

Radiofrequency Ablation versus Controlled Venospasm-Assisted Foam Sclerotherapy with High Ligation for Great Saphenous Vein Incompetence: A Propensity Score Matched Study

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Abstract

Background

Symptomatic primary great saphenous vein (GSV) incompetence is commonly treated with minimally invasive thermal ablation techniques such as radiofrequency ablation (RFA). Controlled venospasm-assisted foam sclerotherapy (CVAFS) combined with high ligation represents a novel non-thermal, non-tumescent alternative; however, comparative data on its perioperative and mid-term outcomes against RFA remain limited.

Aims

To compare the perioperative and 12-month clinical outcomes of controlled venospasm-assisted foam sclerotherapy (CVAFS) combined with high ligation versus radiofrequency ablation (RFA) in patients with symptomatic primary great saphenous vein (GSV) incompetence.

Methods

This was a single-centre, retrospective comparative study. Consecutive patients who underwent RFA or CVAFS with high ligation between March 2023 and August 2024 were enrolled. Propensity score matching (PSM) was performed at the patient level to minimise selection bias. Patients lost to follow-up within the 12-month period were excluded from the primary analysis to ensure a complete-case PSM workflow.

Results

A total of 476 patients (615 limbs) were enrolled. After excluding 37 patients lost to follow-up, optimal Hungarian matching yielded 98 well-matched pairs (196 patients, 254 limbs) with no loss to follow-up in the matched cohort. Before matching, the crude 12-month occlusion rate was 95.6% (303/317) for RFA and 95.2% (239/251) for CVAFS ($P = 0.842$). In the matched cohort, the 12-month occlusion rate was 95.3% (122/128) for RFA and 95.2% (120/126) for CVAFS ($P = 1.000$). Mean Venous Clinical Severity Score (VCSS) decreased substantially and comparably in both groups. RFA was associated with a significantly shorter surgical time, while both procedures demonstrated favourable safety profiles.

Conclusion

In this propensity score-matched analysis, CVAFS combined with high ligation demonstrated 12-month occlusion rates and clinical improvement that were comparable to RFA in patients with symptomatic primary GSV incompetence, with both procedures exhibiting a favourable safety profile. These findings suggest that CVAFS may represent a viable non-thermal, non-tumescent alternative to RFA; however, longer term follow-up is required to confirm the durability of vein closure with this technique.

INTRODUCTION

Chronic venous disease (CVD) is highly prevalent, with varicose veins affecting up to 73% of adults[1, 2]. Great saphenous vein (GSV) incompetence, most commonly arising from saphenofemoral junction (SFJ) reflux, is the predominant anatomical substrate for symptomatic varicose veins[3].

Endovenous thermal ablation—radiofrequency ablation (RFA) or endovenous laser ablation—is the first-line treatment for symptomatic GSV incompetence (Class I, Level A)[1, 2, 4], with RFA demonstrating high occlusion rates and a favourable safety profile[5–8]. Ultrasound-guided foam sclerotherapy (UGFS) offers a non-thermal, non-tumescent alternative but is associated with lower and more variable occlusion rates than thermal ablation[9, 10].

Controlled venospasm-assisted foam sclerotherapy (CVAFS) combined with high ligation is a novel modification of foam sclerotherapy incorporating three elements: (1) surgical high ligation 1.0 cm distal to the SFJ to eliminate saphenofemoral reflux[12]; (2) mechanical induction of transient venospasm (> 50% luminal diameter reduction) through rotational catheter manipulation and external cutaneous compression; and (3) fluoroscopically guided injection of 1% polidocanol foam into the spastic, reduced-calibre vein[11]. Venospasm is hypothesised to enhance sclerosant-endothelium contact, promoting more durable sclerosis. To date, no comparative studies have evaluated CVAFS against RFA[11].

This study therefore compared the perioperative and 12-month outcomes of CVAFS combined with high ligation versus RFA for symptomatic primary GSV incompetence, using propensity score matching (PSM) to minimise selection bias.

METHODS

This was a single-centre, retrospective comparative study of patients with symptomatic primary GSV incompetence who underwent RFA or CVAFS combined with high ligation between March 2023 and August 2024 at Nanjing First Hospital, Nanjing Medical University, Nanjing, China. Ethical approval was obtained from the Nanjing First Hospital Ethics Committee (KY20221211-11), and the requirement for individual patient consent was waived owing to the retrospective design. The study was reported in accordance with the STROBE guidelines.

Consecutive patients with symptomatic primary GSV incompetence who underwent RFA or CVAFS were screened. Inclusion criteria were: (1) SFJ reflux duration > 1 second on colour duplex ultrasound (CDUS); (2) CEAP clinical class $\geq$ C2; (3) patent deep veins; and (4) GSV diameter $\geq$ 5 mm. Exclusion criteria comprised contraindications to surgical intervention or foam sclerotherapy. Treatment allocation was determined by the treating surgeon based on clinical indication, patient preference, and shared decision making.

All RFA procedures were performed by experienced interventional radiologists under local tumescent anaesthesia. A ClosureFast catheter (Medtronic, Minneapolis, MN, USA) was introduced into the GSV under ultrasound guidance via a percutaneous puncture at or below the knee level. The catheter tip was positioned 2.0 cm distal to the SFJ. Tumescent local anaesthesia (500 mL of 0.9% saline, 30 mL of 1% lidocaine with epinephrine, and 10 mL of 8.4% sodium bicarbonate) was infiltrated along the perivenous space under

ultrasound guidance. Radiofrequency energy was delivered at 120°C using two 20-second treatment cycles for the most proximal segment, followed by a single 20-second cycle for each subsequent segment. Concomitant ambulatory phlebectomy or adjunctive ultrasound-guided foam sclerotherapy was performed for visible tributary varicosities at the discretion of the operating surgeon.

CVAFS procedures were performed by the same team of interventional radiologists. The patient was positioned supine, and the procedure was performed under local anaesthesia (1% lidocaine) administered at the puncture site, combined with a femoral nerve block. Under ultrasound guidance, a 5-Fr introducer sheath (Terumo, Tokyo, Japan) was inserted percutaneously into the GSV at the level of the medial knee. Following manual contrast injection to localise the SFJ, high ligation was performed 1.0 cm distal to the SFJ using non-absorbable sutures to achieve proximal flow interruption. Proximal GSV occlusion was confirmed by manual contrast injection through the catheter.

A 4-Fr vertebral catheter (Terumo, Tokyo, Japan) was then advanced into the GSV. Controlled mechanical venospasm (> 50% luminal diameter reduction) was induced through rotational catheter manipulation combined with external cutaneous compression along the GSV, verified by contrast imaging (Fig. 1). Sclerosing foam (1% polidocanol, Aethoxysklerol, Kreussler Pharma, Wiesbaden, Germany) was freshly prepared using the Tessari method (4:1 air-to-liquid ratio) and injected through the catheter under fluoroscopic guidance, with manual compression of perforating veins to prevent foam migration into the deep venous system. Below-knee varicosities received adjunctive foam injection under fluoroscopic guidance. Concomitant phlebectomy was performed for tributary veins exceeding 4 mm in diameter or clustered varicosities.

