Impact of patient engagement in a French telemonitoring programme for heart failure on hospitalization and mortality

Rémi Sabatier1*, Damien Legallois1, Mouna Jodar1, Laurène Courouve2, Valérie Donio2, Florence Boudevin3, Thibault De Chalus3, Karine Hauchard4, Annette Belin1 and Paul Milliez1

1Service de Cardiologie et de Pathologie Vasculaire, CHU Caen Normandie, Avenue Côte de Nacre, 14000, Caen, France; 2Cemka, Bourg-la-Reine, France; 3Amgen, Boulogne-Billancourt, France; and 4Normand’E-santé, Caen, France

Abstract

Aims  Management of patients with recently decompensated heart failure by hospital services is expensive, complicated to plan, and not always effective. Telemedicine programmes in heart failure may improve the quality of care, but their effectiveness is poorly documented in real-world settings. The study aims to evaluate the impact of patient engagement in home-based telemonitoring for heart failure (SCAD programme) on rehospitalization and mortality rates.

Methods and results  A retrospective observational study was performed in 659 SCAD participants. SCAD is a patient-oriented service of home-based interactive telemonitoring offered to heart failure patients during hospitalization who agree to participate in a therapeutic education programme. Patients were telemonitored for at least 3 months, and rehospitalization and mortality were documented at 12 months and 5 years. During the telemonitoring period, patients provided daily information on health and lifestyle through an internet-based interface. Data were linked on a patient-by-patient basis between the SCAD database and the French national health insurance database (Système National des Données de Santé). Outcomes were compared as a function of use of the programme. Low, intermediate, and high users were classified by tercile of data return during telemonitoring. Patients were followed for a median of 32.9 months. Rehospitalization rates for cardiovascular disease decreased from 79.4% in the year preceding enrolment to 41.1% in the following year and from 52.8% to 18.8% for hospitalizations for heart failure. The 12 month mortality rate was 11.2%. Significant associations were observed between level of use of the SCAD programme and all-cause rehospitalization (P = 0.0085), rehospitalization for cardiovascular disease (P = 0.0010), rehospitalization for heart failure (27.8% in low users, 14.1% in intermediate users, and 14.5% in high users; P < 0.0001), and mortality (26.8%, 15.2%, and 15.9% respectively; P = 0.0157) in the 12 months following enrolment. The mean number of days alive outside hospital were 279 ± 111 in low users, 312 ± 90 in intermediate users, and 304 ± 100 in high users (P = 0.0022).

Conclusions  Educational home telemonitoring of patients with heart failure following hospitalization provides long-term clinical benefits in terms of rehospitalization and death in real-world settings, according to the level of use of the programme by the patient. These benefits would be expected to have a major impact on the burden of this disease. Low engagement in telemonitoring could be used as a signal of poor prognosis and taken into account in the management strategy.

Keywords  Telemedicine; Heart failure; Cardiovascular disease; Hospitalization; Mortality

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*Correspondence to: Rémi Sabatier, Service de Cardiologie et de Pathologie Vasculaire, CHU de Caen Normandie, Avenue Côte de Nacre, 14000 Caen, France. Tel: +33 2 31 06 30 50. Email: sabatier-r@chu-caen.fr

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Introduction

Management of patients with heart failure (HF) by hospital services alone is expensive, complicated to plan, and not always effective. This problem is exacerbated by an ageing population and by limited resources in hospitals. Switching resources from crisis management by acute hospitalization to prevention strategies may improve the standard of care. In this context, health maintenance through sustained interventions targeting prevention that can be implemented in the patient’s home represents a solution to meet these challenges. The recent COVID-19 pandemic illustrates perfectly the attractiveness of evaluating and managing vulnerable patients at home. Since the publication of the TEN-HMS study in 2005, telemedicine programmes in HF have generally been shown to be an efficacious and cost-effective strategy to manage these patients in the community.

Telemonitoring at home enables symptoms to be followed in real time and interventions made in a timely manner. Educating patients on how to monitor themselves and identify signs of clinical deterioration empowers them to seek support and enables early intervention from the HF team when required. The patient may also come to recognize the positive effect of lifestyle modifications on disease stability. This could reduce hospitalization, improve prognosis, and reduce costs to the health system. Several studies have shown that this approach can significantly reduce hospitalization and mortality in patients with chronic HF. However, the potential benefits of HF care using telemonitoring are poorly documented in real-world settings.

The Suivi Clinique A Domicile (SCAD) monitoring system is one of the first telemedicine programmes for HF to be established in France with the goal of achieving disease stability and minimizing the risk of acute hospitalization. It was initiated by the cardiology department of the Caen University Hospital, promoted by a regional association of cardiologists and specialist HF nurses [Amélioration de la P R ise en charge de l’Insuffisance Cardiaque (APRIC); association for the improvement of HF management], and is funded by the Normandy regional health agency. The programme has now been running since 2007. SCAD is a patient-oriented service of home-based interactive telemonitoring offered to recently decompensated HF patients who agree to participate in a therapeutic education programme. It allows patients to provide health and lifestyle information to the coordinating centre using a daily interactive questionnaire on a tactile pad and receive feedback to adjust their care. The data entered by the patient is also analysed in real time by a risk algorithm in order to identify any risk of acute decompensation, and automatically generate an alert (Table S2). This enables the HF nurse to contact the patient, the general practitioner (GP), the cardiologist, or the emergency services as necessary in order to organize a consultation or a hospital visit. The SCAD is thus based on patient empowerment, reinforced education, and motivational support.

