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

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Abstract
Introduction Few data are available on actual follow-up costs of remote monitoring (RM) of implantable defibrillators (ICD). Our study aimed at assessing current direct costs of 1-year ICD follow-up based on RM compared with conventional quarterly in-hospital follow-ups.
Methods and results Patients (N=233) with indications for ICD were consecutively recruited and randomized at implant to be followed up for 1 year with standard quarterly in-hospital visits or by RM with one in-hospital visit at 12 months, unless additional in-hospital visits were required due to specific patient conditions or RM alarms. Costs were calculated distinguishing between provider and patient costs, excluding RM device and service cost. The frequency of scheduled in-hospital visits was lower in the RM group than in the control arm. Follow-up required 47 min per patient/year in the RM arm versus 86 min in the control arm (p=0.03) for involved physicians, generating cost estimates for the provider of USD 45 and USD 83 per patient/-year, respectively. Costs for nurses were comparable. Overall, the costs associated with RM and standard follow-up were USD 103±27 and 154±21 per patient/year, respectively (p=0.01). RM was cost-saving for the patients: USD 97±121 per patient/year in the RM group versus 287±160 per patient/year (p=0.0001).
Conclusion The time spent by the hospital staff was significantly reduced in the RM group. If the costs for the device and service are not charged to patients or the provider, patients could save about USD 190 per patient/year while the hospital could save USD 51 per patient/year.

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Keywords Follow-up costs · Remote monitoring · Implantable cardioverter defibrillator

1 Introduction

Since the acceptance of indications for primary prevention of sudden cardiac death and the advent of cardiac resynchronization therapy, the number of patients with implantable cardioverter defibrillator (ICD) has increased. To facilitate follow-up, remote monitoring (RM) was introduced in recent years [1–3]. Several reports [4–6] demonstrated that RM is easy to use, safe, and efficient for following up patients with pacemakers and ICD. Furthermore, it has been observed that the possibility of access to continuous remote device diagnostic

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information can enable physicians to rapidly identify patients requiring attention for device-related or clinical problems [7–11]. However, up to the present, few studies have evaluated the economic impact of remote ICD management compared with conventional periodic in-hospital follow-up [12–15].

This study aimed at assessing current direct costs of a cardiac implantable device follow-up strategy based on RM by comparison with a standard approach of quarterly in-hospital visits during a follow-up period of 1 year. During economic analysis, a distinction was made between costs incurred by the hospital and social cost incurred by patients.

2 Methods

2.1 Population selection

Patients with standard indications for ICD with or without cardiac resynchronization therapy (CRT) were consecutively recruited in our clinic and randomized at implant to be followed up for 1 year with a standard schedule of quarterly in-hospital visits (control arm) or by RM with only one in-hospital visit per year (after 1 month of follow-up) unless required due to specific patient conditions or RM alarms/notifications (RM arm). Patients were eligible to be enrolled in this study if they had an approved indication for ICD implant with or without CRT, were ≥18 years old, were not pregnant, and had sufficient GSM signal coverage at home. Patients unwilling to sign the informed consent form approved by the Institutional Review Board were excluded. Patients randomized to the control arm did not receive a transmission unit for remote control. Patients randomized to the RM group received a transmission unit on discharge and RM was activated immediately.

2.2 Remote monitoring systems

The study protocol did not require any restriction in selecting implant devices or RM systems. Any currently available RM system (Biotronik Home Monitoring, Medtronic CareLink, Boston Latitude, and St. Jude Merlin) could therefore be chosen and actually used. The basic concept of RM is similar for each system: implants are provided with wide range radiofrequency telemetry to connect to a patient unit that forwards data to a central server using telephonic/GSM networks. Data are available on protected websites. RM systems are similar, although Biotronik Home Monitoring is based on daily automatic GSM transmissions while the other systems provide periodic transmissions programmable over a range of 7 days to 3 months. With all the RM systems, automatic alarms/notifications are triggered by selectable adverse events, individually tailored to diagnostic and therapeutic needs.

