



Does daily physical activity reflect claudication distance measured on a treadmill and in a community outdoor setting?

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Abstract

Introduction and Objective. Low physical activity in patients with claudication is associated with lower walking abilities as assessed by the treadmill test. The impact of physical activity on the ability to walk in a natural environment is unknown. The study aimed to assess the level of daily physical activity among patients with claudication, as well as the relationship between the level of daily physical activity and claudication distance measured during the outdoor walking and treadmill tests.

Materials and method. The study included 37 patients (24 males), aged 70.03±5.9, with intermittent claudication. Daily step count was assessed using the Garmin Vivofit activity monitor, worn on the non-dominant wrist for 7 consecutive days. Pain-free walking distance (PFWDTT) and maximal walking distance (MWDTT) were measured via the treadmill test. During 60-minute outdoor walking, the maximal walking distance (MWDGPS), total walking distance (TWDGPS), walking speed (WSGPS), number of stops (NSGPS) and stop durations (SDGPS) were assessed.

Results. Mean daily step count – 7,102±3,433. A significant correlation was observed between daily step count and MWDTT, TWDGPS (R=0.33, R=0.37, respectively (p<0.05). Furthermore, 51% of patients reached less than 7,500 steps/day and presented significantly shorter MWDTT, MWDGPS and TWDGPS, compared to the participants covering ≥7,500 steps (p<0.05).

Conclusions. The daily step count reflects claudication distance measured on a treadmill and only partially in a community outdoor setting. The minimal daily step count that should be recommended for patients with claudication, allowing achievement of significantly better results with regard to walking abilities, both on the treadmill and in outdoor settings, is at least 7,500 steps per day.

Key words

physical activity, claudication, step, global positioning system

INTRODUCTION AND OBJECTIVE

Symptomatic peripheral arterial disease (PAD), in which the patient experiences intermittent claudication, is characterised by a stable course. Over the course of a 5-year illness duration, significant disease progression may occur in 20% of patients, while in the remaining 75%, the symptoms are constant. Despite mild prognosis in terms of PAD symptom severity, patients are at a high risk of cardiovascular complications, such as heart attack, stroke or vascular death [1]. The risk is even higher among patients leading a sedentary lifestyle [2]. Intermittent claudication limits patients' ability to walk, and therefore their ability to be physically active on a daily basis [3]. Considering that walking is one of the main activities undertaken by older people, it seems obvious that a sedentary lifestyle predominates among patients with claudication [2]. Interestingly, in this group of patients, it has been shown

that undertaking even a small amount of physical activity, 10 minutes of low-intensity physical activity instead of 10 minutes of a sedentary lifestyle, reduces mortality by as much as 9% [4]. Therefore, in the assessment of patients with intermittent claudication, their daily physical activity should be taken into account. Until now, researchers most often have used such tools as: physical activity questionnaires, pedometers, or monitors of physical activity [5]. In previous studies on the objectively assessment of physical activity among patients with intermittent claudication, the authors have used accelerometers and pedometers measuring energy expenditure and the number of steps taken, respectively [6, 7, 8]. These devices are useful in determining total daily physical activity. Technological progress has contributed to the increased availability of relatively inexpensive physical activity monitors on the market. They can find application in research on the evaluation of physical activity or interventions for its promotion [9].

Low physical activity in patients with claudication is associated with lower walking abilities as assessed by the treadmill walking test [10]. In recent years, outdoor walking

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tests with the use of GPS devices [11, 12] have been proposed for use in the evaluation of walking abilities among patients with claudication. Their accuracy [12, 13], reliability [14] and validity [12, 13, 15] have been confirmed. It has also been shown that the results of the outdoor walking test correlate with the tools used so far to assess walking abilities [11, 12].

