Complications of Catheter-Based Electrophysiology Procedures in Adults With Congenital Heart Disease: A National Analysis

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Objective: **To determine whether adult congenital heart disease patients (ACHD) undergoing catheter-based electrophysiology (EP) procedures have an increased risk for complications compared with adults without congenital heart disease.**

Design: **Retrospective cohort study of a national administrative database.**

Setting: **Nationwide Inpatient Sample, 1998 through 2011.**

Participants: **All admission records of patients who underwent a catheter-based electrophysiology procedure, categorized based on the presence or absence of ACHD.**

Interventions: **ACHD and non-ACHD cohorts were compared with respect to baseline, procedural, and outcome characteristics.**

Measurements and Main Results: **ACHD patients accounted for n = 15,133 (1.7%) of n = 873,437 EP procedure admissions and comprised a significantly increasing proportion over the study period (from 0.8% in 1998 to 2.4% in 2011, $p < 0.0001$). ACHD patients were younger than non-ACHD patients (52.5 ± 0.3 years *v* 61.9 ± 0.04 years; $p < 0.0001$), had a longer length of stay (4.6 ± 0.1 days *v* 4.4 ± 0.01 days, $p = 0.013$), higher total hospital charges ($89,485 ± $1,543 *v* $70,456 ± $175, $p < 0.0001$), and a higher rate of procedure-related complications (odds ratio 1.66, 95% confidence interval 1.49-1.85, $p < 0.0001$). On multivariate analysis, ACHD patients continued to demonstrate an increased risk of procedural complications (odds ratio 1.95, 95% confidence interval 1.75-2.19, $p < 0.0001$).**

Conclusions: **ACHD patients experienced greater morbidity after catheter-based EP procedures. This finding will be of increasing significance as ACHD patients occupy a growing segment of the population undergoing these procedures. Further investigations are warranted to determine whether this increased risk is modifiable, with the aim of improving patient safety.**

KEY WORDS: adult congenital heart disease, procedural complications, electrophysiology, ablations, catheter-based procedures

IMPROVED SURVIVAL to adulthood over the past 3 decades has fueled rapid growth of the population of adults with congenital heart disease (ACHD).[1] One of the major clinical and public health consequences of this demographic change is a significant arrhythmia burden remote from neonatal palliation or repair.[2] A growing literature supports the role of electrophysiology (EP) interventions in improving morbidity and mortality in this population.[3,4] While some investigators have raised the concern of significant complication rates in ACHD patients at the time of EP procedures,[5] prior analyses have been limited to small, single-institution series.[6–12] No comprehensive national analyses have compared complication rates in ACHD and non-ACHD subsets of EP patients.

The present study used the Nationwide Inpatient Sample to examine rates of complications among ACHD and non-ACHD patients, undergoing catheter-based electrophysiology procedures, to assess the hypothesis that ACHD patients experience greater periprocedural morbidity.

METHODS

This research was deemed exempt from institutional human subjects review because it used publicly available, deidentified data. Administrative records were extracted from discharge datasets for the years 1998 to 2011 from the Nationwide Inpatient Sample (NIS), Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality. The NIS is the largest publicly available, all-payer database for inpatient care in the United States. Each dataset year includes records on 7 to 8 million admissions from approximately 1,000 hospitals in now 44 states, which reflect a 20% stratified sample of all United States nonfederal, nonrehabilitation hospitals.[13] It contains discharge sample weights (based on the stratified sampling methodology) to facilitate nationally representative estimates based on the sampling design. While it contains limited administrative data on each inpatient encounter, its size and sampling frame facilitate the analysis of comparatively rare clinical events at a national level.

HCUP-supplied Clinical Classifications Software (CCS) for international classification of diseases, 9th revision, clinical modification (ICD-9-CM) was used to generate diagnostic, comorbidity, and procedural classification codes. Electrophysiology procedures were identified using ICD-9-CM volume 3 procedure codes 37.34 ["Excision or destruction of other lesion or tissue of heart, endovascular approach"] and 37.26 ["Catheter based invasive electrophysiologic testing"]. All adult (age ≥18 years) admission records with an EP procedure code recorded were identified.

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A composite comorbidity point score was calculated to facilitate adjustment for co-existing medical conditions based on the van Walraven modification of the Elixhauser comorbidity measure,[14] which has been shown to outperform other comorbidity schema (eg, Charlson index) in administrative databases.[15–17] The van Walraven modification provides a validated method for calculating a composite comorbidity score (maximum theoretical range = −19 to +89, with greater numbers indicating greater predicted mortality related to baseline comorbidities) that can be used for matching[18] from the individual Elixhauser comorbidity variables, which are supplied by dedicated variables created from HCUP comorbidity software.

ACHD was established based on the presence of ICD9 codes (745.x, 746.x, and 747.1-4), the coding scheme used by the authors in prior ACHD analyses.[19] With one exception, this is equivalent to the case definition strategy used in prior ACHD analyses of the NIS,[20,21] which have used CCS code 213 with exclusions for diagnoses codes 747.5 (absence of the umbilical artery), 747.6 (peripheral vascular anomalies), and 747.8 (cerebrovascular anomalies). The sole difference was that the present study also excluded code 747.9 (unspecified congenital anomaly of circulatory system), because it may not reliably identify true ACHD diagnoses.

