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Multicenter Evaluation of High-Risk Mitral Valve Operations: Implications for Novel Transcatheter Valve Therapies

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Abstract

Background—The MitraClip REALISM (Abbott Vascular, Menlo Park, CA) trial included several inclusion criteria to identify patients at high risk for conventional mitral valve (MV) surgery. This study evaluated contemporary surgical outcomes for high-risk surgical patients who met these defined criteria to serve as a benchmark to evaluate appropriateness in treatment allocation between surgical and percutaneous MV repair.

Methods—A statewide Society for Thoracic Surgeons (STS) database was queried for patients undergoing isolated mitral valve surgery over a 12-year study period from 17 different hospitals. Patients were stratified into high-risk (HR) versus non-high-risk (non-HR) cohorts based upon clinical criteria similar to those utilized in the REALISM trial. Mixed effects multivariable regression modeling was used to evaluate study endpoints including mortality, morbidity, and resource utilization.

Results—Of 2,440 isolated mitral operations, 29% ($n = 698$) were HR per REALISM criteria. Median STS Predicted Risk of Mortality (PROM) for HR patients was 6.6% compared with 1.6% for non-HR patients ($p < 0.001$). The HR patients more commonly underwent MV replacement as well as urgent (30% vs 19%, $p < 0.001$) operations. High-risk patients incurred higher morbidity and mortality (7% vs 1.6%) with longer intensive care unit (48 vs 41 hours) and hospital stays (7 vs 6 days, all $p < 0.001$). Among REALISM criteria, STS PROM 12% or greater and high-risk STS criteria were the only criteria associated with mortality.

Conclusions—Select REALISM criteria, including reoperation with patent grafts and functional MR with ejection fraction less than 0.40, may not identify patients truly at high risk of death with surgery. In addition to conventional STS criteria, risk assessment by surgeons is essential to direct appropriate treatment allocation for high-risk mitral disease.

Mitral valve (MV) surgery remains the gold standard treatment for severe mitral regurgitation (3 to 4+). The clear benefit of MV surgery over medical management for severe mitral regurgitation (MR) is reflected in current guidelines published by both the joint

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American College of Cardiology/American Heart Association (ACC/AHA) as well as the European Society of Cardiology [1, 2]. Despite these benefits, only 50% of patients meeting ACC/AHA guidelines for surgical treatment undergo surgery due to inadequate education and counseling or misperceptions of excessively high risk associated with surgery [3, 4].

During the past decade, significant improvements in technology have led to the development of percutaneous catheter-based MV repair. The MitraClip (Abbott Vascular, Menlo Park, CA) edge-to-edge repair device is the only percutaneous MV repair system currently available. This device has been evaluated in head-to-head evaluations with surgical MV repair. The EVEREST [Endovascular Valve Edge-to-Edge Repair] II trial established the safety for MitraClip compared with conventional MV surgery [5]. However, analyses have also demonstrated that MV surgery provides superior MR reduction compared with MitraClip [6–10]. The recently published REALISM trial investigated patients with severe MR deemed “high risk” for surgery using several prespecified inclusion criteria [11]. Results from this trial ultimately led to recent commercial approval of MitraClip for degenerative MR who are deemed “too high risk” for surgery [12]. Considering that many centers have demonstrated excellent outcomes for MV surgery in high-risk patients, the exact criteria used to identify truly “high-risk” patients for surgery as a referral source for percutaneous alternatives remains unclear.

The purpose of this study was twofold: (1) to evaluate contemporary surgical outcomes for high-risk patients undergoing MV repair or replacement to serve as a clinical benchmark; and (2) to evaluate the appropriateness of high-risk clinical criteria used in REALISM to determine treatment allocation and recommendations for patients with severe MR. We hypothesized that several of the high-risk criteria utilized in the REALISM trial are not associated with risk-adjusted mortality in patients undergoing mitral valve surgery.

Material and Methods

This investigation was exempt from formal Institutional Review Board review at each participating center as it represents a secondary analysis of the Virginia Cardiac Surgery Quality Initiative (VCSQI) data registry with the absence of Health Insurance Portability and Accountability Act patient identifiers and because the data are collected for quality analysis and purposes other than research.

