Cardiac Resynchronization Therapy
US Trends and Disparities in Utilization and Outcomes

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Background—The use of cardiac resynchronization therapy (CRT) has increased significantly since its initial approval in 2001 for use in patients with advanced heart failure. However, trends in utilization of CRT have not been systematically characterized.

Methods and Results—We used the Nationwide Inpatient Sample database to identify all patients with CRT implantation during 2002 to 2010. The overall trends in CRT device implantation, patient characteristics, and outcomes were examined in detail and compared among demographic subgroups. During 2002 to 2010, a total of 374,202 CRT procedures were recorded. Significant and persistent gender and racial disparities favoring men (71.4%) and white (79.6%), respectively, were noted in all years. The highest number of CRT devices were implanted in the 65- to 84-year age group (64.6%), with significant increase in number of CRT implants in older patients ≥85 years over the years (P=0.02). The CRT-associated in-hospital mortality improved from 1.08% in 2003 to 0.70% in 2010 (P=0.03). The correlates of higher mortality included males (0.93% versus 0.71% in females; P=0.04) and older age (age ≥85 years had 1.5% mortality versus 0.8% for age <85 year; P<0.001). The mean hospital length of stay for CRT decreased, while mean CRT-associated hospital charges increased progressively over the years. Factors associated with higher charges were gender (males>females), older age, and greater comorbidities.

Conclusions—CRT implantation is a relatively safe procedure that has become safer in higher risk patients. However, significant disparities in CRT utilization exist in certain demographic subgroups, and these disparities have persisted across the years. (Circ Arrhythm Electrophysiol. 2016;9:e003108. DOI: 10.1161/CIRCEP.115.003108.)

Key Words: cardiac resynchronization therapy ■ disparities ■ outcome ■ trends ■ utilization

According to the 2013 update on heart disease statistics from American Heart Association, an estimated 5.1 million Americans ≥20 years of age have a diagnosis of heart failure.1 In the year 2009, heart failure was noted to be the primary cause of death in >56,000 people and contributed to death of >274,000 people.1 It is one of the most common causes of hospitalization in patients ≥65 years of age,2 and as the US population grows older, heart failure prevalence is projected to increase significantly in the near future.1

In about one third of heart failure patients, conduction delays cause dyssynchronous left ventricular (LV) contractions, which leads to reduction in LV performance, adverse cardiac remodeling, and also increased mortality.3–5 The prevalence of LV dyssynchrony in heart failure has been shown to increase with reduced LV ejection fraction (EF) and with increased QRS width in multiple studies.6–9 Cardiac resynchronization therapy (CRT), which was first introduced for clinical use in 1996, attempts to restore ventricular synchrony in patients with dilated cardiomyopathy and a widened QRS complex to improve the mechanical efficiency of LV contraction. Multiple studies have now documented that CRT improves quality of life, exercise capacity, symptoms of heart failure,6,14,15 LVEF,14,15 morbidity, and mortality16 in patients with moderate to severe LV dysfunction and a wide QRS complex. Several studies have also shown its benefit in mild to moderate heart failure.16–20 Since US Food and Drug Administration (FDA) approval for use in advanced heart failure in the United States in 2001, the use of CRT has steadily increased.21

To our knowledge, this is the first characterization of trends in utilization of CRT in the United States. Thus, using the Nationwide Inpatient Sample (NIS) database (the largest all-payer, inpatient database in the United States), we analyzed the trends of CRT implantation in the United States between 2003 and 2010. We examined various demographic parameters of patients receiving CRT implantation and potential disparities in utilization of this increasingly common...
WHAT IS KNOWN

- Cardiac resynchronization therapy (CRT) is an important and effective treatment option for patients with advanced heart failure.
- Since its initial approval in 2001, the indications for cardiac resynchronization therapy have evolved and become more inclusive.

WHAT THE STUDY ADDS

- CRT device implantation has been established as a safe procedure with low rates of complications, and is being increasingly used in older and higher risk patients.
- Although overall utilization of CRT has increased in the USA over the years, significant disparities exist with lower use of CRT in women compared with men, and in ethnic minorities compared with Caucasians.

intervention. We also analyzed the in-hospital outcomes of CRT implantation and sought to identify the predictors.

