Am J Cardiovasc Dis 2020;10(2):34-47
www.AJCD.us /ISSN:2160-200X/AJCD0115710

Review Article

Telecardiology during the Covid-19 pandemic: past mistakes and future hopes

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Received May 18, 2020; Accepted June 12, 2020; Epub June 15, 2020; Published June 30, 2020

Abstract: Covid-19 has caused a striking global impact on public health services. The inevitable suspension of all scheduled visits without urgency and non-urgent hospitalizations has resulted in relevant modifications in our management of cardiac patients. Our goal should be to maintain high standards in the treatment of cardiovascular diseases, reducing the risk of esposure to Covid-19 for patients and healthcare professionals. Our Division of Cardiology follows 300 patients in a Heart Failure Ambulatory and almost all of these, as CIEDs' carriers, are monitored by remote monitoring; in addition, we follow more than 2000 CIEDs' carriers using remote monitoring. The purpose of telemedicine, using telecommunications technology, must be to optimize the clinical management of heart failure patients at home, in order to improve their quality of life, reducing hospitalization and emergency department access, also promoting self-management. The evolution of technology has led to the development and refinement of telemedicine and remote monitoring and even more in pandemic times these methods are to be considered a cornerstone. So that telemedicine can really become a well-structured reality, the following are fundamental: the uniform recognition of a reimbursement for this type of medical service, the creation of an organizational model with an adequately structured team, a valid integration with the territorial reality.

Keywords: Telemedicine, remote monitoring, COVID-19, heart failure, CIEDs

Introduction

On 31 December 2019, a cluster of pneumonia cases of unknown aetiology was reported in the city of Wuhan in China. On 9 January 2020, the Chinese Centre for Disease Prevention and Control reported that a novel coronavirus (SARS-CoV-2) had been discovered as the causative agent of the respiratory disease later named Covid-19. The epidemic spread rapidly through China and subsequently to the rest of the world. On 30 January 2020, the World Health Organization (WHO) declared a state of Public Health Emergency of International Concern; on 11 March 2020 the WHO announced that Covid-19 can be described as a pandemic. Italy was one of the first Nations in Europe to be affected [1].

Covid-19 has caused a striking global impact on public health services. The reorganization of hospital settings has led to changes in the distribution of human resources (physicians and nurses) with significant consequences on the activity of the Cardiology departments.

The inevitable suspension of all scheduled visits without urgency and non-urgent hospitalizations has resulted in relevant modifications in our management of cardiac patients.

In this challenging context of pandemic, we have tried to identify some cornerstones:

- reduction of the risk of exposure to Covid-19 for patients and healthcare professionals;
- maintenance of high procedural standards in the treatment of cardiovascular diseases;
- adaptation of the therapies in line with the available resources (hospital beds, anaesthetists, personal protective equipment);
- limitation of delays in treatment of patients particularly at high risk of clinical deterioration and death.

Telemedicine (TM), using telecommunications technology, improves the remote care process, allowing the patient to stay at home in conditions of safety and well-being.

Telemonitoring, the remote data collection from a patient through a device, and in particular remote monitoring (RM) in patients with CIEDs (cardiac implantable electronic devices) represents one of the common applications in TM.

The purpose of this manuscript is, in addition to describing our organizational model, to analyse the light and shade of TM, in a context that has severely tested our health system.

The effect of telemedicine on cardiac events: the controversies of the scientific literature

Many studies have been published in recent years at the aim to demonstrate that TM may reduce cardiac events after hospitalization for acute HF; the data appear to be at least conflicting (**Table 1**).

Two randomized controlled trials (Tele-HF [2] and TIM-HF [3]) conclude that when compared with usual care, tele-cardiology is not associated with a significant reduction of cardiovascular death or hospitalization. On the contrary, other two trials [4, 5] showed that TM was associated with lower mortality, emergency admission rates, and shorter length of admission.

Giving a possible explanation of the failure of the TM system in some trials, the following can be seen:

- low adherence of patients to the telecardiology program;

- absence of data about the reactions to alerts and the kind of interventions assumed to solve clinical problems;

- lack of a well-structured organisation to promptly manage large and relevant volumes of clinical data.

The role of remote monitoring: from 2015 HRS guidelines to pandemic time

The insertion of CIEDs - implantable cardioverter defibrillators (ICDs), pacemaker, cardiac resynchronization therapy ICD and pace maker (CRT-D and CRT-P), implantable cardiac monitors (ICMs) - has progressively increased in recent years [6].

The safety and clinical benefits derived by telecardiology in CIEDs patients have been validated in several large trials [7-9]: remote monitoring resulted in increased efficiency for healthcare providers and improved quality of care for patients.

In Italy, several patients need periodic examinations of CIEDs to evaluate their correct performance; RM and control, integrated with at least annual in-person evaluation, represent a class Ia recommendation in the last HRS Expert Consensus Statement, to be preferred over a calendar-based schedule of in-person CIED evaluation alone [10].

Our Division of Cardiology follows 300 patients in a Heart Failure (HF) Ambulatory and almost all of these, as CIEDs' carriers, are monitored by RM; in addition, we follow more than 2000 CIEDs' carriers using RM.

