THAÍS JORDÃO PEREZ SANT'ANNA

AVALIAÇÃO DE UM NOVO SENSOR DE MOVIMENTO EM PACIENTES COM DOENÇA PULMONAR OBSTRUTIVA CRÔNICA

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Dissertação apresentada ao Programa de Pós-Graduação em Ciências da Reabilitação (Programa Associado entre Universidade Estadual de Londrina [UEL] e Universidade Norte do Paraná [UNOPAR]), como requisito parcial à obtenção do título de Mestre em Ciências da Reabilitação.

Orientador: Prof. Dr. Fabio Pitta.

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Londrina, 29 de outubro de 2012.

Dedico este trabalho a meu pai Fernando e minha mãe Leila, além de também dedicá-lo com todo o carinho, a meus avós Hélio, Cida, Jacinto e Otília.

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“É preciso força pra sonhar e perceber que a
estrada vai além do que se vê”.
(Los Hermanos – Além do que se vê)

SANT'ANNA, Thaís Jordão Perez. **Avaliação de um novo sensor de movimento em pacientes com doença pulmonar obstrutiva crônica**. 2012. 59 f. Dissertação (Mestrado em Ciências da Reabilitação - Programa Associado entre UEL e UNOPAR) – Universidade Estadual de Londrina, Londrina, 2012.

RESUMO

Contextualização: Pacientes com doença pulmonar obstrutiva crônica (DPOC) são consideravelmente menos ativos na vida diária quando comparados a idosos saudáveis. A inatividade está associada a diversas complicações da doença, além de ser considerada o mais importante fator preditor de mortalidade em pacientes com DPOC. Por conta disso, sensores de movimento válidos e economicamente acessíveis são necessários para a monitorização da atividade física. **Objetivos:** Avaliar a validade e a reprodutibilidade do sensor de movimento Power Walker 610 (PW) em pacientes com DPOC. **Métodos:** Trinta pacientes com DPOC (17 homens, VEF_1 44±17% do predito) foram filmados enquanto realizavam dois protocolos de atividade física: um incluindo duas caminhadas lentas e duas caminhadas rápidas de 5 minutos e outro incluindo um circuito de atividades de vida diária (AVD). Concomitantemente, os pacientes utilizaram dois sensores de movimento: PW e SenseWear Armband (SAB, previamente validado para uso em pacientes com DPOC). Os desfechos do PW (contagem de passos [CP], gasto energético [GE], distância percorrida [DP], tempo de atividade [TA] e intensidade da caminhada [IC]) foram comparados ao vídeo e ao SAB como métodos critérios. **Resultados:** As correlações entre o PW e os métodos critérios foram altas para a CP durante as caminhadas lentas e rápidas (r=0,79 e 0,95) e para GE durante a caminhada rápida (r=0,83). A correlação foi mais modesta para GE durante a caminhada lenta (r=0,65) e para DP e IC durante as duas velocidades (0,47<r<0,68). O aparelho foi reprodutível quanto ao registro de CP, DP e GE durante a caminhada lenta e para todas as variáveis durante a caminhada rápida (CCI>0,79 para todas). Já durante o circuito de AVD, o PW subestimou em média 55% o TA, mas obteve uma estimativa aceitável do GE para o grupo como um todo (diferença média de 6% quando comparado ao SAB). **Conclusões:** Em pacientes com DPOC, o PW é reprodutível para a maioria dos seus desfechos e válido para a contagem de passos durante caminhadas lentas e rápidas e para estimativa do gasto energético durante caminhadas rápidas. A validade do aparelho é mais limitada para estimar o gasto energético durante a caminhada lenta e a distância percorrida e intensidade da caminhada nas duas velocidades. Durante a realização de AVDs, o PW subestima significativamente o tempo de atividade, mas fornece um estimativa aceitável do gasto energético no grupo como um todo.

Palavras-chave: Doença pulmonar, obstrutiva crônica. Atividade motora. Monitorização ambulatorial. Pedômetro. Estudos de validação.

SANT'ANNA, Thaís Jordão Perez. **Evaluation of a new motion sensor in patients with chronic obstructive pulmonary disease**. 2012. 59 f. Dissertação (Mestrado em Ciências da Reabilitação - Programa Associado entre UEL e UNOPAR) – Universidade Estadual de Londrina, Londrina, 2012.

ABSTRACT

Background: Patients with chronic obstructive pulmonary disease (COPD) are considerably less active in daily life in comparison to healthy individuals. The inactivity is associated with several complications of the disease, besides being the strongest predictor of mortality in patients with COPD. Therefore, valid and economically affordable motion sensors for physical activity monitoring are needed. **Purpose:** We aimed to evaluate the criterion validity and reproducibility of the Power Walker 610 motion sensor (PW) in patients with COPD. **Methods:** Thirty patients with COPD (17 male, FEV_1 44±17% predicted) were videotaped while performing two protocols of physical activity: one including two slow and two fast 5-minute walks, and another including a circuit of activities of daily living (ADL). Concomitantly, patients wore two motion sensors: PW and SenseWear Armband (SAB, previously validated in this population). Outcomes registered by PW (step counting [SC], energy expenditure [EE], walking distance [WD], activity time [AT] and walking intensity [WI]) were compared to video and SAB as criterion methods. **Results:** Correlations between PW and the criterion method were high for SC during slow and fast walking ($r=0.79$ and $r=0.95$) and for EE during fast walking ($r=0.83$). Correlation was more modest for EE during slow walking ($r=0.65$) and for WD and WI during both speeds ($0.47<r<0.68$). The device was reproducible for registering SC, WD and EE during slow walking and for all variables during fast walking (ICC>0.79 for all). Furthermore, during the ADL circuit, PW significantly underestimated AT by an average of 55% but provided an acceptable EE estimation in a group basis (average difference of 6% with SAB). **Conclusions:** In patients with COPD, PW is reproducible for most outcomes and valid for step counting during slow and fast walking and energy expenditure during fast walking. The device's validity is more limited for energy expenditure during slow walking, and for walking distance and walking intensity at both speeds. Furthermore, during the performance of ADL, PW significantly underestimates activity time but provides an acceptable estimation of energy expenditure in a group basis.

Key words: Motor activity. Pulmonary disease, chronic obstructive. Monitoring,Ambulatory. Pedometer. Validation studies.

LISTA DE ILUSTRAÇÕES

LISTA DE TABELAS

LISTA DE ABREVIATURAS E SIGLAS

3D	Three-dimension
6MWT	6-minute walking test
ADL	Activities of daily living
AEE	Active energy expenditure
AFVD	Atividade física na vida diária
AT	Activity time
AVD	Atividades de vida diária
BODE	Body mass, Obstruction, Dyspnea and Exercise
CO_2	Dióxido de carbono
COPD	Chronic obstructive pulmonary disease
CP	Contagem de passos
DP	Distância percorrida
DPOC	Doença pulmonar obstrutiva crônica
EE	Energy expenditure
GE	Gasto energético
GOLD	Global Initiative for Chronic Obstructive Lung Disease
H	Hidrogênio
H_2O	Água
IC	Intensidade de caminhada
ICC	Intraclass correlation coefficient
MET	Metabolic equivalent of task
O_2	Oxigênio
PADL	Physical activity in daily life
PW	Power Walker 610
SAB	SenseWear armband
SC	Step counting
TA	Tempo em atividade
VEF_1	Volume expiratório forçado no primeiro segundo
WD	Walking distance
WI	Walking intensity

SUMÁRIO

1 INTRODUÇÃO

A doença pulmonar obstrutiva crônica (DPOC) é caracterizada por uma limitação persistente ao fluxo aéreo que é usualmente progressiva e associada a um aumento crônico da resposta inflamatória das vias aéreas e dos pulmões a partículas nocivas ou gases[1]. Além do acometimento pulmonar, a DPOC também leva à ocorrência de manifestações extrapulmonares como inflamação sistêmica, aumento do estresse oxidativo, alterações na composição corporal, fraqueza muscular[2] e até mesmo distúrbios psicológicos como ansiedade e depressão[3]. As características da doença levam à sensação de fadiga e dispneia, sintomas comumente relatados pelos pacientes durante a realização de atividades físicas, inclusive atividades de vida diária[4]. Sendo assim, os indivíduos portadores da DPOC passam a evitar a realização de atividades físicas no intuito de reduzir os sintomas, tornando-se cada vez mais descondicio nados e menos ativos fisicamente. Com a redução do nível de atividade física na vida diária (AFVD) e a consequente piora do descondicionamento físico, os pacientes desenvolvem cada vez mais sintomas, o que, por sua vez, dificulta progressivamente a realização de atividades físicas[5]. Por essa razão, pacientes portadores de DPOC são significativamente menos ativos quando comparados a idosos saudáveis[6, 7].

