Remote Follow-up of Implantable Cardioverter Defibrillators: Technology, Patient Management, Integration with Electronic Records, and ICD Product Surveillance

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Abstract

The remote monitoring systems (hereafter referred to as RMS) for follow-up of ICDs is a relatively new technology.[1] It has been utilized in clinical practice for approximately three years. The first large feasibility study, using Medtronic's Carelink System, was published in 2004.[2] This study demonstrated clinical usefulness as well as physician and patient satisfaction.

Recent large scale ICD generator and lead advisories and recalls have significantly increased the requirement to monitor devices more closely. The Heart Rhythm Society has recommended the use of wireless and remote monitoring technologies for improved detection of device or system malfunctions.[3] Financial and ethical constraints by device manufacturers will likely soon result in significant decrease in industry participation in surveillance of devices in clinics and offices. Wider use of electronic medical records begs the integration of device follow-up data with them in a seamless manor. All of these factors have accelerated the need and use of Internet-based monitoring systems. These systems are now offered without charge to the physicians and patients. Reimbursement policies for remote monitoring have been established by Medicare and most other insurance carriers. Remote monitoring is therefore needed and feasible as routine follow-up of ICDs.

It is logical to think that this type of follow-up will eventually be extended to pacemakers as well. The focus thus far has been on ICDs for a variety of reasons, but the advantages and rational for the extension of this technology to pacemaker follow-up are the same.

This article will address the technology of RMS, its potential impact on patient and device management, the integration of RMS with EMR, and the potential need to exploit RMS as a means of post market surveillance from a quality control standpoint, of ICDs. There remain unanswered questions about this technology which will be discussed as well.

Remote Monitoring Systems (RMS): Background

Internet-based follow-up of ICDs was first commercially available in 2002. The appeal of the technology is to decrease time per follow-up, improve patient convenience by decreasing routine office visits, and to improve patient care by utilizing it to rapidly transmit data from patients with symptoms or arrhythmic events. It has significantly increased in usage over the past two years.

Clinics or physician practices were initially charged on a subscription basis by the first device company to market the technology (Medtronic) for utilizing the service. Physicians and clinics operating within an environment of decreasing reimbursement were against this unprecedented model of having the physician subscribe for a service like this. Once comparable competition appeared with the LATITUDE system, which did not involve a subscription fee, adoption increased significantly, eventually becoming the economic model of the technology. The advent of wireless devices which makes transmission logistically easier for patients also contributed significantly to increased acceptance. The utilization of the Carelink system in identifying trends of failure of the Sprint Fidelis leads has brought to the forefront the potentially most important role of remote follow-up: a source of early detection of failure of devices and leads.[4]

RMS: Function

All the major cardiac rhythm device manufacturers currently have remote monitoring capabilities for ICDs. This involves a transmitter within a short distance from the patient, and a land line telephone connection. Some ICDs have antennae on the header of the device which communicates with the transmitter wirelessly. Others require a communication wand placed in close proximity of the ICD which allows communication with the transmitter. The transmitted information, depending upon the company, may have the information sent to a proprietary Internet server with the practitioner able to download the information to a PC. Integration with some electronic medical record systems is a fertile area of active work among the companies, driven by the desire by clinicians to consolidate clinical information as well as eliminate paper-based records (see section Future of the Technology below). Information obtained from the device is identical to that which would be generated by a printed report at the time of a device interrogation in the office. This includes functionality of the ICD generator and leads (battery status, lead impedances, last thresholds clinically obtained), arrhythmia logbook information with stored electrograms, and device settings. These systems are not designed at this time and are restricted by the FDA to allow changes in the device programming or test thresholds. The Medtronic Carelink and Boston Scientific LATITUDE remote follow-up systems are Internet-based, where data is sent via the patient's transmitter (via land line phone modem) to a central proprietary repository Internet server. This information is able to be viewed and then downloaded to computers by the physician following the patient.

