Impact of institutional procedural volume on inhospital outcomes after cardiac resynchronization therapy device implantation: US national database 2003–2011

Ilhwan Yeo, MD,* Luke K. Kim, MD,† Bruce B. Lerman, MD, FHRS,† Jim W. Cheung, MD, FHRS†

*From the *Department of Medicine, Mount Sinai Hospital, New York, New York, and †Division of Cardiology, Department of Medicine, NewYork-Presbyterian/Weill Cornell Medicine College, New York, New York.*

BACKGROUND The relationship between hospital volume and outcomes for cardiac resynchronization therapy (CRT) implantations has not been well established.

OBJECTIVE The purpose of this study was to examine outcomes after CRT device implantation stratified by hospital volume using a large national inpatient database.

METHODS Using the National Inpatient Sample database, we identified all patients undergoing de novo CRT implants between 2003 and 2011. Hospitals were categorized according to tertiles of annual CRT procedural volume. Rates of inhospital adverse events including death, cardiac perforation, pneumothorax, and lead revision were examined. A multivariate logistic regression analysis was performed to compare outcomes across hospital volume categories.

RESULTS Between 2003 and 2011, 410,104 de novo CRT implantations were performed. More than half (50.9%) of hospitals performed ≤16 CRT implants/y. Overall complication rates were higher in the lower-volume centers (3.9%, 3.5%, and 3.2%; $P = .001$) when stratified by first, second, and third tertiles of CRT volume, respectively. The lowest tertile of CRT volume was independently associated with increased inhospital all-cause mortality (adjusted odds ratio [OR] 1.37; 95% confidence interval [CI] 1.10–1.70; $P = .005$), any complication (adjusted OR 1.21, 95% CI 1.07–1.37; $P = .003$), and lead revision (adjusted OR 1.27; 95% CI 1.03–1.58; $P = .03$).

CONCLUSION Lower CRT hospital volume was associated with worse outcomes, including inhospital death, overall complications, and lead revision. Establishment of standards defining minimum CRT volume thresholds to identify centers of excellence may result in improved outcomes.

KEYWORDS Hospital volume; Cardiac resynchronization therapy; Mortality; Lead revision; Complications

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Introduction

Cardiac resynchronization therapy (CRT) is an established treatment for patients with systolic congestive heart failure and electrical dyssynchrony.[1–3] Implantation of CRT devices requires the placement of a left ventricular lead via a coronary venous branch, which increases the complexity of the procedure when compared to implantation of non-CRT implantable cardioverter-defibrillators (ICDs) and pacemakers. Patients undergoing CRT implants have a much higher incidence of severe left ventricular systolic dysfunction and worse congestive heart failure functional class than do patients undergoing non-CRT device implants. Therefore, studies have identified a higher rate of acute complications after CRT procedures than after non-CRT procedures.[4,5]

An inverse relationship between hospital volume and complication rates has been shown for diverse cardiovascular procedures including coronary artery bypass surgery, carotid endarterectomy, coronary intervention, and septal myectomy for hypertrophic cardiomyopathy.[6–8] Similarly, increased rates of early complications associated with pacemaker and ICD implantations performed at low-volume hospitals and with low-volume operators have been identified in registry-based studies.[4,9,10] However, there are limited data on the impact of hospital procedural volume on outcomes after CRT implant procedures. At present, there are no established guidelines for minimum annual experience with CRT implantation for operators and institutions. Given the increased complexity of CRT procedures and the high comorbidity burden in patients undergoing CRT implantation, we hypothesized that hospital

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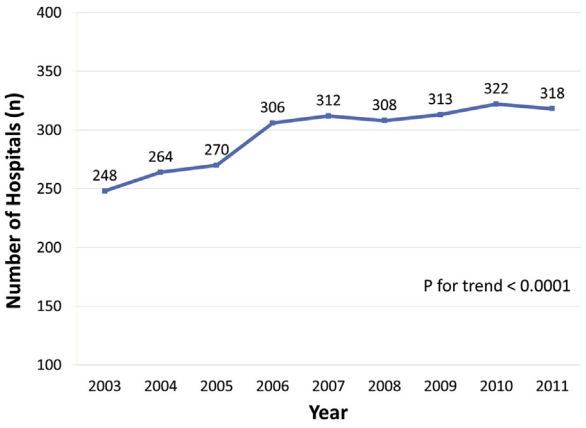

Figure 1 National trends in the number of hospitals performing cardiac resynchronization therapy procedures. An upward trend in the number of hospitals in the National Inpatient Sample database performing cardiac resynchronization therapy implants between 2003 and 2011 is shown.

procedural volume would affect not only inhospital complication rates but also mortality rates in patients undergoing CRT implantation. Therefore, we sought to examine the association between hospital procedural volume and outcomes after de novo CRT implantation procedures by using the National Inpatient Sample (NIS) database of hospital discharges between 2003 and 2011.

