

Haemodynamic Comparison of Intrathecal Hyperbaric 0.5% Bupivacaine 2ml(10mg) with Isobaric 0.75% Ropivacaine 2ml(15mg) with Fentanyl 20µg as Adjuvant in Geriatric Patients undergoing Major Lower Limb Orthopedic Surgery

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Abstract: ***Aims and Objectives:** Spinal anaesthesia is the most commonly used method of anaesthesia and analgesia in lower limb surgeries. In elderly patients spinal anaesthesia causes more sympatholysis and hemodynamic disturbances than young patients. So low dose of local anaesthetic is preferred which may occasionally cause failure of spinal anaesthesia. Therefore, different adjuvants are added to achieve desired level of anaesthesia to local anaesthetic. The aim of this study is to compare intraoperative hemodynamic changes associated with intrathecal use of hyperbaric 0.5% bupivacaine 2ml(10mg) and Isobaric .75% ropivacaine 2ml (15 mg) both with fentanyl 20µg in geriatric patients undergoing major lower limb orthopaedic surgeries. **Method:** Sixty geriatric patients undergoing major orthopaedic surgeries were divided into two groups of thirty each. First group (Group R) was given spinal anaesthesia with isobaric .75% ropivacaine 2ml (15mg) and fentanyl 20µg and second group (Group B) was given spinal anaesthesia with .5% bupivacaine 2ml (10mg) and 20µg fentanyl. Baseline and intraoperative hemodynamic parameters and onset and duration of sensory and motor blockade were evaluated. Unpaired Student's t-test and analysis of variance were applied for quantitative data and Chi-square test for qualitative data. **Results:** Incidence of hypotension was greater in bupivacaine group than ropivacaine group (p value<.05). Duration of sensory and motor blockade was less in ropivacaine group than bupivacaine group (p value<.05). **Conclusion:** Low dose of ropivacaine and fentanyl provides better hemodynamic stability and shorter duration of motor block so it is a better choice of anaesthesia in surgeries requiring early ambulation in geriatric patients.*

Keywords: haemodynamic, hypotension, and fentanyl

1. Introduction

In recent years, several studies have been carried out performing spinal anaesthesia with various doses of ropivacaine and bupivacaine. Most of the comparative studies indicated that ropivacaine caused less motor block than bupivacaine and therefore this can represent an advantage for outpatient procedures. Many of these studies had compared motor block, patient satisfaction and length of hospitalization using relatively high doses of ropivacaine and bupivacaine, none compared the hemodynamic effects of low-dose ropivacaine and bupivacaine in geriatric patients undergoing major orthopaedic surgery. Spinal anaesthesia more often causes side effects such as bradycardia and hypotension in elderly patients than in younger ones. Therefore, a low dose of local anaesthetics may be useful in spinal anaesthesia to avoid these side effects in geriatric patients. However, some studies of plain ropivacaine for spinal anaesthesia have shown a high failure rate. A number of adjuvants, such as clonidine and midazolam, and others have been studied to prolong the effect of spinal anaesthesia. For many years, there has been interest in the efficacy and safety of use of intrathecal opioids also, to relieve post-operative pain. The addition of morphine and fentanyl to hyperbaric bupivacaine improves the quality of intraoperative subarachnoid block and postoperative analgesia. Examples of neuraxial adjuvants include Opioids (Morphine, Fentanyl, Nalbuphine, Buprenorphine), Sodium bicarbonate (NaHCO₃), vasoconstrictors (epinephrine), alpha-2 adrenoceptor agonists (clonidine, dexmedetomidine),

cholinergic agonists, N-methyl-d-aspartate (NMDA) antagonists (Ketamine) and γ-aminobutyric acid (GABA) receptor agonists (Midazolam).

Local anaesthetic and opioid combination techniques have been studied in the surgical population. The local anaesthetic works at nerve axons while the opioid works at the receptacle site in the spinal cord. Fentanyl acts primarily as agonist at µ opioid receptors to enhance spinal analgesia.

