Original Article

Comparison of outcomes of tricuspid annuloplasty with 3D-rigid versus flexible prosthetic ring for functional tricuspid regurgitation secondary to rheumatic mitral valve disease

Haiping Wang[1,2], Xiancheng Liu[2], Xin Wang[2], Zhenqian Lv[2], Xiaojun Liu[2], Ping Xu[1]

[1]Department of Cardiovascular Surgery, Qingdao University, Affiliated Hospital of Qingdao University, Qingdao 266000, China; [2]Department of Cardiovascular Surgery, Qingdao Fuwai Cardiovascular disease Hospital, Qingdao 266034, China

Contributions: (I) Conception and design: H Wang, X Liu, P Xu; (II) Administrative support: X Liu; (III) Provision of study materials or patients: X Liu; (IV) Collection and assembly of data: H Wang, Z Lv, X Liu; (V) Data analysis and interpretation: H Wang, X Wang; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Ping Xu. Department of Cardiovascular Surgery, Qingdao University, Affiliated Hospital of Qingdao University, No.16 Jiangsu Road Shinan District, Qingdao 266000, China. Email: xuping66@yeah.net; Xiancheng Liu. Department of Cardiovascular Surgery, Qingdao Fuwai Cardiovascular disease Hospital, No.201 Nanjing Road Shibei District, Qingdao 266034, China. Email: liuxiancheng66@sina.com.

Background: Annuloplasty bands and rings are widely used for repairing functional tricuspid regurgitation (FTR). However, the question regarding which is the ideal annuloplasty device remains unclear. The aim of this study was to compare the efficacy and mid-term durability of tricuspid ring annuloplasty for FTR secondary to rheumatic mitral valve disease using flexible Cosgrove-Edwards band and the rigid Edwards MC3 ring (Edwards Lifesciences, LLC, Irvine, CA, USA).

Methods: We retrospectively collected the clinical data of those who underwent mitral valve replacement (MVR) in concomitant with tricuspid ring annuloplasty from 2009 to 2013. The flexible band was used in 46 patients (flexible group), and the 3D rigid ring was used in 60 patients (rigid group). Echocardiographic evaluation of tricuspid function was performed preoperatively and postoperatively.

Results: The grade of TR was significantly improved compared to preoperative values in two groups. There was no significant difference regarding postoperative TR grade between the two groups at 1 week and 2–3 months but there was statistical significant difference at postoperative 6–12 months, and 2–3 years. During the follow up period, 25 of 46 patients (54.3%) in flexible group and 22 of 60 patients (30.3%) in rigid group developed recurrent TR. Freedom from recurrent TR in flexible group is significant lower than rigid group in each postoperative follow up period.

Conclusions: These findings suggest that 3D rigid ring annuloplasty might be more effective for tricuspid ring annuloplasty in FTR in mid-term postoperative periods when compared to flexible band.

Keywords: Tricuspid regurgitation (TR); tricuspid valve repair; ring annuloplasty

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Introduction

Functional tricuspid regurgitation (FTR) is common in patients with rheumatic mitral valve disease (1,2). The primary causes of FTR are annular dilation and right ventricular enlargement which may lead to tricuspid anatomical and functional abnormalities (3). FTR is often secondary to left heart failure from myocardial or valvular causes, right ventricular volume and pressure overload, and dilation of cardiac chambers. Secondary (functional) tricuspid regurgitation (TR) is associated with poor outcome and predicts poor survival, heart failure, and reduced functional capacity (4). However, the optimal

surgical technique such as repair *vs*. replacement, access, type of prosthesis to rectify TR remains challenging (5).

