Suture bicuspidization of the tricuspid valve versus ring annuloplasty for repair of functional tricuspid regurgitation: Midterm results of 237 consecutive patients

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Objective: Uncorrected functional tricuspid regurgitation has serious long-term morbidity and mortality. We reviewed our experience with tricuspid posterior annular bicuspidization versus ring tricuspid annuloplasty for treatment of functional tricuspid regurgitation.

Methods: From 1999 to 2003, 237 patients underwent tricuspid annuloplasty for functional tricuspid regurgitation as part of their cardiac surgical procedure. Bicuspidization was performed in 157 patients and ring annuloplasty in 80 patients. Preoperatively, 227 (96%) patients had moderate or greater tricuspid regurgitation with a median regurgitation of 3+. Follow-up information was obtained for 234 (99%) patients with a mean follow-up time of 3 years. Postoperative transthoracic echocardiograms were assessed for severity of tricuspid regurgitation. Moderate or greater tricuspid regurgitation was considered significant. Survival and development of recurrent tricuspid regurgitation were evaluated by Kaplan–Meier analysis. Tricuspid regurgitation and risk factors for recurrent regurgitation were identified and analyzed by multivariable ordinal longitudinal methods.

Results: At 3 years postoperatively, tricuspid regurgitation in patients treated by bicuspidization annuloplasty was zero to mild in 75%, moderate in 11%, moderate to severe in 6%, and severe in 8% of patients. In those undergoing ring annuloplasty, tricuspid regurgitation was zero to mild in 69%, moderate in 14%, moderate to severe in 7%, and severe in 10%. There was no significant difference between the two groups ($P = .18$). Risk factors for recurrent tricuspid regurgitation included higher preoperative regurgitation grade, preoperative tricuspid regurgitation without concomitant mitral regurgitation, and higher pulmonary artery systolic pressure.

Conclusions: Bicuspidization annuloplasty and ring annuloplasty were effective at eliminating tricuspid regurgitation at 3 years postoperatively. Bicuspidization annuloplasty is a simple, inexpensive option for addressing functional tricuspid regurgitation. All patients with moderate-to-severe functional tricuspid regurgitation should undergo tricuspid annuloplasty regardless of the technique used.

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Repair of functional tricuspid regurgitation (TR) is a challenging problem. With relatively few definitive clinical studies to guide management decisions, cardiac surgeons still debate when and how to repair the tricuspid valve. Early investigators advocated a conservative approach, arguing that func-

Abbreviations and Acronyms

ACC	= American College of Cardiology
AHA	= American Heart Association
AI	= aortic insufficiency
EF	= ejection fraction
LV	= left ventricular
MR	= mitral regurgitation
NYHA	= New York Heart Association
PASP	= pulmonary artery systolic pressure
RV	= right ventricular
TR	= tricuspid regurgitation

tional TR, often secondary to pulmonary hypertension and concomitant mitral valve disease, should spontaneously improve after mitral valve repair.¹ Subsequent studies, however, have demonstrated that TR does not necessarily regress after repair of left-sided valve lesions.²⁻⁷ Uncorrected TR increases both postoperative morbidity and mortality and is associated with poor long-term results with medical management alone.^{8,9} Thus, many cardiac surgeons advocate tricuspid annuloplasty at the time of aortic or mitral valve surgery in patients with moderate or severe TR.^{10,11} Several annuloplasty methods have been described; however, few studies have evaluated and compared the efficacy and durability of these techniques.¹²

Suture bicuspidization was originally described by Kay, Maselli-Campagna, and Tsuji¹³ in 1965 as a technique to correct TR. This relatively simple technique involved figure-of-eight suture plication of the posterior leaflet to reduce annulus size. Bicuspidization, however, has since been superseded by other techniques seeking to remodel the annulus by maintaining a trileaflet valve with a more physiologic, stabilized annulus. These techniques include De Vega's semicircular annuloplasty¹⁴ and the use of prosthetic annuloplasty rings, such as the Carpentier-Edwards semirigid ring (Edwards LifeSciences, Irvine, Calif),¹⁰ the Cosgrove-Edwards flexible band (Edwards LifeSciences),¹⁵ and the Duran flexible ring.¹⁶ A small number of studies comparing ring annuloplasty with suture annuloplasties (primarily the De Vega) have concluded that ring annuloplasty offers a more durable repair and that ring annuloplasty should supplant suture annuloplasty for repair of functional TR.^{12,17-19} Other investigators have reported good experience with the De Vega annuloplasty and continue to advocate its use.^{20,21} In North America, most surgeons currently favor ring annuloplasty.

At our institution, we routinely perform a modified suture bicuspidization of the tricuspid valve or a ring annuloplasty in all patients with moderate-to-severe functional TR who present for cardiac surgery. Since the dilation of the tricuspid valve primarily occurs at the posterior leaflet, posterior suture bicuspidization offers an inexpensive, simple, and rapid repair. Bicuspidization may have a role,

particularly in cases of moderate TR, where a simple repair may be all that is required. The option to perform a simple repair without significantly prolonging operative time or requiring a prosthetic ring is appealing. In this study, we review and compare our experience with bicuspidization and ring annuloplasty for repair of functional TR to determine the efficacy and durability of tricuspid annuloplasty.

