

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

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15
16 Short Title: GPS assessment of walking ability in PAD patients

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24 **Summary**

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

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

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

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

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

48

49 **INTRODUCTION**

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

58

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

67

68 Tools used to assess walking ability, include treadmill walking test (Duprez *et al.*, 1999), 4- or
69 6-minute walking tests (Collins *et al.*, 2010) or questionnaires (e.g. walking impairment
70 questionnaire (WIQ) (Ouedraogo *et al.*, 2011), Walking Estimated Limitation Calculated by
71 History (WELCH) questionnaire (Myers *et al.*, 2008). The two questionnaires have been
72 shown to have high correlation with the 6-minute walking test (Gernigon *et al.*, 2015) and
73 treadmill walking assessments (Ouedraogo *et al.*, 2011). These tools however, may not
74 reflect accurately the true walking impairment or may be inappropriate for older or frailer
75 patients). These tests also fail to give an indication of the patients' walking ability under
76 "real" conditions - such as walking that takes place in the community, and don't give
77 information about walking speed or the number of stops between walking episodes. Global
78 Positioning Systems (GPS) have been proposed as reliable, reproducible tools to measure
79 total, mean and maximal walking distances in patients with PAD in community settings
80 (Gernigon *et al.*, 2015).

81

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

88

89 **MATERIALS AND METHODS**

90 The present study was approved by South Yorkshire NHS Research Ethics Committee
91 (13/YH/0088). This research was carried out in accordance with the Declaration of Helsinki

92 of the World Medical Association and all participants gave their written informed consent to
93 participate.

94

95 Forty-three adult men and women with clinically-diagnosed IC due to PAD were identified
96 from vascular clinic attendance lists stored at the Sheffield Vascular Institute, Northern
97 General Hospital, Sheffield (Table 1) between 2013-2016. All participants completed all
98 designated study visits. The sample size was estimated (with MWD being the main outcome
99 measure), based on the number required on previous studies from authors in our group
100 undertaken on the same population (Gernigon *et al.*, 2015). All participants had stable IC
101 (4.4 (3.1) years' duration), with a condition's duration ranging between 8 months and 11
102 years. Patients with critical limb ischaemia, with uniquely impaired walking ability (e.g.
103 wheelchair-bound patients and patients with lower-extremity amputation), with recent
104 major surgery in the previous 6 months, with heart failure of New York Heart Association
105 grade III or IV, with known severe respiratory disease other than obstructive sleep apnoea,
106 who were pregnant at the time and those with Parkinson's disease, hemiplegia or
107 paraplegia or who were in an exclusion period due to participation in other research studies
108 were excluded from the study. Participants did not receive an incentive to take part in the
109 study, with an exception of free parking at the laboratory premises, during assessment days.
110 All participants were receiving medical treatment (e.g. pharmacotherapy) at the time of
111 their participation in the study, as per their individual circumstances, being also followed by
112 their General Practitioners and by physicians within hospital vascular clinics. No MI or stroke
113 or death incident took place within the study period for any of our participants.

114

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

119

120 During the second visit, participants completed the following clinical questionnaires: SF-36
121 (Ware & Sherbourne 1995), WIQ (Myers *et al.*, 2008) and WELCH (Ouedraogo *et al.*, 2011).
122 They completed a standardised treadmill walking test [16], with a constant walking speed of
123 3.2 km/h with a gradient of 10% for 15 minutes. All tests ended when participants could no
124 longer walk despite sustained encouragement or after 15 minutes. Twelve-lead
125 electrocardiogram monitoring with ST segment analysis was performed continuously
126 (Cardioperfect, Welch Allyn, USA) with termination of walk testing if the participant
127 developed angina symptoms or developed ST depression equal or greater than 2mm in any
128 lead. All participants completed the clinical questionnaires retrospectively via post, after
129 their second community-based walking assessment.

