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Aorta: Research

Valve Sparing vs Composite Valve Graft Root Replacement: Propensity Score–Matched Analysis

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ABSTRACT

BACKGROUND Both valve-sparing root replacement and composite valve graft (CVG) are acceptable options in aortic root replacement. We compare outcomes of these 2 approaches and durability of the aortic valve.

METHODS A consecutive 1635 patients without acute dissection underwent primary aortic root replacement from 1997 to 2022; 473 (29%) underwent valve-sparing root replacement, and 1162 (71%) received CVG. Propensity score matching was used to reduce baseline differences.

RESULTS The CVG group was older (59 ± 14 years vs 49 ± 14 years; $P < .001$) with more comorbidities, such as hypertension (88.4% vs 66.4%; $P < .001$), diabetes (7% vs 1.7%; $P < .001$), ischemic heart disease (5.1% vs 1.3%; $P = .001$), pulmonary disease (6.6% vs 1.3%; $P < .001$), renal impairment (8.6% vs 1.3%; $P < .001$), class III-IV heart failure (35% vs 9.2%; $P < .001$), bicuspid aortic valves (44.8% vs 24.1%; $P < .001$), and severe aortic insufficiency (50.2% vs 13.2%; $P < .001$). Operative mortality was 0.4% (0% in valve sparing); incidence of major postoperative complications was 2.9% (3.6% vs 1.1%; $P = .009$). Ten-year survival was 93.1% (91.2% vs 97.7%; hazard ratio [HR], 1.7; 95% CI, 0.9-3.3; $P = .120$). Mean follow-up was 65 ± 60 months; aortic valve reoperations were similar (5.8% vs 5.7%; HR, 0.8; 95% CI, 0.4-1.4; $P = .401$). Recurrent moderate-severe aortic insufficiency was less prevalent in CVG (6.1% vs 11.1%; HR, 0.14; 95% CI, 0.07-0.27; $P < .001$). Propensity score matching identified 225 pairs. There was no difference in 10-year survival or reoperations. Recurrent moderate-severe aortic insufficiency was higher with valve sparing.

CONCLUSIONS Both valve-sparing operations and CVG provide excellent early and late outcomes out to 10 years. Valve sparing is associated with a higher risk for development of aortic insufficiency but no difference in reoperations.

(Ann Thorac Surg 2023;■:■-■)

Aortic root replacement (ARR) using a prosthetic valve conduit, first described by Bentall and De Bono in 1968,[1] is an established method of repairing aortic root aneurysm. Aortic valve-sparing root replacement (VSRR) provides an alternative to composite valve graft (CVG) in carefully selected aneurysm patients with or without aortic insufficiency (AI) and is indicated when repair durability is at least equal to the estimated durability of bioprosthetic valves.[2] However, the optimal technique for ARR is still a matter of debate.[3-10] Modern bioprosthetic valves provide excellent durability because of advancements in tissue engineering that allow valve durability to rival that of native aortic valve (AV) in certain subgroups.[11]

Preservation of native AV leaflets has many potential advantages, including avoidance of anticoagulation and improved resistance to valve infection, and has become popular among aortic experts in the last decade.[12,13] Traditionally, VSRR has been used in patients with

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normal AV leaflets and has proven to be durable with excellent long-term results.[14,15] During the past decade, VSRR has expanded to include patients with anatomic valve abnormalities, such as unicuspid, bicuspid, and prolapsing valve leaflets, and it gained worldwide popularity in patients with connective tissue disease (CTD).[16-24]

We herein present the contemporary trends and clinical and echocardiographic results of ARR with or without AV replacement at a high-volume aortic center.

MATERIAL AND METHODS

STUDY DESIGN. From 1997 to 2022, a consecutive 1881 patients with varying degrees of AI underwent VSRR or CVG (Figure 1). Patients were excluded if they had prior history of AV or root replacement (n = 159) or acute aortic dissection (n = 87). Preoperative, operative, and postoperative data were collected from our departmental database. All clinical and echocardiographic follow-up was carried out through our outpatient clinic.

Patients selected for VSRR were younger (<70 years of age) with better left ventricle function (>40%) and did not have major comorbid conditions, such as end-stage renal disease or advanced hepatic dysfunction, and valve morphology was suitable with no stenosis. Minor calcification is acceptable. In bicuspid AV (BAV) patients, valve repair may include limited resection of a calcified raphe, closure of an incomplete raphe, or central plication of the nonfused leaflet. Complex leaflet repair or pericardial patch is avoided. VSRR is performed in tricuspid AV with moderate or severe AI if the leaflets are symmetric and with limited fenestrations. In bicuspid AV patients, VSRR is rarely performed with moderate or more severe AI.

