Clinical practice recommendations and position paper

Intrahospital organizational model of remote monitoring data sharing, for a global management of patients with cardiac implantable electronic devices: a document of the Italian Association of Arrhythmology and Cardiac Pacing

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In the last years, the increasing number of patients with cardiac implantable electronic device (CIED) has required different approaches in terms of device's control and surveillance. It is increasingly difficult to keep the traditional in-office protocol device's control: we must think of a different organization dedicated to the activity of remote control and monitoring (RC/RM) of devices and patients.
A CIED team structured with nurses, technicians and physicians should be organized inside the hospital, with the aim of CIED patients' managing and of creating a network between the various departments.
Small hospitals may not be able to manage independently the CIEDs RC/RM and it is possible to hypothesize the creation of a collaborative network between neighbouring structures.
This activity must combine the use of technology with the ability to take care of patients and to maintain adequate and meaningful relationships.

J Cardiovasc Med 2019, **20**:000–000

Keywords: cardiac implantable electronic device, cardiac resynchronization therapy, implantable cardioverter defibrillator, pacemaker, remote monitoring

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Received 21 June 2019 **Revised** 30 September 2019
Accepted 28 October 2019

Introduction

The implantation of cardiac implantable electronic devices (CIEDs), implantable cardioverter defibrillators (ICDs), pacemaker, cardiac resynchronization therapy ICD and pace maker (CRT-D and CRT-P), implantable cardiac monitors (ICMs), has grown rapidly in recent years.[1] In Italy, several hundred thousands of patients require periodic checking of devices' correct functionality and monitoring of clinical diagnostics.[2] The latest guidelines pose as standard management of all implanted patients, the devices' remote control and remote monitoring (RC/RM).[1]

The introduction of remote device control technologies in clinical practice is still a challenge and requires really significant changes in the approach with the patient and in the organizational model of the device control ambulatory, of the cardiology department and globally throughout the hospital.

The first change is cultural and must be addressed by the patients: the traditional hospital CIED check is replaced by the periodic remote control of the device's electrical parameters and by the daily or frequent clinical diagnostics' monitoring. There is no more face-to-face contact with the physician, but possibly the phone contact and the hospital visit only if necessary.

Even the physician and coworkers must deal with this cultural change: the use of CIEDs remote control and remote monitoring can totally replace the periodic in-office visit (especially in case of low-risk profile patients with single and dual chamber pace maker). It becomes important to create different relational modalities with the patient and a new management of the whole process. It is essential to build a new, so-called, 'Digital Humanism' adapted to cardiology, making alive the new space of human contact that is created at the crossroads between the 'traditional' medicine and cardiology and technology,

DOI:10.2459/JCM.0000000000000912

understood as 'digital pervasiveness', which represents the picture of our time.[3]

How is the 'patient's taking in charge' from a clinical point of view in this context of 'technological management' of the patient himself?

The HRS guidelines of both 2008 and 2015 confirm that the possibility of pace maker (every 3–12 months) and ICD (every 3–6 months) remote interrogation is associated with the 'recommendation of an annual clinical evaluation of the device carrier patient': this is a crucial point.

The guidelines recommend a yearly general clinical/cardiological evaluation but not an annual cardiological visit at the device clinic.

In this perspective, it is important to think and to build a network dedicated to these patients, involving the family doctors and the hospital general physicians (especially the geriatricians and the general medicine physicians) as well as clinical cardiologists to share with them the annual clinical evaluation of CIED patients, guaranteeing a specialized electrophysiological evaluation to those who need it, especially in order to verify the diagnostics present in the devices and the tailored device programming.[1]

Different hospital realities, different organizational proposals

It becomes mandatory to standardize the organizational models used nowadays, which presents an extreme variability in the different hospitals.

In some of them, the physician directly performs the CIED control; in other cases, specialized nurses or technicians carry out the screening control with the physician's supervision. The CIEDs RC/RM management has even more variables: in some cases, the operating room nurses, usually between procedures or during their spare time, free from other activities, carry out it; in other cases, the physician himself does the job, alone or with the assistance of in training physicians, if present, or of external technicians.

It must be well defined the collaboration with the staff of the CIED companies: they provide cooperation and technical support in the CIED patient's management without direct involvement in daily clinical activity and through the use of technology, for example, by remote consulting, whenever applicable.

Finally, and in this direction, it is no longer possible to 'unhook' the RC/RM of implanted devices from the in-office control: they are two sides of the same coin and must be managed by the same working group.

