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Remote monitoring of cardiovascular implantable electronic devices

Prerequisite or luxury?

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Summary

The number of patients implanted with cardiovascular electronic devices (CIED) like implantable defibrillators (ICD), cardiac resynchronisation (CRT) devices, and pacemakers continues to grow. These devices require regular follow-up interrogation in dedicated device clinics. Contemporary CIED are capable of wireless remote interrogation and monitoring. This technology has been proven to be technically reliable and helpful in certain conditions. It is of particular benefit in monitoring devices that are under a safety alert since it allows early identification of device malfunction and minimises the risk of under-reporting. There is also strong evidence that it helps to reduce heart failure hospitalisations in CRT and ICD patients. Furthermore, this technology proves to be very helpful in the early detection of arrhythmias like atrial fibrillation or ventricular tachyarrhythmias. Remote monitoring significantly reduces the number of follow-up visits, patients' and physicians' time spent per visit, and increases patients' adherence to follow-up visits. Future studies are needed to determine how to best allocate this new technology in a cost-effective manner.

Key words: remote monitoring; implantable defibrillator; cardiac resynchronization therapy; telemedicine

Introduction

The number of patients with implanted pacemakers, cardioverter/defibrillators (ICD), implantable loop recorders, and devices for cardiac resynchronisation therapy (CRT) continues to grow. Cardiovascular implantable electronic devices (CIED) require regular follow-up to ascertain technical integrity. Consequently, more patients require regular follow-up of these devices. Depending on the device and the underlying cardiac condition the frequency of these follow-ups varies [1]. The advent of remote monitoring systems for CIED offers many options and at the same time raises many questions with regard to its implementation, organisation of the obtained wealth of data, safety, legal issues and reimbursement. Undoubtedly, this technology is becoming an integral part of the future treatment for some of the CIED patients. This review explains the technology used, summarises the available technical and clinical data and tries to expand on the unsolved questions regarding remote monitoring.

Clinical background and possible applications

Currently, remote monitoring is mainly employed in patients with ICD or CRT systems. Numerous trials showed that ICDs lower mortality in patients with aborted sudden cardiac death (SCD; secondary prevention [2]) and those at high risk for SCD (primary prevention [3, 4]). Particularly, the wide-spread application of ICD for primary prevention has lead to a dramatic increase in implantation resulting in more than 234 000 ICD patients in the US and more than 87000 ICD carriers in Europe in 2006 [1]. The majority of these patients suffer from concomitant heart disease, reduced left ventricular ejection fraction, and symptomatic heart failure.

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Patients with advanced symptomatic heart failure despite optimal medical therapy and mechanical cardiac dyssynchrony, manifesting itself as left bundle branch block on the surface ECG, benefit from CRT. Randomised controlled trials have demonstrated that CRT lowers mortality and alleviates heart failure symptoms in the majority of patients [5, 6].

Advantages of remote CIED monitoring

A recent expert consensus statement of the Heart Rhythm Society (HRS) and the European Heart Rhythm Association (EHRA) declared the earliest possible identification of abnormal device behaviour, as well as the prevention device malfunction underreporting, as being the primary goal of remote CIED monitoring [1]. CIEDs are generally safe devices. However, particularly the implanted leads have to withstand considerable stress over their lifetime. Five year failure rates have been reported to lie between 2 and 15% [7, 8] and lately high profile ICD lead performance questions, such as those affecting Medtronic Sprint Fidelis and St. Jude Medical Riata leads, have attracted considerable public attention [9]. For that purpose, some remote monitoring systems can cover and report on daily lead integrity measurements of more than 90% of the time [10, 11]. Additionally, remote monitoring allows for early detection of clinical problems that are prevalent in the CIED population, like atrial fibrillation, ventricular tachyarrhythmias or impending cardiac decompensation [12]. Early detection allows for early treatment of these conditions and there is evidence that hospitalisation rates can be reduced [13].

Furthermore, remote CIED monitoring has the potential to allow for fewer clinic visits of the rapidly growing and more mobile patient population [14]. This is certainly desirable for patient comfort and may prove to be cost-effective in the future. A small German study indicated that his may be the case [15]. Currently, numerous larger trials are looking into this issue (CONNECT, EVATEL, IMPACT, OptiLink-HF, TRUST) [16]. The HRS/EHRA consensus paper on CIED suggests that it is safe to reduce clinic visits for ICD and CRT-carriers to once a year provided remote controls are carried out every 3 to 6 months [1].

