Original Paper

Remote Monitoring in Cardiac Resynchronization Therapy-First Experience in Romania with a CRT Virtual Ward

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ABSTRACT: Background: Remote monitoring (RM) is becoming a standard of care for patients with cardiac resynchronization therapy (CRT). This technology combines the use of pacemakers or implantable cardioverter-defibrillators (ICD) and wireless communication to provide physicians with continuous, real-time information on the patient's cardiac activity. The purpose of the study was to evaluate if the remote monitoring technology in the follow-up CRT patients is feasible and safe. Methods: A total of nine patients were enrolled in the study, implanted with a CRT system with wireless transmission capabilities. Immediately after the procedure received the RM, were enrolled in the virtual clinic and instructed by the doctor how to use the device at home. Regular virtual transmissions were made automatically every 3 weeks, respecting optimal transmission conditions. The accumulation of fluid in the lungs, atrial or ventricular tachyarrhythmia together with system integrity automatically activate alerts. Results: One hundred and one transmissions were collected and analyzed from the virtual ward. Average follow-up was 7.7±4.8 months, longest follow-up was 18 months. None of the patients experienced complications during the study period, with three of them being follow-up solely through telemetric means by implanting physician. Treatment optimization was successfully conducted via phone consultations, when necessary, without any adverse events. Conclusions: The results of our study suggest that RM could be integrated into routine CRT management protocols, enhancing patients care and resource utilization.

KEYWORDS: *Remote monitoring, heart failure, CRT, ICD therapy.*

Introduction

Heart failure (HF) is major health problem worldwide, affecting approximately 26 million people worldwide [1].

It is associated with significant morbidity and mortality and places a substantial burden, both economic and social, on effected individuals and their caregivers [2].

CRT is a widely accepted and effective treatment for patients with heart failure associating reduced ejection fraction (HFrEF) who despite receiving medical treatment remain symptomatic [3].

CRT involves the use of pacemakers or ICD to synchronize the ventricles and improve cardiac output. Studies have shown that CRT is associated with significant reductions in morbidity, mortality, and hospitalization rates [4].

However, a percentage of about 30% of patients who receive CRT do not have an appropriate medical response [5].

Supper-response to CRT, defined as significant improvements in the ejection fraction of the left ventricular (LVEF) and reduction of the left ventricular end-systolic volume (LVESV), has been reported in a minority of patients [6].

The clinical significance of super-response is still unclear, and there is a need for further research to understand its predictors and impact on patients outcomes.

Remote monitoring (RM) involves the use of wireless communication technology to transmit information on the patient's cardiac activity from the implanted device to healthcare providers.

It has been shown to be an effective tool for detecting and managing potential complications [7].

RM has the potential to enhance the management of patients who have undergone CRT, particularly those who have experienced supper-response.

Studies have shown that RM can detect device-related issues, such as lead fractures, early battery depletion, and changes in device

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programming, with can impact patient outcomes [8,9].

In addition, RM can identify early signs of deterioration in patient condition, such as heart rate, variability, arrhythmias, and other cardiac events that may require intervention [10,11].

RM has shown to improve patient outcomes by reducing hospitalization rates, improving clinical decision-making, and increasing patient satisfaction [12,13].

In a randomized controlled trial, patients who underwent CRT with RM had a significantly lower rate of hospitalization for heart failure compared to those who received standard care [14].

Furthermore, RM has been found to be cost-effective, particularly in patients who are at high risk of complications [15].

The use of RM can reduce the need for in-person clinic visits, thus reducing healthcare costs and improving efficiency in the healthcare costs and improving efficiency in the healthcare system.

The purpose of our study was to assess the effectiveness of remote monitoring in supper-response to CRT and its impact on patient outcomes.

Methods

Inclusion criteria

A retrospective analysis of CRT patients who underwent RM was conducted.

In the study were included patients with CRT indication, heart failure New York Heart Association (NYHA) class II-IV, having a left-ventricular ejection fraction (LVEF) under 35%, duration of the QRS complex ≥130ms, presenting a typical LBBB pattern, and patients that received optimal doses of pharmacological drugs for 3 months prior to CRT.