There have been suggestions that field test results may better reflect a patient's actual walking abilities than those conducted in laboratory conditions. To date, no studies have been conducted to assess the relationship between the level of physical activity and walking capacity in outdoor settings. Therefore, the aim of the study was to assess the level of daily physical activity among patients with intermittent claudication, as well as the relationship between the level of daily physical activity and claudication distance measured during the outdoor walking and treadmill tests. The null hypothesis is that higher level of daily physical activity is not related to the longer claudication distance measured during the outdoor walking and treadmill tests. The alternative hypothesis is that a higher level of daily physical activity is associated with a longer claudication distance measured during the outdoor walking and treadmill tests.

MATERIALS AND METHOD

Study population. The study included patients aged 50 and over diagnosed with PAD (grade 2 according to the Fontaine classification), with a stable walking distance of 100–300 metres, ABI at rest <0.9, undergoing standard pharmacological treatment (anti-platelet therapy, anti-hypertensive therapy, cholesterol-lowering agents) – no significant changes within the 6 months preceding the research programme or during its implementation. None of the patients took pentoxifylline, cilostazol or selective COX-2 inhibitors. The exclusion criteria were: unstable angina, history of myocardial infarction, undergoing vascular surgery within 1 year prior to the study, cardiovascular disorders, cancer, kidney or liver diseases and osteoarthritis limiting mobility. Moreover, patients unable to walk on a treadmill at a speed of 3.2 km/h were not qualified.

The study was approved by the Bioethics Committee of Karol Marcinkowski Medical University in Poznań (Resolution No. 387/15). The patients provided written informed consent to participate in the trial.

Treadmill testing. Prior to evaluation of the walking time, the patients were acquainted with the specificity of walking on a treadmill. Familiarisation consisted of walking on a treadmill at a speed of 3.2 km/h without inducing pain. The total walking time of familiarisation was not less than 10 minutes. Pain-free walking distance (PFWD_{TT}) and maximal walking distance (MWD_{TT}) were measured using the Gardner protocol [16]. The test was carried out on a treadmill at a constant speed of 3.2 km/h and an initial inclination angle of 0%. Every 2 minutes, the inclination of the treadmill was increased by 2%. The patient reported when pain was experienced (PFWD_{TT}). The test was interrupted when maximal pain symptoms appeared (MWD_{TT}).

Outdoor walking test. This test was performed using a watch with GPS (Forerunner® 310XT, Garmin, USA). The test lasted 60 minutes. In front of the building, the device was turned on 10 minutes before beginning the test for

system initialisation. This is twice as long as the maximal time required for detection by satellites [12]. During this time, the patient rested in a sitting position. The device was worn on the wrist of the non-dominant hand. Patients were instructed to walk for 60 minutes at their usual pace (self-selected) and to stop only in the case of lower limb pain preventing them from continuing the exercise. The patient did not have to wait for the pain to completely dissipate. The patients pressed the 'lap' button on the device each time they stopped because of pain, and when they began walking after rest. The study took place in the city park next to the university. There were flat walking paths and benches in the park. The patients could choose any path. The park was car-free. The recorded data were transferred to a computer and then analysed. The following variables were used for the analysis: maximal walking distance (MWD_{GPS}), the longest distance in the whole test measured between 2 stops, total walking distance (TWD_{GPS}), average walking speed (WS_{GPS}) calculated from all walking bouts, number of stops (NS_{GPS}) and average stop durations (SD_{GPS}). The final walking bout was not taken into account for the calculation of MWD_{GPS} or WS_{GPS} due to the fact that it could be related to the desire to reach the university building where the test was ended. For example, the patient may have slowed down as the claudication increased to avoid severe pain forcing him/her to stop again at the end of the test.

After each outdoor testing day, recordings from the GPS device were downloaded to a computer using the Garmin Express application. The results were analysed by a trained operator. Test-retest reliability of the outdoor marching test using the Garmin Forerunner® 310XT has been validated in the authors' previous research [15]. The weather conditions during each test, such as wind speed, precipitation and temperature, were recorded from a local weather station.

