



Generic Health-related Quality of Life is Significantly Worse in Varicose Vein Patients with Lower Limb Symptoms Independent of Ceap Clinical Grade

K.A.L. Darvall*, G.R. Bate, D.J. Adam, A.W. Bradbury

Birmingham University, Department of Vascular Surgery, Heart of England NHS Trust, Birmingham, UK

WHAT THIS PAPER ADDS

- This study demonstrates that patients with uncomplicated varicose veins (VV) often have severe symptoms that adversely affect their health-related quality of life (HRQL). These patients, who would often not be offered treatment for their varicose veins in a publicly-funded health system, have a lot to gain from treatment. This is the first study that demonstrates that HRQL is lower in patients with symptomatic VV irrespective of the clinical severity of disease.

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ABSTRACT

Objectives: To determine the relationship between lower limb symptoms and generic health-related quality of life (HRQL) in patients with varicose veins (VV).

Methods: 284 patients on the waiting list for VV treatment completed the Short Form-12 (SF12) and a questionnaire asking about the presence of lower limb symptoms commonly attributed to venous disease (pain or ache, itching, tingling, cramp, restless legs, a feeling of swelling, and heaviness).

Results: Median age was 57 years (interquartile range 45–67); 100 (35%) were male, and 182 (64%) had CEAP clinical grade 2 or 3 disease. Jonckheere–Terpstra test for trend revealed that both physical ($P < .0005$) and mental ($P = .001$) HRQL worsened as the reported number of symptoms increased.

Patients reporting tingling ($P = .016$, Mann–Whitney U test), cramp ($P = .001$), restless legs ($P < .0005$), swelling ($P < .0005$), and heaviness ($P < .0005$) had a significantly worse physical HRQL than those who did not. Mental HRQL was also significantly worse in patients with tingling ($P = .010$), cramp ($P = .008$), restless legs ($P = .040$), swelling ($P = .001$), and heaviness ($P = .035$).

These significant relationships remained, and pain was also correlated with worse physical HRQL ($P = .011$), when linear regression was performed to control for CEAP clinical grade, age and sex.

Conclusions: Physical and mental HRQL is significantly worse in VV patients with lower limb symptoms irrespective of the clinical stage of disease. This observation confirms that VV are not primarily a cosmetic problem and that NHS rationing of treatment to those with CEAP C4–6 disease excludes many patients who would benefit from intervention in terms of HRQL. Generic HRQL instruments also allow comparison with interventions for other chronic conditions.

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Introduction

Patient satisfaction including resolution of symptoms and improvement in health-related quality of life (HRQL) are increasingly recognised as important treatment outcome measures,

particularly in chronic venous insufficiency (CVI) where mortality is low.¹ Treatment for varicose veins (VV) has been shown to improve HRQL and eradicate symptoms in a highly cost-effective manner.^{2,3} However, in the United Kingdom (UK) National Health Service (NHS) for financial reasons non-reimbursement for the treatment of symptomatic, but as yet uncomplicated (CEAP C2–3), VV is widespread.^{4,5}

The presence of lower limb symptoms in the general population has been previously shown to be inconsistently associated with CEAP clinical grade, signs of CVI, and also the degree of superficial

* Corresponding author. K.A.L. Darvall, Birmingham University, Department of Vascular Surgery, Flat 5 Netherwood House, Solihull Hospital, Lode Lane, Solihull, West Midlands B91 2JL, UK. Tel./fax: +44 0121 424 5086.

E-mail address: katydarvall@btinternet.com (K.A.L. Darvall).

venous reflux on duplex ultrasound (DUS).^{6–8} This suggests that patients with uncomplicated (CEAP C2 and C3) VV can have significant symptoms and consequent reduced HRQL that could be improved by treatment.

The aim of this study is to determine the relationship between lower limb symptoms and generic HRQL in patients with VV.

Methods

Patients and questionnaires

Local ethical committee approval and written informed consent were obtained. During the study period the local Primary Care Trust (PCT) funded treatment for all symptomatic VV, both complicated (CEAP C4–6) and uncomplicated (CEAP C2 and C3).

