Effectiveness of Peripheral Nerve Block in Terms of Search for a Standardized Treatment Protocol in Diabetic Foot Patients Using Anticoagulants

A Double-Center Study

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Background: Lower-extremity amputation for a diabetic foot is mainly performed under general or central neuraxial anesthesia. Ultrasound-guided peripheral nerve block (PNB) can be a good alternative, especially for patients who require continuous anticoagulation treatment and patients with additional comorbidities. We evaluated bleeding due to PNB application in patients with diabetic foot receiving antiplatelet or anticoagulant therapy. Perioperative morbidity and mortality and the need for intensive care hospitalization were analyzed.

Methods: This study included 105 patients with diabetic foot or debridement who underwent distal foot amputation or debridement between February and October 2020. Popliteal nerve block (17 mL of 5% bupivacaine and 3 mL of saline) and saphenous nerve block (5 mL of 2% lidocaine) were applied to the patients. Postoperative pain scores (at 4, 8, 12, and 24 hours) and complications due to PNB were evaluated. Intensive care admission and 1-month mortality were recorded.

Results: The most common diseases accompanying diabetes were hypertension and peripheral artery disease. No complications due to PNB were observed. Mean ± SD postoperative first analgesic need was determined to be 14.1 ± 4.1 hours. Except for one patient, this group was followed up without the need for postoperative intensive care. In 16 patients, bleeding occurred as leakage from the surgical area, and it was stopped with repeated pressure dressing. Mean ± SD patient satisfaction score was 8.36 ± 1.59. Perioperative mortality was not observed.

Conclusions: Ultrasound-guided PNB can be an effective and safe anesthetic technique for diabetic patients undergoing distal foot amputation, especially those receiving antiplatelet or anticoagulant therapy and considered high risk. (J Am Podiatr Med Assoc 114(2), 2024; doi:10.7547/21-115)

Diabetes mellitus is a common disease with an increasing prevalence worldwide that occurs with chronic complications.[1] Foot ulcers occur in approximately 25% of people with diabetes during their lifetime.[2] Diabetic foot is the most serious, costly, and devastating

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chronic complication of diabetes. It is associated with neuropathy of the lower extremity or peripheral artery disease in diabetic patients.[1,3] Diabetic foot complications are the leading cause of hospital admissions, lower-extremity amputations, and deaths among patients with diabetes worldwide. Appropriate management of patients at risk for amputation by a multidisciplinary team can reduce the rates of these results.[1]

Peripheral artery disease is an independent risk factor for ulceration formation and limb loss and is present in 50% of patients with diabetic foot ulcers. Antiplatelet and anticoagulant treatment is used in such patients after a diagnosis of ulcer, initiation of treatment, or endovascular revascularization procedures.[4,5] Patients with long-standing diabetes mellitus are a special concern for anesthesiologists in terms of multiorgan system failure and multidrug use.[6] In such patients, it may be difficult to provide adequate anesthetic and postoperative analgesic effects while maintaining hemodynamics.

Neurovascular structures and needles can be visualized in ultrasound-guided peripheral nerve blocks, so they can be safely used in patients who use antiplatelet or anticoagulant medication or those who have coagulation disorders. They also provide more stable hemodynamics and adequate postoperative analgesia compared with neuraxial block and general anesthesia while decreasing the duration of hospital stay and the rate of intensive care stay.[7,8] The aim of this study was to evaluate bleeding due to both peripheral nerve block application and surgery in patients with diabetic foot who are receiving antiplatelet or anticoagulant therapy. Furthermore, perioperative 1-month morbidity and mortality and the need for intensive care hospitalization were analyzed.

