

From the Eastern Vascular Society

The utility of the venous clinical severity score in 682 limbs treated by radiofrequency saphenous vein ablation

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Objectives: The goal of endovenous ablation is to reduce the symptoms associated with chronic venous insufficiency. This prospective study was designed to apply the venous clinical severity score to limbs before and after endovenous saphenous vein radiofrequency ablation and to identify risk factors associated with treatment failure.

Methods: Between September 2003 and March 2005, 499 patients underwent 682 saphenous vein radiofrequency ablation procedures. Preoperative venous clinical severity scores were documented. Follow-up clinical and duplex examinations were performed at 4 days, 4 weeks, and 4 months after saphenous vein radiofrequency ablation and at ≥ 6 months thereafter. Venous clinical severity scoring was repeated at follow-up visits, and patients were asked to evaluate their level of satisfaction with the procedure.

Results: The mean \pm standard deviation age of the patients was 53.5 ± 13.3 years (range, 28 to 86 years), and 68% were women. Pretreatment CEAP clinical class C3/C4 comprised 80% of limbs (520/682). Preoperative, 4-day, 4-week, and 4-month venous clinical severity scores were, respectively, 8.8 ± 3.7 in 648 limbs, 5.2 ± 3.0 in 629, 4.1 ± 2.4 in 530, and 3.3 ± 1.6 in 479 limbs. Saphenous vein radiofrequency ablation significantly reduced pain related to lower extremity venous disease from 95.7% to 15.2% ($P < .0001$) and edema from 92.4% to 17.0% ($P < .0001$). Before treatment, venous stasis ulcers were present in 52 limbs and healed at a rate of 86%. Complications in 633 limbs at last follow-up included superficial thrombophlebitis in 12.0%, paresthesia in 0.3%, and nonocclusive thrombus extension in 0.2%. No skin thermal injury was observed. Fewer than 2% of patients reported dissatisfaction with their procedural outcome. Age (relative risk, 0.98; $P = .06$), female sex (relative risk, 0.19; $P < .0001$), and tumescent volume >250 mL (relative risk, 0.59; $P = .06$) were associated with higher rates of occlusion. The overall occlusion rate was 87.1%.

Conclusions: As determined by the venous clinical severity score, treatment of saphenous vein reflux with endovenous radiofrequency ablation results in the clinical improvement of symptoms and aids in the healing of venous ulcers. Age, female sex, and tumescent volume are associated with high success rates of occlusion. We found the venous clinical severity score to be an excellent stand-alone tool for assessing outcomes after saphenous vein radiofrequency ablation. (*J Vasc Surg* 2007;45:1008-15.)

Outcome assessment is a term of growing importance in vascular surgery. Properly formatted and validated outcome assessment tools are valuable. The venous severity score (VSS) was proposed by the Ad Hoc Committee on Venous Outcomes Assessment of the American Venous Forum in March 2000¹ to assess the usefulness of an intervention in patients with chronic venous insufficiency (CVI). The validity of the VSS was later evaluated and was confirmed by different groups^{2,3} and was found to be

reliable when tested against abnormalities seen on ultrasonography.⁴ Various endovenous ablative treatments for CVI have resulted in a dramatic change in the way such patients are treated.⁵⁻⁹

The VSS is composed of the following three elements that are closely aligned with the CEAP (clinical grade, etiology, anatomy, and pathophysiology) clinical class:

- the venous clinical severity score (VCSS): a modification to replace the clinical score of CEAP;
- the venous segmental disease score (VSDS): a combination of the anatomic and pathophysiologic components of CEAP, and
- the venous disability score (VDS): a modification of the original CEAP disability score.¹

The CEAP classification system and its recent revision^{10,11} are primarily descriptive tools used to classify and categorize patients on presentation. The CEAP classification is relatively static, however, changing little over time and is a poor method to assess the usefulness of an intervention.

The VSS is first and foremost an evaluative instrument. It was designed not to replace CEAP but to supplement it and provide a method for serial assessment. It is proven to

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weather intraobserver and interobserver variability.² The basic components of the system are easy to learn and apply. It is critically needed for the longitudinal follow-up of a patient's clinical condition during and after an intervention.²

Despite its proven value and acceptance, the VSS is an underused outcome assessment tool. This study was conceived with the notion that the VCSS component of VSS can be used as a stand-alone scoring system² by the practicing surgeon with little effort. We found the addition of the VSDS or VDS to be impractical in our daily practice. The objectives of this study were to assess the outcome of a large cohort of patients undergoing endovenous saphenous vein radiofrequency ablation (RFA) using the VCSS and to identify risk factors associated with treatment failure.

