



A COMPARATIVE STUDY OF EFFICACY, POTENCY AND RECOVERY OF INTRATHECAL 0.5% ROPIVACAINE WITH FENTANYL AND 0.5% LEVOBUPIVACAINE WITH FENTANYL IN LOWER ABDOMINAL SURGERIES IN PATIENTS OF 18-60 YEARS OF AGE

Anaesthesiology

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ABSTRACT

INTRODUCTION: The recent trend in health care centres everywhere is to provide cost effective care to the patients. There is an increasing trend towards ambulatory day care surgery and rapid discharge of the patients. The operation of inguinal hernia or incisional hernia and even simple ligation surgeries are done without much complexities nowadays and can be completed in 60-90min without much intra or postoperative complications. Hence these have become an ideal procedure for outpatient setting and thereby reducing length of hospital stay.

AIMS AND OBJECTIVE: A comparative study of efficacy, potency and recovery of intrathecal 0.5% ropivacaine with fentanyl and 0.5% levobupivacaine with fentanyl in lower abdominal surgeries in patients of 18-60 years of age.

MATERIALS AND METHOD: This is a prospective, comparative, observational study was conducted on 60 patients undergoing various lower abdominal surgeries under subarachnoid block (SAB) at Nil Ratan Sircar Medical College and Hospital, Kolkata, West Bengal. This study was conducted over a period of 24-month. Approval of the Institutional Ethics Committee was taken. A written informed consent in the local language was taken from every patient.

RESULT AND ANALYSIS: In RF 5 patients (17%) had onset at 3min, 17 patients (57%) at 6min, 7 patients (23%) at 9min, 1 patient (3%) at 12min. In LBF 8 patients had onset at 0 min, 22 patients had onset at 3min. p value is less than 0.0001 which is statistically significant. In RF, 23 patients (77%) had duration of motor block for 150min and 7 patients (23%) had for 180min. In LBF, 26 patients (87%) had duration of motor block for 210 min and 4 patients (13%) had for 180min. The p value is less than 0.0001, which is statistically significant.

SUMMARY AND CONCLUSION: This study was to compare potency, efficacy and recovery between the two groups of drugs. A potency of a drug is a measure of drug activity expressed in terms of the amount required to produce an effect of given intensity. Here both the drugs in comparison was given in equal concentration and found that levobupivacaine produced higher effect, reached Bromage 3 in lesser time than ropivacaine. So levobupivacaine was more potent drug. Efficacy is the ability to get a job done satisfactorily.

KEYWORDS

Intrathecal, 0.5% Ropivacaine, 0.5% Levobupivacaine, Fentanyl And Lower Abdominal Surgeries

The recent trend in health care centres everywhere is to provide cost effective care to the patients. There is an increasing trend towards ambulatory day care surgery and rapid discharge of the patients. The operation of inguinal hernia or incisional hernia and even simple ligation surgeries are done without much complexities nowadays and can be completed in 60-90min without much intra or postoperative complications. Hence these have become an ideal procedure for outpatient setting and thereby reducing length of hospital stay.¹

For such ambulatory day care surgeries ideal anaesthesia should be rapid and smooth onset of action, good intraoperative analgesia and faster recovery period free of side effects or residual effects and early mobilisation.

Spinal anaesthesia is popular regional anaesthesia technique for such setting. It can provide rapid onset, immediate intraoperative and postoperative analgesia at minimum cost. The complication of general anaesthesia and its residual effects are avoided, and recovery is early with minimal alteration in cognitive psychomotor function which helps in early discharge of the patient.²

Bupivacaine is the drug of choice for spinal anaesthesia because of its fast onset and dense block. However longer duration of action and potential for cardiotoxicity are limiting factors for bupivacaine to become an ideal drug for ambulatory spinal anaesthesia.

Ropivacaine is a new local anesthetic drug belonging to amino amide group, a propyl derivative of pipercoloxylidides.³

Generally 'hyperbaric' 0.5% bupivacaine is used for spinal anaesthesia. Plain or glucose free bupivacaine is referred as 'isobaric'. Hyperbaric drugs has higher spread of drug and to prevent unilateral or saddle block patient should be mobilised from sitting or lateral position rapidly. The truly isobaric solutions are less sensitive to positional changes. Hyperbaric solutions produces more hypotension compared to isobaric solution.

Today heavy bupivacaine 0.5% is most commonly used for spinal anaesthesia. Levo-bupivacaine is a new long acting local anesthetic which has less pharmacological activity very similar to that of racemic

system toxicity the use of levo- bupivacaine, a pure S (-) enantiomer of bupivacaine has progressively increased.

