www.jmscr.igmpublication.org
Impact Factor (SJIF): 6.379
Index Copernicus Value: 71.58
ISSN (e)-2347-176x ISSN (p) 2455-0450
crossref DOI: https://dx.doi.org/10.18535/jmscr/v6i2.144

IGM Publication
Journal Of Medical Science And Clinical Research
An Official Publication Of IGM Publication

Effectiveness of Ropivacaine versus Levobupivacaine for Spinal Anaesthesia and Analgesia in Lower Limb Surgery

Authors
Dr Alpa M Patel[1], Dr Astha P Naik[2], Dr Nirali N Panchal[3]
Department of Anesthesiology, Pramukhswami Medical College & Shree Krishna Hospital,
H.M. Patel Centre for Medical Care & Education, Karamsad- 388325, Gujarat, India
Correspondence Author
Dr Astha P Naik
House no 251/2,Plot No 33,Vachlu Faliyu, Behind Valsad RTO, Avas Township, Atak Pardi, Valsad, Gujarat, 396007 India
Mob: +91 9925859491, Email: *naikastha@gmail.com*

Abstract
Introduction: *Newer local anaesthetic amides Ropivacaine and Levobupivacaine have gained popularity for spinal anaesthesia due to lower cardiotxicity and neurotoxicity. In this prospective, randomized double blind study we compare the effects of intrathecal isobaric ropivacaine 0.75% and levobupivacaine 0.5% in regards to the onset, regression, duration of sensory and motor blockade and also their hemodynamic stability, analgesic effect, and surgeon's & patient's satisfaction in term of surgical anaesthesia.*
Material and Methods: *68 patients of ASA1 to ASA3 physical status scheduled for lower limb surgery under spinal anaesthesia were recruited and randomized into Group L and Group R. Group L received 3ml of 0.5% Levobupivacaine and Group R received 3ml of 0.75% Ropivacaine intrathecally. Sensory & motor block onset, regression and hemodynamics were noted intraoperatively. Total duration of blockade and analgesia were noted postoperatively.*
Results: *Group L had faster onset and longer duration of sensory and motor block with shorter motor regression time in comparison to Group R thus not hampering mobilization .Group L also had a longer time to first rescue analgesia and higher degree of patient's and surgeon's satisfaction in terms of surgical anaesthesia and were more hemodynamically stable in comparison to Group R.*
Conclusion: *Both Ropivacaine and Levobupivacaine have desirable blocking property and can be used for lower limb surgery. Levobupivacaine provides more effective anaesthesia in term of onset, duration and longer period of post operative analgesia with lesser side effects and better patient's and surgeon's satisfaction in comparison to Ropivacaine.*
Keywords: *Ropivacaine, Levobupivacaine, spinal anaesthesia, lowerlimb surgery.*

Introduction

Spinal anaesthesia enjoys popularity all over the world for its ease of technique, high degree of success, ability to use fewer drugs and avoiding the complications related to general anaesthesia.

Pain is considered to be the fifth vital sign and is an important variable in assessing the post-operative morbidity in the patients. Perioperative pain relief is an essential component of balanced anaesthesia and plays an important role by, providing comfort to anxious patients, improving morale and mobility contributing to a more rapid and complete recovery, decreasing the incidence of pulmonary complications, reduces the incidence of thromboembolic

phenomenon, reduction in requirement of systemic analgesics and thus their side effects.

The recognition of acute life-threatening cardio-toxicity of bupivacaine led to the search for a local anaesthetic agent comparable with bupivacaine but with lower cardiotoxicity and neurotoxicity resulting in development of a relatively newer amide, Levobupivacaine and Ropivacaine.

The above mentioned properties of levobupivacaine has led to its application as a local anesthetic in a wide variety of applications including sub-arachnoid block, epidural anesthesia and analgesia, brachial plexus blocks, peripheral nerve blocks, ocular blocks as well as local infiltration. It is also being used for labor analgesia, post-operative pain as well as management of acute and chronic pain[1].

