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Tramadol as an adjunct for levobupivacaine in axillary plexus blockade: a prospective, randomized, double-blind study*

Bülent Serhan YURTLU[1], Volkan HANCI[1], Ahmet EGE[2], Selime Evrim BOSTANKOLU[1], Hilal AYOĞLU[1], Işıl ÖZKOÇAK TURAN[1]

Aim: To evaluate the effect of tramadol addition to levobupivacaine in axillary plexus blockade in a prospective, randomized double-blind study.

Materials and methods: A total of 60 patients scheduled to undergo hand and forearm surgery under axillary plexus blockade were randomly divided into 2 groups. Group L received 36 mL of racemic 0.5% levobupivacaine with 2 mL of saline, whereas Group LT received 2 mL (100 mg) of tramadol instead of saline. After routine monitorization, axillary block was performed with a multistimulation technique using a nerve stimulator. Motor (finger, wrist, and elbow movements) and sensory (pinprick sensation for the cutaneous supply) block characteristics for radial, median, ulnar, and musculocutaneous nerves were determined every 5 min. Postoperative motor and sensory block duration, analgesic consumption, and numeric rating scale (NRS) scores were also recorded.

Results: In each group, 2 patients had block failures. The data for the remaining 56 patients were analyzed. There were no significant differences between the study groups according to motor and sensory block characteristics of 4 nerves, block durations, analgesic consumption, and NRS scores.

Conclusion: The addition of 100 mg of tramadol to 0.5% levobupivacaine for axillary brachial plexus blockade neither improved the intraoperative block quality nor prolonged the duration of postoperative analgesia.

Key words: Nerve blockade, levobupivacaine, tramadol

Aksiller blokta levobupivakaine eklenen tramadol: Randomize, prospektif, çift kör bir çalışma

Amaç: Bu randomize prospektif çift kör çalışmada aksiller pleksus bloğunda levobupivakaine tramadol eklenmesinin etkilerini araştırmayı amaçladık.

Yöntem ve gereç: El veya önkolda cerrahisi için aksiller pleksus bloğu planlanan 60 hasta randomize olarak iki gruba ayrıldı. Grup L'de 36 mL % 0,5 levobupivakain ve 2 ml serum fizyolojik; Grup LT'de 36 mL % 0.5 levobupivakain ve 2 mL 100 mg tramadol kullanıldı. Rutin monitörizasyonu takiben aksiller blok sinir stimülatörüyle çoklu stimülasyon tekniği kullanılarak uygulandı. Motor (parmak, el bileği, dirsek hareketleri) ve duyusal (kutanöz pinprik duyusu) blok karakteristikleri radiyal, medyan, ulnar ve muskulokutanöz sinirler için her 5 dakikada değerlendirildi. Postoperatif motor ve duyusal blok süresi, analjezik tüketimi ve nümerik ağrı skoru (NRS) kaydedildi.

Bulgular: Her grupta 2'şer hastada blok başarısızlığı mevcuttu. Kalan 56 hastanın verileri analiz edildi. Çalışma grupları arasında dört sinirin motor ve duyusal blok karakteristikleri, analjezik tüketimleri ve NRS skorları arasında fark yoktu.

Sonuç: Aksiller blokta % 0,5 levobupivakaine 100 mg tramadol eklenmesi intraoperatif blok kalitesini artırmamış ve postoperatif analjezi süresini uzatmamıştır.

Anahtar sözcükler: Sinir bloğu, levobupivakain, tramadol

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[1] Department of Anesthesiology and Reanimation, Faculty of Medicine, Zonguldak Karaelmas University, Zonguldak - TURKEY
[2] Department of Orthopedics and Traumatology, Faculty of Medicine, Zonguldak Karaelmas University, Zonguldak - TURKEY
Correspondence: *Bülent Serhan YURTLU, Department of Anesthesiology and Reanimation, Faculty of Medicine, Zonguldak Karaelmas University, Esentepe, Kozlu, Zonguldak - TURKEY*
E-mail: syurtlu@hotmail.com

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Introduction

Adjuvants such as clonidine and sufentanil were found to be effective in enhancing block quality when used in combination with local anesthetic solutions (1). In recent years, the local anesthetic effect of tramadol, when injected perineurally, has been demonstrated (2).

This effect led to the idea of using tramadol as an adjunct for brachial plexus anesthesia in combination with various local anesthetics including lidocaine, mepivacaine, and ropivacaine (1,3-5).

