Role and Prospective of Remote Monitoring in Management of Patients with Cardiac Implantable Devices

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Abstract: Many studies have now shown that remote control of implantable devices (Home Monitoring, HM) is beneficial for the patient, making very strict and custom controls, allowing an earlier identification of potential problems and avoiding unnecessary visits. HM is also beneficial for the hospitals, which reduce progressively the resources used in routine checks, often not necessary, instead dedicating resources to the management of critical patients in the moment in which real clinical problems arise. According to the current guidelines Italian and European HM can replace the standard ambulatory monitoring, thereby reducing the amount of outpatient visits to be made in the individual patient (instead of testing every 6 months, it is possible to schedule one annual overall clinical evaluation of the patient, while intermediate checks are performed by remote transmissions. To date however, HM, although recommended by the Italian and European guidelines, do not yet have a specific reimbursement charge within the NHS and therefore HM cannot be carried out as an institutional activity within the hospital. Furthermore, many critical issues must yet be resolved before a full utilization of HM system can be used for the clinical management of patients, particularly in patients with heart failure at higher risk of cardiac death.

1 CURRENT STATUS OF REMOTE MONITORING OF IMPANTABLE DEVICES

According to current guidelines both International (HRS / EHRA Expert Consensus) (Wilkoff et al., 2008); (Dubner et al., 2012) and Italian (Consensus Conference AIAC) (Ricci et al., 2009) remote control (Home Monitoring, HM) can now integrate and sometimes replace the traditional ambulatory monitoring the patient with an ICD. The feasibility, safety and efficacy of remote control have now been repeatedly demonstrated in an increasing number of patients followed in the world with this method: to date more than 800,000 patients worldwide, and also in Italy more than 15,000 patients in 180 hospitals, for a total of more than 100,000 transmissions. Many studies have now shown that remote control of the holders of implantable devices, especially implantable cardioverter defibrillators (ICD) is beneficial both for the patient, allowing closer and personalized controls, with earlier identification of possible problems avoiding unnecessary visits, and for the Hospital, which progressively reduces the resources used in routine control, often not indispensable, devoting themselves instead to the management of patients in the moment in which they arise real clinical problems.

Several randomized trials have not only confirmed the equivalence of the remote control with respect to ambulatory control standard in terms of safety (Varma et al., 2010), but have even demonstrated the superiority of the management of the patient with a remote control with respect to the traditional control, resulting in a reduction of planned and unplanned visits, a reduction of access to the ER and the average duration of hospitalization for cardiovascular causes, an increased ability to identify clinically relevant events, and a reduction in the time between the occurrence of an adverse event and the subsequent clinical treatment (Crossley et al., 2009); (Crossley et al., 2011); (Spencker et al., 2009).

The remote control produces a more efficient management of health care resources, both hospital admissions and optimizing the use of time and health professionals, which reduces transportation

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costs and expenses for accompanying persons (Ricci et al., 2008). In general, the remote control makes it possible to reduce the load of outpatient controls to be carried out in the individual patient (instead of checks every 6-9 months, it is thus possible to perform an ambulatory monitoring every 12 months for a global clinical assessment of the patient, while intermediate checks are carried out remotely). Remote control also involves an optimization of timing: from an average of 25-30 min for traditional in-hospital control to an average 4-5 min in the remote control (Ricci et al., 2008); (Klersy et al., 2009).

It is important to distinguish models of remote device control (which is related to the problems of the device, such as breakage of leads or battery depletion), from actual remote surveillance, which instead is focused on clinical problems, such as ventricular arrhythmias, shocks delivered, episodes of atrial fibrillation, fluid accumulation or other.

Currently five of the leading manufacturers of ICD (Biotronic, Medtronic, St. Jude Medical, Boston Scientific and Sorin), have developed different systems for ICD HM. All systems are based on sending of the remote query of the ICD to a central server, which processes the reports and sends them back to the individual clinical centers, where data from the remote control are controlled and integrated with the patient's clinical data. The differences between the various systems are both on the mode of remote interrogation of the ICD (off-line for most of the systems, generally by non-portable systems that query the implantable device at night during sleep), and on the mode of trans-telephonic transmission from the remote modem to the central server (both via analogic lines and increasingly Mobile via GSM or GPRS).