Levobupivacaine produces subarachnoid block with similar sensory and motor characteristics and recovery like bupivacaine. The regression of motor block occurs earlier with levobupivacaine and ropivacaine as compared with bupivacaine. At low concentrations, levobupivacaine produces a differential neuraxial block with preservation of motor function, which may be favorable for ambulatory surgery.[1,2] Study comparing the effects of bupivacaine, ropivacaine and levobupivacaine in subarachnoid block for cesarean delivery showed that the time to onset of sensory and maximum motor block as well as the duration of analgesia is slightly longer with intrathecal levobupivacaine as compared to bupivacaine in cesarean section.[3,4,5]

Different studies have compared levobupivacaine, ropivacaine and bupivacaine in brachial plexus block for upper limb surgery which concluded that Levobupivacaine is a good substitute for bupivacaine and that, compared to ropivacaine, levobupivacaine provides a significantly longer duration of analgesia. Long duration of sensory block associated with good analgesia and less toxicity of levobupivacaine makes it a better choice for upper extremity blocks. .

The objective of our study is to compare Ropivacaine and Levobupivacaine in spinal anaesthesia in terms of onset, regression and duration of sensory and motor blockade, time to requirement of first rescue analgesia. Their hemodyanamic effects and side effects if any, and to assess patient's and surgeon's satisfaction in terms of surgical anaesthesia.

Materials and Methods

A prospective, randomized double blind controlled trial was conducted on patients undergoing lower limb surgery.

After obtaining ethical committee approval and patient's written and informed consent. Sixty eight patients were recruited after satisfying the inclusion and exclusion criteria. The inclusion criteria being any patient undergoing lower limb surgery, of ASA 1 to ASA 3 physical status of age 18-80 years and the exclusion criteria being patient's refusal, history of allergy to local anesthetic and any other contraindications to spinal anaesthesia.

68 patients were randomly divided into two groups, Group L and Group R based on computer generated randomization (WINPEPI).

GROUP L:Inj. Levobupivacaine (0.5%) isobaric 3ml

GROUP R: Inj. Ropivacaine (0.75%) isobaric 3ml

The data collection was done by junior residents who were unaware of the drug that was administered and was validated by us.

Patients were kept NBM 8 hours prior to surgery. Intravenous access was established and intravenous fluid (Inj. Ringer lactate / Inj. Normal saline) 10-15 ml/kg/hr was started 30 min prior to surgery. Baseline vital parameters were recorded. Inj. Ondensetron 0.08mg/kg was administered 30 mins prior to surgery.

The Following sensory block parameters were assessed-:Onset of Sensory Block- Time from injection to onset of loss of pin prick sensation at S2 dermatome, time taken for sensory blockade to reach T10 level- time from administration of drug till the loss of pin prick sensation at the level of T10 dermatome, time taken for sensory blockade to reach peak level- Time from administration of drug till the loss of pin prick sensation at maximum sensory peak level, two segment regression time- Time from administration of drug till the recovery

of pin prick sensation as sharp pain at two levels below peak level, total duration of sensory block- Time from administration of drug till recovery of pin prick sensation as sharp pain at S2 dermatome.

The Following motor block parameters were assessed-Onset of motor block- Time of administration of drug till the attainment of modified bromage scale, Time taken for motor blockade to reach Modified bromage scale B3- Time of administration of drug till the attainment of modified bromage scale of 3, Time taken for motor blockade to recede to B1 level- Time from administration of drug till the recovery of motor blockade to modified bromage scale of 1, Duration of motor block- Time from administration of drug till recovery of motor block level to Modified bromage scale of 0.

Patient was also monitored for other side effects intraoperatively like shivering, nausea, vomiting, respiratory distress and the same was documented. In case of shivering inj. Tramadol 50 mg was administered intravenously and inj. Odensetron 4mg in cases experiencing nausea and vomiting. The time for request for first rescue analgesia was noted from the time of administration of spinal anaesthesia to complain of pain (VAS score >/= 3 at rest, VAS score >/= 5 on movement). Postoperatively patient was also monitored for changes in vital parameters, nausea, vomiting, shivering, and retention of urine. Patient's satisfaction was judged on the basis of them to accept the same mode of anaesthesia for their next surgical procedure, whereas Surgeon's satisfaction was judged on the basis of the lower limb relaxation.

