Clinical and linguistic validation of the Polish version of VascuQol: a disease-specific quality-of-life questionnaire assessing patients with chronic limb ischemia

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KEY WORDS
health-related quality of life, intermittent claudication, patient-reported outcome measures, peripheral arterial disease, validation studies

ABSTRACT
INTRODUCTION Objective clinical assessments should include patient-reported outcome measures. VascuQol is an established disease-specific questionnaire assessing the quality of life in patients with peripheral artery disease (PAD). Quality-of-life questionnaires require geographical localization and validation.

OBJECTIVES The goal of this study was to validate the Polish version of the VascuQol: a patient-reported health-related quality-of-life (HRQoL) instrument specific for PAD.

PATIENTS AND METHODS The linguistic validation of VascuQol followed Mapi Institute methodology. Clinical validation process compared VascuQol, EQ-5D-3L, and SF-36 questionnaires in 100 patients with both intermittent claudication and critical limb-threatening ischemia. Cronbach α coefficients for reliability, receiver operating characteristic curves for clinical discriminative performance, standardized response means for responsiveness, and Pearson correlations for construct validity were evaluated. Additionally, in a separate cohort of 58 patients with stable disease, the test–retest was characterized with intraclass correlation, Bland–Altman analysis, and Pearson correlation coefficients.

RESULTS VascuQol proved to perform better than SF-36 and EQ-5D-3L. Cronbach α coefficients showed good internal consistency (α values >0.9 for all summary scores). All test–retest Pearson r values for VascuQol were above 0.70. The intraclass correlation of absolute agreement consistency exceeded 0.8. The Bland–Altman 95% limits of agreement were between 2.72 and 4.87. There were strong and moderate correlations for total scores in all domains between VascuQol and SF-36, and for most of the domains between VascuQol and EQ-5D-3L.

CONCLUSIONS The Polish version of VascuQol is a sensitive, accurate, and reliable tool for assessing HRQoL in patients with PAD.

INTRODUCTION Chronic limb ischemia has an adverse effect on the quality of life. Evaluation of the outcomes of peripheral arterial disease (PAD) treatment based on objective clinical parameters does not allow for a reliable assessment of pain discomfort, social and emotional aspects, as well as daily functional status associated with PAD and treatment process. For this reason, objective clinical assessments were extended by patient-reported outcome measures. The most common generic questionnaires, the Medical Outcome Study Short Form-36 (SF-36) and
the EuroQol-5D (EQ-5D-3L) are not sufficiently sensitive to accurately measure deterioration in the quality of life related to limb ischemia, functional walking impairment, and treatment process. Therefore, specific questionnaires were required and developed. They include, but are not limited to, the Walking Impairment Questionnaire,4 Claudication Scale questionnaire,5 Peripheral Artery Questionnaire,6 PAD Quality of Life Questionnaire,7 and Intermittent Claudication Questionnaire (ICQ).8 Some of these instruments were validated for local languages other than English.9,10

Although the quality of life in patients with PAD was systematically evaluated in Poland,11-14 mostly general questionnaires were used. Only recently, the Intermittent Claudication Questionnaire, a PAD-specific health-related quality of life (HRQoL) questionnaire was validated in Polish.15 We selected another questionnaire specific to HRQoL in PAD, namely, the Vascular Quality of Life Questionnaire (VascuQol), because it covers not only a spectrum of claudication symptoms but also demonstrates good reliability in evaluating patients with CLTI, who frequently present at our center.16

Characteristics of the VascuQol The VascuQol consists of 25 questions covering 5 domains: activities, symptoms, pain (physical domains), as well as emotions and social behavior (mental domains). The answer to each question is rated with a 7-point scale, where 1 stands for the worst, and 7, for the best rating. The questionnaire was developed by Mark Morgan, MD, from the Surgical Unit of King’s College Hospital in London.17 The VascuQol questionnaire was used in the BASIL study (Bypass vs Angioplasty in Severe Ischaemia of the Leg)18 and has afterward been translated and validated in other European countries where high psychometric value and applicability in PAD patients was confirmed.6,11,12 The linguistic validation of the VascuQol in several languages was carried out using Mapi’s methodology.20 Within 25 years, Mapi has linguistically validated more than 2500 instruments in over 170 languages in a wide range of therapeutic areas. Due to cultural differences between nations, the validation process should include both linguistic and cultural adaptation and clinical efficacy of the questionnaire.

