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Remote Monitoring in Patients with Pacemakers and Implantable Cardioverter-Defibrillators: New Perspectives for Complex Therapeutic Management

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1. Introduction

For more than 50 years, antibradycardia pacemakers have been implanted. Technological developments have led to an improvement, extension of diagnostic and treatment options (such as holter function for detecting arrhythmias and biosensors), and to an increasingly more automated device management (control of sensing and stimulus thresholds). Furthermore, it was possible to extend the runtime of the pacemaker assembly.

In 1980, the first implantable cardioverter-defibrillator (ICD) has been implanted in a human being with the objective of secondary prevention of sudden cardiac death. Meanwhile, advances in technology have led to a size reduction of the device assembly and to the possibility of transvenous implantations. Due to the MADIT II-study, published in 2002, the ICD-implantation indications have broadened to include patients with coronary artery disease in the primary prevention of sudden cardiac death (A.J Moss et al., 2002).

Since the 1990´s, biventricular pacemakers and ICDs enabled with Cardiac Resynchronization Therapy (CRT) are being implanted in patients with reduced left ventricular ejection fraction, prolonged QRS-complex, and advanced heart failure.

These patients undergoing CRT perceived improvement in heart failure symptoms (M.R. Bristow et al, 2004). Clinically asymptomatic patients with reduced left ventricular pump function and prolonged QRS-complexes are now also being considered candidates for implantation of biventricular pacemakers and ICDs to prevent cardiac decompensations (C. Linde et al., 2008; A. J Moss et al. 2009).

In recent years, national and international associations have drawn up guidelines for implantation of antibradycardia, ICD, and CRT devices (biventricular pacemakers and

ICDs) (A.E. Epstein et al., 2008). Recently, implantation rates for antibradycardia pacemakers, ICD and CRT devices have constantly increased.
In the USA, the expansion of indications for ICD and CRT implantations to include *primary prevention* of sudden cardiac death led to an amplification of ICD and CRT implantations.
Device therapy is increasingly used even in elderly multimorbid patients. While the number of pacemaker aggregate replacements remained constant in 1992-2006, the number of ICD aggregate replacements decreased during this period, due to runtime extension of ICD aggregates (C. Zhan et al., 2007, S.M. Kurtz et al, 2010).
However, despite technical improvements in implantation and devices complications are to be expected. Alter et al. studied 440 ICD patients with a median follow-up of 46 (+/ - 36) months and found a complication rate of 31%. This primarily involved peripoerative complications (10%), inadequate shock outputs (12%), ICD-lead related complications (12%) and complications caused by the aggregate (6%) (P. Alter et al., 2005).
Pacemaker and ICD annual reports submitted to the FDA revealed high annual malfunction replacement rates for pacemakers (1.4 – 9.0 replacements per 1000 implants) and for ICD´s (7.9 – 38.6 replacements per 1000 implants). The annual pacemaker malfunction replacement rate per 1000 implants decreased significantly during the study period 1990-2002. In contrast, the ICD malfunction replacement rate per 1000 implants increased markedly during the same period. In recent years, the problems surrounding the sprint fidelis lead showed the risk of lead and aggregate failures (M. Maytin et al., 2010). Defects of ICD-leads may even occur after implantation. Data presented by Kleemann and his colleagues who reported on survival of transvenous defibrillation leads during long-term follow-up revealed that the annual failure rate increased progressively with time after implantation and reached 20% in 10-year-old leads (T. Kleemann et al., 2007)

- increasing rates of implantation (especially for ICD- and CRT-systems)
- growing number of patients with implanted pacemakers, ICD-, and CRT-systems (follow-up appointments, aggregate replacement)
- growing number of elderly patients with comorbid conditions
- new diagnostic options (arrythmia management, biosensor technology)
- trend towards automated aftercare (e.g. automatic stimulus treshold determination)
- risk of device-related malfunctions (e.g. lead defects)
- fast transitions to new models in complex ICD- and CRT-systems

Table 1. Trends and problems in device therapy

The current developments and risks in device therapy (table 1) prescribe requirements to be met in terms of patient safety, follow-up appointments, and an increasingly complex management of ICD- and CRT-patients.
A device-based remote-monitoring represent an important contribution to meet these requirements and fulfill the needs.

2. Principle and development of technology

Remote monitoring overcomes the spatial separation between patient and physician. In the meantime, device-based remote monitoring has become a classical field for telemedical applications in cardiology, in addition to diagnostics of cardiac arrhythmia and telemonitoring of chronic heart failure (CHF)-patients.

Already in the mid of the 1970s, first examinations of transtelephonic monitoring of patients with antibradycardia pacemakers were carried out. At first, ECGs were recorded and transmitted via telephone to a receiving centre. A transmission of pacemaker function was, however, not possible (C. H. Klingenmaier et al., 1973). Medtronic "CareLink 2090" and St. Jude Medical "Housecall" were the first systems to allow remote monitoring. The CareLink-System enabled the computer in the monitoring centre to connect via telephone to the device. Thus, remote monitoring bridged the spatial distance between two different observers and thus a consultation without any active intervention in programming became possible.

St. Jude Medical developed the "Housecall"-System to transmit data from the ICD and the CRT-D to the physician. The system allows the patient to gather and transmit information to the practitioner about the ICD using the Housecall Plus Transmitter. The information provided by the IEGM and the online intracardiac ECG allows realtime ICD-surveillance for the first time. Either the patient or the physician can initiate the call to transmit via the small transmitter up-to-the-second information about how the patient's heart and ICD are working. The system enables the physician to monitor device performance. A determination of stimulus thresholds and a programming of the ICD settings, however, were not possible yet.

In the 1990s, BIOTRONIK started the development of the "Home Monitoring"-technology. First pacemakers were implanted in 2000. Today, hundreds of thousands of BIOTRONIK Home Monitoring systems have been implanted. The Home Monitoring System is the only remote monitoring system in which the transmission of data to the CardioMessenger requires no action by either the patient or the practitioner. The CardioMessenger transmits the data to BIOTRONIK's Service Center via a cell phone. The Service Center analyzes the data and forwards it to the patient's physician either by sms, email or fax. The Home Monitoring concept has been modified slightly and extended, and nowadays it represents the technological basic principle for telemonitoring for patients with electrical implants. All telemonitoring systems consist of the following components: Implanted device, patient monitor, the provider´s data server, data presentation for the physician (figure 1).

In the meantime, almost all manufacturers (BIOTRONIK, Medtronic, St. Jude Medical, Boston Scientific) have developed their own concepts for remote monitoring of pacemakers, ICD´s and CRT-systems, which in spite of their uniform structure vary in their technical realization and features (table 2).

Data can be transmitted from the implant to the patient monitor in various ways. This includes, for instance, transmissions that can be initiated automatically without any user interaction (Home Monitoring, BIOTRONIK) or by radio frequency (RF) wireless telemetry that is used to download data from the device (Merlin.net, St. Jude Medical; LATITUDE, Boston Scientific). In contrast, data can be transmitted manually by the patient (CareLink, Medtronic). Figure 2 shows patient monitors both for automated and manual data transmission.