Mean clinical follow-up was 65 ± 60 months for the entire cohort and 81 ± 62 months for the matched population. Mean echocardiographic follow-up of the entire cohort was 55 ± 58 months and was completed for 1092

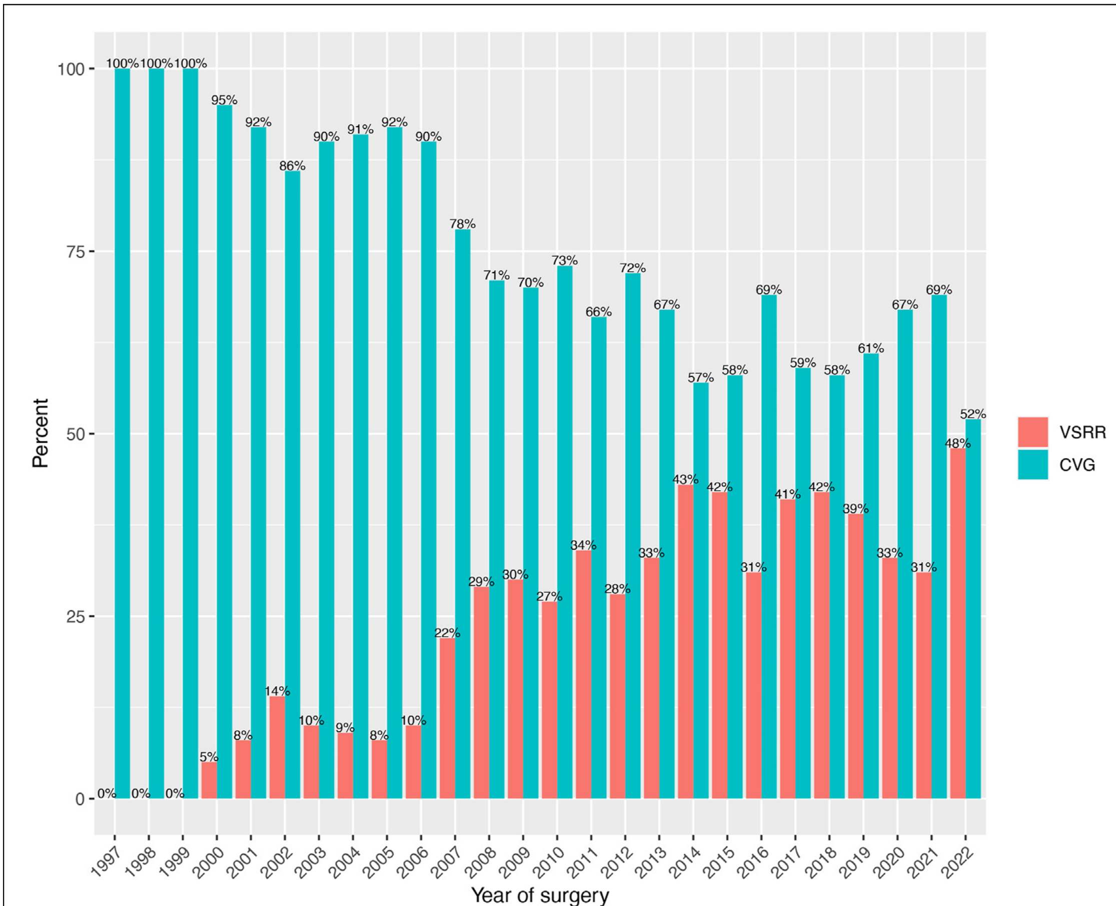

FIGURE 1 Bar plot of pattern over the years of aortic valve-sparing root replacement (VSRR, red) and aortic root replacement with a prosthetic composite valve graft (CVG, blue).

patients (67%). Mean echocardiographic follow-up of the matched cohort was 71 ± 61 months and was 70% completed.

The study was approved by the Weill Cornell Medicine institutional review board (Protocol No. 1607017424; September 1, 2021). The requirement for informed consent was waived for this retrospective study.

