VALVE REPAIR VERSUS REPLACEMENT FOR MITRAL INSUFFICIENCY: WHEN IS A MECHANICAL VALVE STILL INDICATED?

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Objectives: Although many advantages of mitral valve reconstruction have been demonstrated, whether specific subgroups of patients exist in whom mechanical valve replacement offers advantages over mitral reconstruction remains undetermined. **Methods:** This study examined the late results of mitral valve surgery in patients with mitral insufficiency who received either a St. Jude Medical valve ($n = 514$) or a mitral valve reconstruction with ring annuloplasty ($n = 725$) between 1980 and 1996. **Results:** Overall operative mortality was 7.2% in the patients receiving a St. Jude Medical mitral valve and 5.4% in those undergoing mitral valve reconstruction (no significant difference); isolated mortality was 2.5% in the St. Jude Medical group and 2.2% in the valve reconstruction group (no significant difference). The follow-up interval was more than 5 years for 340 patients with a mean of 39.8 months (98.5% complete). Overall 8-year freedom from late cardiac death, reoperation, and all valve-related complications was 72.8% for the St. Jude Medical group and 64.8% for valve reconstruction group (no significant difference). For patients with isolated, nonrheumatic mitral valve disease, 8-year freedom from late cardiac death and reoperation was better in the mitral valve reconstruction group (88.3%) than in the St. Jude Medical valve group (86.0%; $p = 0.05$). Furthermore, Cox proportional hazards regression revealed that mitral valve reconstruction was independently associated with a lesser incidence of late cardiac death ($p = 0.04$), irrespective of preoperative New York Heart Association class. However, the St. Jude Medical valve offered better 8-year freedom from late cardiac death, reoperation, and all valve-related complications than did mitral valve reconstruction in patients with multiple valve disease (77.0% vs 45.3%; $p < 0.01$). **Conclusions:** Therefore, mitral valve reconstruction appears to be the procedure of choice for isolated, nonrheumatic disease, whereas insertion of a St. Jude Medical valve should be preferred for patients with multiple valve disease. (J Thorac Cardiovasc Surg 1998;115:389-96)

Numerous long-term studies have substantiated the excellent durability and freedom from structural degeneration and valve-related complications

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provided by mitral valve reconstruction.¹⁻⁴ Likewise, the St. Jude Medical valve (St. Jude Medical, Inc., St. Paul, Minn.) in the mitral position has repeatedly been shown to provide excellent durability and hemodynamic function.⁵⁻⁷ The St. Jude Medical valve in the mitral position also has been reported to perform well compared with tissue prostheses⁸ and has demonstrated superior freedom from valve-related complications compared with earlier mechanical valves.⁵ Use of any mechanical valve, however, exposes the patient to an incremental risk of thromboembolism and anticoagulant-related complications.

Unfortunately, few direct comparisons have been made between the performance of the St. Jude Medical valve in the mitral position and mitral valve reconstruction among various patient groups.⁴ Such

Table I. Etiology of the valvular disease in mitral valve reconstructions (MVP) and St. Jude Medical mitral valve replacements (SJMV)

	MVP patients (%)	STMJ patients (%)
Rheumatic	144 (19.9)	267 (52.0)
Degenerative	356 (49.1)	143 (27.8)
Ischemic	123 (17.0)	12 (2.3)
Infection	60 (8.3)	29 (5.6)
Congenital	34 (4.7)	2 (0.4)
Other	8 (1.1)	61 (11.9)
Total	725	514

studies might prove particularly informative in view of the demonstrated inferior durability of mitral reconstruction in rheumatic patients. We attempted to address this issue by retrospectively comparing our institution's experience with St. Jude Medical mitral valve replacement and mitral valve reconstruction with regard to both patient survival and valve-related complications.

Patients and methods

From January 1976 through July 1996, 2631 patients underwent mitral valve surgery at New York University Medical Center. Of the 677 patients who underwent mechanical valve replacement, 514 (75.9%) received St. Jude Medical valves (SJMV). Of the 1049 patients who underwent mitral valve reconstruction, "ringed" mitral reconstructions (MVP) (Carpentier mitral annuloplasty rings; Baxter Healthcare, Edwards CVS Division, Irvine, Calif.) were performed in 725 (69.1%). Replacements with other mechanical or tissue valves were excluded from the analysis of mitral reconstructions; Kay or Reed annuloplasties, pure mitral commissurotomies, and mitral annuloplasties without ring placement were excluded from the analysis of mitral reconstructions.