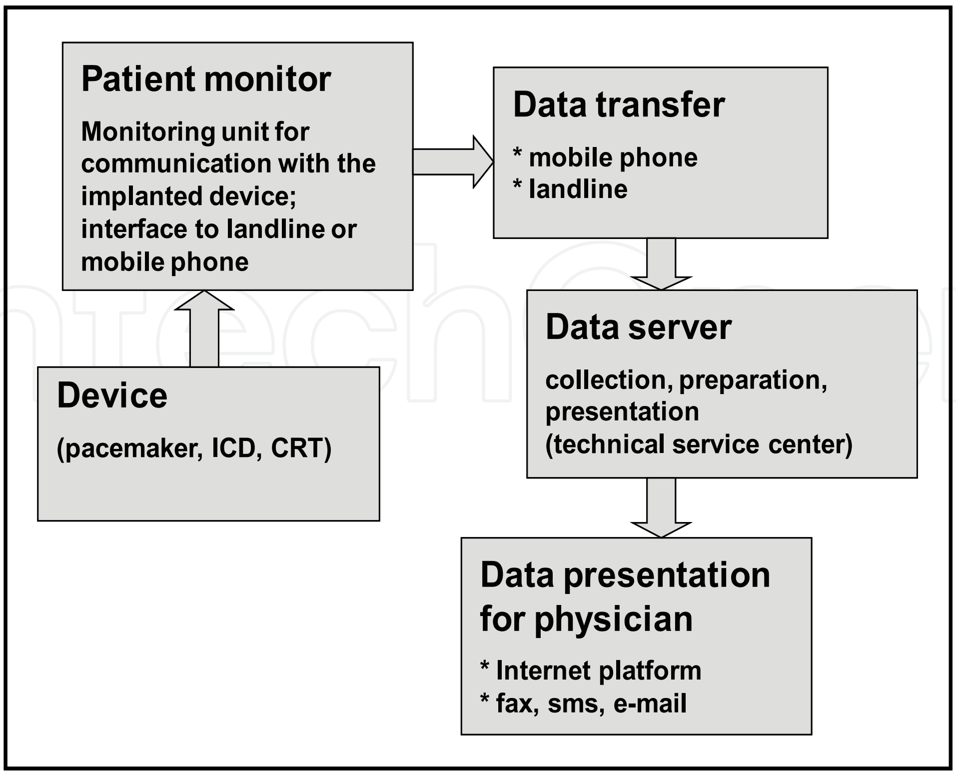

Fig. 1. Individual components of a device-based remote monitoring for patients with pacemakers, ICD´s and CRT-systems

System (manufacturer)	Implants	Patient monitor (data transfer from the implanted device)	Transfer to data server	Data presentation to the physician	Integration into the EHR	Specifics
Home Monitoring (BIOTRONIK)	PM, ICD, CRT	Cardio-Messenger (automatic)	GSM, GPRS	Internet, alerts via sms, e-mail, fax	Possible	IEGM-online-transmission, Heart-Failure-monitor
CareLink (Medtronic)	PM, ICD, CRT (backward compatible)	CareLink-monitor (manual and automatic)	Telephone line	Internet, alerts via sms	Possible	OptiLink-system (intrathoracic impedance measurement), IEGM, Cardiac Compass
Merlin.net(St. Jude Medical)	Specific ICDs, CRTs	Merlin@home (manual and automatic)	GSM, telephone line	Internet, alerts via sms, e-mail, fax	Possible	Holistic data-management-system, line-transmission
LATITUDE (Boston Scientific)	Specific ICDs, CRTs	LATITUDE-Communicator (manual and automatic)	Telephone line	Internet	Possible	Integration of external sensors (weight scale, blood pressure monitor)

Table 2. Overview of different systems for remote monitoring of pacemakers (PM), ICD´s and CRT-systems

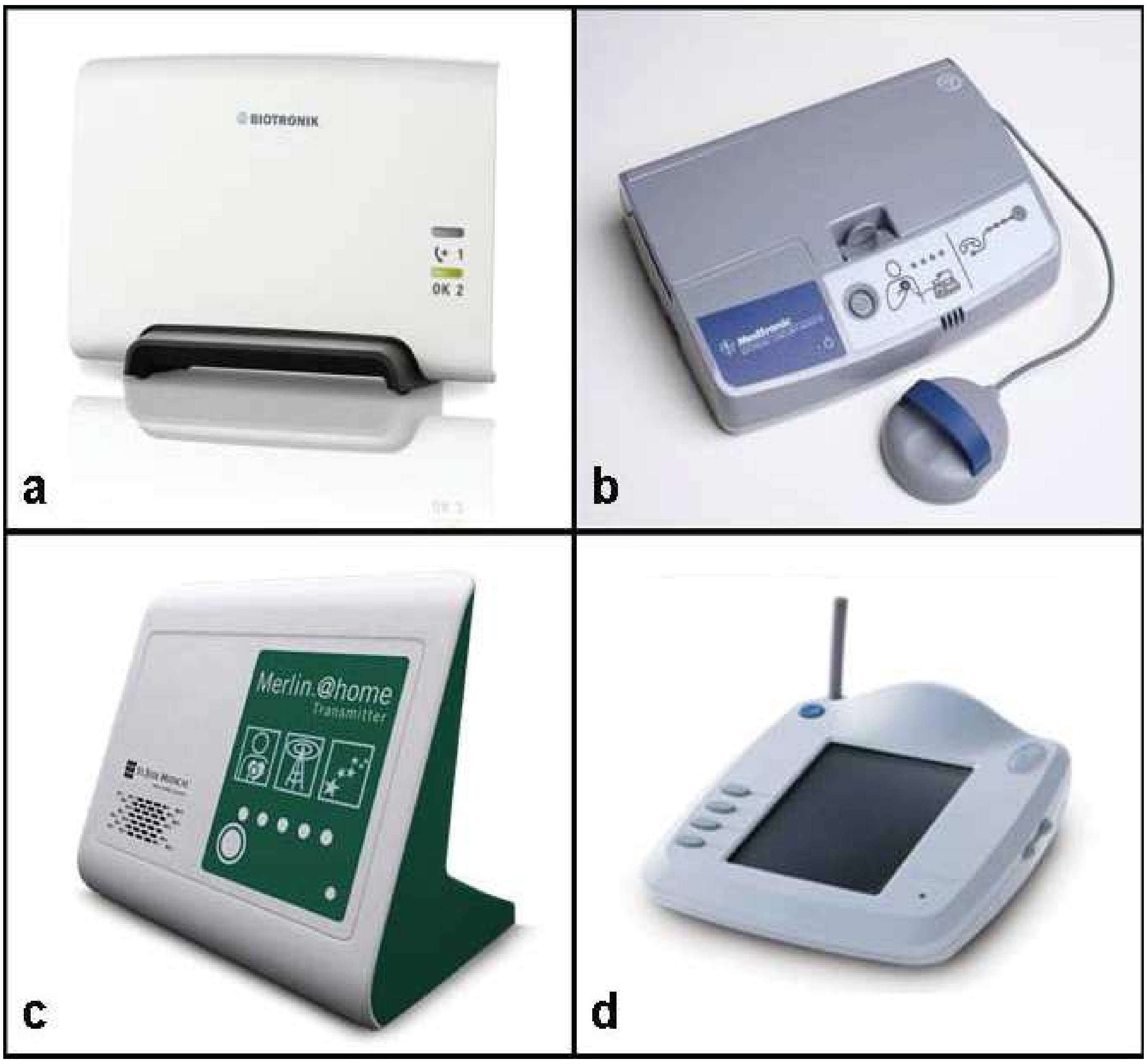

Fig. 2. Various patient monitors for remote monitoring of implants (a: CardioMessenger, BIOTRONIK; b: CareLink-Monitor, Medtronic; c: Merlin@home, St. Jude Medical; d: LATITUDE Communicator, Boston Scientific)

The patient monitor is the interface between the implant and the data servers. The data transmission from the patient monitor to the manufacturer´s data servers can be carried out via landline or mobile phone. Individual providers use both ways. The advantages of data transfer via mobile phone are the independence of location and the absence of a fixed telephone line.

