Remote monitoring of implanted cardiac devices: a plea for a nationwide exploration

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Remote monitoring of implanted cardiac devices is an evolving method for regular checks of their electronic integrity and functioning. The communication with the devices is carried out unsupervised with wireless trans-telephonic or cable-dependent linkage. The interrogation of the device examines several programmed functions and harvests the stored data of numerous events. The collected data constitute the base to decide whether the implanted device is operating properly and can give some information about the physical condition of the device recipient. Preliminary short-term results show favourable effects in terms of safety and cost and time saving as compared with the current face-to-face visits of conventional patient follow-ups. Remote monitoring of implanted devices will extend markedly in the coming years and its development touches many questions ranging from technical accuracy, patient benefit, cost-effectiveness and responsibilities of the provider and receivers of the delivered device data, to the role of the cardiologist and allied professionals and of course privacy rules. In this point of view, these questions are discussed in order to explore the consequences of device remote monitoring with nationwide trials. (Neth Heart J 2009;17:434-7.)

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In Western countries, the yearly implantation rates of cardiac devices have grown markedly in the past decades because of the introduction of new indications and ageing of the population. Nowadays the distribution of new implantations of conventional pacemakers (PMs), cardiac resynchronisation therapy (CRT) devices and implantable cardioverter defibrillators (ICDs) is approximately 81, 11 and 8% of all implantations.¹ This development requires more face-to-face visits for the device patient, with or without device checks. Not only the total number of those patient contacts has increased but for specific patient categories the number of contacts per patient has also grown markedly. The latter is related to the complexity of the cardiac abnormality, progressive comorbidity and polypharmacy of the mostly elderly device recipients. It has to be recognised that clear differences exist between patients with conventional PMs and those with CRT and ICD in terms of prognosis, attitude, quality of life and health perception, all factors that also determine the frequency and intensity of the outpatient controls.

Current cardiac devices contain extensive algorithms for bradycardia pacing with or without facilities for tachycardia intervention or biventricular pacing for resynchronisation of the failing left ventricle. In addition to many programmable parameters, extensive data-logging makes it possible to establish the functioning of the device in the past period of time as well as informing on various characteristics such as daily heart rates, arrhythmias and so forth.² This enormous amount of information can be fully retrieved at the time of patient control with the device check. Interpretation of the stored data, however, is time-consuming and strenuous, and requires experience to ensure appropriate functioning and determine optimal programmed settings to anticipate the next event. Therefore, organisation of the data to allow a quick and reliable analysis constitutes a high priority in the present time of increasing numbers of device recipients.

Remote or trans-telephonic monitoring of stored data via wireless GSM or cable systems has shown to be an

accurate method for control of the implanted cardiac device and with some restrictions also of the device patient.^{1,3,4-6} This tele-cardiology can be applied for the necessary data reduction without loss of periodic crucial information on numerous device parameters and some patient characteristics. This technical breakthrough can have so many consequences that the cardiology profession has to prepare its implementation for daily practice. In this report various aspects and questions will be presented which, in the near future, will need to be clarified regarding how to deal with tele-cardiology and remote monitoring.

Current device follow-up in the outpatient clinical setting

Recent guidelines have indicated how to follow up the implanted device and the device patient⁷ but it is still unclear how these recommendations should be implemented in daily practice. Regarding pure bradypacing, the FOLLOWPACE study⁸ showed that during the first year after first PM implantation, the amount of reprogramming needed was very small, while the 'out of the box' programmed settings, such as manufacturer default choice, were changed in nearly 50% of the patients, mostly limited to minor changes. This practice differs strongly from programmed settings in ICD and CRT recipients in whom onset of ventricular tachyarrhythmias and optimisation, respectively, constitute the triggers to (repeat) follow-up visits and reprogramming of the device. In the latter patients, these face-to-face visits are very time-consuming and demand a deep insight into the arrhythmias, the intervention methods of the device and the interaction of the programmed parameters. These analyses are much more complex than the relatively easy control of the PM patient. This difference in clinical profile as well as in technical characteristics of the device guides the choice to continue face-to-face visits or use of remote monitoring.