Methods

This prospective observational study was conducted after approval was obtained from the ethics committee of the Ministry of Health Diskapi Yildirim Beyazit Training and Research Hospital, Ankara, Turkey. All of the participants provided written informed consent before taking part. The study participants were 105 diabetic patients who had at least one treatment with an antiplatelet or anticoagulant drug, were categorized as American Society of Anesthesiologists class II to IV, were aged 20 to 75 years, and were scheduled for forefoot amputation, toe amputation, or debridement under popliteal and saphenous nerve blocks between February 1 and October 31, 2020. Surgical interventions were performed in Diskapi Training and Research Hospital and Gulhane Training and Research Hospital, Health Sciences University, Ankara, Turkey. The exclusion criteria were refusal to participate, skin infection at the block area, local anesthetic drug allergy, chronic opioid use, and inability to understand pain scores.

All of the patients with diabetic foot were evaluated with Doppler ultrasonography and ankle-brachial index and were diagnosed as having peripheral artery disease (patients with monophasic flow on Doppler ultrasonography or ankle-brachial index <0.5 mm Hg).[9] In patients with delayed wound healing, clinical improvement, or Doppler ultrasonography results inconsistent with the clinical signs, the diagnosis of peripheral artery disease was checked by applying computed tomographic angiography and by distinguishing the vessels in the affected angiosome. Successful endovascular revascularization was defined by angiography imaging, wound healing rate, and granulation or intraoperative vascular imaging with indocyanine green SPY fluorescence angiography (contour value $>30\%$).[10]

Before the block, demographic data, comorbidities, antiplatelet/anticoagulant drugs used, and Wagner and PEDIS classification scores were recorded. Standard monitoring (electrocardiography, pulse oximetry, noninvasive blood pressure) and intravenous vascular access were applied to the patients before the block. Oxygen at 2 to 4 L/min was given by nasal cannula. For sedation, patients were administered dexmedetomidine at 0.5 to 1.0 μg/kg by 10-min loading infusion 15 min before the block. Ramsey sedation scores of the patients were recorded.

For all of the blocks, we used a Sonosite M-turbo (Sonosite, Bothell, Washington) with a high-frequency linear probe (15-6 MHz). For the popliteal nerve block, the patient was placed in a lateral position. The skin was disinfected with 2% chlorhexidine, and then the ultrasound probe was placed in the popliteal fossa and moved toward the cephalad. When the sciatic nerve bifurcation was visualized, a block needle (Echoplex 80 mm; Vygon, Ecouen, France) was advanced using an in-plane technique. Local anesthetic was injected around the popliteal

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nerve intermittently (a total of 20 mL [17 mL of 5% bupivacaine and 3 mL of saline]).[11]

For the saphenous nerve block, the ankle skin was disinfected with 2% chlorhexidine. The saphenous vein was observed by placing the ultrasound probe 5 to 6 cm above the medial malleolus. Local anesthetic (5 mL of 2% lidocaine) was aspirated intermittently and injected near the saphenous vein.[12] After the block applications, the injected area was evaluated by ultrasonography in terms of possible fluid collection (hematoma). All of the blocks were performed by an experienced anesthesiologist, and all of the operations were performed by an experienced surgeon (D.O., K.B.Y). All of the surgeries were performed without applying a pneumatic tourniquet.

Sensory block was assessed at 15 min with an ice mold and a 4-point numeric scale (0 = no cold sensation, 1 = strongly reduced cold sensation, 2 = lightly reduced cold sensation, 3 = normal cold sensation). All of the blocks with scores of more than 1 point were considered incomplete. After the anesthesia in the surgical area, the surgery was started. The surgical time and intraoperative hemodynamic parameters were recorded. At the end of the surgery, paracetamol (1 g) was administered to the patients. The plan was to administer tramadol (50-mg capsule) to patients with Numeric Rating Scale (NRS) scores of 4 and higher and to record the time when the first analgesic was needed.

The postoperative pain scores of the patients were recorded with an 11-point NRS (0 = no pain, 10 = unbearable pain), and the postoperative satisfaction of the patients was recorded with another 11-point NRS (0 = dissatisfied, 10 = extremely satisfied). The patients were evaluated in the postoperative period in the postanesthesia care unit at 4, 8, 12, and 24 hours. Complications due to peripheral nerve block (local infection, neurologic deficit, vascular puncture, and hematoma) and surgical bleeding were recorded. Intensive care admissions and 1-month mortality of the patients were recorded.