A prática regular de atividade física, seja ela programada ou não, está associada a diversos benefícios relacionados à saúde. Esses benefícios vão desde aumento na sensação de bem-estar até a prevenção de todas as causas de morte[8]. Em contrapartida, a inatividade física, além de favorecer a ocorrência de exacerbações da doença em pacientes com DPOC[9], é comprovadamente um fator preditor de mortalidade nesta população[10]. Sendo assim, é imprescindível a correta avaliação do nível de AFVD em populações tipicamente sedentárias, como é o caso dos pacientes com DPOC, para que seja possível prescrever o tratamento adequado, tendo como um dos principais objetivos tornar o paciente mais ativo fisicamente[1]. Dessa forma, é possível reduzir o impacto da doença na vida dos pacientes por meio da redução dos sintomas e melhora da qualidade de vida[11].

Devido ao crescente interesse na correta monitorização da AFVD de pacientes com DPOC nos últimos anos, a literatura científica descreve diversos métodos para se quantificar essa variável[12]. Porém, alguns métodos atualmente disponíveis, apesar de quantificarem de maneira acurada o nível de AFVD, são

relativamente caros, exigem análises complexas ou mesmo não são validados para utilização em pacientes com DPOC. Outros métodos são simples, acessíveis financeiramente, porém não são acurados. Portanto, o objetivo da presente dissertação foi avaliar a validade e a reprodutibilidade de um novo sensor de movimento financeiramente mais acessível (Power Walker 610, ou PW) em pacientes com DPOC. Adicionalmente, a parte introdutória dessa dissertação traz um levantamento bibliográfico sobre a AFVD em pacientes com DPOC, assim como discorre sobre os diferentes métodos para se quantificar essa variável.

2 REVISÃO DA LITERATURA – CONTEXTUALIZAÇÃO

2.1 DOENÇA PULMONAR OBSTRUTIVA CRÔNICA (DPOC)

Atualmente, a DPOC é a quarta principal causa de morte no mundo e, provavelmente, ocupará a terceira posição dentro dos próximos 20 anos[13]. Sua principal causa é o tabagismo, mas indivíduos não-fumantes também podem ser acometidos pela doença por diversas outras causas como asma ou infecções respiratórias na infância, poluição do ar, exposição ocupacional a poeiras e tabagismo passivo, entre outras[14, 15]. Ela é definida como uma doença prevenível e tratável caracterizada por limitação persistente ao fluxo aéreo que é usualmente progressiva e associada a uma resposta inflamatória crônica das vias aéreas e dos pulmões a partículas nocivas e gases[1]. Devido ao quadro inflamatório crônico, ocorrem mudanças estruturais, como o estreitamento das vias aéreas[1]. Além disso, o processo inflamatório destrói o parênquima pulmonar, prejudicando o recolhimento elástico dos pulmões[1]. Tais alterações fazem com que haja uma redução da capacidade das vias aéreas se manterem abertas durante a expiração, o que resulta em aprisionamento aéreo[1]. A obstrução crônica é causada pela associação entre o dano das pequenas vias aéreas e a destruição do parênquima pulmonar, sendo que a contribuição de cada tipo de acometimento varia entre os indivíduos portadores da doença[1]. Adicionalmente, exacerbações e comorbidades contribuem para a gravidade da DPOC[1].

Apesar de sua definição estar associada ao acometimento das vias aéreas, a DPOC apresenta manifestações sistêmicas importantes que em conjunto com o comprometimento respiratório prejudicam a capacidade de exercício dos pacientes. Além de apresentarem limitações na ventilação pulmonar[16] e nas trocas gasosas[17], os pacientes podem apresentar disfunção cardíaca, especialmente sobrecarga do ventrículo direito[18]. Outra manifestação extrapulmonar comum é a disfunção muscular periférica, que pode ser atribuída à inflamação sistêmica, uso de corticoesteróides, estresse oxidativo e redução da massa muscular[19]. Pacientes com DPOC também costumam desenvolver anormalidades na composição corporal, como perda de peso e redução da porcentagem de massa magra[20]. Essas características dão origem à sensação de dispneia e fadiga, inclusive durante a realização de simples atividades da vida diária nos casos mais graves[4].

2.2 Atividade Física na Vida Diária

O termo “atividade física” é definido como qualquer movimento corporal produzido pelos músculos esqueléticos que resulta em gasto energético[21]. Já “atividade física na vida diária (AFVD)” refere-se à totalidade de movimentos voluntários produzidos pelos músculos esqueléticos durante atividades cotidianas[22].

A prática regular de atividade física, seja ela programada ou simplesmente relacionada às atividades de vida diária, está associada a benefícios físicos e mentais, além de prevenir uma série de doenças crônicas e até mesmo evitar a progressão daquelas doenças previamente instaladas[8]. Outros benefícios associados à realização frequente de atividade física são a atenuação das alterações biológicas relacionadas ao envelhecimento e o aumento da expectativa de vida[23]. Em outras palavras, um estilo de vida fisicamente ativo colabora com um envelhecimento saudável.

Especialistas recomendam que sejam realizados, no mínimo, 30 minutos de atividade física de intensidade moderada em pelo menos 5 dias da semana[8]. Tal atividade pode ser realizada de forma contínua ou em blocos de pelo menos 10 minutos, no caso de indivíduos com dificuldade de atingir a “meta” de maneira contínua[8]. Entretanto, as mesmas recomendações sugerem que indivíduos muito descondicionados fisicamente podem realizar a atividade física em blocos menores que 10 minutos e até mesmo se beneficiar de volumes menores de atividade física[8]. Portanto, é clara a importância de se atingir um limiar mínimo de volume de atividade física para se obter os benefícios desejados. Porém, apesar de também estar estabelecido que quanto maior o volume da atividade física maiores serão os benefícios, as recomendações supracitadas também trazem a orientação de que até mesmo uma quantidade de atividade física abaixo do recomendado é benéfica para indivíduos que são inativos fisicamente. Isso nos mostra o quanto a atividade física é indispensável para a saúde, com os especialistas chegando a utilizar a seguinte expressão quando se referem à prática de atividade física: “alguma coisa já é bom, mais é melhor”.

2.3 DPOC E ATIVIDADE FÍSICA NA VIDA DIÁRIA

Devido às manifestações pulmonares e sistêmicas da DPOC, os pacientes desenvolvem uma sintomatologia que torna desconfortável a realização de um esforço físico. A dispneia e a fadiga, comumente relatadas por essa população, podem dificultar até mesmo a realização de atividades relacionadas ao cotidiano dos pacientes. Dessa forma, para evitar o desconforto (que muitas vezes é extremo), os indivíduos com DPOC evitam a realização de atividades físicas, tornando-se cada vez menos ativos fisicamente. Infelizmente, esse comportamento dá origem a um ciclo vicioso, pois conforme o paciente reduz seu nível de AFVD, mais descondicionado fisicamente ele fica, agravando a sensação de dispneia e fadiga durante a realização de atividades físicas. Isso é amplamente conhecido e citado na literatura científica como “ciclo vicioso da inatividade”[5, 24, 25].

Pitta e colaboradores compararam o nível de AFVD entre pacientes com DPOC e idosos saudáveis de um país europeu e concluíram que os pacientes caminhavam durante apenas 6% do dia, o que representava praticamente a metade do tempo que os idosos saudáveis caminhavam. Os pacientes também permaneciam quase a metade do tempo em pé e três vezes mais tempo deitados, em comparação com o grupo controle (Figura 1)[6]. Um estudo semelhante, ao traçar o perfil de AFVD dos pacientes com DPOC brasileiros, confirmou o fato de que pacientes com DPOC são significativamente menos ativos em relação a idosos saudáveis[7]. Apesar de haver evidência de que pacientes com DPOC que vivem em regiões extremamente diferentes em relação a clima, cultura e status socioeconômico (Brasil e Áustria, por exemplo) apresentam níveis diferentes de AFVD, isso não altera a constatação de que indivíduos portadores de DPOC são menos ativos na vida diária do que idosos saudáveis[26].

Diversos estudos científicos evidenciam o impacto da inatividade física na vida dos pacientes com DPOC. Já é sabido que portadores de DPOC que realizam algum nível de atividade física, mesmo que seja baixo, apresentam menor risco de internação hospitalar por exacerbação da doença do que os pacientes que apresentam nível de atividade física muito baixo[9]. Adicionalmente, quanto menor o nível de AFVD, maior o risco de mortalidade avaliado pelo índice BODE[27, 28]. Waschki e colaboradores, em uma coorte prospectiva, concluíram de forma alarmante que a inatividade física é o maior preditor de todas as causas de morte em

pacientes com DPOC[10]. Tamanha é a importância da inatividade física para o quadro clínico da DPOC que evidências indicam que ela surge antes dos pacientes começarem a relatar sensação de dispneia, e especialistas sugerem até mesmo que ela teria relação com a origem do declínio da função pulmonar e do início dos sintomas[29, 30].

