The Epidemiology of Pacemaker Implantation in the United States

BARBARA G. SILVERMAN, MD, MPH
THOMAS P. GROSS, MD, MPH
RONALD G. KACZMAREK, MD, MPH
PEGGY HAMILTON, BS
STANFORD HAMBURGER, DDS, MPH

All the authors are or have been with the Office of Surveillance and Biometrics, Center for Devices and Radiological Health, Food and Drug Administration, Rockville, MD. Dr. Silverman and Dr. Kaczmarek are Medical Officers. Dr. Gross is Acting Director, Division of Postmarket Surveillance. Ms. Hamilton was a Biomedical Statistician and Dr. Hamburger was Deputy Chief, Epidemiology Branch. Both are retired.

Tearsheet requests to Barbara G. Silverman, MD, MPH, Food and Drug Administration, Center for Devices and Radiological Health, 1350 Piccard Dr., HFZ 541, Rockville, MD 20850; tel. 301-594-0609; FAX 301-594-0050.

Synopsis

Data on pacemaker implantation were obtained from the Medical Device Implant Supplement to the 1988 National Health Interview Survey, a nationally representative, population-based survey of 47,485 households (122,310 persons). The survey yielded an estimate of 456,482 noninstitutionalized adults with pacemakers (prevalence, 2.6 per 1,000).

Prevalence rose significantly with age, from 0.4 per 1,000 among persons ages 18–64 to 26 per 1,000 among those ages 75 or older. Age-adjusted prevalence in males was 1.5 times that in females, and in whites 1.6 times that in nonwhites, although these differences were of borderline statistical significance. Prevalence did not vary significantly by region of residence, educational level, or income, but was significantly increased (more than threefold) in those reporting any activity limitation compared with those with no limitation.

Fifteen percent of pacemakers in use were replacements; about one-fifth of these had been replaced more than twice. Sixty percent of previous pacemakers had been in place for at least 5 years.

These data provide the first nationwide, population-based estimates of the epidemiology of pacemaker implantation, focusing particularly on the demographics of U.S. pacemaker recipients.

GIVEN THE WIDE VARIETY and differing etiologies of cardiac arrhythmias, their overall incidence in the general population cannot be determined (*1*). Not all arrhythmias require pacing; published guidelines address the appropriate indications for pacemaker implantation and the proper choice of device for the indication (*2*).

As the types of pacing systems available for the treatment of cardiac rhythm disorders increase in cost and complexity, so does the need for ongoing evaluation of these systems for safety, effectiveness, and appropriate use. To date, most published information regarding the demographic characteristics of patients receiving pacemakers, as well as post-implant performance (that is, safety and effectiveness) of these devices has been gathered primarily through reports to manufacturers, physician surveys, registries, and clinical case series (*3–9*). Additional information on pacemaker recipients is available from publications of Medicare data (*10*). Spontaneous reports, submitted through the Food and Drug Administration's Medical Device and Laboratory Product Problem Reporting Program, provide product performance information (*11*).

According to sources in the manufacturing industry, approximately 115,000 cardiac pacemakers were sold in the United States in 1985. This was projected to increase to 130,000 by 1990 (*12*). In 1986, permanent pacemaker implantations in aged Medicare recipients accounted for 59,588 Medicare-funded hospital stays (*10*). Cost to Medicare of cardiac pacemaker implantation and 1 year of followup has been estimated at $24,000 per patient, for an annual cost of $1.4 billion for Medicare-funded pacemaker procedures (*13*).

Although all of these sources provide useful information on pacemaker use and performance, they are limited in scope. For instance, neither reports to manufacturers, which typically are voluntary, nor hospital-based studies, which typically provide clinical data on a select group of patients, describe randomly selected, broadly based samples. As such, these sources do not provide data that are representative of the entire U.S. population.

To supplement information from other data sources, we used data from the 1988 National Health Interview Survey (NHIS) Medical Device Implant Supplement (MDIS) of the National Center for Health Statistics. These data provide the first nationwide, population-based estimates of the epidemiology of pacemaker implantation, focusing particularly on the demographics of U.S. pacemaker recipients.