2.3 Follow-up

All the enrolled patients were followed up for 1 year with a schedule of quarterly in-hospital visits or remotely according to randomization. After the discharge visit (which was excluded from the analysis since it was routine in both groups), each patient had a program of four quarterly remote or in-hospital follow-ups: three remote follow-ups and a 12-month in-hospital visit, if the patient was in the RM group; and four in-hospital visits, if the patient was in the control group. If necessary, unscheduled visits were performed as triggered by patient complaints, special medical conditions, or RM alarms or notifications. Scheduled RM follow-ups were performed according to the technical characteristics of the particular RM system.

RM requires specific organization of the roles and tasks of nursing and medical personnel. Our outpatient clinic workflow was based on previously published models [10] and complied with a standard described within a Consensus Document drawn up by the National Association of Arrhythmology and Cardiac Pacing [2]: each patient was assigned to one reference nurse and a physician. The nurse was responsible for patient training, remote controls, and phone contacts; in the case of preset alarms, special medical conditions, or uncertain remote data interpretation, the nurse had to submit the data to the reference physician who was responsible for diagnosis and medical decision-making. The nurse was also responsible for administrative activities and document filing or archiving. Both the responsible physician and the nurse were present during the patients' in-hospital visits.

The sum of overall time spent by the patient and by healthcare personnel during 1 year of follow-up was recorded for each patient for both groups.

2.4 Cost analysis

Costs were calculated by direct cost accounting with a distinction made between costs incurred by the hospital and accessory social costs incurred by patients. Costs were first calculated in Euro currency and then converted into USD at the official exchange rate of 1.223 USD/EUR (valid July 20, 2012).

2.4.1 Hospital costs

The clinic where this investigation was conducted is part of the Public National Health Service, from which it receives regular Diagnosis-Related Group coded reimbursements for the care and health services provided. Each individual ICD implant is followed by a flat reimbursement, covering device, surgical procedure, and related costs. In-hospital follow-up visits are reimbursed as well. Optimization of follow-up processes may therefore directly result in hospital financial surplus.

Our clinic cost model included the following significant items:

- Costs of medical and nursing hospital staff for standard and RM follow-up for each single patient expressed as amount of USD per minute;
- Depreciation costs of hospital machinery, instruments, and equipment used during in-hospital visits;
- Cost increase due to RM service.

Costs for implant surgical procedures and related hospitalization were neglected since they were considered equal in both arms.

Personnel cost, representing the main cost account in the hospital budget for ICD follow-up, mainly depends on the working time burden necessary to support follow-up. The working time was manually recorded both for RM and for standard in-hospital follow-up strategies and tracked on log sheets grouping activities as follows:

- RM follow-up time: time spent by the physician/nurse to perform each remote follow-up, including website access, data review, and decision if required. Tracking of this time component was automatically performed by custom software.
- In-hospital follow-up visit time: time spent by the physician and the nurse for each in-hospital follow-up from the patient's entrance to exit from ambulatory.
- Time for administrative activities: these include patient file archiving and management, training, phone calls and contacts with patients as well as the administrative work related to the calendar management for scheduled remote follow-ups and medical report relative to the remote follow-ups performed to be prepared and mailed on patient's demand.

For all these activities, a distinction was made between medical and nursing personnel, timed and recorded for 1 year for all the patients included in this investigation.

The cost of every working minute was then calculated based on the 2010 accrual wages and worked hours reports of the Italian National Institute of Statistics [16, 17]. The resulting mean cost per working minute was USD 0.97 and USD 0.77 for medical and nursing personnel, respectively. Overtime payments were neglected.

Hospital equipment normally used in remote or in-hospital follow-up (personal computers with internet connection and ordinary software for patient data management, electrocardiographs, ICD programmers, and other medical tools) are long-life instruments not exclusively dedicated to ICD control (except for ICD programmers, which are provided free of charge to our clinic by the ICD manufacturers). Depreciation costs for these items of equipment were also considered negligible.

Device cost increase due to RM activation and functioning was zero since RM devices and services (remote transmissions, data storage, website) were provided free of charge to our clinic. All the enrolled patients were implanted with ICDs (−CRT) provided with RM technology, regardless of arm assignment. Our cost analysis is based on the assumption that RM is not related to any additional device/service cost.

