PATIENT BENEFIT FROM SEAMLESS IMPLANT MONITORING

NENEHNO MONITORIRANJE – ALI KORISTI BOLNIKU?

Karsten Wallbrück, Jürgen Schrader
Biotronik, Erlangen, Germany

Arrived 2005-04-22, accepted 2005-04-28; ZDRAV VESTN 2005; 74: Supl. I: 75–8

Key words: *cardiac pacing; advanced information technologies; home monitoring*

Ključne besede: *srčno vzpodbujanje; napredne informacijske tehnologije; nadzor doma*

Abstract – Background. *Patients with electrostimulation devices visit the hospital regularly for follow-up. The workload of out-patient departments is ever increasing, but a less frequent check-up is unwanted, as it could impair reliability and effectiveness of the therapy. A system of remote patient monitoring might improve this situation by enabling identification of patients who benefit from a shortened time for corrective action after any undesired event.*
A completely automatic system for patient remote monitoring has been introduced (BIOTRONIK Home Monitoring, HM). Daily patient and device data are displayed on an internet site which allows authorized persons to follow the parameters trends.
Several clinical studies are presently being conducted to investigate the benefit of HM in pacemaker and implantable cardioverter/defibrillator therapy. Preliminary results show the system's ability to individualize implant therapy for the patients' and the physicians' benefits.
Previous studies in heart failure (HF) therapy have shown that hospital readmission rates, hospitalisation duration and also mortality can be reduced by patient monitoring programs. A recently started study investigating HM in heart failure therapy aims to define a HF-indicator that predicts a worsening of the patient's status leading to hospitalisation. With such an indicator, the responsible physician could be alerted and the patient can be called in.
Although several issues connected to Home Monitoring remain to be solved, the time has come for a more flexible patient management. The incorporation of modern information technology into cardiovascular implants offers a way to solve the conflict between limited resources and high quality medical therapy for an aging population.

Izvleček – Izhodišča. *V starajoči se populaciji narašča število pacientov z napravami za elektrostimulacijo srca, ki se morajo redno vračati v ambulanto na kontrolo. Zaradi tega neprestano narašča delovna obremenitev kardioloških ambulantnih oddelkov. Redkejši pregledi pacientov bi zmanjšali zanesljivost in učinkovitost zdravljenja in so zato nezaželeni. Prepoznavanje pacientov z nevarnimi epizodami na daljavo bi lahko zmanjšalo obremenitev zdravnikov v ambulantnih oddelkih in hkrati omogočilo hitro reakcijo pri bolnikih, pri katerih se pokaže potreba po spremembi zdravljenja.*
Vključevanje sodobne informacijske tehnologije v srčne vsadke ponuja dober kompromis uporabe omejenih sredstev in sočasne zahteve po visoko kakovostnem zdravljenju. Sistem za avtomatično kontrolo pacientov na daljavo, ki dnevno spremlja stanje pacienta in naprave za elektrostimulacijo (BIOTRONIK Home Monitoring, HM) zbira podatke na internetni strani, kjer so dostopni pooblaščenim strokovnjakom.
Prednosti HM pri spremljanju pacientov s srčnimi spodbujevalniki in implantibilnimi defibrilatorji se preverjajo v več kliničnih raziskavah v teku. V prispevku povzemamo njihove preliminarne rezultate, ki opisujejo zmožnost sistema za individualizacijo pogostosti pregledov v dobro pacienta in zdravnika.
Pri pacientih s srčnim popuščanjem pogosto spremljanje s strani zdravstvenega osebja dokazano zmanjša število ponovnih hospitalizacij, dolžino hospitalizacije in celo smrtnost bolnikov. V nedavno začeti raziskavi želimo ugotoviti, ali lahko s pomočjo podatkov, zbranih s HM, napovemo ponovno hospitalizacijo. HM bi tako predčasno opozoril lečečega zdravnika na potrebo po kontroli in spremembi zdravljenja in tako pomagal preprečiti kasnejšo hospitalizacijo.
HM predstavlja kljub še nerešenim vprašanjem kakovosten preskok v oskrbi bolnikov z motnjami srčnega ritma.

