Hospitalization Rate for Remote Monitored Advanced Heart Failure Device Patients Compared to Conventional Care during COVID-19 lockdown

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Abstract

Background: The impact of remote monitoring (RM) in advanced heart failure cardiac implantable electronic device (CIED) patients during COVID-19 lockdown has not been established.

Objective: RM can play crucial role in the follow-up of CIED implanted heart failure patients during COVID-19 pandemia.

Methods: This single centre observational study was aimed to assess follow-up data of 61 remote monitored (RMG) vs. 71 conventional followed (CFG), symptomatic heart failure patients with implantable cardiac defibrillators (ICD) or cardiac resynchronization-therapy (CRT) pacemakers/defibrillators during 6 months of lockdown. The investigation analyzed worsening heart failure, arrhythmia, device related adverse evet rates (primary end point) and hospitalization rates for worsening heart failure (secondary end point).

Results: Although, patients in the RMG had significantly more cardiovascular comorbidities and significantly worse functional class at baseline than CFG patients (NYHA class mean ± SD: [2,74 ± 0,44] vs. [2,34 ± 0,48]; $P < .001$), there was no difference in the composite end point of worsening heart failure, arrhythmia or device related adverse events. However, RMG patients had relative modest deterioration in heart failure functional class at in-office patient evaluations for worsening heart failure events (?NYHA mean: 0,8 ; ?NYHA mean: 1,5 ; $P = .026$). In addition, patients in RMG were significantly less hospitalized for worsening heart failure (0,0164 event/patient vs. 0,169 event/patient; $P = .012$).

Conclusions: : In this observational study remote monitored CIED implanted heart failure patients had significant benefit of lower hospitalization rate for worsening heart failure even on short term follow-up during lockdown.

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Introduction

Background

Remote monitoring (RM) has revolutionized the follow-up of cardiac implantable electronic devices (CIED) in the last decade. Prespecified device alerts provide support to detect device related malfunction, certain arrhythmia events and deterioration in patient heart failure status reliable and more rapid than conventional, in-office patient evaluation (IPE) based follow-up. [1, 2] Some studies resulted even in improved survival for patients in certain advanced heart failure populations with complex CIEDs. [3]

At this time, there have been no study performed to assess the effects of RM during severe acute respiratory syndrome caused by coronarvirus type 2 (SARS-COV-2) pandaemia in heat failure CIED patient group and compare follow-up related outcomes to conventional followed CIED patients. Expert recommendations emphasized the potential benefits of RM in non-CIED heart failure patient group for potential better and safer patient management during lock-down [4, 5] and expert position statements were published for CIED patient management during coronavirus disease- 2019 (COVID-19) for reducing in-office follow-up burden and face-to-face visit events resulting in potential minimise exposure of patients and health care workers. [4, 6, 7, 8]

During the spring of 2020, all scheduled ambulatory IPEs were abandoned in our institute for CIED patients due to an exceptional government decree in our country, only urgent/unscheduled CIED visits were implemented.

Goal of this study

In this observational study we tested our hypothesis that symptomatic heart failure patients, with implanted ICDs or cardiac resynchronization therapy pacemakers (CRT-P) or defibrillators (CRT-D) capable to remote monitoring function had benefits in the rapid detection of arrhythmia, device and worsening heart failure related adverse events compared to a conventional followed (non-monitored)

patient group during COVID-19 pandemia related lockdown in our single university hospital centre.

Methods

Recruitment

We collected data retrospectively of 132 patients implanted with single- or dual chamber ICD, CRT-D or CRT-P devices. All the patients involved in this study have been implanted for at least 1 year before 2020 of March and were in NYHA II or III functional class at the begining of follow-up period. All device implantations were in consens with current gudielnies of European Society of Cardiology device therapy for heart failure. [9]

Remote monitoring group (RMG) consisted of 61 patients whereas conventional followed group (CFG) consisted of 71 patients. Follow-up period was 6 months from 15.03.2020 until 15.09.2020. None of the patients died during follow-up. The study was carried out in compliance with Good Clinical Practice and the Declaration of Helsinki and was approved by the ethics committee of our university centre. All participants signed written infromed consent of clinical follow-up and agreed of anonymous scientific use of their data.

Patients in the RMG had Biotronik Home Monitoring™ or Medtronic Care Link™ eligible devices. CFG patients have been implanted with devices from various manufacturers like Biotronik™, Medtronic™ Boston Scientific™ and St Jude Medical™. Study design was represented in Figure 1.

Adverse events definitions

Home monitoring™ and Care Link™ systems transmit automatically data stored in the CIED to the manufacturer-specific service centre. The hospital staff responsible for the patient's care can check information on a secure website, where the patients are automatically classified and flagged for attention. Additionally, physicians were notified on prespecified alerts.

