Comparative Study of Intrathecal Ropivacaine and Levobupivacaine With Fentanyl And Magnesium As Adjuvants For Lower Abdominal Surgeries

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Abstract:

Objective: To compare the block characteristics and haemodynamic stability of intrathecal Ropivacaine and Levobupivacaine with Fentanyl and Magnesium as adjuvants for lower abdominal surgeries. Method: Sixty patients of ASA grade I and II coming for elective lower abdominal surgeries under spinal anaesthesia were randomly allocated to two groups with 30 patients in each group. Group R received Isobaric Ropivacaine 0.75% -2.5ml + Fentanyl 20μ + Magnesium 50mg and Group L received Isobaric Levobuivacaine 0.75% - 2.5ml + Fentanyl 20μ + Magnesium 50mg. Sensory and motor block characteristics were assessed by pin prick and modified Bromage scale respectively and observed haemodynamics were recorded. Results: Time to reach T_{10} dermatome was faster in group L $(1.30\pm0.80mins)$ compared to group R $(4.23\pm0.94mins)$. The onset of motor block was significantly earlier in group L $(1.35\pm0.85mins)$ than group R $(4.63\pm0.85mins)$. Duration of analgesia was similar in both the groups (p=0.929) but resolution of sensory and motor block was significantly earlier in Levobupivacaine group compared to Ropivacaine group (p<0.001). Conclusion: Time for onset and recovery of sensory and motor block is shorter with intrathecal Levobupivacaine in combination with Fentanyl and Magnesium as adjuvants than intrathecal Ropivacaine.

Key words: intrathecal injection, Ropivacaine, Levobupivacaine, Fentanyl, Magnesium

I. Introduction:

Spinal anaesthesia is the most commonly used technique ^[1,2] for lower abdominal and lower limb surgeries. The main advantage being its simplicity, ease of technique and reliability ^[3,4]. Till recently bupivacaine was the only drug used after discontinuation of intrathecal lidocaine use ^[5]. Levobupivacaine and Ropivacaine, pure S-enantiomers of bupivacaine are safer alternative for regional anaesthesia than its racemic parent with lower cardiotoxicity^[6-8]. The sensory and motor block characteristics of intrathecal Ropivacaine and Levobupivacaine are found to be inconsistent in various studies ^[9,10] and the findings differ with varying doses of drug used in different studies. Further there are only fewer studies comparing intrathecal Ropivacaine and Levobupivacaine combined with adjuvants. To achieve more information on this indication this prospective study was performed to compare the sensory and motor block characteristics of intrathecal Ropivacaine and Levobupivacaine combined with Fentanyl and Magnesium for lower abdominal surgeries.

II. Methods:

Sixty patients posted for lower abdominal surgery were included in the study after approval by the ethical committee of the institution and obtaining the informed written consent of the patients. The study population consisted of patients in the age group between 18 to 65 years of ASA grade I and II scheduled for lower abdominal surgeries. Patients were randomly distributed into two equal groups: group R (Ropivacaine group) and group L (Levobupivacaine group), of equal number, and the volume of drug injected intrathecally was identical in both the groups. Group R received Isobaric Ropivacaine 0.75% -2.5ml + Fentanyl 20μ + Magnesium 50mg and Group L received Isobaric Levobuivacaine 0.75% -2.5ml + Fentanyl 20μ + Magnesium 50mg. All the patients were prehydrated with 500ml of ringers lactate. With the patient in left lateral position, lumbar puncture was performed through midline approach with 23G Quincke's spinal needle, with the bevel facing upwards. Following intrathecal drug injection, all patients were positioned in the supine position and received 5 l/min of oxygen via a face mask.

