

# Implantable cardioverter-defibrillator-related procedures and associated complications in continuous flow left ventricular assist device recipients: A multicenter experience



Ashwin Ravichandran, MD,<sup>\*1</sup> Naga Venkata K. Pothineni, MD,<sup>†1</sup>  
Jaimin R. Trivedi, MD, MPH,<sup>‡</sup> Henri Roukoz, MD,<sup>§</sup> Mustafa M. Ahmed, MD,<sup>||</sup>  
Adarsh Bhan, MD,<sup>¶</sup> Geetha Bhat, MD,<sup>¶</sup> Jennifer Cowger, MD,<sup>#</sup>  
Amin Al Ahmad, MD, FHRS,<sup>\*\*</sup> Andrea Natale, MD, FHRS,<sup>\*\*</sup> Luigi Di Biase, MD, FHRS,<sup>††</sup>  
Mark S. Slaughter, MD,<sup>‡</sup> Dhanunjaya Lakkireddy, MD, FHRS,<sup>†</sup>  
Rakesh Gopinathannair, MD, MA, FHRS<sup>†</sup>

From the <sup>\*</sup>St. Vincent Heart Center, Indianapolis, Indiana, <sup>†</sup>Kansas City Heart Rhythm Institute, Overland Park, Kansas, <sup>‡</sup>University of Louisville, Louisville, Kentucky, <sup>§</sup>University of Minnesota, Minneapolis, MN, <sup>||</sup>University of Florida, Gainesville, Florida, <sup>¶</sup>Advocate Christ Medical Center, Oak Lawn, Illinois, <sup>#</sup>Henry Ford Hospital, Detroit, Michigan, <sup>\*\*</sup>Texas Cardiac Arrhythmia Institute, Austin, Texas, and <sup>††</sup>Montefiore Medical Center, New York, New York.

**BACKGROUND** Limited data exist regarding complication rates of implantable cardioverter-defibrillators (ICD) and cardiac resynchronization therapy devices (CRT-D) in patients with left ventricular assist devices (LVAD).

**OBJECTIVE** We describe the incidence and characteristics of ICD- and CRT-D-related procedures and complications in a multicenter LVAD cohort.

**METHODS** A total of 537 LVAD patients with a pre-existing ICD or CRT-D from 5 centers were included. Details on device type, device therapies, procedural complications, and long-term survival were analyzed.

**RESULTS** Of 537 patients, 280 had a CRT-D and 257 had ICD only. During a median follow-up of 538 days, 126 patients underwent generator replacement with significantly higher rate in the CRT group (79 [28.2%] vs 47 [18.3%],  $P = .0006$ ). Device-related complications occurred in 36 (13%) CRT-D and 20 (8%) ICD patients ( $P = .06$ ). Incidence of pocket hematoma (3.2% vs 2.7%), infection

(4.3% vs 1.6%), and lead malfunction (3.1% vs 2.8%) was similar in both groups, with no effect of device complication on long-term survival (log-rank  $P = .7$ ). There was a higher incidence of post-LVAD antitachycardia pacing for ventricular arrhythmias in the CRT-D group compared to the ICD group (35% vs 26%,  $P = .03$ ).

**CONCLUSION** Cardiac implantable electronic device-related procedures are common in LVAD patients. Compared to ICD only, continued CRT-D therapy post-LVAD results in a significantly higher number of generator changes and a trend towards higher device- or lead-related complications. Device-related complications were not associated with reduced survival.

**KEYWORDS** Cardiac implantable electronic device; Generator change; Heart failure; ICD; Left ventricular assist device; Procedures

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## Introduction

Left ventricular assist devices (LVADs) are increasingly utilized for those with end-stage heart failure either as destination therapy or as a bridge to transplant. The majority of patients with LVADs have concomitant cardiac implantable

electronic devices (CIEDs). While implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy (CRT) are standard of care for management of heart failure patients, their role in the post-LVAD population is still unclear.<sup>1–4</sup> Despite limited evidence showing benefit, current guidelines recommend continued ICD and CRT-D implantation and management in LVAD patients.<sup>5,6</sup> Continued need for systemic anticoagulation post LVAD implantation and presence of external hardware increases risks of bleeding and infection in LVAD patients.<sup>7</sup> However, limited evidence exists pertaining to the risk of ICD and

<sup>1</sup>Drs Pothineni and Ravichandran are co-first authors. **Address reprint requests and correspondence:** Dr Rakesh Gopinathannair, Cardiac EP Lab Director, Kansas City Heart Rhythm Institute, Professor of Medicine, University of Missouri-Columbia, 5100 W 110th St, Ste 200, Overland Park, KS 66211. E-mail address: [drrakeshg@yahoo.com](mailto:drrakeshg@yahoo.com); [rakesh.gopinathannair@hcahealthcare.com](mailto:rakesh.gopinathannair@hcahealthcare.com).

