Recommended reporting standards for endovenous ablation for the treatment of venous insufficiency: Joint Statement of the American Venous Forum and the Society of Interventional Radiology

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Lower extremity venous insufficiency is a common medical condition that afflicts approximately 25% of women and 15% of men.[1] Great saphenous vein (GSV) reflux is the most common underlying cause of symptomatic varicose veins. An increasingly popular alternative to traditional surgical stripping of the GSV for management of saphenous vein reflux is endovenous ablation (EVA) of that vein using laser energy, radiofrequency-generated thermal energy, or a chemical sclerosant.[2-9] Comparative studies evaluating long-term EVA clinical treatment outcomes, the optimal timing of adjunctive procedures, and the relative impact of anatomic location, size, length, and energy deposition in the treated segment are expected in the near future. This document provides recommended reporting standards for physicians performing clinical research studies evaluating EVA in the treatment of lower extremity venous reflux and is thereby expected to facilitate comparison between the results of different studies and to improve the overall quality of clinical research on venous disease. These standards have been developed by The Society of Interventional Radiology (SIR) and The American Venous Forum and were approved by the SIR Executive Council on February 28, 2007, and by the AVF Executive Council on February 13, 2007.

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POPULATION DESCRIPTION

The general description of the population from which studied groups were selected should be presented. This should include the total number of patients seen and treated at participating institutions during the study period, patients' gender and age distribution, and frequencies of major treatment modalities used.

For studies including patients with bilateral disease, both the number of patients and the number of treated limbs, and whether limbs were treated concomitantly or staged must be stated. Baseline patient characteristics should include the level II basic CEAP[10] classification (Table I).

Severity of the disease should be reported using validated scales. The Venous Clinical Severity Score (VCSS, Table II) is highly recommended as a measure of overall disease severity.[11,12] Use of both generic and venous disease-specific measures is the accepted standard for studying quality-of-life (QOL) changes. The Venous Insuffi-

Table I. CEAP classification of chronic venous disease

Classification	*Symptom*
Clinical	
C_0	No visible or palpable signs of venous disease
C_1	Telangiectases or reticular veins
C_2	Varicose veins
C_3	Edema
C_{4a}	Pigmentation or eczema
C_{4b}	Lipodermatosclerosis or atrophie blanche
C_5	Healed venous ulcer
C_6	Active venous ulcer
S	Symptomatic, including ache, pain, tightness, skin irritation, heaviness, and muscle cramps, and other complaints attributable to venous dysfunction
A	Asymptomatic
Etiologic	
E_c	Congenital
E_p	Primary
E_s	Secondary (postthrombotic)
E_n	No venous cause identified
Anatomic	
A_s	Superficial veins
A_p	Perforator veins
A_d	Deep veins
An	No venous location identified
Pathophysiologic	
P_r	Reflux
P_o	Obstruction
$P_{r,o}$	Reflux and obstruction
P_n	No venous pathophysiology identifiable
Level of investigation	
Level I	Office visit, with history and clinical examination, which may include the use of a hand-held Doppler scanner.
Level II	Noninvasive vascular laboratory testing, which now routinely includes duplex color scanning, with some plethysmographic method added as desired
Level III	Invasive investigations or more complex imaging studies, including ascending and descending venography, venous pressure measurements, computed tomography, or magnetic resonance imaging.
Example	A patient has painful swelling of the leg, and varicose veins, lipodermatosclerosis, and active ulceration. Duplex scanning shows axial reflux of the great saphenous vein above and below the knee, incompetent calf perforator veins, and axial reflux in the femoral and popliteal veins. There are no signs of postthrombotic obstruction.
	Classification according to basic CEAP: $C_{6,S}$, E_p, $A_{s,p,d}$, P_r. (2004-05-17, L II).

ciency Epidemiologic and Economic Study of Quality-of-Life (VEINES-QOL/Sym) questionnaire scale, the Chronic Venous Insufficiency Questionnaire-2 (CIVIQ-2), and the Aberdeen questionnaires have all been validated in patients with lower extremity venous reflux and are highly recommended for use as venous disease–specific QOL measures.[13-19]

Because patient satisfaction depends upon addressing his or her chief complaint, the specific primary reason for treatment is also important to indicate. Common symptoms of venous disease include aching, burning, itching, heaviness, swelling, cramping, and local inflammation in the affected limb, among others.

