VOLUME-8, ISSUE-2, FEBRUARY-2019 • PRINT ISSN No 2277 - 8160

Original Research Paper

Anaesthesiology

COMPARISON BETWEEN INTRATHECAL ISOBARIC LEVOBUPIVACAINE-FENTANYL AND ISOBARIC ROPIVACAINE-FENTANYL IN ELECTIVE LOWER ABDOMINAL AND LOWER LIMB SURGERIES: A RANDOMIZED CONTROLLED STUDY

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ABSTRACT

Background: We aimed to evaluate the clinical efficacy of intrathecal isobaric ropivacaine-fentanyl and isobaric levobupivacaine-fentanyl combination in elective lower abdominal and lower limb surgeries.

Methods: A Prospective randomized controlled double blind study was done in 68 adult posted for elective lower abdominal and lower limb surgeries under spinal anaesthesia. They were given either 3 ml 0.5% isobaric Levobupivacaine and 25 mcg fentanyl (Group A) or 3 ml 0.5% isobaric ropivacaine and 25 mcg fentanyl (Group B). Onset, duration of sensory and motor blocks, time for maximum sensory and motor block, time for 2 segment sensory regression, analgesia and haemodynamic parameters were recorded and analyzed. **Results:** All patients achieved a sensory block of T10 dermatome. Onset of sensory blockade at T10 was similar in both groups, Group A (5.01 ±1.21 min) and Group B (5.41±1.63 min). Time from injection to two dermatomal regression was 174.38±15.72 min in Group A and 169.24±14.03 min in Group B. Onset of Bromage score of 1 in Group A was 3.68±1.27 min and in Group B was 5.44±1.64 min. The mean duration of motor and complete motor block was prolonged in Group A patients (201.74±18.51min, 188.82±16.90 min) as compared to Group B (152.88±20.41 min, 126.71±11.85 min). The mean duration of analgesia (345.54±15.45 min vs. 225.15± 20.35 min) was significantly higher in the levobupivacaine-fentanyl group. **Conclusions:** Intrathecal isobaric levobupivacaine-fentanyl combination produces a significantly longer duration of analgesia, sensory block and motor block than isobaric ropivacaine-fentanyl combination. Ropivacaine with fentanyl can be considered in day care surgery as it has shorter duration of sensory and motor block, early ambulation with good analgesia.

KEYWORDS : Intrathecal Anaesthesia, Isobaric, Levobupivacaine, Ropivacaine, Fentanyl, Lower abdominal Surgery, Lower Limb Surgery.

INTRODUCTION

Spinal Anaesthesia is a safe, reliable and inexpensive technique with the advantage of providing surgical anaesthesia and prolonged post operative pain relief. Till recently Bupivacaine 0.5% Heavy was the only drug used for spinal anaesthesia after the discontinuation of Lidocaine's intrathecal use. Bupivacaine has the disadvantage of fatal cardiotoxicity due to its R(+)isomer.[1] The S(-)enantiomers of bupivacaine i.e. Levobupivacaine and Ropivacaine which are devoid of such side effects are expected to have better cardiovascular safety.[2]

Various studies comparing intrathecal use of equal volume of isobaric levobupivacaine and ropivacaine and their effect on perioperative hemodynamics and duration of analgesia has been done..[3,11,17] However, there are few studies where intrathecal opioids such as fentanyl is used as an adjuvant. Therefore a randomized study using intrathecal 0.5% isobaric ropivacaine and fentanyl was compared with 0.5% isobaric bupivacaine and fentanyl in terms of block characteristics, analgesia and hemodynamic effects in adult patients undergoing elective lower abdominal and lower limb surgeries.

METHODS

With the approval of the institutional Ethical committee and written informed consent of the patient, 68 ASA I-II patients (20-60 years) of either sex posted for elective lower abdominal and lower limb surgeries under spinal anaesthesia were included. With sealed envelope method they were randomly divided into 2 groups with 34 patients in each group (n=34). Group A: To receive 3ml (15mg) of 0.5% Levobupivacaine with 0.5ml(25 µg) fentanyl and Group B: To receive 3ml (15mg) of 0.5% Ropivacaine with 0.5ml(25 µg) fentanyl.