Introduction

Since the implantation of the first pacemakers, patients with electrostimulation devices have to visit the hospital regularly for follow-up. Besides a medical examination, the device function is checked and the therapy success is assessed with help of the device memory. Patients have to be seen at least once a year, mostly twice to four times.
The number of follow-up visits and the workload of out-patient departments are ever increasing. This is due to several factors. The number of implantations is increasing due to increasing percentage of older people. Indication criteria are being extended due to new study results, and completely new therapy fields are opened, like implantable cardioverter defibrillators (ICDs) fifteen years ago, and cardiac resynchronization therapy (CRT) in heart failure today. Consequently, pressure arises to lengthen the follow-up intervals. On the other hand, a frequent check-up might improve the therapy in many patients. Changes of the medical status, lack of compliance with prescribed drugs or simply device problems may be unnoticed by the patient for the period between two consecutive follow-up visits.

A system of remote patient monitoring, supplying the physician with information on the patient without a visit in the out-patient department, might help to shorten the time for corrective action after any undesired event, and still reduce the workload. Some attempts have been made to supply the patient with simplified tools to interrogate the implant, which transmit data by internet or telephone line. These systems have only gained limited success because of the complicated handling both on the patient's and the physician's side of the data transmission line. The average pacemaker patient is about 70 years of age and one should not expect too much understanding of modern computer technology.

In the last years a completely automatic system for patient remote monitoring has been introduced (BIOTRONIK Home Monitoring, HM). The system comprises an implant with a short distance radio transmission and a patient unit, which receives the message of the implant and hands it further via GSM (mobile) telephone network to a service center. Here data are collected and displayed on an internet site which allows authorized persons to follow the trends of all transmitted parameters.

Since the time of the implant's transmission can be set to a time when the patient is sleeping (e. g. 3:00 am), the patient unit can stay beside the patient's bed. The patient's only task is to switch it on once. Then, unnoticed by the patient, every night a message is sent to the service center. In case the service center finds a potentially risky situation, e.g. an lead fracture, the responsible physician is immediately informed by fax, e-mail or SMS (1).

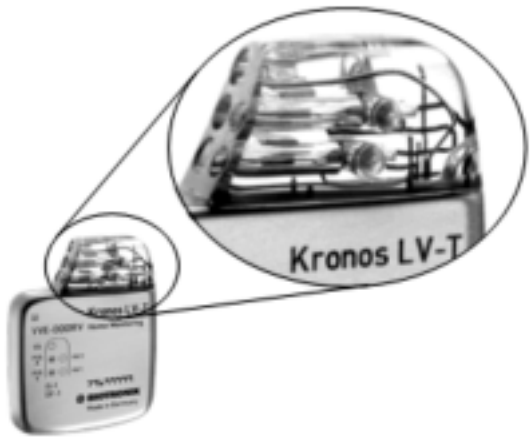

Figure 2. *The Kronos LV-T as an example for the integration of the Home Monitoring technology: The HM antenna is completely embedded into the device header; all electronic parts are integrated into the standard housing. Power consumption is minimized, so, HM has negligible effects on the device longevity: life long HM requires less energy than one shock.*

Sl. 2. *Kronos LV-T kot primer vključitve tehnologije Home Monitoring v implantat. HM antena je v celoti vgrajena v zgornji del naprave (header); vsi deli elektronike so vstavljeni v standardno ohišje. Poraba energije je minimizirana – HM porabi v celotnem času delovanja naprave manj energije, kot se je sprosti pri enem šoku, tako HM ne vpliva na trajnost implantata.*

