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Research Article

Isobaric Ropivacaine 15 mg Versus Hyperbaric Bupivacaine 12.5 mg for Spinal Anesthesia in Geriatric Patients Undergoing Total Knee Arthroplasty

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Keywords

- Hyperbaric bupivacaine
- Isobaric ropivacaine
- Spinal anesthesia
- Total knee arthroplasty

Abstract

Background: We conducted this study to reach up to a safer and effective spinal anesthetic drug for use in high risk geriatric patients undergoing major lower limb surgery by comparing intrathecal isobaric ropivacaine with the commonly used intrathecal hyperbaric bupivacaine in such group of patients.

Methods: Fifty two geriatric patients ASA grade II–III undergoing elective total knee arthroplasty (TKA) surgery under spinal anesthesia were randomized into two groups. Group I including patients who received 12.5 mg (2.5 ml) of hyperbaric bupivacaine 0.5% and group II including patients who received 15 mg (3ml) of isobaric ropivacaine 0.5%. The extent and duration of sensory and motor block and hemodynamics including heart rate (HR), non invasive mean arterial blood pressure (MAP) and respiratory depression were recorded.

Results: Successful block has been attained in all patients in both groups. There were significant statistical difference between the two groups as regards onset time to T10 (group I 7 ± 1.85 min ; group II 10.3 ± 1.34 min; $P < 0.001$), time to maximal sensory level (group I 21.27 ± 9.37 min; group II 26.5 ± 7.21 min; $P < 0.028$) , median maximum sensory extent (group I T6 ; group II T8; $P < 0.031$), duration of T10 anesthesia (group I 93 ± 10.37 min ; group II 60 ± 10.92 min; $P < 0.001$) and onset time to maximal motor block (group I 8.5 ± 1.2 min; group II 12.8 ± 1.6 min; $P < 0.001$). The total duration of both sensory block (group I 180 ± 20 min *vs.* group II 150 ± 25 min; $P < 0.001$) and motor block (group I 160 ± 10.92 min *vs.* group II 130 ± 13.61 min; $P < 0.001$) were shorter in the ropivacaine group significantly but sufficient for surgery. In addition, ropivacaine caused less hemodynamic complications such as hypotension, bradycardia and respiratory depression than did bupivacaine.

Conclusion: Isobaric ropivacaine 15 mg can be used to provide a reliable spinal anesthesia for geriatric patients undergoing total knee replacement surgery that is comparable to that of the commonly used hyperbaric bupivacaine 12.5 mg as regards the efficacy of the block with a shorter recovery profile and less hemodynamic derangement.

The study was registered on www.clinicaltrials.gov, Registration ID: NCT02764723, Registered June 6, 2016.

ABBREVIATIONS

ASA: American Society of Anesthesiologists; BPM: Beat Per Minute; ED: Effective Dose; HR: Heart Rate; ICU: Intensive Care Unit; MBP: Mean Blood Pressure; SD: Standard Deviation; SPO2: Peripheral Capillary Oxygen Saturation; TKA: Total Knee Arthroplasty; T: Thoracic

BACKGROUND

TKA (total knee arthroplasty) is considered a major surgical procedure that requires effective, safe anesthesia and a good postoperative pain control as it is considered a highly painful procedure. Patients undergoing TKA are usually elderly with multiple comorbidities. That is why it is important to choose an anesthetic and analgesic regimen that will minimize side effects as well as providing suitable pain relief. For those patients undergoing knee replacement, spinal anesthesia is considered the anesthetic technique of choice as it is associated with a reduced risk of venous thromboembolism and blood loss as compared with general anesthesia in addition to providing early postoperative analgesia.

Ropivacaine is one of the amide local anesthetic groups that is close to bupivacaine in its chemical structure and can be used as alternative to bupivacaine with a better safety profile because it has the advantage of being less cardiotoxic on a milligram basis [1]. Many clinical trials were required to compare potency of ropivacaine versus bupivacaine in humans before recommending it as a safe anesthetic alternative [2]. Spinal bupivacaine is associated with minimal postoperative complaints [3], but it is not suitable for outpatient anesthesia as it is associated with prolonged sensory and motor recovery profile which will delay patient discharge following outpatient surgery [4], and if less dose of spinal bupivacaine was used, it will allow faster recovery

on the expense of anesthetic quality [5]. In comparison to spinal ropivacaine whose recovery profile is faster which makes it a good choice as a spinal anesthetic in outpatient setting?

This study was designed to test the efficacy and safety of plain ropivacaine 15 mg used in spinal anesthesia for geriatric patients undergoing total knee replacement surgery compared with hyperbaric bupivacaine 12.5 mg.