Characteristics of the generic quality-of-life instruments The SF-36 questionnaire The SF-36 is the world’s most widely used generic questionnaire to assess the quality of life in patients with cardiovascular diseases (including PAD). The instrument consists of 36 items, which evaluate 8 health domains, namely, physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health. Each item is encoded and converted to contribute to subscale scores from 0 (worst possible results) to 100 points (best health status).

The respective domains can be combined into 2 summary measures, representing physical component summary score (PCS) and mental component summary score (MCS). The SF-36v2 is available as a validated Polish version,21 which was kindly provided by Medical Outcomes Trust and Quality Metric Incorporated22 (Hanover, New Hampshire, United States).

PATIENTS AND METHODS Linguistic validation The EQ-SD-3L questionnaire is a generic quality of life instrument. It consists of 2 parts. The descriptive part includes 5 questions regarding mobility, self-care, usual activities, pain, and anxiety/depression. They are further graded into levels of severity corresponding to "no problems" (level 1), "some problems" (level 2) and “extreme problems” (level 3). EQ-SD-3L health states, defined by the EQ-SD-3L descriptive system, may be converted to a single index value ranging from 0.59 (values for quality of life worse than death) to 1 (good quality of life status) (EQ Index). The second part includes a visual analog scale (EQ-VAS), on which patients can assess their health on a scale from 0 to 100. EQ-SD-3L has a validated Polish version,23 which was kindly provided by the EuroQol Research Foundation (Rotterdam, the Netherlands). The Polish value set and index calculator were kindly provided by Dominik Golicki, MD, PhD (Warsaw Medical University, Warsaw, Poland).

In this paper, we refer to questionnaires or tools when speaking about HRQoL evaluation instruments, and to tests when speaking about specific statistical assays.
The SRMs were calculated for each domain of the VascuQol, SF-36, EQ Index, and EQ-VAS, as well as for the ankle–brachial pressure index (ABPI) and clinical presentation according to the Rutherford clinical scale. The SRMs were calculated as the mean difference in score 1 month after endovascular treatment as compared with baseline, divided by the standard deviation of the difference. Cohen criteria for interpreting effect sizes were applied (small effect size ≥0.2 and <0.5; moderate effect size ≥0.5 and <0.8; large effect size ≥0.8). The construct validity of the VascuQol was tested by a correlation analysis versus the SF-36 subscales, EQ Index, EQ-VAS, and ABPI, using the Pearson correlation coefficient. Statistical analysis was performed using SPSS version 18.0 (SPSS Inc. Chicago, Illinois, United States).

**Clinical validation**  
Clinical validation of the Polish version of VascuQol was conducted prospectively in consecutive patients referred for endovascular treatment due to PAD in a single large-volume tertiary angiography center in southern Poland. Patient exclusions were exceptional, not predefined, and concerned only patients refusing participation, not able to attend follow-up visits, or not able to read and fill in the questionnaire in Polish. Patients were evaluated simultaneously using 3 HRQoL tools: validated Polish versions of the EQ-SD-3L and SF-36v2 and the analyzed version of the VascuQol. The questionnaires were administered shortly before treatment and 1 month after revascularization.

An additional sample of patients treated in our center was recruited to determine the test–retest stability of the VascuQol. Patients were in a stable phase of the disease and were tested twice within 4 weeks. Disease stage distribution was similar to the first cohort.

