REVIEW ARTICLE

Challenges in the remote monitoring of cardiac implantable electronic devices in 2021

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ABSTRACT
Patients with cardiac implantable electronic devices have usually been scheduled for routine in-hospital visits. In addition, they are now monitored remotely. The remote monitoring of cardiac implantable electronic devices is a valuable tool to screen and triage patients at very high risk of deterioration. The continuous expansion of remote monitoring in real-world settings brought a substantial increase of published evidence on the topic. Therefore, this review aims to summarize challenges and knowledge gaps in the field. Challenges that were identified as issues to be solved comprise warranty of data security and accessibility, integration with clinical repositories, patient selection and persistence, and resource availability. Future improvements of telemedicine will need to face these significant residual challenges.

Introduction The end of a cardiac implantable electronic device (CIED) procedure marks the very beginning of follow-up of patients undergoing implantation. They have usually been scheduled for routine in-hospital visits to verify whether the device is adequately functioning and to collect data from the built-in memory every 6 to 12 months.[1] In addition to in-person follow-up visits, most implantable devices have nowadays the option to be monitored remotely. Data are transferred from the patient's device into large databases, to which clinicians have online access. The vast majority of relevant technical parameters can be assessed by telemonitoring, including recorded arrhythmias, battery longevity, electrode properties, stimulation percentage, and intracardiac electrograms.[1,2] When conducted on a daily basis, remote monitoring (RM) of CIEDs is a valuable tool to screen and triage patients at very high risk of deterioration, in whom personalized medical interventions can be provided.[3] Even though RM of any kind of CIED, including permanent pacemakers, implantable cardioverter-defibrillators (ICDs), and implantable cardiac monitors, could offer some advantages to patients and physicians,[4] it is particularly true for some subgroups of patients. In patients with heart failure (HF), RM allows for the detection of episodes of life-threatening arrhythmia such as ventricular tachycardia and ventricular fibrillation, along with a timely reaction to shocks delivered by ICDs (appropriate and inappropriate). The early recognition of true atrial high-rate episodes (AHRES) in patients with undiagnosed subclinical atrial fibrillation (AF), especially among high-risk patients,[5] is another seminal contribution of RM to prevent detrimental complications including ischemic stroke or systemic embolism[5-8] and device-related issues such as low pacing percentage of cardiac resynchronization therapy. Moreover, the daily assessment of intervention efficacy indicates the need for device reprogramming, pharmacotherapy modification, or performing invasive procedures such as atrioventricular nodal ablation, ventricular tachycardia or AF ablation.[9] Given the expansion of RM in real-world settings and the growing body of evidence published, in this brief review, we aim to summarize the main residual challenges and knowledge gaps in the field (FIGURE 1).

Patient selection The number of patients with CIEDs is very high and continues to rise.[10] According to guidelines, RM should be offered to all patients with cardiac devices as a complement to routine in-office care.[2] In real life, many clinics do not have enough resources to follow up

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all their patients by telemonitoring. In this setting, it is of great importance to adequately select patients who are likely to benefit most from RM. A study published in 2019 showed that patients with ICDs or cardiac resynchronization therapy defibrillators had a higher rate of critical events detected by RM compared with those with pacemakers.[11] According to those findings, it is sensible to preferentially assign RM to such patients. The underlying clinical condition may also put the patient at higher risk. Reduced ejection fraction,[12,13] chronic renal failure,[14] arrhythmogenic right ventricular cardiomyopathy,[15,16] Brugada syndrome,[17,18] and dilated hypertrophic cardiomyopathy[11] have been regarded as risk factors for critical events. Other studies demonstrated that RM may improve outcomes in patients with severe HF and AF.[19,20] An analysis of the FOLLOWPACE study[21] evaluated various patient- and procedure-related characteristics to identify individuals at high risk of complications following pacemaker implantation. That study found male sex, age at implantation, body mass index, a history of a cerebrovascular accident, congestive HF, anticoagulation, and passive atrial lead fixation to be the predictors of early complications, while age, body mass index, hypertension, and a dual-chamber device independently predicted complications during the follow-up.[22] Continuous research in the field would help in the nearest future to ascertain categories for which RM will be more beneficial. Nevertheless, the expanding role played by allied professionals[23-25] and workflow optimization are thought to make the expansion of RM a reality in the next decade.