Assessment of physical activity. Physical activity was assessed with the Garmin Vivofit activity monitor. The device is equipped with a 3-axis accelerometer which allows the monitoring of steps per day, energy expenditure (kcal), sleep statistics and heart rate (separately required heart rate monitor) [17]. The monitor is worn on the wrist. In the work by El-Amrawy et al. [18], its accuracy was estimated at 97.01%. For the purposes of this study, the mean step count variable and the 5,000-, 7,000-, 7,500-step threshold were used for analysis. The study participants were instructed to constantly wear the monitor on the non-dominant wrist for 7 consecutive days. Recordings from the Garmin Vivofit were downloaded to a computer using the Garmin Express application. The results were analysed by a trained operator. Similarly to other studies, in order to compare the obtained data between participants independently of individual variation in age, weight, height and gender, the monitors were programmed using identical values for the above-mentioned parameters [8].

Statistical analysis. The results were subjected to statistical analysis (Statistica 13.0). A t-test power analysis determined that at least 36 subjects were required to obtain a power of 0.8 at a two-sided level of 0.05 with effect size $d = 0.8$ [19]. This analysis was based on data derived from previous literature [20]. The Shapiro-Wilk test was used to check distribution of the analysed variables; differences between variables with normal distribution were assessed via the Student's *t*-test; the non-parametric Mann-Whitney U test or the Wilcoxon signed-rank

test were employed in the case of variables deviating from the norm. Pearson's r correlation coefficient was applied to check the power of the correlations between quantitative variables with normal distribution. Spearman's rho correlation coefficient was used to test the relationships between categorical variables and those with non-normal distribution. The differences were considered significant at the level of $p < 0.05$. The effect size (ES) was calculated using Cohen's d and interpreted as small (0.2–0.3), medium (0.5) or large (> 0.8).

RESULTS

The study included 46 patients (32 males) aged 69.9 ± 5.84 years with claudication due to peripheral artery disease. Nine subjects were excluded from the analysis: 7 due to unsuccessfully performing the outdoor walking test, 2 due to the lack of stops during the outdoor walking test (these patients reported that after the onset of claudication, walking speed slowed down sufficiently enough to resolve symptoms). Ultimately, 37 respondents were included in the analysis. Their baseline characteristics are presented in Table 1. Walking abilities assessed during the treadmill and outdoor walking tests are shown in Table 2. Data are presented as means and standard deviation.

Table 1. Characteristics of the subjects

Characteristics	
Age (years)	70.03 ± 5.86
BMI (kg/m ²)	26.70 ± 3.54
Gender (F/M)	13 / 24
Current smoker, n (%)	14 (38%)
Education (primary / secondary / higher)	1 / 16 / 20
Type of work (employee / retired-pension)	6 / 31

Abbreviations: BMI – body mass index; F – female; M – male

Table 2. Walking abilities evaluated during the treadmill and outdoor walking tests

Variable	Mean \pm SD
PFWD _{TT} [km]	0.12 ± 0.07
MWD _{TT} [km]	0.32 ± 0.14
MWD _{GPS} [km]	0.76 ± 0.40
TWD _{GPS} [km]	2.64 ± 0.54
WS _{GPS} [kph]	3.41 ± 0.44
NS _{GPS} [n]	6 ± 4
SD _{GPS} [s]	130.56 ± 66.33

Abbreviations: TT – results obtained during treadmill test; GPS – results obtained during outdoor walking test; PFWD_{TT} – pain-free walking distance; MWD_{TT} – maximal walking distance; MWD_{GPS} – maximal walking distance; TWD_{GPS} – total walking distance; WS_{GPS} – walking speed; NS_{GPS} – number of stops; SD_{GPS} – stop duration

Significant correlations were observed between MWD_{GPS} and MWD_{TT}, TWD_{GPS}, WS_{GPS}, NS_{GPS} ($R=0.62$, $R=0.47$, $R=0.36$, $R=-0.67$, respectively; $p < 0.05$).

