Long-Term Complications Related to Biventricular Defibrillator Implantation

Rate of Surgical Revisions and Impact on Survival: Insights From the Italian ClinicalService Database

Maurizio Landolina, MD*; Maurizio Gasparini, MD*; Maurizio Lunati, MD*; Saverio Iacopino, MD; Giuseppe Boriani, MD, PhD*; Carlo Bonanno, MD; Antonello Vado, MD; Alessandro Proclemer, MD; Alessandro Capucci, MD; Chantal Zucchiatti, MS; Sergio Valsecchi, PhD; Renato P. Ricci, MD; Massimo Santini, MD*; on behalf of the Cardiovascular Centers Participating in the ClinicalService Project

Background—Long-term data on device-related untoward events in patients receiving defibrillators for resynchronization therapy (CRT-D) are lacking. We quantified the frequency of repeat invasive procedures and the nature of long-term complications in current clinical practice and examined possible predictors of device-related events and their association with long-term patient outcome.

Methods and Results—We analyzed data from 3253 patients who underwent de novo successful implantation of CRT-D and were followed up for a median of 18 months (25th to 75th percentiles: 9 to 30) in 117 Italian centers. Device-related events were reported in 416 patients, and, specifically, surgical interventions for system revision were described in 390 patients. Four years after the implantation procedure, 50% of patients underwent surgical revision for battery depletion and 14% for unanticipated events. For comparison, at 4 years battery depletion occurred in 10% and 13% of patients who received single- and dual-chamber defibrillators at the study centers, and unanticipated events were reported as 4% and 9%, respectively. In CRT-D, infections occurred at a rate of 1.0%/y, and the risk of infections increased after device replacement procedures (hazard ratio, 2.04; 95% confidence interval, 1.01 to 4.09; \( P = 0.045 \)). Left ventricular lead dislodgements were reported at a rate of 2.3%/y and were predicted by longer fluoroscopy time and higher pacing threshold on implantation. Device-related events were not associated with a worse clinical outcome; indeed, the risk of death was similar in patients with and without surgical revision (hazard ratio, 0.90; 95% confidence interval, 0.56 to 1.47; \( P = 0.682 \)).

Conclusions—In current clinical practice device-related events are more frequent in CRT-D than in single- or dual-chamber defibrillators, and are frequently managed by surgical intervention for system revision. However, a worse clinical outcome is not associated with these events.

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Key Words: heart failure ■ defibrillation ■ cardiac resynchronization therapy ■ complications

The long-term effects of cardiac resynchronization therapy (CRT) have been evaluated in several trials.1 Currently, CRT alone or associated with an implantable cardioverter-defibrillator (CRT-D) is recommended for patients with moderately or severely symptomatic heart failure and evidence of ventricular dyssynchrony.2 After 2 recent randomized trials suggested that CRT can reduce the progression of disease and lower the risk of heart failure events in mildly symptomatic patients,3,4 the 2010 update of the European guidelines extended CRT recommendation to patients in New York Heart Association (NYHA) class II heart failure.5

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Several large-scale registries have reported complications after cardioverter-defibrillator (ICD) implantation, and have described their association with device type, physician spe-
cially and certification,7,8 and hospital implantation volume.9 However, the vast majority of reports refer to periprocedural adverse events or early complications and describe their association only with short-term patient outcome.

By contrast, long-term data on the burden of device-related untoward events in patients receiving CRT-D are lacking. Although long-term data have been published with regard to the loss of CRT in patients enrolled in earlier CRT-D studies10 or complications in single-center series,11 no data from large-scale databases on current clinical practice have been reported. We therefore sought to quantify the frequency of repeat invasive procedures and the nature of long-term complications after CRT-D implantation in general practice, and to examine predictors of device-related events and their association with long-term patient outcome.

