

Surgical Management of Functional Tricuspid Regurgitation with a New Remodeling Annuloplasty Ring

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Abstract

Background: Moderate-to-severe functional tricuspid regurgitation (TR) should be corrected in patients undergoing surgery for left-sided valvular diseases, to improve long-term outcomes. Several techniques of surgical repair (suture annuloplasty or prosthetic annuloplasty) to correct this condition have been described. Multiple clinical studies have shown the superiority of prosthetic remodeling annuloplasty over the other surgical approaches. Despite this, suture-based annuloplasty remains the most commonly used technique for tricuspid valve repair. A new 3-dimensional remodeling prosthesis has been developed to address the issue of residual TR. We report our early experience with this new 3-dimensional prosthetic remodeling ring, the Edwards MC3 system.

Material: From August 2002 to March 2004, 51 patients (24 male, 27 female, mean age 64 ± 15 , ejection fraction 49 ± 15 , median NYHA III [II–IV]) underwent tricuspid valve repair for functional TR due to annular dilatation, with the Edwards MC3 system. Etiology of left-sided valvular disease was: rheumatic (n=19), degenerative (n=16), ischemic cardiomyopathy (n=1), and endocarditis (n=5). Twenty (50%) patients underwent redo operations. Concomitant procedures included: mitral valve surgery (repair n=34, replacement n=14), aortic valve replacement (n=5), coronary artery bypass graft (n=8) and left arterial maze (n=16). Median EuroSCORE was 12% (1–74%) in this patient population.

Results: Operative and late mortality were 3.8% (n=2) and 13.7% (n=7), respectively. Echocardiography at discharge showed a mean TR decrease from 3.1 ± 0.9 to 0.3 ± 0.4 ($p < 0.001$) and mean mitral regurgitation (MR) decrease from 3.2 ± 1 to 0.1 ± 0.1 ($p < 0.001$), while ejection fraction increased to 53% ($p = 0.047$), and at 6-month follow-up, mean TR and MR remained unchanged.

Conclusion: Concomitant tricuspid valve repair for functional TR with left-sided valve surgery carries a low operative mortality. The Edwards MC3 annuloplasty system is relatively simple to implant and corrects TR effectively (without significant residual TR), while providing excellent short-term clinical results. The 3-dimensional saddle shape of this ring may further optimize the fixation of the annulus in systolic position, and improve long-term results. Larger clinical series with longer-term follow-up are necessary to confirm these early promising results.

Key Words: Tricuspid regurgitation, surgery, valve repair, remodeling, annuloplasty.

Introduction

TRICUSPID REGURGITATION is a common finding in patients with severe mitral valve regurgitation. The severity of this condition often increases in the presence of pulmonary hypertension and/or left ventricular dysfunction (1). This so-called functional TR is due to annular dilatation (Carpentier's Type I dysfunction) (2). Previous anatomical studies have shown that annular dilatation does not affect the different segments of the tricuspid annulus equally (3). The diameter of the anterior segment of the annulus can increase up to 40%, whereas its posterior segment can dilate up to 80% of its initial diameter (3). The dilatation of the septal segment is limited (maximum 10%) because of its close anatomical relationship with the fibrous skeleton

of the heart. Several techniques of surgical repair (suture annuloplasty or prosthetic annuloplasty) to correct this condition have been described (4, 5). Multiple clinical studies have demonstrated the superiority of remodeling annuloplasty over other repair procedures (2, 6, 7). In 2002, a new generation of annuloplasty rings was introduced by Edwards-Lifesciences (Edwards MC3 annuloplasty system, Edwards LLC, Irvine, CA). The main characteristic of this prosthetic ring is its 3-dimensional saddle shape, which perfectly fits the anatomical configuration of the tricuspid annulus. We report our early clinical experience with this new prosthetic device in patients undergoing cardiac surgery for functional TR and concomitant left-sided valve diseases.

