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REVIEW

Remote monitoring of pacemakers☆

Télésuivi des pacemakers

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Summary Exactly two decades have elapsed since pacemakers first provided automatic remote monitoring. This innovation has been well received by patients. However, there is still a widely held perception that remote monitoring of pacemakers is non-essential, despite the very similar gains that are achieved compared with remote monitoring of implantable cardioverter defibrillators. Reducing in-office evaluations and overall staff workload is important when these resources are stretched to their limits. The early detection ability provided by remote monitoring facilitates device management (extending battery longevity) and the ability to exercise vigilance over recalled components. Clinical complications, such as arrhythmic events, are also detected earlier. Remote monitoring has been shown to produce similar reductions in the risk of all-cause hospitalization and death for pacemakers and implantable cardioverter defibrillators in a mega-cohort observational study. This review is an evidence-based plea for the recognition and systematic implementation of remote monitoring for pacemakers.

Abbreviations: AF, atrial fibrillation; CI, confidence interval; CIED, cardiac implantable electronic device; HR, hazard ratio; ICD, implantable cardioverter defibrillator; RM, remote monitoring.

☆ Tweet: In this evidence-based review, cardiologists ask for the recognition and systematic implementation of remote monitoring for pacemakers.

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MOTS CLÉS
Pacemaker ;
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Télémedecine

Résumé Il y a vingt ans, les *pacemakers* ont été les premiers dispositifs cardiaques implantables à proposer un télésuivi automatisé. Cette innovation a été particulièrement bien accueillie par les patients. Cependant, pour nombre de professionnels de santé, le télésuivi des *pacemakers* apparaît encore comme optionnel et ce en dépit de bénéfices comparables à ceux du télésuivi des défibrillateurs. Le télésuivi permet de réduire le nombre de consultations et d'alléger la charge de travail des équipes soignantes. La capacité de détection anticipée des complications techniques ou cliniques permet d'augmenter la sécurité des patients ainsi que la gestion des *recalls*. La réduction des hospitalisations et décès associée au télésuivis des *pacemakers* est comparable à celle observée dans le télésuivi des défibrillateurs dans une méga-cohorte observationnelle. Cette revue est un plaidoyer fondé sur les preuves pour la reconnaissance et l'utilisation systématique du télésuivi des *pacemakers*.

Background

Remote monitoring (RM) of cardiac implantable electronic devices (CIEDs) is becoming standard of care as an extension to or even a replacement for in-person follow-up [1]. Although RM of implantable cardioverter defibrillators (ICDs) and pacemakers both have a Class I Level A recommendation, RM of pacemakers has received less attention in terms of research and clinical deployment. A 2014 European survey including 54 centres revealed that RM was regarded to be of high or medium benefit for management of ICDs by 94% of the centres, whereas 86% found RM to be of only medium/small benefit or no benefit at all for pacemakers, and > 80% reported that they did not perform pacemaker RM [2]. This review is an evidence-based plea for the recognition and systematic implementation of RM for pacemakers.

Technical considerations

Active remote follow-up solely based on scheduled patient-activated transmissions has now been abandoned by all pacemaker manufacturers, and will not be discussed in the present review. Biotronik launched the first pacemaker allowing automatic transmissions in 2001. Today, all pacemaker manufacturers deliver pacemakers with automatic transmissions. Transmissions are initiated at scheduled intervals, with additional alerts for prespecified out-of-range variables [3]. The pacemaker communicates first to a nearby transceiver, which in turn transmits the data to the manufacturer's secure website using cellular or landline communication. Proprietary transceivers using radiofrequency are tending to be replaced progressively by smartphones, which communicate with the implanted device through Bluetooth® technology; this strategy is considered more secure, and allows the patient to access a limited amount of information about the pacemaker (mostly battery status) and RM status (date of the next scheduled transmission and past successful transmissions) through the use of an app. Compared with bedside transceivers, the use of such an app is associated with greater adherence to transmission schedule [4]. However, Bluetooth® communication has a higher energy cost for both smartphones and pacemakers and should be deactivated on pacemakers that are not under RM. Nowadays, most pacemakers have autotesting features that allow complete surveillance of the leads and battery. Technical alerts, such as for a lead impedance issue, usually require the device to be interrogated by a programmer to re-enable alert transmissions. Pacemakers can send various numbers of arrhythmic electrograms per session, and between two programmer interrogations. Additional ''real-time'' electrograms are sent, along with periodic remote interrogations. These electrograms enable the identification of pacing/sensing issues, as shown in Fig. 1. One manufacturer provides active periodic electrograms, with transient sequences of encouraged sensing and forced pacing, which enhance the capability to detect problems, a feature which is only available for pacemakers [5]. Unscheduled interrogation can be initiated by the patient on most of the systems. Table 1 summarizes the main technical specificities of the different systems.

