Cardiography as a novel non-invasive diagnostic tool for the detection of coronary artery disease at rest – a first prospective study of diagnostic accuracy

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INTRODUCTION

Coronary artery disease (CAD) is a leading cause of death and disability in Western Countries. Its initial manifestation can be a myocardial infarction or a sudden cardiac death. Therefore, screening of coronary ischemia at rest is a major task in the preclinical setting. Recent experience demonstrated that modified vector analysis possesses the potential to overcome the limitations of conventional diagnostic modalities in the screening of stable CAD. Cardisiography (CSG), a new, easy-to-perform, and examiner-independent screening approach, combines vectorcardiography (VCG) analysis with an intelligent supervised learning system.

OBJECTIVES

The aim of this study was to establish the diagnostic accuracy of CSG with coronary angiography as the reference standard in a prospective trial.

METHOD AND MATERIALS

In total, 209 patients, who were qualified for coronary angiography, were enrolled in this study between 03/2019 and 11/2019 (Sana-Heart Center Cottbus, Germany). 103 patients were excluded because of valvular heart disease (n=72) and previous cardiac surgery (n=31). Concluding, cardisiographic results were obtained from 106 patients. CSG recording can be achieved by applying five electrodes to the chest and was performed before coronary angiography. Subsequently, by an independent reader, cardisiographic results were blindly correlated to the angiographic findings, which were considered the gold standard in this diagnosis of CAD. The CSG approach applies a computer-based three-dimensional calculation of the excitation processes of the mammalian heart together with a machine learning model. Particularly, using VCG, the excitation process of the heart can be described as a three-dimensional signal. By calculating specific physical parameters from this signal and analyzing them with an ensemble of feedforward neural networks, a diagnosis was obtained. Individuals with 1, 2, or 3-vascular disease with a stenosis were defined as being affected (stenosis ≥50%, i.e. Cardisio Index >0), regardless of its location. Sensitivity and specificity results of Cardisiography are the primary outcomes of this study.

RESULTS

Median age of the cohort was 69.5 years (±3.6 years) and 40.5% of the patients were female. A 1, 2 or 3-vascular disease identified by coronary angiography was detected in 86 out of the 106 patients (81.1%). While myocardial ischemia was detected by conventional electrocardiography in only 12 out of 86 patients (13.6%), it was detected by CSG in 82 out of 86 patients (95.4%). In summary, based on this prospective data set, Cardisiography yielded a sensitivity of 95.4%,
specificity of 90%, positive predictive value of 97.6% and negative predictive value of 81.8% in the diagnosis of CAD.

CONCLUSION
Cardiography is a simple, precise and highly valid tool that could serve as a first line non-invasive diagnostic modality for the detection of stable coronary artery disease in the primary clinical setting. This study demonstrated its diagnostic reliability in a first, prospective cohort of 106 patients.