In our retrospective analysis arrhythmia events like all cumulative ventricular arrhythmia or appropriate/inappropriate ventricular shock, new-onset- , IPE or hospitalization requiring atrial fibrillation were collected as arryhtyhmic adverse events in both patient groups.

Worsening heart failure event was defined as decrease at least one grade from the baseline New York Heart Association heart failure functional class (NYHA) during follow-up.

Early detection of worsening heart failure was implemented by specific heart failure detection algorithms of Biotronik and Medtronic devices. Changes in thoracic impendance value, heart rate variability, patient activity level, resting heart rate, arrhthymia events and biventricular pace ratio in CRT patients served as additive information about cardiocirculatory status in RMG heart failure patients.

Onset of adverse event alerts in remote montiroing system of RMG and phyisician, general practioner referral to the out-patient clinics in the CFG were followed by unscheduled ambulatory visits if it was clinically necessary.

Study objectives

The primary objective in our study was to demonstrate significant lower adverse event rates in composite end point of arrhythmia- , device- and worsening heart failure related adverse events in RMG compared to CFG during 6 months of follow-up during the virus pandaemia.

Arrhythmia events were defined as supraventricular or ventricular arrhtyhmia or ventricular appropriate/inappropriate shock events requiring IPE evaluation or institutional hospitalization during follow-up.

Our secondary end point was to prove the benefits of potential rapid detection and intervention of worsening heart failure in the RMG and thus we expected less major cardiac decompensation events and decreased hospitalisation rates for worsening heart failure in this group.

Statistical analysis

All follow-up variables were divided to categorical or continuous variables. Data are presented as mean ± standard deviation for normally distributed continuous variables, median (25th and 75th percentiles) for non-normally distributed variables, or percentages for binary variable. Missing data were not replaced; all available data were used for sample distribution evaluation. Normality was checked with the Shapiro-Wilk test. For normal distributed data Student t test was used. Mann-Whitney test was used for inter-individual comparisons of continuous variables, when normality was rejected. Categorical variables were compared with the Chi square or Fishers exact test. For primary endpoint outcome an adverse event free survival analysis was applied in Kaplan–Meier's survival curve estimation with log rank test. Spearman's correlation test was performed for regression analysis.

Statistical analysis was performed using IBM SPSS statistical software version 25.0. (Armonk, NY, IBM Corp.). The level of significancy was defined as $P < .05$.

Backward binary logistic regressional analysis was used to determine independent predictors of worsening heart failure event. At this analysis significancy level was defined as $P < 0.1$.

Power

The sample size calculation was based on a hypothesis, with a 25% margin for the occurrence of heart failure, arrhythmia and device related adverse events at 6-month follow-up assumed. Pre-set values were 5% for the significance level and 80% for the power. A required sample size of (54+54) 108 patients with complete datasets was calculated in an observational study design. After considering rate of incomplete data sets (predicted at approximately 10 %), a total of ~130 patients were planned for recruitment.

Results

Patient populations

61 patients in the remote monitoring group (RMG) and 71 patients in the conventional followed group (CFG) were involved in this observational study. Patient groups were non-differing in years of age (median+ IQR: 72 [61,5-55,5] vs. 71 [59,0-77,0]; *P*= 0,549), male sex (46 vs.54; *P*=0,931), single- and dual chamber ICD implanted (34 vs. 46; *P* = 0,29), CRT-D implanted (18 vs. 22; *P*=0,854). Significantly more CRT-pacemakers were in the RMG (9 vs. 3; *P*=0,037). Notably ICDs for secondary prevention of sudden cardiac death (SCD) were aslo significantly non-differing (16 vs. 17; *P*=0,763). 18 vs. 21 patients had previously undergone open heart surgery (*P*=0,922). None of the patients showed polimeraze-chain reaction (PCR) positivity for viral RNA or signs of respiratory tract infections during the pandaemic period. Baseline patient characteristics are shown or (Table 1).

Table 1 – Baseline patient characteristics

	Remote monitoring group (RMG), n= 61	**Conventional followed group (CFG), n=71**	***P* value**
ge (years), median (IQR)	72,00 (61,50-77,50)	71,00 (59,00-77,00)	.549
ex (male/female)	46 / 15	54 / 17	.931
ingle chamber ICD, n (%)	27 (44,3)	29 (40,8)	.291
ual chamber ICD, n (%)	7 (11,5)	17 (23,9)	
RT-defibrillator, n (%)	18 (29,5)	22 (30,1)	.854
RT-pacemaker, n (%)	9 (14,6)	3 (4,2)	**.037**
CD for secondary prevention of SCD, n %)	16 (26,2)	17 (23,9)	.763
omorbidities:			
Hypertension, n (%)	55 (90,2)	56 (78,9)	.078
Diabetes, n (%)	30 (49,2)	28 (39,4)	**.038**
Dyslipidaemia, n (%)	33 (54,1)	24 (33,8)	**.028**
Atrial fibrillation, n (%)	24 (39,3)	22 (32,4)	.410
NYHA class, n (%)	II: 16 (26,2)	II: 48 (66,2)	**< .001**
	III: 45 (73,8)	III: 23 (33,8)	
Chronic kidney disease, n (%)	15 (24,6)	12 (16,9)	,277