To date, in Italy, as in many other European countries, projects for the control of HM ICDs, although recommended by the Guidelines Italian and European, not yet have a specific reimbursement charge within the NHS, therefore cannot be institutional activities carried out officially within the Hospitals.

2 EXPERIENCE OF HOME MONITORING OF ICDS AT MILAN NIGUARDA HOSPITAL

Since June 2011, we initiated a project called Project CareLink Niguarda (PCLN) for remote control of patients with implantable devices, especially implantable cardioverter defibrillators (ICD). The project uses the remote control system of Medtronic CareLink called, through which it is possible to transmit a series of electrical parameters and clinical results from devices (ICDs, pacemakers and recorders loop recorder "Reveal"), directly from the patient's home to a secure service to the Hospital. The CareLink system had been since 2009 under the project EVOLVO (research project of the Lombardy Region). (Landolina et al., 2012)

To date, the PCLN has enrolled over 350 patients (out of more than 1000 patients with ICDs followed by Electrophisiology Unit). The operational phase of the PCLN was preceded in the first half of 2011 by a phase of planning and preparation, in which we identified potential critical problems and developed operational flows, contracts and certifications needed to start HM activities safely, given the clear organizational difficulties and implications of medical-legal liability.

The participation of individual patients to PCLN is bound to a specific individual contract, which specifies the terms and obligations of the respective parties. In particular, according to the contract of participation, the patient is made aware of the fact that PCLN does not handle on-line real-time alarm or emergency situations (absolutely does not replace the 118 or access in PS) and that any transmissions will not be handled immediately but only within 5 working days later.

In the initial phase, patients were enrolled in the first carriers with Medtronic ICD with SprintFidelis electrocatheters (subject to recall due to the high risk of sudden rupture of the catheter) patients who cannot hear audible alarms, patients who live outside the province / region outside and pediatric patients. In the second phase, were enrolled all patients with ICD device equipped with a wireless connection and the holders of implantable loop recorders Reveal (for a total approximately 350 patients). In this phase, the remote control system was activated simultaneously to the implant of the device, training the patient and signing the related consents before discharge from hospital. In the next phase, starting from January 2014 we will extend the HM to the vast majority of patients with implantable devices both ICD pacemaker, implantable devices including the other houses, as well as Medtronic, Biotronic, St. Jude, Boston and Sorin.

For the revision of transmission we used the approach defined as "Primary Nurse Model" (Ricci et al., 2008), which provides a critical role in the management to the Nurse, who is responsible of making telephone contacts with patients and in

controlling the flow of transimssions, in particular by identifying lost transmissions, and by making the first revision of the transmissions themselves. The medical coordinator is in charge of the verification and reporting of data transmission, the organization and any necessary actions to manage the problems detected during transmission, such as arrhythmias and severe malfunctioning of the device or leads, which require ambulatory monitoring or any hospitalization.

The data transmission takes place through the appropriate modem CareLink delivered to the patient, which serves as the station detection and transmission trans-telephone, both in manual mode (that is activated by the patient), or in automatic mode (through a wireless connection between the modem CareLink and ICD). CareLink modem transmits the recorded data to a central server (located in the Netherlands), which sends the processed data to a single hospital of reference, which analyzed the data for the clinical management of patients.

The timing used for the controls provided a check every 1-3 months, with monthly checks in pediatric patients in the first 3 months after implantation in carriers of devices in recall or low and in patients with any clinical complications

To date, in approximately 350 patients enrolled, we handled over 1000 transmsiion per year, including scheduled transmissions and transmissions generated by CareAlert, and in about 10% of cases the programs have highlighted the problems that led to both the admission (for severe or recurrent arrhythmias or related problems such as the ICD battery depletion or malfunction or repositioning of the leads) that outpatient visits for reprogramming of recognition or optimization of medical therapies.

