Telemonitoring in subjects with newly diagnosed heart failure with reduced ejection fraction: from clinical research to everyday practice.

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Keywords: heart failure; hospital admission; telemedicine; telehealth; hospitalization.

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Background:

Heart failure is increasingly common, and characterised by frequent admissions to hospital. To try and reduce the risk of hospitalisation, techniques such as telemonitoring (TM) may have a role. We wanted to determine if TM in patients with newly diagnosed HF and ejection fraction <40% reduces the risk of re-admission or death from any cause in a “real world” setting.

Methods: Retrospective study of 124 patients (78.2% male; 68.6±12.6 years) who underwent TM and 345 patients (68.5% male; 70.2±10.7 years) who underwent the usual-care (UC). The TM group were assessed daily by body weight, blood pressure and heart rate using electronic devices with automatic transfer of data to an online database. Follow-up was 12 months.

Results: Death from any cause occurred in 8.1% of the TM-group and 19% of the UC-group, *p*=0.002. There was no difference between the two groups in all-cause hospitalization, either in the number of subjects hospitalized (*p*=0.7) or in the number of admissions per patient (*p*=0.6). There was no difference in the number of heart failure-related readmissions per person between the two groups (*p* =0.5), but the number of days in hospital per person was higher in the UC group (*p*=0.03). Also, there were a significantly greater number of days alive and out of hospital for the patients in the TM-group compared with the UC-group (*p*=0.0001).

Conclusions: TM is associated with lower any-cause mortality and also has the

potential to reduce number of days lost to hospitalization and death.

Introduction

Heart failure (HF) is a complex clinical syndrome, representing the final common pathway of many different pathological processes associated with high mortality rate and frequent hospital admissions (1-4). Over 50% of patients hospitalised with heart failure are readmitted within six months (5). To try and reduce the risk of hospitalisation, approaches such as telemonitoring (TM) have been introduced (6). Home TM involves the use of electronic devices and telecommunication technologies for the digital transmission of physiological and other disease –related data from patient's home to a health care centre assisting in disease management. Recent meta-analyses suggest that TM may be associated with a better prognosis and reduced risk of hospitalisation in patients with HF (7-9).

However, despite the encouraging results and the growing interest in TM among cardiologists, the use of TM has not been widely adopted, as many questions remain unanswered. A major obstacle to the widespread use of TM is the accurate identification of those patients with most to gain. We hypothesised that the patients at high risk, and hence potentially with most to benefit, were those who had recently been diagnosed with HF, and we therefore assessed the effects of TM in patients who were recently diagnosed HF with reduced ejection fraction (HFrEF) and had NYHA class II-III symptoms.

Methods

Subjects

In Kingston-upon-Hull, home-based TM for patients with chronic HF was adopted as a regional health service in 2009. Between 2009-2012, 453 patients were diagnosed during cardiology outpatient review with heart failure with reduced EF, based on ESC guidelines. Among these newly diagnosed HF patients, 124 accepted to receive the TM management and constitute the study group; while the remaining 329 patients, who refused the TM management,received the UC and represent the control group. Hospital records were retrospectively reviewed, and HF-related admissions data were collected. Additional information about the hospitalizations was gathered from individual's general practitioners. All patients gave written consent for their clinical data to be anonymously used for research purposes. All patients gave written wide consent for their clinical data to be anonymously used for research purposes.

Remote Telemonitoring System

TM is performed with the use of the commercial system Motiva telemonitoring system (Philips Healthcare, Amsterdam, Netherlands). This includes a secure broadband home TV channel providing educational material, reminders of medication, health-related surveys and motivational messages to encourage the prescribed lifestyle regimen. Individuals were given automated devices for daily measurements of BP, HR and weight at home; they were asked to obtain the measurements the same time of date, preferable in the morning half an hour after the intake of their tables. A nurse practitioner evaluated the measurements every day using a dedicated clinical user interface. Clinical alerts are dealt with by the HTM nurse calling the patient and then, if necessary, a clinical responder; either a community HF nurse with prescribing qualifications or a cardiologist if long-term changes in therapy are required.

Patients in both groups were seen at a specialist HF clinic, by a cardiologist specialised in HF, for life-style advice and optimization of HF medication. The frequency of clinical follow-up was at the discretion of the HF team. The same cardiologists reviewed the patients in both groups.

Statistical analysis

The statistical analysis was performed using SPSS version 22.0. Baseline characteristics were expressed as mean and standard deviation or median and interquartile range. Continuous variables between the two groups were compared using the independent student's t-test for normally distributed. Variables not normally distributed were logarithmically transformed before the analysis in order to assess normality and fulfil model assumptions. Categorical variables were analysed using the chi-square test. Survival analysis with a Kaplan-Meier curve was constructed for time to death. A p-value of <0.05 was accepted as statistically significant.

