

Surgical Repair of Ventricular Septal Defect After Myocardial Infarction: Outcomes From The Society of Thoracic Surgeons National Database

George J. Arnaoutakis, MD, Yue Zhao, PhD, Timothy J. George, MD, Christopher M. Sciortino, MD, PhD, Patrick M. McCarthy, MD, and John V. Conte, MD

Division of Cardiac Surgery, Johns Hopkins Medical Institutions, Baltimore, Maryland; Outcomes Research and Assessment Group, Duke Clinical Research Institute, Durham, North Carolina; and Division of Cardiac Surgery, Bluhm Cardiovascular Institute of Northwestern Memorial Hospital, Feinberg School of Medicine, Northwestern University, Chicago, Illinois

Background. The development of a ventricular septal defect (VSD) after myocardial infarction (MI) is an uncommon but highly lethal complication. We examined The Society of Thoracic Surgeons database to characterize patients undergoing surgical repair of post-MI VSD and to identify risk factors for poor outcomes.

Methods. This was a retrospective review of The Society of Thoracic Surgeons database to identify adults (aged ≥ 18 years) who underwent post-MI VSD repair between 1999 and 2010. Patients with congenital heart disease were excluded. The primary outcome was operative death. The covariates in the current The Society of Thoracic Surgeons model for predicted coronary artery bypass grafting operative death were incorporated in a logistic regression model in this cohort.

Results. The study included 2,876 patients (1,624 men [56.5%]), who were a mean age of 68 ± 11 years. Of these, 215 (7.5%) had prior coronary artery bypass grafting

operations, 950 (33%) had prior percutaneous intervention, and 1,869 (65.0%) were supported preoperatively with an intraaortic balloon pump. Surgical status was urgent in 1,007 (35.0%) and emergencies in 1,430 (49.7%). Concomitant coronary artery bypass grafting was performed in 1,837 (63.9%). Operative mortality was 54.1% (1,077 of 1,990) if repair was within 7 days from MI and 18.4% (158 of 856) if more than 7 days from MI. Multi-variable analysis identified several factors associated with increased odds of operative death.

Conclusions. In the largest study to date to examine post-MI VSD repair, ventricular septal rupture remains a devastating complication. As alternative therapies emerge to treat this condition, these results will serve as a benchmark for future comparisons.

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The development of a postmyocardial infarction (MI) ventricular septal defect (VSD) is an uncommon but frequently fatal complication, occurring in less than 1% of patients sustaining MI in the modern era of early reperfusion therapy [1]. In medically treated patients with this complication, mortality rates exceed 90%, whereas mortality ranges between 19% and 60% in patients undergoing surgical repair [1–7]. More recently, percutaneous closure devices have permitted less invasive management of patients with post-MI VSD [8–11].

As alternative technologies evolve to treat this highly lethal condition, the establishment of a benchmark for comparison is essential. Moreover, the identification of risk factors for poor outcomes after traditional surgical repair may help identify the patients who are most likely to benefit from percutaneous intervention. Most of the

previous studies on surgical outcomes have been confined to single-series retrospective reviews with a relatively small sample size [3–7]. A single national registry report from Europe documents 189 patients treated during a 7-year span [2]. Therefore, we used national registry data provided by The Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database (ACSD) to examine risk factors for poor outcomes after surgical repair of post-MI VSD.

Material and Methods

Data Source

The STS ACSD encompasses clinical and demographic data on more than 4.5 million patients undergoing cardiac operations at participating centers in North America since 1989. The Duke Clinical Research Institute remains the center for biostatistical analysis for all of the STS National Databases. The data used in analyses of the STS

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Address correspondence to Dr Conte, Division of Cardiac Surgery, Professor of Surgery, Johns Hopkins Medical Institutions, Ballock 618, 600 N Wolfe St, Baltimore, MD 21287; e-mail: jcont@jhmi.edu.

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Abbreviations and Acronyms

ACSD	= Adult Cardiac Surgery Database
CABG	= coronary artery bypass graft
CAD	= coronary artery disease
CI	= confidence interval
CPB	= cardiopulmonary bypass
EF	= ejection fraction
IABP	= intraaortic balloon pump
MI	= myocardial infarction
MV	= mitral valve
NYHA	= New York Heart Association
OR	= odds ratio
PCI	= percutaneous coronary intervention
SD	= standard deviation
STS	= Society of Thoracic Surgeons
VAD	= ventricular assist device
VSD	= ventricular septal defect

ACSD represent a limited data set originally collected for nonresearch purposes, without direct patient identifiers, and this study was therefore considered exempt by the Duke University Health System Institutional Review Board. The Johns Hopkins University Institutional Review Board separately granted approval.