A history of superficial or deep venous disease or interventions, or both, may influence both the performance and the results of EVA procedures and is therefore important to describe. Specifically, the following interventions are important: use of graduated compression stockings; a history of venous stripping and/or ligation of truncal veins, ambulatory phlebectomy, sclerotherapy, subfascial endoscopic perforator surgery (SEPS), previous EVA procedures, thrombolysis, angioplasty, or stent placement; or the presence of endovenous devices including stents, inferior vena cava filters, and central venous access devices.

The presence of major comorbidities may reduce the clinical success rate or increase the rate of complications, or both. Conversely, exclusion of patient subsets due to morbidity can also bias the population and should be considered when comparing patient cohorts. The following comorbidities may influence the results of EVA and should be reported: coronary artery disease, congestive heart failure, diabetes mellitus, thrombophilias, increased body mass index, and poor overall general health.[20]

Additional anatomic and physiologic characterization of venous disease. Potential candidates for EVA include patients with reflux in an incompetent GSV or small saphenous vein (SSV) or in a major tributary branch of the GSV or SSV such as the anterior thigh circumflex vein,

Table II. Venous Clinical Severity Score

Attribute	*Absent = 0*	*Mild = 1*	*Moderate = 2*	*Severe = 3*
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 SSV distribution
Venous edema	None	Evening ankle 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), recent pigmentation
Inflammation	None	Mild cellulitis, limited to marginal area around ulcer	Moderate cellulitis, involves most of gaiter area (lower 2/3)	Severe cellulitis (lower 1/3 and above) or significant venous eczema
Induration	None	Focal, circum-malleolar (<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 months	>3 mo, <1year	Not healed >1 year
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	Wears elastic stockings most days	Full compliance: stockings + elevation

GSV, Great saphenous vein; *SSV,* small saphenous vein

posterior thigh circumflex vein, or anterior accessory GSV. Therefore, the presence of reflux in these veins is important to document using duplex ultrasound imaging, as pertaining to the CEAP A5 nonsaphenous category. Use of the nomenclature recommended by the International Union of Phlebology, the International Federation of Associations of Anatomists, and the Federative International Committee on Anatomical Terminology is expected.[21,22]

Variations to standard venous anatomy, when observed on the ultrasound examination, should be reported. These include tortuosity of the target vein, duplications, atresia, the presence of anatomic venous variants, or variable termination of the SSV. The diameter of the GSV and SSV, ≤2 cm of the junction with the deep vein (common femoral or popliteal) and target vein (if not the GSV or SSV) should be measured. The patient position and site of treatment should be specified.

Although a combination of a directed physical examination and duplex ultrasound imaging (CEAP level II examination) is usually sufficient to characterize the anatomic and physiologic extent of lower extremity venous disease,[23] diagnosis of chronic venous disorders can also be supported by direct or indirect physiologic tests.[24,25] When these tests are obtained, the results should be reported. Similarly, when a CEAP level III examination is performed using computed tomography or magnetic resonance imaging, the reason for their use should be specified, the results should be reported, and the specific criteria used for diagnosis of venous abnormalities should be indicated.

Terminology and definitions. Definitions of clinical signs and symptoms should comply with definitions presented in the revised CEAP classification.[10]

Use of the nomenclature recommended by the International Union of Phlebology, the International Federation of Associations of Anatomists, and the Federative International Committee on Anatomical Terminology is expected.[21,22] Specific recommendations include the terms *great saphenous vein* or *GSV* (instead of long saphenous vein, greater saphenous vein, or internal saphenous vein) and *small saphenous vein* or *SSV* (instead of short saphenous vein, lesser saphenous vein, or external saphenous vein).

The ultrasound criteria used to define reflux should be indicated; in current practice, most vascular laboratories consider the presence of venous flow reversal for >0.5 to 1.0 seconds with proximal compression, Valsalva maneuver, or distal compression and release to represent pathologic reflux.[23,26]

TREATMENT DESCRIPTION

Pretreatment preparation. The aspects of pretreatment preparation that may influence EVA treatment outcomes are important to describe. This includes methods used to increase the distension of the lower extremity veins, such as pretreatment ambulation, patient positioning maneuvers, temperature adjustments to the procedure room, use of tourniquets, or pharmacologic maneuvers such as the administration of vasodilators. The

method of marking and mapping the target vein(s) are also important to indicate.