We need to think again of an organizational model dedicated specifically to the management of the CIEDs patients: in this model, it is necessary to create an integrated working group, a CIED 'team'.[1,2]

This team should consist of:

(1) At least three allied professionals (nurses and/or technicians) expert and constantly updated on the devices' technology, dedicated to the service of the control/monitoring of CIED patients, both in-office and remotely. It is important that these professionals follow a course of training and if possible, take a certification of competence (for example, AIAC or EHRA or IBHRE certification). Their duties include: independent control of the devices of patients hospitalized or present in the clinic, management of the relationship with the patient, the relatives and/or the caregivers and to ensure the first filter of the possible alerts highlighted by RC/RM. In assessing the number of nonmedical operators required for these tasks, it is important to consider the total amount of the CIED patients managed by the service: the number of patients remotely followed, to be assigned to each nurse or technician, can be quantified in 700–1000 if only involved in device clinic. AQ5
(2) The responsible physician. He must be available for daily alerts' verification and for programmed transmissions check. Among the physician's peculiar tasks, it is very important building and maintaining over time, a relational network with a series of near and far entities. In the intrahospital context, the creation of this network provides for the organization of information and training meetings with the medical and nonmedical staff of the departments and services to which the CIED patients are referred. On the other hand, outside the hospital, the network can meet nearby hospitals, territorial realities, such as groups of general practitioners, cardiologists operating out of hospital, operators of retirement homes for the elderly.
(3) Nurses and physicians of the Heart Failure Team ambulatory, with which share clinical diagnostics derived from remote monitoring of CIEDs heart failure patients, in order to optimize their diagnostic and therapeutic pathways.

This organization articulated in the collaboration of different professional roles (nurses, technicians, physicians), represents the best way to manage the CIED patients. It should be considered that the high complexity of devices and the continued upgrading of CIED algorithms render extremely difficult the management of the CIED recipients from spoke cardiologists and other medical figures. Sometimes, it can be really difficult to achieve this kind of organization in all hospitals, especially in small structures and in times of staff and economic resources reduction.

One possibility may be the collaboration between nearby structures (hub and spoke model): it is possible to hypothesize a collaborative network between

neighbouring structures in which the hub center first receives and processes all the transmissions. In case of meaningful alert, the hub center send the data to the spoke center for patient recall and clinical management. In this way, the patient clinical management would still be carried out and maintained in the referent hospital, without moving the patient.

An organizational model like this could guarantee a qualified supervision to a peripheral center that begins the activity of devices' and patients' RC/RM, without experience enough, providing a temporary support pending eventual autonomy, or managing a constant and chronic service, in a real network organizational model. In the 'Hub and Spoke' acute myocardial infarction management, the patient is physically moved from a peripheral hospital to a hemodynamic center with H24 activity, in the network model of CIED patient remotely managed, in case of clinical alert the patient is not moved, but the information concerning the patient is transferred: the patient himself remains physically at home and, in case of need, he is called to the referent hospital, not necessarily the one in which the monitoring activity is carried out.

To this regard, the real challenge is to create a network inside the hospital, between nearby hospitals and between hospital and territory for the best patient-shared management.

As clearly established in the international guidelines, the CIED team activity does not present H24 characteristics and is not aimed at managing emergency situations: it takes usually place in the morning and early afternoon hours, from Monday to Friday, during the weekday daytime.

It is not carried out during the night work schedule, on preholidays and holidays: in fact, any alert is assessed and addressed with a latency degree. This depends on the fact that there is in any case a latency between the event stored by the device and the availability of the data by the control center: most events are detected and transmitted the night after the event itself and the patient at the time of the event may be far away from the monitoring device, the device itself may be inactive or the telephone network and access to the website could be unavailable. The ultimate and real monitoring purpose is the early, but not immediate, events' recognition (especially if asymptomatic) that allows the therapy correction and the implementation of interventional initiatives useful to prevent disease progression. The emergency follows other channels and the patient must be adequately informed about these aspects and how to behave in case of emergency. Latency degree for reaction to alert has to be reported in the patient-informed consent document.

It is essential by the CIED team, to keep track of the transmission that highlighted the events, the reception of the alerts, their communication to the referent physician and the notification of the reaction to the alert itself.

The proposed organizational model and network flow chart is shown in Fig. 1.

How to manage a better intrahospital coordination for the activity related to the cardiac implantable electronic device patients' diagnostic–therapeutic pathways

The CIED patient management improvement is founded much more than in the past, on the clinical knowledge of the patient himself: nowadays, in fact, in an integrated service dedicated to the in-office CIED control/monitoring and to the RC/RM, the possibility of receiving clinical diagnostic data, entails the necessity and the responsibility to be able to manage them adequately. In this direction, it becomes essential to have a lot of clinical information about each patient implanted.

It is the clinical knowledge of the patient even without the necessity of the systematic in-office visit, which characterizes the patient management improvement.[3]

The main clinical information to be included in our 'database' for each patient includes:

(1) essential data of the patient's clinical history;
(2) data identifying the cardio-embolic 'score' CHA2DS2-VASC and hemorrhagic scores, as the HASBLED;
(3) echocardiographic basic data set (left ventricular ejection fraction, volume/atrial dimensions, relevant valvulopathies, pulmonary hypertension);
(4) medical therapy;
(5) any previous ablative, cardiac or interventional procedures (revascularization, previous interventions);
(6) presence of kidney failure (creatinine, glomerular filtration rate – GFR), liver failure (AST, ALT, GGT), anemia (hemochrome), pulmonary disorders; AQ6
(7) any previous hospitalizations especially for congestive heart failure.

