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Effectiveness of traditional Chinese medicine transdermal therapy in preventing lower limb deep vein thrombosis in chronic glomerulonephritis and uremic patients

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Abstract: The aim of this study was to assess the impact of traditional Chinese medicine-based transdermal treatment for the prevention of deep vein thrombosis of the lower limbs in patients with chronic glomerulonephritis and uremia. 100 patients hospitalized from January 2022 to July 2024 were randomly divided into a control group (n=50), which was given routine treatment and a study group (n=50), which was given TCM transdermal treatment in addition to herbal formulations at certain acupoints. The treatment was conducted for a period of one month. Clinical endpoints evaluated were the occurrence of deep venous thrombosis (DVT), lower limb pain, Homans sign, femoral triangle tenderness, limb circumference, femoral venous blood flow and coagulation function in terms of prothrombin time (PT), activated partial thromboplastin time (APTT), platelet count (PLT), fibrinogen (FIB) and D-dimer (D-D). The study group presented with significantly lower incidence of DVT, improved venous blood flow and reduced limb swelling and pain compared to the control group ($P<0.05$). PT and APTT were significantly longer and PLT, FIB and D-D levels were decreased ($P<0.05$). No severe adverse events were observed and treatment compliance was improved in the study group. These findings suggest that TCM-guided transdermal therapy is a safe and effective adjunctive method for reducing DVT risk in CGN uremia patients.

Keywords: Traditional Chinese medicine; transdermal therapy; chronic glomerulonephritis; uremia; deep vein thrombosis

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INTRODUCTION

Chronic glomerulonephritis (CGN), also known as chronic nephritis, is a chronic disease of the glomeruli with clinical manifestations such as edema, hypertension, hematuria and proteinuria. The disease, during its course, causes levels of renal failure and results in end-stage renal disease (ESRD), or uremia (Kiewisz *et al.,* 2022). Uremia is a complex syndrome with the accumulation of waste products of metabolism and toxins, disturbance of water-electrolyte balance and systemic inflammation, significantly increasing mortality and quality of life (Tantisattamo & Kalantar-Zadeh, 2021; Idasiak-Piechocka *et al.,* 2023). CGN typically takes an insidious course with initial symptoms eluding detection, particularly among young and middle-aged men-the population most at risk.

During the uremic phase, patients are in need of long-term hemodialysis or peritoneal dialysis. Immobilization for a prolonged duration, endothelial dysfunction and hypercoagulability predispose such patients to lower limb deep venous thrombosis (DVT). DVT is a serious vascular complication of pain, swelling and local discoloration of the affected limb. More gravely, thrombi dislodge and migrate to the pulmonary circulation, causing pulmonary embolism-a potentially lethal event and a leading cause of mortality in this population (Cheung *et al.,* 2021; Uematsu *et al.,* 2023).

Conventional prophylaxis against DVT includes the application of pharmacologic agents like anticoagulants, along with physical measures like compression stockings and mechanical devices. Compliances are normally low due to discomfort or contraindications, primarily among uremic patients who have high risk for bleeding complications. Additionally, long-term pharmacologic interventions are also associated with severe side effects like thrombocytopenia, hemorrhage and gastrointestinal reactions (Wang *et al.,* 2024).

The information of clinical history for thousands of years, Traditional Chinese Medicine combines a holistic and individualized treatment. DVT in TCM falls into the categories of "blood stasis," "femoral swelling," and "meridian blockage" and is considered to be caused by abnormality of qi, blood stagnation and damp-heat persistence in lower limbs. Therapeutic managements aim at promoting blood flow, eliminating blood stasis, dispelling heat and eliminating swelling. Transdermal therapy-a practice of delivering plant preparations topically to acupoints or the target area—has gained increasing attention for its potential to deliver therapeutic agents directly across the skin without first-pass metabolism and decreased systemic side effects (Liu *et al.,* 2020; Luo *et al.,* 2023).