Patients and Methods**Patients**

From January 1999 to December 2003, 237 patients underwent tricuspid annuloplasty for functional TR as part of their cardiac surgical procedure at the Brigham and Women's Hospital. Patients were identified and preoperative, operative, and postoperative variables were retrieved from the prospective Brigham Cardiac Surgery Database.

Suture bicuspidization was performed in 157 (66%) patients. Ring annuloplasty was performed in 80 (34%) patients. Of those undergoing ring annuloplasty, 60 (75%) patients received a Cosgrove-Edwards flexible band (Edwards LifeSciences), 13 (16%) a Carpentier-Edwards semirigid ring (Edwards LifeSciences), and 7 (9%) a Carbomedics Annuloflex ring (Sulzer Carbomedics, Inc, Austin, Tex). Annuloplasty type depended on surgeon preference. Seven surgeons contributed patients to this study.

Patient preoperative and surgical characteristics are given in Table 1. The mean age of the patients was 67 years (range 20-90 years) and 53% were women. Fifty-three percent of patients were in New York Heart Association (NYHA) functional class III or IV. Concomitant mitral valve surgery was performed in 82% of patients, coronary artery bypass grafting in 32%, and aortic valve surgery in 29%. Triple valve surgery was performed in 53 (22%) patients. Only 23 (9.7%) patients had tricuspid valve repair as the sole valve procedure. There was no significant difference between the bicuspidization and ring annuloplasty patients in age, gender, NYHA class, preoperative pulmonary artery systolic pressure (PASP), preoperative right ventricular (RV) dysfunction, and concomitant surgical procedures. RV dysfunction was defined as any impairment in RV contraction noted on echocardiography. Left ventricular ejection fraction (EF) was higher in patients undergoing bicuspidization annuloplasty than in those undergoing ring annuloplasty (49% vs 43%, $P = .004$). The bicuspidization annuloplasty patients also had a higher prevalence of aortic insufficiency (AI) than the ring annuloplasty patients ($P = .01$).

Preoperative TR was 4+ (severe) in 35% of patients, 3+ (moderate to severe) in 25%, and 2+ (moderate) in 35% (Table 1). Median TR was 3+ for both groups. There was a higher percentage of patients with 3+ to 4+ TR in the ring annuloplasty group than in the bicuspidization annuloplasty group (67% vs 57%; $P = .03$), and the mean TR was worse in the ring group (3.1 vs 2.8; $P = .03$).

Operative Techniques

All annuloplasties were performed during concomitant aortic and/or mitral valve surgery with cardioplegic arrest. Ring annuloplasty was performed by standard operative techniques.^{10,15} The suture bicuspidization technique was performed by placing a double pledget-supported mattress suture of 2-0 Ethibond (Ethicon, Inc, Somerville, NJ) on a large MH needle from the anteroposte-

TABLE 1. Patient preoperative and surgical characteristics overall and by annuloplasty type

Characteristic	Overall		Bicuspidization		Ring		P value
	No.	%	No.	%	No.	%	
No. of patients	237		157	66.2	80	33.8	
Age (y $\pm$ SD)	67 $\pm$ 14		66 $\pm$ 14		68 $\pm$ 14		NS
Female gender	126	53.2	82	52.2	44	55.0	NS
Preoperative NYHA							
Class III	81	34.2	54	34.4	27	33.8	
Class IV	45	19.0	27	17.8	17	21.3	
Preoperative TR grade							.03
0 (none)	0	0	0	0	0	0	
1+ (mild)	10	4.2	8	5.1	2	2.5	
2+ (moderate)	84	35	60	38.2	24	30.0	
3+ (moderate to severe)	59	24.9	42	26.8	17	21.3	
4+ (severe)	84	35.4	47	29.9	37	46.3	
Preoperative MR grade							NS
3+	63	26.6	44	28.6	19	24.1	
4+	117	49.4	76	49.4	41	51.9	
Preoperative AI grade							.01
3+	12	5.1	11	7.0	1	1.3	
4+	6	2.5	4	2.6	2	2.5	
Preoperative RV dysfunction	58	24.5	34	21.7	24	30.0	NS
Preoperative LVEF	48 $\pm$ 16		50 $\pm$ 15		43 $\pm$ 18		.004
Preoperative PASP	52 $\pm$ 16		51 $\pm$ 17		52 $\pm$ 15		NS
Bypass time (min)	172 $\pm$ 82		163 $\pm$ 77		190 $\pm$ 88		.02
Crossclamp time (min)	114 $\pm$ 58		108 $\pm$ 53		125 $\pm$ 66		.07
Concomitant procedures							NS
MVP/MVR	195	82.2	133	84.7	62	77.5	
CABG	76	32.1	47	29.9	29	36.3	
AVP/AVR	69	29.1	48	30.6	21	26.3	
PVR	4	1.7	2	1.3	2	2.5	
Other	13	5.5	5	3.2	8	10	
Ring annuloplasty type							
Carpentier-Edwards					13	16.3	
Cosgrove-Edwards					60	75.0	
Carbomedics Annuloflex					7	8.8	