Post-procedural management was identical for both groups. Elastic compression bandaging was applied to the treated limb immediately after the procedure. Patients were mobilised six hours post-operatively with 15 minutes of ambulation every two hours. Elastic bandages were maintained for 72 hours, after which graduated compression stockings (20–30 mmHg) were worn daily for a minimum of three months.

Co-primary outcomes were: (1) 12-month target vein occlusion rate, defined as complete absence of flow within the treated GSV segment on CDUS; and (2) change in Venous Clinical Severity Score (VCSS) from baseline to 12 months. Perioperative outcomes included surgical time (skin puncture to completion of compression bandaging), technical success, thrombophlebitis, deep vein thrombosis (DVT), wound infection, bruising, paraesthesia, and post-operative pain (Visual Analogue Scale score ≥ 1). Target vein recanalisation was defined as loss of complete occlusion confirmed by CDUS; time to recanalisation was measured from the index procedure to the first CDUS documenting recanalisation, or the date of last follow-up for censored observations.

All patients underwent clinical evaluation and CDUS at baseline, 6 months, and 12 months (± 7 days). VCSS was assessed by a clinician not involved in the index procedure. CDUS was performed with the patient standing to evaluate GSV occlusion status, reflux duration, and venous diameter. Reflux was defined as retrograde flow lasting > 0.5 seconds after calf compression and release.

Statistical analysis was performed using SPSS 26.0 (IBM Corp., Armonk, NY, USA) and Python 3.12 (Python Software Foundation, Wilmington, DE, USA) with scipy.stats (version 1.14), lifelines (version 0.30.3), and

matplotlib (version 3.9). Continuous variables were expressed as mean $\pm$ standard deviation and compared using the Mann–Whitney U test. Categorical variables were expressed as frequencies with percentages and compared using Fisher's exact test. A two-sided $P < 0.05$ was considered statistically significant.

Propensity score matching was performed at the patient level to minimise selection bias inherent to the non-randomised treatment allocation. Propensity scores were estimated using a multivariable logistic regression model with treatment assignment (RFA vs. CVAFS) as the dependent variable and the following eight baseline covariates as independent variables: age, sex, body mass index (BMI), diabetes mellitus, hypertension, hyperlipidaemia, smoking status, and pre-operative CEAP clinical class. Model discrimination was assessed by the area under the receiver operating characteristic curve (AUC).

To identify the optimal matching strategy, six candidate schemes were systematically evaluated by combining two matching algorithms (greedy nearest neighbour matching vs. optimal matching using the Hungarian algorithm) with three caliper widths ($0.20, 0.25$, and $0.30 \times \text{SD}$ of the logit of the propensity score). All schemes employed 1:1 matching without replacement with a random seed of 42. The primary criterion for scheme selection was achieving standardised mean differences (SMD) < 0.10 for all covariates. Among schemes meeting this criterion, the one yielding the largest number of matched pairs was selected.

Covariate balance was assessed using standardised mean differences (SMD), with $\text{SMD} < 0.10$ considered indicative of adequate balance. After PSM, the matched patient cohort was linked back to limb-level records. Because matching was performed at the patient level and some patients underwent bilateral procedures, limb counts were asymmetric (RFA: 128 limbs; CVAFS: 126 limbs).

Kaplan–Meier survival analysis was performed to compare freedom from target vein recanalisation between the RFA and CVAFS groups, both before and after PSM. For the pre-matching analysis, all 615 treated limbs from the 476 enrolled patients were included. For the post-matching analysis, the PSM-matched cohort was used. Kaplan–Meier curves were compared using the log-rank test. Cumulative freedom from recanalisation rates at 6 and 12 months were estimated with 95% confidence intervals (CIs) using Greenwood's formula. A complete-case analysis approach was adopted: patients lost to follow-up or lacking 12-month primary outcome evaluation were excluded prior to matching (Fig. 2).

Because some patients underwent bilateral treatments, limb-level outcomes involved clustered data. Continuous and categorical variables at the limb level were compared using generalised estimating equations (GEE) with an exchangeable working correlation structure. To assess the robustness of the primary findings, all perioperative and 12-month outcomes were compared both before and after PSM.

RESULTS

A total of 476 patients (615 limbs) were enrolled. During the 12-month follow-up, 37 patients (47 limbs; 7.8%) were lost to follow-up. After excluding these individuals, 439 patients (568 limbs) constituted the pre-matching complete-case pool. A 1:1 PSM was performed on this complete-case cohort.

The logistic regression model for propensity score estimation demonstrated good discrimination ($\text{AUC} = 0.8734$). The SD of the logit propensity score was 2.0754, yielding a caliper width of 0.4151 for the final

scheme (caliper = $0.20 \times \text{SD}[\text{logit PS}]$). Optimal Hungarian matching with caliper = $0.20 \times \text{SD}$ produced the largest number of matched pairs (98) among schemes achieving acceptable balance. After matching, seven of eight covariates achieved $\text{SMD} < 0.10$. Hypertension showed an SMD of 0.1112, marginally above the 0.10 threshold, corresponding to a raw prevalence difference of 5.1 percentage points (27.6% vs. 32.7%). The mean $|\text{SMD}|$ across all covariates was 0.0528 at the patient level (0.0495 at the limb level). Propensity score distributions showed substantial separation before matching (Kolmogorov–Smirnov $D = 0.611$, $P < 0.001$) and were well aligned after matching ($D = 0.173$, $P = .105$; Fig. 3). Covariate balance is visualised in the Love plot (Fig. 4).

Because matching was performed at the patient level and some patients had undergone bilateral procedures, the matched cohort comprised 196 patients (98 pairs) yielding 254 limbs (RFA: 128; CVAFS: 126). No patients in the matched cohort were lost to 12-month follow-up, confirming the integrity of the complete-case PSM workflow.

Before matching, substantial imbalances were observed: the RFA group was younger (59.0 ± 7.6 vs. 67.3 ± 10.4 years; $\text{SMD} = 0.935$) and had a lower BMI (24.4 ± 2.9 vs. 28.7 ± 3.9 kg/m^2 ; $\text{SMD} = 1.282$) compared with the CVAFS group. After PSM, baseline characteristics were well balanced between groups (Table 1). Age (62.5 ± 7.5 vs. 62.6 ± 9.1 years, $P = .952$), BMI (26.2 ± 2.5 vs. 26.4 ± 3.1 kg/m^2 , $P = .756$), and CEAP class (3.1 ± 1.1 vs. 3.2 ± 1.0 , $P = .128$) were comparable, with no significant differences in sex, diabetes mellitus, hypertension, hyperlipidaemia, or smoking status (all $P > .05$).

