Original Article

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Bupivacaine versus Ropivacaine for Postoperative Analgesia in Femorosciatic Blocks in Lower Limb Surgeries-A Randomised Clinical Trial

Anaesthesia Section

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ABSTRACT

Introduction: Peripheral Nerve Blockade (PNB) is a well-accepted component of comprehensive anaesthetic care. Ropivacaine is a newer local long acting anaesthetic agent. Despite the extensive use and relative safety of bupivacaine, ropivacaine has been developed as alternative agent to decrease the risk for cardiac and nervous system.

Aim: To compare safety, efficacy and duration of postoperative analgesia between bupivacaine and ropivacaine in femorosciatic blocks.

Materials and Methods: This randomised clinical study was conducted, from August 2017 to April 2018, at HBT Medical College and Dr R.N. Cooper Municipal General Hospital, Mumbai, Maharashtra, India. Total of 78 patients scheduled to undergo elective knee and below knee orthopaedic surgeries under subarachnoid block were divided into two groups- group A, patients received 25 mL of 0.25% injection bupivacaine for femoral nerve block and sciatic nerve block each and in group B, patients received 25 mL of 0.25% Inj. ropivacaine for femoral nerve block and sciatic nerve block each. After giving femorosciatic block, Sub-Arachnoid Block (SAB) was given to all patients. The primary and secondary outcome variables were duration of analgesia and time of rescue analgesia, Visual Analogue Scale (VAS) score, patient satisfaction score, surgeon satisfaction score, respectively. Continuous variables were analysed by unpaired t-test. The ordinal data was analysed using Mann-Whitney U test. Categorical data was analysed using chi-square test.

Results: Demographic and haemodynamic parameters were statistically not significant. Time to the first rescue analgesia in group A was 718.2 minutes and in group B time was 652.1 minutes which was statistically significant (p-value=0.001). There was no statistically significant difference in VAS score at each time interval postoperatively. Both the drugs provided effective postoperative pain relief. All surgeons and patients were in agreement with analgesia, as evidenced by good patient satisfaction score. Mean surgeon satisfaction score was 7 in each groups.

Conclusion: Bupivacaine provides longer duration of postoperative analgesia than ropivacaine. Both bupivacaine and ropivacaine achieved comparable quality of analgesia. Ropivacaine being a more cardiostable drug can be effectively used as an alternative to bupivacaine for femorosciatic nerve block in several clinical situations.

Keywords: Nerve block, Peripheral nerve stimulator, Regional anaesthesia, Rescue analgesia, Visual analogue scale

INTRODUCTION

The Peripheral Nerve Blockade (PNB), in providing anaesthesia, have become an ideal outpatient anaesthetic since the emergence of techniques like ultrasound and Peripheral Nerve Stimulator (PNS). It has the advantage of providing surgical anaesthesia with better cardiorespiratory stability as compared to central neuraxial blockade [1]. PNBs decreases the need for postoperative analgesics, decreases the incidence of nausea, shortens postanaesthesia care unit time, and increases patient and surgeon satisfaction [2].

The most painful orthopaedic procedures are lower limb surgeries. They should be provided with effective postoperative management. Poorly treated pain can also have negative impact on recovery, especially owing to disruption during physiotherapy resulting in stiffness of joints and slow progress in mobility. Femorosciatic (3:1) blocks are the most utilitarian combination technique for lower limb surgical interventions [3]. Combined femoral and sciatic nerve block (3:1) for lower limb surgery provides longer duration of postoperative analgesia of about 12-13 hours as compared to central neuraxial block of about 4-5 hours. Hence, this requires less Non Steroidal Anti-Inflammatory Drugs (NSAIDs) and opioids [4].

Bupivacaine is a long acting amide local anaesthetic with slow onset of action i.e., within 15 minutes and lasts for 4-8 hours [5]. It has cardiotoxic and central nervous system toxicity properties [6]. Ropivacaine is a new long acting amide local anaesthetic agent. It has similar local anaesthetic properties to bupivacaine but with a reduced potential for both neurotoxicity and cardiotoxicity [7-10]. The use of femorosciatic block for lower limb surgeries was less frequent in this hospital. This encouraged us to perform this comparative study and hence, guide the anaesthetists in peripheral hospitals across the country to safely use this technique as a routine and provide a good pain relief to the patients during and after surgery.

Thus, the present study was conducted to compare safety, efficacy and duration of postoperative analgesia between bupivacaine and ropivacaine in femorosciatic blocks. Primarily outcome of the study was duration of analgesia, VAS scores, haemodynamic parameters. Secondary outcome of the study was patient satisfaction score and surgeon satisfaction score.