Pregnant females, emergency surgeries, patients with Body Mass Index more than 28kg/m2, patients shorter than 150 cm or taller than 180cms, patients with known hypersensitivity to study drugs and other contraindications to regional anaesthesia were not included in the study. The patients were premedicated with tablet alprazolam 0.5 mg and tablet ranitidine 150 mg orally at bed time on the night before surgery. Patients were kept nil orally from 10 pm onwards on the previous night. On the day of surgery an intravenous line was secured with a 18-gauge cannula and patients were preloaded with Ringer lactate 500 ml half an hour before anaesthesia.

ECG, Heart rate, automated non invasive blood pressure (NIBP) and pulse oximetry(SpO2) were monitored. All patients were placed in left lateral position. Under aseptic precautions lumbar puncture were performed at the level of L3-L4 through a midline approach using 25 G Quincke spinal needle and study drug was injected after confirmation of needle tip in the subarachnoid space by free flow of CSF. The study drugs either Levobupivacaine 0.5% 3ml (15mg) with 0.5ml(25 µg) fentanyl or Ropivacaine 0.5% 3ml (15mg) with 0.5ml(25 µg) fentanyl were loaded in a 5ml syringe by the senior anaesthesiologist who was not involved in the study. All the subarachnoid blocks were performed by the same anaesthesiologist who was also the observer of the study. Thus double blinding was achieved where both the observer and the participant were blinded to the study drugs.

Patients were made to lie down in the supine posture immediately after the subarachnoid injection of the study drug, keeping the table flat. Pinprick method with a hypodermic needle was used to test the Sensory blockade at1 min interval for the first 5 min after the spinal injection, followed by at 3min interval in the next half an hour, and every 15 min interval till the completion of surgery and thereafter every half an hour interval until complete recovery. To assess the motor block Modified Bromage scale was used (grade 0-no loss of motor power to grade 4 -complete paralysis).

Using a preformed sturctured proforma the following parameters were recorded: Onset of sensory blockade to T10 level, Onset of motor blockade (Bromage scale 1), Maximum dermatomal level of sensory blockade attained and the time to achieve it, Two segment sensory regression time, Maximum grade of motor blockade attained and the time to achieve it, Total duration of analgesia (time to regression to L1) and Duration of motor blockade (regression to Bromage 0). Hemodynamic monitoring was done till the full recover of sensory and motor block. Hypotension (SBP < 90 mm of Hg or > 30% fall in SBP from the baseline value) was treated with rapid IV fluid boluses and if needed inj. Mephenteramine 3mg IV was given. Bradycardia (HR < 60 bpm) was treated with injection Atropine0.6mg IV.

Duration of analgesia was defined from the time of a successful intrathecal block to the time of request for first rescue analgesia or NRS more than 4 whichever was earlier was also noted. Rescue analgesia was administered postoperatively when NRS (Numeric rating scale) for pain was more than 4 or when patient requested for analgesia. Further Pain management was done according to WHO analgesic ladder. The endpoint of the study was when the patient requested for rescue analgesia or when NRS was more than 4.

Other parameters such as total duration of surgery, total intraoperative fluid given, any adverse effects like nausea and vomiting, pruritus and

any hypersensitivity reactions for the drug. The data collected was entered into a computer spreadsheet for analysis. The statistical tests applied included proportions, student t-test, Fischer's exact probability test and Chi-square tests for significance of associations. All the statistical calculations were done through SPSS 16.0 (2007) for windows. P<0.05 was considered to be statistically significant.

