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International Psychometric Validation of the Chronic Venous Disease Quality of Life Questionnaire (CIVIQ-20)

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Abstract *Objective:* To review the psychometric validation of the Chronic Venous dIsease quality of life Questionnaire (CIVIQ-20) in the countries that have used it since 1996.
Design: Prospective, clinical, international study in 18 countries.
Patients: Patients with venous disease of the lower limb in the clinical, aetiological, anatomical and pathophysiological (CEAP) clinical stages C0s to C4 presenting to surgical outpatient departments and general practices and receiving drug treatment for 6 months.
Methods: Quantification of symptoms on a four-point scale and pain on a visual analogue scale, and self-administration of CIVIQ-20 to patients before visit (baseline, 2, 4 and 6 months).
Results: In 3956 patients, CIVIQ-20 showed good internal consistency and reliability (above 0.80) through test–retest correlations. The discriminating power of items was good in known groups of patients. Factor analysis identified physical, psychological and pain factors as important, but revealed instability of the social factor. CIVIQ-20 was highly sensitive to changes in the quality of life of patients clinically improved after drug treatment. CONCLUSION: CIVIQ-20 is valuable in assessing treatment effects in longitudinal, multinational studies, but comparisons of different populations should use the global score rather than scores per dimension.

The World Health Organization has defined quality of life (QoL) as a state of complete physical, mental and social well-being, and not merely the absence of disease. Determination of QoL has been accorded increasing scientific attention in recent years, mainly because the question of direct benefit of medical treatment for patients has been raised.

Chronic venous disease (CVD) needs specific scales of measurement for many reasons. First, it is common;[1] second, physicians usually underestimate the negative impact CVD may have on patients' daily life;[2] and third, as

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fashion tends to draw attention to women's legs, blemishes caused by CVD may add social impairment to the physical and psychological ones. A 20-item self-reported scale was created and validated in France in 1996,[3] as a sensitive instrument to capture the key dimensions of QoL specifically impaired by CVD: the ChronIc Venous dIsease quality of life Questionnaire (CIVIQ-20). In the original French version, the five conditions required for validation (relevance, acceptability, reliability, construct validity and sensitivity) were met. Four dimensions of the CIVIQ-20 were identified: physical (four items), psychological (nine items), social (three items) and pain (four items). Details of the phases of its development are described elsewhere.[3] The CIVIQ-20 was validated in its French version and thus could not be generalised to other countries.

Objective of the Study

The purpose of the present analysis, therefore, was to review the psychometric validation of CIVIQ-20 through the Reflux assEssment and quaLity of lIfe improvEment with micronised Flavonoids (RELIEF) study.

RELIEF was a prospective, clinical, epidemiological, multicentre, international study, the primary objective of which was the assessment of the clinical effect of drug therapy, while the secondary objective was the measurement of the quality of life (QoL) of patients before and after drug treatment with micronised, purified flavonoid fraction (MPFF, Daflon 500 mg, Servier, France). Clinical and QoL results of the RELIEF study are published elsewhere.[4]

In the present analysis, we focussed exclusively on QoL parameters by verifying that the psychometric properties of CIVIQ-20 in the country of origin (France) were also found in the 18 countries of the RELIEF study (Argentina, Brazil, Brunei, Czech Republic, Egypt, Hong Kong, Hungary, India, Malaysia, Philippines, Poland, Russia, Singapore, Slovakia, Spain, Sri Lanka, Turkey and Venezuela).

Method

From February 1997 to February 1999, patients with CVD-related symptoms and/or signs, who presented in surgical outpatient departments and who signed an informed consent form, participated in the QoL section of the RELIEF study. CVD signs were reported according to the clinical, aetiological, anatomical and pathophysiological (CEAP) classification, which categorises affected legs into seven clinical classes designated C0s to C6.[5] Only patients over 18 years of age and clinically defined as C0s to C4 were included.

Before each visit, patients completed the self-questionnaire CIVIQ-20 in the waiting room at the selection visit (day −15), day 0 (day of treatment start with 1000 mg of MPFF daily for 6 months), day 60, day 120 and day 180. The secretary handed out the questionnaire and collected it once completed. No particular assistance was to be provided to patients. This procedure was chosen on purpose to avoid any interference from an investigator.