Patients and Methods

A computer-based registry of all cardiac surgery patients at the Mount Sinai Medical Center was used to identify patients undergoing tricuspid valve surgery for functional TR between August 2002 and March 2004. In this period, 51 patients underwent tricuspid valve replacement (TVR) with the new Edwards MC3 annuloplasty system in ad-

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Accepted for publication January 2006.

dition to left-sided valve surgery. Medical charts were reviewed for preoperative, intraoperative, and postoperative clinical variables. Follow-up information such as survival, clinical status and most recent echocardiography was obtained by contacting patients and/or referring physicians, and reviewing charts. Additional survival information was obtained using the social security death index. This research was done in accordance with our local institutional review board.

This patient population included 27 women (53%) and 24 men (47%). The mean age in this series was 64±15 years. Eighty-five percent (n=42) of the patients were in New York Heart Association (NYHA) functional class III and IV preoperatively. Mean left ventricular ejection fraction was 49±15%. Twenty patients (39%) underwent reoperative cardiac surgery. Eighteen patients (35%) were in atrial fibrillation and the remaining 33 patients (65%) were in sinus rhythm. Pulmonary hypertension, defined as a systolic pulmonary artery pressure greater than 45 mm Hg, was present in 32 patients (63%). Median expected mortality by EuroSCORE was 12% (1–74%) in this patient population. Preoperative characteristics of these patients are summarized in Table 1.

A trans-thoracic echocardiography (TTE), as well as right and left heart catheterization, was performed on all patients. The mechanism of TR was Carpentier's functional classification Type I (annular dilatation). The severity of TR, as assessed by Doppler echocardiography, was graded on a scale from 1+ to 4+ (1+ mild, 2+ moderate, 3+ moderate to severe, 4+ severe) (8). The results were as follows: forty-one patients (80%) had >3+ TR, eight (16%) had 2+ TR, and two (4%) had only 1+ TR. Mean TR grade was 3.2±0.9. Patients with 1+ and 2+ TR had a severe dilatation of the tricuspid annulus on the TTE (annular diameter greater than 40

mm). Etiology of left-sided valvular disease was: rheumatic (n=19), degenerative (n=16), ischemic cardiomyopathy (n=1), and endocarditis (n=5) (Table 2).

Intraoperative trans-esophageal echocardiography (TEE) was used for all patients. It was not used to assess the severity of TR, but played a crucial role in evaluating left ventricular function, quality of repair, and de-airing of the cardiac cavities at the end of the procedure.

Following a median sternotomy, cardiopulmonary bypass (CPB) was instituted between the ascending aorta and superior and inferior venae cavae with mild-to-moderate systemic hypothermia. Myocardial protection was achieved with antegrade and retrograde cold-blood, high-potassium cardioplegia. Left-sided valvular heart diseases were corrected first. The mitral valve was exposed through Sondergaard's groove. In patients with a history of atrial fibrillation, a modified left atrial maze procedure was performed by cryothermia (CryoCath Technology, Pointe-Claire, Canada) prior to the mitral valve procedure (n=16, 31%). Mitral valve repair was performed using Carpentier's techniques in 34 patients (66%), whereas replacement was done in 14 (27%). Other concomitant procedures included aortic valve replacement (n=5, 10%) and coronary artery bypass graft procedures (n=8, 16%) (Table 3).

A right atriotomy parallel to the atrio-ventricular groove was used to expose the tricuspid valve. Tricuspid valve analysis confirmed the presence of Type I dysfunction according to Carpentier's functional classification, with severe annular dilatation in all patients. Tricuspid valve (TV) repair was performed using the Edwards MC3 annuloplasty system. The prosthetic ring has a 3-dimensional shape, and is constructed of a titanium alloy with a

TABLE 1
Patient Demographics

Characteristics	n (%)
Female/male	27/24
Mean age (years)	64±15
NYHA class I	3 (6)
II	6 (12)
III	27 (53)
IV	15 (29)
Atrial fibrillation	18 (35)
Pulmonary HTN	32 (63)
Mean EF (%)	49±15
Reoperation	20 (40)

EF=ejection fraction, NYHA=New York Heart Association, HTN=hypertension.