Technical aspects of remote monitoring

An increasing number of implantable cardiac devices are equipped with telemetry technology that does not require the presence of a telemetry wand directly above the device for data communication with the device. This enables automatic, patient-independent transmission of diagnostic information stored in the device memory. Some devices use technology where the patient him/herself places a minimised communication wand above the implant. The communicated signals are relayed to a local module in the vicinity of the patient. That module delivers the messages to a dedicated service centre which decodes, analyses and organises the data. The service centre can post the messages on a secured website with access restricted to the physician in charge or allied health care professionals. Other systems automatically generate electronic mail messages to the hospital office of the individual device centre. The contents of the event reports can vary

Table 1. Remote PM monitoring: event notifications.

Pacemaker and leads: integrity and functioning of the implanted device

- Battery condition: depletion condition and impedance measurements; elective replacement indicator
- Pacing or shock lead condition: impedance and its changes
- Automated pacing threshold measurement
- Automated sensing threshold measurement
- Detection of interference interrupting correct device functioning

For ICD: arrhythmias episode diagnostics, shock effectiveness

- Diagnostic features of the device recipient
- Incidence, duration, onset and offset of atrial and ventricular arrhythmic events, mode switching for atrial tachycardia and other arrhythmic events
- Survey of daily heart rate: to determine the medication effects, pacing rate, pattern of rate response pacing
- Atrial/ventricular pacing percentage, see CRT
- Vital signs: including daily activity pattern, heart rate variability and intrathoracic impedance as a measure of pulmonary capillary wedge pressure

from information about the functioning of the device to integrity system alerts and diagnostic data (table 1).

Initial results of remote monitoring

Recently, several small and large-scale outcome studies showed that remote monitoring is safe and effective but the follow-up time of these observations is limited to some months or less than one year. Reviews of ICD remote monitoring demonstrated that the safety and quality of care was equivalent or higher than in-office care.^{3,5,9,10} The risk of missing a clinical event requiring a clinical visit was estimated at 0.1 to 0.46% and the number of clinical visits of patients with remote monitoring diminished by 50 to 75%. In addition, physician time for the ICD checks dropped by 40 to 70% as compared with conventional visits. Moreover ICD remote monitoring shortened the time needed for the outpatient visit of patients with trans-telephonic monitoring. This reduction was threefold higher in patients without 'VT/VF episodes' and twofold higher in those with 'VT/VF episodes' than the visit time required for patients controlled in the conventional manner. The OEDIPE trial⁶ comparing remote monitoring after 24 hours to one month after discharge after conventional PM implantation or replacement versus a standard in-hospital stay (mean 2.8 days) observed that 50% of adverse events emerged in the first 24 hours of hospitalisation. After early discharge the reception of 1±1.5 messages/patient/month before

the 5th day after implantation diminished to 0.5 messages/patient/month afterwards, as measured during a one-month follow-up after the implantation. The reaction time was 3.0 days for major adverse events and 8.2 days for non-major adverse events in the remote monitoring group versus 6.6 days for major adverse events and 17.5 days for non-major adverse events in patients followed conventionally. It is of importance to note that in 40% of patients correctly no warning message was delivered with remote monitoring: this finding is consistent with a negative predictive value of absence of message of 94%. It is also noteworthy to mention that most major medical adverse events were mailed by the device patients. A small study of patients with various implanted devices (n=117) demonstrated the impact on patient care. After mean follow-up of seven months, in >1/3 of patients data on remote monitoring led to major drug changes or device programming.⁴ Finally, the AWARE retrospective study on the contribution of home monitoring in >11,000 patients with various types of implanted devices could demonstrate that adverse events occurred after a mean of 26 days after the last visit, advancing the diagnosis to 154 days.³ One can easily conclude that device patients can profit from remote monitoring in terms of early adverse event diagnosis and secondly the device centres probably save time and energy with trans-telephonic monitoring.¹⁰