At study times, symptom severity was quantified using a four-point scale (0 = absent, 1 = mild, 2 = significant, 3 = severe) for sensation of swelling, cramps and leg heaviness. Leg pain was assessed with a 10-cm visual analogue scale.

The scores of CIVIQ-20 ranged from 0, the worst score, to 100, the best score.

Statistical Analysis

Statistical analysis was carried out by MAPI Values (Lyon, France) on an IBM-compatible computer using SAS software release 6.12 (SAS Institute, Cary, NC, USA).

Results

Patient characteristics

At baseline, the majority of the 4048 patients enrolled in the QoL study were of Caucasian ethnic origin (77.9%), women (81.1%), professionally active (61.8% were employed full-time) and mean age 45.6 standard deviation (SD) 12.3 years. They had experienced CVD for 12.4 SD 9.8 years and were defined as C0s—C2 of the CEAP clinical classification in 60.4% of cases and C3—C4 in 39.4%. The most frequently encountered complaints were pain (99.5% of patients) and heaviness (94%), sensation of swelling (78%) and cramps (69%). Using the four-point scale, heaviness was scored 3 or 4 (severe or significant) in 57.2% cases while swelling and cramps were usually of mild intensity or even not present (67.8% and 70%, respectively, were scored 0 or 1). As regards pain, the mean value at baseline was 3.8 SD 2.5 cm on visual analogue scale.

Acceptability

The acceptability of a questionnaire depends on the quality of its construction. The acceptability of CIVIQ-20 was assessed from the response rates to each of the questions and by the number of questionnaires completed.

All 4048 patients completed CIVIQ-20 at least once. Only 53 did not complete it at baseline and were removed from the database. Out of the 3995 patients with a usable baseline questionnaire, 91.5% (n = 3656) had five usable QoL assessments (one assessment at each of the five planned visits) and 99.0% (n = 3956) had at least one other usable CIVIQ-20 after baseline and could therefore be included in the longitudinal analyses.

As regards the responses of the 4048 patients who completed CIVIQ-20 at least once, the following results were obtained: 8.0% (D0—day 0) and 12.6% (D180—day 180) of the questionnaires had at least one missing value, and the average percentages of missing data by item were 1.67% (D0) and 7.34% (D180).

Reliability

A scale is reliable if it produces similar results in measuring the same phenomenon on a number of occasions. Internal consistency and test—retest reproducibility are commonly used to determine reliability.

Internal consistency

Internal consistency verifies that items in a dimension remain homogeneous even if they are worded differently. It is assessed using Cronbach's alpha coefficients, which are considered acceptable if >0.70. CIVIQ-20 gave a Cronbach's alpha coefficient of 0.94 for the global index, and 0.86, 0.89, 0.83 and 0.76, respectively, for the physical, psychological, pain and social dimension. These results confirm the satisfactory internal consistency of the scale, but display less homogeneity for the social dimension items than for those of the other dimensions. A floor effect was seen in 0.9—8.5% of patients, and a ceiling effect in 0.0—0.3%, meaning that most items dealing with the disease are covered by the scale.

Test—retest reproducibility

Reproducibility means that the answers to the same questionnaire remain unchanged in clinically stable patients. It was assessed over the washout period (between D—15 and D0) in stable patients, that is, patients for whom symptoms did not improve or deteriorate, and CEAP class remained stable during this period. The number of patients qualified as stable ranged from 3749 (unchanged CEAP clinical stage) to 3147 patients (unchanged heaviness score). In general, 2406 patients (61%) qualified as stable over the screening period. Retest reliability showed a high correlation, $r > 0.80$, in dimension scores at a 2-week interval (Table 1).

Construct validity

An instrument is said to be accurate when there is a congruence between the measuring operations and the theoretical items these operations are designed to measure.

Multi-trait/multi-item analysis

The multi-trait/multi-item matrix analyses the correlation of each item with its own dimension. For each item, two correlation coefficients are calculated: *R*1 assesses the correlation between an item and the dimension it belongs to, and *R*2 the correlation with the other dimensions. If *R*1 is >0.40, the convergent validity between an item and its dimension is considered as good. If *R*1 is >*R*2, the item matches its dimension and its discriminating validity is good. As shown in Table 2, all items correlate successfully with the dimension they belong to ($R1 > 0.40$ for all items, success rate: 100%), meaning that the scale structure of CIVIQ-20 is good. Regarding the discriminating validity of the items, all but two items correlate with their own dimensions ($R1 > R2$). The success rate (SR) was 100% for the items in the physical and psychological dimensions. Weaknesses were found in the social dimension (SR 67%) and pain dimension (SR 75%).

