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REVIEW

Home Monitoring for Implantable Devices: New Technology & New Service

Herwig Schmidinger, MD

Department of Cardiology, University of Vienna, Vienna, Austria

ABSTRACT

The use and need for follow-up of cardiac electronic implantable devices, such as pacemakers and implantable defibrillators, is constantly increasing, and constitutes an ever-growing burden and cost in clinical practice and the health system in general. Telemedicine or remote, wireless home monitoring (HM) has recently come to aid in this situation and reliably retrieve information on the patient's and device's status and transmit it to the implanting center and physician. It thus offers considerable convenience and assurance to both patient and physician. To date this technology of remote monitoring allows continuous and episode related arrhythmia monitoring as well as continuous monitoring of the status of the implanted system (battery status, lead impedance). Preliminary data from ongoing large multicenter studies are promising and relate to the diagnostic power of telemetrically transmitted data, necessity for patient follow up, the influence of HM on the optimisation of device and medical therapy, and the impact of HM on cost- effectiveness in device therapy.

KEY WORDS: *pacemaker; implantable defibrillator; telemedicine; wireless data transmission; home monitoring; remote monitoring*

INTRODUCTION

In contemporary cardiology the use of highly sophisticated implantable devices, such as pacemakers (PM) and implantable cardioverter defibrillators (ICD), is increasing, constituting an ever-growing burden on both clinical routine and costs. Due to the technological complexity of these devices and their use in critically ill patients regularly scheduled follow -up visits are mandatory to obtain information on both device status and performance. On top of these regularly scheduled clinical visits, event related visits further increase the burden to the health system.

ABBREVIATIONS
HM = home monitoring
ICD = implantable cardioverter defibrillator
PM = pacemaker

Correspondence to:
Herwig Schmidinger, MD
Professor of Cardiology
Department of Cardiology
University of Vienna
Vienna, Austria
E-mail:
herwig.schmidinger@univie.ac.at

CURRENT DEVICE FOLLOW-UP SCHEME

The currently used follow-up scheme has some marked disadvantages: 1) many follow-up procedures are performed routinely only not requiring any change in device or drug therapy, 2) programmer based tests are performed under artificial conditions not reflecting real life, 3) asymptomatic arrhythmia episodes or changes in the arrhythmia pattern are hidden until the next regular follow up is performed, 4) there is

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no direct feed back on the efficiency or adverse effects of the device therapy, and 5) early indicators for potential device failure in the near future are of reduced or no value.

WIRELESS REMOTE HOME MONITORING

To overcome the drawbacks of the current scheme the idea of telemedicine or home monitoring (HM) has come up which would allow to reliably retrieve information on the patient's and device's status although analyser and patient are distant from each other.[1-9] To date this technology allows continuous and episode related arrhythmia monitoring as well as continuous monitoring of the status of the implanted system (battery status, lead impedance). Future perspectives include monitoring of vital cardiovascular parameters and bidirectional telemetry i.e. telemetrically reprogramming of the device. The possible advantages of HM include a close medical supervision of improved quality, monitoring of success and adverse effects of device therapies with increased resolution and documentation of complications. Thus the follow up scheme probably may be individualized for the patients reducing the overall burden on the health system.

Figure 1 graphically shows the HM system. The implanted device automatically transmits data from the device memory over a distance of several meters using unidirectional long-range telemetry, i.e. without the need of a programmer head. The data is transmitted to a patient device that is placed a few meters away from the patient, and this device forwards the data via mobile phone technology to the BIOTRONIK Service Centre. This transmission happens in an automatic, periodic or event triggered manner. Pacemaker messages may also be patient triggered via application of a magnet. The data received by the BIOTRONIK Service Centre is gathered, presented in graphs and tables as a Cardio Report and forwarded to the physician via fax or e-mail in the intervals he/she specifies. The intervals can be chosen to be patient specific and can easily and instantaneously be adapted to the physician's actual needs. Furthermore, the sending of a Cardio Report can also be triggered by event criteria, i.e. a Cardio Report goes out to the physician whenever the incoming data fulfils certain criteria specified in advance by the physician.

