European Journal of Vascular and Endovascular Surgery 44 (2012) 582–586

Contents lists available at SciVerse ScienceDirect

European Journal of Vascular and Endovascular Surgery

journal homepage: www.ejves.com

Chronic Venous Disease in Spain: Doctor–Patient Correlation

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WHAT THIS PAPER ADDS?

- Chronic venous disease (CVD) is a significant public health problem.
- There is a correlation between the quality of life perceived by patients with CVD and the severity of the disease objectively evaluated by doctors.
- It is essential that doctors consider their patients' opinions about their disease and its progress since this enables them to reinforce their clinical decisions.

ARTICLE INFO

Article history:
Received 2 April 2012
Accepted 5 September 2012
Available online 13 October 2012

Keywords:
Chronic venous disease
Chronic venous insufficiency
Quality of life
CEAP classification
Venous clinical severity score
SF-12 health survey
CIVIQ questionnaire

ABSTRACT

Aim: The present study aimed to demonstrate how the quality of life (QoL) perceived by patients with chronic venous disease (CVD) is correlated with the severity of their disease objectively assessed by primary care physician.

Material and methods: A total of 1560 patients with CVD were evaluated using four measurement instruments: CEAP clinical classification, Venous Clinical Severity Score (VCSS), SF-12 Health Survey and Chronic Lower Limb Venous Insufficiency Questionnaire (CIVIQ-20). Statistical correlations between these tools were analysed using Spearman's coefficient.

Results: Patients were distributed in C0, 58 (3.7%); C1, 243 (15.6%); C2, 328 (21.0%); C3, 357 (22.9%); C4, 368 (23.6%); C5, 136 (8.7%); and C6, 70 (4.5%). The VCSS score for the whole cohort was 0.89 ± 0.53. The correlation between CEAP and VCSS was moderately strong ($r = 0.69$). The overall QoL scores measured by SF and CIVIQ were 56.84 ± 19.63 and 65.11 ± 14.35, respectively. The correlation between the two QoL questionnaires was very strong ($r = 0.81$). The correlations of the SF and CIVIQ with the VCSS were moderately strong ($r = -0.47$ and -0.48). The correlations between QoL questionnaires and CEAP were moderate and lower than those with VSCC.

Conclusions: While there is correlation between VCSS, CEAP, modified CIVIQ and venous ultrasound findings, subgroup analysis indicates that this correlation is driven by different components of VCSS compared with the other venous assessment tools. Patients' opinions about their disease are correlated with those assessed by primary care physicians.

Chronic venous disease (CVD) is a well-known disorder with a variable prevalence with respect to the signs and symptoms by which it is evaluated.[1] Various epidemiological studies have been carried out in Spain,[2–4] and, like other international studies, these have drawn attention to this raised prevalence. The most recent study reported that 71% of the Spanish population aged over 16 years has some sign or symptom of CVD, with this being serious in 49% of them.[4] These high percentages have marked health-care, human, social and economic consequences.

The different classifications of CVD have enabled an objective approach to be taken to its various stages, resulting in less variability in epidemiological studies.[5] Without doubt, some of these

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http://dx.doi.org/10.1016/j.ejvs.2012.09.002

classifications allow the moderate (varicose veins and oedema) and severe (cutaneous dystrophy and ulcer) grades of the syndrome to be rigorously determined, but they do not evaluate the clinical symptomatology in any depth or measure their impact on the quality of life (QoL) of the patients who suffer the condition.

However, there are various QoL questionnaires (generic or specific to venous diseases) that provide information about patients' perception of their own health.[6] The application of these in a number of studies has proved conclusive about the effects of CVD on certain physical and psychic dimensions.

In this context, objective evaluation by the doctor and subjective evaluation by the patient frame the hypothesis put forward by the scientific societies promoting this study. Specifically, the main aim of the study was to test whether the health-related quality of life (HRQL) perceived by Spanish patients with CVD is directly correlated with the severity of the pathology objectively assessed by their primary care physician (PCP).

Materials and Methods

The present study is observational, cross-sectional and multicentre (covering the entire country). It was approved by the Salamanca University Hospital Scientific and Ethics Committee (Protocol: SEA-NUL-2010-01).

Study population

The total study population comprised 1598 patients who attended a primary care consultation in which a diagnosis of CVD was considered to be present and who had had signs or symptoms of CVD at least 1 year before the start of study (Table 1). The diagnosis of CVD was performed by 330 experienced PCPs in venous disease. We used a nationally representative sample of PCPs. PCPs were trained in CVD and have participated in several previous studies of CVD.[3] Each PCP recruited at least five patients with CVD. Thirty-eight patients were excluded because they met one or more of the exclusion criteria, giving a total of 1560 evaluable patients. All included patients gave their informed consent to enter the study.