The CIEDs' RM started in our Hospital in January 2013; since then, all the new implantations and all battery replacements were followed up remotely.

The strengthening of RM has had positive effects on waiting room overcrowding, costs and traffic associated with patient transport and utilization of resources (human and structural) that can be used for other activities [11].

A recent Heart Rhythm Society COVID-19 Task Force Update on CIEDs management establishes that our goal should be to provide adequate care to CIEDs carriers while limiting exposure to staff and patients during this pandemic. Therefore every effort should be made to execute CIEDs interrogations via RM rather than ambulatory visits. In-person outpatient visits should be limited to potentially dangerous issues concerning the leads or the generator, which cannot be managed by RM or in the case of absolute need to reprogram the device [12].

There is an absolute need for a standardised organisational model; even today in Italian hospitals, where extremely variable situations are documented, we consider it appropriate to set

Table 1. Summary of the main studies on the effects of telemedicine on cardiovascular outcomes

Study	Type of intervention	Results
Chaudhry et al. (2010) [2]	Patients: 1653. Follow up: 180 days. Intervention: telephone-based interactive voice-response system. Primary end-point: readmission for any reason or death from any cause within 180 days after enrollment. Secondary end points: hospitalization for heart failure, number of days in the hospital, and number of hospitalizations.	Primary end point: 52.3% for telemonitoring group; 51.5% for the usual-care group. No significant differences between the two groups with respect to the secondary end points. Among patients recently hospitalized for heart failure, TM did not improve outcomes.
Koehler et al. (2011) [3]	Patients: 710. Follow up: median follow-up 26 months (minimum 12). Intervention: portable devices for ECG, blood pressure, and body weight measurements were sent via cell phones to the telemedical centers. Primary end point: death from any cause. Secondary end point: a composite of cardiovascular death and hospitalization for HF.	Compared with usual care, TM had no significant effect on all-cause mortality or on cardiovascular death or HF hospitalization. In ambulatory patients with chronic HF, TM compared with usual care was not associated with a reduction in all-cause mortality.
Steventon et al. (2012) [4]	Patients: 3230. Follow up: 12 months. Interventions: remote exchange of data between patients and healthcare professionals available. Primary end-point: hospital admission during 12 month trial period.	Compared with controls, the intervention group had a lower admission proportion within 12 month follow-up (odds ratio 0.82, p 0.017). Mortality at 12 months was also lower for intervention patients than for controls (4.6% vs. 8.3%; $p < 0.001$).
Ferrante et al. (2010) [5]	Patients: 1518. Follow up: 36 months. Intervention: evaluation of compliance with diet, weight control, and treatment was evaluated. Primary end-points: mortality and HF hospitalizations.	The rate of death or hospitalization for HF was lower in the intervention group (37.2% vs. 42.6%; $p = 0.013$) 1 and 3 years (55.7% vs. 57.5%; $p = 0.05$) after the intervention ended. This benefit was mainly caused by a reduction in admission for HF (28.5% vs. 35.1% after 3 years; $p = 0.0004$).

TM: telemonitoring; HF: heart failure.

up a specific team dedicated to the management of these patients, using the tools of RM and, more generally, of the TM. It is essential to adapt one's own organization in order to manage a significant number of controls performed remotely rather than in ambulatory and get the maximum benefit.

The roles of our organizational model

Our organizational model foresees the involvement of different health care professionals [13].

The cardiovascular technicians

There are four expert professional technicians constantly updated on the CIEDs' technology, dedicated to the service of the control/monitoring of CIEDs patients, both in-office and remotely. During the emergency in which it has been essential to have the minimum resources necessary to carry out the activities in the hospital, but at the same time avoiding the possibility of contagion between operators, we established that no more than two technicians were to be in hospital each day.

Their fundamental responsibilities are represented by:

• patient education and training on the correct use of the remote transmission system;

• input of patient data on the dedicated website;

• review of transmissions with data screening;

• identification and notification of significant alerts to the responsible physician;

• continuous contact with the patient, with verification of the compliance and the benefits of therapy.

The responsible physician

The position is responsible for the analysis of the highlighted technical and clinical problems by monitoring the devices and the patients. He coordinates the activities and maintains a relational network with a number of other "actors": in the intrahospital context, with the medical and non-medical staff of the departments and services to which the CIED patients are referred; outside the hospital with general practitioners, cardiologists operating out of hospital, operators of retirement homes for the elderly.

In some cases, the critical events reported by the interrogation of the CIEDs are evaluated and managed by an electrophysiological cardiologist; in other cases, the data relating to the patient's clinic, must be communicated to the cardiologists dedicated to the HF ambulatory.

The heart failure team ambulatory

Physicians and nurses of the HF Team ambulatory represent key figures with whom to share clinical information derived from RM of CIEDs' HF patients, with the aim of improving their diagnostic and therapeutic pathways.

The territorial reality

The second environment for sharing clinical information of the RM clinic is that of the territory in which Cardiology performs its service. Reporting to the General Practitioner and Outpatient Cardiologist, who work in the Districts, the clinical information relating to each individual patient (presence of atrial fibrillation or other arrhythmias and signs of possible HF), is the most timely way to improve their health status (survival and quality of life) and to avoid hospitalization.

