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Quality of life in chronic venous insufficiency

An Italian pilot study of the Triveneto Region

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***Aim*. Chronic venous insufficiency (CVI) is a chronic disease, whose disability has not been appreciated clearly, and several treatment costs are not covered by Public Health Service, probably because its any social impact is not well known. The aim of the study was to assess the impact of CVI on quality of life (QoL), and to compare the sensitivity of more diffused instruments for QoL assessment.**

***Methods*. One hundred and four patients with CVI received the Italian version of four QoL assessment instruments (MOS SF-36; CIVIQ-2; Euro-QoL 5D and a visual analogical scale). The poorest QoL was adjusted as 0, the best as 100. After filling the questionnaires, patients underwent a clinical and instrumental examination to assess the diagnosis according to the CEAP classification.**

***Results*. The QoL is progressively impaired from CEAP class C_1 to class C_{5-6}. The SF-36 showed a normal QoL in patients of CEAP class C_1 and C_2. Class C_3 showed a significant (P<0.0018) reduction of QoL (physical role and bodily pain), and the decline was more significant (P<0.0001) in class C_4, involving all physical items and several mental ones. Class C_{5-6} showed very low scores of physical and social functioning, general health and vitality. Physical and emotional scores were better than C4 patients.**

***Conclusion*. QoL is progressively impaired in CVI, involving primarily the physical items and the emotional role, with worsening of mental items only in advanced stages. This early involvement of physical items underlines how CVI is not an esthetic problem, but, a disease. Its impact on the lifestyle and QoL is similar to that of other chronic diseases (diabetes, cancer, chronic pulmonary disease), reaching in the class C5-6 the poorest level, similar to heart failure.**

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Key words: **Venous insufficiency - Quality of life - CEAP classification - Vein disease.**

*Italian Society for Angiology and Vascular Medicine (www.siapav.it).

** Statistical Analysis and Psycometric Measurement.

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Chronic venous insufficiency (CVI) is a chronic disabling disease, whose prognosis is not severe *quoad vitam*, but very bad *quoad valetudinem*, because venous hypertension and serious involvement of cutaneous and subcutaneous tissues with symptoms and signs (heaviness, pain, hypodermitis, and ulcer) limit patients' lifestyle.

Its prevalence shows a very large variability, from 2.3% in males to 4% in females in the studied population in the San Paulo study,[1] and 3% male and 3.7% women in the Tecumseh community study [2] to 15% in the Basel III study.[3]

Active chronic leg ulceration has a prevalence of 0.1-0.2% of the adult population in developed countries.[4]

The natural history of CVI is characterized by chronicity and relapse, and it gives rise to massive health care expenditure, which is approximately 1-2% of the health care budget of European countries.[5]

However, CVI rarely appears in the tables of Insurance Companies, and most of the CVI costs (drugs, elastic stocking) are not covered by Public Health Services.

This gap is probably due to several uncertainties in the diagnosis and treatment of CVI. In a Swedish study, the medical staff responsible for the treatment of patients with venous ulcers was unsure about the etiological diagnosis in as many as 40% of the cases, because most symptoms and signs of venous disorders are not specific.[6] The Edinburgh Study reached the same conclusions, underlining the fact that the symptoms of CVI are not specific even if very closely related.[7]

With the wide dissemination of the CEAP classification [8] and with a better and uniform quality of diagnosis of CVI all these gaps are now improving.

Also the measurement of quality of life (QoL), which provides a better understanding of the impact the disease has on the patient, could add to the appreciation of the problem.

Two previous papers from our Group [9, 10] showed that patients with CEAP C_{0-1-2} did not present any difference from the healthy Italian population, irrespective of the etiology, anatomy or pathophysiology.

The groups of patients with CEAP $C_{3-4-5-6}$ showed a QoL profile significantly ($P<0.01$) worse in physical items, independently from etiology, anatomy or pathophysiology, whilst in the mental domains only the role-emotional has been impaired. The patient with an active ulcer had a worsen QoL profile than the group with healed skin wounds, but without statistical difference due to the low number of considered patients.

More than a hundred papers appear on PubMed when searching with the key-words "venous disease" and "quality of life", but several studies dealt with other issues (e.g. pain in gynecology clinic), leading to unclear conclusions. Only a few studies report with original data.

Kurz *et al.*, in their multicentric study, conclude that varicose veins do not impair QoL *per se* but only if other venous abnormalities such as edema, skin changes or ulcers are present.[11] Fortunately, this study utilized the CEAP classification and it is helpful to understand the meaning of the sentence: the QoL is impaired only in the classes C_{4-5-6}.

