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Decreasing Mortality for Aortic and Mitral Valve Surgery In Northern New England

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Background. **Although numerous reports have documented declining mortality rates associated with coronary artery bypass surgery in recent years, it is unknown whether similar trends have occurred with valve surgery during this time.**

Methods. **We conducted a regional, prospective study to assess trends in patient casemix and in-hospital mortality rates over time with aortic valve replacement (AVR), mitral valve replacement (MVR), and mitral valve repair. Data were collected from all patients undergoing AVR (n = 2,596), MVR (n = 759), or mitral valve repair (n = 522) in Northern New England between January 1992 and December 1997. Logistic regression was used to identify significant predictors of in-hospital mortality and to calculate risk-adjusted mortality rates.**

Results. **For AVR, the trend in patient casemix was toward increased risk with increases in patient age and in the proportion of patients with: body surface area less than 1.7, diabetes, coronary artery disease, and prior valve surgery. A decrease was noted in the proportion of patients undergoing additional surgical procedures. For MVR, patient risk improved over the time period with fewer female patients and fewer patients with coronary artery disease. For mitral valve repair patient risk increased over the time period with increases in the proportion of patients with coronary artery disease, diabetes, and whose surgical priority was classified as urgent. In addition, there was a borderline significant increase in the proportion of mitral valve repair patients in New York Heart Association class IV preoperatively. Risk-adjusted mortality decreased 44% from 9.3% in 1992 through 1993 to 5.3% in 1996 through 1997 for patients undergoing AVR ($p = 0.01$) and decreased 53% from 13.6% in 1992 through 1993 to 8.2% in 1996 through 1997 for patients undergoing MVR ($p = 0.01$). We observed a statistically insignificant increase in risk-adjusted mortality over the time period for patients undergoing mitral valve repair (from 3.6% in 1992 through 1993 to 5.0% in 1996 through 1997; $p = 0.34$).**

Conclusions. **Significant improvement in mortality rates with valve replacement was observed in northern New England during this time period. This improvement persisted following adjustment for changes in patient casemix over this time. These trends mirror improvements in mortality with other cardiac surgical interventions that have been observed in recent years in our region and nationally.**

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Despite trends toward older and sicker patients, perioperative mortality with coronary artery bypass grafting (CABG) has been decreasing in recent years [1–4]. For example, in the National Medicare population, mortality rates among patients undergoing CABG fell 18% from 1987 to 1990 [1]. In our region, mortality rates with coronary bypass declined 24% between 1987 and 1993, from 4.5% to 3.6%, following the initiation of a regionwide coronary bypass quality improvement program [2].

Compared with those of coronary bypass, mortality rates associated with valve surgery have traditionally been twice as high for those undergoing aortic valve replacement (AVR), and three times higher for those undergoing mitral valve replacement (MVR). Although mortality rates reported in modern case series of valve operation are substantially lower than those from earlier eras [5–7], mortality with valve operation has not been studied on a population-based level. With the declining incidence of rheumatic heart disease, the characteristics of patients undergoing valve replacement are also changing; valve replacement is now performed primarily for degenerative valve disease in increasingly older patients [8].

The Northern New England Cardiovascular Disease

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Study Group (NNECDSG) is a voluntary research consortium that maintains prospective data registries that contain information on all coronary bypass, angioplasty, and valve operations performed in the region. This large, prospective database provided us the opportunity to assess population-based trends in patient casemix and in-hospital mortality rates over time with aortic and mitral valve operations.

Material and Methods

The medical centers that participate in the NNECDSG include the five medical centers that perform cardiac surgical procedures in Maine, New Hampshire, and Vermont and one hospital in Boston, Massachusetts. These analyses include all patients undergoing AVR (n = 2,570), MVR (n = 757), and mitral valve repair (n = 522) between January 1992 and December 1997. Due to the small number of patients undergoing operation on the tricuspid or pulmonic valve or surgical procedures on multiple valves, these groups of patients were excluded from these analyses.

