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Electroacupuncture at Taixi (KI3) and Sanyinjiao (SP6) Alleviates Re-Ischemic Injury after Endovascular Intervention in Patients with Diabetic Foot: A Randomized Controlled Trial

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Abstract

Objective: To evaluate the efficacy and potential mechanisms of electroacupuncture (EA) at Taixi (KI3) and Sanyinjiao (SP6) in preventing re-ischemic injury following percutaneous transluminal angioplasty (PTA) in patients with diabetic foot (DF). **Methods:** A randomized controlled trial was conducted between January 2023 and December 2025. A total of 180 DF patients who underwent successful PTA were randomly assigned to three groups (n = 60 each): conventional therapy group (CT), sham acupuncture group (SA), and electroacupuncture group (EA). All patients received standard pharmacological therapy postoperatively. The EA group received EA at KI3 and SP6 on the affected limb (disperse wave, 15 Hz, 30 min/day for 7 consecutive days); the SA group received superficial needling at non-acupoint sites (≈2 cm lateral to target points); the CT group received conventional therapy alone. Primary outcomes included incidence of re-ischemia within 7 days post-PTA. Secondary outcomes comprised ankle-brachial index (ABI), mean blood flow velocity in the dorsalis pedis artery (Vm), numerical rating scale (NRS) for pain, and activated partial thromboplastin time (APTT). **Results:** ABI, Vm, and NRS scores significantly improved postoperatively in all groups ($P < 0.001$), but no intergroup differences were observed ($P > 0.05$). The re-ischemia incidence was 1.67% (1/60) in the EA group, significantly lower than 13.33% (8/60) in

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the CT group ($P = 0.008$) and 11.67% (7/60) in the SA group ($P = 0.015$). Postoperatively, the activated partial thromboplastin time (APTT) in the EA group was 32.00 (29.00, 35.00) s, which was significantly longer than that in the CT group ($P < 0.05$), whereas platelet counts decreased similarly across groups ($P = 0.970$). **Conclusion:** Adjunctive EA at KI3 and SP6 significantly reduces the risk of re-ischemia after PTA in DF patients, potentially via modulation of coagulation function—specifically, prolongation of APTT to suppress thrombus formation—without compromising metabolic control or increasing bleeding risk. This strategy offers a safe, feasible, and cost-effective complementary approach for post-interventional vascular protection.

Keywords

Diabetic Foot, Percutaneous Transluminal Angioplasty, Re-Ischemic Injury, Electroacupuncture, Taixi (KI3), Sanyinjiao (SP6), Coagulation Function

1. Introduction

Diabetic foot (DF) is a multifactorial complication arising from chronic hyperglycemia-induced damage to the nervous, vascular, and immune systems. The risk of major amputation in DF patients is 15 - 40 times higher than in non-diabetic individuals [1]. With advances in interventional radiology, percutaneous transluminal angioplasty (PTA) has become the preferred revascularization modality for ischemic DF due to its minimal invasiveness and high technical success rate. However, re-ischemic injury—a consequence of acute thrombosis, distal embolization, and endothelial denudation following endovascular manipulation—occurs in 15–30% of cases, severely compromising limb salvage [2]. Current pharmacological strategies, primarily dual antiplatelet therapy (DAPT), are limited by bleeding complications and heterogeneous patient responses. Hence, identifying safe, adjunctive interventions targeting the pathophysiology of re-ischemia remains a critical unmet need [3].

In traditional Chinese medicine (TCM), DF is classified as *Tuojü* (gangrene), characterized by *ben xu biao shi* (fundamental deficiency and secondary excess), with blood stasis as the predominant pathophysiological mechanism. Acupuncture, a cornerstone TCM modality, has demonstrated efficacy in improving peripheral perfusion and alleviating neuropathic pain [4]. Electroacupuncture (EA), combining mechanical stimulation with low-frequency electrical current, exhibits anti-inflammatory, antithrombotic, and tissue-protective properties [5].

Taixi (KI3), the *yuan* (source) point of the Kidney meridian, is traditionally indicated for nourishing kidney yin, reinforcing primordial qi, and unblocking meridians. Sanyinjiao (SP6), the confluent point of the Liver, Spleen, and Kidney meridians, is employed to harmonize blood, resolve stasis, and regulate the three Yin channels. Preclinical studies suggest that acupuncture at SP6 modulates vascular endothelial growth factor (VEGF) and basic fibroblast growth factor (bFGF) ex-

pression, promoting collateral circulation [6]. We hypothesized that EA at KI3 and SP6, applied during the critical window of endothelial repair (post-PTA days 1 - 7), would reduce re-ischemic events by regulating coagulation and enhancing endothelial function. This randomized controlled trial was designed to test this hypothesis and elucidate underlying mechanisms.

