Clinical Comparison of 12 mg Ropivacaine and 8 mg Bupivacaine, Both with 20 µg Fentanyl, in Spinal Anaesthesia for Major Orthopaedic Surgery in Geriatric Patients

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Key Words

Ropivacaine · Bupivacaine · Fentanyl · Spinal anaesthesia · Geriatric patients

Abstract

Objective: The aim of this study was to compare the haemodynamic and anaesthetic effects of 12 mg ropivacaine and 8 mg bupivacaine, both with 20 µg fentanyl, in spinal anaesthesia for major orthopaedic surgery in geriatric patients.

Subjects and Methods: Sixty American Society of Anesthesiologists (ASA) II–III patients scheduled for hip arthroplasty were randomly assigned to receive an intrathecal injection of either 12 mg ropivacaine with 20 µg fentanyl (group R, aged 70 ± 7 years, range 67–89) or 8 mg hyperbaric bupivacaine with 20 µg fentanyl (group B, aged 69 ± 6 years, range 66–92). Motor and sensory block, haemodynamics and side effects were recorded. **Results:** Mean levels of sensory block were similar, but the onset time of sensory block in group B (2.52 ± 0.69 min) was shorter than that in group R (3.17–0.72 min); the difference was statistically significant ($p < 0.01$), and the number of patients who had motor Bromage scale 3 in group B (24) was greater than in group R (16). The difference was also statistically significant ($p < 0.05$). Systolic and diastolic arterial pressures (SAP, DAP) and heart rate (HR) decreased after the block in both groups. SAP (after the 60th and 120th min of block), DAP (all measurement times), and

HR (after the 20th, 25th and 30th min of block) were lower in group B than in group R. **Conclusions:** The data showed that 12 mg of ropivacaine and 8 mg of bupivacaine with 20 µg fentanyl in spinal anaesthesia can provide sufficient motor and sensory block for major orthopaedic surgery in geriatric patients. However, ropivacaine caused less motor block and haemodynamic side effects than bupivacaine during the procedure.

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Introduction

In recent years, several studies have been carried out performing spinal anaesthesia with various doses of ropivacaine and bupivacaine [1–5]. Most of the comparative studies indicated that ropivacaine caused less motor block than bupivacaine and therefore maintained that this can represent an advantage for outpatient procedures [6, 7]. Many of these studies had compared motor block, patient satisfaction and length of hospitalization using relatively high doses of ropivacaine (>15 mg) and bupivacaine (>10 mg), none compared the haemodynamic 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 youn-

ger ones [8]. 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 [4, 9]. For this reason glucose was added to plain ropivacaine to make a hyperbaric solution, thereby increasing the success rate [10–12]. Therefore we added glucose to ropivacaine to obtain sufficient motor and sensory block in our patient groups. In an earlier study, it was shown that 8 mg bupivacaine and 12 mg ropivacaine established equivalent levels of sensory and motor block in patients undergoing caesarean section [6]. Thus, we used the same doses, thought to be comparably effective, to study haemodynamic and other side effects.

The aim of this prospective, randomised study was to compare the haemodynamic and anaesthetic effects of low-dose ropivacaine (12 mg) and bupivacaine (8 mg) with 20 µg fentanyl in spinal anaesthesia for major orthopaedic surgery in geriatric patients.

Subjects and Methods

This was a randomised, double-blind study. The study protocol was approved by the Local Ethics Committee; written informed consent was obtained from American Society of Anaesthesiologists (ASA) score II–III patients (a normal healthy patient = 1; a patient with mild systemic disease = 2; a patient with severe systemic disease = 3; a patient with severe systemic disease that is a constant threat to life = 4; a moribund patient who is not expected to survive without the operation = 5; a declared brain-dead patient whose organs are being removed for donor purposes = 6) aged 65 and above scheduled for primary hip arthroplasty. Patients who suffered from hypertension or had hypersensitivity to bupivacaine, ropivacaine or fentanyl, or any contraindication to spinal anaesthesia, were excluded from the study.

