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ORIGINAL ARTICLE

Mortality characteristics of aortic root surgery in North America†

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Abstract

OBJECTIVES: Aortic root surgery is transitioning to aortic valve sparing (AVS), but little is known about the relative early outcomes of AVS versus composite graft-valve replacement (CVR). This study assessed mortality differences for AVS versus CVR to guide future practice decisions.

METHODS: From January 2000 to June 2011, 31 747 patients had aortic root replacement with AVS (n = 3585; 11%) or CVR (n = 28 162; 89%). The cohort of *Overall* patients was divided into two subgroups: *high-risk* patients (n = 20 356; 6% AVS) having age >75 years, endocarditis, aortic stenosis, dialysis, multiple valves, reoperation or emergency/salvage status, and the remaining *low-risk* patients (n = 11 388; 21% AVS). Using logistic regression analysis, outcomes were presented as unadjusted operative mortality (UOM), risk-adjusted operative mortality (AOM) and adjusted odds ratio (AOR) for mortality.

RESULTS: Baseline characteristics for the Overall group (AVS versus CVR) were: mean age (52 vs 57 years), endocarditis (1 vs 11%), aortic stenosis (4 vs 36%), dialysis (1 vs 2%), multiple valves (7 vs 10%), reoperation (6 vs 17%) and emergency status (14 vs 12%) (all $P < 0.0001$). In high- and low-risk groups, baseline differences narrowed, and lower mortality was generally observed with AVS: (AVS versus CVR) UOM group Overall (4.5 vs 8.9%)*, group High-risk (10.5 vs 11.7%), group Low-risk (1.4 vs 3.1%)*; AOM group Overall (6.2 vs 8.6%), group High-risk (10.1 vs 11.7%), group Low-risk (2.2 vs 2.8%); AOR group Overall (0.59)*, group High-risk (0.62)*, group Low-risk (0.69). *$P < 0.05$.

CONCLUSIONS: Relative risk-adjusted mortality seemed comparable with AVS versus CVR in low- and high-risk subgroups. These data support judicious expansion of aortic valve repair in patients having aortic root replacement.

Keywords: Aortic root surgery • Aortic valve repair • Heart valve surgery

INTRODUCTION

Since the initial description of composite aortic root replacement by Bentall [1] in 1968, surgical treatment of aortic root disease has centred primarily on prosthetic replacement of both the aortic valve and root [2]. In recent years, aortic valve-sparing (AVS) surgery utilizing aortic valve repair has emerged as an attractive alternative to composite graft-valve replacement (CVR), and practice has gradually transitioned towards AVS [3]. This change has been motivated, at least in part, by observations of lower long-term valve-related complications with AVS [4–7]. However, the adoption of AVS has lagged somewhat, likely due to perceived technical complexity and lack of comparative outcome data. Thus, the purpose of this study was to perform risk-adjusted short-term outcome comparisons between AVS and CVR in the Society of Thoracic Surgeons (STS) national database.

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METHODS

Data source

The STS database currently records over 90% of adult cardiac surgery in North America, having evolved over 20 years as an instrument for clinical outcome research and quality improvement. Participating programmes submit data to the Duke Clinical Research Institute (DCRI) following strict guidelines of patient privacy. Patient information is entered according to pre-established data collection forms (DCFs) that conform to standard definitions available at www.sts.org. Designated trained clinical managers at participating programmes are responsible for data accuracy, and software safe-checks are in place to monitor for possible inconsistencies. Storage and analysis of the collective clinical data are performed at the DCRI, and periodic site auditing is accomplished to ensure data accuracy. For de-identified STS clinical research studies with quality improvement objectives, individual patient consent was waived by the Duke University Institutional Review Board.

Study design

The database was searched from January 2000 through June 2011 to identify patients having aortic root surgery. Two categories were defined: 'Root Reconstruction w/Valve Conduit', corresponding to CVR, and 'Root Reconstruction w/Valve Sparing', corresponding to AVS. Although precise procedural details were not available, AVS cases likely corresponded to valve reimplantation [8] or modified remodelling [9, 10] procedures. These categories were mapped to versions 2.35, 2.41, 2.52, and 2.61 of the DCFs, which corresponded to progressive time frames of the study. Aortic valve surgery with supracoronary aortic replacement was not considered aortic root surgery. Ten patients with missing age, gender or operative procedure were excluded from the study.