Patients and Data Acquisition

De-identified patient records for isolated mitral valve operations were evaluated from the VCSQI database for the study period January 1, 2001 thru December 31, 2012. The VCSQI is a voluntary consortium of 17 different cardiac surgical centers within Virginia that voluntarily collaborate to improve cardiac surgical care, quality, and costs. This group exchanges and compares de-identified clinical data. Each center individually contributes patient data to the national Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database. Excluded patient records included those with missing calculated STS Predicted Risk of Mortality (PROM) as well as a history of endocarditis. Patient records were stratified into high risk (HR) versus non-high-risk (non-HR) study cohorts based upon clinical criteria similar to those utilized in the REALISM trial [11]. All mitral valve

operations represent standard surgical approaches. Patient preoperative risk was assessed by individual calculated STS PROM.

Measured Outcomes

The primary outcomes of interest included risk-adjusted associations between the likelihood of operative mortality and REALISM criteria used to define HR status for mitral operations. Secondary outcomes included unadjusted differences in the prevalence of preoperative patient risk profiles and operation-related characteristics as well as the incidence of postoperative morbidity, mortality, and hospital resource utilization. Standard STS definitions for preoperative variables (prior documented history of heart failure), postoperative events, and complications were utilized, including prolonged ventilation (>24 hours of mechanical ventilation), presence of any new onset atrial fibrillation, and renal failure (increase in serum creatinine level > 2.0 or a doubling (2×) of the most recent preoperative creatinine level) [13].

Statistical Analysis

All study outcomes and data comparisons were established a priori before data collection. Categorical variables are expressed as group percentages, while continuous variables are expressed as either mean $\pm$ standard deviation (SD) or median [25th, 75th percentile] depending upon overall variable distribution. Descriptive, univariate statistics included either the Pearson χ^2 or Fishers exact test for categorical variables, and either independent sample single factor analysis of variance for comparisons of normally distributed data or the Mann-Whitney *U* test for non-normally distributed data comparisons. Calculated test statistics were utilized to derive all 2-tailed *p* values with standard statistical significance set to *p* less than 0.05.

Multivariable generalized linear mixed effects regression modeling was used to estimate confounder-adjusted associations between the main effects of modeled predictor variables (various selection criteria for HR mitral valve operation status) and the likelihood of the dependent outcome (operative mortality). Modeled predictor variables (STS PROM score > 12%, 3 STS high-risk factors, functional MR + EF < 0.40, age 75 + EF < 0.40, reoperations with patent grafts, or 2 prior chest surgeries) were selected based upon established use as selection criteria for percutaneous MV repair and high-risk surgical status in the REALISM trial. The model was adjusted for the main effect of each modeled factor as well as the random (or mixed) effect of varying hospitals included in the multi-institution study cohort. The relative strength of association between modeled factors and the dependent outcome of interest was determined by quantifying each factors likelihood ratio (*z* statistic) within the logistic regression model. Results of model are reported as likelihood ratios, adjusted odds ratios (AOR) with 95% confidence intervals. Model discrimination performance was assessed using the models' C statistic. All statistical analyses were conducted using R statistical software, version 2.12.1 (<http://www.R-project.org>).

Results

Differences in Patient Characteristics and Operative Features

Table 1 displays patient characteristics and risk factors for all patients undergoing isolated mitral valve operations ($n = 2,440$) stratified by HR operative status. Overall, 29% ($n = 698$) met REALISM criteria for HR mitral valve status. High-risk patients were on average slightly older (62 vs 58 years). The HR patients also presented with a higher burden of preoperative comorbid disease including hypertension, diabetes, dyslipidemia, renal failure, hemodialysis requirements, prior myocardial infarction, heart failure, and advanced New York Heart Association functional class (all $p < 0.05$). As a result, HR patients expectedly demonstrated higher median STS PROM (6.6% vs 1.8%, $p < 0.001$) compared with non-HR patients. Table 2 displays differences in operative features between groups. The HR patients more commonly underwent mitral repair operations (60.7% vs 50.9%, $p < 0.001$) as well as urgent (29.9% vs 19.0%, $p < 0.001$) and emergent (3.2% vs 1.0%, $p < 0.001$) operations compared with non-HR patients.

Table 3 displays the frequency of REALISM high-risk inclusion criteria. Overall, the presence of functional mitral regurgitation with concomitant ejection fraction less than 0.40 was most common (57%), followed by calculated STS PROM greater than 12% (38%) and reoperation with patent bypass grafts (25%).