Method of vein access, intraprocedural imaging, and anesthesia. The method of venous entry—percutaneous, surgical cutdown, or venotomy—should be stated. Imaging guidance for venous access, administration of anesthetic injections, and monitoring of other aspects of the procedure that is provided by ultrasound guidance, fluoroscopic guidance, or a combination should be reported. The type of access system (eg, micropuncture system vs larger needle) is important to report. The precise location of the percutaneous access site(s) is important to indicate as well as the reason for selection of this point (eg, absence of reflux, potential access difficulties below a certain point, and multiple large tributaries). Tumescent anesthesia is usually administered using a dilute local anesthetic to provide local anesthesia, protect surrounding tissues (including adjacent nerves and overlying skin) from the thermal injury, and mechanically collapse the vein to decrease the distance between the catheter-based heat source and the vein walls and thereby enable nonthrombotic ablation of the vein.[3] The concentration, volume, and method of administration (ie, hand-injection or mechanical device) of local anesthetic drugs should therefore be described. The use of fluoroscopy or venography must be reported.

Method of endovenous ablation. For thermal ablation techniques, the type of energy (endovenous laser or radiofrequency) along with the manufacturer of the device should be reported. The energy level (power in watts), time of energy deployment (seconds), mode of delivery (pulsed or continuous mode), and total amount of energy emitted must be reported. If a pulsed mode is used during endovenous laser ablation, the duration and frequency of the pulse should be noted.

For radiofrequency, temperature of the catheter–vein interface, size of the catheter (6F, 8F), catheter and generator model, rate of catheter pull-back in cm/min, and total treatment time should be reported.

For chemical ablation techniques, the concentration, type of sclerosant (including manufacturer), and volume of the sclerosing agent must be reported. If a foam solution is used, the foaming technique should be recorded.

The starting point, ending point, and total length of the ablated segment should be reported in a quantitative fashion (eg, from 1 cm below the saphenofemoral junction to 1 cm above the puncture site; total, 40 cm), and for GSV ablation in relation to groin tributaries (ie, below epigastric vein).

The type and timing of postprocedure care such as compression therapy should also be reported. The class and type of compression therapy and activity restrictions should be reported.

Adjunctive procedures. Adjunctive procedures such as sclerotherapy and stab phlebectomies are commonly used in patients undergoing EVA. Because of their influence on treatment outcomes, the use and timing of any adjunctive procedures used at the time of EVA or before the initial outcomes assessment should be described. Administration of sclerosant solution through the vascular sheath encasing the laser or radiofrequency probe should be reported. The type of sclerosant, concentration, volume, and foaming technique for foam sclerotherapy should be noted. It should also be clear whether adjunctive procedures were intended as part of the initial treatment approach.

OUTCOMES ASSESSMENT

Clinical research studies on EVA may be generally categorized into two types: clinical outcome studies and technology assessment studies.

Clinical outcomes studies. These studies are designed to assess the clinical efficacy and to verify the safety of EVA procedures and are expected to quantify the impact of therapy on *clinical outcomes that are meaningful to patients*, such as:

1. relief of presenting symptoms,
2. frequency of skin ulcer healing and time to recurrence,
3. prevention of progression of chronic venous insufficiency,
4. improvement in quality of life, and
5. improvement in cosmesis, or a combination of these.

EVA may succeed in achieving all, some, or none of these goals; similarly, EVA may alleviate all, some, or none of the presenting symptoms. It is therefore important for authors to define the *primary clinical intent* of the procedure and to adjudicate success or failure by this criterion. The primary clinical intent must be a clinical outcome of importance to patients (eg, relief of the dominant presenting symptom) rather than an anatomic/imaging outcome (eg, ultrasound-proven occlusion of the target vein). Other end points of interest may also be reported, such as the continued need for compression stockings and antiinflammatory medications after EVA and the need for additional endovenous or surgical procedures.

Because causation of clinical outcomes is generally implied as related to treatment, anatomic and imaging outcome at the same follow-up points must be reported.

Technology assessment studies. These studies are designed to answer specific technical questions about a new treatment modality before embarking on full-scale clinical outcomes studies. For such studies, it is acceptable to report an anatomic or imaging outcome (eg, successful ultrasound-proven ablation of the target vein) as the primary outcome, but the authors must limit their conclusions accordingly and no mention of clinical efficacy may be made unless a clinical outcome was systematically evaluated. Because the specific goals of therapy will vary among patients, investigators should report outcomes in as many of the following relevant categories as possible.

