Am J Transl Res 2026;18(6):5193-5209
www.ajtr.org /ISSN:1943-8141/AJTR0172789

Original Article

Improvement of wound healing after diabetic foot debridement by a novel high ankle block: a randomized controlled trial

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Received March 20, 2026; Accepted May 11, 2026; Epub June 15, 2026; Published June 30, 2026

Abstract: Objective: To evaluate the effect of ultrasound-guided high ankle block (HAB) on postoperative wound healing and foot perfusion after diabetic foot debridement. Methods: This prospective, assessor-blinded randomized controlled trial (NCT06395961) enrolled 70 patients with Wagner II-IV diabetic foot ulcers undergoing debridement. Thirty-five patients received HAB with 35 mL of 0.375% ropivacaine, and 35 received general anesthesia (GA). The primary outcome was ulcer area on postoperative day 7, measured using ImageJ boundary delineation. Ulcer area was also assessed on days 1, 7, 14, 28, and 60. Secondary outcomes included: anterior and posterior tibial artery hemodynamics assessed by Doppler ultrasound on days 1, 7, and 14; foot skin temperature measured by infrared thermography on days 2, 4, 6, 8, 10, 12, and 14 (to avoid interference with ultrasound measurement); and visual analog scale (VAS) pain scores, opioid consumption, and adverse events assessed at various time points. Results: The HAB group showed significantly higher ulcer healing rates on day 7 (42.2% vs. 29.4%, P=0.04), day 14 (67.9% vs. 53.2%, P=0.02), day 28 (85.7% vs. 75.2%, P=0.02), and day 60 (96.8% vs. 91.2%, P=0.01). Arterial flow volume, peak systolic velocity, end diastolic velocity, time-averaged mean velocity, and time-averaged maximum velocity were significantly improved in the HAB group on days 1 and 7 (all P<0.001). The HAB group also had significantly higher foot skin temperatures (P<0.05), lower VAS scores (P<0.001), and lower opioid consumption (P<0.001). Pneumonia occurred less frequently with HAB (2.9% vs. 20.0%, P=0.055). No significant differences were observed in reoperation or amputation rates. Conclusion: HAB enhances foot perfusion, accelerates early ulcer healing, and provides superior analgesia with fewer complications compared with GA.

Keywords: High ankle block, nerve block, diabetic foot, ulcer, wound healing, postoperative pain

Introduction

Diabetic foot (DF) is a severe complication in the advanced stages of diabetes and is closely associated with diabetic neuropathy and peripheral arterial disease [1]. The Wagner classification system is a core standard for assessing DF wound severity and guiding clinical management. For patients with Wagner grades II-IV, lesions have penetrated the skin surface, presenting common challenges including deep tissue damage, local ischemia and hypoxia, and impaired wound healing. Diabetic foot ulcers (DFUs) are the most common manifestation of DF, with main symptoms including ulceration, infection, deformation, necrosis of foot tissues, as well as lower extremity neuropathy and vasculopathy. International guidelines recognize ulcer area as a common indicator for assessing DF recovery [2]. A major factor impeding DFU healing is lower limb vascular disease, in which microcirculatory disorders and inadequate tissue perfusion in the distal foot can lead to ischemia and hypoxia [3]. Current treatment approaches for DF focus on multidimensional combined interventions, including fundamental me-

https://doi.org/10.62347/EHMK3754

dical management (e.g., glycemic and blood pressure control) and surgical interventions (e.g., antimicrobial therapy, debridement, bone reconstruction, amputation, and vascular reconstruction). Enhancing wound healing and improving patient prognosis are current focal points of clinical research. Studies have shown that continuous epidural infusion of ropivacaine can significantly alleviate symptoms in DF patients. The underlying mechanism involves local anesthetics blocking sympathetic nerves, leading to vasodilation, increased blood supply, collateral circulation reconstruction, and improved foot reperfusion [4]. However, continuous epidural analgesia poses substantial risks and limitations for patients requiring anticoagulant therapy in surgical settings [5]. General anesthesia (GA), commonly used for DFU debridement surgery, can adequately meet analgesic requirements. However, for patients with diabetic peripheral neuropathy and vascular disease, the combined use of various general anesthetics may increase the incidence of complications such as hemodynamic instability and delayed postoperative recovery. Zou et al. confirmed through a prospective randomized controlled trial that, compared with GA, peripheral nerve block (PNB) provides more stable intraoperative hemodynamics for DF patients undergoing below-knee surgery, reduces the incidence of hypotension and postoperative pain scores within 48 hours, and decreases airway complications such as postoperative sore throat, making it a more optimal anesthetic choice for such patients [6].

High ankle block (HAB) is a novel nerve block approach that has emerged in the past two years. HAB provides comprehensive intraoperative and postoperative analgesia by blocking the tibial nerve (TN), deep peroneal nerve (DPN), superficial peroneal nerve (SPN), saphenous nerve (SaN), and sural nerve (SuN). Because the blocking plane is below the mid-lower leg, it does not affect knee joint movement and has minimal impact on muscle strength related to ankle joint movement. This allows for early postoperative ambulation and functional exercise, making HAB a novel option for anesthesia in foot and ankle surgeries [7]. Whether HAB can also achieve vasodilation, improve blood supply to the foot, and enhance postoperative wound healing in DF patients has not yet been studied. This study therefore aims to explore the effects of intraoperative HAB analgesia on postoperative wound recovery and blood perfusion in the foot and ankle of DF patients.

Methods

Study design

This prospective, randomized, controlled study was designed to investigate the efficacy and feasibility of intraoperative HAB analgesia on postoperative wound healing and blood perfusion of the foot and ankle in patients with DF. Patients with DFUs were enrolled at the Department of Anesthesiology, Xuzhou Clinical School of Xuzhou Medical University, Xuzhou Central Hospital, from June 17, 2024, to July 31, 2025. After providing written informed consent, all participants were randomly assigned at a 1:1 ratio to either the HAB group or the GA group. The study protocol was approved by the Ethics Committee of Xuzhou Central Hospital (Ethics No. XZXY-LK-20231029-0175) and registered at ClinicalTrials.gov (NCT06395961) before patient enrollment. All procedures followed the Declaration of Helsinki (October 2013) and relevant clinical practice guidelines.

Participants

The inclusion criteria were as follows: (1) patients meeting the diagnostic criteria for DF according to the 2019 edition of the *Global Guidelines on the Prevention and Management of Diabetic Foot* [8, 9], specifically those classified as Wagner grades II-IV; (2) patients with good communication skills who are capable of complying with various monitoring procedures. The exclusion criteria were as follows: (1) presence of skin infection at the puncture site; (2) patients undergoing amputation; (3) severe cardiovascular or cerebrovascular diseases; (4) significant coagulation disorders; (5) mental disorders; (6) dementia or cognitive impairments.

All study interventions were administered by anesthesiologists with no less than five years of clinical experience.

Randomization and blinding

Participants were randomly assigned in a 1:1 ratio to either the HAB group or the GA group. A

research assistant not involved in patient management prepared opaque envelopes containing a randomization code generated using SPSS version 20 (IBM Corp), corresponding to the HAB or GA group. Based on the surgical application list, a study coordinator not involved in the follow-up screened patients who met the inclusion criteria as potential participants. After explaining the study purpose and procedures, interested patients were asked to sign an informed consent form. The order of signing the consent form was recorded as the participant's number. The researcher opened the envelope marked with the corresponding number to obtain the group assignment. A blinded study evaluator, who was not directly involved in the anesthetic management of the patient, collected all preoperative and postoperative data. The study assessor was also blinded to the group assignment. Because of the different anesthetic protocols used, researchers and participants were not blinded to the group assignment.

Interventions

Patients fasted for 6 hours and abstained from drinking water for 2 hours prior to surgery. No preoperative medications were administered. Upon arrival in the operating room, a peripheral venous access was established, continuous monitoring of electrocardiography and pulse oxygen saturation was initiated, and oxygen was delivered via nasal cannula at a flow rate of 2 L/min. Radial artery puncture and catheterization were then performed for invasive arterial pressure monitoring.

