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Comparison of the Effects of a Single Dose of Epidural Ropivacaine and Bupivacaine in Arthroscopic Operations

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Abstract: In the current study, in 40 patients with ASA I-II preoperative health status undergoing arthroscopic surgery; onset, length, duration of motor and sensory block, two segment regression time, postoperative first analgesic requirement and side effects of bupivacaine and ropivacaine on epidural anesthesia have been compared. Patients were into two equal groups randomly. Group R received 15 mL 0.5% ropivacaine, Group B received 15 mL 0.5% bupivacaine for epidural anesthesia. The groups were similar with respect of demographic proporties, Mean Arterial Pressures (MAP), Heart Rate (HR) and ASA. In both groups, onset of sensory block sufficient enough for surgery was found to be similar (Group R 16.7 min, Group B 19.2 min). Time elapsed for two segment sensory regression and total sensory regression for both groups were also similar, but total sensory regression in Group B is found to be aproximately 65 min later than in Group R, but this had statistical significance (Grup B min 286.2 min, Grup R 220.6 min) ($p = 0.004$). In lower extremities, motor block regression time was significantly longer in group B than in group R ($p<0.001$). We concluded that, ropivacaine which have similar properties with rasemic bupivacaine had shorter sensory block time and motor block removal time which allowed enough motor and sensory block for arthroscopic surgery with more safety and less side effect.

Key words: Ropivacaine, bupivacaine, epidural anesthesia, single dose, arthroscopic surgery

INTRODUCTION

It is believed that regional anaesthesia has a vast superiority over general anesthesia in orthopedic operations on the lower extremity. Methods of regional anaesthesia are preferred more today due to reasons such as low incidences of postoperational nausea and vomiting, venous thrombosis and pulmonary embolism and postoperational analgesia these methods offer, rapid mobilization of the patient and early feeding (Morgan *et al*., 2002).

With its structure, effect and pharmacodynamics similar to those of bupivacaine, ropivacaine is a newer amide-type local anaesthetic agent. In preclinic research, it was observed that ropivacaine had a lower toxic effect and that it produced an ideal anesthetic level and less motor block when applied in the same doses as bupivacaine (Brown, 2000; Berde, 2000).

The aim of this randomized, multi-center study was to compare the effects of the application of ropivacaine 0.5% and bupivacaine 0.5% in the patients who were to undergo arthroscopic operations and who were hospitalized for one day in terms of the onset of anesthesia, its duration, duration of sensory and motor block, times to two-segment regression, analgesia and side effects.

MATERIALS AND METHODS

This study, by getting the permission of the ethics committee of our hospital, was conducted on 40 subjects from ASA I-II risk group who did not have contraindications to epidural anaesthesia and who were planned to have athroscopic operations. This prospective, randomized, double blind and clinical study was carried out between February to November 2004, in the theater of Orthopaedics and Traumatology Department of the Faculty of Medicine, Gazi University, Türkiye. All the subjects received 5 mg midazolam IM 1 h before the operation with premedicational purposes.

Subjects who were taken to the operation room an hour before the operation received 15 mL kg^{-1} Ringer's lactate solution within the time elapsed till the injection of regional anaesthetic and liquid infusion maintained

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with 5 mL kg^{-1}during the operation. All 40 subjects in the study were divided into two groups based on the drugs to be injected into the epidural space. Group R was administered 15 mL ropivacaine 0.5% and Group B 15 mL bupivacaine 0.5%.

Noninvasive method was used in order to monitor Heart Rate (HR) and Mean Arterial Pressure (MAP) of all of the patients included in this study. In all subjects, while they were regionally anaesthesized in L_{3-4} interspace in a sitting position, epidural space was identified by loss of resistance technique with saline solution using 18G Tuohy standard epidural needle in a median approach. First, epidural space was checked for negative aspiration of blood or Cerebral Spinal Fluid (CSF) by a 2 mL empty injector. A test dose of 2 mL lidocaine 2% + 15 μg adrenaline was administered and, in the meantime, the patients were asked if they could feel warmth around his/her body, legs or hips, tingling sensation, numbness around the mouth or ear tingling. Aside from the test dose, 3 min later, after ensuring the absence of subjective symptoms and negative aspiration of blood or CSF, Group R was administered 15 mL ropivacaine 0.5% and Group B was administered 15 mL bupivacaine 0.5% in 3 min, with slow injection, using the single shot method. Before (control) and after the block HR and MAP were recorded noninvasively in the 5, 10, 20, 25, 30, 35, 40, 45, 60, 120 min and 4, 6, 12, 24 h. The patients whose HR decreased to below 50 per min were injected 0.5 mg atropine (atropine sulfate) Intravenously (IV). That systolic arterial pressure decreased to below 100 mmHg and that MAP decreased by 15% when compared to control values was considered to be hypotension and in that case 5mg IV ephedrine and rapid infusion of 250 mL Ringer's lactate solution were administered. The doses of ephedrine and atropine that were given when needed were recorded in the study protocol.

