

Remote Monitoring of Implantable Cardioverter-Defibrillator Therapy

MJ Pekka Raatikainen and Ulla-Maija Koivisto¹
Heart Center Tampere University Hospital, Tampere,
¹Division of Cardiology, Oulu University Hospital, Oulu,
Finland

1. Introduction

With increasing awareness of the indications of implantable cardioverter defibrillator (ICD) therapy, the number of patients with ICDs has been growing rapidly. Patient with an ICD require high-quality care and intense follow-up to ensure safe and effective device performance. Given the expanding use and the complexity of these devices, there has been an urgent need to improve the safety and cost-effectiveness of ICD follow-up and to alleviate the burden of the pacemaker clinics. Remote monitoring is quickly becoming the standard of care for surveillance of patients with ICDs and other cardiovascular implantable electronic devices (CIED). Transtelephonic data transmission via analog phone lines has recently been replaced by sophisticated Internet-based, automatic monitoring systems, which enable transmission of ICD performance and therapy data via a mobile monitor located in the patient's home to a secure server. Within minutes, the data are available to the physician online via a secure Internet access 24/7.

Each company employs somewhat different technology and degree of automation in their systems. For several years Biotronik was the only company with fully automatic wireless data transmission, but recently also the other manufactures have developed GSM-based wireless systems. Currently remote monitoring systems are widely used for the surveillance of ICD patients in the USA and Europe and their use in the other parts of the world is increasing rapidly. We were the first to start using the Medtronic CareLink system in Europe in 2004. It has been estimated that at the moment more than 1 000 000 patients with CIEDs around the world are using remote monitoring systems. The technology is evolving toward fully automated wireless remote monitoring systems which allow instantaneous event transmission without any patient involvement and have the ability of rapidly bring to the physician attention all significant data. Recent trials have demonstrated that remote monitoring reduces clinic burden, and permits early detection of patient and device problems, enabling clinically appropriate intervention and an opportunity to enhance patient safety.

In this article, we describe the currently available remote monitoring systems (Table 1), review the available evidence in the literature regarding remote ICD follow-up and discuss some unresolved issues. In addition, we provide several examples that clarify the benefits of the remote ICD monitoring.

Manufacturer	Name of the system	ICD	CRT	PM	ILR
Biotronik	Home Monitoring	+	+	+	-
Boston Scientific	LATITUDE	+	+	-	-
Medtronic	CareLink	+	+	+	+
St Jude Medical	Merlin.net	+	+	+	+

Table 1. Remote monitoring systems of the major CIED manufactures. ICD = implantable cardioverter defibrillator, CRT = cardiac resynchronization therapy with (CRT-D) or without defibrillator functions (CRT-D), PM = conventional pacemaker, ILR = implantable loop recorder. *The LATITUDE system is currently compatible only with CRT-D devices.

2. Overview of currently available remote monitoring systems

Since Biotronik pioneered the technology with FDA approval of their first system in 2001, remote monitoring systems have now been introduced by each of the major CIED manufacturers. Presently remote monitoring is primarily used for the surveillance of ICD systems, but the technology is also feasible for the follow-up of other CIEDs including pacemakers (PM), cardiac resynchronization devices (CRT), implantable loop recorders (ILR) and implantable cardiovascular monitors (ICM).

A remote monitoring system consists of an implanted device, a mobile patient monitor, a central database in a secure server, and a password-protected website, where clinicians can view and analyze the data saved in the memory of the patient's device (Figure 1). Systems differ regarding data transfer from the device to the patient monitor. In the early models data transfer required patient's active involvement as he/she had to interrogate the device manually with a specific wand. In the more recent systems data transmission is performed wirelessly from the implanted device to a patient monitor, but each company employs somewhat different technology and degree of automation in their systems.



Fig. 1. Components of remote monitoring system. Systems differ regarding data transfer, which may require patient's active involvement or is performed wirelessly from the implanted device to a patient monitor. Data from the patient monitor is sent to a central database using either an analogue phone landline or via GSM network. The data are accessible to the clinical staff on a secure Internet site.

