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A study to compare bupivacaine and ropivacaine for postoperative analgesia in ultrasonography guided femoro sciatic nerve block in patients undergoing below knee surgery

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Abstract

Postoperative pain following lower limb surgeries is distinct. Sciatic and femoral nerve blocks are highly useful in providing postoperative analgesia for lower limb surgeries. The use of ultrasound increases the efficacy of the procedure making it more reliable and decreasing the complication rate. Bupivacaine has a slow onset of action with a high rate of cardiac and neurotoxicity. Ropivacaine is a relativity new amide local anaesthetic and long-acting agent with a reduced potential for neuro and cardiotoxicity. Search for a lesser toxic alternative to bupivacaine was being investigated, thus it was decided to study ropivacaine in comparison to bupivacaine to evaluate the efficacy for the analgesia postoperatively. The primary objective of the study is to compare duration of post-operative analgesia between the two groups. The secondary objective of the study is to note total analgesic consumption in the first 24 hours in both groups, the VAS in both the groups, the ease of administration of blocks and procedural complications, if any. Fifty patients in the age group of 18-60 years belonging to ASA I and II who underwent elective lower limb below knee orthopaedic surgery, under subarachnoid SAB were included and randomly allocated to one of the two groups- Group B where patients were administered ultrasound guided femoral-sciatic nerve blocks with 20ml of 0.25% bupivacaine and Group R where patients were administered ultrasound guided femoral-sciatic nerve blocks with 20ml of 0.25% ropivacaine. Ropivacaine and bupivacaine provided adequate and efficient analgesia in the postoperative period for below knee surgeries with a significantly longer duration for ropivacaine. Ropivacaine being a more cardio stable drug can be effectively used as an alternative to bupivacaine for femoro sciatic nerve block.

Keywords: ultrasound, peripheral nerve block, bupivacaine, ropivacaine, lower limb surgery, visual analog score

Introduction Management of postoperative pain plays an essential role in facilitating fast recovery and reduce adverse physiological and psychological effects associated with acute

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and uncontrolled pain. Peripheral nerve blocks reduce postoperative pain significantly and provide an ideal operating condition when used optimally. They cause least interference with the vital physiological functions of the body when compared to the conventional techniques. Femoro sciatic nerve block is a reliable, safe and effective method of providing analgesia in the immediate postoperative period. The use of ultrasound guided sciatic nerve block has various advantages including precise needle insertion, less block administration time, improved block quality and decreased dosage of local anaesthetics.[1]

Bupivacaine is the most commonly used local anesthetic in femoral nerve block, however, the onset of action is delayed, and bupivacaine has been associated with high rate of cardiac and local toxicity. Based on investigation and etiological mechanisms of local anesthetic induced cardiac toxicity, the search for less toxic alternatives to bupivacaine has concentrated on amide linked agents comprised of a single enantiomer. Unlike bupivacaine, which is a racemate, ropivacaine is pure S (-) enantiomer developed for the purposes of reducing the potential toxicity and improving the relative sensory and motor block profiles. Thus, we decided to compare both drugs.[2]

Aim and objectives The aim of the study is to compare bupivacaine and ropivacaine for ultrasound guided femoro -sciatic nerve block for postoperative pain management in below knee surgeries. The primary objective is to compare duration of post-operative analgesia between two groups. The secondary objective of the study is to note total analgesic consumption in the first 24 hours in both groups, the VAS in both the groups, the ease of administration of blocks and procedural complications, if any.

Subjects and methods

Subjects- The present prospective, randomized, single blind study was conducted in the Department of Anaesthesiology and Critical Care, Pt. B. D. Sharma PGIMS, Rohtak after obtaining approval from Institutional Ethics Committee. The study period was from April 2021 to May 2022. Fifty patients in the age group of 18-60 years belonging to ASA I and II who underwent elective lower limb below knee orthopaedic surgery, under subarachnoid SAB were included in the study.

Patients with known hypersensitivity or allergy to study drugs, bleeding disorders, infection at the site of the block, pregnant and lactating females, uncontrolled diabetes mellitus and hypertension, history of cardiac, liver or kidney disease, psychiatric illness, patients on chronic pain medication and patients not willing to participate in the study were excluded from the study. Written informed consent was obtained from each patient (Additional file 1).

