Evaluation of outcomes in chronic venous disorders of the leg: Development of a scientifically rigorous, patient-reported measure of symptoms and quality of life

Donna L. Lamping, PhD,[a] Sara Schroter, PhD,[a] Xavier Kurz, MD, PhD,[b] Susan R. Kahn, MD, MSc,[c,d] and **Lucien Abenhaim, MD, ScD,[c,d]** *London, United Kingdom; Liège, Belgium; and Montreal, Canada*

Objective: **The purpose of this study was to develop a practical and scientifically rigorous, patient-reported outcome measure to evaluate quality of life and symptoms across the range of conditions (eg, telangiectasias, varicose veins, edema, skin changes, leg ulcers) in chronic venous disorders of the leg (CVDL).**

Methods: **This study was a psychometric study within the VEnous INsufficiency Epidemiological and Economic Study (VEINES), an international, prospective cohort study to evaluate clinical outcomes, quality of life, costs, and use of health services in CVDL. The study was set in the 166 general practices and 116 specialist clinics in Belgium, France, Italy, and Canada (Quebec) that participated in the VEINES study plus in additional specialist clinics in Ottawa and Montreal. Field testing was carried out in three samples of patients in four countries (Belgium, France, Italy, Canada), including participants in the VEINES study (n = 1531) and patients recruited in additional samples of 88 English-speaking patients (Canada) and 53 French-speaking patients (Belgium, France). The reliability and validity sample (n = 615) included 527 VEINES patients and 88 patients from the supplementary English-speaking sample. The test-retest sample (n = 135) included 53 French-speaking and 82 English-speaking patients from the supplementary samples. The responsiveness sample included 1516 VEINES patients. The 26-item VEINES-QOL/Sym is a new, patient-reported questionnaire to evaluate symptoms and quality of life and is available in four language versions (English, French, Italian, French Canadian).**

Results: **Standard psychometric tests confirmed the acceptability (missing data, item endorsement frequencies, floor and ceiling effects), reliability (internal consistency, item-total, inter-item correlations) and validity (content, construct, convergent, discriminant, known groups) of the four language versions of the VEINES-QOL/Sym and the test-retest reliability of the English and French versions and provided preliminary evidence of responsiveness in a pooled language sample.**

Conclusion: **The VEINES-QOL/Sym is a practical and scientifically sound, patient-reported measure of outcomes in CVDL that has been developed with rigorous methods. As the only fully validated measure of quality of life and symptoms that is appropriate for use across the full spectrum of CVDL-related conditions, that is quick and easy to administer, and that is available in four languages, the VEINES-QOL/Sym provides a rigorous tool for improving the evaluation of outcomes in clinical trials, epidemiologic studies, and audit. (J Vasc Surg 2003;37:410-9.)**

Chronic venous disorders of the leg (CVDL) is an umbrella term that encompasses a variety of clinical presentations of chronic venous insufficiency. These presentations include venous symptoms (eg, leg swelling, pain, heaviness), telangiectasias, varicose veins, edema, skin changes, and leg ulcers.[1,2] CVDL is common in the general population,[2-4] and its rate is likely to increase because of population aging.[5] The direct costs of CVDL are high because of its prevalence, morbidity, and chronicity.[1,2,6-8] Substantial indirect costs are also associated with the pain, disability, and distress that characterize CVDL and have a detrimental impact on quality of life.[2]

Treatments for CVDL[1,9] have generally been evaluated solely on the basis of clinical outcomes (eg, signs, symptoms, laboratory tests, and clinical judgments of treatment

From the Health Services Research Unit, Department of Public Health and Policy, London School of Hygiene and Tropical Medicine[a]; the Department of Pharmacology, University of Liege[b]; the Centre for Clinical Epidemiology and Community Studies, SMBD Jewish General Hospital[c]; and the Department of Epidemiology and Biostatistics, McGill University.[d]

Dr Kahn is a Clinical Research Scholar Supported by the Fonds de Recherche en Sante du Quebec.

Competition of interest: This study was carried out as part of the VEINES study, an international research program on chronic venous disorders of the leg supported by an unrestricted grant from IRIS to the Jewish General Hospital (coordinated by Dr Abenhaim). The work reported in this paper is based on an add-on study designed exclusively to develop and psychometrically validate a measure of symptoms and quality of life; it is not a drug study, and no product is mentioned in the text. The unrestricted grant from IRIS provided: salary support to Drs Schroter, Kurz, and Kahn; support for conference attendance to Drs Lamping, Kurz, Kahn, and Abenhaim; and consulting fees to Dr Lamping.

Additional material for this article may be found online at www.mosby.com/jvs.

Reprint requests: Dr Donna L. Lamping, Health Services Research Unit, Department of Public Health and Policy, London School of Hygiene and Tropical Medicine, Keppel St, London WC1E 7HT, United Kingdom (e-mail: donna.lamping@lshtm.ac.uk).

0741-5214/2003/$30.00 + 0
doi:10.1067/mva.2003.152

efficacy, adverse reactions, and compliance[1,2]). A limitation of clinical outcome measures is that they do not directly capture the burden of CVDL or patients' views of impact on quality of life and symptoms. Because patient-reported outcomes are considered a key component in assessment of outcomes,[10] it is important that new treatments are evaluated with scientifically rigorous measures of quality of life and symptoms that are reliable, valid, and responsive.[2,11]

Generic quality-of-life measures, intended for use across different diseases, permit cross-study comparisons and enhance generalizability, whereas disease-specific measures, developed for use in a specific condition to target disease-associated effects, are more responsive in detection of treatment effects.[12] The most commonly used generic measure in CVDL is the SF-36, which has been used to assess outcome in varicose veins[13-15] and leg ulcers.[16-18] Other generic measures include the Nottingham Health Profile, used in four studies of leg ulcer,[17-21] and the EuroQol, used in a study of ulcers.[17] The strength of generic measures is that all are scientifically rigorous measures with proven psychometric properties (ie, reliability, validity, responsiveness). However, generic measures do not give a full picture of the impact of CVDL per se on quality of life. Moreover, previous studies that have used generic measures have investigated quality of life in varicose veins or leg ulcers and not the full spectrum of CVDL.

Disease-specific scales have also been used to evaluate quality of life, but only three of these were developed for use across the range of CVDL-related conditions. Of these, one has not been adequately evaluated for reliability, validity, and responsiveness,[22] and two have not been validated in English.[23,24] In addition to these all purpose measures that are appropriate for use across the full spectrum of CVDL-related conditions, three measures have been developed exclusively for use in leg ulcers[18,25,26] and one in varicose veins.[13,15] Only two of these condition-specific measures show good psychometric properties and can be recommended for use in evaluating quality of life in ulcers[18] or varicose veins.[13,15]

Symptom scales fare poorly in terms of scientific credibility. Four scales have been used to evaluate patient-reported symptoms, including three for use across the range of CVDL-related conditions[27-30] and one for varicose veins.[31] All assess standard CVDL symptoms (eg, pain, heaviness, fullness, swelling, discomfort, itching, cramps, aching legs, sensation of heat/burning, restless legs, paresthesias, tired legs, skin irritation, discomfort during prolonged standing/sitting, and the urge to elevate the legs) but differ in the number of symptoms measured, how these are rated, and whether summary scores are used. Some scales, for example, measure only a few key symptoms, whereas others assess several symptoms. Some evaluate symptoms with global ratings, whereas others use quantitative categoric or visual analogue scales. Some scales provide scores for individual symptoms, whereas others provide summary scores or symptom indexes. The most important limitation of all these scales is that none have been fully evaluated for reliability, validity, and responsiveness. Without evidence of their psychometric properties, none of the currently available measures of symptoms can be considered to be adequately scientifically robust for use in research or clinical practice.