Unadjusted Comparisons of Postoperative Morbidity, Mortality, and Hospital Resource Utilization

Table 4 displays unadjusted differences in postoperative morbidity, mortality, and resource utilization between HR and non-HR patients. The HR patients incurred a higher incidence of readmission to the intensive care unit, atrial fibrillation, cardiac arrest, gastrointestinal events, pneumonia, prolonged mechanical ventilation (> 24 hours), renal failure, and new onset hemodialysis (all $p < 0.001$). No significant differences were observed in deep sternal wound infection rates or need for reoperation. Operative mortality was approximately 4 times higher among HR patients compared with non-HR patients (7.0% vs 1.7%). The HR patients also accrued longer median intensive care unit (48 vs 41 hours, $p < 0.0001$) and postoperative (7 vs 6 days, $p < 0.001$) lengths of stay. Figure 1 displays the incidence of operative mortality stratified by HR criteria.

Adjusted Associations Between Operative Mortality and High-Risk REALISM Selection Criteria

To determine the association between high-risk REALISM criteria and operative mortality, unadjusted as well as adjusted associations between REALISM criteria and the likelihood for operative mortality were estimated using multiple regression methodology (Table 5). Upon univariate modeling, STS PROM greater than 12%, reoperation with patent grafts, and the presence of STS high-risk criteria were all associated with operative mortality (all $p < 0.001$). In addition, when EF alone was modeled as a continuous function, a significant relationship was demonstrated with a small reduction in the odds of death with increasing ejection fraction (UOR: 0.97 [0.96 to 0.99], $p = 0.007$). After accounting for the confounding influence of correlated events within hospitals using a mixed effects regression

model, 2 of 6 selection criteria demonstrated significant associations with operative mortality: STS PROM score 12% (AOR: 5.8, $p < 0.001$) and the presence of 3 or greater STS high-risk criteria (AOR: 1.5, $p < 0.001$). A trend toward a significant measure of association with operative mortality was observed for the presence of functional MR with EF < 0.40 ; however, this relationship failed to achieve statistical significance (AOR: 2.5, $p = 0.07$). The statistical performance of the logistic regression model achieved adequate discrimination between survivors and decedents with a C statistic = 0.78. Furthermore, among HR patients meeting REALISM criteria, operative mortality for patients with STS PROM greater than 12% was 20.1%, and for patients with 3 or greater STS high-risk criteria, mortality was 7.5%. The combined mortality for patients meeting all other high-risk REALISM criteria was 4.7%.

Comment

The present study reports upon the impact of high-risk surgical status on surgical isolated mitral valve repair and replacement as well as the adjusted associations that exist between select REALISM trial criteria for high-risk surgical status and observed surgical mortality. In this multi-institution cohort analysis of more than 2,440 surgical patients over a 10-year study period, high-risk patients had an operative mortality of 7%, and mitral replacement was more commonly performed compared with repair. Moreover, among high-risk REALISM criteria used to select patients for percutaneous mitral repair, there were significant variations in the risk-adjusted associations with mortality in this surgical cohort, including several criteria that had little to no association with mortality. These results highlight the importance of surgeon involvement in the decision-making processes related to candidacy for percutaneous versus surgical mitral repair and treatment allocation for patients with mitral disease.

High-risk mitral valve surgery has been the focus of an increasing body of literature, including a recent STS Adult Cardiac Surgery Database analysis of 77,836 patients, which stratified outcomes for isolated MV repair by predicted surgical risk (2002 to 2010) [14]. In this analysis, MV repair rates were noted to have increased over time, while significant reductions in operative mortality were observed for patients with STS PROM greater than 8%. Reported operative mortality rates for MV repair among patients with STS PROM 8% to 12% and PROM greater than 12% were 7.9% and 16.8%, respectively. Similarly, operative mortality rates for MV replacement among patients with STS PROM 8% to 12% and PROM greater than 12% were 9.2% and 20.1%, respectively. These results are consistent with those of the present study, which demonstrated an operative mortality rate of 20% for patients undergoing mitral repair or replacement with STS PROM greater than 12%. However, while STS PROM greater than 12% remains one of the criteria used in the REALISM trial, this criteria alone accounted for only 38% of the high-risk patients analyzed in this study. The significantly lower operative mortality reported for all high-risk patients (7%) in this series suggest that the influence of other REALISM criteria may be a result of inaccurate assessments of those with truly increased operative risk.

