



Quality of Life in Chronic Venous Disease: Bridging the Gap Between Patients and Physicians

Fabricio Santiago¹

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Abstract

Chronic venous disease (CVD) has a negative impact on patients' quality of life (QoL). This was demonstrated in the recent Patient Journey on CVD study, which examined QoL in patients with early- and advanced-stage CVD (Clinical, Etiological, Anatomical and Pathophysiological classification C0 to C4), and the gaps between the way in which physicians and patients viewed the impact of CVD on QoL. The study was conducted in five countries (Brazil, China, Czech Republic, Italy and Russia) and included 100 patients with CVD and 60 CVD specialists. Patients completed the 14-item Chronic Venous Insufficiency Questionnaire (CIVIQ-14) to assess their QoL, and all patients and physicians were questioned during a 60-minute qualitative structured interview, focusing on four key dimensions—physical symptoms, aesthetics/appearance, emotional impact and impact on relationships. The study found that physicians tended to focus more on physical symptoms than on other impacts of CVD and rarely measured QoL in clinical practice. Patients were significantly less satisfied with the management of their QoL than physicians perceived them to be. About 25% of patients with CVD reported disturbed sleep, but physicians did not routinely ask them how CVD affected their sleep. These data reinforce the importance of physicians obtaining information about the impact of CVD on all aspects of the patient's life, including sleep and QoL. Evidence from randomised controlled trials and real-world studies demonstrates that some veno-active drugs, particularly micronised purified flavonoid fraction, can positively impact QoL in patients with CVD.

1 Introduction

Chronic venous disease (CVD) is a highly prevalent condition with a negative impact on the quality of life (QoL) of affected individuals. Approximately 25–33% of women and 10–40% of men have varicose veins, and the prevalence increases with age and body mass index [1]. When all stages of CVD are included, the prevalence may be as high as 84% in the general practice setting [2]. The condition inevitably progresses (defined as progressing to a higher clinical class, or the development of venous reflux and/or varicose veins in veins not previously affected) at a rate of approximately 4% per year [3]. The evolution is mostly dependent on the appearance of axial reflux along with the progressive involvement of the tributaries,

Key Points

Chronic venous disease (CVD) negatively impacts patient quality of life (QoL); however, patient and physician perspectives regarding this impact differ.

Data from the recent, multinational Patient Journey on CVD study indicate that patients consider that aesthetics/appearance associated with CVD cause the greatest impact on QoL, with sleep disturbance also impacting QoL significantly, while physicians rated physical symptoms as causing the greatest impact. Furthermore, physicians rarely assess QoL in clinical practice, leading to patient dissatisfaction with their management.

Clinical studies (although somewhat heterogenous) indicate that some veno-active treatments, particularly micronised purified flavonoid fraction, improve QoL in patients with CVD.

✉ Fabricio Santiago
fsan09@hotmail.com

¹ Department of Surgery, Federal University of Goiás, Goiás 74180-040, Brazil

perforator veins and occasionally, the deep venous system [1]. On average, it takes about 5 years for CVD to progress from a venous stasis diagnosis to the development of a venous ulcer [4] with an estimated prevalence of approximately 1% in the adult population [3].

The most common symptoms of CVD are leg pain, cramps, heaviness, a sensation of swelling, itching and paraesthesia. Patients also dislike the cosmetic impact [1]. Therefore, it is not surprising that CVD has a negative impact on QoL from the very earliest stages of the disease. Data show that QoL is impaired in patients with CVD classified as C2 to C6 on the Clinical, Etiological, Anatomical and Pathophysiological (CEAP) classification, and at all levels of the Venous Clinical Severity Score (VCSS), and worsens with increasing disease severity [5]. Patients with venous ulceration have a QoL that is comparable to people with congestive heart failure [6].

The aim of the current review article is to describe the results of a recent study, which examined the QoL in patients with C0 to C4 CVD and the gaps between ways in which physicians and patients viewed the impact of CVD on QoL [7]. Finally, the article examines the body of evidence regarding the impact of venoactive treatments on the QoL of patients with CVD.