Evidence from the literature[1] and expert opinion[2] confirm the need for a scientifically rigorous measure, which is appropriate across the full spectrum of CVDL-related conditions, to evaluate patient-reported outcomes in clinical trials, epidemiologic studies, and audit. We describe the development and validation of the VEnous INsufficiency Epidemiological and Economic Study (VEINES)–QOL/Sym, a new, patient-reported measure of quality of life and symptoms in CVDL. We used rigorous psychometric methods[32] to guide the development and evaluation of the VEINES-QOL/Sym. These standard scientific methods, borrowed from the social sciences for application in healthcare,[33] allow regulatory bodies, clinicians, researchers, and patient advocacy groups to determine whether an instrument is a "good" measure that provides scientifically credible information. Psychometrics provide well-established scientific methods for measurement of subjective judgments with numeric scales and for evaluation of the quality of measurement scales (ie, acceptability, reliability, validity, responsiveness). Rigorous criteria are now available for evaluation of the scientific robustness of patient-reported health outcome measures[34,35] and have been applied in several areas of medicine and surgery.[36-38] We developed and undertook a thorough psychometric evaluation of the VEINES-QOL/Sym questionnaire as part of the VEINES study, an international, prospective, cohort study to evaluate epidemiology (natural history, risk factors) and outcomes (clinical outcomes, quality of life, costs, health service use) in CVDL.

PATIENTS AND METHODS

Questionnaire development

Development of questionnaire content. We used the following three sources of information to develop the content of the questionnaire: 1, findings from the literature review of patient-reported outcomes in CVDL[1,11]; 2, a review of existing measures of outcome in CVDL; and 3, expert clinical opinion about the problems commonly reported by patients with CVDL.[2] We developed a conceptual model of patient-reported outcomes in CVDL that included two content domains: quality of life and symptoms. We then generated questionnaire items for both domains through consensus discussions with a multidisciplinary expert group of clinicians and methodologists with expertise in CVDL, questionnaire design, psychometrics, and epidemiology. The content and format of questionnaire items and response scales were modeled after the SF-36.[39,40] We modified generic SF-36 questions to make them specific to CVDL and developed new CVDL-specific questions with the same format and response scales of the SF-36. The draft questionnaire was developed in English.

Translation and expert review. Members of the expert group revised the content and format of the English

version of the questionnaire through a formal, independent review of several drafts of the questionnaire. Modifications were made to ensure clarity, consistency, and clinical relevance. The questionnaire then was translated into French (for use in Belgium and France) with standard translation-backtranslation procedures.[41,42] Both the English and French versions were again independently reviewed by the expert group. Final modifications were made, and the questionnaire then was translated into Italian and French Canadian (for use with French-speaking patients in Canada).

Pre-testing with patients. The preliminary versions of the questionnaire were pre-tested by face-to-face interview with a small sample of consecutive patients, selected by one of the study clinicians in each country, to clarify ambiguities in wording, to confirm the appropriateness of response scales, and to determine acceptability and completion time. Modifications to the questionnaires then were made, and final translations agreed.

VEINES-QOL/Sym questionnaire

The 26-item VEINES-QOL/Sym (Appendix, online only) measures the impact of CVDL on symptoms and quality of life from the patient's perspective. Twenty-one items cover symptoms (10 items), limitations in daily activities (9 items), time of day of greatest intensity (1 item), and change over the past year (1 item), and five items cover psychological impact. Responses are rated on 2-point to 7-point response scales of intensity, frequency, or agreement. The time frame for questions about symptoms, daily limitations, and psychological impact is the past 4 weeks, as in the SF-36. The VEINES-QOL/Sym is a patient-based questionnaire that is designed for self completion.

Two summary scores can be computed. The VEINES-QOL summary score (25 items) provides an estimate of the overall impact of CVDL on the patient's quality of life. The VEINES-Sym summary score (10 items) measures symptom severity. This score includes nine CVDL symptoms (heavy legs, aching legs, swelling, night cramps, heat or burning sensation, restless legs, throbbing, itching, tingling sensation), rated on a 5-point scale of frequency (1, every day; 2, several times a week; 3, about once a week; 4, less than once a week; 5, never), and leg pain, rated on a 6-point scale of intensity (1, none; 2, very mild; 3, mild; 4, moderate; 5, severe; 6, very severe; reverse scored). One item (Q2) regarding the time of day that the leg problem is most intense is not included in the summary scores; it provides descriptive information only, which may be of use in epidemiologic research. Three items (Q3, Q6, Q7) are reversed scored so that for both the VEINES-QOL and VEINES-Sym scales, high scores indicate better outcomes.

Because questionnaire items have a varying number of response categories, it is not valid to simply sum items to create summary scores. The VEINES-QOL/Sym uses the standard method for scoring questionnaires with items with different response scales[33] that is now routinely used.[43] Raw scores are first transformed to z score equivalents (mean, 0; standard deviation, 1), which then are transformed to T scores (mean, 50; standard deviation, 10) to give an easily understood range of scores. Scores for missing data are imputed with the same algorithm recommended for scoring the SF-36.[39,40] A person-specific estimate is imputed for any missing item in cases where the patient answered at least 50% of the items in the scale. A computerized scoring program is also available.

VEINES study

The VEINES study is an international, prospective cohort study that evaluated epidemiology (natural history and risk factors) and outcomes (clinical outcomes, quality of life, costs and use of health services) in CVDL.[44,45] Sampling of the study population was based on a prospective registration of 5688 consecutive outpatients from 18 to 75 years of age who consulted 166 general practitioners and 116 specialists (vascular surgeons, phlebologists, angiologists) in four countries. Registered patients at each clinical site were organized into a sampling frame in which all male patients and patients with ulcers were at the top of the list, followed by all other registered patients in random order. Study coordinators then randomly selected study patients from the registered patient sampling frame until target sample sizes were achieved. Male patients and patients with ulcers were deliberately oversampled. A total of 1531 patients, randomly selected from all registered patients, agreed to participate in the VEINES study (n = 484 in Belgium, n = 593 in France, n = 359 in Italy, n = 95 in Canada). Of these, 947 patients were recruited by general practitioners and 584 by specialists. Ethics approval was obtained from the relevant committees in each country, and written informed consent was obtained from all patients before study entry.

