Outcome of MC3 ring annuloplasty for moderate and severe functional tricuspid regurgitation associated with rheumatic mitral valve disease

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Abstract

Background: To evaluate early and midterm outcomes of tricuspid ring annuloplasty using three-dimensional (3D) MC3 ring for treatment of functional tricuspid regurgitation (FTR) during mitral valve replacement for rheumatic valve disease.

Results: This prospective study included 105 patients who underwent repair for ≥ moderate tricuspid regurgitation (TR) during mitral valve replacement for rheumatic valve disease. Between January 2016 and December 2018, a group of 23 patients who underwent ring annuloplasty with Edward MC3 rings was compared to another group of 82 patients who underwent standard suture (DeVega) repair. The primary outcome was residual TR (≥ moderate TR). During an average follow-up period of 18.84 ± 9.90 months (range 3–33 months), the preoperative grade of TR improved significantly in both groups. The postoperative mean of TR in the MC3 group was significantly lower than that in the DeVega group (0.17 ± 0.49 versus 0.77 ± 0.93, $P = 0.004$). The rate of TR recurrence (≥ 2+ TR) was significantly higher after MC3 ring annuloplasty (4.3% versus 23.1%, $P = 0.03$). Freedom from mild TR was 30.5% in the DeVega group and 61% in the ring annuloplasty group ($P = 0.007$). Freedom from residual TR was 76.8% in the DeVega group and 95.7% in the ring annuloplasty group ($P = 0.04$).

Conclusions: The use of MC3 rings is a safe and effective alternative to DeVega repair for the management of FTR. However, further evaluation of long-term durability is recommended.

Keywords: Tricuspid valve, Functional tricuspid regurgitation, Suture annuloplasty, Ring annuloplasty

Background

Functional tricuspid regurgitation (FTR) is a common consequence with mitral valve disease (rheumatic, ischemic, degenerative, or dilated cardiomyopathy), secondary to dilation or dysfunction of the right ventricle, tricuspid annular dilatation, leaflet tethering, atrial fibrillation (AF), or pulmonary hypertension [1]. In patients with rheumatic heart disease (RHD), leaflet thickening and restriction of the tricuspid valve (TV) can result in FTR, but the incidence of organic TV involvement may be higher [2].

The available guidelines recommend the surgical treatment of severe FTR during valve surgery regardless of the presence of symptoms. However, in less than severe FTR, the decision for surgery is controversial, with a preference for surgery if there is a significant annular dilatation [1, 3].

Currently, the surgical techniques for FTR vary from suture repair to implantation of prosthetic rings. Since the first introduction of prosthetic rings for tricuspid annuloplasty in 1971, multiple ring designs have been developed to reinforce the tricuspid annulus by fixing the annulus during systole, restoring the physiologic valve geometry, reducing the annular dilatation, or restoring the 3D morphology [4]. The prosthetic rings for tricuspid annuloplasty have been categorized in

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accordance with the degree of rigidity, the completeness of the circularity, and the dimensionality. Therefore, the prosthetic ring may be rigid or flexible, complete or incomplete, and planar or three dimensional (3D) [5, 6].

The MC3 ring (Edwards LifeScience, Irvine, CA, USA), the first 3D ring, was introduced to restore the geometry of the tricuspid annulus relying on the advantage of accommodating the 3D aspect of the tricuspid annulus [7]. In literature, some studies have reported favorable early outcomes of MC3 rings for the management of FTR during surgery for left-valve disease [8, 9].

Generally, there is good evidence supporting ring annuloplasty over De Vega's annuloplasty supporting its use for moderate to severe TR [6]. However, the data still limited regarding the specification of outcomes to the pathology of the heart valve disease and type of prosthetic ring. Therefore, this study aimed to evaluate our own experience with the early and midterm outcomes of tricuspid annuloplasty using MC3 ring for repair of FTR associated with rheumatic mitral valve disease, in comparison to outcomes of suture repair.