Level of sensory and motor block was checked in the 5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 90, 120 min and 4 h. and the level of dermatome for each patient was recorded. The desirable anaesthesia level achieved for our patients was at T_{10} level. In the groups, after the injection of the anaesthetic through the epidural space, the time for the sensory block to reach T_{10} level was determined by using pinprick testing and the operation began with the patients having adequate anaesthesia. The time when the block recessed 2 segments from the highest segment it reached was called time to 2 segment regression and the time when the block totally disappeared was called ending time of the sensory block. The level of motor block was recorded using Bromage scale [0. (no block) the patient has full flexion of feet and knees, 1 (partial block) the patient can not lift the leg up straight, is just able to move knees, 2 (almost complete block) the patient can not bend the knees, is able tomove feet only and 3 (complete block) the patient is unable to move feet joints or thumbs, has full paralysis] (Brown, 2000). Time for a degree of regression of motor block according to Bromage scale was called time to motor block regression. Time elapsed from the beginning of the athroscopic operation, skin incision to stitching was considered to be the operation period. Intraoperatively, in case of the surgeon finding the softness of the operational area insufficient or the subject needing sedation and/or analgesia, 0.5 mg kg^{-1} midazolam and/or 1 μg kg^{-1} IV bolus of fentanyl was applied; if insufficient, the operation was continued with general anaesthesia. The subjects given general anaesthesia were excluded from the evaluation in our study.

The subjects being transferred to the recovery room following the operation were observed in terms of their vital signs until the time to 2 segment regression was identified and the degree of motor block decreased to 1. After the 2 segment regression, of the patients whose motor block degree decreased to 1, those with stable hemodynamic signs were transferred to orthopedic ward.

In the post-operative period, in order to determine the first analgesic request, severity of pain was measured with Visual Analog Scale (VAS) (0: no pain 10: worst possible pain). Time elapsed till the first application of analgesic was identified as time to first request of analgesic. When VAS was ≥4, ward nurse was advised to give 50 mg diclofenac IM with at least 4 h between the doses. Each subject was restricted to a maximum daily dose of 150 mg diclofenac Sodium IM. Moreover, side effects that would possibly occur were observed and data recorded within the perioperative and postoperative 24 h. Surgeons were visited after the operation and patients were visited in the ward again at the end of first postoperative day. Surgeon and patient satisfaction degree scales were used to record data (4-excellent, 3-very good, 2-good, 1-average, 0-insufficient).

Statistical analysis was performed using SPSS 10,0 for windows (SPSS Institue, Chicago, IL). P value of less than 0.05 was considered significant. Age, weight, height, duration of the operation, time for the block to reach T_{10} level, time needed to reach a steady-state block, time to 2 segment regression and ending, comparison of the data of first analgesic requests from both groups Student's t test; evaluation of MAP and HR data, repeated measures analysis of variance, comparison between control values within the group and MAP and HR data in which time factor is found to be important in the repeated measures analysis of variance Bonferroni correction; motor and sensory block, VAS, comparison of

surgeon and patient satisfaction data between groups Mann-Whitney-U test; comparison of motor and sensory block data between groups Wilcoxon test; ASA, gender, the number of patients who developed motor block, comparison of rates of side effects between groups chi square test and Fisher's exact test were used.

RESULTS

In our study, according to the groups of the subjects no statistically significant difference was observed in terms of demographic properties, ASA distribution and operation period ($p > 0.05$), (Table 1). When MAP and HR of the groups were compared in terms of the changes they display in time, no difference was found between the groups or within the groups. The data of MAP and HR according to measurement times can be seen in Fig. 1.

