

Comparative study of quality of life in patients with C4-C6 CEAP stage chronic venous disease using CIVQ-20 questionnaire

Tony L. Hangan¹,
Dan Navolan²,
Simona Vladareanu³,
Sergiu Chirila⁴,
Gheorghe Nicola^{1,5}

1. Clinic of Dermatology, Faculty of Medicine, "Ovidius" University of Constanta, Romania
2. Department of Obstetrics-Gynecology and Neonatology, "Victor Babes" University of Medicine and Pharmacy Timisoara, City Emergency Clinical Hospital Timisoara, Romania
3. Department of Neonatology, Elias University Hospital, "Carol Davila" University of Medicine and Pharmacy, Bucharest, Romania
4. Department of Informatics and Biostatistics, Faculty of Medicine, "Ovidius" University of Constanta, Romania
5. Dermatology and Venereology Department, County Emergency Hospital from Constanta, Romania

Correspondence:
Dr. Tony L. Hangan
e-mail: tony@medcon.ro

Received:
January 14, 2016
Revised:
February 24, 2016
Accepted:
March 23, 2016

Abstract

Chronic venous disease is a common condition among adult population that has a determinant effect on the quality of life (QoL). In this study we assessed the QoL for 56 patients with venous insufficiency and stages C4-C6. The aim of this study was to determine which components of the CIVIQ-20 questionnaire are influenced by the development of stasis ulcers. The results show that, overall, the QoL depreciates significantly once the first stasis ulcer appears. From the components of the questionnaire, the pain is more intense and the mood of the patients is much more affected once the disease evolves from C4 stage to C5-C6 stages.

Keywords: venous insufficiency, varicose veins, varicose ulcer, quality of life

Introduction

Chronic Venous Disease (CVD) is a consequence of an increased pressure inside the veins located at the level of the legs. It is defined as morphological and functional abnormalities of the venous system of long duration manifested either by symptoms and/or signs indicating the need for investigation and/or care⁽¹⁾. It represents a common condition with reported prevalence of up to 83.6%⁽²⁾. Among the major risk factors are venous thrombosis, leg injury of surgery, excess weight or weight gain and long periods of orthostatism⁽³⁾. Through the symptomatology, CVD has a major impact on the quality of life (QoL) of the patients⁽⁴⁻⁶⁾. This symptomatology is proportionate with the "C" from the Clinical-Etiology-Anatomy-Pathophysiology (CEAP) classification⁽⁷⁾. Moreover there are different options to evaluate the way QoL is affected. One of these methods used for the assessment of the QoL is the well-established Chronic Venous Insufficiency Quality of life Questionnaire (CIVIQ-20)⁽⁸⁾.

The aim of the study is to assess the influence of stasis ulceration (healed or open) on the QoL compared to patients without ulceration but with advanced CVD (stage 4).

Methods

Fifty-six patients from Constanta county, diagnosed and treated in the Dermatology and Venereology Department of the County Emergency Hospital from Constanta, Romania for CVD. At initial evaluation, class C from the CEAP classification has been determined. Age of the patients also has been recorded. The inclusion criteria were a C score of 4, 5 or 6 according to the CEAP classification.

After giving the informed consent for the participation in this study, they were asked to use a QoL assessment tool developed specially for patients with chronic venous insufficiency, CIVIQ-20. The patients completed the questionnaire mostly unaided. For some of them intervention was needed, but the influence of the investigator was kept at minimum. The results of the questionnaire are reported as total points.

For the statistical analysis we used descriptive statistics. To determine the normality of the distribution we used Shapiro-Wilk test. For comparison between groups we decided to use either t test or Mann Whitney-u test, depending of the distribution of the data. The p value to reject the null hypothesis was considered 0.5.

Results

Average age of the patients was 55.89 years, with a standard deviation of 11.55. The minimum age was 25 years and the maximum was 72 years.

According to the CEAP score, almost 45% of the patients were in C4 stage, 21.5% in C5 stage and 33.9% in C6 stage (Figure 1).

The median age for patients in C4 stage was 59 years, while for the C5 and C6 had a value of 61 years (Table 1). The differences were not statistically significant (p=0.49).

From the total of 56 patients, more than half, 53.6% were women. The average age of the women in this study was lower than the one registered for males (Table 2), but the difference was not statistically significant (p=0.48).

In this study we notice that there are more women in the group of patients without ulcers compared to males

($p=0.001$), their distribution being according to the data from Table 3.

For being able to assess the influence of the stasis ulceration (healed or open) on QoL, we divided the group of patients into two subgroups. One with patients in C4 stage and the second group with patients from C5 and C6 categories.

