A comparison of different volumes of bupivacaine used in fascia iliaca compartment block

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ABSTRACT

BACKGROUND: Fascia iliaca compartment block (FICB) is one of the regional techniques applied for post-operative pain control after femoral and knee surgery. To the best of our knowledge, there are limited reports focusing on local anesthetic (LA) volume. Our aim in this study was to find the most clinically effective volume by comparing three different volumes of LA used frequently in the literature for US-guided infra-inguinal FICB for post-operative pain control in patients undergoing femur and knee surgery.

METHODS: A total of 45 patients with ASA I-III physical scores were included in the study. When the surgical procedure was completed under general anesthesia, FIKB was applied with 0.25% Bupivacaine under ultrasound guidance to the patients before extubation. Patients were randomly divided into three different groups for the volume of local anesthetic to be administered. Bupivacaine was administered 0.3 mL/kg in Group 1, 0.4 mL/kg in Group 2 and 0.5 mL/kg in Group 3. After FIKB, the patients were extubated. The patients were followed up for 24 h postoperatively in terms of vital signs, pain scores, additional analgesic requirement, and possible side effects.

RESULTS: When the post-operative pain scores were compared, the scores of Group I were found to be statistically higher than Group 3 at the post-operative Ist, 4th, and 6th h (p<0.05). When the additional analgesia requirement compared, the post-operative 4th h was highest in Group I compared to the other groups (p=0.03). At the post-operative 6th h, additional analgesic requirement was less in Group 3 than in the other groups, and there was no difference between Groups I and 2 (p=0.026). As the LA volume increased, the amount of analgesic consumed in the first 24 h decreased, but there was no statistically significant difference (p=0.051).

CONCLUSION: Our study showed that ultrasound-guided FIKB is a safe and effective method for post-operative pain relief as a part of multimodal analgesic components, and 0.25% bupivacaine in 0.5 mL/kg volume provides more effective analgesia than the other two groups without any side effects.

Keywords: Bupivacaine; fascia iliaca compartment block; femur surgery; post-operative analgesia; ultrasound.

INTRODUCTION

By providing early mobilization, the effective application of pain control is helpful in the reduction of potential mortal complications such as pulmonary emboli, shortening hospital stays, and reducing health-care costs.^[1]

With current technological developments in the area of re-

gional anesthesia and the guidance of training materials, applications of postoperative analgesia are continuously increasing. Fascia Iliaca compartment block (FICB) is one of the methods applied in post-operative pain control in the lower extremities, particularly following femur and hip, and knee surgery, and is a technique which does not require a nerve stimulator and it can be applied from anatomic landmarks or under US guidance. [2] Although the volume of local anesthetic (LA) is

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very important for plan blocks include FICB, the increased risk of toxicity cannot be ignored in high volumes.^[3]

There are many studies proving that FICB is a successful perioperative analgesic method. However, different volumes of LA were used in those studies and naturally different analgesia duration and opioid consumption were reported. To the best of our knowledge, there are limited reports focusing on LA volume. Our aim in this study was to find the most clinically effective volume by comparing three different volumes of bupivacaine used frequently in the literature for US-guided infra-inguinal FICB for post-operative pain control in patients undergoing femur and knee surgery.

MATERIALS AND METHODS

Design and Patients

This was a prospective, randomized, and double-blind study. Approval for the study was granted by the Ethics Committee of Gaziantep University Şahinbey Research and Application Hospital. Informed consent was obtained from all the patients. The study included a total of 54 patients, aged 18-80 years, with an ASA I-III physical score, whom were going to undergo elective knee or femur surgery by the Orthopaedics Clinic. Patients were excluded if the ASA score was IV-V, if consent for study participation was not given, if the coagulation profile was not normal, those with neurological deficits, a history of allergy to the drugs to be used in the study, with dermatological or psychiatric disorders, who were pregnant or those to whom FICB could not be applied. The patients were randomized to one of the three infra-inguinal FICB study groups using the sealed envelope technique on the operation list.

