Do varicose veins affect quality of life? Results of an international population-based study

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Purpose: **This study assessed the impact of varicose veins (VV) on quality of life (QOL) and patient-reported symptoms.**
Methods: **A cross-sectional population-based study was held in 166 general practices and 116 specialist clinics for venous disorders of the leg in Belgium, Canada (Quebec), France, and Italy. Study subjects included a sample of 259 reference patients without VV (CEAP class 0 or 1) and 1054 patients with VV who were classified as having VV alone (367; 34.8%), VV with edema (125; 11.9%), VV with skin changes (431; 40.9%), VV with healed ulcer (100; 9.5%), and VV with active ulcer (31; 2.9%). The main outcome measure was generic and disease-specific QOL, as measured by means of the Short-Form Health Survey-36 (SF-36) and the VEINES-QOL scale, and patient-reported symptoms as measured by the VEINES-SYM scale.**
Results: **In patients with VV, age-standardized mean SF-36 physical (PCS) and mental (MCS) scores were 45.6 and 46.1 in men and 44.2 and 43.2 in women, respectively, compared with population norms of 50. PCS scores decreased according to increasing severity of concomitant venous disease, with the lowest mean scores of 37.3 and 35.5 found in patients with VV and active ulcer. However, adjusted analyses showed no statistically significant differences between patients with VV alone and patients without VV for PCS (0.0), MCS (1.0), VEINES-QOL (–0.1), or VEINES-SYM (0.0) scores. In comparison with patients without VV, the largest differences were seen in patients with VV and edema (PCS, VEINES-QOL, and VEINES-SYM score differences of –1.8, –2.5, and –2.9, respectively) and in patients with VV and ulceration (differences of –3.3, –3.4, and –2.7, respectively). The high prevalence of major symptoms of venous disorders in patients in CEAP class 0 or 1 being treated for venous disorders (76.1% of patients had heaviness, aching legs, or swelling) might have contributed to the impairment of QOL in the reference group.**
Conclusion: **Results indicate that impairment in physical QOL in patients with VV is associated with concomitant venous disease, rather than the presence of VV per se. Findings concerning QOL in patients with VV can only be reliably interpreted when concomitant venous disease is taken into account. In patients with VV alone, the objectives of cosmetic improvement and the improvement of QOL should be considered separately. (J Vasc Surg 2001;34:641-8.)**

Varicose veins are one of the most common medical conditions in the Western world. The estimated prevalence of visible tortuous veins in individuals older than 15 years has been estimated at 10% to 15% in men and 20% to 25% in women.[1] The cost of surgical treatment for the health system is therefore a matter of concern for many regulatory authorities.[2-4] A recent population-based study in Scotland found a poor agreement between symptoms and severity of varicose veins, especially in men.[5] However, it is now widely recognized that the evaluation of disease burden in chronic conditions such as varicose veins must take into account the impact on quality of life (QOL)[6-9] in addition to clinical outcomes such as symptoms.

To date, the few studies that have assessed QOL in patients with varicose veins by the use of standardized and scientifically rigorous instruments[8] have produced conflicting results. Two postal surveys that used the Short-Form Health Survey-36 (SF-36) found that patients with varicose veins reported significantly poorer QOL than general population control subjects,[10] but better QOL than patients with low back pain, menorrhagia, and suspected peptic ulcer.[11] Other studies that have used the SF-36[12,13] and a disease-specific measure[12] reported no significant differences in QOL between patients with varicose veins and the general population.

One explanation of these contradictory results is that no earlier studies have adjusted for the effect of concomitant venous disorders of the leg, such as edema, skin changes, and ulceration, that are frequently associated with varicose veins.[14] Because symptoms and impaired QOL[15-17] may also be the result of concomitant venous disease, it is unknown whether outcomes are attributable to varicose veins per se or to concomitant venous disease of the leg.

