External Validation of the "Walking Estimated Limitation Calculated by History" (WELCH) Questionnaire in Patients with Claudication

P. Abraham ^{a,b,c,d,*}, R. Godet ^a, M. Harbonnier ^a, D. Laneelle ^b, G. Leftheriotis ^{a,b,c,d}, N. Ouedraogo ^{a,b,c,d}

^a Laboratory for Exercise Investigations and Sports Medicine, Angers, France

^b Laboratory for Vascular Investigations, Angers, France

^c LUNAM Université, Angers, France

^d INSERM1083/CNRS6214, Angers, France

WHAT THIS PAPER ADDS

The routine use of the Walking Impairment Questionnaire is limited by the number of errors when selfcompleted and by its scoring complexity. We recently proposed a new simple and easily scored four-item questionnaire to standardise patient reporting of walking capacity: the "Walking Estimated Limitation Calculated by History" (WELCH) questionnaire. This study confirms that the accuracy of the WELCH in predicting the inability to walk for 5 minutes on the treadmill is satisfactory in patients reporting claudication. The WELCH seems an attractive tool for routine clinical use.

Objective: To externally validate the recently proposed "Walking Estimated Limitation Calculated by History" (WELCH) questionnaire.

Methods: A prospective study was performed on 450 new patients referred to our laboratory for treadmill testing (constant load 3.2 km/h and 10% slope for 15 minutes and then incremental increases). Results are presented as mean \pm SD or median [25th-75th percentiles] or number (percentage). An ankle brachial index <0.90 defined the presence of peripheral artery disease (PAD). Typical "vascular-type claudication" is a lower-limb pain or discomfort that is absent at rest, appears at exercise, forces stopping, and disappears within 10 minutes of exercise stopping. The Spearman *r* coefficient of correlation between maximal walking time (MWT) on treadmill and WELCH scores was calculated for patients with (PAD+) or without (PAD-) PAD, and reporting typical vascular-type claudication (VTC+) or not (VTC-).

Results: The WELCH score was obtained in all included patients. The number (%) of patients with a WELCH score <25 was 37 (54%), 198 (65%), 14 (44%), and 18 (38%), and the Spearman correlation coefficient between WELCH score and treadmill MWT was 0.588, 0.609, 0.581, and 0.591 in the VTC-/PAD+, VTC+/PAD+, VTC-/PAD-, and VTC+/PAD- groups respectively (all p < .001). In PAD+/VTC+ patients, the WELCH positive predictive value for the inability to walk for 5 minutes on the treadmill was 79%.

Conclusion: The WELCH score correlates moderately with treadmill-walking capacity in patients with or without PAD, and with or without typical VTC. It appears to be a simple to complete and easily scored instrument to help clinicians standardise the subjective estimation of walking capacity in their patients.

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Article history: Received 7 August 2013, Accepted 22 November 2013, Available online 3 December 2013 Keywords: Claudication, Exercise, Exercise testing, Peripheral arterial disease, Questionnaires, Walking impairment

INTRODUCTION

Walking limitation is a frequent symptom in elderly patients. Lower-limb pain or fatigue on exertion may result from peripheral artery disease (PAD) or various nonvascular diseases (e.g., lumbar spine, cardio-pulmonary,

http://dx.doi.org/10.1016/j.ejvs.2013.11.010

or osteo-articular diseases). The use of standard questionnaires facilitates and standardises the quantification of walking impairment and provides information additional to exercise testing.^{1,2} Among the available tools to estimate walking capacity, the recently proposed "Walking Estimated Limitation Calculated by History" (WELCH) questionnaire is of interest because it is simple for patients to complete and is easily scored.³ Previous publications have shown that its correlation with the maximal walking time (MWT) observed during a standard treadmill test is comparable with the one observed with the more complex Walking Impairment Questionnaire.³ Further, the initial validation of the WELCH suggested that a score <25

^{*} Corresponding author. P. Abraham, Laboratory for Vascular Investigations, University Hospital, 4 rue Larrey, Angers Cedex 09 F-49933, France.