The median value for the total score was 64 for patients in C4 stage and 70 for patients in C5 and C6 stage (Figure 2). This difference was statistically significant ($U=265.5$, $Z=-2.029$, $p=0.042$).

There were no statistically significant differences between males and women in total score ($U=324.5$, $z=-1.086$, $p=0.278$), the median score for males being 67, while the median score for women was 65.

In the next part of the study we evaluated the results for each of the five sections of the CIVIQ-20 questionnaire in order to identify which are the elements that suffer most of the alteration.

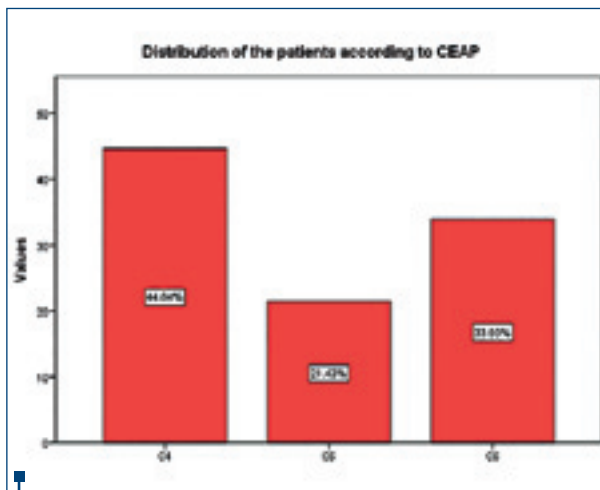


Figure 1. Distribution of the patients according to CEAP

Table 1 Average age of the patients stratified by CEAP classification

CEAP Stage	Mean	Std. Deviation	Median
C4	53.600	13.2791	59.000
C5	60.167	7.2467	61.000
C6	56.211	11.0029	61.000
Total	55.893	11.5533	61.000

Table 2 Average age of the patients stratified by sex

Sex	N	Mean	Std. Deviation	Median
Male	26	57.08	11.328	61.00
Women	30	54.87	11.840	58.00
Total	56	55.89	11.553	61.00

Table 3 Distribution according to gender and study group

		Group		Total
		C4	C5-C6	
Gender	Male	20.0%	67.7%	46.4%
	Feminine	80.0%	32.3%	53.6%
Total		100.0%	100.0%	100.0%

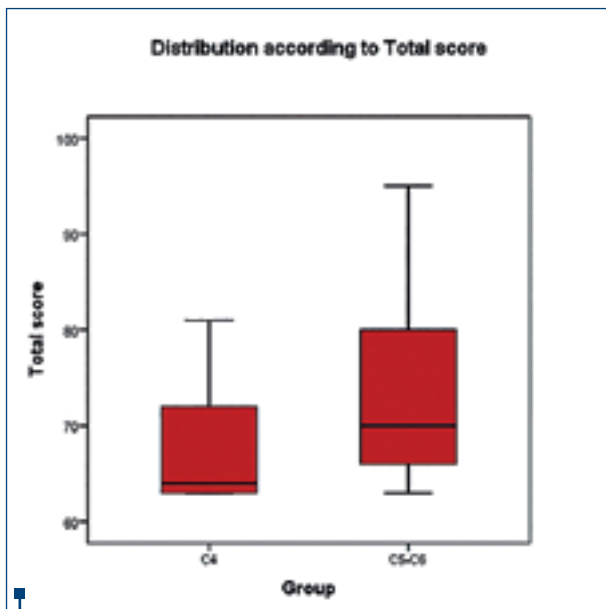


Figure 2. Total score distribution

Evaluation of the pain

The first question of the CIVIQ-20 questionnaire relates to how the patients felt the pain at legs or ankle level in the last four weeks, and the severity.

The median answer for patients with C4 stage was 4 (meaning considerable pain) and for patients with C5 and C6 stage the median was 5 (Severe pain) (Table 4). The difference was statistically significant (U=245, z=-2.583, p=0.01).

Influence on work and usual daily activities

The next section assesses the degree of the work capacity. The maximum core for this section is 5. For both groups the result indicates a moderate trouble (median score was 3). The average was slightly higher for the C5-C6 group (3,613) when compared to C4 group (3.32) (Table 5). The statistical analysis indicates that there was no statistically significant difference between the two groups (U=301, z=-1.762, p=0.072).

