	0.00
Duration of analgesia	96.50±9.84	259.83±29.60	0.00
Total number of doses of rescue analgesia	4.47±0.51	3.33±0.70	0.03
Maximum motor block	2	2	-
Time for maximum motor block	6.40±1.45	9.73±1.77	0.00
Total duration of motor block	75.13±10.41	173.80±31.47	0.00
Time to unassisted ambulation	99.33±7.3	195.10±20.4	0.00
Time to micturition	102.45±5.6	214.12±22.44	0.00

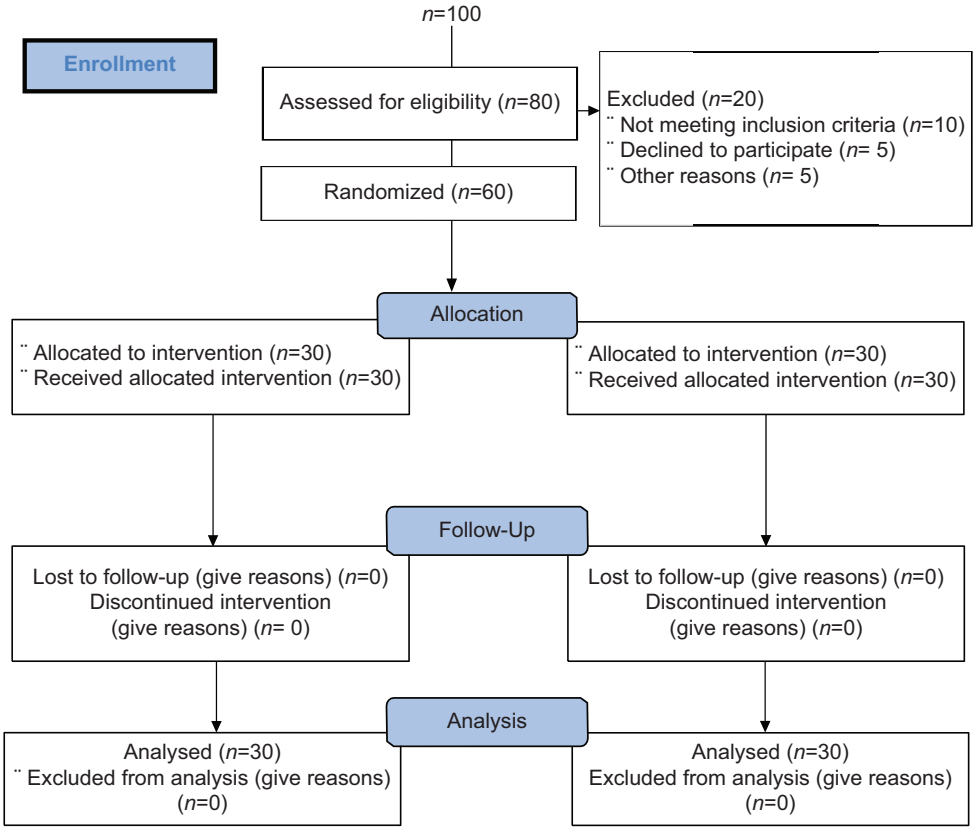

Figure 1: Consort flow diagram

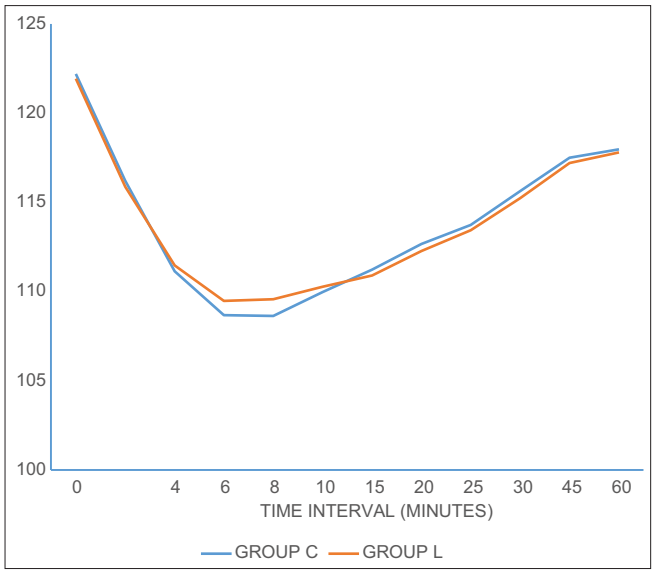

Figure 2: Systolic blood pressure in two groups at different time intervals during the intraoperative period

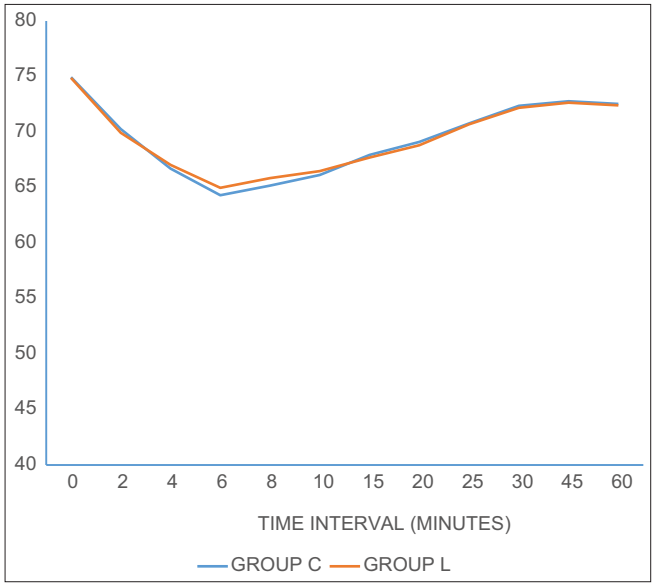

Figure 3: Diastolic blood pressure in two groups at different time intervals during the intraoperative period

