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The Effect of Local Anaesthesia at Different Temperatures on Spinal Anaesthesia

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Abstract

Background: Aim: The aim of this study was to evaluate the effects of the use of 0.5% levobupivacaine at room temperature and at 4ºC on the characteristics of subarachnoid block. **Methods:** Approval for this prospective, randomised, single-centre and double-blind study was granted by the Local Ethics Committee. Informed consent was obtained from all the patients. The study comprised 60 patients, for whom orthopaedic lower extremity surgery. In the operating room, after standart monitorization spinal anesthesia was made with a 27-gauge Quincke spinal needle from the L3-L4 interspinous gap. The patients were randomly separated into 2 groups. Patients in Group I were injected 3ml 0.5% levobupivacaine solution which had been kept at room temperature (mean 23ºC) and the patients in Group II with 3ml 0.5% levobupivacaine solution which had been kept at 4ºC for at least 24 hours. The patients were evaluated in respect of sensorial and motor block parameters, haemodynamic profiles and the incidence of side-effects. **Results:** The time to reach T12 sensory block was determined as statistically significantly shorter in Group I compared to Group II ($p<0.05$). The maximum sensory block levels in Group II were found to be in the lower dermatomes to a significant degree compared to Group I ($p<0.05$). No statistically significant difference was determined between the groups in respect of another parameters. **Conclusion:** It was determined that the application of spinal anesthesia with 0.5 % levobupivacaine at 4ºC causes lower levels of sensory block, with a slower onset and which are of shorter duration.

Key words: Spinal Anesthesia, Local Anesthesics, Temperature.

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Introduction

Many factors affect the intrathecal dissemination of local anesthetics (LA). The maximum analgesia level which occurs as a result of the injection of LA solution to the subarachnoid region is defined as a sufficient amount of local anesthetic uptake by neural tissues to be able to create the block and distribute it in a cephalic direction within the cerebral spinal fluid (CSF).[1]

Immediately following injections of room temperature LA solution into body temperature CSF, local decreases occur in the CSF temperature (2-3ºC with 2.4ml bolus, 6-8ºC with 12ml bolus) but within 2 mins the CSF temperature returns to normal. This occurs immediately before fixation of the local anesthetics to the spinal roots (2-7). A curvilinear reduction is seen in the densities with increasing temperatures in LA solutions. The changes in density occurring with temperature are reflected in baricity; for every increase in temperature of 1ºC between 23ºC and 37ºC, all local anesthetic densities reduce by 0.0003g/ml-1. However minimal the change in density seems to be, even a change as low as 0.0006 g/ml-1 can affect the distribution of local anesthesia.[2-10]

In this study it was aimed to compare the effects of an injection to the subarachnoid space of 0.5% levobupivacaine solution, which had been kept for at least 24 hours at room temperature (20-24ºC) or at refrigerator shelf temperature (4ºC) on the characteristics of spinal anesthesia in patients undergoing planned elective lower extremity orthopaedic surgery.

Materials and Methods

The study comprised 60 patients aged 18-75 years, in the ASA I-III risk group for whom lower extremity surgery was planned under elective conditions. Any patients contra-indicated for spinal anesthesia with with neurological deficit or allergy to local anesthetics were excluded from the study.

The patients were allocated to one of two groups by the closed envelope randomisation method.

Group I: (n:30) 3ml 0.5% levobupivacaine solution (0.5%Chirocaine, Abbott Laboratories, Istanbul) stored at room temperature (mean 23ºC) for at least 24 hours.

Group II (n:30) 3ml 0.5% levobupivacaine solution (0.5%Chirocaine, Abbott Laboratories, Istanbul) stored at refrigerator shelf temperature (4ºC) for at least 24 hours.

The gloves, spinal needle and injectors to be used in Group II were also stored in the refrigerator together with the solution. The refrigerator shelf temperature of 4ºC was confirmed with a thermometer.

