ISSN 0973-2063 (online) 0973-8894 (print)

Bioinformation 22(8): 5325-5330 (2026)

BIOINFORMATION
Discovery at the interface of physical and biological sciences

BIOMEDICAL INFORMATICS

www.bioinformation.net

Volume 22(8)

Research Article

Received August 1, 2026; Revised August 31, 2026; Accepted August 31, 2026, Published August 31, 2026

DOI: 10.6026/973206300225325

SJIF 2026 (Scientific Journal Impact Factor for 2026) = 8.478
2022 Impact Factor (2023 Clarivate Inc. release) is 1.9

Edited by Vini Mehta
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Citation: Rahangdale *et al.* Bioinformation 22(8): 5325-5330 (2026)

Hyperbaric ropivacaine versus bupivacaine for spinal anesthesia in lower limb orthopedic surgery: A double-blind randomized controlled trial

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https://www.mgims.ac.in/

ISSN 0973-2063 (online) 0973-8894 (print)
Bioinformation 22(8): 5325-5330 (2026)

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Abstract:
Spinal anesthesia is commonly used for lower limb orthopedic surgery because it provides rapid onset, reliable sensory and motor blockade, reduced blood loss, and good postoperative analgesia. Hence, this randomized double-blinded controlled trial compared hyperbaric ropivacaine 18 mg with hyperbaric bupivacaine 18 mg in 80 ASA I and II adults undergoing elective lower limb orthopedic surgery under spinal anesthesia, with 40 patients in each group. Hyperbaric bupivacaine produced a faster onset and longer duration of sensory and motor blockade, whereas ropivacaine allowed earlier motor recovery and better intraoperative hemodynamic stability, with fewer episodes of hypotension and bradycardia. Both agents provided satisfactory surgical anesthesia with acceptable block quality. Thus, we show that hyperbaric ropivacaine is a useful alternative to bupivacaine when shorter motor blockade and greater cardiovascular stability are preferred.

Keywords: Hyperbaric ropivacaine, hyperbaric bupivacaine, spinal anesthesia, orthopedic surgery, sensory blockade, motor blockade, hemodynamic stability.

Background:
Spinal anesthesia is one of the most commonly used regional anesthetic techniques for orthopedic surgeries of the lower limb, as it offers profound sensory and motor blockade, excellent muscle relaxation, reduced peri-operative blood loss, lower incidence of thromboembolic complications and effective post-operative analgesia, especially in orthopedic surgeries of the lower limbs where rapid onset and reliable anaesthesia is required **[1]**. Spinal anesthesia has been shown to have a lower incidence of postoperative nausea and vomiting; a lower stress response and better postoperative recovery compared to general anesthesia, as well as reduced airway manipulation. Hyperbaric bupivacaine has been historically considered as the gold standard intrathecal local anesthetic due to its predictable spread in CSF and reliable anesthetic profile, which is particularly useful for lower limb surgeries. Despite these benefits, there are some drawbacks of bupivacaine, such as profound sympathetic blockade, significant hypotension, bradycardia, prolonged motor blockade, delayed ambulation, urinary retention and dose-dependent cardiotoxicity, which are of increasing importance in modern anesthetic practice where enhanced recovery protocols and early mobilization are emphasised **[2–4]**. It is a relatively new long-acting amino-amide local anaesthetic developed as a safer alternative to bupivacaine and is the pure S(-) enantiomer, which has a lower lipid solubility and hence less penetration into large, myelinated motor fibres and cardiac tissues. This selectivity for sensory blockade over motor blockade has led to significant interest in the use of ropivacaine for neuraxial anesthesia, especially in ambulatory and orthopedic procedures where early recovery of motor function is desired **[1]**. The distribution of isobaric solutions in CSF has been well studied and has been found to produce satisfactory sensory anesthesia with relatively brief motor blockade, but the distribution of isobaric solutions is variable and unpredictable. Hyperbaric ropivacaine containing dextrose has thus become a potential alternative to hyperbaric bupivacaine for spinal anesthesia **[2, 5]**. This is especially advantageous for orthopedic procedures, where postoperative physiotherapy and ambulation are a crucial part of the recovery process, as ropivacaine allows for quicker return to motor function. These properties are particularly advantageous in orthopedic surgery, where postoperative physiotherapy and ambulation are a crucial part of the recovery process **[6, 7]**. One of the major concerns during spinal anesthesia is hemodynamic stability. Furthermore, ropivacaine has been proposed to have a less intense sympathetic blockade than hyperbaric bupivacaine, which would maintain more stable intraoperative hemodynamics, and reduced cardiotoxic potential makes ropivacaine safer in cases of inadvertent systemic absorption or overdose **[8]**. Although there is increasing evidence in favour of ropivacaine, there is limited data on comparative efficacy with hyperbaric bupivacaine in lower limb orthopedic surgeries particularly in rural tertiary care centres in India. These agents should be further evaluated under standardized clinical conditions due to variations in drug dosage, baricity, patient population, and surgical procedure **[9]**. Therefore, it is of interest to compare the sensory and motor blockade characteristics, intraoperative hemodynamic stability and perioperative complications of hyperbaric ropivacaine 18 mg with hyperbaric bupivacaine 18 mg for spinal anesthesia in lower limb orthopedic surgeries.