Due to the high-risk of postoperative complications after tricuspid valve replacement, repair is currently the preferred surgical method for FTR (6). The two principal surgical methods of tricuspid valve repair include suture and prosthetic annuloplasty (i.e., flexible band and remodeling ring). Suture annuloplasty, such as the Kay method (7) and the De Vega method (8), are routinely used for tricuspid valve repair by bicuspidization or reduce annular size semicircularly. It has the advantages of technically easy and low patient's economic burden, however associated with relatively high recurrent TR rate (9,10). Ring annuloplasty can reduce or remodel the dilated annulus by using prosthetic rings (flexible or rigid). Compared with suture methods, prosthetic ring annuloplasty may be associated with better prevention of annular dilation, right ventricular volume overload and right ventricular failure (11). Ring annuloplasty is currently favored for surgical treatment of secondary TR. However, despite the advantages of ring annuloplasty for functional TR (5), the efficacy and durability of specifically shaped tricuspid prosthetic rings (i.e., flexible or rigid) have not yet been thoroughly elucidated.

Currently, whether flexible or rigid rings should be used remains controversial. Navia *et al*. (12) and Izutani *et al*. (13) reported a lower rate of recurrent TR with a rigid annuloplasty ring compared with a flexible ring. On the contrast, Pfannmüller *et al*. (14) reported a higher rate of annuloplasty dehiscence after the implantation of a rigid ring. In the present study, the purpose was to compare the efficacy and mid-term durability of tricuspid ring annuloplasty for FTR secondary to rheumatic mitral valve disease using Cosgrove-Edwards flexible band and the Edwards MC3 rigid ring (Edwards Lifesciences, LLC, Irvine, CA, USA).

Methods

This retrospective study was approved by the ethics committee of Qingdao Fuwai Hospital (No. 002/2009) and conducted in accordance with the Declaration of Helsinki. Written informed consent before the surgical procedures and for the use of personal information for research purposes was obtained from each patient. We retrospectively collected and analyzed the clinical data of patients undergoing mitral valve replacement (MVR) and tricuspid ring annuloplasty using Cosgrove-Edwards flexible band or Edwards MC3 rigid ring for FTR with concomitant rheumatic mitral valve disease at our hospital from September 2009 to December 2013. The indications for tricuspid ring annuloplasty were moderate and above FTR. Patients with tricuspid insufficiency caused by congenital tricuspid valve abnormalities or primary lesion such as trauma, infective endocarditis and autoimmune disease were excluded from this study. Patients who were treated with simultaneous aortic valve replacement, coronary artery bypass surgery, radiofrequency ablation of atrial fibrillation, and surgical correction of congenital heart disease were also excluded.

Preoperative echocardiographic assessment

All patients were assessed preoperatively by transthoracic two-dimensional and color Doppler echocardiography. The severity of TR were evaluated using the apical four chamber view and was graded as 0 for no regurgitation, 1+ for mild regurgitation, 2+ for moderate regurgitation, 3+ for moderately severe regurgitation, and 4+ for severe regurgitation (5,15).

Surgical procedures

All surgeries were performed through median sternotomies with bicaval and aortic cannulation and standard hypothermic cardiopulmonary bypass (CPB) by the same surgeon. After clamping the ascending aorta, the right atrium and interatrial septum were dissected. If there existed left atrial thrombus, thorough clearage can be achieved bluntly or vacuum aspiration as appropriate. Thereafter, tricuspid valve repair was performed with flexible band or with rigid ring annuloplasty following concomitant MVR and closure of atrial septal incision. In this study, two kinds of tricuspid annuloplasty devices were used: Cosgrove-Edwards flexible band and Edwards MC3 rigid ring. For patients receiving flexible band, tricuspid ring annuloplasty was done with the use of the Cosgrove-Edwards annuloplasty system. Seven to ten 2–0 Ethibond Excel sutures (Ethicon Endo-Surgery, LLC, USA) were placed on the annulus along the anterior and posterior leaflets. A Cosgrove-Edwards flexible band was tied down with the sutures and placed on the annulus under cardiac arrest. For patients receiving rigid ring, tricuspid ring annuloplasty were done with the use of the Edwards MC3 tricuspid annuloplasty system. Nine to eleven 2–0 Ethibond Excel sutures were placed on

the annulus, running from the anteroseptal commissure to the middle of the septal leaflet along the anterior and posterior leaflets. A MC3 rigid ring was tied down with the sutures and placed on the annulus under cardiac arrest. In both conditions, the ring size was determined by the length between the commissures along the septal leaflet under cardiac arrest. The prosthetic valves used during MVR were all On-X Mitral Prothetic Heart Valve (On-X Life Technologies, Inc., USA).

