ORIGINAL ARTICLE

REmote SUpervision to Decrease HospitaLization RaTe. Unified and integrated platform for data collected from devices manufactured by different companies: Design and rationale of the RESULT study

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The number of patients with heart failure implantable cardiac electronic devices (CIEDs) is growing. Hospitalization rate in this group is very high and generates enormous costs. To avoid the need for hospital treatment, optimized monitoring and follow-up is crucial. Remote monitoring (RM) has been widely put into practice in the management of CIEDs but it may be difficult due to the presence of differences in systems provided by device manufacturers and loss of gathered data in case of device reimplantation. Additionally, conclusions derived from studies about usefulness of RM in clinical practice apply to devices coming only from a single company. An integrated monitoring platform allows for more comprehensive data analysis and interpretation. Therefore, the primary objective of Remote Supervision to Decrease Hospitalization Rate (RESULT) study is to evaluate the impact of RM on the clinical status of patients with ICDs or CRT-Ds using an integrated platform. Six hundred consecutive patients with ICDs or CRT-Ds implanted will be prospectively randomized to either a traditional or RM-based follow-up model. The primary clinical endpoint will be a composite of all-cause mortality or hospitalization for cardiovascular reasons within 12 months after randomization. The primary technical endpoint will be to construct and evaluate a unified and integrated platform for the data collected from RM devices manufactured by different companies. This manuscript describes the design and methodology of the prospective, randomized trial designed to determine whether remote monitoring using an integrated platform for different companies is safe, feasible, and efficacious (ClinicalTrials.gov Identifier: NCT02409225).

KEYWORDS

heart failure, integrated platform, remote monitoring, RESULT study

1 | INTRODUCTION

Implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy devices (CRT-Ds) have played an essential role in improving the prognosis of patients with heart failure (HF) (Dubner et al., 2012). The number of implantations is likely to increase over time as a result of the quickly expanding group of patients with indications for implantation of ICDs or CRT-Ds (Camm & Nisam, 2010). The results of randomized trials proved that ICDs and CRT-Ds implanted in primary and secondary prevention of sudden cardiac death (SCD) are efficacious and prolong life (Bardy et al., 2005; Connolly et al., 2000). The indications for ICD and CRT-D implantation have expanded after the publication of the results of clinical trials and updated guidelines (Brignole et al., 2013; European Heart Rhythm Association, 2006). Accordingly, patients with ICDs/CRT-Ds have become a large group among patients with HF, and this is a constantly growing economic burden for national health care systems, especially for outpatient clinics.

Remote monitoring (RM) of parameters known to have a strong impact on HF stability (such as the mean heart rate and heart rate variability, atrial fibrillation burden, patient activity, number of premature ventricular beats per hour, ventricular tachycardia, and others) can detect early indicators of the worsening condition of HF patients (Adamson et al., 2004; Madsen, Rasmussen, & Hansen, 1997; Opasich et al., 2001). In HF patients implanted with ICDs or CRT-Ds, all the parameters mentioned above and other parameters defined by the device function can be remotely followed by telemetric means. Therefore, among other recommendations, the RM of CIEDs was introduced, positively clinically assessed (Crossley, Boyle, Vitense, Chang, & Mead, 2011; Hindricks et al., 2014; Varma, Michalski, Epstein, & Schweikert, 2010) and addressed in a joint European and American Expert Consensus Statement (Dubner et al., 2012) and is now a class IIa recommendation of the 2013 ESC guidelines on cardiac pacing and cardiac resynchronization therapy (Bardy et al., 2005).

However, in our opinion, the most important RM is the fact that CIEDs are produced by different manufacturers, which prevents the collection of signals (information) sent from different devices in a single integrated database, thus limiting further comprehensive standardized analyses. Important data are lost when a patient is implanted with a new device from a different manufacturer because of an upgrade or battery depletion. In many clinical scenarios, it is also unknown what type of medical intervention would be optimal in response to information acquired by the means of RM.

The RESULT study is designed to assess the impact of RM on the clinical status of patients with ICDs or CRT-Ds using an integrated platform for different companies, including the following: Carelink (Medtronic, Minneapolis, MN, USA), Merlin (Saint Jude Medical, St. Paul, MN, USA) and Home Monitoring (Biotronik, Berlin, Germany).