Methods

Patient Population and Study Procedures

Patients who underwent successful implantation of a CRT-D system were included consecutively by the cardiovascular centers that participate in the Italian Clinical Service project, a national medical care project that started in 2004 and with the mission of evaluating and improving the use of implantable cardiac devices in clinical practice. The project consists of a shared environment for the collection, management, analysis, and reporting of clinical and diagnostics data from patients wearing Medtronic (Minneapolis, MN) implantable devices. These data are prospectively collected and may be mined to perform observational research. An independent physician steering committee prospectively identifies key clinical questions on a yearly basis for analysis and publication. A charter assigns the ownership of data to the centers and governs the conduct of and relationship between the steering committee and Medtronic personnel.

Each patient signed an informed consent form, which had been approved by the Institutional Review Board of each center. All patients underwent biventricular ICD placement with transvenous coronary sinus lead for left ventricular (LV) pacing (Medtronic) in all patients (except for patients in permanent atrial fibrillation), and a single- or dual-chamber ICD. These data are prospectively collected and may be mined to perform observational research. An independent physician steering committee prospectively identifies key clinical questions on a yearly basis for analysis and publication. A charter assigns the ownership of data to the centers and governs the conduct of and relationship between the steering committee and Medtronic personnel.

We determined the annual volume of activity at each hospital on the basis of data from the National ICD Registry of the Italian Society of Arrhythmology and Cardiac Pacing (AIAC).12 Specifically, we ranked the participating centers according to the number of first implantations of CRT-D performed in 2007, which ranged from 1 to 107 (median 12), and for descriptive analysis we divided them into tertiles in the case of skewed distribution. Categorical variables are reported as percentages. The rate of events is reported as the number of events observed per patient-year. Survival analysis was performed by means of the Kaplan-Meier method, and the log-rank test was applied to evaluate differences between survival trends (level of significance: P = 0.017 after adjustment for multiple testing by Bonferroni correction). For all estimations of time to events, patients were censored at death or at their last follow-up visit.

Hazard ratios (HRs) and their 95% confidence intervals (CIs) were computed by means of Cox regression models, where baseline predictors were considered as fixed covariates and device-related events were considered as time-dependent covariates. After checking for collinearity, we included in the multivariate Cox models any variable with P < 0.1 on univariate analysis. A P value < 0.05 was considered significant for all tests. All statistical analyses were performed using SPSS software (SPSS Inc, Chicago, IL).

Results

Study Population

From 2004 to 2009, a total of 3865 heart failure patients received a CRT-D and were enrolled at the 117 study centers. After excluding patients with a previous ICD or CRT device, we included in the analysis 3253 patients who underwent successful de novo CRT-D implantation. Baseline clinical variables, echocardiographic parameters, and pharmacological treatment of these patients are summarized in Table 1.

Data collected on implantation are reported in Table 2. Implanting physicians at the study centers used different LV lead models in a variety of sizes, polarity configurations, and fixation systems. The majority of leads were deployed in a lateral or posterolateral cardiac vein, and the mean LV pacing threshold was 1.3 ± 0.8 V at 0.5 ms pulse width.

During the same period, 1576 patients underwent de novo implantation of single- (n = 741) or dual-chamber (n = 835) ICD at the study centers for primary (1104 patients) or secondary (472 patients) prevention of sudden cardiac death.

Follow-Up

During a median follow-up of 18 months (25th to 75th percentiles, 9 to 30), device-related events occurred in 416 CRT-D patients; 483 events resulting in surgical intervention for system revision were reported in 390 patients. Specifically, on excluding patients undergoing only device replacement for battery depletion, 220 events requiring surgical revision occurred in 210 patients. Details of the events
occurring during follow-up and resulting in surgical revision are provided in Figure 1. In addition to these, 16 episodes of incisional infection at the pocket site were effectively treated by means of a conservative approach without system removal, thus yielding a total rate of 1.0 infection per 100 patient-years. Moreover, 22 additional events of LV lead dislodgment were noninvasively managed, and CRT was restored by increasing the pacing output or modifying the LV pacing configuration.