Chronic lung disease, n (%)	12 (19,7)	15 (21,1)	,837
Ischemic heart disease, n (%)	39 (63,9)	43 (60,6)	,692
Previous myocardial infarction, n (%)	33 (54,1)	18 (25,4)	**.001**
Previous open heart surgery	18 (31,6)	21 (32,4)	.922
V systolic function/diameter:			
LVEF, median (IQR)	35,00 (30,00-48,00)	38,00 (31,00-45,00)	.073
LV EDD, median (IQR)	62,00 (54,00-65,00)	59,00 (56,00-68,50)	.980
LV ESD, median (IQR)	45,00 (43,00-50,00)	45,50 (41,00-50,50)	.852
Iedications:			
ACEi/ARB (%)	95,1	66,2	**< .001**
ARNI (%)	0,00	12,7	**.004**
BB (%)	95,1	100,0	.065
MRA (%)	44,3	70,6	**.003**
Amiodarone (%)	26,2	36,8	.201
Antiplatelet agent (%)	55,7	38,2	**.047**
OAC (%)	44,3	47,1	.751
Statin (%)	54,1	48,5	.529

Abbreviations: ICD:implantable cardioverter defibrillator ; CRT: cardiac resynchronization therapy ; SCD: sudden cardiac death; NYHA: New York Heart Association; LV: left ventricular; LVEF:left ventricular ejection fraction ; EDD:end-diastolic diameter ; ESD:end-systolic diameter ; ACEi:angiotensin converting enzyme-inhibitor ; ARB:angiotensin receptor blocker ; ARNI:angiotensin receptor blocker/nephrilysin inhibitor ; BB:beta receptor blocker; MRA: mineralocorticoid receptor antagonist; OAC: oral anticoagulant

Comorbidities, heart failure functional class

RMG and CFG consisted of patients with comparable cardiovascular risk factors like basline hypertension (55 vs. 56 ; *P*=0,078), paroxysmal/permanent atrial fibrillation (24 vs. 22 ; *P*=0,41), chronic kidney disease with glomerular filtration ratio below 60ml/min (15 vs. 12; *P*=0,277), chronic lung disease (12 vs. 15; *P*=0,837), ischaemic heart disease (39 vs. 43; *P*=0,692). More patients in the RMG had concomitant diabetes (30 vs. 28; *P*=0,038), dyslipidaemia (33 vs. 24; *P*=0,028), previous myocardial infarction (33 vs. 18; *P*=0,001).

Although all involved participants were symptomatic heart failure patients according to New York Heart Association (NYHA) functional class stage II. or III., patients in RMG had significantly worse baseline NYHA functional class (mean ± SD: [2,74 ± 0,44] vs. [2,34 ± 0,48]; *P*<0,001).

Echocardiography, left ventricular function and dimensions

No difference was seen multiple parameteres measured with echocardiography; baseline left ventricular ejection fraction (LVEF) (median+IQR: 35% [30,00-48,00] vs. 38% [31,00-45,00]; *P*=0,073), left ventricular end-diastolc diameter (LVEDD) (median+IQR: 62,00 mm [54,00-65,00] vs. 59,00 mm [56,00-68,50]; *P*=0,98), left ventricular end-systolic diameter (LVESD) (median+IQR: 45,00 mm [43,00-50,00] vs. 45,50 mm [41,00-50,50]; *P*=0,852).

Baseline medications

No significant difference was seen in beta receptor blocker agent (58 vs. 68; *P*=0,065), amiodarone (16 vs. 25; *P*=0,201), oral anticoagulat agent (27 vs. 32; *P*=0,751) and statin (33 vs. 33; *P*= 0,529) treatment.

There were significantly more patients in the RMG on angiotensin-converting-enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB) treatment (58 vs. 47; *P*<0,001) and antiplatelet agent treatment (34 vs. 26; *P*=0,047), whereas patients in the CFG were more likely to be treated with angiotensin receptor blocker/neprilyzin inhibitors (ARNI) (0 vs. 9; *P*=0,004) and mineralocorticoid-receptor antagonist (MRA) agents (27 vs. 48; *P*=0,003).