HAB group: Only HAB was performed. Ultrasound-guided HAB was administered on the operative side by the same senior anesthesiologist in the preoperative holding area. The local anesthetic formulation consisted of 35 mL of 0.375% ropivacaine. Patients were positioned supine or in the lateral decubitus position, with the lower leg of the operative limb fully exposed. Standard skin disinfection was performed using iodophor. A high-frequency linear array probe (6-15 MHz) was placed at the level from the middle-lower 1/3 to the mid-segment of the lower leg (approximately 15-20 cm above the medial and lateral malleoli), ensuring that the long axis of the probe was perpendicular to the long axis of the limb. Under real-time ultrasound guidance, the target nerves were identified by translating the probe. All procedures were performed using the in-plane puncture technique combined with hydrodissection for precise localization. The needle tip was clearly visualized, and nerve tissue was avoided. After negative aspiration for blood, the anesthetic was injected. The specific nerve block procedures were as follows: (1) DPN block (**Figure 1A**): The needle was inserted from the anterolateral aspect of the lower leg. The interspace posterior to the extensor hallucis longus and tibialis anterior muscles was located, and the DPN adjacent to the anterior tibial artery (ATA) was identified, followed by injection of 10 mL of local anesthetic. (2) SPN block (**Figure 1B**): In the same scanning plane as the DPN, the SPN, which is located in the superficial subcutaneous layer and within the fascial interspace between the extensor digitorum longus and peroneal muscles, was observed, and 5 mL of local anesthetic was injected. (3) TN block (**Figure 1C**): The needle was inserted from the posteromedial aspect of the lower leg, with the tibia as the landmark. The TN, which runs deep to the soleus muscle and lies in the interspace between the flexor digitorum longus, flexor hallucis longus, and tibialis posterior muscles (adjacent to the posterior tibial artery, PTA), was identified, and 10 mL of local anesthetic was injected. (4) SuN block (**Figure 1D**): The needle was inserted from the posterior aspect of the lower leg. The SuN, which runs in the superficial subcutaneous layer around the small saphenous vein, was located, and 5 mL of local anesthetic was injected. (5) SaN block (**Figure 1E**): The needle was inserted from the anteromedial aspect of the lower leg, with the tibia as the bony landmark. The SaN, which runs in the superficial subcutaneous layer adjacent to the great saphenous vein, was located, and 5 mL of local anesthetic was injected. Following completion of the block procedures, a 20-minute waiting period was observed, and anesthetic efficacy was assessed using the pinprick test. Block success was defined as the absence of pinprick sensation in the following areas: the plantar aspect of the foot and posterior ankle (innervated by TN branches); the dorsum of the foot and lateral lower leg (innervated by the DPN and SPN); the medial lower leg and ankle (covered by the SaN); and the lateral lower leg and ankle (innervated by the SuN). Cases failing to meet the above block criteria were excluded from the study.

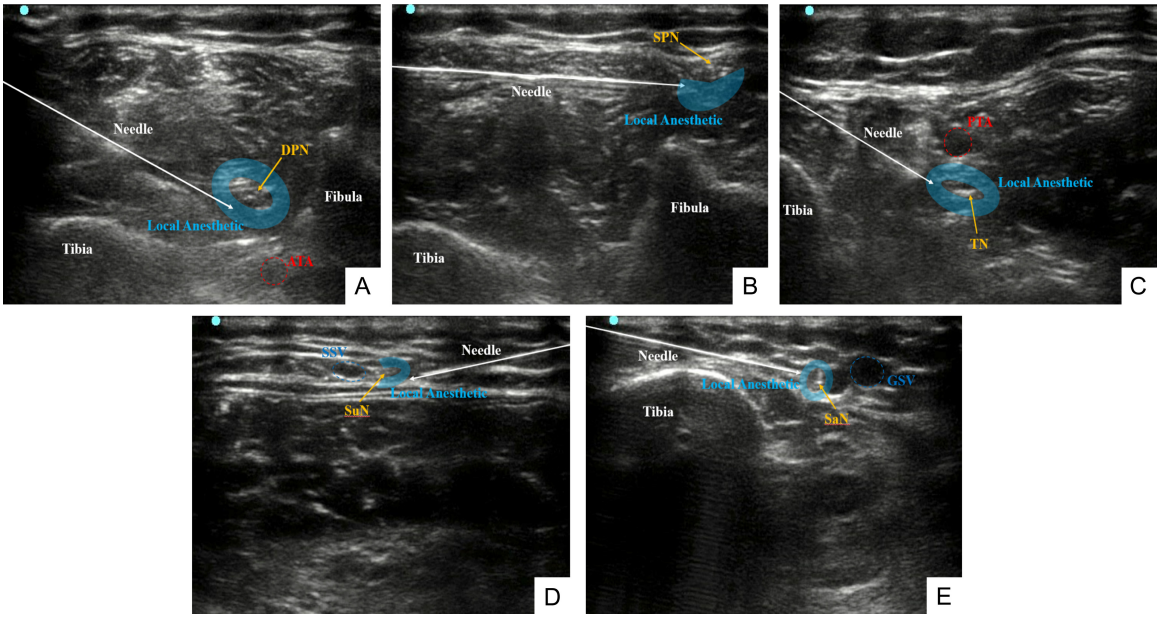

Figure 1. Ultrasound-guided HAB image. Under ultrasound vision, local anesthetic injections were performed near the (A) DPN, (B) SPN, (C) TN, (D) SuN, and (E) SaN. HAB: high ankle block; DPN: deep peroneal nerve; ATA: anterior tibial artery; SPN: superficial peroneal nerve; TN: tibial nerve; PTA: posterior tibial artery; SuN: sural nerve; SSV: short saphenous vein; SaN: saphenous nerve; GSV: great saphenous vein.

GA group: GA was administered, with no nerve block performed. Following the completion of monitoring, anesthesia was induced and surgery was performed as usual. Anesthesia induction involved intravenous administration of midazolam (0.03-0.05 mg/kg), etomidate (0.15-0.20 mg/kg), cisatracurium (0.15-0.20 mg/kg), and sufentanil (0.3-0.5 μg/kg). Intraoperative anesthesia was maintained with an intravenous infusion of remifentanil (0.1-0.3 μg/kg/min) and propofol (4-6 mg/kg/h), keeping the bispectral index values between 40 and 60. Blood pressure and heart rate were maintained within ±20% of baseline values. Cisatracurium was administered intermittently as needed. For additional analgesia, flurbiprofen axetil injection (50 mg) was administered intravenously 30 minutes before the end of surgery. All anesthetic agents were discontinued 5 minutes before the end of the procedure. Postoperatively, patients were transferred to the post-anesthesia care unit. The endotracheal tube was removed once the patient was awake and had resumed spontaneous breathing. Patients were transferred to the ward upon meeting post-anesthesia care unit discharge criteria.

Postoperative analgesia (both groups): No additional postoperative analgesia pumps were used. If patients reported a visual analog scale (VAS) score greater than 4, extended-release oxycodone tablets were administered orally for pain relief.

Debridement procedure (both groups): All patients underwent standardized debridement for DFUs. During the procedure, scabs and necrotic tissues were excised, healthy skin at the ulcer margins was preserved, and the skin was carefully apposed to cover the wound bed to the greatest extent possible.

Biochemical parameter measurement

All study subjects had peripheral venous blood collected after an 8-12 hour overnight fast for the measurement of several serological indicators: glycated hemoglobin, C-reactive protein, and white blood cell count.

Observational indicators

All postoperative outcomes were assessed by a separate group of investigators who did not participate in the anesthesia or surgery, were unaware of the trial group assignment, and were instructed not to discuss the type of anesthesia with patients or other healthcare providers.

