Valvular Heart Disease

Long-Term Survival of Patients Undergoing Mitral Valve Repair and Replacement
A Longitudinal Analysis of Medicare Fee-for-Service Beneficiaries

Christina M. Vassileva, MD; Gregory Mishkel, MD; Christian McNeely, BS; Theresa Boley, MSN; Stephen Markwell, MA; Steven Scaife, MS; Stephen Hazelrigg, MD

Background—Despite the established superiority of mitral repair over replacement, its adoption in the treatment of elderly patients has not been uniform, partly because of a lack of robust long-term survival data. We present the long-term survival of Medicare fee-for-service beneficiaries undergoing mitral valve repair and replacement over a 10-year period.

Methods and Results—We used the Medicare database to identify 47,279 fee-for-service beneficiaries ≥65 years of age undergoing primary isolated mitral valve repair or replacement from 2000 to 2009. Operative mortality and long-term survival are presented for repair and replacement. Operative mortality was 3.9% for patients undergoing repair and 8.9% for patients undergoing replacement. The 1-, 5-, and 10-year Kaplan-Meier survival estimates for patients undergoing repair were 90.9%, 77.1%, and 53.6%. The 1-, 5-, and 10-year Kaplan-Meier survival estimates for patients undergoing replacement were 82.6%, 64.7%, and 37.2%. Important predictors of mitral repair included younger age (odds ratio, 1.10; 95% confidence interval, 1.05–1.14), elective admission status (odds ratio, 1.34; 95% confidence interval, 1.27–1.41), and annual mitral procedure volume >40 cases per year (odds ratio, 1.57; 95% confidence interval, 1.36–1.81). Female sex and the presence of comorbidities were associated with a lower likelihood of repair.

Conclusions—Mitral valve surgery in the Medicare population carries less risk than previously reported. Given the favorable outcomes of elderly patients undergoing mitral valve surgery, especially mitral valve repair, an approach of earlier identification and surgical referral appears justified regardless of age. (Circulation. 2013;127:1870-1876.)

Key Words: aged • outcomes research • mitral valve • surgery • valve repair

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DOI: 10.1161/CIRCULATIONAHA.113.002200

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Received October 11, 2012; accepted March 12, 2013.
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1870
Study Population and Data Variables

All Medicare beneficiaries 265 years of age undergoing mitral valve repair (International Classification of Disease, Ninth Revision [ICD-9-CM] codes 35.12 and replacement [35.23 or 35.24] from 2000 through 2009 were considered for inclusion (Figure 1). Patients were excluded if they had concomitant coronary artery bypass grafting (ICD-9-CM codes 35.11, 35.21, 35.13, 35.25, 35.26, 35.10, 35.20); closed heart valvuloplasty (ICD-9-CM codes 35.21, 35.22, 35.25, 35.26, 35.10, 35.20); other valvular repair or replacement except tricuspid (ICD-9-CM code 35.11, 35.21, 35.22, 35.13, 35.25, 35.26, 35.10, 35.20); other valvular repair or replacement except tricuspid (ICD-9-CM codes 35.11, 35.21, 35.22, 35.13, 35.25, 35.26, 35.10, 35.20); closed heart valvuloplasty (ICD-9-CM code 35.11, 35.23, 35.24) from 2000 – 2009 were considered for inclusion (Figure 1). Patients were excluded if they did not have 12 months of Medicare Part A and Part B coverage in the year preceding their index admission. In addition, patients who at any point in the year before their index admission had a period of enrollment under a Medicare managed plan were also excluded from the analysis. Demographic and comorbidity data were obtained from the Medicare Provider Analysis and Review files. Comorbidities were determined using the ICD-9-CM diagnostic codes from both the index admission and any hospitalizations during the 12-month period before the index admission.

Outcomes

The study end points were operative mortality and long-term survival. Operative mortality was defined as hospital mortality or 30-day mortality, whichever was longer. For example, if a patient was discharged from the hospital on postoperative day 7 and died on postoperative day 28, the death would be counted as operative mortality. Similarly, a patient who died in the hospital on postoperative day 45 without having been discharged from the hospital would be counted as an operative mortality. Long-term survival was calculated using data from the Vital Status File and reflects all-cause mortality. Long-term survival was then compared with survival estimates for the age- and sex-matched general population in the United States.

