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Isolated aortic valve replacement in North America comprising 108,687 patients in 10 years: Changes in risks, valve types, and outcomes in the Society of Thoracic Surgeons National Database

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Objective: More than 200,000 aortic valve replacements are performed annually worldwide. We describe changes in the aortic valve replacement population during 10 years in a large registry and analyze outcomes.

Methods: The Society of Thoracic Surgeons National Database was queried for all isolated aortic valve replacements between January 1, 1997, and December 31, 2006. After exclusion for endocarditis and missing age or sex data, 108,687 isolated aortic valve replacements were analyzed. Time-related trends were assessed by comparing distributions of risk factors, valve types, and outcomes in 1997 versus 2006. Differences in case mix were summarized by comparing average predicted mortality risks with a logistic regression model. Differences across subgroups and time were assessed.

Results: There was a dramatic shift toward use of bioprosthetic valves. Aortic valve replacement recipients in 2006 were older (mean age 65.9 vs 67.9 years, $P < .001$) with higher predicted operative mortality risk (2.75 vs 3.25, $P < .001$); however, observed mortality and permanent stroke rate fell (by 24% and 27%, respectively). Female sex, age older than 70 years, and ejection fraction less than 30% were all related to higher mortality, higher stroke rate and longer postoperative stay. There was a 39% reduction in mortality with preoperative renal failure.

Conclusions: Morbidity and mortality of isolated aortic valve replacement have fallen, despite gradual increases in patient age and overall risk profile. There has been a shift toward bioprostheses. Women, patients older than 70 years, and patients with ejection fraction less than 30% have worse outcomes for mortality, stroke, and postoperative stay.

The first aortic valve replacement (AVR) was performed by Harken 48 years ago.[1] In the setting of aortic valve disease, patients are predominantly seen with aortic stenosis, which necessitates valve replacement. Ferguson and colleagues[2] reviewed the Society of Thoracic Surgeons (STS) database with regard to coronary artery bypass grafting. They found that the population undergoing this procedure had aged and was at higher risk yet had a lower mortality. Edwards and associates[3] developed a model for risk prediction in the setting of valve replacement surgery. This model was validated and proved accurate in predicting outcomes. Two percent of the population have bicuspid aortic valves, which are at risk for stenosis.[4,5] Four percent of the elderly population have significant aortic stenosis.[6,7] The size of the population older than 65 years will grow 50% between 2000 and 2030.[8,9] Devices for transcatheter AVR are in development and clinical investigation. Early results suggest the feasibility of transcatheter valve therapy[10,11]; however, standard outcome measures must continue to drive clinical behavior. To this end, we explored the last 10 years of isolated AVR in the STS database with regard to the characteristics and outcomes of this group of patients as a whole and with time.

MATERIALS AND METHODS

Patient Population

The study population consisted of patients 20 years old or older who underwent isolated AVR at STS-participating hospitals between January 1, 1997, and December 31, 2006. From an initial population of 115,163 isolated AVR cases, we identified a subset of 108,791 patients (94.5%) without a history of endocarditis. From these, we excluded 104 patients (0.1%) with missing data on two key study variables, age and sex. The final study population consisted of 108,687 patients from 928 participating hospitals and surgeon groups. Although 928 participants contributed data during the study period, the number of participants in any single calendar year ranged from 365 to 756.

End Points

Outcome measures consisted of in-hospital mortality, permanent stroke, and postoperative stay. Postdischarge 30-day mortality was not analyzed, because this end point was not captured consistently by many participants during the study period.

Analysis

The distributions of patient characteristics and outcomes were summarized with percentages for categorical variables and means and medians for continuous variables. Differences in the prevalence of risk factors and outcomes in 1997 versus 2006 were assessed with stratified Mantel–Haenszel χ^2 statistics, with STS participant identity serving as the stratification variable. Confidence intervals for the relative change in risk factor

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Abbreviations and Acronyms
AVR = aortic valve replacement
STS = Society of Thoracic Surgeons

prevalence in 1997 versus 2006 were calculated by fitting generalized linear models with a log link function. SEs were calculated with an empirical sandwich estimator to account for correlation of observations within the same participant.

To create a patient-level summary measure of case severity, we used logistic regression to estimate the probability of mortality for each patient in the study sample. Explanatory variables consisted of age, sex, ejection fraction, congestive heart failure, diabetes, renal failure, cerebrovascular accident, peripheral vascular disease, myocardial infarction, and surgical status. The patient's estimated probability of death is a simple summary measure that combines several individual risk factors into a single number. The observed to expected ratio statistic was then used to compare temporal trends in actual mortality with the average predicted probability from the logistic regression model. For each calendar year, the risk-adjusted mortality was calculated by multiplying the observed to expected ratio times the overall mortality during the study period. Finally, a test of trend was calculated by adding surgery year to the logistic regression model described previously and testing whether the coefficient was zero.

Missing Data

Patients with missing data were included in the denominator when reporting the prevalence of binary (yes/no) risk factors. We report the percentage of patients for whom each risk factor was coded as present and the percentage of patients for whom the data were unavailable. We included missing data in the denominator, because patient records frequently list risk factors that are present without enumerating the risk factors that are absent. For four variables (chronic obstructive pulmonary disease, New York Heart Association functional class, ejection fraction, and aortic insufficiency), there were large differences in the frequencies of missing data in 1997 and 2006. For these variables, we repeated the analysis with the subset of participants with at least 90% complete data for the variable. Records missing data for outcomes (mortality and stroke) were imputed to the no category.