of the patient had nausea, vomiting, urinary retention, shivering, headache, backache, local anesthetic toxicity, and respiratory depression throughout the study period in both the groups.

DISCUSSION

Spinal anesthesia remains a preferred technique for infraumbilical surgeries due to its rapid onset and offset, easy administration, minimal expenses, and negligible side effects. With a trend toward ambulatory surgery, lower doses of local anesthetics are being used, but sometimes inadequate anesthesia occurs.

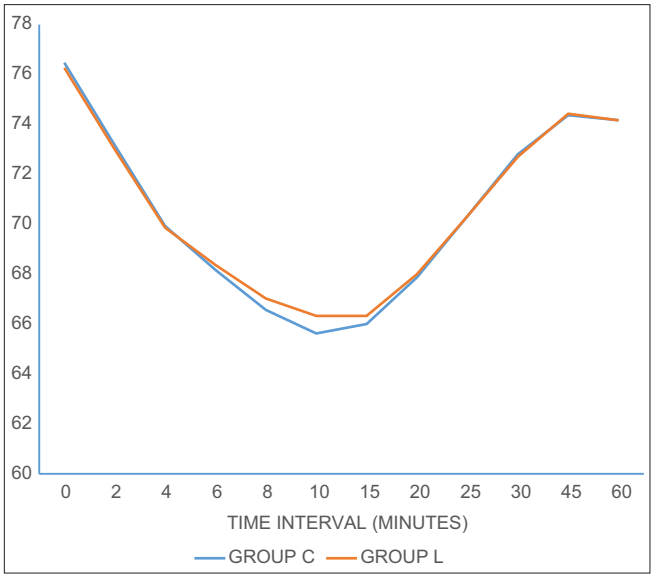

Figure 4: Mean heart rate in two groups at different time intervals during the intraoperative period

