Incidence, Predictors, and Procedural Results of Upgrade to Resynchronization Therapy

The RAFT Upgrade Substudy

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Background—The resynchronization-defibrillation for ambulatory heart failure trial (RAFT) study demonstrated that adding cardiac resynchronization therapy (CRT) in selected patients requiring de novo implantable cardiac defibrillators (ICD) reduced mortality as compared with ICD therapy alone, despite an increase in procedure-related adverse events. Data are lacking regarding the management of patients with ICD therapy who develop an indication for CRT upgrade.

Methods and Results—Participating RAFT centers provided data regarding de novo CRT-D (CRT with ICD) implant, upgrade to CRT-D during RAFT (study upgrade), and upgrade within 6 months after presentation of study results (substudy). Substudy centers enrolled 1346 (74.9%) patients in RAFT, including 644 de novo, 80 study upgrade, and 60 substudy CRT attempts. The success rate (initial plus repeat attempts) was 95.2% for de novo versus 96.3% for study upgrade and 90.0% for substudy CRT attempts ($P=0.402$). Acute complications occurred among 26.2% of de novo versus 18.8% of study upgrade and 3.4% of substudy CRT implantation attempts ($P<0.001$). The most common complication was left ventricular lead dislodgement. The principal reasons for not yet attempting upgrade in the substudy were patient preference (31.9%), New York Heart Association Class I (17.0%), and a QRS $<150$ ms (13.1%).

Conclusions—Among a broad group of implant physicians, CRT upgrades were performed in patients with an ICD in situ with no difference in implant success rate and a reduced acute complication rate as compared with a de novo CRT implant. Decisions to upgrade were influenced by predictors of benefit in subgroup analyses of the RAFT study and other trials. (Circ Arrhythm Electrophysiol. 2015;8:152-158. DOI: 10.1161/CIRCEP.114.001997.)

Key Words: cardiac resynchronization therapy  ■ complication  ■ implantation  ■ implantable cardioverter-defibrillator

Cardiac resynchronization therapy (CRT) has become a well-established treatment for patients with severe left ventricular (LV) dysfunction who have persistent heart failure (HF) symptoms, despite optimal medical therapy. Randomized studies of CRT versus standard care have demonstrated improvements in quality of life, reductions in HF hospitalizations,1-3 and ventricular arrhythmia burden4 and a decreased risk of death.5,6 These benefits have been demonstrated in patients with New York Heart Association (NYHA) class II, class III, and ambulatory class IV functional status limitation. However, the vast majority of patients have been those with de novo CRT implants. Data are lacking regarding patients with a preexisting implantable cardioverter-defibrillator (ICD) or pacemaker, who later became eligible for CRT. Because of the added risks of repeat surgery, the risk benefit of CRT in patients requiring upgrade to CRT is less clear.6

Data on the success rate and risk of acute complications with upgrade to CRT are sparse.6,7 To date, no randomized trial of upgrading to CRT versus continued standard care has been performed. It is generally believed that upgrading to CRT carries...
WHAT IS KNOWN

- The resynchronization-defibrillation for ambulatory heart failure trial study demonstrated that adding cardiac resynchronization therapy to de novo implantable cardiac defibrillator therapy in selected patients with heart failure reduced mortality, despite an increase in procedure-related adverse events.
- Data are lacking regarding the management of patients with implantable cardiac defibrillators who develop new indications for cardiac resynchronization therapy.

WHAT THE STUDY ADDS

- The results of this study provide reassurance that cardiac resynchronization therapy upgrade has a high success rate with a reduced risk of acute complications as compared with de novo implant.
- Decisions to upgrade were influenced by predictors of benefit in subgroup analyses of the resynchronization-defibrillation for ambulatory heart failure trial study and other trials.

