



Undersized Rigid Nonplanar Annuloplasty: The Key to Effective and Durable Repair of Functional Tricuspid Regurgitation

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Background. Previous clinical experiences have demonstrated high early and late recurrence rates after repair of functional tricuspid regurgitation (TR). We investigated the results of functional TR repair with undersized rigid nonplanar annuloplasty rings.

Methods. From January 2007 to December 2013, 216 consecutive patients with moderate or greater functional TR were treated with undersized (size 26 mm or 28 mm) rigid nonplanar annuloplasty rings.

Results. The mean age was 69 ± 13 years. There was a previous history of cardiac operation in 25% (54 of 216 patients). Tricuspid regurgitation was graded as severe in 47% (102 of 216) and moderate in 53% (114 of 216). Concomitant operations included mitral valve procedures in 92% (198 of 216), coronary artery bypass grafting in 21% (45 of 216), aortic valve procedures in 9% (20 of 216), and cryomaze procedures in 35% (76 of 216). Size 26 mm

rings were used in 38% of patients (81 of 216), and size 28 mm in 62% (135 of 216). The perioperative mortality rate was 6% (14 of 216). On predischarge echocardiography, TR grade was none or mild in 94% (176 of 187 patients), moderate in 4% (7 of 187), and severe in 2% (4 of 187). At a mean follow-up of 33.0 ± 24.0 months, TR grade was none or mild in 81% of patients (130 of 160), moderate in 16% (26 of 160), and severe in 2% (4 of 160). There were no reoperations for recurrent TR, and no patients have had tricuspid stenosis or annuloplasty ring dehiscence.

Conclusions. Treatment of functional TR with undersized (26 mm or 28 mm) nonplanar rigid annuloplasty rings is safe and highly effective, with a near absence of recurrent severe TR at midterm follow-up.

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More than 20% of patients undergoing surgery for mitral valve disease have significant functional tricuspid regurgitation (TR) [1, 2]. Functional TR results from left-side heart disease that causes right ventricular (RV) remodeling, tricuspid annular dilation, and failure of leaflet coaptation [3–5]. If left uncorrected, functional TR can lead to right-side heart failure and death [6]. Functional TR can be treated with suture annuloplasty (DeVega) or annuloplasty ring (rigid or flexible) insertion [7]. More than 30% of suture-based tricuspid valve (TV) repairs develop TR recurrence by 5 years [8, 9]. Although tricuspid annuloplasty ring implantation is clearly more effective than suture-based techniques for treating

functional TR [10, 11], annuloplasty-based repairs have a significant failure rate of 10% to 20% [8–11].

We reasoned that fixing the tricuspid annulus in a normal anatomic configuration with an undersized rigid nonplanar annuloplasty ring would reduce the tricuspid annular dimensions to normal, assure adequate leaflet coaptation, and achieve effective and durable repair of functional TR. We have previously published an initial experience using undersized nonplanar rigid annuloplasty rings in 101 patients [12]. The present report extends this experience.

Material and Methods

Between January 2007 and December 2013, 216 consecutive patients with functional TR underwent TV repair with undersized (size 26 mm or 28 mm) nonplanar annuloplasty rings (MC3; Edwards Lifesciences, Irvine, CA [Fig 1]). All patients had moderate or greater TR based on preoperative two-dimensional transthoracic or transesophageal echocardiography, using standard

