Clinical Biomechanics 32 (2016) 1–7

Contents lists available at ScienceDirect

Clinical Biomechanics

journal homepage: www.elsevier.com/locate/clinbiomech

Gait and balance assessments as early indicators of frailty in patients with known peripheral artery disease

Rebecca Thiede [a], Nima Toosizadeh [a,b], Joseph L. Mills [a,c], Mahmoud Zaky [a], Jane Mohler [a,b], Bijan Najafi [a,b,c,*]

[a] Interdisciplinary Consortium on Advanced Motion Performance (iCAMP) and Southern Arizona Limb Salvage Alliance (SALSA), Department of Surgery, College of Medicine, University of Arizona, Tucson, AZ, USA
[b] Arizona Center on Aging, University of Arizona, Tucson, AZ, USA
[c] Division of Vascular Surgery and Endovascular Therapy, Michael E. DeBakey Department of Surgery, Baylor College of Medicine, Houston, TX, USA

A R T I C L E I N F O

Article history:
Received 12 July 2015
Accepted 14 December 2015

Keywords:
Peripheral artery disease
Locomotion
Balance postural control
Frailty
Dual task
Wearable sensor technology

A B S T R A C T

Background: Peripheral artery disease is associated with increased morbidity and mortality, and frailty syndrome may mediate the risk of these adverse health outcomes to predict intervention results. The aim of this study was to determine the association between motor performance impairments based on in-clinic gait and balance measurements with frailty at intermediate stages (pre-frailty) in peripheral artery disease patients.
Methods: Seventeen participants with peripheral artery disease (≥55 years) were recruited and frailty assessed using Fried criteria. Gait and balance were quantified using wearable sensor technologies in the clinical setting. Between-group differences in frailty were assessed using analysis of variance, and independent associations between gait and balance parameters with frailty were determined using logistic regression models.
Findings: Based on Fried index nine (53%), participants were pre-frail and eight (47%) were non-frail. Although no between-group differences in demographics or clinical parameters was observed, gait parameters were worse among pre-frail compared to non-frail participants. The highest effect sizes for between-group differences were observed in double support during habitual normal walking (effect size = 1.86, $p < 0.01$), speed variability during dual-task (effect size = 1.26, $p = 0.03$), and trunk sway during fast walking (effect size = 1.43, $p = 0.02$). No significant difference was observed in balance parameters ($p > 0.07$). The regression model using gait parameters demonstrated a high sensitivity and specificity in predicting pre-frailty.
Interpretation: A short 25-step sensor-based in-clinic overground gait test objectively identified pre-frailty independent of age. Double support was the most sensitive parameter in identifying pre-frail aging adults.

1. Introduction

Lower extremity peripheral artery disease (PAD) has an age-adjusted prevalence of nearly 12%, affecting 8 to 12 million Americans with the highest prevalence among older adults (Hirsch et al., 2001; Mozaffarian et al., 2015). PAD is associated with reduced quality of life and increased morbidity and mortality in older adults (Eraso et al., 2012). Recent advancements in both PAD treatment and prevention include aggressive risk factor management for prevention of cardiac and cerebrovascular complications, structured exercise therapy, endovascular approaches for revascularization, and, less frequently, surgical interventions (Adams et al., 2007; Norgren & Hiatt, 2007). Although advancing age has been persistently associated with adverse health outcomes, predicting the risk of adverse health conditions is challenging due to the heterogeneity of health status in older adults (Makary et al., 2010; Saxton & Velanovich, 2011). PAD patients, including those with carotid, aortic, and peripheral occlusive diseases, are generally considered a highly vulnerable population with a high prevalence of cramping, fatigue, and pain in lower extremities, and higher risk of cardiovascular morbidity and mortality compared to individuals without PAD, and they are susceptible to postoperative complications (Meijer et al., 1998).

