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Abstract
Background: Diagnosing suspected coronary artery disease (CAD) continues to require substantial health care resources. Despite improved risk stratification algorithms, the incidence of normal investigations remains high with the use of traditional diagnostic modalities. We therefore tested the diagnostic accuracy to rule out CAD of a new acoustic system CADscor® based on advanced sound analysis from the coronary circulation and myocardium obtained from a simple stethoscope like device.

Methods: We included 1675 patients with a low to intermediate likelihood of CAD referred for Cardiac CT. If CAD was suspected in any coronary segments, patients were referred to invasive angiography with FFR. CADscore was recorded in all patients. The CADscore algorithm included both acoustic features and clinical risk factors. Low risk is indicated by a CADscore value ≤20. The algorithm was developed using recordings from 711 patients from previous studies and a trainings cohort of 589 patients from the present study. The remaining 1086 patients were used as the validation cohort.

Results: CADscore was successfully analyzed in 1464 (87%) patients. Hemodynamic significant CAD was present in 134 (9.3%) patients. There were no differences in the performance of the CADscore algorithm in the training vs. validation cohorts. In the entire cohort, the CADscore differed between coronary artery calcium score (CACS) groups CACS=0 (n=745), CACS 1-400 (n=550) and CACS > 400 (n=142); CADscore: 17 ±11, 24 ±12 and 30 ±12 (p<0.001). CADscore was also significant lower for patients without vs. with hemodynamic significant stenosis 20 ±12 vs 30 ±12 (p<0.001). Diagnostic performance evaluated by receiver operating characteristic curve showed an accuracy of 72% (CI: 67% - 77%). Sensitivity, specificity, PPV and NPV were 81% (CI: 74% to 88%), 53% (CI: 50% to 56%), 15% (CI: 13% to 18%), and 97% (CI:95% to 98%).

Conclusion: A simple sound based recording device and analysis model enables risk stratification in suspected CAD patients. With a negative predictive value of 97 %, this new acoustic system could be utilized as a first line rule-out test which could reduce demands on more advanced diagnostic modalities.