

THE PERIPHERAL ARTERY QUESTIONNAIRE: VALIDATION OF THE PORTUGUESE VERSION

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Abstract

Peripheral Arterial Disease (PAD) is a prevalent condition that predisposes the patients to major cardiovascular events. The majority of patients are asymptomatic, however PAD has a great impact in the patients' lifestyle due to its chronic nature. The Peripheral Arterial Questionnaire (PAQ) is a validated tool to quantify the patients' subjective experience of the disease. The aim of this work is to validate the Portuguese version of PAQ.

A retrospective study of 59 patients with aortoiliac disease Trans-Atlantic Inter Society Consensus (TASC) type D from two centers in Portugal was conducted. Only 36 patients were able to answer the PAQ and two Portuguese validated questionnaires – a disease-specific (Walk Impairment Questionnaire – WIQ) and a generic one (EuroQol 5 dimensions – 5 level EQ5D-5L). Convergent validity of the PAQ was evaluated by correlating the extracted PAQ subscales and Summary score with the WIQ subscales and summary score, as with EQ5D-5L Summary score and EQ5D-5L index by calculating the covariance.

The Portuguese version of the peripheral artery questionnaire presented a Cronbach's α for the Summary scale of 0.913. Mean inter-item correlation for the Physical Function domain was 0.471, 0.551 for the Perceived Disability, and 0.464 for Treatment Satisfaction.

In summary, the Portuguese version of PAQ demonstrated a good level of discrimination between patients with or without symptomatic PAD and its severity and was sensitive to the presence of risk-factors relevant for PAD.

INTRODUCTION

Peripheral Arterial Disease (PAD) is a chronic condition with a total disease prevalence of 15% to 20% in population over 70 years¹⁻³, in which the underlying atherosclerotic process narrows the arteries, predisposing the patient to serious cardiovascular events, such as myocardial infarction and stroke.⁴ Intermittent claudication is the cardinal symptom of PAD and the primary target of its therapy.⁵ Despite the majority of patients are asymptomatic, they often suffer mentally and physically from the chronic nature of the disease.⁵ Therefore, its treatment focuses almost exclusively in the improvement of health status and in the relief of pain, rather than survival or limb preservation.⁶ For that reason, and considering the wide variety of treatment options now available to the patient, it is understandable that PAD has a great need, perhaps the greatest need of all cardiovascular diseases, for a disease-specific health status measure.⁷ The measurement of health status is particularly important, given that other outcomes such as limb amputation and death are relatively rare in the current era.⁸

Therefore, in order to characterize patients' health status in a valid, reliable and responsive way to the clinical change, several disease-specific outcome measures have been created. Several questionnaires focus predominantly on the registration of limitations instead of the subjective experience of the disease.⁹ This work employs the Peripheral Arterial Questionnaire (PAQ), which has been proved to be useful in the quantification of the health status improvement after peripheral endovascular revascularization.^{7,10} This questionnaire was developed for the US population, and it has already been translated and validated for Dutch and Korean populations.^{5,9,10} It now consists of a self-administered 20-item health status measure for PAD, that quantifies the symptoms (frequency, severity, and recent change over time), function and quality of life (QoL) of these patients.^{7,9} Besides being useful in health status outcomes research, PAQ can be used as a disease management tool in pursuance of patients who are at higher risk for adverse outcomes, and that might benefit from a closer follow-up.¹¹

The aim of this work is to validate a Portuguese version of the PAQ in order to promote comparisons of PAD

management and outcomes across different countries. In this way, beyond its translation to Portuguese, PAQ's validity and reliability were analyzed.

METHODS

Between October and November 2017, 47 patients with aortoiliac disease Trans-Atlantic Inter Society Consensus (TASC) type D were contacted in 2 centers in Portugal (Centro Hospitalar São João, EPE (CHSJ) and Centro Hospitalar entre Tâmega e Sousa (CHTS) from a previous retrospective cohort. Out of the original 59 patients of the cohort, 12 had died at the time of the survey.¹² All the remaining 47 survivors were transversely contacted in November 2017 and 36 willingly answered the questionnaire in person. All patients included in this study were evaluated at the participating vascular surgery departments and had undergone lower limb revascularization surgery due to PAD (18 endovascular, 18 open procedures). Endovascular procedures included aortoiliac stenting and open procedures included exclusively aortobifemoral bypass graft. The contact was made by a supervised medical student (AF), specifically trained for the purpose. Furthermore, two language validated questionnaires were simultaneously applied to the population, a disease-specific - the Walking Impairment Questionnaire (WIQ) - and a generic - the EuroQol 5 dimensions - 5 level (EQ-5D-5L) questionnaire.^{13,14} At the contact date, patients' median follow-up from surgery was 47,25 (Interquartile Range (IQR) 17,45 – 70,58) months.

