Original Article



# Comparison of Hyperbaric Levobupivacaine with Hyperbaric Bupivacaine in Unilateral Inguinal Hernia Operations Performed Under Spinal Anesthesia

Orhan Gozaydin<sup>1</sup>, Guven Gulen<sup>2</sup>, Guneri Atalan<sup>2</sup>, Mehmet Kaydul<sup>3</sup>

#### Abstract

**Aim:** The aim of this study was to compare hyperbaric bupivacaine used for spinal anesthesia in the patients with inguinal hernia with the same amount of hyperbaric levobupivacaine.

**Materials and methods:** Forty ASAI-II patients, with a unilateral inguinal hernia operation planned under spinal anesthesia by the surgeon, were included in the study. It was planned that the study be prospective and double-blind. The patients were allocated into two groups, each of which had 20 persons allocated randomly. Hyperbaric levobupivacaine and hyperbaric bupivacaine at 3 ml of 0.5% were given into the intrathecal space for groups HL and HD. Perioperative and postoperative blood pressure, peripheral oxygen saturation, and sensorial and motoric block levels of groups were measured. Visual analog scale (VAS) values, side effects and complications were recorded.

**Results:** There were no statistical differences between the groups for age, body weight, body mass index, ASA distributions, and operation period. Peripheral oxygen saturation values during intraoperative 10, 15, 20, 25 and 30 min, and postoperative 30 min, 1, 1.5 and 3 hours were significantly decreased in group HB compared to group HL. The starting of sense block and full motor block time in group HB was found to be significantly short compared to group HB. One patient had hypotension in group HB, and one had intraoperative nausea in group HL. Postoperative urinary retention occurred in two patients in group HB and in one patient in group HL.

**Conclusions:** Hyperbaric levobupivacaine was found to have similar effects to hyperbaric bupivakain for anesthetic effects, hemodynamic parameters, postoperative analgesic necessity time, and the first 24-hour side effects and complications. Levobupivacaine, having a lesser cardiovascular and central nervous system, was suggested as an alternative to bupivacaine.

Key words: Hyperbaric, levobupivacaine, bupivacaine

## Introduction

Inguinal hernia operation is one of the most common surgical procedures made under regional, general and local anesthesia. According to international epidemiologic data and widespread local studies, general anesthesia, central neural block and local infiltration anesthesia have been used in 60-70%, 10-20% and 5-15% for inguinal hernia operations, respectively [1]. The popularities of spinal anesthesia have increased in inguinal hernia operations. Consciousness is always available in spinal anesthesia; this provides cooperation with Department of Anesthesiology and Reanimation <sup>1</sup> Doruk Yıldırım Hospital Bursa, Turkey <sup>2</sup> Medical Park Hospital Elazığ, Turkey <sup>3</sup> Şevket Yılmaz Training and Research Hospital Bursa, Turkey

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Corresponding author: Guneri Atalan, MD Department of Anesthesiology and Reanimation Medikal Park Hospital Elazığ, Turkey guneriatalan@gmail.com the patient and prevents possible complications in the early stage. Moreover, protecting of airway reflex, minimum drug usage, instant effect of drug, and effective sensorial and motor blockage are considered to be the other advantages. However, post-spinal headache, some other undesirable hemodynamic alterations and urinary retention have been reported as complications [2,3].

Selecting of the local anesthetic agents depends on many factors. Preferable anesthetic agents should provide an effective anesthesia and analgesia during operation. Moreover, this effect should proceed postoperatively, with side effects on the central and cardiovascular system being minimal [4].

Bupivacaine, a subgroup of the amino acid compound, is a long-lasting, effective local anesthetic agent used in the peripheral nerve block, epidural and spinal anesthesia. Cardiovascular side effects of bupivacaine may occur because of slowly leaving from sodium canals. Therefore, local anesthetic agents similar to bupivacaine (but which have minimal effects on the cardiovascular system) are required.

Previous clinical studies have indicated that levobupivacaine has a similar pharmacokinetic characteristic to bupivacaine but with less cardiotoxic and neurotoxic effect [5,6]. When the drug dosage and patient position are provided and stable, the most important factor determining the spinal block level is the baricity of local anesthetic. Baricity depends on the rate between specific gravity of local anesthetic and BOS. Hyperbaric solutions are generally preferred because they provide sufficient block, do not exceed high block levels, and have less side effects [7].