In future, however, the mobile phone technology is certainly going to be the dominant model. The provider´s data servers collect the data and present it to the physician. There is no active processing of the medical data. In addition, all transmitted data are saved in the servers according to the requirements with data security.

The treating physician can receive the data via fax, sms or internet. In the meantime, all vendors have developed password protected internet platforms. This permits an access to patient data from any computer. Apart from data concerning system integrity (actual

programming of the aggregate, battery status, thresholds, impedances etc.) diagnostic data are also available (heart rate at rest and during exercise, atrial fibrillation etc.). The data transfer is carried out at scheduled times (e.g. once a day). Moreover, additional data transmissions can be carried out in case of ICD-Rx. Thus, due to the modern remote monitoring systems offered by the vendors complete datasets can be transmitted and presented. The manufacturers have therefore developed special user interfaces in order to allow an immediate data review. Furthermore, the physician can ask the patient via patient monitor to contact the physician by phone.
The different systems for remote monitoring (Home Monitoring, BIOTRONIK; CareLink, Medtronic; Merlin.net, St. Jude Medical; LATITUDE, Boston Scientific) are described in detail below.

3. Different systems for remote monitoring

3.1 Home Monitoring

BIOTRONIK Home Monitoring System is the first wireless, mobile remote monitoring system for patients with implantable cardiac devices on the market today. All devices have an integrated antenna in the header, enabling an automatic and patient-independent remote and wireless telemetry to a transmitter device (CardioMessenger®, figure 2). Data transmission is initiated at times predetermined by the physician, normally during night-time. Data transfer from the implant to the CardioMessenger® is provided via ULP-AMI (ultra low-power active medical implants) operating in the 402-405 MHz Band, which is worldwide standardized; its terms of use are laid down in relevant standards. In Europe, the standard ETSI EN 301 839-1 V1.2.1 (2007-07) is applied. The data are transmitted from the patient monitor via a mobile phone network to the BIOTRONIK Service Center. There, the data are put into an easily accessible form and can then be viewed by the physician online via the internet on a password protected website (Home Monitoring Platform®). BIOTRONIK Home Monitoring uses an intuitive, color-coded, web-based system (red and yellow) physicians and clinic staff, which allows for automatic patient classification aimed at significantly simplifying clinic workflow. In addition, the types of events which trigger an alert can be customized for each patient. The physician is informed by e-mail, sms, fax or phone messages whenever critical data or pre-defined, individual events are available for consultation. In addition to exporting data in CSV files, files can be exported using the Portable Document Format (PDF) standard. Data transfer is fully automated and requires no manual support by the patient. Furthermore, the system provides the opportunity to configure individual filter settings for data transfer according to individual patient needs and the desired level of safety. As an additional feature, IEGM Online HD®, a high-definition intracardiac ECG, can also be transmitted for patients with implanted ICD and CRT-devices (figure 3).
In addition, mathematical modeling enables the integration of different parameters (e.g. heart rate, right ventricular impedance, intrathoracic impedance measurement) into a complex monitoring concept (Heart Failure Monitor®). This unique system allows the attending physician to monitor each patient with dual-chamber pacemaker or CRT devices very closely and to react in time to prevent potential cardiovascular events at an early stage. Home Monitoring has, however, the disadvantage that only aggregates using an antenna integrated in the device can be monitored; external sensors (blood pressure monitor, weight scale etc.) cannot be integrated into the system.

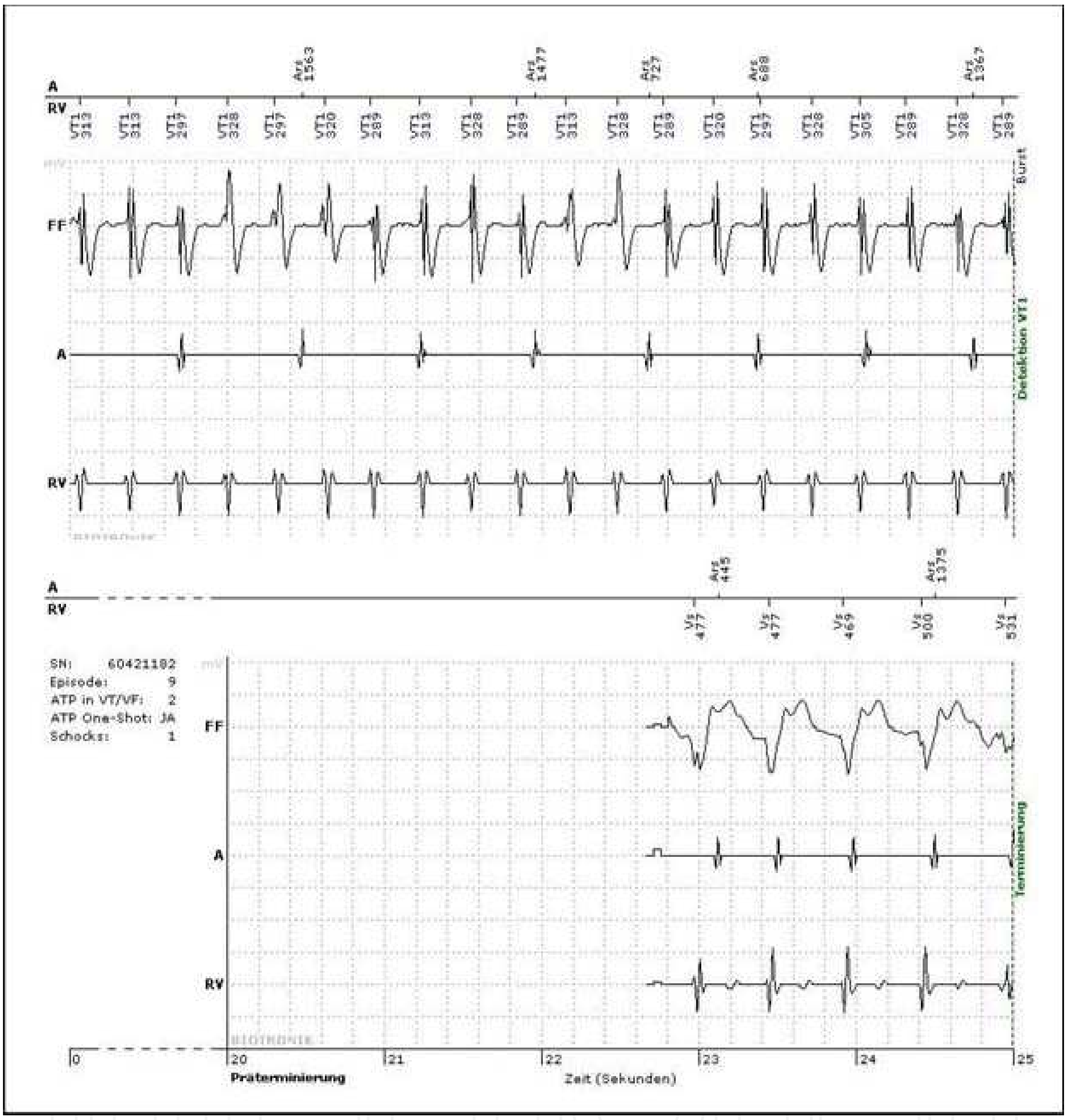

Fig. 3. Intracardiac ECG (IEGM), transmitted via Home Monitoring: detection of a sustained ventricular tachycardia (above) – Termination after shock (below)