The principal findings of this study concern the risk-adjusted associations estimated for high-risk REALISM criteria and surgical mortality. Only 2 criteria that demonstrated a

significant relationship with operative mortality were the following: (1) an STS PROM score greater than 12%; and (2) the presence of 3 or greater STS high-risk factors (Cr > 2.5 mg/dL, prior chest surgery, age > 75 years, EF < 0.35). Overall, the combined frequency of these criteria accounted for only 40% of the patients analyzed in the high risk surgical cohort. These results, therefore, imply that the other REALISM criteria utilized to identify nearly 60% of high-risk patients in this study may not reliably correlate with true surgical mortality. These results are supported even further by the observation that the combined mortality for the 60% patients meeting all other high-risk REALISM criteria was 4.7%. Thus, there exists a legitimate potential for patients to undergo percutaneous mitral repair due to a perceived high-risk status for surgery when they may, in fact, be better candidates for a more durable surgical mitral procedure. In contrast, certain REALISM criteria not assessed in this study include the presence of a porcelain aorta, prior mediastinal radiation, previous mediastinitis, and the presence of hepatic cirrhosis as these are not captured in the STS database. Other criteria that surgeons use in evaluating surgical risk include pulmonary hypertension, right ventricular function, and overall frailty. As such, surgeon involvement in treatment allocation decisions for percutaneous versus surgical mitral valve repair or replacement remains critical.

This study has limitations. The retrospective study design is subject to inherent selection bias. The reported results describe observed associations and do not demonstrate a direct cause and effect relationship between analyzed criteria and surgical mortality. The de-identified nature of the dataset did not allow for the analysis of certain data. In these analyses, we utilized available data within the VCSQI de-identified data registry to proxy similar criteria as that utilized in the REALISM criteria. Certain REALISM trial criteria could not be assessed (eg, presence of porcelain aorta or mobile ascending aortic atheroma, cirrhosis, or previous mediastinitis) as these factors were not available within the analyzed dataset. Similarly, we could not analyze data with respect to mitral valve morphology or etiology of disease. It is important to note that the STS PROM score does have predictive limitations, and REALISM trial developers were attempting to better define those serious risk factors not well accounted for in the STS score. Furthermore, MitraClip is currently approved for degenerative MR while patients with functional MR who are not appropriate for surgery are currently eligible for the Cardiovascular Outcomes Assessment of the MitraClip Therapy Percutaneous Therapy for High Surgical Risk Patients (COAPT) trial [15]. All analyses were limited to short-term, operative outcomes, and long-term follow-up related to success and durability of MV repair or replacement was not available. Finally, unrecognized miscoding of data must also be considered in any secondary analysis of a data registry.

The present results suggest that certain REALISM criteria used to identify patients at high risk for surgery, including reoperation with patent grafts and functional mitral regurgitation + EF less than 0.40 may not accurately represent patients at high risk of death with surgery. The REALISM trial inclusion criteria may not be indications for MitraClip instead of surgery. Patients with STS PROM greater than 12% and those with 3 or greater established STS high-risk criteria appear to be at increased risk for surgical mortality after mitral valve repair or replacement. However, in addition to conventional STS criteria, these data suggest

that risk assessment by surgeons is essential to direct appropriate treatment allocation for high-risk mitral disease.

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Fig 1.

Incidence of operative mortality stratified by high-risk REALISM criteria among patients undergoing mitral valve operations. (EF = ejection fraction; FMR = functional mitral regurgitation; PROM = Predicted Risk of Mortality; Reop = reoperation; STS = The Society of Thoracic Surgeons.)

Table 1

Frequency of Patient Demographic and Preoperative Risk Factors for High-Risk Versus Non-High-Risk Patients Undergoing Mitral Valve Operations

Factor	High Risk (n = 698)	Non-High Risk (n = 1,742)	p Value
Patient age (years)	62 ± 14	58 ± 13	<0.001
Female	352 (50.4%)	850 (48.8%)	<0.001
Hypertension	468 (67.0%)	887 (50.9%)	<0.001
Diabetes	164 (23.5%)	186 (10.7%)	<0.001
Stroke	43.3 (6.2%)	105 (6.0%)	<0.001
Renal failure	63 (9.0%)	45 (2.6%)	<0.001
Hemodialysis	73 (10.5%)	38 (2.2%)	<0.001
Heart failure	402 (57.6%)	697 (40.0%)	<0.001
NYHA class III or IV	447 (64.0%)	836 (48.0%)	<0.001
Previous myocardial infarction	125 (17.9%)	65 (3.7%)	<0.001
Ejection fraction	0.50 [0.37–0.60]	0.60 [0.53–0.65]	<0.001
STS PROM (%)	6.6 [1.5–15.3]	1.8 [0.9–3.9]	<0.001

NYHA = New York Heart Association; PROM = Predicted Risk of Mortality; STS = The Society of Thoracic Surgeons.

