Healthcare costs of a telemonitoring programme for heart failure: indirect deterministic data linkage

analysis

Atul Pathak^{1*}, Pierre Levy², François Roubille³, Gilles Chatellier⁴, Grégoire Mercier^{5,6}, Sarah Alami⁷, Guila Lancman⁷, Hélène Pasche⁷, Corinne Laurelli⁸, Cécile Delval⁷, Juan Fernando Ramirez-Gil⁸ and Michel Galinier^{9,10}

¹Department of Cardiovascular Medicine, Princess Grace Hospital, Monaco, Principality of Monaco; ²LEDa – LEGOS, Université Paris Dauphine, PSL Research University, Paris, France; ³Cardiology Department, INI-CRT, CHU de Montpellier, PhyMedExp, Université de Montpellier, INSERM, CNRS, Montpellier, France; ⁴Clinical Research Unit and CIC 1418 INSERM, George-Pompidou European Hospital, Paris, France; ⁵Economic Evaluation Unit (URME), University Hospital of Montpellier, Montpellier, University, Montpellier, France; ⁶IDESP, Univ Montpellier, INSERM, Montpellier, France; ⁷Air Liquide Santé International, Bagneux, France; ⁸Air Liquide Santé International, Bagneux, France; ⁸Air Liquide Santé International, Bagneux, France; ⁹Cantiology Department, Rangueil University Hospital, Toulouse, France; ⁹Canter, Iniversity of Paul Sabatier-Toulouse III, Toulouse, France;

Abstract

Aims We aim to evaluate the costs associated with healthcare resource consumption for chronic heart failure (HF) management in patients allocated to telemonitoring versus standard of care (SC).

Methods and results OSICAT-ECO involved 745 patients from the OSICAT trial (NCT02068118) who were successfully linked to the French national healthcare database through an indirect deterministic data linkage approach. OSICAT compared a telemonitoring programme with SC follow-up in adults hospitalized for acute $HF \le 12$ months. Healthcare resource costs included those related to hospital and ambulatory expenditure for HF and were restricted to direct costs determined from the French health data system over 18 months of follow-up. Most of the total costs (69.4%) were due to hospitalization for HF decompensation, followed by ambulatory nursing fees (11.8%). During 18-month follow-up, total costs were 2% lower in the telemonitoring versus the SC group, due primarily to a 21% reduction in nurse fees. Among patients with NYHA class III/IV, a 15% reduction in total costs (€3131 decrease) was observed over 18-month follow-up in the telemonitoring versus the SC group, with the highest difference in hospital expenditure during the first 6 months, followed by a shift in costs from hospital to ambulatory at 12 months.

Conclusions HF hospitalization and ambulatory nursing fees represented most of the costs related to HF. No benefit was observed for telemonitoring versus SC with regard to cost reductions over 18 months. Patients with severe HF showed a non-significant 15% reduction in costs, largely related to hospitalization for HF decompensation, nurse fees, and medical transport.

Keywords Heart failure; Telemonitoring; Patient education; Hospitalization; Health economics

Received: 29 April 2022; Revised: 1 June 2022; Accepted: 21 June 2022

*Correspondence to: Atul Pathak, Department of Cardiovascular Medicine, Princess Grace Hospital, 1 Avenue Pasteur, BP 489 MC 98012, Monaco, Principality of Monaco. Tel: +377 97 98 2412; Mobile: +33621516352. Email: atul.pathak@chpg.mc

Introduction

Chronic heart failure (CHF) is a common yet potentially preventable and treatable condition.¹ It can also be lifethreatening, characterized by acute episodes of decompensation that often lead to hospitalization.^{2–4} CHF is an important contributor to healthcare expenditure, and new approaches are being sought to reduce its high morbidity and mortality, improve patient quality of life, and reduce healthcare costs. 3,5,6

Non-invasive home telemonitoring may be considered in patients with heart failure (HF) (Class IIb recommendation) to reduce the risk of recurrent cardiovascular and HF hospitalizations and cardiovascular death.¹ Telemonitoring can

© 2022 The Authors. ESC Heart Failure published by John Wiley & Sons Ltd on behalf of European Society of Cardiology.

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

facilitate rapid access to care when needed—particularly in at-risk patients (i.e. frail, living in a remote area, low socioeconomic status)—can lower patient transport costs and reduce the frequency of face-to-face consultations, the relevance of which was emphasized during the COVID-19 pandemic.¹ Remote medical monitoring is also being investigated as a way to increase the cost-effectiveness of patient management by reducing hospital admissions, especially for chronic conditions such as HF.⁷

The French ETAPES programme (Telemedicine Experiments for the Improvement of Health Care Paths),⁷ launched in 2014, is investigating the use of telemonitoring in improving healthcare pathways in several patient groups, including those with CHF, and has been extended to 2022 to more clearly evaluate and define the role of telemonitoring.⁸ The anticipated benefits of telemonitoring will be evaluated in ETAPES, based on healthcare resource consumption and associated costs, care organization, and patient satisfaction.⁹

The French Optimization of the Ambulatory Monitoring for Patients With Heart Failure by Tele-cardiology Economic study (OSICAT-ECO) was set up as an ancillary study of the OSICAT trial to investigate healthcare resource use and associated costs through linkage of OSICAT-study participants^{10,11} to the French national health insurance data system. The objective of the OSICAT-ECO study was to compare healthcare costs associated with HF healthcare resource consumption in patients on telemonitoring versus standard of care (SC) in France.