2 | METHODS

2.1 | Study design

The RESULT trial is a prospective, single-center, randomized, open label, parallel study. All consecutive patients with symptomatic HF and reduced ejection fraction ($\leq 35\%$) with ICDs or CRT-Ds implanted accordingly to current ESC practice guidelines will be prospectively randomized in a 1:1 fashion to either a traditional or an RM-based follow-up model. Six hundred patients will be enrolled. The inclusion and exclusion criteria are shown in Table 1. The clinical status of patients will be estimated using the composite endpoint of all-cause death and hospitalization due to cardiovascular reasons. The study protocol has been approved by a local ethics committee and complies with the Declaration of Helsinki. A written informed consent will be obtained from all study participants.

2.2 | Primary endpoint

The primary endpoint of the trial will be a composite of all-cause death or hospitalization due to cardiovascular reasons. Hospitalization for cardiovascular reasons should consist of:

- Hospitalization due to progression of heart failure.
- Hospitalization due to persistent arrhythmia (AF, VT).
- Hospitalization due to embolic episode.
- Hospitalization due to acute coronary syndrome.

Every patient will be followed up for at least 12 months after randomization. Assessment of hospitalization events for cardiovascular reasons will be performed according to a recently published consensus (Chen, Ling, Kiuchi, Yin, & Krucoff, 2013). The final classification of hospital admissions due to cardiovascular reasons will be made by a blinded endpoints committee.

TABLE 1 Inclusion and exclusion criteria

1. Age 18-80 years	1. Existence of factors that may cause risk for lack of cooperation in trial regimen (distant residence, mental illness, lack of skills in operating simple electronic devices).
2. Indication for ICD or CRT-D implantation according to ESC-guidelines	2. Unavailability of mobile network service in the place of residence/stay.
3. EF $\leq 35\%$ prior to implantation	3. Device implanted during intravenous administration of inotropic agents.
4. Period up to 30 days after implantation	
5. Agreement for telemetric supervision	
6. Informed consent for clinical trial.	

CRT-D, cardiac resynchronization therapy with defibrillator; EF, ejection fraction; ESC, European Society of Cardiology; ICD, implantable cardioverter-defibrillator.

FIGURE 1 Study flowchart

The primary technical endpoint is to construct and evaluate a unified and integrated platform for data collected from RM devices manufactured by different companies: Carelink, Merlin, and Home Monitoring.

2.3 | Secondary endpoints

Both elements combined in the primary endpoint will be analyzed separately to estimate their relative impact on the primary endpoint.

The secondary endpoints include the following:

- All-cause death.
- Hospitalization due to cardiovascular reasons.
- Time to medical intervention in case of relevant incidents (arrhythmic, device malfunction, signs of HF decompensation).
- Average number of visits to an outpatient clinic (scheduled and unscheduled) per patient.
- Time to first unscheduled visit in an outpatient clinic.
- Incidence of inappropriate ICD shocks.
- Proportion of visits to outpatient clinics with relevant findings (necessity of changes of device programming or pharmacological therapy, rehospitalization, interventions, invasive procedures).
- Assessment of quality of life of living study participants according to the Minnesota Quality of Life Questionnaire.
- Cost-effectiveness, defined as the cost of hospitalizations and/or scheduled and unscheduled visits in both groups.

2.4 | Study flowchart

The study flowchart is shown in Figure 1. The study protocol has been approved by a local ethics committee and complies with the Declaration of Helsinki. All consecutive patients after implantation of an ICD or CRT-D manufactured by St. Jude Medical, Biotronik or

Medtronic will undergo an initial evaluation. Patients who have given informed consent and who fulfill the inclusion/exclusion criteria will be screened. Randomization to the RM or control group will be conducted within 30 days after ICD or CRT-D implantation and after the final programming of sensing and stimulation parameters. The time of observation in both groups will be 12 months after randomization. In the RM group only, one follow-up visit will be planned 12 months after being enrolled in the trial. In the control group, follow-up visits will be planned at 3, 6, 9, and 12 months after being enrolled in the trial, according to the normal procedure in our center. Unscheduled visits in both groups can be initiated either by the patient or by the supervising staff member. The limits of therapeutic intervention will be individualized depending on the clinical situation according to valid ESC guidelines and will include the following: modification of device settings, modification of pharmacotherapy, and performing necessary invasive diagnostic and therapeutic procedures.

