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CLINICAL RESEARCH

Costs of remote monitoring vs. ambulatory follow-ups of implanted cardioverter defibrillators in the randomized ECOST study

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Aims The Effectiveness and Cost of ICD follow-up Schedule with Telecardiology (ECOST) trial evaluated prospectively the economic impact of long-term remote monitoring (RM) of implantable cardioverter defibrillators (ICDs).

Methods and results The analysis included 310 patients randomly assigned to RM (active group) vs. ambulatory follow-ups (control group). Patients in the active group were seen once a year unless the system reported an event mandating an ambulatory visit, while patients in the control group were seen in the ambulatory department every 6 months. The costs of each follow-up strategy were compared, using the actual billing documents issued by the French health insurance system, including costs of (i) (a) ICD-related ambulatory visits and transportation, (b) other ambulatory visits, (c) cardiovascular treatments and procedures, and (ii) hospitalizations for the management of cardiovascular events. The ICD and RM system costs were calculated on the basis of the device remaining longevity at the end of the study. The characteristics of the study groups were similar. Over a follow-up of 27 months, the mean non-hospital costs per patient-year were €1695 ± 1131 in the active, vs. €1952 ± 1023 in the control group ($P = 0.04$), a €257 difference mainly due to device management. The hospitalization costs per patient-year were €2829 ± 6382 and €3549 ± 9714 in the active and control groups, respectively ($P = 0.46$). Adding the ICD to the non-hospital costs, the savings were €494 ($P = 0.005$) or, when the monitoring system was included, €315 ($P = 0.05$) per patient-year.

Conclusion From the French health insurance perspective, the remote management of ICD patients is cost saving.

Clinical trials registration NCT00989417, www.clinicaltrials.gov

Keywords Telemedicine • Remote monitoring • Implantable cardioverter defibrillator • Costs • Cost analysis

Introduction

Remote monitoring (RM) of implantable cardioverter defibrillators (ICDs) was introduced just over10 years ago and its use is rapidly increasing.[1] The clinical relevance of remotely monitoring ICD recipients has been confirmed. Randomized studies have shown that RM was as safe as conventional ambulatory follow-ups.[2,3] Most importantly, RM was highly effective in lowering the incidence of appropriate and inappropriate shocks.[2] Furthermore, it shortens the medical follow-ups of ICD recipients.[4,5] Besides these obvious benefits, its economic value needed to be examined,[6] as several studies suggested that RM might be cost saving compared with ambulatory follow-ups.[7–9] However, these studies used expected costs based on estimates and did not take into account the multiplicity of variables that determine costs.

The ECOST trial was designed to compare prospectively the safety and the costs of remote ICD monitoring with standard

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What's new?

- Effectiveness and Cost of ICD follow-up Schedule with Telecardiology is the first study that has evaluated the real economic impact of long-term remote monitoring (RM) of implantable cardioverter defibrillators (ICDs), using the actual billing documents issued by the French health insurance system.
- After it was shown to be safe and clinically efficacious, ICD RM was found cost-saving. Device management with RM optimizes patient care and clinical resources, without supplementary costs.
- The findings on this study have direct implications on the management of ICD patients and may therefore impact clinical practice. Remote monitoring tends to become the new gold standard of care for ICD recipients follow-up.

ambulatory follow-ups. The safety results have been previously reported.[2] We present here the results of the economic analysis.

Methods

Trial design

We randomly assigned patients, in a 1 : 1 design, to RM (active group) vs. ambulatory follow-ups (control group), before they underwent implantation of single- or dual-chamber ICD, and after they had granted written consent to participate in the study. The protocol of ECOST has been previously published.[2] The study included 433 recipients of commercially available ICD equipped with Biotronik Home Monitoring® (HM; Biotronik SE and Co. KG), a wireless communication system, which automatically transmits diagnostic data and trend analyses between the implanted device and the caregiver on a daily basis. The system and its operating mode have been previously described.[3,10,11] Patients assigned to the active group were followed with HM and were seen by a cardiac electrophysiologist in the ambulatory department within 1–3 months of ICD implantation, and at Months 15 and 27 of follow-up, thereafter. At any time, additional ambulatory visits could be triggered by HM data or scheduled at the request of the patient or a physician. In the control group, the patients were seen in the ambulatory department at 1–3 months after ICD implantation for a first follow-up, and at 9, 15, 21, and 27 months of follow-up, thereafter. Additional visits could be scheduled if requested by the patient or a physician. In addition, all study participants were followed by a cardiologist, as needed, for management of their underlying heart disease.

