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Clinical experience

# Unilateral spinal anaesthesia for varicose vein surgery: a comparison of hyperbaric bupivacaine 7.5 mg versus hyperbaric bupivacaine 5 mg + fentanyl 25 μg

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**Abbreviations:**
mg – miligram
μg – microgram
ASA – American Society of Anestheiologist
SAP – systolic arterial pressure
DAP – diastolic arterial pressure
MAP – mean arterial pressure
HR – heart rate

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## Abstract

***Background and Purpose**: Unilateral spinal anaetshesia restricts the distrubution of spinal block preferentially to the operative side. Intrathecal coadministration of opioids increases sensory block without enhancing motor or sympathetic block. In this study we compared unilateral hyperbaric bupivacaine spinal anaesthesia with or without fentanyl in patients undergoing varicose vein surgery.*

***Material and Methods:** 40 ASA I-II adults randomly received unilateral spinal anaestehsia with hyperbaric bupivacaine 7.5 mg (Group B, n=20) or hyperbaric bupivacaine 5 mg+ fentanyl 25mg (Group BF, n=20). Sensory and motor block, hemodynamic data and side-effects were recorded.*

***Results:** Maximum level of sensory block on operative leg was Th11 (Th12-Th8) in Group B and Th12 (Th12-Th10) in Group BF, P=0.09. Complete motor block had 12 (60%) Group B and 4 (20%) Group BF patients, P=0.02. Total regression of motor block required 127 ± 31 min in Group B and 87 ± 18 min in Group BF, P<0.001. Maximum decrease of systolic arterial pressure from start value was 19 ± 9% in Group B and 16 ± 6% in Group BF, P=0.32 and of heart rate 23 ± 10% and 17 ± 7%, P=0.06, respectively. Pruritus had 9 (45%) Group BF patients, P = 0.001.*

***Conclusion:** Unilateral hyperbaric bupivacaine 5mg+fentanyl 25 mg spinal anaesthesia provides adequate intraoperative sensory block in operated leg and results in similar cardiovascular stability, less intense motor block and faster motor recovery than unilateral hyperbaric bupivacaine 7.5 mg spinal anestehesia in patients undergoing varicose vein surgery.*

## INTRODUCTION

Conventional-dose bilateral spinal anaesthesia, providing fast onset and adequate sensory and motor block, has been widely used for varicose vein surgery for many years. However, due to prolonged block recovery, urinary retention and high degree of cardiovascular instability, its use has not been suitable in cardiac risk patients and short and outpatient procedures.

Unilateral spinal anaesthsia, using small doses of hypobaric or hyperbaric local anaesthetic solutions slowly injected through directional

needles and lateral decubitus position maintained for a certain period, restricts the distribution of spinal block preferentially to the operative side *(1, 2)*. Unilateral distribution of spinal block results in fewer hemodynamic side effects with higher cardiovascular stability, better patient acceptance, increased postoperative autonomy, easier nursing during and after the procedure and reduced delay in patient discharge *(3)*.

Combination of local anaesthetic and opioid administered together intrathecally has a potent synergistic analgesic effect *(4)*. Intrathecal opioids greatly enhance subtherapeutic doses of local anaesthetic and make it possible to achive succseful spinal anaesthesia by using otherwise inadequate doses of local anaesthetic *(5)*.

In this prospective, randomized, double-blind study we compared the clinical profile of unilateral spinal anaesthesia produced with either 7.5 mg of hyperbaric bupivacaine or 5 mg of hyperbaric bupivacaine coadministered with 25 μg of intrathecal fentanyl in patients undergoing varicose vein surgery.

## MATERIAL AND METHODS

After obtaining an approval from the Institutional Ethics Committee and written informed consent, a total of 50 American Society of Anesthesiologist (ASA) physical status I and II adult patients undergoing varicose vein surgery under unilateral spinal anaesthesia, were enrolled in study. Patients with contraindication to regional anaesthesia (1 patient) or to any drug used in study (1 patient), body mass index > 32 (2 patients), peripheral neuropathy (2 patients) and patients receiving chronic analgesic therapy (4 patients) were excluded.

Remaining 40 patients were premedicated with peroral midazolam (7.5 mg) 30 minutes before block placement. A 20-Gauge intravenous cannula was inserted on the forearm and intravenous infusion of 7 ml/kg of Ringer solution was started after arrival in the operating room.