In the Czech Republic, Poland, and Spain, all item-scale correlations were higher than 0.40, confirming the good convergent validity. Flaws were seen in the discriminating validity of items mainly in the social dimension for which SR was 67%, 0% and 33%, respectively in Czech Republic, Poland and Spain, while SR for items in the other dimensions ranged from 75% to 100%. These analyses questioned the match between the set of items in CIVIQ-20 and the social dimension.

Factorial structure

To confirm the factorial structure of the instrument, principal axis factoring with Promax rotation was performed with a four-factor model, the number of factors corresponding to the number of dimensions in CIVIQ-20. Fifty-seven percent of the variance was explained (Table 3). The first factor has three items from the original definition and can be interpreted as physical, but is not fully consistent with the initial definition of the physical dimension of CIVIQ-20 since one item was from the original psychological dimension ('to get tired easily') and two were from the social dimension ('to go out in the evening' and 'to practice a sport'). The second factor can be seen as psychological, with loading of seven of the nine items from the original psychological dimension of CIVIQ-20. The four items from the original pain dimension load on the third factor, which can be clearly identified as pain. The fourth factor is mixed, with one item of the original social dimension and two items from other dimensions of the CIVIQ-20 (physical and psychological).

Principal axis factoring was applied separately to the data from Czech Republic, Poland and Spain. In Czech Republic and Poland, factors 1, 2 and 3 might be interpreted respectively as physical, psychological and pain factors, with most items from the original dimensions of CIVIQ-20 loading on these factors (three out the four for the physical, eight of the nine for the psychological and four for the pain dimension), but the fourth factor could not be interpreted. In Spain, factors were not easy to interpret as many items were mixed.

Table 1 Test—retest reproducibility of the CIVIQ-20 global index according to the clinical parameters of the RELIEF study.

Clinical parameter	Number of stable patients	Change[a] in global index		
	(MD)	(Mean and SD)	ICC	*P* value
CEAP ($N = 3749$)	3635 (114)	0.59 SD 6.74	0.9319	0.0001
Swelling ($N = 3250$)	3153 (97)	0.64 SD 6.40	0.9385	0.0001
Heaviness ($N = 3147$)	3050 (97)	0.62 SD 6.10	0.9441	0.0001
Cramps ($N = 3075$)	3069 (96)	0.43 SD 6.20	0.9427	0.0001
Pain ($N = 3714$)	3605 (109)	0.57 SD 6.47	0.9376	0.0001
All parameters together ($N = 2406$)	2339 (67)	0.54 SD 5.38	0.9561	0.0001

[a] Change was expressed by the difference between Global Index (GI) at selection (D-15) and GI at baseline (D0); MD, missing data; SD, standard deviation; ICC: intra-class correlation coefficient.

Table 2 Multi-trait/multi-item analysis of the CIVIQ-20 in the 18 countries of the RELIEF Study.

	Physical dimension	Psychological dimension	Social dimension	Pain dimension
Physical items	*R*1	*R*2	*R*2	*R*2
1 To climb stairs	++	−	−	−
2 To crouch/to kneel	++	−	−	−
3 To walk briskly	++	−	−	−
4 To do the housework	+	−	−	−
Psychological items	*R*2	*R*1	*R*2	*R*2
1 Feel on edge	−	++	−	−
2 Get tired easily	−	++	−	−
3 Feel like a burden to people	−	++	−	−
4 Must take precautions	−	++	−	−
5 Embarrassed to show one's legs	−	+	−	−
6 Easily irritable	−	++	−	−
7 Feel handicapped	−	++	−	−
8 Difficulty getting going in the morning	−	++	−	−
9 Do not feel like going out	−	++	−	−
Social items	*R*2	*R*2	*R*1	*R*2
1 To go out in the evening	−	−	++	−
2 To practice a sport	++	−	+	−
3 To travel by car/bus/plane	−	−	++	−
Pain items	*R*2	*R*2	*R*2	*R*1
1 Pain in legs	−	−	−	++
2 Interferes with work	−	−	−	++
3 Sleep badly	−	−	−	+
4 To stand for a long time	++	−	−	+
Convergent validity (*R*1>0.40)	100%	100%	100%	100%
Discriminating validity (success rate of *R*1>*R*2)	100%	100%	67%	75%

Correlation factors: *R*1, correlation between an item and its own dimension: +, >0.40; ++, >0.60; *R*2, correlation between an item and a dimension other than its own: +, >0.40; ++, >0.60; *R*1>*R*2 is marked by −.

