Gain in real-world cardiac resynchronization therapy efficacy with SyncAV dynamic optimization: Heart failure hospitalizations and costs

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BACKGROUND SyncAV, a device-based cardiac resynchronization therapy (CRT) algorithm, promotes electrical optimization by dynamically adjusting atrioventricular intervals.

OBJECTIVE The purpose of this study was to evaluate the impact of SyncAV on heart failure hospitalizations (HFHs) and related costs in a real-world CRT cohort.

METHODS Patients with SyncAV-capable CRT devices followed by remote monitoring and enrolled in Medicare fee-for-service for at least 1 year preimplant and up to 2 years postimplant were studied. Patients with SyncAV OFF were 4:1 matched to those with SyncAV ON on preimplant HFH rate, demographics, comorbidities, disease etiology, and left bundle branch block. HFHs were determined from the primary diagnosis of inpatient hospitalizations, and the cost for each event was the sum of Medicare, supplemental insurance, and patient payment.

RESULTS After 4:1 propensity score matching, 3630 patients were studied (mean age 75 ± 8 years; 1386 [38%] female), including 726 (25%) patients with SyncAV ON. The pre-CRT HFH rate was 0.338 HFH events per patient-year. Overall, CRT diminished the HFH rate to 0.204 events per patient-year (P < .001). SyncAV elicited a larger reduction in HFH rate (SyncAV ON: hazard ratio [HR] 0.52; 95% confidence interval [CI] 0.41–0.66; P < .001 and SyncAV OFF: HR 0.68; 95% CI 0.59–0.77; P < .001). After 2 years, the HFH rate was lower in the SyncAV ON group than in the SyncAV OFF group (0.143 HFHs per patient-year vs 0.193 HFHs per patient-year; HR 0.70; 95% CI 0.55–0.89; P = .003) and fewer HFHs were followed by 30-day HFH readmissions (4.41% vs 7.68%; P = .003) and 30-day all-cause hospital readmissions (7.04% vs 10.01%; P = .010). The total 2-year HFH-associated costs per patient were lower with SyncAV ON (difference $1135; 90% CI $93–$2109; P = .038).

CONCLUSION This large, real-world, propensity score–matched study demonstrates that SyncAV CRT is associated with significantly reduced HFHs and associated costs, incremental to standard CRT.

KEYWORDS Cardiac resynchronization therapy; Heart failure hospitalization; Optimization; Propensity score matched; Readmissions; SyncAV

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Introduction

Cardiac resynchronization therapy (CRT) is an important treatment for patients with heart failure (HF) with electrical dyssynchrony. However, CRT benefit is not uniform and patient responses vary. Those responding favorably typically manifest suppression of HF within weeks of implantation, while others may experience recurrent HF, which is typically accompanied by poor outcomes and increased health care expenditures. Optimized programming to deliver therapy more effectively is a potential mitigating solution. A wide range of CRT optimization methods have been tested over the last 2 decades, but findings remain inconclusive, and

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none are recommended by guidelines. Most devices are left at nominal settings, and the need for an improved optimization method remains.

Paced responses to left ventricular (LV) stimulation vary among patients. This heterogeneity of electrical substrate suggests that optimization, if performed, should be individualized. This is supported by acute hemodynamic and chronic studies. The timing of the atrioventricular (AV) interval relative to intrinsic conduction is a key factor, with suboptimal AV timing being cited as a potential cause of nonresponse. Further, a dynamic platform to automatically adjust to natural variations in AV interval (eg, during activity) may maintain optimized settings and improve the “quality” of delivered CRT. A device-based algorithm to enable both these functions has been lacking until recently.

The SyncAV automatic optimization algorithm was introduced in 2016 and designed to combine AV timing optimization and a dynamic platform to deliver improved CRT. In the present study, we used a real-world cohort of patients treated with CRT with available preimplant HF hospitalization (HFH) data to examine the postimplant impact of CRT overall, and then any incremental value of SyncAV CRT, in reducing HFH frequency and associated costs.

