Reproducibility of A Novel Noninvasive Index of Vascular Reactivity

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Introduction
The measurement of peripheral arterial flow-mediated dilation by ultrasound is the most commonly used non-invasive method of assessing vascular endothelial function, a marker of vascular health. However, the reproducibility of flow-mediated dilation, requires equipment, technical skills of the operator, and imaging software and time for processing of the acquired images are factors that limit its clinical utility. Cordex has developed an operator-independent device for assessing peripheral vascular reactivity noninvasively. The output measure of the device, the EnDys™ Score, is derived from time-dependent changes in arterial compliance in the setting of post-ischemic hyperemia following the release of an upper-arm limb occlusion cuff. It is intended to be an index of endothelial function. The data processing is done by embedded software and provides immediate results not requiring further post-test processing. We evaluated the reproducibility of the EnDys Score to determine whether it met a coefficient of variation (CV) of ≤ 20%, widely considered to be an accepted standard for clinical medical device testing.

Methods
The study protocol was approved by the Johns Hopkins IRB and all subjects gave written informed consent. We enrolled 20 subjects, aged 45.7 ± 13.1 years old; 50% were female. They were instructed to fast for 6 hours prior to testing. The Cordex device consists of an inflatable cuff, and circuitry that controls the degree and timing of cuff inflation and deflation. The test was performed three times, at 0, 45, and 90 minutes. At each of these time points, the cuff was inflated to at least 20 mmHg above systolic pressure for 5 minutes, followed by a graduated deflation, during which time data, at a rate of 200 measurements/sec, was accumulated to assess the arterial compliance over time throughout the entire transmural pressure curve. Descriptive statistics and the intra-subject, intra-day coefficient of variation was calculated on the three EnDys Scores.

Results
The overall EnDys Score was 84.5 ± 23.3. The CV was 15.33% (10.81 to 19.33, 95% CI). The testing protocol was well tolerated by all participants and no adverse events were reported.

Conclusion

The key finding was that the Cordex device, an operator-independent device for assessing peripheral vascular reactivity, which reflects vascular health, had excellent reproducibility, which exceeded the established goal for marketable medical devices. The device was well tolerated by all subjects.