

A Comparative Study of Intrathecal Ropivacaine-Fentanyl versus Levobupivacaine-Fentanyl in Adult Patients Undergoing Planned Inguinal Hernioplasty

Khushbu Patel¹, Komal Modi²

¹Ex- Resident, Department of Anaesthesia, Government medical College, Baroda, Gujarat, India, ²Assistant Professor, Department of Anaesthesia, Government medical College, Baroda, Gujarat, India .

Abstract

Introduction: Levobupivacaine and Ropivacaine are S-enantiomer of Bupivacaine and have less cardiac toxicity than Bupivacaine. Very few studies have compared these two cardio-stable drugs with Fentanyl as an adjuvant in spinal blockade. The objective is to evaluate the characteristics of spinal anaesthesia with equipotent doses of intrathecal Levobupivacaine-Fentanyl versus Ropivacaine-Fentanyl. **Subjects and Method:** 80 adult patients, ASA I and II undergoing hernioplasty under subarachnoid block were arbitrarily divided into Group LF (n=40) to get intrathecally 3.0 ml of 0.5% Isobaric Levobupivacaine + 25µg Fentanyl and Group RF(n=40) to receive 3 ml of 0.5 % Isobaric Ropivacaine + 25 µg Fentanyl. The onset, peak effect and duration of sensory and motor block, effective analgesia were noted. **Result:** No significant dissimilarity among demographic parameters and the haemodynamic parameters. Onset of sensory block was earlier in group RF (1.49±0.45min) than Group LF (2.17±0.45min), p<0.01. Period of effective analgesia was considerably larger in group LF (270.92±15.94min) than group RF (193.52±16.94min), **Conclusion:** Intrathecal use of Isobaric Ropivacaine-Fentanyl produced early onset of sensory block but period of effective analgesia was longer in Levobupivacaine-Fentanyl group.

Keywords: Isobaric, Ropivacaine, Levobupivacaine, Spinal anaesthesia, Hernioplasty

Corresponding Author: Komal Modi, Assistant Professor, Department of Anaesthesia, Government medical College, Baroda, Gujarat, India .
E-mail: komalmodi@gmail.com

Received: 09 November 2020

Revised: 22 January 2021

Accepted: 29 January 2021

Published: 05 June 2021

Introduction

Central neuraxial blockade in form of subarachnoid block has been practiced successfully worldwide since long back. The ideal agent for subarachnoid block should make a rapid onset of block given that sufficient surgical anaesthesia of suitable duration and rapid regression motor and sensory blocks with negligible side effects. Over the last few decades, regional anaesthesia technique have been developed numerous modifications with the arrival of newer and safer local anaesthetic agent.

Bupivacaine remains the gold standard long acting local anaesthetic for most loco-regional procedure under spinal anaesthesia. Following the reports of Bupivacaine induced cardiovascular and neurological toxicity, efforts were made to find out a better and safer agent.

Levobupivacaine, has a pharmacological movement very comparable to that of racemic Bupivacaine.^[1] Ropivacaine

belongs to propyl derivatives of pipercoloxylidides local anaesthetic agent, which is less cardiotoxic than butyl derivatives (Bupivacaine).

Intrathecal opioids improve sensory block devoid of extending motor and sympathetic block. Amongst them, Fentanyl has quick onset of action, attach powerfully to plasma proteins and potentiates the afferent sensory blockade therefore helps decrease in the dose of local anaesthetics. Fentanyl is highly selective μ receptors agonist and also binds Kappa receptors causing spinal analgesia, sedation and anaesthesia.^[2,3]

Subjects and Methods

After taking permission from the Ethical Research committee of the institute and written informed consent from patient 80 adult patients of ASA PS I/II and aged among 18 and 60 years planned to experience voluntary inguinal hernioplasty under subarachnoid block during period of one year (OCT

2017- OCT 2018), were included under Randomized double blind control trial. Patient with contraindications to spinal anaesthesia, allergy to amide local anaesthetics and morbid obesity were barred from research. In any case, if failure of spinal anaesthesia on supplementation of general anaesthesia was required then that case was excluded from study. The subjects were aimlessly owed into two groups of 40 patients each utilizing sealed envelope method. Group RF (Receiving Ropivacaine and fentanyl) and Group LF (Receiving Levobupivacaine and Fentanyl). In Group RF receiving Inj Isobaric Ropivacaine (0.5%) 3ml+ Inj Fentanyl (25 mcg) 0.5 ml and Group LF receiving Inj Isobaric Levobupivacaine (0.5%) 3.0 ml+ Inj Fentanyl (25 mcg)0.5ml, total drug prepared was 3.5 ml.

