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Trends in permanent pacemaker implantation in the United States from 1993 to 2009: increasing complexity of patients and procedures.

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Trends in Permanent Pacemaker Implantation in the United States 1993-2009: Increasing Complexity of Patients and Procedures

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Structured Abstract

Background: The Medicare National Coverage Determination for cardiac pacemakers (PM), which emphasized single chamber pacing, has not significantly changed since 1985. We sought to define contemporary trends in PM utilization by analyzing a large national database.

Methods: We queried the Nationwide Inpatient Sample (NIS) to identify PM implants between 1993-2009 using the ICD-9-CM procedure codes for dual chamber (DDD) PM, single ventricular (VVI) PM , single atrial (AAI) PM or bi-ventricular (BiV) PM. Annual PM implantation rates and patient demographics were analyzed over time.

Results: Between 1993-2009, 2.9 million patients received PM in the U.S. Overall utilization increased by 55.6%. By 2009, DDD increased from 62% to 82% ($p<0.001$) while VVI fell from 36 to 14% ($p=0.01$). Utilization of DDD was higher in urban, nonteaching (79%) as compared to urban, teaching (76%) and rural hospitals (72%). Patients with private insurance (83%) more commonly received DDD than Medicaid (79%) or Medicare (75%) pts ($p<0.001$). Age of PM patients increased over time for both DDD and VVI ($p<0.001$). VVI were older than DDD patients**.** Charlson Co-morbidity Index (CCI) increased over time. By 2009, 45% VVI and 42% DDD had CCI>2. Hospital charges ($2011) increased 45.3% driven by the increased cost of DDD.

Conclusions: There is a steady growth in the utilization of PM in the U.S. DDD PM are increasing while VVI PM are decreasing. PM patients are getting older with more medical co-morbidities. These trends have important implications for health care policy.

Abbreviations:

PM= Permanent pacemaker

DDD= Dual chamber pacemaker

VVI= Single chamber ventricular pacemaker

AAI= Single chamber atrial pacemaker

BiV= Bi-ventricular pacemaker

NCD= National Coverage Determination

Implantation of cardiac pacemakers in the United States has increased.[1-4] This is likely due to an aging population along with improvements in the treatment of heart disease. Pacemaker technology has advanced from fixed-rate single chamber pacemakers to dual chamber pacemakers with pacing algorithms to enhance rate response and minimize ventricular pacing. Despite these advancements, the National Coverage Determination (NCD) for Cardiac Pacemakers, published by the Centers for Medicare and Medicaid Services (CMS), has not significantly changed since 1985.[5] We evaluated the trends in cardiac pacemaker implantation in the United States to evaluate the disparity between the policies outlined in the NCD, which emphasized the role of single chamber pacing, and contemporary medical practice.

Methods

The Nationwide Inpatient Sample (NIS) was queried to identify patient demographics (e.g. age, sex), health risk profile/risk (incidence and severity of co-morbidities), and health economic (in-hospital charges) data for pacemaker patients between 1993 and 2009 using the International Classification of Diseases-9th Revision-Clinical Modification (ICD-9-CM). The annual NIS is a statistically valid annual survey of ~20% of hospitalizations in the U.S. regardless of payment source. For each patient, the type of pacemaker implanted was characterized as either a dual chamber (DDD), single chamber ventricular (VVI), single chamber atrial (AAI), or bi-ventricular (BiV) pacemaker. For the present study, we identified pacemaker implants by the ICD-9 codes for DDD (37.83), VVI (37.81-82+37.71), AAI (37.81-81+37.73), or BiV (00.51). Trends were also analyzed for the subgroup of patients with sinus node dysfunction using diagnosis codes 427.8 and 427.6.

