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Measurement of Health-related Quality of Life with the Dutch Translated Aberdeen Varicose Vein Questionnaire before and after Treatment

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Abstract *Objective:* This clinical trial evaluated the use of the Dutch translated Aberdeen Varicose Vein Questionnaire (AVVQ) and SF-36 before and after treatment in patients with clinical-severity classes 1–6 venous disease of the lower limb.
Methods: A total of 145 patients with symptomatic venous disease of the leg were included. Numbers of patients were evenly distributed among the six clinical-severity classes 1–6 (clinical, aetiology, anatomy and pathophysiology; CEAP). Patients completed two preoperative AVVQ questionnaires and one short-form health survey with 36 items (SF-36) questionnaire to evaluate test–re-test reliability of the AVVQ. Patients completed one postoperative AVVQ and SF-36 to evaluate the effect of treatment.
Results: The test (99%) and re-test responses (97%) of the AVVQ were sufficient. Internal consistency of the Dutch translated AVVQ showed a Cronbach's α of 0.76. Correlation of test and re-test of the AVVQ was high ($\rho = 0.86$, $P < 0.001$). A significant negative association, by Spearman's correlation coefficient, was found between the preoperative baseline Dutch translated AVVQ score and all eight domains of the preoperative SF-36 ($P < 0.001$). These significant associations were also found in the postoperative scores.
The mean preoperative AVVQ score of 19.5 (SD 11.8) and mean postoperative AVVQ score of 16.1 (SD 12.0) differed significantly ($P < 0.01$). Analysis of three subgroups of clinical-severity classes (C1–2, C3–4 and C5–6) showed significant score changes before and after surgery ($P < 0.01$). Preoperative and postoperative SF-36 scores were not significantly different.
Conclusions: This study established the use of the Dutch translated AVVQ as a valid, health-related quality of life (QOL) questionnaire for measuring QOL before and after treatment in patients with clinical-severity classes 1–6 venous disease of the leg.

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A large amount of the health-service resources in the Western world is spent on the treatment of venous disease of the legs.[1,2] Anatomical or physiological tests may not be the best outcome measures when procedures are done to palliate symptoms of venous disease. Instead of only evaluating the outcome with venous duplex, it is better to assess the effect when it is combined with a health-related quality of life (HR-QOL) measurement. The Aberdeen Varicose Vein Questionnaire (AVVQ) was developed by Garratt et al., in 1993, for measuring QOL in patients with venous disease of the leg.[3] The questionnaire consists of 13 items related to problems of venous disease of the leg (Table 1).

Generic health status in patients with venous disease can be measured with the short-form health survey with 36 items (SF-36). The 36 items results in eight domains after recoding related to physical and mental health and social functioning. To completely assess the QOL of patients with venous disease, a health-related and a generic health status should be obtained to maximise detection of change after treatment. An evaluation of preoperative and postoperative AVVQ scores, in combination with SF-36 scores, in a cohort of patients with symptomatic varicose veins, but with the exclusion of active venous ulceration, has been reported by Smith et al.[4]

This study aims to test the hypothesis that the Dutch translated AVVQ is a useful instrument for measuring HR-QOL in patients with venous disease, before and after treatment.

Patients and Methods

This study was performed in combination with a validation and reliability study of the Dutch translated AVVQ. The study protocol was approved by the local ethics committee. Patients who visited our out-patient clinic in Rotterdam, The Netherlands, with symptomatic venous disease of the leg were asked to participate in this study. The exclusion criteria were: body mass index (BMI) >40, recurrence of venous incompetence in the great saphenous vein (GSV) or small saphenous vein (SSV), occlusion of the deep venous system, peripheral arterial disease as indicated by absent pulses and an ankle–brachial index (ABI) <0.9, already being part of the study with the contralateral leg, and the inability to understand the Dutch language.

None of the patients refused to participate. In total, 145 patients were included, with a minimum of 20 patients in each group of the clinical-severity classes (C1–C6).

Most patients had a primary aetiology for their venous disease, and only three patients had a secondary aetiology (post-thrombotic). None of the patients had congenital venous disease. Considering anatomy and pathophysiology, all patients had reflux to some extent in their superficial venous system. Deep venous reflux was found in 42 patients (29%), while perforating vein reflux was found in 58 patients (41%). None of the patients had deep venous obstruction.

