Tele-guidance of chronic heart failure patients enhances knowledge about the disease. A multi-centre, randomised controlled study

Aggie H. Balk a,⁎, Wim Davidse b, Paula van Dommelen b, Ellen Klaassen a, Kadir Caliskan a, Pieter van der Burgh c, Christina M. Leenders d

a Department of Cardiology, Thoraxcentre, Erasmus MC, Rotterdam, The Netherlands
b TNO Quality of Life, Leiden, The Netherlands
c Department of Cardiology, Medisch Spectrum Twente, Enschede, The Netherlands
d Department of Cardiology, Havenziekenhuis, Rotterdam, the Netherlands

Received 25 March 2008; received in revised form 8 June 2008; accepted 18 August 2008
Available online 13 September 2008

Abstract

Background: New strategies are required to optimize care in increasing numbers of chronic heart failure patients. The aim of this randomised trial was to evaluate a remote guidance system.

Methods: Intervention group patients received a home TV-channel providing educational materials. Tele-guidance was performed by a Medical Service Centre. Control group patients were followed by cardiologists and HF-nurses. Primary endpoints were total days in hospital for all causes and days alive and out of hospital. Secondary endpoints were: quality of life and knowledge of disease and self care.

Results: 214 patients were enrolled, median age was 66 years, 89% had systolic LV dysfunction, and 90% were in NYHA class II or III. The mean LVEF was 31%. Over a mean follow-up duration of 288 days, there were 199 hospital admissions in 105 patients. Comparison of the groups revealed no differences for the primary outcomes or for QoL or self care behaviour. Knowledge about heart failure however, increased significantly more in the Intervention group (p<0.001).

Conclusion: Tele-guidance may play a role in the management of heart failure patients since it takes over some of the tasks of HF-nurses. This may facilitate delivery of optimal care to more patients with the same level of experienced staff.

© 2008 European Society of Cardiology. Published by Elsevier B.V. All rights reserved.

Keywords: Tele-medicine; Telemonitoring; Heart failure; Education; Knowledge

1. Introduction

Patients suffering from chronic heart failure (HF) benefit from evidence-based treatment and intensive, multidisciplinary follow-up [1–5]. As a result of such treatment, the prognosis of hospitalised HF patients has improved and, after a steep increase in the number of hospital admissions for HF during the 1980s and early 1990s, we have witnessed a decline in hospitalisations since 1994 [6,7]. However, this improved prognosis does not apply to the very elderly, in whom evidence-based treatment is underused [8].

Since the prevalence of HF increases with age, and the proportion of the Western world population that is aged over 65 years is likely to increase considerably in the coming years [9,10], it is likely that we will become responsible for the treatment of increasing numbers of HF patients in the future [11,12]. Many of these elderly patients will be less mobile and will depend on others to visit doctor’s offices and hospital clinics.

Awareness of these developments and a relative lack of expert staff have stimulated the search for novel strategies to...
facilitate the provision of optimal care to all HF patients. Advances in technology and the availability of patient-friendly equipment have provided methods for the evaluation of vital signs in the home setting. To date, several models of remote monitoring (transfer of data such as blood pressure, weight, rhythm etc.) or structured telephone support have shown positive effects on clinical outcome and/or costs in randomised controlled trials [13].

The benefit of pharmacological HF treatment can only be achieved when follow-up is combined with measures to enhance patients’ knowledge about their condition as well as with measures to improve adherence to the necessary lifestyle regimen. These measures must also take into account the cognitive impairment which is relatively common in patients with heart failure [14]. Therefore, the logical next step in HF telemedicine is the incorporation of educational materials and scheduled reminders to enhance adherence to the agreed treatment regimen.

Supported by the experience gained in the TEN-HMS study, the purpose of this randomised controlled study was to evaluate the effects of guidance provided by the MOTIVA system, in patients with chronic heart failure [15]. In addition to telemonitoring of physiological data, the MOTIVA system also provides educational and motivational materials to improve patients’ knowledge and adherence to treatment.