Methods

Study design and patients

OSICAT-ECO is based on data from patients enrolled in the randomized, open-label OSICAT trial (NCT02068118); the study design and primary results are described elsewhere.^{10,11} The OSICAT study was conducted between 2013 and 2017, and involved patients hospitalized for acute HF in the preceding 12 months who were randomized to telemonitoring plus a therapeutic coaching programme every 3 weeks versus SC and followed for 18 months. Patients in the telemonitoring group were each given a set of electronic scales and a device for answering symptom questions. Measurement of body weight and recording of HF symptoms were communicated daily by the patient to a secure server and were analysed automatically by a system that generated alerts, with the objective of predicting an episode of cardiac decompensation. In the event of an alert, nurses working at the telemonitoring platform contacted the patient to validate its relevance; if the alert was regarded as clinically relevant, the nurse advised the patient to contact their general practitioner or cardiologist, and telephoned the patient again 48 h

later. SC follow-up was performed according to usual practice by the patient's general practitioner or cardiologist, and generally involved pharmacological and device treatments, along with lifestyle advice and management of coexisting conditions. The results of OSICAT showed that telemonitoring did not lower the rate of the primary outcome (a composite of all-cause death or unplanned hospitalization at 18 months),¹⁰ but it reduced by 21% the relative risk of a first unplanned hospitalization for HF (P = 0.044) and led to improvements in the 36-Item Short Form Survey (SF-36) domains of vitality (P = 0.034) and social functioning (P = 0.025). The study also suggested a possible benefit in three pre-specified subgroups, with a relative risk reduction of first unplanned hospitalization for HF of 29% (P = 0.02) in patients with severe HF (NYHA III or IV), of 38% (P = 0.043) in socially isolated patients, and of 37% (P = 0.006) in patients adherent to body-weight measurement.

The OSICAT-ECO study was based on data from patients in OSICAT who were successfully linked to the French national health insurance data system¹² through an indirect deterministic data linkage approach. In France, almost 99% of French residents are affiliated to French health insurance plans, which collect all reimbursement in public and private practices concerning hospitalization, ambulatory care and medications.¹³ These data can be accessed through the Système National des Données de Santé [SNDS]) (http:// www.snds.gouv.fr/). Patient-level data are available, collected locally from a variety of sources (carte vitale [health insurance card of the French national healthcare system], treatment forms, private institution invoices and procedures, and outpatient visits invoiced by public hospitals) and relating to ambulatory and hospital reimbursements.¹² A unique pseudonymized identification number (numéro d'inscription au répertoire de l'INSEE [NIR]) derived from the subject's social security number is generated.

In the OSICAT-ECO study, patients aged \geq 18 years on 1 January 2013 with HF were identified from SNIIRAM-IC (*système national d'information inter-régimes de l'Assurance Maladie-IC*), extracted from SNDS on 22 June 2016, the date the last patient was enrolled in the OSICAT trial (see *supporting information*). As information on NIR was not collected in the OSICAT trial, an indirect deterministic data linkage approach using multiple indirect identifiers (sex, birth month and birth year, date of hospitalization(s), hospital identifier, date of consultation(s), and date of death if applicable) was applied to the SNIIRAM-IC cohort to identify the OSICAT-ECO cohort.

Cost items

The cost of healthcare resources analysed in the study included direct costs reimbursed by national health insurance related to both hospital expenditure (see *supporting*) *information*) and ambulatory expenditure in relation to HF, and comprised the following:

- 1. Hospitalization for HF
- a. hospitalization (>1 day) for HF decompensation in an acute-care hospital (including cost for emergency visits when preceding hospitalization);
- b. stay in day-care facility (≤1 day) for cardiovascular event (including cost for emergency department visits when preceding hospitalization);
- visits to the emergency department (not followed by hospitalization);
- d. drugs for HF (diuretics, beta-blockers, angiotensinconverting enzyme inhibitors, angiotensin II receptor blockers, digoxin, and ivabradine) delivered in hospital but not during a hospitalization;
- e. general medicine and cardiology consultations in hospital.
- 2. Post hospitalization (for HF decompensation)
- a. hospitalization in a post-acute care facility;
- b. home-based care hospitalization;
- 3. Ambulatory expenditure
- a. drugs and medical devices for HF provided in pharmacies;
- b. general practitioner, cardiologist, and nurse fees;
- ambulatory laboratory tests (blood and urinary ionograms, haemostasis, blood ferritin, natriuretic peptides, lipid profile, renal function);
- ambulatory medical procedures (cardiac echocardiography, electrocardiogram, magnetic resonance imaging);
- e. payments for sick leave (regardless of whether related to HF);
- f. medical transport costs for HF (limited to those on the day of HF hospitalization admission or discharge, or consultation with general practitioner or cardiologist).

Cost analysis

Costing was restricted to direct costs and was determined from the perspective of the French national health insurance data system. Costs were attributed from official French national tariffs in 2019 and are expressed in Euros. A national tariff was applied to each hospitalization based on the Groupes Homogènes de Malades (GHM) code attributed in the Programme de Médicalisation des Systèmes d'Information (PMSI) database (see supporting information). GHM tariffs include mainly medical and related procedures, nursing care, treatments (except specific expensive drugs and implants), drugs/devices used, food and accommodation, and investment costs for hospitalized patients. Additional

costs per day of hospitalization in an intensive care unit were added to GHM tariffs, when appropriate. For private hospitals, physicians' fees were also added.