Levobupivacaine, a pure S(-)-enantiomer of racemic bupivacaine, was introduced into clinical practice with the advantage of producing less cardiotoxicity when compared with bupivacaine. Although this is very valuable in peripheral plexus blockades where high doses of the local anesthetic is needed (6,7), the long onset time of the drug obscures this advantage (8). Since many investigators have demonstrated that the addition of tramadol to local anesthetics increases the duration of analgesia (1,3-5), we hypothesized that tramadol could increase analgesia duration when coadministered with levobupivacaine for brachial plexus anesthesia. This study was designed to determine the effect of tramadol addition to 0.5% levobupivacaine on the onset and duration of motor block and the duration of analgesia during axillary brachial plexus block.

Materials and methods

Ethics: After approval of the Ethics Committee of Zonguldak Karaelmas University Hospital, Zonguldak, Turkey (number 2008/03-16) and receipt of written informed consent from patients scheduled for orthopedic or reconstructive hand and forearm surgery, 60 patients were enrolled in this prospective, double-blind randomized study. Patients with a body mass index above 30 kg m^{-2} and American Society of Anesthesiologists (ASA) physical status over II, who received analgesic drugs 12 h prior to surgery, or who suffered from central or peripheral neuropathies, cardiac rhythm abnormalities, hepatic or renal insufficiency, and bleeding disorders were not included in the study.

Patients were premedicated with 0.07 mg kg^{-1} intramuscular midazolam 30 min prior to arrival to the operating room. All patients had been previously informed of the numeric rating scale (NRS), with scores ranging from 0 (no pain) to 10 (worst pain imaginable). After standard anesthesia monitorization, baseline hemodynamic values and pain scores were recorded. An infusion of 0.9% saline solution was begun with a 20-gauge intravenous cannula placed on the nonoperated arm. An anesthesiologist who was not involved in the block procedure prepared the study drugs according to the random envelope method. The axillary plexus blockade in Group L was performed with a combination of 36 mL of 0.5% levobupivacaine and 2 mL of 0.9% saline. Group LT received the same amount and concentration of levobupivacaine, which was combined with 2 mL of tramadol (50 mg mL^{-1}). Another anesthesiologist blinded to the study drugs performed the block procedures and recorded all of the data. After skin preparation with an antiseptic solution, the block site was infiltrated with 1 mL of 2% lidocaine, and a standard approach for plexus blockade was applied by using a peripheral nerve stimulator (Stimuplex® HNS 11; B. Braun, Melsungen, Germany) and a 22-gauge needle (50 mm, insulated short bevel, Stimuplex®; B. Braun). The triple injection technique was used in order to achieve a higher success rate with the blockade of the musculocutaneous nerve (9). The needle was first placed above the artery to localize the median nerve and 15 mL of the study drug was injected following the unique muscle responses at 0.3 mA (100 μs 2 Hz^{-1}). The needle was then placed below the artery seeking radial or ulnar nerve responses, and another 15 mL of the drug combination was injected. Finally, the musculocutaneous nerve was localized outside the brachial sheet and 8 mL of the study drug was injected. An additional 5 mL of 2% lidocaine was injected subcutaneously on both sides of the axillary artery pulsation to block the intercostobrachial nerve. The sensory and motor block evaluations were done when the injections were completed and repeated every 5 min for an interval of 45 min. The sensory block was assessed with the pinprick test at cutaneous innervation sites (0 = no block; 1 = loss of pinprick sensation, analgesia; 2 = loss of touch, complete anesthesia). The time between completion of the block procedure and loss of sensation to the pinprick test was accepted as the onset time of sensory block. The time required for sensory block to reach its maximum level

was defined as time to maximal sensory block. Motor block was also evaluated for each nerve by abduction of thumb or wrist extension for the radial nerve, wrist flexion for the median nerve, flexion of fingers for the ulnar nerve, and flexion of elbow or supination of forearm for the musculocutaneous nerve. The degree of motor block was graded according to the strength of corresponding movement with a 3-point scale (0 = no motor block, 1 = reduced power, 2 = total abolishment of movement). Time required for motor block to reach its maximum level was defined as time to maximum block. Hemodynamic parameters and sedation scores (1 = awake and alert; 2 = sedated, responding to verbal stimulus; 3 = sedated, responding to physical stimulus; 4 = not arousable) were recorded with sensory and motor block assessments at the same time intervals. At the end of 45 min, if the patient had no evidence of sensory block at any of the 4 nerves' distribution areas, this was considered as block failure. These patients received additional nerve block or general anesthesia and were excluded from the study. The addition of 50 μg of incremental fentanyl with a maximum dose of 200 μg was planned if the patient complained of pain at the surgical site. The patients who needed supplementary analgesics were excluded from the study. Motor block duration was accepted as the time elapsed between the end of the block procedure and the patients' first feeling that their fingers, hands, or arms were moving freely. Duration of analgesia was accepted as the time between the end of axillary block and the patient's first request for analgesia. Postoperative analgesia was achieved with 75 mg of intramuscular diclofenac upon the patient's first analgesic request and intravenous patient-controlled analgesia with tramadol.