Methodology

Patient was placed in lateral position. After checking the basic necessities like anaesthesia trolley and resuscitation drugs, with all aseptic and sterile safety measures, painting and draping was done. After identification of L3 –L4 intervertebral space, 23G Spinal needle was inserted. Following confirmation of free CSF flow, study drug was injected over 10-15secs intrathecally according to randomization. Monitoring was started immediately on turning the patient supine. Surgery was allowed once the peak sensory and motor blockade are achieved.

Following factors were assessed:

1. Onset of sensory blockade at L1
2. Highest sensory level accomplished
3. Time to achieve highest sensory level
4. Two section regression occasion from highest sensory level.
5. Time for regression upto level L1 from highest sensory level.

Motor Block was evaluated by Modified Bromage scale

Vital Parameters was observed before blockade and after giving blockade and then 1,3,5,10,15,20,30 minutes following spinal blockade and then each 15 minutes untill 1 hour then each 30 minutes untill the finish of surgery and in postoperative period vitals was monitored hourly for four hours.

Sedation was evaluated with the help of Ramsay sedation score after giving spinal anaesthesia (Assessed every 15 minutes).

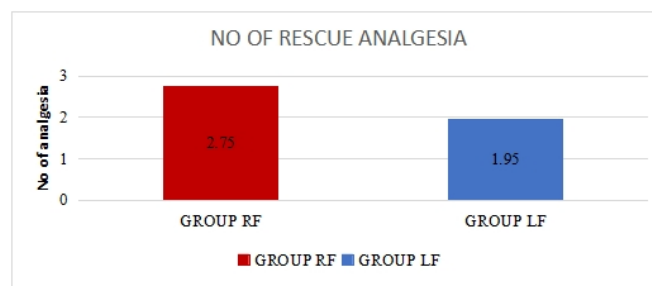
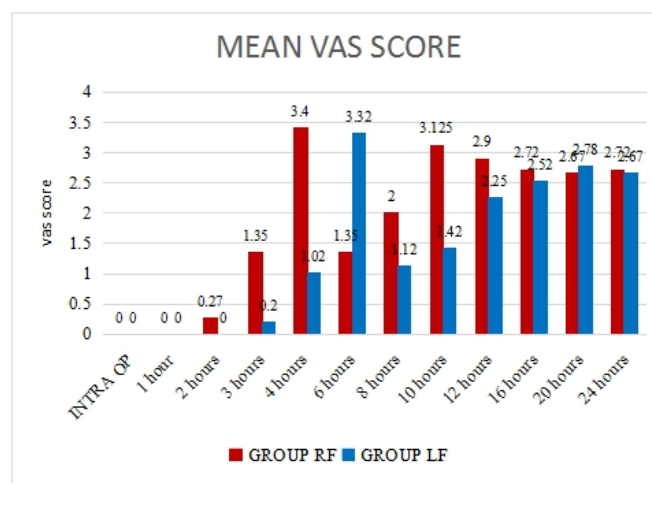
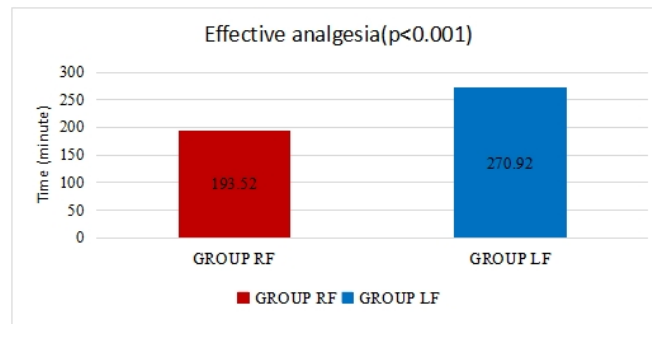
Duration of analgesia: The period of effective analgesia was counted starting from njection of spinal drug to VAS score of 4 or more. At this time they were given rescue analgesic in the form of inj. Diclofenac 3cc (75mg) IM given.

Intra operative and post-operative complications like bradycardia, hypotension, respiratory distress, nausea, vomiting,

cardiac arrhythmias, rigor, PDPH, backache, urinary retention, neurological complications were observed and manage accordingly.

With the help of Mann-Whitney U Test, Confidence interval=95%, power=80% alpha error=5% and beta error = 20%.Required sample size came to be 32 in each group. We were study 40 patients in each group to authenticate study more Data were investigated Student t test and one way ANNOVA.