Follow-up

After surgery, patients were followed up on postoperative day seven and regularly every three to six months. The patients were followed at outpatient clinic in our hospital. During the follow up period, patient's clinical status and echocardiographic results were obtained by the cardiologists.

Statistical analysis

All data analyses were performed by using the Statistical Package, version 17.0 (SPSS Inc., Chicago, IL, USA). Categorical variables were expressed as numbers and/or percentage and compared using the χ^2 test or Fisher's exact test as appropriate. Continuous variables are expressed as mean ± standard deviation (SD) and compared by Student's *t*-test or Mann- Whitney U test. Survival probabilities were constructed using Kaplan–Meier survival estimates. Comparisons between survival curves were performed by using the log-rank test. The differences were considered statistically significant at a $P<0.05$.

Results

Baseline data

A total of 106 patients undergoing MVR and tricuspid ring annuloplasty for FTR with concomitant rheumatic mitral valve disease were included in this study. The flexible bands were used in 46 patients (flexible group) between September 2009 and November 2011. Since then, the rigid rings were used in the remaining 60 cases (rigid group) between December 2011 and December 2013. The mean age of patients in flexible group and rigid group was 56±5.2 years old and 58±4.8 years old, respectively. The degrees of preoperative FTR were 3.31±0.39 and 3.47±0.31 in flexible group and rigid group, respectively. There was no significant difference between the two groups regarding age, sex, BMI, New York Heart Association (NYHA) functional classification, Mitral disease, degree of FTR, tricuspid annular diameter, tethering distances, right ventricular diameter (RVD), left ventricular ejection fraction (LVEF), and left ventricular end diastolic dimension (LVDD) (all $P>0.05$) (*Table 1*).

Operative characteristics and Mortality

Operative outcomes in two groups are shown in *Table 2*. There was no statistical significant difference regarding prothetic mitral valve size, annuloplasty ring size, operation time, CPB time, cardiac arrest time, intensive care unit (ICU) stays, hospital stays, and ventilator time mortality between the flexible group and the rigid group (all $P>0.05$).

Mortality and follow up

Postoperatively, three were two cases (including 1 of 46 cases in flexible group and 1 of 60 cases in rigid group) who died during hospitalization, giving a hospital mortality rate of 1.9%. Late death occurred in five patients including two cases in flexible group and three cases in rigid group. The overall mortality was 3 of 46 (6.5%) in flexible group and 4 of 60 (6.7%) in rigid group ($P>0.05$). The causes of hospital and late mortality were shown in *Table 3*.

The mean follow-up was 34.5±9.3 months (range, 24–48 months). Follow up of 93 cases (90%) was successfully achieved. During the follow-up period, there was one case of infective endocarditis in each group, who occurred at 8 months after surgery (flexible group) and 2 years after surgery (rigid group), respectively. Between 30 and 40 months after surgery, echocardiography was performed in 15 cases in flexible group, and 22 cases in rigid group. There were no prosthetic-related complications such ring dehiscence, thromboembolic event in two groups during the follow up period.

Cardiac function improvement was seen in all surviving patients after operation. The average NYHA functional class was significantly improved compared to preoperative values in two groups (all $P<0.01$) (*Table 4*). There was no significant difference regarding postoperative NYHA functional class between the two groups at postoperative day 7, 2–3 months, and 6–12 months but there was statistical significant difference at 2–3 years. These may be due to three-dimensional MC3 rigid ring is able to provide better long-term stability of tricuspid valve repair.

