ESC European Society of Cardiology

Europace (2017) **19**, 1493–1499
doi:10.1093/europace/eux017

CLINICAL RESEARCH
Sudden death and ICDs

Economic impact of remote monitoring after implantable defibrillators implantation in heart failure patients: an analysis from the EFFECT study

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Received 1 September 2016; editorial decision 16 January 2017; accepted 20 January 2017; online publish-ahead-of-print 12 April 2017

Aims Heart failure (HF) patients with implantable cardioverter-defibrillators (ICD) require admissions for disease management and out-patient visits for disease management and assessment of device performance. These admissions place a significant burden on the National Health Service. Remote monitoring (RM) is an effective alternative to frequent hospital visits. The EFFECT study was a multicentre observational investigation aiming to evaluate the clinical effectiveness of RM compared with in-office visits standard management (SM). The present analysis is an economic evaluation of the results of the EFFECT trial.

Methods and results The present analysis considered the direct consumption of healthcare resources over 12-month follow-up. Standard tariffs were applied to hospitalizations, in-office visits and remote device interrogations. Economic comparisons were also carried out by means of propensity score (PS) analysis to take into account the lack of randomization in the study design. The analysis involved 858 patients with ICD or CRT-D. Of these, 401 (47%) were followed up via an SM approach, while 457 (53%) were assigned to RM. The rate of hospitalizations was 0.27/year in the SM group and 0.16/year in the RM group (risk reduction =0.59; $P = 0.0004$). In the non-adjusted analysis, the annual cost for each patient was €817 in the SM group and €604 in the RM group ($P = 0.014$). Propensity score analysis, in which 292 RM patients were matched with 292 SM patients, confirmed the results of the non-adjusted analysis (€872 in the SM group vs. €757 in the RM group; $P < 0.0001$).

Conclusion There is a reduction in direct healthcare costs of RM for HF patients with ICDs, particularly CRT-D, compared with standard monitoring.

Clinical Trial Registration http://clinicaltrials.gov/Identifier, NCT01723865.

Keywords ICD • CRT-D • Heart failure • Remote monitoring • Healthcare costs

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What's new?

- This study provides original data demonstrating that Remote monitoring (RM) was associated with lower costs for the healthcare service in a real-world cohort of HF patients with implantable cardioverter-defibrillators (ICD).
- This analysis shows that RM of ICD is effective and produces savings especially for patients who received CRT-D.

Introduction

Implantable cardioverter-defibrillators (ICD) and ICDs for cardiac resynchronization therapy (CRT-D) are effective therapies for patients with heart failure (HF).[1] The Heart Rhythm Society (HRS) consensus statement on remote interrogation and monitoring for cardiovascular implantable electronic devices advocates monitoring both device functioning and patients' conditions after implantation through a regular calendar-based system of follow-up.[2]

Standard protocols of follow-up consist of in-office visits performed every 3-6 months. Periodic evaluations impose a significant workload on physicians, which episodically increases when devices approach their elective replacement indicator (ERI), or in the case of unscheduled events (e.g. shocks delivered, automatic device notifications). In-office follow-up also poses additional challenges, such as the difficulty in promptly detecting problems and the management of unscheduled encounters.[3] The new remote monitoring (RM) technologies facilitate patient follow-up. In RM, data on the status of the device and patient information gathered by the device are transmitted over a network from the patient's location via a central database to a hospital or physician's office.[3]

Over the last few years, prospective trials have compared in-clinic and remote follow-up not only from a clinical standpoint, but also in terms of resource consumption. In particular, the TRUST trial found that RM reduced healthcare utilization by 50%.[4] The CONNECT trial confirmed the results of the TRUST trial, demonstrating an 18% reduction in the length of hospitalization for cardiovascular events following the adoption of RM.[5] These findings were confirmed by recent European studies that demonstrated a reduction in scheduled in-office visits in several clinical settings.[6–9] In terms of both reduced resource consumption and clinical effectiveness, RM has proved to be a cost-effective technology for HF patients following ICD implantation.[10–14]

Recently, the EFFECT multicentre observational study compared the clinical effectiveness of standard management (SM) by means of in-office visits SM and management through RM in patients with either ICD or CRT-D devices, in the clinical practice of 25 Italian centres.[15]

The present analysis is an economic evaluation of the results of the EFFECT trial. The aim was to assess the affordability of RM from the Italian National Healthcare Service (NHS) perspective.

