Real-life adaptations in walking patterns in patients with established peripheral arterial disease assessed using a global positioning system in the community: A cohort study

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Real-Life Adaptations in Walking Patterns in Patients with Established Peripheral Arterial Disease Assessed Using a Global Positioning System in the Community: a Cohort Study.

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Short Title: GPS assessment of walking ability in PAD patients

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Summary

Objective: Lower extremity peripheral arterial disease (PAD) is a chronic condition most commonly presenting with intermittent claudication (IC). IC limits walking ability and may negatively affect health-related quality of life. Treadmill assessment of maximal walking distance (MWD) is the gold standard to assess PAD symptom severity. Despite being a well-established and reproducible tool, it may be inappropriate (due to frailty or fear) for some patients and only describes maximal abilities for a single walk test. Global Positioning Systems (GPS) have been proposed as reliable and reproducible tool to measure total, mean and maximal walking distances in PAD patients, in the community setting. Using GPS our study attempted to explore what happens to the walking ability of patients with IC following no intervention under "real-life" conditions.

Design and Methods: Using the GlobalSat DG100 GPS, forty-three patients (69±9yrs; 9 female; no invasive interventions or rehabilitation) undertook two 60-minute walking assessments, 6 months apart. Assessments took place in community spaces that had even terrain, no tall trees or buildings and were free from motorised vehicles. GPS-measured maximum walking distance was the main study outcome measure.

Results: Over the 6-month period, patients demonstrated significantly shorter GPS-measured, mean (552m vs 334m; p=0.02) and maximum (714m vs 545m; p=0.04) walking distances, stopping also more frequently (9 v 5 times; p=0.03).

Conclusions: Given the reported symptom progression we advocate early intervention (e.g. exercise interventions) combined with frequent patient monitoring in attempts to maintain or improve walking ability.

Key Words: peripheral arterial disease; Global Position System; maximum walking distance; intermittent claudication; community assessments.

INTRODUCTION

Peripheral arterial disease (PAD) is a disease caused by atherosclerosis, resulting in narrowing of the arteries, characterised by obstruction of blood flow in the arteries supplying the lower limbs. PAD prevalence increases with age, reaching 25% for individuals over the age of 75 years of age (Fowkes *et al.*, 2013). The majority of symptomatic patients with PAD experience intermittent claudication (IC) (Vodnala *et al.*, 2010). IC is defined as a pain or discomfort that occurs during walking due to insufficient blood flow increase, limiting walking ability (Norgren *et al.*, 2017), which negatively affects patients' health-related quality of life (Regensteiner *et al.*, 2008).

The limiting walking ability is measured by “claudication distance” (e.g. the distance walked at the onset of claudication pain) and by “maximal walking distance” (MWD), which is defined as the absolute maximum distance walked before limb discomfort or pain forces the patient to stop. Reduced walking ability has been associated with increased mortality (due mainly to cardiovascular disease) (Mcdermott *et al.*, 2008), which may reach 30% over a 5-year period (Golomb 2006). Interventions designed to improve walking ability can reduce this morbidity and mortality; Interventions need to be patient-centred to maximise compliance.

Tools used to assess walking ability, include treadmill walking test (Duprez *et al.*, 1999), 4- or 6-minute walking tests (Collins *et al.*, 2010) or questionnaires (e.g. walking impairment questionnaire (WIQ) (Ouedraogo *et al.*, 2011), Walking Estimated Limitation Calculated by History (WELCH) questionnaire (Myers *et al.*, 2008). The two questionnaires have been shown to have high correlation with the 6-minute walking test (Gernigon *et al.*, 2015) and treadmill walking assessments (Ouedraogo *et al.*, 2011). These tools however, may not reflect accurately the true walking impairment or may be inappropriate for older or frailer patients). These tests also fail to give an indication of the patients' walking ability under "real" conditions - such as walking that takes place in the community, and don't give information about walking speed or the number of stops between walking episodes. Global Positioning Systems (GPS) have been proposed as reliable, reproducible tools to measure total, mean and maximal walking distances in patients with PAD in community settings (Gernigon *et al.,* 2015).