Methods

Data Source

We used discharge data from the NIS database for the years 2002 to 2010 to identify all patients who underwent a CRT device implantation during their hospital stay. NIS is the largest all-payer inpatient database in the United States and contains a 20% stratified sample of all discharges from USA nonfederal short-term general hospitals, specialty hospitals, and public hospitals, which are stratified based on the number of beds, ownership, hospital teaching status, USA region, and state. This stratified random sampling ensures that the database is representative of the US population and accounts for 90% of all hospitalizations in the United States. Reliable national estimates can be obtained using the discharge weight assigned to each record. NIS data compares favorably with the National Hospital Discharge Survey, supporting the validity of this database.

Study Population

We initially analyzed NIS 2002 to NIS 2010 databases to identify all patients who underwent a CRT implantation during a hospitalization. CRT implantation was identified by the presence of appropriate principal procedure implantable cardioverter defibrillator (ICD)-9 codes in the individual discharge records. Patients who underwent implantation of CRT-P (biventricular pacemaker only, ICD9 code 00.50) and CRT-D (biventricular pacemaker with defibrillator, ICD9 code 00.51) devices were included in our study. We included only de novo implantation of devices and did not include generator changes, redo procedures, revisions, and such. We also did not include stand-alone ICD placements.

Variables

Demographic variables included patient age (in 5 categories: 0–17, 18–44, 45–64, 65–84, and ≥85 years), gender, and ethnicity (whites, blacks, and Others). Patient comorbidity was measured using the age-independent Deyo-Charlson Comorbidity Index. This index contains 17 comorbid conditions with differential weights. The patients were grouped into mild (Charlson score 0–1), moderate (Charlson score 2–3), and severe (Charlson score >3) comorbidity groups. The primary outcomes of our study included (1) in-hospital mortality; (2) hospital length of stay; and (3) hospital charges. We also examined the trends in major complications associated with CRT implantation: pericardial effusion, pneumothorax, and hematoma formation. We examined the trends in primary outcomes and compared the outcomes among demographic, clinical, and comorbidity subgroups.

Data Analysis

All statistical analyses were performed using SPSS 20 complex samples. Appropriate hospital and discharge level weights were applied to the NIS data to estimate the total number of hospitalizations involving CRT implantation in the United States in the years 2003 to 2010. Descriptive statistics outlined the trends of CRT implantation in specific demographic, clinical, and comorbidity categories. Outcomes were compared in different patient categories using Chi-square tests for categorical variables and Student’s t-tests or linear regression analysis for continuous variables, as appropriate. Data are presented as means±SEM.

Results

After estimating the total number of CRT implants across years between 2002 and 2010, we noted that the number CRT implants in 2002 was considerably lower than the subsequent years. CRT implantations in 2002 likely represented a specific subset comprising early adopters of this technology after its initial approval by FDA in 2001 and might not compare well with outcomes from wider use of CRTs in subsequent years. Therefore, we excluded data from 2002 from analyses of disparities and outcomes. All of the category-specific data from 2003 to 2010 are provided in Table I in the Data Supplement.

Overall CRT Implantation Trends

Between 2002 and 2010, a total of 374,202 CRT devices were implanted in the United States, with an average of 41,578 implants per year. The total number of CRT implants increased significantly between 2002 and 2006 (P value for trend 0.01 using a linear regression model) but has not shown a significant increase since 2006. The majority of devices implanted were CRT-Ds (n=321,564 over 9 years of study, constituting 86% of all CRTs). CRT-Ps constituted a minority of devices (n=52,865 over 9 years, 14% of all CRTs), and CRT-P use decreased progressively from 2002 (28.8% of all CRTs) to 2010 (15.2% of all CRTs; Figure 1).

