Comparative study of the CardioSecur pro ECG system with the EASI Philips M2601B

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Aim of the Study

A comparative study was conducted to validate the ECG measurements of CardioSecur. CardioSecur is a tablet-based ECG system using 4 electrodes to derive a 22-channel ECG (standard 12-leads + V7-V9 and VR1-VR9). The technology of CardioSecur is based on the calculation of 12 leads gained from 4 electrodes and these are comparable to the standard 12 lead ECG.

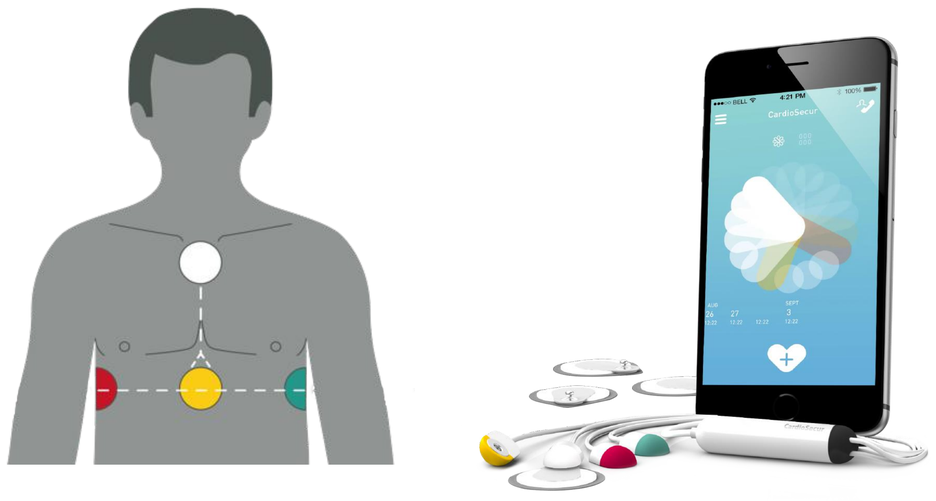

Figure 1: Electrode Placement and technical components of CardioSecur

Methods

To assess both the technical and the medical comparability of the systems, the setup was divided into two procedures, the first test covering the medical diagnostic accuracy of the two systems, the second test covering the technical comparability of the ECG signal, generated with the reduced lead system. In the first test ECG measurements were taken from 41 individuals with both systems. A clinical diagnosis was made on these ECGs by two independent cardiologists and the orientation of the waves P, R, T and S were evaluated and compared. To assess the technical waveform of the two systems, ECGs were simulated with an ECG simulator to ensure identical electrical input on both systems. These ECGs were simulated at frequencies between 30 and 180bpm. Additionally, pathological ECG patterns were simulated and recorded with the systems. These waveforms were compared with respect to morphology and height of the electrical signal in the standard 12 leads of the two systems.

Results

The clinical diagnosis for 41 measured patients was identical in the ECGs measured with both CardioSecur and Philips M2601B. These diagnoses included a variety of clinical patterns including rhythm disorders, acute MI and old MI. A paerson correlation coefficient was calculated for CardioSecur and Philips for the classical 12 leads and was high for all measured parameters (see table 1). The additional 10 leads of CardioSecur were not analyzed as part of the study as the Philips device does not offer this option.

The second test, covering a technical analysis including waveforms and peak heights of simulated ECGs, revealed differences in the heights of the R- and S-wave. CardioSecur showed an absolute R peak 10% higher than the Philips device (see figure 2). This difference can be explained by the use of different filter settings in the devices. The Philips M2601B clearly states that the recorded ECG may not be used for ST-segment evaluation. CardioSecur uses a filter setting compliant with the regulatory standards to allow ST-segment evaluation. Consequently, a difference in absolute peak height can be also seen in figure 3. Morphologically, all ECGs (patient and simulated) showed identical orientation of the measured parameters.

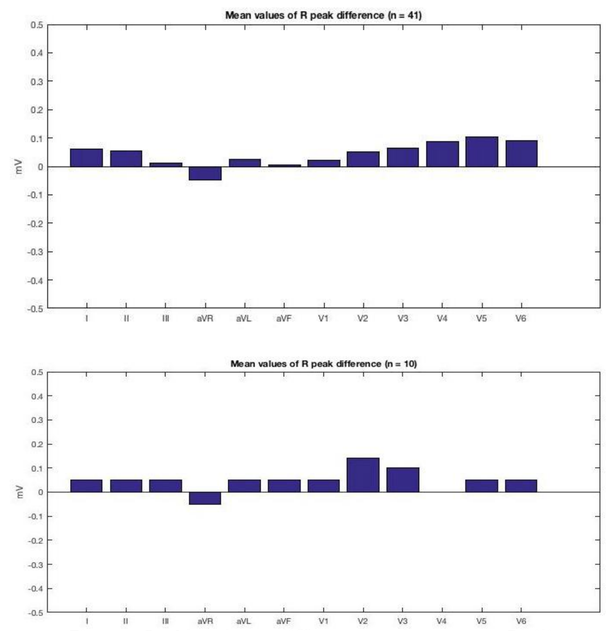

Figure 2: Absolute differences between Philips and CardioSecur in R-Peak amplitude.