2.4.2 Social costs

Among social costs, direct visit costs, transportation/travel costs, and cost of lost employment income for the time spent for in-hospital visits, the following were considered:

- *Direct visit costs*: patients contribute in part to the visit costs by paying a fee per visit. The amount is periodically set by the Regional Administration. At present, a patient pays USD 49.10 for an in-hospital visit for ECG and ICD follow-up. Patients may have an exemption from this tax based on their annual income (retired patients are exempt).
- *Transportation and travel costs*: for each visit, patients were asked to indicate what means of transportation they used to reach our clinic, what distance they had travelled, and whether or not they were escorted by a relative or carer. The means of transportation and their costs were then broken down into five categories:

  1. Bus or tube/subway costs were calculated according to current rate of the local public urban transport company in Rome, which is USD 1.22 per stretch per person;
  2. Costs for train use have been evaluated on the basis of the official Italian Train Company's mean rates: for example, a train journey of 500 km costs USD 61.15; a 300-km journey costs USD 42.80. These rates apply per person and depend on time slots on days of the week. No promotions were considered.
  3. Costs for cab use were derived from the official rates of the taxi companies in Rome for daytime urban transport during working hours. These rates are the same for all the companies and are periodically negotiated with the Municipal Administration. In 2010, taxi rates consisted of an initial cost of USD 2.85 plus USD 0.95/km for minimum sums of USD 9.78.
  4. Estimation of private car costs was fairly complex. The tables of the National Federation of Italian Car Clubs [18], which are generally used to quantify fringe benefits or reimbursement for car wear and tear, were consulted. These tables provide global indicators including fuel, insurance, wear and tear, and accident-risk-related costs. We selected a representative sample of 35 car models (16 petrol, 16

gasoline, 3 gas) for which a mean cost of USD 0.584/km was calculated. Sports or large-engine cars were excluded from our car model sample.

5. Lastly, the costs for reaching the hospital on foot were set to zero.

- *Cost of lost employment income for the time spent for in-hospital visits*: although most of the patients are generally retired, the social costs due to lost income for working patients and escorts should be considered. During in-hospital visits, patients were asked to state whether they were retired or still working, and whether or not they were escorted by other working people (relatives or friends) other than carers under contract. Patients and escorts were not asked to disclose the category of their job or their income. The mean income was estimated basing on 2008 data from the Italian National Institute for Social Security [19]: for each working category, the annual net salary was obtained from the daily net salary and the number of paid days in the year 2008 for that category. The results were then averaged among all the working categories, weighted with the number of workers in each category, to arrive at an estimate of a mean net daily income of USD 96.77, which is about USD 0.20 per minute, considering an 8-h working day. Our cost model took into consideration absence from work for a full day or half day. When including this information in calculations, the estimate of lost income per minute was USD 0.147.

2.5 Statistical analysis

The study was designed to detect a 20 % relative difference in total costs between the study arms with a 90 % power under the following assumptions: USD 147 per year costs in the treatment group; 50 % SD; bilateral test significance level 0.05.

Continuous variables were usually reported as mean ± SD, except for non-normally distributed variables for which median and interquartile ranges were preferred. Student *T* test for uncoupled variables was generally used to compare groups, except where equivalent non-parametric tests were more appropriate for non-normality reasons. Yates chi-squared test or Fisher's exact test were used to compare categorical variables between groups.

3 Results

3.1 Patient characteristics

Two hundred thirty-three patients with standard indication for single- or dual-chamber ICD with/without CRT were recruited in this study and randomized with a 1:1 ratio into the RM arm and the control arm (standard follow-up with no RM system). All the RM systems currently available on the market were used: 43 patients (37 % of the RM group) used Biotronik Home Monitoring; 42 (36 %), the Medtronic Carelink system; 13 (11 %), the Boston Latitude system; and 19 (16 %), the St. Jude Merlin system. Clinical characteristics of patient population at baseline are provided in Table 1.

