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Appraisal of Long-Term Outcomes of Tricuspid Valve Replacement in the Current Perspective

Amedeo Anselmi, MD, PhD, Vito Giovanni Ruggieri, MD, PhD, Majid Harmouche, MD, PhD, Erwan Flécher, MD, PhD, Hervé Corbineau, MD, Thierry Langanay, MD, Bernard Lelong, MD, Jean-Philippe Verhoye, MD, PhD, and Alain Leguerrier, MD

Division of Thoracic and Cardiovascular Surgery, Pontchaillou University Hospital, Rennes, France

Background. **We address the differential long-term results of tricuspid valve replacement and late valve-related events among bioprostheses versus mechanical prostheses.**

Methods. **In a single-institution investigation, we reviewed the patients' prospectively collected data and performed a clinical follow-up. Both the Kaplan-Meier (actuarial) and the competing risks (actual) methodologies were used.**

Results. **Overall, 188 tricuspid valve replacements were performed during 1971 to 2012. In this complex population (reoperations, 48.1%; associated procedures in 71.3%), operative mortality was 27.6% (significantly declining in recent years). A bioprosthesis was used in 82.4%. Follow-up was 10.2 ± 9.1 years (as long as 37.3 years, or 1,270 patient-years; 91.2% complete). At 15 years, freedom from structural valve deterioration was 93.3% ± 6.4% (competing risks 94.7 ± 5.1%) in the mechanical group and 85.2% ± 5.4% (competing risks 92% ± 2.9%) in the bioprostheses group ($p = 0.19$). Freedom from any valve-related adverse events was lower among mechanical valves versus bioprostheses (although not statistically significant). Mechanical valves showed significantly lower freedom from thromboembolic events (actuarial 62.3% ± 14.3% versus 97.7% ± 1.6%; competing risks 74.1% ± 10% versus 98% ± 1.4%; $p < 0.001$) and earlier adverse events (4.9 ± 4.5 versus 11.1 ± 9.4 years) than bioprostheses. There were 11 reoperations for bioprosthetic structural valve deterioration (89.8% and 94.3% actuarial and actual freedom, respectively).**

Conclusions. **Bioprostheses for tricuspid valve replacement have a very good long-term durability. Mechanical valves display earlier and more severe morbidity at follow-up.**

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Tricuspid valve disease has earned increasing interest during recent years [1, 2]. Several series published in the late 1990s addressed the long-term fate of valve prostheses in the tricuspid position [3–6]. In more recent series, it appears that different policies exist with respect to the choice of biological versus mechanical valve substitutes for tricuspid valve replacement (TVR) [7, 8]. The current practice largely relies on tricuspid valve repair to treat secondary regurgitation, although nonnegligible rates of recurrent tricuspid regurgitation can still be observed at midterm follow-up despite recent annuloplasty devices [9]. Tricuspid valve replacement plays a role when etiologic mechanisms besides annular dilation coexist [7]. Transcatheter valve-in-valve implantation has been proposed for the tricuspid position [10]. The choice of valvular substitute for TVR, the long-term results of prostheses for TVR, and the feasibility of redo TVR in the current era are major contributors to such discussion.

Our purpose was to appraise the comparative long-term results of TVR using either bioprostheses or mechanical prostheses, with particular regard to durability and late valve-related adverse events of biological valve substitutes. Because mechanical prostheses were specifically used during the initial part of our experience, we are able to provide long-term data about their performance.

Patients and Methods

Patient Selection

Since 1980, the data of all patients undergoing cardiac operations at Rennes University Hospital have been prospectively entered into an electronic database including

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Address correspondence to Dr Anselmi, Division of Cardiovascular and Thoracic Surgery, Pontchaillou University Hospital, 2 rue Henri le Guilloux, Rennes 35000, France; email: amedeo.anselmi@alice.it.

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preoperative and intraoperative variables as well as postoperative inhospital results. In March 2014, we retrospectively queried the database to identify patients who received TVR from January 1, 1971, to December 31, 2012. Both mechanical and bioprosthetic TVRs were included. Long-term follow-up was performed in mid 2014 by research nurses; the referring cardiologists were contacted. In cases when it was impossible to get in touch with cardiologists, the general practitioners, the patients themselves, or their families were contacted. Practitioners were provided with a questionnaire concerning patients' vital status, occurrence of adverse events, causes of death, and time at which adverse events had presented. Valve-related and nonvalve-related events were defined according to the Akins recommendations [11], including structural valve deterioration (SVD), nonstructural valve dysfunction, and operated-on valve endocarditis (infective endocarditis [IE]).