The patients were not given any premedication or sedation during the pre-operative period. When patients arrived in the operating room, standard monitoring (pulse oximeter, non-invasive blood pressure, electrocardiogram) was applied. A 20-gauge intravenous cannula was inserted into the forearm and a standard volume infusion of lactated Ringer's solution 8 ml/kg was given intravenously. Using a computer-generated sequence of numbers and the sealed envelope technique, patients were randomly divided into two groups. The first group received 8 mg of 0.5% hyperbaric bupivacaine and 20 µg of fentanyl and 1 ml normal saline (group B, n = 30), and the second group received 12 mg of 1% plain ropivacaine and 20 µg of fentanyl and 1.4 ml 10% dextrose (group R, n = 30) in an equal volume. The anaesthetic solutions were prepared by an anaesthesiologist who was not involved in subsequent patient care or assessment. After the skin was disinfected, spinal anaesthesia was administered at the L3–4 interspace using a 25-gauge spinal needle with the patient placed in the lateral decubitus position and lying on the operated side. Patients were kept on the operative side for 10 min.

Table 1. Patient characteristics

	Group B (n = 30)	Group R (n = 30)
Age, years	69 ± 6 (66–92)	70 ± 7 (67–89)
Weight, kg	68 ± 7	70 ± 5
Height, cm	165 ± 7	167 ± 6
Gender, M/F	12/18	14/16
ASA, II/III	21/9	19/11
Duration of surgery, min	93 ± 24	87 ± 21
Data are presented as mean ± SD (range in parentheses).		

After intrathecal injection, sensory block was evaluated using loss of pinprick sensation every 5 min before surgery was commenced and then every 30 min during surgery. Motor block was evaluated using a modified Bromage scale (no paralysis, able to flex hip/knee/ankle = 0; able to flex knee but unable to raise extended leg = 1; able to flex ankle but unable to flex knee = 2; unable to flex ankle, knee or hip = 3 [13]). The operation was allowed to start after the level of sensory block had reached the T₁₂ dermatome and a Bromage score ≥ 2.

Systolic and diastolic arterial pressure (SAP, DAP) and heart rate (HR) were recorded every 5 min for the first 30 min and then at the 45th, 60th and 120th min. Hypotension was defined as a decrease in blood pressure of more than 30%. This was treated with 5–10 mg i.v. of ephedrine and further infusion of lactated Ringer's solution as required. Bradycardia was defined as HR < 50 beats/min. This was treated with 0.02 mg/kg i.v. atropine as required. The occurrence of side effects, including nausea/vomiting, pruritus and headache, was recorded, and these were managed by the attending anaesthesiologist as clinically indicated.

The time from local anaesthetic injection to onset of sensory and motor block was recorded. The highest level of sensory block, onset time of sensory block to T₁₀, time to maximal cephalic spread and time to maximal motor block and Bromage scores were also recorded.

All patients received 3 litres min⁻¹ oxygen by nasal cannula during surgery. Respiratory rate < 8 min⁻¹ and SPO₂ < 90% were considered respiratory depression. Sedation was evaluated every 15 min as a wakeful response to verbal stimulation and response to painful stimulation.

Statistical Analysis

The Kolmogorov-Smirnov test was used for determining the normality and homogeneity of data distribution. Demographic data, onset time of sensory and motor block, and haemodynamics (SAP, DAP, HR) were compared using Student's *t* test between the two groups. Gender, ASA score and side effects were compared using the χ^2 test. HR and blood pressures over time within the groups were compared by repeated measures of ANOVA with post-hoc testing. A *p* value of < 0.05 was considered statistically significant. A power analysis was performed on the difference of the blood pressures (20%) between the two groups. Sample size was calculated accepting a β error of 20% and an α error of 5%.

Fig. 1. Comparison of SAP between the groups. * $p < 0.05$, bupivacaine compared to ropivacaine.

Fig. 2. Comparison of DAP between the groups. * $p < 0.05$, bupivacaine compared to ropivacaine.