### Methods

#### Data sources

This retrospective cohort study used 3 data sources: (1) the Abbott cardiovascular implantable electronic device patient device tracking database containing implant information and basic patient demographics (eg, age and sex), (2) the Merlin.net Patient Care Network (Abbott, Chicago, IL) remote monitoring database containing cardiovascular implantable electronic device programmed parameters, and (3) the Medicare fee-for-service (FFS) repository containing beneficiary enrollment data and all billing claims, that is, inpatient hospitalization claims filed by institutions, the outpatient file including claims related to hospital outpatient services, and the carrier file covering claims filed by noninstitutional organizations and physicians. Each file includes dates of service, diagnosis codes, and procedure codes. The Master Beneficiary Summary File is the annual summary file that contains eligibility and enrollment information for each beneficiary, demographics, and dates of birth and death.

Abbott patient device tracking database device implant records were combined with Abbott Merlin.net via device serial numbers and then linked to Medicare FFS using a combination of secondary patient identifiers. Medicare FFS data were accessed through the Centers for Medicare and Medicaid Services Virtual Research Data Center (VRDC). Analysis was performed in the VRDC. The process was approved through a data use agreement (RSCH-2018-52161) with Centers for Medicare and Medicaid Services. The methods for linking data from the manufacturer device registration database to Medicare claims files and the research protocol were granted an exemption determination, a full waiver of informed consent, and a Health Insurance Portability and Accountability Act waiver by Western Institutional Review Board.

#### Study cohort

The study included US patients implanted with CRT-pacemakers or -defibrillators (Abbott) between May 2016 and March 2019 and enrolled in Merlin.net. Patients were excluded from the study if they did not link to Medicare FFS claims, were enrolled in a Medicare Advantage Plan, had less than 1 year of Medicare FFS enrollment before the implant, or had a previous CRT implant. The Medicare FFS data were available from May 2015 through September 2019.

#### SyncAV technology

SyncAV is a dynamic timing feature incorporated into Abbott quadripolar CRT devices that promotes electrical optimization on an individual basis. It dynamically adjusts timing of AV delays on the basis of the intrinsic AV interval to create a triple fusion between LV and right ventricular pacing and intrinsic conduction. The algorithm is designed to provide a consistent reduction in QRS duration. Every 256 cycles, the AV interval is extended for 3 cycles, allowing SyncAV to measure the intrinsic AV conduction and calculate the new AV interval. This process repeats to dynamically adjust the AV interval with changing conditions and to promote fusion pacing. Patients were grouped by last SyncAV programming in the first 6 weeks after implant or first SyncAV programming if the SyncAV programming data were available only after 6 weeks (see the Online Supplement for further details).

#### Propensity score matching

To ensure baseline similarity between groups, propensity score matching was used to select patients in the SyncAV OFF group with matching baseline characteristics to those in the SyncAV ON group. The propensity score was generated via a logistic regression model that included age, sex, device type, MultiPoint Pacing (MPP) programming, comorbidities (Online Supplemental Table 1), left bundle branch block (LBBB), and baseline HFH rate. Each patient in the SyncAV ON group was matched with 4 patients in the SyncAV OFF group with the closest propensity score up to 0.1 in difference.

#### Clinical outcomes

The main clinical outcome was the cumulative rate of HFHs per patient-year. HFH (identified from Medicare inpatient claims) was defined as hospitalization with a primary diagnosis of HF on the basis of International Classification of Diseases, Ninth Revision, Clinical Modification or International Classification of Diseases, Tenth Revision, Clinical Modification codes (Online Supplemental Table 1). A unique feature of our methodology was the inclusion of preimplant HFH data in our comparative analyses.
First, we compared HFH rate before CRT implant vs after CRT implant in the cohort overall. Second, we compared these before CRT vs after CRT HFH rates separately in the SyncAV ON and OFF groups. Then, we conducted a direct comparison of HFH rates between SyncAV ON and OFF groups from implant to 2 years after implant (primary aim). HFH information was also presented as the percentage of patients with ≥1, ≥2, or ≥3 HFH events over 2 years postimplant in the SyncAV ON and OFF groups. HFH readmissions and all-cause hospital readmissions within 30 days of the previous HFH, including the initial CRT implant, were counted. Readmission event rates and the percentage of HFHs followed by readmission were compared between the 2 groups. All-cause mortality was identified via the Medicare Master Beneficiary Summary File and compared between groups.