2. Materials and Methods

2.1. Sample Size Calculation

Based on literature and our preliminary study, the expected re-ischemia rates for the CT, SA, and EA groups were assumed to be 25%, 20%, and 10%, respectively. To achieve a statistical power of 80% ($1 - \beta = 0.80$) with a two-sided significance level of 5% ($\alpha = 0.05$), a total sample size of 156 patients was required (calculated using G*Power 3.1 software for chi-square tests). Assuming a 20% dropout rate, we planned to recruit 195 patients (65 per group).

2.2. Study Population

This study, entitled "Clinical Research on Electroacupuncture at Taixi (KI3) and Sanyinjiao (SP6) for Postoperative Re-ischemic Injury in Patients with Lower Extremity Ischemic Disease," was approved by the Institutional Ethics Committee (No. ZSLL-KY-2023-019-01) and conducted under the Non-registered Clinical Trial Protocol No. 20230302075515067.

From January 2023 to December 2025, a total of 198 consecutive DF patients who underwent successful PTA at our institution were enrolled and randomly assigned (1:1:1) to the CT, SA, and EA groups (n = 66 per group) using a computer-generated random number table. Each participant provided written informed consent. During the 7-day intervention and follow-up period, 18 patients were excluded from the analysis: 5 due to protocol violations (specifically, the addition of unauthorized adjunctive therapies), 8 were lost to follow-up, and 5 withdrew their consent. These dropouts were distributed evenly across the groups (n = 6 per group). Consequently, a final total of 180 patients (n = 60 per group) who completed the full 7-day protocol were included in the per-protocol (PP) analysis.

2.3. Diagnostic and Inclusion/Exclusion Criteria

Outcome assessors (ultrasonographers) and statisticians were blinded to the treatment assignments. DF diagnosis conformed to Wagner grading (I-IV) and criteria for ischemic peripheral arterial disease [1]. Re-ischemia was defined as: 1) ≥50% decline in post-PTA peak Vm (by color Doppler ultrasound) or return to preoperative level; 2) new-onset skin coolness, worsening pain, or petechiae; or 3) angiographic confirmation of re-occlusion. In cases where clinical findings (e.g., skin coolness) and Doppler findings (Vm decline) were inconsistent, the adjudication of re-ischemia was determined by a consensus of two independent vascular surgeons who were masked to the group allocation.

Inclusion criteria: 1) confirmed DF and indication for PTA; 2) no prior treatment for DF; 3) age 45 - 80 years; 4) complete clinical records; 5) written informed consent.

Exclusion criteria: 1) severe cardiopulmonary or renal dysfunction; 2) psychiatric disorders or communication impairment; 3) PTA failure; 4) concurrent participation in other trials; 5) needle phobia or intolerance to acupuncture.

2.4. Intervention Protocols

All patients received standardized post-PTA care: DAPT (aspirin 100 mg/day + clopidogrel 75 mg/day for ≥6 months, then aspirin monotherapy), individualized glycemic control (HbA1c ≤ 8%), blood pressure target ≤ 130/80 mmHg, and LDL-C ≤ 1.81 mmol/L.

- *CT group (n = 60)*: Conventional therapy only.
- *SA group (n = 60)*: Superficial needling (0.25 × 40 mm needle, depth ≤2 mm) at non-acupoint sites (2 cm lateral to KI3 and SP6), 30 min/day, once daily for 7 days.
- *EA group (n = 60)*: After achieving *deqi* (sensation of soreness, numbness, or distension) via needle manipulation at KI3 and SP6 (0.30 × 50 mm needle), EA was delivered using a disperse wave (15 Hz, 2 - 3 mA intensity, adjusted to induce mild local muscle contraction), 30 min/day, once daily for 7 days.

2.5. Outcome Measures

Primary endpoint: Incidence of re-ischemia within 7 days post-PTA.

Secondary endpoints:

- ABI: Measured with VP-1000 ABI/PPG system (Oscillometry + Doppler; Beijing Lanxun Technology Co., Ltd.).
- Vm: Assessed by color Doppler ultrasound (SD2 Doppler, Beijing Lanxun).
- NRS: 0 - 10 scale (0 = no pain; 10 = worst imaginable pain).
- Laboratory parameters: Fasting venous blood (10 mL) drawn preoperatively, and on postoperative day 7, for glucose (GLU), platelet count (PLT), and APTT (automated coagulation analyzer).

