

Early Clinical Outcomes of Tricuspid Valve Repair with a Tri-Ad Annuloplasty Ring in Comparison with the Outcomes Using an MC³ Ring

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Background: We evaluated the early clinical outcomes of tricuspid valve annuloplasty (TAP) with the Tri-Ad annuloplasty ring for functional tricuspid regurgitation (TR). **Methods:** From January 2015 to March 2017, 36 patients underwent TAP with a Tri-Ad ring for functional TR. To evaluate the early clinical outcomes of TAP with the Tri-Ad ring, we conducted a propensity score-matched analysis comparing the Tri-Ad and MC³ tricuspid annuloplasty rings (n=34 in each group). The follow-up duration was 11.0±7.07 months. **Results:** There was 1 case of operative mortality (2.8%) and no cases of late mortality. Postoperative complications occurred in 15 patients (41%), including acute kidney injury in 6 patients (16%), bleeding requiring reoperation in 4 patients (11%), and low cardiac output syndrome in 4 patients (11%). There were no ring-related complications, such as atrioventricular block or ring dehiscence. The TR grade decreased significantly (from 2.03±1.06 to 1.18±0.92, p<0.01), as did the systolic pulmonary artery pressure (from 43.53±13.84 to 38.00±9.72 mm Hg, p=0.03). There were no cases of severe residual TR, but moderate TR was observed in 3 patients, all of whom had severe TR preoperatively. Severe preoperative TR was also associated with moderate in the univariate analysis (p<0.01). In the propensity score-matched analysis comparing the Tri-Ad and MC³ rings, there was no significant difference in early clinical outcomes. **Conclusion:** TAP with the Tri-Ad ring corrected functional TR effectively and provided good early clinical and echocardiographic results without ring-related complications. However, severe preoperative TR was associated with moderate or severe residual TR in the immediate postoperative period. A follow-up study is necessary to confirm the stability of this procedure.

Key words: 1. Tricuspid valve
2. Tricuspid valve insufficiency
3. Cardiac valve annuloplasty

Introduction

Functional tricuspid regurgitation (TR) is usually associated with left-sided valvular disease. It increases the dimensions of the right ventricle (RV)

and right atrium (RA) and distorts the normal geometrical relationships of the tricuspid leaflets, chords, and papillary muscles, which results in tethering of the tricuspid leaflets and incomplete coaptation. If left untreated, the progression of functional TR can ag-

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gravate clinical outcomes, regardless of its severity [1].

Functional TR can be treated with suture or ring annuloplasty. Notably, tricuspid annuloplasty (TAP) with an Edwards MC³ annuloplasty ring (MC³; Edwards LifeScience, Irvine, CA, USA) demonstrated better mid- and long-term outcomes than Non-surgical treatment [2]. In comparison, the recently released Tri-Ad Adams tricuspid ring (Tri-Ad; Medtronic, Minneapolis, MN, USA), consists of a large open area to protect the conduction system, flexible ends combined with a 3-dimensional (3D) semi-rigid mid-portion, and a short septal lateral dimension to allow optimal correction of the main lesion while protecting the delicate tissue around the tricuspid valve (TV) [3].

The purpose of our study was to investigate the early outcomes of TAP with the Tri-Ad ring and to demonstrate its safety and efficacy in comparison to the MC³ ring.

Methods

1) Patient characteristics

From January 2015 to March 2017, 36 patients with functional TR underwent TV repair with a Tri-Ad ring by 1 surgeon at Seoul National University Hospital. The control group, who underwent TAP with an MC³ ring for functional TR from January 2007 to February 2015, comprised 193 patients (the MC³ group). Clinical data were assessed retrospectively, and follow-up information (e.g., survival, clinical status, and echocardiography) was acquired from the patients' electronic medical records. The clinical follow-up period ended on May 31, 2017, with an average duration of 10.39±7.24 months (range, 1.3 to 27 months). Table 1 presents patients' baseline characteristics. Operative mortality was defined as any death within 30 days after surgery or during the same hospital admission. All patients were followed up in the outpatient clinic (follow-up period, 10.39±7.24 months; range, 1.3 to 27 months). The study was approved by the Institutional Review Board of Seoul National University Hospital (SNUH IRB no., 1708-067-877) and written informed consent was obtained from the patients for publication of this study and any accompanying images.

