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Original Article

Clinical efficacy and safety analysis of ultrasound-guided radiofrequency ablation for varicose veins of lower extremities

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Abstract: Objective: To compare the efficacy of ultrasound-guided radiofrequency ablation (RFA) and high ligation and stripping (HL/S) for lower extremity varicose veins (VV). Methods: Clinical data from 160 VV patients treated at Hangzhou Fuyang Hospital of Traditional Chinese Medicine between January 2023 and December 2024 were retrospectively analyzed. Patients were assigned to either the RFA group (n = 82, ultrasound-guided RFA) or the HL/S group (n = 78, HL/S) based on the treatment modality. Operative time, intraoperative blood loss, length of stay (LOS), Visual Analogue Scale (VAS) scores, levels of bradykinin (BK), substance P (SP), plasminogen activator inhibitor-1 (PAI-1), fibrinogen (Fib), dorsal foot vein pressure, complication rates, and 1-month follow-up outcomes including 36-Item Short Form Survey (SF-36) scores and venous clinical severity scores (VCSS) were compared between the two groups. Results: The RFA group demonstrated shorter operative time, less blood loss, and shorter LOS compared to the HL/S group ($P < 0.05$). On postoperative days 1, 3, and 7, VAS scores were significantly lower in the RFA group compared to the HL/S group ($P < 0.05$). On postoperative day 7, levels of BK, SP, PAI-1, Fib, and dorsal foot vein pressure were significantly lower in the RFA group ($P < 0.05$). At 1-month follow-up, the RFA group showed a lower complication rate, higher SF-36 scores, and lower VCSS compared to the HL/S group ($P < 0.05$). Conclusion: Ultrasound-guided RFA outperformed HL/S in reducing perioperative trauma, pain, dorsal foot vein pressure, and coagulation and inflammatory markers, while offering higher safety and improved short-term quality of life for VV patients.

Keywords: Ultrasound-guided radiofrequency ablation, varicose veins of lower extremities, clinical efficacy, safety, high ligation and stripping

Introduction

Varicose veins (VV) of the lower extremities are a prevalent peripheral vascular disorder, primarily characterized by abnormal dilation and tortuosity of the superficial veins, frequently accompanied by complications such as skin pigmentation, edema, and ulcers [1]. Epidemiological studies have reported that the prevalence of VV among adults in China is approximately 15%, with a higher incidence in women than in men and an increasing prevalence with age [2, 3]. VV not only significantly impairs quality of life but may also lead to severe complications, including deep vein thrombosis.

Traditional surgical treatment primarily involves high ligation and stripping (HL/S) of the great saphenous vein. While HL/S yields a definitive therapeutic effect, it is associated with significant trauma, a high incidence of postoperative complications, and prolonged recovery time [4]. Research has demonstrated that traditional surgical methods are linked to wound infections, hematoma formation, nerve injury, considerable postoperative pain, and low patient satisfaction [5]. Furthermore, traditional surgery often requires extended operative time and prolonged length of stay (LOS), constraining their broader clinical applicability.

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With advancements in minimally invasive techniques, ultrasound-guided radiofrequency ablation (RFA) has emerged as a novel therapeutic approach for VV in clinical practice. RFA utilizes thermal energy to induce collagen denaturation and venous wall contraction, thereby achieving vein closure [6]. Compared to traditional surgery, RFA offers several advantages, including reduced trauma, faster recovery, and fewer complications [7]. However, systematic studies evaluating the clinical efficacy and safety of RFA, particularly regarding perioperative inflammatory markers and coagulation function, remain limited. Therefore, this study aimed to compare the efficacy and safety of ultrasound-guided RFA and traditional HL/S in the treatment of VV of the lower extremities.

Study methods

Sample size determination

In this retrospective study, the sample size was estimated prior to study initiation using the formula:

$$N = \frac{2\delta^2 (t_\alpha + t_\beta)^2}{(\mu_1 - \mu_2)^2}$$

Where δ represents the standard deviation (SD) of the two populations, typically selecting the larger value from the two samples, μ_1 and μ_2 denote the population means, which can be estimated using the sample mean).

Assuming a statistical power of 0.8 and a significance level of α = 0.05, the minimum estimated sample size required for each group was 50 participants.

