

Increase in Specific Density of Levobupivacaine and Fentanyl Solution Ensures Lower Incidence of Inadequate Block

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ABSTRACT

The clinical presentation of a subarachnoid block (SAB) is dependent upon the intrathecal spread of local anesthetic (LA). Intrathecal distribution depends on the chemical and physical characteristics of LA, puncture site, technique used, patient anatomical characteristics and hydrodynamic properties of cerebrospinal fluid. We tried to determine whether a combined glucose/LA solution can render a clinically significant difference in sensory block distribution and motor block intensity. This was a controlled, randomized and double blinded study. The surgical procedures were stripping of the great or small saphenous vein and extirpation of remaining varicose veins. The study included 110 patients distributed into two groups: Hyperbaric (7.5 mg levobupivacaine (1.5 ml 0.5% Chirocaine®) + 50 µg Fentanyl (0.5 ml Fentanil®) and 1 ml 10% glucose (Pliva)) vs. Hypobaric (7.5 mg levobupivacaine (1.5 ml 0.5% Chirocaine®) + 50 µg Fentanyl (0.5 ml Fentanil®) and 1 ml 0.9% NaCl (Pliva, Zagreb)) adding to a total volume of 3.5 ml per solution. Spinal puncture was at L3-L4 level. Spinal block distribution was assessed in five minute intervals and intensity of motor block was assessed according to the modified Bromage scale. Pain was assessed with the Visual Analogue Scale. A statistically significant difference in sensory block distribution, motor block intensity and recovery time was established between hyperbaric and hypobaric solutions. By increasing the specific density of anesthetic solution, a higher sensory block, with lesser variability, a diminished influence of Body Mass Index, decreased motor block intensity and faster recovery time may be achieved.

Key words: spinal anesthesia, hyperbaric block, levobupivacaine and fentanyl

Introduction

The clinical presentation of a subarachnoid block (SAB) is dependent upon the intrathecal spread of the local anesthetic (LA) solution. Intrathecal distribution of local anesthetic solutions depends on the chemical and physical characteristics of the LA solution, puncture and injection technique, anatomical characteristics of the patient and hydrodynamic properties of the cerebrospinal fluid (CSF)^{1–5}. In vitro studies show that a difference in the specific density of the LA solution, expressed to the fourth decimal, can significantly affect the clinical presentation of the SAB⁶. The aim of this study was to deter-

mine whether the addition of glucose to the LA solution with a concentration range of up to 2.8%, can render a clinically significant difference in sensoric block distribution and motor block intensity.

Patients and Methods

With approval from the local Ethics committee and signed consent from the patients regarding participation in the study, a controlled, randomized, double blinded

study was conducted on patients who were planned for an elective surgical procedure on varicose veins with stripping of the great or small saphenous vein and extirpation of the remaining varicose veins.

The pilot study included 20 patients with a determined sensoric block at Th10 level in 20% of patients, in whom a solution of 7.5 mg 0.5% levobupivacaine and 50 µg fentanyl + 0.9% NaCl was administered. The clinical significance of the result was a 25% increase of maximum desired block height. The calculated sample size with $\alpha=0.05$ and test power of 80%, for distinguishing a clinically significant difference in achieved block height of 2 dermatome levels and motor block intensity of 2 on a scale of 1–6, was 55 subjects per group. The inclusion criteria were: age between 25 and 60 years, ASA status I – II and estimated surgery time of up to 110 min. Patients who refused regional anesthesia techniques or had a history of allergy to local anesthetics, coagulation defects, or were suffering from conditions associated with a possibly increased concentration of proteins or glucose in the cerebrospinal fluid, were excluded from the study.

Patients were randomly assigned to either the hypobaric (Hypo – 7.5 mg levobupivacaine 0.5% Chirocaine®, Abbott (1.5 ml) and 50 µg fentanyl (0.5 ml, 50 µg/ml Fentanil®, Janssen), with 1 ml 0.9% NaCl (Pliva, Zagreb)), adding up to a total volume of 3.5 ml, or the hyperbaric group (Hyper – 7.5 mg levobupivacaine (1.5 ml 0.5% Chirocaine®, Abbott) and 50 µg fentanyl (0.5 ml Fentanil®, Janssen 50 µg/ml) with 1 ml 10% glucose (Pliva) adding to a total volume solution of 3.5 ml. Randomization was performed in advance with the aid of a randomizer from the web address www.graphpad.org.