Table 2

Frequency of Operative Features for High-Risk Versus Non-High-Risk Patients Undergoing Mitral Valve (MV) Operations

Factor	High Risk (n = 698)	Non-High Risk (n = 1,742)	p Value
Procedure			<0.001
MV repair	423 (60.7%)	887 (50.9%)	
MV replacement	274 (39.3%)	855 (49.1%)	
Incidence			<0.001
First operation	450 (64.5%)	1,577 (90.5%)	
Reoperation (1)	200 (28.7%)	165 (9.5%)	
Reoperation (2)	37 (5.3%)	0 (0.0%)	
Reoperation (3+)	11 (1.5%)	0 (0.0%)	
Status			<0.001
Elective	461 (66.0%)	1,394 (80.0%)	
Urgent	209 (29.9%)	331 (19.0%)	
Emergent	29 (4.1%)	18 (1.0%)	

Table 3

Distribution of High-Risk Criteria Among Patients Undergoing Mitral Valve Operations

High Risk Criteria	Count	%
STS PROM > 12%	164	37.80%
Functional MR with EF < 0.40	398	57.00%
Age > 75 years with EF < 0.40	32	4.60%
Reoperation with patent grafts	176	25.20%
Two or more prior chest surgeries	48	6.90%
STS high-risk factors		
1	280	40.10%
2	134	19.20%
3	16	2.30%

EF = ejection fraction; MR = mitral regurgitation; PROM = Predicted Risk of Mortality; STS = The Society of Thoracic Surgeons.

Table 4

Unadjusted Outcomes for High-Risk Versus Non-High Risk Patients Undergoing Mitral Operations

Outcome	High Risk (n = 698)	Non-High Risk (n = 1,742)	<i>p</i> Value
Stroke	16 (2.3%)	26 (1.5%)	<0.001
Atrial fibrillation	163 (23.4%)	320 (18.4%)	<0.001
Pneumonia	39 (5.6%)	50 (2.9%)	<0.001
Prolonged ventilation	136 (19.5%)	150 (8.6%)	<0.001
Renal failure	44.6 (6.4%)	61 (3.5%)	<0.001
ICU LOS (hours)	48 [25–108]	41 [23–72]	<0.001
Hospital LOS (days)	7 [5–11]	6 [4–8]	<0.001
Mortality	49 (7.0%)	30 (1.7%)	<0.001

ICU = intensive care unit; LOS = length of stay.

Table 5

Unadjusted (UOR) and Adjusted (AOR) Odds Ratios for Univariable and Multivariable Logistic Regression Models to Determine Measures of Association Between REALISM Criteria and Surgical Mortality Among Patients Undergoing Mitral Valve Operations

High-Risk Criteria	Univariable Model			Multivariable Model ^a		
	UOR [95% CI]	p Value	Likelihood Ratio	AOR [95% CI]	p Value	
STS PROM > 12%	10.14 [6.10–16.86]	<0.001	42.3	5.8 [4.05–8.5]	0.001	
Three or more STS high-risk factors	2.69 [2.60–3.52]	<0.001	4.91	1.54 [1.29–4.33]	0.01	
Functional MR with EF < 0.40	0.66 [0.33–1.34]	0.25	0.07	2.52 [0.30–2.76]	0.07	
Age > 75 years with EF < 0.40	0.98 [0.13–7.24]	0.98	1.61	0.3 [0.01–2.53]	0.27	
Reoperation with patent grafts	3.86 [2.20–6.68]	<0.001	0.28	1.32 [0.57–2.60]	0.44	
Two or more prior chest surgeries	0.64 [0.09–4.70]	0.66	2.53	0.17 [0.02–1.48]	0.09	

^aMixed effects multivariable logistic regression model for the outcome of mortality after mitral valve operations: modeled covariates include all high-risk criteria; model performance characteristics (C statistic = 0.78, PseudoR² = 0.18).

CI = confidence interval; EF = ejection fraction; MR = mitral regurgitation; PROM = Predicted Risk of Mortality; STS = The Society of Thoracic Surgeons.