Clinical outcomes were assessed at clinical visits at baseline and at 3-month (range, 2 to 6 months) and 12-month follow-up. These included four outcomes evaluated with clinical examination (disease severity, varicose veins, varicose vein–related pain, and edema, defined as pitting edema, and objectively measured edema, assessed with a standardized tape measure device, the Leg-O-Meter).[46] For each of the five clinical outcomes, patients were classified as clinically improved or unimproved (no change, worse) at each follow-up visit. Ulcers also were assessed in the clinical examination, but improvement in this clinical outcome was not included in the psychometric analyses reported in this paper because of insufficient numbers. Disease severity was assessed with the CEAP system[47] (0, no visible or palpable signs of venous disease; 1, telangiectasia or reticular veins; 2, varicose veins; 3, edema; 4, skin changes from venous disease; 5, skin changes with healed ulceration; 6, skin changes with active ulceration). Patients with symptoms alone (eg, heavy legs), without any visible or palpable signs of venous disease but judged by study clinicians to have a possible venous origin, were included in CEAP category 0.

We assessed patient-reported symptoms and quality of life at the same three assessment points with the appropriate language versions of the VEINES-QOL/Sym and

SF-36.[39,40] The SF-36 produces two summary scores: a Physical Component Summary score (PCS) and a Mental Component Summary score (MCS). At baseline, patients completed both questionnaires via postal survey before the clinic visit. At follow-up assessments, questionnaires were given to patients at the clinic visit with instructions to complete them at home and return via post.

Psychometric evaluation of the VEINES-QOL/Sym

We evaluated the psychometric properties of the VEINES-QOL/Sym in extensive field testing in three samples of patients, including 1516 patients from the VEINES study plus additional samples of 88 English-speaking patients in Canada and 53 French-speaking patients in Belgium and France. We also recruited two supplementary convenience samples from specialist clinics in Canada, Belgium, and France to: 1, evaluate the English version of the questionnaire (because only 15 English-speaking patients were included in the VEINES study); and 2, evaluate the test-retest reliability of the English and French versions of the questionnaire.

Reliability and validity sample. Reliability and validity analyses were carried out in a sample of 615 of 657 patients (94%) who provided scorable VEINES-QOL/Sym questionnaires (20% or less missing data). The sample included 88 English-speaking patients recruited through specialists in Canada (Ottawa and Montreal) and 527 patients recruited through specialists in the VEINES study (305 French speakers, including 201 patients from France and 98 patients from Belgium, 143 Italian speakers, and 79 French-Canadian speakers).

Test-retest reliability sample. Test-retest reliability was evaluated for the English and French versions in 53 French-speaking patients, recruited through specialists in Belgium (n = 25) and France (n = 28), and in 82 of the 88 English-speaking patients (93%), recruited through specialists in Canada. Patients completed the VEINES-QOL/Sym via postal survey on two occasions separated by a 14-day to 30-day interval. Six English-speaking patients who did not complete the retest within the specified interval were excluded from the test-retest sample.

Responsiveness sample. Responsiveness was evaluated in the pooled sample of 1516 of 1531 patients in the VEINES study (excluding 15 English-speaking patients). Because evaluation of the responsiveness for individual language versions was not possible because of insufficient sample sizes, we used the same approach to perform analyses on pooled data that has been used in previous psychometric validations of other commonly used international outcome measures.[48] We were unable to evaluate the responsiveness of the English-language version. Only 15 English-speaking patients were included in the VEINES study, and in the supplementary sample of 82 English-speaking patients, responsiveness data were not collected.

The pooled sample for the responsiveness analyses included 484 patients recruited in Belgium, 593 in France, 359 in Italy, and 80 in Canada (excluding 15 English-speaking patients) who were recruited by specialists (n = 569) and general practitioners (n = 947). Patients were included in the responsiveness analyses if they satisfied the following three criteria: 1, less than 20% missing data on the VEINES-QOL/Sym; 2, data available for at least two assessment points for both patient-reported and clinical outcomes; and 3, one of the target clinical conditions used in the responsiveness analyses (eg, varicose veins or edema) or a CEAP score. The third criterion was necessary for evaluation of improvement in clinical condition during the follow-up period.

We used standard psychometric tests and criteria (Table I) to evaluate the acceptability, reliability, validity, and responsiveness of VEINES-QOL/Sym scores.

RESULTS

Respondent characteristics

Table II shows the characteristics of patients in the reliability and validity sample. Most of the sample was female. The proportion of women was highest in the English-speaking (Canadian) and French-speaking (France) samples. Respondents ranged in age from 23 to 75 years (mean age range, 46 to 53 years). Respondents were on average oldest in the Italian sample and youngest in the French-Canadian sample. A higher proportion of patients in the English-speaking (Canadian) sample were in CEAP class 2 (varicose veins), and a lower proportion in CEAP classes 1 (telangiectasia or reticular veins) and 4 (skin changes). Higher proportions of patients in the Italian sample were in CEAP class 3 (edema) and in the French-speaking (Belgium) sample in CEAP class 5 (skin changes with healed ulceration). Table III shows the age and gender of respondents in the responsiveness sample. Over three quarters of the sample were women. Respondents ranged in age from 20 to 75 years (mean, 54 years).

Psychometric properties

Results are reported separately for VEINES-QOL and VEINES-Sym scores for each of the four language versions. Results for the French language version are reported separately for Belgium and France.

Acceptability. All four language versions show good acceptability. Pre-testing indicated that the questionnaire took less than 10 minutes to complete. Table IV shows a low proportion of missing data and low floor/ceiling effects. Examination of item endorsement frequencies (results not shown) showed that responses were well distributed across response categories.

Internal consistency reliability. As shown in Table IV, Cronbach's[49] α coefficients indicate high internal consistency for all four language versions. Values exceed the standard criterion of 0.70. All item-total correlations satisfied the criterion of more than 0.20, ranging from 0.21 to 0.79 for the VEINES-QOL and from 0.22 to 0.82 for the VEINES-Sym.