Fentanyl is a potent, short acting, highly lipophilic, synthetic opioid analgesic. It has been commonly used as an adjuvant for post operative analgesia. It has advantages over morphine because of its rapid onset of action and superior intraoperative conditions. The duration of post operative analgesia is prolonged with the use of fentanyl than with spinal local anaesthetics alone. The benefits also include haemodynamic stability with use of smaller doses of spinal anaesthetics and less troublesome side effects than morphine. Use of epidural fentanyl with epidural bupivacaine provides quicker onset and spread of anaesthesia, and prolonged analgesia but is associated with side effects notably nausea, vomiting, pruritus, urinary retention, respiratory depression. Spinal anaesthesia more often causes side effects such as bradycardia and hypotension, more in elderly patients than in younger ones. Therefore, a low dose of local anaesthetic may be useful in spinal anaesthesia to avoid these side effects in geriatric patients.

Intrathecal opioids are synergistic with local anaesthetic and intensify the sensory block without increasing the

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sympathetic block while achieving satisfactory quality of spinal anaesthesia at a much lower dose of local anaesthetic.

This study was sought to compare intraoperative haemodynamic changes with low dose hyperbaric Bupivacaine.5% (10 mg) with low dose isobaric Ropivacaine .75%(15 mg) both with 20 µg fentanyl in spinal anaesthesia in Geriatric patients undergoing major orthopedics surgeries.

2. Materials and Methods

The study was done in department of anaesthesia S.M.S. Medical College and Group of Attached Hospitals, Jaipur.

Study Design

Hospital based, prospective, comparative, randomized, double blind study.

Study Population

Patients undergoing lower limb orthopaedic surgery in department of orthopaedic anaesthesia.

Selection of Patients

Inclusion Criteria

- Patients aged 60-80 years
- Patients who were fit for spinal anaesthesia
- Patients who had given written informed consent.
- ASA grade II-III
- Undergoing Lower Limb Procedures

Exclusion Criteria

- Chronic history of headache and backache.
- Spinal deformity or infection at the local site.
- Patients having hypertension.
- Known history of allergic reaction to local anaesthetics.
- Sample Size- Sample size of 30 in both groups was calculated accepting a beta error of 20% and an alpha error of 5%.
- Group B (n=30) included patients receiving 10 mg (2ml) of 0.5% hyperbaric bupivacaine plus 20 mcg (0.4ml) Fentanyl. Total volume was 2.4ml.
- Group R (n=30) included patients receiving 15 mg (2ml) of 0.75% isobaric ropivacaine plus 20µg (0.4ml) Fentanyl. . Total volume was 2.4ml.

On the basis of selection criteria, sixty patients who were posted for lower limb orthopedic procedures were included in the study and with the help of an assistant were allocated in two groups using chit in box method. . To eliminate subject and observer bias double blind technique was followed.

Analysis of Data

Mean & Standard Deviation

- Patient parameters
- Surgical parameters.
- Incidence of S/E etc.

Unpaired t-test for quantitative data & Chi ² test for qualitative data

p value < 0.05 was taken as statistically significant.

3. Procedure

All patients were visited on the day prior to surgery and explained about the anaesthetic technique and perioperative course. Each patient had a preanaesthetic checkup which includes:

- 1) Any significant present and past medical/surgical history
- 2) Physical examination
- 3) Vital parameters like B.P., pulse, temperature & respiratory rate
- 4) All routine and specific investigations required for major surgeries were obtained.

Written Informed consent of the patient for the study was taken prior to surgery.

After confirming written informed consent and overnight fasting patient was taken on the operating table. Baseline vitals like B.P., pulse rate, respiratory rate were recorded. After securing a 18G i.v. cannula, preloading was done with 8ml/kg Lactated Ringer solution.. An independent assistant randomly assigned a particular group to the patients by chit in box method by asking the patient to pick a chit from the box and he prepared the drug according the mentioned group in the chit. The prepared drug was handed to me for intrathecal administration to the patient. Vitals just before lumbar puncture were noted. Patient was placed in sitting position. After proper painting and drapping under strict aseptic precautions lumbar puncture was performed in sitting position at L3-L4 interspace with a 25G quincke needle and the drug was given intrathecally at the rate of 0.2 ml/sec. After the injection, patient were shifted to supine position. A pillow was placed under the shoulder. The patient was given 4.0 L/min of oxygen by venti- mask.

