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Evaluation of a telemedicine system for heart failure patients: Feasibility, acceptance rate, satisfaction and changes in patient behavior Results from the CARME (CAtalan Remote Management Evaluation) study

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Abstract

Background: Telemedicine can be useful for managing heart failure (HF), but patient acceptance of telemedicine and its impact on patient behavior are unclear.
Aims: To assess a telemedicine program in a HF Unit.
Methods and results: This sub-analysis of the CARME study assessed the use of an interactive telemedicine platform. This prospective intervention study had a before/after design with HF patients randomized 1:1 into two groups: A) Motiva system (educational videos, motivational messages, and questionnaires); and B) Motiva system + telemonitoring of blood pressure, heart rate and weight. Of 211 patients screened, 44 were excluded, 62 did not consent to participate and 8 withdrew consent prior to installation of the system. The final study population included 97 patients. During 1 year of follow-up, 22 patients voluntarily discontinued use of the system, 5 died (three after early discontinuation) and 5 withdrew consent before the last evaluation. A total of 15,017 questionnaires were sent to patients, with a median response rate of 88%. Satisfaction with the system and tools was high (median score 8.4/10), especially with the self-monitoring chart, scale and sphygmomanometer. Positive changes were observed in patient behavior, especially for blood pressure and weight control ($p < 0.001$). After the study, 65% of the patients wished to continue with telemonitoring, particularly those in Group B ($p = 0.004$).
Conclusion: Less than half of our patients participated in the telemedicine study. However, those who completed the study had confidence in the system, a high degree of satisfaction with the tools and positive behavioral changes.

Keywords: Heart failure; Information and communication technologies; Disease management; Telemonitoring; Telemedicine; Behavior; Satisfaction

1. Introduction

Heart failure (HF) has a high prevalence, a poor prognosis and a high rate of hospital readmission [1,2]. Patient compliance with recommendations regarding lifestyle changes, adherence to treatment and self care is the key to reducing hospitalizations. Information and communication technologies provide new alternatives for patient monitoring

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and health education, complimenting other methods for involving patients in the treatment process that already exist [3–5]. Telemedicine can be useful when the following conditions are met: the system is easy to use; the patient complies with the program and plays an active role in managing the disease; there is adequate monitoring; the system has a direct impact on the fundamental aspects of patient management; and the system provides educational interventions that promote changes in patient behavior. Over the last few years, advances in technology and greater availability of user-friendly equipment had led to greater patient adherence and satisfaction with these technologies [6]. The results obtained with different telemonitoring systems in patients with HF have shown a global tendency towards a reduction in hospitalizations, although there is a great level of heterogeneity in the results achieved with the different telemedicine systems [4–8]. However, a very recent review has suggested a decrease in HF related hospitalisations, an improvement in quality of life and in evidence-based prescribing and even a reduction in all-cause mortality with telemonitoring [9]. Between 2007 and 2009, our unit evaluated a telemedicine program for patients with HF. The results of the CARME (CAtalan Remote Management Evaluation) study showed that the telemedicine program led to a significant reduction in hospital admissions and the number of days in the hospital for HF and other cardiac causes, as well as to a perception of better quality of life for the patients [10].

Few studies have addressed the feasibility of using telemonitoring programs in daily practice and satisfaction with the systems. This subanalysis of the CARME study evaluated the use of a telemedicine system in clinical practice for 1 year. This system used specifically designed educational videos as a new feature that was combined with questionnaires, messages to patients and self-monitoring equipment and involved patients in a multidisciplinary HF unit. The study evaluated the feasibility of the system as well as patient acceptance, confidence and satisfaction. It also estimated the impact of the program on patient behavior and analyzed compliance with recommendations and responses to questionnaires in relation to the length of follow-up.

2. Methods

2.1. Design and study population

This prospective intervention study had a before/after design. The study evaluated an interactive telemedicine platform in a multidisciplinary HF unit at a university hospital. All patients were followed-up at regular predefined intervals with additional visits as required in case of decompensation. The regular schedule of visits included a minimum of quarterly visits with nurses, biannual visits with physicians, and elective visits with geriatricians, psychiatrists and rehabilitation physicians. Each patient kept a weight chart that was reviewed at every visit. Face-to-face education was reinforced with printed leaflets for patients and relatives, and posters in the waiting room that alerted patients to the warning signs of worsening HF [11].