All patients were premedicated with midazolam 0,9 mg/kg per os (Dormicum Roche®, Basel) and atropine sulphate 0.5 mg im. (Atropini Sulfas®, Belupo, Koprivnica). During the 20 minute period after spinal puncture, all patients were hydrated with 6 ml/kg 0.9% NaCl (Pliva, Zagreb) followed by 4 ml/kg/h until the end of the procedure.

The L3-4 level at which spinal puncture was performed was determined with the aid of an ultrasound device (Sonoline G50, Siemens, Germany, convex probe 2–5 Hz). A Whitacre®, No 27 G (Vygon, France) spinal needle was used for puncture. The LA solution was injected after gaining CSF from the needle for 30 seconds, with the needle opening facing in the cranial direction. All patients were positioned in the sitting position during puncture and were put in the supine position immediately after injection of the LA solution. The surgical table was in a neutral position. The specific density of the hypobaric solution was calculated according to the formula:

$$\rho (\text{Hypo}) = (\rho \text{ LA} \times \text{vol LA} + \rho \text{ Fent.} \times \text{vol. Fent.} + \rho \text{ 0.9\% NaCl} \times \text{vol. 0.9\% NaCl}) / \text{vol.solut.} = 0.99998 \text{ g/ml}$$

categorizing the solution as hypobaric.

The specific density ρ (Hyper) of the hyperbaric group is calculated according to the formula: $\rho (\text{Hyper}) = 1.00024 + (0.00027 \times \text{conc. glucose in the solution})^6$ and amounts to 1.00101 g/ml making it hyperbaric with respect to the

CSF. The calculated difference between specific densities of the two solutions is 0.00103 g/ml. An anesthesiologist who was not involved in the clinical assessment of patients prepared the solutions for each patient immediately before spinal puncture. Intraoperative monitoring included the standard non-invasive anesthesiological monitoring (EKG, SpO₂, NIBP). Spinal block distribution was assessed in five minute intervals with the use of ice packs, according to the dermatomes in a caudo-cranial direction along the anterior axillary line. The last dermatome, in two consecutive testings, at which the patient has a loss of temperature discrimination to sensoric stimulus, were considered the highest point of the sensoric block. At the point of time when the highest level of achieved block had been determined (first point of measurement) and at the end of the surgical procedure (second point of measurement), we assessed the achieved intensity of motor block according to the modified Bromage scale as used previously^{8,9}: 1-complete loss of movement in the lower extremities, 2-possibility of moving the feet, 3-partial flexion at the knee, 4-complete flexion at the knee, 5-flexion at the knee and hip, 6-proprioception test completed. Inadequate block was defined by the presence of pain, uncomfortable tingles or a burning sensation at any of the dermatome levels and at any stage of the surgical procedure, which required additional intravenous analgesia or sedation. Intraoperative hemodynamic stability was defined by change of mean arterial pressure (MAP) and heart rate (HR) of more than 30% of baseline value. All of the patients were admitted to the surgery ward immediately after surgery. Time of spontaneous miction and unassisted verticalization were considered as criteria for complete recovery. Pain intensity was assessed by using the visual-analogue scale at 1h, 6 h and 12h from the end of surgery as well as the time of additional analgesia with diclofenac. The indication for administering parenteral analgesia (diclofenac 150 mg/ 100 ml 0.9% NaCl i.v.) was a pain intensity level ≥ 4 . On the first postoperative day, the patients were interviewed prior to discharge and data was collected on possible side effects of the performed subarachnoid block.

The gathered information is expressed as a mean value with a standard deviation for continuous variables and for categorical values with a measure of central tendency: median and range. Group comparability was determined with a t-test for independent samples and for establishing the difference in sensoric block height and motor block intensity between groups we used the Mann Whitey U-test. The significance of correlation between sensoric block height and BMI was determined by using the Person test. Statistical significance was defined as $p < 0.05$.

