

The Comparison of Spinal Ropivacaine and Levobupivacaine for Transurethral Surgery

Transüretral Cerrahide Spinal Anestezide Ropivakain ve Levobupivakainin Karşılaştırılması

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Abstract

Objective. It was aimed to compare the efficacy of levobupivacaine and ropivacaine during transurethral resection of the prostate under spinal anesthesia.

Material and Methods: In this prospective, randomized, double-blind trial, 40 patients undergoing elective transurethral resection of the prostate under spinal anesthesia were randomized into two groups. 0.75% levobupivacaine 7.5mg (Group I) and 0.75% ropivacaine 7.5mg (Group II) were used intrathecally.

Results: There were no differences the time for sensorial block to reach T10, maximum sensorial block level, the time to reach maximum block level, motor block level at the end of surgery between the groups. The two-segment regression time was 53.75 ± 10.75 minutes in Group I and 73.25 ± 15.50 minutes in Group II ($p<0.000$), the regression time to reach T12 was 70.25 ± 17.05 minutes in Group I and 88.00 ± 20.42 in Group II ($p<0.005$), the duration of the motor block was 60.75 ± 36.93 minutes in Group I and 92.00 ± 26.03 minutes in Group II ($p<0.004$). There was not any significant difference between groups with regard to hemodynamic data and side effects.

Conclusions: This study showed that, low-dose levobupivacaine and ropivacaine used in transurethral surgery have similar effects and delivers sufficient and reliable anesthesia. Use of ropivacaine constitutes an advantage since the motor blockage level is shorter with it. As a result, it was concluded that low-dose ropivacaine and levobupivacaine used in transurethral surgery had similar effects, provided adequate and reliable anesthesia, but ropivacaine was an advantage because of the short duration of motor block.

Keywords: Spinal anesthesia, Transurethral Resection of the prostate, Ropivacaine, Levobupivacaine

INTRODUCTION

Today, endoscopic procedures for urinary system almost replaced the open surgery. The patients who are eligible for endoscopic urological procedure are usually old people. They may have associated diseases such as circulation problems, kidney function disorders and hypertension. The anesthesia which is applied for urological procedures constitutes approx. 10-20% of all of the anesthesia applications (1, 2). Regional anesthesia and specifically spinal anesthesia are preferred as

Öz

Amaç: Çalışmamızda prostatın transüretral rezeksiyon (TUR-P) cerrahisinde spinal anestezide kullanılan levobupivakain ve ropivakainin etkinliklerinin karşılaştırılması amaçlandı.

Gereç ve Yöntemler: Prospektif, randomize çift kör olarak ASA I-III risk grubunda 40 hasta çalışmaya dahil edildi. I. Grupta ($n=20$) intratekal aralığa % 0.75'lik levobupivakain 7.5mg, ikinci grupta % 0.75 'lik ropivakain 7,5 mg verilerek spinal anestezi uygulandı.

Bulgular: Gruplar arasında duyusal bloğun T10'a ulaşma süreleri, maksimum blok seviyesi, maksimum bloğa ulaşma süreleri, operasyon sonu motor blok seviyesi bakımından istatistiksel olarak anlamlı fark yoktu. İki segment regresyon süresi, grup I'de $73,25 \pm 15,50$ dk, Grup II'de $53,75 \pm 10,75$ dk, T12'ye regresyon süresi grup I'de $88,00 \pm 20,42$ dk, grup II'de $70,25 \pm 17,05$ dk, motor blok süresi ise grup I'de $92,00 \pm 26,03$ dk, grup II'de $60,75 \pm 36,93$ dk. bulundu. Hemodinamik veriler ve yan etkiler bakımından istatistiksel olarak anlamlı fark saptanmadı.

Sonuç: Çalışmamızda; düşük doz levobupivakain veya ropivakain ile yapılan spinal anestezide TUR için yeterli duyusal ve motor blok sağlandı. Ropivakain grubunda motor blok süresi anlamlı olarak kısa bulundu. Sonuç olarak transüretral cerrahide kullanılan düşük doz ropivakain ve levobupivakain'in birbirine benzer etkilerinin olduğu, yeterli seviyede ve güvenilir anestezi sağladığı, ancak motor blok süresinin kısa olması nedeniyle ropivakain kullanımının bir avantaj olduğu kanısına varıldı.