2.4 Monitorização da AFVD em Pacientes com DPOC

Devido aos importantes efeitos deletérios da inatividade física no quadro clínico dos indivíduos com DPOC, é fundamental que o tratamento tenha como principal objetivo a melhora do nível de AFVD dos pacientes, interrompendo assim o “ciclo vicioso da inatividade”. Para que isso seja possível, faz-se necessária a monitorização do nível de AFVD dos pacientes, sendo que esse tipo de avaliação deve ser realizada por meio de instrumentos acurados e validados para essa população.

A quantificação da AFVD pode ser realizada por meio de questionários, medidas do gasto energético, utilização de sensores de movimento e observação direta, na qual todas as atividades realizadas pelos indivíduos são registradas por uma câmera de vídeo e quantificadas posteriormente por pessoas que assistem a esses vídeos. Esse último método é o que reflete da maneira mais próxima do real o nível de AFVD dos indivíduos. Porém, a observação direta exige longo tempo para sua realização e invade a privacidade do paciente, dificultando sua aplicação prática[12]. Portanto, comentaremos mais detalhadamente apenas sobre os outros três métodos citados.

Questionários são instrumentos simples, baratos e de fácil aplicação, inclusive em estudos populacionais, e essas são suas principais vantagens. Entretanto, por depender da memória do paciente que responde ao questionário, a confiabilidade das informações coletadas diminui à medida em que aumenta o período recordatório exigido[31]. Além disso, a confiabilidade dos dados também pode variar de acordo com as características dos pacientes e até mesmo com o *design* dos questionários[31]. Vale lembrar que os pacientes com DPOC são capazes de relatar corretamente suas limitações e sintomas relacionados à doença por meio de questionários. Porém, quando se trata de quantificar a duração, frequência e intensidade das atividades físicas realizadas no dia a dia, questionários podem ser

úteis para estimar o nível de AFVD de um grupo, mas são inacurados para estimativas individuais[12, 32].

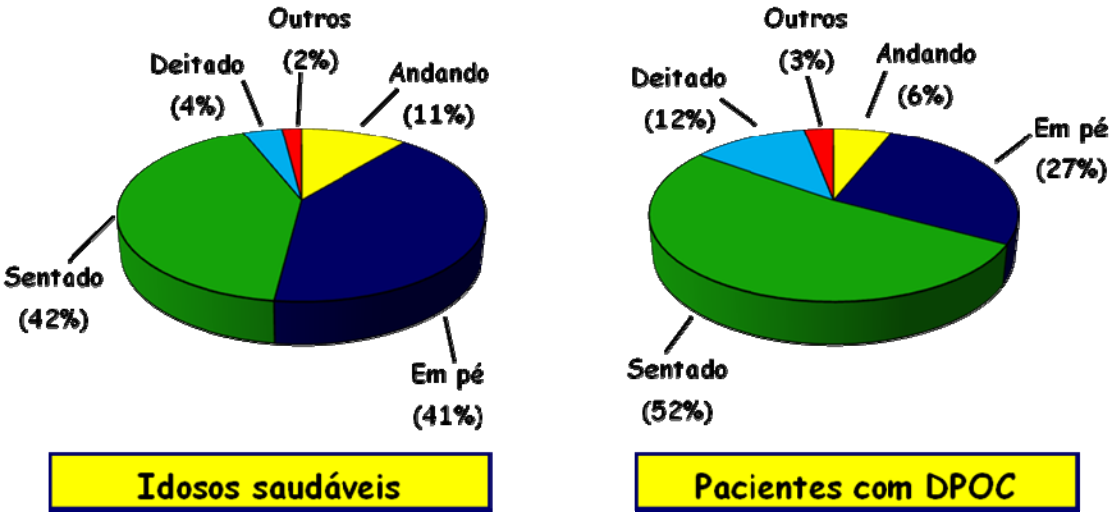
Os métodos considerados “padrão-ouro” para a quantificação do gasto energético são a calorimetria (direta e indireta)[33, 34] e o método da água duplamente marcada[34-36]. Para a realização da calorimetria direta, o indivíduo deve ser colocado dentro de uma câmara térmica, onde o calor dissipado por ele será registrado de maneira acurada[34]. Já a calorimetria indireta registra a produção de dióxido de carbono (CO_2) e o consumo de oxigênio (O_2) por meio de uma máscara facial conectada a um analisador de gases e, portanto, o método mede indiretamente a quantidade de energia produzida[33, 34]. Por outro lado, o método da água duplamente marcada fornece informações sobre o gasto energético total durante um período de 4 a 20 dias[35, 36]. Para isso, o indivíduo deve ingerir uma dose de água contendo isótopos de hidrogênio (H) e O_2. Conforme o organismo gasta energia, CO_2 e água (H_2O) são produzidos. O CO_2 é eliminado pelo corpo por meio da respiração, enquanto a H_2O é eliminada por meio da respiração, urina e suor. O isótopo de O_2 está contido tanto no CO_2 como na H_2O e o isótopo de H está contido na H_2O, mas não no CO_2. Portanto, a diferença entre a perda de isótopos de O_2 e de H reflete a produção de CO_2, que pode ser utilizada para estimar o gasto energético[34]. Contudo, esses métodos são relativamente caros e exigem treinamento específico para sua complexa manipulação, dificultando sua aplicabilidade[12]. Por conta disso, métodos baseados em acelerometria e características antropométricas e fisiológicas dos indivíduos foram desenvolvidos, facilitando a quantificação do gasto energético na vida diária, como é o caso do multisensor SenseWear Armband (Body Media, Estados Unidos), validado em comparação com a calorimetria indireta[37-39]. Porém, a estimativa do gasto energético não provê dados relativos à duração ou frequência das atividades físicas, componentes essenciais para a caracterização do nível de AFVD dos pacientes[12].

Por conta das limitações encontradas nos métodos citados anteriormente, é cada vez maior o interesse dos pesquisadores em sensores de movimento. Esses instrumentos detectam os movimentos corporais, quantificando objetivamente o nível de AFVD. Basicamente eles se dividem em pedômetros e acelerômetros[12]. Pedômetros são instrumentos simples, pequenos e acessíveis financeiramente que registram o número de passos realizados pelo indivíduo ao longo de um período de tempo[12]. Eles podem ser mecânicos ou piezoelétricos,

sendo o último mecanismo mais sensível para a detecção correta do número de passos[40]. Como a contagem dos passos é baseada na movimentação vertical do quadril, qualquer movimento no plano vertical (levantar-se de uma cadeira, por exemplo) pode ser registrado equivocadamente como um passo[25]. Outra desvantagem que a maioria dos pedômetros apresenta é a inacurácia em registrar passos durante caminhadas lentas, típicas em pacientes com DPOC[41]. Já os acelerômetros são equipamentos tecnologicamente mais avançados que os pedômetros e são capazes de registrar a quantidade e a intensidade dos movimentos durantes longos períodos de tempo[22]. Eles podem ser uniaxiais ou multiaxiais. Os acelerômetros uniaxiais são comparáveis a pedômetros, já que detectam movimento em um único plano, mas com a vantagem de registrarem a intensidade do movimento e permitirem uma análise mais detalhada dos dados[12]. Os multiaxiais detectam movimentos em dois ou três planos, permitindo o registro de dados mais detalhados em comparação com os acelerômetros uniaxiais[12]. Alguns acelerômetros multiaxiais podem até mesmo diferenciar as atividade e posturas realizadas pelo paciente[32, 42]. Acelerômetros costumam custar mais que pedômetros e, apesar da tecnologia mais avançada e maior diversidade de variáveis fornecidas, eles também podem registrar movimentos de maneira equivocada, como por exemplo vibrações enquanto o indivíduo se locomove por meio de um veículo[12, 43]. Uma das desvantagens dos sensores de movimento está associada ao seu posicionamento: a maioria deles é utilizada na cintura ou no tornozelo, impedindo o registro de atividades realizadas com os membros superiores e atividades em que o tronco permanece estático[12]. Os sensores de movimento também exigem a colaboração do paciente quanto ao horário de colocação e posicionamento do aparelho, evitar colisões do dispositivo com outras estruturas e muitas vezes realizar anotações em um diário, para facilitar as análises posteriores dos dados coletados[12].

Em suma, os métodos para se monitorar o nível de AFVD de pacientes com DPOC são vários, cada um com características próprias, vantagens e desvantagens. Sendo assim, a escolha do melhor método deve levar em consideração os objetivos da avaliação, as variáveis de interesse, se o instrumento escolhido é validado para utilização na população em questão e se o dispositivo é viável (financeiramente e do ponto de vista prático).

Figura 1 Comparação do tempo gasto em diferentes atividades e posturas entre pacientes com DPOC e idosos saudáveis (Figura adaptada de Pitta et al [6]).