3.2 Follow-up

There were 520 follow-ups (remote or in-hospital) in the RM group and 489 in the control group (Table 2): 52 (40

Table 1 Patient characteristics

Population	RM group	%	Control group	%	*p* value
Number of patients	117	100 %	116	100 %	
Gender					
Male	85	73 %	83	71 %	0.96
Female	32	27 %	33	28 %	0.96
Age					
25–40	1	1 %	1	1 %	0.48
41–55	13	11 %	12	10 %	0.98
56–70	45	38 %	43	37 %	0.93
71–85	54	46 %	55	47 %	0.94
>85	4	3 %	5	4 %	0.99
ICD implant indication					
Primary prevention	98	84 %	96	83 %	0.98
Secondary prevention	19	16 %	20	17 %	
Etiology					
CAD	65	55 %	59	51 %	0.56
DCM	44	38 %	49	42 %	0.56
HCM	2	2 %	2	2 %	1.00
Brugada syndrome	4	3 %	4	3 %	0.73
Other	2	2 %	2	2 %	1.00
CRT indication	34	29 %	22	19 %	0.10
LVEF (%)	29.7±8.8		31.6±14.4		0.99
Prior CABG	23	19 %	23	20 %	0.89
Prior PTCA	33	28 %	24	21 %	0.24
NYHA class					
I	4	3 %	3	2 %	1.00
II	20	17 %	17	15 %	0.74
III	84	72 %	90	78 %	0.39
IV	9	8 %	6	5 %	0.60

CABG coronary artery bypass graft, *CAD* coronary artery disease, *CRT* cardiac resynchronization therapy, *DCM* dilated cardiomyopathy, *HCM* hypertrophic cardiomyopathy, *LVEF* left ventricle ejection fraction, *PTCA* percutaneous transluminal coronary angioplasty

Table 2 Number of RM or in-hospital follow-ups

	RM group		Control group		p value
RM follow-ups	Total	Per patient	Total	Per patient	
Scheduled	351 (97 %)	3	–		
Unscheduled	12 (3 %)	0.10	–		
Total	363	3.10			
In-hospital visits					
Scheduled	117 (75 %)	1	464 (95 %)	4	0.001
Unscheduled	40 (25 %)	0.34	25 (5 %)	0.21	0.07
Total	157	1.34	489	4.21	

RM remote monitoring

unscheduled in-hospital visits + 12 unscheduled remote follow-ups, 10 %) were unscheduled in the former group; 25 (5 %) in the latter group. Most common reasons for unscheduled in-hospital or remote follow-ups were as follows: in the RM group, remote alerts for atrial or ventricular arrhythmia episodes [17], appropriate or inappropriate ICD therapy deliveries including anti-tachycardia pacing [12], out-of-range lead (pacing or shock) impedance [10], alerts for parameter values possibly related with a worsening heart failure [6], and other non-device-related causes [7]; in the control group, appropriate or inappropriate ICD shock deliveries [11], symptoms related with worsening heart failure [4] or atrial and ventricular arrhythmias not associated with ICD therapies [7], and other reasons [3]. All the unscheduled in-hospital visits in the RM group were triggered by RM alerts.

On average, for each patient in the RM group there were 3.10 remote follow-ups in a year and 1.34 in-hospital visits, while each patient in the control group was visited 4.21 times in a year. As expected, the number of scheduled in-hospital visits was significantly lower in the RM group than in the control group (p=0.001), while there were 0.34 and 0.21 unscheduled in-hospital visits per patient in the RM group and in the control group, respectively (p=0.07). RM and in-hospital follow-ups are further detailed in Table 2.

3.3 Time spent by hospital personnel for follow-up activities

Mean times spent by the hospital staff (responsible physician and nurse) for all activity concerning RM and in-hospital visits for each patient in 1 year are shown in Table 3. While RM visits required about 22 min per patient in a year for the responsible physician and about 15 min for the nurse, standard in-hospital follow-ups took about 25 min per patient/year in the RM group and 74 min per patient/year in the control group. According to our organization model, all the administrative tasks concerned with RM (alarm notifications filing, patient file archiving and management, training, phone calls with patients) were delegated to the responsible nurse; conversely, for standard in-hospital follow-ups, these activities are shared. This resulted in a significant (p=0.03) gain of 40 min per patient/year for the physician (Table 3). For the responsible nurses, the time saving generated by RM was partially offset (75.5±26.2 min, p=0.41) by the increase in the administrative tasks involved in RM (35.2±15.2 vs. 18.0±5.1, p=0.07). Overall, hospital personnel were involved in follow-up activities for 122 min per patient/year in the RM group and 178 min per patient/year in the control group, with a significant (p=0.02) time saving of almost 1 h per patient in a year.

