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Impact of telemonitoring at home on the management of elderly patients with congestive heart failure

Roberto Antonicelli*, Paolo Testarmata*, Liana Spazzafumo*, Cristina Gagliardi*, Grzegorz Bilo†, Mariaconsuelo Valentini†, Fabiola Olivieri*‡ and Gianfranco Parati†

*Department of Cardiology and Telemedicine, Italian National Research Centre on Ageing, Ancona; †Department of Cardiology, Istituto Auxologico Italiano and Department of Clinical Medicine and Prevention, University of Milan-Bicocca, Milan; ‡Department of Molecular Pathology and Innovative Therapy, Polytechnic University of Marche, Ancona, Italy

Summary

We studied the effects of home telemonitoring in elderly patients with congestive heart failure (CHF) on mortality and rate of hospitalization, compliance with treatment, quality of life and costs of CHF management, by comparison with a group receiving usual care. Fifty-seven elderly CHF patients were randomized to standard care or to home telemonitoring-based care and followed for 12 months. In the subjects who were monitored, weekly reports on their clinical status were obtained and their management was modified accordingly. Home telemonitoring was associated with improvements in the composite endpoint of mortality and rate of hospitalizations ($P = 0.006$), a better compliance with therapy, more frequent use of beta-blockers and statins, lower total cholesterol level and a better reported health perception score. The improved results with home telemonitoring in CHF were probably due to better compliance and to closer monitoring of the patients.

Introduction

Congestive heart failure (CHF) is a clinical syndrome whose occurrence is increasing in Western industrialized countries,[1] with a high yearly mortality rate, ranging from 5% to 50%.[2] Among the reasons for the increase in CHF prevalence, two factors appear to be particularly important. The first is the progressive ageing of the general population, which is responsible for an increased prevalence of arterial hypertension and coronary artery disease and of the resulting left ventricular dysfunction. The second is the progressive increase in life expectancy of acute cardiac patients, due to the efficacy of intensive care procedures, indirectly (and paradoxically) leading to an increase in CHF prevalence in subjects surviving a heart attack.[3] The increasing prevalence of CHF has not only clinical, but also socioeconomic implications. The cost of CHF management in the USA is at least $20 billion, and amounts in European countries to nearly 2% of the total health-care cost. A significant portion of CHF management cost comes from frequent hospital re-admissions. In fact, this condition is typically unstable and this relates both to the disease progress and to poor patient compliance with the often complex treatment regimen to be followed at home.[4]

Patients telemonitoring at home, including regular transtelephonic interaction with CHF clinic staff, has been proposed as an approach to improve CHF management and to reduce the costs associated with long-term care of this condition,[5,6] at least in middle-aged subjects.[7–9] In this age category, some studies,[10,11] but not others[9] have shown that it may lead to a decrease in mortality, too. Conversely, in elderly CHF patients there is only limited and conflicting evidence concerning the clinical value of home telemonitoring.[12]

The aim of our study was to explore whether, as compared to standard care from a specialized CHF management team, the addition of home telemonitoring to an integrated CHF patient care system may reduce mortality and rate of re-admission to hospital in elderly CHF patients. The secondary aims of our study were to assess the impact of telemonitoring on patients' compliance with prescribed therapeutic regimens, on patients' quality of life and on the costs of CHF management in this population.

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Correspondence: Dr Roberto Antonicelli, Department of Cardiology and Telemedicine, Italian National Research Centre on Ageing, Via della Montagnola 81, 60100 Ancona, Italy (*Fax: +39 071 800 3203*; *Email: r.antonicelli@inrca.it*)

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Methods

Ninety-six CHF patients aged 70 years or older, consecutively admitted over a period of 16 months to the Italian National Research Centre on Ageing Hospital, located in Ancona, central Italy, for worsening of symptoms and signs of CHF, were considered for enrolment in the study after having achieved sufficiently stable clinical conditions during the hospitalization period. The diagnosis of CHF was documented by:

(1) the presence of CHF signs and symptoms such as dyspnoea and peripheral or pulmonary oedema requiring diuretic administration (New York Heart Association [NYHA] functional class II–IV);
(2) evidence of pulmonary congestion on chest X-rays;
(3) ejection fraction by cardiac ultrasonography <40% as an index of systolic dysfunction, combined or not with a left ventricular filling pattern supporting the presence of diastolic dysfunction, according to the American College of Cardiology/American Heart Association Guidelines for chronic heart failure.

Patients with NYHA class II–III who had an ejection fraction >40% and evidence of diastolic LV dysfunction were also included in the study.

