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Pilot Study: “An assessment of the endothelial function utilizing finger pulse oximetry (PPG) waveform”

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Introduction:

Endothelial dysfunction describes a shift that occurs in the endothelium of blood vessels towards vasoconstriction, constituting a pro-thrombotic and pro-inflammatory state [1]. Endothelial dysfunction is heavily associated with cardiovascular disease, coronary artery disease, peripheral vascular disease, diabetes mellitus, stroke and the progression of atherosclerosis [1] [2] [3]; thus, it is of great interest to screen for endothelial dysfunction. The present non-invasive gold standard for assessing endothelial function is Flow Mediated Ultrasound (FMD) [4]. However, FMD is operator dependent, is associated with a high degree of inter-observer variability, and requires special training, thus, Peripheral Arterial Tonometry (PAT) is considered the next best method for non-invasive assessment of endothelial function as it is operator independent, but unfortunately requires special costly equipment.

Our study aims to assess endothelial function utilizing finger pulse oximetry waveforms. Pulse oximeters are more readily available, cheaper, and do not require much patient preparation.

Methods:

Study Population: With IRB approval, the study was carried out in two parts; part #1 involved 12 healthy subjects, and part #2 involved 10 patients suffering from either diabetes mellitus, peripheral vascular disease or coronary artery disease (thus, having endothelial dysfunction). Seven of the patients suffered from both PVD and DM.

Endothelial assessments were carried out using EndoPAT and Nonin Xpod pulse oximeter (Photoplethysmographic). EndoPAT is a non-invasive technique that measures changes in digital blood volume during reactive hyperaemia (RH) [5]. PAT testing involved placement of a blood pressure cuff on the testing arm as well as a finger tonometer probe which utilizes an inflatable balloon cushion placed over the index finger of both hands that prevents venous distention in the finger while an in-probe photoplethysmography takes pulse oximeter readings.
Pulse oximeter testing involved the placement of probes on the middle finger of both hands. The reactive hyperaemia test consisted of baseline readings for 6 mins, then the BP cuff was inflated above systolic pressure for 5 mins and later released where a reading of reactive hyperaemia was taken for 5 mins. Volunteer subjects were asked to be NPO (nothing by mouth), to abstain from smoking and exercise for at least 4 hours prior to the assessment.

Data Analysis:

Peripheral Arterial Tonometry: The device’s software component automatically analyses the peripheral arterial tonometry data and calculates the Reactive Hyperaemia Index (RHI) as well as the natural logarithm of the RHI (LnRHI). Both represent the post-deflation: baseline pulse amplitude ratio in the hyperaemic finger divided by the same ratio of the contralateral finger that serves as control.

LnRHI score of 0.51 and 0.70 indicates the critical and average points respectively, where values below 0.51 are regarded as having poor endothelial function [6](7).

Pulse oximetry (PPG) waveform processing: We used a high-pass filter of 2 Hz to eliminate the baseline venous and respiratory modulation of the waveforms. PPG RHI was calculated by taking the ratio of post-deflation: baseline pulse amplitude in the hyperaemic finger divided by the same ratio of the contralateral finger that served as control and the natural log of the RHI was calculated.

Results:

Upon observing the data in table 1 and the consequent figures, a relevant semblance is noted when comparing the readings of finger PPG to those of PAT, this resulted in establishing a cut-off point of LnRHI for the PPG > 0.40.

Part #1: In healthy volunteers; 11 subjects showed normal values of PAT LnRHI (above 0.51), with only one subject (#12) who had low LnRHI (0.32). The same results were observed with PPG LnRHI. All the volunteers were above the critical level of (0.4), except subject #12, as demonstrated in Table 1.

Part#2: In diseased patients; the same agreement between the PAT and PPG LnRHI scores was observed in the patient cohort. (Figure 1)

We have 5 patients who showed endothelial dysfunction by the PAT RHI and 6 patients who showed endothelial dysfunction by PPG RHI.

The 7 patients who suffered from both DM and PVD had PPG LnRHI ranging from -0.53 to 0.38 and PAT LnRHI ranging from 0.29 to 0.67, r value = 0.94, P value < 0.01 (Figure 2).

Correlation between PAT LnRHI and PPG LnRHI for all subjects (n=22), r= 0.713, p<0.01 (figure 3).

Out of the 10 patients, patients 2, 5, 7 and 10 exhibited good endothelial health according to both the PAT and PPG LnRHI and patient 3 showed good endothelial health on the PAT. This could be explained by the reversal of endothelial dysfunction via the actions of statins, ascorbic acid, and ACE inhibitors prescribed to them. [1]

Conclusion:
When we factor in the availability and reusability of pulse oximeter devices and probes, it becomes clear that if finger pulse oximeters were to be manufactured with the preceding calculations automatically applied into the proprietary software and guidelines published, they would have the potential to at least predict if not diagnose conditions involving endothelial dysfunction. Further trials with more diverse study populations need to be conducted to strengthen this pilot statement, and establish clearer values for endothelial health.