Methods

Design of the analysis

The present economic analysis was conducted on the resource consumption data collected during the EFFECT study, which was a prospective, non-randomized, multicentre trial.[15] A population of 987 consecutive patients who had undergone ICD/CRT-D implantation in 25 Italian centres were assigned to either RM ($n = 499$) or SM ($n = 488$). Patients were followed up in accordance with the standard practice of the participating centres.[2] In the SM arm, patients underwent at least two in-clinic visits per year, while in the RM arm patients underwent at least one in-clinic visit per year and one remote device interrogation every 6 months.

All patients with complete clinical and economic data (i.e. baseline characteristics, resource consumption, and clinical status at the end of the follow-up) were included in the analysis.

Economic analysis

The present economic analysis was designed to evaluate potential cost differences between RM and SM patients over the first 12 months after study enrolment, from the national healthcare perspective.

In this setting, the following events were considered in the cost analysis: (i) scheduled and unscheduled in-office visits; (ii) remote device interrogations; (iii) cardiovascular and non-cardiovascular hospitalizations. A unit cost of €20.66 (current Italian tariff for a specialist examination)[16] was attributed to in-office visits. Although remote follow-ups were not covered by an official reimbursement scheme in Italy, we attributed an economic value to remote follow-ups, in agreement with previous studies.[11] The cost of a remote follow-up was assumed to be equal to that of an in-office visit, as it occurs in the countries where there is reimbursement. Hospitalization costs were measured on the basis of diagnosis related group (DRG) tariffs. The DRG of each hospitalization was determined on the basis of diagnosis and procedural information (ICD-9 version 24) collected during the study (Supplementary material online, *Table S1*). The diagnosis and procedural codes of each hospitalization were then crosschecked in order to calculate DRGs (3M manual for DRG coding).[17] Finally, unit tariffs for the DRGs calculated were retrieved from the Italian Tariff Book of hospital care (Ministry of Health).[16] In Italy and other countries, the use of the technology (the RM device, network server, and website) is included in the initial cost of the ICD without any adjunctive fee, thus it does not represent a marginal cost in the economic evaluation.

In line with the published clinical analysis, the economic outcomes were evaluated for the entire population and for the two subgroups: CRT-D and conventional ICD.

Statistical analysis

Descriptive and inferential statistics were used to conduct the analysis. Standard descriptive statistics were used to analyse patients' baseline characteristics and to evaluate overall costs. *T*-test for continuous variables, and χ^2 test for categorical variables were used to detect differences between the groups at the baseline. Economic variables are reported as average or median values. Non-parametric tests (i.e. rank-sum) were used to perform inferential analysis for economic outcomes. A *P*-value of <0.05 was considered significant for all tests. Economic comparisons were also carried out by means of propensity score (PS) analysis to take into account the lack of randomization in the study design.[18]

The following variables were considered in the PS analysis: age, gender, NYHA class at the baseline, history of ischaemic disease, hypertension, device type (ICD vs. CRT-D), and enrolling centre. The complete list of variables is reported in Supplementary material online, *Table S2*. The full Mahalanobis -nearest neighbour-matching was used, by applying the *psmatch2* STATA routine. All analyses were performed by means of STATA 13 (Stata Corp Stata Statistical Software: Release 13. College Station, TX: StataCorp LP).

