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What is This?

Comparison of disease-specific quality of life tools in patients with chronic venous disease

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Abstract

Objectives: Quality of life (QoL) is an important outcome measure in the treatment for chronic venous disease. The Aberdeen Varicose Vein Questionnaire (AVVQ) and the Chronic Venous Insufficiency quality of life Questionnaire (CIVIQ-14) are two validated disease-specific QoL questionnaires in current use. The aim of this study is to evaluate the relationship between the AVVQ and the CIVIQ-14 to enable better comparison between studies and to compare these disease-specific QoL tools with generic QoL and clinician-driven tools.

Methods: Adults attending our institution for management of their varicose veins completed the AVVQ, CIVIQ-14 and EuroQol-5D (EQ-5D). Clinical data, CEAP classification and the Venous Clinical Severity Score (VCSS) were collected. The relationship between the AVVQ and CIVIQ-14 scores was analysed using Spearman's correlation. The AVVQ and CIVIQ-14 scores were also analysed with a generic QoL tool (EQ-5D) and a clinician-driven tool, the VCSS.

Results: One hundred patients, mean age 57.5 (44 males; 56 females), participated in the study. The median AVVQ score was 21.9 (range 0–74) and the median CIVIQ-14 score was 30 (range 0–89). A strong correlation was demonstrated between the AVVQ and CIVIQ-14 scores (r = 0.8; p < 0.0001). Strong correlation was maintained for patients with C1-3 disease (r = 0.7; p < 0.0001) and C4-6 disease (r = 0.8; p < 0.0001). The VCSS correlated strongly with the AVVQ and CIVIQ-14 scores (r = 0.7; p < 0.0001 and r = 0.7; p < 0.0001 and r = 0.7; p < 0.0001, respectively). Both the AVVQ and CIVIQ-14 scores correlated well with the EQ-5D score (r = -0.5; p < 0.0001 and r = -0.7; p < 0.0001, respectively).

Conclusions: This study demonstrates that there is good correlation between two widely used varicose vein specific QoL tools (AVVQ and CIVIQ-14) across the whole spectrum of disease severity. Strong correlation exists between these disease-specific QoL tools and generic and clinician-driven tools. Our findings confirm valid comparisons between studies using either disease-specific QoL tool.

Keywords

Varicose veins, chronic venous disease, patient-reported outcome measures, quality of life, Aberdeen Varicose Vein Questionnaire, Chronic Venous Insufficiency Quality of life Questionnaire

Introduction

The introduction of endovenous treatments has heralded new advances in the management of chronic venous insufficiency over the past decade.¹ Key to understanding the burden of venous disease and the long-term efficacy of newer endovascular approaches is the use of outcome measures relevant to the functional status of the patient.

Traditional objective measures of disease severity that focus on the morbidity and mortality of venous disease, whilst readily quantifiable, do not necessarily correlate with the functional status of the patient. To meaningfully capture outcomes in venous disease, the full biopsychosocial consequence of the disease must also be established.² As the role for patient-centred care in venous disease increases, the assessment of quality of life (QoL) in venous disease is becoming

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increasingly important. Currently, there are a wide variety of validated outcome measures in use and these can be divided into generic and disease-specific QoL tools.

Generic QoL instruments permit a patient's overall functional status to be measured regardless of their specific disease state and thus have the advantage of allowing comparison across different studies of different diseases. The EuroQol 5 Domain score (EQ-5D) is a well-validated generic OoL score.³ Disease-specific OoL tools directly assess attributes related to a particular disease. They are increasingly becoming utilized in the study of varicose veins as they are more sensitive for assessing venous disease outcomes. The Aberdeen Vein Questionnaire⁴ (AVVQ) and Varicose the Venous Insufficiency quality ChronIc of life Questionnaire⁵ (CIVIQ) are two validated disease-specific OoL questionnaires most commonly used. Other examples of disease-specific QoL tools include the Charing Cross Venous Ulceration Questionnaire (CXVUQ),⁶ the Venous Insufficiency Epidemiological and Economic Study instrument (VEINES)⁷ and the Specific Quality of Life and Outcome Response-Venous questionnaire (SQOR-V).⁸