RESULTS

Both the number of AVRs and the number of participating programs increased during the 10-year study period (Table 1). Table 2 comprehensively outlines patient population characteristics in the overall population, in 1997, and in 2006. Selected patient characteristics are presented in Table 3. The incidences of age older than 70 years, obesity, diabetes, hypertension, chronic obstructive pulmonary disease, cerebrovascular disease, previous stroke, and renal failure all increased during the 10-year study period. The use of bioprosthetic valves increased to 78.4% of total valves used, whereas the mechanical valve use declined to 20.5% ($P < .000001$; Figure 1).

Despite increases in comorbidity and predicted risk of death after AVR, the overall observed mortality and risk-adjusted mortality decreased ($P < .01$; Table 4 and Figure 2). Similarly, the incidence of stroke declined during the last 10 years ($P < .05$; Table 4 and Figure 3). Subgroup analysis (Table 5) demonstrated that mortality was higher for women than for men overall (not shown) and in the 1997 and 2006 populations ($P < .01$; Figure 4). Nonwhite patients had a higher mortality from AVR, which was not improved during the study period (Table 5). Age greater than 70 years, diabetes, peripheral vascular disease, ejection fraction less than 30%, and body mass index were all associated with higher mortality (Table 5). Mortality decreased more than 30% between 1997 and 2006 in the presence of diabetes, nonurgent cases, and renal failure and in the younger than 55 years, 55 to 60 years, 60 to 65 years, and older than 85 years age groups (Figure 5). In 2006 there were 2,431 patients who had undergone previous cardiac surgery and their associated mortality was 6.17%. By comparison, there were 12,966 patients with no prior heart surgery and the mortality was 2.35% (not shown). Stroke was reduced in the 55 to 60 years and the 65 to 70 years age groups (Figure 6). Overall stay was unchanged during the study period (not shown). Age older than 75 years, female sex, and ejection fraction less than 30% were associated with longer median stay (9.23 days vs 7.06 days, 7.80 days vs 7.40 days, and 9.53 days vs 7.67 days, respectively, $P < .01$ for all).

DISCUSSION

We defined a population of patients undergoing AVR in STS-participating North American centers from 1997 to 2006. Methods used in this study allow for completeness and accuracy of database information, as delineated in

TABLE 1. Numbers of patients and participants by year of surgery

		Isolated atrial valve replacement recipients			Participants	
Year	Patients in database	Total	Excluding endocarditis	Excluding missing age or sex	Total	In study population
1997	252,688	9,932	9,421	9,407	466	447
1998	240,590	10,108	9,570	9,551	460	431
1999	210,295	9,108	8,612	8,597	380	367
2000	200,804	9,039	8,584	8,562	365	359
2001	205,418	9,656	9,145	9,135	422	410
2002	227,783	11,342	10,719	10,705	499	485
2003	232,044	12,070	11,358	11,355	549	537
2004	235,335	12,671	11,948	11,947	616	594
2005	250,028	14,907	14,034	14,031	709	688
2006	258,417	16,330	15,400	15,397	756	742

TABLE 2. Distribution of patient characteristics in study population: Overall, in 1997, and in 2006