### KEY FINDINGS

- In this large, multicenter analysis of continuous flow left ventricular assist devices (LVADs), rates of generator replacements in patients with preexisting implantable cardioverter-defibrillator (ICD) / cardiac resynchronization therapy (CRT-D) devices was 23.5%, with a higher proportion of generator changes being performed in patients with CRT-D devices.
- Rates of overall device-related complications such as infection, lead malfunction, and pocket hematoma needing evacuation approach about 10.4% in this cohort, with rates being similar in ICD and CRT cohorts.
- Occurrence of device-related complications does not appear to affect long-term survival even when stratified by device type.
- These findings call attention to careful selection of LVAD patients for generator change procedures.

CRT-D procedures in the LVAD population. We performed this large multicenter study to describe the incidence and characteristics of device-related procedures and complications and their impact on long-term survival in a multicenter LVAD cohort. We also sought to examine differences in outcomes between CRT-D and ICD groups.

### Methods

The present study was conducted at 5 high-volume LVAD centers in the United States (University of Louisville, Louisville, Kentucky; University of Minnesota, Minneapolis, Minnesota; Advocate Christ Medical Center, Oak Lawn, Illinois; University of Florida, Gainesville, Florida; St. Vincent Heart Center, Indianapolis, Indiana). The study protocol was approved by the Institutional Review Boards at all the centers, and informed consent was completely waived given the retrospective study design. The study adheres to the Helsinki Declaration (as revised in 2013) for human research. Data collection and analysis were performed on consecutive advanced heart failure patients with an existing ICD or CRT-D, who underwent continuous flow (CF)-LVAD placement and subsequent follow-up at these institutions between 2007 and 2016. Those who died during the index hospitalization for LVAD implant were excluded from the analysis. Also, those patients who underwent de novo ICD or CRT-D implantation after LVAD implant were excluded. All patients had CF-LVADs implanted either as a bridge to transplantation or as destination therapy. Implanted CF-LVADs included HeartMate II® (Abbott Medical, Chicago, IL) and Heartware® (Medtronic, Minneapolis, MN). Details on CIED-related procedures and complications were then collected and analyzed. The study results represent a retrospective analysis of prospectively followed patients.

**Table 1** Baseline characteristics of the study cohort categorized by cardiac implantable electronic device type

Variable	CRT-D (n = 280)	ICD only (n = 257)	P value
Mean age (y)	61 ± 12	55 ± 14	<.0001
Male	83%	78%	.1
White	69%	63%	.2
Mean BMI (kg/m <sup>2</sup> )	29.3 ± 7.6	29.7 ± 6.7	.2
Ischemic cardiomyopathy	52%	48%	.6
LVAD as bridge to transplant	45%	51%	.2
Coronary artery disease	61%	54%	.1
Hypertension	67%	67%	.9
Dyslipidemia	69%	61%	.04
Diabetes mellitus	44%	42%	.6
Chronic kidney disease	45%	41%	.3
COPD	21%	21%	.9
Obstructive sleep apnea	35%	34%	.7
Pulmonary hypertension	43%	45%	.6
LV ejection fraction (%)	16 ± 6	16 ± 7	1.0
QRS duration (ms)	159 ± 29	125 ± 34	<.0001
Medications			
Beta-blocker	82%	86%	.2
ACE inhibitors	39%	39%	.6
Aldosterone antagonists	45%	51%	.1
Amiodarone	40%	29%	.006
Digoxin	42%	36%	.2

ACE = angiotensin-converting enzyme; BMI = body mass index; COPD = chronic obstructive pulmonary disease; CRT-D = cardiac resynchronization therapy device; ICD = implantable cardioverter-defibrillator; LV = left ventricular; LVAD = left ventricular assist device.

