

Remote control resp. Home Monitoring integrated in ICD's and CRT and Implantable Loop Recorders for AF Detection

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Remote control monitoring in ICDs/CRT

In the last decades, the advances in information and communication technology have permitted that telehealth supports are diffusing rapidly into all aspects of healthcare. Integration of traditional medical practices with computerized supports and Internet functionalities may improve quality of life and solve problems of access health disparities for some patient categories.

Home-care is a term often used to describe telemedicine applications in which medical services are delivered to patients at their homes. Home-care is especially important for a specific group of patients with long-term chronic conditions, such as chronic cardiac diseases. Recently, there is a growing interest also in the remote monitoring and follow up of implantable cardioverter defibrillators (ICDs). The number of patients with implantable devices has been growing steadily, mainly because indications for ICD shifted from secondary to primary prevention of sudden death (Multicenter Automatic Defibrillator Implantation Trial II (MADIT II)).

According to current guidelines (issued by AHA, ACC, etc.), patients with an ICD should be followed up every 3–6 months (increasing frequency as the battery approaches elective replacement) to ensure proper device function. However, a more frequent control could avoid bad workings of the device, so to guarantee a longer time-life of batteries. In particular, continuous telemonitoring of ICD can provide a valid support for follow up and can potentially enhance also patient safety.

A major problem associated with ICD therapy is the occurrence of inappropriate shocks which impair patients quality of life and may also be arrhythmogenic. In particular, arrhythmia episodes or oversensing that have led to delivered or aborted ICD therapies can be analyzed using telemonitoring and the opportune countermeasures considered. Indeed, inappropriate shocks for atrial arrhythmias with rapid ventricular conduction or for abnormal sensing result in multiple adverse effects including impaired quality of life, psychiatric disturbances, and even provocation of fatal ventricular arrhythmia. A recent study reports that inappropriate shock occurred in 11.5% of the patients population considered; the inappropriate shocks resulted in 31.2% of the total shock episodes. Atrial fibrillation was the most common trigger for inappropriate shock (44%), followed by supraventricular tachycardia (36%), and then by abnormal sensing (20%), which can be due mainly to electromagnetic interferences.

Major ICD factories supply their telemonitoring systems such as Home Monitoring (Biotronik); CareLink Network (Medtronic); Latitude Patient Management system (Boston Scientific); Merlin.net (St. Jude Medical). Remote pacemaker and ICD follow up and monitoring system by Biotronik received the first FDA approval in 2001.

The transmitter provided to each patient is a little bigger than a cell phone and communicates wirelessly with the ICD within a distance of 2m. Once internal ICD data are received from the personal transmitter, they are automatically sent to a gathering centre using the GSM network. The choice of the GSM network does not force the patient to have a fixed phone or a DSL connection at home; this permits a great freedom of movement during daily life to the patient, ICD monitoring can take place continuously and does not require patient involvement. EGM of 30 s duration are sent periodically to the reference centre that may assist with data interpretation and are available to medical doctors via secured webpage on the Internet. Whenever critical data are available for consultation, the doctor is informed by one of the following modalities previously established: e-mail, SMS, fax, or phone messages. The types of events which trigger an alert can be customized for each patient.¹

In a number of randomized clinical studies the clinical benefit of home monitoring could be demonstrated. In the TRUST trial² a reduction of 43 % of in-office follow-up visits was delivered by home monitoring without losing clinically relevant events. The ECOST trial³ showed a 52% reduction of inappropriate shocks and a 76% reduction of charged shocks leading to a 8 months saving of longevity of the device.

In the COMPAS Trial⁴ atrial tachyarrhythmias and stroke could be significantly reduced by 2/3 caused by early detection of events at risk.

The important recently presented IN-TIME study is the first study to demonstrate a significant reduction in all-cause mortality by 65% in heart failure patients with implant-based home monitoring; HM patients were intensively cared about following their automated interrogation leading to instantaneous reaction of a medical staff with respect to pathological alerts and trends. Pts intensified care consisted of immediate medical contact, interviews and hospital admissions that led to rapid medical aid of the heart failure patients. Thus the number of HF patients with worsening of their clinical status was reduced and the total and cardiovascular mortality was reduced by around 2/3 (not yet published).