To evaluate total expenditure for patients in the study, costs were evaluated over the follow-up period of each patient in the OSICAT trial, either during 18 months for those who completed the study as planned or until death or early discontinuation for other reasons. In addition, to assess the dynamics of costs over time, costs between inclusion and 6 months of follow-up for patients with \geq 6 months of follow-up for patients with \geq 12 months of follow-up, and costs between 12 and 18 months of follow-up for patients with \geq 18 months of follow-up were calculated secondarily.

Statistical methods

The statistical analysis plan was developed by Stève Consultants (Oullins, France) and validated by the sponsor and the OSICAT-ECO Scientific Committee. The analyses were performed using SAS version 9.4 (SAS Institute Inc. Cary, NC, USA) and using data from all the OSICAT-ECO study patients. Additional cost analyses were carried out in one of the subgroups identified in the OSICAT trial who may benefit from telemonitoring (i.e. New York Heart Association [NYHA] class III or IV).¹⁰ Owing to the low frequency of patients in NYHA IV, the analyses combined those with NYHA III or IV.

Exploratory comparisons of costs between the telemonitoring and SC groups were carried out using Student's *t*-test via bootstrap estimation. As commonly recommended for cost data,¹⁴ bootstrapping was used to estimate empirically the shape of a statistical sampling distribution. For the cost comparison, random samples were generated from the telemonitoring data with replacement. Similarly, random samples were generated from the SC data with replacement. This procedure was repeated 10 000 times, and the mean of the bootstrapping sample means was calculated for each group. Based on the high number of replicates, the real value of the mean cost could be estimated from the distribution of obtained samples and compared between both groups.

Ethics

The study was approved by the French ethics committee (*Comité éthique et scientifique pour les recherches, les études et les évaluations dans le domaine de la santé*) (*Commission Nationale de l'Informatique et des Libertés* authorization number 919019). In accordance with European and French laws, patients were contacted by letter requesting consent to reuse their data for this study.

Results

Data linkage

Of 990 patients enrolled in the OSICAT trial, 937 were included in the intention-to-treat (ITT) analysis. Fifteen patients in the ITT dataset withdrew their consent to participate in the OSICAT-ECO study and three were excluded because they did not receive the letter requesting consent to reuse their data. Therefore, 919 patients were eligible to participate in the OSICAT-ECO study.

The SNIIRAM-IC extraction included 4 155 885 beneficiaries. A total of 745 patients from the 919 eligible patients were successfully linked to the SNIIRAM-IC cohort, with a linkage success rate of 81.1% (745/919). Of these patients, 49.7% (n = 370) were in the telemonitoring group and 50.3% (n = 375) were in the SC group (*Figure 1*). The characteristics of the study groups remained balanced after data linkage, indicating that the initial randomization was retained, and the OSICAT-ECO cohort was similar to the OSICAT cohort (Supporting Information, *Table S1*). The percentage of men was similar in OSICAT and OSICAT-ECO (72.3% vs. 72.9%, respectively), the mean age was approximately 70 years, and half (49.1% vs. 51.3%) had a NYHA class III or IV.

Study patients

The mean age of the study patients was 69.6 \pm 12.5 years at inclusion, 72.9% were men, and 51.3% were in NYHA class III or IV. Most patients (62.6%) had HF with reduced ejection fraction (\leq 40%). The baseline characteristics of patients in the telemonitoring and SC groups are shown in *Table 1*. Median (Q1, Q3) length of follow-up was around 18 months (546 days; 361, 548) (mean follow-up 14 months for the telemonitoring group [422 \pm 183 days] and 15 months for the SC group [455 \pm 167 days]).

Cost analysis and healthcare resource use

All study patients

Most of the total costs (69.4%) were due to HF hospitalization (12 164 of 17 431 Euros) over 18-month follow-up. Ambulatory nursing fees were the second highest cost (11.8%, 2067 Euros), followed by ambulatory medical procedures or laboratory tests for HF (4.7%, 829 Euros) and medical transport for HF (3.2%, 558 Euros). During 18-month follow-up, total costs were 2% lower in the telemonitoring group than in the SC group (*Table 2*), due primarily to a 21% reduction in ambulatory nursing fees.