Results

Fifty five subjects were assigned to each group. Data on demographic characteristics of the patients are shown in Table 1. Groups are mutually comparable in demographic characteristics and duration of surgery $p > 0.05$.

Maximum height of the sensoric component of the subarachnoid block

We have evidenced a statistically significant difference in sensoric block height Hyper vs. Hypo Th10 (Th5-L1) vs. Th 11 (Th 4-L3), $p=0.001$ with a lower variability of block height in the Hyper group (Figure 1). Inadequate block had appeared in both groups: 2/55 (3%), in the Hyper and 9/55 (16%) in the Hypo group. A statistically significant correlation between BMI and sensoric block height was observed in the Hypo group $r=-0.50$, while in the Hyper group there was no correlation established $r=-0.07$ (Figures 2 and 3).

Motor block intensity

The difference in the motor block component of the subarachnoid block between the Hyper and Hypo groups was established in both measurement points: Hyper FP vs. Hypo FP 3(1-6) vs. 2(1-5), $p=0.012$ (Figure 4) and Hyper SP vs. Hypo SP 5(1-6) vs. 2 (1-5), $p<0.001$. A significant block regression was noted between the two points of measurement in the Hyper group, Hyper FP vs. Hyper SP, $p<0.01$ while in the Hypo group motor block regression was not noted $p=0.90$ (Figure 4).

Perioperative patient recovery and side effects

Intraoperative MAP decrease or HR change of more than 30% was not noted in any of the groups. The time interval from spinal puncture to first unassisted verticalization, spontaneous miction and postoperative administration of diclofenac was shorter in the Hyper group.

TABLE 1
DEMOGRAPHIC CHARACTERISTICS OF THE PATIENTS

	Hypo Group	Hyper Group
Age (years)	48.7±12.3	45.1±11.7
Weight (kg)	82.4±12.1	80.2±16.9
Height (cm)	173±8.2	173.5±10
BMI(kg/m ²)	27.22±3.55	26.52±4.23
Duration of surgery (min)	64±22	58±17

BMI – body mass index

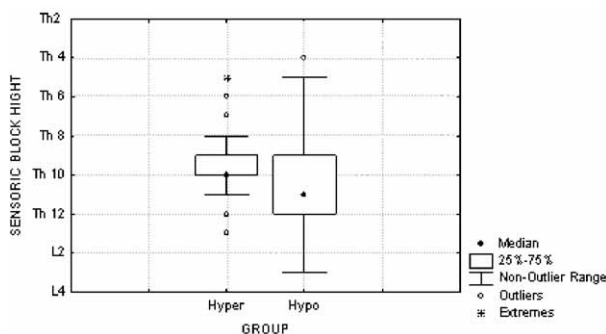


Fig. 1. Maximum height of the sensoric component of the subarachnoid block.

Pain intensity assessed during the first postoperative hour was significantly higher in the Hyper group when compared to the Hypo group, $p<0.03$, while at 6 and 12 hours postoperatively, there was no pain present. Table 2 Side effects during the first 24 hours do not differ between groups (Table 3).

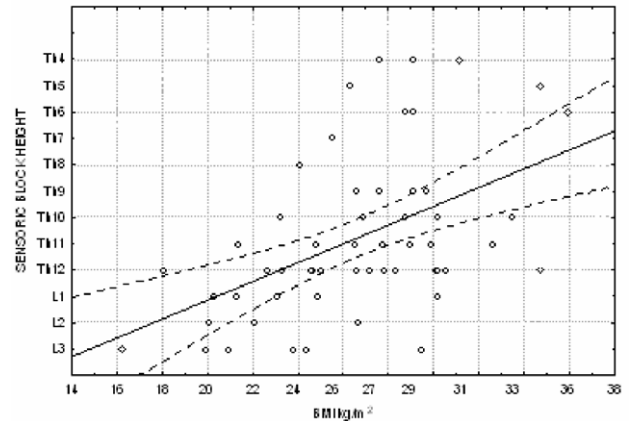


Fig. 2. Hypo group: correlation between BMI and sensoric block height; $r=-0.5$; BMI – body mass index.