In a joint statement by the American Venous Forum and the Society of Interventional Radiology, the use of both disease-specific and generic QoL tools in conjunction with clinician-driven assessment is recommended in all clinical trials investigating venous insufficiency.^{9,10} There are significant differences in the choice of QoL tools amongst studies, making it challenging for the clinician to make direct comparisons between studies.¹¹ Therefore, the correlation between different QoL tools is of huge significance if clinicians are to make valid comparisons between studies. However, at present the relationship between the various QoL tools has not been fully characterized. The aim of this study is to evaluate the relationship between two disease-specific QoL tools; the extensively validated AVVQ and more recently validated CIVIQ-14, to enable better comparison between studies and to compare these tools with generic QoL tools and cliniciandriven tools.¹²

Methods

Patient selection

Adult patients attending the vascular surgery outpatient clinic at our Institution for management of their varicose veins were prospectively invited to participate in this study. Patients were recruited over a four-month period, from August 2012 to December 2012 in a consecutive manner. Demographic data including patient age and gender were collected. All participants were asked to complete the two disease-specific QoL tools, the AVVQ and CIVIQ-14, prior to their outpatient appointment. The AVVQ consists of 13 questions addressing various biopsychosocial attributes of chronic venous disease, including specific signs and symptoms, use of compression stockings and daily functional impact.¹³ The overall score ranges from 0 to 100, with a higher score denoting greater burden of disease. The CIVIQ-14 is a revised version of the well-validated CIVIQ-20 instrument and has been shown to be valid in studies of patients across different countries.^{2,5} The CIVIQ-14 contains 14 questions covering three QoL dimensions: physical, pain and psychological and is scored from 0 to 100, with a higher score denoting a lower QoL.

Patients also completed the EuroQol-5D questionnaire (5-level version of the EQ-5D, EuroQoL Group, Rotterdam, the Netherlands).^{3,14} The EQ-5D measures the biological, psychological and social aspects of a disease state to generate an overall score.

The clinical severity of venous disease for each patient was stratified by a single clinician using the following clinician-driven tools: the Clinical Etiologic Anatomic Pathophysiologic (CEAP) score¹⁵ and the revised Venous Clinical Severity Score¹² (VCSS). The VCSS comprises nine characteristics of venous disease and each component is scored independently on a scale from 0 to 3.

Statistical analysis

Outcomes were scored for each patient. In cases of bilateral venous disease, scores were recorded for each leg and the score of the worst leg was used. Statistical analysis was performed using Prism 5.0a (GraphPad Software, Inc, La Jolla, CA). The relationship between the AVVQ and CIVIQ-14 scores was analysed using Spearman's correlation for nonparametric data. Correlation was also analysed separately for patients with less severe (C1-3) disease and more severe (C4-6) disease.

The AVVQ and CIVIQ-14 scores were analysed against the EQ-5D and EQ-VAS. Both the AVVQ and CIVIQ-14 were analysed against the VCSS. Spearman's correlation was used to assess the relationship for each analysis, and p values less than 0.05 were considered statistically significant.

Results

Patient demographics

Over a four-month period between August 2012 and December 2012, fully complete questionnaires were collected for 100 patients. There were 44 males (44%) and 56 females (56%). The mean age of participants was

57.5 years (range 22–84 years); 50% of patients were aged 65 years and over. The median AVVQ score was 21.9 (range 0–74; IQR 13.3–30.7) and the median CIVIQ-14 score was 30 (range 0–89; IQR 17.6–46).

