The Potential of Advanced Information Technology for Telemonitoring of Heart Patients

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Summary

Continual and rapid advancement of information and telecommunication technology is the most powerful megatrend of globalization. Instantaneous and worldwide exchange of data is possible by different communication technologies based on both stationary and mobile telephone systems, Internet, and satellite transmission. These technologies are becoming integrated more and more. User-friendly software, standardized transfer protocols and high-level data management systems support this development. In the medical community, telemedicine has become a synonym for different kinds of advanced medicine based on information and telecommunication technology. Among the various trends in telemedicine, medical telemonitoring can be regarded as one of the most challenging and attractive applications. Flexible monitoring has been proven to lower health care costs. Telemonitoring of heart patients with well-defined risk factors has already entered the phase of realization, e.g., rejection monitoring in heart transplant patients. Telemonitoring will contribute to the establishment of virtual hospitals whose service is not restricted to the facilities and resources that are available in the building. Telemonitoring not only offers hospitals the opportunity to extend their services to areas such as home care and retirement homes, but also links hospitals to centers that offer specialized services that cannot be provided in hospitals. These kinds of teleservice may include signal processing with software designed for parameter extraction and report generation, comfortable database systems, and collaboration in multicentric studies. Telemonitoring also contributes to improved therapy management. This paper will supply relevant information that is helpful to hospitals as they prepare for the future.

Key Words

Globalization in health care provision, integrated information exchange systems, advanced information and telecommunication technology, medical and cardiac telemonitoring

Introduction

One of the primary objectives of developing global health care systems based on modern telecommunication facilities and information technology is to provide patient monitoring that is independent of a patient's actual location and the timing of essential service delivery. This requires that the patient's data be stored in such a way that quick access is possible from any place around the world. The driving force for this development is not only the increasing mobility of patients, but also the necessity of lowering health care costs, i.e. of increasing the efficiency of health care provision. In the near future, the need for worldwide access can be realized by a universal service provider for health care data. This service, whose necessary technology is becoming increasingly available, must be accomplished using standardized data processing protocols. A global service provider for health care data can be based on data exchange networks such as the Internet, stationary and mobile telephone systems, and satellite communication technology. The number of Internet hosts has increased from 1,000 in 1984 to 10 million in 1995, and it is estimated that it will reach more than 70 million in 2000. Recent studies have shown that public access to the Internet is increasing rapidly in almost every country in the world. It has reached more than 50 % in the USA and an average of 18 %, in the European Union, ranging from about 7 % in Greece up to about 50 % in Finland [24]. In some countries, the accessibility of cellular telephone networks is already approaching 100 %. All parts of these countries are covered, even the most remote island and mountain areas. Users of this technology can be served anywhere regardless of their location. The attraction of this service is emphasized by the fact that in some populations the percentage of users is over 50 %. However, technology is still progressing with impressive speed and aiming at linking the different telecommunication systems. Gateways are being developed that enable data exchange between different networks, e.g., between the telephone network and the Internet. These gateways are becoming increasingly effective through the control of standardized protocols and procedures. In addition, completely new aspects may be realized if the ever expanding capabilities of satellite communication technology become integrated. Technology assessment studies suggest that this technology has not been tapped until recently, so it holds great promise for future expansion.

Telematics in health care has been among the topics of past research programs in the European Union. In the period 1994 - 1998, about 68 projects were funded [26]. The scope of these projects ranged from such special applications as medical emergency service, telematics in ophthalmology, diabetic care, and teleradiology, to such basic programs as electronic patient data recording, telemedicine, a European health care information system, and advanced network architecture for health care [3,16,18,19,25]. At their recent meeting in Lisbon in March 2000, the prime ministers of the European Union decided that the present decade shall be the decade for the advancement of information and telecommunication technology in Europe, and that every effort should be made to make Europe a leader in this technology. It can be expected that this decision will have a strong impact on the basic structures of the health care system within each member state of the European Union. While the industries and economies of these countries are well developed, their economic power is becoming increasingly restricted by rising costs for the health care delivery system in relation to the gross national product and the aging of the population. One of the great challenges for the future is to utilize advanced information and telecommunication technology for the purpose of combining resources to reduce costs without lowering the level and quality of health care provision [1,10,21].

Information and Telecommunication Technology

Transmission characteristics

Modern communication technology is based on the transmission of digital data. For many purposes, the data transfer rate is the limiting feature if it is not high enough. For medical purposes, this transfer rate must be sufficient for the respective purpose, especially if real time transmission is essential.