Demographic Trends in CRT Implantation

Age

The mean age of CRT implantation was 69.94±0.13, and this did not change significantly across the different years of our study. The 65- to 84-year age group received the largest number of CRTs (64.6% of all CRTs) followed by the 45- to 64-year (25.3%) and ≥85-year (7%) age groups (Figure 2A). There has been a significant increase in the percentage of CRT’s implanted in older patients, aged ≥85 years (4.9% [n=1370] in 2003 to 8% [n=3418] in 2010; P<0.001; Figure 2B).

Gender

Male patients received the majority of CRT implantations in the United States (71.4% of all CRTs). This significant gender difference was persistent across all of the study years (Figure 3A).

Ethnicity

Whites accounted for the majority of CRTs implanted in the United States (79.6% of all CRTs), followed by blacks (9.9%).
and other racial groups combined (10.4%). This ethnic difference in CRT implantation rates was persistent across all of the study years (Figure 3D).

Disparities in CRT Utilization
To further assess whether the above disparities in the utilization of CRT therapy were simply because of the differences in the incidence of heart failure, the total numbers of admissions with a principal diagnosis of heart failure in the United States were estimated from 2003 to 2010, stratified by different gender and racial subgroups (Figure 3B and 3E). The numbers of CRT implantations in the different categories were then adjusted for heart failure admissions (Figure I in the Data Supplement) to identify any true disparity in utilization. These results identified significant disparities in CRT utilization favoring men and whites compared with women and black patients, respectively, despite adjustments for heart failure rates (Figure 3C and 3F).

Comorbidities and CRT Implantation
The highest numbers of implants were noted in the patient group with moderate comorbidity (n=178,302, 48% of all CRTs), followed by mild comorbidity group (n=147,323, 39.7%; Figure 4A). The overall number of CRT implantations in the severe comorbidity group was the lowest (n=45,872, 12.3% of all CRTs). However, in the recent years, there has been a significant increase in the percentage of CRTs implanted in this category (4.9% in 2003 to 18.5% in 2010; P<0.001; Figure 4B).

Trends in In-Hospital Outcomes of CRT Implantation
Length of Stay
The overall mean length of stay associated with CRT implantation was 5.11 days. The median length of stay for all CRT implantation was 2.00 days. Importantly, for an elective CRT procedure, the mean length of stay was 2.81 days and the...
median was 1.00 day. For a nonelective implantation, the mean length of stay was 7.58 days and median was 6.00 days. Hospital length of stay associated with CRT-D device implant was significantly higher compared with CRT-P devices (mean 5.56 days versus 5.04 days; P<0.001). The average length of stay has decreased in the recent years (5.71 days in 2003 to 5.14 days in 2010; P=0.03). The mean length of stay was higher for black patients compared with whites (6.62 days versus 5.09 days; P<0.001). The mean length of stay was higher for patients with severe comorbidities compared with groups with mild or moderate comorbidities. Importantly, the average length of stay for this group has decreased in the recent years (8.5 days in 2003 to 6.59 days in 2010; P=0.006). There was no significant difference in the average length of stay between males and females (Figure II in the Data Supplement).

Mortality

The overall in-hospital mortality rate associated with CRT implantation was 0.87%, which has decreased significantly from 2003 to 2010 (1.08% in 2003 to 0.70% in 2010; P=0.03; Figure 5). The overall mortality associated with CRT-P implantation was higher at 1.4% compared with 0.8% with CRT-D implantation (P<0.001). Mortality associated with elective CRT implantation

Figure 3. Gender and racial disparities in utilization of CRT in the United States. Top, Gender disparity by showing the absolute number of CRT devices implanted in each gender group (A); heart failure admissions in each gender group (B); and CRT implants in each gender group adjusted for heart failure admission rates (C). Bottom, Racial disparity by showing the absolute number of CRT devices implanted in each ethnic group (D); heart failure admissions in each ethnic group (E); and CRT implants in each ethnic group adjusted for heart failure admission rates (F). CRT indicates cardiac resynchronization therapy.