The mean patient age was 60.9 years (range 1 to 83 years) for the SJMV patients and 59.4 years (range 3 to 87 years) for the MVP patients. Concomitant bypass surgery was performed in 86 (16.7%) of the SJMV patients and 219 (30.2%) of the MVP patients ($p < 0.001$). Concomitant valvular heart surgery was performed in 243 (47.3%) of the SJMV patients and 94 (13.0%) of the MVP patients ($p < 0.001$). The distribution of the causes of the valvular disease in the SJMV and MVP patients is listed in Table I. Fifty-two percent (267/514) of the SJMV mitral replacements were in patients with rheumatic disease, whereas the preponderance (66.1%, 479/725) of valves treated with MVP were in patients with degenerative or ischemic mitral disease. To attempt to identify any relative advantages of use of the SJMV or MVP approaches for specific types of patients, this study was further restricted to the following subgroups: patients without rheumatic valve disease undergoing isolated mitral procedures; patients with rheumatic disease undergoing isolated mitral procedures; and patients with multiple valve disease undergoing mitral procedures plus one or more other valve proce-

Table II. Basic characteristics for all patients, and isolated, nonrheumatic, isolated, rheumatic, and multivalve patient subgroups

	All	Isolated, nonrheumatic	Isolated, rheumatic	Multivalve
No. of patients	1239	377	182	337
Mean age (yr)	60.9	57.6	54.9	60.5
% Male	48.7 (603)	55.7 (210)	23.1 (42)	41.5 (140)
NYHA class 3 or 4 (%)	1008 (81.4)	254 (67.4)	148 (81.3)	304 (90.2)
Pure mitral insufficiency (%)	941 (75.9)	344 (91.2)	81 (44.5)	202 (59.9)
Mixed insuf- ficiency and stenosis (%)	298 (24.0)	33 (8.8)	101 (55.5)	135 (40.1)

dures irrespective of the cause of their mitral disease. Table II gives the basic characteristics of the overall patient group and these subgroups.

The ultimate choice of valve operation was determined by technical feasibility and surgeon preference. Operative techniques included moderate hypothermia and intermittent cold blood cardioplegia. Since 1987, retrograde cardioplegia has been used in most operations. The techniques used for the mitral valve reconstructions and criteria for patient selection have been reported elsewhere.⁹ Throughout most of the study period, the posterior subvalvular apparatus was preserved when the mitral valve was replaced.

Although this was a nonrandomized study, most of data for this study were collected prospectively. Patient follow-up was performed at 6-month intervals with a nurse specialist interviewing the patient. Three hundred forty patients had a follow-up interval longer than 5 years; 51 patients had a follow-up interval longer than 10 years (mean follow-up 39.8 months; 98.5% complete; total follow-up 4045 patient-years). The recommended guidelines for nomenclature and reporting morbidity and mortality after cardiac valvular operations were observed.¹⁰ Data were analyzed using SPSS statistical software (SPSS, Inc., Chicago, Ill.). Comparisons of categorical variables were performed with the χ^2 test; continuous variables were compared by the nonpaired Student's t test. Survival and freedom from late complications were determined by life table methods and the Wilcoxon (Gehan) statistic was used for intergroup comparisons. The Cox proportional hazards regression model was used to examine multiple predictors of time-related events.

Results

Table II lists the basic clinical characteristics of all the patients who received either MVP or mitral valve replacement with a SJMV and the isolated nonrheumatic, isolated rheumatic, and multivalve subgroups. Table III compares the basic clinical

Table III. Comparison of basic characteristics of mitral valve reconstruction (MVP) and St. Jude mitral valve replacement (SJMVP) patients in isolated, nonrheumatic and isolated, rheumatic patient subgroups

