Epidemiologic Research

The Epidemiology of Prosthetic Heart Valves in the United States

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The Center for Devices and Radiological Health of the Food and Drug Administration, in collaboration with the National Center for Health Statistics, conducted the Medical Device Implant Supplement to the 1988 National Health Interview Survey, generating the 1st available population-based estimates of the use of prosthetic heart valves in the United States. The 1988 National Health Interview Survey was a massive, nationally representative cross-sectional survey that encompassed 47,485 households and 122,310 individuals.

Data from the Medical Device Implant Supplement indicate that an estimated 253,283 persons with 279,175 heart valves were present in the civilian, non-institutionalized US population (population prevalence of 1.1/1,000, 95% CI 0.8 - 1.3). Prevalence of valve prostheses ranged from 0.2 per 1,000 in those age 44 and under to 5.3 per 1,000 in those 75 years of age and older. Age-adjusted prevalence of valve prostheses did not differ significantly according to sex, race, region of residence, education, or income of recipients. Two thirds of aortic valve recipients identified by the survey were male, compared with only one third of mitral valve recipients. Approximately two thirds of both aortic and mitral valve implants were reported as mechanical. Reported use of anticoagulative agents was significantly more common in recipients of mechanical than of bioprosthetic valves. The single most common reported reason for prosthetic valve implantation was rheumatic heart disease. These data provide useful epidemiologic and public health planning information on prosthetic heart valve use. ***(Tex Heart Inst J 1995;22:86-91)***

On a population basis, the overall impact of valvular heart disease can be placed in perspective by looking at its major components. Acute and recurrent rheumatic fever and chronic rheumatic heart disease, with a combined prevalence in 1986 of 7 per 1,000 persons of all ages, remain the major cause of valvular heart disease.[1] Congenital heart defects, occurring with a prevalence of 8 to 10 per 1,000 among live births, may be associated with valvular heart disease or may predispose individuals to its later development.[2] Less frequent causes of valvular heart disease include degenerative changes of the valve leaflets, such as calcification and infective endocarditis.[3]

Rheumatic heart disease most commonly affects the mitral valve, whereas congenital heart defects are seen most often at the aortic valve.[4] These conditions can lead to progressive structural changes in the heart valves, resulting in bicuspid valve deficiencies such as stenosis and regurgitation. Subsequently, other areas of the heart may show pathologic changes, including hypertrophy, dilatation, ischemic effects, and effects of pulmonary hypertension, as a consequence of increasing pressure or volume overloads (or both) resulting from malfunction of heart valves. These changes may lead to impaired cardiac function requiring valve replacement surgery.[4]

Prosthetic heart valve implantation was first performed on the aortic valve in 1960 by Harken.[5] In 1961, mitral valve replacement was accomplished by Starr and Edwards.[6] Today, all 4 cardiac valves can be replaced, but the aortic and mitral valves remain the most commonly implanted.[4] Both mechanical and bioprosthetic heart valves are available for valve replacement surgery. Mechanical valves offer the advantage of greater durability than bioprostheses, but the need to prevent

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thrombogenesis associated with mechanical valves carries with it an increased risk of hemorrhagic episodes.[7]

This report provides the 1st population-based national estimates of the use of prosthetic heart valves in the United States based on a cross-sectional survey. These estimates were obtained from the Medical Device Implant Supplement (MDIS), which was administered as a part of the 1988 National Health Interview Survey (NHIS). The MDIS was developed by the Food and Drug Administration's Center for Devices and Radiological Health, and the survey was conducted by the National Center for Health Statistics (NCHS).

Methods

The NHIS is a massive, nationally representative, cross-sectional survey that is conducted by the NCHS. This survey serves as the principal source of information about the health of the United States population. Each year, basic health and sociodemographic information is collected on a multi-stage probability sample of the civilian, non-institutionalized population of the United States, through home interviews conducted by Bureau of the Census personnel. Additionally, detailed information on selected health topics is obtained by using supplemental questionnaires. A post-stratification adjustment procedure was used to produce a weight for each person sampled, which enabled the generalizing of results to the US population.

A total of 47,485 households and 122,310 individuals were included in the 1988 NHIS. As an important supplement to the 1988 survey, the MDIS was designed to generate the 1st ever population-based estimates of the use of selected generic types of medical device implants. The weighting process accounted for the survey design and was adjusted for non-response.

The questionnaire used in the MDIS contained a screening section followed by detailed specific questionnaires pertaining to implanted medical devices such as heart valves. Questions regarding replacement, duration of use, and morbidity were included. All data were obtained by questionnaire. The response rate was 92%.

