

## Contemporary outcomes of surgical ventricular septal defect closure

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**Objectives:** Surgical closure of ventricular septal defects remains the most common pediatric cardiac surgical procedure. No studies, however, have comprehensively analyzed risk factors and drivers of nonmortality outcomes in the current era. The purpose of this study was to assess both baseline characteristics and outcomes of children undergoing surgical repair of ventricular septal defects in a contemporary cohort.

**Methods:** This retrospective study examined a consecutive series of 369 ventricular septal defect closures at a single institution. Because mortality is low in nearly all centers for repair of these defects, we focused on morbidity and identified drivers of risk via multivariable linear regression modeling.

**Results:** For children younger than age 6 months undergoing ventricular septal defect closure, every extra kilogram in operative weight results in a 2.3-day shorter length of stay. In an analysis of composite risk, patients younger than age 6 months undergoing ventricular septal defect repair exhibited a 1.8-fold increase in composite risk for each kilogram decrease in weight, whereas patients older than age 6 months experienced no significant difference.

**Conclusions:** Even in the current surgical era, weight remains a significant predictor of morbidity and driver of length of stay in young infants undergoing ventricular septal defect closure. Weight still should be considered when discussing operative risks for children younger than age 6 months undergoing this procedure, irrespective of the indication for operation. (*J Thorac Cardiovasc Surg* 2013;145:641-7)

Isolated ventricular septal defects (VSDs) are the most common congenital structural heart disease, occurring in 0.34 to 2.68 per 1000 live births.<sup>1-3</sup> Although 80% of patients with VSDs presenting before age 1 month will have spontaneous closure of the defect, patients in whom closure does not occur often require surgery.<sup>4</sup> Surgical closure of VSDs remains the most common pediatric cardiac surgical procedure, and there have been continued advances in surgical and medical care since Lillehei and colleagues<sup>5,6</sup> performed the first successful repair in 1957, yet surprisingly few studies have been published during the past decade evaluating postoperative morbidity and

mortality for VSD closure,<sup>7-12</sup> and even fewer that comprehensively analyze current risk factors and drivers of outcomes.<sup>4,13-15</sup> The purpose of this study was to assess baseline characteristics of and outcomes for children undergoing surgical repair of simple VSDs in a contemporary cohort, as well as to determine drivers of these outcomes. We performed a retrospective chart review of a consecutive surgical series (n = 369) of simple VSD closures at a single large institution. Because mortality is low in nearly all centers for repair of VSD, we focused on morbidity and identified drivers of risk via multivariable linear regression modeling, with secondary analysis focusing on length of stay.

### METHODS

#### Patient Population

This retrospective study examined a consecutive series of 369 surgical patients presenting to the Children's Hospital of Philadelphia for surgical closure of simple VSD between January 1, 2002, and December 31, 2008. Patients with a concomitant atrial septal defect, patent ductus arteriosus, patent foramen ovale, coarctation of the aorta, or stenotic/regurgitant semilunar valves were included. Patients with all other complex cardiac anomalies, including tetralogy of Fallot and double outlet right ventricle, were excluded. Patients who had undergone previous pulmonary artery banding were included in this study. The medical records for these patients were retrospectively reviewed with permission from the Children's Hospital of Philadelphia Institutional Review Board.

Of 369 patients initially identified from the surgical database, 84 were excluded because of incomplete data sets (mostly related to perfusion data). A combination of echocardiography reports, clinic, inpatient, and operative notes were reviewed. Outcomes were assessed through the first postoperative visit.

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**Abbreviations and Acronyms**

|      |   |                                     |
|------|---|-------------------------------------|
| VSD  | = | ventricular septal defect           |
| ECMO | = | extracorporeal membrane oxygenation |
| TEE  | = | transesophageal echocardiogram      |
| TTE  | = | transthoracic echocardiogram        |

Preoperative characteristics, including sex, race, gestational age, birth weight, age at operation, weight at operation, days in hospital preoperation, days ventilated preoperation, type of VSD, size of VSD, operative indication, product of multiple gestation or in-vitro fertilization, maternal history of diabetes, underlying genetic condition, and comorbid noncardiac medical conditions, were assessed. The sizes of preoperative and residual VSDs were recorded from the official interpretation by staff echocardiographers. VSD size was categorized as “small” (<3 mm), “moderate” (3-5 mm), “large” (6-9 mm), and “very large” (>10 mm). In the setting of multiple VSDs, size was recorded as the sum of the total sizes. The magnitude of semilunar valvar insufficiency was determined by review of reports by staff echocardiographers. The indications for operation was classified into 1 of 3 mutually exclusive groups: (1) failure to thrive/congestive heart failure (Category Q: “Flow”); (2) right ventricular obstruction, aortic insufficiency, or double chamber right ventricle (Category O: “Obstruction”); and (3) elevated pulmonary vascular resistance (Category P: “Pulmonary”). Although some overlap was inevitable, patients were separated into the diagnostic group for which they were referred for operation by their primary cardiologists. A diagnosis of failure to thrive was determined by the primary cardiologist and generally based on clinical criteria, including weight less than the fifth percentile for age or crossing 2 major percentile channels; all patients carrying the diagnosis of failure to thrive had been prescribed either diuretics or digoxin, or both, and were receiving fortified feeds. A diagnosis of heart failure was made based on a combination of subjective signs and symptoms, diagnosed by the referring cardiologist, including feeding or exercise intolerance, significant ascites, or hepatomegaly. A diagnosis of obstruction was made by echocardiography. A diagnosis of rising pulmonary vascular resistance was made by either cardiac catheterization or echocardiography.

