Risk Monitoring Using Implant Technology for ECG Recording and Computer-Assisted Signal Processing

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Summary

Early detection of developing risk situations in cardiac patients utilizing computer-assisted signal processing of intramyocardial electrograms. Acquisition of high-resolution electrograms from patients after heart transplantation, cardiac infarction or with different types of cardiomyopathies. Intramyocardial electrograms were obtained either from the paced or the spontaneously beating heart using fractally coated electrodes and pacemakers with broad-bandwidth telemetry, advanced methods for signal processing and extraction of relevant risk parameters. With retrospective analysis of intramyocardial electrograms from heart-transplant patients a parameter has been evaluated that renders possible reliable risk assessment if the examination period does not exceed 30 days. In another retrospective analysis ECG recordings of patients after cardiac infarction have been analysed. Another parameter has been identified that may be used for monitoring the risk for these patients. Additionally it is shown in patients with cardiomyopathies that a parameter obtained from intramyocardial electrograms correlates significantly with hemodynamically relevant parameters and thus allows assessment of cardiac performance. Continuous monitoring of patients with certain cardiac risks is possible by ECG recording and computer-assisted signal processing. The challenge is to develop implant devices with sufficient power to render possible the application of intelligent methods for parameter extraction. Monitoring may be accomplished by using event-triggered alarm (watch-dog function) or periodical transmission. Employing already available modern telecommunication technology for world-wide data exchange, this approach may be utilized for permanent cardiac home care telemonitoring and, hence, increased patient safety.

Key Words

Risk monitoring, implant devices, computer-assisted signal processing, intelligent instrumentation, cardiac home care telemonitoring

Introduction

Since its first acquisition at the end of the 19th century, the ECG has become one of the most relevant sources for diagnostic information in clinical routine. Computer-assisted signal processing has found broad application not only in hospitals, but also in the offices of general practitioners. Portable devices for ECG recording have gained great importance for long-term patient monitoring under daily routine conditions, however suffer by different shortcomings:

- Their application is limited to 24 hours or maximum some days, e.g. ambulatory Holter monitoring;
- The results are not obtained by on-line signal processing and, hence, do not immediately indicate the risk situation.

There is now increasing evidence that intelligent instrumentation, primarily based on advanced implant technology, in combination with modern telecommuni-

P < 0.02	Alive	Exit	Sum
VER Tslew/c_v > 26 mV	12	3	15
VER Tslew/c_v ≤ 26 mV	2	5	7
Sum	14	8	22

SENS	63 %
SPEC	86 %
NPV	80 %
PPV	71 %
DQI	73 %

a

P < 0.002	Alive	Exit	Sum
VER Tslew/c_v > 26 mV	12	0	12
VER Tslew/c_v ≤ 26 mV	2	4	6
Sum	14	4	18

SENS	100 %
SPEC	86 %
NPV	100 %
PPV	67 %
DQI	93 %

b

Table 1. The upper part shows a comparison of all alive and all dead patients independent of the time of the last examination. The lower part shows a comparison for all alive and only for those dead patient for which the last examination has been made not more than 30 days before death. SENS = sensitivity; SPEC = specificity; NPV = negative predictive value; PPV = positive predictive value; DQI = diagnostic quality index.

cation technology offers the chance for permanent monitoring of patients with certain cardiac risks. This approach requires the extraction of parameters that are definite indicators for the augmentation of the risk level. It has been shown in the CHARM study that processing the intramyocardial electrograms from the spontaneously beating or the paced heart supplies relevant information on heart transplant rejection that cannot be obtained from extracorporeal ECG [1]. It has additionally been demonstrated that hemodynamic assessment can be achieved by evaluation of intramyocardial electrograms [2].

Materials and Methods

In this study, ECGs have been evaluated retrospectively from different groups of patients. In a first group of heart transplant patients, 1 minute-sequences of Ventricular Evoked Responses (VER) have been acquired with a fractally coated electrode in epiymocardial position at the right ventricle. These signals have been transmitted to an extracorporeal data acquisition station employing a pacemaker equipped with broad-bandwidth telemetry. Signal processing consists of beat detection, beat classification, averaging, and parameter extraction. The most significant parameter has been found to be represented in the negative slope during the repolarization phase. In a second group of patients after heart infarction, 24-hour ECG sequences have been processed that have been acquired by extracorporeal recording. Premature beats with myocardial origin have been detected with tailored software. Intervals between two premature beats have been considered if the duration has been smaller than a pre-determined threshold. In a third group of patients with cardiomyopathies, some hemodynamically relevant parameters determined by echocardiography have been compared with parameters obtained from VER

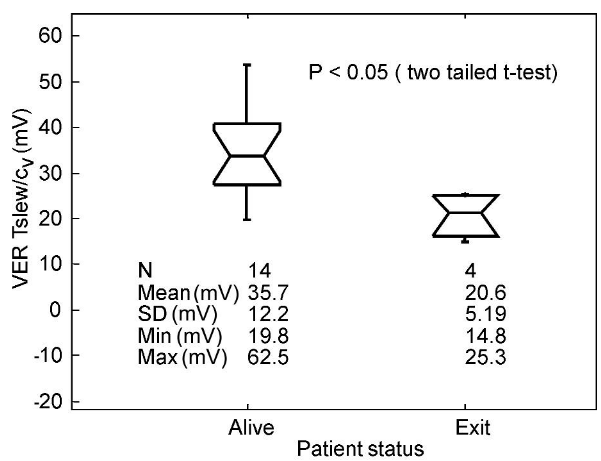

Figure 1. Comparison by t-test of all alive and those dead patients for which the last examination has been made not more than 30 days before death.