We evaluated symptoms and QOL in an international, population-based study of patients with varicose veins, by using generic and disease-specific QOL measures. To

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study the association between outcomes and varicose veins per se, we compared patients with varicose veins alone or in combination with concomitant venous disorders of the leg and patients without varicose veins. Our analyses are based on data from the Venous Insufficiency Epidemiological and Economical Study (VEINES).[18]

METHODS

Study design. The VEINES study was an international, prospective cohort study carried out from 1994 to 1997. The main objective of the study was to compare clinical outcomes, QOL, costs, and use of health services in patients with chronic venous disorders of the leg (CVDL).[18] The study population was based on a prospective registration of 5688 consecutive outpatients, 18 to 75 years old, who consulted 166 general practitioners and 116 specialists in venous disorders in Belgium, Canada (Quebec), France, and Italy. The choice of these countries was guided by means of the socioeconomic part of the study. Data recorded at registration included age, sex, and symptoms and signs of venous disorders of the leg. All men and all patients with an active leg ulcer were entered into the study. The remaining study patients were randomly sampled among the other registered patients, with the aim of recruiting 1600 patients in the four countries. Patients who consented to participate were invited to a baseline visit, which included a medical history and physical examination by the clinician. To obtain independent evaluations of patient-reported QOL and symptoms and physician-based clinical status, we mailed QOL questionnaires to patients for completion before the baseline visit. This study reports on baseline assessments of QOL and clinical data only for the subgroup of patients in the VEINES study with varicose veins, compared with a reference group of patients without varicose veins.

Clinical classification. Patients with varicose veins were identified at the baseline visit by means of clinical diagnosis on the basis of the assessment of the signs of varicose veins (ie, the presence of dilated, elongated, or tortuous veins on either leg). Patients were classified as having (1) varicose veins alone, (2) varicose veins and venous edema, (3) varicose veins and skin changes, (4) varicose veins and healed ulcer, and (5) varicose veins and active ulcer. Each category could include signs present in a lower order category (eg, edema could be present in the category "varicose veins and skin changes"). A reference group of patients without varicose veins was defined by selecting patients in class 0 (no physical signs of venous disorders) or class 1 (presence of telangiectasias or reticular veins only on either leg) of the international CEAP classification.[19]

A history of thrombophlebitis was reported by clinicians at the baseline visit. Specialists were asked to specify the anatomical segment(s) affected by varicose veins: short saphenous, long saphenous, or nonsaphenous. They also had to provide a global rating of the severity of varicose veins by choosing one of these categories: mild, moderate, severe, very severe (categories "severe" and "very severe" were pooled in the analysis because of the small number of observations in the "very severe" category).

Quality of life and patient-reported symptoms. Self-administered generic and disease-specific instruments were used as a means of measuring QOL. We used the generic Short-Form Health Survey-36 (SF-36) to measure physical (PCS) and mental (MCS) QOL.[20] High scores indicated good QOL. We also used the VEINES-QOL, a disease-specific measure of CVDL-related QOL and symptoms that was developed as a part of the VEINES study.[21] The 26-item questionnaire includes 10 items on symptoms of CVDL (heavy legs, aching legs, swelling, night cramps, heat or burning sensation, restless legs, throbbing, itching, and tingling sensation), 9 items on limitations in daily activities caused by CVDL, 5 items on psychological impact, and 2 items on changes in the past year and time during the day of highest symptom intensity. Four language versions (English, French, French Canadian, and Italian) were developed and evaluated in field testing involving 615 patients in four countries. Results confirmed the acceptability (item nonresponse, item endorsement frequencies, item/scale floor and ceiling effects), reliability (internal consistency, item-total and inter-item correlations, test-retest reliability), validity (content, construct, convergent and discriminant validity, known groups), and responsiveness of the four language versions.[21] The VEINES-QOL produces two summary scores: the VEINES-QOL provides an overall estimate of QOL, and the VEINES-SYM provides an overall estimate of CVDL symptom frequency. High scores indicate good QOL.

Statistical analysis. A dichotomous variable was created to indicate the presence or absence of at least one of three major patient-reported venous symptoms on either leg (heaviness, aching legs, swelling). In descriptive analyses, standard statistical tests (χ^2 test and analysis of variance) were used as a means of comparing the distribution and the mean values of a patient variable by clinical category. Mean scores for SF-36 PCS, SF-36 MCS, VEINES-QOL, and VEINES-SYM were computed separately by sex and clinical classification. To estimate QOL in a representative population of patients who were consulting clinicians, we standardized results for men and women in each clinical category by age (18-59 and 60-75 years), with the age distribution of registered patients in the same category as the standard.[22] Scores for all patients with varicose veins were also standardized according to the distribution of registered patients by clinical class of varicose veins. Analysis of covariance[23,24] was used as a means of estimating adjusted differences in PCS, MCS, VEINES-QOL, and VEINES-SYM scores between patients with varicose veins and patients without varicose veins. Analysis of variance was used in preliminary analyses as a means of measuring the strength of association between QOL and each of the these variables: sex, age, body mass index, education, comorbidity (measured by the presence of at least one of these clinician-reported diseases: cardiac disease, chronic respiratory disease, diabetes mellitus, severe hepatic disorder, hypertension, hypothyroidism, lymph-