The aim of this study was to make levobupivacaine into a hyperbaric form and to compare with the same amount and level of hyperbaric solution for anesthetic effect, hemodynamic parameters, complications, and side effects.

## **Materials and Methods**

The study was carried out in the Anesthesiology and Reanimation Department in Dışkapı Yıldırım Beyazıt Research and Education Clinic after ethical approval. The study was planned to be double-blind and randomized. Forty ASA I-II patients aged between 20 and 60 years were included in the study. the anesthesia method and visual analog scale (VAS), and patient approval was obtained. Patients with ASA III and over, neuromuscular or neuropsychiatric disease, alcohol or drug addiction, hypersensitivity to local anesthetic agent, back ache, scoliosis or having a history of back surgery, infection on the injection side, clotting and hemorrhagic disorders, shorter than 150 cm or longer than 180 cm, and weighing less than 45 kg or more than 100 kg were excluded from the study. The patients were allocated randomly to one of the groups. Each patient was premeditated with 0.07 mg/ kg of midazolam 30 min before the operation. Standard monitoring was provided by electrocardiogram, pulse oximeter and non-invasive blood pressure. Crystalloid solution was administered intravenously before spinal anesthesia at 15 ml/kg/hour and after spinal anesthesia at 6-8 ml/kg. Each patient was positioned on the sitting position. The puncture side was sterilized by 10% povidone iodine, and covered by sterile porous compress. A 23-gauge Quincke-type needle was inserted into the intrathecal space. Following the BOS flowing, 3 ml of 0.5% hyperbaric levobupivacaine and 3 ml of hyperbaric bupivacaine were given for groups HL and HB. The drug was injected by a stable rate of 0.3 ml/ sec while the needle tip clarity was cephalic. The anesthetic drugs were prepared by the other doctors in sterile conditions; therefore, the doctors made the application and were not aware of the type of drug injected. 2 ml (15 mg, 7.5 mg/ml) of levobupivacaine was diluted by 0.8 ml of dextrose (30%) and 0.2 ml of sodium chloride, and then 3 ml of mixture obtained. All drugs and medication were prepared for each patient separately and used only one time. The patients were positioned in the supine position following the injection. Pulse, blood pressure, oxygen saturation, VAS (Visual Analog Score) values, and possible side effects (hypotension, bradycardia, nausea, vomiting) were evaluated in 5-minute intervals prior to, during and after the application. Evaluations of sensitive block and motor block levels were made by a bilateral pin-prick test in the middle clavicular region and a modified Bromage scale respectively (Table 1) after injection of local anesthesia every 2 minutes. Sensitive block starting time, maximum motor block time, maximum sensational

All patients were informed preoperatively about

block level, the time of decline of the motor block to sub-level, and the time of two segments of sensational block regression were recorded. Initiating of sensational block, the time of sensational loss at T10 dermatome, two segments of sensational regression time, and the time of two segments of regression, in which the sensational block reached the maximum dermatome, were recorded. Surgery was started when sensational block reached the T10 level. For the evaluation of VAS, the patient was requested to mark their pain on a 10cm line, pointing 0 at the tip and 10 at the end.

## 0---1--2---3---4---5---6---7---8---9---10 0= No pain 10= Severe pain

50 µgr of fentanyl was injected for the patients with intraoperative VAS  $\geq$  4, and the same amount of drug dosage was repeated if no satisfactory analgesia was obtained. Moreover, the patients were excluded from the study when no satisfactory results and appropriate sensational block were monitored.

Each patient was visited postoperatively at 30 min, 1, 1.5, 2, 3, 6, 12, and 24 hours, and their blood pressure, pulse, oxygen saturation, sensorial block level, VAS values of motor block level, complaints (nausea, vomiting, itching, hypotension, bradycardia, respiratory depression, headache, urinary retention), the time of first analgesia, and micturition were recorded. 75 mg of diclophenac sodium was IM-injected when the postoperative VAS values were  $\geq$ 4.

