Screening for peripheral arterial disease by a four-cuff digital oscillometric device and a manual Doppler method: a comparative evaluation

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This comparative evaluation was conducted with the objective to evaluate the performance reliability of four-cuff digital oscillometric device (DOD) for automated ankle-brachial systolic index (ABSI) measurement in comparison with the standard manual Doppler method that is presently used in the Wound Care Unit of Hospital Kuala Lumpur. (WCUHKL) The DOD used is equipped with four cuffs for automated measurement (left/right brachia and left/right ankle). There were 31 patients from the WCUHKL involved in this comparative evaluation. The ABSI of each patient, left and right respectively, are determined using both Doppler method and DOD method as described in the methodology section. Statistical results from the comparative evaluation shows that the DOD is able to produce equivalent ABSI measurements as the Doppler method. Moreover, the DOD demonstrated a higher consistency in this comparative evaluation as it was able to detect 67% more peripheral artery disease (PAD) cases, which was verified positive by Hospital Kuala Lumpur vascular team. Furthermore, it also provides a range of additional advantages that would make the measurement of ABSI more reliable and convenient for screening of PAD.

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Peripheral artery disease (PAD), a commonly seen disease, is caused by manifestation of atherosclerosis in the lower extremities (Dinesh et al, 2015). It is highly associated with diabetic foot ulcers (DFU) in patients with diabetes and has been associated with significant mortality and morbidity (Dinesh et al, 2015). However, it is an under diagnosed condition, estimated to affect more than 200 million people worldwide. The most defining symptom of PAD, intermittent claudication, is only present in 27% of patients diagnosed with the disease (Amudha et al, 2003). This shows that PAD is unlikely to be detected based on symptoms alone and requires a reliable method for detection (Amudha et al, 2003). The ankle-brachial systolic index (ABSI) measurement is a simple, effective non-invasive diagnostic method for detecting lower-extremity PAD, as recommended by a number of guidelines and recent consensus documents (Jing et al, 2017; Marie et al, 2017; Ousey et al, 2018). The current standard for measuring ABSI is done using the Doppler method which is manual and requires a skilled medical operator. Additionally, this method is time-consuming due to pre-measurement resting and measurement process. To streamline this process, automated devices such as the digital oscillometric device (DOD) for measuring ABSI have been developed. This evaluation studies the comparison between the DOD and the Doppler method.

METHODOLOGY

Here is an outline of the two techniques and calculation methods involved when taking ABSI measurements:

Paired Sample Statistics

		Mean	N	Std. Deviation	S.E. Mean
Pair 1	HKL_Doppler_left	1.05	30	.21	.04
	Arterio_Vision_left	1.03	30	.22	.04
Pair 2	HKL_Doppler_right	1.06	29	.16	.03
	Arterio_Vision_right	1.06	29	.21	.04

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	HKL_Doppler_left & Arterio_Vision_left	30	.75	.000
Pair 2	HKL_Doppler_right & Arterio_Vision_right	29	.85	.000

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	HKL_Doppler_left - Arterio_Vision_left	.02	.15	.03	-.04	.07	.59	29	.558
Pair 2	HKL_Doppler_right - Arterio_Vision_right	.00	.11	.02	-.05	.04	-.15	28	.885

Table 1. T test results for ABSI using Doppler and DOD methods (left and right)

The Doppler method

The manual ABSI measurement is done using the Doppler method with the following procedure:

- The patient's arm systolic blood pressure is first measured using a single-cuff oscillometric device
- The procedure is repeated on the other arm. The highest of the two values is used to calculate the ABSI
- The patient is then asked to rest in a supine position for around 10 minutes before taking measurement
- After resting, the ankle pressure is measured using the Doppler probe in combination with ultrasound gel and blood pressure cuff by noticing the Doppler signal generated
- The same procedure is repeated for both legs to record the ankle systolic pressure respectively for left and right leg
- After the systolic pressures are recorded, the ABSI is calculated manually.

The ABSI for the Doppler method is then calculated manually, using the highest arm pressure and the highest ankle pressure:

- Left or right ABSI=Systolic blood pressure of left or right ankle/systolic blood pressure of single brachial artery.

The four-cuff DOD method

The automated ABSI measurement is done using the DOD with the following procedure:

- Allow patient to lie flat comfortably for about 5 minutes
- Attach the four blood pressure cuffs to left and right arm, and similarly for both ankle positions simultaneously
- Run the test and ABSI results will automatically be ready within five minutes, while both systolic and diastolic blood pressure of each brachia and ankle are displayed.
- The ABSI is calculated automatically for each leg. The ABSI value is determined by taking the higher pressure of the two arteries at the ankle, divided by the brachial arterial systolic pressure. In calculating the ABSI, the higher of the two brachial systolic pressure measurements should be used (Vowden and Vowden, 2018).
- Left or right ABSI=Systolic blood pressure of left or right ankle/systolic pressure of left or right brachial artery (whichever is higher).