Table I. Characteristics of study population

	No VV	*VV alone*	*VV and edema*	*VV and skin changes*	*VV and healed ulcer*	*VV and active ulcer*
N	259	367	125	431	100	31
Sex*						
Men	23 (8.9)	90 (24.5)	21 (16.8)	120 (27.8)	31 (31.0)	15 (48.4)
Women	236 (91.1)	277 (75.5)	104 (83.2)	311 (72.2)	69 (69.0)	16 (51.6)
Mean age (SEM)†	43.5 (0.8)	50.4 (0.7)	55.5 (1.3)	60.6 (0.5)	62.1 (1.1)	63.5 (2.0)
Symptoms						
Heaviness	165 (63.7)	279 (76.0)	98 (78.4)	335 (77.7)	85 (85.0)	22 (71.0)
Aching legs	148 (57.1)	249 (67.8)	91 (72.8)	302 (70.1)	78 (78.0)	24 (77.4)
Swelling	94 (36.3)	155 (42.2)	90 (72.0)	259 (60.1)	71 (71.0)	16 (51.6)
Any	197 (76.1)	303 (82.5)	114 (91.2)	368 (85.4)	93 (93.0)	26 (83.9)
History of thombophlebitis*	20 (7.7)	51 (13.9)	31 (24.8)	125 (29.0)	47 (47.0)	18 (58.1)
Compression therapy						
Bandages	5 (1.9)	4 (1.1)	2 (1.6)	20 (4.6)	14 (14.0)	13 (41.9)
Stockings	10 (3.9)	30 (8.2)	10 (8.0)	77 (17.9)	30 (30.0)	6 (19.4)
Tights	19 (7.3)	34 (9.3)	20 (16.0)	54 (12.5)	13 (13.0)	2 (6.5)
Type not specified	4 (1.5)	2 (0.5)	—	1 (0.2)	1 (1.0)	1 (3.2)
Any*	37 (14.3)	69 (18.8)	32 (25.6)	151 (35.0)	56 (56.0)	22 (71.0)

With the exception of age, figures are numbers of patients with percentages in parentheses.
*$P < .05$ for the test of differences in variable distribution by clinical category.
†$P < .05$ for the test of differences in mean age by clinical category.
VV, Varicose veins.

edema, osteoarthritis, peripheral arterial insufficiency of the lower legs, renal insufficiency), country, and type of physician (specialist or general practitioner). A *P* value less than .10 was the criterion used as a means of identifying potential confounders to be adjusted for in covariance analyses. Age and sex were forced into all final models. Because of missing values, the sample size was reduced in models that included education and body mass index. Two categories in the clinical classification, "varicose veins and healed ulcer" and "varicose veins and active ulcer," were pooled in the covariance analyses to increase the sample size in the group of patients with varicose veins and ulcer. Statistics are reported as mean difference scores between patients with varicose veins and patients without varicose veins and 95% CIs.

Sensitivity analyses were carried out on the subsample of patients recruited by specialists to determine the effect of a possible misclassification in the diagnosis of CVDL by general practitioners. This analysis also allowed us to test whether the extent of varicose veins (measured by means of the number of affected anatomical segments and the rating of severity of varicose veins) could explain differences in QOL between patients with varicose veins alone and patients with varicose veins and concomitant venous disorders (edema, skin change, or ulceration). For this purpose, the number of affected segments was represented by a variable with two categories: (1) only one affected segment and (2) two or more affected segments. The association of this variable and of the severity of varicose veins with QOL scores was first tested with analysis of variance. In case of an association with one of the QOL variables (on the basis of $P < .10$), a covariance analysis with patients who had varicose veins alone as the reference group was used as a means of comparing differences in QOL scores in models with and without the variable indicating the extent of varicose veins.

