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Validation of the 5-lead 3D-electrocadiography, the Cardisiography, with myocardial SPECT in suspected and known CHD.

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Background

Computer-based processing, automated machine-learning using an extensive global clinical data bank information with AI-derived diagnosis can overcome previous hindrances to conventional vectorcardiography (VCG). VCG (3D-electrocardiography of the excited cardiac tissue) derived from 5 leads, including a dorsal electrode offers additional information with ensemble of artificial neural networks (ANN) over standard 12-lead electrocardiography (ECG) in the detection of cardiac ischaemia. The aim of this study was to validate VCG with ANN (Cardisiography, CSG) with the gold standard, myocardial perfusion gated SPECT (MPS), for diagnostic accuracy in coronary heart disease (CHD) in order to optimise the decision-making for coronary intervention.

Patients and Methods:

In this monocentric exploratory prospective study, all consecutive patients with suspected or known CHD in whom MPS was clinically indicated, were analysed with CSG prior to MPS with the predefined primary endpoint to test the cut-off value of 0.0 (CSG-P index, range -1.0 to +1.0) of the CSG AI-index for cardiac pathologies. Categorisation of cardiac ischaemia in MPS was performed semiautomatically with visual correction using 17 segment scoring for quantification of resting or stress-induced ischaemia (4 grades). MPS results were read by 2 independent experienced investigators and categorised dichotomously as normal or pathological. For the AI-index of CSG a total of 731 parameters, including QRS-t angle, superposition for each heartbeat as well as new in-house features, calculated in time and frequency domain, e.g. beat moments were analysed. Diagnostic accuracy of automated CSG-evaluation to detect cardiac ischaemia was analysed using the Chi^2 test.

Results:

From all 112 patients with the usual CVR-profile (m:w 61%:39%, aged 66 ±10 y), of these 76 with suspected (m:w 51%:49%, aged 64±9 y) and 36 patients with known CHD (m:w 81%:19%, aged 70±11 y), a strong trend towards accuracy of CSG related to pathological MPS was seen (Chi^2: 3.2, p=0.07) with sensitivity of 75% of CSG for a moderately or highly pathological MPS, specificity of 58% and a negative predictive value (NPV) of 97%.

In the subgroup of 76 patients with clinically suspected CHD, significant accuracy of CSG related to MPS was seen (Chi^2: 5.6, $p<0.05$) with sensitivity 83%, specificity 66%, and NPV 98%;

in the subgroup of known CHD, including patients for control of previous intervention (n=36), no significant accuracy was seen with sensitivity 50%, specificity 41%, NPV 93%. Compared to

pathological CSG, patients with normal CSG demonstrated significantly reduced (n=112, $p<0.05$) CHD diagnoses, as defined by MPS.

Conclusion:

In the preselected study group of patients with clinically suspected, or known CHD, CSG has the potential to identify those patients not requiring interventional procedures as detected by MPS, with a significant NPV of 96%. Thus, patients with normal CSG are significantly less likely to have a pathological MPS. Meticulous research is needed to differentiate different aspects of MPS (scars vs. stress-induced ischaemia), concomitant cardiac pathologies and subsequent need for revascularisation to explain the pathological findings in CSG in patients with pre-existing CHD. Future large-scale clinical trials will have to ascertain if MPS might be delayed or replaced in case of a negative CSG.