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What is the Potential for False Positive Results in Ankle Brachial Index Measurements Performed by Emergency Providers?

George L Higgins*

Director of Research, Department of Emergency Medicine, Maine Medical Center, USA

Abstract

Introduction: The Ankle-Brachial Index measurement (ABI) is an easily performed bedside test used to screen for lower extremity arterial injury. It is possible that the ABI is not always correctly performed in the acute setting, depending on available equipment and provider familiarity with validated measurement techniques. We sought to determine the potential for false positive ABI results in healthy subjects if the ABI is performed incorrectly. We also sought to identify the method most likely to minimize false positive results.

Materials and methods: Healthy volunteers and low acuity emergency department patients were enrolled. Exclusion criteria included a known history of documented peripheral arterial disease or extremity trauma. Subjects were examined by two investigators. "Most Accurate" (MA) ABI measurements used the higher of the two ankle readings and the higher of the two brachial readings to calculate the result. "Least Accurate" (LA) measurements used the lower of the two ankle readings and the higher of the two brachial readings.

Results: 118 study subjects were enrolled: mean age 32.8 years (range 19 to 49), 50% female, none with known peripheral vascular disease or extremity trauma, and none with documented femoral artery bruit at the time of the study. When a single provider performed LA ABI's, the false positive rate was 29%, while single provider MA ABI's lowered the false positive rate to 2%. For two provider ABI's, these rates were 4% and 0%, respectively.

Conclusions: We identified an unacceptably high rate of false positive ABI results if the test is performed incorrectly. We recommend strict adherence to standardized ABI measurement protocols to minimize this error. Ideally, an ABI measurement of less than 0.9 in a patient with lower extremity trauma should be confirmed by a second provider in order to minimize the risk of inappropriately implementing invasive diagnostic procedures.

Keywords: Ankle-brachial index measurement (ABI); False positive results; Peripheral arterial disease

Introduction

Initially tested and validated as a valuable procedure in diagnosing patients with clinically significant atherosclerotic peripheral vascular disease, the Ankle-Brachial Index (ABI) has emerged as a noninvasive, easily performed and safe method used by emergency providers to evaluate patients for clinically significant traumatic vascular injuries of the lower extremities [1-5]. This procedure is currently applied in the setting of both penetrating and blunt injuries, including major joint dislocations. The calculated measurement often determines critical and invasive next steps in the evaluation process. Recent emergency medicine and surgery textbooks recommend that an ABI of less than 0.9, in certain clinical circumstances, requires immediate further diagnostic testing, including consideration of arteriography [6-8]. However, this assumes that precise ABI measurement and calculation protocols are followed.

It is reasonable to assume that, on occasion, ABIs are currently being performed in emergency departments (EDs) using alternative methods, depending on available equipment, and that the ABI procedure performance and calculation are not always uniformly conducted depending on provider familiarity with the recommended measurement technique. Given the recommendation for further, often invasive testing in patients with ABI values less than 0.9, this variability can have important clinical consequences. The risk of a false positive result is not insignificant. In addition to the expense and resource requirements associated with computerized tomographic angiography or percutaneous arteriography, these procedures have the potential to cause serious complications including radiation exposure, hemorrhage, thrombosis, pseudoaneurysm formation, contrast allergy, and acute renal injury [9,10].

The primary goal of this study was to determine the number of relatively young, asymptomatic, non-traumatized subjects with no known history of peripheral vascular disease who would prove to have an ABI values less than 0.9, presumably a false positive subgroup. We hypothesized that strict adherence to a validated ABI measurement and calculation protocol would reduce the likelihood of a false positive result when compared to a less accurate method that could realistically be utilized in the acute clinical setting.

Materials and Methods

We used a prospective, observational design to evaluate the variability and reliability of ABI measurements. The study took place in the Department of Emergency Medicine (ED) at Maine Medical Center, a 606-bed academic ACS Level I trauma center. At the time of the study, the ED treated approximately 60,000 adult and pediatric patients annually. The institutional review board exempted the study and waived the requirement for written informed consent.

Study participants included ED patients presenting with low acuity

***Corresponding author:** George L Higgins III, MD, FACEP, Maine Medical Center, Department of Emergency Medicine, Portland, ME 04102, USA, Tel: (207) 662-1452; E-mail: higgig@mmc.org

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complaints (Emergency Severity Index triage categories 3, 4, and 5) unrelated to lower extremity trauma. Additionally, volunteers were recruited from among the ED staff and from a local EMS system. All were required to be between 18 and 50 years old and have no history of documented peripheral arterial disease or extremity trauma. Potential subjects were approached by study investigators who explained the purpose of the study and interventions while providing a written document describing the rights and responsibilities of the study participants. Those who agreed to participate were enrolled and participated in the study interventions.

