Are Toe Pressures Measured by a Portable Photoplethysmograph Equivalent to Standard Laboratory Tests?

Phyllis A. Bonham  ■  Teresa Kelechi  ■  Martina Mueller  ■  Jacob Robison

PURPOSE: The purpose of this study was to determine if toe pressures (TPs) obtained by a registered nurse using a portable photoplethysmograph (PPG) were equivalent to TPs obtained by a registered vascular technologist (RVT) using standard laboratory equipment.

DESIGN: A within-subjects, comparative design was used for the study.

SETTING AND SUBJECTS: Thirty subjects referred to a vascular laboratory for arterial studies were recruited. All tests were performed in the outpatient vascular laboratory of a large, urban medical center.

METHODOLOGY: Toe pressures were measured on subjects by the same RN and RVT during the same visit. Data were analyzed using the Bland-Altman method that compares bias (mean difference) and precision (limits of agreement) of measurements to previously determined cutoff criteria for clinically important limits of difference (±15 mm Hg) in order to assess equivalence and repeatability of measurements. Kappa statistic was calculated to assess RVT-RN agreement to detect lower extremity arterial disease (LEAD) (ie, TP < 50 mm Hg). Sensitivity and specificity of the portable PPG measures were determined.

RESULTS: Precision for RVT-RN TPs exceeded the previously determined cutoff criteria (±15 mm Hg), but precision for repeated RN PPG measures fell within the clinically important limits. Kappa statistic calculation (κ = 0.76) revealed substantial agreement (90%) between the RVT and RN measures to detect LEAD (<50 mm Hg). The portable PPG technique had good sensitivity (79%) and high specificity (95%) for detection of LEAD.

CONCLUSION: Although TPs obtained by the portable PPG were not equivalent to standard laboratory tests, the portable technique agreed sufficiently with the RVT to detect LEAD. The good sensitivity and high specificity of the portable PPG make it suitable for nurses and other primary care providers to use for high-risk patients or patients with wounds, when the ankle brachial index either is elevated above 1.3 or cannot be performed. Photoplethysmograph is also suitable to assess healing potential and the need for referrals to the vascular laboratory, surgeon, or the need for adjunctive therapies.

■ Introduction

The effects of lower extremity arterial disease (LEAD) go far beyond what many clinicians view as benign leg discomfort. Rather, LEAD is associated with increased morbidity and mortality from cardiovascular events. Yet, this awareness has been slow to translate into clinical practice as evidenced by the high rate of undiagnosed LEAD. Early detection of asymptomatic LEAD is key to implementing behavioral changes for risk reduction (ie, tobacco cessation, weight loss, exercise, and pharmacotherapy to control hypertension and hyperlipidemia). The severity of LEAD also guides specific therapeutic interventions for patients with lower extremity wounds such as debridement, compression, adjunctive treatments, and referral for surgical intervention.

Noninvasive tests such as ankle brachial index (ABI) are recommended to assess for LEAD in high-risk individuals. If the ABI is higher than 1.3, measurement of toe pressure (TP) or toe brachial index (TBI) is recommended. Both ABI and TP/TBI tests correlate well with angiographically proven LEAD. Despite the magnitude of unrecognized LEAD, ABI and TP/TBI are not routinely performed by nurses and other primary care providers, and noninvasive testing for LEAD by nurses or other primary care providers has not been adequately studied.

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The goal of this pilot study was to explore how well TP, when measured with a portable photoplethysmograph (PPG), compared to standard laboratory tests. The long-range goal of this line of investigation is to enhance the ability of nurses and primary care providers to identify persons with LEAD at an early stage so that risk reduction and interventions to enhance wound healing and reduce limb loss can be implemented.

**Literature Review**

LEAD is a chronic, progressive disorder primarily caused by atherosclerosis that affects approximately one-third of adults in the United States who are over 65 years of age or have diabetes mellitus. LEAD is unrecognized in over half of sufferers until a complication occurs such as severe pain, nonhealing wounds, infection, or loss of a limb. Premature LEAD occurs in persons less than 60 years of age who use tobacco or have diabetes mellitus. Ten percent to 25% of individuals with LEAD progress to critical limb ischemia within 5 years, and 3% to 8% will experience limb loss. African American men and women have higher rates of LEAD compared to whites. Asymptomatic LEAD, identified by a low ABI, occurs in 21% to 48% of affected patients even though they do not experience the classical symptom of intermittent claudication.