TABLE 2
*Intraoperative Mitral Valve Analysis:
Valve Dysfunction According to Carpentier's Functional
Classification and Etiology*

Dysfunction Type	n (%)
Type I	9 (18)
Type II	10 (20)
Type IIIa	14 (27)
Type IIIb	17 (33)
Etiology	n (%)
Rheumatic	19 (37)
Degenerative	16 (32)
Ischemic cardiomyopathy	9 (18)
Dilated cardiomyopathy	1 (2)
Endocarditis	5 (10)

TABLE 3
Surgical Procedures

Procedure	n (%)
Tricuspid Valve Repair with MC3 Ring	51
26 mm	17 (33)
28 mm	14 (27)
30 mm	7 (14)
> 32 mm	13 (26)
Concomitant Procedures	
MV repair	34 (66)
MVR	14 (27)
AVR	5 (10)
CABG	8 (16)
LA maze	16 (31)
Others	2 (3.9)

MV=mitral valve, MVR=MV regurgitation, AVR=aortic valve replacement, CABG=coronary artery bypass grafting, LA=left atrial.

sewing ring that consists of a layer of silicone rubber, covered with polyester velour cloth sewn with a single seam. Using the tricuspid valve sizer, the appropriate ring size was selected based on the distance between the antero-septal and postero-septal commissures, and the surface area of the anterior leaflet. For functional TR, based on the measured distance, the size of the ring was downsized by at least one size. Ring size implanted for TV repair varied from 26–34 mm: for 17 patients (33%) a 26-mm ring was used, for 14 (27%) a 28-mm ring, for 7 (14%) a 30-mm ring, and for 13 (26%) a 32-mm ring or larger. Ring implantation was performed without any complications, in all patients, in less than 20 minutes. The mean CPB time was 179 ± 64 min and cross-clamp time 116 ± 66 min.

Statistical Analysis

Values are expressed as the mean \pm standard deviation, median (range) or as a percentage. Statistical significance was considered when a p value was less than 0.05. Comparison between groups was performed with use of analysis of variance, Student's test, or the chi-square test, as appropriate. The Kaplan-Meier method was used to determine the actuarial survival curve.

Results

Mortality and Morbidity

Operative mortality was 3.8% (n=2), cause of death being multi-organ system failure in both patients (Table 4). Postoperative morbidities were respiratory failure (requiring ventilation >72 h

TABLE 4
Mortality and Morbidity

	n (%)
Mortality	2 (3.9)
Multi-organ system failure	2 (3.9)
Morbidity	3 (5.9)
Low cardiac output	1 (1.9)
Sternal infection	1 (1.9)
Respiratory failure	1 (1.9)

postoperatively) (n=1), low cardiac output requiring pharmacological support (n=1), and deep sternal infection (n=1). A permanent pacemaker insertion was necessary in 7 patients (13.7%), mainly due to sick sinus syndrome after maze procedure.

Follow-up

Patients and/or referring physicians were contacted by telephone for follow-up information and medical charts were reviewed. Median follow-up time was 523 days (range: 37–1004) and follow-up was 90% complete. Late mortality was 13.7% (n=7). The causes of death were gastrointestinal hemorrhage (n=1), systemic neoplasia (n=2), and unidentified (n=4). No valve-related complications (ring dehiscence, prosthetic endocarditis, or thrombo-embolic events) were documented during the follow-up period.

Echocardiographic Results

Tricuspid regurgitation was effectively reduced after this remodeling annuloplasty. At discharge, TTE showed a significant decrease of the mean TR from 3.1 ± 0.9 to 0.3 ± 0.4 ($p < 0.001$) in all patients. Similarly, in patients who underwent mitral valve repair, mean MR decreased from 3.2 ± 1 to 0.1 ± 0.1 ($p < 0.001$). No significant change in mean ejection factor was demonstrated (from 49 ± 14 to $48 \pm 14\%$, $p = \text{ns}$). No patient had more than mild (>1+) TR after surgery.