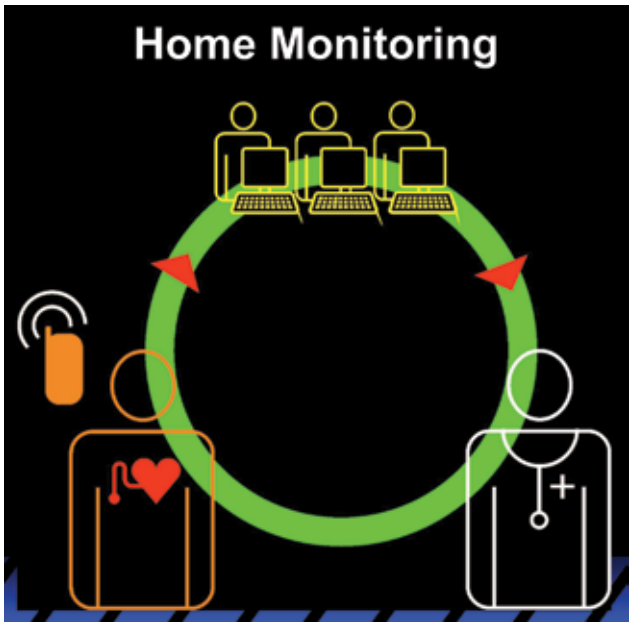

FIGURE 1

Figures 2 a+b show an example of a Cardio Report generated by the BIOTRONIK dual chamber PM "Philos DR-T". Information is given on the intrinsic and stimulated heart rhythm, AV conduction and battery and lead status. Figure 3 shows an example of a Cardio Report generated by the BIOTRONIK single chamber ICD "Belos VR-T". Episode data report the number of episodes detected in the different tachycardia zones, therapy data report the number of anti-tachycardia pacing episodes/shocks that have been delivered and the proportion of success and system data give information on the battery and lead status.

MULTICENTER STUDIES

There are 2 ongoing international multicenter studies (Philos DR-T and Belos VR-T) that investigate the diagnostic power of telemetrically transmitted data with regard to the necessity for patient follow up, the influence of HM on the optimisation of device therapy and additional medication, the acceptance of HM by the implanted patient and last but not least the impact of HM on cost- effectiveness in device therapy. Preliminary analysis shows that 100% of messages were correctly transmitted and that 97% of all messages reach the Service Centre in less than 3 minutes. So far it can be concluded that the technology for mobile seamless monitoring is available and the technical feasibility is proven. It appears that HM indeed does enhance PM and ICD diagnostics by automatic monitoring with 24 hour resolution and event related reporting. Extrapolated from retrospective data obtained at our own institution it may be anticipated that HM is cost effective. Between 1990 and 2003 a total of 627 patients received an ICD. During this period a total of 10.634 follow up visits was performed of which in only 23.2 percent one or the other action had to be done. Given the cost of 139 € per follow up a total amount of 1.140.999,0 € could have been saved had HM been available.

In **summary**, HM is technically available and feasible. Preliminary data from ongoing large international multicenter studies are promising. Recent analysis of a world-wide data-

