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ASSOCIATION BETWEEN MEETING DAILY STEP COUNT GOALS WITH AMBULATORY FUNCTION AND QUALITY OF LIFE IN PATIENTS WITH CLAUDICATION

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Abstract

Objectives.—To determine (a) whether patients with peripheral artery disease (PAD) who walked at least 7,000 and 10,000 steps/day had better ambulatory function and health-related quality of life (HRQoL) than patients who walked less than 7,000 steps/day, and (b) whether differences in ambulatory function and HRQoL in patients grouped according to these daily step count criteria persisted after adjusting for covariates.

Methods.—Two hundred forty-eight patients were assessed on their daily ambulatory activity for one week with a step activity monitor, and were grouped according to daily step count targets. Patients who took fewer than 7,000 steps/day were included in Group 1 (n=153), those who took 7,000 to 9,999 steps/day were included in Group 2 (n=57), and patients who took at least 10,000 steps/day were included in Group 3 (n=38). Primary outcomes were 6-minute walk distance (6MWD) and Walking Impairment Questionnaire (WIQ) distance score, which is a disease-specific measurement of HRQoL. Patients were further characterized on demographic variables, comorbid conditions, and cardiovascular risk factors.

Results.—The groups were significantly different on ankle/brachial index (p=0.02), and on prevalence of hypertension (p=0.04), diabetes (p<0.01), abdominal obesity (p<0.01), arthritis (p=0.04), and chronic obstructive pulmonary disease (p<0.01). Thus, these variables served as covariates in adjusted analyses, along with age, weight, and sex. 6MWD (mean±SD) was significantly different among the groups in unadjusted (p<0.01) and adjusted (p<0.01) analyses (Group 1=313±90 m, Group 2=378±84 m, Group 3=414±77 m), with Groups 2 and 3 having higher 6MWD than Group 1 (p<0.01). WIQ distance score was significantly different among the groups in unadjusted (p<0.01) and adjusted (p<0.01) analyses (Group 1=30±30%, Group

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2=45±35%, Group 3=47±34%), with Groups 2 and 3 having higher WIQ distance scores than Group 1 ($p<0.01$).

Conclusions.—PAD patients who walked more than 7,000 and 10,000 steps/day had greater ambulatory function and HRQoL than patients who walked fewer than 7,000 steps/day. Secondly, the greater ambulatory function and HRQoL associated with walking 7,000 and 10,000 steps/day persisted after adjusting for covariates. This study provides preliminary evidence that PAD patients who walk more than 7,000 steps/day have better ambulatory function and HRQoL than patients below this threshold.

Table of Contents Summary

This prospective cross-sectional study of 248 patients with claudication found that 6-minute walk distance was greater in those who walked more than 7,000 and 10,000 steps/day than patients who walked fewer than 7,000 steps/day. Patients should be encouraged to walk more than 7,000 steps/day for better ambulatory function.

INTRODUCTION

Peripheral artery disease (PAD) is a significant medical concern, as it is highly prevalent worldwide,¹ costly,² and associated with a high rate of all-cause and cardiovascular mortality.³ The most common symptom of PAD is claudication,⁴ defined as lower extremity pain that is reproducibly induced by walking and relieved with rest, and which is secondary to inadequate arterial blood flow to the exercising leg musculature. Consequently, claudication pain impairs ambulation,⁵ physical function,^{6,7} daily physical activity,^{8,9} and health-related quality of life.¹⁰

Walking is the most common form of exercise performed by older adults,¹¹ and is the primary activity that elicits claudication in PAD patients. Therefore daily step counts is the most clinically relevant and appropriate metric to evaluate daily activity levels in PAD patients. Based on a comprehensive literature review, a range between 7,000 and 10,000 steps/day has been proposed as a daily step count goal for older adults,¹² as this range approximately translates to meeting the physical activity guidelines for US adults.¹³ Health benefits associated with meeting physical activity guidelines in older adults include weight loss, lower risk of falls and fall-related injuries, and lower risk of all-cause and disease-specific mortality.¹³ A lower step count range between 6,500 and 8,500 steps/day was proposed for individuals with disabilities and/or chronic diseases, but this was based on very limited data.¹² We^{9,14-17} and others¹⁸⁻²⁰ have found that daily step counts of PAD patients are below the 7,000 and 10,000 steps/day thresholds, and that PAD patients are much less likely to achieve these daily step count goals compared to age- and sex-matched controls.⁹ However, it is not clear whether attaining the 7,000 or 10,000 steps/day goals are associated with better ambulatory function and health-related quality of life (HRQoL) in PAD patients with claudication, particularly with the more realistic target of 7,000 step/day. The current investigation is focused to addresses this knowledge gap.