The data variables collected include demographics, etiology of heart failure, comorbidities, LVAD type, type of CIED, indication and date of implant, medications, electrocardiographic and echocardiographic parameters, and device-specific information on ICDs and CRT-Ds including type of device, percentage of biventricular pacing, and incidence of ICD shocks and ventricular arrhythmias. CIED complications that were assessed included occurrence of pocket hematomas requiring evacuation, infection/endocarditis, and lead integrity failures. Patients were classified into ICD and CRT-D groups. Effect of CIED type (ICD vs CRT-D) on incidence of procedural complications and long-term survival was assessed. The day of CF-LVAD implant marked the start date for follow-up. The last day of follow-up was date of heart transplantation, CF-LVAD explantation, or date of death, whichever came first.

Occurrence of ventricular arrhythmias post LVAD implant, progression to heart transplant, and incidence of LVAD explantation were also assessed. Patient charts were reviewed to assess utilization of cardiac medications during follow-up. Reported electrocardiographic and echocardiographic parameters during follow-up were assessed during the 6- to 12-month period post-LVAD implant. In those patients who had less than 6 months of follow-up, the latest available information on these parameters were selected. Patient medical records as

**Table 2** Arrhythmia episodes in the study cohort

Arrhythmia episodes/therapy	CRT-D group (n = 280)	ICD group (n = 257)	P value
Pre-LVAD atrial arrhythmias	64%	50%	.006
Pre-LVAD ventricular arrhythmias	35%	38%	.6
Post-LVAD ventricular arrhythmias	39%	43%	.3
Post-LVAD ATP	35%	26%	.03
Post LVAD ICD shocks	29%	35%	.2

ATP = antitachycardia pacing; CRT-D = cardiac resynchronization therapy device; ICD = implantable cardioverter-defibrillator; LVAD = left ventricular assist device.

well as institutional databases at each participating center were reviewed to assess the cause of death.

### Statistical analysis

Continuous variables are shown as mean  $\pm$  standard deviation or median with interquartile range when appropriate. Categorical variables are presented as percentages. Continuous variables were analyzed using nonparametric (Kruskal-Wallis) tests. Categorical variables were analyzed using Fisher exact and/or  $\chi^2$  tests. Within groups, pre- and post-LVAD parameters were compared using paired *t* tests. Kaplan-Meier analysis was used to assess survival differences between patients with CIED-related complications and those who did not. The log-rank test was used to compare survival estimates. A *P* value  $<.05$  was considered statistically significant. All statistical analyses were performed using SAS 9.3 (SAS Institute, Cary, NC).

### Results

A total of 537 patients with CIEDs undergoing CF-LVAD implantation were included in the analysis. Of these, 257 had an ICD and 280 had a CRT-D device. Baseline demographics of patients in the ICD and CRT-D groups are shown in Table 1. LVAD implantation was performed as destination therapy in about half the patients. Patients in the CRT-D group were older and had a higher incidence of pre-LVAD atrial arrhythmias and a higher incidence of amiodarone use. As expected, baseline QRS duration was significantly wider in the CRT-D group. Incidence of pre-LVAD ventricular arrhythmia and ICD therapies was similar be-

tween both groups (Table 2). Median time from ICD/CRT-D implant to LVAD implantation were comparable between the groups (1080 vs 1039 days, *P* = .4). Occurrence of post-LVAD ventricular arrhythmias and incidence of ICD shocks were similar in the ICD and CRT-D groups as well. However, a higher incidence of post-LVAD antitachycardia pacing was seen in the CRT-D group (35% vs 26%, *P* = .03).

During the follow-up period, a total of 126 (23.5%) patients underwent generator replacements. There were significantly more generator replacements in the CRT-D group compared to the ICD group (28.2% vs 18.3%, *P* = .0006). Overall incidence of a device-related complication in the entire cohort was 10.4%. Incidence of device-related complications in the ICD and CRT-D groups was 8% and 13%, respectively (*P* = .06). Rates of individual device-related complications in both groups are depicted in Table 3. Pocket hematoma needing evacuation and device-related infection were the most common complications, occurring in 16 patients each. There was no statistically significant difference in rates of these complications between the ICD and CRT-D groups, although there was a trend towards higher infection rates in the LVAD patients with CRT-D. Device complication rates were not significantly different between diabetic and nondiabetic patients (8.7% vs 7%, *P* = .5). Among the 126 patients that underwent a generator replacement, the rates of acute procedure-related complications such as pocket hematoma and pocket infection were 21.5% in the CRT-D group and 17% in the ICD group.

A total of 86 (16%) patients underwent ICD/CRT-D explant during the follow-up period. Most common reason for explant was removal of the device at the time of heart transplantation (59, 68.7%). Device-related infection (15.1%) and lead fracture (15.1%) were the other indications for extraction (Table 4).

