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COMPARISON OF LEVOBUPIVACAINE AND LEVOBUPIVACAINE WITH FENTANYL IN LOWER ABDOMINAL & LIMB SURGERIES UNDER SPINAL ANAESTHESIA

Anaesthesiology

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ABSTRACT

BACKGROUND: Levobupivacaine, the pure S (−)-enantiomer of Bupivacaine, has strongly emerged as a safer alternative for regional anaesthesia than its racemic sibling, Bupivacaine. The intrathecal administration of a combination of opioids and local anaesthetics produces a well-documented synergistic effect without prolonged motor nerve block or delayed hospital discharge.

OBJECTIVE: Present study was conducted to compare the characteristics of spinal blocks produced by 0.5% levobupivacaine with and without fentanyl in lower abdominal and limb surgeries

METHODS: The study was a hospital based randomized controlled double blinded study where 80 patients planned for lower abdominal and lower limb surgeries were randomly divided into two groups of 40 patients each. In Group-I (LF 40) 2.5 ml of total volume 0.5% isobaric Levobupivacaine 7.5mg(1.5ml) + fentanyl 25ugs(0.5ml) + 0.5ml normal saline and in Group-II (L 40) 0.5% Levobupivacaine 10mg (2ml) + normal saline (0.5 ml) was given.

RESULTS: There were no significant differences between the two groups for patient demographic, intraoperative hemodynamic parameters, side effects and satisfaction. The highest level of sensory block was T7 in the Group LF, and T9 in the Group L. Duration of motor block was shorter in Group LF than in Group L (162.75±15.02 min in Group LF; 185.25±11.54 min in Group L.

CONCLUSION: Combination of intrathecal fentanyl with low dose levobupivacaine provides good quality surgical anaesthesia with early motor recovery which could lead to early ambulation of the patient as a day care surgery.

KEYWORDS

Levobupivacaine, Fentanyl, Lower limb surgeries, motor block

INTRODUCTION

The advantages of a uniform total muscle relaxation, a conscious patient, and relatively uneventful recovery after spinal anaesthesia on the one hand and the protection from potential complications of general anaesthesia on the other, were the main reasons for selecting spinal anaesthesia as the first choice.[1]

Spinal anaesthesia is popular and commonly used worldwide. The advantages of an awake patient, minimal drug costs and rapid patient turnover has made this the method of choice for many surgical procedures.[2] A higher level of sensory block acquired by increasing the dose of long acting local anaesthetics may produce extensive sensory and motor block as well as arterial hypotension and this might result in delayed discharge from hospital.[3]

Recent advances in anaesthesia has allowed more surgeries to be performed on day case basis. The properties an anaesthetic agent used for day care surgeries in spinal anaesthesia should have decreased incidence of anaesthesia related complications, should provide adequate postoperative analgesia and allow early patient discharge.[4]

The quest for searching newer and safer anaesthetic agents has always been one of the primary needs in anaesthesiology practice. Levobupivacaine, the pure S (−)-enantiomer of Bupivacaine, has strongly emerged as a safer alternative for regional anaesthesia than its racemic sibling, Bupivacaine. Levobupivacaine has been found to be equally efficacious as Bupivacaine, but with a superior pharmacokinetic profile.[5]

For lower abdominal surgeries, low-dose spinal Bupivacaine in combination with Fentanyl has been evaluated, [2] however no comparative data are available on the use of low-dose Levobupivacaine with intrathecal Fentanyl. The intrathecal administration of a combination of opioids and local anaesthetics produces a well-documented synergistic effect without prolonged motor nerve block or delayed hospital discharge.[6,7]

The objective of this study was to identify whether the minimum dose of spinal Levobupivacaine (7.5 mg) in combination with Intrathecal Fentanyl (25µg) would provide adequate surgical conditions for lower abdominal surgeries without prolonging recovery, early ambulation and lesser chances of intraoperative and postoperative cardiovascular & central nervous system side effects.[8]

SUBJECTS AND METHODS

STUDY DESIGN, SETTINGS AND PARTICIPANTS:

It was a hospital based prospective randomized controlled study conducted over a period of 20 months from October 2014 to June 2016 in anaesthesia department of tertiary care hospital in New Delhi, India. 80 patients of American Society of Anesthesiologists grade I of either sex, in the age group of 18–60 years scheduled for lower abdominal and lower limb surgeries under spinal anaesthesia constituted the study population. Patient belonging to ASA grade II, III, and IV., with known contraindication to spinal block, chronic neuropathic syndromes, history of cardiovascular and respiratory disorders, height <150 cm or >180 cm, known history of allergy or pruritus and known coagulopathies were excluded from the study

DATA COLLECTION

After taking written informed consent patients were randomly divided into two groups of 40 each using a computer generated table of random numbers.

