European multicenter experience with valve-sparing reoperations after the Ross procedure

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ABSTRACT

Background: Autograft valve preservation at reoperation may conserve some of the advantages of the Ross procedure. However, results of long-term follow-up are lacking. In this retrospective multicenter study, we present our experience with valve-sparing reoperations after the Ross procedure, with a focus on long-term outcome.

Methods: A total of 86 patients from 6 European centers, who underwent valve-sparing reoperation after the Ross procedure between 1997 and 2013, were included in the study.

Results: Reoperation was performed a median of 9.1 years after the Ross procedure in patients with a median age of 38.4 years (interquartile range: 27.1-51.6 years). Preoperative severe autograft regurgitation (grade ≥ 3) was present in 46% of patients. In-hospital mortality was 1%. During a median follow-up of 4.3 years, 3 more patients died of noncardiac causes, resulting in a cumulative survival at 8 years of 89% (95% confidence interval: 65%-97%). Fifteen patients required a reintervention after valve-sparing reoperation, mostly owing to prolapse or retraction of autograft cusps. Freedom from reintervention was 76% (95% confidence interval: 57%-87%) at 8 years. The reintervention hazard was increased in patients who had isolated and/or severe aortic regurgitation at valve-sparing reoperation. In patients without reintervention after valve-sparing autograft reoperation ($n = 63$), severe aortic regurgitation was present in 3% at last follow-up.

Conclusions: Valve-sparing autograft reoperations after the Ross procedure carry a low operative risk, with acceptable reintervention rates in the first postoperative decade. Patients with isolated and/or severe autograft regurgitation have an increased hazard of reintervention after valve-sparing reoperation; for these patients, careful preoperative weighing of surgical options is required. (*J Thorac Cardiovasc Surg* 2015;150:1132-7)

Estimated freedom from reintervention after valve-sparing reoperation.

Central Message

Valve-sparing autograft reoperations carry low operative risk, with acceptable reintervention rates in the first postoperative decade.

Perspective

This study provides surgeons with important information on the characteristics and outcome after valve-sparing reoperations after the Ross procedure. Durable valve-sparing reoperation is shown to be possible in most patients. However, in patients with isolated autograft regurgitation, careful reconsideration of the surgical approach may be necessary.

See Editorial Commentary page 1138.

Aortic valve replacement through the Ross procedure offers patients a living valve substitute that provides good hemodynamics and freedom from long-term use of anticoagulation

methods. The main concern after the Ross procedure in adult patients is reoperation on the autograft, as a result of progressive root dilation and/or autograft insufficiency.¹

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Historically, reoperations after the Ross procedure consisted of excision of autograft material followed by a Bentall procedure.² Currently, surgeons prefer to preserve the autograft valve if possible, by performing a reoperation, to maintain the advantages associated with a functioning valve.^{3,4} However, concern remains about the long-term fate of the autograft cusps after reoperation.

Evidence on outcome after valve-sparing reoperations after the Ross procedure is scarce; only a few centers have published their short-term results.^{4,5} The current retrospective study aims to determine the durability of valve-sparing reoperations after the Ross procedure in the first postoperative decade, in a European multicenter cohort.

METHODS

Institutional review board permission for this study was obtained in each center. Informed written consent was obtained from all patients. The study was performed in accordance with the Declaration of Helsinki.

Patient Inclusion and Data Collection

All patients who underwent a valve-sparing reoperation after the Ross procedure in 1 of the 6 participating centers were included in the study. Our cohort includes patients reported on previously by Luciani and colleagues⁴ (N = 17), de Kerchove and colleagues⁵ (N = 26), and Charitos and colleagues⁶ (N = 24).

Preoperative patient characteristics, including information on the initial Ross procedure, perioperative surgical data on the valve-sparing reoperation after the Ross procedure, and postoperative follow-up data were retrospectively collected in each of the participating centers. In all, 86 patients who underwent operation between 1997 and 2013 were included in the study.

Statistical Analysis

Statistical analyses were performed using IBM SPSS, version 21.0 (IBM, Armonk, NY). Normal distribution of continuous data was assessed using the Shapiro-Wilk test. Continuous variables are displayed as mean $\pm$ SD, or median $\pm$ interquartile range; discrete variables are displayed as counts and percentages.