The NNECDSG heart valve registry has included information on all of the following variables since 1992: age, sex, marital status, insurance carrier, New York Heart Association (NYHA) functional class, smoking, treated hypertension, prior cerebrovascular accident, diabetes, atrial fibrillation, coronary artery disease, congestive heart failure, prior valve operation, prior revascularization, concomitant surgical procedures, height, weight, ejection fraction, left ventricular end diastolic pressure, pulmonary artery pressures, valve area, mean gradient, degree of stenosis, degree of regurgitation, type of procedure, prosthetic valve type, priority of operation, use of balloon pump, concomitant cardiothoracic surgical procedures, and status at hospital discharge. Coronary artery disease was categorized as follows: no; yes, without concomitant coronary bypass; or yes, with concomitant coronary bypass. Other concomitant cardiothoracic surgical procedures included aortic dissection repair, other dissection repair, and use of valve conduits. Priority of operation was assessed by the cardiothoracic surgeons and was defined as follows: *emergency* means that medical factors relating to the patient's cardiac disease dictated that an operation should be performed within hours to prevent morbidity or death; *urgent* means that medical factors required the patient to stay in the hospital for an operation before discharge; and *elective* means that medical factors indicated the need for operation, but the clinical situation allowed discharge from the hospital with readmission at a later date. The number of patients in the dataset and their discharge status has been validated periodically using hospital discharge data.

Backward stepwise logistic regression analysis was used to assess the associations between patient risk factors and in-hospital mortality. Separate models were fit for patients undergoing aortic and mitral valve operation. In each of the models, the dependent variable was binary, with 1 denoting in-hospital death and 0 denoting a live discharge. All first-order interaction terms of significant variables in the models were investigated to test for nonlinear relationships. The final models were tested for goodness of fit by comparing the expected and actual mortality rates within deciles of predicted risk using the Hosmer-Lemeshow test [9]. The discrimination of the models were tested using the C statistic [10], which compares all possible pairs of patients (1 of whom died in the hospital and 1 of whom was discharged alive) and records the proportion of times that the patient who died had a higher predicted risk than the patient who lived.

The resulting models were then used to find the expected and risk-adjusted mortality rates for each individual time period (1992 through 1993, 1994 through 1995, 1996 through 1997). The expected mortality rate for each year was obtained by summing the expected probabilities of death corresponding to each of the patients operated on in that time period and dividing by the number of patients. The risk-adjusted mortality rate for each time period was obtained by dividing the observed mortality rate by the expected mortality rate and then multiplying that quotient by the observed mortality rate for the whole time period (1992 through 1997).

Results

Changes in the prevalence of factors that were significant predictors of mortality in multivariate analysis for patients undergoing AVR are presented in Table 1. For AVR, the trend in patient casemix was toward increased risk with increases in patient age and in the proportion of patients with body surface area less than 1.7, diabetes, coronary artery disease, and prior valve operation. There was a decrease in the proportion of patients undergoing additional surgical procedures. There were no significant changes with regard to NYHA class or priority of operation for patients undergoing AVR. The analogous analysis for patients undergoing mitral valve operation is presented in Table 2. During this time period, rates of mitral valve repair increased from 33% to 47% of all mitral valve operations. For MVR, patient risk improved over the time period with fewer female patients and fewer patients with coronary artery disease. For mitral valve repair patient risk increased over the time period with increases in the proportion of patients with coronary artery disease, diabetes, and whose surgical priority was classified urgent. In addition, there was a borderline significant increase in the proportion of mitral valve repair patients in NYHA class IV preoperatively. In contrast to patients undergoing AVR, there was no change in patient age over the time period for patients undergoing either mitral valve operation.

Both the aortic and mitral valve models were well calibrated with high degrees of correlation ($r > 0.98$) between observed and expected mortality rates within deciles of predicted risk, indicating that the models performed well at all levels of predicted risk. The Hosmer-Lemshow chi-square statistic was nonsignificant for both models, indicating no significant deviations from fit and the C statistics (aortic = 0.78, mitral = 0.81)

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Table 1. Changes Over Time in the Prevalence of Factors That Are Significant Predictors of In-Hospital Mortality With Aortic Valve Replacement

Variable	1992–1993	1994–1995	1996–1997	*p*
Number of procedures	774	854	968	
Age (mean)	67.6	68.5	70.4	< 0.001
Body surface area < 1.7 (%)	25.8	22.8	20.9	0.02
Coronary artery disease (%)	52.5	53.8	59.8	< 0.001
Diabetes (%)	11.8	16.5	19.0	< 0.001
Additional cardiac procedures (%) (other than CABG)	7.2	6.1	4.7	0.02
NYHA class IV (%)	16.4	17.7	16.2	0.87
Prior valve surgery (%)	8.2	6.4	12.0	0.01
Priority of surgery (%)				
Urgent	35.8	39.2	38.2	0.98
Emergency	2.6	3.6	3.0	0.72

CABG = coronary artery bypass grafting; NYHA = New York Heart Association.

indicated good discrimination between in-hospital survivors and nonsurvivors for both models.