Methods

This prospective study evaluated early and midterm outcomes after operations for TV repair which were performed at our institution, between January 2016 and December 2018. The mean follow-up duration was 18.84 ± 9.90 months (range 3–33 months). The study included 105 patients who underwent repair for FTR during mitral valve replacement for rheumatic valve disease. There were 82 patients who underwent suture (DeVega) repair and 23 patients underwent ring annuloplasty using Edward MC3 incomplete 3D ring. The indications of surgery for FTR were (1) severe TR or (2) moderate TR with annular dilatation greater than 40 mm and/or preoperative systolic pulmonary artery pressure (SPAP) > 50 mmHg. We excluded patients with non-rheumatic mitral disease, combined mitral and aortic valve replacement, mitral valve repair, concomitant coronary artery or aortic surgery, mild or organic tricuspid regurgitation, emergency surgery, reoperations, or missed data. Based on echocardiographic data, the severity of TR was graded as 0 (no TR), 1+ (mild TR), 2+ (mild to moderate TR), 3+ (moderately severe TR), or 4+ (severe).

The type of tricuspid valve repair was chosen according to the surgeon's preference and echocardiographic criteria of TV. The DeVega repair was performed when the patient had minimal annular dilation and lower severity of pulmonary hypertension, while ring annuloplasty was performed in patients with severe tricuspid annular dilation and severe pulmonary hypertension. The DeVega repair was performed on a beating heart using pledget-supported two 4-0 polypropylene running

parallel sutures. The MC3 ring annuloplasty was performed through right atriotomy using cardiopulmonary bypass and cardioplegic arrest. The ring size was determined after measurement of the length of the attachments of the tricuspid septal leaflet (the distance between the anteroseptal and septoposterior commissures) or the surface area of the anterior leaflet. The chosen ring was undersized by at least one size. The ring was implanted from the anteroseptal commissure to the middle of the septal leaflet. A series of 8 to10 mattress sutures with a 2-0 Ethibond multifilament suture were made on the tricuspid annulus starting from the center of the septal annulus to the anteroseptal commissure in the counter-clockwise direction, to avoid the atrioventricular conduction tissue. Thereafter, the sutures were placed through the sewing ring of the prosthesis (Fig. 1), followed by the lowering and securing of the ring to the annulus (Fig. 2).

The collected preoperative data included age, sex, New York Heart Association (NYHA) functional class, and the type of preoperative mitral valve disease. The primarily assessed postoperative outcome was residual TR ($\geq$ moderate TR; $\geq$ grade + 2). Other assessed pre- and postoperative parameters included the NYHA functional class and echocardiographic data regarding the grade of TR, SPAP, tricuspid annulus (TA) diameter, tricuspid annular plane systolic excursion (TAPSE), left atrial diameter (LAD), left ventricular end-diastolic dimension (LVEDD), left ventricular end-systolic dimension (LVESD), and left ventricular ejection fraction (LVEF).
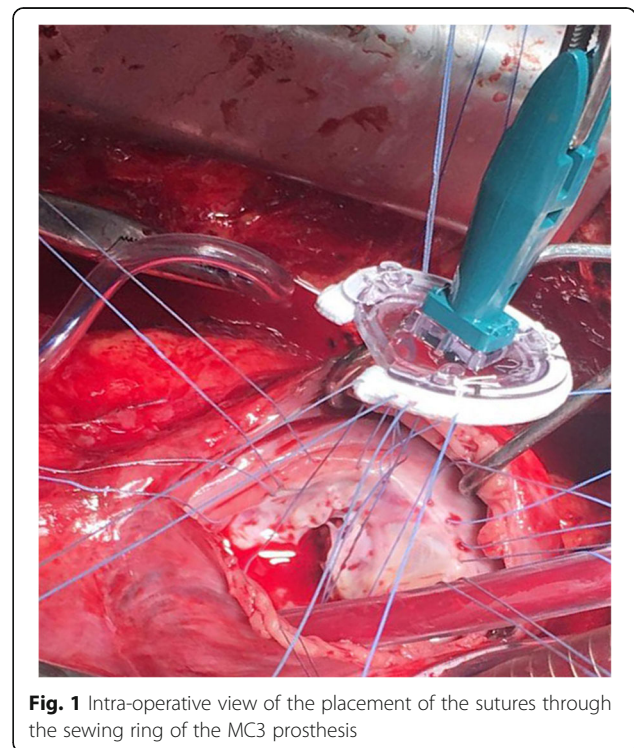
Fig. 1 Intra-operative view of the placement of the sutures through the sewing ring of the MC3 prosthesis
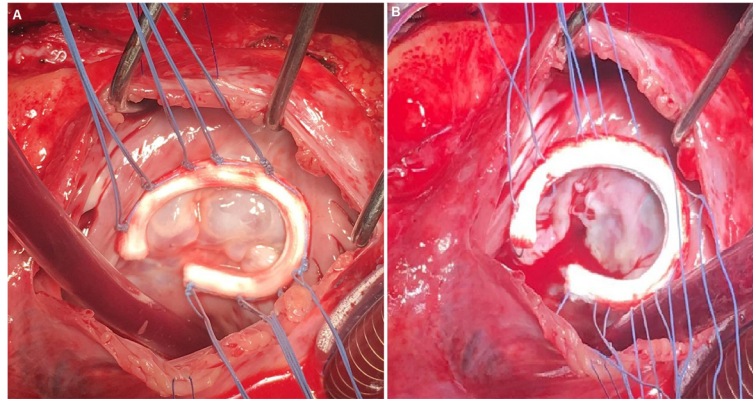
Fig. 2 Intra-operative view of lowering and securing of the MC3 ring to the tricuspid annulus. **a** During systole. **b** During diastole