 Patients were censored at death, heart transplant, device explant or out of service, end of enrollment in Medicare FFS, start of Medicare Advantage enrollment, or end of 2 years of follow-up time. Heart transplant was identified with International Classification of Diseases, Ninth Revision, Clinical Modification or International Classification of Diseases, Tenth Revision, Clinical Modification procedure codes (Online Supplemental Table 1) in Medicare inpatient claims. In the SyncAV OFF group, patients were also censored if the algorithm was turned on after 6 weeks postimplant.

Cost analysis
The cost for each HFH event was defined as the sum of Medicare, supplemental insurance, and patient payment extracted from Medicare inpatient and carrier claims. Cost per patient-year was calculated as the sum of cost from all patients divided by the sum of the follow-up period (in years) from all patients, stratified by the SyncAV group. Costs were compared for the first year, the second year, and overall by using nonparametric methods.

Statistical analysis
Continuous demographic variables are summarized as mean ± SD and categorical variables as count and percentage. Continuous variables were compared using the t test and categorical variables using the χ² test.

The HFH event rate preimplant was compared with that postimplant by using Cox regression with Andersen-Gill extension. The results were not adjusted for other variables since each patient served as his or her own control. A similar model with the addition of the interaction term of the SyncAV group and before/after CRT was used to test the significance of the difference in reduction between SyncAV groups.

To compare cumulative HFH event rate, HFH readmission, and all-cause readmissions within 30 days of the previous HFH up to 2 years postimplant between SyncAV groups, the Fine and Gray model was applied to model the cumulative rate of HFHs, with death and heart transplant as competing risks. The event rate was adjusted for age, sex, device type, comorbidities, baseline HFH rate, presence of LBBB, and MPP programming. The parameters were estimated with the sandwich variance estimate.

The proportional hazards assumption for the Cox regression models was assessed with the Schoenfeld residuals plot and the significance test for the independence between covariates and time.

The percentage of patients with ≥1, ≥2, or ≥3 HFH events were compared with 2-sample proportion tests, with the null hypothesis that the percentage of patients in each HFH group was similar between patients with SyncAV ON and those with SyncAV OFF. A similar test was conducted for the percentage of HFHs followed by 30-day HFH readmission and all-cause readmission in the SyncAV ON and OFF groups.

All-cause mortality was analyzed using Cox regression, with SyncAV programming, age, sex, device type, baseline HFH rate, comorbidities, presence of LBBB, and MPP programming as dependent variables.

Outliers in the cost by each patient were identified by robust regression, in which log-transformed positive cost by each patient was the dependent variable, and the independent variables were patient age, sex, device type, MPP programming, comorbidities, proportion of follow-up days to the maximum follow-up days (731 days), and baseline HFH rate. The outliers were detected when they exceeded the standardized robust residual cutoff value and not included in the subsequent analysis.

HFH cost difference between groups was analyzed using bootstrapping, in which 10,000 bootstrap sample pairs were randomly drawn from the matched groups in the propensity score–matched sample. Cost per 2 patient-years from each SyncAV group was calculated from each bootstrap sample; the P value was estimated as the percentage of iterations, with cost per 2 patient-years in the SyncAV ON group being higher than that in the SyncAV OFF group. For consistency with the 1-tail P-value estimation, 90% CI of the cost difference was estimated using the 5th and 95th percentiles of the cost per 2-patient-year difference in the 2 groups, and the result was summarized as the average cost per bootstrap sample and the 95% CI (2.5th and 97.5th percentiles of the cost per 2 patient-years) for each group.

All analyses used SAS Enterprise Guide 7.15 software (SAS Institute, Cary, NC) in VRDC.

Results
Baseline patient characteristics
The study cohort comprised 12,269 patients in the SyncAV OFF group and 737 patients in the SyncAV ON group. After 4:1 propensity score matching, there were 2904 and 726 patients in the SyncAV OFF and ON groups, respectively (Figure 1). There were significant differences in patient characteristics between groups before matching (Table 1). The baseline HFH rate was significantly higher in patients with SyncAV ON. After matching, all patient characteristics (including baseline HFH rates) became similar. The postimplant follow-up time was slightly shorter in the SyncAV ON
group than in the SyncAV OFF group (mean [1st quartile, 3rd quartile] 545 [428, 731] days vs 587 [478, 731] days).