'The estimate from the MDIS . . . yields an annual implant rate of 232 per million in the U.S. . . . in 1988, comparable to estimates of 238 million in Western Europe in 1986 . . . and 279 per million in Canada in 1989.'

Methods

The NHIS is a nationwide household interview survey of the civilian, noninstitutionalized U.S. population that has been conducted continuously since 1957 (*14*). Data are collected on use of health care and indicators of health status such as acute and chronic illness, injury, restriction of activity, and disabilities through interviews conducted by personnel of the U. S. Census Bureau. Participation is voluntary and respondents are assured of confidentiality.

There are two parts to the NHIS. The first questionnaire elicits basic demographic and health data from all participants and remains virtually unchanged from year to year. The second part consists of supplemental questionnaires on selected topics that differ from year to year; in 1988, the NHIS included the MDIS. The intent of the MDIS was to generate nationally representative, population-based estimates of the prevalence and use of medical device implants in the United States, as well as the morbidity associated with their use (*15*). A medical device implant was defined as a device that had been surgically implanted to replace a body part or function and could not be removed by the recipient.

Information was obtained in the survey on five categories of implants—artificial joints, fixation devices, artificial heart valves, intraocular lens implants, and pacemakers, as well as a category of "other devices," which included such devices as ear-vent tubes and silicone breast implants (*16*). These categories were chosen on the basis of two criteria—(*a*) the devices were implanted frequently enough to make national projections possible or (*b*) they had been reported to have associated adverse effects resulting in significant morbidity or mortality, or both. Each household member who reported having one or more implants at the time of the initial interview was asked a series of questions, including the number of implants, type, and location of each device, date(s) of implantation or replacement, frequency of replacement, and the age of the implant(s).

The 1988 NHIS was conducted on a sample of 47,485 households (122,310 persons), using a multistage probability design (*14*). To make the NHIS sample representative of the 1988 U.S. population and thereby provide national estimates, a post-stratification adjustment procedure was used to produce a weight for each sample person interviewed. The estimates of population prevalences and proportions presented in this report were derived using these weights. The SUDAAN (Survey Data Analysis for Multistage Sample Designs, Release 6.0) software package (*A*) was used to perform age-adjustment of the data with the 1988 U.S. population as the standard, as well as to calculate the standard errors used to produce 95 percent confidence intervals (defined as the range of values having a 95 percent probability of containing within it the true value of the parameter of interest) (*17,18*). For the purposes of this report, two point estimates were concluded to be significantly different when their 95 percent confidence intervals (CI) did not overlap.

Summary data from the Medical Device Implant Supplement, including prevalence data for pacemakers, have been previously published (*16*). This report expands upon that information by providing age-adjusted prevalence figures, comparing pacemaker recipients with nonrecipients, estimating incidence of pacemaker implantation by examining implants during the year prior to the survey, and summarizing self-reported complication data.

For the purposes of this report, "current pacemaker" refers to the pacemaker in place at the time of the interview. "Previous pacemaker" refers to the pacemaker in place prior to the current pacemaker (for those respondents reporting pacemaker replacement).

Results

Recipient characteristics. There were 244 persons in the 1988 NHIS sample who reported having a pacemaker at the time of the interview. Of these, 242 were adults (ages 18 years or older). This yielded a projected population estimate of 456,482 civilian,

Percentage distribution[1] of pacemaker recipients and prevalence[1] of pacemakers by selected demographic characteristics, U.S. adult population, 1988

