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The Australian Vascular Quality of Life Index (AUSVIQUOL): An Improved Clinical Quality of Life Tool for Peripheral Vascular Disease☆

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Objectives. *To validate the Australian Vascular Quality of Life Index (AUSVIQUOL) as a quality of life (QOL) tool appropriate for peripheral vascular disease patients in the clinical setting.*
Design. *Cross-sectional study.*
Materials. *The study group consisted of 71 patients with vascular claudication of varying severity attending a tertiary hospital outpatient department.*
Methods. *The results of the AUSVIQUOL and Medical Outcomes Short Form Health Survey (SF-36) were compared through factor and regression analyses. A group of 12 patients was then reassessed to compare the reliability and internal consistency of the two indices.*
Results. *The AUSVIQUOL took less time to complete than the SF-36 (3.27 v 10.79 min;* $p < 0.0001$*) and fewer patients found the questions confusing (2% v 26%). The AUSVIQUOL was easier to administer and had a higher level of patient acceptance than the SF-36. The regression analysis showed that for each of the domains in the AUSVIQUOL there was a significant correlation with measures in the SF-36 (adjusted R-squared 0.420, 0.480 and 0.331). The AUSVIQUOL demonstrated a good level of internal consistency when compared to the SF-36 (Cronbach's alpha 0.8702 vs 0.6307).*
Conclusion. *In comparison with the SF-36, the AUSVIQUOL is an improved tool for the QOL assessment of patients with peripheral vascular disease in the clinical setting.*

Keywords: Peripheral Vascular Disease (PVD); Quality of Life (QOL); Medical Outcomes Short Form Health Survey (SF-36); Claudication.

Introduction

The practice of medicine is undergoing continual change and development. In the last century, there has been a significant shift in emphasis from curative medicine alone to quality of life health outcomes. This is embodied in the World Health Organisation's definition of health; a state of physical, social and mental well-being and not simply an absence of infirmity.[1]

A majority of QOL indices are generic and are designed to assess all areas of disease-associated morbidity. These tools are a comprehensive holistic measure of the relative burden of illness in the general population,[2] however, this can make them time consuming and arduous for patients to complete. Furthermore, generic indices lack sensitivity[3,4] and may not adequately assess QOL in patients with a specific chronic disease process where many of the questions may be irrelevant, unnecessary and repetitive. Hence, disease-specific QOL indices are now being developed for use in various disciplines of medicine and surgery. These disease-targeted instruments may be used to elucidate specific domains of particular importance to the patient.

Health-related QOL is significantly impaired in individuals with peripheral vascular disease. Intermittent claudication refers to leg pain consistently produced by walking, and is relieved by rest. This impacts on QOL in several ways, including pain, sleep disturbance and restrictions in activities of daily

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living.[5] Patients also demonstrate significant impairment in social, emotional and mental health.[3] QOL as an outcome measure in the management of peripheral vascular disease is especially important because intervention, including conservative or invasive measures, aim to improve quality rather than quantity of life.[3] Studies have shown that the severity and nature of occlusive peripheral vascular symptoms and the response to treatment are more adequately assessed by a disease-specific QOL measure.[3,4,6] Examples of measures currently available include the VascuQol[7] and the Claudication Scale (CLAU-S).[8]

The Australian Vascular Quality of Life Index was developed as a QOL index specific for vascular disease patients.[9] It was first validated in abdominal aortic aneurysm (AAA) patients,[9] yet the question areas are relevant to all fields of vascular surgery. The aim of the present study was to demonstrate this QOL index as an appropriate tool for patients with vascular claudication.

Materials and Methods

Patients

The prospective study group consisted of seventy-one patients with intermittent claudication due to peripheral vascular disease attending the Royal Perth Hospital (RPH) outpatient vascular clinic. The inclusion criteria were patients with the symptom of claudication of varying severity, secondary to peripheral vascular disease. They were recruited consecutively over a 3-month time period. Patients who were non-English speaking or with diagnosed dementia were excluded. No patient refused to participate.

In order to validate the AUSVIQUOL against the SF-36 for use in vascular patients, patients were asked to complete both questionnaires with or without assistance. The SF-36 was presented first, then the AUSVIQUOL. A random subset of 12 patients from the original group was then asked to complete the questionnaires for a second time at one month following completion of the first and without any intervention within that time period, to demonstrate reliability of the scale. All interviews were conducted in person by one of the authors (MS or EH) at RPH or in the patients' home. Table 1 shows patient characteristics.