The short-term benefits of SCAD have been assessed in the Suivi Educatif à Domicile dans l’Insuffisance Cardiaque (SEDIC) pilot study, which demonstrated a 46% reduction in hospitalization at 1 year in patients following the programme. The recent availability of the Système National des Données de Santé (SNDS: a national medico-administrative database) has made it possible to conduct retrospective linking studies to retrieve information on all healthcare use for cohorts such as SCAD. This database contains exhaustive information on all healthcare resource consumption by all beneficiaries of the French public national health insurance.

The objectives of this study were to evaluate the long-term health impact of the SCAD programme in terms of rehospitalizations and deaths in a real-life setting and, in particular, to assess the impact of patient engagement in the telemonitoring programme on outcomes.

Methods

Study design

This retrospective observational study was performed in all patients telemonitored by the SCAD system in seven out of the 10 participating centres between 1 January 2009, when the programme was made available throughout Normandy, and 31 December 2016. The study included a period of telemonitoring in the SCAD programme (generally 3 months) and a long-term follow-up period in which rehospitalizations and mortality were documented from the SNDS database. The date of discharge from hospital was taken as the index date. Patients were followed for at least 1 year following the index date or until they died. Outcomes were compared as a function of level of use of the programme. Level of use was classified by tertile of data return during telemonitoring. All healthcare resource consumption during this period, as well as in the 12 month period prior to enrolment, were documented. The study was funded by the APRIC association. Operational management of the study and statistical analysis was delegated to CEMKA (Bourg-la-Reine, France).

SCAD programme

The SCAD programme is open to any patients hospitalized with HF in one of the participating hospital centres (Figure 1). This includes patients hospitalized for an acute exacerbation of HF, those with an unplanned cardiovascular hospitalization with subsequent HF diagnosis or (rarely) patients with a planned hospitalization for HF follow up. The programme is coordinated centrally by a full-time project manager, under
the supervision of a cardiologist from the Caen University Hospital, and implemented locally in each participating hospital by a dedicated trained HF nurse from the cardiology department. A healthcare team is designated for each patient consisting of the treating cardiologist, the dedicated HF nurse, and the patient’s GP.

Prior to discharge from the hospital (the vulnerable period), the cardiologist proposes participation in the SCAD programme to the patient and the dedicated HF nurse ensures eligibility. If the patient agrees to participate, a therapeutic education programme and training on operation of the SCAD system are started before the patient is discharged.

An initial review of educational needs of the patient is made by the HF nurse and goals are negotiated, taking into account the patient’s knowledge and wishes, and the acceptability of the proposed programme to the patient. Therapeutic education is based on the French I-Care programme\textsuperscript{11} and consists of patient tutorials and workshops concerning HF, its treatment, the importance of physical activity and diet, and warning signs that should incite the patient to consult a physician.

On discharge, each patient is provided with a dedicated programme installed on a tactile pad for entering data through a secure internet portal. On 6 days a week (Sunday excluded), the patient enters information into the system. In order to limit the amount of time that the patient needs to spend at any one-time, different types of information are provided on different days so that a complete evaluation can be made each week. Information on the patient’s clinical state (weight, heart rate, blood pressure, and occurrence of cardiac symptoms) are provided on Mondays, Wednesdays, and Fridays; on lifestyle factors (diet and physical activity) on Tuesdays and Thursdays; on effort training on Saturday; and on psychological state (evaluation of fatigue and morale rated on a 10-point visual analogue score) and treatment compliance (assessed with an open question) on Fridays.

Any member of the healthcare team can access the data entered by the patient. Personalized feedback is provided to the patient by the HF nurse through a telephone call or a text message. This call provided an opportunity to confirm the data on treatment compliance and lifestyle. The data entered by the patient is also analysed in real time by a risk algorithm in order to identify any risk of acute decompensation, and automatically generate an alert, if necessary (Supporting Information, Table S1).\textsuperscript{6–9} In each participating centre, the dedicated HF nurse checks the system daily during office hours to collect data on their patients. The system also interacts directly with the patient, providing advice for corrective actions or recommending a GP visit. The patient is also informed that the system is not designed to treat emergencies and advised to contact the emergency services if necessary.

This enables the HF nurse to contact the patient, the GP, the cardiologist, or the emergency services according to the level of alert (yellow, orange, and red) in order to propose a modification of the patient’s treatment or lifestyle, or organize a consultation or, in last resort, a visit to the hospital.
The actions triggered by the alert were graded according to the level of the alert. For a yellow alert, the HF nurse would telephone or text the patient to check the information, advise on corrective actions wherever possible (e.g. salt intake), and recommend careful monitoring over the following days. For an orange alert, the HF nurse would telephone the patient to check the information and, if necessary, contact the GP to request a visit to the patient. For a red alert, the HF nurse would telephone the patient to determine the risk, contact the GP to request an immediate visit to the patient (if the patient had not already done so as advised by the system), and if the GP was unavailable, contact the emergency services.