RESULTS

Of 5688 study subjects with CVDL who were registered in 166 general practices and 116 specialist clinics, 1531 were recruited into the VEINES study, including 484 subjects in Belgium, 95 in Canada (Quebec), 593 in France, and 359 in Italy. Of these, 218 had edema, skin changes, or ulceration without varicose veins and were not included in the study population. The remaining 1313 subjects included 259 reference patients without varicose veins and 1054 patients with varicose veins. Patients with varicose veins were classified as follows: 367 (34.8%) with varicose veins alone, 125 (11.9%) with varicose veins and edema, 431 (40.9%) with varicose veins and skin changes, 100 (9.5%) with varicose veins and healed ulcer, and 31 (2.9%) with varicose veins and active ulcer. Among patients without varicose veins, 58 (22.4%) were in class 0 and 201 (77.6%) were in class 1 of the CEAP classification. The numbers of study patients recruited by specialists and general practitioners were 483 (36.8%) and 830 (63.2%), respectively.

Characteristics of the study population are shown in Tables I and II. Heaviness, aching, or swelling was reported by 76.1% of patients in the reference group. The proportion of patients with varicose veins who reported at least one of these symptoms was 85.8% (82.7% of men, 86.9% of women). A history of thrombophlebitis was reported in 22.2% of all patients. This percentage was 47.0% for patients with varicose veins and skin changes and 58.1% for patients with varicose veins and active ulcer. The use of bandages, stockings, or tights was mentioned by 28.0% of patients, ranging from 14.3% (no varicose

Table II. Extent of varicose veins measured in patients recruited by specialists

	VV alone	*VV and edema*	*VV and skin changes*	*VV and healed ulcer*	*VV and active ulcer*
N	128	35	118	37	9
Severity of VV*					
Mild	55 (43.0)	8 (22.8)	18 (15.3)	5 (13.5)	2 (22.2)
Moderate	60 (46.9)	25 (71.4)	65 (55.1)	14 (37.8)	2 (22.2)
Severe/very severe	12 (9.4)	1 (2.9)	33 (28.0)	18 (48.7)	5 (55.6)
Unknown	1 (0.7)	1 (2.9)	2 (1.7)	—	—
Affected segment					
Unknown	3 (2.3)	1 (2.9)	6 (5.1)	—	—
Short saphenous	10 (7.8)	5 (14.3)	18 (15.2)	8 (21.6)	0
Long saphenous	75 (58.6)	20 (57.1)	73 (61.9)	21 (56.8)	6 (66.7)
Nonsaphenous	72 (56.2)	25 (71.4)	74 (62.7)	24 (64.9)	5 (55.6)
Segments affected*					
Only 1	97 (75.8)	19 (54.3)	65 (55.1)	23 (62.2)	7 (77.8)
≥ 2	28 (21.9)	15 (42.8)	47 (39.8)	14 (37.8)	2 (22.2)

With the exception of age, figures are numbers of patients with percentages in parentheses.
*$P < .05$ for the test of differences in variable distribution by clinical category.
VV, Varicose veins.

Table III. Age-standardized SF-36 mental and physical component scores, by sex and clinical category

	No VV	*VV alone*	*VV and edema*	*VV and skin changes*	*VV and healed ulcer*	*VV and active ulcer*
Men						
n	19	80	18	106	27	11
MCS mean (SEM)	47.2 (2.2)	46.2 (0.9)	46.8 (2.4)	45.2 (1.0)	46.2 (1.9)	53.8 (2.4)*
PCS mean (SEM)	45.6 (2.1)	47.6 (1.0)	48.0 (2.3)	45.4 (0.9)	42.9 (1.7)	37.3 (2.5)
Women						
n	205	249	89	254	63	14
MCS mean (SEM)	43.0 (0.8)	43.9 (0.5)	41.8 (1.3)	44.5 (0.7)	40.9 (1.5)	43.4 (3.4)
PCS mean (SEM)	48.3 (0.6)	46.5 (0.5)	43.6 (1.0)	43.6 (0.6)	39.4 (1.2)	35.5 (2.7)

*Estimate based on one patient younger than 60 years and 10 patients 60 years or older.
VV, Varicose veins; *MCS,* mental component score; *PCS,* physical component score.

veins) to 71.0% (varicose veins and ulcer). The severity of varicose veins as assessed by specialists increased with the severity of concomitant venous disorders. About 50% of patients with a healed or active ulcer had varicose veins rated as severe or very severe. The long saphenous and nonsaphenous anatomical segments were the venous segments most frequently affected by varicose veins (59.6% and 61.2%, respectively).