The translation was made by two different translators (JRN and AF) whose native language is Portuguese. These translations were combined for making a first agreed-upon translation. Two other members of the bilingual group (MN and JS) then evaluated the quality of this first version regarding clarity and readability and checked for further inconsistencies in the translation. Adaptations upon this evaluation were amended when appropriate. A Pilot study with 10 patients was performed and further adjustments were added. The final version of the Portuguese translation is presented in appendix 1.

Trained research assistants (CHSJ - JRN and JS; CHTS - JRN and AN) obtained data on patient characteristics, cardiac treatments, and the surgical procedure from the patients' hospital files.

The Portuguese version of the EQ-5D-5L was used as a standardized generic instrument for describing and valuing health.¹³ This instrument has been used to assess health status across a wide range of chronic conditions, including PAD.¹⁵ A single summary index (EQ-5D index) representing the patients' self-rated health was calculated by the Spanish EQ5D5L index calculator.¹⁶ The results of the EQ-5D in this study were presented using the 5-dimensional descriptive system (EQ-5D index), the weighted index and using the EQ Visual Analogic Scale (VAS) as a measure of overall self-rated health status.¹⁶

The walking impairment questionnaire (WIQ) has

been extensively used in results evaluation in PAD providing detailed information about patient mobility (17). This questionnaire is composed by three domains with a Likert Scale Questions: distance (WIQDistance 2), velocity (WIQVelocity 3) and stairs (WIQStairs 4).¹⁸

Baseline characteristics were described for the total sample and differences between responders and non-responders regarding these variables were examined using Student's t-tests for continuous variables and Chi-square tests for dichotomous variables to assess for potential selection biases.

Principal components analysis (PCA) was applied to determine the number of factors present in the PAQ. Factors with an eigenvalue of 1.0 or more were retained for further analysis. Oblimin rotation was used to interpret the pattern of loadings on the identified factors. Internal consistency of the factors was examined using Cronbach's α coefficient.

Convergent validity of the PAQ was evaluated by correlating the extracted PAQ subscales and Summary score with the WIQ subscales and summary score, as with EQ5D-5L Summary score and EQ5D-5L index by calculating the covariance.

The analysis was performed using SPSS 25.0 (IBM Corp., released 2017. IBM SPSS Statistics for Windows, version 25.0, Armonk, NY, USA)

The study protocol was approved by the local Ethics Committee (protocol 246 -18) and is in accordance with the Declaration of Helsinki.

RESULTS

A total of 36 (74%) patients answered the questionnaire, 18 who had been previo aortobifemoral bypass graft, and 18 were submitted to aortoiliac stenting. The baseline demographics did not differ, exception for smoking history ($P=0.016$) (Table 1). Sensivity analysis was performed, responders did not differ from non-responders regarding baseline characteristics (Table 2). The total of missing items in the PAQ was inferior to 1%.

Factor analyses were performed on all PAQ items (except for the first item that indicates the most symptomatic leg). Three factors explained most of the variance in the observed data (using the criterion of eigenvalues above 1.0) and therefore two factors could be retained in the final model (Physical Function; Perceived Disability; Treatment Satisfaction). The first factor explained 51%, the second 12.89%. A more than two factor solution did not add significant value to the interpretability of the data. Items are presented and numbered according to the order of the original instrument. All PAQ items had factor loadings ranging from 0.45 to 0.90.

Internal reliability was documented using Cronbach's α and Inter-item correlation; Cronbach's α for the Physical Function domain was 0.799, for the Perceived Disability domain 0.917, and for the Treatment Satisfaction domain 0.741 (Table 4). The Cronbach's α for the

Table 1 Demographics considering revascularization

	ABF (n=18)	Endovascular (n=18)	P=
Sex	100% (18)	94.4% (17)	0.309
Age (mean)	62.5 ± 7.1	66.1 ± 10.4	0.241
HTA	83.3% (15)	77.8% (14)	0.674
Smoking	100% (18)	72.2% (13)	0.016
CKD	11.1% (2)	22.2% (4)	0.371
DM2	27.8% (5)	38.9% (7)	0.480
Dislipidemia	50% (9)	77.8% (14)	0.083
CAD	22.2% (4)	22.2% (4)	1.0
CHF	0% (0)	16.7% (3)	0.070
COPD	11.1% (2)	11.1% (2)	1.0
SFA disease	72.2% (13)	72.7% (12)	0.717
Critical ischemia	44.4% (8)	72.2% (13)	0.091
Rutherford classification (mean)	3.72±0.9	4.17±0.9	0.152

ABF: aortobifemoral bypass graft; CAD: coronary artery disease; CHF: chronic heart failure; CKD (creat>1.5mg/dl); COPD: chronic pulmonary obstructive disease; DM2: diabetes mellitus type 2; SFA disease: superficial femoral artery hemodynamically significant atherosclerotic disease.

