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Impact of COVID-19 Pandemic on Cardiac Electronic Device Management and Role of Remote Monitoring



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KEYWORDS

- COVID-19 • Remote monitoring • Telemedicine • CIED • Telehealth • Pacemaker
- Implantable cardiac defibrillator

KEY POINTS

- The aim of remote monitoring is to optimize the clinical management of CIED patients, improve quality of life, and reduce hospitalization and emergency department access.
- A well-established organizational model should include an adequately structured team, a valid integration with the primary health care centers, and an appropriate response to clinical alerts.
- The development and refinement of telemedicine during the pandemic period suggest that remote monitoring should be recommended for all CIED patients.

INTRODUCTION

On December 31, 2019, a cluster of pneumonia cases of unknown origin was reported in the city of Wuhan; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was then discovered as the causative agent of the respiratory disease named coronavirus disease 2019 (COVID-19).¹ The epidemic spread rapidly through China and subsequently to the rest of the world, leading the World Health Organization to declare the pandemic state on March 11, 2020.

COVID-19 has caused a global impact on public health services that led to the reorganization of hospital settings, including in-office visits for patients with cardiac implantable electronic device

(CIED). Remote monitoring (RM) of CIED patients represents an appropriate strategy to minimize any potential risk of virus exposure for patients and health care providers, without compromising the quality of care.²⁻⁵ RM offers access to the same information as an in-office visit and may contribute to the early detection of atrial and ventricular arrhythmias,^{6,7} prevent heart failure (HF) decompensation, and manage device-related issues.⁸⁻¹² RM has also confirmed its usefulness in decreasing the hospitalization rate and improving clinical outcomes.¹³ Moreover, since the onset of the COVID-19 pandemic, physicians have suspended nonurgent scheduled visits and made a rapid transition to virtual visits (VV).¹⁴⁻¹⁶ Thanks

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to the technological improvement, patients utilizing wearable sensors for the measurement of hemodynamic parameters (blood pressure and saturation, heart rate) and adopting virtual health platforms may be monitored directly from home without any risk of infection.

In this review, we provide an overview of the many possible applications of RM, its limitations and challenges in patients with CIED during the COVID-19 pandemic.

THE ROLE OF RM IN CIED MANAGEMENT DURING COVID-19

RM of CIED patients has become increasingly popular in clinical practice, especially during the COVID-19 pandemic.¹⁷ Indeed, in the new guidelines of the European Society of Cardiology (ESC) on cardiac pacing, RM is recommended to reduce the number of in-office follow-up in patients with pacemaker (PMK) who have difficulties to attend in-person visits. RM may also be useful in case of a device component that has been recalled or is on advisory, to enable early detection of actionable events in patients at high risk.¹⁸ RM provides the same information as an in-person visit ensuring an early identification of cardiac arrhythmias, such as ventricular tachycardias or atrial fibrillation, device therapy, and device-related issues like lead malfunction and early battery discharge.^{19–22} Additional benefits were also demonstrated among HF patients in terms of preventing unfavorable cardiovascular events and reducing hospital readmissions.^{12,23}

Although guidelines recommended the use of RM for the follow-up of patients with CIED, the coverage of RM was limited because of the organizational problems of health care systems and reimbursement issues.^{18,20} The COVID-19 pandemic forced all health care providers to minimize interpersonal contacts to limit the spread of the virus, which led to a total reshaping of outpatient cardiology management and accelerated the deployment and widespread use of RM.²⁴ Indeed, the consensus document of the Heart Rhythm Society (HRS) and ESC for the management of cardiovascular disease during the COVID-19 pandemic recommended that RM should replace in-office visits for device interrogation and, whenever possible, postpone the scheduled in-person visit.^{3,4,14,24,25}

A questionnaire-based survey by the European Heart Rhythm Association (EHRA) to assess the influence of the COVID-19 pandemic on RM in CIEDs demonstrated a strong implementation of RM in patients with PMKs and implantable loop recorders (ILRs; PMK 24.2 vs 39.9%; $P = .002$; ILR

61.5 vs 73.5%; $P = .028$). A nonsignificant increasing trend was registered for RM of cardiac resynchronization therapy-pacemaker (CRT-P) devices (44.5 vs 55%; $P = .063$), implantable cardioverter defibrillators (ICDs; 65.2 vs 69.6%; $P = .408$) and CRT-defibrillators (CRT-D; 65.2 vs 68.8%; $P = .513$).²⁶