Test-retest reliability. As shown in Table IV, both the English-language and French-language versions show

Table I. Psychometric tests and criteria

Psychometric property	*Definition/test*	*Criteria for acceptability*
1. Acceptability	Quality of data; assessed with completeness of data and score distributions	Missing data for summary scores <5% Even distribution of endorsement frequencies across response categories Floor/ceiling effects for summary scores <10%
2. Reliability		
2.1 Internal consistency	Extent to which items comprising scale measure same construct (eg, homogeneity of scale); assessed with Cronbach's α[48] and item-total correlations.	Cronbach's α for summary scores >0.70[32] Item-total correlations >0.20[32]
2.2 Test-retest reliability	Stability of measuring instrument; assessed with administering instrument to respondents on two different occasions and examining correlation between test and retest scores*	Test-retest reliability correlations for summary scores >0.80[32]
3. Validity		
3.1 Content validity	Extent to which content of scale is representative of conceptual domain it is intended to cover; assessed qualitatively during questionnaire development stage through pretesting with patients, expert opinion, and literature review	Qualitative evidence from pre-testing with patients, expert opinion, and literature review that items in scale are representative of CVDL
3.2 Construct validity		
3.2.1 Within-scale analyses	Evidence that single entity (construct) is being measured and that items can be combined to form summary score; assessed on basis of evidence of good internal consistency and correlations between scale scores	Internal consistency (Cronbach's α) >0.70 High correlation between VEINES-QOL and VEINES-Sym scores (which purport to measure related aspects of outcome)
3.2.2 Analyses against external criteria		
3.2.2.1 Convergent validity	Evidence that scale is correlated with other measures of same or similar constructs; assessed on basis of correlations between VEINES-QOL/Sym and SF-36 scores	Correlations are expected to vary according to similarity of constructs being measured by each instrument. Specific hypotheses are: because both VEINES-QOL and SF-36 assess quality of life, the two measures should be correlated because VEINES-QOL and SF-36 differ in being disease-specific versus generic, correlations are expected to be in moderate range because VEINES-QOL/Sym items tap more physical than mental aspects, higher correlations are expected between VEINES-QOL and SF-36 PCS (physical) score than with MCS (mental) score higher correlations are expected between VEINES-QOL and SF-36 than between VEINES-Sym and SF-36 because there is less overlap in content between latter two
3.2.2.2 Discriminant validity	Evidence that scale is not correlated with other measures of different constructs; assessed on basis of correlations with age and gender	Low correlations between VEINES-QOL/Sym scores and age and gender
3.2.2.3 Known groups differences	Ability of scale to differentiate known groups; assessed with comparing VEINES-QOL/Sym scores for patients who differ in severity of disease	VEINES-QOL/Sym scores should decrease (ie, poorer quality of life, more frequent symptoms) with increasing severity of disease across CEAP classes
4. Responsiveness	Ability of scale to detect clinically important change over time; assessed by comparing mean scores for change in VEINES-QOL/Sym scores from baseline to follow-up (*t* tests) in patients with conditions defined as clinically improved or unimproved during same period†,‡	Mean scores for change in VEINES-QOL/Sym scores from baseline to follow-up should show improvement/no improvement in patient conditions defined as improved/unimproved according to: clinically measured varicose veins, varicose vein-related pain, and edema; objectively measured (Leg-O-Meter) edema; CEAP scores
	To compare responsiveness of disease-specific VEINES-QOL/Sym with that of a generic measure, we used same methods†,‡ to evaluate responsiveness of SF-36 PCS and MCS scores	Mean scores for change in SF-36 scores from baseline to follow-up should show improvement/no improvement in patient conditions defined as improved/unimproved according to: clinically measured varicose veins, varicose vein-related pain, and edema; objectively measured (Leg-O-Meter) edema; CEAP scores

*Length of test-retest interval must be short enough to ensure that clinical change in symptom being measured is unlikely to occur but sufficiently long to ensure that respondents do not recall their responses from first assessment. Test-retest interval in this study was 14 to 30 days.

†Standard method for evaluating responsiveness is in context of intervention study where pretreatment/posttreatment change scores are used to determine effect sizes. Because VEINES Study is cohort study with no systematic intervention component, we evaluated responsiveness by comparing change in VEINES-QOL/Sym in patient conditions defined as clinically improved or unimproved according to five clinical outcomes.

‡Responsiveness analyses were performed on pooled data from all four countries/language versions because sample sizes for individual countries/language versions were generally not sufficiently large to guarantee robustness of analyses. This approach to performing analyses on pooled data has been used in previous psychometric validations of other commonly used international outcome measures.[47]

Table II. Respondent characteristics: reliability and validity sample (n = 615)

	English-speaking sample (Canada; n = 88)	*French-speaking sample (n = 305)*		*Italian-speaking sample (Italy; n = 143)*	*French Canadian–speaking sample (Canada; n = 79)*
		France (n = 207)	*Belgium (n = 98)*		
Female gender	92%	84%	76%	78%	73%
Age (y)					
Range	28-77	20-75	23-75	23-75	23-74
Mean (standard deviation)	47.5 (12.1)	48.5 (13.1)	47.8 (12.8)	53.1 (12.7)	45.5 (11.8)
CEAP score					
0	0.0%	3.9%	6.1%	6.3%	6.3%
1	2.3%	22.2%	22.4%	17.5%	31.6%
2	67.0%	23.7%	25.5%	19.6%	17.7%
3	8.0%	8.2%	5.1%	16.8%	6.3%
4	6.8%	32.9%	24.5%	32.9%	24.1%
5	0.0%	6.3%	11.2%	3.5%	6.3%
6	0.0%	1.9%	3.1%	1.4%	2.5%
Missing	15.9%	1.0%	2.0%	2.1%	5.1%

Table III. Respondent characteristics: responsiveness sample (n = 1516)

	Pooled sample (n = 1516)	*French-speaking sample (n = 1077)*		*Italian-speaking sample (Italy; n = 359)*	*French Canadian–speaking sample (Canada; n = 80)*
		France (n = 593)	*Belgium (n = 484)*		
Female gender	78%	80%	80%	71%	75%
Age (y)					
Range	20-75	20-75	22-75	23-75	23-74
Mean (Standard deviation)	54.0 (13.8)	52.5 (14.5)	57.0 (13.3)	54.2 (12.7)	46.0 (12.0)

Table IV. Acceptability and reliability of VEINES-QOL/Sym

	English-speaking	*French-speaking*		*Italian-speaking*	*French Canadian–speaking*
		France	*Belgium*		
Missing data					
VEINES-QOL	0%	1%	0%	4%	0%
VEINES-Sym	2%	2%	2%	3%	0%
Floor/ceiling effects (%)					
VEINES-QOL	1/1	1/1	1/1	1/1	1/1
VEINES-Sym	1/6	1/2	1/4	1/3	1/6
Internal consistency (Cronbach's α)					
VEINES-QOL	0.91	0.88	0.92	0.94	0.90
VEINES-Sym	0.87	0.82	0.88	0.87	0.87
Test-retest reliability (ICC)					
VEINES-QOL	0.89	0.89*	–	–	
VEINES-Sym	0.86	0.88	–	–	

*Test-retest data were collected in France and Belgium for French-language version.
ICC, Intraclass correlation coefficient.

good test-retest reliability. All intraclass correlation coefficients were more than 0.85.

Content validity. Content validity was evaluated during the development of the questionnaire. Evidence from pre-testing with patients, expert opinion, and a review of literature supports the content validity of the VEINES-QOL/Sym.