2. Methods

2.1. Patients and study design

This prospective, multi-centre, randomised study was proposed and funded by the health care insurance company Achmea and was designed by the first two authors. TNO Quality of Life regulated the randomisation process and analyzed the data. Patients with chronic heart failure, who were in a stable condition, in NYHA class I–IV and who were under the care of cardiologists and HF-nurses at 8 Dutch hospitals (one heart failure/transplant centre, seven general hospitals), were eligible for inclusion. Contrary to most other randomised trials of telemonitoring, prior hospital admission for treatment of heart failure was not a prerequisite. After informed consent, patients were assigned to either the Intervention group (I) or the Control group (C). Patients in Group I received a MOTIVA system, in addition to their scheduled visits to the cardiologist. The system included a secured broad band home TV-channel providing educational material, reminders of medication, health related surveys and motivational messages to encourage the prescribed lifestyle regimen. A subgroup of patients (Intervention-plus), who had been in hospital for HF treatment in the year preceding enrollment, were also given automated devices for daily measurements of blood pressure and weight. Each device contained a short-range radio-transmitter that allowed it to communicate automatically with a hub connected to the patients’ telephone line and thereby automatically to a central web server. The web server was linked to workstations at a Medical Service Centre (MSC) and the participating Cardiology Departments via secure Internet connections. Data were encrypted during transmission to ensure patient confidentiality. Patients from both Intervention groups received instructions on how to use the TV-channel and the measurement devices by a service engineer who visited each patient at home. Tele-guidance and monitoring of daily measurements were performed by MSC nurses who had been trained in heart failure management and who were supervised by physicians.

The guidance provided to each patient by the MSC followed a personalized plan, which was specified by the treating cardiologist and hospital-based HF-nurse at the start of the study. The plan included the prescribed medication, advice about salt restriction and fluid intake as well as the agreed lifestyle regimen. Additionally, the medical history of the patient and information about his/her social environment was provided. Individual problems, often related to co-morbid conditions, were given extra attention. For the patients equipped with the measurement devices, ranges were set for blood pressure as well as weight. MSC staff was available during office hours for telephone contacts and analysis of the daily measurements of the telemonitored patients. Changes in treatment were only made in consultation with the hospital-based cardiologist or HF-nurse. Patients in group I therefore had no direct contact with their cardiologist or hospital-based HF-nurse between outpatient clinic visits. Group C patients were followed by their cardiologists and HF-nurses according to standard local practice. HF-nurses were available during office hours, but the degree of availability during those hours varied in the participating hospitals. All patients kept records, in a diary, on their contacts with health care professionals and hospital admissions.

Quality of life was measured using the following questionnaires: SF-36 and the Dutch version of the Minnesota Living with Heart Failure Questionnaire. Self care was measured by the European Heart Failure Self Care Behaviour Scale [16,17]. The EuroQol questionnaire was added to assess cost-effectiveness.

Knowledge about heart failure and its management was tested using the Dutch Heart Failure Knowledge Score, which had been developed for the COACH study [18,19]. The questionnaires were completed at baseline and every 4 months thereafter. Data were collected both by the hospital-based HF-nurses and the MSC staff. The latter group entered the data into an electronic database.

The study conformed with the principles outlined in the Declaration of Helsinki and was approved by the Institutional Review Board of the Erasmus MC as well as the boards of all other participating hospitals [20]. All patients provided written informed consent.

2.2. Outcome measures, sample size and randomisation

Primary outcomes of the study were: total days in hospital for all causes per year (based on hospital days and days in
trial) and days alive and out of hospital. Secondary outcomes were: quality of life and knowledge of disease and self care.

A meaningful power analysis was not possible because of the absence of data in the literature and insufficient data from the hospitals on hospital admissions for these patients, who had not necessarily had a recent admission to hospital for heart failure treatment.

Randomisation was performed in a 1:1 ratio, in randomly permuted blocks of 30 per participating centre. Randomisation was independently performed by TNO Quality of Life, Leiden, the Netherlands, via a special Web-based application.