Recent studies have shown that herbal-based transdermal preparations can enhance microcirculation, inhibit inflammation and modulate coagulation factors. However,

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there are few clinical reports on TCM-guided transdermal therapy against DVT in patients with CGN-induced uremia. In this regard, the present research set out to evaluate the safety and efficacy of TCM-guided transdermal therapy as an adjuvant to conventional treatment in the prevention of bilateral lower extremity DVT. The study hopes to fill a necessary clinical gap and present evidence-based proof for integrating traditional and modern medical practices to improve outcomes in high-risk renal patients.

MATERIALS AND METHODS

General information

One hundred patients with chronic glomerulonephritis (CGN) uremia hospitalized at our center from January 2022 to July 2024 were selected for this study. They were randomly divided into a control group (n=50) and a study group (n=50) using the envelope method. The control group received conventional treatment, while the study group received additional Traditional Chinese Medicine (TCM)-guided transdermal therapy alongside conventional care. Statistical differences between the groups were not significant based on gender, age, body mass index (BMI), or disease duration ($P > 0.05$), indicating comparability (table 1).

Inclusion and exclusion criteria

Subjects in the current study were diagnosed as having etiology-specific chronic glomerulonephritis (CGN) uremia by blood routine examination, electrocardiogram and other clinical examination. Eligible patients had a Padua thrombotic risk score of ≥4 and showed no indication of deep venous thrombosis (DVT) in both lower limbs on color Doppler ultrasonography before treatment. Participants aged 18 to 80 years with normal mental and cognitive status and an expected survival time of six months or more. Exclusion criteria included active cerebrovascular disease or respiratory depression, allergy to the study medication or to its components, or participation in other clinical trials during the study period.

Study design and sample size calculation

This was a randomized controlled trial that randomized 100 patients into two groups of equal size. The sample size was calculated based on preliminary data with 80% power to identify significant difference in incidence of DVT at a 5% level of significance.

METHODS

Control group was exposed to daily care, which included the application of graduated compression stockings of leg length, position of legs in abducted neutral position with elevation between 20 to 30 degrees and massage of calf and thigh muscles by family members. The patients were provided with a vitamin and protein-rich diet that was less salt- and fat-rich and asked to have an almost daily fluid intake of approximately 2000 mL. They were also requested to perform active exercises such as ankle dorsiflexion, plantarflexion and isometric quadriceps contraction, all for 10 seconds every two hours and were also instructed to walk with help for 10 minutes twice daily.

The same routine therapy coupled with Traditional Chinese Medicine (TCM)-guided transdermal therapy was administered to the study group. The patients were placed in a supine position and the region surrounding the points of acupuncture was cleaned. Electrode pads were placed over corresponding areas on both lower limbs and connected to a transcutaneous electrical nerve stimulation device (Beijing Huawei Industry Development Co., Model: LH202H). The intensity of stimulation was adjusted from 0 to 50 to induce muscle contractions within the tolerance of pain of the patient. Each session was 20 minutes and was administered twice a day. Both groups underwent continuous treatment for one month.

Observation Index

Incidence of DVT

Assessed by color Doppler ultrasonography of both lower limbs for interrupted blood flow, narrow-beam flow, flat spectrum, and low velocity, collateral circulation with reverse flow, vein dilatation and positive compression test. Homans' sign and tenderness of femoral triangle were also recorded (Bhatt *et al.,* 2020; Qazi *et al.,* 2023).

Lower limb circumference

Measured 15 cm above and 10 cm below the patella before and after intervention.

Hemodynamics

Femoral vein blood velocities and flows by color Doppler ultrasound (Myriad, Model: DC-38) pre- and post-treatment.

Coagulation function indices

3 mL fasting venous blood samples pre- and post-treatment for PT, APTT (Beijing Plan New Technology Co., Ltd., Model: PUN-2048A), platelet (Myriad, Model: BC-5000 Vet), fibrinogen (FIB) and D-dimer (D-D) (Wuhan Medical Shield Medical Instrument Co., Ltd., Model: YD-480) levels.

Adverse reactions

All adverse events monitored and recorded.

Treatment compliance

Quantified by counting dislodgments, refusals and withdrawals.