A secondary endpoint of the study was to identify predictors of mitral valve repair with baseline characteristics, admission status, and hospital volume, used as covariates. Individual surgeon volumes were not available within the limitations of the Medicare database. Hospitals were divided into high-volume (>40 cases per year) and low-volume (≤40 cases per year) centers on the basis of their annual mitral procedure volume.
Statistical Analysis
All results are reported as median and interquartile range or percentages as appropriate. Postsurgery survival time was computed using the Vital Status File from the Centers for Medicare and Medicaid Services. Kaplan-Meier estimates were used to generate survival curves for patients undergoing mitral valve repair and those undergoing mitral valve replacement. All analyses were performed with SAS version 9.2 (SAS Institute Inc, Cary, NC). Expected mortality rates were calculated using the National Vital Statistics Reports (2007) from the Centers for Disease Control and Prevention. These rates reflect the expected mortality, based on the US population, within our patient subsets when adjusted for age and sex distribution. For the predictors of mitral repair analysis, a hierarchical logistic regression model was fit with hospital provider number as a random effect to control for the clustering of patients within hospitals. A backward elimination approach was used to identify a subset of variables that were independently predictive of undergoing repair.

The study was approved by the Institutional Review Board, which waived the requirement for informed consent. Because the files used for this study are considered Research Identifiable Files and contain patient-specific information, beneficiary confidentiality data were protected through a rigorous data use agreement with the Centers for Medicare and Medicaid Services.

Results

Patient Characteristics
The study population included a total of 47,279 patients, of whom 17,360 (36.7%) underwent mitral valve repair and 29,919 (63.3%) underwent mitral valve replacement. Median age was 75 years. It is noteworthy that the majority of our cohort (58.6%) were patients in their 70s, and octogenarians and nonagenarians made up an additional 23% of the patient cohort. Women represented 60.6% of the study cohort, and 91.9% of the cohort were white. The cohort was characterized by a relatively high burden of comorbid conditions, including heart failure in 60.4%, renal insufficiency (including end-stage renal disease) in 17.5%, chronic obstructive pulmonary disease in 17.6%, and atrial fibrillation in 48.5% of the patients. The baseline characteristics of patients undergoing repair and replacement are presented in Tables 1 and 2, respectively. In general, patients who underwent replacement had a higher prevalence of heart failure, renal insufficiency, chronic obstructive pulmonary disease, atrial fibrillation, anemia, and nonelective admission.

Operative Mortality
Operative mortality for these elderly patients undergoing mitral valve surgery was 7.1% overall. Operative mortality for patient undergoing repair was 3.9%. For patients who underwent replacement, operative mortality was 8.9%.

Long-term Survival
Long-term survival data are presented in Figure 2. Median length of follow-up across all patients was 5 years. The 1-, 5-, and 10-year Kaplan-Meier survival estimates for patients undergoing repair were 90.9%, 77.1%, and 53.6%, respectively. Survival estimates at 1, 5, and 10 years for patients undergoing replacement were 82.6%, 64.7%, and 37.2%, respectively. Survival estimates at 1, 5, and 10 years for patients undergoing repair had 1-, 5-, and 10-year Kaplan-Meier survival estimates of 93.6%, 83.3%, and 66.4% compared with 88.1%, 70.7%, and 40.3% for those ≥75 years of age, respectively (Figure 3A). Survival estimates for patients <75 years of age undergoing replacement were 85.9%, 70.7%, and 47.4% at 1, 5, and 10 years, respectively, compared with 79.7%, 59.5%, and 28.1% for those ≥75 years of age (Figure 3B).

Predictors of Mitral Valve Repair
Not surprisingly, as seen in Table 3, the presence of comorbidities predicted lower likelihood of mitral valve repair. Women were less likely to undergo repair (odds ratio, 0.63; 95% confidence interval, 0.61–0.66; \( P=0.0001 \)). Younger age (odds ratio, 1.10; 95% confidence interval, 1.05–1.14; \( P=0.0001 \)) and elective admission status (odds ratio, 1.34; 95% confidence interval, 1.27–1.41; \( P=0.0001 \)) predicted a higher likelihood of mitral valve repair. The strongest predictor of mitral repair in this model was annual mitral procedure volume >40 cases per year (odds ratio, 1.57; 95% confidence interval, 1.36–1.81; \( P=0.0001 \)).