2) Surgical technique

A full sternotomy was performed in all patients. After cardiopulmonary bypass was instituted, left-sided valvular heart disease was corrected first. In patients with a history of atrial fibrillation, the Cox maze procedure was performed by cryothermal ablation (n=27, 75%). A mitral valve operation was performed in 29 patients (82% for mitral valve repair, 18% for replacement). Other concomitant procedures included aortic valve replacement (n=8, 22.2%) and atrial septal defect closure (n=1, 2.8%) (Table 2). Next, a right oblique atriotomy parallel to the atrioventricular (AV) groove was performed, and the TV was analyzed to confirm type I dysfunction (i.e., annular dilatation) in all patients. The annular diameter and size of the Tri-Ad annuloplasty ring was determined by measuring the distance between the antero-septal and postero-septal commissures using a tricuspid ring annuloplasty sizer. Annular dilatation was assumed to be present if the annulus of the TV was larger than the ring sizer. The indications for TAP were (1) TR of grade 1 or greater with annular dilatation, or (2) pulmonary hypertension (systolic pulmonary artery pressure >50 mm Hg on preoperative echocardiography) with annular dilatation, irrespective of the TR grade. The size of the Tri-Ad ring implanted for TV repair ranged from 26 to 32 mm: 5 patients (13.9%) had a 26-mm ring, 29 (80.6%) had a 28-mm ring, 1 (2.8%) had a 30-mm ring, and 1 (2.8%) had a 32-mm ring.

3) Echocardiographic evaluation

Two-dimensional echocardiography and Doppler color-flow imaging were performed in all patients before and after surgery (pre-discharge echocardiographic follow-up). Pre-discharge follow-up echocardiography was available for all patients (n=35, excluding 1 case of early mortality). The time interval between surgery and pre-discharge echocardiography was 9.94±10 days (range, 5 to 26 days).

Echocardiographic evaluations were performed by experienced echocardiographers according to the American Society of Echocardiography guidelines [4]. TR was graded as none, trivial, mild, moderate, or severe. The TV annulus diameter of all patients was measured in the transthoracic apical 4-chamber view in late diastole at the time of maximal tricuspid opening [5].

Characteristic	Overall study population			Matched groups ^{a)}				
	Tri-Ad (n=36)	MC ³ (n=191)	p-value	St. Diff	Tri-Ad (n=34)	MC ³ (n=34)	p-value	St. Diff
Demographics								
Age (yr)	61.8±9.66	56.9±13.33	0.01	0.382	61.4±9.72	59.4±14.45	0.52	0.162
Men	11 (30.0)	108 (56.5)	0.01	0.598	11 (32.4)	9 (26.5)	0.60	0.157
Clinical history								
Smoking	5 (13.8)	31 (16.3)	0.72	0.101	5 (14.7)	6 (17.6)	0.74	0.120
Diabetes	4 (11.1)	20 (10.5)	0.91	0.037	4 (11.8)	4 (11.8)	> 0.99	0.000
Hypertension	12 (33.3)	41 (21.5)	0.12	0.333	12 (35.3)	13 (38.2)	0.80	0.070
Stroke history	7 (19.4)	23 (12.0)	0.23	0.313	7 (20.6)	8 (23.53)	0.77	0.094
Chronic renal failure	1 (2.8)	4 (2.1)	0.82	1 (2.9)	1 (2.9)	> 0.99	> 0.99	0.000
Coronary artery disease	3 (8.3)	8 (4.2)	0.29	0.404	3 (8.8)	3 (8.8)	> 0.99	0.000
Main etiology								
Left side valvular heart disease	35 (97.2)	166 (86.9)	0.08	0.916	33 (97.1)	34 (100.0)	0.33	-
Atrial septal defect	1 (2.8)	25 (13.1)	0.08	0.916	1 (2.9)	0	0.33	-
Cardiovascular assessment								
Body mass index (kg/m ²)	23.0±4.15	22.4±3.37	0.42	0.171	23.17±4.02	23.08±3.21	0.92	0.074
Preoperative New York Heart Association class ≥ III	25 (69.4)	64 (33.5)	<0.01	0.831	23 (67.6)	22 (64.7)	0.80	0.073
Atrial fibrillation	29 (80.5)	131 (68.6)	0.12	0.353	28 (82.4)	29 (85.3)	0.74	0.120
Reoperation	5 (13.9)	2 (1.0)	<0.01	1.502	3 (8.8)	2 (5.9)	0.64	0.241
Preoperative echocardiographic data								
LV dysfunction ≥ moderate	2 (5.6)	9 (4.7)	0.83	0.096	1 (2.9)	1 (2.9)	> 0.99	0.000
Pulmonary hypertension ≥ moderate	20 (56)	129 (67.5)	0.17	0.281	19 (55.9)	22 (64.7)	0.32	0.204
Tricuspid valve annulus diameter/body surface area (mm/m ²)	22.0±3.58	22.6±4.74	0.96	0.138	22.34±3.42	23.20±5.38	0.43	0.191
Preoperative tricuspid regurgitation grade ≥ severe	6 (16.7)	23 (12.0)	0.45	0.209	6 (17.6)	7 (20.3)	0.76	0.105