The primary risk factors associated with LEAD are tobacco use, advanced age, diabetes mellitus, hyperlipidemia, hypertension, hyperhomocysteinemia, African American ethnicity, a family history of cardiovascular disease, and renal insufficiency. The long-term prognosis for individuals with LEAD is poor. Data from a 10-year study revealed that death rates in men and women with LEAD are 3 to 5 times higher than unaffected men and women, respectively. LEAD is a marker of systemic atherosclerosis and both asymptomatic and symptomatic individuals have an increased risk of cardiovascular or cerebrovascular morbidity and mortality. Cardiovascular disease is still the number 1 cause of death in the United States. The prevalence of coronary disease in persons with LEAD is 40% to 90%, and greater than 50% of individuals with LEAD have cerebrovascular disease.

The cumulative cost of leg wounds in the United States is approximately $1 billion annually, resulting in an estimated 2 million lost workdays. The direct medical cost for a lower-extremity amputation is approximately $46 900. During an 8-year period, the United States averaged 133 235 limb-loss-related discharges annually. Ischemia accounted for 82% of limb-loss discharges and 97% of those were lower limb amputations. Primary amputation rates are highest in African Americans with LEAD. In addition to the high burden of cost, LEAD has an impact on patients’ quality of life. Individuals with LEAD experience a limited life style due to pain, impaired physical function, altered social and role function, and fear and uncertainty about their condition. Therefore, there is emerging interest in early identification of LEAD using inexpensive, noninvasive vascular tests in primary care settings.

**Noninvasive Assessment of LEAD**

Ankle brachial index measurement is recommended in patients at high risk for LEAD and cardiovascular disease and for those with lower extremity wounds because palpation of pulses and a history of claudication have not proven sensitive indicators of the disease. The ABI is 94% sensitive and 99% specific in detecting LEAD in patients with arteriographically proven disease. ABI is a ratio calculated by dividing the higher of the ankle systolic pressures for each leg by the higher brachial systolic pressure. If arterial blood flow is normal, the pressure in the ankle should equal or be slightly higher than brachial pressure and ABI should be 1.0 or more. An ABI less than 0.9 indicates LEAD, and an ABI less than 0.5 indicates severe ischemia.

In some cases, ABI may be elevated (>1.3) because of noncompressible vessels due to medial arterial calcification in certain patients with diabetes mellitus, renal insufficiency, and rheumatoid arthritis. Okamoto and colleagues reported a low sensitivity of ABI (29.9%) in patients with diabetes mellitus, renal failure, and those on hemodialysis. Therefore, alternative tests such as TP are needed when ABI is elevated.

Toe pressure has been used since the early 1930s to assess for arterial disease in individuals with an ABI greater than 1.3. Digital arteries are less affected by calcification and incompressibility than ankle arteries and provide an alternative test site. TP is valuable in assessing the overall extent and severity of LEAD and especially its magnitude in vessels distal to the ankle. Similar to ABI, TP can be used to calculate a TBI by dividing the TP by the higher brachial pressure. A TBI < 0.64 indicates LEAD.

In recent years, portable continuous wave Doppler units have been used to measure TP when the ABI is elevated. However, when the toes are cold, Doppler-derived TP are unreliable due to vasoconstriction of digital arteries. This effect persists even when attempts are made to control the temperature of the testing environment. Therefore, a low TP may be associated with LEAD or vasoconstriction of the arteries.

Commonly, TPs are measured in vascular laboratories by trained technicians or technologists using nonportable PPG equipment. Photoplethysmography assesses blood flow by emitting an infrared light that is reflected by the red blood cells in superficial vessels and detected by the transducer. The amount of reflected light corresponds to pulsatile changes and tissue blood volume. Photoplethysmography does not measure absolute blood flow, but it does provide a functional assessment of perfusion status. To measure TP, a photosensor is placed...
on the toe pad to record pulse changes and a pressure cuff is placed at the base of the toe, which is inflated above systolic pressure. During the slow deflation of the cuff, the first reappearance of the pulse waveform signifies the systolic pressure under the cuff.

Carter\(^{44}\) compared TPs with angiographic findings in 102 limbs and found abnormal pressures in 97% of limbs with arterial occlusion and 74% of limbs with stenotic lesions. Carter asserted that 50 mm Hg is the lower limit of normal for TP. An absolute systolic TP less than 30 mm Hg, or a measurement less than 50 mm Hg in a patient with diabetes mellitus, indicates critical limb ischemia and associated with nonhealing lower extremity wounds.\(^{28,62,63}\) Ramsey and colleagues\(^{44}\) reported that PPG TP greater than 80 mm Hg was 78% sensitive and 88% specific for asymptomatic conditions and TP less than 30 mm Hg was 86% sensitive and 94% specific for ischemia.