The observation time points were defined as follows: T0 (preoperative), T1 (postoperative day 1), T2 (postoperative day 2), T4 (postoperative day 4), T6 (postoperative day 6), T7 (postoperative day 7), T8 (postoperative day 8), T10 (postoperative day 10), T12 (postoperative day 12), T14 (postoperative day 14), T28 (postoperative day 28), and T60 (postoperative day 60). Ulcer area was measured at T0, T1, T7, T14, T28, and T60. The wound healing rate was calculated as follows: Healing rate (%) = (Preoperative ulcer area - Ulcer area at follow-up time point)/Preoperative ulcer area × 100%. Photographs of the ulcer areas were taken using a mobile phone, and the ulcer area was calculated using National Institutes of Health ImageJ software (version 1.46) [10]. A specialist manually outlined the clear visual boundary between the ulcer and normal tissue, after which the software automatically calculated the area of the enclosed region. All measurements were conducted by the same researcher, with each wound measured twice and the average value used to ensure consistency.

The following indicators were evaluated: Lower leg arterial blood flow parameters at T0, T1, T7, and T14, including flow volume (FV), peak systolic velocity (PSV), end diastolic velocity (EDV), time-averaged mean velocity (TAmean), and time-averaged maximum velocity (TAmax); Skin temperature of the toes and dorsal foot at T0, T2, T4, T6, T8, T10, T12, and T14; VAS scores and oxycodone dosage at T1 and T2; Operative time, intraoperative blood loss, and total intraoperative fluid infusion volume; Incidence of adverse events (including pneumonia, nausea, vomiting, urinary retention, and delirium); Amputation rate and reoperation rate at T60.

The workflow for collecting lower leg arterial blood flow parameters was as follows: Immediately after nerve block completion, the patient was instructed to assume a supine position with both legs fully exposed and abducted/externally rotated, avoiding limb-to-limb contact. Using a 10 MHz high-frequency linear array probe, the ATA and PTA were located via color Doppler ultrasound. The probe was positioned 3-5 cm above the ankle on the anterolateral aspect of the calf. Sagittal axis images of the arteries were first acquired in color 2D mode; the mode was then switched to pulsed Doppler. The sampling volume was adjusted to one-third of the vessel diameter and positioned centrally within the vessel lumen. The Doppler angle (θ) was corrected to 60° relative to the blood flow direction. Automatic tracking was employed to record all relevant blood flow parameters of the lower leg arteries [11, 12]. Skin temperature was measured using an infrared thermal imager (resolution up to 0.1°C) [13]. The camera was mounted on an adjustable stand positioned 30 cm above the patient's ankle skin, with the patient keeping the leg stationary during the measurement. For pain assessment, the VAS was used to help patients define their pain intensity.

Sample size and statistical analysis

The sample size was calculated using PASS 2021 software. The primary outcome was the ulcer area at T7. To determine the sample size for the formal trial, a pilot study was conducted as part of the present research from June 17, 2024, to September 30, 2024 (within the overall study period). A total of 24 diabetic patients with a confirmed diagnosis of DFU were enrolled and randomly assigned in a 1:1 ratio to the HAB group and the GA group, with 12 patients in each group. In the pilot study, the mean ulcer areas in the HAB and GA groups were 7.48±1.89 cm^2 and 9.10±2.23 cm^2, respectively. With an alpha level (α) of 0.05, a power (1-β) of 0.8, and accounting for an expected dropout rate of 20%, 35 patients per group were required.

Statistical analyses were performed using GraphPad Prism software (version 7.0; GraphPad, San Diego, CA, USA). Continuous data are represented as mean (standard deviation, SD) and were compared using an unpaired two-tailed t-test. Data that were not normally distributed are reported as median (interquartile range) and were analyzed using the Mann-Whitney U test. Repeated-measures one-way analysis of variance was used to compare continuous outcomes (e.g., ulcer area, blood perfusion indices) between groups over multiple time points (preoperative, T1, T7, T14), with Bonferroni post-hoc tests for pairwise comparisons. This method accounts for group–time interactions and avoids type I error inflation from repeated t-tests. Categorical variables are reported as numbers (%) and were compared using the χ^2 test or Fisher's exact test, as appropriate. All statistical tests were two-sided, and a *P* value

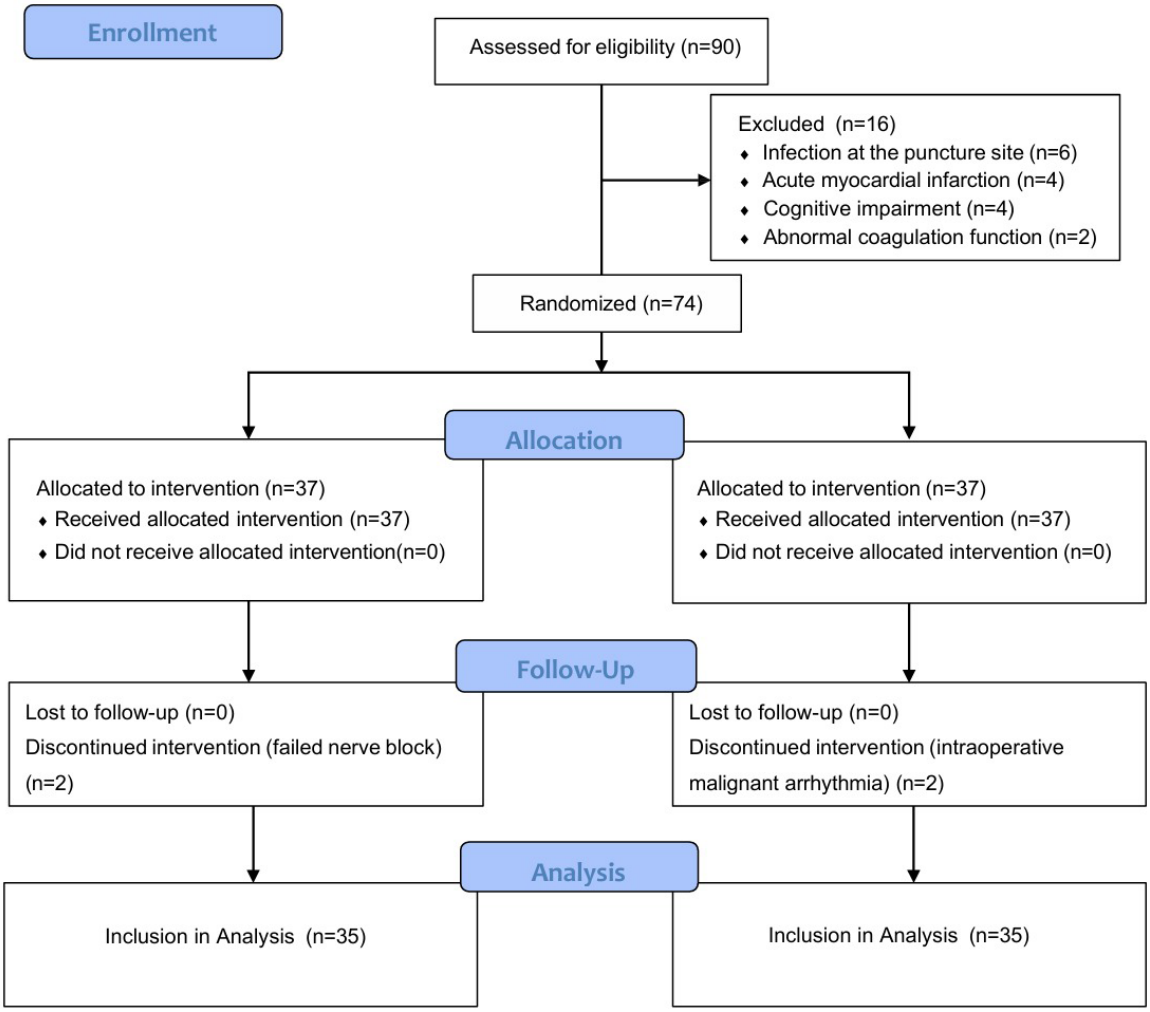

Figure 2. CONSORT flow diagram showing the progression of participants through each stage of the randomized controlled trial. CONSORT: Consolidated Standards of Reporting Trials.

of less than 0.05 was considered statistically significant.