Anahtar Kelimeler: Spinal anestezi, Prostat Transüretral Rezeksiyon (TUR-P), Ropivakain, Levobupivakain

well as the general anesthesia.

Levobupivacaine is the enantiomer of the bupivacaine S (-) and it was substantiated that it has less side effects for the cardiovascular and central nervous system in many studies. It is being increasingly recognized that an alternative agent can be existent with the patients having a heart associated disease (3).

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Ropivacaine is an S enantiomer of the bupivacaine which was produced as an alternative to bupivacaine. Ropivacaine is less soluble in lipids. It blocks the A δ and C fibrilla, which are responsible for pain transmission, faster than the A α and A β fibrilla controlling the motor functions. Therefore, ropivacaine provides analgesia with less motor blockage when compared to the other local anesthetics in similar dose and concentrations (4).

In this study, systemic problems with regard to the age group of the patients to undergo transurethral surgery were considered and the sufficient sensory and motor blockage was aimed with minimal hemodynamic change. For this purpose, spinal anesthesia was applied and 7.5 mg 0.75% levobupivacaine was injected to the first group of patients and 0.75% 7.5 mg ropivacaine to the second group. It has been planned that characteristics of anesthesia and analgesia between the two agents and their impacts on the hemodynamic parameters are compared.

MATERIAL AND METHODS

ASA (American Society of Anesthesiologist) I-III risk 40 patients at the age of 40 to 80 were included into this study between 01.09.2008- 01.12.2008, who were planned to undergo transurethral resection of prostate (TURP) after the approval of the Ethical Board of our hospital was obtained. The patients who did not accept to undergo regional anesthesia or to be included into the scope of the study and had motor or sensory loss before the surgery and are contraindicated to regional anesthesia were not included into the study.

During our post-operative evaluation, informed approval forms were given to the patients and ensured that they read it and their oral and written approvals were obtained. It was explained what the post-operative pain is and how the Visual Analog Scale (VAS) to be applied for the evaluation of the pain shall be questioned. According to this, 0 was described as No Pain, 1 as Slight Pain and 10 as the worst pain imaginable within the VAS system and the patient was told that he shall be requested to assign one of these numbers to his pain.

The subjects involved into the study were randomized into 2 groups according to the medications to be injected to their intrathecal space. The study was planned as double-blind. The medication to be used for the spinal anesthesia was prepared by the researcher to apply the spinal anesthesia and monitor the patient another and an anesthesiologist who is anonymous to the patient.

All patients who were taken into the operation room were monitored. Peripheral vascular access was opened on the dorsum of the hand preferably by use of a 20G cannula. Non-invasive systolic pressure (SAP), diastolic pressure (DAP), average arterial pressure (AAP) and heart rate (HR) values were measured and recorded as pre-operative values. The patients were taken into sitting position. Asepsis/antisepsis rules were complied with and following the skin cleaning and sterile covering, 25-Gauge Quincke spinal needles were used for the L3- L4 intervertebral space and injection was made to the subarachnoid space. After free BOS flow was seen in every angle; 1 ml 0.75% levobupivacaine (7.5mg) (Chirocaine® 0.75%, Abbott) was injected to the Group I, 1 ml 0.75% ropivacaine (7.5mg) (Naropin® 0.75% AstraZeneca) to the Group II in 120 seconds. Patients were taken into supine position after injection and 0.03 mg.kg $^{-1}$ iv midazolam was injected. When

the sensory block reached to T10, surgery was started.

At the 1st, 5th, 10th, 15th, 20th, 30th and 45th minutes of the spinal injection, and at the end of the operation, and following 5th, 15th and 30th minutes of the end of the operation, HR, SAP, DAP, AAP values were measured non-invasively and recorded.