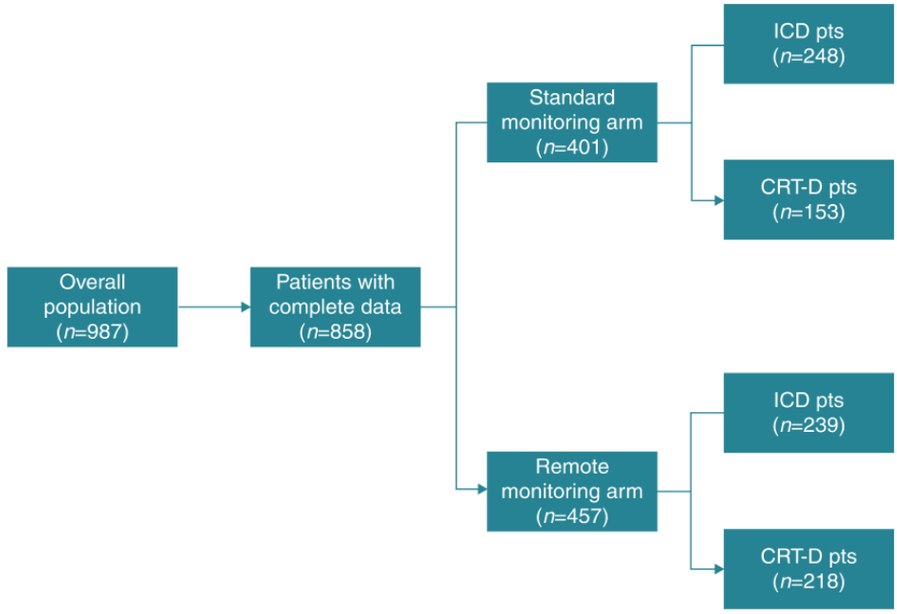

Figure 1 Distribution of patients, according to monitoring arm and type of implanted device.

Results

As previously reported,[15] 987 consecutive patients were enrolled from 2011 to 2013 and followed up for at least 12 months. Remote monitoring was assigned to 499 patients (51%). Three hundred and forty-six, 62, 59, and 32 patients used the Boston Scientific LATITUDE monitoring system, Medtronic CareLink Network, Biotronik Home Monitoring system, and St Jude Medical Merlin.net System.

Of the 987 patients, 129 (13%) were excluded because no data on resource use were available for them, and 858 (87%) were included in the economic analysis (*Figure 1*). Of these, 401 (47%) were followed-up via an SM approach, while 457 (53%) were assigned to RM. Patients with an ICD numbered 487 (57%).

Subjects were predominantly male, and were aged around 65 years; 86% were in NYHA HF classes II and III on enrolment. Patients with CRT-D were more likely to be included in the RM group (48% in RM vs. 38% in SM; $P = 0.0049$; *Table 1*). Except for this difference, patients' baseline characteristics were similar between the two groups.

Patients in the RM group experienced fewer hospitalizations (71 events in 56 (12%) patients) than those in the SM group (108 events in 83 (21%) patients) during the observation period (*Table 2*). Overall, the rate of hospitalizations in the first 12 months of follow-up was 0.16 and 0.27/year in the RM and SM group, respectively (risk reduction: 0.59; $P = 0.004$). The majority of hospitalizations were due to cardiovascular episodes (162 (91%) of 179 hospitalizations; 64 in the RM group and 98 in the SM group) with HF being the most common main diagnosis reported in the hospital discharge form (136 (76%) of 179 hospitalizations). Similarly, more patients remained free from hospitalization in the RM group than in the SM group during follow-up ($P = 0.0008$; *Figure 2*).

Hospitalization rates were also evaluated in the ICD and CRT-D subgroups (*Table 2*, *Figure 2*). In the ICD population, the burden of hospitalizations was non-significantly ($P = 0.054$) lower in the RM group. In the CRT-D group, both the rate of hospitalizations and the proportion of hospitalized patients were significantly lower in the RM group than in the SM group ($P = 0.020$ and $P = 0.006$, respectively).

No differences were observed in the rate of in-office visits. The average number of in-office visits was 3.02/year in the SM group and 3.09/year in the RM group ($P = 0.358$). Indeed, the slight reduction in scheduled in-office visits in the RM group was offset by the increased number of unscheduled visits due to remote notification.