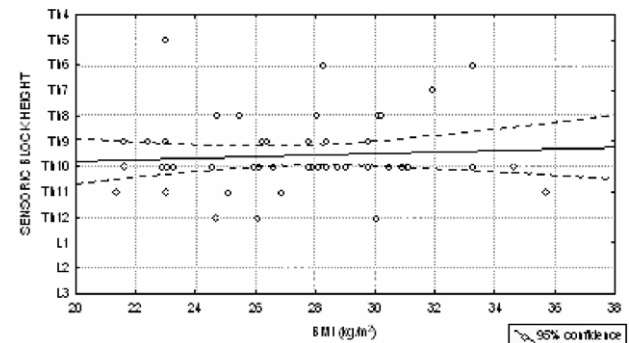


Fig. 3. Hyper group: correlation between BMI and sensoric block height.

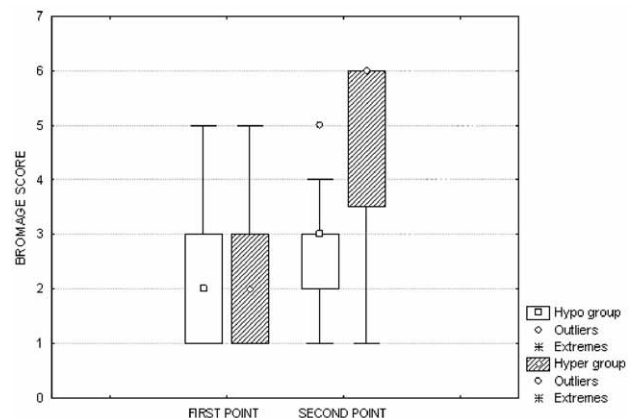


Fig. 4. Motor block regression in the hypo and hyper group at the first and second point of measurement.

TABLE 2
RECOVERY PROFILE AND PAIN INTENSITY DURING THE FIRST 24 H

	Hyper group	Hypo Group	p
Unassisted verticalization (min)	249±77	381±144	<0.01
Miction (min)	289±141	372±106	0.01
Analgesics (min)	318±150	686±290	<0.01
Pain VAS (median (range))	7 (0–9)	0 (0–3)	0.03
1 hour 6 hours	3 (0–5)	2 (0–5)	0.07
12 hours	4 (0–8)	4 (1–8)	0.06

VAS – visual analogue scale

TABLE 3
SIDE EFFECTS DURING THE FIRST 24 HRS

Side effects	Hypo Group (n/N)	Hyper Group (n/N)
Postoperative nausea and vomiting	3/55	3/55
Headache	6/55	4/55
Lumbar pain	8/55	3/55
Pruritus	19/55	11/55
Urinary retention	0/55	0/55

Discussion

In this investigation we showed that, by increasing the specific density of the local anesthetic solution, whereby the solution becomes either slightly hypobaric or slightly hyperbaric, we can ensure a lesser variability in the sensoric component of the subarachnoid block, a smaller intensity of the motor block component and reduce the time to complete mobilization of the patient along with a smaller incidence of inadequate subarachnoid blocks.

The height of the sensoric block component is dependent upon the characteristics of the administered LA solution, clinical technique applied and characteristics of the patient¹. The conventional dose of 15 mg 0.5% levobupivacaine, for varicose vein surgery, ensures an adequate sensoric block in 90% of cases with maximum block height at Th8 (Th4-L3)¹⁰. By reducing the dose to 13 mg and 10 mg 0.5% levobupivacaine, the achieved height falls to the Th 7 (Th3-Th10) and Th10 (C8-L1) dermatomes^{11,12}. At doses smaller than 10 mg 0.5% levobupivacaine, there is an increased incidence of inadequate block with the need to add an opioid analgesic to achieve the necessary degree of anesthesia for a successful bilateral block¹³. A solution of fentanyl and levobupivacaine is hypobaric with regard to the CSF¹⁴. Even though *in vitro* studies suggest that hypobaric solutions provide a more cranial block distribution, clinical studies did not confirm a difference in sensoric block height with the addition of 20 µg of fentanyl and 0.2 mg of morphine into a 15 mg (3ml) 0.5% bupivacaine solution, Th 3.5 (Th1-Th10)

