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

Running title: Vassileva et al.; Long term survival of MV surgery in the elderly

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Abstract:

**Background**—Despite the established superiority of mitral repair over replacement, its adoption in the treatment of elderly patients has not been uniform, partly due to 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 ten year period.

**Methods and Results**—We used the Medicare database to identify 47,279 fee-for-service beneficiaries age ≥ 65 undergoing primary isolated mitral valve repair or replacement from 2000-2009. 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. One, 5 and 10 year Kaplan-Meier survival estimates for patients undergoing repair were 90.9%, 77.1%, and 53.6%. One, 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 [OR 1.10, 95%CI 1.05-1.14], elective admission status [OR 1.34, 95%CI 1.27-1.41] and annual mitral procedure volume greater than 40 [OR 1.57, 95%CI 1.36-1.81]. Female gender and the presence of comorbidities were associated with 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, and especially mitral valve repair, an approach of earlier identification and surgical referral appears justified regardless of age.

**Key words:** elderly, Medicare, mitral valve, outcomes research, survival
Introduction

Contemporary advances in mitral valve surgery for mitral regurgitation (MR) have led to lower mortality, decreased morbidity, and increased utilization of mitral valve repair (MVP). However, the outcomes for elderly patients undergoing mitral valve (MV) surgery are generally worse than younger patients. Whereas ACC/AHA guidelines recommend early surgical treatment of MR in the "nonelderly" regardless of symptoms, special consideration is urged for the “elderly”, that they be treated medically unless severely symptomatic. The evidence base for these guideline recommendations stems from studies which predate the timeframe of the current Medicare review and cite operative mortality of 14-20%. Moreover, operative mortality in excess of 20% was cited for low volume centers using older data from 1994 to 1999 in the Medicare population.

Few studies have specifically examined the long term survival for mitral valve surgery in the elderly patient population. With this investigation, we present the largest contemporary series on the operative mortality and the long term survival of Medicare fee-for-service beneficiaries undergoing primary isolated mitral valve repair and replacement over a ten year period.

Methods

Data sources

We obtained the Medicare Provider Analysis and Review (MEDPAR) Files and corresponding Beneficiary Annual Summary Files (BASF) from 1999 through 2009 from the Center for Medicare and Medicaid Services. The MEDPAR files contain institutional claims for inpatient services covered under Part A. The BASF files contain information on patient demographics, eligibility, enrollment, summarized service utilization and payment, and chronic condition flags for eligible beneficiaries. The current Vital Status File, through February 2012, was used to
provide the most recent death information for the study cohort.

Study Population and Data Variables

All Medicare beneficiaries ≥ 65 years of age undergoing mitral valve repair (ICD-9 code 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 (CABG) (ICD-9-CM codes 36.11, 36.12, 36.13, 36.14, 36.15), 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 codes 35.00, 35.01, 35.02, 35.03, 35.04), surgery for congenital anomalies (ICD-9-CM code 35.8, 35.4, 35.53, 35.54, 35.62, 35.63, 35.9, 39.0, 39.21), heart transplant (37.51), awaiting organ transplant status (V49.83) or history of heart transplant (V42.1), history of surgery to heart and great vessels (V15.1), history of valve replacement (V42.2 and 43.3), history of CABG (V45.81), history of acute MI (ICD-9-CM codes 410.00, 410.01, 410.02, 410.10, 410.11, 410.12, 410.20, 410.21, 410.22, 410.30, 410.31, 410.32, 410.40, 410.41, 410.42, 410.50, 410.51, 410.52, 410.60, 410.61, 410.62, 410.70, 410.71, 410.72, 410.80, 410.81, 410.82, 410.90, 410.91, 410.92, 411.0, 412), left ventricular, right ventricular or biventricular circulatory support implantation or removal (ICD-9-CM codes 37.52, 37.60, 37.62, 36.64, 37.65, 37.66, 37.68, 39.65, 39.66), implantation of external cardiac support device (ICD-9-CM code 37.41), history of ventricular assist device (VAD) or artificial heart (V43.21 and V43.22), excision of ventricular aneurysm (ICD-9-CM codes 37.32 and 37.35, 37.49), replacement of thoracic aorta (ICD-9-CM code 38.45), aortic fenestration (39.54), concomitant carotid endarterectomy (same hospitalization) (ICD-9-CM code 38.12), unspecified valve repair (ICD-9-CM code 35.10) and unspecified valve replacement (ICD-9-CM code 35.20). Patients with missing gender information, Medicare status codes 20 (disabled without ESRD),
21 (disabled with ESRD), and 31 (ESRD only, not aged), and emergent admission status, as well as those who were recorded as having had mitral valve repair (MVP) and replacement (MVR) during the same hospital stay, were also excluded from the analysis.