Patients were excluded if they had severe comorbidities (e.g., renal, lung or liver failure, cerebral insufficiency, or terminal cancer), noncardiac diseases that limit physical activity (e.g., orthopedic conditions, paresis) or if they were reluctant to this technology.

After device implantation with wireless transmission capabilities, patients received the RM.

Immediately after the procedure were enrolled in the virtual hospital and were instructed by the doctor how to use the device at home.

Patient data was collected from electronic health records and remote monitoring systems.

Device programming and diagnostic features

The strategy of RM presents well established steps:

1. interrogation immediately after implant procedure: 12-lead ECG pacing on/off and complete interrogation. Initially the devices were programmed having a base heart rate of 50bpm and associating a maximum tracking rate (MTR) of 130bpm. The AV interval was individually programmed in order to achieve the best fusion or biventricular capture.

2. Assigning monitors and enrollment in the virtual clinic

3. Instructions for monitor use at home (monitor connected to power source, located in the bedroom at a maximum distance of 2-3 meters from the bed, automatic transmissions carried out during the night every 3 weeks and instruction for manual transmission) see Figure 1.

4. 24h check after implantation and discharge check-up.

5. Regular outclinic transmission (virtual transmission) every 3 weeks. The accumulation of fluid in the lungs (OptiVol), together with atrial tachyarrhythmia (atrial tachycardia/ fibrillation), and, nevertheless, with the system integrity activate automatic alerts. If alerts where temporarily active with transmissions in-office device checks were required.

6. In clinic follow-up every 6 months with echocardiography and treatment optimization if needed.

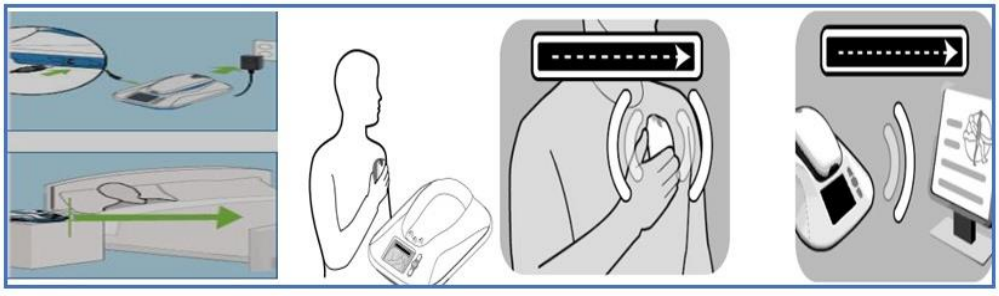

Figure 1. Monitor connected to power source, located in the bedroom at a maximum distance of 2-3 meters from the bed and manual transmission.

Echocardiographic evaluation

All patients had a transthoracic echocardiography (TTE) at 6 months. ECG was simultaneously recorded for each patient.

Parameters such as LV end-diastolic together with end-systolic diameters (LVEDD, LVESD), also the ejection fraction of the left ventricle, and, nevertheless, volumes (LVEDV, LVESV), were measured.

Moreover, atrioventricular, interventricular, intra-LV synchrony parameters were evaluated for all the patients included in the study.

Response evaluation to CRT was based on the following criteria [16,17]:

- Clinical response to CRT, that is defined as an improvement in NYHA functional class and workload.
- Echocardiographic response (defined as an increase of more than >5% in LVEF, and a decrease of 15% in LV end-systolic/diastolic volume and a reduced degree of the mitral regurgitation).
- Evaluation of outcomes consisting of number of hospitalizations caused by worsening heart failure, morbidity and mortality of all causes.

Statistical analysis

For continuous variables data are presented as mean±standard deviation and as proportions for categorical variables.

The student T-test or the Chi-square test were used, as appropriate, to see if there is a statistical difference between the groups.

SPSS, version 18.0 (SPSS Inc., Chicago, Illinois) statistical software was used to perform all analyses.

All subjects included in the study gave their informed consent.

The study was conducted in accordance with the Declaration of Helsinki, the Ethics Committee of University of Medicine and Pharmacy „Victor Babes", Timisoara, Romania approved the protocol used in the study (Nr. 46/28.09.2018).

