



Investigating the Effect of Pericapsular Nerve Group Block on Postoperative Analgesia in Hip Surgery

Kalça Cerrahisinde Perikapsüler Sinir Grubu Bloğunun Postoperatif Analjeziye Etkisinin İncelenmesi

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Abstract

Aim: With increasing numbers of patients undergoing hip surgery, postoperative analgesia planning for patients also becomes more important. Post-hip surgery pain is categorized as acute and severe, and its effective treatment is paramount. Our study investigates the effectiveness of Pericapsular Nerve Group (PENG) block in postoperative analgesia, the amount of opioid used, and the presence of postoperative nausea and vomiting in hip surgeries in a multimodal analgesia context.

Material and Method: This is a prospective study that includes 102 patients in total, undergoing elective hip surgery. The patients were randomly divided into two groups, and the first group (Group P, n=51) received a PENG block, while the second group (Group C, n=51) received no block. Intraoperative hemodynamic data, discharge-hospitalization time, presence of complications, visual pain scores (VAS) (rest and dynamic) were recorded. Total tramadol dose consumed, additional analgesic requirement, and time of first analgesic were evaluated.

Results: 102 patients completed the study. Rest and dynamic VAS scores were significantly lower in the blocked PENG group at all times postoperatively (p<0.001). Total tramadol dosage and additional analgesic rates were significantly lower in the blocked PENG group (p<0.001). Also, the rate of requiring additional analgesics and receiving rescue analgesia at an earlier time was significantly higher in the non-block group compared to the blocked PENG group (p<0.001, p=0.023).

Conclusion: We believe that application of a PENG block in hip surgeries will reduce patient pain scores, allowing for experiencing less pain with fewer opioids, and protection from side effects of opioids.

Keywords: Hip surgery, PENG block, Postoperative analgesia

Öz

Amaç: Kalça cerrahisi uygulanan hasta sayısının artmasıyla birlikte postoperatif dönemde hastaların analjezi planlaması da önem kazanmaktadır. Kalça cerrahisi sonrası ağrı akut ve şiddetli ağrı grubundadır ve etkin tedavisi büyük önem arz etmektedir. Çalışmamızda multimodal analjezi kapsamında kalça cerrahilerinde Perikapsüler Sinir Grubu bloğunun (PENG) postoperatif analjeziye etkinliğini, opioid miktarı ve postoperatif bulantı-kusma varlığını araştırmayı amaçladık.

Gereç ve Yöntem: Çalışmamız prospektif bir çalışma olup elektif şartlarda kalça cerrahisi planlanan toplam 102 hasta dahil edildi. Hastalar rastgele iki gruba ayrılarak ilk gruba PENG bloğu (Grup P, n=51) yapılırken ikinci gruba (Grup C, n=51) blok uygulanmadı. Hastaların intraoperatif hemodinamik verileri, taburculuk- hastanede kalış süresi ve komplikasyon varlığı, vizüel ağrı skorları (VAS) (istirahat ve dinamik) kaydedildi. Toplam tüketilen tramadol dozu, ek analjezik ihtiyacı ve ilk analjezik saati değerlendirildi.

Bulgular: 102 hasta çalışmayı tamamladı. Postoperatif tüm zamanlarda istirahat ve dinamik VAS skorları PENG bloğu yapılan grupta anlamlı bir şekilde daha düşük bulundu (p<0.001). PENG bloğu yapılan grupta total kullanılan tramadol dozları ve ek analjezik yapıma oranı anlamlı bir şekilde daha düşük bulundu (p<0.001). Ayrıca blok yapılmayan grupta PENG bloğu yapılan gruba göre daha erken saatte ek analjezik gereksinim gösterip kurtarma analjezisi yapıma oranları anlamlı bir şekilde daha yüksek olduğu bulundu (p<0.001, p=0.023).

Sonuç: PENG bloğu uygulamasının kalça cerrahilerinde hasta ağrı skorlarını azaltarak daha az opioidle daha az ağrı duyacağı opioid nedenli yan etkilerinden koruyacağı kanaatindeyiz.