METHODS

All consecutive patients who underwent RFA between September 2003 and March 2005 for varying degrees of symptomatic CVI in a private office by a single surgeon (M. A. V.) were prospectively entered into a database. Preoperative CEAP clinical class (Fig 1; Table I, online only) and full VCSSs (Fig 1; Table II) were documented during an office-based examination by one of three examiners. All patients underwent color flow duplex ultrasound examination with a high-resolution linear probe (7 to 12 MHz) using the Acuson Aspen (Siemens Medical Solutions, Erlangen, Germany). They all had documented saphenofemoral or saphenopopliteal reflux. Reflux was defined as reverse flow in the saphenous vein >0.5 seconds after calf compression or when placed in the standing position. All anatomic locations of reflux were recorded.

The RFA treatment was offered only to patients who had persistent symptomatic venous disease CEAP clinical class II through VI, including persistent pain, swelling, itching, heaviness, achiness, fatigue or complications, hemorrhage, phlebitis, skin changes, or venous ulceration (Fig 1). These patients were unresponsive to conservative treatment measures, including leg elevation, weight loss in appropriate patients, and the use of graduated compression stockings (20 to 40 mm Hg) for at ≥3 months. Patients with venous ulcers, recurrent phlebitis, or bleeding varices did not require a trial of conservative measures before being offered surgical treatment.

Patients were excluded on the basis of recent deep vein thrombosis (DVT), venous outflow obstruction, arterial insufficiency with an ankle-brachial index <0.8, planned future pregnancy, noncompliance with conservative measures, or severe obesity making visualization of the saphenofemoral junction with ultrasound imaging difficult. Patients were not excluded on the basis of having a post-thrombotic state or concomitant deep or perforator reflux.

No adjunctive treatments (ie, sclerotherapy, microphlebectomy, perforator ablation) were performed for approximately 6 months after RFA.

All RFA procedures were performed with tumescent local anesthesia and intravenous sedation. The Closure procedure (VNUS Medical Technologies, San Jose, Calif) was used for RFA. Patients' refluxing great saphenous veins

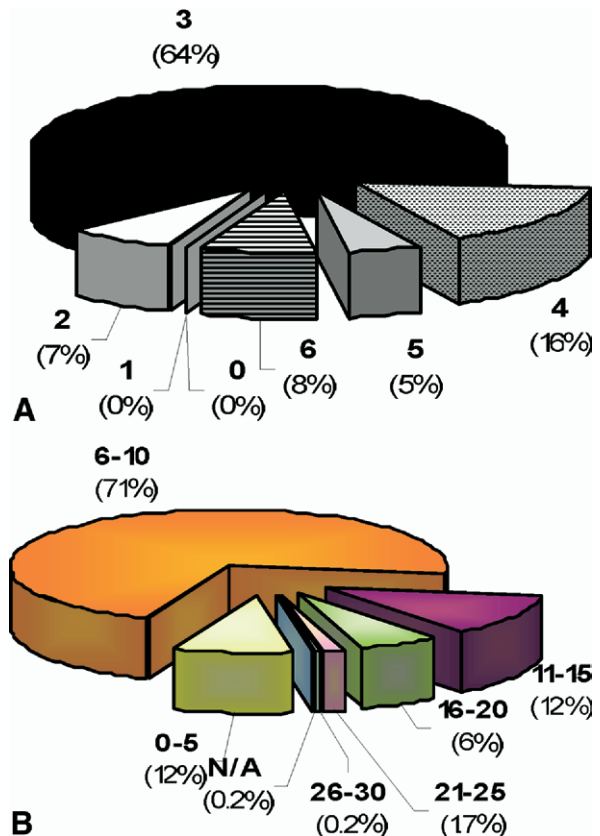


Fig 1. A, CEAP classification at the time of screening. B, venous clinical severity score (VCSS) at screening.

(GSVs), short saphenous veins (SSVs), and accessory saphenous veins (SVs; anterior SV and posterior SV) were mapped before surgery. Most GSVs were accessed percutaneously near the knee. The size of the catheter (6F or 8F) was determined by the greatest diameter of the GSV (6F for <0.8 cm and 8F for ≥0.8 cm). Most SSVs were accessed in the mid to lower calf. Most anterior SVs were accessed in the mid anterolateral thigh. Refluxing GSVs, SSVs, and accessory SVs were treated, especially when found to be feeding symptomatic clusters. Occasionally, 150-cm hydrophilic-coated wires were used for vein segments that were difficult to traverse.

Ultrasound (SonoSite Titan, Bothell, WA) guidance was used to verify the position between 0.5 and 1.0 cm from the saphenofemoral junction (or saphenopopliteal junction for SSV) near the orifice of the superficial epigastric vein. Intraoperative ultrasound was then used to guide delivery of tumescent anesthesia (0.1% lidocaine with epinephrine). This was infiltrated generously along the course of the vein underneath the perivenous fascia throughout the entire length of the vein, creating a good halo effect and good compression of the vein throughout its length. The vein was positioned with the tumescent anesthesia well below the skin (>1 cm). Trendelenburg positional exsanguination also was used.