Results

Nine patients, 63.9±10.4 y.o (78% males), with dilated cardiomyopathy (2 ischemic, 1 amyloidosis, 1 genetic) HF NYHA class II-III and CRT indication were included in the study.

All patients received a CRT (1 CRT-P, 8 CRT-D) system with wireless transmission capabilities implant, in a tertiary center between 2021-2023.

All patients presented a QRS complex >130ms having typical LBBB morphology.

Demographic parameters together with medical treatment are found in Table 1.

Table 1. Demographic parameters and medical treatment.

Male gender, %		7 (78%)
Age, y.o, mean±SD		63.9±10.4
HF, N, %	NYHA II	2 (22%)
	NYHA III	7 (78%)
Associated pathology, N, %	Hypertension	4 (44%)
	CKD	5 (56%)
	Diabetes Mellitus	4 (44%)
	COPD	1 (11%)
Ischemic etiology		2 (22%)
Medical treatment, N, %	Betablockers	9 (100%)
	ACEI/ARB	2 (22%)
	Antialdosteronics	7 (78%)
	ARB+ARNI	4 (44%)
	Ivabradine	2 (22%)
CRT-D		8 (89%)

CKD-chronic kidney disease, COPD-chronic obstructive pulmonary disease, SD-standard deviation, ACEI-angiotensin converting enzyme inhibitor, ARB-angiotensin receptor blockers, ARNI-angiotensin receptor nepriliysin inhibitor, CRT-D-triple chamber cardiac defibrillator.

Intra or periprocedural during implantation there were no important complications.

At baseline, all devices were programmed to have a rest rate of 50 beats/min and also a maximum tracking rate (MTR) of 130b/min.

Fusion pacing in all patients included in the study was allowed by using individualized AV interval programming with an AV paced of 138±21ms together with an AV sensed of 104±27ms.

Average EF at baseline was 22.9±6.5%.

All patients presented a severe dilation of the LV (mean LVEDV 286.7±123.9ml).

At baseline, severe mitral regurgitation (MR) was noticed in 11% of the patients, 78% of patients presented moderate MR and only 11% mild MR.

Before CRT implantation patients where in NYHA class II (22%) and NYHA class III (78%).

See table 2 for details parameters at baseline and 6 months follow-up.

10.12865/CHSJ.49.02.12

Table 2. Echocardiography and functional parameters at baseline and 6 months follow-up.

	Baseline	6 months follow-up	*P*-value
LVEF (%)	22.9±6.5	43.2±9.1	<0.01[#]
LVEDV, ml, mean±SD	286.2±123.9	212.85±116.5	0.024[#]
LVESV, ml, mean±SD	219.7±108.7	131±99.0	<0.01[#]
Severe MR, n, %	1(11%)	0 (0%)	
Moderate MR, n, %	7 (78%)	2 (22%)	0.015*
Mild MR, n, %	1 (11%)	7 (78%)	
NYHA I	0 (0%)	5 (56%)	
NYHA II	2 (22%)	3 (33%)	<0.01*
NYHA III	7 (78%)	1 (11%)	

[#] Student T test. * Chi-square test.

Average follow-up was 7.7±4.8 months, longest follow-up was 18 months.

After device implantation with wireless transmission capabilities, patients received the RM.

Immediately after the procedure were enrolled in the virtual clinic and were instructed by the doctor how to use the device at home.

Regular virtual transmissions were made automatically every 3 weeks, respecting optimal transmission conditions (monitor connected to power source, located in the bedroom at a maximum distance of 2-3 meters from the bed, transmissions were carried out only during night, while asleep provided that the patient was in the room at that moment).

Accumulation of fluid in the lungs (OptiVol), atrial tachyarrhythmia (atrial tachycardia/ fibrillation) together with ventricular tachyarrhythmia, and, nevertheless system integrity enables automatic alerts.

In-office device checks were required if alerts were temporarily active with transmissions.

The patients had the possibility to carry out transmissions manually, depending on the symptoms (e.g. palpitations, dyspnoea).

The parameters monitored during remote follow-up are included in Table 3.

Table 3. Parameters monitored during remote follow-up.