De Novo CRT-D Implantation

The 15 Canadian centers in this substudy enrolled 1350 (75%) of the total RAFT study patients and followed 1307 patients until completion or exit from RAFT (43 patients were transferred to nonparticipating centers). Of these, 650 patients were randomized to CRT-D (Figure 1). Baseline characteristics are seen in Table 1. The initial success rate of de novo CRT-D implantation was 91.0% (586 of 644). Of the 58 patients who had an unsuccessful initial implant, 26 were as a result of an inability to cannulate the coronary sinus, 15 were as a result of an inability to place the LV lead, 7 were as a result of coronary sinus dissection, 3 were as a result of LV dislodgement, 1 was as a result of inability to perform implant caused by a clinically unstable patient, and 6 were as a result of other reasons (Table 2). Of these 58 initially unsuccessful implants, 31 (53.4%) underwent an additional attempt and 27 (47.1%) of these patients had a successful implant on a second (n=24) or third (n=3) attempt, resulting in success rate of 95.2%. Of the 644 CRT-D implants, there were 169 (26.2%) patients with acute complications, within 30 days of device implant. These included 12 (1.9%) hemothorax and pneumothoraces, 8 (1.2%) pocket hematomas requiring intervention, 19 (3.0%) pocket infection requiring antibiotics or surgery, 56 (8.7%) lead dislodgements requiring repositioning, 8 (1.2%) coronary sinus dissections preventing LV lead placement, and 3 (0.5%) patients with HF requiring hospitalization or prolongation of a hospitalization (Table 3).

Results

De Novo CRT-D Implantation

Table

Details of the RAFT study have been described previously.3 Briefly, a total of 1798 patients with HF from ischemic or nonischemic cardiomyopathy and a wide QRS were randomized to CRT-D or ICD alone. The primary outcome was death from any cause or hospitalization for HF. Patients were followed for a mean of 40 months.

This RAFT upgrade substudy population consisted of RAFT patients randomized to ICD alone in 15 of the 24 participating RAFT centers. All patients provided written informed consent, and the study was approved by the institutional review committee at all respective substudy centers. Data were collected regarding upgrade to CRT within the 6-month period after presentation of the RAFT study results (November 14, 2010). Patients were seen as per local practice. Data obtained included the rate of upgrade to CRT, procedural details, and acute complications at 30 days, including death, HF exacerbation requiring hospitalization >24 hours, hemothorax or pneumothorax, tamponade, device-pocket hematoma requiring hospitalization >24 hours or surgical revision, device-pocket infection requiring antibiotics or extraction, lead dislodgement requiring lead revision, and coronary sinus dissection preventing the delivery of an LV lead.

Data on initial (de novo) CRT implantation success rates and complications from the main RAFT study (ie, patients initially randomized to CRT-D) at these 15 centers, patients in the trial randomized to an ICD alone who underwent upgrade during the trial (study upgrade), and substudy patients are reported. Further, data on the incidence of complications, the variables associated with a higher risk of complications, and CRT-D success rates were evaluated. The sponsor of RAFT, Medtronic Canada, provided CRT devices and LV leads free of charge to patients in RAFT who were randomized to ICD and in whom CRT-D upgrade was performed within 1 year after presentation of the study results.

Continuous variables are presented as the mean and standard deviation (SD) as well as median and inter-quartile range. Baseline characteristics were compared among the upgraded and nonupgraded patients using χ² and Fisher’s Exact analyses for categorical variables. Pair-wise comparisons of continuous variables were made using a Student’s t test. The Bonferroni correction was applied to account for multiple comparisons at baseline. Success rates and procedural complications related to CRT upgrade procedures were compared with de novo CRT implant procedures. Analyses were conducted with the use of SAS software, version 9.2 (SAS Institute). Two-sided P values <0.05 were considered statistically significant, except where adjustments were made for multiple comparisons.

Methods

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CRT Upgrade During the RAFT Study

Of the 1350 patients enrolled in RAFT at the substudy centers, 657 were randomized to ICD without CRT with a total of 651 patients undergoing ICD implant (Figure 1). A total of 80 patients in the upgrade substudy centers had an attempted upgrade from ICD to CRT-D during the main RAFT study follow-up period. The timing and proportion of upgrades over the
course of the study is displayed in Figure 2. Baseline patient characteristics of the 651 RAFT ICD patients at substudy centers are seen in Table 1. The only clinical characteristics that were significantly associated with decisions to upgrade during the RAFT study were wider QRS width and NYHA class III.