Results

The patients were well matched for age, but the proportion of men was higher in the TM group. A higher proportion of the TM group had diabetes, but their NT-pro BNP tended to be lower, albeit not statistically significantly. The baseline clinical and demographics characteristics for the two groups are shown in *Table 1*. Finally, there were no differences between the two groups in the treatment with beta-blockers, ACE inhibitors/angiotensin receptor blockers and aldosterone antagonists.

Mortality

After 12 months of follow-up, all-cause mortality was significantly lower in the TM group than usual care (8.1% vs 18.8%; p=0.005). The Kaplan-Meier curves for mortality are shown in *Figure 1*. The mean number of days alive and out of hospital was significantly higher in TM group compared to UC group, 340.4 ± 96.9 vs. 341.7 ± 78.4 respectively (p= 0.0001).

All hospitalizations

There was no significant difference between the two groups in all-cause hospitalization, either in the number of subjects hospitalized (63.7% in the TM group vs. 62% in the UC group, p=0.7) or in the number of admissions per patient (1.3 ± 1.7 in TM group vs. 1.4±1.7, p=0.6). There was no difference in the number of days lost to hospitalizations per patient (8.1 ± 12.8 days in TH group and 9.5 ± 17.3 in UC group, *p*=0.4).

Heart failure-related hospitalizations

Readmission for heart failure occurred in 11.3% in the TM group and 14.9% in the UC group, *p*=0.2. There was no difference in the number of heart failure-related readmissions per person between the two groups (0.2 ± 0.3 in UC vs. 0.2 ± 0.4 in TM, *p* =0.5), but the number of days in hospital per person was higher in the UC group (2.6 ± 8.8 in UC group vs. 1.3 ± 4.1 in TM group, *p*=0.03).

Other cardiac hospitalizations

The number of patients readmitted for any cardiac cause except HF was higher in UC group compared to TM group (22.8% vs. 13.7% respectively, *p*=0.02). The number of days in hospital per person was higher in UC group (2 ± 6) compared to TM group (0.9 ± 2.7), *p*=0.01.

Renal failure hospitalizations

Readmissions for renal failure was much more common in the UC group, 12.5% of subjects in UC group and 3.2% in TM group, *p* = 0.003.

Discussion

In recent years, home TM has become an increasingly attractive option to supplement the care of patients with chronic HF. Advances in data collection (such as simple automated sphygmomanometers) and transfer (Bluetooth; broadband; Wifi) allow for the regular, reliable and accurate communication of vital signs and symptoms from community-based patients. Indeed, the data transferred by TM has become as reliable as those collected through face-to-face patient examination (10-11). Home-based TM has the advantage of providing regular monitoring whilst overcoming potential geographic and logistical obstacles. However, despite all the advantages and the associated policy support, the use of TM has not been developed at the pace and scaled anticipated. Most studies show that TM programs are associated with a trend toward improvement in morbidity, although heterogeneity of results across studies has been noted (12). There are two main contributors to this heterogeneity. Firstly, the heterogeneity of study populations and secondly the heterogeneity in structure and function of TM service design.

The main finding of this study is that TM can reduce mortality in patients who have been recently diagnosed with HF and have LV dysfunction. Moreover, the reduction in the mortality is achieved without an increase in the duration of time spent in hospital. On the contrary, TM reduced the number of days lost to death or hospitalization. Although, there was no reduction in readmissions for HF between home TM group and UC, there was a reduction in the number of days spent in the hospital. Similarly, while in both groups there was no reduction in the hospitalization rate for other cardiac cause, the TM group demonstrated a reduction in the duration of hospitalization. Finally, compared with UC, TM reduced the both the hospitalization rate and duration of admission for renal failure.

There are a number of possible mechanisms of action that may explain these findings. The reduced mortality in the TM patients may reflect the fact that TM improves patient heart failure knowledge and self-care behaviors. For example, participation in TM requires patients to weigh themselves on a daily basis, which is, in itself a recommendation for patients living with the condition (13). TM helps to educate patients on the importance of measuring other physiological parameters and taking their medication (14-15). Furthermore patients learn to recognize a change in themselves (such as increased weight), evaluate the symptoms, implement a treatment strategy in collaboration with the HF team (such as taking an extra diuretic dose), and evaluate the response to therapy. Several studies have shown that counseling and education of patients, promotion of patient compliance, daily weight measurements and easy access to a specialized HF team can reduce mortality in heart failure (16-17). Another aspect of our study that can be highlighted is the decrease in days in hospital for HF and for other cardiac causes. This probably reflects early detection of decomposition (18). TM most likely allowed for earlier detection of cardiovascular problem and more prompt and effective therapy through the bi-directional communication established between the patient and health care team.

Our study extended the evidence base for TM for HF, in that we examined patients newly diagnosed with HF. To the best of our knowledge, this is the first study focusing on this population. In contrast with the other studies, which are randomized and have strict inclusion criteria, our study is based on real-world results and a study population that represents the typical HF patient.