Because of missing values for some items, SF-36 PCS and MCS, VEINES-QOL, and VEINES-SYM scores were available for 1135 (86.4%), 1234 (94.0%), and 1224 (93.2%) patients, respectively. In patients with varicose veins, age-standardized mean PCS and MCS scores were 45.6 and 46.1, respectively, in men and 44.2 and 43.6, respectively, in women, compared with population norms of 50. Age-standardized mean scores for sex and clinical category are shown in Table III. Whereas there is no clear relationship between MCS scores and clinical category for either men or women, PCS scores decreased according to increasing severity of concomitant disease in both men and women (eg, difference in scores of 10 between patients with varicose veins alone and patients with varicose veins and active ulcer). VEINES-QOL and VEINES-SYM scores show a similar pattern (Table IV). Age-standardized mean scores in patients with varicose veins were 50.7 and 50.3, respectively, in men and 49.0 and 49.1, respectively, in women. VEINES-QOL and VEINES-SYM scores were lower in men than in women in all clinical classes.

No significant differences in PCS scores between patients with varicose veins alone and patients without varicose veins (difference, 0.0; 95% CI, –1.6 to 1.6) were shown by means of adjusted covariance analyses (Table V). In the other clinical classes, the largest difference in mean PCS scores was found between patients with varicose veins and healed or active ulcers and patients without varicose veins (–3.3; 95% CI, –5.6 to –1.0). The difference in mean PCS scores between patients with varicose veins and edema and patients without varicose veins approached, but did not reach, statistical significance (–1.8; 95% CI, –4.0 to 0.4). There were no differences in MCS scores between patients with varicose veins in any of the clinical categories and patients without varicose veins.

Table IV. Age-standardized mean VEINES-QOL and VEINES-SYM scores, by sex and clinical category

	No VV	*VV alone*	*VV and edema*	*VV and skin changes*	*VV and healed ulcer*	*VV and active ulcer*
VEINES-QOL in men						
n	21	87	20	116	30	13
Mean (SEM)	51.9 (1.1)	52.6 (0.6)	51.5 (1.4)	50.2 (0.5)	48.5 (1.1)	46.9 (1.5)
VEINES-SYM in men						
n	22	87	19	114	30	12
Mean (SEM)	52.2 (1.1)	52.3 (0.6)	48.9 (1.8)	49.4 (0.6)	48.8 (1.2)	50.3 (1.3)
VEINES-QOL in women						
n	222	259	97	288	67	16
Mean (SEM)	52.0 (0.3)	50.8 (0.3)	47.8 (0.6)	48.7 (0.4)	45.5 (0.8)	43.1 (1.7)
VEINES-SYM in women						
n	220	260	95	284	66	15
Mean (SEM)	52.1 (0.4)	50.9 (0.4)	47.6 (0.7)	48.7 (0.4)	45.9 (0.9)	45.4 (2.1)

VV, Varicose veins.

Table V. Adjusted mean SF-36 physical and mental scores and differences by category of the clinical classification (adjusted covariance analysis)

	*SF-36 PCS**			*SF-36 MCS†*		
Clinical classification	*n*	*Mean*	*Difference (95% CI)*	*n*	*Mean*	*Difference (95% CI)*
1: No signs or telangiectasia alone	194	46.5	0.0	224	45.4	0.0
2: VV alone	284	46.5	0.0 (–1.6 to 1.6)	329	46.4	1.0 (–0.9 to 2.9)
3: VV and venous edema	89	44.7	–1.8 (–4.0 to 0.4)	107	44.9	–0.5 (–3.1 to 2.1)
4: VV and skin changes	322	46.3	–0.2 (–1.9 to 1.5)	360	45.9	0.5 (–1.5 to 2.5)
5/6: VV and healed or active ulcer	100	43.2	–3.3 (–5.6 to –1.0)	115	45.4	0.0 (–2.7 to 2.7)

*Results adjusted for sex, age, body mass index, educational level, comorbidity, country, and type of physician; n = 989 because of missing values for some of the variables.
†Results adjusted for sex, age, country, and type of physician; n = 1135.
VV, Varicose veins; *PCS,* physical component score; *MCS,* mental component score.