ARTIGO

EVALUATION OF A NEW MOTION SENSOR IN PATIENTS WITH COPD.

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ABSTRACT: Objective: To assess the criterion validity and reproducibility of the Power Walker 610 motion sensor (PW) in patients with chronic obstructive pulmonary disease (COPD). **Design:** Cross-sectional study. **Setting:** Outpatient Physiotherapy Clinic from an University Hospital. **Participants:** Thirty patients with COPD (17 male, FEV_1 44±17%pred) were videotaped while performing two protocols: one including two slow and two fast 5-minute walks, and another including a circuit of activities of daily living (ADL). Concomitantly, patients wore two motion sensors: PW and SenseWear Armband (SAB). **Interventions:** None. **Main outcome measures:** Step counting (SC), energy expenditure (EE), walking distance (WD), activity time (AT) and walking intensity (WI) registered by PW were compared to video and SAB as criterion methods. **Results:** Correlations between PW and the criterion method were high for SC during slow and fast walking (r=0.79 and r=0.95) and for EE during fast walking (r=0.83). Correlation was more modest for EE during slow walking (r=0.65) and for WD and WI during both speeds (0.47<r<0.68). The agreement between methods was also good, according to Bland&Altman plots. The device was reproducible for registering SC, WD and EE during slow walking and for all variables during fast walking (ICC>0.79 for all). During the ADL circuit, PW underestimated AT by an average of 55% but provided an acceptable EE estimation in a group basis (average difference of 6% with SAB). **Conclusions:** In patients with COPD, PW is reproducible for most outcomes and highly valid for SC during slow and fast walking

and EE during fast walking. The device's validity is more limited for EE during slow walking, and WD and WI at both speeds. Furthermore, during the performance of ADL, it significantly underestimates activity time but provides an acceptable estimation of EE in a group basis.

Keywords: motor activity, pedometer, pulmonary disease, chronic obstructive,

LIST OF ABBREVIATIONS

3D: Three-dimension

6MWT: 6-minute walking test

ADL: Activities of daily living

AEE: Active energy expenditure

AT: Activity time

BODE: Body mass, Obstruction, Dyspnea and Exercise

COPD: Chronic Obstructive Pulmonary Disease

EE: Energy expenditure

GOLD: Global Initiative for Chronic Obstructive Lung Disease

ICC: Intraclass correlation coefficient

MET: Metabolic equivalent of task

PADL: Physical activity of daily living

PW: Power Walker

SAB: SenseWear armband

SC: Step counting

WD: Walking distance

WI: Walking intensity

Patients with chronic obstructive pulmonary disease (COPD) are typically less active in daily life than healthy elderly[1,2]. Sedentary lifestyle in this population is commonly related to dyspnea (the most frequent symptom reported by patients) and impairment in exercise capacity[1,2]. In addition, inactivity in patients with COPD is also associated with poor functional status and higher risk of mortality evaluated by the BODE index[3,4], besides being considered the strongest predictor of death in this population[5]. These are the main reasons for the growing interest in physical activity monitoring, especially in a markedly sedentary population such as patients with COPD.

In order to accurately measure the patient´s level of physical activity in daily life (PADL) in clinical practice, valid and affordable motion sensors are needed. Pedometers are very simple motion sensors that provide information on step counts and are not expensive in comparison to more complex activity monitors. Despite its practicality, the use of 'classic' pedometers (i.e., those not involving accelerometry) has been not recommended in slow-walking populations[6,7,8], as is clearly the case of patients with COPD[1,2], due to their low sensitivity. Possibly to counteract this limitation, the Power Walker 610[a] [PW] is a pedometer developed with an embedded three-dimension accelerometer. In contrast to the classic 'pendulum' mechanism of regular pedometers, this 3D electronic sensor system could theoretically improve pedometer´s sensitivity to step counting and other activity outcomes. Its price, despite higher than regular pedometers, is considerably lower than technologically advanced activity monitors. Therefore, PW could be a potential motion sensor for objective measurement of PADL in patients with COPD in clinical practice and epidemiological large studies developed with limited budget, in which more advanced activity monitors might not be an option. However, to the present date, validity and reproducibility of the PW pedometer have not yet been investigated in depth neither in patients with COPD nor in any other population. Therefore, the objective of the present study was to evaluate the criterion validity and reproducibility of the PW in patients with COPD.

METHODS

Study Design and Subjects

Thirty patients with COPD (17 men) with no exacerbation episodes for at least three months were recruited to take part in this cross-sectional study. All participants had take part recently or were currently enrolled in programs of respiratory physiotherapy at the University Hospital of the State University of Londrina (HU-UEL), Brazil, composing a convenience sample. The latest patient´s assessment of lung function (<6 months) performed by hospital staff was used to confirm COPD diagnosis and classify subjects´ degree of obstruction according to Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria[9]. Even if patients had an exacerbation between the last assessment of lung function and the begining of the participation in the present study we did not repeat the exam, because our main objective with the espirometry was only to confirm the diagnosis of COPD. None of the participants was long-term oxygen user or had other pathologic conditions that could impair physical activity performance. Initially, height and weight were registered and body mass index (BMI) calculated. Characteristics of study participants are described in Table 1. In order to calculate the average step length, patients were asked to perform ten steps on their own pace; then, the distance walked was registered and divided by ten. Additionally, patients were questioned about date of birth, smoking habit and predominant hand. These data were necessary in order to configure the motion sensors used in this study. The study was approved by the institution's Research Ethics Committee (HU-UEL n.04624) and all involved subjects gave formal and written consent prior to their inclusion.

Measurement protocols

All participants were submitted to two physical activity protocols: a walking protocol and a circuit comprising different activities of daily living (ADL). The first protocol consisted of two slow and two fast walks, in this order, with 5-minute duration each, performed in a 30-meter corridor. Speed of walking was established asking patients to walk at a regular pace as developed in daily life (slow walking) and to walk at a pace as if “late for an appointment” (fast walking). Between walks, patients were able to rest until they felt ready to start the next walk. The second protocol was performed in a 70 m^2-room and encompassed a 5-station ADL circuit. The stations comprised the following: patients had to seat, climb up and down a step, lie down (one minute each activity), dress and remove a shirt, as if they were at home. Between stations, participants had to walk straight and in curves, dodging objects (Fig. 1). This circuit was repeated three times, successively. In each patient, both protocols were recorded throughout by a video camera[b].

Activity monitoring

During the protocols, patients wore two activity monitors simultaneously: SenseWear Armband[c] [SAB] and Power Walker 610 [PW]. SAB is a multisensor composed by a biaxial accelerometer and physiological sensors. It is a small (8.8 x 5.6 x 2.1 cm) and light (82g) monitor that was already validated for energy expenditure estimation in patients with COPD[10,11]. The device is worn at the upper right arm and provides, among other variables, an acceptable estimation of active energy expenditure (AEE)[6,8]. In the present study, SAB was configured to detect as physical activity all movements that reached at least 2 METs, as this intensity is

equivalent to slow walking, typical in patients with COPD[12,13,14]. A final data report can be obtained by specific software (InnerView Professional 6.1).

PW is a pedometer combined with accelerometry which comprises a three-dimension sensor, instead of the classic pendulum system. It is relatively new, affordable, and its criterion validity and reproducibility were not yet studied. Outcomes provided by PW are step counting (in steps), energy expenditure estimative (in calories), walking distance (in meters), activity time (in minutes) and walking intensity (in m/min). The manufacturer recommends its use inside pocket of pants or shirt, but in a pilot study in our laboratory, we concluded that the most accurate position to wear the PW is attached to the waist, in the hemi-clavicular line[15], the same position as most pedometers have been worn. Therefore, this position was used, always on the right side. As criterion methods, PW was compared to video recording concerning number of steps, walking distance, activity time and walking intensity (speed); and compared to SAB concerning energy expenditure. Two PW devices were used for data collection in the present study. Both of them were tested for accuracy during a normal 5 minute-walk prior to the protocols, and presented less than 3% of difference between them.

Statistical Analysis

Data distribution was checked by Kolmogorov-Smirnov test and, as variables presented normal distribution, data were reported as mean and standard deviation and parametric statistics were used. Comparisons between PW and SAB and between PW and video were performed using paired Student *t* test. To evaluate PW validity, Pearson´s correlation was used. Bland & Altman plots and Intraclass

Correlation Coefficient [3,2][16] were used to analyze agreement with criteria methods and pedometer reproducibility. Statistical significance was set at 5%. Statistical analysis was performed using Prism 5.0[d] and SPSS Statistics 17.0[e].

