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Review

Remote monitoring of implantable devices: Should we continue to ignore it?

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ABSTRACT

The number of patients with implantable cardioverter defibrillators (ICDs) is increasing. In addition to improve survival, ICD can collect data related to device function and physiological parameters. Remote monitoring (RM) of these data allows early detection of technical or clinical problems and a prompt intervention (reprogramming device or therapy adjustment) before the patient require hospitalization. RM is not a substitute for emergency service and its consultation is now limited during working hours. Thus, a consent form is required to inform patients about benefits and limitations. The available studies indicate that remote monitoring is more effective than traditional calendar face to face based encounters. RM is safe, highly reliable, cost efficient, allows quick reply to failures, and reduces the number of scheduled visits and the incidence of inappropriate shocks with a positive impact on survival. It follows that RM has the credentials to be the standard of care for ICD management; however, unfortunately, there is a delay in physician acceptance and implementation. The recent observations from randomized IN-TIME study that showed a clear survival benefit with RM in heart failure patients have encouraged us to review both the negative and positive aspects of RM collected in a little more than a decade.

1. Introduction

Indications to implantable cardioverter defibrillators (ICDs) with or without cardiac resynchronization (CRT-D) are increasing. Clinical trials show that ICD with or without CRT improves survival in patients with arrhythmic cardiomyopathy and in those with heart failure (HF) of any cause. A correct programming of the device therapy is essential to ensure precise detection and termination of arrhythmias and itself imparts survival benefit [1]. ICD setting may need to be adapted to the progression of the clinical conditions [2]. Thus, post implant monitoring is an integral part of both devices and patient care [3] and it is a responsibility for the physician [4]. There is consensus for the need of in-clinic checks at 3- to 6-months intervals with increased frequency when the battery approaches replacement indication or in response to product advisories. The limit of this conventional follow-up is the lack of information in between the visits. Remote monitoring (RM) fills this gap, avoiding several in-person evaluations and has progressed from a curiosity and occasional use, to large prospective trials [5] opening new avenues for further exploration. We have reviewed the actual position, current success and still unresolved problems of RM [3,6–8].

2. The history

The first attempts of RM were undertaken in the 1970s, in the USA. RM was performed by phone, transmitting just pacing rate and pulse duration as markers of the battery status and device failure, which, at the time, was common. The same approach failed to have an early impact in Europe, where the concept was introduced by Biotronik in 2001. Such a delay was mainly due to issues related to data transfer. Thereafter, RM was used to reduce multiple in-hospital contacts, particularly for elderly patients. Thus, the goal of the first studies was to prove safety and efficacy in reducing in-persons visits. Technical improvements and internet availability made the rest. Today each ICD has automatic transmission mechanisms independent of patient or physician interaction (Table 1). The devices are equipped with a micro-antenna for communication with a transmitter located close to the patient. They perform daily transmissions, with additional alerts for pre-specified out of range parameters, using the wireless global system for mobile communication network or landline communication, while the patient is at home. The alerts may relate to change in device performance (battery status, lead impedance), or programming (disabling of ventricular fibrillation therapy, insufficient safety margins for sensing or capture), or on occurrence of medical data (arrhythmias, heart rate variability, fluid accumulation). In this way, RM has progressed from mostly monitoring the device performance to provide information on the disease progression. The events generating the alert are transmitted to a central database, where they are processed and sent to physicians and or nurses by website, e-mail,

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Table 1
The different remote monitoring system.

	Biotronik Home Monitoring	Medtronic CareLink	Boston Scientific Latitude	St. Jude Medical Merlin.net	Sorin SMARTVIEW
Patient device					
Transmitter	Stationary or mobile Simple	Stationary Interactive	Stationary Interactive	Stationary Vocal interactivity	Stationary
FDA approval	2001	2005	2005	2007	NA
Wireless communication with implanted device	Radiofrequency	Radiofrequency	Radiofrequency	Radiofrequency	Radiofrequency
Data transmission	GSM network	GSM network	Phone line, GSM, Ethernet	Analog or GSM	Analog or GSM
Frequency of transmissions	Scheduled FU; daily FU; alert events	Scheduled FU; alert events; on patient demand.	Scheduled FU; alert events; patient initiated interrogation	Scheduled FU; alert events	Scheduled FU; alert events; on patient demand
Remote follow up	Yes	Yes	Yes	Yes	Yes
Remote monitoring	Yes	Yes	Yes	Yes	Yes
Physician notification	SMS; e-mail; fax	SMS; e-mail	Fax, phone	SMS; e-mail; fax	SMS; e-mail; fax
IEGM at remote follow up	30 sec	10 sec	10 sec	30 sec	7 sec
IEGM at alert event	All memorized episodes	All memorized episodes	All memorized episodes	All memorized episodes	All memorized episodes
Sensor	Heart failure monitor	OptiVol, cardiac compass	Weight, blood pressure	Corvue, ST segments monitoring	SonR, sleep apnea monitoring

FU: follow up.