Figure 4. Patient comorbidities and CRT implantation. A, CRT implantation trends stratified according to comorbidity categories. Groups were based on Charlson comorbidity index score: mild (Charlson score 0–1), moderate (Charlson score 2–3), and severe (Charlson score >3). B, CRT devices implanted in patients with severe comorbidities, expressed as a percentage of total CRT implants in the United States in each year. CRT indicates cardiac resynchronization therapy.
was 0.4% compared with 1.0% with nonelective CRT implantations. The mortality was higher in men (0.93%) compared with women (0.71%), and decrease in mortality was observed in both gender categories (Figure 5B). When stratified according to different age categories, the mortality rate in age group ≥85 years was significantly higher compared with the <85-year group (1.5% versus 0.8%; *P*<0.001). The mortality rate in ≥85-year group has decreased significantly in recent years (2.22% in 2002 versus 0.9% in 2010; Figure 5A). When stratified across the comorbidity subgroups, patients with severe comorbidities experienced significantly higher overall mortality (1.5%) compared with those with moderate (0.8%) or mild (0.7%) comorbid conditions (*P*<0.001). However, mortality in all 3 comorbidity groups has decreased over these years, most notably in the severe comorbidity group (1.7% in 2003 to 0.8% in 2010; Figure 5C). Mortality across all of the racial groups also showed a declining trend; however, no statistically significant difference in mortality rates was observed among the groups (Figure 5D).

**Procedural Complications**

Pericardial effusion was noted in 0.2% of all CRT implantation procedures (0.2% in CRT-D and 0.3% in CRT-P implants; *P*<0.001). Pneumothorax was noted in 1.4% of all CRT implantation procedures (1.4% in CRT-D and 1.8% in CRT-P implants; *P*<0.001). Hematoma was noted in 3.0% of all CRT procedures (3.1% in CRT-D and 2.5% in CRT-P implants; *P*<0.001). There was no significant change in the rates of these complications across the years of study, 2003 to 2010 (Figure III in the Data Supplement).

**Hospital Charges**

The overall mean hospital charges associated with CRT implantation was $129,098 per implant. Mean charges associated with an elective CRT implantation was $117,472 compared with $141,409 with a nonelective CRT implantation. Hospital charges associated with CRT-D device implants were significantly higher than those in CRT-P devices (mean $134,953 versus $92,974; *P*<0.001). Importantly, hospital charges for CRT implantation have increased from $111,197 in 2003 to $154,297 in 2010 (*P* value for trend <0.001 using linear regression; Figure IV in the Data Supplement). This increase in charges over the years continued to be significant even after adjustment for 2010 dollars using consumer price index for medical care ($145,382 [adjusted] in 2003 to $154,297 in 2010; *P* value for trend 0.03; Figure IV in the Data Supplement). Charges associated with CRT implantation were higher in males compared with females ($130,342 versus $126,009; *P*<0.001); in ≥85-year group compared with <85-year group ($130,010 versus $117,106; *P*<0.001); and in patients with higher comorbidities (severe comorbidities: $147,030; moderate comorbidities: $130,730; mild comorbidities: $121,535; *P* value for trend <0.001).

**Discussion**

Cardiac resynchronization confers significant benefits in eligible patients with heart failure, and the scope of this therapy may even become broader in the future. The current results represent the first analysis of US trends in utilization and
outcomes of CRT, the use of which continues to evolve. The salient findings include the following: (1) the number of CRT implants increased significantly between years 2002 to 2006 and then plateaued; (2) the use of CRT was lower in patients aged ≥85 years and in those with severe comorbidities, although an upward trend in CRT use in these groups was noted; (3) significant and persistent disparities in CRT implantation was noted among gender and ethnic groups even after adjustment for heart failure admissions; (4) hospital length of stay and in-hospital mortality were higher in patients ≥85 years or with severely comorbid conditions, however, with statistically significant improvement in recent years; and (5) hospitalization charges associated with CRT implantations have increased steadily over the years even after adjustment.

CRT was first approved by the FDA in 2001, and our data spanning from 2003 to 2010 encompass a major part of US experience with clinical application of CRT. The results of our study provide national multi-year data, reflecting US healthcare utilization trends. These results are also based on multicenter data, including both community hospitals and academic centers, and are generalizable to a broad national patient population, thus providing a reference for patients and physicians to help guide practice decisions within the US healthcare system. The use of large data sets also enabled analysis of the impact of different demographic and clinical characteristics on the CRT outcomes with greater statistical power. The current findings, therefore, accurately characterize the US trends for CRT, a beneficial yet expensive procedure, and may provide useful insights toward overall usage, patient selection, and resource allocation for the future.

