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The correlation of ankle oscillometric blood pressures and segmental pulse volumes to Doppler systolic pressures in arterial occlusive disease

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Short Title:
Oscillometric ankle BP and pulse volume vs. Doppler BP.

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ABSTRACT

PURPOSE: This study was designed to evaluate the accuracy and failure rates of automatically collected oscillometric ankle systolic pressures (Psys) and pulse volumes (Pvol) using a new algorithm (VascuMAP) as compared to Psys obtained by standard manual Doppler-and-cuff technique.

METHODS: One hundred and ten consecutive patients of a vascular laboratory had brachial and ankle Psys measured via the two methods. Pvol at or near the mean arterial pressure (MAP) was also obtained automatically by the oscillometric device.

RESULTS: Both methods showed a 6.6% failure rate when measuring Psys at the ankle. Oscillometric Psys measurement was possible where Doppler Psys failed due to non-occluding arteries. No difference was found between the two methods in occluding limbs with ankle-brachial indexes $\geq$1.30. Sequential brachial Psys values had a mean difference (Doppler minus oscillometric) of 2 +/-10.9 mmHg and a correlation coefficient (r) of 0.92. Measurements at the ankle had a mean difference of minus 8.4 +/-16.8 mmHg and r = 0.90. These differences were not statistically significant. MAP Pvol recorded at the ankle also correlated with ankle Doppler Psys (r = 0.71) and showed a 1.9% failure rate.

CONCLUSION: Both automatic VascuMAP Psys and Pvol at the ankle are shown to correlate well with Doppler-and-cuff Psys in patients with vascular disease. Oscillometric measurements can replace Doppler measurements in most clinical situations.

KEYWORDS: blood pressure, Doppler, noninvasive, oscillometric, brachial, ankle, pulse volume.

INTRODUCTION

Although automated blood pressure measurements using oscillometric methods have become accepted in many areas of medicine (1,2,3), and have been shown to be accurate at the ankle in normal subjects (4), the accuracy of standard oscillometric measurements in arterially compromised limbs has been poor (5). This study tests the clinical accuracy and utility of a new automatic oscillometric plethysmograph designed for peripheral vascular use (VascuMAP Model AP-102V, Carolina Medical Inc., King, NC) which uses an algorithm that compensates for the arterial compliance of the subject.

In determining clinical blood pressures by oscillometry, the pulse amplitudes at descending cuff pressures are gathered, and any variations due to changing cardiac stroke volume, respiratory effort, etc. are minimized using a low-pass filtering algorithm to obtain the "oscillometric curve." If the proper cuff size for the segment under test has been used, the mean arterial pressure (MAP) is taken to be the cuff pressure where the oscillometric curve is maximum (6). Systolic and diastolic pressures must then be calculated by algorithm (7). Instead of using a fixed point on the oscillometric curve to determine systolic pressure (Psys), the VascuMAP algorithm picks different Psys endpoints depending on the arterial compliance detected during the data gathering process. The effect of arterial compliance on oscillometric Psys endpoints has been previously demonstrated by mathematical modeling (8).

Patients who have medial wall calcification in their peripheral arteries are difficult to evaluate by standard Doppler-and-cuff Psys measurements because the rigid arterial walls may prevent occlusion by the pressure cuff. This problem is especially prevalent in the diabetic patient (9). Because oscillometric Psys determination does not require arterial occlusion, it offers a possible method of determining Psys in this condition. Thus particular attention was given to the data from patients who demonstrated "rigid vessels" with an ankle-brachial index (ABI) of 1.30 or greater, or with arteries that could not be occluded at a reasonable cuff pressure for Doppler Psys determination.

The VascuMAP is also programmed to record and print the largest pulse volume waveform detected, which occurs at or near the MAP point on the oscillometric curve. The MAP waveform is calibrated in cubic centimeters by the automatic introduction of a 0.50 cc volume change to the air cuff system similar to manual methods previously described (10). This volume calibration method has been shown to be virtually as accurate as hydroplethysmographic methods and corrects for air volume within the cuff, thus cuff wrap tightness is not critical (11,12).

