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Risk of Surgical Mitral Valve Repair for Primary Mitral Regurgitation

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ABSTRACT

BACKGROUND Risk estimation for surgical intervention is an essential component of heart team shared decision-making. However, current mitral valve (MV) surgery risk models used in practice lack etiologic or procedural specificity.

OBJECTIVES The purpose of this study was to establish a comprehensive method for assessment of operative risk of MV repair of primary mitral regurgitation (MR).

METHODS A novel etiology and procedure-specific algorithm identified 53,462 consecutive (July 2014 to June 2020) intention-to-treat MV repair patients with primary MR from The Society of Thoracic Surgeons Adult Cardiac Surgery Database. Risk models were fit for 30-day operative mortality, mortality and/or major morbidity, and conversion-to-replacement (CONV). As-treated mortality and morbidity models were derived separately.

RESULTS Event rates for mortality (n = 619; 1.16%), mortality plus morbidity (n = 4,746; 8.88%), and CONV (n = 3,399; 6.36%) were low. Mortality was higher in CONV patients vs repair (3.18% vs 1.02%). All event rates were lower with increasing program volumes. The mortality risk model had excellent discrimination (AUC: 0.800) and calibration and confirmed very low mortality risk for isolated MV repair for primary MR, with mean mortality risk of 1.16% and median of 0.55% (IQR: 0.30%-1.17%) with 90th and 95th percentiles 2.48% and 3.99%, respectively. The mortality risk was <0.5% in patients <65 years of age, with 97% of the total population across age groups having a risk of <3%. Only 1 in 4 patients age 75 or older had >3% estimated risk of mortality.

CONCLUSIONS This etiologic and procedure-specific risk model establishes that the contemporary mortality risk of MV repair for primary MR is <1% for the vast majority of patients. (J Am Coll Cardiol 2023;81:636-648) © 2023 American College of Cardiology and The Society of Thoracic Surgeons. Published by Elsevier Inc. All rights reserved.

Risk estimation of interventional and surgical procedures is an essential component of heart team shared decision-making. Existing risk models from The Society of Thoracic Surgeons Adult Cardiac Surgical Database (STS ACSD) incorporated mitral valve (MV) repair or replacement across the spectrum of valve etiologies or dysfunctions.[1] To approximate outcomes of surgical therapy of primary mitral regurgitation (MR), these risk estimates have been further studied to confirm that MV repair is safe, with improved 30-day outcomes compared with MV replacement, with nationally reported repair

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rates of nonstenotic valves ranging between 75% to 84%.[1,2] However, the existing MV surgery risk model and the subset analyses are based on operative data from 2011 to 2016.[1,2] More recent versions of the STS ACSD have been expanded to include specific information on MR etiology and mechanism, and additional granular technique details of operative MV repair.

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To date, risk assessment of MV repair of primary MR using clinical registry data focusing only on patients with degenerative lesions of the MV apparatus is lacking.[3] However, institutional series have highlighted superior repair rates and outcomes with this subset of primary MR patients.[4-8] While a clear volume-outcome relationship has been established for MV surgery,[6] currently established risk models focus on standard postoperative complications without accounting for the risk for conversion to MV replacement in patients undergoing intention-to-treat (ITT) MV repair.

The objectives of this study were to examine contemporary national registry data from the STS ACSD with complete information on MR etiology, MR mechanism, as well as operative details; to assess current outcomes and risk of MV repair of primary MR; and to develop a new risk model and clinical decision tool. We hypothesized that patients undergoing ITT MV repair for primary MR have a very low risk of mortality or conversion to MV replacement.

METHODS

PATIENT DATA. The study population of MV repair for primary MR was derived from the STS ACSD for the period between July 2014 and June 2020 (data versions 2.81 and 2.9). The STS ACSD penetration has been estimated to be 97% of all adult cardiac operations performed in the United States based on a comparison with CMS CABG data.[9]

Data for this analysis included cases from all 50 states. The study cohort included all consecutive first-time MV surgeries for primary MR that were isolated, nonemergent (elective or urgent), and planned or attempted (ie, ITT). This cohort included cases of isolated MV surgery, which is defined by the STS ACSD as MV surgery alone or with 1 or more of the following concomitant procedures: surgical ablation of atrial fibrillation (AF), left atrial appendage obliteration, closure of secundum atrial septal defect (ASD) or patent foramen ovale (PFO), and/or tricuspid valve repair, which are all commonly performed at the time of MV surgery. Patients that underwent any other form of concomitant cardiac or noncardiac surgery were excluded. Additional analyses were performed on MV repair alone, without any concomitant procedures.

Participating sites in the STS ACSD reported patient demographics, risk factors, operative variables, and outcomes in accordance with established database definitions and specifications.[9] The STS ACSD data quality is validated by random, independent, third party, professional audits of 10% of all STS ACSD programs annually, generally demonstrating overall accuracy of approximately 97%.[9]

The current analysis was approved and facilitated by the STS Research Center. As this analysis was based on deidentified retrospective data, waiver of informed consent was obtained from the Northwestern University Institutional Review Board (#STU00206997).

POPULATION ALGORITHM. Stepwise identification of the MV repair population undergoing surgery for primary MR followed a novel algorithm summarized by the consort diagram (Figure 1). The algorithm sequentially refined overall MV operations identified in the STS ACSD to arrive at the final ITT isolated MV repair population for primary MR inclusive of both completed surgical repairs as well as attempted repairs that converted to replacement during the same operation. This stepwise approach included the following 6 steps:

1. Exclude procedures other than planned surgical MV repair. Transcatheter mitral procedures, percutaneous access, unplanned MV repair, procedures without cardiopulmonary bypass, planned MV replacement, and cases involving circulatory arrest or beating heart surgery were excluded.
2. Exclude nonisolated MV repair. All cases with concomitant cardiac and noncardiac surgery except for tricuspid valve repair, AF ablation surgery, left atrial appendage obliteration, and/or secundum ASD or PFO repair were excluded.
3. Restrict to primary MR. This first involved excluding all nondegenerative cases defined as ischemic, calcific/mitral annular calcification, rheumatic, or mixed etiology. Included were a predefined subset of allowed combinations of etiology that comprised myxomatous/degenerative, leaflet prolapse, and elongated ruptured chords. Mitral stenosis was excluded. Lesion types included were as follows: type II lesions; leaflet prolapse—anterior, posterior, bi-leaflet, or unspecified; and elongated/ruptured chord(s)/flail,