Group-I (LF 40) recieved 0.5% isobaric levobupivacaine 7.5mg (1.5ml) + fentanyl 25ug (0.5ml) + Normal saline (0.5ml) and **Group-II (L 40)** recieved 0.5% levobupivacaine 10mg (2ml) + Normal saline (0.5 ml). Total volume of the drug was kept constant as 2.5 ml in both groups to avoid bias during drug administration.

PRE-ANAESTHETIC CLINICAL EVALUATION:

A day before surgery detailed preanaesthetic check-up was done. General physical examination along with proper systemic examination, assessment of airway and local examination of lumbar spine was done. Relevant investigations were reviewed. The patients were explained the projected sequence of events of the perioperative study period. Patients were kept fasting overnight and advised tab. 0.25 mg Alprax as premedication on the day before surgery. Patients were asked to restrict solids and fluids by mouth at least 6 h before surgery.

On the day of surgery, after shifting the patient from the preoperative area to operation theatre, multipara monitor was attached and baseline values of pulse rate, respiratory rate, non-invasive systolic and diastolic blood pressure (SBP & DBP), oxygen saturation and electrocardiography (ECG) were recorded. Intravenous line was secured with a wide bored 18 gauge cannula and patient was preloaded

with Ringer's Lactate solution (10 ml/kg) over a period of 15-20 minutes prior to the start of the procedure of subarachnoid block.

Under all aseptic precautions, spinal anaesthesia was given in L3 and L4 space with 25 gauge Quincke spinal needle via midline approach in sitting position. Subarachnoid space was identified by free flow of cerebrospinal fluid. In Group-I (LF 40) 2.5 ml of total volume 0.5% isobaric Levobupivacaine 7.5mg(1.5ml) + fentanyl 25ugs(0.5ml) + 0.5ml normal saline and in Group-II (L 40) 0.5% Levobupivacaine 10mg(2ml) + normal saline (0.5 ml) was given. Study drug was prepared in similar syringes keeping the drug volume constant by an anaesthesiologist, who then handed over the syringe to another anaesthesiologist who performed the spinal block and also monitored all the patient variables.

Patients were immediately turned to supine position and oxygen was started at the rate of 4-6 L/min. The monitoring of HR, respiratory rate, blood pressure and peripheral oxygen saturation were done on a continuous basis as per the chart. The monitoring of the haemodynamics was done every 2 minutes for the first 10 minutes; for every 5 minutes for next half hour; every 10 minutes for next half hour and thereafter every 15 minutes till the end of the surgery.

Hypotension (defined as fall in SBP >20% from baseline) was treated with additional Ringer's lactate solution and Mephentermine (6 mg bolus) I.V. Bradycardia (defined as HR <60 bpm) was treated with injection atropine sulphate 0.6 mg IV.

The sensory block was determined by a loss of pin prick sensation in the midclavicular line on both sides of the body every 2 minutes for the first 10 min and then as per the intraoperative chart. If the levels of anaesthesia are not found to be equal bilaterally, higher level was used for statistical purposes. The surgery was permitted to proceed when adequate sensory levels have been achieved. All determinations of sensory level were based on a standard dermatomal chart.

Motor block was assessed by using the modified Bromage scale.[9] with time periods identical to the monitoring of sensory block- every 2 min for the first 10min, every 5 minutes for the next half hour and then as per the intraoperative chart. Modified Bromage scale was taken as: 0 – No motor block, 1 – able to move knees, unable to raise extended legs, 2 – able to flex ankles, unable to flex knees, 3 – unable to move any part of limb – complete block.

All parameters were noted by taking the time of giving the study drug intrathecally as time 0. During intraoperative period, if any patient felt pain then intravenous Fentanyl 50 µgs was given. If the block is found to be inadequate for a satisfactory progression of surgery or if the patient continues to complain of pain after the administration of a total of 100 µg of Fentanyl, the patient was given general anaesthesia. The induction was with Inj. Propofol + Inj. Vecuronium followed by intubation; maintenance of anaesthesia was on halothane in oxygen and nitrous oxide by providing IPPV via Bain circuit.