Randomization and group allocation- The patients were divided into one of the two groups of 25 each using computer generated randomization number table. Allocation concealment was done using opaque brown envelopes and the envelopes were opened by the anaesthetist in the OR and block administered to the patient. It was a single blinded trial and participants were unaware of the allocation. In Group B patients were administered ultrasound guided femoral-sciatic nerve blocks with 20ml of 0.25% bupivacaine. In Group R patients were administered ultrasound guided femoral-sciatic nerve blocks with 20ml of 0.25% ropivacaine.

Preparation of patients- All patients were subjected to detailed clinical history and examination in the pre-operative room. Informed and written consent was obtained from all the patients after explaining the procedure in detail. Patients were educated about the pain

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score and to rate average pain they experience using VAS where 0 is no pain and 10 is the worst pain imaginable.

Anaesthesia Technique -The procedure was performed under strict aseptic precautions. A high frequency linear Sonosite M-Turbo ultrasound machine was used. All patients included in the study were given SAB in sitting position using 23-gauge Quincke Spinal Needle at L3/L4 interspace with 0.5% 3 ml hyperbaric bupivacaine after ensuring free flow of cerebrospinal fluid. After confirmation of adequate level of anaesthesia surgery was allowed to proceed. After the surgery is over ultrasound guided femoro -sciatic nerve blocks were given to patients.

The femoral block was performed under ultrasound guidance with the patient in supine and leg in neutral position. Femoral nerve and vessels were identified (femoral nerve lies lateral to femoral artery in a groove formed by iliacus and psoas muscle) in short axis view using linear probe (8-12 Hz) covered with sterile plastic sheath and with sufficient application of sterilized gel. A 22-gauge echogenic needle was used under ultrasound guidance 'in -plane' technique and needle tip were positioned between the fascia iliaca and iliopsoas muscle near the lateral corner of the femoral nerve. After checking the exact location of the needle tip, 1ml of normal saline was injected to open the plane and after confirmation of hypoechoic area on the ultrasound image, the injection of corresponding drug solution was given. Next, with the hip abducted and the knee flexed sciatic nerve was identified in the proximal thigh using a curvilinear transducer of 2- 5 MHz from an anteromedial point of view, (just below the lesser femoral trochanter), a 10-12 cm needle was advanced using the 'in-plane' technique to reach up to the sciatic nerve and 1ml of normal saline was injected to open the plane after confirmation of hypoechoic area on ultrasound image. An injection of the corresponding drug solution was given.[3]

Following the block patient was evaluated for pain using VAS in the post anaesthesia care unit at 0, 6, 12 and 24 hours. Patients were asked to rate average pain that they experience over a period of 24 hours post operatively. When the VAS score ≥ 4 the patient was given Inj. Paracetamol 1g i.v. After administration of the Paracetamol if it was assessed VAS ≥ 4 then Inj. Tramadol 100mg i.v was given. Following parameters were recorded to determine the ease of administration of the technique:

- Number of attempts required for the correct placement of the needle.
- Time to perform the block: the starting point was administration of local anaesthetic, and the end point was administration of drug solution.
- Pain during administration of drugs was assessed using VAS.
- Incidence of procedural complications, if any.
- Total analgesic consumption and patient satisfaction was noted

Statistical analysis

25 patients in each group were enrolled for the study. To calculate the number of participants needed for this clinical study, the significance level was set at 95% ($\alpha = 0.05$), and the power of the test was set at 90% with a type II error (β) of 0.10 with reference to previous study.[4] Data were coded and recorded in MS Excel spreadsheet program. SPSS v23 (IBM Corp.) was used for data analysis. Descriptive statistics were elaborated in the form of means/standard

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deviations and medians/IQRs for continuous variables, and frequencies and percentages for categorical variables. Group comparisons for continuously distributed data were made using the independent sample 't' test when comparing two groups. If data were found to be non-normally distributed, appropriate non-parametric tests in the form of the wilcoxon test were used. Chi-square test was used for group comparisons of categorical data. In case the expected frequency in the contingency tables was found to be <5 for >25% of the cells, Fisher's Exact test was used instead. Linear correlation between two continuous variables was explored using Pearson's correlation (if the data were normally distributed) and Spearman's correlation (for non-normally distributed data). Statistical significance was kept at $p < 0.05$.