Frailty is an increasingly important geriatric syndrome that is characterized by low physiologic reserves, increased vulnerability to acute stressors, and overall functional decline (Fried et al., 2001), and it has been linked to poor treatment outcomes and health conditions (Singh et al., 2012). Therefore, frailty can be useful in stratifying the risk of adverse health outcomes in older adults with PAD. As a reflection of biologic, rather than chronologic age, frailty is predictive of adverse outcomes independent of old age or disability and may explain the substantial heterogeneity of health status and surgical outcomes among the elderly patient population (Fried et al., 2001; Jarrett et al., 1995). The necessity of making an initial distinction based on frailty status in the treatment of elderly with vascular disease was first indicated in 1996 (Forconi & Cuerrini, 1996). Further, frailty proved to independently predict postoperative complications, length of stay, mortality, and

* Corresponding author at: Interdisciplinary Consortium on Advanced Motion Performance (iCAMP), Michael E. DeBakey Department of Surgery, Baylor College of Medicine, One Baylor Plaza, MS: BCM390, Houston, TX 77030, USA.
E-mail address: najafi.bijan@gmail.com (B. Najafi).

http://dx.doi.org/10.1016/j.clinbiomech.2015.12.002

discharge to a skilled or assisted-living facility (Fried et al., 2001; Purser et al., 2006). Recently, the *ACS NSQIP®/AGS Best Practice Guidelines: Optimal Preoperative Assessment of the Geriatric Surgical Patient* was published, recommending frailty measurement for all elders aged 65 and above undergoing surgical interventions (Chow et al., 2012).

Assessment of the five Cardiovascular Health Study (CHS) "Fried" frailty index criteria (unintentional weight loss, self-reported exhaustion, weakness (grip strength), slow walking speed, and low physical activity) is the most established approach for defining older adults as non-frail, pre-frail, or frail. Among these criteria, gait speed has been reported as one of the strongest predictors of adverse outcomes, such as mobility disability, falls, or hospitalization (Cesari et al., 2005; Gill et al., 1995; Purser et al., 2006).

Advances in wearable technologies allow more precise measurement not only of gait speed, but also of other spatial and temporal gait variables and balance behaviors. These technologies are highly valid and practical and offer a promising, cost-effective way to analyze gait and balance parameters associated with frailty in the clinical setting (Najafi et al., 2003; Najafi et al., 2009; Toosizadeh et al., 2015a). Using such technologies may facilitate identifying frailty in intermediate stages (i.e., pre-frailty) where its identification is more difficult using clinical or "eye-ball" judgments. Furthermore, routine frailty assessment could be incorporated in pre-surgical screening, per NSQIP guidelines. Although these practical methods exist to assess the decline in physical function due to frailty in older adults, no study to the best of our knowledge has identified gait and balance deficits as markers of physical functional impairments in older frail PAD individuals in the clinical settings. Hence, the aim of the current study was to determine the association between motor performance impairments with frailty at intermediate stages in PAD patients. The specific aims were (1) to compare gait and balance parameters among PAD patients with differing frailty status and (2) to determine sensitive gait and balance parameters to objectively diagnose pre-frailty in PAD patients. Wearable sensor technologies, could provide fast, in-clinic assessment of physical impairments, and therefore, the current study would provide results regarding in-clinic assessment of physical function in older population with PAD for the first time. Further, results from the current pilot study can be used to determine a better objective assessment method (balance versus gait) and identify sensitive parameters within each test for identifying pre-frailty in PAD patients to enhance preoperative clinical decision making.