The factorial structure of CIVIQ-20 lacks stability, more particularly with regard to the social dimension.

Known group differences

To verify whether the scale is able to discriminate between severity states of chronic venous disease, we used Spearman's correlation coefficient to search for significant negative associations in stable patients (between day −15 and day 0) with known differences in symptom scores and CEAP classes at baseline. Significant associations ($P = 0.0001$) were found in all groups of patients (Table 4). For all clinical parameters, the highest association was found in the 'pain dimension'. The highest association ($r = -0.46400$) was observed with the visual analogue scale pain parameter (not shown), and the lowest with the CEAP.

For the four dimensions and for the global index (GI), a significant difference was seen in the mean scores according to the CEAP clinical classes at baseline. The mean variation of GI between C0s and C4 was 16 points (Table 5).

Responsiveness

Longitudinal changes in CIVIQ-20 scores after treatment

One important aspect of QoL scales is their ability to reflect changes in the clinical variables that occur during treatment.

The end points used for clinical improvement after treatment were decrease in CVD-related symptoms and change in CEAP class. Improvement in swelling, heaviness and cramps was defined as a decrease of at least one point on the four-point scale. For pain, a decrease on the visual analogue scale of 2.5—5 cm and of more than 5 cm was used for improvement and great improvement, respectively. As regards the clinical signs, their improvement was assessed by a decrease of one class of the CEAP. Of the 3956 patients included in the longitudinal analysis between day 0 and day 180, on average, 63.3% had improved symptoms, 34.4% were stable and 2.3% had worsened; 80.2% were stable as regards the CEAP, 18.1% had improved and 1.7% had worsened. This confirms that the CEAP cannot serve the purpose of quantifying changes in response to treatment.

All patients included, the GI of CIVIQ-20 was a mean of 64.1 SD 18.5 at day 0, 73.1 SD 17.2 at day 60, 78.2 SD 16.3 at day 120 and 82.1 SD 15.7 at day 180, meaning that the patients' QoL improved overall after treatment (18 points on GI between D0 and D180; $P < 0.0001$). The greatest QoL improvement was seen after 2 months, but increased further after 4 and 6 months. The highly statistically significant differences in scores ($P < 0.0001$) between day 0 and day 180 were 18.80 for 'physical', 14.11 for 'psychological', 17.17 for 'social' and 24.63 for 'pain'.

Table 3 Factorial structure of the CIVIQ-20 in the 18 countries of the RELIEF study.

Principal axis factoring-EQUAMAX-PAIRWISE-KMO = 0.96% of variance explained = 57%	Factor 1	Factor 2	Factor 3	Factor 4
Physical items				
1 To climb stairs	++	−	−	−
2 To crouch/to kneel	++	−	−	−
3 To walk briskly	++	−	−	−
4 To do the housework	−	−	−	+
Psychological items				
1 Feel on edge	−	+	−	−
2 Get tired easily	+	−	−	−
3 Feel like a burden to people	−	++	−	−
4 Must take precautions	−	−	−	+
5 Embarrassed to show one's legs	−	+	−	−
6 Easily irritable	−	++	−	−
7 Feel handicapped	−	++	−	−
8 Difficulty getting going in the morning	−	+	−	−
9 Do not feel like going out	−	+	−	−
Social items				
1 To go out in the evening	+	−	−	−
2 To practice a sport	+	−	−	−
3 To travel by car/bus/plane	−	−	−	+
Pain items				
1 Pain in legs	−	−	++	−
2 Interferes with work	−	−	++	−
3 Sleep badly	−	−	+	−
4 To stand for a long time	−	−	+	−

Factor loadings: −, ≤0.40; +, >0.40; ++, >0.60.

In clinically improved patients, a parallel increase of CIVIQ-20 scores was found over time after treatment and was correlated with clinical improvement (Table 6).