Patient initiated remote transmission requires that the patient manually interrogates and initiates the data transmission using a telemetry wand incorporated in the home transmitter. This encounter may be a scheduled follow-up interrogation or an unscheduled interrogation activated by a patient symptom (*e.g.* ICD shock) or detection of a device alert (audible tone or vibration). Wireless technology allows for automatic data transmission without any patient interaction. Automatic wireless interrogation requires that the implanted device is equipped with an integrated antenna for communication with the transmitter located close to the patient (Figure 2). Data transmission is initiated either at pre-scheduled time intervals or triggered immediately by programmed device alerts (*e.g.* abnormal lead impedance, delivery of ICD therapies, or changes in hemodynamic status).

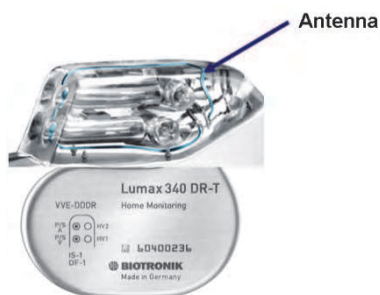


Fig. 2. An advanced ICD with an internal antenna for wireless data transmission to the patient monitor.

Data from the patient monitor is sent to a central database using either an analogue phone landline or via a GSM network. Within minutes from transmission, the processed data are accessible to the follow-up physician on a secure Internet webpage when and where he/she chooses. Available information includes all data within the device memory, which is comparable to the information provided during an in-clinic device follow-up visit. When a therapy-relevant event or device status change is detected, remote monitoring system also generates an event alert via email, SMS, or fax to the physician while simultaneously displaying the severity of alert on the internet website.

Devices with CRT-delivery have the capability to track the percentage of biventricular stimulation and several physiologically diagnostic parameters such as heart rate, heart rate variability, and patient activity. Some devices include also fluid status monitoring by assessing intrathoracic impedance. Fluid accumulation within the lungs leads to a decrease in impedance and provides an early indication of congestion. Remote monitoring system automatically generates wireless alert notification when the device detects a loss of CRT delivery or a change in hemodynamic status indicating risk for worsening heart failure.

3. Safety of remote ICD monitoring

Remote monitoring is easy to use and it provides a feasible alternative for long-term surveillance of patients with ICD. It allows the physician to view and analyze transmitted device data from any computer in a format similar to the information gathered during a typical in-clinic visit (Figure 3). In addition to the device parameters (*e.g.* battery voltage and longevity, lead impedance and trends, automatic capture thresholds) and the summary of

stored ventricular and supraventricular arrhythmia episodes, the physician can also review the intracardiac electrograms of the arrhythmic events (Figure 4) and a real-time electrogram with the presenting rhythm. The information is automatically saved on the server for future comparison and analysis.

Clinical Status: Since Aug 09, 2006							
Episodes			% Pacing				
VF	0		Sensed	98.4 %			
FVT	4		Paced	1.6 %			
VT	0						
SVT	0						
NST	45						
Observations (0)							
- No observations based on currently interrogated data.							
ICD Status							
Battery Voltage (ERI=2.62 V)			3.17 V		Dec 13, 2006		
Last Full Energy Charge			7.49 sec		Oct 12, 2006		
Last Capacitor Formation (Interval=Auto)					Oct 12, 2006		
Lead Information							
ICD	Medtronic	Marquis VR 7230	PKD610790S	May 20, 2005			
RV/SVC	Medtronic	SPRINT FIDE	LFJ048743V	May 20, 2005			
Lead Performance				Ventricular			
EGM Amplitude				10.3 mV		Dec 13, 2006	
Pacing Impedance				408 ohms		Dec 13, 2006	
Defibrillation Impedance				48 ohms		Dec 13, 2006	
SVC (HVX) Impedance 63 ohms						Dec 13, 2006	
Parameter Summary							
Type	Detection	Rx1	Rx2	Rx3	Rx4	Rx5	Rx6
VF	On 188-500 bpm	30 J	30 J	30 J	30 J	30 J	30 J
FVT	via VF 188-250 bpm	Burst(1)	30 J	30 J	30 J	30 J	30 J
VT	On 150-188 bpm	Burst(3)	Ramp(3)	5 J	30 J	30 J	30 J
SVT Criteria On: Wavelet(Monitor)							
Modes		Rates					
Mode	VI	Lower	40 ppm				
Lead Parameters				Ventricular			
Amplitude				3 V			
Pulse Width				0.4 ms			
Sensitivity				0.3 mV			

Fig. 3. Example of stored device data in the Medtronic CareLink network. The patient had had 4 fast VT episodes.