Follow-up and adverse event rate outcomes

Patients in RMG ad CFG were equally close followed at in-office patient evaluations (IPE), there were no differences in abandoned scheduled IPEs (0,6557 IPE/patient vs. 0,6197 IPE/patient; *P*= 0,633) and unscheduled/urgent IPE events (0,6065 IPE/patient vs. 0,5915 IPE/patient; *P*= 0,855). Remote monitoring served as additional information source of the patients in RMG during the follow-up period. No significant difference was observed in RMG and CFG observed patient groups regarding worsening heart failure- (0,164 event/patient vs. 0,211 event/patient; *P*=0,491), arrhythmia- (0,065 event/patient vs. 0,1267 event/patient; *P*=0,264) or device related adverse event (1 vs. 1 electrode dysfunction) requiring IPE or hospitalisation. During follow-up 10 versus 15 cases

of worsening heart failure with meaningful functional deterioration were registered. Notably patients with worsening heart failure in CFG requiring IPE and/or hospitalisation had significantly more deterioration from baseline NYHA functional class than patients in RMG (*P*=0,026). (Figure 2)

Using binarly logistic regressional analysis for determining independent predictors of worsening heart failure event, among LVEF, LV EDD/ESD, NYHA functional class, patient age, remote monitoring follow-up, only low LVEF (r^2 = 50,70% ; *P*=0,005) and dilated LV ESD (r^2= 52,70%; *P*=0,057) and LV EDD (r^2 =58,40% ; *P*=0,038) were the only independent predictors.

Arrhythmia events were 2 cases of cumulated ventricular fibrillation/ventricular tachycardia, 2 cases of inappropriate ventricular shocks with high ventricular rate new onset atrial fibrillation in RMG.

3 cases of cumulated ventricular arrhythmia, 4 cases of new onset atrial fibrillation and 2 cases of inappropriate ventricular shock in one case due to atrialfibrillation and in other case for shock-electrode impairment were present in CFG.

The composite end-point of above adverse events was also non-significant int the follow-up period. Figure 3 represents adverse event free survival in both patient groups during follow-up.

Hospitalisation events

Significant less adverse events requiring hospitalisations were observed in RMG (0,082 event/patient vs. 0,281 event/patient in CFG; *P*=0,004). This result was mainly driven by the significant difference of worsening heart failure hospitalisation events (0,0164 event/patient in RMG vs. 0,169 event/patient in CFG; *P*=0,012), besides non-differing value of composite arrhythmia and device related hospitalisations (0,049 event/patient vs. 0,070 event/patient; *P*= 0,629). (Figure 4)

Post-hoc power analysis calculation for overall hospitalisation outcome showed 98,9% and worsening heart failure raleted hospitaliation 86% statistical power with 0,05 value of *alpha*.

Discussion

Principal results

The two observed patient population is not homologous in several baseline patient characteristic features. RMG patients had significantly more diabetes, dyslipidaemia, previous myocardial infarction and had significantly worse NYHA functional class at baseline. Moreover, patients in the CFU group were more likely to be treated with ARNI, and MRA, although these patients were significantly less on ACE-inhibitor or ARB treatment. These differences can play substantial role in interpreting outcomes.

All scheduled IPEs in both patient groups were abandoned in the follow-up period, thus patients in RMG had obviously significant advantage in the timely detection of device, arrhythmia and worsening heart failure related adverse events. In CFG patients were relying on general practionioner and/or treating physician referral to device/heart failure ambulance, thus detection in this patient group was symptom based, and in terms of worsening heart failure, these patients had more advanced decreased functional capacity at ambulatory in-office presentation.

The effects for of automated daily remote monitoring in heart failure CIED patients for all-cause mortality and hospitalization for heart failure exacerbation is well known form a recet meta-analysis [10], these result gained on importance in the COVID-19 related health care restrictions.

Despite more comorbidities and worse functional class among RMG patients, these patients required significantly fewer hospitalisations for the composite of the upper mentioned adverse events during COVID-19 lockdown, this difference was mainly driven by the proportional less hospitalization event for worsening heart failure. Remote monitoring of CIEDs in advanced heart failure patients enabled closer patient follow-up, more rapid detection and fast clinical intervention at impeding cardiac decompensation. Fast detection and intervention lead to relative less functional class deterioration at the patients presentation for worsening heart falure than in CFG. Moreover, RM mediated follow-up allowed more safeness for the treating physician for ambulatory heart failure treatment, fewer hospital admissions and inhospital treatment for worsening heart failure.

Comparison to prior work

The primary end-pont of our observational study was to asses the composite end-point of arrhythmia, device and worsening heart failure realted adverse events. These event rates were higher in our patient groups compared to an observational study comined anti-bradycardia, ICD and CRT implanted patients which was performed during the SARS Cov-2 lockdown in Italy. [11] More patient comorbidities in our study can partially explain higher adverse event rates during follow-up. The expected beneficial difference in adverse event rates for RMG was not estabilished by the observations of our study.

