Validation of the Artificial Intelligence-Based 5-Lead 3D Vectorcardiography in Comparison to the 12-Lead ECG in a Mixed Population

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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 cardiac pathology at rest
- Basis for investigation of 5L3DVCG-AI as a new screening tool for cardiac pathology in ongoing prospective multinational trials

Hypothesis
Variables from the reconstructed "12-lead ECG" (5L12L-ECG, modified Dower transformation) correspond with the standard 12-lead ECG (ECG).

Methods

Design:
- Monocentric, retrospective design
- Comparison of parameters and heart axis of 12-lead ECG (Top D/BTMedset) and 5L3DVCG-AI-derived ECG (Pearson correlation coefficients)
- 5L3DVCG-AI-Reconstruction of "12-lead ECG" (5L12L-ECG, modified Dower transformation)
- Use of II and V2 in both methods
Predefined primary endpoint:
- Suitability of 5L3DVCG-AI in comparison with traditional ECG
Inclusion criteria:
- Patients ≥ 18 y
- Clinical indication for further diagnostics to confirm or exclude cardiac pathology
- ECG and CSG performed within <28 days
- Absence of atrial fibrillation (AF)
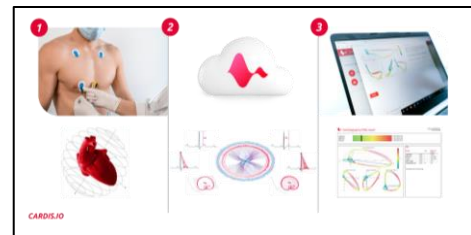
(1) Five electrodes are attached to the body for signal recording. (2) The collected data is transmitted to the manufacturer's web service and processed using an AI algorithm. (3) After a few minutes, the result is available in the form of a report.
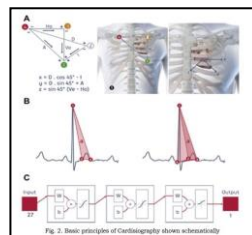
(A) Positioning of the electrodes in a geometrically predefined position. (B) Extract of characteristic parameters recorded by 5L3DVCG-AI. (C) Neural network architecture: Ensemble of five feedforward neural networks.

Definition of 5L3DVCG-AI-Outcomes

| Factors	Components	Outputs
P-Factor indicates reduced perfusion of heart at rest, caused, e.g., by CAD or microvascular dysfunction.	Combination of trained CSG-Index (AI) and relevant VCG-parameters	CSG-Index (AI) & VCG-parameters
S-Factor indicates structural changes in myocardium, e.g. enlargement of heart, thickening of myocardium or vitia, myo- and pericarditis.	Combination of trained CSG-Index (AI) and relevant ECG- and VCG-norm deviations, NOT related to ischaemia	CSG-Index (AI) ECG- & VCG-norm deviation
A-Factor indicates presence of arrhythmia and other abnormalities, e.g. extrasystoles, atrial fibrillation, atrial flutter, conduction disturbances, tachycardia, bradycardia.	Combination of trained AI-based algorithm and relevant ECG-parameters	ECG-parameters

Results

Patient Characteristics

Patient characteristic	Total population
n	244
Gender [m:f]	147:97
Age [years]	55.3±16.8
Body Mass Index [kg m^{-2}]	26.1±5.4
Ethnicity	A:4%,AF:1%,C:93%,T:2%*
No. of CVRF [3] [CVRF-Score; 0 - 7]	2±1
Smoking	16.4%
Diabetes	8.2%
Hypertension	38.1%
HLP	50.8%
Family history	2.5%
Cardiac pathology (none / mild / severe)	72%/ 22% / 6%

*A=Arabic, AF=African, C=Caucasian, T=Turkish

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

	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)

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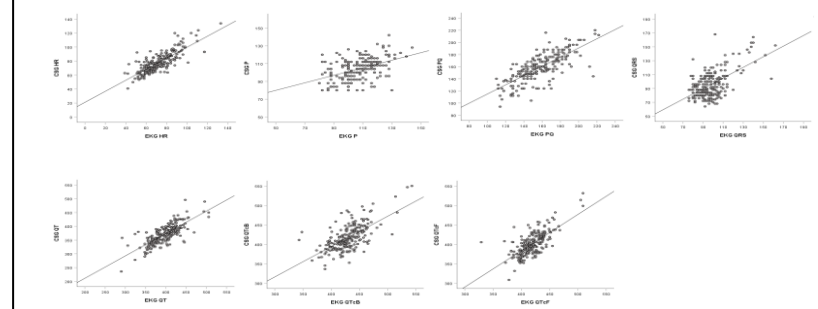
Intra-day comparison of heart axis in supine position (12-lead ECG) and sitting position (5L3DVCG-AI)

		ECG (supine)				
		LAD (< -30°)	LT (-30° - 30°)	IT + ST (30° – 90°)	RT + RAD (90° - >120°)	Σ
5L3DVCG-AI (sitting)	LAD	10	12	1	1	24
	LT	2	39	4	0	45
	IT + ST	1	40	97	2	140
	RT + RAD	0	4	5	0	9
	Σ	13	95	107	3	218

Spearman correlation: 0.553; p<0.001
Deviations between methods possibly attributable from difference in body position (supine vs. sitting).

Conclusions

- 5L3DVCG-AI-derived ECG showed high correlation and low bias compared to standard 12-lead ECG.
- Easy to use 5-lead ECG may replace 12-lead ECG without major training or expertise.
- Shorter intervals to be considered when interpreting 5L12L-ECG and "normal" values in the ongoing prospective large-scale performance clinical trials
- 5L3DVCG-AI identifies persons at risk for CVD (s. abstract 15181, PSu3119)

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