Figure 3 shows the results of the unadjusted cost analysis. In the overall population, RM reduced the annual cost per treated patient by €213 in comparison with SM (rank-sum test, $P = 0.014$). The analysis of subgroups showed that the cost reduction was mainly attributable to CRT-D patients, while costs in the ICD subgroup were quite similar in SM and RM patients.

The PS analysis performed to correct potential bias is reported in *Figure 4*. In the overall population, the PS analysis was conducted in 292 RM patients and 292 matched SM controls. The cost reduction associated to RM, albeit lower was confirmed (€115; rank-sum test, $P < 0.0001$).

The results of the PS analysis applied to ICD and CRT-D subgroups confirmed the findings of the unadjusted analysis. Indeed, among ICD patients, the annual costs were similar between the arms, while among CRT-D, RM was associated with lower costs.

Discussion

The EFFECT study is one of the largest observational studies conducted in Europe on the RM of patients affected by HF and treated

with ICD or CRT-D. In the previously published analysis of data from the EFFECT study, we showed that RM was associated with a reduction in death and cardiovascular hospitalization burden.[15] The present analysis showed that this reduction translated into an economic advantage for the healthcare service. Indeed, significantly lower costs were observed in the overall population and in the CRT-D subgroup, while direct costs were similar between groups in the ICD population. However, in none of the settings analysed was RM associated with an increase in healthcare costs. While a reduction in mortality and/or CV morbidity on RM was demonstrated in a previous study[19] and a recent meta-analysis,[10] the economic effect associated with fewer CV hospitalizations has not been clearly assessed so far. Our results obtained in the overall population showed a significant annual difference in healthcare costs between SM and RM strategies: €213 per patient in the unadjusted analysis and €115 in the PS-adjusted analysis. This difference illustrates the economic benefit that the Italian NHS could obtain by adopting RM. In other words, if the Italian NHS invested up to €115/patient in managing patients by means of RM, this option would remain cost-saving vs. SM, and more effective in terms of the reduction in the clinical burden of CHF.

While the economic benefit was clear in the CRT-D subgroup, in the ICD group, RM was associated with better clinical outcomes at the same costs as SM. This difference is hard to explain, owing to the observational setting of the EFFECT study. It is plausible, however, that the ability to adjust the delivery of resynchronization therapy in response to remote device notifications may result in larger benefits than the simple monitoring of anti-tachycardia therapies delivered by conventional ICDs. Moreover, the ICD subgroup showed higher cost than CRT-D in the PS analysis, regardless of similar admission rate. This result is explained by a higher proportion of more costly HF hospitalizations and agrees with recent findings showing a better outcome of HF patients treated with CRT-D than narrow QRS ICD recipients in routine clinical practice.[20]

Unlike certain studies[8,9] the EFFECT study did not show a reduction in the overall burden of in-office visits. This discrepancy probably requires some comments. In previous randomized clinical trials, in-office visits were scheduled at pre-defined milestones, while unscheduled visits occurred only when certain clinical problems arose. In contrast, in an observational trial performed in routine

Table 1 Demographics, baseline clinical parameters and pharmacological treatment of the study population at the time of enrolment

Variable	SM arm ($n = 401$)	RM arm ($n = 457$)	P
Male gender, *n* (%)	308 (77)	353 (77)	0.880
Age, years (SD)	65 (13)	66 (12)	0.222
Ischaemic heart disease, *n* (%)	229 (57)	239 (52)	0.158
Atrial fibrillation, *n* (%)	117 (29)	118 (26)	0.271
Ventricular fibrillation, *n* (%)	126 (31)	131 (29)	0.379
QRS duration, ms (SD)	121 (31)	123 (33)	0.356
NYHA class[a]			
Class I, *n* (%)	54 (14)	55 (12)	0.407
Class II, *n* (%)	188 (47)	201 (44)	
Class III, *n* (%)	157 (39)	195 (43)	
Class IV, *n* (%)	2 (0.5)	6 (1)	
Primary prevention, *n* (%)	326 (81)	391 (86)	0.093
CRT defibrillator, *n* (%)	153 (38)	218 (48)	0.005
Peripheral vascular disease, *n* (%)	36 (9)	41 (9)	0.998
Hypertension, *n* (%)	233 (58)	248 (54)	0.258
Diabetes, *n* (%)	119 (30)	118 (26)	0.208
COPD, *n* (%)	69 (17)	62 (14)	0.139
Pulmonary hypertension, *n* (%)	29 (7)	22 (5)	0.135
Chronic kidney disease, *n* (%)	61 (15)	75 (16)	0.631
LV ejection fraction, % (SD)	31 (10)	31 (11)	0.966
CHADS2 score (SD)	2.3 (1.5)	2.1 (1.4)	0.105