Time for adequate sensory block to reach T_{10} for surgery was 16.7±7.5 min for Group R and 19.2±8.9 min for Group B, with no statistically meaningful difference observed (Table 2). When the time to two segment regression of the sensory block was considered, Group R and Group B were found to be similar with no statistically meaningful difference observed between the groups. Time for full regression of sensory block in Group R was 220.6±59.3 min and 286.2±68.2 min in Group B, with a statistically meaningful difference of ~65 min later occurrence in Group B than Group R. Time for regression (75.5±14.2 min in Group R, 120±32.4 min in Group B) and ending (133.8±63.1 min in Group R, 230.8±72.9 min in Group B) of motor block in lower extremity was observed to be longer in Group B when compared to Group R, with a statistically meaningful difference ($p < 0.001$) (Table 2) (Fig. 2). Although, motor block was achieved in 65% of the patients in Group R and all of the patients in Group B, the occurrence of motor block was meaningfully higher in Group B ($p = 0.004$) (Table 2) (Fig. 3). Although subjects were divided into groups using equal method, it was observed that the average operation periods of the subjects in Group R were 5 min longer than Group B ($p > 0.05$), (Table 1). The peak level of sensory block was identified to be T8 in Group R (30 min) and T5 in Group B (35 min). The average data of the dermatomal distribution of the sensory block levels according to measurement times can be seen in Fig. 2. When the averages of dermatomal distribution of the sensory block in the

Table 1: Demographics variables, ASA and duration of surgery [Mean ±SD, n (min-max)]

	Group R (n = 20)	Group B (n = 20)
Sex (M/F)	9/11	8/12
Age (Years)	44.4±12.1 (24-68)	49.9±15.3 (20-74)
Weight (kg)	76.4±10.7 (57-95)	84.2±17.8 (51-110)
Height (cm)	165.5±5.5 (158-178)	166.9±11.1 (148-187)
ASA (I/II)	17/3	12/8
Duration of surgery (min)	45.8±12.9 (21-70)	41.7±22.4 (16-95)

Table 2: Efficacy results sensory and motor block [Mean±SD, n (%) (min-max)]

	Group R (n = 20)	Group B (n = 20)	p
Onset to T_{10} (min)	13.6±5.1 (7-26)	12.2±6.5 (5-45)	NS
Time to onset of sensory block adequate for surgery (min)	16.7±7.5 (7-30)	19.2±8.9 (10-45)	NS
Time to two-segment regression (min)	98.0±29.1 (45-145)	108.1±51.8 (45-210)	NS
Time to complete regression in sensory block (min)	220.6±59.3 (105-360)	286.2±68.2* (170-425)	0.004
Time to regression in motor block (min)	75.5±14.2 (55-100)	120±32.4* (65-185)	0.000
Time to complete regression in motor block (min)	133.8±63.1 (85-345)	230.8±72.9* (135-415)	0.000
Patient with motor block	13(65)	20 (100)*	0.004

*p<0.05: Group R with comparative

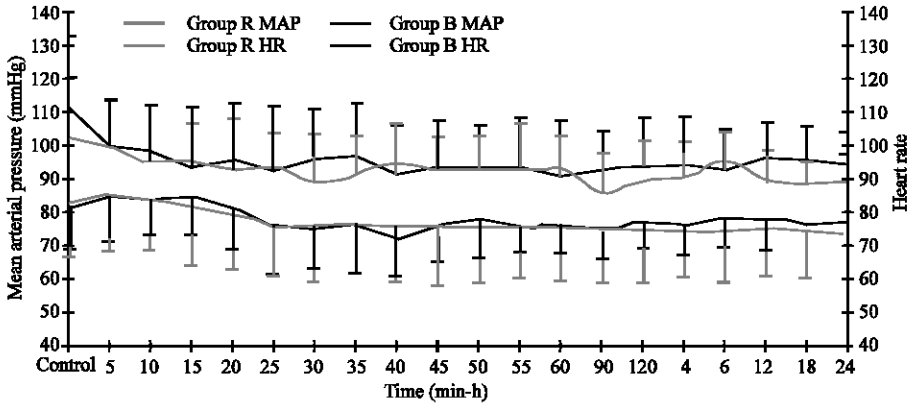

Fig. 1: Heart rate and mean arterial blood pressure (mean. SD)