Construct validity (within-scale analyses). Evidence of high internal consistency supports the construct validity of the VEINES-QOL/Sym. High α coefficients (Table IV) and moderately high item-total correlations indicate that a single construct is being measured and that the items can be combined to form summary scores. High intercorrelations between VEINES-QOL and VEINES-

Table V. Convergent and discriminant validity of VEINES-QOL/Sym: correlations with other measures

	English-speaking	*French-speaking*		*Italian-speaking*	*French Canadian–speaking*
		France	*Belgium*		
VEINES-QOL					
SF-36 physical (PCS)	0.61	0.52	0.69	0.73	0.71
SF-36 mental (MCS)	0.19	0.49	0.34	0.55	0.26
Age	–0.22	–0.20	–0.18	–0.25	–0.11
Gender	–0.11	0.02	0.07	–0.15	0.12
VEINES-Sym					
SF-36 physical (PCS)	0.46	0.34	0.48	0.64	0.65
SF-36 mental (MCS)	0.15	0.37	0.24	0.42	0.21
Age	–0.17	–0.09	–0.16	–0.20	–0.22
Gender	–0.19	0.03	0.07	–0.16	0.24

Table VI. Known groups differences validity: mean VEINES-QOL/Sym scores by CEAP classification

	CEAP score†	*English-speaking*	*French-speaking*		*Italian-speaking*	*French Canadian–speaking*
			France	*Belgium*		
VEINES-QOL*	0	–	51.39 (3.7)	55.18 (7.9)	51.06 (7.2)	56.36 (2.9)
		n = 0	n = 8	n = 6	n = 8	n = 5
	1	52.98 (6.1)	51.96 (5.4)	52.66 (5.0)	52.34 (5.0)	53.07 (4.9)
		n = 2	n = 46	n = 22	n = 24	n = 25
	2	50.17 (6.0)	52.05 (4.7)	50.09 (6.1)	51.94 (6.3)	54.20 (3.4)
		n = 59	n = 48	n = 25	n = 28	n = 14
	3	50.69 (7.1)	49.16 (3.6)	48.18 (4.4)	51.12 (6.7)	49.99 (5.8)
		n = 7	n = 17	n = 5	n = 21	n = 5
	4	47.23 (3.1)	51.06 (4.8)	49.93 (6.3)	49.72 (7.0)	51.33 (6.6)
		n = 6	n = 68	n = 24	n = 46	n = 19
	5	–	48.31 (5.7)	46.08 (3.4)	44.07 (5.4)	51.71 (3.5)
		n = 0	n = 13	n = 11	n = 5	n = 5
	6	–	41.07 (4.9)	44.22 (4.2)	45.85 (2.9)	48.03 (2.5)
		n = 0	n = 4	n = 3	n = 2	n = 2
VEINES-Sym*	0	–	52.86 (4.8)	56.52 (6.4)	50.74 (6.4)	56.32 (4.2)
		n = 0	n = 8	n = 6	n = 9	n = 5
	1	59.02 (--)	52.95 (6.6)	53.29 (6.6)	51.52 (5.9)	53.28 (5.5)
		n = 1	n = 46	n = 21	n = 24	n = 25
	2	49.94 (7.1)	52.26 (5.5)	50.59 (6.4)	51.65 (6.7)	53.94 (4.6)
		n = 58	n = 49	n = 25	n = 28	n = 14
	3	50.36 (8.7)	49.33 (3.7)	45.75 (6.5)	49.42 (8.2)	50.20 (6.1)
		n = 7	n = 16	n = 5	n = 22	n = 5
	4	45.56 (5.8)	51.68 (5.2)	50.66 (7.2)	50.22 (7.1)	50.45 (8.1)
		n = 6	n = 68	n = 23	n = 46	n = 19
	5	–	49.69 (6.0)	46.68 (4.0)	43.52 (8.2)	50.27 (4.9)
		n = 0	n = 12	n = 11	n = 5	n = 5
	6	–	49.93 (3.5)	46.51 (3.6)	40.47 (10.3)	45.12 (8.3)
		n = 0	n = 2	n = 3	n = 2	n = 2

Numbers in brackets are standard deviations.
*Higher scores indicate better outcomes. Numbers are less than 615 due to missing data.
†Higher scores indicate more severe disease.

Sym scores ($r = 0.88$, English; $r = 0.88$, France; $r = 0.90$, Belgium; $r = 0.89$, Italian; $r = 0.88$, French-Canadian) support the convergent validity of all four language versions of the two scales.

Construct validity (convergent validity). Table V shows correlations between the VEINES-QOL/Sym and the SF-36. All correlations support hypotheses. The VEINES-QOL/Sym is moderately correlated with SF-36 PCS and MCS summary scores. Second, correlations between the VEINES-QOL and SF-36 are higher for PCS (physical) than MCS (mental) scores. Third, correlations with the SF-36 are higher for the VEINES-QOL than the VEINES-Sym.

Construct validity (discriminant validity). Low correlations between the VEINES-QOL and VEINES-Sym and age and gender (Table V; all correlations ≤ 0.25) support the discriminant validity of both scales. These results suggest that responses to the VEINES-QOL/Sym are not biased in terms of age or gender.

Construct validity (known group differences). Table VI presents mean VEINES-QOL/Sym scores for patients classified by CEAP scores. As hypothesized,

Table VII. Responsiveness of VEINES-QOL/Sym: mean change scores between baseline and final assessments

Clinical outcome	*Clinically improved (n)**	*Clinically unimproved (n)**	P *value*
Clinically measured varicose veins†			
VEINES-QOL	–1.44 (80)	0.29 (810)	.001
VEINES-Sym	–1.66 (79)	0.28 (796)	.003
SF-36 PCS	–0.44 (65)	0.22 (664)	.50
SF-36 MCS	–1.30 (65)	–0.50 (664)	.55
Varicose vein–related pain†			
VEINES-QOL	–0.87 (129)	1.20 (162)	.000
VEINES-Sym	–0.61 (127)	1.40 (156)	.002
SF-36 PCS	0.66 (102)	1.22 (130)	.57
SF-36 MCS	–2.49 (102)	0.66 (130)	.02
Clinically measured edema†			
VEINES-QOL	–0.41 (175)	0.89 (295)	.005
VEINES-Sym	–0.53 (173)	1.21 (286)	.002
SF-36 PCS	–0.87 (145)	0.60 (236)	.07
SF-36 MCS	–0.08 (145)	0.30 (236)	.72
Objectively (Leg-O-Meter) measured edema†			
VEINES-QOL	–0.009 (56)	0.80 (225)	.29
VEINES-Sym	0.39 (57)	0.85 (218)	.62
SF-36 PCS	–1.49 (49)	0.25 (185)	.17
SF-36 MCS	2.06 (49)	–0.41 (185)	.17
CEAP score‡			
VEINES-QOL	0.74 (183)	–0.11 (1034)	.02
VEINES-Sym	0.78 (181)	–0.15 (1018)	.04
SF-36 PCS	1.27 (167)	–0.22 (867)	.02
SF-36 MCS	–1.44 (167)	–0.36 (867)	.20

*Sample sizes vary because target clinical conditions used to evaluate improvement were relevant only to subsample of patients who had target condition.
†Negative change scores indicate improvement.
‡Positive change scores indicate improvement.