Results of the adjusted analyses for VEINES-QOL and VEINES-SYM scores are comparable with those for PCS (Table VI). The difference in VEINES-QOL scores between patients with varicose veins alone and patients without varicose veins was –0.1 (95% CI, –1.1 to 0.9). The largest difference in mean VEINES-QOL scores was found in patients with varicose veins and healed or active ulcers compared with patients without varicose veins (–3.4; 95% CI, –4.9 to –1.9). The largest differences in mean VEINES-SYM scores were found in patients with varicose veins and edema (–2.9; 95% CI, –4.5 to –1.3) or ulcer (–2.7; 95% CI, –4.4 to –1.0) compared with patients without varicose veins.

Comparable results were produced by means of sensitivity analyses performed in the subgroup of patients recruited by specialists. The adjusted differences in mean PCS, MCS, VEINES-QOL, and VEINES-SYM scores between patients with varicose veins alone and patients without varicose veins were –0.1, 2.1, 0.2, and –0.1, respectively. None of these differences was statistically different from zero. In comparison with reference patients without varicose veins, the largest differences in PCS and VEINES-QOL scores were found in patients with varicose veins and ulcer (–3.8 and –3.9, respectively) and in VEINES-SYM scores in patients with varicose veins and edema (–4.2). In patients recruited by specialists, the number of segments affected was associated with concomitant venous disorders (Table I). However, no statistically significant association was found between this variable and any of the four QOL scores used in the study. The severity of varicose veins was significantly associated only with VEINES-QOL ($P < .01$). In the analysis of covariance with patients with varicose veins alone as the reference group and including severity of varicose veins as a covariate, the difference in VEINES-QOL was –2.5 for patients with varicose veins and edema, –1.2 for patients with varicose veins and skin changes, and –3.1 for patients with varicose veins and ulcer. These estimates were –2.5, –1.7, and –4.0, respectively, in a model in which severity of varicose veins was omitted. These results suggest that the extent of varicose veins could explain part of the difference in VEINES-QOL in patients with varicose veins and concomitant venous disorders. This contribution would be modest and not exceed 25% of the total score difference for patients with varicose veins and healed or active ulceration.

Table VI. Adjusted mean VEINES-QOL and VEINES-SYM scores and differences by category of the clinical classification (adjusted covariance analysis)

	*VEINES-QOL**			*VEINES-SYM**		
Clinical classification	*n*	*Mean*	*Difference (95% CI)*	*n*	*Mean*	*Difference (95% CI)*
1: No signs or telangiectasia alone	208	51.7	0.0	207	51.4	0.0
2: VV alone	301	51.6	–0.1 (–1.1 to 0.9)	301	51.4	0.0 (–1.2 to 1.2)
3: VV and venous edema	96	49.2	–2.5 (–3.9 to –1.1)	95	48.5	–2.9 (–4.5 to –1.3)
4: VV and skin changes	361	50.3	–1.4 (–2.5 to –0.3)	355	49.9	–1.5 (–2.8 to –0.2)
5/6: VV and healed or active ulcer	109	48.3	–3.4 (–4.9 to –1.9)	108	48.7	–2.7 (–4.4 to –1.0)

*Results adjusted for sex, age, body mass index, educational level, comorbidity, country, and type of physician; n = 1075 (VEINES-QOL) and 1066 (VEINES-SYM) because of missing values for some of the variables.
VV, Varicose veins.

DISCUSSION

Varicose veins represent a chronic condition that may have an impact on QOL. Earlier research, however, has not examined the effect of varicose veins per se, separately from the effect of concomitant venous disorders of the leg. Results from this study indicate that 65.2% of patients with varicose veins also have concomitant venous diseases such as edema, skin changes, or ulcers. Because concomitant venous diseases may also be associated with symptoms and impaired QOL,[14-17,25] they should be taken into account when evaluating the impact of varicose veins on QOL. The average SF-36 PCS score for women with varicose veins ranged from 47.6 in patients with varicose veins alone to 37.3 in patients with varicose veins and ulcer. Comparable findings were observed for VEINES-QOL and VEINES-SYM scores. Therefore, findings on QOL are meaningful only if they are interpreted in relation to the presence or absence of concomitant venous disorders.