Table 3 compares the characteristics of patients undergoing MVR and mitral valve repair. Compared with patients undergoing MVR, fewer patients undergoing mitral valve repair were female (57.7% versus 39.5%). Patients undergoing repair were less likely to have coronary artery disease or to be in NYHA class IV preoperatively. With regard to priority of surgery, patients undergoing mitral valve repair were more likely to be classified urgent but less likely to be classified emergency than patients undergoing MVR.

Table 2. Changes Over Time in the Prevalence of Factors That Are Significant Predictors of In-Hospital Mortality With Mitral Valve Replacement and Repair

Variable	1992–1993	1994–1995	1996–1997	*p*
Number of procedures				
MVR	250	241	268	
Repair	124	165	233	
Age (mean)				
MVR	66.3	65.6	66.2	0.90
Repair	66.0	66.5	66.4	0.44
Female sex (%)				
MVR	66.1	52.3	54.9	0.01
Repair	40.3	37.0	40.8	0.82
Coronary artery disease (%)				
MVR	52.4	52.3	53.4	0.82
Repair	52.4	59.4	65.5	0.02
Diabetes (%)				
MVR	21.6	17.4	16.8	0.16
Repair	8.9	17.0	18.9	0.02
Additional cardiac procedures (%) (other than CABG)				
MVR	4.8	4.2	1.9	0.07
Repair	2.4	3.6	2.2	0.75
NYHA class IV (%)				
MVR	26.8	27.4	28.4	0.69
Repair	18.6	22.4	26.2	0.10
Urgent surgery (%)				
MVR	40.4	39.0	43.7	0.44
Repair	43.8	40.6	57.5	< 0.001
Emergency surgery (%)				
MVR	11.3	11.2	6.7	0.08
Repair	0.8	3.0	2.6	0.38

CABG = coronary artery bypass grafting; MVR = mitral valve replacement; NYHA = New York Heart Association.

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Table 3. Differences in Factors That Are Significant Predictors of In-Hospital Mortality Between Patients Undergoing Mitral Valve Replacement and Mitral Valve Repair

Variable	Repair	Replacement	*p*
Age (mean)	66.3	66.0	0.65
Female sex (%)	39.5	57.7	< 0.001
Coronary artery disease (%)	60.5	52.7	0.01
Diabetes (%)	15.9	18.6	0.22
Additional cardiac procedures (%) (other than CABG)	2.7	3.6	0.38
NYHA class IV (%)	23.2	27.5	0.08
Urgent surgery (%)	48.9	41.1	0.01
Emergency surgery (%)	2.3	9.6	< 0.001

CABG = coronary artery bypass grafting; NYHA = New York Heart Association.

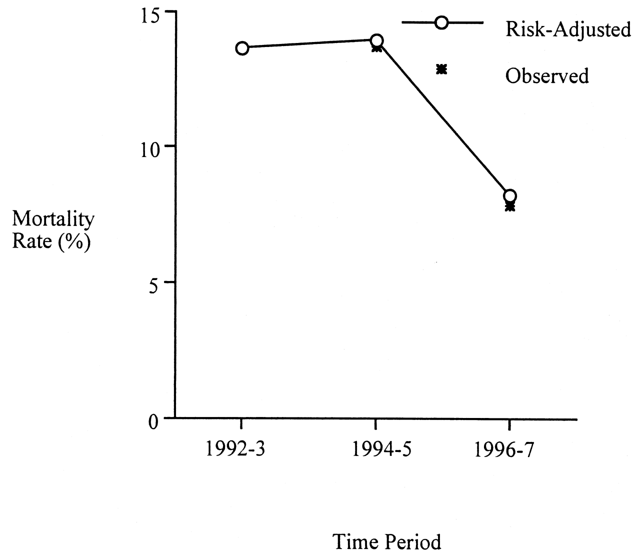

Fig 2. In-hospital mortality with mitral valve replacement over time (1992–1997).