E-mail address: piabraham@chu-angers.fr (P. Abraham).

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Please answer each of the following 4 items by placing an "X" in the box that best describes your situation. Please mark only one box per item. If you never perform an activity, estimate what it would be like if you did perform it. For the first 3 items, if you think that you would not be able to perform a specified task for at least 30 seconds without stopping to rest, please answer "impossible".

For each of the three following activities, how long can you perform the task easily on level ground & without stopping when ...

1/... walking slowly (slower than usual speed of relatives, friends, or other people of your own age)?

Impossible	30 seconds	1 minute	3 minutes	10 minutes	30 minutes	l hour	3 hours
							or more
-	4						

2/ ... walking normally (same as usual speed of relatives, friends, or other people of your own age)?

Impossible	30 seconds	1 minute	3 minutes	10 minutes	30 minutes	l hour	3 hours or more
			Y				
-	1	0		1	<u> </u>	C	7

3/ ... walking quickly (faster than usual speed of relatives, friends, or other people of your own age)?

Impossible	30 seconds	1 minute	3 minutes	10 minutes	30 minutes	l hour	3 hours or more
	Y						
0	1	2	3	4	5	6	7

Compared to the usual walking speed of your relatives, friends, or people of your own age, do you think that you personally usually walk ... (Tick only one box)

2

much slower moderately slower	Ţ
a bit slower	
at the same speed	
faster	

THANK YOU: You should have 1 box per item ticked ... please check.

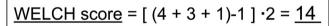


Figure 1. Example of the scoring of a "Walking Estimated Limitation Calculated by History" (WELCH) questionnaire. Note that item values and coefficients are presented to facilitate the reading of the figure, but are not available to the patient.

predicts the inability to walk for 5 minutes on a treadmill with 75% sensitivity and 80% specificity in PAD patients. In PAD patients, a walking time of <5 minutes on a treadmill characterises severe claudication according to the Rutherford classification.^{1,2} As the performance of predictive models is generally higher with data on which they are constructed compared with new data,⁴ so-called "external validation" was required to confirm our initial findings with a new group of patients. Whether the previous cutoff point (WELCH score <25) proposed to detect patients with severe claudication (i.e., MWT <5 minutes) is valid in a prospective study of a new population with PAD has not been reported.

METHODS

Study population

A prospective study was performed from January 2012 on all new patients referred to our laboratory for treadmill testing for the diagnosis or follow-up of claudication.⁵ Eligibility criteria included ability to walk on a treadmill, native French speakers, age >18 years, stable symptoms for >3 months, absence of known or apparent cognitive or psychiatric disorders, and ability to read alone. Written informed consent was obtained from all patients. Patients who were referred more than once during the study period were only included once. Patient characteristics, medical

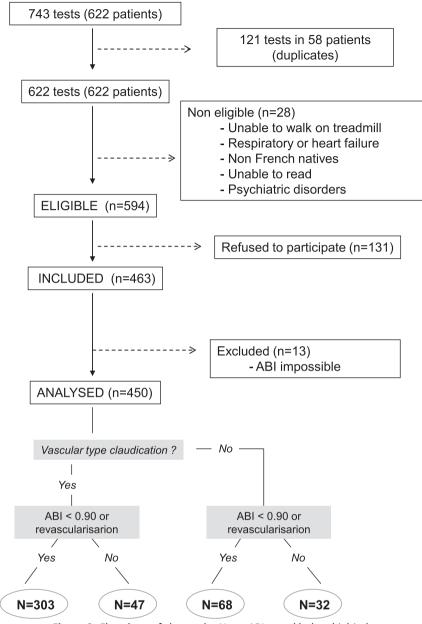


Figure 2. Flowchart of the study. Note. ABI = ankle brachial index.

history, and treatments were retrieved from medical files and by patient interview. The study was approved by the local ethics committee, conforms to the Declaration of Helsinki, and is an ancillary study of that referenced on the clinicaltrial.gov website (NCT01114178).

