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LEVOBUPIVACAINE VERSUS ROPIVACAINE EPIDURALLY IN LOWER LIMB SURGERIES.

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ABSTRACT

To compare the postoperative analgesic effect of epidural Levobupivacaine and Ropivacaine under Combined Spinal Epidural technique, we randomly allocated 60 ASA physical status I and II outpatients of age group 20-65years undergoing lower limb surgeries to receive Inj. Levobupivacaine 0.125% 6cc (Group–L, n-30) and Inj. Ropivacaine 0.125% 6cc (Group–R, n-30) 24 hours postoperatively in form of top-ups. Epidural catheter was inserted in sitting position at L2-L3, L3-L4 level with Touhy's needle after confirming with loss of resistance technique, Spinal anaesthesia was given with 3 to 3.5cc of 0.5% Bupivacaine (Heavy) one space below the epidural catheter insertion with 25G Quinkes spinal needle intra-operatively. The mean number of top-ups in the study groups were 4.1 (±0.4) and 4.5 (±0.5) in Levobupivacaine and Ropivacaine respectively, with p value = 0.010. The mean duration of hours between topups was 5.8(±0.6) and 5.4(±0.6) in Group L and Group R respectively, with p value = 0.010. We conclude that patients undergoing lower limb surgeries, Levobupivacaine has a longer duration of action and better analgesia than Ropivacaine.

KEY WORDS: Combined Spinal epidural technique, Postoperative analgesia.

INTRODUCTION

Combined Spinal Epidural (CSE) anaesthesia commands a unique place among the various techniques used for neuraxial blockade. In principle, the combination of two different administrations of anaesthesia routes on the same patient improves effectiveness and reduces side effects. Spinal anaesthesia provides fast and reliable segmental anaesthesia with minimal risk for toxicity, while epidural anaesthesia provides intra-operative anaesthesia, with excellent analgesia in the postoperative period. At the present time, CSE anaesthesia is widely used in orthopaedic, urologic and gynaecological surgery [1].

Epidural anaesthesia is a central neuraxial block with various applications. Improvement in equipment, drugs and technique has made it versatile anaesthetic procedure. Both single injection and catheter technique can be used [2]. Epidural anaesthesia provides prolonged postoperative analgesia which eases patient suffering, decreases cardiovascular and respiratory complications and ensures early mobilization [3]. Levobupivacaine and Ropivacaine, are newer long acting local anaesthetics and have been developed as an alternative to Bupivacaine, after the evidence of its severe toxicity. Both of these agents are pure left-isomers and the three-dimensional structure seems to have less toxic effects on the central nervous system and cardiovascular system [4].

Little information is available in the literature directly comparing the use of Levobupivacaine or Ropivacaine to produce postoperative analgesia for lower limb procedures. To achieve more information on this indication, we conducted this prospective, randomized, study to compare the postoperative analgesic effect of epidural Levobupivacaine and Ropivacaine in lower limb surgeries under Combined Spinal Epidural (CSE) using Inj. Levobupivacaine 0.125% 6cc and Inj. Ropivacaine 0.125% 6cc administered epidurally as per requirement for pain relief for 24 hours postoperatively.

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EXPERIMENTAL

After approval by the hospital ethics committee, a bilingual written informed consent was obtained from all the participating patients. Sixty patients, ASA physical status I and II aged 20 to 65 years, scheduled for elective lower limb surgery of duration between 2hrs to 2.5 hrs were selected. Thirty patients were randomly allocated to one of the two groups L and R. Patients hypersensitive to the drugs, on long term analgesic therapy, with peripheral neuropathy, local skin infections and spinal deformities or having coagulation abnormalities were excluded.

