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Pediatric ICD Utilization in the United States from 1997-2006

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Abstract

Background—Indications for implantable cardioverter-defibrillator (ICD) implantation in children have expanded, yet pediatric population based data on ICD implantation are lacking.

Objective—We characterized trends in pediatric ICD use in the United States from 1997-2006.

Methods—We examined national hospital administrative data from the 1997, 2000, 2003, and 2006 Kids' Inpatient Database (KID) for new ICD implants in patients younger than 18 years of age and characterized patients, hospitals, and hospitalization-related outcomes.

Results—The number of pediatric ICD implants per year increased three-fold (from 130 in 1997 to 396 in 2006, p= 0.003). Implants with a concomitant diagnosis of life-threatening arrhythmia decreased from 77% to 45% (p=0.001). The average age decreased from 13.6 to 12.2 years (p=0.01), and the percentage of patients younger than 5 years of age tended to increase (up to 10%, p=0.09). In 2006, the number of implants per center ranged from 1 to 24 (median= 3). Over time, the complication rate tended to decrease (from 16 to 10%, p=0.07). Complication rate was not related to a diagnosis of congenital heart disease, age, or implant volume.

Conclusions—ICD use increased dramatically in children from 1997 to 2006, although implantation declined in patients with a concomitant diagnosis of life-threatening arrhythmia (those likely to be implanted for secondary prevention). The complication rate tended to decrease overall. Each center implants relatively few ICDs per year, which may have implications for competency and training.

Keywords

Implantable Cardioverter-Defibrillator; Pediatric; Congenital Heart Disease; Administrative Data; Population Based Data

Introduction

Less than 1% of implantable cardioverter-defibrillators (ICDs) are placed in children and patients with congenital heart disease.(1) As a result, there is a dearth of prospective data on pediatric patients regarding survival benefit and outcomes following ICD placement. Previous reports have shown a high rate of appropriate shocks in pediatric patients,

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suggesting a potential benefit in children.(2,3) The low incidence of sudden cardiac death in children relative to adults further limits the ability to perform randomized clinical trials to evaluate risk stratification or primary prevention strategies.(4) The majority of existing studies on ICDs in children are retrospective, containing small numbers of patients at single institutions. The largest pediatric ICD study to date involved a registry of four centers and a total of 443 patients over 12 years.(2) Therefore, the data that provides the basis for development of indications for pediatric ICD implantation is primarily extrapolated from adult studies.

Indications for ICD implantation in adults have evolved over time, with the focus expanding from secondary prevention of sudden cardiac death to primary prevention in patients known to be at higher risk of sudden cardiac death.(5,6) Correspondingly, use of ICDs in adults has increased steadily over the last decade. Zhan et al. demonstrated that, at a population level, ICD implantation increased by 60% in adults from 1997-2004.(7) To date, no such population based data have been analyzed for the pediatric population. Recognizing that such analysis may provide insight into implantation trends, changes in underlying diagnoses leading to implantation, and pediatric-specific complications, we sought to attain population based data on ICD use in children.

In order to understand the landscape of pediatric ICD utilization in the United States, we used the Kids' Inpatient Database (KID), a national, all-payer, hospital administrative database, to examine trends in ICD use in pediatric patients from 1997 to 2006 at a population level.

Methods

The KID is the only all-payer, inpatient care database for children in the United States. Released every three years, the KID is a sample of discharges from all community, non-rehabilitation hospitals in states participating in the Healthcare Cost and Utilization Project (HCUP) of the Agency for Healthcare Research and Quality (AHRQ). After 1997, the KID includes patients aged 20 or less at admission. The KID contains information typically found in a discharge abstract, with safeguards to protect the privacy of hospitals, physicians, and patients. The data can be weighted to produce national estimates. The KID for 2006 includes 3,739 hospitals (which represent 73% of all American Hospital Association designated hospitals) from 38 states, whereas the 2003 KID includes 3,438 hospitals (71%) from 36 states. The KID for 2000 includes 2,784 hospitals (58%) from 27 states, and the 1997 KID includes 2,521 hospitals (49%) from 22 states.(8)

We queried the KID from 1997, 2000, 2003, and 2006 for discharges involving patients younger than 18 years of age with International Classification of Diseases, Ninth Revision (ICD-9) procedure codes for new ICD implantation (37.94, 00.51, and 37.95+37.96).(9) We excluded hospitalizations in which the procedure was solely a generator change. Each discharge was examined for the following information: patient characteristics (age, gender, and underlying diagnoses), hospital characteristics (type of hospital and implant volume), and hospitalization-related outcome data (mortality, length of stay, and complications).