The radiofrequency generator was activated and the vein was heated to $85^{\circ} \pm 5^{\circ}\text{C}$. The pullback proceeded at a rate of 1 cm/min for the first 3 minutes and then increased to 2 to 3 cm/min for the remainder of the treatment. Intraoperative duplex ultrasound imaging was used to assess the adequacy of the occlusion. Patent veins were immediately retreated until closed.

All legs were wrapped with elastic bandages and self-adhering wrap (Coban, 3M, St. Paul, Minn), which were removed the next day. Patients were sent home that day and were allowed to engage in all usual activities, except heavy exercise for 2 weeks. Instructions were given for compression to be used indefinitely¹² but especially for the first several months. Prophylaxis for deep vein thrombosis was not used.

Follow-up clinical and duplex ultrasound examinations were performed at 4 days, 4 weeks, and 4 months after RFA and at 6 or more months thereafter. All components of the VCSS were individually evaluated for assessing the contribution of each component over time. At follow-up visits, limbs were rescored and patients were asked to evaluate their level of satisfaction with the procedure (very satisfied, partially satisfied, or not satisfied). Complications such as superficial thrombophlebitis, infection, paresthesia, significant ecchymosis, or skin burns were identified. At later periods, a small percentage of patients (<10%) who were unable or unwilling to come in were contacted by telephone to determine their VCSS and their level of satisfaction. All ulcers were followed up until healed. Most ulcer care consisted of a multilayered compression dressing.

Statistical analysis. Data were analyzed using SAS 9.1 software (SAS Institute, Cary, NC). Comparison of treatment effect on variables related to the VCSS was analyzed by χ^2 statistics. Wilcoxon statistics were used to evaluate the treatment effect on the VCSS owing to the non-normal distribution of the VCSS. Generalized mixed-effects models^{13,14} were used to evaluate the effects of treatments and time since surgery on occlusion rate. Occlusion was considered as a repeated event and measurement in the model because some limbs underwent repeat RFA for a first treatment failure. The model also adjusted for within-subject correlation between the left and right limbs by using subject and limb as random effects. The independent variables that were evaluated included age, sex, baseline VCSS, time since surgery, size of catheter used (6F or 8F), length in centimeters of SV treated, and volume in milliliters of tumescence. Continuous data are presented as means \pm standard deviation.

RESULTS

The study included 499 patients (68% female) with 682 limbs (52% left). The mean age was 53.5 ± 13.3 years (range, 28 to 86 years). There were 47 limbs in C2 class, 417 limbs in C3, 104 limbs in C4, 31 limbs in C5, and 49 limbs in C6. Pretreatment CEAP clinical class C3/C4 comprised 80% of limbs (523/682; Fig 1). The mean pullback length was 29 ± 4 cm, and the mean amount of tumescent anesthesia used was 247 ± 10 mL. The GSV was the only treated vein in 83% of limbs, whereas the anterior accessory SV and SSV were treated in 14% and 3% of limbs,

Table III. Longitudinal venous clinical severity score component change

Variable*	Initial screening [†] (n = 648)	Last follow-up [†] (n = 631)
Pain		
None	28 (4.3)	535 (84.8)
Occasional	202 (31.2)	79 (12.5)
Daily	361 (55.7)	14 (2.2)
Daily with medications	57 (8.8)	3 (0.5)
Varicose veins		
None	8 (1.2)	208 (33.0)
Few	116 (17.9)	381 (60.4)
Multiple	409 (63.1)	40 (6.3)
Extensive	115 (17.7)	2 (0.3)
Venous edema		
None	50 (7.7)	524 (83.0)
Evening only	215 (33.2)	92 (14.6)
Afternoon	290 (44.8)	12 (1.9)
Morning	93 (14.4)	3 (0.5)
Skin pigmentation		
None	449 (69.3)	501 (79.4)
Limited, old	100 (15.4)	96 (15.2)
Diffuse, recent	75 (11.6)	27 (4.3)
Wider, recent	24 (3.7)	7 (1.1)
Inflammation		
None	582 (89.8)	619 (98.1)
Mild cellulitis	49 (7.6)	12 (1.9)
Moderate cellulitis	15 (2.3)	0
Severe	2 (0.3)	0
Induration		
None	538 (83.0)	587 (93.0)
Focal <5 cm	40 (6.2)	30 (4.8)
Medial leg	58 (9.0)	10 (1.6)
Diffuse leg	12 (1.9)	4 (0.6)
Active ulcers (n)		
0	596 (92.0)	624 (98.9)
1	35 (5.4)	5 (0.8)
2	14 (2.2)	2 (0.3)
>2	3 (0.5)	0
Ulcer duration (months)		
0	596 (92.0)	624 (98.9)
<3	13 (2.0)	2 (0.3)
3-12	33 (5.1)	3 (0.5)
>12	6 (0.9)	2 (0.3)
Active ulcer size (cm)		
0	596 (92.0)	624 (98.9)
<2	23 (3.5)	5 (0.8)
2-6	23 (3.5)	1 (0.2)
>6	6 (0.9)	1 (0.2)
Compression therapy		
None	7 (1.1)	39 (6.2)
Intermittent	37 (5.7)	68 (10.8)
Most days	439 (67.7)	360 (57.1)
Fully comply	165 (25.5)	164 (26.0)
VCSS mean score	8.8	3.6

VCSS, Venous clinical severity score.