Upgrade was initially successful in 74 of 80 (92.5%) patients and successful after subsequent procedures in 77 of 80 (96.3%) patients (Table 2). Of the 3 patients who had an initial unsuccessful attempt, but went on to successful upgrade, 1 was as a result of an inability to cannulate the coronary sinus, which required epicardial LV lead implantation via a minithoracotomy, 1 was as a result of initial difficulty in cannulating the coronary sinus requiring a subsequent successful procedure, and 1 as a result of patient instability for which a CRT-D device without an LV lead was placed initially, followed by LV lead placement at a later date (3rd attempt successful). Of the 3 that were unsuccessful with no further attempt, 1 had an LV lead dislodgement at the end of the case, but did not undergo further attempt at repositioning because of the initial difficulty of lead placement and the associated long procedure time. The 2 other patients had unsuccessful upgrade attempts because of left subclavian vein occlusion. There were 15 (18.8%) patients with adverse events (within 30 days of implant; Table 3).

**CRT Upgrade After Presentation of RAFT Results**

A total of 406 patients randomized to ICD completed follow-up during RAFT without CRT upgrade (after excluding patients exited from RAFT because of death, withdrawal, loss to follow-up, or transplant, as well as all patients with CRT upgrade attempt during the study). Of these, a total of 342 patients were eligible for CRT upgrade in the substudy, after excluding deaths, loss to follow-up, and patients upgraded after RAFT but before presentation of the RAFT study results (Figure 1). Only 60 out of 342 patients (17.5%) underwent CRT upgrade attempt from November 15, 2010, to May 15, 2011. Baseline patient characteristics are seen in Table 1. The success rate of upgrade to CRT was 90.0% (54 of 60 patients). Of the 6 patients who failed upgrade, 1 was as a result of subclavian vein occlusion, 4 were as a result of an inability to cannulate the coronary sinus, and 1 was as a result of the absence of an adequate branch (Table 2). Acute complications occurred in 3.4% (2 of 60 patients) of RAFT upgrade substudy patients, which included 1 LV lead dislodgement and 1 HF exacerbation (Table 3).

**Comparison of De Novo Versus CRT Upgrade Success Rates and Complications**

When comparing de novo CRT-D implantation during RAFT with upgrade from ICD to CRT-D during RAFT and upgrade from ICD to CRT-D after presentation of the RAFT results (substudy), the overall success rates were similar (95.2% versus 96.3% versus 90.0%, respectively; P=0.402). The success rate of the initial attempt during de novo CRT-D implant during RAFT (91.0%) was similar to the success rate of the initial attempt at upgrade during RAFT (92.5%; P=0.835). Note that there were no repeat attempts in the upgrade substudy.
Acute complications within 30 days occurred in a higher proportion of de novo CRT implants at the substudy centers (26.2%) than in patients undergoing upgrade during RAFT (18.8%) and patients with upgrade attempt after presentation of RAFT study results (3.3%; P<0.001).

### Clinical Reasons for Decisions Regarding Upgrade After RAFT Results

The principle reasons for the 282 (82.5%) patients randomized to an ICD alone not undergoing upgrade to CRT in the initial 6 months largely included deferring the CRT upgrade to a later date (9.6%), deferring the upgrade to the time of battery replacement (11.0%), or awaiting re-evaluation (8.5%). Patient preference was a reason for not performing upgrade in 31.9% of cases. Physicians recommended against upgrade in 129 (37.7%) patients in whom an upgrade was not considered clinically appropriate for the main following reasons (not mutually exclusive): absence of LBBB (9.6%), permanent atrial fibrillation (5.3%), a QRS <150 ms (13.1%), NYHA class I (17%), or a more recent LVEF >35% (5.0%).