	Isolated, nonrheumatic			Isolated, rheumatic		
	MVP	SJMVP	<i>p</i> Value	MVP	SJMVP	<i>p</i> Value
No. of patients	286	91		76	106	
Mean age (yr)	57.2	58.9	0.34	48.8	59.3	0.001
No. male (%)	172 (60.1)	38 (41.8)	0.002	24 (31.6)	18 (17.0)	0.02
Mean NYHA class	2.8	3.3	0.001	2.8	3.3	0.001
Mixed insufficiency and stenosis (%)	5 (1.8)	28 (30.8)	0.001	27 (35.5)	74 (69.8)	0.001
Degenerative type (%)	214 (74.8)	53 (58.2)	0.002			
Ischemic type (%)	10 (3.5)	2 (2.2)	0.74			

characteristics of MVP and mitral valve replacement with a SJMVP in the isolated, nonrheumatic and the isolated, rheumatic subgroups. In the isolated, nonrheumatic subgroup, MVP patients had a greater incidence of degenerative disease (75% vs 58%; $p < 0.01$), a higher proportion of men (60% vs 42%; $p < 0.01$), and a better mean preoperative New York Heart Association classification (2.8 vs 3.3; $p < 0.001$). In addition, preoperatively 46.2% of the SJMVP patients had atrial fibrillation/flutter compared with 35.1% of the MVP ($p = 0.06$). Postoperatively, 99% of the SJMVP patients were on a warfarin sodium (Coumadin) regimen compared with only 33% of the MVP patients ($p < 0.001$).

In the isolated, rheumatic subgroup, MVP patients had a significantly lower mean age ($p = 0.001$), more men (32% vs 17%, $p = 0.02$), and a better mean preoperative New York Heart Association classification (2.8 vs 3.3; $p = 0.001$). Similar to the isolated, nonrheumatic group, a higher incidence of mixed mitral insufficiency/mitral stenosis was observed in the SJMVP group (70% vs 36%, $p = 0.001$).

A comparison of preoperative risk factors for patients with multivalve procedures is shown in Table IV. It is important to note that 50% of these MVP patients had a rheumatic cause for their valvular heart disease. In 72% of the patients with multivalve replacements, the second valve operation was aortic valve replacement. Among the SJMVP patients 100% had a second St. Jude Medical valve placed, whereas 54% of the MVP had a second valve placed.

Overall operative mortality was 7.2% for the SJMVP patients and 5.4% for the MVP patients; for isolated mitral valve operations the mortality was 2.5% and 2.2%, respectively. Table V lists the actuarial survival of patient subgroups from late cardiac death, freedom from reoperation for valve

Table IV. Univariable analysis of preoperative factors in patients undergoing multivalve mitral operation

	SJMVP patients	MVP patients	<i>p</i> Value
No. of patients	243	94	
Mean age (yr)	61.1	58.7	>0.05
No. male (%)	88 (36)	52 (55)	<0.01
Mean preoperative NYHA classification	3.5	3.1	<0.01
Degenerative etiology (%)	64 (26)	29 (31)	<0.01
Rheumatic etiology (%)	134 (55)	46 (50)	>0.05

dysfunction, and freedom from all valve-related complications (thromboembolic, anticoagulant related, and endocarditis). Table VI lists the actuarial survival from the individual valve-related complications. Cox proportional hazards regression revealed that concomitant coronary artery bypass grafting significantly decreased the survival from late cardiac death in all patients ($e^{\beta} = 1.88$; 95% confidence intervals 1.51 to 2.34; $p < 0.001$). The linearized valve-related complication rates for all patients and for patients with isolated nonrheumatic disease are listed in Table VII.

In the subgroup of patients with isolated nonrheumatic mitral disease, MVP patients experienced significantly better survival from late cardiac death than the SJMVP patients (95.4% vs 91.6%, respectively, at 8 years; $p = 0.03$) and better freedom from both late cardiac death and reoperation (88.3% vs 86.0%, respectively, at 8 years; $p = 0.05$). Multivariable analysis in these patients revealed that performance of an MVP procedure was independently associated with increased survival from late cardiac death ($\exp^{\beta} = 2.07$; 95% confidence interval 1.1 to 3.90; $p = 0.02$), irrespective of cause, gender, preoperative New York Heart Association classification, or cardiac rhythm.

Table V. Freedom from late cardiac death (LCD), valve related mortality (VRM), reoperation (REOP), and all valve-related complications (AVC) in various groups of patients undergoing mitral St. Jude Medical valve replacement (SJMV) or mitral reconstruction (MVP). The percentage is listed with the number of patients entering the follow-up interval in parentheses. *P* values are for entire 8-year time span

