

Outcome assessment after varicose veins treatment

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Keywords

Varicose veins, chronic venous disorders, evaluation, severity score, patient reported outcomes, quality of life

Summary

It is a general problem in chronic venous disorders (CVD) that there are very few solid outcomes, and that there is no simple manner to evaluate the severity of the disease. Many items must be taken into account: clinical status, anatomy, haemodynamics, prevention of complications, risk of recurrence, patients' preferences, cost effectiveness, and most of all, patients' main concerns relief.

Assessment through physician reported outcomes has been the most common for decades but a fundamental progress has been made when patient reported outcomes have been described, validated and used. We consider that evaluation – not only of results, but also of the natural history of CVD – cannot be done by a single, physician driven, tool, and that it must include: clinical assessment, instrumental assessment and most of all patient reported outcomes such as quality of life scales. The SQOR-V, developed and validated by our team, serves specifically this latter goal. Use of such an instrument, specifically designed for CVD reduces biases in clinical studies and improves the value of evidences.

Schlüsselwörter

Varizen, chronische Venenerkrankungen, Beurteilung, Schweregrad, Bewertung der Lebensqualität

Zusammenfassung

Ein allgemeines Problem ist, dass es für chronische Venenerkrankungen kaum ein robustes Bewertungskriterium und auch kein Verfahren gibt, mit dessen Hilfe der Schweregrad problemlos beziffert werden kann. Hierbei sind viele Kriterien zu berücksichtigen: Klinik, Anatomie, Hämodynamik, Prävention von Komplikationen, Rezidivrisiko, Präferenzen des Patienten, Kosten/Nutzenverhältnis und vor allem die Linderung der Primärerkrankung des Patienten.

Bisher erfolgte diese Bewertung vorwiegend durch den Arzt. Die Erarbeitung und Anwendung von Verfahren zur Selbstbeurteilung durch den Patienten stellen jedoch einen erheblichen Fortschritt dar. Wir sind der Ansicht, dass sich die Beurteilung chronischer Venenerkrankungen, die nicht nur nach der Behandlung, sondern auch im Krankheitsverlauf selbst erfolgt, auf ein Bewertungssystem stützen muss: klinische und paraklinische Beurteilung sowie vor allem Selbstbeurteilung, z. B. anhand einer Skala zur Bewertung der Lebensqualität. Zu diesem Zweck hat unser Team den Fragebogen SQOR-V entwickelt und validiert. Der Einsatz eines solchen Werkzeugs, das speziell zur Beurteilung chronischer Venenerkrankungen konzipiert wurde, verringert den Umweg über klinische Studien und erhöht den Wert der dabei gewonnenen Ergebnisse.

Mots clés

Varices, affections veineuses chroniques, évaluation, score de sévérité, échelles de qualité de vie

Résumé

C'est un problème général dans les affections veineuses chroniques: il n'y a guère de critère de jugement robuste, et pas non plus de manière simple de chiffrer la sévérité de la maladie. Beaucoup de critères doivent être pris en compte: cliniques, anatomiques, hémodynamiques, prévention des complications, risque de récurrence, préférences des patients, rapport coût-efficacité, et surtout amélioration de la plainte principale des patients.

Le jugement du médecin a été le plus employé à ce jour, mais la description puis l'utilisation d'outils d'évaluation auto administrés par les patients a représenté un progrès majeur. Nous considérons que l'évaluation des maladies veineuses chroniques (non seulement après traitement, mais aussi leur cours naturel), doit reposer sur un faisceau d'éléments: évaluation clinique, para-clinique et surtout auto évaluation, par échelle de qualité de vie par exemple. Le SQOR-V développé et validé par notre équipe a un tel but. L'emploi d'un tel outil, conçu spécialement pour l'évaluation des affections veineuses chroniques réduit les biais des études cliniques et augmente la valeur des preuves.