Values are presented as mean±standard deviation or number (%). The bold values indicate statistical significance at 95% confidence levels. Chronic renal failure was considered to be present in patients needing hemodialysis or peritoneal dialysis. Left side valve disease was defined as aortic valve disease or mitral valve disease. Moderate LV dysfunction was defined as an LV ejection fraction less than 40%. Moderate pulmonary hypertension was defined as a systolic pulmonary artery pressure more than 40 mm Hg. St. Diff, standardized difference; LV, left ventricle.

^{a)}All variables used to describe the baseline characteristics were used to calculate the propensity score, and patients were matched at a 1:1 ratio on the basis thereof. The differences between the propensity scores of matched patients were less than 0.1.

Table 2. Operative data and clinical outcomes

Variable	Overall study population			Matched groups ^{a)}		
	Tri-Ad	MC ³	p-value	Tri-Ad	MC ³	p-value
Basic operative data						
No. of patients	36	191		34	34	
Cardiopulmonary bypass time (min)	234.5±64.15	225.8±66.80	0.46	237.56±64.69	241.88±57.88	0.77
Aortic cross-clamping time (min)	156.1±55.07	148.0±50.70	0.41	158.21±55.98	162.53±43.06	0.72
Concomitant procedure						
Coronary artery bypass graft surgery	0	6 (3.1)	0.28	0	2 (5.9)	0.16
Aortic valve operation	8 (22.2)	48 (25.1)	0.71	8 (23.5)	9 (26.5)	0.59
Mitral valve operation	29 (80.6)	153 (80.1)	0.95	27 (79.4)	28 (82.4)	0.76
Cox maze procedure	27 (75.0)	118 (61.8)	0.13	26 (76.5)	26 (76.5)	>0.99
Atrial septal defect closure	1 (2.8)	31 (16.2)	0.03	1 (2.9)	0	0.32
Mortality						
Early mortality (≤30 day)	1 (2.8)	6 (3.1)	0.91	1 (2.9)	3 (8.8)	0.48
Morbidity						
Bleeding requiring reoperation	4 (12.0)	11 (5.8)	0.20	4 (11.8)	2 (5.9)	0.68
Acute renal failure	6 (18.0)	13 (6.8)	0.04	6 (17.6)	6 (17.6)	0.72
Stroke	1 (2.8)	4 (2.1)	0.58	1 (2.9)	1 (2.9)	0.48
LCOS	4 (12.0)	11 (5.8)	0.25	4 (11.8)	4 (11.8)	0.68
Postoperative echocardiographic results^{b)}						
No. of patients	35	185		31	31	
LV dysfunction ≥moderate	3 (8.6)	29 (15.7)	0.43	2 (5.9)	6 (3.2)	0.29
Pulmonary hypertension ≥moderate	8 (22.9)	44 (23.8)	>0.99	7 (25.5)	11 (41.9)	0.39
Tricuspid regurgitation grade ≥moderate	3 (8.3)	3 (1.6)	0.05	3 (9.7)	1 (6.5)	>0.99

Values are presented as mean±standard deviation or number (%), unless otherwise stated. The bold values indicate statistical significance at 95% confidence levels. LCOS was defined as being present in patients who needed mechanical support postoperatively to maintain cardiac output. Moderate LV dysfunction was defined as an LV ejection fraction less than 40%. Moderate pulmonary hypertension was defined as a systolic pulmonary artery pressure more than 40 mm Hg.

LCOS, low cardiac output syndrome; LV, left ventricle.

^{a)}All variables used to describe the baseline characteristics were used to calculate the propensity score, and patients were matched at a 1:1 ratio on the basis thereof. The differences between the propensity scores of matched patients were less than 0.1. ^{b)}Echocardiographic data from a case of early mortality were not included.