2.2. Procedures

Consecutive outpatients who attended our HF unit between July 2007 and December 2008 were asked to participate in the study. Inclusion criteria included: a) age ≥ 18 years; b) NHYA functional class II–IV HF; c) having a permanent residence (i.e. residing at one's own home or at the home of a family member/friend); d) having a television at home; and e) understanding and being able to adequately carry out self-monitoring at home as per the unit HF specialist nurse evaluation. Patients with a life expectancy of less than one year, patients participating in another study, and patients who did not consent to participate in this study were excluded. The study complied with the requirements of the declaration of Helsinki and was approved by the hospital's ethics committee. All participants gave informed written consent. Upon enrolment, the following information was collected and recorded: a) demographic characteristics, baseline clinical status and treatment; b) hospitalizations in the previous year and number of days spent in the hospital (for HF or for other cardiac causes); c) physical examination data; d) perception of quality of life using the EuroQoL visual analogue scale and the Minnesota Living With Heart Failure Questionnaire; and e) knowledge of the disease and compliance with blood pressure and weight self-monitoring as well as with other measures of health education.

Follow-up visits took place at 6 months and at the end of 1 year of telemonitoring. The nurses that participated in the study were the same than those involved in patients' usual care. By contrast, a physician not included in regular patient assistance (M.D.) performed the data registry.

Compliance with self-monitoring of blood pressure and weight (using a patient diary) and with other aspects of health care was evaluated. Global satisfaction with the information provided (messages, educational videos and graphs) and with each of the telemonitoring tools used (questionnaires, graphs, scale and sphygmomanometer) was evaluated (scoring from 1 to 10). Finally, patients were specifically asked if they wanted to continue to use the telemonitoring system at the end of the study. Changes in patient's behavior were measured with a scale that ranged from 1 ("never") to 5 ("as recommended by my doctor").

In parallel with patients' evaluation, structured interviews were conducted with the nurses in charge of the telemonitoring with the goal of assessing their level of satisfaction with the system and its components (i.e. ease of use, satisfaction with the system interface, use of alarms, time efficiency, patient feedback, monotony of the system and technical problems). They scored each item and their global satisfaction from 1 to 10.

During the study period, all patients continued to receive the standard care provided to patients at the HF unit.

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2.3. Telemonitoring

The Motiva telemedicine system (Philips Healthcare) is an interactive platform that transmits data via a broadband Internet connection from the patient's home (using the patient's television) to a workstation at the hospital's HF unit. The system allows the medical staff performing the telemonitoring to send information, which is then shown on the patient's television. This information includes educational videos, questionnaires to establish the patient's baseline status, personalized messages and alarms. Patients in one of the study groups (Group B; see below) also received automated self-monitoring equipment, a scale and a sphygmomanometer, to use at home to record weight, heart rate and blood pressure. These data were presented graphically on the patient's television and transmitted, analyzed and presented to the health care staff supporting the patients via a dedicated web application (Fig. 1).

The study patients were assigned 1:1 to one of two groups, termed A and B, following blinded randomization. Group A utilized the Motiva System (educational videos, motivational messages, questionnaires) with no self-monitoring equipment; Group B utilized the Motiva System + self-monitoring tools (Motiva Plus). Patients in Group B had to carry out the self-monitoring measurements every morning before breakfast. The system had two types of alarms that were activated if a) the patient's blood pressure, heart rate or weight surpassed the limits set for each patient or b) when the patient did not perform the required self-monitoring measurements.

Patients were sent 20 videos covering the following topics: disease overview (symptoms, daily care, etiology), medication (therapeutic changes, compliance), doctor visits, relapse prevention, cholesterol management, hypertension, lifestyle (physical activity, family and friends, emotional control, travel, stress), nutrition (eating out, liquids, low sodium diet), vaccinations and alcohol consumption. In addition, patients were given 18 videos containing real-life patient interviews.

Patients were also sent 25 different questionnaires that addressed issues such as physical activity, nutrition, signs and symptoms, control of emotions, traveling and medication. Questionnaires were sent according to a schedule: weekly (edema); every two weeks (fatigue and new symptoms or compliance with blood pressure and diabetes recommendations); monthly (changes in medication or visits to the hospital); or once a trimester (quality of life). Satisfaction with the system and the tools was evaluated at six months and at the end of the study.