The aims of this investigation were to determine (a) whether PAD patients who walked at least 7,000 and 10,000 steps/day had better ambulatory function and HRQoL than patients

who walked less than 7,000 steps/day, and (b) whether differences in ambulatory function and HRQoL in patients grouped according to these daily step count criteria persisted after adjusting for demographic variables, comorbid conditions, and cardiovascular risk factors. We hypothesized that patients who walked at least 7,000 steps/day would have significantly better ambulatory function, as measured by greater 6-minute walk distance (6MWD), and better HRQoL, as measured by a higher distance score on the Walking Impairment Questionnaire (WIQ), than patients who walked less than 7,000 steps/day, and that patients who walked more than 10,000 steps/day would have the best values. Furthermore, we hypothesized that the group differences in these primary outcomes of ambulatory function and HRQoL would persist after adjustment for demographic variables, comorbid conditions and cardiovascular risk factors.

METHODS

Patients

Approval and Informed Consent.—The procedures of this study were approved by the institutional review boards from the University of Oklahoma Health Sciences Center (HSC). Written informed consent was obtained from each patient prior to beginning the investigation.

Recruitment and Screening.—PAD patients who had claudication (Fontaine Stage II and Rutherford Grade I)⁴ and who were not currently in an exercise program were recruited from the University of Oklahoma HSC vascular clinic and vascular laboratory for possible enrollment into the study. Patients did not have a history of previous or current participation in an exercise program or patient education program to improve physical activity. Patients were evaluated in the University of Oklahoma HSC Clinical Research Center, and were screened on inclusion and exclusion criteria that have been used in a previous study,²¹ and which are listed below to begin the study visit.

Inclusion and Exclusion Criteria.—Patients with PAD were included in this study if they met the following criteria: (a) a history of ambulatory leg pain, (b) ambulatory leg pain confirmed by treadmill exercise,⁵ and (c) an ankle/brachial index (ABI) ≤ 0.90 at rest²² or ≤ 0.73 after exercise.²³ Patients were excluded for the following conditions: (a) absence of PAD (ABI > 0.90 at rest and ABI > 0.73 after exercise), (b) non-compressible vessels (ABI > 1.40), (c) asymptomatic PAD (Fontaine Stage I; Rutherford Grade 0),²² (d) rest pain due to PAD (Fontaine stage III; Rutherford Grade II), (e) tissue loss due to PAD (Fontaine stage IV; Rutherford Grades III and IV), (f) use of medications indicated for the treatment of claudication (cilostazol or pentoxifylline) initiated within three months prior to investigation, (g) exercise limited by other diseases or conditions, (h) active cancer, and (i) stage 5 chronic kidney disease (end stage), as defined by an estimated glomerular filtration rate < 15 ml/min per 1.73 m.²⁴

Tests on Objective Measurements

Medical History and Physical Examination.—On the initial study visit, patients arrived in the morning fasted, but were permitted to take their usual medications. Vital signs,

demographic information, education level, height, weight, body mass index, anthropometric measurements, waist circumference, and ABI according to standard guidelines²⁵ were obtained by research personnel. Subsequently, patients had blood samples drawn by study nurses, which were then sent to a central lab for analyses for fasting blood chemistries. Patients then underwent a medical history and physical examination by study physicians, in which claudication history, co-morbid conditions, cardiovascular risk factors, and current medications were recorded. Patients were instructed to bring a list of their current medications, which was carefully reviewed by the study physicians. Based on this battery of baseline assessments, patients were coded on cardiovascular risk factors and co-morbid conditions according to standard definitions,²⁶ and patients were characterized on the presence, severity, and symptoms of PAD.

