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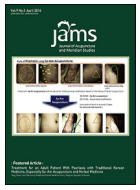
Journal of Acupuncture and Meridian Studies

journal homepage: www.jams-kpi.com



TECHNICAL NOTE

Pulse Waveform Analysis of Chinese Pulse Images and Its Association with Disability in Hypertension

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Available online 2 July 2015

Received: Feb 25, 2015
Revised: Jun 23, 2015
Accepted: Jun 23, 2015

KEYWORDS
functional capacity;
hypertension;
rehabilitation;
study protocol;
traditional Chinese medicine

Abstract
Hypertension affects functional capacity and quality of life. Pulse wave analysis (PWA) quantifies the pulse waveform's propagation and its changes resulting from arterial remodeling. Pulse image analysis (PIA) in traditional Chinese medicine contributes to pattern differentiation and therapeutic intervention. This protocol study evaluates the relationships between the parameters of both PWA and PIA to identify patterns in patients with hypertension and the associations of those patterns with functional capacity. In this observational, cross-sectional study protocol 40 patients were subjected to clinical and laboratorial examinations to assess the risk factors for cardiovascular disease and pattern differentiation. PWA was noninvasively performed at the radial artery to estimate the pulse wave's velocity, arterial compliance, and reflection index. PIA using the "simultaneous pressing" method was performed to assess nine indicators. Handgrip strength and physical activity was assessed as functional outcomes. We hypothesized that interactions between patterns and pulse images affect the PWA parameters and that the functional outcomes are weakly associated with personal, hemodynamic and risk factors for cardiovascular disease. Performing a PIA in patients with hypertension might allow the identification of early target-organ damage, standardization of the PIA based on the PWA, and unification of the pulse diagnosis.

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pISSN 2005-2901 eISSN 2093-8152
http://dx.doi.org/10.1016/j.jams.2015.06.012

1. Introduction

Hypertension is a major public health problem worldwide, and is the cardiovascular disease (CVD) with the highest prevalence in developed countries [1]. Chronic hypertension affects functional capacity [2,3] and impacts the quality of life of patients [4], often subjecting them to cardiac rehabilitation. High blood pressure acts silently through arterial remodeling [5] until signs or symptoms secondary to target—organ damage (TOD) [1] or skeletal muscles [6] occur. Clinical history, physical examination, and complementary exams are needed to monitor the disease's progress and the effects of therapeutic interventions [1]. In this sense, pulse waveform analysis (PWA) is a noninvasive and reliable method for assessing the cardiovascular system based on the phenomenon of waveform propagation and reflection throughout the arterial system [7]. PWA can be performed at both central and peripheral arteries, such as the aorta and radial arteries, respectively, and evidence shows that variables obtained from PWA of proximal arteries are similar to those obtained from peripheral arteries [8].

Traditional Chinese medicine (TCM) is a traditional health practice with systematic-philosophic reasoning based on the relationships between humanity and nature. TCM experts do not diagnose diseases, but they identify patterns as their morbid counterparts. Currently, the paradigm of pattern/disease is advocated for research [9]; i.e., patterns are studied within the context of a given disease. Contemporary literature relates five patterns to patients with hypertension, and these are identifiable by using inspection, auscultation-olfaction, inquiry, and palpation [10—15]. Even nowadays, pulse image analysis (PIA) is an important diagnostic procedure in TCM [16,17] and is performed on the radial artery bilaterally at three different positions and depths, setting the so-called nine indicators [18—20].

Previous studies achieved important findings due to advances in biomedical instrumentation, albeit with major limitations from the perspectives of either traditional or conventional medicines. Theories developed in animal models were not tested in humans and showed no theoretical correspondence with TCM [21,22]. Findings from healthy participants could not be extrapolated to other populations without proper evidence [23—25], and incomplete descriptions of the diagnostic criteria for hypertension, as well as traditional descriptions of PIA, were also found [24,26]. Finally, a lack of comparison among patterns of hypertension was found [26]. Most importantly, the relationship between PWA and PIA among TCM patterns of hypertension, as well as the relationship between those patterns and functional capacity, remains unknown.

Because structural and functional changes in hypertension primarily impact the arteries and, thus, determine the waveform's morphology, patients with hypertension present with different phenotypes due to gene—environment interactions; in addition, the radial artery can be used for both PWA and PIA. Thus, we hypothesized that variables related to PWA might have sufficient information to describe PIA. Therefore, this study protocol aims to describe the PIA by using PWA variables in patients with hypertension, to compare the variables from PWA and PIA with the hypertension-related patterns, and to quantify the association of PWA and PIA variables with the clinical and functional characteristics of the sample.

2. Materials and methods

A printed case report form was developed to collect data from each participant regarding all procedures (Supplementary file 1). Primary data obtained from the paper case report form was typed in an electronic worksheet developed in Excel for Mac (Microsoft Corp., Redmond, WA, USA) with data formatting and data validation of entries. Secondary data was calculated by using equations inserted in the spreadsheet. Statistical analysis was performed by using SPSS version 22 (IBM Corp., Armonk, NY, USA) after data importing.

The arterial function analysis system [27—29] was used to acquire noninvasive blood pressure signals. The software was developed in LabVIEW 8.0 (National Instruments, Austin, TX, USA) and controls a preamplifier circuit connected to a 14-bit acquisition board (USB 6009, National Instruments). Noninvasive piezoelectric transducers (PT-102, iWorx System Inc., Dover, NH, USA) was attached to the upper arm with Velcro straps.

The pattern differentiation algorithm (PDA) was used for pattern differentiation and was also developed in LabVIEW 8.0 (National Instruments). Data from the electronic worksheet was imported into the PDA for automated pattern differentiation. The accuracy of the PDA for pattern differentiation was 94.7% (sensitivity = 89.8%; specificity = 99.5%) [30].

2.1. Timing and study design

This is an observational, cross-sectional protocol study with prospective admission of cases. Fig. 1 exhibits the study's flowchart with the respective timing of each procedure. The same examiner (N.G.R.M.), a certified TCM expert who has had a 2-year training period and 6 years of TCM clinical practice, performed all procedures and measurements.

2.2. Ethics

This study protocol was approved by the Institutional Ethics Committee (Centro Universitário Augusto Motta (Rio de Janeiro, RJ, Brazil)) prior to its execution (CAAE 34723714.2.0000.5235). Participants, after having received an explanation of the study's aims and potential risks and of the benefits associated with their participation, signed a written informed consent form to participate in this study.

2.3. Participant recruitment: Inclusion and exclusion criteria

Data were collected at the Division of Arterial Hypertension at the National Institute of Cardiology (Rio de Janeiro, RJ, Brazil) between 08:00 AM and 11:00 AM, as recommended for PWA [7] and PIA [18,19], from September 2014 to June 2015. Patients enrolled for antihypertensive drug treatment were addressed for eligibility by checking the inclusion and the exclusion criteria discussed below. Medications used