Materials and Methods:
The present randomized double-blinded controlled trial was carried out in the Department of Anaesthesiology at a tertiary care teaching hospital and medical college with 770 beds in rural area of Maharashtra, India. It serves a variety of surgical disciplines such as General Surgery, Orthopedics, Obstetrics & Gynecology, ENT, Ophthalmology, Urology, Neurosurgery, Plastic Surgery and Laparoscopic Surgery. The department also provides anesthesia support to the trauma centres, intensive care units, casualty services, and radio-diagnosis and radiotherapy departments in addition to routine operation theatre services. After obtaining approval from the Institutional Ethics Committee; the study was conducted from 2014 to 2016. Written

informed consent was obtained from all participants in a language understandable to them. The confidentiality and anonymity of the participants were carefully observed throughout the study. No participant had any extra costs associated with the study drugs or investigations. The study was designed as a prospective randomized double-blinded controlled trial with 80 adult patients who were going to have elective orthopedic surgery on the lower limb under spinal anesthesia. Patients aged 18 years and above belonging to American Society of Anaesthesiologists (ASA) physical status I and II were screened during pre-anesthetic evaluation either in the pre-anesthesia clinic or bedside assessment.

Inclusion criteria:

Adult patients (age ≥18 years)

[1] ASA physical status I or II

[2] Male or female patients

[3] Patients with expected surgery duration of ≤ 2.5 hours in the lower limb orthopedic surgery area.

Patients who are willing to receive spinal anesthesia

Valid written informed consent from patients

Exclusion criteria:

Patients were excluded if they had:

[1] Not being able to agree to take part in the research study.

[2] Failure to consent to research study.

[3] Pregnancy, lactation or menstruation

[4] Coagulopathy, local infection, raised ICP, CNS disorders are contraindications to spinal anaesthetic.

[5] Uncontrolled seizure disorder or psychiatric illness

[6] Acute alcohol intoxication

[7] Severe cardiovascular instability such as unstable angina, recent myocardial infarction, bradycardia, hypotension, or complete heart block (without pacemaker)

[8] Any deformities of the spine's shape

[9] Any systemic disease that would be considered to increase anesthetic risk by the investigator.

Randomization and blinding:

Sealed opaque envelopes were used to randomise the 80 eligible patients into two equal groups. Group R was given hyperbaric ropivacaine 18 mg and Group B was given hyperbaric bupivacaine 18 mg. Randomization was done by an independent person who was not further involved in the study. Double blinding was achieved by having a different anesthesiologist prepare the study drugs and different anesthesiologists administer the spinal anesthesia and make the observations. The identity of the intrathecal drug was kept unknown during the data collection.

Preparation of study drugs:

Hyperbaric ropivacaine was prepared by adding 1 ml of 25% dextrose to 4 ml of preservative-free 0.75% ropivacaine under sterile conditions, to obtain a final concentration of 6 mg/ml with a glucose concentration sufficient to achieve hyperbaricity for Group R. This preparation was given intrathecally in the dose of 18 mg in 3 mL. Commercially available 0.5% hyperbaric bupivacaine (18 mg drug/mL) was used in Group B. Intravenous access was obtained on arrival in the operating room and standard ASA monitoring was instituted which included electrocardiography, pulse oximetry, non-invasive blood pressure monitoring, skin temperature monitoring, and end-tidal carbon dioxide monitoring. Intravenous ondansetron 4 mg and ranitidine 50 mg were given as premedication to all patients. During spinal anesthesia, crystalloid co-loading was given at about 20 ml/kg. Subarachnoid block was done under strict aseptic precautions using a 25G Quincke-Babcock spinal needle at the lumbar intervertebral level in sitting position. After confirmation of free flow of cerebrospinal fluid, the study drug was injected intrathecally. Patients who had inadequate block, breakthrough pain (requiring supplemental analgesia), insertion of supraglottic airway, or conversion to general anesthesia were not included in the analysis. The study variables were demographic, surgical, hemodynamic, sensory-motor blockade, quality of anesthesia and perioperative complication parameters. Demographic data collected for all subjects consisted of age, sex, body mass index (BMI) and American Society of Anaesthesiologists (ASA) physical status. Surgical parameters included the type of lower limb orthopedic surgery performed and the length of surgery. Hemodynamic parameters measured in the peri-operative period were heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP). The following parameters were measured at baseline before the induction of spinal anesthesia and then at regular intervals during surgery. Pinprick method was used to assess sensory blockade. The onset of sensory block at the T10 dermatome level, maximum cephalad spread of sensory block, and duration of sensory blockade were recorded. Motor blockade was assessed by Modified Bromage Scale: Grade I free movement of legs and feet, Grade II flex knees and free movement of feet, Grade III inability to flex knees and preserved foot movement, Grade IV complete inability to move legs and feet. The time of onset, intensity and duration of motor blockade was noted in each patient.

