The follow-up of cardiac devices: what to expect for the future?

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The number of implanted cardiac devices has dramatically increased in recent years. Moreover, these devices have developed from simple, fixed-rate pacemakers to multi-programmable systems with an ever-increasing amount of information retrievable and programming options available. With the advent of the implantable cardioverter-defibrillators and cardiac resynchronization therapy, devices have become even more complex. New sensors for heart failure monitoring may be expected to make an important impact and at the same time make follow-ups more time consuming. This will increase the demands on follow-up centres, physicians, technologists, and nurses while there is only a limited workforce available due to budgetary restrictions. Therefore, new ways of patient management after cardiac device implantation are needed. This article discusses what new approaches for patient follow-up are currently being developed and investigated in the clinical arena with an emphasis on telemetric device surveillance.

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Remote monitoring

There is no doubt that pacemaker therapy has made major advances in the 50 years since the first pacemaker implant: the antibradycardia pacemaker has developed from a simple single-chamber, fixed rate device without programming capabilities to the multiprogrammable, dual-chamber rate-modulated pacemaker.

The implantable cardioverter-defibrillator (ICD), moreover, has added multiple tachycardia options, both for detection of supraventricular and ventricular arrhythmias as well as treatment including antitachycardia pacing, cardioversion, and defibrillation. Apart from antibradycardia and antitachycardia pacing, cardiac resynchronization therapy (CRT) has significantly widened the therapeutic spectrum for electrical therapy of the heart.

At the same time, the number of cardiac rhythm device implants has almost exploded. For example, in the US, the number of pacemaker implants per year has tripled and the number of ICD implants increased 10-fold between 1990 and 2002, adding up to more than 350 000 device implants in 2002.1 This impressive development, however, has recently created new problems, namely the increasing time demands and knowledge required by physicians to provide the optimal post-operative care for all implanted patients. A sophisticated device that has the capability to deliver optimal diagnostics and therapy to meet each patient’s needs requires individualized programming, which is usually different from the ‘default’ setting provided by the manufacturer. Moreover, with change in the patient’s clinical status adjustments of device programming are frequently necessary and device malfunctions need to be discovered as soon as they appear, because they may impair patient safety. In fact, with more complex devices, malfunctions have become an increasing problem, especially in ICDs.1

With the increasing complexity of pacemaker interrogation and programming, a higher level of training of the caring physician is required and the chance of programming errors is increased. These demands clash with the increasing shortage of physician and paramedical work and the increasing time demands and knowledge required by physicians to provide the optimal post-operative care for all implanted patients. A sophisticated device that has the capability to deliver optimal diagnostics and therapy to meet each patient’s needs requires individualized programming, which is usually different from the ‘default’ setting provided by the manufacturer. Moreover, with change in the patient’s clinical status adjustments of device programming are frequently necessary and device malfunctions need to be discovered as soon as they appear, because they may impair patient safety. In fact, with more complex devices, malfunctions have become an increasing problem, especially in ICDs.1

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force, mostly caused by healthcare and hospital budget restrictions. The most important question for the future of device follow-ups, therefore, is whether technological improvements can reduce the demands on the physicians and their teams taking care of device recipients. Automatic adjustment of pacing output according to the actual pacing threshold of the patient has been shown to be safe and effective for increasing device longevity and thus therapy costs. However, this technology is not suitable for reducing the follow-up workload because follow-up of modern pacemakers requires much more than simple measurement of the pacing threshold. There are two major routes that physician and industry have pursued in recent years in order to cope with this problem: (1) telemetric device surveillance and (2) expert systems helping physicians in decisions concerning device indication, choice of device type, and optimal individualized device programming.

Telemetric device surveillance

Current follow-up schedules of pacemaker and ICD patients consist of regular visits, usually at 4–6 weeks after the initial implant and every 6–12 months in pacemaker patients or 3–6 months in ICD patients, respectively. Additional follow-ups may become necessary in case of symptoms (e.g. dizziness, syncope, or ICD shock). This follow-up scheme has several disadvantages: many follow-ups are made without any clinical consequences and arrhythmias (e.g. episodes of atrial fibrillation) as well as potentially dangerous device malfunctions may go undetected until the time of the next scheduled follow-up. The consequences of therapeutic decisions made at one follow-up can only be assessed months later, at the next visit. In addition, time resources in the pacemaker clinic are difficult to plan because simple routine checks and demanding cases are scheduled with the same amount of time.

Telemetric transmission of pacemaker data to the follow-up centre is an appealing approach to provide the physician with close supervision of device system integrity, measured pacing, and sensing parameters as well as arrhythmia episode data without the patient having to come to the hospital. Several systems for telemetric device surveillance have been launched by different pacemaker companies, such as the Latitude™ system (Boston Scientific, Natick, USA), the HouseCall™ system (St. Jude Medical, St. Paul, USA), the CareLink™ system™ (Medtronic, Minneapolis, USA), and the HomeMonitoring system (Biotronik, Berlin, Germany). Each of these systems has some individual features.