* $P < .0001$ for all variables.

[†]Data are given as number (percentage).

respectively. The overall patient satisfaction (partly or very satisfied) at the last follow-up was 98.4%.

Treatment effects on the venous clinical severity score-related signs or symptoms. The effects of treatment on the VCSS components are summarized in Table III and

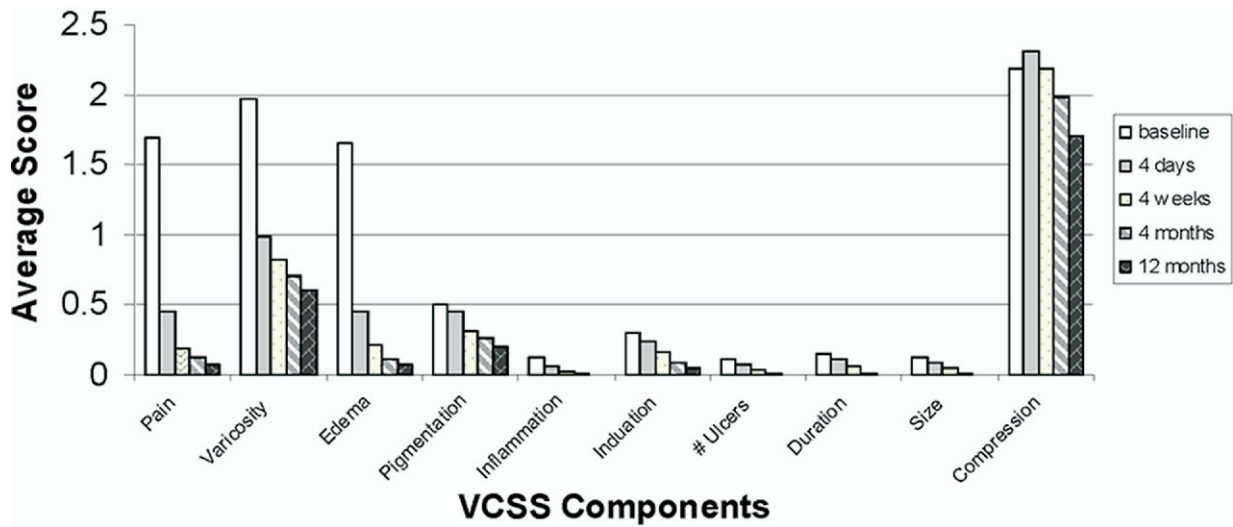


Fig 2. Venous clinical severity score (VCSS) components over time.

depicted in Fig 2. The RFA significantly reduced symptoms of pain (95.7% to 15.2%, $P < .0001$), the percentage of limbs with multiple or extensive varicosities (80.8% to 6.6%, $P < .0001$), venous edema (92.4% to 17.0%, $P < .0001$), skin pigmentation (15.3% to 5.4%, $P < .0001$), cellulitis (10.2% to 1.9%, $P < .0001$), and induration (17.1% to 7.0%, $P < .0001$).

RFA also significantly encouraged ulcer healing. The number of limbs with one, two, and more than two active ulcers were 35 (5.4%), 14 (2.2%), and three (0.5%) before RFA and five (0.8%), two (0.3%), and zero after RFA, respectively ($P < .0001$). The number of limbs with lower extremity ulcers for <3 months, 3 to 12 months, and >12 months were 13 (2.0%), 33 (5.1%), and six (0.9%) before RFA and two (0.3%), three (0.5%), and two (0.3%) after RFA, respectively ($P < .0001$). The number of limbs with ulcer sizes <2 cm, 2 to 6 cm, and >6 cm were 23 (3.5%), 23 (3.5%), and six (0.9%) before RFA and five (0.8%), one (0.2%), and one (0.2%) after RFA, respectively ($P < .0001$). The overall rate of ulcer healing was 86%.

The distribution of the number of limbs using compression therapy was significantly different before and after RFA. The number of limbs in which compression therapy was intermittently used, used most days, and fully complied with was 7 (1.1%), 37 (5.7%), 439 (67.7%), and 165 (25.5%) before RFA and 39 (6.2%), 68 (10.8%), 360 (57.1%), and 164 (26.0%) after RFA, respectively ($P < .0001$).