SD, Standard deviation; NYHA, New York Heart Association; TR, tricuspid regurgitation; MR, mitral regurgitation; AI, aortic insufficiency; RV, right ventricular; LVEF, left ventricular ejection fraction (% $\pm$ SD); PASP, pulmonary artery systolic pressure (mm Hg $\pm$ SD); MVP, mitral valvuloplasty; MVR, mitral valve replacement; CABG, coronary artery bypass grafting; AVP, aortic valvuloplasty; AVR, aortic valve replacement; PVR, pulmonary valve replacement; NS, not significant.

rior commissure to the posteroseptal commissure along the posterior annulus (Figure 1). This double multifilament suture is then tied down over an obturator, such as the barrel of a 20-mL syringe or 29-mm valve sizer, which satisfactorily reduces the orifice size without placing undue strain on the annuloplasty repair and obliterates the posterior leaflet. Studies by Deloche and associates²² have shown that the primary anatomic problem in functional TR is anatomic dilation of the posterior tricuspid annulus, because this is the only unsupported area of the tricuspid valve ring, as opposed to the anterior and septal positions. Thus, a posterior annuloplasty should be effective for most cases of functional TR. The entire procedure may be accomplished in less than 8 minutes and does not produce tricuspid stenosis. In all patients, intraoperative transechocardiography was performed to confirm elimination of TR.

Follow-up

The status of all patients was assessed cross-sectionally in 2005. Follow-up data (vital status, functional status, and/or postoperative echocardiograms) were obtained for 234 (99%) patients. Echocardiographic reports were solicited from the Brigham and Women's/Partners HealthCare clinical database or obtained from the patient's cardiologist. Postoperative echocardiograms were available for 210 (89%) patients. The Social Security Death Index was used to determine vital status. Surviving patients were assessed by telephone interviews with questionnaires approved by the institutional review board. Mean follow-up time was 3 years. Functional status and occurrence of subsequent cardiac operations were determined. A total of 540 patient-years of follow-up information was available for analysis.

Figure 1. Suture bicuspidization is performed by placement of a 2-0 pledget-supported Ethibond mattress suture from the antero-posterior to the posteroseptal commissures along the posterior annulus.

Assessment of Repair

Preoperative and postoperative transesophageal echocardiographic reports were used to assess TR grade. Interpretation of follow-up echocardiograms was obtained at as many time points as available for each patient. Transesophageal echocardiographic data were excluded so that TR grade determination would be consistent between patients and time points. A total of 519 postoperative echocardiographic reports were obtained. Twenty-seven patients had no postoperative echocardiograms available for analysis and were excluded. Median time of echocardiographic assessment was 1 year (25th percentile = 1 week, 75th percentile = 1.5 years, range = 0-4.7 years). TR was graded as 0 for no regurgitation, 1+ for mild, 2+ for moderate, 3+ for moderate to severe, and 4+ for severe, as defined by the American Society of Echocardiography.

End Points

We sought to address the following questions:

1. What is the efficacy and durability of tricuspid annuloplasty with suture bicuspidization and ring annuloplasty over the midterm postoperative period?
2. How does bicuspidization annuloplasty compare with ring annuloplasty?
3. What is the survival of patients after tricuspid valve repair?
4. What is the functional improvement after tricuspid valve repair?
5. What are the risk factors for repair failure?

Data Analysis

Preoperative variables were compared between groups by the Fisher exact test (categorical variables) and the Student *t* test (continuous variables). Kaplan–Meier analysis was used to evaluate mortality and development of 2+ (moderate) recurrent TR.²³ In the Kaplan–Meier analysis, development of 2+ TR was defined as the presence of sustained 2+ TR on serial echocardiograms. Patients were censored at time of mortality or last follow-up. To evaluate TR (mean TR and TR grade) over time, we performed repeated-measures mixed models (using SAS Proc Mixed; SAS Institute, Inc, Cary, NC) and longitudinal ordinal logistic regression (using SAS Proc Glimmix) for each annuloplasty technique.^{24,25} These longitudinal methods ensure that patients with

more repeat echocardiograms and/or more follow-up are not given excessive weight and do not have a disproportionate influence on estimated means and proportions over time. We performed a similar longitudinal regression on postoperative recurrent mitral regurgitation (MR) to evaluate the effect of MR on TR. To evaluate the risk factors for development of higher recurrent postoperative TR, we performed univariate followed by multivariate Cox regression. Because there were preoperative differences in TR, EF, and AI between the bicuspidization and ring annuloplasty groups, weighted propensity score adjustment was performed to better compare the two groups when performing the longitudinal and survival analyses for recurrent TR.²⁶ In this propensity score approach, the data for each patient are weighted by the inverse of the probability of receiving his or her treatment given the preoperative TR, EF, and AI. This propensity score analysis ensures that the effect of treatment is not confounded by the fact that bicuspidization patients tended to have better lower preoperative TR, better EF, and higher prevalence of AI. In all analyses, both weighted and unweighted comparisons were performed.