Participants

This retrospective study was approved by the Ethics Committee of Hangzhou Fuyang Hospital of Traditional Chinese Medicine and conducted in accordance with the principles outlined in the Declaration of Helsinki. Patients diagnosed with VV of the lower extremities who underwent surgical treatment between January 2023 and December 2024 were retrospectively included according to the following inclusion and exclusion criteria.

Inclusion criteria: (1) Diagnosis of VV of the lower extremities with a Clinical-Etiology-Anatomy-Pathophysiology (CEAP) classification [8] of grade C2 or higher; (2) Unilateral limb involvement; (3) Availability of complete demographic data (e.g., sex, age, body weight); (4) Age between 18 and 80 years.

Exclusion criteria: (1) Presence of deep vein thrombosis in the lower limbs or pelvic tumors; (2) Poor general condition or severe cardiovascular or cerebrovascular diseases; (3) Advanced-stage malignancies; (4) Surgical history for VV of the lower extremities; (5) Active infection in the affected limb; (6) Congenital immune system disorders or systemic infectious diseases.

After screening based on these criteria, 160 of the initially selected 197 patients were ultimately included in this study. These patients were assigned to two groups according to the surgical procedure received: the RFA group (n = 82, undergoing ultrasound-guided RFA) and the HL/S group (n = 78, undergoing traditional HL/S).

Data collection

Utilizing the hospital's Healthcare Information Technology (HIT) system, the following data were meticulously gathered.

Patient baseline data: Sex, age, disease duration, body weight, affected side, and Venous Clinical Severity Scores (VCSS) [9] at the time of admission.

Perioperative indicators: Operation time, intraoperative blood loss, and LOS.

Perioperative Visual Analogue Scale (VAS) scores [10]: VAS scores were collected at multiple time points: preoperative day 1, and postoperative days 1, 3, and 7. The VAS scale consists of a 10 cm straight line, where 0 denotes no pain and 10 represents severe pain. Patients were instructed to mark the point on the line that most accurately reflected their pain intensity at each specified time.

Preoperative and postoperative laboratory indicators: On preoperative day 1 and postoperative day 7, 10 mL of fasting venous blood was drawn from the antecubital vein of each patient in the early morning. The samples were collected into sterile vacuum tubes, with 5 mL left at room temperature for 30 min, followed by centrifugation at 3,000 rpm for 15 min. The super-

natant was collected and stored at -80°C. Serum levels of bradykinin (BK; ER-20240315B), substance P (SP; ES-20240228A), and plasminogen activator inhibitor-1 (PAI-1; EP-20240-301C) were quantified using Enzyme-Linked Immunosorbent Assay (ELISA) kits from Shanghai Enzyme-linked Biotechnology Co., Ltd. The remaining 5 mL was centrifuged at 2,500 rpm for 10 min at room temperature to isolate plasma. Fibrinogen (Fib) levels were measured using the coagulation method on a CS-5100 automated coagulation analyzer (Sysmex Corporation, Japan).

Preoperative and postoperative dorsal foot vein pressure: Dorsal foot vein pressure was measured on preoperative day 1 and postoperative day 7 using a CVP-2000 digital venous pressure monitor (Mindray Bio-Medical Electronics Co., Ltd.).

Complications at postoperative 1 month: The incidence of complications within 1 month postoperatively was recorded, including incision bleeding, localized swelling, and incision infection.

One-month postoperative follow-up: Upon discharge, the patients and their family members were instructed to attend a follow-up visit 1 month after surgery. Their contact information was recorded in the hospital's HIT system. Approximately 25 days after surgery, telephone follow-ups were conducted to emphasize the importance of follow-up. Short-term postoperative outcomes were assessed using the 36-Item Short Form Survey (SF-36) scale [11] and the VCSS scale [9]. The SF-36 scale comprises 36 items across 8 dimensions, with higher scores indicating a better quality of life. The VCSS scale includes 10 dimensions, with higher scores indicating more severe symptoms.

Outcome measurements

The following outcomes were compared between the two groups: baseline characteristics, perioperative indicators, perioperative VAS scores, preoperative and postoperative laboratory parameters and dorsal foot vein pressure, incidence of complications and quality of life within 1 month postoperatively, and VCSS.