	Overall (n = 108,687)	In 1997 (n = 9407)	In 2006 (n = 15,397)	*P* value
Demographic characteristics				
Age* (y)				<.0001
Median	69.00	69.00	70	
25th	59.00	58.00	60	
75th	77.00	76.00	78	
Mean	66.90	65.91	67.91	
Dichotomous age (No.)				
<70 y	54,363 (50.02%)	4946 (52.58%)	7368 (47.85%)	<.0001
≥70 y	54,324 (49.98%)	4461 (47.42%)	8029 (52.15%)	
Age ranges (No.)				<.0001
<55 y	19,659 (18.09%)	1857 (19.74%)	2470 (16.04%)	
55 to <60 y	9371 (8.62%)	719 (7.64%)	1344 (8.73%)	
60 to <65 y	11,120 (10.23%)	1000 (10.63%)	1595 (10.36%)	
65 to <70 y	14,213 (13.08%)	1370 (14.56%)	1959 (12.72%)	
70 to <75 y	17,349 (15.96%)	1654 (17.58%)	2283 (14.83%)	
75 to <80 y	18,610 (17.12%)	1547 (16.45%)	2707 (17.58%)	
80 to <85 y	13,127 (12.08%)	911 (9.68%)	2180 (14.16%)	
85 to <90 y	4556 (4.19%)	294 (3.13%)	765 (4.97%)	
≥90 y	682 (0.63%)	55 (0.58%)	94 (0.61%)	
Sex (No.)				.7097
Male	62,013 (57.06%)	5382 (57.21%)	8827 (57.33%)	
Female	46,674 (42.94%)	4025 (42.79%)	6570 (42.67%)	
Ethnicity (No.)				
Missing	1951 (1.80%)	288 (3.06%)	99 (0.64%)	.0010
White	95,140 (87.54%)	8164 (86.79%)	13453 (87.37%)	
Nonwhite	11,596 (10.67%)	955 (10.15%)	1845 (11.98%)	
Risk factors				
Body mass index (No.)				<.0001
Missing	1964 (1.81%)	445 (4.73%)	85 (0.55%)	
<30 kg/m^2	69,810 (64.23%)	6387 (67.90%)	9502 (61.71%)	
≥30 kg/m^2	36,913 (33.96%)	2575 (27.37%)	5810 (37.73%)	
Diabetes (No.)				<.0001
Missing	1314 (1.21%)	448 (4.76%)	21 (0.14%)	
No	85405 (78.58%)	7505 (79.78%)	11460 (74.43%)	
Yes	21968 (20.21%)	1454 (15.46%)	3916 (25.43%)	
Type 1 diabetes (No.)				
Missing	1703 (1.57%)	520 (5.53%)	32 (0.21%)	.0008
No	101,280 (93.19%)	8451 (89.84%)	14,375 (93.36%)	
Yes	5704 (5.25%)	436 (4.63%)	990 (6.43%)	
Hypertension (No.)				<.0001
Missing	900 (0.83%)	303 (3.22%)	18 (0.12%)	
No	39713 (36.54%)	4241 (45.08%)	4292 (27.88%)	
Yes	68074 (62.63%)	4863 (51.7%)	11087 (72.01%)	
Surgical status (No.)				<.0001
Missing	373 (0.34%)	63 (0.67%)	17 (0.11%)	
Elective	88,016 (80.98%)	7896 (83.94%)	12,042 (78.21%)	
Urgent	19,361 (17.81%)	1318 (14.01%)	3252 (21.12%)	
Emergency	808 (0.74%)	101 (1.07%)	80 (0.52%)	
Emergency salvage	129 (0.12%)	29 (0.31%)	6 (0.04%)	
Nonelective status (No.)				<.0001
Missing	373 (0.34%)	63 (0.67%)	17 (0.11%)	
No	88,016 (80.98%)	7896 (83.94%)	12,042 (78.21%)	
Yes	20,298 (18.68%)	1448 (15.39%)	3338 (21.68%)	
Chronic obstructive pulmonary disease (No.)				.0005
Missing	17,641 (16.23%)	5575 (59.26%)	70 (0.45%)	
No	73,908 (68.00%)	3243 (34.47%)	12,262 (79.64%)	
Yes	17,138 (15.77%)	589 (6.26%)	3065 (19.91%)	
Chronic obstructive pulmonary disease in subset (No.)				<.0001
Missing	257 (0.29%)	17 (0.48%)	15 (0.10%)	
No	71,299 (80.89%)	2992 (85.12%)	12,130 (79.92%)	
Yes	16,582 (18.81%)	506 (14.40%)	3033 (19.98%)	

TABLE 2. Continued

	Overall (n = 108,687)	In 1997 (n = 9407)	In 2006 (n = 15,397)	*P* value
Peripheral vascular disease (No.)				.6522
Missing	1568 (1.44%)	562 (5.97%)	29 (0.19%)	
No	97,874 (90.05%)	8074 (85.83%)	13,969 (90.73%)	
Yes	9245 (8.51%)	771 (8.20%)	1399 (9.09%)	
Cerebrovascular disease (No.)				<.0001
Missing	1696 (1.56%)	636 (6.76%)	29 (0.19%	
No	95,659 (88.01%)	8059 (85.67%)	13,459 (87.41%)	
Yes	11332 (10.43%)	712 (7.57%)	1909 (12.40%)	
Cerebrovascular accident (No.)				.7272
Missing	1513 (1.39%)	536 (5.70%)	29 (0.19%)	
No	100,661 (92.62%)	8357 (88.84%)	14,397 (93.51%)	
Yes	6513 (5.99%)	514 (5.46%)	971 (6.31%)	
Renal failure (No.)				.0135
Missing	1576 (1.45%)	542 (5.76%)	27 (0.18%)	
No	101,719 (93.59%)	8484 (90.19%)	14,521 (94.31%)	
Yes	5392 (4.96%)	381 (4.05%)	849 (5.51%)	
Preoperative dialysis (No.)				.3389
Missing	1705 (1.57%)	578 (6.14%)	29 (0.19%)	
No	105,344 (96.92%)	8701 (92.49%)	15,104 (98.10%)	
Yes	1638 (1.51%)	128 (1.36%)	264 (1.71%)	
Immunosuppressive treatment (No.)				.0016
Missing	1785 (1.64%)	605 (6.43%)	64 (0.42%)	
No	103,899 (95.59%)	8616 (91.59%)	14,885 (96.67%)	
Yes	3003 (2.76%)	186 (1.98%)	448 (2.91%)	
Previous cardiovascular interventions				
Coronary artery bypass grafting (No.)				<.0001
Missing	937 (0.86%)	203 (2.16%)	62 (0.40%)	
No	97,956 (90.13%)	8582 (91.23%)	13,702 (88.99%)	
Yes	9794 (9.01%)	622 (6.61%)	1633 (10.61%)	
Valve surgery (No.)				.0058
Missing	967 (0.89%)	257 (2.73%)	40 (0.26%)	
No	101,518 (93.4%)	8490 (90.25%)	14,541 (94.44%)	
Yes	6202 (5.71%)	660 (7.02%)	816 (5.3%)	
Preoperative cardiac status				
Myocardial infarction (No.)				.0004
Missing	1594 (1.47%)	569 (6.05%)	30 (0.19%)	
No	97,466 (89.68%)	8079 (85.88%)	13,809 (89.69%)	
Yes	9627 (8.86%)	759 (8.07%)	1558 (10.12%)	
Myocardial infarction within 21 d (No.)				.0126
Missing	1917 (1.76%)	642 (6.82%)	36 (0.23%)	
No	104,728 (96.36%)	8609 (91.52%)	15,057 (97.79%)	
Yes	2042 (1.88%)	156 (1.66%)	304 (1.97%)	
Congestive heart failure (No.)				<.0001
Missing	1652 (1.52%)	510 (5.42%)	32 (0.21%)	
No	65,837 (60.57%)	5016 (53.32%)	10,169 (66.05%)	
Yes	41,198 (37.91%)	3881 (41.26%)	5196 (33.75%)	
Angina (No.)				.6543
Missing	1508 (1.39%)	503 (5.35%)	33 (0.21%)	
No	77,586 (71.38%)	6302 (66.99%)	10,971 (71.25%)	
Yes	29593 (27.23%)	2602 (27.66%)	4393 (28.53%)	
Arrhythmia (No.)				<.0001
Missing	1695 (1.56%)	592 (6.29%)	41 (0.27%)	
No	89,475 (82.32%)	7047 (74.91%)	13,203 (85.75%)	
Yes	17517 (16.12%)	1768 (18.79%)	2153 (13.98%)	
New York Heart Association functional class (No.)				<.0001
Missing	8877 (8.17%)	1819 (19.34%)	636 (4.13%)	
I	14,690 (13.52%)	859 (9.13%)	2225 (14.45%)	
II	28,866 (26.56%)	1613 (17.15%)	5348 (34.73%)	
III	42,452 (39.06%)	3621 (38.49%)	5672 (36.84%)	
IV	13,802 (12.70%)	1495 (15.89%)	1516 (9.85%)	