2.6. Statistical Analysis

Data were analyzed using SPSS 22.0. Continuous variables are expressed as mean ± SD (normal distribution) or median (interquartile range, IQR) (non-normal distribution). Categorical data are presented as frequencies (%). Within-group comparisons used paired *t*-test or Wilcoxon signed-rank test; intergroup comparisons used one-way ANOVA or Kruskal-Wallis test, followed by Bonferroni-corrected post hoc tests. $P < 0.05$ was considered statistically significant.

3. Results

3.1. Baseline Characteristics

The 180 patients (83 male, 97 female; mean age 61.6 ± 9.3 years) were well-bal-

anced across groups (Table 1). No significant between-group differences were observed in sex, age, baseline ABI, Vm, GLU, PLT, APTT, or NRS ($P > 0.05$ for all).

Table 1. Baseline characteristics of participants (n = 180).

Variable	CT (n = 60)	SA (n = 60)	EA (n = 60)	$\chi^2/F/Z$	P
Male/Female, n	31/29	32 / 28	31 / 29	$\chi^2 = 0.044$	0.978
Age, years	61.32 ± 9.28	62.13 ± 8.86	61.27 ± 9.49	$F = 0.165$	0.848
Preoperative Vm, cm/s	75.50 (57.25, 87.00)	66.50 (55.00, 80.50)	70.00 (51.25, 87.50)	$Z = 2.908$	0.234
GLU, mmol/L	8.96 ± 1.98	9.31 ± 1.74	9.27 ± 1.77	$F = 0.663$	0.516
PLT, $\times 10^9$/L	209.10 ± 53.00	194.42 ± 53.56	208.00 ± 57.75	$F = 2.487$	0.086
ABI	0.64 (0.48, 0.74)	0.67 (0.53, 0.80)	0.58 (0.48, 0.73)	$Z = 4.597$	0.100
APTT, s	18.00 (15.00, 21.00)	21.00 (15.00, 26.00)	20.05 (16.00, 26.00)	$Z = 4.831$	0.089
NRS	6.00 (5.00, 7.00)	6.00 (5.00, 7.00)	6.00 (4.25, 7.75)	$Z = 0.424$	0.810

3.2. Hemodynamic and Symptomatic Outcomes

ABI and Vm improved significantly postoperatively in all groups ($P < 0.001$), but no intergroup differences were detected (ABI: $P = 0.480$; Vm: $P = 0.152$) (Table 2, Table 3). NRS scores decreased significantly in all groups ($P < 0.001$), with no between-group variation ($P = 0.223$) (Table 4).

Table 2. Changes in dorsalis pedis artery mean blood flow velocity before and after endovascular intervention across the three treatment groups.

	Pre-intervention	**Post-intervention**	Z	P
CT	75.50 (57.25, 87.00)	31.00 (24.00, 37.50)	−6.067	<0.001
SA	66.50 (55.00, 80.50)	32.00 (28.00, 37.75)	−5.717	<0.001
EA	70.00 (51.25, 87.50)	29.00 (25.00, 35.75)	−6.699	<0.001
Z	2.908	3.765		
P	0.234	0.152		

Table 3. Changes in ABI before and after endovascular intervention across the three treatment groups.

	Pre-intervention	**Post-intervention**	Z	P
CT	0.640 (0.483, 0.740)	0.920 (0.883, 0.960)	−5.471	<0.001
SA	0.670 (0.530, 0.800)	0.970 (0.880, 0.970)	−5.412	<0.001
EA	0.580 (0.483, 0.728)	0.930 (0.890, 0.978)	−6.593	<0.001
Z	4.597	1.467		
P	0.100	0.480		

Table 4. Comparison of Numerical Rating Scale (NRS) pain scores before and after intervention among the three groups.

	Pre-intervention	Post-intervention	Z	*P*
CT	6.00 (5.00, 7.00)	3.00 (1.00, 4.00)	−5.695	<0.001
SA	6.00 (5.00, 7.00)	2.00 (1.00, 4.00)	−5.927	<0.001
EA	6.00 (4.25, 7.75)	2.00 (0.00, 4.00)	−6.553	<0.001
Z	0.424	2.997		
P	0. 810	0.223		

3.3. Metabolic and Coagulation Parameters

GLU and PLT declined significantly postoperatively across groups ($P < 0.001$), but intergroup differences were non-significant (GLU: $P = 0.914$; PLT: $P = 0.970$) (Table 5, Table 6). APTT increased in all groups ($P < 0.001$), yet the EA group exhibited significantly higher postoperative APTT than CT (26.00 s vs. 32.00 s; $P < 0.001$) and SA (28.00 s; $P < 0.001$) (Table 7; Table 8).