A statistical software program (IBM SPSS Statistics for Windows, Version 22.0; IBM Corp, Armonk, New York) was used for analysis. Data are presented as median (interquartile range) and mean ± SD. Descriptive statistics are used to illustrate the results.

Results

Peripheral nerve block was successful in all of the patients. There was no conversion to general anesthesia in any patient. Fentanyl 50 μg intravenously was given to three patients for intraoperative analgesia support. Demographic data are shown in Table 1. The most common diseases accompanying diabetes were hypertension and peripheral artery disease. The anticoagulant and antiplatelet medication intakes of the patients were as follows: two patients with monotherapy, 13 patients with dual therapy, 85 patients with triple therapy, and five patients with quadruple therapy. Intraoperatively, the mean arterial pressure did not fall below 60 mm Hg in any patient, and heart rates and blood pressure levels were within normal limits. Oxygen saturation levels of the patients were 95% and higher.

Complications due to peripheral nerve block (local infection, neurologic deficit, vascular puncture, and hematoma) were not observed in any patient. One patient who received continuous positive airway pressure treatment due to a preoperative diagnosis of obstructive sleep apnea syndrome received postoperative continuous positive airway

Table 1. Perioperative Details of the 105 Study Patients

Characteristic	Value
Age (mean ± SD [years])	64.09 ± 11.6
BMI (mean ± SD)	30.1 ± 3.2
Duration of surgery (mean ± SD [min])	40.5 ± 12.4
ASA class (No. [%])	
II	38 (36.2)
III	48 (45.7)
IV	19 (18.1)
Sex (No. [%])	
Female	33 (31.4)
Male	72 (68.6)
Comorbidities (No. [%])	
Hypertension	86 (81.9)
Coronary artery disease	63 (60.0)
Heart failure	10 (9.5)
Chronic renal insufficiency	16 (15.2)
Peripheral artery disease	92 (87.6)
Atrial fibrillation	1 (1.0)
Medication (No. [%])	
Acetylsalicylic acid	104 (99.0)
Enoxaparin sodium	91 (86.7)
Coumadin	2 (1.9)
Ticlopidine	96 (91.4)
Apixaban	1 (1.0)
Cilostazol	9 (8.6)
Laboratory tests (mean ± SD)	
Hemoglobin A_{1c} (%)	9.2 ± 2.01
PTT (sec)	18.2 ± 7.91
INR	1.11 ± 0.14
Ramsey score (mean ± SD)	2.15 ± 0.56
First analgesic use (mean ± SD [h])	14.1 ± 4.1
Patient satisfaction score (mean ± SD)	8.36 ± 1.59

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; INR, international normalized ratio; PTT, partial thromboplastin time.

pressure therapy in the intensive care unit, and all other patients were followed up without the need for postoperative intensive care. The pain scores of the patients in the first 24 hours postoperatively are shown in Figure 1.

In 16 patients, bleeding occurred in the form of leakage from the surgical area, which was stopped with repeated pressure dressing. There was no need for repeated admission to the operating room, temporary or permanent discontinuation of anticoagulant therapy, or additional surgery. The mean ± SD time until the first need for analgesics postoperatively was determined to be 14.1 ± 4.1 hours. There were no perioperative 1-month deaths. The mean ± SD satisfaction score of the patients was 8.36 ± 1.59.

Table 2 shows the patients' Wagner and PEDIS classifications and their types of surgery. The study included patients who underwent surgical procedures for debridement, grafting, toe amputation, ray amputation, and forefoot amputation (Chopart, Lisfranc, and transmetatarsal amputation). There were seven patients (6.6%) who underwent forefoot amputation, and an extra drain was placed in these patients.

Discussion

This observational study examined diabetic foot interventions performed with popliteal and saphenous nerve block in patients undergoing at least one antiplatelet or anticoagulant treatment. No bleeding or other complications due to peripheral nerve block and surgery were observed in any patient. Despite having many comorbidities, intraoperative hemodynamic stability and adequate postoperative analgesia were provided in all of the patients. Except for one patient, this group was followed up without the need for postoperative intensive care.