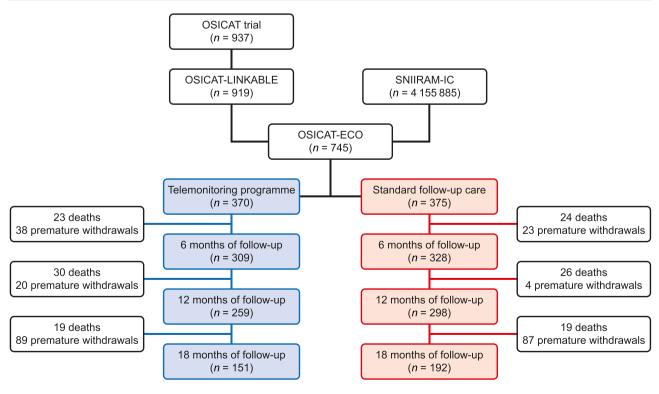


Table 1 Baseline characteristics of OSICAT-ECO patients

	Telemonitoring	Standard of care	
Characteristic	(<i>n</i> = 370)	(<i>n</i> = 375)	
Male sex	277 (74.9%)	266 (70.9%)	
Age in years, mean (SD)	69.2 (12.6)	70.0 (12.4)	
$BMI \ge 30 \text{ kg/m}^2$	115 (31.1%)	103 (27.5%)	
NYHA class	N = 365	N = 372	
	19 (5.2%)	19 (5.1%)	
II	154 (42.2%)	163 (43.8%)	
III	148 (40.5%)	159 (42.7%)	
IV	44 (12.1%)	31 (8.3%)	
HF category			
HF with reduced ejection fraction (<40%)	224 (60.5%)	242 (64.5%)	
HF with preserved ejection fraction (>40%)	143 (38.7%)	133 (35.5%)	
Undefined	3 (0.8%)	0 (0.0%)	
Coronary heart disease	182 (49.2%)	183 (48.8%)	
History of atrial fibrillation	140 (37.8%)	128 (34.1%)	
Chronic renal disease	106 (28.7%)	113 (30.1%)	
COPD	69 (18.6%)	76 (20.3%)	
Cancer ^a	55 (14.9%)	58 (15.5%)	
Depression	15 (4.1%)	19 (5.1%)	
Arterial hypertension	226 (61.1%)	211 (56.3%)	
Dyslipidaemia	207 (55.9%)	203 (54.1%)	
Diabetes	115 (31.1%)	140 (37.3%)	
Socially isolated at inclusion ^b	85 (24.7%)	88 (25.1%)	

^aMedical history or coexisting condition.

^bDefined as SF-36 mental health subscore <45, or mental component summary composite score <35, or combination of SF-36 mental health subscore <50 and mental component summary composite score <40, or medical history of depression or mood disturbances/alterations, or use of concomitant antidepressant medications.

	Cost (€)		Difference (TLM minus SC)	
Cost items	Telemonitoring $(n = 370)$	Standard of care $(n = 375)$	ۻ	%
Hospital expenditure				
Hospitalization for HF (>1 day) in an acute-care hospital facility	12 274	12 057	+217	+2%
Stay in day-care facility for cardiovascular event	439	541	-101	-19%
Hospitalization in a post-acute care facility after HF hospitalization	63	198	-135	-68%
Home-based care hospitalization for HF	23	66	-44	-66%
Visit to emergency department ^b	8	10	-2	-20%
Drugs for HF delivered in hospital	90	105	-15	-14%
General medicine consultation in hospital	42	39	+3	+6%
Cardiology consultation in hospital	24	29	-5	-17%
Ambulatory expenditure				
Drugs for HF in pharmacies	291	316	-25	-8%
Medical devices for HF in pharmacies	60	43	+17	+40%
GP fees	155	150	+5	+3%
Cardiologist fees	49	38	+11	+27%
Nurse fees	1829	2303	-474	-21%
Ambulatory laboratory tests of interest	762	686	+77	+11%
Ambulatory medical procedures of interest	96	116	-19	-17%
Payments for sick leave	486	539	-53	-10%
Medical transport for HF	586	531	+55	+10%
Total				
Hospital expenditure ^d	13 002	12 913	+89	+1%
Ambulatory expenditure	4313	4721	-407	-9%
Total	17 273	17 588	-315	-2%

GP, general practitioner; HF, heart failure.

^aNone of the differences were statistically significant. ^bNot followed by hospitalization.

^aThe specialty of the physician seen during the consultation is not well coded in hospital. ^aTotal of hospital expenditure is not equal to the sum of hospital item costs due to missing data.

Table 3 Mean cost and cost savings in Euros for patients with NYHA III and IV at inclusion (during a median of 18 months' follow-up, with a mean follow-up of 13 months in the telemonitoring group and 14 months in the SC group)

	Co	st (€)	Difference (TLM minus SC)	
Cost items	Telemonitoring $(n = 192)$	Standard of care (n = 190)	ۻ	%
Mean (SD) follow-up (days)	400.0 (193.5)	432.8 (179.0)		
(95% confidence interval)	(371.8, 427.1)	(407.2, 457.7)		
Hospital expenditure				
Hospitalization for HF (>1 day) in an acute-care	13 115	15 025	-1910	-13%
hospital facility				
Stay in day-care facility for cardiovascular event	370	539	-169	-31%
Hospitalization in a post-acute care facility after	121	188	-68	-36%
HF hospitalization				
Home-based care hospitalization for HF	44	75	-32	-42%
Visit to emergency department ^b	8	11	-3	-31%
Drugs for HF delivered in hospital	119	103	+16	+16%
General medicine consultation in hospital	42	37	+5	+13%
Cardiology consultation in hospital ^c	25	27	-2	-9%
Ambulatory expenditure				
Drugs for HF in pharmacies	284	308	-24	-8%
Medical devices for HF in pharmacies	33	71	-38	-53%
GP fees	164	127	+37 ^d	+29%
Cardiologist fees	47	35	+13	+37%
Nurse fees	2141	3106	-965	-31%
Ambulatory laboratory tests of interest	699	757	-58	-8%
Ambulatory medical procedures of interest	101	123	-23	-18%
Payments for sick leave	500	366	+134	+37%
Medical transport for HF	466	776	-310	-40%
otal				
Hospital expenditure ^e	13 917	15 776	-1860	-12%
Ambulatory expenditure	4434	5668	-1234	-22%
Total	18 237	21 368	-3131	-15%

^aNone of the differences were statistically significant except for GP fees.

^bNot followed by hospitalization.

The specialty of the physician seen during the consultation is not well coded in hospital.

 $^{d}P = 0.047.$

'Total of hospital expenditure is not equal to the sum of hospital items costs due to missing data.

GP, general practitioner; HF, heart failure; SD, standard deviation.

