Economic analysis of remote monitoring of cardiac implantable electronic devices: Results of the Health Economics Evaluation Registry for Remote Follow-up (TARIFF) study

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BACKGROUND Remote monitoring (RM) of cardiac implantable electronic devices has been demonstrated to improve outpatient clinic workflow and patient management. However, few data are available on the socioeconomic impact of RM.

OBJECTIVE The aim of this study was to assess the costs and benefits of RM compared with standard care (SC).

METHODS We used 12-month patient data from the Health Economics Evaluation Registry for Remote Follow-up (TARIFF) study (N = 209; RM: n = 102 (48.81%); SC: n = 107 (51.19%)). Cost comparison was made from 2 perspectives: the health care system (HCS) and patients. The use of health care resources was defined on the basis of hospital clinical folders. Out-of-pocket expenses were reported directly by patients.

RESULTS *HCS perspective:* The overall mean annual cost per patient in the SC group (€1044.89 ± €1990.47) was significantly higher than in the RM group (€482.87 ± €2488.10) ($P < .0001$), with a reduction of 53.87% being achieved in the RM group. The primary driver of cost reduction was the cost of cardiovascular hospitalizations (SC: €`886.67 ± €1979.13 vs RM: €432.34 ± €2488.10; $P = .0030$). *Patient and caregiver perspective:* The annual cost incurred by patients was significantly higher in the SC group than in the RM group (SC: €169.49 ± €189.50 vs RM: €56.87 ± €80.22; $P < .0001$). Patients' quality-adjusted life-years were not significantly different between the groups. *Provider perspective:* The total number of inhospital device follow-up visits was reduced by 58.78% in the RM group.

CONCLUSION RM of patients with cardiac implantable electronic devices (CIEDs) is cost saving from the perspectives of the HCS, patients, and caregivers. Introducing appropriate reimbursements will make RM sustainable even for the provider, i.e. the hospitals which provide the service and encourage widespread adoption of RM.

KEYWORDS Telemedicine; Remote monitoring; Implantable cardioverter-defibrillator; Reimbursement; Cost-effectiveness

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Background

The remote monitoring (RM) of cardiac implantable electronic devices (CIEDs) has a record of improved clinical outcomes. Indeed, patients undergoing RM have been shown to have lower mortality than those not on RM.[1] Moreover, the 3-year all-cause hospitalization rate has proved to be significantly lower in patients with RM. In spite of its clinical benefits, however, RM is not universally adopted.[1–3] RM offers a unique opportunity to improve clinic efficiency and to provide continuous monitoring of device functioning and patients' clinical status, as established in the recently published HRS consensus document.[4] Several trials have demonstrated the effectiveness of RM in the early detection

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of technical malfunctions and clinical events without compromising patient safety.[5–8] Finally, RM has been associated with high patient acceptance and satisfaction and with increased adherence to programmed follow-up.[9]

The cost-effectiveness of RM of CIEDs continues to be a matter of debate, and there is a dearth of information on cost analysis from the perspectives of the payer, that is, the national health care system (HCS),[10–13] of the providers, that is, the hospitals which provide the service, and also of the patients and caregivers.

The Health Economics Evaluation Registry for Remote Follow-up (TARIFF) (clinicaltrials.gov ID: NCT01075516) study was designed with the objectives of quantifying the costs and benefits of both RM and standard care (SC) from the perspectives of 3 major stakeholders: the payer, the provider, and the patient.

Methods

Data

We used data collected from the TARIFF patient cohort for this cost-analysis. The TARIFF study design and data collection method are described in detail elsewhere.[14] Briefly, the TARIFF study was a prospective, nonrandomized, multicenter clinical trial designed to assess the economic benefits of RM follow-up in comparison with SC follow-up. From December 2009 to March 2011, 209 patients in whom a St. Jude Medical (Sylmar, CA) CIEDs had been implanted were enrolled in 6 Italian hospitals: the 107 patients enrolled in phase I (SC group) underwent in-person follow-up examinations at 3, 6, 9, and 12 months; the 102 patients enrolled in phase II (RM group) underwent in-person examinations on enrollment and after 12 months and RM follow-up examinations at 3, 6, and 9 months by means of a Merlin@home transmitter (St. Jude Medical) combined with continuous monitoring according to predefined technical and clinical alerts. Management strategies and data collection were predefined.