Studies have shown a >90% successful transmission rate of automatically generated data collected by the device within several minutes and no direct safety issues with remote monitoring have been identified (Varma et al., 2005). It has been estimated that remote

monitoring of ICD patients can potentially diagnose >99,5% of arrhythmia- and device-related problems (Heidbüchel et al., 2008). In our study physicians were satisfied with the performance of the system and found the data comparable to traditional device interrogation in the majority of the cases. In 2 of 137 cases, the physicians felt that an in-office visit would have provided more detailed information of the device function, because it was not possible to measure the pacing threshold remotely.

Remote monitoring systems do not allow remote programming of devices or manual determination of pacing thresholds. Although technically feasible, protecting patient safety is the primary concern not to enable remote programming yet. Meanwhile, most new devices have automatic features to measure pacing and sensing thresholds. The lack of possibility for remote programming appears also as an issue of minor relevance during the routine ICD follow-up. In a retrospectively analyzed data of 1739 ICD follow-up visits by Heidbüchel et al (2008), changes in device programming were made only in 4% of all scheduled follow-up visits. Likewise, problems with pacing threshold were detected only in 0,4% of the evaluations and typically in the early postoperative period. Due to the clustering of system-related complications in the early postoperative period, in-clinic visits are recommended for the post-implant and after 4-12 weeks follow-ups for patients with remote monitoring (Wilkoff et al., 2008).

4. Efficiency of remote ICD follow-up

According to the current HRS/EHRA expert consensus on the monitoring of CIEDs, patients with an ICD should be followed up in person after implantation and subsequently every 3-6 months (Wilkoff et al., 2008). More frequent monitoring may be required when the device approaches its elective replacement indicator. During the maintenance phase of follow-up and when the patient's medical condition is stable and no anticipated device programming is required, follow-ups can be accomplished remotely. It is also recommended that any patient with an ICD should be assessed in-clinic once a year.

Remote monitoring technology reduces the need for hospital visits and may facilitate, when needed, visits triggered by clinical event. It has been estimated that remote follow-up could be used to replace majority of scheduled in-clinic visits, as in only 10% of routine follow-ups does device interrogation lead to changes in medical treatment or device programming (Heidbüchel et al., 2008). Unscheduled clinic visits initiated by the patient due to perceived ICD shocks, other arrhythmic events or system related complications are actionable more often, in 40-90% of the cases. Thus, of the majority of the patient-initiated unscheduled clinic visits could be managed by remote monitoring with no need to visit the device clinic.

Our results showed that at least two out of three in-clinic visits can be replaced by scheduled remote monitoring data transmission without compromising the safety of the patients (Raatikainen et al. 2008). The data from the TRUST trial demonstrated in the first prospective, randomized multicenter study that remote home monitoring with wireless automatic daily surveillance can safely and effectively replace conventional in-hospital ICD follow-up visits (Varma et al., 2010). The results showed that remote monitoring with only one scheduled annual in-clinic visit reduced the overall number of clinic visits by 45% without any negatively impact on quality of care or safety of the patients. Remote monitoring provided sufficient assessment in the majority of 3-monthly follow-ups, in 85,8% of the cases. In addition, the TRUST trial also demonstrated that automatic daily

surveillance provided early detection and notification of both symptomatic and asymptomatic arrhythmic events and device system anomalies allowing for earlier physician intervention than conventional in-hospital follow-ups. Detection was advanced by more than 30 days compared with conventional care.