Intraoperatively, intravenous line was secured with 18/20 Gauge intra venous catheter, patients were preloaded with 10ml/kg Ringer's lactate solution, premedication with I.V. Inj. Ondensetron 4mg. Under all aseptic conditions, Patient in sitting position, Epidural catheter inserted in epidural space at L2-L3, L3-L4 level with Touhy's needle after confirming with loss of resistance technique. Spinal anaesthesia is given with 3 to 3.5cc of 0.5% Bupivacaine (Heavy) one space below the epidural catheter insertion with 25G Quinkes spinal needle. Surgeon was asked to start the procedure after confirming complete sensory and motor block by Bromage scale below the level of T10 dermatome. [1=Complete block (unable to move feet or knees), 2=Almost complete block (able to move feet only), 3= Partial block (just able to move knees), 4= Detectable weakness of hip flexion while supine (full flexion of knees), 5= No detectable weakness of hip flexion while supine, 6= Able to perform partial knee bend]. Level of sensory block was assessed by pin prick. Observations were performed under end of surgery time & onset time of pain, (VAS ≥3), No. of top-up required in 24 hours postoperatively, Time duration between two consecutive top-up. Post operatively, pain, motor block, hemodynamic parameters like Heart rate, Systolic B.P., Diastolic B.P., Mean Arterial pressure, Respiratory rate were monitored for every 5 min for 15 min and then after 15 min after each subsequent top-up. Pain intensity was evaluated by using a Visual Analog Scale (VAS) (0 = no pain and 10 = worst imaginable pain).

All statistical analyses were carried out using IBM SPSS 21.0 for Windows. Independent sample t test is used to compare differences in means of two groups. Test of proportion i.e. chi-square test was used to assess bivariate association between categorical variables such as gender of the patients across two groups. An ANOVA with repeated measures is used to compare difference in means across the groups where multiple (after 0 min, 5 min, 10 min, and 15 min) readings were taken of the same patients to assess changes in the hemodynamic parameters.

RESULTS

Table 1. Distribution of the patients by end of surgery time to VAS ≥ 3 (hours) in study groups

Sx Time toVAS≥3 (Hrs)	Levobupivacaine (n=30)		Ropivacaine (n=30)		Total (n=60)		Test statistics[!]
	Frequency	%	Frequency	%	Frequency	%	
2	6	20.0	6	20.0	12	20.0	χ^2 (df) = 1.116 (3) p value= 0.773[ns]
3	4	13.3	7	23.3	11	18.3	
4	11	36.7	10	33.3	21	35.0	
5	9	30.0	7	23.3	16	26.7	

! Chi-square (χ^2) test was used to compare difference in the proportions across the two intervention groups.
ns the difference was non-significant as p >0.05.

Table 2. Number of Top-ups required within 24 hours by the patients in study groups

Statistics	Levobupivacaine (0.125%) (n=30)	Ropivacaine (0.125%) (n=30)	Total (n=60)	Test statistics[!]
Mean score VAS (Hrs)	3.6	3.7	3.7	t value = 0.594 p value= 0.555[ns]
Standard deviation	±1.07	±1.10	±1.08	

! Independent sample t test was used to compare difference in the mean VAS of the patients across the two intervention groups
ns the difference was non-significant as p >0.05.

Table 3. Mean number of Top-ups required within 24 hours by the patients in study groups

Number of Top-ups	Levobupivacaine (n=30)	Ropivacaine (n=30)	Total (n=60)	Test statistics[!]
3	1 (3.3 %)	0 (0.0 %)	1 (1.7 %)	χ^2 (df) = 6.541 (2) p value= 0.038*
4	23 (76.7 %)	15 (50.0 %)	38 (63.3 %)	
5	6 (20.0 %)	15 (50.0 %)	21 (35.0 %)	

! Chi-square (χ^2) test was used to compare difference in the proportions across the two intervention groups.
** the difference was statistically significant as p <0.05.*

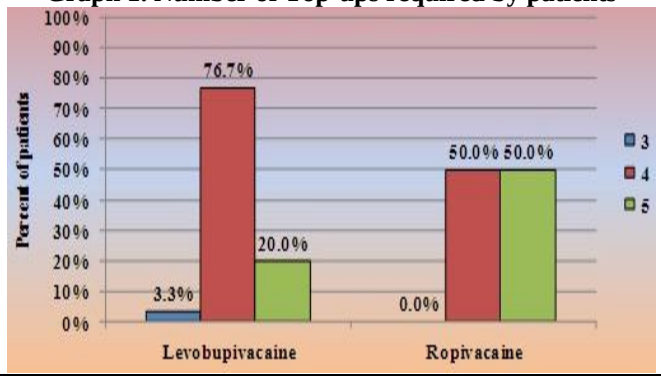
Table 4. Mean duration between Top-ups required within 24 hours by the patients in study groups