3.2 CareLink

Medtronic CareLink has evolved from the Remote-View-System. The patient can collect data by holding an antenna over his implanted device. The system is backward compatible, so that patients with older devices can also be monitored. The data are captured by the antenna, downloaded by the monitor (CareLink-Monitor®) and transferred to the Medtronic CareLink Network (figure 2). Through this network, patient data are transmitted from their implantable device using a portable monitor that has to be connected to a standard telephone line. The patient's physician can view the data on a secure internet website (figure 4).

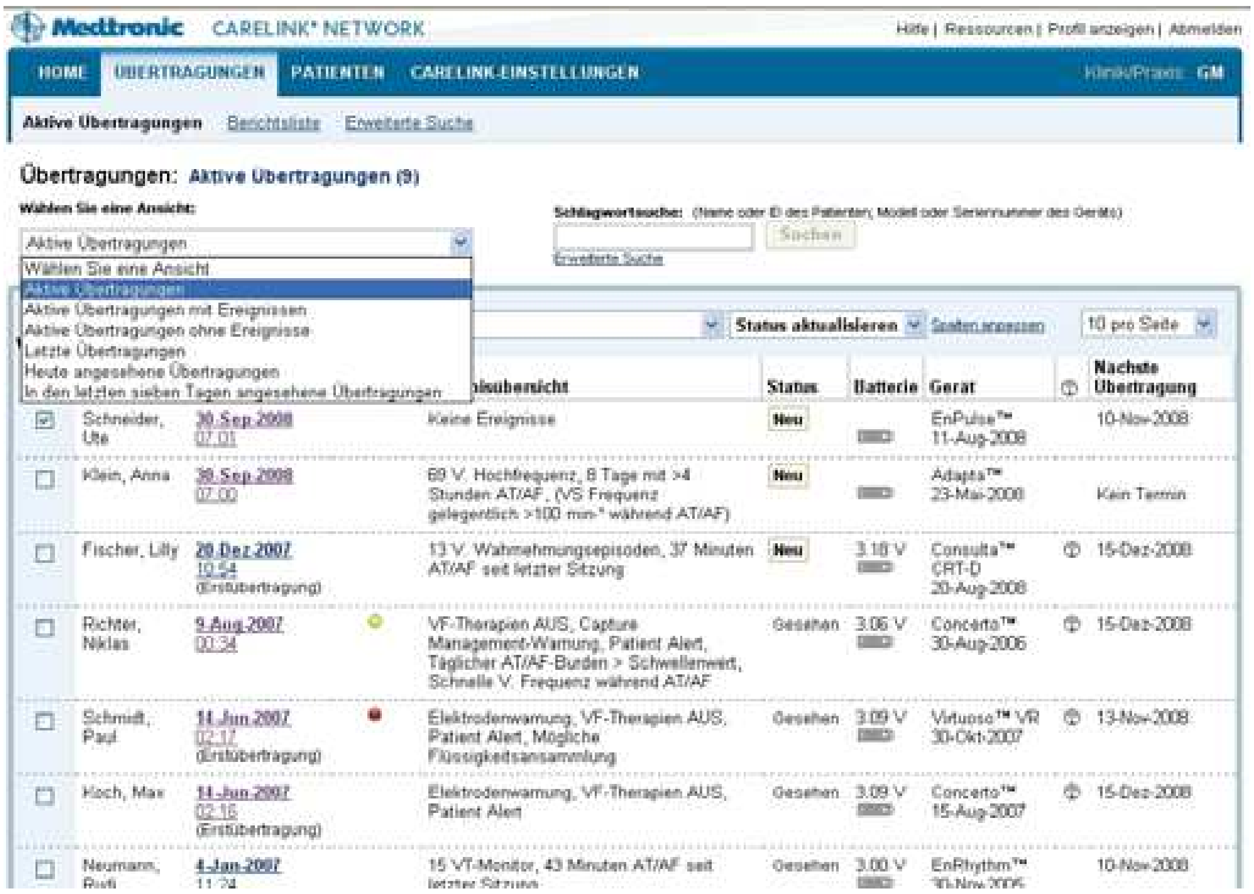

Fig. 4. Password-protected internet platform of the CareLink-system (source: Medtronic)

The network also allows Medtronic CareAlert® notifications to be transmitted when any of the programmable alert conditions from a patient's implanted device has occurred. The data transfer performs via standard telephone line. The system can be used for remote monitoring of implantable event recorders (Medtronic Reveal®). CareLink allows to transmit information on system and diagnostic data (Cardiac Compass®) and IEGM´s (event-triggered and on demand).

Another option for remote monitoring is OptiLink®, which incorporates CareLink and OptiVol®. The latter was developed to monitor patients with implanted CRT-D devices and to detect possible cardiac decompensations at early stage. The system measures the drop of intrathoracic impedance upon intrapulmonary fluid accumulation. Data are reliably transmitted via Medtronic's exclusive Conexus Wireless Telemetry®. This provides the physican with helpful tools to prevent cardiac decompensation. This may also lead to prevent hospitalizations for acute decompensated heart failure.

3.3 Merlin.net

St. Jude Medical Merlin.net is the successor to the Housecall Plus®-Remote Patient Monitoring. The monitor Merlin@home® is the core of the system (figure 2). Data are transmitted daily wirelessly (via RF) to the Merlin@home® Transmitter and from there via telephone to the internet-based Merlin.net server. Merlin@home supports all RF telemetry equipment (ICD, CRT-Ds).

The system also allows physicians to compile a more complete patient record, by easily transferring cardiac device data into electronic health records (EHRs), figure 5. Data transfer is compatible with IHE HL7 and IEEE 11073.