METHOD

One hundred ten consecutive patients undergoing noninvasive ankle-brachial vascular evaluation at the Veterans Affairs Medical Center vascular laboratory in Castle Point, NY were studied. Mean age of the subjects was 68.9 years (range: 41-86 yrs). There were 1 female and 109 male patients. Fifty-three (48%) reported a history of Diabetes Mellitus, 30 (27%) had previous lower extremity arterial bypass surgery or repair of an abdominal aortic aneurysm, and 7 (6.4%) had a previous unilateral amputation of the lower extremity. One hundred ten brachial and 213 ankle measurement pairs were obtained for analysis using the following technique:

The subject was placed in a supine position and instructed to remain quiet. All measurements were obtained by a trained vascular technologist. Properly fitting cuffs of 12cm or 15cm width (WA Baum, Inc, Hauppague, NY) were placed on the upper arms and 12cm cuffs were placed cylindrically on the ankles. Psys was measured bilaterally at the brachial artery using a mercury manometer (WA Baum, Inc.) and a 9 MHz continuous wave Doppler (Parks, Inc, Aloha, OR). The cuff on the arm with the higher Psys was then connected to the VascuMAP instrument and the oscillometric and plethysmographic measurements were taken automatically (this takes approximately one minute). Following this, Psys was measured in the right posterior tibial and dorsalis pedis arteries via Doppler, then oscillometric measurements and MAP pulse volumes (Pvol) were obtained at the right ankle. Lastly, similar measurements were taken in the left ankle by Doppler followed by oscillometry. Cuffs were not re-wrapped or moved between Doppler and oscillometric measurements. All data and tracings from the patient were entered on a single-page form and all forms submitted for statistical analysis. A typical output tracing from the VascuMAP instrument appears in figure 1.

RESULTS

The failures of the three measurement groups were studied as follows: "Failure" was defined as the lack of the measurement on the original data sheets submitted for analysis. The Doppler-and-cuff Psys method had no failures (0%) in 220 brachial measurements. This method failed in 28 of 426 ankle artery measurements (6.6%) due to inability to occlude the vessel in 13 (3%), flow not audible in 11 (2.6%), and data not recorded in 4 (1.0%). The oscillometric Psys method had no failures (0%) in 110 brachial measurements. The oscillometric method failed in 14 of 213 ankle measurements (6.6%) due to "Bad Oscillometric Curve" (a curve with two or more maxima) in 10 (4.7%), and to "Pulseless Limb" (maximum Pvol detected less than approximately 0.015 cc) in 4 (1.9%). Pvol measurement failed in 4 of 213 ankle measurements (1.9%) because of "Pulseless Limb" in 3 (1.4%) and patient movement during trace recording in 1 (0.5%).

After removal of incomplete data pairs due to the failures noted above, oscillometric versus Doppler Psys analyses were performed on

110 sets of brachial data and 191 sets of ankle data. The <u>higher</u> of the two ankle Doppler readings (dorsalis pedis or posterior tibial) was used for the analysis because the averaged pressure of the two ankle vessels did not correlate as well with Doppler Psys values. Ankle Pvol versus higher Doppler Psys were analyzed for 200 data pairs.

Mean brachial Doppler Psys was 155.8 mmHg (range: 80 - 240 mmHg) with a standard deviation (S.D.) of +/-28.2 mmHg. Mean brachial oscillometric Psys was 153.3 mmHg +/-27.3 mmHg (range: 93 - 223 mmHg). Mean ankle Doppler Psys was 128.3 mmHg +/-40.6 mmHg (range: 32 - 236 mmHg). Mean oscillometric ankle Psys was 140.7 mmHg +/-34.4 mmHg (range: 44 -255 mmHg). Mean Doppler ankle-brachial Index (ABI), defined as the higher ankle artery Psys divided by the higher brachial Psys, was 0.84 +/-0.27. The mean oscillometric ABI, defined as the oscillometric ankle Psys divided by the oscillometric brachial Psys, was 0.94 +/-0.24. There were no significant differences between these Psys and ABI measurement pairs.

To analyze the Psys data more closely, the mean difference and standard deviation of the differences were employed by subtracting each oscillometric Psys reading from the corresponding Doppler Psys value. This gave a brachial mean difference of +2.0 mmHg with a standard deviation of 10.9 mmHg. Ankle mean difference was -8.4 mmHg with a standard deviation of 16.8 mmHg. Neither of these differences were statistically significant.

Figure 2 shows the scatter plot for the brachial data points, which had a correlation coefficient (r) of 0.92. Figure 3 shows the scatter plot for the ankle data. The correlation coefficient for the ankle points was 0.90.