According to our data the time needed by the patients for remote data transmission (6.9+3.7 min) was significantly shorter than the duration of an in-office visit, which took over six hours (391+282 min) when the travel time was included in the analysis. The average one-way distance and travel time to the hospital were 130+95 km (range 3–350) and 182+148 min (range 10–670 min), respectively. Most patients (90%) found the system convenient to use and classified the time needed for the remote data transmission for all follow-ups as very short (21%) or short (69%).

5. Workflow of the device clinic

It is obvious that remote monitoring reduces significantly the device clinic workload for routine cases by decreasing the number of non-actionable in-clinic visits. In addition, remote follow-up requires less physician and technician or nurse time than in-clinic follow-up. In an Italian study (Masella et al., 2008), remote follow-up with the CareLink system required on average 5 minutes per transmission compared with 15 minutes for in-clinic follow-up. In keeping with this, our data indicated that prescheduled data transmission significantly alleviated the time burden of the device clinic staff. In our study, two of four in-office visits were substituted by remote monitoring. As a result the physicians had at least 45 min and the nurses 90 min more time for other activities per patient during the 9-months study period, respectively (Raatikainen et al. 2008). New wireless remote monitoring systems allow automatic data transmission on a daily basis and instantaneous event transmission without any patient involvement. This permits physicians and clinic staff to focus on patients who urgently require a consultation for diagnostics or treatment.

Recently, remote monitoring with automatic data transmission has been shown to improve early detection of device malfunction and asymptomatic arrhythmias such as atrial fibrillation. On the other hand, it has been postulated that automatic transmission of all device- or therapy-related events via a fully automated wireless remote monitoring system may pose a challenge to workflow in ICD clinics. Transmitted data should be assessed in a regular timely fashion and responded to if events are observed. The remote monitoring system quickly and easily identifies patients who need immediate attention by automatically reviewing, filtering and communicating clinically relevant patient and device status data. Despite daily remote monitoring, the event alert notifications are triggered infrequently and most can be managed remotely. In the TRUST trial (Varma et al, 2010), about 90% of the alert notifications were managed remotely. Thus, replacement of routine in-clinic visits with remote monitoring only slightly raised the number of unscheduled in-clinic visits (0,7 vs. 0,5 per year). The commonest trigger for the transmission of event alert was the detection of atrial tachycardia or atrial fibrillation. In our study there were 18 unscheduled patient- or physician-initiated data transmissions during the study period. In accordance with the results of Varma et al. (2010), all of these were solved remotely and the patient did not need to come to the hospital for reassurance. An example of a symptom-initiated data transmission which was solved remotely is shown in Figure 2. Other events which have been commonly diagnosed and treated on the basis of symptom-initiated data transmissions include atrial fibrillation and “phantom” shocks.

Lead failure is a long-term complication of ICD therapy. The annual rate of ICD leads requiring intervention increases with time and reaches 20% in 10-year-old leads (Kleemann et al., 2007). Inappropriate shocks due to noise oversensing are revealed as the most common presentation of lead failure. Studies have shown that early detection of lead failure by remote monitoring may reduce the risk of inappropriate ICD shocks (Hauck et al., 2009, Spencker et al., 2009). Spencker et al (2009) reported that fewer patients undergoing remote monitoring experienced ICD shocks for sensing failure prior to lead revision than those with standard in-clinic follow up. Inappropriate shocks occurred in 27,5% of the patients followed remotely compared with 46,5% of those followed up in-clinic. In 91% of all incidents, remote monitoring system transmitted an early alert message that enabled the correct diagnosis of lead failure. By accurately detecting lead failures, remote monitoring has also proven to be useful in the follow-up of ICD leads under advisory (Swerdlow et al., 2008, Theuns et al., 2009, Guédon-Moreau et al., 2010). An example of a lead problem which could actually have been detected by remote monitoring already a day before the inappropriate shock Figure 3.

OBSERVATIONS (3)

- Sensing issue: 486 short V-V intervals since 10-Sep-2008 10:04:11. Check for double-counted R waves, lead fracture, or loose set screw.

- 1 shocks for VT/VF, 0 failed.