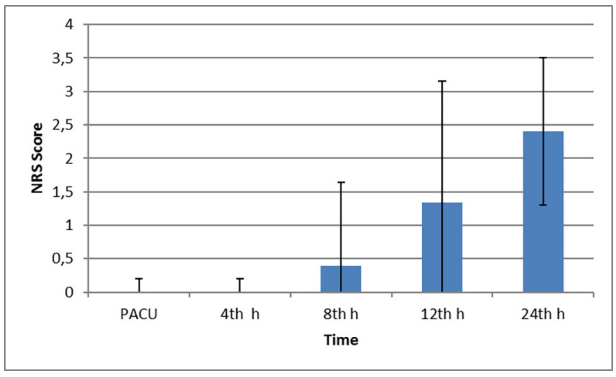


Figure 1. Postoperative Numeric Rating Scale (NRS) pain scores of the patients. Data are expressed as mean ± SD. PACU indicates postanesthesia care unit.

Table 2. Classification of Severity of Diabetic Foot and Types of Surgery

Variable	Patients (No. [%]) (N = 105)
Wagner classification	
Grade 1	2 (1.9)
Grade 2	4 (3.8)
Grade 3	13 (12.4)
Grade 4	86 (81.9)
PEDIS scale	
Grade II	42 (40.0)
Grade III	47 (44.8)
Grade IV	16 (15.2)
Endovascular revascularization	
Successful	64 (79.0)
Unsuccessful	17 (21.0)
Type of surgery	
Toe amputation	55 (52.4)
Debridement	22 (20.9)
Ray amputation	15 (14.3)
Grafting	6 (5.7)
Forefoot amputation	7 (6.7)

Diabetes mellitus is one of the most common metabolic diseases. It has a silent onset, and its prevalence is increasing day by day.[7] Ulceration of diabetic foot is an urgent medical problem. It has been reported that every 30 seconds, a lower limb is lost somewhere in the world as a consequence of diabetes.[13] Chronic hyperglycemia in diabetes mellitus is associated with microvascular complications (retinopathy, nephropathy, and neuropathy) and macrovascular complications (coronary heart disease, peripheral artery disease, and cerebrovascular disease).[4,5]

Patients undergoing debridement for limb preservation and minor amputation for diabetic foot are frequently treated with invasive methods such as peripheral angiography before surgical treatment and increased vascular bed blood supply, especially with the angiosome model.[14] For peripheral vascular disease occurring based on diabetes, antiplatelet or anticoagulant therapy and subsequent prophylaxis are included in the treatment protocol and are recommended by treatment guidelines for the continuation of vascularization.[15] Multiorgan system failure and the use of multiple drugs, especially antiplatelet or anticoagulant therapy, complicate anesthesia management. The demographic findings of the patients in the present study are consistent with these findings in the literature.

Peripheral nerve block is a method that is frequently applied for patient comfort and safety in outpatient procedures such as diabetic foot surgery.[16] Compared with general anesthesia and central regional block methods, peripheral nerve blocks provide more stable hemodynamics, better postoperative analgesia, and less postoperative morbidity, making this method especially attractive for high-risk patients.[6,7,16,17] However, complications related to needle intervention (vascular puncture, hematoma, or aneurysm) cause drawbacks in both peripheral and central regional anesthesia applications. On the other hand, discontinuation of anticoagulant therapy may lead to treatment losses that may lead to organ losses. Therefore, it may be difficult for both the anesthesiologist and the surgical team to calculate the costs and benefits to decide whether to discontinue such agents in diabetic patients receiving antiplatelet or anticoagulant therapy.