Intervention and Anesthesia Protocol

The patients were positioned on the operating table and standard monitorization was applied of electrocardiography in DII derivation, non-invasive arterial blood presssure (BP), heart rate (HR), and peripheral oxygen saturation. Then, a peripheral vascular route was opened with an 18-20 gauge intravenous cannula, pre-oxygenation was applied with a face mask and general anesthesia induction was applied with 2 μg/ kg fentanyl, 2 mg/kg propofol, and 0.6 mg/kg rocuronium. Anesthesia maintenance was administered with 1.5-2% sevoflurane within 60% air and periodically 0.1 mcg/kg rocuronium and I µg/kg fentanyl were added. At the end of the surgical procedure, allocation to a study group was determined by opening the sealed envelope. Before the patient was extubated, while in a supine position, the skin of the area to be injected was disinfected with 10% povidone iodine. For the US (Esoate MyLab 30, Florence, Italy) to be used, the tip of a 36 mm linear probe (L36, 10-18 MHz Transducer) was smeared with gel, covered in clingfilm then disinfected with povidone iodine. To identify the femoral artery, iliopsoas muscle and fascia iliaca, the probe was placed over the inguinal crease. Af-

ter visualization of the femoral artery, the probe was moved towards the lateral of the femoral artery, following the course of the fascia iliaca. With one hand holding the probe steady over the iliopsoas muscle, the practitioner advanced a 50 mm 20G needle (B Braun Stimuplex, Melsungen, Germany) to the target tissue with the in-plane technique depending on the probe. The advancement of the needle was checked at the same time on 15-18 MHz images. After passing the fascia lata and fascia iliaca, the localization was confirmed by injecting Iml saline between the fascia iliaca and iliopsoas muscle following negative aspiration. The injected LA was allocated to the fascia iliaca and iliopsoas muscle and was seen to be disseminated both transversely and longitudinally between the fascia and iliopsoas muscle. All blocks were performed under ultrasound guidance by two experienced anesthetists. Bupivacaine was applied at 0.25% concentration in 0.3 mL/kg to Group I, in 0.4 mL/kg to Group 2 and 0.5 mL/kg to Group 3, with a maximum volume of 45 mL to any patient. Following the application of infra-inguinal FICB, the patient was extubated with decurarization with the effect of muscle relaxant and all patients were transferred to the recovery unit and then to the patient rooms. The type of operation and duration was recorded at the end of the surgery.

In the post-operative period, HR, BP, and pain scores were recorded at 0, 1, 2, 4, 6, 12, and 24 h by an anesthesia nurse blinded to the study groups. Due to the nature of the study, the practitioner was not sightless, but the patients and the nurses were blinded to the groups. For the evaluation of pain, the visual analog scale (VAS) was used, where 0= no pain and 10 = intolerable pain. Patients with a score of ≥5 in any time interval were administered with 75 mg diclofenac sodium intramuscularly (IM) as our hospital surgical clinical protocol. If the VAS score did not fall below 5 within 30 min of the diclofenac administration, then 0.1 mg/kg morphine IM was administered. Additional used analgesia, the total amount of analgesia consumed in 24 h and unwanted side-effects such as nausea and vomiting were recorded.

Statistical Analysis

Since there has not been a comparative study on this subject before, based on our own preliminary reports, as there was a statistically significant difference of 20% in the analgesia requirement between Groups I and 3 at post-operative h 4, the minimum sample size was calculated as at least 15 in each group for a=0.05 and power of the test (I-p) to be 0.80. With the estimation of a 20% loss of cases throughout the study, it was planned to include a total of 54 patients.

The data obtained in the study were evaluated with the SPSS 22.0 package software. As a result of the normality test, when evaluating differences between two groups, the Independent Samples t-test was used for variables with normal distribution and the Mann–Whitney U test for variables not with normal distribution. For the evaluation of normally distributions

uted data in more than two groups, one-way analysis of variance was applied. To determine which group has statistically a significant difference, the post hoc Tukey test was used. For the evaluation of non-normally distributed data in more than two groups, the Kruskal–Wallis test was applied and to determine which group has a statistically significant difference, the Mann–Whitney U test with Bonferroni correction for significance level was used. In the comparison of hemodynamic data with baseline values, repeated measurement variance analysis was applied. Chi-square analysis was used to examine the relationships between categorical values. P<0.05 was considered statistically significant.

RESULTS

Of the 54 patients enrolled in the study, nine patients were excluded from the study; in four patients, the analgesia used was outside the study protocol, in three patients the block could not be obtained and in two patients, follow-up could not be made. Thus, the study was completed with a total of 45 patients. No statistically significant difference was determined between the patients in respect of age, gender, ASA, height, weight, and body mass index (P>0.05) (Table 1).

