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## Claudication distances and the Walking Impairment Questionnaire best describe the ambulatory limitations in patients with symptomatic peripheral arterial disease

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**Claudication Distances and the Walking Impairment Questionnaire best describe the Ambulatory Limitations in Patients with Symptomatic Peripheral Arterial Disease**

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## **Abstract**

*Objective:* Claudication secondary to peripheral arterial disease (PAD) leads to reduced mobility, limited physical functioning and poor health outcomes. Disease severity can be assessed with quantitative clinical methods and qualitative self-perceived measures of quality of life. Limited data exists to document the degree to which quantitative and qualitative measures correlate. The current study provides data on the relationship between quantitative and qualitative measures of symptomatic PAD.

*Design:* Descriptive case series

*Setting:* Academic vascular surgery unit and biomechanics laboratory

*Subjects:* Symptomatic PAD patients presenting with claudication

*Main outcome measures:* Quantitative evaluation included measurement of ankle-brachial index (ABI), initial claudication distance, absolute claudication distance, and self-selected treadmill pace. Qualitative measurements included the Walking Impairment Questionnaire (WIQ) and the Medical Outcomes Survey Short Form-36 (SF-36). Spearman rank correlations were performed to determine the relationship between each quantitative and qualitative measure and also between WIQ and SF-36.

*Results:* Forty-eight patients (age:  $62 \pm 9.6$  years; weight:  $83.0 \pm 15.4$  kg) with claudication (ABI:  $0.50 \pm 0.20$ ) were included. ABI correlated with the distance ( $r=.29$ ) and speed ( $r=.32$ ; 2 of 4) WIQ subscales. Initial claudication distance and absolute claudication distance correlated with the pain (r value .40 and .43 respectively), distance (r value .35 and .41 respectively) and speed (r value .39 and .39 respectively; 3 of 4) subscales of the WIQ. ABI did not correlate with any of the SF-36 subscales. Initial claudication distance correlated with the bodily pain ( $r=.46$ ) and social functioning ( $r=.30$ ; 2 of 8), while absolute claudication time correlated with the

physical function ( $r=.31$ ) and energy ( $r=.30$ ; 2 of 8) subscales of the SF-36. The results of both questionnaires showed reduced functional status in claudicating patients.

*Conclusions:* Initial and absolute claudication distances and WIQ pain, speed and distance subscales are the measures that correlated the best with the ambulatory limitation of patients with symptomatic PAD. These results suggest the WIQ is the most specific questionnaire for documenting the qualitative deficits of the patient with claudication, while providing strong relationships with the quantitative measures of arterial disease. Future studies of claudication patients should include both quantitative and qualitative assessments to adequately assess disease severity and functional status in PAD patients.

## INTRODUCTION

Peripheral Arterial Disease (PAD) affects approximately eight to twelve million people in the United States <sup>(1)</sup>. PAD leads to reduced mobility, reduced physical functioning and poor health outcomes, in addition to its association with increased cardiovascular morbidity and mortality <sup>(1-3)</sup>. Disease severity and functional status of PAD patients can be assessed using quantitative clinical measures (such as ankle brachial index (ABI) and claudication distances) and qualitative, self-perceived measures of quality of life (QOL). Despite a wealth of studies documenting either quantitative or qualitative measures in patients with PAD, few studies exist to document the degree to which quantitative and qualitative measures correlate. Conflicting data exists with several studies demonstrating significant correlations <sup>(4-8)</sup> while others show minimal if any correlation <sup>(9,10)</sup>. What is clear is an absence of standardization in studies evaluating PAD patients, evidenced by a variety of reported quantitative test protocols and similar variation of qualitative questionnaires. This lack of standardization makes it difficult for physicians to choose the most appropriate measures to evaluate patients, determine indications for treatment and consistently document and report treatment outcomes. The purpose of this study was to determine the relationship between the most commonly used quantitative variables and the currently recommended self-reported qualitative measures of physical function in PAD patients. In addition we examined, the correlation between the two qualitative measures most commonly used in PAD.