Table 2 Sensivity analysis from participants and non-participants

	No Answer (n=11)	Answer (n=36)	P value
Sex			
Age (mean)	61.45	64.28	0.528
HTA	54.5% (6)	80.6% (29)	0.083
Smoking	100% (11)	86.1% (31)	0.191
Chronic Kidney disease	0% (0)	16.7% (6)	0.147
Diabetes	45.5% (5)	33.3% (12)	0.464
Dislipidemia	81.8% (9)	63.9% (23)	0.264
Coronary artery disease	36.4% (4)	22.2% (8)	0.347
Chronic heart failure	0% (0)	31.3% (10)	0.099
COPD	18.2% (2)	11.1% (4)	0.539
Femoral superficial artery disease	54.5% (6)	69.4% (25)	0.361
Critical limb ischemia	36.4% (4)	58.3% (21)	0.201
Rutherford classification (mean)	3.55	3.94	0.55

CKD: chronic Kidney disease (creat>1.5mg/dl); COPD: chronic obstructive Pulmonary disease; Femoral superficial artery disease – superficial femoral artery hemodynamically significant atherosclerotic disease.

Summary scale was 0.913. Mean inter-item correlation for the Physical Function domain was 0.471, for the Perceived Disability 0.551, for Treatment Satisfaction 0.464.

DISCUSSION

PAD is a chronic condition with a significant impact in the patients' daily life and overall status. This study

sought to translate and validate the PAQ questionnaire for the Portuguese population, which is a useful tool to evaluate the health status after revascularization surgery. The main finding is that PAQ has good clinical validity, discriminating well for the severity of the disease and for the presence of symptoms and risk factors among PAD patients.

Unlike the original instrument, three factors were discerned in the Portuguese version of the PAQ, explaining most of the variance in the observed data (89%). The other

original domains (Symptom, Symptom Stability, Social Limitation, and Quality of Life) were combined in a domain labeled the Perceived Disability domain. The three domains identified in this study were internally reliable. Previous validations found similar results.⁹ A two domain approach would also be valid, due to the result, future validation could be performed, although with few practical implications.

The strongest associations of PAD symptoms here observed were with pain and physical limitations, i.e., the PAQ sub-domains of Physical Functioning and Perceived Disability. The correlation and linear correlation between the scores and the Ankle-Brachial index were weak, specially above >0.5 . Previous studies have demonstrated a better discriminative ability of disease-specific vs generic questionnaires to detect changes in QoL in PAD patients congruent with the findings of our study, which demonstrated that the PAQ discriminated better between the clinical indices than the generic EQ-5D index.¹⁹

The convergent validity was established using two questionnaires, a well standardized generic health status questionnaire, the EQ-5D, and a previously language

validated disease-specific questionnaire – WIQ (Table 4). Although the EQ-5D index and EQ VAS scale could differentiate between asymptomatic and symptomatic disease, the EQ indices were not able to display the clear dose-response relationship between the number of risk factors and worsening of health status.

Convergent validity of the PAQ domains was documented by medium to large correlations with the EQ-5D and WIQ and by comparisons of the mean scores of the PAQ scales with the stratified EQ-5D and WIQ domains. Both the inter-correlations of the PAQ domains and the correlations of the Treatment Satisfaction domain with the EQ-5D scales pointed to the uniqueness of the Treatment Satisfaction domain.

Inter-correlations of the PAQ domains Perceived Disability and Physical Function were all high, indicating that the domains were strongly related to the construct that the questionnaire purported to measure, namely disease-specific health status (Table 4).