Table 1. Patient characteristics of Study and Subset groups

Characteristic	Study group ($n = 71$)	Subset group ($n = 12$)
Mean age (years)	72.8	73.7
Gender		
Male	48	8
Female	23	4

Australian Vascular Quality of Life Index

The AUSVIQUOL (Fig. 2) was developed as a new QOL index to be used specifically for patients suffering from vascular disorders. It consists of ten questions which are divided into three domains: General Health Perceptions; Function, Mobility and Pain; and Psycho-Social Aspects. Each question is scored using weighted values which give a range of possible total scores from zero (significant impairment in QOL within all dimensions) to 100 (no impairment in QOL). Table 2 shows the QOL categories for the AUSVIQUOL. The AUSVIQUOL has been demonstrated as a disease-specific QOL appropriate for patients with AAA and hence, may be appropriate for use throughout a range of vascular surgical patients.

Medical Outcomes Short Form 36 Health Survey (SF-36)

The SF-36 was developed by Ware *et al*[10] and designed to assess the generic health concepts of QOL. As such, it was not designed to be specific to age, disease or treatment group.[11] It includes 36 questions covering eight domains: Bodily Pain, Physical Function, Physical Role Function, Mental Health, Vitality, Social Function, Social Role Function, and General Health. Responses to questions are either yes/no or in a scaled score format. Scores are then used to calculate an average score[12] and transformed on a scale from zero (very poor) to 100 (excellent).

Statistical analysis

(a) Study group

The validity of the AUSVIQUOL was assessed through factor and regression analyses comparing the domain scores of the AUSVIQUOL and SF-36. For the factor analysis, all eleven domain scores across the two scales [8 (SF-36) plus 3 (AUSVIQUOL)] were analysed simultaneously in a single Maximum Likelihood Factor Analysis with a Promax rotation. The

Table 2. QOL categories for the AUSVIQUOL

QOL Category	Total score
Excellent	100
Very good	80–99
Good	55–79
Fair	21–54
Poor	0–20

domain scores were treated as a single set of scores to identify which domains from each questionnaire were related through underlying latent factors. For the regressions analysis, the three domain scores from the AUSVIQUOL were regressed individually against the eight domain scores from the SF-36 to further identify the relation between domain scores from the two questionnaires. Each of the Regression analyses was treated as an Ordinary Least Squares Multiple Regression (MRA) and the method used was Stepwise regression. The purpose of these analyses was to determine the corresponding domain measures in the SF-36 to each of the domain measures in the AUSVIQUOL.

The internal consistency of each scale was assessed with Cronbach's alpha and was based on correlations between domain scores for each scale.

(b) Subset group reassessment

A correlated t-test was carried out on the average score of the SF-36 for the subgroup of 12 patients who completed the two scales twice. Similarly, a correlated t-test was conducted on the total score of the AUSVIQUOL in the same group to ascertain whether or not there was a change in scores over time, under the expectation that there would be no change. In order to reinforce this analysis given the small number of cases and the possibility of anomalous data distribution, a Bootstrap version of the Wilcoxon signed ranks test was also used to test these differences.

Results

(a) Study group

The average time to complete the AUSVIQUOL and SF-36 questionnaires was 3.27 (Range 2–9; SD 1.53) and 10.79 (Range 7–22; SD 4.31) minutes respectively. Thirty-six percent of patients required assistance completing both questionnaires as their reading glasses were not available at the time. Twenty-six percent of patients found questions confusing within the SF-36 compared to only 2% with the AUSVIQUOL. One patient was unable to understand most of the questions in the SF-36. Comparison of the average score of the SF-36 and the total score of the AUSVIQUOL is presented in Fig. 1.