Security/early detection of events

Because the CIED RM technology is similar for pacemakers and ICDs, patients implanted with pacemakers also benefit from the early detection capabilities of automatic RM. This means that clinical events (such as atrial or ventricular arrhythmia) and technical events (such as signs of lead dysfunction or an empty battery) may be detected and acted upon before the onset of symptoms. In the COMPAS randomized trial (COMPArative follow-up Schedule with home monitoring) the median delay in medical intervention was 17 days (interquartile range 4—48 days) in the RM group versus 139 days (interquartile range 33—201 days) in the control group, corresponding to a mean gain of 117 days (95% confidence interval [CI] 49—184 days; $P = 0.001$) [6]. By way of comparison with ICDs, the median time from onset of arrhythmias to physician evaluation in the randomized TRUST (Lumos-T safely reduces routine office device follow-up) trial was 1 day using RM versus 36 days using conventional care [7]. In a worldwide proprietary database that included 4631 patients under RM, the estimated temporal gain in detection of asymptomatic events (clinical or technical) was 154 days [8].

Table 1 Technical specificities.

	Transceiver				
					
Manufacturer (date of release)	Biotronik (2001)	Abbott (2009)	Boston Scientific (2012)	Medtronic (2018)	Microport (2021)
Name	Home Monitoring®	Merlin.net™	Latitude™ NXT	Carelink™	Smartview™
Cellular	2G-3G-4G	3G-4G	3G-4G	GPRS/3G	2G-3G-4G
Landline	USA only	✓	✓	✓	—
Internet	—	✓	✓	USA only	—
Patient-initiated transmission	—	✓	✓	✓	✓
Scheduled follow-up[a]	Daily	1w—1y	1w—1y	1w—1y	1d—1y
Transmitted electrogram/session[b]	1	All	All	All	All
Remote enabling/disabling of alerts[c]	✓	✓	✓	✓	—
Remote customization of alerts[d]	All	—	AF burden %; RV pacing %	—	—
Alert recurrence limit	Five AF and five VT episodes; all technical	Clinical alerts only	Clinical alerts only	No	Two alerts of the same type
Limitations	Down sampling of the electrograms	—	—	—	No alert for VT
Special features	Mobile; active periodic electrogram		A smartphone can be used as transceiver	A smartphone can be used as transceiver	Mobile

2G/3G/4G: second/third/fourth generation of mobile phone technology; AF: atrial fibrillation; GPRS: General Packet Radio Service; RV: right ventricular; VT: ventricular tachycardia.
[a] 1w—1y: programmable from every week to every year; 1d—1y: programmable from every day to every year.
[b] ''All'' refers to all memorized electrograms that have not been already sent.
[c] Capability to switch an alert on/off remotely through the website; some alerts remain only accessible through the use of a programmer.
[d] Capability to remotely change the boundaries of an alert (e.g. Biotronik allows the lower and upper limits for lead impedances to be changed).