Discussion
The Medicare database has been used extensively in the recent past to study cardiovascular outcomes and for quality assessment and improvement efforts. With the enhanced longevity of the US population and the cost implications of potentially expensive interventions, the outcomes of elderly patients undergoing contemporary cardiac surgery merit greater scrutiny.

Within the cardiology and cardiac surgery community, there is an ongoing debate on the treatment of the elderly with mitral valve disease. Indeed, current guidelines favor a tempered medical approach based on a perceived high surgical mortality in the elderly. The overall operative mortality of our patient cohort, consisting of 58.6% of
patients in their 70s and an additional 23% who were ≥80 years of age, was 7.1%. This mortality is substantially lower than that reported in the ACC/AHA guidelines for the elderly of 14% to 20%. Moreover, our reported mortality is based on a more contemporary series than that cited in the most recent guidelines. Furthermore, this study demonstrates a much lower operative mortality for patients who underwent repair (3.9%) compared with those who underwent replacement (8.9%). Although we have avoided a direct comparison between mitral repair and replacement because we did not feel we could properly account for the variety of biases in an administrative data source, our data demonstrate that in those patients who are offered repair, outcomes are excellent. Even in patients ≥75 years of age, the operative mortality of 5.1% for repair and 10.6% for replacement supports a surgical approach as reasonable.

**Table 2. Mitral Valve Replacement Patient Characteristics (n=29919)**

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, median (interquartile range), y</td>
<td>75 (71–79)</td>
</tr>
<tr>
<td>Age 65–74 y, %</td>
<td>46.2</td>
</tr>
<tr>
<td>Age ≥75 y, %</td>
<td>53.8</td>
</tr>
<tr>
<td>White, %</td>
<td>91.5</td>
</tr>
<tr>
<td>Female, %</td>
<td>65.2</td>
</tr>
<tr>
<td>Hypertension, %</td>
<td>51.5</td>
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<tr>
<td>Diabetes mellitus, %</td>
<td>16.7</td>
</tr>
<tr>
<td>Peripheral vascular disease, %</td>
<td>2.9</td>
</tr>
<tr>
<td>Stroke/transient ischemic attack, %</td>
<td>8.8</td>
</tr>
<tr>
<td>Heart failure, %</td>
<td>64.9</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease, %</td>
<td>19.7</td>
</tr>
<tr>
<td>History of respiratory failure, %</td>
<td>11.5</td>
</tr>
<tr>
<td>Renal failure, %</td>
<td>19.6</td>
</tr>
<tr>
<td>End-stage renal disease, %</td>
<td>1.5</td>
</tr>
<tr>
<td>Atrial fibrillation, %</td>
<td>53.0</td>
</tr>
<tr>
<td>Anemia, %</td>
<td>17.4</td>
</tr>
<tr>
<td>Urgent admission status, %</td>
<td>54.5</td>
</tr>
</tbody>
</table>

Long-term survival data reports have come from a limited number of high-volume centers and have typically focused on younger patients, that is, those in their 60s. We provide the most short- and long-term survival data for mitral valve repair and replacement in an elderly patient population consisting of Medicare fee-for-service beneficiaries undergoing mitral valve surgery over a 10-year period in the United States. Compared with survival estimates for the age- and sex-matched general population in the United States, patients who underwent repair appear to have similar life expectancy, even in the cohort of patients ≥75 years of age.

The overall repair rate for our patient subset was 36.7%. This is substantially lower than what has been reported in series of all-comers in which the mean age of patients is typically in the 60s. Our findings reflect the reality of current clinical practice in which elderly patients are more likely to receive mitral replacement compared with their younger counterparts. Indeed, younger age was an important predictor of mitral valve repair in our data set. Other predictors of lower likelihood of repair included the presence of a variety of comorbidities. Comorbidities increase with age, which may partly explain the lower repair rates in the elderly. Female sex has been previously found to be an independent predictor of lower likelihood of mitral valve repair. Because women live longer than men, their over-representation in the elderly subset may offer an additional explanation of the observed lower repair rates in the elderly. These observations offer no explanation of the underlying reason for the findings. It is unlikely that an administrative data source can shed further on this issue; it can merely describe its presence.