Table 1
Baseline characteristics before and after propensity score matching

Variables	Before matching				After matching			
	RFA (266 pts, 346 lim)	CVAFS (210 pts, 269 lim)	t/ χ^2	P value	RFA (98 pts, 128 lim)	CVAFS (98 pts, 126 lim)	t/ χ^2	P value
Sex, n (%)								
Female	133 (50.0%)	102 (48.6%)			49 (50.0%)	50 (51.0%)		
Male	133 (50.0%)	108 (51.4%)	0.047	0.828	49 (50.0%)	48 (49.0%)	0.000	1.000
Age (yr)	58.75 $\pm$ 7.55	67.53 $\pm$ 10.31	-10.726	< 0.0001	62.51 $\pm$ 7.47	62.58 $\pm$ 9.07	-0.060	0.9521
BMI (kg/m ²)	24.46 $\pm$ 2.88	28.65 $\pm$ 3.88	-13.513	< 0.0001	26.23 $\pm$ 2.55	26.35 $\pm$ 3.11	-0.312	0.7557
Smoking, n (%)	41 (15.4%)	45 (21.4%)	2.476	0.116	17 (17.3%)	20 (20.4%)	0.133	0.715
Diabetes mellitus, n (%)	48 (18.0%)	49 (23.3%)	1.710	0.191	24 (24.5%)	24 (24.5%)	0.000	1.000
Hypertension, n (%)	66 (24.8%)	76 (36.2%)	6.725	0.010	27 (27.6%)	32 (32.7%)	0.388	0.533
Hyperlipidemia, n (%)	42 (15.8%)	65 (31.0%)	14.625	< 0.001	22 (22.4%)	25 (25.5%)	0.112	0.738
Coronary artery disease, n (%)	25 (9.4%)	29 (13.8%)	1.853	0.173	14 (14.3%)	11 (11.2%)	0.183	0.668
Chronic kidney disease, n (%)	18 (6.8%)	21 (10.0%)	1.229	0.268	5 (5.1%)	11 (11.2%)	1.701	0.192
Stroke, n (%)	8 (3.0%)	13 (6.2%)	2.115	0.146	3 (3.1%)	7 (7.1%)	0.948	0.330
Peripheral artery disease, n (%)	15 (5.6%)	18 (8.6%)	1.142	0.285	6 (6.1%)	7 (7.1%)	0.000	1.000
Previous venous surgery, n (%)	33 (12.4%)	14 (6.7%)	3.723	0.054	8 (8.2%)	8 (8.2%)	0.000	1.000
CEAP grade, n (%)								
C2	124 (35.8%)	88 (32.7%)		0.6689	50 (39.1%)	43 (34.1%)		0.1278
C3	77 (22.3%)	65 (24.2%)			35 (27.3%)	30 (23.8%)		

Variables	Before matching				After matching			
	RFA (266 pts, 346 lim)	CVAFS (210 pts, 269 lim)	t/ χ^2	P value	RFA (98 pts, 128 lim)	CVAFS (98 pts, 126 lim)	t/ χ^2	P value
C4	97 (28.0%)	86 (32.0%)			27 (21.1%)	44 (34.9%)		
C5	36 (10.4%)	23 (8.6%)			13 (10.2%)	8 (6.3%)		
C6	12 (3.5%)	7 (2.6%)			3 (2.3%)	1 (0.8%)		

Perioperative outcomes are presented in Table 2. Technical success was 100.0% in both groups (RFA: 128/128 limbs; CVAFS: 126/126 limbs). In the matched cohort, RFA was associated with significantly shorter surgical time (39.5 ± 11.0 min vs. 53.6 ± 15.7 min; $P < 0.001$). Bruising was more frequent after CVAFS (18.3% vs. 10.2%; $P = .095$), as was paraesthesia (6.3% vs. 1.6%; $P = .059$), though neither reached statistical significance. Thrombophlebitis rates were low and comparable (1.6% vs. 3.2%; $P = .445$). No cases of DVT, pulmonary embolism, or wound infection were recorded in either group. Post-operative pain rates were similar (19.5% vs. 16.7%; $P = .667$).

Table 2
Perioperative outcomes in RFA and CVAFS groups before and after propensity score matching

Characteristics	Before matching				After matching			
	RFA (266 pts, 346 lim)	CVAFS (210 pts, 269 lim)	t/ χ^2	P value	RFA (98 pts, 128 lim)	CVAFS (98 pts, 126 lim)	t/ χ^2	P value
Surgical time (min)	39.93 $\pm$ 10.25	52.76 $\pm$ 14.76	-12.697	< 0.001	39.49 $\pm$ 10.95	53.58 $\pm$ 15.68	-8.311	< 0.001
Technical success, n (%)	346 (100.0%)	269 (100.0%)	-	1.000	128 (100.0%)	126 (100.0%)	-	1.000
Thrombophlebitis, n (%)	9 (2.6%)	20 (7.4%)	6.831	0.009	2 (1.6%)	4 (3.2%)	Fisher	0.445
Deep vein thrombosis, n (%)	0 (0.0%)	0 (0.0%)	-	1.000	0 (0.0%)	0 (0.0%)	-	1.000
Wound infection, n (%)	0 (0.0%)	0 (0.0%)	-	1.000	0 (0.0%)	0 (0.0%)	-	1.000
Bruising, n (%)	51 (14.7%)	64 (23.8%)	7.572	0.006	13 (10.2%)	23 (18.3%)	2.789	0.095
Paresthesia, n (%)	12 (3.5%)	10 (3.7%)	Fisher	1.000	2 (1.6%)	8 (6.3%)	Fisher	0.059
Postoperative pain (VAS $\geq$ 1), n (%)	76 (22.0%)	45 (16.7%)	2.305	0.129	25 (19.5%)	21 (16.7%)	0.185	0.667

Before matching, the crude 12-month occlusion rate was 95.6% (303/317) for RFA and 95.2% (239/251) for CVAFS ($P = .842$). In the matched cohort, occlusion rates were 95.3% (122/128) for RFA and 95.2% (120/126) for CVAFS ($P = 1.000$). Both modalities yielded substantial and comparable VCSS improvements. Pre-operative VCSS was comparable (RFA: 7.8 ± 3.3 ; CVAFS: 8.0 ± 3.1 ; $P = .401$). At 6 months, VCSS decreased to 1.98 ± 2.00 and 2.25 ± 2.23 , respectively ($P = .519$); at 12 months, to 0.71 ± 0.81 and 0.85 ± 0.89 ($P = .264$). The mean VCSS reduction from baseline to 12 months was comparable (-7.1 ± 3.3 vs. -7.1 ± 3.2 ; Fig. 5).