Relationship between disease-specific QoL tools (AVVQ and CIVIQ-14) and EQ-5D

The EQ-5D score demonstrated a strong negative correlation with both the AVVQ (Figure 1(a)) and CIVIQ-14 scores (Figure 1(b)) (r = -0.5; p < 0.0001 and r = -0.7; p < 0.0001, respectively).

Relationship between disease-specific QoL tools (AVVQ and CIVIQ-14) and VCSS

There was a strong positive correlation between the VCSS and both the AVVQ (Figure 2(a)) and CIVIQ-14 scores (Figure 2(b)) (r = 0.7; p < 0.0001 and r = 0.7; p < 0.0001, respectively).

Relationship between the AVVQ and CIVIQ-14

Strong positive correlation was seen between the AVVQ and CIVIQ-14 scores (r = 0.8; p < 0.0001) (Figure 3(a)). Strong correlation was maintained for patients with C1-3 disease (r = 0.7; p < 0.0001) (Figure 3(b)) and C4-6 disease (r = 0.8; p < 0.0001) (Figure 3(c)).

Discussion

Measurement of QoL is now common place in studies of chronic venous disease. Over the past decade, there has been increasing recognition amongst phlebologists that disease-specific QoL tools provide a more



Figure 1. Graphs demonstrating the relationship between the EQ-5D score and: (a) the AVVQ score (r = -0.5; p < 0.0001); (b) the CIVIQ-14 score (r = -0.7; p < 0.0001).

AVVQ: Aberdeen varicose vein questionnaire; CIVIQ: chronic venous insufficiency quality of life questionnaire.



Figure 2. Graphs demonstrating the relationship between the VCSS and: (a) the AVVQ score (r = 0.7; p < 0.0001); (b) the CIVIQ-14 score (r = 0.7; p < 0.0001).

VCSS: venous clinical severity score; AVVQ: Aberdeen varicose vein questionnaire; CIVIQ: chronic venous insufficiency quality of life questionnaire.

meaningful correlate of a patent's functional status than objective anatomical or haemodynamic outcome measures.^{16,17} Reporting guidelines published by the American Venous Forum now recommend the use of disease-specific and generic QoL tools along with clinician-driven outcome measures in studies of chronic venous disease.^{9,10} In 2005, a review commissioned by the United Kingdom Department of Health recommended the routine use of patient-reported outcome measures after intervention for venous disease.^{18,19}

The choice of disease-specific QoL questionnaire is crucial to permit both the evaluation of the efficacy of current endovenous treatments and valid comparison of results from different trials. Currently, there are a number of different disease-specific and generic QoL tools and clinician-driven tools being utilized in studies of chronic venous disease.^{11,20} The AVVQ and CIVIQ-14 were chosen for evaluation in this study. The AVVQ is a commonly used validated disease-specific QoL tool that has been shown to be sensitive in assessing functional outcome after treatment for chronic venous disease.²¹ The CIVIQ-14 was recently developed as a more stable version of the CIVIQ-20 instrument, which itself has been commonly used and validated since 1996.^{2,5,22}

This study has established that a strong correlation exists between the two disease-specific OoL tools selected for evaluation, the AVVQ and CIVIQ-14, further demonstrating that these disease-specific questionnaires are useful tools in the assessment of QoL in chronic venous disease. The findings from this study show that the relationship between the AVVQ and CIVIQ-14 scores are predictable, thereby supporting the validity of making comparisons between studies regardless of whether the study has utilized the CIVIQ-14 or AVVQ QoL tool. The AVVQ differs in several aspects from the CIVIO-14 questionnaire. In comparison with the CIVIQ-14, the AVVQ assigns a greater proportion of questions to the physical aspects of chronic venous disease. The CIVIQ-14 is validated for the entire spectrum of chronic venous disease,⁵ except venous ulcers, whilst the AVVO specifically targets varicose veins and includes ulceration.⁴ Despite these differences, the current study shows that the two OoL tools closely correlate, and the correlation is maintained across the spectrum of disease severity, from less severe (C1-3) to more severe disease (C4-6).