Results

Figure 2 presents the Consolidated Standards of Reporting Trials flow diagram. From June 17, 2024, to July 31, 2025, a total of 74 patients were enrolled and randomized. However, two patients in the HAB group were excluded from the final analysis due to failed nerve block and subsequent conversion to GA. No mechanism-based classification records were made for these two failed cases during the study period; therefore, a definitive judgment on the reasons for the failure could not be made. Based on clinical operative experience, we believe the failure may be related to the following factors: individual anatomical variations, local tissue edema or inflammation making nerve identification under ultrasound difficult, insufficient perineural spread of local anesthetic, or incomplete blockade of some nerves in combined nerve blocks. Additionally, two patients from the GA group were excluded due to the occurrence of malignant arrhythmias during surgery and loss to follow-up. Consequently, the final analysis included 35 participants in the HAB group and 35 participants in the GA group. The study followed the manufacturer's protocol and adhered to established procedures and guidelines [13].

Baseline data

A total of 70 patients were included. Comparisons between the HAB group and the GA group in terms of baseline characteristics,

Table 1. Baseline characteristics of the patients

Characteristic	HAB group (n=35)	GA group (n=35)	t/χ^2	*P* value
Age (years)	58.32±12.98	55.79±13.54	0.798	0.43
Female sex, n (%)	7 (20.0)	5 (14.3)	0.402	0.53
ASA classification, n (%)			0.050	0.81
II	18 (51.4)	19 (54.3)		
III	17 (48.6)	16 (45.7)		
BMI (kg/m^2)	22.98±3.37	24.35±3.65	1.626	0.11
Duration of diabetes (years)	13.31±3.89	12.22±3.78	1.180	0.24
Duration of DF (months)	11.89±5.97	9.18±6.76	1.756	0.08
Left-sided DF, n (%)	10 (28.6)	12 (34.3)	0.265	0.61
FBG (mmol/L)	11.13±2.01	10.45±1.88	1.458	0.15
HbA1c (%)	10.15±1.16	9.03±3.49	1.754	0.08
WBC (×10^9/L)	10.12±9.55	11.78±8.44	0.774	0.44
CRP (mg/L)	20.92±5.28	23.02±5.11	-1.676	0.10
Wagner classification, n (%)			0.273	0.89
II	18 (51.4)	20 (57.1)		
III	10 (28.6)	9 (25.7)		
IV	7 (20.0)	6 (17.1)		
Preoperative ulcer area (cm^2)	12.71±3.24	13.05±3.51	0.425	0.67
Hypertension grade, n (%)			0.152	0.96
None	12 (34.3)	14 (40.0)		
Grade 1	9 (25.7)	9 (25.7)		
Grade 2	9 (25.7)	8 (22.9)		
Grade 3	5 (14.3)	4 (11.4)		

Data are presented as mean ± SD, n (%), or number (%). SD: standard deviation; HAB: high ankle block; GA: general anesthesia; ASA: American Society of Anesthesiologists; FBG: fasting blood glucose; BMI: body mass index; HbA1c: glycated hemoglobin; WBC: white blood cell; CRP: C-reactive protein; DF: diabetic foot.

including age, female sex, American Society of Anesthesiologists classification, body mass index, duration of diabetes, duration of DF, left-sided involvement, fasting blood glucose, glycated hemoglobin, white blood cell count, C-reactive protein, Wagner classification, preoperative ulcer area, and hypertension, showed no statistically significant differences (all $P>0.05$), as shown in **Table 1**.

Comparison of ulcer area

In this study, T0, T1, T7, T14, T28, and T60 were selected as the time points for ulcer area assessment. The period of 1-2 weeks postoperative constitutes a critical window for improved local perfusion, inflammation resolution, and analgesic efficacy evaluation, which can directly reflect the therapeutic effect of HAB [2]. T7 allows assessment of whether HAB, via sympathetic blockade-induced vasodilation, can initiate wound repair by enhancing oxygen and nutrient delivery and reducing inflammatory mediator accumulation. T14 corresponds to the mid-term healing phase, during which sustained perfusion improvement and infection control translate into quantifiable ulcer size reduction. The use of two consecutive time points enables dynamic visualization of the ulcer healing trajectory, enhancing the reliability of the results.

At T0, there was no significant difference in ulcer area between the HAB group and the GA group (12.71±3.24 cm^2 vs. 13.05±3.51 cm^2, $P=0.67$), indicating good baseline comparability. At T1, the ulcer area in the HAB group was 10.82±2.56 cm^2, and that in the GA group was 11.94±2.87 cm^2. The ulcer area was smaller in the HAB group, but the difference was not statistically significant ($P>0.05$). At T7, the remaining ulcer area in the HAB group was 7.35±1.91 cm^2, representing approximately 42.2% healing compared with the preoperative area. In the GA

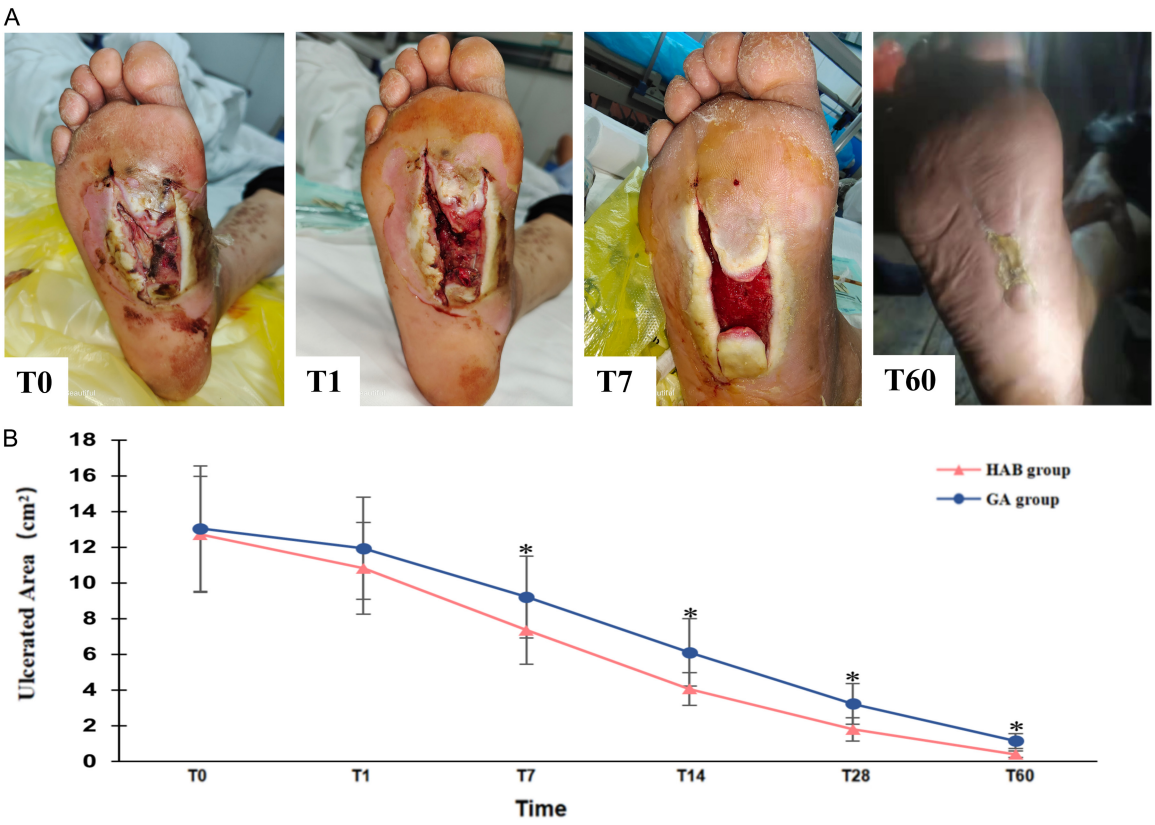

Figure 3. Changes in ulcer area. A. Preoperative and postoperative images of foot ulcers. B. Statistical comparison of ulcer area between the two groups. The difference between the two groups was significant (*P<0.05). HAB, high ankle block; GA, general anesthesia; T0: preoperative; T1: postoperative day 1; T7: postoperative day 7; T14: postoperative day 14; T28: postoperative day 28; T60: postoperative day 60.