130

131 *Community-based walking assessment*

132 Walking capacity was assessed in the community using a commercially-available global
133 positioning system (GPS) data logger (DG-100 GPS data logger and the AT-65 GPS Active
134 Antenna, GlobalSat Technology Corp., New Taipei City, Taiwan), as previously described
135 (Faucheur *et al.*, 2010). Community-based walking assessments took place on two
136 occasions: once following their laboratory visit, and the second 6 months after their first
137 community-based assessment. The walking assessment lasted 60-65 minutes in total, on
138 each occasion. The device was worn above their outermost clothing layer. It was

139 emphasised to the participants that the aim of this unconstrained walking was to reproduce
140 their daily walking limitation during an outdoor, unsupervised, walk at their usual pace.
141 Participants were also encouraged to undertake a short "test" walk, prior to their main
142 walking assessment, in order to familiarise themselves with the equipment. Patients were
143 given a leaflet with detailed instructions, and were given a detailed demonstration of the
144 equipment use being also instructed to:

- 145 a) avoid undertaking the assessment during adverse weather conditions (e.g., heavy rain,
146 high wind, snow),
- 147 b) wait for ≥ 10 minutes on arrival at the self-chosen, flat, open space to allow for
148 initialisation of the system. This duration is greater than twice the maximal time required for
149 satellite detection and avoids adding the effects of previous walks to the recorded MWD,
- 150 c) walk at their usual walking speed for at least 45 minutes, including rest periods,
- 151 d) stop at maximal claudication pain rather than voluntarily slowing down to avoid pain
152 when walking discomfort occurs (onset of pain). No recommendation was provided about
153 the duration of the stops.
- 154 e) wait for an additional 10 minutes at the end of the 45-minute walk before switching off
155 the GPS device. This allowed the research team to detect the end of the walking period.

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

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

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

169

170 *Statistical Analysis*

171 Outcome measures were assessed for normal distribution using the Kolmogorov–Smirnov
172 goodness-of-fit test. As they were normally distributed, the student paired t test was
173 performed to compare results between visits. Statistical analyses were performed with
174 SPSS (V17.0.0 SPSS Inc., 2008). For all statistical tests, a two-tailed probability level of p
175 $< .05$ was used to indicate statistical significance. Data are expressed as mean (Standard
176 Deviation; SD).

177

178 **RESULTS**

179 *Treadmill Walking Assessment – Questionnaire-based Walking Measurements*

180 Study participants reported diminished health-related quality of life (i.e., 30.5 (6.6) for
181 Physical Component Summary and 35.7 (7.5) for Mental Component Summary), as assessed
182 by SF-36 health-related quality of life questionnaire (Table 2). Similarly, they had low
183 walking capacity, as assessed using treadmill-walking test (355 (268)) and questionnaires
184 (i.e. 24.5 (9.6) for WIQ distance sub-score and 26% (22%) for WELCH). Both their health-

185 related quality of life and WELCH-assessed walking ability were reduced significantly
186 following their 2nd questionnaire-based assessment (Table 2). No treadmill follow-up
187 assessments were conducted due to operational reasons.

188

189 *Community Walking Assessment*

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

193 However, mean- (552 (112) m vs 334 (78) m; p=0.02) and maximum- walking distance
194 (714 (150) m vs 545 (123) m; p=0.04) were significantly reduced over the 6-month
195 period (Figure 1). Similarly, study participants stopped more frequently during their 2nd
196 walk (number of stops being 7(5) vs 9(5) for 1st and 2nd walk respectively; p=0.03).

197 On the other hand, participants:

- 198 i) Walked for a similar time on both occasions (49 (13) on the first occasion vs
199 49 (11) 6 months later; p=0.96),
- 200 ii) walked at a similar speed (3.49 (1) km/h on first occasion vs 3.45 km/h (1) 6
201 months later; p=0.81) and
- 202 iii) had a similar mean recovery time (1.42 (1) minutes on the first occasion vs
203 1.27 (1.26) minutes on the second occasion; p=0.57).

204

205 **DISCUSSION**

206 Although treadmill walking assessments are considered as the "gold standard"
207 measurement of walking impairment in PAD patients with IC (Gernigon *et al.*, 2015),
208 having the highest levels of reproducibility and reliability (Nicolai *et al.*, 2012) they suffer

209 from a number of disadvantages. They can be costly (as in most of circumstances they
210 are conducted under physician supervision in a hospital environment), have poor
211 availability, are time-consuming and repeat testing may be less frequent than desirable
212 due to service restraints and equipment/personnel availability. Additionally, treadmill
213 assessments may not be appropriate for some participants who are older, frail and
214 without exercise/treadmill walking experience. Consequently, it is possible that
215 measurements may not be representative of the true degree of IC in this sub-group of
216 PAD patients or measure “real-life” walking.