STATISTICAL ANALYSIS

Data analysis was performed using SPSS 18.0. Continuous data were summarized as mean ± standard deviation ($\overline{x} \pm s$) and compared using independent samples t-test. Categorical data were described as counts and percentages (%) and compared using chi-square (χ^2) tests. Statistical significance was obtained with a two-tailed P value <0.05.

RESULTS

Comparison of bilateral lower limb dvt incidence, homans' sign and femoral triangle pressure pain between two groups

The incidence of bilateral lower limb deep venous thrombosis (DVT), lower limb pain, positive Homans' sign and femoral triangle tenderness were all much lower in the study group compared to the control group ($P < 0.05$) (Table 2). Thus, 4% only in study group patients had bilateral DVT versus 22% in the control group. Similarly, limb pain frequencies (2% vs. 22%), positive Homans' sign (0% vs. 16%) and tenderness over femoral triangle (2% vs. 20%) were all significantly less in the study group. These results suggest that TCM directional transdermal therapy greatly reduced clinical manifestations and the occurrence of DVT complications in GGN uremia patients.

Fig. 1 clearly illustrates how the TCM directional transdermal therapy reduced the occurrence of DVT and associated symptoms (pain, Homans' sign, femoral tenderness) compared to the control group. The decreased values in the study group indicate the efficacy of the treatment in preventing thrombotic complications among CGN uremia patients.

Comparison between lower limb circumference of the two groups before and after treatment

No significant differences in thigh and calf circumferences between the groups were found before intervention ($P > 0.05$). Both groups significantly reduced in thigh and calf circumference after intervention ($P < 0.05$). The reductions were significantly greater in the study group compared with the control group ($P < 0.05$) (table 3).

Comparison of hemodynamics between the two groups before and after intervention

No statistically significant differences were noted for femoral venous blood flow volume and velocity between the groups pre-treatment ($P > 0.05$). Both groups developed increased femoral venous blood flow velocity and volume post-treatment ($P < 0.05$), which were greater in the study group compared to the control group ($P < 0.05$) (table 4).

Comparison of coagulation function between the two groups before and after intervention

No statistically significant differences were observed in prothrombin time (PT), activated partial thromboplastin time (APTT), platelet count (PLT), fibrinogen (FIB) and D-dimer (D-D) between groups at pre-treatment level ($P > 0.05$). Following intervention, PT and APTT significantly increased, while PLT, FIB and D-D were significantly reduced in both groups ($P < 0.05$). The improvement was significantly greater in the study group compared to the control group ($P < 0.05$) (table 5).

Fig. 2 shows that the study group attained more notable improvements in coagulation function compared to the control group after treatment. Significant changes are 1) Increased PT and APTT: Indicating better regulation of coagulation time and 2) Reduced PLT, FIB and D-D: Suggesting reduced hypercoagulability and fibrinolysis activity. These changes show the effectiveness of TCM transdermal therapy in increasing hemodynamic and coagulative indicators among CGN uremia patients, which helps prevent DVT.

Adverse reactions

No severe adverse effects were experienced in either group throughout the study duration. Both the control and study patient groups well tolerated the intervention with no reports of skin irritation, allergies, bleeding complications, or infection at the application site. This indicates that the TCM directional transdermal therapy is not only efficient but also safe and well tolerated by GGN uremia patients.

Comparison of compliance between the two groups

Compliance among the study group was significantly higher than among the control group ($P < 0.05$) (Table 6). Withdrawal, exclusion and dropout rates were lower in the study group, reflecting higher patient compliance with the treatment regimen. These gains can be attributed to the non-invasive, well-tolerated characteristics of TCM directional transdermal therapy, in addition to perceived therapeutic outcomes. These findings highlight the importance of patient-centered interventions to provoke adherence, especially in chronic disease patients such as in the case of GGN uremia.

