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Cross-Cultural Adaptation and Validation of the Brazilian Portuguese Version of the Edinburgh Claudication Questionnaire

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Summary

Objective: Translation, cultural adaptation and validation of the Brazilian Portuguese version of the Edinburgh Claudication Questionnaire (ECQ) a specific tool to assess intermittent claudication.

Methods: The Brazilian Portuguese version of the ECQ was developed after authorization by the University of Edinburgh. It was applied to 217 individuals: São Paulo Capital District residents with complaints of leg pain. Individuals under research were invited through mass communication media to participate in the I Campaign to Fight Peripheral Arterial Disease (PAD). In stage 1, participants filled out the ECQ and another questionnaire on risk factors and cardiovascular history. In stage 2, participants had anthropometric measures and ankle-brachial index (ABI) at rest measured by vascular Doppler. In case of doubt, vascular treadmill test was applied (VTT). PAD condition was defined by ABI ≤ 0.90 and/or positive VTT and/or documented PAD. Statistical analysis – which included performance assessment and the comparison between proportions and means – was performed using SAS software, version 8.2.

Results: Mean age of participants was 60±11.5 years, female sex predominated in the sample studied (53.4%). Sensitivity, specificity, positive predictive value, negative predictive value and accuracy were 85%, 93%, 80%, 95% and 91%, respectively. No differences in performance were found between elderly (≥65 years)and non-elderly subjects.

Conclusion: The Brazilian Portuguese version of the Edinburgh claudication questionnaire maintained good sensitivity and specificity and can be recommended for screening of PAD in clinical practice and epidemiological research in Brazil.

Key words: Intermittent claudication; questionaire; translating (process); transcultural adaptation.

Introduction

Peripheral Arterial Disease (PAD) is a result of artery lumen narrowing and stiffening in the lower limbs as part of the process of systemic atherosclerotic disease. Prevalence is high, and is associated to high risk for fatal and non-fatal cardiovascular events (death, myocardial infarction and cerebral vascular accident)[1-2].

Intermittent claudication is a classical symptom in the PAD condition. It occurs as a result of reduced blood flow to skeletal muscle tissue in lower limbs during exercise. Claudication is characterized by pain or discomfort in the calf, thigh, or gluteus region while walking. Symptoms disappear after less than 10 minutes at rest. Prevalence ranges from 0.4 to 14.4% in the general population depending on specific characteristics of the population being assessed (age, gender, region, among other factors) as well as of method used for diagnosis[3].

Ankle-Brachial Index (ABI) is the golden standard for PAD screening since it detects both symptomatic and asymptomatic conditions[4]. The use of claudication questionnaires, however, may help screening PAD both for epidemiologic research purposes and in clinical practice. Claudication questionnaires validated in Brazilian Portuguese are not available in this country today. The Bambuí Project – to assess the prevalence of intermittent claudication in residents of Bambuí, in Minas Gerais State – used a Brazilian Portuguese version of the World Health Organization Questionnaire. However, no published data were found on questionnaire validation or on performance in Brazilian Portuguese[5].

The purpose of the present study was the translation, cultural adaptation and validation of the Brazilian Portuguese version of the Edinburgh Claudication Questionnaire (ECQ).

Methods

Translation of questionnaire - The translation and cultural adaptation of the original version into Brazilian Portuguese were performed based on methodology previously

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published[6], following authorization by Professor Gerry Fowkes, from the University of Edinburgh. The translation was done independently by three members in our team and by two English teachers. As a result, five renditions were made available, with slight differences. The versions were then compared and discussed in a meeting where a consensual choice was made for Version 1. That version was then sent to three other independent translators who are fluent in English and who were not familiar with the original version for backtranslation into English. The three new versions were then compared to generate a consensual version in English (Version 2). When compared to the original version, Version 2 showed to be grammatically and semantically equivalent, which allowed Version 1 to be accepted by the group as the final version for the questionnaire in Brazilian Portuguese.

