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Title: A Novel Operator-Independent Noninvasive Device for Assessing Vascular Endothelial Function

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Background: Endothelial dysfunction is associated with increased cardiovascular disease (CVD) risk, yet its evaluation is not widely used clinically, partly because current methods are invasive, operator-dependent, or require non-reusable expensive probes. We tested a novel device that overcomes these limitations by obtaining a measure of endothelial function using a standard blood pressure cuff. The device assesses endothelial vasodilator function by measuring time-varying brachial arterial compliance during a staged cuff release after 5 minutes of upper arm occlusion. The calculated index is called the EnDys score, and we examined its relationship to established indices and markers of CVD risk.

Methods: Adults with a range of CVD risk factors were enrolled. We measured demographic, behavioral, anthropometric, and biological markers needed to calculate the Framingham Risk Score (FRS) and identify metabolic syndrome (MetSyn) defined as having 3 of the 5 component risk factors. The presence of carotid artery plaque was assessed by ultrasound. Cardiorespiratory fitness was assessed by the 6-minute walk test (6MWT). EnDys score was measured using the new device, SmartCuff.

Results: Among 135 participants, the mean age was 49.3 +/- 17.9 years, 47% were female, 7% were smokers, 7% had coronary artery disease, 10% had type 2 diabetes mellitus, and 34% had MetSyn. Carotid plaque was found in 38% of participants. Those with MetSyn had a 24% lower EnDys score than those without, p<0.001. Using bivariate analysis, a lower EnDys score was associated with a higher FRS percentile, r=-0.29, p<0.001; a higher number of MetSyn factors, r=-0.30, p<0.001; a higher number of carotid plaques, r=-0.22, p=0.01; and with a lower 6MWT, r=0.34, p<0.0001.

Conclusion: A new index of endothelial function, EnDys score, is associated with established CVD risk indices, the presence of carotid plaque, and lower cardiorespiratory fitness. Further study is needed to assess the clinical utility of the EnDys score for identifying individuals at high risk for CVD, and whether the score changes in response to interventions such as exercise, diet, and medical therapy.