The sensory level was assessed by pinprick sensation using a blunt 25-gauge needle along the mid clavicular line bilaterally. The times to reach the T_{10} dermatome, two segment regression and the duration of analgesia were recorded. The motor level was assessed according to the modified Bromage scale. The times to reach Bromage 3 and regression to Bromage 0 were also recorded. All durations were calculated considering the time of intrathecal injection as time zero. In the case of a discrepancy in the dermatomal level between the right

and left side, the higher level was used for the statistical analysis. The haemodynamic parameters [heart rate and blood pressure] were recorded at 5 minutes interval intraoperatively and every 15minutes in the post anesthesia care unit up to regression of motor block to Bromage 0. The results thus obtained were statistically analyzed.

III. Results:

There was no statistical difference between the two groups in terms of their demographic characteristics and the duration of surgery (Table 1).

Table 1: Demographic data

	Group R	Group L	P value
Age in years	40.60±12.20	39.90±13.01	0.831
Weight [kg]	59.23±5.86	61.40±4.72	0.120
Height [cm]	158.90±5.16	159.13±4.74	0.856
Duration of surgery [min]	72.83±14.78	75.17±11.93	0.504

The time to reach T_{10} dermatome was 4.23 ± 0.94 mins in group R and 1.30 ± 0.80 mins in group L. The mean time to reach Bromage 3 motor block was 1.35 ± 0.85 mins in group L and 4.63 ± 0.85 mins in group R. Group L had significantly earlier onset of sensory and motor block than group R (p<0.001) as shown in table 2. The time for two segment regression and mean regression time to Bromage 0 motor block was significantly shorter in Levobupivacaine group compared to Ropivacaine group (Table 2).

Duration of analgesia, the time interval between intrathecal drug injection to first analgesic dose request by the patient, was similar in both the study groups (p=0.92). Changes in heart rate and mean arterial pressure were not statistically significant (Fig: 6 and 7). No significant side effects were noted in any of the groups.

Table 2: Comparison of block characteristics in two study groups

Study variables	Group R	Group L	P value
Time to reach T ₁₀ in min	4.23±0.94	1.30±0.80	<0.001**
Time to reach T ₈ in min	5.80±1.10	2.36±1.20	<0.001**
Onset motor blockade in min	4.63±0.85	1.35±0.85	<0.001**
Two segment regression in min	126.17±21.52	89.63±14.03	<0.001**
Time for motor recovery in min	252.83±33.13	194.93±18.15	<0.001**
Duration analgesia in min	281.10±36.53	287.50±390.28	0.929

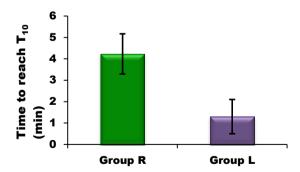


Figure 1: Time to reach T_{10} dermatome

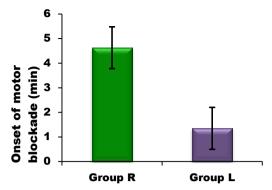


Figure 2: Onset of motor block

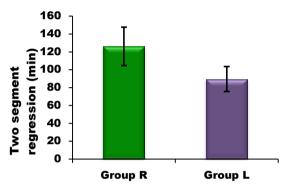


Figure 3: Time for two segment regression of sensory block

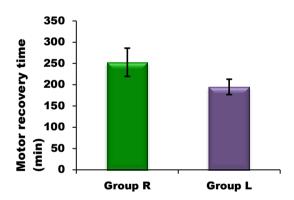


Figure 4: Time to reach Bromage 0 motor block

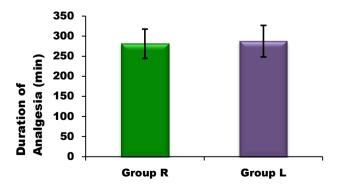


Figure 5: Duration of analgesia

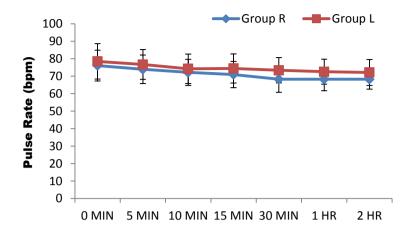


Figure 6: Changes in heart rate

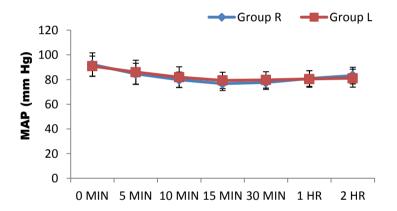


Figure 7: Changes in mean arterial pressure

Statistical Methods: Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean \pm SD [Min-Max] and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance. Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. [11, 12] Significant figures:

- + Suggestive significance (P value: 0.05<P<0.10)
- * Moderately significant (P value: $0.01 < P \le 0.05$)
- ** Strongly significant (P value: P≤0.01)

Statistical software: The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1 ,Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

IV. Discussion:

In the present study sixty patients undergoing lower abdominal surgery received either 2.5ml of 0.75% isobaric Ropivacaine or 0.5% isobaric levobupicacaine intrathecally along with 20μ Fentanyl and 50mg Magnesium sulphate as intrathecal adjuvants. A total volume of 3ml was injected intrathecally in all the patients. Both the groups were comparable with respect to demographic data and duration of surgery.

In our study the time for sensory block to reach T_{10} dermatome level and time to reach Bromage 3 were significantly earlier in group L than group R (p<0.001). This was comparable with other studies ^[13,14]. Mehta et al^[13] in 2007 compared 15mg isobaric Levobupivacaine and 15mg isobaric Ropivacaine administered intrathecally for patients undergoing lower limb surgeries and showed that mean onset of sensory and motor block was longer in Ropivacaine group than Levobupivacaine group. Cappelleri et al.^[15] reported that time for

onset of sensory and motor block was similar with that of Levobupivacaine and Ropivacaine group which is in contrast to our results.

The two segment regression of sensory block in our study was faster in Levobupivacaine group compared to Ropivacaine group (p<0.001) and the regression of motor block to bromoge 0 was significantly earlier in Levobupivacaine group (194.93±18.15mins) compared toRopivacaine group (252.83±33.13mins). Cappelleri et al ^[15] compared unilateral spinal block produced by 7.5mg of hyperbaric Ropivacaine with that produced by 5mg and 7.5mg of hyperbaric Levobupivacaine and concluded that time for resolution of spinal block was shorter with 7.5mg of 0.5% hyperbaric Ropivacaine group and 5mg 0.5% hyperbaric Levobupivacaine group compared to 7.5mg of 0.5% hyperbaric Levobupivacaine group. Breebart et al ^[16] compared 10mg levobupivacaine and 15mg Ropivacaine for outpatient knee arthroscopy and reported L₂ regression of sensory block after 173mins and 167mins, with home discharge after 311mins and 305mins respectively. The results of above studies ^[15, 16] are in contrast to our study which may be attributed to differences in the race of people, density, baricity and /or concentration of local anaesthestic mixture used in various studies. The main problem with Levobupiavacaine and Ropivacaine is that hyperbaric formulations are not readily available in market and the final density of diluted mixture may be less predictable than the commercially available specific hyperbaric preparations and in 2004 Mc Leod ^[17] determined the density of Levobupivacaine and Ropivacaine with addition of 8% dextrose to be 1.030 and 1.029 respectively. The density of the local anaesthetic mixture we used in our study was 1.018 in group L and 1.026 in group R.

Similar duration of analgesia was reported in both our study groups and it was comparable to studies by Lim et al^[18] and Sia et al^[19]. Haemodynamic parameters in the intra and postoperative period were similar in both our study groups. This was comparable with other studies ^[13,15].

V. Conclusion:

The present study shows that 12.5mg isobaric Levobupivacaine with 20μ Fentanyl and 50mg Magnesium provides faster onset and recovery of sensory and motor block with stable haemodynamic conditions making intrathecal Levobupivacaine more suitable for day care surgeries than intrathecal Ropivacaine.