The study carried out by the San Diego Group [12] analysed the physical component score (PCS) and mental component score (MSC) and their relationship with the visible (teleangectasia or spider veins, varicose veins, trophic skin changes) and the functional (superficial, deep, perforator veins, reflux and/or obstruction) categories of the venous disease. These definitions are equivalent, respectively, with class C, class A and class P of the CEAP classification,[13] but it is still not clear why the word "functional" is used in place of " anatomic".

Other studies utilize generic or specific instruments to assess QoL and different diagnostic categories with the collected data that are difficult to compare.

The aims of the present pilot study, carried out by the Working Group Quality of Life on Vascular Medicine of the Italian Society for Angiology and Vascular Medicine (SIAPAV), are the assessment of QoL in the Italian population and the comparison of the reliability and sensitivity of more diffused instruments(whether generic, specific or utility(for the assessment of QoL.

Materials and methods

One hundred and twelve patients (age: 48-75 years) living in the Triveneto Region (Veneto, Trentino Alto Adige, Friuli Venezia Giulia), consecutively observed in 10 Vascular Laboratories by 14 angiologists or vascular surgeons (Appendix) have been enrolled to the study. The patients were informed about the target and modality of the study, and gave their informed consent.

Each patient then received a preliminary Mini-Mental State Examination (MMSE).[14] Two people with MMSE score <24 were excluded from the study.

One hundred and ten patients received the QoL questionnaires, and were asked to fill them out by themselves, helped by the nurses only if required.

The utilized instruments were:

— the SF-36 (a generic questionnaire, the most used instrument to assess QoL, with 8 items: 4 physical(physical activity, physical role, bodily pain, general health(and 4 psycho-mental(vitality, social activity, emotional role, mental health).[15-17] The results are reported with a single score for each item:

— the CIVIQ-2 questionnaire, a specific instrument for venous disease with 20 questions.[18, 19] The results are reported as global index score (GIS);

— two utility measurement instruments, the Euro-QoL 5D and the visual analogue scale:[20] the results are reported as single score.

The score scales of all questionnaires have been adjusted to reflect the poorest QoL as 0 and the best QoL as 100.

After answering the questionnaire the patients underwent a clinical and instrumental examination to assess the diagnosis following the CEAP criteria.[8, 13] The class C criteria have been assessed in the clinic (visible and palpable) categories. The class E has been assessed by clinical history. The A and P criteria have been assessed by echo-duplex examination (reflux, obstruction, superficial, deep and perforating veins) following the criteria of the consensus statement on the investigation CVI.[21]

Thirty days after the first administration, a sam-

TABLE I.—*CEAP classification of enrolled patients.*

	No.	Clinical	Etiologic	Anatomy	Pathophysiology
C 1-2 subjective symptoms (heaviness, evening swelling, restless leg)					
Teleangectasia	4	1	P	??	SMALL R
Post-thrombotic syndrome	13	1	S	D 134-14	R
Saphenous varicose veins	30	2	P	S 2-3	R
Total	47				
C 3-4 serious symptoms (oedema, skin changes, heaviness)					
Varicose veins	6	3	P	S 2-3	R
Post-thrombotic syndrome	7	3	S	D 13-14-16	RR + O
Varicose veins	16	4	P	S 2-3 P 18	RR
Post-thrombotic syndrome	13	4	S	D 13-14-16 P 18	RR + O
Total	42				
C 5-6 advanced CVI (disability, oedema, skin changes, ulcer)					
Varicose veins + healed ulcer	2	5	P	S 2-3 D 16 P 18	RR
Post-thrombotic syndrome + healed ulcer	3	5	S	D 13-14-16 P 18	RR
Varicose veins + active ulcer	5	6	P	S 2-3 D 16 P 18	RR
Post-thrombotic syndrome + active ulcer	5	6	S	D 13-14-16 S 5 P 18	RR
Total	15				

ple of 60 patients received the same questionnaires to evaluate the test-retest reliability.

Missing data: several patients were withdrawn and not considered in the final analysis; 6 were excluded because of incomplete filling of questionnaires in the baseline step, and 20 because of no-show during the follow-up.

The final available data for this study were in relation to 104 patients.

Forty-seven patients have been classified as C1-2. Their symptoms were heaviness, evening swelling and restless of the legs. Four of them showed only teleangectasia, 13 had a post-thrombotic syndrome (PTS) with venous reflux in the femoral and popliteal veins, and 30 had varicose veins with involvement of the greater saphenous vein.