Table 3: Side effects and complications in Group C and Group L

Side effects and complications	Group C (*n*=30) (%)	Group L (*n*=30) (%)	*P*-value
Bradycardia	4 (13.33)	3 (10)	0.6433
Hypotension	6 (20)	4 (13.33)	0.2923
Pruritis	4 (13.33)	4 (13.33)	0.118
Respiratory depression	0	0	1
Nausea	0	0	1
Vomiting	0	0	1
Local anesthetic toxicity	0	0	1
Headache	0	0	1
Body ache	0	0	1
Urinary retention	0	0	1

As the duration of anesthetic action of local anesthetics is dose-dependent, a study was done to find the minimum effective dose of chloroprocaine for intrathecal use, where three different doses 30, 40, and 50 mg were compared for block characteristics. It was found that 40 mg is the effective dose, as reducing the dose to 30 mg resulted in an insufficient block.[7] Similarly, for levobupivacaine, 10 mg intrathecal dose was found to be the minimum effective dose for sensory and motor block.[8] In the present study, fentanyl 25 μg was added to above local anesthetics, that is, 10 mg levobupivacaine (Group L) and 40 mg chloroprocaine (Group C) with an aim to enhance the duration of sensory analgesia without intensifying the motor block with hemodynamic stability. In the present study, it was found that the addition of 25 μg fentanyl to equipotent doses of chloroprocaine and levobupivacaine results ins different sensory and motor block characteristics. In the chloroprocaine group, there was a faster onset and early regression of sensory and motor block as compared to

the levobupivacaine group. The maximum level of sensory block achieved was T4 in Group C and T6 in Group L and it was achieved earlier in Group C as compared to Group L. However, the duration of analgesia was shorter in Group C as patient demanded more doses of rescue analgesia in the post-operative period as compared to Group L. However, due to early block resolution, patients were able to ambulate and micturate early in Group C. There was no significant difference in hemodynamic parameters, side effects and complications in both groups.

A study was done using 30 mg chloroprocaine + 12.5 μg fentanyl intrathecally and observed that onset of sensory block was achieved in 4.7 ± 0.79 min, maximum sensory level achieved was T8 (6.2 ± 0.76 min), regression of sensory block to S1 in 94.72 ± 5.32 min, and duration of analgesia was 105 min.[9] Similarly, the onset and duration of motor block are 5.36 minutes and 81.46 min, respectively.[9] In the present study, the maximum sensory level achieved was T4 and was earlier, and regression was also delayed. This difference can be due to the higher doses of chloroprocaine and fentanyl used in the present study. In a study done by Vath and Kopacz[10] studied the block characteristics of 40 mg chloroprocaine with 20 μg fentanyl as an adjuvant observed that the maximum sensory level achieved was T5 (T4 in the present study) and regression to L1 was in 78 min and duration of sensory block was 104 min (101.50 ± 10.32 min in Group C). Hence, the sensory block characteristics of the present study are almost comparable to the above study. To test the hypothesis that addition of dextrose increases the baricity of chloroprocaine and how it affects block pattern, Warren and Kopacz[11] used 10% dextrose as an adjuvant to 40 mg 2-chloroprocaine and observed that maximum sensory level achieved was T3 which is almost consistent with the present study (T4) but time to achieve this level was more 14 ± 9 min as compared to the present study (4.40 ± 1.45 min). Duration of sensory and motor block was 95 ± 8 min and 80 ± 14 min, respectively (101.50 and 75.13 min, respectively, in Group C of the present study), and time to ambulate was 96 ± 7 min (99.33 min in Group C) and time to void was 101 ± 7 min (102.45 min in Group C of the present study). Although we have used the same dose of chloroprocaine as the above study with fentanyl as an adjuvant in place of dextrose, the duration of sensory and motor block, time to ambulate, and time to void is still consistent with the results of above study.