No significant differences in total costs and healthcare resource use were observed between the telemonitoring and SC groups at any time during follow-up (Supporting Information, *Figure S1*). The costs decreased in a similar manner in both groups, being highest in the first semester of follow-up (reflecting HF hospitalizations) and decreasing thereafter. Ambulatory expenses remained relatively constant throughout.

Subgroup of New York Heart Association class III and IV patients

Costs and cost reductions in the subgroup of patients with NYHA class III or IV are shown in *Table 3* and *Figure 2*. A substantial but not statistically significant reduction in costs with telemonitoring, related primarily to reduction of HF hospitalization, nurse fees, and medical transports was observed: a decrease of €3131 (15% reduction) was made over a median follow-up of 18 months (mean 13 months in telemonitoring group vs. 14 months in SC group). Total cost reductions were observed in the telemonitoring group relative to the SC group throughout the study, with a 14% reduction from 0–6 months (€1513 saving), a 26% reduction over 6–12 months (€1003 saving)

(Supporting Information, *Table S2*). Savings in hospital expenditure were 15% in the first semester, rising to 30% in the second (both driven by savings in HF hospitalization), and decreasing to 3% in the third. In contrast, savings in ambulatory expenditure increased from 10% to 20% and 37% over the corresponding follow-up periods.

Discussion

This economic analysis compared the overall costs related to HF in patients from the French OSICAT study who were randomized to telemonitoring versus those allocated to SC follow-up. The costs of HF hospitalization represented 69.4% of the total costs related to HF, similar to what is reported in the literature^{15,16}; ambulatory nursing fees accounted for a further 11.8% of total costs. No benefit was observed for telemonitoring versus SC with regard to cost savings over 18 months of follow-up in the overall population. Among the subgroup with severe HF (NYHA class III or IV), a substantial but not statistically significant reduction in

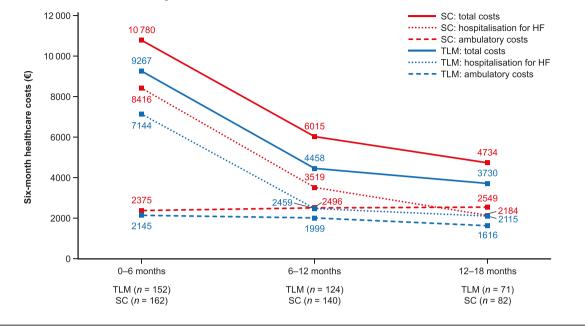


Figure 2 Mean cost analysis over time according to telemonitoring or standard of care follow-up for patients with severe HF (NYHA III or IV) at inclusion. SC, standard of care; TLM, telemonitoring.

costs was observed with telemonitoring, with the highest difference in hospital expenditure apparent during the first 6 months—the period when the patient is most at risk of rehospitalisation—then a shift in costs from hospital to ambulatory at 12 months.

The OSICAT-ECO study adopted a design approach mixing data from a randomized controlled trial with the comprehensive real-world data issued from the French national health insurance data system. Data from the OSICAT study were matched with data in the French national administrative reimbursement database, enabling the inclusion of costs related to HF over 18 months of follow-up regardless of whether incurred in or out of hospital. The linkage success rate was above 80% and compares favourably with previous studies reporting rates ranging from 76% to 90%.^{17–19} Moreover, the characteristics of the two study groups remained balanced in OSICAT-ECO patients, which is an important criterion for data linkage validity.

Conflicting results have been reported from randomized trials in non-invasive telemonitoring,^{20–25} largely due to differences in the populations, healthcare structures, and types of remote monitoring, whereas meta-analyses have shown more consistent benefits for morbidity and mortality.^{26–29} Health-economic data on telemedicine are now emerging. A cost-utility analysis from a Danish study in 274 patients with HF reported that 'telehealthcare' (comprising a tablet, digital blood pressure monitor, and a set of scales) in addition to usual care was highly cost-effective.³⁰ Patients were instructed to perform measurements once to twice a week, and specialized HF nurses were responsible for the education, instructions, and monitoring, and were given the authority to

change medications if indicated. The nurses could also contact the HF clinic for guidance on specific issues. Patients in the control group received the usual care, whereby general practitioners were responsible for monitoring patients. The authors reported an adjusted reduction in costs of £5096 (5960 Euros) (95% confidence interval 8736–1456) per patient, corresponding to a reduction in total healthcare costs of 35%.

The Telemedical Interventional Management in Heart Failure II trial (TIM-HF2) has shown that non-invasive remote patient management in HF reduced days lost due to unplanned cardiovascular hospital admissions and all-cause death; it was also cost-effective compared with usual care alone, being associated with overall cost savings and improved clinical effectiveness.³¹ One difference between TIM-HF2 and our study is that patients with major depression were excluded in the former, whereas socially isolated patients (based on SF36 score, depression, or use of antidepressant medication) were retained in our study.

A retrospective cohort study using SCAD data matched with French Health Insurance data involved 528 patients with HF in Normandy, France.³² SCAD, funded by ETAPES, is a 3-month telemonitoring programme associated with therapeutic education. This study assessed the difference in direct costs between the year before and the year after inclusion in the SCAD programme, which differs from the methods used in OSICAT-ECO, and showed that total health expenditure decreased significantly by a mean of 18% (€3210/patient) in the year after enrolment versus the 12 months prior (P < 0.0001). There was a bias; however, as 99 patients who died within the 12 months after SCAD initiation were ex-

cluded, which is the period most of the costs occur during the end of life. Together, these studies demonstrate the potential for medical telemonitoring to optimize patient care and reduce total costs related to HF decompensation.