Observations

The relevant data like VAS score, total duration of analgesia, total analgesic consumption, number of attempts required for the correct placement of the needle, time to perform the block, pain during administration of drugs and incidence of procedural complications were noted and entered into the patient proforma. At the end of study period, all the data was compiled and analyzed statistically.

Patient profile

The trial flow chart is shown in **Figure 1**. The three groups were comparable in terms of demographic profile as shown in **Table 1**. Haemodynamically no significant difference was noted among the groups (**Figures 2-4**). There was no significant difference between the two groups in terms of change in SPO2 from the pre-operative to any of the follow-up time points.

No adverse event was encountered in any patient.

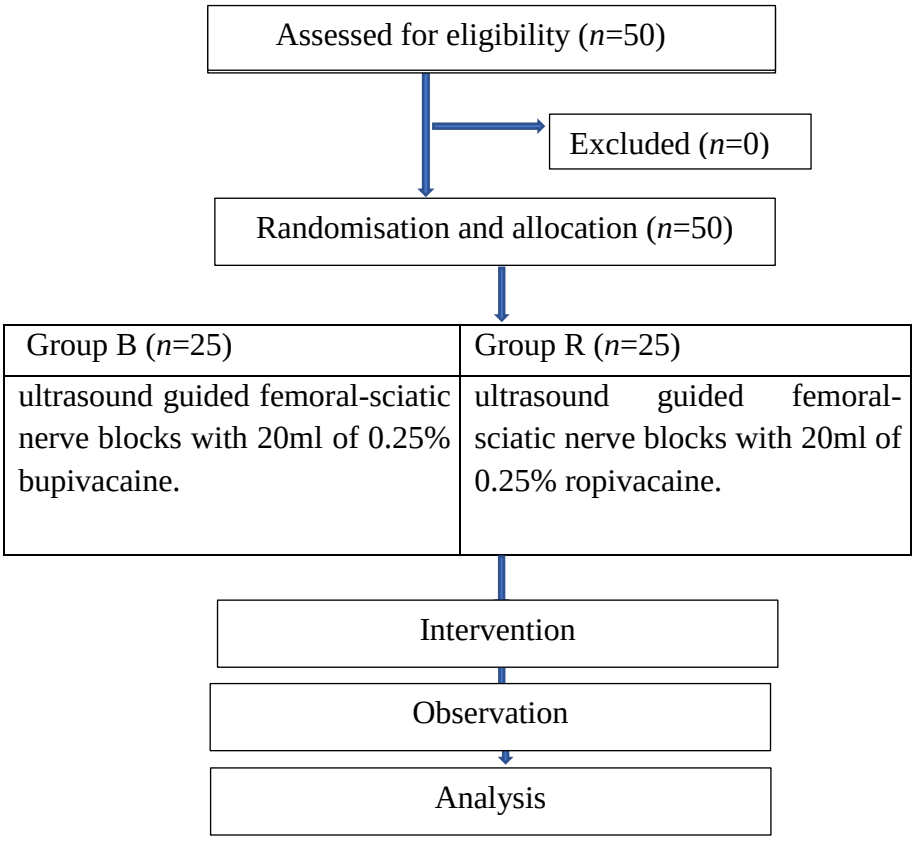

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Figure 1 The trial flow chart.

Table 1: Demographic profile of patients

Variable	B (n=25)	R (*n*=25)	*P*-value
Age (yr)	40.04 (9.65)	39.60 (10.36)	0.877
Sex			1
Male	18(72%)	18(72%)	
Female	7(28%)	7(28%)	
Weight (kg)	60.48±8.05	60.52±3.10	0.977

Note: Data are represented as mean ± SD or number (percentage), and were analyzed by repeated measures analysis of variance followed by post hoc Boneferroni test.

