Evaluation of an Advanced Cardiac Telemonitoring System for Multicenter Studies Based on Data Transmission via Internet

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Summary

Modern telecommunication technology including mobile telephone networks (e.g. GSM technology), television cable networks, worldwide networks for data exchange (e.g. Internet), and radio transmission via satellites provides new platforms for the advancement of telemedicine applications. In this study, two joint applications have been assessed: (1) the suitability of the Internet for transmission of ECGs representing the signal morphology with diagnostic quality, and (2) the employment of specialized centers for the automatized and computerized evaluation of ECGs as cooperational partner in the framework of multicentric clinical studies. Although some problems cannot finally answered, e.g. national regulations for medical data protection and procedures for cost reimbursement by third party payers, the results of the studies are convincingly positive. No serious problems have been identified, neither with data transmission nor with access to the password secured account for each hospital. The unlimited availability of the evaluation center for 24hrs each day offers hospitals a high degree of freedom to organize their respective examination program. These results enhance the utilization of modern telecommunication technology for worldwide cardiac telemonitoring and multicentric studies.

Key Words

Cardiac telemonitoring, telecommunication technology, multicentric studies, computer-assisted automatized ECG evaluation

Introduction

The idea of biotelemetry has fascinated medical doctors and engineers from the beginning of that century. Signal transmission has been realized in different forms (e.g. wireless, ultrasound and infrared transmisson), telephone transmisson, and storage telemetry. Different modes of analog and digital modulation have been used. The spectrum of application has comprised nearly every medical discipline. However, although biotelemetry had always been related with high expectations, it has never found broad application in clinical routine. Some few exceptions have been bidirectional pacemaker telemetry and monitoring of patients in hospitals. Its most relevant shortcomings have been restricted range, interference problems, and limited transmission capacity.

With the advancement of modern telecommunication technology, the terms "telemedicine" and "health care telematics" came up. The most advanced telecommunication systems are the Internet with an annual growing factor of about 3, GSM-based mobile telephone systems (in some countries 20 - 30% of the population are already using mobile devices), satellite radio transmission, and television cable networks. The European Union has funded the development and assessment of numerous projects in healthcare telematics, especially in the fields of teleradiology, telepathology, teleconsulting, emergency medicine, electronic patient record, telehomecare, and teletraining. At present, different telecommunication systems are joining to complex networks. This trend is supported by recent developments like multimedia and virtual reality. Realized applications that make use of flexible and mobile patient monitoring demonstrate the feasibility of nation-wide hospital networks, of virtual hospitals by

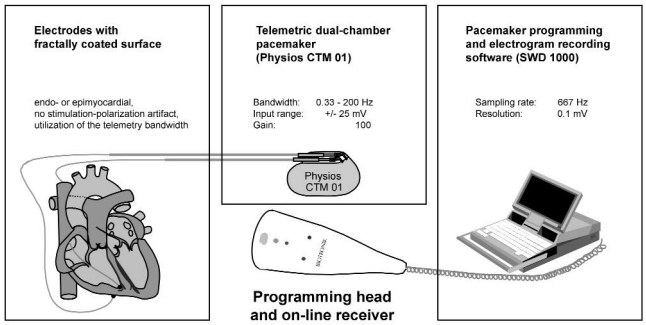

Figure 1. Telemetric pacemaker system.

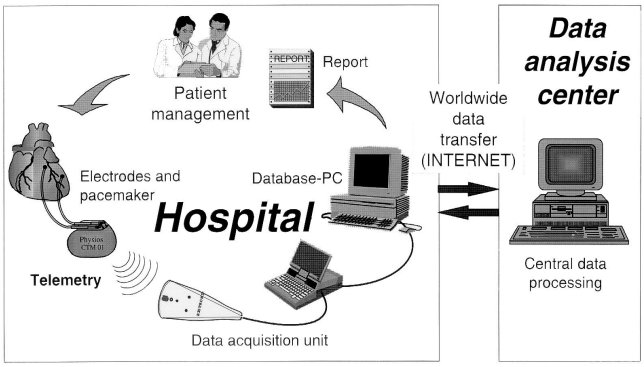

Figure 2. Cardiac telemonitoring system.

combining indoor departments with outdoor services like homecare and nursing homes, and render possible international cooperation.