OSICAT was conducted before ETAPES was launched, so there are differences in the approaches used for telemonitoring. ETAPES is based on three elements: a medical device with algorithm generating alerts, direct management by a cardiologist of the transmitted alerts, and a therapeutic coaching programme,³³ whereas remote monitoring in OSICAT was based on two elements, with no direct monitoring by a cardiologist. In the event of a clinical alert, the nurse telephoned the patient to contact their physician or cardiologist after the alert was validated by the patient.¹⁰ In contrast, today, ETAPES involves a direct alert to the patient's cardiologist, facilitating a rapid treatment response.

Limitations

An indirect deterministic data linkage approach using multiple identifiers was applied to the SNIIRAM-IC cohort. The most severe patients (NYHA class III and IV) were more easily linked, as expected, because data linkage was based on hospitalizations. Some of the cost items, such as payments for sick leave and emergency department visits not followed by hospitalizations, were not strictly specific to HF. The study sample size calculation for the OSICAT trial was based on its primary clinical objective, with a composite outcome. It was not therefore designed to show a statistical difference in costs between study groups. This was particularly true for subgroup analyses performed in OSICAT-ECO, which should be interpreted with caution and considered as preliminary exploratory results in the absence of sufficient statistical power. Moreover, it is well known that in studies with low numbers of patients, mean costs may be sensitive to small numbers of patients with high levels of resource use, resulting in skewed distribution of costs. However, the arithmetic mean remains the most informative measure of total healthcare costs as needed for healthcare policy decisions. Indeed, as less than half (43.4%) of the OSICAT-ECO study patients had at least one classic hospitalization for HF decompensation over their 18-month follow-up, median values do not provide any information. As this study was randomized, the costs of HF management before entry were not considered. Finally, the findings may not be applicable to other national healthcare systems.

Conclusions

In this economic study, based on patients enrolled in a randomized, open-label clinical trial, HF hospitalization and ambulatory nursing fees represented the majority of the costs related to HF. Whereas no benefit was observed for telemonitoring versus SC with regard to cost reduction over 18 months in the overall population, patients with severe HF showed a substantial non-significant reduction in costs, largely related to hospitalization for HF decompensation, nurse consultations, and medical transports.

Acknowledgements

The authors thank the Air Liquide Santé International Project Team (Les Loges-en-Josas and Gentilly, France) and CDM e-Health Team (Jouy-en-Josas, France). Stève Consultants (Oullins, France) performed the statistical analysis. Sophie Rushton-Smith, PhD (MedLink Healthcare Communications, London) provided medical writing assistance, under the direction of the authors, and was funded by CDM e-Health.

Conflict of interest

Prof. Pathak reports grants, personal fees and non-financial support from CDM e-Health; and personal fees and non-financial support from Novartis, Abbott, Merck, Servier, Medtronic, Boston Scientific. P. Levy received personal fees from stève consultants. Prof. Roubille reports grants, personal fees and non-financial support from Air Liquide Santé International; grants and personal fees from Abbott, Novartis, Astra Zeneca; and personal fees from Vifor, Servier, Abiomed, Zoll, Medtronic, Resmed, LVL, Eole and Pfizer. Dr Chatellier reports personal fees from Air Liquide Santé. Dr Mercier reports personal fees from Air Liquide Santé International, during the conduct of the study. S. Alami is an employee of Air Liquide Santé International and shareholder in Air Liquide. Dr Lancman is an employee of Air Liquide Santé International and shareholder in Air Liquide. H. Pasche is an employee of Air Liquide Santé International and shareholder in Air Liquide. C. Laurelli is an employee of Air Liquide Santé International and shareholder in Air Liquide. Dr Delval is an employee of Air Liquide Santé International and shareholder in Air Liquide. Dr Ramirez-Gil is an employee of Air Liquide Santé International and shareholder in Air Liquide. Prof. Galinier reports grants and personal fees from Chronic Care Connect/Air Liquide.

Funding

The study was supported by Alere E-Sante (Jouy-en-Josas, France) from 2013 to beginning of 2016 and by CDM e-Health (Jouy-en-Josas, France) from 2016 onwards.

Supporting information

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

Table S1. Characteristics of patients before and after matching.

