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Single Versus Multi-Center Surgeons' Risk-Adjusted Mitral Valve Repair Procedural Outcomes

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TITLE: Single Versus Multi-Center Surgeons' Risk-Adjusted Mitral Valve Repair Procedural Outcomes

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I. Study Background:

Mitral valve repair and replacement procedures are technically challenging even for experienced cardiothoracic surgeons. Among cardiothoracic surgeons, mitral valve surgery experts have better patient outcomes (LaPar 2014). Heart Valve and Mitral valve repair subspecialty training programs are emerging around the country.

Numerous studies have shown long term-survival benefit of mitral valve repair compared to mitral valve replacement. (Gammie 2009). Technical expertise in mitral valve repair allows surgeons to perform mitral valve repair as a substitute to mitral valve replacement. This has been well studied and is referred to in the literature as 'rates of mitral repair' (Gammie 2009, Chickwe 2017). As the surgeon's 'repair rate' (based on the total number of mitral valve procedures performed for each surgeon) is thus an important variable and there are ongoing efforts on how to improve the rate of mitral valve repair. Experienced surgeons and institutions in mitral valve surgery proved to have better patient outcomes through increasing 'repair rates' (LaPar 2009) and decreasing readmission rates (Goel 2019).

In our prior study of the STS ACSD database (Shroyer 2018), we observed that coronary artery bypass graft surgery patients of single center surgeons had better outcomes than patients of multicenter surgeons. Using hospital NPI, surgeons were categorized as MC if they had > 2 consecutive quarters with procedures performed at > 2 hospitals; this accounted for surgeon switching hospital affiliations during a quarter. Their primary "home" hospital was identified as their highest volume center versus their "satellite" secondary hospital(s). Based on this study, multicenter surgeons had better risk-adjusted outcomes when performing surgery at their home institution than at satellite hospitals.

The goal of this study is to improve future mitral valve repair patients' clinical outcomes. In our prior study of the STS database (Shroyer 2018), we observed that coronary artery bypass graft surgery patients of single center surgeons had better outcomes than patients of multicenter surgeons. Furthermore, multicenter surgeons had better outcomes when performing surgery at their home institution than at satellite hospitals.

This pattern may be apparent in mitral valve repair surgery and we propose to study the impact of single-versus multi center surgeons on mitral valve repair outcomes and on rates of mitral repair. We plan to base this study on the model that we previously developed to study STS CABG procedures.

A. Overarching research question:

Are the risk-adjusted outcome rates for surgeons that perform mitral valve repair procedures at a single center [i.e., SC surgeons] versus multiple centers [i.e., MC surgeons] different? Specific outcomes of interest include 30-day operative mortality, major perioperative complications, postoperative length of stay, and 30-day readmission rates.

B. Most relevant historical publication:

For CABG-only procedures, our collaborative STS/DCRI/SBU SOM co-author team recently examined the variation in CABG risk-adjusted outcomes between SC versus MC surgeons. Important differences were found – where SC surgeons had lower rates for risk-adjusted outcomes as compared to MC surgeons. (Shroyer, 2018)

II. Study Plan/Approach:

A. Study Patients:

This mitral valve repair (MVR) study is a retrospective cohort comparing postoperative outcomes of two groups of patients: MVR patients of SC surgeons and MVR patients of MC surgeons. The patient population includes all cardiothoracic surgical patients undergoing a non-emergent, first-time (primary), mitral valve repair-only procedure at US centers reporting data to the Society of Thoracic Surgeons Adult Cardiac Surgery Database (STS ACSD). Characteristics of the surgeons (e.g., geographic location and rates for mitral valve repair versus mitral valve replacement, as well as annual cardiac surgery caseload) will be used for this analysis.

STS ACSD records from 2011 to 2018 will be used for this de-identified database analysis. Since January 2011, surgeon- and hospital-specific national provider identifiers [NPI] have been recorded in the STS ACSD; thus the STS ACSD mitral valve procedural processes of care and risk-adjusted outcomes can be compared for SC versus MC surgeons for purpose of this project from 2011 onward. From 2002 to 2006 there were 21,238 Mitral valve repair patients in the STS ACSD (O'Brien 2009). In 2011-2014 there was 35,114 mitral valve repair patients in the STS ACSD (Badhwar 2016). Therefore, we estimate that the population of mitral valve repair patients included in the STS ACSD during 2011-2018 ranges from 80,000 to 100,000 patients.