The study protocol was approved by the local ethics committees responsible for each site. The investigation conformed to the principles outlined in the Declaration of Helsinki. All patients gave written informed consent, and data were treated confidentially.

Study design

The objective of the study was to quantify the costs and benefits of RM vs SC from the perspectives of both the HCS and the patient. Specifically, with regard to the HCS perspective, we assessed health care services used (hospitalizations, visits, and examinations). Concerning the patient perspective, we assessed out-of-pocket expenses (eg, travel), informal care (time spent by the caregiver), and the time spent by the patient for follow-up. The use of health care resources was defined on the basis of hospital clinical folders. Regarding the patient perspective, all data were collected through case report forms administered to patients during in-person visits.

The benefit outcomes were assessed by means of the EQ-5D questionnaire (EuroQol five dimensions questionnaire).

Cost analysis: HCS perspective

For both groups, the following costs were included for the HCS perspective: all costs related to urgent and nonurgent in-office visits, scheduled and unscheduled remote follow-up examinations, emergency service accesses, hospitalizations, and diagnostic tests.

The costs associated with hospitalizations were calculated in euros by using the diagnosis-related group tariffs (version 24). The diagnosis-related group economic values were calculated using the Italian national reimbursement tariffs.[15] The costs of in-office follow-up visits and diagnostic tests were estimated by using the national tariffs applied for these services. In the Italian HCS, the cost of access to emergency services is not available; this was therefore calculated by considering the available regional reimbursement rates.[16]

In the Italian HCS, there is no established reimbursement for RM; hence, the costs associated with scheduled and unscheduled RM sessions were considered to be zero in our analysis.

The time spent reviewing RM transmissions was measured in order to have a raw estimate of the costs for the provider.

Cost analysis: Patient perspective

In order to evaluate the socioeconomic impact of RM on patients and caregivers, the following data points were collected at each inhospital visit: (1) all costs incurred in order to reach the hospital; (2) productivity loss, assessed in terms of the number of working hours lost; (3) impact on daily activity (number of hours); (4) cost of assistance, assessed through the "market value" approach: specifically, the cost of a care worker was applied to the hours that the caregiver spent attending to the patient.[17]

Benefits

For the patient perspective, the quality of life associated with the 2 strategies was assessed. The annual cost and the quality-adjusted life-years (QALYs) of RM vs SC were calculated in order to compare the 2 groups. QALYs were based on utility (patients' preferences). The EuroQoL EQ-5D-3L questionnaire was administered to each patient at baseline and at 12 months[18] in order to calculate utility values (from 0 to 1). Only if all 5 of the EQ-5D dimensions were completed was utility defined. Moreover, missing utility values at 12 months were imputed by using regression models, in which the dependent variable was the utility value at 12 months and the independent variable was the baseline value. QALYs were calculated from the area under the curve of the mean utility values at 12 months in relation to the baseline value. It was assumed that utility values changed in a linear fashion from baseline to 12 months. Utility values were calculated only for those patients who completed the questionnaires at baseline and at 12 months and for surviving patients.

Statistical analysis

Continuous data are summarized as mean ± SD. Categorical data are summarized as count and percentage and were compared using the χ^2 test or Fisher exact test, when appropriate. Cost data are typically highly skewed[19] since a few patients incur particularly high costs; hence, the Wilcoxon rank-sum test was used to compare costs across groups. As TARIFF was not a randomized study, a multivariable linear regression analysis was also performed to account for differences in baseline characteristics. This analysis evaluated the impact of group membership (SC vs RM) on total health care cost (outcome), adjusting for covariates that were significantly different between the groups at the .2 significance level. However, as the arithmetic mean is the most informative measurement for policy decisions, differences between the 2 groups were assessed using differences in sample means (point estimates) and t distributions (confidence intervals). As the data were skewed, these confidence intervals were compared with those based on the resampling-based bootstrap method (1000 resampled data sets). In all cases, since the confidence interval widths from the 2 methods were on average within 2% (range 0%–5.1%) of each other, confidence intervals are reported from those based on the t distribution. Poisson regression was used to compare the mean hospital visits in the 2 groups. A P value less than .05 was considered significant. All statistical analyses were performed in SAS 9.3 and R version 3.2.3, SAS Institute Inc.,Cary, NC, USA.