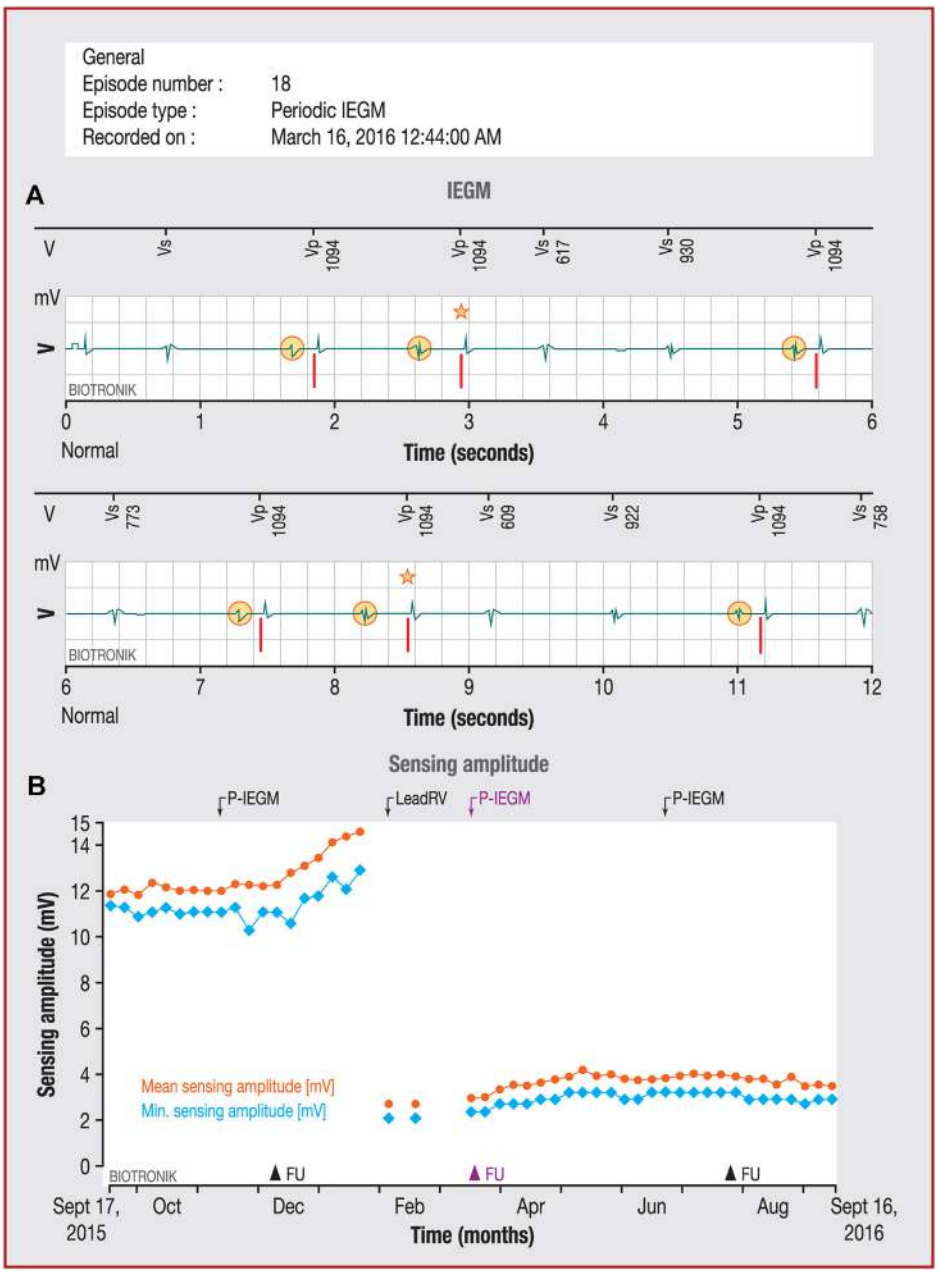

Figure 1. Ventricular undersensing. A single-chamber pacemaker (Evia SR-T; Biotronik, Berlin, Germany) was implanted in an 84-year-old women with chronic atrial fibrillation following an aortic valve replacement in 2011. For an unknown reason, in March 2016, ventricular detection dropped suddenly from 12 mV to < 2 mV, with stable pacing threshold and impedance. A. The diagnosis was made remotely using the periodic intracardiac electrogram (P-IEGM), which shows intermittent ventricular undersensing (orange circles). As a consequence, ventricular pacing occurred asynchronously, with a risk of inducing ventricular arrhythmia (orange stars). B. Ventricular sensing trends, time of the P-IEGM (purple square) and the subsequent in-person follow-up (FU; purple square). The AUTO sensitivity (with a minimal threshold of 2 mV) was switched to a fixed 1 mV value.

Atrial fibrillation (AF) episodes account for the vast majority of events [8]. These notifications may permit early treatment strategies for this largely asymptomatic problem. The SETAM (Strategy of Early Detection of Atrial Arrhythmias with Home Monitoring) randomized trial showed that RM reduces the time to treatment of atrial fibrillation by 44%. After a mean follow-up of 12.8 ± 3.3 months, the AF burden was decreased in the RM arm (8 ± 26%/day vs 28 ± 43%/day; $P = 0.04$) [9]. There is recognition that short subclinical AF episodes carry prognostic value, although categorization of AF events is inconsistent across different studies. The ability to quantify AF in hours per day was first enabled using Biotronik RM, which archived daily datasets (device memory at that time was insufficient for this degree of granularity) [10]. The importance of AF episodes lasting < 24 hours for risk stratification was shown in the ASSERT trial [11]. The value of anticoagulation for events with a duration of < 24 hours is expected to be revealed by the ARTESIA trial [12]. Thus, although no published randomized trial to date has shown that RM is associated with a reduction in the rate of stroke,