**CRT Implantation Trends**

The steep increase in CRT implantation between 2003 and 2006 might reflect an early catch up after the approval of CRT device in 2001 by the FDA. However, compared with other cardiac device implant rates, which have increased across all years, CRT implantation rate has plateaued after 2006. Interestingly, the number of admissions to US hospitals with a principal diagnosis of heart failure has also shown a declining trend in the recent years (Figure I in the Data Supplement). This trend may reflect a decrease in the overall incidence of heart failure, perhaps because of early and improved management of ischemia. The reduction in heart failure admissions may also be secondary to improved outpatient management of patients with cardiomyopathy. The plateau in CRT implantations between 2006 and 2010 may be because of this improvement in management strategies of cardiomyopathy, thereby decreasing the overall number of patients eligible for CRT in the recent years in the general population.

Analysis of CRT subtypes identified that a majority of implants in the United States were of the CRT-D (with a defibrillator) subtype, with CRT-P (without a defibrillator) becoming an increasingly minor subset. According to the current guidelines, ICDs are indicated in all patients with an LVEF ≤35%, and CRTs are indicated for all patients with LVEF <35% and QRS width ≥120 ms. Thus, logically all of the patients who are a candidate for cardiac resynchronization are also, by the current guidelines, a candidate for ICDs. However, patient preferences (eg, desire to not receive shocks) and factors (eg, end-stage noncardiac diseases) may still warrant implantation of CRT-P alone. Our data indicate that CRT-Ps constitute a small percentage of all CRT implants.

These results also show that CRT use has increased in older patients as well in those with severe comorbid conditions. As discussed later, these are the same groups who experience worse in-hospital outcomes associated with CRT device implants. The increase of CRT usage in these groups may reflect continued and significant improvement in device technology and also improved experience and confidence of electrophysiologists to operate on these higher risk individuals. Importantly, the outcomes associated with CRT in these subgroups have also improved significantly in recent years. This is an encouraging trend for the healthcare system of a nation with an aging population.

**Disparities in CRT Utilization**

Our results indicate that CRT suffered from utilization disparities: male patients received more CRT devices compared with females; and whites received more CRT devices compared with blacks. To adjust for the differences that may exist in heart failure disease burden and CRT eligibility across the demographic categories, we examined the number of admissions to US hospitals related to the principal diagnosis of heart failure across all years. Although this is not an adjustment for the true estimates of eligibility for CRT implants, this approach provides a reasonable surrogate for estimates of heart failure burden in different demographic groups. We found that even after adjustment for the number of heart failure admissions, the disparities in utilization of CRT device persisted. Although similar findings have previously been reported for other cardiac devices, the underlying reasons for this disparity remain unclear. Nonetheless, the current findings in the context of CRT utilization may serve to draw attention of the physicians and healthcare policy makers alike.

**Outcomes of CRT**

The average hospital length of stay associated with CRT device implantation did not change significantly during the study years. However, the mean length of stay for patients with severe comorbidities was significantly higher. We also noted that the length of stay associated with implants in patients aged ≥85 years was greater compared with patients aged <85 years. Importantly, the differences in length of stay have improved in both groups in the recent years, likely reflecting improvement in technology and operator experience.

We also noted a significant improvement in in-hospital mortality associated with CRT from 2003 to 2010. When mortality rates were stratified by comorbidities, mortality was higher in patients with severe comorbidities, albeit with a declining trend. Patients aged ≥85 years experienced higher inhospital mortality compared with younger subjects; however, mortality in this group also showed an encouraging declining trend. The observed decrease in mortality, especially in older patients and those with severe comorbid conditions, is possibly because of increasing operator experience and advances in technology over the years. The mortality associated with
CRT-P implants was higher compared with CRT-D implants in our analysis (1.4% compared with 0.8%; P<0.001). This increased mortality with CRT-P is likely because of the fact that in the real world, CRT-P recipients usually represent patients whose life expectancy is low and do not qualify for an ICD implantation. These patients also have greater comorbidities often with noncardiac life-threatening diseases, such as malignancies.