3.4 Demographic characteristics of and time spent by the patients for in-hospital visits

Table 4 provides several data concerning demographics and social information on the patient population enrolled in this study, along with distances from home to hospital, transportation, and waiting times for in-hospital visits. The majority of patients were retired (188/233, 81 %) and were accompanied

Table 3 Time spent per patient by the hospital staff for activities concerning RM and in-hospital follow-ups in a year

	RM group Mean time per patient in a year (min)	Control group Mean time per patient in a year (min)	p value
Responsible physician			
RM follow-ups	22.0±11.5	–	
In-hospital visits	24.8±7.6	74.1±22.8	0.001
Administrative activities	0	12.0±6.7	
Total	46.8±19.1	86.1±29.5	0.03
Responsible nurse			
RM follow-ups	15.5±3.6	–	
In-hospital visits	24.8±7.6	74.1±22.8	0.006
Administrative activities	35.2±15.2	18.0±5.1	0.07
Total	75.5±26.2	92.1±27.9	0.41
Total	122.3±45.3	178.2±57.3	0.02

RM remote monitoring

Table 4 Demographic and social information concerning in-hospital visits

	RM group	Control group	*p* value
Patients			
Accompanied by a relative or a carer	90 (77 %)	79 (68 %)	0.17
Not accompanied	27 (23 %)	37 (32 %)	
Total	117	116	
Employment			
Patient			
Retired	100 (86 %)	88 (76 %)	0.09
Employed	17 (14 %)	28 (24 %)	
Total	117	116	
Accompanying person			
Employed	43 (48 %)	35 (44 %)	0.65
Not working	47 (52 %)	44 (56 %)	
Total	90	79	
Transport to the hospital			
Private car	106 (91 %)	104 (90 %)	0.98
Bus	7 (6 %)	8 (7 %)	0.99
Train	2 (1 %)	2 (1 %)	0.95
Taxi	1 (1 %)	1 (1 %)	0.48
On foot	1 (1 %)	1 (1 %)	0.48
Total	75.5±26.2	92.1±27.9	0.41
Home-to-hospital distances			
Median (interquartile range)	25 (10–45) km	20 (6–40) km	0.75
Time for home-to-hospital transport			
Median (interquartile range)	40 (20)	40 (20–60)	0.53
Waiting time before in-hospital visits			
Median (interquartile range)	20 (10–30)	15 (10–25)	0.57
Overall time spent for an in-hospital visit (including transport to and from hospital, waiting time, and visit time)			
Median (interquartile range)	115 (85–150)	120 (80–165)	0.96

by a relative or a carer (169/233, 72 %) who, in 43 % of the cases, had to ask for a day off or a special permission at work. Private car was by far the most commonly used means of transportation, with a median home-to-hospital distance of about 20 km and transportation time of about three fourths of an hour. The median waiting time for a visit was 20 min or less. Overall time spent by a patient for a single visit, including home-to-hospital trip, waiting time, visit time, and return trip, was about 2 h. No significant differences were observed between the two groups in regard to any of these data.

3.5 Hospital and social costs

Leaving to one side depreciation costs of hospital equipment and the cost increase due to the RM technology of the implantable devices, the costs incurred by the hospital administration were essentially due to the manpower required by the follow-up type, as reported in Table 5. The cost increase in the control group was mostly due to longer periods of time in which physicians were involved in follow-up activities: on average, 46.8 min per patient/year in the RM group as compared with 86.1 min per patient/year (p=0.03) in the control group, generating cost estimates for the responsible physicians of almost USD 45.25 and USD 83 per patient in a year, respectively. The difference for nurses' work costs was less evident (about USD 59 per patient and USD 71 per patient/year, p=0.41).