Three physician investigators (identified herein as raters A, B and C) performed all ABI measurements using a standardized methodology [11]. Rater A examined essentially all study subjects, while raters B and C examined approximately half of the study subjects. All subjects received two different rater examinations.

Subjects were examined in the supine position. The same 8 MHz continuous-wave Doppler ultrasound probe (Mini Duplex model D900, Huntleigh Healthcare Inc, Eatontown, NJ) was used for all exams. Doppler ultrasound measurements were chosen over stethoscope measurements because of their proven superiority for both interrater and intrarater reliability when calculating ABIs in patients with peripheral vascular disease [12]. Appropriately sized blood-pressure cuffs were chosen, with bladder diameter corresponding to 40% of the patient's limb circumference. The blood-pressure cuff was placed on the subject's arm but was not inflated and the brachial pulse was palpated. Songraphic gel was applied at the pulsatile site and a Doppler signal was obtained by placing the probe at a 60-degree angle toward the participant's head. The cuff was then rapidly inflated to 20 to 30 mmHg above the point of cessation of brachial artery Doppler flow and then was slowly deflated in order to note the first discerned systolic value, which was recorded on a standardized data collection sheet. The procedure was repeated on the contra-lateral arm.

For the lower extremity measurement, the cuff was placed over the distal leg. The dorsalis pedis artery pulsation can be located just lateral to the extensor hallucis longus tendon. The Doppler probe was placed on the palpable dorsalis pedis pulse or on the site that produced the best arterial Doppler signal. The blood pressure cuff inflation/deflation and Doppler auscultation procedures were identical to those performed in the upper extremity. The entire procedure was repeated for the posterior tibial artery.

Two complete sets of blood pressure measurements (brachial right and left, dorsalis pedis right and left, posterior tibial right and left) were obtained for each study subject, one set by each of two investigators.

The ABI was calculated by dividing the appropriate systolic blood pressure in the ankle by the appropriate systolic blood pressure in the arm. The higher of the two brachial systolic pressures was used in order to control for possible occult upper extremity arterial occlusive disease. In the lower extremity, the higher of the systolic pressures from the dorsalis pedis or posterior tibial artery was used. The ABI was calculated for both legs.

The ABI values were recorded for each subject by the investigator performing the procedure. Investigators were blinded to each other's recordings. Basic demographic information was also collected by investigators. "Most Accurate" ABI measurements were defined as using the higher of the two ankle readings and the higher of the two brachial readings to calculate the result, i.e. the correct calculation method. "Least Accurate" ABI measurements used the lower of the two ankle readings and the higher of the two brachial readings, an incorrect calculation method that has the greatest potential to produce false positive results.

Given that previous investigators have reported an intra-class correlation coefficient (ICC) ranging from 0.87 to 0.92 for the ABI in patients with peripheral vascular disease, we relied upon the recommendations of a subsequent analysis that determined optimal sample sizes for investigations of reliability using the ICC based upon desired power, magnitude of the predicted ICC and the lower confidence limit [13,14]. Given these, we determined that for a confidence level of 0.95, a power of 0.80, two ratings per subject, and an estimated ICC of 0.8, 117 subjects would be necessary.

Data elements were entered into a Microsoft Excel (Redmond, WA) database. Data were analyzed using both SPSS for Windows, version 16.0 (Statistical Package for the Social Sciences, Inc., Chicago, IL) and MedCalc, version 9.6.4.0 (Frank Schoonjans, Belgium) statistical software. Statistical significance was set at an alpha of less than 0.05. Descriptive statistics were used to describe the demographic characteristics of the study cohort.

We used the ICC, which compares the variance among multiple raters (within a single subject) to the overall variance (across all ratings and subjects), in order to present a measure of reliability [15]. The ICC estimates the proportion of variance in the data that is due to differences in the subjects rather than differences in the raters. ICC values of greater than or equal to 0.75 are considered excellent, indicating that the measurements can be used to discriminate between subjects [16]. In addition, the *F*-test was utilized to evaluate for differences in ABI measure variability between raters.

Results

118 subjects were enrolled and completed the study protocol. Consistent with exclusion criteria, no subject reported a history of peripheral artery disease or extremity trauma. Demographic and physical examination data for all subjects are shown in Table 1.