Mean daily step count – $7,102 \pm 3,433$. For 16% of patients ($n=6/37$), the daily step count totalled 10,000 or more. Among 51% of patients, a total of less than 7,500 daily step count was noted (mean = 4,591). Significant correlations were observed between daily step count and MWD_{TT}, TWD_{GPS} ($R=0.33$, $R=0.37$, respectively; $p < 0.05$).

Participants who took less than 7,500 steps per day had significantly shorter MWD_{TT}, MWD_{GPS} and TWD_{GPS} compared to those who walked $\geq 7,500$ steps ($p < 0.05$). These results are presented in Table 3.

Table 3. Walking abilities depending on daily step count

Variable	< 7,500 daily step count (n=19)	$\geq 7,500$ daily step count (n=18)	p	ES
MWD _{TT} [km]	0.27 ± 0.11	0.36 ± 0.15	< 0.05	0.68
MWD _{GPS} [km]	0.64 ± 0.28	0.89 ± 0.46	< 0.05	0.66
TWD _{GPS} [km]	2.46 ± 0.34	2.82 ± 0.65	< 0.05	0.69

Abbreviations: TT – results obtained during treadmill test; GPS – results obtained during outdoor walking test; MWD_{TT} – maximal walking distance; MWD_{GPS} – maximal walking distance; TWD_{GPS} – total walking distance; ES – effect size (Cohen d)

Among the 37 subjects, 10 had a daily step count of $< 5,000$. This subgroup tended to show poorer results in both the treadmill and outdoor walking tests, but the differences did not reach statistical significance ($p > 0.05$). An identical trend of poorer scores ($p > 0.05$) was observed using the division according to the 7,000-step-per-day threshold (22 subjects had a daily step count of $\leq 7,000$).

It was noted that current smokers had significantly shorter MWD_{GPS}, TWD_{GPS} and slower WS_{GPS} ($p < 0.05$) than non-smokers. The results of the treadmill walking test and the daily step count were also weaker compared to non-smokers; however, the differences did not reach statistical significance ($p > 0.05$) (Tab. 4).

Table 4. Walking abilities and daily step count depending on current smoking status

Variable	Current smoker		p	ES
	Yes (n=14)	No (n=23)		
MWD _{GPS} [km]	0.57 ± 0.29	0.87 ± 0.42	< 0.05	0.83
TWD _{GPS} [km]	2.31 ± 0.40	2.84 ± 0.52	< 0.05	1.44
WS _{GPS} [kph]	3.16 ± 0.33	3.56 ± 0.43	< 0.05	1.04
PFWD _{TT} [km]	0.10 ± 0.04	0.13 ± 0.08	> 0.05	1.90
MWD _{TT} [km]	0.28 ± 0.11	0.34 ± 0.15	> 0.05	0.46
Daily step count	$5,999 \pm 3,257$	$7,774 \pm 3,432$	> 0.05	0.53

Abbreviations: TT – results obtained during treadmill test; GPS – results obtained during outdoor walking test; PFWD_{TT} – pain-free walking distance; MWD_{TT} – maximal walking distance; MWD_{GPS} – maximal walking distance; TWD_{GPS} – total walking distance; WS_{GPS} – walking speed; ES – effect size (Cohen d)

There was a significant negative correlation between BMI and daily steps count ($R = -0.32$; $p < 0.05$). Gender did not have a differentiating effect on the analysed variables ($p > 0.05$).

DISCUSSION

The most frequently repeated recommendation regarding step count relevant to adult health benefits is 10,000 steps per day [21]. In research on the subject, it has been shown that healthy adults take an average of 4,000 – 18,000 steps a day [22]. With age, a decrease in daily step count can be observed, i.e. people aged 65–74 years perform an average of 4,030 steps per day [23]. This is a number that can be reached during the performance of daily routine activities [24]. Among the subjects in the current study with intermittent claudication, the average daily step count was 7,102. This number, according

to the division proposed by Tudor-Locke, puts them in the 'low active' group (5,000–7,499 steps/day) [25].