References

- McDonagh TA, Metra M, Adamo M, Gardner RS, Baumbach A, Bohm M, Burri H, Butler J, Celutkiene J, Chioncel O, Cleland JGF, Coats AJS, Crespo-Leiro MG, Farmakis D, Gilard M, Heymans S, Hoes AW, Jaarsma T, Jankowska EA, Lainscak M, Lam CSP, Lyon AR, McMurray JJV, Mebazaa A, Mindham R, Muneretto C, Francesco Piepoli M, Price S, Rosano GMC, Ruschitzka F, Kathrine Skibelund A, ESC Scientific Document Group. ESC guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur Heart J*. 2021; 2021: 3599–3726.
- 2. Ponikowski P, Voors AA, Anker SD, Bueno H, Cleland JGF, Coats AJS, Falk V, Gonzalez-Juanatey JR, Harjola VP, Jankowska EA, Jessup M, Linde C, Nihoyannopoulos P, Parissis JT, Pieske B, Riley JP, Rosano GMC, Ruilope LM, Ruschitzka F, Rutten FH, van der Meer P, Group ESCSD. 2016 ESC guidelines for the diagnosis and treatment of acute and chronic heart failure: The task force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC). Developed with the special contribution of the heart failure association (HFA) of the ESC. Eur Heart J. 2016; 37: 2129-2200.
- Heidenreich PA, Albert NM, Allen LA, Bluemke DA, Butler J, Fonarow GC, Ikonomidis JS, Khavjou O, Konstam MA, Maddox TM, Nichol G, Pham M, Pina IL, Trogdon JG, American Heart Association Advocacy Coordinating C, Council on Arteriosclerosis T, Vascular B, Council on Cardiovascular R, Intervention, Council on Clinical C, Council on E, Prevention, Stroke C. Forecasting the impact of heart failure in the United States: A policy statement from the American Heart Association. Circ Heart Fail, 2013: 6: 606–619.
- Gabet A, Juilliere Y, Lamarche-Vadel A, Vernay M, Olie V. National trends in rate of patients hospitalized for heart failure and heart failure mortality in France, 2000-2012. Eur J Heart Fail. 2015; 17: 583–590.
- Dunlay SM, Redfield MM, Weston SA, Therneau TM, Hall Long K, Shah ND, Roger VL. Hospitalizations after heart failure diagnosis a community perspec-

tive. J Am Coll Cardiol. 2009; 54: 1695–1702.

- Chun S, Tu JV, Wijeysundera HC, Austin PC, Wang X, Levy D, Lee DS. Lifetime analysis of hospitalizations and survival of patients newly admitted with heart failure. *Circ Heart Fail*. 2012; 5: 414–421.
- 7. Le Douarin Y, Traversino Y, Graciet A, Josseran A, participants of Giens Xxxv Round Table Health e. Telemonitoring and experimentation in telemedicine for the improvement of healthcare pathways (ETAPES program). Sustainability beyond 2021: What type of organisational model and funding should be used? *Therapie*: 2020: 43–56.
- Ministere des Solidarites et de la Sante. Remote monitoring: STEPS. https:// solidarites-sante.gouv.fr/soins-et-maladies/prises-en-charge-specialisees/teles ante-pour-l-acces-de-tous-a-des-soins-adistance/article/la-telesurveillance-eta pes. (6 October 2021)
- Order of October 11, 2018 laying down specifications for experiments relating to support by remote monitoring implemented on the basis of Article 54 of Law No. 2017–1836 on the financing of social security for 2018. https://www. legifrance.gouv.fr/jorf/id/JORFTEXT00 0037533105. (1 November 2021)
- Galinier M, Roubille F, Berdague P, Brierre G, Cantie P, Dary P, Ferradou JM, Fondard O, Labarre JP, Mansourati J, Picard F, Ricci JE, Salvat M, Tartiere L, Ruidavets JB, Bongard V, Delval C, Lancman G, Pasche H, Ramirez-Gil JF, Pathak A, Investigators O. Telemonitoring versus standard care in heart failure: A randomised multicentre trial. *Eur J Heart Fail.* 2020; 22: 985–994.
- 11. Bendelac H, Pathak A, Molinier L, Ruidavets JB, Mayère A, Berry M, Delmas C, Roncalli J, Galinier M. Optimization of ambulatory monitoring of patients with heart failure using telecardiology (OSICAT). Eur Res Telemedicine/La Recherche Européenne en Télémédecine. 2014; 3: 161–167.
- Tuppin P, Rudant J, Constantinou P, Gastaldi-Menager C, Rachas A, de Roquefeuil L, Maura G, Caillol H, Tajahmady A, Coste J, Gissot C, Weill A, Fagot-Campagna A. Value of a na-

Table S2. Mean cost savings over time in Euros for patients

 with NYHA III and IV at inclusion.

Figure S1. Mean cost analysis over time according to telemonitoring or standard of care follow-up for all patients. HF, heart failure; SC, standard of care; TLM, telemonitoring.

tional administrative database to guide public decisions: From the systeme national d'information interregimes de l'Assurance Maladie (SNIIRAM) to the systeme national des donnees de sante (SNDS) in France. *Rev Epidemiol Sante Publique*. 2017; **65**: S149–S167.

- Bezin J, Duong M, Lassalle R, Droz C, Pariente A, Blin P, Moore N. The national healthcare system claims databases in France, SNIIRAM and EGB: Powerful tools for pharmacoepidemiology. *Pharmacoepidemiol Drug Saf.* 2017; 26: 954–962.
- Henderson AR. The bootstrap: A technique for data-driven statistics. Using computer-intensive analyses to explore experimental data. *Clin Chim Acta*. 2005; **359**: 1–26.
- 15. Comin-Colet J, Enjuanes C, Verdu-Rotellar JM, Linas A, Ruiz-Rodriguez P, Gonzalez-Robledo G, Farre N, Moliner-Borja P, Ruiz-Bustillo S, Bruguera J. Impact on clinical events and healthcare costs of adding telemedicine to multidisciplinary disease management programmes for heart failure: Results of a randomized controlled trial. J Telemed Telecare. 2016; 22: 282–295.
- l'Assurance Maladie. Personnes prises en charge pour insuffisance cardiaque (IC) aigue en 2019 - Fiches pathologie https://assurance-maladie.ameli.fr/sit es/default/files/2019_fiche_insuffisan ce-cardiaque-aigue.pdf. (15 December 2021)
- 17. Perlbarg J, Allonier C, Boisnault P, Daniel F, Le Fur P, Szidon P, Bourgueil Y. Feasibility and practical value of statistical matching of a general practice database and a health insurance database applied to diabetes and hypertension. *Sante Publique*. 2014; **26**: 355–363.
- Didier R, Gouysse M, Eltchaninoff H, Le Breton H, Commeau P, Cayla G, Glatt N, Glatt B, Gabbas M, Tuppin P, Liepchitz L, Boussac M, Iung B, Gilard M. Successful linkage of French large-scale national registry populations to national reimbursement data: Improved data completeness and minimized loss to follow-up. Arch Cardiovasc Dis. 2020; 113: 534–541.
- 19. Raffray M, Bayat S, Lassalle M, Couchoud C. Linking disease registries

and nationwide healthcare administrative databases: The French renal epidemiology and information network (REIN) insight. *BMC Nephrol.* 2020; **21**: 25.