217 GPS has been proven to offer a reliable assessment of IC patients' walking ability
218 allowing testing to occur in conditions as close as possible to a usual walk (Gernigon *et al.*,
219 *et al.*, 2015; Gernigon *et al.*, 2015b). Although some critique exists in regards to
220 equipment cost and time needed to explain procedures to patients and to analyse
221 findings (Lejay *et al.*, 2015), the benefits may supersede the disadvantages, even though
222 additional testing of such devices may be necessary, in larger cohorts (Gernigon *et al.*,
223 2015; Faucheur *et al.*, 2010).

224

225 Our study is the first to report a statistically- and clinically- significant deterioration in
226 the community (GPS- assessed) maximum and mean walking distance (Figure 1) in
227 patients with established IC, who have not received either an invasive (e.g. surgical)
228 treatment or followed a formalised exercise intervention or had a modified treatment.
229 The importance of the finding becomes more significant, considering that: a) the total
230 walking time remained similar while the number of stops was increased between walks
231 and b) patients' health-related quality of life assessment was already significantly
232 affected at the time of the first visit (Table 2), which would have been at least 8 months

233 since they have been originally diagnosed with IC, an amount of time sufficient for them
234 to adapt to their new life circumstances. It is also important to note that our baseline,
235 health-related quality of life findings are similar to those reported in other studies,
236 where improvements were only noted following structured (home or supervised)
237 exercise programmes or surgery [Jakubsevičienė *et al.*, 2014; Prévost *et al.*, 2015].

238

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

246

247 The National Institute for Health and Care Excellence (NICE) guidelines in the U.K. – as it
248 is the case in most Western countries - recommend a trial of supervised exercise for all
249 patients with IC, prior to any, more invasive, treatment (NICE guidelines 2017). As this
250 however, is not available in most clinical units, in many cases standard practice is
251 restricted in monitoring of the patient's condition in relatively infrequent hospital
252 appointments and the advice provision to "go home and walk as much as possible" (Al-
253 Jundi *et al.*, 2013). Our study demonstrates – being in agreement with recent
254 aggregating publications (Al-Jundi *et al.*, 2013; Gommans *et al.*, 2013)- that this is not
255 sufficient, as there are significant changes in walking patterns, manifested by more
256 frequent stops and lower maximum walked distance (714m vs 545m; $p=0.04$) (Figure 1)

257 using a real-life walking assessment in this patient group. It may, therefore, be
258 necessary for rehabilitation referrals to occur earlier in disease course and a different
259 approach to earlier treatment be implemented, which would include patient monitoring
260 using “real-life”, community-based (e.g. GPS) walking assessments. Our results certainly
261 emphasise the need to provide a timely exercise intervention, otherwise we risk
262 demotivating patients resulting in poor compliance and quality of life: It is worth noting
263 that the study participant with the worst deterioration in MWD required a more
264 invasive surgical intervention.

265

266 *Study limitations*

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

280

281 *Conclusions*

282 Given the marked changes in walking patterns revealed by our study, we suggest
283 modifications to clinical strategies in this patient group to maintain function and
284 optimise walking ability. This could be a combination of more frequent patient
285 monitoring (including community-based assessments with GPS or other similar
286 methods/tools) and rehabilitation (with the preference being for supervised exercise
287 sessions as recommended by the American College of Cardiology (Rooke *et al.*, 2011)
288 and/or home-exercise programmes; Gommans *et al.*, 2013).
289 Our findings strengthen the viewpoint that GPS technology can help clinicians in the
290 monitoring of 'real world' walking ability in this patient group and may support the
291 decision-making process for their future therapeutic pathways.

292

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300

301 **CONFLICT OF INTEREST STATEMENT**

302 The authors have no conflicts of interest.

303

304

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401 TABLES

Gender Allocation	34 men, 9 women
Age (years)	69 (9)
Weight (kg)	83.8 (15.4)
Height (cm)	170 (9)
BMI (kg/m²)	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%)

402

Table 1: Patient Demographics

403

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

404 ^a Walking Impairment Questionnaire in PAD, ^b Walking Impairment Questionnaire,

405 ^c Short Form-36 quality of life Questionnaire

406 **Table 2: Patient Questionnaire-based and Treadmill Measurements**

407

408 **FIGURE**

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