

Validation of QuantaFlo as a Screening Tool for Peripheral Artery Disease

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INTRODUCTION

The Ankle Brachial Index (ABI) is the current noninvasive gold standard to detect and monitor Peripheral Artery Disease (PAD)

- Limitations
 - Requires expensive equipment
 - Requires experienced, licensed technologist
 - Arterial calcification can falsely elevate results

QuantaFlo (*Semler Scientific*) uses infrared technology to measure insufficient blood flow

- Benefits:
 - Short duration study
 - Equipment is highly portable
 - No need for experienced technologist
 - Results reportedly not impacted by arterial calcification

Objective: To assess QuantaFlo as a screening tool for PAD compared to the gold standard, ABI.

METHODS

Prospective cohort study

- Inclusion criteria:
 - New diagnosis of PAD within the last year
 - Established PAD diagnosis with worsening of symptoms (i.e. new ischemic rest pain, nonhealing wounds, or tissue loss)
- Exclusion criteria:
 - Major lower extremity amputation prior to enrollment
 - Prior lower extremity revascularization
- Baseline visit
 - Performed by registered vascular sonographer
 - Supine position for approximately 3 minutes in dimly lit room
 - QuantaFlo performed, followed by ABI
 - Room temperature maintained between 68-70°F

Chi-square and t-test used to analyze categorical and continuous variables, respectively (SPSS Version 29.0).

RESULTS

Table 1. Patient demographics

Characteristics	Total (n=85 patients)
Age	69.7 [64.2, 76.8]
Race/Ethnicity:	
Black/Non-Hispanic	50 (58.8%)
White/Non-Hispanic	28 (32.9%)
Other	3 (3.6%)
Unknown	4 (4.8%)
Males	77 (90.6%)
Smoking History	
Current	29 (34%)
Former	34 (40%)
Hypertension	73 (85.9%)
Hyperlipidemia	58 (68.2%)
Diabetes Mellitus	51 (60%)
CKD	26 (30.6%)
CHF	12 (14.1%)
COPD	14 (16.5%)

CKD= Chronic kidney disease (stage 3, 4, or 5), CHF= Congestive heart failure, COPD= Chronic obstructive pulmonary disease.

Table 2. QuantaFlo troubleshooting

Irregular waveforms encountered	Total (n=51 limbs)
No obvious reason	39 (76.5%)
Extremity movements	3 (5.9%)
Cold extremities	3 (5.9%)
Thickened/distorted nails	2 (3.9%)
Polish	2 (3.9%)
Bruised extremity	1 (1.9%)
Patient talking	1(1.9%)
More than 1 reason	3 (5.9%)

Table 3. Cross-tabulation findings for all patients

QuantaFlo	Ankle Brachial Index				
	Total (n=148)*	≤0.5 (n=17)	0.5 - 0.8 (n=57)	0.9 - 1.4 (n=57)	≥1.4/NC (n=18)
0.0-0.29 (severe)	34 (23%)	11 (64.7%)	15 (26%)	5 (8.8%)	3 (18%)
0.3-0.59 (moderate)	36 (24.3%)	5 (29.4%)	21 (37%)	6 (11%)	4 (24%)
0.6-0.89 (mild)	20 (13.5%)	0 (0%)	12 (21%)	6 (11%)	2 (12%)
0.9-0.99 (borderline)	10 (6.8%)	1 (5.9%)	4 (7%)	5 (8.8%)	0 (0%)
1.0-1.40 (normal)	48 (32.4%)	0 (0%)	5 (8.8%)	35 (61.4%)	8 (47%)
QuantaFlo	Toe Pressure				
	Total (n=144)**	<30 (n=23)	30-39 (n=9)	40-59 (n=29)	≥60 (n=83)
0.0-0.29 (severe)	33 (23%)	13 (56.5%)	5 (55.6%)	9 (31%)	6 (7.2%)
0.3-0.59 (moderate)	34 (23.6%)	8 (34.8%)	3 (33.3%)	11 (38%)	12 (15%)
0.6-0.89 (mild)	19 (13.2%)	2 (8.7%)	0 (0%)	6 (21%)	11 (13%)
0.9-0.99 (borderline)	10 (7%)	0 (0%)	1 (11%)	2 (7%)	7 (8.4%)
1.0-1.40 (normal)	48 (33.3%)	0 (0%)	0 (0%)	1 (3.4%)	47 (56.6%)

NC= Non-Compressible; *QuantaFlo not obtained in 1 limb due to TMA; **Hallux pressure not obtained in 5 limbs due to TMA (1), hallux amputation (2), gangrene, (1) & lack of patient immobility (1).

Table 4. QuantaFlo test validity in various disease states

Characteristic		Sensitivity	Specificity	PPV	NPV
All Limbs	ABI	77.9%	90.9%	98.0%	41.7%
	Toe Pressure	92.2%	75.8%	86.5%	85.4%
Diabetic patients' ABI		81.0%	87.5%	98.5%	31.8%
CKD patients' ABI		76.4%	90.5%	97.0%	48.7%

Abnormal ABI - <0.9, ≥ 1.4, with blunted toe waveforms, or biphasic/monophasic ankle waveforms. Abnormal toe pressures - <80mmHg.

DISCUSSION

- QuantaFlo classified 61.4% of limbs with normal ABI as normal.
 - Classified 8.8% of limbs with normal ABI as severe.
 - QuantaFlo classified 56.6% of limbs with normal toe pressure as normal
 - Classified 7.2% of limbs with normal toe pressure as severe.
 - Sensitivity was greater when utilizing toe pressure as the reference standard compared to ABI.
- Troubleshooting QuantaFlo is a frequent occurrence
- Among the 51 limbs that required troubleshooting
 - 76.5% exhibited no identifiable underlying cause for the irregular waveforms.
 - QuantaFlo classified 18.2% of the limbs with normal ABI as severe
 - QuantaFlo did NOT classify any limbs with severe ABI as normal.

CONCLUSION

- When performed under ideal laboratory conditions, QuantaFlo is a reasonable screening tool for PAD.
- Further investigation is necessary to determine its real-world performance in community settings or for home-based PAD screening.