The type of device implanted (DDD vs. VVI vs. AAI vs. BiV) was analyzed along with the patient health profile using coding for such items as renal failure, heart failure, respiratory failure, and diabetes mellitus. The severity of co-morbidities was characterized by the Charlson Comorbidity index which consists of 19 different disease co-morbidity categories, weighted yield a total score.[6] The CCI has previously been validated as a predictor of mortality in patients with a pacemaker.[4]

Statistical analyses of the NIS records with the relevant surgical codes were conducted using SAS (version 9.2, Cary, North Carolina). Hospital charges over the time period of this study were adjusted to the equivalent amount in January 2011 using the consumer price index for medical services published by the Bureau of Labor Statistics. The sampling weights and the stratified sampling design of the NIS were taken into consideration when computing summary statistics and standard errors of these estimates. The number of surgeries performed for a particular demographic group is a positive integer and is assumed to follow a Poisson distribution. A regression model was used to estimate the surgery rate, and was normalized by the size of the population, and evaluation of the calendar year trend. The surgery rate was adjusted by age, sex, race, and census regions to accommodate differences in the prevalence among demographic subpopulations. The patient health profile was calculated for each year and linear regression was used to test for changes over time. The type of hospital performing pacemaker surgery was divided into one of three groups: urban non-teaching, urban teaching, and rural. The distribution of pacemaker surgery was also analyzed for the three types of hospitals as well as the type of insurance (private vs. Medicaid vs. Medicare).

RESULTS

Between 1993 and 2009, 2.9 million patients received a permanent pacemaker in the United States. During this time period, overall utilization increased by 55.6%, from 121,300 in 1993 to 188,700 in 2009. This represents 46.7 implantations/100,000 persons in 1993, which increased to 61.6 implantations/100,000 persons in 2009 [Figure 1]. DDD pacemakers increased annually from 29.1/100,000 to 50.4/100,000 ($p<0.0001$) while, at the same time, VVI pacemakers decreased from 17.2/100,000 to 8.7/100,000 ($p=0.01$). By 2009, DDD increased from 62% to 82% of all implants ($p< 0.001$) while VVI decreased from 36% to 14% ($p=0.01$). AAI remained constant at 1% while BiV pacemakers increased to 4% in 2009 from a base in 2001.

Demographic trends

The impact of gender on pacemaker utilization was analyzed. During the study period, DDD pacemakers were implanted in 77.3 % of men, while 20.1 % received VVI, 0.5 % AAI and 1.9 % BiV pacemakers. By contrast, 76.8 % of women received DDD pacemakers, while 21 % received VVI, 0.6 % AAI, and 0.6 % received BiV pacemakers. The mean age of pacemaker patients at the time of implantation increased over time. [Figure 2] In addition, patients receiving a VVI pacemaker were older than those with a DDD pacemaker ($p<0.0001$). In 1993, those receiving DDD pacemakers averaged 73.3 years which increased to 75.4 years in 2009 ($p<0.0001$). By contrast, in 1993 those receiving a VVI pacemaker were 77.5 years which increased to 80.1 in 2009 ($p<0.0001$). Those receiving a BiV pacemaker also increased in age from 71.8 in 2002 to 74.7 years in 2009 ($p<0.0001$).

Trends Based on Type of Hospital and Insurance

The influence of hospital location was analyzed by evaluating pacemaker utilization in rural hospitals, urban non-teaching hospitals, and urban teaching hospitals. Utilization of DDD pacemakers was higher in urban non-teaching hospitals (79%) as compared to urban teaching (76%), and rural hospitals (73%) which was significant ($p<0.01$). Patients with private insurance (83%) more commonly received DDD than Medicaid (79%) or Medicare (75%) patients ($p<0.001$). To further analyze the impact of insurance type, the utilization of DDD pacemakers was evaluated after adjusting for factors such as age, sex, race, calendar year, urban/rural, and hospital size. After controlling for these factors, Medicaid patients were less likely than Medicare patients (HR 0.84, C.I. 0.79-0.886, $p<0.001$) whereas private insurance patients were more likely than Medicare patients (HR 1.205, C.I. 1.165-1.247, $p<0.001$) to receive DDD pacemakers.