Maximal Treadmill Test.—Patients performed a standardized Gardner-Skinner graded treadmill test to determine study eligibility, and then repeated the test on a following visit within one week to obtain the outcome measures of claudication onset time and peak walking time, as previously described.⁵ Peak oxygen uptake was determined by oxygen uptake obtained during the peak exercise work load with a Medical Graphics VO2000 metabolic system (Medical Graphics Inc, St. Paul, MN). The measurement of claudication onset time, peak walking time, and peak oxygen uptake during our graded treadmill test are highly stable and reliable with repeat testing^{5,27}.

6-Minute Walk Test.—Patients performed a 6-minute walk test in which two cones were placed 100 feet apart in a marked corridor, as previously described.²⁸ The 6-minute walk pain-free distance as well as the 6MWD were recorded. After completing the 6-minute walk test, patients evaluated the level of difficulty of the test from a Borg Rating of Perceived Exertion scale.²⁹

Gait Speed, Cadence, and Stride Length from a 4-Meter Walk Test.—Gait speed was measured from a 4-meter walk test in a hallway.³⁰ This test was performed twice at usual walking pace, and the walk with the faster speed was used in the analyses. During this timed test, the number of footfalls over the 4-meter course were counted, and cadence and stride length were calculated.

Tests on Patient-Based Measurements

WIQ.—A patient-based, disease-specific measurement of HRQoL that focuses on ambulatory ability was obtained using a validated questionnaire for PAD patients that assesses ability to walk at various distances and speeds, and to climb stairs on a scale ranging from 0 to 100%, with higher scores reflecting better ability.³¹

Medical Outcomes Study Short-Form 36 (MOS SF-36 – Rand Version 1.0).—A patient-based, general measurement of HRQoL was assessed from this instrument.³² The MOS SF-36 is a reliable and valid generic instrument that includes multi-item questions, which assess eight health subscales. For each subscale, multiple item scores are standardized into a scale from 0 to 100, with higher scores reflecting better health states.

Activities of Daily Living (ADL).—Patient-based physical functioning was determined from six ADL's primarily requiring lower extremity function as the major component.³⁰ The ADL's consisted of walking across a small room, bathing, transferring from a bed to a chair, using the toilet, walking up and down stairs to the second floor without help, and walking a half mile without help.^{33,34} Patients selected one answer for each ADL from the following three possible choices: no difficulty, some difficulty, or unable to do.

Balance, Falls, and Physical Activity Status.—Balance and fall history were assessed by asking the patients if they had often stumbled or felt unsteady when they walked over the past year,³⁵ and whether they had fallen over the past year.³⁶ Additionally, patients were assessed on their perceived physical activity level with two questionnaires. The Johnson Space Center physical activity scale was used to assess the activity level of the patients over the preceding month.³⁷⁻³⁹ Patient-based physical activity level was also assessed using the Baltimore Activity Scale for Intermittent Claudication,^{40,41} consisting of items pertaining to the development of intermittent claudication, and the frequency of ambulating at a fast pace, up and down hills, and up and down flights of stairs during the previous week.

Daily Step Count Groups Determined from Ambulatory Activity Monitoring.

Daily walking was measured using a step activity monitor (StepWatch3,TM OrthoInnovations, Inc., Oklahoma City, OK), as we have previously described.^{9,14-17} Walking was measured during seven consecutive days in which patients were instructed to wear the monitor during waking hours and to remove it before retiring to bed and while showering. The patients were further instructed to engage in their normal routine daily activities, and were not given any daily step goals to attain, such as 7,000 or 10,000 steps/day. The step activity monitor does not display the number of steps taken, thereby blinding patients to their daily steps. The step activity monitor was attached to the right ankle above the lateral malleolus using an elastic Velcro strap, and continuously recorded the number of steps taken each day and the number of minutes spent walking each day. These outcome measures were recorded for each day in which the steps were obtained in many different daily environments encountered by the patients, such as walking inside and near their homes, walking while performing daily errands and trips, walking in the community, etc. The daily averages of the steps taken and minutes spent walking were then averaged over the seven-day monitoring period. The accuracy of the step activity monitor exceeds 99% ± 1% in patients with claudication, and the test-retest intraclass reliability coefficient for the measurement of daily step counts is $R = 0.87$.⁹ Based on previous goals of attaining at least 7,000⁴² and 10,000⁴³ steps/day, patients were grouped according to these daily step count targets. Patients who took fewer than 7,0 steps/day were included in Group 1, those who took 7,000 to 9,999 steps/day were included in Group 2, and patients who took at least 10,000 steps/day were included in Group 3.