Because the present study is focused on the outcomes of TVR, only events related to the prosthesis implanted in the tricuspid position were included in the final analyses. Patients' data were revised to discriminate the tricuspid-related versus nontricuspid-related status of each adverse event. Cerebral or systemic noncerebral embolic events were not attributed to tricuspid prostheses. Embolism had to be documented either operatively, at autopsy, or clinically, with concurrence of dedicated imaging. Valve thrombosis was any thrombus not caused by endocarditis attached or near to the tricuspid prosthesis, evident at either operation, autopsy, or imaging. Freedom from the composite of thrombosis and embolic events was provided. Cerebral or noncerebral hemorrhagic events were attributed to mechanical tricuspid prostheses as these patients were receiving anticoagulant therapy. Any pulmonary embolism was attributed to the tricuspid prosthesis unless another origin (ie, deep venous thrombosis) could be formally demonstrated. Valve-related reinterventions (including the valve-in-valve procedure) were defined when indication to reoperate derived from any dysfunction of the tricuspid prosthesis. In case of insufficient information concerning the attribution of a given adverse event, unknown causes were considered as valve-related events. Valve-related mortality was defined as any death after reintervention on the tricuspid prosthesis or after any adverse event attributable to the TVR prosthesis.

Regarding long-term follow-up, a considerable death rate (45% of all late deaths, n = 42) was due to unknown causes; such a remarkable rate was likely determined by extremely long follow-up in several cases (63.5% of patients being operated on before 1991) with consequent unavailability of medical records. Therefore, we decided to exclude these deaths from the curves of freedom from valve-related mortality, although the rate and significance of these cases is detailed in the text. The expression "valve-related" events only refers herein to events attributed to the TVR prosthesis, even though other valve prostheses might be present in the same patient. Renal insufficiency was defined as serum creatinine greater than 200 μmol/L. Left and right side heart failures were defined as signs and symptoms of heart insufficiency attributable to left or right ventricular failure associated with instrumental demonstration of dysfunction. Transthoracic echocardiography was performed before hospital discharge, at the first postoperative month, and later on a regular basis. Unscheduled echocardiography was performed when clinically indicated.

Because all data were managed anonymously and no additional therapeutic or diagnostic protocols other than standard clinical practice were performed, patients' informed consent to enter the study was waived. Our database is registered within the CNIL (Commission Nationale de l'Informatique et des Libertés [National Committee for Informatics and Freedom]) website under the number 1207754, in accordance with French law.

Postoperative management included lifelong treatment with lysine acetylsalicylate for tricuspid bioprostheses, unless differently indicated. Early anticoagulation therapy was administered during the first 3 months after implantation of a bioprosthesis in the tricuspid position and discontinued thereafter (unless differently indicated). An oral anticoagulant regimen was used for mechanical tricuspid prostheses (target international normalized ratio: 2.5 to $\leq$ 3.5).

Endpoints

Endpoints were (1) long-term survival and freedom from SVD among patients treated by TVR using a bioprosthesis; (2) comparative survival and freedom from valve-related adverse events among patients treated by TVR using either a biological or mechanical prosthesis (valve-related adverse events were studied both individually and by building a composite endpoint including valve-related death, SVD, nonstructural valve dysfunction, IE, thromboembolic and hemorrhagic events, and tricuspid reoperation); and (3) clinical characteristics and results in the subgroup of patients undergoing reoperative TVR.

Statistical Analysis

Continuous and categoric variables were reported as mean ± SD and as percentages, respectively. Intergroup comparisons were conducted using the χ^2 test and Fisher's exact test for categoric and continuous variables, respectively. Concerning time-to-event analysis, both the Kaplan-Meier (actuarial) and the cumulative risks (actual) methodologies were used, as previously described [12–14]. The log rank statistic was computed to compare opposite Kaplan-Meier curves. For Kaplan-Meier estimates, operative deaths were excluded and only deaths occurring during the follow-up were computed. For data analysis, SAS software, version 9.33 (SAS Institute, Cary, NC) was used. The alpha level was 0.05.

Results

Early Results

In all, 188 TVRs were performed in 171 patients during the study period (Fig 1). The modality of tricuspid valve