Data was entered on an excel sheet. The data was analyzed statistically using statistical programme for social science (SPSS). Quantitative parameters were analyse using 'T' test. A 'P' value of < 0.05 was regarded as statistically.

Results

The time taken for sensory blockade to reach T10 level was noted which was (3.47±0.76) in group L and (5.82±0.797) in group R. The mean time taken for sensory blockade to reach peak level in Group L was (4.74±0.828) and in Group R was (6.47±0.861).(P<0.001)

The mean time for sensory regression by two levels was (101.91±11.848) in Group L and (94.18±7.941) in Group R.(P value=0.002)

The duration of sensory blockade in Group L was (223.62±23.034) and in Group R was (180.65±11.586). (P<0.001)

The time for motor onset i.e to attain a bromage scale of 1 was (1.68±0.638) in Group L and (2.28±0.626) in group R. The time taken to attain bromage scale 3 in group L was (6.68±1.147) and (7.97±0.87) in Group R.(P<0.001). Whereas the time taken for motor blockade to regress to bromage scale 1 was shorter in group L which was (142±0.937) and (147±9.64) in group R(P<0.05). The total duration of motor blockade was (183±10.59) in group L and (154±9.61) in group R was.(P<0.001)

In our study mean time to first rescue analgesia that is the time from drug administration till the time patient complained of pain (VAS score>3 at rest or >5 on movement) in Group L was 238+_18.9 mins and in Group R was 194+_12.9 mins.(P<0.001)

In our study, mean drop in blood pressure in Group L was 6.79+_7.5% and 12.6+_10.9% in Group R. 1 case(2.9%) required one dose that is 6mg of inj. Mephentramie in Group L, whereas 3 cases(8.8%) in Group R required inj. Mephentramine.

The mean %drop of pulse rate in Group L was 2.97%+_4.0 and Group R was 7.62+_9.5. 1 case in Group R(2.9%) required inj. Glycopyrolate 0.2 mg intravenously due to fall in heart rate of 33% from baseline, whereas none of the cases in Group R required inj. Glycopyrolate.

Study the 'Quality' of anaesthesia as judged by the patient was good in 85.29% in group L while only 52.94% of patients in group R judges it as good.

The quality of anaethesia as judged by the surgeon was good in 88.23% of cases in group L whereas it was good only in 58.82% of cases.