Standard intraoperative monitoring, including continuos electrocardiogram, heart rate, pulse oxymetry and noninvasive arterial blood pressure, was applied. Using a sealed envelope technique, patients were randomly assigned to one of two groups. In group B (n = 20) patients intrathecally received 7.5 mg of hyperbaric bupivacaine (0.5% plain bupivacaine 1.5 ml + 50% glucose 0.3 ml) and in group BF (n=20) 5 mg of hyperbaric bupivacaine coadministered with 25 μg of fentanyl (0.5% plain bupivacaine 1 ml + fentanyl 0.5 ml + 50% glucose 0.3 ml). The hyperbaric anaesthetic solutions with or without fentanyl in total volume of 1.8 ml and final glucose concentrations of 8.33%, were aseptically prepared immidiately before spinal injection by an anaesthesiologist who was not involved in further patient care. Spinal anaesthesia was administered in the lateral decubitus position with the limb to be operated in dependent position. Using an aseptic technique, dural punture was performed in the midline at L3–L4 intervertebral space, using a 22-Gauge introducer and 27-Gauge pencil-point spinal needle with the orifice turned toward the dependent side. After free flow of cerebrospinal fluid had been obtained, the anaesthetic solution was slowely injected over 60 seconds and lateral decubitus position was maintained for 15 minutes before patients were turned supine.

Sensory and motor blocks were evaluated bilaterally by an investigator blinded to the injected anaesthetic solution. Sensory block was assessed using pin-prick test every 5 minutes from the end of spinal injection until adequate surgical anaesthesia was obtained on the operative side (loss of pin-prick sensation at Th12). Time from the end of spinal injection to readiness for the surgery was noted. Motor block was evaluated using a modified Bromage scale (0 = no motor block; 1 = hip blocked; 2 = hip and knee blocked; 3 = hip, knee and ankle blocked) *(6)*, every 5 minutes during the first 30 minutes after block placement and then every 15 minutes until the complete motor block resolution. In case of inadequate surgical anaesthesia, 100 μg of fentanyl with or without general anaesthesia with propofol (4 mg/kg/h) was applied. Sedation score (0 = awake; 1 = asleep, open eyes to verbal stimulus; 2 = asleep, open eyes to physical stimuli; 3 = unarousable) every 15 minutes during the first 2 hours after spinal injection was determined.

Hemodynamic variables (systolic, diastolic and mean arterial pressure and heart rate) were recorded every 5 minutes during the first 60 minutes after spinal injection. Clinical relevant hypotension (decrease in systolic arterial pressure > 30% of baseline) was initially treated with a rapid intravenous infusion of 250 ml of Ringer solution, and if that was ineffective, 5 mg of ephedrin was administered. Bradycardia (decrease in heart rate to < 45 bpm) was treated with 0.5 mg of intravenous atropin. Postoperatively, rescue analgesic therapy (50 mg of peroral diclofenac) was given on patient request and the time between spinal administration and first analgesic and first micturion was documented. Side effects, such as pruritus, nausea, vomiting, respiratory depression (frequency of breathing < 8 per min or $SaO_2$ < 90%), postdural puncture headache or neurological complications were also recorded.

Data were statisticaly analyzed and expressed as mean ± standard deviation (SD) or median ± range for quantitavive variables and percentage of patients for nominal variables.

Averages were comapred using unpaired two-sample t-test or Mann-Whitney U test when appropriated and proportions were compared using Fisher's exact test. P value < 0.05 was considered statistically significant.

## RESULTS

There were no significant differences between the 2 groups with respect to age, gender, weight, height, ASA (American Society of Anesthesiologist) physical status, operation time (Table 1) and basal hemodynamic data (systolic, diastolic and mean arterial pressure and heart rate), Table 2.

**TABLE 1**

Patients characteristics and operation time.

| | Group B (n = 20) | Group BF (n = 20) | P |
|---|---|---|---|
| Age (years) | 47 ± 14 | 47 ± 11 | 0.95 |
| Gender (M / F) | 8 / 12 | 7 / 13 | 0.99 |
| Weight (kg) | 79 ± 11 | 79 ± 13 | 1.0 |
| Height (cm) | 171 ± 7 | 167 ± 10 | 0.19 |
| ASA I / II | 11 / 9 | 10 / 10 | 0.99 |
| Operation time (min) | 49 ± 16 | 44 ± 13 | 0.29 |

Values are mean ± standard deviation or number of patients; ASA: American Society of Anesthesiologist

**TABLE 2**

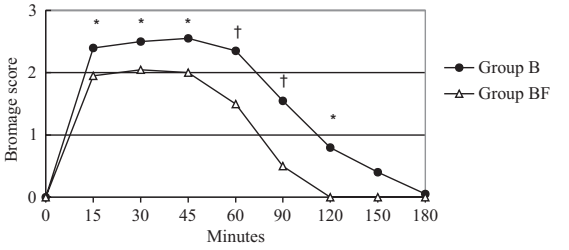
Basal hemodynamic parameters.