T-test for continuous variables; pr-test for relative frequencies.
RM, remote monitoring; SM, standard management; CRT-D, cardiac resynchronization therapy; SD, standard deviation.
[a]χ^2 test

Table 2 Hospitalizations by group and type of implanted device

	All patients ($n = 858$)		ICD patients ($n = 487$)		CRT-D patients ($n = 371$)	
Annual rate	SM ($n = 401$)	RM ($n = 457$)	SM ($n = 248$)	RM ($n = 239$)	SM ($n = 153$)	RM ($n = 218$)
0 hospitalizations	318 (79%)	401 (88%)	195 (79%)	204 (85%)	123 (80%)	197 (90%)
1 hospitalization	68 (17%)	46 (10%)	42 (17%)	29 (12%)	26 (17%)	17 (8%)
≥ 2 hospitalizations	15 (4%)	10 (2%)	11 (5%)	6 (3%)	4 (3%)	4 (2%)
Pearson χ^2 test	$P = 0.004$		$P = 0.143$		$P = 0.020$	
Overall hospitalization rate (number of events/patient per year)	0.27	0.16	0.28	0.18	0.25	0.12
Reasons for admission, number of events (annual rate)						
Heart failure	44 (0.12)	24 (0.06)	25 (0.11)	18 (0.08)	19 (0.13)	6 (0.03)
Arrhythmias	16 (0.04)	15 (0.04)	13 (0.06)	11 (0.05)	3 (0.02)	4 (0.02)
Device-related	24 (0.07)	16 (0.04)	12 (0.06)	2 (0.01)	12 (0.08)	14 (0.07)
Other	14 (0.04)	9 (0.02)	11 (0.05)	8 (0.04)	3 (0.02)	1 (0.005)

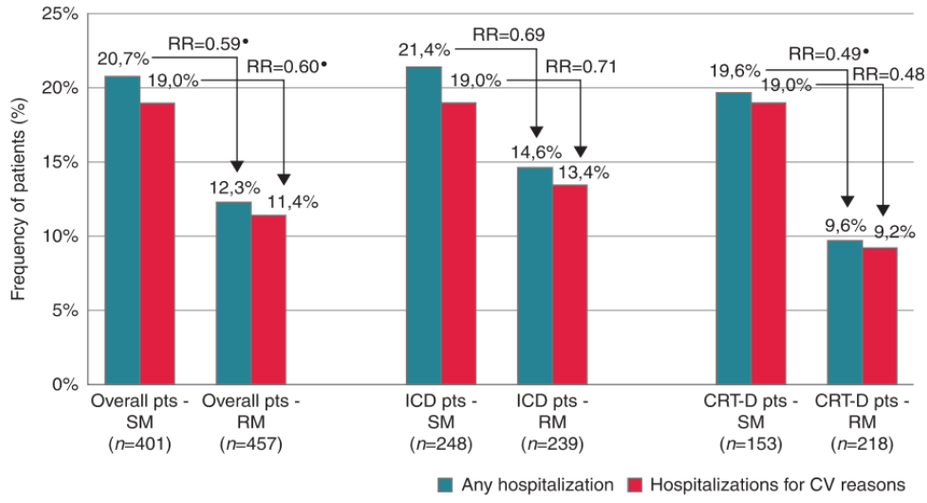

Figure 2 Proportion of hospitalized patients. *$P < 0.05$.