SURGICAL PROCEDURE. VSRR was performed in 473 patients (29%) by the reimplantation technique as previously described.[22] Briefly, the aorta is resected to within 3 to 4 mm of the annulus. Coronary buttons are mobilized. The valve leaflets are assessed for preservation. A plane is developed circumferentially around the left ventricular outflow tract. A Hegar dilator is used to size the annulus, and a graft 5 mm larger is selected. Nonpledgeted sutures are placed through the left ventricular outflow tract below the level of the annulus. Sutures are passed through the base of the Valsalva graft (Terumo Aortic) and tied over a Hegar dilator. The valve is reimplanted with 4-0 running polypropylene suture, and the left main coronary button is reattached. The cusps are assessed for prolapse or excessive free edge length and repaired as necessary. The neoroot is pressurized with cardioplegia to test the valve. The distal aortic anastomosis is performed, followed by right coronary button reattachment.

Root replacement with CVG was done in 1162 patients (71%) by an exclusion technique with button reimplantation of coronary arteries.[22]

STATISTICAL ANALYSIS. Data are presented as mean ± SD for normal distribution or median (interquartile range) for nonnormal distribution. Categorical variables are given as frequencies and percentages. The χ^2 test was used for comparison of categorical variables; Student *t*-test was performed for comparison of normally distributed continuous variables, and Mann-Whitney *U* test was performed for nonnormal distribution. Multivariable logistic regression analysis was used to identify factors relating to VSRR (vs CVG). All statistically different variables ($P < .1$) in Table 1 were entered into the model.

To reduce treatment selection bias and potential confounding factors and to adjust for significant differences in patient characteristics, propensity score matching was performed. Propensity scores were estimated by a multivariable logistic regression model for

TABLE 1 Patient Demographics

	Unmatched			Matched		
Variable	VSRR (n = 473)	CVG (n = 1162)	*P* Value	VSRR (n = 225)	CVG (n = 225)	SMD
Age, y	49.1 ± 13.9	59 ± 13.6	<.001	51.8 ± 13.7	52.1 ± 14.6	0.019
Sex, female	80 (16.9)	150 (12.9)	.042	38 (16.9)	31 (13.8)	0.086
Ischemic heart disease			.001			0.078
Previous PCI	6 (1.3)	38 (3.3)		2 (0.9)	0 (0)	
Previous CABG	0 (0)	21 (1.8)		0 (0)	0 (0)	
Hypertension	314 (66.4)	1025 (88.4)	<.001	166 (73.8)	175 (77.8)	0.093
Chronic pulmonary disease	6 (1.3)	76 (6.6)	<.001	4 (1.8)	5 (2.2)	0.032
Diabetes			<.001			0.032
Non–insulin dependent	8 (1.7)	78 (6.7)		5 (2.2)	4 (1.8)	
Insulin dependent	0 (0)	3 (0.3)		0 (0)	0 (0)	
Previous stroke	16 (3.4)	94 (8.1)	.001	8 (3.6)	5 (2.2)	0.080
Peripheral vascular disease	7 (1.5)	35 (3)	.108	6 (2.7)	1 (0.4)	0.093
Atrial fibrillation	17 (3.6)	110 (9.5)	<.001	9 (4)	7 (3.1)	0.048
Renal insufficiency	6 (1.3)	100 (8.6)	<.001	4 (1.8)	1 (0.4)	0.072
Previous operation	15 (3.2)	117 (10.1)	<.001	11 (4.9)	7 (3.1)	0.091
Bicuspid aortic valve	114 (24.1)	521 (44.8)	<.001	70 (31.1)	75 (33.3)	0.048
Connective tissue disease	105 (27.8)	85 (8.8)	<.001	43 (19.1)	35 (15.6)	0.094
Aneurysm size, cm	5.4 ± 0.4	5.6 ± 0.8	<.001	5.4 ± 0.4	5.7 ± 0.6	0.096
Ejection fraction, %	51 ± 5.7	45.9 ± 8.3	<.001	49.7 ± 5.2	49.9 ± 6.8	0.042
Aortic regurgitation			<.001			0.890
None/trivial	167 (35.7)	100 (8.7)		83 (36.9)	25 (11.1)	
Mild	148 (31.6)	200 (17.3)		67 (29.8)	43 (19.1)	
Moderate	91 (19.4)	275 (23.8)		44 (19.6)	57 (25.3)	
Severe	62 (13.2)	579 (50.2)		31 (13.8)	100 (44.4)	

Categorical variables are presented as number (percentage). Continuous variables are presented as mean (SD). CABG, coronary artery bypass graft; CVG, composite valve graft; PCI, percutaneous coronary intervention; SMD, standardized mean difference; VSRR, valve-sparing root replacement.