Transmission of physiological signals in the required diagnostic quality requires a sufficient bandwidth. The bandwidth for a single-lead ECG with diagnostic quality ranges from 0.1 - 150 Hz. Analog-to-digital conversion of this signal requires a minimum sampling rate of 300 samples per second. In order to obtain a resolution of 0.01 mV in a full scale range of 2.5 mV, 8 bit are necessary. Hence, the real time transmission of this single-lead ECG in digitized form requires a transfer rate of 2,400 bit/s. For the simultaneous transmission of 3 ECG channels, the total transfer rate must be at least 7,200 bit/s. The required transfer rate for the transmission of other physiological signals can be calculated in a similar way. In order to monitor the ventilatory flow during physical exercise, the upper frequency would be around 5 Hz. With the required sampling rate of 10 samples per second and 8 bits per sample, the transfer rate must be only 80 bit/s.

The transmission of medical images requires a much higher transfer rate. A CT image with 256 x 256 pixels (which is a rather poor spatial resolution) and 12 bit per pixel in order to represent the gray scaling, adequately contains 786,432 bit. If this image is transmitted within 1 second, the transfer rate must be 786,432 bit/s or 787 kbit/s.

Cellular or mobile telephone systems, which utilize the GSM technology, provide a transfer rate of 9,600 bit/s. This transfer rate is sufficient for the simultaneous transmission of 4 ECG signals or of 3 ECG signals along with other physiological signals such as ventilatory flow, blood pressure, etc. Transmission of a CT image with 787 kbit using a GSM device will take about 127 seconds. Although it is a long time, this transmission would be possible in principle if the device is equipped with the necessary input for the data from the imaging machine.

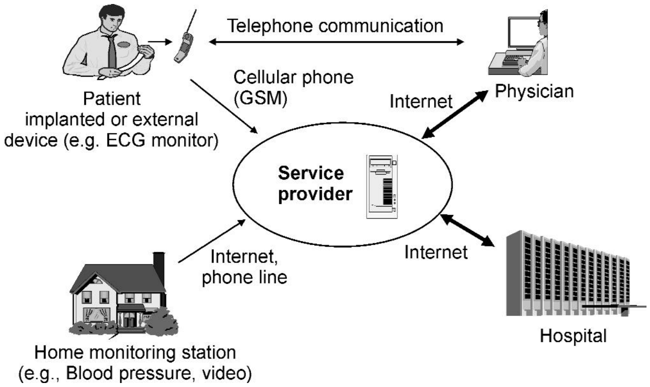

Figure 1. The universal concept of a telemonitoring system. Autonomous data acquisition devices (stationary via the Internet or mobile via cellular phone networks) transmit recorded data to a central service provider. These data, together with the results of signal analysis, can be accessed by authorized physicians independent of the patient's location or the time of day or night.

For data transmitted via the Internet, the bottleneck is usually the connection between the user and the provider. If this access is provided by a modem, the transfer rate is 9,600 bit/s, i.e. the same as for GSM telephone technology for the whole transmission pathway between the users. ISDN offers a transfer rate of 64 kbit/s, i.e. about 6 times the transfer rate of GSM technology. Consequently, the transmission time for the CT image is only about 12 s. If an ECG sequence of 1 min containing about 100 heart beats is transmitted, this can be achieved via ISDN in a very short time. The total amount of data for that ECG sequence is 60 x 2,400 = 144 kbit which can be transmitted within 2.2 s via ISDN.

Special procedures have been developed that allow for the compression of data without loss of information. In the case of a 1-minute ECG sequence in diagnostic signal quality, the data amount can be compressed to about half, thus enabling transmission via ISDN in approximately 1 s.

The transfer rate on the Internet does not only depend on the available technology, which is based increasingly on fiber optic technology, but also on the amount of use by other users. On average, the effective transfer rate, even in times of poor transmission capacity, has been enlarged considerably during the last few years, and this process will continue. A special technology called ATM (Asynchronous Transmission Mode) offers a transfer rate of approximately 155,000 kbit/s (or 155 Mbit/s). With ATM, the transmission time of the above-mentioned CT image is reduced to only 50 ms. However, even more powerful technologies are under development. For the near future, the installation of the so-called super-backbone technology with 2,400 Mbit/s is announced, i.e. more than ten times the transfer rate of ATM, thus reducing the transmission time for the CT image to about 3.3 ms. Medical images with high diagnostic quality have 1,024 x 1,024 pixels, i.e. 16 times the data amount of the CT image. These images can be transmitted within 54 ms, i.e. with nearly 20 images per second, thus approaching video standard. Intranets which are comparable with the Internet but accessible only for authorized persons, provide features that meet nearly all requirements for fast and reliable data exchange.

Data base organization

In the combination of telemonitoring with telecommunication, a central database represents a key component of an extensive surveillance system. Data received from an autonomous monitoring system (e.g., home monitoring device) must be stored independent of human supervision, analyzed, and, in case of critical situations, the treating physician has to be informed immediately to initiate adequate medical treatment. At the same time, physicians should have the possibility of easily accessing patient related data, creating new patient records, or modifying existing ones (Figure 1). The requirements for such a database systems are as follows:

- high level of reliability;
- permanently online and accessible;
- simple and easy-to-use graphical user interface (Figure 2).