In the postoperative period, patients were monitored for haemodynamic parameters and Visual analogue scale (VAS) score. VAS score was explained to the patients to determine the level of analgesia in the postoperative 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." Mild pain was classified as VAS less than 30mm, moderate pain (VAS between 31-69mm) was treated with Inj. Diclofenac 75 mg IM and severe pain (VAS more than 70 mm) was treated with Inj. Tramadol 50mg I.V. in bolus doses repeated on emergent basis till the patient is pain free. Time at which patient demanded first dose of rescue analgesia was taken as total duration of analgesia. Number of doses of rescue analgesia required in the postoperative period was also noted. Patients were monitored for any side effects or complications like hypotension, bradycardia, nausea, vomiting, sedation, urinary retention, pruritis, headache, backache and neurological changes for 24 hrs.

STATISTICALANALYSIS

Data were analyzed and statistically evaluated using SPSS software, version 17 (Chicago II, USA).[10] Quantitative data was expressed in mean, standard deviation while qualitative data were expressed in percentage. Quantitative data between two groups were compared by student 't' test or Mann Whitney 'u' test while statistical differences between the proportions were tested by chi square test or Fisher's exact test. 'p' value less than 0.05 was considered statistically significant.

ETHICAL ISSUES

All participants were explained about the purpose of the study. Confidentiality was assured to them along with informed written consent. The study was approved by the Institutional Ethical Committee.

RESULTS

A total of eighty patients were enrolled in the present study and randomly assigned equally in one of two treatment group. Both the groups were comparable with respect to demographic data, baseline hemodynamic parameters or duration of surgery (Table 1) and operation types .

All spinal blocks performed in both groups were successful. No statistically significant difference was seen in the onset of sensory and motor blockade. The highest median sensory blockade levels achieved were T7 (range T6-T8) and T9 (range T8 – T10) in groups LF and L, respectively (Table 2). There were no significant differences between the two groups in terms of the maximum motor blockade score that was achieved. Duration of motor block was significantly high in Group L compare to Group LF. The time to reach two-segment regression was significantly shorter in group LF than group L (Table 2).

The time to ambulation, urination and hospital discharge were all significantly shorter in group LF than group L ($P < 0.05$ for all recovery parameters; Table 3). In our study adverse effect was not observed in any patients.

DISCUSSION

The present study was a hospital based prospective randomized controlled study conducted to to evaluate the effect of low dose levobupivacaine with fentanyl and levobupivacaine alone in lower abdominal and lower limb surgeries in which 80 patients planned for lower abdominal and lower limb surgeries were randomly divided into two groups of 40 patients each. In Group-I (LF 40) 2.5 ml of total volume 0.5% isobaric Levobupivacaine 7.5mg(1.5ml) + fentanyl 25ugs(0.5ml) + 0.5ml normal saline and in Group-II (L 40) 0.5% Levobupivacaine 10mg (2ml) + normal saline (0.5 ml) was given.

In present study 5 patients achieved T6 dermatome level and 35 patients achieved T8 dermatome level in group LF while in group L 29 patients achieved T8 dermatome level 11 patients achieved T10 dermatome level. In Group LF, higher sensory level was achieved than Group L. Another study by Cuvas O et al. [11] found T9 (T4-T10) and T6 (T3-T10) in Group L and in Group LF, respectively while Akcaboy E et al.[12] found T (T6-T10) in group L and T7 (T6-T10) in group Bupihacaine. This has been explained by Cuvas O et al.[11] who concluded that levobupivacaine plus fentanyl solution is more hypobaric than the pure levobupivacaine solution. Opioids such as Fentanyl are hypobaric and when added to a local anaesthetic rendered the subsequent mixture even more hypobaric. The densities of pure levobupivacaine and levobupivacaine plus fentanyl solutions were measured and found to be 1.008 & 1.007 respectively at 37°C by refractometry. This could possibly explain the higher level of sensory block achieved in LF group.[11]

Time to achieve maximum modified Bromage score was almost similar in both the groups which was also reported by other studies done by NK Girgin et al.[8], Akcaboy E et al.[12], Ben-David et al.[13], Kuusniemi et al.[14]

Maximum motor score achieved was 2 in all the patients of both the groups in our study. Our findings were similar to the studies done by NK Girgin et al.[8] who observed maximum Bromage grade 2 in both the groups. Akcaboy E et al. [12] observed maximum Bromage grade 2 in all patients of levobupivacaine group while grade 3 in three patients of bupivacaine group.