METHODS

The study was registered on www.clinicaltrials.gov, Registration ID: NCT02764723, principal investigator's name: Mohamed Sayed Mohamed Abbas, Registered June 6, 2016.

The study was conducted as a prospective randomized trial between January 2013 and December 2015 and included 52 patients II–III ASA physical status (ASA II: a patient with mild systemic disease, ASA III**:** a patient with severe systemic disease (Table 1)), aged 65 years and above (from 65 to 74 years: 25 patients, from 75 to 79 years: 18 patients, from 80 years and above: 9 patients) of average weight and height and planed to undergo total knee replacement under spinal anesthesia. Ethical Committee approval and written informed consent from all the patients enrolled in the study were obtained.

Exclusion criteria were psychiatric disorders, inability to communicate, allergy to amide local anesthetics, contraindication to spinal anesthesia such as local infection at the puncture site, coagulopathy, thrombocytopenia, brain space occupying lesions and abnormal spine anatomy.

We randomized the patients into two equal groups, 26 patients each , Group I : patients who are anesthetized with an intrathecal injection of 12.5 mg (2.5 ml) of 0.5% hyperbaric bupivacaine, *Group II:* patients who are anesthetized with an intrathecal injection of 15 mg (3 ml) of 0.5% isobaric ropivacaine. All the patients of both groups were pre medicated with omeprazole 40 mg IV, metoclopramide 10 mg IV and normal saline solution 0.9% % 1000 ml infused over 15 min prior to induction of the spinal block. Patients were positioned in the lateral position. After sterilization and draping, the inter space between L3-4 or L4-5 were identified then Quincke Babcock Spinal needle 27 gauge was introduced in the midline with the needle bevel facing caudal until free clear CSF flow was obtained, then the spinal anesthetic was injected slowly without barbotage. After that, the spinal needle was removed and the patient was positioned supine immediately after injection. NC 4 L/min was applied all over the time of surgery. IV metoclopramide 10 mg was used if the patient experienced nausea or vomiting and IV fentanyl 50 µg was given if pain or discomfort occurred during surgery. The surgeon was allowed to start only after the sensory block level had reached the L1 dermatome and a Bromage score > 2.

Table 1: Associated comorbidities (no).

	Bupivacaine group (n = 26)	Ropivacaine group (n = 26)
Cardiac diseases (CHF, valvular heart disease)	5	7
Pulmonary diseases (COPD, asthma)	6	4
Renal diseases (ESRD, renal impairement)	8	6

All patients of these two groups were assessed and monitored for hemodynamics as regards ECG for heart rate (HR) and non invasive mean arterial blood pressure (MAP). Baseline blood pressure and heart rate values were recorded before the anesthetic induction and then every 5 min all over the surgery and in the recovery room. Pulse oximetry was used to monitor the patient oxygen saturation throughout surgery. IV ephedrine 10 mg and normal saline bolus were used if the patient experienced hypotension (defined as mean arterial blood pressure < 65 mm Hg). IV atropine 0.5 mg was used if bradycardia (defined as heart rate < 60 bpm) has occured. Respiratory depression (defined as respiratory rate < 8 min and SPO2 < 90%) was managed by verbal stimuli, if failed, endotreacheal intubation.

Sensory block to pinprick was assessed every 2 minutes until 10 minutes post intrathecal injection then at 15 minutes and after that every 15 minutes until regression to L5. Sensory assessment was done using a short-beveled 27-gauge needle done on both sides at the mid clavicular line. Onset of sensory blockade was defined as the time taken from injecting the study drug into the subarachnoid space till the patient did not feel the pin prick at T10 level. Time taken for maximum sensory blockade was defined as the time taken from injecting the study drug into the subarachnoid space to the maximum sensory blockade attained. Duration of sensory block was measured from the sensory block onset until the patient required the first analgesic dose.

Assessment of Motor block in the lower limb was done following sensory block assessment until normal motor function has been attained. Assessment was done using modified Bromage scale (0 = no motor block, 1 = can flex knee, move foot but cannot raise leg, 2 = can move foot only, 3 = cannot move foot or knee). Onset to maximal motor blockade was defined as time taken from injecting the study drug into the subarachnoid space until Bromage 3 score was obtained. Duration of motor blockade was taken as the time from injecting the study drug into the subarachnoid space till the patient attained slight motor recovery to < Bromage 3.