group, the remaining ulcer area was 9.21±2.28 cm^2, representing approximately 29.4% healing. The difference between the groups was statistically significant, with an intergroup difference of -1.86 cm^2 (95% CI: -3.67 to -0.04, P=0.04). At T14, the difference became more pronounced. The remaining ulcer area in the HAB group was 4.07±0.92 cm^2 (approximately 67.9% healing), whereas that in the GA group was 6.11±1.88 cm^2 (approximately 53.2% healing). The intergroup difference was -2.04 cm^2 (95% CI: -3.85 to -0.22, P=0.02). At T28, the remaining ulcer area in the HAB group was 1.81±0.65 cm^2 (approximately 85.7% healing), compared with 3.23±1.13 cm^2 (approximately 75.2% healing) in the GA group. The intergroup difference was -1.42 cm^2 (95% CI: -2.63 to -0.21, P=0.02). At T60, the remaining ulcer area in the HAB group was 0.41±0.18 cm^2 (approximately 96.8% healing), whereas that in the GA group was 1.15±0.42 cm^2 (approximately 91.2% healing). The intergroup difference was -0.74 cm^2 (95% CI: -1.23 to -0.25, P=0.01) (**Figure 3A**, **3B**).

Comparison of intraoperative variables

There were no statistically significant differences between the two groups in terms of surgery duration (54.08±5.12 min vs. 55.67±4.06 min, P=0.15) or intraoperative blood loss (133±125 mL vs. 143±108 mL, P=0.72). Total fluid intake was significantly lower in the HAB group than that in the GA group (410±142 mL vs. 540±320 mL, P=0.03) (**Table 2**).

Comparison of hemodynamic parameters of the ATA and PTA

Ultrasound measurements of the hemodynamic parameters of the ATA revealed that the FV in the HAB group was significantly greater than that in the GA group at T1 (24.28±3.43 mL/s vs. 15.54±3.12 mL/s, P<0.001), T7 (22.91 ±3.09 mL/s vs. 14.77±2.86 mL/s, P<0.001),

Table 2. Intraoperative variables and postoperative indicators

Variable		HAB group (n=35)	GA group (n=35)	*t*	*P* value
Duration of surgery (min)		54.08±5.12	55.67±4.06	-1.440	0.15
Intraoperative blood loss (mL)		133±125	143±108	-0.358	0.72
Total fluid intake (mL)		410±142	540±320	-2.197	0.03
Intraoperative blood pressure (mmHg)		85.26±7.35	83.98±8.12	0.691	0.49
Postoperative blood pressure (mmHg)		86.02±7.11	84.75±7.83	0.710	0.48
Intraoperative HR (bpm)		72.35±5.82	75.62±6.18	-2.279	0.03
Postoperative HR (bpm)		70.58±5.12	73.86±5.79	-2.511	0.01
VAS scores	T1	1.33±0.61	4.95±1.12	-16.79	<0.001
	T2	2.45±0.73	4.73±0.97	-11.11	<0.001
Oxycodone consumption (mg)	T1	1.43±1.48	5.57±1.94	-10.04	<0.001
	T2	2.98±1.55	7.37±2.69	-8.365	<0.001

Data are expressed as mean ± SD. SD: standard deviation; HAB: high ankle block; GA: general anesthesia; VAS: visual analogue scale; T1: postoperative day 1; T2: postoperative day 2; HR: heart rate.

and T14 (21.26±2.81 mL/s vs. 15.68±2.63 mL/s, *P*<0.001). Similarly, the PSV in the HAB group was greater than that in the GA group at T1 (84.63±6.25 cm/s vs. 45.40±7.61 cm/s, *P*<0.001), T7 (64.16±5.69 cm/s vs. 45.21±6.11 cm/s, *P*<0.001), and T14 (55.51±5.12 cm/s vs. 44.87±5.85 cm/s, *P*=0.02). The EDV in the HAB group was also greater than that in the GA group at T1 (11.53±1.75 cm/s vs. 6.83±1.63 cm/s, *P*<0.001) and T7 (8.76±2.11 cm/s vs. 6.54±1.54 cm/s, *P*<0.001). The TAmean in the HAB group was greater than that in the GA group at T1 (11.92±2.17 cm/s vs. 6.96±1.92 cm/s, *P*<0.001) and T7 (8.85±2.24 cm/s vs. 6.76±1.71 cm/s, *P*<0.001). The TAmax in the HAB group was greater than that in the GA group at T1 (23.33±3.89 cm/s vs. 11.83±2.11 cm/s, *P*<0.001) and T7 (18.19±2.91 cm/s vs. 11.62±2.53 cm/s, *P*<0.001) (**Figure 4**).

The hemodynamic parameters of the PTA were similar to those of the ATA. Ultrasound measurements showed that the FV of the PTA in the HAB group was higher than that in the GA group at T1 (22.23±3.55 mL/s vs. 15.09±3.37 mL/s, *P*<0.001), T7 (20.17±2.89 mL/s vs. 14.12±3.03 mL/s, *P*<0.001), and T14 (19.67 ±2.77 mL/s vs. 14.88±2.56 mL/s, *P*<0.001). Similarly, the PSV in the HAB group was higher than that in the GA group at T1 (81.11± 6.46 cm/s vs. 44.10±7.31 cm/s, *P*<0.001), T7 (61.49±5.29 cm/s vs .43.65±6.02 cm/s, *P*<0.001), and T14 (53.20±5.35 cm/s vs. 43.83±5.79 cm/s, *P*=0.04). The EDV in the HAB group was also higher than that in the GA group at T1 (11.11±1.89 cm/s vs. 6.53± 1.73 cm/s, *P*<0.001) and T7 (8.72±2.23 cm/s vs. 6.13±1.99 cm/s, *P*<0.001). The TAmean in the HAB group was higher than that in the GA group at T1 (11.44±2.37 cm/s vs. 6.78± 1.95 cm/s, *P*<0.001) and T7 (8.29±2.46 cm/s vs. 6.56±1.87 cm/s, *P*<0.001). The TAmax in the HAB group was also significantly higher than that in the GA group at T1 (23.10±3.28 cm/s vs. 11.94±2.54 cm/s, *P*<0.001) and T7 (16.53±2.86 cm/s vs. 11.23±2.69 cm/s, *P*< 0.001) (**Figure 5**).

Comparison of postoperative recovery and pain indicators

Infrared thermography measurements revealed that the skin temperatures of the toes and dorsal feet in the HAB group were higher than those in the GA group (both *P*<0.05) (**Figure 6**). Compared with the GA group, the HAB group had significantly lower VAS scores and oxycodone consumption at T1 and T2 (all *P*<0.001) (**Table 2**).