Kaplan–Meier analysis of freedom from recanalisation was performed before and after PSM (Fig. 6). Before PSM, 26 recanalisation events were observed among 568 limbs (RFA: 14 events, 317 limbs; CVAFS: 12 events, 251 limbs). The 12-month freedom from recanalisation was 95.6% (95% CI 92.7–97.4) for RFA and 95.2% (95% CI 91.7–97.2) for CVAFS (log-rank $P = .814$). After PSM, 12 recanalisation events were observed among 254 limbs, evenly distributed (RFA: 6 events, 128 limbs; CVAFS: 6 events, 126 limbs). The 12-month freedom from recanalisation was 95.0% (95% CI 89.2–97.7) for RFA and 94.9% (95% CI 89.0–97.7) for CVAFS (log-rank $P = .976$). Owing to the low overall event rate (4.2% [26/615] before PSM; 4.7% [12/254] after PSM), the median time to recanalisation was not reached in either group.

All outcome comparisons were performed both before and after PSM (Tables 2 and 3). The direction and magnitude of treatment effects were consistent between pre- and post-matching analyses. The significantly

shorter surgical time for RFA was robust to PSM adjustment (pre-matching: RFA 39.9 ± 10.3 min vs. CVAFS 52.8 ± 14.8 min, $P < 0.001$; post-matching: RFA 39.5 ± 11.0 min vs. CVAFS 53.6 ± 15.7 min, $P < 0.001$). The co-primary outcomes—12-month occlusion rate and VCSS change—also showed no significant differences in either analysis, confirming the consistency of the primary findings.

Table 3

12-month clinical outcomes in RFA and CVAFS groups before and after propensity score matching

Outcome	Before matching			After matching		
	RFA (245 pts, 317 lim)	CVAFS (194 pts, 251 lim)	P value	RFA (98 pts, 128 lim)	CVAFS (98 pts, 126 lim)	P value
Crude 12-month occlusion rate	303/317 (95.6%)	239/251 (95.2%)	0.842	122/128 (95.3%)	120/126 (95.2%)	1.000
Preoperative VCSS	8.29 ± 3.53	8.35 ± 3.30	0.546	7.78 ± 3.30	7.96 ± 3.08	0.401
VCSS at 6 months	2.17 ± 2.06	2.28 ± 2.16	0.611	1.98 ± 2.00	2.25 ± 2.23	0.519
VCSS at 12 months	0.83 ± 0.84	0.86 ± 0.89	0.830	0.71 ± 0.81	0.85 ± 0.89	0.264
*Crude 12-month occlusion rate is presented as raw proportions based on the complete-case pre-matching population (excluding 29 RFA limbs and 18 CVAFS limbs lost to follow-up before the 12-month endpoint) and the post-matching cohort.						

DISCUSSION

This propensity score-matched study demonstrated that CVAFS combined with high ligation achieved comparable 12-month occlusion rates to RFA for symptomatic primary GSV incompetence (95.2% [120/126] vs. 95.3% [122/128]; $P = 1.000$). Clinical improvement, as measured by VCSS, was also comparable (mean reduction of 7.1 points in both arms). RFA was associated with significantly shorter surgical time (39.5 ± 11.0 min vs. 53.6 ± 15.7 min; $P < 0.001$). Both modalities demonstrated a favourable safety profile, with no DVT, pulmonary embolism, or wound infection recorded in either group.

The 12-month RFA occlusion rate of 95.3% is consistent with the existing literature (1-year rates: 90%–98%). The 95.2% rate for CVAFS compares favourably with the 70%–85% typically reported for standard UGFS[11, 13–15], suggesting that the three-component CVAFS technique—surgical high ligation, mechanical venospasm induction, and fluoroscopically guided foam injection—may address the principal limitations of conventional UGFS. Venospasm is hypothesised to minimise foam washout and enhance the duration and uniformity of sclerosant contact with the venous endothelium, while high ligation eliminates the source of high-pressure reflux[12].

The significantly longer surgical time for CVAFS (approximately 14 minutes; $P < 0.001$) reflects the additional procedural steps inherent to the technique, including high ligation via groin incision, controlled venospasm induction, and real-time DSA monitoring. However, this time differential did not translate into increased

perioperative burden: both groups achieved 100% technical success with no major complications (Table 2). The additional time invested in CVAFS is therefore considered clinically acceptable.

The comparable VCSS improvement (– 7.1 points in both groups) aligns with the broader literature, in which reductions of 5–8 points at 12 months are commonly reported irrespective of ablation modality[16]. This reinforces the concept that clinical improvement may be driven by effective elimination of saphenofemoral reflux rather than by the specific mechanism of vein closure[17]. The surgical time difference favouring RFA likely reflects the additional procedural steps of CVAFS; whether this carries clinical significance warrants further investigation.

The safety profile of both procedures was favourable, with no DVT, pulmonary embolism, or wound infection in the matched cohort[18, 19]. The numerically higher rates of bruising (18.3% vs. 10.2%; $P = .095$) and paraesthesia (6.3% vs. 1.6%; $P = .059$) after CVAFS did not reach statistical significance. The paraesthesia rate remains within the range reported for non-thermal ablative techniques[5, 20, 21]. This is the first comparative study to evaluate CVAFS against RFA for GSV incompetence. The PSM methodology was rigorous: six candidate schemes were systematically evaluated, and the final scheme achieved adequate balance (mean $|SMD| = 0.0528$). Kaplan–Meier and sensitivity analyses confirmed the robustness of the findings, and outcome assessment was performed by a clinician not involved in the index procedure[22].

Several limitations should be considered. First, the single-centre, retrospective design limits generalisability, and residual confounding by unmeasured variables—such as GSV diameter or treated vein length—cannot be excluded. Second, the 7.8% loss to follow-up led to exclusion of these patients via complete-case analysis; although sensitivity analyses did not suggest material influence, bias from differential attrition cannot be ruled out. Third, the 12-month follow-up is insufficient to evaluate long-term durability of CVAFS. Fourth, the modest sample size after matching (98 pairs, 254 limbs) may have limited statistical power for low-frequency events. Fifth, GSV diameter was not included as a matching covariate, as it was recorded at the limb level while PSM was performed at the patient level.

In this single-centre, propensity score-matched analysis of 196 patients (254 limbs), CVAFS combined with high ligation demonstrated comparable safety and 12-month efficacy to RFA for symptomatic primary GSV incompetence. Both modalities achieved comparable freedom from recanalisation and significant VCSS improvement. Although RFA required shorter procedural time, CVAFS exhibited a favourable complication profile. These findings suggest that CVAFS represents a viable non-thermal, non-tumescent alternative, particularly where thermal ablation is unavailable, contraindicated, or declined. Further randomised controlled trials with extended follow-up are warranted to evaluate long-term durability and cost-effectiveness.

Declarations

Ethical approval

was obtained from the Nanjing First Hospital Ethics Committee (KY20221211-11), and the requirement for individual patient consent was waived owing to the retrospective design. The study was reported in accordance with the STROBE guidelines. This study was in compliance with the Helsinki Declaration.