Areas of uncertainty

As with every new technology, there are high logistical demands for its incorporation into clinical routine. The wealth of possible data transmission needs to be organised. Ideally, every other clinic visit in a patient with a chronically implanted CIED could be substituted by a scheduled remote control and personnel and resources allocated accordingly. On the other hand, some out-of-schedule messages will be generated, which require the attention of a physician. Although numerous organising systems, using red and yellow flags, are provided by the manufacturers, it remains to be seen how much more time is needed to deal with these alerts. Using automatic daily routine transmission by the Home Monitoring System™ (Biotronik, Berlin, Germany), Lazarus reported a mean of 0.6 events per patient per month ranging from 0.3 in single-chamber ICD to 2.1 in CRT-ICD recipients [17]. According to this study, 86% of these events were due to medical conditions (e.g. detection of supraventricular or ventricular tachycardia, ICD-therapy, first detection of atrial fibrillation) and only a minority for system related problems.

Legal issues

Another area of uncertainty is related to the question of liability. How fast must a physician react to the electronically transmitted alerts? Is it legally acceptable not to check messages sent by remote monitoring systems while the practice is closed? In the judicial literature some lawyers advocate that a physician is liable if a patient suffers from a severe event that could have been avoided by telemonitoring provided the treating physician did not inform him about the availability of this technology [18]. On the other hand, there are pending questions about the property, privacy and safety of the patient data. Urgent clarification by the respective legislative bodies is needed in order not to put physicians at risk of litigation for malpractice. In our opinion, the scheduled remote monitoring follow-up appointments should have the same legal status as clinic visits. The legal consequences of actions taken or not taken for out-of-schedule alerts are unclear, since all systems allow the user to predefine these alerts. Ideally, the respective legal body should define if there are alerts which must be programmed and for which immediate action is mandatory.

Reimbursement

Another pertinent and hitherto unresolved issue pertains to reimbursement and cost effectiveness. In most European countries there are no reimbursement schemes for remote monitoring and most authorities will ask for studies that prove the cost effectiveness. Most likely this data will soon become available in the CRT population. In a recent study by Catanzariti and coworkers monitoring of intrathoracic impedance (OptiVol, Medtronic Inc.), which can be transmitted by the Carelink™ system (Medtronic Inc.), reduced the number of costly hospitalisations in heart failure patients [13]. At the same time, there are additional costs that come with remote monitoring (transmitter, back-office, repository and website maintenance) which increase the price for the implantable device.

Currently available technologies

Most manufacturers of CIED have developed their own remote patient management systems. In all systems, the CIED is equipped with a micro-antenna that transmits data to an external transmitter (fig. 1). This occurs either automatically at preset times (wandless) or patient activated (via a wand). Subsequently, the encrypted data will be forwarded to a central database of the manufacturer (fig. 2). This happens either through analogue standard land telephone lines or via cellular technology using GSM technology. From the manufacturer-run data handling facility the data will then be transmitted to the respective internet platform, which can be accessed by the physician or authorised personnel. Optionally, the treating physician can also be alerted via fax or other modes of communication. The alert status of different transmitted events can be selected and changed online (fig. 3). However, it is and will not be possible to reprogramme the CIED remotely. This implies that pacing threshold tests cannot be performed remotely. The data of automated pacing threshold measurements, however, can be retrieved easily. Data typically collected and transmitted by the different systems are listed in table 1.

Home-Monitoring™ (Biotronik) was introduced in 2001 and automatically transmits data on a daily basis. It is wandless and requires virtually no patient action. The system is portable and the only one currently using GSM technology.

CareLink Network™ (Medtronic) wirelessly transmits the data to a communicator. The retrieved data is transmitted via standard phone lines and stored in a central repository. It requires patient participation since the patient will be alerted by an audible tone in case of a pre-specified event and then needs to initiate a communication session. Automatic transmissions can be programmed manually at intervals not shorter than 21 days. The CareLink™ network is the only system that incorporates the Optivol™ sensor. This system measures the drop of intrathoracic impedance upon intrapulmonary fluid accumulation (fig. 4). Yu et al. demonstrated that the

Figure 1

Components of a remote monitoring system (Latitude™, Boston Scientific). An ICD equipped with a microantenna sends data to a transmitter (usually placed on the bedside table). These will be transmitted through a phone line to a central data repository where it will be processed and placed on a website.