The factor analysis revealed two identifiable factors which were interpreted as 'Health and Physical Condition' and 'Psychological State'. The pattern matrix is displayed in Table 3. This shows that Factor 1 correlates the Physical Function, Bodily Pain, Vitality, General Health and Role Physical domains of the SF-36 with the Function, Mobility and Pain, and General Health Perceptions domains of the AUSVIQUOL (Pattern loading > 0.5); and Factor 2 correlates the Mental Health, Role Emotional, and Social Function domains of the SF-36 with the Psycho-Social Aspects domain of the AUSVIQUOL (Pattern loading > 0.5). The Goodness-of-Fit test was non-significant ($p = 0.620$), revealing that there were no more factors to extract and the two factors fit the data without any significant residual. The correlation between the two factors is large (0.67), so much of the variance is shared between the two factors.

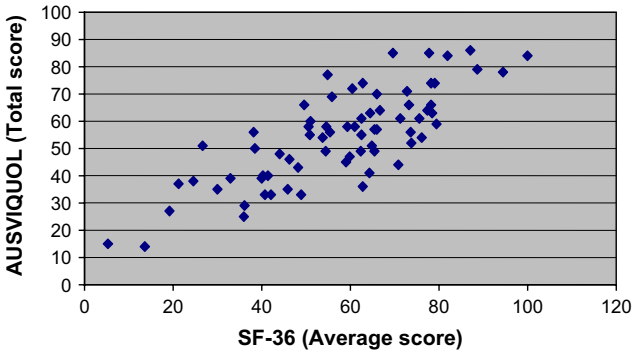

Fig. 1. Comparison of Average score of SF-36 with Total score of AUSVIQUOL.

The regression analysis, relating the domain scores of the two questionnaires, showed that for each of the domains in the AUSVIQUOL there was a significant relation with domains in the SF-36. Some of the SF-36 scores contained variance unrelated to the scores in the AUSVIQUOL. In relation to General Health Perceptions domain in the AUSVIQUOL, the General Health domain of the SF-36 was significant and accounted for 42% (adjusted) of the variance, as shown in the regression equation $\text{GHP} = 0.166 \times \text{GH} + 6.271$.

Table 3. Factor Analysis Pattern Matrix

	Factor	
	Health and Physical Condition	Psychological State
Physical Function (SF-36)	**.958**	−.198
Function, Mobility and Pain (AUSVIQUOL)	**.758**	−.011
Bodily Pain (SF-36)	**.743**	.022
Vitality (SF-36)	**.716**	.249
General Health (SF-36)	**.641**	.180
General Health Perceptions (AUSVIQUOL)	**.621**	.023
Role Physical (SF-36)	**.510**	.117
Mental Health (SF-36)	−.016	**.887**
Role Emotional (SF-36)	−.145	**.861**
Social Function (SF-36)	.191	**.588**
Psycho-social Aspects (AUSVIQUOL)	.156	**.528**

The Australian Vascular Quality of Life Index

Preliminary Details: *Name:* *Date of Birth:*
Type of procedure:

1. General Health Perceptions

Q1 How has your health been in the last month in comparison with other people you know of the same or similar age?

1. Excellent
2. Very Good
3. Good
4. Fair
5. Poor

Q2 During the last month, how many days have you spent sick in bed?

1. None
2. Between 1 and 5 days
3. Between 6 and 14 days
4. Between 15 and 30 days
5. Everyday

If you have had your vascular surgery, go to Q3a. If not, go to Q3b

Q3a In comparison with your health before vascular surgery, how would you rate your health now?

1. A lot better than before the surgery
2. A little better than before the surgery
3. The same as before the surgery
4. A little worse than before the surgery
5. A lot worse than before the surgery

Q3b In comparison with your health 1 year ago, how would you rate your health now?

1. A lot better than one year ago
2. A little better than one year ago
3. The same as one year ago
4. A little worse than one year ago
5. A lot worse than one year ago

2. Function, Mobility and Pain

Q4 At a steady pace, how far are you able to walk on the flat before becoming short of breath, or experience chest pain, leg pain or another limitation?

1. More than 1km
2. Between 500m and 1km
3. Between 100m and 500m
4. Between 1m and 100m
5. I can't walk/I have pain at rest

Q5 Do you have pain or discomfort in your legs or feet that limits your mobility or disturbs your sleep, ulcers on your feet or have you lost a limb?

1. None of these
2. Leg or foot pain when I walk
3. Leg or foot pain at night
4. I have an ulcer on my foot or leg
5. I've had a limb(s) amputated

Q6 Are you able to do most of the chores around the house and do your grocery shopping?