We prospectively identified four major categories of underlying diagnosis: congenital heart disease (CHD), cardiomyopathy (CM), Long QT Syndrome (LQTS) and “Other.”

Hospital type is specified within the KID, and is based on information provided by the National Association of Children's Hospitals and Related Institutions (NACHRI).(8) We evaluated three categories of NACHRI hospitals: “not children's hospital”, “children's unit in a general hospital”, and “children's hospital” (the latter is a combination of “children's specialty hospital” and “children's general hospital”).

We described implant volume as the number of implants per center per year. Based on the clinical competency statement on training pathways for implantation of ICDs in pediatric and congenital heart patients, we deemed centers implanting fewer than ten ICDs per year low-volume centers for the purpose of this study.(10)

Length of stay in the KID is determined by calendar dates. Patients who were admitted and discharged on the same calendar day are reported as having a length of stay of zero days. Patients who were admitted on one calendar day and discharged the next day are counted as having a length of stay of one day, even if the duration of hospitalization was fewer than 24 hours.

We identified complications as a composite of the following ICD-9 codes: mechanical complications caused by ICDs (996.04, 996.72, and E878.1) and infection and inflammatory reaction due to cardiac device, implant and graft (996.61).(2,7,9,11) AHRQ's Pediatric Quality Indicators provided the basis for other complications. These indicators are a set of measures that can be used with hospital inpatient discharge data to identify iatrogenic events and potentially preventable complications in pediatric inpatients.(7) The following Pediatric Quality Indicators were felt to be the most relevant to ICD implantation and were therefore also included in the composite of complications: iatrogenic pneumothorax (512.1), accidental puncture or laceration (E870.0, E870.6, 998.2), and postoperative hemorrhage or hematoma (998.11, 998.12).(9,12)

Because of difficulty differentiating those ICDs implanted for primary versus secondary prevention using this particular database, we presumed that cases with codes for both ICD implantation and a life-threatening arrhythmia were more likely performed for secondary prevention. We therefore identified discharges with a code for both ICD implantation as well as one of the following ICD-9 diagnosis codes for life-threatening arrhythmia: paroxysmal ventricular tachycardia (427.1), ventricular fibrillation (427.41), ventricular flutter (427.42), and cardiac arrest (427.5).(9,13)

Statistical analysis

Data in the KID are stratified by geographic region, location/teaching status, bed size category, ownership, and whether the hospital is a freestanding children's hospital. Discharges are also stratified by uncomplicated in-hospital births, complicated in-hospital births, and non-newborn pediatric discharges. Discharge weights are created for each stratum in proportion to the number of known American Hospital Association discharges nationally. Using the discharge weights, individual observations (discharges) are then extrapolated to produce national estimates. (14)

The domain for analysis of this study consisted of 597 observations over the 4 sample years with an ICD diagnostic code and that met the criteria of age ≤ 17 years and length of stay ≤ 365 days.(15) The primary sampling unit is the hospital. With the exception of hospital data, all data presented are weighted national estimates, not actual observations. Data regarding the number of hospitals reflect only the hospitals within the KID hospital sample; therefore hospital data are not weighted for national estimates. Cells based on ten or fewer observations were suppressed in the tables due to the HCUP data use agreement, but we included those values in the analysis.(16)

We used survey analysis methods for stratified, two-stage cluster samples. Trends in continuous variables across years were estimated by linear regression for discharges (implants) and ANOVA for age and length of stay.(17,18) We used t-tests to compare pair-wise differences between means of continuous variables. Trends in categorical variables across years were estimated by logistic regression. In order to test for interaction between categorical variables in contingency tables, we used Rao-Scott chi-square tests.(19) Three missing values of hospital category for a single hospital identifier in 2003 were imputed from the value of the same identifier in 2006. The remaining 21 missing values of hospital category for seven other hospital identifiers and four missing values of gender in the domain were excluded from calculations.

To determine predictors of complications, univariate analysis was performed using composite data from all four years. We compared the complication rates of children's hospital types individually against the “not children's hospital” group.

Calculations were performed with SAS for Windows 9.2 (SAS Institute Inc., Cary NC).