Results show that impairment in physical QOL is associated with concomitant disease, rather than the presence of varicose veins per se. This is particularly apparent when the concomitant disease is a healed or active ulcer. The extent of impairment associated with ulcers is evident through a comparison of SF-36 scores in our sample and US norms. For example, compared with US norms, PCS scores for patients with varicose veins and ulcer (37.5 in men, 35.5 in women) are similar to scores in patients who have limitations in the use of an arm or a leg (37.7) and lower than scores in patients with chronic lung disease (42.3), back pain (43.1), or arthritis (43.2).[20] These data are consistent with findings of other studies that showed impaired QOL in patients with chronic leg ulceration.[15,26,27] These results were confirmed by means of findings based on the VEINES-QOL , a disease-specific measure of QOL that provides scores that are more sensitive to the combination of venous disorders with varicose veins than those provided by the SF-36. In comparison with patients without varicose veins, statistically significant differences in VEINES-QOL and VEINES-SYM scores were observed for patients in all clinical classes, except patients with varicose veins alone. More severe varicose veins in patients with concomitant venous disorders could explain part of the difference in QOL. Results from patients recruited by specialists suggest that this effect is likely to exist only for the specific VEINES-QOL scale and would explain only a small proportion of the observed differences. The second conclusion that can be derived from results on physical QOL is that patients in CEAP class 0 or 1 have a deterioration of QOL that is equal to those patients who have varicose veins alone.

Although there is also evidence of impairment in mental QOL, particularly in women with varicose veins alone and women with concomitant disease, this was true even for the reference group of patients without varicose veins. Compared with US norms (50.0),[20] MCS scores for women without varicose veins (43.0), women with varicose veins alone (43.9), and women with varicose veins with concomitant disease (40.9 to 44.5) were statistically ($P < .05$) and clinically significant. The differences were less pronounced in men. These findings suggest that, in women only, the entire range of venous diseases of the leg, including conditions with symptoms or telangiectasias only, or with varicose veins with and without concomitant disease, is associated with compromised mental QOL.

Study limitations might explain the lack of difference in QOL between patients with varicose veins alone and patients without varicose veins. The study sample was based on patients who consulted clinicians for chronic venous disorders of the leg. The reference group of patients without varicose veins included patients in classes 0 and 1 of the CEAP classification, 77.6% of whom were in class 1. This large proportion of patients with telangiectasia in patients without varicose veins could reduce the difference in QOL scores between patients with varicose veins and patients without varicose veins. However, a high prevalence of telangiectasia or reticular veins is not unusual and has also been found in the Scottish general population (> 80%).[28] Moreover, we are unaware of data showing an effect of telangiectasia on symptoms or QOL.

The high prevalence of any of three major symptoms of venous disorders (heaviness, aching legs, swelling) in the reference group (76.1%) might explain impairment of QOL among these patients. This effect would, however, not account for large differences in QOL scores between patients with varicose veins and ulcer and patients in other clinical categories (eg, varicose veins and edema), despite similar prevalence of major symptoms (> 90%).

We cannot exclude the possibility that telangiectasia or reticular veins have been misclassified as varicose veins, and vice versa, resulting in a reduction of differences in QOL scores between patients with varicose veins alone and patients without varicose veins. However, the sensitivity analyses performed in the subsample of patients recruited by specialists, who are less likely to misclassify varicose veins, showed differences in PCS, MCS, VEINES-QOL, and VEINES-SYM scores of –0.1, 2.1, 0.2, and –0.1, respectively. These results are consistent with those for all patients. We cannot exclude the possibility that the SF-36 and VEINES-QOL scales were not sensitive enough measures for detecting small but relevant differences between groups in aspects such as cosmetic appearance or domains of QOL not assessed by these questionnaires. Further research is needed to identify such domains and assess the impact of varicose veins.

Bradbury et al[5] have shown that the age-adjusted prevalence of symptoms did not differ with the presence and severity of trunk and hyphenweb varices, especially in men. This study provides additional evidence, showing that impairments in QOL are only evident in patients with varicose veins who have concomitant venous disorders, such as venous edema or ulcers. These findings have implications for the treatment of patients with varicose veins. In patients with varicose veins, the objectives of cosmetic improvement and improvement of QOL (including relief of symptoms) should be considered separately. In patients with varicose veins alone without concomitant disease, it may be useful to investigate other medical causes of symptoms and QOL impairment. Controlled clinical trials are, nevertheless, still needed as a means of evaluating the impact of varicose vein treatments on important patient-based outcomes such as QOL and symptoms.

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Information on the VEINES-QOL measure can be obtained from Dr D. Lamping, Health Services Research Unit, London School of Hygiene and Tropical Medicine, Keppel Street, WC1E 7HT, London, UK.