Home delivery of the transmitter for RM should be preferred over in-office delivery, as it limits the exposure of patients to the hospital environment. To date, home delivery of transmitter is feasible for Boston Scientific and Abbott PM and ICDs, as well as for the latest Medtronic CIEDs with BlueSync.²⁴ As demonstrated in a recent multicenter study, the communicator LATITUDE was home delivered to 1324 patients from 49 different Italian centers and successful activation through telephone training was achieved in 92% of cases.²⁷ Moreover, De Larochelière and colleagues confirmed that switching from a follow-up model with in-person visits to an RM model did not impair the management of ICD patients, and significantly reduced the number of in-person visits.²⁸ In **Fig. 1**, we summarized a protocol for setting up and managing RM during the COVID-19 pandemic. When the device is suitable for RM, home delivery of the transmitter is an appropriate strategy for minimizing any potential risk of virus exposure for patients and health care providers.

Overall, the available evidence confirmed that RM is an easy-to-use and effective tool for the management of CIED patients even during the pandemic and demonstrated that the home delivery and activation of communicators without an in-patient visit is a potential opportunity to further extend RM in the future.

SUPPLEMENTATION OF TELECONSULTATION IN CIED PATIENTS

The ESC and HRS consensus documents stated that in-person visits should be replaced by telemedicine consultations in order to prevent the spread of the virus among cardiovascular patients.^{3,24} Indeed, the worldwide survey by Han and colleagues about the use of eHealth technologies during the COVID-19 pandemic showed a significant increase in the use of teleconsultations in the management of cardiological patients (5.9% vs 58.6%; $P < .001$) for all types of consultations compared with the prepandemic period.²⁵

Supplementing teleconsultation in CIED patients could be a key tool in the management of these patients during the COVID-19 pandemic, especially for those affected by HF. ICD and CRT have the capability of monitoring HF by measuring

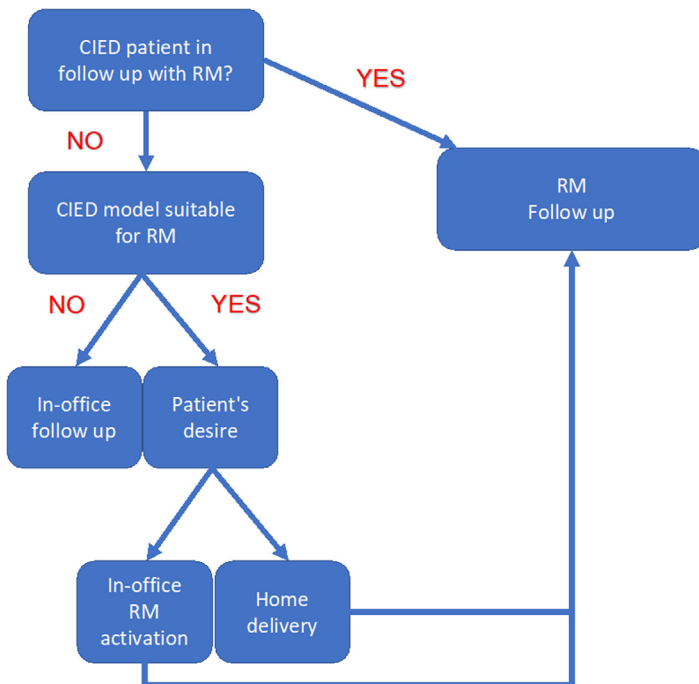


Fig. 1. Remote monitoring setup protocol. CIED, cardiac implantable electronic device; RM, remote monitoring.

thoracic impedance (Optivol, Medtronic; CorVue, Abbott)²⁹ or by integration of several indices (HeartLogic, Boston Scientific).³⁰ Nevertheless, guidance statements issued by experts in electrophysiology and HF recommend that every effort should be made to convert in-office visits to telehealth and VV. Specifically, the VVs used for decades to reach remote communities,³¹ but less commonly used in advanced health care systems, have now emerged as the cornerstone of ambulatory care in all subspecialties.³² The potential benefits of VV for HF patients are providing access to care and medical advice, which would be otherwise difficult to obtain and reducing in-person exposure to SARS-CoV-2. Cardiac rhythm professionals are advantaged by having wireless technology available to transmit monitored information to keep them connected.³³ Moreover, VVs have the advantage of detecting and alerting caregivers about relevant parameter changes, allowing earlier hospitalization of the patient, even in a presymptomatic phase.³⁴ A flowchart for VV is summarized in **Fig. 2**; VV was recommended in patients with atrial arrhythmias, alert for HF decompensation and nonsustained ventricular tachycardia.