Sleeping problems

In the case of sleeping problems both groups had a high median score (table III) and there was no statistically significant difference between groups (U=365,

Table 4 Score of the pain evaluation section

(During the past four weeks, have you had any pain in your ankles or legs, and how severe has this pain been?)				
Group	Mean	Std. Deviation	N	Median
C4	4.120	.7257	25	4.000
C5-C6	4.581	.6204	31	5.000
Total	4.375	.7023	56	4.000

Table 5 Assessment for work or normal activities

(During the past four weeks, how much trouble have you experienced at work or during your usual daily activities because of your leg problems?)				
Group	Mean	Std. Deviation	N	Median
C4	3.320	.7483	25	3.000
C5-C6	3.613	.8032	31	3.000
Total	3.482	.7860	56	3.000

Table 6 Assessing sleeping problems

During the past four weeks, have you slept badly because of your leg problems, and how often?				
Group	Mean	Std. Deviation	N	Median
C4	3.400	1.0408	25	4.000
C5-C6	3.484	1.2075	31	4.000
Total	3.446	1.1269	56	4.000

Table 7 Assessment for normal activities

(During the past four weeks, how much trouble have you experienced carrying out the actions and activities listed below because of your leg problems?)				
Group	Mean	Std. Deviation	N	Median
C4	29.4400	3.01496	25	29.0000
C5-C6	28.5484	5.50659	31	29.0000
Total	28.9464	4.55040	56	29.0000

$z=-0.393$, $p=0.694$). It seems that C4 stage and above all cause very often sleep problems. On a scale from 1 to 5 both groups had the median value of 4 (Table 6).

Other activities

Other activities were affected in all patients. The maximum score for this section was 40 points. The average score of this section was 29.44 for people with C4 stage CVD (S.D. 3.01), while for the patients from C5-C6 group the average value was almost 1 point smaller, with an average score of 28.54 (S.D. 5.5) (Table 7). The median had the same value. These differences were not statistically significant ($U=331$, $z=-0.94$, $p=0.35$).

Emotional aspects

Patients with C5-C6 stage of CVD seem to have a significantly higher average score for the section that deals with the emotional aspects from the CIVIQ-20 questionnaire.

The average value for them was 34.45 and a median of 36 out of the maximum score of 45 points. The patients in C4 stage seem to be less affected from an emotional point of view, the average score for them being 28.24 with a median of 29 points. The difference was statistically significant ($U=97.5$, $z=-4.83$, $p<0.001$) (Figure 3).

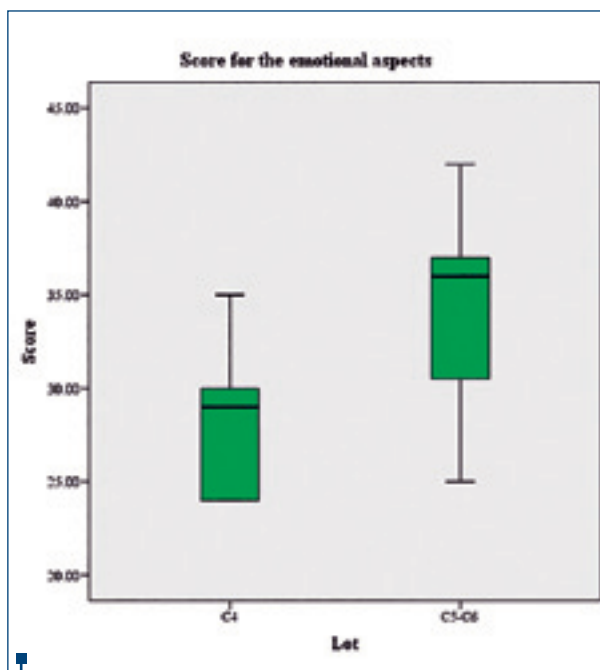


Figure 3. Score for the emotions assessment

Discussion

In this study we assessed the influence of varicose ulceration, and the way it affect the QoL of the patients. The main result of the study indicates that overall, patients within C5 or C6 category on the CEAP scale have a higher CIVIQ-20 score than patients within C4 category. The only difference is the presence of a healed or active ulceration. This aspect of a decreased QoL correlated with an increase of the CEAP stage is well documented in the literature^(5,9).

The pain is statistically significant more severe in the case of C5-C6 group compared to C4 group. In our study the median pain level on a 1 to 5 score, where 5 is the most severe was 5 in C5-C6 group and 4 in the C4 group. This result is similar to the observations from other studies⁽²⁾ but at the same time other studies suggest that there is no relationship between pain and CEAP classification⁽¹⁰⁾. The result of a systematic review conducted by Herber and contributors⁽¹¹⁾ shows that the pain is described by patients as the worst thing, patients experiencing significantly more pain than the controls.