Both of these systems have the ability to detect ‘alerts’ issued by the device itself. Some alerts are automatically active and some are programmable on or off by the clinician (must be done via the ICD with Medtronic, but can be done via the Internet with LATITUDE). Wireless technology allows for automatic transmission of alerts to the company servers, which trigger a communication (via Internet, email, or telephone) to the clinician. Medtronic nominal alerts include electrical reset, asynchronous pacing modes programmed on, and charge circuit timeout. Programmable alerts include device and lead integrity alerts, and clinical management alerts (AF burden or with rapid ventricular rates, multiple shocks for an episode, or exhaustion of therapies for an episode). Medtronic alerts are transmitted in non-wireless devices when the patient hears audible tones and then initiates a transmission. Wireless devices will automatically transmit alerts, and the physician determines which alerts to be personally notified for. Examples of nominal alerts of the LATITUDE system are: pacing and high voltage impedances out of programmed acceptable range, generator end of life (EOL), high or low shock lead impedance detected when attempting to deliver a shock, high voltage detected on shock lead during charge, tachy mode change due to magnet, tachy mode set to value other than Monitor + Therapy, possible device malfunction, or device parameter error. Programmable alerts include low sensing amplitudes or impedances, arrhythmias prompting shock therapy, arrhythmia acceleration as a result of therapy delivery, atrial tachyarrhythmias, and device reaching the elective replacement time. With non-wireless devices, the transmitter will once weekly flash an indicator to the patient to download device info, looking only for alerts. With wireless devices, the information pertaining to

alerts is automatically downloaded every 24 hours. The physician or clinic is notified on a schedule according to predetermined agreement with the company.

St. Jude's Housecall Plus system is not Internet-based, and has its basis in transtelephonic monitoring, consists of transmission to the follow-up clinic or to a commercial device monitoring company. This nature of the transmission allows for real-time electrograms. St. Jude has developed for use in the near future an Internet-based system, Merlin.net. It is comparable to Carelink and LATITUDE in design. St. Jude is about to launch the Merlin.net system which is not only Internet-based, but utilizes IHE (Integrating the Healthcare Enterprise) technology which is superior to the HL7 technology used by Boston Scientific and Medtronic with reference to integration with EMRs (see below).

Carelink and LATITUDE systems have functions of monitoring patients with heart failure who have CRT-D devices. Carelink will display data derived from their devices that have the capability to monitor transthoracic impedance over time (Optivol)®. Studies are under way to determine how intervening using this data may affect patient outcome. The LATITUDE system is called INSIGHT™. Information namely weight, blood pressure, % activity (via accelerometer), heart rate, and heart rate variability are available to view. Arrhythmias, counters and histograms are also available on the INSIGHT ™ report. In addition, clinical questions the patient answers are posed by the communicator (dyspnea, edema, and others). Currently, the CHF part of remote monitoring is not approved for reimbursement. Outcome studies are needed to determine clinical utility and, if so, the optimal frequency of transmission, and appropriate medical interventions based on the data.

Biotronik's remote monitoring system, in widespread use predominantly in Europe, and notably, is cellular phone technology-based (versus land line modem-based systems of Medtronic, Boston Scientific, and St. Jude Medical). The information is sent to a central center, and reports are then sent to the follow-up physician. This data is also accessible via Biotronik's website by the physician.

Because of the utilization of special bandwiths, patient-specific transmitters are currently utilized by the Carelink, LATITUDE, and Biotronik systems. The new St. Jude Merlin.net system will use these as well.

Why is Remote Follow-up Needed?

I. Patient and Device Management

Though studies looking at remote follow-up versus in-clinic follow-up are lacking, the usefulness of information derived from remote follow-up of ICDs affecting patient management has been described.[2,5,6] Newly discovered atrial tachyarrhythmias and/or those with rapid ventricular rates many be detected. Antiarrhythmic drug therapy can then be instituted and further transmissions used to assess the patient's rhythm thereafter. Appropriate institution of antithrombotic therapy for atrial tachyarrhythmias may also be prompted by events transmitted. Patients may initiate a transmission due to symptoms which may be arrhythmia related: VT treated with ATP, AF, bradyarrhythmias, pacemaker syndrome, pacing output failure, pacemaker-mediated tachycardia, or rhythm disturbances caused by device under or oversensing.

A large retrospective study using the Biotronic Home Monitoring system (6,548 ICD pts.) and 445 pts. with CRT-D was recently published.[5] There were 66 alerts from 40 devices for abnormal function detection. 38 devices were in an inactive mode, and two devices exhibited a random malfunction. Interestingly, 4.1% of devices transmitted alerts of ineffective maximum output shocks.