Statistical methods

Data entry was performed using Excel 2021, and statistical analyses were conducted with SPSS 22.0. Continuous variables were tested for normality and expressed as mean ± standard deviation (mean ± SD). Intergroup comparisons of continuous data were performed using independent sample *t*-tests. Categorical variables were expressed as rates, and intergroup comparisons were analyzed using chi-square tests. Graphical representations were generated using GraphPad Prism 10.1.6. A *P*-value of < 0.05 was considered statistically significant.

Results

Comparison of baseline data between the two groups

The baseline clinical data, including sex, age, weight, affected side, and disease duration, were collected and compared between the two groups. No statistically significant differences were observed in these variables ($P > 0.05$), suggesting good comparability (**Table 1**).

Comparison of perioperative indicators between the two groups

The RFA group demonstrated significantly shorter operation duration, reduced intraoperative blood loss, and shorter LOS compared to the HL/S group ($P < 0.05$) (**Figure 1**).

Comparison of VAS scores at the different time points between the two groups

On preoperative day 1, there was no significant difference in VAS scores between the two groups ($P > 0.05$). However, on postoperative days 1, 3, and 7, VAS scores in the RFA group were significantly lower than those in the HL/S group ($P < 0.05$) (**Figure 2**).

Comparison of preoperative and postoperative serum BK and SP levels between the two groups

There were no significant differences in serum BK and SP levels between the two groups on preoperative day 1 ($P > 0.05$). However, on postoperative day 7, serum BK and SP levels significantly increased in both groups com-

Table 1. Comparison of baseline data between the two groups ($\bar{x} \pm s$)/[n (%)]

General data	RFA group (n=82)	HL/S group (n=78)	t/χ^2	*P*
Male/female	40/42	32/46	0.971	0.324
Average age (years)	49.45±8.19	50.23±7.62	0.623	0.534
Average weight (kg)	67.82±9.56	68.51±8.55	0.480	0.632
Affected side (left/right)	46/36	40/38	0.373	0.541
Average disease duration (years)	7.02±2.15	6.98±1.98	0.122	0.903
Preoperative VCSS	4.23±0.51	4.35±0.38	0.265	0.881

Note: RFA: radiofrequency ablation; HL/S: high ligation and stripping; VCSS: venous clinical severity scores.

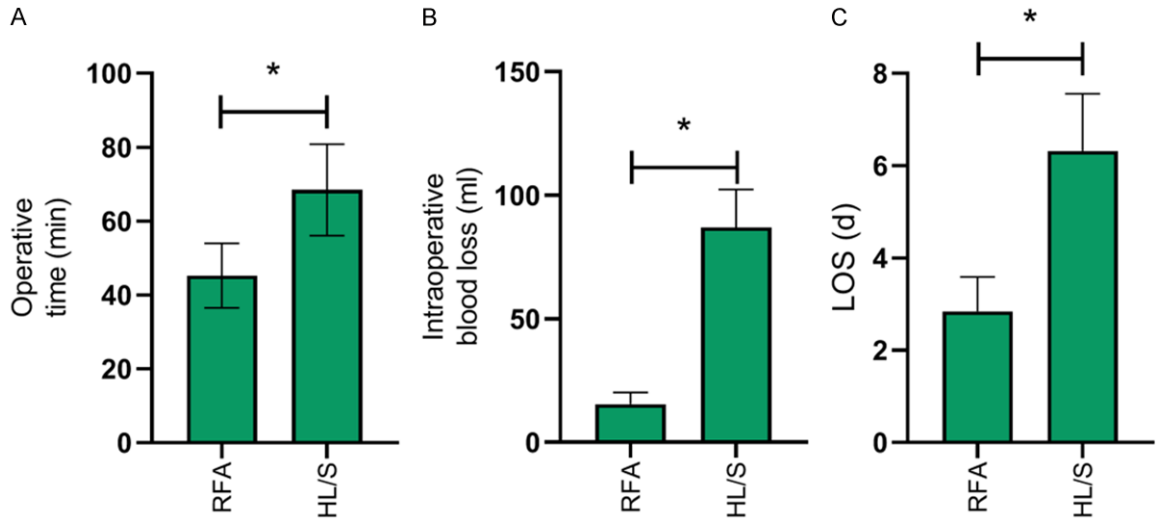

Figure 1. Comparison of perioperative indicators between the two groups. A: Operation time; B: Intraoperative blood loss; C: LOS. Note: LOS: length of stay; RFA: radiofrequency ablation; HL/S: high ligation and stripping. *$P < 0.05$.