One of the main objectives of PCLN was to integrate as much as possible the remote monitoring of ICDs to classic ambulatory clinic visit, in order to anticipate future forms of clinical management of patients when this type of management will be recognized and made payable inside the institutional flow-chart of the Hospital.

Among the priorities of PCLN was also to identify operational synergies with other Divisions of the Department, in particular the Unit of care for heart failure, to which belonged many of the patients with ICD (ICD-CRT in particular) with heart failure already enrolled in the project, and which is already running at an additional model of remote monitoring of patients with heart failure, and with the CardioPediatricians (with whom we already co-managed 5 small patients with ICD).

3 NEW ISSUES AND PROSPECTS FOR THE CONTROL OF REMOTE ICD

There are many critical issues that must be addressed and resolved once the HM systems actually become the universal system of remote monitoring of implantable systems, in particular ICD and CRT. Among the main problems include:

1. Changes to billing systems of HM service by the NHS. To date, the NHS only provides reimbursement for outpatient visits for the control of devices made in the presence of the patient. The billing systems of HM may be based on either the repayment of the reporting of individual transmissions, or more probably on some sort of "canon" of annual assistance for single patient with a device, regardless of the number of transmissions performed. Such fees may be different according to the complexity of the implantable device (e.g. could be greater in the case of patients with an ICD-CRT compared with single-chamber ICD): in particular, should be ideal to have different billings for remote device control, compared to the more comprehensive remote patient surveillance. To date, the Lombardy Region, based on the results of the project EVOLVO is developing a pilot system of reporting, which could come into force by 2014 (the conditional is a must).

2. Uniformity and a standardization of the models of HM. While taking into account the specificities and characteristics of each company hospital, also in view of a forthcoming charging by the NHS, it must be identified and shared a reference standard pattern for remote control involving:

   a. Well-defined roles for doctors and nurses (the shared framework of reference is currently the "Primary Nurse Model"), in particular with respect to their responsibilities medico-legal

   b. Minimum precise timing for remote controls with respect to outpatient controls, also taking into account the characteristics of individual devices (first installation, replacements, devices subject to recall, etc.).

   c. Forms reference in particular as regards the informed consent, explaining in particular the limits of the remote control with respect to the management of emergency situations (the system of HM is not an emergency service and does not replace the 118!)

   d. Minimum reporting deadlines and the need for specific reporting for single transmission

(through special note fields with signature and date unique and can not be changed afterwards).

3. Integration of HM Systems with Hospital Informatic Systems To date, the systems of HM the various companies are worlds unto themselves who do not interact with each other and especially not interact with the hospital portals. Given the increasing number use of "paperless" hospitals high computerization, will be needed more integration of systems of HM the device with hospital portals, so that data transmissions are integrated into the medical records of the patient and thus available to all members of the hospital (for example, First Aid, Care Unit Heart Failure etc). In this sense, it is desirable that individual manufacturers are available to communicate with the computer systems of the hospitals to implement such a complex integration.

4. Remote management of patients with heart failure. The current HM systems of implantable device are currently able to provide numerous clinical parameters very important for the management of patients with heart failure, such as the loading of supraventricular arrhythmias (in particular atrial fibrillation) and ventricular, the level of heart rate and its variability, the percentage of ventricular pacing in carriers of CRT, and changes in thoracic impedance, possible evidence of intra-thoracic fluid accumulation. The evaluation and integration of these parameters may allow an effective monitoring the hemodynamic situation of a patient with heart failure. However, to date accurate models for the real remote management of patients with heart failure, in particular for the specific medical-legal implications, are still lacking.

5. Coordinating HM systems with other health care professionals within and outside the hospital. The HM systems following by definition very critically ill patients must identify operational synergies with other professionals who are in charge of these patients, in particular the Unit of care for heart failure, to which belong many of the patients with ICDs (particularly ICD-CRT). Another critical aspect is to engage in the systems of HM also territorial care professionals (general practitioners or specialists outside), to realize the concept of "continuity of care" really crucial towards patient extremely fragile and at high risk of fatal arrhythmias, "the sickest of the sick".

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