Results

The total number of pediatric ICD implants per year increased from 130 ± 27 in 1997 to 396 ± 50 in 2006, a three-fold increase (p=0.003). Table 1 provides the number of total ICD implantations by year, as well as associated patient data. The mean age of patients decreased from 13.6 ± 0.4 to 12.2 ± 0.3 years (p=0.01), and the percentage of patients under 5 years of age receiving an ICD showed a trend toward increasing (up to 10% in 2006, p= 0.09). Figure 1 displays the proportions of implants per year in patients with each major diagnostic category. Long QT Syndrome as an underlying diagnosis did not appear in our data set until 2006, reflecting the fact that an ICD-9 code for the Long QT syndrome was first introduced in 2005.(20)

During the study period, the percentage of patients who received an ICD who also had a diagnosis of life-threatening arrhythmia decreased by 32% (p= 0.001), (Table 1, Figure 2). Restricting this analysis to those with a concomitant diagnosis of ventricular fibrillation or cardiac arrest (34% of those with a life-threatening arrhythmia) revealed a trend towards decreasing number of implants over the study period (from 25% in 1997 to 15% in 2006, p=0.06).

Table 2 reveals the characteristics of implanting hospitals during the study period. The majority of implanting centers were designated as “children's unit in a general hospital.” The percentage of implants being performed at “children's hospitals” ranged from 34-51%, with a similar percentage of implants being performed in hospitals designated as “children's unit in a general hospital” (28-46%). The percentage of implants in “not children's hospitals” tended to decrease over time (from 23% in 1997 to 8% in 2006). The median number of implants per center was low (2-3), and although the percentage of centers implanting more than 10 ICDs per year increased over the study period, the overall percentage of high-volume centers remained low at 10% in 2006. Implants by age and hospital type are depicted in Figure 3. The majority of implants in “not children's hospitals” were performed in older patients.

Hospitalization-related outcome data are displayed in Table 3. Mortality during hospitalization for ICD implantation was rare. Length of stay was not significantly changed over time (median: 10 days in 1997 to 4 days in 2006, p=0.86), though the range in length of stay was highly variable. The percentage of ICD implantations with associated complications tended to decrease during the study period (from 16 in 2000 to 10% in 2006, p= 0.07).

Results of univariate analysis for predicting complications in the pediatric population undergoing ICD implantation are shown in Table 4. The rate of complications was not related to an underlying diagnosis of congenital heart disease, age, or hospital implant volume. Compared to centers designated as "not children's hospitals," the complication rate was lower for implants performed in "children's units in a general hospital" (p=0.05).

Discussion

These results, based on weighted national estimates from a validated inpatient database, reflect trends in ICD implantation nationwide, incorporating data from centers of various sizes, hospital types, and degrees of experience with ICD implantation in children. These data provide a real-world snapshot of pediatric ICD use from 1997-2006.

Our results illustrate that the total number of ICD implants per year among children increased dramatically from 1997 to 2006. This 3-fold increase in implantation volume in our study is comparable to the increase reported by Walsh from a single center over the same time period.(4) This increase also mirrors the growth rate of ICD utilization in adult patients as the indications for adult ICD implantation have expanded over time.(7) Pediatric guidelines for ICD implantation for secondary prevention parallel the adult guidelines, and recommendations regarding pediatric ICD implantation for primary prevention are extrapolated from data from adult studies.(1,21,22) The rate of increase in pediatric ICD implantation may be the result of expanding indications in children. Likewise, ICD implantation in children may still be in the "early adoption phase", and the dramatic increase may be reflective of a change in a small denominator of implants overall.

Although the majority of pediatric implants were performed in adolescents, age at implantation decreased significantly throughout the study period, and the percentage of patients younger than 5 years of age showed a trend toward increasing as well. This may reflect improvements over time in technology and technique (e.g. epicardial patches and subcutaneous arrays), allowing for implantation in younger, smaller patients.(23)

In a registry of 443 pediatric and congenital heart disease patients with ICDs, Berul et al. reported a total of 46% of patients with an underlying diagnosis of congenital heart disease and 23% with cardiomyopathy.(2) Our data include fewer patients with congenital heart disease (22-42%) and more with cardiomyopathy (30-39%). This difference likely reflects ascertainment bias between registry data obtained from large children's hospitals with robust congenital heart disease programs and administrative data from a cross-section of hospitals nationwide.

As indications for implantation have been refined over the last decade, there has been a shift in focus towards implantation of ICDs for primary prevention in patients at high risk of sudden cardiac death. Berul et al. reported an increase in primary prevention indications in the registry population during the more recent era (2000-2004).(2) Unfortunately, the type of data available in the KID database limits our ability to determine whether implants were performed for primary or secondary prevention of sudden cardiac death. We surmised that patients with a concomitant diagnosis of life-threatening arrhythmia during hospitalization for ICD implantation were likely undergoing placement for secondary prevention. This percentage decreased during the study period, suggesting that the incidence of implantation for primary prevention may have increased over time.

