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Integration of remote monitoring of device diagnostic parameters into a multidisciplinary heart failure management program ☆

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Some implantable cardiac resynchronization therapy (CRT) devices and internal cardioverter defibrillators (ICDs) are able to continuously monitor heart rate (both day and night) and heart rate variability (HRV), patient daily activity, atrial and ventricular tachyarrhythmia frequency and duration, percentage (%) (biventricular) pacing, and intra-thoracic impedance. These device diagnostic data have been suggested as clinically useful tools to predict heart failure (HF) events [1–4]. However, the sensitivity of single variables is often suboptimal [3,5]. Multiple studies have shown improved risk stratification when several device diagnostic data are combined [6–8]. If the clinical use of such an approach translates into reduced morbidity and mortality is yet to be proven.

We have tested the hypothesis that integrating remote monitoring of selected device diagnostic data into an ambulatory HF care plan, involving a specialized multidisciplinary team with cardiologists, HF nurses and general practitioners (GPs), can improve the management of patients with chronic HF and reduce HF hospitalizations.

Between December 2010 and May 2012, we recruited patients who were at least 18 years of age, had HF with reduced ejection fraction (EF) and a history of CRT and/or ICD implantation (Consulta, Secura, Concerto, Virtuoso, InSync Sentry and Protecta, Medtronic Inc, Minneapolis, MN). Study participants were prospectively followed for a minimum of 6 months. Besides individualized optimal medical therapy, all the patients received HF education by a specialist HF nurse and instructions about remote transmission of device data.

Transmission of device information was scheduled weekly, or earlier in case of symptoms. Using the Medtronic CareLink Monitor, patients sent data – either wirelessly or manually – from their device over a phone line (standard or cellular) to a secure server. Members of the HF team could access all device-related data on the CareLink Network Website via a secure ID and password. All the patients gave written informed consent and the local ethical committee approved the study.

A dedicated HF nurse reviewed all transmissions immediately and, if necessary, coordinated referral of patients to the GP or cardiologist according to a pre-specified algorithm (Fig. 1). When the OptiVol threshold was crossed, the HF nurse contacted the patient by telephone and inquired about symptoms. Also, the GP was notified and requested to evaluate the patient clinically and change treatment if deemed necessary. Following this visit, the GP entered clinical findings and changes in medication into a standard 'GP visit form', which was returned to the HF clinic by post, fax or e-mail. If, despite this intervention, the OptiVol alert remained positive for at least 14 days and/or other major device diagnostic alerts were triggered, the patient was referred to the cardiologist. Standard outpatient visits to the HF clinic were scheduled every 3 months.

To determine the appropriate thresholds of device diagnostic variables for identifying increased risk of worsening HF, data from the PARTNERS HF trial were used [6]. Summarized, the threshold for

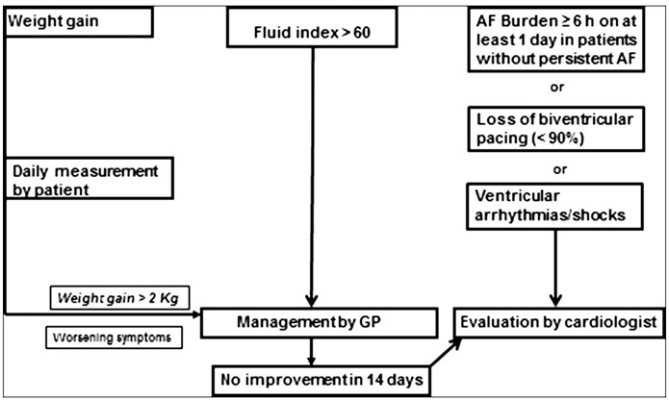

Fig. 1. Study algorithm.

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Table 1
Baseline characteristics.