Hypotension level was accepted as a bradycardic level and a 30% (or over) declining of mean arterial blood pressure. 300–400 cc of crystalloid fluid was given rapidly in the case of hypotension, and 5 mg of IV ephedrine injected when no positive response was seen. 0.5 mg of atropine IV injection was made when bradycardia occurred. Desaturation level was accepted as SpO2 at 95%, with 2 L/min of oxygen being given to patients under the saturation level.

## **Statistical Analyses**

Analyses of data were made using the SPSS for Windows 11.5 packet program. The Shapiro Wilk test was used to check normal distribution of data. Mean and median statistical differences between the groups were examined by the Student's t test and Mann-Whitney U test respectively. Nominal changes were evaluated by Pearson's Chi-square test or Fisher's probability test. Statistical significance was accepted when p<0.05. Bonferroni correction was applied to control Tip-I errors in the comparison between the groups for hemodynamic measurements.

## Results

Forty ASAI-II patients (Group HB, n: 20 and Group HL, n=20), having unilateral hernia operation under spinal anesthesia and aged between 20 and 60 years, were included in the study. There was no statistical significance between groups HB and HL for age, length, body weight, BMI, ASA, and operation times

Table 1. Bromage scale.			
0	No paralysis, the patient can bring his knee and foot flexion completely		
1	The patient can move his knee and foot but cannot lift his leg		
2	No flexion of his knee, but can only move his foot		
3 Cannot move foot joint or thump, a sign of complete paralysis			

## Table 2. Demographic data.

Variations	Group HB (n=20)	Group HL (n=20)	Р
Age (Years)	48.7±11.2	45.2±10.6	0.317ª
Length (cm)	170.6±5.0	167.4±6.9	0.114ª
Body weight (kg)	72.7±9.5	72.7±12.9	0.989ª
$BMI (kg/m^2)$	25.0±3.1	25.8±3.5	0.431ª
ASA 1 / 2	16 / 4	13 / 7	$0.288^{b}$
Operation time (min)	56.1±18.6	53.2±17.3	0.583ª
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<sup>a</sup> Student's t test.

<sup>b</sup> Pearson's chi-square test.

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Time	Group HB (n=20)	Group HL (n=20)	P <sup>a</sup>
Before Spinal	105.4±17.5	100.5±9.9	0.285
During Spinal	104.5±15.5	95.0±8.5	0.023
Intraoperative 5 min.	98.7±14.3	94.7±9.4	0.302
Intraop. 10 min.	98.9±13.1	96.3±10.3	0.480
Intraop. 15 min.	95.4±11.1	93.5±11.0	0.591
Intraop. 20 min.	94.5±10.1	94.7±12.2	0.955
Intraop. 25 min.	94.5±10.1	93.7±9.7	0.800
Intraop. 30 min.	93.4±13.7	92.6±11.4	0.842
Intraop. 40 min.	94.8±10.3	88.8±8.5	0.049
Intraop. 50 min.	94.7±11.0	91.7±8.5	0.340
Intraop. 60 min.	96.8±10.9	92.0±8.5	0.130

<sup>a</sup> Student's t test (results for p<0.003 were significant according to Bonferroni correction).

**Table 4.** Distributions of heart beat levels between the groups.

Time	Group HB (n=20)	Group HL (n=20)	P <sup>a</sup>
Before Spinal	76.7±9.5	77.5±11.4	0.811
During Spinal	79.2±10.2	79.4±7.3	0.958
Intraoperative 5 min.	78.6±10.0	78.2±7.7	0.902
Intraop. 10 min.	74.9±10.0	77.8±9.6	0.348
Intraop. 15 min.	74.0±9.9	76.7±10.4	0.414
Intraop. 20 min.	71.5±10.8	73.8±10.9	0.506
Intraop. 25 min.	69.1±10.4	73.4±10.5	0.207
Intraop. 30 min.	67.9±9.6	73.0±8.4	0.081
Intraop. 40 min.	68.3±7.9	73.0±9.1	0.093
Intraop. 50 min.	69.6±10.8	73.1±8.3	0.256
Intraop. 60 min.	69.1±10.3	72.7±7.8	0.219

<sup>a</sup> Student's t test (results for p<0.003 were significant according to Bonferroni correction).