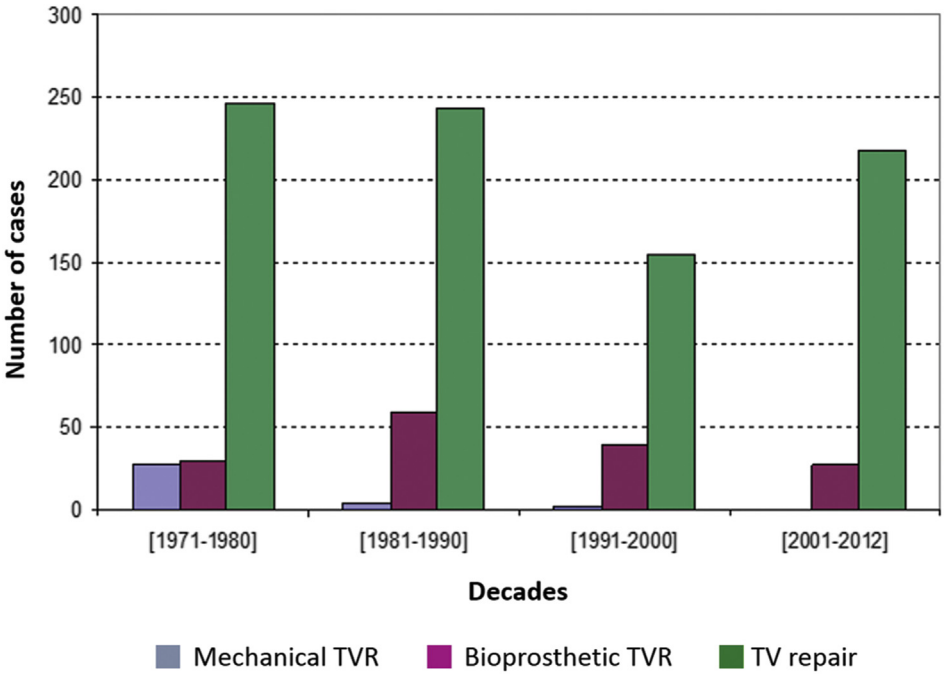

Fig 1. Number of tricuspid valve replacements with either a mechanical prosthesis (blue columns) or a bioprosthesis (purple columns) and number of tricuspid valve repairs (green columns) performed at our hospital by decade.

dysfunction was predominant regurgitation in 83% of cases, predominant stenosis in 16.5%, and mixed in 1.1%. Indications for TVR were rheumatic lesions in 32.2%, annular dilation or degenerative disease in 36.2%, IE in 10.3%, and other etiologies in 21.3%. Average preoperative systolic pulmonary artery pressure was 48.1 ± 14.7 mm Hg (bioprostheses group only). Of all cases, 48.1% were reoperations (interval after previous surgery, 14.5 ± 11.1 years). Previous operations were left-sided valve surgery (n = 56, 29.6%), left-sided valve surgery and TVR (n = 13, 6.8%), left-sided valve surgery and tricuspid valve repair (n = 13, 6.8%), isolated TVR (n = 4, 2.1%), isolated tricuspid valve repair (n = 3, 1.6%), and coronary artery bypass (n = 2, 1.1%). Preoperatively, left ventricular ejection fraction was 55.2% ± 11.9%.

For TVR, a bioprosthesis was used in 155 cases (82.4%) and a mechanical prosthesis in the remainder. Models of bioprostheses were as follows: Carpentier-Edwards (Edwards Lifesciences, Irvine, CA) standard, 34%; Carpentier-Edwards supraannular, 23.9%; Medtronic (Minneapolis, MN) Hancock II, 11.7%; Carpentier-Edwards pericardial, 7.9%; St. Jude Medical (St. Paul, MN) Epic, 4.2%; and Medtronic Mosaic, 0.5%. Models of mechanical prostheses were Starr-Edwards Silastic, 8.5%; CarboMedics (Sorin Group, Milan, Italy), 5.8%; St. Jude Medical Regent, 2.6%; and St. Jude Medical Silzone, 0.5%. Sizes of valve implanted in the tricuspid position were as follows: 25 mm (2.1%), 27 mm (8.5%), 28 mm (1.6%), 29 mm (20.7%), 30 mm (1.6%), 31 mm (38.3%), 33 mm (23.4%), and 35 mm (2.7%).

Concomitant procedures were performed in 71.3% of cases. Details of associated procedures were as follows: TVR and other valve surgery (62.2%); TVR, other valve surgery, and thoracic aortic surgery (1.1%); TVR, other valve surgery, and coronary bypass (1.1%); TVR, other valve surgery, and correction of congenital heart defect (1.1%); TVR and correction of congenital heart defect (4.2%); and TVR and coronary artery bypass (1.6%). Table 1 compares the preoperative and intraoperative characteristics of patients receiving a bioprosthesis or a mechanical valve.

Operative mortality was 27.6% overall; early valve-related mortality occurred in 15.4% of these patients (2.6% of the overall population; n = 8, including 2 deaths due to undetermined causes). No significant difference was observed between the mechanical group and the bioprostheses group ($p = 0.09$). Lower mortality was observed in recent years, namely, 2001 to 2012 (9.6%) compared with the 1991 to 2000, 1981 to 1990, and 1971 to 1980 periods (26.9%, 25%, and 38.5%, respectively). Operative mortality was due to cardiac nonvalve-related causes in 48.1% (n = 25, 13.3% of the overall population), and was due to noncardiac causes in the remainder (36.5% of mortality cases, 10% of the overall population, n = 19).