ABBREVIATIONS AND ACRONYMS

AF = atrial fibrillation

ITT = intention to treat

MR = mitral regurgitation

MV = mitral valve

PPM = permanent pacemaker

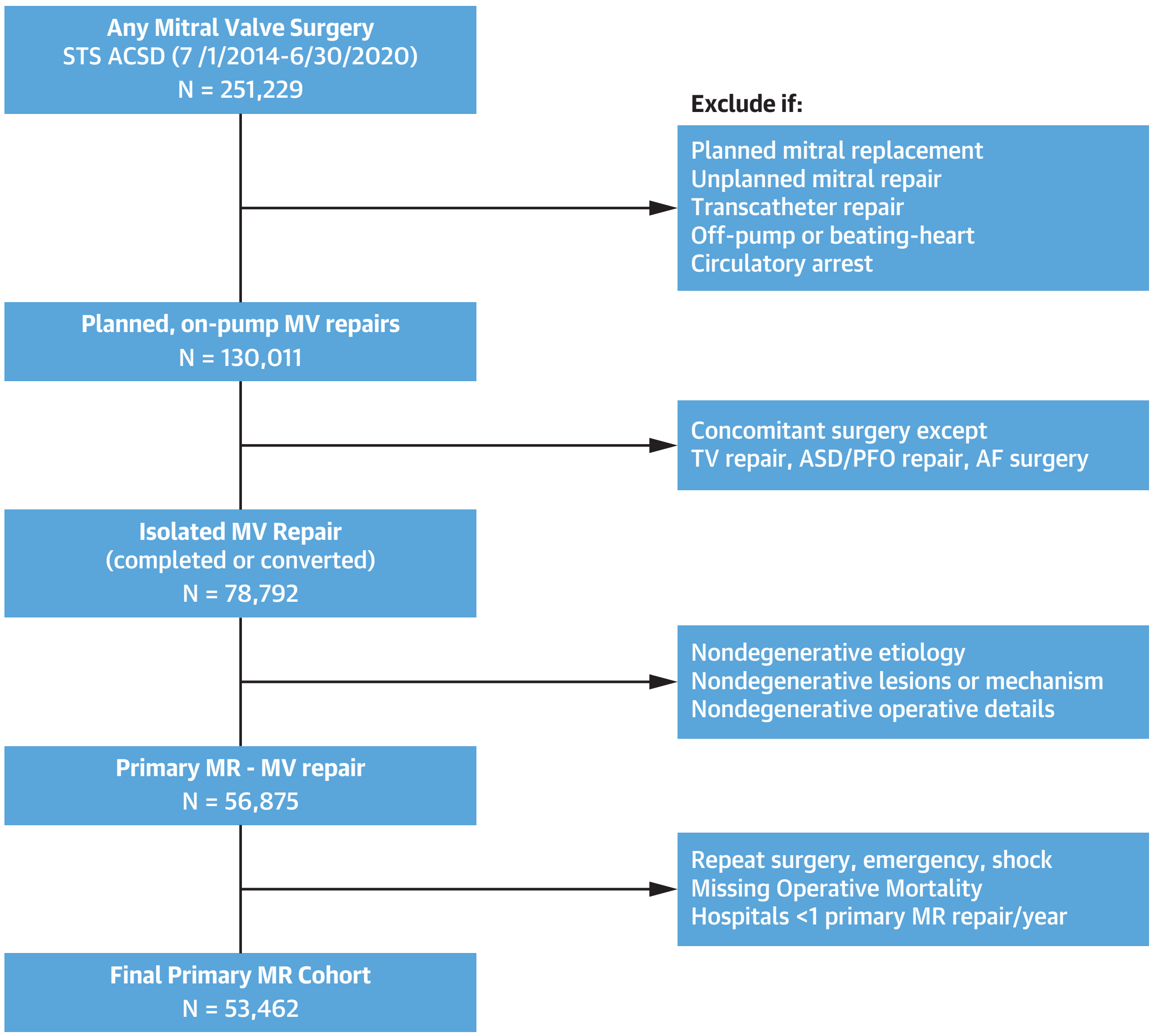
PROM = predicted risk of mortality

STS ACSD = The Society of Thoracic Surgeons Adult Cardiac Surgery Database

TEER = transcatheter edge-to-edge repair

TV = tricuspid valve

FIGURE 1 **Consort Diagram Defining the Study Cohort**



Starting population of 251,229 patients in The Society of Thoracic Surgeons Adult Cardiac Surgery Database (STS ACSD) undergoing mitral valve (MV) intervention. After exclusions, we identified 130,011 planned MV repairs with 78,792 isolated repairs including concomitant tricuspid valve (TV) repair, atrial septal defect (ASD) or patent foramen ovale (PFO) closure, or atrial fibrillation (AF) surgery. Once applying the novel algorithm for primary mitral regurgitation (MR), there are 53,426 patients in the final cohort for analysis.

with or without concomitant annular dilation. Finally, details of MV technique were included consistent with primary MR repair such as chordal reconstruction and leaflet resection, but excluded were techniques not consistent with primary MR repair, such as commissurotomy, annular decalcification/debridement, leaflet extension/replacement/patch, and/or paraprosthetic leak repair.[10]

4. Restrict to elective or urgent MV surgery. Excluded were emergency or salvage cases, patients with prior MV surgery, preoperative cardiac shock, and any form of preoperative mechanical circulatory support.
5. Confirm data completeness to exclude cases where the operative mortality (OM) was missing or unknown.
6. Outlier determination alignment by excluding rare very low MV surgery volume sites (<1 case/y over the 6-year study period).

STUDY ENDPOINTS. The primary study outcome was OM defined as in-hospital death during index admission or death within 30 days of surgery, whether in or out of hospital in accordance with established STS models. The 2 secondary outcomes were a composite of mortality plus morbidity (MM) and conversion to replacement (CONV). Morbidity was defined as the presence of any of the following major postoperative complications: stroke, renal failure, cardiac reoperation, prolonged mechanical ventilation (>24 hours), and deep sternal wound infection. CONV was defined as ITT MV repair for primary MR that was converted to MV replacement during the same operation.

SENSITIVITY ANALYSES. The STS definition of isolated MV repair was used for this analysis, which includes patients with or without concomitant tricuspid valve repair, AF ablation surgery, left atrial appendage obliteration, and/or ASD/PFO repair. A subgroup of isolated MV repair without any concomitant procedure was also evaluated.

In this homogenous cohort of primary MR patients, we performed sensitivity analyses to characterize the incidence of postoperative permanent pacemaker (PPM) and OM in the cohort of patients undergoing concomitant tricuspid valve (TV) repair vs no TV repair, and the impact on CONV on PPM. We further stratified OM by severity of preoperative TV regurgitation. For PPM analyses, patients with pre-existing PPM were excluded.

To fully characterize the surgical treatment of primary MR in the STS ACSD, we identified patients undergoing ITT MV replacement using the same primary MR algorithm except for the operative details because these were specific to repair. For this subgroup analysis, all planned ITT MV repair patients were excluded, as were those converted to replacement (CONV). This analysis was stratified by center volume.