<b>Table 5.</b> Distribution of saturation	level according	g to intraoperative time
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Time	Group HB (n=20)	Group HL (n=20)	P <sup>a</sup>
Before Spinal	97.6±0.8	98.2±0.8	0.022
During Spinal	97.5±0.8	98.2±0.8	0.005
Intraoperative 5 min.	97.3±0.8	98.1±0.9	0.004
Intraop. 10 min.	97.3±0.7	98.2±0.9	<0.001
Intraop. 15 min.	97.3±0.8	98.4±1.1	0.002
Intraop. 20 min.	97.2±0.7	98.3±1.2	<0.001
Intraop. 25 min.	97.3±0.6	98.2±1.1	<0.001
Intraop. 30 min.	97.2±0.9	98.2±1.0	0.002
Intraop. 40 min.	97.4±0.9	98.1±0.9	0.015
Intraop. 50 min.	97.5±0.8	97.9±0.8	0.086
Intraop. 60 min.	97.7±0.7	98.3±0.8	0.018

 $^{\rm a}$  Student's t test (results for p<0.003 were significant according to Bonferroni correction).

Time	Group HB (n=20)	Group HL (n=20)	P ª
Postop. 0.5 hours	86.7±8.0	94.1±8.9	0.009
Postop. 1 hour	87.9±7.6	95.9±10.6	0.009
Postop. 1.5 hours	86.5±8.6	92.7±10.3	0.046
Postop. 2 hours	88.2±5.3	88.5±8.7	0.896
Postop. 3 hours	87.5±6.0	91.4±11.3	0.183
Postop. 6 hours	87.8±6.7	92.3±7.2	0.049
Postop. 12 hours	86.9±7.7	92.3±12.6	0.111
Postop. 24 hours	88.1±5.7	94.3±7.6	0.006

Table 6. Distribution of mean arterial pressure levels between the groups.

<sup>a</sup> Student's t test (results for p<0.003 were significant according to Bonferroni correction).

Table 7. Distributions of heart beat rate according to postoperative time between the groups.

Time	Group HB (n=20)	Group HL (n=20)	P <sup>a</sup>
Postop. 0.5 hours	69.8±7.9	72.8±4.9	0.156
Postop. 1 hour	71.4±7.5	73.6±4.2	0.250
Postop. 1.5 hours	71.7±7.2	73.7±4.1	0.279
Postop. 2 hours	72.0±7.2	73.5±5.1	0.451
Postop. 3 hours	72.7±6.4	74.0±4.6	0.449
Postop. 6 hours	73.2±6.7	72.8±4.7	0.829
Postop. 12 hours	73.2±6.6	73.0±4.7	0.934
Postop. 24 hours	73.4±6.5	73.6±4.0	0.907

<sup>a</sup> Student's t test (results for p<0.003 were significant according to Bonferroni correction).

Table 8. Distribution of saturation level according to postoperative time between the groups.

Time	Group HB (n=20)	Group HL (n=20)	P <sup>a</sup>
Postop. 0.5 hours	97.0±0.7	98.0±0.7	<0.001
Postop. 1 hour	96.9±0.8	98.0±0.7	< 0.001
Postop. 1.5 hours	97.0±0.7	97.9±0.6	< 0.001
Postop. 2 hours	97.1±0.9	97.8±0.8	0.011
Postop. 3 hours	96.8±1.1	98.1±0.9	< 0.001
Postop. 6 hours	97.1±1.0	98.0±1.1	0.010
Postop. 12 hours	97.2±1.0	97.8±0.8	0.041
Postop. 24 hours	97.2±0.7	97.6±0.8	0.065

<sup>a</sup> Student's t test (results for p<0.003 were significant according to Bonferroni correction).

(Table 2). Moreover, no significant differences in the initial and intraoperative intervals were obtained for the mean arterial pressure and heart rate (Tables 3, 4).