The analysis was designed to provide risk-adjusted outcome comparisons between AVS and CVR. Since it was observed in early evaluations that AVS was performed more often in lower risk patients, an effort was made to balance procedural baseline characteristics by defining low- and high-risk subgroups for analyses. The entire population, which included all patients, was defined as the Overall group. Then, 7 patient categories with higher risk and low tendency for AVS were identified within the Overall group and were termed the *high-risk* group. Each of the 7 patient categories had a low incidence of AVS and included: age >75 years, endocarditis, aortic stenosis, dialysis, concomitant valve procedures, previous valve surgery, emergent or salvage clinical status. The remaining patients constituted a Low-risk group, with a higher tendency to undergo AVS. Unadjusted and risk-adjusted outcome comparisons for operative mortality (defined as death during index hospitalization or within 30 days of the procedure) were then performed in all 3 groups. Secondary outcomes included the following perioperative events: cerebrovascular accident, renal failure, dialysis, atrial fibrillation, deep sternal wound infection, reoperation for bleeding, prolonged hospital length of stay and a composite of any major morbidity and mortality.

Statistical analysis

Baseline and operative patient characteristics and unadjusted outcomes for AVS versus CVR were summarized for the three groups. Continuous variables were presented as means and compared with Wilcoxon rank-sum tests. Categorical variables were presented as percentages and compared with Pearson χ^2 tests. Then, multivariable logistic regression was used to evaluate risk-adjusted differences in operative mortality between the two procedural categories: AVS versus CVR. Variables previously identified in STS valve surgery risk studies [11–13] were selected for the regression analyses. Time trend was modelled as a linear variable composed of three time periods: January 2000–December 2003 (P1), January 2004–December 2007 (P2) and January 2008–June 2011 (P3). Aortic insufficiency was defined by three levels of severity: (i) none/trivial/mild (reference group), (ii) moderate and (iii) severe. To allow the effect of the explanatory variables in the model to be different between AVS and CVR, interaction terms were evaluated between 'surgery type' and several covariates: age, diabetes, dialysis, creatinine, reoperation, endocarditis, emergent status, chronic lung disease (CLD), congestive heart failure (CHF), ejection fraction (EF), sex, shock, intra-aortic balloon pump/inotropes,

Table 1: Baseline patient characteristics in Overall group

Patient baseline characteristics	AVS	CVR	*P*-value
Age (years, mean)	52.1	57.6	<0.0001
Hypertension (%)	60.9	65.6	<0.0001
Diabetes (%)	7.7	13.5	<0.0001
Chronic lung disease (moderate/severe) (%)	4.6	7.0	<0.0001
Cerebrovascular disease (%)	8.1	11.0	<0.0001
Peripheral vascular disease (%)	15.8	15.1	0.22
Creatinine >1.5 mg/dl (%)	7.1	12.2	<0.0001
Dialysis (%)	0.8	2.0	<0.0001
Endocarditis (%)	1.5	11.7	<0.0001
Non-elective (%)	28.6	35.1	<0.0001
Congestive heart failure (%)	12.2	30.5	<0.0001
Ejection fraction <0.45 (%)	7.6	16.1	<0.0001
Predominant aortic stenosis (%)	3.6	35.9	<0.0001
Severe (level 3) aortic regurgitation (%)	17.2	34.8	<0.0001
Reoperation (%)	8.6	20.3	<0.0001
Previous CABG (%)	3.2	6.3	<0.0001
Previous valve surgery (%)	6.2	17.3	<0.0001
Concomitant CABG (%)	15.4	26.9	<0.0001
Aortic clamp time (min, mean)	150.9	150.8	0.6
Cardiopulmonary bypass time (min, mean)	198.6	205.4	0.007

AVS: aortic valve-sparing root replacement; CVR: composite graft-valve replacement; CABG: coronary artery bypass graft.

mitral insufficiency, aortic insufficiency, mitral stenosis and aortic stenosis.