There is a paucity of data about acceptable repeatability in TP with PPG. Carter and Lezack\(^{58}\) reported the average differences of 2 digital pressure measurements, performed on 48 limbs with a strain gauge phlethysmograph, was 15.0 ± 11.0 mm Hg. de Graaff and coinvestigators\(^{65}\) measured interobserver and intraobserver repeatability of PPG TP measurements (the specific type PPG was not reported) and found mean differences of +0.6 mm Hg and −7.2 mm Hg, respectively.

TP is an indirect assessment of perfusion status, and cannot determine the precise location of vascular obstruction.\(^{54}\) TP is also influenced by vasoconstriction of the digital arteries that occurs from changes in the skin temperature from cooling the body. Therefore, it is important to maintain a room temperature of 21–23 °C during measurement.\(^{34,55,65,66}\)

Alternative Noninvasive Tests

Other noninvasive tests such as transcutaneous oxygen measurement,\(^{50}\) continuous wave Doppler-derived segmental pressures,\(^{8}\) TP obtained by laser Doppler,\(^{67,68}\) and skin perfusion pressures on the foot measured with a laser Doppler\(^{69,70}\) can be used to assess tissue perfusion and confirm LEAD. However, these other tests are more time-consuming than PPG, and transcutaneous oxygen measurement equipment requires calibration prior to each test. The main drawback of other noninvasive tests is cost of the equipment. For example, the portable equipment to measure transcutaneous oxygen measurement and skin perfusion pressures costs 5 to 8 times more than the portable PPG system.

Purpose

Studies have shown that physicians and nurses often use unreliable methods to diagnose LEAD and have limited knowledge about noninvasive diagnostic tests.\(^{71-73}\) A search of MEDLINE, CINAHL, and Cochrane Library databases for literature, published in English, from 1966 to November 2008 identified no studies using portable PPG equipment to measure TP. The aims of this study were (1) to assess the repeatability of TP measured by an RN using a portable PPG and (2) to determine the level of agreement between the portable PPG TP and TP performed by a registered vascular technologist (RVT) using standard laboratory equipment. We assumed that differences of 15 mm Hg or less\(^{58,65}\) indicated sufficient intraobserver repeatability and interobserver agreement for the techniques to be considered equivalent.

Methods

We used a within-subjects comparative design for this study. The study was conducted in the outpatient vascular laboratory of an urban university medical center. Data were collected at various times during the day based on subjects’ appointment times and the availability of the RN and RVT. After approval for the study’s procedures by the university’s institutional review board, data were collected between November 2008 and March 2009.

A convenience sample of 30 subjects\(^{54}\) was recruited from individuals referred to the vascular laboratory for arterial tests. Subjects were eligible for inclusion if they were 21 years of age and older, available during planned time for the tests, and able to communicate in English and provide written consent (subject or legal guardian). Subjects were excluded if they had absent or inaccessible sites for TP measurements, wounds, infection, or gangrene that prohibited placement of a cuff or sensor or were unable to lie supine for the duration of the tests. To avoid measurement variability due to activities causing vasoconstriction, subjects were excluded if they had consumed food or caffeine or used tobacco within 1 hour of data collection.\(^{49,58}\) Every subject invited to participate was found eligible, consented to the participate in the study, and completed testing.

Instruments

Demographic data were recorded on a standardized form developed by the principal investigator. These data included age, gender, ethnicity, height, weight, health and family history, LEAD risk factors, symptoms, medications, and surgeries. Information about the time of day, room temperature, and amount of rest time prior to the tests was also collected.

The RN used a battery-operated, portable PPG and MD6VR chart recorder (D. E. Hokanson, Inc, Bellevue, Washington) for all measurements. The RVT inspected the PPG and sensor for damage prior to each test. The alkaline battery used to operate the instrument was charged at least weekly. The equipment was stored, cleaned, and used in accordance with the manufacturer’s recommendations. Small digit cuffs (DC 2.5 × 9 cm) were used for the great toe (D. E. Hokanson, Inc, Bellevue, Washington). The RVT used standard laboratory equipment (Parks model 2100-C...
ultrasound, Parks Medical Electronics, Aloha, Oregon) that included a PPG to measure TP.