Clinical outcomes
Unique to our analysis was characterization of preimplant HFH rate in patients. The cumulative HFH rate up to 1 year before CRT implant was 0.338 per patient-year. After intervention with CRT, this diminished significantly to 0.204 per patient-year (hazard ratio [HR] 0.64; 95% confidence interval 0.57–0.72; P < .001) (Figure 2A). The reduction was significantly greater (P = .035) in the SyncAV ON group (HR 0.52; 95% CI 0.41–0.66; P < .001) than in the SyncAV OFF group (HR 0.68; 95% CI 0.59–0.77; P < .001) (Figure 2B).

The cumulative HFH rate was compared directly between the SyncAV ON and OFF groups up to 2 years after CRT implant (Figure 3). The proportional hazards assumption was met for the SyncAV ON and OFF variable. SyncAV ON programming was associated with a significant reduction

![Figure 1](image-url) Cohort diagram of the study population. CRT = cardiac resynchronization therapy.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Patient characteristics before and after propensity score matching</th>
</tr>
</thead>
<tbody>
<tr>
<td>Characteristic</td>
<td>Before matching (n = 13,006)</td>
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<tr>
<td></td>
<td>SyncAV OFF</td>
</tr>
<tr>
<td>N</td>
<td>12,269</td>
</tr>
<tr>
<td>Age at implant (y)</td>
<td>76.8 ± 8.3</td>
</tr>
<tr>
<td>Sex: female</td>
<td>3,837 (31)</td>
</tr>
<tr>
<td>Device type (CRT-D)</td>
<td>7,596 (62)</td>
</tr>
<tr>
<td>Implant year 2016</td>
<td>3,369 (28)</td>
</tr>
<tr>
<td>Implant year 2017</td>
<td>5,084 (41)</td>
</tr>
<tr>
<td>Implant year 2018</td>
<td>3,795 (31)</td>
</tr>
<tr>
<td>Implant year 2019</td>
<td>21 (0.17)</td>
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<td>Charlson Comorbidity Index (0–29)</td>
<td>5.4 ± 2.9</td>
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<tr>
<td>HFH rate in the year before CRT implant</td>
<td>0.274 ± 0.672</td>
</tr>
<tr>
<td>Medical history</td>
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<td>Atrial fibrillation</td>
<td>8,310 (68)</td>
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<td>Hypertension</td>
<td>11,622 (95)</td>
</tr>
<tr>
<td>Renal disease</td>
<td>5,149 (42)</td>
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</tbody>
</table>

Values are presented as mean ± SD or n (%).
CRT = cardiac resynchronization therapy; CRT-D = cardiac resynchronization therapy–defibrillator; HFH = heart failure hospitalization.
in cumulative HFH rate (HR 0.70; 95% CI 0.55–0.89; \(P = .003\)). The proportion of patients with \(\geq 1\), \(\geq 2\), and \(\geq 3\) HFH events during the follow-up time was also lower when SyncAV was programmed ON (Figure 4). Additionally, the percentage of HFHs with 30-day HFH readmission and that

with all-cause hospital readmission were both significantly lower in the SyncAV ON group (HFH readmission: 4.41% vs 7.68%, \(P = .003\) and all-cause hospital readmission: 7.04% vs 10.01%, \(P = .010\)). Similarly, the cumulative rates of 30-day HFH readmission and all-cause hospital readmission were also lower when SyncAV was programmed ON (Figure 4).

**Figure 2** Effects of cardiac resynchronization therapy (CRT) on heart failure hospitalizations (HFHs): relative beneficial effects. Cumulative HFH rate in the year post-CRT compared with the year pre-CRT. A: Whole cohort. CRT reduced HFH rate dramatically. B: SyncAV OFF CRT maintains a reduction in HFH rate. SyncAV ON CRT demonstrated the strongest suppression of HFHs after treatment. The hazard ratio (HR), the corresponding 95% confidence interval, and the \(P\) value are presented on each graph. (The HR in panel A should be interpreted as average HR for the before and after CRT implant variable because of the evidence of mild violation of proportional hazards assumption for this variable).