2.4. Statistical analysis

The statistical package Stata 11 was used for the statistical analysis. Groups A and B were compared using the χ^2 test for categorical variables, using Fisher's exact test when the expected frequency of any cell was less than 5. The Student's

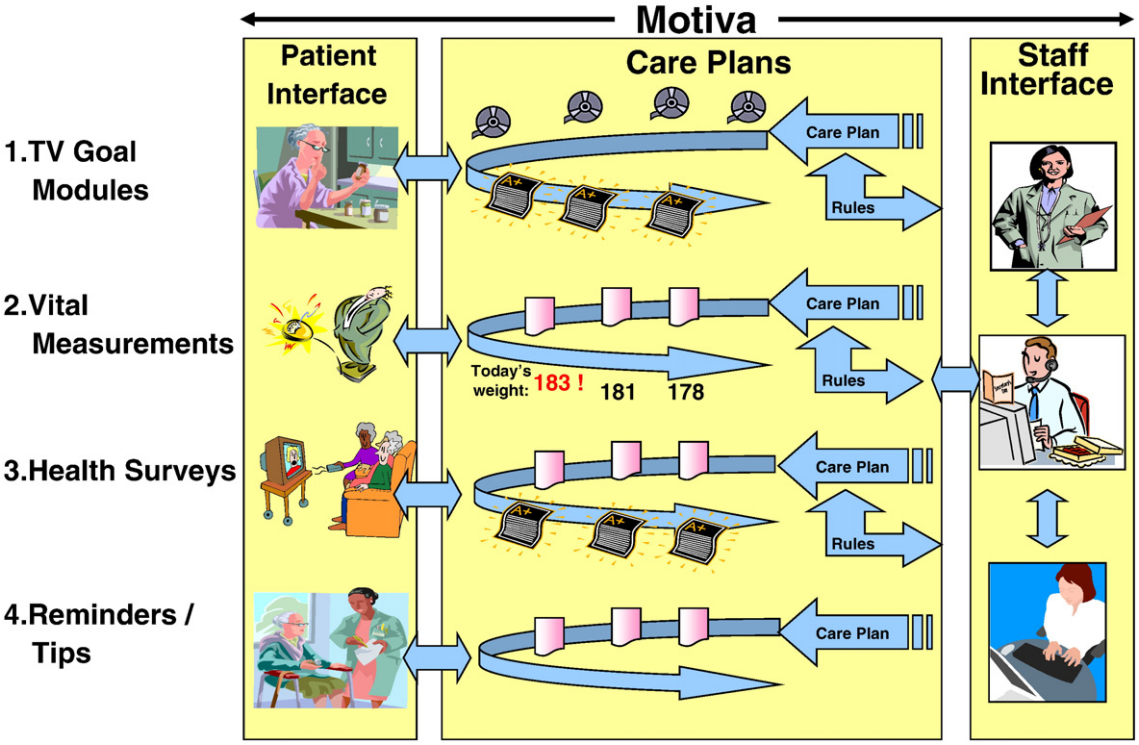

Fig. 1. Remote monitoring of patients using bidirectional information through the telemedicine system (videos, self-monitoring, questionnaires and messages).

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t-test was used to compare continuous variables and the Wilcoxon test was used for paired data with an asymmetric distribution. All of the comparisons were bilateral with an alpha error of 5%.

3. Results

3.1. Feasibility

Of the 211 consecutive patients who were screened, 44 (20.8%) met one or more of the exclusion criteria and 62 (29.4%) did not consent to participate in the study (Fig. 2). Reasons for exclusion from the study are shown in Fig. 3A. The nursing staff who screened the patients excluded 36% of the patients who did not appear to be capable of carrying out the required self-monitoring assessments. Reasons for not consenting to participate in the study are shown in Fig. 3B; 56% of the non-consenting patients were not interested in participating in a telemedicine study and 24% did not feel capable of carrying out home telemonitoring.

Of the 105 patients who initially consented to participate in the study, 8 withdrew their consent after randomization but before the system was installed in their homes. The final study sample thus included 97 patients, with 51 assigned to Group A and 46 to Group B (Fig. 2). Table 1 shows the demographic and clinical characteristics of the patients, as well as their medical treatments. They were relatively young, mainly female and of ischemic etiology, with significantly depressed LVEF although mainly in class II, and they were treated according to international guidelines, with a very high percentage of them receiving betablockers and angiotensin-converting enzyme inhibitors or angiotensin II receptor antagonists.