**Study Procedures**

Data were recorded at the time of each test and rechecked for accuracy and completeness prior to filing. To minimize extraneous variability, measurements were performed consecutively on the same subjects, during the same scheduled visit by the same RN and RVT throughout the study.

After obtaining informed consent, subjects were escorted to an examination room and asked to remove shoes, socks, and restrictive clothing to permit placement of pressure cuffs and PPG sensors. They were assisted to lie supine on the examination table with only 1 small pillow beneath their head. The small pillow provided comfort while preventing hydrostatic effects on blood pressures. Pressure cuffs were placed on the great toe and a PPG photocell was affixed to the pad of the great toes with double-sided tape. Cuff placement was standardized at the base of the great toes. The trunk and extremities were covered with towels, sheets, or blankets to prevent cooling. Subjects rested supine for at least 10 minutes prior to the tests to allow for stabilization of blood pressure. The tests were performed in a private environment where the room temperature was maintained at a minimum of 21 to 23 °C to prevent vasoconstriction of digital arteries. Subjects were asked to avoid conversation during the rest period and tests to minimize measurement variability.

After the 10-minute rest period, the RVT performed arterial studies ordered by the referring physician, including the PPG test. Pressures were measured sequentially on the right and left great toe. After these measurements were completed, the subject was allowed to rest 5 minutes in the same position and the RN repeated the PPG tests twice on each subject on the right and left great toes using an established protocol (see Box). To protect against bias in obtaining or interpreting TP measures, the RVT and RN were blinded to each other’s results until final data entry and analysis.

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**BOX**

**Protocol: RN TP Measurement With Portable PPG**

A. Gather equipment and supplies
   1. Gather equipment and supplies to measure TPs.
   2. Place materials in exam room: (a) portable PPG and chart recorder, (b) aneroid sphygmomanometer, (c) digital cuffs (1.9-2.5 cm width), (d) double stick tape to affix photo sensor to toe, (e) disposable gloves, (f) sheets, blankets, and towels to cover trunk and lower extremities, (g) paper and pen for recording the measurements, and (h) chart recorder paper.
   3. Charge battery for PPG/chart recorder.

B. Prepare room and equipment
   1. Inspect PPG and sensor, pressure cuffs, and sphygmomanometer for damage and replace if damaged. Check chart recorder and install paper.
   2. Set the room thermostat to achieve the desired room temperature of a minimum of 21-23 °C.

C. Prepare patient
   1. Greet patient and inquire if the patient has eaten or used tobacco or caffeine within the hour.
   2. Encourage patient to use the bathroom prior to the tests.
   3. Assist patient to remove shoes, socks, and restrictive clothing.
   4. Assist patient to lie on the exam table/bed in a reclining, supine position with the toes at heart level and pointed to the ceiling to prevent hydrostatic effects on the pressure readings. Place one small, flat pillow under the head for comfort.
   5. Place appropriately sized cuffs around the base of the right and left toes: 2.5 cm for hallux (great toe) or 1.9 cm for the second toe.
   6. Tape the PPG photosensor on great toe or second toe if necessary.
   7. Cover the trunk and extremities with towels, sheets, or blankets to prevent cooling.
   8. Ensure the patient is comfortable.
   9. Have the patient rest for a minimum of 10 min to stabilize the blood pressure.
   10. Avoid conversation during the examination to reduce measurement variability.

D. Measurement of TPs with a portable PPG
   1. Measure TPs after patient has rested for 10 min.
   2. Inflate the pressure cuff on the right toe to a maximum of 200 mm Hg and slowly deflate the cuff until the pulse wave signal returns.
   3. Record the point at which the arterial pulse wave signal first returns as the toe systolic pressure for the right toe.
   4. Repeat steps 2 and 3 for the left toe.
   5. Remove the cuffs, photosensors, and tape from the toes.
   6. After completion of the test, assist the patient to dress as needed.
   7. Document the results.