Although current reports show that TM is a useful tool to keep patients out of hospital and prolong their survival, a lot of unsolved issues remain. There is a fundamental requirement for health services research to find out more about: the identification of patients that actually would benefit form TM and the mechanism of action of TM.

In summary, TM has the potential to improve patient care in many ways. In patients newly diagnosed with HF and with reduced left ventricle systolic function, TM is associated with lower any-cause mortality. Furthermore TM has the potential to reduce the number of days lost to hospitalization and death.

Limitations

This study is based on the retrospective analysis of available data with its inherent limitations.

Acknowledgments

The authors thank the Hull City Health Care Partnership CIC, and Mr. Mike Cosgrove for their assistance.

Conflict of interests

The authors declare that there is no conflict of interest.

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Table 1. Baseline subject characteristics of telemonitoring and usual care group.

	Usual care (N= 329)	**Telemonitoring (N= 124)**	***p*-value**
Mean age, years (SD)	67.5 (10.6)	68.1 (12.7)	0.9
Male (%)	224 (68.1)	97 (78,2)	0.03
Primary cause of HF			
Coronary Heart Disease, n (%)	185 (56.2)	70 (56.5)	0.2
Idiopathic dilated cardiomyopathy, n (%)	60 (18.2)	20 (21.9)	
Hypertension, *n* (%)	26 (7.9)	4 (3.2)	
Arrhythmia related, *n* (%)	16 (4.9)	5 (4)	
Valve related, *n* (%)	12 (3.6)	8 (6.5)	
Other, *n* (%)	30 (9.1)	17 (13.7)	
Co-morbidities			
Chronic lung disease, *n* (%)	31 (9.4)	14 (11.3)	0.5
Stroke any, *n* (%)	21 (6.4)	11 (8.8)	0.4
Hypertension, *n* (%)	96 (29.2)	41 (33.1)	0.4
Diabetes mellitus, *n* (%)	85 (25.8)	49 (39.5)	0.004
Renal impairment, *n* (%)	29 (8.8)	10 (8)	0.9
Chronic or paroxysmal AF, *n* (%)	99 (30.1)	40 (32.2)	0.6
Blood pressure (mmHg)			
Systolic (mean, SD)	124.3 (22.8)	130.5 (24.1)	0.01
Diastolic (mean, SD)	76.3 (13.9)	77.3 (14.7)	0.5

Serum creatinine (µmol/L)(mean, SD)	117.6 (62.2)	112.9 (47)	0.5
NYHA class, n (%)			
II	174 (52.9)	64 (51.6)	0.8
III	155 (47.1)	60 (48.4)	
Body mass index (mean, SD)	27.8 (5.6)	28 (6.3)	0.8
NT-proBNP (pg/ml), (mean, SD)	4,102.4 (6279)	2,997.5 (3859.6)	0.06
Haemoglobin (g/L) (mean, SD)	13.3 (1.8)	13.1 (2)	0.3
Medication			
ACE inhibitor or ARB, *n* (%)	260 (79)	103 (83)	0.3
Beta-blocker, *n* (%)	269 (81.7)	105 (84.6)	0.5
Aldosterone antagonist, *n* (%)	194 (58.9)	77 (62.1)	0.6

Table 2. Study outcome: mortality and hospitalizations.

	Usual care	**Telemonitoring**	***p*-value**
All-cause mortality	62 (18.8%)	10 (8.1%)	0.005
Days alive	341.7± 78.4	320.4 ± 96.9	0.0001
Days alive and out of hospital	319.8 ± 89.8	340.2 ± 64.7	0.0001
Patients hospitalized for all-cause	204 (62%)	79 (63.7%)	0.7
Hospitalizations for all cause /patient	1.4 ± 1.7	1.3 ± 1.7	0.6
Days of hospitalizations for all-cause /patient	9.2 ± 17.3	8.1 ± 12.8	0.4
Patients hospitalized for heart failure	49 (14.9%)	14 (11.3%)	0.2
Heart failure Hospitalizations/patient	0.2 ± 0.3	0.2 ± 0.4	0.5
Days of heart failure hospitalizations/patient	2.6 ± 8.8	1.3 ± 4.1	0.03
Patients hospitalized for other cardiac cause	75 (22.8%)	17 (13.7%)	0.02
Hospitalizations for other cardiac cause/patient	0.3 ± 1	0.3 ± 0.7	0.5
Days of hospitalizations for other cardiac cause/patient	2.3 ± 6.2	0.9 ± 2.7	0.01
Patients hospitalized for renal failure	41 (12.5%)	4 (3.2%)	0.003
Hospitalizations for renal failure/patient	0.1 ± 0.3	0.04 ± 0.2	0.002

Days of hospitalizations for renal failure/patient	0.3 ± 0.5	0.1 ± 1.5	0.01

Figure 1. Kaplan-Meier curve: mortality from all causes in the telemonitoring group and usual care group; *p*= 0.0001.