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Section: Original Research

Article Title: Barriers and Levels of Physical Activity in Symptomatic Peripheral Artery Disease Patients: Comparison Between Women and Men

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Running Head: Sexes differences in barriers to PA in PAD

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Original Article BARRIERS AND LEVELS OF PHYSICAL ACTIVITY IN SYMPTOMATIC PERIPHERAL ARTERY DISEASE PATIENTS: COMPARISON BETWEEN WOMEN AND MEN

Running head: Sexes differences in barriers to PA in PAD

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ABSTRACT

This cross-sectional study compared physical activity levels and barriers between 212 men and women with symptomatic peripheral artery disease (PAD). Physical activity was objectively measured by an accelerometer. Barriers to physical activity were obtained using a validated questionnaire. Women reported higher amounts of light physical activity (P<0.001) and lower moderate to vigorous physical activity (P<0.001) than men. Women more often reported barriers such as "not having anyone to accompany" (P=0.006), "lack of money" (P=0.018), "fear of falling or worsening the disease" (P=0.010), "lack of security" (P=0.015), "not having places to sit when feeling leg pain" (P=0.021), and "difficulty in getting to a place to practice physical activity" (P=0.015). In conclusion, women with symptomatic PAD presented with lower amounts of moderate to vigorous activity and more barriers to activity than men. Strategies to minimize the barriers, including group actives and non-painful exercises are recommended for women with PAD.

Keywords: exercise, walking; exercise, intermittent claudication, peripheral arterial disease.

INTRODUCTION

Peripheral artery disease (PAD) affects more than 202 million people globally (Fowkes et al., 2013). Intermittent claudication (IC), the main symptom of PAD, is defined as muscle discomfort in the legs caused by exercise and is relieved by short periods of rest (Norgren et al., 2007). IC reduces walking capacity and daily physical activity levels (Sieminski & Gardner, 1997) leading to a progressive deconditioning cycle that impairs aerobic (Ritti-Dias et al., 2009) and muscle (Basyches et al., 2009) functions, affecting the quality of life (Menêses et al., 2011).

Increasing physical activity levels is considered a main objective in the treatment of PAD patients (Norgren et al., 2007). However, few patients have effectively achieved the recommended physical activity levels. In this context, identifying barriers to physical activity practice has been considered important in order to find potential factors that can affect physical activity practice in PAD patients (Barbosa et al., 2015; Bentley & Kelechi, 2018; Cavalcante et al., 2015; Galea, Bray, & Ginis, 2008).

Sex plays an important role in PAD (Schramm & Rochon, 2018). Women with PAD suffer more from the consequences of the disease than men, presenting with worse microvascular function, slower walking speed, and a shorter absolute 6 min walk distance (Gardner, 2002; Gardner, Montgomery, Blevins, & Parker, 2010; Gardner, Parker, et al., 2010; Gardner et al., 2015; Jackson et al., 2014). In addition, a previous study observed an 18% lower total daily activity level in women than in men (Gardner, 2002), and that women ambulate at a slower pace during daily activities than men (Gardner, Parker, et al., 2010). Interestingly, the reasons for these lower physical activity levels are unknown. In a previous study it was observed that women with PAD are 72% less likely to get out the house at least once per week, 189% less likely to leave their neighborhood at least once per week, and 66% less likely to sweat at least once per week than women without PAD (McDermott et al., 2002). Therefore, it

is possible that women with PAD experience more barriers to daily life physical activities than men.

Understanding the barriers to physical activity is useful to develop strategies to increase physical activity levels. The aim of the present study was to compare the physical activity levels and the physical activity barriers between men and women with symptomatic PAD.