Comparison of postoperative adverse events

The incidence of pneumonia was lower in the HAB group than that in the GA group (2.9% vs. 20.0%, Fisher's exact test *P*=0.055). No statistically significant differences were observed in the rates of nausea/vomiting, fever, puncture site infection, urinary retention, or delirium (all

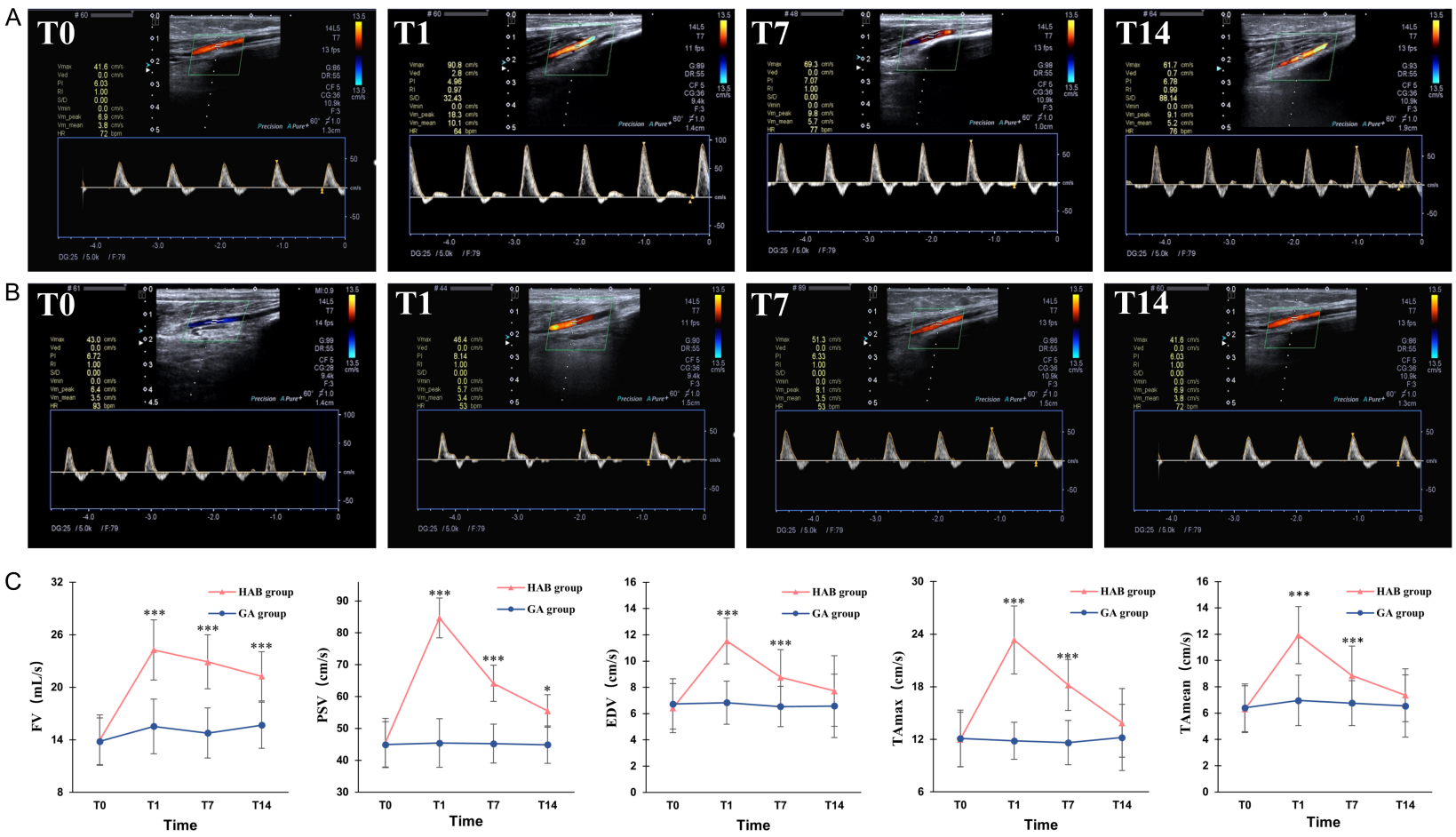

Figure 4. Ultrasound measurement of ATA hemodynamic parameters. A. ATA hemodynamic parameters in the HAB group. B. ATA hemodynamic parameters in the GA group. C. Statistical comparison between the two groups. ATA: anterior tibial artery; HAB: high ankle block; GA: general anesthesia; FV: flow volume; PSV: peak systolic velocity; EDV: end diastolic velocity; TAmean: time-averaged mean velocity; TAmax: time-averaged maximum velocity; T0: preoperative; T1: postoperative day 1; T7: postoperative day 7; T14: postoperative day 14; SD: standard deviation. Data are presented as mean ± SD. **P*<0.05, ****P*<0.001 for comparisons between groups.

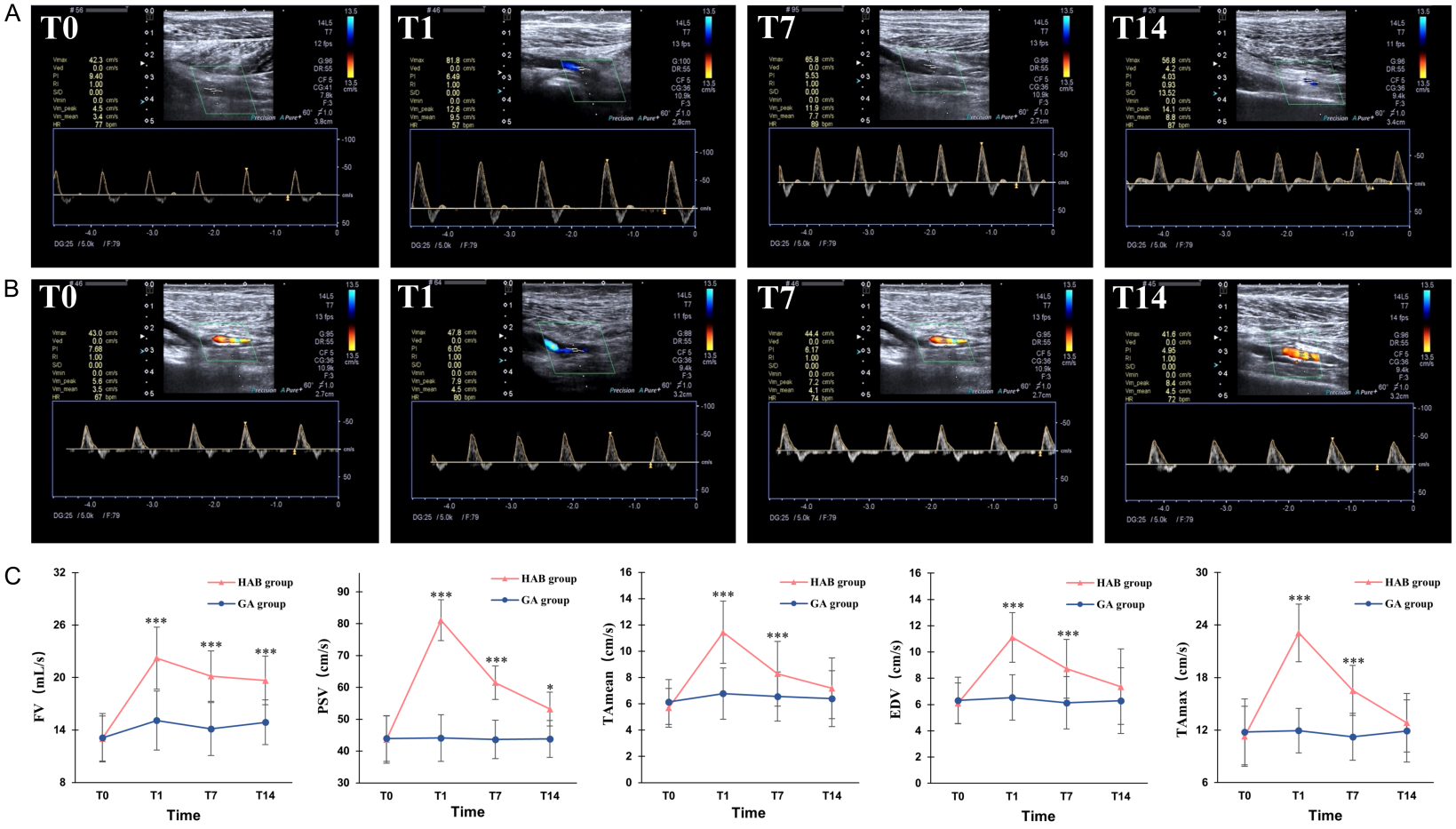

Figure 5. Ultrasound measurement of PTA hemodynamic parameters. A. PTA hemodynamic parameters in the HAB group. B. PTA hemodynamic parameters in the GA group. C. Statistical comparison between the two groups. PTA: posterior tibial artery; HAB: high ankle block; GA: general anesthesia; FV: flow volume; PSV: peak systolic velocity; EDV: end diastolic velocity; TAmean: time-averaged mean velocity; TAmax: time-averaged maximum velocity; T0: preoperative; T1: postoperative day 1; T7: postoperative day 7; T14: postoperative day 14; SD: standard deviation. Data are presented as mean ± SD. **P*<0.05, ****P*<0.001 for comparisons between the groups.