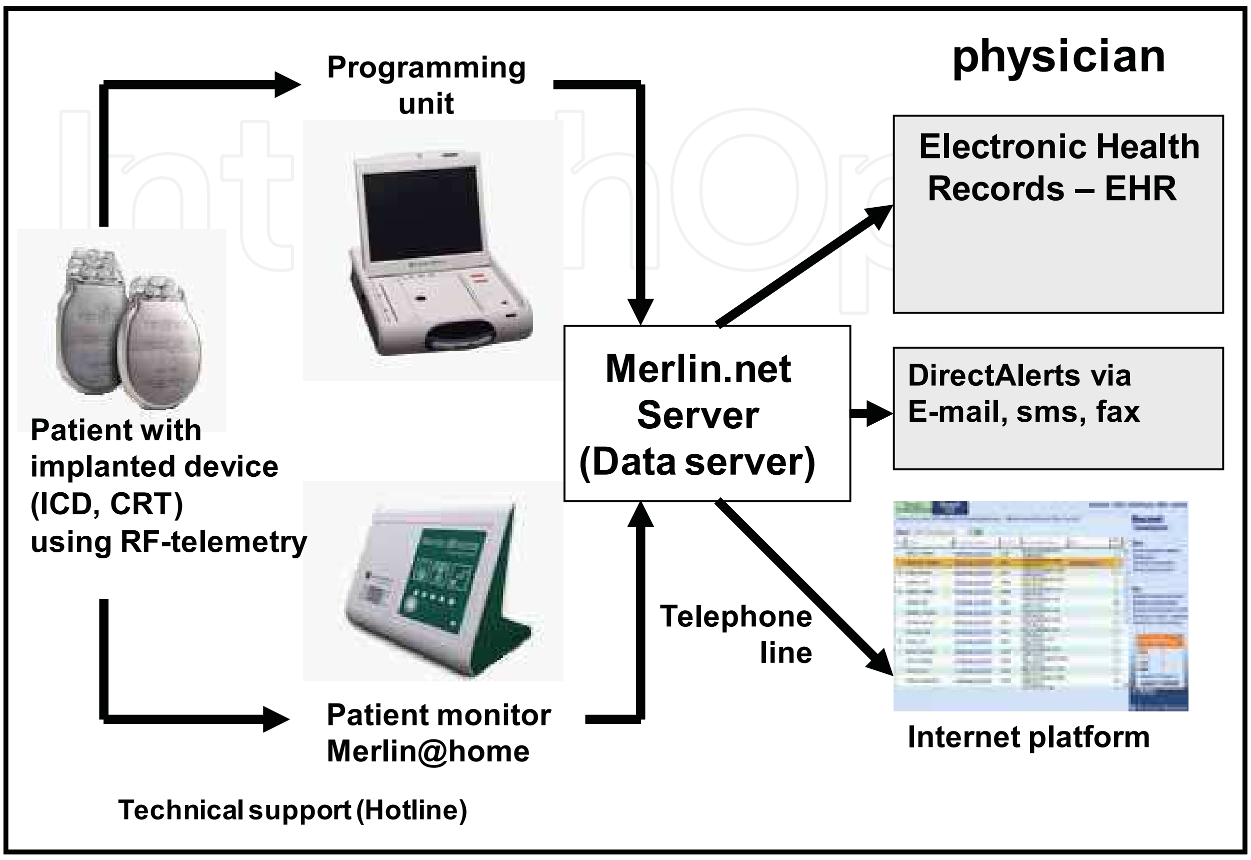

Fig. 5. Complex remote monitoring with St. Jude Medical Merlin.net – Integration of telemedical and direct aftercare (modified according to St. Jude Medical)

Data gathered during outpatient aftercare can also be integrated into the system. Additionally, St. Jude Medical provides help service that both patients and physicians may call with any technical questions or problems they may be experiencing. Merlin.net features include DirectCall® message, which provides pre-recorded messages that clinics can program to call patients to remind them of upcoming scheduled follow-ups, inform them if they have missed a follow-up, confirm that their transmitted data has been reviewed or ask them to call their physician's office or the hospital for more information. The DirectAlerts® Notification feature can be used to alert a physician to changes in the device or the patient's disease state.

3.4 LATITUDE

The Boston Scientific LATITUDE Patient Management system is being used mainly in the USA. It integrates remote monitoring of ICD- and CRT-systems (Remote Follow-up), telemonitoring, and heart failure management. Patients may initiate data transmission. LATITUDE Communicator® serves as the patient monitor (figure 2). The LATITUDE Communicator® uses RF to send and receive signals from the implanted device and a bluetooth communication system to communicate with an optional weight scale and blood

pressure monitor. The information is then transmitted via the phone line to a secure server. An Internet-based system provides easy access to diagnostic information from a patient's device and puts the physician in control of remote data collection. Design of the internet platform largely corresponds to that of the device.
The internet platform provides several care providers secure access to patient data (figure 6).

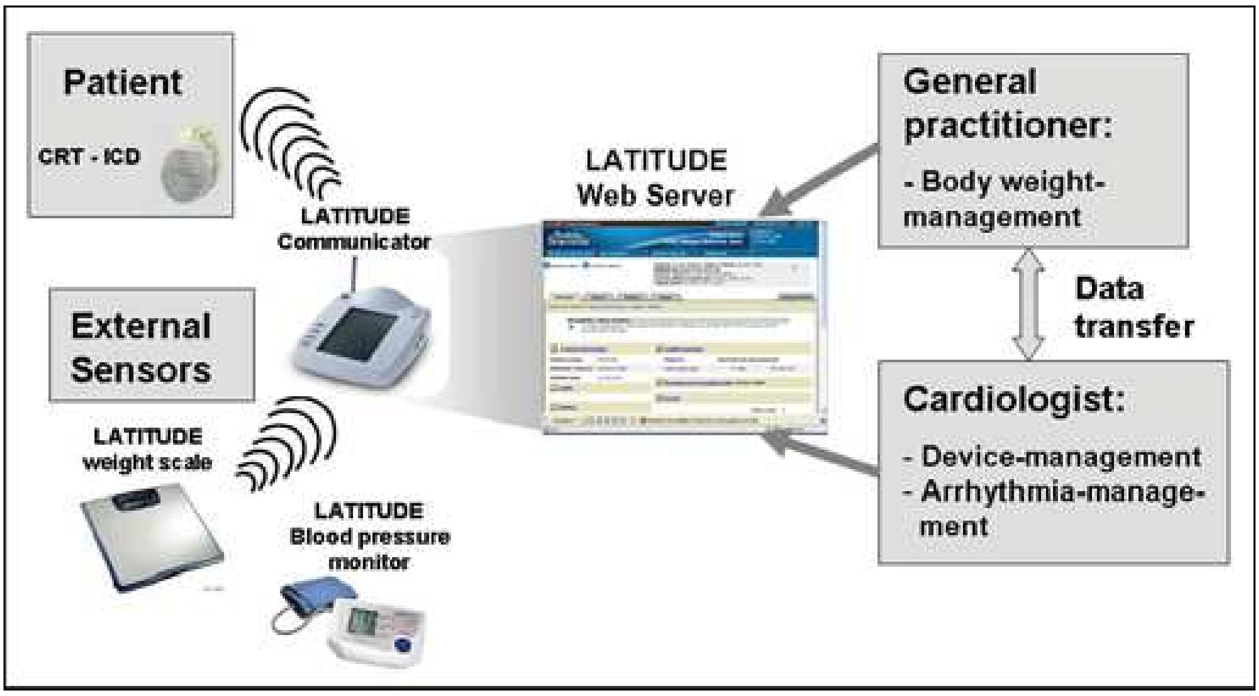

Fig. 6. LATITUDE-system (Boston Scientific) – Integration of external sensors (weight scale and blood pressure monitor) into the device-based remote monitoring (modified according to Boston Scientific)

The advantage of the LATITUDE -system is the possibility to integrate external devices (weight scale and blood pressure monitor), which reflects a fundamental part in monitoring patients with CHF.