Trends in Patient Co-morbid Conditions

Patient co-morbidities were analyzed by measuring the average Charlson Co-morbidity Index for each calendar year. The patient level of co-morbidity increased over time for all types of pacemakers. Co-morbidities were analyzed for each type of pacemaker. In 1993, the average CCI was 0.6±0.9 for patients with a dual chamber pacemaker vs. 0.6±1 for patients with a single chamber VVI pacemaker. By contrast, in 2009 dual chamber pacemaker patients had a CCI of 1.5±1.5 and single chamber VVI patients had a CCI of 1.6±1.6. The complexity of the patient's condition was measured by determining the number of patients with a CCI of greater than 2. In 1993, a CCI of greater than was 2 present in 14.1% of VVI patients which increased to 45.1% in 2009. A similar trend was seen in the group of patients receiving a DDD pacemaker. In 1993, 13.5% of patients had a CCI greater than 2 which increased to 42.4% in 2009.

Pacemaker Implantation Trends in Patients with Sinus Node Dysfunction

In order to evaluate the impact of the diagnosis of sick sinus dysfunction on device utilization, we analyzed PM implants in this subgroup by using codes 427.81 (sick sinus syndrome) and 426.6 (sinoatrial block). (Figure 3) Utilization of DDD PM increased while VVI PM decreased. By 2009, over 80% of patients with sinus node dysfunction received a DDD PM while 1.4% of these patients received a BiV pacemaker. Therefore, the diagnosis of sinus node dysfunction did not appear to have an impact on the type of device implanted.

Economic Trends in PM Implantation

We queried the NIS to determine hospital charges associated with pacemaker insertion between the years 1993 and 2009 as an indicator of economic cost. Total hospital charges associated with pacemaker procedures increased during the study period. (Figure 4) Hospital charges in $2011 increased by 45.3% from $53,693 in 1993 to $78,015 in 2009.

DISCUSSSION

The major findings of this analysis of a large national database are: (1) there has been a growth in permanent pacemaker implantations in the United States, (2) there has been a plateau in the yearly rate of pacemaker implantation since 2001, (3) utilization of dual chamber pacemakers increased whereas single chamber VVI pacemakers decreased. DDD pacemakers now represent more than 80% of all pacemaker implants, (4) pacemaker patients are getting older and have a greater number of medical co-morbidities, (5) the utilization of dual chamber pacemakers was impacted by the type of hospital and type of health insurance, (6) these trends have financial implications as hospital charges increased.

Trends in Permanent Pacemaker Implantation

We found that although there has been an overall increase in the annual pacemaker implantation rate (number of implants/100,000 persons) since 1993, the rate has remained fairly constant since 2001. The 2005 World Survey of Cardiac Pacing confirmed this trend as new implants in the U.S. were 786 per million in 2001 and 752 per million in 2005.[2] Our previous study showed that overall pacemaker implantation peaked in 2001, while the overall utilization of cardiac implantable electronic devices (CIED) continued to increase through 2006, driven by the marked increase in ICD implantation and introduction of cardiac resynchronization therapy.[1]

Utilization of Dual Chamber Pacemakers

Dual chamber technology has been adopted as the technology of choice in the United States. This technology represents an advance over single chamber ventricular demand pacemakers. Current dual chamber pacemakers have the capability to provide bradycardia support at the lower rate limit while maintaining AV synchrony, as well as rate responsiveness at faster heart rates by tracking the intrinsic P wave. At the same time, current pacemaker algorithms minimize ventricular pacing by allowing intrinsic AV conduction.[7,8] In our study, the rate of utilization of dual chamber pacing was similar for all patients, regardless of the indication for pacing.