2.3. Data analysis and statistics

Comparisons between the Intervention and the Control groups were made by intention-to-treat. Comparisons of baseline data were made using the Chi-square test (categorical data) or by analysis of variance (ANOVA). A $p$-value $<0.05$ was considered significant. Differences found by analysis of variance were checked by the non-parametric Mann–Whitney test. Differences in hospital days and “days alive and out of hospital” were tested by a one-sided $T$-test. Log transformation was applied to the number of hospital days in order to acquire a

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control</th>
<th>Intervention</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Numbers randomly assigned</td>
<td>113</td>
<td>101</td>
<td>214</td>
</tr>
<tr>
<td>Age, years (median, range)</td>
<td>65 (42–87)</td>
<td>68 (33–85)</td>
<td>66 (33–87)</td>
</tr>
<tr>
<td>Age ≥70 years ($n$)</td>
<td>47 (42%)</td>
<td>45 (45%)</td>
<td>92 (43%)</td>
</tr>
<tr>
<td>Female ($n$)</td>
<td>28 (25%)</td>
<td>36 (36%)</td>
<td>64 (30%)</td>
</tr>
<tr>
<td>Primary cause of heart failure ($n$)</td>
<td>Ischaemic HD 69 (61%)</td>
<td>53 (53%)</td>
<td>122 (57%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>6 (5%)</td>
<td>9 (9%)</td>
<td>15 (7%)</td>
</tr>
<tr>
<td>Valvular disease</td>
<td>6 (5%)</td>
<td>10 (10%)</td>
<td>16 (8%)</td>
</tr>
<tr>
<td>Dilated CMP</td>
<td>26 (23%)</td>
<td>23 (23%)</td>
<td>49 (23%)</td>
</tr>
<tr>
<td>Other</td>
<td>6 (5%)</td>
<td>6 (6%)</td>
<td>12 (6%)</td>
</tr>
<tr>
<td>Comorbidities ($n$)</td>
<td>Hypertension 35 (30%)</td>
<td>36 (35%)</td>
<td>71 (32%)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>36 (31%)</td>
<td>31 (30%)</td>
<td>67 (31%)</td>
</tr>
<tr>
<td>COPD</td>
<td>23 (20%)</td>
<td>28 (27%)</td>
<td>51 (23%)</td>
</tr>
<tr>
<td>Functional class ($n$)</td>
<td>NYHA I 8 (7%)</td>
<td>6 (6%)</td>
<td>14 (7%)</td>
</tr>
<tr>
<td>NYHA II</td>
<td>44 (38%)</td>
<td>43 (41%)</td>
<td>87 (40%)</td>
</tr>
<tr>
<td>NYHA III</td>
<td>56 (48%)</td>
<td>50 (48%)</td>
<td>106 (48%)</td>
</tr>
<tr>
<td>NYHA IV</td>
<td>3 (3%)</td>
<td>2 (2%)</td>
<td>5 (2%)</td>
</tr>
<tr>
<td>ECG</td>
<td>Sinus rhythm ($n$) 72 (62%)</td>
<td>75 (72%)</td>
<td>147 (67%)</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>24 (21%)</td>
<td>11 (11%)</td>
<td>35 (16%)</td>
</tr>
<tr>
<td>PM rhythm</td>
<td>17 (15%)</td>
<td>15 (14%)</td>
<td>32 (15%)</td>
</tr>
<tr>
<td>QRS ≥120 ms ($n$, %) (without pacemaker) 62 (56%)</td>
<td>53 (54%)</td>
<td>115 (55%)</td>
<td></td>
</tr>
<tr>
<td>Patients with CRT</td>
<td>11 (10%)</td>
<td>9 (9%)</td>
<td>20 (9%)</td>
</tr>
<tr>
<td>Patients with ICD</td>
<td>19 (17%)</td>
<td>14 (14%)</td>
<td>33 (15%)</td>
</tr>
<tr>
<td>LV systolic dysfunction ($n$, %)</td>
<td>107 (92%)</td>
<td>89 (86%)</td>
<td>196 (89%)</td>
</tr>
<tr>
<td>LV function measurements</td>
<td>EF measured ($n$) 87 (75%)</td>
<td>79 (76%)</td>
<td>166 (75%)</td>
</tr>
<tr>
<td>LV EF (% mean, range)</td>
<td>31 (11–71)</td>
<td>31 (9–69)</td>
<td>31 (9–71)</td>
</tr>
<tr>
<td>LVEF &lt;25% ($n$, %)</td>
<td>27 (31%)</td>
<td>24 (31%)</td>
<td>51 (31%)</td>
</tr>
<tr>
<td>LVED echo (mm, mean, range)</td>
<td>63 (41–87)</td>
<td>61 (37–99)</td>
<td>62 (37–99)</td>
</tr>
<tr>
<td>Laboratory investigations</td>
<td>Hb (mmol/L, mean, SD) 8.6 (±1.0)</td>
<td>8.5 (±0.9)</td>
<td>8.6 (±0.9)</td>
</tr>
<tr>
<td>Serum sodium (mmol/L)</td>
<td>139 (±3.3)</td>
<td>139 (±3.0)</td>
<td>139 (±3.2)</td>
</tr>
<tr>
<td>Serum creatinine (μmol/L)</td>
<td>118 (±43)</td>
<td>128 (±53)</td>
<td>123 (±48)</td>
</tr>
<tr>
<td>Creatinine &gt;180 μmol/L ($n$, %)</td>
<td>6 (57%)</td>
<td>16 (16%)</td>
<td>22 (11%)</td>
</tr>
<tr>
<td>NT-proBNP (pg/ml, mean, range)</td>
<td>340</td>
<td>288</td>
<td>314</td>
</tr>
<tr>
<td>Number of hospital admissions for HF &lt;12 mos (mean, range, SD)</td>
<td>0.74 (0–5), SD 0.99</td>
<td>0.41 (0–2), SD 0.53</td>
<td>0.58 (0–5), SD 0.77</td>
</tr>
<tr>
<td>Number of hospital admissions &lt;12 mos for other cardiac problems</td>
<td>0.49 (0–7), SD 1.15</td>
<td>0.32 (0–3), SD 0.68</td>
<td>0.41 (0–7), SD 0.96</td>
</tr>
<tr>
<td>Number of hospital admissions &lt;12 mos for non-cardiac problems</td>
<td>0.20 (0–4), SD 0.59</td>
<td>0.41 (0–8), SD 1.13</td>
<td>0.30 (0–8), SD 0.89</td>
</tr>
</tbody>
</table>