Side effects such as respiratory depression, pruritus, nausea, and vomiting were recorded.

Statistical analysis

Power analysis was based on the duration of analgesia, which was the primary outcome variable for our study. The study sample size and standard deviation (SD) were determined from previous work and data (10). In order to detect a 25% difference in analgesia duration with a SD of 4.1 h (10), a significance level of 0.05, and a power of 80%, the adequate sample size was calculated as 27 patients per group. Assuming a 10% dropout rate, 30 patients were enrolled in each group.

Data were expressed as mean ± SD. SPSS 11.5 (SPSS Inc., Chicago, IL, USA) was used in the analysis of the data. The Mann-Whitney U test was used to compare continuous measures such as hemodynamic variables, SpO_2, onset time of analgesia, and motor block values. The chi-square test was used to compare data that denoted frequency, such as sex and ASA risk category. A value of $P < 0.05$ was considered as statistically significant.

Results

A total of 60 patients were enrolled in this study. There were 2 block failures in each group. The data for the remaining 56 patients were analyzed.

Demographic data

No difference was observed between Group L and Group LT with respect to age (P = 0.549), sex (P = 0.373), weight (P = 0.712), or ASA physical status (P = 0.384) (Table 1).

Characteristics of the operations

Surgical sites (P = 0.384) and duration of the operations (P = 0.521) were similar (Table 2). An upper arm tourniquet was used in all of the operations.

Table 1. Demographic data of the study groups.

	Group L (n = 28)	Group LT (n = 28)	P
Age (years, mean ± SD)	38.14 ± 14.50	36.14 ± 13.37	0.549
Weight (kg, mean ± SD)	75.00 ± 13.37	73.14 ± 11.76	0.712
Sex (F/M; n, %)	7 (25%) / 21 (75%)	5 (17.9%) / 23 (82.1%)	0.373
ASA (I/II; n, %)	19 (67.9%) / 9 (32.1%)	21 (75%) / 7 (25%)	0.384

Table 2. Operation sites and duration of the operation.

	Group L (n = 28)	Group LT (n = 28)	P
Operation duration (min, mean ± SD)	95.00 ± 55.73	114.29 ± 77.62	0.512
Operation sites			0.384
Hand (n, %)	19 (67.9%)	21 (75%)	
Forearm (n, %)	9 (32.1%)	7 (25%)	

Characteristics of the brachial plexus blockade

Onset times of sensory and motor block, maximum sensory and motor block levels, and times needed to reach to the maximum sensory and motor block levels were similar in both groups (Tables 3 and 4).

The numbers of patients who developed anesthesia, analgesia, or no block at the peripheral innervation areas of the median, ulnar, radial, and musculocutaneous nerves at 5, 10, 15, 30, and 45 min after injection were similar (Figure 1).

Analgesia and motor block durations of the groups were also similar.

Hemodynamic changes, complications, and intraoperative analgesic requirements

No significant differences were found in the mean blood pressure, heart rate, peripheral oxygen saturation, or sedation scores between the groups. Throughout the study period, side effects such as respiratory depression were not observed in either group ($P > 0.05$). Intraoperative fentanyl was needed in 3 patients in Group L and 1 patient in Group LT,

Table 3. Characteristics of sensory block (mean ± SD).