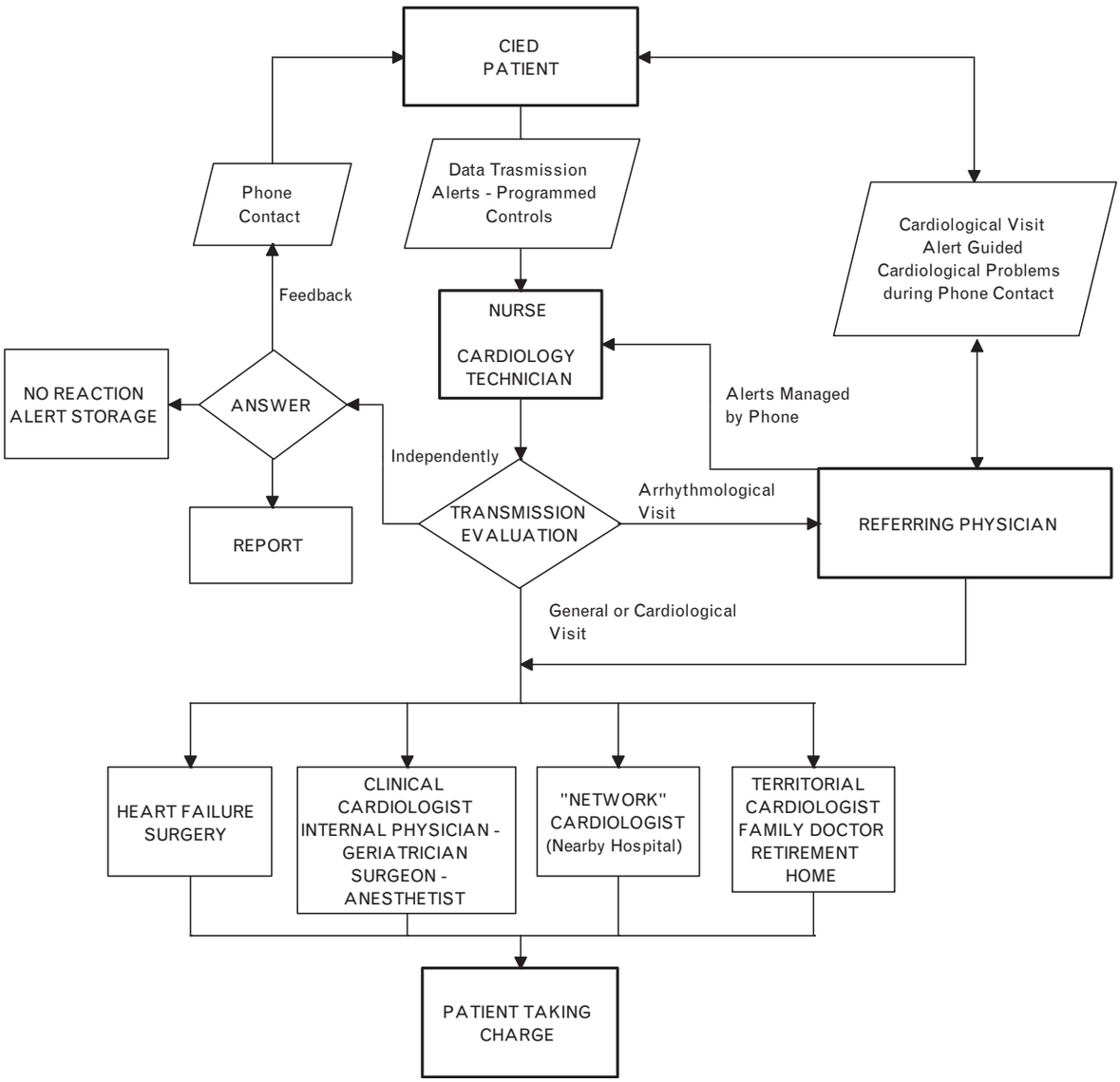
This data must supplement the patient's personal data, the phone number of the patient/relatives/care-giver, the name of the family doctor and, possibly, its address and its e-mail.

What clinical information can we obtain from implantable devices: atrial fibrillation

Atrial fibrillation is the most widespread cardiac arrhythmia. In 2010, 8.8 million of adult subjects over the age of AQ7
55 years, in Europe, were suffering from atrial fibrillation. It is estimated that this number will double by 2060 (17.9 million), especially for the ageing population.[4]

Even in CIED patients, the detection of atrial tachyarrhythmia is the most frequently encountered clinical event in the remote monitoring activity.[5]

Fig. 1



Organizational model and 'network' flow chart.

Remote monitoring of implantable devices provides valuable information regarding the diagnosis of atrial fibrillation (diagnosis of certainty in patients implanted with dual chamber device, presumption with the need for confirmation by ECG or Holter Monitoring in case of single chamber devices), with the possibility of establishing an adequate cardioembolic prophylaxis, wherever indicated, to carry out an adequate monitoring after therapeutic updates or related to the follow-up of ablative procedures.