B. Study Inclusion Criteria:

All cardiothoracic surgical patients undergoing a non-emergent, first-time (primary), mitral valve repair-only procedure at US centers participating in the STS ACSD database.

C. Study Exclusion Criteria:

The records for all mitral valve repair-only patients with complete data points (that enable us to perform the study) will be analyzed. Patient records with a surgeon with a missing NPI number or missing endpoints will be excluded. As the focus is placed upon non-emergent, first time mitral valve repair procedures only, the emergent and MVR+CABG combination procedures will be excluded. From the included records, however, $\leq 5\%$ missing data rate is anticipated.

D. Statistical Methods

We will compare risk-adjusted outcomes of patients of SC surgeons to those of patients of MC surgeons. In general, basic descriptive statistics will be used to summarize the study's MVR records.

This study's had two primary post-MVR outcomes: 1) 30-day operative mortality (defined as in-hospital death or death within 30 days) and 2) major perioperative complications (i.e., stroke, new renal failure, prolonged mechanical ventilation (> 24 hours), or reoperation for bleeding/tamponade that occurred as in-hospital complications as well as deep sternal wound infections that occurred either in-hospital or within 30-days). Length of stay and hospital readmission will be secondary endpoints.

Patients' baseline characteristics, unadjusted outcomes, and risk-adjusted outcomes will be compared between 1) SC versus MC surgeon sub-groups and 2) for MC surgeons, their home versus satellite centers. As overall program or hospital performance may confound measurements of surgeon performance, the STS hospital-level ACSD star ratings (i.e., a National Quality Forum-endorsed methodology used to evaluate quality) were compared between SC versus MC sub-groups.

Descriptive statistics will be reported; continuous variables will be compared using Wilcoxon rank sum tests and categorical variables will be compared using Chi-square tests. Based upon published MVR-only risk modeling approaches, multivariable logistic regression models' variable coefficients will be recalibrated (i.e., overall observed-to-expected [O/E] ratio = ~ 1.0); published STS imputation approaches will be used. Patient risk estimates for 30-day operative mortality and major complications will be computed.

Surgeon-specific O/E ratios with 95% confidence intervals [CI] will be calculated; these O/E ratios subsequently will be compared SC versus MC surgeons and among MC surgeons, as well as their home versus satellite hospitals. The CIs will be calculated by treating the observed number of deaths as random and the expected number of deaths as a constant with an empirical variance estimator to account for surgeon-specific effects. Non-overlapping O/E ratios' 95% CIs will be used to identify significant differences.

Risk-adjusted outcomes will be compared between the two SC versus MC surgeon MVR patient records for the following endpoints: 30-day operative mortality (primary), major operative complications (primary), post-operative length of stay (secondary), and 30-day readmission

(secondary). In order to calculate risk based outcomes, the STS-approved multivariate logistic regression models (based on most recent STS publications) data will be used.

III. Timetable for Executing the Study:

| Task - Projected Timeline | Start | End |
|--|-----------|------------|
| Data Receipt | 2/1/2020 | 2/28/2020 |
| Data Cleaning and Inter-Field Checks for Quality | 3/1/2020 | 3/31/2020 |
| Preliminary Analysis and Preliminary Reports | 4/1/2020 | 4/30/2020 |
| STS Abstract Preparation | 5/1/2020 | 5/29/2020 |
| STS Abstract Preparation and Submission | 6/1/2020 | 8/14/2020 |
| STS Manuscript Preparation & Submission | 8/15/2020 | 12/18/2020 |
| STS Presentation | 1/30/2021 | 2/2/2021 |

IV. Dissemination Plans:

The primary study manuscript, entitled “**Single Versus Multi-Center Surgeons' Risk-Adjusted Mitral Valve Repair Procedural Outcomes**” is planned to be submitted as an abstract to the 2021 national Society of Thoracic Surgeons meeting; pending abstract acceptance, a manuscript is planned to be submitted to the Annals of Thoracic Surgery.

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