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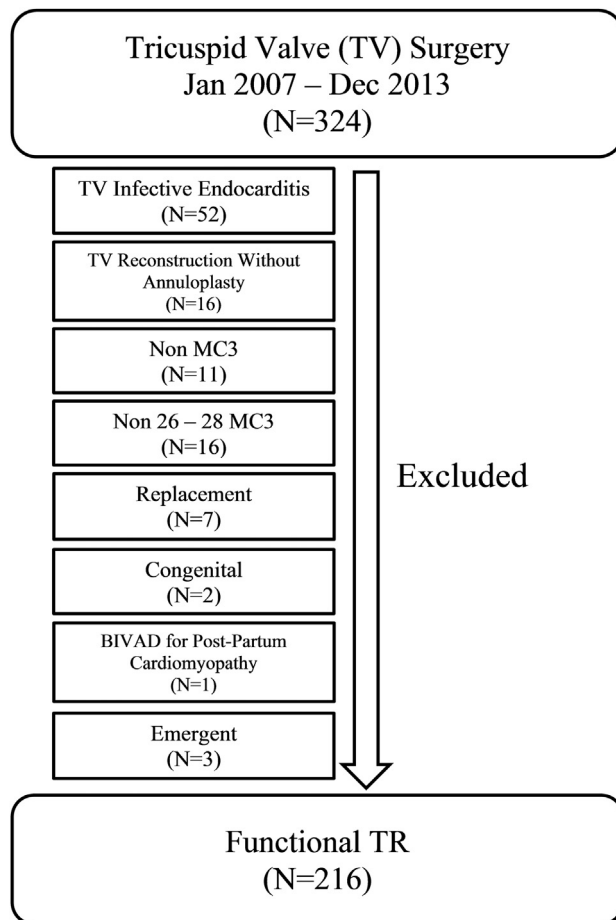


Fig 1. Patient group studied. (BIVAD = biventricular assist device; MC3 = three-dimensional tricuspid annuloplasty ring [Edwards Lifesciences, Irvine, CA]; TR = tricuspid regurgitation.)

methods established by the American Society of Echocardiography [13]. The highest grade of TR on any preoperative study was used as an indication for repair. The TR was graded as none/trace, mild, moderate, or severe, as recommended by the American Society of Echocardiography [13]. Patients with TR characterized as moderate to severe were categorized as having severe TR. Pre-discharge echocardiography was performed in a core clinical laboratory. Follow-up echocardiograms were obtained from primary care physicians or the referring cardiologist. Grade of TR from the most recent follow-up echocardiogram was used to analyze the durability of repair. Indication for TV repair was the presence of moderate or greater TR on any preoperative echocardiogram. Baseline tricuspid annular dimension was not used as a criterion for TV repair. Perioperative mortality was defined as death within 30 days after surgery or in-hospital death. The Institutional Review Board of the University of Maryland Medical Center (HP-00044247) approved this retrospective study, and patient consent was waived.

Operative techniques were described previously [12]. In brief, TV repair was always performed on the arrested heart. Before mitral valve operation, the TV was exposed

through an oblique right atriotomy and analyzed to confirm the absence of organic TV disease. Annuloplasty ring size was chosen based on the observed TV annular size: a 26-mm annuloplasty was chosen for patients in the lower half of the population size distribution and a 28-mm annuloplasty for those in the upper half. Non-pledgeted braided 2-0 nylon overlapping sutures were used to anchor the ring; suturing began at the nine o'clock position, approximately 1 cm above the annular "crux" between the septal and anterior leaflets and extended clockwise to halfway across the base of the septal leaflet (six o'clock position). Ten to 12 sutures were commonly used.

Statistical Analyses

Statistical software (JMP 8.0; SAS Institute, Cary, NC) was used for data analysis. Values are presented as mean \pm SD or median with first and third quartiles (interquartile range [IQR]). Median values were used when the data had skewed distributions. Student's *t* tests were used to compare means of preoperative and postoperative echocardiographic values. Owing to small sample sizes, Fisher's exact test was used to compare the percentages of some of the possible TR recurrence risk factors. A *p* value less than 0.05 was considered significant.

Results

Patient Characteristics

Preoperative patient characteristics are summarized in Table 1. The mean age of patients was 69 ± 13 years (range, 32 to 92), 69% were women (150 of 216), and 25% (54 of 216) had undergone previous cardiac operations. Atrial fibrillation was present in 48% (104 of 216 patients). Twelve percent (26 of 216) had a permanent pacemaker, and 43% (93 of 216) were in New York Heart Association functional class III or IV. Moderate TR was present in 114 patients (53%), and severe TR in 102 (47%). The mean systolic pulmonary artery pressure was 47 ± 17 mm Hg. The Society of Thoracic Surgery mean predicted risk of mortality was 6.25%.

