5-lead 3D-vectorcardiography differentiates between high and low cardiovascular risk profiles in patients with suspected or known coronary heart disease

Caroline Schmidt-Lucke[1], Simon Kohl[1], Annett Kammeier[2], Hermann Knobl[2], Wolfgang Burchert[2], J. A. Schmidt-Lucke[3], Betty Lischke[1], Oliver Lindner[2]

[1]MEDIACC, Medico-Academic Consultings, Berlin; [2]Institute of Radiology, Nuclear Medicine and Molecular Imaging, HDZ-NRW; [3]Internal medicine practice, Berlin

Purpose of the study

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-Validate Artificial Intelligence-based 5-lead 3D-vectorcardiography (5L3DVCG-AI)
-use additional information of 5L3DVCG-AI over standard 12-lead electrocardiography (ECG) in the detection of coronary vascular disease (CVD) at rest
-basis for investigation of 5L3DVCG-AI as a new screening tool for CVD in ongoing prospective multinational trials

Hypothesis
Patients with mild to overt signs and / or history of CVD, as diagnosed according to current guidelines and SPECT can be detected with 5L3DVCG-AI - with a special focus on female patients.

Methods

Inclusion criteria: Clinical indication for further diagnostics to confirm or exclude CVD in two centres

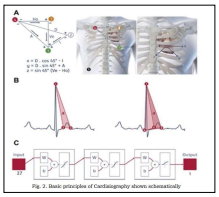
Predefined primary endpoint: Suitability of 5L3DVCG-AI in predicting clinical relevant CVD

Design: multicentric, retrospective design with prespecified primary endpoint

- Intra-day comparison of heart axis of 12-lead ECG (Top D/BTMedset) and 5L3DVCG-AI -derived ECG (Spearman correlation coefficient)
- 5L3DVCG-AI with calculation of CSG-Index (including 731 parameters, e.g., QRS-T angle and in-house features calculated in time and frequency domains, such as beat moments)
- Patient classification as high or low CVD risk, based on CSG-Index [-1 to 1] (CSG-Index cut-off: -0.27)
- Quantification of CVRF-Score as number of risk factors according to mod. PROCAM-Score [1, 2]
- Confirmation of CVD was performed according to the practitioners' discretion blinded to the CSG-Index and ischaemia by SPECT
- Definition of clinical status of CVD: control (exclusion of any signs or symptoms of CVD), minimal subclinical findings of CVD, overt clinical signs and / or symptoms of CVD

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

References: [1] Schmidt-Lucke, Circulation, 2005, [2] Assmann, Circulation, 2001



(A) Positioning of the electrodes in a geometrically predefined position. (B) Extract of characteristic parameters recorded by 5L3DVCG-AI. (C) Neural network architecture: Ensemble of five feedforward neural networks.

Results

Demographic Data

Patient characteristic	Total population	Female subpopulation
n	407	149
Gender [m:f]	258:149	-
Age [years]	63 ± 14	62 ± 14
Control	215 (60%)	106 (71%)
Mild:overt CVD	83:58 (23%:16%)	40:3 (27%:2%)
No. of CVRF [1,2] [CVRF-Score; 0 - 7]	3.1 ± 1.4	2.6 ± 1.4
Smoking	32%	26%
Diabetes	19%	16%
Hypertension	65%	62%
HLP	55%	52%
Family history	21%	23%

Inclusion of 468 patients, 407 patients with complete data for analyses. 16% had arrhythmias or conduction disturbances (AF, PM, BBB), 15% had consecutive PCI or CABG

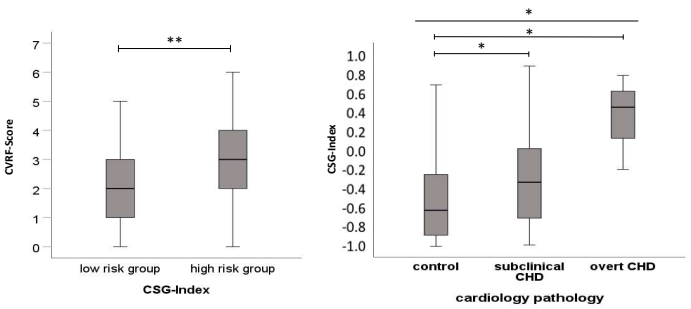
Intra-day comparison of heart axis in supine position (12-lead ECG) and sitting position (5L3DVCG-AI)

5L3DVCG-AI (sitting)		ECG (supine)							
		LAD (< -30°)	LT (-30° - 30°)	IT (30° – 60°)	ST (60° - 90°)	SagT	RT (90° -120°)	RAD (>120°)	Σ
	LAD	2	11	4	5	5	1		28
	LT	2	40	4	1				47
	IT	1	32	44	17	3	1		98
	ST	1	14	14	23	1		1	54
	SagT								
	RT		3	1	1		1		6
	RAD								
	Σ	6	100	67	47	9	3	1	233

LAD: left axis deviation, RAD: right axis deviation

Correlation (Spearman) of heart axis ECG vs. 5L3DVCG-AI: r=0.53, p<0.001

Correlation of CVRF-Score, CSG-Index and clinical status of CVD in the female subpopulation



Interdependency of CVRF-score, CSG-Index and clinical status of CVD

variable	r^2	significance
CSG-Index vs. CVRF-Score	0.26	< 0.001
CSG-Index vs. clinical status CHD	0.71	< 0.001
CVRF-Score vs. clinical status CHD	0.18	< 0.001

CSG-Index correlates stronger with cardiovascular risk (r^2=0.71, p<0.001) compared to CVRF-Score (r^2=0.18, p<0.001).

Variables influencing clinical status of CVD

variable	β	T	significance
CSG-Index	0.24	3.34	0.001
CVRF-Score	0.19	2.57	0.011

CSG-Index is better predictor for cardiovascular risk than CVRF-Score.
CSG-Index differentiated between suspected CVD with or without consequent PCI or CABG (Chi^2 = 4.02, p<0.05).

Conclusion

- Data extend the previous findings of 5L3DVCG-AI identifying CVD patients with cardiac ischaemia
- Now differentiating healthy controls from CVD and those with higher risk for CVD

- Confirmation of results in female population
- Validation of ECG-reconstruction via heart axis

- CSG-Index is superior to CVRF-Score in identification of CVD

The ongoing prospective large-scale performance clinical trials will have to confirm these preliminary data to verify the diagnostic accuracy.

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