Sensory blockage level as dermatome level was evaluated and recorded with the "pin-prick" test (touching the dermatomes with a pointed needle) on the bilateral anterior axillary line until the blockage level regressed to T12, at each 2 minutes within 30 minutes after the spinal injection was completed and at each 5 minutes after the 30th minute and at each 15 minutes after the surgical procedure is finalized.

Motor block degrees, again at the same times with the Bromage scale (0 = No paralysis, 1= Can move knees and feet, cannot lift his legs properly, 2 = Cannot bend his knees, can only move his feet, 3 = Full paralysis) were measured and recorded.

Following data were recorded: the duration of the sensory block to reach T10, duration of maximum sensory block, duration to reach to maximum sensory block, regression level of sensory block to T12 and 2-segment regression time (the time passed for the sensory blockage to reach to maximum and regressed back two dermatomes), motor block degree following the surgery, finalization durations of the motor block.

Side effects such as hypotension, bradycardia, nausea, itch, headache, back ache and surgical complications such as TUR syndrome, bleeding, perforation were observed throughout the whole monitoring process. Decrease of SAP under 90 mmHg or decrease of AAP by more than 25% compared to its pre-operative value was accepted to be hypotension and 10mg ephedrine was injected to the patient in a bolus of iv. Decrease of HR under 50 beats per minute or its decrease by more than 25% compared to its pre-operative value was accepted to be hypotension and 0.5mg atropine was injected to the patient in a bolus of iv. 10 mg iv metoclopramide was administered to the patients having pre-operative and post-operative nausea complaints, 50 mg iv diphenhydramine HCl was administered to the those having itches. Oxygen saturation < 93% was accepted to be hypoxia and 3 l/min oxygen was delivered by facial mask.

If the patient felt a pain during the operation, fentanyl 1 mcg.kg $^{-1}$ was injected in a bolus of iv and recorded. Apart from this, in case of the need for sedoanalgesia, passing to general anesthesia or the change in the operation type, the patient was excluded from the study.

The patients were followed-up in post-operative recovery unit for one hour. When the sensory block level receded to T 12, if the maximal motor block level was 1 and hemodynamic parameters were stable they were sent to the service. The patients were followed-up in the service for 24 hours. VAS (Visuel Analog Scale) was recorded after assessing at 1, 3, 6, 12 and 24. hours in terms of analgesic need and the side effects.

The time passed until the first analgesic need of the patients in the post-operative period was recorded. When the VAS value reached to 4 and higher, 75 mg of diclofenac sodium i.m. was given.

After surgery the patients had been followed-up until they were discharged from the hospital in terms of complications such as pain in head, back and legs, loss of strength, urine and stools incontinence, and they were informed that they can communicate with the researchers in case of complaints after discharge.

Statistical analysis was performed by using SPSS 13.0, Statistics Packet Program. When evaluating the data, frequency distributions, percentages, standard deviations, percent values and cross tables were used. Categorical comparisons were made by using Chi-Square or Fischer's exact test. The One-Way Anova Analysis of Variance was used in order to compare whether there is a difference between the study groups of the research; and Repeated Measures Analysis of Variance was used in order to compare whether there is a within-group variance. In cases where there is a difference between the groups in terms of multiple comparisons, Tukey's HSD (Honestly Significantly Different) and Dunnett's Test were applied in order to find out into which groups the difference exists. The values of which probability (p) is lower than $\alpha=0.05$ are considered as significant and there is a difference between the groups, and therefore the values of which probability (p) is higher than $\alpha=0.05$ are considered as insignificant and there is not any difference between the groups.

RESULTS

A statistically significant difference in terms of age, gender, height, weight, ASA classification, operation type and duration between groups was not found ($p>0,05$) (Table 1).