2 International survey on QoL in CVD patients

2.1 Methods and Participants

The Patient Journey on CVD study was conducted in five countries (Brazil, China, Czech Republic, Italy and Russia) in September/October 2020, and involved 100 patients with CEAP C0 to C4 CVD (20 from each country) and 60 CVD specialists (12 from each country) [7]. Patients and physicians were identified in each country by local recruiters of a fieldwork agency and their local databases, as such the patients were not necessarily patients of the participating physicians. Patients completed the 14-item Chronic Venous Insufficiency Questionnaire (CIVIQ-14) in local languages

to assess their QoL. In addition, physician–patient paired interviews were conducted (with at least two patients for each participating physician). Both patient and physician were questioned during a 60-minute qualitative structured interview using standardised discussion guides for physicians and patients. As part of the interview, patients were asked to rate how well their physicians managed four key dimensions of their disease—physical symptoms, aesthetics/appearance, emotional impact and impact on relationships—on a scale from 1 (dissatisfied) to 5 (very highly satisfied). Physicians were asked to rate how they thought CVD affected their patients' QoL across the same four dimensions on a scale from 1 (very small impact) to 5 (very high impact), and how satisfied they thought patients were with management of their QoL on a scale from 1 (dissatisfied) to 5 (very highly satisfied). In addition, both patients and physicians were asked qualitative questions to gain more insight into how QoL is assessed and the impact of CVD (Table 1) [7].

Of the 100 patients in the study, 69% were female, and the mean age was 48.7 years (range 21–79 years), with 57% of patients aged between 41 and 60 years and 18% aged >60 years. The mean \pm standard deviation body mass index was 26.2 ± 7.2 kg/m². The majority of patients had been diagnosed 2–5 years previously, and 56% had C2–C3 CVD (18% had C0–C1 and 26% had C4 CVD) [7]. Overall, 75% of patients were using veno-active drugs. Among the 60 physicians, 48 (80%) were male, and 57% were vascular surgeons; the others were angiologists (24%) or phlebologists (19%). There were 31 physician–patient pairs.

2.2 Impact of CVD on Patients

When asked to rate the factors that had the greatest impact on QoL, patients gave aesthetics/appearance the highest rating, while physicians rated physical symptoms highest (Fig. 1). Overall, 58% of physicians considered that physical symptoms had a high or very high impact on QoL, compared with 33% of patients [7]. The proportion of patients whose QoL was impacted by each CVD factor increased with age,

Table 1 Key qualitative questions asked during the Patient Journey in CVD study [7]

| Patients | Physicians |
|---|---|
| How do these symptoms affect your quality of life? | Do you ask your patients about their quality of life? |
| Give me some examples in your daily life | What do you say? |
| Considering both night and day, what aspects of your daily life are affected? | How do you measure it? |
| Did your physician ask something about your quality of life? | |
| What did they say? | |
| How did they measure it? | |

female sex/gender and CVD severity, with significantly higher proportions of C4 patients reporting a high or very high emotional impact or impact on relationships compared with C0 to C3 patients ($p < 0.05$).

An interesting finding of this study was that 25% of patients reported disturbed sleep, which negatively impacted their lives and relationships. Some of these patients experienced cramps or ‘a nagging tingling sensation’ that was worse at night, and anticipation of these symptoms contributed to their problems with falling asleep. Relationships were impacted because the patient’s symptoms and/or wakefulness affected their partner. Impaired sleep was more common in patients with C3 or C4 disease than in those with C0 to C2 CVD. However, physicians rarely asked patients about how CVD affected their sleep, particularly patients with early-stage (C0–C2) disease [7].

2.3 QoL Assessment and Measurement

Patients were also asked about the CIVIQ-14 questionnaire, and 80% indicated that it covered most of the important factors affecting QoL, such as pain, social impact, sleep, work, daily activities and treatment. Among the items in the emotional burden domain, the item reported most by patients (39%) was feeling embarrassed to show their legs, whereas experiencing trouble during work or daily activities had the highest response (26%) in the physical domain. Patient feedback on the CIVIQ-14 also noted that this questionnaire was more focused on the functional impact of CVD, and that the psychological, aesthetic and financial impacts were not adequately addressed [7].

Physicians had a very low awareness of CIVIQ-14 and other CVD-related QoL instruments, and those who did use QoL assessment scales tended to reserve them for patients with more severe CVD, which in this cohort of patients refers to C4 CVD. Given the low use of QoL assessment by physicians in this study, it is perhaps not surprising that only 48% of patients felt that their QoL was being satisfactorily managed by their doctor. The patients who were dissatisfied and/or more disillusioned with their physician tended to be at an earlier stage of CVD, and believed their physician to be more interested in their clinical or symptomatic progress than in their emotional well-being [7]. In contrast, 85% of physicians felt that they were satisfactorily managing the QoL of their CVD patients, indicating a clear disconnect between patient and physician impressions.

The qualitative interviews identified similar discrepancies between physician and patient perspectives on the definition of QoL in CVD. Physicians place a heavy emphasis on the physical symptoms of CVD, defining well-being primarily in terms of symptomatology and secondarily considering the patient’s ability to perform daily activities, and cosmetic effects. In contrast, patients place importance on how they are feeling and the impact of CVD on other factors in their life, such as freedom, serenity, a feeling of good health, and a good night’s sleep.