During the anesthesia procedure and the operation, standard monitorisation was applied to all patients of electrocardiography, non-invasive artery pressure, heart rate and oxygen saturation with pulse oximeter and 7-10 ml/kg-1 0.9% saline was administered. With the patient in a sitting position, the subarachnoid space was entered with a 25-gauge Quincke spinal needle from the L3-L4 interspinous gap under antiseptic conditions. When free CSF flow was seen from all angles, the tip of the spinal needle was turned in a caudal direction and the 3ml local anesthetic solution was injected at the rate of 0.2ml/sec-1. The patient was kept in the sitting position for 3 mins. The patient was laid supine and 2lt/min-1 O2 was administered via a face mask. A sufficient block level for surgical anesthesia was accepted as T12 dermatome and above.

The perioperative mean arterial blood pressure (MAP), heart rate (HR) and SpO2 were recorded throughout the operation starting from the moment of the patient taken into the operating room; at 5-min intervals for the first 30 mins, at 10-min intervals in the next 30 mins, at 15-min intervals until 90 mins then at 30-min intervals for the remaining time.

Side-effects of nausea and vomiting, bradycardia, hypotension, reduced SpO2(<93%) were monitored. During the monitoring, if there was a decrease of more than 30% of the MAP preoperative basal values, 0.9% saline infusion was rapidly administered intravenously and when necessary, 10mg ephedrine bolus at a 1-min interval. If HR fell below 50/min, it was planned to administer 0.5mg atropine iv bolus. If SpO2 fell below 93% it was evaluated as hypoxia and 4lt/min-1 oxygen was administered with a face mask.

The sensory block level and motor block level were evaluated and recorded at 5-min intervals for the first 30 mins, at 10-min intervals in the next 30 mins, at 15-min intervals until 90 mins then at 30-min intervals for the remaining time. The sensory block level was determined with the pinprick test.

A record was made of the time to reach T12 sensory block, the level of maximum sensory block, the time to reach maximum sensory block (the time from LA solution injection into the subarachnoid gap to the highest sensory block level), the time to 2 segment regression, the time to L1 dermatome regression of the sensory block (the mean time taken to fall from the highest level to the L1 dermatome) and the duration of the sensory block (the mean time from the LA solution injection into the subarachnoid gap to the fall to the level of the L1 dermatome).

Motor block was evaluated according to the 'Modified Bromage Scale'.

A record was made of the Bromage score at 10 minutes, the time to the start of full motor block (the time to reach Bromage score 3), the time of Bromage score regression from 3 to 2 and the time of return from full motor block (ability to move the feet).

According to the pilot study, to achieve a difference up to the level of at least 2 dermatomes at the highest sensory block level, at least 12 subjects were required in each group to have statistical significance at 5% error and 90% power.

Statistical Analysis

Statistical analysis of the data was performed using SPSS 11.5 (Statistical Package for Social Science) software program. Conformity to normal distribution was tested with the Shapiro Wilk test for continuous variables (operating time, time to reach maximum sensory block, time of sensory block at T12 and above, start time of motor block, 2 segment, time of regression to L1 and Bromage score 3 to 2, heart rate, blood pressure and saturation measurements). Descriptive statistics for continuous variables were stated as mean ± standard deviation (SD) or median (minimum-maximum and categorical variables (gender, ASA, sensory block and Bromage level) were stated as number (n) and percentage (%).

To determine whether or not there was a statistically significant difference between the mean values of the groups, the Student's t-test was applied and the significance of the difference in respect of median values was examined with the Mann Whitney U-test. Repeated Measurements Variance Analysis was used to evaluate whether or not there was a statistically significant difference between the repeated measurements within the groups (heart rate, systolic blood pressure, diastolic blood pressure, mean blood pressure and saturation). When the result of the Repeated Measurement Variance Analysis was found to be significant, from which time measurement the difference originated was determined with the Bonferroni Correction multiple comparison test. The Friedman test was applied to show whether or not a significant difference was seen at the different times in the Bromage and sensory block levels. When the Friedman test result was found to be statistically significant, the Bonferroni Correction Wilcoxon Sign test was used to determine which time measurement caused the difference. Categorical variables were evaluated with the Pearson Chi-Square test. A value of $p<0.05$ was accepted as statistically significant for all the results. Bonferroni correction was made in all multiple comparison tests to keep probability below Type I error.