Exclusion criteria were: lack of cooperation and/or of reliable family assistance at home, severe dementia or debilitating psychiatric disorders, inability to access a home telephone line, end-stage heart failure requiring regular inotropic drug infusions, cachexia, chronic renal failure requiring dialysis treatment and unstable angina.

Out of the 96 screened subjects, 39 were not included in the study, either because of recent myocardial infarction leading to unstable angina ($n = 7$), death before discharge ($n = 5$), need for starting dialysis treatment ($n = 7$), lack of a telephone line ($n = 4$), severe cognitive impairment ($n = 10$) or no reliable family assistance at home ($n = 6$). The remaining 57 elderly subjects (33 men), with a mean age of 78 years (SD 7) were enrolled.

Study design

During the hospitalization period, treatment was tailored to achieve relatively stable clinical conditions in each patient. At discharge from hospital, based on the severity of their symptoms, patients were classified as NYHA class II ($n = 33$), class III ($n = 21$) and class IV ($n = 3$), and were randomized to: (1) a control group, receiving standard care based on routinely scheduled clinic visits, performed by a team specialized in CHF patient management; or (2) a home telemonitoring group, managed by the same specialized CHF team. Both groups entered a 12-month follow-up period. Subjects of the control group were contacted monthly by telephone to collect data on new hospital admissions, cardiovascular complications and death. They were regularly seen in the CHF outpatient clinic every four months, additional visits being performed whenever required by changes in clinical status. Subjects randomized to the home telemonitoring group, or one of their relatives, were contacted by telephone at least once a week by the CHF team, to collect information on symptoms and adherence to prescribed treatment as well as blood pressure, heart rate, body weight and 24 h urine output on the previous day. A weekly ECG transmission was also required.

Based on the evaluation of all these parameters, the therapeutic regimen was regularly re-assessed and altered when necessary. In addition, clinic visits were performed whenever needed, based on telemonitored data or on telephone interviews. Decision for hospital re-admission during follow-up in both groups was always taken after consulting a CHF team member and according to predefined criteria based on a set of clinical signs and symptoms related to worsening of cardiac insufficiency or to its complications. These included appearance or worsening of dyspnoea at rest or during exercise (worsening of NYHA class to III or IV), appearance or worsening of peripheral oedema, severe hypotension, clinically significant arrhythmias, progressive worsening of renal function, acute coronary syndromes, transient cerebral ischaemic episodes or stroke.

Patients and home caregivers (spouses, children or close relatives) underwent a training course during the hospitalization period, to apply the home study protocol and ensure correct use of equipment. Patients randomized to the control group underwent a similar course, aimed at explaining the importance of adherence to therapeutic prescriptions as well as of maintaining a suitable lifestyle.

In both groups the relevant clinical values and the type and dose of administered drugs were assessed at the end of the 12-month follow-up, and compared with baseline data at discharge from hospital. Mortality and rate of hospitalization during follow-up were also assessed. A quality-of-life questionnaire (SF-36) was administered both during the initial hospitalization and at the end of follow-up.

The study was approved by the appropriate ethics committee. All subjects provided informed consent before entering the study.

Endpoints

The primary composite endpoint was combined rate of mortality and hospitalization. The secondary endpoints were rates of mortality and hospitalization separately considered, and quality-of-life score over the follow-up period.

Measurements

During the initial hospitalization patients underwent a thorough clinical evaluation, including careful history collection and physical examination, ECG, cardiac doppler ultrasonography, chest X-ray and routine blood

examination, and were administered an SF-36 questionnaire on health-related quality of life. Blood pressure was measured three times at 1-minute intervals in the sitting position according to the ESH-ESC 2003 Guidelines, making use of the same validated oscillometric device (A&D UA 767 PC) selected for home BP measurements in the group randomized to remote monitoring (see below). In the latter group, patients were required to measure their home BP daily, a transtelephonic ECG recording (Card-Guard CG-7100 12-lead device, Card Guard Scientific Survival Ltd, Israel) being obtained weekly and checked.

Statistical analysis

Data were tested for normal distribution using the Shapiro-Wilks test. Within-group differences between baseline and follow-up were assessed by repeated measures analysis of variance for normally distributed continuous variables. The χ^2 test was used for discrete variables and the Mann-Whitney and Wilcoxon rank sum tests for non-normally distributed variables. Between group differences in the incidence rate of the predefined combined end point (recurrent hospitalization plus death) were assessed by the Z-test. Differences in type of drugs administered at baseline and at follow-up were assessed by the non-parametric McNemar test.