For this purpose, we have implemented the use of teleconferencing technologies with general practitioners. Each group can refer to a cardiologist to facilitate the diagnostic-therapeutic path of the assisted patients. Thanks to teleconsultation, this figure can share clinical information, ask for specialist consultation and understand if the patient needs an outpatient visit.

The patient

The patient is responsible for the periodic sending of transmissions using their own transmitter at home. Transmitted data are evaluated on all working days, and patients are contacted by phone in case of relevant RM alerts which need clinical interventions. The staff working in the RM clinic should represent a point of reference for the patient in case of doubts and difficulties and share with him/her the technical and clinical information. The use of technology in this

case can represent a valid tool for communication, education and sharing of clinical information.

The doctor-patient relationship is a collaborative one: the patient's lack of cooperation can lead to the failure of the monitoring system and its non-compliance must be reported.

In order to provide the best possible medical assistance to our patients, it is necessary to have the main clinical information readily available, included in a database equipped with privacy-preserving features and protocols: the phone number of the patient/relatives/caregiver, the name of the family doctor and, possibly, their address and e-mail; patient's clinical history; data identifying CHA_2DS_2-VASC and HASBLED scores; echocardiographic data (in particular, left ventricular ejection fraction, volume/atrial dimensions, relevant valvulopathies, pulmonary hypertension); drug therapy; any previous ablative, cardiac or interventional procedures; laboratory exams (kidney and liver function, hemochrome); any previous hospitalizations especially for congestive HF.

Patient data must be treated appropriately, in compliance with privacy laws: they should be kept for no longer than is necessary and their owners should be informed regarding the handling of their data.

How has the role of the heart failure cardiologist changed in the context of the pandemic?

HF represents a growing public health problem worldwide; the prevalence is going to increase due to the ageing population and improvements in care [14].

The purpose of TM must be to optimize the clinical management of patients at home, in order to improve their quality of life, reducing hospitalization and emergency department access.

TM allows to control weight and fluid balance (in order to manage diuretic therapy), to monitor heart rate, blood pressure and arrhythmias, to titrate therapy (in particular after hospital discharge), to educate the patient on self-management.

The role of daily monitoring of body weight and vital signs has been highlighted by the most recent HF Guidelines [15]. During the closure of the elective outpatient activity, we offered the possibility to our patient to use mobile devices (smartphones, tablets...) and popular communication technologies (SMS, e-mail, video call, WhatsApp) for remote health status monitoring. The contact has been finalized to evaluation of symptoms, weight variations, changes in arterial pressure, pharmacological therapy variations, correct drugs intake, intercurrent diseases.

A properly trained nurse, exclusively dedicated to this work, is fundamental: this position maintains the relationship with the patient and his/her family or the care-givers, ensuring support and health education and representing a telephone reference in case of need as well as the point of connection with the responsible physician. It is important to give clear messages on how to self-monitor symptoms and signs of worsening and how/when to communicate with us or call 118 for an ambulance.

A lot of CIEDs are implanted in patients with HF or heart diseases that may predispose to HF. Currently available devices allow for easy implementation of TM programs and high-quality patient care; a lot of diagnostic information can be obtained using RM, permitting a timely reaction with an associated therapeutic intervention to avoid hospitalization. The available diagnostics include measuring heart rate variability, daily activities, percentage of right ventricular pacing (in single- and dual-chamber devices), and effective cardiac resynchronization (in biventricular devices), thoracic impedance (**Figure 1**).

Increasingly sophisticated diagnostic algorithms have been developed in the last years. In the Multisensor Chronic Evaluation in Ambulatory HF Patients (MultiSENSE) study, a novel algorithm for HF monitoring was implemented. The HeartLogic (Boston Scientific, St. Paul, Minnesota) index integrates data from multiple sensors (accelerometer-based first and third heart tone, intra-thoracic impedance, respiratory rate, the ratio of respiratory rate to tidal volume, night heart rate, and level of daily physical activity) and has shown to be a sensitive and timely predictor of impending HF decompensation [16]. The effectiveness of multiparametric evaluation of HF exacerbation has appeared also in the SELENE study [17].