Percentages have been corrected for missing values. HD = heart disease, CMP = cardiomyopathy, CRT = cardiac resynchronization therapy, ICD = implantable cardiac defibrillator, COPD = chronic obstructive pulmonary disease, LVEF = left ventricular ejection fraction, LVED = left ventricular enddiastolic dimension mos = months, $p=0.011$, $**p=0.001$, $p=0.006$ in non-parametric test.
more normal distribution and less extreme durations of admission.

Differences in quality of life between the baseline and the last measurement per patient were tested in two ways: by analysis of variance using the baseline measurement as covariate (ANCOVA) and by analysis of variance using the difference score as the independent variable (ANOVA).

3. Results

3.1. Patients

Between July 1, 2005 and August 31, 2006 a total of 214 patients were enrolled into the study and randomly assigned to the Control group (n = 113) or the Intervention group (n = 101). Patient characteristics are shown in Table 1. Unsurprisingly given the study population, most patients suffered from systolic dysfunction of the left ventricle. Only 43% of patients were aged 70 years or older, ischaemic heart disease was the cause of heart failure in more than half of the population and co-morbidity was high. Most patients were moderately ill as is shown by their functional class (90% in NYHA class II or III), left ventricular ejection fraction (mean 31%) and NT-proBNP levels (median 314 pg/ml). Over 30% of the patients had severely depressed LV function (LVEF < 25%) and in 55% a QRS duration of 120 ms or more was noted. Patients were treated according to current guidelines: 96% received an angiotensin converting enzyme inhibitor (ACE-I) or angiotensin receptor blocker (ARB), 78% received a β-blocker and 46% received an aldosterone antagonist (Table 2).

There were some slight differences in baseline characteristics between patients in the Control group and those in the Intervention group. The mean number of hospital admissions during the year prior to enrollment was larger in the Control group than in the Intervention group. In addition, there were more patients with serum creatinine levels >180 μmol/l (= 2.0 mg/dl) and more patients on thyroid medication in the Intervention group compared with the Control group.

3.2. Follow-up and hospital admissions

Follow-up ranged from 2 to 537 days with a mean of 288 days. Eighteen patients participated for less than 120 days and 57 patients for more than 365 days. During the follow-up period, 199 all-cause hospital admissions were registered for 105 patients (39 of these were for only 1 day). Ten patients, each of whom had more than 3 admissions, accounted for a total of 58 admissions. The other 95 patients had 1 (61 pts), 2 (22 pts) or 3 (12 pts) admissions. Seventeen patients died, 8 in the Control group and 9 in the Intervention group.