Disclosure

The authors report no proprietary or commercial interest in any product mentioned or discussed in this article.

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Author Contribution

CY: Conceptualization and Design, Writing-Original Draft, Writing-Review & Editing, Approval, Accountability, Statistical Analysis; LZL: Analysis and Interpretation, Data Collection, Writing-Original Draft, Writing-Review & Editing, Approval, Accountability, Statistical Analysis; XLW: Conceptualization and Design, Writing-Original Draft, Writing-Review & Editing, Approval, Accountability, Statistical Analysis; GMF: Analysis and Interpretation, Data Collection, Writing-Review & Editing, Approval, Accountability, Statistical Analysis; JR: Analysis and Interpretation, Writing-Review & Editing, Approval, Accountability, Statistical Analysis; DCH: Conceptualization and Design, Writing-Original Draft, Approval, Accountability, Statistical Analysis; HX: Data Collection, Writing-Review & Editing, Approval, Accountability, Statistical Analysis; KJ: Conceptualization and Design, Analysis and Interpretation, Data Collection, Writing-Original Draft, Writing-Review & Editing, Approval, Accountability, Statistical Analysis, Funding Acquisition. All authors approved the final manuscript.

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Data Availability

Due to privacy regulations, relevant data of this study can be obtained by contacting the corresponding author.

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Figures

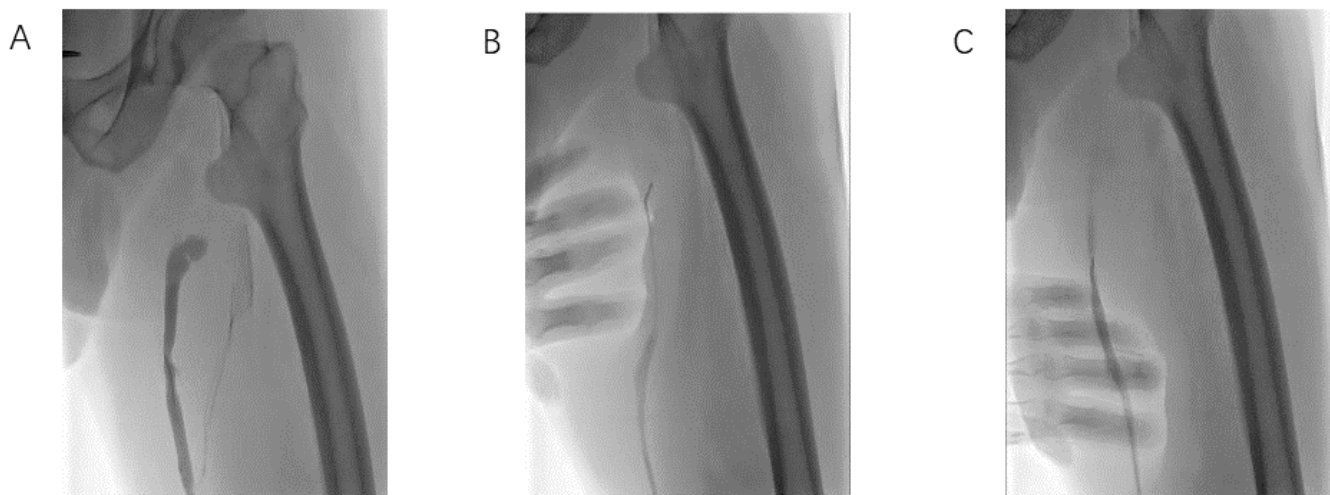
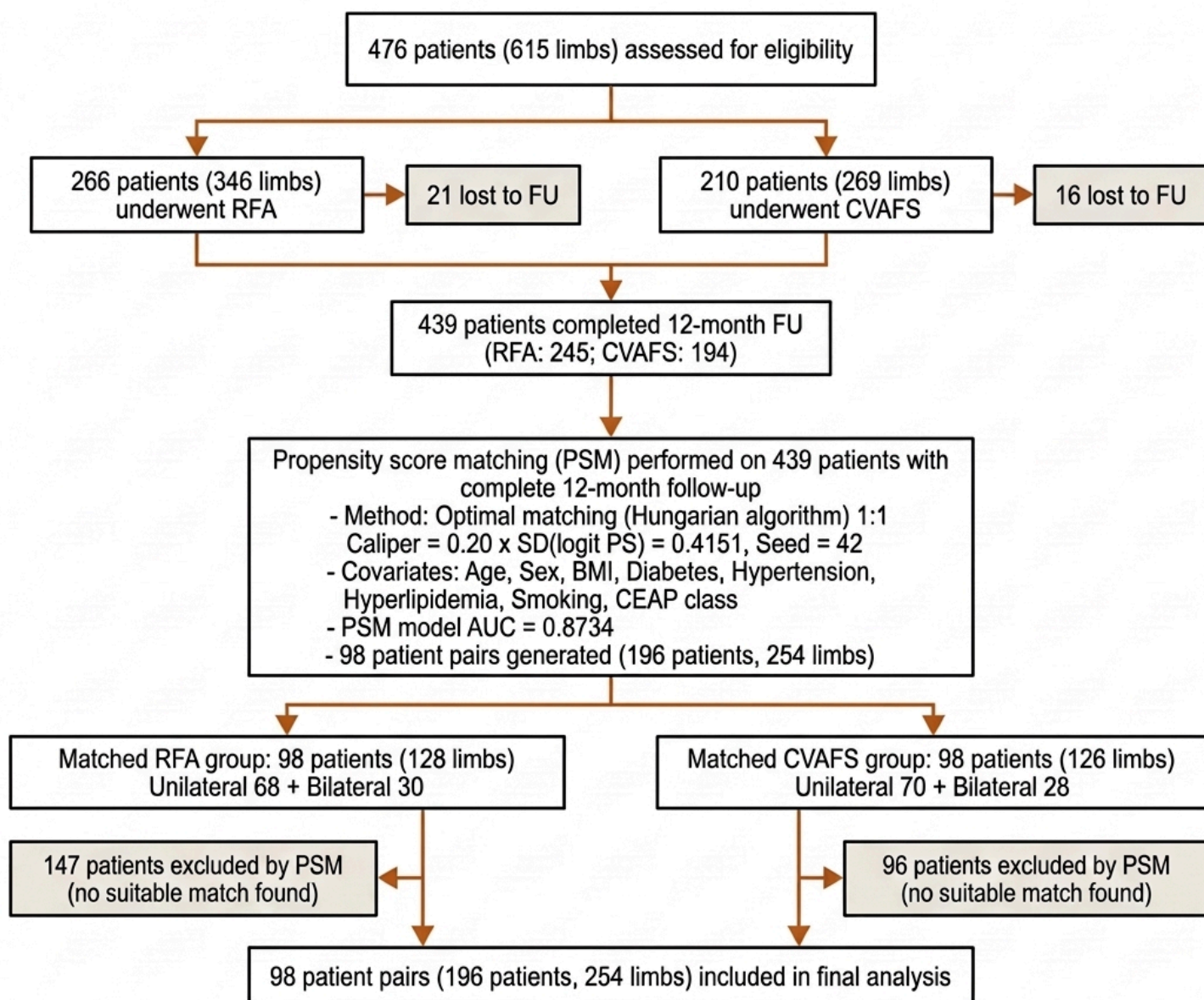


Figure 1

Procedural steps of controlled venospasm-assisted foam sclerotherapy combined with high ligation (CVAFS+HL) under fluoroscopic guidance.