One retrospective study of 271 patients followed for 12 months using the Biotronik Home Monitoring system by Brugada et al examined the utility of remote monitoring in forecasting the necessity of a previously scheduled routine in-clinic visit[6]. There was a 67% true negative rate, 16% true positive rate, 3% false positive rate, and 14% false negative rate. Interestingly, lead problems were all detected either with the first follow-up or with subsequent follow-ups when a problem was initially detected in the first follow-up. Based on their findings, a decision tree was formulated in which the following events since the previous remote follow-up would lead to an in-office follow-up instead of the subsequent routine remote follow-up: previous lead problem, hospitalization, arrhythmias requiring therapy, or significant clinical symptoms.

A short prospective data from the Carelink feasibility study (53 pts with two transmissions seven days apart) revealed more device-related observations than patient related ones.[2] Device-related issues were: atrial undersensing (2 pts), T wave oversensing (2 pts), and far-field R wave sensing (4 pts). Patient-related observations consisted of: atrial fibrillation (5 pts with egrams), and VT episodes (2 pts). Detection of incessant VT has also been reported.[7] Inappropriate shocks can be detected with remote monitoring possibly eliminating emergency room visits as well as prompting an office visit for reprogramming the ICD or prompt referral for lead revision. In one study of 230

pts. being followed with remote monitoring, 18/72 pts. receiving either ATP or shock therapy had experienced atrial tachyarrhythmias as the cause.[8]

II. Integration with Electronic Medical Records

Practices and clinics with electronic medical records realize the power of technology to improve management of patients. All physician practices and hospitals will have electronic medical records (EMRs) in the near future as mandated by the federal government. Currently there are at least two bills on the floor of Congress dealing with EMRs. The marriage of remote monitoring systems with EMRs is a natural one. A sophisticated cardiology practice with an EMR system is currently paperless-except for its cardiac rhythm device follow-up clinic. It is ironic that a technology-heavy subspecialty such as EP is hindered by the current IT constraints on integrating RMSs with EMRs. There are only a couple of EMRs that have been integrated with remote monitoring. Medtronic's Carelink currently only has the Medtronic Paceart® system is as a portal to an EMR system. Paceart is one of the most widely used cardiac rhythm device data storage programs. The remote monitoring data is transferred via Carelink into the physician's Paceart system. The data from Paceart then needs to be transferred to an office EMR. As of now, Paceart serves as a portal for only for Medtronic Carelink data to be transferred into it. Medtronic is now working with other companies to have their remote data enter Paceart. Currently one modality of getting around this is to download data from LATITUDE for example, into a PC. It is saved as a pdf file and then can be transferred into the Paceart program on the computer.

Paceart as a repository of downloaded remote monitoring data and will eventually be replaced by the integration of RMSs directly with EMRs. An easy integration with seamless flow of data is certainly a natural progression and expectation of clinicians already using EMR systems.

There are other technical issues to resolve with integration. The way in which the data is formulated in the computer program is of paramount importance. Boston Scientific and Medtronic utilize HL7 and this is cumbersome and difficult to use from an IT perspective for transfer of data. St. Jude's system is the only one to have written to the IHE (Integrating the Healthcare Enterprise) Device standard. This is actually an international endeavor aimed at having healthcare data transfer seamlessly regardless of the application or IT system. All companies will eventually need to conform to IHE standards. Ideally there needs to be bidirectional communication between the RMS and EMR for easy transfer of data. This means that the two systems can communicate back and forth to recognize and transfer data easily. Currently, only Medtronic's Carelink has bidirectional capability and it is rudimentary. Patient identifiers may be different in the RMS and EMR. The patient's identifier at the time of implant may be that used by the hospital, which is what is generally entered at implant by the device company rep when enrolling the patient for remote follow-up. One way to resolve this is to enroll the patient in the office. If necessary, the identifier in the RMS can be changed when the patient is seen later in the office. Integration of RMSs and EMRs will eventually be realized. At this time it seems that there is not much clamoring for this from either clinicians or the device companies. Most physicians still do not have EMRs, and of those that do, most are not utilizing RMSs to a major extent yet. The device companies aren't running to do

it because not many customers are demanding it, and it is something that is not going to result in direct profit. The force behind the integration of the RMS and EMR will be the rapid expansion of both RMS and EMR in the next few years.