- 1 treated VT/VF episodes longer than 30 sec.

RV Pacing Impedance

At Implant	536 ohms	Highest	752 ohms
Last	1664 ohms	Lowest	456 ohms

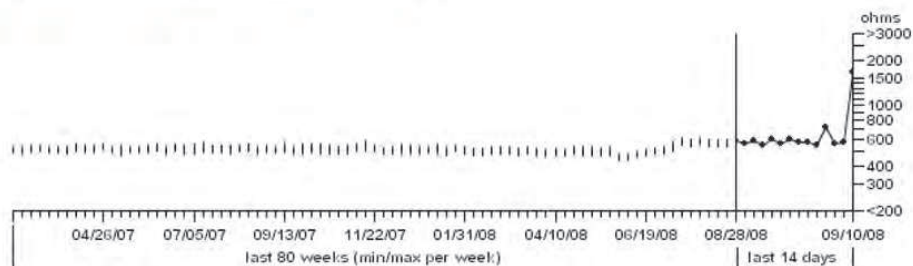


Fig. 3. Automatic data transmission showing high number of short V-V intervals suggesting double counting of R waves, lead fracture or loose set of screw. The impedance of the lead increased markedly on 09/10/08, *i.e.*, day before the patient had an inappropriate shock due to the lead fracture.

Recently the CONNECT trial for the first time showed that remote follow-up actually creates reliable outcome measures which improves care (Crossley et al., 2011). The study measured the time from an adverse event to a clinician's decision on how to handle it in patients with an ICD with or without CRT capabilities randomized to wireless remote monitoring with automatic clinician alerts versus standard in-clinic care. The results showed that remote monitoring significantly reduced the time from a clinically-actionable event to a clinical decision. The median time from a patient's clinical event (arrhythmias, cardiovascular disease progression, and device issues) to the physician's clinical decision

was 22 days for those monitored in-clinic, versus 4.6 days for patients in the remote monitoring group. The data also showed that remote monitoring reduced average length of cardiovascular hospital stay by 18% (0,7 days). Due to the shorter length of stay, cardiovascular hospitalization costs were reduced by an estimated \$1,793 per hospitalization. Furthermore, the data showed that replacement of routine in-clinic visits with remote monitoring did not significantly increase other healthcare utilization, such as emergency room visits, cardiovascular hospitalizations, and unscheduled clinic visits.