The mean age was 54 years (range: 23–85 years); 69% of patients were female. All patients received two AVVQs preoperatively for test and re-test evaluation, with a two-week interval. The AVVQ can have a score ranging from 0 to 100, with 0 representing the best score, and 100 the worst score. AVVQs were filled out at home and returned directly by mail. No patients were treated for their venous disease of the leg between test and re-test. On the day of hospital admission, patients were asked to fill out an SF-36 before treatment. SF-36 scores resulted in eight domains after recoding. These were Physical Functioning (PF), Role Limitation due to Physical problems (RP), Bodily Pain (BP), General Health (GH), Vitality (VI), Social Functioning (SF), Role Limitation due to Emotional problems (RE) and Mental Health (MH).

The scores in the domains range from 0, the worst score, to 100, the best score.

Six weeks after treatment, patients visited our out-patient clinic for physical examination. Immediately after this visit, patients completed their third AVVQ. The SF-36 was given to patients with the instruction to fill in the questionnaire at home and return it by mail. This strategy was chosen to get maximum postoperative AVVQ responders. The SF-36 took too much time to fill in at the out-patient clinic visit; therefore, patients were asked to complete it at home.

Treatment

Obstruction of the deep venous system was a contraindication for surgical treatment.

Patients with clinical-severity class C1 and a duplex-proven competent GSV and SSV were treated with phlebectomy and sclerotherapy. Phlebectomy was performed under local anaesthesia.

Patients with clinical-severity classes C2–C5 and duplex-proven incompetence of the GSV and/or SSV were treated surgically. The treatment consisted of Babcock stripping of the GSV and/or ligation and division of the SSV.

Patients with clinical-severity class C6 and duplex-proven incompetence of the GSV and/or SSV and/or perforating veins were treated surgically.

Surgical treatment consisted of Babcock stripping of the GSV and/or ligation and division of the SSV. Sub-fascial endoscopic perforating vein surgery (SEPS) was performed for incompetent perforating veins.

To increase mobility and decrease the risk of deep venous thrombosis, only one leg at a time was treated in all patients. Phlebectomy and/or sclerotherapy in patients with C2–C6 venous disease was performed, if necessary, not less than 2–3 months after the surgery. All patients received preoperative low-molecular-weight heparin injections and graduated elastic compression stockings postoperatively. Babcock stripping of the GSV, ligation and division of the SSV and SEPS were performed under spinal anaesthesia. This was normal policy in our hospital and was not specific to the protocol for this study. Endovenous techniques, including radiofrequency ablation and laser ablation, were used in our hospital in separate clinical trials. Therefore, none of the patients in this study underwent these newer techniques.

Validation

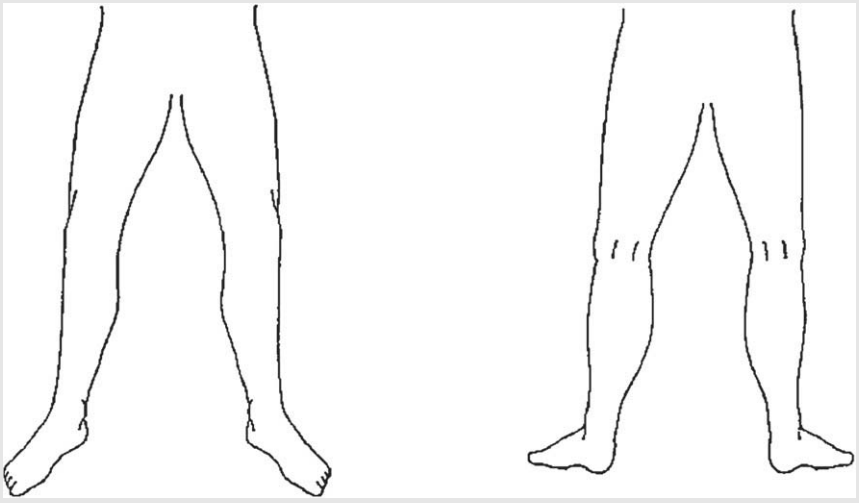
The validity and reliability of the Dutch translated AVVQ was assessed in this cohort of patients and was reported