4) Statistical analysis

Statistical analysis was performed using IBM SPSS ver. 19.0 (IBM Corp., Armonk, NY, USA). Continuous and categorical data were expressed as the mean±standard deviation and median with range or proportion, respectively. The predicted probability acquired from the logistic equation and all the variables describing the baseline characteristics in Table 1 were used to calculate the propensity score for each case. Using the propensity score, patients who underwent TAP with a Tri-Ad ring were matched on a 1:1 basis with those in the MC³ group. The maximum allowable difference in the propensity score for matching was 0.1. Comparisons between the 2 groups were made using the Wilcoxon signed-rank test for continuous variables and the McNemar test for catego-

rical variables. Risk factor analysis for residual TR was performed using the chi-square test (Pearson chi-square and Fisher exact tests) for categorical variables and the Mann-Whitney test for continuous variables. All p-values <0.05 were considered to indicate statistical significance.

Results

Table 2 presents the operative and postoperative outcomes of TAP with a Tri-Ad ring. There was 1 case (2.8%) of operative mortality, and the cause of death was unidentified bleeding and hypovolemic shock. There were no late deaths. Postoperative complications occurred in 15 patients (41%), including acute renal failure in 6 patients (16%), bleeding re-

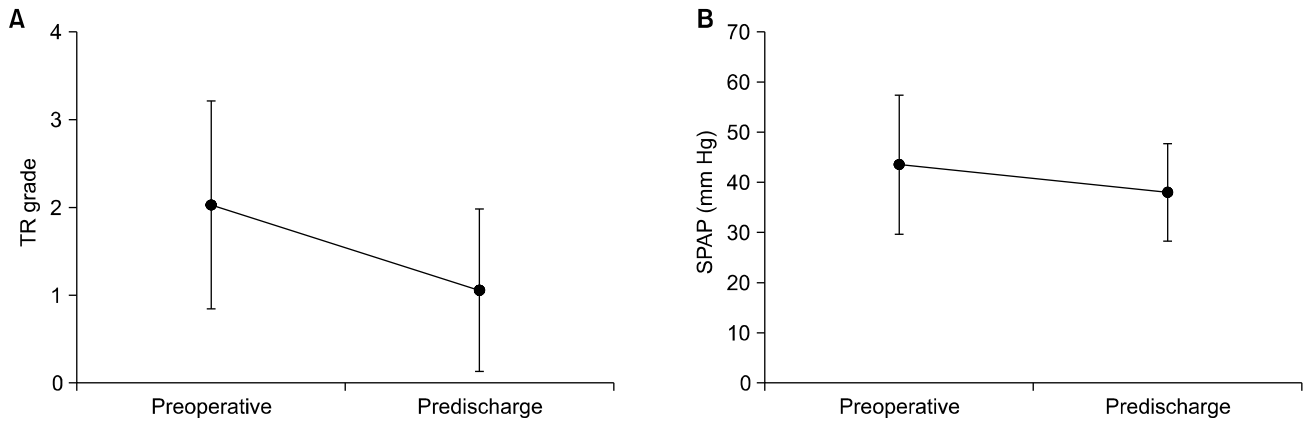


Fig. 1. Serial changes of TR grade (A) and SPAP (B). TR, tricuspid regurgitation; SPAP, systolic pulmonary artery pressure.

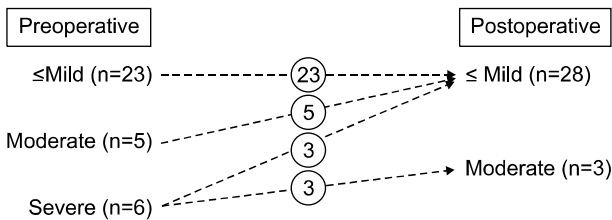


Fig. 2. Changes in tricuspid regurgitation (TR) severity before and after the procedure using the Tri-Ad ring. TR severity was classified as mild, moderate, or severe.

quiring reoperation in 4 patients (11%), low cardiac output syndrome in 4 patients (11%), and stroke in 1 patient (2.8%). No reoperations were performed for residual TR or permanent pacemaker insertion. In the propensity score-matched analysis, there was no significant difference in operative mortality and morbidity between the 2 groups.

After surgery with a Tri-Ad ring, the TR grade significantly decreased (from 2.03 ± 1.06 to 1.18 ± 0.92 , $p < 0.01$), as did the systolic pulmonary artery pressure (from 43.53 ± 13.84 to 38.00 ± 9.72 mm Hg, $p = 0.03$) (Fig. 1). Moderate TR was observed in 3 patients (8.3%) (Fig. 2) and the incidence of residual moderate or severe TR was significantly greater than in the MC³ group before matching. However, this difference was not observed in the matched analysis.