This report is restricted to prosthetic heart valves. Population prevalence and proportions presented in this report were calculated using the post-stratification weights. Approximate standard errors and 95% confidence intervals (CIs) of the prevalences were computed using the SUDAAN package.[8] Statistical significance was assessed at the 0.05 level. Itemized totals may not equal 100% because of rounding errors or missing data. The age reported by respondents was the age at the last birthday. For the variable of geographic region, the United States was divided into 4 regions: Northeast, Midwest, South, and West.

Results

A total of 151 heart valve prostheses were reported among 135 individuals in the MDIS survey sample. Projected to the non-institutionalized US population, this yields a 1988 estimate of 253,283 (95% CI 203,219 - 303,347) persons with 279,175 (95% CI 223,048 - 335,302) heart valves (population prevalence, 1.1/1,000, 95% CI 0.8 - 1.3). The majority of valve recipients (91%) had only 1 valve prosthesis; 9% had 2 or more. During the year prior to the survey, an estimated 27,294 heart valves (95% CI 10,478 - 44,110) were implanted in 21,188 new recipients (95% CI 9,262 - 34,514).

The prevalence of valve prostheses rose steadily with patient age, from 0.2 per 1,000 in those 44 years of age and younger to 5.3 per 1,000 in those 75 years of age and older. Age-adjusted prevalence of valve prostheses did not differ significantly with sex, race, region of residence, education, or income of recipients (Table I). Age-adjusted prevalence in persons reporting limitation of activity was 7 times that in persons with no or unknown limitations of activity.

Of the estimated 279,175 valves in place at the time of the survey, 10% had been in place for less than 1 year, 34% had been in place 1 to 4 years, and 50% had been in place 5 years or more; the duration of implant was unknown for the remaining 6%. Five percent of heart valve prostheses at the time of the survey were replacements of previous prostheses.

Forty-nine percent of valves in the survey were aortic valve prostheses, 36% were mitral, 1% were tricuspid or pulmonic, and the valve position of the remaining 14% was unknown. The mean age of aortic valve recipients (58 years) was not significantly different from that of mitral valve recipients (61 years) (Table II). However, the 2 groups differed significantly with regard to sex. Two thirds of aortic valve recipients identified by the survey were male, in comparison with only one third of mitral valve recipients. There were no significant differences between mitral and aortic valve recipients in race, region of residence, educational level, annual income, or level of activity.

Sixty-three percent of the prosthetic heart valves identified by the survey were reported to be mechanical and 27% to be biological. Recipients of the remaining 10% of heart valves did not know the type of material with which their valves were made. At the time of the survey, recipients reported the use of anticoagulant medication for 83% of mechanical valves (95% CI 75 - 90), compared with 51% of tissue valves (95% CI 33 - 68).

TABLE I. Proportional Distribution* of Selected Sociodemographic Characteristics among Prosthetic Heart Valve Recipients and Non-Recipients and Prosthetic Heart Valve Prevalence* by These Characteristics, 1988 US National Health Interview Survey

	Recipients % (95% CI)	**Non-Recipients†** %	**Prevalence per 1000** (95% CI)
Total			1.1 (0.8, 1.3)
Age (years)			
≤44	13 (8, 19)	69	0.2 (0.04, 0.4)
45-64	35 (26, 44)	19	2.0 (1.3, 2.6)
65-74	29 (21, 37)	7	4.2 (2.8, 5.6)
≥75	23 (16, 30)	5	5.3 (3.4, 7.2)
Sex			
Male	62 (48, 77)	48	1.3 (0.9, 1.7)
Female	38 (23, 52)	52	0.9 (0.6, 1.1)
Race			
White	79 (67, 92)	84	1.1 (0.9, 1.3)
Non-White	21 (8, 33)	16	0.7 (0.3, 1.1)
Region			
Northeast	18 (9, 27)	20	0.9 (0.4, 1.4)
Midwest	41 (26, 56)	25	1.4 (1.0, 1.9)
South	23 (10, 36)	34	1.0 (0.6, 1.3)
West	18 (6, 30)	21	0.9 (0.6, 1.2)
Education**			
<12 years	52 (42, 63)	42	1.1 (0.7, 1.5)
≥12 years	47 (37, 58)	57	1.2 (0.9, 1.4)
Annual income**			
<$20,000	39 (25, 54)	34	1.2 (0.8, 1.5)
≥$20,000	59 (45, 74)	63	1.2 (0.9, 1.5)
Activity			
Limited	72 (59, 86)	14	3.5 (2.6, 4.4)
Not limited	28 (14, 41)	86	0.5 (0.3, 0.7)

* Age-adjusted
† 95% confidence intervals (CIs) for all point estimates were within ± 1.0 of the estimate.
** Percentages do not total 100 due to unknown responses.