**Abbreviations:** PPG, photophlethysmograph; TP, toe pressure.
Data Analysis
Descriptive statistics were used to summarize the demographic data. Mean and standard deviations, along with the difference between the means of the PPG by the RN and RVT, were reported for all subjects. Mean TP for the RVT and RN and the RN at time points 1 and 2 were compared using the paired t test and Wilcoxon signed rank test, respectively. Bland-Altman plots were used to examine the agreement between the TP obtained by the RVT and RN (time point 1). Initially, the degree of clinically important difference between the alternate methods was established a priori as 15 mm Hg. Next, mean differences (bias) between the test methods were calculated to assess how well the measurements agreed on average. The distribution of the differences was evaluated for normality and the standard deviations of the differences were determined to define the limits of agreement/precision (ie, the range of values in which 95% of the differences from the bias are expected to fall). The 95% limits of agreement (ie, mean difference ± 1.96 second) were calculated and the level of agreement was displayed. Differences between the RVT-RN PPG measures for each subject were plotted on the vertical axis against the mean of the measures for each subject on the horizontal axis (Figure 1). The same procedure was followed to assess repeatability between the measurements of the RN at time points 1 and 2 (Figure 2). Agreement between the RVT’s and RN’s PPG measures to detect LEAD (<50 mm Hg) was determined by calculation of the kappa statistic. Sensitivity and specificity of the portable PPG, compared to the standard laboratory test to detect LEAD, were also calculated.

Results
Two-thirds of the subjects were over 60 years of age (n = 20; 66.6%) with a mean age of 66.5 years (range, 48-90). Slightly more men (n = 16; 53.3%) than women (n = 14; 46.7%) participated in the study. Whites represented 63.3% (n = 19) of the sample and 36.7% (n = 11) were African Americans. A summary of subject characteristics is provided in Table 1.

Almost 3 quarters of subjects were overweight or obese, including 43.3% deemed overweight and 30% found to be obese. Claudication was the most commonly reported symptom and the primary reason subjects were referred for testing. Over half (63.3%) described claudication as

**FIGURE 1.** Bland-Altman plot of difference in RVT-RN (time point 1) toe pressure measures (mm Hg) on each subject plotted against the mean of the 2 measures on each subject (n = 58). Note: Solid shading: area within clinically important limits.
muscle pain that occurred during exercise but subsided with rest. Pain was present for a mean period of 20 months prior to referral for testing. Six subjects (20%) also reported having night pain or rest pain. Two subjects (6.7%) had open leg wounds at the time of referral and 3 (10%) had a history of healed wounds.

The most commonly reported risk factor for LEAD was tobacco use. Ninety percent of participants reported a history of smoking and 26.7% were current smokers. Tobacco users reported smoking an average of 28 cigarettes a day for 26 years. A majority also reported hypertension and almost one-third had been diagnosed with diabetes mellitus. Data about symptoms, risk factors, comorbid conditions, and medication use are summarized in Table 2. Data about comorbid conditions, stratified by ethnicity and gender, are reported in Tables 3 and 4, respectively. Table 5 summarizes family histories of predisposing comorbid conditions.

**Toe Pressures**

Data were collected on 58 lower limbs, including 30 right-sided limbs and 28 left-sided limbs. One subject had an above-the-knee amputation on the left and another individual had nonhealing wounds on the left toes, which prohibited placement of the TP cuff and PPG sensor. The RVT measured a mean TP (±SD) of 64.5 ± 33.9 mm Hg as compared to 60.7 ± 31.2 mm Hg for the RN at time point 1 (P = .005 from paired t test) (Table 6). The bias (mean difference) for the RVT-RN TP was 3.8 mm Hg (95% confidence interval [CI] = 1.2-6.4), the standard deviation was 9.8 mm Hg, and the precision (limits of agreement, 95% CI) was (15.4, 23.0) (Table 7). According to the Bland-Altman plots, 5 (9%) of the measurements fell outside the lower limit of agreement and 7 measurements (12%) fell outside clinically important limits (Figure 1). Precision (upper and lower limits of agreement) of the RN’s and RVT’s PPG measurements exceeded the established clinically important limits (±15 mm Hg), indicating that the 2 methods were not equivalent.

Kappa statistic calculation showed substantial agreement of 90% (52/58) between the RVT and RN at time point 1 (κ = 0.76) (Table 8). Additionally, the portable PPG, compared to the standard laboratory test to detect LEAD (<50 mm Hg), demonstrated good sensitivity (79%) and high specificity (95%).
Repeatability
The mean TP of the RN at time 1 was 60.7 ± 31.2 mm Hg as compared to 62.2 ± 31.1 mm Hg at time 2 (P = .03 from Wilcoxon signed rank test) (Table 6). The bias (mean difference) for time 1 was −1.5 mm Hg (95% CI = −2.8, −0.2), the standard deviation was 5.0 mm Hg, and the precision (limits of agreement, 95% CI) was −11.2, 8.2 (Table 7). On the Bland-Altman plots, 3 (5%) of the measurements fell outside the lower limit of agreement; 1 (2%) fell outside the upper limit of agreement, and 1 measurement (2%) fell outside the clinically important limits (Figure 2). For the RN’s time 1 and 2 PPG measures, the precision did not exceed the clinically important limits in either direction. Approximately 95% were within 2 standard deviations, indicating acceptable repeatability of the portable PPG method.

