



A COMPARATIVE EVALUATION OF 0.5%LEVOPUPIVACAINE AND 0.5%RACEMIC BUIPIVACAINE ON SPINAL ANAESTHESIA FOR ACL TEAR REPAIR: A RANDOMISED CONTROLLED TRIAL.

Anesthesiology

Dr Tulika Singh* *Corresponding Author

Dr.Kislay Kant

ABSTRACT

In the quest for safer and effective anaesthesia and analgesia, local anesthetics such as levobupivacaine has been introduced into the clinical practice. Traditionally available bupivacaine is a racemic mixture of both the enantiomers. However, technological advancements in the recent era have allowed the production of specific enantiomer containing optically pure molecules. The two enantiomers are exactly similar in physicochemical properties, but can have different affinity for the site of action or the side effects. The differential affinity of these enantiomers for sodium, potassium, and calcium channels results in a significant reduction of neurological and cardiac toxicity of the S-enantiomer in comparison to the R-enantiomer. Hence Levobupivacaine can be used as a safer alternative to bupivacaine for spinal anaesthesia. The overall outcome of the study showed that levobupivacaine has similar sensory and motor characteristics and recovery time like bupivacaine and no significant difference was observed between the two forms of the same drug. However, intrathecal levobupivacaine produces less toxicity.

Aim – The aim of the study was to compare the anaesthetic potency of intrathecally administered levobupivacaine with racemic bupivacaine in anterior cruciate ligament (ACL) tear repair surgeries. **Methods** – 60 adult cases ranging in age from 20 to 60 years with ASA Grade I & II, presenting for elective ACL repair surgery were randomly allocated into two groups containing 30 cases each. Cases in Group L received 3ml of 0.5% levobupivacaine and those in Group R received 3ml of 0.5% bupivacaine. **Results** – Cases in both groups showed similarity and no statistically significant differences were observed. Cardiovascular parameters were stable and similar between both groups. **Conclusion** – Levobupivacaine and racemic bupivacaine show equally effective potencies for spinal anaesthesia in ACL repair surgeries.

KEYWORDS

Bupivacaine, levobupivacaine, anterior cruciate ligament, Racemic.

INTRODUCTION –

Spinal anaesthesia is a widely used technique providing faster onset with effective and uniformly distributed sensory and motor block for lower limb surgeries. Bupivacaine is the currently available local anaesthetics with long duration of action^[1] and its maximum analgesic effect is upto 6-12 hours^[2]. Several clinical methods and techniques have been implemented to extend the duration of regional anaesthesia with local anaesthetics. In an attempt to further minimize the effects of local anesthetics and prolong the duration of intraoperative and postoperative analgesia, various adjuvants such as vasoconstrictors, alpha-2 agonists, and opioids have been used^[3] but each of these has its own documented adverse effects. Levobupivacaine has a similar mechanism of action and pharmacodynamic properties as that of bupivacaine.^[4,5] It reversibly blocks the sodium channels at the nodes of Ranvier in myelinated nerves leading to faster onset as compared to unmyelinated nerves. Similarly, nerves which are small in diameter are more easily blocked than large nerves. The primary aim of this study was to compare the pharmacological anaesthetic efficacy of levobupivacaine with bupivacaine and observe the risk of cardiotoxicity and neurotoxicity. The volume of the drug was kept constant (3 ml) in both the groups to avoid bias in the study

MATERIAL & METHODS –

The present study was carried out in the Department of Anaesthesiology, IGIMS Patna, After obtaining ethical clearance from the Institutional Ethics Committee and obtaining written consents from the participants, 60 adult cases ranging in age from 20 to 60 years with ASA Grade I & II requiring Acl repair surgery under spinal anaesthesia were selected for this prospective, randomized, double-blind study. Cases were randomly allocated into two groups containing 30 cases each. Cases in Group L received levobupivacaine 3ml of 0.5% and those in Group R received racemic bupivacaine 3ml of 0.5%.