Table 1 Preoperative characteristics in two groups

Patient characteristics	Flexible group (n=46)	Rigid group (n=60)	P
Age, years	56±5.2	58±4.8	0.857
Weight (kg)	63±7.3	58±8.1	0.674
Sex, n (%)			0.975
Male	19 (45.0)	31 (46.0)	
Female	27 (55.0)	29 (54.0)	
NYHA functional class	3.15±0.66	3.17±0.67	0.875
I	0	0	
II	6	9	
III	24	32	
IV	16	19	
Mitral disease, n (%)			0.873
Stenosis	12 (26.1)	17 (28.4)	
Predominant insufficiency	5 (10.9)	8 (18.3)	
Mixed lesions	29 (63.0)	35 (58.3)	
Preoperative TR grade, n	3.31±0.39	3.47±0.31	0.371
None	0	0	
Mild	0	0	
Moderate	6	11	
Moderate to severe	10	15	
Severe	20	34	
*Tricuspid annular diameter (mm)	56±13.1	58±11.8	0.660
*Tethering distances (mm)	7.1±2.4	6.9±2.7	0.243
RVD	38±9.3	39±11.6	0.380
LVEF (mm)	51±6.3	50±7.6	0.427
LVDD (mm)	52±6.1	51±5.7	0.752

*, tricuspid annular dilatation and tethering distances measured by transthoracic echocardiography on the four-chamber view from the cardiac apex. RVD, right ventricular diameter; LVDD, left ventricular end diastolic dimension; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association.

Table 2 Operative characteristics in two groups

Patient characteristics	Flexible group (n=46)	Rigid group (n=60)	P
CPB time (min)	96±16.8	102±19.3	0.380
Cardiac arrest time (min)	65±11.3	72±15.3	0.460
Operation time (hours)	3.7±0.9	3.8±0.6	0.242
ICU stay (hours)	50.6±19.2	53.9±17.8	0.211
Hospital stays (days)	10.9±3.1	11.1±3.7	0.548
Ventilator time (hours)	20.3±5.0	18.8±5.7	0.387
Size of prothetic mitral valve (mm)	28±1.8	28±1.9	0.551
Annuloplasty ring size (mm)	28±1.9	28±2.1	0.521

CPB, cardiopulmonary bypass; ICU, intensive care unit.

Table 3 Cause of mortality

Outcomes	Flexible group (n=46) (%)	Rigid group (n=60) (%)
In-hospital death	1 (2.2)	1 (1.7)
Sudden cardiac arrest	1 (2.2)	—
Infective shock	—	1 (1.7)
Late death	2 (4.3)	3 (5.0)
Cerebral hemorrhage	1 (2.3)	—
Excessive hydropericardium	—	1 (1.7)
Sudden death	1 (2.3)	1 (1.7)
Malignant tumor	—	1 (1.7)
Total	3 (6.5)	4 (6.7)

Table 4 Postoperative NYHA functional class in two groups

Time	Flexible group (n=46)	Rigid group (n=60)
Preoperatively	3.13±0.54	2.98±0.61
1 week after operation	1.91±0.81[a]	1.86±0.79[a]
2–3 months after operation	1.31±0.74[a]	1.35±0.81[a]
6–12 months after operation	1.53±0.78[a]	1.36±0.77[a]
2–3 years after operation	1.85±0.84[a]	1.38±0.75[a,b]

[a], *vs*. preoperative values, P<0.01; [b], *vs*. flexible group, P<0.05; NYHA, New York Heart Association.

Table 5 Postoperative TR grade in two groups

Time	Flexible group (n=46)	Rigid group (n=60)	P
Preoperative	3.31±0.39	3.47±0.31	0.371
1 week after operation	1.46±0.47[a]	1.52±0.55[a]	0.405
2–3 months after operation	1.51±0.55[a]	1.33±0.37[a]	0.128
6–12months after operation	2.18±0.67[a]	1.35±0.45[a,b]	0.034
2–3 years after operation	2.38±0.51[a]	1.57±0.47[a,b]	0.002

[a], *vs*. preoperative, P<0.05; [b], *vs*. flexible group, P<0.05; TR, tricuspid regurgitation.