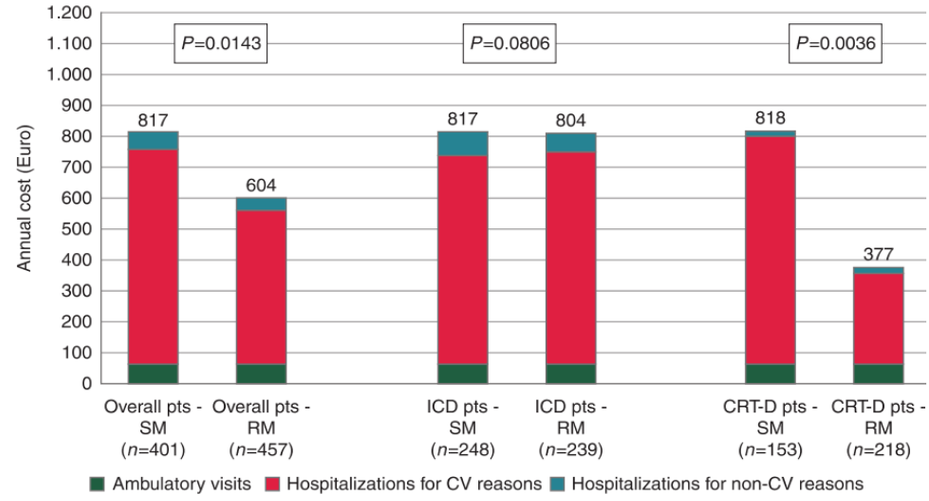

Figure 3 Unadjusted cost comparison between SM and RM.

clinical practice, like the EFFECT study, unscheduled visits in response to remote data transmission may be more frequent, as they are left to the discretion of the single physician.

However, although RM did not reduce the number of in-office visits vs. SM, it probably increased the rate of "useful" visits, thereby avoiding unnecessary scheduled controls if patient or device conditions did not require intervention. In other words, RM was an efficient means of targeting and prioritizing visits according to the real clinical need of patients. In this context, the results of the EFFECT study are in line with the findings of the EVOLVO study,[11] in which the increase in unscheduled visits in the RM group, attributable to device notification, was offset by the reduction in scheduled visits.

Although the results of this analysis can be considered robust, this evaluation presents some methodological limitations. The main limitation was the lack of randomization. However, the PS matching used to overcome this issue confirmed the findings yielded by the unadjusted analysis. Moreover, from an economic perspective, the analysis captured the burden of in-office visits and hospitalizations (including emergency room visits and day-hospital admissions), but did not consider the cost of pharmacological treatment and the cost of

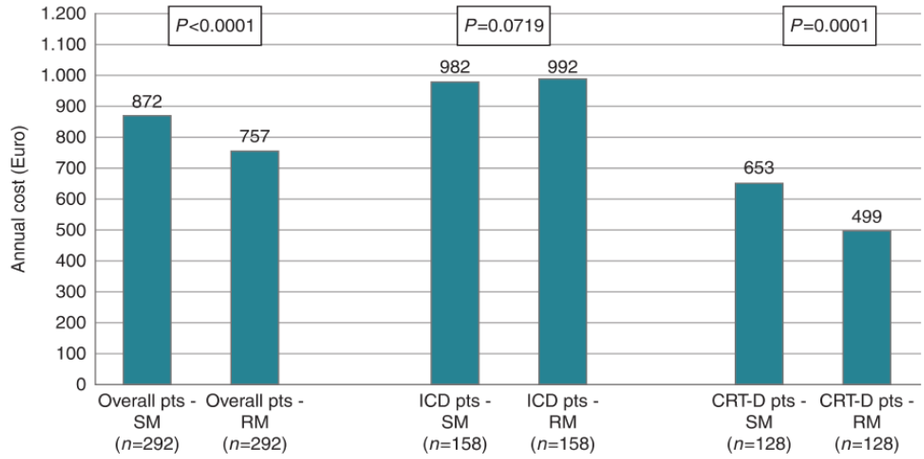

Figure 4 Propensity-score-adjusted cost comparison between SM and RM.

diagnostic examinations performed outside the hospital. However, although the inclusion of other direct costs could provide a more realistic estimate of healthcare expenses, there is no reason to believe that the adoption of RM would increase pharmacological costs in comparison with SM. In addition, as the present findings were obtained with implanted devices and RM systems from different manufacturers, they might have been affected by a lack of homogeneity.

