

## Remote Monitoring of Implantable Cardioverter Defibrillators

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**I**mplantable cardioverter defibrillators (ICDs) are used extensively for the termination of life-threatening ventricular arrhythmias and hence the prevention of sudden cardiac death.<sup>1</sup> Different risk stratification schemes are currently implemented to detect patients who are vulnerable to arrhythmic death and suitable for ICD implantation.<sup>2</sup> After ICD implantation, regular follow up of these implantable electronic medical devices is required for many reasons. These include the evaluation of device integrity, interrogation of the device for recorded arrhythmias, reprogramming of the device, and hence the adaptation of the patient's medication to his/her clinical status.<sup>3</sup> Routine in-office follow up of ICDs presents a series of significant limitations.<sup>4-8</sup> Firstly, the late detection of medical events or technical problems might be associated with potentially serious health outcome implications. Secondly, the high intensity of calendar-based follow up increases health care costs and may test the patient's willingness to adhere to given instructions.<sup>4-8</sup> Remote monitoring has been developed to address these limitations by offering continuous surveillance of both ICDs and patients, in order to improve the safety and cost-effective delivery of health care.<sup>3</sup>

Today, remote monitoring allows ICDs to transmit, on a regular basis, sys-

tem integrity and episode details to a data centre through a fixed telephone line or using mobile phone technology.<sup>3</sup> Remote telemetry data are transmitted from the ICD to the remote monitoring centre either by a "wand",<sup>9-11</sup> or by wireless communication between the device and the remote monitoring centre. Both scheduled, planned interrogation and data transmission sessions, as well as automatic, or alert-triggered data can be transmitted, depending on the device.<sup>12,13</sup> The latter may include the recording of a significant change in lead impedance, the development of persistent atrial fibrillation with a rapid ventricular response close to the ventricular fibrillation zone, the occurrence of frequent episodes of ventricular tachycardia and/or the delivery of frequent shocks, or possibly significant alterations in the haemodynamic status of the ICD recipient. This home monitor is linked by landline or wireless telephone to a central (internet-based) secure server/secure website, so that it can deliver the interrogated data automatically for further analysis. The physician can receive an alert notification from the remote monitoring centre via pager, fax, SMS, voice message, or email. Many systems require access to a dedicated (device- or company-specific) website to retrieve the interrogated and transmitted ICD data. The

physician can send messages to patients reminding them of forthcoming remote follow-up appointments, notifying them of missed follow-up appointments, acknowledging receipt of remote transmissions by the clinic, etc.<sup>14,15</sup> Currently, remote reprogramming of ICDs is not available in clinical practice, mainly because of safety considerations.

Several recent studies (CONNECT, PREFER, REFORM, and TRUST<sup>5,6,16-19</sup>) in addition to important registry data (ALTITUDE<sup>16</sup>) constitute a strong evidence base for the remote monitoring of ICDs. The Pacemaker Remote Follow-up Evaluation and Review (PREFER) study demonstrated that remote pacemaker monitoring led to quicker and more frequent detection of clinical or technical events compared with standard in-office evaluation.<sup>5</sup> The Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision (CONNECT) trial<sup>6</sup> verified that remote monitoring may significantly reduce the time to a clinical decision in ICD recipients who develop events such as atrial arrhythmias, ICD therapies, and system integrity alerts. Similarly, Elsner et al (REFORM<sup>17</sup>), in a prospective, randomised, multi-centre comparison study, investigated the effect of remote monitoring of ICDs versus standard follow up in 115 MADIT II patients. The results of the REFORM study proved that the simplified ICD follow-up scheme with additional remote monitoring in MADIT II patients can significantly reduce the number of in-office visits needed. A comparison between automatic remote monitoring and conventional in-person follow-up was prospectively investigated in the Lumos-T Safely RedUceS Routine Office Device Follow-up (TRUST) multi-centre Trial.<sup>18</sup> The elapsed time from event onset to physician evaluation was assessed for both conventional care during in-office interrogation, and remote monitoring of ICDs upon receipt of event notifications in response to the detection of pre-programmed events. The TRUST investigators demonstrated that remote monitoring enhanced the identification of clinically silent as well as symptomatic events, despite less frequent hospital visits.<sup>18</sup> In TRUST, same-day discovery of ICD dysfunction was accomplished. For those events not evaluated within 24 h, even asymptomatic events, repetitive messaging promoted earlier discovery. Therefore, the TRUST investigators proposed a reorganisation of ICD follow-up methods to maintain a capability for the early detection of adverse events.<sup>19</sup>

Although its initial reception was questionable, both patients and physicians nowadays report satis-

faction with ICD remote monitoring.<sup>20</sup> Remote monitoring is patient-friendly and easy to use, while it maintains a continuous connection with the follow-up centre.<sup>20</sup> In addition, it improves the patient's psychological well-being and safety, especially following an advisory, and is therefore considered an important alternative to the current standard of care.<sup>21-23</sup>

The rapid evolution and growing implementation of remote monitoring will likely present new legal challenges. The transmission, storage, sharing, and analysis of ICD data will each fall under scrutiny to ensure that patients' and caregivers' rights are fully protected. Patients need to be informed of the scope and limitations of remote monitoring. They should comprehend that remote monitoring does not replace an emergency visit to the hospital. Moreover, it does not ensure continuous dealing with alert events outside office hours. Of course, limitations do exist regarding both the frequency of ICD transmission times, due to battery longevity constraints, and the reviewing of ICD data by health care providers. Institutional guidelines and/or physician and patient contracts may need to be devised in order to limit the periods of liability. Moreover, guidelines should be established to determine the periodicity with which ICD transmissions need to be reviewed and documented.<sup>3</sup>

Therefore, legal and organisational hurdles are currently hampering the widespread implementation of remote ICD monitoring in the healthcare system. Today, in some European countries (Finland, Germany, Sweden, and the UK) remote monitoring replacing part of the in-hospital follow up is reimbursed similarly to the in-clinic follow up. The monitoring equipment and the supporting services are currently not reimbursed in any of the European countries. Currently, companies mostly provide the remote monitoring service for free as part of their marketing policy. In Greece, remote ICD monitoring is largely underdeveloped. The Medtronic CareLink<sup>TM</sup> remote monitoring system has been applied in less than 100 ICD recipients in connection with 9 hospitals, while implementation of Home Monitoring was provided freely by Biotronik for 6 ICD recipients in 2006 in the Hippokraton Hospital, Athens. The number of ICD recipients is constantly increasing in Greece. Many of these patients live permanently in rural areas on the mainland or on islands, far from the ICD implantation centres. Early detection of ICD adverse events and/or avoidance of unnecessary travel to the implantation centres are of paramount importance for these

ICD recipients. Remote monitoring may be particularly useful for these patients, and cost-effective for both patients and health care providers.

Technological advances continue to change our practice of medicine, but they often bring with them new legal challenges. In order to minimise the risk to patients and the liability of caregivers, clarification of the expectations and limitations of remote monitoring between patients and health care providers is strongly recommended.

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