Results

Cardiopulmonary Bypass and Aortic Crossclamp Times

Patients who underwent bicuspidization annuloplasty with concomitant left-sided valve procedures had a mean cardiopulmonary bypass time of 163 ± 77 minutes and an aortic crossclamp time of 108 ± 53 minutes. Ring annuloplasty patients had times of 190 ± 88 minutes and 125 ± 66 minutes, respectively (Table 1). Cardiopulmonary bypass and aortic crossclamp times were thus 27 minutes ($P = .02$) and 17 minutes ($P = 0.07$) shorter, respectively, in the bicuspidization patients. Controlling for number of concomitant procedures, there was no statistically significant difference in operative times between surgeons ($P = .7$).

Mortality, Reoperations, and Functional Improvement

There were 10 (6.4%) early deaths (within 30 days or during the same hospitalization after the operation) in the bicuspidization annuloplasty group and 9 (11.3%) early deaths in the ring annuloplasty group. The Kaplan–Meier survival curve is shown in Figure 2. There was no statistically significant difference in mortality between the two groups; however, the ring annuloplasty patients demonstrated a trend to poorer survival ($P = .07$). Interestingly, the ring group had a lower preoperative EF and higher preoperative TR than the bicuspidization group. This may account for the trend to poorer survival. There was no statistically significant difference ($P = .37$) in mortality in patients who had significant recurrent TR. The actuarial survival at 3 years postoperatively was 75.3% in the bicuspidization group and 61.2% in the ring annuloplasty group.

Only 6 patients underwent reoperative valve surgery during the follow-up period of this study. Of these, only 1 (0.4%) patient underwent a reoperative tricuspid valve repair. NYHA class significantly improved for both groups ($P < .05$). Pre-

Figure 2. Kaplan–Meier survival analysis.

Figure 3. Kaplan–Meier analysis of freedom from moderate TR.

operatively, 45.8% of bicuspidization and 43.2% of ring annuloplasty patients were in NYHA class III or IV. At follow-up, 15% of bicuspidization and 14% of ring patients remained in class III or IV. The mean NYHA class improved from 2.3 to 1.6 with bicuspidization and from 2.4 to 1.5 in ring annuloplasty patients.

Efficacy and Durability of Tricuspid Annuloplasty

To evaluate overall efficacy and durability of annuloplasty, we evaluated TR grades by 3 different methods. We deter-

mined TR grade at last follow-up, assessed freedom from development of 2+ TR over time using Kaplan–Meier analysis (Figure 3), and used the serial echocardiographic data to predict mean TR and TR prevalence over time using longitudinal regression analyses (Figure 4). All annuloplasty types proved efficacious at reducing TR. Mean TR grade decreased by approximately 40% in both groups from before the operation to the last follow-up. The mean TR grade for each group was 3+ preoperatively and improved

Figure 4. Predicted mean TR and TR prevalence using propensity score-adjusted longitudinal regression. A, Mean TR over time for both groups. B, Percentage of patients in each group in whom the development of 3+ or 4+ TR is predicted over time. C, Predicted prevalence of TR grades after bicuspidization. D, Predicted prevalence of TR grades after ring annuloplasty. TR, tricuspid regurgitation.

TABLE 2. Risk factors for development of higher recurrent TR

Risk factor	Coefficient ($\pm$ SE)	Hazard ratio	P value
Age	$-.01 \pm .01$	0.990	0.35
Gender	$-.15 \pm .33$	0.264	0.66
Preoperative NYHA	$.07 \pm .20$	1.076	0.71
Annuloplasty type	$-.45 \pm .30$	0.640	0.14
Preoperative TR	$1.29 \pm .34$	4.031	<0.001
Preoperative EF	$.03 \pm .02$	1.027	0.08
Preoperative MR	$-.24 \pm .11$	0.786	0.04
Preoperative PASP	$-.004 \pm .02$	0.996	0.81
Preoperative RV dysfunction	$.04 \pm .53$	1.044	0.94
Postoperative PASP	$.05 \pm .02$	1.056	0.01

TR, Tricuspid regurgitation; SE, standard error; NYHA, New York Heart Association; EF, ejection fraction; MR, mitral regurgitation; PASP, pulmonary artery systolic pressure; RV, right ventricular.

to 2+ TR at last follow-up. TR, however, was not significantly reduced in all patients. At last echocardiographic follow-up, TR in bicuspidization annuloplasty patients was zero to mild in 75%, moderate in 11%, moderate to severe in 6%, and severe in 8%. In ring annuloplasty patients, TR was zero to mild in 69%, moderate in 14%, moderate to severe in 7%, and severe in 10%. There was no statistically significant difference in mean TR grade or prevalence of TR at last follow-up between the two groups ($P = .18$). Between the different ring annuloplasty techniques, there was no statistically significant difference in mean TR grades at last follow-up ($P = .21$). In the Cosgrove-Edwards band group, 7 (12%) patients had 3+ or 4+ recurrent TR at last follow-up, compared with 1 (8%) patient in the Carpentier-Edwards ring group.