TABLE 2. Continued

	Overall (n = 108,687)	In 1997 (n = 9407)	In 2006 (n = 15,397)	*P* value
New York Heart Association functional class in subset (No.)				<.0001
Missing	416 (0.45%)	52 (0.86%)	25 (0.17%)	
I	13,756 (14.97%)	777 (12.81%)	2177 (15.09%)	
II	26,861 (29.23%)	1277 (21.05%)	5233 (36.26%)	
III	38,539 (41.93%)	2797 (46.10%)	5532 (38.34%)	
IV	12,339 (13.42%)	1164 (19.19%)	1463 (10.14%)	
Ejection fraction (%)				<.0001
N (% missing)	94,207 (13.32%)	7100 (24.52%)	14,169 (7.98%)	
Median	55%	52%	56%	
25th percentile	45%	41%	50%	
75th percentile	61%	60%	62%	
Mean	53.39%	51.86%	54.38%	
Ejection fraction ranges (No.)				.0003
Missing	14,480 (13.32%)	2307 (24.52%)	1228 (7.98%)	
<30%	5488 (5.05%)	447 (4.75%)	715 (4.64%)	
≥30%	88,719 (81.63%)	6653 (70.72%)	13,454 (87.38%)	
Ejection fraction in subset (%)				<.0001
N (% missing)	62,360 (2.52%)	2868 (3.01%)	10,925 (2.43%)	
Median	55%	50%	56%	
25th	45%	45%	50%	
75th	60%	60%	62%	
Mean	53.36%	51.34%	54.43%	
Ejection fraction ranges in subset (No.)				.0183
Missing	1614 (2.52%)	89 (3.01%)	272 (2.43%)	
<30%	3460 (5.41%)	157 (5.31%)	539 (4.81%)	
≥30%	58,900 (92.07%)	2711 (91.68%)	10,386 (92.76%)	
Aortic stenosis (No.)				<.0001
Missing	2273 (2.09%)	712 (7.57%)	61 (0.40%)	
No	18,467 (16.99%)	1550 (16.48%)	2327 (15.11%)	
Yes	87,947 (80.92%)	7145 (75.95%)	13,009 (84.49%)	
Aortic insufficiency (No.)				<.0001
Missing	10,916 (10.04%)	3233 (34.37%)	277 (1.80%)	
No	46,062 (42.38%)	2472 (26.28%)	7831 (50.86%)	
Yes	51,709 (47.58%)	3702 (39.35%)	7289 (47.34%)	
Aortic insufficiency in subset (No.)				.1996
Missing	442 (0.52%)	41 (1.52%)	31 (0.21%)	
No	41,736 (49.15%)	1319 (48.76%)	7615 (52.38%)	
Yes	42,744 (50.33%)	1345 (49.72%)	6891 (47.40%)	
Operative data				
Valve type (No.)				<.0001
Missing	1947 (1.79%)	335 (3.56%)	72 (0.47%)	
None	280 (0.26%)	24 (0.26%)	16 (0.10%)	
M	35,284 (32.46%)	4695 (49.91%)	3164 (20.55%)	
B	69,448 (63.90%)	4104 (43.63%)	12,069 (78.39%)	
H	1192 (1.10%)	169 (1.80%)	20 (0.13%)	
A	324 (0.30%)	72 (0.77%)	10 (0.06%)	
R	147 (0.14%)	8 (0.09%)	12 (0.08%)	
BA	65 (0.06%)	0 (0%)	34 (0.22%)	

*There were no missing data regarding age.

Tables 1 through 5. Despite increases in morbidity and predicted mortality, this study demonstrated improved mortality and stroke rates during the 10-year study period. For patients younger than 60 years, mortality from AVR in 2006 was less than 1.0%; for those younger than 70 years, 1.3%; for those younger than 80 years, below 3.5%; and for those under 85 years, below 5% (Table 5). Overall mortality fell 24%, and risk-adjusted mortality fell 33%. Assuming that the risk models that have been developed and validated[12-16] for heart valve surgery and the model developed by the STS and Duke Clinical Research Institute[3] are accurate, we conclude that surgical teams participating in the STS database have dramatically improved performance for isolated AVR.

