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
Telemicine • Remote monitoring • Implantable cardioverter defibrillator • Costs • Cost analysis

Introduction
Remote monitoring (RM) of implantable cardioverter defibrillators (ICDs) was introduced just over 10 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 and proportion of inappropriate shocks.2,3 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
ambulatory follow-ups. The safety results have been previously reported. 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. The study included 433 recipients of commercially available ICD equipped with Biotronik Home Monitoring®, 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, 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, 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, we ana-
lysed 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). 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 χ² 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 popula-
tion for this economic analysis, with clinical characteristics similar to
the initial population. The baseline clinical characteristics of the 158
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 at-
tributable particularly to the lower costs of device management.

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

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

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

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. 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...
$430 per patient per year, including $121 per transportation and $94 per medical service. 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. 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.

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. Remote monitoring, on the other hand, is time saving. 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. The HM system is highly automated, 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.

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. 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.

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 features of telemedicine, which are quality, accessibility, cost and acceptance criteria.

Supplementary data

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


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