Clinical follow-up was 12 months, with a median real-time remote management program time of 11.7 months [IQR 7.9–12]. Twenty-two patients discontinued the telemedicine program during follow-up (median, 3.8 months [IQR 1.9–5.8]). The reasons for voluntary discontinuation of the telemonitoring system included patient rejection of use of the system (13 patients); incidents related to the telemonitoring

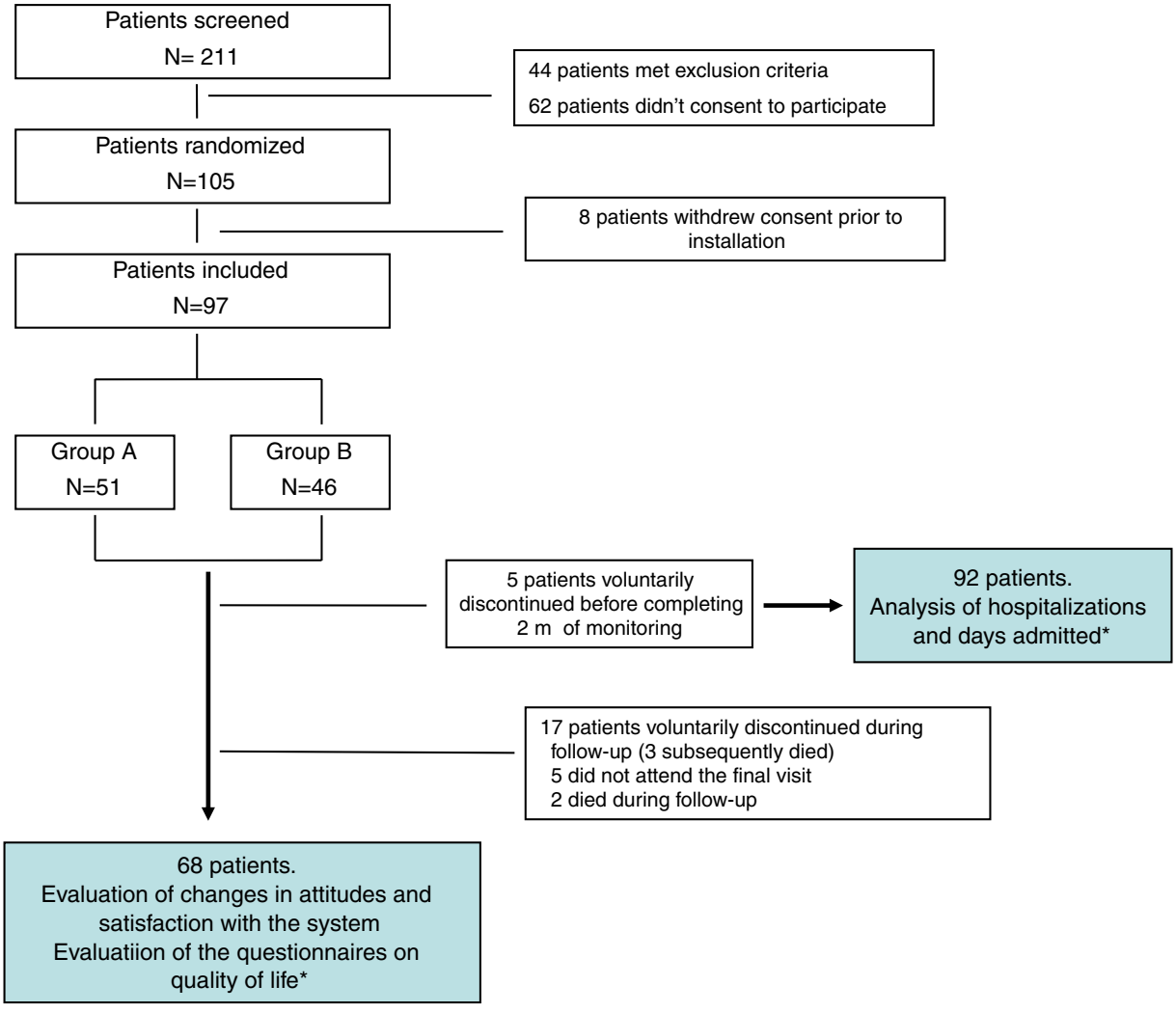

Fig. 2. Study flow chart. *CARME hospitalizations and quality of life analysis (Rev Esp Cardiol, in press, doi:10.1016/j.recesp.2010.10.032).