Ropivacaine has a less systemic toxic profile, especially cardiotoxic profile than both racemic and levo-bupivacaine. So intrathecal ropivacaine may prove useful than bupivacaine or levo-bupivacaine when anaesthesia of similar quality and shorter duration is desired.⁴

A comparative study of efficacy, potency and recovery of intrathecal 0.5% ropivacaine with fentanyl and 0.5% levobupivacaine with fentanyl in lower abdominal surgeries in patients of 18-60 years of age.

OBJECTIVES:

- Primary objective is to assess duration of analgesia
- Onset of sensory block (time to reach T10 dermatome)
- Peak sensory block height
- Time taken to reach peak sensory block height
- Time to regress by two segment dermatomes
- Time to regress to T10 dermatome
- Time to reach motor block as per Bromage score 3 (onset of complete motor block)
- Complete regression of motor block to Bromage score 0 (duration of motor block)

MATERIALS AND METHOD

This is a prospective, comparative, observational study was conducted on 60 patients undergoing various lower abdominal surgeries under subarachnoid block (SAB) at Nil Ratan Sircar Medical College and Hospital, Kolkata, West Bengal. This study was conducted over a period of 24-month. Approval of the Institutional Ethics Committee was taken. A written informed consent in the local language was taken from every patient.

EXCLUSION CRITERIA

1. Patient's refusal
2. ASA physical status III/IV
3. Patients on sedative medications/opioids/anti-depressants
4. History of intake of non-steroidal anti-inflammatory drugs within 24 h before surgery
5. History of drug or alcohol abuse

6. History of chronic pain or daily intake of analgesics
7. Ischaemic heart disease or any other cardiac illness
8. Uncontrolled medical disease (diabetes mellitus and hypertension)
9. Patients with neuropathy due to any reason
10. Renal or Hepatic dysfunction
11. Patient's with psychiatric illness
12. Known coagulopathy
13. Seizure disorder
14. Hypersensitivity to any of drugs used in study
15. Patients with deformity of spine

INCLUSION CRITERIA

- ASA I-II
- Age 18-60 years of Age
- Scheduled for elective lower abdominal procedure

RESULT AND ANALYSIS

We found that in LBF, the mean age (mean $\pm$ s.d.) of patients was 39.1000 $\pm$ 9.2265 years. In RF, the mean age (mean $\pm$ s.d.) of patients was 42.4000 $\pm$ 10.9406 years. Distribution of mean age vs. group was not statistically significant ($p=0.2117$). In LBF, the mean duration of surgery (mean $\pm$ s.d.) of patients was 97.6667 $\pm$ 21.2024 min. In RF, the mean duration of surgery (mean $\pm$ s.d.) of patients was 97.6667 $\pm$ 15.2978 min. Distribution of mean duration of surgery vs. group was not statistically significant ($p=1.0000$). In LBF, the mean T10 sensory block (mean $\pm$ s.d.) of patients was 3.6667 $\pm$ 8.442 min. In RF, the mean T10 sensory block (mean $\pm$ s.d.) of patients was 5.3000 $\pm$.6513 min. Distribution of mean T10 sensory block vs. group was statistically significant ($p<0.0001$). In LBF, the mean time max SB height (mean $\pm$ s.d.) of patients was 8.6667 $\pm$ 9.223 min. In RF, the mean time max SB height (mean $\pm$ s.d.) of patients was 10.5333 $\pm$ 2.3450 min. Distribution of mean time max SB height vs. group was statistically significant ($p=0.0002$).

Our study showed that in LBF, the mean time regress (mean $\pm$ s.d.) of patients was 137.1667 $\pm$ 5.3632 min. In RF, the mean time regress (mean $\pm$ s.d.) of patients was 104.9333 $\pm$ 7.7768 min. Distribution of mean time regress vs. group was statistically significant ($p<0.0001$). In LBF, the mean regress to T10 level (mean $\pm$ s.d.) of patients was 140.6667 $\pm$ 6.9149 min. In RF, the mean regress to T10 level (mean $\pm$ s.d.) of patients was 103.5000 $\pm$ 8.5973 min. Distribution of mean regress to T10 level vs. group was statistically significant ($p<0.0001$). In LBF, the mean SB duration T10-T12 (mean $\pm$ s.d.) of patients was 152.8333 $\pm$ 7.2734 min. In RF, the mean SB duration T10-T12 (mean $\pm$ s.d.) of patients was 123.4333 $\pm$ 5.7994 min. Distribution of mean SB duration T10-T12 vs. group was statistically significant ($p<0.0001$). In LBF, the mean 1st dose of analgesic (mean $\pm$ s.d.) of patients was 217.6667 $\pm$ 15.4101 min. In RF, the mean 1st dose of analgesic (mean $\pm$ s.d.) of patients was 192.8333 $\pm$ 17.5521 min. Distribution of mean 1st dose of analgesic vs. group was statistically significant ($p<0.0001$).