Operative Characteristics

Size 26 annuloplasty rings were used in 38% of patients (81 of 216), and size 28 in 62% (135 of 216). Mitral valve operations were performed in 198 patients, 102 repairs (52%) and 96 replacements (48%). A concomitant cryomaze procedure was performed in 35% (76 of 216); and 3% of patients (6 of 216) needed intraoperative intraaortic balloon pump support. Median aortic cross-clamp time was 106 minutes (IQR: 84 to 130), and median cardiopulmonary bypass time was 131 minutes (IQR: 107 to 159; Table 2).

Clinical Outcomes

Perioperative mortality was 6% (14 patients). Causes of death were multiple organ failure in 12 patients, RV failure in 1 patient, and respiratory failure in 1. One patient (0.5%) had a cerebrovascular accident, 12 patients

Table 1. Patient Characteristics

Patient Characteristics	Mean ± SD or n (%)
Age, years	69 ± 13
Female	150 (69)
NYHA functional class	
I	81 (38)
II	42 (19)
III	80 (37)
IV	13 (6)
Previous cardiac surgery	54 (25)
Atrial fibrillation	104 (48)
Preoperative permanent pacemaker	26 (12)
Aortic valve disease	
Aortic stenosis	33 (15)
Aortic insufficiency	49 (23)
Left ventricular ejection fraction	50 ± 14
Systolic pulmonary artery pressure, mm Hg	47 ± 17
TR grade	
Moderate	114 (53)
Severe	102 (47)

NYHA = New York Heart Association; SD = standard deviation; TR = tricuspid regurgitation.

(6%) had renal failure requiring dialysis, 10 patients (5%) had reoperation for bleeding, and 22 patients (10%) required a new permanent pacemaker (Table 3). Among patients with new pacemakers, 45% (10 of 22) underwent a cryomaze procedure. Therefore, 6% of the patients (12 of 216) who did not have a cryomaze procedure required a new permanent pacemaker. The median length of stay was 10 days (IQR: 7 to 18) days. Actuarial survival was 83% ± 6% at 1 year and 80% ± 6% at 2 years (Fig 2).

Echocardiographic Outcomes

Intraoperative postbypass transesophageal echocardiography was available for all 216 patients and showed no or mild TR in 93% (200 of 216) and moderate TR in 7% (16 of 216). No patient had more than moderate

Table 2. Operative Characteristics

Operative Characteristics	n (%)
Concomitant procedures	
Mitral valve operation	198 (92)
Repair	102 (52)
Replacement	96 (48)
Bioprosthesis	67 (70)
Mechanical	29 (30)
Aortic valve replacement	20 (9)
Three valves—mitral, tricuspid, and aortic	18 (8)
Coronary artery bypass graft surgery	45 (21)
Cryomaze procedure	76 (35)
Atrial septal defect closure	12 (6)

Table 3. Operative Morbidity and Mortality

Morbidity and Mortality	Values
Mortality, n (%)	
Perioperative	14 (6)
Morbidity, n (%)	
Bleeding	10 (5)
New pacemaker	22 (10)
Renal failure (dialysis)	12 (6)
Permanent CVA	1 (0.5)
Length of stay, days	
Median (IQR)	10 (7–18)

CVA = cerebrovascular accident; IQR = interquartile range.

TR. Among 202 hospital survivors, predissmissal echocardiography was available for 93% of patients (187 of 202). Of these patients, 94% (176 of 187) had no or mild TR, 4% (7 of 187) had moderate TR, and 2% (4 of 187) had severe TR. The mechanism of severe TR in these patients was leaflet tethering from severe RV dysfunction in 3 patients and immobility of the septal leaflet from an incorporated pacemaker lead in 1 patient. Among the 3 patients with severe RV dysfunction and severe TR at discharge, RV function improved and TR decreased to none or mild at midterm follow-up (mean 9 months). Severe TR persisted in the patient with the immobilized septal leaflet.

