

Venous severity scoring: An adjunct to venous outcome assessment

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Some measure of disease severity is needed to properly compare the outcomes of the various approaches to the treatment of chronic venous insufficiency. Comparing the outcomes of two or more different treatments in a clinical trial, or the same treatment in two or more reports from the literature cannot be done with confidence unless the relative severity of the venous disease in each treatment group is known. The CEAP (Clinical-Etiology-Anatomic-Pathophysiologic) system is an excellent classification scheme, but it cannot serve the purpose of venous severity scoring because many of its components are relatively static and others use detailed alphabetical designations. A disease severity scoring scheme needs to be quantifiable, with gradable elements that can change in response to treatment. However, an American Venous Forum committee on venous outcomes assessment has developed a venous severity scoring system based on the best usable elements of the CEAP system. Two scores are proposed. The first is a Venous Clinical Severity Score: nine clinical characteristics of chronic venous disease are graded from 0 to 3 (absent, mild, moderate, severe) with specific criteria to avoid overlap or arbitrary scoring. Zero to three points are added for differences in background conservative therapy (compression and elevation) to produce a 30 point–maximum flat scale. The second is a Venous Segmental Disease Score, which combines the Anatomic and Pathophysiologic components of CEAP. Major venous segments are graded according to presence of reflux and/or obstruction. It is entirely based on venous imaging, primarily duplex scan but also phlebographic findings. This scoring scheme weights 11 venous segments for their relative importance when involved with reflux and/or obstruction, with a maximum score of 10. A third score is simply a modification of the existing CEAP disability score that eliminates reference to work and an 8-hour working day, substituting instead the patient's prior normal activities. These new scoring schemes are intended to complement the current CEAP system. (*J Vasc Surg* 2000;31:1307-12.)

Methods of outcomes assessment need to be able to gauge change in status after treatment in a meaningful and objective way, and for purposes of analysis and comparison, they should usually be quantitative rather than qualitative. They should result in a practical assessment of the success of a given treatment over time, whether applied to groups of patients of varying levels of severity or patients grouped into similar levels of severity. Both, but particularly the

former, require a quantitative method of gauging the severity of disease. Properly comparing the outcomes of two or more treatments in the same institution, the reported results of the same treatment from different institutions, or the results of the same treatment using different adjunctive measures is not possible unless the relative severities of the underlying disease in the treatment groups are known.¹ However, if the severity of the disease is uniformly quantified and the score changes with treatment, a disease severity score can not only serve as a background against which to view other outcome criteria in comparing treatment groups, but can itself reflect the degree of change in disease severity associated with treatment. As such, disease severity scores can be very useful in outcomes assessment. The widespread use of a properly designed disease severity scoring scheme should allow patient groups of simi-

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lar degrees of severity to be selected for entry into clinical trials and to be compared in regard to outcome following different therapies. If generally adopted, the reported outcomes after a given treatment by different practices, groups, or institutions can also be compared knowing the relative severity of disease of the treated patients in each report. Thus a venous severity scoring system can become a valuable adjunct in venous outcomes assessment.

The increasingly popular CEAP (Clinical-Etiology-Anatomic-Pathophysiologic²) classification system, particularly its clinical classes C1 to C6, does represent a progressive gradation of disease severity. It gauges the severity of disease at a given point in time, but because a number of its components are relatively static and do not change significantly in response to treatment and other components have alphabetic designations, it cannot be used for disease severity scoring in its current form. For example, the healing of an active ulcer would drop the patient from C6 to C5, but no further. Some of the elements of C4, particularly subcutaneous fibrosis and cutaneous atrophy, are unlikely to change significantly with treatment. The elimination of edema or varicose veins, or reticular veins and telangiectasias for that matter, conceivably could produce an improvement in clinical class, but the results of their treatment are not usually so absolute. Significant improvements short of complete elimination of the characteristic venous state would not result in categorical improvement.