During follow-up, the majority of unanticipated device-related events proved to be lead dislodgments, specifically the dislodgment of the LV lead, and device-related infections. The present CRT-D series also included 1985 patients with a right ventricular ICD lead of the Sprint Fidelis family (subject of the advisory issued in October 2007). Thus, we recorded 44 lead failures among patients with Sprint Fidelis (1.5 failures per 100 patient-years), and 7 elective replacements of nonmalfunctioning leads. The actuarial lead failure survival probability was 99.7% at 1 year, 98.5% at 2 years, 96.9% at 3 years, and 94.2% at 4 years. In addition, we reported surgical revisions for 3 failures of different ICD lead models and 4 failures of LV leads.

The Kaplan-Meier estimates of time to first surgical revision, first unanticipated event, and battery depletion were performed for patients with CRT-D and compared to single- and dual-chamber ICDs (Figure 2). Cardiac resynchronization therapy defibrillator systems demonstrated significantly higher rates of all events than single-chamber ICDs, as well as higher rates of surgical revision and battery depletion than dual-chamber ICDs (all P<0.001). Specifically, the actuarial rate of battery depletion was 50% in CRT-D and 10% in the single- and 13% in the dual-chamber ICD group at 4 years. Similarly, unanticipated events were reported in 14% of CRT-D patients and 4% of single- and 9% of dual-chamber ICD patients. Kaplan-Meier curves showing survival free from device-related infection and LV lead dislodgment for patients with CRT-D systems are reported in Figure 3.

### Predictors of Device-Related Infections

Clinical parameters and implantation data were evaluated for their predictive value for device-related infections by univariable and multivariable analysis, as reported in Table 3. No independent predictors of device-related infections were identified among baseline parameters, except for an association with the presence of chronic obstructive pulmonary disease bordering on significance (P=0.050).

Device replacement procedure showed a significant association with the occurrence of infections during follow-up at multivariable analysis (P=0.045), with a rate of device-related infections of 0.9 events per 100 patient-years after the first implantation and 1.8 events per 100 patient-years after device replacement procedure during the entire follow-up.

### Predictors of Left Ventricular Lead Dislodgements

Although the occurrence of LV lead dislodgements during follow-up was not predicted by any baseline clinical variable, it proved to be significantly related to a longer fluoroscopy time of patients with Sprint Fidelis. In this context, predictors of device-related infections and LV lead dislodgement have been identified among patient characteristics and procedural factors. These findings are important for the proper management of patients with CRT-D systems to minimize the risk of device-related infections and LV lead dislodgement.
time during implantation and to a higher baseline LV pacing threshold (Table 4).

Patient Outcome
During follow-up, 167 patients (rate 4.0 per 100 patient-years of follow-up) died or underwent urgent heart transplantation. The risk of death or heart transplantation was comparable between patients with and without device-related events requiring surgical revision (HR, 0.90; 95% CI, 0.56 to 1.47; \(P = 0.682\)), between those with and without episodes of device-related infections (HR, 1.28; 95% CI, 0.32 to 5.18; \(P = 0.730\)), and between those with and without LV lead dislodgement and subsequent repositioning (HR, 1.22; 95% CI, 0.57 to 2.62; \(P = 0.602\)).

Discussion
Our analysis of the current clinical practice of a large number of Italian centers showed that 4 years after a successful implantation procedure, 50% of patients with a CRT-D system underwent surgical revision for battery depletion and 14% for unanticipated events, such as device-related infections and LV lead dislodgements. For comparison, surgical revision for battery depletion occurred in 10% and 13%, and unanticipated events in 4% and 9%, respectively, of patients who underwent implantation of single- or dual-chamber ICDs.

Recently, Freeman et al\(^9\) examined the relationship between hospital ICD implantation volume and procedural complications in a contemporary population. They showed that patients who have an ICD implanted at a high-volume hospital are less likely to suffer a procedure-related adverse event. However, a weaker volume–outcome relationship was observed for biventricular ICDs.

Knight et al\(^10\) analyzed CRT-D patients enrolled in the VENTAK CHF/CONTAK CD Biventricular Pacing Study to determine the frequency and causes of intermittent and permanent loss of CRT. They reported that CRT was interrupted in 36% of patients during a mean follow-up of 2.5 years but that most of these patients underwent intervention that enabled the reinstition of CRT, with the result that only 5% experienced permanent loss of therapy. However, the frequency of complications requiring invasive procedures was not quantified.