TABLE 1.
Subject Characteristics: Gender and Ethnicity (N = 30)

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>African American males</td>
<td>4</td>
<td>13.3</td>
</tr>
<tr>
<td>African American females</td>
<td>7</td>
<td>23.3</td>
</tr>
<tr>
<td>White males</td>
<td>12</td>
<td>40</td>
</tr>
<tr>
<td>White females</td>
<td>7</td>
<td>23.3</td>
</tr>
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TABLE 2.
Symptoms, Risk Factors, Comorbid Conditions, and Medication Use by Subjects (N = 30)

| Symptoms                          | N (%)
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>History of claudication</td>
<td>19 (63.3)</td>
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<tr>
<td>Pain at night (dangle pain)</td>
<td>6 (20)</td>
</tr>
<tr>
<td>Wounds present</td>
<td>2 (6.7)</td>
</tr>
<tr>
<td>Healed wound</td>
<td>3 (10)</td>
</tr>
<tr>
<td>Sensitive to cold</td>
<td>4 (13.3)</td>
</tr>
<tr>
<td>Risk factors and comorbid conditions</td>
<td></td>
</tr>
<tr>
<td>Tobacco use</td>
<td>27 (90)</td>
</tr>
<tr>
<td>Quit smoking</td>
<td>19 (63.3)</td>
</tr>
<tr>
<td>Diagnosed with diabetes</td>
<td>8 (26.6)</td>
</tr>
<tr>
<td>Diet controlled</td>
<td>0</td>
</tr>
<tr>
<td>Oral medication</td>
<td>7 (23.3)</td>
</tr>
<tr>
<td>Insulin dependent</td>
<td>1 (3.3)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>23 (76.7)</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>10 (33.3)</td>
</tr>
<tr>
<td>Myocardial infarct</td>
<td>5 (16.7)</td>
</tr>
<tr>
<td>Cerebrovascular accident</td>
<td>7 (23.3)</td>
</tr>
<tr>
<td>Lung disease</td>
<td>4 (13.3)</td>
</tr>
<tr>
<td>Kidney disease</td>
<td>1 (3.3)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>19 (63.3)</td>
</tr>
<tr>
<td>Unknown</td>
<td>1 (3.3)</td>
</tr>
<tr>
<td>Vascular disease of lower extremities/digits</td>
<td>14 (46.7)</td>
</tr>
<tr>
<td>Vascular surgery</td>
<td>12 (40)</td>
</tr>
</tbody>
</table>

| Medications                      | N (%)
<table>
<thead>
<tr>
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<th></th>
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<tbody>
<tr>
<td>Medication use</td>
<td>24 (80)</td>
</tr>
<tr>
<td>Anticoagulants</td>
<td>1 (3.3)</td>
</tr>
<tr>
<td>Antplatelets</td>
<td>20 (66.7)</td>
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<tr>
<td>Antplatelets and statins</td>
<td>1 (3.3)</td>
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<tr>
<td>Unknown</td>
<td>2 (6.7)</td>
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TABLE 3.
Comorbid Conditions Associated With Lower Extremity Arterial Disease Stratified by Ethnicity (N = 30)

<table>
<thead>
<tr>
<th>Comorbid Condition</th>
<th>White (N = 19), N (%)</th>
<th>African American (N = 11), N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>14 (73.6)</td>
<td>9 (81.8)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>4 (21)</td>
<td>4 (36.3)</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>9 (47.3)</td>
<td>1 (9)</td>
</tr>
<tr>
<td>Myocardial infarct</td>
<td>4 (21)</td>
<td>1 (9)</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>5 (26.3)</td>
<td>2 (18.1)</td>
</tr>
<tr>
<td>Kidney disease</td>
<td>0</td>
<td>1 (9)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>13 (68.4)</td>
<td>6 (54.5)</td>
</tr>
<tr>
<td>Vascular disease</td>
<td>11 (57.8)</td>
<td>3 (27.2)</td>
</tr>
<tr>
<td>Vascular surgery</td>
<td>9 (47.3)</td>
<td>9 (81.8)</td>
</tr>
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</table>