III. RMS as an ICD System Registry

The issue of utilizing remote monitoring for post-market surveillance of leads and devices is a burning one in view of recent device and lead advisories and recalls. Since most devices are implanted for primary prevention, bad outcomes psychological as well as physical due to system malfunction or other complications, need to be avoided at all costs. Problems with ICD system failure are not new.[9, 10] The Carelink system was utilized by Medtronic to survey the most recent leads which were eventually recalled. This system was instrumental in helping to identify the problem. Most interestingly, a set screw issue was identified in up to 20% of the confirmed lead integrity issues.[4] This represents the first time that a device or system failure was successfully identified using a remote monitoring system database. There are many issues involved with the use of these systems for ICD post-market release surveillance. Not all patients are or will be using the system, by choice. Most patients like the system. It decreases visits to the office which is time and cost-saving to the patient. Patient acceptance and satisfaction are high.[2,5] However, some patients are technology-averse or just desire an in-office check. In my personal experience these are in the minority (approximately 10%). For remote monitoring systems to become a de facto registry, all patients must be in the system. Perhaps one way to do it is to mandate that all patients be followed remotely in a

system. If the patient doesn't wish to transmit from home, this can be done from the physician's office during the visit.

Remote monitoring systems are proprietary. For example, patient alerts are similar, though not the same among the companies. Presently companies use proprietary algorithms in looking at the data to determine if there is a problem. Some uniformity would be beneficial from an oversight perspective. HRS has recommended remote monitoring of ICDs as a tool of surveillance.[3] HRS cannot mandate or enforce this and industry has no incentive to give up stewardship of the remote monitoring data (there are still legal questions as to who owns the data and who can use it for reasons for research, for example), nor of the surveillance itself. In light of perception (and/or perpetuation of it via the press) that companies have acted too slowly in contacting the FDA, and that the FDA itself has been slow in acting, perhaps a different mode of surveillance is warranted. The use of data derived from remote monitoring may be the answer. HRS, industry, and the FDA all must work together to resolve these issues. The focus of patient safety must not be lost. The devil would certainly be in the details of the who and how of the process. A certain amount of standardization of alerts, and data collection would be in order. One may propose a model whereby an independent panel of expert physicians not affiliated with industry in any way, would review data on a regular basis and determine if an early trend was occurring which would then trigger closer scrutiny, earlier than company quality control departments would, perhaps. These physicians would not have any apparent conflict of interest in the process. This is certainly not to say the companies are acting with a conflict, but it would remove a public perception of one. The importance of the issue of device surveillance and the potential role of remote monitoring

in the process cannot be overstated. The failure of devices is devastating to patients, industry, and health care professionals alike. But the big elephant in the room is the number of high risk patients (primary or secondary prevention) who will choose not to receive an ICD because of these failures, publicity surrounding them, and eager trial lawyers. It is time for industry to use remote follow-up technology for its highest purpose and provide the support for all of us to monitor ICDs with transparency.

Unanswered Questions

There remain other questions about RMS unanswered since the advent of this technology. Who owns the data? Can physicians access it for the purpose of conducting research (without patient identifiers, of course)? Some electronic medical record companies claim *they* own all data in their repositories. If RMS integrates with an EMR, who then owns the data?

This new technology will eventually be integrated in follow-up clinics in all academic centers. New training requirements as per COCATS will need to be put into place for cardiology fellows for minimum device follow-ups with RMS, to familiarize them with the follow-up process. All allied professionals involved in device follow-up should become familiar with RMS. Requirements of physician qualifications for RMS follow-up should conform to HRS guidelines.

There are medicolegal questions regarding this technology. Patients should download data only with an appointment. Downloading information without an appointment may result in data not being reviewed or lost. Patients should sign an agreement when enrolling, stipulating they will transmit only by appointment.

RMS is here to stay and its potential for improving patient and device management is unquestioned. The more intriguing and perhaps just as important role of this technology lies in its potential for post market quality control of ICD generators and leads. The future is now!

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