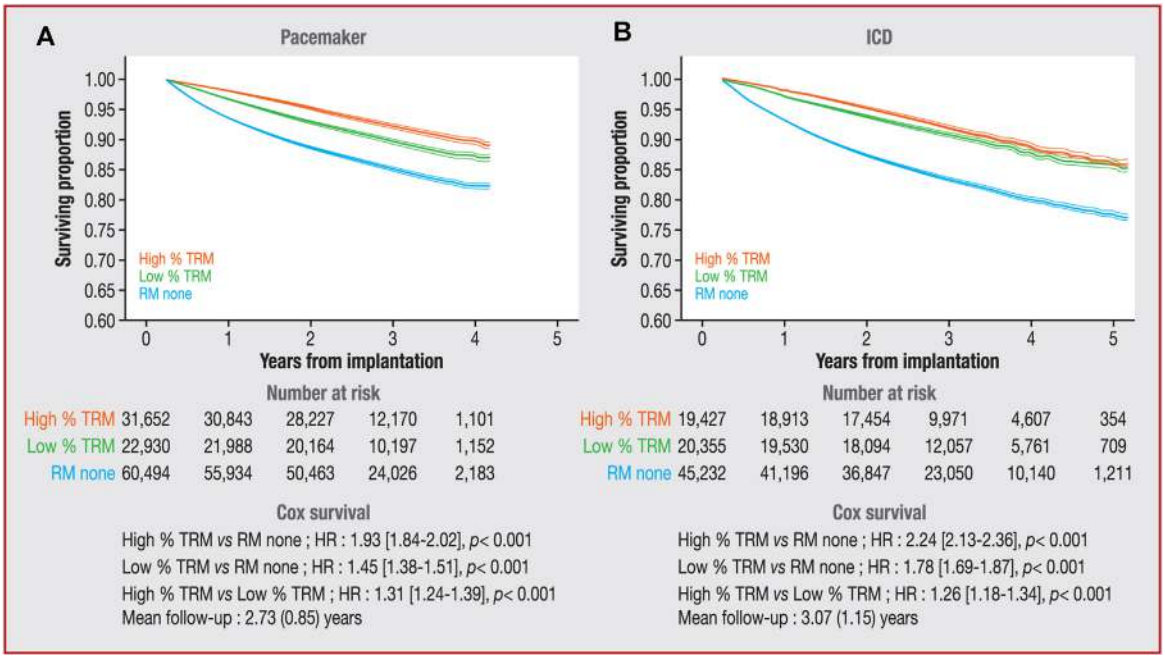

Figure 2. Survival curves of pacemaker recipients versus implantable cardioverter defibrillator (ICD) recipients under remote monitoring (RM). A and B. High percentage of time in RM (%TRM; orange line) consistently had higher survival curves compared with low %TRM (green line) and RM None (blue line) for both pacemakers (A) and ICDs (B). HR: hazard ratio. Reproduced with permission from Elsevier from Varma et al., 2014 [19].

identification of short AF events is expected to be an important part of the management of patients with pacemakers in the future; this is best enabled by RM, possibly facilitated by artificial intelligence mechanisms [13].

Regarding device function, RM management improves the battery longevity of pacemakers similarly to that of ICDs, and this indication receives a Class 1 recommendation [14,15]. Automatic RM of pacemakers is able to alert practitioners to lead or device malfunction before this manifests clinically. The Heart Rhythm Society 2015 consensus statement recommends that patients with a CIED component that has been recalled or is under advisory should be enrolled in RM [1]. Recently, a pacemaker safety notification was released regarding a potential device malfunction that could lead to loss of ventricular pacing or battery depletion [16]. The first recommendation was to ensure remote follow-up for the 95,000 active devices worldwide that were impacted by this issue.

Mortality gain

No randomized trials have demonstrated a survival benefit for pacemaker RM. However, this question was addressed in a mega-cohort observational study, which included 269,471 patients, of whom 115,076 were pacemaker recipients [17]. This study not only showed that RM was associated with improved survival, but also that the degree of adherence to remote management correlated strikingly with the magnitude of survival gain. As shown in Fig. 2, the observed effect was similar in ICDs and pacemakers. In this study, clinical profiles beyond age and sex were unavailable, but the similar effects of RM observed in both pacemakers and ICDs suggest that underlying cardiomyopathy does not play an important role. Although socioeconomic factors (estimated from ZIP codes) significantly affected connectivity, the magnitude of the association was insubstantial, and was insufficient to explain the results. Survival data from the same cohort also indicated that when compared with delayed initiation (after 3 months), prompt initiation of pacemaker RM was associated with a greater adjusted survival (hazard ratio [HR] 1.19, 95% CI 1.12—1.27; $P < 0.001$) [18]. The survival benefit observed with pacemaker RM is probably multifactorial. Early interventions for atrial arrhythmias, ventricular high-rate episodes (caused by sinus tachycardia, AF or ventricular tachycardia) and lead/device malfunctions may translate into better outcomes. Illustrative cases of actionable alerts that may have changed patient prognosis are depicted in Figs. 3—5. Patient contacts prompted by RM (or interruption of RM) may occasionally reveal worsening of their clinical status. It has been postulated that the use of RM may be more likely in patients who are generally healthier and more compliant. However it has been shown that patients randomized to RM are less likely to be lost to follow-up and are more likely to adhere to in-person follow-up [19]. Finally, intensified follow-up may improve health-conscious behaviour beyond device management.