Statistical analysis

The statistical analysis was performed using the SPSS software package (version 20.0; SPSS Inc., Chicago, IL, USA). The analyzed data were expressed as mean and standard deviation or as proportions. The studied groups were compared using the unpaired Student's t test for continuous independent variables and paired t test to compare related measurements. The categorical variables were compared using chi-squared test or Fisher's exact test if the expected frequency is less than 5. The Kaplan-Meier method was used to determine freedom from residual TR at the end of follow-up. P value < 0.05 was considered statistically significant.

Results

Preoperative demographic and clinical characteristics were similar between both groups (Table 1). There was a significant improvement in the preoperative grade of TR following surgery in each group (Fig. 3). There was no significant difference in the preoperative echocardiographic parameters between both groups of tricuspid annuloplasty regarding the grade of TR, SPAP, TA diameter, TAPSE, LAD, LVEDD, LVESD, and LVEF (Table 1).

Regarding comparisons of postoperative and baseline preoperative echocardiographic measurements in each group, there was a significant decrease in the mean of TR grade, SPAP, TA diameter, LAD, and LVESD in both groups, with a significant increase in the mean of LVEDD and LVEF. Moreover, there was a significant increase in the mean of postoperative TAPSE after MC3 ring annuloplasty (Table 2). Comparing the postoperative echocardiographic measurements between both groups revealed non-significant differences, except for the postoperative mean of TR in the MC3 group which was significantly lower than that in the DeVega repair group (0.17 ± 0.49 versus 0.77 ± 0.93, P = 0.004) (Table 3). The postoperative frequency of patients without TR

(grade 0) in the MC3 group was significantly higher than that in the DeVega repair group (87% versus 51.2%, P = 0.002). The rate of TR recurrence (≥ 2+ TR) was significantly higher after MC3 ring annuloplasty (4.3% versus 23.1%, P = 0.03) (Table 4).

Regarding operative data and early postoperative outcomes (Table 5), the group of MC3 ring annuloplasty had significantly higher cardiopulmonary bypass (CPB) time (128.8 ± 24.7 min versus 141.9 ± 28.4 min, P = 0.03) and cross-clamp time (71.8 ± 23.7 min versus 84.3 ± 19.2