Table 5. Changes in fasting blood glucose levels before and after intervention across the three.

	Pre-intervention	Post-intervention	Mean	SD	*t*	*P*
CT	8.96 ± 1.976	8.15 ± 1.595	0.810	2.205	2.845	0.006
SA	9.31 ± 1.739	8.15 ± 1.884	1.162	2.489	3.615	<0.001
EA	9.27 ± 1.774	8.04 ± 1.696	1.235	2.037	4.695	<0.001
F	0.663	0.90				
P	0.516	0.914				

Table 6. Changes in platelet count before and after intervention across the three groups.

	Pre-intervention	Post-intervention	Mean	SD	*t*	*P*
CT	209.10 ± 52.995	162.23 ± 56.237	46.867	72.298	5.021	<0.001
SA	194.42 ± 53.56	163.98 ± 44.431	30.433	69.667	3.384	<0.001
EA	208.00 ± 57.750	161.95 ± 44.838	46.050	73.049	5.243	<0.001
F	2.487	0.31				
P	0.086	0.970				

Table 7. Comparison of APTT before and after intervention among the three groups.

	Pre-intervention	Post-intervention	Z	*P*
CT	18.00 (15.00, 21.00)	26.00 (22.25, 29.00)	−6.461	<0.001
SA	21.00 (15.00, 26.00)	28.00 (22.25, 31.00)	−6.371	<0.001
EA	20.05 (16.00, 26.00)	32.00 (29.00, 35.00)	−6.717	<0.001
F	4.831	3.765		
P	0.089	0.152		

Table 8. Postoperative APTT: Pairwise Comparisons (Bonferroni-corrected).

Comparison	Mean Difference (EA − Group)	*P* (Adj.)
CT vs. SA	−10.742	0.774
CT vs. EA	−59.958	<0.001
SA vs. EA	−49.217	<0.001

3.4. Incidence of Re-Ischemia

The re-ischemia incidence in the EA group was 1.67%, significantly lower than in the CT group (13.33%; RR 0.125, 95% CI 0.016 - 0.965; $P = 0.008$) and SA group (11.67%; RR 0.143, 95% CI 0.018 - 1.121; $P = 0.015$). (Table 9; $\chi^2 = 7.037$, $P = 0.030$). No significant difference was observed between CT and SA ($P = 0.793$).

Table 9. Incidence of Re-ischemia within 7 Days Post-PTA.

Group	Re-ischemia (n)	No Re-ischemia (n)	Total (n)	vs. EA		
				RR	95% CI	*P*
CT	8	51	60	0.125	0.016 - 0.965	0.008
SA	7	52	60	0.143	0.018 - 1.121	0.015
EA	1	59	60			—

3.5. Safety Evaluation

No serious adverse events, such as major bleeding, systemic infection, or hematoma requiring intervention, were reported in any group. In the EA group, 2 patients (3.3%) experienced minor localized ecchymosis at the needle site, which resolved spontaneously without treatment. These findings support that adjunctive EA does not increase the risk of bleeding complications.

4. Discussion

Re-ischemic injury remains a major obstacle to long-term patency after endovascular revascularization in DF. Although PTA effectively restores immediate hemodynamic parameters (ABI, Vm), the high recurrence rate (15% - 30%) underscores the need for adjunctive strategies targeting the underlying thrombotic and inflammatory milieu [1] [2]. Our RCT demonstrates that EA at KI3 and SP6, initiated within 24 h post-PTA and sustained for 7 days, significantly reduces re-ischemia incidence by 87.5% compared with conventional care, with no associated increase in bleeding or metabolic disturbances.