More recently, Duray and colleagues\(^11\) described the complications that occurred in their 7-year single-center experience of ICD implantation and showed that the incidence of complications was significantly higher in CRT-D than in single- and dual-chamber ICD, accounting for an annual incidence of surgical revision of \(\approx 12\%\).

Our experience constitutes the first large analysis of the frequency and nature of long-term device-related events after CRT-D implantation in current clinical practice. In Europe, and especially in Italy, CRT-D use is rising faster than the use of any of the other devices indicated for heart failure treatment.\(^12\) In the light of the recent extension of European CRT recommendations to mildly symptomatic patients,\(^5\) further growth can be expected. Recently, attention has been drawn to the number of ICD recipients who may not benefit from the device but are still exposed to procedural and device-related complications, raising the question of whether current complications of ICD therapy have been underestimated and the benefits overestimated.\(^14\) As shown in the present analysis, the risk of repeat invasive procedure is higher for CRT-D recipients than for patients who undergo implantation of single- or dual-chamber ICDs. Nevertheless, when the defibrillation device also delivers CRT, further reducing the risk of death\(^15\) and providing the well described...
Figure 2. Kaplan-Meier estimates stratified by device type of time to first (A) surgical revision, (B) unanticipated event requiring surgical revision, and (C) device replacement for battery depletion. CRT-D indicates cardiac resynchronization therapy with defibrillator; DC-ICD, dual-chamber implantable cardioverter-defibrillator; and SC-ICD, single-chamber implantable cardioverter-defibrillator.
benefits in terms of improved quality of life, functional capacity, exercise performance, and reduction in heart failure events, the risk-benefit balance becomes more favorable.

**Device-Related Infections**

During long-term follow-up, device-related infections occurred at a steady rate of 1.0 events per 100 patient-years. Infection of implantable cardiac devices remains a serious problem despite improvements in implantation techniques. Previous studies quantified the incidence of infections in cardiac device recipients in the early postimplantation phase.16–18 On measuring the frequency of major complications on implantation among Medicare beneficiaries with ICD, Reynolds et al16 reported an infection rate of 0.7% in CRT-D recipients. The multicenter Prospective Evaluation of Pacemaker Lead Endocarditis (PEOPLE) study17 examined the 1-year incidence of infectious complications after the implantation of antiarrhythmic devices; however, no CRT-D were included in the study. In their analysis, these investigators identified some risk factors of infection (eg, fever on implantation, use of temporary pacing before the procedure, and pulse generator replacement) and confirmed the efficacy of antibiotic prophylaxis on implantation. In our long-term analysis of a large population of CRT-D recipients, we did

![Figure 3.](image-url)

**Figure 3.** In CRT-D group, Kaplan-Meier estimates of time to first (A) device-related infection and (B) LV lead dislodgment. LV indicates left ventricular; CRT-D, cardiac resynchronization therapy with defibrillator.

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<th>Table 3. Univariable and Multivariable Analysis of Factors Predicting Device-Related Infections</th>
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HR indicates hazard ratio; CI, confidence interval; NYHA, New York Heart Association; COPD, chronic obstructive pulmonary disease; LV, left ventricular; and CRT-D, cardiac resynchronization therapy with defibrillator.
not find independent predictors of infections among baseline clinical characteristics; thus, we did not identify subgroups of patients more at risk of this kind of complication. Nonetheless, we observed a significantly higher risk of infections after device replacement procedures.

In our study, the majority of device infections were successfully managed through system removal. No prospective studies have examined the treatment of infections with antibiotics versus device extraction. Most previously published studies, however, have shown unacceptably high failure rates for conservative treatment without hardware removal.19–21 Because of the difficulty of differentiating between local infection and infective endocarditis in device recipients, the recently published European Society of Cardiology guidelines on the treatment of infective endocarditis22 recommend full system removal even when extension of the infection to the electrode leads is only suspected.