Although patients with IC have been the focus of a large number of studies (Bauman & Arthur 1997, Nicolaï *et al.*, 2012, Klonizakis *et al.,* 2016), the natural history of walking ability under "real-life" settings is largely understudied and poorly understood. We therefore wanted to study what happens to the walking ability of patients with IC using GPS in patients not receiving any intervention following a 6-month period. We hypothesised that the condition caused a deterioration in MWD of patients, over a 6-month period.

MATERIALS AND METHODS

The present study was approved by South Yorkshire NHS Research Ethics Committee (13/YH/0088). This research was carried out in accordance with the Declaration of Helsinki of the World Medical Association and all participants gave their written informed consent to participate.

Forty-three adult men and women with clinically-diagnosed IC due to PAD were identified from vascular clinic attendance lists stored at the Sheffield Vascular Institute, Northern General Hospital, Sheffield (Table 1) between 2013-2016. All participants completed all designated study visits. The sample size was estimated (with MWD being the main outcome measure), based on the number required on previous studies from authors in our group undertaken on the same population (Gernigon *et al.,* 2015). All participants had stable IC (4.4 (3.1) years' duration), with a condition's duration ranging between 8 months and 11 years. Patients with critical limb ischaemia, with uniquely impaired walking ability (e.g. wheelchair-bound patients and patients with lower-extremity amputation), with recent major surgery in the previous 6 months, with heart failure of New York Heart Association grade III or IV, with known severe respiratory disease other than obstructive sleep apnoea, who were pregnant at the time and those with Parkinson's disease, hemiplegia or paraplegia or who were in an exclusion period due to participation in other research studies were excluded from the study. Participants did not receive an incentive to take part in the study, with an exception of free parking at the laboratory premises, during assessment days. All participants were receiving medical treatment (e.g. pharmacotherapy) at the time of their participation in the study, as per their individual circumstances, being also followed by their General Practitioners and by physicians within hospital vascular clinics. No MI or stroke or death incident took place within the study period for any of our participants.

All patients attended the Centre for Sport and Exercise Science (CSES) of Sheffield Hallam University for an initial consultation session during which they were screened by a Vascular Consultant. Patients were familiarised with the study protocol and provided written informed consent.

During the second visit, participants completed the following clinical questionnaires: SF-36 (Ware & Sherbourne 1995), WIQ (Myers *et al.*, 2008) and WELCH (Ouedraogo *et al.*, 2011). They completed a standardised treadmill walking test [16], with a constant walking speed of 3.2 km/h with a gradient of 10% for 15 minutes. All tests ended when participants could no longer walk despite sustained encouragement or after 15 minutes. Twelve-lead electrocardiogram monitoring with ST segment analysis was performed continuously (Cardioperfect, Welch Allyn, USA) with termination of walk testing if the participant developed angina symptoms or developed ST depression equal or greater than 2mm in any lead. All participants completed the clinical questionnaires retrospectively via post, after their second community-based walking assessment.

Community-based walking assessment

Walking capacity was assessed in the community using a commercially-available global positioning system (GPS) data logger (DG-100 GPS data logger and the AT-65 GPS Active Antenna, GlobalSat Technology Corp., New Taipei City, Taiwan), as previously described (Faucheur *et al.*, 2010). Community-based walking assessments took place on two occasions: once following their laboratory visit, and the second 6 months after their first community-based assessment. The walking assessment lasted 60-65 minutes in total, on each occasion. The device was worn above their outermost clothing layer. It was emphasised to the participants that the aim of this unconstrained walking was to reproduce their daily walking limitation during an outdoor, unsupervised, walk at their usual pace. Participants were also encouraged to undertake a short "test" walk, prior to their main walking assessment, in order to familiarise themselves with the equipment. Patients were given a leaflet with detailed instructions, and were given a detailed demonstration of the equipment use being also instructed to:

