Remote monitoring of patients with cardiac implantable electronic devices: maximizing gains by addressing workflow

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This editorial refers to ‘Effectiveness of remote monitoring of CIEDs in detection and treatment of clinical and device-related cardiovascular events in daily practice: the HomeGuide Registry’ by R.P. Ricci et al., on page 970 and ‘Incidence and predictors of pacemaker reprogramming: potential consequences for remote follow-up’ by E.O. Udo et al., on page 978.

Innovations are usually greeted guardedly, especially those demanding changes in clinical habits. When and how these should be applied are obvious questions to physicians and patients alike. Automatic remote monitoring (RM) of cardiac implantable electronic devices (CIEDs) is no exception, over a decade after its introduction. This, despite the need stated by professional societies and impressive trial data.1–3 However, diffidence in the community is reflected in slow adoption. In this issue of the Journal, two large (>1500 patients) prospective registries address some critical aspects of the operating mechanics of this technology.

First, Udo et al.4 aimed to define the candidate population for RM (although, importantly, did not actually test its application). They measured the frequency of non-actionable follow-up encounters in a large cohort of patients with pacemakers. This concept is critical—remote follow-up can only replace conventional in-person scheduled evaluation if the bulk of such appointments do not trigger any changes in patient management, i.e. are ‘non-actionable’. If, on the other hand they are frequently actionable, then discoveries from remote data download will require those patients to be contacted and brought to hospital, duplicating effort rather than promoting efficiencies. The results, however, confirmed that the vast majority (>80%) of patients studied did not need reprogramming changes (visits-with-reprogramming), in keeping with conclusions from implantable cardioverter-defibrillator (ICD) trials. The authors looked at this from another vantage—whether it is possible to identify those patients at high risk of requiring management changes and assign these to conventional rather than remote follow-up. However, although those with arrhythmias (e.g. atrial fibrillation), more likely to receive right ventricular pacing, and/or with early (<3 months) device-related issues tended to need more management changes, these were not strong predictors. It then appears that the best strategy is to use RM for all patients with exception-based in-person evaluation.

An important practice point is made. Patients at higher risk (such as the ones illustrated) demand close clinical attention in any case, and does not mean that follow-up schedules are inviolable during remote follow-up. Thus, a first post-implant 3-month in-person evaluation is mandatory. Some patient interventions (e.g. introduction of antiarrhythmic drug therapy) demand increased patient contact during periods of adjustment. These cannot be supplanted by remote management, which may however, be reverted to after the condition has stabilised. This is particularly apt for higher risk patients, e.g. those with cardiac resynchronization therapy (CRT) for heart failure, who are characterized by repeating cycles of acute decompensation followed by recovery.

A significant limitation of the current study was that it addressed the theoretical impact of remote follow-up in distinction to the continuous RM available in current era devices, able to automatically alert device- or disease-related problems irrespective of follow-up schedule. In this regard, the role of remote technologies extends far beyond the realm of simply supplanting routine calendar-based interrogations. In support, continuous monitoring in the COMPAS (COMPArative follow-up Schedule with home monitoring) pacemaker trial suggested reduced morbidity.5 This advantage may be greater in higher risk ICD/CRT patients. Some aspects of continuous monitoring were evaluated in the second large-scale registry reported in this issue.

Ricci et al.6 assessed remote patient management in a population receiving ICD/CRT therapy in addition to pacemakers, testing the value of a pre-specified organizational model according to follow-up recommendations (HomeGuide registry). The results are

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important, timely, and well written, and a tribute to the initial design which recognized that this innovative technology demanded changes in workflow (and mindsets) to be successful. Thus, prior to implementation, all involved personnel, including patients, were primed to process and expectations. Virtually all clinical events expected to be seen among patients attending a device clinic were catalogued. Major cardiovascular events were defined as any untoward cardiovascular occurrence, disease, or signs (including abnormal device findings) whether or not related to the implanted device. Such definition was broad enough to encompass a large class of significant events, including arrhythmias, worsening heart failure, device-related complications, as well as events that are not supposed to be detected by CIEDs or remotely transmitted via home monitoring (such as strokes or acute myocardial infarctions). The quality of remotely acquired data was high since the majority (>80%) of clinically meaningful events were remotely detected (sensitivity 84%; positive predictive value 97%). Detection took ~3 days, remarkably similar to the results from a separate trial with the same technology. Drug therapy changes constituted the commonest reaction.