## **METHODS**

### *PAD Subjects*

Forty-eight symptomatic PAD patients diagnosed with moderate arterial occlusive disease who experienced claudication in at least one leg were recruited from the vascular surgery clinics of the Nebraska and Western Iowa Veterans Affairs Medical Center and the University of Nebraska Medical Center. All study patients were symptomatic and seen for initial evaluation of their PAD with no prior treatment. Patients were specifically evaluated and screened by two vascular surgeons. Patient evaluation included detailed history, physical exam and direct assessment/observation of the patient's walking impairment. A vascular surgeon observed the patient walking and recorded all symptoms and signs affecting ambulation insuring ambulatory limitation was secondary to vasculogenic claudication. Those patients with ambulation limiting cardiac, pulmonary, neuromuscular or musculoskeletal disease or those who experienced any pain or discomfort (even mild) during walking for any reason other than claudication (i.e. arthritis, low back pain, musculoskeletal problems, neuropathy) were excluded. Presence and extent of disease was documented with standard lower extremity noninvasive evaluation supplemented on selected cases by Computerized Tomographic, Magnetic Resonance or invasive angiography. Noninvasive evaluation included measurement of ABI, femoropopliteal and tibial duplex and evaluation of Doppler waveforms at the femoral, popliteal and pedal levels. Level of disease was established by the vascular surgeon after review of all available studies. The study was approved by the institutional review boards of the Nebraska/Western Iowa VA Medical Center and the University of Nebraska Medical Center. Written informed consent was obtained from all subjects prior to data collection.

## **Quantitative Measures**

**Ankle Brachial Index:** The ABI values obtained during patient evaluation were used for the correlations. The highest ABI value from the most symptomatic leg was reported as the ABI for each subject.

**Claudication Distance:** To determine the initial and absolute claudication distances, patients walked on a treadmill at .67 m/s (1.5 mph) and 10% grade <sup>(11)</sup>. The first indication of claudication pain was recorded as initial claudication distance, and the total distance the patients could walk on the treadmill before stopping due to pain was absolute claudication distance <sup>(12)</sup>. During the test, the technician asked the patient to confirm the presence or absence of pain to ensure the correct initial claudication distance was recorded.

**Self Selected Speed:** Subjects were given ample time to familiarize themselves with walking on the treadmill prior to beginning the test <sup>(13)</sup>. To determine self-selected speed, subjects walked on the treadmill at 1.61 km/hr (1.0 mph) and were asked to adjust the speed up or down until it matched their typical pace. Prior to walking on the treadmill, the subjects were shown how to adjust the speed. Subjects were encouraged to choose the speed in a timely manner (within 10-20 seconds), to avoid the onset of claudication while determining the preferred pace. This has been shown to be enough time to attain a steady state for knee kinematics and most spatio-temporal parameters on a treadmill <sup>(14)</sup>. Determining self-selected treadmill pace was conducted as a separate test prior to the onset of any claudication.

## **Qualitative Measures**

Physical function and health related QOL were assessed using the Walking Impairment Questionnaire <sup>(15)</sup> (WIQ) and the Medical Outcomes Study Short Form 36 <sup>(16-18)</sup> (SF-36).



**Walking Impairment Questionnaire:** The WIQ is a disease-specific questionnaire validated in patients with intermittent claudication <sup>(4)</sup>. The questionnaire consists of four sub categories: pain, distance, walking speed and stair climbing.

**Medical Outcomes Survey Short Form-36:** Eight health domains are assessed with the SF-36: physical function, limitation due to physical health, limitation due to emotional problems, energy, mental health, bodily pain, general health and social function. The SF-36 has been extensively evaluated and tested with a variety of populations and is able to distinguish between groups of varying health status <sup>(16,19)</sup>. Both the WIQ and SF-36 use a scale from 0 to 100, with a score of 0 representing the low score and 100 being the high score. Specific descriptions of each subscale can be found in Appendix A. In the beginning of our study the SF-36 forms given to both PAD patients and controls were missing the questions for the “Limitations-Physical” and “Limitations-Emotional” subscales. This was corrected after more than half of all subjects were recruited in the study.