Adherence Notwithstanding its numerous advantages, RM is burdened by a low rate of adherence. In 2013, Akar et al[26] reported that only 76% of patients who were enrolled into an RM system actually activated their device. In their analysis, age, race, health insurance, geographic location, clinical condition, and presence of comorbidities played a role in determining RM activation. A further retrospective analysis carried out in 156 426 patients in the United States, in a real-world setting, demonstrated that compliance to scheduled RM since activation was 61.8% during a mean follow-up of 3 years, and subgroup analysis identified patients at the age of 60 years and younger to be less compliant than those older than 60 years (52.8% vs 62.8%).[27] The importance of adherence to RM was outlined by an observational cohort study that included 269 471 patients with CIEDs implanted, which showed a graded relationship between the level of adherence to RM and survival. In particular, patients with high RM adherence showed 53% better survival than those with low RM adherence as well as 140% better survival compared with lack of RM.[28] In the last years, a growing effort have been made to find a solution to this problem. A recent study showed that the provision of free cell phone adapters following CIED implantation increased adherence to RM in all patients, regardless of race, place of residence, and age.[29] Recently, an application-based remote management system for CIEDs has emerged as a new promising digital health solution that focuses on patients' enablement,[30] a concept that concerns patients' ability to better understand, participate in, or have a greater responsibility for their own care.[31] In a large retrospective analysis performed in the United States, 84.4% of patients assigned to application-based remote follow-up activated their devices for RM. Of those, 89% were considered adherent by the authors, as they had at least one more transmission within 3 months to 1 year after activation, with no difference observed either in those having a generator change or a de novo device implantation or between men and women.[32] In this context, smartphone applications that enable interaction and data input by each patient may be seen as an example of the quantified self hybrid model of telemedicine.[30] This approach promotes patient enablement[33] and has a promising positive impact on the management of chronic diseases.[34]

Privacy The management of a great amount of data relayed by CIEDs is related to inevitable privacy and ethical issues. At present, the possibility for patients to access their own clinical data depends on health privacy laws being in force in their country. European Union citizens, for instance, are granted greater access to device-collected data by the General Data Protection Regulation compared with patients in the United States, whom rights are granted under the Health Insurance Portability and Accountability Act Privacy Rule.[35] The emerging role of smartphone applications will further modify the situation. Moreover, the wide flow of sensitive information between devices and a central cloud server raises concerns about cybersecurity, and, although no cyberattack leading to patient harm has been documented to date,[36] vulnerabilities do exist and device recall due to cybersecurity concerns has already occurred.[37-39] It is believed that the next decades will be the scenario of huge improvements in this field.

Big data and remote monitoring The possibilities of RM, especially of continuous transmission systems, are multiple and unexploited to date. In the future, one of the challenges physicians and industries may face would be to make most from the extraordinary amount of data collected.[40] Artificial intelligence could help to triage patients, integrating millions of records in electronic datasets. At present, this