Follow-Up

We had 1,270.78 patient-years available for analysis over an average follow-up of 10.2 ± 9.1 years (longest follow-up, 37.3; Fig 2). At the end of follow-up, 144 patients (76.6%) were dead; 15-year actuarial survival was 36% ± 5.2% in the bioprostheses subgroup versus 38.9% ± 11.5% in the mechanical prostheses subgroup ($p = 0.78$). Death was valve-related in 4 cases (15-year actuarial freedom from valve-related death, 97% ± 2.1%). Late death was due to unknown causes in 42 instances (29.2%). Overall survival was not significantly different between the mechanical group and bioprostheses group

Table 1. Comparison of Baseline and Intraoperative Characteristics Among Patients Who Received Bioprosthesis or Mechanical Valve

Characteristic	Mechanical Group	Bioprostheses Group	*p* Value
Male	10 (30.3%)	70 (45.2%)	0.11
Age, years	51.2 ± 12.8	57.4 ± 15.6	0.03
NYHA III or IV	30 (93.8%)	122 (81.3%)	0.08
Left-side heart failure	25 (75.8%)	69 (44.5%)	0.001
Right-side heart failure	8 (24.2%)	97 (62.6%)	<0.001
Renal insufficiency	1 (3%)	6 (3.9%)	0.9
LVEF, %	46.7 ± 23.1	55.6 ± 11.2	0.8
Preoperative sPAP, mm Hg	NA	48.1 ± 14.7	…
Preoperative LVEDD, mm	NA	50.1 ± 10.6	…
EuroSCORE I logistic	16.8 ± 15.4	20.6 ± 16	0.2
Nonelective priority	5 (15.2%)	17 (11%)	0.5
CPB time, minutes	134.6 ± 44.4	127.5 ± 51.6	0.4
Operative mortality	13 (39.4%)	39 (25.2%)	0.09
Permanent pacing	6 (18.2%)	21 (13.5%)	0.5

CPB = cardiopulmonary bypass; EuroSCORE = European System for Cardiac Operative Risk Evaluation; LVEDD = left ventricular end-diastolic diameter; LVEF = left ventricular ejection fraction; NA = not available; NYHA = New York Heart Association; sPAP = systolic pulmonary artery pressure.

(actuarial 15-year survival 38.9% ± 11.5% and 36% ± 5.2%, respectively; $p = 0.78$). Freedom at 15 years from valve-related mortality was 98.2% ± 1.8% for bioprostheses versus 91.7% ± 8% for mechanical prostheses, without statistical significance ($p = 0.07$), although that may have inherent clinical significance (stratified Kaplan-Meier curve in Fig 3A).

In the overall population, we observed 18 SVD events (all but one in the bioprosthesis group). Models of prostheses presenting SVD were St. Jude mechanical valve (1 case), Medtronic Hancock (7 cases), Carpentier-Edwards standard (7 cases), and Carpentier-Edwards supraannular (3 cases). Such data reflect the distribution of the used bioprostheses in the population, and we could not identify any model presenting statistically increased SVD frequency. The 15-year actuarial freedom from SVD was 85.2% ± 5.4% in the bioprosthesis group and 93.3% ± 6.4% in the mechanical group ($p = 0.19$; Fig 3B). Nonetheless, if the competing risks methodology is used (which depicts the factual number of nonlethal events occurring in the population and provides the real estimation of patients' outcomes), the 15-year freedom from SVD is 92% ± 2.9% for the bioprostheses versus 94.7% ± 5.1% for mechanical valves (Table 2). Freedom from SVD

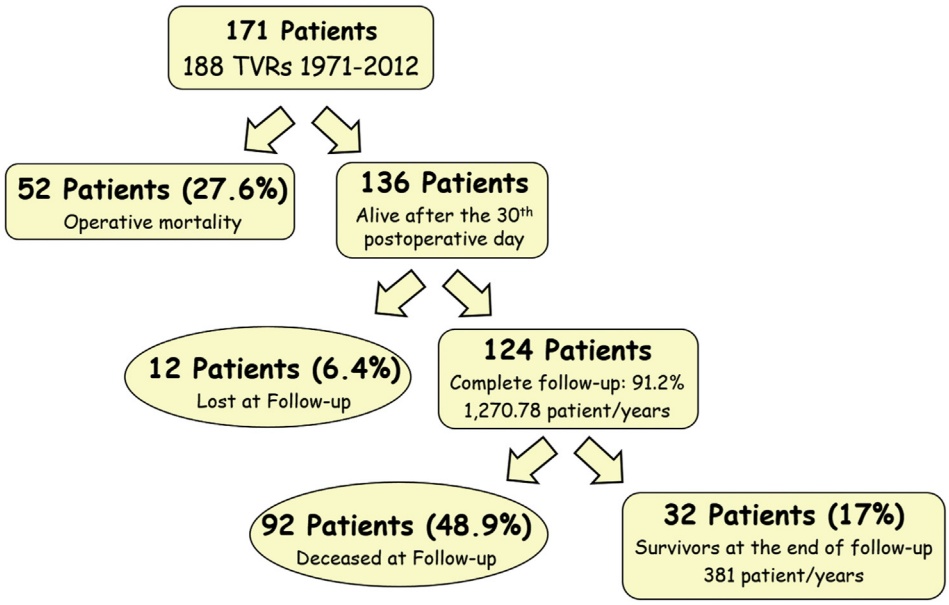

Fig 2. Study outline. (TVR = tricuspid valve replacement.)