In the comparison of post-operative analgesia requirement, there was a statistically significant higher requirement for additional analgesia in Group I compared to the other two groups at the post-operative 4th h (p<0.05), but no statistically significance was between group 2 and 3 (p>0.05). The analgesic requirement of Groups I and 2 was found to be similar, and statistically significantly higher than that of Group 3 at the post-operative 6th h (p<0.05) (Table 2). There was no difference between groups at other measurement times. The first analgesic requirement was observed at 1-2th h postoperatively in Group I, while it was observed at 4-6th h in Group 2 and at 6-12th h in Group 3. Additional analgesia was required in the first 24 h by 15 patients in Group I, seven patients in Group 2, and four patients in Group 3 (Table 2). When the post-operative VAS scores between the groups were compared, lower scores were observed in Group 3 compared to Group I at the Ist, 4th, and 6th h (p<0.05). How-

Table 1. Comparison of the demographic data of the groups

	Group I (n=15)	Group 2 (n=15)	Group 3 (n=15)	р
Age*	38.7±26.6	48.1±22.9	36.8±20.9	0.268
Sex (male/female)	13/2	9/6	13/2	0.127
ASA (I/II/III)	5/6/4	2/9/4	4/7/4	0.749
Height (cm)*	166.1±5.2	164.3±5.8	167.4±5.5	0.301
Weight (kg)*	63.7±10.3	70.8±10.5	67.6±10.7	0.154
BMI $(kg/m^2)^*$	23.1±3.6	26.2±3.3	24.2±3.4	0.061

*Standart deviation. n: Number of patients. BMI: Body mass index; ASA: American Society of Anesthesiologists.

ever, no statistical difference was observed between Group I and 2 and between Group 2 and 3 (Table 3).

When the post-operative hemodynamic data (BP and HR) were compared, there was no statistically significant difference between the groups (p>0.05). Type of operation and duration of surgical procedures were similar between the all groups, and there was no significant difference between them (Table 4).

The arithmetical mean of NSAIDs consumed was found to be 75 mg in Group 1, 35 mg in Group 2, and 20 mg in Group 3. No statistically significant difference was observed between the groups in the total analgesia consumed in the first 24 h. However, clinically, the analgesic consumption used in Group 3 was less than the other groups. No patient required morphine. No statistically significant difference was observed between the groups in the comparisons of post-operative mean arterial pressure and HR (p>0.05). No statistically significant difference was determined between the groups in respect of post-operative nausea-vomiting. Nausea developed in two patients in Group 1, in two patients in Group 2, and in one patient in Group 3. Vomiting was not determined in any patient. No

Table 2. Additional analgesia used in the postoperative time intervals

Postoperative analgesia time	Group I (n)	Group 2 (n)	Group 3 (n)	р
After ekstubation	0 (0)	0 (0)	0 (0)	_
0–1. hours	0 (0)	0 (0)	0 (0)	_
I-2. hours	2 (13.3)	0 (0)	0 (0)	0.101
2-4. hours	3 (20.0)	0 (0)	0 (0)	0.030*
4–6. hours	4 (26.7)	4 (26.7)	0 (0)	0.026#
6-12. hours	3 (20.0)	2 (13.3)	4 (26.7)	0.655
12-24. hours	3 (20.0)	I (6.7)	0 (0)	0.098

n: Number of patients. Values are given as number of cases (%). *P<0.05 in Group I compared to Group 2 and Group 3. *P<0.05 in Group 3 compared to Group I and Group 2.

Table 3. Comparison of the VAS scores of the groups

After extubation (hour)	Group I (n=15)	Group 2 (n=15)	Group 3 (n=15)	Р
O th	3 [2–3]	2 [2–3]	2 [2–3]	0.063
 th	2 [1–4]	2 [1–2]	I [I-2]	0.002*
2 nd	2 [1–6]	2 [1–3]	2 [1–2]	0.085
4 th	3 [1–6]	2 [0-3]	2 [1–3]	0.008*
6 th	3 [1–6]	3 [1–6]	2 [1–3]	0.048*
I2 th	3 [1–5]	3 [1–5]	2 [1–5]	0.884
24 th	2 [1–5]	3 [1–5]	2 [1–3]	0.620

Values are given as Median (Minimum-Maximum) *p <005. VAS: Visual Analog Scale.