STATISTICAL METHODS AND MODEL DEVELOPMENT. Categorical variables are presented as n (%), and continuous variables are shown as mean ± SD or median (25th, 75th percentiles) based on normality. Baseline characteristics and short-term outcomes were assessed by univariate analysis. Categorical variables were presented as frequencies and proportions. Results are reported with 95% CIs without *P* values.

The ITT study population was leveraged to develop multiple risk models. First, ITT models for all 3 study endpoints (OM, MM, and CONV) based on intent to repair the MV were developed and validated. Second, the same population was used to develop corresponding “as-treated” models indicating whether the surgery was completed as MV repair or was converted to replacement. Importantly, all 5 models considered covariates to indicate whether the MV surgery was fully isolated or concomitant with AF surgery (surgical ablation and/or left atrial appendage obliteration), and/or tricuspid valve repair, and/or ASD/PFO closure. This modeling approach, including the additional surgery-specific factors, allowed the derivation of risk estimates calibrated to the specific intended operation or the actual performed surgery.

All models were derived using multivariable binary logistic regression. The full complement of preoperative patient variables and their parameterization used in existing ACSD risk models, irrespective of cardiac procedure type, was considered for inclusion in the model (Supplemental Table 1).[11,12] Missing covariate data were estimated with single imputation as previously described for ACSD risk models.[1] The risk models were derived using the backward stepwise selection and confirmed using forward stepwise selection.

An area under receiver-operator-characteristic curve (AUC) of 0.75, comparable to current STS ACSD risk models, was established a priori as an acceptable level of primary endpoint model discrimination. The estimated AUC for each model was optimism corrected using 1,000 bootstrap samples in the “validate” function in the “rms” package in R software version 4.1.2 (R Project Inc). Optimism was also estimated using 5-repeated 9-fold cross-validation, achieving similar results. Calibration plots were created by risk deciles and plotting the observed proportion of events with 95% CIs against the mean prediction per decile. Overall model calibration was also assessed via the Hosmer and Lemeshow Test in addition to broad, numerical, and graphical confirmation of model calibration across multiple patient subcohorts, including low-to-high risk subgroups, age groups, sex, obesity, ejection fraction, mitral lesions and etiology, and whether concomitant atrial fibrillation or tricuspid valve repair surgery was performed. Observed-to-expected ratios (ideal O/E = 1) were calculated for these subgroups. All analyses were performed with the use of R software package and SPSS version 26 (IBM).

RESULTS

STUDY COHORT. Cases of isolated MV repair for primary MR were documented from 1,062 different hospitals over the 6-year study period. A total of 181 institutions where MV repair for primary MR was extremely rare (<6 cases over the entirety of the study period), with a cumulative 6-year caseload of 426 total surgeries (<0.4 repairs/y), were excluded.

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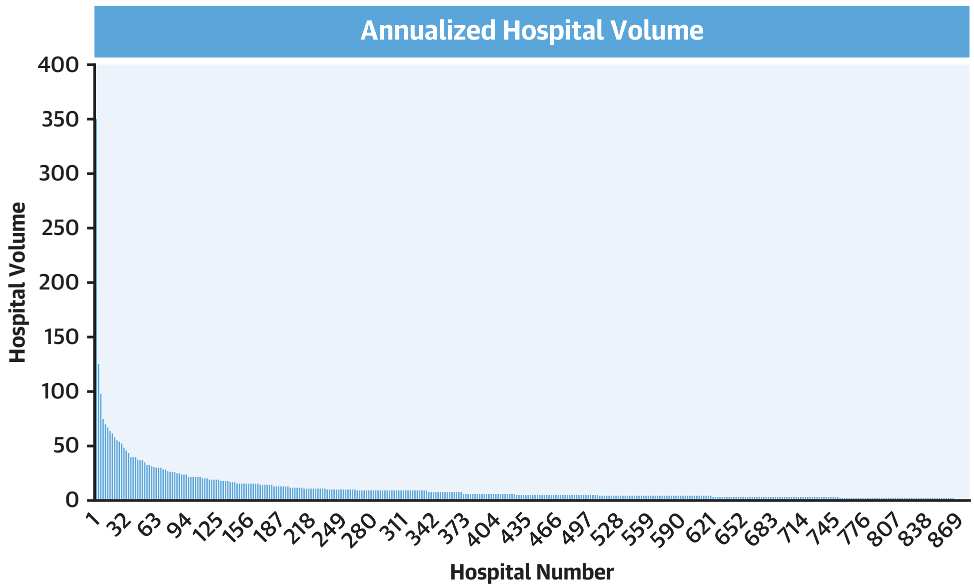
FIGURE 2 Annualized Hospital Volume of Isolated Mitral Valve Repair for Primary Mitral Regurgitation

Mean	11
SD	20
Median	5
25th %	3
75th %	11
10th %	2
90th %	24
95th %	38
97th %	54
Min	1
Max	350



Yearly hospital volume for 53,462 mitral valve repairs for primary mitral regurgitation at 881 hospitals.

The final analyzed ITT cohort was 53,462 total cases performed at 881 hospitals (median 27 [IQR: 12-61]; min = 5; max = 2,098) (Supplemental Figure 1A) by 2,404 unique surgeons (median 8 [IQR: 3-21]; min = 1; max = 1,077) (Supplemental Figure 1B). Annualized volume was calculated for each hospital over the study period (**Figure 2**).

Mortality was associated with higher age (71 years vs 64 years; $P < 0.001$), women (48.6% vs 38.2; $P < 0.00$), a higher burden of comorbid disease, more frequent New York Heart Association functional class IV heart failure (5.2% vs 1.4%; $P < 0.001$), and higher incidence of severe tricuspid regurgitation (17.0% vs 5.6%; $P < 0.001$) (**Table 1**).

OPERATIVE OUTCOMES. A total of 619 operative deaths were observed (OM = 1.16%), with 4,746 cases of mortality and/or morbidity (MM = 8.88%); 3,399 MV repairs were converted to MV replacement (CONV = 6.36%). CONV cases had more than a 3-fold higher mortality (n = 108; 3.18%) compared with successfully completed repairs (511 of 50,063; 1.02%). The overall rates of individual postoperative complications and their comparison in the completed repairs and converted to replacement cases are summarized in **Table 2**.

An association between higher institutional case volume and lower rates of OM and MM was observed (**Table 3**). Over the entire 6-year study period (July 2014 to June 2020), most hospitals had no OM (n = 526; 59.7%; 18,087 surgeries), or only a single OM (n = 203; 23.0%) following isolated MV repair for primary MR. Moreover, of the 2,404 total surgeons, 1,947 (81%) had no documented operative deaths through the study period. Lower mortality (0.56%) and low CONV rates (2.07%) were observed in centers with volumes >50 cases/y. CONV monotonically increased as center volume decreased to the lowest volume center (<10 cases/y; CONV = 11.7%). Both OM and MM were higher with conversion (**Figure 3**). The inflection point analysis for hospital volume revealed that OM was reduced with volumes >10 cases annually, and the volume associated with OM of 1% or less may be estimated at 25 cases (Supplemental Figure 2).