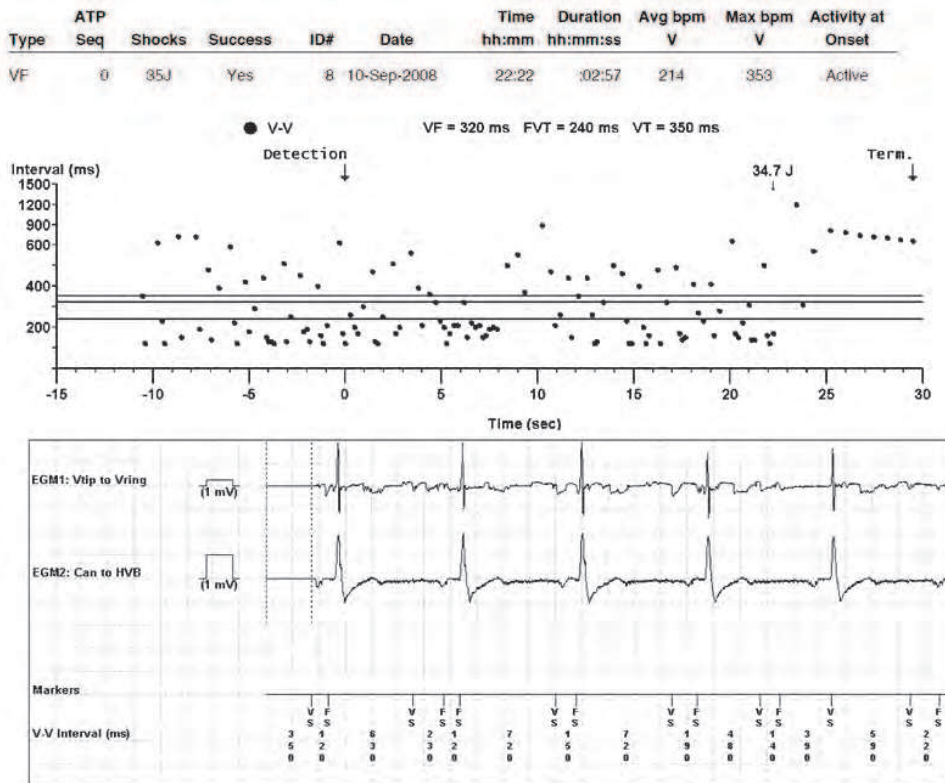


Fig. 4. Inappropriate shock due to lead fracture. Shown are the V-V interval plot and intracardiac ECG. It can be seen that the lead fracture resulted in oversensing of noise in the VT and fast VT zone which caused an inappropriate shock.

Inappropriate shocks are due to lead fracture (Figure 4.), misdiagnosis of sinus tachycardia (Figure 5.) or rapidly conducted AF/AT episodes are also a major concern among ICD recipients. Inappropriate shocks are painful for the patients and also potentially life-threatening. In a recent analysis (van Rees et al., 2011), the first inappropriate ICD shock increased the risk of death by 60%. Mortality risk increased with every subsequent shock. Detection of problems such as sinus tachycardia and T-wave oversensing through remote monitoring followed by prompt device reprogramming may prevent new episodes that could lead to inappropriate therapies (Sacher et al., 2009).

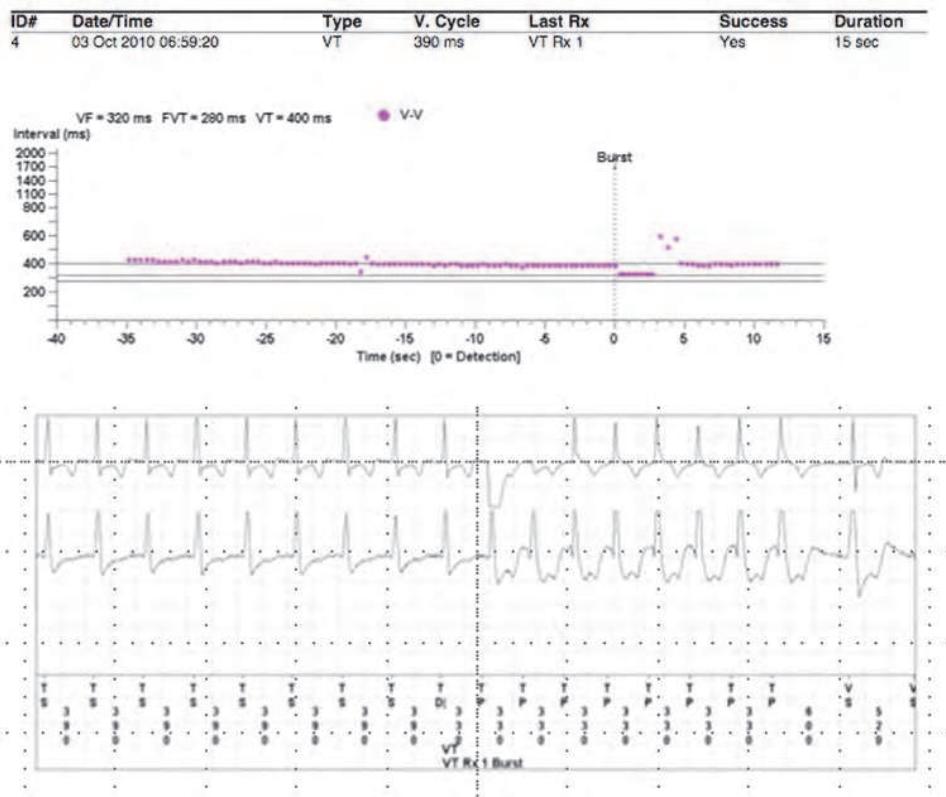


Fig. 5. Event notification via CareLink remote monitoring system. The V-V interval plot and the IEGM show inappropriate ATP-therapy delivery due sinus tachycardia. The patient was invited to device clinic for reprogramming of the device and adjustment of medication.