MATERIALS AND METHODS

This was a randomised clinical study at HBT Medical College and Dr R.N.Cooper, Municipal General Hospital, Mumbai, Maharashtra, India. After Institutional Ethics Committee approval and obtaining written informed consent, patients were enrolled into study from August 2017 to April 2018.

Sample size calculation: The sample size was estimated using the below formula based on mean expected time for rescue analgesia for bupivacaine and ropivacaine reported by a previous study [11].

Formula [12]: $N=2\times(Z_{1-\alpha/2}+Z_{1-\beta})^2\times(\sigma/\mu_A-\mu_B)^2$

A sample size of 35 in each study group was obtained when type 1 error of 0.05 and type 2 error of 0.2 were allowed. The sampling

ratio for each of the study groups was 1:1. Hence, total sample size of 78 and 39 in each group was taken.

Where,

$Z_{1-\alpha/2}$=Critical value of the normal distribution at 1-α/2 (type 1 error =0.05)

$Z_{1-\beta/2}$=Critical value of the normal distribution at 1-β/2 (type 2 error =0.2)

σ=Population Standard Deviation= 312 min

μ_A=Mean expected time to rescue analgesia in Group

B (Bupivacaine)=880 min

μ_B=Mean expected time to rescue analgesia in Group

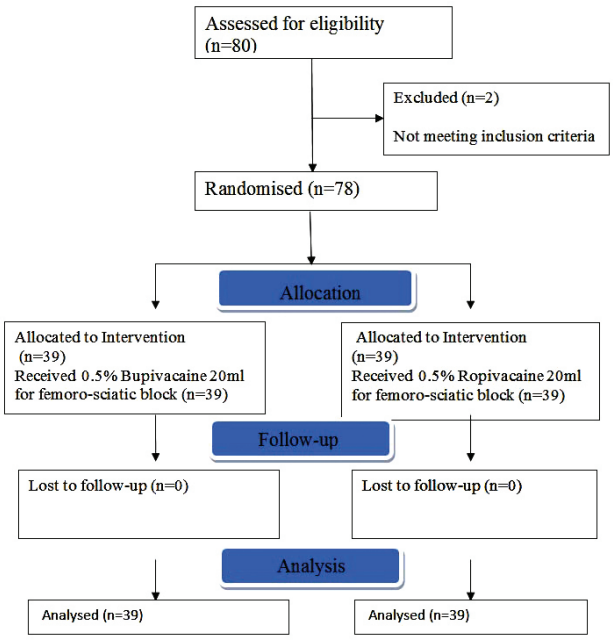
R (Ropivacaine)=670 min

Inclusion and Exclusion criteria: The study was carried out on 78 American Society of Anaesthesiologist (ASA) physical status I and II patients of both gender, in the age group of 18-60 years, scheduled for elective knee and distal surgeries. Patient's refusal, allergy to local anaesthetics drugs, failed/inadequate sub-arachnoid block or femorosciatic block, bleeding disorders, patients taking oral anti-coagulants, antiplatelet agents, infection at block site, patients with hypertension, diabetes mellitus and taking beta-blockers and patients with neuropathy or nerve palsy formed the exclusion criteria.

Study Procedure

During preanaesthetic visit, patients were given information sheet and details of the study were explained about the purpose, risk of the procedure and instructed to demand analgesia as per requirement. The VAS was explained to the patients to determine the level of analgesia in the postoperative period. It was carried out with a 0-10 cm line, where, mark "0" means "no pain" and mark "10" means "severe pain."

By computer generated randomised schedule, patients were allocated to receive bupivacaine (group A) or ropivacaine (group B) to compare postoperative analgesia. In group A, patients received 25 mL of 0.25% Inj. bupivacaine for femoral nerve block and sciatic nerve block each and in group B, patients received 25 mL of 0.25% Inj. ropivacaine for femoral nerve block and sciatic nerve block each [Table/Fig-1].



[Table/Fig-1]: CONSORT flow chart.

A day before surgery detailed preanaesthetic check-up was done. All the patient were kept nil orally for eight hours before surgery. On the day of surgery, Nil by Mouth (NBM) was confirmed. On arrival in operation table multipara monitor was attached and baseline parameters such as Heart Rate (HR), Non-Invasive Blood Pressure (NIBP), peripheral Oxygen Saturation (SpO_2) and Electrocardiography (ECG) and Respiratory Rate (RR) were recorded and were monitored. Oxygen administered via oxygen mask at 6 L/min. Intravenous (i.e.,) line was secured with 18-gauge angiocath and Inj. midazolam 0.04 mg/kg body weight was given. Patients were preloaded with 10 mL/kg body weight of ringer lactate solution over 15-20 minutes. Under all aseptic precautions, sterile syringes containing a local anaesthetic solution were prepared in a double blind fashion by one of the anaesthetist not involved in the management of studied patients.

