Communication Technologies for Improvement of Pacemaker Therapy

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Summary

In the last three decades pacemaker therapy has quickly expanded from merely saving lives to providing highly complex therapies and diagnostics. This article discusses the new possibilities and requirements that come along with the availability of newly-developed communication technologies (GSM, internet) and modern knowledge-based systems. A special emphasis will be placed on ease of use and an even higher degree of safety and comfort as important prerequisites for next-generation active implants.

Key Words

Telemonitoring, tele home care, active medical implants, knowledge-based systems, evidence based medicine

Introduction

The impressive development of pacemaker technology over the past 35 years has been driven mainly by the rapid progress made in the field of microelectronics. As a result, first-generation fixed-rate V00 pacing systems soon incorporated the sensing of spontaneous intrinsic activity (VVI-systems), and were then further developed into DDD pacemaker systems that could provide AV-resynchronization. Various approaches have been made to take into account the patient's current physical load to allow for rate-adaptive pacing.
Other fields like surface and interface physics, as well as materials science, opened the door to new therapeutic approaches such as the use of active-can pacemaker systems and transvenous leads. Today, fractal coated leads allow for high-quality intracardiac signal recordings and, thus, might provide access to new sensor information, such as rejection monitoring by use of the ventricular evoked response (VER) [1].
Based on such milestones in the history of pacemaker therapy, modern communication technologies can today provide valuable new possibilities to support both patients and physicians. Convenient transmission of data from the patient's implant to the attending physician will open the door to new innovative diagnostic and therapeutic options, and will allow for an even more efficient patient follow-up.

Pacemaker Therapy Today

Follow-up at the Physicians Office
Today, a pacemaker patient must visit the attending physician in his office for a follow-up examination. Using near-field telemetry, which has a range of about 10 cm, the physician interrogates the programming parameters and the diagnostic Holter data from the device. Modern implants also allow for real-time IEGM transmission. Based on this information in combination with the patient's general condition, the physician makes his diagnosis and, if required, adjusts programming parameters and/or medication.

TransTelephonic Monitoring
Near-field telemetry requires that the patient be called in for implant interrogation anytime the physician wants to see diagnostic data from the implant. Currently, the only alternative to this is

TransTelephonic Monitoring (TTM), which allows the transmission of diagnostic data via the analog telephone line to a TTM service center, which then relays the data to a physician [2]. The patient can initiate transmission of his/her surface ECG or any selected diagnostic implant data, which must be interrogated from implant memory by means of a special box. The disadvantage of TTM is that it requires the patient to actively initiate and perform data transmission; thus, the use of TTM is restricted to patients with high compliance or to sparsely populated regions. In Europe, with its well-developed infrastructure, TTM is therefore generally of little importance.

General Considerations

Thus, patient follow-up, especially in Europe, is based mainly on patient examinations conducted in the physicians office. The general evaluation is restricted to the patient's current condition; this information is supplemented by the diagnostic data interrogated from the implant memory. Nowadays Implantable Cardioverter/Defibrillators (ICDs) provide considerable memory for diagnostic information. For ICDs, automatic event triggered storing of IEGM strips comprising more than 10 minutes is a common feature to document the occurrence of a ventricular tachycardia and the effectiveness of the device's respective therapeutic countermeasure such as Anti-Tachycardiac Pacing (ATP) or shock delivery. The drawback with current systems is that interrogation of the diagnostic memory is limited by the transmission rate of the near field telemetry link and now takes about 5 minutes for 16 minutes IEGM data. In general, pacemakers without defibrillation capability have limited memory capacity, the interrogated implant data mainly provide basic information and are often lacking in terms of supporting a detailed and differentiated analysis. But even these non-ICD devices provide increasing memory for comprehensive diagnostic data such as IEGMs.

Lack of Compatibility Between Devices from Different Pacemaker Companies

Every pacemaker company today has its own proprietary modulation scheme and data protocol for pacemaker interrogation and programming. The various programmers are therefore not compatible with each other.