At follow-up, 26/42 patients (62%) underwent repeat TTE. Mean TR and MR remained constant. All patients had mild (1+) or less TR at follow-up: none to trace = 11 (42%); mild (1+) = 15 (58%).

Discussion

Indications for Surgery

Tricuspid valve regurgitation has often been neglected in patients undergoing cardiac surgery for left-sided valvular heart disease. The main rea-

son is that it was thought that TR decreases after surgical correction of left-sided lesions. However, the major issue is that the regression of TR is unpredictable after surgical treatment of mitral and/or aortic valve diseases. Left untreated, a significant number of patients will develop severe symptomatic TR over time. The persistence or the worsening of this condition correlates with an increased morbidity and mortality, mainly due to congestive heart failure, demonstrating the limitations of current medical therapy. In addition, most of these patients are not offered a second operation, because tricuspid valve re-operation for severe TR is associated with a high operative mortality (9, 10). Furthermore, in a recent study, Nath et al. have demonstrated that even moderate tricuspid regurgitation negatively impacts survival, regardless of left ventricular function or pulmonary artery pressures (Fig. 1; 1). This better understanding of the negative impact of functional TR on survival has several clinical implications.

The presence of TR and its severity should be evaluated carefully in patients undergoing mitral and/or aortic valve surgery. Since the severity of regurgitation depends upon multiple hemodynamic variables (preload, afterload, and right ventricular contractility), preoperative TTE is the best diagnostic tool to determine the presence and severity of this condition. The use of intraoperative TEE to determine the presence of TR should be avoided because general anesthesia induces a systemic vasodilatation, resulting in a significant afterload reduction that may lead to underestimation of TR severity (11).

This has led to more frequent surgical correction of functional TR at the time of initial operation for mitral and/or aortic valve disease. Cur-

rently, it is well accepted that all patients with TR greater than 2+ should undergo concomitant tricuspid valve repair in combination with other surgical procedures. The surgical indication for patients with TR equal to or less than 2+, however, remains controversial. In these patients the severity of the annular dilatation is another important variable that should be taken into consideration. In a recent study, Dreyfus et al. suggested that annular dilatation might be a more suitable indicator for tricuspid valve repair than the degree of TR (12). In this study, 311 patients were divided into two groups according to the severity of annular dilatation (upon intraoperative inspection). In group 2 (n=148 [47.6%]) patients underwent mitral valve repair with a concomitant tricuspid valve annuloplasty (annular diameter >70 mm), whereas in group 1 (n=163 [52.4%]) the tricuspid valve was not repaired (annular diameter <70 mm). The severity of TR was similar in both groups according to preoperative echocardiography (Group 1: 0.7 ± 0.5 vs. Group 2: 0.9 ± 0.6). After a mean follow-up of 4.8 years, TR increased by more than two grades in 48% of the patients in group 1 and in only 2% of the patients in group 2 ($p < 0.001$). The authors concluded that tricuspid annular dilatation is an ongoing process that will lead to severe TR over time and warrants surgical correction regardless of the severity of TR.

Our group, in collaboration with Professor A. Carpentier, has developed and implemented the following algorithm for surgical decision making in the management of patients with TR equal to or less than 2+, based on the severity of annular dilatation (Fig. 2). In this setting we recommend inspection of the tricuspid valve. If organic lesions are present, they should be addressed and treated using Carpentier's standard repair techniques. If the patient presents with only functional TR, an appropriate valve sizer is used to measure the surface of the anterior leaflet. After appropriate selection of the ring, which also indicates the optimal shape and size of the annulus, the degree of annular dilatation is assessed using a sizer one size larger. If the sizer covers the orifice area, this indicates the presence of mild-to-moderate annular dilatation. In this case it is likely that after the correction of left-sided lesions, TR will improve, so this condition may be considered reversible. Therefore, a conservative approach without tricuspid annuloplasty seems justified. In the presence of severe annular dilatation (if the larger sizer does not cover the orifice area) it is unlikely that the annular dilatation and TR will recede completely after correction of the left-sided lesions. In this scenario, a remodeling annuloplasty to correct TR