1. Yes, easily
2. Yes, but I find it difficult
3. Yes, with some assistance
4. Yes, with continuous assistance
5. No, not at all

Fig. 2. The AUSVIQUOL.

Q7 Do you suffer from fits, faints, funny turns or memory problems (including epilepsy, transient ischaemic attack, episodes of dizziness, loss of consciousness or stroke)?

1. Never/I used to/I had a non-disabling stroke
2. Occasionally
3. Sometimes
4. Often
5. Continuously/I've had a disabling stroke

Q8 Are you able to read a magazine or newspaper?

1. Yes, easily
2. Yes, but I find it difficult
3. Yes, with prescription glasses
4. No, but I still have some sight
5. No, I am blind

3. Psycho-Social Aspects

Q9 How often do you see your friends and relatives, or participate in hobbies?

1. Everyday
2. Several times per week
3. Once per week
4. Several times per month
5. Rarely/Never

Q10 Have you felt lonely, unhappy, depressed, or anxious over the past month?

1. No
2. Yes, occasionally
3. Yes, sometimes
4. Yes, often
5. All the time

In general, have there been any changes in your life that you feel have been detrimental to your quality of life (For example, are there some things you can't do anymore?)

SCORING (Q1-10):

Response 1 = 10 POINTS, 2 = 5 POINTS, 3 = 2 POINTS, 4 = 1 POINT, 5 = 0 POINTS.

Doimain Score:	General Health Perceptions	…/30
	Function, Mobility and Pain	…/50
	Psycho-social Aspects	…/20
Total Score:		…/100

This person's quality of life is:	**Total score**
Excellent	100
Very Good	80-99
Good	55-79
Fair	21-54
Poor	0-20

Fig. 2. *(Continued)*

For the Function, Mobility and Pain domain in the AUSVIQUOL, two measures were significant in the SF-36. Vitality accounted for 43% of the variance and Physical Function added a further 5%. The total variance of Function, Mobility and Pain accounted for by both measures was 48% (adjusted) and is represented by the equation $FMP = 0.174 \times V + 0.157 \times PF + 10.57$. The AUSVIQUOL's Psycho-Social Aspects domain was associated with the Mental Health domain of the SF-36 (adjusted R-squared 0.331). Hence,

conceptually related domains of the AUSVIQUOL correlated with the relevant domains of the SF-36 which provides evidence of construct validity.

For all three of the regression analyses the power was sufficient to reject H_0: $R^2 = 0$. The value of a single degree of freedom ΔR^2 that could be detected in the first analysis while maintaining $\alpha = 0.05$, $\beta = 0.2$ and $N = 71$ was 0.06, for the second analysis it was also 0.06, and for the third analysis it was 0.08.[12] For each of the regression analyses the variables not included in the reported regression equations only accounted for trivial non-significant increments in R^2.

Internal consistency on domain scores within the AUSVIQUOL according to Cronbach's Alpha revealed a good level of internal consistency (Alpha = 0.8702). In comparison, the internal consistency for the SF-36 was just acceptable (Alpha = 0.6307). These results support proceeding to test time 1 and 2 differences.

(b) Subset group reassessment

The correlated t-test of the average score for the SF-36 and the total score for the AUSVIQUOL showed that differences between the first and second assessments were not significant for either the SF-36 or the AUSVIQUOL demonstrating evidence of test-retest reliability for both measures (See Table 4). The bootstrap version of the Wilcoxon signed ranks test also showed no significant change for either scale between time 1 and time 2. A Wilcoxon paired ranks test could only reliably detect large difference effect sizes of the order f = 0.89 (mean difference/standard error difference). This is the effect size required to detect a difference for a t-test on the data at $\alpha = 0.05$ (1-tailed), $\beta = 0.2$ and $n = 12$.[13] The power of Wilcoxon test approximates that of the t-test adjusted by its asymptotic relative efficiency $3/\pi$. The adjusted *observed* effect size[14,15] was approximately f = 0.02 based on the standard Wilcoxon test for the first comparison (average score of SF-36, time 1 vs time 2). In this instance it is clearly low powered. The power of the bootstrap version would exceed this value, however, would still be low. The actual value cannot be determined without running a large Monte Carlo simulation, but it is likely to be of the same order of magnitude. Notwithstanding the low power of the test in this application, the observed effect size associated with the t-test is trivial and any potential but undetected real difference between times 1 and 2 is also likely to be small. A similar analysis for the second test (total score of AUSVIQUOL, time 1 vs time 2) shows an even smaller observed effect size. Thus one can be reasonably confident that any real differences between time 1 and 2 data are small.