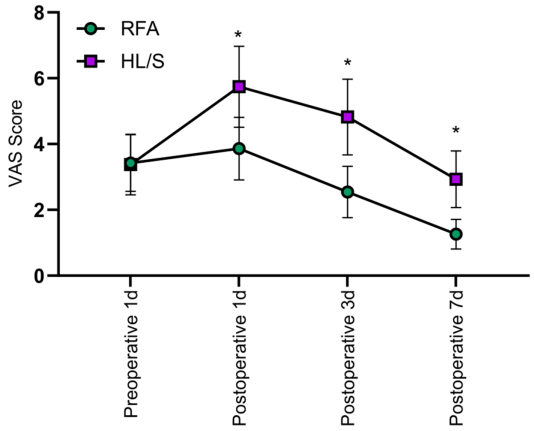

Figure 2. Comparison of VAS scores between the two groups at different time points. Note: VAS: Visual Analogue Scale; RFA: radiofrequency ablation; HL/S: high ligation and stripping. *$P < 0.05$.

pared to preoperative day 1. Additionally, on postoperative day 7, the BK and SP levels were significantly lower in the RFA group than in the HL/S group ($P < 0.05$) (**Figure 3**).

Comparison of preoperative and postoperative coagulation function indicators between the two groups

No significant differences were observed in PAI-1 and Fib levels between the two groups on preoperative day 1 ($P > 0.05$). However, on postoperative day 7, PAI-1 and Fib levels in the RFA group were significantly lower than those in the HL/S group ($P < 0.05$) (**Figure 4**).

Comparison of preoperative and postoperative dorsal foot vein pressure between the two groups

No significant differences were observed in dorsal foot vein pressure between the two groups on preoperative day 1 ($P > 0.05$). However, on postoperative day 7, dorsal foot

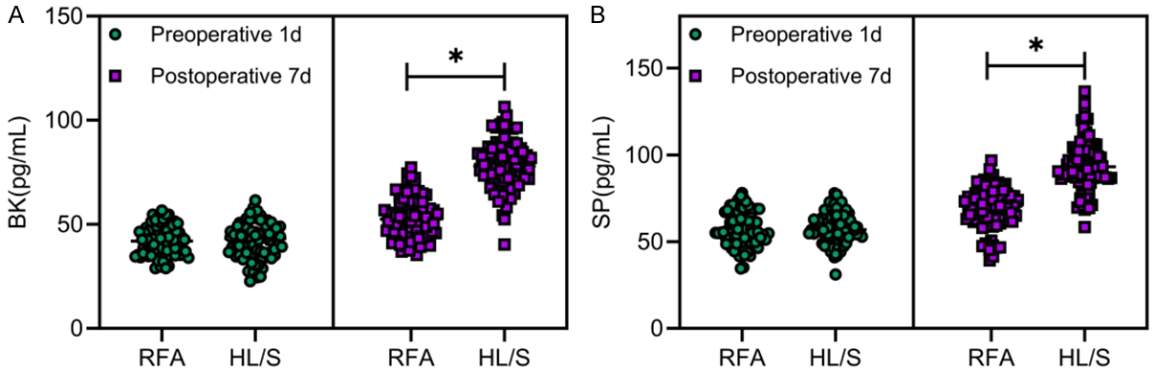

Figure 3. Comparison of preoperative and postoperative serum BK and SP levels between the two groups. A: serum BK level; B: serum SP level. Note: BK: bradykinin; SP: substance P; RFA: radiofrequency ablation; HL/S: high ligation and stripping. *$P < 0.05$.