Sensitivity (effect size)

A scale is considered sensitive when it detects changes in a given variable over time and above the imprecision due to measurement error. The sensitivity to change over time was assessed by the effect size.[6] Table 6 shows effect sizes ranging from 1.24 for heaviness to 1.73 for pain.

Discussion

Numerous specific scales for CVD have been developed in the past 20 years. This may reflect the difficulty of finding an instrument applicable to the wider spectrum of CVD.

Most of the scales have been used for longitudinal comparison in randomised clinical trials. These scales must be able to detect important changes in the patients' QoL after intervention.

The responsiveness of CIVIQ-20 is good and its sensitivity to change high, particularly in the pain dimension. Nevertheless, the demonstration of the responsiveness of CIVIQ-20 related only to symptom improvement as shown in Table 6; other quantifiable variables able to change with therapy would have been welcome. It is unfortunate that the quantifiable disease severity scoring system, which could have served this purpose, was proposed by Rutherford after the RELIEF study was set up,[7] so that at the time of the study, symptoms were the only clinical parameters that were able to change with pharmacological treatment.

The CIVIQ-20 is well suited to longitudinal studies as it is relatively short, has a five-point Likert scale format making

Table 4 Known group differences at baseline according to symptoms and signs.

Clinical parameter	Global Index (mean and SD) in patients suffering from CVD of		Spearman's correlation coefficient	*P* value (Wilcoxon)
	Mild[a]	Severe[b]		
CEAP	68.1 SD 19.1	59.1 SD19.9	−0.22032	0.0001
Swelling	73.8 SD 15.1	45.7 SD 19.4	−0.38561	0.0001
Heaviness	77.9 SD 15.4	47.8 SD 19.1	−0.41706	0.0001
Cramps	71.5 SD 16.7	52.2 SD 20.5	−0.33244	0.0001

[a] Mild was defined as follows: clinical CEAP classes, C0s to C2; swelling, heaviness, cramps, scored 0 or 1.
[b] Severe was defined as follows: clinical CEAP classes, C3 to C4; swelling, heaviness, cramps, scored 3 or 4.

Table 5 Known group differences at baseline according to the clinical CEAP classes.

Clinical CEAP class	Physical dimension	Psychological dimension	Social dimension	Pain dimension	Global Score
C0s ($N = 103$)	66.90	75.48	69.19	60.53	70.06
C1 ($N = 730$)	67.13	72.95	70.65	58.42	68.49
C2 ($N = 1557$)	66.34	72.01	69.70	58.16	67.84
C3 ($N = 1028$)	57.66	64.29	60.40	50.75	59.70
C4 ($N = 522$)	54.60	62.21	59.03	50.82	57.95
P (ANOVA)	<0.001	<0.001	<0.001	<0.001	<0.001

it more sensitive than a binary response format and has no items showing a floor or ceiling effect. Thus, the ability of CIVIQ-20 to detect change makes it a good QoL scale for use in randomised clinical trials. This is confirmed by extensive use of CIVIQ-20 in recent years, to compare the effect of surgery techniques for varicose veins,[8–14] or after venous stenting,[15] or to assess the efficacy of compression therapy,[16,17] vein electrostimulation,[18] drug therapy,[4,19–21] or physical therapy.[22] Most of these trials were conducted in C2 to C5 patients. Some included C0s and C1 patients,[4,16–18,21] but none include C6 patients. This is because the scale was deliberately not targeted towards patients with venous ulcers, as items that are relevant to patients with varicose veins or oedema do not fit patients with venous ulcer. While most C0s to C4 patients report limited social or physical activities and psychological frustration such as not being able to do sport or to travel by bus or plane, and feel embarrassed to show their legs; patients with ulcers, who are elderly for the most, are less likely to complain about such things. It is questionable whether it is realistic to require the construction of a single scale with a set of items covering the full spectrum of CVD. As pointed out by Hyland, "QoL scales are not like thermometers or spirometers, where the reading is independent of the type of patient."[23]

Regarding its psychometric properties in the 18 countries of the RELIEF study, CIVIQ-20 has been shown to be acceptable to patients and easy to complete, to have a high level of reliability and to provide good discrimination between the severity of symptoms and the clinical CEAP classes. Because CIVIQ-20 was developed by taking into account complaints of CVD patients, it reflects the importance they attach to each complaint and the wording they use to express the unpleasantness. Being in symbiosis with patients' concerns, it is not surprising that the questionnaire was easily completed, and this is one of the strengths of CIVIQ-20.