RESULTS

Both the groups were comparable with respect to their demographical characteristics, ASA grading, type and duration of surgery [Table 1]. Onset of sensory blockade at T10 was achieved by 5.01 ±1.21 minutes in Group A and 5.41±1.63 minutes in patients of Group B. This was not clinically or statistically significant. All the patients attained a level of T10 sensory blockade in both the groups which was sufficient for surgery. Highest level of block achieved was T6 in both the groups. Time from injection to two dermatomal regression was 124.68±14.54 minutes in Group A and 110.38±12.35 minutes in Group B (P= 0.001). Time required for sensory level to regress below T10 dermatomal level was 174.38±15.72 minutes for Group A and 169.24±14.03 minutes for Group B (P=0.100). The mean time required for the onset of Bromage score of 1 in Group A was 3.68±1.27 minutes and in Group B was 5.44±1.64 minutes. The results were clinically and statistically highly significant with P-value of <0.001. The mean duration of motor block in Group A patients was 201.74±18.51 minutes and in Group B was a 152.88±20.41 minute which was statistically highly significant as P-value is < 0.001. The mean duration of complete motor block in Group A patients was 188.82±16.90 minutes while that of Group B was 126.71±11.85 minutes which were clinically and statistically highly significant as P-value is < 0.001.

In the first 3 postoperative hours, NRS score was significantly lower in the Group A than in Group B (P < 0.05) suggesting that the patients who received levobupivacaine-fentanyl combination experienced much lower pain for a prolonged period of time than ropivacaine-fentanyl combination. The mean duration of analgesia (345.54±15.45min vs. 225.15± 20.35 min) was significantly higher in the levobupivacaine-fentanyl group (Group A).

There were no significant hemodynamic changes reported in either of the groups statistically or clinically. 2 patients in each group developed bradycardia. There was no immediate incidence of nausea, vomiting, shivering, 0xygen desaturation or late post dural puncture headache or transient neurological symptoms in either of the groups.

Table 1: Demographic profile of the patients in two groups (mean ± SD)

Patient's characteristics	Group A Mean±Sd	Group B Mean±Sd
Age (years)	45.53±11.01	44.16±11.02
Weight (kg)	56.42±5.67	56.34±4.97
Height (cm)	160.54±5.03	160.32±4.04
Sex (male/female)	20/14	19/15
ASA PS (I/II)	22/12	24/10
Duration of surgery	80.09±15.04	81.12±12.08

(ASA PS = American Society of Anesthesiologists Physical Status, SD = Standard deviation)

Table 2: Type of surgery

Surgery	Group A	Group B
Gynaecological	4	6
Orthopaedic	4	5
Appendicectomy	2	3
Hernia	14	12
Urethral	5	4
Hydrocele	2	2
Anal	3	2

Table 3: Comparison Of Sensory, Motor Block Characteristics and Analgesia duration

Parameter	Group A Mean±Sd	Group B Mean±Sd	P* value sig
Sensory block at T10(min)	5.01 ±1.21	5.41 ±1.63	0.5 NS
Two dermatomal regression (min)	124.68±14.54	110.38 ±12.35	<0.001 HS
Regression of sensory block to below T10(min)	174.38 ±15.72	169.24 ±14.03	0.1 NS
Bromage scale 1(min)	3.68 ±1.27	5.44 ±1.64	<0.001 HS
Duration of motor blockade (min)	201.74 ±18.51	152.88 ±20.41	<0.001 HS
Duration of complete motor blockade (min)	188.82 ±16.90	126.71 ±11.85	<0.001 HS
Duration of effective analgesia (min)	345.54 ±15.45	225.15 ± 20.35	<0.001 HS

DISCUSSION

Thus Levobupivacaine and Ropivacaine which are pure S(-) enantiomers of Bupivacaine, are identical to Bupivacaine in terms of onset, quality and duration of sensory block with a better cardiac safety profile.[2] Intrathecal administration of Levobupivacaine and Ropivacaine are well tolerated and provide similar, effective anaesthesia for lower abdominal and lower limb surgeries. The anaesthesia in both groups was well accepted by surgeons and blinded anaesthesiologist. Majority opined that the quality of anaesthesia, relaxation and post operative analgesia is good to excellent with both the drugs.