Table 2. Characteristics of sensory and motor blocks between the groups

	Group B (n = 30)	Group R (n = 30)
Onset time of sensory block, min	2.52 ± 0.69	$3.17 \pm 0.72^*$
Onset time of motor block, min	4.82 ± 1.47	4.98 ± 1.03
Onset time of sensory block to T ₁₀ , min	7 ± 1.0	8 ± 1.2
Duration of T ₁₀ anaesthesia, min	145 ± 20	$91 \pm 10^*$
Highest level of sensory block	T ₅ (T ₄ to T ₇)	T ₆ (T ₄ to T ₇)
Time to maximum cephalic spread, min	9 ± 1.9	10 ± 2.2
Time to maximum motor block, min	4 ± 1.5	5 ± 1.2
Duration of motor block, min	162 ± 48	$115 \pm 25^{**}$
Number of patients with Bromage score of 3	24	16 ^{**}
Mean Bromage score	2.6 ± 0.4	2.3 ± 0.4

Data are presented as mean $\pm$ SD or range. * $p < 0.01$; ** $p < 0.05$.

Results

There were no statistical differences between the groups with respect to age, weight, height, gender, ASA score and duration of surgery (table 1). Onset time of sensory block in group B was shorter than that in group R ($p < 0.01$). Duration of T₁₀ anaesthesia and duration of motor block in group R were shorter than that in group B ($p < 0.01$, $p < 0.05$, respectively) (table 2). Regarding onset time of motor block, onset time of sensory block to T₁₀, highest level of sensory block, time to maximum cephalic spread and time to maximum motor block, there were no statistical differences (table 2). The number of patients who had motor Bromage scale 3 in group B ($n = 24$) was greater than that in group R ($n = 16$) ($p < 0.05$).

However spinal anaesthesia was adequate for the surgical procedure in all patients.

SAP and DAP are shown in figures 1 and 2. In intra-group comparison, significant decreases in SAP values in comparison with pre-operative levels were observed at all measurement times in group B ($p < 0.05$) and were observed at the 30th, 45th, 60th and 120th min in group R ($p < 0.05$). When SAP values were compared between the groups, the values at the 60th and 120th min in group B were significantly lower than those in group R ($p < 0.05$) (fig. 1). 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 B and group R ($p < 0.05$). When DAP values were compared between the groups,

Fig. 3. Comparison of HR values between the groups. * $p < 0.05$, bupivacaine compared to ropivacaine.

Table 3. Frequency of side effects (n) in the two groups

	Group B (n = 30)	Group R (n = 30)
Ephedrine requirement	3	3
Itching	2	2
Nausea/vomiting	3	4
Headache	2	2
Bradycardia	3	1

the values at the 5th, 10th, 20th, 25th, 30th and 120th min in group B were significantly lower than those in group R ($p < 0.05$) (fig. 2).

In intragroup analysis, significant reductions in HR were determined in both group B and group R at the 30th, 60th and 120th min in comparison with pre-operative values ($p < 0.05$), and these decreases were more evident in group B. Significant reductions were determined in HR in group B at the 20th, 25th and 30th min in comparison with group R ($p < 0.05$), though no significant differences were found at other measurement times (fig. 3) ($p > 0.05$).

Bradycardia was observed in 3 patients in group B and in 1 patient in group R, though no significant difference was determined between the two groups regarding the frequency of bradycardia. No statistical difference was found with regard to ephedrine requirement, nausea, vomiting, headache or itching between the groups (table 3).

As a result, the respiratory rate fell to below 8 in 2 patients in group B and in 1 patient in group R, with SpO_2 falling below 90% in only 1 of these patients. These patients responded to verbal stimuli and the respiratory rate was raised up to 9 in all patients.