In CIED patients, remote monitoring often becomes critical, effectively replacing other traditional diagnostic, such as Holter ECG, especially in absence of symptoms, frequent situation in patients with pace maker.

The presence of cardioembolic risk factors associated with the diagnosis of atrial fibrillation entails an increase in thromboembolic risk and an indication for adequate anticoagulant drug prophylaxis.

From the literature data, the burden of atrial fibrillation considered at cardioembolic risk is not univocally standardized: it goes from a few minutes to several hours in the various clinical studies and in the registers that have dealt with this objective.[6,7]

The nursing or technical staff in charge of remote monitoring and in office control of implanted devices, once found or simply suspected a new onset atrial fibrillation, must submit the data to the reference physician. These patients should be called for an in-office cardiological evaluation to address the problem, to evaluate the indication to oral anticoagulant therapy, to define a rhythm or rate control strategy, to indicate invasive procedures whenever applicable.

The prescriptions indicated to the patient during the visit, in the project to keep alive the CIED patient's management network, should be shared with the clinical cardiologist who takes care of the patient and with his general practitioner.

The atrial fibrillation management in CIED patients through remote monitoring flow chart is depicted in Fig. 2.

Cardiac implantable electronic device patient and heart failure

Heart failure is a clinical picture progressively increasing with age (5–10% of the population over 70 years) and is the most frequent cause of hospitalization over 65 years of age (it is responsible for approximately 2% of all hospitalizations): many CIED patients have cardiac failure (the majority implanted with CRT) or are at risk of developing acute or chronic heart failure.[8]

Most implantable devices are equipped with diagnostics dedicated to heart failure management and several clinical studies have tried to validate their capability to predict the acute phase of heart failure and to prevent hospitalizations: the results, if from one side confirmed the validity of these diagnostic parameters in predicting the risk of exacerbations of the heart failure framework, from the other side were disappointing as it concerns the actual possibility to prevent hospitalization and to change the outcome of these patients.[9]

The use of the diagnostics dedicated to the evaluation of the compensation status of CIED patients proved to be more effective when several parameters were evaluated (multiparametric evaluation).

Several recent studies have validated the possibility of a better management of heart failure patients, with the simultaneous analysis of several devices' diagnostics: a multiparametric analysis and the possibility to elaborate a 'multisensor' algorithm are potentially able to predict worsening heart failure hospitalizations.[10,11]

Another important consideration is the importance of daily monitoring in heart failure patients.[12]

The remote diagnostics monitoring in heart failure patients, should be performed with these four important landmarks:

(1) patients' clinical knowledge;
(2) daily alerts in clinical diagnostic monitoring;
(3) multiparametric evaluation of clinical diagnostics, even in the absence of 'score' validated for clinical use;
(4) presence of a multidisciplinary team dedicated to this activity, with close collaboration between CIED team, nurse and physicians of heart failure team, cardiology personnel, geriatrics and internal medicine personnel, territorial realities dedicated to heart failure patients' management.

This last remark is probably the critical point of the topic we are dealing with: in managing patients with previous or potential episodes of acute heart failure, it is crucial to build a real and close collaboration with all the realities dedicated to the management of heart failure patients.

The presence of adequately trained nursing staff, updated and exclusively dedicated to this activity, remains fundamental: this is the key professional that maintains the relationship with the patient, his family or the care-givers. It provides support and health education, guarantees a telephone reference in case of necessity and represents the necessary point of connection with the physician in charge of the clinic.

The heart failure management in CIED patients using remote control and monitoring flow chart is reported in Fig. 3.