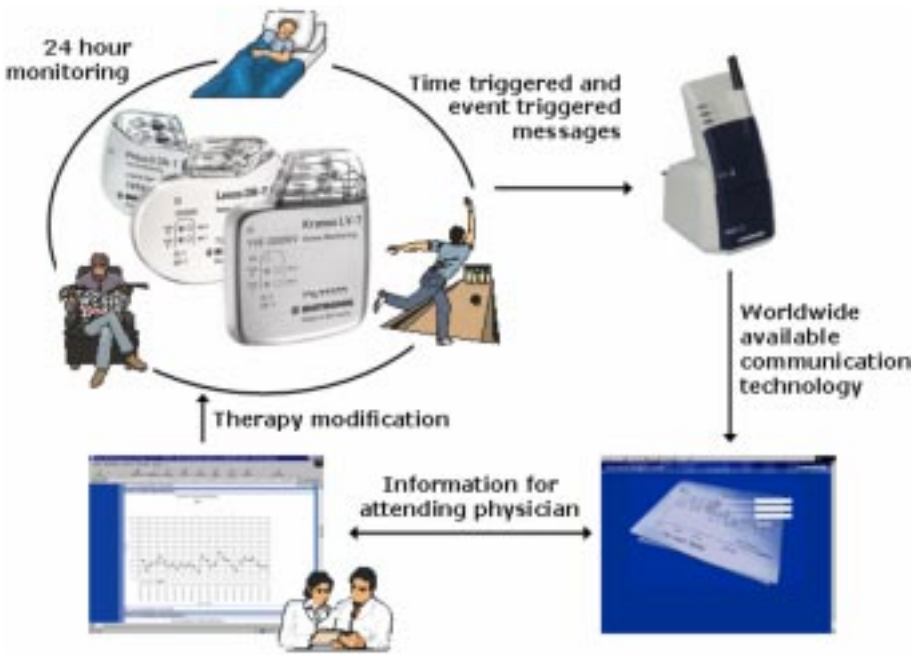

Figure 1. *Components of the Home Monitoring Service: Home Monitoring implants (top left) are available for pacing, defibrillation, cardiac resynchronisation. They provide seamless monitoring by time triggered daily messages and event triggered messages. The patient device (top right) relays the messages via worldwide available mobile communication technology to the Service Center (bottom right), where the data are provided on a secure internet web site. This site can be entered by the attending physicians at any time to monitor their patients and analyse data trends, or events (bottom left).*

Sl. 1. *Delovanje sistema Home Monitoring: HM implantati (zgoraj levo) so dostopni za stimulacijo, defibrilacijo in srčno resinhronizacijo. Implantati neprestano spremljajo stanje pacienta in enkrat dnevno ali pri neželenih dogodkih pošiljajo podatke preko bolnikove naprave (zgoraj desno) do servisnega centra. Bolnikova naprava za komunikacijo s servisnim centrom uporablja po vsem svetu razširjeno tehnologijo za mobilno komunikacijo. Servisni center (spodaj desno) posreduje podatke na varno internetno stran, kjer so dostopni odgovornemu zdravniku. Ta lahko dostopa do strani kadar želi, spremlja svoje paciente ter analizira trende zdravstvenega stanja ali patološke dogodke (spodaj levo).*

The HM system will gain general acceptance easiest if all parties involved see their respective advantages. Both the patients and the staff at out-patient departments benefit from less frequent out-patient visits, esp. such visits, in which no changes of therapy are necessary. The patients additionally benefit from shorter reaction time after any event which needs corrective action, because HM transmits data on a daily basis. Finally, the health insurance may profit if the number of out-patient visits and the number and severity of implant associated complications is sufficiently reduced.

During the course of electrostimulation therapy, many different possible events may happen which call for corrective action. They may be of technical or medical nature. All device-related events which can be found during follow-up, like lead failure or battery depletion, can also be detected by HM. In this article we want to discuss experience from ongoing clinical studies, in which changing the medical status of the patient is in the focus of interest.

Methods

Today, HM is available in dual chamber pacemakers, single- and dual-chamber ICDs, and in pacemakers and ICDs for CRT. The technical success of message transmission has been extensively tested and proven (2).
The medical data transmitted by HM are extracts of the device's memory. They are selected depending of the implant type. Among other parameters, HM pacemakers report heart rate, AV-conduction, ventricular and atrial extrasystolies and tachyarrhythmia, and mode-switch. HM ICDs send data on arrhythmia detections and therapy success, and soon also ECG-data will be transmitted. CRT devices additionally report percent of pacing, AV-synchrony and average and lowest heart rates.
Several clinical studies are presently being conducted to investigate the benefit of the HM in different patient groups.

Results

Atrial fibrillation in pacemaker patients

The first generation of dual chamber HM devices can transmit the daily number of mode switch events, the time the device is in mode switch, the percentage of atrio-ventricular synchrony and the ventricular rate. Varma et al. report that they detected AF in 29 out of 276 consecutive patients with HM-pacemakers (3). They concluded that HM allows precise measurement of AF burden and fast decision-making concerning appropriate anticoagulation therapy. The second generation of HM dual chamber pacemakers focuses even more on detection and management of atrial tachyarrhythmia. The »Home-PAT« study presently investigates the possibility of reducing the incidence of paroxysmal atrial fibrillation with immediate reaction after onset of each episode of AF.

