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A comparative clinical study to evaluate the effect of intrathecal levobupivacaine and bupivacaine in patients scheduled for infraumblical surgeries under spinal anaesthesia

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Abstract

Introduction: A comparative clinical study was conducted to evaluate the effect of intrathecal levobupivacaine and bupivacaine in patients with infraumbilical surgeries under spinal anaesthesia. We sought to evaluate the the onset of time sensory and motor block, haemodynamic changes during intraoperative and postoperative period and its complications.

Methods: In this prospective randomised double-blind study, 60 American Society of Anesthesiologists grade I and grade II of either sex, 20-65 years of age were enrolled. They were randomly divided into two groups of 30 each. Group B received 0.5% bupivacaine 3ml intrathecally and Group L received 0.5% levobupivacaine 3ml intrathecally. Sensory and motor block, duration of analgesia, haemodynamic changes during intraoperative and post-operative period and its complications were assessed.

Results: The onset of sensory block was rapid in Group B (4.33+/-1.99 min) in comparison to Group L (4.46+/-2.38) which was statistically insignificant. Maximum level of sensory block achieved was T6 in both groups. The duration of sensory block was longer in Group B (134+/-18.86 min) in comparison with Group L and (143+/-20.36 min). The duration of motor block was also more in Group B(184+/-33.17 min) in comparison with Group L (175+/-27.38).

Conclusion: Intrathecal administration of 0.5% levobupivacaine provides almost same amount of sensory and motor blockade achieved with bupivacaine. Haemodynamically levobupivacaine is more stable than bupivacaine during intraoperative and postoperative period with lesser complications.

Keywords: infraumbilical, bupivacaine, levobupivacaine, spinal anaesthesia, intrathecal

Introduction

Spinal anaesthesia was introduced in clinical practice by August Bier in 1898 [1]. Spinal anaesthesia using local anaesthetics, like hyperbaric bupivacaine is one of the most popular drugs for both elective and emergency surgical procedures [2]. In 1957, Ekenstam and his colleagues synthesized bupivacaine hydrochloride which was clinically introduced in 1963. Although it has slow onset of sensory level but produces good muscle relaxation and prolonged sensory and motor blockade. Quality of motor and sensory blockade is dose dependent but increasing this doses of hyperbaric bupivacaine leads to increased cephalic spread of drug which accounts for more incidences of hypotension, bradycardia and in some cases, respiratory difficulty and cardio-respiratory arrest [3]. Prolonged motor weakness associated with use of bupivacaine is also a limiting factor for its use especially when used for surgeries of short duration as it delays the ambulation. It is also associated with side effects including cardiovascular and central nervous system toxicity. In cases of inadvertent intravascular injection of bupivacaine, it was often fatal and responded poorly to conventional resuscitation methods. Its association with side effects likes persistent post-operative motor weakness, cardiovascular and central nervoussystem toxicity it resulted in continuing search for new and safer local anaesthetic agents [4].

Levobupivacaine is a levorotatory isomer of bupivacaine. Levobupivacaine is the pures (-) enantiomer of racemic bupivacaine. Protein binding of levobupivacaine is more (97%) than that of racemic bupivacaine (95%). Less than 3% of the drug circulates free in plasma. Due to less free volume of drug there is less toxicity of CVS and CNS. It's used in subarachnoid block may offer special advantages because this property may translate to a more predictable spread & less side effects.

Hence, we undertook this study to evaluate the effect of intrathecal levobupivacaine on onset and duration of motor and sensory block, cardiovascular system and incidence of side effects compared with bupivacaine in spinal anaesthesia in patients undergoing infra umbilical surgeries.

Method

This study was conducted after obtaining approval from the institutional ethical committee and written informed consent from patients. Study was conducted on 60 patients of ASA-I and II of 'American Society of Anesthesiologists' between the ages of 20 to 65 years, who were scheduled for infra umbilical surgeries under spinal anaesthesia. Patients were randomly divided into two groups of 30 each. In Group B – patients received 0.5% bupivacaine 3.0 ml intrathecally and in Group L – patients received 0.5% levobupivacaine 3.0 ml intrathecally. All routine and specific investigations were done. All patients were kept nil by mouth after 10 pm. On arrival of patient in the operating room an intravenous line was secured with 18G cannula. Pre-loading with the ringer lactate at 10 ml/kg was done. Pulse, blood pressure, respiratory rate, SpO_2 and temperature were recorded.