Device Diagnostic	Heart Failure Monitoring	Remote Transmission and Alerts
Battery Status	Daily weight	Successful transmission rate
Lead impedance	Blood pressure	Detection of device malfunctions
Atrial and ventricular sensing	Heart rate	Arrhytmia detection
Atrial and ventricular threshold	Symtoms assessment (e.g., dysnea, edema)	Procent of ventricular pacing
Heart rate variability	Activity level	Alerts

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All patients were compliant with the proposed technology.

During follow-up period 90 automatic transmissions and 11 manual transmissions were collected and analyzed from the virtual ward.

Automatic alert transmissions were successfully transmitted in 94%.

Among the 6% failed transmissions, 2% failed because one patient was admitted in a hospital due to severe pulmonary insufficiency requiring mechanical ventilation secondary to COVID infection, 7 months after CRT, leading to exitus.

Excluding these transmissions, success was up to 96%.

Other reasons for failure were: unplugged monitor (1%), temporary absence from home (2%) or unstable network connection (1%).

From total 101 admissions to the virtual ward, 11% were made by the patients during symptoms, all were appropriately, managed off clinic by phone, optimizing medication telemetric, avoiding hospital admission.

Most manual virtual admissions were due to AF 36% or fluid accumulation 45% (amyloidosis patient).

In the AF transmission, half of them were newly diagnosed AF and required introduction of anticoagulant treatment.

In heart failure decompensation transmission diuretic doses were increased.

None of the patients demanded to unilaterally terminate the monitoring or stopped the virtual transmission.

Eight alerts were received during follow-up, 4 due to fluid accumulation (OptiVol alerts- l in the same patient- amyloidosis patient), 2 alert for un-sustained ventricular tachycardia (RYR2 mutation DCM patient-see Figure 2) and 2 due to AF burden needing reprogramming of the devices for left ventricular only pacing to biventricular pacing.

One patient with AF high burden required also ablation with pulmonary vein isolation.

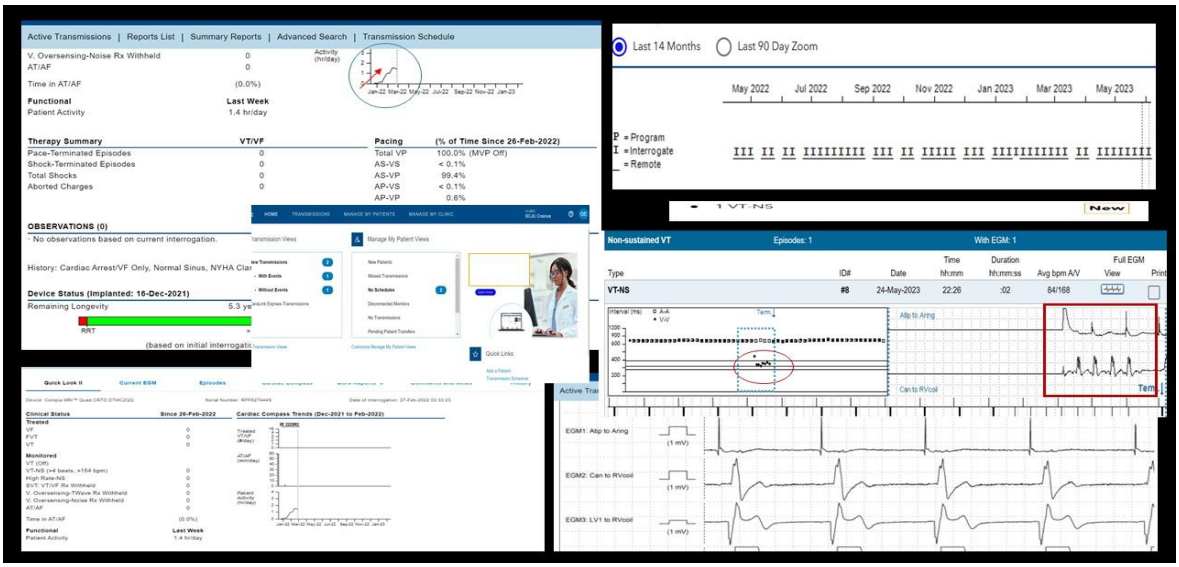

Figure 2. Example of alert for un-sustained ventricular tachycardia (highlight in red square).