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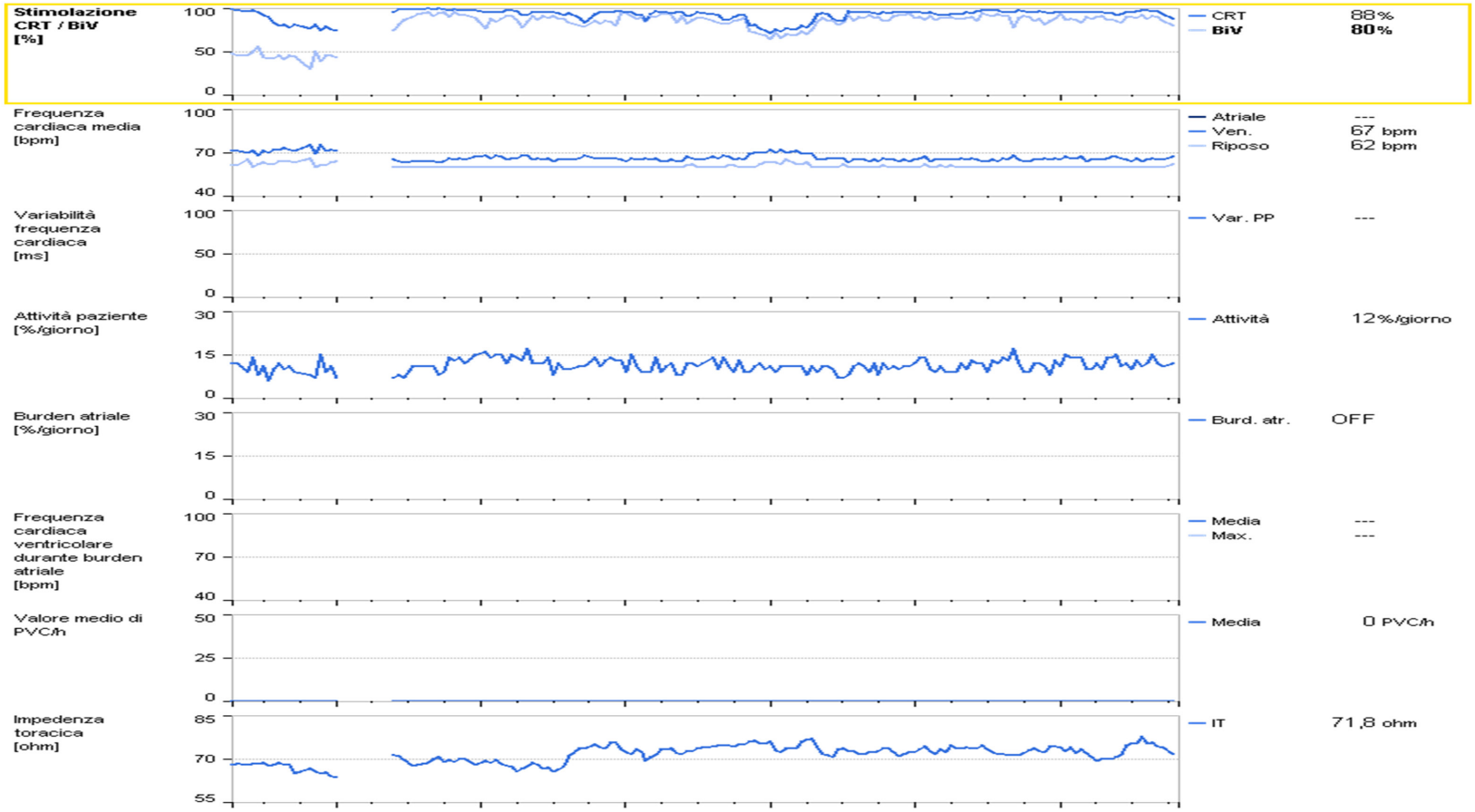
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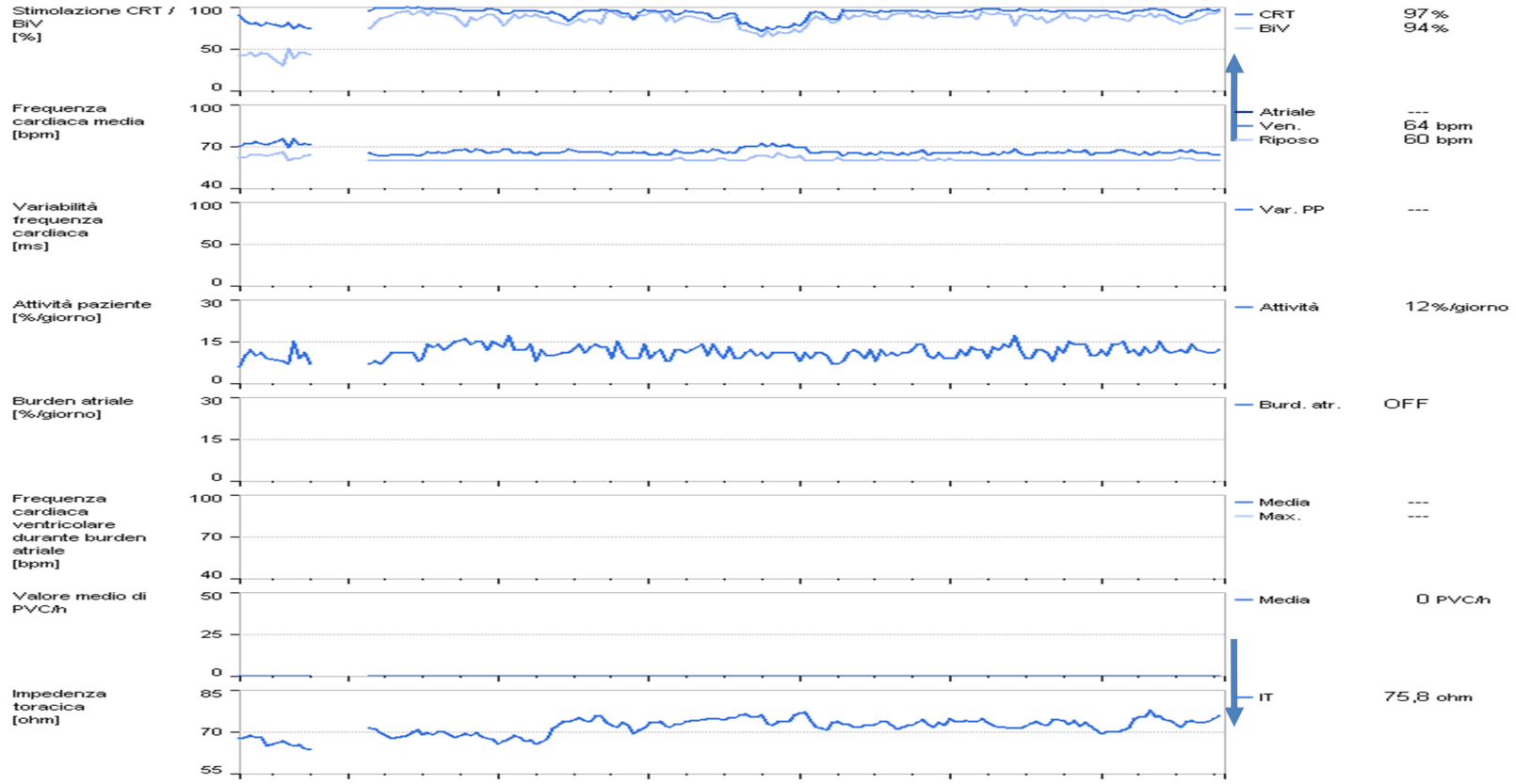