DISCUSSION

Uremia caused by glomerulonephritis (GGN) leads to progressively worsening renal function and it has adverse effects on patients' occupational and family functions (Al-Worafi, 2024). Deep vein thrombosis (DVT), primarily in the lower extremities, is primarily caused by a triad of factors: hypercoagulability, venous stasis and damage to vascular endothelium (Li *et al.,* 2022). In GGN uremic patients, systemic metabolic disturbances disrupt fibrinolytic, anticoagulant and coagulation pathways significantly enhancing the risk of thrombotic events such as pulmonary embolism. Increased blood viscosity and impaired circulation lead to a hypercoagulable state that predisposes to DVT development (Rudnin *et al.,* 2022).

Traditional Chinese Medicine (TCM) directional transdermal therapy combines herbal pharmacology and the methods of medical physics like intermediate frequency electrical stimulation, thermomagnetic therapy and bionic massage. Intermediate frequency current produces an electric field that enhances transdermal ion delivery of drugs to target such as the iliac vein, gastrocnemius venous plexus and femoral vein. This reduces skin resistance, dilates capillaries and arterioles and increases local blood circulation.

Table 1: Comparison of general data between groups

General Information	Control Group (n=50)	Study Group (n=50)	t/χ^2 Value	P Value
Sex [n (%)]				
Male	28 (56.00)	30 (60.00)	0.023	0.887
Female	22 (44.00)	20 (40.00)		
Average Age (years)	56.12 ± 6.38	55.88 ± 6.14	0.372	0.708
Mean BMI (kg/m²)	23.52 ± 2.52	23.25 ± 2.75	0.974	0.332
Mean Duration of Illness (years)	4.18 ± 1.09	4.26 ± 0.98	0.459	0.639

Table 2: Comparison of the incidence of bilateral lower limb DVT, pain, Homans' sign, and femoral triangle tenderness between the two groups [n (%)]

Project	Control group (n=50)	Study group (n=50)	χ^2 value	P value
Bilateral lower limb DVT	11 (22.00%)	2 (4.00%)	5.311	0.022
Bilateral lower limb pain	11 (22.00%)	1 (2.00%)	5.463	0.020
Homans' sign	8 (16.00%)	0 (0.00%)	5.286	0.023
Femoral triangle tenderness	10 (20.00%)	1 (2.00%)	5.354	0.022

Table 3: Comparison of thigh and calf circumference before and after intervention between the two groups ($\bar{x}$±s, cm)

Project	Control group (n=50)	Study group (n=50)
Thigh circumference (cm)		
Pre-intervention	58.56 ± 2.88	58.62 ± 2.48
Post-intervention	54.33 ± 2.67*	52.20 ± 2.53*#
Calf circumference (cm)		
Pre-intervention	41.68 ± 3.37	42.03 ± 3.01
Post-intervention	38.19 ± 3.01*	35.64 ± 3.07*#

Note: *P < 0.05 compared with pre-intervention; #P < 0.05 compared with control group.

Table 4: Comparison of the femoral venous hemodynamics before and after the intervention between the two Groups ($\bar{x}$ ± s)

Indicator	Control group (n=50)	Study group (n=50)
Femoral venous blood flow velocity (cm/s)		
Pre-intervention	14.82 ± 1.82	15.15 ± 1.60
Post-intervention	23.18 ± 2.43*	28.65 ± 1.35*#
Femoral vein blood flow (cm³/s)		
Pre-intervention	9.71 ± 0.77	9.54 ± 0.77
Post-intervention	12.86 ± 0.34*	14.98 ± 1.11*#

Note: *P < 0.05 vs. pre-intervention; #P < 0.05 vs. control group.

Herbs including Cao Wu, Chuan Wu, Safflower, *Angelica dahurica* and Cinnamon are traditionally applied to unblock meridians, dispel pain, stimulate blood flow and relieve stasis. However, there are few reports on evaluating the protective effects of TCM directional transdermal therapy on bilateral lower limb DVT in GGN uremic patients (Marshall, 2020).

Our findings validate TCM directional transdermal therapy significantly diminishes the incidence of bilateral lower limb DVT, relieves related symptoms, improves coagulation indices and reestablishes hemodynamics, with excellent safety and patient compliance. Uremia is an aftermath of irreversible nephron damage due to varied disorders of the kidneys and results from systemic toxicity with characteristics of metabolic toxin accumulation, fluid-electrolyte imbalance and hormonal imbalance (Goraya and Wesson, 2020). Contributing factors for uremia include heart failure, infection, urinary tract obstruction, liver failure, malnutrition, anemia, aging, smoking, hypertension and hyperglycemia (Li *et al.,* 2023; Ding *et al.,* 2022).