The first hospitalization documenting a mitral valve repair or replacement during the 10-year period from 2000 through 2009 was identified as the ‘index’ admission. 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 prior to their index admission had a period of enrolment under a Medicare managed plan were also excluded from the analysis. Demographic and comorbidity data were obtained from the MEDPAR file. 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 endpoints were operative mortality and long term survival. Operative mortality (OM) was defined as hospital mortality or 30-day mortality whichever was longer. For example, if a patient was discharged from the hospital on the 7th postoperative day (POD) and died on POD # 28, the death would be counted as OM. Similarly, a patient who died in the hospital on POD # 45, without having been discharged from the hospital, would also be counted as an OM. Long term survival was calculated using data from the Vital Status File and reflects all-cause mortality. Comparison of long term survival was then made to survival estimates for the age- and gender-matched general population in the United States.

A secondary endpoint of the study was to identify predictors of mitral valve repair, using baseline characteristics, admission status and hospital volume as covariates. Within the limitations of the Medicare database, individual surgeon volumes were not available. Hospitals
were divided into high volume (> 40 cases/year) and low volume (≤ 40 cases/year) centers based on their annual mitral procedure volume⁷.

**Statistical analysis**

All results are reported as median and inter-quartile range (IQR) or percentages as appropriate. Post-surgery survival time was computed using the Vital Status File from CMS. Kaplan-Meier (KM) estimates were used to generate survival curves for patients undergoing MVP and patients undergoing MVR. All analyses were performed using SAS v 9.2 (SAS Institute Inc., Cary, NC, USA). Expected mortality rates were calculated using the National Vital Statistics Reports (2007) from the Centers for Disease Control and Prevention⁶. These rates reflect the expected mortality, based on the US population, within our patient subsets when adjusting for age and gender 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 was protected through a rigorous data use agreement with CMS.

**Results**

**Patient characteristics**

The study population included a total of 47,279 patients, of which 17,360 (36.7%) underwent MVP and 29,919 (63.3%) underwent MVR. Median age was 75 years. It is noteworthy to point
out that the majority of our cohort (58.6%) was comprised of patients in their 70s, while octogenarians and nonagenarians comprised an additional 23% of the patient cohort. Females represented 60.6% of the study cohort and 91.9% were white. The cohort was characterized by a relatively high burden of comorbid conditions, including heart failure in 60.4%, renal insufficiency (including ESRD) in 17.5%, COPD 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 higher prevalence of heart failure, renal insufficiency, COPD, atrial fibrillation, anemia and non-elective 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. One, five and ten year KM survival estimates for patients undergoing repair were 90.9%, 77.1%, and 53.6%. Survival estimates at one, five and ten years for patients undergoing replacement were 82.6%, 64.7%, and 37.2%.

Following stratification by age, patients <75 years of age undergoing repair had 1,5 and 10 year KM survival estimates of 93.6%, 83.3%, and 66.4%, compared to 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 to 79.7%, 59.5% and 28.1%, for those ≥ 75 years of age (Figure 3b).
Predictors of mitral valve repair

Not surprisingly, as seen from Table 3, the presence of comorbidities predicted lower likelihood of mitral valve repair. Females were less likely to undergo repair [OR 0.63, 95%CI 0.61-0.66, p=0.0001]. Younger age [OR 1.10, 95%CI 1.05-1.14, p=0.0001] and elective admission status [OR 1.34, 95%CI 1.27-1.41, p=0.0001] predicted higher likelihood of mitral valve repair. The strongest predictor of mitral repair in this model was annual mitral procedure volume greater than 40 cases/year [OR 1.57, 95%CI 1.36-1.81, p=0.0001].

Discussion

The Medicare database has been extensively used in the recent past to study cardiovascular outcomes, as well as for quality assessment and improvement efforts [8-10]. 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 merits greater scrutiny.

An ongoing debate within the cardiology and cardiac surgery community exists regarding the treatment of the elderly with mitral valve disease. Indeed, the 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% > 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 to those who underwent replacement (8.9%). While we have
avoided a direct comparison between mitral repair and replacement because we did not feel we can 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 or older, the operative mortality of 5.1% for repair and 10.6% for replacement supports a surgical approach as reasonable.

Long term survival data reports have come from a limited number of high volume centers and have typically focused on younger patients, i.e. those in their sixties\textsuperscript{11,12}. We provide the largest 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 ten year period in the US. When compared to survival estimates for the age and gender matched general population in the United States, patients who underwent repair appear to have similar life expectancy, even in the cohort of patients $\geq 75$ 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 to 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. As comorbidities increase with age, this may partly explain the lower repair rates in the elderly. Female gender has been previously found to be an independent predictor of lower likelihood of mitral valve repair\textsuperscript{13}. As women live longer than men, their overrepresentation 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 light into 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 dataset, hospital annual mitral volume of greater than 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 [OR1.57, 95% CI 1.36-1.81]. Within the limitations of the Medicare database, important covariates 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 that age should not preclude consideration of mitral repair Second, while 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 mitral regurgitation in the elderly.