Most systems for the documentation of a pacemaker patient's history are paper-based; the PC-based patient data systems which are designed to support devices from different pacemaker companies require manual data input and are mainly restricted to administrative aspects and to the documentation of programming parameters. Automatic data transfer to a PC system is difficult because every pacemaker company has a specific and proprietary communication protocol. Furthermore, comfortable and automatic transfer of diagnostic Holter data is complicated by the fact that nearly every pacemaker or pacemaker family has its own special way of organizing its diagnostic implant memory. As most PC-based patient data systems are company-specific solutions, they do not support the broad variety of implants prevalent in a pacemaker clinic or a physician's office. In addition, not every pacemaker company offers such a PC-based system for its implants, and, as a result, searching for distinct events in a pacemaker patient's history using paper-based documentation is generally very time-consuming.

Because overcoming the incompatibility between implants and programmers from different pacemaker companies can be expected to take a quite long time, the following paragraphs will focus on company-specific solutions.

The complete filing of patient histories on a PC system (e.g., with CDM3000, Biotronik, Germany) is a prerequisite for allowing a physician to ask for rapid second opinions from an expert colleague. Such an on-line consultation might be valuable in case a difficult situation is detected and a second opinion is required within the next few minutes in order to discharge the patient with optimized programming parameters afterwards. As there is usually no emergency situation, the ECG strips and implant data print-outs would normally be sent by mail, resulting in a referral of the patient to the expert colleague, who then performs a complete re-evaluation of the patient.

The transfer of relevant data by means of current internet technology would speed up consultation and could be expected to yield a solution within minutes [3,4]. Such an approach is already implemented in the so-called CHARM-project (Computerized Heart Allograft Recipient Monitoring) to allow for immediate non-invasive rejection monitoring for heart transplanted patients: VER signals are measured at any participating clinic or physician's office with the help of the implanted pacemaker and then transferred via internet to a service center. The service center per-

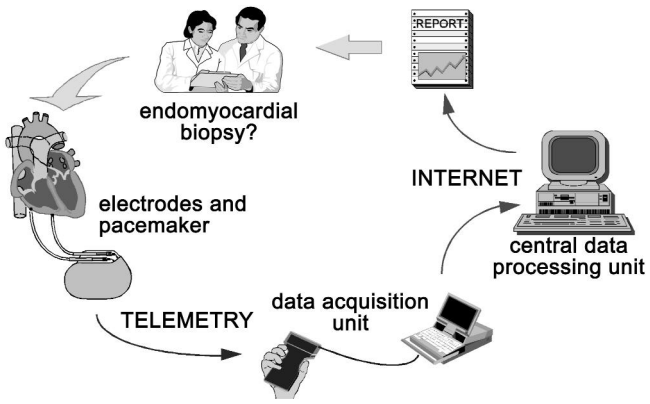

Figure 1. Use of the Internet for remote data analysis: In the CHARM-project (Computerized Heart Allograft Recipient Monitoring) intracardiac signals are telemetrically measured and transferred directly from the data acquisition system to the analysing centre via Internet. The result is then again send to the attending physicians via Internet.

forms signal analysis and immediately sends back the results to the attending physician (Figure 1) [1,5,6].
Due to the present limitations and restrictions in pacemaker therapy, the ideas of evidence-based medicine may hardly be implemented in reality: Today, expert knowledge is only locally available, and generally isolated with no "quick" links. This results in the situation that new therapies are only slowly introduced into broad clinical practice.

Next Generation Pacemaker Therapy

Significance of Diagnostic Functions, Confluence of Antibradycardia and Antitachycardia Devices
In the next future the diagnostic pacemaker functions will be of even more increased significance. This is due to several reasons: Pacemakers have direct access to cardiac signals, bear no additional patient load and may be programmed to automatically store data of relevant episodes without any active contribution by the patient. Next generation implants will provide more memory for diagnostic data and, thus, allow for an even more comprehensive and specific patient evaluation by the physician. Regarding diagnostic features and memory capacity there will be a confluence between antitachycardia and antibradycardia implants. This will permit a very high flexibility regarding relevant diagnostic information in case of any progression of the patient's underlying cardiac disease. Devices with highly sophisticated detection of relevant intermediate or chronic changes in the patient's cardiovascular disease will allow for reliable automatic documentation of relevant diagnostic data even in case of asymptomatic events [7,8].