The clinical class of CEAP does not allow a practical assessment of change in response to treatment or adverse events, but then it was not intended to do so. Nevertheless, the American Venous Forum's Ad Hoc Committee on Venous Outcomes believed that CEAP identifies most if not all the necessary components involved in comprehensive outcomes assessment, and many of its elements could be individually graded to produce a venous severity scoring system. This approach was selected, and the results of these deliberations are reported here.

It should be noted that a "Clinical Score" is included in the full CEAP document and is included in the most recent edition of the *Handbook of Venous Disorders* (see Table 38.3, page 656).² It uses a 0 to 2 grading of a number of symptoms and signs, which include pain and venous claudication, as well as the characteristic elements of the C3 to C6 levels of CEAP, for a maximum score of 18. Varicose veins are not included in this clinical score, so a patient with successful removal of these could only be gauged by a change in pain, at the most two points. Although

the approach used in this clinical score is conceptually sound, it is rather simplistic. Furthermore, the scores assigned can be rather arbitrary and subjective because many of the scoring levels are inadequately delineated by the descriptive terms associated with them. Also, some of the characteristics (eg, number of ulcers, duration of ulcers, recurrence of ulcers) are not capable of improvement; the score can only remain unchanged or increase. It has not gained widespread acceptance or use and was not included in the current version of venous reporting standards.³

In the development of a severity scoring system based on CEAP, it was obvious that a clinical severity score could be primarily based on the *C* of CEAP, and that the *E* or etiology is fixed and could not be incorporated. However, both the anatomic (*A*) and pathophysiology (*P*) segments, which essentially involve the presence or absence of reflux and/or obstruction, could be combined and adapted into a grading scheme reflecting disease severity, and in some situations even gauge change with treatment, as in a comparison of anticoagulant therapy, thrombolysis, or thrombectomy for deep venous thrombosis (DVT). It was believed that such a scheme could be scored using duplex scan findings. Therefore, a Venous Segmental Disease Score was also developed, in addition to a Clinical Severity Score. These two elements of the proposed venous severity scoring system will thus be seen to be closely allied to CEAP.

Finally, it was considered important to avoid confusing or undermining the existing venous reporting standards, and particularly the CEAP classification system in developing new methods for venous outcomes assessment such as venous severity scores. The importance of the uniform classification framework provided by CEAP is acknowledged and seen in its increasing use. Thus, the goal of this report is *not* to replace or change any aspect of *the classification scheme* of CEAP, but to augment it with additional, closely related, and compatible methods, some of which are modifications of other features of CEAP (ie, the clinical score and the disability score), to further improve the ability to assess venous outcomes.

THE VENOUS CLINICAL SEVERITY SCORE—A MODIFICATION TO REPLACE THE CLINICAL SCORE OF CEAP

Design considerations and rationale. Although it was considered desirable to use the basic clinical elements of CEAP where possible, it was important to not mimic them so closely as to cause confusion with CEAP classification. It was for this reason that simply scoring each of the six clinical classes from 0 to 3 was rejected.

Table I. VCSS

<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 VV's	Multiple: GS varicose veins confined to calf or thigh	Extensive: Thigh <i>and</i> calf or GS <i>and</i> LS 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) <i>or</i> recent pigmentation (purple)	Wider distribution (above lower 1/3) <i>and</i> recent pigmentation
Inflammation	None	Mild cellulitis, limited to marginal area around ulcer	Moderate cellulitis, involves 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 third of leg	Entire lower third of leg or more
No. of active ulcers	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- to 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

*"Varicose" veins must be > 4-mm diameter to qualify so that differentiation is ensured between C1 and C2 venous pathology.

†Presumes venous origin by characteristics (eg, Brawny [not pitting or spongy] edema), with significant effect of standing/limb elevation and/or other clinical evidence of venous etiology (ie, varicose veins, history of DVT). Edema must be regular finding (eg, daily occurrence). Occasional or mild edema does not qualify.

‡Focal pigmentation over varicose veins does not qualify.