Intraoperative peripheral oxygen saturation values at 10, 15, 20, 25, and 30 min for group HB were found to be statistically significant compared to Group HL (p<0,001, p=0,002). However, no differences were obtained for the time intervals for the two groups (Table

5). No significant differences for postoperative mean arterial pressure and heart beats for the groups were recorded (Tables 6 and 7). Postoperative oxygen saturation values at 1, 1.5 and 3 hours were significantly lower in group HB than group HL (p<0.001), but no significant differences were found for the other time intervals (Table 8). For groups HB and HL, there were no statistical differences for patients requesting analgesic drug

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Fable 9. Distribution of postoperative extra analgesic requireme	nt, urination and sensational block time between groups
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Variations	Group HB (n=20)	Group HL (n=20)	Р
Post-op extra analgesic requirement	16 (80.0%)	15 (75.0%)	1.000ª
First analgesic time (min)	157 (90-618)	188 (101-294)	0.379 <sup>b</sup>
Urination time (min)	351 (146-442)	322 (246-416)	0.217 <sup>b</sup>
Sensational block starting time (min)	8 (6-16)	11 (6-16)	0.023 <sup>b</sup>
Sensational block regression time (min)	68.5 (50-127)	72 (48-88)	0.883 <sup>b</sup>
Motor block starting time (min)	4 (2-8)	5 (2-8)	0.079 <sup>b</sup>
Complete motor block time (min)	10 (6-18)	12 (8-18)	0.013 <sup>b</sup>
Motor block regression time (min)	92 (56-249)	92.5 (60-152)	0.792 <sup>b</sup>
Motor block disappearing time (min)	181 (120-332)	171.5 (102-218)	0.380 <sup>b</sup>
Sensational block disappearing time (min)	244 (86-367)	227 (186-270)	0.327 <sup>b</sup>
Maximum sense block level	T7 (T10-T4)	T8 (T10-T5)	0.253 <sup>b</sup>

<sup>a</sup>Fisher's probability test, <sup>b</sup> Mann-Whitney U test.



Figure 1. Distribution of maximum sensorial block levels between groups.

supplements, first analgesic injection time, micturition time, sensational loss and regression, motor block starting, regression and disappearing time, and maximum sensational block. Sensational block starting time and complete motor block time were statistically shorter in group HB compared to group HL (p=0,023, p=0,013) (Table 9).

Maximum sensational block levels for the two groups were indicated in Figure 1.

No statistical significance was found for the intraoperative and postoperative side effects and complications in the two groups. One patient had hypotension in group HB and was treated with hydration and ephedrine application. Only one patient in group HL had intraoperative short-time nausea but requested no treatment. Two patients in group HB and one in group HL had urinary catheter application because of urinary retention.

## Discussion

Spinal anesthesia is a reliable anesthesia technique for lower abdominal, extremity surgery [4,8-14]. 15 mg of isobaric bupivacaine, 15 mg of isobaric levobupivacaine, and 15 mg of isobaric ropivacaine were compared in the patient undergoing lower abdominal surgery by Mantouvalou et al. OAB and KTA in all groups decreased slightly compared to basal values. However, decreasing in OAB value was higher than the other groups. Hypotension requesting treatment with ephedrine and bradycardia was observed mostly in the bupivacaine group. Complete motor block time was shortest in the bupivacaine group. Loss of sensational and motor block time and accessing time of sensational block to T8 were similar for all groups [9].

In our study, intraoperative OAB decreased slightly in the 40 minutes compared to the initial value, but this was not significant for intraoperative and postoperative OAB in both groups. Mean arterial pressure before spinal application in the group HB patient was 96 mm, but this decreased to 58 mmHg at 30 min after spinal application. An amount of 300-400 ml of fluid was administered rapidly to correct decreased arterial pressure, but no improvement was obtained; therefore, 0.5 mg of IV ephedrine given caused the normal level of arterial pressure. No significant differences were found for intraoperative and postoperative heart rate for both groups. Peripheral oxygen saturation intraoperatively from 10 to 30 min and postoperatively from 30 min to 3rd hour was lower statistically in the bupivacaine group than the other group. Oxygen saturation did not decrease under 95%, and no oxygen supplementation was required.

The most important factors affecting spinal block level are baricity, drug dosage and patient position during and following drug injection. In general, when the drug dosage and patient position are stable, the most important factor determining the spinal block level is the baricity of local anesthetic [7].

Snansilp et al. compared the same dose of hyperbaric and isobaric levobupivacaine for the patients undergoing gynecological operation under spinal anesthesia. Sensational block was provided in a short time at the level T10; moreover, a higher sensational block level was obtained at 5 and 10 minutes. Sensational block was obtained for the isobaric group at a wide space like the C8-L1 interval and for the hyperbaric group between T2-T7 intervals. According to that study, hyperbaric levobupivacaine provided preferable sensational block [11].