If a patient did not enter any data, a telephone call was made by the HF nurse to motivate the patient to participate. The computer interface also provides access for the patient to information and advice on treatment and on leading a healthy lifestyle. This material could be accessed whenever the patient desired. However, access was not registered in the system and was not monitored. No further continuous education or support was provided after the telemonitoring period, but the patient could remain in the SCAD programme for longer than 3 months if this was considered necessary. Continued participation required a prescription from the cardiologist. The decision to continue was taken by the healthcare team after discussion with the patient according to the number of alerts and the needs of the patient.

The idea behind the SCAD programme was that patient empowerment, reinforced education, and motivational support by HF nurses will reduce the risk of hospitalization over the long-term and thus reduce the medical and economic burden of HF. Over the last 10 years, over 1000 patients in Normandy have been enrolled in this programme.

**SNDS database**

The SNDS is the database of the French national health insurance system and covers all reimbursed healthcare resource consumption by the entire French population. Each individual is coded in the database with a unique identifier, which allows their healthcare to be tracked over their lifetime. The database is anonymized, but information is available on date of birth, gender, and place of residence. Hospitalizations are identified by a diagnostic code based in the International Classification of Diseases 10th Edition (ICD-10). The reason for hospitalization is identified as the principal diagnosis (the primary reason for hospitalization), the related diagnosis (the underlying disease of the patient) or the significant associated diagnosis (any other morbidity that would influence the course or cost of hospitalization). All medical procedures and laboratory tests are documented, but the reasons for their prescription is not available, nor the results of any tests. If an insuree dies, then the date of death is recorded. Patients eligible for full reimbursement of healthcare expenditure due to a serious chronic disease (ALD status) or due to limited financial status (CMU-c status) are identified.

**Study population**

All patients who were hospitalized for acute HF in a participating hospital in Normandy were eligible for the SCAD programme and were invited to join the programme. The diagnosis of HF was made by a cardiologist according to the New York Heart Association (NYHA) criteria. All patients entered in the SCAD programme in the seven participating centres were included in the study. Participants agreed to use the SCAD telemedicine system at home and received therapeutic education and programme training during the inclusion stay. Patients on a waiting list for a surgical or interventional procedure for the treatment of HF, such as heart transplantation or transcatheter aortic valve implantation (TAVI) were excluded from this analysis.

**Patient matching**

Data were linked on a patient-by-patient basis between the SCAD database (as a source of clinical data) and the SNDS database (as a source of data on healthcare resource utilization). The index date was the date of enrolment in the SCAD programme (usually a few days following hospital discharge for acute HF). Patients were linked by indirect deterministic matching between the SCAD and SNDS databases on the basis of an encrypted unique identifier based on gender, month and year of birth, postal code, dates of hospitalization, and the identification code of the hospital.

In order to preserve patient anonymity, and as specified in the procedures governing access to the SNDS, data extraction was performed by the French National Health Insurance Fund [Caisse Nationale de l’Assurance Maladie (CNAM)]. A data table containing the information required for matching between data sources (gender, month and year of birth, postal code, hospitalization date, and hospital identification code) was sent to the CNAM through a secure server, who performed the data extraction and made the results available to the study managers through the same secure server.

**Data collection**

Socio-demographic and clinical characteristics of patients at inclusion were extracted from the SCAD database. Information on medical history, body mass index, NYHA functional class, and left ventricular ejection fraction (LVEF) were retrieved from the patient’s medical records. Data from the SNDS database were extracted on comorbidities, healthcare resource consumption, and death. Comorbidities documented in the year preceding inclusion in the SCAD
The HF team was documented. and orange alerts only, the type of response provided by over each 3 month follow-up period were retrieved. For red morbidity listed as a principal or related diagnosis was consid-

zation for HF. Any other hospitalization with a cardiovascular was listed as HF, then the event was considered as hospitali-

sation of use was calculated as the proportion of expected data en-

ertered by patients into the system three times a week (on Mondays, Wednesdays, and Fridays), the expected number of data entries over a 3 month period is 39 or 40. The level of use was calculated as the proportion of expected data en-

tries delivered for the treatment of HF (angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, beta-blockers, loop diuretics, mineralocorticoid receptor antagonists, or cardiac glycosides) in the 3 months preceding inclusion were documented by ATC code and date.

All data entered by the patient in the SCAD system during the telemonitoring period were retrieved. These included patient-reported symptoms (cough, dyspnoea, palpitations, or presence of oedema), fatigue and morale rated on a 10-point visual analogue score (VAS) (ranked from 0 to 10) and vital signs (weight, heart rate, and blood pressure). Alerts generated by the system were classified by seriousness into three levels (yellow, orange, and red) as specified in Table S2. The number, level, type, and outcome of alerts triggered over each 3 month follow-up period were retrieved. For red and orange alerts only, the type of response provided by the HF team was documented.