Overall survival and freedom from reintervention after valve-sparing reoperation were analyzed using the Kaplan-Meier method. Curves were truncated when the number of patients at risk dropped below 9 (<10% of the original population at risk). Ninety-five percent confidence intervals were calculated using log transformation of the cumulative hazard function.

With Cox regression, a univariable analysis of potential risk factors for reintervention after valve-sparing reoperation was performed. Variables included the following: gender; bicuspid aortic valve (yes/no); indication for initial Ross procedure (aortic regurgitation; aortic stenosis; combination); Ross technique (full root; inclusion cylinder; subcoronary); interval from the Ross procedure at time of valve-sparing reoperation; age at time of valve-sparing reoperation; isolated aortic regurgitation as indication for valve-sparing reoperation (yes/no); prolapse (yes/no); severe aortic regurgitation at the time of valve-sparing reoperation (grade ≥ 3 ; yes/no); valve-sparing autograft root replacement (yes/no); reimplantation versus remodelling technique; annulus repair (yes/no); and isolated autograft valve repair (yes/no). Pearson's correlation coefficient was used to assess correlations between variables included in the univariable analyses. A 1-way ANOVA with Tukey honestly significant difference post hoc test

was performed to assess possible differences in reintervention rates after valve-sparing reoperation among the 3 types of valve-sparing autograft root replacement techniques.

RESULTS

In the participating centers, 1783 Ross procedures were performed from 1997 to 2013. During this period, 87 patients (44.2%) received a valve-sparing reoperation after the Ross procedure, of a total of 197 patients who required ≥ 1 reoperation on the autograft. One patient was excluded from our study population, owing to intraoperative conversion to autograft valve replacement. An overview of patient and procedural characteristics at the time of the initial Ross procedure (Table 1) and of the perioperative details of the valve-sparing reoperation after the Ross procedure (Table 2), as well as details of autograft valve repair (Table 3), are provided. At the time of the valve-sparing reoperation after the Ross procedure, the median age of patients was 38.4 years (interquartile range: 27.1-51.6 years).

Early Outcome

After the valve-sparing reoperation after the Ross procedure, 1 patient died on day 9 postoperatively after cardiac arrest. With this 1 death, 30-day mortality was 1.2% (binomial 95% confidence interval: 0.03%-6.24%).

One patient, who had isolated autograft valve repair, underwent reintervention after valve-sparing reoperation on day 5 postoperatively, owing to grade III autograft regurgitation. The autograft valve was replaced by a homograft valve. Bleeding complications occurred in 3 patients, requiring re sternotomy in 2. One patient suffered a transient ischemic attack. The median hospital stay was 7 days (interquartile range: 6-9 days; range: 4-17 days).

Late Mortality

Follow-up after the valve-sparing reoperation after the Ross procedure was 95% complete, with a median duration of 4.3 years (interquartile range: 2.4-6.3 years; range: 54 days to 16.2 years; 343 patient years). Three cancer-related deaths occurred at 5.8 years, 7.5 years, and 10.0 years, respectively. Estimated freedom from all-cause mortality at 8 years' follow-up was 89% (95% confidence interval: 65%-97%).

Reintervention After Valve-Sparing Reoperation

Surgical reintervention after valve-sparing reoperation was performed in 15 patients (Table 3). Estimated freedom from reintervention was 76% at 8 years' follow-up (95% confidence interval: 57%-87%) (Figure 1). Although most autograft cusps appeared thin and pliable at explantation, 2 patients had autograft cusp calcifications.

Univariable analysis revealed several variables that were potentially associated with the hazard of reintervention after valve-sparing reoperation (Table 4). Isolated autograft

TABLE 1. Patient characteristics at initial Ross procedure

Characteristic	Value
Gender	
Male	69 (80)
Female	17 (20)
Age at Ross procedure (y)	
Median	29.9
Interquartile range	16.5-42.2
Range	7.5-58.3
Children (<18)	23 (27)
Native aortic valve	
Unicuspid	6 (7)
Bicuspid	61 (71)
Tricuspid	15 (17)
Unspecified	4 (5)
Previous cardiac surgery	
Patients	18 (21)
Procedures, n	20
Indication for Ross procedure	
Regurgitation	41 (48)
Stenosis	16 (19)
Combined	28 (33)
Unspecified	1 (1)
Etiology	
Congenital	49 (57)
Degenerative	23 (27)
Endocarditis	4 (5)
Rheumatic	1 (1)
Prosthesis mismatch	1 (1)
Prosthesis thrombosis	1 (1)
Cusp repair failure	1 (1)
Unspecified	6 (7)
Ross technique	
Root replacement	73 (85)
Inclusion cylinder	10 (12)
Subcoronary	3 (3)
RVOT graft type	
Homograft	84 (98)
Bioprosthesis	2 (2)