Figure 3 demonstrates the Kaplan–Meier analysis of freedom from moderate TR over time for both groups. There was no significant difference between the two groups in the Kaplan–Meier analysis ($P = .16$ weighted by propensity score; $P = .13$ unweighted). At 3 years postoperatively, 75% of bicuspidization and 69% of ring annuloplasty patients had zero to mild TR. In the majority of the 44 patients in whom moderate or greater recurrent TR developed, it did so within the first 6 months in both groups. The median time to development of moderate TR in these 44 patients was 46 days (25th percentile = 10 days, 75th percentile = 286 days, range = 0–4.9 years).

Figure 4 demonstrates the predicted TR prevalence over time for both groups. The evolution of TR is similar between both groups. Mean TR drops significantly postoperatively, increases in the next 6 months, continues to gradually increase up to 2 years postoperatively, and then remains relatively unchanged up to 3 years postoperatively (Figure 4, A). The percentage of patients with 3+ and 4+ TR is the same between the two groups (Figure 4, B). The

TABLE 3. Preoperative and follow-up PASP in patients with and without 2+ recurrent TR

	Preoperative PASP (mm Hg)	Follow-up PASP (mm Hg)
With recurrent TR (n = 44)	51 ± 16	52 ± 16
Without recurrent TR (n = 193)	52 ± 16	43 ± 12

PASP, Pulmonary artery systolic pressure; TR, tricuspid regurgitation; follow-up PASP, PASP at time of development of 2+ recurrent TR or at last follow-up.

distribution of TR grades is also similar between the two groups (Figure 4, C and D).

Risk Factors for Repair Failure

According to the Cox proportional hazards model, higher preoperative TR and the presence of preoperative TR with lower concomitant preoperative MR were found to be risk factors for development of recurrent TR (Table 2). Higher left ventricular EF demonstrated a trend to being a risk factor for significant recurrent TR. In patients with better left heart function (ie, better left ventricular EF and lower MR), preoperative TR may indicate a greater degree of valve dysfunction, such as annular dilation or valve tethering, which may be less amenable to repair.²⁷ Significantly, tricuspid annuloplasty type was not found to be a risk factor for recurrent TR. Preoperative and follow-up NYHA class were also not found to be significant factors. Of the 19 patients in NYHA class III or IV, only 4 (17%) had 2+ or greater TR at last follow-up. There was no statistically significant difference ($P = .32$) in prevalence of TR between patients in NYHA class I/II and those in NYHA class III/IV. Similarly, preoperative PASP and RV dysfunction were not found to be risk factors for recurrent TR. To evaluate whether there was a correlation between postoperative PASP and tricuspid repair failure, we determined the PASP at the time of failure (from the echocardiographic data) and, using a time-varying covariate Cox model, compared it with patients whose repair did not fail. Higher postoperative PASP was a significant risk factor for repair failure, regardless of annuloplasty type. PASP was higher in patients who had unsuccessful annuloplasty than in patients who did not (Table 3).

To evaluate whether there was a correlation between left heart valve repair failure and tricuspid repair failure, we determined the predicted mean MR over time in patients in whom moderate recurrent TR developed postoperatively. There was no correlation between tricuspid repair failure and recurrent MR. Other studies, by Matsunaga,²⁸ Dreyfus,²⁹ and their associates, have also demonstrated a lack of correlation between recurrent MR and recurrent TR after mitral valve surgery.

Discussion

Few studies have evaluated the long-term outcomes of tricuspid valve annuloplasty. The decision to perform an annuloplasty is often dictated by institutional or surgeon bias, with little objective data to guide decision making. Most series of tricuspid valve repairs are small and focus on outcomes such as survival and freedom from reoperation. Survival itself may be dependent on multiple factors and is not necessarily related to the tricuspid annuloplasty. Freedom from reoperation may not take into account many patients who have high rates of recurrent TR, but are not offered surgery owing to operative risk.⁸ Despite logistical and statistical challenges, a better outcome to evaluate is the degree of TR, as this is typically the indication for operation.³⁰

In this study, we have evaluated TR over time after bicuspidization and ring tricuspid annuloplasty. In our experience, both bicuspidization and ring annuloplasty produce an effective, durable repair at 3 years postoperatively. Significant 3+ or 4+ residual TR occurred in 8% of patients early after operation for all types of annuloplasty. These results are similar to a previous study performed by McCarthy and colleagues.¹² Their detailed study of 790 patients found that 14% of patients had 3+ or 4+ residual TR early after operation for all annuloplasty types, but ring repairs (Carpentier semirigid ring and Cosgrove-Edwards flexible band) provided a more durable repair than suture annuloplasty over an 8-year period. In McCarthy's study,¹² at 3 years postoperatively, 3+ or 4+ TR occurred in approximately 25% of De Vega patients, 27% of Peri-Guard (Bio-Vascular, Inc, St Paul, Minn) patients, 15% of Carpentier-Edwards ring patients, and 18% of Cosgrove-Edwards band patients. In this study, 16% of bicuspidization and 18% of ring annuloplasty patients had 3+ or 4+ TR at 3 years postoperatively. Thus, at 3 years, our outcomes with suture bicuspidization were superior to the De Vega and Peri-Guard annuloplasties and equivalent to ring annuloplasty outcomes presented in the McCarthy study.