Following the end of the telemonitoring period, patients continued to be followed in the SNDS database until the end of the study period. All rehospitalizations and deaths occurring during or following the telemonitoring period were retrieved. All hospital stays were documented by date, reason for hospitalization (ICD-10 code), and length of stay. If the principal diagnosis on the hospital discharge summary was listed as HF, then the event was considered as hospitalization for HF. Any other hospitalization with a cardiovascular morbidity listed as a principal or related diagnosis was considered ad hospitalization for cardiovascular disease.

Derived variables

Engagement in the SCAD programme was determined from the levels of use. As vital signs and symptoms were to be entered by patients into the system three times a week (on Mondays, Wednesdays, and Fridays), the expected number of data entries over a 3 month period is 39 or 40. The level of use was calculated as the proportion of expected data entries that were actually entered into the system over a 3 month period. Periods of hospitalization during which the patient could not use the monitoring system were excluded from the calculation, as were patients who died during the 3 month follow up. The level of use was classified into terciles.

The Charlson comorbidity index was calculated on the basis of comorbidities listed in hospital discharge summaries and coded for ALD status. Hospitalizations for cardiovascular disease in general and for HF in particular were identified from the ICD-10 codes recorded on the SDS. The relevant codes are listed in Table S2. Days alive and out of hospital (DAOH) were calculated for each patient by subtracting the number of days since death, or spent in hospital, from the time period of interest.

Definition of hospitalizations

Only unscheduled hospitalizations were considered. All-cause hospitalization was defined as hospitalizations with emergency room visits or with at least night spent in the hospital.

Hospitalizations for a cardiovascular diagnosis included all stays where one of the following diagnoses was documented on the SDS: myocardial infarction, stroke, arteritis of the lower limbs, cardiac rhythm disorders, valvular heart disease, pulmonary embolism, or HF. Principal diagnoses only were retained for myocardial infarction and pulmonary embolism, and any diagnoses (principal, related, or associated) were considered for the other cardiovascular diseases.

Hospitalizations for HF were defined as any hospitalization with any HF code (as listed in Table S2) as a principal diagnosis, as well as unspecified hypertensive heart and renal disease, pulmonary oedema, or chronic passive congestion of the liver as a principal diagnosis with HF as a secondary or associated diagnosis. The minimum stay duration for HF stays was set at >3 days in order to exclude stays for other reasons than an acute exacerbation of HF. In clinical practice, an unscheduled hospital stay for an acute exacerbation is unlikely to last <3 days.

Data analysis

Continuous variables are presented as mean values and standard deviations or median values with interquartile range. Categorical variables are presented as frequency counts and percentages. Inferential testing was performed to compare variables between the three alert levels. The χ² test or Fisher’s exact test was used for categorical variables, and Student’s t-test or analysis of variance was performed for continuous variables with a normal distribution. If not, non-parametric tests were used.

The principal evaluation criteria were time to hospitalization and time to death at 12 and 24 months. These variables were analysed using Kaplan–Meier actuarial survival analysis, with censoring at 60 months due to the paucity of data beyond this time point. A secondary objective was to determine the relationship between the level of use of the programme and health outcomes. Outcomes of interest were all-cause and HF rehospitalizations at 12 months, DAOH at 12 months, and death at 12 and 24 months. Survival functions were compared between the three different classes of level of use using the logrank test. All analyses were performed directly on the IT portal of the SNDS using SAS® Enterprise Guide® software V7.15 (SAS Institute, Cary, USA).
**Ethics**

The study complied with relevant international and French legislation pertaining to medical research, and with Good Epidemiological Practice. The protocol study was submitted and approved by the CEREEES (Expertise Committee for Research, Studies and Evaluations in the field of Health), the relevant ethical review body. The study was performed under the auspices of an agreement with the French National Data Protection Agency (CNIL) authorizing the linking of clinical datasets with the SNDS. The scope of the study was defined in a signed agreement with the CNAM. All patients were provided with an information leaflet and gave written informed consent for telemonitoring at home. All patient data were anonymized prior to analysis.

**Results**

**Participants**

Seven hospital cardiology departments accounting for >80% of all patients participating in the SCAD programme contributed patients to the study. After exclusion of ineligible patients, the eligible population consisted of 767 patients. Because 102 eligible patients (13.3%) could not be linked in the SNDS database and clinical data were missing for six others, 659 patients (85.9% of the eligible population) were finally available for analysis (Figure 2).

The median follow-up time in the study from inclusion in the SCAD programme until the last event documented in the SNDS database (including both the telemonitoring period and the post-monitoring period) was 32.9 months [interquartile range: 18.2–50.4] (mean ± standard deviation: 37.0 ± 25.5 months).