Anahtar Kelimeler: Kalça cerrahisi, PENG blok, Postoperatif analjezi

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INTRODUCTION

Acute postoperative pain is defined as pain that gradually decreases with the healing of tissue that develops as a result of previous illness, surgical intervention, or a combination of the two in a patient who has undergone surgery. Postoperative pain is affected by many factors such as the location, type, duration of surgery, type of anesthesia, pain treatment applied pre- and post-surgery, the patient's previous pain experiences, and environmental factors.^[1]

Total hip arthroplasty (THA) is an orthopedic surgical method used within the indications for degenerative and inflammatory hip diseases.^[2] Hip fracture is a common orthopedic emergency in the elderly and is associated with significant mortality and morbidity.^[3] Pain after hip surgery is categorized as severe pain, difficult to relieve with oral analgesics. Uncontrolled pain can cause reflex endocrine, metabolic and inflammatory responses that can lead to serious problems such as pulmonary, cardiac or renal problems and thromboembolism. Most of the adverse physiological effects can be prevented with effective postoperative pain management.^[4]

The use of multimodal analgesia is recommended for postoperative pain management in hip surgery. Multimodal analgesia consists of pharmacological methods and neuraxial-regional-local techniques.^[5] Regional anesthesia techniques are widely used due to their postoperative pain management and proven safety.^[6] A Pericapsular Nerve Group (PENG) block, which blocks the nerves innervating the hip joint, was described by Giron-Arango et al. in 2018. For postoperative analgesia in patients undergoing hip surgery, fascia iliaca compartment block (FICB), lumbar plexus block, femoral nerve block, quadratus lumborum block, erector spinae plane block, PENG block and lateral femoral cutaneous nerve (LFCN) block are commonly used blocks.^[7] However, the best method for hip surgery has not yet been determined.^[8] Studies show that a PENG block can be used for both acute pain and postoperative pain in hip fracture patients and for analgesia after elective hip surgeries (primary and revision total hip arthroplasties).^[7,9,10]

In this study, we aim to compare the postoperative pain level, first analgesic time, amount of opioid and additional analgesic use primarily, and postoperative nausea and vomiting levels of patients, complications secondarily undergoing hip surgery with or without applying a PENG block under ultrasound guidance.

MATERIAL AND METHOD

Approval for this randomized prospective study was granted by the Ethics Committee of our University (2011-KAEK-2/05.11.2021) and written informed consent was obtained from each patient. All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki.

A total of 102 patients undergoing hip surgery, aged 18 years and over, with American Society of Anesthesiologists (ASA) physical status I–IV, were enrolled in this study.

Patients with coagulation disorders, allergy to local anesthetics, anticoagulant use, local/systemic infection, or serious arrhythmia were excluded from the study. Also, patients who gave up participating in the study at any time, who were uncooperative, had chronic analgesic/opioid use, and had mental or psychiatric disorders were excluded from the study. The visual analog scale (VAS) was clarified to all patients during the preoperative visit.

Patients were randomly divided into 2 groups using a sealed envelope system: Group P (n=51) patients received the PENG block and Group C (n=51) patients did not receive the PENG block.

Standard anesthesia monitoring (oxygen saturation, electrocardiogram, end-tidal carbon dioxide, noninvasive blood pressure) was applied throughout the surgery. Patients in both groups received midazolam before surgical procedures. While the PENG block was applied to the patients in Group P in the supine position before general anesthesia, it was not applied to Group C patients. Anesthesia was induced by 2 mg/kg propofol, 1 mg/kg lidocaine, 2 µg/kg fentanyl, and tracheal intubation was facilitated with 0.5 to 0.6 mg/kg rocuronium. Maintenance of anesthesia was provided with 50% air and 1 to 2% sevoflurane in oxygen. All patients were administered 1mg/kg tramadol IV for postoperative analgesia approximately 15 minutes before the end of the operation.

In Group P, before general anesthesia, the linear ultrasound probe was placed in the transverse plane over the spina iliaca anterior superior (SIAS) in the supine position and moved downward to visualize the pubic ramus. After visualizing the femoral artery and the iliopubic eminence, visible block needle was inserted into the skin on ultrasound with a 30 to 45-degree incision and advanced from lateral to medial, and 20 mL of 0.25% bupivacaine was applied locally between the psoas tendon anteriorly and the pubic ramus posteriorly. All procedures were performed by an experienced anesthesiologist. Recording any side effects and complications such as hypotension, vascular puncture, paresthesia and local anesthetic toxicity was planned during the block application, but no side effects or complications were observed during the applications.