The trial protocol, which complied with the declaration of Helsinki, was reviewed and approved by the pertinent ethics committees. All patient information and data collected were treated confidentially by the sponsor and all other parties involved in the trial, and all clinical centres were regularly monitored by the study team.

Costs analysis

The costs, presented per patient per year, were calculated in Euros (€), using the actual charges entered in the database of the French national health insurance billing system. Their written authorization was requested to the patients to anonymously retrieve pertinent data from the system, based on social security numbers, including (i) direct costs of ambulatory ICD follow-ups and associated transportation expenses, (ii) direct costs of ICD-unrelated ambulatory follow-ups, cardiovascular treatments and procedures, and (iii) direct hospital costs for management of cardiovascular disorders. The classifications used by the health insurance databases, such as diagnosis-related groups, major diagnostic categories and the classification of medical acts or drug treatments <http://www.ameli.fr>, were used to differentiate and analyse cardiovascular hospitalizations, cardiovascular procedures, and drugs costs separately. The hospitalization cost was determined by the health insurance system by its diagnosis-related group class, which is weighted by the hospitalization duration and associated co-morbidities. The approximately €60 medical charges for ambulatory follow-up of ICD and transportation costs were specifically identified in the databases by the dates of follow-ups collected during the study. The travel reimbursements were based on a flat rate, mainly related to the (i) types of transportation, such as ambulance, taxi, personal vehicle or public transportation, and (ii) mileage.

A cost analysis compared the individual costs in each study group, during the study period. Incurred and reimbursed costs per patient-year were analysed, as well as their difference, reflecting the costs supported by the patient or by a supplemental insurance. The French national health insurance system typically covers 55–75% of non-hospital costs, 80% of the hospital costs, and 65% of the transportation costs, though chronically ill patients are 100% covered. In addition, co pays are collected from the patients for each reimbursed service, including €18 for hospitalizations, €1 for consultations, €2 for transportation, and €0.5 for drug prescriptions. Incurred, reimbursed and supported costs used for this study were all recorded in the national health insurance databases, except for the additional costs generated by the management of the RM which are not yet reimbursed in France and have therefore not been accounted for the analysis.

The costs of ICD are invoiced in addition to the diagnosis-related groups and also covered by the health insurance system. Their prices, which are set by a France's economics committee for health products, appear on the list of products and services. At the time of this study, the prices and reimbursements were €12 000 for a single-chamber and €14 000 for a dual-chamber ICD. The cost of ICD per patient was calculated as a function of the remaining device longevity at the end of the study, which was evaluated by the slope of battery depletion over time, using a linear regression model. In case of death or device explantation before the end of the study, the full price of a partially unused device was entered in the analysis. The costs of the hardware and service provided for the telemonitoring were not taken into account in the analysis since, as they were not covered by health insurance at the time of the study, they were not invoiced by the manufacturer.

Patient acceptance analysis

Additional variables that we analysed included patient quality of life and willingness to pay for HM services. The quality of life was measured at several stages of the study, including (i) enrolment, (ii) first follow-up, (iii) 15-month follow-up, and (iv) last follow-up, using the SF-36 questionnaire. The benefits conferred to the patients were measured as willingness to pay, i.e. the monetary amount which they were willing to pay for the HM service, as well as the preference expressed for one vs. the other type of follow-up. This was ascertained at the end of the study by a questionnaire probing into (i) preferred ambulatory follow-ups every 6 months, (ii) preferred HM + yearly ambulatory follow-ups, or (iii) no preference.

Statistical analysis

After confirmation of the statistical non-inferiority of the primary safety endpoint of the study, by comparing the proportion of patients who

experienced one or more major adverse event in each group,[2] we analysed the costs of healthcare associated with each follow-up strategy. Consecutive costs incurred and reimbursed in both study groups throughout the entire study period were calculated per patient-year and reported as means, standard deviations, medians and inter-quartile ranges. Because the data were not normally distributed, a non-parametric bootstrap method was used to derive bias-corrected confidence levels (10 000 replications).[12,13] The mean between-group differences were compared, using Student's *t*-test with bootstrap-based *P* values. The baseline nominal characteristics of the study groups were compared by χ^2 test. The normal distribution of variables was verified, using the Kolmogorov–Smirnov and Shapiro–Wilk tests. Normally distributed variables were compared, using Student's *t*-test, after confirmation of the equality of variances by Levene's test. Mann–Whitney's non-parametric test was used to compare the SF-36 scale data and summary scores between both the groups.

All tests were performed at a *P* value of 0.05 significance level. The SPSS, version 18.0 (SPSS Institute, Inc.) and R, version 2.14.1 statistical software, were used for the analyses.