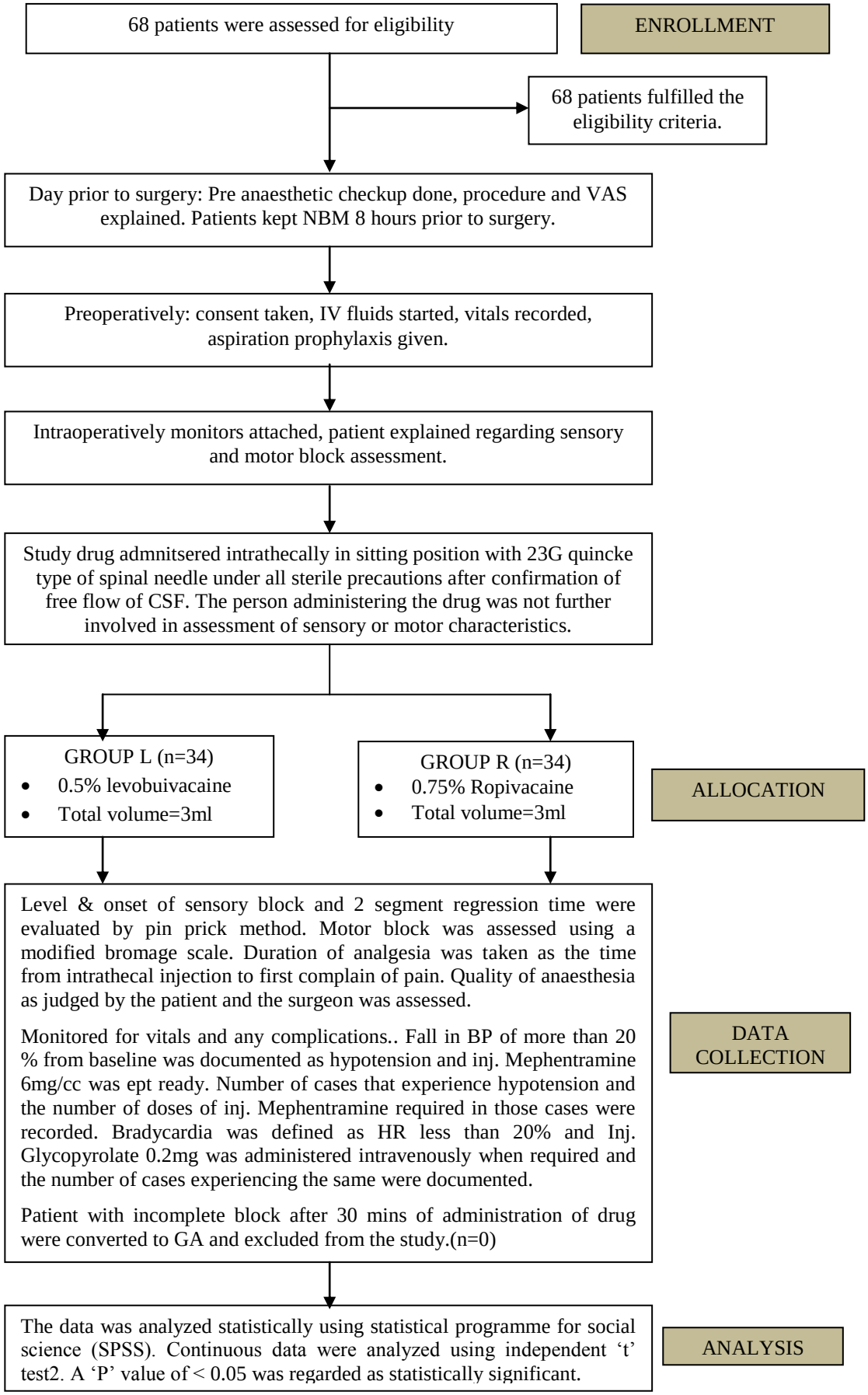

Figure I: Consort Flow Diagram

Sensory Characteristics

Table I: Comparison of sensory characteristics between the two study groups

	GROUP L			GROUP R			P VALUE
	Maximum	Minimum	Mean±SD	Maximum	Minimum	Mean±SD	
Sensory onset	2 mins	0 min	1.06±0.649	3 mins	1 min	1.94±0.649	P<0.001
Sensory T10 level	5 mins	3 mins	3.47±0.706	7 mins	5 mins	5.82±0.797	P<0.001
Sensory Peak level	6 mins	3 mins	4.740.828	8 mins	5 mins	6.47±0.861	P<0.001
Sensory two level Regression	150 mins	80 mins	101.91±11.848	110 mins	80 mins	94.18±7.941	P=0.002
Sensory duration	280 mins	190 mins	223.62±23.034	210 mins	160 mins	180.65±11.586	P<0.001

Motor Charateristics

Table II: Comparison of motor characteristics between the two study groups

	GROUP L			GROUP R			P VALUE
	Maximum	Minimum	Mean±SD	Maximum	Minimum	Mean±SD	
Motor Onset	3 mins	1 min	1.68±0.638	4 mins	2 mins	2.82±0.626	P<0.001
Motor blockade level Modified bromage scale 3	8 mins	4 mins	6.68±1.147	10 mins	7 mins	7.97±0.87	P<0.001
Regeression to Modified bromage scale 1	170 mins	130 mins	142±0.937	172 mins	132 mins	147±9.64	P=0.047
Motor Duration	200	160	183±10.59	176	140	154±9.61	P<0.001