Preoperative, 4-day, 4-week, and 4-month venous clinical severity scores were 8.8 ± 3.7 in 648 limbs, 5.2 ± 3.0 in 629, 4.1 ± 2.4 in 530, and 3.3 ± 1.6 in 479, respectively. Limbs in which the vein remained occluded had a mean baseline score of 8.84, and a last follow-up score of 3.60. Limbs with veins that failed to occlude had a mean baseline score of 8.70 and last follow-up score of 3.85. The overall mean VCSS was 8.8 at baseline and 3.6 at last follow-up ($P < .0001$).

Table IV. Factors associated with treatment failure

Factor	RR (95% CI)	P
Age	0.98 (0.96-1.00)	.06
Female sex	0.19 (0.09-0.41)	<.0001
Catheter size, 6F vs 8F	0.74 (0.43-1.28)	.28
GSV side, right vs left	1.03 (0.98-1.09)	.19
Tumescent volume	0.59 (0.34-1.02)	.06

RR, Relative risk; CI, confidence interval; GSV, great saphenous vein.

Complications associated with therapy. RFA therapy resulted in 160 patients experiencing 184 complications. Complications that developed after RFA in the 633 limbs included ecchymosis in 83 (13.1%), thrombophlebitis in 76 (12.0%), erythema in 16 (2.5%), hyperpigmentation in 4 (0.6%), infection in 3 (0.5%), and paresthesia in 2 (0.3%). None of the complications were permanent. No thermal skin injury was observed. One patient had a non-occlusive asymptomatic deep vein thrombosis (DVT) discovered on routine initial postoperative duplex ultrasound imaging.

Factors affecting occlusion rate. Our overall occlusion rate was 87.1%. Table IV gives the variables associated with the failure of venous occlusion. Each year of age increment is associated with a 2% risk reduction of occlusion failure. The relative risk (RR) of patient age in association with the patency of the treated vein was 0.98 (95% confidence interval [CI], 0.96 to 1.00; $P = .06$). Women were 81% less likely to experience occlusion failure than men (RR, 0.19; 95% CI, 0.09 to 0.41; $P < .0001$). Limbs treated with 6F catheters had a 26% lower risk of occlusion failure than those treated with 8F catheters (RR, 0.74; 95% CI, 0.43 to 1.28; $P = .28$). Each 1-cm length increment of treated SV was associated with a 3% risk increment in vein recanalization (RR, 1.03; 95% CI, 0.98 to 1.09; $P = .19$). Limbs receiving >250 mL of

tumescent anesthesia had a 41% lower risk of recanalization than those that received less (RR, 0.59; 95% CI, 0.34 to 1.02; $P = .06$). Limbs overall had a mean VCSS decrease whether they remained occluded (5.3 ± 3.3) or whether they recanalized (4.9 ± 2.8) that was not found to be statistically significant ($P = .16$).

DISCUSSION

Although clinical occlusion rates, durability, quality-of-life, and patient satisfaction with endovenous RFA have been reported,^{5,6,8,9} few data exist on outcome assessment using an existing reliable, reproducible, and validated tool such as VCSS in a substantial patient population. We believe that documenting the VCSS by itself on initial and subsequent visits is an easy and effective way to monitor clinical progress or regression, independent of CEAP classification or ultrasound findings.

The importance of evaluating each of the components of the VCSS cannot be overemphasized. We disagree with the suggestion by Kakkos et al⁵ that “further modifications in VCSS might increase its sensitivity in monitoring outcome of venous surgery.” Although some components of the VCSS do not change after surgery as much as others, we found statistically significant improvement for each component of the VCSS after RFA. The strength of the VCSS lies in its evaluative properties identifying subtle intrasubject changes after an intervention over time. Teasing out these componential differences has proven valuable in several ways:

1. It has allowed us to identify technical factors that may contribute to better outcomes.
2. It has helped us to know what to expect after the intervention and to relay those expectations to patients.
3. It provides a method to compare, in a structured format, different types of SV ablative techniques.

The most dramatic symptom improvement was observed at 1 month (Fig 2), with significant reduction in pain and swelling. Correspondingly, we found a significant sequential drop in the VCSS over each time interval (preoperative, 4 days, 4 weeks, and 4 months) to 8.8 ± 3.7 , 5.2 ± 3.0 , 4.1 ± 2.4 , and 3.3 ± 1.6 , respectively (Fig 3). This was not reliably accompanied by disappearance of varicose veins.

There is ongoing debate about the timing of adjunctive procedures.^{15,16} We found that most limbs did not require microphlebectomy or sclerotherapy after RFA for smaller varices. Larger residual varices diminished most in size during the first 4 months after ablation, but less so thereafter (Fig 2). Therefore, we do not perform routine microphlebectomy at RFA, but rather wait at least 4 months for reassessment to determine the necessity.