Results

Among the 433 study participants, 310 (71.6%) granted permission to access their health insurance data and comprised the study population for this economic analysis, with clinical characteristics similar to the initial population. The baseline clinical characteristics of the158 patients in the active and 152 patients in the control group were also similar (*Table 1*). The mean follow-up duration was 26.5 ± 3.4 months.

Direct, non-hospital costs reimbursed by healthcare insurance

The costs of non-hospital care (*Table 2*), including (i) costs related to the device management and (ii) other non-hospital costs, were 13% lower in the active than in the control group, corresponding to a €257 (95% CI: 5–489) cost saving per patient-year ($P = 0.04$), a decrease attributable particularly to the lower costs of device management.

Table 1 Baseline characteristics of patients included in the economic analysis of the ECOST study

	All patients ($n = 310$)	Study groups	
		Active ($n = 158$)	Control ($n = 152$)
Age, year	60.7 ± 12.6	61.4 ± 13.1	59.9 ± 11.9
Men/women	279 (90.0)/31 (10.0)	140 (88.6)/18 (11.4)	139 (91.4)/13 (8.6)
Left ventricular ejection fraction,	35.2 ± 13.8	34.6 ± 13.3	35.7 ± 14.3
Indication for ICDs			
Primary prevention	170 (54.8)	86 (54.4)	84 (55.3)
Secondary prevention	140 (45.2)	72 (45.6)	68 (44.7)
Implanted device			
Single chamber	232 (74.8)	119 (75.3)	113 (74.3)
Dual chamber	78 (25.2)	39 (24.7)	39 (25.7)
Device implant			
First implantation	269 (86.8)	133 (84.2)	136 (89.5)
Replacement	41 (13.2)	25 (15.8)	16 (10.5)
New York Heart Association functional class			
I	86 (27.7)	42 (26.6)	44 (28.9)
II	196 (63.2)	104 (65.8)	92 (60.5)
III	22 (7.1)	8 (5.1)	14 (9.2)
Underlying heart disease			
Coronary artery disease	196 (63.2)	100 (63.3)	96 (63.2)
Non-ischemic dilated cardiomyopathy	54 (17.4)	29 (18.4)	25 (16.4)
Brugada or long QT syndrome	16 (5.2)	7 (4.4)	9 (5.9)
Hypertrophic cardiomyopathy	11 (3.5)	3 (1.9)	8 (5.3)
Other cardiomyopathy	11 (3.5)	5 (3.2)	6 (3.9)
Undetermined	8 (2.6)	5 (3.2)	3 (2.0)
None	14 (4.5)	9 (5.7)	5 (3.3)
History of			
Sustained ventricular tachycardia	71 (22.9)	38 (24.1)	33 (21.7)
Ventricular fibrillation	43 (13.9)	21 (13.3)	22 (14.5)
Torsade de pointes	2 (0.6)	1 (0.6)	1 (0.7)
Atrial arrhythmia	48 (15.5)	27 (17.1)	21 (13.8)

Values are expressed as means ± SD, or numbers (%) of observations. Between-group differences are all statistically non-significant.

Table 2 Mean hospital and non-hospital costs per patient-year reimbursed by healthcare insurance in each study group

		Study group		Bootstrap results	
		Active (n = 158)	Control (n = 152)	Cost saving in the active group (95% CI)	P
TOTAL direct hospital and non-hospital costs (€)	Mean Median	4524 ± 6634 2346 (1348–4786)	5501 ± 9815 2512 (1451–5067)	977 (−617; 3203)	0.33
Direct non-hospital costs (€)	Mean Median	1695 ± 1131 1606 (1022–2265)	1952 ± 1024 1865 (1299–2661)	**257 (5; 489)**	**0.04**
Direct non-hospital costs related to device management (€)	Mean Median	215 ± 185 139 (83–284)	290 ± 212 206 (135–401)	**74 (30; 118)**	**0.001**
Costs related to ICD-related ambulatory visits (€)	Mean Median	99 ± 33 87 (81–112)	139 ± 34 136 (120–161)	**40 (32; 47)**	**<0.001**
Costs related to transportation for ICD ambulatory visits (€)	Mean Median	116 ± 177 0 (0–200)	151 ± 205 31 (0–263)	34 (−8; 77)	0.12
Other direct non-hospital costs (€)	Mean Median	1480 ± 1091 1333 (793–2036)	1662 ± 999 1479 (1006–2291)	182 (−60; 408)	0.14
Costs related to cardiovascular procedures (€)	Mean Median	121 ± 213 50 (0–142)	162 ± 305 58 (135–358)	41 (−12; 106)	0.19
Costs related to ICD-unrelated ambulatory visits (€)	Mean Median	231 ± 151 209 (108–326)	260 ± 153 234 (135–358)	29 (−4; 63)	0.10
Costs related to cardiovascular treatments (€)	Mean Median	1128 ± 979 1040 (549–1546)	1240 ± 797 1068 (693–1761)	113 (−114; 296)	0.27
Direct hospital costs related to cardiovascular disorders (€)	Mean Median	2829 ± 6382 91 (0–3063)	3549 ± 9714 0 (0–2490)	720 (−879; 2902)	0.46

Values are means ± SD and median with inter-quartile in euros (€); bootstrap results of 10 000 samples (bias corrected) with replacement for the difference in mean cost comparisons between both groups; CI, confidence interval.