The demographic and clinical characteristics of the 659 patients analysed are presented in Table 1. Most of the patients were in NYHA class II (55.6%) or III (32.8%), and 52.8% presented HF with an LVEF < 40%. Overall, 94.8% had at least one comorbidity as rated with the Charlson comorbidity index. Around nine out of 10 (90.7%) patients had been delivered a treatment for HF in the 3 months before enrolment (Table 2).

**Use of the SCAD programme**

Eighty-two of the 659 patients enrolled (12.4%) never used the SCAD programme. The mean duration of remote monitoring in the SCAD, calculated between enrolment and the last use of the monitoring system, was 118.8 days (3.9 months). Half of the patients were monitored for at least 99 days (3.2 months). Forty-six patients (8.0%) were monitored for < 30 days and 79 (13.7%) for over 180 days (Table 3).

Twenty-six patients died before 3 months, of whom 23 were low users (including 10 deaths in the 82 non-users), 2 intermediate users, and 1 a high user.

For the 633 patients who survived at 3 months, the mean level of use was 65.7% (median: 79.5%). The lower tercile of use corresponded to patients who used the system for < 66.7% of the anticipated monitoring sessions (including 72 patients who never used the system), the middle tercile to those using the system for 66.7% to 87.5% and the upper tercile to those using the system for ≥ 87.5%. Patients in the three terciles of level of use did not differ significantly with

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**Figure 2** Patient flow diagram. SCAD, Suivi clinique à domicile; SNDS, Système National des Données de Santé; TAVI, transcatheter aortic valve implantation.
respect to comorbidities, NYHA class, LVEF or HF treatment. Low users had a lower VAS morale score (6.9 ± 1.9 vs. 7.5 ± 1.7 for high users; \( P = 0.01 \)). The characteristics of these patients are presented in Table S3.

The nature of the signs and symptoms triggering an alert over the 3 month monitoring period are presented in Table 3. Most of the alerts (74.1%) were answered within 24 h, and 57.9% were answered on the same day, with no difference between type of alert (the service is not available round the clock). The patient was contacted by telephone or message in 92.1% of cases following a red alert, and in 84.4% of cases following an orange alert. Overall, 50.9% of red alerts and 43.3% of orange alerts were followed by a medical consultation with a GP or a cardiologist within 7 days.

Rehospitalizations during the telemonitoring period

For 128 alerts (5.7%), the alert was followed by rehospitalization within 7 days, including hospitalization for acute HF in 52 cases. The proportion of alerts followed by hospitalization varied according to the type of alert (\( P < 0.0001 \)), being highest after red alerts (11.6%; \( N = 31 \)) for all-cause hospitalization and 6.0% (\( N = 16 \)) for hospitalization for HF (Table 4). Dyspnoea was the principal reason for all-cause hospitalization following a red alert (45.2%) and weight gain the principal reason following an orange alert. However, most alerts did not lead to hospitalization (88.4% for red alert and 95.5% for orange alert), principally due to early consultation by the patient or rapid intervention by the HF team.

Of the 75 unplanned hospitalizations for HF in 51 patients that occurred while the patient was under remote monitoring, at least one alert had occurred within the 7 days prior to hospitalization in 38 cases (50.7%). In 15 cases, multiple alerts (more than or equal to three) had occurred and in 16 at least one red alert had occurred (Table S4).

Table 1 Socio-demographic and clinical characteristics of the study population

| Study population \( N = 659 \) | HFrEF population \( N = 336 \) |
|---------------------------------|----------------------------------|
| **Gender, n (%)** | |  
| Men 477 (72.4%) | 250 (74.4%) |
| **Age at enrolment (years)** | |  
| Mean ± SD 67.3 ± 13.4 | 67.4 ± 13.3 |
| <60 years 171 (25.9%) | 122 (36.5%) |
| 60–69 years 177 (26.9%) | 112 (33.5%) |
| 70–79 years 181 (27.5%) | 103 (30.8%) |
| ≥80 years 130 (19.7%) | 71 (21.2%) |
| **Body mass index at enrolment (kg/m²)** | |  
| Underweight: <18.5 kg/m² 11 (2.1%) | 10 (3.0%) |
| Normal weight: 18.5–25 kg/m² 176 (34.4%) | 112 (33.5%) |
| Overweight: 25–30 kg/m² 166 (32.4%) | 105 (31.2%) |
| Obesity: ≥30 kg/m² 159 (31.1%) | 107 (31.9%) |
| **Comorbidities in 12 months before enrolment** | |  
| Hypertension 386 (63.3%) | 250 (74.4%) |
| Atrial fibrillation 307 (50.3%) | 197 (58.8%) |
| Diabetes 185 (28.7%) | 127 (37.8%) |
| Psychological disease 120 (18.2%) | 80 (23.9%) |
| Myocardial infarction 117 (17.8%) | 79 (23.6%) |
| Peripheral vascular disease 106 (16.1%) | 70 (20.9%) |
| Chronic pulmonary disease 104 (15.8%) | 68 (20.2%) |
| Cancer 98 (14.9%) | 61 (18.2%) |
| Cerebrovascular disease 49 (7.4) | 33 (9.9) |
| **Charlson comorbidity index** | |  
| Mean ± SD 2.8 ± 2.2 | 2.9 ± 2.3 |
| ≤1 219 (33.2%) | 140 (41.8%) |
| 2–4 325 (49.3%) | 188 (56.0%) |
| ≥5 115 (17.5%) | 58 (17.2%) |
| **VAS scores at enrolment (median [interquartile range])** | |  
| Fatigue score (\( N = 573 \)) 4 [2–6] | 4 [2–6] |
| Morale score (\( N = 572 \)) 8 [6–9] | 8 [6–9] |
| **NYHA stage at enrolment** | |  
| N = 604 | |  
| Stage I 43 (7.1%) | 30 (9.0%) |
| Stage II 336 (55.6%) | 211 (62.9%) |
| Stage III 198 (32.8%) | 128 (37.9%) |
| Stage IV 27 (4.5%) | 16 (4.8%) |
| **LVEF at enrolment** | |  
| N = 636 | |  
| <40%—HFrEF 336 (52.8%) | 235 (70.0%) |
| 40–49%—HFrEF 156 (24.5%) | 87 (26.2%) |
| ≥50%—HFpEF 144 (22.6%) | 104 (31.8%) |