2.5 | Remote monitoring—Integrated platform for data collection

The platform was created by Wasko S.A. in collaboration with physicians from the Silesian Center for Heart Diseases. We assumed that the integration of the data from RM systems is based on international standards. The implantable cardiac device companies have their own databases and follow-up systems. The implantable cardiac device companies are implementing the Integrating the Healthcare Enterprise Implantable Device Cardiac Observation (IHE IDCO) profile and the IEE 11073-10103 nomenclature standard, which supports terminology. The IHE IDCO profile has a standardized workflow (Figure 2).

Most of these companies implement communication with a local electronic health records system (EHR)/EMR Hospital Management Systems using the Health Level Seven (HL7) protocol. Wasko S.A. became a member of the HL7 International organization to understand and implement the standard in its own systems.

FIGURE 2 Integrating the Healthcare Enterprise Implantable Device Cardiac Observation/IEEE 11073-10103 usage diagram

FIGURE 3 Information platform—the workflow

The platform was designed on the basis of ITIL methodology. In ITIL methodology, level management presupposes different time to solve the different kinds of incidents. The platform is organized to support the different levels of support, including a primary support level, secondary support level, and tertiary support level. Users of the platform are assigned to support levels corresponding with their duties and knowledge. Within the framework of these principles, we determined a model of cooperation between the medical personnel in the

monitoring and care of patients, as shown in the following schedule (Figure 3). The users have their own lists of cases to manage. The incidents or follow-up transmissions are the cases to manage. The first-line/primary support level analyzes the data and determines a course of action. There are also screens that allow a physician to analyze a selected patient's transmissions, despite the workflow, to monitor a patient's data. Producers name the parameters and their values using the IEEE11073-10103 standard. In the reports, there are parameters

and values that enhance the IEEE standards and specific data defined by the device producers. Some of the data, for example, the graphic charts, is stored in the embedded binary data as pdf files.

2.6 | Data analysis

The Central Monitoring Unit, situated in the Silesian Center for Heart Diseases (Zabrze, Poland) and consisting of two physicians (a cardiology resident and a cardiology specialist) and two electrophysiology-trained nurses, will perform all analyses of the HM data.

2.7 | Randomization

Randomization will be performed through a centralized, concealed process implemented by the integrated platform for the RM producer, Wasko S.A. (Gliwice, Poland).

3 | STATISTICAL CONSIDERATIONS

3.1 | Sample size calculation

The sample size calculation is based on the primary research question, which is the comparison of the occurrence of the composite primary endpoint (death or cardiovascular hospitalization, whichever comes first) in RM and conventionally supervised patients. The prevalence of events corresponding to our primary endpoint in the In-Time study in the conventionally supervised arm was 16.3% (54/331; 27 deaths and 27 hospitalizations) (Hindricks et al., 2014). In a meta-analysis by Chen et al. (2013), comprising eight trials evaluating the efficacy of cardiac resynchronization therapy, the hospitalization rate in the CRT-D arm was 15.7% and mortality was 9.8%. Considering these data, we estimated that the occurrence of our primary endpoint in conventionally supervised patients would be at least 16.0%. According to previously published results (Hindricks et al., 2014; Saxon et al., 2010), an expected relative reduction in our primary endpoint in the RM group compared to the standard-care group can be estimated as approximately 50%. Based on these assumptions, with a two-sided α of 5% and a statistical power of 80%, the obtained total sample size in both study arms is 522 patients, anticipating a normal distribution of data and equal group sizes. With a dropout rate of 15%, a final sample of 600 patients was calculated.