Conclusions

Remote monitoring mediated follow-up resulted in decreased hospitalization rate for worsening heart failure in advanced heart failure CIED implanted patient population compared to conventional followed patients in our institute during 6 months of follow-up periodin lockdown. Remote monitored patients had significantly less functional class deterioration at institutional in-office detection.

Noteworthy, that arrhythmia, device or worsening heart failure related adverse events in general were non-differing in the two patient populations.

Further trials with larger patient populations are needed to confirm our findings.

Limitations

This study was a single centre observational study analysing retrospective collected follow-up data of 2020 COVID-19 pandemia lockdown affected CIED implanted advanced heart failure patients. This study has the following limitations:

The two patient cohorts were non-randomized and clinically non-homologous, the patients in remote monitoring group had more comorbidites and had singificantly worse functional state at baseline, albeit the meaningful beneficial effects of remote monitoring follow-up were observed in this patient group.

Patients were followed with different implanted devices with different device types and manufacturers. The remote monitored patients had devices with RM capability of Biotronik with automated daily transmission RM (Home Monitoring™) and Medtronic with weekly transmission RM (Care Link™). Detection and trasnmission algorithms differ in the upper two device types and notably, this kind of allocation limits the generalizability of results seen in our study.

Furthermore, the relevance of medical and technical findings was determined at the physician's discretion, potentially leading to subjectivity bias in our follow-up.

Conflicts of interests

The authors of this study declare no conflicts of interest.

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All co-authors have seen and agreed with the contents of the manuscript. There is no financial interest of the report. We hereby, certify that the submitted work is an original one is not under review at any other publication.

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Abbreviations

ACEi: angiotensin concerting enzyme inhibitor
ARB: angiotensin receptor blocker
ARNI: angiotensin receptro blocker/ nephrilysin inhibitor
BB: beta blocker

CRT: cardiac resynchronization-therapy
CIED: cardiac implantable electronis device
COVID-19: coronavirus disease 2019
LV EDD: left ventricular enddiastolic diameter
LV ESD: left ventricular endsystolis diameter
LVEF: left ventricular ejection fraction
MRA: mineralocorticoid receptor antagonist
NYHA: New York Heart Association functional class
OAC: oral antiocoagulant
RM: remote monitoring
SARS-COV-2 : severe acute resiratory syndrome by coronavirus type 2
IPE: in-office patient evaluation
ICD: implantable cardioverter defibrillator

Figure legends

Figure 1. Study design.

Design of follow-up of study. Primary endpoint was the composite endpoint of worsening heart failure, arrhythmia and device related adverse events. Secondary endpoint was hospitalization rate for worsening heart failure during 6 months of follow-up.

Figure 2. Comparison of change in NYHA functional class at institutional patient admission.

The mean change is in New York Heart Association heart failure functional class was more prominent in the conventional followed patient group (CFG) than in the remote monitored patient

group (RMG); (ΔNYHA mean: 0,8 ; ΔNYHA mean: 1,5), p=0,026.

Figure 3. Adverse event-free survival in patient groups.

The adverse event-free survival is significantly non-differeing in the two observed patient groups during 180 days of follow-up. Log rank; p=0,214.

Figue 4. Distribution of hospitalization events during follow-up.

Patients in the remote monitored group (RMG) were singificantly less hospitalized for worsening heart failure, arrhtyhmia and device ralted cause (0,082 event/patient vs. 0,281 event/patient in CFG; p=0,004). The highest difference was seen regarding hospitalizations for worsening heart failure (0,0164 event/patient in RMG vs. 0,169 event/patient in CFG; p=0,012).