Table 2: Comparison of the two Groups in Terms of change in Visual Analog Score over time

Visual Analog Score	Group		P value for comparison of two groups at each of the time points
	B	R	
	Mean (SD)	Mean (SD)	
Before Block	0.16 (0.80)	0.00 (0.00)	0.337
1 Hour After Block	0.80 (0.76)	0.40 (0.71)	0.030
6 Hours After Block	2.88 (1.17)	2.48 (1.39)	0.188
12 Hours After Block	4.24 (1.48)	3.04 (0.20)	<0.001
24 Hours After Block	5.28 (1.06)	4.08 (0.40)	<0.001
P Value for change in VAS over time within each group	<0.001	<0.001	
P Value for change in VAS over time between the two groups	<0.001		

Comparison of Rescue Analgesia with PCM in Group B and Group R

The overall change in VAS over time (before block, 1 hour, 6 hours, 12 hours and 24 hours after block) was compared in the two groups using the generalized estimating equations method. There was a significant difference in VAS at 12 hours and 24 hours after block between the two groups (p = <0.001). (Table 2)

Table 3: Comparison of rescue analgesia with Paracetamol and Groups

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Time Duration	Number of PCM Doses	Group B	Group R	P value
0-6 hours	1	0	0	<.05
	2	0	0	
6-12 hours	1	20	16	
	2	0	0	
12-24 hours	1	16	8	
	2	6	0	

Comparison of Rescue Analgesia with Tramadol in Group B and Group R				
Time Duration	Number of Tramadol Doses	Group B	Group R	P Value
0-6 hours	1	0	0	<.05
6-12 hours	1	0	0	
12-24 hours	1	6	0	

Table 4: Comparison of rescue analgesia with Tramadol and Groups

Total duration of analgesia was found to be superior in group R as compared to group B (W = 112.000, p = <0.001). The mean (SD) of total duration of analgesia in the Group B group was 6.60 (1.68) while in Group R group was 9.28 (2.30). The mean time taken for femoral block was 3.72 minutes and sciatic block was 6.58 minutes.

Rescue analgesia was given in the form of inj paracetamol at VAS >4. There was significant difference between the groups in terms of distribution of number of PCM doses with more requirement in Group B as compared to Group R. After administration of the Paracetamol if it was assessed VAS ≥ 4 then Inj. Tramadol 100mg i.v was given. No tramadol consumption was noted in Group R. From 12 to 24 hours 6 patients received one dose of Tramadol ($p<0.05$).

Patient satisfaction was noted at various time periods after the block (6 hours, 12 hours and 24 hours after the block). Patients had significantly better level of satisfaction in group B 6 hours after the block whereas in group R, 12 hours after the block.

DISCUSSION

Sciatic and femoral nerve blocks are highly useful in providing postoperative analgesia for a variety of lower limb surgeries. Anterior approach to sciatic nerve is an ergonomic method of providing postoperative analgesia of the lower limb in combination with a femoral nerve block.[2] The use of ultrasound increases the efficacy of the procedure making it more reliable and decreasing the complication rate. [6]Bupivacaine has a slow onset of action and is associated with high rate of cardiac and neurotoxicity. Ropivacaine is a relativity new amide local anaesthetic and long-acting agent with a reduced potential for both neuro and cardiotoxicity. Search for a lesser toxic alternative to bupivacaine was being investigated

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based on the clinical observation of the etiology, thus it was decided to study ropivacaine in comparison to bupivacaine to evaluate the efficacy for the analgesia postoperatively.[7]

The chief finding in our study was better VAS scores in Group R. In our study, both groups were administered subarachnoid block with 0.5% hyperbaric bupivacaine before surgery. VAS in both groups was <1 before the femorosciatic nerve block due to effect of subarachnoid block. The mean VAS score after 6 hours of block in Group B was 2.88 and in Group R was 2.48 which was statistically insignificant. Studies by Patel et al and Bansal et al had similar results. [2,4] . The mean VAS score after 12 hours of block in Group B was 4.24 and in Group R was 3.04 ($p<.001$). The mean VAS score after 24 hours of block in Group B was 5.28 and in Group R 4.08 ($p<0.001$). This is because we got better analgesia with ropivacaine than bupivacaine.