(A) Proximal great saphenous vein (GSV) occlusion confirmed by manual contrast injection via catheter; the white arrow indicates the occlusion site at the level of surgical high ligation 1.0 cm distal to the saphenofemoral junction. (B) Mechanical venospasm induction: a 4-Fr vertebral catheter is rotated within the vein lumen while simultaneous targeted external cutaneous compression is applied along the course of the GSV. (C) Fluoroscopic validation of > 50% reduction in GSV luminal diameter following mechanical venospasm induction, confirming adequate venospasm prior to foam injection.



PSM model AUC = 0.8734; Covariates with matched SMD < 0.10: 7/8 (Age, Sex, BMI, Diabetes, Hyperlipidemia, Smoking, CEAP); Hypertension SMD = 0.111 (marginally above 0.10, clinically acceptable); Mean [SMD] = 0.053

Figure 2 Flowchart of the study. RFA: Radiofrequency ablation; CVAFS: Controlled venospasm-assisted foam sclerotherapy; PSM: Propensity score matching; SMD: Standardized mean difference; FU: Follow-up.

Figure 2

CONSORT-style patient flow diagram.

A total of 476 consecutive patients (615 limbs) with symptomatic primary great saphenous vein incompetence were screened for eligibility between March 2023 and August 2024. After exclusion of 37 patients (7.8%) lost to 12-month follow-up, 439 patients entered the propensity score matching (PSM) pool (RFA: 245 patients, 317 limbs; CVAFS: 194 patients, 251 limbs). Optimal Hungarian matching with caliper = 0.20 × standard deviation of the logit propensity score yielded 98 matched pairs (196 patients, 254 limbs) with no patients lost to follow-up in the matched cohort. CVAFS, controlled venospasm-assisted foam sclerotherapy; PSM, propensity score matching; RFA, radiofrequency ablation.

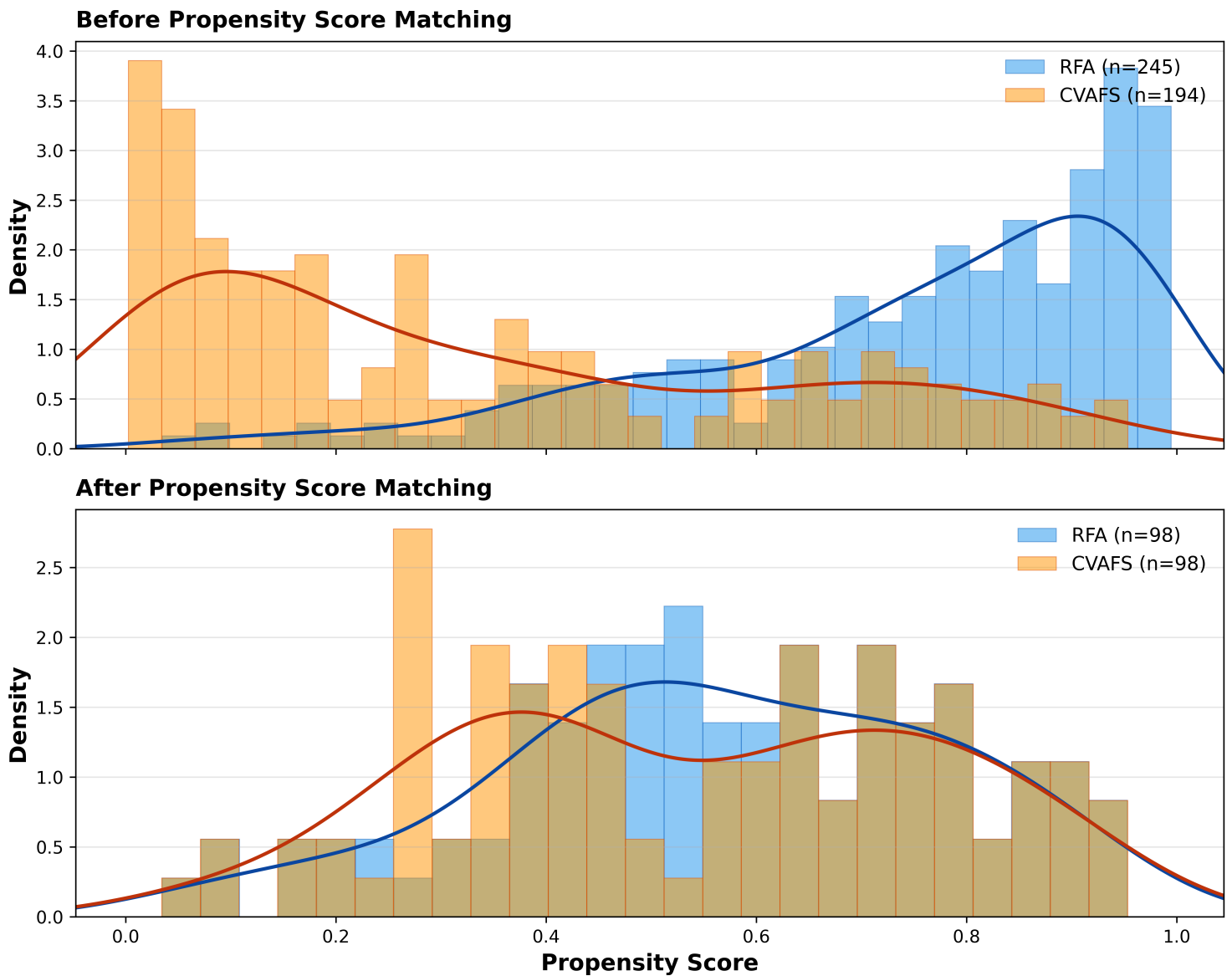


Figure 3

Propensity score distribution before and after matching.

(A) Before matching: a distinct separation in propensity score distribution is observed between the RFA group (blue line) and the CVAFS group (orange line) (Kolmogorov-Smirnov $D = 0.611$, $P < .001$), indicating significant imbalances in baseline characteristics. (B) After matching: the propensity score distributions show a high degree of overlap (Kolmogorov-Smirnov $D = 0.173$, $P = .105$), demonstrating excellent covariate balance. The curves are smoothed using kernel density estimation. The area under the receiver operating characteristic curve (AUC) of the logistic regression model is 0.8734.