The goal of high reliability can be reached on the one hand with appropriate hardware architectures and on the other hand with safety measures such as periodic backups. The requirement of 24-hour accessibility and short response times can be accomplished with geographically distributed database systems. Especially with regard to global databases, only systems with additional mirror-servers (server with identical database content) in different locations fulfill the requirement of permanent accessibility in case of partial system failure.

In order to link received patient data from an autonomous monitoring device to the correct patient record, all data packets must include a unique identifi-

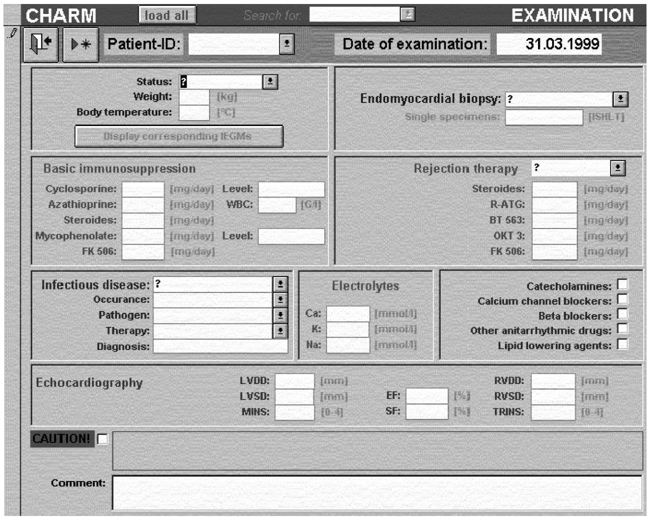

Figure 2. Example of an input mask for structured acquisition of clinical data.

cation code. This code can either be generated automatically by the monitoring device or, in case of shared devices, with other unique identifiers such as "smart-cards" entered into an appropriate card reader. With existing media, primarily short transmissions of preprocessed and compressed data are feasible. Under development are systems that provide continuous and real time transmissions. The technical requirements of such databases are correspondingly high (e.g., real time ECG recording with 300 samples per second and 8 bit resolution results in approximately 26 MByte a day for a single channel or 9.5 GByte a year, respectively). At the same time, multiple concurrent access from different sides must not influence operation of the database (multitasking capability of the system).

An object-relational database system with a preprocessing and a post-processing stage (e.g., report generation, statistics) is possible (Figure 3). The possibilities of a preprocessing stage can range from simple filter function up to sophisticated expert systems, neural networks, and decision support systems.

To offer a user interface that is as simple as possible, access through a patient monitoring device should be completely automatic and, therefore, without any patient interaction. Access by the physician can also take place automatically, e.g., periodical or event triggered forwarding of reports by e-mail or through an interactive graphical interface. Using the Internet offers the possibility of accessing a central database that is similar to exploring the World Wide Web with a common web browser. Technical developments might