§Largest dimension/diameter of largest ulcer.

||Sliding scale to adjust for background differences in use of compressive therapy.

GS, Greater saphenous; LS, lesser saphenous.

We wanted to take advantage of the progressive order of severity intrinsic to the clinical classes of CEAP, but also give additional weight to some of the upper levels (C4 and C6). This was done by separately scoring certain attributes of each of these levels.

It was necessary to avoid elements that are static and use only those with ability to reflect change over a relatively short period of time (months). Thus, subcutaneous fibrosis, one of the hallmarks of C4, was not considered.

Because of its success in the Society for Vascular Surgery and the International Society for Cardiovascular Surgery reporting standards⁴ and its common use by clinicians, we used the 0 to 3 grading scheme and applied it to all clinical descriptors (0 = absent, 1 = mild, 2 = moderate, and 3 = severe). This allowed improvement at each level to be gauged. In addition, it was important to define and describe each level and each grade in sufficient detail to minimize overlap and arbitrariness in assigning scores.

Both ascending and flat scales were considered and, several were constructed. An ascending scale assigns the score to the highest level achieved. Thus, if six descriptors were each scored 0 to 3, the score

would increase from 0 to 18 for each box in ascending fashion. However, this approach did not fit with our goal to develop a severity scoring scheme that covered the full spectrum of disease with a wide spread of scores capable of significant change with treatment. One might achieve improvement in lower descriptors (eg, remove varicosities, relieve edema, and pain), but if there were little change in a higher descriptor, the score would change little (eg, an ulcer healed but pigmentation and induration remained). In a flat scale, where points for each descriptor are added to give the total score, this same degree of improvement would result in a greater score change. Therefore, a flat scale was chosen.

Clinical descriptors considered and chosen.

All six clinical class levels (C1-C6) as well as separate characteristics of C4 to C6 (pigmentation, inflammation, induration, ulcer size, number, multiplicity, duration) were considered as potentially gradable clinical descriptors. In addition, pain, disability, neuropathy, venous eczema, and venous claudication were considered.

C1 (telangiectasias and reticular veins) was eliminated because it was not considered a major patho-

logic characteristic of the patient with chronic venous disease (CVD), the treatment of which was the focus of these outcome assessment methods. C5 (healed ulcer) was also not represented because its gradable characteristics (eg, total number of ulcers or episodes of recurrent ulceration) were not capable of positive change (ie, showing improvement). The number of healed ulcers or episodes of ulceration could only remain stable or increase. However, improvement at this clinical level could be reflected in improvements in pigmentation, induration, and inflammation.

Disability scoring was important in its own right and was retained as a separate score. A new Venous Disability Score (VDS) is presented separately below.

Venous claudication was not included. It is much rarer than other features of CVD, and besides, patients with this degree of venous obstruction would be represented with high scores for pain and swelling. Neuropathy, while more common than realized, was not considered common enough or easily gauged by most investigators. Venous eczema was considered for inclusion, not separately, but as a severe form of inflammatory change.

Ultimately, nine clinical descriptors were selected: pain, varicose veins, edema, pigmentation, induration, inflammation, number of active ulcers, duration of active ulceration, and size of largest current ulcer. There was considerable sentiment for trying to compensate, in scoring, for background differences in the use of compressive therapy and limb elevation, because it was realized that, for example, advanced skin changes without ulceration in a very compliant patient may well represent more severe disease than multiple active ulcers in a non-compliant patient, or one who had never been introduced to compressive therapy and elevation. At one point, when a 30-point flat scale was being worked on, a superimposed sliding scale of 0 to 3 was considered, with the score not to exceed 30. When one of the descriptors was dropped in the final deliberations, it was simply decided to include 0 to 3 points for differences in background conservative therapy, bringing the severity score back to an even 30-point scale.