STATISTICAL ANALYSIS

Data were collected, coded, tabulated, and then analyzed using Minitab® 16 computer software. Numerical variables were presented as mean and standard deviation or median and interquartile range as appropriate and then analyzed by student-t test. Categorical variables were presented as frequency and percentage, and analyzed by chi-square test. Any difference with p-value <0.05 was considered statistically significant.

Sample size estimation revealed that at least 26 patients are needed in each group to detect at least 5% difference in the duration of sensory block, at a power of 0.95 and significance level of 0.05, assuming that its mean and standard deviation for hyperbaric bupivacaine is 175.8 min and 8.6 min respectively [6].

RESULTS

No significant statistical differences were observed between both groups with respect to age, weight, height, gender, ASA score and duration of surgery (Table 2).

Acceptable levels of sensory block were obtained in all patients before surgery. The onset time to T10 was significantly shorter in the bupivacaine group (5 ± 1.85 min) compared with ropivacaine (8.3 ± 1.34 min) with P < 0.001. The median maximal block height was higher in the bupivacaine group (T6) than in the ropivacaine group (T8) and the time taken to achieve such block height was significantly shorter in the bupivacaine group (21.27 ± 9.37 min) than in the ropivacaine group (26.5 ± 7.21) with P < 0.05. The duration of T10 anesthesia and the total duration of sensory block were shorter significantly in the ropivacaine group with P < 0.001 but it was sufficient to complete the surgery (Table 3).

Acceptable degrees of motor block were obtained in all patients before surgery. The onset time to Bromage 3 was significantly shorter in the bupivacaine group (8.5 ± 1.2 min) than in the ropivacaine group (12.8 ± 1.6 min) with P <0.001. The total duration of motor block was significantly shorter in the ropivacaine group (130 ± 13.61 min) than in the bupivacaine group (160 ± 10.92 min) with P <0.001 (Table 3, Figure 1,2).

As regards hemodynamics, intraoperative hypotension treated with ephedrine occurred in 13 patients in the bupivacaine group compared with only 4 patients in the ropivacaine group (P <0.05). Nine patients in the bupivacaine group experienced intraoperative bradycardia which required treatment with atropine compared with only two patients in the ropivacaine group (P <0.05). No significant statistical difference was noted between both groups (7 patients in the bupivacaine group compared with 4 patients in the ropivacaine group) as regards respiratory depression which was managed only with verbal stimuli without the need for endo tracheal intubation (Table 4).

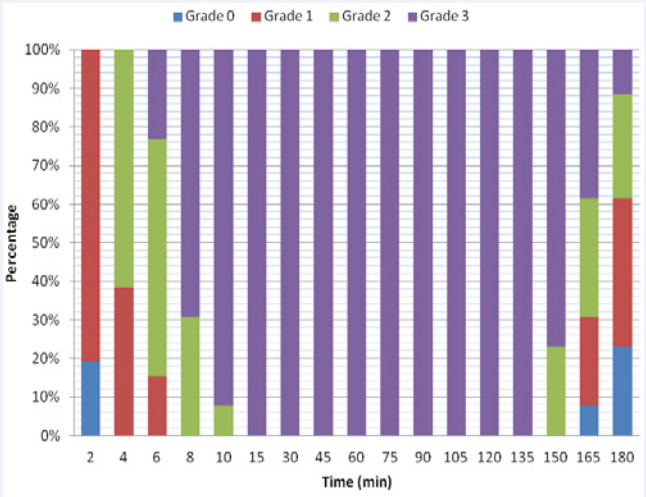

Figure 1 Motor block following intrathecal administration of hyperbaric bupivacaine assessed by Bromage scale.

No patient in both groups required IV fentanyl for intraoperative pain or discomfort.

Nausea and vomiting were noticed in patients suffered from hypotension in both groups and were managed with IV metoclopramide and treatment of hypotension

Table 2: Demographic data (mean ± SD).

	Bupivacaine group (n = 26)	Ropivacaine group (n = 26)	P-value
Height (cm)	162 ± 6	160 ± 10	0.386
Weight (kg)	74 ± 12	76 ± 9	0.499
Gender (M/F)	16/10	14/12	0.779
ASAII /ASAIII	18 \ 8	21 \ 5	0.523
Duration of surgery (min)	90 ± 10	89 ± 11	0.733

Table 3: Sensory and motor block profile.