vs. Th4 (Th2-Th10)^{15,16}. Contrary to this, adding 20 µg of fentanyl to 10 mg (2ml) 0.5% bupivacaine increases the achieved median maximum height of sensoric block for 1 dermatome, from Th7 to Th6¹⁷. When administering hyperbaric solutions, block distribution depends upon patient position during block fixation¹⁸. A median maximum of sensoric block height when administering 15 mg of hyperbaric levobupivacaine solution is at the Th 4 dermatome (Th 2-8)¹⁹, with 13,5 mg it decreases to the Th7 dermatome (Th4-Th10)²⁰. At a dose of 15 mg with 8% glucose, sensoric block height reached the Th5 dermatome, while solutions with 10, 7.5 and 5 mg bupivacaine, regardless of the final concentration of glucose in the solution, provided a block height at the Th8 dermatome. An inadequate block was present in the 5 mg bupivacaine group²¹. Studies investigating groups with doses of 13 and 12.5 mg of levobupivacaine show the same results^{10,22}. These studies conclude that the value of specific solution density in hyperbaric solutions is of little importance in regard to block distribution. Contrary to these studies, investigations comparing the height and variability of sensoric block when administering solutions with a final concentration of glucose at 0.33%, 0.83 % and 8%, showed a more cranial block distribution with less block variability in solutions with a higher final concentration of glucose²³. Also, a combination of a hyperbaric bupivacaine (10 mg) solution containing morphine or fentanyl showed an increase in sensoric block height by 1 dermatome in comparison to separate intrathecal administration of the same drugs²⁴. In our study, the median height of sensoric block in the Hypo group is for 1 dermatome lower Th 11 (Th4-L1), compared to the studies mentioned earlier, which can be explained as due to a lower local anesthetic dose. The block height range of 10 dermatomes in the Hypo group is consistent to the findings of other investigations. In the Hyper group, the median sensoric block height is at the Th 10 dermatome with an 8 dermatome range (Th 6-L1). By adding 10% glucose we created a borderline hyperbaric solution and the results support earlier claims that hyperbaric solutions have a more cranial distribution and lesser block variability in comparison to hypobaric solutions²².

Inadequate block in the Hypo group was present in 16% (9/55) of patients, whereas in the Hyper group it was present in 3% (2/55) of patients. Three patients had a

complete absence of sensoric block with motoric block being present – Bromage 3. In the other 6 patients of the Hypo group and 2 patients of the Hyper group, systemic analgesia had to be administered due to insufficient block height early on in the procedure or at the end of the surgical procedure. Intravenous administration of fentanyl 50–100 µg ensured adequate intraoperative analgesia. Enhancement of the analgesic component of the block could be explained as due to the increased height of the sensoric component of the block with intravenously administered opioids¹⁶. The correlation between BMI and CSF volume with sensoric block distribution, without a predictive value, has been established earlier^{2,25}. In our model, the correlation coefficient for BMI and height of sensoric block was $r=-0.50$. BMI is an independent characteristic of the patient which may have a predictive value of developing an inadequate sensoric block height when administering a hypobaric solution with a reduced dose of local anesthetic. The confidence limit of BMI for the least acceptable block height at the Th12 dermatome were, $CL\pm 95\%$ 24.6–26.7 kg/m². By increasing the specific density of the solution, we can diminish the influence of the BMI on spinal block distribution (correlation coefficient $r=-0.07$) thus presenting a more predictable clinical presentation of the block.

Motor block intensity in both points of measurement was greater in the Hypo group. A clinically significant difference in motor block intensity was visible at the second point of measurement where in the Hyper group, 37 out of 55 patients (67%) had a complete regression of the block (Bromage 5 or 6). The differences in motor block intensity at the end of the surgical procedure, intensity of postoperative pain in the first postoperative hour and a smaller time interval to complete mobilization were in coherence to earlier claims that block regression has a quicker onset when using hyperbaric solutions as compared to isobaric or hypobaric solutions^{23,26,27}.