Generic health status instruments are not sensitive enough to provide clinicians and researchers with

Table 3 Results from Peripheral Artery Questionnaire

	Mean ($\pm$ SD)	Median [percentile 25-75]
PAQLado	1.53 $\pm$ (1.298)	1 [0 - 3]
PAQ2.1	3.39 $\pm$.934	4 [3 - 4]
PAQ2.2	3.06 $\pm$ 1.286	4 [2 - 4]
PAQ2.3	2.11 $\pm$ 1.369	2 [1 - 3]
PAQ2.4	2.64 $\pm$ 1.775	4 [0 - 4]
PAQ2.5	1.69 $\pm$ 1.721	1 [0 - 2.75]
PAQ2.6	2.17 $\pm$ 2.348	1 [0 - 5]
PAQ3	2.14 $\pm$ 1.125	2 [2 - 2]
PAQ4	3.89 $\pm$ 1.924	4 [2 - 6]
PAQ5	2.81 $\pm$ 1.091	3 [2 - 4]
PAQ6	3.25 $\pm$ 1.273	4 [3 - 4]
PAQ7	3.47 $\pm$.971	4 [3 - 4]
PAQ8	3.44 $\pm$.735	4 [3 - 4]
PAQ9	3.25 $\pm$ 1.131	4 [3 - 4]
PAQ10	2.97 $\pm$ 1.055	3 [2 - 4]
PAQ11	2.86 $\pm$ 1.073	3 [2 - 4]
PAQ12	3.00 $\pm$ 1.095	3 [2 - 4]
PAQ13.1	3.28 $\pm$ 0.974	4 [2.25 - 4]
PAQ13.2	3.11 $\pm$ 1.166	4 [2 - 4]
PAQ13.3	3.11 $\pm$ 1.063	3.5 [2 - 4]

Table 4

Inter-item correlation Peripheral Artery Questionnaire to Walking Impairment Questionnaire and EQ-5D-5L

		correlation	P value
PAQ Summary	WIQ 1b score	0.539	0.001
	WIQ 2 score	0.416	0.012
	WIQ 3 score	0.384	0.021
	WIQ 4 score	0.510	0.001
	EQ5D5L index Median	0.839	0.000
	EQ6 (Visual scale)	0.457	0.005
PAQ Physical	WIQ 1b score	0.269	0.113
	WIQ 2 score	0.333	0.047
	WIQ 3 score	0.299	0.077
	WIQ 4 score	0.421	0.011
	EQ5D5L index Median	0.579	0.000
	EQ6 (Visual scale)	0.162	0.342
PAQ Satisfaction	WIQ 1b score	0.136	0.43
	WIQ 2 score	0.037	0.831
	WIQ 3 score	0.297	0.078
	WIQ 4 score	0.342	0.041
	EQ5D5L index Median	0.417	0.012
	EQ6 (Visual scale)	0.234	0.169
PAQ Perceived	WIQ 1b score	0.636	0.000
	WIQ 2 score	0.396	0.017
	WIQ 3 score	0.372	0.026
	WIQ 4 score	0.476	0.003
	EQ5D5L index Median	0.868	0.000
	EQ6 (Visual scale)	0.589	0.000

useful information that makes adequate evaluation of PAD treatments possible.

The main limitation of this study is the sample size and the transversal application of the questionnaire, which did not enable to access the test-retest reliability.

CONCLUSION

In conclusion, this study demonstrated good clinical validity of the PAQ as the instrument discriminated well between patients with or without symptomatic PAD and its severity and was sensitive to the presence of relevant risk factors for PAD.

Furthermore, it should be noted that the assessment of the validity of questionnaires is not straightforward as there is no gold-standard for outcome measurement in PAD patients. PAQ is now a useful tool, to be used as a mean for measuring health status and physical functioning in the Portuguese patients with PAD.

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ANNEX 1

PERIPHERAL ARTERY QUESTIONNAIRE – PORTUGUESE VERSION

QUESTIONÁRIO DE DOENÇA ARTERIAL PERIFÉRICA

O questionário que se segue é dirigido a obstruções arteriais do seu corpo, particularmente das suas pernas, e de como pode afetar a sua vida. Por favor leia e complete as seguintes questões. Não há respostas certas ou erradas.

Por favor marque aquela que se adequa à sua situação.

1

As obstruções arteriais, habitualmente chamadas de doença arterial periférica, afetam cada pessoa de forma particular. Qual das suas pernas ou nádegas lhe causa mais desconforto, cansaço, dor, aperto ou câibra?

☐

Direita

☐

Esquerda

☐

Ambas

☐

Nenhuma

2

Por favor reveja a lista abaixo apresentada e indique o grau de limitação derivado da sua doença arterial periférica (desconforto, cansaço, dor, aperto, câibra nas nádegas ou “barriga” da perna) nas últimas 4 semanas.