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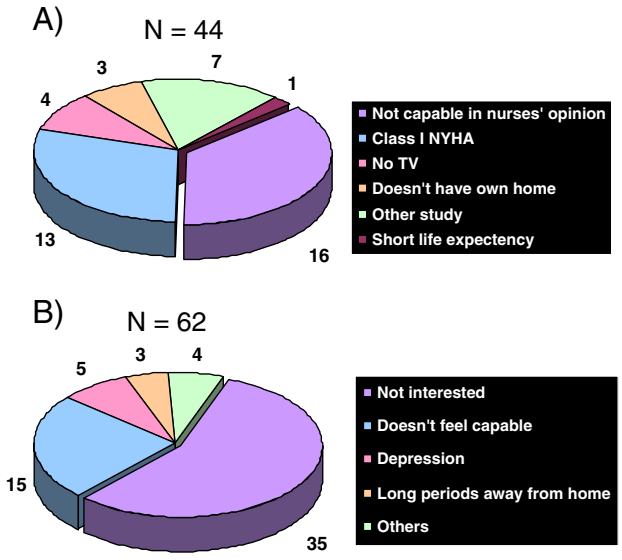

Fig. 3. A) Reasons for exclusion from the study (number of patients). B) Reasons for denying consent to participate in the study (number of patients).

equipment, including lack of internet coverage (5 patients); inability to complete the requirements of telemonitoring (3 patients); and severe functional deterioration (1 patient). A similar number of discontinuations were observed between patients in Groups B and A (i.e. with and without self-monitoring tools) (21.7% vs. 23.5%, respectively, p=0.833). Five patients died during the evaluation period, three after voluntary discontinuation of telemonitoring. Five patients did not attend the last interview. A total of 68 patients completed the final questionnaires (Fig. 2).

3.2. Compliance

Of all the videos sent, patients watched a median of 67% [IQR 41.2–83.7]; however, 85% of the videos with educational material were viewed completely [IQR 60–95]. There were no differences in video viewing between Groups A and B: 72.5% [IQR 22.5–92.5] vs. 67.5% [IQR 42.5–77.5], respectively, for all videos (p=0.20), and 85% [IQR 30–95] vs. 82.5% [IQR 70–95], respectively, for the educational videos (p=0.80).

During the follow-up period, a total of 15,017 questionnaires were sent to the patients, with a median response rate of 87.9% [IQR 55.9%–98.6%]. There were no differences in questionnaire compliance between Groups A (median 85.3% [IQR 56.2–98.1]) and B (median 88.8% [IQR 51.5–99.4]) (p=0.54). For patients who completed the final visit, the median response compliance was analyzed for the first and second six-month portions of the study. Despite similar median responses in the two time periods, 99.0% [IQR 97.8–99.1] and 98.5% [IQR 83.9–100], the difference in response compliance was statistically significant (p=0.038), with greater compliance in the first 6 months of the study.

Table 1
Patient demographic characteristics, baseline clinical status and treatments.

	TOTAL	Group A motiva	Group B motiva plus	p
	N=97	N=51	N=46	
Age	66.5±11.5	66.4±12.1	66.5±11.0	0.966
Age >70 years	28 (28.9%)	10 (19.6%)	18 (39.1%)	0.034
Female sex	68 (70.1%)	37 (72.5%)	31 (67.4%)	0.580
Lower educational level	68 (70.1%)	37 (72.5%)	31 (67.4%)	0.580
Etiology				
Ischemic heart disease	69 (71.1%)	40 (78.4%)	29 (63.0%)	0.095
Idiopathic dilated cardiomyopathy	13 (13.4%)	5 (9.8%)	8 (17.4%)	0.273
Hypertensive heart disease	2 (2.1%)	1 (2.0%)	1 (2.2%)	1.000
Valvular	1 (1.0%)	1 (2.0%)	0 (0.0%)	1.000
Others	12 (12.4%)	4 (7.8%)	8 (17.4%)	0.130
Time of HF in months	62.5±51.5	60.6±43.8	64.6±59.5	0.705
LVEF	36%±14%	37%±14%	35%±13%	0.469
Functional class				0.616
II	80 (82.5%)	43 (84.3%)	37 (80.4%)	
III	17 (17.5%)	8 (15.7%)	9 (19.6%)	
Co-morbidities				
Hypertension	55 (56.7%)	30 (58.8%)	25 (54.3%)	0.657
Diabetes mellitus	40 (41.2%)	20 (39.2%)	20 (43.5%)	0.670
COPD	17 (17.5%)	7 (14.7%)	10 (21.7%)	0.300
Peripheral vascular disease	16 (16.5%)	12 (23.5%)	4 (8.7%)	0.049
Therapy				
ACEI/ARB	83 (85.6%)	43 (84.3%)	40 (86.9%)	0.712
Beta blockers	91 (93.8%)	48 (94.1%)	43 (93.5%)	1.000
Spironolactone/ eplerenone	43 (44.3%)	22 (43.1%)	21 (45.7%)	0.803
Loop diuretic	79 (81.4%)	39 (76.5%)	40 (87.0%)	0.185
Digoxin	33 (34.0%)	15 (29.4%)	18 (39.1%)	0.313
Statins	65 (67.0%)	36 (70.6%)	29 (63.0%)	0.430
Anticoagulants	31 (32.0%)	15 (29.4%)	16 (34.8%)	0.571
ASA	54 (55.7%)	30 (58.8%)	24 (52.1%)	0.510
CRT ± ICD	18 (18.6%)	12 (23.5%)	6 (13.0%)	0.185