Cardiac implantable electronic device patients and ventricular arrhythmias

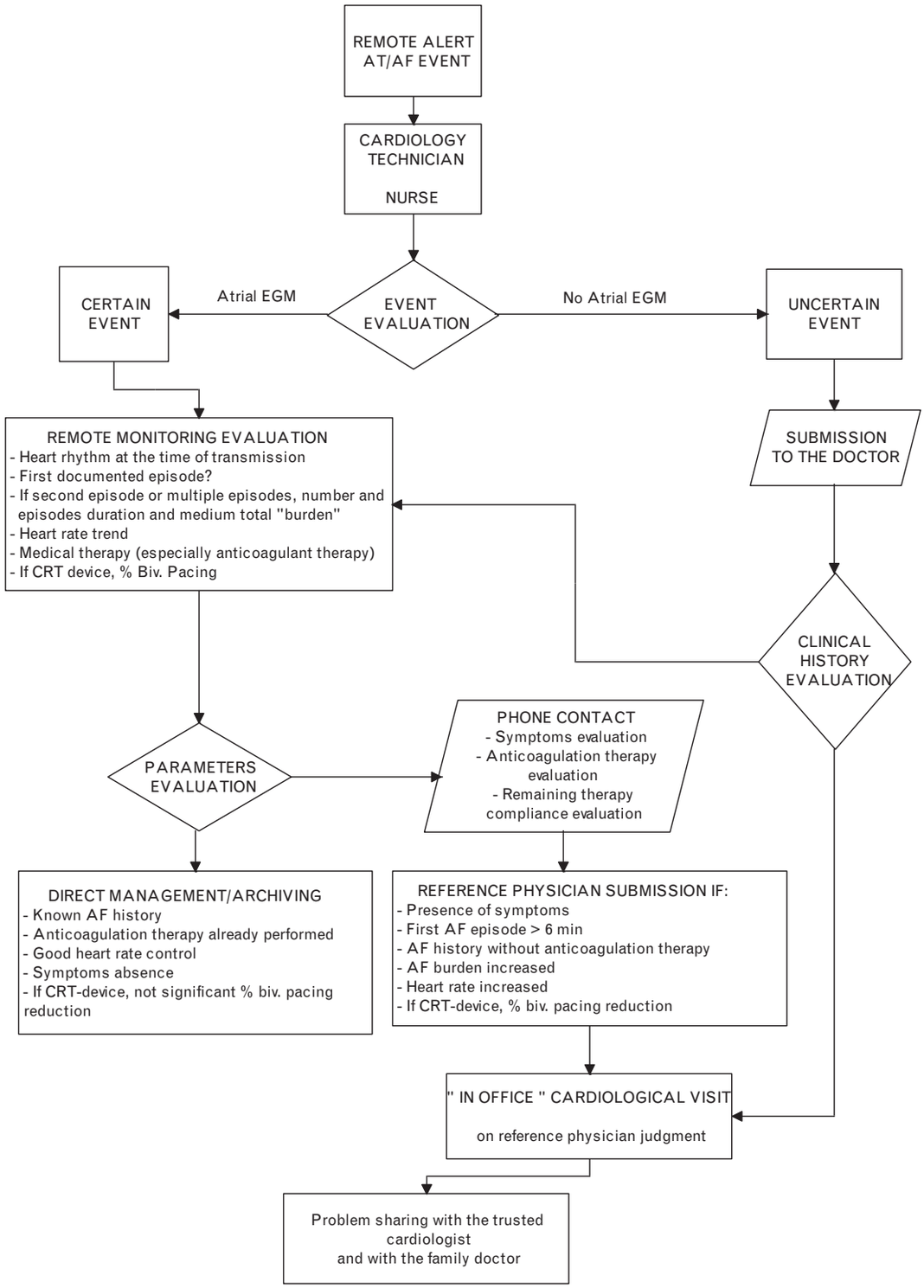
Among the data detectable through the remote control, ventricular arrhythmias occurrence represent a frequent observation, often in the absence of symptoms. It is essential, also in this area, the availability of patient data set, which may drive the reaction to the information obtained by remote monitoring.

In the group of patients with pace maker/CRT-P and normal or near-normal left ventricular ejection fraction, the evidence of increased burden of ventricular arrhythmias (VEB) should lead to an assessment of possible symptoms (phone contact) and a potential update of medical therapy.

If patients show mild or severe ventricular dysfunction (ejection fraction $<45\%$), they should be evaluated for an arrhythmic risk stratification, on a clinical basis (evaluation of implant indication, any related symptoms) and, if indicated, with specific test (exercise test, imaging, coronary angiography or electrophysiological study).[13]