Table 1 Aberdeen Varicose Vein Questionnaire

Aberdeen Varicose Vein Questionnaire

1. Please draw in your varicose veins in the diagrams(s) below:

Legs viewed from front **Legs viewed from back**



2. In the last two weeks, for how many days did your varicose veins cause you pain or ache? (Please tick one box for each leg)

	Right Leg	Left Leg
None at all		
Between 1 and 5 days		
Between 6 and 10 days		
For more than 10 days		

3. During the last two weeks, on how many days did you take painkilling tablets for your varicose veins? (Please tick one box)

None at all	
Between 1 and 5 days	
Between 6 and 10 days	
Fore more than 10 days	

4. In the last two weeks, how much ankle swelling have you had? (Please tick one box)

None at all	
Slight ankle swelling	
Moderate ankle swelling (eg. causing you to sit with your feet up whenever possible)	
Severe ankle swelling (eg. causing you difficulty putting on your shoes)	

5. In the last two weeks, have you worn support stockings or tights? (Please tick one box for each leg)

	Right Leg	Left Leg
No		
Yes, those I bought myself without a doctor's prescription		
Yes, those my doctor prescribed for me which I wear occasionally		
Yes, those my doctor prescribed for me which I wear every day		

(*continued on next page*)

Table 1 (*continued*)

6. In the last two weeks, have you had any itching in association with your varicose veins? (Please tick one box for each leg)

	Right Leg	Left Leg
No		
Yes, but only above the knee		
Yes, but only below the knee		
Both above and below the knee		

7. Do you have purple discolouration caused by tiny blood vessels in the skin, in association with your varicose veins? (Please tick one box for each leg)

	Right Leg	Left Leg
No		
Yes		

8. Do you have a rash or eczema in the area of your ankle? (Please tick one box for each leg)

	Right Leg	Left Leg
No		
Yes, but is does not require any treatment from a doctor or district nurse		
Yes, and it requires treatment from my doctor or district nurse		

9. Do you have a skin ulcer associated with your varicose veins? (Please tick one box for each leg)

	Right Leg	Left Leg
No		
Yes		

10. Does the appearance of your varicose veins cause you concern? (Please tick one box)

No	
Yes, their appearance causes me slight concern	
Yes, their appearance causes me moderate concern	
Yes, their appearance causes me a great deal of concern	

11. Does the appearance of your varicose veins influence your choice of clothing including tights? (Please tick one box)

No	
Occasionally	
Often	
Always	

12. During the last two weeks, have your varicose veins interfered with your work/housework or other daily activities? (Please tick one box)

No	
I have been able to work but my work has suffered to a slight extent	
I have been able to work but my work has suffered to a moderate extent	
My veins have prevented me from working one day ore more	

13. During the last two weeks, have your varicose veins interfered with your leisure activities (including sport, hobbies and social life)? (Please tick one box)

No	
Yes, my enjoyment has suffered to a slight extent	
Yes, my enjoyment has suffered to a moderate extent	
Yes, my veins have prevented me taking part in any leisure activities	

beforehand. Internal consistency was tested using Cronbach's α. This is a coefficient of reliability (or consistency), and it assesses the average level of correlation between the questions (items) in a questionnaire. If the questionnaire is measuring a specific problem (venous disease of the leg), there should be a high level of concordance between these questions. If a questionnaire is to be reliable, α should exceed 0.7. Test–re-test reliability was assessed using the two-tailed Wilcoxon's signed ranks test. Assessment for discrimination between subgroups of preoperative patients with different clinical-severity classes was done by Mann–Whitney *U*-tests.

Analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS 15.0) for Windows.

Evaluation of the Dutch translated AVVQ and SF-36 before and after treatment of leg venous disease consisted of preoperative and postoperative Wilcoxon signed rank tests.

Extra validity was evaluated in this study – the correlation of AVVQ score and SF-36 scores of each of the eight domains using Spearman's correlation coefficient.

Results

Response

The first AVVQ (preoperative) was returned by 143 patients resulting in a test response of 99%. The second AVVQ (preoperative) was returned by 140 patients resulting in a re-test response of 97%. The five patients who did not return the second AVVQ included the two patients who also did not return the first AVVQ. These two patients also did not show up on their out-patient clinic appointments and, thus, were not treated for their venous disease. In this cohort, 143 patients were treated for their venous disease of the leg. These 143 patients all completed their first SF-36 (preoperative) on the day of hospital admission. After a reminder telephone call, eventually all postoperative patients attended their out-patient clinic appointment, where all patients completed their third AVVQ. Unfortunately, only 118 patients returned their second SF-36 by mail, resulting in a response of 83%.