Statistical analysis

A paired sample T-test was done for this comparative evaluation *(Table 1)*. The measurements from the Doppler method and the four-cuff DOD method were compared to determine if there is a significant difference for the ABSI measurements between the two methods. The standard significance value, $\alpha=0.05$ is used and the p value from the test was compared to determine if the null hypothesis is to be rejected.

Qualitative analysis

To illustrate the results for graphical representation, the patients were classified as diagnosed with PAD if the ABSI was <0.90. This was based on the ABSI value standard interpretation where ABSI<0.90 is classified as some arterial disease detected (Tahir et

Patient	LEFT ABSI				RIGHT ABSI			
	Doppler ABSI	4-Cuff DOD ABSI	Doppler Results	4-Cuff DOD Results	Doppler ABSI	4-Cuff DOD ABSI	Doppler Results	4-Cuff DOD Results
1	1.10	1.27	OK	OK	0.90	0.98	OK	OK
2	1.12	1.06	OK	OK	1.19	1.24	OK	OK
3	-	-	-	-	1.26	1.18	OK	OK
4	1.00	1.06	OK	OK	1.04	0.97	OK	OK
5	1.21	1.22	OK	OK	1.28	1.23	OK	OK
6	1.18	1.24	OK	OK	1.06	1.12	OK	OK
7	1.15	1.03	OK	OK	1.10	1.29	OK	OK
8	0.81	0.76	Abnormal	Abnormal	1.00	1.01	OK	OK
9	1.27	1.28	OK	OK	1.21	1.30	OK	OK
10	0.99	1.13	OK	OK	1.04	1.15	OK	OK
11	1.30	0.70	OK	Abnormal	1.08	1.03	OK	OK
12	0.77	0.65	Abnormal	Abnormal	1.11	0.94	OK	OK
13	1.36	1.11	OK	OK	1.20	1.13	OK	OK
14	1.10	1.21	OK	OK	1.06	1.18	OK	OK
15	0.98	1.09	OK	OK	0.93	1.18	OK	OK
16	1.01	0.88	OK	Abnormal	0.93	0.62	OK	Abnormal
17	1.03	1.04	OK	OK	0.96	0.85	OK	Abnormal
18	1.05	1.09	OK	OK	0.92	1.06	OK	OK
19	1.29	1.12	OK	OK	1.07	1.05	OK	OK
20	0.60	0.55	Abnormal	Abnormal	-	-	-	-
21	1.05	1.12	OK	OK	1.02	1.02	OK	OK
22	1.26	1.21	OK	OK	1.18	1.12	OK	OK
23	0.60	0.78	Abnormal	Abnormal	-	-	-	-
24	1.11	1.17	OK	OK	1.14	1.15	OK	OK
25	0.94	1.06	OK	OK	1.08	1.06	OK	OK
26	1.10	1.20	OK	OK	1.20	1.25	OK	OK
27	0.52	0.48	Abnormal	Abnormal	0.42	0.28	Abnormal	Abnormal
28	1.28	1.33	OK	OK	1.17	1.24	OK	OK
29	1.11	1.06	OK	OK	1.03	0.97	OK	OK
30	1.10	1.07	OK	OK	1.00	0.98	OK	OK
31	1.10	1.03	OK	OK	1.20	1.29	OK	OK
Abnormal Count			5	7			1	3

Table 2. Interpretation of left and right ABSI results using threshold value of ABSI <0.90

al, 2017). Other qualitative factors of the two methods were also collected and examined. These factors included measurement time, ease of use, consistency and more.

Results and discussions

Quantitative paired samples T test:

α: The standard level of significance of **0.05** is used

$\mathbf{H_0}$: $p>0.05$, there is **no significant** difference between ABSI results taken using Doppler method and DOD ABSI value

$\mathbf{H_a}$: $p<0.05$, there is a **significant** difference between ABSI results taken using Doppler method and DOD ABSI value.

From the above analysis, the left ABSI sample group has $p=0.558$ and the right sample group has $p=0.885$ respectively. Using the standard significance level, both $p>0.05$ hence the null hypothesis was accepted and the authors concluded there was no significance difference for ABSI measurements using the Doppler and DOD method.

Therefore, health professionals using the DOD are able to reproduce similar ABSI results compared with using the conventional manual Doppler method but has the added advantage of being automated, faster and less prone to human errors as it has minimal dependency on operator technique.

Qualitative analysis

According to clinical guidelines, an ABSI value within the range of 0.9–1.1 is a normal result (Aboyans et al, 2012). Therefore, we can interpret the measurement values as normal or abnormal by comparing them to the range. Applying this theory to the data collected, we can see the detection results of using manual Doppler ABSI collection versus DOD in ***Table 2***.