RISK MODELS. Parameters included in all ITT (OM, MM, and conversion) and as-treated (OM and MM) operative risk models are summarized in Supplemental Table 2. The multivariable risk model for OM was highly discriminative (AUC: 0.800) with excellent calibration for operative death following ITT MV repair for primary MR. The corresponding model calibration plots are outlined in **Figure 4**. The optimism corrected estimates of the AUC for all 5 models and the ROC curves are displayed in Supplemental Table 3 and Supplemental Figures 3A to 3C, respectively. The Operative ITT risk model calibration for the OM primary endpoint was also excellent for a variety of patient demographics, risk factors, and surgical subgroups (Supplemental Figure 4).

The frequency distribution (**Figure 5A**) of the ITT predicted risk of operative mortality (PROM) demonstrated very low operative risk, with mean risk of 1.16% and median risk of 0.55% (IQR: 0.30%-1.17%). Overall, the 90th and 95th percentiles of the PROM (%) were 2.48% and 3.99%, respectively. For patients <65 years of age, the risk of operative death was <1% (**Figure 5B**). For 97% of the cohort, the PROM was <3%, and only 2,118 of 8,568 patients ≥75 years of age (24.7%) had a calculated PROM >3% (**Figure 5B**).

For Isolated MV repair without concomitant procedures, we demonstrate an exceedingly low mortality with mean risk of 0.83% and median risk of 0.43% (IQR: 0.25%-0.83%) for all patients (**Figure 5A, Central Illustration**). Overall, the 90th and 95th percentiles of the PROM were 1.66% and 2.68%, respectively. For patients <65 years of age, the risk of operative death was <0.5% with 97% of the cohort having a PROM <1.5% (**Figure 5B**).

CLINICAL DECISION TOOL FOR ISOLATED MV REPAIR FOR PRIMARY MR. The 5 ITT and as-treated risk models were combined into a single clinical decision tool (**Figure 6**). This tool provides estimates of operative outcomes (OM and MM) as well as the risk of conversion from planned repair to MV replacement. This decision tool provides a total of 28 different risk estimates stratified by whether a conversion to replacement occurred or if the MV repair was associated with one or more concomitant procedures.

SENSITIVITY ANALYSES. When the cohort was stratified by TV repair, we demonstrate a significantly higher rate of PPM in patients undergoing concomitant TV repair during MV repair (7.1% vs 2.1%; $P < 0.001$) (**Table 4**). There was further increase in the incidence of PPM after concomitant TV repair with addition of surgical ablation of AF (12.4% vs 5.0%; $P < 0.001$), CONV (17.8% vs 8.2%; $P < 0.001$), or surgical ablation with CONV (22.4% vs 14.3%; $P < 0.001$) (**Table 4**). Although the presence of moderate or severe TR was associated with incrementally increased observed OM in patients undergoing MV repair, adding a TV repair at each level of TR severity was not associated with an increase observed OM rates (Supplemental Table 4).

We identified 13,151 planned MV replacements in patients who met etiology criteria for primary MR. After stratifying by center volume, we observed an inverse monotonic association of rates of planned MV replacement vs planned MV repair as center volume increased (11.7% >200 cases vs 34.8% ≤10 cases over 6 years) (Supplemental Table 5).

TABLE 1 Baseline Characteristics and Demographics Stratified by Operative Mortality Status

	Operative Mortality		
	No	Yes	*P* Value
Number of patients	52,843 (98.84)	619 (1.16)	<0.001
Age, y	64 (56-71)	71 (63-77)	
Female	20,176 (38.2)	301 (48.6)	<0.001
Body mass index, kg/m^2	26.4 (23.5-29.9)	26.6 (22.9-31.5)	0.015
Black race	3,398 (6.4)	72 (11.6)	<0.001
Hypertension	32,820 (62.1)	482 (77.9)	<0.001
Diabetes	5,435 (10.3)	149 (24.1)	<0.001
Dialysis	402 (0.8)	18 (2.9)	<0.001
Home O_2	750 (1.4)	42 (6.8)	<0.001
Cerebrovascular accident	3,827 (7.2)	101 (16.3)	<0.001
Peripheral vascular disease	1,543 (2.9)	41 (6.6)	<0.001
NYHA functional class IV	757 (1.4)	32 (5.2)	<0.001
Ejection fraction, %	60 (55-65)	58 (48-62)	<0.001
Cardiac reoperation (any)	1,337 (2.5)	64 (10.3)	<0.001
Severe tricuspid insufficiency	2,936 (5.6)	105 (17.0)	<0.001
Moderate tricuspid insufficiency	8,129 (15.4)	158 (25.5)	<0.001
Recent AF	7,642 (14.5)	136 (22.0)	<0.001
Remote AF	10,938 (20.7)	222 (35.9)	<0.001
Urgent/nonelective surgery	6,134 (11.6)	139 (22.5)	<0.001
Concomitant surgery	28,091 (12.5)	408 (65.9)	<0.001
Tricuspid valve repair	7,473 (14.1)	165 (26.7)	<0.001
ASD/PFO repair	5,050 (9.6)	48 (7.8)	0.129
AF ablation	13,807 (26.5)	241 (39.4)	<0.001
Atrial appendage closure	23,191 (43.9)	350 (56.5)	<0.001
Converted to mitral replacement	3,291 (6.2)	108 (17.4)	<0.001

Values are n (%) or median (IQR).
AF = atrial fibrillation; ASD/PFO = atrial septal defect/patent foramen ovale; NYHA = New York Heart Association.

DISCUSSION

This study examined 53,462 consecutive nonemergent patients with primary MR undergoing

TABLE 2 Outcomes Stratified by Mitral Valve Repair vs Conversion to Replacement

	Completed Mitral Valve Repair (n = 50,063)	Converted (n = 3,399)	OR (95% CI)	*P* Value
Operative mortality	511 (1.0)	108 (3.2)	3.18 (2.58-3.93)	<0.001
Operative morbidity and mortality	4,068 (8.1)	678 (20.0)	2.81 (2.57-3.08)	<0.001
Permanent stroke	622 (1.2)	81 (2.38)	1.94 (1.54-2.45)	<0.001
Renal failure	550 (1.1)	119 (3.6)	3.29 (2.69-4.02)	<0.001
Cardiac reoperation	1,439 (2.9)	206 (6.1)	2.17 (1.87-2.52)	<0.001
Prolonged ventilator >24 h	2,317 (4.6)	456 (13.4)	3.19 (2.87-3.55)	<0.001
Deep sternal infection	57 (0.1)	7 (0.2)	1.81 (0.83-3.97)	0.133
Postoperation atrial fibrillation	12,911 (25.8)	1,010 (29.7)	1.22 (1.13-1.31)	<0.001
Permanent pacemaker[a]	1,800 (3.7)	371 (11.2)	3.30 (2.93-3.71)	<0.001
Unplanned cardiac surgery	94 (0.2)	15 (0.4)	2.36 (1.37-4.07)	0.002

Values are n (%). [a]Excludes 1,302 cases with previous pacemaker implantation.