Characteristic	Recipients	Nonrecipients	Pacemaker prevalence per 1,000	95 percent confidence interval
Age (years):				
18 and older	. . .	. . .	2.6	2.1, 3.0
18–64	13	84	0.4	0.2, 0.6
65–74	25	10	6.4	4.2, 8.7
75 and older	62	6	25.8	20.1, 31.5
Sex:				
Male	60	47	3.4	2.8, 3.9
Female	40	53	2.2	1.8, 2.7
Race:				
White	94	86	2.8	2.4, 3.2
Nonwhite	6	14	1.7	0.9, 2.4
Region:				
Northeast	22	21	2.4	1.6, 3.2
Midwest	30	24	3.1	2.4, 3.8
South	29	34	2.6	2.0, 3.3
West	19	21	2.7	2.0, 3.3
Education: [2]				
Less than 12 years	33	22	3.2	2.6, 3.8
12 years or more	67	77	2.5	2.1, 2.9
Income: [2]				
Less than $20,000 a year	36	35	2.8	2.3, 3.3
$20,000 a year or more	60	62	2.4	1.9, 3.0
Activity: [3]				
Limited	63	17	5.3	4.3, 6.3
Not limited	37	83	1.7	1.3, 2.0

[1] Age-adjusted, using SUDAAN™.
[2] Percentages do not add up to 100 because of incomplete responses.
[3] "Not limited" category includes unknowns.

noninstitutionalized adults with pacemakers, for an overall prevalence of 2.6 per 1,000 (95 percent CI 2.1, 3.0). During the year before the survey, an estimated 72,558 pacemakers had been implanted (77 percent of which were first implants).

As expected, pacemaker recipients were significantly older than nonrecipients; 87 percent of all adults with pacemakers were ages 65 or older, compared with 16 percent of nonrecipients (table). In addition, pacemaker prevalence increased significantly with age, peaking at 26 per 1,000 among those ages 75 and older.

Overall, pacemaker recipients were more likely to be male and white than nonrecipients (see table). Age-adjusted prevalence of pacemakers in males (3.4 per 1,000) was approximately 1.5 times that in females (2.2 per 1,000) and in whites (2.8 per 1,000) approximately 1.6 times that for nonwhites (1.7 per 1,000). These differences were of borderline statistical significance.

Pacemaker recipients did not differ significantly from nonrecipients by region of residence, education, or income (see table). However, they were significantly more likely than nonrecipients to report limited activity. Pacemaker prevalence among survey respondents reporting any limitation in activity (5.3 per 1,000) was more than three times that of those reporting no limitation in activity (1.7 per 1,000).

Pacemaker characteristics. Fifteen percent of pacemaker recipients reported that their current implants were replacements. Of all pacemaker recipients, 9.6 percent reported one replacement, 2.1 percent two replacements, and 3.6 percent more than two replacements. Of an estimated 72,558 pacemakers that had been implanted during the year before the survey, 16,609 (23 percent) were replacements and 55,949 (77 percent) were first implants.

Of those who reported receiving more than one pacemaker, 44 percent reported that the most recent replacement resulted from battery depletion. The remaining pacemaker replacements were reportedly for mechanical failures other than battery failure or unspecified "other" reasons. No pacemakers had been replaced because of infection, healing problems, pain, or irregular heart beat. The previous pacemakers had been in place prior to replacement less than 1 year in 5 percent, between 1 and 5 years in 30 percent, 5 or more years in 59 percent, and an undetermined amount of time in 6 percent.

As expected, current pacemakers had been in place somewhat less time than previous pacemakers—16

percent had been in place less than 1 year, 44 percent between 1 and 5 years, 37 percent 5 years or more, and 3 percent an undetermined amount of time. Twenty-four percent of pacemaker recipients reported at least one complication with a current pacemaker, including 18 percent who reported an "irregular heart beat," (possibly indicative of arrhythmias with diverse etiologies). Of these, 24 percent reported that this complication occurred less than 30 days after implantation, 13 percent between 30 and 90 days, 56 percent more than 90 days after implantation, and 6 percent at an unknown point after implantation. Mechanical problems such as battery depletion and lead failure were reported in 5 percent of current pacemaker recipients.

Of all current pacemakers, 45 percent were reportedly programmable. Of those implanted during the year before the survey, 64 percent were programmable. Information on programmability was not collected for previous pacemakers.