Previous studies have examined the relationship between hospital volume and likelihood of mitral valve repair. Within our data set, hospital annual mitral valve volume of >40 cases per year predicted a higher likelihood of mitral valve repair and, in fact, was the strongest predictor of repair of the covariates examined (odds ratio, 1.57; 95% confidence interval, 1.36–1.81). Within the limitations of the Medicare database, important covariates that we were not able to examine included ventricular function, valve morphology, and individual surgeon volume.
Our study identifies a couple of areas that could be the focus of future improvement efforts in the care of patients with mitral valve disease. First and foremost is the recognition by both the surgical and cardiology communities that age alone should not preclude a surgical assessment and/or consideration of mitral repair. Second, although practice guidelines have become an important tool to standardize care, it appears that deviations often occur when it comes to the evaluation and treatment of MR in the elderly.

Current guidelines strongly recommend referral to mitral valve surgery in symptomatic patients, preferably before the onset of left ventricular dysfunction and congestive heart failure. Sixty percent of the patients in this Medicare database had heart failure identified as a diagnosis in a hospital admission in the year preceding their operation, an evident delay in referral to intervention. The limitations of an administrative data base preclude definitively linking a heart failure diagnosis with a mitral valve etiology; however, our strict exclusion criteria, removing patients with other valve disease (except tricuspid), previous cardiac surgery, concomitant coronary artery bypass grafting, and a history of previous myocardial infarction, offer a robust data set and make it less likely that heart failure would be caused by something other than mitral valve disease. Given the favorable outcomes of elderly patients undergoing mitral valve surgery, especially mitral valve repair, our data support an approach of earlier identification and surgical referral as appropriate.

Table 3. Predictors of Mitral Valve Repair

<table>
<thead>
<tr>
<th>Variable</th>
<th>Odds Ratio</th>
<th>95% Confidence Interval</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age &lt;75 y</td>
<td>1.10</td>
<td>1.05–1.14</td>
<td>0.0001</td>
</tr>
<tr>
<td>Female sex</td>
<td>0.63</td>
<td>0.61–0.66</td>
<td>0.0001</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1.23</td>
<td>1.18–1.28</td>
<td>0.0001</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>0.80</td>
<td>0.76–0.85</td>
<td>0.0001</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>0.81</td>
<td>0.71–0.92</td>
<td>0.0012</td>
</tr>
<tr>
<td>Stroke/transient ischemic attack</td>
<td>0.80</td>
<td>0.74–0.87</td>
<td>0.0001</td>
</tr>
<tr>
<td>Heart failure</td>
<td>0.78</td>
<td>0.74–0.81</td>
<td>0.0001</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease</td>
<td>0.78</td>
<td>0.74–0.83</td>
<td>0.0001</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>0.80</td>
<td>0.74–0.86</td>
<td>0.0001</td>
</tr>
<tr>
<td>Renal failure</td>
<td>0.80</td>
<td>0.75–0.85</td>
<td>0.0001</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>0.79</td>
<td>0.75–0.83</td>
<td>0.0001</td>
</tr>
<tr>
<td>Anemia</td>
<td>0.93</td>
<td>0.88–0.99</td>
<td>0.0146</td>
</tr>
<tr>
<td>Elective admission</td>
<td>1.34</td>
<td>1.27–1.41</td>
<td>0.0001</td>
</tr>
<tr>
<td>Hospital annual mitral volume</td>
<td>1.57</td>
<td>1.36–1.81</td>
<td>0.0001</td>
</tr>
</tbody>
</table>
Our findings are in agreement with those of others, who have similarly found delay in referral to mitral valve surgery and frequent deviation from established practice guidelines, especially in the elderly. In a survey of the determinants of referral to cardiac surgery in patients with MR, Toledano et al. found that deviation from published guidelines was most notable for asymptomatic patients with severe MR and mild left ventricular dysfunction (ejection fraction, 50%–60%). Despite a Class I indication to consider a surgical evaluation, only 57% of cardiologists responded that they would refer the patient to surgery. Surgery often is not considered even in symptomatic patients. In the EuroHeart Study, 49% of symptomatic patients with severe MR did not receive a surgical evaluation. In multivariate analysis, older age was 1 of the 5 characteristics strongly associated with a decision not to operate on a patient with MR. Age, either singly or in combination, was specifically cited as a reason not to refer for surgical evaluation in 28% of the cases. Furthermore, in patients with severe MR who were in the 70- to 80-year age group, surgery was thought to be inadvisable by their primary cardiologist 58% of the time.