Figure 1. A representation of all the remote monitoring diagnostic tools regarding heart failure. In this case we found in the last 7 days a reduction in the percentage of left and right stimulation, a slight increase in the mean ventricular rate and a decrease in thoracic impedance (A). Following a telephone interview with the patient with evidence of increased body weight and dyspnea, there was an increase in the dosage of diuretic and continuation of home daily monitoring by phone contact; after seven days there was significant improvement in the parameters of the device (B) and the clinical status of the patient, avoiding hospitalization.

HF patients could benefit from remote clinical management using a multiparametric analysis of transmitted data, which integrate technical information of the device with clinical information.

Formal pathways should also be considered for patients who are not device carriers, but who have significant clinical risk factors; we think, for example, of patients suffering from postinfarction ischemic heart disease with severe reduction of left ventricular ejection fraction, relevant functional mitral regurgitation and/or history of acute pulmonary edema contextual to the myocardial infarction event.

It is essential to customize the characteristics of the TM program according to the characteristics of the patient, considering age, socio-cultural level, family context and presence of caregiver, as well as the HF stage.

The final objective should be to obtain a different type of strategy: from a 'reactive' type (a treatment is determined in response to worsening of symptoms) to a 'pro-active' type (changes in therapy are decided when the patient is still asymptomatic) [18].

How has the role of the electrophysiologist changed in the context of the pandemic?

The activity has been limited to procedures with urgent condition (to be performed within 2 weeks, at the latest): ventricular arrhythmic storm ablation not controlled by drug therapy; atrial fibrillation or flutter ablation with significant hemodynamic impact, refractory to drugs or cardioversion; ablation of nodal atrioventricular conduction in patients with refractory HF; replacement for generator depletion (in state of minimum residual charge); revision/extraction of leads in dependent pacemaker patient or with inappropriate defibrillator interventions; lead/generator extraction for infection, bacteremia, endocarditis or pocket infection.

Going into details of how we could handle the most frequent issues, below are described some of the most frequent circumstances.

The management of ventricular arrhythmias

CIEDs' carriers with evidence of un-sustained ventricular tachycardia, asymptomatic and with normal systolic function of the left ventricle, should be managed at home, possibly indicating an optimization of medical therapy and obviously monitoring the evolution using RM. In patients with a pacemaker, in the presence of a left ventricular ejection fraction < 40%, will be indicated a test of inducibility of sustained ventricular arrhythmias and in case of sustained ventricular arrhythmias an upgrading to ICD will be indicated.

For ICD carriers, and in the case of infrequent events and correct device intervention (with ATP or shock), we should restrict our action to a phone contact and to an evaluation of the hemodynamic tolerance of the arrhythmia and the impact of the device intervention.

A prompt in-hospital evaluation is essential in case of: poorly tolerated ventricular arrhythmias; significant emotional impact due to an ICD intervention with shock; multiple ICD interventions (**Figure 2**); inappropriate shock.

The management of atrial fibrillation

In CIEDs' patients, the detection of atrial fibrillation is the most frequently experienced event. A RM evaluation should consider: the presence of symptoms, first AF episode, if second event, number and episode duration, heart rate trend, medical therapy, % biventricular pacing in case of CRT device. The burden of atrial fibrillation considered at cardioembolic risk is not univocally standardized [19, 20].

In-hospital evaluation should be considered only in case of poor hemodynamic tolerance and need of intravenous drugs or cardioversion.