Costs related to the device management

The mean costs of non-hospital care for device management, including ICD-related ambulatory visits and associated transportation costs, were 26% lower in the active than in the control group, representing a mean €74 (95% CI: 30–118) saving per patient-year (P = 0.001, *Table 2*). The cost saving per patient/year was €50 (95% CI: €4–96), an 18% reduction (P = 0.04), for the first 15 months, and €110 (95% CI: €62–160), a 36% reduction (P < 0.001), for the last 12 months of follow-up.

Costs of ambulatory visits for ICD management

The costs of ambulatory visits for ICD management were dependent on the number of follow-ups in each group. During the 27-month follow-up period, the mean number of scheduled or additional ambulatory follow-ups per patient-year was 26% lower (P < 0.001) in the active than in the control group (*Table 3*). The costs of these follow-ups were 29% lower in the active than in the control group, representing a mean €40 cost saving per patient-year (*Table 2*).

Transportation costs

The transportation costs hinged on (i) the number of ambulatory follow-up visits, (ii) the proportion of patients whose transportation costs were reimbursed, (iii) the transportation distance, and (iv) the type of transportation. In both the groups, 48% of patients had reimbursed transportation costs (*Table 3*), including taxis (74.3%), personal vehicles (10.7%), ambulances (5.6%), and other means of transportation (0.2%). The mean cost of a single round trip was €136 ± 90 and the mean home-hospital round trip distance was 132 ± 92 km. The cost of transportation in the 48% of patients was €50 lower per patient-year (*Table 3*), though this 17% between-groups difference was not statistically significant (P = 0.11).

Other direct, non-hospital costs reimbursed by the healthcare insurance

The other non-hospital costs were similar in both groups (*Table 2*).

Direct hospital costs reimbursed by healthcare insurance

No significant between-groups difference was observed in the costs of hospitalizations for management of cardiovascular disorders (*Table 2*).

Costs supported by the patients

The costs supported by the patients for non-hospital-based device management (*Figure 1A*), including (i) non-reimbursed transportation costs (*Table 3*), (2) co-payments after reimbursement of transports and ambulatory visits, and (3) personal contributions, represented a mean of 14 ± 17% of all costs incurred, or €28 ± 40 per patient-year in the active vs. €33 ± 48 in the control group (P = 0.16). The overall costs supported by the patients represented 8 ± 10% of non-hospital costs (*Figure 1B*), or €112 ± 93 per patient-year in the active vs. €118 ± 102 in the control group (P = 0.49), plus 1 ± 2% of hospital costs (*Figure 1C*), or €64 ± 148 per patient-year in the active vs. €50 ± 141 in the control group (P = 0.44), representing 7 ± 9% of all costs (*Figure 1D*), or €176 ± 188 per patient-year in the active vs. €170 ± 171 in the control group (P = 0.80).

Table 3 Transportation costs for ICD ambulatory visits, reimbursed by insurance or supported by patients

	Active group ($n = 158$)	Control group ($n = 152$)	P
Number of ambulatory visits per patient-year	1.38 ± 0.61	2.07 ± 0.53	<0.001*
Transportation reimbursed by insurance			
Number of patients with reimbursed transports	73 (46.2)	76 (50.0)	0.51
Distance home/ medical institution, roundtrip (km)	145.5 ± 99.9	128.4 ± 87.7	0.24
Mean costs of transports per patient-year (€)	252 ± 183	302 ± 197	0.11
Transportation supported by patients			
Number of patients without reimbursed transports	85 (53.4)	76 (50.0)	0.51
Mean distance home/ medical institution, round trip (km)	60.0 ± 61.1	59.1 ± 63.4	0.61
Mean costs of transports per patient-year (€)	32 ± 34	41 ± 54	0.21

Values are expressed as means ± SD or numbers (%) of observations.

Costs of devices

The mean estimated ICD costs per patient, based on the remaining longevity of the devices after the 27 months of follow-up, were €5832 ± 2047 in the active vs. €6365 ± 3125 in the control group (bootstrap-based $P = 0.08$).