TABLE 4.
Comorbid Conditions Associated With Lower Extremity Arterial Disease Stratified by Gender (N = 30)

<table>
<thead>
<tr>
<th>Comorbid Condition</th>
<th>Male (N = 16), N (%)</th>
<th>Female (N = 14), N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>14 (87.5)</td>
<td>9 (64.2)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>11 (68.7)</td>
<td>11 (78.5)</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>8 (50)</td>
<td>2 (14.2)</td>
</tr>
<tr>
<td>Myocardial infarct</td>
<td>5 (31.2)</td>
<td>0</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>3 (18.7)</td>
<td>4 (28.5)</td>
</tr>
<tr>
<td>Kidney disease</td>
<td>1 (6.2)</td>
<td>0</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>12 (75)</td>
<td>7 (50)</td>
</tr>
<tr>
<td>Vascular disease</td>
<td>10 (62.5)</td>
<td>4 (28.5)</td>
</tr>
<tr>
<td>Vascular surgery</td>
<td>7 (43.7)</td>
<td>11 (78.5)</td>
</tr>
</tbody>
</table>

TABLE 5.
Family History of Comorbid Conditions Associated With Lower Extremity Arterial Disease (N = 30)

<table>
<thead>
<tr>
<th>Family Comorbid Condition</th>
<th>Yes, N (%)</th>
<th>No, N (%)</th>
<th>Uncertain, N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>17 (56.7)</td>
<td>13 (43.3)</td>
<td>2 (6.7)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>20 (66.7)</td>
<td>8 (26.7)</td>
<td>2 (6.7)</td>
</tr>
<tr>
<td>Coronary disease</td>
<td>15 (30)</td>
<td>14 (28.6)</td>
<td>1 (3.3)</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>9 (30)</td>
<td>20 (66.7)</td>
<td>1 (3.3)</td>
</tr>
<tr>
<td>Vascular disease</td>
<td>6 (20)</td>
<td>22 (73.3)</td>
<td>2 (6.7)</td>
</tr>
</tbody>
</table>
respectively. The reported interobserver and intraobserver reproducibility of strain gauge phlethysmographs was established. Our findings indicate that the limits of agreement between the RVT and RN exceeded established clinically important limits. Several techniques reported by other investigators have suggested that repeating pressure measurements improves precision. In the interest of time and convenience for subjects who had appointments to see their clinic physicians immediately after completing the tests, only the RN repeated the PPG measures in our study. Other researchers recommend randomizing the order of tests to prevent potential systematic bias when one technique is consistently performed before another. The order of testing was not randomized in our study. Toe pressures were measured first by the RVT to ensure that subjects received the tests ordered by their physician in case they were unwilling or unable to complete repeated tests with the investigational technique (portable PPG). Additional studies are needed to determine whether test order influences results.

**Limitations**

The generalizability of our results are limited due to the use of a convenience sample drawn from referrals to a single hospital-based, and data collection in a single vascular laboratory that might not represent the staff, equipment, and environment seen in other laboratories. Other factors that may have caused variability in pressure measurements or their interpretation include the following: (1) the RVT used an automated system and the RNs equipment was manually controlled, (2) a possible “white coat effect” caused by exposure to 2 different testers, (3) in a few tests, the RVT used a different machine (same type, brand, model of equipment) due to emergencies that necessitated changing rooms, (4) nonrandomized testing, (5) occasional interruptions by staff and construction noise, (6) movement and talking by some subjects during testing procedures, (7) the RVT has greater expertise and environment seen in other laboratories. Other factors that may have caused variability in pressure measurements or their interpretation include the following: (1) the RVT used an automated system and the RNs equipment was manually controlled, (2) a possible “white coat effect” caused by exposure to 2 different testers, (3) in a few tests, the RVT used a different machine (same type, brand, model of equipment) due to emergencies that necessitated changing rooms, (4) nonrandomized testing, (5) occasional interruptions by staff and construction noise, (6) movement and talking by some subjects during testing procedures, (7) the RVT has greater expertise and years of experience performing and interpreting PPG tests than the RN, and (8) the RVT did not perform repeated measures.