Results

Baseline characteristics

The baseline characteristics of patients are summarized in Table 1. The SC group comprised 107 (51.81%) patients; and the RM group, 102 (48.19%). The baseline clinical characteristics of the population enrolled were homogeneous, without significant differences between the 2 groups. Similarly, there were no significant differences between the 2 groups with regard to social and economic profile (journey costs, distances, working activities, loss of productivity, and prevalence of retired patients). During the study, 14 (6.70%) patients died (9 (8.82%) in the RM group and 5 (4.67%) in the SC group; $P = .41$); 8 (3.83%) were withdrawn (5 (4.90%) RM and 3 (2.80%) SC; $P = .49$), and 12 (5.74%) were lost to follow-up (2 (1.96%) RM and 10 9.35%) SC; $P = .037$), as shown in Figure 1; 89 SC patients and 86 RM patients completed the 12-month study period. All results are reported for these patients.

Table 1 Baseline clinical and socio-economic characteristics

	Standard care (SC) [pts: 107]	Remote Monitoring (RM) [pts: 102]	p value
Male	92 (85.98)	86 (84.31)	.73
Age	68.89 ± 11.46	69.69 ± 10.17	.83
NYHA:			.14
I	25 (23.36)	30 (29. 41)	
II	51 (47.66)	33 (32.35)	
III	28 (26.17)	38 (37.25)	
IV	3 (2.80)	1 (0.98)	
EF% (Mean ± Std)	32.25 ± 10.57	31.82 ± 9.58	.91
Primary Prevention Secondary	83 (77.57)	82 (78.95)	.62
Prevention	24 (22.43)	20 (21.05)	
Cardiomyopathy:			.38
- Ischemic	62 (57.92)	55 (53.92)	
- Dilated	34 (31.78)	40 (39.21)	
- Hypertrophic	2 (1.87)	3 (2.94)	
Brugada (%)	2 (1.87)	0 (0.0)	
Other (%)	2 (1.87)	3 (2.94)	
None (%)	2 (1.87)	1 (0.98)	
Implanted device:			.10
SC-ICD	30 (28.04)	16 (15.69)	
DC-ICD	25 (23.36)	28 (27.45)	
CRT-D	52 (48.60)	58 (56.86)	
Total Distance Traveled at Enrollment (km) (Mean ± Std [n])	43.61 ± 49.31 [107]	43.80 ± 41.98 [102]	.52
Total Journey Cost at Enrollment (€) (Mean ± Std [n])	9.91 ± 10.37 [103]	11.20 ± 11.66 [99]	.11
Total Loss of work or activity at Enrollment for patient (Hours) (Mean ± Std [n])	2.98 ± 1.63 [92]	3.02 ± 1.34 [93]	.51
Total Loss of work or activity at Enrollment for caregiver (Hours) (Mean ± Std [n])	3.08 ± 1.67 [80]	3.45 ± 1.79 [75]	.17
Patients retired from work	84 (78.50)	75 (74.64)	.52

Values are mean ± SD (min, max) or mean difference (95% confidence interval).

CRT-D = cardiac resynchronization therapy with defibrillator; DC = dual-chamber; EF = ejection fraction; ICD = implantable cardioverter-defibrillator; NYHA = New York Heart Association; SC = single-chamber.