Values are n (%), unless otherwise indicated. Total patients = 86. The category of age at Ross procedure does not conform to a normal distribution. RVOT, Right ventricular outflow tract.

valve repair was associated with an increased hazard of reintervention. Estimated freedom from reintervention at 8 years' follow-up was 33% in patients with isolated autograft valve repair (7 of 11), compared with 85% in patients with valve-sparing autograft root replacement, with or without valve repair (8 of 70). Reintervention rates after valve-sparing reoperation were not significantly different for patients who received valve-sparing autograft root replacement using reimplantation (4 of 37), versus remodelling (3 of 17), versus the supracoronary technique (1 of 16) ($P = .503$).

Given that the low number of events precluded performing a multivariable analysis, we performed correlation

analysis on the variables that were significant in the univariable analysis. Isolated autograft regurgitation as an indication for valve-sparing reoperation after the Ross procedure was negatively correlated with use of the full root technique at the initial Ross procedure (coefficient -0.459 , $P < .001$) and valve-sparing autograft root replacement (coefficient -0.891 , $P < .001$). It was not correlated with age at the time of valve-sparing reoperation (coefficient -0.060 , $P = .594$).

Clinical Status

At latest follow-up, 80% of patients were in New York Heart Association class I, 12% in class II, and 8% in class III. Ninety-five percent of patients were in sinus rhythm, 3% had a permanent pacemaker, and 2% were diagnosed with atrial fibrillation. Oral anticoagulation was used by 10% of patients. Several patients experienced cardiac-related complications during follow-up, including stroke (8%), heart failure (5%), and myocardial infarction (2%). After valve-sparing reoperation after the Ross procedure, at least 4 women had a total of 5 successful pregnancies.

At latest follow-up, 63 patients were still alive and under active follow-up without having had a reintervention after valve-sparing reoperation. Autograft valve regurgitation was absent in 41% of patients, grade I in 43%, grade II in 13%, and grade III in 3% of patients.

DISCUSSION

This multicenter European study provides important information on the characteristics and outcome after valve-sparing reoperations after the Ross procedure. The findings illustrate that the indication for surgery, and the presentation of the patient at the time of valve-sparing reoperation, varies widely. Most patients in our cohort underwent the initial Ross procedure as young adults. Therefore, a substantial proportion of patients presented with a bicuspid aortic valve. Somewhat surprisingly, the indication for the Ross procedure was isolated aortic regurgitation in almost one half of the patients. The absence of aortic stenosis as an indication in such a large proportion of patients might be explained in part by prior balloon valvotomy or surgical valvuloplasty in these patients. Another part of the explanation may be that patients in whom the indication for the Ross procedure is aortic stenosis have a lower risk of autograft-related complications.

In experienced hands, valve-sparing reoperation after the Ross procedure is safe, with acceptable early morbidity and mortality. The reported low early mortality is especially striking, considering that in 21% of patients, the valve-sparing reoperation was their third or even fourth cardiac surgical procedure. After the valve-sparing reoperation, patients may again enjoy the claimed benefits of their autograft valve and avoid use of oral anticoagulants. This benefit

TABLE 2. Characteristics of valve-sparing reoperation after Ross procedure

Characteristic	Value
Type of procedure	
Emergency	1 (1)
Elective	79 (99)
Time after Ross procedure (y)	
Median	9.1
Interquartile range	5.8-12.6
Range	0.0-20.7
Indication	
Aneurysm	36 (42)
Regurgitation	16 (19)
Combined	28 (33)
RVOT graft stenosis	1 (1)
Unspecified	5 (6)
Etiology	
Degenerative	72 (84)
Endocarditis	6 (7)
Acute dissection	1 (1)
Unspecified	7 (8)
Autograft root diameter, mean (SD; mm)*	
Annulus	26.6 ± 4.9
Sinus	49.7 ± 5.0
STJ	47.0 ± 5.3
Ascending aorta	49.2 ± 4.9
Autograft regurgitation grade (n = 79)	
None/trace	3 (4)
I	17 (22)
II	23 (29)
III	23 (29)
IV	13 (16)
Annulus repair (n = 80)	57 (71)
Circular annuloplasty†	40
Cabrol stitches	16
Unspecified	1
Valve-sparing autograft root replacement (n = 81)	70 (86)
Reimplantation	37
Remodeling	17
Supracoronary	16
STJ remodeling (n = 74)	20 (27)
Cusp abnormalities (n = 81)	33 (41)
Prolapse	31
Fenestration	2
Perforation	3
Retraction	2
Calcification	1
Autograft valve repair (n = 79)	34 (43)
Central plication	28
Suture-free edge	10
Pericardial patch	2
Perfusion time, mean (SD; min; n = 66)	145.0 ± 60.3
Crossclamp time, mean (SD; min; n = 66)	107.1 ± 46.2
Circulatory arrest, mean (SD; min; n = 54)	4 (7)
	26.3 ± 35.0