Pulse volume at the mean arterial pressure was measured by comparing the vertical height of the systolic upstroke of the pulse wave to the volume scale printed with the wave tracing. Figure 4 shows the ankle MAP pulse volume in cc's plotted against the corresponding Doppler Psys value. The plot of the linear regression formula is also shown. This regression line intersects the X axis (i.e., Pvol approaches zero) as the Doppler Psys value decreases to 47.9 mmHg. The correlation coefficient is 0.71 for these two data sets.

Ten subjects had 13 limbs with occludable arteries showing an ABI of 1.30 or greater. Eight limbs had a Doppler ABI $\geq$1.30, and eight showed an oscillometric ABI $\geq$1.30. Three limbs had both oscillometric and Doppler ABIs $\geq$1.30. Table I shows the comparison of the two groups. Except for the number of diabetic limbs represented, the two groups were very similar, and there were no significant differences between them.

Six patients had eight limbs with one or more arteries that could not be occluded for Doppler Psys determination. Seven of the eight limbs were diabetic, and in these seven the Posterior Tibial artery could not be occluded. In all eight limbs, reasonable oscillometric ABI values were obtained, and MAP pulse volume and waveform analysis provided further vascular information - see Table II.

DISCUSSION

Measurement failure rates were identical in the two methods for measuring Psys at the ankle, but the mechanism for failure were distinctly different.

In Doppler Psys determination, inability to occlude the artery was the most frequent mode of failure. The next most frequent failure mode - inability to hear the arterial flow - should not be considered a failure in the hands of an experienced vascular technologist, as this provides valid information concerning the vessel being studied. The 1% failure rate in manual recording of the Doppler data in this study reflects a real but often overlooked source of error. Error rates in handwritten or computer-entered hospital orders have been shown to be of the same magnitude (13).

The most frequent failure mode for oscillometric Psys measurement was due to production of an oscillometric curve with more than one apex. This failure can probably be eliminated by more robust software algorithms that allow for this possibility, but more clinical experimentation will have to be done to assure validity of the measurements. In most situations, repeat testing on the segment will provide a good oscillometric curve with a valid Psys value. Retesting was not done routinely in this study. Failures due to "pulseless limb" messages indicate a marked decrease in pulse volume of the limb segment under the cuff, thus they should not be considered as clinical failures in that they provide useful data indicating that global segmental perfusion is indeed compromised.

Automatic MAP pulse volume measurements showed the least failures at the ankle, providing a volume-calibrated waveform tracing 98.1% of the time. Although not done in this experiment, the VascuMAP can obtain a volume-calibrated waveform at any desired cuff pressure (such as 65 or 40 mmHg) using the manual plethysmographic routine programmed into the instrument. Only uncontrollable limb movement of large amplitude will prevent Pvol determination in this manual mode.

For determining the equivalence of two noninvasive blood pressure measurement methods, the present standard (U.S.A.) states that the mean difference and standard deviation of the differences for three averaged simultaneous paired readings in a minimum of 85 subjects representing the general population should not exceed +/-5 mmHg and 8 mmHg, respectively (14). The VascuMAP instrument has been previously shown to meet this standard (see U.S. Food and Drug

Administration device application K914200). In this experiment, use of the instrument in an older patient population with vascular disease gives results that come close to but do not meet the standard completely. This may be due to the following reasons: First, the patient population had an average brachial systolic pressure 35 mmHg (29%) higher than the general population and included a large number of subjects with severe vascular disease; second, the readings were obtained sequentially, not simultaneously, due to limitations of the methods involved; third, the readings were single readings, not an average of three or more readings per patient as stated in the standard. Considering these factors, this experiment indicates that the excellent correlation and equal failure rates of the two methods of measuring Psys in the face of vascular compromise make automated, compliance-corrected oscillometric Psys measurements acceptable in the patient population seen by the vascular surgeon.