Statistical Analyses

Summary statistics including means (standard deviations, SD) for continuous variables and frequencies with percentage (%) for categorical variables were presented by group (Table I). Group comparisons were performed based on ANOVA tests or Kruskal–Wallis tests for continuous variables and Pearson's Chi-square tests or Fisher exact tests for categorical

variables, as appropriate. If overall group effect was detected to be significant, post-hoc tests on pairwise comparisons (Group 2 vs Group 1; Group 3 vs Group 1) were further pursued. For each of ambulatory outcomes and patient-based health outcomes, we conducted two types of models to evaluate the difference between groups according to these daily step count targets, where Model 1 is univariable (unadjusted) regression, and Model 2 is multivariable regression adjusted for age, weight, sex, ABI, hypertension, diabetes, abdominal obesity, arthritis, and chronic obstructive pulmonary disease (Tables II and III). Age, weight, and sex were selected as covariates because we previously adjusted for these variables due to their significant associations with daily steps in PAD patients.¹⁷ The remaining covariates were selected because they were significantly different among the groups and are also associated with daily steps in PAD patients.¹⁷ The p-values in Model 1 and Model 2 are obtained from Type III tests based on F-test statistic. All hypothesis tests were two-sided with the significance level of 0.05. Data was analyzed using SAS 9.4 Software (SAS Institute, Cary, North Carolina).

RESULTS

The demographic and clinical characteristics of PAD patients grouped according to their daily step count are shown in Table I. By definition, the group main effect was significantly different on daily steps ($p < 0.01$), and the daily time of activity ($p < 0.01$). Additionally, the group main effect was significantly different on ABI ($p = 0.02$), and prevalence of hypertension ($p = 0.04$), diabetes ($p < 0.01$), abdominal obesity ($p < 0.01$), arthritis ($p = 0.04$), and chronic obstructive pulmonary disease ($p < 0.01$). The groups were similar on all of the remaining variables.

Ambulatory outcomes in PAD patients grouped according to their daily step count are shown in Table II. Each ambulatory outcome, except for stride length, was significantly different among the three groups in unadjusted analyses (model 1) and after adjusting for covariates (model 2). For pairwise group comparisons between Group 2 and Group 1, 6MWD, peak walking time, peak oxygen uptake, gait speed, cadence, and the percentage of patients who completed the 6-minute walk test without stopping were significantly higher in Group 2 in unadjusted analyses, but only 6MWD and peak walking time remained significantly higher in Group 2 in adjusted analyses. For pairwise group comparisons between Group 3 and Group 1, each ambulatory outcome, except for stride length, was significantly higher in Group 3 in unadjusted analyses, and 6MWD, peak walking time, peak oxygen uptake, gait speed, cadence, and the percentage of patients who completed the 6-minute walk test without stopping remained significantly higher in Group 3 in adjusted analyses.

Patient-based health outcomes in PAD patients grouped according to their daily step count are displayed in Table III. The WIQ distance score, WIQ speed score, WIQ stair climbing score, MOS SF-36 physical function score, physical activity score, BASIC score, and the ADL associated with stair climbing were significantly different among the three groups in both unadjusted (model 1) and adjusted (model 2) analyses. For pairwise group comparison between Group 2 and Group 1, 8 variables were significantly different in unadjusted analyses, with only the WIQ distance score and the MOS SF-36 physical function score remaining significant in adjusted analyses. For pairwise group comparison between Group 3

and Group 1, the WIQ distance score, WIQ speed score, WIQ stair climbing score, MOS SF-36 physical function score, physical activity score, BASIC score, and the ADL associated with stair climbing were significantly different in both unadjusted and adjusted analyses, whereas the MOS SF-36 general health score was only significant in the adjusted analyses.