Freedom from	5 Years		8 Years		<i>p</i> Value
	SJMV	MVP	SJMV	MVP	
All patients					
LCD	90.2 (130)	90.9 (268)	89.3 (31)	84.1 (129)	0.90
LCD and REOP	86.6 (130)	82.9 (268)	83.4 (31)	73.1 (129)	0.09
LCD, REOP and AVC	80.4 (121)	74.4 (255)	72.8 (25)	64.8 (117)	0.13
Isolated, nonrheumatic etiology					
LCD	91.6 (25)	98.1 (108)	91.6 (7)	95.4 (59)	0.03
VRM	97.6 (25)	100 (108)	97.6 (7)	100 (59)	0.07
LCD and REOP	86.0 (25)	93.6 (108)	86.0 (7)	88.3 (59)	0.05
LCD, REOP, and AVC	82.5 (23)	87.5 (106)	82.5 (6)	82.1 (58)	0.42
Isolated, rheumatic etiology					
LCD	97.0 (30)	98.1 (37)	97.0 (9)	98.1 (14)	0.70
LCD and REOP	89.5 (30)	84.0 (37)	89.5 (9)	84.0 (14)	0.33
LCD, REOP, and AVC	82.5 (28)	71.5 (34)	74.7 (6)	71.5 (12)	0.26
Multivalve procedure					
LCD	90.3 (60)	81.1 (47)	90.3 (14)	64.4 (24)	0.17
VRM	99.5 (60)	95.4 (47)	99.5 (14)	95.4 (24)	0.12
LCD and REOP	89.4 (60)	71.8 (47)	89.4 (14)	50.0 (24)	<0.001
LCD, REOP, and AVC	83.4 (57)	64.3 (44)	77.0 (12)	45.3 (21)	<0.001

A comparison of the patients with isolated rheumatic disease in both groups failed to reveal any significant differences in freedom from late cardiac death, reoperation, or all valve-related complications (Table V). The relatively small number of patients in each group, however, should be noted.

In the multivalve subgroup the SJMV patients fared better than MVP patients in freedom from late cardiac death and reoperation (89.4% vs 50.0% at 8 years; $p < 0.001$) (Table V). This difference was also noted in freedom from late cardiac death, reoperation, and all valve-related complications (SJMV 77.0% vs MVP 45.3% at 8 years; $p < 0.001$). The SJMV patients in this subgroup also had better freedom from reoperation (SJMV 99.0% vs MVP 76.1% at 8 years; $p < 0.01$), endocarditis (SJMV 99.5% vs MVP 91.3% at 8 years; $p = 0.03$), and thromboembolic complications (SJMV 91.7% vs MVP 84.7% at 8 years; $p = 0.02$) (Table VI).

Discussion

The results presented here show that both St. Jude Medical mitral valve replacement and mitral valve reconstruction provided good results in the overall patient group with freedom from late cardiac death, reoperation, and all valve-related complications at 8 years of 72.8% for SJMV replacement and 64.8% for MVP ($p > 0.13$) (Table V). As noted

previously, however, concomitant coronary artery bypass grafting profoundly diminished survival from late cardiac death in all patients. When various other subgroups are compared, additional important distinctions emerge.

Isolated, nonrheumatic mitral insufficiency. For isolated mitral insufficiency in patients with non-rheumatic disease, mitral reconstruction appears to provide some advantages, with an 8-year survival from late cardiac death of 95.4% compared with 91.6% for the SJMV group ($p = 0.03$). Likewise in this subgroup, 8-year freedom from late cardiac death and reoperation was marginally significantly better in the MVP group (88.3%) compared with the SJMV group (86.0%; $p = 0.05$). It might be suggested that this difference in survival from late cardiac death was due to significant differences in the incidence and severity of preoperative risk factors between the SJMV and MVP groups, as shown in Table III. However, multivariable analysis showed that only the use of MVP was a significant predictor of survival from late cardiac death. This may be related to the fact that although both groups had comparable freedom from major late valve-related complications (Table VI), the complications in the SJMV group were more likely to be fatal, resulting in this group's lower survival from late cardiac death (Table V).