HF: Heart failure; LVEF: Left ventricular ejection fraction; COPD: Chronic obstructive pulmonary disease; ACEI: Angiotensin-converting enzyme inhibitors; ARB: angiotensin II receptor antagonists; ASA: Acetylsalicylic acid; CRT: Cardiac resynchronization therapy; and ICD: Implantable cardioverter defibrillator.

Compliance with self-monitoring of vital signs in patients randomized to Group B was 76.4%±19.6% for weight and 71.8%±22.1% for blood pressure, with 52.2% and 44.4% of the patients monitoring weight and blood pressure at least 80% of the time. For patients who completed the entire study, including the final visit, there was significantly lower monitoring compliance in the second 6-month period compared to the first, both for weight (75.1%±17.7 vs. 82.2%±21.8, p=0.030) and for blood pressure (67.8%±25.3 vs. 78.8%±27.9, p=0.036).

3.3. Changes in behavior

Positive changes in patients' behavior were observed during the study period, with statistically significant improvement in behavior towards self-monitoring of weight

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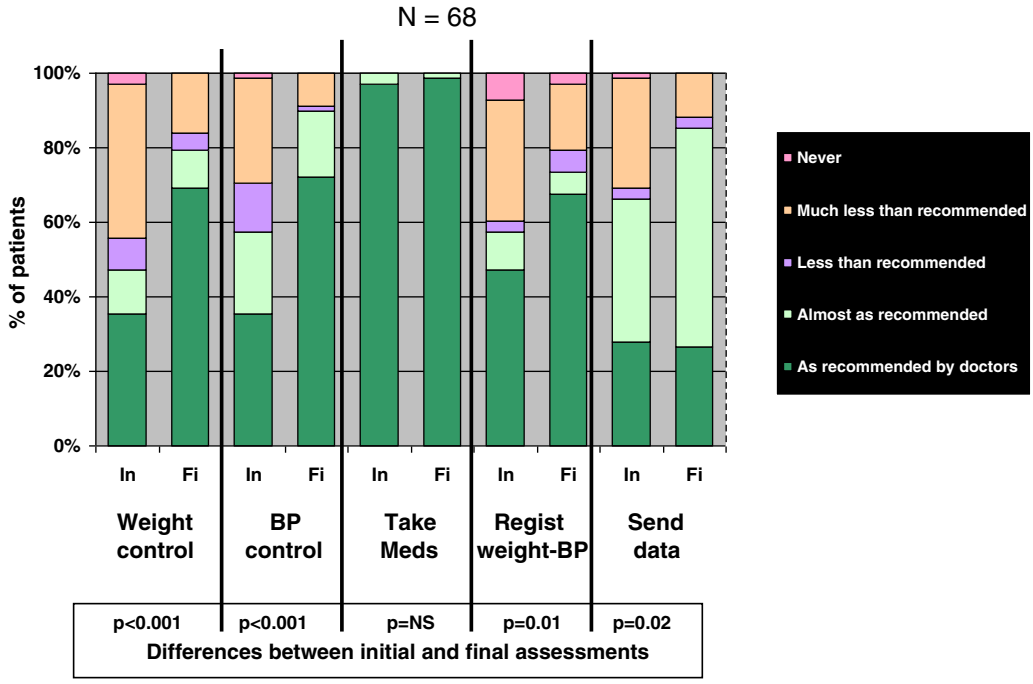

Fig. 4. Compliance with the health education measures recommended using the telemonitoring system. In: initial; Fi: final; Meds: medications.

($p<0.001$) and blood pressure ($p<0.001$) (Fig. 4); comparing groups A and B, there was greater improvement in behavior in Group B for weight control ($p=0.021$), registration of weight and blood pressure ($p<0.001$) and sending data ($p=0.002$). The changes in behavior were measured at 6 and 12 months, and there were no significant subsequent changes between 6 and 12 months ($p=0.822$ for weight and $p=0.554$ for blood pressure; $p=0.140$ for patient register data; $p=0.251$ for sending data). No differences were found after the intervention in terms of the percentage of patients who took their daily medications, but compliance was already high when the study started.