VEINES-QOL and VEINES-Sym scores for each of the four language versions show the expected gradient of poorer outcome with increasing disease severity.

Responsiveness. Table VII shows mean change scores for the VEINES-QOL/Sym and SF-36 and tests of differences between change in scores from the first to final assessment for patients with conditions defined as clinically improved or unimproved according to five clinical outcomes. Results show that the VEINES-QOL and VEINES-Sym are both highly responsive to clinical change but that the SF-36 is much less responsive. For four of the five clinical outcomes (change in clinically measured varicose veins, varicose vein-related pain, clinically measured edema, CEAP scores), the VEINES-QOL and VEINES-Sym successfully discriminate between clinically improved and unimproved conditions. By contrast, SF-36 PCS and MCS scores only show responsiveness to change on one of five clinical outcomes (change in CEAP scores and change in varicose vein-related leg pain, respectively). For change in objectively measured edema, neither the VEINES-QOL/Sym nor the SF-36 shows responsiveness to clinical change.

DISCUSSION

Comprehensive assessment of quality of life should include both generic and disease-specific measures that are reliable, valid and responsive.[2,11,12] The VEINES-QOL/Sym is a practical and scientifically sound, patient-reported disease-specific measure of outcome in CVDL that meets standard criteria for acceptability, reliability, validity, and responsiveness. As the only fully validated measure of quality of life and symptoms in CVDL that is appropriate for use across the full spectrum of CVDL-related conditions, is quick and easy to administer, and is available in English and three other languages, the VEINES-QOL/Sym provides a rigorous method for improving the evaluation of outcomes in clinical trials and audit. As a short questionnaire that takes less than 10 minutes to complete, it can be easily incorporated into clinical trials, epidemiologic studies, and routine audit.

This new outcome measure offers a valuable tool for evaluation of the efficacy of new treatments for CVDL because it provides evidence that will be scientifically credible to regulatory bodies, clinicians, researchers, and patient advocacy groups. It will be particularly important in evaluation of outcomes in clinical trials of new drug treatments because decisions about licensing and reimbursement now require the kind of rigorous evidence about patient-reported outcomes provided by the VEINES-QOL/Sym.

CVDL is associated with significant disease burden in terms of pain and suffering, loss of mobility, impairment of function at work and at home, and psychological distress. However, research on these important patient-reported outcomes has been limited by the lack of suitable or scientifically rigorous measures of outcome in CVDL. Although generic measures, such as the SF-36, have proven to be useful, results from this study clearly show the superiority of the disease-specific VEINES-QOL/Sym in detection of clinical improvement. As a more responsive instrument than the SF-36, the VEINES-QOL/Sym holds promise in evaluation of new treatments whose impact may not be detected with less sensitive generic measures.

Although there are well-validated condition-specific measures for varicose veins[13,15] and ulcers,[18] and for related conditions such as deep vein thrombosis,[50] there is the need for an outcome measure that is suitable for use across the full spectrum of CVDL-related conditions. The VEINES-QOL/Sym is the only English-language CVDL-specific measure that is suitable for use across the range of CVDL-related conditions. It therefore permits evaluation of the comparative impact of different clinical manifestations of CVDL, such as ulcers and varicose veins, on quality of life and symptoms in the same study or across studies. Because it is also available in three additional validated language versions, the VEINES-QOL/Sym is particularly well suited for use in international epidemiologic studies and clinical trials.

The VEINES-QOL/Sym has applications in both research and routine monitoring of healthcare. As an outcome measure in clinical trials, it will provide scientifically

credible information about the efficacy of treatment from the patient's point of view. When combined with information about clinical outcomes and costs, rigorous data about important patient-reported outcomes, such as quality of life and symptoms, allow the type of comprehensive evaluation advocated for new treatments in all areas of healthcare.[51] Routine use of the VEINES-QOL/Sym in clinical audit will enable clinicians and managers to evaluate outcomes on a continuing basis. Such information can be used to improve practice by identifying strengths and deficiencies in quality of care.

Our conclusions about the acceptability, reliability, validity, and responsiveness of the VEINES-QOL/Sym are based on the results of field testing in a sample of more than 1600 patients with a broad spectrum of CVDL-related disorders in four countries. Our findings are based on a large, population-based sample of randomly selected patients with self-reported symptoms that is likely to be representative of CVDL in the community. One limitation of the VEINES sample is that despite intentional oversampling of men and limbs with ulceration, the sample remained skewed toward women (78%) and less severe forms of CVDL. This potential sampling bias is, however, of less concern in a psychometric study than in an epidemiologic study. Testing of the VEINES QOL/Sym in other studies would be useful to confirm the psychometric properties of the new measure in independent samples. Another limitation is that case definition and the assessment of clinical outcomes in the VEINES study were with clinical examination without anatomic confirmation of a venous component.

Further evaluation of the ability of the VEINES-QOL/Sym to detect changes in outcome following different treatments of known efficacy would provide useful evidence of responsiveness to specific interventions. Future work should be undertaken to investigate the suitability and psychometric performance of the VEINES-QOL/Sym for use in related conditions, such as deep vein thrombosis, and to compare this new all-purpose CVDL measure with existing condition-specific measures of varicose veins and ulcer-specific measures in these two patient groups. Subsequent studies are also needed to establish population norms in different countries, so that the appropriate population-based weights can be used in place of current sample-specific scoring algorithms and to determine how VEINES-QOL/Sym scores map on meaningful clinical differences. Finally, the test-retest reliability of the Italian and French-Canadian versions and the responsiveness of the four individual language versions of the VEINES-QOL/Sym need further evaluation.

A copy of the VEINES-QOL/Sym and the SPSS scoring program (please provide a blank floppy disk) can be obtained from Dr Lamping.

We thank F. Lert, F. Zuccarelli, and G. Pillion for their contributions as members of the expert group to the development of the VEINES-QOL/Sym. We also thank the following people for their contributions to the main VEINES study: members of the VEINES Task Force, including D. Clement (Belgium), L. Norgren (Sweden), U. Baccaglini (Italy), A. Berard (Canada), J. P. Cooke (United States), A. Cornu-Thenard (France), M. Depairon (Switzerland), J. A. Dormandy (United Kingdom), I. Durand-Zaleski (France), G. R. Fowkes (United Kingdom), H. Partsch (Austria), J. H. Scurr (United Kingdom), and F. Zuccarelli (France); collaborators in the VEINES study, M. Boutsen, J. Brau, A. Claes, A. Dresse, Y. Staelens (Belgium), A. Berard, J. P. Collet, K. Kourad, P. Raymond-Martimbeau (Canada), B. Avouac, H. Boccalon, D. Bry, J. J. Busso, I. Durand-Zaleski, H. Falkoff, G. de Kervella, G. Pillion, P. Serey (France); E. Giraldi, G. Spreafico, P. Pave, M. Piron (Italy); the general practitioners and specialists who provided data; and C. Bobhot, P. Camporese, L. Carfagnini, F. Lipari, and S. Marango for administrative assistance.