Table VI. Freedom from reoperation for valve dysfunction (REOP), endocarditis (ENDO), thromboembolic complications (TE), and anticoagulant-related complications (ANTIC) in various groups of patients undergoing mitral St. Jude Medical valve replacement (SJMV) or mitral reconstruction (MVP). Listed is cumulative percentage complication free and in parenthesis the number of patients entering the follow-up interval; *p* values are for entire 8-year time span

Freedom from	5 Years		8 Years		<i>p</i> Value
	SJMV	MVP	SJMV	MVP	
All patients					
REOP	95.5 (130)	90.8 (268)	93.4 (31)	86.5 (129)	0.01
ENDO	99.0 (129)	97.1 (268)	99.0 (31)	95.7 (128)	0.22
TE	94.7 (124)	91.7 (258)	89.5 (26)	90.6 (121)	0.40
ANTIC	96.2 (128)	97.6 (262)	95.1 (30)	97.6 (124)	0.40
Isolated nonrheumatic etiology					
REOP	91.6 (25)	95.4 (108)	91.6 (7)	92.6 (59)	0.30
ENDO	100 (25)	96.3 (108)	100 (7)	94.5 (59)	0.20
TE	96.3 (23)	97.3 (107)	96.2 (6)	97.3 (59)	0.83
ANTIC	97.6 (25)	98.7 (106)	97.6 (7)	98.7 (58)	0.78
Isolated rheumatic etiology					
REOP	92.3 (30)	85.6 (37)	92.3 (9)	85.6 (12)	0.21
ENDO	97.8 (30)	100 (37)	97.8 (9)	100 (14)	0.24
TE	94.6 (28)	85.7 (34)	85.6 (6)	85.7 (12)	0.36
ANTIC	97.8 (30)	97.5 (36)	97.8 (9)	97.5 (13)	0.44
Multivalve procedure					
REOP	99.0 (60)	86.7 (47)	99.0 (14)	76.1 (24)	<0.01
ENDO	99.5 (60)	94.0 (47)	99.5 (14)	91.3 (23)	0.03
TE	96.4 (59)	87.3 (45)	91.7 (13)	84.7 (23)	0.02
ANTIC	95.7 (58)	96.2 (46)	93.3 (13)	96.2 (23)	0.87

Isolated rheumatic mitral insufficiency. Prior reports have documented that patients with isolated rheumatic mitral disease do not obtain as much long-term benefit from mitral repair as do patients with nonrheumatic disease.^{1,2} We have previously reported freedom from reoperation at 5 years for a group of all patients with rheumatic disease undergoing mitral reconstruction to be only 77.4%.² In recent years refinements in our selection criteria for patients undergoing mitral reconstruction, as well as improvements and innovations in mitral reconstruction, have improved freedom from reoperation for isolated mitral reconstruction with a ring in patients with rheumatic disease to 85.6% at 8 years. Nevertheless, the fact that the SJMV-isolated rheumatic replacement group does not show a significantly better freedom from reoperation compared with a similar group of MVP patients may be because so few patients were in the follow-up at 8 years. In the future, a longer follow-up period with a greater number of patients should reveal a difference in freedom from reoperation between SJMV and MVP patients because of the known progression of the rheumatic valvular disease.

Table VII. Linearized complication rates (percent per patient-year) for reoperation for valve dysfunction (REOP), endocarditis (ENDO), thromboembolic complications (TE), and anticoagulant related complications (ANTIC) in all patients undergoing mitral St. Jude Medical valve replacement (SJMV) or mitral reconstruction (MVP)

Complication	All patients		Isolated nonrheumatic	
	SJMV	MVP	SJMV	MVP
REOP	1.08	2.22	1.92	1.00
ENDO	0.29	0.58	0.00	0.64
TE	1.40	1.59	0.79	0.74
ANTIC	0.95	0.51	0.38	0.37

Nevertheless, the possibility of using mitral valve reconstruction in patients with isolated rheumatic mitral valve disease should not be summarily excluded. Under certain circumstances, such as in a woman of child-bearing age and intention, the advantages of mitral reconstruction with the reduced need for an anticoagulant regimen could well outweigh considerations based on the inferior durabil-

ity of mitral reconstruction in patients with rheumatic mitral valve disease.

Patients with multivalve disease. All the SJMV patients who underwent concomitant aortic valve replacement had another St. Jude Medical valve placed in the aortic position, whereas among the MVP patients only half the concomitant aortic valve replacements were done with a St. Jude Medical valve. In patients with multivalve disease the differences between the SJMV and MVP groups for late cardiac death or valve-related mortality were not statistically significant (Table V). However, the results for the SJMV group were significantly better for freedom from late cardiac death and reoperation and for freedom from late cardiac death, reoperation, and all valve-related complications. As might be anticipated in patients with double valve disease, 50% of the MVP patients and 55% of the SJMV patients had rheumatic mitral disease. The high number of reoperations and valve-related complications in the MVP group may be attributable to the known inferior durability of MVP in patients with rheumatic disease.