AUC, area under the curve; CVAFS, controlled venospasm-assisted foam sclerotherapy; PSM, propensity score matching (1:1 optimal matching, caliper = 0.2, seed = 42, 98 pairs, 8 covariates); RFA, radiofrequency ablation.

**Covariate Balance Before and After Propensity Score Matching
(PSM v2: Optimal Matching, Caliper=0.2, 98 Pairs, 7/8 SMD < 0.1)**

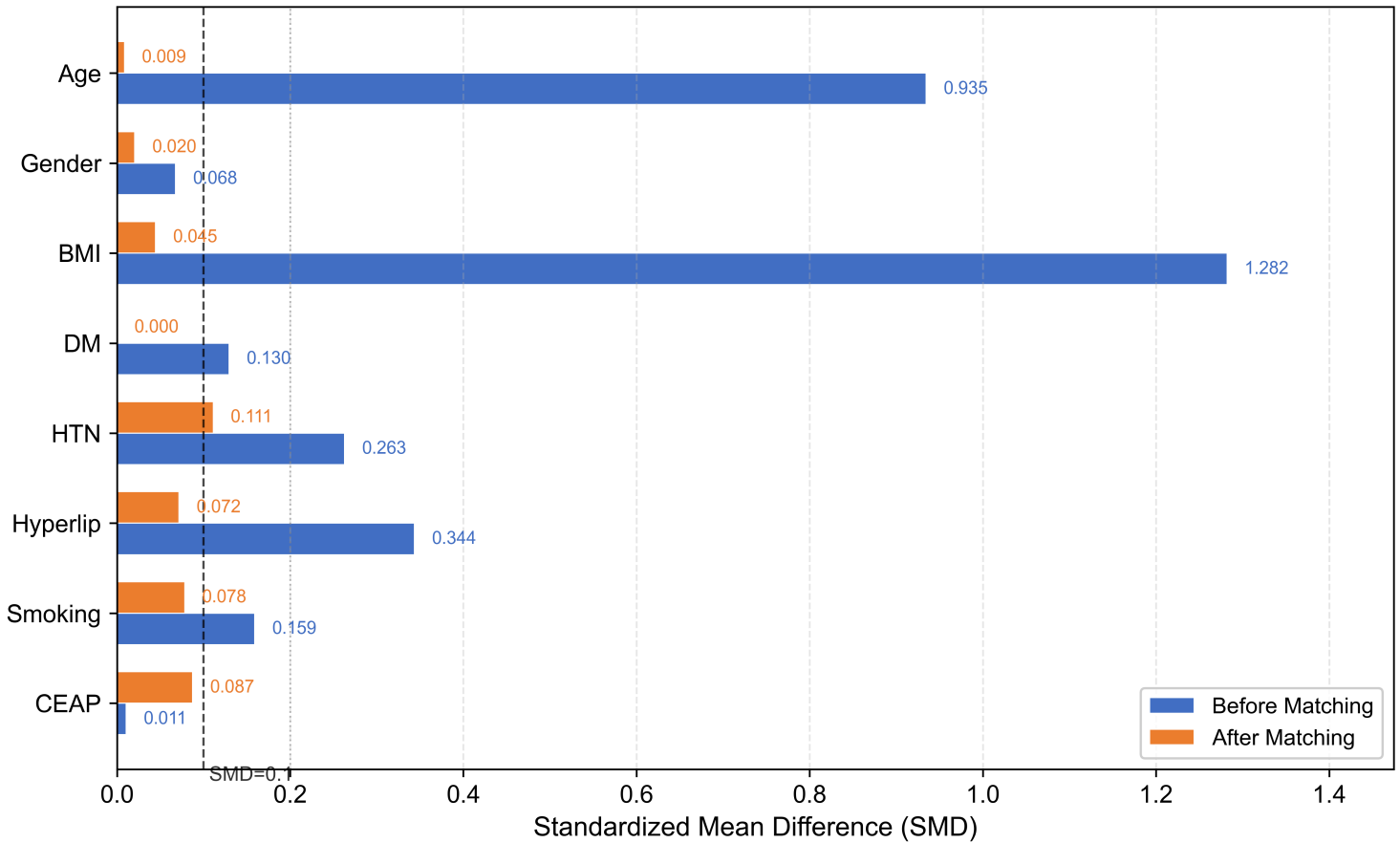


Figure 4

Love plot of standardized mean differences (SMD) for baseline covariates before and after propensity score matching.

Blue bars represent the SMDs of the eight baseline covariates (age, sex, BMI, diabetes mellitus, hypertension, hyperlipidemia, smoking, and CEAP classification) before matching; orange bars represent the SMDs after matching. The dashed vertical line indicates the standard balance threshold of SMD = 0.1. After matching, seven out of eight covariates achieved an SMD well below 0.1 (the SMD for hypertension was 0.1112, slightly exceeding the threshold but remaining within a clinically acceptable range).

CVAFS, controlled venospasm-assisted foam sclerotherapy; PSM, propensity score matching; RFA, radiofrequency ablation; SMD, standardized mean difference.