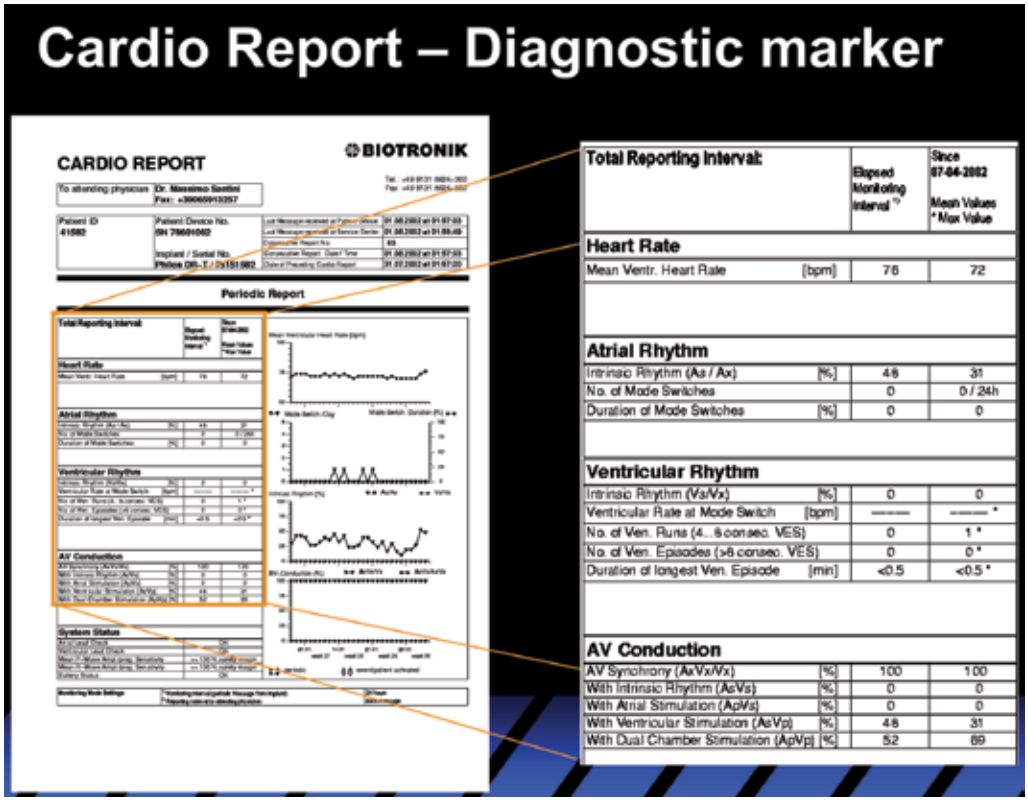

FIGURE 2A

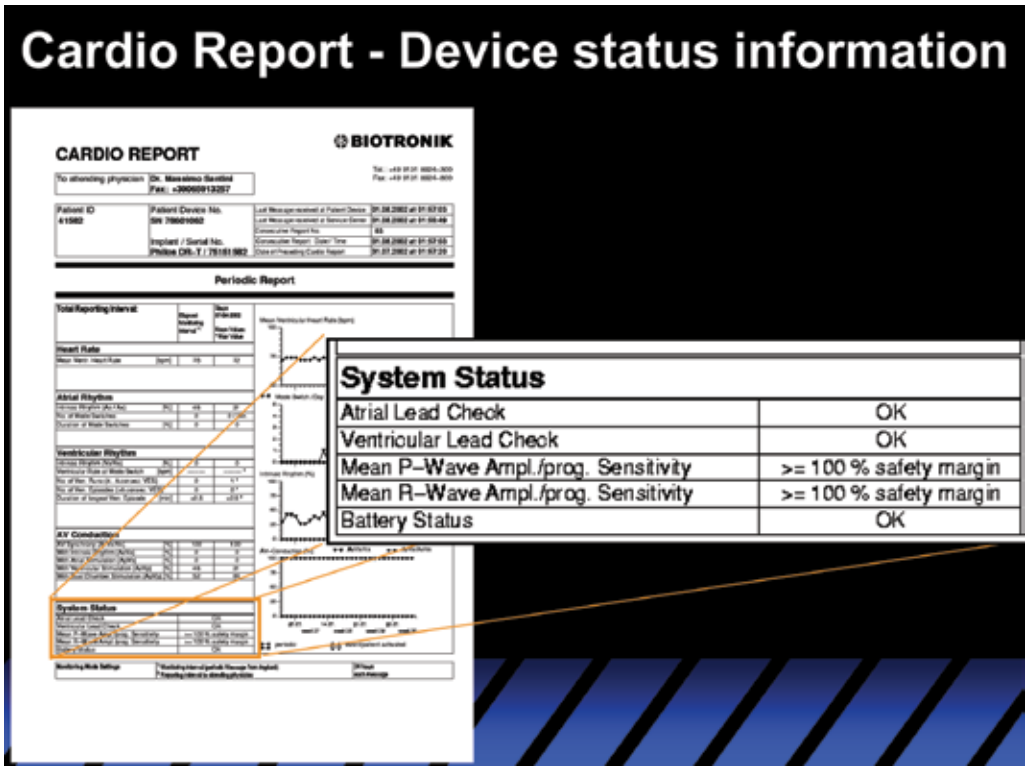

FIGURE 2B

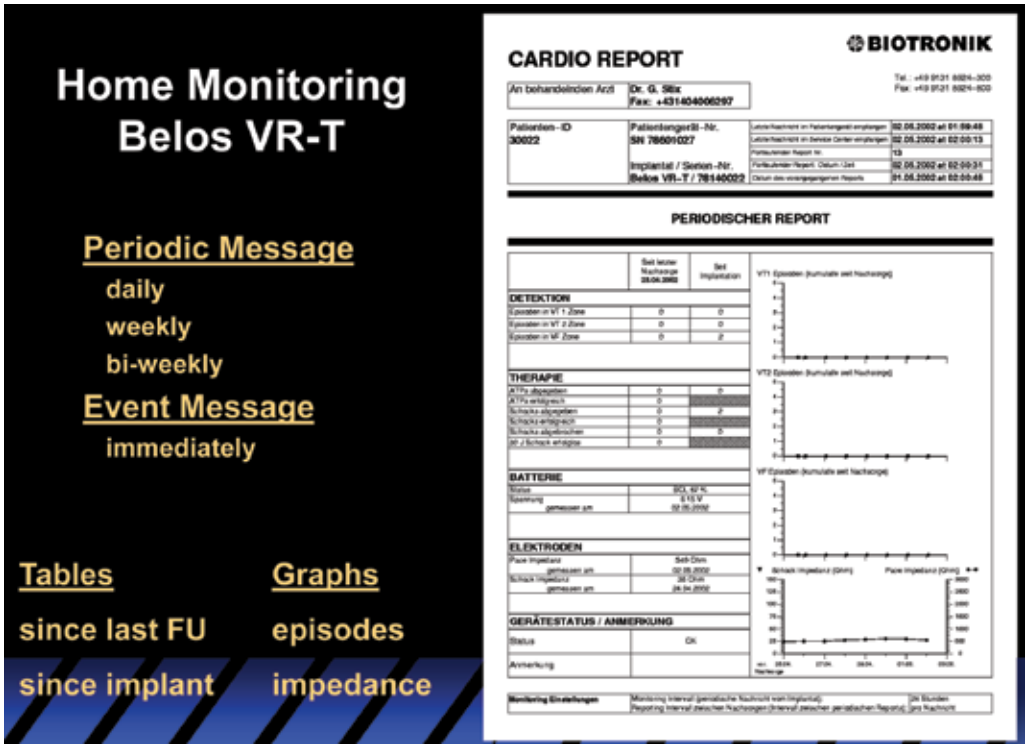

FIGURE 3

base of HM supports its capability to improve patient care and safety, and optimize the allocation of health resources.[7]

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