Quality-of-life estimates

The between- and within-groups differences in mean physical, psychological, and overall SF-36 quality-of-life scores were all statistically non-significant.

Patient willingness to pay

The patient preferred ICD follow-up strategy was based on 194 (44.8%) questionnaires completed at the end of the study. A preference in favour of the active group follow-up strategy was expressed by 73.7% of patients assigned to the active group vs. 65.3% assigned to the control group ($P = 0.21$), while 7.1% of patients in the active and 14.7% in the control groups expressed a preference in favour of the follow-up strategy applied in the control group. The remaining patients expressed no preference. The mean amount that the patients were willing to pay for the use of HM was €84 ± 112 per month (median €43; $P = 0.11$ between both groups).

Discussion

In this randomized comparison, we found that, over a follow-up of 27 months after ICD implantation, the direct non-hospital-related costs of HM were 26% lower than the costs of ambulatory follow-up. This decrease was not associated with other higher costs, such as those incurred for ambulatory visits unrelated to the ICD, or for cardiovascular procedures or hospitalizations for the management of cardiovascular disorders.

While the methodology of medico-economical studies is often criticized,[6,14] Effectiveness and Cost of ICD follow-up Schedule with Telecardiology was based on a rigorous methodology, which yielded reliable results. The strengths of ECOST are (i) its randomized and controlled design, (ii) the clear definition and homogeneity of the study sample, (iii) the reliability and comprehensiveness of the sources of cost information, (iv) its duration, and (v) the combined cost analysis and evaluation of the efficacy of the follow-up strategies. These strengths separate ECOST from earlier publications pertaining to the RM of ICD recipients.[7,8]

It was worthwhile to focus the cost analysis on the direct non-hospital costs and the costs related to the devices, both of which might be influenced by the RM strategy. While one might suspect the RM to shorten the life of the ICD battery because of the energy consumed by data transmission, it is quite the opposite. This slight consumption was more than compensated by the battery saving due to fewer delivered or undelivered capacitor charges during the study.[2] In those two cost items, the saving attributable to RM was €494 per patient per year. This saving represents €3 295 968 per year for the first 27 months of follow-up when applied to the 6672 French single- and dual-chamber ICD recipients implanted in 2011, and grows even further when extrapolated to an ICD longevity approaching 8 years in ~24 000 French recipients. The cost saving is expected to increase with the life of the ICD, since the annual between-group difference in the number of ambulatory visits increases after the 3-month mandatory follow-up in both the groups, and because of the differences linked to the device end-of-life management. The saving conferred by RM was predicted by the estimation of Fauchier *et al.*, who calculated that the elimination of two ambulatory visits per year would lower the cost by