Suture annuloplasties, particularly the continuous running type, like the De Vega,¹⁴ have been criticized for being unpredictable and unreliable, perhaps owing to the long suture line or the use of polypropylene suture material, which may break and slide through the tissue as the annulus dilates.³¹ Bernal and colleagues,²⁰ however, have reported excellent results in 232 patients with the De Vega annuloplasty at 6.8 years postoperatively, with 86% of patients having zero to mild TR. Similar to the Revuelta segmental annuloplasty, the posterior suture bicuspidization technique described in this article is performed with a braided, multifilament suture (2-0 Ethibond).³² This suture is less likely to break and thus provides a more durable repair to the area that primarily dilates to produce functional TR. This repair may be performed in less than 8 minutes. In this study, we

found that cardiopulmonary bypass and aortic crossclamp times were 27 minutes and 17 minutes shorter in the bicuspidization group. Since there were no differences in the number and distribution of concomitant procedures between the two groups, the reduced cardiopulmonary bypass and aortic crossclamp times were primarily because of the faster tricuspid annuloplasty performed.

Despite 40 years of evolving annuloplasty techniques, there has been no consensus on the management of functional TR. Recent guidelines from the American College of Cardiology (ACC) and American Heart Association (AHA) recommend tricuspid annuloplasty during mitral or aortic valve surgery in patients with severe TR.³³ Although most surgeons agree that a patient with severe, symptomatic TR requires repair, many surgeons favor a conservative approach in patients with only moderate TR. The ACC/AHA guidelines suggest that functional TR without annular dilation or significant pulmonary hypertension does not require repair.³³ There is a growing body of information, however, that the conservative approach is ineffective and that a substantial number of patients will be left with residual TR, which is associated with increased perioperative and late postoperative morbidity and mortality.^{6,8,9,28} In this study, significant 3+ or 4+ early residual TR developed in 8% of patients and 2+ or greater TR developed within 3 years in 27% of patients. Although these results are inferior to outcomes of mitral valve repair, tricuspid annuloplasty was effective in the majority of patients and may be significantly better than the alternative—no repair. Matsunaga and Duran²⁸ have recently reported that 53% (10/19) of patients have 2+ or greater TR at 3 years after mitral valve repair alone. Matsuyama and colleagues⁷ recently reported that 37% (17/46) of patients with 2+ preoperative TR have 3+ or 4+ TR at 8 years after mitral valve repair alone. It should be noted that, in the Matsunaga study, only 30% of patients had 2+ or greater preoperative TR. In this study, 96% of patients had 2+ or greater TR preoperatively. Thus, the difference between conservative management and tricuspid annuloplasty may be even more pronounced in patients with 3+ or 4+ TR. A prospective study may be indicated to definitively compare conservative management versus tricuspid annuloplasty.

Previously, patients with zero to mild TR have demonstrated a significantly lower mortality than patients with moderate-to-severe TR.⁹ At 3 years, 73% of patients in this study had zero to mild TR. Thus, we believe that tricuspid annuloplasty should be performed not only in patients with severe TR, but in all patients with even moderate TR, especially when an effective annuloplasty technique can be performed rapidly and reproducibly. Dreyfus and colleagues²⁹ even advocate that any patient with substantial annular dilation should undergo repair regardless of TR grade or even no TR. We believe that our suture bicuspidization is a relatively simple, inexpensive technique that

can be performed rapidly and should be used in all patients with at least moderate TR who present for left-sided valve surgery. In our experience, this technique has been as effective as ring annuloplasty in the midterm postoperative period.

Limitations

This study has several limitations. First, the echocardiographic data obtained are subject to significant selection and ascertainment bias. Symptomatic patients were probably more likely to receive follow-up echocardiography than asymptomatic patients. Even though the statistical methods used^{23,24} adjust for such follow-up data, the true TR prevalence may in fact have been lower if all patients were routinely screened with echocardiography. Second, this is a retrospective review and, as such, patients were not randomized, creating an inherent selection bias with regard to the annuloplasty performed. Although the two groups were very similar, the ring annuloplasty group had slightly worse preoperative TR and left ventricular EF. We adjusted for this difference using propensity scores, and there was no difference in the findings with and without adjustment. Third, the ring annuloplasty group was a composite of three different prosthetic annuloplasty techniques. The Cosgrove–Edwards band, the Carpentier–Edwards ring, and the Carbomedics Annuloflex ring are different prosthetic annuloplasty systems, each with different sizes, shapes, and rigidities. We did find a lower percentage of patients with recurrent 3+ or 4+ TR who received the Carpentier–Edwards semirigid ring compared with the Cosgrove–Edwards flexible band. However, we did not have a sufficient number of patients to compare each subgroup. No study, however, has demonstrated that any one of these prosthetic annuloplasties is superior to the others. Therefore, we believe it is appropriate to combine these annuloplasties into a single group to simplify the comparison of prosthetic annuloplasty with suture bicuspidization.