Table 1 Preoperative demographic, clinical, and echocardiographic data

Variables	DeVega ($n =$ 82)	MC3 ring ($n =$ 23)	P value
Age (years)	48 ± 11.8	46.2 ± 11.2	0.53
Female gender	53 (64.6%)	14 (60.9%)	0.74
NYHA class (III/IV)	52 (63.4%)	16 (69.6%)	0.58
Atrial fibrillation	45 (54.9%)	13 (56.6%)	0.88
Mitral valve disease			
Stenosis	18 (23.2%)	6 (26.1%)	0.68
Insufficiency	25 (30.5%)	4 (17.4%)	0.29
Stenosis and insufficiency	38 (46.3%)	13 (56.5%)	0.38
Preoperative TR grade	2.55 ± 0.61	2.39 ± 0.65	0.28
SPAP (mmHg)	47.87 ± 14.70	52.21 ± 15.43	0.21
TA diameter (mm)	34.62 ± 5.33	34.56 ± 5.56	0.96
TAPSE (mm)	18.23 ± 3.11	17.13 ± 2.76	0.12
LAD (mm)	42.97 ± 4.10	42.13 ± 4.33	0.39
LVEDD (mm)	42.34 ± 2.37	42.08 ± 2.87	0.66
LVESD (mm)	34.32 ± 1.79	34.21 ± 1.47	0.78
LVEF (%)	55.73 ± 8.93	55.13 ± 9.45	0.77

NYHA New York Heart Association, *TR* tricuspid regurgitation, *SPAP* systolic pulmonary artery pressure, *TA* tricuspid annulus, *TAPSE* tricuspid annular plane systolic excursion, *LAD* left atrial diameter, *LVEDD* left ventricular end-diastolic dimension, *LVESD* left ventricular end-systolic dimension, *LVEF* left ventricular ejection fraction
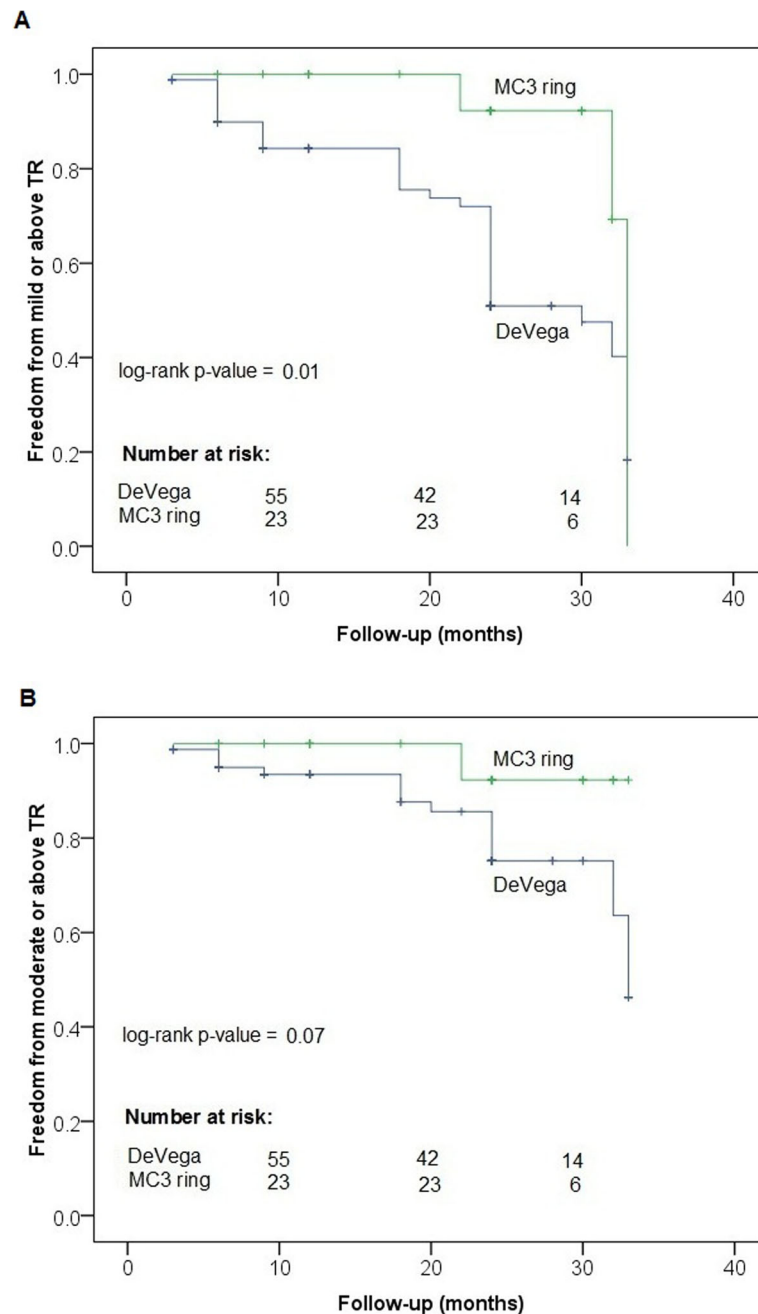
Fig. 3 a Freedom from ≥ mild tricuspid regurgitation (TR) after DeVega repair and MC3 ring annuloplasty. **b** Freedom from ≥ moderate tricuspid regurgitation (TR) after DeVega repair and MC3 ring annuloplasty