An analysis conducted to assess the factors associated with postoperative residual TR after TAP with a Tri-Ad ring demonstrated that patients with moderate or severe residual TR had more severe preoperative TR and a larger preoperative TV annulus and body surface area (Table 3).

Discussion

This study had 2 main findings. First, TAP with the new 3D prosthesis, the Tri-Ad Adams TAP ring, demonstrated good early clinical and echocardiographic outcomes that were comparable to those of the MC³ ring. Second, severe preoperative TR was associated with moderate or severe residual TR in the immediate postoperative period when using a Tri-Ad ring for TAP.

The tricuspid annulus has a 3D nonplanar structure. Hence, the ideal annuloplasty device should take into account its geometric characteristics and restore the innate 3D shape of the annulus to reduce leaflet stress and tethering. It should also remodel the RV along the area of maximal annular dilation and the RV free wall margin, while having an ‘open’ design to protect the conduction system as much as possible [6]. A ring device that is also flexible may provide good initial leaflet coaptation by preserving the dynamic motion of the annulus during the cardiac cycle [7]. More durable repair, however, may be better achieved by using a rigid annuloplasty ring [8,9]. McCarthy and colleagues analyzed 790 patients who underwent TV repair with either a suture or ring annuloplasty. They found that the incidence of TR increased gradually with the flexible Cosgrove-Edwards band, while it remained constant after implantation of the rigid Carpentier-Edwards ring [1]. The unique 3D design of the Tri-Ad ring, with its large open area, flexible ends, and rigid mid-portion, theoretically addresses all of the above necessities of an ideal annuloplasty ring. The Tri-Ad and MC³ rings

Table 3. Findings of patients with moderate or severe residual TR

Predischarge TR grade	Tri-Ad ring (n=35)		
	≤Mild (n=32)	≥Moderate (n=3)	p-value
Rhythm status			
Preoperative status			0.53
Normal sinus rhythm	7 (100.0)	0	
Atrial fibrillation	25 (78.1)	3 (10.7)	
Postoperative status			>0.99
Normal sinus rhythm	22 (91.7)	2 (8.3)	
Atrial fibrillation	10 (90.9)	1 (9.1)	
Preoperative tricuspid valve annulus diameter/body surface area (mm/m ²)	22.46±3.70	24.27±0.95	0.05
Preoperative pulmonary hypertension			0.57
SPAP ≤40 mm Hg	13 (86.7)	2 (13.3)	
SPAP >40 mm Hg	19 (95.0)	1 (5.0)	
Preoperative TR grade			
≤Moderate	29 (100.0)	0	<0.01
Severe	3 (50.0)	3 (50.0)	

Values are presented as number (%) or mean±standard deviation, unless otherwise stated. The bold values indicate statistical significance at 95% confidence levels.

TR, tricuspid regurgitation; SPAP, systolic pulmonary artery pressure.

Table 4. Characteristics of patients who underwent an add-on DeVega tricuspid valve annuloplasty maneuver

Sex	Age (yr)	Preoperative characteristics				Postoperative characteristics				Ring size	Etc.
		TR grade	TVA Ø (mm)	TVA Ø/BSA (mm/m ²)	SPAP (mm Hg)	TR grade	TVA Ø (mm)	TVA Ø/BSA (mm/m ²)	SPAP (mm Hg)		
M	72	Moderate	46	24	31	Trivial	34	18	37	28	Severe annular dilatation
M	50	Moderate	42	26	41	Mild	34	20	50	28	Severe annular dilatation
F	68	Severe	52	31	36	None	44	26	32	26	
F	62	Severe	39	25	35	Trivial	32	20	28	28	
F	75	Severe	32	22	33	Trivial	27	18	37	28	
F	84	Severe	35	25	26	Moderate	32	23	56	28	Preoperative RV dysfunction
F	69	Severe	36	23	64	Moderate	32	21	66	32	
F	49	Severe	37	24	22	Moderate	32	21	38	28	Preoperative RV dysfunction

TR, tricuspid regurgitation; TVA Ø, tricuspid valve annulus diameter (mm); BSA, body surface area; SPAP, systolic pulmonary artery pressure; M, male; F, female; RV, right ventricle.

both have a 3D design, a rigid portion, and a configuration to accommodate the saddle shape of the annulus. The rigid component of the Tri-Ad ring is located in the region corresponding to the RV free wall aspect of the annulus, and therefore functions as a remodeling ring. In contrast to the MC³ ring, both ends of the Tri-Ad ring are completely flexible, with a more open design that allows 3D movement and wider accommodation of the conduction system to reduce iatrogenic injuries [3]. Pfannmuller et al. [10] reported an 8.7% risk of TAP dehiscence in a large series using a rigid annuloplasty ring, compared to a