TABLE 2 Operative Data

Variable	Unmatched VSRR (n = 473)	Unmatched CVG (n = 1162)	P Value	Matched VSRR (n = 225)	Matched CVG (n = 225)	SMD
Bioprosthetic valve (vs mechanical valve)	NA	858 (73.8)	NA	NA	126 (56)	NA
Arch/hemiarch replacement	39 (8.6)	232 (20)	<.001	17 (7.6)	39 (17.3)	0.298
Concomitant procedure	53 (11.7)	291 (25.7)	<.001	32 (14.2)	29 (12.9)	0.039
Mitral valve repair/replacement	15 (3.3)	61 (5.4)	.107	9 (4)	3 (1.3)	0.167
Tricuspid valve repair	3 (0.7)	9 (0.8)	1.000	0 (0)	0 (0)	<0.001
CABG	25 (5.5)	203 (17.9)	<.001	17 (7.6)	24 (10.7)	0.108
Maze	12 (2.7)	56 (5)	.059	7 (3.1)	4 (1.8)	0.087
Aortic leaflet repair	61 (12.9)	NA	NA	27 (12)	NA	NA
Graft size, mm	29.8 ± 1.4	25.6 ± 2.2	<.001	29.8 ± 1.3	25.8 ± 2.3	1.650
Graft size, mm			<.001			1.650
17-18	0 (0)	1 (0.1)		0 (0)	0 (0)	
19-20	0 (0)	1 (0.1)		0 (0)	0 (0)	
21-22	0 (0)	35 (3)		0 (0)	7 (3.1)	
23-24	1 (0.2)	190 (16.4)		0 (0)	36 (16)	
25-26	10 (2.1)	518 (44.6)		4 (1.8)	86 (38.2)	
27-28	90 (19)	293 (25.2)		47 (20.9)	70 (31.1)	
29-30	294 (62.2)	92 (7.9)		138 (61.3)	15 (6.7)	
≥ 31	78 (16.5)	32 (2.8)		36 (16)	11 (4.9)	
Cardiopulmonary bypass time, min	135 ± 25	131 ± 35	.027	131 ± 24	123 ± 30	0.323
Ischemia time, min	115 ± 23	106 ± 29	<.001	111 ± 23	100 ± 24	0.461

Categorical variables are presented as number (percentage). Continuous variables are presented as mean (SD). CABG, coronary artery bypass graft; CVG, composite valve graft; NA, not applicable; SMD, standardized mean difference; VSRR, valve-sparing root replacement.

treatment by either VSRR or CVG. All variables presented in Table 1 were entered to calculate the propensity score.

Survival analysis was performed with the Kaplan-Meier method, and statistical differences between the 2 periods were tested with the log-rank test. Cox

TABLE 3 Early Postoperative Complications in Matched Population

Variable	VSRR (n = 225)	CVG (n = 225)	P Value
Operative mortality	0 (0)	0 (0)	NA
Postoperative aortic insufficiency			.007
None/trivial	216 (96)	225 (100.0)	
Mild	9 (4)	0 (0)	
Pacemaker	2 (0.9)	8 (3.6)	.110
Stroke	2 (0.9)	2 (0.9)	1.000
Respiratory complications			1.000
>48-hour intubation	2 (0.9)	1 (0.4)	
Pneumonia	1 (0.4)	0 (0)	
Reintubation	2 (0.9)	0 (0)	
Renal complications			.368
Acute tubular necrosis	0 (0)	1 (0.4)	
Renal replacement therapy	1 (0.4)	0 (0)	
Sternal wound infection			1.000
Superficial	1 (0.4)	1 (0.4)	
Chest tube 24 hours, mL	461 ± 248	488 ± 250	.276
Reexploration for bleeding	5 (2.2)	5 (2.2)	1.000
Atrial fibrillation	52 (23.1)	35 (15.6)	.056
Major adverse events[a]	3 (1.3)	2 (0.9)	.996
Major adverse valve-related event[b]	4 (1.8)	10 (4.4)	.177

[a]Major adverse events include the following: mortality, stroke, use of renal replacement therapy, myocardial infarction, and deep sternal wound infection; [b]Major adverse valve-related events include valve-related mortality, valve-related morbidity, and need for permanent pacemaker. Categorical variables are presented as number (percentage). Continuous variables are presented as mean (SD). CVG, composite valve graft; NA, not applicable; VSRR, valve-sparing root replacement.

proportional hazards model was constructed to assess factors associated with mortality by a stepwise selection process. Variables that were associated with 1 of the groups ($P < .1$ in Table 1) were included in the model, as were prespecified clinically significant variables. For nonfatal outcomes, cumulative incidence function per Fine-Gray model was applied to take into account the competing risk of death.