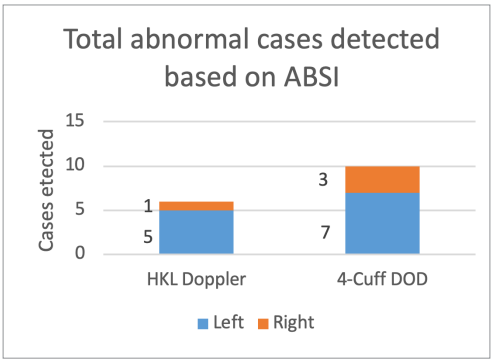

Figure 1. Bar chart for number of abnormal cases detected

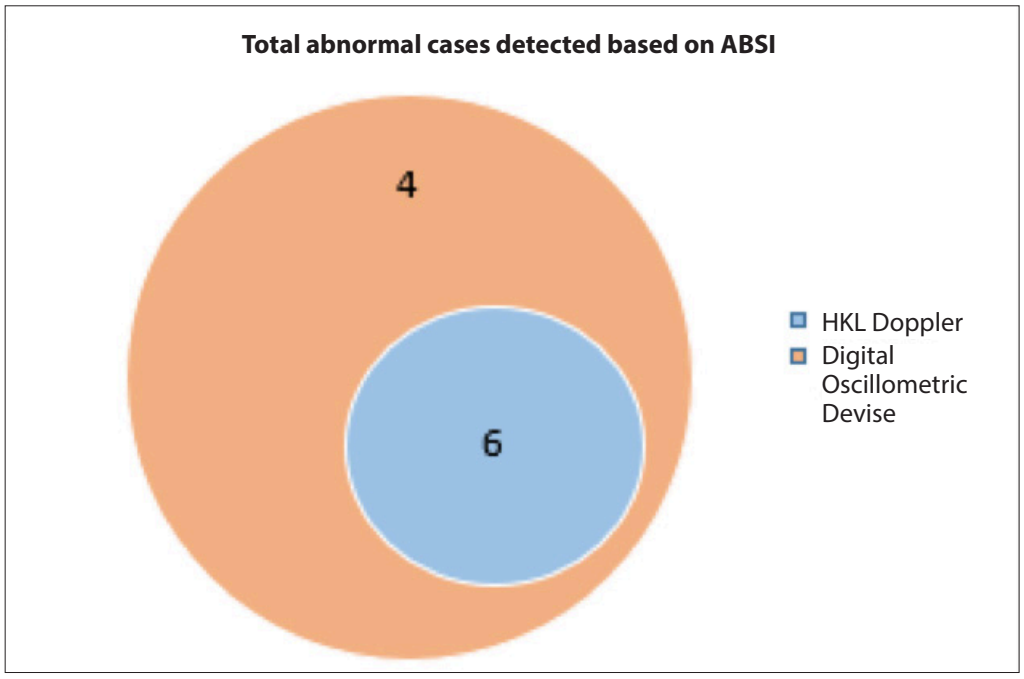

Figure 2. Venn diagram for total abnormal cases detected

Table 3. Comparison between Doppler method and four-cuff DOD

Factors	Doppler	Four-cuff DOD
Technique-dependent	Yes	No
Measurement duration	20–30 minutes	5 minutes
Measuring process	One limb at a time	Four limbs simultaneously
Measurement consistency	Operator-dependent	Automated
Results	Manual calculation	Automated calculation with instant results
Additional Results	Depends on usage and calculations	Blood pressure, arterial stiffness index Pulse wave velocity, Pressure pulse volume recording

Figure 1 shows the number of abnormal cases detected using Doppler method and the four-Cuff DOD. It can be seen that the number of abnormalities detected by the DOD was more than the Doppler method (approximately 67% more). It was further confirmed by HKL vascular team that the four additional cases detected by DOD were patients with PAD.

Furthermore, results in *Figure 2* shows that the DOD was able to fully match the detection of abnormal cases detected by the Doppler and more. Thus, using DOD can reduce the number of false negative detections compared with the manual Doppler method.

The four false-negative cases undetected by the Doppler method would likely be due to its dependence on operator skills. Using the four-cuff DOD might be more consistent as it is less operator dependent.

From the qualitative data collected in *Table 3*, we can see that the most impactful factor of DOD is saving of clinical time. Including the pre-measurement rest time, using DOD provides an estimated 75% faster process time, which will have a compounding effect after a large number of ABSI measurements are done, as seen in *Figure 3*.