ICD therapy

Implantable cardioverter/defibrillators with HM transmit information on anti-tachycardia therapy. An ongoing study (HOME-ICD) investigates whether the data transmitted by HM are suitable to correctly decide beforehand, if during a follow-up visit changes of therapy (programming, drug therapy) will be needed. From preliminary results the authors conclude that it will be probably possible to concentrate the follow-up on those patients with arrhythmic events, while the large proportion of patients without events in the study period can be seen less frequent. The study's final results are awaited for summer 2005. Several cases have already been reported in which HM allowed fast correction after inappropriate tachycardia therapy (4).
Based on these promising preliminary results, two randomized studies now investigate the extension of the standard routine follow-up interval for ICD-follow-up supported by HM. The studies' endpoints comprise the number of follow-up visits per year, mortality and morbidity, total costs and quality of life in patients with indication for primary and secondary prevention of sudden cardiac death.

Heart failure

The mortality and morbidity of heart failure patients is high even in patients with optimized medical therapy and with CRT. Numerous studies have investigated the impact of disease management programs in heart failure patients and have brought evidence that improved outpatient management reduces hospital readmission rates and shortens hospitalisation (5, 6). Theses effects were observed for clinic based programmes led by heart failure specialists, as well as for home based programmes conducted by trained nurses. The addition of regular automatic transmissions of weight, blood pressure and ECG to the management programmes increases the flexibility of patient care, while preserving the positive effects on hospital readmission and length of stay (7, 8). The TEN-HMS-study could additionally show a significant improvement in survival due to the regular data transmission and monitoring (9). Important predictors for rehospitalisation and death in heart failure patients comprise the occurrence of atrial and ventricular tachycardia, and changes in mean heart rate (10, 11).
HM CRT devices transmit the patient's average heart rate, the heart rate at rest, duration of daily activity and parameters indicating the success of resynchronization therapy. The recently started Home-CARE-study investigates the question

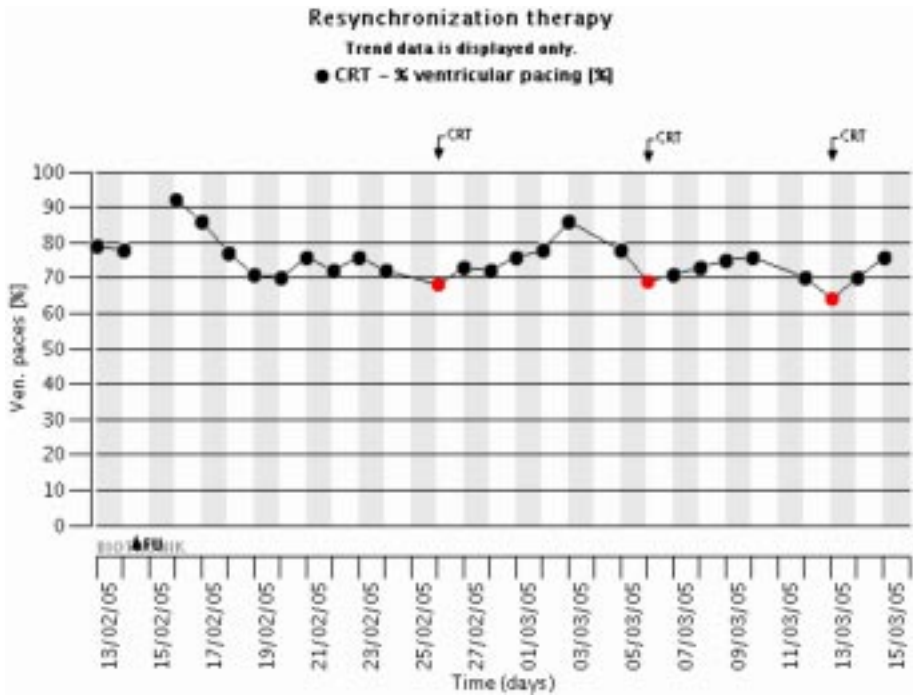

Figure 3. *Kronos LV-T resynchronisation data as an example of a Service Center Online graphical representation of HM data: The percentage of biventricular pacing is displayed for the last 4 weeks. The physician wanted to be alerted if the resynchronising pacing drops to less than 70%, which happens three times during the 4 weeks. These events are displayed in red and are marked with the »CRT«-flag in the headline above the graph.*