Outcome comparisons between AVS and CVR were presented as unadjusted operative mortalities (UOMs), risk-adjusted operative mortalities (AOMs) and risk-adjusted odds ratios for mortality (AOR). To calculate AOM for each surgery type, a risk model was created without the inclusion of the AVS versus CVR variable, and observed and predicted mortality rates were calculated for all patients. AOM for each surgery type was then computed according to the formula: AOM = [observed mortality rate/predicted mortality rate] × overall mortality rate. Finally, AOR for AVS versus CVR was calculated following the inclusion of 'surgery type' back into the logistic regression model. All analyses were performed using SAS 9.2 (SAS Institute, Cary, NC, USA) and R version 2.11 (R Foundation for Statistical Computing, Vienna, Austria). A P-value of ≤0.05 was considered significant.

RESULTS

Between January 2001 and June 2011, 31 747 patients underwent aortic root surgery (Overall group), and UOM for all levels of patient risk was 8.4%. Baseline characteristics for all patients (AVS versus CVR) in the Overall group are listed in Table 1. Risk factors generally were worse in the CVR category, although aortic cross-clamp and cardiopulmonary bypass times were similar. For the Overall group, AVS was performed in 11.3% (3585/31 747; UOM = 4.5%) and CVR in 88.7% (28 162/31 747; UOM = 8.9%).

Table 2: Baseline patient characteristics in High-risk and Low-risk groups

Patient characteristics	High-risk group			Low-risk group		
	AVS	CVR	P-value	AVS	CVR	P-value
Age (years, mean)	57.9	59.3	0.03	49.1	54.1	0.0001
Hypertension (%)	67.9	65.3	0.02	57.3	66.3	0.0001
Diabetes (%)	10.3	15.6	<0.0001	6.4	9	0.0008
Chronic lung disease (moderate/severe) (%)	5.7	7.4	0.002	4	6	0.0001
Cerebrovascular disease (%)	12.9	13.3	0.73	5.6	6.12	0.37
Peripheral vascular disease (%)	19.2	15.2	0.0001	14.1	15.0	0.28
Creatinine >1.5 mg/dl (%)	12.9	13.3	0.74	3.47	5.9	0.0001
Dialysis (%)	2.4	2.9	0.44	0	0	N/A
Endocarditis (%)	4.4	7.2	0.0001	0	0	N/A
Non-elective (%)	55.5	41.8	0.0001	15.2	20.7	0.0001
Congestive heart failure (%)	17.9	34.6	0.0001	9.2	21.9	0.0001
Ejection fraction <0.45 (%)	10.3	15.9	0.001	6.1	16.5	0.0001
Predominant aortic stenosis (%)	10.6	52.9	0.0001	0	0	N/A
Severe (level 3) aortic regurgitation (%)	16.9	29.7	0.0001	17.3	45.5	0.0001
Reoperation (%)	21.8	28.7	0.0001	1.7	2.6	0.0196
Previous CABG (%)	6.1	8.1	0.01	1.7	2.6	0.02
Previous valve surgery (%)	18.2	25.4	0.0001	0	0	N/A
Concomitant CABG (%)	20.1	29.4	0.0001	13	21.7	0.0001
Aortic clamp time (min, mean)	142.4	156.8	0.0001	155.2	138.2	0.0001
Cardiopulmonary bypass time (min, mean)	203.1	215.4	0.0001	196.3	184.1	0.0001

AVS: aortic valve-sparing root replacement; CVR: composite graft-valve replacement; CABG: coronary artery bypass graft; N/A: not applicable.

Table 3: Unadjusted outcomes in overall, Low-risk and High-risk groups

Operative outcomes	Overall group			Low-risk group			High-risk group		
	AVS	CVR	P-value	AVS	CVR	P-value	AVS	CVR	P-value
Operative mortality (%)	4.5	8.9	<0.0001	1.4	3.1	0.0001	10.5	11.7	0.2
CVA (%)	3.0	3.2	0.42	1.5	2.2	0.03	5.9	3.7	0.0001
Renal failure (%)	5.2	8.3	<0.0001	2.9	3.8	0.04	9.7	10.4	0.43
Dialysis (%)	2.1	3.5	0.0003	1.2	1.4	0.91	3.9	4.5	0.57
Atrial fibrillation (%)	21.5	24.4	<0.0001	19.8	24.8	0.0001	24.9	24.2	0.61
Prolonged ventilation (%)	17.7	22.9	<0.0001	10.1	13.7	0.0001	32.3	27.3	0.0001
DSWI (%)	0.4	0.6	0.17	0.1	0.5	0.008	1.1	0.7	0.10
Reoperation for bleeding (%)	5.2	7.6	<0.0001	4.2	6.2	0.0002	7.3	8.3	0.19
Prolonged LOS (%)	10.0	14.5	<0.0001	5.5	8.0	0.0001	18.7	17.5	0.28
Major morbidity/mortality (%)	20.4	30.6	<0.0001	12.6	18.5	0.0001	35.5	36.3	0.58

AVS: aortic valve-sparing root replacement; CVR: composite graft-valve replacement; CVA: cerebrovascular accident; DSWI: deep sternal wound infection; LOS: length of stay.