Several prospective randomized studies are presently underway on the clinical effectiveness of event-triggered active heart failure and AF management though remote monitoring in reducing cardiovascular related hospitalizations and mortality in patients with an ICD or a CRT-D device. In the ALTITUDE study (Saxon et al., 2010), analysis of a large manufacturer's database of ICD patients undergoing remote monitoring with LATITUDE system showed higher survival rates for patients followed remotely than those followed in-clinic only. Survival outcomes in ALTITUDE appeared also better than those observed previously in clinical trials, suggesting that closer management though remote monitoring allows to intervene more effectively with impact on survival.

An additional benefit is that remote monitoring provides convenient means to address the situation that the ICD or its leads can become subject to the an official safety advisory ("recall"). With remote monitoring, patients with advisory devices can be followed more closely, their issues addressed more promptly, and clinicians and device manufacturers get exquisitely detailed data on how the device is performing.

7. Patient preference

Several studies have shown a high degree of patient satisfaction with the convenience and ease of use of remote monitoring systems (Marzegalli et al., 2008, Masella et al., 2008, Raatikainen et al., 2008). From a patient's perspective, the biggest value of remote monitoring is convenience with fewer in-clinic visits and less time traveling to and from their clinics. Remote monitoring also leads to greater patient reassurance and improved patient follow-up adherence (Varma et al., 2010). Most patients prefer remote monitoring over in-clinic visits (Marzegalli et al., 2008, Masella et al., 2008). In TRUST trial, 98% of patients elected to retain remote monitoring as a follow-up mode on trial conclusion (Varma et al., 2010).

The current HRS/EHRA expert consensus states that remote monitoring of ICD devices is indicated when the patient's medical condition is stable and no anticipated device programming is needed (Wilkoff et al., 2008). The technology is not, however, intended to replace direct patient contacts completely. In-clinic visits are recommended for the post-implant follow-up, after 2-12 weeks and at least once a year. If the patient's cardiovascular status is unstable, in-clinic visit may be required to address the management of the underlying medical problem. The continuation of patient's clinical follow-up for the heart failure management should be ensured regardless of the place of care.

8. Cost effectiveness

As a result of expanding indication for use and complexity of the devices, the costs associated with ICD follow-up have risen sharply over the past several years. Remote monitoring may result in reduced overall costs to the healthcare system, although the cost-effectiveness will highly depend on differences in national healthcare systems. Potential cost savings of remote monitoring would include a reduced number of scheduled in-clinic visits and fewer hospitalizations due to early identification of problems followed by prompt intervention. It can be calculated that if remote monitoring were to be applied to all the patients with new ICDs, the annual saving for the healthcare system in Western Europe, would be 16-23 million Euros. In addition, remote monitoring gives physicians extra time to counsel patients with critical conditions, ensuring medical efficiency, and better overall patient management, which is expected to reduce the cost of the treatment even further.

The major indirect cost driver in the ICD follow-up is travelling to the hospital. Therefore, the greatest cost benefit is expected among patients who live far away from the device clinic and are still actively working (not retired). Several studies have evaluated the cost savings attributable to remote monitoring of ICD devices (Fauchier et al., 2005, Elsner et al., 2006, Raatikainen et al., 2008). The greatest benefit is seen among patients with long traveling distances to the device clinic. In a French study (Fauchier et al., 2005), remote monitoring appeared cost-effective for patients after a mean follow up of 33.5 months by saving on transportation costs. In our study (Raatikainen et al., 2008), replacing two scheduled routine in-clinic visits by remote monitoring reduced the total expenditure of ICD follow-up by 524€ per patient during the 9-month study period. In addition, an average of 100€ per patient was saved, because all unscheduled data transmissions during the study period were solved remotely and the patient did not need to come to the hospital for reassurance. Thus, depending on the number of unscheduled visits, it was calculated that the annual saving of remote monitoring was 524-749€ per patient (Table 2). Further prospective health economic

studies are presently underway. They are aimed at assessing the economic impact of remote monitoring from the societal perspective and from the healthcare payer's perspective.