Assessment of treatment effectiveness—symptom relief. A number of methods may be used to report treatment success in relieving presenting symptoms. In general, the use of validated patient-reported measures of venous symptom status is preferred over "homemade" scales or

other subjective assessments. Authors may choose to use disease-specific validated scales designed to provide an assessment of venous symptoms (eg, VEINES-Sym, Aberdeen Varicose Vein Score, and the Charing Cross Venous Ulcer Score). Authors may also focus on objectively documenting improvement in one or more specific symptoms; for example, validated pain scales such as a Likert scale may be used to assess lower extremity pain, although pain and discomfort are routinely addressed in the above QOL measures. Such assessments may be supplemented by objective measures of clinical improvement that are based upon physician assessment of clinical signs (eg, measurement of leg circumferences in standardized fashion for assessment of lower extremity swelling), but determination of treatment success should not rely exclusively on physician assessments because they may or may not correlate with clinical improvement, which is meaningful to patients.

Assessment of treatment effectiveness—disease severity and quality of life. Presenting symptoms and QOL may improve rapidly after EVA, but meaningful evaluation of the progression of chronic venous insufficiency needs a significantly longer time. Clinical follow-up should therefore be graded as short-term (<1 year), mid-term (1 to 3 years), or long-term (>3 years).

Although the CEAP system is a useful descriptive tool, it is thought to have too many static elements to be effective in monitoring change in disease status with treatment.[27] For this reason, a number of alternative scoring systems have been developed and partially validated for assessment of venous disease severity in patients with chronic venous insufficiency. The American Venous Forum has recommended use of the VCSS to quantify the clinical severity of venous disease (Table II). The VCSS is based on physician assessment of the presence and severity of nine common stigmata of chronic venous disease and the use of compression stockings. VCSS scores correlate well with CEAP clinical class and with the presence of abnormalities in the venous system documented with ultrasound imaging.[28-30] For studies that focus primarily on patients with venous ulcers, there also exist measures targeted to this subgroup.[15,16]

It is important to assess QOL in patients with venous insufficiency because it provides valuable information on the patient-perceived burden of illness. When QOL is assessed, a *generic* QOL measure, such as the Medical Outcomes Study Short Form 36 (SF-36) measure, and a *venous disease–specific* QOL measure should be used. In recent years, a number of venous disease–specific QOL measures have been developed and at least partly validated; three are listed here:

- The VEINES-QOL/Sym consists of 26 question items that measure venous symptoms, limitations in daily activities due to venous disease, psychologic impact of venous disease, and change over time. The VEINES-QOL/Sym has undergone comprehensive and rigorous psychometric evaluation and is acceptable, reliable, valid, and responsive for use as a patient-reported measure of outcome in chronic venous disease.[11,13,17]
- The CIVIQ-2 is a 20-question survey that has been validated for use in patients with chronic venous disease and has been used in a previous randomized trial comparing EVA with surgical therapy.[18,19] Response to each question is rated on a 5-point scale and is classified in one of four dimensions: Pain, Physical, Social, or Psychological. The scores on the four dimensions are combined to form a single global QOL score.[18]
- The Aberdeen QOL is a 15-question survey that has also been validated for use in patients with chronic venous disease.[31]

The Charing Cross Venous Ulcer scale likely has less utility in the population treated by EVA but is certainly pertinent for those focused on this aspect of the chronic venous disease.[15]

Assessment of treatment effectiveness—cosmesis. Successful treatment of venous reflux commonly leads to complete disappearance or marked reduction in the size and visibility of varicose veins. This effect of therapy often enhances patient satisfaction and may lead to improvements in both body image and social functioning, which are comparable with those of cosmetically directed interventions in other body areas. Quantification of these effects in future EVA studies is expected. In general, the use of validated measures of body image, social functioning, and patient satisfaction, such as have been used for other forms of cosmetic intervention, is recommended rather than the use of "homemade" scales. However, because such measures have not yet been validated for use in varicose vein populations, recommendations for reporting in this area cannot be firmly made at this time. It is hoped that future versions of this document will be able to provide greater guidance in this regard.

The assessment of recurrent symptomatic or asymptomatic varicosities remains controversial. Use of a validated classification, such as Recurrent Varicose Veins after Surgery[32] should be encouraged. However, a clear and reliable way to discriminate between persistent (residual) veins, "true recurrences," and varicose veins developed as a result of disease progress remains subject to future investigation.