Conclusions

In summary, we have demonstrated that bicuspidization annuloplasty and ring annuloplasty for functional TR were equally efficacious and durable at reducing TR up to 3 years postoperatively. Significant residual TR occurred in 8% of patients early after annuloplasty. Sixty-nine percent of ring annuloplasty and 75% of bicuspidization annuloplasty patients remained free from moderate TR in the midterm postoperative period. Risk factors for annuloplasty failure included greater preoperative TR grade, preoperative TR without concomitant MR, and higher postoperative PASP. NYHA, preoperative PASP, preoperative RV dysfunction, and recurrent MR were not significant risk factors.

Bicuspidization annuloplasty is inexpensive, simple to perform, and reduces operative time. Our experience sug-

gests that bicuspidization annuloplasty is a reliable method for tricuspid annuloplasty and should be given consideration when approaching every patient with functional TR undergoing aortic or mitral valve surgery.

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Discussion

Dr P. McCarthy (Chicago, Ill). Congratulations, Dr. Ghanta, on an excellent paper and presentation. They say that beauty is in the eye of the beholder—and so it is with this paper from the Brigham regarding tricuspid valve repair in patients with functional TR. One could say that the results of bicuspidization for TV repair are equal to that of ring annuloplasty, but one could also say that both are equally bad. Three years postoperatively, 3 or 4+ TR was present still in 25% of the bicuspidization patients and 31% of the ring patients. These are clearly not results that we would accept in patients undergoing valve repair for a condition such as myxomatous mitral regurgitation, for which we are now recommending surgery for patients with asymptomatic disease, because the repairs are very durable.

For some reason, we as surgeons have come to accept that a significant percentage of our patients who undergo tricuspid repair will redevelop significant TR. While it may not always be clinically significant early after surgery, increasing clinical evidence indicates that over time the patient will suffer for this.

I would like to note one clarification regarding your paper. Your grading of TR indicates that moderate is 3+. This is consistent with the STS database. Unfortunately, we have a disconnect with our colleagues in cardiology such that the American Society

of Echo refers to 3+ regurgitation as moderate to severe, and in their system moderate is only 2+. Just to clarify for the audience, then, when you are referring to moderate regurgitation in this paper, it is 3+. Anytime we see a patient who redevelops 3 or 4+ regurgitation, we should consider that a failure of the repair technique.

I have three questions. Your study has the usual problems with a retrospective study in that the patients treated with a ring had at baseline lower ejection fractions and worse tricuspid regurgitation, both very significant risk factors for failure in our study from the Cleveland Clinic. The propensity matching helps to control for this discrepancy. But seeing that we are mostly a group of surgeons and not statisticians, did there appear to be a bias towards using a ring for worse patients, or was the use of the different techniques simply due to surgeon preference in this group practice?

Dr Ghanta: Thank you very much, Dr. McCarthy. I agree with you that there is probably some bias in what type of procedure patients may have. If they have very severe TR and are symptomatic, they probably were more likely to get a ring at our institution than a bicuspidization repair. However, there was a small difference in the actual distribution of preoperative TR grades between the two groups; the mean TR was 3.4 in the bicuspidization group and 3.5 in the other group. Sixty-seven percent of the patients in the ring group had severe TR preoperatively, and 56% of the patients had severe TR in the bicuspidization group preoperatively.

And I would agree with you that a 75% and 69% success rate at three years may be marginally acceptable. However, it might be better than the alternative, which is no repair. We converted patients who were preoperatively moderate/severe-to-severe TR to mild TR at three years. Looking at the mortality study done by Naff and colleagues in the *Journal of the American College of Cardiology*, mild TR had significantly better survival in comparison to moderate TR as an independent risk factor. So although we should develop, ideally, better techniques and get better results, the results that we outlined here may be better than the alternative, which is no repair at all.

Dr McCarthy. I certainly agree with that. Also, we should be looking at doing earlier repairs and lower the threshold, for which we would do a repair in this group of patients.

In our paper permanent pacing wires and ICD wires that cross the tricuspid valve led to our highest risk for recurrence, especially late. By 5 years, 42% of those patients had redeveloped 3 or 4+ TR. Do you have any data on the use of pacemakers in your patients, especially for the group with low ejection fractions that these days are treated with biventricular pacemakers, and did some of those patients receive late pacemakers?

Dr Ghanta. None of our patients preoperatively had permanent pacemakers in place. Postoperatively, 23 (or 10%) patients required pacemakers. There was no difference between the bicuspidization and ring annuloplasty groups in the number of patients who got permanent pacemakers after the operation. Six patients developed a complete heart block—three in the ring and three in the bicuspidization group.