Patients with symptomatic VV already booked for treatment completed the Short Form-12 (SF12) and a questionnaire asking about the presence of a number of lower limb symptoms that they attributed to their CVI. The symptoms, taken from the Edinburgh Vein Study (EVS), were pain or ache, itching, tingling, cramp, restless legs, a feeling of swelling, and heaviness. Patients were asked to bring the completed questionnaires with them when they attended hospital for treatment.

Responses to the 12 questions of the SF12 were used to calculate Physical Component Summary (PCS) and Mental Component Summary (MCS) scores. These scores were normalised to UK population norms, where the mean PCS and MCS for the general population is 50. A higher score indicates a better HRQL.

The presence of each symptom, attributed by the patient to their CVD, was recorded as present or absent. If the venous disease was bilateral the symptom was recorded as present if it was present in either leg.

Baseline information was collected at the time of attendance for treatment, and included age, gender, the presence of bilateral disease, and the CEAP clinical grade of both legs (the worst was used for analysis).⁹

Statistical analysis

Non-parametric methods within Statistical Package for the Social Sciences (SPSS) version 17.0 (SPSS, Chicago, IL, USA) were used. The Jonckheere–Terpstra test (a non-parametric alternative to analysis of variance) was used to assess trend in PCS and MCS across groups; Mann–Whitney *U* (MWU) test was used to examine the difference in median PCS and MCS according to the presence or absence of each lower limb symptom. Finally, linear regression was performed to control for CEAP clinical grade, age and sex.

Results

Questionnaires were sent to 395 consecutive patients. Of these, 284 (72%) completed both questionnaires. Patient and disease characteristics are shown in Table 1. There were no significant differences between the group of patients who completed the questionnaires and the patients who did not in terms of age, gender, CEAP clinical grade, bilateral disease and treated veins (GSV or SSV) and recurrent disease.

Number of lower limb symptoms and HRQL

Patients were allocated according to how many symptoms they had (out of a total of 7) into three groups: 1–2 symptoms (18%), 3–4 symptoms (35%), and 5–7 symptoms (47%). There was no significant relationship between the number of symptoms and CEAP clinical grade (Fig. 1).

Table 1
Patient and disease characteristics.

Parameter	
No. of patients	284
No. of legs	375
Age: median (interquartile range) in years	57 (45–67)
Sex	
Male	100 (35.2)
Female	184 (64.8)
CEAP clinical grade	
C ₂	228 (60.8)
C ₃	25 (6.7)
C ₄	84 (22.4)
C ₅	20 (5.3)
C ₆	18 (4.8)
A(E)tiology	
Primary (<i>E_p</i>)	375 (100)
Secondary (<i>E_s</i>)	0 (0)
Anatomical patterns of venous reflux	
Superficial and deep (<i>A_{sd}</i>)	7 (1.9)
Superficial only (<i>A_s</i>)	368 (98.1)
Primary GSV	251 (66.9)
Recurrent GSV	97 (25.9)
Primary SSV	54 (14.4)
Recurrent SSV	15 (4.0)
Pathophysiological classification	
Reflux (<i>P_r</i>)	344 (100)
Obstruction (<i>P_o</i>)	0 (0)

The Jonckheere–Terpstra test was used to assess trend in PCS and MCS across the groups. Both median PCS ($P < .0005$) and MCS ($P = .001$) worsened as the number of symptoms increased (Fig. 2).

Specific lower limb symptoms and physical HRQL (PCS)

Patients reporting tingling ($P = .016$, MWU), cramp ($P = .001$), restless legs ($P < .0005$), swelling ($P < .0005$), and heaviness ($P < .0005$) had a significantly worse physical HRQL (PCS) than those who did not (Fig. 3).

Specific lower limb symptoms and mental HRQL (MCS)

Mental HRQL (MCS) was also significantly worse in patients with tingling ($P = .010$), cramp ($P = .008$), restless legs ($P = .040$), swelling ($P = .001$), and heaviness ($P = .035$), than those without these symptoms (Fig. 4).