It is noteworthy that the CIVIQ-20 was able to discriminate between severities of CVD as shown in Tables 4 and 5, even if the need for a good discriminative instrument in CVD is met by the CEAP classification. The CEAP is considered to be an excellent descriptive and discriminative tool, allowing the categorisation of CVD patients into seven classes of progressive severity, but categorisation of patients is based on physical parameters only in the CEAP, while it relates to physical, psychological and social variables in CIVIQ-20.

In some studies, CIVIQ-20 has correlated well with other QoL tests, that is, the Short Form36 Health Survey (SF-36) and SF-12.[16,21] This is another reason for selecting it in longitudinal studies.

To our knowledge, CIVIQ-20 is the only specific scale for CVD to have used item and factor analysis to demonstrate to what extent the items are convergent with their dimension and if they have a high factor loading. This analysis revealed the lack of stability of the scale in its social dimension. Flaws in the social dimension were also seen in the Czech Republic, Poland and Spain. This raised the question of whether this was due to cultural differences or other reasons, such as cumbersome translation. During the cross-cultural adaptation of CIVIQ-20, we had to modify the ways in which some questions were expressed to adapt the questionnaire to different cultural contexts; and, yet, it is not granted that we succeeded in the cross-cultural validation of the social items. In a seminal article, Ware considered that the definition of personal health should be restricted to physical and mental components, because "…physical and mental variables are similar in that they 'end at the skin'. They do not directly involve other people or factors outside the individual,"[24] and that the social component is difficult to grasp in cross-cultural validation processes. A shortened version of the instrument made of 14 questions (CIVIQ-14) of which the factorial stability has

Table 6 Responsiveness of the CIVIQ-20 global index to change over time.

Clinical parameter	Clinical evolution	Number of patients	Change in Global Index between D180 and D0; mean and SD	Effect size
Swelling*	Improved	2310	21.1 SD 16.8	1.26
Heaviness*	Improved	3014	20.1 SD 16.2	1.24
Cramps*	Improved	2374	21.1 SD 16.4	1.29
Pain**	Much improved	442	29.2 SD 16.9	1.73
	Improved	1892	23.8 SD 16.2	1.46

Improvement* was defined as a decrease of one class for swelling, heaviness and cramps; for pain, improvement** was defined according to change in score (10-cm visual analogue scale): much improved = decrease of 5 cm or more, improved = decrease of 2.5—5 cm.

been rigorously validated is pending. This short version will make up for the instability found with CIVIQ-20. In the meantime, our recommendation is to use the easy-to-handle GI of CIVIQ-20 in multinational studies.

Conflict of Interest

R. Launois received honoraria for the interpretation of data.

A. Mansilha and G. Jantet received none.

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References

1 Nicolaides A, Allegra C, Bergan J, Bradbury A, Cairols M, Carpentier P, et al. Management of chronic venous disorders of the lower limbs. Guidelines according to scientific evidence. *Int Angiol* 2008;**27**(1):1—59.

2 Chassany O, Le-Jeune P, Duracinsky M, Schwalm MS, Mathieu M. Discrepancies between patient-reported outcomes and clinician-reported outcomes in chronic venous disease, irritable bowel syndrome, and peripheral arterial occlusive disease. *Value Health* 2006;**9**(1):39—46.

3 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**(6):539—54.

4 Jantet G. Chronic venous insufficiency: worldwide results of the RELIEF study. *Angiology* 2002;**53**(3):245—56.

5 Porter JM, Moneta GL. Reporting standards in venous disease: an update. *J Vasc Surg* 1995;**21**(4):635—45.

6 Liang MH, Lew RA, Stucki G, Fortin PR, Daltroy L. Measuring clinically important changes with patient-oriented questionnaires. *Med Care* 2002;**40**(Suppl. 4):45—51.

7 Rutherford RB, Padberg Jr FT, Comerota AJ, Kistner RL, Meissner MH, Moneta GL. Venous severity scoring: an adjunct to venous outcome assessment. *J Vasc Surg* 2000;**31**:1307—12.

8 Kalteis M, Berger I, Messie-Werndl S, Pistrich R, Schimetta W, Pölz W, et al. High ligation combined with stripping and endovenous laser ablation of the great saphenous vein: early results of a randomized controlled study. *J Vasc Surg* 2008;**47**(4): 822—9.