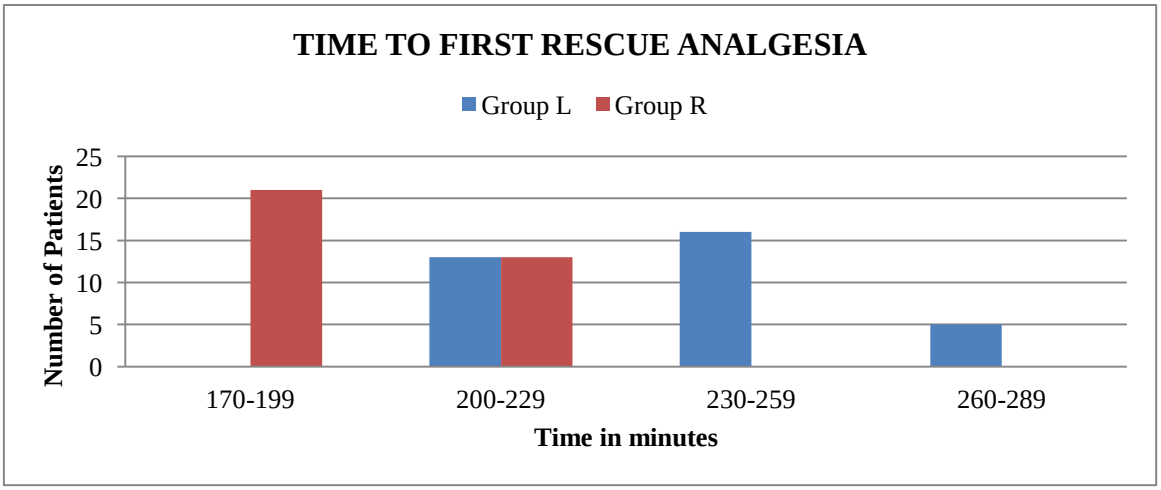

Figure II: Comparison of time to first rescue analgesia between both study groups