(Continued)

TABLE 2. Continued

Characteristic	Value
Concomitant surgery	20 (23)
RVOT graft replacement	16
Hemi-arch replacement	3
ASD closure	1
VSD closure	1

Values are n, or n (%), unless otherwise indicated. Total number of procedures N = 86. For several variables, number of patients from which data were available is indicated by “(n =).” The categories of cusp abnormalities, autograft valve repair, and concomitant surgery are overlapping. RVOT, Right ventricular outflow tract; SD, standard deviation; STJ, sinotubular junction; ASD, atrial septal defect; VSD, ventricular septal defect. *For autograft root diameter, diameters are provided only for patients with autograft root aneurysms, without severe autograft valve regurgitation. †Includes 37 patients who had aortic root reimplantation (David procedure).

is superbly illustrated by the 4 women in our cohort who became pregnant after the valve-sparing reoperation. In our cohort, no cardiac-related deaths were observed during follow-up. This finding suggests that valve-sparing reoperations after the Ross procedure conserve the survival advantage observed after the Ross procedure.⁷ However, the 3 cancer-related deaths resulted in a slightly lower estimated survival at 8 years, compared with the age-matched general population in The Netherlands (89% vs 98%; calculated using StatLine; Statistics Netherlands, The Hague, The Netherlands).

Reintervention after valve-sparing reoperation is not uncommon. Most reinterventions were performed within the first 2 postoperative years. This finding may explain why the case reports on valve-sparing reoperations after the Ross procedure do not report failure, as follow-up in these reports rarely extend beyond a few months postoperatively.^{8,9} Most patients who did not require a reintervention were in excellent clinical condition and had good autograft valve function at latest follow-up.

TABLE 3. Reinterventions after valve-sparing reoperation

Reintervention characteristic	Value
Indication	
Autograft regurgitation	13 (86.7)
Autograft stenosis	1 (6.7)
Autograft root dilation	1 (6.7)
Cusp abnormalities	
Prolapse	8 (66.7)
Retraction	4 (26.7)
Combination	1 (6.7)
Calcifications	2 (13.3)
Procedure	
Autograft valve repair	1 (6.7)
Replacement with mechanical prosthesis	10 (53.3)
Replacement with biological prosthesis	4 (26.7)

Values are n (%). Total N = 15.

FIGURE 1. Kaplan-Meier curve of freedom from reintervention after valve-sparing reoperation: (A) entire cohort and (B) cohort split according to operation technique used at the time of the Ross procedure. Techniques are indicated in parentheses. *FR*, Full root; *IC*, inclusion cylinder; *SC*, subcoronary.

We have identified several factors related to characteristics of the patient and to the initial Ross procedure, as well as to autograft valve function at the time of the valve-sparing reoperation, that are associated with reintervention. These findings may help guide the decision-making process when reoperation on the pulmonary autograft is needed.

The technique used for the initial Ross procedure was associated with outcome after the valve-sparing reoperation. Compared with the full root technique, the inclusion cylinder technique was associated with an increased risk of failure of the valve-sparing reoperation. Although a similar association in the subcoronary group was not statistically significant, this lack of significance may be attributed to the limited number of patients in this group.

We believe that the inclusion cylinder and subcoronary techniques may lead to distortion of the complex geometry of the autograft cusps. Over time, this may lead to cusp prolapse and other degenerative cusp changes in some patients. Not surprisingly, most patients in whom the initial Ross procedure was performed according to the inclusion cylinder or subcoronary technique presented with isolated, and often severe, autograft regurgitation at the time of reoperation.