All-cause mortality

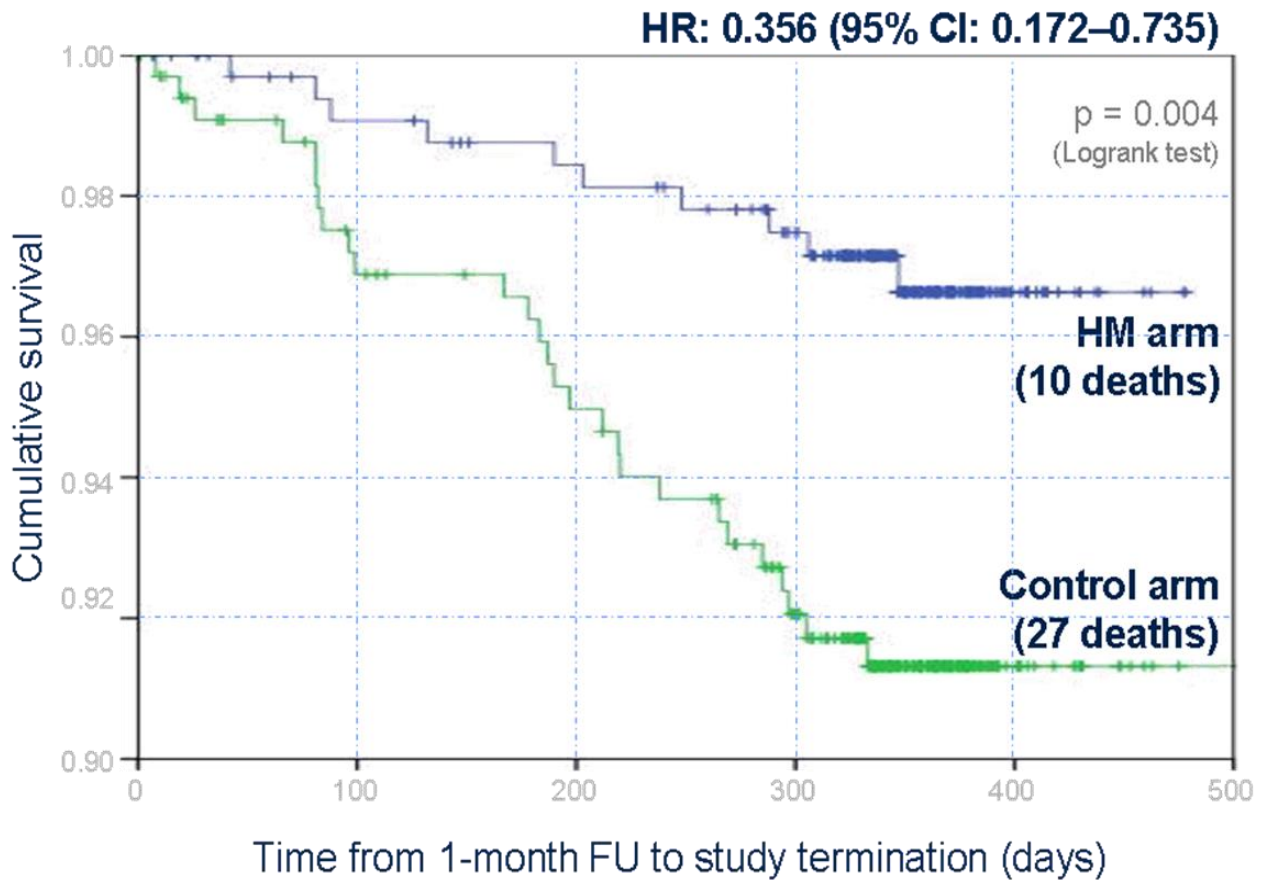


Fig. 1

Event recorder for AF and VT/VF detection

Device-detected atrial fibrillation (AF) episodes predict poor clinical outcome regardless of symptoms. Potential benefits of remote monitoring are early arrhythmia detection and patients continuous monitoring. Several studies of device remote monitoring consistently demonstrated that AF represents the most common clinical alert and that detailed information on arrhythmia onset, duration, and burden as well as on the ventricular rate may be early available for clinical evaluation. Reaction time to AF alerts was very short in all series involving either pacemakers or defibrillators and action ability of AF alerts was very high. In the Home Guide Registry, in which 1650 patients were enrolled, AF was detected in 16.3% of patients and represented 36% of all cardiovascular events during the follow-up. Timely anticoagulation introduction in asymptomatic patients may impact on the stroke rate. According to the results of repeated Monte Carlo simulations based on a real population of 166 patients, daily monitoring may reduce the 2-year stroke risk by 9–18% with an absolute reduction of 0.2–0.6%, compared with conventional inter-visit intervals of 6–12 months. In the COMPAS trial, the incidence of hospitalizations for atrial arrhythmias and related stroke was significantly higher in the control group than in the remote monitoring group. Major questions will be addressed by the ongoing IMPACT trial in which a remote monitoring guided anticoagulation strategy based on AF detection will be compared with a physician

directed standard strategy. In patients with heart failure, AF early detection combined with other indexes may help prevent hospitalizations.⁵

Implantable loop recorders (ILRs) have demonstrated clinical benefit in patients with unexplained syncope and symptoms that may be related to arrhythmias. Current ILRs offer heart rhythm monitoring with both a manual activation of electrocardiogram (ECG) storage in response to symptoms and an automated detection and storage of suspected arrhythmias, including asystole, bradycardia, tachycardia, and atrial fibrillation. Automated detection of arrhythmias is essential to detect asymptomatic arrhythmias. Several reports have indicated added clinical benefit from the automated detection features. However, inappropriate detections that result from noise, oversensing, or undersensing have limited the overall clinical value of automated tachycardia detection.