### Table 1: Characteristics of the clinical validation cohort: demographic data, risk factors, comorbidities

| Parameter                | All patients (n = 100) | CLTI (n = 50) | IC (n = 50) | P value* |
|--------------------------|------------------------|--------------|------------|----------|
| Median age, range        | 68 (49–99)             | 69 (55–99)   | 67 (49–81) | 0.051    |
| Male sex, %              | 83                     | 78           | 88         | 0.18     |
| Smoking, %               | 78                     | 72           | 82         | 0.33     |
| Diabetes, %              | 36                     | 44           | 30         | 0.21     |
| Hypertension, %          | 65                     | 66           | 64         | 0.83     |
| Lipid disorders, %       | 40                     | 44           | 36         | 0.41     |
| CHD, previous MI, %      | 39                     | 42           | 36         | 0.54     |
| Kidney diseaseb, %       | 12                     | 14           | 10         | 0.54     |
| COPD, %                  | 12                     | 8            | 16         | 0.22     |
| TIA/stroke, %            | 4                      | 6            | 2          | 0.31     |

*Significance for nominal data was assessed by the χ² test, and for the numerical data, by the Mann–Whitney test.

**Abbreviations:** CHD, coronary heart disease; CLTI, critical limb-threatening ischemia; COPD, chronic obstructive pulmonary disease; GFR, glomerular filtration rate; IC, intermittent claudication; MI, myocardial infarction; TIA, transient ischemic attack

**Statistical methods and calculations**  
Descriptive statistics was used. Statistical significance for nominal data was assessed by the χ² test, and the Mann–Whitney test was used for numerical data.

For VascuQol internal reliability assessment, Cronbach α coefficients were calculated for each domain and for the total score.

The receiver operating characteristic (ROC) curves and areas under the curve (AUC) were evaluated and compared to determine the ability of the VascuQol and other tools to discriminate between patients with intermittent claudication (IC) and critical limb-threatening ischemia (CLTI) before treatment. DeLong nonparametric method was applied to compare differences between ROC curves.

For the test–retest cohort, intraclass correlations (ICC) and Bland–Altman limits of agreement (LOA) were calculated.

Responsiveness was assessed by evaluating significance of differences between the values for each domain before and after treatment (Wilcoxon signed-rank test). Also, standardized response means (SRMs) were calculated according to Husted et al for each domain of the VascuQol, SF-36, EQ Index, and EQ-VAS, as well as for the ankle–brachial pressure index (ABPI) and clinical presentation according to the Rutherford clinical scale. The SRMs were calculated as the mean difference in score 1 month after endovascular treatment as compared with baseline, divided by the standard deviation of the difference.

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| Hypertension, %          | 65                     | 66           | 64         | 0.83     |
| Lipid disorders, %       | 40                     | 44           | 36         | 0.41     |
| CHD, previous MI, %      | 39                     | 42           | 36         | 0.54     |
| Kidney diseaseb, %       | 12                     | 14           | 10         | 0.54     |
| COPD, %                  | 12                     | 8            | 16         | 0.22     |
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We also enrolled a group of 58 patients to assess the test–retest stability. Their characteristics are presented in Table 2.

RESULTS Linguistic validity No cultural issues were encountered during the translation process. For all items, the most prevalent problem was syntactic with the use of the preterit equivalent tense in Polish to render the use of the present perfect tense in the original English questionnaire. Of the 25 items, 6 generated difficulties, mostly semantic and syntactic (i.e., items 3, 8, 11, 15, 19, and 20). The addition of the adjective “physical” in the response categories of items 3, 8, and 20 (“very great deal of discomfort or distress” to “no discomfort or distress”) clarified the meaning of the original and enabled a better understanding by the patients.

The translation of item 8 (“In the last two weeks my legs have caused me...”) was challenging. The Polish version tested on patients (back-translation: “In the last two weeks tingling or going numb of the leg [or foot] caused me...”) was not entirely understood as it should have been. Patients kept referring to “stiffness” and not to “numbness,” that is, lack of sensation. Therefore, it was decided to change the translation and add the Polish equivalent of “missing sensation.” The new version was retested on patients who, this time, understood the intended meaning. The addition of “missing sensation” made the Polish item broader in meaning as it included feelings such as “paralyzed, foreign body, not sensitive to touch, as if not mine.”