Non-sudden cardiac death occurred in 2 patients**,** one as mentioned above due to COVID infection, and one due to intraabdominal hemorrhage.

Three patients were followed only telemetric by the implant physician, for a period up to 12 months.

Treatment optimization was made by phone and through the clinician doctor from the patient region.

None of the patients developed complication and they were very satisfied with this type of follow-up.

Data concerning the patient and caregiver travel (e.g. distance, cost and time) for medical visits were also gathered.

Only two patients live in the city where they were implanted, rest of the patients live up to 200km away.

Cost of visit and device checks from the perspective of the patient is pretty high, to travel from home to hospital, two-way journey, they have to do an average distance of 140km with an average time of two hours.

In 100% of the time, they should be accompanied by a relative, making it difficult for the family (e.g., employees who need leave for in person visits).

Discussions

The purpose of the present is to investigate if the use of remote RM with CRT in a cohort of nine patients is feasible and safe, marking the first such study conducted in our country.

The result obtained from this study demonstrate that remote monitoring of CRT is not only feasible but also a safe approach for managing patients with therapy.

Importantly, none of the patients developed any complications throughout the duration of the study.

One key finding of the study was that three patients (33%) were able to receive follow-up care solely through telemetric means from the implant physician.

This indicates that RM can effectively replace in-person follow-up for a subset of patients, potentially reducing the burden on both patients and healthcare providers.

Additionally, treatment optimization was successfully conducted via phone communication when necessary, and no complications or adverse events were reported as a result.

Studies have shown that remote monitoring is associated with a significant reduction in heart failure-related hospitalizations [8,9].

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Early detection of clinical deterioration, arrhythmias, or fluid overload through remote monitoring allows timely intervention and potentially prevents hospital admissions.

Patient satisfaction was another significant outcome observed in this study.

Acceptance and engagement with RM technology are crucial for its successful implementation.

Some patients may be resistant to frequent data transmission, perceiving it is intrusive or burdensome [13].

Education, patient support, and clear communication about the benefits of remote monitoring can enhance acceptance and engagement.

All patients in our study expressed satisfaction with the remote follow-up, citing advantages such as no longer needed to spend money and time on travelling to the hospital for in-person visits.

By eliminating the need for frequent hospital visits, patient felt a sense of convenience and appreciated the increased flexibility in managing their condition.

Moreover, the patients responded positive to CRT, indicating the effectiveness of the CRT treatment itself as we already know.

The satisfaction of healthcare physician was also noted.

The implementation of RM allowed for a more streamlined approach to patient care, reducing the number of consultations required and the associated workload.

By leveraging RM technology, the doctor was able to efficiently monitor patients progress, make necessary adjustments and provide guidance remotely.

This not only saved time but also enhanced the overall efficiency of healthcare delivery in our region.

As shown by Firdaus et al [18] telemonitoring enables healthcare providers to remotely assess patient adherence to prescribed therapy, including diet and medication regimens.

Patient-specific notifications and reminders can enhance treatment compliance.

Overall, the findings of this study demonstrate that use of RM in conjunction with CRT is not only feasible and safe but also highly advantageous.

Implementing this technology, healthcare providers can optimize treatment remotely, reducing the burden on patients and healthcare systems.

Moreover, patients reported high levels of satisfaction, appreciating the convenience and cost savings associated with remote follow-up.

Future studies with large cohorts and longer follow-up periods should be conducted to further validate these results and explore additional benefits of remote follow-up in CRT patients.

Conclusions

In conclusion, this study is the first in our country to assess the feasibility and safety of remote follow-up in CRT patients.

The findings indicate that RM is a viable and secure approach for managing patients with CRT.

None of the patients experienced any complications, and treatment optimization conducted via phone communication was successful without adverse events.

RM is a promising solution that offers convenience, cost savings, and efficient healthcare delivery.

Authors' contributions

Concept/design: EVG, DC; Data collection: EVG, AU, AM; Data analysis/interpretation: CV, LP, AU; Drafting article: EVG, AU, GT; Critical revision of article: EVG, DC.

Conflict of interests

None to declare.

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