Discharge weights were used to create national estimates for the occurrence of EP procedural admissions within the NIS-stratified sampling frame. ACHD cases within the subset of records containing an EP procedure code comprised the study cohort. Adult records with an EP procedure code and no code for ACHD comprised the control cohort.

Demographic, preoperative, and perioperative outcome variables were compared between the two cohorts. Hospitals were divided into terciles of procedural volume (all catheter-based electrophysiology procedures in adults, as defined above) for the purposes of examining the effect of volume on procedural complications, which resulted in the following levels: High volume (average >25 procedures/year), medium volume (average 5-24 procedures/year), and low volume (average <5 procedures/year). A data-driven, tercile-based definition of volume was used rather than prespecified definitions because the heterogenous nature of procedures in this population mitigates the relevance of prior literature in predicting meaningful cutoffs.

The authors elected not to include individual operator volume in the analysis because most data (79%) were missing for this variable. Primary rhythm abnormality was defined in a hierarchical fashion, as detailed in Appendix A. The primary outcome measure was a composite morbidity outcome that included all-cause in-hospital mortality, as recorded in the NIS dataset (variable DIED) and major nonfatal cardiac, vascular, respiratory, and neurologic complications, identified by ICD-9-CM diagnosis and procedure codes and classified (see Appendix B) based on methodology previously utilized in a similar, large, NIS-based analysis of procedural complications during atrial fibrillation procedures.[22] Many of these codes are based on established Agency for Health Research and Quality Patient Safety Indicators.[23]

Length of stay (variable LOS) and total hospital charges (variable TOTCHG) also were compared between groups. Hospital charges were indexed to inflation by adjusting all values to 2011 dollars using the Bureau of Labor Statistics Consumer Price Index (CPI). The CPI subindex specific to inpatient hospital services was used, with a baseline of December, 1996 taken as 100, and yearly CPI values used to generate a conversion factor to 2011 dollars.[24]

Because the stratified sampling frame of the NIS requires the use of advanced techniques (facilitated by PROC SURVEYMEANS in SAS) to estimate variance, continuous variables are presented as mean ± standard error; median [interquartile range] also is reported for variables with a skewed distribution. Continuous variables were compared using the Wilcoxon test or Kruskal-Wallis test, as appropriate. Discrete variables were compared using Fisher's exact test or Pearson's chi-squared test, as appropriate. For outcome variables, odds ratios with 95% confidence intervals also were calculated. Trends over time were examined using a Mann-Kendall test (a nonparametric test to determine the presence and direction of a trend over time[25]). A predetermined alpha of 0.05 was used as the threshold of statistical significance; for the purposes of evaluating the individual contributors (n = 8) to the composite outcome, a Bonferroni-adjusted significance level of 0.00625 was used to account for the increased possibility of

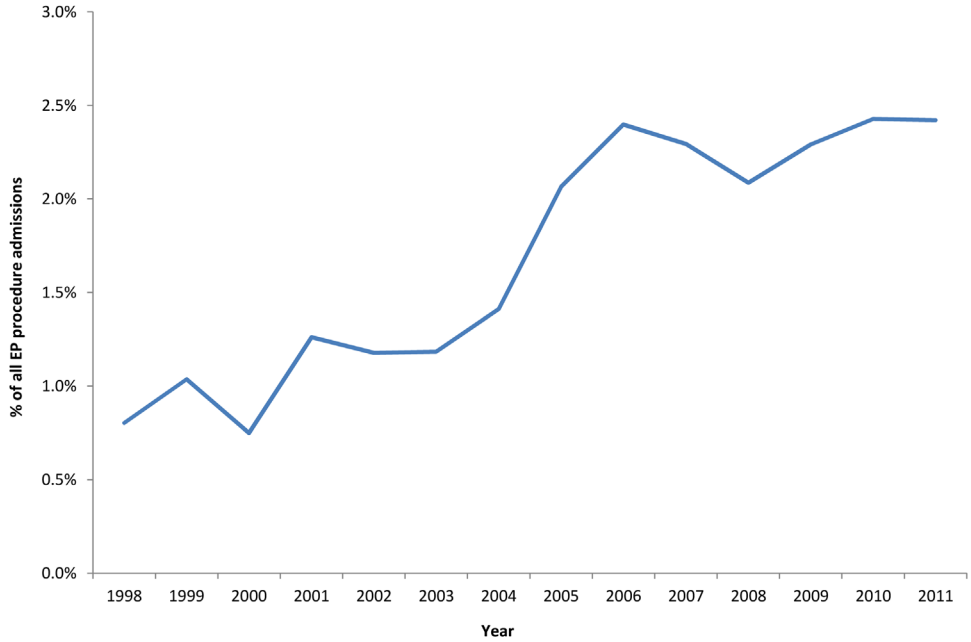

Fig 1. Admissions involving a catheter-based electrophysiology procedure in ACHD patients as a percentage of all admissions involving a catheter-based electrophysiology procedure (increasing over the study period, p for trend <0.0001).