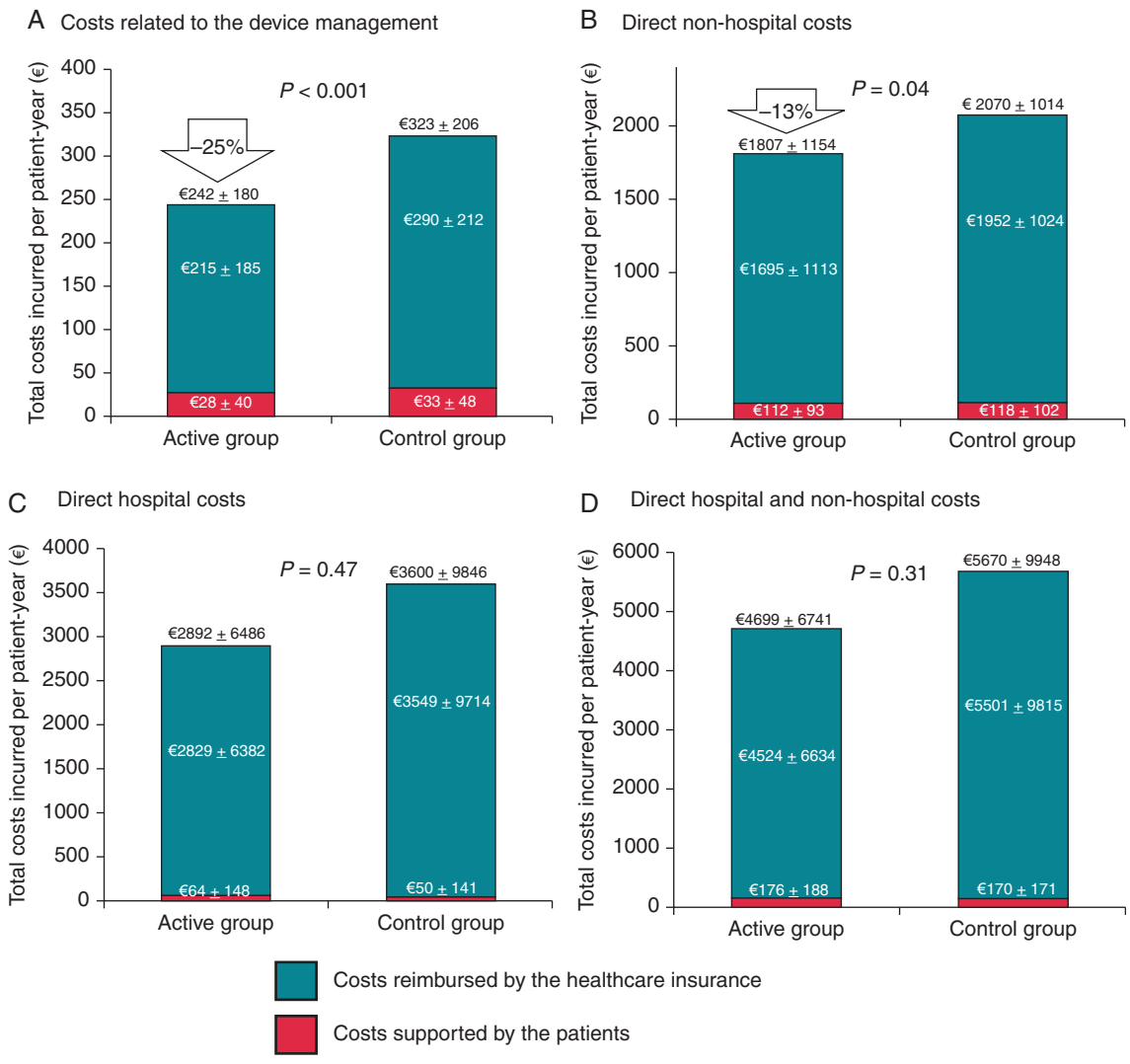

Figure 1 Costs incurred, reimbursed by the healthcare insurance and supported by the patients, per patient-year. The costs supported by the patients are the difference between the costs incurred and the amount reimbursed by the health insurance. (*A*) The costs related to the device management, including ambulatory follow-ups of ICD and related transportations. (*B*) The addition of the device management costs and other non-hospital costs. (*C*) Costs of hospital care for the management of cardiovascular disorders. (*D*) Addition of non-hospital and hospital costs. The *P* values correspond to the between-group differences in incurred costs. The *P* values corresponding to differences in costs supported by patients are shown in the text.

$430 per patient per year, including $121 per transportation and $94 per medical service.[7] The savings recorded in ECOST were lower because the study protocol had planned a difference of a single annual visit between the two study groups, and because the mean costs for medical services were actually lower. Effectiveness and Cost of ICD follow-up Schedule with Telecardiology also accounted for additional ICD consultations prompted by HM notification events or requested by patients or physicians. Furthermore, in the study by Fauchier *et al.*, the costs covered by third parties were not distinguished from those supported by the patients, whereas only 48% of patient transportations costs in ECOST were absorbed by the health insurance. While one might have expected a parallel increase in costs other than those directly related to the ICD, for example a greater number of supplemental general cardiology visits counterbalancing the decrease in the number of ICD-related ambulatory visits, this was not the case.

The savings observed in this study were particularly significant in view of the greater efficacy of RM (fewer shocks delivered) combined with its equivalent safety (no increase in major adverse events) compared with ambulatory visits.[2] Moreover, the large epidemiological ALTITUDE study, which included nearly 186 000 patients, suggested that RM could have a positive impact on survival, even though this result has to be confirmed by a controlled study.[15]

From the patient standpoint, as expected, RM did not significantly lower the direct costs, since the health insurance system in France covers nearly all expenses, particularly in the case of chronic illnesses. Indirect costs, such as lost wages, were not included in this analysis, because they were not important enough, as a large proportion of

patients were retired or on disability. Neither did we include a cost-utility analysis based on the quality-of-life questionnaire, as it seemed overly generic and insufficiently specific. The overall cost–benefit analysis, however, was clearly in favor of RM.