Volume-calibrated pulse waveform recording is also useful in vascular diagnosis (15,16). Normal ankle segmental pulse volume has been reported to be 0.5 cc (range: 0.3-0.7 cc) when measured with a cuff of 8 cm width and manual volume-injection calibration techniques which provide near-isothermal volume results (17). The data shown in Figure 4 support this range as normal for the 12 cm cuffs and adiabatic volumes provided by the VascuMAP, but statistical confirmation of this in a known normal population remains to be done. Direct comparison of manual versus automatic volume calibration is difficult because a 1.0 cc. pulse volume as measured by adiabatic volume calibration would measure up to 1.24 cc. by isothermal calibration methods in the same cuff system, depending on the settling time allowed for the isothermal method (unpublished data, JSC). Simultaneous clinical t-tube comparison of the VascuMAP calibration system to the "PVR millimeters of chart height" volume calibration of the PVR Pulse Volume Recorder (PVR-IV, Life Sciences, Greenwich, CT) at the ankle has shown a linear relationship of 1 cc. = 63 mm. of chart height (see FDA application K914200). Using previously described PVR criteria for vascular diagnosis, a VascuMAP ankle pulse volume of over 0.24 cc. indicates adequate arterial perfusion (PVR chart height > 15 mm. = PVR category 1 or 2), and a volume less than 0.08 cc. indicates compromised perfusion (PVR chart height < 5 mm. = PVR category 4) (16).

Evaluation of limbs with possible "rigid vessel" disease resulted in the identification of two distinct conditions - those vessels with a high ABI that could be occluded, and those that could not. Limbs where the vessels could be occluded were indistinguishable by Doppler methods (where resistance to compression would raise the ABI) compared to oscillometric methods (where resistance to expansion would raise the ABI). Resistance to arterial expansion is doubtful considering the good pulse volumes found in all limbs showing a high ABI with occludable vessels. This would suggest that the measured ABIs (both Doppler and oscillometric) are indicative of increased "systolic amplification" due to physiologic or pathologic conditions of the large and/or small arteries (18), and not due to partial medial calcinosis of the ankle artery segments.

Limbs demonstrating true "rigid vessel" disease that did not occlude for Doppler Psys measurement showed reasonable oscillometric ABI values in all cases. Although some of these limbs had signs of proximal arterial occlusive disease (decreased pulse volume and lack of reflected waves), the majority had reflected waves present, pulse volumes in the normal range (by PVR standards), and normal oscillometric ABIs. Unfortunately, without Doppler Psys values for comparison, the accuracy of the oscillometric ABIs could not be verified in this study. Further studies comparing oscillometric Psys to intra-arterial pressures in limbs with medial calcinosis will probably be necessary for such verification.

Though manual Doppler-and-cuff methods for determining peripheral Psys will probably remain the "gold standard" of noninvasive methods for some time, allowing separate determination of Psys in parallel arteries and requiring only $500 to $600 of equipment (as compared to about $8000 for a volume-calibrated VascuMAP), this study shows that fully automated oscillometric methods are accurate and dependable enough to replace Doppler Psys in most situations. Computerized oscillometry can provide a wide range of functions with less chance of human error in performing the study and recording the results, including complete documentation of Psys and volume-calibrated waveforms, date/time stamps, and accuracy warnings. Less time is required per segment to acquire both Psys and plethysmographic waveforms with no active intervention required of the operator. Fully hands-off operation is possible by using preset timed intervals for repeating studies in exercise recovery testing, Raynaud's Disease, operative and post-operative monitoring (with adjustable Psys warning limits if desired), and following of pharmaceutical interventions. As operator training is simpler than learning Korotkoff pressure techniques, and no gels or electrical probes are required, oscillometric methods are more suitable for mass screening. Simpler operation also allows office follow-up where a skilled vascular technologist may not be present. Oscillometric Psys seems to work where arteries cannot be occluded with reasonable cuff pressures, such as in medial calcinosis and at trans-metatarsal sites. And although oscillometry tracks the artery with the highest Psys (this could even be in a peroneal artery), the VascuMAP allows a Doppler Psys in any of the arteries to be reported during the oscillometric test run. Pressing a button when flow return is detected in the chosen artery documents the cuff pressure of the last systolic peak as "Psys by operator input."

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LEGENDS

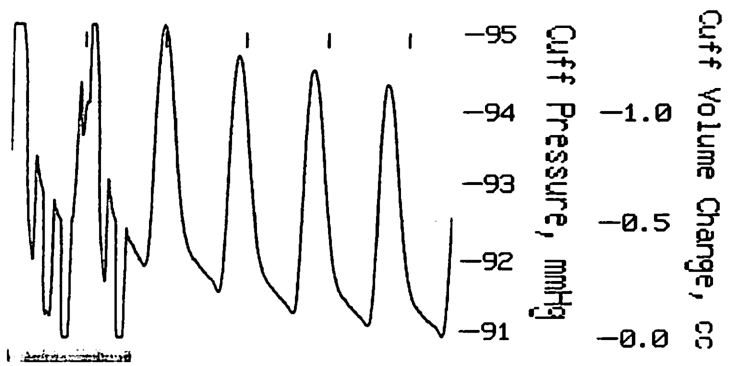
Figure 1: Ankle MAP pulse volume and blood pressure in a 75 Kg male with normal palpable pulses as printed by the VascuMAP AP-102V. Square-wave pulses on the left of the pulse tracing are rapid 0.50 cc volume changes. This volume change is sensed by the instrument to create the scale labeled "Cuff Volume Change, cc."