Kaplan-Meier survival analysis showed no statistically significant differences in long-term survival in patients with and without device-related complications (Figure 1). Similarly, there were no differences in long-term survival between CRT-D and ICD groups (Figure 2).

### Discussion

In this large, multicenter analysis of CF-LVADs, the rate of generator replacements in patients with preexisting ICD/CRT-D devices was 23.5%, with a higher proportion of generator changes being performed in patients with CRT-D

**Table 3** Implantable cardioverter-defibrillator- and cardiac resynchronization therapy device-related complications in the study cohort

Device-related complications	Total	CRT-D group (n = 280)	ICD group (n = 257)	P value
Pocket hematoma needing evacuation	16 (2.9%)	9 (3.2%)	7 (2.7%)	.80
Pocket infection/erosion	9 (1.7%)	8 (2.9%)	1 (0.4%)	.04
Lead endocarditis	7 (1.3%)	4 (1.4%)	3 (1.2%)	1.00
Lead dislodgement	4 (0.7%)	3 (1.1%)	1 (0.4%)	.63
Lead fracture	16 (2.9%)	8 (2.9%)	8 (3.1%)	1.00
Other	4 (0.7%)	4 (1.4%)	0 (0)	.13
Total	56 (10.4%)	36 (12.9%)	20 (7.8%)	.06

CRT-D = cardiac resynchronization therapy device; ICD = implantable cardioverter-defibrillator.

**Table 4** Indication for lead/device removal

Indication for lead/device removal	Total	CRT-D group	ICD group	P value
Lead/device infection	13	9	4	.27
Lead fracture	13	5	8	.40
At time of heart transplant	59	32	27	.78
Patient preference	1	0	1	1.00
Total	86	46	40	.81

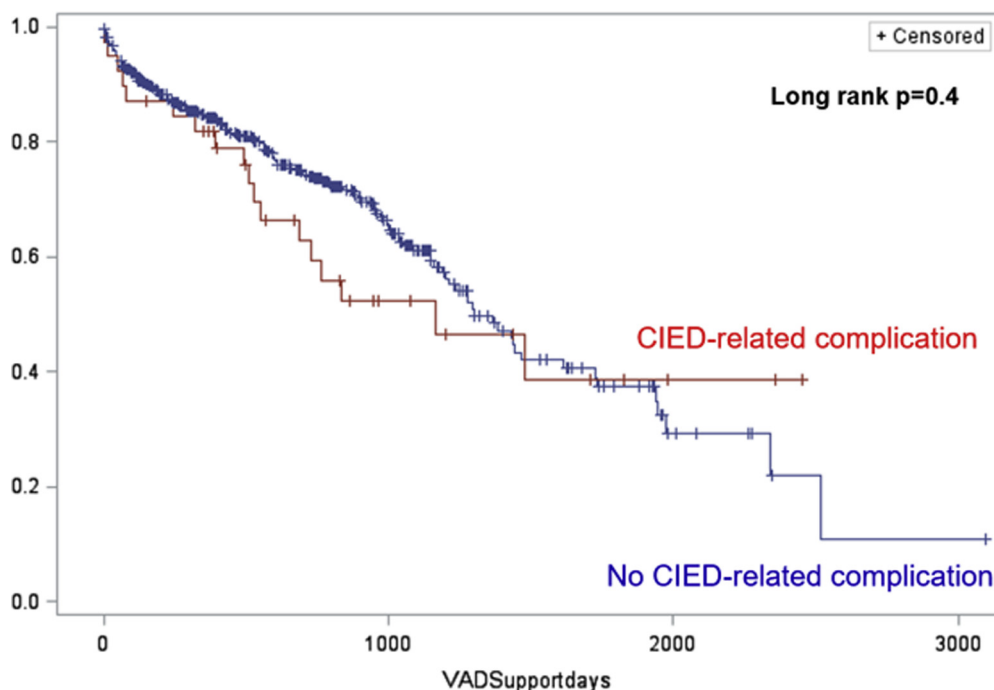
CRT-D = cardiac resynchronization therapy device; ICD = implantable cardioverter-defibrillator.

devices. Overall incidence of device-related complications was 10.4%. Occurrence of device-related complications does not appear to affect long-term survival even when stratified by device type.