METHODS

Study design, ethical issues, and patients

This cross-sectional study was conducted in line with the STROBE checklist. Patients with symptomatic PAD were recruited at tertiary vascular disease treatment centres. The inclusion criteria were as follows: a) age > 50 years with symptomatic PAD (i.e. intermittent claudication symptoms) in one or both legs; b) ankle brachial index <0.90; c) absence of critical limb ischemia, rest pain, non-compressible vessels, amputated limbs, and/or ulcers, and; d) absence of pulmonary diseases. Patients were excluded if they accumulated less than 4 days of accelerometer use (10 hours/day), did not use the accelerometer at least 1 day over a weekend, or did not provide sufficient data related to physical activity barriers in the questionnaire.

The study was approved by the Ethics Committee in Research and it was performed according to the International Ethics Standards and conforms to the Helsinki Declaration. All patients provided written informed consent to participate in this study.

Data collection

Data collection was prospectively performed between September 2015 and January 2017. Measurements were performed in two visits. On the first visit, patients were screened with a medical history evaluation, assessed on their sociodemographic data, and received the accelerometer. On the second visit, patients completed a complete evaluation including the assessment for barriers for physical activities.

Measurements

Clinical data

Sociodemographic, comorbidity, and medication information were obtained through a face-to-face interview. Sociodemographic and risk factor variables obtained were as follows: sex (predictor variable), age, education status (incomplete high school, high school or more), history of smoking habits (ex-, current-, or never-smoker), obesity (body mass index (BMI) \geq 30 kg/m²), diabetes (physician-diagnosed or use of glucose lowering drugs), hypertension (systolic/diastolic blood pressure \geq 140/90 mmHg or use of antihypertensive drugs), dyslipidemia (physician-diagnosed or use of lipid lowering drugs), coronary heart disease, heart failure, and cerebrovascular disease. Body weight was measured via a calibrated scale to the nearest 0.1 kg, whereas height was measured with a stadiometer to the nearest 0.01 m. Body mass index was calculated as body weight divided by height in meters squared.

PAD severity was identified by a single evaluator using the ankle-brachial index in accordance with standardized guidelines (Aboyans et al., 2012). Briefly, ankle brachial index was measured as the highest systolic blood pressure in the posterior tibial or dorsalis pedis artery divided by the highest systolic blood pressure in the brachial artery. The blood pressure measurements were recorded in both limbs using a Doppler vascular monitor (legs) (Medmega DV160, Brazil) and a mercury sphygmomanometer (arms).

Barriers to physical activity (Primary outcome)

Personal barriers to physical activity were assessed by a questionnaire previously used for PAD patients (Barbosa et al., 2015; Cavalcante et al., 2015), which included the following items: fatigue, lack of time, not having anyone to accompany them in physical activity, not having enough money to practice physical activity, lack of knowledge and uncertainty regarding the benefits of physical activity, being afraid of falling, and having urinary incontinence. In addition, specific barriers for PAD patients (lack of physical energy, needing to rest because of pain, and pain induced by walking) were also included.

Environmental barriers were assessed using a previously validated questionnaire including the following barriers: lack of security in the environment, inclement weather conditions, lack of green areas, lack of flat streets, lack of satisfactory sidewalks, lack of street crosswalks, the presence of obstacles that exacerbate leg pain (e.g., hills and stairs), not having places to sit when feeling leg pain, vehicular traffic that hinders locomotion, and difficulty in getting to a place where physical activity can be performed. For all barrier questions, the patients reported whether each barrier affected their ability to practice physical activity (closed "yes or no" answers).

The indicators of reliability between questions involving the personal barriers ranged from 0.48 (lack of knowledge about benefits of physical activity) to 0.91 (other disease, injury, or disability). For the environmental barriers, the values ranged from 0.25 (difficulty in getting to the location) to 0.92 (vehicular traffic disrupts their walking) (Barbosa et al., 2015).