Left Ventricular Lead Dislodgements
Left ventricular lead dislodgements requiring surgical revision occurred at a rate of 2.3 events per 100 patient-years, and, on Kaplan-Meier analysis, seemed to be more frequent during the first 6 months after implantation of the lead. The analysis of predictors also revealed a close relationship with the implantation procedure. Indeed, longer fluoroscopy time and higher baseline LV pacing threshold, both signs of a challenging implantation procedure, were associated with LV lead dislodgments during follow-up. It had previously been demonstrated that patients with higher LV pacing thresholds also showed marked fluctuations in threshold and were at risk of inconsistent resynchronization therapy during follow-up.23 This was ascribed to suboptimal stability and contact of the LV electrode with the epicardium. Our findings confirm this hypothesis and demonstrate an association between LV threshold and lead stability. Nevertheless, our centers showed an overall good performance on implantation in terms of procedure times, coronary vein achieved for permanent pacing, and mean pacing parameters. This may be also ascribed to the wide range of available LV pacing leads.

**Lead Malfunctions**
The present series also included patients with ICD leads under safety advisory; consequently, surgical revisions for lead malfunction or elective replacement contributed to the
total number of device-related events reported. The failure rate of Sprint Fidelis leads was 1.5 per 100 patient-years, and was comparable to that reported by Medtronic in its semianually updated Product Performance Report. On the contrary, Hauser et al reported more frequent lead failures (2.8 per 100 patient-years) in their recent independent multicenter study. This discrepancy may be due to our shorter observation period and, most probably, to the fact that our population did not include representative samples of high-risk groups: young patients, women, individuals with hypertrophic cardiomyopathy, and patients with arrhythmogenic right ventricular dysplasia or channelopathies.

**Device Longevity**

In agreement with previous reports, device replacements for battery depletion started to occur after 3 years of follow-up and involved 50% of CRT-D patients after 4 years at Kaplan-Meier analysis. Previous data from a large US registry showed that 53% of normally performing ICDs and, specifically, only 4% of CRT-D were in service 4 years after implantation.

In our series, battery depletion represented the main cause of earlier surgical revision in patients with CRT-D. Indeed, it has been shown that CRT-D are the most demanding antiarrhythmic devices in terms of battery consumption because of the need for continuous biventricular pacing, although device longevity may differ significantly among manufacturers and modern algorithms for pacing output reduction have been demonstrated to improve longevity.

Nevertheless, the risk of earlier surgical revision for battery depletion in CRT-D should be considered not only per se, but also in relationship with the observed higher risk of infection following replacement. Moreover, system revisions for battery depletion represent an important source of incremental costs. Indeed, extension of system longevity was shown to significantly improve cost-effectiveness estimates.

Narrowing the mismatch between the service life of ICDs and patient longevity (ie, providing an ICD that lasts a lifetime) must represent the goal for technological research. This result should be more achievable for CRT-D systems because of the short life expectancy of their recipients, and could be obtained not only by enhancing battery capacity but also by using algorithms for pacing output minimization, as well as through progress in lead technology to ensure good electric performance.

**Patient Outcome**

In our experience, device-related events necessitating surgical revision or involving specific complications, such as infections or lead dislodgments, were documented during long-term follow-up. These events proved not to be associated with a worse clinical outcome, as shown by the comparable risks of death in patients with and without device-related events, confirming findings from a recent CRT trial. This differs from the case of direct implantation-related complications and major perioperative events, which have been associated with an increased risk of death.

Nonetheless, in addition to possible clinical consequences, the occurrence of complications during follow-up clearly represents a source of incremental costs to the healthcare system, as already demonstrated with regard to early complications, which have proved to be associated with significant increases in length of hospitalization and total hospital costs. Therefore, efforts to reduce these events could have significant financial as well as clinical benefits.

**Limitations**

As already mentioned, only successful implantations were included in the study, and information on perioperative complications and intraoperative death were not reported. However, a success rate of 93.7% for CRT-D, with peri-implantation deaths occurring in 0.5% of patients, was previously reported in a large meta-analysis of published CRT experiences.