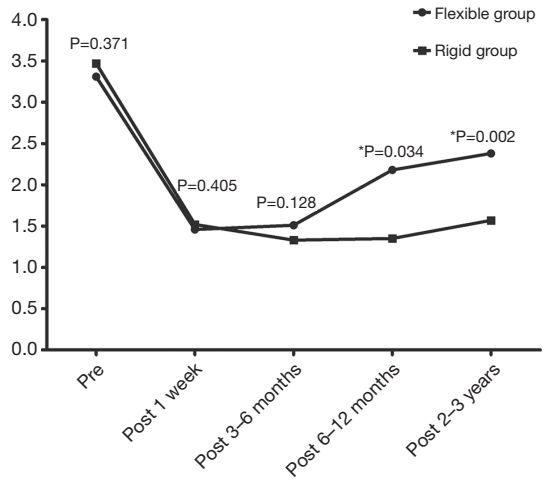

Figure 1 Changes of pre- and postoperative TR grade in flexible group and Rigid group. *, statistically significant; TR, tricuspid regurgitation.

During the follow up period, the grade of TR was greatly improved compared to preoperative values for patients in both flexible and rigid groups (all P<0.05) (*Table 5*). Changes of preoperative and postoperative TR grade in flexible group and rigid group were shown in *Figure 1*. There was no significant difference regarding postoperative TR grade between the two groups at 1 week and 2–3 months but there was statistical significant difference at postoperative 6–12 months, and 2–3 years.

Recurrent TR was defined as postoperative moderate and above TR (grade 2–4). During the follow up period, 25 of 46 patients (54.3%) in flexible group and 22 of 60 patients (30.3%) in rigid group developed recurrent TR. Freedom from recurrent TR in two groups was shown in *Figure 2*. Freedom from recurrent TR in flexible group is lower than rigid group in each postoperative follow up period (P=0.046). 28 or 30 mm annuloplasty ring use, LVDD >55 mm, NYHA functional class III–IV, tethering distances >8 mm RV dimension >40 or MAZE procedure was not a predictor for recurrent TR identified by univariate analysis of the patients with recurrent TR (*Table 6*).

Discussion

TR is one of the most commonly encountered valvular

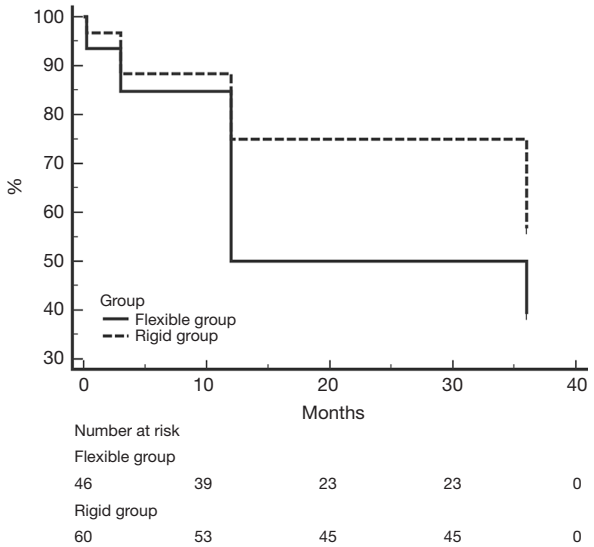

Figure 2 Freedom from recurrent TR in two groups (time means months postoperative). TR, tricuspid regurgitation.