Femorosciatic Block Technique [13]

For femoral nerve block:

Position-Supine with leg extended and the table flat

Technique- Under all aseptic precautions and guidance of PNS, a 10 cm 22-gauge needle was inserted at 30-45° angle 1.5-2 cm lateral to the femoral artery and 1-2 cm distal to an inguinal ligament in a cephalic direction. The needle was then advanced till motor response in the form of patellar movements was achieved using a current of 2.0 mA. The drug was injected when contractions were elicited at a current of 0.3-0.5 mA.

For sciatic nerve block:

Position- lateral decubitus, with the normal hip and knee in extension and the hip joint (of limb to be blocked) in 40° of flexion, 20-30° of adduction and neutral rotation. The knee was flexed at a 90° angle. This brings posterior superior iliac spine, greater trochanter, and knee in a straight line.

Technique- Under all aseptic precautions, under guidance of PNS, a 10 cm 22-gauge needle was inserted at the intersection point of two perpendicular lines, first being the line joining greater trochanter to posterior superior iliac spine and the other being the line drawn between greater trochanter to sacral hiatus. The needle was advanced until plantar flexion of foot was achieved. The drug was injected when contractions were elicited at a current of 0.3–0.5 mA.

For sub-arachnoid block: After giving femorosciatic block, SAB was given to all patients. Position- same (lateral) position.

Technique- Under all aseptic precautions, 25 gauge Quincke spinal needle was inserted at the L3-L4 interspace and 15 mg (3 mL) 0.5% hyperbaric bupivacaine was injected after ensuring free flow of cerebrospinal fluid and negative aspiration of the blood.

Block assessment was done after four hours of SAB at hourly interval up to 24 hour by a blinded anaesthesiologist. Postoperatively, the patients were evaluated for haemodynamic parameters {Heart Rate (HR), systolic blood pressure} VAS, the time of rescue analgesia, patient satisfaction score, after surgeon satisfaction score at 0, 2, 8, 12 and 24 hours postoperatively by an investigator blinded to group assignment. VAS score was assessed at four hours (after SAB) then at interval of two hours, till VAS $\geq$4. Time of rescue analgesia is the duration of effective analgesia or pain free interval was counted from the time of giving block to when VAS $\geq$4. The rescue analgesia was given in the form of Injection diclofenac sodium 1.5 mg/kg intramuscularly. Patient satisfaction score was divided as: a) fair; b) good; c) excellent for postoperative analgesia. Surgeon satisfaction score was done by using 7-point Likerts scale: a) Strongly agree (Score 7); b) Agree (Score 6); c) More or less agree (Score 5); d) Undecided (Score 4); e) More or less disagree (Score 3); f) Disagree (Score 2); g) Strongly disagree (Score 1).

STATISTICAL ANALYSIS

IBM Statistical Package for the Social Sciences (SPSS) Version 21.0 and Microsoft Office Excel 2007 were used. Continuous data has been expressed as mean (standard deviation). The ordinal data is expressed as median (interquartile range). The categorical data is summarised as frequencies and percentages. The normality of the continuous data was tested by Shapiro-Wilk test. The continuous

variables are analysed by unpaired t-test. The ordinal data is analysed using Mann-Whitney U Test. Categorical data is analysed using chi-square test. The p-values <0.05 are accepted as indicative of statistical significance. The data is graphically represented using box-plot, line diagram with error bars and bar diagrams.

RESULTS

The study was carried on 78 patients divided into two groups of 39 each. Both the groups were comparable with respect to demographic variables such as age, sex, body weight, ASA Grade, type of surgery and duration of surgery [Table/Fig-2].

Demographic variables	Group A (n=39)	Group B (n=39)	p-value
Mean age distribution (years)	41.6 (10)	43.6 (11.2)	0.391* (Unpaired t-test)
Sex distribution			
Males	24 (61.5)	27 (69.2)	0.475* (Chi-square test)
Females	15 (38.5)	12 (30.8)	
Body weight (kg)	59.4 (6.2)	58.8 (4.6)	0.648* (Unpaired t-test)
American Society of Anaesthesiologist (ASA) grade			
I	31 (79.5)	25 (64.1)	0.131* (Chi-square test)
II	8 (20.5)	14 (35.9)	
Duration of surgery (minutes)	143 (16.5)	147.7 (21.9)	0.284* (Unpaired t-test)
Type of surgery			
Knee arthroscopic	22 (56.4)	19 (48.7)	0.496* (Chi-square test)
Frature fixation	17 (43.6)	20 (51.3)	

[Table/Fig-2]: Comparison of demographic variables in Group A and Group B, data in {mean(SD)}.