a) avoid undertaking the assessment during adverse weather conditions (e.g., heavy rain, high wind, snow),

b) wait for ≥10 minutes on arrival at the self-chosen, flat, open space to allow for initialisation of the system. This duration is greater than twice the maximal time required for satellite detection and avoids adding the effects of previous walks to the recorded MWD,

c) walk at their usual walking speed for at least 45 minutes, including rest periods,

d) stop at maximal claudication pain rather than voluntarily slowing down to avoid pain when walking discomfort occurs (onset of pain). No recommendation was provided about the duration of the stops.

e) wait for an additional 10 minutes at the end of the 45-minute walk before switching off the GPS device. This allowed the research team to detect the end of the walking period.

While doing assessments, patients had access to technical support on the use of the device. On return of the device, the walking data was downloaded and analysed to determine the patients' walking speed, distances of interest and the duration of rest periods. The maximum walking distance was identified from the longest distance period of continuous walking (but not the last boot).

Patients' community-based walking ability was analysed as soon as possible after receipt of the GPS dataloggers. In 2 cases of poor signal quality or non-interpretable/missing data patients were asked to repeat the relevant test.

Information collected included: MWD, minimum (defined as the minimum walking distance walked between complete stops on each walk) and mean walking distance (defined as the average walking distance walked between complete stops for each walk), the number of stops, total walking time, the average walking speed and recovery time (defined as the time required for a participant to resume walking following a complete stop).

Statistical Analysis

Outcome measures were assessed for normal distribution using the Kolmogorov–Smirnov goodness-of-fit test. As they were normally distributed, the student paired t test was performed to compare results between visits. Statistical analyses were performed with SPSS (V17.0.0 SPSS Inc., 2008). For all statistical tests, a two-tailed probability level of $p < .05$ was used to indicate statistical significance. Data are expressed as mean (Standard Deviation; SD).

RESULTS

Treadmill Walking Assessment – Questionnaire-based Walking Measurements

Study participants reported diminished health-related quality of life (i.e., 30.5 (6.6) for Physical Component Summary and 35.7 (7.5) for Mental Component Summary), as assessed by SF-36 health-related quality of life questionnaire (Table 2). Similarly, they had low walking capacity, as assessed using treadmill-walking test (355 (268)) and questionnaires (i.e. 24.5 (9.6) for WIQ distance sub-score and 26% (22%) for WELCH). Both their health-related quality of life and WELCH-assessed walking ability were reduced significantly following their 2nd questionnaire-based assessment (Table 2). No treadmill follow-up assessments were conducted due to operational reasons.

Community Walking Assessment

Study participants walked a shorter total distance on the second occasion (2273 (460) m vs 2345 (478) m on the first), although this difference did not reach statistical significance (p=0.4).

However, mean- (552 (112) m vs 334 (78) m; p=0.02) and maximum- walking distance (714 (150) m vs 545 (123) m; p=0.04) were significantly reduced over the 6-month period (Figure 1). Similarly, study participants stopped more frequently during their 2nd walk (number of stops being 7(5) vs 9(5) for 1st and 2nd walk respectively; p=0.03).

On the other hand, participants:

i) Walked for a similar time on both occasions (49 (13) on the first occasion vs 49 (11) 6 months later; p=0.96),

ii) walked at a similar speed (3.49 (1) km/h on first occasion vs 3.45 km/h (1) 6 months later; p=0.81) and

iii) had a similar mean recovery time (1.42 (1) minutes on the first occasion vs 1.27 (1.26) minutes on the second occasion; p=0.57).

