The Effects of Alkalinization of 0.5% Ropivacaine by Adding Sodium Bicarbonate on Block Onset, Ending Time and Quality, and Postoperative Analgesic Efficiency for Peripheral Nerve Block in Unilateral Extremity Surgery

Tek Taraflı Alt Ekstremite Cerrahisinde Periferik Sinir Bloğu Sırasında Kullanılan %0,5'lik Ropivakaine, Sodyum Bikarbonat Eklenmesiyle Oluşturulan Alkalinizasyonun Blok Başlangıç/Sonlanış Zamanları, Blok Kalitesi ve Postoperatif Analjezi Üzerine Etkisi

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ABSTRACT Objective: To evaluate block onset/ending times and quality, and the postoperative analgesic efficiency of ropivacaine compared with ropivacaine alkalinized by the adding sodium bicarbonate solution for femoral, anterior sciatic and lateral femoral cutaneous block. **Material and Methods:** ASA1-2 48 patients undergoing lower extremity surgery were randomized into one of two groups: combined femoral, anterior sciatic and lateral femoral cutaneous block with 0.5% ropivacaine, or the same blocks with 0.5% ropivacaine+8.4% sodium bicarbonate in a ratio of 1:20. Postoperative analgesia was achieved by femoral catheter using 0.2% ropivacaine, in all patients. Groups R (non-alkalinized) and RB (alkalinized) were both further subdivided into "infusion" (10 ml.hour) and "infusion+bolus" (5 mL bolus+5 mL/hour) groups. Block onset/ending times, pain scores and amounts of local anesthetic consumed were evaluated. **Results:** Sensorimotor "onset times" were shortened and "ending times" were prolonged in the alkalinized group. Motor and the majority of dermatome sensorial block ending times were prolonged in the alkalinized "infusion+bolus" group, although the amount of local anesthetic consumed was lower. **Conclusion:** The alkalinization of 0.5% ropivacaine with 8.4% sodium bicarbonate in a 1:20 ratio used in peripheral nerve block may provide a shorter onset block time. The application of "infusion+bolus" via femoral catheter may lead to prolonged block time and reduce the consumption of local anesthetic, especially in the alkalinized group.

Key Words: Peripheral nerves; nerve block; sodium bicarbonate; lower extremity

ÖZET Amaç: Ropivakaine bikarbonat eklenmesiyle oluşan alkalinizasyonun femoral, anterior siyatik, lateral femoral kutanöz blok başlangıç/sonlanış zamanlarına, blok kalitesine, postoperatif analjeziye etkilerini değerlendirmek. **Gereç ve Yöntemler:** Alt ekstremite cerrahisi geçirecek ASA 1-2 48 hasta randomize olarak iki gruba ayrıldı. Her iki gruba femoral, anterior siyatik, lateral femoral kutanöz blok kombinasyonu yapıldı, bir grupta %0,5 ropivakain, diğer grupta ropivakaine ilave olarak %8,4'lük sodyum bikarbonat 1/20 oranında kullanıldı. Tüm hastalarda postoperatif analjezi femoral kateter aracılığıyla %0,2 ropivakainle sağlandı, ancak Group R (non-alkalinize) ve Grup RB (alkalinize), kendi içlerinde "infüzyon"(10 mL/saat) ve "infüzyon+bolus"(5 mL bolus+5 mL/saat) olarak tekrar ikiye ayrıldı. Blok başlangıç/sonlanış zamanları, lokal anestezik tüketim miktarları karşılaştırıldı. **Bulgular:** Alkalinize grupta sensorimotor blok başlangıç zamanı kısalmış, sonlanış zamanı uzamıştı. Motor ve çoğu dermatomda sensorial blok sonlanış zamanı alkalinize "infüzyon+bolus" grubunda lokal anestezik tüketimi daha düşük olmasına rağmen uzamıştı. **Sonuç:** %0,5'lik ropivakainin %8,4'lük sodyum bikarbonatla alkalinizasyonu, alt ekstremite periferik sinir blok uygulamasında blok başlangıcını kısaltabilir. Femoral kateterden "infüzyon+bolus" uygulaması özellikle alkalinize grupta uzamış blok zamanına, azalmış lokal anestezik tüketimine neden olabilir.