Internal consistency, test–re-test reliability and discriminative validity

Internal consistency testing of the AVVQ showed a Cronbach's α of 0.76.

Mean preoperative AVVQ test score was 19.2 (SD 12.1) and mean preoperative AVVQ re-test score was 19.6 (SD 11.8). There was a significant correlation between both preoperative AVVQ scores (Spearman's correlation coefficient, $\rho = 0.86$, $P < 0.01$).

No correlations were observed for AVVQ score compared to patients age or gender.

The preoperative AVVQ score was able to differentiate between subgroups of patients with different clinical-severity classes; C1–C2, C3–C4 and C5–C6 (Mann–Whitney *U*-test, $P < 0.01$).

Correlation of the AVVQ and SF-36

Because of the small differences in scores between the first and second AVVQ (both preoperative), the mean score of both questionnaires was used as a preoperative baseline AVVQ score. In three patients we did not receive a second preoperative AVVQ; therefore, we used their first AVVQ as a baseline preoperative AVVQ score.

A significant negative association, by Spearman's correlation coefficient (ρ) was found between the baseline preoperative Dutch translated AVVQ score and all eight domains of the preoperative SF-36. Three of the four highest associations ($\rho < -0.4$, $P < 0.01$) were found in the physical domains: PF ($\rho = -0.541$, $P < 0.01$), RP ($\rho = -0.448$, $P < 0.01$), BP ($\rho = -0.439$, $P < 0.01$) and the remaining high association in SF ($\rho = -0.412$, $P < 0.01$). These significant associations were also found in the postoperative scores.

Preoperative and postoperative AVVQ scores

The mean preoperative baseline AVVQ score was 19.5 (SD 11.8) and mean postoperative AVVQ score was 16.1 (SD 12.0). A two-tailed Wilcoxon's signed ranks test was significant ($P < 0.01$) for the differences between preoperative and postoperative AVVQ scores.

We examined preoperative and postoperative AVVQ scores of three subgroups of patients with different clinical-severity scores. These three subgroups are as follows:

- Subgroup A: clinical-severity classes C1 and C2 ($n = 50$)
- Subgroup B: clinical-severity classes C3 and C4 ($n = 50$)
- Subgroup C: clinical-severity classes C5 and C6 ($n = 43$)

Because of small numbers of patients in subgroup-analyses we combined two clinical-severity classes in each subgroup (Table 2). In all these subgroups, we found significant changes in the mean preoperative AVVQ score and mean postoperative AVVQ score (Wilcoxon's signed ranks test).

Preoperative and postoperative SF-36 scores

Seven of the eight domains of the SF-36 had higher postoperative scores. The domain 'social functioning' had a lower postoperative score. Preoperative and postoperative SF-36

Table 2 Preoperative and postoperative AVVQ scores (standard deviation)

Group	Preoperatively AVVQ score (SD)	Postoperatively AVVQ score (SD)	P[a]
All patients $n = 143$	19.5 (11.8)	16.1 (12.0)	<0.01
Subgroup A $n = 50$	11.1 (5.4)	9.24 (6.6)	=0.01
Subgroup B $n = 50$	18.7 (9.0)	15.0 (9.8)	<0.01
Subgroup C $n = 43$	30.4 (11.6)	25.4 (13.4)	<0.01

Subgroup A: clinical-severity classes C1 and C2
Subgroup B: clinical-severity classes C3 and C4
Subgroup C: clinical-severity classes C5 and C6.
[a] Two-sided Wilcoxon's signed ranks test.

scores were not significantly different (Wilcoxon signed ranks test). There was a trend of a higher postoperative score in the domains 'physical functioning' and 'vitality', but significance was not reached in both domains (Table 3).

Complications

There was no major complication. There were six patients with a wound infection that healed with conservative treatment. Four of these patients had C2, and two patients had C4, venous disease.