The shift in utilization to dual chamber technology likely reflects the improvements in lead and pacemaker design, that simplify implantation, as well as the results of clinical trials which highlighted the clinical benefits of atrial- based pacing. Five major clinical trials compared atrial- based pacing to ventricular-based pacing.[9-13] These trials are more commonly known as the Danish trial, PASE, MOST, CTOPP, and UKPACE. Results from these clinical trials consistently demonstrate that atrial- based pacing prevents pacemaker syndrome, reduces the incidence of atrial fibrillation, decreases the incidence of congestive heart failure, and improves quality of life. A meta-analysis of the results of eight pacing trials also demonstrated a modest reduction in stroke[14] while the Danish trial showed a decrease in mortality.[15] Following publication of these trials, the ACC/AHA/HRS 2008 guidelines for device based therapy of cardiac rhythm abnormalities recommended dual chamber pacing for the treatment of symptomatic bradycardia in patients who were in sinus rhythm and in whom AV synchrony and rate responsiveness were desirable.[16] This represents most patients referred for cardiac pacing. It is possible that the timing of the shift towards dual chamber technology that we observed may have been a response to these clinical trials. Our study confirms that the NCD for pacing, which emphasized single chamber pacing and was last modified in 1985, is not in line with contemporary clinical practice.

Demographics of Pacemaker Patients

Pacemaker patients are generally elderly with associated medical co-morbidities. Our study confirms that pacemakers are being implanted later in life in patients with a greater number of medical co-morbidities. These findings are consistent with the 30 year study of pacemaker recipients in Olmstead County, Minn.[4] In that study, the age adjusted Charlson index increased from 3.15 to 4.60 over the study period ($p<0.0001$). Increasing Charlson index had an adverse effect on prognosis following pacemaker implantation.

Implantation Trends: Influence of Health Insurance and Hospital Type

Pacemaker selection is likely influenced by factors other than the patient's age or associated medical conditions. Lamas and co-workers analyzed a cohort of pacemaker recipients sampled from 20% of all Medicare beneficiaries over a 2-year period.[17] They found that patients referred to large, urban, teaching hospitals were more likely to receive dual chamber pacemakers. In addition, Medicaid patients were less likely to receive a dual chamber pacemaker (OR, 0.78, CI, 0.71 to 0.86). We found that both type of insurance and implanting hospital impact pacemaker selection. Previous investigators have raised the possibility that economically disadvantaged patients may have less access to more advanced technology.[4,17] The reasons for these disparities cannot be readily explained by our study.

Financial Implications of Pacemaker Utilization

Finally, we observed that hospital charges are increasing despite a decrease in the length of stay. Improvements in technology, often associated with dual chamber pacing, come at a higher cost. It is unclear whether these costs will continue to rise and to what extent the healthcare system can withstand this financial burden.

Limitations

The present analysis utilized the NIS which is a national survey of hospital discharges. This survey thus underestimates the total pacemaker implantation rate since it does not capture outpatient procedures. In addition, the NIS suffers from the inherent limitations of administrative data, namely the absence of clinical data. Nonetheless, it is a large database representing national trends in hospitalized patients.

Conclusions

In summary, pacemaker implantation in the United States has increased over a 17 year period. Patients are older and have more medical co-morbidities. The vast majority of pacemakers are dual chamber pacemakers, regardless of the indication for pacing. There are disparities in the utilization of dual chamber pacing, which may be based, in part, on the type of hospital and insurance. The costs associated with pacemaker implantation are rising as well. These findings have important implications for future healthcare policy decisions.

FIGURE 1: Pacemaker Utilization in the United States from 1993 to 2009: The rate of dual chamber pacemaker implantation (number of implants/100,000 persons) has increased over time until 2001 when utilization reached a plateau. Biventricular pacemakers, introduced in 2002, have leveled off after their initial introduction while the utilization of single chamber atrial pacemakers remains low.