Type of operation	Group I (n=15)	Group 2 (n=15)	Group 3 (n=15)
Distal femur fracture	3	4	4
Proximal femur fracture	3	3	3
Femur intertrochanteric fracture	3	3	4
Knee prosthesis	2	3	2
Extraction of femoral implant	4	2	2
Duration of surgical procedures	88.00±46.86	79.00±25.58	85.80±29.11

edema, hematoma, or hyperemia was observed on the skin or subcutaneously following infra-inguinal FICB in any patient.

DISCUSSION

In this study, in which three different volumes of LA for infra-inguinal FICB were compared, volume was an important factor for quality of analgesia in the block and it was determined that the most effective volume was 0.5~mL/kg of 0.25% bupivacaine.

In many studies in the literature related to FICB, it can be seen that it is applied to reduce pain and agitation in the pre-operative period, particularly in the emergency department. [8–10] When the LA volumes used are examined, it can be seen that there is no standard application or volume dosage. In general, volumes of 20–40 mL are administered to adults. For a Salter operation in pediatric patients, Wang et al. [11] applied I mL/kg LA up to a maximum of 30 mL.

Høgh et al.^[10] reported the routine use of FICB for analgesia in patients presenting at the Emergency Department with a hip fracture and stated that extremely effective pain treatment was achieved in the pre-operative period with the use of 30 mL 0.25% bupivacaine and 10 mL 2% lidocaine.

In another study, patients with a femoral neck fracture were applied FICB with 30 mL (3.75 mg/mL) ropivacaine 20 min before spinal anesthesia and were compared with another group applied with alfentanyl infusion. ^[12] The FICB patients were placed in a lateral position during spinal anesthesia and felt no pain and were also seen to have more effective analgesia in the post-operative period compared to the patients given alfentanyl.

Although there are many clinical studies on FICB in which LA volume is important, unfortunately, there is limited study to determine the most appropriate volume for post-operative pain management. In a past study, the authors compared 0.5% Bupivacaine and Ropivacaine with epinephrine in the FICB conducted with the landmark technique. They reported that the minimum effective volumes of bupivacaine capable of producing a blocking in 95% and 99% of the cases were 36.1

mL and 37.3 mL, respectively. However, it should be noted that US was not used in this study and 0.5% LA with epinephrine were used. At the second study, EV50 and EV95 of 0.25% ropivacaine for US-guided supra-inguinal FICB calculated with logistic regression analysis were 15.01 mL and 26.99 mL, respectively. Both studies show us the effective volumes for the onset of the block, but do not provide clinical information about the duration of the block and analgesic consumption.

Rather than using a standard volume in the present study, the LA volume applied was calculated as mL//kg and when this was multipled by the mean weight of the groups, it was approximately, 21, 28, and 35 mL, respectively. In a study, the authors placed a catheter for FICB, and they applied 20 mL (body weight <50 kg), 25 mL (body weight 50 kg–70 kg), or 30 mL (body weight >70 kg) as bolus LA volume.^[13] We also think that patient weight should be considered in volume-dependent blocks like FICB.

Just as in the two above-mentioned studies, the most effective and long-lasting (6-12 h) analgesia in the present study was obtained in the group applied with LA of 0.5 mL/kg and the lowest NSAID consumption in the first 24 h postoperatively was also in this group. Supporting this conclusion, a recently published review reported the mean duration of analgesia as 8 h.^[14] In the patients in Group I with 0.3 mL/kg LA, the need for analgesia started in the 2nd h. In another study, patients undergoing planned total hip prosthesis surgery were administered FICB with 0.3 mL/kg 0.45% ropivacaine for post-operative analgesia and were compared with a control group.[15] The block applied was reported to only be effective for the first few hours and was insufficient thereafter. Lopez et al.[16] reported that FICB with 20 mL 1.5% lidocaine and 1/200,000 epinephrine which was applied to cases with femoral fracture either at the site of the trauma or before arriving at hospital, provided effective analgesia for a time period of only a few hours. In the present study, it was also seen that the effect of this volume finished earlier compared to the other two groups and after the first few hours, the effect disappeared. Recent articles help us to understand the large surface area of the fascia iliaca, and we understand that a low LA volume will be insufficient for this plane block.[17]