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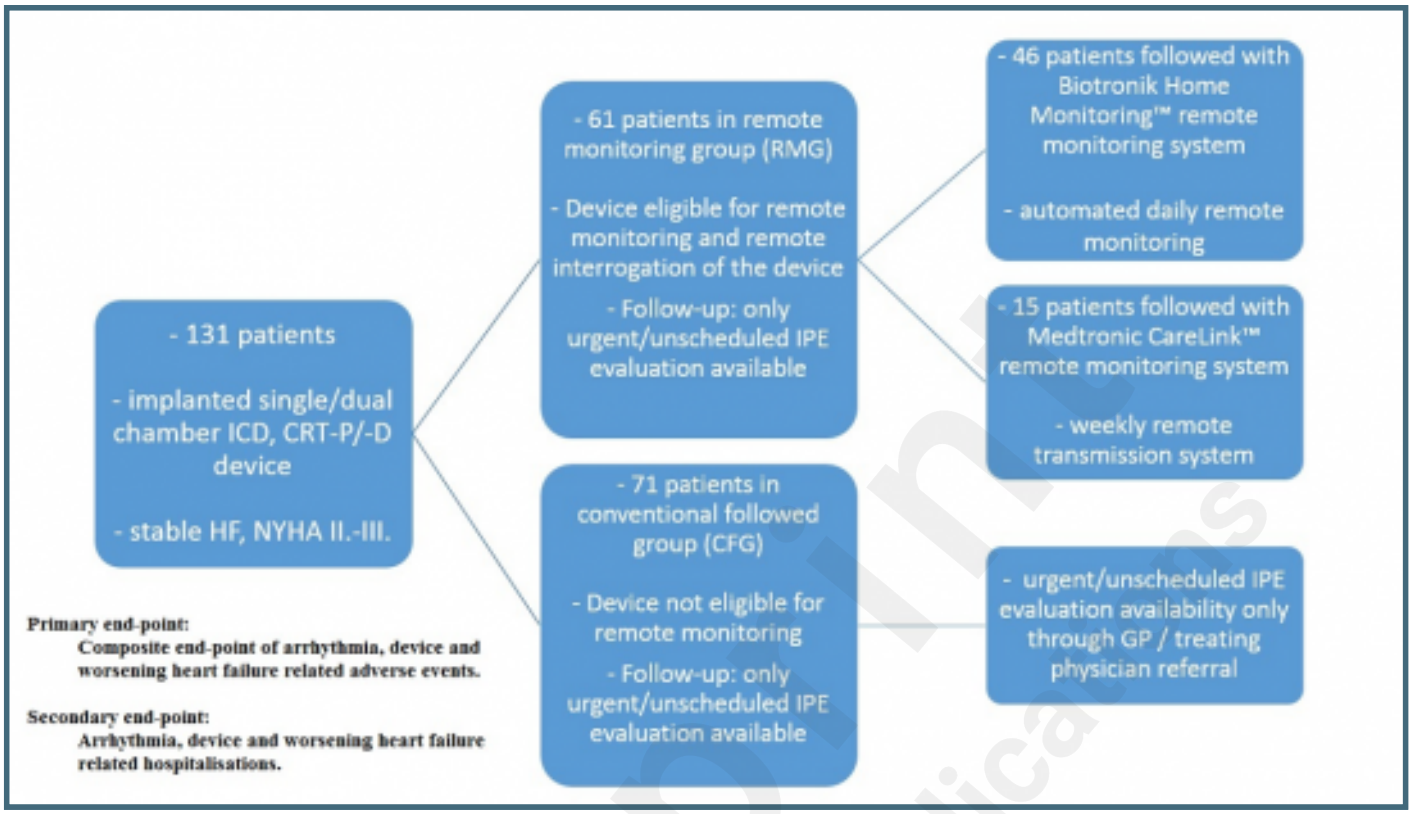
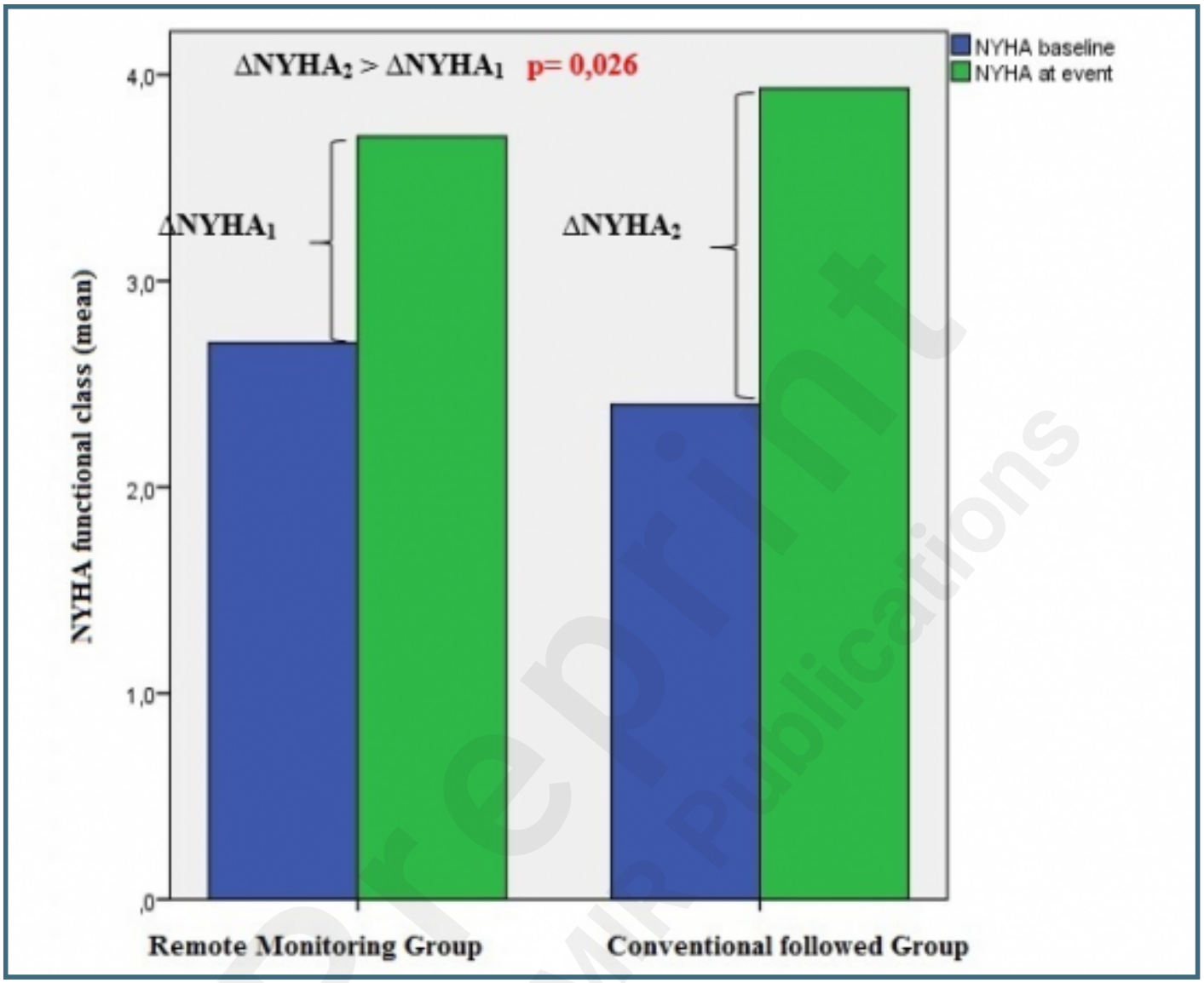
Supplementary Files

