Telecardiology — Optimizing the Diagnostic and Therapeutic Efficacy of the Next Implant Generation

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Summary

The use of telecommunications as a tool to enhance the safety of implant patients, to provide more efficient therapies, and to reduce the burden to patients during follow-up visits at the physician's office is well known. Both medical and financial benefits are expected with this approach. Shorter monitoring cycles result in early detection of situations requiring intervention by the attending physician, therefore contributing to enhanced patient safety and reduced subsequent costs. Nevertheless, present technical limitations have hindered widespread acceptance and use of such home-based outpatient monitoring systems. With the rapid developments in the field of telecommunications and wireless data transmission during the last decade, these goals have become more and more achievable. An essential task is to develop a telemetric connection between the implant and an external patient base station, located at a distance of 2 to 5 meters from the implant. This article describes the initial approaches for such monitoring systems, as exemplified by the computerized heart acute rejection monitoring system (CHARM), and also discusses future goals and prospects. Overall, enhanced service for the patient and physician will be an important aspect for the next generation of implants.

Key Words

telecardiology, implantable pacemakers and defibrillators, implant telemetry

Introduction

Due to the rapidly developing field of microelectronics, present pacemaker and defibrillator implants provide a very broad spectrum of diagnostic and therapeutic functions. Features like multiprogrammability and extended data storage support these functions and supply the physician with powerful tools to optimize patient care and safety. As microelectronics have done in the past, telecommunications will markedly shape the functionality of future implants. By making use of modern telecommunication technologies, patient monitoring will no longer be restricted to just the follow-up visit at the physician's office. Instead, it may be extended to the periods between follow-ups, thus integrated into the patient's workaday world.

Moreover, implants with special functions open doors to new therapeutic approaches, reducing the patient's physical and psychological load as well as time and money spent for routine follow-ups. One important example, which is already in clinical use, relates to rejection monitoring after cardiac transplantation. Telecardiology is defined by several modules and aspects. The most important of these are shown in Figure 1.

A brief historical outline describes the first approaches to home-based monitoring systems and demonstrates the technical limitations of these early systems. A discussion of present and future applications follows.

Historical Aspects

The electrocardiogram (ECG) provides valuable information for the analysis of a patient's state of health. Transtelephonic transmission of ECG signals for remote monitoring has been known since

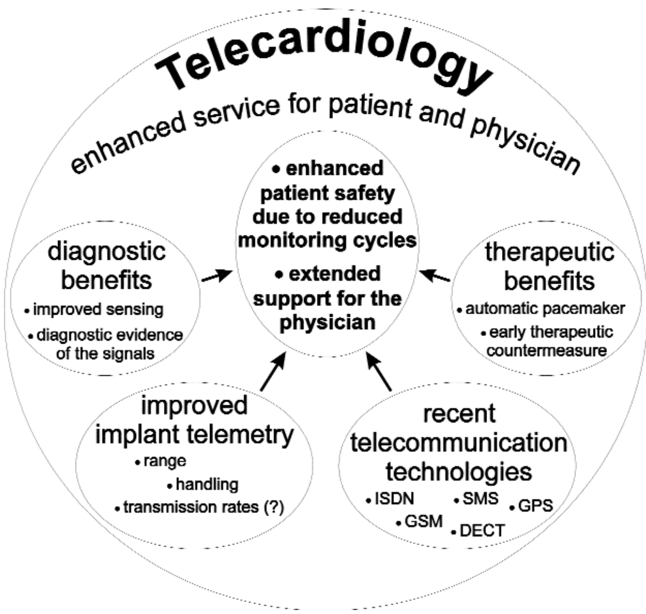

Figure 1. Telecardiology: modules and aspects.

the beginning of this century [1]. Holter monitoring, which typically comprises a period of 24 hours, facilitates ECG analysis. Since the seventies, it has become an important tool for analyzing intermittent arrhythmias [2][3]. However, a certain probability remains that arrhythmias can symptomatically occur outside of the monioring period.

In these cases, transtelephonic monitoring has proven to be useful in therapy: If an arrhythmia occurs, the patient may initiate ECG recording and transtelephonic transmission.