Power Analysis

A sample of thirty individuals had a power of 93% to detect a difference of at least 15 steps (approximately 3%) between PW and video recording in the walking protocol of the present study, using the standard deviation of the difference between methods (23 steps) and adopting the statistical significance of 5%. We assumed these values based on our own data regarding slow walking, and we considered a difference of 3% as not denoting clinical significance concerning step counting. The data used in the calculation of the sample power were extracted from the results of the present study in its complete form.

RESULTS

All of the 30 recruited patients successfully completed the protocols uneventful. As there was no difference between first and second walk in both speeds concerning almost all variables of interest ($p>0.17$), we standardized to use only the first walk of each speed in the analysis. Regarding the number of steps, walking distance and walking intensity, there was a statistical difference between first and second slow walking ($p<0.002$), although not representing a clinically important difference (1.5%, 2% and 3%, respectively). Average speed during the walking protocol was 3.8±0.5 Km/h and 4.7±0.5 Km/h during slow and fast walks, respectively. During the ADL circuit, although we were not able to detect the real

walking speed, PW registered it as 3.7±0.8 Km/h, strongly resembling the walking speed obtained during the slow walking in our study (3.8±0.5 Km/h). The results concerning validity (correlations), agreement of the device with the criterion methods and reproducibility (Bland & Altman analysis and ICCs) are described below.

Walking protocol

During slow walking, there was strong correlation between PW and video concerning number of steps (r=0.79; p<0.001), and moderate correlation concerning walking distance (r=0.63; p<0.001) and walking intensity (r=0.61; p<0.001). Regarding energy expenditure, there was also moderate correlation between PW and SAB (r=0.65; p=0.0001) (Fig. 2). The ICC between the two slow walks was excellent to PW step counting, energy expenditure, walking distance and walking intensity (0.89 [95% CI, 0.77 – 0.95], p<0.0001; 0.98 [95% CI, 0.96 – 0.99], p<0.001; 0.91 [95% CI, 0.81 – 0.96], p<0.001; 0.79 [95% CI, 0.56 – 0.90], p<0.001). ICC was low and non-statistically significant regarding PW activity time between two slow walks (-0.42 [95% CI, -1.99 – 0.32], p = 0.82).

During fast walking, there was excellent correlation between PW and video regarding step counting (r=0.95; p<0.001), with moderate correlation regarding walking distance (r=0.48; p=0.006) and walking intensity (r=0.47; p=0.009). Still concerning the fast walking, there was strong correlation between PW and SAB on energy expenditure estimative (r =0.83; p<0.001) (Fig. 3). High ICCs between the two fast walks were found for all outcomes provided by the PW (0.96 [95% CI, 0.92 – 0.98], p<0.001 for step counting; 0.99 [95% CI, 0.98 – 0.99], p<0.001 for energy expenditure; 0.95 [95% CI, 0.90 – 0.97], p<0.001 for walking distance; 0.79 [95% CI,

0.57 – 0.90], p<0.001 for activity time and 0.95 [95% CI, 0.88 – 0.97], p<0.001 for walking intensity).

The statistical software was not able to analyze correlation between PW and video concerning activity time because it represented a vertical or horizontal line. In other words, both methods registered the same activity time. Activity time registered by PW during slow walking was very similar to real walking time (4.8 ± 0.4 vs. 5.0 ± 0.0 minutes) and identical to real walking time during fast walking (5.0 ± 0.2 vs. 5.0 ± 0.0).

Figure 4 shows the Bland and Altman plots comparing PW with video and SAB concerning step counting and energy expenditure, respectively, during both slow and fast walking. Regarding step counting, the ICC between PW and video was 0.88 (95% CI, 0.75 – 0.94; p<0.001) during slow walking and 0.97 (95% CI, 0.93 – 0.98; p<0.001) during fast walking. The ICC between PW and SAB concerning energy expenditure was 0.79 (95% CI, 0.56 – 0.90; p<0.001) for slow walking and 0.89 (95% CI, 0.78 – 0.95; p < 0.001) for fast walking. ICC concerning walking distance between PW and video was 0.75 (95% CI, 0.48 – 0.88, p<0.001) for slow walking and 0.53 (95% CI, 0.02 – 0.77, p=0.003) for fast walking. No significant ICC was found regarding walking intensity between PW and the real value for any speed.

ADL Circuit

For logistical reasons, during the ADL circuit we compared only energy expenditure and activity time between PW and the criterion methods considered in this study. No significant difference between PW and SAB energy expenditure

estimation was observed (10±6 vs. 9.4±3.9 calories, respectively, corresponding to an average difference of only 6% in a group basis; p=0.65). However, there was no significant ICC between the methods (0.22 [95% IC, -0.63 – 0.62], p=0.25). Furthermore, PW significantly underestimated activity time by an average of 55% in comparison to video recording (2.9±1.2 vs. 6.4±0.7 minutes, respectively; p<0.001) (ICC = -0.97 [-3.14 – 0.06], p=0.96).

DISCUSSION

The present study showed that, in patients with COPD, although PW had a somewhat limited validity to estimate walking distance, walking intensity and energy expenditure during the slow walk, it was highly valid to register the number of steps. Additionally, it was reproducible not only for step counting, but also in the estimation of walking distance and energy expenditure in the slow walk. During the fast walk, PW was reproducible concerning all variables and highly valid to estimate number of steps and energy expenditure, although presented limited validity to estimate walking distance and walking intensity. Finally, during the performance of ADL, the PW underestimated activity time and was shown to provide an adequate estimation of energy expenditure in a group basis, but not in an individual basis.

The present results clearly demonstrate that PW has advantages regarding step counting in comparison to other available pedometers, especially considering patients with slow walking pattern. The poor sensitivity of the ‘classic’ pedometers to detect steps during slow walking is due to the mechanism used to register movement counts: a horizontal, spring-suspended lever arm that deflects with vertical movement of the hips during walking. As this mechanism registers steps based on the up-and-down motion during ambulation, a slow walking pattern (i.e.,

with less pronounced up-and-down hip movement) hinders the accurate detection of steps[7]. A previous study concluded that one of the most highly recommended "classic" pedometers (Digiwalker 701[17,18]) significantly underestimates the number of steps during slow walking in patients with COPD and healthy age-matched subjects. This study protocol was performed on a treadmill and walking speeds were determined based on the average speed developed during the 6-minute walking test (6MWT), what is considerably different in comparison to the present study. Due to this methodological difference, the walking speed was lower than the observed in the present study. However, the slow walking speed observed in the present investigation is similar to the walking speed of healthy elderly which yielded inaccurate step detection by the Digiwalker in that previous study by Furlanetto et al. This finding by itself demonstrates that the PW is more accurate than the Digiwalker for step counting at slow speeds. Melanson et al.[19] also showed that 'classic' pedometers underestimate the number of steps as the walking speed decreases, and the inaccuracy is more evident below 3 mph (equivalent of 4.8 Km/h, which is similar to the average self-selected fast walking speed of our patients). Recent literature in patients with COPD shows a study evaluating the accuracy of a pedometer with a similar mechanism as the PW for step counting, the Omron HJ-720ITC. However, this pedometer presented a difference of 14 ± 26% and 1.7 ± 6.9% from the actual value (manual count) regarding the number of steps during natural walking in a corridor in patients that walked slower and faster, respectively. In the present study, PW presented a difference of only 0.09±5.8% and 1.2±6.9% from the actual value of step counting during slow and fast walking, respectively, being evaluated in similar walking speeds as the aforementioned study. This happens presumably due to some differences in the mechanisms used to register movements. Another accelerometer

(StepWatch) also demonstrated high accuracy when registering steps during very slow walking in elderly[21,22]; however, it is considerably more expensive than PW and has a more complex process when handling the data. Certainly prices may be highly variable, and this has also to be taken into consideration when one makes the decision of which pedometer to adopt.

The correlation between real value and PW registration of walking distance and walking intensity was poorer in fast walking than in slow walking. This may initially be seen as a surprising result, but we have a hypothesis for its explanation. This probably happened because these outcomes from the PW (walking distance and walking speed) depend not only on the number of steps registered but also on the step length entered in the device's configuration before initiation of its use by the patient, which in our study was calculated based on a 10-step walk at slow speed. However, during fast walking people tend to naturally increase step length[23,24]. Therefore, the fixed step length entered in the device's configuration to that specific patient naturally decreases the possibility to maintain a correct estimate of the walking distance and intensity as the step length increases along with the increasing speed.