4. Remote monitoring in clinical practice

Since the 1990s, device-based Remote Monitoring is being used in clinical practice. Now almost all pacemaker and ICD manufacturers have developed and improved internet-based solutions. Due to evidence-based medicine scientific studies are being required to prove efficacy or effectiveness and efficiency of remote monitoring.
Especially aspects concerning data security, advantages over conventional aftercare and cost efficiency have to be taken into consideration.
Clinical studies on remote monitoring of patients with pacemakers, ICDs, and CRT-systems investigated technical feasibility and safety of data transfer, first. In these breaking studies focusing on patients with implanted pacemakers, stability and safety of transtelephonic data transmission could be proved. In a study of 93 patients, Wallbrück et al. assessed the feasibility of an automatic long-distance monitoring system (Home Monitoring®, BIOTRONIK) for pacemaker patients, and the clinical relevance of transmitted data. Three patients (3.2%) were excluded due to insufficient mobile net coverage at their living site. For

the other patients, 5311 of 5911 messages were successfully registered. Interrupts in the sequence of messages occurred 331 times. Two hundred ten of these (63%) lasted just 1 day, 14 interrupts (4%) lasted 5 or more days. This rate could be reduced by providing information to the patients (K. Wallbrück et al., 2002). In a prospective study, 59 ICD-patients were followed remotely using the CareLink-system; patient acceptance of the system was high; satisfaction by the medical staff with data quality was also very favourable (M. H. Schoenfeld et al., 2004). The PREFER-study showed that the strategic use of remote pacemaker interrogation follow-up (CareLink, Medtronic) detects actionable events that are potentially important more quickly and more frequently than transtelephonic rhythm strip recordings (G.H. Crossley et al., 2009).

Stability of data transfer can be optimized in various ways:

The patient monitor can indicate disturbed data transmission through the flashing of its associated visual indicator. Another option is to use systems that remind patients to initiate data transmission (Merlin@net, St. Jude Medical). The Home Monitoring system enables the physician to define automatic and individually configurable notification if data transfer is missing. A service-hotline for patients can increase data transmission rate.

The application of unified bandwidths allows secured data transfer. However, reprogramming of the implant via remote monitoring is not possible due to law restrictions.

Device-based remote monitoring of patients with implanted antibradycardia pacemakers, ICDs and CRT-systems includes the four following aspects (figure 7):

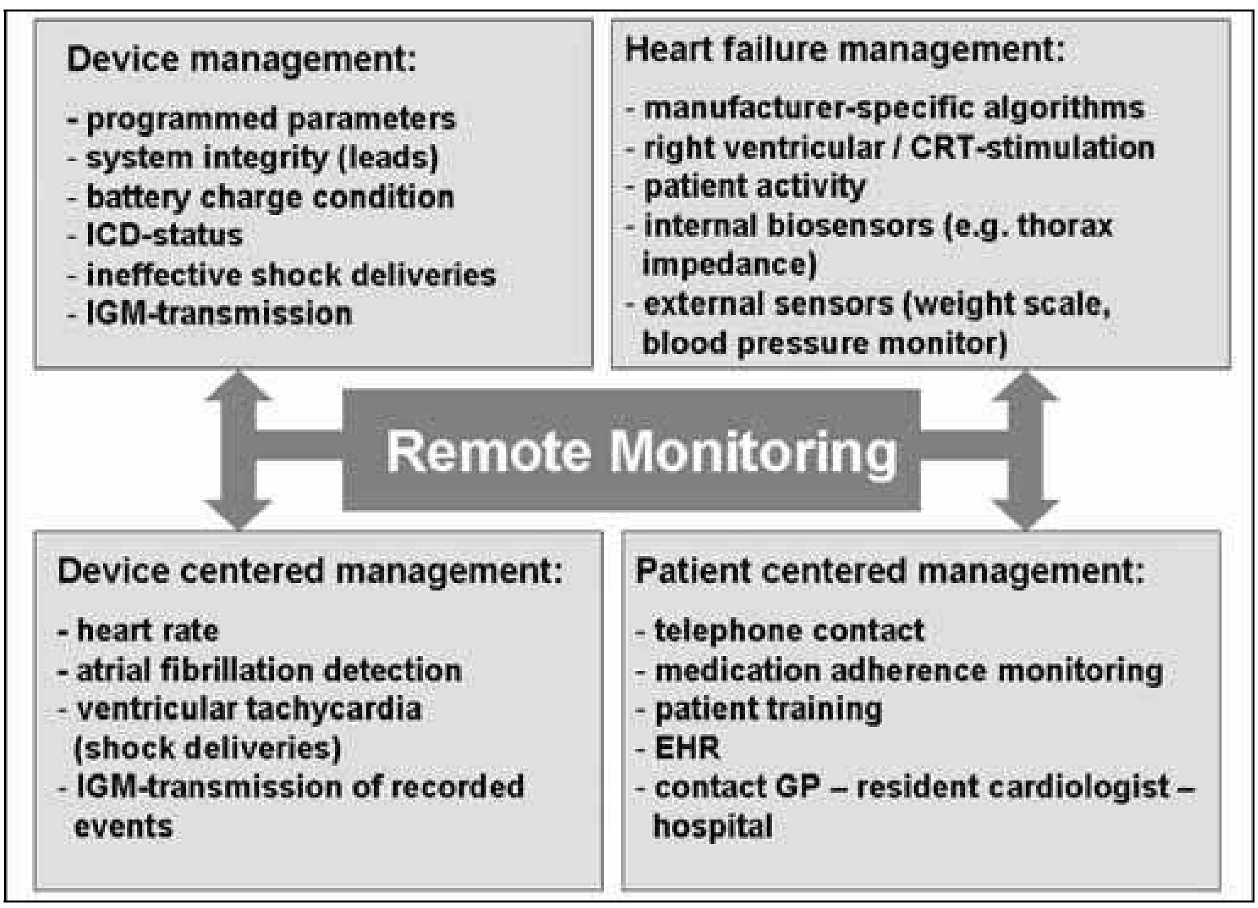

Fig. 7. Four relevant aspects of device-based remote monitoring in patients with implanted antibradycardia pacemakers, ICD, and CRT- systems