DISCUSSION

Although treadmill walking assessments are considered as the "gold standard" measurement of walking impairment in PAD patients with IC (Gernigon *et al.,* 2015), having the highest levels of reproducibility and reliability (Nicolaï *et al.*, 2012) they suffer from a number of disadvantages. They can be costly (as in most of circumstances they are conducted under physician supervision in a hospital environment), have poor availability, are time-consuming and repeat testing may be less frequent than desirable due to service restraints and equipment/personnel availability. Additionally, treadmill assessments may not be appropriate for some participants who are older, frail and without exercise/treadmill walking experience. Consequently, it is possible that measurements may not be representative of the true degree of IC in this sub-group of PAD patients or measure "real-life" walking.

GPS has been proven to offer a reliable assessment of IC patients' walking ability allowing testing to occur in conditions as close as possible to a usual walk (Gernigon *et al.*, 2015; Gernigon *et al.,* 2015b). Although some critique exists in regards to equipment cost and time needed to explain procedures to patients and to analyse findings (Lejay *et al.,* 2015), the benefits may supersede the disadvantages, even though additional testing of such devices may be necessary, in larger cohorts (Gernigon *et al.,* 2015; Faucheur *et al.*, 2010).

Our study is the first to report a statistically- and clinically- significant deterioration in the community (GPS- assessed) maximum and mean walking distance (Figure 1) in patients with established IC, who have not received either an invasive (e.g. surgical) treatment or followed a formalised exercise intervention or had a modified treatment. The importance of the finding becomes more significant, considering that: a) the total walking time remained similar while the number of stops was increased between walks and b) patients' health-related quality of life assessment was already significantly affected at the time of the first visit (Table 2), which would have been at least 8 months since they have been originally diagnosed with IC, an amount of time sufficient for them to adapt to their new life circumstances. It is also important to note that our baseline, health-related quality of life findings are similar to those reported in other studies, where improvements were only noted following structured (home or supervised) exercise programmes or surgery [Jakubsevičienė *et al.,* 2014; Prévost *et al.,* 2015).

Therefore, the significant change in walking patterns (confirmed by WELCH) within a 6-month time-period is likely to have substantial negative effect on activities of daily living, patients' life choices (as it was confirmed by SF-36 questionnaires) and compliance to exercise programmes that these patients may be referred to (with compliance being a common problem on most exercise programmes for IC patients (Al-Jundi *et al.,* 2013; Gommans *et al.,* 2013). This may in turn impact further their health-related quality of life and disease progression.

The National Institute for Health and Care Excellence (NICE) guidelines in the U.K. – as it is the case in most Western countries - recommend a trial of supervised exercise for all patients with IC, prior to any, more invasive, treatment (NICE guidelines 2017). As this however, is not available in most clinical units, in many cases standard practice is restricted in monitoring of the patient's condition in relatively infrequent hospital appointments and the advice provision to "go home and walk as much as possible" (Al-Jundi *et al.,* 2013). Our study demonstrates – being in agreement with recent aggregating publications (Al-Jundi *et al.,* 2013; Gommans *et al.,* 2013)- that this is not sufficient, as there are significant changes in walking patterns, manifested by more frequent stops and lower maximum walked distance (714m vs 545m; p=0.04) (Figure 1) using a real-life walking assessment in this patient group. It may, therefore, be necessary for rehabilitation referrals to occur earlier in disease course and a different approach to earlier treatment be implemented, which would include patient monitoring using "real-life", community-based (e.g. GPS) walking assessments. Our results certainly emphasise the need to provide a timely exercise intervention, otherwise we risk demotivating patients resulting in poor compliance and quality of life: It is worth noting that the study participant with the worst deterioration in MWD required a more invasive surgical intervention.