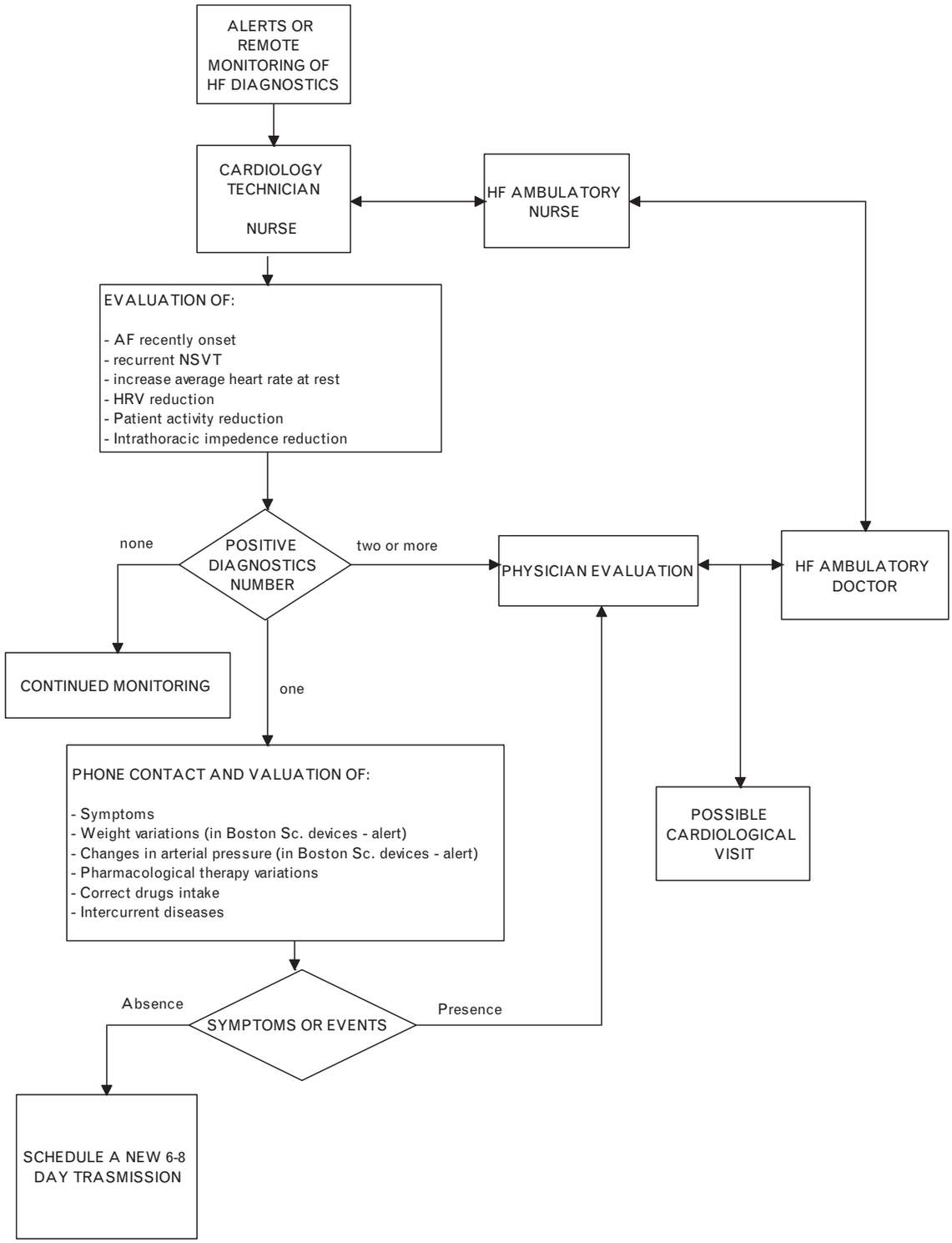
In case of evidence of nonsustained ventricular tachycardias (NSVT, duration <30 s), in patients asymptomatic and with normal systolic function (ejection fraction $>50\%$), the first option could be an optimization of medical therapy, and the maintenance of remote monitoring.

Fig. 2



Atrial fibrillation management in cardiac implantable electronic device patients through remote monitoring flow chart.

Fig. 3



Heart failure management in cardiac implantable electronic device patients using remote control and monitoring flow chart.

In the case of NSVT, but with the presence of left ventricular dysfunction (FE <40%) an EP study is indicated to test inducibility of sustained VT. In case of sustained ventricular tachycardias (SVT, duration >30 s), upgrading to ICD is directly indicated.

In the group of ICD/CRT-D patients, the approach should be different. In case of evidence of increased burden of ventricular arrhythmias (VEB), the first approach should be phone contact for clinical evaluation and update of medical therapy whenever indicated. Substrate ablation will be considered only in case of frequent not tolerated VEB or when they lead to deterioration of LVEF.

In the case of NSVT or well tolerated SVT, with isolated or infrequent episodes and correct and effective device intervention (ATP, shock), we could limit our intervention to the phone contact and to the evaluation of the hemodynamic tolerance of the arrhythmia and the device intervention: the patient will be called to the hospital only in case of the arrhythmia's poor hemodynamic tolerance or of significant emotional impact consequent to the intervention of the ICD, even for a single arrhythmia and a single device intervention. The clinical in-hospital evaluation and the discussion with the patient are in every case recommended at the delivery of the first shock in the patient's history.

In case of well tolerated SVT, but with frequent episodes, the patient will be called to the hospital for clinical evaluation haematochemical control (electrolytes), for a therapeutic update, and schedule of diagnostic tests and interventional procedures including SVT ablation.

In case of poorly tolerated SVT, the patient will be recommended to directly access to the emergency department whose physician will be preliminary alerted by the EP team and will have full access to remote monitoring data.

Probably the direct access to the emergency room is not justified by the single appropriate intervention of the defibrillator with shock, if the patient has well tolerated arrhythmia: the access to the emergency room is advisable for multiple ICD interventions ($\geq$2 shocks) although with good hemodynamic tolerance and is mandatory in case of poor hemodynamic tolerance of the arrhythmia.

In case of inappropriate shock, the patient must be called to the hospital to re-evaluate device programming and pharmacological therapy.

The CIED team will share information about ventricular arrhythmias with the patient's clinical reference cardiologist and general practitioner.

The ventricular arrhythmia management in CIED patients using remote control and monitoring flow chart is shown in Fig. 4.

Cardiac implantable electronic device patients and periodic remote control/ monitoring of electrical parameters

One of the most important activities of the CIED team is the periodic remote control of the device electrical parameters, their monitoring in case of alerts related to the integrity of the leads and the battery and circuit status. This activity is carried out by the nursing and technical staff, whereas the reference physician is involved only for troubleshooting or to confirm and validate the analysis performed by the allied professionals. In relation to verifying the electrical parameters and the integrity of the battery, the periodic devices' remote control, could fully replace the traditional outpatient check: in fact the latest ICD and PM generation are equipped with automatisms that make the electrical control in-office and remotely overlapping. The general schedule for periodic remote control of electrical parameters should be every 3 months with daily alerts if available.