**Figure 3** Postimplant cumulative 2-year heart failure hospitalization (HFH) rate in SyncAV ON vs SyncAV OFF. SyncAV ON exerted a stronger suppression of heart failure events. The hazard ratio (HR), the corresponding 95% confidence interval, and the \(P\) value are presented.
readmission were both significantly lower with SyncAV programmed ON 2 years after CRT implant (HFH readmission: HR 0.59; 95% CI 0.38–0.90; $P = .015$; Figure 5 and all-cause hospital readmission: HR 0.66, 95% CI 0.46–0.94; $P = .020$; Online Supplemental Figure 1). No significant difference was seen in all-cause mortality at 2 years postimplant between groups (SyncAV OFF 16.8%; SyncAV ON 18.1%; $P = .746$).

**Figure 4** Percentage of patients with ≥1, ≥2, or ≥3 heart failure hospitalization (HFH) events post–cardiac resynchronization therapy (CRT). SyncAV ON CRT reduced the proportion of patients with recurrent HFHs. The actual percentage of patients in each group is depicted at the top of each bar. $P$ values are shown for each comparison.

**Figure 5** Thirty-day heart failure hospitalization (HFH) readmission was reduced in cardiac resynchronization therapy–treated patients with SyncAV ON vs SyncAV OFF. The graph shows cumulative 30-day HFH readmission rates from implant to 2 years post-implant in the 2 groups. The hazard ratio (HR), the corresponding 95% confidence interval, and the $P$ value are presented.
Cost for HFHs

Cost data were available for all patients in the study. In the entire population, there were 608 patients with any HFH-related costs. Robust regression identified 17 of these (2.8%) as outliers owing to extremely high HFH costs, with single events ranging in payments from $100,000 to $830,000 (Online Supplemental Table 2). After excluding these outliers, 10,000 patient pairs were generated for bootstrap analysis.

The 2-year cost of HFHs per patient with SyncAV ON was $3786 (95% CI $2760–$4961) vs SyncAV OFF, which was $4921 (95% CI $4382–$5492), amounting to a 23.0% or a $1135 (90% CI $93–$2109) reduction (P = .038) (Figure 6). When considered by year, costs were lower with SyncAV ON during the first year 78% of the time and during the second year 99.7% of the time, with average savings of $326 (90% CI $450 to $1023] and $1039 (90% CI $474–$1561), respectively (Online Supplemental Figures 2 and 3).

Discussion

This large, real-world investigation of patients receiving CRT indicated that the application of SyncAV, an automatic device-based optimization algorithm to promote dynamic electrical resynchronization, was associated with a significant reduction in the rate of postimplant HFH, additive to the effect of CRT alone. Furthermore, we found that SyncAV was associated with a reduction in the number of patients with multiple HF events and with 30-day hospital readmissions after HFH. These clinical benefits were accompanied by significant cost savings to the health care system.

Past CRT optimization trials have yielded neutral results. Echocardiography-based optimization lacks reproducibility and has been largely replaced by device-based algorithms, though none have improved patient outcomes in randomized controlled trials (RCTs). Therefore, the current guidelines offer little guidance for postimplant management of CRT recipients beyond maximizing %biventricular (BiV) pacing.

However, one recent RCT indicated that patient-individualized electrical resynchronization improved outcomes measured by structural remodeling compared to nominal settings. Interestingly, electrical optimization was largely dependent on the AV interval and usually required BiV (ie, right ventricular and LV) pacing rather than LV-only pacing to deliver “triple fusion” (BiV pacing at longer AV intervals permits contribution of native right bundle branch conduction). The authors commented that a dynamic platform may have enhanced benefits, but this was unavailable in that study. In another trial, a dynamic algorithm designed to accommodate spontaneous changes in AV interval (but without electrical optimization) revealed improved delivery of timed LV pacing (independent of %BiV pacing).