The Reveal Implantable Loop Recorder with Full-View Software demonstrated very high sensitivity to detect induced ventricular tachycardia /ventricular fibrillation (99.3%).

Detection of asymptomatic AF in cryptogenic stroke with ILR

Ischemic stroke is among the leading causes of death and disability. The cause remains unexplained after routine evaluation in 20 to 40% of cases, resulting in the classification, by exclusion, of cryptogenic stroke. Atrial fibrillation is a well-recognized cause of ischemic stroke, though the risk is markedly reduced by anticoagulation. Documentation of atrial fibrillation is required to initiate anticoagulant therapy after ischemic stroke. In the absence of documented atrial fibrillation, antiplatelet agents are recommended. Given the often paroxysmal and asymptomatic nature of atrial fibrillation, it may not be detected with the use of traditional monitoring techniques. Strategies for detection of atrial fibrillation have included in-hospital monitoring, serial electrocardiography (ECG), Holter monitoring, monitoring with the use of external event or loop recorders, long-term outpatient monitoring, and monitoring by means of insertable cardiac monitors (ICMs), yielding detection rates ranging from 0 to 25%. However, differences among studies with respect to eligibility criteria, end points, and duration of monitoring make it difficult to translate these findings into changes in clinical practice.

Current guidelines suggest performing 24 or more hours of ECG monitoring to rule out atrial fibrillation in patients with an ischemic stroke but acknowledge that the most effective duration of monitoring has not been determined. The use of additional ECG monitoring beyond 24 hours after cryptogenic stroke is currently left to physician discretion. We conducted a randomized, controlled study to assess whether a long-term ECG monitoring strategy with an ICM is superior to conventional follow-up for the detection of atrial fibrillation in patients with cryptogenic stroke.⁷

In the multicenter prospective randomized CRYSTAL-AF trial it was assessed whether a long term cardiac monitoring strategy with an implantable cardiac monitor (ICM) is superior to standard monitoring for the detection of AF in patients with cryptogenic stroke. In deed the ICM was highly superior compared to standard of care showing a hazard ratio for the detection of AF of 6.43 at 6 months and 8.78 after 36 months. In the ICM arm AF was detected in 8.9; 12.4 and 30% after 6, 12 and 36 months. 93 % of patients with AF in the ICM

arm had a day of greater than 6 minutes of AF. Detection of AF changed the oral anticoagulation strategy in 97% of patients.