From the perspective of healthcare providers, the ambulatory follow-ups are highly time-consuming, with a mean 27 min for scheduled visits measured in the joint EHRA-Eucomed survey.[16] Remote monitoring, on the other hand, is time saving.[4,5,17] The equipment of patients with transmitters and their registration on the site of telemonitoring can be assumed by paramedical staff. Furthermore, this time is more than compensated by the decreased number of ambulatory visits. An analysis of the REFORM trial found that RM saved 81 h of medical time per year per 100 patients followed.[9] The HM system is highly automatized, and the review of ICD data posted on the Internet site is useful only after an event notification of an adverse rhythm or technical event. In our experience, the yearly number of notifications per patient for single- or dual-chamber ICD is 3.5, and the time spent by physicians and nurses in the management of event notifications is 7 and 9 min per patient per year, respectively. This workload generates a cost that only slightly minimizes the cost saving. This performance level is achievable only with an appropriate alert system, which no longer depends on audible or tactile warnings, which disturb the patient with variable degrees of relevancy. Finally, from the hospital perspective, one may surmise that the cost of hospitalizations is lowered by RM because of a shorter mean duration of hospitalization.[18]

Limitations of the study

Effectiveness and Cost of ICD follow-up Schedule with Telecardiology evaluated a single RM system, Biotronik Home Monitoring®. One might hypothesize that other systems, which operate with different functions, might not be associated with the same cost differences, compared with ambulatory follow-ups.

The costs of the system itself were not included in this analysis because, in France, these costs were absorbed by the device manufacturer at the time of the study. Since 2011, however, the HM system is reimbursed by the French healthcare insurance, at a rate of ~€1000, which includes the transmission costs and the service for each implanted device for its entire life. If this cost, based on the remaining device longevity at the end of the study, is added to the direct non-hospital costs and the costs related to the devices, the cost saving is lowered by only 7% (€4466 ± 1492 per patient-year in the active vs. €4781 ± 1594 per patient-year in the control group) and remains a substantive €315 per patient-year. Furthermore, although the medical staff used additional time to manage event notifications in the group followed remotely, our analysis did not include a pricing for remote follow-up, a reimbursement that does not currently exist in France. In view of cost savings of €315 per patient-year highlighted in ECOST and according to the reimbursement that could be implemented for the medical staff, a cost balance between both monitoring strategies could be obtained. In addition, the field of healthcare financing is complex and financing modalities differ greatly among countries.[19] The results of the ECOST apply to the French system. However, the details of the study methodology which are provided should allow a conversion of the results to different funding systems. Finally, our results were obtained in recipients of ICD without resynchronization therapy. Compared with our sample, cardiac resynchronization therapy defibrillator (CRT-D) recipients typically suffer from more severe heart disease and generate higher medical costs. However, in a previous study, RM reduced the total amount of healthcare consumption, including by patients suffering from heart failure who were recipients of ICD or CRT-D.[20]

Conclusion

After it was shown to be safe and clinically efficacious, RM of ICD was found cost saving from the French health insurance perspective. Remote management of ICD patients meets the criteria proposed by Scott for the validation of activities of telemedicine, which are quality, accessibility, cost and acceptance criteria.[21]

Supplementary data

The French investigators and institutions that participated in the ECOST trial are given as supplementary data available at *Europace* online.

Conflict of interest: L. G.-M. receives consulting fees from Biotronik, Boston Scientific, Medtronic, Inc., St. Jude Medical and Sorin Group; N. S. receives consulting fees from Biotronik, Boston Scientific, Medtronic, Inc., St. Jude Medical and Sorin Group; C. K. receives consulting fees from Biotronik, Boston Scientific, Medtronic, Inc. and Sorin Group; J.-S. H. receives consulting fees from St. Jude Medical; E. A. receives consulting fees from Biotronik, Medtronic, Inc., St. Jude Medical; S. K. is the recipient of institutional grants and of consulting and speaker fees from Biotronik, Boston Scientific, Medtronic, Inc., St. Jude Medical and Sorin Group.

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References

1. Dubner S, Auricchio A, Steinberg JS, Vardas P, Stone P, Brugada J *et al.* ISHNE/EHRA expert consensus on remote monitoring of cardiovascular implantable electronic devices (CIEDs). *Europace* 2012;**14**:278–293.
2. Guédon-Moreau L, Lacroix D, Sadoul N, Clémenty J, Kouakam C, Hermida JS *et al.* ECOST trial Investigators. A randomized study of remote follow-up of implantable cardioverter defibrillators: safety and efficacy report of the ECOST trial. *Eur Heart J* 2013;**34**:605–614.
3. Varma N, Epstein AE, Irimpen A, Schweikert R, Love C; TRUST Investigators. Efficacy and safety of automatic remote monitoring for implantable cardioverter-defibrillator follow-up: The Lumos-T Safely Reduces Routine Office Device Follow-Up (TRUST) trial. *Circulation* 2010;**122**:325–332.