We found that the most important technical factor associated with successful occlusion was the amount of tumescent anesthesia used. Tumescent extrudes blood from the vein, narrows the vein diameter during treatment, and protects surrounding tissues from the radiofrequency energy. Our mean length of pullback was 29 ± 5 cm, and our mean volume of tumescence was 247 ± 10 mL. Our occlusion rate improved as the volume increased, ap-

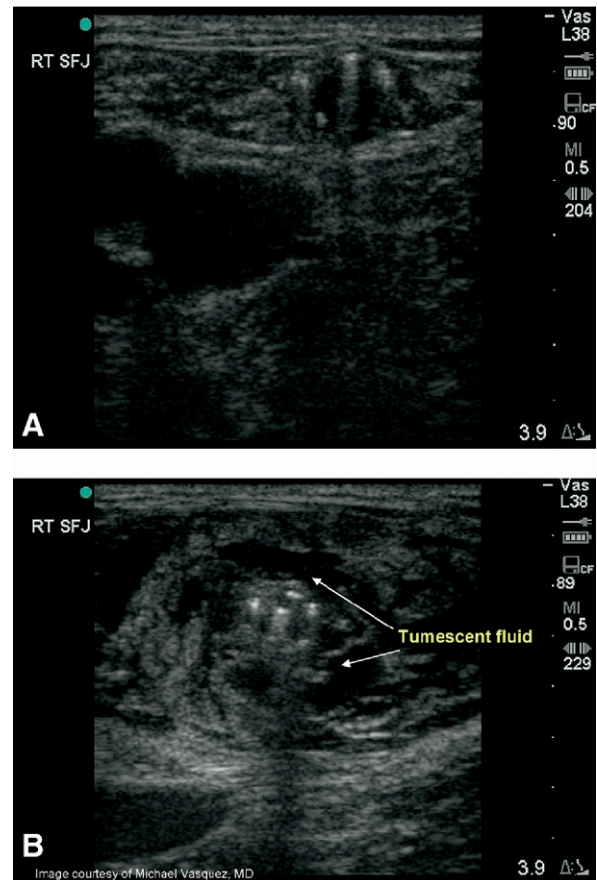


Fig 3. A, Before and (B) after tumescent compression at the saphenofemoral junction. Arrows point to tumescent fluid.

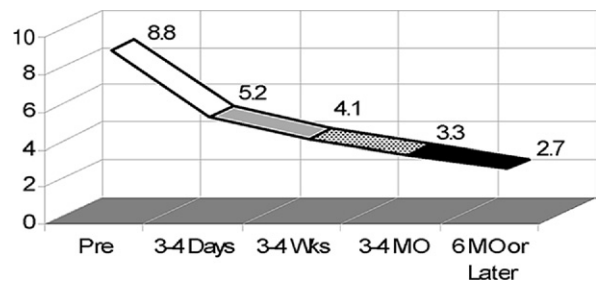


Fig 4. Mean venous clinical severity score (VCSS) throughout the study.

proaching statistical significance at 250 mL. We therefore recommend using at least 10 mL of tumescence per 1-cm segment treated. Infiltration of fluid just beyond and around the tip of the catheter near the saphenofemoral junction to better compress it as it splays is of primary importance (Fig 4).

There was no statistically significant difference in recurrence associated with the catheter size, although veins treated with the 6F catheter tended to stay closed longer. We expected to find a higher rate of recurrence with larger

vein diameter. We tended to use higher volumes of tumescence with larger-diameter veins. We also found it safe to treat large-caliber veins with RFA without concomitant high ligation.⁵

Our occlusion failure rate is comparable to that described by others for RFA.^{5,7,9} Our observations were similar to previous reports that anatomic occlusion failures did not necessarily result in symptom regression, physiologic reflux, or patient dissatisfaction.^{5,7,9} Our findings supported this observation with no significant differences in the VCSS between limbs with treated segments that remained occluded and those that recanalized. The reason for this is not entirely clear. It may be related to segmental partial occlusions or to luminal narrowing. Male sex and younger age were associated with significantly higher rates of occlusion failure. Some have speculated that differences in collagen structure or inflammatory response in the vein wall may offer an explanation, but this is not proven.⁵

The relevance of increasing occlusion failure per centimeter of increased pullback length is in question, with weak statistical significance. Nevertheless, in our experience, treatment at a suitable point by ultrasound imaging near the knee is satisfactory for most limbs to achieve a reduction in the VCSS with few resultant paresthesias. There are anatomic reasons why this is satisfactory.¹⁷ Proximal to the posterior arch vein-GSV junction, perforators do not typically communicate with the GSV. Ablation to this point eliminates most of the hydrostatic forces of superficial vein reflux.¹⁸

A few limbs with swelling, ulceration, or persistent unchanged symptomatic varicosities have required retreatment from the previously occluded low thigh to the mid calf after the study period. In most of these limbs, a large Boyd perforator, an accessory meandering vein, or a more recently described “popliteal fossa vein”¹⁹ reconnected with the GSV at this point, causing the problem. We have since adapted our preoperative mappings to look for these to preemptively treat.