TABLE 3 Annualized Hospital Volume-Based Outcomes of Intent-to-Treat Mitral Valve Repair for Primary Mitral Regurgitation

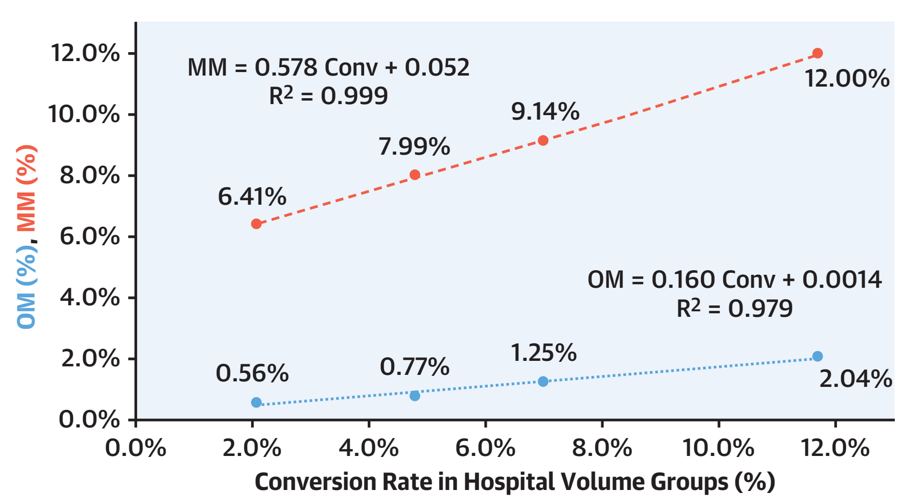
Annual Hospital Volume	Hospitals	Cases	Mortality	Morbidity/Mortality	Converted to Replacement
≥50	29	14,696	82 (0.56)	942 (6.41)	304 (2.07)
25-49	58	11,194	86 (0.77)	894 (7.99)	536 (4.79)
10-24	166	14,085	176 (1.25)	1,287 (9.14)	983 (6.99)
<10	628	13,487	275 (2.04)	1,623 (12.00)	1,576 (11.70)
Overall	**881**	**53,462**	**619 (1.60)**	**4,671 (8.74)**	**3,399 (6.36)**

Values are n or n (%). **Bold** indicates subtotals.

isolated MV surgery between 2014 and 2020 generating several important findings. First, the overall risk of mortality for MV repair of primary MR was <2% for nearly all patients, with 59.7% (526 of 881) of hospitals and 81.0% (1,947 of 2,404) of surgeons experiencing no mortalities over the entire 6-year study period. Second, for patients undergoing ITT MV repair of primary MR, 93.6% of valves were repaired. Third, mortality and risk of conversion to MV replacement were lower at higher-volume centers, with 135 of 881 hospitals (15.3%) performing 31,617 (59.1%) of the operations with a mortality of 0.73% and conversion rate of 3.69%. Finally, the expected mortality in two-thirds of all primary MR patients was <1%, with the 90th percentile OM being only 2.5%. These data help to establish a new benchmark for the assessment of risk for isolated MV repair for primary MR.

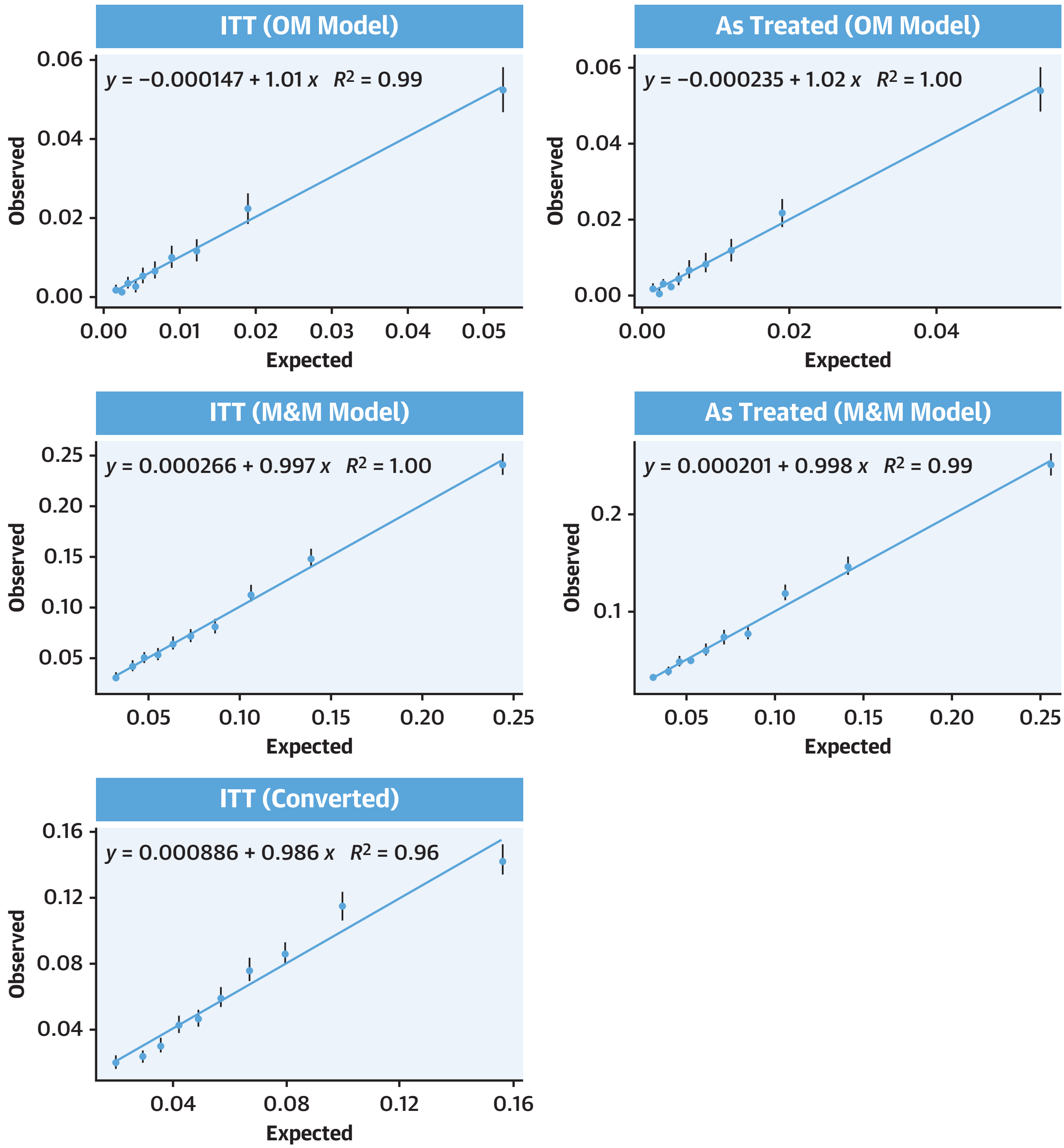
Current international guidelines recommend MV repair as first-line therapy for patients with symptomatic primary MR, or asymptomatic primary MR in the setting of reduced left ventricular systolic function (ejection fraction <0.60, end-systolic dimension >4.0 cm). As well, MV repair is reasonable for asymptomatic patients with normal LV function and size for whom the likelihood of successful repair at low operative risk exceeds 95%.[13,14] A MV surgery volume-outcome association has been further clarified to note that over 80% of the U.S. population has close regional access to higher-volume MV repair centers.[6] The current study corroborates a volume-related impact on repair rates and outcome for primary MR. Importantly, however, by examining a homogeneous cohort of patients with primary MR in the STS ACSD defined by MR etiology, lesion, and mechanism, this analysis establishes that the overall performance of MV repair is safe, with a mortality of <1%