Overall, the cost estimates associated with RM strategy and standard follow-up strategy were as high as USD 103.38±27.38 and 154.15±21.50 per patient per year, respectively (p=0.01).

Social costs incurred directly by the patients are described in Table 6 and included visit cost, transport cost, and lost income costs for all the in-hospital visits performed in a year. Ninety percent of patients in both study groups were exempted from paying for visit; therefore, direct visit cost was the lowest cost item. Due to the significantly higher number of in-hospital visits performed in the control arm, RM was found to be cost-effective for patients, who enjoyed mean cost savings of about USD 191 per year (96.66±20.42

Table 5 Costs incurred by hospital administration per patient

	RM group	Control group	*p* value
Responsible physician			
Labor costs per minute	USD 0.97 per minute/year	USD 0.97 per minute/year	
Required time	46.8±19.1 min	86.1±29.5	
Personnel costs for in-hospital visits	USD 45.21±18.45/year	USD 83.19±28.50/year	0.03
Responsible nurse			
Labor costs per minute	USD 0.77 per minute/year	USD 0.77/min	
Required time	75.5±26.2 min	92.1±27.9 min	
Personnel costs for in-hospital visits	USD 58.16±20.19/year	USD 70.96±21.50/year	0.41
Hospital equipment depreciation costs	Negligible	Negligible	
Increased costs for RM technology purchase	Negligible	Negligible	
Total costs per patient	USD 103.38±27.36/year	USD 154.15±35.70/year	0.01

per patient/year in the RM group as compared with 287.87± 160.26 per patient/year, $p=0.0001$).

Figure 1 synoptically summarizes both hospital and social costs broken down by visit cost, lost income, and transport costs.

4 Discussion

4.1 Main findings

Our study, conducted in 233 patients with standard indication for ICD (with/without CRT) randomized with a 1:1 ratio into the RM arm and the standard follow-up of quarterly in-hospital visits, included all the RM systems available on the market for the first time. The following main results were obtained: (1) the number of scheduled in-hospital visits was significantly lower in the RM group than in the control group, while the number of unscheduled in-hospital visits per patient-year was 0.34 in the RM group and 0.21 in the control group ($p=0.07$); (2) the time spent by hospital staff was significantly reduced in the RM group (with a gain of 56 min per patient/year); the difference between the two groups was mainly due to a shorter time spent by physicians on follow-up activities; (3) the hospital costs associated with RM strategy were lower than for standard follow-up strategy, with money savings of almost USD 50.14 per patient/year; (4) in terms of social costs, RM resulted in reduction of costs for the patients, who enjoyed mean cost savings of about USD 191 per year.