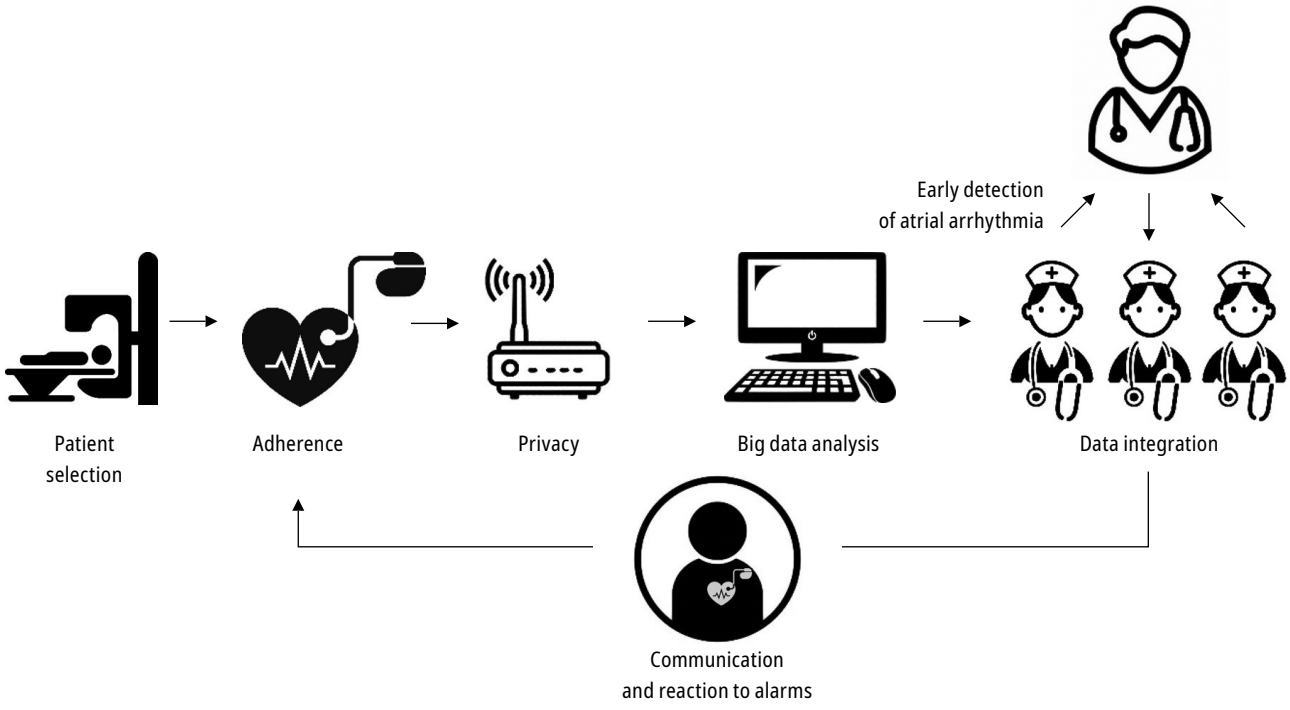

FIGURE 1 Future challenges in the remote monitoring process enabling the continuous flow of information between device clinics and patients with cardiac implantable electronic devices from the time of implantation

seems to be very attractive for caring of patients with HF, who could benefit from remote clinical management, using a multiparametric analysis of transmitted data.[41] Some examples in clinical research have already underscored the potential role of such a huge amount of data in the field of AF.[42] After promising data from relevant clinical trials,[43] a large, remotely monitored population of patients with CIEDs was studied to correlate new-onset HF, HF hospitalization, and all-cause mortality with AF, which strengthened the findings from clinical trials conducted in a selected, relatively small sample.[42] In the nearest future, a strong collaboration between clinicians, industries, and researchers should investigate ways to optimize and timely utilize big data derived from RM. Those data, if integrated with electronic medical records, may also help regulatory authorities to understand the social impact of cardiac diseases and better plan health policies. Cardiac implantable devices are nowadays on the edge of "big data" revolution; nevertheless, there is still concern about the quality of data. It is believed that continuing to thrive on excellence in data handling in CIED RM would enable physicians to practice most efficiently.[44]

Data integration Implantable cardioverter-defibrillators and cardiac resynchronization therapy devices have been linked to the substantial improvement of prognosis in patients with HF.[45] However, there have been some concerns about the usability of RM-derived data and storage from different manufacturers.[46] The RESULT (Remote Supervision to Decrease Hospitalization Rate) trial[47] was designed to overcome loss of data when a patient is implanted with a new device from a different manufacturer and to provide a shared platform for CIED RM. The study demonstrated that the integrated RM of HF patients with CIEDs by different manufacturers significantly reduced all-cause mortality or hospitalizations due to cardiovascular disease. Some exploratory studies focused on another aspect of data integration regarding RM—providing better care through RM using the interoperability and patient-centered approach.[48,49] In one study, a single platform was designed to facilitate clinical workflow and provide patients with a single platform to self-review their own data.[50] Moreover, such an approach needs a tailored CIED data sharing protocol and patient education.[51]

In the field of information technology, a lot of effort was made to define standards of interoperability to aggregate CIED data into a third party designed repository. The data flow would pass from CIED reporting systems to clinical repositories and finally to registries and referring physicians; as a potential application, even to patient-accessible portals. Such collected and organized data,[50] avoiding multiple information entry, linked to inherent errors and inefficiencies,[51] may be used for multiple purposes. Some authors claimed that such an inevitable future improvement could become a prerequisite for vendor certification.[52] Nowadays, there are still only few experiences and the situation is far from complete data integration.

