Free-living Physical Activity as a Novel Outcome Measure in Patients with Intermittent Claudication

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WHAT THIS PAPER ADDS?

This study has used seven-day continuous ambulatory monitoring in order to objectively quantify the fragmented nature of walking bouts in patients with Intermittent Claudication [IC]. Of particular importance is the description of an index which corresponds to the classic stop/start walking pattern universally described by this patient group. The index provides a novel, objective, functional outcome specifically tailored to the unique impairments experienced by patients with IC. Such an outcome measure could significantly enhance the clinicians' ability to objectively determine the effectiveness of interventions in both clinical and research environments.

Objective: To develop a method of event-based analysis that quantifies the fragmented nature of walking bouts in individuals with intermittent claudication [IC] and compare outcomes with age and gender-matched healthy controls.

Design: Cross-sectional.

Materials: The activPAL™ physical activity monitor.

Methods: 7-day physical activity patterns were compared between individuals with IC ($n = 30$) and controls matched for age and gender ($n = 30$). The ratio of the number of walking events to upright events was calculated to provide an event-based claudication index (EBCI) that represented the fragmented nature of walking bouts commonly reported in those with IC.

Results: Individuals with IC had a greater EBCI than age matched controls indicating a more fragmented walking pattern (5.8 ± 2.0 vs. 7.7 ± 3.1, $p < 0.01$). The difference between groups was more pronounced when the EBCI was calculated from upright events that included >400 steps (23.4 ± 11.3 vs. 35.8 ± 14.2, $p < 0.01$).

Conclusion: The classic fragmented stop/start walking pattern universally described by individuals with IC can be quantified using the EBCI. This method of measurement potentially provides a novel method of assessing the effectiveness of clinical interventions for this patient group.

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INTRODUCTION

Many individuals with intermittent claudication (IC) report that they need to regularly stop whilst walking due to ischaemic pain. Anecdotally, the more frequently a patient needs to stop the more severely they are affected by the condition.[1] Assessment of IC using patient interview is subjective and consequently is an insensitive and poorly reproducible tool to determine severity of symptoms.[2] Objective clinical measurements such as Doppler ultrasonography and angiography provide only information on vessel patency and lesion severity. These imaging techniques provide no information on the functional impact of the symptoms on the patients' life.[3]

Objective measurement of daily physical activity (PA) patterns may be a particularly useful method for measuring the functional impact of IC symptoms. Studies using objective PA measurement devices to measure free-living daily Energy Expenditure of Physical Activity (EEPA) have shown that patients with IC have lower PA levels than healthy controls.[4–6]

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Individuals with IC were found to expend on average less than 380 kcal/day, 51% lower than age-matched controls that had an EEPA level of 769 kcal/day.[6]

Gardner et al. (2007) compared patterns of PA between individuals with and without IC. They found that individuals with IC spent less time walking and took fewer steps, particularly at medium to high cadence levels.[7] Gardner et al. (2008) also reported that patients with earlier onset ischaemic pain (lower absolute claudication distance (ACD)) may walk more slowly than those with a later onset ischaemic pain when completing ambulatory activities of prolonged durations.[8] In this particular study,[8] prolonged duration referred to walking continuously between 30 and 60 min. There is evidence that step count moderately correlates with existing severity measures such as treadmill testing and post-exercise Ankle Brachial Pressure Index (ABPi).[9] However, cadence and step count does not provide insight into the pattern by which these steps are accumulated giving no information on the primary symptom of the need for frequent stops during bouts of walking.

Identification and quantification of the fragmented nature of walking bouts in those with IC has not been investigated. This study aimed to develop and use an event-based analysis method to compare the fragmented nature of walking bouts in individuals with and without IC.

MATERIALS AND METHODS

Participants

Thirty patients with varying degrees of IC were recruited from a vascular out-patient clinic. Thirty healthy participants on the Glasgow Caledonian University (GCU) PA database were matched for age and gender.

Ethical approval for this cross-sectional study was obtained from NHS Tayside B Research Ethics Committee and the Glasgow Caledonian University School of Health Ethics Committee. All patients were screened for inclusion and provided written informed consent. Patients were between 50 and 90 years of age and were excluded if their exercise tolerance was limited by any other factor than ischaemic leg pain, had active cancer, renal or liver disease, and psychiatric disturbance or had had any vascular or other surgical intervention within the previous six weeks. Patients with hirsutism were also excluded as the film dressing used to attach the monitor to the thigh (Opsite FlexifixTM) did not maintain its adhesiveness sufficiently with this condition.

Procedure

Ankle-brachial pressure index measurement. Ankle-Brachial Pressure Index (ABPi) was recorded following a 5-min period of rest in a supine position using a hand-held 5-MHz Doppler probe (Dopplex SD2 Bi-directional pocket Doppler, Huntleigh Healthcare, Cardiff, UK). Systolic blood pressure was measured in both dorsalis pedis and posterior tibial arteries of the lower extremities. Pressures were then normalised to the higher brachial pressure of either arm to form the ABPi according to the Transatlantic Intersociety Consensus for the Management of PAD guidelines (TASC II).[10]

Patients had unilateral and/or bilateral disease. The ABPi for the most symptomatic leg was used for analysis purposes. Patients with an ABPi >0.9 were not excluded given that this would have excluded those participants with IC and calcification of the arteries. When an ABPi measurement was recorded and diagnosis of arterial disease was still in question; an exercise test (using a calf ergonometer) was performed in conjunction with Duplex ultrasound and/or Magnetic Resonance Angiogram (MRA) to confirm diagnosis.

ActivPAL™ physical activity monitor. Daily free-living PA was measured using the activPAL™ uni-axial PA monitor (PAL Technologies, Glasgow, UK); a small unobtrusive accelerometer-based device with dimensions of $53 \times 35 \times 7$ mm and weighing only 15 g. The monitor was wrapped in a waterproof sleeve and attached to the anterior part of patients' right mid-thigh with Opsite FlexifixTM transparent dressing and worn continuously for 7-days (Fig. 1). Participants were able to shower whilst wearing the device and had the option of removing it if required.

The activPAL™ monitor allows for differentiation of sedentary [sitting or lying], standing and ambulatory activity using proprietary algorithms (Intelligent Activity Classification™, PAL Technologies). It has been validated for the amount of time spent sedentary, upright, standing and stepping and has also shown to be highly accurate for step number and cadence.[11–13] The activPAL™ has been used with a range of clinical populations including back pain,[14]

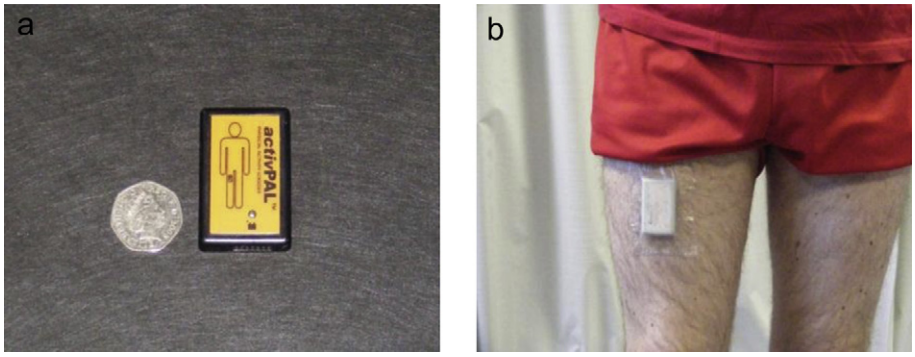

Figure 1. a: The activPAL™ PA monitor. b: Monitor attachment to thigh.