Our study is unique for reporting HFHs in the year before CRT implant. This insight has been missing from past CRT studies. This event rate, acting as a control when compared to post-CRT implant events, enables a direct assessment of treatment effect. The pre-CRT HFH rate in our study cohort of 0.338 events per patient-year falls midway between rates reported for control groups in prior CRT trials for patients with New York Heart Association class III/IV HF (0.73 events per patient-year) and those with New York Heart Association class I/II HF with low comorbidity burden.

![Figure 6](average_2-year_costs_post-cardiac_resynchronization_therapy.png)

Average 2-year costs post–cardiac resynchronization therapy. SyncAV ON reduced costs. The graph shows the summary of the bootstrap analysis, with the average of 10,000 bootstrap samples and 95% confidence interval (CI) using a nonparametric percentile-based approach for each group. Δ indicates average difference in cost between groups and 90% CI, the P value corresponds to the significance of the higher cost in the SyncAV OFF group.
(0.12–0.16 events per patient-year). When compared to post-implant events on an individual basis, treatment effect was similar in magnitude to that reported in RCTs enrolling similar proportions (70%) of patients with LBBB (HR 0.67 in the SyncAV OFF group for cumulative events vs MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial With Cardiac Resynchronization Therapy): HR 0.54 for the first HF event and HR 0.62 for the second HF event in patients with class III HF). A further strength of our study is thorough matching on key parameters, including LBBB, baseline HF rate, and comorbidities, often lacking in real-world studies and which can bias results. Comorbidities, especially diabetes and renal failure, are increasing in patients with HF and are major modifiers of HFH risk, response to therapy, outcomes, and cost of HF management. The history of atrial fibrillation in our cohort was similar to that reported in recent CRT trials. Collectively, these data indicate that we tested representative patient samples and HF events in real-world practice. In this context, the incremental value of SyncAV is significant.

Clinical implications
HFHs lead to negative patient outcomes and high management costs. HF events after CRT are disappointing to patients and physicians and mark an especially high-risk group. In contemporary practice, prospectively identified CRT “nonresponders” had an 8-fold higher risk of HF events after implant than did responders. Occurrences of first and second HF events were associated with 7- and nearly 19-fold respective increases in subsequent mortality risk. This emphasizes the necessity to identify measures to prevent repetitive HF episodes. SyncAV-enabled CRT addresses this need by reducing HF events in patients with any or multiple HFHs.

Preventing avoidable hospitalizations is a US national priority and 30-day rehospitalizations generate financial penalties (Hospital Readmissions Reduction Program, CMS.gov, 2020). Recurrent HF in CRT recipients is managed largely with inpatient hospitalizations, which is the most expensive form of care. Thus, the observed 23% reduction in HFH-related expenditures with SyncAV-enabled CRT is notable. Assuming 7.8- and 4.2-year life expectancy of patients with CRT-pacemakers and CRT-defibrillators, respectively, lifetime savings amount to $4031 per CRT patient when SyncAV is enabled.

Limitations
Several traditional limitations of retrospective cohort studies were mitigated by linking to an administrative claims database, propensity score matching to include important patient baseline characteristics (eg, LBBB and comorbidities), and matching on preimplant HF event rate. However, QRS width, New York Heart Association class, and medications (which seldom change after HFH recurrence in practice) were lacking and residual differences between groups may remain. Reasons for programming SyncAV ON vs OFF were un-known (higher prematch HF rates in patients with SyncAV ON suggest application of this algorithm to higher-risk patients). The cohort of patients with SyncAV enabled was low and therefore may not be representative of the overall CRT population. The study was limited to patients on Medicare FFS insurance and excluded enrollees in private insurance or Medicare Advantage Plans. Structural remodeling changes were unavailable, but our metric of HFH is used most often in practice, has driven the primary end point of pivotal CRT trials, and is advocated to be a robust marker of clinical outcomes.

Conclusion
This large, real-world study showed that HFHs were significantly reduced after CRT implant. This effect was more pronounced in patients receiving SyncAV CRT compared to standard CRT. Furthermore, SyncAV CRT was associated with a significant reduction in the rate of 30-day readmission and overall HF-related costs. These data indicate the value of a device-based algorithm delivering dynamic electrical optimization.

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Appendix
Supplementary data
Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hrthm.2021.05.006.

References