SMS, or fax [9]. The reliability of this system is excellent [10]. The TRUST trial [11] firstly explored the usefulness of RM in clinical practice demonstrating a median delay of 1 day from occurrence of the event to physician evaluation, compared to 1 month with conventional care. The CONNECT study [12], including patients with ICD or CRT-D confirmed these data. The IN-TIME study [13] also shows a median reaction time to contact the patient after a telemonitored alert of 1 day. Such rapid reaction time applies also for asymptomatic alerts, with the potential to improve outcome. Those results were unexpected, considering that just a few years ago the PREFER study showed that RM improved the mean reaction time from 7.7 months of the control arm to 5.7 months [14,15].

3. The present

Once the safety and reliability are confirmed, the remaining problems to be solved were reimbursement, privacy and fear of data overload [16]. Today, in theory, these concerns should no longer exist and an expert consensus document suggests implementation of RM in the daily practice for ICD recipients [17]. It was quickly recognized that the ever increasing office visits are impractical, onerous, and inefficient since the likelihood to miss potential serious problems occurring between device interrogations is high. The classical follow up checks do not anticipate problems and only <10% of planned in-clinic visits require device reprogramming or medications change. RM system based on patient-driven communication is also unable to detect asymptomatic problems while, the automatic ones provide continuous monitoring with transmission of alert data when the patient is unaware of the problem. Thus, at least half of the regularly scheduled visits can be omitted, without impairing patient safety [7]. Only 6% of patients undergo device reprogramming or admittance to hospital at in-clinic visits; thus 94% of these visits could be executed remotely [18].

4. Can RM avoid clinic visits and follow-up?

Clinic visits are still needed as no system allows remote device programming, diagnosis of co-morbidities and possibilities to change medication to the patients. In addition, the added value of patient/physician relationship should not be underestimated. Regular follow-up, however, can be avoided. The Lumos-T Safely RedUceS RouTine Office Device Follow-Up (TRUST) trial [11] is the first that validated and recently confirmed [19] the ability for RM to avoid routine periodic in-clinic evaluations. RM reduced health care utilization by almost 50%, predominantly by reducing scheduled visits, the bulk of which did not require any clinical intervention [11] (Fig. 1). It is important to distinguish between remote follow-up, RM and patient initiated interrogation [17]. The remote follow-up is a scheduled automatic device interrogation, which replace in-office visit. It is aimed to assess device function (e.g. battery status, thresholds…). RM is an automatic unscheduled transmission of alert events (e.g. atrial fibrillation, abnormal lead impedance…) often requiring a visit. Patient-initiated device interrogation is a non-scheduled follow-up initiated manually by the patient because of a perceived clinical event [3]. Finally, RM may be integrated with sound alerts from device. Indeed, the sound alerts sometimes are erroneously felt from patients and RM may discriminate whether the problem is present or not and, consequently, determine an additional outpatient visit or just reassure the patient by phone. Something similar may happen also for the phantom shocks.

5. The workload

In several European centers a nurse reviews the data and forwards some (not all) of them to the responsible physician. This model, implemented since 2005, is called "primary nursing" [20]. Each patient is assigned to a nurse; he or she screens and registers patient's data in the website. In case of critical events (arrhythmias, ICD intervention, change in electric or clinical parameters…) the nurse submits the case to the physician for decision making. The nurse can contact the patient, asking information about symptoms, clinical status, and compliance to medical therapy. The approach is bidirectional as in case of symptoms or device sound alerts, the patient is encouraged to contact the nurse for assistance (Fig. 2). The "HomeGuide Registry" study shows that, by so doing, the median manpower time required for 100 patients is only 55.5 min × health personnel per month [20]. This model is adopted in the "consensus document on cardiac implantable electronic devices remote monitoring" of the Italian Society of Pacing and Arrhythmology (AIAC) and it has become the standard in Italy [21].