| | Group B (n = 20) | Group BF (n = 20) | P |
|---|---|---|---|
| SAP (mmHg) | 131 ± 18 | 131 ± 16 | 0.84 |
| DAP (mmHg) | 78 ± 12 | 79 ± 10 | 0.81 |
| MAP (mmHg) | 98 ± 15 | 97 ± 16 | 0.98 |
| HR (bpm) | 79 ± 16 | 73 ± 11 | 0.21 |

The median upper level of sensory block on operative leg was Th11 (Th12 – Th8) in group B and Th12 (Th12 – Th10) in group BF, P = 0.09. The mean time to achive adequate surgical anaesthesia was 6 ± 2 and 9 ± 4 min in group B and group BF, respectively, P = 0.04. None of the patients in both groups required fentanyl or propofol supplementation. Strictly unilateral motor block had 16 (80%) group B and 19 (95%) group BF patients, P = 0.34.

Maximal modified Bromage score on non-operative leg was 1 in all 4 group B and in 1 group BF patient with bilateral distribution of spinal block. Complete motor block (modified Bromage score 3) on operative side had 12 (60%) group B and 4 (20%) group BF patients, P = 0.02. The mean modified Bromage scores on operative leg during 180 min after spinal injection are shown in Figure 1. Motor block on the operative side was more profound in group B than in group BF at all testing times, but 150 and 180 minutes after spinal injection. Complete motor recovery 120 min after spinal injection had 11 (55%) group B and all 20 (100%) group BF patients, P = 0.001. Total regression of motor block required 127 ± 31 min in group B and 87 ± 18 min in group BF, P < 0.001. Time to first analgesics was 265 ± 89 min in group B and 292 ± 89 min in group BF, P = 0.34, and time to first micturition 349 ± 107 and 362 ± 17 min, P = 0.54, respectively.

There were no significant differences between the 2 groups regarding systolic and diastolic arterial pressure (Figure 2), mean arterial pressure and heart rate (Figure 3) during all 60 minutes after spinal injection. Maximum decrease in systolic arterial pressure from baseline was 19 ± 9% in group B and 16 ± 6% in group BF, P = 0.32, and in heart rate 23 ± 10% and 17 ± 7%, P = 0.06, respectively. Clinically relevant hypotension was reported in 4 (20%) group B patients only, P = 0.11, and was effectively treated with rapid intravascular volume expansion. Bradycardia was reported and effectivelly treated with 0.5 mg of intravenous atropin in 2 (10%) group B and 1 (5%) group BF patients, P = 0.99. Pruritus was documented in 9 (45%), P = 0.001, nausea and vomiting in 2 (10%), P = 0.49 and sedation score > 2 in 1 (5%), P = 0.99 group BF patients only. No case of respiratory depression, postdural puncture headache or neurological complications were reported.




* P < 0.05 between the groups; † P < 0.01 between the groups

**Figure 1.** *Modified Bromage score on operative leg during 180 min after spinal injection.*

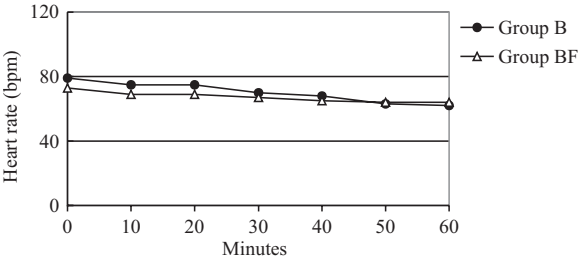



**Figure 2.** *The mean systolic arterial pressure (SAP) and diastolic arterial pressure (DAP) during the first 60 minutes after spinal injection.*

## DISCUSSION

The dose of local anaesthetic usually used for spinal block is an overdosage in relation to the minimum concentration required to block various types of nerve fibres. New spinal anaesthetic techniques focus on the possibility to control the spread of intrathecal drug, thereby restricting the distribution of spinal block just to the area which is necessary for the surgery. Unilateral spinal anaesthesia, using small doses of hyperbaric local anaesthetic solution and limiting the block only to the operative side provides higher hemodynamic stability and makes good option for elderly, compromised and ambulatory surgery patients *(6–8)*.