Questionnaire Validation

Population - The Brazilian Portuguese version of the ECQ was applied to 217 individuals: São Paulo Capital District residents with complaints of leg pain. Individuals under research were invited through mass communication media (television, radio, newspapers) to participate in the I Campaign to Fight Peripheral Arterial Disease (PAD). In Campaign phase 1 - carried out on July 20, 2004 – all participants filled out the claudication questionnaire and another questionnaire on risk factors and cardiovascular history. Stage 2 – in October-November, 2004 – anthropometric measures and Ankle-brachial index (ABI) were taken, and vascular treadmill test (VTT) for threshold ABI values. PAD condition was defined by ABI ≤ 0.90 and/or positive VTT and/or documented PAD. All participants signed the Informed Consent Form.

ABI measure and calculation - To calculate ABI, systolic pressures of brachial arteries, dorsalis pedis and posterior tibial arteries were measured bilaterally after 5 minutes at rest in supine position using a handheld vascular Doppler and aneroid pressure equipment. Four cuff sizes were used (small size adult, median size adult, large size adult and thigh), based on right arm circumference at middle position between acromium and olecranium. ABI was calculated for each lower limb using arm highest systolic pressure as denominator, and ankle highest pressure as numerator[7].

Vascular treadmill test - Vascular treadmill test was performed only for ABI threshold values (0.91 to 0.94). An incremental protocol was used for VTT on the treadmill at 3 km/hour, inclination from 0 to 15%, with 5% increment every 3 minutes. Pressures were measured with vascular Doppler in supine position at rest and after exercise. The test was considered POSITIVE for the diagnosis of PAD whenever ankle systolic pressure decrease measured at minute 1 after exercise was higher than or equal to 20% as compared to baseline, with baseline recovery time over 3 minutes[8].

Exclusion criteria - Patients with ABI > 1.40 (noncompressible arteries) and those with limitations or contra-indication to vascular treadmill test, if indicated.

Results from the Edinburgh Claudication Questionnaire -

Following original guidelines, result was classified as POSITIVE (=presence of claudication) if responses to questions 1 = "yes" AND 2 = "no" AND 3 = "yes" AND 5 = "usually disappear in 10 minutes or less" AND 6 = marked "calf" and/or "thigh" and/or "gluteus region" (irrespective of other sites having also been marked) or NEGATIVE for any combination that differed from the one just described.

Question 4 is not used to define presence, but rather severity of claudication; if "No"=Grade 1 (=lower severity) and if "Yes"=Grade 2 (=higher severity).

Patients with POSITIVE questionnaire were also classified as carriers of "Typical or definitive claudication" (if "calf" had been marked for question 6, irrespective of other sites also having been marked) and "Atypical claudication" (in case "calf" had not been marked, but "thigh" and/or "gluteus region" had been marked, irrespective of other site).

Definition for truly positive/negative and false positive/ negative - If the claudication questionnaire was NEGATIVE, and ABI was between 0.91 and 1.40 bilaterally, with no history of documented PAD, classification would be "truly negative". If ABI was ≤ 0.90 with/without a previous history of PAD, "false negative".

If questionnaire was POSITIVE and ABI ≤ 0.90 with/ without documented PAD, questionnaire was classified as "truly positive". If ABI was between 0.91 and 1.40, with no previous PAD, and vascular treadmill test was negative, questionnaire classification was "false positive".

Statistical analysis - Questionnaire performance was assessed by SAS software, version 8.2 to calculate sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy with Fleiss Quadratic 95% CI. Diagnosis accuracy was calculated by dividing the number of individuals under correct classification on questionnaire (summing up of truly positives and truly negatives) by the total number of individuals under assessment. Proportions were then compared through chi-square test or Fisher Exact Test, whenever applicable, and means were compared by Student's "t" test.

Results

Overall results - The Brazilian Portuguese Version of the Edinburgh Claudication Questionnaire can be found in Figure 1.

Mean age of the 217 individuals under assessment was 60 ± 11.5 years (30 to 86 years of age). Females were predominant (53.9%). Prevalence of PAD was 24% (n=52); prevalence of intermittent claudication was 25% (n=55).