Further analysis

Increasing CEAP clinical grade and age were significantly associated with a worse HRQL on univariate analysis. When linear

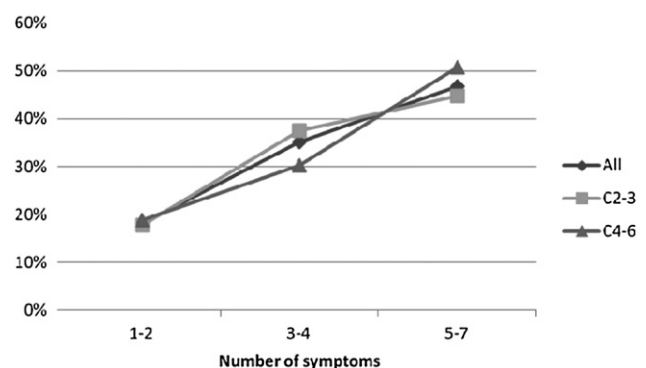


Figure 1. The number of lower limb symptoms reported according to CEAP clinical grade.

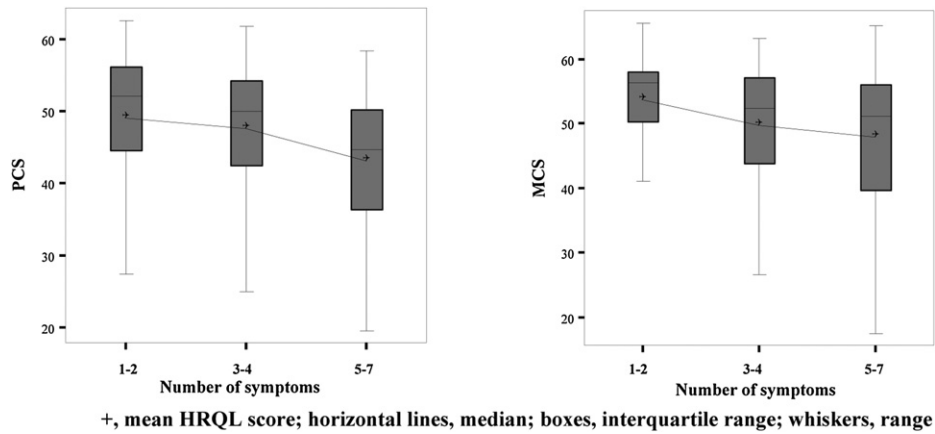


Figure 2. Box and whisker plots of HRQL scores by the number of lower limb symptoms.

regression was performed to control for these two variables, the significant relationships between HRQL and individual symptoms remained, and pain was also correlated with worse physical HRQL ($P = .001$).

Discussion

The main finding of the current study is that physical and mental HRQL is significantly worse in VV patients with lower limb symptoms irrespective of the CEAP clinical grade of disease.

Traditionally, the presence of one or more lower limb symptoms thought likely to be due to CVI, together with duplex, hand-held Doppler or clinical evidence of saphenous reflux, has been considered an indication for intervention.⁶ In 2000, the National Institute for Health and Clinical Excellence (NICE) published guidance for general practitioners on who should be referred for VV treatment.¹⁰ They recommended referral for patients with either significant symptoms from their VV resulting in a reduction in their HRQL, or those with complications of VV, namely ulceration, bleeding, thrombophlebitis or extensive skin changes. It is clear from questionnaire studies that some PCTs have taken this further for local financial reasons and only reimburse treatment for “complicated” (CEAP C4–6) VV.^{5,11–13} The “excuse” for such rationing may have been inconsistent relationships that had previously been reported between lower limb symptoms and severity of CVI, both clinical and on DUS; as well as the lack of good evidence that treating such VV was cost-effective.^{6–8,14,15}

Over the last decade it has become abundantly clear that treatment of VV, whether by surgery or a newer minimally invasive option, improves both symptoms and HRQL, and results in high

levels of patient satisfaction.^{2,16–27} Results of a recent randomized trial have also shown that surgery for uncomplicated VV gives a significant benefit over conservative treatment in terms of HRQL, health status and patient satisfaction at a relatively small cost to the NHS.^{2,3} Despite this, rationing continues. We have also previously found a much greater improvement in SF12-PCS in the 12 months after ultrasound-guided foam sclerotherapy (UGFS) for VV, in the patients with CEAP C2–3 disease compared with those with CEAP C4–6 disease.²⁵