HFrEF, heart failure with mid-range ejection fraction; HFpEF, heart failure with preserved ejection fraction; HFrEF, heart failure with reduced ejection fraction; VAS, visual analogue scale.

Table 2 Heart failure treatment in the 3 months before enrolment in the study population and in patients with HFrEF

| Study population \( N = 659 \) | HFrEF population \( N = 336 \) |
|---------------------------------|----------------------------------|
| **Heart failure treatment in 3 months before enrolment** | |  
| All ACE-I or ARB 468 (71.0%) | 250 (74.4%) |
| All beta-blockers 499 (75.7%) | 267 (79.5%) |
| All loop diuretics 477 (72.4%) | 246 (73.2%) |
| All MRA 220 (33.4%) | 134 (39.9%) |
| All digoxin 42 (6.4%) | 18 (5.4%) |
| **Therapeutic combinations** | |  
| ACE-I or ARB + beta-blockers 399 (60.5%) | 223 (66.4%) |
| ACE-I or ARB + beta-blockers + loop diuretic 324 (49.2%) | 188 (56.0%) |
| ACE-I or ARB + beta-blockers + MRA 154 (23.4%) | 101 (30.1%) |
| ACE-I or ARB + beta-blockers + loop diuretic + MRA 127 (19.3%) | 87 (25.6%) |

ACE-I, angiotensin-converting enzyme inhibitors; ARB, angiotensin receptor antagonist; MRA, mineralocorticoid receptor antagonist; HFrEF, heart failure with reduced ejection fraction.

*HFrEF = LVEF < 40%.*
Table 3 Use of the SCAD telemonitoring system and alerts in the system

| Study population N = 659 |
|--------------------------|
| Patients using the telemonitoring system at least once | 577 (87.6%) |
| Home telemonitoring duration (days) | N = 577 |
| Mean ± SD | 118.8 ± 84.4 |
| Median [IQR] | 99 [83–128] |
| <30 days | 46 (8.0%) |
| 30–179 days | 452 (78.3%) |
| ≥180 days | 79 (13.7%) |
| Patients surviving at least 3 months | 633 (96.1%) |
| Level of use (% total possible) over 3 month period | N = 633 |
| Mean ± SD | 65.7% ± 33.5% |
| Median [IQR] | 79.5% [50.0–92.3%] |
| Low user (lower tercile; <66.7%) | 209 (33.0%) |
| Medium user (middle tercile; 66.7–87.5%) | 217 (34.3%) |
| High user (upper tercile > 87.5%) | 207 (32.7%) |

Alerts triggered by the patient

| Type of alert | Red | Orange | Yellow | Total |
|---------------|-----|--------|--------|-------|
| Patient with at least one alert triggered over 3 months period (N = 633) | 112 (17.7%) | 402 (63.5%) | 105 (16.6%) | 427 (67.5%) |
| Number of alerts by type | 267 (12.0%) | 1682 (75.5%) | 279 (12.5%) | 2228 (100%) |
| Number of alerts over 3 month period (mean ± SD) | 2.2 ± 2.0 | 4.1 ± 4.1 | 2.6 ± 3.2 | 5.1 ± 5.0 |
| Signs and symptoms triggering alerts over the 3 month monitoring period | | | | |
| Weight gain | 23 (8.6%) | 1141 (67.8%) | — | 1164 (52.2%) |
| Cough | — | 396 (23.5%) | 127 (45.5%) | 523 (23.5%) |
| Oedema | 66 (24.7%) | 0 (48.0%) | 134 (48.0%) | 200 (9.0%) |
| SBP and pulse | 84 (31.5%) | 77 (4.6%) | 18 (6.5%) | 179 (8.0%) |
| Dyspnoea | 94 (35.2%) | 18 (1.1%) | 0 (4.2%) | 112 (5.0%) |
| Weight gain + oedema | — | 50 (3.0%) | — | 50 (2.2%) |

IQR, interquartile range; SD, standard deviation.