Device-management is an important tool used to monitor system integrity and to provide security of implants.
Important parameters (battery charge condition, atrial and ventricular signals, ICD-status etc.) are transferred.
Today, the complete actual device programming is transferred and visualized. This data primarily ensures patient security by enabling a complex device monitoring. In various cases, remote monitoring has been shown to confer clinical benefits.
BIOTRONIK Home Monitoring enables physicians to detect severe lead problems (e.g. lead fracture, lead micro dislocations, Twiddler-syndrome) early and to react quickly (N. J. Varma, 2008; M. L. Loricchio et al., 2008; M. F. Scholten et al., 2004). Intracardiac ECG serves as an important tool used to detect device malfunctions. Patient safety may be increased due to remote monitoring. This particularly concerns patients with highly complex devices (ICDs and CRT-systems). Nevertheless, the overall prevalence of technical problems was rather low. Nielsen et al. monitored a total of 260 patients with Home Monitoring ICDs. Technical events for single and double chamber ICDs occured only in 0.8% of patients and included invalid shock coil impedance, invalid ventricular lead impedance and special implant status (J. C. Nielsen et al., 2008). The retrospective study by Lazarus, which reported on the results of 11,624 patients implanted with a pacemaker, an ICD or a CRT-system using the BIOTRONIK Home Monitoring, revealed similar findings. Most transmitted events had medical reasons (e.g. cardiac arrhythmia) (A. Lazarus, 2007).
Arrhythmia management is an important partial aspect of device-based Remote Monitoring. It allows to detect mean patient heart rate at rest and at a workload performance and occurrences of atrial and ventricular arrhythmias. Ahmadi-Kashani et al. could show in their INTRINSIC RV study that an elevated heart rate in patients with a dual-chamber ICD is significantly associated with greater risk of achieving the primary end point of death or heart failure hospitalization. Of patients with a mean HR < 75 bpm, 5.8% died or were hospitalized for heart failure, whereas 20.9% with a mean HR > 90 bpm achieved the same end point, a 3.6-fold difference (M. Ahmadi-Kashani et al., 2009). In addition, early detection of atrial defibrillation is an important aspect in rhythm monitoring. Paroxysmal atrial tachycardias are often asymptomatic. In the presence of atrial fibrillation, thromboembolic events and progression of CHF may further deteriorate the patient's prognosis. During the CHAMP-study, 25 out of 120 patients with CRTs experienced paroxysmal atrial tachycardias, for an incidence rate of 21%. Paroxysmal atrial tachycardias were recorded in 29 and 17% of patients with and without previous history of atrial fibrillation, respectively (C. Leclercq et al, 2010). Remote monitoring allows early detection of atrial fibrillation in patients with implanted pacemakers, ICDs and CRT-systems and early reaction to optimize medical treatment (antiarrhythmic drug therapy, anticoagulation) (N. Varma et al., 2005; R. P. Ricci et al., 2009 a). Compared to scheduled follow-ups (usually every 3-6 months), remote control and, thus, an early detection of paroxysmal atrial tachycardias may lead to a reduction of stroke (R. P. Ricci et al., 2009 b).
Among patients, in whom an ICD is implanted, shocks, appropriate or inappropriate, always represent a major problem as they are associated with a poor prognosis. (M.O. Sweeney et al., 2010). Furthermore, mental and emotional health seems to fall with repeated ICD shocks. Progressive heart failure was the most common cause of death in patients who received a shock (J. E. Poole et al., 2008). Inappropriate shocks are often related to technical failure in device sensing (lead malfunction, T-wave-oversensing) or to cardiac arrhythmia.

These inappropriate shocks can be reduced through remote monitoring which is helpful for early detection of technical and medical events as well as by new algorithms to preven shocks (K.J. Volosin et al., 2010). In addition, intracardiac electrogram is also helpful (J.C.J. Res und Mitarbeiter, 2006; S. Spenker et al., 2009).

In recent years, heart failure management of patients with ICDs and particularly of those with CRT-systems, is attracting interest in clinical scientific studies. There are many complex reasons for that: New methods focussing on biosensors (e.g. intrathoracic impedance measurement) allow better monitoring of potential cardiac decompensations. Another reason is that patients often need residential treatment due to heart failure.

The latter increases costs and also results in a negatively effect quality of life.

Therefore, manufacturers have developed various concepts (e.g. Medtronic Cardiac Compass®, BIOTRONIK Heart Failure Monitor®). The aim of these concepts is to enable an "early warning system" to impeding episodes of worsening heart failure through integration of various components (e.g. heart rate at rest and in the recovery phase, patient´s physical activity, arrhythmia load, intrathoracic impedance). These concepts are currently under investigation in prospective studies. Despite promising approaches in intrathoracic impedance measurement (Optivol®, Medtronic), the method remains problematic due to limited sensitivity, specificity, and positive predictive value (D. Vollmann et al., 2007; D. Cantazariti et al., 2009). Other remote monitoring concepts (LATITUDE, Boston Scientific) are able to integrate external sensors (weight scale, blood pressure monitor via bluetooth). Thus, monitoring of ICD- and CRT-patients with CHF presents a complex problem. Therefore, device-based remote monitoring offers many possibilities and chances. Experiences already exist for Medtronic CareLink and for BIOTRONIK Home Monitoring. Tachyarrhythmia and cardiac decompensation events in patients with an implanted CRT could be treated efficiently due to CareLink. Patients benefited from an early therapeutic interventions (M. Sanitini et al., 2009).

In their "Home CARE" pilot study conducted in 123 patients with clinical indication for CRT Ellery et al. examined Home Monitoring in cardiac resynchronization therapy. In 70% of the rehospitalization events, the retrospective analysis of transmitted data via Home Monitoring revealed an increase in mean heart rate at rest and in mean heart rate over 24 h within 7 days preceding hospitalization. Both duration of physical activity and the rate of biventricular stimulation were reduced. Home Monitoring of these data may predict events leading to hospitalization (S. Ellery et al., 2006). Different studies concerning device-based remote monitoring of patients with CHF are currently being carried out (e.g. InContact-Studie, St. Jude Medical).

Patient-centered management forms a fourth aspect that has to be mentioned in this context. The concept for the monitoring and treatment of CHF is extended by various measures (telephone calls, drug adherence monitoring, patient training). Integration of special telemedical service centres enables comprehensive patient care with the centre taking the role of coordinator within the network consisting of GP, resident cardiologist and hospital. The aim is to implement medical treatment in accordance with the guidelines in order to improve the patients´ quality of life, to prevent hospitalizations and to improve patients´ prognosis. New information processing technologies allow the integration of collected data into an electronic health record (EHR) with password protection which can be accessed by individual physicians (GP, resident cardiologist and physicians at hospital).