Long Distance Telemetry
In order to increase comfort for patient and physician, next generation implants will provide an additional long distance telemetry (LDT) link with a range up to several meters. First such devices with LDT have been recently introduced (BA03 DDDR, Biotronik). In combination with a modified GSM handy the so-called Home Monitoring system will enable the physician to receive specific implant data from remote patients without having the patient in his office and without any active contribution by the patient [9]. Transmission is initiated by the implant and may be triggered by a time criterion or by magnet application; later devices shall also allow for an automatic event triggered transmission. The transmitted data are translated to a one-page fax (Cardio Report), which is sent to the respective patient's attending physician (Figure 2). Based on the patient's individual requirements this feature may be activated permanently or for defined periods and will open new innovative diagnostic and therapeutic options. With the wide spread availability of the GSM communication network diagnostic data will be available at any daytime and irrespective of the patients current residence. With the transmitted information the physician can monitor the patient quasi on-line, based on a very dense trend of selected parameters, and thus allow a quick, comfortable and efficient therapy control, also regarding a combined therapy with active implant and medication. Furthermore, the physician may also be automatically and immediately informed in case of a potential emergency situation. Additional localization functions (such as GPS) in the modified handy might provide information on the patients current residence. With the LDT providing transmission rates and bidirectionality comparable to modern near field telemetry links the LDT may also allow for a more comfortable interrogation of extensive implant memory in the physician's office. This interrogation might take place, e.g. in the waiting room of the office. Another application may be the on-line monitoring of the patient's IEGM when undergoing a stress test. With