The management of electrical parameters

In the latest generation devices, those implanted in the last five years, the verification of electrical parameters can be fully carried out remotely: RM allows us a modern and safe management of the electrical alarms of the device (in particular related to the integrity of the leads) and a more adequate evaluation of the final phase of the battery life of the devices, avoiding more than ever, especially in this difficult context, multiple outpatient checks. Variations or increase beyond the normal range of the impedance of the leads or reports of early battery depletion, may suggest an improper function of the device and the early

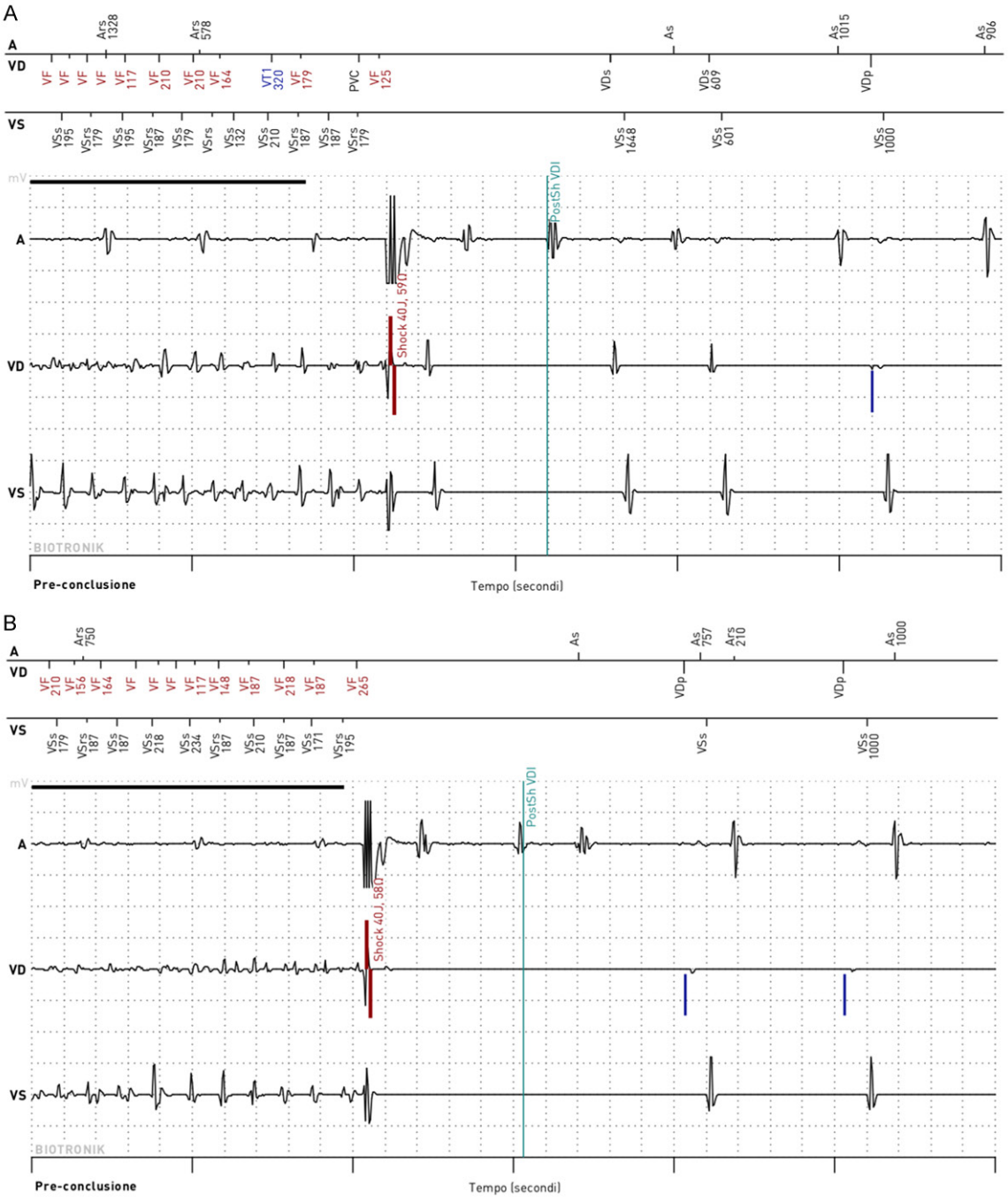

Figure 2. An application of remote monitoring: the management of ventricular arrhythmias. This is the transmission of a 74-year-old patient with a well-known history of ischemic heart disease. Eight months ago, he performed coronary angioplasty on the anterior descending artery and circumflex artery. Following two ventricular fibrillation events in less than 24 hours (A and B) correctly recognized and treated by the device, the patient was admitted to cardiology for the necessary investigations. Coronary angiography showed restenosis on the circumflex artery. The patient was discharged after 72 hours.

detection of this information may prevent any associated disturbances. For a pacemaker patient the loss of the correct functioning of the device may cause the resumption of the symptoms prior to the implant, as syncope or lipotimies, asthenia and exertional breathlessness. For an ICD carrier, the early depletion of the battery may determine the loss of protection by the device on the risk of sudden arrhythmic death, while a lesion of the ventricular