We found in LBF, 19(63.3%) patients had female and 11(36.7%) patients had male. In RF, 12(40.0%) patients had female and 18(60.0%) patients had male. Association of sex vs. group was not statistically significant ($p=0.0705$). In RF 5patients(17%) had onset at 3min, 17patients(57%) at 6min, 7 patients(23%) at 9min, 1 patient(3%) at 12min. in LBF 8 patient had onset at 0 min, 22 patient had onset at 3min. p value is less than 0.0001 which is statistically significant. In RF, 23 patients (77%) had duration of motor block for 150min and 7 patients (23%) had for 180min. In LBF, 26 patients (87%) had duration of motor block for 210 min and 4 patients (13%) had for 180min. The p value is less than 0.0001, which is statistically significant. In LBF, 30(100.0%) patients had ASA II. In RF, 30(100.0%) patients had ASA II. In LBF, 10(33.3%) patients had T7 and 20(66.7%) patients had T8. In RF, 1(3.3%) patient had T10, 4(13.3%) patients had T7, 9(30.0%) patients had T8 and 16(53.3%) patients had T9. Association of max height of SB vs. group was statistically significant ($p<0.0001$).

DISCUSSION

Demographic profile across groups:

In this study majority of patients were middle aged in both groups. The gender selections of patients were random and statistically not significant. The types of surgeries performed were also closely identical in both groups to avoid variations and are not statistically significant.

Onset of peak sensory block: Onset of sensory block at highest dermatomal level using pinprick method was noted in both groups. In LBF, the mean time max SB height (mean $\pm$ s.d.) of patients was 8.6667 $\pm$.9223 min. In RF, the mean time max SB height (mean $\pm$ s.d.) of patients was 10.5333 $\pm$ 2.3450 min. Distribution of mean time max SB height vs. group was statistically significant ($p=0.0002$).

This observation was comparable to the study done by Who compared intrathecal isobaric ropivacaine, 15 mg and isobaric bupivacaine, 10 mg for transurethral resection of bladder or prostate. It was found that the onset of sensory blockade was similar and was 13 $\pm$ 8 mins for ropivacaine group compared to 11 $\pm$ 7 mins in the bupivacaine group.

Highest level of sensory block: Malinowski et al.⁵, in their study, noted a similar trend for maximum cephalic spread and variation of the sensory block between the intrathecal ropivacaine (15 mg) group and bupivacaine (10 mg) group for transurethral resection of bladder or prostate. In this study, the highest level of sensory block achieved was similar in both groups. The highest level of block achieved in group LBF was T7 in n=10(33.3%). The highest level of block achieved in group RF was T7 in n=4(13.3%). In LBF, 20(66.7%) patients had T8. In RF, 16(53.3%) patients had T9. Association of max height of SB vs. group was statistically significant ($p<0.0001$).

Time for two segment regression: In their study, noted the time for two segment regression between the two groups and was 89 $\pm$ 33 mins in the ropivacaine group and was 98 $\pm$ 30 mins in the levo-bupivacaine group when administered intrathecally. This does not correlate with the finding in this study.

In LBF, the mean time regress (mean $\pm$ s.d.) of patients was 137.1667 $\pm$ 5.3632 min. In RF, the mean time regress (mean $\pm$ s.d.) of patients was 104.9333 $\pm$ 7.7768 min. Distribution of mean time regress vs. group was statistically significant ($p<0.0001$).

In LBF, the mean regress to T10 level (mean $\pm$ s.d.) of patients was 140.6667 $\pm$ 6.9149 min. In RF, the mean regress to T10 level (mean $\pm$ s.d.) of patients was 103.5000 $\pm$ 8.5973 min. Distribution of mean regress to T10 level vs. group was statistically significant ($p<0.0001$).

Duration of sensory block (regression to T10-T12): Chung et al.⁶, noted that time of regression of block to S1 was longer (188.56 $\pm$ 28.2 mins) in intrathecal bupivacaine group when compared to ropivacaine group (162.56 $\pm$ 20.2 mins). In this study, in LBF, the mean SB duration T10-T12 (mean $\pm$ s.d.) of patients was 152.8333 $\pm$ 7.2734 min. In RF, the mean SB duration T10-T12 (mean $\pm$ s.d.) of patients was 123.4333 $\pm$ 5.7994 min. Distribution of mean SB duration T10-T12 vs. group was statistically significant ($p<0.0001$).