DISCUSSION

This is the first study to compare PAD patients who met recommended daily step counts of 7,000 and 10,000 steps/day with those who walked fewer steps. A major finding was that PAD patients who walked at least 7,000 and 10,000 steps/day had greater values for the primary outcomes of 6MWD and WIQ distance score than patients who walked fewer than 7,000 steps/day. A second major finding was that after adjusting for covariates, values for 6MWD and WIQ distance score remained higher in patients who walked at least 7,000 and 10,000 steps/day.

Group Differences in Objectively Measured Ambulatory Outcomes

Patients who walked more than 7,000 and 10,000 steps/day had better objectively measured ambulation than patients who walked fewer than 7,000 steps/day, as the primary outcome of 6MWD was 21% and 32% higher, respectively. These relative differences corresponded to higher 6MWD values of 65 and 101 meters in the 7,000 and 10,000 steps/day groups, respectively, which are both considered clinically important as well as statistically significant.⁴⁴ Compared with an older, healthy control group who had a mean 6MWD of 416 meters,⁹ the patients in the current study who walked more than 10,000 steps/day had a similar mean 6MWD, whereas those who walked above and below 7,000 steps/day had lower mean 6MWD values of 38 and 103 meters, respectively. In addition to the 6MWD results in this study, a similar pattern of group differences was noted for peak walking time, as the patients who walked more than 7,000 and 10,000 steps/day had greater values than the patients who walked fewer than 7,000 steps/day by 109 and 217 seconds, respectively. The group differences for 6MWD and peak walking time persisted after adjusting for covariates, including ABI, indicating that walking above 7,000 and 10,000 steps/day was independently associated with better ambulatory function during endurance-related tests. Finally better ambulation associated with higher levels of daily walking were also noted for the 4-meter walk test, as faster walking speeds are positively associated with better health outcomes.³⁰ Gait speed and cadence were significantly higher in the patients who walked more than 7,000 and 10,000 steps/day than those who walked less than 7,000 steps/day, but these differences only remained for the 10,000 steps/day group after adjusting for covariates.

Group Differences in Patient-Based Outcomes

The trend for better objectively determined outcomes in the 7,000 and 10,000 steps/day groups was also found for the patient-based outcomes. The patient-based WIQ distance score was the primary outcome, and was 15 and 17 percentage points higher in the 7,000 and 10,000 steps/day groups than the more sedentary group, respectively. These statistically significant group differences represent a moderate clinically important difference, as we have previously shown that a moderate difference for the WIQ distance score is 15

percentage points.⁴⁵ Furthermore, the significant group differences in the WIQ distance score remained after adjusting for covariates, including ABI, indicating that walking above 7,000 and 10,000 steps/day was independently associated with better self-perceived ability to walk various distances. Group differences after adjusting for covariates were also found for the WIQ speed and stair climbing scores, the MOS SF-36 physical function score and general health score, the physical activity score, the BASIC score, and the ADL associated with stair climbing. It is interesting to note that out of the many measurements obtained from the MOS SF-36 and ADL tests, the adjusted variables that were different among the groups were those related to walking, such as the MOS SF-36 physical function score and the ADL associated with stair climbing. Thus, walking more than 7,000 and 10,000 steps/day was independently associated with better scores on a variety of patient-based outcomes, and this finding is in agreement with better performance on objectively determined outcomes such as 6MWD and peak walking time.

Clinical Significance of Attaining 7,000 and 10,000 Daily Step Counts

This is the first study to report that better ambulatory function and HRQoL of PAD patients is associated with meeting the daily step count goals of 7,000 and 10,000 steps/day. In addition to these functional benefits, there are health benefits in adults associated with meeting these daily steps count goals. For example, accumulating between 7,000 and 10,000 steps/day translates to meeting the physical activity guidelines for US adults,¹² which is associated with numerous health benefits such as weight loss, lower risk of falls and fall-related injuries, and reduced risk of all-cause and disease-specific mortality.¹³ Furthermore, a position stand from the American College of Sports Medicine reports that walking at least 7,000 steps/day is associated with improving and maintaining cardiorespiratory, musculoskeletal, and neuromotor fitness.⁴² Finally, walking more than 10,000 steps/day is associated with better blood pressure and body mass index.⁴³ These findings suggest that PAD patients might also improve cardiovascular risk factors and fitness by reaching these daily step count goals.

