Sensitivity and Specificity of the Artificial Intelligence-Based 5-Lead 3D Vectorcardiography in Patients With Suspected or Confirmed Coronary Heart Disease

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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

We tested the hypothesis of 5L3DVCG-AI being able to detect patients with mild to overt signs and / or history of CVD, as diagnosed according to current guidelines.

Methods

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

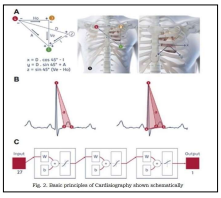
Predefined primary endpoint: Suitability of 5L3DVCG-AI in predicting clinical relevant CVD

Design: multicentric, retrospective design with prespecified primary endpoint

- Comparison of 12-lead ECG (Top D/BTMedset) and 5L3DVCG-AI-derived ECG (Pearsons correlation coefficient, Bland-Altman-Analyses)
- 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 modified PROCAM-Score [1, 2]
- Confirmation of CVD was performed according to the practitioners' discretion blinded to the CSG-Index
- 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
- Follow-up period: 16.2 ± 7.5 months

(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	ECG validation population	CVD population
n	247	407 *
Gender [m:f]	152:95 [62:38%]	258:149 [63:37%]
Age [years]	56 ± 17	63 ± 14
Control	-	215 (60%)
Mild:overt CVD	-	83:58 (23%:16%)
No. of CVRF [1,2] [CVRF-Score; 0 - 7]	2.2 ± 1.3	3.1 ± 1.4
Smoking	17%	32%
Diabetes	9%	19%
Hypertension	41%	65%
HLP	48%	55%
Family history	2%	21%

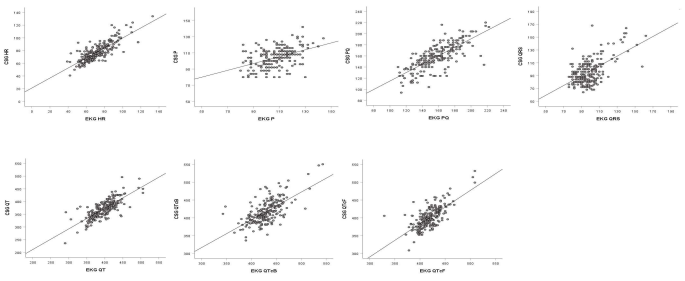
* Inclusion of 468 patients, 407 patients with complete data for analyses. 16% had arrhythmias or conduction disturbances (AF, PM, BBB), 15% had consecutive PCI or CABG

Intervals of 12-lead ECG (II, V2) vs. 5L3DVCG-AI-derived ECG

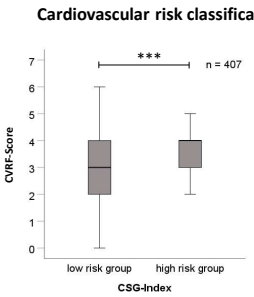
	n	ECG [mean ± SD]	5L3DVCG-AI [mean ± SD]	Pearsons r	Bias (95% LoA)
HF	209	72 ± 15	78 ± 15	0.80 ***	-5.7 (-23.9 – 12.5)
P	202	108 ± 13	105 ± 12	0.45 ***	3.2 (-22.4 – 28.8)
PQ	211	158 ± 24	159 ± 24	0.75 ***	-1.0 (-33.3 – 31.3)
QRS	226	98 ± 14	95 ± 19	0.59 ***	2.2 (-28.4 – 32.8)
QT	224	398 ± 36	372 ± 36	0.76 ***	25.9 (-20.9 – 72.6)
QTcB	209	431 ± 28	418 ± 33	0.65 ***	12.5 (-38.6 – 63.5)
QTcF	209	419 ± 23	402 ± 30	0.70 ***	17.8 (-24.4 – 60.0)

Intervals derived from II, V2 in ECG and 5L3DVCG-AI (same day), *** p<0.001,
LoA: limits of agreement of Bland-Altman-Analysis

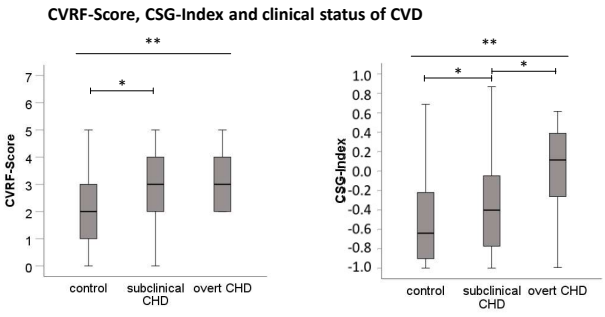
Comparison of intervals of 12-lead ECG with 5L3DVCG-AI-derived ECG



Correlation of CVRF-Score, CSG-Index and clinical status of CVD



62% were classified as low while 38% were classified as high risk for CVD by the CSG-Index.
CVRF-Score was significantly higher in patients with high risk for CVD.



Strong correlation of CVRF-Score, CSG-Index and clinical status of CVD (p=0.016). ROC curve showed correlation between CSG-Index and presence of CVD (R^2=0.72, p<0.05).

Conclusion

These data extend the previous findings of 5L3DVCG-AI identifying CVD patients with cardiac ischaemia from those without to now differentiating healthy controls from CVD and those with higher risk for CVD. 5L3DVCG-AI may thus be a further scalable screening method to identify patients at risk for CVD in need for risk modification or further diagnostic procedures.

5L3DVCG-AI-derived ECG showed high correlation and low bias compared to standard 12-lead ECG. The ongoing prospective large-scale performance clinical trials will have to confirm these preliminary data to verify the diagnostic accuracy.

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