### *Control Subjects*

In addition, 25 healthy age-height-weight matched controls were recruited for the study. Controls had an ABI > 0.9 and absence of subjective or objective ambulatory dysfunction. Similar to PAD patients, control subjects were excluded for the same ambulation limiting conditions. Control patients did not undergo any treadmill testing for the determination of claudication distances or self selected speed but had lower extremity noninvasive evaluation to document absence of appreciable occlusive disease and completed both the WIQ and SF-36 questionnaires.

### *Statistical analysis*

Scores for ABI, initial claudication distance, absolute claudication distance, self-selected walking speed and the sub-scores of each questionnaire were ranked for each subject. Spearman rank correlations were performed between ABI, initial claudication distance, absolute claudication distance, self-selected walking pace and each sub score of the questionnaires. In addition, rank correlations were calculated between the WIQ and SF-36. If questions were not answered on the WIQ or SF-36, the patient was excluded from the specific subscale analysis. All analyses were performed using SPSS (SPSS Inc., 14.0) statistical package and tested at  $P < .05$ .

## RESULTS

Demographic characteristics and results of the quantitative clinical tests are summarized in Table I and mean scores for each subscale of the SF-36 and the WIQ are listed in Table II. Findings from noninvasive lower extremity testing supplemented by data from Computerized Tomographic, Magnetic Resonance or invasive angiography revealed the majority of our patients (52.1%) have multi-level disease consisting of a combination of aortoiliac, femoropopliteal and tibial levels of occlusive disease (Table I). The remaining patients had single level disease with 19.6% having aortoiliac occlusive disease, 28.3% having femoropopliteal disease, and no patients having solely tibial occlusive disease. No significant relationship existed between occlusive disease levels and SF-36 and WIQ measures ( $P>0.05$ ).

When relating the quantitative measures of functional status with the qualitative questionnaire subscales, three of the four quantitative measures had significant correlations with one or more of the questionnaire subscales (Table II and III). ABI had significant correlations with the distance and speed components of the WIQ but did not correlate with any of the SF-36 subscales nor any of the claudication distances. Initial claudication distance and absolute claudication distance had significant correlations with several WIQ and SF-36 subscales. More specifically, both initial claudication distance and absolute claudication distance had significant correlations with the pain, distance and speed subscales of the WIQ. In addition, absolute claudication distance correlated with physical function and energy and initial claudication distance correlated with bodily pain and social functioning subscales of the SF-36. Of all correlations, those between claudication distances (initial and absolute) and the WIQ pain, distance and speed components were the strongest. Weaker were the correlations between claudication distances and SF-36 subscales, while the weakest correlation was noted between

ABI and WIQ subscales. Self-selected pace had no significant correlations with any of the questionnaires subscales.

The correlation coefficients between questionnaire subscales indicated that many subscales from the questionnaires had significant correlations (Table IV). The WIQ pain, distance, speed and stair components were each correlated with six or more subscales of the SF-36. Both the WIQ and the SF-36 results indicated reduced functional status in PAD patients compared to healthy controls (Table II). Compared to controls, PAD patients exhibited significantly ( $P < 0.5$ ) lower scores for all four subscales of the WIQ and for seven of the subscales of the SF-36, with the eighth subscale approaching significance ( $p=0.061$ ).

## **DISCUSSION**

Our study demonstrates that initial and absolute claudication distances are the quantitative tests with the highest and most consistent correlation with qualitative parameters. Furthermore, the WIQ is the qualitative measure that best reflects actual ambulatory performance of the PAD patients. More specifically, pain, distance and speed (with the pain subscale being the strongest) appear to be the WIQ subscales that more thoroughly describe the ambulation related limitations of PAD patients. When we compared quantitative clinical measures with questionnaire subscale scores, we found 12 of 48 (25.0%) comparisons were significantly related. Of the quantitative measures, the absolute claudication distance and initial claudication distance were related with the largest number of subscales of the questionnaires. The pain, distance and speed components of the WIQ, all correlated with both the absolute and initial claudication distances. Our finding is in agreement with previous work on WIQ validation <sup>(5)</sup> and suggests that either test (absolute and initial claudication distances) could be used as a quantitative measure of physical function.