	Bupivacaine group (n = 26)	Ropivacaine group (n = 26)	P-value
Time to maximal sensory level (min)	21.27 ± 9.37	26.5 ± 7.21	0.028
Median maximum block (dermatome) median (range)	T6 (T4-T7)	T8 (T6-T10)	0.031
Duration of T10 anesthesia (min)	93 ± 10.37	60 ± 10.92	<0.001
Total duration of sensory block	180 ±20	150 ±25	<0.001
Onset time to maximal motor block (min)	8.5 ± 1.2	12.8 ± 1.6	<0.001
Total duration of motor block (min)	160±10.92	130±13.61	<0.001
Data are presented as mean ±SD			

DISCUSSION

Ropivacaine is an amide local anesthetic that was initially prescribed for epidural anesthesia and peripheral nerve block not for intrathecal use. Trials for the use of ropivacaine in spinal anesthesia have proved its safety and efficacy [7]. Isobaric ropivacaine at body temperature will behave as slightly hypobaric which will make its analgesic spread variable and unpredictable reaching up to the level of higher thoracic segments [8]. That is why it should be used cautiously in spinal anesthesia especially in geriatric patients.

Many studies were done to decrease the dose of hyperbaric bupivacaine in spinal anesthesia in order to decrease the subsequent hemodynamic complications such as hypotension and bradycardia either by using unilateral spinal anesthesia [9] or by adding opioid such as sufentanil [10].

In this study, we have shown that intrathecal plain ropivacaine 15 mg produced spinal anesthesia in geriatric patients undergoing total knee replacement surgery with a slower onset and shorter duration of both sensory and motor blocks, lower maximum sensory block height and earlier time to first analgesic request compared to hyperbaric bupivacaine 12.5 mg allowing earlier patient ambulation and discharge. It also showed that ropivacaine caused less hemodynamic side effects

Table 4: Frequency of adverse complications in both group.

	Bupivacaine group (n = 26)	Ropivacaine group (n = 26)	P-value
Hypotension, *n* (%)	13 (50%)	4 (15.4)	0.018
Bradycardia, *n* (%)	9 (34.6)	2 (7.7)	0.042
Respiratory depression, *n* (%)	7 (26.9)	4 (15.4)	0.497

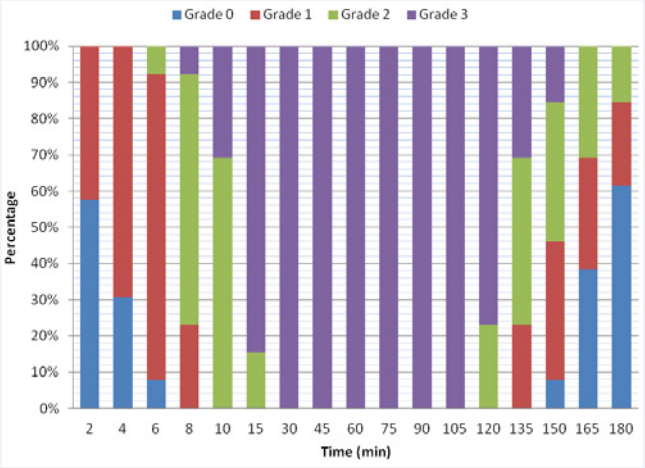

Figure 2 Motor block following intrathecal administration of isobaric ropivacaine assessed by Bromage scale.
X-axis represents time at which motor block grade was checked.
Y-axis represents the percentage of motor block garde (assessed by Bromage scale) at each time.

than bupivacaine which represents some advantage especially in the elderly patients aged 65 years or above undergoing major orthopedic surgery. With spinal anesthesia, sensory and sympathetic block are higher in the elderly patients than in the young adults which might be attributed to age-related degeneration in the central and peripheral nervous systems, anatomical changes in the lumbar and thoracic spinal cord and a reduction in the cerebrospinal fluid volume [11].

The less power of ropivacaine can be ascribed to the lesser lipid solubility which will allow this medication to enter the large myelinated nerve fibers more slowly than the highly lipid soluble bupivacaine [12]. Studies has determined the block intensity difference between ropivacaine and bupivacaine to be 20%–40% in epidural [13,14] and 50 % in spinal [8,15] Anesthesia favoring bupivacaine. At the same dosage, ropivacaine produces less motor blockade than bupivacaine on the grounds that it is less potent.

Lee Y. Ying et al., conducted a dose response study which had given a helpful manual for clinicians to pick ideal dosage of the spinal ropivacaine under various clinical circumstances. They found that the spinal ropivacaine ED50 and ED95 which covers 50 min or less in lower limb surgery were 7.6 mg and 11.4 mg respectively [16]. As TKA surgery requires a more prolonged time, we utilized a dosage of 15 mg to cover the duration of the surgery.