Anahtar Kelimeler: Periferik sinirler; sinir bloğu; sodyum bikarbonat; alt ekstremite

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Innervating the lower extremity with two plexuses and the requirement for greater volumes of local anesthetic (LA) for peripheral nerve block (PNB) in this region encouraged research into shortening block onset time by adding an adjuvant to the LA agents, thus improving the quality and total time of block.[1-6] One such adjuvant is bicarbonate. The pH values of commercial amide LAs are between 3.2 and 6.5. Since most local anesthetic solutions have a pKa between 7.5 and 9, less than 3% of LAs are 'non-ionized free-based'. The addition of sodium bicarbonate to the LA solution in order to raise the pH close to the pKa value increases the non-ionized form and solubility of LA solutions in fat, and therefore enhances conduction to the axonal membrane. As a result, this accelerates and prolongs block times, making for better anesthesia.[7] Although many clinical studies have been performed to establish the effects of alkalinization of LAs on onset and duration of regional blocks. There is a scarcity of clinical data for the alkalinization of ropivacaine, particularly in lower extremity nerve block, compared to other LAs encouraged. In addition, the majority of studies concerning alkalinization involve the single-shut technique and have focused on block commencement and conclusion. We thought that the prolonged effect of alkalinization on continuous techniques could be observed in more detail. We planned to determine whether there would be any difference in ropivacaine consumption during the first postoperative day between the groups with or without sodium bicarbonate.

Our primary aim was to investigate the impacts of adding 8.4% in a ratio of 1:20 sodium bicarbonate to ropivacaine on onset, ending times, quality of peripheral nerve block in the lower extremity. Another aim was to investigate the prolonged efficacy of alkalinization on "infusion" and "infusion+bolus" patient-controlled analgesic protocols using femoral catheters on postoperative analgesia.

MATERIAL AND METHODS

This prospective, randomized, double-blind study was conducted after institutional Ethics Committee approval and obtaining written informed consents from all patients. Fifty ASA 1-2 adult patients of both sexes who scheduled for lower extremity surgery were included. Exclusion criteria included refusal to participate, age <18 or >65, weight <50 kg or >100 kg, pregnancy, allergy to LAs, pre-existing neurological/neuromuscular deficit or inability to understand use of patient-controlled analgesia (PCA) device or pain scale.

Patients were randomized into one of two groups using sealed envelopes. In Group R (non-alkalinized), pure 0.5% ropivacaine was used, while 0.5% ropivacaine+1:20 sodium bicarbonate was used in Group RB (alkalinized) (Table 1). Patients were informed about the use of the PCA device, and a 0-100 mm visual analogue pain scale (VAS) was employed where 0 represented "no pain at all" and 100 mm represented "worst pain imaginable". IV access was established before the nerve block. Hemodynamic values including continuous electrocardiogram, noninvasive blood pressure and pulse oximetry values were monitored during all procedures. Blocks were performed after sedation with 0.05 mg/kg of midazolam IV. A "facet type unipolar needle" 20 G, 150 mm (Pajunk; Germany) was used for anterior sciatic block (ASB) and lateral femoral cutaneous block (LFCB), and a "stimulong plus catheter set" 19.5 G 50 mm (Pajunk; Germany) for femoral block (FB). All peripheral blocks were performed using the anterior classic approach (ASB with Meier's technique, FB with inguinal perivascular approach and LFCB with classic anterior approach) by the same anesthesiologist using a nerve stimulator "stimuplex" (HNS Braun; Germany). All other details concerning randomization, block application, ropivacaine and bicarbonate use and postoperative analgesic treatment protocols are shown in Table 1. Sterile syringes with LA solution were prepared by one of the authors who were not involved in group assignment and further evaluation of the patients. All follow-ups after block, surgery and postoperative period were observed by a third observer, blinded to the group assignment.

In order to evaluate the success of the block, the sensory block and motor block test results were

TABLE 1: Demographic data and surgical procedures.