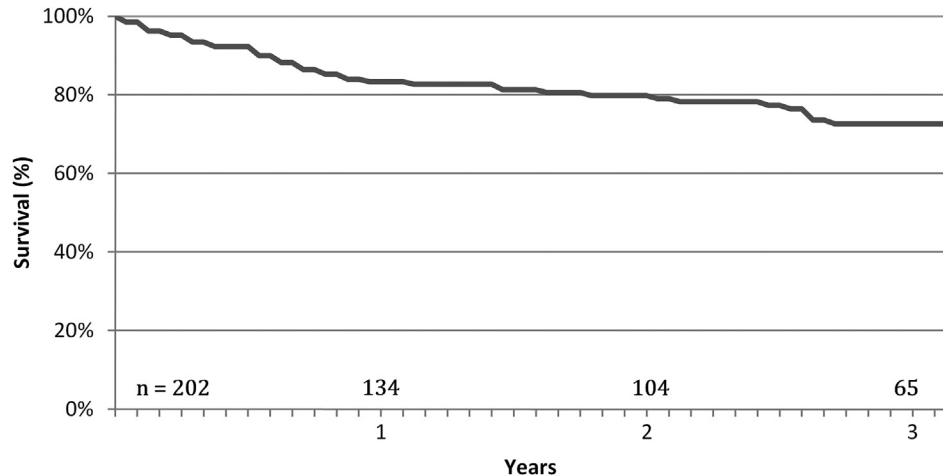
Of the 53 patients who died during follow-up, 25 died without follow-up echocardiography. Follow-up echocardiography was therefore available for 90% of operative survivors (160 of 177). The mean time to echocardiographic follow-up was 33.0 ± 24.0 months (range, 2 to 99). At latest follow-up, 81% of patients (130 of 160) had no or mild TR, 16% (26 of 160) had moderate TR, and 2% (4 of 160) had severe TR (Fig 3). Of the 4 patients with severe TR at follow-up, 3 had severe RV dysfunction with resultant leaflet tethering and insufficient coaptation. All 3 patients initially had normal preoperative and predissmissal RV function with no or trace TR on predissmissal echocardiography; they had severe RV dysfunction with resultant leaflet tethering over time. The other patient had a persistently restricted septal leaflet from an adherent pacemaker lead.

The measured mean pressure gradient across the TV was identical on predischarge and follow-up echocardiography (3.2 ± 2 mm Hg). Mean systolic pulmonary artery pressure decreased to 43 ± 15 mm Hg from 47 ± 17 mm Hg at preoperative assessment. Figure 4 demonstrates the Kaplan-Meier analysis of freedom from recurrent (severe) TR; 98% ± 0.5% of patients had freedom from recurrent TR at both 1 year and 2 years.

Late Clinical Outcomes

No patient required TV reoperation. There was no documented clinically significant tricuspid stenosis. No patient was found to have annuloplasty ring dehiscence, and there were no late episodes of repaired valve endocarditis.

Fig 2. Kaplan-Meier postoperative actuarial survival curve.



Comment

The findings of this study support our hypothesis that implantation of undersized nonplanar tricuspid annuloplasty rings restores tricuspid annular dimensions to normal and results in effective, safe, and durable resolution of functional TR. The tricuspid annulus is a complex three-dimensional structure, and nonplanar tricuspid annuloplasty rings were designed to restore normal annular geometry [7]. Previous work by Sugimoto and colleagues [14] has demonstrated a remarkably close correlation between tricuspid annular diameter and the degree of functional TR. In their study of 128 patients with either valvular heart disease or atrial septal defects and functional TR, there was a progressive rise in the quantitative severity of TR with increasing tricuspid annular dimensions. There was no TR at tricuspid annular dimensions of 30 mm or less. Because the normal tricuspid annular diameter is 2.8 ± 0.5 cm, we reasoned that fixing the tricuspid annular dimension with either a 26 mm or 28 mm rigid nonplanar annuloplasty ring would reduce the tricuspid annular diameter to normal or below normal, ensure sufficient leaflet coaptation, and result in effective and durable repair of functional TR.

The present study substantially extends the size and duration of follow-up of our previously reported experience using undersized rigid nonplanar tricuspid annuloplasty rings for the treatment of functional TR [12]. In the present experience, the rate of residual (severe) TR at the time of hospital discharge was minimal (2%). At follow-up, the rate of severe TR was stable (2%), and there was no risk of TV stenosis (mean gradient 3.2 ± 2 mm Hg). There was a clear cause for TR among the 2% (4 patients) who were discharged with severe TR: in 3 patients, temporary severe RV dysfunction was present that caused leaflet tethering (and insufficient coaptation); and in 1 patient, leaflet motion was restricted by an adherent pacemaker lead. The TR resolved in the 3 patients at midterm follow-up as the RV function returned to normal. Among the 2% (3 patients) who had new TR on

late follow-up, the mechanism of TR was leaflet tethering related to new (or progressive) moderate to severe or severe RV dysfunction. Although there was some progression of the prevalence of moderate TR over time (4% at discharge, to 16% at midterm follow-up), the prevalence of severe TR was negligible. Late severe TR was clearly associated with the development of severe RV dysfunction. Among patients with moderate or less TR, 13% had moderate or severe RV dysfunction, whereas 75% of patients with severe TR had moderate or severe RV dysfunction (Table 4).