Baseline characteristics (AVS versus CVR) are given in Table 2 for High-risk and Low-risk groups. The process of stratifying patients into High and Low-risk groups better balanced baseline characteristics between the two procedural types, although risk factors remained somewhat worse in the CVR category.

Unadjusted mortality and morbidity data for the Overall group are given in Table 3. UOM was lower with AVS compared with CVR (4.5 vs 8.9%, $P < 0.0001$). Likewise, combined major morbidity and mortality were lower with AVS (20.4 vs 30.6%, $P < 0.0001$). Unadjusted rates of postoperative renal failure, atrial fibrillation, prolonged ventilation, reoperation for bleeding and prolonged hospital stay were higher in patients receiving CVR, although this finding could at least partially be explained by worse baseline risk factors in CVR patients.

After excluding the High-risk group ($n = 20\,349$, 6.0% AVS, UOM = 10.5% AVS vs 11.7% CVR, $P = 0.20$), a more homogeneous, lower risk population with a higher tendency for AVS remained as the Low-risk group ($n = 11\,388$, 20.7% AVS, UOM = 1.4% AVS vs 3.1% CVR, $P < 0.0001$). The difference in AVS versus CVR operative mortality narrowed in both groups (Table 3) compared with the

Table 4: Individual operative mortalities in high-risk patient subgroups

High-risk subgroups	Number	AVS (%)	Operative mortality (%)		
			AVS	CVR	*P*-value
Age > 75	4064	7.2	15.1	16.6	0.49
Endocarditis	3034	1.7	13.5	15.1	0.74
Aortic stenosis	7852	2.0	3.2	5.1	0.28
Dialysis	188	14.0	7.7	22.2	0.09
Concomitant valve procedure	926	19.0	5.2	11.1	0.02*
Previous valve surgery	1558	18.6	4.1	8.2	0.08
Emergency or salvage status	2727	13.9	14.6	22.5	0.0005*

*Statistically significant: <0.05
AVS: aortic valve-sparing root replacement; CVR: composite graft-valve replacement.