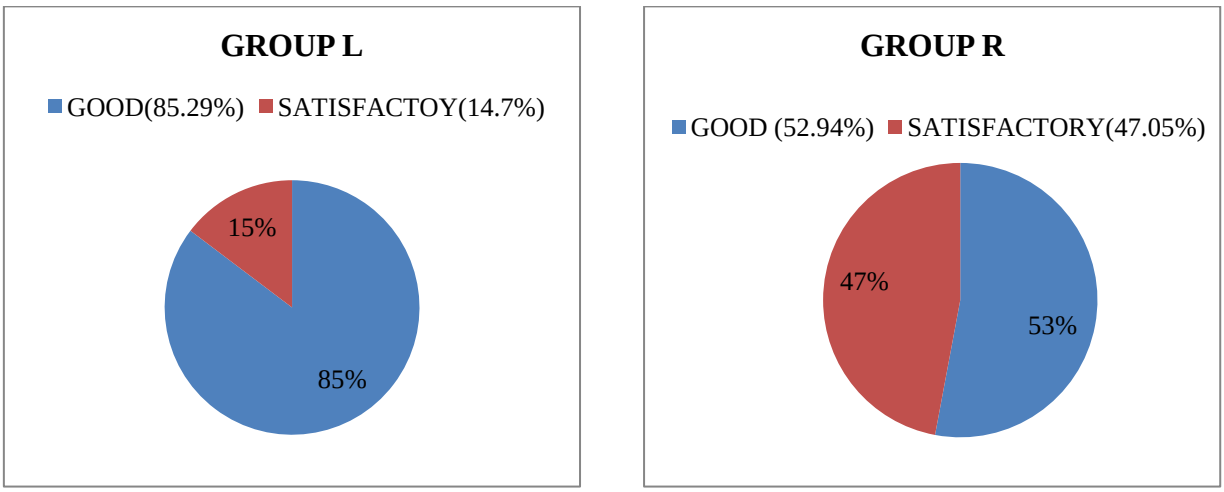

Figure III: Comparison of patient's satisfaction between the both study groups

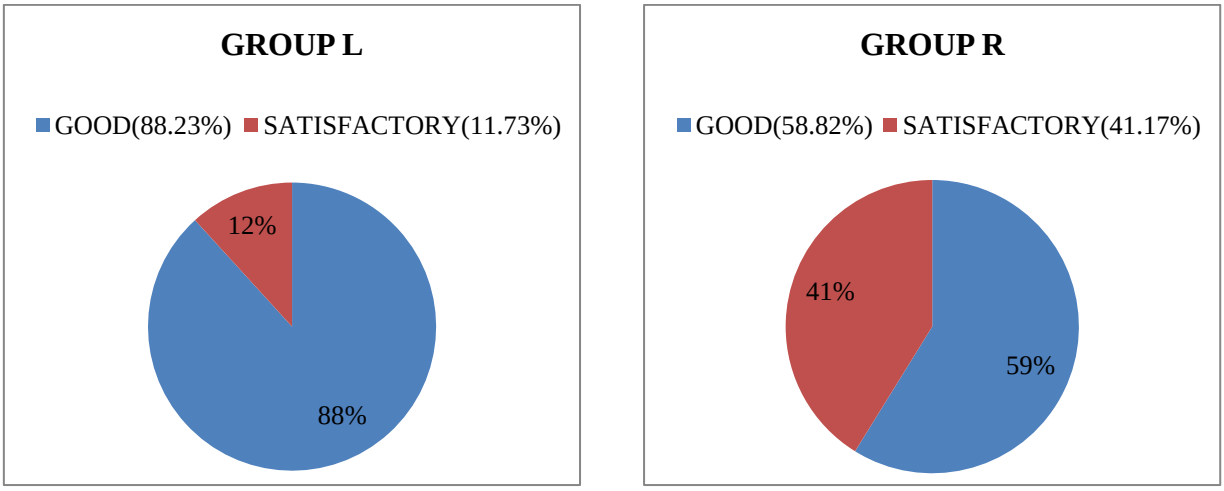

Figure IV: Comparison of surgeon's satisfaction between both study groups

Table III: Comparison of side effects between the two study groups

	Hypotension	Bradycardia	Shivering	Nausea & Vomiting	Retention of urine
GROUP L	2.9%	0	5.88%	2.94%	0
GROUP R	8.8%	2.9%	8.82%	0	2.94%

Discussion

Till today spinal anaesthesia is the most versatile block available and being used for various surgeries on the lower half of the body.

The advantages of spinal anaesthesia includes simplicity, ease of performance, good muscle relaxation, postoperative analgesia, blunts autonomic, somatic, endocrine response and prevention of complications like deep vein thrombosis.

Ying et al[6], kannai et al[7] and Gautier et al[3] showed that Bupivacaine is the most potent local anaesthetic equivalent to levobupivacaine followed by ropivacaine. The dose of levobupivacaine and bupivacaine were found to be equipotent, whereas ropivacaine was found to be two third as efficacious of either bupivacaine or levobupivacaine as per the study of Lee et al[8].Greater lipid solubility and formulation of levobupivacaine could partly explain its potency differences to ropivacaine[9].We thus chose 5mg/ml concentration of levobupivacaine and 7.5mg/ml of ropivacaine in our study, keeping the volume constant.

Regarding the sensory block characteristics our study shows that the onset of sensory block was significantly shorter for levobupivacaine whereas the the time for regression by two level and the duration of sensory block was longer for levobupivacine which was similar to the study conducted by conducted by Ashok Das et al[10] comparing the effect of isobaric intrathecal Bupivacaine 0.5%, Levobupivacaine 0.5% and Ropivacine 0.75% (total volume of drug being 3ml in all groups) in lower abdominal surgery which showed that, Ropivacaine group had significantly delayed onset, but significantly shorter duration of sensory block & 2 segment regression time(P value<0.001).In another sty done by Senthil Kumar et al[11]comparing intrathecal isobaric 0.75% Ropivacaine versus 0.5% levobupivacaine (total volume of both drugs=3ml) in inguinal hernia surgery showed that, Levobupivacaine had a faster onset with longer 2 level regression time and duration of sensory block though the difference was not statistically significant(P>0.05). Udayagiri Ravisankar et al[12] conducted a study comparing relative potencies of 0.5% Ropivacane, 0.5% Levobupivacaine and 0.5% Bupivacaine (total volume of drug being 3ml in all groups) in lower abdominal and lower limb surgeries showed faster onset and longer duration of sensory block with levobupiavcaine with statistical significance. (P<0.05) Similarly in a study conducted by Ritika Jindal et al[13] comparing isobaric 0.5% Ropivacaine and 0.5% Levobupivacaine (total volume of both