Figure 2. Scatter plot showing correlation of brachial systolic pressures. The dotted line is the line of identity. The solid line is the plot of the linear regression formula shown in the upper left. The correlation coefficient (r) and number of samples (n) are also shown.

Figure 3. Scatter plot showing the correlation of ankle systolic pressures. The dotted line is the line of identity. The solid line is the plot of the linear regression formula.

Figure 4. Scatter plot showing the relation of MAP pulse volumes to Doppler systolic pressures at the ankle. The line is the plot of the linear regression formula.

TOP



ID# 1864---------------- 3 Apr 1994
12:34 pm

Blood pressure (mmHg):	153/68
Mean Arterial Pressure:	92 mmHg
Pulse (beats per minute):	68
Pulse Height Variation: [avg]	5%
[maximum]	16%
Pulse Rate Variation:	2%

Lee BY, Campbell JS, and Berkowitz P.

FIGURE 1

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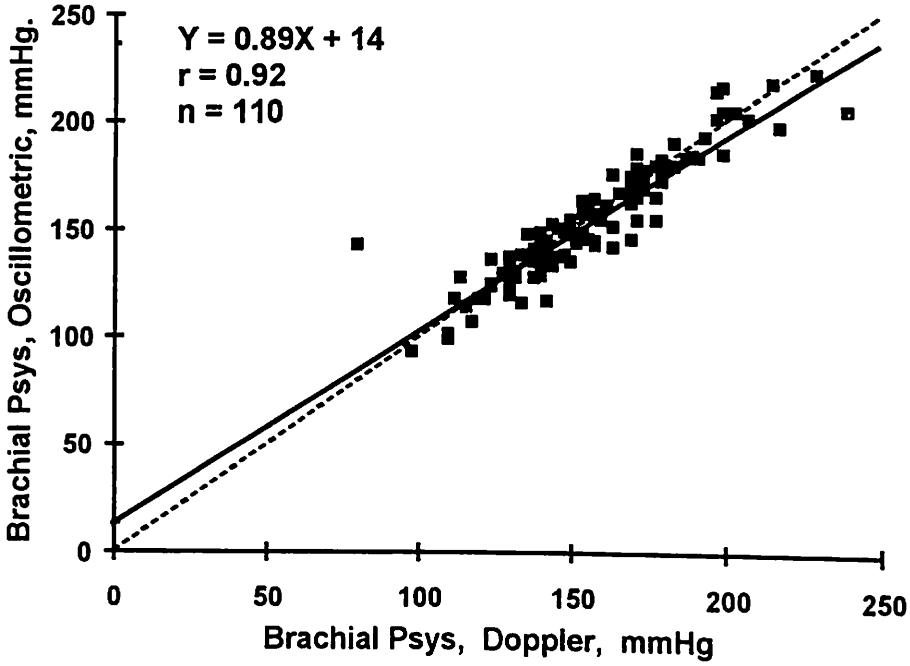
FIGURE 2



Lee BY, Campbell JS, and Berkowitz P.