Statistical significance was assumed when the null hypothesis could be rejected at $P < .05$. All P values are results of 2 sided tests. Statistical analyses were conducted using R (version 4.0.3) software (R Foundation for Statistical Computing).

RESULTS

BASELINE CLINICAL CHARACTERISTICS. More patients were male (86%); mean age was 56 ± 14 years, 190 (12%) had CTD, and 635 (39%) had bicuspid AV. Preoperative echocardiography showed that 62% had moderate or severe AI (≥3+; Table 1). The most common CVG used was bioprosthetic (Supplemental Table 1).

Patients treated by CVG were older with more comorbidities, such as hypertension, diabetes, ischemic heart disease, chronic pulmonary disease, renal impairment, and class III-IV heart failure. More had bicuspid AV and severe AI (Table 1). After propensity score matching, baseline clinical characteristics presented no significant differences (Tables 1 and 2).

FACTORS ASSOCIATED WITH VSRR. Multivariable logistic regression analysis showed that a tricuspid AV was the most powerful predictor for VSRR. Patients with tricuspid AV were 4.5 times more likely to have VSRR compared with bicuspid or unicuspid (95% CI, 3.12-6.25; $P < .001$). Additional independent predictors for VSRR included younger age (odds ratio [OR], 0.97; 95% CI, 0.96-0.99; $P < .001$), higher ejection fraction (OR, 1.1; 95% CI, 1.07-1.13; $P < .001$), class I-II heart failure (OR, 2.08; 95% CI, 1.32-3.45; $P = .003$), absence of previous operation (OR, 0.24; 95% CI, 0.11-0.47; $P < .001$), absence of hypertension (OR, 0.64; 95% CI, 0.42-0.97; $P = .033$), and family history of aortic disease (OR, 2.28; 95% CI, 1.52-3.43; $P < .001$).

EARLY OUTCOMES. All patients left the operating room with no more than mild AI. Postoperative residual mild AI was found in 15 (3.2%) patients who underwent VSRR.

Early outcomes are presented in Table 3 and Supplemental Tables 2 and 3. In the matched patients, VSRR and CVG had similar rates of operative mortality (0% vs 0%; $P = 1.000$); pacemaker implantation (0.9% vs 3.6%; $P = .110$); stroke (0.9% vs 0.9%; $P = 1.000$); and major adverse cardiovascular events, defined as mortality, stroke, renal failure requiring dialysis, deep sternal wound infection, or myocardial infarction at 30 days (1.3% vs 0.9%; $P = .996$).

FOLLOW-UP SURVIVAL. The 10-year mortality was 4.4% (3.6% vs 5.3%; log-rank, $P = .630$) in the propensity score-matched comparison, showing no survival advantage for either procedure (Figure 2). Nonproportional multivariable analysis showed that VSRR was not associated with a reduction in risk of 10-year mortality (hazard ratio [HR], 1.7; 95% CI, 0.88-3.3; $P = .115$). Predictors of 10-year mortality included older age (HR, 1.05; 95% CI, 1.03-1.07; $P < .001$), renal impairment (HR, 3.47; 95% CI, 2.18-5.53; $P < .001$), lower ejection fraction (HR, 0.97; 95% CI, 0.95-0.99; $P = .004$), and CTD (HR, 2.19; 95% CI, 1.16-4.11; $P = .015$).

FOLLOW-UP RECURRENT AI AND REOPERATION. Recurrent moderate-severe AI was found in 87 patients