- Chaudhry SI, Mattera JA, Curtis JP, Spertus JA, Herrin J, Lin Z, Phillips CO, Hodshon BV, Cooper LS, Krumholz HM. Telemonitoring in patients with heart failure. *N Engl J Med.* 2010; 363: 2301–2309.
- Koehler F, Winkler S, Schieber M, Sechtem U, Stangl K, Bohm M, Boll H, Baumann G, Honold M, Koehler K, Gelbrich G, Kirwan BA, Anker SD, Telemedical Interventional Monitoring in Heart Failure I. Impact of remote telemedical management on mortality and hospitalizations in ambulatory patients with chronic heart failure: The telemedical interventional monitoring in heart failure study. *Circulation*. 2011; 123: 1873–1880.
- 22. Angermann CE, Stork S, Gelbrich G, Faller H, Jahns R, Frantz S, Loeffler M, Ertl G, Competence Network Heart F. Mode of action and effects of standardized collaborative disease management on mortality and morbidity in patients with systolic heart failure: The interdisciplinary network for heart failure (INH) study. Circ Heart Fail. 2012; 5: 25–35.
- Lynga P, Persson H, Hagg-Martinell A, Hagglund E, Hagerman I, Langius-Eklof A, Rosenqvist M. Weight monitoring in patients with severe heart failure (WISH). A randomized controlled trial. *Eur J Heart Fail*. 2012; 14: 438–444.

- 24. Boyne JJ, Vrijhoef HJ, Crijns HJ, De Weerd G, Kragten J, Gorgels AP, investigators T. Tailored telemonitoring in patients with heart failure: Results of a multicentre randomized controlled trial. *Eur J Heart Fail*. 2012; 14: 791–801.
- 25 Seferovic PM, Ponikowski P, Anker SD, Bauersachs J, Chioncel O, Cleland JGF, de Boer RA, Drexel H, Ben Gal T, Hill L, Jaarsma T, Jankowska EA, Anker MS, Lainscak M, Lewis BS, McDonagh T, Metra M, Milicic D, Mullens W, Piepoli MF, Rosano G, Ruschitzka F, Volterrani M, Voors AA, Filippatos G, Coats AJS. Clinical practice update on heart failure 2019: Pharmacotherapy, procedures, devices and patient management. An expert consensus meeting report of the heart failure Association of the European Society of cardiology. Eur J Heart Fail. 2019; 21: 1169-1186.
- Xiang R, Li L, Liu SX. Meta-analysis and meta-regression of telehealth programmes for patients with chronic heart failure. *J Telemed Telecare*. 2013; 19: 249–259.
- Nakamura N, Koga T, Iseki H. A meta-analysis of remote patient monitoring for chronic heart failure patients. J *Telemed Telecare*. 2014; 20: 11–17.
- Inglis SC, Clark RA, Dierckx R, Prieto-Merino D, Cleland JG. Structured telephone support or non-invasive telemonitoring for patients with heart failure. *Cochrane Database Syst Rev.* 2015; 2015: CD007228.
- 29. Yun JE, Park JE, Park HY, Lee HY, Park DA. Comparative effectiveness of

Telemonitoring versus usual Care for Heart Failure: A systematic review and meta-analysis. *J Card Fail*. 2018; **24**: 19–28.

- 30. Vestergaard AS, Hansen L, Sorensen SS, Jensen MB, Ehlers LH. Is telehealthcare for heart failure patients cost-effective? An economic evaluation alongside the Danish TeleCare north heart failure trial. *BMJ Open*. 2020; **10**: e031670.
- 31. Sydow H, Prescher S, Koehler F, Koehler K, Dorenkamp M, Spethmann S, Westerhoff B, Wagner CJ, Liersch S, Rebscher H, Wobbe-Ribinski S, Rindfleisch H, Muller-Riemenschneider F, Willich SN, Reinhold T. Cost-effectiveness of noninvasive telemedical interventional management in patients with heart failure: Health economic analysis of the TIM-HF2 trial. *Clin Res Cardiol.* 2021.
- 32. Sabatier R, Legallois D, Jodar M, Donio V, Courouve L, Hauchard K, Boudevin F, Chalus TD, Belin A, Milliez P. Cost-effectiveness analysis of a telemonitoring program on patients with heart failure in Normandy: An 8-year retrospective analysis (2009–2017). Eur Heart J. 2020; 41: 3468.
- Ministry of Solidarity and Health. ETAPES: Telemedicine Experiments for Improving Health Pathways. https:// solidarites-sante.gouv.fr/soins-et-maladies/prises-en-charge-specialisees/ telemedecine/article/etapes-experimentations-de-telemedecine-pour-l-amelioration-des-parcours-en. (28 January 2020)