REFERENCES

1. Kurz X, Kahn SR, Abenhaim L, Clement D, Norgren L, Bacaglini U, et al. Chronic venous disorders of the leg: epidemiology, outcomes, diagnosis and management: summary of an evidence-based report of the VEINES Task Force. Int Angiol 1999;18:83-102.
2. Task Force on Chronic Venous Disorders of the Leg. The management of chronic venous disorders of the leg: an evidence-based report of an international task force. Phlebology 1999;14(Suppl 1):1-126.
3. Evans CJ, Fowkes FGR, Ruckley CV, Lee AJ. Prevalence of varicose veins and chronic venous insufficiency in men and women in the general population: Edinburgh Vein Study. J Epidemiol Community Health 1999;53:149-53.
4. Fowkes FGR, Evans CJ, Lee AJ. Prevalence and risk factors of chronic venous insufficiency. Angiology 2001;52(Suppl 1):S5-15.
5. Heit JA, Rooke TW, Silverstein MD, Mohr DN, Lohse CM, Petterson TM, et al. Trends in the incidence of venous stasis syndrome and venous ulcer: a 25-year population-based study. J Vasc Surg 2001;33:1022-7.
6. Laing W. Chronic venous diseases of the leg. London: Office of Health Economics; 1992. p. 1-44.
7. Van den Oever R, Hepp B, Debbaut B, Simon I. Socio-economic impact of chronic venous insufficiency: an underestimated public health problem. Int Angiol 1998;17:161-7.
8. Phillips T, Babette S, Provan A, Lew R. A study of the impact of leg ulcers on quality of life: financial, social, and psychological implications. J Am Acad Dermatol 1994;31:49-53.
9. Weingarten MS. State-of-the-art treatment of chronic venous disease. Clin Infect Dis 2001;32:949-54.
10. Quality of life and clinical trials [editorial]. Lancet 1995;346:1-2.
11. Lamping DL. Measuring health-related quality of life in venous disease: practical and scientific considerations. Angiology 1997;48:51-7.
12. Patrick DL, Deyo RA. Generic and disease-specific measures in assessing health status and quality of life. Med Care 1989;27(3 Suppl):S217-32.
13. Garratt AM, Macdonald LM, Ruta DA, Russell IT, Buckingham JK, Krukowski ZH. Towards measurement of outcome for patients with varicose veins. Qual Health Care 1993;2:5-10.
14. Garratt AM, Ruta DA, Abdalla MI, Buckingham K, Russell IT. The SF-36 health survey questionnaire: an outcome measure suitable for routine use within the NHS. Br Med J 1993;306:1440-4.
15. Smith JJ, Garratt AM, Guest M, Greenhalgh RM, Davies AH. Evaluating and improving health-related quality of life in patients with varicose veins. J Vasc Surg 1999;30:710-9.
16. Price P, Harding K. Quality of life [letter]. Lancet 1995;346:445.
17. Walters SJ, Morell JC, Dixon S. Measuring health-related quality of life in patients with venous leg ulcers. Qual Life Res 1999;8:327-36.
18. Smith JJ, Guest MG, Greenhalgh RM, Davies AH. Measuring the quality of life in patients with venous ulcers. J Vasc Surg 2000;31:642-9.

19. Lindholm C, Bjellerup M, Christensen OB, Zederfeldt B. Quality of life in chronic leg ulcer patients. Acta Derm Venereol 1993;73:440-3.
20. Hamer C, Cullum NA, Roe BH. Patients' perceptions of chronic leg ulcers. J Wound Care 1994;3:99-101.
21. Franks PJ, Bosanquet N, Brown D, Straub J, Harper DR, Ruckley CV. Perceived health in a randomised trial of treatment for chronic venous ulceration. Eur J Vasc Endovasc Surg 1999;17:155-9.
22. Franks PJ, Wright DDI, Fletcher AE, Moffatt CJ, Stirling J, Bulpitt CJ, et al. A questionnaire to assess risk factors, quality of life, and use of health resources in patients with venous disease. Eur J Surg 1992;158: 149-55.
23. Launois R, Reboul-Marty J, Henry B. Construction and validation of a quality of life questionnaire in Chronic Lower Limb Venous Insufficiency (CIVIQ). Qual Life Res 1996;5:539-54.
24. Augustin M, Dieterle W, Zschocke I, Brill C, Trefzer D, Peschen M, et al. Development and validation of a disease-specific questionnaire on the quality of life of patients with chronic venous insufficiency. Vasa 1997;26:291-301.
25. Franks PJ, Moffatt CJ, Connolly M, Bosanquet N, Oldroyd M, Greenhalgh RM, et al. Community leg ulcer clinics: effect on quality of life. Phlebology 1994;9:83-6.
26. Hyland ME, Thomson B. Quality of life of leg ulcer patients: questionnaire and preliminary findings. J Wound Care 1994;3:294-8.
27. Motykie GD, Caprini JA, Arcelus JI, Reyna JJ, Overom E, Mokhtee D. Evaluation of therapeutic compression stockings in the treatment of chronic venous insufficiency. Dermatol Surg 1999;25:116-20.
28. Weiss RA, Duffy D. Clinical benefits of lightweight compression: reduction of venous-related symptoms by ready-to-wear lightweight gradient compression hosiery. Dermatol Surg 1999;25:701-4.
29. Beltramino R, Penenory A, Buceta AM. An open-label, randomized multicenter study comparing the efficacy and safety of Cyclo 3 Fort® versus hydroxyethyl rutoside in chronic venous lymphatic insufficiency. Angiology 2000;51:535-44.
30. Rutherford RB, Padberg FT Jr, Comerota AJ, Kistner RL, Meissner MH, Moneta GL. Venous severity scoring: an adjunct to venous outcome assessment. J Vasc Surg 2000;31:1307-12.
31. Bradbury A, Evans C, Allan P, Lee A, Ruckley VC, Fowkes FGR. What are the symptoms of varicose veins? Edinburgh vein study cross sectional population survey. Br Med J 1999;318:353-6.
32. Nunnally JC, Bernstein IH. Psychometric theory, 3rd ed. New York: McGraw Hill; 1994.
33. Streiner DL, Norman GR. Health measurement scales: a practical guide to their development and use, 2nd ed. Oxford: Oxford University Press; 1995.
34. Lohr KN, Aaronson NK, Alonso J, Burnam MA, Patrick DL, Perrin EB, et al. Evaluating quality-of-life and health status instruments: development of scientific criteria. Clin Ther 1996;18:979-92.
35. McDowell I, Jenkinson C. Development standards for health measures. J Health Serv Res Policy 1996;1:238-46.
36. McDowell I, Newell C. Measuring health: a guide to rating scales and questionnaires, 2nd ed. Oxford: Oxford University Press; 1996.
37. Bowling A. Measuring disease: a review of disease-specific quality of life measurement scales, 2nd ed. Buckingham: Open University Press; 2001.
38. Bowling A. Measuring health: a review of quality of life measurement scales, 2nd ed. Milton Keynes: Open University Press; 1997.
39. Ware JE, Snow KK, Kosinski M, Gandek B. SF-36 Health Survey: manual and interpretation guide. Boston: The Health Institute; 1993.
40. Ware JE, Kosinski M, Keller SD. SF-36 physical and mental health summary scales: a user's manual. Boston: The Health Institute; 1994.
41. Guillemin F, Bombardier C, Beaton D. Cross-cultural adaptation of health-related quality of life measures: literature review and proposed guidelines. J Clin Epidemiol 1993;46:1417-32.
42. Ware JE, Keller SD, Gandek B, Brazier JE, Sullivan M. Evaluating translations of health status questionnaires: methods from the IQOLA Project. Int J Technol Assess Health Care 1995;11:525-51.
43. Ware JE, Kosinski M. SF-36 physical and mental health summary scores: a manual for users of version 1, 2nd ed. Lincoln (RI): Quality Metric; 2001.
44. Abenhaim L, Kurz X, for the VEINES Group. The VEINES Study (VEnous INsufficiency Epidemiologic and Economic Study): an international cohort study on chronic venous disorders of the leg. Angiology 1997;48:59-66.
45. Kurz X, Lamping DL, Kahn SR, Baccaglini U, Zuccarelli F, Spreafico G, et al. for the VEINES Study Group. Do varicose veins affect quality of life? Results of an international population-based study. J Vasc Surg 2001;36:641-8.
46. Bérard A, Kurz X, Zuccarelli F, Ducros JJ, Abenhaim L, the VEINES Group. Reliability study of the Leg-O-Meter, an improved tape measure device, in patients with chronic venous insufficiency of the leg. Angiology 1998;49:169-73.
47. Porter JM, Moneta GL. Reporting standards in venous disease: an update. International Consensus Committee on Chronic Venous Disease. J Vasc Surg 1995;21:635-45.
48. Rosen RC, Riley A, Wagner G, Osterloh IH, Kirkpatrick J, Mishra A. The international index of erectile dysfunction (IIEF): a multidimensional scale for assessment of erectile dysfunction. Urology 1997;49: 822-30.
49. Cronbach LJ. Coefficient alpha and the internal structure of tests. Psychometrika 1951;16:297-334.
50. Mathias SD, Prebil LA, Putterman CG, Chmiel JJ, Throm RC, Comerota AJ. A health-related quality of life measure in patients with deep vein thrombosis. Drug Information J 1999;33:1173-87.
51. Jenkinson C, editor. Measuring health and medical outcomes. London: UCL Press; 1994.