	In-clinic F-U	Remote F-U	Savings
Number of scheduled visits			
In-office visits*	164	82	
Remote data transmission**	0	82	
Direct cost			
In-office visit (210 € per visit)	34440.00 €	17220.00 €	17220.00 €
Remote monitoring (55 € per visit)	0.00 €	4510.00 €	-4510.00 €
Patient fee (22 € per in-office visit)	3608.00 €	1804.00 €	1804.00 €
Indirect cost			
Traveling (77.68 € per in-office visit)	12195.04 €	6097.52 €	6097.52 €
Accommodation (20.18 € / night)	40.36 €	20.18 €	20.18 €
Sickness allowance (44 € / day)	1672.00 €	836.00 €	880.00 €
Total costs	51955.40 €	30487.70 €	21467.70 €
Total costs per patient	1267.20 €	743.60 €	523.60 €

Table 2. Comparison between the cost of ICD follow-up according to the generally applied in-clinic follow-up scheme and remote monitoring. Adapted from Raatikainen et al. (2008).

9. Summary and future directions

In summary the major benefits of the currently available remote monitoring systems include:

- Improved quality of patient care
- Improved patient safety
- More efficient device clinic workflow
- Increased patient convenience
- Potential cost savings

The reality on the ground is that physicians should also have the ability to make adjustments to certain programmed ICD parameters remotely. As technology continues to evolve, a variety of new applications related to cardiac monitoring will emerge and an exponential growth in implementation of remote monitoring for the surveillance of a variety of devices including all new ICDs, pacemakers and other implantable disease monitors is likely to occur. Meanwhile, a wide range of medico-legal and reimbursement issues needs to be resolved before full implementation of the technology.

10. Conclusions

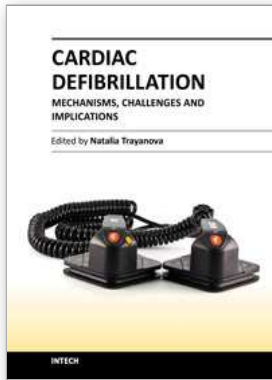
Remote monitoring has become the preferred method for ICD follow-up. It provides a tremendous convenience for the patients and reduces the burden of in-clinic follow-up on healthcare system. Continuous remote monitoring with fully automated wireless system also enables early detection of clinically relevant events and alerts physicians, allowing

earlier medical intervention that increases the level of patient care. Despite 24/7 surveillance, the technology is not a substitute for an emergency system and should not create a false sense of complete security.

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The only known effective therapy for lethal disturbances in cardiac rhythm is defibrillation, the delivery of a strong electric shock to the heart. This technique constitutes the most important means for prevention of sudden cardiac death. The efficacy of defibrillation has led to an exponential growth in the number of patients receiving implantable devices. The objective of this book is to present contemporary views on the basic mechanisms by which the heart responds to an electric shock, as well as on the challenges and implications of clinical defibrillation. Basic science chapters elucidate questions such as lead configurations and the reasons by which a defibrillation shock fails. Chapters devoted to the challenges in the clinical procedure of defibrillation address issues related to inappropriate and unnecessary shocks, complications associated with the implantation of cardioverter/defibrillator devices, and the application of the therapy in pediatric patients and young adults. The book also examines the implications of defibrillation therapy, such as patient risk stratification, cardiac rehabilitation, and remote monitoring of patient with implantable devices.

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University Campus STeP Ri
Slavka Krautzeka 83/A
51000 Rijeka, Croatia
Phone: +385 (51) 770 447
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InTech China

Unit 405, Office Block, Hotel Equatorial Shanghai
No.65, Yan An Road (West), Shanghai, 200040, China
中国上海市延安西路65号上海国际贵都大饭店办公楼405单元
Phone: +86-21-62489820
Fax: +86-21-62489821

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