Cardiovascular Revascularization Medicine 20 (2019) 207–209

Contents lists available at ScienceDirect

Cardiovascular Revascularization Medicine

Validation of digital ankle-brachial index as a screening tool in symptomatic patients with peripheral arterial disease

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ARTICLE INFO

Article history:
Received 5 May 2018
Accepted 26 June 2018

Keywords:
Peripheral arterial disease
Digital ankle-brachial index
Peripheral angiography

ABSTRACT

Introduction: There is scarcity of data validating portable digital ankle-brachial index (ABI) with contrast angiography in peripheral arterial disease (PAD). Our aim was to provide an objective analysis of the relationship between digital ABI (dABI) and peripheral angiographic data.

Methods: Consecutive patients with symptoms of PAD between May 2014 to May 2015 at Einstein Medical Center, Philadelphia, who were undergoing simultaneous dABI and peripheral angiography, were evaluated. Measurements were made using the FloChec™ Digital ABI system (Bard) prior to the scheduled peripheral angiogram.

Results: The final cohort consisted of 51 patients. Mean age was 68.8 ± 9.5 years with 55% being male. Aorto-iliac disease accounted for 13% of the total lesions, while femoro-popliteal lesions comprised 55%. The FloChec™ digital ABI had a sensitivity of 84% and a positive predictive value of 84%. The area under the receiver operating characteristic curve was 0.74 ($p = 0.007$). On multivariate analysis, FloChec™ digital ABI was still an independent predictor of PAD, Odds ratio 6.8 (2.3–20.6, $p = 0.001$).

Conclusion: A portable, point-of-care digital ABI system can be used as a valuable, simple, cost-effective and reliable screening tool with high sensitivity and accuracy. To date, ours is the first study validating FloChec™ digital ABI with the gold standard angiographic data.

1. Introduction

Peripheral arterial disease (PAD) is a systemic disease associated with reduced quality of life, and increased cardiovascular (CV) morbidity and mortality [1–3]. PAD is under diagnosed for a variety of reasons including lack of awareness among physicians, and relative inaccessibility of equipment required to diagnose this condition with precision [4]. When PAD is suspected, the guidelines recommend measuring resting ankle-brachial index (ABI) [5]. One of the drawbacks of Doppler ABI is that it is time consuming and requires technical expertise [6, 7]. Automated Doppler ABI testing through plethysmography (digital ABI) may be preferred due to its speed and ease of use [7, 8]. Studies comparing digital ABI methods to Doppler ABI have shown concordance above 90% [9, 10]. All these screening tests have been validated against symptoms [11, 12] but none of the studies have compared these tests to the peripheral angiography. There is scarcity of data validating portable digital ABI with peripheral angiography in PAD. The aim of this study was to provide an objective analysis of the relationship between digital ABI (dABI) and peripheral angiographic data.

2. Methods

This is a retrospective study of consecutive patients with symptoms and/or risk factors for symptomatic PAD, who presented to Einstein Medical Center, Philadelphia between May 2014 and May 2015. Patients with prior interventions for PAD were excluded. In the outpatient setting, patients first had their dABI measured using the FloChec™ Digital ABI system [Bard]. The FloChec™ system consists of a portable netbook PC, a printer, and a Sensor assembly. A proprietary algorithm calculates the Blood Flow Index (BFI), which is a measure of proximal patency. Comparison of BFI in the lower extremity to BFI in the upper extremity provides the ratio known as digital ABI. A digital ABI result of <0.92 indicates the presence of flow obstruction. Patients with digital ABI <0.92 were subsequently referred for peripheral angiography. An angiographic stenosis >50% of the vessel luminal diameter was considered

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https://doi.org/10.1016/j.carrev.2018.06.025
1553-8389/

Table 1
Baseline characteristics.