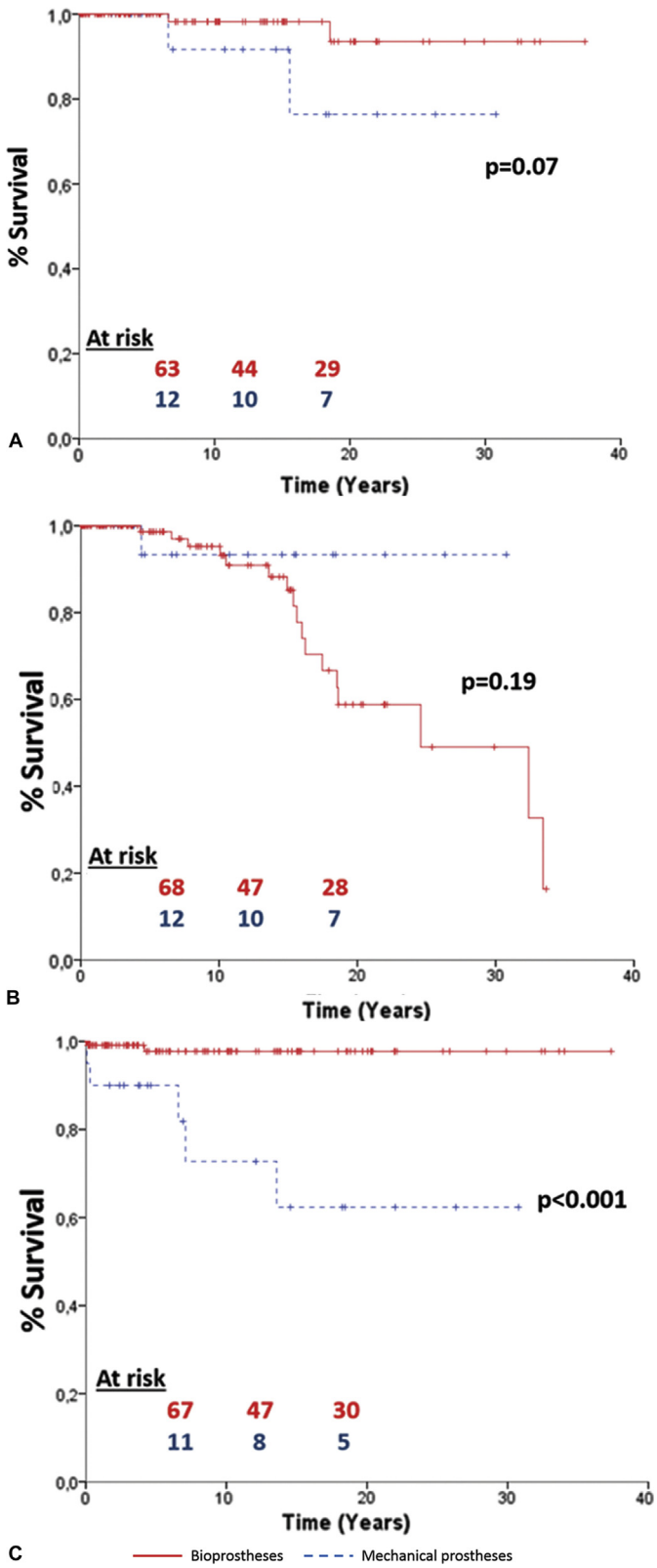

Fig 3. Kaplan-Meier survival curves according to type of tricuspid valve replacement prosthesis, biological (red continuous lines) or mechanical (blue dotted lines). (A) Survival free from tricuspid valve-related death. (B) Survival free from Structural valve deterioration of tricuspid prosthesis. (C) Survival free from thromboembolic events related to tricuspid valve.

Table 2. Freedom From Tricuspid Valve-Related Adverse Events During Long-Term Follow-Up, Stratified by Type of Valve[a] for Tricuspid Valve Replacement

Events	No. of Events	5-Year Freedom	10-Year Freedom	15-Year Freedom	*p* Value
Structural valve deterioration					
Bioprostheses	17	98.6 ± 1.4 (98.9%); n = 68	95.2 ± 2.7 (96.8%); n = 47	85.2 ± 5.4 (92%); n = 28	0.19
Mechanical prostheses	1	93.3 ± 6.4 (94.7%); n = 12	93.3 ± 6.4 (94.7%); n = 10	93.3 ± 6.4 (94.7%); n = 7	
Hemorrhagic events					
Bioprostheses	6	94.4 ± 2.5 (95.1%); n = 65	94.4 ± 2.5 (95.1%); n = 44	91.8 ± 3.5 (93.9%); n = 27	0.8
Mechanical prostheses	2	100; n = 12	100; n = 10	90 ± 9.5 (94.3%); n = 6	
Thromboembolic events					
Bioprostheses	4	97.7 ± 1.6 (98%); n = 67	97.7 ± 1.6 (98%); n = 47	97.7 ± 1.6 (98%); n = 30	<0.001
Mechanical prostheses	5	90 ± 6.7 (90%); n = 11	72.7 ± 12.3 (79.4%); n = 8	62.3 ± 14.3 (74.1%); n = 5	

[a] Bioprostheses, n = 155; mechanical, n = 33.