The Biotronik system, for example, has a pacemaker with a small antenna that can automatically transmit pacemaker data via a short-messaging-service system. This has the advantage that patient cooperation is not necessary. Early trials have demonstrated that the system has satisfactory function. However, the clinical benefit is hard to measure and data are lacking on whether this technology is actually cost-saving.

Other systems rely on transtelephonic messaging. In this instance, the patient actively puts a telemetry wand on the device and the interrogation is transmitted by a modem. In fact, transtelephonic monitoring is not a new technology. Early studies with transtelephonic monitoring of electrocardiograms date back to the late 1970s and its use with pacemakers was studied in the early 1980s. However, the type and amount of information provided by modern devices is now much different from these earlier studies and modern technology allows the transmission of complex information such as ICD episode data or stored electrograms. Usually, the information derived from the pacemaker is sent to a call centre, which generates a pacemaker report that optimally should be almost identical to the type of report the physician is used to see during a patient visit at his clinic. This report is usually accessible via the internet. Eventually, the telemedicine surveillance of implanted devices will need to be cost-effective to be successful, i.e. regular follow-up attendance will have to be omitted. Preliminary data indicate that prolonging regular follow-ups in ICD patients with the use of home monitoring is safe and does not lead to an increased number of unscheduled clinic visits.

The spectrum of remote device monitoring will be further broadened by the additional information that modern devices provide apart from the electrical data and arrhythmia analysis. With the increasing number of heart failure patients being implanted with ICD and CRT systems, measuring physiological parameters that reflect the patient’s haemodynamic status will become more important. Thus, the device of the future will not only be a therapeutic implant but will also potentially prevent clinical deterioration by detecting subtle changes in the cardiac status before frank cardiac decompensation occurs. Several such parameters are already incorporated in devices today such as heart rate variability analysis, transthoracic impedance measurement, and haemodynamic sensors of right-sided pressures integrated into the pacing leads. Current studies evaluate whether these parameters are sufficiently reliable to predict cardiac decompensation so that they can be used in a routine setting. If the information from reliable haemodynamic sensors could be combined with remote data transmission, it seems possible that such technology may lead to a major reduction in hospitalizations in these patients with advanced cardiac disease.

Despite these advantages, some problems with remote device monitoring remain. First, remote programming will not be possible in the foreseeable future due to regulatory issues. Secondly, some legal issues must be resolved, e.g. the question of who is legally responsible in the case that a message of a severe device malfunction is transmitted to the follow-up centre when there is nobody available there and the patient has an adverse event before anybody can react to the message. Thirdly, the infrastructure of telemedicine services is costly and in many healthcare systems in Europe the question of reimbursement by the healthcare providers is as yet unresolved. Fourthly, telemetric surveillance
allows close patient supervision, i.e. on a day-to-day basis. If this amount of data is to be screened by the physician and reaction is required in case of potential problems, this would result in an enormous additional burden to the physician, nursing, and technical personnel. Thus, data filtering to prevent flooding of pacemaker follow-up centres with unnecessary information is of utmost importance, as are tools for quick and easy handling of the information provided. Finally, if remote monitoring of implanted devices will become the standard of care, this will have important implications on how pacemaker clinics need to be organized in the future. Nevertheless, remote monitoring of implanted devices will certainly become increasingly important in the years to come.

Expert systems for easier indication decisions, device choice, and programming

Another way to alleviate the work for the physician who performs pacemaker programming and follow-up is an expert system with integrated existing knowledge about implantable cardiac devices, which is integrated into the programming device. In this setting, the physician would only have to enter the patient’s clinical data and the programmer would make recommendations for programming the device settings, optimally independent of the manufacturer. Initially, expert systems have only been used for aiding physicians in the analysis of pacemaker ECGs.14 More recent data on an implant assistant for ICDs have been more encouraging.15 However, with the current speed of development of new parameters integrated into devices and the competition between manufacturers, such a system, especially for device follow-up, would need to be constantly adjusted to the current needs, which is likely to make such a development rather costly. Nevertheless, because of the growing complexity of pacemakers, ICDs, and CRT devices, such systems may ultimately become indispensable tools for optimized patient care in the future.

Conclusions

In summary, the growing number and complexity of cardiac pacemakers, ICDs, and CRT devices requires new approaches for device follow-up. Future devices will probably have even more programmable parameters and diagnostic features available, at the same time there will be no increase in physician work force in the foreseeable future to meet these growing demands. Technical solutions such as remote device surveillance and expert-system-based programming assistants are currently in development. Implementing these tools will eventually reduce the problems of increase in follow-up burden. On the way to this goal, however, many technical, regulatory, and legal questions will have to be solved.

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