Our findings have expanded on the findings of Shepherd et al.¹⁶ who found that the AVVQ correlated



Figure 3. Graphs demonstrating the relationship between AVVQ and CIVIQ-14 scores for: (a) CEAP 1-6 disease (r = 0.8; p < 0.0001); (b) CEAP 1-3 disease (r = 0.7; p < 0.0001) and (c) CEAP 4-6 disease (r = 0.8; p < 0.0001). AVVQ: Aberdeen varicose vein questionnaire; CIVIQ: chronic venous insufficiency quality of life questionnaire; CEAP: clinical etiologic anatomic pathophysiologic.

strongly with another disease-specific QoL tool, the SQOR-V questionnaire. The degree of correlation (Spearman coefficient 0.702) was similar to our findings (Spearman coefficient 0.8). Both the SQOR-V⁸ and CIVIQ-14 place a greater emphasis on patient-reported symptoms rather than physical signs and this may in part explain the comparable degree of correlation.

Other types of outcome measures utilized to assess chronic venous disease were also shown in this study to correlate with the AVVO and CIVIO-14 OoL tools. The study evaluated a generic QoL questionnaire, the EO-5D, which was shown to correlate strongly with both of the disease-specific QoL tools. This is in contrast to findings from previous studies, which have compared different generic QoL questionnaires with disease-specific QoL questionnaires. Shepherd et al.¹⁶ found that the AVVO only correlated weakly with a generic OoL tool, the Short Form-12 (SF-12) questionnaire. The reasons for the differences in our findings are not immediately clear, but may be attributed to the difference in construction of health profile-based questionnaires (Short Form series) and preference-based questionnaires (EQ-5D).²³

This study also evaluated a clinician-completed assessment tool (VCSS) against the AVVQ and CIVIQ-14. A very strong correlation was found between the clinical scoring system and both of the disease-specific QoL tools. This relationship highlights the sensitivity of the AVVQ and CIVIQ-14 towards the physical aspects of QoL in chronic venous disease. Our results strongly reinforce the findings by Carradice et al.²⁴, which also found that increasing venous disease severity was associated with poor disease-specific and generic QoL scores as measured by the AVVQ and EQ-5D, respectively.

The lack of consensus on which disease-specific QoL tool to use for measuring outcomes in chronic venous disease has contributed to an inconsistency in the choice of the QoL tool used in studies of venous disease.^{11,25} The need to make comparisons between studies using different outcome measures has highlighted the importance of understanding the relationship between these disease-specific QoL tools as well as the relationship with generic QoL and clinician-driven tools.

A limitation of this study was the relatively small number of participating patients with C1 disease. This may limit the generalizability of our findings. The number of patients with C1 disease treated in secondary care is restricted due to the limitation of referrals from primary care under the United Kingdom National Healthcare System. In the current study, the patient selection was performed in a consecutive manner, and not randomized. This would have been unlikely to impact on the results as the primary purpose of this study was ascertain the correlation between the CIVIQ-14 and AVVQ QoL tools rather than to compare the outcomes between interventions. What remains to be seen is the relationship of the responsiveness between the disease-specific QoL tools, generic QoL tools, and clinician-completed outcome measures several weeks post-procedure. It will be important to see if changes in post-procedure AVVQ scores correlate with respective changes in CIVIQ-14 scores and this will contribute further to our understanding of these QoL tools relative to one another. Further data points are required to generate a reliable conversion formula.

Conclusion

This study demonstrates that there is a strong and significant linear correlation between two of the main disease-specific QoL tools for varicose veins (AVVQ and CIVIQ-14) across the whole spectrum of disease severity. Strong correlation also exists between these diseasespecific QoL tools and the generic EQ-5D QoL tool as well as the clinician-driven VCSS tool. Our findings support the validity of comparisons of results between studies using either the CIVIQ-14 or AVVQ diseasespecific QoL tool.

Conflict of interest

None declared.

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