In our study, the total duration of analgesia in Group B was 6.60 ± 1.68 hours and in Group R was 9.28 ± 2.30 hours which is statistically significant ($p<.001$). Patel R et al compared 0.25% bupivacaine with 0.25% ropivacaine in the femoral block for knee surgeries and found that duration of analgesia is longer with Group R (7.83±0.98hrs) than Group B (6.33±0.76hrs).[2] In our study, Ropivacaine provided better postoperative analgesia than bupivacaine which is similar to Patel R et al. Our findings defer from, Kotmire et al, Theodosiadis P et al and Fanelli et al studies.[8,9,10] In our study and Patel R et al study used an analgesic dose of bupivacaine and ropivacaine which is 0.25% but the rest of the studies used 0.5% which can give surgical analgesia. Rescue analgesia was given when VAS ≥ 4. Mean VAS ≥ 4 was attained in 6.8 hours in Group B and 9 hours in Group R. Group R required a comparative lesser number of rescue analgesia than Group B. It is assumed that the requirement of rescue analgesia is less in Group R because of better postoperative analgesia and longer duration of analgesia in Group R. The results are comparable with the study by Patel R et al who compared 0.25% bupivacaine and ropivacaine for postoperative analgesia in the femoral block after knee surgeries and found better analgesia with ropivacaine.[2]

The time taken to administer the femoral block was much less as compared to sciatic block. All femoral blocks were successfully done on the first attempt. The femoral nerve was easy to identify as it lies superficially. Sciatic nerve block was done with the hip abducted and the knee flexed. Out of fifty cases, two sciatic nerve blocks we took two attempts to reach the nerve. This is because the sciatic nerve is located deep anteriorly and anisotropy of the sciatic nerve. In our study, none of the patients from either group had any adverse complications. Majority of the studies also did not report any significant incidence of complication in either group. With the advancement of newer techniques and USG, multiple pricks are avoided causing less discomfort to patients and lesser incidence of any complications.

Our study concluded that femoral and sciatic nerve blocks under ultrasound guidance provide safe and effective postoperative analgesia without any complications with better hemodynamic stability in patients undergoing below knee lower limb surgery. Ropivacaine and bupivacaine provided adequate and efficient analgesia in the postoperative period for below knee surgeries with a significantly longer duration for ropivacaine. Ropivacaine being a more cardio stable drug can be effectively used as an alternative to bupivacaine for femoro sciatic nerve block.

Conflicts of interest

Nil.

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Contributions

ST is involved in conceptualization and design of the study, E is involved in literature search, clinical and experimental studies and data acquisition, VG is involved in data acquisition and manuscript preparation, PG is involved in manuscript editing and review and AL is involved in data analysis and statistical analysis. All the authors approved the final version of the manuscript.

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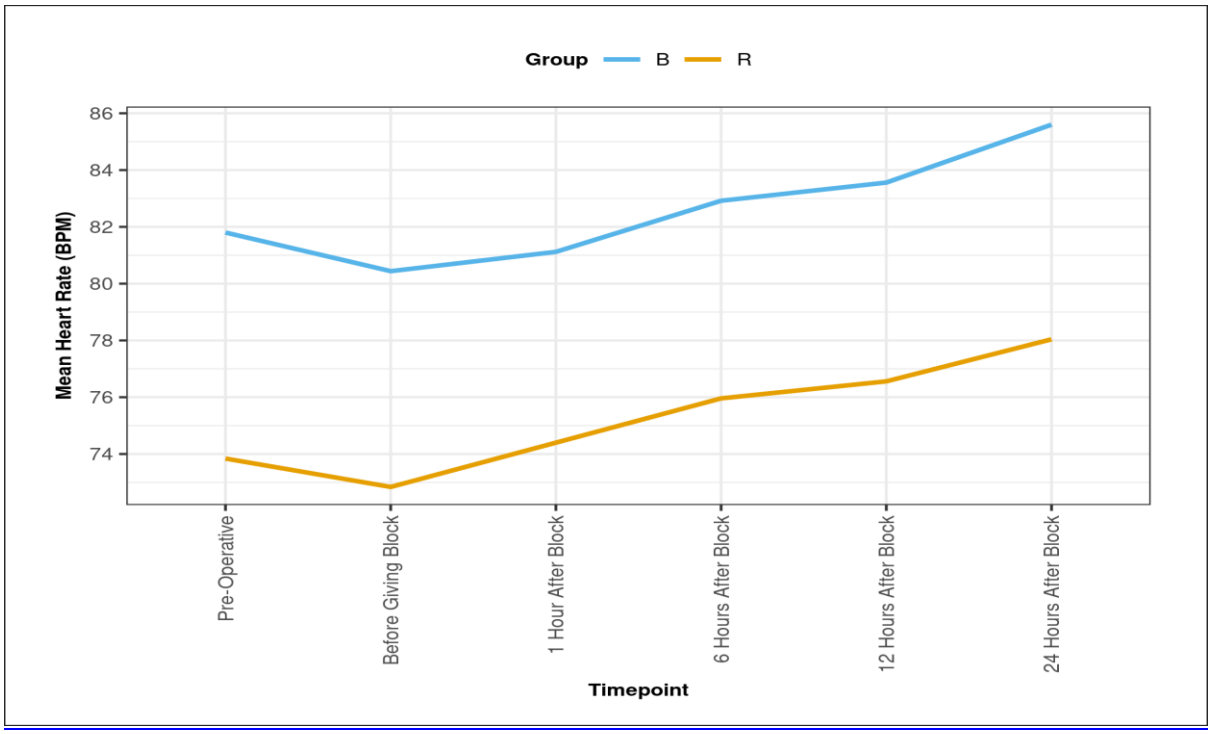