In both groups, there were no significant difference in haemodynamic parameters such as Heart Rate (HR), Systolic Blood Pressure (BP) and Diastolic BP and Visual Analogue Score (VAS) [Table/Fig-3] at regular intervals in postoperative period. A VAS score of ≥4 was considered as the criterion for administration of rescue analgesia. In this study, it was found that the time for rescue analgesia in Group A (Bupivacaine) was 718.2 minutes and in Group B (Ropivacaine) was 652.1 minutes after giving femorosciatic nerve block. This difference in the two groups was found to be statistically significant p-value=0.001.

Time in hours	Group A	Group B	p-value (Unpaired t-test)
4	0	0	-
6	0.4 (0.5)	0.6 (0.7)	0.100
8	1.4 (0.7)	1.7 (1)	0.175
10	2.2 (0.8)	2.3 (0.9)	0.602
12	2.6 (0.8)	3.2 (0.9)	0.089
14	4(0)	4(0)	-

[Table/Fig-3]: Changes in the VAS score postoperatively in both groups, data in {mean (SD)}.
p-value <0.05 was statistically significant

All the patients were haemodyanamically stable at all time intervals in the postoperative period. There were no statistical difference in haemodyanamic parameters at VAS score was 4 [Table/Fig-4].

Vital parameter	Time in minutes	Group A	Group B	p-value (Unpaired t-test)
Heart rate	4	76.7 (6.1)	78.2 (4.9)	0.216
	6	77.8 (5.6)	78.4 (5.5)	0.638
	8	78.7 (5.5)	79.4 (5.1)	0.596
	10	78.1 (6.8)	79.4 (5.3)	0.396
	12	78 (5.2)	80.8 (4)	0.122
	14	80.8 (6.6)	81.3 (1.2)	0.879
Systolic blood pressure	4	117.4 (7.5)	118 (7.8)	0.746
	6	119.1 (7.2)	118.7 (5.9)	0.770
	8	117.1 (5.8)	119.6 (6.5)	0.078
	10	119.5 (5.5)	117.7 (8)	0.295
	12	118.3 (6.2)	120.4 (7.9)	0.385
	14	120.4 (7.7)	120 (5.7)	0.950
Diastolic blood pressure	4	74.3 (5.2)	75.1 (5.9)	0.532
	6	75.7 (4.9)	76.2 (4.4)	0.665
	8	76.5 (5.5)	76.9 (6)	0.770
	10	76.9 (5.3)	76.2 (6.6)	0.627
	12	79.3 (6.8)	76.8 (4.6)	0.249
	14	77.6 (7.7)	79 (1.4)	0.818

[Table/Fig-4]: Changes in the Heart Rate (HR) and blood pressure postoperatively, data in {Mean (SD)}.

Both the patients and surgeons were satisfied with effective analgesia achieved [Table/Fig-5,6].

Patient satisfaction score	Group A	Group B
Fair	2 (5.1)	5 (12.8)
Good	23 (59)	30 (76.9)
Excellent	14 (35.9)	4 (10.3)
Total	39 (100)	39 (100)

[Table/Fig-5]: Patient satisfaction score.

Surgeon satisfaction score (7 to 1)	Group A	Group B
Median (Interquartile range)	7 (1)	7 (1)

[Table/Fig-6]: Surgeon satisfaction score.

DISCUSSION

Sciatic and femoral nerve block is highly useful in providing anaesthesia and analgesia for a variety of surgical procedures of the lower leg or foot [14]. Combined femoral and sciatic nerve block provides almost three times longer duration of analgesia after surgery (12-13 hours) vis-a-vis central neuraxial block (4-5 hours). Bupivacaine is a long-acting amide local anaesthetic with slow onset of action i.e., within 15 minutes and lasts for 4-8 hours. It is cardiotoxic and central nervous system toxicity such as circumoral numbness, facial tingling, vertigo, tinnitus, seizure and coma are known complications. Ropivacaine is a relatively new amide local anaesthetic and long acting agent with similar local anaesthetic properties to bupivacaine but with a reduced potential for both neuro- and cardiotoxicity. It has a greater tendency to block A-delta and C-fibers. Bupivacaine has been associated with high rate of cardiac and local toxicity. Based on investigations of aetiological mechanisms of local anaesthetic induced cardio toxicity, the search for less toxic alternatives to bupivacaine has concentrated on amide-linked agents. Thus, it was decided to study ropivacaine in comparison to bupivacaine to evaluate the efficacy of the analgesia postoperatively.