Completion and correction of questionnaires

On arrival, patients were asked to complete the Edinburgh Claudication Questionnaire (ECQ) and the WELCH questionnaire. Reading glasses were provided to each patient if required. The ECQ is used to describe symptoms and does not evaluate walking capacity. When resulting from PAD, claudication is expected to fulfil vascular-type criteria (VTC) on the ECQ, including lower-limb pain or discomfort that is absent at rest, occurs while walking, and that forces the patient to slow down or stop walking, with pain disappearing within 10 minutes of stopping exercise. Patients were asked to self-complete the questionnaires while in the waiting room and were given sufficient time (\sim 15 min) to complete it, read the information letter, and consent to their answers being used for research purposes. For those patients who consented to the study, a trained technician or nurse screened the questionnaires for errors before the patient was admitted to the treadmill test room. This screening searched for missing (no answer to an item), duplicate (two or more answers to the same item), or paradoxical (e.g., lower duration for an easier task) answers. Each detected error was discussed with the patient and corrected as appropriate.

Walking capacity on treadmill

Thereafter, patients were admitted to the treadmill room. Characteristics (age, body mass, stature, ankle brachial index [ABI], current medications) were retrieved from

	VTC-/PAD+	VTC+/PAD+	VTC-/PAD-	VTC+/PAD-
Number of patients	68	303	32	47
Age, years	65 ± 11	65 ± 11	59 ± 15	63 ± 12
Stature, cm	169 \pm 10	169 \pm 7	170 ± 9	170 \pm 7
Body mass, kg	79 ± 17	76 ± 15	81 ± 20	79 ± 15
Bronchitis, n (%)	17 (25)	64 (21)	5 (14)	9 (18)
Hypertension, n (%)	47 (70)	183 (61)	22 (69)	24 (51)
Dyslipidaemia, n (%)	47 (70)	228 (75)	29 (91)	29 (62)
Blood glucose, mg/l	108 ± 28	120 ± 67	100 ± 19	118 ± 54
Haemoglobin, g/l	14.1 ± 1.7	14.1 ± 1.6	14.1 ± 1.7	14.2 \pm 1.6
Systolic blood pressure, mmHg	137 ± 13	137 ± 15	137 ± 12	135 ± 13
Diastolic blood pressure, mmHg	82 ± 17	77 ± 9	78 ± 9	74 ± 8
Ankle brachial index	0.69 ± 0.18	0.64 ± 0.18	1.02 ± 0.11	1.00 ± 0.09

Table 1. Characteristics of the population.

Note. VTC = vascular-type claudication; PAD = peripheral artery disease.

patient's files and completed with the patient if necessary. The treadmill test was continued to maximum claudication pain and/or exhaustion. The first 15 minutes of treadmill-walking were performed at 3.2 km/h with a 10% slope (transition phase from 0 to 3.2 km/h within 1 minute). After minute 15, the slope and speed were progressively increased in 1-minute steps, as previously reported.⁶ With this procedure (combined constant load and incremental test) most patients with claudication stop during the constant load phase, but all patients reach their limit on treadmill. For all tests we recorded MWT in seconds. Physicians doing the treadmill test were blinded to the result of the questionnaires.

Classification of patients

Patients were classified based on the presence (PAD+) or absence (PAD-) of PAD. The presence of PAD was defined as either an ABI at rest <0.90 or a history of lower-limb arterial revascularisation. Patients with an ABI >1.30 and/ or non-compressible arteries on both sides were excluded from the study. Further subgroups were defined from the presence or absence of typical vascular-type claudication in their answers to the ECQ. Exercise-related typical vasculartype claudication (VTC+) was defined from the ECQ as symptoms fulfilling all vascular type criteria. All patients who were asymptomatic or who reported symptoms not fulfilling these criteria were categorized VTC-.