Healthcare utilization and costs

Pacemaker RM diminishes the need for interim follow-ups, which do not require programming changes in 79—99% of cases [6,20]. The randomized COMPAS trial first showed that automatic RM was a safe alternative to conventional long-term follow-up over an 18-month period. Among other

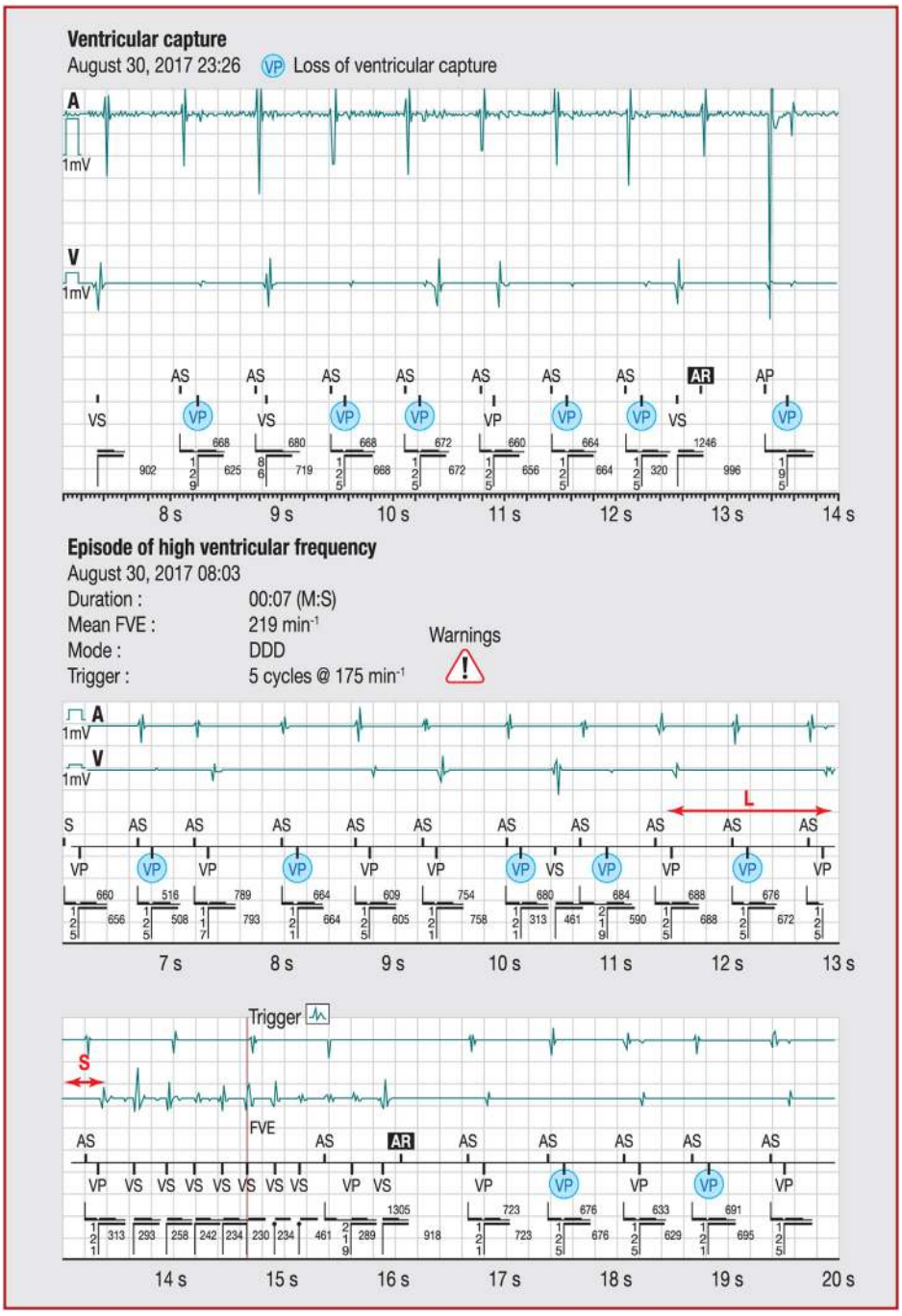

Figure 3. Intermittent loss of ventricular capture and non-sustained ventricular tachycardia. This 71-year-old patient was first implanted in 2009 for a complete atrioventricular block with a chronically high ventricular pacing threshold: 2.75 V/0.4 ms. After a generator change in 2017, the safety margin was decreased, with a programmed output at 3.5 V/0.4 ms. A few weeks later a remote monitoring transmission was initiated by a ''High Ventricular Rate'' alert. The freeze capture electrogram (real-time electrocardiogram; ''Tracé Capturé''—top panel) showed an intermittent ventricular loss of capture (purple circles). The ''High Ventricular Rate'' electrogram (''Episode: *Fréq. V. Elevée*'' — bottom panel) showed a non-sustained polymorphic ventricular arrhythmia, probably induced by a long-short RR sequence (orange arrows; L: long; S: short), which resulted from the intermittent ventricular loss of capture (purple circles). The patient was contacted and urgently hospitalized; he admitted to having had multiple episodes of near-syncope since the generator change.