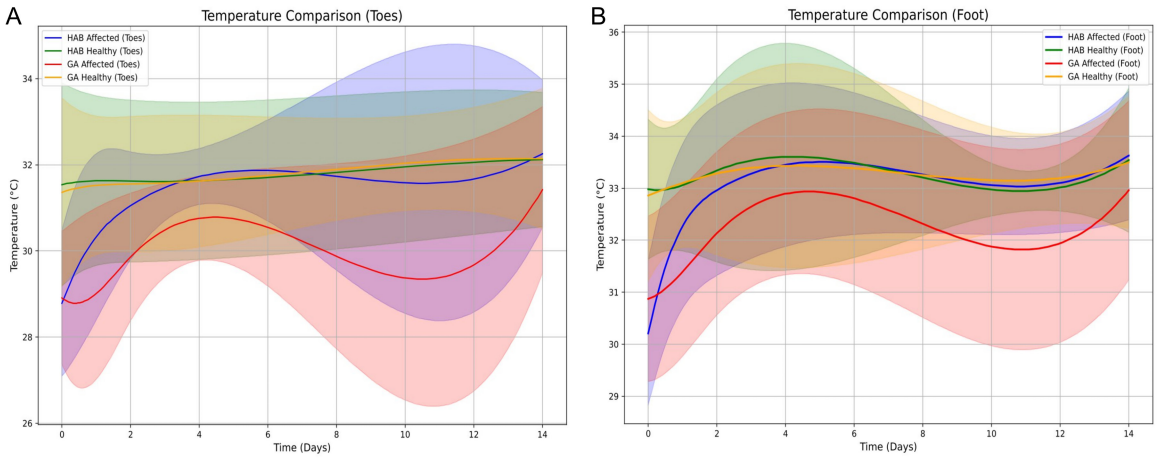

Figure 6. Skin temperature changes in the toes and dorsal feet of bilateral lower extremities. A. Temperature changes in the toes. B. Temperature changes in the dorsal feet. Blue, affected side of the HAB group; green, healthy side of the HAB group; red, affected side of the GA group; yellow, healthy side of the GA group. HAB, high ankle block; GA, general anesthesia.

Table 3. Postoperative adverse events

Adverse event	HAB group (n=35)	GA group (n=35)	χ^2	*P* value
Pneumonia	1 (2.9)	7 (20.0)	/	0.055
Fever	0 (0.0)	2 (5.7)	/	0.49
Puncture site infection	0 (0.0)	1 (2.9)	/	>0.99
Puncture site hematoma	0 (0.0)	0 (0.0)	/	/
Nerve injury	0 (0.0)	0 (0.0)	/	/
Local anesthetic allergy	0 (0.0)	0 (0.0)	/	/
Local anesthetic toxicity	0 (0.0)	0 (0.0)	/	/
Nausea/vomiting	0 (0.0)	4 (11.4)	/	0.11
Urinary retention	1 (2.9)	3 (8.6)	/	0.61
Delirium	0 (0.0)	1 (2.9)	/	>0.99
Reoperation rate	2(5.7)	7(20.0)	/	0.15
Amputation rate	1 (2.9)	2 (5.7)	/	>0.99

Data are presented as n (%). Fisher's exact test was used for between-group comparisons; no χ^2 values are reported.

P>0.05). No events of puncture site hematoma, nerve injury, local anesthetic allergy, or local anesthetic toxicity occurred in either group.

At the 60-day follow-up, the reoperation rate was 5.7% (2/35) in the HAB group and 20.0% (7/35) in the GA group (*P*=0.15). The amputation rate was 2.9% (1/35) in the HAB group vs. 5.7% (2/35) in the GA group (*P*>0.99) (**Table 3**).

Discussion

The International Working Group on the Diabetic Foot defines DF as "infection, ulceration, or destruction of tissues of the foot in a person who is currently or previously diagnosed with diabetes", typically accompanied by lower extremity neuropathy or peripheral arterial disease [14]. The Wagner classification system is crucial for assessing wound severity and guiding clinical treatment. Grade 0 patients present with no overt wounds and do not require debridement. Grade I patients exhibit rapid wound healing and favorable prognosis, with most avoiding the need for debridement. Inclusion of Grade I cases would dilute the true therapeutic effect of nerve block observed in Grade II-IV patients, reducing the effect size of statistical tests and potentially leading to false-negative results. Grade V patients require immediate amputation, precluding their eligibility for local debridement. In contrast, Grade

II-IV patients share core pathophysiological characteristics, establishing a homogeneous research foundation. Grade II ulcers extend to tendons/ligaments, Grade III is complicated by abscesses or osteomyelitis, and Grade IV involves localized gangrene. Wound healing in all three subgroups relies on adequate local blood supply, effective infection control, and appropriate analgesic intervention. This pathophysiological homogeneity eliminates intergroup confounding factors arising from excessive differences in lesion severity between mild (Grade I) and severe (Grade V) cases, providing a uniform response basis for comparing the efficacy of nerve block intervention. Current clinical treatments for DF include improving microcirculation, nutritional nerve therapy, growth factor applications, hyperbaric oxygen therapy, negative pressure therapy, and surgical interventions. Additionally, emerging therapies such as magnetic field therapy show great potential in promoting wound healing and have been applied in the treatment of DF wounds [15, 16].

Among all treatment modalities, surgery is widely used as an effective method to thoroughly assess wounds and remove necrotic tissue. The choice of anesthesia for surgery is equally crucial. DF patients often have comorbid conditions such as coronary artery atherosclerosis, hypertension, and a high frailty index, particularly in elderly patients, which increases the risk of surgical anesthesia. Selecting the appropriate anesthesia method not only reduces perioperative risk but has also been shown to improve surgical outcomes and promote faster patient recovery. GA is the most commonly used method; however, it requires the use of multiple drugs to maintain anesthesia and significant amounts of opioids for postoperative pain management, which can adversely affect the patient's circulatory, respiratory, and cognitive functions [17].

In terms of ulcer healing, the ulcer area in the HAB group healed by approximately 42.2% at T7 and 67.9% at T14. In contrast, the GA group showed 29.4% and 53.2% healing at the same time points, respectively. The significant difference between the groups indicates that HAB provides a beneficial adjunctive treatment for the healing of DFUs. The underlying mechanism may involve vasodilation and increased arterial blood flow due to sympathetic blockade, leading to improved microcirculation and enhanced oxygen and nutrient delivery to tissues. This mechanism facilitates the metabolism of local inflammatory mediators, promotes antibiotic delivery to the lesion site, effectively breaks the vicious cycle of DFUs, and aids in their treatment [7]. Secondly, sympathetic nerve block can promote the release of nitric oxide from endothelial cells, reduce endothelin-1 levels, lower inflammatory factors such as IL-1β, IL-6, and TNF-α, alleviate local inflammatory stress and tissue edema, and subsequently increase vascular endothelial growth factor levels, promote granulation tissue proliferation and re-epithelization, and ultimately accelerate wound contraction. In this study, the foot ulcer area in the HAB group was smaller, which supports the above mechanism from a clinical perspective and is consistent with the findings of Bosanquet et al. [18]. Furthermore, DFUs are characterized by sympathetic overactivation, persistent microvascular spasm, arteriovenous shunt opening, and insufficient tissue oxygen supply, leading to decreased transcutaneous partial pressure of oxygen ($TcPO_2$) and delayed healing [19, 20]. The increased blood flow in the anterior and posterior tibial arteries and the elevated skin temperature observed in this study are consistent with the pathophysiological changes of improved microcirculation and tissue oxygenation after sympathetic block. Previous studies have reported that nerve block can induce functional sympathetic blockade, resulting in local vasodilation, increased FV, and improved tissue oxygenation [21-23]. The nerves innervating the lower leg and ankle originate from the sensory branches of the sciatic and femoral nerves, including the tibial, deep peroneal, superficial peroneal, sural, and SaNs. The HAB technique used in this study effectively blocks these nerves, leading to vasodilation and increased FV in the blocked region. Our results demonstrated that ultrasound-monitored blood flow perfusion indices, including FV, PSV, EDV, TAmean, and TAmax, were significantly greater in the HAB group than those in the GA group at T1 and T7. Greater perfusion corresponds to higher skin temperatures, as evidenced by infrared thermography, which revealed significantly greater toe and dorsal foot temperatures in the HAB group than those in the GA group. Specifically, in the HAB group, the temperature of the affected toes