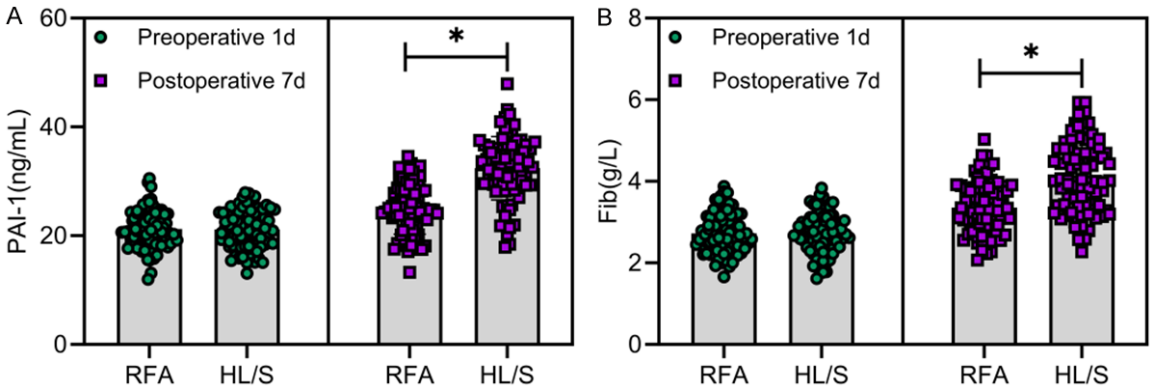

Figure 4. Comparison of preoperative and postoperative coagulation function indicators between the two groups. A: PAI-1 level; B: Fib level. Note: PAI-1: plasminogen activator inhibitor-1; Fib: fibrinogen; RFA: radiofrequency ablation; HL/S: high ligation and stripping. *$P < 0.05$.

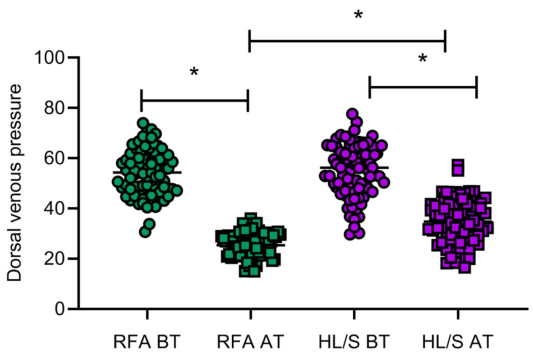

Figure 5. Comparison of preoperative and postoperative dorsal foot vein pressure between the two groups. Note: RFA: radiofrequency ablation; HL/S: high ligation and stripping. BT represents preoperative day 1, and AT represents postoperative day 7. *$P < 0.05$.

vein pressure in the RFA group was significantly lower than that in the HL/S group ($P < 0.05$) (**Figure 5**).

Comparison of incidence of complications at 1 month postoperatively between the two groups

During the 1-month follow-up, two cases of incision bleeding, three cases of localized swelling, and one case of incision infection were recorded in the RFA group. The overall incidence of complications was 7.32% (6/82) in the RFA group, significantly lower than 32.05% (25/78) in the HL/S group ($P < 0.05$) (**Table 2**).

Comparison of 1-month postoperative follow-up between the two groups

At the 1-month follow-up, the RFA group exhibited significantly higher SF-36 scores and markedly lower VCSS compared to the HL/S group ($P < 0.05$) (**Figure 6**).

Discussion

In this study, the clinical efficacy of ultrasound-guided RFA and traditional HL/S in the treat-

Table 2. Comparison of incidence of complications at postoperative 1 month between the two groups [n (%)]

Group	Number of cases	Incision bleeding	Localized swelling	Incision infection	Overall incidence
RFA group	82	2 (2.44)	3 (3.66)	1 (1.22)	6 (7.32)
HL/S group	78	8 (10.26)	12 (15.38)	5 (6.41)	25 (32.05)
X^2	-	-	-	-	15.656
P	-	-	-	-	<0.001

Note: RFA: radiofrequency ablation; HL/S: high ligation and stripping.