10 cm VAS (0= no pain, 10=maximal pain) was used by an anesthesiologist (who was unaware of the procedure) for the assessment of resting and dynamic pain at 1st, 2nd, 6th, 12th, 18th and 24th postoperative hours. At the end of the surgery, 4×1 g paracetamol and 2×1 mg/kg tramadol were given to all patients. 100 mg tramadol was given to all patients when VAS score was over 4 during postoperative follow-up as additional analgesia. And also when the

patient noticed strong pain despite these treatments, 20 mg meperidine IV was administered as rescue analgesic. When the VAS score evaluation was completed, the first analgesic time, the total tramadol dose administered to the patient, whether additional analgesic (tramadol) was needed, whether rescue analgesia was applied, the presence of nausea and vomiting, and the presence of complications were investigated and recorded.

Demographic data of the patients, such as age, sex, body mass index, comorbidities, type of surgery performed (e.g.) were recorded. Hemodynamic parameters including mean arterial pressures (MAP), heart rate (HR), and saturation of oxygen were noted before anesthesia induction (T0), at the 5th minute (T1), 30th minute (T2), 60th minute (T5), 90th minute (T6), 120th minute (T7), and at the end of the surgery (T8) intraoperatively. In addition, duration of the surgery, use of blood products during operation, discharge after surgery (service or intensive care need) and length of hospital stay were recorded. In the postoperative period, patients' VAS scores (at rest and dynamic at 1, 2, 6, 12, 18 and 24 hours) were evaluated and recorded. We evaluated the dynamic VAS score with the 15-degree straight leg raising test.

Statistics

G-Power 3.1.9.2 package program was used to determine the number of observations. With an effect size of 0.5, $\alpha = 0.05$, and a power of 80%, a total sample size of 102 was determined for the study. A dropout margin of 10% was calculated and 112 patients were included in the study.

IBM SPSS Statistics version 20 was used for statistical analysis. Data were expressed as ratio, median (Interquartile range (IQR)), mean \pm SD. The suitability of variables for normal distribution was determined by visual (histogram) and analytical methods (Kolmogorov-Smirnov test). Student T or Mann Whitney U test was used to compare continuous variables, and Chi-square test was used to compare categorical variables. A p-value less than 0.05 was considered to show a statistically significant difference.

RESULTS

Of 112 patients who were assessed for eligibility, ten refused to sign informed consent and were therefore not included. The remaining 102 patients were randomly and equally divided between two groups. The data of a total of 102 patients who underwent PENG block (Group P; n: 51) and those who did not undergo PENG block (Group C; n: 51) were statistically analyzed (**Figure 1**). The patients' age, gender, body mass index (BMI), presence and distribution of additional diseases, and ASA scores were compared. There was no significant difference between the groups in the demographic data of the patients (**Table 1**).