Despite the overall increase in number of implants at a national level, the median number of implants per center remains low, as does the percentage of centers implanting more than 10 ICDs per year. Current recommendations for maintenance certification criteria for experienced pediatric electrophysiologists for ICD implantation suggest 10 primary implants, revisions or replacements per year.(10) Our study excluded patients older than 17 years of age and generator replacements; nevertheless, the data suggest that few centers implant an adequate volume in children to meet this criterion. Of note, the data also did not show a statistically significant association between implant volume and complication rate.

A 2008 survey of 49 pediatric electrophysiology programs reported a median implant volume of 7 ICDs per center per year (range 1-30).(10) Our lower median implant volume of 2-3 ICDs per center per year (range in 2006: 1-24) likely reflects the breadth of the KID data from a nationwide sample that includes adult hospitals as well. The same survey included eleven programs that identify as having a specialized pediatric electrophysiology training program, with a median implant volume of 12 ICDs per center per year (range 1-30).(10) Our data from 2006 are comparable, including nine hospitals with an implant volume of greater than or equal to 10 implants per year, and a maximum implant volume of 24 ICDs per year.

Device implantation is known to be more technically challenging in the pediatric population, due not only to patient size, but also to complex anatomy related to congenital heart disease. Therefore, complication rates in pediatric ICD implantation are likely to be higher than in adults. In fact, children have been shown in prior studies to have a relatively higher incidence of infections and lead malfunctions than adults with ICDs.(24) The adult complication rate for ICD implantation from 1997-2003 was reported by Zhan to be 2.3-3.4%.(7) The complication rate in our study showed a trend towards decreasing over time (16% in 2000 to 10% in 2006, p=0.07), and is comparable to the 13 % perioperative complication rate reported by Silka and the 14% acute complication rate reported by Alexander.(3,25) Complication rate in our study was not related to a diagnosis of congenital heart disease or age. The rate of complications was also not related to hospital implant volume, a reassuring result given the overall low volume of implants at each center.

Study limitations

Administrative, population based databases have the benefit of including large groups of patients and providing a cross-section of national data. For rare diseases, they can be particularly helpful in garnering larger sample sizes than would be available from single or even multi-institution studies. Yet, administrative databases are limited by a lack of clinical detail and are susceptible to coding errors.(7,26) Because of the lack of clinical information available in the KID, we were unable to ascertain the exact indication for ICD implantation (primary versus secondary prevention), a question of particular interest as ICD indications evolve over time.

Data in the KID are limited to one particular hospitalization (in our case, the hospitalization in which the ICD was implanted). As a result, complications occurring after discharge were not captured in our analysis. In children, common complications such as lead fracture would be missed.

For the same reason, analysis of this particular database did not allow for determination of whether patients received appropriate or inappropriate shocks, an important source of morbidity in pediatric patients with ICDs. Children with congenital heart disease and ICDs, in particular, have been found to receive more inappropriate shocks than adults with congenital heart disease, due to lead failure, sinus or atrial tachycardias and oversensing.(2)

Implant volume in our study refers to the number of pediatric ICD implantations in a given hospital per year. Since the KID is limited to patients younger than 18 years of age, it does not include data on the total number of ICD implants (adult and pediatric combined) per center per year. As a result, we were unable to determine whether a low volume center in our sample is actually a high volume adult electrophysiology group implanting an ICD in an occasional pediatric patient.

Finally, one of the strengths of the KID database is its ability to produce national estimates. This has been validated in comparison with both administrative and clinical databases. Compared with the National Hospital Discharge Survey, a geographically representative administrative database of 445 hospitals from all 50 states and the District of Columbia, the KID estimates of length of stay and discharge counts were accurate and precise. Estimates of mortality were generally lower in the KID.(27) Relative to clinical databases (the Congenital Heart Surgeons Society database and a Society of Thoracic Surgeons cohort), Welke showed that the KID had slightly higher mortality rates, although our data revealed very few procedural mortalities.(28) Yet pediatric ICD implantation, a highly specialized and relatively uncommon procedure, is not necessarily evenly distributed geographically. How this affects our ability to extrapolate national estimates from the KID is uncertain.