ABI correlated significantly with two WIQ subscales, again indicating WIQ may be the most specific questionnaire to capture both the physiologic (reflected by ABI) and quantitative ambulatory dysfunction (reflected by claudication distances) associated with PAD and claudication. Different subscales of SF-36 demonstrated correlation with the quantitative measures, but unlike WIQ subscales no single SF-36 subscale consistently related with them, again suggesting that the SF-36 (as a general QOL measure) is less suitable than WIQ in fully describing the ambulatory limitation of claudicants.

In contrast to claudication distances, self-selected speed did not correlate with any qualitative measures. Our data demonstrated that self-selected pace exhibited no significant

correlation with the WIQ or SF-36 scores. Therefore, our results suggested that self-selected walking pace itself is not a predictor of QOL in patients with symptomatic claudication.

Previous studies have compared different quantitative measures with self-reported QOL measures, and our results strengthen and add to their findings. Izquierdo-Porrera et al <sup>(6)</sup> calculated Pearson correlations between ABI, time to maximal claudication and distance walked in six minutes with all subscales of the SF-36 and with the distance, stair and speed components of the WIQ (the WIQ pain subscale was not included in their study). Of the 36 associations evaluated, 18 were found to be significant. Another study by Regensteiner et al <sup>(5)</sup> related maximal walking time and time to onset of claudication with individual questions from the WIQ in 26 PAD patients. A total of 22 comparisons were made, with 10 of those being significant. McDermott et al <sup>(20)</sup> performed linear regression analysis between ABI category (0.9 to < 1.5, 0.4 to < 0.9 and < 0.4) and subscales of the WIQ and SF-36 in 158 PAD patients with a variety of leg symptoms. Results of the regression analyses between ABI and WIQ found that ABI was a predictor of walking distance and speed when the PAD group was evaluated in its entirety. However when the effect of leg symptoms, comorbidities and previous revascularization were removed, ABI only predicted walking distance. For the analyses with SF-36 subscales, ABI was not independently associated when controlling for leg symptoms and comorbid diseases. These results are consistent with our findings showing that WIQ more appropriately describes problems due to flow limitations compared with the SF-36, which is a more general measure of QOL. McDermott et al <sup>(20)</sup> also pointed that ABI is less predictive of leg function in patients with claudication (similar to our study population) compared to a group including PAD patients with varying leg symptoms (including asymptomatic, claudicating and rest pain PAD patients). This is

consonant with our finding that claudication distances are more related with QOL than ABI values.

Our study is also in agreement with prior work demonstrating PAD patients have reduced QOL,<sup>(1, 6)</sup> and that this QOL deterioration is similarly reflected in both WIQ and SF-36. When relating the SF-36 and the WIQ, 26 of the 32 (81.3%) comparisons were significantly related. Our results are in accordance with those of Izquierdo-Porrera et al<sup>(6)</sup>, which demonstrated significant correlations between 22 of the 24 comparisons between WIQ and SF-36. Although the SF-36 is a generic measure of health related QOL and the WIQ is a disease specific measure, the significant correlations in greater than eighty percent of the comparisons between them, shows that both questionnaires can be useful in providing information about the QOL of PAD patients. In the absence of SF-36 data, WIQ can adequately reflect overall drop in QOL in claudicants.

Our study is unique as all patients were carefully screened and those with any gait dysfunction other than claudication (even mild ones) were excluded. Due to the strict exclusion criteria, our data accurately reflect that the ambulatory and QOL limitation are due solely to claudication. However, our results may not be reflective of the overall PAD population since claudicants frequently have comorbidities (osteoarthritis, neurogenic claudication, peripheral neuropathy) that affect walking in varying degrees<sup>(21-23)</sup>.

In conclusion, our data demonstrated that absolute and initial claudication distances and WIQ pain, speed and distance subscales are the measures with the best ability to describe the ambulatory limitation of the claudicant while they also closely relate to his/her QOL. It is the authors opinion that future claudication research should include both quantitative and qualitative measures consisting of claudication distances and WIQ at a minimum. These complementary

measures are essential and requisite tools to adequately characterize and determine the degree of a PAD patient's impairment.



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