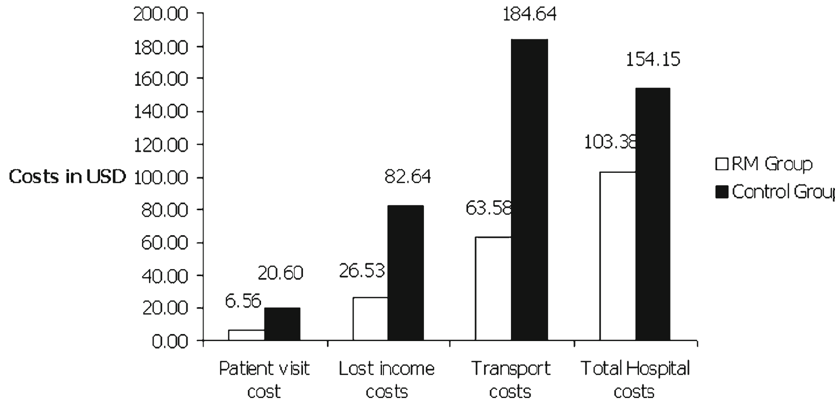
4.2 Previous studies

Few studies analyzed the cost/benefit ratio of RM in pacemaker and ICD patients. Fauchier et al. [12], in a retrospective analysis of 502 patients with remotely monitored ICDs, found that RM reduced the social costs of ICD follow-up by as much as USD 2,149 over the 5 years of expected life of the device. This study included the costs of transportation and medical services, but did not consider the cost of lost employment income for the time spent on in-hospital visits for patients and accompanying persons. More recently, Raatikainen et al. [13] assessed the economic impact of RM in a small prospective non-randomized single-center study. They found that the direct cost and the social costs of ICD follow-up by RM accounted for savings of 38 % and 41 %, respectively. On the other hand, Al-Khatib et al. [14] showed no significant reduction in cardiac-related resource utilization of ICD with RM. The REFORM trial [15] compared ICD remote monitoring (yearly in-hospital visit and 3-monthly remote follow-ups) with conventional follow-up (3-monthly in-hospital visits) in 115 MADIT II-like patients. In this study, RM reduced the number of visits significantly, by 63.2 %. Approximately 40 % of physician time (50 min per

Table 6 Social cost per patient in a year

	RM group	Control group	*p* value
Costs per patient per year			
Visit costs	USD 6.55±19.82	USD 20.59±62.30	
Transportation costs	USD 63.58±98.43	USD 184.63±435.79	
Lost income costs	USD 26.53±43.10	USD 82.64±176.60	
Total costs per patient in a year	USD 96.66±120.42	USD 287.87±160.26	0.0001

Fig. 1 Histogram of total annual costs in each considered item. The first three columns make up social costs



patient/year) was reduced per patient/year in the RM group and additionally an average of USD 134.53 transportation costs were saved per patient/year. Also, in the TRUST trial [5], RM reduced total in-hospital device evaluations by 45 % without affecting morbidity. The data of the REFORM and TRUST trials are comparable to our results. In fact, in our study we found a significant reduction of total in-hospital visits (1.34 visits per patient in the RM group versus 4.21 in controls) and a gain of 40 min per patient/year for physicians when using remote follow-up. The savings (about USD 50 per patient/year) that we observed in the RM group were mainly due to this cost component. In consideration of the number of patients currently followed in a medium volume outpatient clinic, a net saving of USD 49 per patient per year would rapidly result in a huge annual work-cost saving for the National Health system, even when compared with less frequent regimes of in-person visit schedules.

Of note, administrative activities represented a relatively important burden in the nurse annual workload per patient associated with RM: in the RM group, this time component was almost double than in the control group (35.2 min vs. 18.0 min, respectively; $p=0.07$). It should be mentioned that this time remarkably varied among RM systems depending on the frequency of remote data transmissions. In general, calendar management, documentation relative to remote follow-ups (to be prepared for internal archive and mailed to patients on demand), and assessment of the causes for an unsuccessful or skipped scheduled remote follow-up may add remarkable workload to nurse activities with RM systems based on periodic transmissions (quarterly in our study), while these may have a relatively lower impact with a RM system based on continuous and daily data transmissions.

Our estimates obviously depended on the particular follow-up scheme used in this study for the control group patients. Based on our data, the hospital cost per patient per visit was about USD 77.15 in the RM group and USD 36.62 in the control group. It is worth noting that for the hospital administration, follow-up costs would have been similar for both monitoring strategies should a 6-monthly visit schedule be adopted for the control study arm. On the other hand, since social costs per visit was roughly independent of the study arm (USD 72.13 in the RM group and USD 68.38 in the control group), RM would have been convenient as long as in-hospital visit frequency for scheduled follow-up in the control arm were set higher than once in a year. Therefore, according to our data, RM can remarkably reduce direct costs of follow-up visits in the perspective of an indefinite extension of the scheduled in-hospital visit interval.

Such cost reduction should be considered on top of the potential clinical benefits arising from the use of RM. Despite a cause–effect relationship that still needs to be definitively demonstrated, there is recent evidence that RM might be associated with a reduction of inappropriate ICD shocks [20]; emergency department or urgent in-office visits for heart failure, arrhythmias, or ICD-related events [21]; and even mortality [9]. Such potential clinical benefit might be explained by early detection of critical events: in the CONNECT trial [11], the median time from clinical event to clinical decision per patient was reduced from 22 days in the control group to 4.6 days in RM group. This difference determined an 18 % reduction in duration of cardiovascular hospitalization ($p=0.002$), which translated into lower hospitalization costs and an estimated saving of USD 1,675. In the TRUST trial [5], in comparison with controls, symptomatic and asymptomatic complications were also detected earlier in RM group (median, 1 vs. 35.5 days and 1 vs. 41.5 days, respectively).