The recommended annual clinical evaluation of patients with low cardiovascular risk (usually patients implanted with single or dual chamber PM), may be carried out by the family doctor, the geriatrician or internist to whom the patient is entrusted, or by the trusted cardiologist the patient relies on. To every patient will be guaranteed an urgent cardiological visit in case of necessity or in case of meaningful events detected by remote monitoring.

In patients with ICD and CRT (D-P), a periodic cardiological evaluation is advisable: this will be guided by remote monitoring and carried out according to the referral cardiologist and to heart failure team if available.

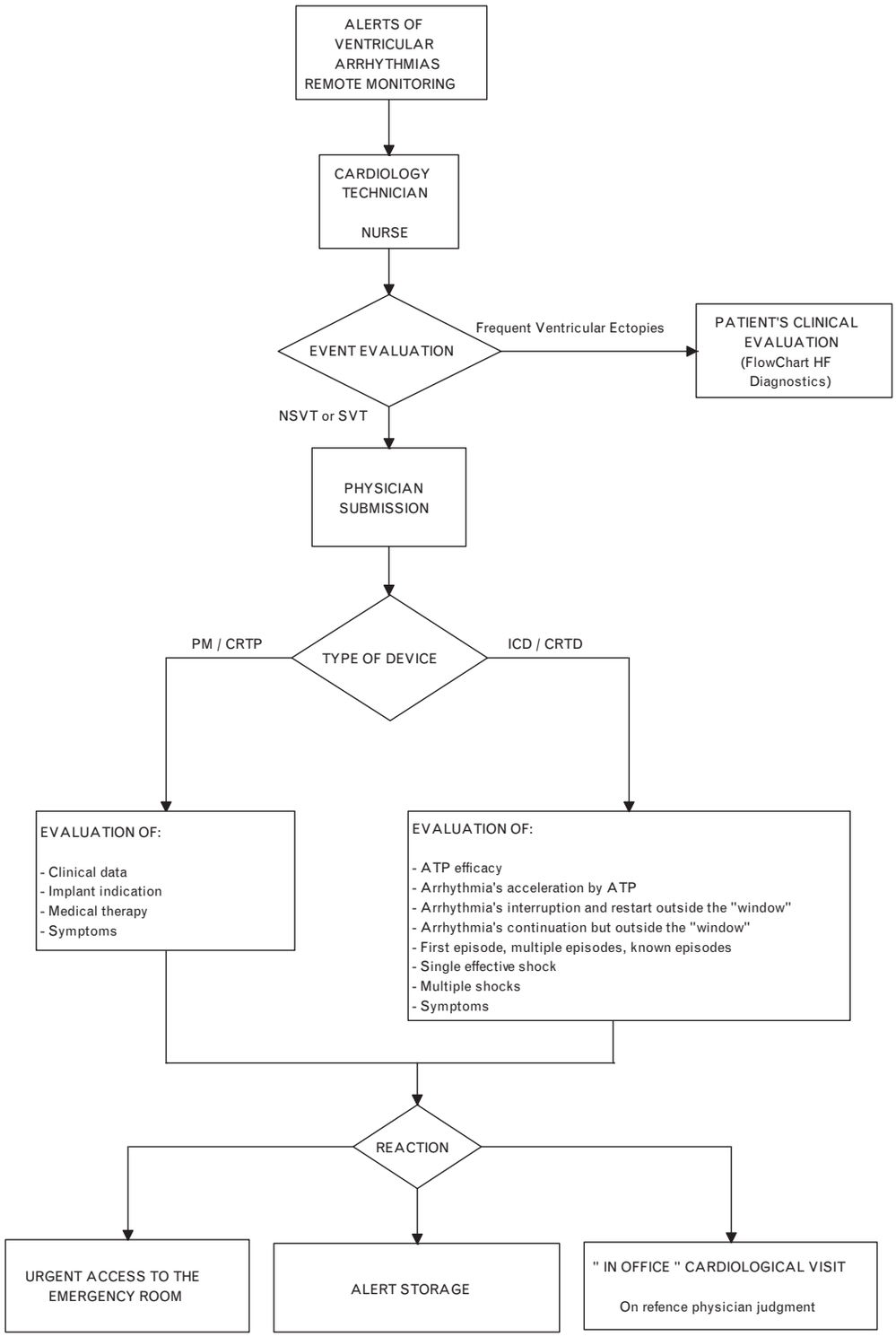
The service of cardiac implantable electronic device control ('in office' and 'remote') and intrahospital 'network': cardiology, geriatrics and internal departments

In the daily clinical practice, it is not uncommon that the colleagues working in the cardiology department do not know the possibility of remote management of CIED patients and the valuable diagnostic information obtainable from their interrogation: the CIED patients' management network must open data access and sharing to all hospital services.