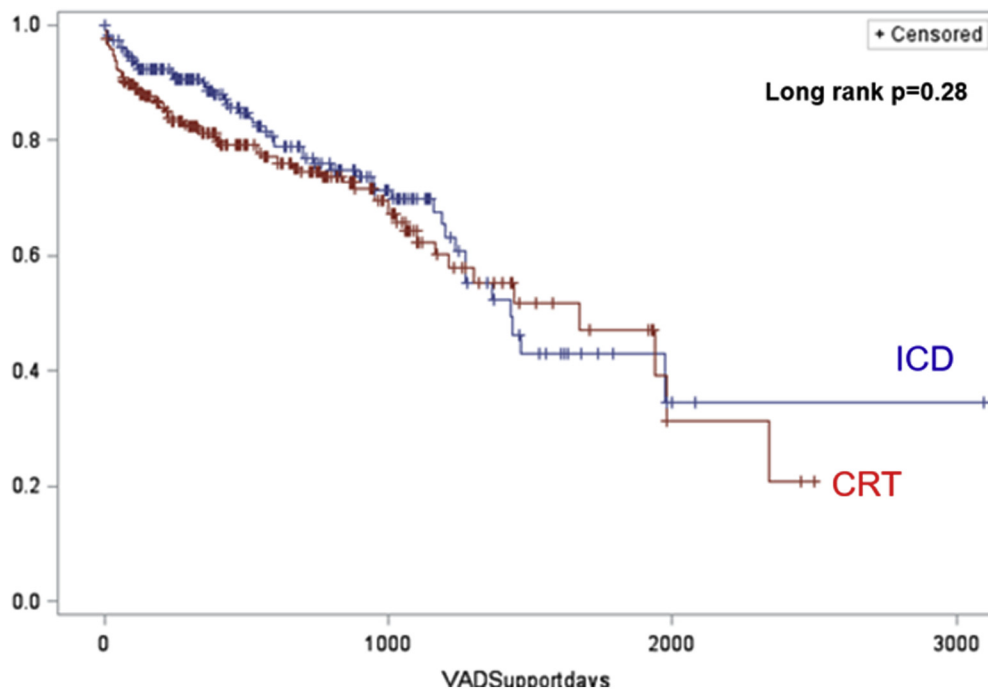
CF-LVADs play an important role in the management of advanced heart failure patients.<sup>8</sup> Decisions regarding CIED management in the post-LVAD population remains a clinical challenge with limited evidence available for guiding clinical decision-making.<sup>9–11</sup> Data from ICD/CRT-D procedures in non-LVAD heart failure patients are frequently used to assess procedural risk in the LVAD population as well, with very few studies examining procedural complications in this particular subset. In a single-center observational study, Black-Maier and colleagues<sup>12</sup> examined outcomes of CIED surgeries in 159 LVAD recipients. The majority of these patients underwent generator changes, followed by lead revisions and de novo device implants. Overall incidence of pocket hematoma in this study was 13.2%, with no significant differences based on type of CIED procedure. Rate of CIED infection was 3.2%, with all cases occurring in patients who developed a pocket hematoma, consistent with prior

studies demonstrating a significant correlation between pocket bleeding and infections.<sup>13</sup> A third of the patients received appropriate ICD therapy post LVAD. In a more recent multicenter cohort, Gilge and colleagues<sup>14</sup> examined complication rates of CIEDs in 179 LVAD patients. Rates of pocket hematoma and CIED infection within 30 days of the procedure were 16% and 2%, respectively, in this cohort. Of note, the rate of new appropriate device therapy post LVAD implant in patients with no prior history of ICD therapies was 14.3%. However, further analysis examining effects of these therapies on long-term outcomes was not performed.

Our current study is the largest to assess complications of CIEDs, specifically ICD and CRT-D devices, in LVAD patients with preexisting devices and adds to the findings of other reports. The rate of CIED-related infections in our cohort was ~3%, comparable to infection rates in other studies. There was a trend towards higher rates of infections in patients with CRT-D compared to those with ICD (4.3% vs 1.6%), likely driven by a significantly higher number of generator changes in the CRT-D group. Rates of pocket



**Figure 1** Kaplan-Meier curves showing long-term survival in patients with and without cardiac implantable electronic device (CIED)-related complications. VAD = ventricular assist device.