Fig 2 change in heart rate over time

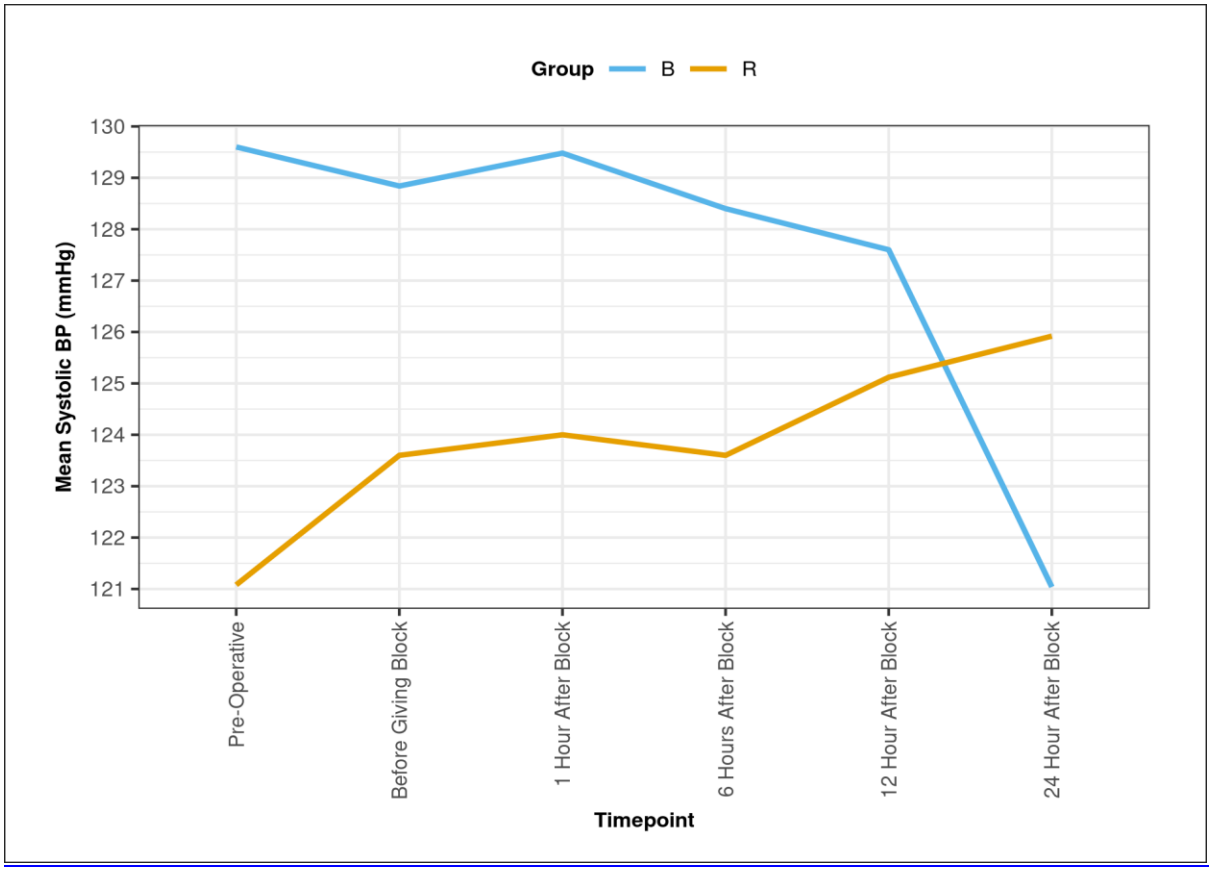

Fig 3 change in systolic blood pressure over time