Methods

Data source and study population

Data were obtained from the Agency for Healthcare Research and Quality Healthcare Cost and Utilization Project NIS files from January 1, 2003, through December 31, 2011.[11] The NIS is a 20% stratified sample of all nonfederal US hospitals. Institutional review board approval and informed consent were not required for this study, as all data were collected from a de-identified administrative database. Discharge weight variables generated based on the sampling design of the NIS database was used for analysis to obtain national estimates of patients receiving CRT implants.[12] Each patient record from the NIS included all *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* procedure and diagnosis codes recorded for the patient's hospitalization. In addition, the NIS provides additional unique diagnosis and procedure codes, namely, Clinical Classification Software codes, that groups multiple *ICD-9-CM* codes into a smaller number of categories for facilitated analyses. Using a combination of *ICD-9-CM* codes and Clinical Classification Software codes, we identified the study population and clinically relevant variables.

Records from the NIS were selected for inclusion in this study by searching for *ICD-9-CM* procedure codes 00.50 for de novo CRT-pacemaker (CRT-P) procedures and 00.51 for de novo CRT-implantable cardioverter defibrillator (CRT-D) procedures. Of note, 0.1% of patients had both 00.50 and 00.51 codes and were included in the analysis. Patients younger than 18 years or those with missing mortality data were excluded from the study.

Clinical variables and end points

Patient-level and hospital-level variables were included as baseline characteristics. Hospital-level data elements were derived from the American Heart Association annual survey database. The Agency for Healthcare Research and Quality comorbidity measures based on the Elixhauser methods[12] were used to identify comorbid conditions. *Older patients* were defined as those aged 75 years and older. Significant comorbidities and cardiac diagnoses that were included in the analysis were hypertension, diabetes, chronic pulmonary disease, chronic renal failure, obesity, coronary artery disease, nonischemic cardiomyopathy, atrial fibrillation, left bundle branch block, and complete heart block using *ICD-9-CM* codes as previously described.[13] Annual hospital volume was determined on a year-to-year basis using the unique hospital identification number to calculate the total number of procedures performed by a particular institution in a given year. Hospitals were grouped into procedural volume tertiles using annual procedure volume cutoffs based on 33rd and 67th percentiles of the total number of patients in the data set. The *first tertile* was defined as centers with the lowest procedural volume. The outcome measures examined included inhospital all-cause mortality, cardiac perforation/tamponade, pneumothorax, and lead revision. Cardiac perforation was identified by *ICD-9-CM* codes 423.0 and 423.3 in addition to procedure codes 37.0 and 37.12. Pneumothorax was identified by *ICD-9-CM* codes 512.1 and 860. Lead revision was identified by *ICD-9-CM* procedure code 37.75 that occurred during the days after the day of initial CRT implantation.

Statistical analysis

Baseline characteristics of patients in each tertile were compared using the Rao-Scott χ^2 test for categorical variables, and either survey-specific linear regression or the Kruskal-Wallis nonparametric test was used for continuous variables. To assess the independent association between annual hospital volume of CRT procedures and postprocedural outcomes, separate multivariate logistic regression models were created for each outcome by forcing CRT volume into a stepwise model selection procedure with candidate comorbidity variables using entry and stay criteria of a P value of $<.25$ and .1, respectively.[14] The Cochran-Armitage trend test was used to examine temporal trends of outcomes. SAS version 9.4 (SAS Institute Inc., Cary, NC) was used for all analyses, with 2-sided P values $<.05$ indicating statistical significance.

Results

Study population

Between 2003 and 2011, 410,104 de novo CRT implantation procedures were performed in the United States in the inpatient setting and included in the study analysis. Of these, 14.4% were CRT-P implants and 85.6% were CRT-D