The major weakness of this study is that the patients were not randomized into the MVP and SJMV study groups. However, we have attempted to describe any factors that may have affected treatment selection and results.

In conclusion, the present results suggest that in patients with isolated nonrheumatic mitral valve disease, repair offers better freedom from late cardiac death and reoperation. In patients with isolated rheumatic mitral valve disease, mitral valve reconstruction, although its durability is not as good as in patients without rheumatic disease, offers a great advantage in certain subgroups of patients in whom the need to avoid anticoagulation exists. In patients with multiple valve disease, St. Jude Medical valve replacement offered better freedom from combined late cardiac death, reoperation, and all valve-related complications. Therefore mitral valve repair appears to be the procedure of choice for patients with isolated, nonrheumatic valve disease, whereas St. Jude Medical mitral valve replacement seems to provide improved late results in patients with multiple valve disease.

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Discussion

Dr. Cary W. Akins (Boston, Mass.). Previous comparisons of mitral valve replacement and mitral valve reconstruction, including our own, have almost invariably demonstrated an advantage in event-free survival for mitral valve reconstruction versus mitral valve replacement, especially when the operations are done for degenerative or ischemic mitral regurgitation. Today in a large, long-term study comparing mitral valve reconstruction and mitral valve replacement with a St. Jude Medical mechanical prosthesis, Grossi and colleagues have examined the freedom from late cardiac death and valve-related complications after the two operations in all patients.

As expected, mitral valve reconstruction patients in the nonrheumatic subgroup had significantly better freedom from late cardiac death and late cardiac death or reoperation than the St. Jude Medical mitral valve replacement patients. In addition, by multivariate analysis, only mitral valve reconstruction predicted improved freedom from late cardiac death.

The study then compares patients with rheumatic mitral valve disease and patients having multivalve operations. In the abstract for the rheumatic subgroup, patients with the St. Jude Medical mitral valve replacement had better freedom from late cardiac death and reoperation, but in the manuscript no significant difference was observed. In the multivalve subgroup, both in the abstract and the

manuscript, St. Jude Medical mitral valve replacement was associated with better freedom from late cardiac death, reoperation, and valve-related complications. The authors suggest that some of this can be explained by the well-known higher reoperation rate after mitral valve reconstruction in patients with rheumatic mitral valve disease. Are there other possible explanations?

Concomitant coronary artery bypass grafting was performed twice as often in the mitral valve reconstruction patients as in the St. Jude Medical valve replacement patients, and the authors statistically document the important negative influence of coronary artery disease on late survival.

My first question to the authors is, did you assess the impact of concomitant coronary disease on survival for the two operations in the patients with rheumatic and multivalve disease? Indeed, while you performed a multivariate analysis of the risk factors for patients with nonrheumatic disease, you did not for those with rheumatic and multivalve disease. In a comparison of two disparate and nonrandomized patient populations, isn't multivariate analysis into which procedure performed is inserted as a variable the best way to assess a multivariate situation?

Secondly, all mitral valve reconstructions were presumably done for isolated mitral regurgitation. My second question to the authors is whether the St. Jude Medical valve replacement patients had isolated mitral regurgitation. Is it possible that the inclusion of patients with other valve diseases in the St. Jude Medical operative group of rheumatic and multivalve patients influenced the late results (another question that can be addressed by multivariate analysis)?

Finally, in the manuscript the authors list very low linearized rates for thromboembolism and anticoagulant-related bleeding for the St. Jude Medical valve replacement patients. In fact, the linearized rates for anticoagulant-related bleeding were all less than 1% per patient-year. Yet we know from the placebo arms of the various randomized trials of anticoagulants that the background rate of bleeding in the normal population varies from 1% and 1.5% per patient-year. How did the authors define anticoagulant-related bleeding, and how do they account for bleeding rates in an anticoagulated population that are lower than the background rate of bleeding in the unanticoagulated population?

Dr. Jacques R. Seguin (*Creteil-Paris, France*). I would like to congratulate the authors on this excellent presentation and to thank the New York University team for promoting valve repair with such wonderful results.

I think, like your team, in nonrheumatic disease, mitral regurgitation can be repaired in a very large group of patients, probably more than 90% of the patients, whereas I do not share totally your conclusions concerning patients with rheumatic disease. We have the impression there is not one type of rheumatic disease but multiple types of thoracic lesions, and to make things simple, probably two groups of patients: one with severely calcified anterior leaflet where repair might not be advisable, whereas in patients with calcified posterior leaflets, repair is possible with excellent long-term results. Don't you think there are different types of patients with rheumatic lesions and they

should be differentiated in your presentation and thus possibly modify your conclusions?