Hemodynamic instability is associated with block height reaching above the Th5 dermatome level²⁸. Consistently, due to a lower block level, none of the groups required neither additional volume replacement nor use of vasoactive drugs. Incidence of postoperative side effects was equal in both groups and did not require specific

pharmacological therapy nor did they result in delayed discharge of patients from the hospital. Pruritus was present in 37% of patients during the postoperative period. When considering that 50 µg of fentanyl were administered intrathecally, we would have expected a higher incidence of pruritus^{29,30}. We believe that premedication with midazolam and the amnestic effect it possesses is responsible for a smaller number of patients complaining of pruritus.

A methodological weak point of this study is that the preparation of the LA solution for each patient was carried out immediately prior to its administration and could therefore result in minor variability of solution concentrations. However, since this method is the method applied in daily clinical practice, we believe that the probability of error is equal in both groups and should therefore not affect the final results significantly. The specific density of the prepared solutions was not measured directly but was calculated based on earlier mentioned formulas. Considering that every solution with a glucose concentration greater than 0.8% behaves as a hyperbaric solution and a combined solution of levobupivacaine and fentanyl behaves as a hypobaric solution, we believe that knowing the exact value of the specific density of these solutions is not a vital element for this experimental model.

Conclusion

In this study, we proved that with the same dose of levobupivacaine and fentanyl, we can achieve a higher sensoric block by increasing the specific density of the solution, with a lesser degree of block variability at commencement of surgery, a decreased incidence of inadequate block due to diminished influence of BMI on block distribution, a decreased intensity of motor block and a faster mobilization of the patients.

Acknowledgements

This study was funded through departmental funding only. The authors have no conflicts of interest.

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POVEĆANJE SPECIFIČNE GUSTOĆE OTOPINE LEVOBUPIVAKAINA I FENTANILA OSIGURAVA NIŽU UČESTALOST NEDOSTATNOG SPINALNOG BLOKA

SAŽETAK

Klinička slika subarahnoidalnog bloka ovisi o intratekalnom širenju otopine lokalnog anestetika (LA). Intratekalno širenje je uvjetovano kemijskim i fizikalnim osobinama otopine lokalnog anestetika, mjestu uboda, tehnicima primjene, anatomskim karakteristikama bolesnika te hidrodinamičkim svojstvima cerebrospinalnog likvora. Ovim istraživanjem pokušali smo ustanoviti, može li se kombiniranjem glukoze i otopine lokalnog anestetika značajno utjecati na raspon i intenzitet postignutog senzoričkog i motoričkog bloka. U ovu svrhu, proveli smo kontroliranu, randomiziranu i dvostruko slijepu studiju. Kirurški zahvati su uključivali ekstirpaciju varikoznih vena nogu sa podvezivanjem safenofemoralnog ušća. U studiju je uključeno 110 bolesnika, podijeljenih u dvije grupe: Hiperbarična (7,5 mg levobupivacaine (1,5 ml 0,5% Chirocaine®) + 50 µg Fentanyl (0,5 ml Fentanyl®) i 1 ml 10% glucose (Pliva)) vs. Hipobarična (7,5 mg levobupivacaine (1,5 ml 0,5% Chirocaine®) + 50 µg Fentanyl (0,5 ml Fentanyl®) i 1 ml 0,9% NaCl (Pliva, Zagreb)) stvarajući ukupni volumen od 3,5 ml po otopini. Punkcija je izvršena na nivou L3-L4. Distribucija subarahnoidalnog bloka je procjenjivana u pet minutnim intervalima a intenzitet motoričkog bloka je procjenjivan prema modificiranoj Bromageovoj ljestvici. Bol je procjenjivana uz pomoć Vizualno Analognе ljestvice. Statistički značajna razlika je utvrđena za: raspon senzoričkog bloka, intenzitet motoričkog bloka te vrijeme oporavka između hiperbaričnih i hipobaričnih skupina. Povećanjem specifične gustoće otopine lokalnog anestetika, postiže se viši senzorički blok, uz nižu učestalost odstupanja od predmnijevane vrijednosti, smanjen je utjecaj indeksa tjelesne mase na kliničku prezentaciju bloka, manji je intenzitet motoričkog bloka te je vrijeme oporavka značajno skraćeno.