Conclusions

ICD use has increased dramatically in the pediatric population from 1997 to 2006, paralleling the increase in the adult population and reflecting expansion of indications for ICD implantation. Despite the technical challenges of a physically smaller population with potentially more complex anatomy, implantation among younger patients increased as well. Moreover, younger patients and those with more complex anatomy related to congenital heart disease did not have an increased rate of complications. Although the overall implant volume increased from 1997 to 2006, each center implants relatively few ICDs per year, which may impact competency and training requirements.

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Glossary of Abbreviations

ICD	implantable cardioverter-defibrillator
KID	Kids' Inpatient Database
HCUP	Healthcare Cost and Utilization Project
AHRQ	Agency for Healthcare Research and Quality
ICD-9	International Classification of Diseases, Ninth Revision
NACHRI	National Association of Children's Hospitals and Related Institutions
CHD	congenital heart disease
CM	cardiomyopathy
LQTS	Long QT Syndrome

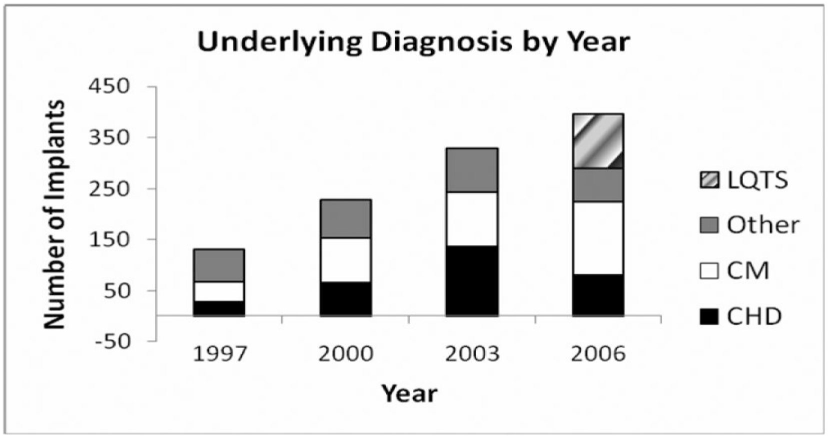

Figure 1. Implants by Underlying Diagnosis by Year

The number of implants is depicted for each of the four major categories of underlying diagnosis: congenital heart disease (CHD), cardiomyopathy (CM), Other, and Long QT syndrome (LQTS). The ICD-9 code for LQTS was first introduced in 2005; therefore implants performed in patients with a diagnosis of LQTS did not appear in the KID until 2006.

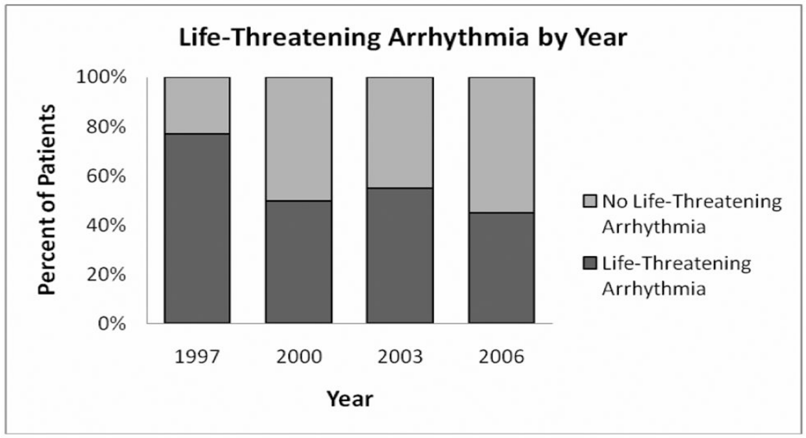

Figure 2. Life-Threatening Arrhythmia by Year

Implants with an associated diagnosis of life-threatening arrhythmia (dark gray bars) are presented as a percentage of the total implants per year.