problems in clinical practice. More than 80% of TR encountered in clinical practice is secondary or functional in nature. FTR usually results from left-sided heart disease, most often MV stenosis or regurgitation (16). The common mechanism of FTR is annular dilatation and leaflet tethering. The principles of surgery for FTR include elimination of increased right ventricular afterload (e.g., by correction of left-sided valve disease) and correction of tricuspid annular dilatation. Currently, the best method of correcting FTR in terms of timing and surgical techniques is still debated. Recently, valve annuloplasty is the preferred surgical treatment for FTR (17-19). However, to date there is no clear evidence of the superiority of one annuloplasty device over the other (14,19). To our knowledge, this is the first report explored and compared the efficacy and mid-term outcomes of the tricuspid ring annuloplasty for FTR secondary to rheumatic mitral valve disease using flexible band and rigid ring. In this study, we found that rigid ring annuloplasty was inclined to be better in restoring and maintaining tricuspid valve function in mid-term postoperative periods.

Pfannmüller *et al*. (14) investigated a large number of patients with either a flexible band and found that use of a rigid ring increases risk of subsequent ring dehiscence. In addition, Galiñanes *et al*. (20) and Kay *et al*. (21) reported four cases of extremely rare complication, i.e., fracture of the Carpentier rigid ring in the tricuspid position. In this study, we observed no occurrence of ring dehiscence in rigid group during the postoperative and follow period. These may be due to be utilized one suture spanning the conjunction region of valve leaflet rather than two sutures on each side of the valve leaflet.

In this study, the hospital mortality and late death rate were similar in the two groups, but was lower that of the previous literatures. These may be due to the high homogeneity of our samples. With regard to improvement of cardiac function, we found significant improvement when compared to preoperatively. Our results were consistent

Table 6 Univariate analysis of risk factors for recurrent TR

Risk factor	Odds ratio	95% CI	P value
Tricuspid annular diameter >55 mm			
Flexible group	2.863	2.235–4.587	0.024
Rigid group	3.317	1.472–5.269	0.017
LVEF <0.50			
Flexible group	0.967	0.613–4.287	0.023
Rigid group	2.315	1.186–4.389	0.016
Preoperative TR grade (serve)			
Flexible group	1.638	1.241–2.253	0.004
Rigid group	3.986	2.237–4.531	0.018
NYHA functional class III–IV			
Flexible group	1.211	0.689–2.158	0.092
Rigid group	0.967	0.387–1.163	0.155
Annuloplasty ring 28 or 30 mm			
Flexible group	0..834	0.428–1.183	0.241
Rigid group	0.917	0.667–2.239	0.079
LVDD >55 mm			
Flexible group	1.192	0.882–2.257	0.471
Rigid group	0.912	0.884–1.134	0.237
Tethering distances >8 mm			
Flexible group	0.675	0.447–1.144	0.720
Rigid group	1.114	0.882–2.217	0.416
RV dimension >40			
Flexible group	0.659	0.116–1.527	0.364
Rigid group	0.883	0.582–2.227	0.177

TR, tricuspid regurgitation; CI, confidence interval; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; LVDD, left ventricular end diastolic dimension

with the previous studies (22,23). In addition, we found no significant difference between the two groups at the postoperative early periods (within 1 year) but significant difference 2 years after surgery. Our study demonstrated that 3D rigid ring annuloplasty had more efficacies in restoring and maintaining tricuspid valve function in early and mid-term postoperative periods.

McCarthy *et al*. (5) reported that grade of TR was stable across time with the rigid ring and increased slowly with the flexible band. TR grade at discharge and the follow-up period showed better results in the rigid group. Navia *et al*. (12) compared two large groups (rigid ring: 584; flexible band: 1,052) of using rigid ring and flexible band for TR secondary to left-sided valve disease and found that patients with either standard or 3D rigid prosthetic ring annuloplasty had the least increase across time compared with those receiving flexible rings after 5-year of follow-up. In this study, we found that the grade of TR after surgery and at the follow up period was greatly improved compared to preoperative values for patients in both of flexible and rigid groups. Furthermore, we found that the grade of TR was relative stable across time with the rigid ring and increased slowly with the flexible band. Moreover, we found that the postoperative grade of TR for patients receiving rigid rings was relatively lower compared to that of patients receiving flexible bands at 2–3 years of follow up. This may be due to rigid MC3 annuloplasty ring has a 3-dimensional design and is preconfigured to accommodate the saddle shape of the annulus. In contrast, a flexible band follows physiological motion of the tricuspid annulus during cardiac cycle, but may not keep the optimal saddle shape of the tricuspid annulus. Our results were consistent with the above-mentioned literatures.