In equal mg dose Ropivacaine produces a shorter duration of motor and sensory block than Levobupivacaine.[4] Because of sensory motor dissociation, ropivacaine could be a favourable local anaesthetic for day-care surgery and could be associated with early postoperative mobilization than Levobupivacaine. Advantages claimed are shorter duration of motor block [5]with similar sensory block properties compared to Levobupivacaine (McDonald SB)[6]. It minimizes the psychological discomfort of being immobile for long time. Isobaric solutions of both agents were used in order to overcome the denser and prolonged motor blockade which hyperbaric solution would offer.[7] Similarly in our study, the duration of motor block, two dermatone regression time of sensory block and duration of analgesia was found to be higher in levobupivacaine- fentanyl group (Group A). However, the peak height of sensory block and time to reach peak block height were similar in both the groups.

Malinovsky et al, [21]found a lower cephalad extent (median dermatome level T9) of anesthesia associated with less intense block in the ropivacaine group, resulting in requirement of supplemental analgesia. However ,The difference can be explained by use of fentanyl as adjuvant in our study. The net transfer of fentanyl in CSF occurs in a cephaled direction resulting in higher sensory block.[22]

The two dermatome regression time of sensory block in our study was significantly higher in patients who received levobupivacaine. McNamee et al.[11] didn't measure the two dermatome regression time, but the duration of sensory block at dermatome level T10, which was significantly higher in the levobupivacaine group . Malinovsky et al.[5] also found that time for two segments regression to be higher in levobupivacaine .

In levobupivacaine group, the patients demand time(345.54±15.45min) for first rescue analgesic was higher as compared to ropivacaine group (225.15± 20.35min). However, in both the groups, patients had adequate analgesia to about 3-4 hrs postoperatively. Also, VAS score was significantly lower in levobupivacaine group than ropivacaine group, suggesting that the patients who received levobupivacaine-fentanyl combination experienced much lower pain for a prolonged period of time than ropivacaine-fentanyl combination. Majority opined that the quality of anaesthesia and relaxation is good to excellent with both the drugs.

Montouvalou et al [17] used isobaric solutions of Ropivacaine and levoBupivacaine for lower abdominal surgeries and concluded that intraoperative hypotension requiring treatment occurred less in Levobupivacaine group 17.5% than in Ropivacaine group 25%. In our study hypotension occurred in 17% of patients in group A and 26.47% of patients in group B comparable to above mentioned study. None of the patients in both groups had bradycardia. Haemodynamic parameters including heart rate, systolic blood pressure were comparable between the two groups but diastolic and mean arterial pressure at 10 and 15 min showed statistically significant difference but the difference was 5 mmHg which is clinically insignificant. Incidence of hypotension was comparable in both groups, which was easily managed by mephenteramine boluses. Incidence of nausea and vomiting was comparable between the two groups. There was no incidence of post dural puncture headache, transient neurological symptoms in either of the two groups.

CONCLUSION

Our study reveals that intrathecal administration of both 0.5% isobaric (15 mg) Levobupivacaine with 25 µg fentanyl and 0.5% isobaric (15 mg) Ropivacaine with 25 µg fentanyl provides adequate anaesthesia for lower abdominal and lower limb surgeries. Both are well tolerated and provide similar & effective anaesthesia.

In equal mg doses, Ropivacaine-fentanyl combination produced a delayed onset of motor block with shorter duration of analgesia, motor and sensory blockade. This is associated with rapid post operative recovery of motor and sensory function, shorter home discharge time and less psychological distress of being immobile for a longer time. Therefore, Intrathecal isobaric ropivacaine-fentanyl combination may be preferred in day care lower abdominal and lower limb surgeries

ACKNOWLEDGEMENTS

We would like to thank all the colleague residents working with us in our department and we are also grateful to our surgeon colleague for their patience and cooperation during the study.

DECLARATIONS

Funding: None
Conflict of interest: No
Ethical approval: Taken

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