FIGURE 3 Effect of Conversion to Replacement Rates on Observed Operative Outcomes



Graphical depiction of increasing operative mortality (OM) **(blue)** with increasing rate of conversion to mitral valve replacement for intent-to-treat mitral valve repair for primary mitral regurgitation. Similarly increasing major morbidity or mortality (MM) **(red)** with increasing rates of mitral valve replacement.

FIGURE 4 **Calibration Plots for Risk Models**

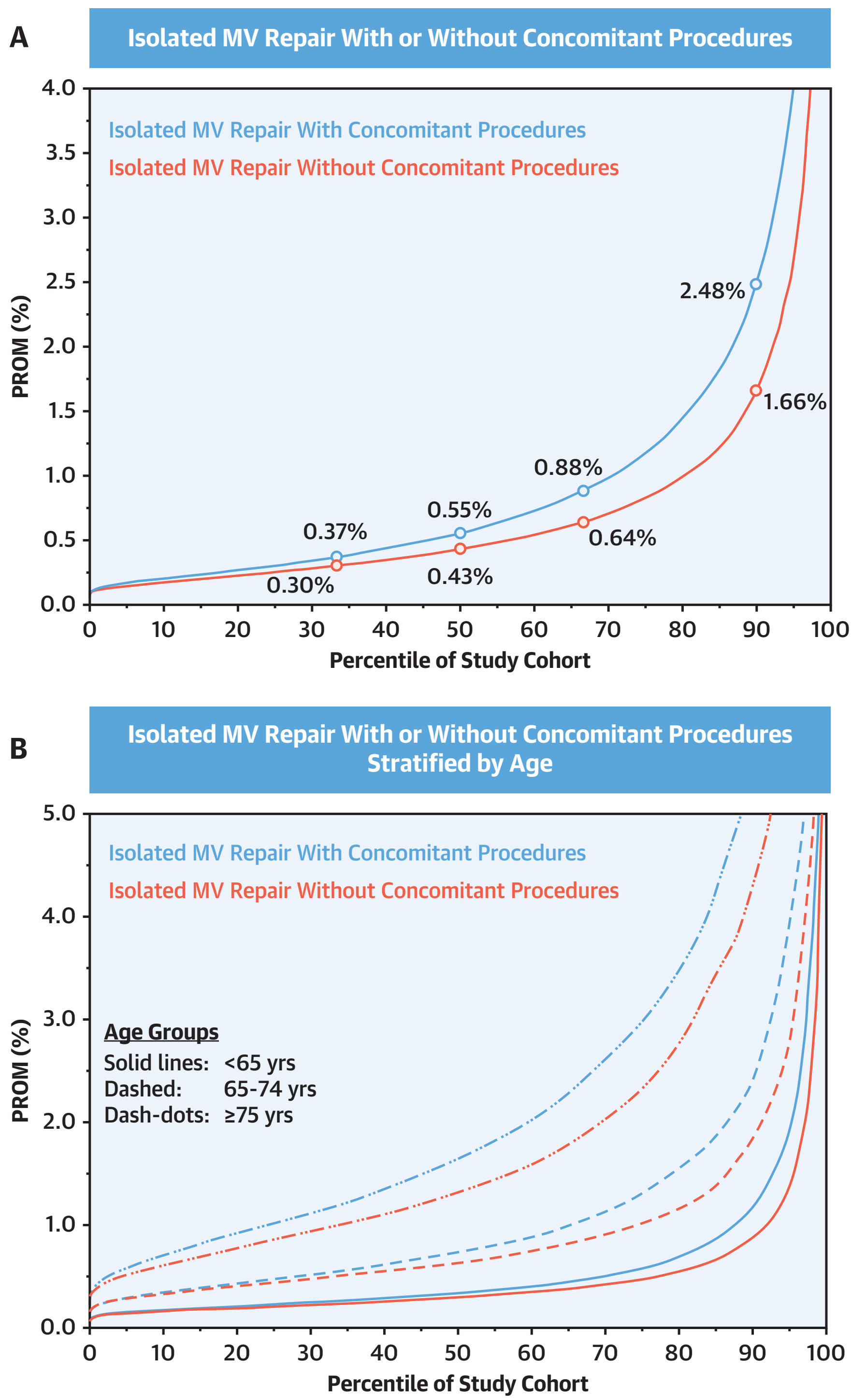


Calibration plots for each of the 5 models with outstanding performance all $R^2 > 0.95$. ITT = intention to treat; other abbreviations as in Figure 3.

in over two-thirds of a nonemergent population, and when the intention is to repair, the contemporary repair rate of primary MR in the United States is 93.6%. A sensitivity analysis of planned intention to perform a replacement found a monotonic decrease in MV replacement as center volume increases. These findings support existing guideline recommendations for higher-volume or reference center MV repair.