The numbers of follow-up will increase with the number of pacemaker-, ICD- and CRT-implants and can thus become an additional exposure for resident cardiologists and hospitals.
Furthermore, high individual costs arise for patient transport. Remote monitoring can act as a contribution to individualization of follow-up scheduling. This is of particular importance in the way that different patient groups require different follow-up scenarios.
One retrospective study of 271 patients with ICD-indication followed for 12 months using Home Monitoring by Brugada et al. examined the utility of remote monitoring in forecasting the necessity of a previously scheduled routine in-clinic visit. 908 pairs of Home Monitoring data and follow-up data were evaluated. The largest fraction of 608 (67%) consisted of true negative forecasts, while a total of 141 (16%) of the forecasts turned out to be true positive in accordance with retrospective follow-up view. There was a 14% false negative rate. Problems would not have been detected without routine follow-up visits. This particularly effects is caused by an increase in ventricular or atrial pacing threshold, discovery of lead dislodgement, ventricular episodes, misinterpretation of atrial fibrillation. However, the incidence of false negative forecasts decreased over time. A patient management with additional sources of information (first follow-up, lead problems, hospitalization etc.) could decrease the number of misinterpretations and, therefore, the numbers of follow-ups (P. Burgada, 2006).
Despite these positive results, there are still some controversial issues concerning particularly the efficiency of device-based remote monitoring in reducing the number of follow-ups. Heidbüchel et al. estimated that remote monitoring could potentially lead to a decreased frequency of follow-up, if combined with clinical follow-up by the local general practitioner (H. Heidbüchel et al., 2008). In contrast, Al-Khatib et al., who assigned 151 patients with an ICD to remote monitoring versus quarterly interrogations in clinic, could found no significant differences in cardiac-related resource utilization at 1 year (S. M. Al-Khatib et al., 2010).
Yet, currently available remote monitoring systems can neither substitute an emergency service nor can they replace entirely direct contact. Device-based remote monitoring is recommended for patients with stable device-function who have no need of reprogramming (B.L. Wilkoff et al., 2008).
The potential cost/ benefit of remote monitoring for patients with cardiac devices (ICDs, CRTs or pacemakers) is another important aspect which has to be taken into account. A study by Fauchier et al. showed that remote monitoring of ICDs diminished the costs of follow-up. Particularly, they calculated that remote monitoring reduced the overall cost of ICD follow-up when the distance between home and the device clinic was >100 km (L. Fauchier et al., 2005). A trial of remote monitoring by Raatikainen et al. from Finland demonstrated that compared with the in-office visits, remote ICD monitoring required less time from both patient and physician to complete the follow-up. Substitution of two routine in-office visits during the study by remote monitoring reduced the overall cost of routine ICD follow-up by 41% per patient (M.J P. Raatikainen et al., 2008). Furthermore, it could be demonstrated in a study from France that remote monitoring decreases the duration of post-operative hospitalization after implantation of pacing systems or replacement of pulse generators (F. Halimi et al., 2008).
The issue of patient and physician acceptance of remote monitoring still remains. This specifically relates to the concern that direct patient-physician-communication may get lost.

An Italian study with 119 patients revealed a high level of acceptance and satisfaction after 1-year remote control (R. P. Ricci et al., 2010).
However, despite these promising data and possibilities, device-based remote monitoring of antibradycardia pacemaker patients has failed to diffuse so far. There are various reasons for that: Different remote monitoring systems are not backward compatible and, thus, not able to monitor old generation devices. Secondly, routine follow-ups of patients with implanted pacemakers do not impose additional burden on the clinical workload. Furthermore, antibradycardia pacemakers are primarily inserted in elderly patients; this might create a treshold to apply remote monitoring, despite the fact that experience had shown that the technology is manageable by elderly patients. The situation is different for patients with ICDs and CRTs; due to its various possibilities device-based remote monitoring will grow in importance and, moreover, the population consists of heart failure patients.
However, there are still barriers for wider adoption. Among physicians, significant barriers may be technical problems (e.g. missing internet access, different systems), suspected additional expenditure of time and missing refund of expenses. The other barrier is the flood of data produced by remote monitoring. In a study by Lazarus 3,004,763 transmissions were made by 11,624 recipients of pacemakers, defibrillators and combined ICD-cardiac resynchronization therapy (CRT-D) systems. On average, 47.6% of the patients were event-free (A. Lazarus, 2007). Theuns et al. who examined the impact of remote monitoring on clinical workload showed that despite the large number of data transmissions, remote monitoring imposed a minimal additional burden on the clinical workload. The median number of clinical events/ patient/ month was 0.023 (D.A.J Theuns et al., 2009). In order to guarantee an efficient analysis and selection of relevant data, specially trained nurses are deployed. These pacing expert nurses consult the website and submit critical cases to physician (R. P. Ricci et al., 2008).
Last but not least, the acceptance of device-based remote monitoring in future will depend on the development of standards and clinical guidelines. Remote monitoring must prove to be of great value in optimizing patient care and increasing efficiency of the health system.

5. Conclusion and perspective

Device-based remote monitoring has been increasingly established for many years. This system enables data transfer from pacemakers, ICDs and CRTs to the physician. Despite technical differences between the providers, the remote monitoring systems consist of unified components. The patient monitor connects to the device and transfers the data via landline or mobile phone to the providers´ server. There, data are anonymously decoded, analysed, and uploaded to a secure internet platform. The patient's physicians have access to this platform through identity codes and personal passwords and can also be informed of critical events via e-mail, sms or fax.
Meanwhile, most manufacturers (BIOTRONIK, Medtronic, St. Jude Medical, Boston Scientific) have provided their own device-based remote monitoring systems, all of which are already used in clinical practice. Safety and stability of data transmission was proven in clinical trails. Modern remote monitoring systems are taking several aspects of patient monitoring into account; they have developed from pure device monitoring to complex patient management systems integrating device-, arrhythmia-, heart failure-, and patient

centered-management resulting in comprehensive monitoring with the option of early interventions. Modern information processing technologies allow the integration of collected data into an electronic health record (EHR) providing, therefore, holistic aftercare services and patient monitoring. In the future, fast mobile communication technologies for data transfer and internet platforms will be the most important tools. Device-based remote monitoring will become standard in monitoring of patients being implanted with complex cardiac devices (ICDs, CRTs) which is in accordance to the current guidelines. The next step is the transition from monitoring management to therapeutic management. This would be of particular benefit for CHF patients. However, although proven to be technically manageable, the implementation of these possibilities essentially depends on the acceptance on the part of patients, physicians and health insurances. Problems such as data security, data storage, cost reimbursement of telemedical solutions should be resolved in this context. Further clinical studies are needed to prove the benefits of device-based remote monitoring such as patient safety, individual patient´s follow-up settings and cost/ benefit.

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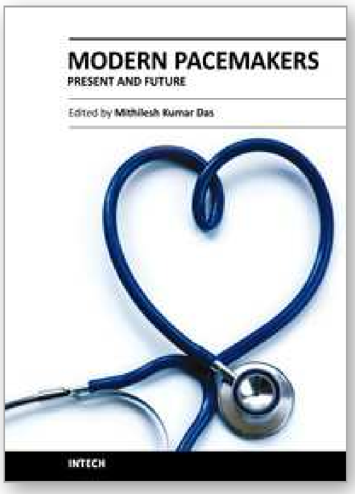

Modern Pacemakers - Present and Future
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The book focuses upon clinical as well as engineering aspects of modern cardiac pacemakers. Modern pacemaker functions, implant techniques, various complications related to implant and complications during follow-up are covered. The issue of interaction between magnetic resonance imaging and pacemakers are well discussed. Chapters are also included discussing the role of pacemakers in congenital and acquired conduction disease. Apart from pacing for bradycardia, the role of pacemakers in cardiac resynchronization therapy has been an important aspect of management of advanced heart failure. The book provides an excellent overview of implantation techniques as well as benefits and limitations of cardiac resynchronization therapy. Pacemaker follow-up with remote monitoring is getting more and more acceptance in clinical practice; therefore, chapters related to various aspects of remote monitoring are also incorporated in the book. The current aspect of cardiac pacemaker physiology and role of cardiac ion channels, as well as the present and future of biopacemakers are included to glimpse into the future management of conductions system diseases. We have also included chapters regarding gut pacemakers as well as pacemaker mechanisms of neural networks. Therefore, the book covers the entire spectrum of modern pacemaker therapy including implant techniques, device related complications, interactions, limitations, and benefits (including the role of pacing role in heart failure), as well as future prospects of cardiac pacing.

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