Overall, new technologies and digital platforms to aid in remote care should be developed and further research on the role of telehealth, continuous data collecting, advanced automotive features, and RM is needed to guide best practices.

PATIENT ACCEPTABILITY AND SATISFACTION OF RM DURING COVID-19

As in any health care interaction, patient involvement plays an important role, and in the case of RM, active participation is fundamental. Patients must adhere to transmission timetables and keep in contact with the physician to guarantee a successful health care system based on RM. Therefore, from a positive reciprocal interaction between patient and caregiver usually derives a high acceptability and satisfaction. From the point of view of the patient, especially during the COVID-19 period, RM should be ease of use,^{35–37} even when manual transmission of the data is requested, and guarantee a positive relationship with their health care provider at enrollment and during all the monitored period.^{36,38–40} The Home Monitoring Acceptance and Satisfaction Questionnaire is administered to evaluate the acceptability and satisfaction of RM (HoMASQ) and showed that ICD patients had a higher level of acceptance and satisfaction than patients with PMK.^{35,39} Moreover, RM was demonstrated to be easy to use and well accepted even for older people and patients with a low level of scholarship.⁴¹ Otherwise, the most frequent causes of noncompliance seem to be:

- age-related: age under 40 years was associated with lower compliance.

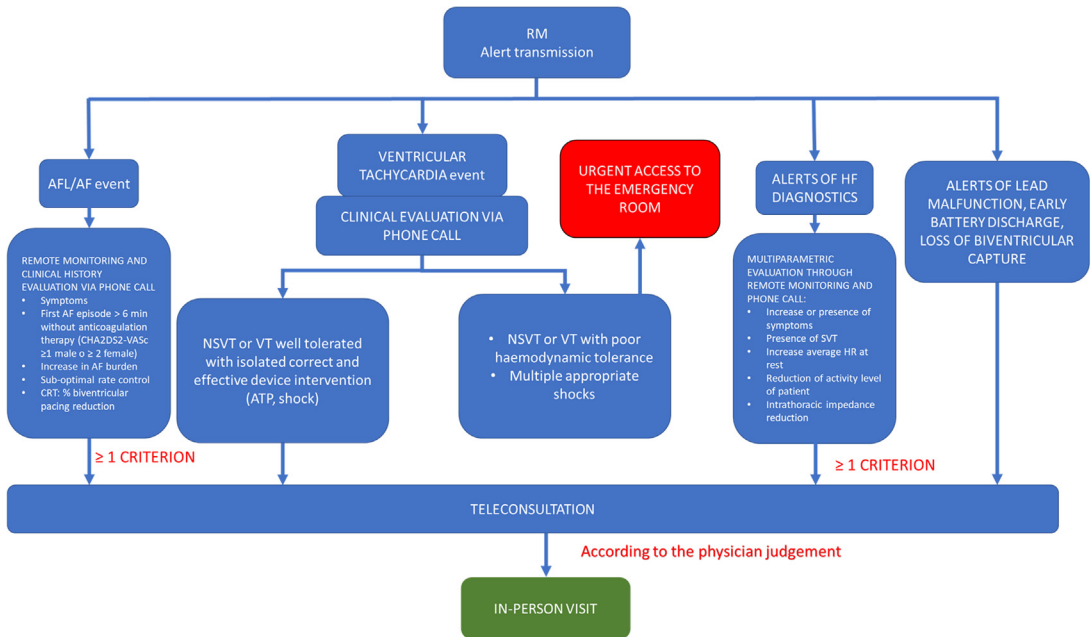


Fig. 2. Remote monitoring management protocol. AF, atrial fibrillation; AFL, atrial flutter; HF, heart failure; HR, heart rate; NSVT, non-sustained ventricular tachycardia; RM, remote monitoring; SVT, supraventricular tachycardia; VT, ventricular tachycardia.