Scoring of the WELCH

An example of the scoring of a WELCH questionnaire is provided in Fig. 1. The WELCH questionnaire was scored as previously reported.³ In brief, the completely empiricallydefined scoring is as follows. Each of the eight answers within the first three questionnaire items has a value ranging from 0 to 7, and each of the five answers proposed for the last item dealing with usual walking speed has a coefficient ranging from 1 to 5. The score is calculated as the sum of the values found for items 1–3, minus one (thus, a result ranging from 0 to 20 considering that all patients are at least able to walk for 30 seconds at the lowest speed), multiplied by the coefficient found for the last questionnaire item. As a result, the WELCH score ranges from 0 to 100, with 0 indicating a patient that can only walk for 30 seconds when walking slowly and who usually walks much slower than relatives, friends, or other people of the same age. A score of 100 would indicate that the patient that can walk for 3 hours or more, even when walking fast, and who usually walks faster than relatives, friends, or other people of the same age.

Sample size calculation and statistical analysis

Results are presented as mean \pm SD or median [25th–75th percentiles] when appropriate, or number (percentage). The Spearman coefficient of correlation (ρ) between MWT and WELCH scores was calculated. A minimum of 32 patients was required in each group to estimate the coefficient of correlation with treadmill results with a two-sided hypothesis, an alpha of 0.05, and a power of 90% with an anticipated effect size of 0.35. The study was performed until a sufficient number of patients was included in each group.

Sensitivity, specificity, positive and negative predictive values, and accuracy of a WELCH score <25 in VTC+ or VTC- and PAD+ or PAD- patients was studied and reported with 95% confidence intervals (CI). Unpaired *t* tests were used to compare the results in PAD+ versus PAD- patients. Analyses were performed using SPSS V15.0, with bilateral statistical significance set at p < .05.

RESULTS

Inclusion and exclusion processes are presented in Fig. 2. Note that the rejection rate was 35% during the first 6 months of the study and only 10% during the subsequent 12 months. This was probably due to a simplification of the initial administrative procedure where a three-page study information document and consent form changed to a simple half-page.

Population studied

The characteristics of the 450 included patients are presented in Table 1. Among these patients, 371 had PAD and 79 did not based on ABI and history. As shown, limitation was more severe the PAD+ patients than PAD- patients for

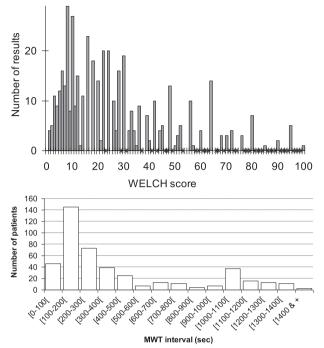


Figure 3. Distribution of the "Walking Estimated Limitation Calculated by History" (WELCH) scores (upper panel) and maximal walking time (MWT) on treadmill (lower panel) among the population. For the WELCH score, "*" indicates impossible scores.

both the self-reported and the treadmill-measured capacity (p < .001).

Answers to questionnaires

Although all patients were referred to the laboratory for typical vascular-type claudication, according to the ECQ data, 14 PAD+ patients and 3 PAD- patients reported no claudication. Another 38 PAD+ patients and 22 PAD- patients reported pain at rest and exercise, while 16 PAD+ patients and seven PAD- patients reported various other symptoms. Thereby, typical VTC was found in 82% of the 371 PAD+ patients and in 59% of the 79 PAD- patients.

The WELCH scores were calculated for all patients. The scores observed in the population are reported in Fig. 3 (upper panel). As shown, the scores do not follow a

Gaussian distribution, but rather follow a log-normal type. It can also be noted from Fig. 3 that, as a result of the scoring method, some scores are impossible (e.g., no score of 23, 55, or 97 can be found from the calculation $[a + b + c - 1] \cdot d$ when "a", "b", and "c" range from 0 to 7, and "d" ranges from 1 to 5). The median WELCH score observed in PAD+ patients was 18 [9–33]. It was significantly lower than the WELCH score found in the PAD-group: 30 [16–54] (p < .001). The percentage of patients with a WELCH score <25 was 54%, 65%, 44%, and 38% in the VTC-/PAD+, VTC+/PAD+, VTC-/PAD-, and VTC+/PAD- groups respectively.