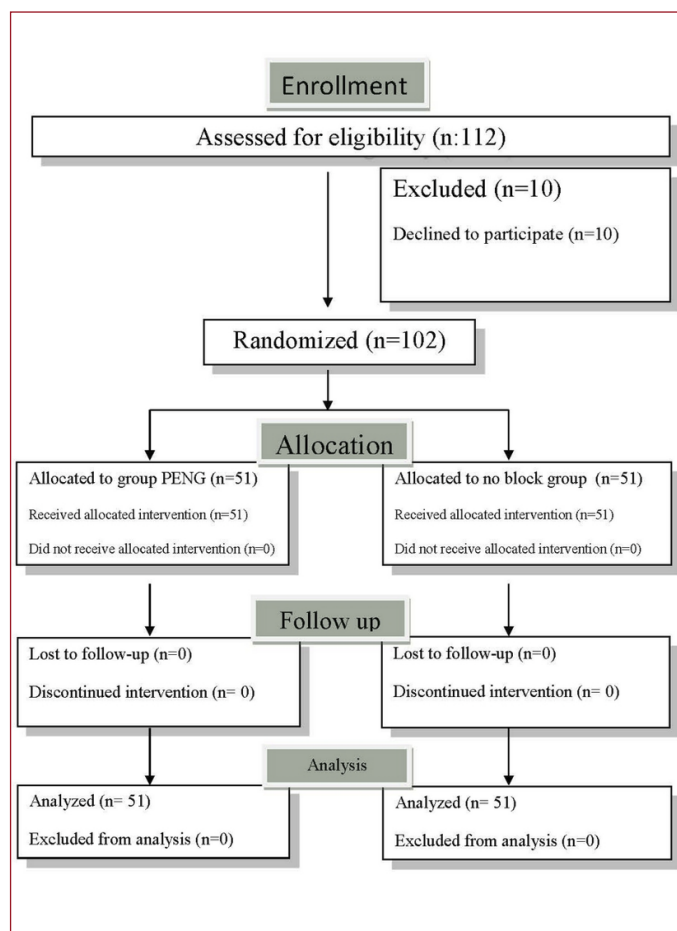


Figure 1. Study flow diagram shows the patient selection process

Table 1. Demographic data of patients

	Group P (n=51)	Group C (n=51)	Total (n=102)	P
Gender, F/M, n (%)	28 /23 (54.9/45.1)	25 /26 (49/51)	53 /49 (52/48)	0.552*
Age, year, Median (IQR)	74 (16)	70 (22)	72 (19.25)	0.078#
BMI, kg/m2, Mean \pm SD	29.10 \pm 6.45	29.29 \pm 5.92	28.94 \pm 6.16	0.806€
ASA, n (%)				
I	1 (2)	0	1 (1)	
II	9 (17.6)	18 (35.3)	27 (26.5)	0.182*
III	36 (70.6)	29 (56.9)	65 (63.7)	
IV	5 (9.8)	4 (7.8)	9 (8.8)	
Co-morbidity, Yes/no, n (%)	37 /14 (72.5/27.5)	38/13 (74.5/25.5)	75/27 (73.5/26.5)	0.822*

Data are given as number of patients (%), mean \pm SD (standard deviation), median (Interquartile range (IQR)), Group P; PENG block group, Group C; non- block group. BMI; Body mass index, F/M; Female/ Male, ASA; American Society of Anesthesiologists #Mann Whitney U, *Chi Square, €Student T-test,

The types of surgeries performed were similar between the two groups ($p=0.929$). The median surgical duration was 110 minutes, while the median hospital stay was 7 days, and there was no significant difference between the two groups ($p=0.316$, $p=0.984$). After the operation, 65.7% of the patients were transferred to the ward and 39.2% to the intensive care unit, and there was no significant difference between the two groups in terms of discharge ($p=0.297$, **Table 2**).

Table 2. Distribution of operation features according to groups

	Group P (n=51)	Group C (n=51)	Total (n=102)	P
Surgery performed, n (%)				
THA	14 (27.5)	16 (31.4)	30 (29.4)	0.929*
PFN	16 (31.4)	17 (33.3)	33 (32.4)	
Bipolar H	17 (33.3)	14 (27.5)	31 (30.4)	
Revision THA	4 (7.8)	4 (7.8)	8 (7.8)	
Operation time, min, median (IQR)	105 (45)	110 (65)	110 (42.50)	0.316#
Postoperative discharge, n (%)				
Service	36 (70.6) /	31 (60.8) /	67 (65.7) /	0.297*
ICU	15 (29.4)	20 (39.2)	35 (34.3)	
Length of hospital stay, days, median (IQR)	8 (4)	7 (6)	7 (6)	0.984#

Data are given as number of patients (%), mean±SD (standard deviation), median (Interquartile range (IQR)), Group P; PENG block group, Group C; non-block group THA; Total hip arthroplasty, PFN: proximal femoral nail, Bipolar H: bipolar hemiarthroplasty, ICU; Intensive care unit. #Mann Whitney U, *Chi Square,

Intraoperative heart rates and mean arterial pressures of the patients are shown in **Figure 2** and **Figure 3**. Heart rates and mean arterial pressure values were similar in both groups at all measured times.