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Beurteilung der Ergebnisse von Varizenbehandlungen

L'évaluation des résultats dans le traitement des varices

On what criteria can we judge the efficacy of a treatment for varicose veins?

For many diseases, we can find a solid outcome (e. g. reduction of thromboembolic events, survival at five years, limb salvage). The problem with chronic venous disorders (CVD) is that they are chronic, lifelong, unlikely to be lethal and that solid outcomes are (fortunately) rare and late (skin changes and ulcers). For all patients, a good result means satisfaction of the main concerns that can be as different as aesthetics, or fear of an ulcer in an asymptomatic limb by a patient

with family history of ulcers. The absence of a surrogate marker (like blood pressure, blood glucose level, or walking perimeter) is partly responsible for fuzzy evaluation and monitoring which explain both diversity of methods and a certain lack of solid evidences. To this problem we can add the extreme difference between treatment modalities, which cannot be seriously compared (nor allow any blinded study):

- compression alone,
- phlebotropic drugs,
- surgery alone,
- sclerotherapy alone,

- associations of two or more of the previous, etc.

Furthermore, in many cases, different treatments may be equally valid in a single patient, or, conversely, the same treatment may be applied to very different cases. Also, patients' preliminary opinions influence their choice of physician and methods. Other confusing factors include: unpredictable evolution of the disease, and lack of correlation between haemodynamic abnormalities and clinical features.

We do not think that a single evaluation criterion for varicose veins treatment can be

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sufficient, but that the various aspects of the problem must be addressed separately. We do not know what a *good* result is. The only sure thing is that if the patient is not happy with his post therapeutic status, it means a failure. Whether his dissatisfaction is due to complications, or to a lack of improvement of his main concern changes nothing: If you cure the reflux but leave the varicose veins the patient is likely to complain.

The plea for preservation of saphenous trunks for possible vascular grafts complicates the decision since there is no consensus on this matter. A treatment can be *theoretically perfect* but unacceptable or unsatisfactory for the patients. Obviously, *doctors know better*, but times are changing and patients are invited to tell their opinion too.

Patient reported outcomes

When evaluating treatment, the most important is to get the patient's opinion on the result, meaning that his complaints must be understood and improved. D. Revicki observes "*the patient's perspective and patient-reported HRQL (Health Related Quality of Life) is the ultimate outcome for health care interventions*" (12). Due to their clinical symptoms (pain, heaviness, feeling of swelling, cramps, restless legs, paresthesias, etc.), to their signs (reticular varices, telangiectasias, varicose veins, skin changes, ulcers), and to their possible complications (superficial thrombophlebitis, haemorrhage, ulcers), chronic venous disorders are responsible for many potential patients' complaints:

- discomfort,
- restriction of movements and activities,
- bad appearance,
- emotional troubles,
- fear of risk and/or complications.

A global assessment is possible through PRO (patient reported outcomes) measures. In case of evaluation of treatment results, auto-questionnaires provide data that are independent of the physician's appraisal and whose partiality won't be discussed. Until recently, generic – e. g. SF12 (15) – and specific venous – e. g. CIVIQ (7), AVVQ (8) –

Tab. 1 SQOR-V questionnaire in English (4)

N° Patient:
Dear Patient,

we would like to learn more about the effects your leg problems are having on your personal and professional life. Below you will find a number of situations, symptoms, sensations, and discomforts that you may or may not experience, and that may make your daily life more or less difficult. Please answer the questions related to each stated situation, symptom, sensation, or discomfort. For each question, there are five possible answers. Please answer as spontaneously as possible.