No differences between the two groups were found for the number of days in hospital and days alive and out of hospital (Table 3). A per protocol analysis did not show any difference either (data not shown).

Reasons for hospital admission were decompensated heart failure in 19% and other cardiac problems in 52%. Non-cardiovascular problems were the cause in 29% of the admissions. Differences between the Intervention and Intervention-plus groups have not been tested because the groups were not comparable at baseline (Intervention-plus patients had to have had at least one HF admission in the year preceding enrollment). A trend towards a beneficial effect of...
telemonitoring however, was seen in a lower number of hospital admissions in the sickest group (the ones who had a recent admission for HF: Intervention-plus), although the number of days in hospital per day in the trial did not differ.

To get an impression of the effect of the duration of guidance by the MOTIVA system, the study population was divided into patients who were in the study for longer than 120 days, for longer than 240 days and for longer than 360 days. Results in this series of declining numbers of patients (only 34 patients in the Intervention- and 37 patients in the Control group survived long enough to participate longer than 360 days) suggest that less hospital admissions may occur in the Intervention group in the long run.

### 3.3. Quality of life and knowledge of heart failure

No differences in quality of life and self care behaviour were found between the Control group and the Intervention group either at the start or at the end of the study. Knowledge about heart failure and its management, as tested by the Dutch Heart Failure Knowledge Score, was the same in both groups at the start of the study ($p$-values untransformed 0.71 and transformed 0.61). However, the increase in knowledge about heart failure was significantly higher in the Intervention group than it was in the Control group ($p$-values untransformed 0.001 and transformed <0.001).

### 3.4. Consumption of health care

Apart from the hospital admissions and contacts with the Medical Service Centre, a trend towards a reduction in contacts with health care professionals in the Intervention group compared with the Control group was observed. With no decrease in hospital days or health care consumption and with the extra costs of the MOTIVA system and the Medical Service Centre, overall costs were higher in the Intervention group than the Control group.

### 3.5. Acceptability of the system

Although 45% of the patients in the Intervention group were aged 70 years or older, the acceptance of the guidance system was high. The ease of use was rated very good or good by 80% of the users. Seventy percent of the users mentioned that their access to doctors and nurses was better with remote patient management compared to the service they had received before.

Cardiologists and HF-nurses adopted a wait-and-see attitude to the interposition of a Medical Service Centre between heart failure clinics and patients. However, no problems related to this interposition, for example misunderstandings or delays in treatment, were noted during the study.

### 4. Discussion

This study shows that tele-guidance can increase patients’ knowledge about heart failure and its management. As education is the most time consuming part of the HF-nurses’ work, this means that the use of tele-guidance as part of a disease management system will significantly lighten the load of HF-nurses. Thus HF-nurses can either spend more time on other tasks, or can provide care to larger numbers of patients. This is very important when considered in light of the increasing number of heart failure patients, many of whom will experience difficulties in reaching hospital clinics and/or will suffer from cognitive impairment [8–11,14]. In order to deliver the intensity of follow-up that has been shown to result in longer survival, and sometimes in a reduced number of hospital admissions, we are obliged to search for strategies that are more efficient in terms of staff and thereby costs.

Although education is a precursor of self care behaviour, no significant difference was found for the changes between baseline and end of the study in the Self Care Behaviour Scale between the Intervention and the Control groups. An explanation may be that almost all patients were already being followed by HF-nurses prior to enrolment in the study. Therefore, to explore the total effects of the MOTIVA system, it needs to be evaluated in “clean” patients and in heart failure patients who are followed by care-givers who are not specialized in the management of heart failure, such as general physicians and internists.