Table 5: Regression coefficients of multivariable analyses in the three groups

Variable	Overall group (*n* = 31 747)			High-risk group (*n* = 28 162)			Low-risk group (*n* = 3585)		
	OR	CI	*P*-value	OR	CI	*P*-value	OR	CI	*P*-value
Status salvage	16.82	12.8, 22.10	<0.0001	14.19	10.8, 18.7	<0.0001	–	–	–
Status emergent	6.32	5.50, 7.26	<0.0001	5.35	4.61, 6.21	<0.0001	–	–	–
Dialysis	3.92	3.03, 5.07	<0.0001	3.70	2.86, 4.79	<0.0001	–	–	–
Second reoperation	2.53	2.07, 3.10	<0.0001	2.21	1.80, 2.71	<0.0001	5.73	3.20, 10.30	<0.0001
Status urgent	1.90	1.66, 2.18	<0.0001	1.76	1.51, 2.05	<0.0001	2.40	1.78, 3.25	<0.0001
First reoperation	1.86	1.66, 2.09	<0.0001	1.64	1.46, 1.84	<0.0001	3.31	2.41, 4.55	<0.0001
Shock	1.86	1.56, 2.21	<0.0001	1.85	1.55, 2.20	<0.0001	2.91	0.76, 11.10	0.1176
MI <21 days	1.65	1.39, 1.95	<0.0001	1.59	1.33, 1.91	<0.0001	1.92	1.14, 3.22	0.0140
Mitral stenosis	1.41	1.09, 1.81	0.0078	1.37	1.06, 1.76	0.0153	1.66	0.48, 5.80	0.4262
Prior stroke	1.35	1.17, 1.56	<0.0001	1.29	1.11, 1.49	0.0011	1.86	1.20, 2.88	0.0053
Mitral insufficiency	1.33	1.15, 1.52	<0.0001	1.32	1.14, 1.51	0.0001	1.05	0.63, 1.75	0.8424
Tricuspid insufficiency	1.30	1.09, 1.56	0.0035	1.31	1.09, 1.57	0.0039	1.24	0.72, 2.13	0.4316
Atrial fibrillation	1.30	1.15, 1.46	<0.0001	1.30	1.14, 1.48	<0.0001	1.29	0.90, 1.84	0.1684
Unstable angina	1.30	1.13, 1.50	0.0002	1.27	1.10, 1.47	0.0015	1.46	0.96, 2.21	0.0766
Hispanic race	1.30	1.03, 1.63	0.0258	1.36	1.07, 1.74	0.0133	0.92	0.40, 2.07	0.8314
Black race	1.28	1.09, 1.52	0.0034	1.22	1.02, 1.46	0.0258	1.51	1.06, 2.16	0.0232
Endocarditis	1.27	1.09, 1.49	0.0030	1.30	1.11, 1.52	0.0011	–	–	–
Hypertension	1.23	1.11, 1.37	0.0001	1.19	1.06, 1.33	0.0030	1.66	1.22, 2.28	0.0014
NYHA IV CHF	1.21	1.01, 1.44	0.0361	1.18	0.99, 1.42	0.0676	1.37	0.85, 2.21	0.1965
Periph. vasc. dis.	1.20	1.06, 1.36	0.0046	1.21	1.06, 1.37	0.0045	1.20	0.87, 1.65	0.2572
Female gender	1.20	1.05, 1.37	0.0078	1.22	1.05, 1.40	0.0073	1.03	0.70, 1.51	0.8881
N. dis. vessels	1.19	1.10, 1.29	<0.0001	1.18	1.09, 1.28	<0.0001	1.15	0.94, 1.41	0.1728
Age >50 years (/yr)	1.03	1.03, 1.04	<0.0001	1.03	1.02, 1.04	<0.0001	1.04	1.03, 1.06	<0.0001
Time trend (/3 years)	0.82	0.76, 0.88	<0.0001	0.83	0.76, 0.90	<0.0001	0.78	0.67, 0.91	0.0014
Aortic insufficiency	0.69	0.61, 0.79	<0.0001	0.73	0.64, 0.84	<0.0001	0.58	0.40, 0.86	0.0060
AVS versus CVR	0.54	0.43, 0.69	<0.0001	0.57	0.44, 0.73	<0.0001	0.65	0.38, 1.09	0.1041

In the low-risk analysis, the seven high-risk subgroups were removed—thus, four variables were absent, and patients for three other variables were modified: first reoperation: one previous non-valve heart operation; second reoperation: two or more previous non-valve heart operation. Mitral stenosis and insufficiency along with tricuspid insufficiency represent patients not having multiple valve procedures. Age >50 years limited to less than 75.
OR: odds ratio; CI: confidence interval; AVS: aortic valve-sparing root replacement; CVR: composite graft-valve replacement; Periph. vasc. dis: peripheral vascular disease; N. dis. vessels: number of diseased coronary arteries, by Standard Criteria. This variable also defines patients having concomitant coronary bypass surgery.

Table 6: Adjusted mortality comparisons between AVS and CVR

	Overall group			High-risk group			Low-risk group		
	AVS	CVR	*P*-value	AVS	CVR	*P*-value	AVS	CVR	*P*-value
Number of patients	3585	28 162	–	1223	19 126	–	2362	9026	–
UOM (%)	4.5	8.9	<0.0001	10.5	11.7	0.2	1.4	3.1	<0.0001
Predicted operative mortality (%)	6.0	8.7	–	12.1	11.6	–	1.8	3.0	–
AOM (%)	6.2	8.6	–	10.1	11.7	–	2.2	2.8	–
Unadjusted OR (95% CI)	0.48 (0.41–0.57)	–	<0.0001	0.88 (0.73–1.07)	–	0.2	0.44 (0.31–0.64)	–	<0.0001
AOR for mortality (95% CI)	0.59 (0.47–0.75)	–	<0.0001	0.62 (0.48–0.79)	–	0.0002	0.69 (0.41–1.16)	–	0.16

CI: confidence interval; AVS: aortic valve-sparing root replacement; CVR: composite graft-valve replacement; UOM: unadjusted operative mortality; AOM: adjusted operative mortality; OR: odds ratio; AOR: adjusted odds ratio.

unselected Overall group population. Likewise, the difference in combined major morbidity and mortality also narrowed: Low-risk (12.6% AVS vs 18.5% CVR, $P < 0.0001$) and High-risk (35.5% AVS vs 36.3% CVR, $P = 0.19$).