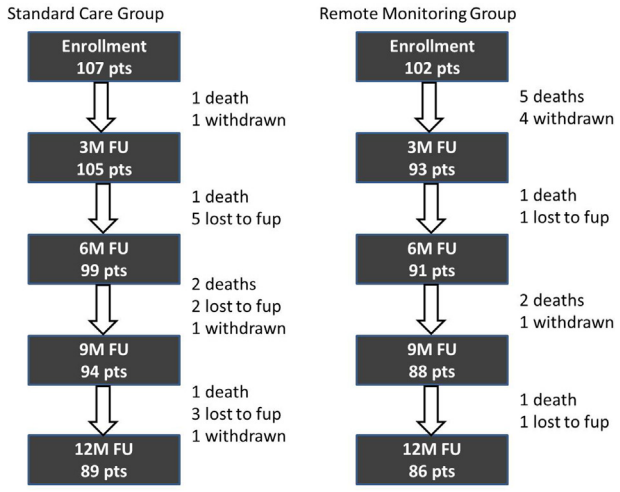

Figure 1 Study diagram showing the number of patients enrolled in each group. During the study, 14 patients died, 8 were withdrawn, and 12 were lost to follow-up. FU = follow-up; M = month.

HCS perspective

The components of the health care resources consumed are presented in Figure 2. patients with SC underwent more hospitalizations for cardiovascular reasons than did patients with RM (SC: 22 (24.72%) vs RM: 7 (8.14%); $P = .0032$), more emergency department visits (SC: 5 (5.62%) vs RM: 0 (0.00%); $P = .059$), more outpatient diagnostic tests (SC: 59 (66.29%) vs RM: 40 (46.51%); $P = .0083$), and more outpatient visits (SC: 26 (29.21%) vs RM: 14 (16.28%); $P = .0416$). Regarding cardiovascular hospitalizations, there was no statistically significant difference in the length of hospital stay neither between patients with RM and patients with SC (6.6 ± 4.7 days [44 hospitalizations] vs 6.4 ± 4.8 days [14 hospitalizations]; $P = .8990$) nor according to the type of device implanted (cardiac resynchronization therapy with defibrillator 6.8 ± 4.8 days [30 hospitalizations] vs single-/dual-chamber implantable cardioverter-defibrillator 6.3 ± 4.7 days [28 hospitalizations]; $P = .7014$).

Patients enrolled in the SC group had per protocol more scheduled inhospital device follow-up visits than those enrolled in the RM group (mean hospital visits 3.76 ± 0.52 vs 1.00 ± 0.00; $P < .001$). Conversely, patients enrolled in the RM group had more unscheduled inhospital device follow-up visits than did those enrolled in the SC group (0.66 ± 1.01 vs 0.13 ± 0.40; $P < .001$). The total number of inhospital device follow-up visits (scheduled + unscheduled) was reduced by 58.78% in the RM group (RM: 143 vs SC: 347; $P < .0001$) (Figure 3).

Health care costs are reported in detail in Table 2. The overall mean annual costs for each patient with SC were significantly higher than those for each patient with RM (SC: €1044.89 ± €1990.47 vs RM: €482.87 ± €2488.10; $P < .0001$), with a reduction of 53.87% being achieved in the RM group. The difference remained statistically significant (difference (SC − RM): €1053.41; $P = .0149$) in the multivariable regression analysis, which adjusted for the following variables that were significantly different at the .2 significance level between the 2 groups at baseline: New York Heart Association class, total journey cost at enrollment, type of device, and total loss of work or activity at enrollment for caregivers. The mean annual costs for patients with RM were significantly lower than those for patients with SC with regard to all items that contributed to the overall costs, that is, cardiovascular hospitalizations, emergency department visits, outpatient clinical evaluation visits, outpatient diagnostic tests, and in-office device follow-up visits. The main driver of cost reduction, however, was constituted by cardiovascular hospitalizations (SC: €886.67 ± €1979.13 vs RM: €432.34 ± €2487.86; $P = .0030$).