drugs=3ml) in patients undergoing lower abdominal surgery showed that time to reach onset and peak sensory level was delayed in Ropivacaine group but the difference was insignificant (P>0.05). Duration of sensory block and 2 segment regression was more prolonged in Levobuivacaine group (P<0.05).

Regarding the motor block characteristics the onset of motor block and regression of motor block to modified bromage scale to 1 was faster with levobupivacaine whereas the total duration of block was shorter with Ropivacaine. Other studies showing similar results are as follows, Ashok Das et al[10]showed that Ropivacaine had delayed onset and shorter duration of motor blockade in comparison to Levobupivacaine. Both the difference being statistical significant.(P<0.001)And that conducted by Udayagiri ravishankar et al[12], concluded that Levobupivacaine had a faster onset and longer duration of motor block in comparision to Ropivacine and both the results were statistically significant.(P<0.05)

The study conducted by Michela Camorcia et al[14] to find out the minimum local analgesic doses of Ropivacaine, Levobupivacaine and Bupivacaine for intrathecal labor analgesia showed that the relative analgesic potency ratio were 0.80 for ropivacaine: levobupivacaine, 0.65 for for ropivacaine: bupivacaine and 0.81 for levobupivacaine: bupivacaine. And that conducted by Ying Y. Lee et al[9] to compare the median effective dose of bupivacaine, levobupivacaine and levobupivacaine after intrathecal injection in lower limb surgery showed that : the ED50s were 5.50 mg for bupivacaine ,5.68 mg for levobupivacaine ,and 8.41 mg for ropivacaine in intrathecal anesthesia. The relative anesthetic potency ratios are 0.97 for levobupivacaine/bupivacaine, 0.65 for ropivacaine/ bupivacaine, and 0.68 for ropivacaine /levobupivacaine. The above studies prove levobupivacaine to be more potent in comparison to ropiavacine which is similar to our study in terms of onset and duration of sensory & motor block.

The results of above study support our study proving the better potency of levobupivacaine in comparison to ropivacaine.

In our study mean time to first rescue analgesia that is the time from drug administration till the time patient complained of pain (VAS score>3 at rest or >5 on movement) was much longer with levobupivacaine. (P<0.001) The study conducted by Ashok Das et al[10] showed similar results. A metanalysis of randomized controlled trials of ropivacaine versus levobupivcaine in peripheral nerve block done by Ang li et al[15] also had a similar conclusion in the form that the incidence of postoperative rescue analgesia was significantly higher in ropivacaine group than that in levobupivacaine group.

In our study levobupiavacaine group was more hemodyanamically stable in terms of blood pressure and pulse rate in comparison to ropivacaine group which was contrast to the results of the studies conducted by Ashok das et al[10] and Udayagiri Ravishankara et al[12] which showed that both the groups were comparable with regard to side effects profile. This discrepancy with the study conducted by Udayagiri Ravishankara[12] could be due to the useof non equivalent dosesof ropivacaine and levobupivacaine as per the studies conducted by Michela Camorcia et al[13] and by YingY. Lee et al that prove that ropivacaine is only two third as efficacious as levobupivacaine.

In our study the patient's and surgeon's satisfaction in term of surgical anaesthesia was higher with levobupivacaine which was similar to the result of Ashok et al's[11] study.

Conclusion

We concluded from this study that both Ropivacaine and Levobupivacaine have desirable blocking property and can be used for lower limb surgery. Levobupivacaine has a superior efficacy in terms of faster onset & longer duration of sensory and motor block with shorter time for regression of motor block and also a longer duration of analgesia in comparison to ropivacaine. Levobupivacaine is also more cardiostable, with lesser side effects, better surgeon and patient satisfaction.