0.9% risk using a flexible band. In our study, no cases of immediate postoperative annuloplasty ring dehiscence were reported. None of the patients who underwent TV repair with a Tri-Ad ring reported a conduction block that required pacemaker implantation following surgery. In comparison, 2 of 193 patients (1.04%) in the MC³ group required pacemaker implantation after surgery for complete AV block during the follow-up. Although those cases of AV block might also be attributed to the Cox maze procedure or other concomitant surgery, the wider open area of the Tri-Ad ring may provide a protective effect on

the conduction system compared to the MC³ ring.

Moderate TR was observed in 3 patients (8.3%) after surgery with a Tri-Ad ring. The incidence of moderate or severe residual TR was significantly greater than in the MC³ group before matching, but this difference was not observed in the matched analysis (after propensity score matching, moderate or severe residual TR was found in 3 of the 31 patients [9.6%] in the Tri-Ad group and 2 of the 31 [6.5%] patients in the MC³ group). In the literature, the factors associated with residual TR after TV repair include atrial fibrillation, greater TR severity, higher pulmonary artery pressure, larger annular size, poorer left or right ventricular function, and the presence of intra-annular pacemaker leads [1,9,11-14]. In our study, patients with moderate or severe residual TR after TAP with a Tri-Ad ring had more severe preoperative TR and a larger preoperative TV annulus diameter and body surface area (Table 3).

In a sub-analysis of the patients with severe preoperative TR, moderate or severe residual TR was observed in 3 of the 6 patients in the Tri-Ad group (Fig. 2) and 2 of the 33 patients in the MC³ group. This finding may suggest that the TR correction effect of the Tri-Ad ring in the immediate postoperative period was weaker than that of the MC³ ring in the setting of severe TR. Compared to the MC³ ring, the Tri-Ad ring has a wider open area to reduce conduction injury and a shorter septal lateral dimension to allow more aggressive remodeling of the dilated RV and right atrium. Conversely, the Tri-Ad ring has relatively narrow coverage of the TV annulus, which may explain the higher incidence of residual TR in patients with severe TR preoperatively. Considering this, we performed an additional DeVega TAP procedure if the preoperative TR grade was severe, or if very severe annular dilatation was observed in the operative field (Table 4). This additional enforcement may explain why there was no significant residual TR in patients with very severe annular dilatation. Thus, in situations where severe annular dilatation is a concern, additional procedures such as DeVega TAP, pericardial patch enlargement of the tricuspid leaflets [15], or the edge-to-edge 'clover' technique [16] may be helpful in reducing residual TR. However, even with extra precautions, moderate residual TR was observed in 3 patients. When further investigated, 2 patients had pre-

operative RV dysfunction and 1 patient had a relatively high systolic pulmonary artery pressure preoperatively that did not diminish after surgery. Therefore, attention should be paid to the use of the Tri-Ad ring in patients with severe TR, especially when accompanied by RV dysfunction or high systolic pulmonary artery pressure. Even though TAP with a Tri-Ad ring did not result in significant TR, it would be prudent to evaluate the mid- and long-term outcomes of the Tri-Ad ring in terms of the incidence of residual TR in patients with severe preoperative TR.

In this study, several efforts were made to minimize selection bias. We only included patients with functional TR without any evidence of organic pathology. Due to the small number of cases, we compared the clinical outcomes of the Tri-Ad ring to those of patients who underwent TAP with an MC³ ring, which has well-established early and long-term clinical outcomes, and we chose to analyze the patients using matched propensity scores to minimize selection bias. This study was conducted at a single center and the procedures were performed by a single surgeon. Furthermore, we collected preoperative and pre-discharge echocardiographic data of all patients and investigated other relevant characteristics. Although this is the first study presenting the early clinical outcomes of the Tri-Ad ring, the retrospective study design and its small sample size, limited by the novelty of the Tri-Ad ring, could be limitations of this study.

In conclusion, TAP with the Tri-Ad ring corrected functional TR effectively and provided good early clinical and echocardiographic outcomes that were comparable to those obtained using the MC³ ring, with the absence of residual significant TR. However, care should be taken when using this product in patients with severe preoperative TR, and a follow-up study is necessary to confirm the stability of this procedure.

Conflict of interest

No potential conflict of interest relevant to this article was reported.

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