(A) INCLUSION CRITERIA: All stable cases requiring elective Acl repair surgery

(B) EXCLUSION CRITERIA:

1. Cases who did not want to participate in this study
2. Cases with history suggestive of cardio-respiratory illness
3. Cases with history of drug sensitivity to the drugs in this study
4. Cases with pre-existing neurologic, spinal or sacral degenerations
5. Cases with infection at or around the site of injection
6. Cases with existing increased intracranial or intraocular pressure
7. Cases receiving medications likely to have interaction with local anaesthetics

All cases were briefed and examined one day before the study. The intrathecal technique was explained to them. They were told that in case of failure of spinal anaesthesia they would be induced with general anaesthesia and in that case they would automatically be removed from the study. All cases were directed to remain nil per orally from the night before the surgery. They were premedicated with 5mg Diazepam orally on the night before surgery. All cases were preloaded with 1000ml of Ringer's Lactate through a 18G intravenous cannula before proceeding for the operation theatre. Equipments for general anaesthesia was kept prepared in the operation theatre. Under strict sterile conditions and after proper cleaning and draping the patient lying in sitting position, L3 and L4 space was located. A Quincke spinal needle of 25G or 26G was used for spinal anaesthesia. After verifying the free flow of cerebrospinal fluid (CSF), study drug was injected into the CSF which was prepared by another investigator to facilitate double blinding.

Oxygen was given at the rate of 5–6 L/min through a face mask. The anesthesiologist performing the technique recorded the intraoperative data and followed the patient postoperatively until discharged from post anaesthesia care unit.

Assessment of sensory block by the loss of sensation to pinprick of 22 gauge blunt hypodermic needle and motor block by modified Bromage score^[6] was done every 2 min for first 10 min, then every 5 min up to 30 min, every 15 min up to 120 min, half-hourly up to 240 min, and hourly until 12 h of surgery.

Continuous multi-parameter monitoring of respiratory rate, heart rate, noninvasive systolic and diastolic blood pressure, SpO₂, and electrocardiogram was done for hemodynamic response. Readings were recorded preoperatively, then intraoperatively at 0, 3, and 5 min, then at an interval of every 5 min up to 30 min, every 15 min up to 120 min, half-hourly up to 180 min, hourly until 12 h, and thereafter 3 hourly till 24 h of surgery in both the groups. Bradycardia (defined as heart rate <60 bpm) was treated with injection atropine sulfate intravenously according to heart rate. Hypotension (defined as systolic blood pressure <20% less than base value) was treated with intravenous ephedrine intravenously as per required and additional Ringer's lactate solution. The operation was started when surgical anaesthesia (up to the T10 sensory dermatome) has developed. In case of failed or partial neuraxial block, the patient was given general anaesthesia and that patient was excluded from the study. Post surgery the cases were transferred to the postoperative ward for pain management and resuscitation.

Observation – 60 adult cases ranging in age from 20 to 60 years with ASA Grade I & II, requiring elective ACL repair surgery under spinal anaesthesia were selected for this study. Cases were randomly allocated into two groups containing 20 cases each. Cases in Group L received 0.5% levobupivacaine and Group R received 0.5% bupivacaine.

Table–1: Age in years of each participant in each group

Case no.	Group L (Levo-Bupivacaine)	Group R (Racemic –Bupivacaine)
01	29	30
02	28	45
03	41	57
04	54	47
05	52	37
06	38	58
07	39	28
08	51	60
09	59	46
10	37	51
11	48	54
12	54	29
13	28	41
14	42	35
15	55	24
16	29	36
17	36	39
18	24	29
19	43	51
20	40	40
21	34	55
22	40	45
23	30	28
24	35	34
25	29	25
26	60	40
27	44	29
28	43	30
29	55	20
30	20	35

Note: It was observed that the cases in both groups were comparable on the basis of mean age being 40.56 years and SD 10.73 (Group L) and mean age of 39.26 years and SD 11.01 (Group R)