DVT also commonly presents in the setting of GGN uremia owing to several contributing factors: Immobilization for prolonged periods, sodium and water retention leading to edema and cardiogenic swelling, pitting edema from malnutrition and hypoalbuminemia, vascular endothelial injury secondary to central venous catheters and coagulation dysfunction due to internal environment disruption (Ellenbogen *et al.,* 2022; Erben *et al.,* 2023). DVT not only adds clinical complexity and complications like pulmonary embolism and death, but since curative therapy is not available, prevention is the key (Salem *et al.,* 2021).

Table 5: Comparison of pre- and post-intervention coagulation function indicators between the two groups ($\bar{x} \pm s$)

Indicator	Control group (n=50)	Study group (n=50)
PT (s)		
Pre-intervention	10.78 ± 0.68	10.94 ± 0.77
Post-intervention	11.77 ± 0.71*	14.12 ± 0.82*#
APTT (s)		
Pre-intervention	10.63 ± 1.06	10.60 ± 1.08
Post-intervention	12.62 ± 1.20*	17.49 ± 0.99*#
PLT (×10⁹/L)		
Pre-intervention	503.44 ± 71.96	502.82 ± 73.11
Post-intervention	324.41 ± 45.42*	235.36 ± 32.06*#
FIB (g/L)		
Pre-intervention	6.58 ± 1.26	6.53 ± 1.37
Post-intervention	3.87 ± 0.57*	2.80 ± 0.78*#
D-D (μg/L)		
Pre-intervention	834.31 ± 50.67	843.20 ± 49.21
Post-intervention	427.86 ± 23.11*	253.48 ± 22.18*#

Note: **P < 0.05 vs. pre-intervention; #P < 0.05 vs. control group.

Table 6: Comparison of patient compliance and withdrawal rates between the two groups [n (%)]

Item	Control group (n=50)	Study group (n=50)	χ^2 value	P value
Withdrawal	4 (8.00%)	0 (0.00%)	-	-
Exclusion	1 (2.00%)	0 (0.00%)	-	-
Dropout	2 (4.00%)	1 (2.00%)	-	-
Total	7 (14.00%)	1 (2.00%)	4.893	0.034