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References:

- [1]. Hunt CO. spinal anaesthesia for obstetrics. International anaesthesiology clinics. 1989;27:26-30
- [2]. Riley E T, Cohens S E, Macaria et al. spinal anaesthesia versus epidural for ceasarean section: a comparision of time efficiency, costs, charges and complications. Anaesth Anal 1995;80:709-12
- [3]. Morgan p.spinal anaesthesia in obstetrics. Can J Aesthesia 1995;42:1145-63.
- [4]. Lucy S J, Naugler M A. Spinal anaesthesia for caesarean section[letter]. Can J Anaesthesia 1991;38:940-1
- [5]. Shamuel Evron, Victoria Gurstieva, Tiberiu Ezri,transient neurological symptoms after isobaric subarachnoid anaesthesia with 2% lidocaine: the impact of needle type. Anaesth. Analg. Nov 2007;105:1494-99.
- [6]. Foster R H., Markham A., Levobupivacaine: a review of its pharmacology and use as local anaesthetic, Drugs, 59[3],551-79,2000.
- [7]. Markham A., Faulds D., Ropivacaine. A review of its pharmacology and therapeutic use in regional anaesthesia, DRUGS, 52[3], 429-49, 1996.
- [8]. McClellan K. J., Sppencer C. M.Levobupivacaine. Drugs,56[3], 355-62,1998.
- [9]. McDonald S, Liu SS, Kopacz DJ ,Stephen CA. Hyperbaric spinal rpivacaine: a comparision to bupivacaine in volunteers. Anaesthesiology 1999;90:971-77
- [10]. P. Gautier, M De kock, L Huberty,T Demir, et al. comparision of the effects of intrathecal Ropivacaine,Levobupivacaine and bupivacaine for ceasarean section; Br J Anaesthesia,2003,Vol.91,[51]684-89.
- [11]. Bernard Rosner [2000], Fundamentals of Biostatistics, 5th Edition, Duxbury, page 80-240
- [12]. Suresh K.P. and Chandrasekhar S [2012]. Sample Size estimation and Power analysis for Clinical research studies. Journal Human Reproduction Science, 5[1], 7-13.
- [13]. Mehta A, Gupta V, Wakhloo R, Gupta N, Gupta A, Bakshi R, et. al.; Comparative evaluation of intrathecal administration of newer local anaesthetic agentsRopivacaine andLevobupivacaine with Bupivacaine in patients undergoing lower limb surgery; The Internet Journal of Anesthesiology. 2008 Volume 17 Number 1
- [14]. **Mantouvalou M, Ralli S, Arnaoutoglou H, Tziris G, Papadopoulos G**; Spinal anesthesia: Comparison of plainRopivacaine, bupivacaine and Levobupivacaine for lower abdominal surgery; Acta Anaesth. Belg., 2008, 59, 65-71
- [15]. Cappelleri G, Aldegheri G, Danelli G, et al. Spinal anesthesia with hyperbaricLevobupivacaine andRopivacaine for outpatient knee arthroscopy:a prospective, randomized, double-blind study. Anesth Analg. 2005;101:77–82.
- [16]. Breebaart MB, Vercauteren MP, Hoffmann VL, et al. Urinary bladder scanning after day-case arthroscopy under spinal anaesthesia:comparison between lidocaine, Ropivacaine, and Levobupivacaine. Br J Anaesth. 2003;90:309–13.
- [17] McLeod GA. Density of spinal anesthetic solutions of bupivacaine, Levobupivacaine, and Ropivacaine with and without dextrose. Br J Anaesth 2004:92:547–51.
- [18]. Lim Y, Ocampo CE, Sia AT. A comparison of duration of analgesia of intrathecal 2.5 mg of bupivacaine, Ropivacaine, and Levobupivacaine in combined spinal epidural analgesia for patients in labor. Anesth Analg. 2004;98:235–239.
- [19]. Sia AT, Goy RW, Lim Y, Ocampo CE. A comparison of median effective doses of intrathecalLevobupivacaine andRopivacaine for labor analgesia. Anesthesiology. 2005;102:651–656.