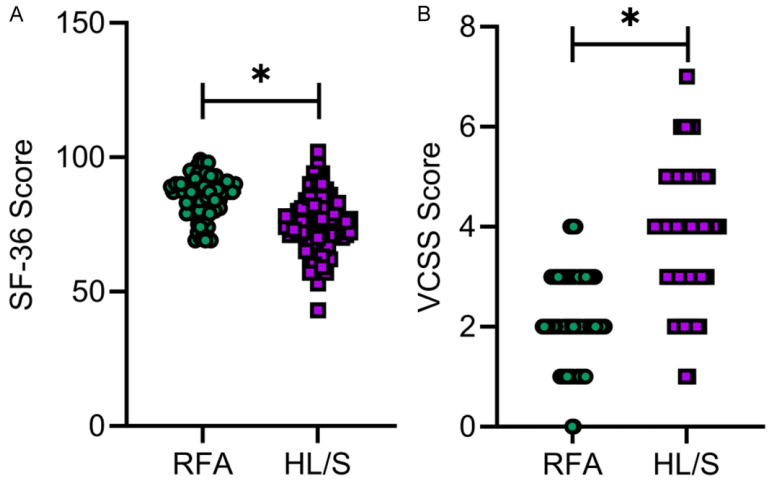

Figure 6. Comparison of quality of life at postoperative 1 month between the two groups. A: SF-36 scores; B: VCSS scores. Note: SF-36: 36-Item Short Form Survey; VCSS: venous clinical severity scores; RFA: radiofrequency ablation; HL/S: high ligation and stripping. $^*P < 0.05$.

ment of VV of the lower extremities was compared. The results demonstrated that the RFA group outperformed the HL/S group in several perioperative parameters, including operation duration, intraoperative blood loss, and LOS. Additionally, the RFA group exhibited significant advantages in postoperative indicators, such as lower postoperative pain scores, reduced inflammatory marker levels, improved coagulation function parameters, and a lower incidence of complications. Moreover, the RFA group achieved higher postoperative quality of life scores and lower VCSS. These results confirm the superior efficacy of RFA in treating VV of the lower extremities from various perspectives. Muhammad et al. [12] found that, compared to conventional surgery, RFA significantly reduced operation duration, which is crucial for minimizing patient trauma and accelerating postoperative recovery. This reduction may b e attributed to the simplified nature of RFA, which, unlike conventional surgery, eliminates the need for extensive tissue dissection or vascular stripping, offering a more direct and efficient technique [13]. Additionally, the integration of ultrasound guidance has enhanced procedure accuracy [14], allowing surgeons to precisely target veins and monitor ablation process in real-time, thus minimizing unnecessary exploration and improving surgical efficiency. Atay et al. [15] analyzed data from 709 patients between January 2018 and May 2021 and found that standardized RFA significantly reduced operation duration, while CEAP, VAS, and VCSS scores improved notably during follow-up; they concluded that RFA demonstrated high short-term and long-term occlusion success rates, favorable postoperative recovery, excellent perioperative outcomes, and a low incidence of adverse effects. Based on these findings, we propose that reducing operation duration and LOS not only minimize surgical trauma and accelerate postoperative recovery but also enhance the efficiency of medical resource utilization.

In terms of postoperative pain, this study demonstrated that the VAS scores at all postoperative time points were significantly lower in the RFA group than those compared to the HL/S group. Wang et al. [16] conducted a retrospective study of 165 incompetent perforator veins in 138 limbs of 117 consecutive patients, revealing a 100% success rate for RFA without major complications. Among the 93 patients followed for one year, VCSS significantly decreased compared to preoperative levels, accompanied by a marked reduction in pain, indicating a low recanalization rate after RFA. Based

on these findings, we propose that traditional surgical techniques cause substantial trauma, whereas RFA primarily employs thermal energy for targeted ablation of affected veins, thereby avoiding the mechanical traction and stripping characteristic of conventional procedures. This approach minimizes damage to surrounding tissues and nerves, which is essential in alleviating postoperative pain. Hong et al. [17] analyzed 217 patients (345 veins) and found that the occlusion rate of saphenous veins following RFA treatment was 100% at 3 years and 95.4% at 5 years, with a significant reduction in postoperative pain. Compared to conventional surgical procedure, ultrasound-guided ablation offers superior precision in delineating the surgical area. This enhanced controllability significantly mitigates damage to surrounding tissues, thereby expediting postoperative tissue repair. Such advantages may explain the reduced postoperative inflammatory response observed in the RFA group.