Physical activity level (Secondary outcome)

Physical activity was recorded using a GT3X+ triaxial accelerometer (Actigraph, Pensacola, FL, USA) at a sampling rate of 60 Hz. Each patient was instructed to use the accelerometer for 7 consecutive days, taking it off only when sleeping, bathing, or performing activities in the water. The device was attached to an elastic belt and fixed to the right side of the hip. Following recordings, data were uploaded and analyzed as 60 sec epochs via Actilife software, version 6.02 (Actigraph, Pensacola, FL, USA). Periods that contained consecutive values of 0 for 60 min or longer were interpreted as "accelerometer not worn" and such patients excluded from analyses. Physical activity data were included only if the patient had accumulated a minimum of 10 hours/day of recording for at least 4 days, including 1 weekend

day. Using previously reported cut off thresholds for older people (Copeland & Esliger, 2009) (i.e. light physical activity as 100–1041 counts/min, moderate-to-vigorous physical activity as \geq 1041 counts/min), total daily physical activity levels and levels within each physical activity category (i.e. light and moderate-vigorous) were calculated and expressed as minutes of physical activity per day.

Statistical analysis

The sample size was estimated based in a previous study that compared the physical activity level between men and women PAD patients (Gardner, Parker, et al., 2010). Considering a power of 80, an alpha error of 0.05, and an effect size of 0.85, the minimum sample per group was of 23 subjects.

The Gaussian distribution and the homogeneity of variance of the data were confirmed by Kolmogorov-Smirnov and Levene tests. The chi-square test was used to compare the prevalence of physical activity barriers, risk factors, and medication between men and women. The independent t-test was used to compare men and women in terms of the continuous variables.

Crude and adjusted analyses were performed by binary logistic regression to analyze the relationship between barriers to physical activity and sex. Male and negative answers to the barriers were taken as references. The stepwise backward-forward modeling was performed, and 2 models were presented. The first model had age, ankle brachial index, body mass index, presence of cancer, presence of chronic obstructive pulmonary disease, and presence of coronary arterial disease as adjusts. The second model had age, ankle brachial index, body mass index, presence of cancer, presence of chronic obstructive pulmonary disease, presence of coronary arterial disease, and total physical activity as they are classic confounding variables as reported by Barbosa et al., (2015). Residual analysis, multicollinearity (VIF >5), tolerance, and Hosmer-Lemeshow tests were performed to confirm the quality of the associations.

The significance level was set at $P \le 0.05$. The data are presented as mean, standard deviation, or relative frequency. All analyzes were performed using IBM SPSS Statistics, version 20.0.

RESULTS

From the 262 patients initially enrolled in the present study, 44 did not meet the inclusion criteria and 23 did not attend the second visit. Therefore, 195 patients were included in the analyses. Table 1 shows clinical characteristics of the patients. The age range was 43 to 96 years (95% confidence interval 65.6 - 67.9 years); on average, patients were overweight and presented with several risk factors such as hypertension, dyslipidemia, and diabetes mellitus.

Table 2 shows comparison of objective physical activity levels between the sexes. Women presented with lower amounts of sedentary time (P=0.010) and higher amounts of light physical activity (P<0.001), whereas men presented higher amounts of moderate to vigorous physical activity (P<0.001).

Table 3 shows the personal and environmental barriers to physical activity in men and women. Compared to men, women more often reported the following barriers: "not having anyone to accompany" (P=0.006), "lack of money" (P=0.018), "fear of falling or worsening the disease" (P=0.010), "lack of security" (P=0.015), "not having places to sit when feeling the pain in the leg" (P=0.021), and "difficulty in getting to a place to practice physical activity" (P=0.015). Men, more often than women, reported the barrier "lack of green areas" (P=0.019).

Table 4 shows the adjusted binary logistic regression between the barriers of physical activity and sex. All the barriers reported more often by women remained significant even

when adjusted by age; ankle brachial index; body mass index; presence of cancer; presence of chronic obstructive pulmonary disease, and; presence of coronary arterial disease (model 1) and all previous adjustments plus physical activity levels (model 2) (P<0.039). On the other hand, when adjusted for in model 1 and 2, "lack of green areas" lost it significance (P>0.137) and the findings were similar between men and women.