Operative factors, including crossclamp, bypass, and total operation times, as well as surgical technique (patch closure vs primary closure) were also assessed as drivers of outcomes, including length of stay, incidence of reoperation, wound infection, postpericardiotomy syndrome, chylothous effusion, chest tube, transient or complete heart block, seizure, rehospitalization, extracorporeal membrane oxygenation (ECMO), and death. A composite factor of major adverse events was also assessed, defined as death, cardiac arrest, ECMO, reoperation, stroke, or heart block necessitating a permanent pacemaker.

**Surgical Technique**

All patients underwent median sternotomy. Cardiopulmonary bypass was used for all patients. Circulatory arrest was rare. All operations were performed by 1 of 7 surgeons at the Children’s Hospital of Philadelphia (98% of surgeries were performed by the same 3 surgeons). Primary or Dacron patch closure, using either interrupted (rare) or running techniques (most), was employed at surgeons’ discretion. Concomitant infundibular muscle resection, valvuloplasty, vascular ring repair, atrial septal defect repair, patent foramen ovale closure, patent ductus arteriosus ligation, and/or division were performed when indicated. Modified ultrafiltration was used in all patients. All patients received a preoperative transthoracic echocardiogram and either intraoperative transesophageal echocardiogram (95.1%) or postoperative transthoracic echocardiogram (90.9%) at the surgeon’s discretion.

**Statistical Methods**

All statistical analyses were conducted in SAS (version 9.1. SAS Institute, Inc, Cary, NC). Descriptive statistics were computed for demographic and clinical variables using means, medians, and standard deviations for continuous variables, and frequency tables for categorical variables. One-way analysis of variance was used to measure the associations between indication for operation and continuous variables. Fisher’s exact test was used to measure associations with categorical variables. Length of stay was  $\log_{10}$ -transformed to include in correlations and regression models. Parameter estimates were then back-transformed to correspond to length of stay. Residuals of regression models were examined, using  $\log_{10}$ -transformation of length of stay, and no substantial deviation from normality was observed. Relationships between length of stay in the hospital and continuous or categorical variables were measured using Pearson correlation coefficients and unpaired *t* tests, respectively. A multivariable linear regression model of length of stay was built using variables significantly associated with length of stay in univariable analyses, assessing fit by adjusted  $R^2$ . The results from stepwise regression were consistent with this analysis. Associations between the composite end point and various predictors were assessed using logistic regression.

**RESULTS****Descriptive Characteristics**

We analyzed demographic information for 285 patients who met inclusion criteria (Table 1). Boys and girls were equally represented (51.6% boys, 0.7% ambiguous genitalia). A majority of patients were white (61.4%), followed by black (16.5%), Hispanic (7.0%), and Asian (3.5%). A majority of patients (71.2%) were aged <12 months, with more than half (57.9%) younger than age 6 months. The median age was 144 days (range, 16 days to 48.5 years) (Appendix Table 1). Somewhat surprisingly, an underlying genetic syndrome was present in 25.6% of patients, of whom 49.3% had Trisomy 21 (12.6% of the total cohort). Six percent were products of twin or triplet gestation (vs 2.6% of all live US births), 2.5% were products of in vitro fertilization, and 2.8% were infants of mothers with insulin-dependent diabetes.

For most patients, the primary indication for operation was failure to thrive/congestive heart failure (81.4%). The next most common indication was right ventricular obstruction, aortic insufficiency, or double chamber right ventricle (11.0%), followed by rising pulmonary vascular resistance (7.8%). Anatomic VSD types were represented as follows: 8.4% single conoseptal (Type I), 77.9% single conoventricular (Type II), 1.8% single inlet/canal type (Type III), 2.8% single muscular (Type IV), and 9.1% multiple. Of the total cohort, 15.1% were associated with a patent ductus arteriosus, 33.7% with a patent foramen ovale, and 22.8% with 1 or more atrial septal defect. One patient had associated partial anomalous venous return (Table 2).

Hospital and operative characteristics were also examined (Appendix Table 1 and Table 2). Of the patients, 22.6% were inpatients preoperatively; 10.2% were transferred from outside hospitals for the operation. Preoperative ventilation was a characteristic of 2.8% of patients. Mean operative time was  $122.9 \pm 34.9$  minutes

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