The venous clinical severity score (VCSS) finally recommended is presented in Table I. It is accompanied by qualifying comments regarding its application. It is realized that the final version represents considerable arbitrariness and another group of "experts" might have come up with a different scheme that might also serve well. However, after months of deliberation, the committee could not arrive at a better

scheme, and it was believed that future field-testing, as recommended below, would provide a more objective basis for further modifying it.

THE VENOUS SEGMENTAL DISEASE SCORE—A COMBINATION OF THE ANATOMIC AND PATHOPHYSIOLOGIC COMPONENTS OF CEAP

Design consideration and rationale. The concept behind the Venous Segmental Disease Score (VSDS) was to combine the pathophysiologic designation of reflux and obstruction with the venous segments of the anatomic classification. Points are assigned for pathophysiologic findings of reflux and/or obstruction. At one point it was called the Venous Anatomic-Pathophysiologic Score, but this was considered awkward and not fully descriptive. In addition to an objective score, one that could complement the clinical score, a major motivation for pursuing this approach was the opportunity to gather the necessary information for scoring by duplex scanning, which has become a standard in investigating venous disease.

However, 18 venous segments are designated for the anatomic localization of disease in the CEAP classification system. We recognized that scoring all 18 would be unwieldy and unnecessarily complex, and besides, not all could or would be evaluated by the usual duplex scan. Furthermore, while some were easy to eliminate as playing relatively insignificant roles when incompetent or obstructed, the relative roles of the remainder were not considered equal, nor did they play as significant a role in obstruction as reflux and vice versa. For example, superficial venous incompetence is a common and significant cause of venous insufficiency, but superficial vein obstruction, by thrombus or ligation/excision, played no significant role in obstruction of venous return, except that the greater saphenous vein, if thrombosed (or previously excised) could, as a major collateral, contribute to the degree of obstruction in femoropopliteal DVT. Allowance was made for this.

More proximal veins, such as the inferior vena cava and the iliac and common femoral veins, play a greater role in symptomatic venous obstruction than many distal veins, but the first two play little role in reflux because they normally have no valves. Conversely, distal veins, specifically the popliteal and tibial veins, play a greater role in producing venous insufficiency than most proximal veins. Therefore, after beginning by assigning one point to each of the venous segments considered to play a significant role in overall obstruction or reflux, we dropped those of

Table II. VSDS (based on venous segmental involvement with reflux or obstruction*)

<i>Reflux</i>	<i>Obstruction†</i>
½ Lesser saphenous	‡
1 Greater saphenous	1 Greater saphenous (only if thrombosed from groin to below knee)‡
½ Perforators, thigh	‡
1 Perforators, calf	‡
2 Calf veins, multiple (PT alone = 1)	1 Calf veins, multiple
2 Popliteal vein	2 Popliteal vein
1 Superficial femoral vein	1 Superficial femoral vein
1 Profunda femoris vein	1 Profunda femoris vein
1 Common femoral vein and above‡	2 Common femoral
	1 Iliac vein
	1 IVC
10 Maximum reflux score§	10 Maximum obstruction score§

Note: Reflux means that all the valves in that segment are incompetent. Obstruction means there is total occlusion at some point in the segment or > 50% narrowing of at least half of the segment. Most segments are assigned one point, but some segments have been weighted more or less to fit with their perceived significance (eg, increasing points for common femoral or popliteal obstruction and for popliteal and multiple calf vein reflux and decreasing points for lesser saphenous or thigh perforator reflux). Points can be assigned for both obstruction and reflux in the same segment. This will be uncommon but can occur in some postthrombotic states, potentially giving secondary venous insufficiency higher severity scores than primary disease.

*As determined by appropriate venous imaging (phlebography or duplex scan). Although some segments may not be routinely studied in some laboratories (eg, profunda femoris and tibial veins), points cannot be awarded on the basis of presumption, without interrogating the segments for obstruction or reflux.

†The excision, ligation, or traumatic obstruction of deep venous segments counts toward obstruction points just as much as their thrombosis.

‡Normally there are no valves above the common femoral vein, so no reflux points are assigned to them. In addition, perforator interruption and saphenous ligation/excision do not count in the obstruction score, but as a reduction of the reflux score.