In the PAD group individuals were older (65.8 ± 10.3 years *versus* 58.2 ± 11.3 years, p<0.0001). Males were predominant (61.5% *versus* 41%, p=0.01). No difference was found between the groups in regard to schooling (7.38 ± 4.38 years at school *versus* 7.57±3.87 years at school, p=0.786) or coexisting atherosclerotic disease. As for traditional risk factors, higher prevalence was reported for diabetes, dyslipidemia, and smoking in the PAD group. Claudication prevalence, typical claudication and the lack of one or more ankle pulses was significantly higher in PAD
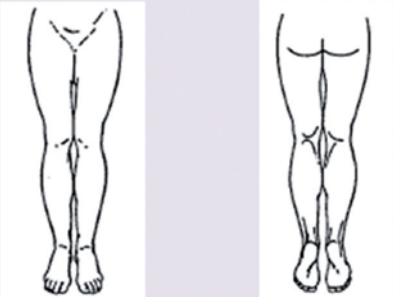
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Fig. 1 - The Brazilian Portuguese Version of the Edinburgh Claudication Questionnaire.

individuals (Table 1).

Brazilian portuguese version: performance assessment - Table 2 shows diagnostic performance of the Brazilian Portuguese Version of the Edinburgh Claudication Questionnaire. Portuguese version sensitivity was similar to that of original version (85%, CI95%=0.714-0.927 *versus* 91.3%, CI95%=0.881-0.945, p=0.675) whereas specificity was lower (93%, CI95%=0.881-0.965 *versus* 99%, CI95%=0.989-1.00, p=0.001). No difference was found in performance between the elderly (≥ 65 years of age) and non-elderly (<65 years of age) (Table 3).

Discussion

The Edinburg Claudication Questionnaire was originally developed and validated in English by Professors Leng and Fowkes, University of Edinburgh, In Scotland, with the objective of improving the sensitivity of the WHO Claudication Questionnaire published by Rose in 1962[9]. Although Rose Questionnaire had high specificity level (between 90% and 100%), sensitivity reached up to 9%[10] due to the strict claudication criteria used. As the Edinburgh Questionnaire was developed, performance of the nine questions from the Rose Questionnaire were analyzed to verify whether any changes were needed. At process ending, the questionnaire was reduced to six questions. A diagram was added for exact site of pain, thus making self-application easier.

Sensitivity and specificity were 91% and 99% in the version originally published by Leng and Fowkes in 1992, higher than the valves obtained by the Rose Questionnaire[11]. In 2000, Aboyans and cols. published a French version of the questionnaire with 86.5% sensitivity and 95.6% specificity[12]. In 2002, in another publication of the French version validation, Lacroix and cols. found difference in questionnaire performance, especially in regard to sensitivity (sensitivity= 47% and specificity 98.8%)[13].

The Brazilian Portuguese version of the Edinburgh Claudication Questionnaire presented in this study showed 85% sensitivity, 93% specificity, 80% positive predictive value, 95% negative predictive value, and 91% accuracy. When compared to data in literature – showing a 15 at 91% range in sensitivity and a 91.3 to 99% range in specificity when the English version was used for different populations – the performance of Brazilian Portuguese version was ranked as very good[14].

When compared to the original English version, the Brazilian Portuguese version showed lower sensitivity (85% *versus* 91%, p=0.675) and specificity (93% *versus* 99%, p=0.001) levels, although the difference in specificity did reach statistical significance. That may have occurred due to differences in population characteristics, and in the methodology used for validation. In the English version, PAD diagnosis was carried out based on clinical assessment only, which increased the chances of matching