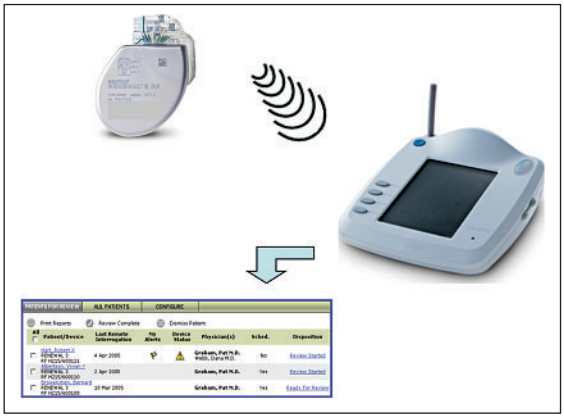

Figure 2

Example of periodically transmitted atrial and ventricular electrograms as it appears on the online screen (CareLink™, Medtronic).

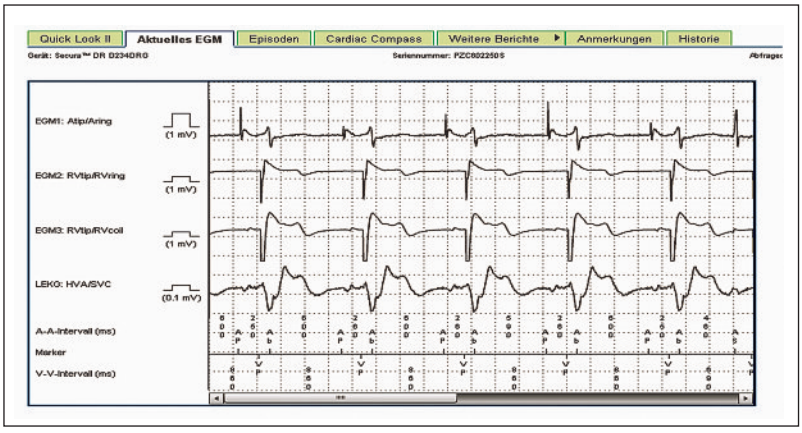

Figure 3

Remotely programmable alert options (Home Monitoring™, Biotronik).

Status	Implant settings	Holter	History	Patient profile	Options
Applied:	Individual options				
Implant					
	Special implant status, Ven. detection off, Emergency brady active, Back-up mod				
	ERI				
	Programmer triggered message received				
Lead					
	RV pacing impedance: < 250 ohm or > 1500 ohm				
	RV sensing amplitude (daily min.): < 2.0 mV				
	RV pacing threshold safety margin (only Lumax 500/540): < 1.0 V				
	Daily shock impedance: < 30 ohm or > 100 ohm				
	Shock impedance: < 30 ohm or > 100 ohm				
Ven. arrhythmia					
	VF detected: every				
	Ineffective ven. max. energy shock(s)				
Episode					
	Ven. therapy episode with long duration: > 2 min				
	Ven. episode with acceleration of ven. rhythm				
	Ven. episode with fulfilled ATP time-out criterion				
	Ven. episode with 2 or more started shocks				
	Episode details received				
	Periodic IEGM received				
Home Monitoring					
	First message received				
	No messages received for 14 days				

Figure 4

Example of intrathoracic impedance and heart rate variability measurement (Optivol™, MedtronicCareLink™).

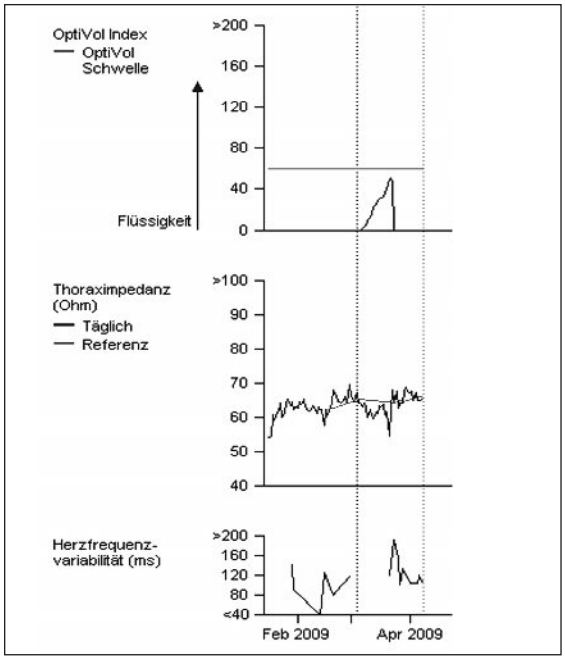

Table 1
Examples of commonly detected and transmitted data in remote device monitoring.