§Not all of the 11 segments can be involved in reflux or obstruction. Ten is the maximum score that can be assigned, and this might be achieved by complete reflux at all segmental levels.

IVC, Inferior vena cava; PT, posterior tibial.

lesser significance to one half and raised those of greater significance to two.

Finally, there was much discussion over whether one should assign both obstruction and reflux points to the same segment. Although it could be said that any given abnormal segment would not be refluxing if it were totally obstructed and it would not be obstructed if patent and refluxing, in fact, there are recanalized postthrombotic veins that are incompetent, but also significantly narrowed. Therefore, in concert with CEAP, those segments with both reflux and significant obstruction received points for both. This circumstance would not be commonplace, but would not inappropriately give some cases of secondary, postthrombotic disease somewhat higher scores than those with pure primary disease. However, the requirements for assigning points for both are clearly spelled out to avoid abuse.

The final version of the VSDS is presented in Table II, which includes qualifying comments regarding its application. It is clear that this VSDS is arbitrary, albeit after long deliberations. Therefore, the committee recommends that further modifications be done after appropriate field-testing, using objective correlative data.

THE VENOUS DISABILITY SCORE—A MODIFICATION OF THE ORIGINAL CEAP DISABILITY SCORE

The disability score, originally developed with CEAP, is featured in the *Handbook of Venous Disorders*,² but is not part of the revised venous reporting standards.³ Unfortunately, in this version, disability is related (score 2) to an 8-hour working day and (score 3) the ability to work. It is believed that this should be modified in recognition of the many patients with CVD who do, or did, not ordinarily work an 8-hour day (eg, housewives, retirees, students). That disability score also refers to the ability to work with or without “support device,” which is not explained, but is presumed to mean compression therapy. It was believed that support device should be identified as compression therapy with or without intermittent leg elevation, to avoid misinterpretation by others, including those in health care agencies.

A slightly modified wording of the disability score is therefore offered to accommodate the reality that not all individuals will be expected to work an 8-hour day while retaining the original concept of compression therapy and intermittent limb elevation

Table III. VDS

0 = asymptomatic
1 = symptomatic but able to carry out usual activities* without compressive therapy
2 = can carry out usual activities* only with compression and/or limb elevation
3 = unable to carry out usual activities* even with compression and/or limb elevation

*Usual activities = patients activities *before* onset of disability from venous disease.

facilitating maintenance of reasonable or usual daily activities. "Usual activities" is further qualified as being normal for the patient (ie, those carried on *before* being disabled by venous disease). This modification, presented in Table III, is intended to widen the application of this aspect of CEAP to a broader population.

CONCLUSIONS

The need and potential value of disease severity scoring in venous outcomes assessment seems clear to the committee. The added perspective of combining a VCSS with a segmental disease score based on objective imaging data (the VSDS) is also attractive. It is recommended that both scores be used wherever possible, rather than one or the other, and the VDS should be included for additional perspective. Only their use in clinical studies will determine the degree to which they correlate with each other and/or change in parallel in response to treatment. However, these scores represent the view of a few individuals and, as such, are admittedly arbitrary. It is clear that such a severity scoring system would best be based on data

from large multicenter studies of patients with venous disease, in whom clinical and duplex scan data were gathered and correlated with CEAP classification, other outcome criteria, and tests of venous function. Such studies are still needed in order to evaluate and modify it.

However, in spite of many years of physiologic testing, there is little agreement on universally accepted tests for reflux and obstruction, and although 6 years of venous evaluation using CEAP have brought us closer, we simply do not yet have the data from its use at this point in time to develop a venous scoring system more objectively. We enthusiastically advocate and encourage such correlative studies and sincerely hope they will be forthcoming, but this prospective approach will require considerable time, even if it began immediately. In the meantime, these venous severity scores are offered now to provide additional needed dimensions to comparisons of venous outcomes.

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