Table 4 Hospitalization events in the 7 days following alerts

| Type of event | Red | Orange | Yellow | TOTAL | P |
|---------------|-----|--------|--------|-------|---|
| N = 267 | N = 1682 | N = 279 | N = 2228 | (Χ² test) |
| All-cause hospitalizationa | 31 (11.6%) | 76 (4.5%) | 21 (7.5%) | 128 (5.7%) | <0.0001 |
| Hospitalization for a CV diagnosis | 24 (9.0%) | 55 (3.3%) | 14 (5.0%) | 93 (4.2%) | <0.0001 |
| Hospitalization for heart failureb | 16 (6.0%) | 29 (1.7%) | 7 (2.5%) | 52 (2.3%) | <0.0001 |

CV, cardiovascular.

Long-term outcome

In the year following the index date, the rate of all-cause readmission was 58.9%. Rates of unplanned hospitalizations for a cardiovascular diagnosis decreased from 79.4% in the year preceding enrolment to 41.1% in the following year, and rates of unplanned hospitalizations for HF decreased from 52.8% to 18.8%. The rates of readmission and of rehospitalization for HF are presented in Table 5.

The mean number of days alive and out of hospital over the 12 months following enrolment was $298 ± 101$ (median: 357 days [interquartile range: 267–366]) and increased significantly ($P = 0.0022$; Student’s t-test) between low and intermediate/high user (Table 5).

Rehospitalization and mortality rates increased as a function of age and of NYHA class, but no such association was observed with LVEF (Table S5). High users had a similar prognosis to intermediate users. Twelve-month mortality rates
varied significantly (P = 0.0017) with level of use, being highest in low users (Table 5). Kaplan–Meier survival curves for each outcome according to level of use are presented in Figure 3.

Discussion

This matched database study demonstrated that patient engagement in the SCAD telemonitoring programme in HF is associated with clinically important benefits. Better outcome was associated with a higher level of use of the telemonitoring programme for all outcomes evaluated, with a reduction of over 50% in the proportion of patients hospitalized for HF in the highest use tertile compared with the lowest, and a reduction of one third in the mortality rate.

This relationship between the intensity of telemonitoring and performance has been a consistent finding of previous studies of telemedicine programmes, as reviewed by Yun et al. The recent TIM-HF2 study demonstrated a significant reduction in mortality with a 24 h/7 day telemonitoring system in a population of highly compliant patients, with >70% compliance observed in 97% of the population. In contrast, the large randomized BEAT-HF study in the United States failed to show a reduction in the primary outcome of 6 month all-cause readmission, but compliance with coaching telephone calls and transmission of collected clinical data was very poor in this study. A recent post hoc analysis of the BEAT-HF trial assessing whether telemonitoring adherence is associated with a patient’s risk of hospitalization, emergency department visits, or death reported that lower adherence to weight telemonitoring in a given week was associated with an increased risk of subsequent hospitalization or death in the following week, which is consistent with the findings of the present study in suggesting that poor adherence to a telemonitoring programme is associated with an increased risk of intervention. In the French randomized OSCAT study, a therapeutic coaching programme did not reduce all-cause mortality or unplanned hospitalizations in the total HF population. However, in the subgroup with >70% adherence to body-weight measurement (53.8% of the telemonitoring group), a significant 42% relative risk reduction in the primary composite endpoint was observed. In our study, 67% of the patients use the system on >67.5% of expected occasions, and these patients presented lower rates of rehospitalization, mortality, and DAOH. Adherence to self-monitoring of symptoms thus seems to be one of the keys to the success of telemonitoring programmes in HF. In addition to early detection of symptom worsening, self-monitoring may also act as a coaching system for the patient. Educational telemonitoring could therefore help improve compliance with ESC...
Figure 3 Kaplan–Meier survival estimates for rehospitalization and death by level of use. Green curves: high level of use; blue curves: intermediate level of use; red curves: low level of use. (A) All-cause rehospitalization. (B) Rehospitalization for heart failure. (C) Death.
guidelines\textsuperscript{20} for HF, which recommend adequate training on adherence and self-care, through empowerment of the patient.

In our population, we were not able to identify patient characteristics that were associated with low use of the programme. Low engagement in telemonitoring, which is easy to measure in contrast to treatment compliance, could therefore be used as a signal of poor prognosis and taken into account in the management strategy. Sustained support and positive coaching of such patients by closer interactions with the HF team may be useful for preventing patient drop out and building engagement. A challenge remains to find alternative management strategies for patients who do not use or fail to engage with the SCAD programme.

We also observed a reduction in event rates during participation in the SCAD programme compared with the year prior to enrolment in the programme, with a decrease of \textasciitilde{}30\% in the rate of all-cause rehospitalization during the first year, a decrease of \textasciitilde{}50\% for rehospitalizations for cardiovascular disease and a decrease of \textasciitilde{}65\% for rehospitalization for HF. However, caution should be exercised in interpreting these findings, given the observational nature of the study.