Because it is not possible to predict in which patients late RV dysfunction will develop, we cannot recommend adjunctive procedures such as leaflet elongation during functional TR repair to prevent recurrence [15]. Our approach of using undersized rigid nonplanar tricuspid annuloplasty rings represents a simple and effective strategy for minimizing the likelihood of recurrent severe TR. Despite the use of aggressively undersized rings, we observed no ring dehiscence during follow-up. The risk of dehiscence may be minimized by placing sutures on the arrested heart, rather than performing TV repair on the beating heart. We believe that this enhances precise suture placement and symmetric tension-free reduction of the tricuspid annulus during suture tying.

Pfannmueller and colleagues [16] reported an 8.7% risk of tricuspid annuloplasty dehiscence in a large series using a rigid annuloplasty ring, compared with a 0.9% rate for a flexible band. Dehiscence was typically located at the base of the septal leaflet, was recognized before hospital discharge, and was associated with recurrent TR and reoperations. It was not reported whether the TV repair was performed during aortic cross-clamping, although the investigators reported a prolonged difference between cardiopulmonary bypass and cross-clamp time (68 minutes), suggesting that repair was done on the beating heart. In a subsequent series, the same investigators [17] compared outcomes with beating-heart compared with arrested-heart TV repair and reported

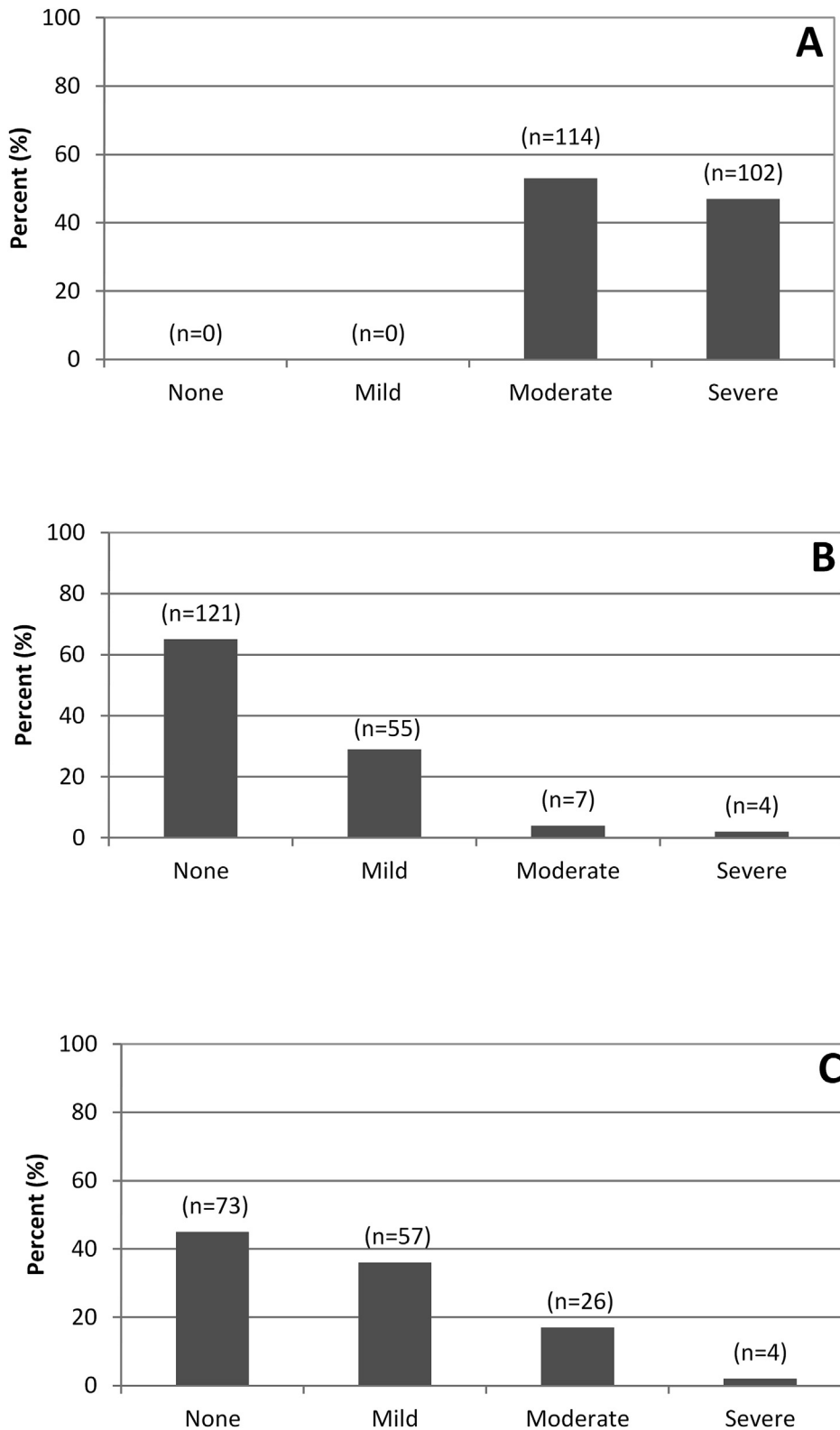
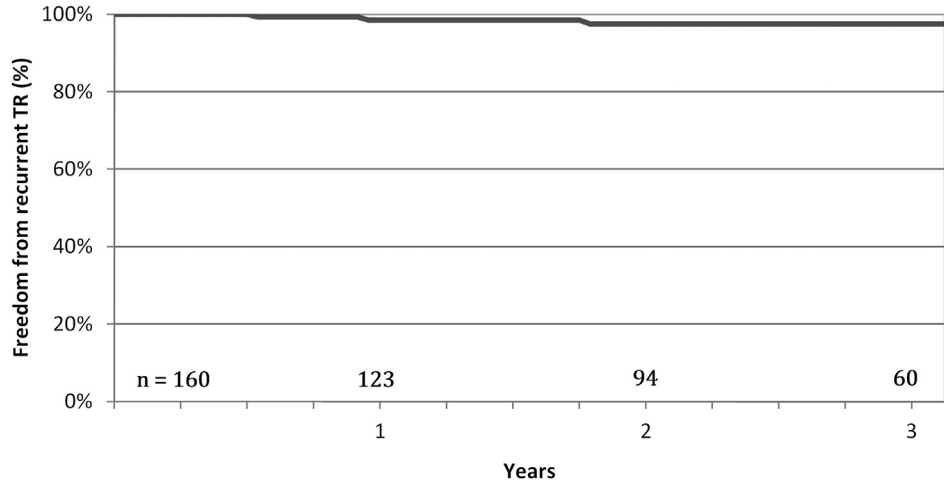


Fig 3. Changes in tricuspid regurgitation grades are shown (A) pre-operatively, (B) before discharge, and (C) during follow-up.

rigid ring dehiscence exclusively in the beating-heart group. They concluded that increased shearing forces at the septal portion of the annulus during beating-heart operations were likely responsible for the dehiscence

[17]. We believe that dehiscence can be avoided by using appropriate suturing techniques on the arrested heart. We have not seen right coronary artery compromise related to TV repair, as has been reported by others

Fig 4. Kaplan-Meier analysis showing freedom from recurrent severe tricuspid regurgitation (TR). Patients without follow-up echocardiograms have been excluded (n = 17).



[1-3, 18]. The present experience demonstrated that transvalvular pressure gradients across an undersized rigid nonplanar tricuspid annuloplasty ring are low both early and late after implantation. We have never diagnosed a patient with clinically evident tricuspid stenosis related to an annuloplasty repair using the described strategy, and there is only a single case report in the literature of tricuspid stenosis after annuloplasty in which a TV was repaired with a complete rigid mitral annuloplasty ring [19]. The internal geometric orifice area of the MC3 annuloplasty ring is 2.9 cm² for the size 26 ring and 3.5 cm² for the size 28 ring.