The overall rates of major complications associated with CRT implantation were noted to be relatively low (peri-cardial effusion in 0.2% and pneumothorax in 1.4%). The rates of these complications in CRT-P patients were noted to be slightly higher. The greater prevalence of comorbidities in CRT-P recipients may possibly explain these observations. The rates of hematoma formation associated with CRT implantation were noted to be around 3.0% (3.1% with CRT-D implants and 2.5% with CRT-P implants). The larger size of CRT-D devices may potentially contribute to the higher hematoma rates with these devices.

The overall hospital charges for admission associated with CRT increased for both device types across all years. Because CRT-D costs significantly higher compared with CRT-P, the increase in charges may be explained, at least in part, by the increasing use of CRT-D. However, other economic and operational factors may also contribute to the significant and progressive increase in hospital charges for CRT in recent years.

Limitations
Because HCUP-NIS is an administrative database, complete clinical data, such as details of heart failure symptoms, EF, or creatinine levels, were not available. We circumvented the lack of information on EF and QRS complex width by using total number of admissions with principal diagnosis of heart failure as a surrogate for disease burden. Although errors in ICD-9 coding and documentation are limited in this database,27 nondifferential misclassification bias cannot be completely excluded. Finally, because the NIS database is limited to single hospitalizations and does not contain information on longer-term outcomes, including out-of-hospital mortality and symptoms, conclusions regarding effectiveness of CRT implantations in heart failure patients cannot be drawn from our analysis.

Conclusions
Analysis of information from a large US population-based data set indicates that the use of CRT has plateaued after an initial increase. However, significant disparities in CRT utilization exist in certain demographic subgroups, and these disparities have persisted across years. The in-hospital mortality with CRT has decreased in high-risk patient groups in recent years. The average hospital length of stay for CRT has decreased, whereas hospital charges have increased. These data may prove useful to physicians and policy makers with regard to clinical decisions and resource allocation.

Disclosures
Dr Lakkireddy has received modest speaker’s honorarium from SJM/Boehringer Ingelheim/Janssen/Pfizer/BMS; modest consulting fees from SJM, and a modest unrestricted research grant from SentreHeart. The other authors report no conflicts.

References


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Supplemental Figure 1. US trends in hospital admissions with primary diagnosis of heart failure. Heart failure diagnosis was identified by appropriate ICD-9 codes.

Supplemental Figure 2. Hospital length of stay (LOS) associated with CRT stratified according to different patient characteristics. LOS is expressed in days. Panel A shows LOS stratified by age; Panel B shows LOS stratified by gender; Panel C shows LOS stratified by comorbidity; and Panel D shows LOS stratified by race. LOS, Length of Stay.

Supplemental Figure 3. Complications associated with CRT Implantation. The rates of pericardial effusion, pneumothorax and hematoma formation were identified using appropriate ICD-9 codes.

Supplemental Figure 4. US trends in hospital charges associated with CRT device implantation-related index hospitalization. Hospital charges in different years presented as both absolute charges and charges corrected for inflation using CPI. CPI, Consumer Price Index for medical care.
### Supplemental Table 1. CRT device implantation trends in the United States

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* Deyo-Charlson Comorbidity Index: Mild – Score 0-1; Moderate – Score 2-3; Severe – Score >3. CRT, cardiac resynchronization therapy.
Supplemental Figure 1. US trends in hospital admissions with primary diagnosis of heart failure
Supplemental Figure 2. Hospital length of stay (LOS) associated with CRT stratified according to different patient characteristics
Supplemental Figure 3. Complications associated with CRT Implantation
**Supplemental Figure 4.** US trends in hospital charges associated with CRT device implantation-related index hospitalization

* CPI – Consumer Price Index for medical care. The Charges are adjusted for 2010 dollars