FIGURE 3

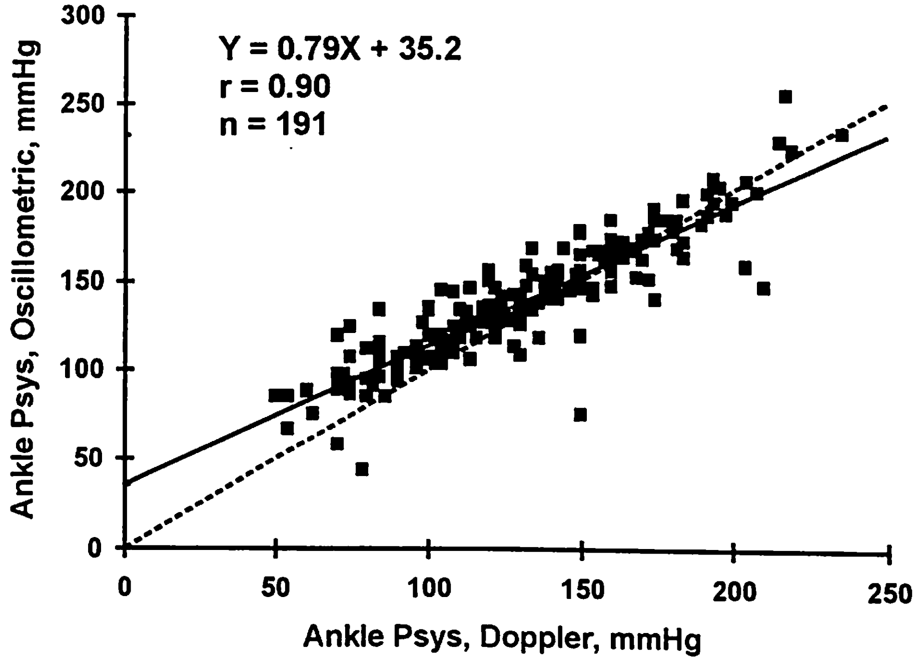


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FIGURE 4

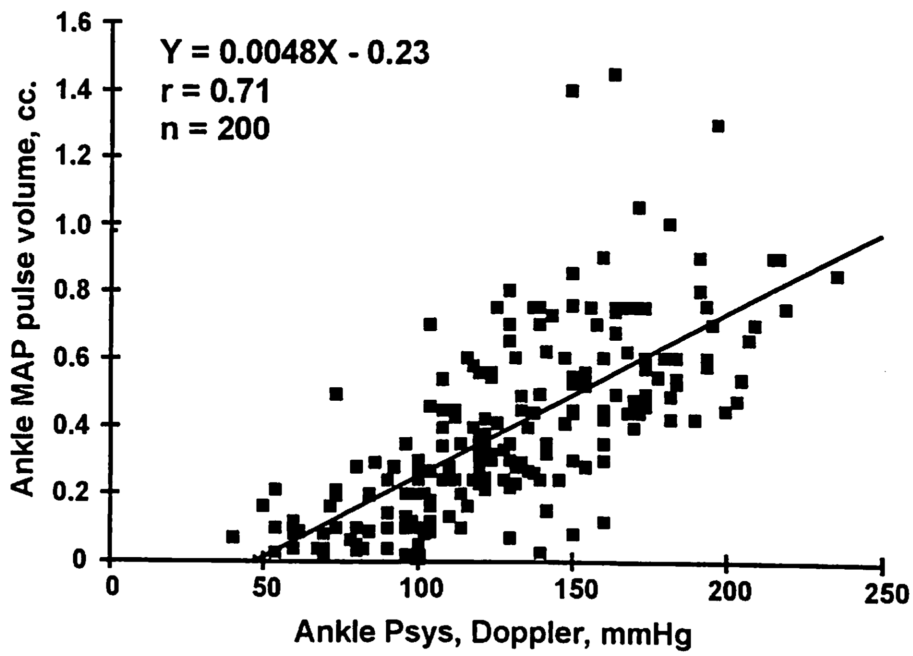

Table I. Comparison of occluding limbs with ABI ≥ 1.30

limb group	*number of limbs*	*number of diabetic limbs*	*Doppler ABI mean ±S.D.*	*Oscillometric ABI mean ±S.D.*	*MAP pulse volume, cc. mean ±S.D.*	*reflected wave present*
Doppler ABI ≥ 1.30	8	5 of 8 (62%)	1.37 ±0.05	1.24 ±0.15	0.60 ±0.11	8 of 8 (100%)
Oscillometric ABI ≥ 1.30	8	2 of 8 (25%)	1.23 ±0.14	1.35 ±0.07	0.59 ±0.19	8 of 8 (100%)

Table II. Data from limbs with non-occluding arteries

limb number	*non-occluding artery* *Posterior Tibial*	*non-occluding artery* *Dorsalis Pedis*	*Oscillometric ABI*	*MAP pulse volume, cc.*	*reflected wave present*
95-L	X	X	1.18	0.45	Y
86-L	X	X	1.11	0.20	Y
95-R	X	X	1.08	0.24	Y
62-L	X	X	1.05*	0.065	N
51-R	X	X	0.81	0.25	N
104-L	X		1.23	0.49	Y
86-R	X		1.20	0.36	Y
41-R		X	1.12	0.45	Y

* Result may be inaccurate due to rhythmic movement artifact confusing oscillometric measurement.