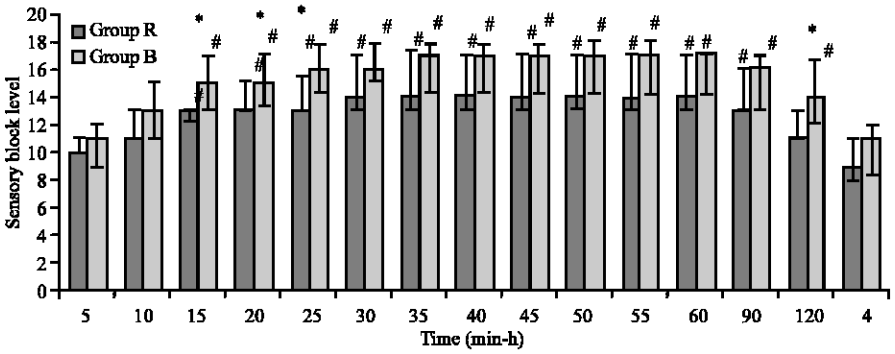

Fig. 2: Sensory block level [Median (25-75%)], *p<0.05, Group R with comparative, #p<0.05, 5. Min value with comparative

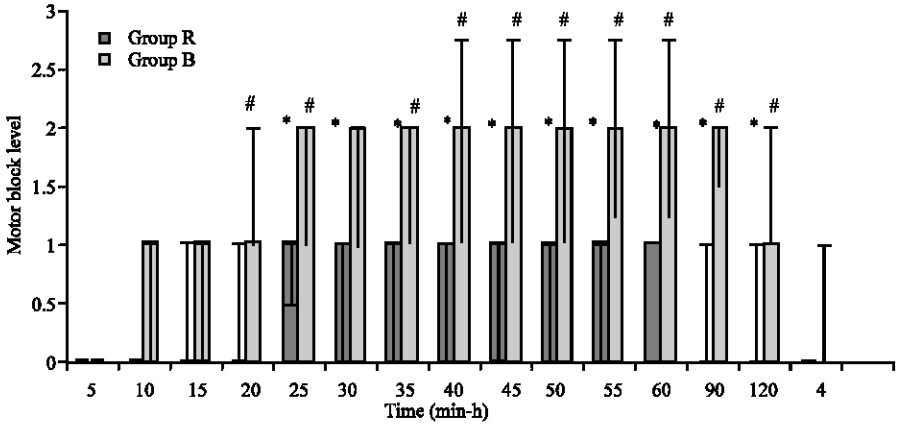

Fig. 3: Motor block level [median (25-75%)], *p<0.05, Group R with comparative, #p<0.05: 5. Min value with comparative

groups were compared in terms of the changes they display in time, it was observed that the15, 20, 25 and 120 min values in Group B were significantly high ($p<0.05$). The following results were obtained when, within the group, the differences in time were compared to control values. The dermatomal distribution average of the sensory block in the subjects, according to the average of dermatomal distribution of 5 min sensory block levels, were found to be significantly high in Group R except for the measurements from 15 min to 90 min and in Group B except for 10 min and 4 h measurements ($p<0.05$) (Fig. 2). When the distribution averages of degrees of motor block in groups were compared in terms of the changes they display in time, a difference between the groups was observed. The values between 25 and 120 min in Group B were significantly higher than in Group R ($p<0.05$). When the differences within the group were investigated according to 5 min value, the following results were obtained. The motor block degrees of the subjects in Group B increased significantly between 20 and 120 min measurements according to the distribution average of 5 min motor block ($p<0.05$). The motor block degrees of the subjects in Group R were similar to the distribution average of 5 min motor block ($p>0.05$) (Fig. 3). The satisfaction of the patient and the surgeon with anaesthesia was found to be similar in both groups. Ninety percent of the patients and 100% of the surgeons in Group R and 70% of the patients and 80% of the surgeons commented that the technique used was perfect. After the operation, when compared in terms of VAS the values being 5.00 in Group R and 4.00 in Group B, no statistically meaningful difference was observed between the groups (Table 3). First analgesic request was 415.9±158.4 min in Group B and 300.0±135.5 min in Group R, which was observed to be longer in Group B than in Group R ($p = 0.02$) (Table 3).