Conclusion

PAD is a commonly underdiagnosed disease that requires an easy method for early detection (Angel et al, 2016), namely ABSI measurement. The current standard method for ABSI measurement is the manual Doppler method, which is error prone, due to technique

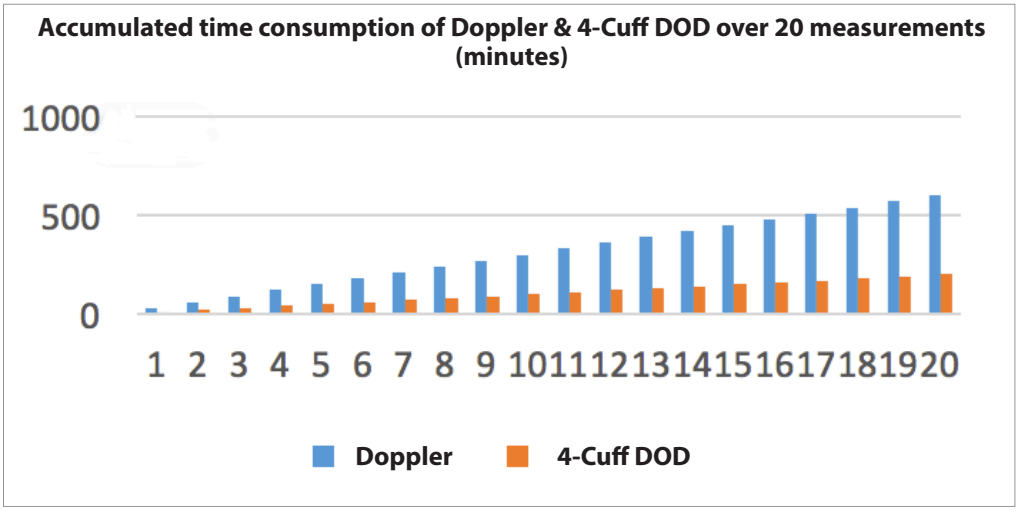

Figure 3. Bar chart for estimated accumulated time consumption

and skill dependency. Additionally, it is also very time-consuming.

As such, it is appropriate to identify an automated measurement device such as the four-cuff DOB to make the measurement process more efficient.

Our comparative evaluation shows that the ABSI measurements by DOD matched the results of the manual Doppler method. Additionally, the DOD demonstrated better sensitivity in detecting low ABI (<0.9) as it is less operator dependent.

In comparison with manual Doppler method, DOD provides better efficiency in terms of consistency, lower time consumption, ease of use and is able to produce multiple measurements simultaneously, such as ankle brachial index, arterial stiffness index, pulse wave velocity and more.

From the results shown and in consideration of its qualitative advantages over the manual Doppler method, using DOD for ABSI measurement would be a reliable and suitable method for screening PAD.

Limitations

The limitation of this comparative evaluation was the small sample size (31 patients), which might not depict the results of the general population.

WAS

References

Aboyans V, Criqui MH, Abraham P et al (2012) Measurement and Interpretation of Ankle-Brachial Index A Scientific Statement from the American Heart Association. *Circulation* 126(24): 2890–909

Amudha K, Chee KH, Tan KS et al (2003) Prevalence of peripheral artery disease in urban high-risk Malaysian patients. *Int J Clin Pract* 57(5): 369–72

Angel H, Vincente M, Ivan C et al (2016) Diagnostic Accuracy Study of an Oscillometric Ankle-Brachial Index in Peripheral Arterial Disease: The Influence of Oscillometric Errors and Calcified Legs. *PLoS One* 11(11): e0167408. https://doi.org/10.1371/journal.pone.0167408 (accessed 26.11.2019)

Dinesh A, Langenberg C, Rapsomaniki E et al (2015) Type 2 diabetes and incidence of a wide range of cardiovascular diseases: a cohort study in 1.9 million people. *Lancet* 385(1): S86

Jing M, Min L, Dawei C et al (2017) The Validity and Reliability between Automated Oscillometric Measurement of Ankle-Brachial Index and Standard Measurement by Eco-Doppler in Diabetic Patients with or without Diabetic Foot. *Int J Endocrinol* 2017: 2383651. https://https://tinyurl.com/y4nq9zua (accessed 26.11.2019)

Marie D, Heather L, Coletta B et al (2017) AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Artery Disease 2016. *Circulation* 135(12): e726–e779

Ousey K, Chadwick P, Jawien A et al (2018) Identifying and treating foot ulcers in patients with diabetes: saving feet, legs and lives. *J Wound Care* 7(Sup5): S1–S52

Tahir H, Falahat A, Khusrow N (2008) Critical review of the ankle-brachial index. *Curr Cardiol Rev* 4(2): 101–106

Vowden P, Vowden K (2018) The importance of accurate methodology in ABSI calculation when assessing lower limb wounds. *Br J Community Nurs* 23(Sup3): S16–S21