Results



Demographic parameters like Age in years, gender, ASA Grade, Mean period of surgery (mins) were similar in equal

Table 1: Demographic Data

Group	Group RF	Group LF	P-Value
Age in years (Mean±SD)	43.85±13.46	43.07±13.65	>0.05
Gender (Male) (Mean±SD)	40	40	
ASA Grade (I:II)	28:12	30:10	
Mean Duration of Surgery(Minutes)	89.5±13.90	90.25±13.15	>0.05

Table 2: Assessment of Sensory Block

Sr. No.	Parameter	Group RF Mean±SD	Group LF Mean±SD	P-value
1	Time to onset of anaesthesia at L1(min)	2.17±0.42	1.49± 0.45	P<0.001
2	Peak sensory level achieved			
	T6	13(32.5%)	24(60%)	
	T8	27(67.5%)	16(40%)	
3	Time to achieve peak sensory level (min)	7.89±1.60	7.22±1.00	P<0.05
4	Time to two segmental dermatomal regression (min)	59.35±6.29	100.25±11.98	p<0.001
5	Time for regression to L1 (min)	128.4±10.98	155.25±19.51	p<0.001

Table 3: Assessment of Motor Block

Sr. No.	Parameter	Group RF Mean ±SD	Group LF Mean ±ASD	P-value
1	Time for onset of motor block (min)	2.23±0.27	1.33±0.37	P<0.001
2	Maximum Bromage score achieved II:III	7:33	40	
3	Time for maximum Bromage score (min)	5.65±1.16	5.52 ±0.98	p>0.05
4	Duration of motor block (min)	172.15±19.64	241.5±12.77	p<0.001

the groups [Table 1]. In both groups there was no significant dissimilarity between mean pulse rate, mean systolic blood pressure, mean diastolic blood pressure, mean SpO₂.

In our study time of onset at L1 level was 2.12±0.45 minutes in Group RF and 1.49±0.45 minutes in Group LF. Time to 2 segments regression and Time to achieve peak sensory level was earlier in Group LF than Group RF [Table 2].

Onset time of motor block was 2.23±0.27 minute in Group RF and Group LF was 1.33±0.37 minutes. Bromage grade was 5.65±1.16 minutes in Group RF while it was 5.52±0.98 minutes in Group LF. Duration of motor block was 172.15±19.64 minutes in Group RF and 241.5±12.77 minutes in Group LF. [Table 3] In Group RF 26 (65%) patients developed sedation score 2 sedation while sedation score 3 was observed in 14 (35%) patients. In Group LF, 252 while 15(37.5%) patients

developed sedation score 3. None of the patients were heavily sedated.

The duration of effective analgesia was 193.52+ 16.94 minutes in Group RF and 270.92 +15.94 minutes for Group LF. The difference was statistically very highly significant (p<0.001). The total no. of doses of rescue analgesic required in 24 hours was highly significantly in both the Groups. It was 2.75±0.43 in Group RF, while 1.95±0.59 in Group LF in 24hours duration.

Discussion

According to physiochemical property of Ropivacaine, it has high pKa and low solubility so that less expected to penetrate huge myelinated motor fibers.(Aβ fibers).^[4,5]Sunita et al

observed that onset of sensory block was delayed with 0.5% Ropivacaine than 0.5% Levobupivacaine.^[6] Kajal A bhatt et al showed that onset of sensory block was comparable with 0.5% Ropivacaine 0.5% Levobupivacaine.^[2]

In our study majority of cases, crest sensory level achieved was T8 in Group RF and T6 in Group LF. Amitava Layek et al studied that higher sensory level achieved was T7 with 0.5% Isobaric Ropivacaine with Fentanyl and 0.5% Isobaric Bupivacaine with Fentanyl.^[7] Alpa Patel et al observed that Peak sensory level was delayed with 0.5% Ropivacaine than 0.5% levobupivacaine.^[8] Bupivacaine is the most potent local anaesthetic equivalent to Levobupivacaine followed by Ropivacaine. Malinovsky JM et al 2000,^[9] described also similar findings.

The mean time in use for two segmental regression was shorter in Group RF than Group LF. Our study are in consonance with Amitava Layek et al 2015.^[7] We concluded that duration effective analgesia was higher in Group LF than Group RF. Time for two segments regression, time for regression to L1 level and effective analgesia was shorter in group Ropivacaine may be owing to the dissimilarity in the physiochemical properties of Ropivacaine, which has fewer protein binding property and more quickly eradicated when compared to Bupivacaine.

The mean onset of motor block was delayed in Group RF than Group LF, the maximum bromage score achieved in both the groups were comparable. This results are in consonance with Anita saran et al.^[10] This phenomenon can be explained by addition of fentanyl which intensifies the motor block in our study.

Changes in vitals parameters were comparable in both the groups. The reserve of cardiac contractility is proportionate to lipid solubility and nerve jamming strength of local anesthetic signifying that cardiotoxic potency of three local anesthetics are in order of Bupivacaine >Levobupivacaine >Ropivacaine i.e. Ropivacaine has most stable hemodynamic profile among three.^[11]

None of the patients had heavy sedation in any group. The total no of rescue analgesia was elevated in Group RF than Group LF. We observed that vas score in first 3 hrs post operatively was higher in Group RF than Group LF. In Group RF, only 2 patients had bradycardia and 2 patients had hypotension. In Group LF, 4 patients had bradycardia, 3 patients had hypotension, and 2 patient had nausea /vomiting. But fall in Pulse rate and BP was within physiological limits and clinically not significant. None of the patients developed respiratory depression, urinary retention or hypersensitivity to drugs.