	Group R	Group RB	p
Age	40.8±17.5	42.3±17.6	0.769
BMI (kg/height^2)	31.1±1.9	31.4±1.4	0.912
Sex (M/F)	19/5	13/11	0.126
ASA (I / II / III)	14/6/4	13/6/5	0.929
Op. duration (min)	67.1±21.6	75.0±28.2	0.281
Initial Data			
MAP	94.5±9.5	96.4±14.7	0.616
HR	87.3±15.1	82.7±16.9	0.319
RR	15.6±3.7	15.5±2. 8	0.896
SpO_2	98.2±1.8	97.7±2.4	0.418
Op type(n:48)	24	24	
Arthroscopy	14	14	
Amputation	2	2	
Pin removal	2	1	
Grefting	1	1	
Y.tibial osteotomy	1	1	
Plate placement	1	1	
Tendon transfer	0	1	
Achilloplasty	2	2	
Patellectomy	1	0	
Mass excision	0	1	

MAP: Mean Arterial Pressure; HR: Heart Rate; RR: Respirataury Rate). (R: Group Ropivacaine; RB: Group Ropivacaine-Bicarbonate).

recorded every minute. N. femoralis and N. obturatorius sensory blocks were checked for FB**,** N. peroneus communis, N. peroneus superficialis, N. suralis and N. femoralis cutaneus posterior for ASB, and N. cutaneus femoralis lateralis for LFCB, using the pin prick test (0: normal sensation, patient feels the pin pressure, 1: dulled sensation/analgesia, does not feel the pin being applied, 2: no sensation/anesthesia, does not feel the pin touch). In sensory tests, values of 1 and 2 were regarded as sufficient for every single dermatome. Motor block was evaluated using the Bromage Scale (BS) (0: no motor block, 1: hip flexion normal but weak knee and ankle movements, 2: weak hip and knee movements, normal ankle movement, 3: weak hip, knee and ankle movements).[8] In the BS test, 2 and 3 are regarded as sufficient values. Cases determined as sufficient in terms of sensorimotor block were operated on at the end of 30 min. A standard thigh tourniquet inflated to 150 mmHg, higher than systolic blood pressure was used on the operated leg. All hemodynamic (Hewlett-Packard Corp, CA) and VAS values were recorded during all surgical procedures.

The general clinical success of regional block was evaluated using the following scores.[9] 0: Insufficient-unsuccessful block; additional analgesic application is insufficient, additional medication or general anesthesia is needed. 1: Unsatisfactory-partly successful block; there is a need for additional analgesia and use of more than 100 μg fentanyl, 2**:** Satisfactory-successful block; no need for additional analgesia, or less than 100 μg of fentanyl used as analgesic. Patients who felt pain or discomfort at any time during surgery were given 1 μg/kg fentanyl and 0.01 mg/kg midazolam intravenously in repetitive doses. In those cases in which this was inadequate, the block was considered insufficient and general anesthesia was planned. All patients (Group R and RB) were given postoperative analgesia with 0.2% ropivacaine using a femoral catheter. Two groups of 24 patients each were randomly divided into four sub-groups (R1+R2 and RB1+RB2; n=12 in all groups) (Figure 1). VAS values were investigated 1, 2, 4, 6, 12 and 24 h after surgery. When additional analgesic (VAS>40) was required, 50 mg meperidine was administered. Sensorimotor block was evaluated every hour from onset to resolution. At postoperative hour 24, the PCA device was removed, the PNB catheter was extracted and total consumptions of LA (ml) and the frequency of bolus in all groups were recorded.

Our endpoints were block onset and ending times. A sample size of 20 per group was determined from previous studies (in which duration of sensorimotor block decreased or increased by 10%) for %99 power of study in the time of sensorimotor block onset and ending. These numbers were determined using Power and Precision version 4 statistical programs. Compatibility with normal distribution of data obtained by measurements in each group was evaluated using the Kolmogorov-Smirnov test. Two different tests were applied to evaluate alterations over time in both groups: the Mann Whitney U test was used for not normally distributed data and Student's t test for normally distributed data. The Chi-square test was used to ana-