benefits, RM provided a 36% reduction in the number of follow-ups per patient. The RM-ALONE study showed that was safe to replace in-office interrogations with periodic remote interrogations in a randomized population of 294 pacemaker recipients followed by automatic RM for at least 24 months [21]. The proportion of patients experiencing at least one major cardiac event was similar in the two groups, but remote interrogations were associated with an 83% reduction in face-to-face visits and a significant decrease in staff workload [21] The same design was applied in the At-Home Study, which included 1274 patients [20]; after 24 months, the absence of in-office scheduled interrogations

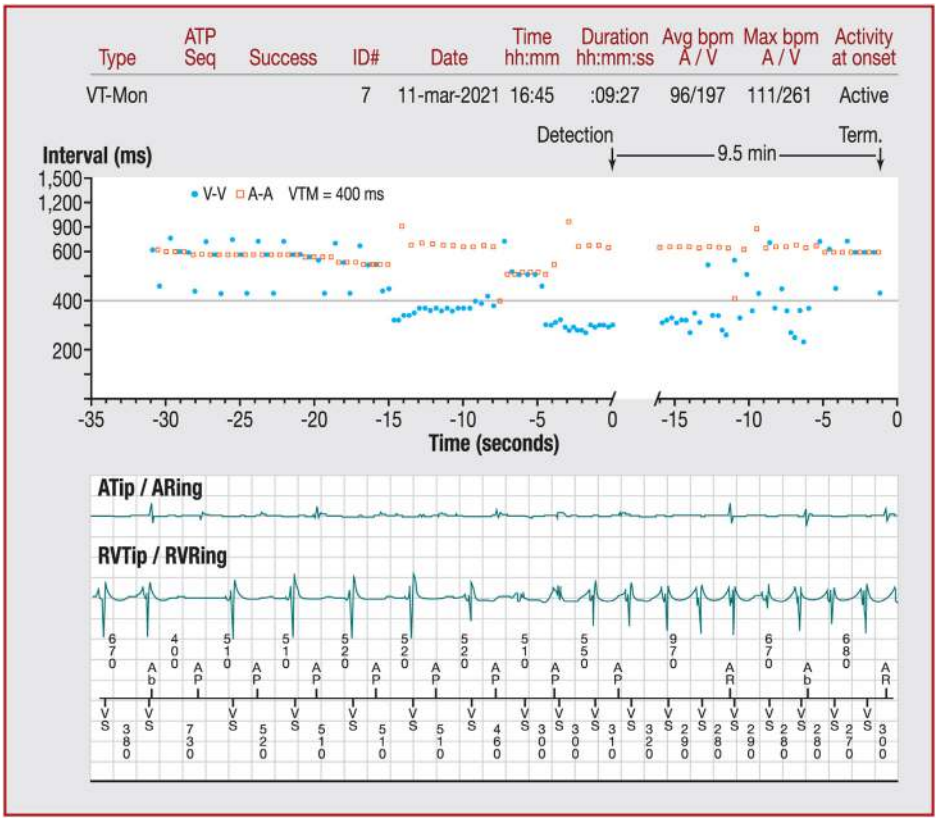

Figure 4. Ventricular tachycardia (VT) episode alert. A 73-year-old patient was implanted with a dual-chamber pacemaker (Azure™ XT-DR; Medtronic Inc., Minneapolis, MN, USA) for sinus node dysfunction. A few weeks later a ''Monitored VT Episode'' triggered a transmission. The corresponding electrogram shows an exercise-induced unstable VT, lasting 9.5 minutes, with average and maximum ventricular rates of 197 and 261 beats per minute (bpm), respectively. The patient was immediately called, and he reported a near-syncope during the episode. The in-hospital workup revealed a dilated left ventricle with preserved ejection fraction, without signs of coronary artery disease. The patient was subsequently upgraded to a dual-chamber ICD.

provided a 70% reduction in in-office follow-ups, without an increase in major cardiac events. The rate of hospitalization was not significantly different between groups in any of these trials.

RM is also a useful strategy to limit time spent in hospital. In the OEDIPE (OnE Day pacemaker Implantation Program with homE-monitoring) trial, RM was used to enable early hospital discharge after pacemaker implant or replacement. The use of RM was shown to be safe, and provided a 34% reduction in the mean duration of hospitalization ($P < 0.001$) [22]. Piccini et al. assessed healthcare utilization in a nationwide cohort study in the USA, which included 54,520 pacemaker recipients, of whom 15,571 were remotely monitored [23]. The use of RM (either active or automatic) was associated with a reduced risk (adjusted for geography, age, sex and 20 preimplant comorbidities) of all-cause hospitalization (HR 0.83, 95% CI 0.81—0.86; $P < 0.001$) and cardiovascular hospitalization (HR 0.86, 95% CI 0.82—0.91; $P < 0.001$). The number of days spent per year was also reduced from 3.3 days/patient/year to 2.1 days/patient/year under RM ($P < 0.001$). As a result, RM was associated with 31% lower hospitalization costs ($P < 0.001$). Interestingly, these results were similar to those observed in the 27,816 ICD recipients included in the same study.