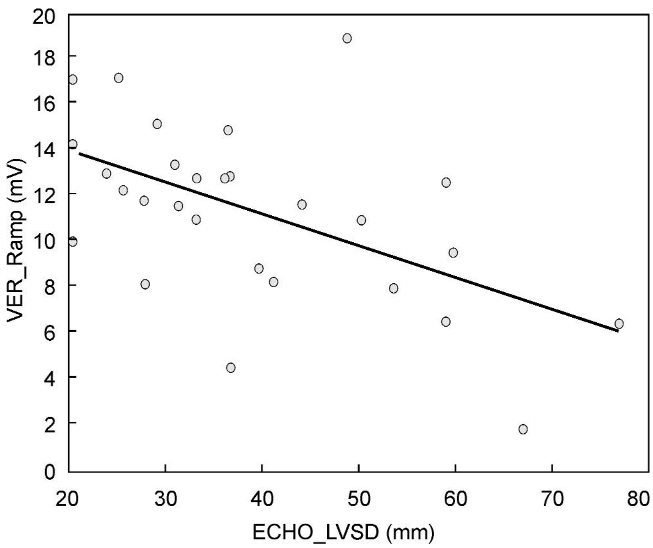

Figure 2. Correlation between the left-ventricular endsystolic diameter (LVSD) determined by echocardiography and the parameter VER_Ramp that is obtained from the intramyocardial electrograms VER for N = 29 patients.
VER_Ramp (mV) = 16.84 – 0.14 LVSD (mm); r = – 0.54; P > 0.005.

processing, i.e. beat detection, beat classification, averaging, and parameter extraction. In this case a parameter has been identified to possess the highest significance that is extracted from the early or depolarization phase of the intramyocardial electrogram.

Results

Table 1 shows the four-fold table for the first group of 22 patients of which eight have died and 14 have been still alive at the date of study end. The risk parameter is called VER Tslew/cV with the value of 26 for the critical threshold. In Table 1a all patients are considered. The threshold parameter can identify high risk patients with sufficient significance, a sensitivity of 63 %, a specifity of 86 %, and a diagnostic quality index of 73 %. If however only those dead patients are considered who had an examination in the last 30 days before death, the results are improved considerably. This is shown in Table 1b, where all patients that have died within 30 days after examination have been identified by a value below 26 for the risk parameter. The sensitivity has increased to 100 %, the specificity to 86 %, and the diagnostic quality index to 93 %. These results are illustrated in the box-plot presentation of Figure 1 where the two subgroups have been compared by the t-test. Table 2 shows the four-fold table for the second group of 95 patients with 90 as the value for the risk parameter. With that threshold, only three patients that later on have died would not have been identified. The sensitivity is 79 %, the specifity 75 % , and the diagnostic quality index 77 %. Figure 2 illustrates for the patients with cardiomyopathies the correlation between the left-ventricular endsystolic diameter (LVSD) determined by echocardiography and another parameter obtained from VER evaluation. The significance is with $P < 0.005$ very high.

In Figure 3 the patients are subdivided into two subgroups in accordance with their NYHA classification. In Figure 3a the two groups are compared with regard to their parameter calculated from the VERs, in Figure 3b the same comparison is made based on the echocardiographically determined LVSD. It is obvious that both parameters represent the same clinically relevant information on the hemodynamic performance of the heart.

Conclusions

The results obtained from different studies convincingly show that computer-assisted ECG processing renders possible the extraction of parameters that are

P < 0.002	Alive	Exit	Sum
Par ≤ 90	61	3	64
Par > 90	20	11	31
Sum	81	14	95

SENS	79 %
SPECT	75 %
NPV	95 %
PPV	35 %
DQI	77 %
PREV	15 %

Table 2. Comparison of all alive and all dead patients regarding a value of 90 for the risk parameter. PAR = risk parameter; SENS = sensitivity; SPEC = specificity; NPV = negative predictive value; PPV = positive predictive value; DQI = diagnostic quality index.