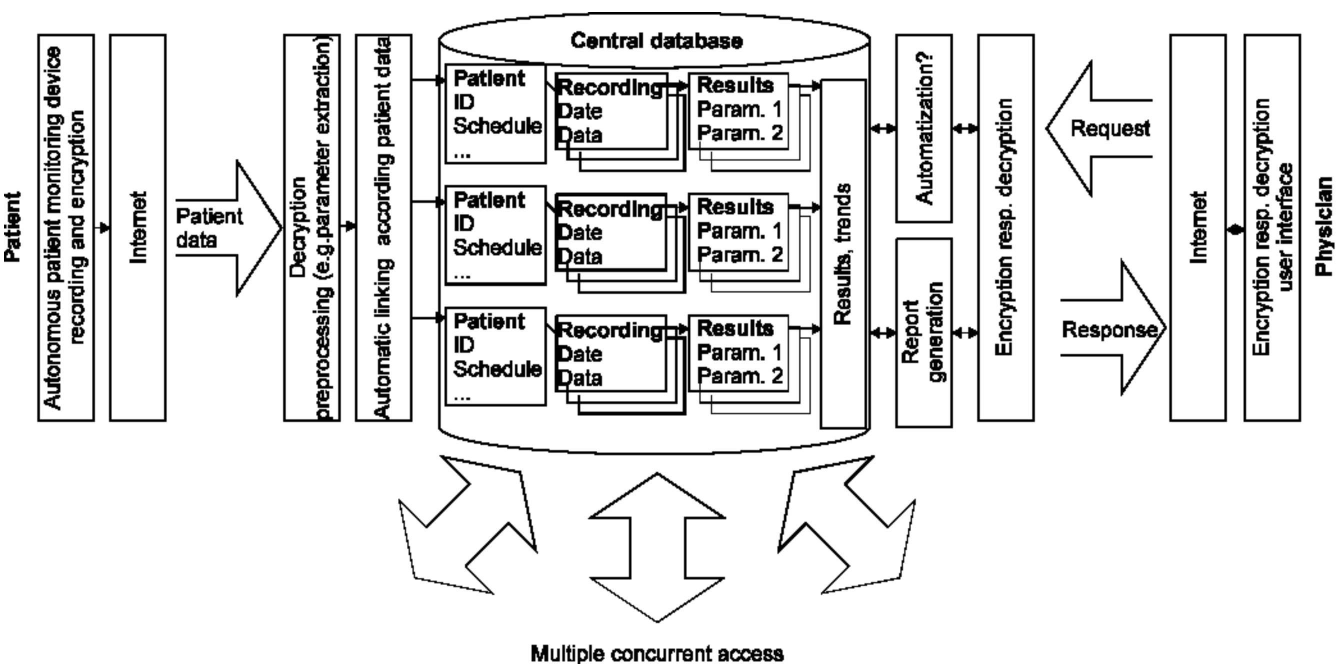

Figure 3. Simplified database architecture with patient monitoring system and physician connected via the Internet to provide global accessibility. All data transferred via the Internet must be encrypted.

offer a new communication interface such as speech recognition. With increasing computer power and network bandwidth, multimedia presentation of database records (e.g., time dependent morphological changes as a video sequence) will be possible. It can be expected that a combination of diagnoses from different experts will be established in a central database and build a base for decision support systems (intelligent expert systems).

Safety aspects for medical data transmission and processing

Security measures can be subdivided into 3 main topics:

- Reliable transmission: Not even one data segment from the patient's monitoring device to the central database or a request from a physician should be lost. Appropriate transmission protocols must guarantee detection and correction of erroneous transmissions. In case of an inaccessible remote system - e.g., a monitoring device that is out of the range covered by the cellular phone network - the monitoring device should be capable of storing recorded data locally and, after reestablishing the connection to the central database, re-transmitting them.
- Encrypted transfer: Because a universally accessible network is used, all precarious medical data must be encrypted before transmitting via the Internet including recorded data from the patient's monitoring device as well as requests and reports from and to the physician. Using standardized encryption algorithms guarantees a high level of security. Due to the need for high security standards in many different industrial and commercial organizations (bank transactions, insurance, medical applications), security measures are persistently under development. A combination of both symmetric and asymmetric encryption provides high security. Symmetric encryption systems are based on a single secret key known only to the receiver and sender for encryption and decryption. An asymmetric encryption system uses a combination of public and private keys to encrypt and decrypt information. The importance of the asymmetric key encryption model is increasing in the context of digital signatures.
- Restricted access: To ensure the privacy of medical data stored in the central database, access has to be restricted to authorized users only. This means that physical access to hardware as well as access over computer networks has to be controlled. For network connections, user identification with a username and password are very common. Additional security measures such as identification via finger print sensor or voice authorization are under development or are about to be introduced into the market. With accepted user identification, individual privileges and restrictions can be associated. In consequence, every user has limited access only to his own patient records. With optional security measures such as time slot restrictions or access limitation from and to certain IP-addresses (every computer connected to the Internet is characterized by a unique IP-address), a central database system can meet very high security guidelines (firewalls).

User support provided by information processing centers

Both comprehensive experience with information technology and extensive knowledge of electrophysiology have been acquired during the last ten years. Clinical users can be provided with this know-how, particularly for designing study protocols, initializing and performing single or multicenter studies, and developing new methods for signal analysis. Additionally, the information processing center provides complete assistance in implementing systems, configuring individual user interfaces, preparing reports, performing statistics, and in solving problems during daily usage of the system.

Cardiac Telemonitoring

CHARM

CHARM was started in 1992 and was originally intended as a study on **C**omputerized **H**eart **A**cute **R**ejection **M**onitoring. The aim was to develop and evaluate a procedure for computer-assisted rejection monitoring of heart transplant patients [4,15]. The procedure is based on the processing of intramyocardial electrograms (IEGMs) obtained either from a spontaneously beating heart or a paced heart. These signals can be acquired using implanted pacemakers that have broad-bandwidth telemetric capability. Since no software was available for the processing of IEGMs, the required software had to be developed by a specialized center. Additionally, this center had to provide the necessary support to hospitals that collaborated in the study. These had been strong arguments for consider-