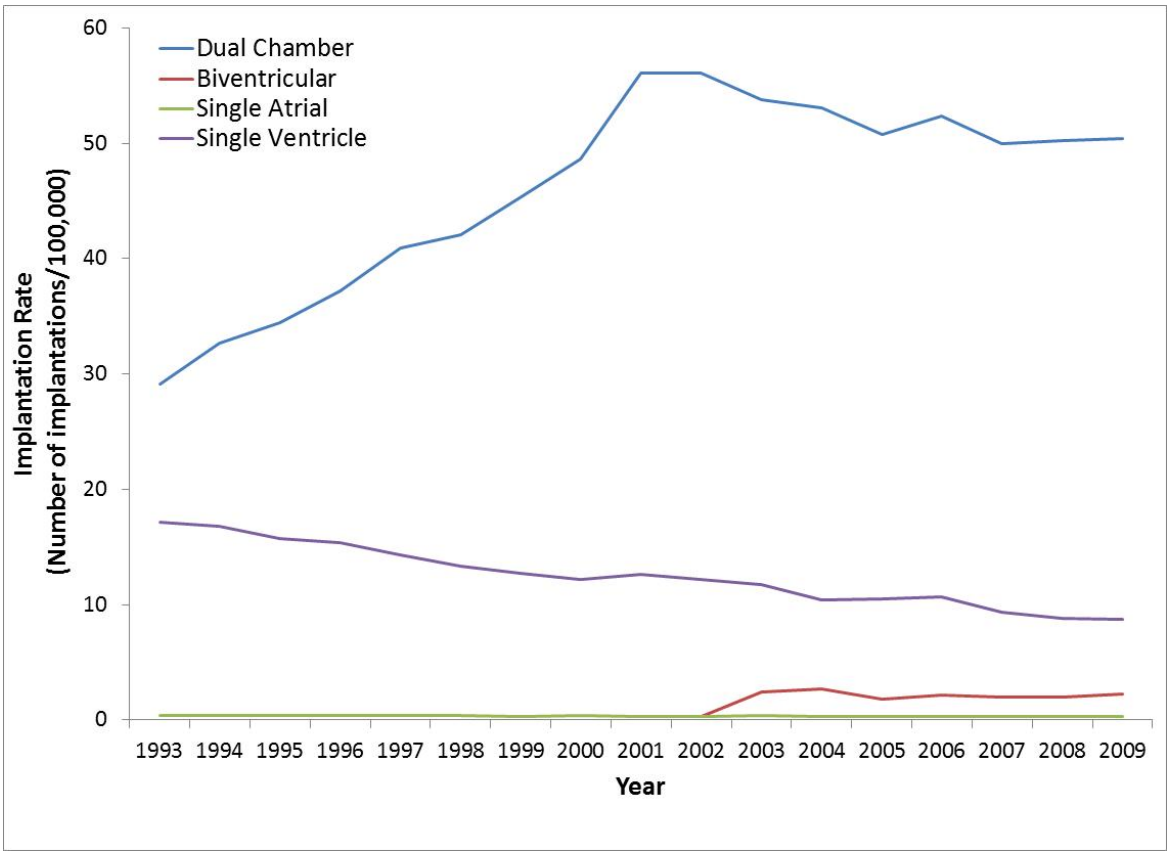


FIGURE 2: Age of pacemaker patients at implantation over time. The average age of pacemaker patients has slowly increased.