Item 11 (“In the last two weeks being [or becoming] housebound has been a concern of mine...”) was problematic because of 2 challenges: 1) the use of the idiomatic expression “housebound” which requires translation with a periphrasis, i.e., “unable to leave home”; and 2) the juxtaposition of an existing situation (being) with a hypothetical one (becoming), which raised much discussion about the syntax of the Polish version and on how to make it clear and not complicated to respondents. Several translations were tested, and the following option was chosen: “In the last two weeks I worried about that now, or in the future, I may be unable to leave home.”

As for item 15 (“In the last two weeks because of the poor circulation to my legs, my ability to take part in social activities has been...”), the issue concerned the phrase “to take part in social activities.” It required translation into an equivalent of “to participate in social and public life” for a better understanding by the patients.

The main issue in item 19 (“In the last two weeks problems caused by poor circulation to the legs have made me feel frustrated...”) was the use of “frustrated” in the original. The translation team felt that the patients would not easily understand a literal translation. It was decided to use the substantive, “frustration,” instead, and to add the term “discouragement” to convey the meaning of a deep chronic sense or a state of insecurity and dissatisfaction arising from being unable to change or achieve something.

Finally, item 5 (“In the last two weeks my legs have felt tired or weak...”) was not an issue, but interestingly, all respondents used the term “heavy” to describe their feeling.

Reliability The values of Cronbach α coefficients for the VascuQol summary score were in the range of 0.92 to 0.98 and exceeded 0.7 for most of the VascuQol domains.

For the “symptoms” subscale in the pretest for CLTI and IC groups, the α values were 0.6 and 0.58, respectively. The α coefficients for the “symptoms” domain in the posttest for CLTI and IC groups were 0.84 and 0.87, respectively. The results for all subscales are presented in Table 3.

Diagnostic reference Baseline VascuQol scores were significantly lower in the CLTI group, both for all and for each separate domain (Table 4). Similarly, the differences were significant in the generic SF-36 and EQ-SD-3L questionnaires (Supplementary material, Table S1). The ROC curves and AUCs confirmed a high ability of the VascuQol to discriminate the clinical status of patients.
### Table 4: Mean VascuQol scores before treatment in patients with critical limb-threatening ischemia and intermittent claudication

| Domain      | CLTI (n = 50) | IC (n = 50) | P valuea |
|-------------|---------------|-------------|----------|
| Activities  | 2.20 (0.80)   | 3.00 (1.26) | <0.001   |
| Symptoms    | 2.50 (1.07)   | 4.00 (1.08) | <0.001   |
| Pain        | 2.30 (0.90)   | 3.20 (1.30) | <0.001   |
| Emotions    | 2.60 (1.08)   | 4.10 (1.49) | <0.001   |
| Social      | 2.70 (1.58)   | 3.70 (1.70) | 0.003    |
| Total score | 2.40 (0.75)   | 3.55 (1.18) | <0.001   |

Data are presented as mean (SD).

a Mann–Whitney test

### Table 5: Area under the curve values for VascuQol, SF-36, EQ Index, and ankle–brachial pressure index

|                      | AUC       | SE        | P value |
|----------------------|-----------|-----------|---------|
| VascuQol (total score)| 0.802     | 0.044     | <0.001  |
| EQ Index             | 0.738     | 0.050     | <0.001  |
| EQ-VAS               | 0.670     | 0.055     | 0.004   |
| PCS                  | 0.709     | 0.054     | <0.001  |
| MCS                  | 0.638     | 0.056     | 0.02    |
| ABPI                 | 0.600     | 0.061     | 0.08    |

Abbreviations: ABPI, ankle–brachial pressure index; AUC, area under the curve; MCS, mental component summary of SF-36; PCS, physical component summary of SF-36; SE, standard error

### Table 6: VascuQol intraclass correlation results

| Domain      | ICC        | 95% CI     | P value |
|-------------|------------|------------|---------|
|             | LL         | UL         |         |
| Activities  | 0.88       | 0.80       | 0.93    | <0.001  |
| Symptoms    | 0.89       | 0.82       | 0.94    | <0.001  |
| Pain        | 0.83       | 0.71       | 0.90    | <0.001  |
| Emotions    | 0.92       | 0.86       | 0.95    | <0.001  |
| Social      | 0.80       | 0.67       | 0.88    | <0.001  |
| Total score | 0.90       | 0.84       | 0.94    | <0.001  |