Seventeen percent of the prosthetic valves had been associated with at least 1 adverse clinical event. The most frequently reported adverse events were thromboembolism (8%), a presumed defect (unspecified) in the valve (7%), bleeding (6%), and infection (2%). The small number of events in each category precluded stratified analysis on the basis of valve type or position.

Respondents were permitted to give more than 1 reason for which their heart valve implantations were necessary. For 93% of the valves, recipients gave 1 reason for implant; 2 or 3 reasons were given for 6%, and no reason was given for 1%. Twenty-three percent of valve prostheses were reported to be required as a result of rheumatic heart disease, 15% as a result of a congenital anomaly, 12% for a complication following myocardial infarction, 6% for valve calcification, 2% for endocarditis, and 48% for other reasons, these probably including valve prolapse, myxomatous degeneration, etc.

Discussion

Although the estimate of the number of prosthetic heart valves (27,294) implanted during the year prior to the MDIS is based on a relatively small number of

TABLE II. Comparison of Characteristics of Recipients* of Mitral and Aortic Valves, 1988 National Health Interview Survey

Total	Mitral Valves N = 101,173 (95% CI = 72,694 - 129,652) % (95% CI)	Aortic Valves N = 135,223 (95% CI = 99,514 - 170,932) % (95% CI)
Mean age (years)	58 (55, 62)	61 (57, 65)
Sex		
Male	33 (21, 46)	66 (54, 79)
Female	67 (54, 79)	34 (21, 46)
Race		
White	88 (77, 99)	91 (86, 97)
Non-White	12 (86, 23)	9 (3, 14)
Region		
Northeast	17 (7, 27)	21 (7, 35)
Midwest	40 (26, 53)	30 (18, 42)
South	25 (12, 38)	32 (21, 43)
West	18 (7, 29)	17 (7, 26)
Education**		
<12 yrs	34 (20, 48)	30 (19, 41)
≥12 yrs	65 (50, 79)	67 (56, 78)
Income**		
<$20,000	48 (33, 63)	37 (25, 48)
≥$20,000	49 (33, 64)	61 (50, 72)
Activity		
Limited	68 (55, 82)	67 (56, 77)
Not limited	32 (18, 45)	33 (23, 44)
Valve type**		
Mechanical	66 (55, 76)	61 (45, 76)
Biological	25 (15, 35)	34 (19, 49)

* No need for age-adjustment due to similar age distributions of aortic and mitral valve recipients.
** Percentages do not total 100 due to unknown responses.

heart valve recipients and has a large standard error, it correlates well with the results of the National Hospital Discharge Survey of the same year, which reported an estimated total of 41,000 valves implanted.[9] However, the MDIS figures are based on data from the civilian non-institutionalized population, so they produce underestimates of the incidence and prevalence of heart valve replacement in the general US population.

Data from the MDIS also indicate that in 1988, prosthetic heart valves were less prevalent than pacemakers in the non-institutionalized US population. Silverman and colleagues[10] reported that 456,482 non-institutionalized Americans had cardiac pacemakers in 1988, in contrast to the estimated 253,283 persons with prosthetic heart valves noted here. Furthermore, the prevalence of prosthetic heart valves increased with age less dramatically than did the corresponding increases for cardiac pacemakers, artificial hip implants, and intraocular lens implants.[10-12] This finding has an important implication for needs assessment in medical care: as the US population ages, demand for heart valves is not expected to rise as sharply as that for devices more prevalent in the elderly population, such as cardiac pacemakers, artificial hips, and intraocular lens implants. We submit that public health planners need to know where we are, in order to allocate resources appropriately to move toward desired goals.

Although the overall prevalence of valve prostheses did not differ by sex, the MDIS reported a marked difference by sex in implantations of aortic and mitral valve prostheses: aortic valve recipients were almost twice as likely to be male and mitral valve recipients almost twice as likely to be female. This result probably reflects the fact that women are more likely than men to be affected by valvular heart disease at the mitral position, while men are more likely than women to be affected at the aortic position.