Statistics	Levobupivacaine (n=30)	Ropivacaine (n=30)	Total (n=60)	Test statistics[!]
Mean score	4.1	4.5	4.3	t value = 2.660
Standard deviation	±0.4	±0.5	±0.5	p value= 0.010*
! Independent sample t test was used to compare difference in the mean number of Top-ups required by the patient across the two intervention groups. ** the difference was statistically significant as p <0.05.*				

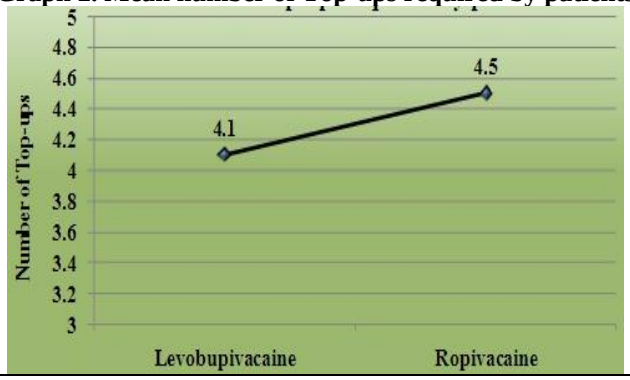
Table 5. Statistics

Statistics	Levobupivacaine (n=30)	Ropivacaine (n=30)	Total (n=60)	Test statistics[!]
Mean duration (hours)	5.8	5.4	5.6	t value = 2.651
Standard deviation	±0.6	±0.6	±0.6	p value= 0.010*
! Independent sample t test was used to compare difference in the mean duration between Top-ups required by the patients across the two intervention groups. ** the difference was statistically significant as p <0.05.*				

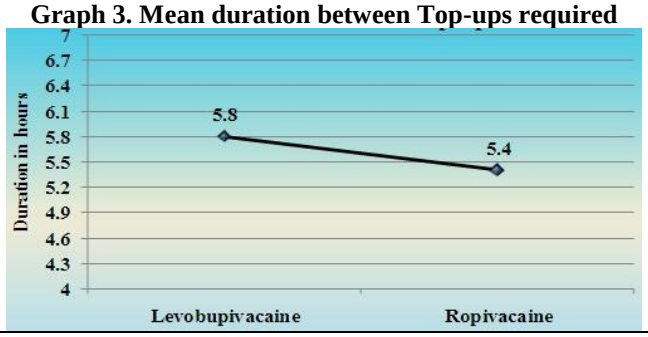
Graph 1. Number of Top-ups required by patients



Graph 2. Mean number of Top-ups required by patients



Graph 3. Mean duration between Top-ups required



DISCUSSION

Combined Spinal Epidural (CSE) anaesthesia commands a unique place among the various techniques used for neuraxial blockade. The singularity lies in its ability to combine the rapidity, density, and reliability of the subarachnoid block with the flexibility of continuous epidural block to titrate a desired sensory level, vary the intensity of the block, control the duration of anaesthesia and deliver postoperative analgesia. In principle, the combination of two different administrations of anaesthesia routes on the same patient improves effectiveness and reduces side effects. The use of local anaesthetic in epidural to provide post-operative analgesia is becoming more popular nowadays and postoperative analgesia is mandatory in lower limb surgeries in geriatric age groups with multiple co-morbid conditions for better outcome. Although CSE technique appears to be more complicated than either epidural or spinal block alone, intrathecal drug administration and placement of the epidural catheter are facilitated by the various modifications of the combine spinal-epidural technique.

In our study we gave more attention to post-operative analgesia with epidural local anaesthetics.

We conducted elective lower limb orthopaedic procedures with CSE technique and postoperative analgesia was carried out with Inj. Levobupivacaine 0.125% (6cc) and Inj. Ropivacaine 0.125% (6cc) administered epidurally as per requirement for pain relief for 24 hours postoperatively. The end of surgery time to VAS ≥3 in hours was studied in both groups and showed the mean VAS score of ≥3 after surgery in hours with standard deviations of 3.6±1.07 and 3.7±1.10 in Group L and Group R respectively. There was no statistical significance in study groups.