	Group L (n = 28)	Group LT (n = 28)	P
Loss of pinprick sensation			
Onset time (min)			
Radial nerve	10.39 ± 6.80	8.50 ± 5.97	0.088
Ulnar nerve	10.75 ± 8.67	9.04 ± 6.98	0.361
Median nerve	9.11 ± 5.01	9.29 ± 6.36	0.709
Musculocutaneous nerve	11.32 ± 7.59	9.10 ± 5.64	0.257
Maximal sensory block level (1/2; n, %)			
Radial nerve	4 (14.3%) / 24 (85.7%)	3 (10.7%) / 25 (89.3%)	0.500
Ulnar nerve	3 (10.7%) / 25 (89.3%)	2 (7.1%) / 26 (92.9%)	0.500
Median nerve	2 (7.1%) / 26 (92.9%)	5 (17.9%) / 23 (82.1%)	0.211
Musculocutaneous nerve	6 (21.4%) / 22 (78.6%)	4 (14.3%) / 24 (85.7%)	0.364
Time to maximal sensory block level (min)			
Radial nerve	19.54 ± 9.52	18.82 ± 10.86	0.487
Ulnar nerve	19.25 ± 10.90	18.32 ± 11.40	0.666
Median nerve	19.96 ± 11.59	20.46 ± 11.55	0.784
Musculocutaneous nerve	19.64 ± 10.69	18.92 ± 10.85	0.842
Analgesia duration (min)	606.79 ± 171.64	669.46 ± 248.67	0.278

Table 4. Characteristics of motor block (mean ± SD).

	Group L (n = 28)	Group LT (n = 28)	P
Motor block			
Onset time (min)			
Radial nerve	9.25 ± 3.61	8.78 ± 6.72	0.081
Ulnar nerve	9.29 ± 6.97	10.75 ± 8.21	0.732
Median nerve	10.10 ± 6.06	9.75 ± 6.64	0.462
Musculocutaneous nerve	8.50 ± 4.28	10.60 ± 8.10	0.690
Maximal motor block level (1/2; n, %)			
Radial nerve	9 (32.1%) / 19 (67.9%)	6 (21.4%) / 22 (78.6%)	0.274
Ulnar nerve	6 (21.4%) / 22 (78.6%)	8 (28.6%) / 20 (71.4%)	0.379
Median nerve	4 (14.3%) / 24 (85.7%)	7 (25%) / 21 (75%)	0.251
Musculocutaneous nerve	8 (28.6%) / 20 (71.4%)	8 (28.6%) / 20 (71.4%)	1
Time to maximum motor block (min)			
Radial nerve	15.18 ± 8.31	18.82 ± 9.30	0.079
Ulnar nerve	18.96 ± 10.97	20.53 ± 10.74	0.509
Median nerve	20.54 ± 10.19	19.82 ± 10.38	0.729
Musculocutaneous nerve	17.39 ± 11.47	19.53 ± 9.29	0.151
Motor block duration (min)	608.21 ± 152.93	656.96 ± 212.36	0.147

and the difference was not statistically significant (P = 0.305). Four patients in Group L and 3 patients in Group LT experienced nausea/vomiting, but the difference was not significant (P = 0.500). Self-limited pruritus occurred in 1 patient in group L and 3 patients in Group LT (P = 0.305).

Postoperative analgesic consumption

There were no significant differences between the groups in terms of the postoperative NRS scores (Figure 2) and postoperative analgesic consumption (P = 0.816).

Discussion

This prospective, randomized double-blind study has shown that coadministration of 100 mg of tramadol with 0.5% levobupivacaine in axillary brachial plexus anesthesia did not affect the block onset, intraoperative block quality, postoperative analgesia and motor block duration, or postoperative analgesic consumption.

Previous studies performed at our institution showed the local anesthetic-like effects of tramadol (11-14). The local anesthetic effect of tramadol, when used as a sole agent for nerve blockade, led to the idea of using this drug as an adjunct for neuraxial blocks and peripheral nerve blockades (1-5,9,10,15,16). However, its mechanism of action on peripheral nerves was not clearly explained. According to a comparative study on frog sciatic nerve with lidocaine, the nerve blocking capacity of tramadol was 3 to 6 times weaker than that of lidocaine (17). Furthermore, the local anesthetic effect of tramadol was enhanced by the addition of calcium to the test solution, whereas the effect of lidocaine decreased (17). This finding may suggest a mechanism of action of tramadol that is different from local anesthetics, which create their action by sodium channels. It