Walking at least 7,000 steps/day is particularly challenging in PAD patients due to claudication, as evident by the current study in which 62% of the patients were below this step count target. Therefore, a more realistic approach to these absolute walking goals may be to have patients increase their daily step counts by 2,000 steps/day, regardless of their baseline step count. Each 2,000 daily step increment is associated with a 10% lower cardiovascular event rate, and an 8% annual reduction in cardiovascular event rate in people with impaired glucose tolerance,^{46,47} as well as a 29% reduction in 6-year metabolic syndrome score,⁴⁸ a 25% decrease in 5-year incidence of dysglycemia,⁴⁹ and a 5.5% lower risk of incident type 2 diabetes.⁵⁰ Most importantly, these benefits have a linear dose-response relationship, indicating that some benefit is achieved even without increasing the amount of walking by 2,000 steps/day. Thus, PAD patients may experience some of these health benefits by only increasing their daily step count by 1,000 steps/day. This could be accomplished by walking approximately 15 more minutes each day, and is congruent with the recently updated physical activity guidelines for US adults¹³ that engaging in at least some physical activity is good compared to no physical activity.

Limitations

There are several limitations to this study. A common limitation with clinical studies is that there may have been a self-selection bias regarding study participation. Individuals who agreed to participate were volunteers and may have been more affluent. Consequently, they may have had the most interest in clinical research, the most time to spend, the best access to transportation to the research center, and the best health compared with non-volunteers. Furthermore, the results of this study are only generalizable to patients with claudication and not to individuals with different stages of PAD, such as those with asymptomatic PAD or critical limb ischemia. Although peripheral neuropathy was evaluated with the purpose of excluding patients if it limited exercise, we did not quantify the magnitude of neuropathy. Given that we adjusted groups for diabetes status, we believe peripheral neuropathy had minimal impact on the study outcome measures. There are limitations associated with the cross-sectional design of the study. Significant differences found in the variables among the three daily step count groups of patients does not provide evidence of causality, even with statistical adjustment of covariates in multivariable models. Additionally, although our analyses were adjusted for covariates, it is possible that statistically significant findings are due to confounding variables that were not measured or to residual confounding. Although these limitations exist, we believe that the findings of the present study are generalizable to the large number of patients with claudication because of the relatively high prevalence of cardiovascular risk factors, such as hypertension, dyslipidemia, diabetes, obesity, abdominal obesity, and metabolic syndrome. These comorbid conditions are typically observed in PAD patients in the clinical setting.

Conclusion and Clinical Significance

In conclusion, PAD patients who walked more than 7,000 and 10,000 steps/day had greater ambulatory function and HRQoL than patients who walked fewer than 7,000 steps/day. Secondly, the greater ambulatory function and HRQoL associated with walking 7,000 and 10,000 steps/day persisted after adjusting for covariates. This study provides preliminary evidence that PAD patients who walk more than 7,000 steps/day have better ambulatory function and HRQoL than patients below this threshold.

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ARTICLE HIGHLIGHTS**Type of Research:**

Single-center, prospective, cross-sectional study.

Key Findings:

Patients with claudication were grouped on daily step counts according to the following: (Group 1: <7,000 steps/day, Group 2: 7,000-9,999 steps/day, Group 3: > 10,000 steps/day). 6-minute walk distance was greater ($p<0.01$) in Groups 2 and 3 than Group 1 (Group 1=313±90 m, Group 2=378±84 m, Group 3=414±77 m).

Take home Message:

Patients with claudication who walked more than 7,000 and 10,000 steps/day had greater ambulatory function than patients who walked fewer than 7,000 steps/day. Secondly, greater ambulatory function associated with walking 7,000 and 10,000 steps/day persisted after adjusting for covariates.

Table I.

Demographic and clinical characteristics of patients with peripheral artery disease grouped according to their daily step count. Values are means (standard deviation) or number and percentage of patients.