Gender male female Year of birth:
Are you employed yes no
If yes, does your job require prolonged standing yes no

Please rate the 5 following items concerning your leg problems from most concerning (1) to least concerning (5):

Discomfort/pain
Appearance/Attractiveness
Risk/threat to your health
Restriction of movement/activities
Emotional distress

Please evaluate the intensity of each symptom for both of your legs:

① if you do not experience this symptom
② if the symptom is mild
③ if the symptom is moderate
④ if the symptom is severe
⑤ if the symptom is extreme

left leg	symptom to be evaluated	right leg
① ② ③ ④ ⑤	Overall discomfort	① ② ③ ④ ⑤
① ② ③ ④ ⑤	Pain	① ② ③ ④ ⑤
① ② ③ ④ ⑤	Heaviness	① ② ③ ④ ⑤
① ② ③ ④ ⑤	Itching	① ② ③ ④ ⑤
① ② ③ ④ ⑤	Night cramps	① ② ③ ④ ⑤
① ② ③ ④ ⑤	Swelling	① ② ③ ④ ⑤
① ② ③ ④ ⑤	Warm or burning sensation	① ② ③ ④ ⑤
① ② ③ ④ ⑤	Tingling	① ② ③ ④ ⑤
① ② ③ ④ ⑤	Stinging or stabbing sensation	① ② ③ ④ ⑤
① ② ③ ④ ⑤	Restless legs	① ② ③ ④ ⑤
① ② ③ ④ ⑤	Worse with heat (improvement with cold)	① ② ③ ④ ⑤

Do your vein problems affect the overall appearance of both of your legs?

Left leg	Right leg
① no	① no
② yes, slightly	② yes, slightly
③ yes, moderately	③ yes, moderately
④ yes, severely	④ yes, severely
⑤ yes, extremely	⑤ yes, extremely

Do you choose your clothing based on your vein problems?

① never ② rarely ③ often ④ usually ⑤ always

Do you choose your activities based on your vein problems?

① never ② rarely ③ often ④ usually ⑤ always

Tab. 1 Fortsetzung

To what extent do your vein problems affect your activities?						
	Does not apply to me	No impact	Slight	Moderate	Severe	Extreme
Overall restriction	<input type="checkbox"/>	①	②	③	④	⑤
... at work	<input type="checkbox"/>	①	②	③	④	⑤
... at home	<input type="checkbox"/>	①	②	③	④	⑤
... sport or leisure activities	<input type="checkbox"/>	①	②	③	④	⑤
... prolonged standing	<input type="checkbox"/>	①	②	③	④	⑤
... prolonged sitting	<input type="checkbox"/>	①	②	③	④	⑤
... when walking	<input type="checkbox"/>	①	②	③	④	⑤
... when using stairs	<input type="checkbox"/>	①	②	③	④	⑤
... during sleep	<input type="checkbox"/>	①	②	③	④	⑤
... social activities	<input type="checkbox"/>	①	②	③	④	⑤
... intimate or sexual relations	<input type="checkbox"/>	①	②	③	④	⑤

When do you experience the most discomfort or pain in your legs?					
	No	Yes, slightly	Yes, moderate	Yes, severe	Yes, extreme
Day and night	①	②	③	④	⑤
Morning	①	②	③	④	⑤
Middle of the day	①	②	③	④	⑤
Evening	①	②	③	④	⑤
At bedtime	①	②	③	④	⑤

Have your leg problems changed in either of your legs since last year?

Left leg	Right leg
① severe worsening	① severe worsening
② moderate worsening	② moderate worsening
③ no change	③ no change
④ moderate improvement	④ moderate improvement
⑤ major improvement	⑤ major improvement

Evaluate the emotional consequences caused by your vein problems:

	No	Yes, slightly	Yes, somewhat	Yes, very	Yes, extremely
Overall emotional consequences	①	②	③	④	⑤
„Because of my vein problems, I am on edge“	①	②	③	④	⑤
„Because of my vein problems, I am irritable“	①	②	③	④	⑤
„Because of my vein problems, I feel like I am a burden to others“	①	②	③	④	⑤

Overall, do your vein problems worry you?

① no	② yes, slightly	③ yes, somewhat	④ yes, a lot	⑤ yes, a great deal
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Does the possible worsening of your vein disease worry you?