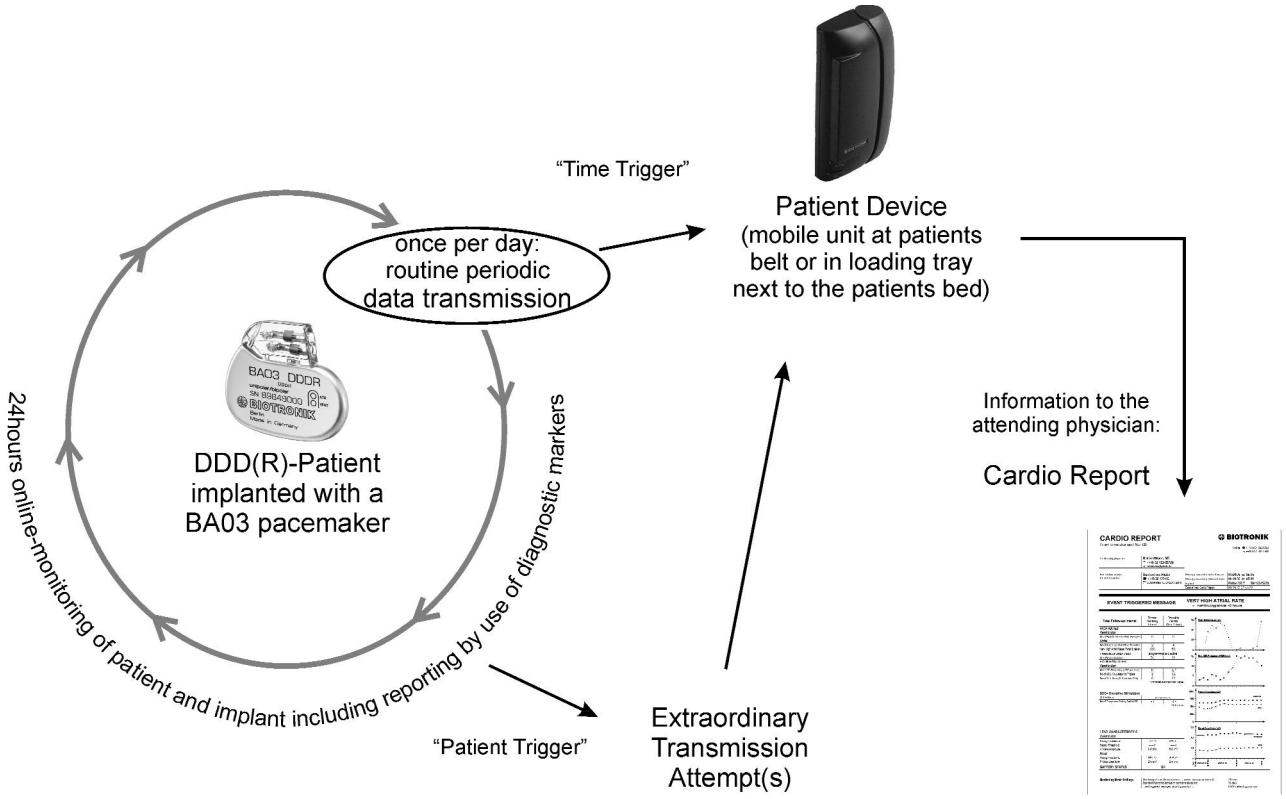

Figure 2. The Home Monitoring concept, based on a pacemaker with long distance telemetry (BA03 DDDR, Biotronik) and a so-called patient device, which forwards the received implant data via GSM communication network. The patient's attending physician receives the data as a one-page fax (Cardio Report).

full duplex LDT the effects of modified implant parameter settings can be immediately monitored.

Data Analysis, Knowledge-based Systems and Data Network

The growing amount of diagnostic data in the implant memories require new efficient tools to support the physician when analyzing the comprehensive data in order to evaluate the patient's specific condition. The so-called Scholiast system (Biotronik) is a first prototype for knowledge-based analysis of implant Holter data [10,11]. To increase ease of use, such assisting systems shall present the data according to the individual physician's preferences and the respective situation's requirements. The PC-systems shall provide interfaces which allow to link to any office or clinic system. The data acquisition and presentation will be optimized with respect to the patient's situation and the physician's need by increasingly sophisticated implants and interrogation/programming devices: It will evolve from a static presentation of a fixed scope of implant data towards a representation of the cardiovascular state combined with a proposal for an optimized solution; from programming the whole set of parameters towards a goal oriented programming (Figure 3).

Quick access to all data from pre-implantation until the current follow-up's interrogation demands for network solutions which organizes all the patient's data and diagnoses from several involved physicians. It must allow different clinical and technical expert colleagues to access simultaneously to the relevant data and find the best solution by interactive communication. The system will assist this interactive search for the best solution by active support. Optimal decision support given by a PC-based expert system comprises:

- The presentation of the best matching similar cases extracted from a case base by similarity metrices;
- The solution derived from a rule base incorporating the state-of-the-art clinical expertise;