However, in contrast to the results of the current study, some authors have reported good results from a low LA volume. In a study by Monzon et al.,[9] FICB with 0.3 mL/kg 0.25% bupivacaine was applied to hip fracture patients with the resistance loss technique in the Emergency Department. Effective analgesia was reported to have been obtained for up to 8 h in the pre-operative period. In a study of patients presenting at hospital with a proximal femur fracture, Fujihara et al.[8] applied FICB with 10 mL 0.75% ropivacaine and 10 mL 2% mepivacaine to one group and NSAID to the other group for pre-operative and post-operative analgesia. In both the pre-operative and post-operative periods, FICB was reported to reduce the pain scores for up to 12 h. These two studies differ from the present study in that the application was made preoperatively and therefore, the surgical factor had not yet taken a role in pain. Therefore, a lower LA volume may alleviate fracture pain, but it would not be appropriate to generalize it for post-operative pain. In addition, in the Fujihara study, a second block was applied to patients undergoing surgery after the first FICB. As it is not known how much LA had been absorbed within the compartment from the first block, it is not possible to comment on a volume of more than 20 mL in the compartment at the end of the second dose.

There are few studies in which FICB has been applied for hip and femur surgery in children. In one study, I mL/kg 0.2% ropivacaine was applied and lower pain scores for up to 24 h and better patient satisfaction were reported compared to a control group.[11] Paut et al.[18] applied FICB to children with 0.7 mL/kg volume of ropivacaine at concentrations of 0.375% and 0.5%. In the 0.5% concentration group, high plasma concentrations of ropivacaine were determined and it was concluded that a lower dose volume range should be used in children. To achieve effective analgesia in the present study, a high volume was used and the concentration of 0.25% was preferred to avoid toxic effects. No findings of toxicity were observed in any patient of the present study. Similarly, FICB and IV PCA were compared to reduce post-operative analgesia and agitation in 64 children aged 3-7 years who were planned to have femoral osteotomy and instrumentation removed. It was statistically determined that in the FICB group, analgesia was better and agitation was less at the 10th and 20th min of arrival at the recovery room.[19]

FICB has been compared not only with traditional analgesia methods but also with other regional techniques. In a study of hip prosthesis patients, Deniz et al.^[20] compared FICB with 30 mL 0.25% bupivacaine and 3-in-1 block and a control group and showed that both techniques had similar effects in respect of analgesia and the requirement for additional analgesia and the results of both were superior to those of the control group. In reports from different authors, while some have shown a more rapid onset from 3-in-1 block but the effect of FICB was longer lasting,^[21] and that there is an equivalent analgesic effect in femoral block and FICB,^[22] others have de-

termined FICB to be superior to the 3-in-I block and that the lateral femoral cutaneous nerve was blocked more. [23,24] From our clinical experience, it was seen that the quality of the analgesia is increased by the blockage of the femoral nerve, lateral femoral cutaneous nerve, and obturator nerve within the compartment.

FICB was applied under US guidance first by Swenson et al.^[25,26] in 2006 and 2007 and later by Dolan et al.^[27] in 2008. In that study, US was compared with the resistance loss technique and block success was found to be 47% in the resistance loss group and 82% in the US group. The high success rate of 94% in the present study compared to reports in the literature can be attributed to it having been applied by practitioners experienced in the routine use of US.^[28]

In successful applications of FICB in the aforementioned literature, the duration of analgesia was found to be approximately 6–8 h. [12,14,19,20] The duration of analgesia in the present study was determined to be consistent with literature. In Group 3 of the current study, the analgesic effect lasted for 6–12 h. In addition, in the early period after extubation, that the VAS scores were found to be a little higher than those of the 2nd h, can be considered due to it was previous from the time of onset of the effect of the block. From our clinical experience, it can be said that approximately 20–30 min is necessary for the onset of the block effect.

Although there was a clinical difference of almost 4-fold between Groups I and 3 in the total consumption of diclofenac sodium given as rescue analgesia, that the difference was not statistically significant could be explained by the low number of patients. In respect of FICB-related complications, it has been stated to be an extremely safe block and no serious complications have been reported. In the present study, there were no systemic complications and nausea was determined in only five patients. In these patients operated on under general anesthesia, no reason could be found to associate the nausea with FICB. No skin redness, local hematoma, or other complications were observed in any of the patients.