Using a generic HRQL score allows health providers to compare interventions for different conditions to enable appropriate allocation of resources.²⁷ The relative priority of VV treatment, compared to other procedures, has not been well-defined. For example, our group has previously found that the improvement in generic physical and mental HRQL (measured by SF12) in the 12 months after surgery, was the same between patients having surgery for VV and those undergoing laparoscopic cholecystectomy for biliary colic.²⁸

PROMS (Patient Reported Outcome Measures) is a Department of Health-led programme in the UK, requiring collection of HRQL data before and after elective surgery for unilateral hip and knee replacements, groin hernia and VV surgeries since April 2009.²⁹ PROMS published their first report in August 2011, which found that generic HRQL improvement, measured by EQ-5D index and EQ-VAS, was slightly better following VV surgery, compared with groin hernia surgery.²⁹ So, why should treatment for VV be rationed, rather than elective groin hernia or gallbladder surgery?

In this study we only used a generic measure of HRQL, whereas it is recommended that for a full assessment both generic and disease-specific instruments should be used.¹ The reason for this is

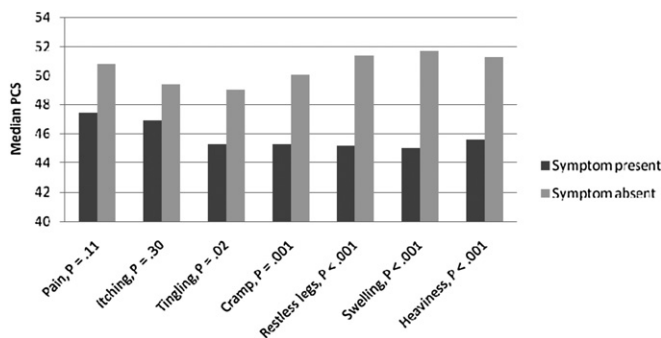


Figure 3. The effect of specific lower limb symptoms on physical HRQL (PCS).

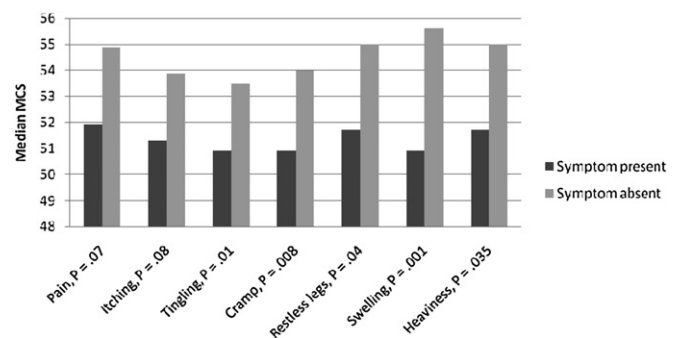


Figure 4. The effect of specific lower limb symptoms on mental HRQL (MCS).

simple as the relationship between, for example, the Aberdeen Varicose Vein Symptom Severity Score (AVSS) and the presence of symptoms would be obvious, expected and previously demonstrated, however, it was a little surprising to see that the presence of lower limb symptoms had such a marked effect on the physical and mental health of patients. In addition, this study also confirms that the SF12, a very short and easy to complete questionnaire, is both responsive and sensitive to change in the CVD population, obviating the need for more lengthy, complicated instruments. In our experience, these two questionnaires (SF12 and AVSS) are easy to administer in the clinical setting and could be used in combination as a screening tool to aid selection of patients for treatment.

The response rate of 72% in this study is in line with other questionnaire studies including VV patients.^{16,27,30} Questionnaires were administered by post which probably reduced the response rate, but prevented the social desirability bias associated with interview. Also, patients were unlikely to inflate their symptoms (“fake bad”) in this study as they were already attending for treatment at the time of completing the questionnaires.

In conclusion, these observations confirm that VV are not primarily a cosmetic problem and that NHS rationing of treatment to those with complicated VV excludes many patients with a lot to gain.

Conflict of Interest/Funding

None.

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