Leads	R-peak	S-peak	ST-segment
I	0,99	0,99	0,94
II	0,99	0,98	0,98
III	0,99	0,97	0,98
aVR	0,98	0,95	0,98
aVL	0,98	0,84	0,98
aVF	0,99	0,97	0,94
V1	0,99	0,95	0,96
V2	0,96	0,98	0,94
V3	0,94	0,97	0,97
V4	0,97	0,99	0,96
V5	0,98	0,99	0,94
V6	0,98	0,98	0,95

Table 1: Correlation coefficients for parameters of CardioSecur and Philips over 41 patients.

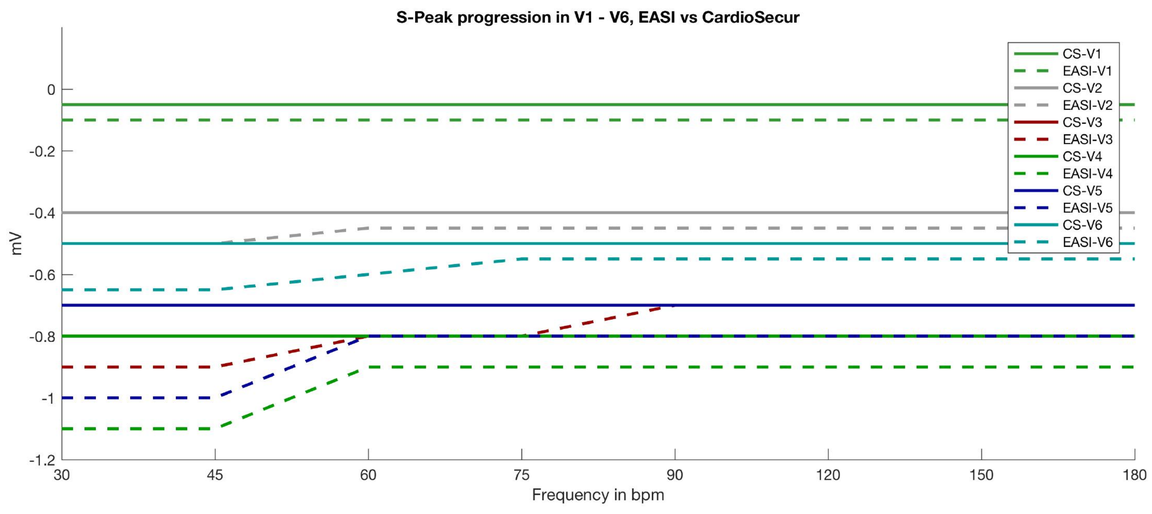

Figure 3: Absolute S-peak amplituds for CardioSecur and Philips over diffferent frequencies for V1 to V6.

Conclusion

This study has shown that the clinical information in the CardioSecur device is identical to the information of ECGs of the Philips M2601B device. A small difference in peak heights of the raw signal arises from the different filter systems.
Morphologically, the orientation of all recorded ECGs and the R-wave progression were identical in all measured ECGs. Therefore the diagnostic capabilities of the CardioSecur device can be seen as fully comparable to those of the Philips ECG. The possible benefits of an additional 10 leads in the CardioSecur device will be the subject of future studies.

References

- Dower, G.E., The ECGD: a derivation of the ECG from VCG leads. Journal of Electrocardiology, 1984. 17(2): p. 189-91.
- Horacek, B.M., et al. Diagnostic accuracy of derived compared to standard 12-lead electrocardiograms. in International Society for Computerized Cardiology. 2000. Yosemite, California: Journal of Electrocardiology.
- ESC Guidelines on ST segment elevation acute myocardial infarctionEuropean Heart Journal (2012) 33, 2569–2619
- Comparison of standard and derived 12-lead electrocardiograms registrated by a simplified 3-lead setting with four electrodes for diagnosis of coronary angioplasty-induced myocardial ischemia. Bonaventura K, Wellnhofer E, Fleck E. European Cardiology. 2012 Jul;8(3):179.

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