Actuarial rates are displayed and competing risks rates are given in parentheses, followed by number of patients at risk at each timepoint.

was not statistically different among porcine versus pericardial bioprostheses (log rank $p = 0.9$), although there were no SVD cases in the pericardial group. This comparison was limited by smaller case number and shorter follow-up in the pericardial subgroup (survival free from SVD 85.2% ± 5.4% at 15 years for the porcine subgroup, and 100% at 5 years for the pericardial subgroup). There were no nonstructural valve dysfunction events and 1 case of IE among bioprostheses (not requiring reoperation).

At the end of follow-up, 63 patients in the bioprosthesis cohort (54% of the operative survivors in the subgroup) were receiving oral anticoagulants for reasons other than the tricuspid prosthesis. Although the late freedom from hemorrhagic events was comparable among groups (Table 2), we observed significantly better freedom from thromboembolic events in the bioprostheses group ($p < 0.001$; Fig 3C and Table 2). In the mechanical group, all thromboembolic events were cases of pulmonary embolism, and no cases of valve thrombosis could be demonstrated.

Fourteen patients underwent reoperation on the tricuspid valve at an average 9.6 ± 14.2 years after primary TVR. No reoperation occurred among patients who had received a mechanical prosthesis; among bioprostheses, the 15-year freedom from reoperation was 84.6% ± 5.4% (actuarial) and 91.1% ± 3% (competing risks), without statistical difference versus the mechanical group ($p = 0.1$; Fig 4A and Table 3). In 2 of these 14 reoperations, a well-functioning tricuspid bioprosthesis was replaced during redo surgery motivated by left-sided valve dysfunction. Such "prophylactic" tricuspid re-replacements were decided on the basis of the age of tricuspid bioprostheses (more than 10 years). Eleven tricuspid reoperations were due to SVD (15-year freedom from reoperation for SVD 89.8% ± 4.5% actuarial and 94.3% ± 2.5% competing risks; $p = 0.15$ versus the mechanical group; Fig 4B and Table 3). Reoperations for SVD were performed after 16 ± 9.4 years (range, 4.3 to 33.4) from implantation of bioprosthesis. The SVD presented as significant stenosis (average mean gradient 14.3 mm Hg), with significant regurgitation in 45% of cases. The composite endpoint was attained in 30 patients (21.6% in the bioprosthesis group and 25% in the mechanical group). The bioprostheses showed higher 15-year freedom from the composite endpoint according to both the actuarial and actual methodologies, although statistical significance was not reached ($p = 0.84$; Fig 4C and Table 3). The average delay between previous surgery and reoperation on the tricuspid valve (14 ± 9.6 years) was longer than the delay between previous operation and redo surgery due to causes other than the tricuspid prosthesis (9.4 years ± 8.5, $p = 0.02$). Of patients undergoing reoperation for SVD of their tricuspid prosthesis, 3 died postoperatively (27.3% mortality rate).

Comment

Candidates for TVR have been considered a challenging subgroup owing to frequently complex clinical scenarios and advanced heart disease [3, 15]. The appraisal of long-term outcomes related to the tricuspid prostheses demands an insightful assessment of each patient's data (attribution of adverse valve-related events in patients with more than one valve device). Herein, events were attributed to the tricuspid prostheses on the basis of either a direct cause and effect relationship or absence of other known causes for the events. Such "conservative" methodology, adopted in compliance with the current guidelines [11, 14], may overestimate the rates of valve-related adverse events.

We present the largest single-institution TVR series so far in terms of both number of patients (n = 188) and follow-up duration. Recent years have seen a progressive decline in operative mortality [7]. Comparison of operative mortality among different series should account for variable inclusion criteria (reoperative TVR only in some [7], isolated TVR only in others [16], and so forth). Instead, the present investigation was focused on the durability of the TVR prostheses and freedom from adverse events. One major finding is the very good durability of