Pain is a subjective sensation which can only be described by the patient. As when or how the pain experienced by the patients in the study could not be exactly determined, all groups of patients were assumed to have the same sensitivity, and this can therefore be considered a limitation of the study.

Conclusion

FICB is a safe compartment block providing extremely effective post-operative analgesia for femur and knee surgery. The duration of analgesia is directly affected by the LA volume in FICB. In this study, the lowest pain scores and analgesic requirements were obtained in the group where 0.5 mL/kg LA was used. The difference between the groups was more evident in the first 6–8 h in particular. Related to this, the

additional analgesia used and the total amount of analgesia consumed in 24 h was clinically reduced.

Infra-inguinal FCIB with a 0.5 mL/kg LA applied under US guidance can be used as a safe and effective method as a part of multimodal analgesic treatment to relieve post-operative pain. However, there is a need for further studies including a more extensive patient series to investigate the optimal volume and dosage for this block.

Ethics Committee Approval: This study was approved by the Gaziantep University Clinical Research Ethics Committee (Date: 19.11.2013, Decision No: 19.11.2013/409).

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ORİJİNAL ÇALIŞMA - ÖZ

Fascia iliaka kompartman bloğunda kullanılan bupivakainin farklı volümlerinin karşılaştırılması

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AMAÇ: Fasya iliaka kompartman bloğu (FICB), femur ve diz cerrahisi sonrası postoperatif ağrı kontrolü için uygulanan rejyonel tekniklerden biridir. Bildiğimiz kadarıyla, LA hacmine odaklanan sınırlı sayıda rapor bulunmaktadır. Bu çalışmadaki amacımız femur ve diz cerrahisi geçiren hastalarda postoperatif ağrı kontrolünde US kılavuzluğunda kasık altı FICB için literatürde sıklıkla kullanılan üç farklı LA hacmini karşılaştırarak klinik olarak en etkili hacmi bulmaktı.

GEREÇ VE YÖNTEM: Çalışmaya ASA I-III fiziksel skorları olan toplam 45 hasta dahil edildi. Genel anestezi altında cerrahi işlem tamamlandığında hastalara ekstübasyon öncesi ultrason eşliğinde %0.25 bupivakain ile FIKB uygulandı. Hastalar uygulanacak lokal anestezik miktarına göre rastgele üç farklı gruba ayrıldı. Grup 1'e 0.3 ml/kg, Grup 2'ye 0.4 ml/kg ve Grup 3'e 0.5 ml/kg bupivakain uygulandı. FIKB sonrası hastalar ekstübe edildi. Hastalar ameliyat sonrası 24 saat vital bulgular, ağrı skorları, ek analjezik gereksinimi ve olası yan etkiler açısından takip edildi.

BULGULAR: Ameliyat sonrası ağrı skorları karşılaştırıldığında Grup 1'in skorları ameliyat sonrası 1., 4. ve 6. saatlerde Grup 3'e göre istatistiksel olarak yüksek bulundu (p<0.05). Ek analjezi ihtiyacı karşılaştırıldığında postoperatif 4. saat diğer gruplara göre Grup 1'de en yüksekti (p=0.03). Ameliyat sonrası 6. saatte ek analjezik gereksinimi Grup 3'te diğer gruplara göre daha azdı ve Grup 1 ile 2 arasında fark yoktu (p=0,026). LA hacmi arttıkça ilk 24 saatte tüketilen analjezik miktarı azaldı ancak istatistiksel olarak anlamlı fark yoktu (p=0.051).

TARTIŞMA: Çalışmamız, ultrason rehberliğinde uygulanan FIKB, ameliyat sonrası ağrıyı giderme için multimodal analjezik bileşenleri bir parçası olarak güvenli ve etkili bir yöntem olduğunu, 0.5 ml/kg hacimdeki %0.25 bupivakainin hiçbir yan etki gözlenmeden diğer iki gruba göre daha etkin analjezi sağladığını göstermiştir.

Anahtar sözcükler: Ameliyat sonrası analjezi; bupivakain; fasya iliaca kompartman bloğu; femur cerrahisi; ultrason.

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