- Health care systems-related: high volume clinics were associated with better compliance.
- Device-related: wireless devices are characterized by a better compliance compared with those requiring use of a wand.⁴²

The institution of an RM patient agreement supported by the HRS enhances the compliance because patients can freely share information and experiences.¹⁷

During the COVID-19 pandemic, also the delivery of the communicator for RM could reduce the risk of contagion and influence patient's acceptability. Piro and colleagues demonstrated that home delivery of the communicator and intensive transtelephonic support for its activation resulted in an easy understanding of the device activation process, as well as high satisfaction with the use of the transmitter.² In addition, despite the ongoing pandemic and national lockdown, patients referred a sense of security and expressed interest in continuing with RM; also, in-office modem delivery and activation was associated with a higher prevalence of anxiety symptoms due to COVID-19 pandemic, compared with home modem delivery.^{2,27}

In conclusion, several studies showed a high level of patient satisfaction and compliance, making it possible to extend this form of management

to a growing volume of patients, especially in times of pandemics.

RM FOR CIED PATIENTS WITH OTHER COMORBIDITIES

CIED patients are usually affected by multiple comorbidities: neurologic syndromes, chronic kidney disease, chronic obstructive pulmonary disease, diabetes mellitus, and other endocrinological disorders. New technologies and the adaptation of existing telemedicine tools represent an alternative option for an integrated monitoring.^{3,32} For example, diabetes patients need recurrent medical consultations to optimize drug therapy and blood sugar levels, and telemedicine can be a valuable alternative, especially during a pandemic when contacts need to be limited.⁴³ To confirm the effectiveness of RM for diabetes management, a recent meta-analysis demonstrated a reduction in glycated hemoglobin in the RM group compared with controls.⁴⁴ Moreover, continuous glucose monitoring is effective in the management of high-risk patients with type 1 diabetes mellitus without any diabetic ketoacidosis.⁴⁵

Telemedicine also spread into the field of neurology and a telestroke unit was established to allow remote assessment of patients with suspected stroke to minimize unnecessary in-person

visits.⁴⁶ The latest evidence demonstrated that in-hospital management of end-stage renal disease patients increased the risk of infection up to 4 times compared with telemedicine-based home management and was more expensive. Similarly, RM appeared effective in the rehabilitation and management of chronic obstructive pulmonary disease patients, leading to a reduction in hospitalizations and emergency department visits.⁴⁷

All this evidence shows how the pandemic escalated the adoption of telemedicine and all aspects of digital health, and this new reality is now likely to define medicine in the future not only in cardiology but also in other branches of medicine.

ECONOMIC ASPECTS

In addition to primary analyses focusing on cardiovascular outcomes (hospitalizations, cardiovascular death, overall death), another important aspect to consider for the adoption of digital health solutions is their impact on health care expenditure.^{48,49} Owing to the outbreak of the SARS-CoV-2, a prompt reorganization of health care services was necessary with a related new economic-financial business plan.

The TARIFF study demonstrated that the overall mean annual cost per patient for in-office follow-up was significantly higher than an RM-based one (−53.87% in the RM group). The main reason for cost reduction is due to the cost of cardiovascular hospitalizations (€ 886.67 ± €1979.13 vs €432.34 ± €2488.10; $P = .0030$).⁵⁰ The same findings were reported in the EVOLVO study, a multicenter clinical trial aiming at measuring the benefits of RM for HF patients with ICDs. The results of this study showed that RM was cost-effective with an average saving of €888.10 per patient.⁴⁸ Notably, cost-effectiveness between countries varied considerably depending on whether there was specific reimbursement for RM services. In fact, there was heterogeneity among countries, with RM generating less profits for providers in the absence of specific reimbursements and similar or increased profits in cases such reimbursements existed.⁵¹ Indeed, according to a recent European survey, the absence of reimbursement in many countries is generally considered the major barrier to the implementation of RM in standard practice.²⁰

RM was cost-effective for health care systems because of lower follow-up costs and hospitalization reductions; the future challenge will be a more uniform deployment of appropriate reimbursement systems.

SUMMARY

The COVID-19 pandemic imposed challenges to the traditional rules of access and delivery of health care worldwide.⁵² It accelerated the adoption of telemedicine and digital health, confirming a new era in the management of CIED patients. Patient outcomes could be improved with device-based intensive monitoring compared with traditional in-clinic follow-up at regular intervals.⁵³ The pandemic experience promoted the search for alternative solutions for an effective patient follow-up, such as validation of digital technologies, data management strategies, implementation of predictive analytics, cybersecurity, development of limited forms of remote CIED programming, and reimbursement.^{19,51,54}

CLINICS CARE POINTS

- Remote Monitoring should be proposed in all CIED patients.
- Remote Monitoring is safe and effective also during COVID pandemic.
- Virtual Visit might be used in patients with multiple cardiac comorbidities.

DISCLOSURES

The authors have nothing to disclose.

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