ATIVIDADES	Extremamente limitado	Bastante limitado	Moderadamente limitado	ligeiramente limitado	Sem qualquer limitação	Limitado por outros motivos/ Não realizou a actividade
Andar nas imediações de sua casa	☐	☐	☐	☐	☐	☐
Andar 100-200 m em plano horizontal	☐	☐	☐	☐	☐	☐
Andar 100-200 m em plano inclinado	☐	☐	☐	☐	☐	☐
Andar 300-400 m em plano horizontal	☐	☐	☐	☐	☐	☐
Andar em passo acelerado	☐	☐	☐	☐	☐	☐
Exercício vigoroso	☐	☐	☐	☐	☐	☐

3

Comparando com há 4 semanas, os seus sintomas de doença arterial periférica (desconforto, cansaço, dor, aperto, câibra nas nádegas ou “barriga” da perna) mudaram de características?
Os meus sintomas ficaram...

Muito pior

☐

Ligeiramente pior

☐

Sem alteração

☐

Ligeiramente melhor

☐

Muito melhor

☐

Não tive sintomas nas últimas 4 semanas

☐

4

Nas últimas 4 semanas, com que frequência tem sentido desconforto, cansaço, dor, aperto, caibra nas nádegas ou “barriga” da perna?

Todo o tempo

☐

Diversas vezes ao dia

☐

Pelo menos uma vez por dia

☐

3 ou mais vezes por semana

☐

Uma ou duas vezes por semana

☐

Menos de uma vez por semana

☐

Nunca nas últimas 4 semanas

☐

5

Nas últimas 4 semanas quantifique o grau de incómodo causado pelo desconforto, cansaço, dor, aperto ou caibra nas nádegas ou “barriga” da perna.

Extremo	Bastante	Moderado	Ligeiro	Não incomodou
☐	☐	☐	☐	☐

6

Nas últimas 4 semanas com que frequência tem sido acordado com desconforto, cansaço, dor, aperto ou caibra nas nádegas ou “barriga” da perna.

Todas as noites	Três ou mais noites por semana	Uma a duas vezes por semana	Menos de uma vez por semana	Nunca nas últimas 4 semanas
☐	☐	☐	☐	☐

7

Relativamente a tudo o que se tem feito tudo no tratamento da sua doença arterial, qual é o seu nível de satisfação?

Muito Insatisfeito	Ligeiramente insatisfeito	Pouco satisfeito	Bastante satisfeito	Completamente Satisfeito
☐	☐	☐	☐	☐

8

Quantifique o seu grau de satisfação com a informação que lhe foi dada pelo seu médico em relação à doença arterial periférica.

Muito Insatisfeito	Ligeiramente insatisfeito	Pouco satisfeito	Bastante satisfeito	Completamente Satisfeito
☐	☐	☐	☐	☐

9

Na generalidade, quantifique o seu grau de satisfação com o seu tratamento da doença arterial periférica.

Muito Insatisfeito	Ligeiramente insatisfeito	Pouco satisfeito	Bastante satisfeito	Completamente Satisfeito
☐	☐	☐	☐	☐

10

Quantifique, nas últimas 4 semanas, o quanto a doença arterial periférica tem limitado o seu prazer em viver.

Extremamente	Bastante	Moderadamente	Ligeiramente	Não limitou
☐	☐	☐	☐	☐

11

Se tivesse de viver o resto da sua vida com a doença arterial periférica como ela se apresenta neste momento, como se sentiria?

Muito Insatisfeito	Ligeiramente insatisfeito	Pouco satisfeito	Bastante satisfeito	Completamente Satisfeito
☐	☐	☐	☐	☐

12

Nas últimas 4 semanas, com que frequência se sentiu desencorajado ou desmotivado devido aos sintomas da doença arterial periférica?

Todo o tempo	A maioria do tempo	Ocasionalmente	Raramente	Nunca
☐	☐	☐	☐	☐

13

Quantifique quanto a doença arterial periférica influencia a sua vida diária. Por favor indique como desconforto, cansaço, dor, aperto, caibra nas nádegas ou “barriga” da perna possa ter interferido na realização das seguintes tarefas nas últimas 4 semanas.

ATIVIDADES	Extremamente limitado	Bastante limitado	Moderadamente limitado	Ligeiramente limitado	Sem qualquer limitação	Não se aplica ou não realizado por outros motivos
Hobbies e atividades recreativas	☐	☐	☐	☐	☐	☐
Visitar familiar e amigos fora de sua casa	☐	☐	☐	☐	☐	☐
Trabalhar ou realizar tarefas de casa	☐	☐	☐	☐	☐	☐