Prolapse and degenerative cusp changes present at the time of reoperation may prevent reoperation durability. In addition, such reoperations may be technically more challenging with use of the inclusion cylinder or subcoronary technique, owing to scarring and possible reduced compliance of the autograft wall. A substantial proportion of these patients who required a reintervention after the valve-sparing reoperation presented with prolapse and/or retraction of ≥ 1 cusps at the time of reintervention. The 2 patients in whom cusp calcifications were reported at the time of autograft valve explantation had an inclusion cylinder Ross procedure.

In contrast, use of the full root technique at the initial Ross procedure preserves the complex geometry of the autograft root. After the full root technique, the predominant mechanism of failure is autograft root dilation, generally with either only moderate autograft regurgitation, or none. Degenerative cusp changes are expected to be limited. Supporting this theory is our finding that in patients in whom the full root technique was used, autograft root aneurysm was the indication for a valve-sparing autograft root replacement in most patients. The interval between the initial Ross procedure and the valve-sparing reoperation was longer when the indication for reoperation was autograft root aneurysm (10.7 years), compared with isolated autograft regurgitation (3.4 years).

Our findings are in accordance with 2 smaller cohort studies that showed an association between isolated autograft valve pathology and reintervention after valve-sparing reoperation.^{4,5} In a case series with 7 patients, the authors did not report any reintervention after a mean echocardiographic follow-up of 3.2 years.¹⁰ Their excellent results may be explained in part by the absence of patients who had isolated autograft regurgitation. Reported results after primary valve-sparing aortic root operations are excellent: de Kerchove and colleagues¹¹ report a freedom from reoperation after primary valve-sparing aortic root operation at 8 years of 90%; Aicher and colleagues¹² report 96% at 10 years. These results are comparable to our reported freedom from reintervention of 85% at 8 years in

TABLE 4. Univariable analysis of the hazard of reintervention after valve-sparing reoperation

Variable	Hazard ratio (95% CI)	P value
Ross technique		
Full root	1.000	
Inclusion cylinder	4.358 (1.454-13.064)	.009
Subcoronary	4.005 (0.497-32.286)	.193
Age	0.944 (0.906-0.985)	.007
Isolated aortic regurgitation (as repair indication)	5.021 (1.721-14.649)	.003
Severe aortic regurgitation (grade ≥ 3)*	3.736 (1.165-11.978)	.027
Isolated autograft valve repair	5.041 (1.677-15.154)	.004
Valve-sparing autograft root replacement	0.199 (0.070-0.565)	.002

CI, Confidence interval. *At the time of valve-sparing reoperation after Ross procedure.

the subgroup of patients who received valve-sparing autograft root replacement.

Durable valve-sparing reoperations after the Ross procedure in patients with diseased autograft cusps may not be possible in some patients, especially when isolated autograft regurgitation is present, or may require careful consideration of the surgical approach. Several participating centers do not consider patients with leaflet calcifications, fenestrations, or retraction-suitable candidates for valve-sparing reoperations after the Ross procedure. Given this context, some centers advocate the use of intraoperative measurements of the autograft cusps to guide the reoperation. Although this approach may prove to be more reliable than visual inspection with the naked eye, no difference in outcome of autograft valve repair was observed in the current study between centers that used intraoperative measurements versus those that did not. In patients in whom a durable repair is unlikely, surgeons may consider the Bentall procedure with implantation of a mechanical or biological prosthesis.

Limitations

The retrospective nature of this study resulted in limitations with respect to data collection, because information on several variables was not available for all patients. These limitations underscore the need for a prospective registry to assess (variables associated with) outcome of valve-sparing reoperations after the Ross procedure. Such a registry may have been achieved in the recently initiated AVIATOR (<http://heartvalvesociety.org/working-groups.cgi>), a prospective international registry of patients undergoing surgery for ascending aorta aneurysm and/or isolated aortic regurgitation.

CONCLUSIONS

Valve-sparing reoperations after the Ross procedure may be performed with limited early morbidity and mortality in most patients. This approach provides patients with the continued benefit of a functioning autograft valve. However, the need for reintervention after valve-sparing reoperation is common in the first 2 postoperative years in patients with isolated and/or severe autograft regurgitation;

careful consideration of the surgical approach in these patients is warranted.

Conflict of Interest Statement

Dr Weimar reports consulting fees from Atricure. All other authors have nothing to disclose with regard to commercial support.

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