Acknowledgement

We are greatly indebted for the support provided by the department and the institute. We are also very thankful to Indian society of anesesthesiologist conference, Gujarat for acknowledging our study and awarding it with the M.T. Bhatia award.

References

1. Huang YF, Pryor ME, Mather LE, Veering BT. Cardiovascular and central nervous system effects of intravenous levobupivacaine and bupivacaine in sheep. Anesth Analg 1998;86:797-804.
2. Morrison SG, Dominguez JJ, Frascarolo P, Reiz S. A comparison of the electrocardiographic cardiotoxic effects of racemic bupivacaine, levobupivacaine, and ropivacaine in anesth-etized swine. Anesth Analg 2000;90:1308-14
3. Gautier P, De Kock M, Huberty L, Demir T, Izydorczic M, Vanderick B. Comparison of the effects of intrathecal ropivacaine, levobupivacaine, and bupivacaine for caesarean section. Br J Anaesth 2003;91:684-9.
4. Buyse I, Stockman W, Columb M, Vandermeersch E, Van de Velde M. Effect of sufentanil on minimum local analgesic concentrations of epidural bupivacaine, ropivacaine and levobupivacaine in nullipara in early labour. Int J Obstet Anesth 2007;16:22-8.
5. Mantouvalou M,Ralli S,Arnautoglou H,Tziris G,Papadopoulos G. Spinal anestheisa: cpmaprison ofplain ropivacaine, bupivacaine for lower abdominalsurgery. Acta Anaesthesiol Belg. 2008:59(2):65-71.
6. Ying Y. Lee,Warwick D. Ngan Kee, 2009. The Median Effective Dose of Bupivacaine, Levobupivacaine, and Ropivacaine After Intrathecal Injection in Lower Limb Surgery. Anesth Analg 2009;109:1331–4
7. Kannai Y,Katsuai H ,Takasaki N,Comparision of the anesthetic potency and intracellular concentration S(-) and R(+) Bupivacaine and Ropivacaine in crayfish giant axon in vitro.Anesth analg.2000;90:415-20.
8. Lee YY, Muchhal K, Chan CK.2003 Levobupivacaine versus racemic bupivacaine in spinal anaesthesia for urological surgery. Anaesth Intensive Care 2003;31:637–41
9. Mather, L. and Chang, D. 2006. Cardiotox-icity with modern local anaesthetics: is there a safer choice? Drugs., 61(3): 333-42.
10. Ashok Das, Rajdip Hazra, Bivash Halder, Susmita Ghosh. 2015. Comparison of the effects of intrathecal bupivacaine, levobupivacaine and ropivacaine in lower abdominal surgery: a double-blind, randomized controlled trial using isobaric preparations. International Journal of Information Research and Review.2015; 2,636-41.
11. Senthil kumar, V Arun pothan raj. 2017. Intrathecal isobaric 0.75% ropivacaine versus isobaric0.5% levobupivacaine. International Journal of Current Medical And Pharmaceutical Research. 2017;3;1352-55
12. Ravisankar VU, Jyothi S. Relative potencies of motor blockade after intrathecal ropivacaine, levobupivacaine and bupivacaine. J Evid Based Med Healthc 2015; 2(61), 9040-50.
13. Ritika Jindal , Mohit Gupta.2016. Comparison of isobaric Ropivacaine and Levobupivacaine in patients undergoing lower abdominal surgery under spinal anesthesia . International Journal of research and education. 4(5),5288-93.
14. Michela Camorcia, Giorgio Capogna, Cristiana Berritta, Malachy O. Columb. 2007.The Relative Potencies for Motor Block After Intrathecal Ropivacaine, Levobupivacaine, and Bupivacaine. Anesth Analg 2007;104:904–7.
15. Li et al.2017. Ropivacine versus levobupivacaine in peripheral nerve blocks. Medicine (2017) 96:14.