9 Gavrilenko AV, Sandrikov VA, Vakhratian PE, Dutikova EF, Fateeva IE. [Role of valvular insufficiency of the femoral vein in clinical course and relapse of lower limb varicosity.]. *Angiol Sosud Khir* 2006;**12**(3):61—8 [Russian].

10 Pokrovsky AV, Saveljev VS, Kirienko AI, Bogachev VY, Zolotukhin IA, Sapelkin SV, et al. [Surgical correction of varicose vein disease under micronized diosmin protection (results of the Russian multicenter controlled trial DEFANS)]. *Angiol Sosud Khir* 2007;**13**(2):47—55 [Russian].

11 Lorenz D, Gäbel W, Redtenbacher M, Weissenhofer W, Minzlaff M, Stengel D. Randomized clinical trial comparing bipolar coagulating and standard great saphenous stripping for symptomatic varicose veins. *Br J Surg* 2007;**94**(4):434—40.

12 Intsertov MA. [Assessment of the efficacy of surgical management of lower limb varicosity from the viewpoint of patients' quality of life as dependent on their psychological status.]. *Angiol Sosud Khir* 2005;**11**:60—3 [Russian].

13 Veverková L, Kalac J, Jedlicka V, Wechsler J. [Analysis of surgical procedures on the vena saphena magna in the Czech Republic and an effect of Detralex during its stripping.]. *Rozhl Chir* 2005;**84**:410—6 [Czech].

14 Trepto D, Rogowski-Tylman A, Maruszyński M. [Influence of operative treatment on quality of life of patients with primary varicose veins of bottom limbs.]. *Pol Merkur Lek* 2007;**22**: 117—20 [Article in Polish].

15 Neglén P, Hollis KC, Olivier J, Raju S. Stenting of the venous outflow in chronic venous disease: long-term stent-related outcome, clinical, and hemodynamic result. *J Vasc Surg* 2007; **46**(5):979—90.

16 Andreozzi GM, Cordova R, Scomparin MA, Martini R, D'Eri A, Andreozzi FQuality of Life Working Group on Vascular Medicine of SIAPAV. Effects of elastic stocking on quality of life of patients with chronic venous insufficiency. An Italian pilot study on Triveneto Region. *Int Angiol* 2005;**24**(4):325—9.

17 Vayssairat M, Ziani E, Houot B. [Placebo controlled efficacy of class 1 elastic stockings in chronic venous insufficiency of the lower limbs.]. *J Mal Vasc* 2000;**25**(4):256—62 [French].

18 Le Tohic A, Bastian H, Pujo M, Beslot P, Mollard R, Madelenat P. [Effects of electrostimulation (Veinoplus) on lower limbs venous insufficiency-related symptoms during pregnancy. Preliminary study.]. *Gynecol Obstet Fertil* 2009;**37**(1):18—24 [French].

19 Guex JJ, Enriquez Vega DM, Avril L, Boussetta S, Taïeb C. Assessment of quality of life in Mexican patients suffering from chronic venous disorder — impact of oral *Ruscus aculeatus*-hesperidin-methyl-chalcone-ascorbic acid treatment — 'QUALITY Study'. *Phlebology* 2009;**24**(4):157—65.

20 Martínez-Zapata MJ, Moreno RM, Gich I, Urrútia G, Bonfill X; Chronic Venous Insufficiency Study Group. A randomized, double-blind multicentre clinical trial comparing the efficacy of calcium dobesilate with placebo in the treatment of chronic venous disease. *Eur J Vasc Endovasc Surg* 2008;**35**(3):358—65.

21 Guex JJ, Myon E, Didier L, Nguyen Le C, Taieb C. Chronic venous disease: health status of a population and care impact on this health status through quality of life questionnaires. *Int Angiol* 2005;**24**(3):258—64.

22 Carpentier PH, Satger B. Randomized trial of balneotherapy associated with patient education in patients with advanced chronic venous insufficiency. *J Vasc Surg* 2009;**49**(1):163—70.

23 Hyland ME. Recommendations from quality of life scales are not simple. *BMJ* 2002;**325**:599.

24 Ware JE, Brook RH, Davies AR, Lohr KN. Choosing measures of health status for individuals in general populations. *Am J Public Health* 1981;**71**:620—5.