For each group, the rates of side effects that could possibly occur in the perioperative period can be seen in Table 4. No statistically meaningful difference was identified between the groups in none of the side effect data. In Group R, hypotension in 3 subjects, bradycardia in 2 subjects; in Group B, hypotension in 6 subjects, bradycardia and insufficient analgesia in 3 subjects were observed. All of these side effects were cured. The subjects with hypotension received 5 mg ephedrine IV and rapid infusion of 250 mL Ringer's lactate solution, the

Table 3: VAS, time to first analgesic adequate (min), satisfaction of patient and surgeon [mean ±SD, median (% 25-% 75), (min-max)]

	Group R (n = 20)	Group B (n = 20)	p
VAS	5 (1.25-7) (0-7)	4 (0-6.75) (0-8)	NS
Time to first analgesic adequate (min)	300.0±135.5 (195-720)	415.9±158.4* (225-695)	0.02
Patient satisfaction	4.0 (4-4) (3-4)	4.0 (2.25-4) (1-4)	NS
Surgeon satisfaction	4.0 (4-4) (4-4)	4.0 (4-4) (2-4)	NS

*p<0.05: Group R with comparative

Table 4: Adverse reactions showed incidence [n(%)]

	Group R (n = 20)	Group B (n = 20)	p
Nausea-vomiting	.	.	
Hypotension	3 (15)	6 (30)	0.451
Bradycardia	2 (10)	3 (15)	0.633
Vascular injury	.	.	
Dural puncture	.	.	
Confusion	.	.	
Insufficient anaesthesia	.	.	
Insufficient analgesia	.	3 (15)	0.231

subjects who developed bradycardia received 0.5 mg atropine IV, the subject with nausea and vomiting received 10 mg metoclorpropamide IV, the subject with insufficient analgesia received 1 μg kg^{-1} IV bolus of fentanyl and none of the subjects were excluded from the study.

DISCUSSION

It was observed that both regional anesthetics were effective in producing epidural anesthesia and well tolerated in patients to undergo arthroscopic surgery (Katz *et al*., 1990; Morrison *et al*., 1994; Berde, 2000). With its structure, effect and pharmacodynamics similar to those of bupivacaine, ropivacaine is a newer amide-type local anaesthetic agent. Ropivacaine is clinically used in concentrations of 1, 0.75, 0.5% (Katz *et al*., 1990; Berde, 2000).

In the clinical research conducted, it was observed that anesthetic profiles of ropivacaine and bupivacaine are similar when they are used in equal volume and concentrations in peripheral nerve block and lumbar epidural block. When it is used in peripheral nerve blocks with concentration of 0.5% and 30-35 mL volumes, the average analgesia period is 13-14 h. It is used in concentrations of 0.5-0.75 -1% and 15-25 mL volume with epidural block purposes and block period varies between 3 and 6 h in relation to volume and concentration (Katz *et al*., 1990; Morrison *et al*., 1994; Campbell *et al*., 2000; Berde, 2000).

In the preclinical studies, it was observed that ropivacaine has less toxic effect and when administered in doses equal to bupivacain, it produces an ideal level of anesthesia and less motor block (Katz *et al*., 1990; Morrison *et al*., 1994; Campbell *et al*., 2000).

In our study, there was no statistically significant difference observed in terms of demographic properties or ASA distribution. It was observed that, in both groups, the average beginning times to adequate level of anesthesia for surgery were equal (Group R 16.7 min and Group B 19.2 min). When the time to two segment regression of the sensory block is evaluated, it was observed to be similar in Group R and Group B, with no statistically meaningful difference. The time to full regression of sensory block in groups being 220.6 min in Group R and 286.2 min in Group B, a significant difference of ~65 min later occurrence in Group B than Group R was observed. Time to regression of motor block (Group R 75.5 min and Group B 120 min) and full regression of motor block (Group R 133.8 min and Group B 230.8 min) in lower extremity was found to be meaningfully longer in Group B than in Group R. Although motor block was achieved in 65% of the subjects in Group R and all of the subjects in Group B, The occurrence of motor block was meaningfully more in Group B.

In a study they conducted with a group of patients to undergo elective varix and inguinal hernia operations, Morrison *et al*. (1994) compared the anesthetic and analgesic properties of the epidural application of 0.5% ropivacaine 20 mL (100 mg), 1% ropivacaine 10 mL (100 mg) and 0.5% bupivacaine 20 mL (100 mg) and the application's effect on extra analgesic requirement. They did not observe a significant difference between the groups in terms of the onset time, duration and regression of sensory block. In both groups in our study, it was observed that the onset times of sensory block adequate for surgery were equal; however, Group B was found to be high in 15, 20, 25 and 120 min values in terms of dermatomal distribution of sensory block levels. Besides, patient and surgeon levels of satisfaction with anesthesia were found to be similar in both groups in our study.