Two complete sets of blood pressure measurements (brachial right and left, dorsalis pedis right and left, posterior tibial right and left) were obtained for each subject. The results of the calculated ABI measurements are shown in Table 2 for the Most Accurate ABI and Table 3 for the Least Accurate ABI measurements.

When the ABI measurement was calculated by a single rater using the LA method, the false positive result rates were as follows: overall, 29% (95% CI: 21.7-33.1%); right sided measurements, 21% (95% CI: 15.4%-30.6%); and left sided measurements, 31% (95% CI: 23.9%-40.9%). These error rates decreased when two raters performed the calculation using the LA method: overall, 4% (95% CI: 3.4%-10.8%); right sided measurements, 4% (95% CI: 2.5%-12.6%); and left sided measurements, 4% (95% CI: 2.9%-14.3%).

When a single rater performed the calculation using the MA method, the false positive result rates were as follows: overall, 2% (95% CI: 1.1-5.4%); right sided measurements, 2% (95% CI: 0.5%-5.9%); and left sided measurements, 3% (95% CI: 1.4%-8.4%). These error rates also decreased when two raters performed the calculation using the MA method: overall, 0% (95% CI: 0%-3.1%); right sided measurements, 0% (95% CI: 0%-3.1%); and left sided measurements, 0% (95% CI: 0%-3.2%).

Overall, 53 (45%) different study subjects had at least one ABI measurement of less than 0.9 and, therefore, in the appropriate clinical setting, would have been identified as possibly having a traumatic

Characteristic	n (%)
Age: mean (SD)	32.8 (7.5)
Sex	
Female	59 (50)
Male	59 (50)
Race	
Caucasian	115 (97.5)
Asian	1 (0.8)
Hispanic	1 (0.8)
Black	1 (0.8)
Pulses by Palpation	
Left Dorsalis Pedis	
Present	116 (98.3)
Absent	2 (1.7)
Right Dorsalis Pedis	
Present	113 (95.8)
Absent	5 (4.2)
Left Posterior Tibial	
Present	118 (100)
Absent	0 (0)
Right Posterior Tibial	
Present	118 (100)
Absent	0 (0)
Femoral Bruit	
Present	118 (100)
Absent	0 (0)

Table 1: Characteristics of the study subjects (n=118).

ABI Measurement Mean ABI and Rater	N SD	Minimum ABI Variance	Maximum ABI
Rater A–Right **1.09 0.084**	117 0.007	0.8943	1.3390
Rater B–Right **1.07 0.109**	60 0.012	0.8154	1.3793
Rater C–Right **1.09 0.082**	59 0.007	0.9167	1.2727
Rater A–Left **1.08 0.082**	117 0.007	1.3404	0.8333
Rater B–Left **1.06 0.103**	60 0.011	0.7887	1.3103
Rater C–Left **1.09 0.094**	59 0.009	0.9333	1.2982

*Differences in variability (standard deviation) between the raters were evaluated with the F-test:
Right side, rater A and rater B: F=1.6838, p=0.018,
Right side, rater A and rater C: F=1.0494, p=0.853,
Right side, rater B and rater C: F=1.7670, p=0.031,
Left side, rater A and rater B: F=1.5778, p=0.038,
Left side, rater A and rater C: F=1.3141, p=0.215,
Left side, rater B and rater C: F=1.2007, p=0.487.

Table 2: Variability in "Most Accurate" ABI measurements.*

vascular injury requiring further, potentially invasive evaluation. When considering those who had two ABI measurements of less than 0.9, this number dropped to 10 (9%) subjects. The numbers of subjects with ABI measurements less than 0.9 and equal to or greater than 0.9, as determined by one and two raters, are presented in Table 4.

The mean variation, or standard deviation, within subjects, between subjects, and between raters is provided in Table 5. Intra-observer variation was 0.063 ABI points, while variation among subjects was 0.129 ABI points. Examining this in relation to total variance, the ICC was determined to be 0.884, or 88%. The ICC represents inter-rater agreement over the range of ABI values.