2. Methods

2.1. Participants

Aging adults (age ≥ 55 years) seen in the established outpatient clinic of an experienced vascular surgeon (JLM) with a clinical and hemodynamic diagnosis of PAD based on the 2011 ACCF/AHA criteria (Guideline Recommendations: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines (Jneid et al., 2012)), were recruited from the University of Arizona Division of Vascular and Endovascular Surgery between July 2012 and July 2014. Participants were excluded if they had any clinically significant medical or psychiatric condition (including dementia, or serious mental illness based on their medical history or the mini–mental state examination (MMSE) < 24), or laboratory abnormality that could, in the judgment of the investigators, interfere with the ability to participate in the study. PAD participants were excluded if they had known disorders associated with severe gait and balance deficits (including stroke or Parkinson's disease), recent surgery, an active foot ulcer, major foot deformity (e.g., Charcot neuroarthropathy), or major foot amputation. Furthermore, participants with major mobility disorders (e.g., who were unable to walk a distance of 25 steps without walking assistance) or balance impairments (e.g., who were unable to perform balance trials as explained below) were also excluded. Ability of participants in performing gait and balance tests were assessed within the actual measurements, and those who failed to perform either tests were excluded. The study was approved by the University of Arizona Institutional Review Board. Written informed consent according to the principles expressed in the Declaration of Helsinki (Association, 2013) was obtained from all subjects before participation. Participants were informed that they could withdraw from the study at any time without loss of benefits.

2.2. Frailty evaluation

The Fried index (Fried et al., 2001) was used as the "gold standard." Individuals with three or more positive Fried criteria were considered "frail," those with one or two Fried criteria were considered "pre-frail," and those with none of Fried criteria were considered "non-frail."

2.3. Ankle–brachial index (ABI) measurement and subjective questionnaires

Lower extremity blood flow was quantified via ABI determination in both legs using a 10 MHz handheld Doppler as described previously (Mills et al., 2014). Subjective questionnaires included the SF-12 health survey (Ware et al., 1996) and the visual analog scale (VAS) for pain (Langley & Sheppeard, 1985). SF-12 health survey was used to assess generic health status based on physical and mental components.

2.4. Objective assessment of gait and balance

Gait and postural balance were objectively assessed using validated wearable sensor technology. Three-dimensional acceleration and angular velocity of shins, thighs, and the trunk were measured using five wearable sensors, each of which included a tri-axial accelerometer and a tri-axial gyroscope (LEGSys™ and BalanSens™—BioSensics LLC, Boston, MA), to derive gait and balance outcome measures using established methods previously reported (Aminian et al., 2002; Najafi et al., 2009; Najafi et al., 2010; Toosizadeh et al., 2015b). Sensors were attached to the shin above the ankle, to the thigh above the knee, and to the lower back in the lumbar region. This wireless technology allows quantification of spatiotemporal parameters during overground walking in clinic.

Gait was assessed with a minimum of 25 steps under three conditions: (1) habitual overground normal walk (preferred speed), (2) dual-task overground walk, and (3) fast overground walk. The habitual normal walk consisted of patients walking at the normal pace at which they perform everyday activities. The dual-task walk consisted of patients counting backward from 100 by one while walking, in order to observe the impact of an attention-demanding task on their walking habits (Lindenberger et al., 2000). Counting is a rhythmic task and may highly interfere with another rhythmic task that has a different frequency such as walking (Beauchet et al., 2005; Taga et al., 1991). The dual-task of counting backward by "one" was chosen here since it has been proven to be simpler and more appropriate for older adults (Beauchet et al., 2003). Lastly, the fast walk consisted of patients walking as fast as they comfortably could without jogging or falling. LEGSys™ allows the extraction of over 30 different gait parameters. In this study, we measured gait speed, gait cycle time, stride length, double support, trunk sway during walking (i.e., anterior–posterior and medial–lateral trunk sway), speed variability, and mid-swing speed during gait steady state (see Table 1 for parameter definitions). Briefly, each sensor measures the angular velocity and acceleration of the segment. The stance and swing phase was estimated by determining heel strike (when the foot first touches the floor) and toe-off (when it takes off) using angular velocity data from shins within each gait cycle (Aminian et al., 2002). To compute the spatiotemporal gait parameters from the angular velocity of lower limbs, a mechanical model was used, and gait speed, gait cycle time, stride length, double support, speed