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

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Background and aim of the study

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
- dorsal electrode for additional information
- ensemble of artificial neural networks (ANN) over standard 12-lead electrocardiography (ECG) in the detection of cardiac ischaemia

Sensitivity and specificity of this tool has already been demonstrated compared to coronary angiography[1].

In this study we aimed to test diagnostic accuracy of cardisiography (CSG = ANN + 12-lead ECG) with myocardial perfusion gated SPECT (MPS) in coronary heart disease (CHD). Results may help to optimise the decision-making process for coronary interventions.

Methods

Inclusion criteria:
- clinical indication for MPS

Exclusion criteria:
- Structural heart failure, cardiomyopathy, myocarditis

Predefined primary endpoint: 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

Design:
- monocentric, exploratory, prospective study
- consecutive patients with suspected or known CHD
- Complete data sets from all patients from 21.4.2021 to 20.10.2021
- CSG prior to MPS
- Categorisation of cardiac ischaemia in MPS semiautomatically + visual correction
- 17 segment scoring for quantification of resting or experienced stress-induced ischaemia (4 grades: normal, mild, moderate or severely pathologic). 2 independent investigators
- Categorisation: normal or pathological

- Grouping of patients acc. to
  1. “CHD requiring intervention”
  2. “no CHD or documented CHD, no intervention”
  3. “CHD, control after previous intervention and suspected further relevant stenosis”.

Signal processing, neuronal networks

Signal processing	Import data Sanz transformation Filtering (high-pass filter, bandstop filter, Savitzky-Golay smoothing, cosine transformation) Data quality check Heartbeat detection (annotation)
Postprocessing	Position-type correction Breathing correction Another heartbeat detection (annotation) for parameter calculation
Training of neural networks	Feature Selection from 731 parameters (Maximum relevance minimum redundancy method) Data sources and population (Generative adversarial networks) Model development / architecture (ensemble of 25 neural networks) Training (five-fold nested cross validation) Performance evaluation on test data

Patients

Demographic Data

	Total	CHD, intervention	susp. CHD no intervention
n	112	36	76
Gender m:f	68:44	29:7	39:37
Age [years]	66.3 [40.2-87.9]	70.9 [40.2 – 87.9]	64.2 [41.5 – 86.3]
Metabolic syndrome (%)	26 (23.2%)	17 (47.2%)	9 (11.8%)
No. of CVRF[2]	3.6 [0 - 7]	4.2 [2 - 7]	3.3 [0 - 6]
Arrhytmia, PM and BBB	18 (16.1%)	5 (13.9%)	13 (17.1%)
Consecutive PCI	24 (21.4%)	24 (66.7%)	N/A
Consecutive CABG	3 (2.7%)	3 (8.3%)	N/A
Not specified	2 (1.8%)	9 (5.6%)	N/A

Results

Diagnostics for detection of cardiac ischaemias

	Total	CHD, intervention	susp. CHD no intervention
n	112	36	76
Perfusion defect in MPS	27 (24.1 %)	14 (51.9%)**	13 (17.1%)
Path. ECG (reconstructed)	52 (46.4%)	20 (55.6%)	32 (42.1%)
CSG AI-index (> cut-off)	50 (44.7%)	21 (58.3%)	29 (38.2%)

*** p < 0.001*

Diagnostic performance of CSG compared to MPS and coronary interventions

MPS (all)

		0 bis 1	2 bis 3	Predictive value
CSG-AI-Index	**> cut-off**	44	6	positive: 0.12
	< cut-off	60	2	negative: 0.97
		Sensitivity: 0.75	Specificity: 0.58	

MPS (susp. CHD, no intervention)

		0 to 1	2 to 3	Predictive value
CSG-AI-Index	**> cut-off**	24	5	positive: 0.17
	< cut-off	46	1	negative: 0.98
		Sensitivity: 0.83	Specificity: 0.66	