Patient Population

This study included all adult patients (aged ≥ 18 years) who underwent surgical repair of a post-MI VSD between 1999 and 2010. Eligible patients were identified by an affirmative response in the STS data field for MI. Patients who underwent concomitant coronary revascularization procedures or combined valvular procedures were included; however, 65 patients with congenital heart disease were excluded.

Outcomes

The primary outcome was operative mortality, defined as death from any cause in-hospital or within 30 days of the index operation. Additional complications included length of stay, postoperative infection, respiratory failure, renal failure requiring renal replacement therapy, and cerebrovascular accident (CVA).

Study Design

Clinically relevant variables and previously reported predictors of 30-day postcoronary artery bypass grafting (CABG) operative death according to the STS database were included as candidate variables in the full model of this analysis [12]. These included demographic characteristics, medical comorbidities (hypertension, hypercholesterolemia, chronic lung disease, diabetes, cerebrovascular accident, peripheral vascular disease, immunosuppressive treatment, renal function, left ventricular ejection fraction, present smoker, valvular disease, or arrhythmia), medical acuity (angina, timing of recent myocardial infarction [< 6 hours, 6 to 24 hours, 1 to 7 days, 8 to 21 days, and ≥ 21 days]), percutaneous coronary intervention ≤ 6 hours, preoperative intraaortic balloon pump (IABP), inotropes,

surgical status (emergency/salvage, urgent, elective), New York Heart Association classification, left main disease, previous cardiovascular intervention and cardiogenic shock, concomitant procedures, and year of operation. Cardiogenic shock is defined as hypoperfusion with (1) systolic blood pressure below 80 mm Hg or cardiac index below 1.8 L/min/m² despite maximal treatment, or (2) intravenous inotropes or IABP, or both, necessary to maintain systolic blood pressure above 80 mm Hg or cardiac index above 1.8 L/min/m². Anatomic site of VSD rupture (posterior vs anterior) is not contained in the STS ACSD, and this operative factor was not analyzed.

Statistical Analysis

Summary statistics for outcomes and baseline patient characteristics are presented as percentages for categorical variables and means with standard deviation (SD) for continuous variables. The Pearson χ^2 test was used to compare categorical variables, whereas the Kruskal-Wallis test was used for continuous variables. SAS 9.1 software (SAS Institute, Cary, NC) was used for all calculations.

Missing data in the baseline characteristics were handled by multiple imputations under the assumption of missing-at-random and using Gibbs sampling [13]. Variables included in the imputation models were operative death and the covariates in the full model (as described previously). Ten complete imputed data sets were created. A proposed model was then fitted to each of the completed data sets, and the 10 sets of results were combined.

Logistic regression modeling was used to estimate the risk of operative death as a function of patient baseline variables. Covariates were selected from the full list of candidate variables using a backward algorithm with a significance criterion of $p = 0.05$ within each of the 10 imputed data sets. Variables that were selected in any of the 10 data sets were included in the reduced model. The year of operation was forced into the reduced model to adjust time trends. Discrimination of full and reduced models was assessed by C index. The enhanced bootstrap was used to estimate the bias (ie, overestimated C index) due to model overfitting in the original sample [14]. Risk-adjusted odds ratios (ORs) of covariates were estimated. Robust sandwich variance estimates were used to obtain 95% confidence intervals (CI) to account for statistical dependence of patients within sites [15].

Results

Demographics

The overall cohort consisted of 2,876 patients (1,624 men [56.5%]) with an average age of 68 ± 11 years. Surgical status was listed as an emergency in 1,430 (49.7%), and 1,869 (65.0%) were supported preoperatively with an IABP.

Concomitant coronary revascularization was performed in 1,837 (63.9%). Mitral valve procedures were performed simultaneously in 211 patients (7.3%), and intraoperative ventricular assist device was required in 84 (2.9%). A total of 950 (33%) had undergone a previous

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