Results

No statistically significant difference was determined between the groups in respect of demographic characteristics (age, gender, height, weight), ASA classification or operating time ($p>0.05$) [Table 1].

A statistically significant difference was determined between the groups in respect of the time to reach T12 sensory block (Group I: 9±3.32, Group II: 12.33±4.49 mins), duration of sensory block at T12 and above (Group I:162.66±38.37, Group II:143.66±42.44 mins), maximum sensory block level

(Group I: T8 (T4-T11), Group II: T10 (T6-T12)) ($p<0.05$) [Table 2-5].

No statistically significant difference was determined between the groups in respect of the time to reach maximum sensory block (Group I: 20.5±6.5, Group II: 20.3±7.1 mins), 2 segment regression time (Group I: 98±32.89, Group II: 96.83±32.76 mins), L1 regression time (Group I: 148.33±40.58, Group II:136±39.02 mins) duration of sensory block (Group I: 170.66±35.34, Group II: 156.33±40.72mins) motor block start time, (Group I: 21±9.94, Group II: 23.67±9.82 min) Bromage score regression from 3 to 2 (Group I: 129.67±39.67, Group II: 117±37.79 min) ($p>0.05$) [Table 2-7].

The difference seen in the sensory block levels at all the times, apart from at 75 minutes, were found to be statistically significant (5-60 mins and 90 mins, $p<0.05$; 75 mins, $p=0.075$) [Table 5].

Table 1: Demographic characteristics of the patients, ASA classifications and operation times.

	Group I (room temperature) n=30	Group II (4 oC) n=30	p value
Age (years)	46.7±12.7	46.8±12.6	0.976a
Gender M / F	13/17	14/16	0.795b
Body weight (Kg)	78.6±10.1	77.3±11.7	0.638a
Height (cm)	166.3±7.9	166.4±9.0	0.964a
ASA I / II / III	15/15/0	13/16/1	0.458b
Operation time (mins)	30 (10-70)	35 (15-175)	0.882c

a Student's t test.
b Pearson' s Chi-Square test.
c Mann Whitney U test.

At 10 mins, the Bromage score was 2 in Group I and 1 in Group II [Table 7]. The difference between the groups was found to be statistically significant ($p=0.004$).

No statistically significant difference was determined between the groups in respect of saturation (SpO2) values, heart rate (HR) or mean arterial pressure (MAP) ($p>0.05$) [Table 8, 9].

In the comparison of HR with preoperative values within the groups, a statistically significant reduction was determined in both groups in the values from 15 mins onwards compared to the preoperative values ($p<0.001$).

In the comparison of MAP with preoperative values within the groups, a statistically significant reduction was determined in both groups compared to the preoperative values ($p<0.001$). In Group I, the statistically significant reduction started from the 20th minute and in Group II, it started from the 10th minute.

In respect of side-effects, in only 1 patient in Group II, the HR fell to below 50/min (48/min)and this was corrected with the application of 0.5mg atropine iv bolus. Nausea, vomiting, hypotension or SpO2 decrease (<93%) did not develop in any patient of either group.

Table 2: Comparison of the sensory block data.

	Group I (room temperature) n=30	Group II (4 oC) n=30	p value
Time of sensory block to rreach T12 (mins)	9±3.32	12.33±4.49	0.003b *
Time to reach maximum ssensory block (mins)	20.5±6.5	20.3±7.1	0.873a
Duration of sensory block at T12 and above (mins)	162.66±38.37	143.66±42.44	0.047b *
Duration of 2 Segment regression (mins)	98±32.89	96.83±32.76	0.976b
Duration of L1 regression (mins.)	148.33±40.58	136±39.02	0.205b
Duration of sensory block (mins)	170.66±35.34	156.33±40.72	0.193b

a .Student's t test.
b. Mann Whitney U test.
* the difference between groups was statistically significant ($p<0.05$).