Figures 1 through 3 show changes in observed and risk-adjusted mortality over the time period of study. Risk-adjusted mortality decreased 44% from 9.3% in 1992 through 1993 to 5.3% in 1996 through 1997 for patients undergoing AVR ($p = 0.01$) and decreased 53% from 13.6% in 1992 through 1993 to 8.2% in 1996 through 1997 for patients undergoing MVR ($p = 0.01$). Compared with MVR, mortality rates with valve repair were low (5%) and did not vary significantly over the time period (from 3.6% in 1992 through 1993 to 5.0% in 1996 through 1997; $p = 0.34$).

Comment

This study evaluated changes in patient characteristics and in-hospital mortality rates for patients undergoing aortic or mitral valve operation in northern New England between January 1992 and December 1997. Observed mortality rates decreased significantly for both AVR and MVR. These trends persisted following adjustment for patient casemix. No statistically significant change in observed or risk-adjusted mortality rates was observed for patients undergoing mitral valve repair.

There are no prior population-based studies of trends in mortality and patient casemix with valve operation. However, several large, single institution case series reported declining mortality rates with AVR in prior decades. In a study of 30-day mortality among 690 patients undergoing AVR for aortic stenosis between 1965 and 1986, mortality declined from 20% (1965 through 1972) to 6.8% (1973 through 1986) [6]. In a study of 1,689

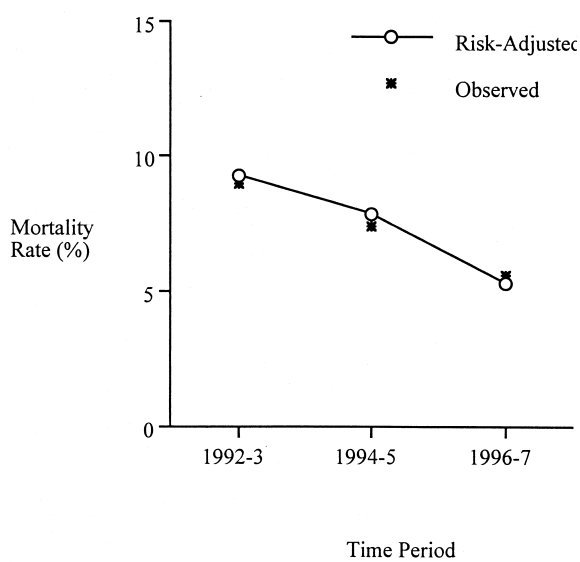

Fig 1. In-hospital mortality with aortic valve replacement over time (1992–1997).

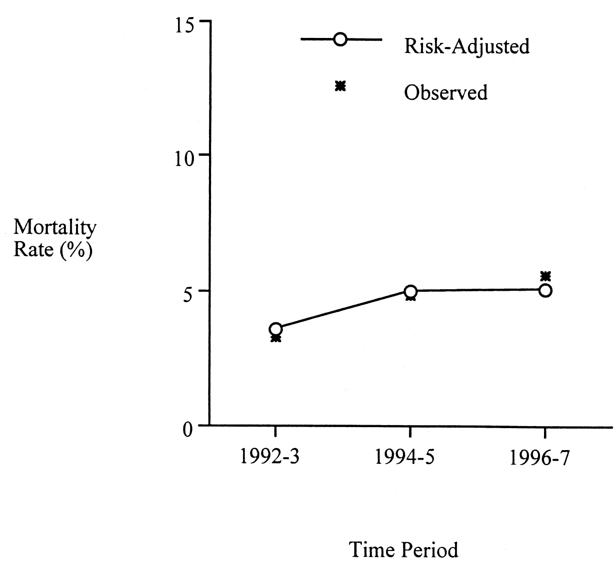

Fig 3. In-hospital mortality with mitral valve repair over time (1992–1997).