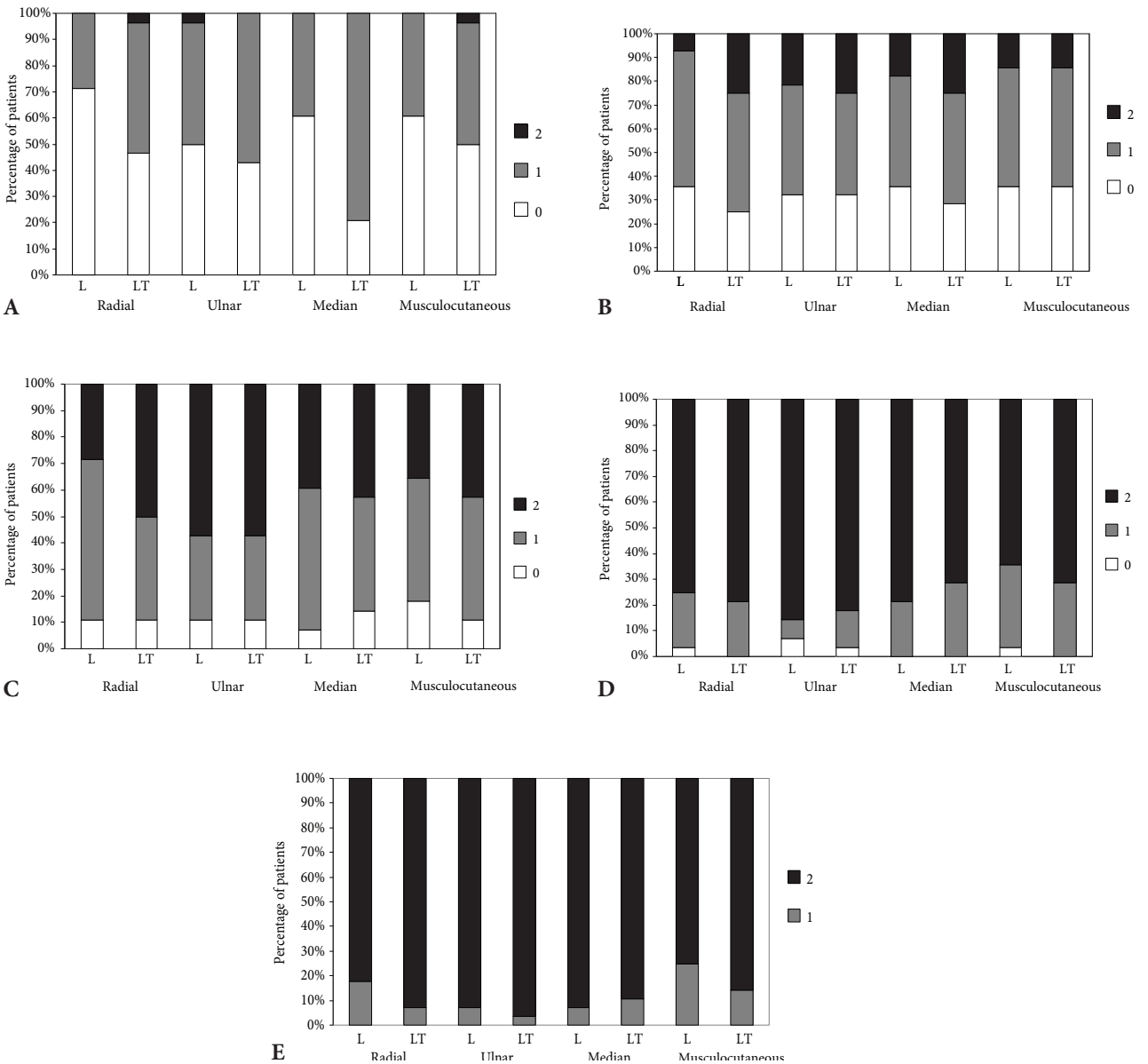

Figure 1. Number of patients receiving axillary brachial plexus block with levobupivacaine (L) or levobupivacaine plus tramadol (LT) who developed anesthesia (black, 2), analgesia (gray, 1), or no block (white, 0) at the peripheral innervation areas of the median, ulnar, radial, and musculocutaneous nerve A) 5 min after injection, B) 10 min after injection, C) 15 min after injection, D) 30 min after injection, and E) 45 min after injection.

has been suggested that tramadol shows its effect by potassium channels, like meperidine (17).

In clinical studies, the beneficial effect of tramadol as an adjuvant in perineural procedures is controversial. When administered epidurally, 100 mg of tramadol was found to be effective for postoperative analgesia after cesarean section (18). On the other hand, the intrathecal coadministration of 25 mg of tramadol with 15 mg of bupivacaine was not more beneficial than intrathecal saline with 15 mg of bupivacaine (15).