Onset of complete motor block: Malinovsky et al.⁵, found that onset of motor blockade was similar in the two groups receiving ropivacaine and bupivacaine intrathecally for transurethral resection of bladder or prostate. Kallio et al. and McNamee et al. also found similar time to onset of the complete motor block. But this does not correlate with this study. In RF the mean onset of complete motor block was (mean $\pm$ SD) 6.4 $\pm$ 2.19 and in LBF it was 2.2 $\pm$ 1.34 and this was statistically significant.

Duration of motor block: McNamee et al.⁷, noted that duration of motor block was significantly shorter in the ropivacaine group (2.1 hrs) as compared to the bupivacaine group (3.9 hrs). Also noted the duration of motor block was significantly shorter with ropivacaine (150 mins) as compared to bupivacaine (210 mins). The duration of motor block was significantly shorter in the ropivacaine group also when compared to the bupivacaine group. This correlates with the findings in this study where the time to recovery of the complete motor block from ropivacaine was 157 $\pm$ 12.6 min, whereas from levobupivacaine was 206 $\pm$ 10.3min which was statistically significant $p<0.0001$.

Need for first dose for analgesics: The first dose of analgesic requirement was delayed in L-bupivacaine. In LBF, the mean 1st dose of analgesic (mean $\pm$ s.d.) of patients was 217.6667 $\pm$ 15.4101 min. In RF, the mean 1st dose of analgesic (mean $\pm$ s.d.) of patients was 192.8333 $\pm$ 17.5521 min. Distribution of mean 1st dose of analgesic vs. group was statistically significant ($p<0.0001$).

Hemodynamic parameters: The hemodynamic parameters including heart rate, systolic, and diastolic BPs were comparable between both groups.

Heart rate in both groups were not significant, systolic BP for ropivacaine was statistically significant at 0min,60min,90min and 120min and DBP was statistically significant at 9min, 12min, 25min, 30min, 120min, 210min and 240min. MAP for group RF was statistically significant at 9min,120min,210min and 240min. This shows ropivacaine was hemodynamically better according to our study.

SUMMARY AND CONCLUSION

- This study reveals that the intrathecal 3ml of 0.5% ropivacaine with fentanyl 25 µg provides adequate anaesthesia for lower abdominal and lower limb surgeries.
- Ropivacaine achieves a lesser duration of sensory and motor blockade, lesser degree of the motor blockade as compared with

levo-bupivacaine. With the quality and duration of block achieved with ropivacaine, it can be justified to use it for lower abdominal surgeries which are short duration ambulatory surgeries and not requiring intense motor blockade, like inguinal hernia or incisional hernia, hydrocele, ligation, vaginal hysterectomy.

- Hence, ropivacaine with fentanyl in spinal anaesthesia for lower abdominal and lower limb surgeries is a better alternative compared to levo-bupivacaine with fentanyl favouring day care ambulatory surgeries.
- This study was to compare potency, efficacy and recovery between the two groups of drugs. A potency of a drug is a measure of drug activity expressed in terms of the amount required to produce an effect of given intensity. Here both the drugs in comparison was given in equal concentration and found that levobupivacaine produced higher effect, reached Bromage 3 in lesser time than ropivacaine. So levobupivacaine was more potent drug. Efficacy is the ability to get a job done satisfactorily.

Table: Distribution of mean T10 sensory block (MIN), Time regress (MIN), Regress to T10 level (MIN), SB duration T10-T12 (MIN) and 1st dose of analgesic (MIN) : GROUP

		Number	Mean	SD	Minimum	Maximum	Median	p-value
T10 sensory block (MIN)	LBF	30	3.6667	.8442	2.0000	5.0000	4.0000	<0.0001
	RF	30	5.3000	.6513	3.0000	6.0000	5.0000	
Time regress (MIN)	LBF	30	137.1667	5.3632	125.0000	145.0000	137.5000	<0.0001
	RF	30	104.9333	7.7768	90.0000	118.0000	105.0000	
Regress to T10 level(MIN)	LBF	30	140.6667	6.9149	130.0000	155.0000	140.0000	<0.0001
	RF	30	103.5000	8.5973	85.0000	120.0000	105.0000	
SB duration T10-T12 (MIN)	LBF	30	152.8333	7.2734	140.0000	165.0000	150.0000	<0.0001
	RF	30	123.4333	5.7994	110.0000	135.0000	125.0000	
1st dose of analgesic (MIN)	LBF	30	217.6667	15.4101	185.0000	240.0000	217.5000	<0.0001
	RF	30	192.8333	17.5521	145.0000	220.0000	195.0000	

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