Abbreviations: ICC, intraclass correlations coefficient; LL, lower limit; UL, upper limit

Discussion: Evaluation of the effects of treatment based on patient-reported outcome measures is an important part of good clinical practice. Although recent efforts of Rosloniec et al have resulted in the first disease-specific HRQoL instrument for PAD that is validated in Polish, it would be not adequate for patients with CLTI, as they can barely walk. Literature reports and a review of available HRQoL questionnaires indicated that the VascuQol is a robust tool for the assessment of the quality of life in PAD with a wide spectrum of clinical stages of the disease. Therefore, we decided to perform a linguistic and clinical validation of the VascuQol in Polish. The methodology developed by Mapi was used to carry out a linguistic validation of the VascuQol, and a clinical evaluation was done using a previously described methodology for other languages.

Our analysis showed that the Polish version of VascuQol is adequate to evaluate patient-reported outcomes in PAD in patients undergoing endovascular treatment. The results of the linguistic validation demonstrated that the Polish version of the questionnaire is conceptually equivalent to the original. The Bland–Altman analysis showed repeatability of the questionnaire, demonstrating a good agreement between test and retest results in stable patients with both CLTI and IC. Even though the VascuQol consists of 7 grades that define the whole spectrum of the quality of life, and therefore repeatability is difficult to prove, we found a concordance of test–retest results.
TABLE 7  VascuQol Bland–Altman analysis

| Domain      | Mean difference | SD of difference | SE of difference | 95% CI for mean difference | Limit values for 95% LOA |
|-------------|-----------------|------------------|------------------|----------------------------|-------------------------|
| Activities  | −0.05           | 0.71             | 0.09             | −0.24                      | 0.13                    | −1.45 to 1.33            |
| Symptoms    | 0.14            | 0.81             | 0.11             | −0.07                      | 0.35                    | −1.46 to 1.73            |
| Pain        | −0.02           | 0.99             | 0.13             | −0.28                      | 0.24                    | −1.94 to 1.91            |
| Emotions    | 0.08            | 0.76             | 0.10             | −0.12                      | 0.28                    | −1.41 to 1.57            |
| Social      | −0.03           | 0.23             | 0.16             | −0.36                      | 0.29                    | −2.45 to 2.38            |
| Total score | 0.02            | 0.69             | 0.09             | −0.16                      | 0.21                    | −1.33 to 1.38            |

Abbreviations: LOA, Bland–Altman limits of agreement

TABLE 8  Health-related quality of life instruments in domain scores in the study population before and after treatment