Discussion

Response

The response rate of the preoperative and postoperative AVVQ was very good. This was due to the fact that we asked patients to complete the postoperative AVVQ in the out-patient clinic, and that it took around 5 min to complete the questionnaire. The response rate of the preoperative SF-36 was very good because patients had to complete the questionnaire in the hospital on the day of their admission. The postoperative SF-36 response was disappointing (83%). A reason could be that patients could complete this questionnaire at home. The reason why so many patients did not return their last SF-36 is speculative. Patients could have forgotten to complete the questionnaire or were 'questionnaire-tired' after completing a lot of the same questionnaires in a relatively short time. In a similar study, Smith also found an 80% of patients lost to follow-up; these patients did not show up on their out-patient clinic appointment.[4]

Validity and reliability

Internal consistencies, test—re-test reliability and discriminative validity of the Dutch translated AVVQ and original AVVQ have been tested and reported before.[3,5] The original AVVQ and Dutch translated AVVQ showed good validity and reliability.

Correlation of AVVQ score and SF-36 score

There was a significant negative association of preoperative AVVQ scores and the eight domains of the preoperative SF-36. Smith found only four domains to be significant.[4] These were exactly the same four domains which showed the strongest association in this cohort of patients. Three of these domains were physical domains: 'physical functioning', 'role limitation due to physical problems' and 'bodily pain', which was expected because the AVVQ has many questions about physical discomfort and pain. The remaining domain, 'social functioning', also showed a strong association and was expected because the last two questions of the AVVQ are related to social functioning, which was also reported previously.[5]

The significant association of the eight domains gives extra validity to the Dutch translated AVVQ as an instrument to measure HR-QOL.

Table 3 Preoperative and postoperative SF-36 domain scores

Domain	Preoperatively	Postoperatively	P^a
PF	71.4	78.3	0.055
RP	66.8	71.4	0.96
BP	66.9	74.0	0.19
GH	67.7	71.9	0.64
VI	64.1	69.8	0.059
SF	82.5	81.8	0.19
RE	77.2	79.9	0.61
MH	54.2	57.6	0.71

[a] Two-tailed Wilcoxon signed ranks test.

Preoperative and postoperative AVVQ scores

A highly significant decrease in postoperative AVVQ scores was found in this cohort. Smith found similar results only with lower preoperative and postoperative AVVQ scores.[4] This is almost certainly due to the fact that patients with active venous ulceration were excluded in their study. This is the group of patients with the highest AVVQ scores.

We also found a significant decrease in postoperative AVVQ scores in the three subgroups with different clinical-severity classes.

Preoperative and postoperative SF-36 scores

We found no significant increase in postoperative scores in any of the eight domains of the SF-36. There was a trend of a higher postoperative score in the domain 'physical functioning' which is to be expected because, after treatment, patients will have less physical complaints of their venous disease, like a heavy and tired feeling in the leg, pain and ankle swelling.

The domain 'vitality' also showed a trend of a higher postoperative score; this domain is also known as 'energy' and patients could feel better because of a decrease in physical discomfort.

Smith et al. found a significant increase in the domain 'mental health'.[4] Remarkably, this is the only domain that has a very different preoperative score in the Dutch cohort (mean 54.2) compared to the UK cohort (mean about 70). This could be due to a chance or a real difference between the samples because of the exclusion of patients with active venous ulceration in the UK sample. These patients scored the worst in this study on the domain mental health. The other seven preoperative domain scores were similar to the UK cohort.

The domain 'social functioning' had a non-significant, lower postoperative score. It is reasonable that patients treated for venous disease will engage less in social activities, such as sports, or other leisure activities for a few weeks. Therefore, a slightly lower score was expected in this domain.

Conclusions

Treatment of venous disease of the leg can increase QOL. Patients with venous disease of the leg have specific clinical complaints. The SF-36 is a measurement of generic health status; therefore, it cannot fully detect these specific clinical complaints.

The AVVQ was designed a year before the introduction of the CEAP-classification system. Although the name 'AVVQ' suggests an instrument which measures HR-QOL in patients with only varicose veins (C1 and C2) this study shows that it can be used for the whole spectrum of venous disease (C1—C6). Contrary to the SF-36, the AVVQ can measure the specific clinical complaints in patients with venous disease. This study established the use of the Dutch translated AVVQ as a valid questionnaire for measuring preoperative and postoperative HR-QOL in patients with clinical-severity classes C1—C6 venous disease.

Conflict of Interest

None

Funding

None.

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