As in the REFORM study [15], a reduction in travel costs of almost USD 122 was observed in our study. It should be noted that social costs for RM may present relevant differences in various countries with significant changes, for instance, between rural and urban hospitals. In general, the greatest cost benefit is expected among patients who live far away from the referring hospitals, who are not retired, or who are accompanied by actively working persons. In our study, the majority of patients were retired (81 %) and accompanied by a relative or a carer (72 %) who had to ask for a day off or special permission at work in 43 % of cases. Private car was by far the most commonly used means of transportation (median home-to-hospital distance of about 20 km and a transportation time of about three fourths of anhour). Overall time spent by a patient for a single visit, including home-to-hospital trip, waiting time, visit time, and return trip, was about 2 h. Within the specific context of our hospital, RM was therefore found to be cost-saving for patients, who enjoyed mean cost savings of about USD 191 per year (social costs).

Of course one should not underestimate that in-hospital visits may be preferred by some patients as they do give the opportunity to interact with medical professionals, which can be beneficial when it comes to assessments of vital signs and reporting of symptoms. However, overall, the potential benefit of RM is important not only in terms of hospital and social costs but also in terms of other potential advantages deriving from early diagnosis of device-related events such as lead failure or T-wave oversensing [22], and clinical events such as AF [10, 23] or heart failure [5, 7, 8, 11, 24, 25]. Moreover, these adverse events detected by RM are often silent [5] and, in the case of AF, occurred in about 30 % of the patients as new onset AF [23]. Such early diagnosis may reduce the rate of hospitalization and/or length of in-hospital stay [11], decrease the incidence of strokes [26, 27], and reduce the number of inappropriate shocks causing early depletion of ICD therapy [20, 22]. Such clinical benefit may result in an additional and even more important reduction of overall healthcare resource consumption, making RM economically attractive.

4.3 Study limitation

The main objective of our study was limited to comparing direct costs of 1-year follow-up between RM and standard in-hospital visits for a single-center ICD population based on the initial assumption that RM technologies were provided with no additional costs. Our results can thus not be used to determine a reasonable cost increase related to RM technology and connected services. Early detection of clinical and device-related critical events provided by RM may have a positive impact on major complication rates, hospitalizations, and deaths, with huge potential benefits in terms of social and hospital expenditure restraint which were not evaluated here. The effect of RM on clinical outcome was beyond the scope of our analysis as should be appropriately assessed in large, multi-center (desirably), international, long-term-follow-up randomized trials.

As it is inevitable in studies conducted in a single country, our economic analysis was strictly correlated with the Italian context and results are not straightforwardly extendable to other contexts. Also, physician and nurse salary values used in this study were consistent with current national standards and may substantially differ from other European countries. Techniques based on official retail price indexes, like those provided by the United Nations [28], may be useful to adapt our findings to different contexts.

5 Conclusions

In our experience, we observed greater economic value for RM as compared to standard quarterly ICD follow-up if RM bedside patient devices and service cost are not charged to patients or the hospital. RM determined shorter periods of time spent by the hospital staff (particularly by physicians)—who are thus potentially enabled to take on more patients—plus more efficient utilization of resources. In terms of hospital costs, RM strategy was able to save USD 50 per patient/year. In terms of social costs, patients on RM could save about USD 191 per year.

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Author contributions All co-authors have substantially contributed to the study conduct and paper draft and approved this manuscript
Leonardo Calò: concept/design, data analysis/interpretation, drafting of article, critical revision of article, approval of article.
Alessio Gargaro: data analysis/interpretation, drafting of article, statistics
Ermenegildo De Ruvo: concept/design, data analysis/interpretation, drafting of article, critical revision of article, approval of article, data collection
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