| Domain      | Pretest | Posttest | ∆      | P value* | SRM | Pretest | Posttest | ∆      | P value* | SRM |
|-------------|---------|----------|--------|----------|-----|---------|----------|--------|----------|-----|
| VascuQol    |         |          |        |          |     |         |          |        |          |     |
| Activities  | 2.2 (0.8)| 3.3 (1.6)| 1.1 (1.3) | <0.001  | 0.86| 3.0 (1.2)| 4.5 (1.5)| 1.5 (1.6)| <0.001  | 0.94|
| Symptoms    | 2.5 (1.1)| 3.9 (1.4)| 1.3 (1.5) | <0.001  | 0.90| 4.0 (1.0)| 4.8 (1.4)| 0.8 (1.1)| <0.001  | 0.7 |
| Pain        | 2.3 (0.9)| 3.7 (1.3)| 1.4 (1.3) | <0.001  | 1.1 | 3.2 (1.3)| 4.6 (1.6)| 1.4 (1.3)| <0.001  | 1.0 |
| Emotions    | 2.6 (1.1)| 3.8 (1.6)| 1.2 (1.3) | <0.001  | 0.9 | 4.1 (1.50)| 4.8 (1.6)| 0.7 (1.0)| <0.001  | 0.69|
| Social      | 2.7 (1.6)| 3.8 (1.8)| 1.1 (1.5) | <0.001  | 0.76| 3.7 (1.7)| 4.7 (1.8)| 1.1 (1.8)| <0.001  | 0.61|
| Total score | 2.4 (0.7)| 3.6 (1.4)| 1.2 (1.2) | <0.001  | 1.0 | 3.5 (1.2)| 4.6 (1.5)| 1.1 (1.2)| <0.001  | 0.93|
| EQ-SD-3L    |         |          |        |          |     |         |          |        |          |     |
| EQ index    | 0.5 (0.2)| 0.6 (0.2)| 0.1 (0.2) | 0.001  | 0.51| 0.6 (0.2)| 0.69 (0.2)| 0.05 (0.2)| 0.104  | 0.24|
| EQ-VAS      | 44.4 (17.0)| 53.1 (17.4)| 8.7 (15.5) | 0.001  | 0.49| 51.9 (11.6)| 60.8 (18.1)| 8.9 (16.6)| 0.001  | 0.53|
| SF-36       |         |          |        |          |     |         |          |        |          |     |
| PCS         | 25.3 (13.6)| 38.5 (17.7)| 13.2 (14.8) | <0.001  | 0.89| 33.4 (11.3)| 45.0 (10.6)| 11.6 (8.7)| <0.001  | 1.3 |
| MCS         | 36.6 (17.7)| 46.3 (17.5)| 9.7 (12.1) | <0.001  | 0.79| 45.3 (17.0)| 54.4 (12.5)| 9.0 (12.6)| <0.001  | 0.71|
| BP          | 19.8 (15.9)| 23.6 (24.0)| 24.0 (21.8) | <0.001  | 1.1 | 28.8(12.1)| 46.4 (10.9)| 17.6 (10.9)| <0.001  | 1.6 |
| SF          | 33.0 (26.2)| 44.8 (23.4)| 11.8 (22.0) | 0.001  | 0.53| 45.8 (20.1)| 54.8 (16.4)| 9.0 (18.9)| 0.003  | 0.47|
| PF          | 20.6 (20.0)| 34.7 (23.5)| 14.1 (18.3) | <0.001  | 0.76| 30.6 (16.4)| 40.6 (12.7)| 10.0 (13.2)| <0.001  | 0.75|
| RP          | 22.9 (20.4)| 38.2 (24.3)| 15.4 (17.7) | <0.001  | 1.86| 31.0 (18.7)| 46.0 (15.7)| 15.0 (15.5)| <0.001  | 0.96|
| MH          | 43.4 (16.2)| 54.7 (12.8)| 11.3 (13.0) | <0.001  | 0.86| 48.1 (17.2)| 59.7 (11.2)| 11.6 (14.8)| <0.001  | 0.78|
| GH          | 38.2 (12.6)| 37.4 (11.5)| −0.8 (11.5) | 0.55   | −0.06| 43.4 (11.5)| 47.1 (12.2)| 3.7 (10.2)| 0.028  | 0.36|
| VT          | 34.0 (17.5)| 42.9 (14.9)| 8.9 (13.1) | <0.001  | 0.67| 37.5 (16.4)| 50.0 (11.3)| 12.5 (11.8)| <0.001  | 1.12|
| RE          | 36.0 (26.4)| 42.8 (26.5)| 6.8 (17.8) | 0.002  | 0.38| 50.0 (27.8)| 53.0 (21.8)| 3.0 (21.0)| 0.24   | 0.14|

Data are presented as mean (SD). ∆ denotes difference between post- and pretest.

a Wilcoxon signed-rank test

Abbreviations: BP, bodily pain; GH, general health; MH, mental health; PF, physical functioning; RE, role emotional; RP, role physical; SD, standard deviation; SF, social functioning; SRM, standardized response mean; VT, vitality; others, see TABLES 1 and 5

Internal consistency for this instrument was excellent for the summary score and acceptable for almost all domains. The only domain that showed a relatively low α value for the scale items was the “symptoms” domain in posttest (<0.7), but in a posttest assessment, it exceeded the value of 0.8. Nordanstig et al11 who conducted validation in the Swedish population noted a similar low value for the “symptoms” domain. Traditionally, psychometry scaling assumes all items to be “effect indicators” manifesting the same latent construct with a high correlation structure and internal consistency.11 Conversely, “causal indicators” (eg, symptoms) are subjective. Therefore, they reveal a weaker correlation structure and lower internal consistency in many cases.