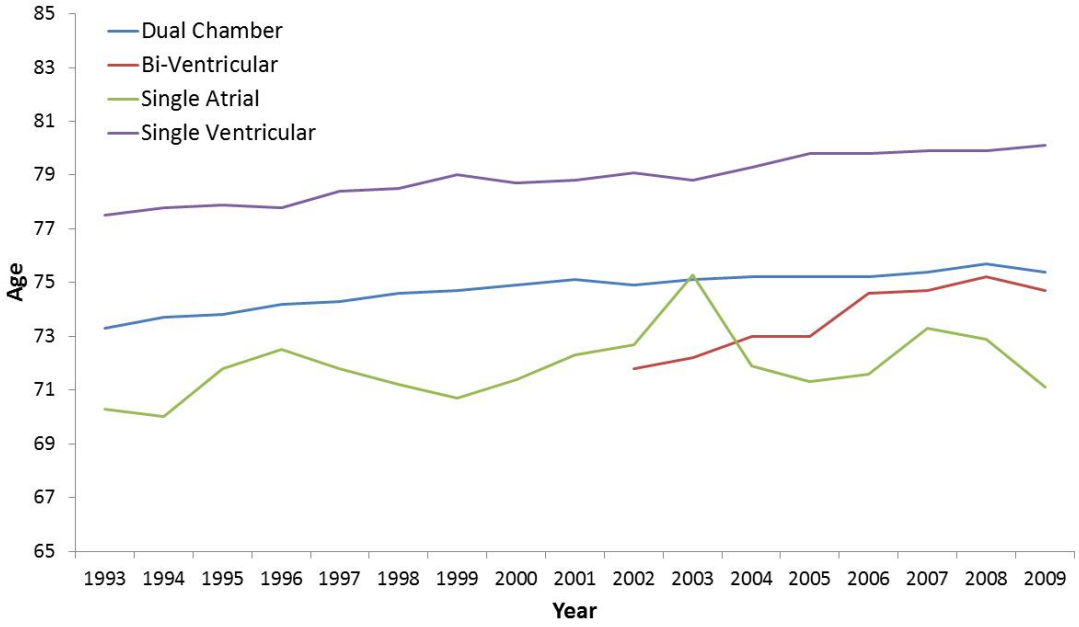


FIGURE 3: Utilization of pacemakers in patients paced for sinus node dysfunction. The distribution of pacemaker type is similar to the group as a whole.