Although we studied patients with a wide range of functional classes and ventricular dysfunction, it has to be kept in mind that the population was a selected one. All patients were under the care of a cardiologist and the majority suffered primarily from systolic dysfunction of the left ventricle. Medical treatment was according to current guidelines and co-morbidity was high. From the finding that 55% of the patients had QRS durations of >120 ms on their ECG and many had low LV ejection fractions, it may be deduced that there was room for improvement in treatment, as many patients could be candidates for resynchronization therapy and prophylactic ICD implantation. The median age of the patients in our study was about 10 years younger than the age of heart failure patients in the community [21]. However, more than 40% of our patients were older than 70 years and despite this, the acceptance of and coping with the MOTIVA system was excellent.

Repeated presentation of information is a requirement for adherence to the necessary lifestyle regimen in heart failure, therefore our findings support application of tele-guidance to the whole range of heart failure patients. A medical service centre can support the logistics of such educational activities or provide telemonitoring services.

Although not measured, it became clear that patients who feel relatively well and who have shown themselves capable of self care do not benefit from having measurement devices. However, patients who have been diagnosed with heart failure for the first time or patients who still fail to recognize warning signs can learn from daily measurements and feedback by their local HF-nurse or the MSC staff. During uptitration of beta-blockers patients can be monitored closely.
and changes in medication can be made without scheduled visits to an outpatient clinic. In this study, some of the HF-nurses considered the involvement of a Medical Service Centre in the remote management of the patients an unnecessary detour. It took them more time than before to get regimens changed after problems had been noticed by the MSC via the telemonitoring system or by phone contacts. However, nurses who had less time available valued the involvement of the MSC because of its triage function. Implementation of remote management systems therefore should allow heart failure clinics to make independent choices for the different components of the system.

Because the reasons for hospital admission are not important in terms of health care costs, we evaluated all-cause admissions and found no differences between the Intervention and the Control groups for days in hospital or days alive and out of hospital. The latter finding is in line with almost all previous studies of the effects of intensive follow-up by structured telephone support or telemonitoring which did not show reductions in all-cause admissions [13,22,23]. With the proven effects of intensive follow-up on survival and quality of life however, the absence of more hospitalisations or higher mortality in patients who are guided by tele-technology is an encouraging finding. We also found no differences in NT-proBNP values between the two groups at the end of the study. When costs are counterbalanced by the need for less experienced staff, the use of telemedicine may prove to be affordable. A formal comparison of the hospital admission data from the two Intervention subgroups (with or without telemonitoring of daily vital signs) has not been made because the groups were not comparable at baseline. Care should also be taken when comparing the results of the Intervention group “with devices” with results from studies which included patients at or immediately after discharge of a heart failure admission.

In the Intervention group a trend was noted toward a decrease in visits to the Emergency Department, to the cardiologists’ outpatient clinic as well as less telephone contacts to the HF-nurse or general practitioner, but with the same number of visits to the HF-nurse outpatient clinic. The latter may be explained by the involvement of the MSC nurses. When problems were noted by the MSC, the hospital-based HF-nurses tended to see the patient themselves.

4.1. Study limitations

Our population was a selected one: the median age of the patients was relatively young, all patients were followed by cardiologists and about 90% suffered from systolic dysfunction of the left ventricle. Moreover, the majority of patients who participated in this study had already been followed by heart failure nurses prior to enrolment. This raises the question of whether the effects of the studied tele-guidance system would have been better in a “clean” heart failure population. Another weakness of the study is the interposition of a Medical Service Centre between the cardiologist/heart failure nurse and the patient without defining a further intervention group wherein HF-nurses and patients are directly connected with each other by the tele-guidance system. The total number of patients however was too small for this approach.

4.2. Conclusion

This study has shown that tele-guidance may play a role in the management of heart failure patients by taking over some of the tasks of the heart failure nurse. Careful selection of patients is required for the different components of telemedicine for heart failure: with education and information for all and telemonitoring of vital signs in patients who recently have been diagnosed with heart failure, or for patients who still fail to recognize the warning signs or patients who have to be monitored closely during up titration of medication. The involvement of a Medical Service Centre can be valuable for logistical reasons and can be used for triage, depending on the need of the individual heart failure clinics.

Acknowledgements

We thank the heart failure nurses of the participating Cardiology departments for enrolling the patients and providing follow-up and support. We thank the staff of the MSC for their contributions to the follow-up of the patients and for the data entry. Many thanks go to Jelle van der Weyde, Christoph Westertjeicher and Udo Goldbach of Philips for provision of the MOTIVA system.


References