Peri-Operative Monitoring

Systolic and diastolic arterial pressure (SAP,DAP) and heart rate were observed at 2mins,5mins and then every 5 mins for first 30 minutes, thereafter at 45th,60th and 120th min. Hypotension was defined as a fall in mean arterial pressure greater than 30% from the baseline value and was treated with incremental doses of mephentermine 6 mg i.v. Bradycardia was defined as a fall in heart rate below 60 beats per min and was treated with incremental doses of atropine 0.6 mg i.v.

Adverse effects nausea,vomiting,shivering and pruritis after intrathecal injection or in peri-operative period were noted and treated with ondasteron ,tramadol and pheniramine respectively. The level of sensory block was assessed every 30 sec after intrathecal injection of the study drug by using 20G hypodermic needle (pin prick method) on midclavicular line on both sides until the level had stabilized for 4 consecutive tests .The onset of sensory block was defined as the time from the intrathecal injection of the study drug to the time taken to achieve anesthesia to pin prick at T10 dermatomal level. Duration of sensory block was defined as the time taken for the sensory block to regress upto L3 dermatome from the highest level achieved.

Grading of sensory blockade

0-Sharp pain.

1-Touch sensation only.

2-Not even touch sensation.

Postoperatively sensory block was tested every 30 minutes until it regressed upto L3 dermatome.

Onset of motor block was defined as the time taken for motor block to reach modified Bromage Grade 3.

Degree of motor block was assessed every 5 minutes till highest modified Bromage score is achieved and every 30 mins postoperatively.

Duration of motor block was assessed by recording the time elapsed from the maximum to the lowest modified Bromage score.

4. Results

There was no statical diference between two groups regarding age, weight, height and sex. Our primary objective was to compare haemodynamic difference between two groups. Intraoperative systolic, diastolic and mean arterial blood pressure trends are shown in figure1,2 and 3,and heart rate trends are shown in figure 4.