① no	② yes, slightly	③ yes, somewhat	④ yes, a lot	⑤ yes, a great deal
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Does the possibility of your condition causing complications worry you?

① no	② yes, slightly	③ yes, somewhat	④ yes, a lot	⑤ yes, a great deal
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Does it worry you that someone related to you suffers from vein disease?

① no	② yes, slightly	③ yes, somewhat	④ yes, a lot	⑤ yes, a great deal
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QoL (quality of life) questionnaires have been used, most of the time in association of one specific and one generic. In a previous study (3), we observed that chronic venous disorders were associated (fig. 1) with an

- impairment of general health status (SF12),
- impairment of specific QoL (CIVIQ),
- increased daytime sleepiness (EP-WORTH questionnaire) and
- depressive symptoms (CES-D questionnaire).

But the administration of such an association of questionnaires is tedious and time consuming. We developed the SQOR-V (specific quality of life and outcome response-venous) (tab. 1) for this precise purpose, and to avoid the administration of two or more forms, initial results have demonstrated its validity (4, 5) and an improvement of sensitivity when compared to AVVQ (13). All specific QoL questionnaires present an only partial correlation with CEAP classes, but this should not be considered as a flaw since the CEAP is a description of venous disorders, not an evaluation of severity. Some patients graded C4 have a lower SQOR-V score than C3 patients, which can be suspected an explanation for a delayed treatment. By the way, CEAP grades should never be used as a criterion of assessment as it is still seen in some studies, it is only a description.

Physician reported outcomes

Clinical

The physician's opinion counts also and, for example, the VCSS associated to the CEAP classification, though requiring further adjustments and refinements (especially in C0s-C3 patients) is useful and reliable. Many publications (2, 9, 14) demonstrate the validity of the VCSS and, for the time being, it can be considered as the principal physician reported outcome. Doctors can, however, gather relevant clinical information which could be inappropriately reported by patients such as bruising, oedema or tenderness.

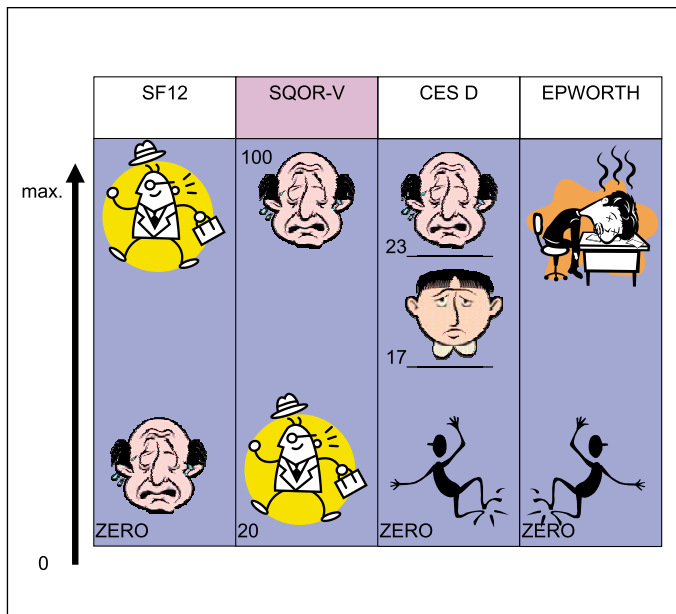


Fig. 1 Generic quality of life questionnaires associate high values to good health status, while with specific QoL, high values are associated with the severity of the disease (SF12: generic health status; SQOR-V: venous patient reported outcome; CES-D: depressive symptoms; EPWORTH: daytime sleepiness). The SQOR-V comprises 45 items in five dimensions (discomfort, aesthetics, limitation of activities, threat for health, emotional problems) and varies between 20 and 100 (5).