The researchers involved in this study acknowledge that it has its limitations, with respect to sample size and qualitative methodology [7]. Nevertheless, the key findings (Table 2) raise some important research questions related to the assessment and management of QoL in CVD patients during routine clinical practice.

Fig. 1 Proportion of physicians and patients who scored the impact of each chronic venous disease factor on quality of life as a 4 (high impact) or 5 (very high impact) [7] Used with permission of Future Medicine, from The impact of lower limb chronic venous disease on quality of life: patient and physician perspectives. Santiago FR, et al., J Comp Eff Res. 11 (11) 2022; permission conveyed through Copyright Clearance Center, Inc.

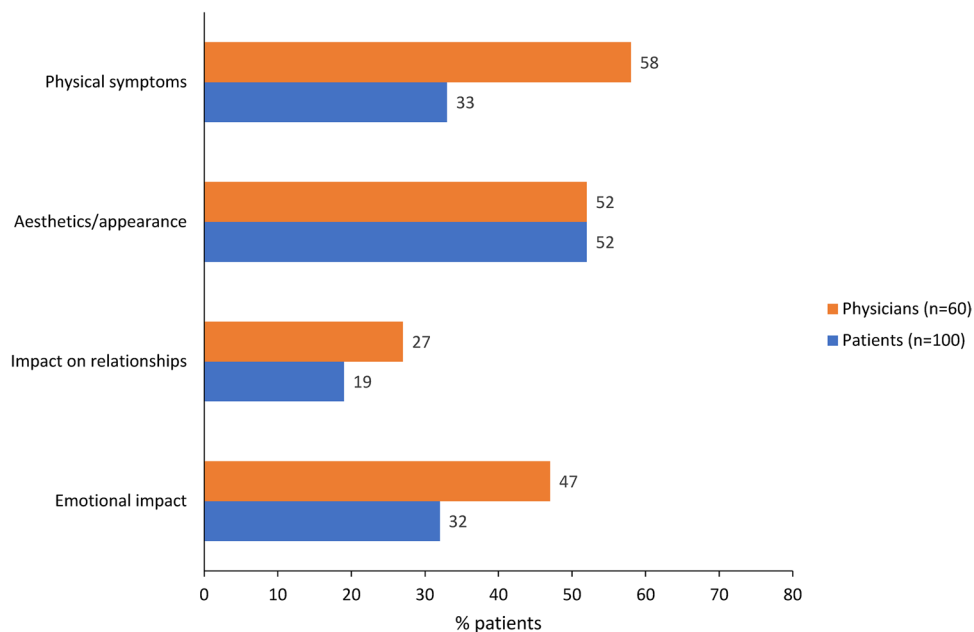


Table 2 Key findings of the Patient Journey in CVD study [7]

Patient perspectives

The impact of CVD on QoL was real irrespective of age or sex/gender, but increased significantly with disease severity for all dimensions (physical, aesthetic, emotional, relational)

Physician perspectives

Physicians tend to focus more on the physical symptoms of CVD than on other impacts

Physicians consider the emotional impact to be high only in female patients with C3–C4 CVD, and do not recognise the impact in male patients or those with less severe disease

Management of QoL

QoL questionnaires are not used in clinical practice

Patients were significantly less satisfied with the management of their QoL than physicians perceived them to be

Impact of CVD on sleep

About 25% of CVD patients have disturbed sleep, and sleep difficulties were more prevalent in patients with C3 or C4 disease than with C0–C2