Discussion

The 1988 MDIS provides the first nationwide population-based data on the epidemiology of pacemaker implantation in the United States. These data provide a broader and more representative picture of pacemaker use in the country than has previously been available. This survey is more likely to reflect accurately the variation in sociodemographic characteristics of pacemaker recipients, as well as the diversity in underlying medical conditions and variations in physician practice patterns, than other sources of data such as manufacturers' registries and center-based clinical series. This type of survey data, however, has the following limitations:

1. Information is reported by the patient or a proxy and is not accompanied by provider data, raising the possibility of inaccuracies due to errors in recall or patient misinformation.
2. No information is collected on institutionalized persons, potentially a large group of pacemaker users (judging from the increased age and limitation of activity of pacemaker recipients).
3. The projected number of nonwhite recipients, even as determined in this large survey, is small, making detailed analysis of their characteristics impossible.

Pacemaker prevalence, as measured by the survey, is dependent not only on the incidence of pacemaker implantation, but on the survival of the pacemaker recipient (*19*). Given that females have a longer life expectancy than males (*20*), the lower prevalence of pacemakers in females compared with males suggests that they may have a lower incidence of the medical conditions necessitating pacemaker implantation. Data on comparative implantation rates as well as comparative incidence of medical conditions for which pacemakers are inserted would help to address this issue.

The decreased prevalence of pacemakers in nonwhites relative to whites, while of borderline statistical significance, raises concerns that it may indicate, among other possibilities, decreased access to care in minority groups. Analysis of Medicare claims for pacemaker procedures has indicated a similar finding (*21*). Although the number of pacemaker recipients who are nonwhite is too small to allow for income-adjustment, income is unlikely to explain the difference, since pacemaker recipients as a group had lower incomes than nonrecipients. In light of literature suggesting racial differences in the incidence and treatment of cardiovascular disease that may be due to disparities in access (*22,23*), this finding is worthy of further study.

The lack of regional differences in pacemaker prevalence does not rule out the possibility of regional variation in pacemaker use as a function of particular medical centers or individual high-volume implanting physicians. One limitation of regional comparisons using NHIS data is that the regions defined by the study were very large. Furthermore, a patient may have received the pacemaker in an area of the country different from his or her residence at the time of the survey, either because he or she had travelled to receive care or had moved since surgery.

The finding that pacemaker prevalence is higher in the segment of the population with some limitation in activity does not come as a surprise, given that the need for a pacemaker and activity limitation are both reflective of poor health. In fact, because the survey included those whose activity level was unknown under the heading of "unlimited" activity, it is possible that the survey data underestimate the association between activity limitation and the presence of a pacemaker.

It is interesting to compare the findings of this survey with existing data. The estimate from the MDIS of 55,949 first implants during the year prior to the survey yields an annual implant rate of 232 per million in the total U.S. population in 1988, comparable to estimates of 238 per million in Western Europe in 1986, between 300 and 350 per million from a population-based registry in Fyn County, Denmark, in 1989, and 279 per million in Canada in 1989 (*8,24,25*).

Furthermore, the finding that 23 percent of pacemakers implanted during the year prior to the 1988 survey were replacements correlates well with the conclusion from a survey of physicians that of the pacemakers implanted throughout the world during 1986, 20 percent were replacements for previous implants (*8*). The figure generated by the MDIS for total implants (72,558) during the year prior to the survey is considerably lower than industry estimates of between 115,000 and 130,000 pacemakers sold annually (*1*). This difference underscores the fact that the survey did not include the institutionalized population and therefore would not have counted pacemakers implanted in that group. Also, manufacturers' estimates of devices sold are not necessarily exact tallies of devices actually implanted.

In summary, population-based data on the use of pacemakers are useful for a variety of purposes, including health care planning and surveillance. Future surveys would be strengthened by (*a*) the inclusion of information on the reason for the pacemaker and the type of unit implanted for each person, (*b*) medical record verification of at least a portion of survey information collected (especially patient-reported complications), and (*c*) more precise data regarding minority populations.

Valuable information on pacemaker use and performance also may be obtained through analysis of data maintained by Medicare and other third-party payers. In addition, new requirements that medical device manufacturers implement formal post-marketing safety and effectiveness studies of selected devices are likely to provide yet another broadly based source of information on the demographics of pacemaker recipients and pacemaker survival (*26*).

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Equipment

A SUDAAN, Research Triangle Institute, Research Triangle Park, NC.