Sl. 3. *Podatki o srčni resinhronizaciji z implantata Kronos LV-T kot primer grafične prezentacije HM podatkov na internetni strani servisnega centra. Odstotek biventrikularne stimulacije je prikazan za zadnje štiri tedne. Zdravnik je želel biti opozorjen v primeru, da resinhronizirajoča stimulacija pade pod vrednost 70%, kar se je zgodilo trikrat v zadnjih štirih tednih. Ti dogodki so prikazani rdeče in označeni s »CRT«-zastavico v naslovni vrstici nad grafom.*

if future hospitalisations can be predicted with the information provided by HM. The study shall lead to the definition of a combined HF-indicator that predicts a worsening of the patient's status leading to hospitalisation. With such an indicator, the service center will be able to alert the responsible physician and the patient can be called in to have drug or device therapy optimized, to avoid lengthy hospitalisation for decompensation.

Discussion

As mentioned above, there is increasing evidence that intensified patient care reduces morbidity and mortality even in high risk patient groups. However, this intensified care conflicts with limited resources and growing restrictions in the health systems in most countries. Furthermore, this intensification competes with broadened indications for implantable devices, especially ICDs and CRT devices, which often have to be closely followed for optimal results (12, 13).

The dilemma's solution suggested herein is the use of HM: The automatic daily remote transmission of implant data, combined with user selectable alert criteria and 24 hours access to the data for the attending physician. HM has been shown to transmit data about the patient and the implant with a high reliability (2). If the home of the patient has a sufficient GSM coverage, the messages of the implant reach the service center within minutes. The data are extracted from the implant with the focus on the most promising scenarios for improving patient management: Incidence and characteristics of atrial and ventricular tachycardia, and indicators for worsening heart failure. The 24 hour resolution of the transmitted data together with automatic alert criteria enables short reaction times. The combination of the data to a scalable trend of up to two years allows a continuous disease monitoring with feed-back on therapy success and side effects.

The first clinical trial in ICD therapy is close to its completion. Preliminary results have revealed the great potential of HM for meeting today's demands for improved flexibility in patient follow-up without sacrificing patient safety and therapy effectiveness (14). Hence, several randomized controlled clinical trials have been started to prove the clinical benefit of the regular automatic implant data transmission. They mainly intend to improve the patients' follow-up by shortening of the reaction time after undesired changes in the course of the therapy, and by avoiding unnecessary but time and resources consuming routine follow-up.

Although final results are not yet available, it is anticipated that the studies will prove a large benefit for patients and physicians. More detailed analyses will reveal which subsets of patients benefit most, and in which periods. Irrespective of the precise results, the participants in the ongoing ICD studies are already starting to change their general clinical practice: A large percentage of patients is routinely equipped with a HM implant and monitored for the first period after the implantation, during changes of the accompanying therapy and towards the expected end of battery lifetime. Furthermore, some centres have started to pre-classify their patients into groups requiring more or less intense care according to the HM data.

The tendency to implant HM devices is even more pronounced in heart failure patients, although the HM resynchronisation device has only become available beginning of 2005. Following the above mentioned results from patient management, training, and monitoring programmes, it is generally expected that the heart failure patient will probably benefit from lifelong HM. The transmitted data reflects progression and reversal of heart failure. Success and side effects of resynchronisation and medication therapy are monitored. Critical phases of the therapy may be seen much earlier than without remote monitoring. Shortened reaction times may avoid manifestation of adverse events.

Several issues remain to be solved. The psychological impact on the patient and relatives will be investigated. Being under constant surveillance may give the patient a subjective feeling of safety, or also be burdensome. The organization of the outpatient departments must adapt to more flexible follow-up periods, and to call patients in by telephone if HM warns of an undesired situation. The reimbursement of the costs involved with HM, most important the necessary hardware and the analysis of HM data by hospital staff, is still open in most countries. Nevertheless, the time has come for a more flexible patient management. The conflict between limited financial and time resources and high quality medical therapy for an aging population requires changes in the traditional way of patient follow-up. The incorporation of modern information technology into cardiovascular implants – as it is done with HM – offers a reliable way to do this.

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