min, $P = 0.02$). There were no significant differences between both groups regarding the need for postoperative intraaortic balloon pump (IABP) support (2.4% versus 4.3%) and the incidence of heart block (1.2% versus 8.7%). During the follow-up period, freedom from mild TR was 30.5% in the DeVega group and 61% in the ring annuloplasty group ($P = 0.007$) (Fig. 3a). Freedom from residual TR was 76.8% in the DeVega group and 95.7% in the ring annuloplasty group ($P = 0.04$) (Fig. 3b).

Discussion

The repair of FTR in patients undergoing left heart valve surgery has a controversy among surgeons in terms of timing for intervention and technique of repair [10]. However, the persistence of moderate and severe TR after mitral valve surgery may lead to progressive heart failure or death [11].

The DeVega suture repair is the most commonly used technique of TV repair. However, high recurrence rates

Table 2 Mean difference between follow-up and preoperative echocardiographic data in relation to the type of tricuspid repair

Echocardiographic variables	DeVega (n = 82)		MC3 ring (n = 23)	
	Mean difference	P value	Mean difference	P value
TR grade	− 1.78	< 0.001*	− 2.22	< 0.001*
SPAP (mmHg)	− 15.35	< 0.001*	− 18.95	< 0.001*
TA diameter (mm)	− 4.20	< 0.001*	− 4.78	0.001*
TAPSE (mm)	+ 0.66	0.17	+ 1.87	0.02*
LAD (mm)	− 10.54	< 0.001*	− 8.96	< 0.001*
LVEDD (mm)	+ 0.16	0.001*	+ 2.22	0.002*
LVESD (mm)	− 1.28	< 0.001*	− 1.78	< 0.001*
LVEF (%)	+ 10.63	< 0.001*	+ 16.04	< 0.001*

TR tricuspid regurgitation, *SPAP* systolic pulmonary artery pressure, *TA* tricuspid annulus, *TAPSE* tricuspid annular plane systolic excursion, *LAD* left atrial diameter, *LVEDD* left ventricular end-diastolic dimension, *LVESD* left ventricular end-systolic dimension, *LVEF* left ventricular ejection fraction
*Significant difference between follow-up and preoperative values within the same group

have been reported with DeVega repair, particularly in patients with severe tricuspid annular dilation and/or pulmonary hypertension [12]. To overcome this issue, the search focused on the use of more anatomically relevant techniques for the management of FTR. For this purpose, ring annuloplasty has been used in the tricuspid position and achieved better results than suture repair [13–15]. The nonplanar, saddle-shaped, 3D structure, the tricuspid annulus favors the use of MC3 ring annuloplasty since its introduction in 2004 [16].

Table 3 Comparison of postoperative echocardiographic between types of tricuspid repair

Echocardiographic variables	DeVega (n = 82)	MC3 ring (n = 23)	P value
TR grade	0.77 ± 0.93	0.17 ± 0.49	0.004*
SPAP (mmHg)	32.52 ± 7.50	33.26 ± 8.83	0.69
TA diameter (mm)	30.42 ± 2.99	29.78 ± 3.20	0.37
TAPSE (mm)	18.89 ± 2.55	19 ± 2.81	0.85
LAD (mm)	32.43 ± 4.71	33.17 ± 5.22	0.52
LVEDD (mm)	43.50 ± 2.04	44.30 ± 1.22	0.07
LVESD (mm)	33.04 ± 1.46	32.43 ± 0.99	0.06
LVEF (%)	66.35 ± 2.07	66.73 ± 2.11	0.43