A minimum sample size of 55 was required in relation to the primary endpoint, with a power of 80% and an α error of 0.05 (two-tailed test). The study power was >95% for almost all the variables considered with the exception of differences in ejection fraction (power 79%), and in number of patients treated with ACE inhibitors (power 88%). Analysis was carried out using standard software (SPSS Version 10.0, SPSS Inc., Chicago, Illinois, USA).

Results

The clinical characteristics of the 29 patients randomized to the control group and of the 28 patients randomized to the home telemonitoring group are shown in Table 1. In baseline conditions, at the time of discharge from hospital, no significant between-group difference was observed in age, NYHA class, ejection fraction (echocardiography), pulse pressure, systolic and diastolic blood pressure (average of three measurements taken in the sitting position), heart rate, pCO_2, serum creatinine, sodium and potassium concentration, urine output, and in the use of the various types of drugs commonly employed in CHF patients (data not shown). Two patients in the control group and one in the home telemonitoring group had an ICD implanted. The low rate of statins prescribed at baseline was due to failure by GPs to strictly follow the recommended scientific guidelines, probably due to their exposure to heavy pressure by public health-care authorities to reduce patients' management costs.

Table 1 Baseline clinical characteristics of the subjects included in the two study groups. None of the differences were significant ($P > 0.05$)

	Home telemonitoring ($n = 28$)	Controls ($n = 29$)
Age, years (SD)	77 (8)	79 (6)
Men/Women (*n*, %)	16 (57/43%)	19/10 (66/35%)
Idiopathic dilated CMP	2 (7%)	3 (10%)
Ischaemic CMP	19 (68%)	19 (66%)
Valvular CMP	2 (7%)	1 (3%)
Hypertensive CMP	5 (18%)	6 (21%)
NYHA Class (*n*,%)		
II	15 (54%)	18 (62%)
III	12 (43%)	9 (31%)
IV	1 (4%)	2 (7%)
Ejection fraction, % (SD)	35 (6)	37 (7)
Pulse pressure – supine, mmHg (SD)	41 (8)	38 (8)
Systolic BP – supine, mmHg (SD)	130 (17)	135 (13)
Diastolic BP – supine, mmHg (SD)	80 (8)	83 (6)
Heart rate – supine min (SD)	73 (7)	74 (6)
Respiration rate, breaths/min(SD)	17 (2)	17 (2)
PaO_2, mmHg (SD)	63 (5)	60 (5)
$PaCO_2$, mmHg (SD)	38 (4)	37 (4)
Serum creatinine, mg/dl (SD)	1.5 (1.9)	1.3 (0.5)
Serum sodium, mmol/L (SD)	139 (2)	139 (2)
Serum potassium, mmol/L (SD)	4.2 (0.3)	4.1 (0.3)
Plasma cholesterol, mg/dl (SD)	223 (29)	229 (29)
24 h urine output, ml/24 h (SD)	1536 (421)	1479 (326)

Between-group differences in the type of prescribed drugs were conversely found at the end of the 12-month follow-up. While the home telemonitoring group was characterized by a significant increase in the use of beta-blockers, statins and aldosterone antagonists and by a reduction in nitrates administration as compared to baseline, no such differences between baseline and follow-up was observed in the control group. Patients compliant with prescribed treatment amounted to 26 (91%) in the home telemonitoring group versus 10 (46%) in the control group ($P < 0.03$). As shown in Table 2, in the home telemonitoring group there was at follow-up a tendency (NS) towards an increase in left ventricular ejection fraction, accompanied by a reduction in diastolic blood pressure and heart rate ($P < 0.01$). A reduction in diastolic blood pressure and heart rate at follow-up was observed also in the control group ($P < 0.01$), while plasma cholesterol was significantly reduced only in the home telemonitoring group. No significant between-group differences in diastolic function at baseline and between baseline and follow-up could be observed (data not shown). In the home telemonitoring group, ECG teletransmission did not allow any myocardial infarction to be diagnosed at home, while we observed five episodes of atrial fibrillation.