Owen *et al*. (1998) conducted with ropivacaine and bupivacaine in concentration of 0.125% without the use of opioid, did not identify a difference in terms of the effectiveness of the 2 local anesthetics and the frequency of motor block. In our study, it was observed that the average onset times of sensory block adequate for surgery did not show difference between groups (Group R 16.7 min and Group B 19.2 min). When the time to 2 segment regression of the sensory block was considered, Group R and Group B were found to be similar with no statistically meaningful difference observed between the groups. Time for full regression of sensory block was observed to be ~65 min later in Group

B than in Group R, with a statistically meaningful difference. Time to regression of motor block (Group R 75.5 min and Group B 120 min) and full regression of motor block (Group R 133.8 min and Group B 230.8 min) in lower extremity was found to be meaningfully longer in Group B than in Group R. Although, 65% of the subjects in Group R and all of the subjects in Group B developed motor block, the occurrence of motor block was meaningfully more in Group B. According to these results, sensory block occurred in both groups although it lasted shorter in group R and motor block occurred less in Group R and it lasted shorter.

Capogna *et al.* (1999) reported that bupivacaine is a much stronger analgesic than ropivacaine in birth analgesia. McCrae *et al.* (1995) by using 0.5% ropivacaine and 0.5% bupivacaine in epidural birth analgesia, evaluated the quality of analgesia and reported that the quality of analgesia was not different in 2 groups. In our study, the quality of analgesia that both local anesthetics produced in concentration of 0.5% was found to be perfect judging by analgesic activity between the groups being more meaningfully obvious in bupivacain group than in ropivacaine group.

Finucane *et al.* (1996) administered ropivacaine in concentrations of 0.5, 0.75 and 1% and bupivacaine in concentration of 0.5% with 25 mL volume to patients to undergo lower abdominal surgery with epidural anesthesia. In terms of maximum sensory block levels, they observed no difference between groups; however, when durations of motor and sensory block were compared, as the ropivacaine dose was increased, they obtained a significant dose- response effect. In terms of motor block in groups, bupivacaine group was observed to be significantly high at certain times in comparison to ropivacaine group. It was found in our study that duration of sensory block was longer in Group B than in Group R. Although, 65% of the subjects in Group R and all of the subjects in Group B developed motor block, the occurrence of motor block was meaningfully more in Group B. According to these results, sensory block occurred in both groups although it lasted shorter in group R and motor block occurred less in Group R and it lasted shorter.

Crosby *et al.* (1998) administered ropivacaine in concentration of 0.5% and bupivacaine in concentration of 0.5% with 20-30 mL volume to patients to undergo cesarean operation with epidural anesthesia. When durations of sensory and motor block were compared, they obtained a longer sensory and motor block quality in bupivacaine group than in ropivacaine group. Besides, they observed more significant hypotension in bupivacaine group than in ropivacaine group. In our study as well, although a longer sensory and motor block quality was obtained in bupivacaine group than in ropivacaine group, hypotension and bradycardia were more significant in bupivacaine group.

McGlade *et al.* (1997) administered ropivacaine in concentration of 0.5% and bupivacaine in concentration of 0.5% with 20 mL volume to patients to undergo lower extremity surgery. When durations of sensory and motor block were compared, they obtained a longer sensory and motor block quality in bupivacaine group than in ropivacaine group. Moreover, when cardiovascular side effects were investigated, similarities between bupivacaine group and ropivacaine group were observed. In our study as well, although a longer sensory and motor block quality was obtained in bupivacaine group than in ropivacaine group, hypotension was more significant in bupivacaine group. As can be seen in literature, more side effects on cardiovascular system were encountered in our study as well.

Griffin *et al.* (1995) administered ropivacaine in concentration of 0.5% and bupivacaine in concentration of 0.5% with 20 mL volume to patients to undergo cesarean operation with epidural anesthesia. Although, onset and ending times of sensory block and onset time and spread of motor block were similar, they obtained a longer duration of motor block in bupivacain group than in ropivacaine group. Similarly, in our study, a longer sensory and motor block quality was obtained in bupivacaine group than in ropivacaine group.

In various clinical studies conducted, it was reported that anesthetic and analgesic effects of ropivacaine were similar to those of bupivacaine in the same doses. It was observed that following the epidural administration of ropivacaine, it produced a shorter sensory and motor block than bupivacaine.

It is possible to say that ropivacaine can be preferred to bupivacaine because of its similar structure to bupivacaine, producing a shorter sensory and motor block quality, producing an adequate level of sensory and motor block for arthroscopic operations and especially because of its fewer side effects.

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