Under strict antiseptic precaution, subarachnoid block was performed in the sitting position. Skin and subcutaneous infiltration was done with 2 ml of 2% lignocaine. Spinal needle was inserted in the midline at L3-4 or L4-5 inter-space. Correct needle placement was identified by free flow of cerebrospinal fluid. Drugs for spinal anaesthesia was prepared under aseptic precautions and injected according to group allocation. Patients were placed supine immediately after injection to achieve at least T 10 level of sensory block and Bromage scale of 3 for motor blockade and when the sensory block of T_{10} and Bromage scale of 3 was achieved, surgeon were allowed to start with the surgery.

The onset of sensory block was measured from the time of intrathecal injection till sensory block at T_{10} dermatome achieved. This was determined bilaterally using pin prick test and cold test using spirit. To assess the maximum level of the block; sensory block was assessed at 2, 4, 6, 8, 10 min post-injection and at 5min intervals thereafter until two consecutive levels of sensory block was identical. After which assessment was done every 30 minutes till the completion of surgery. Duration of sensory block was measured from time of sensory onset till the time when sensory block regressed to L_1 dermatome.

The onset of motor block was be assessed by using a modified Bromage scale. The degree of motor block was assessed after intrathecal injection at 2, 4, 6,8 and 10 minutes and then at 5 minutes intervals thereafter until two consecutive degree of motor block was identical, after which assessment was done every 30 minutes till the completion of surgery. Duration of motor block assessment was done from the time of onset of modified Bromage scale at 3 till normal motor function returned. (Bromage score 0).

All patients of both groups were monitored for Heart rate (HR), Blood pressure (SBP & DBP) and Oxygen Saturation (SpO_2) at 2, 4, 6,8,10,15,20,30 minutes and then half hourly till the surgery was completed and then every hour till the block regressed fully. The fall in systolic bold pressure (SBP) for more than 20% below the pre-anesthetic value was considered significant hypotension and ephedrine 6 mg was given intravenously. Bradycardia i.e. heart rate less than 20% of pre-anaesthetic value or less than 60/min, was treated with atropine sulphate 0.6 mg intravenously. All patients were shifted to recovery room after assessing the block and level of consciousness. All patients were observed for complications like nausea, vomiting, bradycardia, hypotension, shivering, intra and postoperatively and treated accordingly.

Post-operative pain was assessed by VAS (Visual Analogue Scale) to which, the patient was familiarized with VAS on 10cm scale telling him that one end (0) represent no pain and the other end (10) was the worst imaginable pain, on which the patient had to mark the degree of pain he was suffering. The distance from the end level no pain to the mark of the patients was measured in cm and designed on the pain score. When the VAS ≥4, rescue analgesic, Inj. tramadol 50-100 mg I.V was given. Duration of analgesia was recorded. Statistical analysis was done by Student's 't' test and Chi square's test and p value less than 0.05 considered as significant.

Results

The two groups were statistically similar with demographic data (Table no 1).

Table 1: Demographic Data (Mean ±SD)

Demographic Data	Group B	Group L	P Value
Age (years)	48.4 ±14.21	50.16±12.40	0.6112
Weight (kg)	58.3 ± 6.28	58.93±5.21	0.6726
Height (cm)	163.46 ±6.46	164.76 ±8.18	0.4977

Onset and duration of sensory and motor block were comparable in both groups (Table no 2).

Table 2: Patient Variable

Variable	Group B	Group L	P value
Onset of Sensory Block	4.33±1.99	4.46±2.38	0.8117
Onset of Motor Block	4.6±2.23	4.96±2.97	0.5917
Duration of Sensory block	143±20.36	134±18.86	0.081

Duration of Motor Block	184±33.17	175±27.38	0.256
Duration of Analgesia	260±39.5	248±40.5	0.253

Maximum level of sensory block was upto T_6 dermatome level in 16.7% of patients in group L and 50% of patients in group B.