Study limitations

Due to original study design constraints it was not possible to repeat treadmill measurements. Although the focus of the study was to monitor community based walking and demonstrate the utility of GPS systems in this patient group, we acknowledge that the lack of repeated treadmill assessments might have influenced our ability to draw safer conclusions from this study. Finally, it may be considered that the changes in walking patterns are due to additional effort made by our participants to fulfil what they perceived as the study team's expectations of their walking ability. We however, believe that this is not the case, as our participants were instructed to treat the assessment as one of their "normal" walks, the equipment used for the assessment caused- due to its small size - minimal discomfort and there was a 6-month gap between assessments, which made it very difficult for the participants to remember the distance that they originally covered, especially as they were unaware of the actual distance values of their assessment.

Conclusions

Given the marked changes in walking patterns revealed by our study, we suggest modifications to clinical strategies in this patient group to maintain function and optimise walking ability. This could be a combination of more frequent patient monitoring (including community-based assessments with GPS or other similar methods/tools) and rehabilitation (with the preference being for supervised exercise sessions as recommended by the American College of Cardiology (Rooke *et al.,* 2011) and/or home-exercise programmes; Gommans *et al.,* 2013).

Our findings strengthen the viewpoint that GPS technology can help clinicians in the monitoring of 'real world' walking ability in this patient group and may support the decision-making process for their future therapeutic pathways.

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CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest.

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TABLES

Gender Allocation	34 men, 9 women
Age (years)	69 (9)
Weight (kg)	83.8 (15.4)
Height (cm)	170 (9)
BMI (kg/m^2)	27.6 (7.4)
Waist Circumference (cm)	134.2 (12.3)
Duration of Claudication (years)	4 years, 4 months (3 years, 1 month)
Systolic Blood Pressure (mm/Hg)	134 (12)
Diastolic Blood Pressure (mm/Hg)	74 (11)
Previous Lower Limb Surgery no.	1
ABPI	0.70 (0.14)
Comorbidities no. (history of) (%)	Smoker (current or former) 28 (65%) Coronary disease 5 (12%) Hypercholesterolaemia 28 (65%) Diabetes 5 (12%)
Current Medication no. (%)	Fibrates or statins 34 (79%) Anti-diabetic 5 (12%) Anti-hypertensive 28 (65%) Beta blocker 29 (67%) Antiplatelet 42 (98%) Other 7 (16%)

Table 1: Patient Demographics

Measure	Visit 1	Visit 2	P value
Maximum Treadmill Walking Distance (m)	355 (268)	Not Repeated	N/A
WELCH[a] questionnaire (%)	26 (22)	18 (13)	0.04
WIQ[b] speed subscore (%)	18.2 (8.1)	17.4 (8.5)	<0.001
WIQ[b] distance subscore (%)	24.5 (9.6)	21.3 (7.9)	0.08
WIQ[b] total (%)	43.1 (29.1)	38.9 (25.6)	0.45
SF-36[c] Physical Functioning	35.7 (9.6)	31.5 (9.8)	0.04
SF-36[c] Role-Physical	36.7 (5.1)	32.2 (9.3)	0.04
SF-36[c] Bodily Pain	39.1 (7.1)	32.3 (5.9)	<0.001
SF-36[c] General Health	38.7 (6.1)	31.8 (6.5)	<0.001
SF-36[c] Vitality	51.4 (6.9)	47.6 (10.2)	0.04
SF-36[c] Social Functioning	39.7 (6.1)	34.3 (10.9)	0.02
SF-36[c] Role-Emotional	39.8 (3.9)	33.1 (11.4)	0.01
SF-36[c] Emotional Well-Being	47.5 (5.7)	39.4 (9.5)	<0.001
SF-36[c] Physical Component Summary	30.5 (6.6)	25.1 (10.4)	0.03
SF-36[c] Mental Component Summary	35.7 (7.5)	29.5 (11.8)	0.03

[a] Walking Impairment Questionnaire in PAD, [b] Walking Impairment Questionnaire,

[c] Short Form-36 quality of life Questionnaire

Table 2: Patient Questionnaire-based and Treadmill Measurements

FIGURE

Figure 1: Comparison of main community walking measurements between the two walks