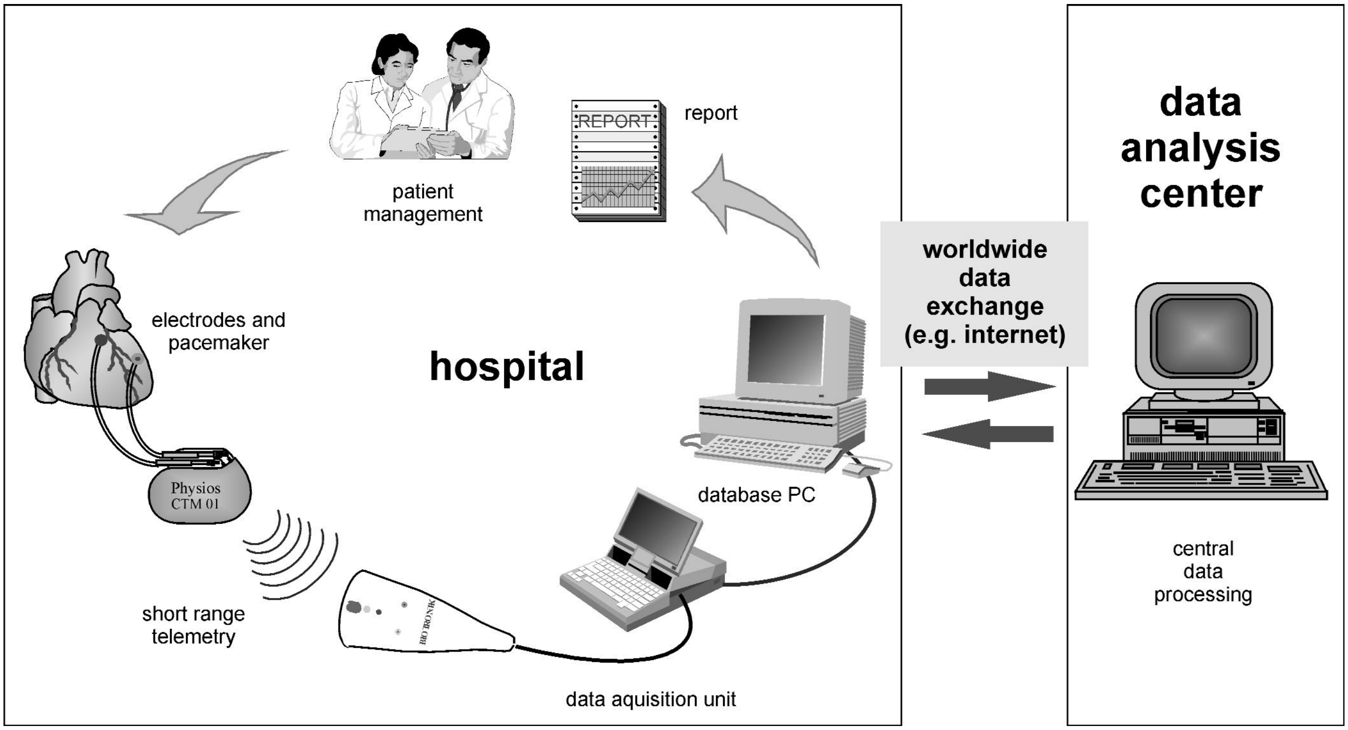

Figure 4. Overview of the Cardiac Telemonitoring System which has been developed and successfully tested in the course of a multicenter study on CHARM **- C***omputerized* **H***eart* **A***llograft* **R***ecipient* **M***onitoring [17].*

ing telecommunication technology and especially the Internet for data transmission (Figure 4) [5-8,13]. Standardized transfer protocols as well as different firewall concepts and software platforms in the cooperating hospitals had to be considered. Consequently, this center is now provided with a large body of experience to address all problems that may be related to this kind of data transmission. Within the framework of CHARM, over 20,000 ECG sequences with about 100 heart beats per sequence have been transmitted to Graz.

At the beginning, only limited knowledge had been available to assess the signal morphology of IEGMs and to identify the rejection sensitive parameter. For these reasons, it had been decided to store not only the raw data of all IEGM sequences, but also supplemental data of clinical relevance. It had been necessary to install a powerful data base system that allows direct access to all stored data whenever new aspects are considered or new parameters are extracted. It had been found that the participating hospital appreciated the provision of a whole report on the respective patient instead of a single parameter (Figure 5). Today, the center in Graz can provide each hospital with a report that is organized in accordance with the hospital's wishes. Of course, each hospital only has access to its own data. The center in Graz provides comfortable procedures that support in a user-friendly manner the data entry and report monitoring in the hospital (Figure 6).

Two multicenter studies have been performed. The service center in Graz was responsible not only for signal processing and data handling, but also for coordinating services and generating statistics [2,12,17]. This service was appreciated by the participating hospitals. No problems have occurred to call into question this kind of organizational support for multicentric studies.