### Discussion

This analysis describes the management of RAFT patients randomized to ICD who were later screened for CRT-D upgrade. Success rates of CRT upgrades were similar to de novo implants without an increased risk of acute complications. Clinical predictors of upgrade during the main RAFT study included NYHA class III versus II and a wider QRS. Decisions to upgrade patients after presentation of RAFT results were influenced by clinical predictors of benefit derived from subgroup analyses of the RAFT study (principally NYHA class II, sinus rhythm with LBBB and QRS >150 ms). A large proportion of patients initially enrolled in RAFT were not upgraded to CRT during the 6-month substudy period. This is in part because 97 of 651 (14.9%) patients initially receiving ICD were already upgraded before presentation of study results and likely represented those patients with strongest clinical indications. Lack of upgrade of eligible patients within 6 months of study results was mostly related to scheduling of the upgrade procedure or patient preference. However, a CRT upgrade was not considered clinically appropriate in 37.7% of patients.
The data regarding upgrade from pacemaker to pacemaker plus CRT (CRT-P) or ICD to CRT-D therapy is limited to observational studies.\textsuperscript{3,6,7,10,12} The rate of CRT upgrade varies widely among studies; in a retrospective single center study, the upgrade rates from ICD to CRT-D at 1, 3, and 5 years were 0.03%, 2.4%, and 5.1%, respectively,\textsuperscript{10} and Palmisano et al the upgrade rates from ICD to CRT-D at 1, 3, and 5 years were widely among studies: in a retrospective single center study, upgrade was complicated by an occlusion of the left subclavian (17 of 18 patients). The reason for failure in this 1 patient is

\begin{table}
\centering
\caption{Reasons for Unsuccessful Upgrade}
\begin{tabular}{lccc}
\hline
 & De Novo CRT-D & Upgrade During RAFT & Upgrade After Presentation of RAFT Results \\
 & Implant in RAFT, n=644 & (1st attempt), n=80 & Results, n=60 \\
\hline
Successful initial CRT implant, n, % (95% CI) & 586, 91.0 & 74, 92.5 & 54, 90.0 \\
 & (88.8–93.0) & (84.3–96.8) & (79.5–95.7) \\
Reasons for unsuccessful upgrade & n=58\textsuperscript{*} & n=6\textsuperscript{†} & n=6\textsuperscript{‡} \\
Inability to cannulate coronary sinus & 26 (44.8) & 1 (16.7) & 4 (66.7) \\
Inability to place LV lead & 15 (25.9) & 1 (16.7) & 1 (16.7) \\
Coronary sinus dissection & 7 (12.1) & 0 & 0 \\
LV lead dislodgement & 3 (5.2) & 1 (16.7) & 0 \\
Occlusion of left subclavian vein & 0 & 2 (33.3) & 1 (16.7) \\
Clinically unstable patient & 1 (1.7) & 1 (16.7) & 0 \\
Other\textsuperscript{§} & 6 (10.3) & 0 & 0 \\
\hline
\end{tabular}
\end{table}

CI indicates confidence interval; CRT, cardiac resynchronization therapy; LV, left ventricle; and RAFT, resynchronization-defibrillation for ambulatory heart failure trial.\textsuperscript{*}Thirty-two of 58 patients underwent a second attempt of which 24 were successful with an additional 3 successful after a third attempt (total successful CRT after repeat attempts 613/644=95.2%). \textsuperscript{†}Two of 6 patients underwent a successful second attempt with an additional patient successful after a third attempt (total successful CRT after repeat attempts 77/80=96.3%). \textsuperscript{‡}No repeat attempts. \textsuperscript{§}Other reasons included exacerbation of congestive heart failure, phrenic nerve stimulation, pneumothorax, and hypotension.

The initial success rate of ICD upgrade to CRT-D in our study was 91% during RAFT and 90% in the substudy, after the presentation of the RAFT results. Although prior data are limited to small studies, the success rates in our study are similar. Duray et al, in a prospectively designed observation study, compared 61 patients undergoing de novo CRT-D implantation versus 18 patients undergoing upgrade to CRT-D, 15 of whom had an existing ICD and 3 with an existing pacemaker.\textsuperscript{13} Of the 18 who underwent upgrade, the success rate was 94% (17 of 18 patients). The reason for failure in this 1 patient is not described; however, it was noted that in 2 patients, CRT upgrade was complicated by an occlusion of the left subclavian vein but successful venous recanalization was accomplished. In another study of 56 patients (44 of whom underwent upgrade to CRT after the exclusion of 12 patients), the overall LV lead implantation success rate was 82%.\textsuperscript{14} Successful reintervention was seen in 4 patients with early LV lead dislodgement and 1 patient with phrenic nerve stimulation.