Technical	Battery Status
	Pacing lead impedances
	Shock impedances
	Sensing amplitudes
	Automated threshold measurements
	Percentage of stimulated beats (esp. in CRT)
	Periodic intracardiac electrogramme (EGM)
Medical	
Arrhythmias	Detected VF or VT episodes
	Detection of atrial fibrillation
	Treated VT or VF episodes
Heart failure	Continuous intrathoracic impedance measurements (Optivol)
	Heart rate variability
	Heart rate histograms

impedance drop preceded the onset of clinical heart failure symptoms by a mean of 15 days [19]. This feature is a powerful tool to prevent heart failure hospitalisations in CRT and ICD-patients if medical therapy is adjusted quickly on an outpatient basis.

Boston Scientific's Latitude™ System also utilises wireless transmission from the device to a communicator. From the communicator the data is sent through a landline to a central repository. From there the data is made available on an internet platform. As with the other systems, the surface of the internet site closely resembles the surface of the respective manufacturers' programmer in order to make the system as user-friendly as possible. With this system prearranged appointments for remote controlling can be programmed. Additionally, a red light on the communicator prompts the patient to initiate on-demand transmission if an alert has been detected. Furthermore, the Latitude system optionally allows for connection of a blood pressure cuff and a weight scale for ambulatory monitoring of heart failure patients.

Clinical data

Data transmission

With the current technology data transmission is reliable and safe. Rare initial transmission problems can usually be dealt with by simple troubleshooting phone calls [14]. In the largest series, Lazarus analysed more than 3 million transmissions by 11 624 recipients of CIED using Home Monitoring (4631 pacemakers, 6548 defibrillators, and 445 CRT devices) [17]. Eighty-six percent of events were disease-related. In average, the number of events per patient per month was 0.6. Furthermore, the events occurred after a mean of 26 days after the last follow-up, resulting in a putative gain of 154 days if the patients were controlled only every 6 months. However, the overwhelming majority of these events would not have resulted in any clinical action. Theuns and coworkers recently studied 146 ICD recipients who transmitted more than 57 000 episodes [20]. Of these, only 1.9% were triggered by prespecified events, including induced ventricular fibrillation (VF). In total, 95% of events were classified as clinical and not system related. The median number of events per patient per month was only 0.14 and did not differ between patients with primary and secondary prevention indication for their ICD.

Detection of technical problems and arrhythmias

The difference in the event rates between these studies indicates that the additional work burden is directly related to the pre-specified events. Technically, particularly the impedance measurements of the different leads are extremely helpful to identify failing leads. Furthermore, certain measurements that indicate battery depletion are necessary. Clinically, however, one can curtail the events that need to be transmitted. For instance, regular reports on paroxysmal atrial fibrillation (AF) events are unnecessary, if the patient is already anticoagulated and it has been decided to treat this individual with a rate control strategy. Another example is a patient who has known long-standing asymptomatic non-sustained ventricular tachycardia (NSVT) and who has no signs of myocardial ischaemia. Transmissions outside the scheduled routine follow-up scheme would not result in therapeutic changes. On the other hand, transmission of a first AF episode in a patient at risk for thromboembolic complications is of great importance since the institution of anticoagulant therapy significantly lowers the risk for cerebrovascular accidents [21]. Remote monitoring can also be helpful in patients who experience a cluster of ICD shocks. Immediate remote interrogation of the device clarifies whether the patient experiences appropriate shocks in the context of an electrical storm or if he suffers from inappropriate shocks caused for example by rapidly conducted AF or a lead fracture [22]. Appropriate advice (e.g. inactivation of ICD therapy by placement of a magnet over the device) can thereby be given to emergency medical personnel treating the patient.