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patients undergoing isolated AVR between 1972 and 1986, in-hospital mortality declined from 5.0% in the years 1972 through 1975 to 1.6% in the years 1984 through 1986 [11]. In a study of 1,479 patients undergoing AVR between 1967 and 1981, operative year was a significant independent determinant of operative mortality (odds ratio = 0.89, $p = 0.013$) for the subgroup of patients with regurgitant lesions [7]. Finally, a study of in-hospital mortality among 430 patients undergoing AVR reported that mortality declined from 10.6% in the years 1970 through 1976 to 2.0% for the years 1980 through 1985 [5]. Only one study assessed mortality rates with MVR over time. In this study, which compared patient characteristics and mortality among 478 MVR patients from the years 1975 to 1979 with those of 341 patients from the years 1979 to 1983, hospital mortality increased from 5.4% to 8.5%. Patients in the later era were older (mean = 57 versus 54 years) with higher left ventricular end diastolic pressure (14 versus 11 mm Hg) and underwent longer operations than those in the earlier era. The difference in mortality between the eras was not significant following adjustment for these differences in multivariate analysis [12].

We have found that the mortality rates in the early period of our study are similar to other population-based analyses of patients undergoing valve operation. In our study the overall mortality rate with valve operation in the early period was 9.0%. This is similar to the mortality rates for valve operation patients reported in the Veterans Administration Cooperative Study (9.2% for patients between 1987 and 1989) [13] and in New York state (8.0% for patients in 1989) [14].

Although there are no investigations of time trends in mortality and patient casemix with valve replacement that are contemporaneous to ours, several studies have reported declining mortality rates with CABG during this time [4, 15]. Most recently, an analysis of the national Medicare database showed that mortality with coronary bypass declined substantially between 1987 and 1992 [15]. These trends have been attributed to general improvements in cardiac operative care including surgical techniques, myocardial protection, anesthesia, and postoperative care [1, 16].

In New York state and northern New England, the two areas of the country with organized, regionwide cardiac operation quality improvement initiatives, the observed decline in mortality with coronary bypass was greatest (33% in New York state and northern New England versus 19% in the US overall) [15]. In northern New England, the quality improvement intervention that took place during 1990 and 1991 included feedback of risk-adjusted outcome data, training in continuous quality improvement techniques, and round-robin site visits to other medical centers [2]. Although this program was specifically targeted at coronary bypass, not valve operation, many aspects of preoperative, intraoperative, and postoperative care are common to both types of operations. In addition, 42% of patients undergoing valve replacement in our region over this time period underwent concomitant revascularization. However, the observed declines in mortality with valve replacement could not be attributed to declines in mortality solely for this subgroup of patients. On the contrary, the observed declines in mortality were as large for those undergoing isolated valve replacement as for those undergoing concomitant revascularization.

It is important to consider both the strengths and limitations of our study. The strengths of our study include prospective data collection on a regional level such that biases in the collection of data or selection of study participants should not be limitations. Our study had adequate power to detect the observed trends due to the large size of the population included. In addition, our data registry contained detailed information from which to base risk-adjustment models. These models were well calibrated and had reasonable performance characteristics, so confounding by patient casemix should also not be a serious concern. Although some residual confounding from unmeasured or inaccurately recorded variables is likely, it is implausible that differences of the magnitude noted herein are completely explained by this cause. For residual confounding to be responsible for the entire effect observed, the confounder(s) would have to be strong predictors of outcome, substantially uncorrelated with known predictors that were considered, and distributed unequally over time.

Although our study can exclude many potential explanations for the observed reductions in mortality, including chance, bias, and confounding, its main limitation is its inability to prove what factors do account for them. In our region, a study of causes of death with CABG concluded that 80% of the difference between surgeons with higher (average 5.8%) and lower (average 3.2%) mortality rates was attributable to postoperative heart failure despite virtually identical preoperative patient characteristics among these groups [17]. With this knowledge, our group is now undertaking a focused quality improvement project to develop and implement specific clinical interventions to reduce both the incidence and case-fatality rate of heart failure associated with CABG. Similar analyses are planned for valve patients but we do not have information regarding cause of death for the patients included in this dataset.

In conclusion, substantial declines in in-hospital mortality with valve operation were observed in northern New England during this time period. These trends could not be explained by changes in patient casemix over the time period or to reductions in mortality within certain subgroups of patients. Our data do not permit definitive conclusions about the causes of this improvement. Additional studies are needed to understand whether these trends in mortality with valve operation have been observed outside our region and whether they are the result of both general improvements in cardiac surgical care or specific quality improvement efforts.

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