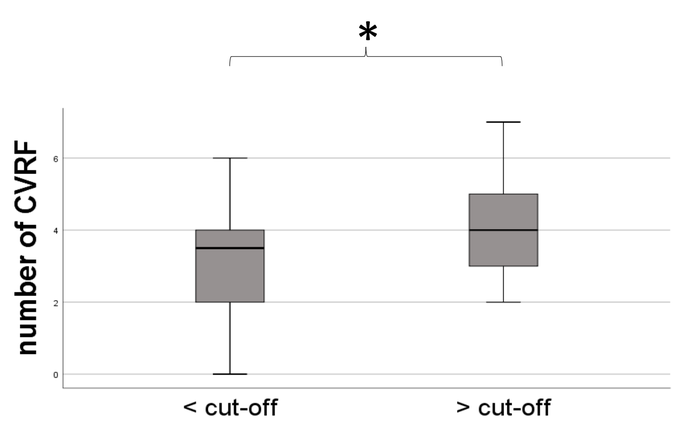
Diagnostic performance of CSG compared to consequent coronary intervention (PCI/stent or CABG)

CSG

	CHD, intervention	Susp. CHD. no intervention	Predictive value
pathological	13	34	positive: 0.28
normal	10	50	negative: 0.83
	Sensitivity: 0.57	Specificity: 0.60	

CSG differentiates between suspected CHD with or without consequent PCI or CABG ($Chi^2 = 4.02$, $p<0.05$)

CSG AI-Index differentiates between high and low CVRF-profiles



Cardisio Procedure

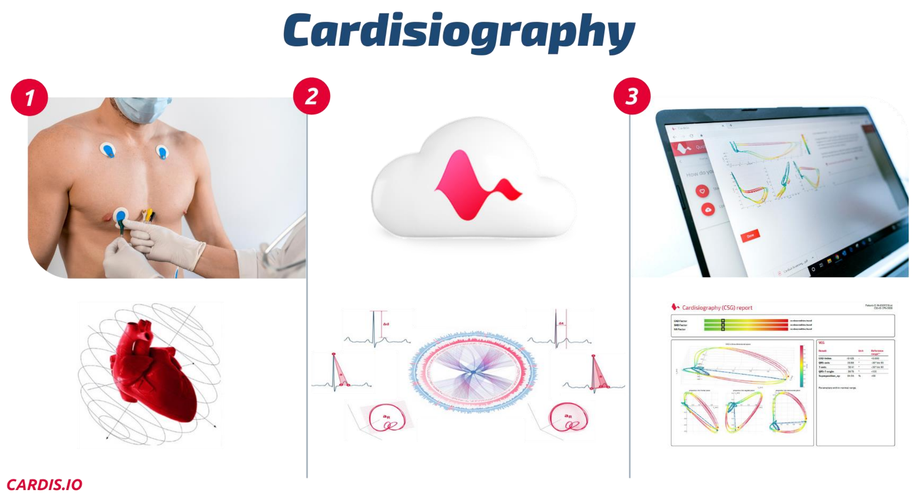


Figure 2. Cardisiography.

(1) Five electrodes are attached to the body for signal recording. (2) The collected data is transmitted to the Cardisio web service and processed using an AI algorithm. (3) After a few minutes, the result is available in the form of a report.

Conclusion

- In patients with suspected or known CHD, CSG has the potential to clinically identify those patients not requiring interventional procedures as detected by MPS, with a significant NPV of 83% comparable to MPS.
- CSG differentiates between higher or lower individual cardiovascular risk profile.
- Strengths of CSG: non-invasive, high negative predictive value compared to MPS, simple application, no radiation, time and cost efficiency
- Differentiation between reversible and fixed ischaemia as next step in large-scale clinical trials to ascertain if MPS might be delayed or replaced in case of negative CSG

References
1. Braun, J Electrocardiol, 2020; 59:100-105
2. Schmidt-Lucke, Circulation; 2005;111(22):2981-2987

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