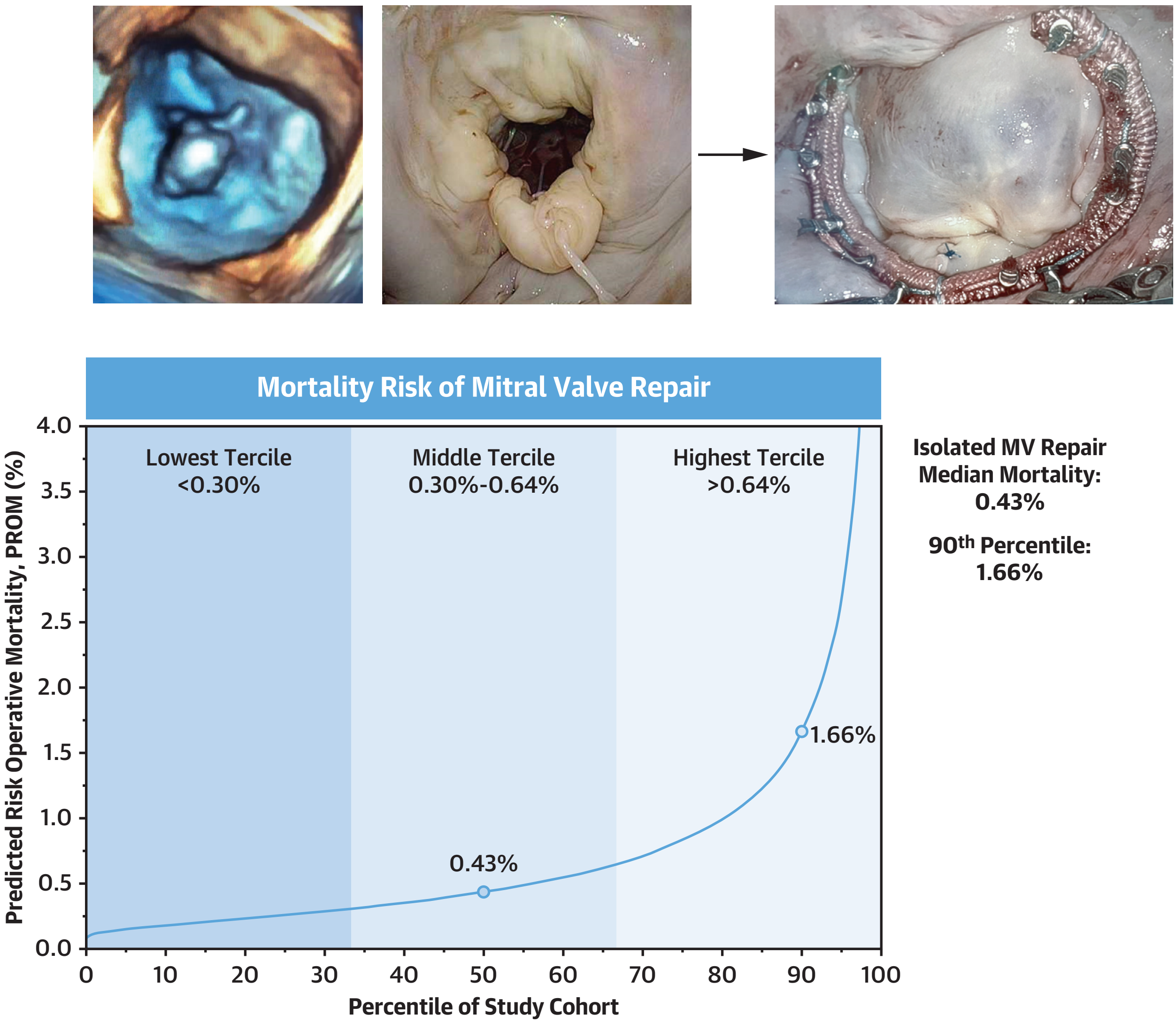
Long-term durability of surgical MV repair in experienced hands has been confirmed by several

FIGURE 5 **Frequency Distribution for Predicted Risk of Operative Mortality in Intent-to-Treat Mitral Valve Repair for Primary Mitral Regurgitation**



(A) Graphical depiction of distribution for predicted risk of operative mortality (PROM) in intent-to-treat isolated mitral valve (MV) repair **(blue)** for primary mitral regurgitation over the study cohort indicating the first tercile of risk is 0.37%, second tercile of 0.88%, and 90th percentile of 2.48% with a median of 0.55%. Isolated MV repair without concomitant procedures **(red)** (n = 28,058) highlighting the first tercile of risk 0.30%, second tercile 0.64%, and 90th percentile 1.66% with median of 0.43%. **(B)** Graphical depiction of distribution for PROM in intent-to-treat isolated MV repair **(blue)** and isolated MV repair without concomitant procedures **(red)** as stratified by age. The **solid lines** denote age <65 years with **red** (no concomitant) n = 15,166, median risk 0.30% (0.25%-0.83%); **dashed lines** indicate age 65-75 years with **red** (no concomitant) n = 7,034, median risk 0.63% (0.44%-1.02%); and **dash-dot lines** indicate age >75 years with **red** (no concomitant) n = 2,858, median risk 1.32% (0.86%-2.36%).

CENTRAL ILLUSTRATION **Mitral Valve Repair for Primary Mitral Regurgitation Is Very Low Risk**



Badhwar V, et al. J Am Coll Cardiol. 2023;81(7):636-648.

In primary mitral regurgitation, operative mortality is very low for isolated mitral valve (MV) repair without concomitant procedures: mean 0.83%, median 0.43%, 90th percentile 1.66%, 95th percentile 2.68%.

multicenter observational studies.[4-8,15,16] Although the procedural safety of transcatheter edge-to-edge repair (TEER) is well established, understanding the long-term durability of TEER will be critical in clinical decision-making between transcatheter vs surgical intervention for primary MR.[17-21] Furthermore, surgical MV repair has a significantly lower success rate after failed TEER, highlighting the importance of appropriate patient selection.[22] The currently enrolling noninferiority REPAIR MR (Percutaneous MitraClip Device or Surgical Mitral Valve REpair in PAtients With PrImaRy MItral Regurgitation Who Are Candidates for Surgery) trial and superiority PRIMARY (Percutaneous or Surgical Mitral Valve Repair) trial seek to evaluate longitudinal outcomes of TEER and surgical MV repair for patients with primary MR who are not at extreme risk.[23,24] The present study provides specific risk estimation for MV repair for primary MR to inform heart team clinical decision-making. In particular, when equipoise may be