Our mean VCSS is higher than that obtained by others^{2,3,20,21} and is reflected in the higher CEAP classes (Fig 1). We believe the power of the study is derived from these higher scores and CEAP classes. Others have suggested that higher scores offer more sensitivity and may be more appropriate to monitor therapy.^{2,20} Baseline values were obtained in the week before the procedure, which explains the high compression compliance. An overall drop occurred in the VCSS at each time interval, with a starting mean score of 8.8 and an ending mean score of 3.3 at 4 months. The last follow-up mean score of 3.6 is higher because it reflects the scores of all limbs, regardless of the time of drop out, and is statistically significant ($P < .0001$). Those limbs that were followed up at 1 year had a mean score of 2.7 (Fig 3). Symptomatic limbs simply respond better. Nevertheless, the VCSS maintains its validity even with higher limb scores.²

The VCSS drops significantly when an ulcer heals. Our highest VCSS was 26, which dropped to 9 at the 1-year follow-up. Ablation of superficial reflux combined with

Table V. Complications with therapy among 633 patients at last follow-up

<i>Complication</i>	<i>N (%)</i>
Hyperpigmentation	4 (0.6)
Superficial phlebitis	76 (12.0)
Paresthesia	2 (0.3)
Erythema	16 (2.5)
Ecchymosis	83 (13.2)
Infection	3 (0.5)
Thermal injury	0
Deep venous thrombosis	1 (0.2)

compression and wound care compliance contributed to the high rate of ulcer healing by elimination of hydrostatic forces. We are not in agreement with others¹⁸ on the algorithm to follow in the treatment of limbs with leg ulcers. We prefer RFA as the initial step because it is simple to perform, with little morbidity. Recalcitrant or recurrent ulcers are related to untreated hydrodynamic forces and may require adjunctive treatments.^{18,21} Longer follow-up is needed to determine the overall reduction in the rate of ulcer recurrence.¹² We also learned that compression needs to remain a mainstay of treatment for CVI with or without RFA.

We found the VCSS portion of VSS to be not only the most practical but also the more reasonable instrument to use for outcome analysis purposes. Using the VCSS alone is like using the clinical portion of CEAP, but with an expanded scale and the flexibility of changing in response to treatment. The VSDS combines the pathophysiologic mechanisms (reflux and obstruction) with the anatomic distribution of the diseased veins, and in this cohort with predominantly superficial venous reflux, there was little relevance. The VSDS has been deemed “arbitrary”¹ and “especially hard to score and interpret”²⁰ and is not practical for a longitudinal study. In addition, an occlusion failure would have negatively affected the VSDS but does not reliably affect the VCSS.

With respect to the VDS, the scoring system has been found to be simple to use²⁰; however, it has little applicability when two limbs of an individual are involved. In our study, 183 patients had both limbs treated. Last, the VCSS has been found to be valid and reliable on its own merits, with high interobserver and intraobserver agreement.² We subscribe tenaciously to the premise that the VCSS can stand alone for outcome assessment.

We encountered only one DVT (0.2%) in this series (Table V), which resolved after warfarin therapy. This patient had postphlebotic syndrome and was taking long-term warfarin for a previous pulmonary embolism. He had disabling pain from ulceration, with a VCSS of 22 at screening and 6 at the last follow-up. Additional complications were paresthesia in two limbs (0.3%), hyperpigmentation in four (0.6%), and ecchymosis in 83 (13.1%). Superficial phlebitis occurred in 76 limbs (12.0%) and is most frequently found in limbs with large varicosities. This is likely related to relative stagnation in flow in these tributary

ies. Complications in all patients were minor, lasted temporarily, and resolved without further therapy.

Drawbacks to the study include the fact that although three individuals in the same office performed the VCSS documentation, one individual performed all the procedures. As a corollary, bias may be introduced into scoring as familiarity with a patient grows even though the same standardized form was used. In addition, scores may fluctuate significantly during the longer intervals between snapshots. A substantial number of random patients were lost to follow-up after 6 months, necessitating the time of last follow-up as an end-point measure. Also, telephone contact for scoring was used for those patients who were unable or unwilling to come to the office. At the time, all procedures were performed in the operating room under sedation, and now most procedures are performed with local anesthesia in an office setting.

CONCLUSION

Evidence-based medicine and outcome assessment are critical tools for vascular surgery. The results of high-volume procedures should be followed up with a validated instrument. We found the VCSS and each of its components to be useful, significant, and easily applicable for the assessment of outcomes after RFA in limbs with symptomatic venous insufficiency. Increasing age and female sex are independent predictors of higher rates of occlusion. Volume of tumescence per treatment length is the most important technical factor for occlusion. Treatment to the knee is sufficient for most limbs, with few adverse events. Anatomic failure does not necessarily predict a rise in the VCSS. A waiting period of 4 months should be endured before the adjunctive treatment of residual varicosities.