The overall rate of permanent pacemaker implantation in this experience was 10%, and it was 6% among patients not undergoing surgical atrial fibrillation ablation. This rate is not substantially different from the rates of 2% to 7% for pacemaker implantation after isolated mitral valve

operations [20, 21] and is similar to or less than reported in other series of TV repairs [22].

Tricuspid valve repair for functional TR using an annuloplasty is unequivocally more effective than suture-based techniques. In a metaanalysis comparing early and long-term outcomes after TV repair for functional TR, Parolari and associates [11] showed significantly better clinical and echocardiographic outcomes with annuloplasty compared with suture-based approaches. Among 1,483 patients in nine series, freedom from TR recurrence in 8 years with annuloplasty was 90% compared with 80% for suture-based repair techniques (*p* = 0.01). McCarthy and colleagues [8] described 790 patients who underwent TV repair for functional TR with suture-based techniques and annuloplasty. Severe TR was found in 15% of patients 1 month after surgery, regardless of the technique. Late recurrence of TR was more frequently observed with the DeVega technique whereas TR severity remained relatively stable during follow-up with annuloplasty.

Indications for repair of functional TR at our institution during the period of this study included moderate or severe TR. Tricuspid regurgitation is a dynamic lesion, and therefore we used the highest level of TR present on any study before operation as a threshold for intervention. Although severe functional TR is an unequivocal indication for operation (Class 1 recommendation in the 2014 American College of Cardiology/American Heart Association guidelines), there continues to be a lack of consensus regarding the indications to repair moderate TR in patients undergoing mitral valve operations, with some advocates of aggressive intervention [23] and others favoring a nonoperative approach to moderate TR [1, 24]. In North America, analysis of contemporary practice among patients undergoing mitral valve surgery demonstrated that 39% of patients with moderate TR undergo repair (source: The Society of Thoracic Surgeons Adult Cardiac Database, version 2.73, 2011 to 2013; n = 46,500). Although guidelines recommend consideration of intervention (level IIa) for less than moderate functional TR and annular dilation, few patients in The Society of

Table 4. Risk Factors for Tricuspid Regurgitation Recurrence

Risk Factors	TR Recurrence (n = 4)	No Recurrence (n = 212)	<i>p</i> Value ^a
Mean preoperative sPAP	56	47	0.16
Mean follow-up sPAP	67	42	0.002
Mean age, years	71	69	0.37
Mean ejection fraction	55	50	0.25
Male	1 (25)	65 (31)	1.0
Previous pacemaker	1 (25)	25 (12)	0.40
Mitral valve repair	1 (25)	101 (48)	0.62
Mitral valve replacement	2 (50)	94 (44)	1.0
Atrial fibrillation/flutter	3 (75)	101 (48)	0.35
Preoperative severe TR	3 (75)	99 (47)	0.35
Follow-up RV dysfunction	3 (75)	21 (13) ^b	0.01

^a A *p* value less than 0.05 was considered significant. ^b No recurrence, n = 156.

Values are n or n (%).

RV = right ventricular; sPAP = systolic pulmonary artery pressure; TR = tricuspid regurgitation.

Thoracic Surgeons database received repair for this indication (4.9%); and in our practice, we do not perform prophylactic TV repair. Randomized trials are now under way that should inform this practice.

In addition to the inherent limitations of a retrospective study, detailed information about TV structure, right atrial and ventricular dimensions, and the degree of TV leaflet tethering before and after surgery were not studied.

In conclusion, implantation of undersized nonplanar annuloplasty rings stabilize the tricuspid annulus in a physiologic configuration and result in predictable, safe, and durable treatment of functional TR.

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DISCUSSION

DR JOHN STULAK (Rochester, MN): Dr Ghoreishi, I would like to congratulate you on a very nice presentation on the theme of early involvement. That was a very impressive presentation given that you are 16 months into an integrated cardiothoracic residency. So I am honored to review your manuscript.