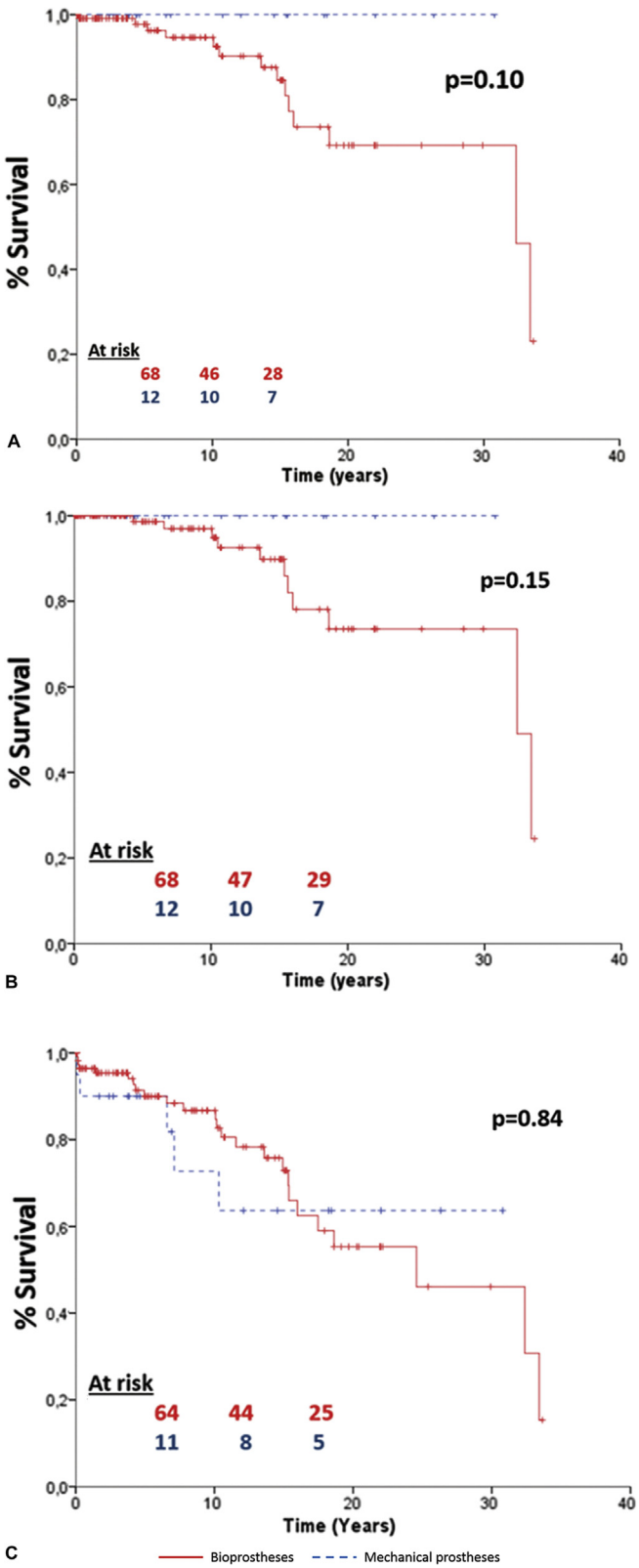

Fig 4. Kaplan-Meier survival curves stratified according to the type of tricuspid valve replacement prosthesis, biological (red continuous lines) or mechanical (blue dotted lines). (A) Survival free from reoperation on a tricuspid prosthesis. (B) Survival free from reoperation for Structural valve deterioration of a tricuspid prosthesis. (C) Survival free from the composite endpoint.

Table 3. Freedom From Tricuspid Valve-Related Reoperation and Composite Endpoint During Long-Term Follow-Up, Stratified by Type of Valve[a] for Tricuspid Valve Replacement

Events	No. of Events	5-Year Freedom	10-Year Freedom	15-Year Freedom	*p* Value
Reoperation (any cause)					
Bioprostheses	14	97.7 ± 1.6 (98.1%); n = 68	94.6 ± 2.7 (95.9%); n = 46	84.6 ± 5.4 (91.1%); n = 28	0.1
Mechanical prostheses	0	100; n = 12	100; n = 10	100; n = 7	
Reoperation for SVD					
Bioprostheses	11	98.6 ± 1.4 (98.9%); n = 68	97 ± 2.1 (97.8%); n = 47	89.8 ± 4.5 (94.3%); n = 29	0.15
Mechanical prostheses	0	100; n = 12	100; n = 10	100; n = 7	
Composite endpoint					
Bioprostheses	41	90 ± 3.2 (91.3%); n = 64	86.7 ± 3.9 (89.2%); n = 44	72.9 ± 6.2 (82.1%); n = 25	0.84
Mechanical prostheses	10	90 ± 6.7 (90%); n = 11	72.7 ± 12.3 (74.1%); n = 8	63.6 ± 13.7 (74.1%); n = 5	

[a] Bioprostheses, n = 155; mechanical, n = 33.

Actuarial rates are displayed, and competing risks rates are given in parentheses, followed by number of patients at risk at each timepoint.

SVD = structural valve deterioration.

bioprostheses for TVR: the 15-year freedom from SVD was 82.5% (actuarial) and 92% (competing risks), which compares favorably with previously published rates, such as 74.3% at 10 years (actuarial) by Buzzatti and coworkers [7] and 78% at 13 years (actuarial) by Ohata and coworkers [17]. Previous series have reported low freedom from tricuspid reoperation at 14 years (49%), only half of the reoperations being due to bioprosthetic SVD [3]. Such rates are comparable to those observed at 15 years for third-generation bioprostheses in the aortic position (actuarial 86.3%, actual 95.1% [14]). As the present series is mixed with respect to models of bioprostheses and covers a large time span, one may assume that the most recent bioprostheses used for TVR would perform even better. A large meta-analysis including more than 1,000 patients was published in 2004 by Rizzoli and coworkers [18]. These investigators found trivial differences in freedom from reoperation among biological and mechanical TVR devices. Nonetheless, this review article presented only limited data about freedom from hemorrhagic and thromboembolic complications, which distinguish the long-term outcomes of biological from mechanical TVR. Additionally, the valve-in-valve procedure is now available, and it should be considered in the decision making for prosthetic devices.