Physicians do not routinely ask patients about the impact of CVD on sleep

CVD chronic venous disease, QoL quality of life

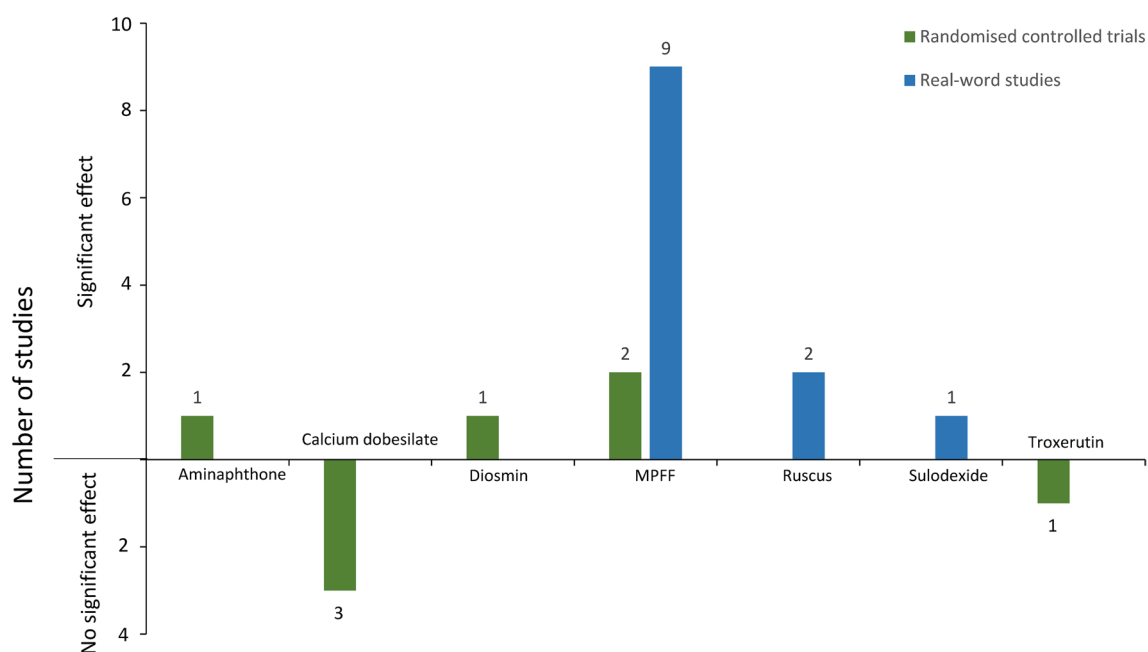


Fig. 2 Number of randomised controlled trials or real-world studies examining the effects of veno-active treatments on quality of life and published on PubMed or Embase up to 1 June 2022

3 Impact of Treatment on QoL in CVD Patients

The impact of veno-active treatment on QoL in CVD patients has been assessed in a Cochrane review, published in 2020 [8]. This analysis included five randomised controlled trials (RCTs) in which veno-active drugs (aminaphthone, calcium dobesilate, micronised purified flavonoid fraction [MPFF] and troxerutin) were compared

with placebo. The total number of patients in these studies was 1639, and the follow-up duration ranged from 2 to 12 months. QoL was assessed using a variety of questionnaires, including CIVIQ-14, CIVIQ-20, the Aberdeen Varicose Veins Questionnaire and the Venous Insufficiency Epidemiological and Economic Study – Quality of Life/Symptoms Scale (VEINES-QoL/SYM). The pooled analysis of all the studies found no statistically significant effect of veno-active treatment on QoL relative to placebo

(standard mean difference of -0.06 [95% confidence intervals (CI) -0.02 to 0.10]), but there was significant heterogeneity among studies.

The heterogeneity is apparent in the results of studies identified in a literature search of English-language studies cited on PubMed and Embase up to 1 June 2022. This search identified 17 studies (excluding reviews, abstracts and studies vs active comparators) investigating the impact of veno-active drugs versus placebo on QoL in patients with CVD [9–25]. In individual RCTs, aminaphthone [9], diosmin [21] and MPFF [9, 18] each significantly improved QoL compared with placebo (Fig. 2). In contrast, studies comparing calcium dobesilate [15, 19, 20] or troxerutin [9] with placebo found no significant effect for these agents on QoL (Fig. 2). Individual real-world studies found a significant improvement in QoL with the use of sulodexide [11], ruscus [12, 13] and MPFF [10, 14, 16, 17, 22–25]. Overall, there appears to be more real-world evidence for the effects of MPFF on QoL than for other veno-active products (Fig. 2).

These findings are supported by the results of a systematic review and meta-analysis of the MPFF RCTs, which showed that this form of treatment does significantly improve QoL relative to placebo [26]. This analysis of two RCTs ($n = 601$) found that MPFF significantly improved QoL relative to placebo (standard mean difference of -0.21 ; 95% CI -0.37 to -0.04 ; $p = 0.01$), as well as significantly improving leg symptoms and oedema [26].

4 Conclusion

CVD affects patients' QoL in a number of ways, and the impact is underestimated by physicians, who tend to focus on symptoms and functionality compared with the emotional, psychological or relational aspects of the disease. As physicians, it is important for us to be aware of the extent to which our perceptions and focus differ from those of our patients, to assess QoL in all our patients with CVD, including men and those with early-stage disease, and to ask patients about how CVD impacts their ability to sleep. These actions will help us to deliver QoL-centred care to our patients and improve both the physician–patient relationship and their satisfaction with treatment

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