Current guidelines strongly recommend referral to mitral valve surgery in symptomatic patients, preferably before the onset of LV 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. Within the limitations of an administrative database, we cannot definitively link the heart failure diagnosis to the mitral valve etiology; however, our strict exclusion criteria, removing patients with other valve disease (except tricuspid), previous cardiac surgery, concomitant CABG, as well as a history of previous MI, offers a robust dataset and make it less likely that heart failure would be of etiology other than mitral valve disease. Given the favorable outcomes of elderly patients undergoing mitral valve surgery, and especially mitral valve repair,
our data support an approach of earlier identification and surgical referral as appropriate.

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 on the determinants of referral to cardiac surgery in patients with mitral regurgitation, Toledano et al found that deviation from published guidelines was most notable for asymptomatic patients with severe MR and mild LV dysfunction (EF of 50-60%)14. Despite a Class I indication to consider a surgical evaluation, only 57% of cardiologists responded that they would refer the patient to surgery2,14. Even in symptomatic patients surgery is often not considered. In the Euro Heart Study, 49% of symptomatic patients with severe MR did not receive a surgical evaluation15. In multivariate analysis, older age was one of the five characteristics strongly associated with a decision not to operate on a patient with MR15. 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 70-80 age group, surgery was felt 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 generate models for quality of care initiatives8,9. 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 managed care plans, elderly without Medicare coverage, previous cardiac surgery, concomitant CABG, other
valve surgery (except tricuspid), as well as patients with history of MI, and 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. Because 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.

In conclusion, our large scale analysis of 47,279 Medicare fee-for-service beneficiaries who underwent primary isolated mitral valve repair or replacement from 2000-2009 supports mitral valve surgery as a feasible treatment in the elderly who present with mitral regurgitation. Current guidelines which 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.

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Conflict of Interest Disclosures: None.

References:


**Table 1. Mitral valve repair patient characteristics.**

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<td>Age – ≥ 75</td>
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*percents reported unless otherwise stated
Table 2. Mitral valve replacement patient characteristics

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<td>Age – ≥ 75</td>
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*perecents reported unless otherwise stated

Table 3. Predictors of mitral valve repair

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<th>p-value</th>
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<td>0.61-0.66</td>
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<td>Hypertension</td>
<td>1.23</td>
<td>1.18-1.28</td>
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<td>Diabetes</td>
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<td>PVD</td>
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<td>0.74-0.87</td>
<td>0.0001</td>
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<td>Heart failure</td>
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<td>0.74-0.81</td>
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<td>COPD</td>
<td>0.78</td>
<td>0.74-0.83</td>
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<td>Respiratory failure</td>
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<td>0.75-0.83</td>
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<td>1.36-1.81</td>
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Figure Legends:

Figure 1. Flowchart of patient inclusion and exclusion criteria.

Figure 2. Ten year survival for Medicare fee-for service beneficiaries undergoing mitral valve repair and replacement from 2000 through 2009 compared to expected survival in the age and gender matched United States population.

Figure 3. A) Ten year survival for Medicare fee-for service beneficiaries undergoing mitral valve repair from 2000 through 2009 stratified by age and compared to expected survival in the age and gender matched United States population. B) Ten year survival for Medicare fee-for service beneficiaries age 75 and older undergoing mitral valve replacement from 2000 through 2009 stratified by age and compared to expected survival in the age and gender matched United States population.
All patients who had 35.12, 35.23, and 35.24 between 2000 – 2009
n=183,792

Excluding those with one or more of the exclusion criteria (n=126,130)

Patients remaining following application of exclusion criteria
n=57,662

Excluding those with < 12mo Part A&B or any HMO in the prior year (n=10,383)

Final sample for analysis
n=47,279

Patients undergoing MV Repair
n=17,360

Patients undergoing MV Replacement
n=29,919

Figure 1
Figure 2A

Survival following mitral valve surgery

Cumulative proportion surviving

Years post surgery

- Repair
- Replacement
- Expected
Survival following mitral valve repair by age

Cumulative proportion surviving

Years post surgery

- Repair < 75
- Expected < 75
- Repair ≥ 75
- Expected ≥ 75

Figure 2B
Survival following mitral valve replacement by age

Cumulative proportion surviving

Years post surgery

- Replacement < 75
- Expected < 75
- Replacement ≥ 75
- Expected ≥ 75

Figure 3
Long Term Survival of Patients Undergoing Mitral Valve Repair and Replacement: A Longitudinal Analysis of Medicare Fee-for-Service Beneficiaries
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