A recent evaluation of the Dutch version of the VascuQol by Conijn et al32 provided additional information on the questionnaire validity, homogeneity, and factor analysis. Some items were found to perform weak in a clinimetric analysis. Additionally, a 3-factor solution was suggested to reduce score variance. As we also noted that some items performed worse, we planned a similar evaluation for the next cohort of our patients, for the Polish version, and after the validation study.

Nevertheless, we believe that valuation of clinical questionnaires should rely on content validity and clinical usefulness rather than on internal consistency.11,30 The VascuQol demonstrated satisfactory responsiveness in a number of studies,11,31 in various populations and language versions.

The reliability of the Polish VascuQol was found to be acceptable by all measures, with the values of ICC above 0.8, according to the criteria defined by Terwee et al.32 While Heerkens et al33 recommend values over 0.9 for the monitoring of ongoing
processes, we think that lower ICC in the “pain” and “social” domains could reflect slight changes of disease perception after the first visit in a specialized reference center.

The adequacy of the Polish VascuQol was good. We confirmed a relationship between the HRQoL and severity of symptoms in PAD. The ROC curve for the VascuQol performed better than for generic tools in classification of patients with IC and CLTI. The AUC for the VascuQol was above 0.8, which is considered to be a good indicator of diagnostic value and the highest among the instruments evaluated. Responsiveness is used as an indicator of the instrument’s sensitivity to change. It also indicates the magnitude of intervention-related change over time. The responsiveness of the VascuQol was good and excellent according to Cohen criteria, in a wide disease spectrum, which is illustrated by the SRM calculations. No floor and ceiling effects were observed based on the criteria described by Terwee et al. These results allow a conclusion that the VascuQol can be a useful tool to evaluate treatment outcomes and to plan further therapy. Good and moderate correlations confirmed the construct validity for the pain, physical, and mental components between the VascuQol and SF-36. As in previous publications, ABPI correlated poorly with HRQoL scores. It confirms that objective clinical parameters do not necessarily correspond to the perception of the severity of disease by patients.

We are aware that our validation strategy has limitations. The VascuQol was tested in a population of patients presenting with more advanced disease referred for endovascular treatment (Rutherford clinical grade 3 and higher). Thus, the groups with less severe presentation and those referred for surgical treatment were not included in the validation cohort. However, with an ongoing shift from traditional surgical to hybrid and endovascular treatment strategies, and interest in more symptomatic patients, our study group represents a population for whom the HRQoL seems most clinically useful.

Some authors incorporated the multitrait multimethod matrix analysis in the clinical validation process. Others did not find any significant additional benefit over methods employed in our study. It is additionally cumbersome and therefore was not performed. Although not a limitation of our study, we find the multi-point scale and a relatively large number of questions in a survey to be time-consuming and quite troublesome, especially for elderly patients. Nordanstig et al. showed that it is possible to simplify the VascuQol to 6 questions with a 4-point response scale without loss of its psychometric values. Accordingly, a particular validation strategy would be useful.

In conclusion, our study showed that the Polish version of the VascuQol questionnaire is valid, more sensitive, and more accurate than the generic questionnaires in assessing the quality of life of Polish patients with symptomatic PAD.

SUPPLEMENTARY MATERIAL
Supplementary material is available with the article at www.mp.pl/paim.

ARTICLE INFORMATION

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CONTRIBUTION STATEMENT AB and LP conceived the concept for the study. All authors contributed to the design and methodology of the research. CA and JL controlled the process of linguistic validation. All authors were involved in data collection. AB, RP, MK, and LP analyzed the data. All authors participated in drafting manuscript but also edited and approved the final version of the manuscript.

CONFLICT OF INTEREST CA and JL are full-time employees of Mapi, Language Services. All other authors declare no potential or existing conflict of interest.

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