The difference between the groups in terms of the

Table 1. Demographic Characteristics (Average \pm SD)

	Group I (n=20)	Group II (n=20)	P
Age (Years)	65,50 \pm 11,96	63,40 \pm 9,31	0,539
Gender (F/M)	20/0	20/0	1,000
Height (cm)	172,15 \pm 6,32	170,25 \pm 5,96	0,334
Weight (kg)	73,85 \pm 11,94	72,25 \pm 10,45	0,655
ASA I/II/III	1/18/1	0/18/2	0,458
Operation Type M/P	6/14	5/15	0,723
Operation Time (min)	44,20 \pm 11,57	44,00 \pm 11,65	0,957

duration to reach T10 and maximum block was not statistically significant ($p>0,05$). In both groups, the maximum block was found at the level of T8($p>0,05$). Among the groups, 2 segment regression duration and the regression time for T12 are longer in 2. Group, and the difference between these groups was found as statistically significant ($p<0,001$)($p<0,01$). A statistically significant difference in terms of the motor block level at the end of the operation was not found between the groups ($p>0,05$). The motor block times between the groups are longer in the second group, and the difference between these groups was found as statistically significant ($p<0,01$) (Table 2).

In intergroup comparisons; there was no statistically significant difference in SAB, DAB, OAB and KAH values that had been synchronously measured during the first 45 minutes following intrathecal injection and the first 30 minutes after operation ($p>0,05$).

Table 2. Block Times and Block Levels (Average \pm SD, n=%)

	Group I (n=20)	Group II (n=20)	P	
The time to reach maximum block (min)	13.8 \pm 4.7	12.7 \pm 3.1	0.40	
Maximum Block Level	T8	13 (65,0%)	11 (%55,0)	0.15
	T9	2 (%10,0)	5 (%25,0)	
	T10	5 (%25,0)	4 (%20,0)	
The time to reach T10 (min)	7,75 \pm 3,51	8,25 \pm 2,07	0.58	
Two Seg. Reg. Time (min)	53,75 \pm 10,75	73,25 \pm 15,50	0.000	
Reg. time to reach T12 (min)	70,25 \pm 17,05	88,00 \pm 20,42	0.005	
Motor Block at the end of the Operation	0	5 (%25,0)	1 (%5,0)	0.11
	1	11 (%55,0)	13 (%65,0)	
	2	4 (%20,0)	3 (%15,0)	
	3	0 (%0)	3 (%15,0)	
Motor Block Time (min)	60,75 \pm 36,93	60,75 \pm 36,93	92,00 \pm 26,03	0.004

Between the groups; a statistically significant difference in terms of additional analgesic use (Fentanyl 50mcg), atropine, antiemetic, ephedrine, headache, nausea, itching back pain ($p>0,05$)(Table 3).

Table 3. Comparison of Complications between the Groups(n / %)

	Group I (n=20)	Group II (n=20)	P	
Additional Anesthetic Fent.50mcg	0	20 (%100,0)	18 (%90,0)	0,513
	1	0 (%0,0)	2 (%10,0)	
Atropine	0	19 (%95,0)	20 (%100,0)	0,311
	1	1 (%5,0)	0 (%0,0)	
Antiemetic	0	20 (%100,0)	20 (%100,0)	1,000
	1	0 (%0,0)	0 (%0,0)	
Ephedrine	0	20 (%100,0)	20 (%100,0)	1,000
	1	0 (%0,0)	0 (%0,0)	
Headache	0	20 (%100,0)	20 (%100,0)	1,000
	1	0 (%0,0)	0 (%0,0)	
Nausea	0	20 (%100,0)	20 (%100,0)	1,000
	1	0 (%0,0)	0 (%0,0)	
Itching	0	20 (%100,0)	20 (%100,0)	1,000
	1	0 (%0,0)	0 (%0,0)	
Back Ache	0	20 (%100,0)	20 (%100,0)	1,000
	1	0 (%0,0)	0 (%0,0)	

DISCUSSION

Considering the age group of the patients who will have a transurethral surgery, the choice of local anesthetic gains an importance. The local anesthesia of which onset of effect is fast, and which is capable of forming enough sensory and motor block, and minimally affecting hemodynamic parameters should be used. Also the use of an isobaric solution is advantageous since it eliminates the necessity of position change after injection. The isobaric solutions dissolve in CSF at the level which they were injected and therefore their usage in urological surgeries is appropriate. The use of levobupivacaine and ropivacaine having these qualities as a local anesthetic

is recommended. Additionally, hemodynamic changes are limited since the block level does not rise much (5).