Other considerations

Patient satisfaction

In the OEDIPE and COMPAS trials, the mean physical, psychological and overall quality of life (SF-36) scores did not differ between the RM and control groups [6,22]. Using a 12-item homemade questionnaire, Rici et al. showed in 119 patients, including 95 implanted with a pacemaker, a high level of acceptance and satisfaction after 1 year of automatic RM [24].

Healthcare access

The benefits of pacemaker RM are independent of the patient socioeconomic status and facilitate healthcare access for isolated patients. A person could be geographically or socially (elderly, incarcerated, low income) isolated or isolated for quarantine. In the Merlin mega-cohort study, high RM adherence was significantly associated with rural residence [17]. RM has been found to be valuable in debilitated elderly patients, and is recommended to limit transport, hospitalization and caregiver expenditure [25]. The usefulness of CIED RM has recently been highlighted by the coronavirus disease 2019 (COVID-19) pandemic, and it

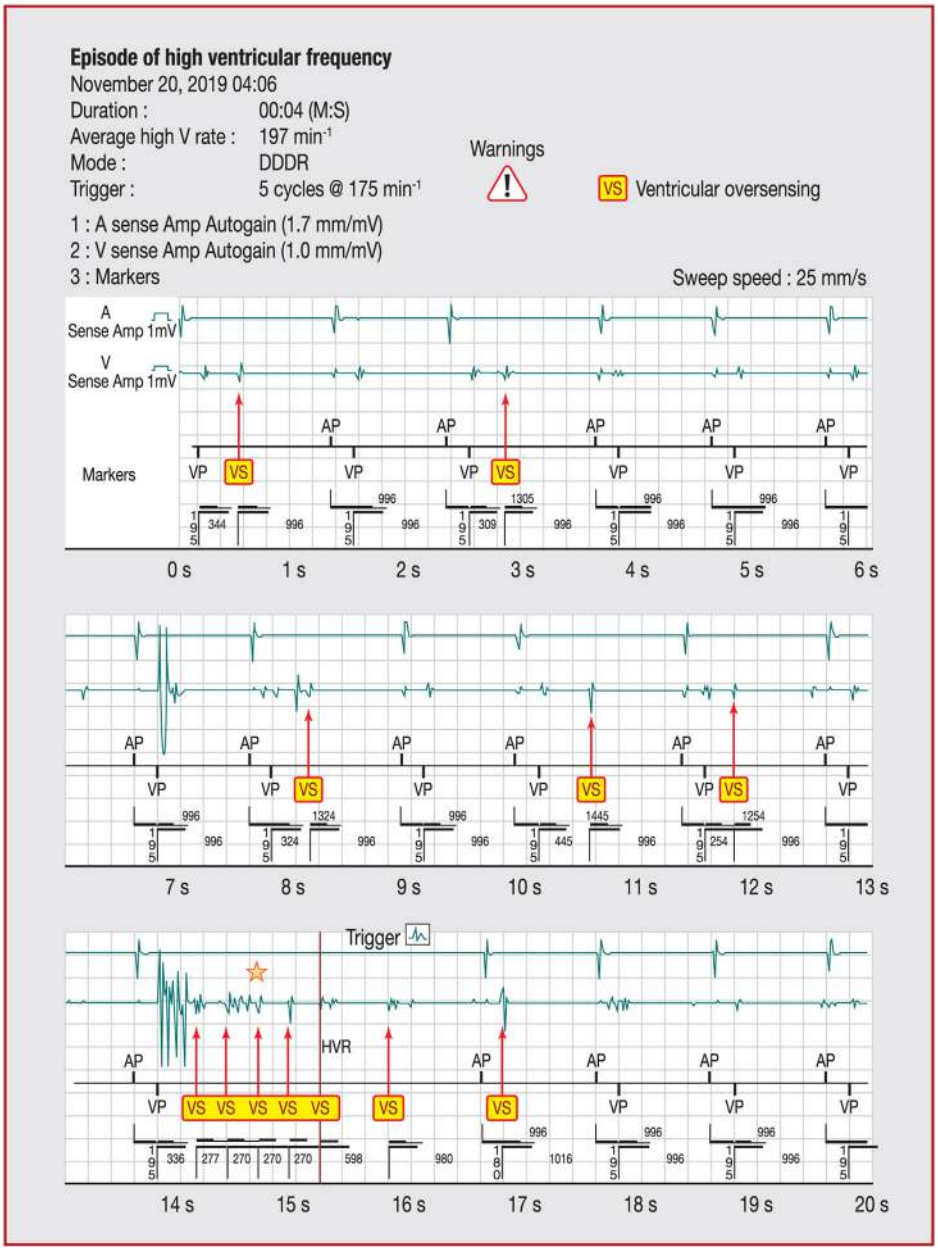

Figure 5. ''High ventricular rate'' alert revealing a lead-conductor fracture. A ''High ventricular rate'' alert initiated a transmission detected on a dual-chamber pacemaker (Assurity^{TM}; Abbott, Chicago, IL, USA). The electrogram episode revealed intermittent oversensed signals (purple rectangles) leading to inappropriate detection of high ventricular rate and pacing inhibition (star); these signals are typical of ventricular conductor fracture. The ventricular lead (implanted in 2001) showed stable impedances (410—430 Ω) and pacing thresholds (0.75 V/0.4 ms), but highly variable sense amplitudes as a result of intermittent noise detection (2.5—7.2 mV). The ventricular lead was replaced before any symptom occurred in this 84-year-old patient with 98% atrial and 99% ventricular pacing. This case illustrates the high diagnostic value of ventricular tachycardia episode alerts for detection of lead failure.

is recognized as a means of complying with public health measures while preserving the care and safety of implanted patients [26,27].

Work burden for healthcare professionals