Table 3: Distribution of maximum sensory block levels according to the groups.
Maximum sensory block level

Group		T4	T5	T6	T7	T8	T9	T10	T11	T12	Total
I (room ttemperature)	Patient number	1	1	7	1	7	5	7	1	0	30
	%	3.3	3.3	23.3	3.3	23.3	16.7	23.3	3.3	0	100.00
II (4oC)	Patient number	0	0	4	1	5	0	10	0	10	30
	%	0	0	13.3	3.3	16.7	0	33.3	0	33.3	100.00
Total		1	1	11	2	12	5	17	1	10	60
	%	1.66	1.66	18.3	3.3	19.9	8.3	28.2	1.66	16.6	100.00

Table 4: Maximum sensory block level.

	Group I (room temp) n=30		Group II (4 oC) n=30		P value
Maximum sensory block level	* T8 (T4-T11)	** T8±1.81	* T10 (T6-T12)	** T9.7±2.11	*** 0.002

*median (min-max)
**mean ± SD
***statistical significance (p=0.002).

Table 5: Sensory block levels of the groups according to the time measurements.

Time (mins)	Group I (room temp)	Group II (4°C)	p
5 mins	L1 (L1-L2)	L1 (T10-L2)	0.020*
10 mins	T12 (T6-L2)	T12 (T8-L2)	0.032*
15 mins	T10 (T6-T12)	T12 (T6-L1)	0.013*
20mins	T9 (T5-T12)	T10 (T6-T12)	0.012*
25 mins	T8 (T4-T12)	T10 (T6-T12)	0.005*
30 mins	T8 (T4-T12)	T10 (T6-T12)	0.018*
40 mins	T8 (T4-T12)	T10 (T6-T12)	0.018*
50 mins	T8 (T5-T12)	T10 (T6-T12)	0.020*
60 mins	T9 (T5-L1)	T10 (T6-T12)	0.035*
75 mins	T9 (T5-L1)	T10 (T6-T12)	0.075
90 mins	T10 (T6-L1)	T10 (T7-L1)	0.037*

Values are stated as median (min-max)
* statistical significance (p<0.05).

Table 6: Comparison of motor block data.

	Group I (room temp) n=30	Group II (4 oC) n=30	p value
10th min Bromage score	2 (0-3) *	1 (0-3) *	0.004**
Time to onset of motor block (min)	21±9.94	23.67±9.82	0.106
Duration of Bromage Score regression from 3 to 2 (min)	129.67±39.67	117±37.79	0.190

*median (min-max) values olarak
** Difference between means was statistically significant (p<0.05).

Tablo 7: Bromage Scores of the groups according to the time measurements

Time (mins)	Group I (room temp)	Group II (4°C)	pa
5 mins	1 (0-2)	0 (0-2)	0.004
10 mins	2 (0-3)c	1 (0-3)c	0.019
15 mins	2 (1-3)c	2 (0-3)c	0.005
20mins	3 (2-3)c	2 (0-3)c	0.019
25 mins	3 (2-3)c	3 (2-3)c	0.021
30 mins	3 (2-3)c	3 (2-3)c	0.557
40 mins	3 (3-3)	3 (2-3)	0.154
50 mins	3 (3-3)	3 (3-3)	1.000
60 mins	3 (2-3)	3 (3-3)	0.154
75 mins	3 (1-3)	3 (2-3)	0.973
90 mins	3 (1-3)	3 (2-3)	0.812
pb	<0.001	<0.001	

a Inter-group comparisons (Bonferroni Correction Mann Whitney U test). (significance p<0.004).
b Intra-group comparisons (Friedman). (significance p<0.025). Evaluation was made in the first 30 mins.
c Statistically significant difference between the Bromage scores at the 5 min observation (p<0.001)