On the other hand, it should be borne in mind that we are comparing the results of subjects with intermittent claudication to the recommendations for healthy adults. In the works by other authors, the daily number of steps in patients with intermittent claudication ranged between 2,247 and 6,722 [26, 27, 28], thus, the results were even lower than for the participants of this study. In the current trial, 16% of patients achieved the recommended threshold of 10,000 steps a day. Similar results (15.7% of patients with PAD) were observed in the study by Gardner et al. [26].

Do we know what the minimal step count per day that would be beneficial for patients with claudication? In the analysed literature, if the subject was below the adopted threshold of 7,500, 7,000 or 5,000 per day, s/he was considered representing sedentary or 'low active' behaviour [17, 29, 30]. Regarding walking ability, it has been indicated in this study that a significant restriction in walking ability is the performance of less than 7,500 steps a day. Patients who walked at least 7,500 steps had significantly better results for both the treadmill and outdoor walking tests. For comparison, in the research by Gardner et al. [29] including patients with intermittent claudication for whom the threshold of 7,000 steps per day was assumed, it was shown that patients with PAD who take more than 7,000 steps/day have better ambulatory function (measured during the 6-Minute Walk Test) and health-related quality of life than patients below this threshold. In the current study, using the division of the respondents according to the limit of 7,000 steps per day, no significant differences were observed between the respondents in terms of walking ability, both for the treadmill and outdoor walking tests. An identical observation using the 5,000-step threshold proposed by Tudor-Locke et al. was observed [30].

The present trial confirmed a significant correlation between daily step count and the maximal walking distance measured during the treadmill test ($R=0.33$). These results are consistent with those presented in the previously published work by Gardner et al. [31] ($r=0.314$) and Nasr et al. [27] ($\rho = 0.35$).

To the best of the authors' knowledge, this is the first study that provides information on the relationship between daily step count and a patient's ability to walk with intermittent claudication in outdoor settings. The evaluation of outdoor walking in patients with claudication takes into account such variables as maximal walking distance (MWD_{GPS}), walking speed (WS_{GPS}), number of stops (NS_{GPS}), stop duration (SD_{GPS}), and total walking distance (TWD_{GPS}).

Special attention is paid to the MWD_{GPS} variable, i.e. the longest distance between two intervals induced by claudication pain. Assuming a constant walking speed, it seems that the MWD_{GPS} length will best reflect the patient's ability to move without limit in an outdoor environment, e.g. walking to the garage, shop, church, etc. In the work by Faucheur et al. [12], as in our study, a high and positive correlation was found between MWD_{GPS} and MWD_{TT} . However, surprisingly, despite the association with MWD_{TT} in the current study no significant correlation was noted between daily step count and MWD_{GPS} . The only significant relationship among the variables from the outdoor walking test was the positive correlation with the TWD_{GPS} variable. Thus, in the analysed population, outdoor walking abilities, with the exception of

TWD_{GPS} , are not related to physical activity level determined by daily step count. Nonetheless, before coming to final conclusions, it would be worth extending the research by evaluating other variables allowing assessment of the daily activity level, such as cadence (steps/min). The usefulness of assessing this variable has been confirmed in research on the subject [32]; unfortunately, the device applied in the current trial did not allow for the assessment of cadence.

Much attention is paid to the search for effective measures to increase the physical activity of patients with intermittent claudication. A recent meta-analysis indicated that participation in supervised exercise training (SET) leads to a moderate increase in daily physical activity. In the same paper, it was suggested that providing a patient with home-based exercise therapy or endovascular revascularisation may have similar benefits [33]. Regrettably, the supervised exercise training recommended in guidelines for intermittent claudication is not reimbursed in most countries [34].