With regard to specific subgroups, the population of AVR recipients became older and more obese and had increased incidences of diabetes, hypertension, pulmonary disease, cerebrovascular disease, and renal failure during

TABLE 3. Relative changes in frequency of selected patient characteristics between 1997 and 2006

	Relative change	95% Confidence interval	χ^2	*P* value
Age ≥70 y	10.0%	6.4% to 13.6%	31.997	<.0001
Female	–0.3%	–3.6% to 3.2%	0.025	.87513
Nonwhite	18.0%	2.8% to 35.6%	5.491	.01911
Body mass index ≥30 kg/m^2	37.9%	31.7% to 44.3%	191.399	<.0001
Diabetes	64.6%	55.5% to 74.1%	299.396	<.0001
Type 1 diabetes	38.7%	22.7% to 56.8%	27.376	<.0001
Hypertension	39.3%	35.7% to 43.0%	603.955	<.0001
Nonelective operation	40.8%	20.9% to 64.1%	19.274	.00001
Emergency operation	–51.6%	–67.6% to –27.8%	12.648	.00038
Chronic obstructive pulmonary disease	217.9%	165.0% to 281.5%	154.655	<.0001
Chronic obstructive pulmonary disease in subset	38.8%	23.9% to 55.5%	32.11	<.0001
Peripheral vascular disease	10.9%	–3.9% to 27.9%	1.994	.15796
Cerebrovascular disease	63.8%	44.9% to 85.2%	62.422	<.0001
Cerebrovascular accident	15.4%	3.6% to 28.6%	6.729	.00949
Renal failure	36.1%	19.5% to 55.1%	21.581	<.0001
Dialysis	26.0%	0.9% to 57.3%	4.168	.04121
Immunosuppressant medication	47.2%	19.2% to 81.7%	12.913	.00033
Previous coronary artery bypass grafting	60.4%	45.0% to 77.5%	83.535	<.0001
Previous valve surgery	–24.5%	–32.6% to –15.3%	23.248	<.0001
Previous myocardial infarction	25.4%	10.0% to 43.0%	11.433	.00072
Myocardial infarction within 21 d	19.1%	–18.8% to 74.6%	0.799	.37146
Congestive heart failure	–18.2%	–23.9% to –12.1%	29.7	<.0001
Angina	3.2%	–5.6% to 12.7%	0.476	.49024
Arrhythmia	–25.6%	–31.3% to –19.5%	53.366	<.0001
New York Heart Association functional class IV	–38.1%	–47.1% to –27.4%	35.059	<.0001
New York Heart Association functional class IV in subset	–47.2%	–55.5% to –37.2%	52.569	<.0001
Ejection fraction <30%	–2.3%	–15.9% to 13.6%	0.09	.76396
Ejection fraction <30% in subset	–9.3%	–24.1% to 8.2%	1.176	.27826
Aortic stenosis	11.2%	8.2% to 14.4%	55.839	<.0001
Aortic insufficiency	20.3%	11.9% to 29.3%	25.148	<.0001
Aortic insufficiency in subset	–4.7%	–14.6% to 6.4%	0.723	.39503
Mechanical valve	–58.8%	–61.8% to –55.7%	549.909	<.0001
Bioprosthetic valve	79.7%	67.6% to 92.6%	273.527	<.0001

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the 10 years. Despite these changes, overall mortality fell for each subgroup. It also fell for most patient subsets outlined in Table 5. Subgroup stroke rate also decreased during the 10-year period despite increasing age and risk in this AVR population (Table 5 and Figure 6). To a degree, stroke and mortality are dependent, because stroke leads to higher mortality. Nonetheless, for patients younger than 70 years, risk of stroke after AVR was 0.7% in 2006. Between the ages of 70 and 80 years, stroke rate in 2006 was less than 2.0%, and even for octogenarians, stroke was less than 2.5% (Table 5 and Figure 6). Stroke rate in this study was time dependent as well as age dependent. Female patients had higher mortality, higher stroke rate, and longer postoperative stay relative to male patients. This was true for the overall population, the 1997 group, and the 2006 group. Bridges and coworkers[17] previously demonstrated a relationship between size and outcome in the STS database in the setting of AVR. Because female patients have a smaller body size on average than do male patients, the increased mortality among female patients is consistent with reports linking body size to outcome. Factors that cause this effect of higher female

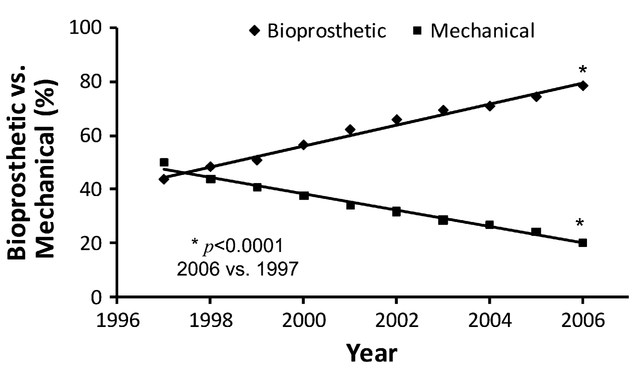

FIGURE 1. Percentage use of bioprosthetic valves relative to mechanical valves from 1997 through 2006. Bioprosthetic valve use increased progressively during 10 years. *Asterisk* indicates $P < .000001$.