Conclusion

Intrathecal Isobaric Levobupivacaine-Fentanyl grouping creates a considerably larger period of analgesia, sensory and

motor block than Isobaric Ropivacaine-Fentanyl.

References

1. Vampugalla P, Vundi V, Kumar K, Kamar C, Mahalakshmi P, Pisipati R. A comparative study of intrathecal ropivacaine with fentanyl and L-bupivacaine with fentanyl in lower abdominal and lower limb surgeries. *Int J Basic Clin Pharmacol.* 2015;4(6):1147–1155. Available from: <https://dx.doi.org/10.18203/2319-2003.ijbcp20151349>.
2. Bhatt KA, Prajapati IA, Nagar S, Residency OA, Vadaj N. A comparison between intrathecal isobaric levobupivacaine 0.5% and isobaric ropivacaine 0.5% in lower limb surgeries: a prospective, randomized, double blind study. *Anaesth Pain Intensive Care.* 2018;22(1):93–97.
3. Mohan S, Saran J, Kashyap M. Comparative Study of 0.5% Levobupivacaine and 0.5% Levobupivacaine with Fentanyl in Transurethral Resection of Prostate. 2017;4(119):67–72.
4. Kuthiala G, Chaudhary G. Ropivacaine: A review of its pharmacology and clinical use. *Indian J Anaesth.* 2011;55(2):104. Available from: <https://dx.doi.org/10.4103/0019-5049.79875>.
5. Agarwal A, Verma RK, Srivastava S. Ropivacaine- the latest local anaesthetic in the indian market. *J Anaesthesiol Clin Pharmacol.* 2010;26(2):223–231.
6. Jain S, Bendwal HP, Deodhar P, Bhambani P, Romday R, Jain P. Comparative study of ropivacaine (0.5%) plain versus levobupivacaine (0.5%) plain in gynecological surgeries. *Int J Reprod Contracept Obstet Gynecol.* 2017;6:1573. Available from: <https://dx.doi.org/10.18203/2320-1770.ijrcog20171431>.
7. Layek A, Maitra S, Gozi N, Bhattacharjee S, Pal S, Sen S, et al. Comparison between intrathecal isobaric ropivacaine-fentanyl and bupivacaine-fentanyl in elective infraumbilical orthopedic surgery: A randomized controlled study. *J Anaesthesiol Clin Pharmacol.* 2015;31:542. Available from: <https://dx.doi.org/10.4103/0970-9185.169086>.
8. Hospital SK, Author C, Faliyu V, Township A, Pardi A. Effectiveness of Ropivacaine versus Levobupivacaine for Spinal Anaesthesia and Analgesia in Lower Limb Surgery. *J Med Sci Clin Res.* 2018;06:930–937. Available from: <https://dx.doi.org/10.18535/jmscr/v6i2.144>.
9. Malinovsky JM, Charles F, Kick O, Lepage JY, Malinge M, Cozian A, et al. Intrathecal Anesthesia: Ropivacaine Versus Bupivacaine. *Anesth Analg.* 2000;91(6):1457–1460. Available from: <https://dx.doi.org/10.1097/00000539-200012000-00030>.
10. Saran A, Raipure A, Singh R. Comparison of intrathecal ropivacaine-fentanyl and bupivacaine-fentanyl for major lower limb orthopaedic surgery: A randomised double-blind study. *Indian J Anaesth.* 2018;22:38–42. Available from: <https://dx.doi.org/10.4103/0019-5049.138985>.
11. Mantouvalou M, Ralli S, Arnaoutoglou H, Tziris G, Papadopoulos G. Spinal anesthesia : Comparison of plain ropivacaine, bupivacaine and levobupivacaine for lower abdominal surgery. *Acta Anaesthesiol Belg.* 2008;59(2):65–71.

Copyright: © the author(s), 2021. It is an open-access article distributed under the terms of the Creative Commons Attribution License (CC BY 4.0), which permits authors to retain ownership of the copyright for their content, and allow anyone to download, reuse, reprint, modify, distribute and/or copy the content as long as the original authors and source are cited.

How to cite this article: Patel K, Modi K. A Comparative Study of Intrathecal Ropivacaine-Fentanyl versus Levobupivacaine-Fentanyl in Adult Patients Undergoing Planned Inguinal Hernioplasty. *Acad. Anesthesiol. Int.* 2021;6(1):96-100.

DOI: [dx.doi.org/10.21276/aan.2021.6.1.17](https://doi.org/10.21276/aan.2021.6.1.17)

Source of Support: Nil, **Conflict of Interest:** None declared.