ABI Measurement Mean ABI and Rater	N SD	Minimum ABI Variance	Maximum ABI
Rater A–Right **1.00 0.169**	117 0.029	0.0000	1.2881
Rater B–Right **0.99 0.173**	60 0.030	0.0000	1.2759
Rater C–Right **1.00 0.161**	59 0.026	0.0000	1.2308
Rater A–Left **0.97 0.192**	117 0.037	0.0000	1.2766
Rater B–Left **0.91 0.271**	60 0.074	0.7887	1.2414
Rater C–Left **1.02 0.111**	59 0.012	0.7636	1.2909

*Differences in variability (standard deviation) between the raters were evaluated with the F-test:
Right side least accurate, rater A and rater B: F=1.0479, p=0.817,
Right side least accurate, rater A and rater C: F=1.1018, p=0.691,
Right side least accurate, rater B and rater C: F=1.1546, p=0.585,
Left side least accurate, rater A and rater B: F=1.9922, p=0.002,
Left side least accurate, rater A and rater C: F=2.9920, p<0.001,
Left side least accurate, rater B and rater C: F=5.9606, p<0.001.

Table 3: Variability in "Least Accurate" ABI measurements.*

	ABI	Right n (%)	Left n (%)	Right Least Accurate n (%)	Left Least Accurate n (%)
Single Rater	< 0.90	2 (1.7)	4 (3.4)	25 (21.2)	36 (30.5)
	≥ 0.90	118 (100)	118 (100)	113 (95.8)	113 (95.8)
Two raters	< 0.90	0 (0)	0 (0)	5 (4.2)	5 (4.2)
	≥ 0.90	116 (98.3)	114 (96.6)	88 (74.6)	77 (65.3)

Table 4: ABI measurements <0.90 and ≥ 0.90.

Variance Component	Observed Variance	SD	95% CI SD
Intraobserver Variation, σ	0.004	0.063	0.062–0.066
Observer Bias, λ	0.0003	0.055	0.053–0.057
Interaction Bias, φ	0.003	0.057	0.056–0.060
Sum of σ, λ, φ	0.010	0.006	
Variance between Subjects, τ*	0.017	0.129	0.125–0.135

*ICC=0.884 (88%), the proportion of total variance that is attributable to differences between the subjects.
σ: Intra-observer variation=variance of ABI measurements when two measurements are performed on the same subject by the same rater.
λ: Observer bias=the variance of ABI measurements when two measurements are performed on the same subject by different raters; assumed to be caused by systematic bias on the part of the rater.
φ:Interaction bias=the variance of ABI measurements when two measurements are performed on the same subject by different raters; assumed to be caused by interaction between the subject and rater.
τ:Variance between subjects=true variance between subjects; variance that is medically meaningful that we interpret clinically.

Table 5: Ankle brachial index measurement variance components.

Discussion

Although somewhat limited, recent literature has suggested that the ABI is a safe, easily performed and accurate screening tool to rule in or out clinically significant arterial injuries of the lower extremities [17-22]. This has important implications as point-of-care ABI evaluation has the potential to identify patients with a low likelihood of vascular injury, thus reducing the cost and morbidity associated with what is generally accepted to be the gold standard diagnostic procedure, contrast arterial angiography. The complication rate of lower extremity angiography can approach 2% and includes hemorrhage, thrombosis

and pseudoaneurysm formation at the puncture site, as well as dye allergy and acute renal injury [9,10].

Mills et al. reported impressive ABI performance in patients with traumatic knee dislocations, with sensitivity, specificity, positive predictive value and negative predictive value all determined to be 100% [18]. However, their study population was relatively small, numbering only 38 patients. Of these, 11 had an ABI of less than 0.9, all requiring surgical intervention. All 27 patients with an ABI of equal to or greater than 0.9 were managed conservatively with observation and repeat physical examinations, and none developed a delayed complication.

Nassoura and colleagues reported ABI and Brachial-Brachial Index (BBI) performance in patients with penetrating extremity injuries [20]. By definition, these injuries were located within proximity of a major arterial structure and could not demonstrate hard (e.g. absence of distal pulse, expanding hematoma, active arterial hemorrhage, bruit or thrill) or soft (e.g. peripheral nerve deficit, small hematoma) evidence of vascular trauma. The study included 298 patients with 323 injuries in the following anatomical distribution: upper extremity proximal to the elbow, 74; upper extremity distal, 10; lower extremity proximal to the knee, 160; and lower extremity distal, 79. ABI/BBI measurements were conducted on all involved extremities, after a thorough physical examination, but prior to angiography (performed on all patients). 40 patients (12%) proved to have occult arterial involvement with angiography. Eleven patients had a normal (equal to or greater than 0.9) ABI/BBI, but an abnormal angiogram. Two of these patients required surgical intervention to repair pseudoaneurysms of the superficial femoral artery, two were treated with endoluminal stents, and one underwent angiographic embolization. Six remaining patients were managed conservatively. All 29 ABI/BBI measurements of less than 0.9 were associated with abnormal angiograms. However, only four of these patients required surgical intervention. The overall ABI/BBI performance in this study was as follows: 283 true negative; 11 false negative; 29 true positive; 0 false positive; sensitivity 72%; specificity 100%; positive predictive value 100%; and negative predictive value 96%.