TABLE 4. Patient characteristics and outcomes by year

	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006
Expected mortality (%)	2.8%	2.9%	2.9%	2.9%	3.0%	3.1%	3.1%	3.1%	3.2%	3.2%
Observed mortality (%)	3.4%	3.3%	3.5%	3.3%	3.2%	2.9%	2.8%	2.8%	2.3%	2.6%
Expected/observed mortality ratio	1.20	1.16	1.21	1.14	1.07	0.95	0.90	0.91	0.73	0.80
Risk-adjusted mortality (%)	3.53%	3.42%	3.58%	3.35%	3.15%	2.79%	2.64%	2.66%	2.16%	2.36%
Observed stroke (%)	1.7%	1.9%	1.6%	1.6%	1.6%	1.7%	1.4%	1.4%	1.5%	1.3%
Mean postoperative stay (d)	8	7.9	7.8	7.8	7.8	7.8	7.8	7.8	7.7	7.8
Mean age (y)	65.9	66.2	66.2	67.0	66.9	66.9	66.9	67.0	67.3	67.9
Mechanical valve (%)	49.9%	43.9%	40.7%	37.9%	34.3%	31.9%	28.8%	27.0%	24.4%	20.5%
Bioprosthetic valve (%)	43.6%	48.3%	50.7%	56.4%	62.1%	65.8%	69.3%	70.8%	74.3%	78.4%
Mechanical and bioprosthetic valves (%)	93.5%	92.2%	91.4%	94.3%	96.4%	97.8%	98.1%	97.8%	98.8%	98.9%
Ratio of bioprosthetic to mechanical valves	0.466	0.524	0.555	0.598	0.644	0.673	0.706	0.724	0.753	0.792

adverse outcome rate and could possibly be manipulated to ameliorate it are unclear, however, and will require further study. Increased adverse outcomes in the nonwhite patients were also observed in this study. This observation in the setting of heart surgery has also been made in previous reports.[18] Again, the study design of this review was not sufficient to explain this finding.

The dramatic shift away from mechanical heart valves toward bioprosthetic heart valves is difficult to explain because of the relatively short time frame in which it occurred. Nonetheless, many young patients refuse long-term anticoagulation, and elderly patients are at high risk when receiving anticoagulation. There has been evidence that reoperation to replace a failed bioprosthetic valve can be accomplished with good outcomes driven by factors other than simple replacement of the valve, such as age, degree of heart failure, and coronary disease.[19,20] Newer generation tissue valves are expected to provide longer reoperation-free survivals. Finally, the population of patients has aged during the study period, and it is expected that the elderly segment of the population will continue to grow dramatically. Multiplying and adding risk through the patient's lifetime to derive a predicted total lifetime risk for valve implantation at the time of the index operation favors a bioprosthetic valve over mechanical valve and may explain the finding in this study of a nationwide shift toward bioprosthetic valves.[21] All these factors taken together have influenced surgeon and patient valve choices.

In conclusion, predicted risk and comorbidities of patients undergoing AVR have increased during the last 10 years in this country. Despite these changes, outcomes, including rates of death and stroke, not only have improved but are quite low for isolated AVR. There has been a dramatic shift toward the use of bioprosthetic valves during the 10-year study period. Female sex is associated with higher rates of death and adverse outcomes in the setting of isolated AVR, a finding that requires a search for cause.

Study Limitations

This study was based on the STS database and therefore by definition was a retrospective review of patient data submitted by participating centers. Furthermore, the cases studied were nonconsecutive and based on voluntary participation in the STS database. In addition, this was a study

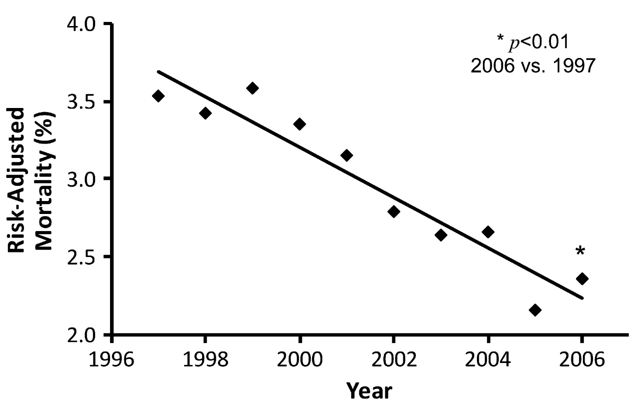

FIGURE 2. Risk-adjusted mortality for aortic valve replacement during 10 years in Society of Thoracic Surgeons database. Mortality for aortic valve replacement decreased with time. *Asterisk* indicates $P < .01$.

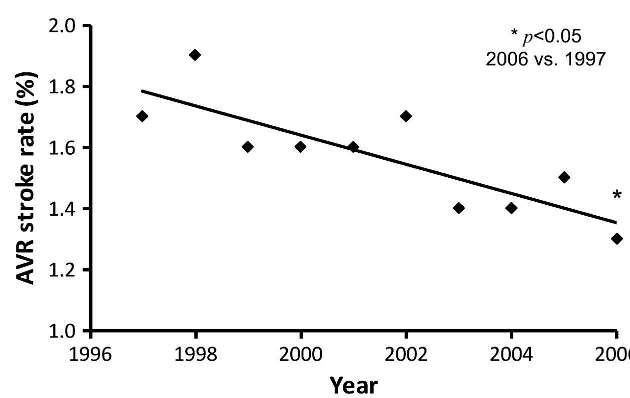

FIGURE 3. Stroke rate after aortic valve replacement *(AVR)* in Society of Thoracic Surgeons database from 1997 through 2006. Stroke rate decreased during 10-year study period. *Asterisk* indicates $P < .01$.