Complication rates reported in the literature are similar in upgraded as compared with de novo CRT implantations, with most complications attributable to LV lead dislodgement. The European Cardiac Resynchronization Therapy Survey noted the peri-procedural complication rate to be 9.1% and 10.8% in upgraded and de novo implanted patients, respectively, with a trend to more lead dislodgement seen in the de novo group.\textsuperscript{7} In the RAFT substudy centers, we found a 26.2% complication rate in de novo CRT-D implants, 18.8% in the patients upgraded during the RAFT study, and 3.4% in the upgrades performed during the substudy. Most of the complications

\begin{table}
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\caption{Adverse Events Associated With CRT at Substudy Centers at Time of: De Novo CRT-D Implant in RAFT, Upgrades from ICD to CRT-D During RAFT, and Upgrades From ICD to CRT-D Within 6 Months After Presentation of RAFT Results}
\begin{tabular}{lccc}
\hline
 & De Novo CRT-D & Upgrade During RAFT, n=644 & Upgrade After Presentation of RAFT Results, n=60 \\
 & Implant in RAFT, n=169 & (1st attempt), n=15, 18.8 & Results, n=2, 3.3 \\
Patients with adverse events at 30 Days, n, % (95% CI) & 169, 26.2 & (23.0, 29.8) & (11.6, 28.8) & (0.3, 12.0) \\
Adverse events at 30 days & 190 & 15 & 2 & \\
Hemo/pneumothorax & 12 (1.9) & 2 (2.5) & 0 & \\
Requiring chest tube & 7 (1.1) & 0 & & \\
Pocket hematoma (requiring intervention) & 8 (1.2) & 0 & 0 & \\
Requiring surgery & 3 (0.5) & & & \\
Requiring hosp. & 5 (0.8) & & & \\
Pocket infection (requiring intervention) & 19 (3.0) & 0 & 0 & \\
Requiring surgery & 4 (0.6) & & & \\
Requiring IV antibiotics & 2 (0.3) & & & \\
Requiring oral antibiotics & 13 (2.0) & & & \\
Tamponade & 1 (0.2) & 0 & 0 & \\
Lead dislodgement (requiring intervention) & 56 (8.7) & 4 (5.0) & 1 (1.7) & \\
Coronary sinus dissection & 8 (1.2) & 0 & 0 & \\
Congestive heart failure exacerbation (requiring longer hospitalization) & 3 (0.5) & 2 (2.5) & 1 (1.7) & \\
Other\textsuperscript{*} & 83 (12.9) & 7 (8.8) & 0 & \\
\hline
\end{tabular}
\end{table}

\textsuperscript{*}Other relatively minor complications included pocket hematoma not requiring hospitalization or surgical intervention, superficial pocket infection not requiring antibiotics, pericardial effusion without tamponade and not requiring drainage, minor lead dislodgement requiring observation or generator programming only, diaphragmatic stimulation not requiring lead repositioning, increased pacing thresholds not requiring lead repositioning, and T wave oversensing not requiring lead repositioning.
observed were attributable to lead dislodgement (8.7%, 5.0%, and 1.7%, respectively). Potential explanations for a lower risk of LV lead–related complications in the upgrade patients include procedures performed more recently in centers where CRT volumes have increased considerably from start of RAFT study, as well as advances in lead delivery systems and operator experience.

Limitations

This substudy reported extended follow-up data collected by each substudy center at routine patient visits and chart review as required. The timing of follow-up after presentation of the main RAFT study results was left to the investigator’s discretion. The method of collection of complications data differed for upgrade procedures, which may partly explain the higher rate in de novo procedures, particularly for minor complications. Our substudy extended out to 6 months after presentation of the RAFT study results to determine the initial effect of the findings on patient management. A longer follow-up would likely have resulted in an increased uptake rate of upgrade to CRT-D. Long-term data on complication rates (including risk of infection) beyond 30 days was not captured by the study. Given that upgrades during and after RAFT occurred in a nonrandomized fashion, it was not possible to compare clinical outcomes.

Conclusions

In patients with ICDs who develop indications for CRT, our study provides reassurance that CRT upgrade has a high success rate with a reduced risk of acute complications. This study demonstrates that the procedural outcome for patients undergoing upgrade compares favorably with those undergoing de novo implant in whom the benefit of CRT implantation has already been confirmed in randomized studies and further suggests that upgrade procedures should receive more support in future guidelines.

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