Conolli C et al., found that duration of analgesia was 8.6 hours in bupivacaine group and 9.1 hours in ropivacaine group which was statistically insignificant [15]. Theodosiadis P et al., compared the use of 0.5% ropivacaine versus 0.5% bupivacaine for 3-in-1 block during total knee arthroplasty [16]. There was no significant difference between the ropivacaine and bupivacaine groups in terms of the mean duration of analgesia. Patel R et al., found similar results regarding VAS score when they compared 0.25% bupivacaine with 0.25% ropivacaine in 3 in 1 block femoral nerve block for knee surgeries [17]. They found out that duration of analgesia is longer with Group R (7.83±0.98) than Group B (6.33±0.76). Bansal L et al., studied lower limb surgeries under combined femoral sciatic nerve block for postoperative analgesia using 20 mL of 0.5% ropivacaine for femoral nerve block and same dose for sciatic nerve block and in

Group B 25 µg fentanyl was added along with ropivacaine [18]. They found that postoperative analgesia was prolonged as compared to neuraxial blockade without any haemodynamic in stability. This study results were similar to the results of our study.

Singh B et al., compared 0.5% Ropivacaine with 0.5% Bupivacaine for sciatic nerve block in below knee surgeries [19]. They concluded that the duration of analgesia was shorter with ropivacaine (440 minutes) as compared to bupivacaine (460 minutes). However, they concluded that difference in duration of analgesia between ropivacaine and bupivacaine was not significant.

Fanelli G et al., when compared 0.5% Bupivacaine, 0.5% Ropivacine and 2% Mepivacaine in femorosciatic blocks for postoperative analgesia, they found duration of postoperative analgesia was significantly longer in Group ropivacaine (670±227 minutes) and Group bupivacaine (880±312 minutes) compared to Group mepivacaine (251±47 minutes) [13]. McNamee DA et al., when compared 0.75% Bupivacaine and 0.75% Ropivacaine for postoperative analgesia in 75 patients posted for primary total knee replacement provided by spinal anaesthesia alone or in combination with femoral and sciatic nerve block [12]. They find out that the first rescue analgesia in the form of Morphine was prolonged in both groups, 912 minutes for the bupivacaine group and 781 minutes for the ropivacaine group. They concluded that femoral sciatic blockade following intrathecal bupivacaine provided superior analgesia when compared to intrathecal bupivacaine alone. In this study, we found that bupivacaine provided better postoperative analgesia than ropivacaine. Fanelli G et al., and McNamee DA et al., also had similar results [12,20]. Conolli C et al., Theodosiadis P et al., and in Singh B et al., showed there were no statistically significant difference in time to rescue analgesia between bupivacaine and ropivacaine [15,16,19].

A VAS score of ±4 was considered as the criterion for administration of rescue analgesia. In this study, it was found that the time to the rescue analgesia in Group A (Bupivacaine) was 718.2 minutes and in Group B (Ropivacaine) was 652.1 minutes after giving femora-sciatic nerve block. Patients in both the groups had good to excellent analgesia. Surgeons agreed with the effect of nerve block as evidence by mean satisfaction score of 7.

It was found that with equivalent doses of ropivacaine and bupivacaine provided adequate and efficient analgesia in the postoperative period for knee and below knee surgeries. Ropivacaine being a more cardio stable drug can be effectively used as an alternative to bupivacaine for femorosciatic nerve block in several clinical situations [19].

Limitation(s)

As the study institution does not have an ultrasound equipment, block was performed with the help of PNS without the aid of an ultrasound machine.

CONCLUSION(S)

Bupivacaine provided longer duration of postoperative analgesia than Ropivacaine. Both bupivacaine and ropivacaine achieved comparable quality of analgesia. Ropivacaine being a more cardiostable drug can be effectively used as an alternative to bupivacaine for femorosciatic nerve block in several clinical situations. Ropivacaine may be preferred in geriatric patients with diabetes mellitus and/or hypertension with cardiac involvement, in patients with valvular or ischemic heart disease and in patients with cardiomyopathy. Sciatic femoral nerve block along with central neuraxial blockade for surgeries of leg, ankle and foot provides prolonged postoperative analgesia without the need of any additional analgesics. This is particularly useful for patients with co-morbidities like cardiac risk factors and elderly patients, where opioids and other analgesics may need to be avoided.

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