CADScor®System Published Data

Study: Coronary artery disease risk reclassification by a new acoustic-based score;		
Int J Cardiovasc Imaging. 2019 Nov;35(11) :2019-2028. Schmidt SE, et al. Retrospective Study n=2,245 3 OUS Sites (PUBMED link)		
OBJECTIVE: To determine the potential of CADScor System to reclassify patients with intermediate pre-test probability (PTP) and clinically suspected stable coronary artery disease (CAD) into a low probability group thereby ruling out significant CAD.	**OUTCOME:** The CAD-score enabled a significant and safe reclassification of patients, which could reduce the need for more expensive testing in patients presenting with chest pain. **Performance:** • AUC=75% (CI: 71-79%) • Sensitivity=89% (CI: 84-92%) • Specificity=42% (CI: 40-44%) • NPV=97% (CI: 96-98%) • PPV=14% (CI: 12-16%)	**CONCLUSION:** Utilization of a low-cost acoustic device in patients with intermediate PTP could potentially reduce the number of patients referred for further testing, without a significant increase in the false negative rate, and thus improve the cost-effectiveness for patients with suspected stable CAD.
Study: Diagnostic performance of an acoustic-based system for coronary artery disease risk stratification (Dan-NICAD I);		
Heart (British Cardiac Society) 2018 Jun;104(11):928-935. doi: 10.1136/heartjnl-2017-311944. Epub 20; Winther S et al. Observational Study; n=1,675 2 OUS Sites (PUBMED link)		
OBJECTIVE: The aim of this study was to test the diagnostic accuracy of a new portable acoustic device for detection of CAD.	**OUTCOME:** In this large, first of its kind prospective trial, we demonstrated that acoustic detection of CAD enables risk stratification in patients with suspected CAD. **Performance:** • AUC=72% (CI: 68-77%) • Sensitivity=80% (CI: 73-87%) • Specificity=53% (CI: 50-56%) • NPV=96% (CI: 94-97%) • PPV=16% (CI: 14-19%)	**CONCLUSION:** Sound-based detection of CAD enables risk stratification superior to clinical risk scores. With a negative predictive value of 96%, this new acoustic rule-out system could potentially supplement clinical assessment to guide decision on the need for further diagnostic investigation.
Study: Likelihood reclassification by an acoustic-based score in suspected coronary artery disease (Dan-NICAD II);		
Heart (British Cardiac Society) 2023 Mar 16;heartjnl-2023-322357; Rasmussen LD, et al. Observational Study; n=1,732 4 OUS Sites (PUBMED link)		
OBJECTIVE: (1) To investigate the diagnostic performance of an acoustic-based CAD score and (2) study the reclassification potential of a dual likelihood strategy by the ESC-PTP and a CAD score.	**OUTCOME:** The overall rule-out properties of the acoustic-based CAD score were excellent with an NPV of 95.4% but sensitivity only moderate. In our cohort, the primary hypothesis was not met as the CAD score did not improve risk stratification compared with the guideline-endorsed ESC-PTP against obstructive CAD by invasive FFR. However, the CAD score improved reclassification beyond the ESC-PTP model as it was able to down-classify nearly half of all grey zone patients (ESC-PTP 5% to ≤15%) without increasing obstructive CAD prevalence. **Performance:** • AUC=70% (CI: 67-75%) • Sensitivity=85% (CI: 80-90%) • Specificity=40% (CI: 38-43%) • NPV=95% (CI: 93-97%) • PPV=16% (CI: 14-19%)	**CONCLUSION:** In a large contemporary cohort of patients with low CAD likelihood, the additional use of an acoustic rule-out device showed a clear potential to downgrade likelihood and could supplement current strategies for likelihood assessment to avoid unnecessary testing.
Study: Advanced heart sound analysis as a new prognostic marker in stable coronary artery disease;		
European Heart Journal - Digital Health, Volume 2, Issue 2, June 2021, Pages 279–289;Winther SE, et al. N=1,463 3 OUS Sites Clinical Trial #: NCT02264717 (PUBMED link)		
OBJECTIVE: To investigate the prognostic value of heart sound analysis as two scores, the Acoustic-score, and the CAD-score, in patients with suspected CAD which is treated according to standard of care.	**OUTCOMES:** The combined primary endpoint was all-cause mortality and myocardial infarction (n = 26). The CAD-score was >20 in 22 of 26 (85%) patients with the combined primary endpoint—in 12 of 16 (75%) of patients who died, and in all 10 patients who had myocardial infarction. In an unadjusted Cox regression analysis of the combined primary endpoint, CAD-scores >20 had an HR of 5.4 (1.9–15.7), P < 0.01.	**CONCLUSION:** Heart sound analysis seems to carry prognostic information and may improve initial risk stratification of patients with suspected CAD.
Health Economic Analysis: Economic Analysis of the CADScor System for Ruling Out Coronary Artery Disease in England;		
PharmacoEconomics - open vol. 6,1 (2022): 123-135; Javanbakht, Mehdi et al. (PUBMED link) Data modeled from Dan-NICAD I Observational Study; n=1,675 2 OUS Sites (PUBMED link)		
OBJECTIVE: Our objective was to assess the cost utility of the CADScor System for the diagnosis of CAD at an early stage in the diagnostic testing pathway in England.	**OUTCOMES:** Findings indicated that the introduction of the CADScor System resulted in per-patient overall cost savings of £131 over a 1-year time horizon. This equates to over £92.6 million cost savings per each annual cohort of patients who have CAD symptoms and need further assessment in England.	**CONCLUSION:** The CADScor System is a potentially cost-saving test for the diagnosis of CAD. When initiated before the use of non-invasive cardiac imaging tests such as computed tomography coronary angiography*, the test reduced costs to the healthcare service over various time horizons.

*Note: Computed tomography is an ACC/AHA guideline class I recommendation for intermediate pre-test probability stable chest pain patients <65 years of age suspected of significant CAD (Gulati M, Levy PD, Mukherjee D, et al. 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines [published correction appears in Circulation. 2021 Nov 30;144(22):e455]. Circulation. 2021;144(22):e368-e454. doi:10.1161/CIR.0000000000001029)