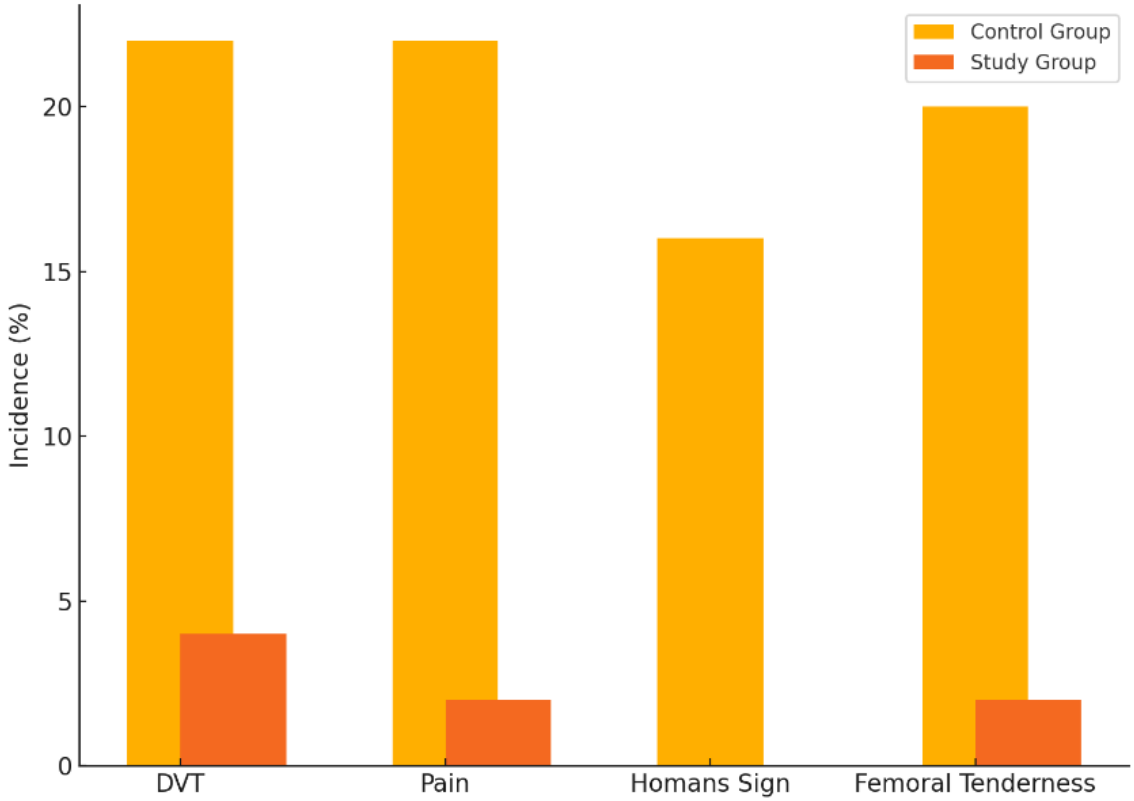

Fig. 1: Incidence of DVT and Symptoms between Groups

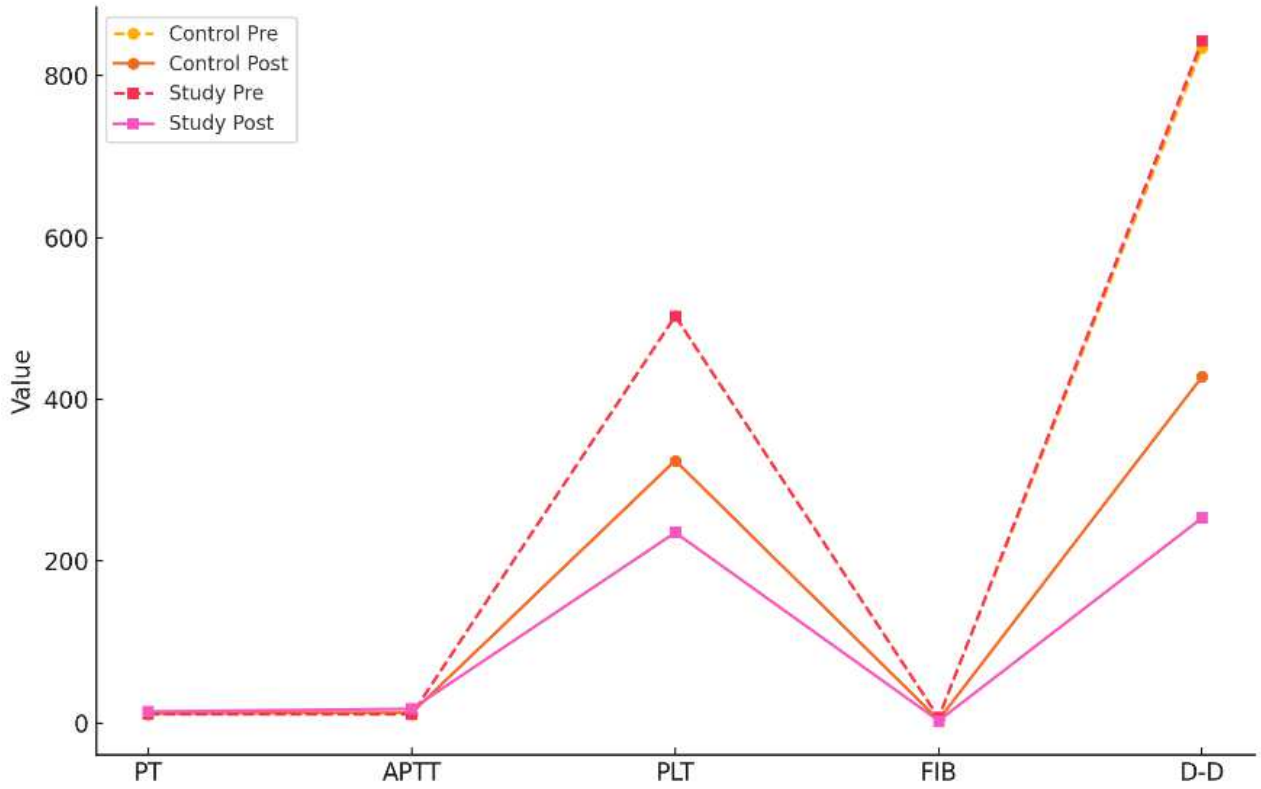

Fig. 2: Changes in coagulation parameters pre- and post-intervention

Herbal medicines such as Taohong Siwu Tang with low molecular weight heparin have previously been found to enhance DVT results following orthopedic surgery. According to this, our intervention group also experienced notable reductions in bilateral lower limb DVT, pain, positive Homans' sign and femoral triangle tenderness and higher compliance levels and reduced limb circumference than controls. There were no notable side effects reported, as has been found before and vindicating the preventive effectiveness of TCM transdermal therapy against DVT (Cai *et al.,* 2024).

Although pharmacologic prophylaxis is useful, it has the side effects of bleeding, coagulopathy disorders and thrombocytopenia. Mechanical intervention like pneumatic compression devices is safer but not as effective, calling for consideration of seeking alternative safer and effective interventions (Guo *et al*., 2022). In TCM, DVT is primarily attributed to stasis of blood and treatment is through activating blood, relieving stasis and regulating qi circulation (Zheng *et al.,* 2022). TCM direction transdermal therapy employs herbal decoctions delivered via medicated pads and electrical stimulation, bypassing hepatic first-pass metabolism, to supply intense, low-dose and efficacious therapy along meridian channels.

DVT pathogenesis involves hypercoagulability, damage to the endothelium and venous stasis, which stimulates platelet and leukocyte aggregation and thrombus formation (Wortmann *et al.,* 2023; Abdalhabib *et al.,* 2022). Prothrombin time (PT) measures extrinsic coagulation factors, activated partial thromboplastin time (APTT) assesses intrinsic coagulation activity, platelet count (PLT) assesses thrombopoiesis, fibrinogen (FIB) plays a critical role in clotting and immune activation and D-dimer (D-D) is a fibrin degradation marker and indicator of hypercoagulability (Lu *et al.,* 2024; Huang *et al.,* 2024; Cheng *et al.,* 2020).