Table 8: Heart Rate values of the groups at the time measurements

Time (mins)	Group I (room temp)	Group II (4°C)	pa
Pre-op	84.6±15.2	86.6±15.0	0.616
0 min	85.1±14.4	84.3±17.1	0.839
5 mins	82.4±13.1	79.8±13.7	0.460
10 mins	79.0±13.5	78.6±12.7	0.914
15 mins	76.1±12.7d	75.9±12.8c	0.960
20 mins	73.4±11.7c	75.3±12.9d	0.545
25 mins	72.6±13.0c	74.3±13.0c	0.614
30 mins	70.7±11.6c	73.6±12.3c	0.345
40 mins	70.3±12.6c	73.3±10.8c	0.337
50 mins	70.4±11.3c	71.5±10.4c	0.706
60 mins	69.2±11.2c	71.9±11.6c	0.363
75 mins	70.3±11.5c	70.8±12.1c	0.887
90 mins	71.0±11.9c	70.6±10.7c	0.892
pb	<0.001	<0.001	

a Inter-group comparisons (Bonferroni Corrections Student's t test). (significance p<0.004).
b Intra-group comparisons (Repeated Measurements Variance Analysis) (significance p<0.025).
c Statistically significant difference with the pre-op value (p<0.001).
d Statistically significant difference with the pre-op value (p<0.01).

Table 9: Mean Arterial Blood Pressure of the groups according to time measurements

Time (mins)	Group I (room temp)	Group II (4°C)	pa
Pre-op	104.0±11.7	106.6±14.0	0.450
0 min	104.4±12.7	104.3±13.3	0.984
5 mins	97.6±12.7	102.2±11.7	0.156
10 mins	96.6±13.7	98.0±11.1c	0.658
15 mins	95.7±12.8	94.7±11.2d	0.749
20 mins	92.1±11.2c	93.1±10.8d	0.726
25 mins	91.7±10.3d	91.7±10.5d	1.000
30 mins	91.3±10.2d	92.2±10.2d	0.743
40 mins	91.5±9.9d	90.3±9.4d	0.624
50 mins	87.7±9.4d	90.9±9.1d	0.181
60 mins	87.7±9.3d	90.4±9.3d	0.259
75 mins	88.9±11.5c	91.4±10.7d	0.387

90 mins	88.2±13.0d	93.5±12.4e	0.111
pb	<0.001	<0.001	

a Inter-group comparisons (Bonferroni correction Student's t test). (significance p<0.004).
b Intra-group comparisons (Repeated Measurements Variance Analysis). (significance p<0.025).
c Statistically significant difference with the pre-op value(p<0.01).
d Statistically significant difference with the pre-op value (p<0.001).
e Statistically significant difference with the pre-op value (p<0.025).

Discussion

In this study to investigate the effects on sensory and motor blocks and haemodynamics of bupivacaine solution administered at different temperatures to the subarachnoid space, the results showed no difference in respect of haemodynamics. The decrease in blood pressure values compared to the basal values which occurred in both groups can be considered to be related to the decrease in peripheral vascular resistance with spinal anaesthesia. No side effects of SpO2 decrease, hypotension or nausea and vomiting developed in any patient to a level which would require treatment and in only 1 patient of Group II was there a fall in HR (48/min) that required the use of atropine. The sensory and motor block in Group II was determined to be at a lower level, with a slower onset and a shorter duration of spinal anesthesia.

According to Richardson et al, the upper limit of baricity in all groups is 1.00124gr/ml-1 (8). It was hypothesised that a temperature increase of levobupivacaine would increase molecular kinetic energy and thereby increase the number of moving particles with the result that it could contribute to the formation of higher sensory block levels by increasing the dissemination of spinal anesthesia (9). It was thought that a higher level of maximum sensory block was reached in Group I with the solution at room temperature by a more rapid balancing of CSF temperature following spinal anesthesia. The reduction in temperature of the Group II solution caused increased density and hyperbaric activity at 4ºC and the block level remained lower (density:1.00742 g.ml–1) (8, 9).