The SAB, used in the present study as the criterion method for the energy expenditure estimation, was already validated for the evaluation of energy expenditure in patients with COPD[6,8,10,11]. The energy expenditure estimative by PW during slow walking was moderately correlated with SAB estimative, although highly reproducible. During fast walking, PW was not only highly reproducible but also strongly correlated with SAB in estimating energy expenditure. In the ADL circuit protocol, PW and SAB estimation of energy expenditure presented no agreement

when considering subjects individually, but they were similar when considering the whole group. Although PW presented acceptable performance concerning energy expenditure estimation when compared with SAB (error estimation of 4%, 6% and 6% concerning slow walk, fast walk and ADL circuit, respectively), its performance is yet considerably better for assessing step counting in patients with COPD than for assessing energy expenditure. Our results are in accordance with the conclusion of Pitta et al. in a comprehensive review about physical activity quantification in COPD, which says that motion sensors are more accurate for measurement of volume of physical activity in daily life than for the estimation of energy expenditure, especially in populations that typically present slow walking speeds[7]. Besides the fact that it estimates energy expenditure indirectly based on other variables programmed into the pedometer settings, it does not account for the additional energy spent in activities such as stair climbing, uphill walking, frequent changes in walking direction, carrying loads, and arm activities[25,26]. The same considerations could be used for the explanation of poorer estimation of walking distance and walking intensity in comparison to the better estimation of the number of steps.

Estimation of activity time by the PW was similar to the real activity time at both speeds during continuous walking. However, during the ADL circuit, which better represents the patient´s real daily activity pattern, PW significantly underestimated activity time. One explanation for this might be that the PW, similarly to other waist-mounted activity monitors, was not able to detect activities done only with the upper limbs (i.e., without whole-body dislocation). Additionally, our ADL circuit lasted an average of 6.4 ± 0.7 minutes. We do not know if during a whole day of real life measurement the underestimation of activity time by the PW would differ from the

present results. Future studies are necessary to evaluate the utility of PW to estimate the time spent in physical activity by patients in non-laboratory based assessments (i.e., daily life).

The lack of reproducibility of activity time estimation of PW during slow walking probably occurred because in some patients there was a difference of one minute in the registration of PW between first and second walk. This happened because the PW´s clock registers only full minutes. If there was even only one second of difference between the times of starting the timer and starting the protocol walk, the PW would register one minute less or more than real. Proportionally, one minute of under or overestimation in a 5-minute walk represent 20% of inaccuracy but, during a longer continuous walk or during a whole day assessment in daily life this difference might be less important. The same argument reinforces the lack of reproducibility of the PW concerning walking intensity during slow speed.

Study limitations

Our study has some limitations. Firstly, patients included in the study were participating or had already recently participated in programs of respiratory physiotherapy, composing a convenience sample. This might indicate that our results are not necessarily extendable for patients not under physiotherapy treatment, and this deserves further investigation. Another limitation is that we did not compare estimation of energy expenditure by the PW with a gold-standard method, as it is recommended by the literature. Nevertheless, as SAB was previously validated for estimating energy expenditure in patients with COPD[6,8,10,11], we believe it might be used as a criterion method for comparison with new tools aimed at estimating the

same outcome. In addition, we were not able to manually count the number of steps performed by the patients during the ADL circuit, since a lot of movements were undefined and would be difficult to standardize what should be considered as a step and what should not. This did not allow us to investigate the validity of PW's step counting during ADL performance, although its capacity to correctly detect steps during walking in patients with COPD has been clearly shown. This is in itself a valuable novel information to be added to the current literature, since 'classic' pedometers are currently regarded as inaccurate (and therefore not indicated for use) in this population.

CONCLUSIONS

In summary, we conclude that, in patients with COPD, the Power Walker 610 is reproducible for most outcomes and highly valid for step counting during slow and fast walking and energy expenditure estimation during fast walking. The device's validity is more limited for energy expenditure estimation during slow walking, and walking distance and intensity at both speeds. Furthermore, during the performance of a circuit of activities of daily living, the device significantly underestimates activity time but provides an acceptable estimation of energy expenditure in a group basis.

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SUPPLIERS

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b. Sony Corporation of America, 550 Madison Avenue, New York, NY 0022 United States of America.

c. BodyMedia, Inc. One Gateway Center, 420 Fort Duquesne Boulevard, Suite 1900, Pittsburgh, PA 15222 United States of America.

d. GraphPad Software Inc, 2236 Avenida de la Playa, La Jolla, CA 92037.

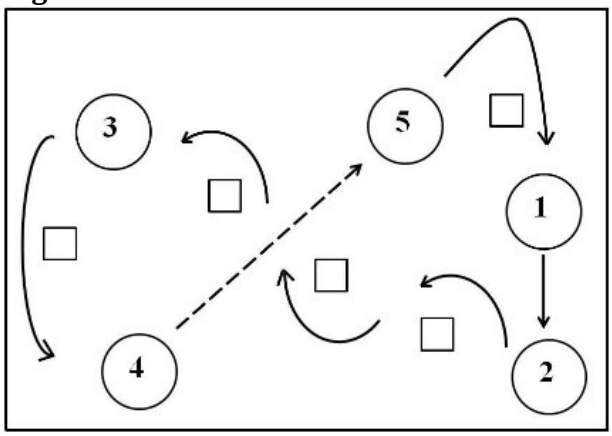
e. IBM North America, 590 Madison Avenue, New York, NY 10022, United States.

Table 1 Subject characteristics (n = 30)

Variables	Mean ± SD
Gender (M/ F)	17/ 13
Age (years)	67 ± 7
Height (m)	1.60 ± 0.1
Weight (Kg)	70 ± 16
BMI ($Kg.m^{-2}$)	27 ± 6
FEV_1 (% of predicted)	44 ± 17
FEV_1/ FVC	53 ± 12

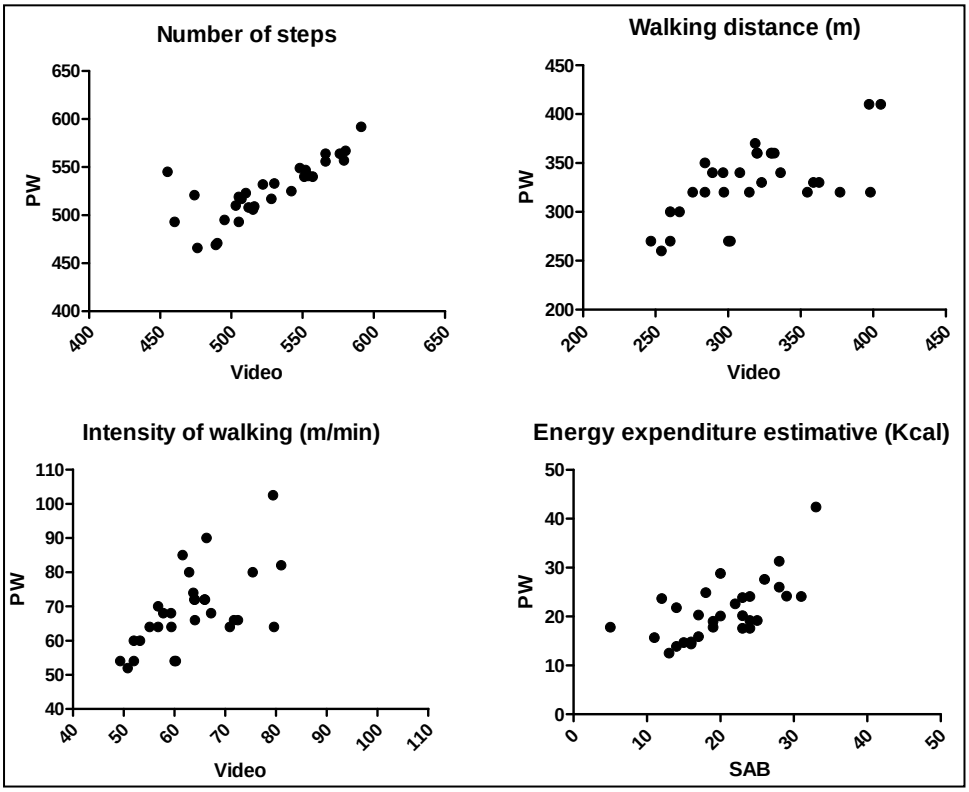
Data are expressed as mean ± standard deviation (SD). BMI = body mass index; FEV_1 = forced expiratory volume in the first second; FVC = forced vital capacity.

Figure 1 Activities circuit in a 70m^2-room.