Among the 17 bioprosthetic SVD events in our series, 11 (64%) required reoperation. The remaining patients did not receive re-replacement because of either stable and clinically tolerated valve dysfunction or excessive reoperative risk. There was only 1 case of IE on a tricuspid prosthesis, and it was managed by medical treatment only. Patients were more likely to undergo reoperation for reasons other than dysfunction of a TVR bioprosthesis ($p = 0.02$), posing the issue of "prophylactic" replacement of a relatively old, well-functioning TVR bioprosthesis. We cannot provide conclusions regarding such an issue, except to recommend the use of competing risks methodology to predict the chances of dysfunction for a bioprosthesis at a given follow-up timepoint. Redo TVR for reasons other than SVD is typically a nonlethal event, which censors the occurrence of SVD and reoperation for SVD. The actuarial method gives excessively pessimistic estimates of freedom from nonlethal events (notably, SVD and reoperation for SVD). The competing risks (actual) methodology appreciates the real risk of incurring SVD or reoperation for SVD for individual patients [12, 19], and becomes of greater importance with clinically severe patient populations [20].

Our experience covers a long period, and the policies for valve choice changed over time. In the initial years, few data about thrombogenicity and no bioprostheses with known durability were available. Subsequently, our policy evolved toward systematic use of bioprostheses. Only one SVD event occurred with the mechanical valves, which were characterized by significantly lower freedom from thromboembolic events than bioprostheses. Such events were represented by pulmonary embolism and tricuspid valve thrombosis. No intergroup difference was observed in terms of freedom from hemorrhagic events; nonetheless, this should be weighed by the frequent coexistence of left-sided mechanical prostheses requiring anticoagulant therapy for patients carrying tricuspid bioprostheses. However, when it comes to the comparison of freedom from the composite endpoint, no intergroup difference emerges ($p = 0.8$; Fig 4C), despite some advantage for the bioprostheses (72.9% actuarial freedom versus 63.6% in the mechanical group). In other terms, the occurrence of complications typical of mechanical prostheses compensates for and possibly outweighs the morbidity associated with SVD of bioprostheses. Previous investigations found significantly lower freedom from valve-related events in the mechanical group owing to major rates of late hemorrhagic events [8, 21, 22]. The SVD is often an indolent process allowing planning of interventions, whereas valve thrombosis is rather a severe event, often requiring higher risk reoperation. Consistently, the average delay between valve implantation and the occurrence of the first valve-related complication was shorter in the mechanical group (4.9 ± 4.5 years) than in the bioprosthesis

group (11.1 ± 9.4 years). These findings support the choice of bioprostheses for TVR regardless of a patient's age [23]. The availability of tricuspid valve-in-valve procedures should enter such a discussion [10].

Few statistically meaningful differences emerged at baseline comparison between groups, suggesting that there are no major baseline discrepancies that may influence the long-term outcomes. The competing risks methodology represents a statistical compensation for any baseline intergroup inequality. The major limitations of the present paper include the large time span covered and the number of patients dying of unknown causes in the long term. There are fewer cases in the mechanical cohort (n = 33) than in the bioprosthesis cohort, and all mechanical valves were implanted at the beginning of our experience. That provides considerable long-term data about mechanical valves; previous comparison papers presented a small number of bioprostheses [24]. This is a retrospective study, but all inhospital data were collected prospectively. We are unable to provide data about the influence of baseline clinical conditions in the choice of prosthetic device, although preoperative characteristics are globally equilibrated among groups (Table 1). The prevalence of preoperative right-sided heart failure was greater in the bioprostheses group. That should be considered in the interpretation of data. We observed no significant difference in either operative mortality or long-term overall survival between the two unmatched groups. The freedom rates obtained through the competing risks method eliminates the confounding effect due to death from nonvalvular causes, including those associated with right-side heart failure. Lack of data about preoperative systolic pulmonary artery pressure prevented any correlation with valve durability. Although valve repair is currently the surgical procedure of choice for tricuspid disease, our data may prove useful in cases when repair is unfeasible.

In conclusion, our data indicate the good long-term durability of bioprostheses for TVR. Given the complex profile of these patients and the impact of advanced heart disease on late survival, the actual methodology should be used to predict the occurrence of valve-related adverse events. Mechanical prostheses for TVR remain associated with important rates of late adverse events. Focused studies will be needed to clarify the risk of reoperative TVR. Treatment options (reoperation versus valve-in-valve implantation) should be evaluated from a heart team perspective.

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