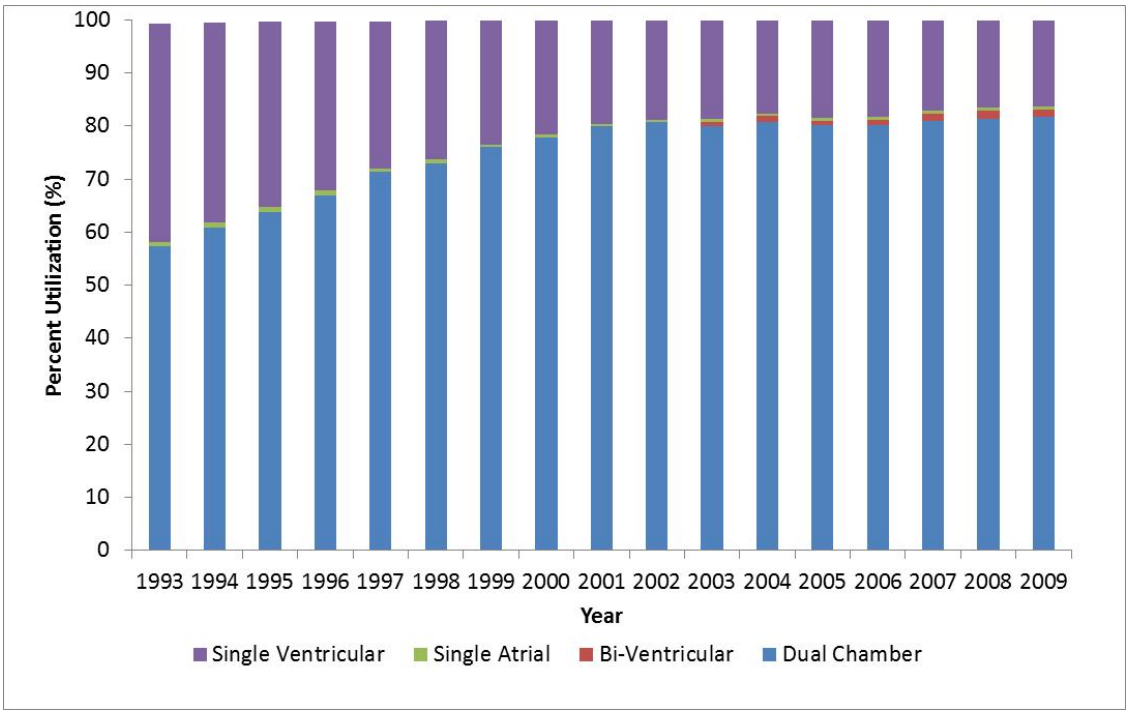
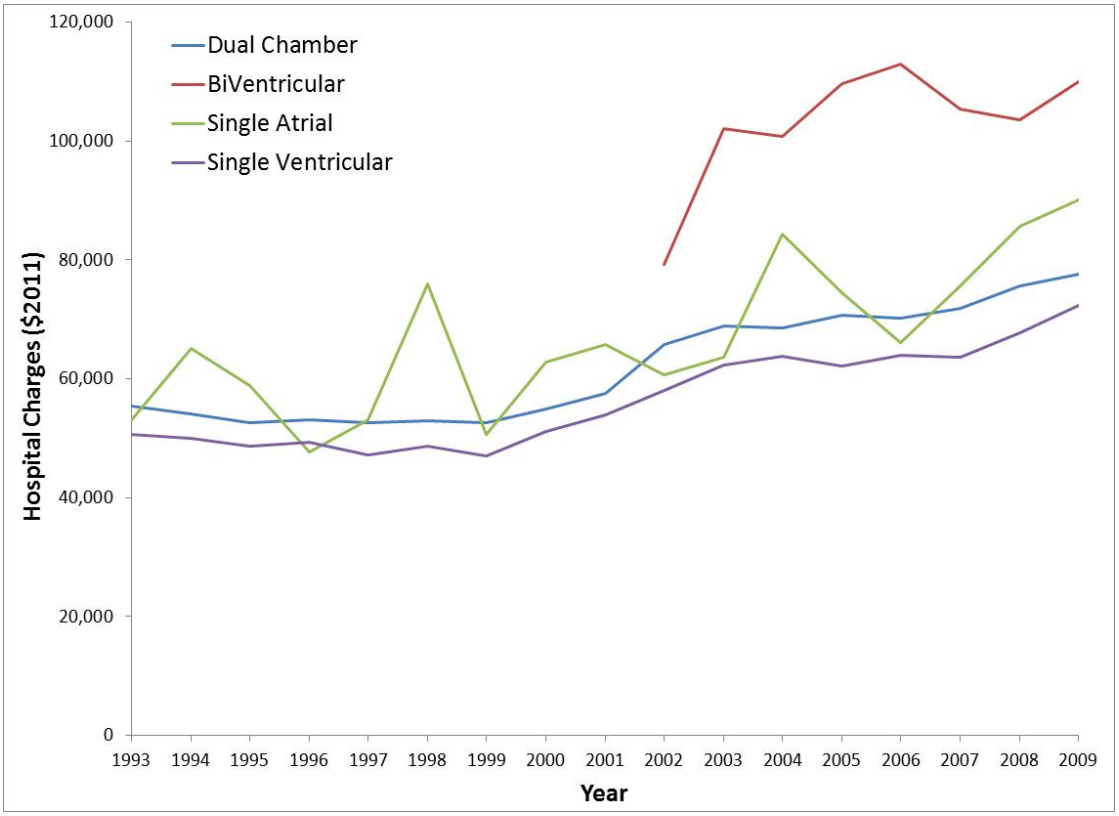


FIGURE 4: Hospital charges associated with permanent pacemaker implantation: 1993-2009 (in $2011): The hospital charges associated with pacemaker implantation have increased over time.



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