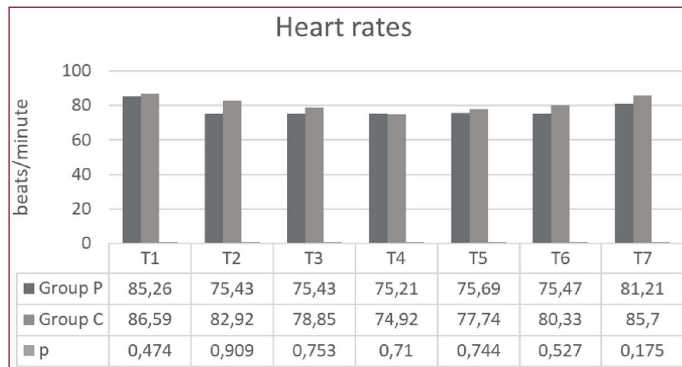


Figure 2. Comparison of patients' heart rates (beats/minute) intraoperatively. Group P; PENG block group, Group C; non-block group. T1:1st, 4th, 8th, 12th, and 24th hours intraoperatively (p > 0.05).

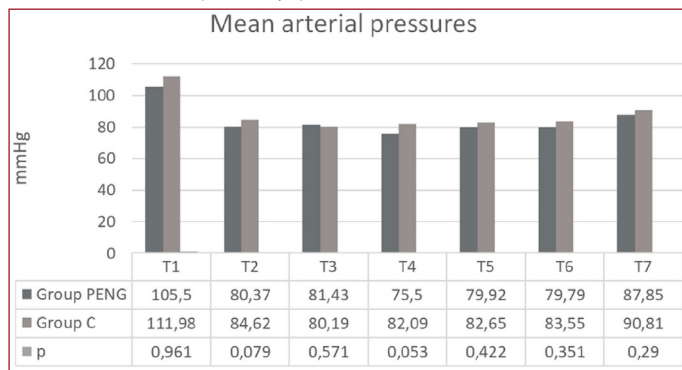


Figure 3. Comparison of patients' mean arterial pressures (mmHg) intraoperatively. Group P; PENG block group, Group C; non-block group. T1:1st, 4th, 8th, 12th, and 24th hours intraoperatively (p > 0.05).

When we evaluated the VAS scores of the patients, resting and dynamic VAS values were significantly lower in the PENG group than in non-block group at all times (**Table 3**). When we compared the patients of PENG group and non-block group according to the types of surgery performed; VAS values were statistically lower in the PENG group than in the non-block group postoperatively at all times in primary THA

patients, after the 18th hour in Proximal Femoral Nail (PFN) patients, and after the 12th hour in bipolar hemiarthroplasty patients (**Table 4**).

Table 3. Comparison of postoperative resting and dynamic VAS scores between groups

	Group P (n=51)	Group C (n=51)	P#
Resting VAS scores			
VAS at 1 st hour	0 (2)	2 (1)	<0.001
VAS at 2 nd hour	2 (2)	4 (2)	<0.001
VAS at 6 th hour	3 (2)	4 (2)	<0,001
VAS at 12 th hour	3 (3)	3 (1)	0.001
VAS at 18 th hour	3 (1)	3 (1)	<0.001
VAS at 24 th hour	3 (1)	3 (1)	<0.001
Dynamic VAS scores			
VAS at 1 st hour	2 (3)	4 (2)	<0.001
VAS at 2 nd hour	3 (2)	5 (3)	<0.001
VAS at 6 th hour	4 (2)	6 (2)	<0.001
VAS at 12 th hour	4 (2)	5 (2)	<0.001
VAS at 18 th hour	4 (2)	5 (2)	<0.001
VAS at 24 th hour	4 (2)	5 (2)	0.017

Data are given as median (Interquartile range (IQR)), Group P; PENG block group, Group C; non-block group, VAS; Visual analog scale, #Mann Whitney U

Table 4. Comparison of resting and dynamic VAS values between groups according to the surgeries performed (p values)

VAS#	THA		PFN		Bipolar H		Revision THA	
	Group P (n=14)	Group C (n=16)	Group P (n=16)	Group C (n=17)	Group P (n=17)	Group C (n=14)	Group P (n=4)	Group C (n=4)
Resting VAS scores								
VAS at 1 st hour	0.002		0.002		0.008		0.114	
VAS at 2 nd hour	<0.001		0.002		0.006		0.343	
VAS at 6 th hour	0.002		0.034		0.005		0.343	
VAS at 12 th hour	0.025		0.021		0.230		0.886	
VAS at 18 th hour	0.002		0.136		0.053		0.886	
VAS at 24 th hour	0.003		0.058		0.056		0.886	
Dynamic VAS scores								
VAS at 1 st hour	0,002		0,007		0,001		0,200	
VAS at 2 nd hour	<0.001		0,019		0,008		0,343	
VAS at 6 th hour	0,001		0,043		0,010		0,200	
VAS at 12 th hour	0,015		0,010		0,215		0,200	
VAS at 18 th hour	0,001		0,444		0,077		0,486	
VAS at 24 th hour	0,070		0,276		0,064		0,686	