Dr. Manuel J. Antunes (*Coimbra, Portugal*). I concur with your conclusions inasmuch as the results for repair for rheumatic mitral valve disease are usually worse than those for nonrheumatic valves, although in your conclusions it appears that the difference was only for patients with multivalve disease. However, your rheumatic population is a selected one; I am quite sure about that. Hence, in my view, you could be sending out the wrong message.

Most of the patients with rheumatic valve disease operated on now are from a Third World population. I continue to operate on many patients coming from Africa, and the last one that I operated on, only about a couple of weeks ago, was 4 years old. In this patient, replacing a valve with a mechanical or with a tissue valve would be short of a crime, I think. And our results have shown that in that particular population, the results of mitral valve repair are still better than those of mitral valve replacement. Hence, I urge surgeons treating these types of patients to continue concentrating their efforts in repairing valves.

Currently in Portugal, where two thirds of our patients still have rheumatic disease, we repair approximately 85% of all mitral valves coming to operation and continue to be pleased with the results. New techniques have been added to surgeons' armamentarium since 1980 when you started your series, and today your story may be a little bit different from that which you depicted. Do you have any information about these questions? Are your results today better than they were in 1980 in respect to rheumatic valves?

Dr. Alain F. Carpentier (*Paris, France*). Any conclusion coming from this group is very important to take into consideration, particularly when we do not think exactly the same way.

I do have two questions. Number one, you mentioned that you had 51 patients over 10 years, 51 patients overall, and based on your presentation, apparently you have about one fourth of your total cohort being rheumatic and three fourths being degenerative.

Now, going back to the 8-year prediction or your 8-year conclusion, if you have only 51 patients beyond 10 years, one fourth means only, let's say, 15% of rheumatic valve disease. How can you derive such a conclusion from 15 patients over 10 years? This is my first question.

Now number two, as far as multiple valve disease is concerned, when you are comparing multiple-valve replacement with multiple-valve repair, does this imply that these patients had aortic valve repair because we all know that aortic valve repair does not work and should not be used. So if you compare a technique that works in the mitral position with a technique that does not work in the aortic position, probably your conclusion is not valid.

Dr. Grossi. Dealing with the questions, first to clarify, in the isolated rheumatic group that we presented, there was no concomitant bypass surgery. The isolated rheumatic patients were those patients with rheumatic etiology undergoing isolated mitral valve replacement or repair without concomitant bypass surgery. So we do not think that was a problem. It was impossible to add that as an additional risk factor.

We demonstrated in the manuscript that overall, looking at all the patients, multivariate analysis showed that the effect of concomitant bypass grafting has the greatest single effect on long-term freedom from late cardiac death.

With regard to the cause of the valve diseases, all these patients had mitral insufficiency. Of those patients who had rheumatic causes, approximately 15% of them had some element of mitral stenosis in addition to that, and that was equal across both the replacements and the reconstructions.

With regard to the linearized rates of anticoagulated bleeding, I do not think in terms of linearized rates. I was quite happy when our rates were calculated. We looked at them, and we thought they were within the table of the review article Dr. Akins had published; they were well within the standard errors of those. The complications that we count as anticoagulants causing bleeding are defined according to the guidelines published in *The Journal of Thoracic and Cardiovascular Surgery*.

With regard to the different types of rheumatic disease

in terms of anterior calcification versus posterior calcification, we did not quantify that or put a label on that type of rheumatic disease and break down our patients into those groups. These are patients with rheumatic disease who we see in North America, and we do have a large percentage of them.

With regard to Professor Carpentier's questions, we do have patients out 15 years after reconstruction, and our reconstruction data goes out that far. We could not present that here because it would be meaningless; we do not have enough data for a uniform mechanical group.

With regard to the patients with multiple valve disease, it is sort of an interesting group. Of those, most of them were aortic valve replacements and either mitral valve replacements or reconstructions. Of those, 50% had either a mechanical valve placed in their aortic valve or a tissue valve placed in their aortic valve. So these are not aortic valve reconstructions.

Specifically when we are talking about the freedom from reoperation, this is with regard to dysfunction of the mitral valve.

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