Diagnostic Tool for Analyzing Results of Flow-Mediated Dilation

Villanova University Investigator

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Background and Unmet Need

One of the important indicators of cardiovascular (CV) health is the structural integrity of arterial walls. One well-known method for assessing the physical state of the arterial wall is the noninvasive and relatively inexpensive brachial artery Flow-Mediated Dilation (BAFMD) test, in which blood flow through the brachial artery is obstructed temporarily (for about five minutes) using a pressure cuff wrapped around the upper arm, causing the artery to become almost completely closed. The cuff is then suddenly deflated, allowing the flow to rush back in while the dilating artery is monitored until full recovery, using an ultrasound scanner[i,ii]. FMD metrics have been proposed in the past as potential cardiovascular health indicators. Correlations have been found linking abnormal FMD results with many underlying conditions and risk factors directly affecting cardiovascular disease[iii] and health[iv,v,vi].

Despite the critical role of FMD in evaluating cardiovascular diseases (CVDs), there is a significant lack of understanding of the fundamental biophysics governing the FMD process, which prevents it from being an effective and pervasive diagnostic tool for cardiovascular diseases.

Opportunity

Villanova University scientist, Qianhong Wu has developed a novel method to assess the results of a BAFMD test, including a system and device that evaluate the output and results of an FMD process. It produces a diagnostic tool that overcomes the previous issues of interpreting an FMD test.

There is significant potential for the tool to be integrated into an ultrasound system and enable new diagnostic methods. Ultrasound already is used widely in cardiology as an inexpensive, noninvasive diagnostic tool. The global CV ultrasound market was valued at $1.3 billion USD in 2020 and is expected to grow at a compound annual growth rate (CAGR) of 6.7% from 2021 to 2028. The increase in CVD and a rise in preventative screening is expected to be the main stimulant of market growth. This invention could enable a novel diagnostic paradigm for ultrasound manufacturers to differentiate their offerings to cardiologists and other medical practitioners[vii].

In addition to enabling a more nuanced risk assessment of CVDs and other health issues that have already been found to correlate with abnormal FMD, another avenue where this invention could exhibit great potential is monitoring the progress of COVID long haulers. This is borne out by recent evidence[viii] that SARS-CoV-2 has been associated with leaky vessels, pointing to a compromised glycocalyx layer, and endothelial function, the evolution of which the model underlying this invention is well-suited to detect.

Finally, there is potential for the invention as a clinical trials support tool. The ability to easily and non-invasively track longitudinal progression of arterial health could be useful for CVD clinical trials. The CVD drug market is expected to reach $63.96B USD by 2026[ix], however there are concerns about the pipeline of promising candidates. CVD drug trials cost approximately six times that of average trials for other indications[x], with much of that cost associated with challenges in evidence generation[xi]. A new, non-invasive, and inexpensive tool for CVDs could significantly reduce the price of developing new CVD drugs.

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Unique Attributes

- Easily understood readout of a BAFMD response using a novel physics-based model.
- The method's sensitivity to anatomical variabilities, even within the same subject, could enable longitudinal tracking of individuals.

Clinical Applications

- Diagnostic assessment of cardiovascular diseases.
- Diagnostic monitoring of COVID long haulers.

Stage of Development

Pre-Clinical.

Intellectual Property

Patent application filed November 2021.

Licensing and Collaboration Opportunity

Villanova University is seeking a licensee to commercialize the invention for diagnostic purposes in the treatment of cardiovascular diseases and / or monitoring of COVID long haul patients.

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