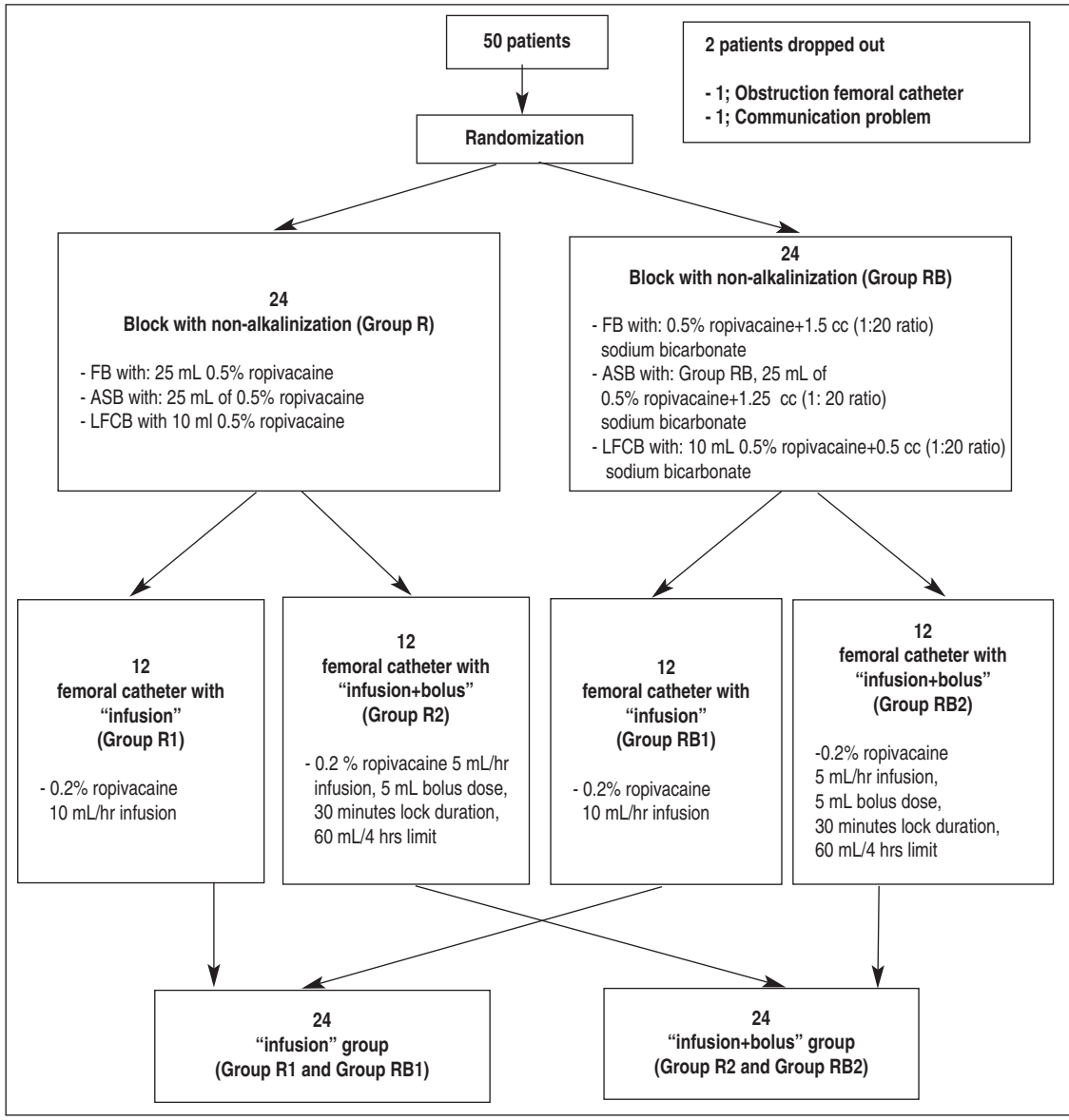

FIGURE 1: Performing blocks and postoperative analgesia treatments protochols/Distribution of patients in the groups after randomization and dropout numbers.

lyze data obtained by measurement. Wilcoxon test was used for intra-group variations. The percentage of temporal changes in the blocks between the two groups were compared. Wilcoxon Signed Ranks Test were used for intra-group comparisons. Correlations between concurrent variables belonging to a specific period were analyzed using Spearman Correlation Analysis. Significance was set at $p<0.05$.