Data are given as p values. #Mann Whitney U. Group P; PENG block group, Group C; non-block group VAS; Visual analog scale, THA; Total hip arthroplasty, PFN: proximal femoral nail, Bipolar H: bipolar hemiarthroplasty

When we look at the postoperative analgesic use of the patients, total tramadol doses and additional analgesic use rates were significantly lower in the PENG group than in the non-block group (p<0.001, **Table 5**). The rate of requiring additional analgesics and receiving rescue analgesia at an earlier time was significantly higher in the non-block group than in the PENG group (p<0.001, p=0.023, **Table 5**). No significant difference was observed in terms of complications in both groups (p=0.375).

Table 5. Comparison of postoperative nausea, vomiting, complications, analgesic needed and consumed.

	Group P n=51	Group C n=51	Total (n=102)	p
Nausea, yes/no, n (%)	19 (36.5) / 33 (63.5)	32 (62.7) / 19(37.3)	51(49.5) / 52 (50.5)	0.008*
Vomiting, Yes/no, n (%)	9 (17.3) / 43 (82.7)	17 (33.3) / 34 (66.7)	26 (25.2) / 77 (74.8)	0.061*
Additional analgesic, Yes/no, n (%)	18 (35.3) / 33 (64.7)	34 (66.7) / 17 (33.3)	52 (51) / 50 (49)	0.002*
First analgesic requirement, hour, median (IQR)	4 (4)	2 (1)	2 (4)	<0.001#
Total tramadol dose, mg, median (IQR)	200 (200)	300 (100)	250 (100)	<0.001#
Rescue analgesic, yes/no, n (%)	13 (25.5) / 38 (74.5)	24 (47.1) / 27 (52.9)	37 (36.3) / 65 (63.7)	0.023*
Complication, yes/no, n (%)	7/44	9/42	16/86	0.375*

Data are given as number of patients (%), median (Interquartile range (IQR)), Group P; PENG block group, Group C; non- block group. *Chi Square, #Mann Whitney U

DISCUSSION

Regional analgesia techniques are widely used in patients with hip fractures because they provide adequate analgesia for pain management in a manner that spares opioids and is relatively safe.^[11] The PENG block is a new and promising ultrasound-guided regional anesthesia technique, aiming to block the branches of femoral nerve, obturator nerve and accessory obturator nerve innervating the anterior hip capsule.^[12,13] Currently, the PENG block has been shown to be effective in reducing pain in different hip-related procedures, including fracture and hip replacement surgery, but the most current evidence is mostly limited to case reports and case series, and clinical studies are few.^[7,14-16]

In this randomized clinical trial, the PENG block reduced postoperative pain scores at resting and dynamic states, and the opioid consumption in the first 24 hours after total hip surgeries. Our findings are consistent with previously published reports. In a randomized, placebo-controlled trial conducted by Zheng J. et al., it was reported that the pain scores were lower in the PENG group compared to the placebo group in patients who underwent total hip arthroplasty.^[17] Farag A. et al. showed in their meta-analysis that there was a statistically significant difference in favor of the PENG group in the overall analysis of dynamic pain scores measured by VAS or numerical rating score (NRS) approximately 30 minutes postoperatively, and there was a statistically significant difference in favor of the PENG group when comparing the postoperative pain scores of the lumbar plexus block or analgesics alone.^[18] Pascarella G. et al. showed that the PENG block improved postoperative analgesia and reduced pain scores and opioid consumption in the first 48 hours after surgery in a study comparing PENG block and control groups in patients with total hip arthroplasty.^[19]