The objective of the CHARM study (CHARM: Computerized Heart Allograft Recipient Monitoring) which started about 7 years ago has been the assessment of advanced telecommunication technology for telemonitoring of heart transplant recipients [1, 2, 5]. Recently, this approach has been further developed to support international multicentric studies by a computer center. This center makes available specially developed and tailored software for automatized electrogram evaluation 24 hrs per day and for complete data administration. One study has been performed in double-blinded form for a period of 12 months for each participating patient. During that period, the computer center has received only the electrograms from the heart transplant patients, transmitted by the cooperating hospitals without any decision affecting information on the actual state of the patient and the therapeutical management. Furthermore, no information on the results of electrogram evaluation has been returned to the hospitals within the individual study period.

In this paper only technical details on the methodological approach and results, however neither the agreed study protocols nor any clinical results will be reported and discussed.

Methods

Data acquisition and transmission:

Intramyocardial electrograms with diagnostic signal quality (bandwidth 0.3 - 200 Hz) have been transmitted both from the spontaneously beating and from the paced heart using a telemetric pacemaker (Physios CTM 01, BIOTRONIK) and fractally coated electrodes (different types, all BIOTRONIK) to an extracorporeal data acquisition station (SWD/SWM 1000, BIOTRONIK) [4, 6, 7, 11] (Figure 1). Transmission of the electrogram signals to this station has been accomplished by analog frequency modulation in the low-frequency range using inductive coupling. The transmitted signals have been headed by the ID code of the pacemaker. After analog-to-digital conversion in the data acquisition station with a sampling rate of 667 Hz and a resolution of 0.1 mV, the digitized data have been compressed and encrypted. When clinical data as agreed in the study protocol have been supplemented, the complete data string for a 1-minute electrogram sequence has contained about 40 Kbytes. Transmission via the Internet to the computer center in Graz (Austria) has been accomplished usually employing the FTP protocol and in few cases by e-mail (Figure 2). In general, different hospitals do not use the same software platform. One of the main tasks of the computer center is to take care that the employed software platforms are harmonized with regard to the study protocol and its requirements.

Data processing:

For each participating hospital a password secured data bank has been installed. After data decrypting, automatic loading of the data string into the patient's data bank is achieved with the pacemaker ID. For further evaluation and processing, the complete set of all raw data has been stored. The usual processing procedures are:

- event detection: this requires well-defined thresh-

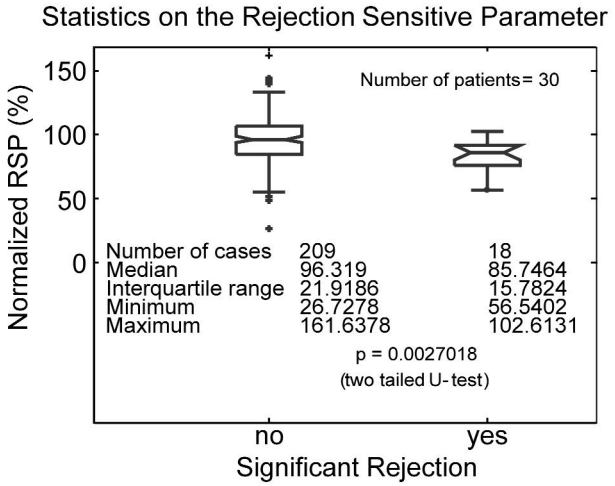

Figure 3. Statistics on the Rejection Sensitive Parameter (RSP) grouped according to whether clinical assessment found Significant Rejection (SR) or not. Application of the U-test indicates that the differences in median are statistically significant [2].