We looked to see how many of the patients who required pacemakers developed moderate residual TR. Surprisingly, it turned out that only 4 of those patients actually developed moderate residual TR within the time period of this study. All 4 of those patients happened to be in the ring group, but the numbers

are so small that we can't draw any meaningful conclusions behind it. I know your study, which had 790 patients, did show that the presence of pacemaker leads increased the risk of residual TR.

Dr McCarthy. Finally, in a follow-up study from our echo group, we found that tricuspid valve tethering due to a very dilated right ventricle was a very strong predictor for recurrent TR. This makes sense with what we know now of mitral valve tethering with functional mitral regurgitation due to LV dysfunction. Do you have any information on other echo findings, such as right ventricular dilatation, tricuspid valve tethering, RV function, and would you anticipate that for that group you may do a more aggressive repair?

Dr Ghanta. Thank you. We actually do not have that information as it is not routinely obtained in echocardiograms, but I agree with you that it is probably very important in determining the outcomes of tricuspid valve repair. We do need to look at the function of the right ventricle so that we can better determine the likelihood of repair being a success. Tethering may be present, and if tethering is present it may indicate that the patient should get a replacement as opposed to a repair. This is something that we would very much like to look at in the future.

Dr H. Bolooki (Miami, Fla). Congratulations, this is a very nice study and a fine presentation of a large number of patients. In support of your work, I would like to indicate that I don't use a ring to repair a functionally incompetent tricuspid valve. I have done the procedure that you are describing for over 20 years. Our technique may be slightly different. In the very first case in early 80s we used only one suture to plicate the lateral leaflet. That did not work for long and within one year we had tricuspid insufficiency needing urgent repair. A more complete and secure suturing method that I call "triple suture, triple bite technique" was used thereafter in all instances, which is similar to your method. The stitches follow the right lower quadrangle of the annulus from three o'clock to six o'clock and it works very well. It has not come loose and has not cut through the annulus. The immediate intraoperative echocardiogram shows minimal insufficiency, and the failure rate or 3+ insufficiency has been less than 20% over 10 years. Failure of the repair, however, has always followed the recurrence of mitral pathology.

I would like to ask, if late tricuspid insufficiency—say, 3 or 4+—returns, what you do when you go back? Do you re-repair these, put a ring on, or change the tricuspid valve? Thank you very much.

Dr Ghanta. Thank you. In our group of patients we only had 6 who required a reoperation, and only one of those patients, or 0.4%, required reoperation on the tricuspid valve. The other five required reoperation on the mitral valve.

We recently had a case at our hospital in which a patient had a mitral valve repair and tricuspid valve repair with a Cosgrove-

Edwards ring at an outside institution. The patient developed recurrent severe tricuspid regurgitation. The patient was taken to the operating room, had the ring removed, and received a bicuspidization annuloplasty, which eliminated the TR. This was done just two weeks ago. So it is possible to do reoperative procedures using the bicuspidization technique.

Dr D. Adams (New York, NY). I wanted to follow up on a question that Dr. McCarthy asked you. That is about the mechanism. It is really not residual; it is recurrent tricuspid regurgitation in your series. Ventricular-related leaflet restriction is the most likely reason for that. I think a remodeling annuloplasty that really fixes the annulus is more effective for that type of mechanism, and do you agree that the same mechanism for recurrent TR is probably right ventricular dysfunction?

The other thing that you didn't mention and that I would like for you to comment on is the difference in pulmonary hypertension between your groups, because that is obviously an important variable.

Finally, I would be careful trying to use operative times as a justification. We know Dr. Cohn is very fast, and we know which technique he likes to use! I believe a remodeling annuloplasty adds about 8 or 10 minutes to the procedure, and I think the long-term durability may be worth it.

Thank you.

Dr Ghanta. We did not look at pulmonary pressures in this study. That data was not catalogued and was not consistently available in all patients, but it would be definitely worth looking at.

Dr G. Dreyfus (Middlesex, United Kingdom). I want to congratulate you on your presentation; however, it seems really that reshaping the tricuspid annulus similarly to the mitral valve does provide, at least in your series, similar results to this bicuspidization technique that you show, which is more a shrinking of the tricuspid orifice and doesn't prevent recurrence of tricuspid regurgitation. I think saying that both methods are showing recurrent tricuspid regurgitation shows really how difficult it is to assess the proper timing for surgery and that regurgitation on the right side is not a reliable criterion. I mean, once you have got such a tethering of the papillary muscle, perhaps we should apply to the right side similar techniques that we apply to the left side. Rather than shrinking the orifice, we should deal with the papillary muscle and the chordae in order to try to overcome the tethering of the right ventricle. Could you comment on that?

Dr Ghanta. We definitely agree with you, and tethering of the papillary muscle needs to be evaluated. In our study, we didn't have any information regarding the papillary muscle or whether or not any tethering was present. But it would definitely be very interesting to take a look at.