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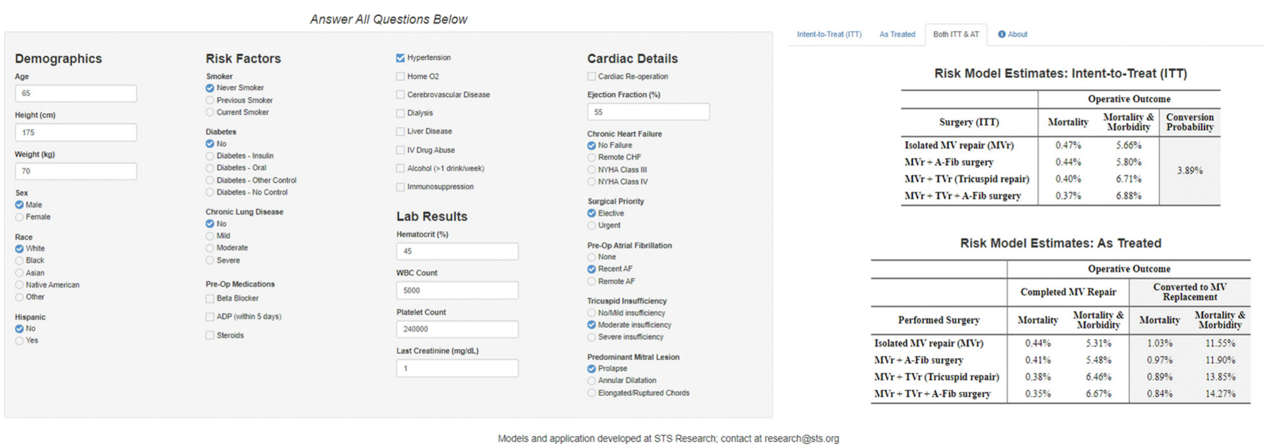
FIGURE 6 Decision Tool of Mitral Repair for Primary Mitral Regurgitation



Screenshot of The Society of Thoracic Surgeons clinical risk calculator interface. ADP = adenosine diphosphate receptor inhibitor; AF = atrial fibrillation; AFib = atrial fibrillation; CHF = congestive heart failure; IV = intravenous; MV = mitral valve; MVr = mitral valve repair; NYHA = New York Heart Association; TVr = tricuspid valve repair; WBC = white blood cell.

present, this study provides clarity when approaching younger age groups at lower risk. When contemplating lifetime management of primary MR as part of shared clinical-decision making, the key finding that the risk of MV repair of primary MR is <1% for the vast majority of patients, akin to risk of an ASD repair, the application of TEER in nonprohibitive-risk patients should remain restricted unless performed as part of an ongoing clinical trial.

The risk of MV replacement is higher than MV repair; yet, existing models based on older operative data to estimate risk may not fully discriminate etiology and may lack precision with respect to operative technique and ITT.[25] When assessing the risk of adding concomitant procedures such as surgical ablation of AF or tricuspid valve repair to MV surgery, existing risk models deemed this to be negligible.[26,27] These risk assessments were applied to risk models that were not etiology specific and included both MV repair and replacement. The current risk model is specific not only to primary MR etiology, but also to isolated first-time MV repair. With these specific parameters, the median OM risk in the cohort was 0.55%. Importantly, the majority of programs and surgeons did not observe any mortality in the entire 6-year period of the current study. Although the presence of increasing grades of TR added to the risk of MV repair, the addition of a concomitant TV repair did not lead to an increase in observed mortality within defined strata of TV severity. Additionally, when TV repair was performed, the overall incidence of PPM was 7%, lower than the PPM rate of 14.1% reported in Cardiothoracic Surgical Trials Network tricuspid repair trial.[28] In our study, the addition of surgical ablation of AF increased the incidence of PPM, as did CONV from MV repair. The increased rate of PPM of 17.8% when TV repair was associated with CONV may be related to a relative increased manipulation of tissues in the vicinity of the conduction system with MV repair followed by replacement.

TABLE 4 Incidence of Permanent Pacemaker Implantation Following Concomitant Tricuspid Repair With or Without Surgical Ablation of Atrial Fibrillation

Permanent Pacemaker by Surgery Type	Tricuspid Valve Repair: No	Tricuspid Valve Repair: Yes	*P* Value
Mitral valve repair	689/32,712 (2.11)	256/3,620 (7.07)	<0.001
Mitral valve repair + surgical ablation	471/9,407 (5.01)	384/3,101 (12.38)	<0.001
Converted to replacement	172/2,095 (8.21)	42/236 (17.80)	<0.001
Converted + surgical ablation	110/771 (14.27)	47/210 (22.38)	0.004

Values are n/N (%).

Estimated repair rates of 75% to 84% for degenerative MR in prior national registry analyses were based on older operative data, a risk model not specified for mitral etiology, and a retrospective hierarchal decision method of excluding nonprimary MR etiology.[1,2] Although of high quality, these estimates were based on the best available data at the time but did not account for etiology, lesion, and operative detail. Given the several upgrades to available MV information in the STS ACSD since 2014, the current study provides much more specific information on etiology, lesion, and operative specificity, thus enabling the creation of a contemporary algorithm to more precisely assess risk of MV repair of primary MR. By excluding redo MV operations and those involving nonprimary MR techniques, such as commissurotomy, patch augmentation, and excision of MAC, a more homogeneous cohort was derived to evaluate outcomes of planned MV repair for primary MR. Although over two-thirds of the cases were performed by programs that had more than 75 cases over the 6-year study period, the risk of MV repair for primary MR was <1% for the majority of patients (Central Illustration), and the repair rate was 93.6% for intent-to-treat patients. These data help to establish a contemporary benchmark.

STUDY LIMITATIONS. Participation in the STS ACSD remains voluntary. However, the database has an estimated penetration of 97% of all programs performing adult cardiac operations in the United States, and the data are highly representative of overall practice.[9] Similarly, data for this analysis may be limited by availability and accuracy of the data in the STS ACSD. However, the STS ACSD remains one of the most rigorously validated surgical databases in health care.[9] Center case volume characteristics are based on experience over the entire study period and may not account for changes in personnel or expertise at various programs. The "as-treated" risk represents a post hoc risk estimation. The STS ACSD does not include specific echocardiographic parameters that may provide more information regarding mitral pathoanatomy, such as leaflet length and coaptation depth, and longitudinal imaging follow-up was not available to assess MV repair durability. Reported outcomes are limited to 30 days.

CONCLUSIONS

The operative risk of mortality of first-time isolated surgical MV repair for primary MR was found to be <1% in the majority of patients, with 97% of patients under 65 years of age having <3% risk of OM. Increasing center volume was associated with lower rate of OM and a lower rate of conversion to replacement. These findings, the etiology- and procedure-specific risk model, and the multiendpoint clinical decision tool that will be made available online serve to support contemporary heart team and patient informed decision-making in the management of primary MR.

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PERSPECTIVES

COMPETENCY IN PATIENT CARE AND PROCEDURAL SKILLS: Mitral valve repair surgery for primary mitral regurgitation is associated with OM <1%, successful repair in >90% of cases, and low rates of conversion to mitral valve replacement, particularly at high-volume centers.

TRANSLATIONAL OUTLOOK: Clinical decision tools can guide future studies assessing optimal treatment for patients with mitral regurgitation.

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KEY WORDS mitral regurgitation, mitral valve repair, primary degenerative, risk model

APPENDIX For supplemental tables and figures, please see the online version of this paper.