In studies comparing PENG block with other regional techniques in hip surgery, it has been shown that PENG block has better analgesic efficacy and reduces opioid consumption.^[20-22] In the meta-analysis of Farag A. et al., the

difference in pain scores between the PENG block control groups and other regional techniques (such as FICB) was found to be significant only in the early postoperative period (first 6 hours), but no significant difference was found in pain scores in longer follow-ups, indicating that the effect of the PENG block decreases over time.^[18] In the case series reported by Kukreja P. et al., the PENG block was performed in patients scheduled for primary THA and revision THA, and it was stated that the opioid consumption used in the primary THA group in the first 24 hours was significantly lower than in the revision THA group.^[10] It has been proven that the PENG block is superior in terms of postoperative analgesia effects and opioid consumption levels in both primary and revision THA patients.^[7,19] In our study, we compared the postoperative 24-hour rest and dynamic VAS scores of all patients. We evaluated the dynamic VAS score with the 15-degree straight leg raising test. As a result, VAS values were significantly lower in the PENG block group compared to non-block group patients, consistent with the literature. We believe that the postoperative analgesic efficacy of PENG block in hip surgery is high. We divided the patients into subgroups according to their surgery types and compared them with and without the block, the PENG block VAS values were found to be significantly lower in the first 18 hours postoperatively in primary THA patients and in the first 12 hours in the PFN and bipolar groups. However, it was determined that the PENG block did not make a difference in revision THAs.

In a study conducted by Lin D. et al., the PENG block and the femoral nerve block were compared and the time from surgery to the patient being ready to be discharged was found to be significantly shorter in the PENG group by an average of 1 day.^[20] In a study conducted by Iglesias S.L. et al., the PENG block, the periarticular infiltration block (PAI) and the plexus nerve block (PNB) were compared in patients who underwent primary THA and the hospital stay was found to be shorter in the PENG group.^[23] While there are studies in which the PENG block has positive effects on the hospital stay, there are also studies in which its effect has not been demonstrated.^[7,8,18,20] In our study, no significant difference was found between the hospital stays of the PENG block group and the non-block group.

In a study conducted by Kukreja P. et al., PENG block was found to be superior in terms of opioid consumption between the PENG group and the group without block, while no significant difference was found in terms of pain scores and postoperative antiemetic requirement.^[24] A meta-analysis conducted by Huda A. et al., with its weak results, showed that there was an insignificant difference in terms of postoperative nausea and vomiting between the PENG block and other groups.^[25] In the meta-analysis conducted by Farag A. et al., it was found that there was no significant difference in the incidence of postoperative nausea, but the incidence of vomiting was lower in the PENG group.^[18] According to our results, the total tramadol dose used in the PENG block group was significantly lower than non-block group consistent with

the literature. And also in the PENG group, patients required less additional tramadol and their need for rescue analgesia significantly lower. We recorded the time when the patients first needed analgesics and it was shown that first analgesic need was significantly later in the PENG group ($p < 0.001$). When we questioned the presence of nausea and vomiting in the first 24 hours postoperatively in our study, nausea was significantly less in the PENG block group compared to the non-block group, but no significant difference was found among the patients who had vomiting. We think that the lower nausea complaints in the PENG group are related to the lower opioid use in the PENG group.

Applying a preoperative block is effective in terms of preemptive analgesia and may also reduce intraoperative hemodynamic stability and intraoperative analgesic consumption. In this study, patients' MAP and heart rates were similar in both groups, but one of the limitations of our study was that we did not evaluate intraoperative opioid consumption. The fact that the PENG block does not cause any motor deficit or clinically significant weakness facilitates the rehabilitation of patients without pain by providing early mobilization in the postoperative period.^[26] One of the limitations of our study was that we did not include the first mobilization times of the patients in the study. Ather limitation is that although our patient group was hip surgery, the surgeries performed were different (revision, PFN, etc) so analgesic needs may also be different.

CONCLUSION

We think that the PENG block contributes effectively to analgesia in hip surgeries, but the type of surgery may reduce the degree of benefit from the PENG block, and prospective studies are needed for other regional techniques that can be combined with the PENG block for postoperative analgesia, especially in patients undergoing revision THA.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study protocol was approved by the Afyonkarahisar Health Science University Clinical Researches Ethics Committee (Date: 05.11.2021, Decision No: 2021/506).

Informed Consent: All patients signed the free and informed consent form.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

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Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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