The first step is that the CIED team starts information, training and educational processes with the staff of cardiology, coronary care unit and surgery (physicians and nurses). The first network that the device control service must weave is with cardiologists who clinically manage CIED patients.

Broadening our attention to other departments in the hospital where CIEDs patients are frequently hospitalized, for clinical problems, such as atrial fibrillation and heart failure, the network must be widened to geriatrics and internal medicine departments.

Fig. 4



Ventricular arrhythmias management in cardiac implantable electronic device patients using remote control and monitoring flow chart.

Probably, the most correct way to manage CIED patients hospitalized is that monitoring is maintained also during hospitalization: the patient home device must be brought to the hospital and the monitoring activity must be continued.

It is crucial that the organization of intrahospital training meetings with internal physicians, geriatricians, first aid staff, and neurologists, in order to make them aware of the potentialities of implanted devices and to share organizational models for management of clinical data obtained from the devices.

The management of cardiac implantable electronic device patients hospitalized in surgical departments

The CIED team must cope with another clinical reality: in fact, with the increasing of the patients subjected to device implant, it is also increasing the number of CIED patients, who need to undergo noncardiac surgery.

These patients should be handled with care and appropriate protocols, as any preintraoperative or postoperative problems could increase the risk of morbidity and mortality or adversely affect the operating time, causing delays and disservices.

The network to be created within the hospital widens to the surgical departments.

The CIEDs implanted and the operating room environment have both become very sophisticated, increasing the potential risk of interactions. The lack of standardization of the various CIEDs, their sophisticated algorithms, the variation of the clinical conditions of the patients according to the CIED programming and the instruments used in the operating room can increase the difficulty of patients' management especially if the physicians are not experts in CIEDs.

The CIEDs Team will be directly involved in the management of these patients.

In case of elective surgery, the remote device's control could simplify the preoperative investigation and make this process safer: if the patient is plugged into the controlled and/or remotely monitored group and its clinical features are already known (type of device, programming mode, ...), a remote interrogation before a programmed surgery, may provide updated diagnostic data, information on the device's programming and advices useful in improving patient management without the need for the patient's physical presence in the hospital.

Moreover, in case of in-office device reprogramming necessity, this activity can be carried out in the immediate preoperative.

In the intraoperative phase, often in implanted patients, it is recommended to apply a magnet to the device itself, whether it is a pace maker or an ICD. The magnet is applied over the area where the device is implanted, alters its functioning, allows this type of response. Nowadays, the recommendation to inhibit in a systematic and simplistic way the interferences of the electrosurgery use in both pace maker and ICD patients, by applying a magnet to the device, is no longer feasible with safety and acceptability, especially in elective interventions: on this subject, in the conclusions of the 'consensus statement' of ASA and HRS, it is not advisable to use the magnet in an undifferentiated and standardized manner.[13,14]

For elective interventions, it is, therefore, advisable that the nurse or the technician of the 'CIEDs team' takes care directly of the preoperative control (potentially remotely controllable in an integral way), of the intraoperative programming (to be realized is based on the characteristics of the patient and the device) and any postoperative verification, the latter to be performed remotely, unless a reprogramming is required.

In case of emergency surgery, it is essential to have shared with the medical staff (surgeon, orthopaedic, anesthesiologist) and nurses of operating theatres a CIED patient management protocol (in this case, usually training in the use of the magnet).[13–16].

The management of external cardiac implantable electronic device patients for the intrahospital execution of examination or therapies with possible interference

An increasing number of CIED patients is indicated for magnetic resonance (MR) imaging: nowadays most CIEDs are MR conditional, but the devices must be properly programmed for the exam. The CIED team must be involved in the management of these patients. The first step is to confirm that the CIED system is MR conditional (kind of CIED, system homogeneity, absence of abandoned leads, body site to be studied, and technological characteristics of the radiological equipment): this first step should be carried out by the nurse or technician of CIED team. The second step consists in the scan scheduling: it must be scheduled on specific days agreed between the radiology staff and the CIED team. The CIED team is also involved in the training of radiology personnel who will have to technically perform the exam. A new recent technology available for both pace maker and ICD is able to recognize automatically the MRI-scan field and switch to an MR conditional programming. This function could be activated up to 14 days before the scan avoiding the need of proper device programming just before the MR scan. This may facilitate the organization also because the MR mode switch off automatically few seconds after the end of the MR field eliminating the need for postscan device re-programming. Another growing need for CIED patients with possible involvement of the CIED team is the need for radiotherapy for cancer problems. The

follow-up of this kind of patients can be performed via remote monitoring, asking the patient to send a transmission after the radiotherapy session.

Conclusion

CIED patients are nowadays, a very important proportion of patients managed in cardiology and deserve adequate attention and dedicated organizational models different from those traditionally structured in our departments. To think of a CIED team dedicated to this activity, constitutes a necessity in daily clinical practice. Equally urgent is to start thinking about an intrahospital network of data sharing, with attention to clinical diagnostics, among different clinical frameworks for a global CIED patient management.

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Manuscript No. JCM-D-19-00338

Journal of Cardiovascular Medicine (JCM)
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