Variables	Group 1 (< 7,000 Steps/Day) (n=153)	Group 2 (7,000 to 9,999 Steps/Day) (n = 57)	Group 3 (≥ 10,000 Steps/Day) (n = 38)	P Value
<u>Values are Means (SD)</u>				
Age (years)	65.8 (10.1)	66.7 (9.9)	64.4 (9.3)	0.65
Weight (kg)	83.5 (20.4)	84.2 (13.1)	78.2 (15.0)	0.20
Height (cm)	168.0 (9.7)	170.4 (8.9)	166.7 (8.6)	0.94
Body Mass Index	29.5 (6.4)	29.2 (5.3)	28.2 (5.7)	0.27
Ankle/Brachial Index	0.66 (0.23)	0.69 (0.18)	0.74 (0.19)	0.02
Daily Steps	4644 (1503)	8342 (813)	12568 (2398)	< 0.01
Daily Time of Activity (min/day)	215 (67)	342 (55)	420 (77)	< 0.01
<u>Values are Number (Percentage %) with Characteristic Present</u>				
Sex (Men)	72 (47.1)	35 (61.4)	21 (55.3)	0.16
Race				0.14
Caucasian	88 (57.5)	24 (42.1)	20 (52.6)	
African-American	59 (38.6)	30 (52.6)	10 (26.3)	
Hispanic	2 (1.2)	2 (3.5)	5 (13.2)	
American Indian	4 (2.6)	1 (1.8)	3 (7.9)	
Education (High school graduate)	121 (79.1)	50 (87.7)	30 (79.0)	0.22
Current Smoking	57 (37.2)	23 (40.4)	11 (28.9)	0.57
Hypertension	136 (88.9)	53 (93.0)	29 (76.3)	0.04
Dyslipidemia	141 (92.2)	48 (84.2)	34 (89.5)	0.23
Diabetes	76 (49.7)	22 (38.6)	6 (15.8)	< 0.01
Obesity	74 (48.4)	22 (38.6)	13 (34.2)	0.19
Abdominal Obesity	90 (58.8)	29 (50.9)	10 (26.3)	< 0.01
Metabolic Syndrome	128 (83.7)	44 (77.2)	28 (73.7)	0.29
Arthritis	85 (55.6)	27 (47.4)	28 (73.7)	0.04
Chronic Obstructive Pulmonary Disease	43 (28.1)	7 (12.3)	16 (42.1)	< 0.01

Table II.

Ambulatory outcomes in patients with peripheral artery disease grouped according to their daily step count. Values are means (standard deviation) or number and percentage of patients in each group.

Variables	Group 1 (< 7,000 Steps/Day) (n = 153)	Group 2 (7,000 to 9,999 Steps/Day) (n = 57)	Group 3 (> 10,000 Steps/Day) (n = 38)	Model 1 P Value	Model 2 P Value
Treadmill Test					
Claudication Onset Time (sec)	201 (185)	210 (121)	273 (188) *	0.04	0.03
Peak Walking Time (sec)	356 (249)	465 (257) ** ††	573 (314) ** ††	< 0.01	< 0.01
Peak Oxygen Uptake (ml/kg/min)	11.7 (3.5)	13.1 (3.0) **	14.1 (4.2) **†	< 0.01	< 0.01
6-Minute Walk Test					
Pain-Free Distance (m)	172 (112)	185 (101)	218 (123) *	0.05	0.04
Total Walk Distance (m)	313 (90)	378 (84) **††	414 (77) ** ††	< 0.01	< 0.01
Rating of Perceived Exertion score	13.7 (2.8)	13.4 (2.1)	12.6 (2.4) *	0.05	0.04
Continuous Walking §	61 (39.9)	37 (64.9) **	27 (71.0) **††	< 0.01	< 0.01
4-Meter Walk Test					
Gait Speed (m/sec)	1.04 (0.20)	1.11 (0.20) *	1.19 (0.18) **†	< 0.01	< 0.01
Cadence (steps/stride)	51.4 (6.9)	53.5 (4.6) *	55.6 (3.4) **††	< 0.01	< 0.01
Stride Length (m/stride)	1.22 (0.25)	1.27 (0.21)	1.29 (0.19)	0.11	0.09

Different than Group 1 in unadjusted model:

* p < 0.05

** p < 0.01.

Different than Group 1 in adjusted model:

† p < 0.05

†† p < 0.01.