Combining an intrathecal opioid with a local anaesthetic might be beneficial for achieving a higher sensory block without the need to increase the dose of local anaesthetic and thus delay hospital discharge. In our study, Ambulation was achieved after 252 min in LF group and 315 min in Levobupivacaine group ($p<0.05$). Our findings were similar to the studies done by NK Girgin et al. This is because of low dose of levobupivacaine provides early motor recovery which leads to early ambulation. In our study discharge time was also shorted in LF

group compare to L group. The shorter time to discharge achieved with 5 mg levobupivacaine plus fentanyl was due to a faster regression of spinal block.

Breebaart et al[5] reported hospital discharge after 311 min with 10 mg levobupivacaine and Casati et al[15] reported hospital discharge after 261 min with 8 mg levobupivacaine. In the present study, hospital discharge was achieved after 371 min with 7.5 mg levobupivacaine compared with 301 min with 5 mg levobupivacaine plus fentanyl ($P < 0.05$).

In our study none of the patients showed any adverse effects like bradycardia, hypotension, pruritus and any other side effects. Other studies reported pruritus as a common side effect due to addition of fentanyl in combination with levobupivacaine.[16,17]

CONCLUSION & RECOMMENDATIONS

In conclusion, Combination of intrathecal fentanyl with low dose Levobupivacaine provides good quality surgical anaesthesia with early motor recovery which could lead to early ambulation of the patient as a day case surgery. This drug was also shown to prolong the duration of sensory spinal block without increasing the incidence of opioid-related side-effects or delaying hospital discharge in patients undergoing lower abdominal or limb surgeries.

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CONFLICTS OF INTEREST

The authors had no conflicts of interest to declare in relation to this paper.

Table 1: demographic data and baseline parameter in the two groupsps

Demographic data	Group LF	Group L	P Value
Age (years)	38.82 ± 11.85	39.60 ± 11.71	0.769
Weight (kg)	61.68 ± 7.71	61.82 ± 7.14	0.928
Height (cm)	164.40 ± 3.76	164.10 ± 3.15	0.700
Sex (male/female)	37/3 (92.5%/7.5%)	38/2 (95%/5%)	0.99
Duration of surgery (min)	88.13 ± 3.07	88.50 ± 5.68	0.776
Heart Rate Per Minute	77.52 ± 8.85	75.12 ± 7.99	0.179
Systolic Blood Pressure (mmHg)	116.52 ± 9.27	118.75 ± 9.34	0.287
Diastolic Blood Pressure (mmHg)	70.00 ± 6.66	73.00 ± 6.67	0.156
Mean Arterial Pressure (mmHg)	85.51 ± 7.03	87.58 ± 8.13	0.227
O2 Saturation (%)	99.03 ± 0.48	99.15 ± 0.36	0.192

Table 2: Mean Sensory/motor block variables in the two groups

Sensory and motor blockade variable	Group LF	Group L	P Value
	Mean ± SD	Mean ± SD	
Time of Onset to Sensory block at T10 (min)	2.65 ± 0.95	2.55 ± 0.90	0.63
Time of Onset of motor block (min)	3.65 ± 0.77	3.75 ± 0.67	0.53
Time to achieve maximum sensory level (min)	4.65 ± 0.95	4.55 ± 0.90	0.63
Time to Achieve Maximum Modified Bromage Score (min)	8.55 ± 0.90	8.50 ± 0.88	0.80
Highest level of sensory block achieved (Dermatome)	7.75 ± 0.67 T7(T6 – T8)	8.55 ± 0.90 T9 (T8 – T10)	<0.001
Time to 2 Segment Regression Level (min)	75.00 ± 4.80	79.13 ± 6.78	0.002
Maximum Modified Bromage Score	2.00 ± 0.00	2.00 ± 0.00	–
Duration of motor block (min)	162.75 ± 15.02	185.25 ± 11.54	<0.001

Table 3: Post-operative anaesthetic recovery and home discharge times for patients receiving spinal anaesthesia with levobupivacaine and intrathecal fentanyl (group LF) or levobupivacaine (group L)

	Group LF	Group L	P Value
Time of Ambulation (min)	252.00 ± 23.34	315.00 ± 20.38	<0.001
Time of urination (min)	271.00 ± 26.43	346.00 ± 26.41	<0.001
Time of home discharge (min)	301.00 ± 31.46	371.00 ± 29.52	<0.001
Any adverse effects	0	0	-

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