UOM rates, as calculated for each of the 7 patient subcategories included under the High-risk group were comparable ($P > 0.05$) for AVS versus CVR, except for emergency or emergency/salvage status (14.6% AVS vs 22.5% CVR, $P < 0.001$) and concomitant valve procedures (5.2% AVS vs 11.1% CVR, $P = 0.02$) (Table 4). On further inspection, however, CVR patients in the 'emergency' category had significantly higher rates of cardiogenic shock and CHF, and CVR patients undergoing concomitant valve surgery had higher rates of mitral valve replacement versus mitral repair. Both of these factors could explain at least some of the observed differences.

Multivariable logistic regression coefficients for all three risk groups are listed in Table 5. Order and magnitude or AORs for Overall and High-risk groups were quite similar, as would be expected with High-risk patients comprising 89% of the Overall group. Because 7 high-risk subgroups were removed from the analysis in the Low-risk group, 4 of the variables were absent and 3 others were modified. Thus, coefficients were somewhat different. However, risk-adjusted AVS versus CVR mortality differences were similar in all three analyses, varying between a 35 and 46% mortality risk reduction with AVS. All formal covariate interactions were negative, and therefore, final results were computed without treatment interaction variables.

Comparison mortality data are given in Table 6. Whether considering UOM, AOM or AOR, mortality tended to be lower with AVS in all three Risk groups. Odds ratios (ORs) were fairly consistent in all comparisons, and again, this finding suggested an appreciable mortality benefit with AVS. The magnitude of risk reduction persisted after statistical adjustment for the worse risk profiles of CVR patients, although *P*-values were marginal in the Low-risk group with a lower sample size.

DISCUSSION

AVS surgery is becoming increasingly applied, with many studies presenting improved outcomes after aortic valve repair. In a companion STS descriptive analysis to this paper, it was observed that application of AVS to High-risk categories has been constant over the last decade at 6%; but in low-risk patients, valve sparing has increased progressively, to 25% in the most recent era [3]. With the largest comparison of AVS and CVR to date, the present analysis observed improved perioperative outcomes for AVS. While these findings, to some extent, could be explained by the higher risk profiles of CVR patients, the results were consistent both after stratification by risk group, and also after multivariable analysis that adjusted for differences in the robust list of STS covariates. These results would support the continued utilization, or even further expansion, of AVS in clinical practice.

Over the last decade, multiple publications have described short- and long-term outcomes of aortic root surgery [14–18]. Only a few, however, have directly compared results for AVS versus CVR, primarily due to low numbers of aortic root procedures at the institutional level. Tourmousoglou and Rokkas [19] published a systematic review of AVS versus CVR and suggested that results of both techniques were excellent and comparable [19]. Karck *et al.* [20] reported 119 patients with Marfan syndrome with a mortality rate of 6.9% for CVS and 0% for AVS. Zehr *et al.* [21] reported 203 patients with a mortality rate of 4.0% for CVR vs 3.7% for AVS. Patel used propensity analysis to compare CVR to AVS in 144 patients with Marfan syndrome and did not identify higher mortality after CVR [22].

Utilization of AVS in higher risk subgroups also has been presented. Kerendi *et al.* [23] reported AVS in patients with reoperations, aortic dissections, and severe aortic regurgitation, with an operative mortality of 5.4% (2/37), and with none to mild aortic insufficiency at discharge. Subramanian et al. described 78 patients having AVS for acute ascending aortic dissection with a mortality rate of 15.3%, compared with 130 CVR patients experiencing a mortality of 27% ($P = 0.1$) [24]. However, studies comparing CVR to AVS invariably have been underpowered and usually have lacked a robust risk-adjustment method. These problems have prevented firm conclusions about relative procedural mortality characteristics.