Forty-two patients showed very serious symptoms such as edema and skin changes. Thirteen of these have been classified as C_3, 6 of them had varicose veins of the greater saphenous vein, and 7 had the PTS.

Twenty-nine patients showed serious skin changes with dermatitis and eczema, and were classified as C4; 16 of these had varicose veins of greater saphenous vein with involvement of leg perforator veins, and 13 had PTS with involvement of leg perforator veins.

Fifteen patients had a history of venous ulceration; 5 of these (2 with varicose veins and 3 with PTS) had ulceration in the past; 10 (5 with varicose veins and 5 with PTS) had an active skin wound. The details are shown in the Table I.

The results of each instrument have been reported class by class of CEAP classification. The scores of each item of the SF-36 instrument have been compared with the scores of the Italian healthy population over 50 years22 (Student's t-test). Analysis of variance has been carried out between the scores of SF-36 and other instruments.

Results

The coefficients of correlation for the test-retest reliability were more than 0.85.

TABLE II.—*Scores of the items of SF-36, in different class C of CEAP classification.*

		Physical functioning	Bodily role	Physical pain	General health	Vitality	Social functioning	Emotional role	Mental health	Healthy population P<
CEAP Class C1	Mean	96.88	87.5	75.5	70.13	70	79.38	84.39	78.5	NS
	SD	4.58	18.9	14.57	12.52	10	17.97	16.91	9.06	
CEAP Class C2	Mean	85.37	80.69	68.06	61.14	55.93	76.74	71.2	65.42	NS
	SD	13.29	27.44	20.23	21.87	19.81	14.99	34.07	22.35	
CEAP Class C3	Mean	67.27	55.45	50.82	53.09	48.64	63.64	60.31	57.55	0.0018
	SD	17.66	31.26	17.55	19.63	14.68	18.92	25.42	14.36	
CEAP Class C4	Mean	50	52.5	52.25	32.58	43.89	59.17	44.44	47.17	0.0001
	SD	12.34	38.82	26.55	24.8	27.66	25.61	41.04	26.19	
CEAP Class C5-6	Mean	28.15	66.67	39.67	25	34.17	45.83	66.65	48	0.00001
	SD	7.86	36.7	10.31	15.81	15.63	12.91	36.53	9.12	
Italian healthy population over 50 y	Mean	79.1	72.53	68.31	60.08	58.71	76.33	69.66	63.18	

P values: Student's *t*-test for paired data, between scores of Italian healthy population and each C CEAP class

TABLE III.—*Global scores of CIVIQ-2, Euro-Qol 5 dimensions and Visual Analogic Scale (VAS), in different class C of CEAP classification.*

		CIVIQ GIS	Euro-QoL 5-d	VAS
CEAP Class 1	Mean	85.78	86.36	82.5
	SD	12.1	11.54	11.34
CEAP Class 2	Mean	80.25	75.67	73.47
	SD	13.62	17.44	11.52
CEAP Class 3	Mean	65.11	76.22	64.09
	SD	11.19	15.94	14.11
CEAP Class 4	Mean	57.92	68	62.08
	SD	16.84	13.42	18.64
CEAP Class 5-6	Mean	41.04	29.88	31.67
	SD	11.22	31.74	10.33

Progressive reduction of QoL from class C1 to class C5-6

All the instruments utilized for the QoL measurement showed a progressive reduction of QoL scores from CEAP class C1 to class C_{5-6} (Tables II and III).

Comparing the results of SF-36 with the data of healthy Italian population, the patients of CEAP class C_1 and C_2 had a normal QoL profile, with several scores higher than the healthy Italian population. Class C_3 showed a significant (P<0.0018) reduction of QoL, especially for physical and pain items, and also in relation to the general health and vitality. The worsening of physical function is less relevant.

In patients of class C4 the worsening of QoL is more significant (P<0.0001), involving all the physical items, general health and vitality, including the emotional role and mental health.

Classes C_{5-6}, matched together because of the small sample size, showed a serious impairment of QoL (P<0.00001) with very low score of physical and social functioning, general health and vitality. The scores of physical and emotional role were better that patients of class C_4.

Analysis of variance between the scores of SF-36 and other instruments showed a very close correlation between GIS of CIVIQ-2 and physical functioning, bodily pain and social functioning of

TABLE IV.—*Analysis of variance between each item of SF-36 and the global index scores (GIS) of CIVIQ-2, Euro QoL 5 dimensions and Visual Analogic Scale (VAS).*

	Physical functioning	Physical role	Bodily pain	General health	Vitality	Social functioning	Emotional role	Mental health
CIVIQ-GIS	**0.81**	0.44	0.7	0.56	0.33	**0.68**	0.41	0.26
Euro QoL 5-D	**0.61**	0.17	0.52	0.46	0.25	**0.68**	0.2	0.17
VAS	**0.72**	0.36	0.53	0.53	0.29	0.6	0.24	0.28

Close, direct correlation between scores of the specific and uility instruments with physical functioning, bodily pain and social functioning of SF-36

SF-36; Euro QoL 5-D correlates with physical and social functioning of SF-36; the utilized visual analogic scale (VAS) correlates only with physical functioning of SF-36 (Table IV).