In conclusion, the present analysis reinforced the evidence that RM is a good management strategy for HF patients in whom defibrillators are implanted. Indeed, better clinical outcomes are achieved with an economic advantage for the healthcare service. In particular, RM seems to result in lower costs in the CRT-D population.

Supplementary material

Supplementary material is available at *Europace* online.

Acknowledgement

The authors would like to thank Gianluca Furneri, an independent health economics consultant, for his analysis, which made this study possible.

Conflict of interest: none declared.

Funding

The EFFECT study was an independent study. Boston Scientific provided funding for the economic analysis, which was conducted by an independent health economics consultant.

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EP CASE EXPRESS

doi:10.1093/europace/euw171
Online publish-ahead-of-print 17 October 2016

'. . . And now what to do?' Direct surgical trans-atrial endocardial pacing electrode implantation in a very complex situation

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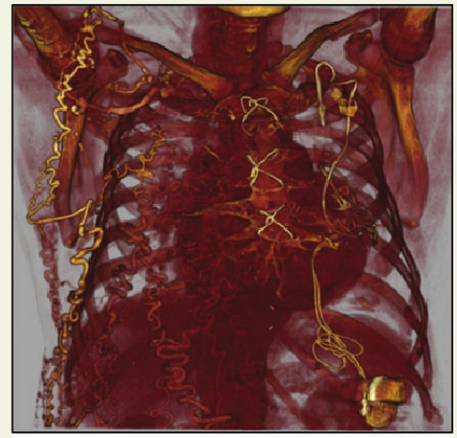
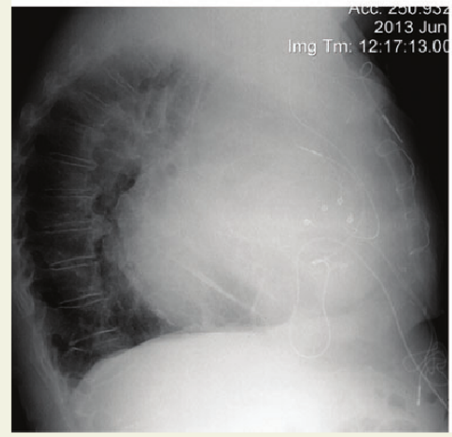
A 66-year-old man, who had a 20-year-old history of mechanical mitral valve replacement for rheumatic valve disease and concomitant epicardial monopolar lead implantation for symptomatic bradycardic atrial fibrillation, was diagnosed with significant increase in pacing threshold. Therefore, a novel endocardial ventricular lead was successfully placed via left subclavian vein.

Four years later, pocket infection occurred, with removal of the pulse generator and lead. An attempt of contralateral transvenous implantation failed because of superior vena cava thrombotic occlusion; thus, an epicardial lead was implanted, with a left-sided abdominal pocket pulse generator.

Six years later, the patient complained of syncope and worsening dyspnoea, and at a follow-up visit, an increase in pacing threshold and stimulation impedance were observed. A diagnostic work-up identified capture failure with prolonged asystole at 24-h ECG recording, as well as a total chronic thrombotic occlusion of superior vena cava at venous phase contrast-enhanced chest CT scan. A hybrid surgical pacing electrode implantation was then performed with a direct right trans-atrial access via minithoracotomy. After surgical access preparation, a standard screw-in lead was fixed in the right ventricular outflow tract, under transoesophageal echocardiography guidance. Lead was tunnelled in a right abdominal pocket and connected to pulse generator.





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