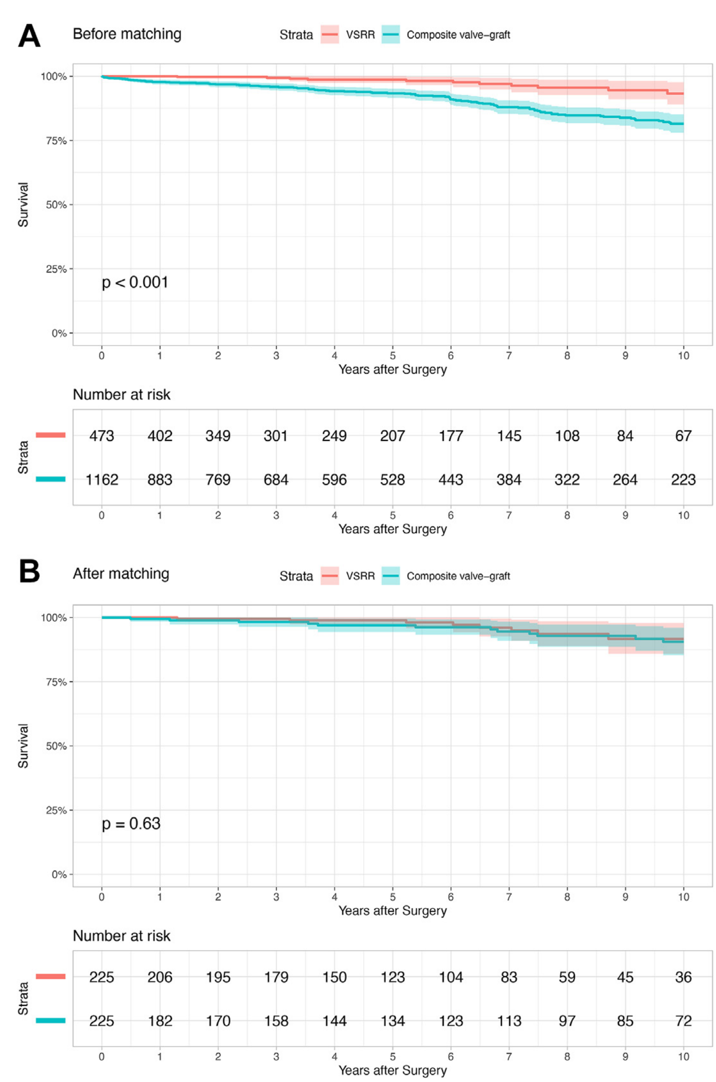

FIGURE 2 Kaplan-Meier curves for survival (A) before and (B) after propensity score matching. (VSRR, valve-sparing root replacement.)

(8%), more prevalent in VSRR (11.2% vs 6.1%; $P = .004$) and least with mechanical CVG (Supplemental Figure 1). VSRR was associated with higher rates of recurrent AI in the matched population ($P = .001$; Figure 3). Risk of significant aortic stenosis was not seen (Supplemental Figure 2).

During follow-up, 108 patients (6.6%) in the unmatched cohort required reintervention (94 reoperations and 11 percutaneous valve implantations) at a median of 8.5 years (5-11.5 years) after the index surgery (Figure 4A; Supplemental Figure 3). For VSRR, the reason for reoperation was recurrent AI in 18 patients (66.7%), infective endocarditis in 7 (25.9%), and aortic stenosis in 2 (7.4%). In contrast, CVG reoperation was due to structural valve deterioration in 44 patients (65.6%), infective endocarditis in 19 (28.4%), prosthetic valve thrombosis in 2 (3%), and other reasons in 2 (3%). Median time from initial operation to reoperation was significantly shorter with VSRR (6 [2.2-8.4] years vs 10 [5.7-12.6] years; $P = .002$). The risk of reoperation, with death as competing risk, was similar between groups (HR, 1.01; 95% CI, 0.92-1.11; $P = .850$; Figure 4B).

Multivariable analysis showed that the only independent predictor for AI or reoperation was younger age (HR, 0.97; 95% CI, 0.96-0.99; $P = .002$).

COMMENT

Valve-sparing root replacement has taken on an increasingly prominent role in ARR in recent years. In certain populations, such as young patients with CTD, VSRR has supplanted CVG as the preferred ARR method at many centers.[24] In our previous analysis, we identified a sharp decrease in number of mechanical CVGs with increases in bio-CVG and VSRR since the early 2000s.[9] At our center, VSRR currently accounts for an increasing proportion of all ARR, with 40% receiving VSRR (Figure 1). The results of this study, similar to several previous reports, showed that both VSRR and CVG are safe, with excellent operative outcomes and low morbidity.[3-10] We achieved very low operative mortality (0% vs 0.5%; $P = .269$) in patients who underwent either ARR procedure.