TABLE 5. Changes in outcome between 1997 and 2006 by subgroup

	N		Mortality					Stroke				
			Rate (%)		Relative change (%)			Rate (%)		Relative change (%)		
	1997	2006	1997	2006	Value	95% Confidence interval	*P* value	1997	2006	Value	95% Confidence interval	*P* value
All	9407	15,397	3.4%	2.6%	–24.3%	–35.1% to –11.6%	<.01	1.7%	1.3%	–21.1%	–35.9% to –2.9%	.03
Male												
No	4025	6,570	4.1%	3.2%	–20.8%	–35.3% to –3.0%	.02	2.0%	1.4%	–28.1%	–45.6% to –5.1%	.02
Yes	5382	8,827	2.8%	2.1%	–27.9%	–42.6% to –9.4%	<.01	1.4%	1.2%	–13.7%	–36.1% to 16.5%	.34
Nonwhite												
No	8452	13,552	3.3%	2.5%	–24.5%	–36.1% to –10.7%	<.01	1.6%	1.3%	–15.3%	–32.3% to 5.9%	.15
Yes	955	1,845	4.4%	3.3%	–26.1%	–49.8% to 8.9%	.13	2.5%	1.2%	–52.6%	–73.1% to –16.5%	<.01
Age ≤70 y												
No	4946	7,368	2.2%	1.3%	–43.8%	–57.4% to –25.7%	<.01	1.2%	0.7%	–43.3%	–62.7% to –13.9%	<.01
Yes	4461	8,029	4.6%	3.7%	–19.1%	–32.8% to –2.6%	.02	2.2%	1.9%	–13.9%	–32.5% to 9.8%	.23
Diabetes												
No	7953	11,481	2.8%	2.2%	–24.0%	–36.9% to –8.4%	<.01	1.4%	1.3%	–8.2%	–27.6% to 16.3%	.48
Yes	1454	3,916	6.3%	3.7%	–41.1%	–53.8% to –24.8%	<.01	3.0%	1.4%	–55.3%	–69.7% to –34.0%	<.01
Peripheral vascular disease												
No	8636	13,998	3.0%	2.3%	–24.6%	–36.3% to –10.9%	<.01	1.6%	1.3%	–19.0%	–36.0% to 2.6%	.08
Yes	771	1,399	7.1%	5.2%	–26.9%	–48.9% to 4.6%	.09	3.1%	2.0%	–35.7%	–62.8% to 11.0%	.11
Previous valve surgery												
No	8747	14,581	3.3%	2.4%	–27.0%	–38.0% to –14.0%	<.01	1.7%	1.3%	–21.6%	–36.8% to –2.8%	.03
Yes	660	816	4.8%	5.6%	16.3%	–25.6% to 81.6%	.51	1.7%	1.5%	–11.8%	–60.4% to 96.7%	.76
Myocardial infarction												
No	8648	13,839	3.1%	2.2%	–28.3%	–39.4% to –15.1%	<.01	1.6%	1.1%	–29.5%	–43.6% to –11.9%	<.01
Yes	759	1,558	6.1%	5.3%	–13.2%	–39.6% to 24.9%	.45	2.2%	2.9%	29.0%	–23.9% to 118.5%	.34
Congestive heart failure												
No	5526	10,201	2.1%	1.6%	–23.6%	–40.0% to –2.7%	.03	1.4%	1.2%	–17.4%	–37.2% to 8.8%	.17
Yes	3881	5,196	5.2%	4.4%	–14.9%	–29.9% to 3.4%	.10	2.1%	1.6%	–20.6%	–41.9% to 8.4%	.15
Urgent operation												
No	7959	12,059	2.8%	1.9%	–31.9%	–43.4% to –18.1%	<.01	1.6%	1.2%	–23.8%	–39.7% to –3.6%	.02
Yes	1448	3,338	6.5%	4.9%	–24.8%	–41.8% to –2.7%	.03	2.0%	1.6%	–17.7%	–47.5% to 28.9%	.39
Ejection fraction <30%												
No	8960	14,682	3.2%	2.4%	–14.3%	–46.2% to 36.5%	.52	1.7%	1.3%	–9.7%	–61.3% to 110.5%	.81
Yes	447	715	6.0%	5.2%	–25.1%	–36.2% to –12.0%	<.01	2.0%	1.8%	–21.8%	–36.6% to –3.5%	.02
Body mass index ≥30 kg/m^2												
No	6832	9,587	3.5%	2.7%	–21.9%	–35.0% to –6.1%	<.01	1.8%	1.5%	–17.4%	–35.0% to 4.8%	.12
Yes	2575	5,810	3.0%	2.3%	–25.6%	–42.8% to –3.1%	.03	1.2%	1.0%	–19.7%	–47.1% to 21.9%	.30
Renal failure												
No	9026	14,548	2.9%	2.2%	–24.6%	–36.2% to –10.8%	<.01	1.6%	1.3%	–17.9%	–33.6% to 1.6%	.07
Yes	381	849	13.9%	8.5%	–39.0%	–55.6% to –16.2%	<.01	4.2%	1.9%	–55.1%	–76.5% to –14.4%	.01
Age (y)												
<55	1857	2,470	1.5%	0.9%	–38.7%	–64.8% to 6.6%	.08	0.6%	0.5%	–18.0%	–63.5% to 84.4%	.63
55 to <60	719	1,344	2.2%	0.6%	–73.3%	–88.5% to –37.9%	<.01	1.1%	0.2%	–79.9%	–94.5% to –26.2%	.01
60 to <65	1000	1,595	3.2%	1.6%	–51.0%	–70.7% to –18.0%	<.01	1.1%	0.9%	–14.5%	–61.3% to 89.1%	.70
65 to <70	1370	1,959	2.6%	1.9%	–26.2%	–52.9% to 15.7%	.19	2.0%	1.0%	–52.5%	–74.5% to –11.8%	.02
70 to <75	1654	2,283	3.2%	2.9%	–9.8%	–37.4% to 30.0%	.58	1.9%	1.5%	–23.0%	–51.9% to 23.2%	.28
75 to <80	1547	2,707	4.6%	3.3%	–29.2%	–47.6% to –4.2%	.03	2.3%	2.1%	–5.3%	–37.4% to 43.3%	.80
80 to <85	911	2,180	6.3%	4.9%	–22.3%	–42.9% to 5.8%	.11	2.2%	2.0%	–10.2%	–45.0% to 46.8%	.67
85 to <90	294	765	7.8%	4.1%	–48.2%	–69.0% to –13.5%	.01	4.1%	2.4%	–42.4%	–71.9% to 18.4%	.13
≥90	55	94	3.6%	9.6%	163.3%	–40.2% to 1059.2%	.20	1.8%	2.1%	17.0%	–89.2% to 1168.6%	.90