Cardiomyopathies

In the framework of CHARM, it was found that information from the IEGMs can be obtained not only for rejection monitoring but also for a more complete assessment of the patient's status. In a retrospective study, a parameter could be identified that has a very high prognostic value for the assessment of the patient's outcome. In the future, it might be possible to

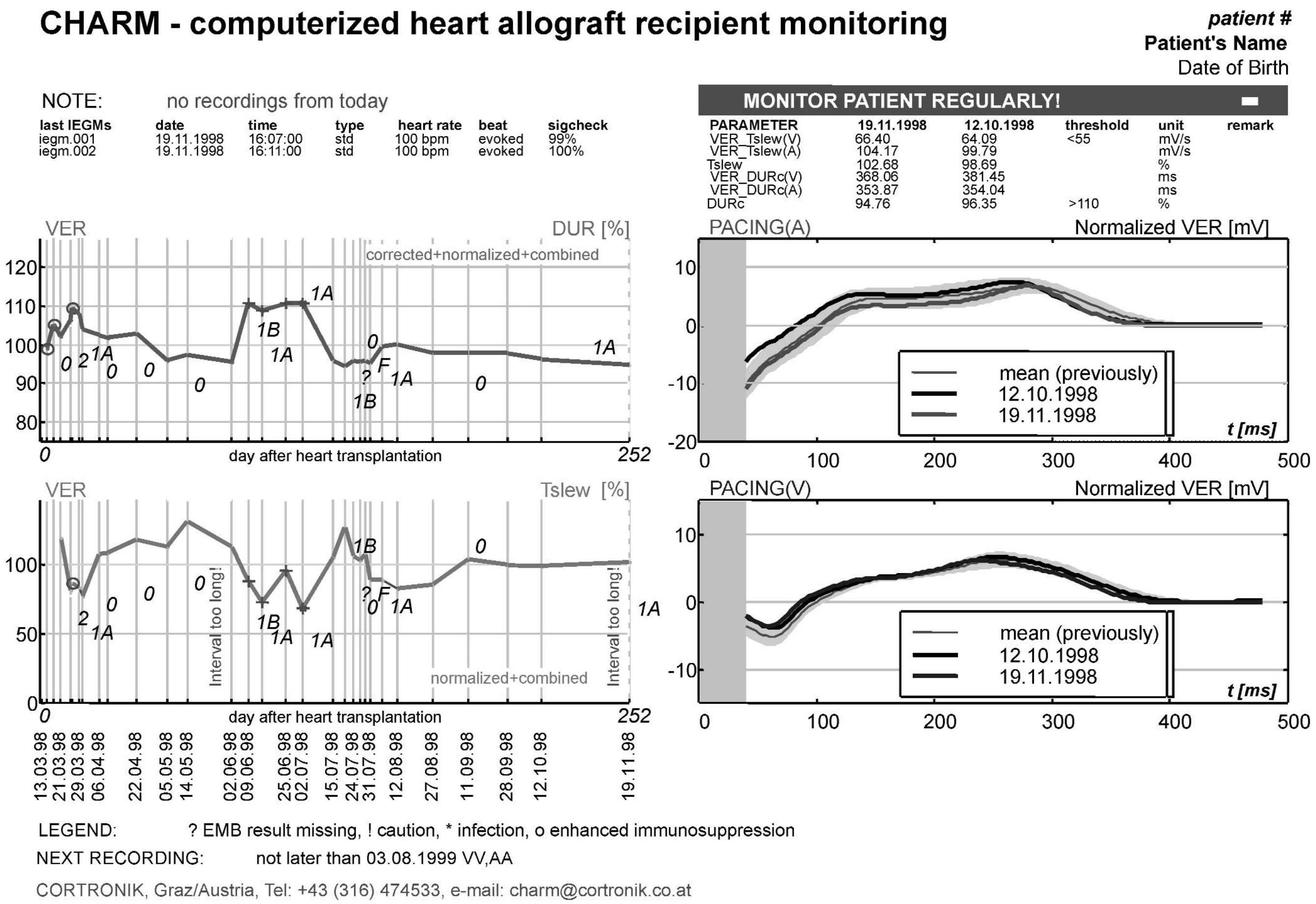

Figure 5. Example of a CHARM patient report: On the left side, trend curves of the diagnostic parameters are displayed relative to a prospectively calculated diagnostic threshold. The right side shows current and previous averaged IEGMs from both pacemaker channels. The tables above contain detailed information about the most recent recordings and the parameter values, respectively.

consider this prognostic parameter for early therapy adjustment. It had been speculated that IEGMs represent some information on the hemodynamic performance of the heart, which can not be obtained by other clinical methods.

In the meantime, this speculation has been tested. IEGMs from patients with different kinds of cardiomyopathies have been examined. Although those clinical studies are still in progress, there is already strong evidence that at least some of the parameters extracted from IEGMs are closely related to parameters obtained with echocardiography. Regression analysis has revealed that IEGM processing provides better reproducibility of the relevant parameters than echocardiography.