§ Values are number (%) of patients who completed the 6-minute walk test without stopping.

Model 1: unadjusted.

Model 2: adjusted for age, weight, sex, ankle/brachial index, hypertension, diabetes, abdominal obesity, arthritis, and chronic obstructive pulmonary disease.

Table III.

Patient-based health outcomes in patients with peripheral artery disease grouped according to their daily step count. Values are means (standard deviation) or number and percentage of patients in each group.

Variables	Group 1 (<i>< 7,000 Steps/Day</i>) (n=153)	Group 2 (<i>7,000 to 9,999 Steps/Day</i>) (n = 57)	Group 3 (<i>> 10,000 Steps/Day</i>) (n = 38)	Model 1 P Value	Model 2 P Value
Medical Outcomes Short Form-36 Questionnaire					
Physical Function Score (%)	41 (20)	50 (20) ^{***††}	56 (23) ^{***††}	< 0.01	< 0.01
Role-Physical Score (%)	43 (41)	59 (41)	51 (43)	0.08	0.07
Bodily Pain Score (%)	60 (24)	63 (22)	64 (24)	0.27	0.19
General Health Score (%)	55 (23)	63 (22)	60 (19) [†]	0.08	0.04
Social Function Score (%)	80 (25)	84 (23)	75 (26)	0.58	0.59
Role-Emotional Score (%)	73 (41)	79 (34)	75 (39)	0.47	0.52
Mental Health Score (%)	78 (17)	78 (16)	77 (20)	0.81	0.81
Vitality Score (%)	54 (22)	61 (18)	57 (22)	0.11	0.08
Walking Impairment Questionnaire					
Distance Score (%)	30 (30)	45 (35) ^{**†}	47 (34) ^{***††}	< 0.01	< 0.01
Speed Score (%)	28 (22)	37 (26) [*]	46 (26) ^{***††}	< 0.01	< 0.01
Stair Climbing Score (%)	33 (288)	45 (29) ^{**}	44 (29) [†]	0.01	< 0.01
Physical Activity, Falls					
Physical Activity Score	1.3 (0.8)	1.7 (1.5) [*]	1.9 (1.3) ^{**†}	< 0.01	< 0.01
BASIC Score	2.4 (1.9)	3.1 (2.1) ^{**}	3.7 (1.7) ^{***††}	< 0.01	< 0.01
Falling History, n (%)	45 (29.4)	11 (19.3)	9 (23.7)	0.31	0.37
Fear of Falling, n (%)	38 (24.8)	14 (24.6)	13 (34.2)	0.52	0.29
Stumble/Unsteady While Walking, n (%)	52 (34.0)	19 (33.3)	16 (42.1)	0.63	0.62
Activities of Daily Living (ADL) [§]					
ADL 1 – Walking/Room	20 (13.1)	4 (7.0)	4 (10.5)	0.44	0.75
ADL 2 – Bathing	31 (20.3)	4 (7.0) [*]	4 (10.5)	0.03	0.08
ADL 3 – Transferring	12 (7.8)	4 (7.0)	2 (5.3)	0.85	0.97
ADL 4 – Toileting	13 (8.5)	3 (5.3)	1 (2.6)	0.33	0.59
ADL 5 – Stairs	116 (75.8)	34 (59.6) [*]	23 (60.5) ^{**††}	0.03	0.02
ADL 6 – Walk Half Mile	131 (85.6)	44 (77.2)	28 (73.7)	0.13	0.19

[§]Values are number (%) of patients who have some difficulty or unable to do each ADL.

BASIC = Baltimore activity scale for intermittent claudication.

Different than Group 1 in unadjusted model:

* p < 0.05

** p < 0.01.

Different than Group 1 in adjusted model:

\dagger
 $p < 0.05$

$\dagger\dagger$
 $p < 0.01$.

Model 1: unadjusted. Model 2: adjusted for age, weight, sex, ankle/brachial index, hypertension, diabetes, abdominal obesity, arthritis, and chronic obstructive pulmonary disease.

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