Missing data were imputed to the no category.

of AVR only. New pioneering therapies, such as aggressive and effective repair techniques for aortic insufficiency, will change the focus to short- and long-term outcomes from treatment of a disease rather than outcomes from a particular procedure.[22] Long-term data cannot yet be linked to the in-hospital and 30-day outcome measures

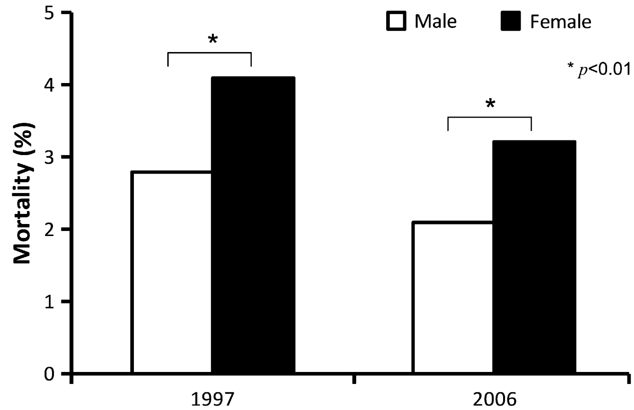

FIGURE 4. Mortality from aortic valve replacement among male and female patients. Female patients had greater mortality in 1997, in 2006, and in overall population. *Asterisk* indicates $P < .01$.

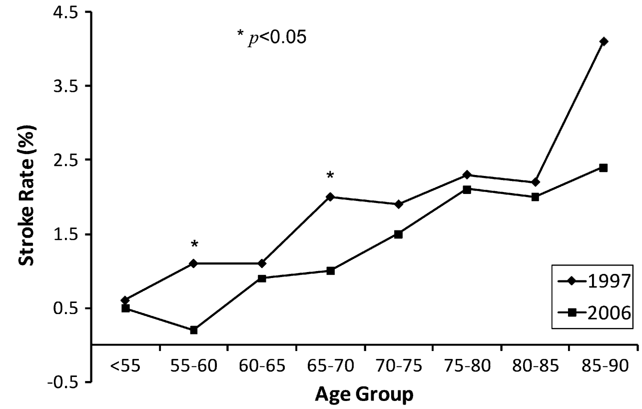

FIGURE 6. Stroke versus age in aortic valve replacement population between 1997 and 2006. Stroke rate was age dependent but also reduced as shown between 1997 and 2006. *Asterisk* indicates $P < .05$.

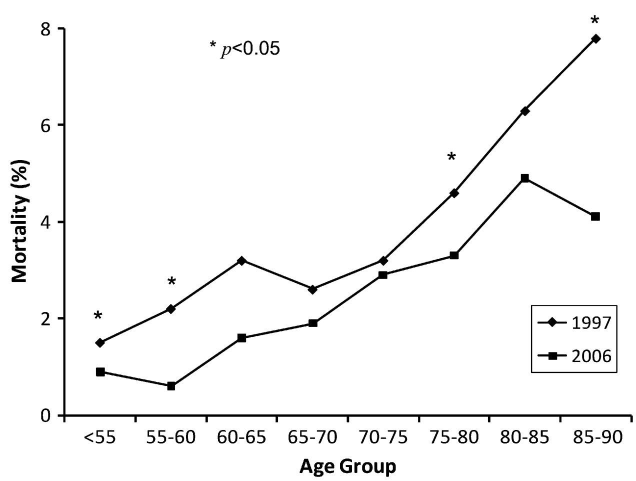

FIGURE 5. Mortality versus age in aortic valve replacement study population. Mortality was age dependent in 1997 and in 2006. For age groups as shown, mortality was less in 2006 than in 1997. *Asterisk* indicates $P < .05$.

provided by the STS database. Further investigation will require inclusion of long-term outcomes and health-related quality of life in any assessment of surgical therapy of valve disease.

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