One of the most interesting results of these studies was that the processing of IEGMs from the paced heart allows for the detection of the degree of capture and, thus, the avoidance of fusion beats through the optimal adjustment of the AV delay (Figure 7a, b) [20,23]. With this approach, it might be possible to delay or even stop the progress of diseases such as hypertrophic obstructive cardiomyopathy. In another study that has just started and needs further evaluation, preliminary evidence shows that analyzing the morphology of IEGMs can help identify the effect of certain drugs. It might be possible in the future to support therapy management with cardiac telemonitoring [9,11].

Risk monitoring

One of the main benefits of cardiac telemonitoring may be the ability to connect the patient to a universal

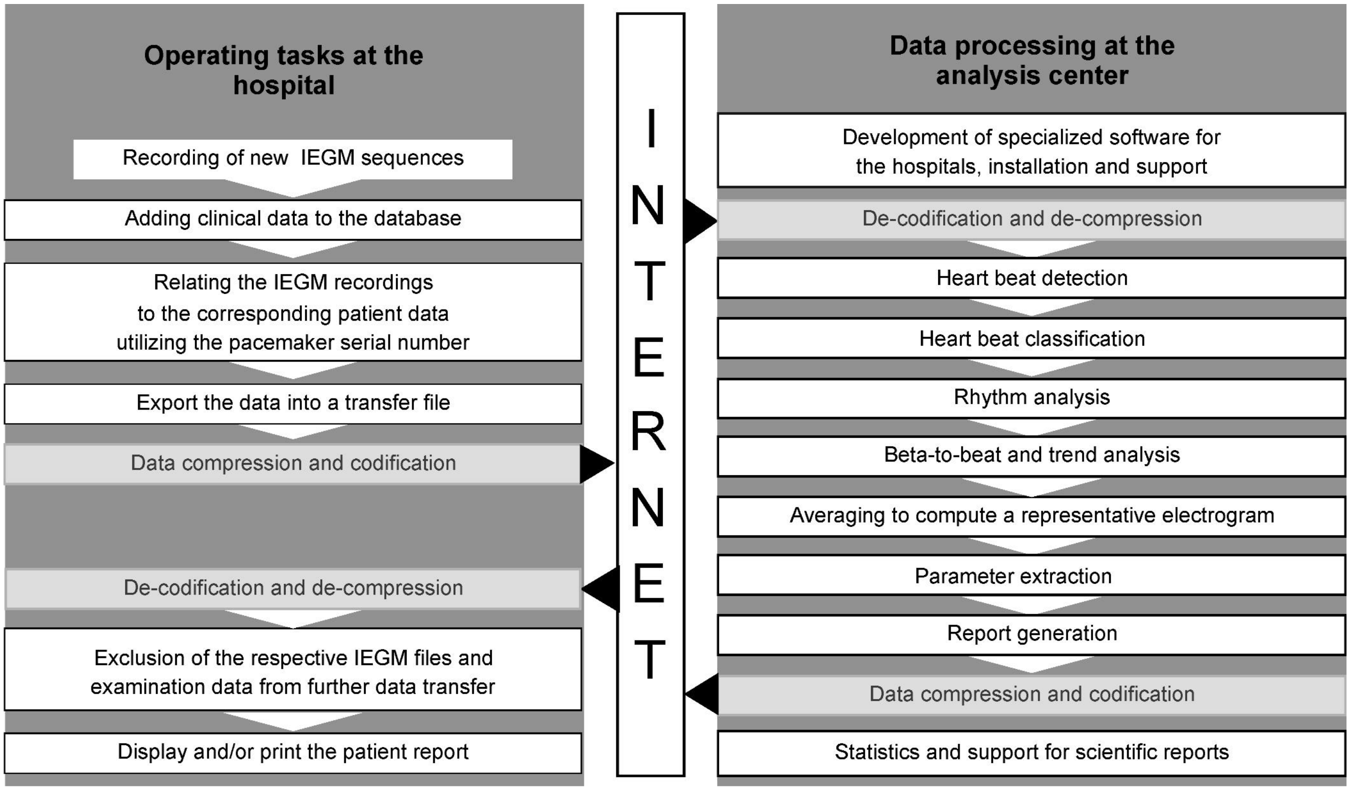

Figure 6. Flowchart of the operating and data processing tasks which are necessary for remote IEGM analysis: The left side shows the main steps performed at the hospital and the right side contains the subsequently executed steps at the analysis center. Both sides are connected via the Internet, which provides worldwide accessibility.

and global health care system that is independent of his actual stay and is available whenever necessary. Especially with the aging of the population, adequate surveillance gains increasing relevance. Modern microtechnology facilitates implantable and miniaturized recording systems that monitor well-defined risk parameters. This can be achieved in various ways, e.g., the implant is provided with intelligent algorithms or other features for adequate processing of the electrograms. This capability allows for the detection of events that indicate a high risk for the patient. The occurrence of these events can be transmitted immediately to the hospital or a specialized center located elsewhere. In other cases, the events can be stored in the device for periodic interrogation and data processing in a manner similar to Holter monitoring.