Tab. 2 Grading of therapeutic effects of foam sclerotherapy. An example of practical standardized evaluation criterion (instrumental) (simplified from 1).

grading	duplex findings and details	clinical features	symptoms
2 full success	no reflux <ul style="list-style-type: none"> complete disappearance of vein or fibrous cord or complete occlusion or patency with reduced diameter and antegrade flow 	normalized	absent or improved
1 partial success	reflux < 1 s partial incompressibility and partial occlusion and diameter reduction	normalized or improved	absent or improved
0 no success	reflux < 1 s or unchanged complete patency or no change in diameter	unchanged or worsened	unchanged or worsened

Tab. 3 Summarized relevance of most frequently used evaluation criteria.

critical features	CEAP	pain VAS	VCSS	CIVIQ	SQOR-V	duplex	APG	REVAS CLASS	photo analysis
symptoms	X	X	X	X	X				
QoL				X	X				
daily activities			X	X	X				
aesthetics					X	X			X
reflux						X			
vein diameter						X			
VV reservoir					X	X			X
varices removal						X		X	
V ablation						X		X	
V sclerosis						X		X	
recurrence					X	X		X	
global V function							X		

Instrumental

Therapeutic modalities have their respective targets, determined by pathophysiological findings and hypothesis and the effect of the treatment on these targets must also be verified and this is where instrumental evaluations find their place. Suppression of veins, abolition or reduction of reflux, and reduction of diameters, can be assessed by duplex ultrasound, while improvement of calf pump function can be measured by air plethysmography. Depending on the technique, different criteria can be proposed, for example, the 2nd European Consensus on Foam Sclerotherapy (1) has presented comprehensive definitions of results after foam injection (tab. 2). Criteria used in published clinical trials may vary, making standardization necessary. Therapeutic modalities have also very different practical consequences in terms of post treatment pain, number of days off, usual side effects, etc. How to place them into the global equation giving a grade to the entire process remains unclear.

The evaluation of the magnitude of the varicose network, the *reservoir*, remains an unsolved problem so far too. No simple evaluation system exists and if the *volume* of varicose veins is somehow trivial, its description is limited to adjectives varying from *enormous* or *historic*, to *limited* or *insignificant*. We should work on this evaluation and a solution has to be found. Several attempts (11) should undergo validation. Standardized photographic evaluation by independent reviewers (6) or computerized analysis is an option which has been used mostly for reticular and spider veins.

Another difficulty of evaluation of varicose veins treatment (10) is related to the evolution of the disease itself and its recurrences after treatment. Some techniques imply *one time treatments* where most of the varicose veins are addressed in one session or on a short period of time (e. g. surgery), others are *repeat treatments* (e. g. ultrasound guided foam sclerotherapy) including repeat procedures guided by follow-up. In this case, comparison of outcomes and therefore comparison of methods is difficult, except if a global approach like with a PRO is used along the years, since it takes into account all parameters including addi-

tional procedures, recurrences, worsening of the disease, etc.

Last important difficulty is the cost effectiveness. We do not know to what extent the price should be taken into consideration, however, it has a decisive importance and in the close future, it may be the key to the choice, especially when social security authorities will decide for us.

Conclusions

The relevance of commonly used evaluation criteria is summarized in table 3. More research is needed to throw light on difficult points like the volume of the varicose reservoir but we can provide some guidelines. Especially in clinical trials, if a complete evaluation is sought, we recommend to analyze, measure and report:

Before treatment

Patient's needs and concerns, health related quality of life with the SQOR-V auto-questionnaire (PRO), clinical status by VCSS, haemodynamic status of all three venous compartments by duplex scan in standing and recline positions. Global venous function by plethysmogram in selected cases.

After treatment

SQOR-V, VCSS, duplex of three compartments (to control technical efficacy on target veins, and to detect complications) and optional plethysmogram. In addition, other data can be gathered like: immediate post treatment pain with visual analog scale, number of painkillers taken, bruising, cost of the procedure, number of days off work, etc. All this depends on the aims of the study.

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