A Comparison of Noninvasive Paired Technologies for the Assessment of Peripheral Arterial Disease

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Background

As the medical community and public at-large develop heightened awareness of the increasingly alarming rates of Peripheral Arterial Disease (PAD), the need for simple, accurate, and timely testing becomes indispensable. The standard "tool kit" for noninvasive vascular testing (NIVT) in patients with lower extremity wounds is limited. Standardized tests are either time consuming, inaccurate or both. While sensitive but non-specific for macrovascular disease, the Ankle-Brachial Index (ABI) can take up to twenty minutes to obtain. It is additionally demonstrated to be inaccurate in patients with arterial calcifications or noncompliant vessels. Transcutaneous Oxygen Monitoring (TCOM), a reasonable tool for microcirculatory conditions, is time consuming to perform and highly dependent on skin condition and operator skill.

Methods

Our single-center, prospective, nonrandomized, IRB approved investigation evaluated outcomes for 100 new patients presenting with lower extremity wounds. The primary objective assessed for time required to conduct paired vascular tests – Transcutaneous Oxygen Monitoring/Ankle-Brachial Index vs. Skin Perfusion Pressure (SPP)/Pulse Volume Recording (PVR) – for each patient. A secondary objective evaluated the paired technologies for accurate correlation with arterial vascular disease detection.

Findings

Study population notable for 48% (48/100) diabetes mellitus rate and 44% (44/100) admitting to current or remote tobacco use.

Primary objective: Utility – Time-To-Test (TTT)

- Time utility comparison was highly significant ($p<0.0001$) with a mean SPP/PVR test time of 6.72 mins (± SD2.41) compared to a mean TCOM/ABI testing time of 35.54 mins (±SD 8.86). Sub analysis of multi-site SPP/PVR testing was accomplished (x3 sites; wound and bilateral hallux) which yielded a cumulative SPP/PVR mean TTT of 18.43 mins. Refer to **Figure 2** for comparative results.

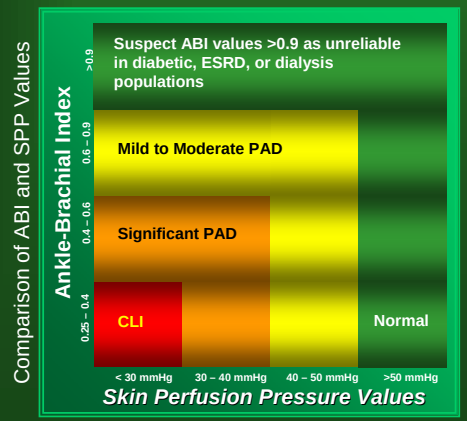
Secondary objective: PAD detection (see **Figure 3**)

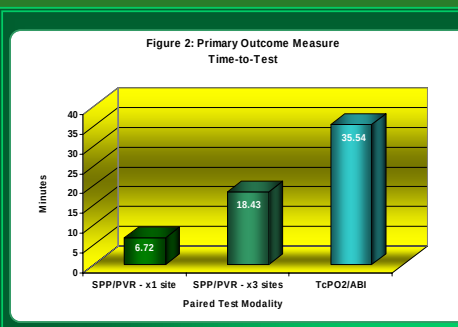
- Arterial disease presence was confirmed in 52/100 patients.
- The observed paired technology PAD detection rate in this diseased patient population was 96.2% (50/52) for SPP/PVR and 61.5% (32/52) for $TcPO_2$/ABI ($p<0.001$).
- Diabetes mellitus was present in 57.7% (30/52) of the diseased population.
- **Of the 52 patients with confirmed PAD, an ABI was unable to be obtained in 32.7% (17/52).**
  - **Of these 17 patients 47.1% (8/17) were diabetic.**
- Worthy of mention: ABI was unable to be obtained bilaterally in almost one quarter of the complete study population (22%; 22/100) with the majority of those being unattainable resultant of calcified or noncompliant vessels. Refer to **Figure 4** for illustration of ABI testing failure rate.

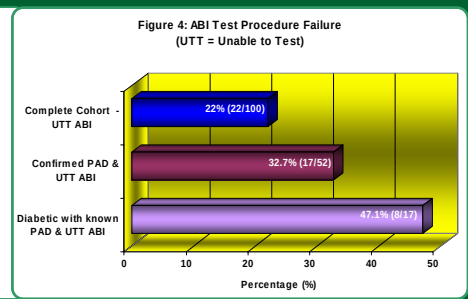
Figure 1: Demographics

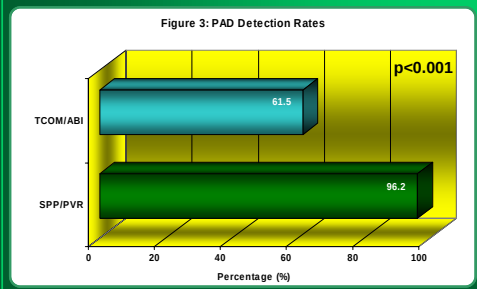
Variable	(n=100)	*Range*	*SD*
Age (mean)	69.3	20-96	16.6
BMI* (mean)	28.04	13.4-48.8	6.7
Male	46	-	-
Diabetes Mellitus	48	-	-
Kidney Disease	10	-	-

*67% of population are overweight or obese per CDC guidelines

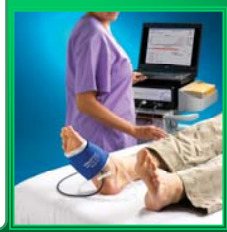








The SensiLase® System



Conclusion

This investigation substantiates Skin Perfusion Pressure and Pulse Volume Recording to be superior to Transcutaneous Oxygen Monitoring and Ankle-Brachial Index in providing vascular disease detection in a time efficient manner.