Several systems have included the possibility to check the battery status of pacemaker implants by measuring and transmitting the asynchronous basic rate (STIMUTEST or BIOFON, all BIOTRONIK), thus opening doors to outpatient implant monitoring.

Among implant patients living relatively close to their physician, these monitoring systems were not widely accepted. Important reasons underlying patient hesitancy may have been the amount of patient participation necessary for data interrogation and data transmission, or merely the impersonal nature of the telephone contact, instead of a more direct interaction with the physician. In summary, widespread acceptance of telecardiology requires a careful balance between patient benefit and effort.

Cardiac Transplant Monitoring

In the wake of every transplantation, the transplanted organ must be monitored for rejection and infection processes. To suppress such processes, the physician administers immunosuppressive medication. Rejection monitoring provides the possibility to weigh the dosage of medication against the rejection process. Since an unnecessarily high dose of medication paralyzes the immune system, striking the right balance is vital. The conventional method for rejection monitoring is a biopsy, i.e. an invasive procedure in which a tissue specimen is taken from the transplanted organ and a histological examination is performed. According to the results of the biopsy, the physician adjusts the dosage of the medication.

In the case of cardiac transplants, changes in intracardiac electrical signals may also be used to supplement the histologically observed structural tissue changes in monitoring the rejection process. Within the CHARM project [4][5], non-invasive recording of intramyocardial electrograms is performed using fractal coated epicardial leads and a pacemaker with high-resolution intracardiac electrocardiogram (IEGM) transmission (PHYSIOS CTM 01, BIOTRONIK). The pacemaker and leads are implanted during cardiac transplantation.

The patient is examined for rejection indications at the transplant center at predefined intervals. During measurements, the implant transmits the ventricular evoked response (VER) through a high-resolution telemetric connection to an external data acquisition system. Via the Internet, the data are sent to a central data analysis workstation and evaluated automatically. The results are sent back to the physician at the transplant center who decides whether and by how much the dose of medication should be changed or whether to perform an endomyocardial biopsy (Figure 2).

A central station for data storage and evaluation has several advantages: especially during the first phase, that of system start-up and ongoing algorithm optimization, a central station facilitates access to the latest algorithm for all participants. Furthermore, central data storage makes all data available for an ongoing optimization of evaluation procedures.

This approach is used by the present CHARM project, which is now in its fifth year of clinical application. Within this project, a significant correlation between the results of endomyocardial biopsy and VER anal-

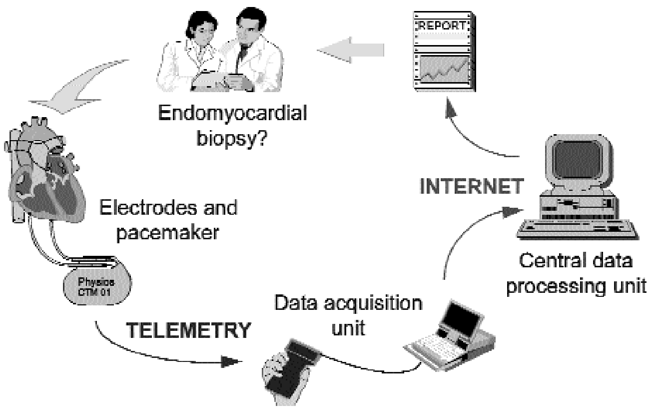

Figure 2. Computerized heart acute rejection monitoring (CHARM).

ysis was obtained. Therefore, this "electronic biopsy" is about to become a viable alternative to the endomyocardial biopsy, possessing advantages that include a lesser burden to the patient and overall lower costs to the health care system. Within the present system, every rejection measurement requires the patient to visit the transplant center. This controls the monitoring intervals and the costs. An improvement in the next stage of telecardiology development will involve a system that allows the patient to remain home during measurements and enables the automatic transmission of rejection monitoring data to a central station. There, the results can be promptly evaluated for the attending physician. Measurements could be performed by the implant at night, for example, while the patient is asleep. As illustrated in Figure 3, the implant will transmit these implant monitoring data over a distance of several meters to a patient base station that is linked to a commercial data network system. The physician will receive the evaluated data and can schedule an appointment with the patient to adjust the therapy.