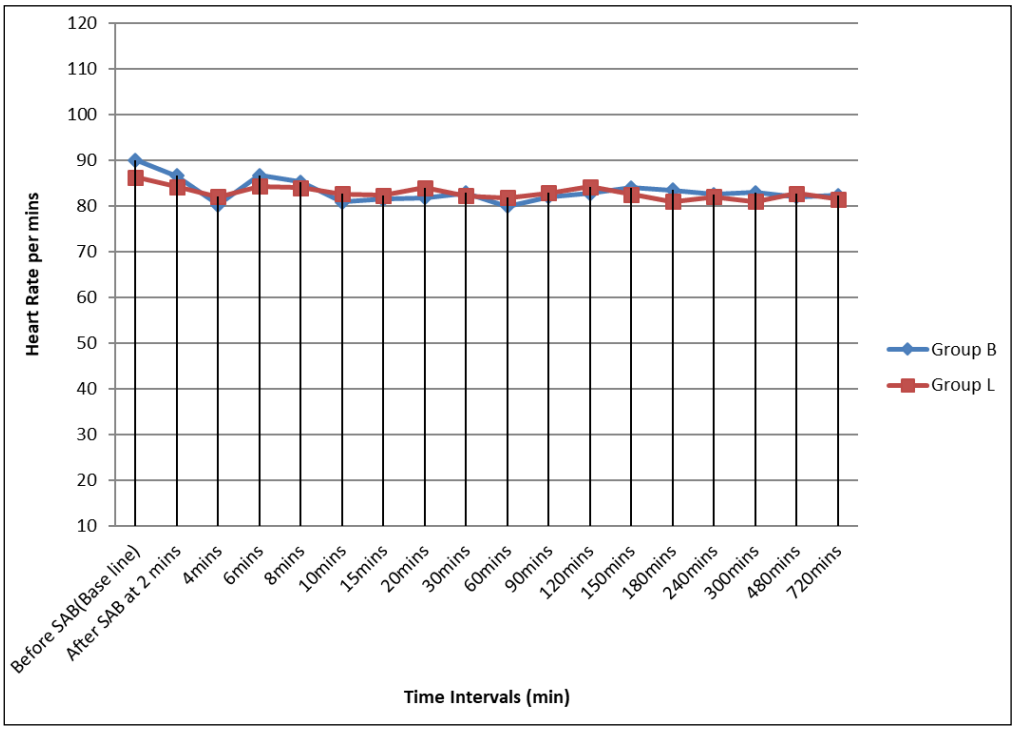

Fig 1: Changes in Heart Rate

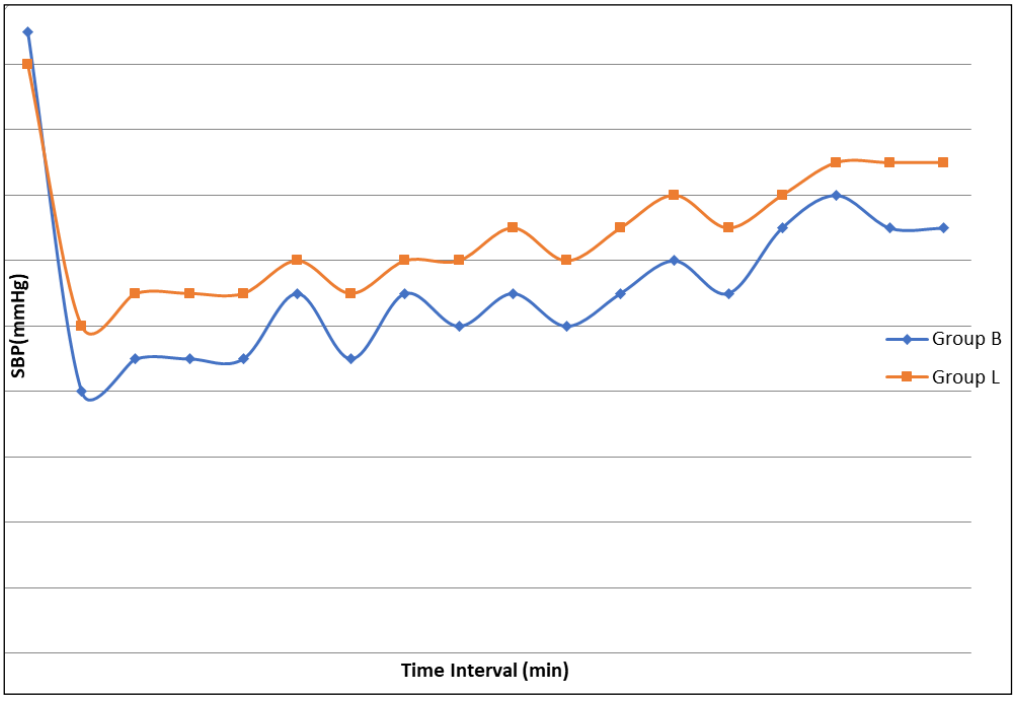

Fig 2: Changes in Systolic Blood Pressure

Mean heart rate and blood pressure were remained comparable in both groups (Fig 1&2)
In both groups changes in mean oxygen saturation during intra operative and post-operative period remained statistically insignificant, suggestive of no hypoxic episode in any of the patient included in the study during whole course of study period.
Hypotension was observed in 3 patients in group L and 7 patients in group B. Bradycardia was observed Nin 2 patients in group B. None of the patients had respiratory depression. Nausea in 1 patient in group L and 2 patients in group B was noted.