In April 2018, the Regional Anesthesia and Acute Pain Section of the Canadian Anesthesiologists' Society convened a panel that made recommendations for patients at high risk for bleeding complications due to coagulopathy, anticoagulation, or antithrombotic therapy. The panel recommended that lower-extremity blocks performed close to large vessels (femoral nerve, adductor canal, and popliteal nerve blocks) be classified as having intermediate risk for bleeding complications and that blocks of nerves in a very superficial location (lateral femoral cutaneous nerve, infrainguinal fascia iliaca, and ankle blocks) be classified as having low risk of bleeding complications. In addition, the use of ultrasonography was recommended by the panel in terms of block safety and performance and early diagnosis of complications.[18]

In another review examining peripheral nerve blocks in patients receiving antiplatelet or anticoagulant medications, the rate of bleeding-related complications was found to be 0.8% according to data from six observational studies and eight case reports. It has been emphasized that this complication is mostly from the lumbar plexus block, which is a deep block. In the same review, it was suggested that antiplatelet or anticoagulant treatment may not be discontinued for peripheral nerve blocks in areas where superficial and pressure bleeding could be stopped. Different treatment recommendations from this review are still included in the guidelines.[19]

Reported complications that may occur in lower-extremity nerve blocks in particular include vascular puncture, hematoma, and nerve compression. However, it is difficult to conduct a randomized controlled study on complications due to peripheral nerve blocks in patients receiving anticoagulants. Current publications consist of only case reports or retrospective studies. In this prospective observational study, the development of vascular puncture, hematoma, and nerve compression during the block application and in the postoperative period was monitored and controlled by ultrasonography. No bleeding-related complications were encountered in any patient who used antiplatelet or anticoagulant medications and underwent a popliteal and saphenous nerve block. A meta-analysis comparing ultrasound-guided peripheral nerve block with classical techniques (paresthesia and neurostimulation) showed a lower incidence of vascular puncture in cases with the aid of ultrasound.[8] In this study, all of the attempts were performed with ultrasonography.

In recent years, peripheral nerve block applications with real-time ultrasonography have enabled imaging of the nerve and reference structures to create an effective and high-quality block.[20] Ultrasonography also has the advantage of visualizing normal and aberrant vessels, as well as allowing the practitioner to plan a safer needle path or to choose an alternative approach away from the vessels.[18] In addition, because the nerve to be blocked can be monitored in real time, it decreases the number of needle passes and can reduce complications related to bleeding.[21] Even bleeding after block can be used to diagnose complications. Thus, it enables early diagnosis and treatment.[18] In the present study, no vascular puncture or bleeding was observed in any patient.

Although anesthesia treatment guidelines suggest the use of more flexible antiplatelet and anticoagulant medications for peripheral block procedures, more precise recommendations are offered in surgical treatment guidelines, and cessation of treatment or bridging is recommended.[22] These recommendations may lead to delays in diabetic foot crisis treatment, which may require urgent actions. In this group of patients, the "time is tissue" principle should not be forgotten, and the benefit of early intervention has been proved for limb preservation.[23]

The change of current treatment with low-molecular-weight heparin with bridging recommended against the risk of bleeding in surgical treatment guidelines, together with the length of time in the period, may lead to treatment disruptions in patients after peripheral angiography.[24] Considering that prophylaxis with early dual agents is recommended after revascularization after peripheral angiography, discontinuation of treatment should be discussed.[25] At this point, the proposition that makes sense to us is that the surgeons and anesthesiologists should consider the risk factors specific to the patient, the surgical procedure, and the anesthetic

technique to be applied; experience should inform the decision around bleeding risk inherent to the procedure; and decisions regarding the management of antithrombotic medications should be made with each individual patient based on their goals of care.

The most important limitation of this study is that it was not a randomized controlled study. Another limitation may be that all of the peripheral nerve blocks were performed by experienced anesthesiologists with ultrasonography. Safety results that can be obtained from future multicenter studies would be beneficial.

Conclusions

In patients with diabetic foot ulcer who have multiple comorbidities and are using more than one antiplatelet or anticoagulant drug, debridement and amputation procedures can be safe with ultrasound-guided peripheral nerve block without discontinuing antiplatelet or anticoagulant therapy. In addition, it may reduce the complications that may occur with general anesthesia and the need for intensive care hospitalization.

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