RESULTS

There were no significant differences between the two groups in respect of demographic characteristics, operation type and duration, or vital signs before block. Immediately post-block, one patient from each group had to be excluded from the study (one for obstruction of femoral catheter and the other one for communication problems); observations of these individuals were discontinued and the study continued with 48 patients (Table 1).

No statistically significant differences were determined in terms of number of blocked nerves between Group R and RB (Figure 2). There were significant differences for intra-group comparisons of block onset and ending times. In terms of sepa-

rate nerve sensory block onset times, a statistically significant decrease was observed in Group RB, too (Table 2). When average sensory blocks onset times for nerves affected by each main block type were compared, there was a statistically significant decrease in block onset times in Group RB (Table 2). Following evaluation of all patients in terms of motor block, a statistically significant decrease was determined in Group RB at the 5th min, though no such difference was observed at mins 10, 15 or 30 (Figure 3).

Sensory block ending times are shown in Table 2. These were initially compared on the basis of Groups R and RB; sensory block was significantly prolonged for every nerve in Group RB except for FS (Table 2). When sensory block ending times were compared grouping FB, ASB and LFCB separately, we observed a significant prolonged duration of block times in Group RB (Table 2). No significant difference was determined between Groups R and RB in motor block ending times 1, 2 or 4 h post-surgery. However, at 6 and 12 h, significantly prolonged motor block times were observed in Group RB. This difference disappeared at 24 h (Figure 4). Average motor block ending times for groups R and RB were 12.54 and 18.96 h, respectively, representing a significant increase in Group RB. The latest motor block ending time in Group R was at 22 h, compared to 24 h in Group RB. The duration of sensorial block was prolonged in the alkalinized "infusion+bolus" group (RB2) compared to the non-alkalinized "infusion+bolus" group (R2). (Figure 5). Motor block durations were prolonged in the alkalinized "infusion" (RB1) and "infusion+bolus" (RB2) groups compared to the non-alkalinized groups R1 and R2 (Figure 6).

No significant difference was observed either within or between the groups for hemodynamics during the perioperative period. No statistically significant difference was determined between the frequencies and doses of the midazolam and fentanyl used during surgery. Nine patients from Group R and 5 from Group RB were given additional analgesics.

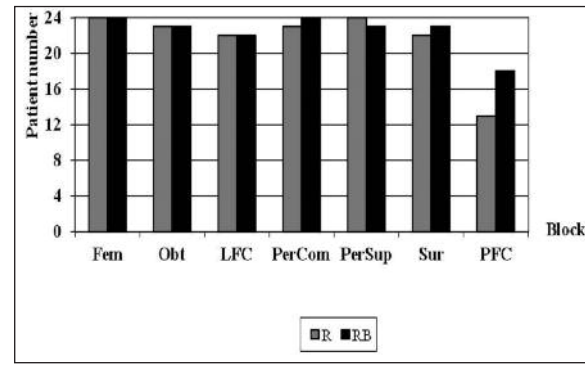

FIGURE 2: The numbers of blocked on dermatomes Femoral (Fem), obturator (Obt), lateral femoral cutaneous (LFC), peroneus communis (PerCom), peroneus superficialis (PerSup), suralis (Sur), femoralis cutaneus posterior (PFC) (respectively p=1.000, p=1.000, p=1.000, p=1.000, p=1.000, p=1.000, p=0.227).

R: Group Ropivacaine; RB: Group Ropivacaine-Bicarbonate.

TABLE 2: Sensory blockade onset and ending times.