A decrease in time spent on follow-up by hospital staff has been demonstrated for ICD RM [28]. In the RM-ALONE study, the time spent per patient/follow-up by the either the physician or the nurse was similar if not shorter in the pacemaker group than in the ICD group under RM (no statistical comparison available) [21]. In the same study, the full RM strategy reduced staff workload per patient-year compared with RM with scheduled in-office interrogation.

Source of ''Big Data''

Pacemaker RM is also a means of gathering large amounts of data in a consistent and digital format that can be used for medical research. Such ''Big Data'' has been used to

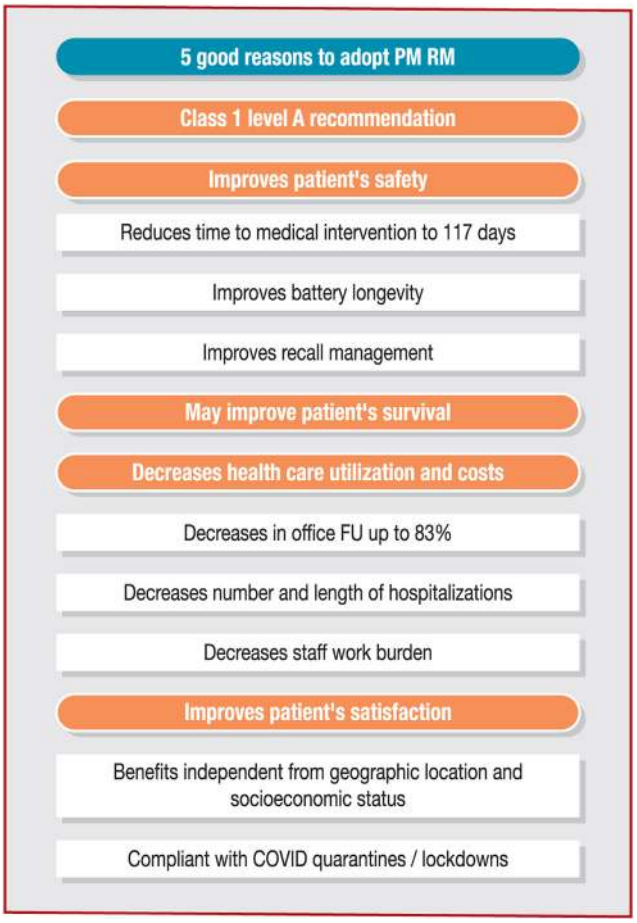

Figure 6. Five good reasons to adopt pacemaker (PM) remote monitoring (RM). COVID: coronavirus disease 2019; FU: follow-up.

evaluate the accuracy of pacing algorithms, lead reliability and the benefits of RM per se [17,29,30] In the near future, RM data will be handled by artificial intelligence to automate triage or event prediction. The ultimate goal of this approach is to further decrease work burden and detection delays.

Conclusions

Exactly two decades have elapsed since pacemakers first provided automatic RM. This innovation has been well received by patients. However, there is still a widely held perception that pacemaker RM is non-essential, despite the very similar gains that are achieved compared with ICD RM (Fig. 6). Reducing in-office evaluations and overall staff workload is important when these resources are stretched to their limits. The early detection ability provided by RM facilitates device management (extending battery longevity) and the ability to exercise vigilance over recalled components. RM has been shown to produce similar reductions in the risk of all-cause hospitalization and death for pacemakers and ICDs in a mega-cohort observational study. It is anticipated that RM will be an important ingredient in anticoagulation decisions for AF. When available, reimbursement is independent of device type. Finally, pacemakers benefit from the same Class I Level A recommendation as ICDs. These extensive benefits indicate that RM should not be denied to pacemaker recipients.

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Disclosure of interest

N.V.: consultant for the companies Abbott, Biotronik, Boston Scientific, Medtronic and Impulse Dynamics.

The other authors declare that they have no competing interest.

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