REFERENCES

1. Callam MJ. Epidemiology of varicose veins. Br J Surg 1994;81:167-73.
2. Laing W. Chronic venous diseases of the leg. Studies of Current Health Problem, no. 108. London: Office of Health Economics; Dec 1992.
3. Piachaud D, Weddell JM. The economics of treating varicose veins. Int J Epidemiol 1972;1:287-94.
4. Van Den Oever R, Hepp B, Debbaut B, Simon I. Socio-economic impact of chronic venous insufficiency: an underestimated health problem. Int Angiol 1998;17:161-7.
5. Bradbury A, Evans C, Allan P, Lee A, Ruckley CV, Fowkes FGR. What are the symptoms of varicose veins? Edinburgh Vein Study cross-sectional population survey. BMJ 1999;318:353-6.
6. Fitzpatrick R, Fletcher A, Gore S, Jones D, Spiegelhalter D, Cox D. Quality of life measures in health care, I: applications and issues in assessment. BMJ 1992;305:1074-7.
7. Anonymous. Quality of life and clinical trials [editorial]. Lancet 1995;346:1-2.
8. Lamping DL. Measuring health-related quality of life in venous disease: practical and scientific considerations. Angiology 1997;48:51-7.
9. Ware JE Jr. SF-36 Health Survey: manual and interpretation guide. Boston: The Health Institute, New England Medical Center; 1993.
10. 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.
11. Garratt AM, Ruta DA, Abdalla MI, Buckingham JK, Russel IT. The SF36 health survey questionnaire: an outcome measure suitable for routine use within the NHS? BMJ 1993;306:1440-4.
12. Smith JJ, Garratt AM, Guest M, Greenhalgh MA, Davies AH. Evaluating and improving health-related quality of life in patients with varicose veins. J Vasc Surg 1999;30:710-9.
13. Baker DM, Turnbull NB, Pearson JC, Makin GS. How successful is varicose vein surgery? A patient outcome study following varicose vein surgery using the SF-36 Health Assessment Questionnaire. Eur J Vasc Endovasc Surg 1995;9:299-304.
14. London NJ, Nash R. ABC of arterial and venous disease: varicose veins. BMJ 2000;320:1391-4.
15. Walters SJ, Morrell CJ, Dixon S. Measuring health-related quality of life in patients with venous leg ulcers. Qual Life Res 1999;8:327-36.
16. Callam MJ, Harper DR, Dale JJ, Ruckley CV. Chronic ulceration of the leg: extent of the problem and provision of care. BMJ 1985;290:1855-6.
17. Nicolaides AN. Edema in chronic venous insufficiency and the effect of modern pharmacotherapy. Angiology 2000;51:1-2.
18. 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.
19. 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.
20. Ware JE Jr, Kosinski MA, Keller SD. SF-36 Physical and Mental Component Summary measures: a user's manual. Boston: The Health Institute, New England Medical Center; 1994.
21. Lamping DL, Abenhaim L, Kurz X, Schroter S, Kahn SR, the VEINES Group. Measuring quality of life and symptoms in chronic venous disorders of the leg: development and psychometric evaluation of the VEINES-QOL/VEINES-SYM questionnaire. Qual Life Res 1998;7:621-2.
22. Rothman KJ, Greenland S. Modern epidemiology. 2nd ed. Philadelphia: Lippincott-Raven Publishers; 1998. p. 45.
23. Anderson S, Auquier A, Hauck WW, Oakes D, Vandaele W, Weisberg HI. Statistical methods for comparative studies: techniques for bias reduction. New-York: John Wiley and Sons; 1980. p. 140.

24. Kleinbaum DG, Kupper LL, Muller KE. Applied regression analysis and other multivariate methods. 2nd ed. Boston: PWS-Kent Publishing; 1988.
25. Abenhaim L, Norgren L, Clement D, the VEINES Task Force. The management of chronic venous disorders of the leg (CVDL): an evidence-based report of an international task force. Phlebology 1999;14 Suppl 1:1-123.
26. Price P, Harding K. Quality of life. Lancet 1995;346:445.
27. Smith JJ, Guest MG, Greenhalg RM, Davies AH. Measuring the quality of life in patients with venous ulcers. J Vasc Surg 2000;31:642-9.
28. Evans CJ, Allan PL, Lee AJ, Bradbury AW, Ruckley CV, Fowkes FG. Prevalence of venous reflux in the study population on duplex scanning: the Edinburgh Vein Study. J Vasc Surg 1998;28:767-76.

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