The same controversy exists for peripheral nerve blockade. Tramadol as an adjunct for brachial plexus anesthesia was shown to have beneficial effects

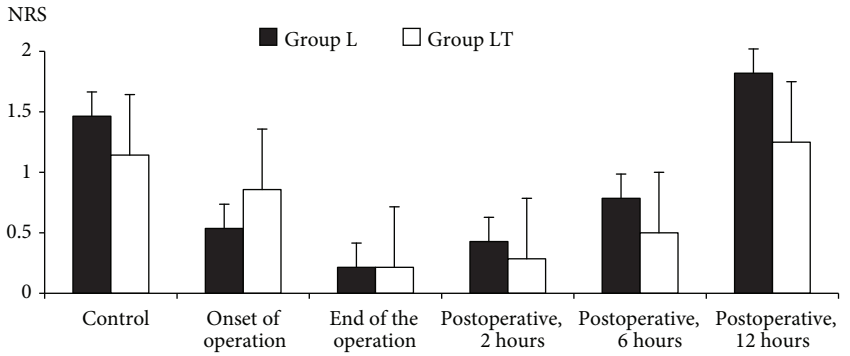

Figure 2. Perioperative NRS scores of the groups.

NRS: Numeric rating scale; 0 = no pain, 10 = worst pain imaginable.

when used with local anesthetics with intermediate duration of action, such as lidocaine and mepivacaine (3,4). The tramadol addition increased sensory block duration and time to first analgesic request when coadministered with lidocaine (3). In another study, adjuvant tramadol with mepivacaine prolonged sensory and motor blockade or delayed the first pain medication time in a dose-dependent fashion (4). Tramadol has also been shown to prolong duration of anesthesia when premixed with articaine for dental extraction procedures (19). Therefore, it can be concluded that tramadol prolongs the duration of analgesia when coadministered with local anesthetics that have a short to intermediate duration of action. In the only study comparing intravenous and adjuvant tramadol in brachial plexus blockade, anesthesia was found to be enhanced by adjuvant tramadol but not by its systemic administration (20).

The combination of tramadol with various long-acting local anesthetics at different block sites has been studied (1,5,10,16). Mannion et al. (10) used 1.5 mg kg^{-1} tramadol as an additive for psoas compartment blockade with 0.4 mL kg^{-1} of 0.5% levobupivacaine and compared the results with those of placebo and systemic tramadol administrations. They concluded that the addition of tramadol did not cause any difference, compared to either placebo or bolus systemic administration, except for higher sedation in systemic use (10). In another study, a catheter was placed into the psoas compartment and continuous infusion of 1.5 mg kg^{-1} tramadol with 0.25% bupivacaine was compared with continuous infusion of 0.25% bupivacaine alone (16). There were no improvements in the quality or duration of analgesia (16). Therefore, despite the different techniques, local anesthetics, and concentrations, tramadol did not exhibit an additional benefit for this type of regional block.

For brachial plexus blockade, Antonucci (1) compared the effect of tramadol with clonidine and sufentanil in combination with 20 mL of 0.75% ropivacaine and stated that tramadol accelerated the onset time of blockade and prolonged the duration of anesthesia and analgesia with minimal side effects. However, Kesimci et al. (5) did not observe these effects when 40 mL of 0.75% ropivacaine was used for the same block. They stated that the high volume of local anesthetic in their study might have had an effect on the local neural spread and concentration of tramadol (5). Tramadol's additive effect may have been masked in our study as we also used 36 mL of 0.5% levobupivacaine. The differences in block sites, choice of local anesthetics, and concentrations and doses of local anesthetics and tramadol make comparisons difficult. The results of this study demonstrate the ineffectiveness of tramadol addition to levobupivacaine, as was previously demonstrated for ropivacaine.

Since the preferred tramadol dose in many of the previous studies was 100 mg, we used the same tramadol dose. Increasing the dose of adjuvant tramadol to 200 mg delayed the onset time of anesthesia (3).

Previous studies have shown that levobupivacaine can be used in high doses for axillary plexus blockade

(21,22). Although no adverse effect has been reported due to such dosages, we limited the upper dose of levobupivacaine to 3 mg kg^{-1} in our study. The addition of 2 mL of either saline or tramadol allowed for an adequate volume of local anesthetic mixture to perform brachial plexus blockade.

Duration of analgesia was determined by patient requests for administration of an analgesic rather than direct evaluation of sensory block for each nerve; this might be considered as a limitation of our study.

In conclusion, 100 mg of tramadol combined with 0.5% levobupivacaine does not offer an advantage in terms of block characteristics or postoperative analgesia in axillary brachial plexus blockade.

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