Variables	N = 51
Age, in yrs	68.8 ± 9.5
Male - no, (%)	28 (55%)
Race	
Caucasians - no, (%)	12 (24%)
Black - no, (%)	35 (68%)
Diabetes Mellitus - no, (%)	27 (53%)
Tobacco abuse - no, (%)	28 (55%)
Stroke - no, (%)	10 (20%)
Dyslipidemia - no, (%)	49 (96%)
Hypertension - no, (%)	44 (87%)
Coronary artery disease - no, (%)	39 (77%)
Chronic kidney disease - no, (%)	9 (18%)
H/O congestive heart failure - no, (%)	13 (26%)
Prior coronary artery bypass graft - no, (%)	7 (14%)
Claudication - no, (%)	46 (90%)
Peripheral angiography findings	
Aorto-iliac disease - no, (%)	7 (13%)
Femoro-popliteal disease - no, (%)	28 (55%)
Multi-level disease - no, (%)	16 (32%)

significant. Demographic data and angiographic results were collected. The data was de-identified, and the study was approved by Institutional Review Board at Einstein Medical center, Philadelphia, PA.

2.1. Statistical analysis

Normally distributed continuous data are expressed as mean values (±standard deviation). Non-normally distributed continuous data are expressed as median (interquartile range). Frequencies of categorical variables are expressed as numbers (percentage). SPSS version 20 was used to perform data analysis.

3. Results

The baseline demographic variables of the study participants are shown in Table 1. The final cohort consisted of 51 patients. The mean age was 68.8 ± 9.5 years with 55% being male. The prevalence of PAD in our study population was 75%. The FloChec™ digital ABI had a sensitivity of 84% and specificity of 48%. The positive predictive value was 84%. The area under the receiver operating characteristic curve was 0.74 (p = 0.007, Fig. 1). On multivariate analysis adjusted for diabetes, hypertension, coronary artery disease, smoking, Flochec digital ABI was still an independent predictor of PAD, Odds ratio 6.8 (2.3–20.6, p = 0.001). The results were in the same range analyzed separately between the right and the left limb.

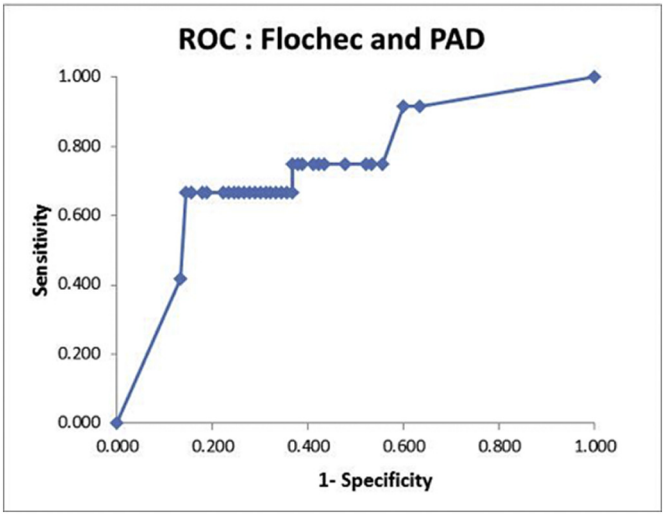

Fig. 1. Receiver Operating Characteristics (ROC) of FloChec Digital ABI.

4. Discussion

The main finding of our study is that the FloChec™ digital ABI system can be used as a valuable, simple, cost-effective and reliable screening tool with high sensitivity and accuracy. Secondly, with a high sensitivity and positive predictive value, it can serve as a portable, point-of-care device to rule out symptomatic PAD.

There are several advantages of FloChec™ System over Doppler ABI. The FloChec™ System measures distal perfusion, as opposed to the two specific tibial vessels at the ankle in Doppler ABI. Doppler ABI are prone to false negatives in non-compressible vessels. FloChec™ is not subject to such a limitation. The FloChec™ test may be performed in few minutes, whereas, Doppler ABI may take between 15 and 20 min. Lastly, the results of FloChec™ measurements are objective, reproducible, and not subject to the technique and trade craft of Doppler ABI measurements. In our study, FloChec™ digital ABI was performed in the office by ancillary staff, supervised by the providers. In PAD, early and accurate diagnosis, and thereby treatment could potentially improve clinical outcomes [13]. Thus, FloChec™, with its ease of use, high sensitivity and positive predictive value, could serve as a reliable tool in symptomatic PAD patients.

5. Conclusions

A portable, point-of-care digital ABI system can be used as a valuable, simple, cost-effective and reliable screening tool with high sensitivity and accuracy. To date, ours is the first study validating FloChec™ digital ABI with the gold standard angiographic data.

6. Study limitations

Our study is a retrospective study with a small sample size.

Statement of authorship (all authors)

All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

Grant support

None.

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