Remote transmission review

In the RM group, 473 remote transmissions to the center were made by the home transmitter. Of these, 234 (49.47%) were scheduled follow-up transmissions and 239 (50.53%) were transmissions triggered by alerts. The success rate of remote transmission was 90.70%. The most common triggers were atrial arrhythmias 61 (25.52%), ventricular arrhythmias 24 (10.04%),

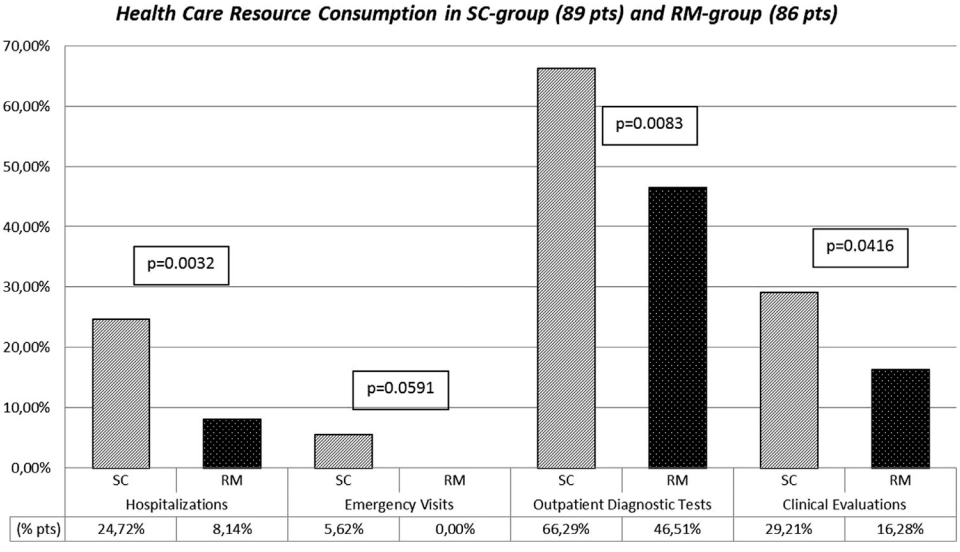

Figure 2 Health care resource consumption in the 2 groups. RM = remote monitoring; SC= standard care.

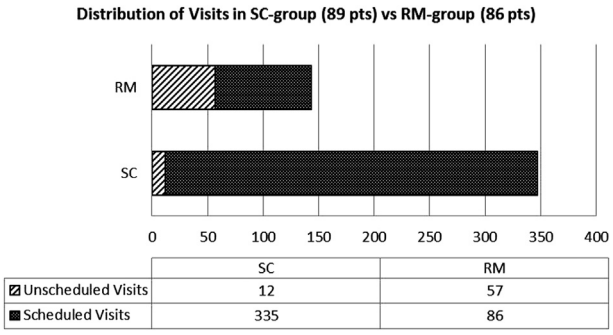

Figure 3 Total number of inhospital device follow-up visits (scheduled + unscheduled) in the 2 groups. Patients in the RM group had 58.78% fewer visits. RM = remote monitoring; SC= standard care.

heart failure events 81 (33.89%), and ST changes 31 (12.97%). Distribution of alerts triggering unscheduled data transmission by the patient home transmitter is presented in detail in Figure 4. The time spent reviewing scheduled remote follow-up data and alert-triggered transmissions was, on average, 4.46 ± 3.35 and 5.89 ± 8.58 minutes, respectively. Considering all remote transmissions (473), we calculated a mean annual time for transmission revision of 47.92 hours per 100 patients.

Patient perspective and quality of life

Detailed patient costs, including traveling, and loss of work and of daily activities for patients and caregivers are summarized in Table 3. The total annual costs per patient were, on average, €169.49 ± €189.50 in the SC group vs €56.87 ± €80.22 in the RM group ($P < .0001$), resulting in a reduction of 66.44%. The average monetary value attributed to the hours spent by the accompanying person, as calculated by means of the "market value" approach, was €60.14 ± €33.37 in the SC group vs €17.81 ± €11.65 in the RM group ($P < .0001$).

Utility values and QALYs over the 12-month study period are reported in Table 4. There were no significant differences in QALYs between the SC group and the RM group in any scenario.