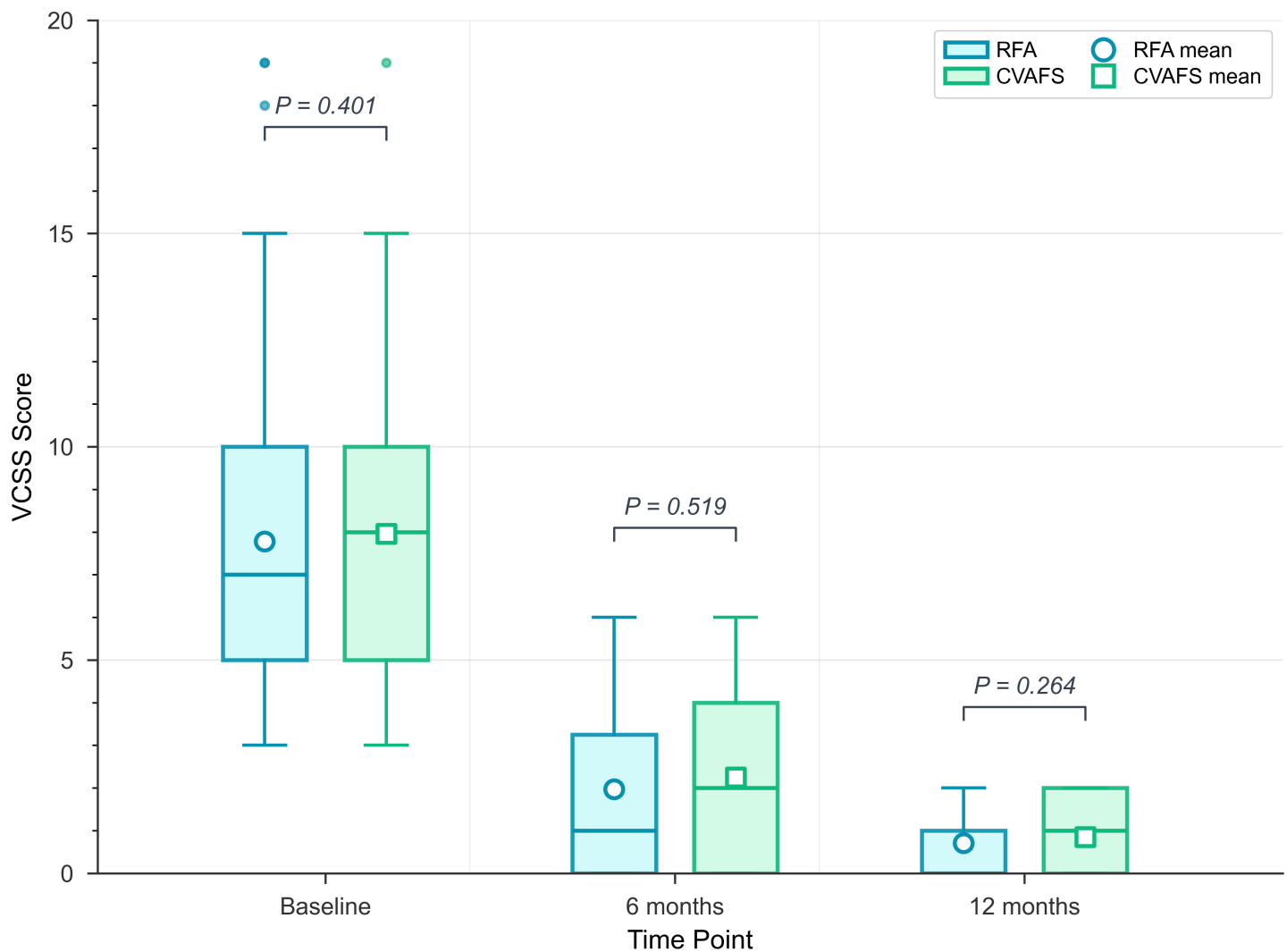


Figure 5

Venous Clinical Severity Score at baseline and at 6 and 12 months after treatment.

Box-and-whisker plots illustrating the distribution of the Venous Clinical Severity Score (VCSS) in the radiofrequency ablation (RFA) and controlled venospasm-assisted foam sclerotherapy (CVAFS) groups at baseline and at 6 and 12 months post-procedure in the propensity score-matched cohort. Boxes represent the interquartile range (IQR; 25th to 75th percentile), horizontal lines within boxes denote the median, and whiskers extend to the most extreme data point within 1.5 x IQR. Individual data points beyond the whiskers are shown as outliers. Pre-operative VCSS was comparable between the two groups (RFA: 7.8 ± 3.3 ; CVAFS: 8.0 ± 3.1 ; $P = .401$). At 6 months, mean VCSS decreased to 1.98 ± 2.00 in the RFA group and 2.25 ± 2.23 in the CVAFS group ($P = .519$). At 12 months, further improvement was observed, with mean VCSS of 0.71 ± 0.81 in the RFA group and 0.85 ± 0.89 in the CVAFS group ($P = .264$). No statistically significant between-group difference in VCSS was observed at any time point (all $P > .05$). CVAFS, controlled venospasm-assisted foam sclerotherapy; IQR, interquartile range; PSM, propensity score matching; RFA, radiofrequency ablation; VCSS, Venous Clinical Severity Score.

Kaplan-Meier Estimates of Freedom from Target Vein Recanalization

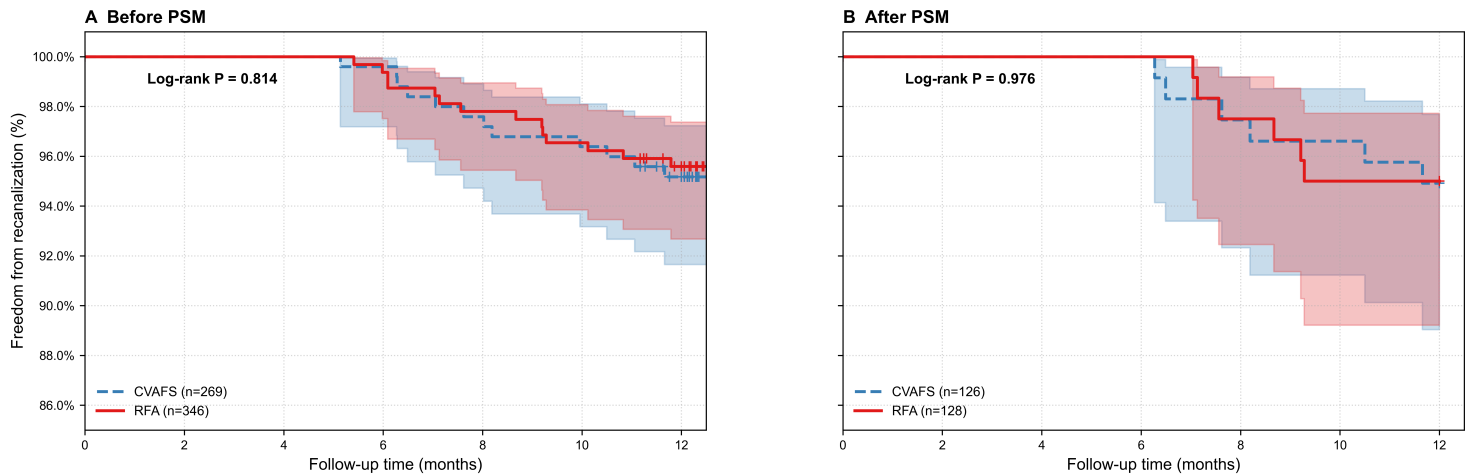


Figure 6

Kaplan-Meier curves for freedom from target vein recanalisation before and after propensity score matching.

(A) Before matching: freedom from recanalisation at 12 months was 95.6% (95% CI 92.7 – 97.4) in the RFA group (317 limbs, 14 events) and 95.2% (95% CI 91.7 – 97.2) in the CVAFS group (251 limbs, 12 events; log-rank P = .814). (B) After matching: freedom from recanalisation at 12 months was 95.0% (95% CI 89.2 – 97.7) in the RFA group (128 limbs, 6 events) and 94.9% (95% CI 89.0 – 97.7) in the CVAFS group (126 limbs, 6 events; log-rank P = .976). Tick marks indicate censored observations. The median time to recanalisation was not reached in either group owing to the low overall event rate (4.7% after PSM). CI, confidence interval; CVAFS, controlled venospasm-assisted foam sclerotherapy; RFA, radiofrequency ablation. Shaded areas indicate 95% confidence intervals.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Table1BaselinePSM.docx](#)
- [Table2PerioperativePSM.docx](#)
- [Table312MonthOutcomesPSMv3.docx](#)
- [TableLegends.docx](#)