Figures

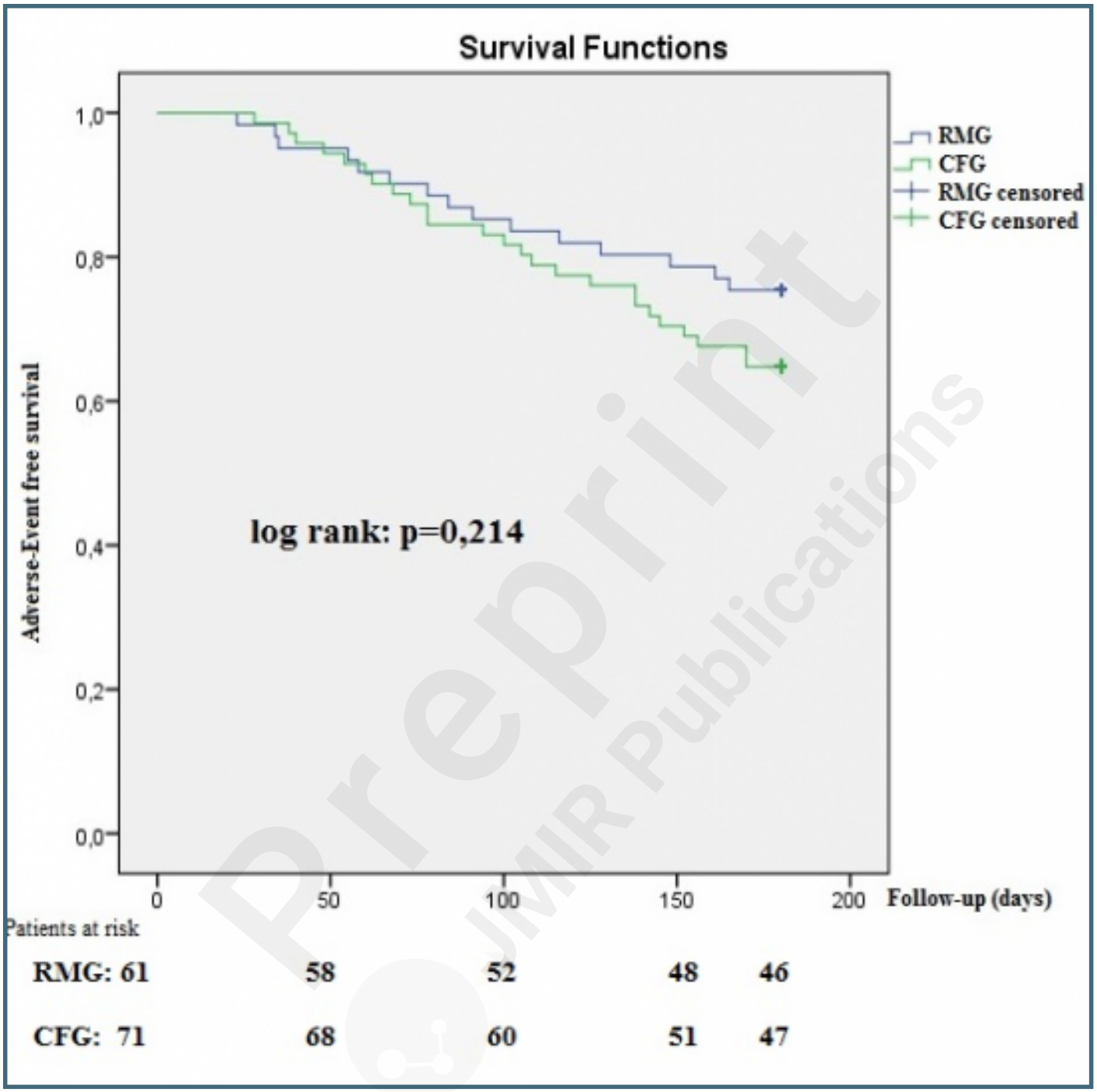
Study design.