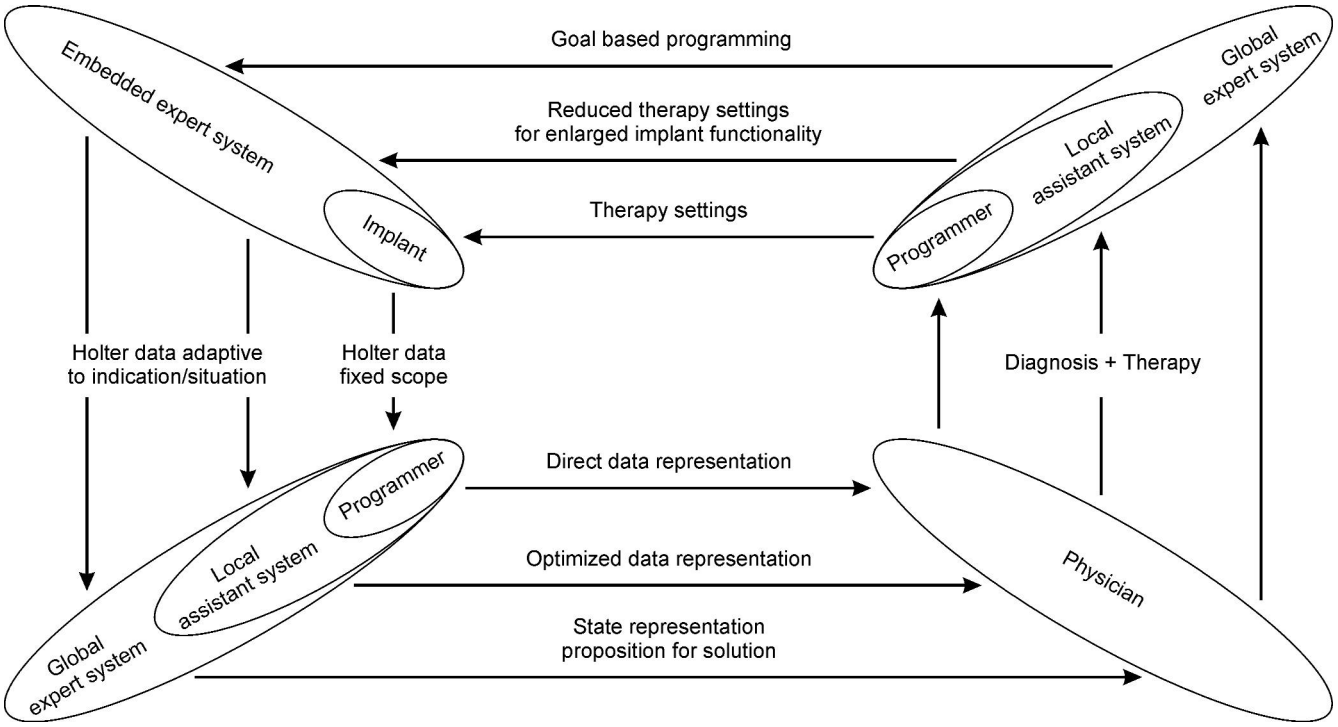

Figure 3. The Evolution of implant programming: Today (inner circle) the physician analyses a predefined set of holter data and reprograms the device by setting the complete set of parameters. With the advent of implant embedded expert systems and local assistant systems (middle circle), the holter data will be specific and self adaptive to the patient's cardiac state and the data will be presented with a focus on data demanding the physician's action. The number of parameters will be reduced irrespective of enlarged implant capabilities. In the future, the global expert system (outer circle) will no longer present raw data to the physician, but representatives of the cardiac state. It will suggest an optimised therapy. The programming of parameters will be replaced by the programming of therapeutic goals.

- Extended data analysis shall be done by the use of a meta analysis correlating data of different origin and yielding limiting values for case classification and reference distributions.

The assisting expert system itself will develop with time from a local assistant of fixed contents with isolated users towards an open system permanently acquiring new cases and deriving new rules from the contributions of an increasing number of participants (Figure 4). The global availability of anonymous and statistical data will strongly support the idea of evidence based medicine in the electrotherapy with implants.

Long Term Perspective for Pacemaker Therapy

One main aspect of the long term perspective for pacemaker therapy is the search for diagnostic key parameters for patient evaluation and to make them available by the development of new sensors. Analysis of the intracardiac signals as the VER for rejection monitoring, for evaluation of a patient's current cardiovascular load, or for evaluation of the ejection fraction, are first steps towards this very promising direction. Such new diagnostic parameters shall provide a more detailed insight into the hemodynamic and energetic conditions the heart currently faces. The implant might automatically reprogram itself in order to optimize electrotherapy according to the changed disease.

Further access to cellular, electrophysiologic, hemodynamic and/or cardiovascular key parameters is also an essential aspect to identify early characteristic hints at upcoming adverse events and/or disease evolution. Such diagnostic precursors allow to develop preventive therapeutic countermeasures to optimize the patient's long term outcome. Especially designed monitoring implants with LDT might support the physician to come to a more detailed individual diagnosis even when conventional methods do not yield sufficient