MWT on treadmill

As for the WELCH score, the treadmill-measured MWT was higher, and the proportion of patients with a MWT <5 minutes was lower in PAD- than PAD+ patients (Table 2). The distribution of times was not Gaussian, but rather lognormal (Fig. 3, lower panel).

Relationships between MWT and WELCH scores

Despite the fact that both the self-reported and treadmillmeasured walking capacity were different in PAD+ and PAD- patients, the different slopes (\pm SE of estimation) of the relationship (10.3 \pm 1.7, 11.0 \pm 0.9, 10.5 \pm 2.7, and 10.3 \pm 2.0), and the Spearman correlation coefficient (0.588, 0.591, 0.581, and 0.609) of MWT to WELCH score in the VTC-/PAD+, VTC+/PAD+, VTC-/PAD-, and VTC+/ PAD+ groups, respectively, were in the same range in all four groups.

In the 371 PAD+ patients, the sensitivity, specificity, positive and negative predictive values, and accuracy [95% CI] of a WELCH score <25 to predict the inability to walk for 5 minutes on treadmill were 78.8% [73.1–83.6], 63.7% [55.3–71.3], 79.2% [73.5–83.9], 63.2% [54.9–70.9], and 73.3% [68.6–70.8] respectively. Results by groups are presented in Table 2.

DISCUSSION

The WELCH questionnaire is derived from the Estimated Ambulatory Capacity by History Questionnaire (EACH-Q).

Table 2. Median [25th–75th percentiles] maximal walking time (MWT), and number (%) of patients with a MWT <5 minutes in the different groups. Diagnostic performance with percentages (95% confidence interval) of the "Walking Estimated Limitation Calculated by History" against the inability to walk for 5 minutes on a treadmill using a score of 25 as a cut-off value. Please refer to text for the description of the groups.

	VTC-/PAD+	VTC+/PAD+	VTC-/PAD-	VTC+/PAD-
Number of patients	68	303	32	47
MWT, s	254 [123—654]	213 [136—386]	721 [173—1,137]	405 [174-1,071]
MWT $<$ 5 mins	37 (54)	199 (66)	9 (28)	19 (40)
Sensitivity, %	75.7 (59.7—86.8)	79.4 (73.2—84.5)	77.8 (44.3—94.7)	63.2 (40.9-81.0)
Specificity, %	71.0 (53.3-84.1)	61.5 (51.9-70.3)	69.6 (48.9-84.6)	78.6 (60.1-90.1)
PPV, %	75.7 (59.7—86.8)	79.8 (73.6–84.8)	50.0 (26.8-73.2)	66.7 (43.4-83.9)
NPV, %	71.0 (53.2-84.1)	61.0 (51.4—69.8)	88.9 (66.0—98.1)	75.9 (57.6–88.1)
Accuracy, %	73.5 (61.9—82.6)	73.3 (68.0–77.9)	71.9 (54.5—84.6)	72.3 (58.1-83.2)

Note. VTC = vascular-type claudication; PAD = peripheral artery disease; PPV = positive predictive value; NPV = negative predictive values.

The EACH-Q, a questionnaire including four items to define walking time sustained at defined paces (three walking paces and one running pace), was proposed in 2011 as an interesting and relatively simple tool,⁷ and was validated in English.⁸ The limit of the EACH-Q was that, despite a limited number of items, its scoring remained relatively complex. We showed that the running item of the initial EACH-Q score could be skipped without impairing concordance with treadmill results. Thus, the EACH-Q could be reduced to three items dealing with the walking time sustained at three different walking paces.⁹ In parallel, we showed that asking the patient what his/ her usual walking pace was allowed correction through a division and multiplication of the score obtained with the EACH-Q (even so, mental calculation of scoring in this version was difficult).¹⁰ Thus, we recently proposed the WELCH, which is based on the first three items of the EACH-Q and uses the usual walking speed item (with answers slightly changed), and, overall, uses an empirical, completely new, and very simple scoring method that can be calculated mentally without need of a computer.³ The present study is the latest step in this development process. The correlations between WELCH score and treadmill results observed in this study (ranging from 0.58 to 0.60) in a large group of patients are consistent, but at the high end of the expected range of results previously reported with disease-specific tools.7,11-13 Reported coefficients ranged from approximately 0.40 to 0.60, and the number of studied patients ranged from 42¹⁴ to 371.9 It is also consistent with our previous observation in another population where the Pearson r coefficient of correlation of the WELCH with MWT was 0.65.³