Furthermore, the present study described a large experience of implantation and long-term management of CRT-D produced by a single manufacturer. Our findings might therefore not be applicable to generators and leads from other manufacturers. However, although the device longevity or the lead malfunctions strictly depend not only on the manufacturer, but also on the specific device family, findings on events such as device-related infections and lead dislodgments are more generally applicable.

The clinical management of the patients in this analysis (ie, the assessment of implantation indications, pharmacological treatment, and CRT-D programming and the management of possible complications) was not standardized, and was performed according to each center’s clinical practice. This aspect may have had an impact on the present findings. However, our study provided insights about the current general practice that could not be obtained with randomized controlled trials.

**Conclusions**

In summary, our analysis of the current clinical practice of a large number of Italian centers showed that long-term device-related events were more frequent in CRT-D than in single- or dual-chamber ICD, as indeed was expected, given the complexity of the implanted device, and that they were frequently managed by surgical intervention for system revision. However, a worse clinical outcome is not associated with these events.

During implantation and follow-up, every effort should be made to address all safety issues associated with cardiac device use, and the continuous study of new preventative strategies is warranted. Moreover, our findings seem to suggest the need for the physician to correctly inform the patient at the time of implantation not only about possible procedural risks, but also about the risk of surgical revisions during follow-up.

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**Disclosures**

Dr Landolina has a speakers’ bureau appointment with St. Jude Medical, Medtronic, and Boston Scientific and an advisory board relationship with St. Jude Medical and Medtronic. Dr Gasparini has...
an advisory board relationship with Boston Scientific. Dr Bonanno receives research grant support and honoraria from Medtronic. Dr Proclemer receives research grant support and has an advisory board relationship with Medtronic. Dr Pacupci has a speakers’ bureau appointment with St. Jude Medical and Boston Scientific. C. Zucchiati and Dr Valsecchi are employees of Medtronic. Dr Ricci receives research grant support from Medtronic, St. Jude, and Biotronik and is a consultant for Medtronic. Dr Santini receives research grant support from Medtronic, St. Jude, and Biotronik and honoraria from Medtronic and Bayer and has a speakers’ bureau appointment with MSD, Medtronic, St. Jude, and AstraZeneca and an advisory board relationship with Boehringer-Ingelheim. The other authors report no conflicts.

References


Cardiac resynchronization therapy (CRT) alone or associated with an implantable cardioverter-defibrillator (CRT-D) is now a common therapy for patients with symptomatic heart failure and evidence of ventricular dyssynchrony. Although several reports have described periprocedural adverse events and early complications of CRT implantation, long-term data on the burden of device-related untoward events are lacking. This study enrolled 3253 CRT-D patients to quantify the frequency of repeat invasive procedures and the nature of long-term complications in clinical practice and to examine possible predictors of device-related events as well as their association with long-term outcome. Four years after implantation, 50% of CRT-D patients underwent surgical revision for battery depletion and 14% for unanticipated events, such as device-related infections or lead dislodgments. For comparison, at 4 years, surgical revision for battery depletion occurred in 10% and 13% of patients who received single- and dual-chamber defibrillators at the study centers, and unanticipated events were reported in 4% and 9%, respectively. Infections occurred at a rate of 1.0%/y, and the risk of infections increased after device replacement procedures (hazards ratio, 2.04; 95% confidence interval, 1.01 to 4.09; \( P = 0.045 \)). Left ventricular lead dislodgements occurred at a rate of 2.3%/y and were predicted by longer fluoroscopy time and higher pacing threshold on implantation, both signs of a challenging implantation procedure. Nonetheless, device-related events were not associated with an increased risk of death. In conclusion, this study demonstrated that in current clinical practice, device-related events are more frequent in CRT-D than in single- or dual-chamber defibrillators, and frequently require surgical intervention for system revision. This information is particularly important because, although device-related events do not seem to be associated with a worse clinical outcome, they represent a source of incremental costs to the healthcare system. Therefore, efforts to reduce them could have significant financial as well as clinical benefits.
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