Direct comparisons of VSRR vs CVG are limited by significant selection bias because VSRR is frequently performed in young, healthy patients, whereas CVG is more universal and includes older, sicker patients. These limitations are highlighted by the significant differences in baseline characteristics (Table 1) and worse survival in the CVG group in unmatched comparisons (Figure 2A). Propensity score matching mitigated differences and resulted in similar 10-year survival in both groups (96.4% vs 94.7%; log-rank, $P = .630$; Figure 2B). However, follow-up outcomes diverge when we examine recurrence of AI. Whereas the reoperation rate was similar between the 2 surgical procedures, there was a higher incidence of recurrent moderate-severe AI with VSRR. Durability of mechanical and biologic prostheses in the CVG group was excellent out to 10 years. With continual improvements in tissue engineering, durability of bioprosthetic valves is expected to become increasingly long.[11] These developments, combined with the possibility of transcatheter valve reintervention,[25] lead to the question of where the age cutoff for VSRR should be and whether VSRR should be performed in older patients.

In younger patients, benefits of native valve preservation may still outweigh the risk of recurrent AI. Price and colleagues[26] found that in young patients with Marfan syndrome, VSRR was associated with fewer thromboembolic or hemorrhagic events (HR, 0.16; 95% CI, 0.03-0.85; $P = .03$). Ouzounian and coworkers[27] found that CVG was associated with increased reoperation with biologic CVG, increased anticoagulant-related hemorrhage with mechanical CVG, and increased long-term major adverse events, including increased cardiac mortality in both. Although VSRR has more recurrent AI at 10 years, risk of reoperation was not different. We will need to observe CVG patients to 15 to 20 years, when bioprosthetic valves are known to fail from structural valve degeneration with increasing incidence.[28]

The long-term durability of the AV is attributed to the principal mechanism of the disease. AI is often central and results from a dilated aortic annulus or sinutubular junction. Long-standing AI may lead to secondary changes, such as fenestrations and cusp elongation or prolapse. We believe that the lack of differences in

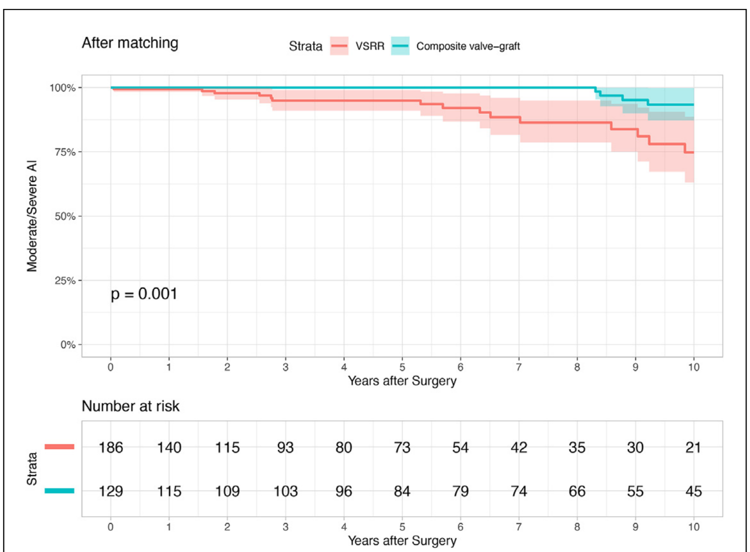

FIGURE 3 Kaplan-Meier curves for recurrent aortic insufficiency after propensity score matching. (AI, aortic insufficiency; VSRR, valve-sparing root replacement.)

outcomes in our study is partially due to targeted selection of patients. Healthier patients may undergo complex procedures, such as VSRR, whereas "sicker" patients are more likely to have a more expedient operation with CVG. Although we do perform VSRR in patients traditionally at higher risk for recurrent AI (preoperative severe AI, larger roots, bicuspid AV), we have a reasonable threshold on when to avoid this operation and to perform CVGs. This includes older patients, bicuspid AV with severe AI, patients with ejection fraction <40%, and those with more comorbidities who are unlikely to outlive a bioprosthetic valve. With this targeted strategy, we maximize safety, and the incidence of major adverse events was minimal (1.1% vs 3.6%; $P = .009$).

Potential advantages of VSRR over CVG include improved resistance to infection. Our endocarditis hazard was 1.5% in both groups. Yamabe and associates[6] reported an incidence of 1% reoperation due to endocarditis after VSRR and 1.7% after CVG. Leontyev and coworkers[8] reported up to 5% infective endocarditis with similar incidence between VSRR and CVG. Price and colleagues[26] did not find significant difference in the infection rate (1.8%). We speculate whether longer follow-up is needed to detect this theoretical advantage, especially in young patients who have long life expectancy.