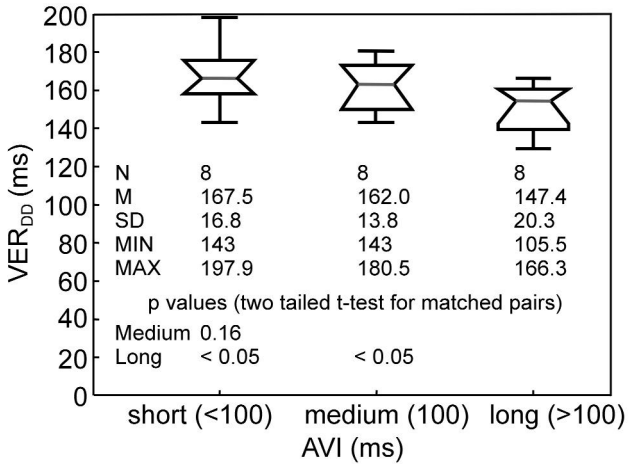

Figure 4. Statistics on Ventricular Evoked Response Depolarisation Duration (VER_{DD}) vs. Atrioventricular Interval (AVI), indicating significantly lower VER_{DD} values for long AVIs as compared with short and medium AVIs [12].

olds and data preprocessing;
- event classification (employing adequate class definition for main class and subclasses, e.g. fusion beats);
- averaging with appropriate trigger setting (different for spontaneous and paced events);
- parameter extraction: those parameters can be amplitudes, intervals, slopes, areas, etc;
- parameter presentation (e.g. trend curves, with or without normalization) with time scaling and supplemented with clinically relevant data;
- statistical evaluation.

Additional features include procedures for checking safe transmission and data completeness.

Regular back-up is another aspect of quality management in the computer center.

Results

In the framework of the multicentric studies with participating hospitals from different countries, more than 24.000 electrogram sequences have been sent to the computer center in Graz. Currently, on the average about 15 IEGM sequences are received per day. No serious problem has been observed either with the access to the data banks or with data transmission including safety aspects. No data have been lost or unacceptably been delayed. Considering safety aspects, it must be emphasized however that no really sensitive clinical data have been transmitted.

It was appreciated by the hospitals that they could sent the data around the clock and without considering differences in time zones or national holidays in the case of international cooperation.

A great body of experience has been collected in the framework of CHARM and related studies aiming at rejection monitoring of transplanted hearts (Figure 3). In the meantime, more studies on cardiac telemonitoring are running, in which single hospitals rely on the service provided by the Graz center for computerized electrogram evaluation. Objectives of such studies are:
- detection of fusion beats;
- optimization of AV delay in patients with hypertrophic obstructive cardiomyopathy (Figure 4) [12];
- adjustment of AV delay in patients with dilative cardiomyopathy [3];
- identification of electrogram parameters with hemodynamical relevance, e.g. the enddiastolic filling volume [8, 9].

Discussion

Multicentric clinical studies require a high level of standardization. Usually, detailed study protocols spec-

ify exactly every detail of the experimental procedure, but not for the processing and handling of raw and accumulated data. Frequent problems that are considered inadequately can be related with incomplete or erroneous data, e.g. caused by confused electrode position, missing or disturbed signals. Another serious problem can arise if individually based subjective assessment is required. The presented cardiac telemonitoring system offers a high degree of flexibility, e.g. if hospitals want to include individual features. Independent centers can provide to the participating hospitals the same service that is provided by accredited bodies to third parties. This support can be supplied without abrogating the agreement on the study protocol.

Usually it is recommended that the data are sent employing the FTP protocol. This requires however that the appropriate equipment is available in the hospital to provide the possibility to connect the data acquisition system to the Internet. Different types of firewall concepts may impede or even prevent the use of the FTP protocol. In such cases it may be necessary to send the data by e-mail although this requires more time for data preprocessing in the computer center.

Conclusions

The results of the present study demonstrate that:

- cardiac telemonitoring with electrograms in diagnostic quality is possible using the Internet (or special intranets) for transmission;
- computer centers can effectively support the realization of multicentric clinical studies. The offered support concerns many aspects as standardization, 24-hrs availability and adaptation of different software platforms.

The future development will lead to an advanced system for telecardiolgy in which telemetric pacemakers will provide new insights in cardiac diseases and will help to support and optimize therapy management [10].

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