The non-Gaussian-type distributions observed in Fig. 3 are consistent with previously reported results.³ Furthermore, the WELCH score is not a strictly continuous variable. Indeed, no prime number above 19 or numbers that are multiple of a prime number above 19 will ever be observed owing to the scoring method itself.

Does the moderate correlation between the treadmillmeasured and self-reported score mean that the questionnaire should not be used? First, there is recent evidence that self-reported capacity correlates better with community-based measurement of walking disability than with treadmill results.⁸ Second, questionnaires remain essential to estimate the feelings of patients, and are easy tools for epidemiological studies (e.g., telephone or mail survey). In the latter case, shorter questionnaires have a lower risk of rebuttal or errors during selfcompletion. From this point of view, the WELCH remains one of the shortest available questionnaires aimed at estimating walking disability in patients with suspected claudication. Preliminary results suggests that it may discriminate revascularised from non-revascularised patients,³ but this point has still to be confirmed in a larger series of patients.

There are limitations to the present study. First, the proportion of patients that refused to participate was high. This point is of particular interest when one aims to study the routine use of a questionnaire, and underlines the importance of minimising questionnaire length (as well as administrative files) to improve patient acceptability. We cannot exclude that it may influence the results for the correlation of the WELCH to MWT, although we think that it is unlikely. Second, in our group, 17.6% of the patients with claudication had a normal resting ABI and no history of arterial revascularisation. This proportion is in the range of previous reports.^{15,16} It is clear that a certain proportion of patients in the PAD- group (ABI \geq 0.90 at rest) did have lower-limb arterial disease. Unfortunately, post-exercise ABI was not used systematically in our population. Third, the treadmill protocol used here is specific and does not allow direct comparison with many previous studies. The protocol that we used is roughly a constant load protocol (at least during the first 15 minutes of exercise). The issue with constant load testing is the risk that some patients have no symptoms or non-limiting symptoms because the exercise load is less than their usual walking pace. This was the case in 87 (19%) out of the 450 studied patients. Thereafter, we performed an incremental load phase once the patient reached minute 15 of the constant load phase. This resulted in all patients being symptom-limited on the treadmill, which is of particular interest when dealing with concordance of selfreported limitation to avoid any ceiling effect of a constant load test over the results.

Direction for future developments

Studies in other groups of patients and other types of objective walking tests (e.g., Gardner protocol, 6-minute walking test) are required to confirm our results. Similarly, evaluation and validation of the WELCH by other centres is required. Specifically, the protocol was developed in France and originally translated into English, but it has not been validated in a native English-speaking population. Finally, many studies remain to be done before the WELCH can be proposed as a routine tool, including determination of whether or not the WELCH questionnaire is sensitive to changes in the actual walking capacity; determination of the long-term reliability of the WELCH score; and the cut-off limit of score-change that is clinically significant at the individual level to determine an improvement or worsening of walking capacity.

CONCLUSION

This study confirms that the WELCH score correlates with the walking capacity observed on a treadmill. In PAD+ patients (resting ABI <0.90 or with a history of lower-limb revascularisation), its value in predicting the inability to walk for 5 minutes on treadmill is 79.1%. The WELCH questionnaire therefore appears to be a valid and simple instrument for subjectively assessing walking limitation.

CLINICAL TRIAL REGISTRATION

NIH database: NCT01114178.

ACKNOWLEDGEMENTS

We are indebted to Dr Bruno Vielle, Dr Guillaume Mahe, and Garry Tew for their useful suggestions and reviewing, and to Isabelle Laporte for technical help.

CONFLICT OF INTEREST

None.

FUNDING

None.

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