Assessment of treatment effectiveness—anatomic/imaging end points. EVA is believed to lead to improved clinical outcomes by eliminating flow in the target vein, enabling reduction in venous hypertension. To properly determine whether treatment failures are due to inability of the technology being evaluated to ablate the vein, use of suboptimal treatment parameters, or other factors, it is therefore important to know if successful ablation of the vein was actually achieved. Because EVA may lead to complete ablation or varying degrees of partial ablation of the vein, it is also important to report the extent of successful ablation. The exact anatomic result that correlates with improved long-term clinical outcomes has not been scien-

Table III. Venous Segmental Disease Score

Reflux	*Score*	*Obstruction*	*Score*
Small saphenous	½		
Great saphenous	1	Great saphenous (only if thrombosed from groin to below knee)	1
Perforators, thigh	½		
Perforators, calf	1		
Calf veins, multiple	2	Calf veins, multiple	1
Posterior tibial vein alone	1		
Popliteal vein	2	Popliteal vein	2
Femoral vein	1	Femoral vein	1
Profunda femoris vein	1	Profunda femoris vein	1
Common femoral vein and above	1	Common femoral	2
Iliac vein	1	Inferior vena cava	1
Maximum reflux score	10	Maximum obstruction score	10

tifically demonstrated. At present, however, *anatomic success* should be defined as successful ablation of the target vein, as demonstrated by complete lack of flow or disappearance of vein by duplex ultrasound imaging in the entire treated segment.

Reporting the length of patent GSV below the saphenofemoral junction after ablation, as measured on the postprocedure ultrasound scan, provides important information on the relation between the treatment starting point and the point of achieved ablation. This can be different for different modalities. There also may be a difference in long-term outcome in patients who have no patent GSV or a 1-cm stump compared with a patient with a 5-cm length of patent GSV.

If complete ablation has not been achieved, the anatomic extent of the open segment, presence or absence of reflux, and time of flow reappearance must be reported. Early failures ($\leq$3 days from procedure) may indicate technical failures, whereas late failures can be result of recanalization.

In some patients, successful ablation of a target refluxing vein results in a reduction in size of other initially refluxing veins, with subsequent restoration of unidirectional flow. For this reason, it may be useful to report the presence or absence of reflux in other ultrasound-evaluable major lower extremity veins as well.

Although more studies are needed to more completely validate its utility, the Venous Segmental Disease Score (VSDS, Table III) enables this information to be represented on a continuous scale with subsequent calculation of an overall "reflux score,"[11,28,30]

Uniform points for clinical and duplex ultrasound follow-up are highly desirable. The most common being within the first 3 days, at 1 month, 1 year after treatment, and annually thereafter. The performance of an early postprocedure ultrasound scan at some point $\leq$1 month after treatment is essential and must be reported. For assessment of short-term (<1 year), mid-term (1 to 3 years), or long-term (>3 years) outcomes, duplex results at the longest follow-up should also be reported.

Assessment of treatment effectiveness—terminology and definitions. Reports of long-term results should use uniform terminology:

a. Recanalization (with or without reflux): documentation of flow in a previously occluded vein.
b. Neovascularization: presence of multiple small tortuous connections between the saphenous stump or the femoral vein and the residual saphenous vein or its tributaries (new, or pre-existing dilated vessels outside the venous wall).
c. Primary ablation: ablation after initial treatment.
d. Primary assisted ablation: successful retreatment of anatomic recanalization before clinical failure has occurred.
e. Secondary (retreatment) ablation: successful retreatment of patients with anatomic and clinical failure.

Assessment of treatment efficacy—recommendations. Authors must explicitly state whether the study is a technology assessment study or a clinical outcomes study.

For clinical outcomes studies, authors must report the proportion of patients for whom the primary clinical intent of EVA is symptom relief, venous ulcer healing, prevention of progression of chronic venous insufficiency, and improvement in cosmesis. Authors must adjudicate the overall clinical success or failure of EVA according to whether the primary clinical intent of the procedure was achieved and must report the proportion of patients in which this occurred.

Anatomic and imaging outcomes (eg, successful ultrasound-proven target vein ablation) may be used as the primary outcome for technology assessment studies but not for clinical outcomes studies. Additional reporting of the proportions of patients in whom symptom relief, ulcer healing, regression of chronic venous insufficiency, or cosmetic improvement was achieved, or a combination of these is highly recommended.