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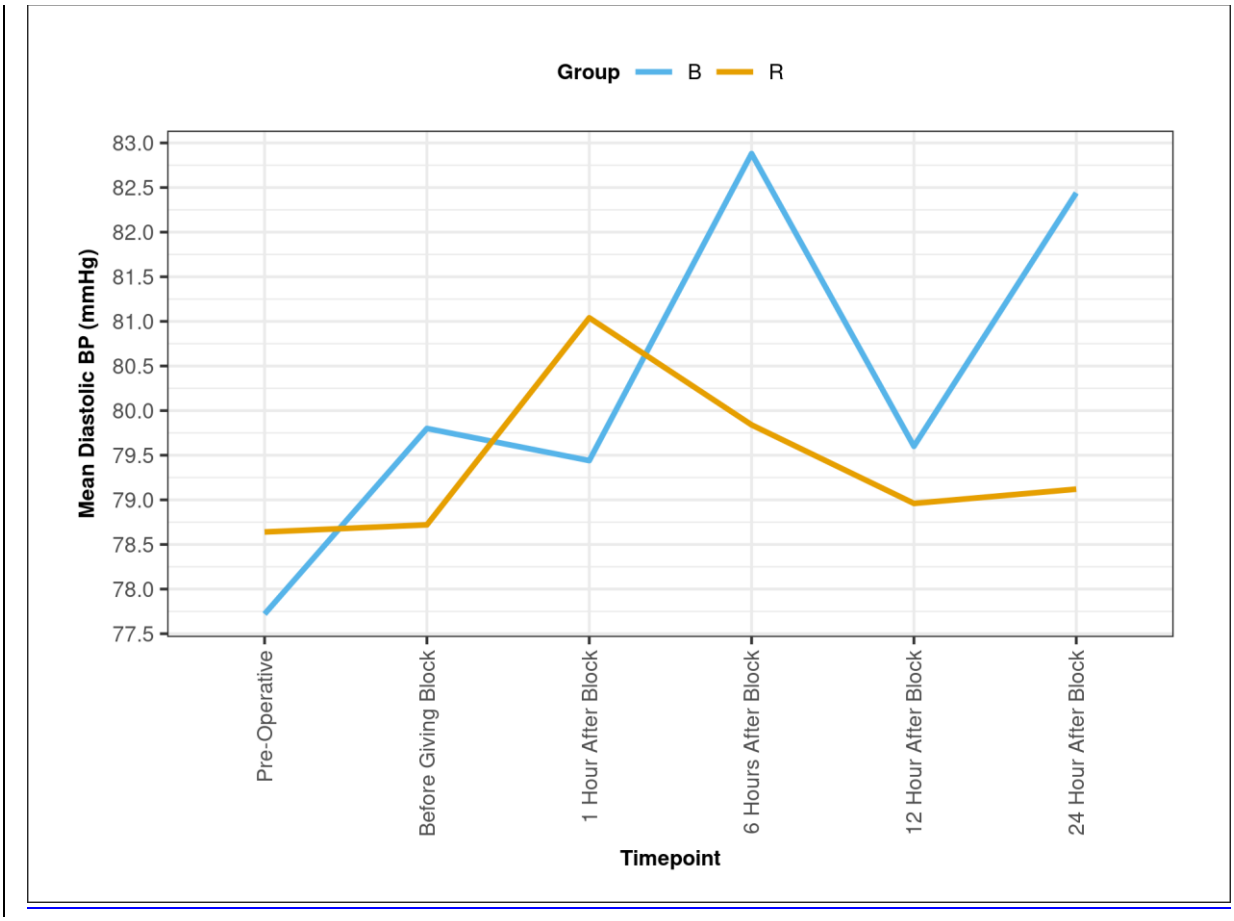

Fig 4 change in diastolic blood pressure over time