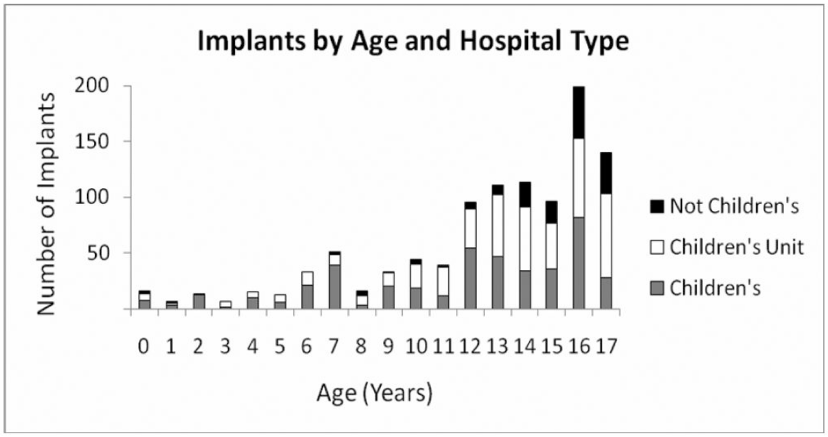

Figure 3. Implants by Age and Hospital Type

ICDs implants are displayed by age and type of hospital. ICDs were placed predominantly in teenage patients. The majority of implants in non-children's hospitals were performed in patients over age 14 years of age.

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Table 1

Patient Data

	1997	2000	2003	2006	p-value
Total Implants/Year: N ± Std Error Total Implants/4 Years: 1083 ± 156	130 ± 27	228 ± 38	329 ± 41	396 ± 50	0.003
Age in Years: Mean ± Std Error	13.6 ± 0.4	12.8 ± 0.5	12.6 ± 0.3	12.2 ± 0.3	0.01
Age ≤ 5 Years: N (%)	--*	--*	24 (7)	39 (10)	0.09
Gender - Female: %	33	39	40	40	0.37
Diagnosis: N (%)					
Congenital Heart Disease	28 (22)	65 (29)	137 (42)	81 (21)	
Cardiomyopathy	39 (30)	89 (39)	105 (32)	143 (36)	
Long QT Syndrome	--†	--†	--†	107 (27)	
Other	63 (48)	74 (32)	87 (26)	65 (16)	
Concomitant Diagnosis of Life-Threatening Arrhythmia: %	77	49	55	45	0.001

*Cells based on ten or fewer observations were suppressed due to the HCUP data use agreement.

†The ICD-9 code for Long QT Syndrome was first introduced in 2005. We suspect that, prior to 2006; patients with LQTS were coded as "abnormal electrocardiogram," which falls in the "Other" category.

Table 2

Hospital Data*

	1997	2000	2003	2006
Hospital Type: N (%)				
Not Children's Hospital	15 (39)	20 (35)	23 (28)	19 (22)
Children's Unit in General Hospital	17 (45)	22 (39)	39 (48)	48 (55)
Children's Hospital	6 (16)	15 (26)	20 (24)	21 (24)
Implants by Hospital Type: N (%)				
Not Children's Hospital	30 (23)	46 (20)	50 (15)	32 (8)
Children's Unit in General Hospital	54 (42)	65 (28)	143 (44)	180 (46)
Children's Hospital	46 (35)	116 (51)	113 (34)	166 (42)
Implants per Center: Median (Range)	2 (1-18)	2 (1-20)	2 (1-14)	3 (1-24)
Hospitals With Implant Volume: N (%)				
≥10 implants/year	2 (5)	3 (5)	5 (6)	9 (10)
5-9 implants/year	4 (11)	11 (19)	18 (21)	14 (15)
<5 implants/year	32 (84)	44 (76)	63 (73)	70 (75)

*Hospital data are based on actual observations, not weighted estimates.

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Table 3

Hospitalization-Related Outcome Data

	1997	2000	2003	2006	p-value
Survival to Hospital Discharge: %	100	100	99	99.6	
Length of Stay - Days: Median	10	3	4	4	0.86
Mean ± Standard Error	11.4 ± 1.2	6.3 ± 0.8	8 ± 1	8.1 ± 1.1	
Range	2-37	1-61	1-91	1-179	
Complication rate: %	--*	16	11	10	0.07

* Cells based on ten or fewer observations were suppressed due to the HCUP data use agreement.

Table 4

Univariate Analysis of Predictors of Complications

Predictor (Denominator)	Complications: N (%)	p-value
Congenital Heart Disease		0.12
Yes (310)	28 (9)	
No (773)	104 (13)	
Age		0.57
≤ 5 years (80)	--*	
>5 years (1,003)	124 (12)	
Hospital Implant Volume		0.7
<5 implants/year (382)	45 (12)	
5-9 implants/year (373)	51 (14)	
≥10 implants/year (329)	35 (11)	
Hospital Type		
Not Children's Hospital (157)	31 (20)	
Children's Unit in General Hospital (447)	44 (10)	0.05†
Children's Hospital (441)	52 (12)	0.12†

*Cells based on ten or fewer observations were suppressed due to the HCUP data use agreement.

†Compared to Not Children's Hospital