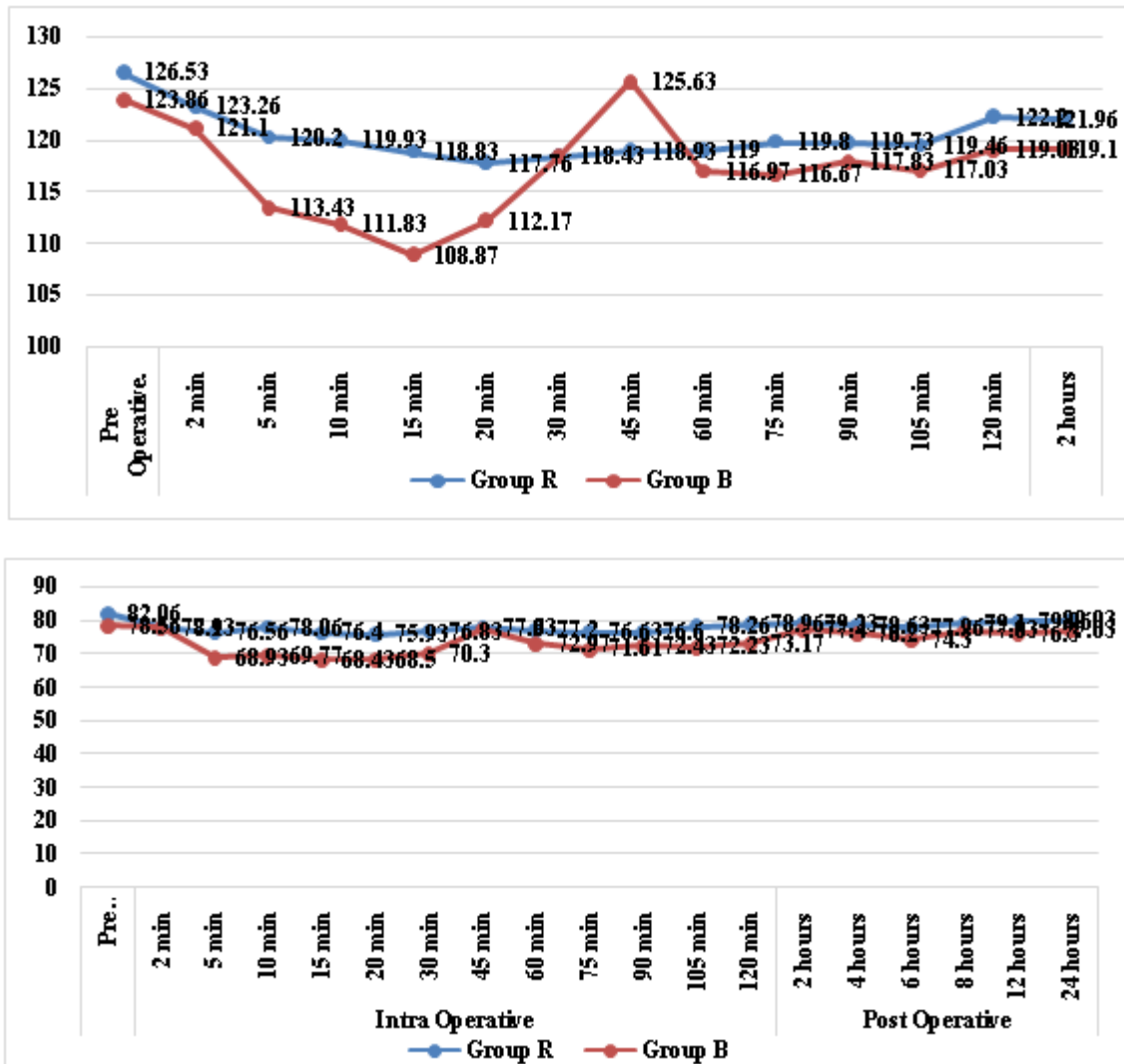


Figure 2: Trends of diastolic blood pressure in two groups

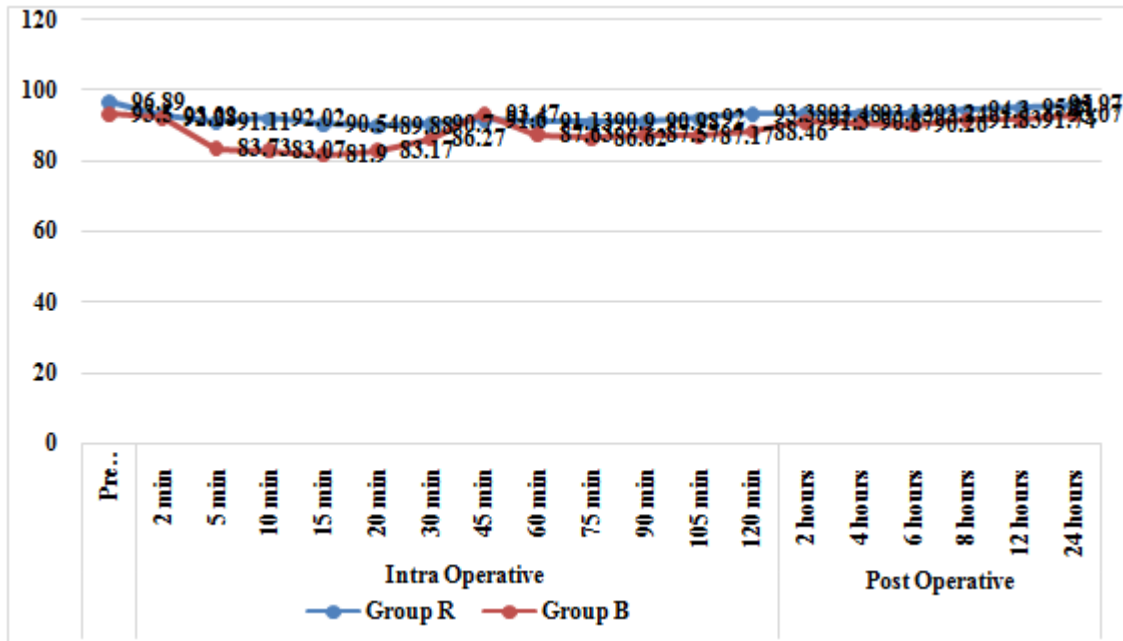


Figure 3: Trends of mean arterial blood pressure in two groups

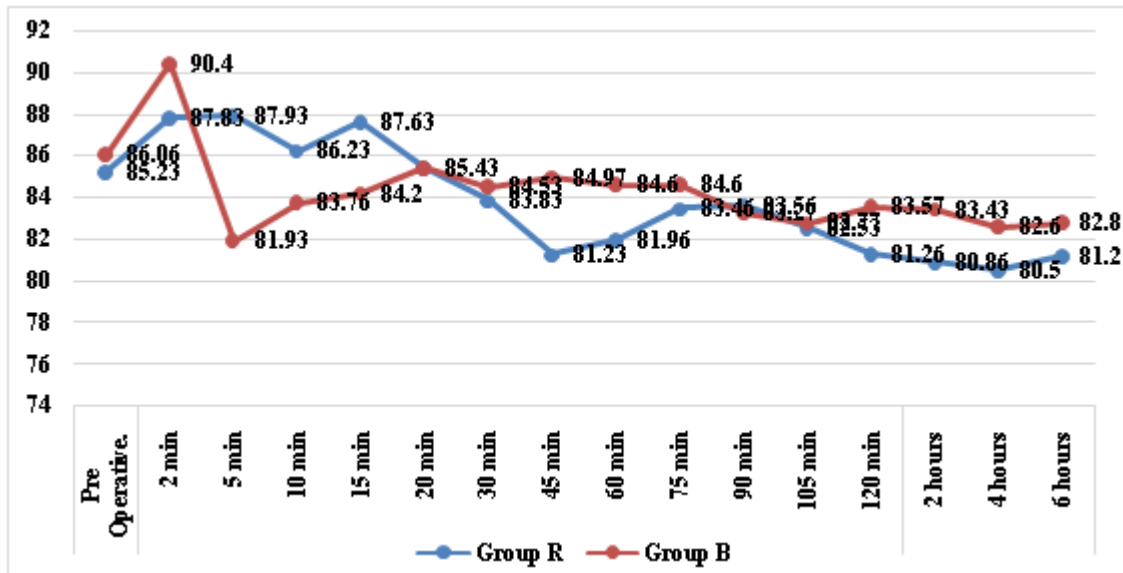


Figure 4: Trends of heart rate in two groups

As we observe the difference in systolic, diastolic and mean arterial blood pressure, there is significant relation between the two groups. On comparing systolic blood pressure, diastolic blood pressure and mean arterial blood pressure there is significant difference between two groups at 5, 10, 15, 20, 30, 60, 90, 105 and 120 minutes with lower systolic, diastolic and mean arterial blood pressure in bupivacaine group than ropivacaine group. Two patients in group R and nine patients in group B developed hypotension, who were managed by giving incremental intravenous doses of mephentramine 6mg. And it was observed that there is a significant difference in occurrence of hypotension between the two groups ($p < .05$). In group R one and in group B three patients developed clinically significant bradycardia for which injection atropine 0.6 mg was given and no statistically significant difference was observed between the two groups.

Onset of sensory and motor block was more rapid in bupivacaine group and duration of motor and sensory block was also more in bupivacaine fentanyl group and the difference was significant ($p \text{ value} < .05$). More patients in bupivacaine fentanyl had cephalad spread up to T4 (total 8) than in ropivacaine fentanyl group (total 2).

Characteristics of sensory and motor blocks between the groups

	Group R (N=30)	Group B (N=30)	
Onset time of sensory block, min	4.7 ± .915	3.1 ± 1.42	$P < .05$
Onset time of motor block, min	8.5 ± 1.07	4.9 ± 1.56	$P < .05$
Duration of T10 anaesthesia, min	224.63 ± 24.10	323.03 ± 39.70	$P < .05$
Duration of motor block, min	184.33 ± 20.24	239.43 ± 30.60	$P < .05$

Spinal anaesthesia is the most common anaesthesia technique used for lower limb surgery. The patient is able to communicate with the health care workers during the surgery and the method is safer than general anaesthesia because it is well tolerated, produces less postoperative confusion and delirium than general anaesthesia in the patient.

