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Implantable cardiac monitor in heart failure: just a toy or a useful tool?

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The use of implantable cardiac monitors (ICMs) has gradually entered clinical practice in various fields. In addition to the consolidated indications in the study of syncope, cryptogenic stroke and in the management of patients with arrhythmias (suspected or defined), today a possible role for these devices in patients with heart failure (HF) is emerging. The rationale for the use of these devices in HF can be identified in three key areas: (i) identification of silent atrial fibrillation and reduction of the risk of stroke, (ii) stratification of the risk of brady-tachy arrhythmias and consequent reduction of the risk of sudden death, and (iii) identification of patients at risk of imminent exacerbation of HF and their early management with reduction of hospitalizations and episodes of clinical deterioration. For each of these areas, there are conflicting data regarding the real usefulness of ICMs; however, it is reasonable to hypothesize that the use of these devices, under certain conditions, may be useful in patients with HF. The adequate selection of patients to be candidates for this strategy is important. The choice of tools and the availability of an organization that allows the possibility of managing these patients remotely also play an essential role. In any case, case-control studies are needed to establish whether this tool can be truly useful in HF.

Introduction

Over the years, implantable cardiac monitors (ICMs) have found increasing use in clinical practice. This device, also known as implantable loop recorder (ILR), is most commonly used for the evaluation of recurrent palpitations, syncope of unknown aetiology, or when other ambulatory monitoring devices of shorter duration are unrevealing.

Implantable cardiac monitors have been progressively miniaturized and improved; remote monitoring has reduced the time needed to make a diagnosis, improved patient compliance, and changed the follow-up strategy with a potential reduction in healthcare costs. In fact, following the monitoring period, there are possible correlations of patient symptoms and electrocardiogram findings, but it is also possible to find indirect signs of heart failure (HF). Because of this valuable feature, in this last field, there has been growing interest in the use of these devices: telemonitoring was introduced with the hope of reducing decompensation and increasing the capacity of HF clinic staff to manage the growing caseload.

Indeed, in patients with HF, such devices could play a role: (i) in the diagnosis of subclinical forms of atrial fibrillation (AF) and subsequent reduction of thromboembolic risk, (ii) in the early diagnosis of brady or tachyarrhythmias and subsequent reduction of the risk of sudden cardiac death, and (iii) in the prevention of HF exacerbations.

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However, the use of such devices must always be carefully evaluated.

We will try below to assess, in these three different areas, the lights and shadows on the usefulness of ICMs in patients with HF.

Atrial fibrillation and stroke

When investigating the incidence of stroke and myocardial infarction in patients with HF, Fonarow *et al*. showed that HF patients with preserved ejection fraction had a higher incidence of AF than patients with reduced ejection fraction, which may also be attributable to the higher mean age and higher proportion of female patients. Even in the absence of a direct proportionality between the incidence of AF and stroke in this group of patients, it is clear that the early detection of AF during the follow-up of patients with HF may be an effective strategy for the prevention of cardioembolic stroke.[1]

As early as in 2006, in an analysis derived from the CHARM study, which enrolled patients with different ejection fractions, the incidence of AF over a follow-up of 3 years was evaluated. Atrial fibrillation was a major predictor of adverse outcome in terms of morbidity, mortality, and adverse cardiovascular events. It is important to emphasize that the relative risk of major adverse outcome, such as cerebrovascular events and mortality due to AF, was greater in patients with preserved ejection fraction than in those with reduced ejection fraction (hazard ratio 1.72 vs. 1.29).[2] Highlighting the importance of rhythm monitoring not only detects events that could be significant in terms of prognosis but also improves the therapeutic strategy of patients with arrhythmic events.

More recently in the loop study, which enrolled subjects without AF, aged 70–90 years, with at least one additional risk factor for stroke (hypertension, diabetes, prior stroke, or HF) to test whether screening for AF and the use of anticoagulants could prevent stroke in high-risk subjects, unexciting results were observed.

In fact, screening by ILR resulted in a three-fold increase in the detection of AF and initiation of anticoagulation, but no significant reduction in the risk of stroke or systemic arterial embolism was observed.

However, patients with HF were under-represented in the study (4.5% of patients enrolled), and it is precisely in this group that a clinical benefit of monitoring by ICM seems to be emerging, even in the absence of statistical evidence.[3]

In the same direction goes a sub-analysis of the loop study by Xing *et al.*,[4] which shows that ILR screening for AF is associated with a significant reduction in stroke risk among subjects with higher N-terminal pro-B-type natriuretic peptide levels, but not among those with lower levels.