	Onset Time (min)			Ending Time (h)		
Blocks	**Group R**	**Group RB**	**p**	**Group R**	**Group RB**	**p**
Fem (n_R:24;n_{RB};24)	13.1±6.5	7.0±3.8	**<0.001**	12.0±4.9	15.5±7.6	**0.700**
Obt (n_R:23;n_{RB};23)	14.0±6.5	7.4±4.1	**<0.001**	11.1±4.5	16.3±6.9	**0.004**
LFC (n_R:22;n_{RB};22)	18.3±6.2	11.3±5.3	**<0.001**	6.2±3.3	10.8±5.1	**0.001**
PerCom (n_R:23;n_{RB};24)	17.1±6.2	12.8± 5.3	**0.006**	6.2±2.5	10.0±4.1	**<0.001**
PerSup (n_R:24;n_{RB};23)	18.0±5.8	12.9±4.8	**0.005**	6.7±3.1	10.3±3.8	**0.001**
Sur (n_R:22;n_{RB};23)	18.5±6.4	13.7±4.4	**0.002**	7.5±4.1	10.4±3.7	**0.001**
PFC (n_R:13;n_{RB};18)	19.6±7.8	13.1±5.0	**0.009**	6.1±2.6	9.2±3.5	**0.011**
Femoral Block	26.9±13.0	14.6±7.9	**<0.001**	23.5±8.6	32.0±14.0	**0.023**
Ant Sciatic Block	20.5±13.7	13.7±5.2	**0.018**	29.1±10.5	43.8±12.4	**0.002**

The sensory block onset and ending times on dermatomes; Femoral (Fem), obturator (Obt), lateral femoral cutaneous (LFC), peroneus communis (PerCom), peroneus superficialis (PerSup), suralis (Sur), femoralis cutaneus posterior (PFC) and main blocks; femoral block, anterior sciatic block, lateral femoral cutaneous block.

R: Group Ropivacaine; RB: Group Ropivacaine-Bicarbonate.

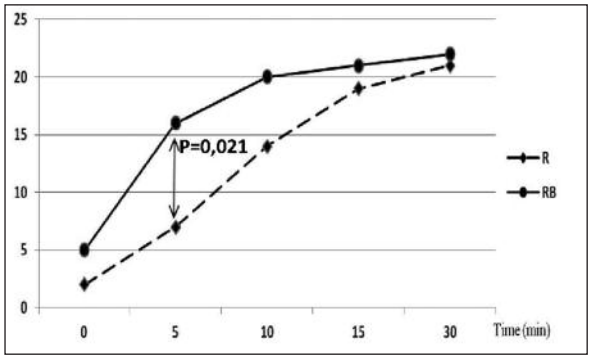

FIGURE 3: Number of patients with motor block. Bromage Score(BS):2-3 was accepted sufficient block. (p=0.021 for R and RB at 5th min).
R: Group Ropivacaine; RB: Group Ropivacaine-Bicarbonate.

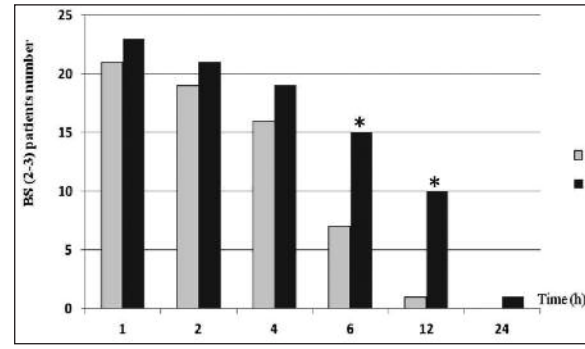

FIGURE 4: Motor block ending times. Bromage Score(BS).0-1 was accepted block ended. (p=0.609, p=0.701, p=0.516, p=0.043, p=0.006, p=1.000, at 1, 2, 4, 6, 12 and 24th hour for R vs RB, respectively).
R: Group Ropivacaine; RB: Group Ropivacaine-Bicarbonate.

Three patients both in groups R and RB needed more than 100 μg of fentanyl during surgery. These patients formed the incomplete block percentages (Group R, 12.5%; Group RB, 12.5%; p=1.000).

The results obtained comparing the total amount of LA used and the bolus application frequency in accordance with the postoperative analgesia protocol are shown in Table 3. On the basis of our 24-h postoperative pain investigation, there was no significant difference between Groups R and RB (mean VAS; 3±1.2 in Group R and 3±1.4 in Group RB, p=0.912). LA consumption and bolus frequency were lower in the alkalinized "infusion+bolus" (RB2) group compared to the non-alkalized "infusion+bolus" (R2) group (Table 3). LA consumption was lower in the "infusion+bolus" groups (R2 and RB2) compared to the "infusion" groups (R1 and RB1), respectively (Table 3).