Intrathecal administration of lignocaine not only provides shorter duration of anaesthetic blockade and can cause transient neurological symptoms, and hence has been withdrawn. Numerous drugs have been used for spinal anaesthesia, among which bupivacaine is most popular. Bupivacaine, the first long-acting amino amide local anaesthetic is widely used because of its prolonged duration of action, however certain features of bupivacaine like prolonged motor blockade, cardiotoxic and neurotoxic effects have made ropivacaine a safer choice. Also, intrathecal administration of bupivacaine induces profound motor blockade of longer duration and delays discharge after ambulatory surgery.

Ropivacaine, a long acting amide local anaesthetic, shares many physiochemical properties with bupivacaine, but with less systemic toxicity and greater margin of safety due to its purity as S-enantiomer form. Recent clinical data have shown that ropivacaine is effective and safe for regional anaesthetic techniques. The low lipid solubility of ropivacaine leads to greater sensory-motor differentiation by blocking sensory nerve fibers more readily than motor fibers. Early recovery of motor function is associated with decreased incidences of venous thrombo-embolism and shorter hospitalization. It has been used for day care procedures as it provides adequate sensory block with early motor recovery. Ropivacaine has an improved safety profile over bupivacaine with a reduced central nervous system and cardio toxic potential and hence is gaining favour.

Neuraxial opioids are widely used in conjunction with local anaesthetics (LAs) as they permit the use of lower dose of local anaesthetics, while providing adequate anaesthesia and analgesia. Neuraxial opioids also allow prolonged analgesia in the postoperative period and faster recovery from spinal anaesthesia. The use of opioids in conjunction with local anaesthetic for spinal anaesthesia has been associated with decreased pain scores and reduced analgesic requirement in the post-operative period. Neuraxial administration of opioids along with local anaesthetics has gained popularity in lower extremity surgeries due to these advantages. The profound segmental antinociception produced by neuraxial opioids in smaller doses much smaller doses is comparable to systemically administered dose thus making them very popular and effective in the treatment of many painful states. They improve the quality of intraoperative anaesthesia, permit lower doses of local anaesthetics, provide faster onset of surgical block and prolong the duration of postoperative analgesia. The antinociception is also devoid of motor, sensory and autonomic blockade so there is no paralysis or hypotension. Furthermore, the availability of a specific opioid receptor antagonist naloxone to reverse their action when necessary has made the use of opioids safer. Spinal anaesthesia blocks sympathetic efferent nerves controlling vascular smooth muscle tone, and if above T4 also blocks

the SA and AV nodes, and decreases myocardial contractility. Therefore heart rate, contractility and peripheral vasoconstrictive compensatory mechanisms are potentially reduced. Given the elderly may already have reduced preload and LV contractility, strict vigilance is required. Sympathetic blockade can extend above the level of sensory blockade. Epidurals and subarachnoid blocks are technically more difficult in the elderly due to spondylosis, osteoarthritis and patient positioning. In addition to intraoperative analgesia, effective post-operative pain control is crucial in for the recovery of orthopaedic patients, as it encourages early mobilization, recovery and rehabilitation. Luck et al., using drugs (ropivacaine, bupivacaine and levobupivacaine) in comparable baricity and doses (15 mg), showed a similar extent of sensory blockade. The baricity of local anaesthetic may affect block characteristics. Hyperbaric local anaesthetics are more predictable, with greater spread in the direction of gravity and less interpatient variability. In contrast, most isobaric local anaesthetics exhibit greater variability in effect and are less predictable, so that the block may be over- or underestimated. The greater mean spread of hyperbaric solutions may be associated with an increased incidence of cardiorespiratory side effects.

Fentanyl is a synthetic lipophilic opioid with a rapid onset of action and unlike morphine, has lesser tendency to migrate rostrally to the fourth ventricle in adequate concentration to cause delayed respiratory depression. It is commonly used as an adjunct to intrathecal regional anaesthesia and reduces visceral and somatic pain but is limited by dose-dependent adverse effects.

Due to age related degeneration in central and peripheral nervous system, changes taking place in lumbar and thoracic spinal cord and a reduction of cerebral spinal fluid sensory block and sympathetic spinal anaesthesia. The addition of opioids to local anaesthetic in this patient group may be alternative method of establishing adequate motor and sensory block at the same time causes lesser alteration in haemodynamics due to reduction in dose of local anaesthetic drug.