Another sub-analysis of the loop study operated by the same research group explored the following endpoints: (i) HF event or cardiovascular death, (ii) HF event, (iii) event with HF with reduced ejection fraction (HFrEF), and (iv) HFrEF event or cardiovascular death.

A significant risk reduction in total events was observed in the ILR group for the composite of HFrEF event or cardiovascular death and for HFrEF event [hazard ratio, 0.74 (95% confidence interval (CI), 0.56–0.98) and 0.65 (95% CI, 0.44–0.97), respectively]. These results suggest that ILR screening for AF tended to be associated with a lower rate of total HF events and cardiovascular death, particularly those related to HfrEF.[5]

Ventricular arrhythmias: bradyarrhythmias

Some authors have proposed utilization of the ILR in patients with HF, mainly with mid-range or preserved ejection fraction, for arrhythmic risk stratification with the intention of prognostic evaluation.

In 2019, Adabag *et al*.[6] in an attempt to identify a risk score that included six variables (age, sex, myocardial infarction, diabetes mellitus, bundle branch block, and N-terminal pro-brain natriuretic peptide) to better define the risk of sudden cardiac death at 5 years demonstrated that sudden cardiac death was the most common single cause of death in patients with HF with preserved ejection fraction (HFpEF). In the same year, Gutierrez *et al*. showed, by applying a 14-day ambulatory monitoring device in 40 patients with HFpEF, that there were 32.5% of patients with episodes of non-sustained ventricular tachycardia (NSVT), 5.0% with paroxysmal AF, and 80.0% with episodes of supraventricular tachycardia during the monitored period.[7] All patients had premature ventricular complexes (PVCs) with 7.5% having a PVC burden that exceeded 5%. Furthermore, Ash *et al*. (on the assumption that ventricular tachycardias could explain a large proportion of SCD events in patients with HFpEF) evaluated the prevalence of NSVT in patients over a follow-up period of 3 years and demonstrated that 44.7% of patients had ventricular arrhythmias registered at device check. In patients with a presence of ventricular tachycardias during the follow-up, there was a trend towards increased mortality (18.4 vs. 8.5%) in respect of those without.[8] More recently, the VIP Study evaluated the incidence of NSVT in patients with preserved or a mid-range ejection fraction. In this study, 113 patients underwent a complete evaluation by imaging technique and 24-h Holter monitoring and were then investigated through continuous rhythm monitoring with an ILR. Patients had a scheduled visit every 6 months for ILR interrogation for a maximum period of 2 years. Despite the low incidence of ventricular tachycardia, the ILR proved to be a more reliable method compared with 24-h Holter monitoring in identifying patients with ventricular tachycardia (almost 10% higher). In contrast to what was expected, the ventricular arrhythmias were not associated with an increased risk of hospitalization or mortality. However, the detection rate of ventricular arrhythmias was meaningful and the implantation of ILR demonstrated an ability to uncover AF and bradyarrhythmias (that have an impact on HF patients' prognosis) with a low incidence of adverse events from the implantation procedure. In particular, among the 113 patients enrolled in the study, bradyarrhythmia requiring pacemaker (PMK) implantation was detected in five cases.[9]

Worsening heart failure

Heart failure is one of the most common chronic diseases in the general population. This syndrome is characterized

by frequent phases of exacerbation in a context of chronic, often labile, balance. To better define the prognosis and risk of worsening HF, various strategies have been hypothesized to follow the patient even outside the outpatient clinic and independent of frequent hospitalizations.

In order to improve haemodynamic monitoring, devices that can provide information on deterioration with possible fluid accumulation and increased filling pressures in patients with HF have also been created, such as the CardioMEMS device, which is implanted in the pulmonary artery.[10] By measuring changes in pulmonary artery pressure, this device is able to use this parameter as an early indicator of haemodynamic deterioration for early optimization and titration of HF therapy.

These devices have proven useful in improving the prognosis of patients with HF regardless of left ventricular ejection fraction (LVEF).[11]

The possibility of remote monitoring with devices such as implantable cardioverter defibrillator (ICD) and cardiac resynchronization therapy (CRT) has been evaluated to reduce hospitalizations. In addition to the monitoring of arrhythmias and possible therapeutic intervention, these devices also have the ability to use parameters such as an increase in mean heart rate, respiratory rate, and thoracic impedance (sensed by the electro-catheters) to predict a deterioration in a patient's clinical condition that could lead to hospitalization.