Table 4. Correlated t-test distribution data

		Mean	*N*	Std. deviation	Std. error mean
SF-36	Average score − Time 1	64.0741	12	12.44225	3.59177
	Average score − Time 2	63.8657	12	16.27311	4.69764
AUSVIQUOL	Total score − Time 1	58.92	12	8.163	2.356
	Total score − Time 2	58.4167	12	12.39837	3.57910

Discussion

The present study was conducted to validate a new vascular disease QOL instrument for use in individuals with intermittent claudication suitable for use in the clinical setting. In contrast to the SF-36, the current gold standard QOL measure,[16] the AUSVIQUOL focuses on symptoms and problems specifically related to vascular disease. The AUSVIQUOL was initially validated in AAA patients;[9] it has now been assessed for its appropriateness for use in patients with vascular claudication with encouraging results.

The AUSVIQUOL was more acceptable for this group of patients for a variety of reasons. It is significantly less time-consuming and overall less confusing than the SF-36. It is easier to administer and has a higher level of patient acceptance, and is also more relevant and less repetitive than the SF-36. It includes specific symptoms that are experienced by vascular patients and excludes question areas covering less common or irrelevant symptomatology. These make it more appropriate for an elderly population and easier to administer from a research perspective.

The factor analysis showed the AUSVIQUOL to be a valid QOL measure for vascular claudication patients. It revealed two identifiable factors which related comparable domains of each questionnaire. The regression analysis revealed that conceptually related domains of the AUSVIQUOL and SF-36 were significantly related, which provides evidence of construct validity. The internal consistency of the AUSVIQUOL was found to be good.

The subset group reassessment demonstrated test-retest reliability for both measures. As the reassessment was made at one month following the first assessment and there was no intervention made during this period, it was reassuring that there was no significant difference between the assessment scores in either the SF-36 or the AUSVIQUOL.

The Claudication Scale (CLAU-S) and the King's College Hospital's Vascular Quality of Life Questionnaire (VascuQol) are both measures specifically targeted at the QOL of claudicants. The CLAU-S, developed in Germany in 1995, is one of the earliest disease-specific measures for intermittent claudication. The VascuQol, developed in London in 2000, was designed to cover a spectrum of chronic lower limb ischaemia rather than claudication alone.[3] The VascuQol has been shown to be a more sensitive measure than the CLAU-S for claudicants.[4,6] It comprises of 25 questions across 5 domains; Pain, Symptoms, Activities, Social and Emotional.[3] Averaged scores range from 1 (worst QOL) to 7 (best QOL).[3] While the purpose of this study was to compare the AUSVIQUOL with the current 'gold standard' QOL tool, the SF-36, a comparison of the AUSVIQUOL with the VascuQol for peripheral vascular disease patients will be the subject for future research.

Peripheral vascular disease rarely occurs in isolation; often these patients are 'vasculopaths' with concomitant cardio- and cerebro-vascular or aneurysmal disease. Neither the CLAU-S nor the VascuQol take this into consideration. The AUSVIQUOL has been developed to bridge this gap and to provide a global assessment of the vasculopath. The AUSVIQUOL has been designed to provide valuable information to the clinician in the clinical as well as in a research setting.

The successful use of the AUSVIQUOL in AAA patients as well as those with intermittent claudication suggests that it will be appropriate for use in all areas of vascular surgery. Further evaluation and assessment in patients with cerebrovascular and cardiovascular disease will be conducted in the future.

As the AUSVIQUOL has compared favourably with the SF-36 across two populations of patients (AAA patients and now peripheral vascular disease patients), we feel that the AUSVIQUOL could be recommended for use without an accompanying generic measure for vascular disease patients.

In conclusion, the benefits of the AUSVIQUOL is that its simplicity and short self-administration time make it very appropriate for use in patient waiting areas, outpatient clinics and private rooms. The domain and overall scores can be calculated such that is amenable to both research and clinical use.

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