Engine Erturk, Cigdem Tutunku et al¹(2009) found in intragroup comparison, significant decreases in SAP values in comparison with pre-operative levels were observed at all measurement times in group Bupivacaine ($p < 0.05$) and were observed at the 30th, 45th, 60th and 120th min in group Ropivacaine ($p < 0.05$). When SAP values were compared between the groups, the values at the 60th and 120th min in group Bupivacaine were significantly lower than those in group Ropivacaine ($p < 0.05$). In intragroup comparisons, significant decreases in DAP values in comparison with pre-operative levels were observed at the 15th, 20th, 25th, 30th, 45th, 60th and 120th min in both group Bupivacaine and group Ropivacaine ($p < 0.05$). When DAP values were compared between the groups, the values at the 5th, 10th, 20th, 25th, 30th and 120th min in group Bupivacaine were significantly lower than those in group ropivacaine ($p < 0.05$).

Whiteside et al² compared 15 mg of either 0.5% ropivacaine or 0.5% bupivacaine in 8% glucose and reported that ropivacaine

provided reliable spinal anesthesia of shorter duration and with less hypotension than bupivacaine

McNamee et al.³ obtained spinal anaesthesia with an average sensory level of T 2 in the bupivacaine(17.5mg) group, with ephedrine use of 26%, and an average sensory level of T 3 in the ropivacaine(17.5 mg) group, with ephedrine use of 12%, which may be regarded as quite high, leading to serious hypotension. These doses may be regarded as quite high for elderly patients. The addition of opioids to local anaesthetics in this patient group may be an alternative method of establishing sufficient sensory and motor block and at the same time reducing haemodynamic side effects to a minimum by reducing the medication level.

We used low doses of ropivacaine and bupivacaine with a combination of fentanyl to avoid complications of neuraxial block. Therefore, we did not encounter serious hemodynamic side effect in our patients. However, SAP and DAP were lower in group B than in group R. This finding may be linked to the number of patients in group B reaching a T4 sensory level, which was greater than that in group R. The dose of ropivacaine (15 mg) used in our study, which can be regarded as quite low, may cause less of a fall in blood pressures.

The pKa of bupivacaine and ropivacaine are identical but ropivacaine is less lipid soluble, envisaging that ropivacaine will block a fibers more slowly than bupivacaine. Thus ropivacaine would cause less motor block than bupivacaine, which is confirmed in this study. This evidence suggests that there is greater degree of sensory –motor separation when using ropivacaine

Koltka et al.⁴ compared equipotent doses of the isobaric ropivacaine, 19.5 mg and bupivacaine, 13 mg, both with fentanyl, 20 mcg for the sub-arachnoid block in lower abdominal surgery, where they found that the RF is associated with lower level of sensory block and a shorter duration of motor block.

In another study by Lee et al.⁵, equal doses of intrathecal ropivacaine and bupivacaine (10 mg) with 15 mcg fentanyl were used for urology surgeries, and it was reported that ropivacaine provided similar sensory anaesthesia but shorter duration of motor block compared to bupivacai

5. Conclusion

In this study we demonstrated that 15 mg ropivacaine or 10 mg bupivacaine, both with 20 µg fentanyl in a hyperbaric solution, provide sufficient motor and sensory blockade without serious complications or side effects for major orthopaedic surgery in geriatric patients. In addition, ropivacaine caused less haemodynamic side effects such as hypotension and bradycardia than did bupivacaine. This may represent an advantage in elderly patients, whose responses to spinal block are more apparent than those of other patients.

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Characteristics of sensory and motor blocks between the groups

	Group B (N=30)	Group R (N=30)
Onset time of sensory block, min		
Onset time of motor block, min		
Onset time of sensory block to T10		
Duration of T10 anaesthesia, min		
Highest level of sensory block T5		
Time to maximum motor block		
Duration of motor block, min		

Characteristics of sensory and motor blocks between the groups

	Group B (N=30)	Group R (N=30)
Onset time of sensory block, min		
Onset time of motor block, min		
Onset time of sensory block to T10		
Duration of T10 anaesthesia, min		
Highest level of sensory block T5		
Time to maximum motor block		
Duration of motor block, min		