4. Masella C, Zanaboni P, Di Stasi F, Gilardi S, Ponzi P, Valsecchi S. Assessment of a remote monitoring system for implantable cardioverter defibrillators. *J Telemed Telecare* 2008;**14**:290–294.
5. Vogtmann T, Stiller S, Marek A, Kespohl S, Gomer M, Kühlkamp V *et al.* Workload and usefulness of daily, centralized home monitoring for patients treated with CIEDs: results of the MoniC (Model Project Monitor Centre) prospective multicentre study. *Europace* 2013;**15**:219–226.
6. Burri H, Heidbüchel H, Jung W, Brugada P. Remote monitoring: a cost or an investment? *Europace* 2011;**13**:ii44–ii48.
7. Fauchier L, Sadoul N, Kouakam C, Briand F, Chauvin M, Babuty D *et al.* Potential cost savings by telemedicine-assisted long-term care of implantable cardioverter defibrillator recipients. *Pacing ClinElectrophysiol* 2005;**28**1:S255–S259.
8. Raatikainen MJ, Uusimaa P, van Ginneken MM, Janssen JP, Linnaluoto M. Remote monitoring of implantable cardioverter defibrillator patients: a safe, time-saving, and cost-effective means for follow-up. *Europace* 2008;**10**:1145–1151.
9. Elsner CH, Sommer P, Piorkowski C, Taborsky M, Neuser H. A prospective multicenter comparison trial of home monitoring against regular follow-up in MADIT II patients: Additional visits and cost impact. *Comput Cardiol* 2006;**33**: 241–244.
10. Lazarus A. Remote, wireless, ambulatory monitoring of implantable pacemakers, cardioverter defibrillators, and cardiac resynchronization therapy systems: analysis of a worldwide database. *Pacing Clin Electrophysiol* 2007;**30**:S2–S12.
11. Guédon-Moreau L, Chevalier P, Marquié C, Kouakam C, Klug D, Lacroix D *et al.* ECOST trial Investigators. Contributions of remote monitoring to the follow-up of implantable cardioverter-defibrillator leads under advisory. *Eur Heart J* 2010;**31**: 2246–2252.
12. Efron B, Tibshirani RJ. *An Introduction to the Bootstrap*. New York, NY: Chapman and Hall; 1993.
13. Barber JA, Thompson SG. Analysis of cost data in randomized trials: an application of the non-parametric bootstrap. *Stat Med* 2000;**19**:3219–3236.
14. Mistry H. Systematic review of studies of the cost-effectiveness of telemedicine and telecare. Changes in the economic evidence over twenty years. *J Telemed Telecare* 2012;**18**:1–6.
15. Saxon LA, Hayes DL, Gilliam FR, Heidenreich PA, Day J, Seth M *et al.* Long-term outcome after ICD and CRT implantation and influence of remote device follow-up: the ALTITUDE survival study. *Circulation* 2010;**122**:2359–2367.
16. Boriani G, Auricchio A, Klersy C, Kirchhof P, Brugada J, Morgan J *et al.*; European Heart Rhythm Association; Eucomed. Healthcare personnel resource burden related to in-clinic follow-up of cardiovascular implantable electronic devices: a European Heart Rhythm Association and Eucomed joint survey. *Europace* 2011; **13**:1166–1173.
17. Calo L, Gargaro A, De Ruvo E, Palozzi G, Sciarra L, Rebecchi M *et al.*; Economic impact of remote monitoring on ordinary follow-up of implantable cardioverter defibrillators as compared with conventional in-hospital visits. A single-center prospective and randomized study. *J Interv Card Electrophysiol* 2013;**37**:69–78.
18. Crossley GH, Boyle A, Vitense H, Chang Y, Mead RH; CONNECT Investigators. The CONNECT (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision) trial: the value of wireless remote monitoring with automatic clinician alerts. *J Am Coll Cardiol* 2011;**57**:1181–1189.
19. Boriani G, Burri H, Mantovani LG, Maniadakis N, Leyva F, Kautzner J *et al.* Device therapy and hospital reimbursement practices across European countries: a heterogeneous scenario. *Europace* 2011;**13**:ii59–ii65.
20. Landolina M, Perego GB, Lunati M, Curnis A, Guenzati G, Vicentini A *et al.* Remote monitoring reduces healthcare use and improves quality of care in heart failure patients with implantable defibrillators: the evolution of management strategies of heart failure patients with implantable defibrillators (EVOLVO) study. *Circulation* 2012;**125**:2985–2992.
21. Scott RE, McCarthy FG, Jennett PA, Perverseff T, Lorenzetti D, Saeed A *et al.* Telehealth outcomes: a synthesis of the literature and recommendations for outcome indicators. *J Telemed Telecare* 2007;**13**:1–38.