Detection of AF at 3 Years

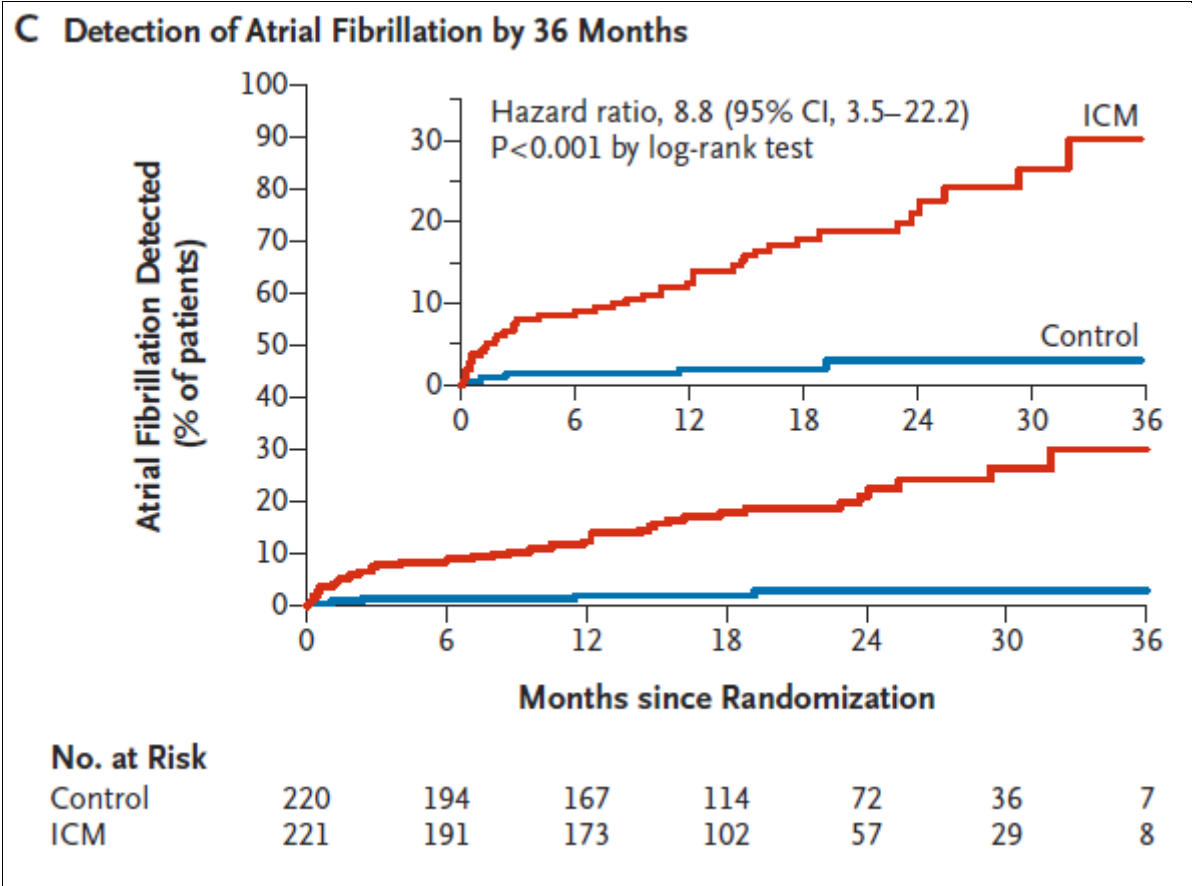


Fig.2: Rate of detection in ICM arms was 30% vs. 3% in control arm.

In conclusion long-term continuous monitoring with ICM should be performed in patients with cryptogenic stroke.

Literature:

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Figures:

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