In our study we used Levobupivacaine 0.125% and Ropivacaine 0.125% in the form of epidural top-ups. The mean number of top-ups in the study groups were 4.1 (±0.4) and 4.5 (±0.5) in Levobupivacaine and Ropivacaine respectively which were statistically significant. Karis Bin Misiran et al showed similar results with Patient Controlled Epidural Analgesia with Ropivacaine 0.165% with Fentanyl 2.0 mcg/ml or Levobupivacaine 0.125% with Fentanyl 2.0 mcg/ml as a method of postoperative analgesia after major orthopaedic surgery and observed that requirement of Ropivacaine was 13% more than Levobupivacaine [5].

The intrathecal study by Ying Y Lee et al administered 8mg of either drug Bupivacaine, Levobupivacaine and Ropivacaine diluted to a volume of 2.5ml with normal saline. It was documented that Ropivacaine was less potent than Levobupivacaine and Bupivacaine when administered intrathecally [6].

In our study the time duration between the top-ups were more in Levobupivacaine as compared to Ropivacaine. The mean duration was 5.8(±0.6) and 5.4(±0.6) in Group L and Group R respectively, which was statistically significant. Takashi Egashira et al conducted a study in spine diseases for pain relief with the top-ups of Levobupivacaine and Ropivacaine for epidural block observed that there was no significant difference in the analgesia, VAS and Bromage scale in between 0.125% Levobupivacaine and 0.2% Ropivacaine but there was haemodynamic stability in study groups. They had not studied the time duration between the study groups as we have observed that the time duration between the top-ups was more in Levobupivacaine as compared to Ropivacaine and was statistically significant [7]. The haemodynamic difference was not seen in our study. We observed three parameters i.e. Heart rate, Mean arterial pressure and Respiratory rate. Zeynep Nur Orhon et al conducted study with comparison of Levobupivacaine and Ropivacaine in epidural anaesthesia for pilonidal sinus surgery which provided effective anaesthesia and was haemodynamically safe though the patients were in prone position. The advantages were haemodynamic stability, onset time of analgesia, duration of sensory block, with lack of motor block, patient's and surgeon's satisfaction with early mobilization. VAS scores were studied between the groups after administration of top-ups showed significant pain relief postoperatively. Both the drugs were useful and potent in relieving pain, but lesser values of VAS were observed in Group L than in Group R indicating more effective pain relief in Group L. No motor blockade was observed after each top-up administration and graded with Modified Bromage scale and was found to be '6'. Similar findings were seen by Zeynep Nur Orhon et al in the above mentioned study [8]. Total of 14 patients required rescue analgesia, 8 patients in Group R and 6 patients in Group L. Though the value in between the groups remained insignificant but showed less use of rescue analgesia in Group L as compared to Group R. Similar results were seen by Anjan Das et al in 2014 in comparison between Intra-Articular Ropivacaine and Levobupivacaine, for pain relief in day care arthroscopic knee relief. They showed the time for requirement of first-operative rescue analgesia in Group R was shorter than Group L and the results were statistically as well as clinically significant, total mean rescue analgesia requirement was less in Group L when compared to Group R, No side effects were observed in both the groups. The analgesic efficacy of intra-articular Levobupivacaine was superior to that of intra-articular Ropivacaine in reducing the pain over first 20 h post-operative period and Levobupivacaine was more effective in day care knee arthroscopic surgery [9].

None of our patients in either group in our study had any significant side effects like respiratory depression, hypotension, urinary retention. Similar results have been proved in various studies mentioned.

CONCLUSION

Thus from our study it was observed that Levobupivacaine 0.125% produces longer duration of analgesia with less no. of doses epidurally when given in top-ups along with better pain relief postoperatively in 24 hours in comparison to Ropivacaine 0.125%, with no incidence of motor blockade and side effects with both the drugs. Additionally both the drugs had haemodynamic stability. From the present study, we conclude that Levobupivacaine has a longer duration of action, provides better analgesia than Ropivacaine. Both the drugs have similar hemodynamic stability. None of the drugs cause motor blockade with this concentration. Reduction in requirement of systemic analgesics and no major adverse effects.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

STATEMENT OF HUMAN AND ANIMAL RIGHTS

All procedures performed in human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This article does not contain any studies with animals performed by any of the authors.

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