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Table 1 - Comparison of baseline clinical characteristics of the 217 individuals in whom the presence of Peripheral Arterial Disease (PAD) was assessed						
Variables	**Total (n=217)**	**Presence of PAD (n=52)**	**Absence of PAD (n=165)**	**Odds ratio**	**CI 95%**	**p**
Age in years (mean ±SD)	60.0±11.5	65.8±10.3	58.2±11.3	-	-	<0.0001
Schooling, number of years at school (mean±SD)	7.48±3.98	7.38±4.38	7.57±3.87	-	-	0.786
Gender (n, %)						
Females	117 (53.90)	20 (38.50)	97 (58.80)	0.44	0.23-0.83	0.010
Males	100 (46.10)	32 (61.50)	68 (41.20)			
Coexisting disease (n,%)*						
Stroke	11(5.07)	2(4.17)	9(5.59)	0.73	0.15-3.52	1.000
Abdominal aortic aneurysm	14(6.45)	4(8.33)	10(6.58)	1.29	0.39-4.32	0.746
Coronary artery disease (CAD)	35(16.10)	9(18.75)	26(16.46)	1.17	0.50-2.70	0.711
Renal artery stenosis	13(5.90)	2(4.55)	11(7.10)	0.62	0.13-2.92	0.737
Carotid stenosis	10(4.60)	2(4.35)	8 (5.41)	0.79	0.16-3.88	1.000
Risk factors (n, %)*						
Diabetes mellitus	34(15.67)	13(27.08)	21(13.82)	2.31	1.05-5.08	0.033
Dyslipidemia	101(46.54)	35(74.47)	66(44.59)	3.62	1.74-7.53	0.0004
Hypertension	129(59.45)	36(72.0)	93(57.76)	1.88	0.94-3.76	0.071
Family history of CAD	74(34.10)	17(33.33)	57(34.55)	0.95	0.49-1.84	0.873
Body mass index (BMI) (Kg/m²)	27.56±4.23	26.86±3.71	27.77±4.36	-	-	0.203
Sedentary life style	132(60.83)	32(62.75)	100(61.35)	1.06	0.55-2.03	0.858
Active smoking	31(14.29)	13(25.49)	18(11.04)	2.75	1.24-6.12	0.010
Active or previous smoking	90(41.47)	30(58.82)	60(36.81)	2.45	1.29-4.66	0.005
Intermittent claudication*	55(25.34)	44(84.61)	11(6.67)	77	29.18-203.20	<0.0001
Typical claudication*	51(23.50)	41(78.85)	10(6.10)	117.53	30.69-450.10	<0.0001
Absence of ≥1 ankle pulses	64(29.49)	36(69.23)	28(16.97)	11.01	5.38-22.52	<0.0001

Reported by the individual in the questionnaire, except for BMI - calculated based on weight and height measured on assessment day. Sedentary life defined as physical activity ≤ 30 minutes 3 times a week. # Based on Edinburgh Claudication Questionnaire Results.

Table 2 - Results from performance assessment of the Brazilian Portuguese Version of the Edinburgh Claudication Questionnaire

	Proportion	**Confidence interval 95%**
Sensitivity	85%	0.714 – 0.927
Specificity	93%	0.881 – 0.965
Positive predictive value	80%	0.666 – 0.891
Negative predictive value	95%	0.902 – 0.977
Accuracy	91%	0.865 – 0.945

questionnaire results and the presence of PAD, since both focus symptomatic PAD. The Brazilian version used a methodology similar to the French version[11], where the choice was made for a more objective diagnosis method (ABI measure), which detects both symptomatic and asymptomatic patients, and which is closer to clinical practice. Through this methodology, an asymptomatic PAD case would be classified as "false positive", whereas the diagnosis based on clinical history only would be more likely to be classified as "truly negative". On the other hand, a case reporting no PAD with positive claudication on questionnaire could be confirmed by clinical history ("truly positive"), but not by ABI measure ("false positive").

No significant differences could be observed in the performance of the Brazilian Portuguese version among elderly and non-elderly, which allows it to be used for that high risk population for PAD as well.

The good performance of the Brazilian Portuguese version of the Edinburgh Claudication Questionnare presented in this study – where specificity levels were kept above 90% with no loss in sensitivity – makes it recommendable for use in the

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Table 3 - Comparison between elderly (≥ 65 years of age) and non-elderly (< 65 years of age) in regard to performance assessment of the Brazilian Portuguese version of the Edinburgh Claudication Questionnaire

	Proportion	Confidence interval 95%	p
Sensitivity			
Elderly	89%	0.697 – 0.971	0.614
Non-elderly	80%	0.587 – 0.924	
Specificity			
Elderly	92%	0.799 – 0.974	0.912
Non-elderly	94%	0.874 – 0.973	
Positive predictive value			
Elderly	86%	0.664 – 0.953	0.459
Non-elderly	74%	0.534 – 0.881	
Negative predictive value			
Elderly	94%	0.821 – 0.984	0.949
Non-elderly	96%	0.895 – 0.983	
Accuracy			
Elderly	91%	0.816 – 0.959	0.899
Non-elderly	91%	0.852 – 0.953	

Brazilian population both for epidemiologic research purposes as in clinical practice.

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