3.4. Satisfaction with telemonitoring tools

The level of satisfaction with the system was high (median global satisfaction scores at the end of the study were 8.4/10), especially with the equipment for self-monitoring measurements (the scale and sphygmomanometer) and the weight and blood pressure graphs. These three elements received a score of $\geq 7/10$ in 95% of the cases (Fig. 5). There were no significant differences in the satisfaction scores obtained at 6 months and at the end of the study, with the exception of the motivational information received: 47% of the patients ($p=0.006$) reported decreased satisfaction with motivational information at the second measurement, probably due to saturation, although the median scores were high both times they were measured (8.5 [IQR 8–10] and 8 [IQR 7.25–9], respectively). Practically all of the patients showed a high level of confidence in the information received.

Of the patients studied, 65% expressed a desire to continue with the telemedicine program at the end of the one-year study, especially those who were randomized to the telemedicine system plus self-monitoring tools (46.8% in Group A and 80.5% Group B, $p=0.004$). For the 75% of patients who did not want to continue to use telemedicine, the patients felt they no longer needed this level of support.

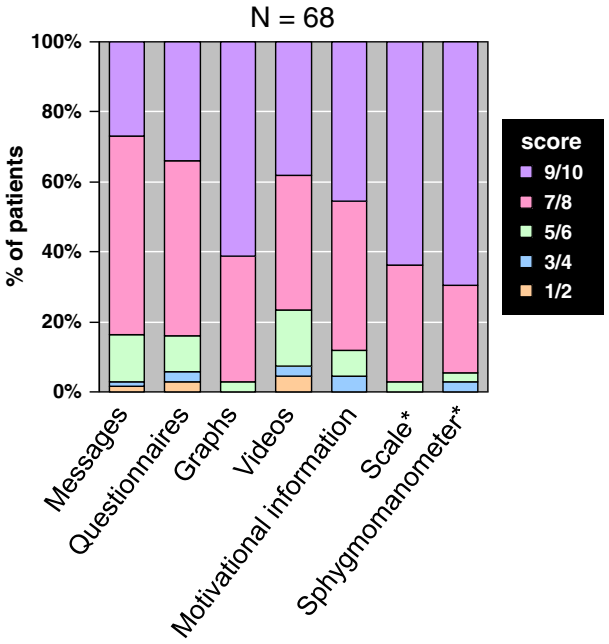

Fig. 5. Patient satisfaction with the components of the telemonitoring system (scoring from 0 to 10). * Evaluated only by patients in Group B (N=46).

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3.5. Evaluation by health personnel

The nursing staff comprised 4 professionals who performed the telemonitoring. They gave a positive global score to the system (mean score, 7.2/10), especially in terms of ease of use and satisfaction with the system's interface, while monotony, accuracy of alarms and technical problems received varying evaluations (Fig. 6). The use of alarms received relatively lower scores due to the annoying repetition of some of these alarms.

3.5.1. Efficacy

As reported previously [10], telemedicine program led to a significant reduction in hospital admissions (67.8%) and in the number of days in the hospital for HF (73.3%) and also other cardiac causes (hospitalizations 57.6% and days in hospital 82.9%), as well as to a perception of better quality of life for the patients, both using a generic ($p<0.001$) and a specific ($p=0.005$) tool.

4. Discussion

Telemedicine can have a positive impact on patient behavior towards managing their illness when it is feasible, reliable and the user is satisfied with the system. This study of non-invasive telemonitoring carried out in an HF unit also showed the limitations of this approach. Only 46% of the patients interviewed could be enrolled in the study, and 22.7% of the participants abandoned the program. However, the patients that completed the study had confidence in the information administered, were satisfied with the tools used and showed positive changes in behavior. This result is particularly important because our HF unit already demonstrated that the nurse education improve patient knowledge and behavior [11,12].

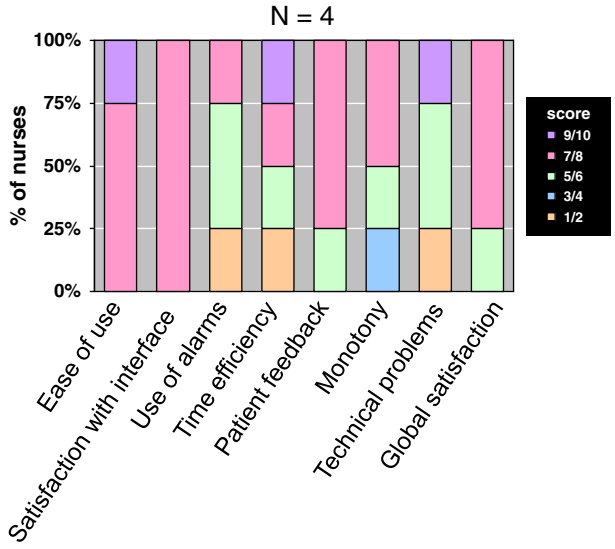

Fig. 6. Evaluation of the Motiva system by the nursing staff (scoring from 0 to 10).