Anesthetic quality was assessed independently by the anaesthesiologist, surgeon and patient and was graded as excellent, satisfactory or unsatisfactory, depending on the adequacy of the intraoperative anesthesia and patient comfort. The intra-operative complications, including hypotension, bradycardia, nausea and vomiting, shivering, hypoxia and high spinal anesthesia were closely monitored and documented. Headache, backache, neck rigidity and other neurological symptoms were observed and recorded until the patient was discharged from the hospital or up to the seventh day after the operation, whichever came first.

Statistical analysis:

Data were entered into Microsoft Excel spreadsheet and analyzed by STATA version 12 (Stata Corporation, Texas, and USA). Data for continuous variables were presented as mean ± SD and analyzed by the Student's t-test. Chi-square test or

Fisher's exact test was used for categorical variables. A p-value <0.05 was considered statistically significant.

Results:

The present randomized double-blinded controlled trial was conducted to compare the efficacy and safety profile of hyperbaric ropivacaine (18 mg) and hyperbaric bupivacaine (18 mg) for spinal anesthesia in lower limb orthopedic surgeries. A total of 80 patients belonging to ASA physical status I and II were included in the study and randomly allocated into two equal groups comprising 40 patients each. Group B received intrathecal hyperbaric bupivacaine 18 mg, while Group R received intrathecal hyperbaric ropivacaine 18 mg. various demographic, hemodynamic, sensory-motor blockade, and complication-related parameters were assessed and statistically analyzed. Among the total 80 patients, 50% belonged to Group B and 50% belonged to Group R. The mean age in Group B was 42.93 ± 17.78 years whereas in Group R it was 42.70 ± 17.40 years. The difference between the groups was statistically insignificant (p=0.954), indicating comparability with respect to age distribution. Male predominance was observed in both groups. In Group B, 87.5% patients were male and 12.5% were female, while in Group R, 82.5% were male and 17.5% were female. The sex distribution between groups was statistically insignificant (p=0.531). Mean BMI values were comparable between Group B (22.41 ± 2.77 kg/m²) and Group R (21.86 ± 2.14 kg/m²) with p=0.323. ASA physical status grading also showed no significant difference, as 80% patients in Group B and 82.5% patients in Group R belonged to ASA grade I (p=0.774). Hence, both groups were demographically comparable and suitable for further comparison **(Table 1).** Hemodynamic stability was assessed using heart rate and mean arterial pressure measurements recorded at regular intervals following spinal anesthesia. Baseline heart rate and MAP values were statistically comparable in both groups (p>0.05). Up to 11 minutes after spinal anesthesia, there was no statistically significant difference between the two groups in terms of heart rate or MAP. However, after 17 minutes, significant differences were observed. Group B demonstrated a greater fall in heart rate and MAP compared to Group R. At 20 minutes after spinal anesthesia, the mean heart rate reduction was significantly greater in Group B compared to Group R (p=0.02). Similar statistically significant differences persisted at 23, 26, and 29 minutes. Mean arterial pressure also showed significantly greater reductions in Group B after 14 minutes post spinal anesthesia, with highly significant p values at later intervals (p<0.001 at 23–29 minutes). The lowest systolic blood pressure recorded within the first 30 minutes was significantly lower in Group B (107.4 ± 6.71 mmHg) compared to Group R (114.7 ± 12.2 mmHg), with p=0.002. Similarly, the lowest MAP values were significantly lower in Group B (79.43 ± 5.76 mmHg) than Group R (83.5 ± 9 mmHg), with p=0.018. Percentage reduction from baseline MAP was 20.19% in Group B and 15.25% in Group R, suggesting comparatively better hemodynamic stability with ropivacaine. Nevertheless, the hemodynamic changes in both groups remained within clinically acceptable limits. Requirement of rescue medications for hypotension and bradycardia was also assessed. Me phentermine was required in 10% of patients in Group B and 5% in Group R. Atropine administration was required in 5% patients of Group B and none in Group R. These differences were statistically insignificant (p>0.05) **(Table 2).** Sensory blockade characteristics revealed that hyperbaric bupivacaine produced a significantly faster onset of sensory block compared to hyperbaric ropivacaine. Mean time for sensory loss to pinprick at T10 dermatome was 4.98 ± 1.3 minutes in Group B compared to 9.94 ± 1.19 minutes in Group R (p<0.001). Similarly, motor blockade onset was significantly faster with bupivacaine. Time required to achieve Bromage grade II, III, and IV motor blockade was significantly shorter in Group B than Group R (p<0.05 for all comparisons). However, duration of both sensory and motor blockade was significantly prolonged in Group B. Sensory regression to two segments and regression to T12 dermatome occurred earlier in Group R compared to Group B. Recovery to Bromage grade I was significantly faster in Group R (182 ± 13.5 minutes) than Group B (203 ± 14.18 minutes), indicating earlier motor recovery with ropivacaine. These findings demonstrate that while bupivacaine produces a more rapid and prolonged block, ropivacaine provides shorter motor blockade and earlier recovery **(Table 3).** Quality of anesthesia was assessed independently by anesthesiologists, surgeons, and patients. Both groups received excellent ratings with score 2 for block effect, muscle relaxation, and patient satisfaction, indicating satisfactory intraoperative anesthesia in all patients. Regarding complications, one patient (2.5%) in Group B developed high spinal anesthesia while none were observed in Group R. Shivering occurred in 10% patients in Group B and 7.5% patients in Group R. Lumbar backache was observed in 15% patients in Group B and 12.5% patients in Group R. These differences were statistically insignificant (p>0.05). No patients in either group experienced nausea, vomiting, hypoxia, postural headache, neck rigidity, requirement of sedation, supraglottic airway insertion, or conversion to general anesthesia **(Table 4).**