Early detection of atrial arrhythmia Atrial fibrillation poses a particularly insidious threat to patients implanted with CIEDs, as it puts them at risk of inappropriate shocks, thromboembolic events, or worsening HF.[53] With RM, it is possible to maintain a continuous surveillance on the development of arrhythmic episodes. Despite this possibility, the role of RM in the detection and management of atrial arrhythmias remains controversial. A meta-analysis published in 2015 showed no difference in the rate of atrial arrhythmias in remotely monitored patients compared with the group with standard follow-up,[54] and 2 more recent studies conducted among patients with pacemakers demonstrated opposite results on the reduction of the arrhythmic burden using RM.[8,55] In the last years, new wearable devices for continuous heart rate monitoring have been developed.[56-59] A recent meta-analysis evaluating patients with both CIEDs and wearable devices showed that RM significantly increases the detection rate of atrial arrhythmia and reduces the risk of stroke.[60] The latter effect may be due to the reduction of the time lag between an event and a clinical decision.[54] Apart from clinical arrhythmias, RM detects AHREs and subclinical AF.[61] The relationship between those episodes and the risk of clinical AF, stroke, and other adverse events has not been completely elucidated, although the duration of an AHRE seems to be a good predictor.[62-66] The decisional pathway to start anticoagulant therapy following the detection of AHREs vary widely among physicians in clinical practice.[67] Ongoing trials are comparing various treatment options in this setting and will provide further information on this debated topic in the next years.[68,69] Based on the current evidence, the management of AHREs should follow the recommendations of guidelines for the diagnosis and management of AF, which state a clear indication for a more intense follow-up and correction of modifiable risk factors in all patients with AHREs and suggest considering anticoagulation therapy in patients with longer AHRE duration (eg, more than 24 hours) and at high risk of stroke.[70]

Communication and reaction to alarms Efficient and effective communication with patients is of key importance for the correct functioning of a telemonitoring program. In fact, it has been reported that patients may experience feelings of anxiety and uncertainty as a consequence of decreased interaction with the clinic[71] and this may lead to the wish for faster and more detailed feedback from remote follow-ups.[72] In this context, telephone calls play a crucial role and represent a non-negligible burden on the device clinic workload.[73] A study conducted at 75 Italian remote CIED monitoring clinics to evaluate the manpower and workload associated with RM showed that a half of patients were contacted during remote follow-ups, with a median telephone call duration of 3 minutes.[74] Another recent study analyzed in detail the role of telephone calls in CIED RM.[75] It was reported that telephone contacts were time consuming and mostly pertained to the home monitoring box, CIED transmission data, and symptoms, with most calls regarding 2 or more topics. Revisiting in the future such a telephone-based approach to RM would require a substantial implementation of novel technologies. It is also of great importance for the CIED clinic to have a structured pathway to react to alarms or events detected via RM, as this may affect patient outcomes.[19,20] In a recently published analysis of the results of the OptiLink HF (Optimization of Heart Failure Management Using OptiVol™ Fluid Status Monitoring and CareLink™) study, for example, appropriate reactions of RM to intrathoracic fluid index threshold crossing alerts were associated with significantly improved clinical outcomes in patients with advanced HF.[9] Of note, in that study, only 55.5% of all transmitted fluid index threshold crossings were followed by an appropriate contact.[9] In the IN-TIME (Implant-Based Multiparameter Telemonitoring of Patients with Heart Failure) trial, additional follow-up visits to a specialized center for device surveillance in response to telemonitoring data were scheduled for 19% of patients in the RM group, with atrial tachyarrhythmia being the medical telemonitoring finding that most often led to patient contact.[76] A consensus document of the Italian Association of Arrhythmology and Cardiac Pacing published in 2020 proposed an in- and inter-hospital organizational model to improve the management of patients with CIEDs.[25] It suggested the creation of dedicated teams and collaborative networks between neighboring structures for small hospitals that may not be able to manage CIED RM independently.[25] Translation of these principles and rules into practice will represent a major challenge for device specialists in the nearest future.

Conclusions Remote monitoring of technical parameters and arrhythmic events by CIEDs plays nowadays an inevitable role in the holistic and continuous care of patients with cardiac disease. For the upcoming years, there are some challenges to be solved, starting from warranty of data security and accessibility and ending with data integration using clinical repositories for optimization of clinical care. Patient selection and persistence under RM should also be weighted, coping with resources availability, and may reduce the total impact of the management of serious chronic diseases on healthcare systems. Widely spreading technology is also starting to promote relevant observations, theoretically not in a selected small sample yet

in the whole population of patients with cardiac disease. It represents an extraordinary tool for improvement of knowledge. Every aspect of these unmet needs have been magnified by the unpredictable situation that the global community is facing in 2021, with SARS-CoV-2 forcing everyone to improve telemedicine and social distancing.[77-82] In this extraordinary time, it is not unpredictable that unexpected applications of remote technologies may lead to seminal advances in telemedicine.

ARTICLE INFORMATION

CONFLICT OF INTEREST None declared.

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