A remarkable HomeGuide result was that clinic time expended per patient assigned to remote management was astoundingly low. The clinic work structure underlying this bears scrutiny. This was based on a cooperative interaction between a reference nurse and a responsible physician with an agreed list of respective tasks and responsibilities. Each nurse–physician pair within the outpatient clinic was exclusively dedicated to an assigned subgroup of remotely controlled patients. Centres underwent an extensive training programme before starting study participation. Patients were encouraged to maintain nurse contact, critical for continuity of bidirectional care. The results pointed to the key role of the trained allied professional dedicated to this task. (Physician-based schemes have been unsuccessful, in comparison.) This is an important factor to consider in countries currently in the throes of generating reimbursement models for remote patient management. Although demanding some extra resources, nurse-based remote patient management improves follow-up quality, generates manpower efficiencies, and directs only problematic remote assessments (which are infrequent) to physicians who can then be released to their other assignments.

Choice of remote technology is important. HomeGuide used only one system, and that was a type requiring negligible patient interaction yet automatically maintaining near-continuous data flow with alerts for out-of-bound parameters. Hence, HomeGuide results cannot be extrapolated readily to all remote technologies with differing operating characteristics and abilities for problem discovery. For example, inductive systems (wand based) depend on patient (and hospital) adherence to set schedules (e.g. 3 monthly). Troubleshooting compliance failure with this generated a huge service burden for follow-up clinics. Net result was not in favour of reducing clinic workload. Wireless automatic systems themselves differ. In the CONNECT (Clinical evaluation Of remote Notification to rEduCe Time to clinical decision) trial, patient inability to set up the system resulted in a 45% loss of transmissions. When alert transmissions for some conditions were successful, manual reset was required to reactivate this notification ability, thus generating an otherwise unnecessary in-person encounter. This design flaw utilizing patient interaction and single transmissions vulnerable to failure limits the role of this technology as an early-warning mechanism and dilutes the strength of remote follow-up. In comparison, the remote technology used in HomeGuide, when tested in the TRUST (Lumos-T Safely RedUceS RouTine Office Device Follow-up) trial, demonstrated excellent operating characteristics. TRUST noted an incidence of remote follow-up failure and not all event notifications were discovered the same day—these lapses were caused by oversight from receiving facilities. This is unsurprising since the majority of personnel had no pre-trial experience or training in managing this new technology and associated workflow. In this regard, HomeGuide provides a structure for capitalizing on the full advantage of this technology, promoting clinical efficiencies, and maintaining continuity of care of patients, themselves well informed about their responsibility and need for active participation. Patients networked in this fashion may gain a survival advantage (ALTITUDE Registry).

HomeGuide has some limitations. Only one RM system was tested, although with all types of CIEDs. Centres managing low volumes of several different remote technologies may find reproducing the current results challenging. Time expended in contacting the responsible physician when necessary was not included in time assessments. Details regarding time taken to deal with actionable encounters when these occurred were not presented. It is anticipated that an actionable alert notification, e.g. in a CRT patient, may require considerable time for resolution. The registry suggested some sensitivity for detection of conditions (e.g. stroke) that was unexpected from RM. Further details regarding this and e.g. heart failure notification, require elucidation.

In conclusion, merely committing patients to ‘RM’ is insufficient to guarantee ‘early’ problem detection and maintain continuity of patient follow-up. It is important to recognize that changes in workflow patterns are necessary to capitalize on the rapid detection power afforded by current generation technology. An offer of a RM service carries an implicit agreement that actual review of transmitted information occurs in a timely manner. There has to be a robust response mechanism in place to realize the logical promise. Implementation of carefully structured workflow patterns as demonstrated in HomeGuide advance the efficacy of automatic continuous RM as an early warning system and provides assurance to both patients and their physicians. This experience should spur adoption of a new standard.

Conflict of interest: N.V. is a consultant to Biotronik TRUST trial and to ALTITUDE Registry.

References


Images in Electrophysiology

Adenosine test during confined pulmonary vein fibrillation: how to identify the dormant conduction?

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Identifying earliest pulmonary vein (PV) potential (entrance site) during adenosine-exposed reconnection is required to eliminate dormant conduction after PV isolation. However, it is impossible during confined PV fibrillation/tachycardia (PVT). A 56-year-old man underwent repeat ablation procedure. Following PV re-isolation, confined ipsilateral left PVT was observed (Panel A). Adenosine provoked clinical recurrent atrial tachycardia (AT) following the adenosine-exposed reconnection (Panel B). The earliest atrial potential (exit site) was finally identified on the circumferential ablation line during the exposed reconnection, and AT was immediately terminated at the site despite persistent PVT. This case highlights how to identify the dormant conduction during confined PVT.

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