Regarding inflammatory and coagulation indicators, this study is the first to systematically compare the effects of RFA and HL/S on serum levels of BK, SP, PAI-1, and Fib. The results demonstrated that, on postoperative day 7, the RFA group exhibited significantly more favorable outcomes across all indicators compared to the HL/S group. Cong et al. [18] retrospectively analyzed 84 patients (151 limbs) and found that, although VAS scores within 24 hours postoperatively did not significantly differ between groups, inflammatory marker levels were lower in the RFA group after 24 hours. Moreover, at 6 and 12 months postoperatively, RFA patients demonstrated significantly superior VCSS and CIVIQ-20 scores compared to those undergoing traditional procedures. We propose that RFA primarily ablates VV through precise thermal targeting, ensuring more controllable tissue injury. This controlled injury likely contributes to a milder postoperative inflammatory response observed in the RFA group. Goshchynsky et al. [19] indicated that the extent of surgical trauma was positively correlated with the levels of inflammatory marker levels. Similarly, Pavlović et al. [20] demonstrated that the type of surgical procedure significantly influences coagulation system activation, which is consistent with the differences in PAI-1 and Fib levels observed between the two groups in our study. These findings help clarify the differing mechanisms underlying the two surgical approaches and provides valuable insights for optimizing surgical strategy for future clinical practice.

Dorsal foot vein pressure is a critical indicator for assessing surgical outcomes. Our study revealed that, on postoperative day 7, the pressure in the RFA group (25.62±3.15 mmHg) was significantly lower than that in the HL/S group. Previous studies have reported that RFA significantly improves dorsal foot vein pressure in VV patients [21]. Arslanturk et al. [22] retrospectively analyzed 84 patients with isolated small saphenous vein insufficiency and found that, although the target vein occlusion rate at one-year follow-up were comparable between cyanoacrylate ablation and RFA, the latter demonstrated superior efficacy in reducing dorsal foot vein pressure, providing new clinical insights for VV treatment. The lower postoperative dorsal foot vein pressure in the RFA group may be attributed to the precise localization and efficient thermal energy delivery under ultrasound guidance. Moreover, RFA significantly enhances dorsal foot hemodynamics in VV patients [23].

In terms of the incidence of complications, the one-month follow-up revealed a significantly lower complication rate in the RFA group compared to the HL/S group, consistent with the findings of Svidersky et al. [24]. We propose that the reduced incidence of complications in the RFA group is attributable to several factors. Primarily, ultrasound-guided ablation is minimally invasive, which reduces the risk of incisional infections. Furthermore, the high precision of ultrasound localization minimizes damage to surrounding tissues, reducing inflammatory responses and alleviating postoperative swelling. Additionally, the shorter operative duration and reduced trauma further contribute to a lower likelihood of incisional infections [25]. Collectively, these factors contribute to the reduced short-term complication rate observed in the RFA group.

According to quality of life assessments, at 1 month postoperatively, the RFA group exhibited significantly higher SF-36 scores and markedly lower VCSS compared to the HL/S group, indicating a more favorable prognosis. Li et al. [26] conducted a retrospective analysis of 339 patients undergoing RFA and observed a significant reduction in VCSS at 12 months postop-

eratively, accompanied by notable improvements in patients' quality of life scores. We propose that postoperative quality of life is influenced by several factors. In this study, patients in the RFA group experienced less surgical trauma, a lower incidence of postoperative complications, and reduced pain, all of which facilitated early postoperative rehabilitation and consequently enhanced their short-term postoperative quality of life.

In conclusion, compared to traditional HL/S, ultrasound-guided RFA markedly minimizes perioperative trauma in patients with VV of the lower extremities, alleviates perioperative pain and dorsal foot vein pressure, improves coagulation function and inflammatory status, enhances safety, and improves short-term postoperative quality of life. The key innovations of this study are as follows: (1) A multidimensional evaluation system was employed, replacing traditional clinical parameter comparisons. This comprehensive framework, including perioperative indicators, pain scores, inflammatory factors, and coagulation function, facilitated a systematic comparison of the two surgical techniques. (2) A detailed analysis of the effects of RFA and traditional HL/S on inflammatory factors and coagulation markers was conducted, offering valuable insights into the underlying mechanisms and micro-level differences between the two procedures. (3) Dorsal foot vein pressure was incorporated as a novel surgical outcome measure, objectively demonstrating the hemodynamic advantages of RFA, thereby providing a reliable reference for clinical practice. However, this study has certain limitations, including its single-center, retrospective design, relatively short follow-up period, and the absence of a cost-effectiveness analysis. Future multicenter prospective studies with extended follow-up periods and comprehensive cost-effectiveness evaluations are needed to further refine surgical strategies, enhance procedural efficiency, and minimize postoperative complications.

Disclosure of conflict of interest

None.

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