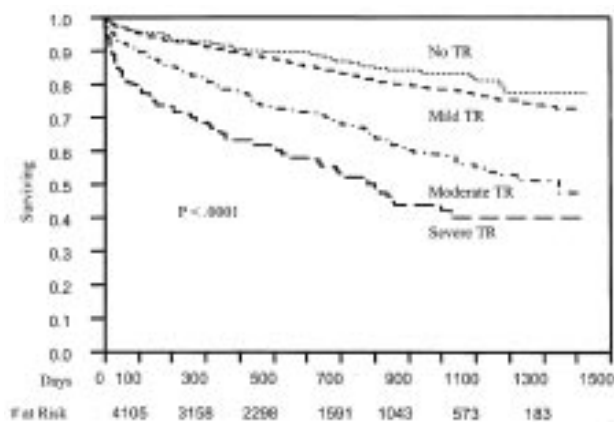


Fig. 1. Kaplan-Meier survival curves for all patients with tricuspid regurgitation (TR). Survival rate was significantly lower for patients with moderate and severe TR. (Reproduced with permission from Nath et al. [1].)

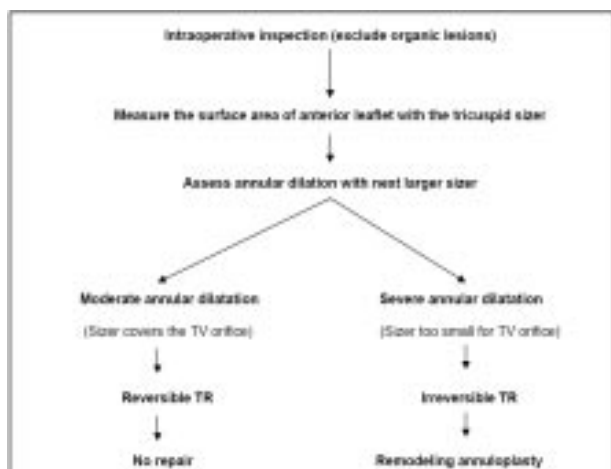


Fig. 2. Decision making for patients with functional tricuspid regurgitation (TR) (<math>< 2+</math>). TV = tricuspid valve.

is recommended. Pulmonary artery pressures and left ventricular function are other important variables that must be taken into consideration. In the presence of pulmonary hypertension and/or left ventricular dysfunction, we have a lower threshold to perform tricuspid valve annuloplasty in patients with mild TR. This algorithm is summarized in Fig. 2.

Operative Techniques

During the last four decades, several repair techniques have been described for the surgical correction of functional TR with severe annular dilatation. The initial repair techniques were palliative; their goal was to reduce the diameter of the annulus by plication or circumferential constriction (Fig. 3A). The Kay suture annuloplasty consisted of the placement of multiple sutures around the posterior segment of the annulus where the dilatation is maximal. The procedure not only significantly reduced the orifice area by eliminating the posterior segment of the annulus, but also transformed the tricuspid valve into a bicuspid structure. However, this technique was associated with multiple drawbacks, including the fibrotic transformation of the posterior leaflet, and continued dilatation of the anterior segment of the annulus. The long-term results were not satisfactory and it was abandoned. The other suture annuloplasty technique (De Vega repair) consists of the placement of two semicircular pursestring sutures from the antero-septal commissure to the postero-septal commissure, to achieve an annular narrowing. This technique produces a semicircular deformation of the tricuspid orifice and, for purely geometric reasons, causes relative invagination of the leaflets,

impairing their motion. Further dilatation of the tricuspid orifice due to migration of the suture is common and is at the origin of recurrent TR (6, 7; Fig. 3A).