Table 1: Distribution and Demographic Profile of Patients

Variables	Group B (n=40)	Group R (n=40)	p value
Mean Age (years)	42.93 ± 17.78	42.70 ± 17.40	0.954
Male : Female	35:5	33:7	0.531
BMI (kg/m²)	22.41 ± 2.77	21.86 ± 2.14	0.323
ASA I/II	32/8	33/7	0.774

Table 2: Comparison of Hemodynamic Parameters

Time Interval	Heart Rate p value	MAP p value
Baseline	0.58	0.598
1–11 min after SAB	>0.05	>0.05
14 min after SAB	0.96	0.002
17 min after SAB	0.40	0.03
20 min after SAB	0.02	0.04
23 min after SAB	0.003	0.000
26 min after SAB	0.005	0.000
29 min after SAB	0.002	0.000

Table 3: Comparison of Sensory and Motor Block Characteristics

Variables	Group B	Group R	p value
Sensory loss at T10 (min)	4.98 ± 1.3	9.94 ± 1.19	0.000
Two-segment regression (min)	121.4 ± 12.75	111.25 ± 13	0.001
Regression to T12 (min)	130.13 ± 13.6	116.25 ± 14.3	0.000
Bromage II onset (min)	1.84 ± 0.7	2.36 ± 0.74	0.002
Bromage III onset (min)	3.28 ± 1	4.7 ± 1.64	0.000
Bromage IV onset (min)	10 ± 1	12 ± 1.1	0.000
Recovery to Bromage I (min)	203 ± 14.18	182 ± 13.5	0.000

Table 4: Quality of Anesthesia and Complications

Variables	Group B	Group R	p value
Excellent anesthesia rating	100%	100%	–
High spinal	2.5%	0%	>0.99
Shivering	10%	7.5%	>0.99
Lumbar backache	15%	12.5%	0.75
Nausea/Vomiting	0%	0%	–
Hypoxia	0%	0%	–
Conversion to GA	0%	0%	–

Discussion:

Spinal anaesthesia is one of the most effective anaesthetic methods for lower limb orthopaedic surgery, due to its simplicity, speed of onset, complete neural blockade and low morbidity after surgery. The search for an ideal intrathecal local anesthetic has continued over the years, focusing on agents capable of providing effective surgical anesthesia with stable hemodynamic and faster postoperative recovery **[2].** In the present study, hyperbaric ropivacaine 18 mg was compared with hyperbaric bupivacaine 18 mg to evaluate sensory and motor blockade characteristics, hemodynamic changes, and complications. There were no significant differences in demographic variables between both groups in the present study ($p>0.05$) such as age, sex distribution, BMI and ASA physical status. Similar demographic comparability has been reported by Bhat *et al.* **[3]** and Chatterjee *et al.* **[4]** indicating that the randomization was successful, and that the demographic factors did not have any impact on the study results. Hyperbaric bupivacaine resulted in a significantly shorter onset of sensory blockade at T10 than hyperbaric ropivacaine (4.98 ± 1.3 min vs 9.94 ± 1.19 min, $p<0.001$) in the present study. Similar findings were reported by Anand *et al.* **[5]** who showed that ropivacaine had delayed onset of action as compared to bupivacaine due to its lesser lipid solubility and potency. The same was seen by Mahajan *et al.* **[6]** and Uppal *et al.* **[7]** as well. The present study showed a significant delay in onset of motor blockade in the ropivacaine group. The time for Bromage grade IV motor block was 12 ± 1.1 min with ropivacaine and 10 ± 1 min with bupivacaine ($p<0.001$). The differential blockade activity of ropivacaine, which has been demonstrated to have more sensory selectivity and less profound motor blockade in comparison to other local anesthetics, is responsible for this delayed and less dense motor blockade seen in our study. The bupivacaine group had significantly longer durations of sensory and motor blockade. Ropivacaine had a more rapid regression to T12 and recovery to Bromage grade I. The results are clinically significant, as early motor recovery allows early mobilization, decreases the complications related to postoperative immobilization, and increases patient turnover. So Rout *et al.* **[10]** and Dar *et al.* **[11]** reported similar findings, stating that ropivacaine has a shorter duration of motor blockade and faster ambulation than bupivacaine. One of the most important factors for safety with spinal anesthesia is hemodynamic stability **[12]**. In this study, the heart rate and MAP decreases were significant in Group B after 17 minutes after spinal anesthesia, which is due to sympathetic blockade caused by intrathecal local anesthetics. The percentage decrease of MAP was 20.19% in the bupivacaine group and 15.25% in the ropivacaine group. Both values were clinically acceptable, but ropivacaine had comparatively greater hemodynamic stability. The results are similar to those of the studies conducted by Khalil, Rashaad *et al.* **[13]** and Singh *et al.* **[14]** which reported hypotension and bradycardia to be reduced with ropivacaine. This is because ropivacaine's reduced sympathetic blockade may be responsible for its cardiovascular stability. Furthermore, ropivacaine is a pure S-enantiomer with reduced affinity for cardiac sodium channels and thus has a lower cardiotoxic potential than lidocaine **[15].** There was a slight increase in the requirement for vasopressor support in the bupivacaine group, but this was not statistically significant. Likewise, atropine was needed only in the bupivacaine group (10% of patients in Group B vs. 5% in Group R). Similar results were reported by Hashemian *et al.* **[16].** The quality of anesthesia was excellent in both groups. None of the patients needed general anesthesia or additional airway assistance. These results suggest that both drugs are effective for surgical anesthesia of the lower limb for orthopedic surgery. The same was reported by Ingale *et al.* **[17]**. In the present study, there were few complications, and no differences in complication rates between the groups. High spinal anesthesia occurred in one patient in the bupivacaine group but in none of the patients in

the ropivacaine group. There was no difference in incidence of shivering and lumbar backache. No serious neurological complications, hypoxia, nausea, vomiting or post-dural puncture headache was observed. Intrathecal ropivacaine has also been shown to have low complication rates by previous investigators such as Barbosa *et al.* **[18]** and Prajwal *et al.* **[19].** Based on the results of the present study, hyperbaric ropivacaine is a safe and effective alternative to hyperbaric bupivacaine for spinal anesthesia, as evidenced by the increasing number of studies confirming this. While bupivacaine has a more rapid onset and longer duration of anesthesia, ropivacaine has been shown to have a more favorable hemodynamic stability, motor blockade duration, and recovery time, especially in the context of modern orthopedic anesthesia practice that focuses on enhanced recovery protocols **[20].**

Conclusion:

Both hyperbaric ropivacaine and hyperbaric bupivacaine provided effective spinal anesthesia for lower limb orthopedic surgeries with satisfactory surgical conditions and minimal complications. Hyperbaric bupivacaine had a faster onset and more prolonged sensory-motor blockade, while hyperbaric ropivacaine had a superior hemodynamic stability and earlier motor recovery. Hence, hyperbaric ropivacaine 18 mg is a safe and effective alternative to hyperbaric bupivacaine particularly in patients where cardiovascular stability and early postoperative mobilization is desirable.

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