Heart failure

All CRT-patients and many ICD carriers are heart failure patients. CRT not only lowers their mortality but also helps to keep patients out of the hospital [23]. The feasibility of remote CRT-ICD monitoring has recently been shown [24, 25].

Table 2

Minimum frequency of CIED in person or remote monitoring (HRS/EHRA recommendations):

Within 72 hours of CIED implantation	In Person
2–12 weeks after implantation	In Person
Every 3–12 months pacemaker/CRT-P	In Person or Remote
Every 3–6 months ICD/CRT-ICD	In Person or Remote
Annually until battery depletion	In Person
Every 1–3 months at signs of battery depletion	In Person or Remote

Using the CareLink Network, 80% of 67 study participants stated that they prefer remote control over clinic visits [24]. The overall duration of the interrogation procedure was 7 ± 5 minutes per patient. The time needed for website review was 5 ± 2 minutes per patient. In terms of cost effectiveness new device features are particularly favourable if they prevent hospitalisations. Automatic warning systems like monitoring intrathoracic impedance, which drops well before clinical symptoms of heart failure occur, are particularly helpful [19]. Recently, Catanzariti and co-workers demonstrated in 532 heart failure patients implanted with a biventricular ICD that intrathoracic impedance monitoring effectively reduces hospitalisation [13]. In their population, they documented 1652 follow-up visits over 11 months of which 172 (10%) were unscheduled. One hundred two patients (19%) had the Optivol feature disabled. During the follow-up period, 230 patients with the Optivol feature "on" showed an impedance drop and 7% of these were hospitalised. In contrast, hospitalisation was necessary in 20% with the impedance monitoring "off". This is in line with the COMPASS-HF study which showed that continuous intracardiac impedance measurement decreases heart failure morbidity [26]. The current heart failure guidelines of the European Society of Cardiology already address this new technology and state, that the use of remote monitoring may decrease health care usage of heart failure patients mainly by reducing hospital admission (class of recommendation IIb, level of evidence C) [27].

Reduction of follow-up time and resources

Undoubtedly, remote monitoring saves time for patients. Particularly in countries where patients have to travel long distances to reach their follow-up centre, time saving can be dramatic. In a Finnish study patients needed 6.9 ± 5 minutes for remote transmission as compared to 182 ± 148 minutes for in-office visits [14]. In this and other studies [10], the individual follow-up is also faster for the physician (8.4 ± 4.5 minutes vs 26 ± 17 minutes). In the Finnish study, the authors suggested that at least for the Finnish system, remote monitoring can slightly lower the direct costs for ICD follow-up (although they did not include the additional costs for remote monitoring in their calculation). This has so far not been shown conclusively for the health care systems in the big European countries. Studies demonstrate that between 85 to 90% of ICD visits are scheduled and only 5% of these resulted in device programming, whereas this is the case in 40% of unscheduled visits [28, 29]. In other words, more than 90% of all ICD interrogations do not result in ICD reprogramming and could mostly be handled by remote monitoring. The results of the so far unpublished TRUST trial [30, 31] showed in a prospective manner that in-office follow-up visits could safely be reduced by 43%, whilst the adherence to follow-up visits increased from 79 to 88%.

Follow up recommendations

Currently, the HRS/EHRA consensus paper proposes a minimum frequency of direct clinical contact with CIED recipients [1]. Although these devices may not require reprogramming one must not forget the importance of the face-to-face contact of the patient with his physician. This is particularly important in the ICD and CRT population, where more patients may require adjustment of their medication or may suffer from other medical conditions. In a study by Heidbüchel and colleagues almost 15% of patients had a change of their medication during follow-up visits [28]. The current minimum follow-up recommendations are summarised in table 2.

Conclusion

Remote monitoring has emerged as a technically reliable and safe new tool to monitor patients with a cardiovascular implantable electronic device and will undoubtedly play its role in the management of the growing CIED population. Since this new technology also has its price, it still needs to be determined, which patients will benefit most and in which cohort this modality proves to be cost effective. Clinically, the early detection of heart failure deteriorations, as measured by continuous intrathoracic impedance measurements, has been shown to reduce heart failure hospitalisations. Remote monitoring has a crucial role in the management of patients whose ICD leads are under a safety alert. It not only allows earliest possible detection of abnormal device behaviour but also limits underreporting of device malfunction. Finally, it certainly increases patient comfort for those living in remote areas or whose mobility is restricted.

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