TR tricuspid regurgitation, *SPAP* systolic pulmonary artery pressure, *TA* tricuspid annulus, *TAPSE* tricuspid annular plane systolic excursion, *LAD* left atrial diameter, *LVEDD* left ventricular end-diastolic dimension, *LVESD* left ventricular end-systolic dimension, *LVEF* left ventricular ejection fraction
*Significant difference between follow-up and preoperative values within the same group

Our study compared early and midterm outcomes after MC3 ring annuloplasty in 23 patients with outcomes after DeVega repair in 82 patients, over an average follow-up period of 18.84 ± 9.90 months (range 3–33 months). We included patients with severe FTR or moderate TR with severe annular dilatation greater and/or pulmonary hypertension, and our primary outcome was residual TR (≥ moderate TR) during the follow-up period. The main findings in the present study are (1) the improvement of midterm echocardiographic parameters in both groups of tricuspid repair on comparison to preoperative values and (2) the superiority of MC3 ring annuloplasty in regards to lower postoperative grade of TR (0.17 ± 0.49 versus 0.77 ± 0.93, *P* = 0.004), lower recurrence rate of ≥ 2+ TR (4.3% versus 23.1%, *P* = 0.03), and higher midterm freedom from mild (61% versus 30.5%, *P* = 0.007) and moderate TR (95.7% versus 76.8%, *P* = 0.04). Additionally, we had acceptable incidences of heart block and postoperative use of IABP, beside the midterm absence of ring dehiscence, prosthetic ring endocarditis, and thromboembolic events.

Our favorable and superior outcomes after MC3 ring annuloplasty are comparable to other studies in literature [7–9, 16, 17]. The early study by Filsoufi et al. [7] included 75 patients with FTR with mean TR grade of 3.1 ± 0.9 and concomitant procedures of mitral valve repair, replacement, aortic valve replacement, coronary artery bypass grafting, and left atrial maze. The echocardiographic study demonstrated a stable significant decrease in TR (0.3 ± 0.5) after a median follow-up of 16 months (range 4–34), with no cases of ring dehiscence, prosthetic ring endocarditis, or thromboembolic events. The echocardiographic follow-up study by Fukuda et al. [16] of 136 patients with FTR confirmed the significant improvement in the severity of TR early after surgery and TR graded greater than moderate in 14% among patients followed more than 1 year. However, additional maneuvers to ensure valve competence were required in patients with extensive leaflet tethering. Jeong and Kim [8] investigated the clinical performance of MC3 rings in 103 patients with an average preoperative TR grade of 2.5 ± 0.8, during a mean follow-up of 26.7 ± 11.2 (range 0–52) months. The TR grade significantly decreased from 2.5 ± 0.8 preoperatively to 0.8 ± 0.8 before discharge (*P* < 0.001), which was stable through a median follow-up of 15 months. Additionally, there was a significant improvement in systolic pulmonary artery pressure. Moreover, comparing the outcomes of tricuspid annuloplasty with 3D-rigid versus flexible prosthetic ring for FTR in the study by Wang et al. [17] revealed that MC3 might be more effective for tricuspid ring annuloplasty in FTR in midterm postoperative periods regarding recurrence of TR in 30.3% of the rigid group versus 54.3% of the flexible group.

Table 4 Grades of tricuspid regurgitation at the last follow-up visit

Grades	DeVega (n = 82)		MC3 ring (n = 23)		P value
	N (%)	Mean follow-up (months)	N (%)	Mean follow-up (months)	
0	42 (51.2%)	23.5 ± 1.24	20 (87%)	20.5 ± 2	0.002*
1+	21 (25.6%)	28.3 ± 1	2 (8.7%)	32.7 ± 0.3	0.09
2+	16 (19.5%)	29.6 ± 0.92	1 (4.3%)	32.1 ± 0.18	0.11
3+	2 (2.4%)	32.7 ± 0.22	0 (0%)	–	1
4+	1 (1.2%)	32.6 ± 0.34	0 (0%)	–	1

SD standard deviation
*Significant difference

Overall, the midterm durability of MC3 rings and the superiority of the MC3 ring annuloplasty over the DeVega suture repair determined in our study and in other studies could be related to the superiority of the ring in remodeling of the TV annulus effectively compared to suture repair. Remodeling of the TV annulus could decrease the tension on suture lines, increase the leaflet coaptation, and prevent the recurrence of annular dilatation [18, 19].