Your report once again rekindles perhaps the ongoing discussion regarding rigid versus flexible annuloplasty bands and whether sizing the valve is important. In my own practice, I utilize flexible bands both for the mitral and tricuspid valves, and like your group, for the tricuspid valve in the setting of

functional tricuspid regurgitation (TR), I almost exclusively use a 26-mm ring. Of course, this is usually in the setting of functional TR, as I mentioned. And also like your group, I have never experienced tricuspid valve stenosis with an undersized band in any patient.

I spoke with Dr Gammie this morning and I am aware that neither he nor any of the coauthors are here in the audience. Having said that, I have a few questions that you can answer after I ask each of them. Clearly, your group has been very active and leaders in valve surgery. Why did you all start using this ring in January 2007, which is when the study period began? What was

your technique before this time? And what events led you all to change to this band?

DR GHOREISHI: Thank you very much, Dr Stulak, again, for reviewing my paper. Back to 2007, my mentor Dr Gammie and other surgeons used to use a floppy band (the Cosgrove-Edwards band) "true-sized" to the tricuspid valve annulus, namely, 30, 32, 34 mm bands. However, it was common to come off bypass and notice significant residual TR, which would persist on pre-discharge echocardiography. Based on the experience with undersized annuloplasty for functional mitral regurgitation, we decided to repair the functional TR with undersized annuloplasty.

DR STULAK: Second is, all patients in this series who had a tricuspid valve operation had moderate or greater TR. So that seems to suggest that your group only uses degree of TR as a trigger to intervene on the tricuspid valve. So if you are in the operating room operating for severe mitral regurgitation and the echocardiographer told you the tricuspid valve annulus was 6 cm and there was mild TR, would you not intervene on that valve?

DR GHOREISHI: At present, we would leave that alone. We do not focus on the annular dimensions; as you say, our decision to repair the valve was based on the degree of TR, not the size of the annulus. We do not at present base the decision on the annular dimension, but we are supportive of answering the question of assessing the value of repair for TR less than moderate with a dilated annulus (tricuspid annular dilation >40 mm).

DR STULAK: And as you noted, the tricuspid valve annulus is not planar, it is saddle shaped, it changes conformation in systole and diastole, and there are very elegant studies showing that once you put a rigid structure in the tricuspid valve annulus that right ventricular (RV) function immediately decreases. Do you have information on RV dysfunction in these patients?

DR GHOREISHI: The only data we have for RV function are qualitative, not quantitative, and we did not report that data. Dr Bolling and his group recently reported using undersized rings for functional TR, and they found no significant RV dysfunction related to undersizing the tricuspid valve annulus. We also did

not see any tricuspid valve stenosis that can cause any RV dysfunction, and based on our clinical experience, we also did not see significant RV dysfunction just based on using a rigid ring in the tricuspid valve position.

DR STULAK: Up to 20% in the follow-up, which was less than 2 years, actually had moderate or greater tricuspid regurgitation. We will not discuss what durability means in this, but can you comment perhaps on the nature or the mechanism of this recurrent TR in those patients?

DR GHOREISHI: That is a very good question. First, about the 15% of moderate recurrence, previous studies that published about tricuspid valve did not consider moderate TR as a recurrence. They considered moderate to severe or severe TR as a clinically significant factor for patients. Because the number of patients with recurrence of TR in our study was not high, we could not have an accurate statistical analysis. However, preoperative high pulmonary artery pressure, pacemaker, and also a higher grade of preoperative TR, and higher preoperative tricuspid annular plane systolic excursion are the risk factors for recurrence of TR, based on other studies.

DR THORALF SUNDT (Boston, MA): Nicely presented. Congratulations. I continue to have some concern about stenosis. We used to say, or it was said by some, that you could not make a mitral valve stenotic. You could put in the smallest ring on the shelf. I can tell you I have reoperated on some of those people for mitral stenosis. With regard to your gradients, are those rest gradients? Do you have any exercise gradients across the tricuspid valve after putting in these undersized rings? Thank you.

DR GHOREISHI: All of the numbers for tricuspid valve gradient are during the rest and not the exercise gradient.

DR CERFOLIO: Do you have any data otherwise in your experience?

DR SUNDT: No. I would just point out that a few millimeters on the left side is not the same as a few millimeters on the right side.