This kind of monitoring, therefore, gives the opportunity of early therapeutic intervention and consequently outpatient and/or home management without the need for hospital care, which equals cost savings and a positive impact on the patient's quality of life, in addition to reducing the chance of adverse events (e.g. infections) caused precisely by frequent hospitalization.[12]

Similar to ICDs and CRTs, ICMs are now available that can also predict the risk of worsening HF. These devices assess the presence of congestion by measuring subcutaneous impedance and combine these data along with those for patient activity, heart rate variability, mean nocturnal heart rate, and respiratory rate to provide a risk score for exacerbation of HF in the following day.[13]

Economic and legal considerations

The use of remote monitoring is certainly also an economic and legal issue.

If we consider the data published in the ARNO DATABASE Italian registry,[14] we can clearly see that the costs of the decompensated hospitalized patient (with a hospital stay that on average exceeds 10 days) equate to a total of 550 million euros spent by the Italian national health system annually. The per-patient annual expenditure is 11 800 euros, 85% of which is solely for hospitalization costs.

In a recent study, Ziegler *et al.*[15] demonstrated how, taking into account the improvement of the quality of life and the reduction of hospitalizations, the cost-benefit ratio of a treatment strategy that includes telemonitoring can be economically advantageous.

A further aspect to be defined is the reimbursement method for healthcare organizations that manage patient telemonitoring.

The management of patients with HF through telemonitoring also poses a series of legal problems ranging from authorization issues to those regarding the protection of patient confidentiality. The solution to these problems will require the production of a specific and updated regulatory framework.[16]

Conclusion

As we have observed, there is conflicting evidence about the usefulness of ICM in patients with HF.

We could reasonably assert that they may be useful in the complex management of these patients in specific conditions.

Heart failure patients who may benefit from the implementation of the loop recorder are clearly those in which there is no indication for an ICD or PMK.

Among these patients, according to what has been previously expressed, ICM use may provide a particular advantage in patients not taking anticoagulant therapy and have no contraindications to its use.

In addition, it is likely that patients with atrioventricular or intraventricular conduction delays may represent a category in which ICM-based management has a major advantage, as well as those in which beta-blocking therapy is indicated or those with evidence of myocardial scar.

A particular benefit is also provided to those not taking anticoagulant therapy, especially if they are symptomatic for episodes of palpitations.

Regarding the choice of device type, we believe that the possibility of remote monitoring is crucial in devices being used in decompensated patients. In addition to the detection of arrhythmic events, the ability to provide information on heart rate variability and congestion status is particularly useful tools in this area. Information from an ICM-based monitoring system will be useful if it is managed by the staff caring for the patient. Therefore, the 'place' where this type of indication could be of real benefit is in the HF clinic.

In the field of HF monitoring, ICM programming and alert management require a tailor-made approach to the individual patient. To prevent the worsening of chronic HF, we also believe it necessary to evaluate transmissions within 7 days in order to provide a sufficiently timely therapeutic response.

To clarify the real clinical utility of loop recorder-based telemonitoring in patients with HF, our group proposes a case-control study: 'Evaluation of a proactive clinical management and early diagnosis of arrhythmias in patients with heart failure and non-severely reduced left ventricular function through a telemonitoring system: a prospective randomized clinical trial—VASCO STUDY (NCT 05974306)'.

This will be a multi-centre, international, prospective, randomized, non-profit study. The study will enrol patients with HF and LVEF > 40% who report episodes of palpitations. The exclusion criteria are as follows: pregnancy, medical contraindications for ILR implantation, patients with PMK/ICD or with an indication for ICD/PMK implantation, cardiovascular events/myocardial revascularization in the previous 3 months, patients already on oral anticoagulant

treatment, patients who do not want to use the telemonitoring system, and presence of other recognized indications to ILR (unexplained syncope, cryptogenic stroke/transient ischemic attack, transient loss of consciousness, and recurrent falls). Going into more detail about the objectives, we want to evaluate the benefits of an ILR-based remote monitoring management compared with standard practice in patients with a high risk of cardiac arrhythmias, HF, and LVEF > 40% in detecting clinically significant events. We also wish to compare ICM-based management vs. conventional management in terms of the incidence rate of a composite endpoint of arrhythmic events, risk reduction of a composite cardiovascular endpoint, and quality of life. In addition, we want to evaluate the cost-effectiveness of ICM-based remote monitoring management vs. standard practice in this population. Ultimately, to determine whether we are dealing with an expensive toy or a useful tool, we need comparative studies that assess the impact of these devices in this specific population, and our group's proposal goes in this direction.

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Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

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