Discussion

Many studies have been done to evaluate the choice between regional and general anaesthesia to perform infraumblical surgeries [5]. Morbidity and mortality has been reported lower in the early postoperative period when spinal anaesthesia was performed [6]. Spinal anaesthesia is often used, the advantage being relatively less amount of local anaesthetic injection leads to a profound nerve block [7]. The properties of local anaesthetic desirable for spinal use are rapid onset of action, prolonged action with adequate postoperative analgesia, minimal cardiorespiratory changes and early ambulation.

Bupivacaine, a racemic (50:50) mixture containing of S and R enantiomers has been regularly used since the time it was introduced in 1963. The cardiotoxic and neurotoxic effects due to its R enantiomer were reported [8]. Hence the need for other local anaesthetic arose and levobupivacaine, is a levorotatory isomer of bupivacaine was used in clinical practice. Levobupivacaine having lower lipid solubility and higher protein binding blocking both sensory and motor nerve fibres with less cardiotoxicity [9, 10]. Numerous studies have been conducted to establish the equipotency, superior haemodynamic profile and safety in elderly of levobupivacaine over bupivacaine [11].

The difference in mean onset time for sensory block was insignificant between the two groups. These results are consistent with the studies done by Christain Glaser *et al* [12] where there was no significant difference in onset time of sensory block (Gr B 4.35±3 mins Vs Group L 4.88 ±2.43mins). In another study done by Casatic A *et al* [13],who observed onset time of sensory block for bupivacaine 4.5mins and for levobupivacaine 4.7mins which was comparable. The maximum sensory block level was upto T_8 in 12 patients out of 30 patients in group B and 17 patients out of 30 patients in group L which was comparable in both groups. Duration of sensory block was comparable in both the groups. Our result are in accordance with previous studies by Burke D *et al* [14]

The onset, degree and duration of motor block was statistically similar in both groups in our study. Similar results were observed in study conducted by Casati A *et al* [13] who stated the duration of motor block was 210 ±63 mins and 190 ±51 mins in group B and L respectively. In the study by Kaur *et al* [15] duration of motor blockade was (160 ±6.56) mins in group B as compared to group L (131.48 ±14.42) mins which was nearly equally effective and comparable between the two groups.

After the administration of spinal anaesthesia with the study drug, mean heart rate was statistically comparable between two groups at various time intervals (P>0.05). In a study conducted by Fattorini *et al* [16] a reduction in heart rate in group B was noted and haemodynamic stability was observed with isobaric levobupivacaine. However they stated the difference was statistically insignificant. Another study by Monica Del Rio *et al* [17] observed insignificant difference between both the groups with regards to heart rate. The basal systolic and diastolic blood pressure were comparable in both groups. Patients in both groups remained haemodynamically stable. When blood pressure went below baseline by more than 20%, it was treated with incremental doses of 6mg Mephentermine iv. and iv. ringer lactate. In group B, 7 out of 30 patients and in group L, 3 out of 30 patients received vasopressor once. However, vasopressor received by patients in both groups was comparable.In both groups changes in mean oxygen saturation during intra operative and post-operative period remained statistically insignificant, suggestive of no hypoxic episode in any of the patient included in the study during whole course of study period. Our results coincides with study of Santhosh K *et al* [18].

Both groups showed statistically insignificant difference in the incidence of complications and side effects (>0.05). Hypotension was observed in 3 patients in group L and 7 patients in group B. Incidence of bradycardia was observed in 2 patients in group B as compared to group L (0). Respiratory depression was noted in none of the patients in any group. Nausea in 1 patient in group L and 2 patients in group B. Similar incidence of side effects were observed in studies of Fattorini *et al* [16].

Conclusion

Intrathecal administration of 0.5% levobupivacaine provides almost same amount of sensory and motor blockade achieved with bupivacaine. Haemodynamically levobupivacaine is slightly more stable than bupivacaine during intraoperative and postoperative period with lesser complications.

Source of Funding

None

Conflict of Interest

None

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