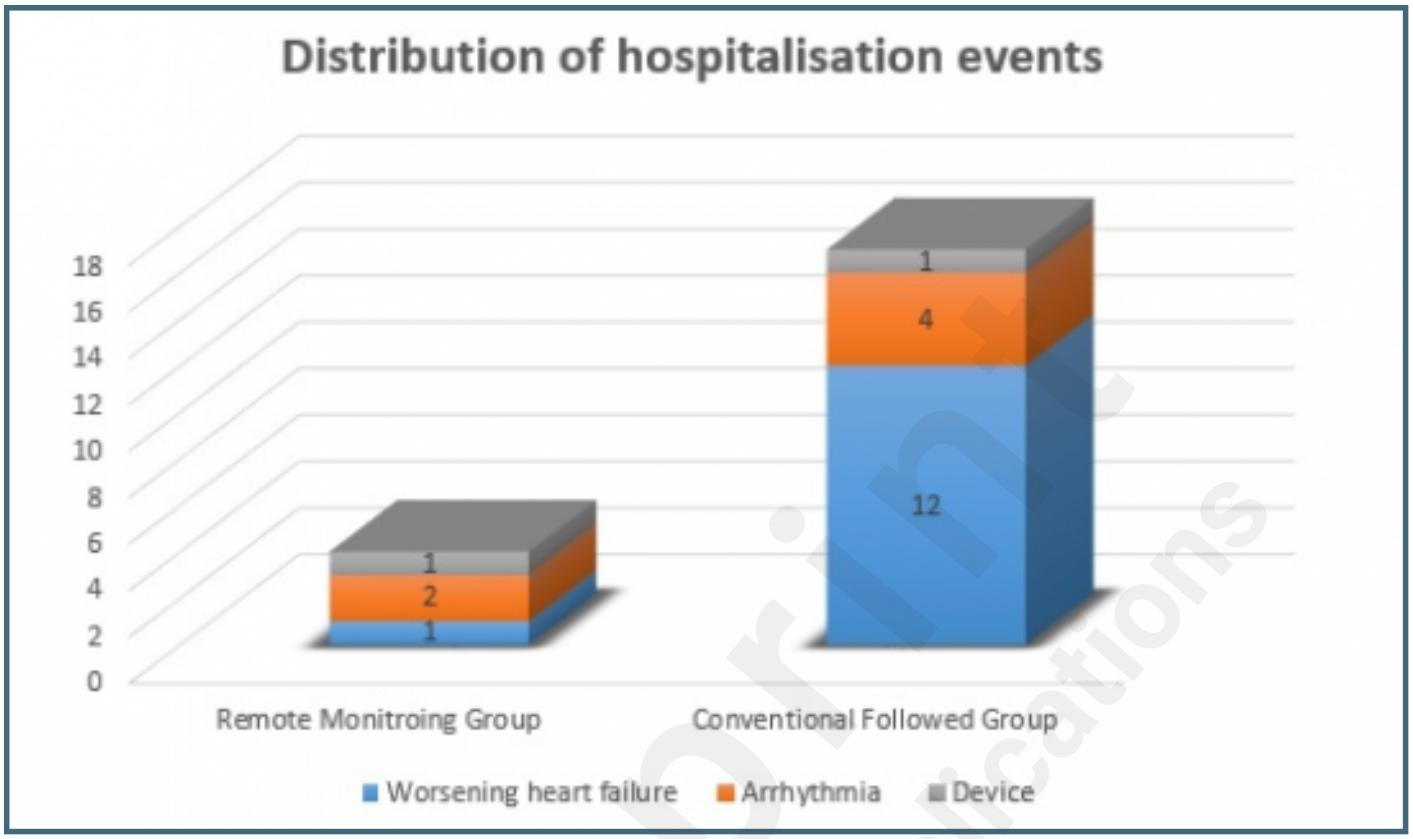
Comparison of change in NYHA functional class at institutional patient admission.



Adverse event-free survival in patient groups.



Distribution of hospitalization events during follow-up.



TOC/Feature image for homepages

Medical doctor working at cardiac implantable device office in COVID PPE.