In Group L, the onset of sensory block to T10 occurred in 4.43 ± 1.12 min, maximum sensory block achieved was T6 in 8.10 ± 0.83 min. Similar findings were observed in previous studies also, using 10 mg levobupivacaine and 25 μg fentanyl. Attri *et al.*[12] used the same dose and observed that the maximum sensory level achieved was T6 and the time taken to achieve was 8.46 ± 1.87 min. Girgin *et al.*[3] used 5 mg levobupivacaine and 25 μg fentanyl, the maximum sensory level achieved was T7 as compared to T6 in the present study difference may be due to less dose of levobupivacaine used in the above study. Akan *et al.*[13] using 7.5 mg 0.5% levobupivacaine combined with 25 μg fentanyl found that the meantime to onset to T10 was 6.9 ± 1.7 min and it is more prolonged as compared to Group L because a lesser dose of levobupivacaine and fentanyl was used. In the present study, maximum motor block achieved was Bromage 2 and the time taken to achieve maximum motor block (9.73 ± 1.77 min) was almost similar to the results of the previous studies done by Attri *et al.*[12] (8.38 ± 2.1 min) and Chattopadhyay *et al.*[14] (8.9 ± 51 min). The duration of sensory and motor block in Group L (264.47 ± 29.97 min and 173.80 ± 31.47 min, respectively) are consistent with the results of the study done by Attri *et al.*[12] (270.98 ± 28.60 min and 188.52 ± 9.81 min, respectively). The duration of analgesia in Group L was 259.83 ± 29.60 min which was comparable to the results of Attri *et al.*[12] (265 ± 26.18 min) and Honca *et al.*[15] (250 min). In the present study, time to micturate was 214.12 ± 22.44 min and time to ambulate was 195.10 ± 20.4 min in Group L. Girgin *et al.*[3] conducted a study using 25 μg fentanyl as an adjuvant to 5 mg levobupivacaine intrathecally and found that time to micturition was 221 ± 58 min and time to ambulate was 201 ± 51 min, which was slightly more than the present study using 10 mg dose.

Hemodynamics remained stable and comparable in both the groups intraoperatively and postoperatively. Bradycardia was observed in 4 patients (13.33%) in Group C and 3 patients (10%) in Group L. Hypotension in 6 (20%) patients in Group C and 4 (13.33%) patients in Group L. Similar findings were observed by Lacasse *et al.*[16] using 40 mg of chloroprocaine, where 6 patients (8%) had bradycardia and 4 patients (8%) had a fall in blood pressure. Chattopadhyay *et al.*[14] observed that 2 (9.1%) patients had bradycardia and 4 (18.2%) patients had hypotension while using 10 mg levobupivacaine and 25 μg fentanyl. Similar findings were also observed by Attri *et al.*,[12] Goyal *et al.*,[17] and Krobot *et al.*[18] using levobupivacaine and fentanyl intrathecally.

The most common side effect observed was pruritus which was comparable in both the group's none of the patient developed urinary retention in both the groups. No other side effects and complications were observed in both groups.

The limitation of the present study was that we had used different volumes of two study drugs to meet the requirement of equipotent doses. We tried to do blinding of the study by not involving the person who performed

the block in monitoring, that is, monitoring was done by the second person who was blinded to the drug given. However, as block regression was much earlier in Group C, the blinded observer could guess the group to which the patient belonged; hence, observer bias could not be ruled out.

CONCLUSION

To conclude, both the drugs were effective in providing surgical anesthesia and hemodynamic stability, but Group C provided earlier onset and offset of sensory and motor block, whereas Group L provided the prolonged duration of analgesia. As voiding and ambulation were earlier in Group C; hence, patients could have been discharged earlier as compared to Group L. This suggests that intrathecal chloroprocaine 40 mg plus fentanyl 25 μg provides adequate duration and depth of surgical anesthesia for short surgical procedures with the advantages of faster block resolution and earlier hospital discharge as compared to intrathecal levobupivacaine 10 mg plus fentanyl 25 μg.

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