The electronic triangle

Implementation of remote device monitoring involves device and patient data being automatically transferred from the patient to the service centre and then to the cardiologist or device technician in charge and vice versa. This electronic traffic evokes the paramount question of the final responsibilities in terms of correct analysis, reaction content and reaction time, attempted reassurance and patient management followed. Secondly, one can question whether remote monitoring fulfils the needs of the device patient in terms of sufficient attention and compassion from the physician. On the other hand overflow of redundant messages might create anxiety impairing health perception. Indeed, remote monitoring produces an enormous amount of information consisting of physician's selected programmes, battery and lead condition predicting longevity, endurance of components and interactions with the paced heart and the patient's surroundings. These numerous events and data can be used for the design of coming generations of devices and are therefore not only profitable for the device manufacturers but also for next generations of device recipients. This triangle potentially offers much more information on device characteristics and behaviour and the natural course of the device recipient than ever before – detailed information that can never be gathered by (inter) national prospective registries. The contribution from tele-monitoring to patient care for recipients of active implantable devices is obvious.

Unanswered questions

Although preliminary findings show that the chain of transmission of stored data and remote analysis appear to offer solutions to many clinical issues, many questions arise, as listed in table 2. It is unclear whether the selection of data retrieved from the memories followed by analysis belongs to the domain of the primary health provider(s) in the implanting centre or can be left to the service centre. This selection should reflect the needs of the individual device recipient (sometimes to circumvent unnecessary interventions evoked by recalls) and the specific interests of the device centre. The interaction between the service centre and the cardiologist and/or device technician strongly determine the time needed for interpretation of the received messages as well as the response time to adapt or reprogram the device or change medication. Actually, the interaction determines whether remote monitoring can improve the quality of the follow-up care. In this respect it is worthwhile to identify the device patient who can profit most from remote monitoring. Up until now, this interaction has only been examined very superficially, yet it constitutes the major contribution of remote monitoring to quality of care. In the next reports of the ongoing FOLLOWPACE study, the discrimination between low- and high-risk PM patients in terms of medical and technical characteristics, (co)morbidity and prognosis will be addressed.⁸ This will allow selection of the patients in whom remote device monitoring will be most beneficial and safe. A very important aspect of remote monitoring is the set of legal, technical and professional conditions to guarantee patient privacy. In contrast to well-defined privacy rules for face-to-face patient visits and hospital data storage, there is no legislation at all for remote monitoring. This gap

Table 2. Remote monitoring: study objectives.

- Safety and accuracy of transmission of data and messages to device centre
- Selection of the transmitted data: analysis leading to data reduction
- Reaction time between message and patient contact: improved quality of care?
- Selection of device recipients suitable for remote monitoring
- Feedback to PM centre: reduced workload for cardiologist and technician
- Legal aspects as privacy rules, responsibilities of various parties
- Patient and physician satisfaction
- Cost of remote monitoring for patient, device centre and assurance company
- Reimbursement for investments and long-term efforts of various parties

requires the development of guidelines for all involved parties. Finally, it is now unclear who pays for remote monitoring and who will be reimbursed. Because insurance companies dictate face-to-face visits for the follow-up of active devices after implantation, evidence-based indications and rules should be formulated in the short term to convince them that remote monitoring improves the quality of follow-up and saves time and budget.¹¹ These outcomes serve to defend the opinion that all parties involved in remote monitoring deserve reimbursement according to their efforts.

Future directions

Although until now remote monitoring has entailed a limited set of technical and vital parameters informing superficially about the physical condition of the device recipient, preliminary data clearly show that this approach is more than a technocult. New biological parameters will undoubtedly be implemented in current device technology and eventually lead to tele-cardiology which surveys the haemodynamic, arrhythmic, pulmonary and metabolic condition of the cardiac device patient. Before the time is ripe to fully incorporate this new technology in daily cardiology, a period of learning and testing is needed. Several prospective trials have already been launched to assess the total number and types of clinically actionable events and possible benefits, such as the PREFER study¹¹ and the TRUST study.¹² A Dutch nationwide prospective comparative study to examine several aspects (table 2) of remote monitoring of implanted cardiac devices can bring out a tailored and sustainable remote device monitoring for the next generation of device recipients. The participation of many implanting centres and all device manufacturers is a requirement to get sufficiently representative data to formulate evidence based recommendations and also reimbursement for the coming efforts in this field. ■

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