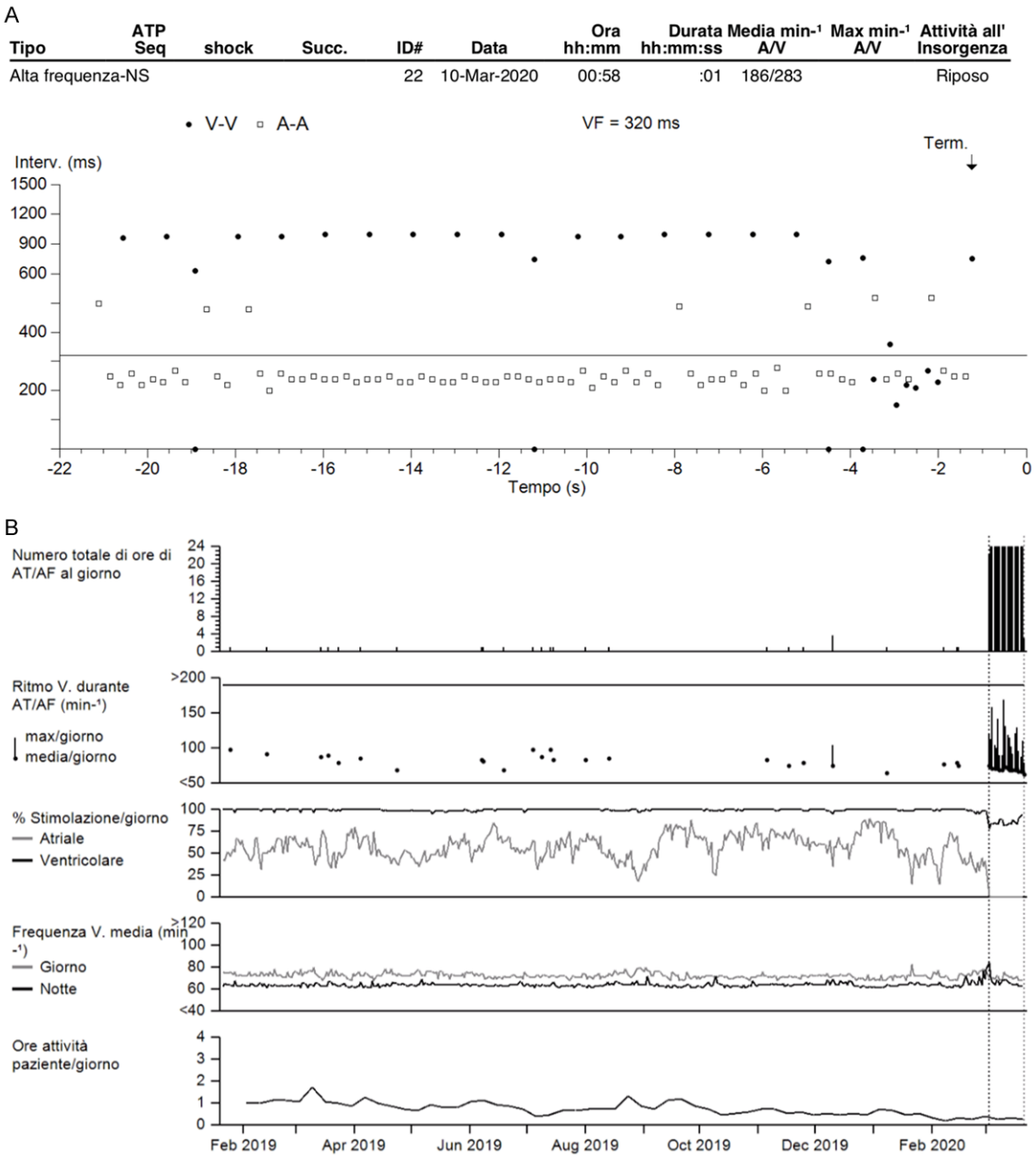

Figure 3. An application of remote monitoring: the management of electrical parameters. This is the transmission of an 84-year-old patient suffering from hypertensive heart disease with dilated evolution, CRT-D carrier. A right ventricular lead integrity alert was reported, confirmed by the evidence of rapid non-sustained ventricular tachyarrhyhmia (High Rate-NS) episodes, the frequency of short ventricular intervals counted on the Sensing Integrity Counter and right ventricular lead impedance trend (A). Moreover, atrial tachyarrhythmias events ≥ 6 hours for 19 days, ventricular stimulation less than 90% and patient activity less than 1 hour/day for 2 week were reported (B). A clear malfunction of the right ventricular lead was confirmed at the outpatient control. The risk-benefit ratio of the repositioning was carefully considered and finally excluded. The patient was discharged after 48 hours after performing a downgrading of the device to CRT-P.

electrocatheter may generate the serious risk of an inappropriate shock.

Remote control of these parameters should be scheduled every three months, with the possibility of receiving daily alerts; in case of relevant events detected by the system, an urgent cardiac examination has been guaranteed (**Figure 3**).