Submitted Dec 19, 2001; accepted Aug 13, 2002.

Additional material for this article may be found online at www.mosby.com/jvs.

APPENDIX, ONLINE ONLY

VEINES-QOL

Many people in Canada complain about leg problems. In this survey, we are interested in finding out more about the effects of your leg problem on your daily activities, both at home and at work. This information will give us a better idea about how to treat such problems.

Thank you for participating in this study. This questionnaire includes questions about your health in general and about your leg problem, as well as questions about your life and usual activities. It will take about 10 minutes to complete. All of your answers are confidential. Do not write your name on the questionnaire.

Please answer every question. If you wish to check or change any answer after you have returned your completed questionnaire, please contact either your doctor or Mrs. X at the address below. She is in charge of the survey.

After you have completed the questionnaire, please return it to us by mail in the envelope provided to you or give it to your doctor at the next visit.

Thank you for your help.

For additional information please contact:

Mrs.X

Address:

tél.:

INSTRUCTIONS
HOW TO ANSWER:
Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

Below are some questions about your views about your legs. This information will help keep track of how you feel and how well you are able to do your usual activities.

1. During the past 4 weeks, how often have you had any of the following leg problems?

(check one box on each line)	**Every day**	**Several times a week**	**About once a week**	**Less than once a week**	**Never**
1. Heavy legs	1	2	3	4	5
2. Aching legs	1	2	3	4	5
3. Swelling	1	2	3	4	5
4. Night cramps	1	2	3	4	5
5. Heat or burning sensation	1	2	3	4	5
6. Restless legs	1	2	3	4	5
7. Throbbing	1	2	3	4	5
8. Itching	1	2	3	4	5
9. Tingling sensation (e.g.pins and needles)	1	2	3	4	5

2. At what time of day is your **leg problem** most intense ? *(check one)*

1 On waking
2 At mid-day
3 At the end of the day
4 During the night
5 At any time of day
6 Never

3. Compared to one year ago, how would you rate your **leg problem** in general now? *(check one)*

1 Much better now than one year ago
2 Somewhat better now than one year ago
3 About the same now as one year ago
4 Somewhat worse now than one year ago
5 Much worse now than one year ago
6 I did not have any leg problem last year

4. The following items are about activities that you might do in a typical day. Does your **leg problem** now limit you in these activities? If so, how much ?

(Check one box on each line)		**I do not work**	**YES, Limited A Lot**	**YES, Limited A Little**	**NO, Not Limited At All**
a.	Daily activities at work	0	1	2	3
b.	Daily activities at home (e.g. housework, ironing, doing odd jobs/repairs around the house, gardening, etc...)		1	2	3
c.	Social or leisure activities in which you are standing for long periods (e.g. parties, weddings, taking public transportation, shopping, etc...)		1	2	3
d.	Social or leisure activities in which you are sitting for long periods (e.g. going to the cinema or the theater, travelling, etc...)		1	2	3

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your **leg problem**?

(check one box on each line)		**YES**	**NO**
a.	Cut down the **amount of time** you spent on work or other activities	1	2
b.	**Accomplished less** than you would like	1	2
c.	Were limited in the **kind** of work or other activities	1	2
d.	Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2

6. During the past 4 weeks, to what extent has your leg problem interfered with your normal social activities with family, friends, neighbors or groups? *(check one)*

1 Not at all
2 Slightly
3 Moderately
4 Quite a bit
5 Extremely

7. How much leg pain have you had during the past 4 weeks? *(check one)*

1 None
2 Very mild
3 Mild
4 Moderate
5 Severe
6 Very severe

8. These questions are about how you feel and how things have been with you during the past 4 weeks as a result of your **leg problem**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks -

	(check one box on each line)	**All of the Time**	**Most of the Time**	**A Good Bit of the Time**	**Some of the Time**	**A Little of the Time**	**None of the Time**
a.	Have you felt concerned about the appearance of your leg(s) ?	1	2	3	4	5	6
b.	Have you felt irritable ?	1	2	3	4	5	6
c.	Have you felt a burden to your family or friends ?	1	2	3	4	5	6
d.	Have you been worried about bumping into things ?	1	2	3	4	5	6
e.	Has the appearance of your leg(s) influenced your choice of clothing ?	1	2	3	4	5	6

Thank you for your help.
Please return this questionnaire to us by mail using the envelope provided or give it to your doctor.

Please write today's date: _____/_____/_____ *(day/month/year)*