rose steadily from 29°C at T0 to approximately 32°C at T4; the temperature of the affected dorsal foot was approximately 30.2°C at T0, increased to approximately 33.5°C at T4, and remained above 33°C thereafter. In the GA group, the temperature of the affected toes was 29°C at T0, rose to approximately 30.8°C at T4, decreased to approximately 29.5°C between T8 and T10, and rebounded to approximately 31.5°C at T14; the temperature of the affected dorsal foot was approximately 30.8°C at T0, rose to approximately 32.8°C at T4, decreased to approximately 32°C at T8-T10, and rebounded to approximately 33°C at T14. Overall, toe and dorsal foot temperatures were significantly greater in the HAB group than those in the GA group, which is consistent with the findings of Zuo's study [24]. As concluded by van Doremalen et al. [25], the increased skin temperature of the toes and dorsal foot in the HAB group is due to HAB relieving vasoconstriction via sympathetic blockade, dilating the anterior and posterior tibial arteries and their branches, enhancing local blood perfusion, and thereby elevating skin surface temperature. Given the prolonged healing time and high recurrence rate of DFUs, a 60-day postoperative telephone follow-up showed no significant difference in reoperation or amputation rates between the two groups. However, the reoperation rate was slightly lower in the HAB group than that in the GA group, indirectly suggesting that HAB may help improve wound healing in DFUs.

In terms of intraoperative variables, total fluid intake was greater in the GA group than that in the HAB group. This may be related to the higher incidence of hemodynamic instability and significant hypotensive events in the GA group intraoperatively, requiring increased fluid input to maintain hemodynamic stability and improve hypotension. Previous clinical studies on DF surgery have also confirmed that PNB can significantly reduce intraoperative colloid intake, total fluid intake, and the proportion of vasoactive drug administration, with its mild effects on the circulatory system being more compatible with the pathophysiological features of multiple organ lesions in patients with DF [6]. Our study also revealed that the HAB group required significantly less adjuvant analgesic medication at T1 and T2, and the incidence of nausea and vomiting was lower than that in the GA group. Pneumonia occurred less frequently in the HAB group (2.9% vs. 20.0%), although the difference did not reach statistical significance (P=0.055). These findings indicate that HAB can safely and effectively meet postoperative analgesia requirements. Epidural anesthesia requires postoperative bed rest, leading to slower recovery of lower limb motor function, which is not conducive to early exercise and accelerated recovery [26]. In contrast, HAB provides excellent intraoperative analgesia and sufficient postoperative pain relief on the first day, when pain stimulus is the strongest [6]. Moreover, HAB does not impair limb mobility, allowing patients to engage in active joint exercises, thereby reducing the risk of lower limb thrombosis. Consistent with the findings of Biz et al. [27], in foot and ankle surgery, both traditional ankle block and sciatic-femoral nerve block alleviate postoperative pain, with no significant difference in the incidence of chronic pain at 6 months postoperatively, while the traditional ankle block is simpler to perform. As a novel HAB technique, the approach used in this study not only inherits the advantages of traditional ankle block but also significantly improves local blood perfusion, thereby promoting wound healing in DF patients. Furthermore, this study confirms that HAB is free of severe complications in DF patients, further validating its clinical safety.

Diabetic patients with peripheral neuropathy often experience early sensory changes in a "stocking" pattern, initially affecting the distal limbs and progressing proximally. This includes diminished light touch, proprioception, temperature perception, and pain sensation [28]. Reduced temperature and pain perception make diabetic patients prone to foot burns during the winter, which is one of the triggers for DFUs. In this study, we also explored postoperative ankle sensation and pain perception in both groups. However, owing to subjective patient factors and the lack of appropriate measurement tools and objective evaluation criteria, no valid results were obtained, and no data were statistically analyzed. Additionally, like other PNBs, HAB shares the same limitation: it cannot be performed in the presence of infection, swelling, or other complications at the puncture site. This could restrict its application in certain clinical scenarios where the site is compromised.

Several notable limitations of this study should be acknowledged. First, the current results are not sufficient to fully elucidate the precise mechanism by which HAB promotes wound healing from the perspective of translational medicine. The study was designed as a prospective randomized controlled clinical trial, with the core objective of evaluating the clinical impact of HAB on wound healing, foot blood perfusion, and postoperative analgesia following debridement of DFUs.

Second, only ultrasound hemodynamic parameters (FV, PSV, EDV, TAmean, TAmax) and skin temperature were used as clinically accessible, non-invasive, and repeatable observational indicators to indirectly reflect changes in local tissue perfusion. Based on these results, we hypothesize that HAB may promote wound healing by improving local blood supply; however, this conclusion currently represents a potential associated mechanism rather than a directly confirmed causal pathway. Third, this study did not measure $TcPO_2$, direct microcirculation indicators, inflammatory factors, or vasoactive molecules, and thus could not establish a complete "mechanism-efficacy" association chain. Future studies will jointly measure $TcPO_2$, microcirculation imaging, inflammatory factors, and vasoactive substances to further verify the biological mechanism by which HAB improves perfusion and promotes wound healing.

Finally, in the formal study, the observed SD for the HAB and GA groups were 1.91 and 2.28, respectively, which were generally consistent with the pre-experimental findings. Despite minor fluctuations, these values remained within the acceptable range of discrepancy between pre-experimental estimates and actual values in clinical research. Back-calculation based on the actual mean and SD of ulcer area at T7 in the formal study indicated that approximately 22 participants per group would be required under the conditions of two-tailed $\alpha=0.05$ and power =80%. Even accounting for a 20% dropout rate, only 28 participants per group would be needed - still fewer than the 35 participants actually enrolled in each group. Thus, the sample size of this study was deemed sufficient. Nevertheless, this was a single-center, small-sample randomized controlled trial without interim analysis or sample size adjustment, which may introduce some uncertainty in variance estimation. Therefore, large-scale, multicenter studies are still needed to verify the robustness of our findings. Additionally, the duration of HAB-induced nerve blockade was not determined, limiting our ability to clarify its temporal association with improved perfusion, elevated skin temperature, and accelerated ulcer healing.

Conclusions

In summary, HAB significantly improves foot blood perfusion, promotes ulcer healing, and alleviates postoperative pain in patients with DF, providing a novel anesthetic option for DF debridement surgery.

Acknowledgements

The authors would like to express their gratitude to the Anesthesiology Department of the Xuzhou Central Hospital for their assistance and support. This research was supported by the National Natural Science Foundation of China (Grant No. 81700078), Xuzhou Medical Key Talent Project (Grant No. XWRCHT2022-0051), the Foundation of Jiangsu Provincial Health Commission (Grant No. M2024008), the Youth Project of Jiangsu Medical Association (Grant No. SYH-32021-0137), and the Project of Jiangsu Geriatric Society (Grant No. JGS-2025ZDM014).

Disclosure of conflict of interest

None.

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