Unfortunately, in our country, commercial preparations of hyperbaric bupivacaine are not currently available on the market. So, in this study hyperbaric anaes-

thetic solutions were prepared by adding 0.3 ml of 50% glucose to 0.5% plain bupivacaine with or without fentanyl, achieving a final concentration of 8.33% glucose. Hallworth *et al*. demonstrated that the addition of glucose to bupivacaine produced solutions of predictable density in linear manner, and also, that the final glucose concentration, and not opioid, largely determined a solution's density. They demonstrated that the mean density of fentanyl was 0.99959 g/ml and the density of plain bupivacaine 0.99950 to 0.99970 g/ml *(9)*. Because the densities of the two agents are virtually identical, the addition of fentanyl to bupivacaine-glucose mixture has negligible effect on the final density of the solution.

The use of small dose of local anaesthetics for spinal anaesthesia can lead to a higher failure rate and Valanne *et al.* reported 6% and 2% failed spinal blocks when 4 and 6 mg of hyperbaric bupivacaine were used, respectively *(10)*. In our prospective, randomized, double-blind study, unilateral spinal anaesthesia was produced with either 7.5 mg of hyperbaric bupivacaine or 5 mg of hyperbaric bupivacaine coadministered with 25 μg of intrathecal fentanyl and adequate surgical anaesthesia was achived in all 40 patients in both groups.

The onset time of achiveing adequate surgical anaesthesia was only slightly prolonged in bupivacaine-fentanyl group and this 3-minute difference was statisticly significant, but clinicaly neglible. Although the upper level of sensory block on operative leg was one dermatome lower in group BF than in group B (Th12 vs. Th11), the difference was not found to be statistically different (P=0.09).

Strictly unilateral motor block was observed in 80% of the patients who received 7.5 mg of hyperbaric bupivacaine and the result is consinstent with previuos study that also reported unilateral motor paralysis with the same dose of local anaesthetic in 80% of the patients while in the lateral position *(11)*. In patients who received 5 mg of hyperbaric bupivacaine together with 25 μg of fentanyl, strictly unilateral motor block was observed in 95% of the patients.

When producing unilateral spinal anaestehisa with 4 mg and 6 mg of hyperbaric bupivacaine, Borghi *et al.* reported complete unilateral motor block in 97% and 93% of the patients, respectively *(12)*.

Complete motor block (modified Bromage score 3) was more often in group B than in group BF, 60% vs 20%, due to the higher concentrations of local anaesthetic achieved near the nerve roots of the operated limb. Also, motor block was less intense and lasted shorter when a small dose of local anaesthetic-fentanyl combination was applied. The similar was observed in study reported by Korhonen *et al.* in which intrathecal hyperbaric bupivacaine 3 mg+fentanyl 10 μg and hyperbaric bupivacaine 4 mg were compared *(13)*. In a dose finding study of unilateral spinal block for outpatient knee arthroscopy, Borghi *et al.* demonstrated faster recovery profile when 4 mg of hyperbaric bupivacaine was administered than when 6 mg or 8 mg dose were used *(12)*. Complete regreesion of spinal anaesthesia required 71 ± 20, 82 ± 25 and 97 ± 37 min, respectively, and in our study, 87 ± 18 and 123 ± 31 min when 5 mg and 7.5 mg of hyperbaric bupivacaine were applied.

In both groups, unilateral spinal anaesthesia provided stable cardiovascular profile with minimal hemodynamic disturbance, due to the low maximum sensory block recorded on the operative side. Similar resultas have been reported in previous studies which demontsrated high degree of hemodynamic stability when unilateral spinal anaesthesia with small doses of hyperbaric bupivacain were used *(6–8)*.

In the present investigation, no case of urinary retention requiring bladder catheterization was reported, whereas Fanelli *et al*. documented an incidence of urinary retention of 2% in patients receiving unilateral spinal anaesthesia with 8 mg of hyperbric bupivacaine *(6)*.

Postoperative pain reliefe was adequate in all 40 patients and time to first analgesics did not differ between the two groups. Coadministration of 25 μg of fentanyl to 5 mg of hyperbaric bupivacaine provided adequate analgesia, but resulted in pruritus in 45% and in postoperative nausea and vomiting in 10% of the patients. Ben David *et al.* reported the similar incidence of pruritus in up to 41% and of postoperative nause and vomiting in up to 18% of the patients when 25 μg of intrathecal fentanyl was administered to 20 mg of spinal lidocaine *(4)*. In our study, no case of postdural puncture headache or neurological complications in either group were noticed.

In conclusion, both unilateral hyperbaric bupivacaine 7.5 mg and unilateral hyperbaric bupivacaine 5 mg + fentanyl 25 μg spinal anaesthesia provide adequate intraoperative sensory block in operated leg and result in similar cardiovascular stability in patients undergoing varicose vein surgery. However, local anesthetic-opioid combination is found to be superior because it provides less intense motor block and faster motor recovery, which permits fast tracking and shorter stay in post anesthesia care unit.

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