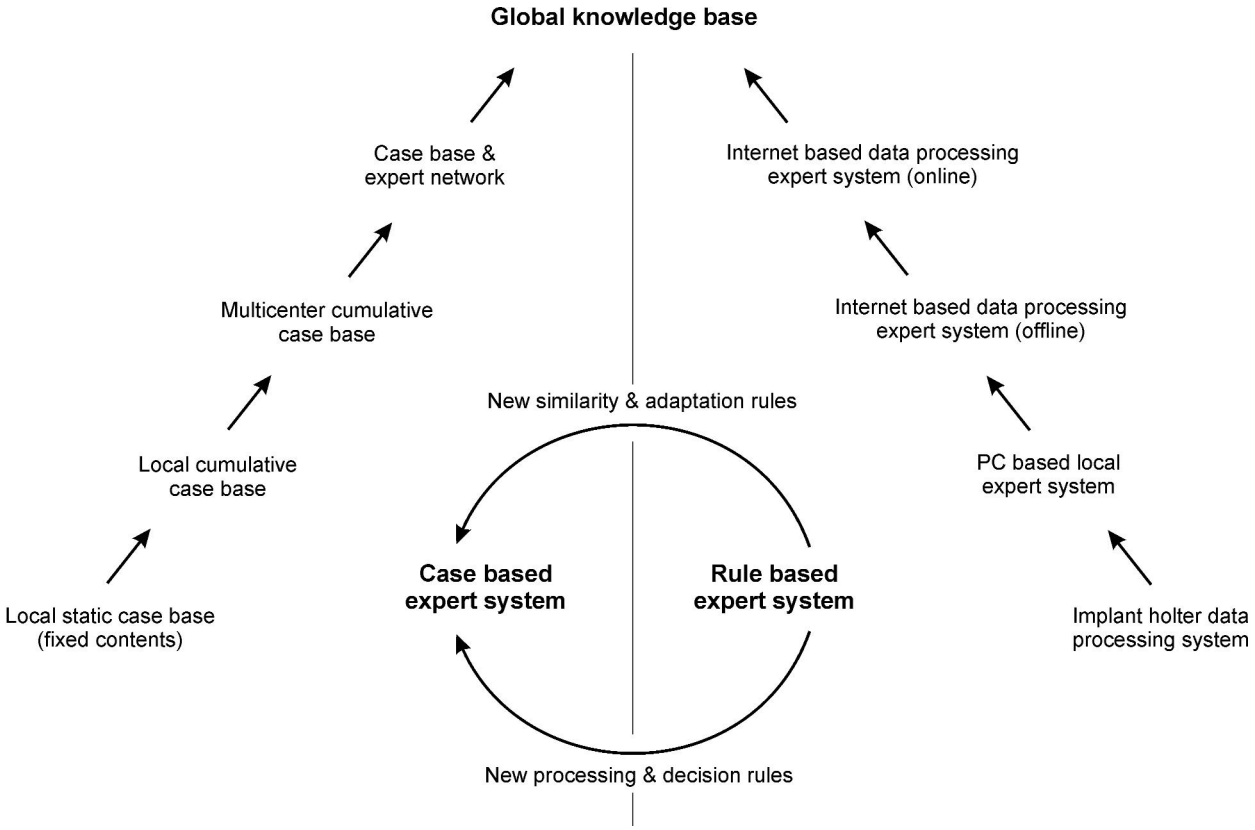

Figure 4. The way towards the global knowledge base: The parallel development of case based and rule based expert systems will eventually result in the knowledge based expert system. The expert systems will change from local assistants giving access to one user only into systems simultaneously accessed by several users. Instead of a fixed number of cases or rules, they will be able to automatically and continually acquire new cases and derive new expert rules.

information. Another interesting topic might be the integration of cardiac monitoring by active implants with information from other remote monitoring technologies such as diabetes monitoring, anticoagulation monitoring, or monitoring patients with sleep apnea. A close cooperation in this field of tele home care may allow for a more detailed insight into the interrelations between the different forms of disease.

Conclusion

Pacemaker therapy has made a very impressive development until now, but the perspectives for the next and long term future are even more promising. Development of new therapeutic strategies will bring clinical benefits to patient groups, which, by use of conventional concepts, have not been accessible until now.

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