In addition, Şen et al. compared 13.5 mg of hyperbaric levobupivacaine and 13.5 mg of isobaric levobupivacaine in the patients undergoing urological surgery under spinal anesthesia. Initial analgesic duration and side effects were similar for both groups, but sensational block time at T10 level, maximum sensational block time, and motor block starting and finishing were measured shorter in the hyperbaric group [13]. Alley et al. also compared hyperbaric bupivacaine and hyperbaric levobupivacaine at the equal doses of 4 mg, 8 mg and 12 mg in the volunteer person and found that motor and sensational block formation and disappearing time were similar. For this reason, they made measurements for the pinprick test, Bromage scale, transcutaneous electrical stimulation, and abdominal muscle power and reported that hyperbaric bupivacaine and levobupivacaine had the same effect at the 4-12mg dose intervals [15]. In the present study, we used both agents at the 15mg dose, which is higher than Alley et al.

Imbelloni et al. investigated a minimum hyperbaric levobupivacaine dose for unilateral spinal anesthesia and compared the effectiveness of 4, 6 and 8 mg of hyperbaric levobupivacaine. They found that the starting of analgesia for the all dosages occurred in the same time, and motor block was to be 78% for the 4mg group, 95% for the 6mg group, and 100% for the 8mg group. They also indicated a correlation between the motor block time and hypotension formation. Furthermore, they reported that 4 mg of hyperbaric levobupivacaine was sufficient for unilateral spinal anesthesia [16]. However, spinal anesthesia was performed bilaterally in our study; thus, a high dose of hyperbaric levobupivacaine was used.

Kazak et al. also compared 3 ml of hyperbaric bupivacaine, hyperbaric levobupivacaine and hyperbaric ropivacaine. The shortest sensational and motor block time was determined in the ropivacaine group, while hypotension, nausea and vomiting were noted in the bupivacaine group. The block generation effect was similar for levobupivacaine and bupivacaine groups [17].

Hakan Erbay et al. added 25 µgr of fentanyl to 7.5 mg of hyperbaric levobupivacaine and 7.5 mg of bupivacaine for spinal anesthesia purposes for the patients undergoing transurethral surgery and found that accessing time to T10 dermatome level and maximum sensational blog and regression were similar. Complete block time in bupivacaine and the time of zero of the Bromage scale were found shorter in levobupivacaine [18].

Casati et al. compared 8 mg of hyperbaric bupivacaine, 8 mg of hyperbaric levobupivacaine and 12 mg of hyperbaric ropivacaine in patients undergoing umbilical hernia. They did not have differences between the groups for starting of sensational time and disappearing of spinal anesthesia. Furthermore, the time of lasting spinal anesthesia in the levobupivacaine group was longer than the other group, but this did not affect the discharge time of the patients. Maximum sensational block levels were T6 in bupivacaine, T8 in levobupivacaine and T11 in ropivacaine [3].

Luck et al. compared 15 mg of equal dosages of hyperbaric bupivacaine, hyperbaric levobupivacaine and hyperbaric ropivacaine. They did not have differences between the groups for the accessing time of sensational block to T10 rather than short motoric and sensational block regression time. Ropivacaine provided shorter and reliable anesthesia [19].

In the present study, the sensational block starting time was 8 (6–16) min in group HB and 11 (6–16) min in group HL. Complete motor block time (when Bromage was 3) was found as 10 (6–18) min for group HB and 12 (8–18) min for group HL. Sensational block starting and complete motor block time were statistically significant in group HB compared to group HL, but this was not clinically significant. Moreover, there were no statistical differences for the patient number requesting extra anesthetic agent, initial analgesic injection time, micturition time, sensational block disappearing and regression time, motor block starting and regression time, and the maximum sensational block level between the groups.

In conclusion, the features of levobupivacaine for anesthetic effect, hemodynamic parameters, postoperative analgesic requirement time, and the first 24-hour side effects and complications were similar to hyperbaric bupivacaine. Therefore, it has been suggested that hyperbaric levobupivacaine may be an alternative to hyperbaric bupivacaine for spinal anesthesia.

## **Conflict of interest statement**

The authors have no conflicts of interest to declare. **References** 

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