The 12-month occurrence of the primary combined endpoint of mortality and hospital re-admission for CHF

Table 2 Changes in clinical variables between baseline and follow-up in the two groups (mean values with SD in parentheses)

	Home telemonitoring ($n = 28$)		Controls ($n = 29$)	
	Baseline	Follow-up	Baseline	Follow-up
Ejection fraction (%)	35 (6)	37 (7)	37 (7)	37 (7)
SBP – supine (mmHg)	130 (16)	129 (9)	135 (13)	132 (14)
DBP – supine (mmHg)	80 (8)	77 (5)**	84 (6)	78 (6)**
Heart rate – supine (min)	73 (7)	67 (7)**	74 (6)	70 (6)**
Serum sodium (mmol/L)	139 (2)	138 (2)	139 (2)	138 (2)
Serum potassium (mmol/L)	4.2 (0.3)	4.2 (0.4)	4.1 (0.3)	4.0 (0.3)
24 h urine output (ml/24 h)	1534 (421)	1532 (321)	1479 (326)	1486 (464)
Plasma cholesterol (mg/dl)	223 (29)	193 (14)**	229 (29)	226 (27)

**$P < 0.01$ for differences between baseline and follow-up

was significantly lower in the home telemonitoring group when compared to controls (Z-test = 2.8, $P = 0.006$) (Table 3). The benefit achieved in the home telemonitoring group in relation to the primary combined endpoint is further illustrated by the Kaplan-Meier curves of Figure 1. As shown in Figure 2, when these two endpoints were separately considered, the patients in the home telemonitoring group still displayed a significantly lower rate of hospital re-admission ($n = 9$) versus the control group ($n = 26$, $P < 0.05$), and a tendency towards a lower death rate ($n = 3$ in home telemonitoring versus $n = 5$ in control group, NS). Table 4 shows the scores obtained from analysis of the health-related quality-of-life SF-36 questionnaire. The ANOVA for repeated measures did not show any difference between groups at baseline. However, patients randomized to home telemonitoring were characterized at follow-up by a significantly better reported health perception (HP) score as compared to baseline. This improvement was significantly greater as compared to controls ($P = 0.046$).

Discussion

The main result of our randomized controlled study is that, in a group of elderly patients with CHF, home telemonitoring-based integrated management resulted in a significant reduction in the combined rate of mortality and hospital re-admission for CHF,[13,14] when compared with a standard care approach. The benefit associated with home telemonitoring was so pronounced as to become already evident after one year, i.e. after a relatively short follow-up period and with the background of high quality health care in both groups. These observations on the clinical usefulness of home telemonitoring in the very elderly represent novel information and extend previous results[15–19] obtained in middle-aged subjects with CHF. Moreover, the significant reduction in our combined endpoint supports the possibility of reduced health-care costs also in the management of elderly patients with CHF, both by reducing disease progression and by improving patients' compliance with treatment.

A few other results of our study deserve mention. First, a higher number of CHF patients in the home telemonitoring than in the control group were able to regularly continue beta-blockers and high doses of diuretics. This was probably due to the possibility offered by home telemonitoring to continuously assess the effects of these treatment strategies on body weight, urine output, blood pressure, ECG and heart rate, as well as to detect early the possible occurrence of side-effects that would require immediate changes in the administered treatment. The result was a more precise dose adjustment in the individual patient, leading to a better tolerability of these drugs and thus to a greater patient's compliance with the prescribed therapeutic regimen as compared to that observed in the control group. Second, the home telemonitoring group was characterized by

Table 3 Incidence of the primary combined endpoint of mortality and hospital admission rate. The effective absolute follow-up period was 10 months (12 months corrected for death of eight patients)

	Home telemonitoring ($n = 28$)	Controls ($n = 29$)
Combined events	12	31
Patient-months follow-up	280	290
Mean incidence rate, events/patient/month*	0.043	0.107

*Z test = 2.8 ($P = 0.006$)

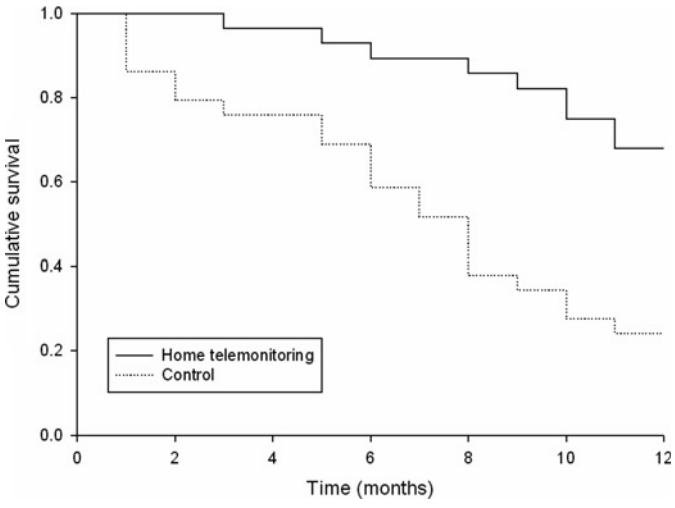

Figure 1 Event-free survival curves related to the study primary endpoint (combination of mortality and hospital re-admission) for the home care telemonitoring and control group (log rank = 12.6, $P < 0.001$)