In the STS cohort, CVR patients had worse risk profiles compared with AVS. Notable differences included significantly higher rates of endocarditis, urgent interventions, CHF, low EF, aortic stenosis, severe aortic regurgitation and reoperation. Zehr *et al.* [21] presented a 30-year experience of aortic root surgery and identified a similar high rate of severe aortic regurgitation, low EF and CHF in patients undergoing CVR. De Oliveira *et al.* [25] reported the results of aortic root surgery with Marfan syndrome and showed that CVR patients had worse baseline risk profiles compared with AVS. These population differences have increased the difficulty of outcome comparisons. Finally, it is interesting to note in the present study that aortic root surgery in North America was performed primarily in high-risk patients

(89% of the total population). This observation may explain the high root surgery mortality previously noted in STS studies [11] compared with single-centre series that usually involve low-risk patients. This finding further illustrates the value of a comprehensive 'real world' database.

To compensate for differences in baseline risk factors in our study, 7 high-risk patient subgroups were identified before the final adjusted comparisons. This procedure produced better matching of AVS versus CVR baseline characteristics for both High- and Low-risk groups. The concept was that closer baseline comparability might improve the accuracy of the multivariable analyses. A fairly uniform study result was observed. Performing AVS seemed to be associated with a 30–40% risk reduction when assessed by any approach (Tables 5 and 6), strengthening the likelihood that AVS produced better than or at least comparable results to CVR. In comparing the three multivariable analyses (Table 5), the marginal *P*-value of 0.10 in the Low-risk group could have been related to the smaller sample size, but perhaps also to removal of the emergency subgroup in whom a large treatment benefit was observed. Finally, risk-adjusted mortality seemed to be improving over time, independent of procedure chosen.

Thus, the concluding hypothesis of this study might be that AVS produces at least as good outcomes as CVR across the spectrum of patient risk. As in any observational analysis, though, questions still remain about undefined treatment selection biases or confounding variables between AVS and CVR categories. During the era examined, STS variables also lacked detail about procedural specifics which is another limitation. Nonetheless, comparability of risk-adjusted early outcomes in aortic root surgery makes further development of AVS attractive, since major advantages in late valve-related complications likely exist with aortic valve repair [5–8]. These findings support the judicious expansion of AVS procedures for aortic root surgery, in both low- and high-risk patient subgroups. In fact, some of the largest mortality benefits of valve sparing were observed in higher risk patients, such as emergency cases in Table 4. This group likely was comprised primarily of aortic dissections and other acute disorders, for which information already exists about the benefits of aortic valve resuspension or sparing. It is interesting that logistic regression analysis of the Overall group produced similar outcome estimates as the other approaches, suggesting that contemporary multivariable analysis of disparate populations can compensate well for differences in baseline characteristics. These findings reinforce the adequacy of logistic regression modelling utilizing large sample sizes, a good array of well-validated variables and contemporary statistical methodology, as employed in STS database studies.

In conclusion, baseline risk profiles of patients undergoing CVR were generally worse than for AVS. Operative mortality and morbidity rates were lower for AVS, partially because of better baseline risk factors. Even afer risk adjustment, however, operative mortality for AVS was better, or at least comparable to CVR, across the complete spectrum of patient risk. With similar early results, AVS is an attractive alternative to CVR, since marked advantages in late valve-related complications likely exist. These data support judicious expansion of AVS in future low- and high-risk populations undergoing aortic root surgery.

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APPENDIX. CONFERENCE DISCUSSION

Dr M. Boodhwani *(Ottawa, ON, Canada)*: In this study, the authors queried the STS database to determine the number of patients undergoing aortic root surgery between 2000 and 2011. Like any large database study, the authors came up with a large group of patients in whom they could analyse the data. However, like most large database studies, there are some important limitations to the conclusions that one can derive.

The first challenge is that procedural data was not accurately available between the groups. Aortic valve-sparing surgery could mean something as simple as resection and replacement of the noncoronary sinus and leaving the valve intact, or could mean the Florida sleeve operation, which is employed by some centres in the United States, and it is not always what we typically think of as the reimplantation or remodelling approach to valve-sparing surgery.

There is also the opportunity for misclassification of data in such a large database, there is the opportunity for incomplete information and, perhaps most important, it is difficult to tease out from a database like this is what we call confounding by indication. Aortic valve-sparing procedures are probably more preferentially performed in patients, who are thought to do better than patients in whom a composite valve graft is used.