DISCUSSION

The main results of the study were as follows: (i) women spend more time performing light physical activity then men; (ii) men presented with more sedentary time and spend more time performing moderate to vigorous physical activity than women; (iii) women reported more barriers to physical activity in comparison with men.

Women spent more time performing light physical activities and less time on moderate and vigorous physical activities than men. Previous studies have shown claudication symptoms are anticipated in women compared to men (Gardner, 2002), and the higher time spent performing light physical activities by women might be a strategy to avoid the occurrence of claudication symptoms. Although recent evidences have suggested a possible benefit of light physical activity for cardiovascular health (Gerage et al., 2015; Healy et al., 2008; Kim, Tanabe, Yokoyama, Zempo, & Kuno, 2013), moderate and vigorous physical activities have been shown to have a crucial impact on cardiovascular profile (Andersson et al., 2015; Horta et al., 2015). Therefore, PAD women's daily physical activity profile probably has a limited impact in their cardiovascular health.

Previous studies in PAD patients have shown that the main barriers for physical activity practice were related to claudication symptoms (Barbosa et al., 2015; Galea et al., 2008). This was confirmed in this study, as several barriers related to claudication symptoms, such as "obstacles that exacerbate leg pain", "not having places to sit when feeling the pain in the leg",

and "exercise induced leg pain", were reported by more than 60% of patients of both sexes. These results reinforce the important role of claudication symptoms in the physical inactivity of PAD patients, suggesting that interventions that minimize claudication pain might be useful to improve physical activity patterns in these patients.

The main novelty of this study was the comparison of barriers for physical activity between men and women with PAD. The results indicated that women with PAD report more barriers for physical activity practice than men. Among the 20 barriers of physical activity analyzed, 6 barriers were significantly more frequent in women than men. These barriers included the personal barriers (not having anyone to accompany, lack of money, and fear of falling and worsening the disease) and environmental barriers (lack of security, not having places to sit when feeling pain in the leg, and difficulty in getting to a place to practice physical activity) that are related to difficulties in getting to a place to practice regular exercises. Given that regular exercise is the most frequent mode of moderate to vigorous physical activities; it explains in part the lower time spent on these activities in women than men.

The results of the present study have significant practical applications to promote physical activity in men and women with symptomatic PAD. Barriers related to claudication symptoms were very frequent in both men and women with PAD. Therefore, non-painful modes of exercise (arm-crank exercise and resistance exercise) or walking without pain could potentially increase physical activity levels in PAD patients with intermittent claudication symptoms. We also found that a lack of someone to accompany them is a frequent barrier in women, which suggests that implementation of group activities could be useful in this group. Finally, women also reported finding it difficult to get to a place to practice physical activity and a lack of security, suggesting that home-based programs based on functional daily activities could also be useful in women with PAD.

This study has limitations that are worth highlighting. This is a double center study in a single city, and the results should be carefully extrapolated for other patients. The crosssectional design did not allow us to determinate causality. The sample included only patients with PAD and intermittent claudication symptoms and the results should not be extrapolated to asymptomatic patients. Although accelerometer has been considered a gold standard method to measure physical activity in free living conditions, it was not possible to measure the type and the context in which physical activity was performed.

In conclusion, women with PAD and claudication symptoms report more physical activity barriers when compared to men, which can explain, in part, their lower moderate to vigorous physical activity levels. Strategies to minimize these barriers could be useful to improve physical activity levels in women.

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Variables	Women	Men	Р	
	n=72	n=123		
Age, years	66.1 (9.7)	66.8 (9.5)	0.586	
Body mass index, kg/m ²	27.9 (5.5)	27.4 (4.3)	0.527	
Ankle brachial index	0.57 (0.16)	0.58 (0.16)	0.673	
Risk factors				
Current smokers, %	21.7	22.1	0.950	
Hypertension, %	87.1	86.7	0.925	
Diabetes mellitus, %	53.6	50.4	0.672	
Dyslipidemia, %	86.8	82.2	0.415	
Coronary disease, %	27.3	33.3	0.395	

Table 1. Clinical characteristics of peripheral artery disease patients and intermittent claudication symptoms.