In the early 1970s, Carpentier introduced the concept of remodeling annuloplasty for the correction of TR. Prosthetic rings of a suitable size are selected, based on the distance between the antero-septal and the postero-septal commissures as well as the surface area of the anterior leaflet. The remodeling annuloplasty restores the normal shape of the annulus and thereby allows both a normal orifice area and normal valve function (Fig. 3B). The goal of reconstructive valve surgery is to preserve leaflet mobility and to create a large surface

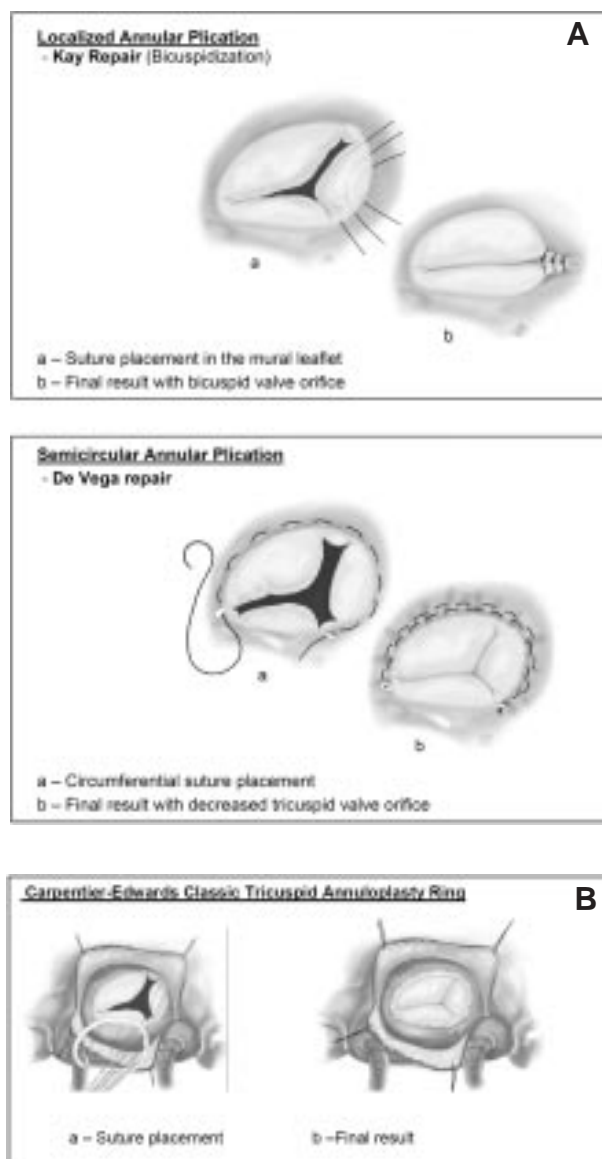


Fig. 3. (A) Tricuspid valve annuloplasty techniques: suture-based procedures. (B) Tricuspid valve annuloplasty technique: remodeling annuloplasty.

of coaptation, while preventing further annular dilatation (2). From a design perspective, the prosthesis has a 2-dimensional shape and is semi-rigid. The ring should be manually bent to fit the 3-dimensional saddle shape of the tricuspid annulus, which is more superficial in the anterior area due to aortic bulging and deeper in the septal area (Fig. 3B). Several clinical studies have demonstrated the superiority of the remodeling annuloplasty over suture-based techniques in terms of freedom from TR and reoperation (2, 6, 7, 13). Despite these excellent results, it has been suggested that this mismatch in configuration between the prosthetic ring and the tricuspid annulus has been at the origin of incidental reports of ring dehiscence. In 2002, a new generation of prosthetic rings was introduced. The Edwards MC3 ring system has adopted the concept of the remodeling annuloplasty. This ring has a 3-dimensional design and is preconfigured to best accommodate the saddle shape of the annulus. As demonstrated in our series, the implantation of this ring was relatively simple and provided excellent early clinical and echocardiographic results. This 3-dimensional configuration may offer a potential advantage with respect to increased stabilization of the annulus. However, the durability of this repair must be assessed with long-term studies, especially those comparing this prosthesis to the current standard, the classical Carpentier Edwards tricuspid ring.

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