Wahedi and et al. stated in their studies by which they compared ropivacaine 15 0,5% mg and 22,5 0,75% mg they ensured enough analgesia 7,2% in the first group, 95% in the second group (6).

Lee and et al reported that the ED(50)s were 5.68 mg for levobupivacaine (95% CI: 4.92-6.44 mg), and 8.41 mg for ropivacaine (95% CI: 7.15-9.67 mg) in intrathecal anesthesia (7). Also we evaluated their efficiencies in our study by using the levobupivacaine and the ropivacaine in a concentration of 0,75% dosage in transurethral surgery due to the fact that there is no need for increase in the level of the anesthesia and the surgery durations are shorter. Although the dosage we used in our study was lower compared to the dosage used by Wahedi and Sell, we ensured an effective and adequate sensory and motor block by the ropivacaine 7, 5 0, 75% mg and the levobupivacaine 7,5 0,75% mg.

Malinovsky and et al. intrathecally administered bupivacaine 10 0, 2% mg to one group, and ropivacaine 15 0, 3% mg to other group for the patients undergoing a transurethral surgery (8). They did not determine a difference between the time for the sensory block to reach T10, two segments regression time and motor block time in both groups. The time for the sensory block to reach T10 was averagely found as 13 minutes, regression time for two segments was found as 24 minutes regarding the group of ropivacaine. In our study, the time for the sensory block to reach T10 was found as 8, 25 minutes in levobupivacaine group, and 7, 75 minutes in ropivacaine group. The difference was not statistically significant. In our study, two segments regression time was found as 73, 25 minutes in levobupivacaine group, and 53, 75 minutes in ropivacaine group, and the difference was statistically significant. In our study, we thought that the reason the time for the sensory block to reach T10 in ropivacaine group was shorter than the study performed by Malinovsky and et al. , and the two segments regression time was determined longer is that we used the ropivacaine in higher concentration although the ropivacaine was at a higher volume.

Cappelleri and et al. compared hyperbaric ropivacaine 7,5mg 0,5% and hyperbaric levobupivacaine 7,5mg 0,5% and hyperbaric levobupivacaine 5mg 0,5% in arthroscopic knee surgery in unilateral spinal anesthesia (9). They found the average maximum block level as T8levobupivacaine group 7,5 mg, T10 in levobupivacaine group 5 mg, T9 in ropivacaine group 7,5 mg. However, it was found as T8 in 55%, T9 in 25%, T10 in 20% of the patients within levobupivacaine group. In our study, the maximum block level was found as T8 in 65%, T9 in 10%, T10 in 25% of the patients within ropivacaine group. Cappelleri's study and our study show parallelism in terms of the average maximum block level but keep in mind that a hyperbaric solution was used for the unilateral block in the study of Cappelleri.

Casati and et al. found the average maximum block level as T6 in bupivacaine group, T8 in levobupivacaine group, T5 in ropivacaine group in a study by which they compared the hyperbaric bupivacaine 8 0,5% mg, levobupivacaine 8 0,5% mg and ropivacaine 12 0,5% mg in inguinal hernia repair surgeries, unilateral spinal block (10). Additionally, they found the ratio of the patients whose motor block ended at the end of 180

minutes as 94% in ropivacaine group, 84% in levobupivacaine group, 55% in bupivacaine group. In our study, the average motor block termination times was found as 92 minutes in levobupivacaine group, 60,75 minutes in ropivacaine group. We thought that the reason motor block termination times was shorter than the study of Casati and et al. is that the local anesthetics we used were at low volume and dosage.