The high percentage of patients who did not want to use new information and communication technologies was comparable to that in other recent studies, such as the HOME-HF study [13], in which only 40% of the patients interviewed could be included and 25.7% did not consent to participate because they felt overwhelmed by their illness and were quite resigned with their situation. Other studies have obtained a much higher rate of participation, such as the HHH [14] study, with a 75.2% inclusion rate (only 16.69% of the patients declined the invitation to participate); the SHL [15] study, with a 72.4% inclusion rate (13.5% declined to participate); and a study by Giordano et al. [16]. with a 73% inclusion rate (7.74% declined to participate).

The percentage of discontinuations in our study, 22.7%, was remarkably high and contrasts with previous studies such as TEN-HMS [17], which had a discontinuation rate of 7%; WHARF [18], with 11.4%; and HOME-HF [13], with only one out of 84 patients discontinuing the program, despite the elderly and multicultural population involved. The high percentage of discontinuations in our study was probably due to local cultural idiosyncrasy and low educational level of our study population, in spite of being younger, which is generally unfamiliar and uncomfortable with electronic systems.

Compliance in terms of responding to the questionnaires was high (median 88%) compared with self-monitoring of weight (76%) and blood pressure (72%). It is notable that only 52% and 44% of the patients monitored their weight and blood pressure on 80% or more of the days of telemonitoring, in contrast to other studies where self-monitoring compliance was 80% in the HHH [14] study and 81% in the TEN-HMS [17] study (although in the latter, only 55% of patients complied with self-monitoring twice a day as prescribed). In the HOME-HF [13] study, 95% of the patients used the system on more than 90% of the days, and WHARF [18] had 98% compliance. We do not have a plausible explanation for this lower compliance, other than that our study was longer than the HOME-HF and WHARF studies. We hypothesize that, as for patients who discontinued the study, the cultural or educational characteristics of the patient population might have affected compliance with self-monitoring; alternatively, patients without a previous admission may have been less motivated to comply. The significant decrease in self-monitoring during the second half of the study supports the theory that the relatively low compliance observed in our study could be due to study duration, although compliance in the HHH [14] study was greater despite a similar study duration.

In our study, telemonitoring resulted in positive changes in patients' behavior with respect to different measurements of health education, especially in the self-monitoring of weight, blood pressure and keeping a daily record. These changes were observed at 6 months and were maintained throughout the 12 months of the study. Other studies have also published favorable results with telemonitoring and have noted that greater therapeutic compliance can be

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achieved with telemonitoring [17,19–21]. In the present study, we found no significant differences in medication compliance, mostly because our patients already had a high percentage of adherence to treatment at the start of the study.

In general, satisfaction with the telemonitoring tools used in our study was high and in agreement with other studies [13,14,17,19,22]. Other studies did not show differences in satisfaction with care between the control and telemonitoring groups [20,23].

There have been few studies regarding the satisfaction of nursing staff with telemonitoring systems. Here, the nurses' global perception of the system was positive, especially in terms of ease of use and satisfaction with the system's interface. In SPAN-CHF [24], nurses showed that they could monitor more patients using telemedicine. This was not addressed in our study.

The main limitations of this study were those inherent to the before/after comparison design; there was no control group; and the study patients attended a structured multidisciplinary HF unit, with optimized treatment and health education, making it impossible to extrapolate these results to other HF patients who are not monitored so closely.

5. Conclusions

The Motiva telemonitoring system is a valid and useful complementary alternative in the management of patients with HF, although it cannot be used for all patients. A high percentage of patients could not or did not want to participate in the study, and many patients abandoned the study during follow-up. However, both patients and the nursing staff were very satisfied with the interactive platform, and the resulting positive changes in patient behavior were evident at 6 months and persisted until the end of the study. Compliance with vital sign monitoring decreased already at 6 months follow-up.

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Conflict of interest

Dr. Mar Domingo received a grant from Philips Healthcare to develop the study and to perform data collection. The other authors declare no conflicts of interest. The data analysis was carried out by the authors independently of the study sponsor.

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