An additional analgesic was administered to 4 patients in Group R and 2 in Group RB during postoperative24-h although the differences were not statistically significant. The total dose of intramuscular meperidine used for this purpose was 170 mg in Group R compared to 60 mg in Group RB. No side-effect or complications were observed in either group up to the end of the 24th hour.

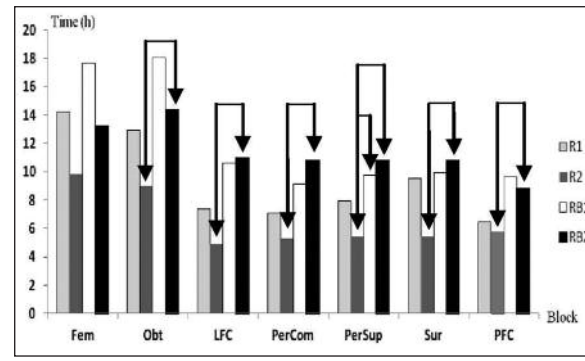

FIGURE 5: Sensory block ending times on dermatomes when comparing subgroups; Femoral (Fem), obturator (Obt), lateral femoral cutaneous (LFC), peroneus communis (PerCom), peroneus superficialis (PerSup), suralis (Sur), femoralis cutaneus posterior (PFC); For R1-RB1; p=0.221, p=0.066, p=0.191, p=0.174, p=0.234, p=0.840 and p=0.089, respectively. For R2-RB2; p=0.143, p=0.010, p=0.001, p<0.001, p<0.001, p<0.001 and p=0.043, respectively. (Group R1; infusion, Group R2; infusion+bolus, GroupRB1; infusion, Group RB2; infusion+bolus).

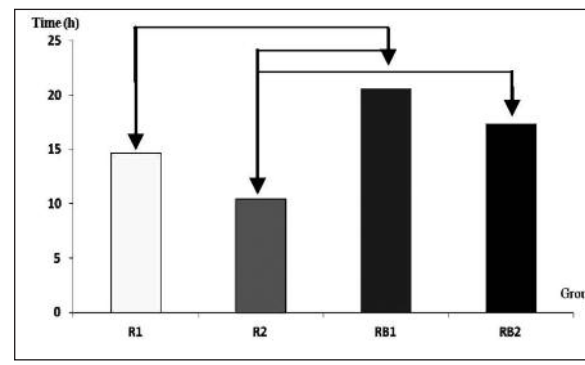

FIGURE 6: Motor block durations when comparing sub-groups (p=0.004 for R1-RB1; p=0.002 for R2 and RB2) (Group R1; infusion, Group R2; infusion+bolus, GroupRB1; infusion, Group RB2; infusion+bolus,)

DISCUSSION

While incomplete block percentage remained unchanged, there was a significant shortening in sen-

TABLE 3: Postoperative analgesia treatment characterizing data.

	Total (mL)	Bolus
R_2	189.2±54.2	13.8±10.8
R_1	240	-
RB2	126.4±15.0	2.0±9.0
R B1	240	-
p	<0.001	<0.001

(p<0.001 for R2 and RB2, R1 and R2, and RB1 and RB2) (Group R1; infusion, Group R2; infusion+bolus, GroupRB1; infusion, Group RB2; infusion+bolus).

sorimotor "onset times" and prolongation in "ending times" in the alkalinized group. Motor and the majority of dermatome sensorial block ending times were more prolonged compared to the alkalinized "infusion+bolus" group, although consumption of LA was lower.