Discussion

The main result of the TARIFF study is that, from the HCS perspective, an RM strategy for managing patients with CIED reduced the overall annual health care costs by 53.87% in comparison with a standard follow-up strategy. This cost reduction was due to a marked reduction in the consumption of health care resources, including hospitalizations for cardiovascular reasons, emergency department visits, outpatient diagnostic tests, outpatient clinical evaluation visits, and device follow-up visits. Overall inhospital device follow-up visits were reduced by more than 50% in the RM group, in which monitoring was continuous. This means that in spite of the high number of remote alerts received, most were remotely managed without inhospital visits. Our findings are consistent with those of previous studies in the field.[5,11,13] Unlike the ECOST (The Effectiveness and Cost of ICD followup Schedule with Telecardiology) trial,[20] in which hospitalization costs per patient-year were not significantly reduced in the RM group, the TARIFF study found that the main driver of cost reduction was the reduction in cardiovascular hospitalizations, which was responsible for 81% of saving. Our findings differ from the review by Burri et al[21] from a UK National Health Service perspective, in which, over 10 years, RM was predicted to be cost-neutral at about £11,500 per patient in either treatment arm. However, the model applied by Burri et al was conservative, in that it did not assume a reduction in cardiovascular events in patients with RM and did not include the patient perspective

Table 2 Health care costs: payer perspective

Variable	SC	RM	Difference (SC − RM)	*P* (Wilcoxon rank-sum test)
Cardiovascular hospitalization costs (€)	886.67 ± 1979.13 (0, 12436)	432.34 ± 2487.86 (0, 20,486)	454.34 (−218.17 to 1126.84)	.0030
Device-related costs (€)	229.07 ± 1186.25 (0, 9384)	0.00 ± 0.00 (0, 0)	229.07 (−20.82 to 478.95)	.0496
Cardiovascular-related costs (€)	657.61 ± 1470.90 (0, 7523)	432.34 ± 2487.86 (0, 20,486)	225.27 (−388.31 to 838.85)	.0136
Emergency visit costs (only emergency department access) (€)	15.67 ± 66.25 (0, 310)	0.00 ± 0.00 (0, 0)	15.67 (1.71 to 29.62)	.0278
Costs of outpatient clinical evaluations (€)	5.22 ± 9.28 (0, 39)	2.10 ± 4.79 (0, 13)	3.12 (0.92 to 5.32)	.0259
Costs of outpatient diagnostic tests (€)	46.72 ± 46.54 (0, 178)	9.79 ± 20.30 (0, 141)	36.93 (26.24 to 47.61)	<.0001
Total costs for scheduled in-office follow-up visits (€)	87.48 ± 12.15 (46, 93)	23.24 ± 0.00 (23, 23)	64.24 (61.68 to 66.80)	<.0001
Total costs for unscheduled in-office follow-up visits (€)	3.13 ± 9.40 (0, 46)	15.40 ± 23.54 (0, 116)	−12.27 (−17.67 to −6.87)	<.0001
Total health care costs (€)	1044.89 ± 1990.47 (46, 12,542)	482.87 ± 2488.10 (23, 20,534)	562.02 (−111.98 to 1236.01)	<.0001

Values are mean ± SD (min, max) or mean difference (95% confidence interval).
RM = remote monitoring; SC = standard care.