In our practice, we balance the need for long-term durability with the goal of minimizing operative morbidity and mortality. The decision to perform VSRR is based on the experience and capability of the surgeon, patients' comorbidities and ability to withstand a longer operation, left ventricular function, and valve morphology that facilitates long-term durability exceeding that of a bioprosthesis.

LIMITATIONS. This is a retrospective, single-center, observational study, which introduces inherent biases. Although propensity score matching mitigates these limitations, unmeasured confounding remains. As all operations were performed in a high-volume aortic center, these findings may not be generalizable. Long-term follow-up beyond 10 years is necessary because of the excellent durability of modern bioprosthetic valves. In addition, the method of ARR was based on surgeon preference, although the techniques used were the same for each type of operation in the entire group.

CONCLUSION. With careful selection of patients, both VSRR and CVG provide excellent early and midterm outcomes. Although VSRR is associated with a higher risk for development of recurrent AI at 10-year follow-up, the risk of reoperation is not different compared with CVG. Further long-term follow-up into the failure period for bioprosthetic valves will help determine the true benefits of VSRR and understand factors that may predict late AI recurrence and reoperation. Based on our current data, we perform VSRR for younger patients to take advantage of the potential for a valve with lifetime durability. We perform CVG in older patients with more comorbidities to reduce the operative risk. The optimal age threshold for VSRR vs CVG will depend on the durability of newer bioprosthetics and remains to be determined.

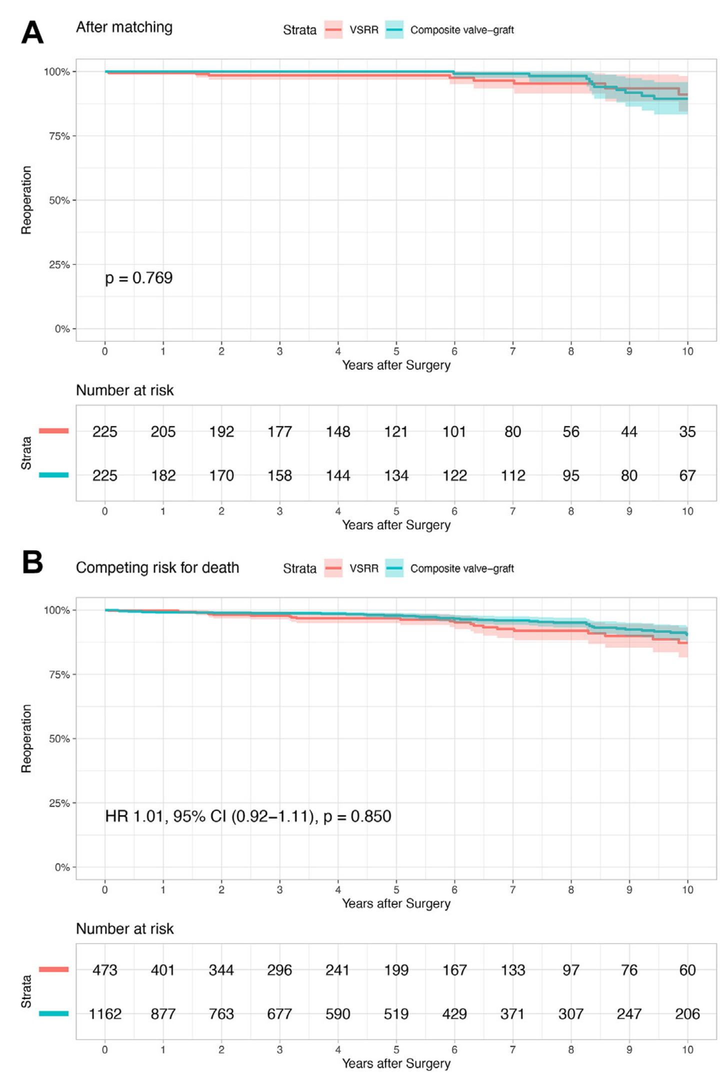

FIGURE 4 (A) Kaplan-Meier curves for reoperation after propensity score matching. (B) Cumulative incidence of reoperation after adjustment for competing risk of death. (HR, hazard ratio; VSRR, valve-sparing root replacement.)

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DISCLOSURES

The authors have no conflicts of interest to disclose.

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