The efficacy of the alkalinized local anesthetic solution was showed on quicker onset of anesthesia and less injection pain not only in peripheral nerve blocks but also in various regional anesthesia techniques such as intraoral or inferior alveolar nerve blocks.[10,11] Alkalinization of various of LAs with bicarbonate has been used to enhance the quality of peripheral nerve block, increasing its speed of onset.[7,12,13] However, keeping a mixture of LAs and bicarbonate for more than 20 min, or an excessive addition of bicarbonate may cause precipitation, and therefore injection of 'free base' with particles reducing bioavailability and anesthetic activity. Bicarbonate should therefore be added to LA solutions in specific concentrations and proportions and it should be added immediately before the regional technique is performed.[7] Different concentrations of LAs (0.5%, 7.5%, 1%) and sodium bicarbonate (7.5%, 8.4%) have been used together in laboratory studies in order to determine ratios that do not establish precipitation.[7,14] However, there are very few studies concerning the alkalinization of ropivacaine. In one such study, Milner et al. stated that 0.75% and 1% ropivacaine in 1% sodium bicarbonate established precipitation.[15] Since we added 8.4% sodium bicarbonate to the syringe at the precise moment of the procedure, we observed no significant precipitation. Studies regarding alkalinization in lower extremity blocks are very rare. The most recent study we found was performed by Yung et al. who used bicarbonate plus epinephrine on sciatic block in rats and demonstrated shortened and prolonged block times.[16] We met with no similar clinical studies performed on the lower extremity.

When we evaluated sensorial nerve block by nerve and took the main three blocks as a reference, block onset time was significantly shortened in the alkalinized group. Motor block establishment was significantly faster in the first 5 min in the alkalinized group, while no difference was observed after 5th min. Incomplete block percentages remained unchanged. We concluded that block success is completely dependent on technique and experience, and no alkalinization-associated effect was observed in the 'incomplete block' percentage, although the block started more quickly.

When we evaluated sensorial block ending times nerve by nerve, we determined prolonged sensorial block times in the alkalinized group in every region except for nervous trace F, and the effect of alkalinization continued during the postoperative period. Femoral block success was very high in both groups, and we observed no additional benefit from alkalinization. The high block success may be attributed to easy conduction of LA due to the superficial location of the femoral nerve. In terms of motor block ending times, no difference was observed at hours 1, 2 or 4, although a significantly prolonged motor block time was observed in the alkalinized group at hours 6 and 12. This difference disappeared at 24 h. Mean motor block ending times were 12.54 h and 18.96 h in our groups and were similar to those reported by Pandin et al.[8] The latest block ending times were hours 22 and 24, respectively. Our results suggest that alkalinization does not have unwanted consequences such as motor blocks over 24 h.

Postoperative pain treatment in peripheral nerve block procedures by means of a continuous catheter installed has been regarded as effective as IV PCA in many forms of surgery, and can be ap-

plied in various forms and combinations.[17,18] We wondered about the alkalinization effect on "infusion" and "infusion+bolus" methods in continuous femoral catheter. We observed that "infusion+bolus" methods in the block with alkalinization and non-alkalinization groups caused a prolonged sensorimotor block duration.

When we compared the non-alkalinized and alkalinized 'infusion+bolus' groups in order to evaluate postoperative pain, a significant inferiority in terms of LA consumption and bolus frequency was determined in the alkalinized 'infusion+bolus' group. Disregarding alkalinization, we again observed significantly lower LA consumption in the 'bolus+infusion' groups. We concluded that the application of "bolus" was an effective method of reducing pain and LA use, reducing the use of unnecessary dose of LA.

There were some limitations to this study. First, our study included different types of surgery. Since mean VAS values under 24-h postoperative PCA monitoring were similar in all groups, we think that the inclusion of different surgeries in the study is a situation that can be disregarded. However, our investigation referred to rest pain, and pain status during exercise was not evaluated separately. Had we also monitored these times we would have been better able to discuss the likely benefit of a "bolus" as desired at such times as movement or conscious exercise.

In conclusion, in this prospective, randomized, double-blinded study, we observed that the alkalinization of ropivacaine shortened block onset time, but had no positive effect in reducing the 'incomplete' block percentage. It also contributed to post-surgical analgesia with its prolonged sensorimotor block periods without an undesirably excessive duration greater than 24 h. We also concluded that the "bolus+infusion" method as a PCA protocol applied by a femoral catheter, in particular following block performed by the alkalinization of LA, may provide more efficient analgesia compared to the "infusion" method, and may thus reduce total LA consumption.

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