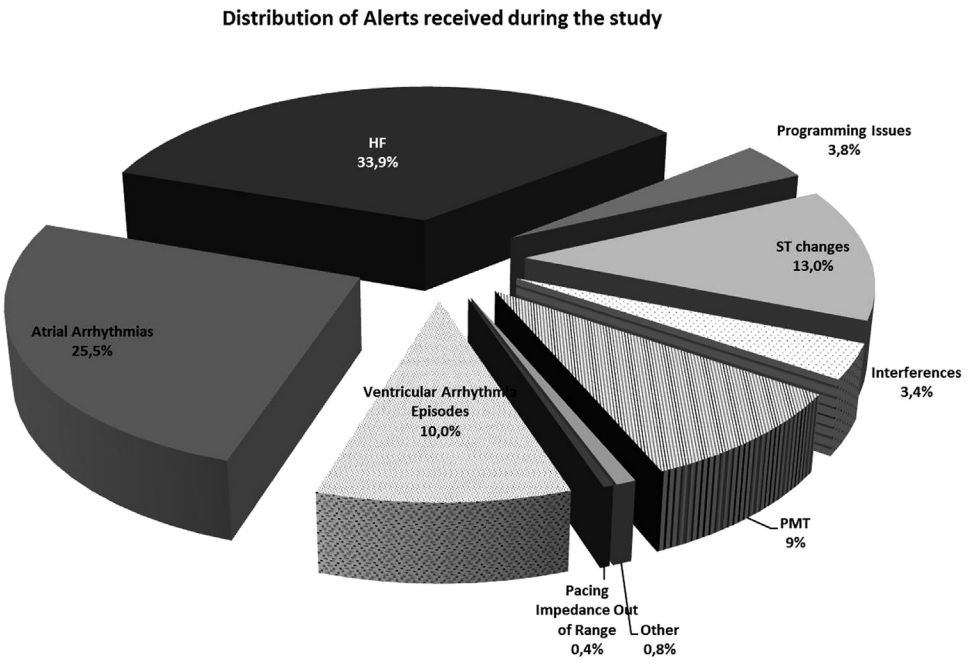

Figure 4 Distribution of alerts triggering unscheduled data transmission by the patient home transmitter. HF = heart failure; PMT = pacemaker-mediated tachycardia; ST = ST segment elevation/depression on internal electrogram.

in the analysis. Moreover, cost savings due to better timing of elective device replacement and the fact that fewer follow-up visits are needed in patients nearing device replacement were not considered. In the Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision trial,[7] patients randomized to the remote arm had significantly shorter hospitalization stays than those randomized to the in-office arm, with an estimated $1659 saving per hospitalization. In the COMPAS (COMPArative followup Schedule with Home Monitoring) trial,[6] hospitalizations for atrial arrhythmias and strokes were fewer in the active arm than in the control group. In the IN-TIME (INfluence of Home MoniToring on mortality and morbidity in heart failure patients with an IMpaired lEft ventricular function) trial,[22] there were no differences in hospitalizations between RM and control groups, but mortality at 1 year was significantly reduced in the RM arm by 61%.

Even from the patient perspective, RM had a favorable impact, yielding a 66.44% reduction in patient costs. This finding is particularly meaningful from the social perspective and may implement patient adherence to follow-up schedule and therapy compliance. Interestingly, the EVOLVO (Evolution of Management Strategies of Heart Failure Patients With Implantable Defibrillators) study[23] did not demonstrate any cost saving in the RM group from the HCS perspective, while it did from the patient perspective. In line with the EVOLVO study, utility values and QALYs over the 12-month study period did not show any difference between the 2 groups.

The TARIFF study results represent a situation in which, through the use of RM instead of SC, a similar level of outcome (QALYs) is obtained at a lower cost. This case does not require calculating the incremental cost-effectiveness ratio (needed when the new alternative is both more expensive and more effective than the old one). RM is consequently to be regarded as a "cost-saving" strategy in comparison with SC.

In the TARIFF study, the costs associated with scheduled and unscheduled RM sessions were artificially considered to be zero since in Italy, as in other countries, there is no reimbursement for RM. This makes RM unsustainable for the provider. The reimbursement tariff for RM should cover the time spent reviewing alerts and RM transmissions, the

Table 3 Cost incurred by patients

Variable	SC (n= 89)	RM (n = 86)	Difference (SC − RM)	*P* (Wilcoxon rank-sum test)
Total distance traveled (km)	165.54 ± 209.13	45.20 ± 41.87	120.34 (75.43–165.25)	<.0001
Total journey cost (€)	36.81 ± 40.83	10.95 ± 10.75	25.86 (16.97–34.74)	<.0001
Total loss of work or activity for patients (h)	10.43 ± 5.38	2.67 ± 1.97	7.76 (6.55–8.96)	<.0001
Total loss of work or activity for caregivers (h)	11.35 ± 6.30 (69)	3.36 ± 2.20 (57)	7.99 (6.37–9.60)	<.0001
Monetary value of caregiver loss of work or activity (€)	60.14 ± 33.37 (69)	17.81 ± 11.65 (57)	42.34 (33.78–50.89)	<.0001
Mean annual cost for each patient (€)	169.49 ± 189.50	56.87 ± 80.22	112.62 (69.32–155.92)	<.0001

Values are mean ± SD (min, max) or mean difference (95% confidence interval).
RM = remote monitoring; SC = standard care.