Previouranss research confirmed that stasis-resolving, blood-activating traditional Chinese herbal drugs prolong APTT and reduce D-D, FIB and blood viscosity in joint replacement patients. Similarly, our trial also showed that in the intervention group, there was an improvement in femoral venous blood flow velocity, PT and APTT and reduction in PLT, FIB and D-D levels as compared to controls. These results validate the hypothesis that TCM transdermal therapy enhances hemodynamics and coagulation function in GGN uremic patients, likely due to the fact that the electric field facilitates targeted herbal delivery along meridians to promote venous circulation (Huang *et al.,* 2021).

The primary limitations of this study are the modest number of patients and lack of long-term follow-up to assess sustained effectiveness. More extensive populations

of patients and extended observation periods should be used in subsequent studies to replicate and extend these findings.

CONCLUSION

In conclusion, Parteng TCM directional drug delivery therapy is effective in the prevention of bilateral lower limb DVT in GGN uremia patients. It improves clinical symptoms, coagulation function and normalizes hemodynamics with good safety profile and excellent patient compliance. These findings support the clinical application of this therapy as a preventive treatment of choice for DVT in these patients.

Ethical approval

The research protocol was approved by the Ethics Committee of Shengzhou People's Hospital, Zhejiang Province, China (Approval No. SPH-2023-05), and informed consent forms were completed by all subjects or their guardians prior to inclusion. All patients or family members provided informed consent before enrollment.

Conflict of interest

The authors declare no conflict of interest.

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