Table–2: Table showing sensory block characteristics

Duration (Seconds)	Group L (n =30)	Group R (n =30)
Onset Time	8.33±3.79	9.13±3.81

Note: It was observed that sensory block onset time was similar in both groups

Table–3: Table showing comparison of maximum thoracic level of sensory block

Thoracic Level	Group L	Group R (minutes)
Level	T 4.92±0.96	T 5.04±0.94

Table–4: Table showing motor block characteristics

Duration (Seconds)	Group L (n =30)	Group R (n =30)
Onset Time	6.33±3.03	6.43±3.19

Note: It was observed that motor block onset time was similar in both groups

Table–5: Incidence of adverse effects in both groups

S. No.	Side effect	Group L (n =30)	Group R (n =30)
1	Hypotension	2	3
2	Bradycardia	1	2
3	Shivering	0	2

Note: Most common side effect was Hypotension, which was observed in 3 cases in Group R

DISCUSSION –

Bupivacaine is most commonly used spinal anaesthesia since its

introduction in 1965 however cases of myocardial depression and cardiac arrest have been reported. Resuscitation after bupivacaine administered cardiovascular collapse may be difficult. Although levobupivacaine has very similar pharmacological properties to racemic bupivacaine, it is noted for lower toxicity. In our study in tables 1-4 we have compared the two forms of bupivacaine and found in Table 5, that incidence of side effects especially hypotension was observed. Hypotension was observed in 2 and 3 cases of Group L and Group R respectively. Bupivacaine is a potentially cardiotoxic drug^[6-8]. Levobupivacaine and racemic bupivacaine show equally effective potencies for spinal anaesthesia with regard to time of onset, duration of motor and sensory block, and haemodynamic changes produced after any form of bupivacaine. Intrathecal levobupivacaine in general is a safer and more reliable local anaesthetic for lower limb surgeries^[9-10].

CONCLUSION –

Our study concluded that both intrathecally administered levobupivacaine and racemic bupivacaine are safe and effective local anaesthetics for lower limb surgeries. Overall parameters observed in this study showed no significant difference between the two forms of the same drug. However, intrathecal levobupivacaine produces less toxicity.

Funding – No source of funding

Conflict of interest – None declared

Ethical approval – The study was approved by the institutional ethics committee

REFERENCES –

- [1] Casati A. Intrathecal Anaesthesia. *Curr Opin Anaes* 2002; 15:543-541.
- [2] Rowney DA, Doyle E. Epidural and subarachnoid blockade in children. *Anaesthesia* 1998; 53:980-1001.
- [3] Reiz S, Häggmark S, Johansson G, Nath S. Cardiotoxicity of ropivacaine – a new amide local anaesthetic agent. *Acta Anaesthesiol Scand* 1989;33:93-8
- [4] Schug SA, Saunders D, Kurowski I, Paech MJ. Neuraxial drug administration: A review of treatment options for anaesthesia and analgesia. *CNS Drugs* 2006;20:917-33
- [5]. Buckenmaier CC 3 rd , Bleckner LL. Anaesthetic agents for advanced regional anaesthesia: A North American perspective. *Drugs* 2005;65:745-59.
- [6] Dar FA, Bhat HA, Javeed T, Najjar MR. The effects of dexmedetomidine added to spinal bupivacaine for lower limb surgery. *IOSR J Dent Med Sci* 2014;13:17-20.
- [7] Kumar P, Rudra R, Pan AA, Asharia A. Comparison among midazolam, Ketamine and neostigmine co-administered with bupivacaine. *Anaesth Analg* 2005; 101:69-73.
- [8] Rosa H. Isobaric Bupivacaine versus Hypobaric Bupivacaine for subarachnoid anaesthesia in patients of hip surgery. *Anaesth Analg* July 2014; 14:97.
- [9] Monica D. Spinal anaesthesia for knee arthroscopy. *Biomed Res* 2014; 34 (9):90-92.
- [10] Foxall G. Levobupivacaine induced seizures and cardiovascular collapse. *Anaesthesia* 2007; 62:516-518.