Although the tests were not equivalent in our study, there was a substantial level of interobserver agreement of 90% between RN and RVT tests for detection of LEAD (kappa statistic 0.76). The outliers were at or above the normal range (50 mm Hg), which would not affect clinical decision making. Additionally, the portable test, when compared to the standard laboratory test, demonstrated good sensitivity (79%) and high specificity (95%) to detect LEAD. Test sensitivity depends on the cut point chosen to indicate a condition. Screening test sensitivity should be at least 70% to 80%. A high specificity is particularly desirable for screening tests. Therefore, when ABI results are inconclusive, elevated (>1.3), or not measurable, the portable PPG provides an option for nurses and primary care providers to assess healing potential, determine if compression or debridement is warranted, and determine the need to refer to a vascular surgeon or laboratory.

The protocol for performing TP used in our study was based on techniques reported by other investigators. Several have suggested that repeating pressure measurements improves precision. In the interest of time and convenience for subjects who had appointments to see their clinic physicians immediately after completing the tests, only the RN repeated the PPG measures in our study.
A falsely low TP due to vasoconstriction and delayed opening of the main digital arteries when toes are cold was discussed previously. In our study, half of the subjects had toes that felt cold to the touch of the examiner. Due to safety concerns, attempts were not made to warm toes prior to testing by any direct application of warming devices. We did standardize room temperature and provided a warm environment by covering feet and toes as much as possible during the tests with towels, sheets, or blankets.

**Significance of Findings**

Our findings suggest that, in the presence of an elevated or unmeasurable ABI, portable PPG provides a noninvasive and cost-effective means to assess lower extremity perfusion prior to wound debridement, compression therapy. Portable PPG can also be used in this scenario to determine when future evaluation, surgery, or adjunctive therapies are indicated. Waiting to make referrals for tests until patients with LEAD are asymptomatic is problematic because asymptomatic and symptomatic persons are at risk for systemic ischemic events, walking impairment, poor quality of life, limb loss, and increased mortality rates. Adoption of TP measures as best practice to assess high-risk individuals with elevated ABIs may impact early identification of LEAD allowing implementation of evidence-based preventive or therapeutic interventions before limb amputation is deemed necessary.

With early detection, interventions can be implemented to control modifiable risk factors such as tobacco cessation and control of glucose/HbA1c, hyperlipidemia, and hypertension. Early diagnosis also provides an opportunity to educate patients about the symptoms of LEAD, the risk of limb-threatening complications, the need to promptly report any injury or wound on the lower extremity, and the importance of proper footwear and foot/nail care.

Nurses and other primary care providers are on the front line of assessment and the portable PPG is a technique that can be used in a variety of settings (eg, home care, nursing homes, long-term care, physicians’ offices, and outpatient clinics). Our findings highlight the importance of establishing a standardized protocol when performing PPG with attention to preparation of the equipment, environment, and subject as well as the education, training, and experience of the tester.

Additional research is needed to define the current level of knowledge and practice related to PPG testing by nurses and other primary care providers, identify barriers to incorporating noninvasive testing into practice, determine clinically important inter- and intraobserver levels of agreement of the portable PPG, and validate protocols for testing using portable PPG devices. Research is also needed to determine whether warming the feet and toes can be done safely in order to improve the ability to detect TPs using a portable PPG device. In addition, studies are needed to establish education needed to increase the accuracy and repeatability of portable PPG tests completed by nurses and primary care providers.

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**Conclusion**

We found that the limits of agreement between the RN’s and RVT’s PPGs exceeded clinically important limits indicating portable PPG is not equivalent to standard vascular laboratory tests. However, despite differences in the RVT’s and RN’s measures, the repeatability of the RN’s PPG measures fell within the clinically important limits. We also found a high level of agreement between RN and RVT tests for detection of LEAD. Further, the portable PPG’s good sensitivity and high specificity make it a suitable, inexpensive test for nurses and primary care providers in physicians’ offices, home health care, outpatient clinics, and long-term care setting to detect LEAD when the ABI cannot be accurately measured.

**KEY POINTS**

- LEAD affects 30% of adults 66 years of age and older. It causes pain, nonhealing wounds, limb loss and impaired quality of life.
- Premature LEAD occurs in individuals younger than 60 years who use tobacco or have diabetes.
- LEAD is unrecognized and underdiagnosed in over 50% of patients while health care providers use unreliable techniques to detect LEAD (ie, pulse palpation, claudication history).
- When ABI is elevated (>1.3) in patients with diabetes mellitus, renal failure, or arthritis, portable PPG offers a simple and affordable test for detecting LEAD.

**ACKNOWLEDGMENTS**

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