Among the candidates for risk monitoring are parameters obtained from heart rate variability, e.g., the low-frequency-to-high-frequency power relation, but also parameters extracted from heart rate subsequent to extrasystoles or defined changes in the signal morphology of the electrograms. It has been proven in the framework of the CHARM study that with regard to signal quality, intramyocardial electrograms are significantly superior to any extracorporeal electrograms [14].

Risk monitoring is a developing field in which only limited knowledge has been available until now. Future studies must show whether it can be utilized to the benefit of patients. However, the necessary technology is available, including implant technology.

Discussion and Conclusions

Assessing health care technology is one of the greatest challenges today since an erroneous assessment of trends in health care may result in decisions that are difficult or sometimes even impossible to correct. However, in the case of assessing telemedicine, the difficulties are reduced since forces coming from other

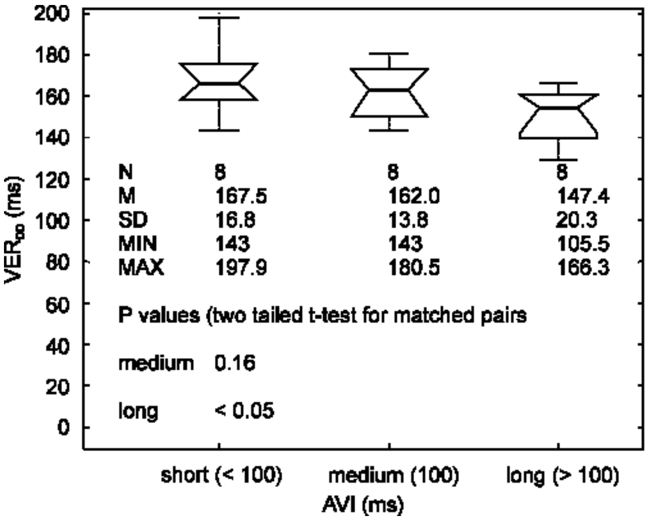

Figure 7a. Statistics on the VER depolarization duration (VER_{DD}) versus the AV interval (AVI), indicating significantly lower VER_{DD} values for long AVIs as compared to short and medium AVIs [20,23].

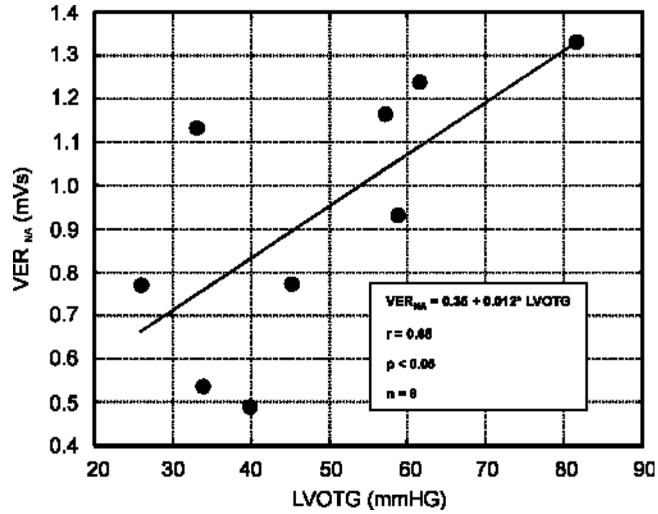

Figure 7b. Linear regression analysis between the left ventricular outflow tract gradient (LVOTG) assessed via echocardiography and the magnitude of the VER, as measured by the area under the negative signal part (VERNA), revealing a significant correlation between hemodynamics and electrical activity [20,23].

application fields are helping to drive the development of information and telecommunication technology. Although these forces have been very effective in the past, nevertheless, the prime ministers of the EU member states during their recent meeting felt that Europe should take a leading position in developing these technologies within the next decade. This decision will stimulate many activities from research groups. Medicine, and especially clinical medicine, should carefully consider the possible benefits that can be gained from technological progress.

The continually expanding capabilities of computers will facilitate the use of sophisticated algorithms and methods such as neural networks, fuzzy logic, expert systems, etc. for real time applications. Together with the increasing amount of clinical data, this allows to develop and to test future methods for patient care, e.g., expert knowledge based on self-adjusting therapy or self-learning implants [22].

This report has shown that powerful systems are already available today that can be used to study and evaluate the effectiveness of telemedicine, especially cardiac telemedicine. Telemonitoring makes possible the sharing of restricted resources, worldwide access to specialized data processing centers and databases, and the realization of multicenter studies.

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