With a home-based monitoring system, both monitoring intervals and costs can be significantly reduced. Shorter monitoring intervals will allow for earlier detection of rejection processes and for a better adjustment of medication dosage. In consequence, complications will be further reduced, resulting in enhanced patient safety and quality of life with lower subsequent health care costs.

Extended Monitoring of Implant Patients

The task has been set for enhancing the safety, quality

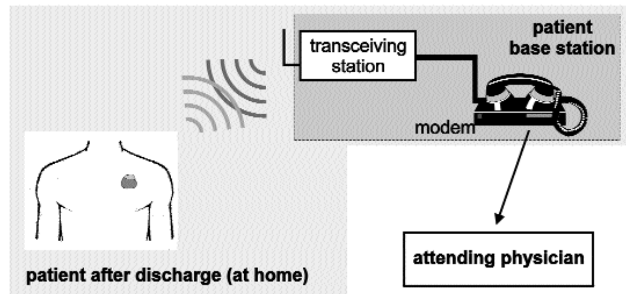

Figure 3. Schematic drawing of the modules of the implant telemetry line.

of life, and service not only for transplant patients but for all patients with a pacemaker or defibrillator implant. Monitoring the cardiac state with an implanted pacemaker and applying telemetry equipment as indicated in Figure 3 help fill the gap between conventional follow-ups. Presently, changing conditions related to the patient's state of health, the underlying cardiac disease, or therapy requirements developing between follow-up visits are detected only if the patient is aware of them and consults his or her physician. The first step is to provide the physician with additional monitoring information by so-called event flags. These flags are short sequences of binary information deduced by the implant, characterizing the implant and patient status. Specifically, these flags inform the physician not only about technical aspects like the battery status but also about important diagnostic topics like the occurrence of atrial and ventricular flutter and fibrillation episodes, reliable R- and P-wave detection, and capture control. Table 1 summarizes possible flags.

Besides flag transmission, short IEGM strips also need to be transmitted to provide the physician with comprehensive information about the patient's state. As with the current devices PHYSIOS CTM or LOGOS (both of BIOTRONIK), all next generation BIOTRONIK pacemakers will provide high-resolution IEGM detection and short-range transmission. Extra effort and a profound understanding of intracardiac signals, such as VER or MAP, will be required to make the valuable diagnostic information accessible for outpatient monitoring. Patient benefits include early arrhythmia and ischemia detection, medication monitoring, or rate adaptation. To ensure widespread acceptance and application, various demands must be met by a home-based outpatient monitoring system. To the greatest

AF flag	occurrence of atrial flutter and fibrillation episodes
Capture flag	effective stimulation pulses
P-wave flag	reliable atrial detection
R-wave flag	reliable ventricular detection
EOL flag	battery status
Electrode flag	pacing impedance of the electrode
PVC flag	premature ventricular contractions
Medication monitoring flag	appropriate medication dose in regard to rejection processes or antiarrhythmic agents
Rate adaptation flag	adequate rate adaptation

Table 1. Event flags for implant patient monitoring.

extent possible, the monitoring procedure must occur without the assistance or awareness of the patient. Data transmission must be performed via a widely available communication network, thus avoiding extensive installation expenditures.

Enhanced Services for Patient and Physician

Future home-based outpatient monitoring systems should not be seen as singular systems but as integrated parts of an enhanced service system. It is intended to provide various grades of service to patients and physicians. The spectrum of ranges can cover a minute problem to an emergency. Specifically, a message may show that nothing abnormal was detected about the patient's state or an indication to consult his or her physician. An emergency message would initiate instantaneous intervention and help. In the case of an emergency, one option may be to support the patient by remotely reprogramming his or her implant. Physicians must also be supported in their daily work to the greatest extent possible, thus facilitating optimum care for their patients. This aim will be achieved by further improving the infrastructure of organizational aspects such as data and information flow.

Discussion

Improved implant telemetry features in the next generation of pacemaker implants will enable physicians to take full advantage of the benefits of enhanced diagnostics. Recent improvements of implant electronics, electrode sensor, and actuator properties made possible by design and surface coating innovations are essential contributions for reaching this ambitious goal. Nevertheless, much work remains to be done and a few more technical problems must be solved in providing patients and physicians with a full range of extended monitoring facilities.

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