All these limitations aside, I want to ask you a few questions. The first is, did you do any sort of a chart audit to determine whether the procedural coding was in fact accurate? Did you look at a subset of patients in whom valve-sparing surgery was performed and actually figure out what was done at the time of surgery?

Dr. Caceres: Regarding chart auditing, the STS database is a voluntary database and the data is entered by designated clinical managers in each participating institution. The data managers receive training specifically to do this, and the STS audits the data as well. I don't have access to the actual raw data or the institutional data. So in that case, as to verifying which procedure was performed, no, we didn't have access to that. However, there are two categories within the label of surgery type for AVS; they are the David and the Yacoub type of procedure. Those are two labels that have been present since 2000.

Now, recently, starting in 2011 or earlier, there is some more degree of detail in the database, with procedural detail, valve resection, valve repair, but that is going to be for the next 10 years. So we have to wait 10 more years to get good numbers of those patients in order to draw any conclusions.

Dr Boodhwani: My next question relates to your risk adjustment. You took seven factors and then divided the cohort into high risk and low risk, and then you performed some multivariate adjustment following that. My question is, why not use more robust techniques for risk adjustment, like propensity matching, that allow you to match patients one-to-one based on the risk, the exposure, which in this case is the valve procedure, or could you stratify based on propensity matching?

Dr Caceres: That was actually proposed; my initial proposal was for propensity matching. Now this was discussed with the DCRI and the STS Access and Publications Task Force because of the major limitation that you just mentioned. There are so many confounding factors and so much that we can miss in these patients. We preferred to just conduct a progressive exclusion of high-risk groups, based on clinical knowledge and the differences in the characteristics of CVR and AVS. Based on that, we decided to exclude all those High-risk patients.

Now this decision had a two-fold purpose. The first is that you can exclude the patients that may have been mislabelled, because many of those patients that are labelled as high-risk and received AVS may not have received AVS in the first place. And the second purpose was to exclude that population that is in the grey zone where many surgeons may not decide to proceed with an AVS.

Would the propensity matching be a better result in an entire population? I don't believe so, because of these inherent differences mentioned between AVS and CVR. Maybe in the low-risk population. We conducted a multivariable analysis in group A (Overall), the entire population, and in groups H and L (High and Low). For the sake of time purposes I only presented the results of group L (Low-risk), but there were similar results in the other groups as well. The significance, though, was lost in the difference of between AVS and CVR in group L (Low-risk), and maybe it was because we had a much lower number of patients in this group.

Dr Boodhwani: I will make it two quick questions in the interests of time. One is, there are 7,000 patients in the data set, 7,800 that had predominant aortic stenosis. Presumably these are patients who are not eligible for both composite valve replacement or valve-sparing. They are presumably not eligible for a valve-sparing procedure. In my opinion, those should be excluded, and perhaps even the 3,000 patients that had endocarditis as their primary pathology, as valve-sparing procedures are infrequently performed in those cases.

My last comment will be related to surgical volume. The valve-sparing procedures are presumably performed by surgeons who do a larger volume of root surgery and may therefore have better outcomes related to root surgery, whereas a composite valve graft can be performed by anyone. Did you have any opportunity to adjust your analysis for the volume of surgery performed by a particular centre or by a particular surgeon?

Dr Caceres: Endocarditis and aortic valve stenosis, yes, those groups were excluded under group H, high risk. That's why the patients in group L, low risk, don't include endocarditis or aortic stenosis, and the logistic regression analysis presented does not include those patients.

Now, regarding volume, that was discussed with the statisticians; however, this number of patients is not that high. Even though it's a registry database, we only have 3,000 patients with AVS, and after applying the exclusion criteria, we end up with 2,000, I believe. If we try to factor in the institutional volume or surgeon-specific volume, the results would be diluted, and that is something that was discussed with the statisticians, and those are all the insights I can bring in that regard.

Dr T. Gudbjartsson *(Reykjavik, Iceland)*: Do you have any information on how many patients were started as repairs and converted to composite procedures? And how did you deal with these converted patients in your comparison, was it according to the intention-to-treat principle?

Dr Caceres: There is a label for this type of entry in the new data collection forms but it doesn't date back to 2000.