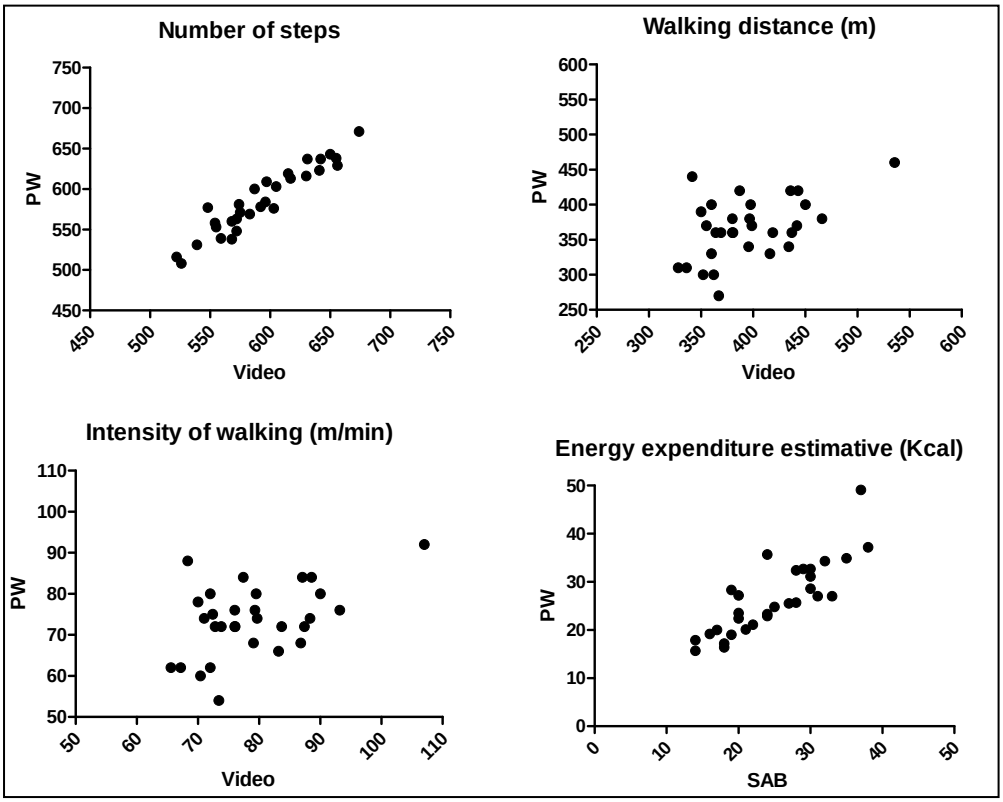
Station 1 = sitting (1 minute); station 2 = up and down a step (1 minute); station 3 = lying (1 minute); station 4 = dressing a shirt; station 5 = removing the shirt.

Figure 2 Correlations between Power Walker 610 (PW), video recording and SenseWear Armband (SAB) during a self-selected 5-minute slow walk.



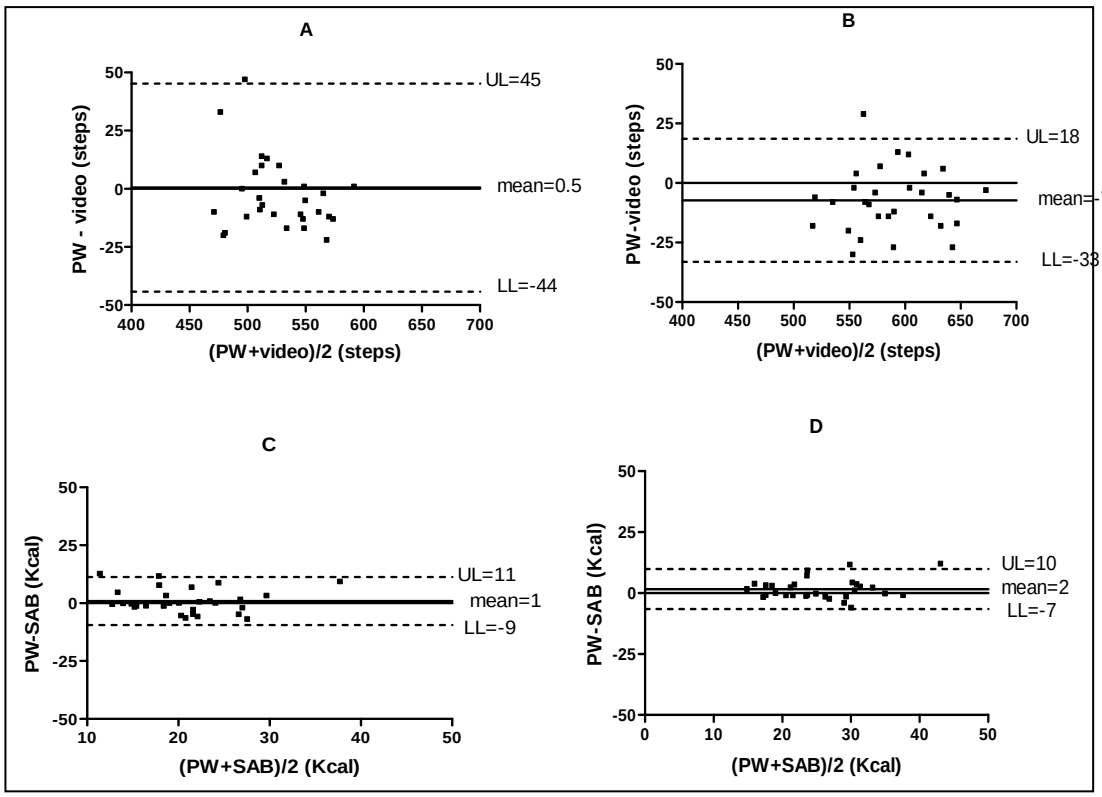
Correlation between PW and video recording concerning number of steps, walking distance and intensity of walking ($r = 0.79$, $p < 0.0001$; $r = 0.63$, $p < 0.001$; $r = 0.61$, $p < 0.001$ respectively) and between PW and SAB concerning energy expenditure estimative ($r = 0.65$, $p = 0.0001$).

Figure 3 Correlations between Power Walker 610 (PW), video recording and SenseWear Armband (SAB) during a self-selected 5-minute fast walk.



Correlation between PW and video recording concerning number of steps, walking distance and intensity of walking ($r = 0.95$, $p < 0.0001$; $r = 0.48$, $p = 0.006$; $r = 0.47$, $p = 0.009$, respectively) and between PW and SAB concerning energy expenditure estimative ($r = 0.83$, $p < 0.0001$).

Figure 4 Bland and Altman plots comparing Power Walker 610 (PW) with video and SenseWear Armband (SAB) concerning step counting and energy expenditure, respectively, during both slow and fast walking.



A and B = Agreement between PW and video recording concerning step counting in slow and fast walking, respectively. C and D = Agreement between PW and SAB concerning energy expenditure estimation in slow and fast walking, respectively. UL = upper limit (+1.96 standard deviations); LL = lower limit (-1.96 standard deviations).

CONCLUSÃO GERAL

O pedômetro avaliado no presente estudo mostrou-se acurado para realizar a contagem do número de passos em pacientes com DPOC, mesmo em velocidades lentas. O aparelho também mostrou-se válido para estimar o gasto energético durante caminhadas rápidas porém limitado para estimá-lo nas caminhadas lentas. A validade do pedômetro também foi limitada quanto à estimativa da intensidade e do tempo de caminhada em qualquer velocidade. Durante um circuito simulando atividades de vida diária, o dispositivo subestimou significativamente o tempo de atividade, mas registrou uma estimativa aceitável do gasto energético no grupo como um todo.

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ANEXO

ANEXO A

Normas de formatação do periódico *Archives of Physical Medicine and Rehabilitation*

Document Formatting

Manuscripts must be double-spaced throughout, including the title page, abstract, text, acknowledgments, references, individual tables, and legends. Use only standard 12-point type and spacing. Use unjustified, flush-left margins. Number the pages of the text consecutively. Put the page number in the upper or lower right-hand corner of each page. Number each line on each page of the text to facilitate peer review.

Authors should format manuscripts for specific attributes such as italics, superscripts/subscripts, and Greek letters. The coding scheme for each such element must be consistent throughout the file.

Text Style

- Enter only 1 space between words and sentences.
- Leave 1 blank line between paragraphs
- Leave 2 blank lines between headings and text.

Do not use indenting or margin-setting features.

Title Page Document

These elements are in the following sequence and are double-spaced.

- Running head of no more than 40 character spaces.
- Title.
- Author(s) full name(s) and highest academic degree(s).
- The name(s) of the institution(s), section(s), division(s), and department(s) where the study was performed are provided and the institutional affiliation(s) of the author(s) at the time of the study are

indicated. An asterisk after an author's name and a footnote may indicate a change in affiliation.

- "Acknowledgment of any presentation of this material, to whom, when, and where.
- Acknowledgment of financial support, including grant numbers.
- Any other needed acknowledgments.
- Requisite financial disclosure as selected from the Disclosure Statements & Copyright Assignment form and an explanation of any conflicts of interest.
- Name, address, business and home telephone numbers, and e-mail address of corresponding author and the author from whom reprints can be obtained.
- If reprints are not available, this is stated on the title page.
- Clinical trial registration number, if applicable.

Acknowledgments

One or more statements should specify: (1) contributions that do not justify authorship (ie, third-party statistical analysis, writing/editing); and (2) acknowledgments of technical help.