Another important finding of our study was that the benefits in terms of rehospitalization and mortality associated with a high level of use of the programme persisted beyond the 3 month educational monitoring period. The readmission rate for HF at 1 year in intermediate and high users (12.9\% and 13.5\%) is lower than the 20\% reported in an observational study of all patients hospitalized for HF in France over the same period.\textsuperscript{21} Mortality was also lower in our population compared with available French data on patients with HF in 2009 (19.3\% vs. 40.3\% at 2 years),\textsuperscript{22} which was around the time when inclusion into the SCAD programme started. This large difference may be partly due to our population being younger, but age-specific mortality was also lower in all age classes. Our findings suggest that intensive therapeutic education during the SCAD telemonitoring period with respect to lifestyle measures and self-monitoring provides a sustained modification of patient behaviour and thus persistent clinical benefits. Therapeutic education would also be expected to increase patient knowledge of HF and its treatment, and thus build patient empowerment over the long-term. It is also possible that increased patient awareness about HF and its management improves adherence to medication. Such a long-term effect of an ‘educational’ telemonitoring programme was considered in the extended follow up of the TIM-HF2 study, which failed to show a significant clinical benefit in the year following the end of the programme.\textsuperscript{23} However, the benefit of telemonitoring in the TIM-HF2 study seemed to reach a plateau after 6 months, as demonstrated by the parallel survival curves between 6 and 24 months of follow up. This would suggest that there is no negative effect of interruption of the telemonitoring, as occurs upon discontinuation of medication. As in our study, we could argue that the effect of the educational telemonitoring is a result of patient education and empowerment during the 3 month intervention and that the effect is maintained at 12 months but without further incremental benefit. Other telemonitoring programmes have not observed a long-term benefit on mortality or hospitalization, such as the BEAT-HF\textsuperscript{17} and Yale NHLBI\textsuperscript{24} studies. A recent systematic review\textsuperscript{5} has highlighted the importance of intensity of monitoring symptoms and medication adherence for the effectiveness of telemonitoring. In the SCAD programme, symptoms and lifestyle are monitored 6 days a week, and the patients are contacted regularly by the programme nurse. This may contribute to the long-term benefits observed.

Use of the programme by participants was effective in that it generated alerts, triggered by an abnormal vital sign or the appearance of a symptom, which could be managed to help avoid worsening of HF. The majority of alerts were managed within 24 h, which would not have been possible if the patient had been obliged to go out and consult a physician when these events occurred. Around half of the red or orange alerts led to a physician consultation or hospitalization.

This study is one of the first in France to match a telemedicine database with comprehensive healthcare utilization data in the SNDS. A high matching rate was achieved (86.7\% of patients), and combining data from the two data sources provides considerable added value.\textsuperscript{10} This approach could be extended to evaluate the impact of telemonitoring on the economic burden of HF by analysing data from the SNDS on healthcare expenditure in these patients.

A limitation of the study is the absence of a control group. This limitation is to some extent mitigated by each patient acting as their own control in the comparison between pre-enrolment and post-enrolment event rates, and in the comparison of patients with different levels of use. Matching rates between the database were high, but one SCAD participant in eight could not be matched. However, there is no reason to think that this should have introduced an inclusion bias. Although in theory all alerts should be documented in the SCAD database, a documented answer is not available for around 10\% of red alerts and 22\% of orange alerts. These observations may help improve the quality of alert management.

Currently, only a small minority of the estimated 12 000 patients with HF in the Lower-Normandy region, of whom around 3800 are hospitalized each year, according to data from French national health insurance, participate in the SCAD programme. This is principally due to the limited resources available in terms of dedicated HF nurses and tactile pads available for patients at home. In addition, not all hospitals in the region currently participate in the programme. In the early phase of the programme, we observed that around 35\% of patients declined to participate, but these data have not been documented systematically. Nevertheless, patients...
are in general interested in participating. In the pilot phase of the programme, only 11 out of the 99 patients who were invited to participate subsequently withdrew, and in the present sample, only 12.5% of patients failed to use the programme. The findings of the present study provide a strong argument for providing more resources so that more patients can benefit from the SCAD programme.

In conclusion, this study identifies long-term clinical benefits associated with active engagement in educational home telemonitoring of patients with HF in terms of rehospitalization rates and death. These benefits would be expected to have a major impact on the economic burden of this disease, as it allows improved management of patients out of hospital. Telemedicine programmes such as SCAD could be relatively easily transposed to the management of other chronic debilitating conditions affecting elderly people with limited mobility. This would be particularly relevant during sanitary crises such as the COVID-19 pandemic.

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**Supporting information**

Additional supporting information may be found online in the Supporting Information section at the end of the article.

**Table S1.** Algorithm-generated alert classes in the SCAD programme.

**Table S2.** ICD-10 codes used for identifying hospitalisations.

**Table S3.** Socio-demographic and clinical characteristics according to the level of use of the SCAD programme.

**Table S4.** Alerts preceding hospitalisations under remote monitoring.

**Table S5.** Hospitalisation and mortality rates as a function of age, NYHA class and LVEF.
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