Assessment of treatment safety. Performance of EVA may be associated with a number of early and late complications. Any invasive therapy can produce an infectious complication, and those that require conscious sedation carry risks of cardiorespiratory compromise. If venography is used to guide therapy, allergic reactions or renal failure, defined as a $\geq$20% increase in serum creatinine level, may occur.[33] Deep vein thrombosis (DVT) or pulmonary embolism, or both, occur with rare frequency in patients treated with EVA and must be reported along with anatomical location and extent of the thrombus.[34] Other complications may include skin burns, paresthesias or other nerve injuries, and superficial thrombophlebitis in the treated vein or in a tributary.[35]

All adverse events occurring during or $\leq$30 days after the EVA plus adjunctive procedures must be considered procedure-related. The SIR classification system for grad-

Table IV. Definition of complications

Minor complications
No therapy, no consequence
Nominal therapy, no consequence; includes overnight admission for observation only
Major complications
Require therapy, minor hospitalization (<48 hours)
Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours)
Permanent adverse sequelae
Death

ing minor or major complications (Table IV) can be used when reporting results.

Assessment of resource utilization. A rigorous analysis of EVA costs should include the cost of all procedures, devices, medications, and the inpatient treatment required; the cost of use of the procedure suite used; the costs of immediate and long-term complications and recovery time; and the costs of long-term monitoring and treatment.[36-38]

COMPARISON BETWEEN TREATMENT GROUPS

The study design, sample size, statistical power, and statistical analyses must be reported as well as institutional review board status and funding source. Consultation with a statistician in the methodology of the study design and statistical analysis is recommended before starting the study. For comparative studies, blinding of the outcomes assessors should be used whenever possible. A description of all methods used to minimize bias in the study is recommended.

Patients in comparative studies should be stratified by the anatomic location of the target vein and baseline clinical disease severity because these key factors may influence treatment outcomes.

Primary statistical analyses must be reported based on intention-to-treat and per-protocol analyses. With an intention-to-treat approach, subjects are analyzed with the group to which they are initially allocated regardless of whether they actually received the treatment or dropped out of the study. Per-protocol analysis considers only those patients who actually received the intended treatment. Discussions of significance should incorporate the study design limitations. If the study conclusions are based on analysis of surrogate (ie, nonclinical) outcomes, they should be tempered accordingly.

STATISTICAL ANALYSIS

Appropriate statistical methods of assessing outcomes should be used. For long-term follow-up studies, life-table analysis is an established standard. In comparison studies, techniques allowing adjustment for covariants are preferential, such as logistic regression, generalized linear model, and Cox proportional hazards model.

Numeric information presented in the report should be sufficient for an independent analysis of major findings. Ideally, the study database should be available for access.

Table V. Recommendations for reporting standards

	Required	*Recommended*
Pre-EVA evaluation (Section 1)		
Patient population	☑	☐
Age, gender, race	☑	☐
Clinical indication for EVA	☑	☐
Anatomic location of treated vein	☑	☐
CEAP staging	☑	☐
Clinical Severity Score	☐	☑
Study design		
Inclusion criteria	☑	☐
Exclusion criteria		☐
Comorbid diseases	☑	☐
Functional status and QOL	☐	☑
Pretreatment imaging	☑	☐
Primary reason for treatment	☑	☐
EVA description (Section 2)		
Pre-treatment preparation	☐	☑
Method of vein access	☑	☐
Intraprocedural imaging	☑	☐
Device or chemical agent description	☑	☐
Energy source, duration	☑	☐
Total energy deposited, or dose of sclerosant	☑	☐
Adjunctive techniques	☑	☐
Anesthesia	☑	☐
Length and diameter of vein	☑	☐
Post-EVA evaluation (Section 3 and 4)		
Complications		
Immediate	☑	☐
30-day	☑	☐
Follow-up imaging at regular intervals	☑	☐
Follow-up of clinical status	☑	☐
QOL assessment	☐	☑
Uniform duration of follow-up	☐	☑
Need for additional procedures	☑	☐
Costs/cost effectiveness	☐	☑
Primary outcome	☑	☐

EVA, Endovenous ablation; *QOL,* quality of life.

CONCLUSION

Endovenous ablations are promising treatment options for lower extremity venous disease. It is the purpose of this document to enhance the uniformity of research reporting on these procedures. A summary of the recommendations and requirement for reporting is provided in Table V.

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