The systematic annual evaluation in patients with low risk profile, generally with pacemakers,

could be replaced by a path based exclusively on RM, without the need for an annual office control. In this regard, it may be useful to identify a multi-parameter risk score suitable for the purpose (for example involving left ventricular ejection fraction, documented significant arrhythmias...).

The use of remote monitoring in Covid-19 dedicated departments

In the course of the pandemic we have often had to check CIEDs of patients admitted to Covid-19 dedicated departments. Thanks to RM, we were able to control devices even in Covid-19 + patients hospitalized in other departments, thus avoiding physical contact with the patient. It is therefore essential at this stage that patients have the transmitter at their disposal as if they were in their own home.

Emergency management

RM's service is not available 24 hours a day, 7 days a week; our technicians are available from Monday to Friday from 8 am to 4 pm. At the time of recruitment, the patient receives detailed information on the service, the protection of personal data and the rules of conduct to be followed in different situations: in particular, it is noted that the system is not dedicated to the management of emergencies, for which it is necessary to follow the traditional routes (in this pandemic context, we suggested to the patient it would be preferable to contact 118).

The main reason lies in the latency between the event stored by the device and the possibility of access to the data by the centre: most of the events are recorded and transmitted the night after the event itself. Therefore, the real purpose of monitoring is the early (not immediate) recognition of events, in order to optimize therapy and implement interventions useful to prevent disease progression.

Open issues

Despite the undeniable advantages of TM, its use is still infrequent and not systematically structured in daily clinical practice.

During the pandemic, recommendations were made to replace routine cardiological visits with TM consultations in patients with stable cardiovascular disease in order to avoid possible hospital-acquired infections. In this regard, many departments of Cardiology have found themselves in difficulty since these programs are not sufficiently widespread yet.

There are several reasons on the failure to implement:

• TM and telemonitoring services are not uniformly reimbursed throughout the Italian territory (for example, as regards RM, an adequate reimbursement is foreseen only in the Veneto region and in the autonomous province of Trento);

• the absence of a standardized organizational model (there is no staff or structures exclusively or specifically dedicated to this activity, often carried out in the free time by other institutional activities and generally with the involvement of the personnel working in the electrostimulation and electrophysiology room);

• an insufficient integration with territorial medicine (cooperation between specialists and GPs should be absolutely implemented both in terms of sharing medical information and collaboration).

The application of TM to the multidisciplinary approach in the HF patient and CIEDs carrier, certainly represents a conquest, but it has also created new problems of health liability. Specifically, it is part of the aforementioned responsibility the correct management of the limitations due to the physical distance in order to guarantee the safety and efficacy of medical and care procedures, as well as compliance with the rules on data processing.

Furthermore, in terms of compatibility with the obligation of personal benefit of the medical service pursuant to art. 2232 of the Italian Civil Code, it will be assessed on a case-by-case basis, depending on the nature of the medical service, i.e. considering whether the physician's physical intervention is required or not, and taking into account that there remains a "grey area" of services which, in theory, would require the presence of the doctor, but which can also be substituted by his only virtual participation.

Another important test bench for TM is informed consent, which must have the same basic

requirements as for normal medical services, but also extended to the correlated additional risks (i.e. the remote intervention could be interrupted due to sudden blackouts...).

In conclusion, TM requires:

• adequate training and updating in the use of systems for all personnel involved;

• adequate organization through protocols and guidelines, with specific definition of the levels of responsibility;

• periodic verification of the quality of the diagnostic tools;

• verification of the quality of the transmitted and received data;

• verification of the "skills" of those who interpret the data received;

• evaluation of the effectiveness of the protection methods of personal and sensitive data.

Conclusion

The 2020 coronavirus pandemic represents one of the most difficult challenges of contemporary medicine. In the light of the current state of knowledge, it is not known how much time can still elapse before having an effective cure or a vaccine; in the meantime, one of the fundamental measures to reduce the infections is certainly to reduce hospital admissions for unnecessary outpatient visits and minimize hospitalizations to those that are really necessary. On the other hand, patients with chronic cardiovascular diseases need to be heartened by the fact that even in times of pandemic, they will have access to different diagnostic-therapeutic paths based on the clinical urgency and the need for medical contact on-site.

The evolution of technology has led to the development and refinement of TM and RM and even more in pandemic times these methods are to be considered a cornerstone. But if the patient no longer sees directly the doctor, would he/she develop a feeling of being treated less thoroughly or even "neglected"? Objectively, this is the problem of the introduction of TM in Cardiology. It's of vital importance that contact with the patient is maintained and even enhanced through the implementation of technologies (i.e. the use of applications for data transmission, the use of specific apps for photos or video call). It is also fundamental that patients enrolled in TM programs receive adequate information about their disease and specific education on self-monitoring.

Better in a hushed tone, as saying it out loud could be somewhat painful: how would things have gone in our country if TM had already been a fully well-structured reality, instead of being applied in a fragmented and inconsistent way among all the regions? How many doctors have paid with their lives for the failure to apply TM?

This epidemic is still ongoing and we do not know what the future evolution will be, nor if we will have to face others in the future. Therefore, our skills in the field of TM must be absolutely expanded and consolidated.

Acknowledgements

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Disclosure of conflict of interest

None.

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