Kleef and et al. compared 3 0,5% ml and 3 0,75% ml concentrations of the ropivacaine that was used intrathecally in patients who would undergo minor lower limb surgery (11). The average time to reach maximum block level was found as 15 minutes in the ropivacaine group of 0,5% , 18,8 minutes in the ropivacaine group of 0,75%. They found the average motor block level as 268 minutes in the ropivacaine group of 0,75%, 178 minutes in the ropivacaine group of 0,5%. They reported that concentration of 0,5% of the ropivacaine may be more useful in lower extremity minor orthopedic surgical procedures and transurethral surgical procedures due to the fact that concentration of 0,5% of the ropivacaine fulfills sensory and motor block in a shorter duration. And we found the average time to reach maximum block as 13,8 minutes, the average motor block time as 60,75 minutes and the regression time of the sensory block to T12 as 70,25 minutes in our study. And these results showed us that the ropivacaine in concentration of 0,75% and low volume provides adequate motor block and sensory block especially for transurethral surgical procedures.

Chung and et al compared hyperbaric bupivacaine 12 0,5% mg and hyperbaric ropivacaine 18 0,5% mg in patients who would undergo an elective cesarean (12). They found the time for the block to reach T10 as averagely 3, 2 minutes in ropivacaine group, 2, 5 minutes in bupivacaine group. They also found the time to reach maximum block level as averagely 10,6 minutes in ropivacaine group, 8,1 minutes in bupivacaine group. In our study, we found the time for the block to reach T10 in ropivacaine group 7,5 0,75 % mg as 7,75 minutes, and the time to reach maximum block level as 13,8 minutes. We thought that the reason the time to reach T10 in ropivacaine group and the time to reach maximum block level were longer in ropivacaine group is that ropivacaine was used at lower dosage and volume.

Mc Namee and et al. divided the patients for which total hip replacement would be applied into 2 groups (13). They intrathecally administered ropivacaine 17,5 0,5% mg to one group, bupivacaine 17,5 0,5% mg to other group. They reported that the sensory and the motor block time in bupivacaine group was longer and they obtained adequate anesthesia. Also in our study, the average motor block duration in ropivacaine group was found significantly shorter than the levobupivacaine group. Glasser and et al. stated in their study executed in order to assess clinical effectiveness of the levobupivacaine and bupivacaine that there had not been a statistically significant difference between levobupivacaine and bupivacaine groups in terms of systolic arterial pressures, diastolic arterial pressures, mean arterial pressures and heart rate values (14).

Taspinar and et al. stated that there had not been a statistically significant difference between levobupivacaine and ropivacaine groups in terms of systolic arterial pressures, diastolic arterial pressures, mean arterial pressures and heart rate values in their studies by which they compared 25 g Fentanyl+ levobupivacaine of 0,75 % and 25 g Fentanyl+ ropivacaine 0, 5 % in urological surgical procedures under

spinal anesthesia (15).

In our study, a statistically significant difference between levobupivacaine and ropivacaine groups in terms of systolic arterial pressures, diastolic arterial pressures, mean arterial pressures and heart rate values was not found like in the studies of Glaser and et al., Lee and et al. However, systolic, diastolic and mean arterial pressures, heart rate values in both groups were below basal value during intraoperative period. We believe that this fall in arterial pressure values depends on the decrease on peripheral vascular resistance by means of spinal anesthesia. Atropine iv 0,5 mg was administered to one patient of the levobupivacaine group whose heart rate decreased. Also, we thought that the fall in the heart rate depended on the sympathetic blockage which was the result of the spinal anesthesia.

In conclusion, the spinal anesthesia which was performed on the patients who would undergo TUR surgery by low dosages of the levobupivacaine and ropivacaine was well tolerated and an adequate anesthesia was provided in terms of the sensory and motor block. The motor block duration in ropivacaine group was statistically found shorter. When time-dependent changes of the hemodynamic parameters were evaluated, a significant difference was not determined between the groups. Any side effect and complication were not seen regarding anesthetic agent used in the patients. In the view of such data that we gained, we are of the opinion that low dosage ropivacaine and levobupivacaine we used can be used as adequate and reliable local anesthetics for transurethral surgical procedures. When we consider the age group of the patients, we are of the opinion that low dosage ropivacaine and low dosage levobupivacaine are appropriate choices so that hemodynamic parameters will be minimally affected.

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