Although the Medicare database is an administrative database designed to gather data for billing purposes, it has been validated as a useful source of information to study cardiovascular outcomes and to generate models for quality-of-care initiatives. A major strength of our study is the inclusion of all varieties of hospitals and care delivery under Medicare, increasing the generalizability of our results. However, this type of study has several limitations. Although our analysis of Medicare fee-for-service beneficiaries was based on a large number of patients, the results cannot be extrapolated to those who did not meet our inclusion criteria. Specifically, those in Medicare managed care plans; elderly without Medicare coverage; those with previous cardiac surgery, concomitant coronary artery bypass grafting, and other valve surgery (except tricuspid); patients with a history of myocardial infarction; and patients with emergent status were excluded.

A major limitation of any administrative database is the lack of detailed intraoperative information. The procedure selection (mitral repair versus replacement) may have been influenced by a variety of confounding variable and biases inherent to an administrative database. These factors limited our ability to directly compare mitral repair and replacement. In addition, although we attempted to identify predictors of mitral repair from a variety of covariates, including baseline characteristics, admission status, and hospital volume, the influence of surgeon bias is unaccounted for in this analysis. Therefore, the Medicare database does not provide longitudinal echocardiographic follow-up, the impact of mitral repair durability on long-term survival could not be examined with this data source.

Conclusions

Our large-scale analysis of 47,279 Medicare fee-for-service beneficiaries who underwent primary isolated mitral valve repair or replacement from 2000 to 2009 supports mitral valve surgery as a feasible treatment in the elderly who present with MR. Current guidelines that favor medical management of elderly asymptomatic or mildly symptomatic patients were based on literature in which the risks of mitral valve surgery now seem overstated, especially with respect to isolated primary mitral valve operations. Although we cannot definitively conclude that mitral repair offers a significant survival advantage in the elderly within the limitations of this administrative database, those elderly patients who received mitral valve repair have near-normal life expectancy after surgery, and every attempt should be made to perform mitral valve repair over replacement unless clinically contraindicated.

Source of Funding

This study was supported by the Division of Cardiothoracic Surgery, Southern Illinois University School of Medicine.

Disclosures

None.

References

CLINICAL PERSPECTIVE

Despite the established superiority of mitral repair over replacement, its adoption in the treatment of elderly patients has not been uniform. Whereas American College of Cardiology/American Heart Association (ACC/AHA) guidelines recommend early surgery for mitral regurgitation in the “nonelderly,” special consideration is urged for the “elderly,” that they be treated medically unless severely symptomatic. These guideline recommendations stem from older studies citing operative mortality rates of 14% to 20%. Our article provides a timely update on the outcomes of 47,279 elderly patients (median age, 75 years) undergoing mitral valve surgery. Operative mortality was 7.1%, which is substantially lower than that reported in the ACC/AHA guidelines for the elderly. Furthermore, operative mortality for patients who underwent repair was 3.9% compared with 8.9% for replacement. Patients who underwent repair appear to have a life expectancy similar to that of the age- and sex-matched US population, even in the cohort ≥75 years of age. Current guidelines strongly recommend referral to mitral valve surgery in symptomatic patients, preferably before the onset of left ventricular dysfunction and congestive heart failure. It appears that deviations often occur in the evaluation and treatment of mitral regurgitation in the elderly. In this cohort, 60% of patients had a prior diagnosis of heart failure, an evident delay in referral to intervention. Given the favorable outcomes of elderly patients undergoing mitral valve surgery, especially mitral valve repair, an approach of earlier identification and surgical referral appears justified regardless of age. These findings have relevance both to cardiologists treating mitral valve disease and potentially to the generation of new guideline recommendations.

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_Circulation_. 2013;127:1870-1876; originally published online April 8, 2013; doi: 10.1161/CIRCULATIONAHA.113.002200
_Circulation_ is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 0009-7322. Online ISSN: 1524-4539

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