Mc Name DA. et al. [7], obtained spinal anesthesia using 17.5 mg plain bupivacaine and 17.5 mg plain ropivacaine in patients with an average age of 66–67 years who were scheduled for orthopedic surgery and they found that both drugs produced a high sensory block level reaching up to T2 in the bupivacaine group and T3 in the ropivacaine group resulting in serious hypotension which required treatment with ephedrine in 26% of patients in the bupivacaine group and 12% of patients in ropivacaine group. That is why we used lower doses of both agents in our study to avoid these complications which might be detrimental in such group of geriatric patients.

Many studies had compared bupivacaine and ropivacaine in spinal anesthesia at different concentrations and baricity either both solutions are isobaric or both are hyperbaric or same solution but at different concentrations. But only few studies compared hyperbaric and isobaric solutions of these two local anesthetics. Of these studies, only five studies compared intrathecal isobaric ropivacaine and hyperbaric bupivacaine and their results were different from each other.

Chari VRR, et al. [6], has compared 22.5 mg of isobaric spinal ropivacaine and 15 mg of hyperbaric spinal bupivacaine in patients scheduled for lower abdominal and lower limb surgeries of ASA score I-II and they concluded that intrathecal plain ropivacaine produced a longer sensory block and a shorter motor block with less hemodynamic affection than intrathecal hyperbaric bupivacaine.

D'Souza et al. [17], compared isobaric ropivacaine 22.5 mg, hyperbaric bupivacaine 15mg and isobaric levobupivacaine 15 mg in ASA grade I-II patients undergoing elective lower abdominal surgeries under spinal anesthesia and they concluded that the spinal block produced by hyperbaric bupivacaine was of earlier onset of significant sensory and motor block compared with isobaric levobupivacaine or isobaric ropivacaine which on the other hand also recovers earlier, but it was associated with a higher incidence of side effects.

Singh VP et al. [18], compared isobaric ropivacaine 24 mg and hyperbaric bupivacaine 12.5 mg in ASA grade I-II patients scheduled for elective cesarean delivery under spinal anesthesia and they concluded that isobaric ropivacaine provided clinically effective surgical anesthesia of shorter duration of both sensory and motor block without compromising neonatal outcome and with less hemodynamic affection.

Tadu Lal Chand, et al. [19], compared intrathecal isobaric ropivacaine 15 mg and hyperbaric bupivacine 10 mg in hundred parturient ASA grade I & II and undergoing elective caesarean section and found that sensory block and hemodynamic parameters were comparable in both groups but the motor block was of slower onset and significantly shorter duration in the isobaric ropivacaine group as compared with the hyperbaric bupivacaine group.

Rani C. Radhika, et al. [20], compared intrathecal 15 mg of isobaric ropivacaine and hyperbaric bupivacaine in sixty patients ASA grade I & II undergoing lower limb surgery with mean age of 39 years and they concluded that isobaric ropivacaine can be used for short duration orthopedic surgeries as it provided shorter duration of both sensory and motor blockade and with a lesser grade of motor blockade and was associated with less

intraoperative hemodynamic complications.

From the above mentioned five studies, we found that isobaric ropivacaine was usually associated with less hemodynamic complications and as all these studies were conducted on patients ASA grade I-II, that is why we sought to conduct our study on a different group of patients which is the geriatric group aged 65 years and above, ASA physical status II–III (that are considered high risk to develop spinal anesthesia complications) and undergoing major lower limb surgery. We used a similar dose of isobaric ropivacaine like the one used in the above two studies and our results were consistent with the results obtained by Rani, C. Radhika, et al. and we did not encounter any limitations for our study,

CONCLUSION

Isobaric ropivacaine 15 mg can be used to provide a reliable spinal anesthesia for geriatric patients undergoing total knee replacement surgery that is comparable to that of the commonly used hyperbaric bupivacaine 12.5 mg as regards the efficacy of the block with a shorter recovery profile and less hemodynamic derangement.

DECLARATIONS

Ethics and consent

The study protocol was approved by Al Mouwasat hospital review board, and all patients, or their legal representatives, provided written informed consent before enrollment. The trial was registered on Clinicaltrials.gov (NCT02764723).

Availability of data and materials

Data supporting this study are provided in full in the results section of this paper.

Trial registration

Clinical Trials.gov ID: NCT02764723, Registry URL: https://clinicaltrials.gov/show/NCT02764723

The study protocol was approved by Al Mouwasat hospital review board, Dammam, KSA, Tel: 00966138200000; Email: mohammed.sayed@mouwasat.com

AUTHORS' CONTRIBUTIONS

MA and HM contributed equally to the design of the study, data collection, interpretation and statistical analysis. The final manuscript was revised and approved by both authors.

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