**Figure 2** Kaplan-Meier curves showing long-term survival in left ventricular assist device patients with preexisting implantable cardioverter-defibrillator (ICD) and cardiac resynchronization therapy (CRT-D) devices. VAD = ventricular assist device.

hematoma in our analysis was much lower, at 2.9%, and this is likely affected by the outcome definition used. In our study, we only accounted for pocket hematomas needing surgical intervention, while other studies included all pocket hematomas. As the definition of a pocket hematoma can be subjective and operator dependent, especially in a retrospective cohort, we opted to include only those needing evacuation. In addition, we reported percentage of complications as a factor of total number of patients in the cohort as opposed to only those that had a device procedure performed. Despite these differences, a 3% rate of pocket evacuation is higher than expected in a non-LVAD CIED population.<sup>15</sup> This represents a potential opportunity to target lower international normalized ratio levels during CIED surgeries in patients with CF-LVADs. It is interesting to note a lack of effect of CIED complications on survival in this cohort. While we did not analyze acute procedural outcomes such as pneumothorax or cardiac perforation, more subacute complications such as pocket hematoma and infections do not seem to alter overall prognosis.

These emerging studies on device-related complication rates in LVAD patients should provide pause to examine the utility of ICD and CRT-D devices in this patient population. Prior studies examining pulsatile flow LVADs showed a modest benefit for ICDs.<sup>16</sup> However, further studies in the era of CF-LVADs have not demonstrated a significant overall benefit.<sup>17</sup> The hemodynamic support provided by CF-LVADs makes decompensation and death unlikely in the event of a ventricular arrhythmia. A propensity-matched analysis of >2000 patients in the Interagency Registry for Mechanically Assisted Circulatory Support (IN-

TERMACS) showed worse outcomes in LVAD patients with ICDs compared to those without ICDs, with no survival benefit of ICDs even in those patients with recurrent ventricular arrhythmias.<sup>18</sup> Studies evaluating ICD and CRT-D programming in LVAD patients also failed to demonstrate a significant benefit. In a randomized study, Richardson and colleagues<sup>19</sup> randomized 83 LVAD patients with an ICD to standard vs ultraconservative programming with maximal allowed duration of ventricular arrhythmias prior to delivering ICD therapy. There were no significant differences in incidence of ICD shocks, arrhythmic death, or heart failure hospitalization between the 2 groups. In addition, 41 patients in this study with CRT-D devices were randomized to CRT on vs CRT off, with no impact of CRT on long-term outcomes. Other large registry-based studies evaluating the effect of CRT also did not demonstrate improved long-term outcomes in LVAD patients.<sup>20,21</sup> The lack of effect of CRT-D on long-term survival compared to ICD alone in our current study supports prior findings. Taken together, the relative lack of efficacy of ICD or CRT-Ds coupled with a higher-than-usual rate of complications warrant further study to better phenotype LVAD patients with CIEDs.

Findings of our study have important implications in the longitudinal management of LVAD patients with CIEDs. A lack of long-term survival benefit seen in CRT-D patients may prompt turning off the LV lead following LVAD implant, thereby preserving battery life and limiting generator replacements in this complex patient population at an already higher risk of bleeding and infection. Additionally, when elective replacement indicators or end of life is reached, the potential morbidity associated with device replacement

needs to be considered and should involve shared decision-making with the patient and family.

Overall, our results show no significant difference in CIED-related procedural complications but do show a significantly higher rate of generator changes in the CRT-D cohort without significant additive benefit.

### Limitations

Our study is limited by its observational, nonrandomized, retrospective design. There was no prespecified management protocol for device procedures and device programming was at the discretion of the local electrophysiology care team. The definition used for pocket hematoma was different compared to other studies but represents a more practical and unbiased way of classifying complication rates. Date of systemic infections and occurrence of driveline infections was not assessed. Data on incidence of inappropriate ICD shocks were not available. Finally, adjudication of cause of death as arrhythmic or nonarrhythmic was not possible.

### Conclusion

In this large, multicenter CF-LVAD cohort, ICD- and CRT-D-related procedures were common. LVAD patients with continued CRT underwent a significantly higher number of generator changes in contemporary practice. There were no statistically significant differences in device complication rates between those with CRT and ICDs. CIED-related complications were not associated with reduced survival. Large, prospective, randomized studies are required to further evaluate the role of CRT in LVAD patients and potentially prevent unnecessary generator changes.

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### Authorship

All authors attest they meet the current ICMJE criteria for authorship.

### Patient Consent

Informed consent was waived given the retrospective study design.

### Ethics Statement

The study protocol was approved by the Institutional Review Boards at all the centers. The study adheres to the Helsinki Declaration (as revised in 2013) for human research.

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