The VCSS, by itself, is an important evaluative instrument in the treatment of CVI. Using VCSS alone is comparable to the common usage of the clinical portion of CEAP. The VCSS should be used for outcome assessment in any study comparing different treatment modalities for SV ablation.

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AUTHOR CONTRIBUTIONS

Conception and design: MV, MM
 Analysis and interpretation: MV, JW, HD, MM
 Data collection: MV, GB, ES, MM
 Writing the article: MV, HD, JW, GB, MM
 Critical revision of the article: MV, HD, JW
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DISCUSSION

Dr Nicholas J. Morrissey (New York, NY). Thank you very much for the opportunity to discuss the paper. I really just have one question. You correlated the French size of the catheter a little bit in terms of the results of failure. Could you correlate that, and did you correlate that, with the size, the diameter of the vein, which I think is probably the most strong predictor of failure using this technology. And that's the only question I have and thank you.

Dr Michael Vasquez. We mapped and measured all veins beforehand, but we did not directly correlate that with the data. Although it wasn't statistically significant, we did notice that people in which we had to use the 8 French catheter—which had larger vein diameters in general—had a slightly higher rate of recanalization than those patients in which we only used a 6 French catheter. We treated many very large veins; however, we did not correlate vein diameter with the data, and it is something that I would like to do at some point. We concentrated mostly on the

scoring system. The study was about the scoring system more than it was about factors for treatment failure.

Dr Robert B. Rutherford (Corpus Christi, Tex). Just a short comment about venous severity scoring in relation to this paper which supports its use in association with superficial vein surgery. Other who have tried to use this score in this setting, particularly the French phlebologists, have reported that it doesn't really help much in superficial venous disease, in patients with low CEAP scores. I think the difference in its utility here lies in your patient population, who mostly had symptomatic varicose veins with higher CEAP scores. Those other studies reflected more of the cosmetic end of varicose vein spectrum, patients with lower CEAP and venous severity scores. I think if you have patients with significant symptoms, the score will work even for superficial venous surgery. I really appreciate your paper. Thank you.

Dr Vasquez. Thank you.

Table I (online only). CEAP clinical class

<i>Class</i>	<i>Description</i>
0	No visible or palpable signs of venous disease
1	Telangiectases, reticular veins, malleolar flare
2	Varicose veins
3	Edema
4	Skin changes ascribed to venous disease
5	Skin changes in conjunction with healed ulceration
6	Skin changes in conjunction with active ulceration

Table II (online only). Venous clinical severity score*

<i>Attribute</i>	<i>Absent = 0</i>	<i>Mild = 1</i>	<i>Moderate = 2</i>	<i>Severe = 3</i>
Pain	None	Occasional, not restricting activity or requiring analgesics	Daily, moderate activity limitation, occasional analgesics	Daily, severe, limiting activities or requiring regular use of analgesics
Varicose veins [†]	None	Few, scattered; branch varicose veins	Multiple: GSV varicose veins confined to calf or thigh	Extensive: Thigh and calf or GSV and lesser saphenous vein distribution
Venous edema [‡]	None	Evening ankle edema only	Afternoon edema, above ankle	Morning edema above ankle and requiring activity change, elevation
Skin pigmentation [§]	None or focal, low intensity (tan)	Diffuse but limited in area, and old (brown)	Diffuse over most of gaiter distribution (lower 1/3) or recent pigmentation (purple)	Wider distribution (above lower 1/3) and recent pigmentation
Inflammation	None	Mild cellulitis, limited to marginal area around ulcer	Moderate cellulitis, involving most of gaiter area (lower 1/3)	Severe cellulitis (lower 1/3 and above) or significant venous eczema
Induration	None	Focal, circummalleolar (<5 cm)	Medial or lateral, less than lower 1/3 of leg	Entire lower 1/3 of leg or more
Active ulcers (n)	0	1	2	>2
Active ulceration, duration	None	<3 mo	>3 mo, <1 y	Not healed >1 y
Active ulcer, size	None	<2 cm diameter	2-6 cm diameter	>6 cm diameter
Compressive therapy [¶]	Not used or not compliant	Intermittent use of stockings	Use of elastic stockings most days	Full compliance: stockings plus elevation

GSV, Great saphenous vein.

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[†]"Varicose" veins must be >4 mm in diameter to qualify, so that differentiation is ensured between C1 and C2 venous disease.

[‡]Presumes venous origin by characteristics (eg, brawny [not pitting or spongy] edema), with significant effect of standing or limb elevation or other clinical evidence of venous cause (ie, varicose veins or history of deep venous thrombosis). Edema must be a regular finding (eg, daily occurrence). Occasional or mild edema does not qualify.

[§]Focal pigmentation over varicose veins does not qualify.

^{||}Largest diameter of largest ulcer.

[¶]Sliding scale to adjust for background differences in the use of compressive therapy.