Table 4 Utility values and quality-adjusted life-years over the 12-mo study period

Variable	SC (n = 87)	RM (n = 79)	Difference (phase II − phase I)	*P* (*t* test)
Utility at baseline	0.86 ± 0.18	0.87 ± 0.13	0.01 (−0.04 to 0.06)	.80
Utility at 12 mo	0.85 ± 0.18	0.87 ± 0.16	0.02 (−0.03 to 0.08)	.38
Quality-adjusted life-years	0.85 ± 0.17	0.87 ± 0.13	0.02 (−0.03 to 0.06)	.53

Values are mean ± SD or mean difference (95% confidence interval).
RM = remote monitoring; SC = standard care.

time needed for administrative duties, patient phone calls and general management activity, and the cost of the transmitter. Even if the HC authority establishes a reimbursement for RM, it will still be cost saving for the HCS. For example, if the same tariff as in-office device follow-up was assigned to the 473 annual transmissions recorded in the RM group during the TARIFF study, it would result in a total annual cost of around €11,000. The average annual cost per patient would be €128. If this value was added to the annual cost of RM, the RM strategy would still prove to be cost saving in comparison with SC.

This finding is in agreement with those of the European Health Economic Trial on Home Monitoring in ICD Patients trial,[24] in which, on comparing RM with SC strategies, there was no difference in the net financial impact on providers; however, there was heterogeneity among countries, with RM generating less profit for providers in the absence of specific reimbursements and maintained or increased profit in cases in which such reimbursement existed. Anyway, from the HCS perspective even in countries with reimbursement, RM was never more costly than SC. Indeed, according to a recent European survey,[25] the lack of reimbursement is generally perceived as a major barrier to the implementation of RM in standard practice.

The RM technology used in this study showed good performance; the success rate of remote transmission was 90.7%, similar to that of other proprietary systems. The time spent reviewing transmissions was quite short (4.5 minutes for remote follow-up and 5.9 minutes for alert-triggered transmissions). We may speculate that the prevalence of actionable events was greater in alert-triggered transmissions than in scheduled transmissions and that actionable events were the main responsible for the difference in time consumption between alert-triggered and scheduled transmissions.

Similar results have been reported for other systems that use similar technology. As also in the TRUST (The Lumos-T Safely Reduces Routine Office Device Follow-Up) study,[9] patient adherence to the follow-up program was superior in the RM group.

Clinical implications

RM reduced hospitalizations for cardiovascular reasons from 24.7% to 8.1%. This may impact on patient outcome. Taking into account that atrial and ventricular arrhythmias, heart failure events, and ST changes were the most common triggers for alerts, we may speculate that early reaction to potentially catastrophic events may have prevented serious complications. Previous studies and registries have demonstrated that RM can prevent stroke[6,26] and the progression of heart failure[22] and may reduce mortality.[1,22]

Study limitations

The main limitation of the TARIFF study is that consecutive patients were enrolled in the 2 arms and that it was not a randomized study. Nevertheless, the populations in the 2 arms were homogeneous not only in terms of clinical profile but also from the socioeconomic perspective. Patient follow-up was per protocol 12 months, and we cannot speculate on the comparison for longer follow-up.

The TARIFF study provides a picture of "real-life" practice in Italy; the results could differ in different HCSs and in different economic and social settings.

Alert setting and clinical reaction to cardiovascular events were left to the investigator's discretion. As manpower analysis focused on patient's RM, the time devoted to enrollment and phone calls, or unanswered calls and unsuccessful attempts, was not calculated. Finally, the time spent contacting the physician responsible, when necessary, was not included.

We evaluated only 1 automatic wireless RM technology. Thus, our results cannot be transferred to other proprietary technologies with their varying transmission frequencies and methods of alert notification.

Conclusion

The results of the TARIFF study show that the RM of patients with CIEDs appears to be a cost-saving solution for the HCS in comparison with the conventional method of in-clinic visits. Furthermore, RM is cost saving for patients and caregivers. Lack of reimbursement is a critical issue from the provider perspective. Introducing appropriate reimbursement would make RM attractive even for the provider, while it would still be cost saving for the HCS.

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