The predominant causes of mitral valve disease are acute and recurrent rheumatic fever and chronic rheumatic heart disease.[3] In the United States, mortality figures from 1984 for rheumatic heart disease yielded an overall female-to-male ratio of 1.26:1, and mortality figures for chronic rheumatic heart disease at the mitral position yielded a female-to-male ratio of 2.31:1.[13] A Canadian study reported that the mortality in females was significantly higher than that in males for chronic rheumatic heart disease, and in particular for rheumatic mitral valve disease.[14] Although the annual incidence of acute rheumatic fever is lower in females than in males,[15] the higher mortality figures suggest that females are more adversely affected by rheumatic fever than are males, especially at the mitral position. A greater propensity toward serious mitral valve disease in females may explain why females have more mitral heart valve prostheses than men.

Aortic valve disease is most often the result of either rheumatic fever or secondary degeneration of a congenitally deformed valve.[3] Mortality figures from 1984 for rheumatic aortic valve disease demonstrated a female-to-male ratio of 0.85:1.[13] Mortality figures from 1985 in Canada also indicated that males have a higher mortality rate for rheumatic

aortic valve disease than do females.[14] Congenital abnormalities of the aortic valve occur 3 to 4 times more often in males,[15] making males more susceptible to degenerative changes of the aortic valve.[3]

The MDIS failed to find a significant difference in the prevalence of prosthetic heart valves between whites and non-whites. This is in contrast to racial differences in the implantation of a number of other important medical devices. For example, using the same data collection instrument, we found and published data that demonstrated a significant difference by race in the prevalence of intraocular lenses.[12] The MDIS data could be construed as encouraging, insofar as they suggest that the cardiac surgery community is doing a good job of overcoming racial barriers to access to prosthetic heart valves. On the other hand, the actual number of non-whites with prosthetic heart valves was limited by the overall size of the MDIS sample population and by the number of non-whites in that sample. The failure to distinguish a racial difference in the prevalence of artificial heart valves may reflect this limitation. It is possible that a larger sample size would demonstrate a significant racial difference.

Age-adjusted prevalence of heart valves did not vary significantly by certain sociodemographic characteristics, including region of residence, educational level, and family income. In comparing activity levels of prosthetic heart valve recipients with those of non-recipients, it was found that a significantly greater proportion of recipients were limited in their activities. This finding may indicate a higher prevalence in the recipient group than in the non-recipient group of coexisting medical conditions that would limit activity.

The single most common reason for prosthetic heart valve implantation was rheumatic heart disease, which was reported for 23% of implanted heart valves in the sample. There was no significant difference between mitral and aortic valves in the proportion implanted for rheumatic heart disease: 30,977 out of 101,173 (95% CI 72,694 - 129,652) mitral valves were implanted for rheumatic heart disease (31%, 95% CI 19 - 42), and 29,018 out of 135,223 (95% CI 99,514 - 170,932) aortic valves were implanted for rheumatic heart disease (21%, 95% CI 12 - 31).

Retrospective cohort studies of prosthetic valve recipients have closely matched the results of the MDIS. Czer and associates[16] reported from a sample of 474 consecutive patients receiving aortic valve replacements between 1969 and 1984 that 27% of the recipients had a rheumatic origin for their valvular disease. Burdon and coworkers[17] reported from a sample of 1,650 patients receiving either aortic or mitral valve replacements between 1971 and 1980 that 21% of all recipients were afflicted with rheumatic heart disease, with 11% of aortic valve recipients and 31% of mitral valve recipients having rheumatic heart disease.

The MDIS reported the use of anticoagulation after heart valve replacement in 83% of mechanical valve recipients (95% CI 75 - 90) and in 51% of bioprosthetic valve recipients (95% CI 33 - 68). The 17% of mechanical valve recipients who were not receiving anticoagulation may represent the subset for whom anticoagulation is contraindicated, such as women who plan to become pregnant and older patients who are prone to hemorrhage.[3]

The current recommendation is for all patients receiving either a mechanical prosthesis or a bioprosthesis to be treated with anticoagulants for the first 3 postoperative months.[3] If no indications for continuing anticoagulation exist in a recipient of a bioprosthetic valve, anticoagulation can be discontinued. Most recipients of mechanical prosthetic valves should continue anticoagulation indefinitely, for the rate of thromboembolism without anticoagulation is 3 to 6 times higher than with adequate doses.[18]

There are important caveats that should be noted in the interpretation of this survey. First, comparison of the study's results to the clinical literature must be conservative because the data were obtained from prosthetic valve recipients, and not from clinical records. Second, surgical therapy for valvular disease may change over time. The study reflects surgical practice at the time of the survey. Further study is warranted to examine trends in prosthetic valve surgery.

The MDIS represents the 1st ever population-based national estimates of the use of prosthetic heart valves in the United States population and a number of subgroups. It provides important epidemiologic information useful for public health needs assessment and planning.

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