Age (yrs)	63 ± 13
Gender (male)	50 (77%)
CRT	52 (80%)
Ischemic cardiomyopathy	33 (51%)
NYHA	
Class 1	15 (24%)
Class 2	34 (54%)
Class 3	13 (21%)
Class 4	1 (2%)
ACE-I	41 (63%)
ARB	14 (22%)
BB	59 (91%)
ARA	54 (83%)
AF	
Paroxismal	17 (26%)
Persistent	7 (11%)
Permanent	9 (14%)
Renal failure (eGFR < 60 ml/min)	33 (51%)
SBP (mmHg)	114 ± 19
EF (%)	29 ± 11
NTproBNP (ng/L; median and IQ range)	2154 (799–4569)
Hemoglobin (g/dL)	13 ± 1,6
Sodium (mmol/L)	137 ± 3
MDRD (ml/min)	57 ± 24
Follow-up (days)	619 ± 160

Table 1: Baseline characteristics of patients (n = 65).
CRT: cardiac resynchronization therapy; NYHA: New York heart association; ACE-I: angiotensin converting enzyme-inhibitor; ARB: angiotensin receptor blocker; BB: beta blocker; ARA: aldosteron receptor antagonist; AF: atrial fibrillation; SBP: systolic blood pressure; EF: ejection fraction; and MDRD: modification of diet in renal disease.

an OptiVol alert was set at 60 Ω. Occurrence of AF warranted clinical assessment if the paroxysmal AF burden was ≥6 h per day or if the ventricular rate during persistent AF was ≥90 bpm on at least 1 day. Loss of biventricular pacing (<90% for 5 of 7 days) and ventricular arrhythmias (with of without ICD shock) required an urgent clinic visit.

To assess the impact of this remote monitoring algorithm, the number of HF hospitalizations per patient during the first 6 months of follow-up was compared with the number of HF hospitalizations in the 6 months preceding enrollment.

The study included 65 HF patients (50 males, mean age: 63 ± 13, mean EF: 29 ± 11 and median NT-proBNP: 2154 ng/L) (IQR: 799 to 4569 ng/L). Mean follow-up was 619 ± 160 days. Baseline characteristics are summarized in Table 1. A total of 4663 device data transmissions were received and reviewed throughout the study period. Of these transmissions, 984 (21%) reported possible fluid accumulation, 711 (15%) increased AF burden (paroxysmal AF ≥ 6 h per day or ventricular rate during persistent AF ≥ 90 bpm), 351 (8%) ventricular arrhythmic events (VT/VF, non-sustained VT and/or shock), and 421 (9%) loss of biventricular pacing. A total of 1357 transmissions (29%) reported 'no events'. The remaining transmissions were related to capture management warnings, lead problems, and ventricular sensing episodes. A warning about possible fluid accumulation was most frequently associated with increased AT/AF daily burden (18.5%), followed by loss of biventricular pacing (10%), VT/VF episodes (3.6%) and shock (<1%). All other "possible fluid accumulation" alerts were isolated events.

By the end of the study, 88 cardiovascular hospitalizations had occurred, of which 41 were due to HF. Triage of patients according to this study algorithm led to a significant reduction in the number of HF hospitalizations when compared to the number of HF hospitalizations in the 6 months before inclusion (0.63 ± 0.11 per patient vs. 0.20 ± 0.07 per patient; $p < 0.001$).

Eight patients died as a result of end-stage HF (mean survival time: 486 ± 97 days). One patient underwent heart transplantation and 2 patients had a ventricular assist device implanted.

We acknowledge that this study is limited by the small sample size and the observational 'before versus after' design. In the absence of a control group, it is challenging to establish a cause–effect relationship. However, the substantial time interval (mean 508 days) between device implantation and study enrollment supports the probability that the observed reduction in hospitalizations is the result of implementation of the study algorithm rather than an effect of device use. Also, the mean survival time of patients who died or underwent heart transplantation or assist device implantation was 456 days. Therefore, the reduction in HF hospitalizations during the first 6 months of follow-up cannot be explained by the fact that the sickest patients had already died.

In conclusion, integration of remote monitoring of device diagnostic data into a multidisciplinary HF management program, involving a specialist HF nurse, cardiologist and GP, is not only feasible but also has the ability to reduce the number of HF hospitalizations.

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