Discussion

Our results showed clearly that patients with CVI have a significant impairment from CEAP class C3 onwards, which is marked by the appearance of edema. This confirms the results described by Kurz *et al.*[11]

Classes C1-2 showed normal values for physical and mental items, and some of them showed better scores than the Italian healthy population of the same age. We do not have data about the healthy population of the Venetian region, and that does not allow us to comment.

The C_4 class showed a progression of QoL impairment, involving more significantly the mental scores; the poorest levels of QoL are reached in the classes $C_{5\text{-}6}$. Paradoxically, in these classes, the physical and emotional role scores were better than those of class C_4. This pattern is very interesting, and probably it is justified by a progressive adapting and acceptance of a chronic disease, and it underlines even more the significance of the negative impact of classes C_3 and C_4 of CVI.

The study also demonstrated that the progressive impairment of the QoL involves primarily the physical items and the emotional role, followed in the advanced stages by the involvement of the mental items. In our opinion, the early involvement of physical items underlines the fact that CVI is not an esthetic problem, but a disease. If the first hypotheses were true, the mental items would be more impaired than the physical ones. The mental scores, in fact, investigate about the patient's well-being and how he perceives the disease, whilst the physical scores investigate what the patient can do.

The conclusions from our previous studies and the San Diego Study were similar, with the only difference that in the latter study the more impaired mental score was the vitality, whilst in our studies it was the emotional role. This difference could be explained by cultural, ethnical and environment differences in the population studied, and it does not affect our conclusions.

Finally, regarding the different instruments used, our results suggest that the best one is the SF-36 because of a more complete assessment of QoL, followed by the CIVIQ-2 global score, which is well tailored on specific venous disturbances, and has a good sensitivity on the physical functioning and pain, but a low sensitivity on the mental domains of QoL. The utility instruments showed a good sensitivity to assess only the physical functioning. Probably, the CIVIQ-2 and the utility instruments could show a higher sensitivity in the interventional studies.

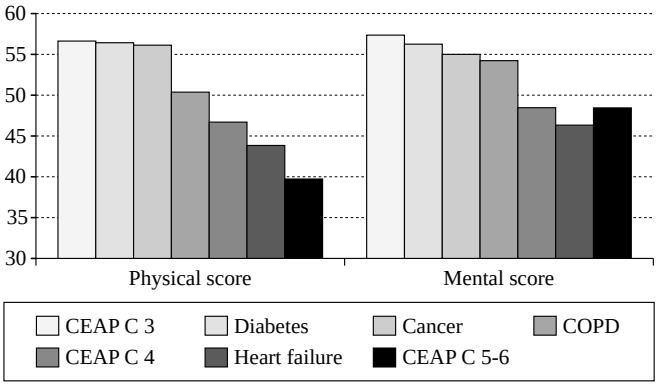

Figura 1.—QoL profile of different CEAP C class, and other chronic diseases: Class C_3 shows a similar QoL than diabetes and cancer; Class C_4 has a worsened QoL than cancer and chronic obstructive pulmonary disease (COPD); Class $C_{5\text{-}6}$ show a poorest QoL, like to the heart failure.

Conclusions

We can affirm that CVI is a chronic disease which invalidates the lifestyle and the patients' quality of life, starting from the appearance of the edema.

Comparing the QoL profile of CVI with the profiles of other chronic disease, which are considered to have a relevant social impact in the whole world, (Figure 1), we can see that CEAP class C3 shows a similar QoL to that of diabetes and cancer, whilst class C_4 has a QoL which is worse than cancer and chronic obstructive pulmonary disease. Finally, classes $C_{5\text{-}6}$ show a very poor QoL, like that of the heart failure.

We believe that CVI should receive more attention from the Health Policy makers than it does today, with therapeutic drugs and devices (such as elastic stockings, and tools for the treatment of venous ulceration [23]) completely covered by Health Insurance Companies, whether public or private.

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Appendix

SIAPAV Working Group Quality of Life in Vascular Medicine Pilot study on quality of life in patients with chronic venous insufficiency Triveneto Region

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