3.2 | Statistical methods

Continuous variables will be presented using the mean and SD or the median, 25th and 75th percentile, as appropriate. Discrete variables will be presented in frequencies and percentages. All analyses will be performed on an intention-to-treat basis. The occurrence of the primary endpoint in both study arms will be compared using survival analysis and Cox proportional hazards regression. The analysis of further secondary clinical and health economic endpoints will be conducted using analysis of variance, analysis of covariance, survival

analysis (including Cox regression), or logistic regression, depending on the scale and distribution of the data. The total number of shocks and the number of appropriate and inappropriate shocks per patient will be compared between study groups using Poisson regression. For all comparisons, an $\alpha < 0.05$ will be considered as significant.

3.3 | Study organization and interim analysis

University-based researchers (Medical University of Silesia, Katowice, Poland) with methodological experience will form the steering committee of the study, which will be responsible for the study design, implementation, data collection, monitoring, and final analyses. The steering committee is also responsible for the preparation and publication of the manuscripts reporting the study results.

No formal interim analysis of the primary endpoint of this study will be performed.

3.4 | Actual state of the study

The first patient was randomized in January 2015, and at the time of writing, 550 patients have been randomized. Recruitment is expected to be completed by the end of August 2016, and the study should close in spring 2017.

4 | DISCUSSION

Remote monitoring (RM) technology has been widely put into practice in the management of ICDs and CRT-Ds. The presence of different device manufacturers on one hand and the absence of a centralized information platform allowing for more comprehensive data analysis and interpretation on the other hand makes it impossible to use this powerful monitoring tool to its full potential.

In daily clinical practice, there are CIEDs with dedicated software for RM produced by at least five manufacturers. In the TRUST study, automatic RM led to earlier detection of more device-related events, however with the use of only one RM system (HomeMonitoring, Biotronik) (Varma et al., 2010). In the CONNECT trial, wireless RM, also produced by one company (CareLink Network, Medtronic) of defibrillator devices (ICD/CRT-D) as compared with standard in-office follow-ups significantly reduced the time to a clinical decision due to clinical events (arrhythmias, cardiovascular disease progression, device issues) and thereby was associated with a significant decrease in the mean length of hospital stay (Crossley et al., 2011). Conclusions derived from these small studies apply only to highly selected patient populations with devices coming only from a single company. There is a pending demand for studies in larger patient populations, implanted with devices from different manufacturers and with various additional features, for such data are still lacking (Boyne et al., 2012; Koehler et al., 2012). None of the aforementioned studies examined the clinical efficacy of RM operated by medical care providers in a wide range of HF patients. The previous studies were limited to

local information systems as well as devices provided by a single manufacturer. Due to the fact that each solution is characterized by a distinct data format, sampling frequency, and method of data presentation, up till now it was impossible to use a unified and comprehensive approach in all patients. The absence of defined exemplary models (of monitoring and treatment) hindered application of computer-based information systems in the process of clinical decision-making using a complete data set. These limitations may explain, at least in part, the striking heterogeneity of clinical outcome results demonstrated in randomized trials of RM using ICD/CRT-D (Boriani et al., 2013; Crossley et al., 2011; Guedon-Moreau et al., 2013; Landolina et al., 2012; Perl et al., 2013; Varma et al., 2010) in which only one has demonstrated clear all-cause mortality risk reduction (secondary endpoint) (Hindricks et al., 2014). In recently published meta-analysis of nine trials comprising of 6469 HF patients, RM taking advantage of ICD/CRT-D did not outweigh the usual care with regard to either all-cause mortality reduction or hospitalizations (Parthiban et al., 2015). Importantly, the examination of effects of different RPM technology showed that in three studies using HomeMonitoring system by Biotronik with daily verification of alarms, there was a clear risk reduction in all-cause mortality by 35% (HR=0.63, 95% CI: 0.45–0.94, $p = .021$), as opposed to four studies with CareLink by Medtronic, where mortality reduction was not demonstrated (HR=1.07, 95% CI: 0.77–1.49, $p = .767$). This finding strongly underscores the need for unification of recordings from different types of ICD/CRT-D, standardization of interpretation, and elaboration of common intervention algorithm.

5 | CONCLUSION

The RESULT is a prospective, randomized trial designed to determine whether remote monitoring using an integrated platform for different companies in patients with ICDs or CRT-Ds is safe, feasible, and efficacious. The goal of the study is to improve the clinical outcomes in patients with heart failure.

CONFLICTS OF INTEREST

None declared.

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