Studies including patients with blunt or penetrating extremity trauma have produced similar impressive ABI and BBI performance, with overall accuracy reaching 95% [20,21]. Incorporating Doppler arterial evaluations into protocols for these patients, investigators demonstrated a significant decrease in angiography rates (14% prior to vs. 5% following implementation of routine ABI/BBI measurement) without adverse impact on eventual clinical outcomes [21].

Given the generally promising results of ABI studies in lower extremity trauma, the ABI has emerged as a diagnostic bedside procedure implemented early in the evaluation of patients at risk for these types of injuries. It is essential, then, that the ABI procedure and calculation be performed accurately. A false negative ABI measurement could result in a delay in diagnosis for a time-sensitive condition, with a possible adverse outcome being a preventable limb amputation. A false positive measurement, on the other hand, could subject the patient to needless angiography with its attendant risks and costs.

Reliance on a single test to drive important and potentially risky management decisions, then, must be based on proven accuracy and reproducibility. We hypothesized that less than strict adherence to the correct performance and calculation of the ABI by a single provider could result in an unacceptably high false positive error rate. We also hypothesized that different providers examining the same patient might calculate clinically significant different ABI results, even when the measurement and calculation were conducted in accordance with a structured protocol that has been tested and validated. Our study population was chosen to screen out subjects with occult peripheral arterial obstruction and include those more likely to sustain blunt and penetrating lower extremity injuries.

The findings of our investigation suggest that an ABI measurement performed or calculated incorrectly by a single a provider could result in a false positive rate that approaches 30%. This error is decreased to a still clinically relevant rate of 4% if two providers perform the measurement and calculation incorrectly. If a single provider performs the measurement and calculation correctly, the false positive rate is less than 2%. Two providers performing the ABI correctly will essentially eliminate the risk of a false positive result.

Limitations

There are several limitations that deserve mention when considering our study findings. We used a single academic tertiary care setting, which may limit the ability to generalize our findings. In addition, all ABI measurements were conducted by only three investigators. It is also possible that over the course of the study they became more proficient in the ABI measurement procedure. By the end of the study period the investigators were able to confidently complete an ABI procedure in less than five minutes. It is possible that ABI measurements conducted infrequently by multiple practitioners in more challenging clinical settings would produce more variable results. However, the skills required are minimal and well within the purview of Emergency Physicians and Trauma Surgeons.

Study subject follow-up was not included as an element of our investigation and our study design did not include a gold standard outcome to determine the presence of occult peripheral vascular disease. Therefore, it is possible that a portion of ABI measurements of less than 0.9 were actually true positives. To mitigate this, volunteers with known atherosclerosis were excluded and the upper age of enrollment was capped at 50 years to obtain a generally healthier population. No study subject had an audible femoral artery bruit. Finally, all subjects had palpable femoral pulses and at least one palpable pedal pulse and were, therefore, unlikely to have significant occlusive disease. Therefore, we believe that is unlikely that we categorized a true positive as a false positive. It should also be mentioned that our study was not designed to evaluate false negative results.

In conclusion, we noted variability in ABI measurements obtained by individual emergency physicians as well as a clinically relevant number of false positive cases when ABI measurements were acquired by a single observer. We recommend strict adherence to standardized ABI measurement and calculation protocols to minimize measurement error. Such protocols are straight forward, require basic skills and tools, and are easily incorporated into clinical practice. We also recommend that an ABI measurement of less than 0.9 in a patient with lower extremity trauma, even if performed accurately and correctly by a single provider, be confirmed by a second provider in order to minimize the risk of inappropriately implementing invasive diagnostic procedures.

Author Contributions

GLH, TEE and ADP conceived the study and designed the trial. TEE supervised the conduct of the trial and data collection. TEE, GLH and ADP undertook recruitment and enrollment of subjects. TDS managed the data, including quality control. TDS provided statistical advice on study design and analyzed the data, and interpreted the study results. GLH, ADP and TDS drafted the manuscript and all authors contributed.

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