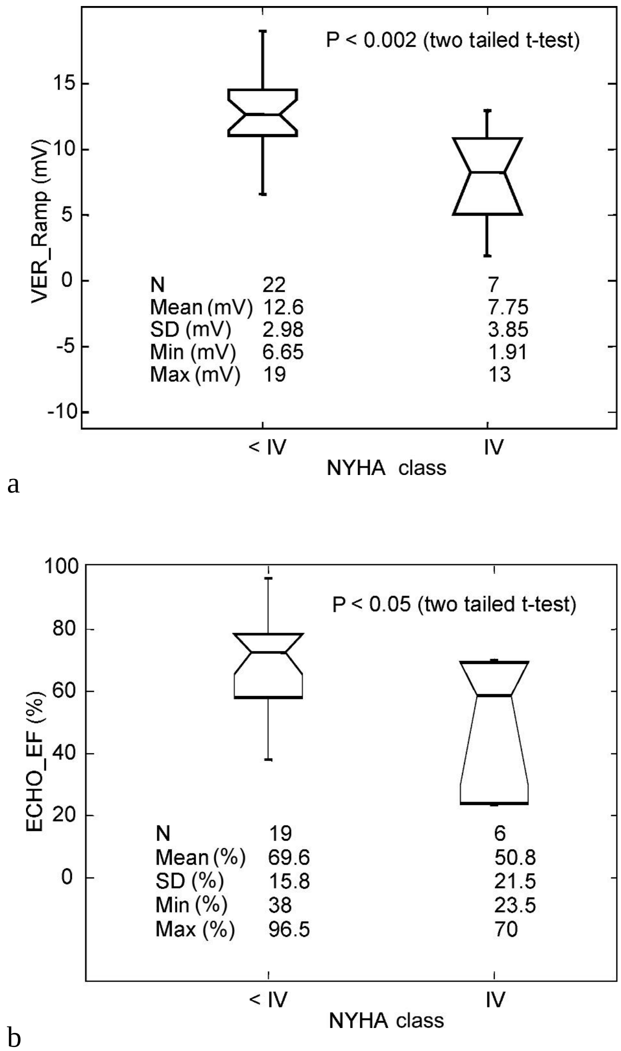

Figure 3. Comparison by t-test for the parameter VERRamp obtained from the intramyocardial electrograms VER in relation to the NYHA classification a) and for the ejaction fraction ECHO_EF obtained by echocardiography in relation to the NYHA classification b).

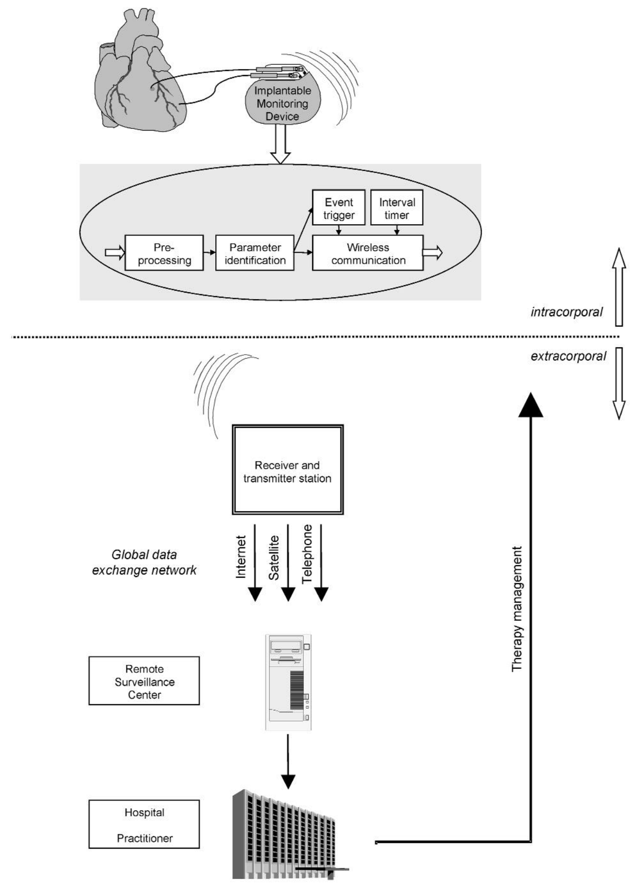

Figure 4. Schematic diagram of a global telecommunication-based system for cardiac home telemonitoring

related with certain risk situations. The challenge is to develop intelligent implant devices with sufficient power for long-term and continuous risk monitoring. These monitoring devices can be combined with modern telecommunication technology. As shown in Figure 4. Signal processing in the implant will perform preprocessing of the intramyocardial electrograms and extraction of the respective risk parameter. Transmission to the extracorporeal receiver and transmitter station can either be started when a certain risk level is reached or by an internal clock. The receiver and transmitter station is functioning is relay station and will transfer the information via any available global data exchange network to specialized surveillance center where all previous of this patient are stored and can be used to create a report that will be send to the hospital or a general practitioner. The hospital and the general practitioner are responsible to take the necessary measures for appropriate therapy management. This approach may render possible cardiac home care telemonitoring surveillance and thus provide a high level of safety for the patients.

References

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