Within the first 1-2 minutes of spinal anesthesia (3, 4), there is a change in baricity from hyper/isobaricity towards hypobaricity. During the process of thermal balancing within the CSF, the change of the 4ºC cold solution from a hyperbaric to a hypobaric solution takes more time and explains the low level of cepahalic dissemination. In short, the balancing of CSF with LA temperature takes longer at a colder temperature. Therefore in the current study, the shorter time of Group I to reach T12 can be considered to be due to the longer time required by 0.5% levobupivacaine at 4ºC for the body temperature thermal balancing within the CSF and that the reduction in density and baricity took longer. In addition, by the reduced temperature LA increasing the pKa value, there is a greater distance from the physiological pH (10-13). Therefore, the increase created in the pKa of levobupivacaine in Group II, slowed the onset with the effect of the reduced non-ionised fraction.

In Group II, the time to 2 segment regression and L1 regression time, although not found to be statistically different, and that the duration of the sensory block at T12 and over was shorter, which was found to be statistically significant can be associated with the hyperbaricity of the solution used. The solution was less disseminated within the CSF and therefore a lower concentration was obtained. As a result of this, the block regressed quickly. The application of hyperbaric solution-weighted spinal anaesthesia in the sitting position can be considered to cause greater sensory block in T10-T12 segments and a more rapid regression.

Although not statistically significant, the onset of motor block in Group II and the regression of the Bromage score from 3 to 2 were longer. At the 10th minute the Bromage score in Group I was mean 2 and in Group II it was mean 1. The changes in the characteristics of the motor block were thought to have occurred for similar reasons to the differences in the sensory block.

In a study by Stienstra et al, a higher and less variable block was found using 3 ml 0.5% bupivacaine injected at 37ºC compared to 4ºC. In a second study, the same solutions were compared at 20ºC and 37ºC and the sensory block was higher, less variable and the duration of the blockage above specified thoracic dermatomes was found to be longer at 37ºC. The time required for 2 segment regression and the onset of sensory blockage did not change by a statistically significant degree (14-15).

Callasen et al examined the effects of 0.5% bupivacaine used at 4ºC, room temperature (23ºC) and 37ºC. The findings were basically consistent with the findings of Stienstra et al and in addition, an equal degree of high variability was determined in the maximum sensory block level of the 4ºC and the room temperature groups. For 2 segment regression, while a statistically significantly shorter time was determined in the 37ºC group than in the 4ºC group, no difference was determined between the 4ºC group and the room temperature group. The use of ephedrine was required significantly more often in the 37ºC group which had the highest sensory blockage and probably sympathetic blockage (16).

In studies investigating the effects of bupivacaine solution applied to the subarachnoid space at different temperatures on sensory block, motor block and haemodynamics, similar results to those of the current study have been obtained (14-17). There have also been in vitro studies showing the effects of the temperature of local anesthetic on density which support the results obtained in the current study (2-7, 18).

In the current study, compared to the solution at room temperature, the 0.5% levobupivacaine solution at 4ºC injected into the subarachnoid space

with the patient in the sitting position, acted hyperbarically for a longer period in the thermal balancing process within the CSF and as a result of this, a significantly lower level of sensory block was seen. In addition as there was high variability between individuals in the maximum sensory block levels obtained with the 0.5% levobupivacaine solution at 4ºC, estimation of distribution could be considered difficult.

The limitations of the current study is that the number of patient and it should be higher than 60 and spinal anesthesia was only applied in the sitting position. For confirmation of the data, it could be necessary to repeat this study by higher than 60 patients and positioning the patient on the operation side in cases where interventions are to be made unilaterally.

Conclusion

In conclusion, the results of this study have shown that in spinal anesthesia block made with 0.5% levobupivacaine which has been rendered hyperbaric at 4ºC, variable block levels originate from there being less cephalic-oriented dissemination and a lower level of sensory block with rapid regression is provided.

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