Some authors investigated the predictors of midterm residual TR after MC3 ring annuloplasty [9, 20]. Little number of patients in our study was against multivariate regression analysis, but mentioning the results of these studies may be helpful for proper selection of patients for other surgical interventions with MC3 rings. Yoda et al. [9] investigated the midterm outcomes of MC3 ring in 136 patients with severe TR, or mild or moderate TR with pulmonary hypertension or TA dilatation. Although, the MC3 ring was effective for the correction of FTR, preoperative severe TR, left ventricular end-diastolic dimension > 70 mm, right ventricular dimension > 40 mm, dilated cardiomyopathy (DCM), and left ventriculoplasty associated with repair failure and residual TR. In the study by De Bonis et al. [20] tricuspid annuloplasty with the MC3 ring provided satisfactory

Table 5 Operative data and early postoperative outcomes

Variables	DeVega (n = 82)	MC3 ring (n = 23)	P value
CBP time (min)	128.8 ± 24.7	141.9 ± 28.4	0.03*
Cross-clamp time (min)	71.8 ± 23.7	84.3 ± 19.2	0.02*
Postoperative IABP support	2 (2.4%)	1 (4.3%)	1
Heart block	1 (1.2%)	2 (8.7%)	0.11

CPB cardiopulmonary bypass, *IABP* intraaortic balloon pump
*Significant difference

early results in 135 patients which remain stable at midterm follow-up of 22 ± 9.5 months (median 23 months). Those authors reported that the presence of other mechanisms besides annular dilatation (leaflet prolapse, pace-maker wires, and fibrotic leaflets' retraction) leads to residual TR after ring annuloplasty alone.

Interestingly, some authors developed certain methods in order to reduce the residual TR after MC3 ring annuloplasty, such as the placement of horizontal mattress sutures on the annulus beyond the anteroseptal commissure and away from the deemed atrioventricular node artery/vein [21], adjustment the point of fixation of the septal portion to the septal annulus [22], and septal plication technique [23]. These modifications are not the concern of our study, but its promising results encourage us to recommend its evaluation in the future studies.

In the present study, our finding of a significant increase in the postoperative TAPSE after MC3 ring annuloplasty in comparison to the preoperative values reflects more preservation of the global right ventricular function with MC3 rings. TAPSE is a parameter of global RV function which describes apex-to-base shortening. TAPSE correlates closely with the RVEF and has been found to be both highly specific and easy to measure [24].

Study limitations
This study is limited by being a single center experience, including a small number of patients. Moreover, the surgeon's preference directed the choice between DeVega repair and ring annuloplasty. Also, other types of annuloplasty rings were not available at our institution, and thus, it could not be compared to the 3D ring annuloplasty.

Conclusions
In conclusion, the low incidence of midterm residual TR and the preservation of the global right ventricular function after tricuspid annuloplasty using MC3 for FTR encourage its substitution to the traditional DeVega repair in patients with rheumatic mitral valve disease. However, there is a need to check its durability in long-term and randomized studies.

Authors' contributions
SEA conceived and planned the study and supervised the findings of the work. YSM conceived of the study, participated in its design and coordination, and helped to draft the manuscript. YAK participated in the design of the study, carried out the collection of the data and drafting the manuscript, and performed the statistical analysis. All authors cared for the patients. All authors read and approved the final manuscript.

Availability of data and materials
The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate
This work was approved by an internal committee under the supervision of the head of departments of surgery at our institution. Additionally, we adhered to a set of ethical principles in the *Declaration of Helsinki* regarding human experimentation. A written consent to participate was taken from all patients. The manuscript has a reference number of 62-15 and it has been registered in ClinicalTrials.gov under number of NCT04078867.

Consent for publication
It was taken from patients.

Competing interests
The authors declare that they have no competing interests.

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