Discussion

This study showed that 12 mg ropivacaine or 8 mg bupivacaine, both with 20 μ g fentanyl, provided sufficient motor and sensory block; it also showed that ropivacaine caused less haemodynamic side effects than bupivacaine. Our results may represent some advantage especially in elderly patients aged 65 or above undergoing major orthopaedic surgery. With spinal anaesthesia, sensory block and sympathetic block are higher in the elderly patient group than in young adults. Age-related degeneration in the central and peripheral nervous systems, changes taking place in the lumbar and thoracic spinal cord, and a reduction of cerebrospinal fluid may be listed among the reasons for this [8]. In a study in which they administered 17.5 mg bupivacaine and 17.5 mg ropivacaine to patients with an average age of 66–67 who were scheduled for orthopaedic surgery, McNamee et al. [14] obtained spinal anaesthesia with an average sensory level of T_2 in the bupivacaine group, with ephedrine use of 26%, and an average sensory level of T_3 in the ropivacaine 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. In our study, an average sensory level of T_5 was achieved for group B and of T_6 for group R with the addition of 20 μ g fentanyl, and thus a sufficient sensory level for hip surgery was established in both groups. In terms of motor block levels, the number of patients with a Bromage score of 3 in group B was higher than that in group R. The reason for this may be that there is more spread of bupivacaine in cerebrospinal fluid when compared to ropivacaine.

Hypotension and bradycardia are the most frequently seen complications of neuraxial blocks. The degree of these hemodynamic side effects may alter according to dose of local anaesthetic. A reduction in dose of local anaesthetic may decrease the degree of motor block and sensory level. However, increasing doses of local anaes-

thetic may cause high sympathetic block and haemodynamic side effects especially in older patients. It was found that the use of 15 mg hyperbaric bupivacaine in a patient group aged 68 and above, and scheduled for urological surgery, caused a 15–25% reduction in SAP and a 33–35% reduction in HR [8]. In patients scheduled for urological surgery who were administered isobaric 10 mg bupivacaine and 15 mg ropivacaine, hypotension was observed in 22% of the bupivacaine group and in 19% in the ropivacaine group, and no difference was determined in terms of ephedrine use [4]. 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 (12 mg) used in our study, which can be regarded as quite low, may cause less of a fall in blood pressures. Throughout all the operations, however, the lowest average SAP in group B was 115.73 ± 18.38 mm Hg and that in group R was 126.57 ± 23.36 , while the lowest average DAP in group B was 58.73 ± 12.97 and that in group R 66.27 ± 17.23 . In addition, no difference was determined between the groups in terms of ephedrine use.

However, Luck et al. [15], 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. In a review article it was stated that some factors such as baricity, volume, dose, concentration injected, temperature of the solution, viscosity, etc. affected intrathecal spread of the local anaesthetics and block quality [16]. Hyperbaric local anaesthetics are more predictable, with greater spread in the direction of gravity and less interpatient variability. In contrast, most plain local anaesthetics exhibit greater variability in effect and are less predictable, so that the block may be over- or underestimated. Although we added glucose (50 mg/ml) to ropivacaine, we did not know whether we obtained the same baricity. The greater mean spread of hyperbaric solutions may be associated with an increased incidence of cardiorespiratory side effects. Further work with local anaesthetics at the same baricity is required to confirm our findings.

Bradycardia was observed in only 3 patients in group B and 1 patient in group R in our study. The occurrence of bradycardia may be associated with the level of sympathetic block and/or intrathecal fentanyl administration

[2, 8]. The highest level of sensory block was higher in group B (T₅) than in group R (T₆). However, bradycardia was similar between the groups in our study and we did not administer any premedication to our patients since sedative agents may affect haemodynamics. Therefore, medium SAP values in our patients remained borderline hypertensive before the spinal block. The use of intraoperative opioid may cause such side effects as nausea, vomiting, itching, sedation or respiratory depression. A rise in the incidence of respiratory depression and sedation in particular has been observed in studies using more than 40 µg fentanyl, and a rise in itching in particular with more than 25 µg [17]. We used 20 µg of fentanyl in our study, and less respiratory depression, sedation and other side effects were observed.

Conclusion

In this study we demonstrated that 12 mg ropivacaine or 8 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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