Advancing from stage C4 to stage C5 and C6, consequently doesn't seem to affect the work and daily activities. To support this aspect, we must note that patients with C4 stage of CVD already have severe modification of the functions and the score on a 1 to 5 scale, where 5 is severe impairment of work or daily activities have a median score of 3, which is above average. Advancing to CEAP grade 5 and 6 did not influence this score, the median score being also 3. The rank difference was not statistically significant ($p=0.07$), thus the presence of ulcerations doesn't seem to significantly influence the QoL from this point of view.

Sleep is severely affected in both groups. The median score was 4 without any statistically difference between the two groups. For normal activities also there was no statistically significant difference between patients

with stage C4 of CVD compared to patients stages C5 and C6. Both groups had a higher score, the median was 29 points out of 40 for both groups. This translates into moderate to considerable trouble in carrying out some actions and activities taken into considerations the problems with the legs.

The implications is highly influenced, patients in C5-C6 group having a statistically significant higher score, with a median of 36 points out of a maximum of 45, while patients in C4 group had a median value of 29. Considering the median values, patients from C5-C6 group are greatly affected by their problem, while patients in C4 group were only moderately affected. This major difference appears in the context of keeping the same impairment of the activities, the same sleep problems or the same effects on their normal activities which is in accordance with other studies⁽¹²⁾.

Another aspect that needs further to be investigated is represented by the higher percentage of women in C4 stage compared to C5-C6 stages. A possible explanation for this is the fact that women tend to care more about the looks, thus seeking medical care in earlier stages of the disease.

Possible reasons for this difference might be due to more severe pain, other symptoms, due to the way the disease is managed and the overall impact it has on the patient.

Conclusions

The study shows that the QoL in patients with C4 stage of CVD the evolution to stages C5 and C6 has a determinant effect on their QoL.

The most affected components are the intensification of the pain and the mood problems that appear. Our results revealed that components related to work and daily activities, sleep and other activities are not influenced by the evolution of the disease from stage C4 to C5 and C6. ■

References

- Eklof B, Perrin M, Delis KT, Rutherford RB, Gloviczki P, American Venous F, et al. Updated terminology of chronic venous disorders: the VEIN-TERM transatlantic interdisciplinary consensus document. *J Vasc Surg* 2009, 49(2), 498-501.
- Rabe E, Guex JJ, Puskas A, Scuderi A, Fernandez Quesada F. Epidemiology of chronic venous disorders in geographically diverse populations: results from the Vein Consult Program. *Int Angiol* 2012, 31(2), 105-15.
- Alguire CP, Mathes BM. Patient Information: Chronic venous disease (Beyond the Basics). UpToDate2016 [updated 2015; cited 2016 April]; Available from: <http://www.uptodate.com/contents/chronic-venous-disease-beyond-the-basics>.
- Lozano FS, Launois R, Reflux A, Quality of Life Improvement with Micronized Flavonoids Spanish g. Quality of life (Spain and France): validation of the chronic venous insufficiency questionnaire (CIVIQ). *Methods Find Exp Clin Pharmacol* 2002, 24(7), 425-9.
- Radak DJ, Vlajinac HD, Marinkovic JM, Maksimovic MZ, Maksimovic ZV. Quality of life in chronic venous disease patients measured by short Chronic Venous Disease Quality of Life Questionnaire (CIVIQ-14) in Serbia. *J Vasc Surg* 2013, 58(4), 1006-13.
- Wilson AB. Quality of life and leg ulceration from the patient's perspective. *Br J Nurs* 2004, 13.
- Capitol Vein & Laser Centers. CEAP Classification for Venous Disease. 2016 [updated 2016; cited 2016 April]; Available from: <http://www.mycvl.com/physician-resources/ceap/>.
- Launois R. CIVIQ user's guide. 2016 [updated 2016; cited 2016 April]; Available from: <http://www.civiq-20.com/>.
- Moura RM, Goncalves GS, Navarro TP, Britto RR, Dias RC. Relationship between quality of life and the CEAP clinical classification in chronic venous disease. *Rev Bras Fisioter* 2010, 14(2), 99-105.
- Conway AM, Nordon IM, Hinchliffe RJ, Thompson MM, Loftus IM. Patient-reported symptoms are independent of disease severity in patients with primary varicose veins. *Vascular* 2011, 19(5), 262-8.
- Herber OR, Schnepf W, Rieger MA. A systematic review on the impact of leg ulceration on patients' quality of life. *Health and Quality of Life Outcomes* 2007 5(1), 1-12.
- Jones JE, Robinson J, Barr W, Carlisle C. Impact of exudate and odour from chronic venous leg ulceration. *Nursing standard (Royal College of Nursing (Great Britain))* (1987). 2008, 16-22, 22(45), 53-4, 6, 8 passim.