Data presented as mean (standard deviation) or relative frequency.

Table 2: Number of mentioned barriers and physical activity levels of women and men with peripheral artery disease and intermittent claudication symptoms.

Variables	Women	Men	Mean	050/01	Effect size	Р
	n=72	n=123	Difference	95%CI		
Sedentary time, min/week	4285 (984)	4638 (745)	-352	-598 to -107	0.42	0.010
Light physical activity, min/week	2101 (733)	1714 (565)	386	202 to 571	0.62	< 0.001
Moderate-vigorous physical activity, min/week	77 (106)	126 (125)	-49	-84 to -14	0.42	< 0.004

Data presented as mean (standard deviation). 95% CI – 95% confidence interval

Women	Men	D	
n=72	n=123	Р	
26.4	27.6	0.849	
63.9	51.6	0.097	
54.2	34.1	0.006	
63.9	46.3	0.018	
72.2	75.4	0.624	
45.8	47.5	0.818	
68.1	69.9	0.786	
62.5	65.0	0.721	
72.2	53.7	0.010	
73.6	56.1	0.015	
68.1	54.5	0.062	
63.9	57.7	0.396	
88.9	80.5	0.126	
81.9	66.7	0.021	
40.3	48.0	0.238	
34.7	52.0	0.019	
62.0	43.9	0.015	
	n=72 26.4 63.9 54.2 63.9 72.2 45.8 68.1 62.5 72.2 73.6 68.1 63.9 88.9 81.9 40.3 34.7	n=72 n=123 26.4 27.6 63.9 51.6 54.2 34.1 63.9 46.3 72.2 75.4 45.8 47.5 68.1 69.9 62.5 65.0 72.2 53.7 73.6 56.1 68.1 54.5 63.9 57.7 88.9 80.5 81.9 66.7 40.3 48.0 34.7 52.0	

Table 3: Frequency of reported barriers to physical activity (PA) of women and men with peripheral artery disease and intermittent claudication symptoms.

Data presented as relative frequency. PA: physical activity

	Model 1			Model 2		
Independent Variables	OR	CI 95%	Р	OR	CI 95%	Р
Lack of physical energy	1.540	0.76; 3.08	0.222	1.664	0.82; 3.39	0.161
Not having anyone to accompany	2.822	1.40; 5.68	0.004	2.525	1.24; 5.16	0.011
Lack of money	2.113	1.04; 4.29	0.039	2.177	1.06; 4.48	0.035
Fear of falling or worsen the disease	2.317	1.13; 4.78	0.022	2.327	1.12; 4.85	0.024
Lack of security	2.341	1.11; 4.92	0.025	2.407	1.13; 5.12	0.023
Inclement weather conditions	1.756	0.88; 3.52	0.112	1.939	0.95; 3.98	0.071
Obstacles that exacerbate leg pain	1.895	0.71; 5.05	0.201	1.910	0.70; 5.20	0.205
Not have places to sit when feel the pain in the leg	3.103	1.34; 7.19	0.008	2.817	1.20; 6.61	0.017
Lack of green areas	0.592	0.30; 1.18	0.137	0.626	0.31; 1.26	0.191
Difficulty in getting to a place to practice PA	2.447	1.21; 4.93	0.012	2.436	1.19; 4.98	0.015

Table 4: Adjusted binary logistic regression modeling for the association between barriers to physical activity and genders.

PA – physical activity. Associations for female patients (male = reference) and positive answers for the barriers (no = reference);

Model 1: adjusted by age; ankle brachial index; body mass index; presence of cancer; presence of chronic obstructive pulmonary disease, and; presence of coronary arterial disease.

Model 2: adjusted by age, ankle brachial index; body mass index; presence of cancer; presence of chronic obstructive pulmonary disease; presence of coronary arterial disease, and; total physical activity per week.