On the other hand, in the case of unsupervised programmes, many patients do not follow the training recommendations over time [35]. In several studies attempts were made to identify factors limiting physical activity among patients with intermittent claudication. In a systematic review by Abaraogu et al. [36], these factors were grouped into personal, walking-related and environmental barriers. Acknowledging them, as well as the most effective strategies to overcome these barriers, is essential in planning activities aimed at increasing the physical activity of patients with claudication.

One of the mentioned factors limiting physical activity and walking abilities is smoking. In this study, compared to non-smokers, smokers had significantly lower scores in the outdoor walking test (variables: MWD_{GPS} , TWD_{GPS} and WS_{GPS}), while the results obtained for the treadmill walking test and the daily step count were also weaker compared to non-smokers; however, these differences did not reach statistical significance.

Similar observations were noted by Dörenkamp et al. [37] with regard to walking distance during the treadmill test. Gardner et al. [38] also observed that patients who smoked presented a less physically active lifestyle than non-smokers. However, the results of the published studies are not unequivocal – for example, in the work by Quintella Farah et al. [39], no significant impact of smoking status was noted on physical activity levels or physical function in IC patients. Importantly, smoking had no limitations on the benefits of participating in supervised treadmill training, including walking abilities, ambulatory function and/or daily physical activity [40]. Considering the above observation and the evidence of worse outcomes in smoking compared to non-smokers at the beginning, the group of smokers should be particularly encouraged to engage in regular activity, including participation in supervised training.

An important issue remains – to find an effective way to increase the physical activity of a patient with intermittent claudication. Perhaps, for some patients, regular monitoring of activity with pedometers would be an effective motivating tool. It was indicated that the use of pedometers translated into an average increase of 2,000 steps in the intervention groups [41]. In turn, in the meta-analysis by Chan et al. [42], it was suggested that interventions with wearable activity monitors appear beneficial for improving walking ability and quality of life among patients with IC. Nevertheless, the authors noted that the considered research works had

numerous limitations; thus, there is a need for further research in this area.

CONCLUSIONS

In patients with intermittent claudication, lower physical activity is associated with poorer walking abilities as measured by treadmill tests and in the outdoor walking test. The minimum daily number of steps that should be recommended for patients with claudication to achieve significantly better performance in terms of both treadmill and outdoor walking is at least 7,500 steps per day. The minimum daily number of at least 7,500 steps might/should be recommended for patients with claudication in order to achieve significantly better performance in both treadmill and outdoor walking.

Study limitations. The limitation of the study is the lack of a control group. A valuable piece of information would be to collect data on the daily step count in a non-claudicant population. However, this research aimed to evaluate the relationship of the daily step count with walk test scores specific to community-dwelling claudicating patients. An additional, limitation of the study is the lack of homogenous group of patients in terms of gender. Fewer women than men in studies of patients with PAD is a known phenomenon. In the current study, the percentage of women was 35%, which is consistent with the statistics of other studies – a 2018 review showed that in more than half of PAD trials, women comprised <35% of the whole study population [43]. Interestingly, some authors suggest that researchers should not consider men and women as a single population and report their data separately [44].

However, in this study, gender did not have a differentiating effect on the analyzed variables (number of steps, treadmill and outdoor tests outcomes). Undoubtedly, the analyzed results could have been influenced by various variables, nonetheless, only the status of the smoker is discussed in the study as it is an important, modifiable variable. The BMI variable was not discussed which significantly correlated with the daily number of steps ($R = -0.32$; $p < 0.05$). This observation is consistent with the results of other authors indicating that a high body mass index was associated with high sedentary behaviour in symptomatic PAD patients [45]; the higher a patient's BMI then the lower the intensity level when that person is active; that the presence of obesity predicted greater overall sedentary time and longer bouts of sedentary time [46].

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