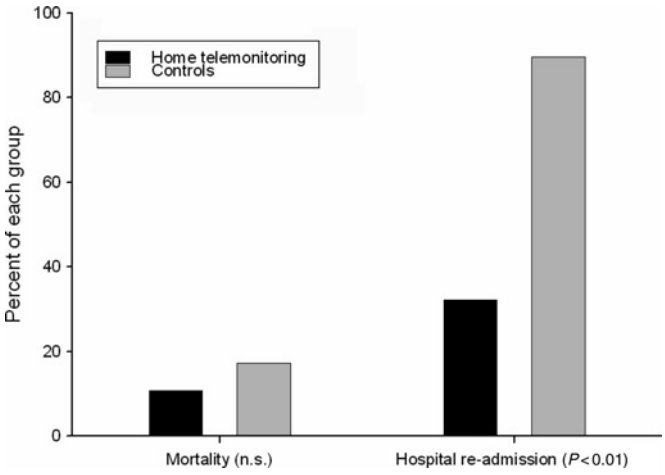

Figure 2 Mortality (3 vs. 5 patients) and recurrent hospital admissions (9 vs. 26 patients) after 12-month follow-up in the home care telemonitoring and in the control group, respectively

a higher frequency of statins administration, and these drugs were also given at higher doses. This difference in treatment, by more effectively treating hypercholesterolaemia ($P < 0.01$), might also have contributed to the lower rate of cardiovascular complications at follow-up. Indeed, in the control group, lack of close monitoring was probably the main reason for the inability to properly titrate drug dosages, and thus for a less effective clinical management. Third, the clinical benefits of home telemonitoring in our elderly patients with CHF were clearly evident even on the background of a high level of care delivered by the same team of clinical cardiologists, to patients randomized to both groups. This indicates a further improvement in the management of elderly patients with CHF by home telemonitoring, compared to the advantages already obtained by the involvement of a specialized CHF clinic team.[20,21] This improvement is further emphasized by the better quality-of-life score achieved by the home telemonitoring than by the control group. Fourth, when considering the relative importance of the various components of the telemonitoring approach, we observed that the home telemonitoring-related benefits were only partly due to the ECG transmission, which was generally less than that of the daily contact of the patient with the nurse or the cardiologist in charge.

Some limitations of our study must also be acknowledged. These include the relatively low number of patients due to highly selective entry criteria (59% inclusion rate) and the fact that telemonitoring was not performed daily. Moreover, the heart failure therapy in our study was not up to date at baseline (as indicated by the high use of digitalis and calcium-channel blockers, the relatively low dose of ACE-inhibitors and the low use of beta-blockers), although the patients were referred to our hospital by general practitioners who were responsible for their daily management before entering the study. In spite of this, our results are very encouraging as they demonstrate the favourable effect that even a simple home telemonitoring approach may have in elderly chronic heart failure patients, characterized by high morbidity and mortality rates.[22] Finally, a detailed analysis of the economic impact of our approach has not yet been performed.

Thus, the present study suggests that telemonitoring of elderly patients with CHF is a valuable tool in improving their clinical management, although our positive results need to be confirmed by additional studies including a larger number of patients followed up over a longer observation period and a formal health economics analysis.

Table 4 Health-related quality-of-life scores (SF-36) (mean values with SD in parentheses)

	Home telemonitoring ($n = 28$)		Controls ($n = 29$)	
	Baseline	Follow-up	Baseline	Follow-up
Physical functioning (PF)	55 (23)	50 (32)	54 (28)	43 (32)
Role functioning – physical (RP)	23 (31)	46 (50)	50 (45)	63 (45)
Bodily pain (BP)	80 (28)	79 (28)	48 (35)	69 (35)
General health (GH)	43 (19)	51 (21)	40 (20)	42 (32)
Vitality (VT)	51 (27)	58 (20)	47 (26)	55 (15)
Social functioning (SF)	68 (29)	90 (25)	66 (27)	85 (31)
Role functioning – emotional (RE)	53 (41)	83 (33)	64 (48)	56 (50)
Mental health (MH)	64 (17)	66 (17)	62 (25)	66 (17)
Reported health perception (HT)	25 (11)	56 (26)*	27 (29)	35 (27)
Physical component summary (PCS)	38 (7)	39 (11)	34 (10)	39 (11)
Mental component summary (MCS)	45 (11)	53 (12)	46 (11)	48 (9)

*$P < 0.05$ for differences between baseline and follow-up

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