Persons who have contributed intellectually to the manuscript but whose contributions do not justify authorship must be named and their function or contribution described, eg, "scientific adviser," "critical review of study proposal," "data collection," or "participation in clinical trial." Such persons must give permission to be named. Authors are responsible for obtaining written permission from persons acknowledged by name because readers may infer their endorsement of the data and conclusions.

Clerical, administrative, and laboratory staff should not be acknowledged, unless they have contributed significantly to the research, writing, or intellectual quality of the article.

Abstract

For Articles reporting original data (Article; Brief Reports; Prosthetics, Orthotics, Devices; Clinical Management Reviews; Clinical Implications of Basic Research) and Review Articles (including Meta-Analyses), see the Instructions for Structured Abstracts. For other manuscripts (eg, Clinical Notes, Commentaries, Special Communications), include a conventional, unstructured abstract of no more than 250 words.

Key Words

Accompanying all abstracts, authors must provide 3 to 5 Key Words. Key words must be selected from the US National Library of Medicine's (NLM) *Medical Subject Headings, which is available at* http://www.nlm.nih.gov/mesh/MBrowser.html.

Abbreviations

Archives editorial policy is to minimize the use of abbreviations. Fewer abbreviations make it easier for the multidisciplinary readership to follow the text. Authors should include a list of abbreviations in their manuscript file following the abstract (just above introduction).*Archives* uses only standard abbreviations with Davis's and Dorland's as our guides. Abbreviations that are used only in tables, appendices, or figures are not included in the list and should be defined in the table, appendix, or figure note; however, abbreviations that are in the list need not be re-defined in a table footnote or legend. All abbreviations must be defined on first mention in the body of the manuscript. The abbreviations SD (standard deviation) and SE (standard error) require no definition in *Archives*.

Headings

Methods, Results, Discussion, and Conclusions. Articles should include the subsection heading Study Limitations at the end of the Discussion section. Longer articles may need other subsection headings to clarify their content, especially the Results and Discussion sections.

Clinical Notes headings: Case Description, Discussion, and Conclusions.

Clinical Management Reviews headings: Summary of Pertinent Research, Therapeutic Approach, and Conclusions.

Other types of articles such as Commentaries and Special Communications do not require this format.

Introduction

State the purpose of the article. Summarize the rationale for the study or observation. Give only pertinent references, and do not review the subject extensively. Do not include data or conclusions from the work being reported. Do not include a heading for this section.

Trade Names

No trade names (i.e., trademarked of non-generic names of commercially available products/services) are permitted prior to the Methods section, including in the article title or abstract.

Methods

Describe the selection of the observational or experimental subjects (patients or experimental animals, including controls) clearly. Discuss eligibility of experimental subjects. Give details about randomization. Describe the methods for any blinding of observations. Identify the methods, equipment and materials, and procedures in sufficient detail to allow others to reproduce the results.

Reference established methods, including statistical methods (see below); provide very brief descriptions for methods that have been published but are not well known; describe new or substantially modified methods, give reasons for using them, and evaluate their limitations. Identify precisely all drugs and chemicals used, including generic name(s), dose(s), and route(s) of administration.

While there may be occasional exceptions, the *Archives* is committed to the need for clinical trial reports to be accompanied by adequate periods of follow-up. A lack of sufficient follow-up may be detrimental to a paper's acceptance.

When reporting work with human subjects, indicate whether the procedures followed protocol and accord with the ethical standards of the responsible institutional review board, ethics committee or with the Helsinki Declaration of 1975, as revised in 1983, as appropriate for the country where the research took place.

Do not use patients' names, initials, or hospital numbers, especially in any illustrative material. When reporting experiments on animals, indicate whether the procedures followed accord with the institution's committee on animal experimentation or with the National Research Council's guide on the care and use of laboratory animals. Archives may require authors to verify the above procedures.

Describe statistical methods in enough detail to enable knowledgeable readers with access to the original data to verify the reported results. When possible, quantify findings and present them with appropriate indicators of measurement error or uncertainty (eg, confidence intervals [CIs]). Avoid sole reliance on statistical hypothesis testing, such as *P* values, which fails to convey important quantitative information.

Researchers should report and identify the specific statistical test used and the obtained statistical value. Researchers should supplement the results of any statistical value. Researchers should supplement the results of any statistical significance test with the use of effect size values or CIs. Measures of effect size or CIs should be routinely included in quantitative clinical trials reported in rehabilitation research. The statistical power values and the corresponding type II error probability should always be reported for statistically nonsignificant results.

The investigator should ensure that there is sufficient power to detect, as statistically significant, a clinically meaningful treatment effect of an a priori specified size.

References for study design and statistical methods should be to standard works (with pages stated) rather than to papers in which designs or methods were originally reported.

Specify any general use computer programs used. Avoid nontechnical uses of technical terms in statistics, such as "random" (which implies a randomizing device), "normal," "significant," "correlation," or "sample." Define statistical terms, abbreviations, and symbols.

When submitting manuscripts on randomized controlled trials (RCTs), authors must include the CONSORT (Consolidated Standards for Reporting Trials) flow diagram.

Results

When data are summarized in the Results section, specify the statistical methods used to analyze them. Describe the success of any blinding of observations. Report treatment complications. Give numbers of observations. Report losses to observation (ie, dropouts from a clinical trial). Present results in logical sequence in the text, tables, and illustrations. Restrict tables and figures to those needed to explain arguments and to assess their support. Use graphs as an alternative to tables with many entries; do not duplicate data in graphs and tables. Do not repeat in the text all the data in the tables, illustrations, or both; emphasize or summarize only important observations.

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Units of Measurement

Metric units are required. Blood pressures in millimeters of mercury (mmHg) and all hematologic and clinical chemistry measurements using the International System of Units (SI).

Discussion

Emphasize the new and important aspects of the study and the conclusions that follow from them. Do not repeat in detail data or other material given in the Introduction or the Results section. Include in the Discussion section the implications of the findings and their limitations, including implications for future research. Authors should address the issue of effect magnitude, in terms of both the statistics reported and the implications of the research. Relate the observations to other relevant studies.

Study Limitations: Include the subsection, Study Limitations, to discuss the limitations of the study.

Conclusions: Link the conclusions with the study's goals but avoid unqualified statements not supported by the data. Avoid claiming priority and alluding to work that is incomplete. State new hypotheses when warranted, but clearly label them as such. Recommendations, when appropriate, may be included.

References

References in manuscripts accepted by *Archives* shall include only material that is retrievable through standard literature searches. Number references consecutively in the order in which they first appear in the text. Identify references in text, tables, and legends by superscript Arabic numerals. References cited only in tables or in legends to figures should be numbered in accordance with a sequence established by the first identification in the text of the particular table or figure.

Try to avoid using abstracts as references; "unpublished observations" and "personal communications" may not be used as references, although references to written, not oral, communications may be inserted (in parentheses) in the text. Avoid "personal communication" unless it provides essential information not available from a public source. In this case, cite the name of the person and date of communication in parentheses in the text. For scientific articles, authors should obtain written permission and confirmation of accuracy from the source of personal communication.Include among the references those papers accepted but not yet published; designate the journal and add "In press." Authors must obtain written permission to cite such papers as well as verification that they have been accepted for publication. Editors will request from the author(s) a copy of the letter from the journal accepting the "in press" article if the manuscript in which it is cited is accepted by Archives. Information from manuscripts submitted but not yet accepted should be cited in the text as "(unpublished observations)" with written permission from the source.

The references must be verified by the author(s) against the original documents. List all authors and/or editors for each reference. Do not insert "et al."

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After the References section, provide a Suppliers list with contact information (names and complete mailing addresses) for manufacturers of devices and other non-drug products used directly in a study (ie, do not provide such information for products not directly used in your research but mentioned in studies you cite). Identify equipment and/or materials in text, tables, and legends by superscript lower case letters. List suppliers consecutively in the order they are mentioned in the text.

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Figures should be numbered consecutively in the order they are first cited in the text. If a figure has been published, acknowledge the original source and submit written permission from the copyright holder to reproduce the material. Permission is required, irrespective of authorship or publisher, except for documents in the public domain.

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Consistency in size within the article is strongly preferred. Any special instructions regarding sizing should be clearly noted.

Photomicrographs must have internal scale markers. Symbols, arrows, or letters used in the photomicrographs should contrast with the background.

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Identify statistical measures of variations such as standard deviation and standard error of the mean. Do not use internal horizontal and vertical rules. Be sure that each table is cited in the text in order. Using too many tables in relation to the length of the text may produce typesetting difficulties.

Data from another published or unpublished source may only be used with permission and must be acknowledged fully. It is the author's responsibility to obtain such permission.

Appendices

An appendix provides data in a format that does not contain an x-y axis that defines the rows and columns, for instance, a listing of the components of a test or evaluative instrument is an appendix, not a table. Appendices are to be called out

sequentially in the text and placement will be immediately before the References section. Submit each in a separate file with a clear Appendix label.