Our data indicate an association between EA treatment and the selective prolongation of APTT (32.00s). This observation suggests a potential link between electroacupuncture and the stabilization of the intrinsic coagulation system, which may contribute to the decreased incidence of re-ischemia observed in patients APTT reflects the integrity of the intrinsic coagulation pathway (factors XII, XI, IX, VIII, X, and II). The absence of between-group differences in platelet count

implies that EA's antithrombotic effect is not mediated via platelet inhibition, but rather through modulation of coagulation factor activity or enhancement of fibrinolysis (e.g., tissue plasminogen activator [t-PA] release). This aligns with preclinical evidence: EA at Zusanli (ST36) upregulates endothelial nitric oxide synthase (eNOS), increasing NO production and suppressing thrombin-induced platelet aggregation [7] [8]; EA at SP6 attenuates tissue factor (TF) and plasminogen activator inhibitor-1 (PAI-1) expression via the vagus nerve–cholinergic anti-inflammatory pathway [9]. KI3, as the source point of the Kidney meridian, modulates sympathetic outflow and reduces circulating norepinephrine, thereby mitigating vasoconstriction and platelet activation [10]. SP6, conversely, promotes endothelial repair through upregulation of VEGF and bFGF [11]. Collectively, these effects suggest EA achieves *multimodal vascular protection*—stabilizing the coagulation-fibrinolysis balance while facilitating endothelial regeneration—thus preserving vessel patency beyond the acute hemodynamic improvement conferred by PTA alone.

Notably, the lack of intergroup differences in ABI, Vm, and NRS underscores that EA's primary benefit is *prophylactic*, not restorative. The single re-ischemic event in the EA group coincided with a rapid deterioration in perfusion and NRS rebound (from 2 to 7), whereas the remaining 59 patients maintained stable symptom relief.

This supports the hypothesis that EA disrupts the ischemia-inflammation-pain cascade, conferring durability to symptomatic improvement. While the "*tong ze bu tong*" (free flow alleviates pain) principle of TCM is corroborated, future studies should incorporate quantitative sensory testing (QST) and skin sympathetic response (SSR) to dissect ischemic versus neuropathic pain components [12].

Additionally, The therapeutic efficacy of EA at KI3 (Taixi) and SP6 (Sanyinjiao) may be deeply rooted in its impact on local hemodynamics and microcirculatory homeostasis. From a vascular surgery perspective, the success of PTA depends not only on the mechanical dilation of the vessel but also on the maintenance of adequate endothelial shear stress. Low or turbulent shear stress in the early post-PTA phase is a major trigger for platelet aggregation and the activation of the intrinsic coagulation pathway. Acupuncture stimulation at specific meridian points near the posterior tibial artery (KI3) and the tibial nerve (SP6) may promote regional vasodilation and enhance microcirculatory perfusion. This "distal pulling" effect (enhanced outflow) could potentially increase the blood flow velocity across the treated segment, thereby optimizing endothelial shear stress and reducing stasis-induced coagulation [13]. Our finding of prolonged APTT in the EA group provides a biochemical reflection of this stabilized internal environment, suggesting that EA may help create a "thrombo-resistant" vascular surface through both hemodynamic and systemic coagulation-modulating pathways.

Clinically, the 7-day EA protocol is highly feasible: it coincides with the standard post-PTA hospitalization period (typically 5 - 7 days) and requires minimal resources [14]. Crucially, it complements—not replaces—DAPT, offering a syn-

ergistic, low-risk strategy. The 2026 *International Expert Consensus on Acupuncture for Diabetic Foot* [5] recommends EA combined with endovascular therapy as a Grade 2B intervention for re-ischemia prevention, and our data provide robust Level I evidence supporting this recommendation.

Limitations:

1) Mechanistic depth is limited: key coagulation markers (e.g., factor VIII:C, IX:C, D-dimer, t-PA/PAI-1 ratio) were not measured; future work should integrate proteomic and metabolomic profiling.

2) Short follow-up: outcomes were assessed only at day 7; long-term endpoints (e.g., 3-month patency, ulcer healing, amputation-free survival) require prospective cohort extension.

3) Acupoint specificity: absence of a non-acupoint EA control group precludes full attribution to *acupoint specificity* versus electrical stimulation per se; functional MRI or near-infrared spectroscopy (NIRS) could objectively map neurovascular responses.

4) Population heterogeneity: Wagner grades I–IV were pooled; subgroup analyses by severity or TASC II classification are warranted.

In conclusion, adjunctive EA at KI3 and SP6 is associated with a significantly lower incidence of re-ischemia after PTA in DF patients. This protective effect is potentially linked to the stabilization of the microcirculatory environment and the modulation of the intrinsic coagulation pathway. By potentially improving distal perfusion and maintaining vascular patency, this approach demonstrates the clinical value of integrating evidence-based TCM into modern vascular care—furthering the advancement toward precision integrative medicine for high-risk diabetic populations.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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