Measurement instruments used

Four measurement instruments were used, two completed by the PCPs and two completed by the patients. For each patient in the study, the PCP collected in a predetermined case report forms the presence or absence of the following symptoms of CVD: pain or aching, burning, swelling, sensations of heaviness, leg tiredness, muscle cramps and/or tingling or itching. The presence of visible manifestations of venous disorders (sings) were also recorded including dilated veins (telangiectasiae, reticular vein and varicose veins); leg oedema; skin changes (pigmentation, eczema and lipodermatoesclerosis) or skin changes included ulcers (healed or active). The therapeutic history, the clinical stage of CVD (C grades of CEAP) and the Venous Clinical Severity Score (VCSS) were obtained from all patients.

Table 1
Criteria for inclusion, exclusion and withdrawal from the study.

Inclusion criteria
Man or woman
Aged 18 years or more
Any race
Written informed consent obtained from the patient
Carrier of some sign or symptom of CVD, lasting at least 1 year
Ability to fill in the quality of life questionnaires
Psychological stability and motivation in the patient
Exclusion criteria
Other severe comorbidities or significant clinical history unrelated with CVD
Patients who are immobile
Women who are pregnant or breastfeeding
New medication for the treatment of CVD received in the previous 3 months
History of surgery or sclerotherapy in the previous 3 months
Patients who have been stressed recently (death of a loved one, serious economic problems, etc.)
Withdrawal criteria
Questionnaire not completed (<80% items) by the researcher
C grade of CEAP not recorded by the researcher
Venous Clinical Severity Score not completed by the researcher
Quality of life questionnaires not completed by the patient

CVD = Chronic Venous Disease.

The 'C' of the CEAP classification was used to categorise the clinical features of the venous diseases.[7–9] The VCSS scale was derived directly from the CEAP clinical class; it was intended to supplement the CEAP classification by providing a method for assessing the severity of CVD over time.[10,11] The original VCSS includes nine hallmarks of venous disease, each scored on a severity scale from 0 to 3 (absent, mild, moderate and severe). The current version of the VCSS contains an extra category for compression. Thus, the scale can have a maximum value of 30 points. We used the mean of all 10 VCSSs.

Additionally, each patient included in the study filled in two QoL questionnaires: the SF-12 Health Survey (a shortened form of the SF-36[12]) and the Chronic Lower Limb Venous Insufficiency Questionnaire (CIVIQ-20).

The SF-12[13] uses just 12 questions to measure functional health and well-being from the patient's point of view. All scores are based on a scale of 0–100, where 0 is the worst, and 100 is the best possible score. The 12 scores can be aggregated into two component scores: physical (PCS) and mental (MCS). We used the validated Spanish version of the SF-12.[14]

CIVIQ-20 is a QoL questionnaire specific to CVD[15] comprising 20 questions and covering four QoL domains: physical, psychological, social and pain. The CIVIQ-20 generates a score ranging from 0 to 100, with higher scores indicating better QoL. We used the validated Spanish version of the CIVIQ-20.[16]

Statistical analysis

The data were collated in a PASW statistic v.18 datafile. Student's *t*-test was used to test hypotheses about differences in the means.

We calculated Spearman's rank correlation coefficient between the results of the different dimensions of the QoL scales and those of the CEAP and VCSS questionnaires. The following general categories indicate a quick way of interpreting a calculated *r*-value: 0.0–0.2, very weak to negligible correlation; 0.2–0.4, weak, low correlation (not very significant); 0.4–0.7, moderate correlation; 0.7–0.9, strong, high correlation; 0.9–1.0, very strong correlation.[17]

Results

Sample

Of the 1598 patients, 1560 yielded valid results. The final number of PCPs participating was 312 (18 PCPs did not recruit any patients). Patients and PCPs were distributed homogeneously throughout Spain. The study was carried out over a period of 90 days (15 October 2010–15 January 2011).

Table 2 summarises the demographic characteristics of the sample. The mean age of the cohort was 59 years (range, 18–99 years), the majority of which were women (74%). The mean body mass index (BMI) was 28 ± 2.04. Thirty-two percent of the population smoked, 68% had a sedentary lifestyle and 59% had a familial history of venous disorders.

Most patients had symptoms (pain, heaviness, swelling and cramps) with an average intensity of 2.03 (on a scale of 1–3). The