Filsoufi *et al*. (22) suggested that systematic downsizing of the prosthetic ring instead of type of the ring had probably played an important role in reducing the incidence of significant residual or recurrent TR, or both, after ring annuloplasty. On the contrast, McCarthy *et al*. (5) reported that the size of the ring was not identified as a risk factor for recurrent TR. They concluded that the strategy of undersizing the tricuspid annulus for functional TR using small rings could not be validated as protection against late recurrent TR. In this study, there is no difference of prosthetic ring size in two groups. In addition, univariate analysis showed that large rings (28 or 30 mm) use was not a risk factor for recurrent TR in both flexible and rigid ring groups. Therefore, ring size was not a risk factor in this study.

In this study, annuloplasty with rigid ring provided better result regarding postoperative incidence of recurrent TR, NYHA functional class, grade of TR and freedom of recurrent TR than those with flexible ring for FTR secondary to rheumatic mitral valve disease in mid-term outcome. These findings suggest the superiority of rigid ring. However, it should be noted that there was also a major difference in the technique of implantation. The flexible band was implanted from the anteroseptal to posteroseptal commissure, whereas the rigid ring was implanted from the anteroseptal commissure to the middle of the septal leaflet. McCarthy and Cosgrove recommended the use of Cosgrove band (24). Whereas Filsoufi *et al*. (22) recommended the use of Edwards MC3 remodeling ring due it is easy to implant and significantly reduces functional TR. The flexible Cosgrove-Edwards band follows physiological motion of the tricuspid annulus during cardiac cycle, but may not keep the optimal saddle shape of the tricuspid annulus. On the contrary, the Edwards MC3 annuloplasty system has a 3-dimensional design and is preconfigured to accommodate the saddle shape of the annulus. Therefore, implantation of the band from the anteroposterior to the posteroseptal commissures—but not up to the middle of the septal leaflet – could potentially compromise the anchoring of the Cosgrove band, which could possibly lead to increased chances of recurrent TR. However, it will be interesting to achieve more value information if new flexible band which can be implanted form the anteroposterior to the middle of the septal leaflet can be developed in the future. It should also be noted that the incidence of recurrent TR at 2 years after annuloplasty with rigid ring still reach to as high as 30.3%. These may be associated with the surgical timing due to patients in China are inclined to receive surgical treatment only when the cardiac function was seriously impaired. Therefore, more aggressive efforts should still be paid to improve the long term outcomes of annuloplasty.

The limitations of this study include its single-center design and retrospective nature, with all of the inherent limitations of such investigations. A non-randomized study with relatively short duration of follow up and small sample size may produce potential bias. Therefore, the results obtained can in no way be considered conclusive and should be confirmed by further studies. Nevertheless, our findings may help cardiac surgeons select an appropriate annuloplasty ring technique for

the treatment of TR secondary to rheumatic heart valve disease.

Conclusions

Both flexible and rigid ring annuloplasty have been proved to be safe, feasible and durable to correct secondary TR. The three-dimensional MC3 rigid ring is inclined to be better than the flexible band in terms of postoperative NYHA functional class, grade of TR and recurrent TR in early and mid-term postoperative periods. However, further studies with a larger number of samples and a longer-term of follow up are necessary to confirm our findings. In addition, the potential effect of the two different techniques of ring implantation on the efficacy and outcome of treatment for secondary TR should also be further investigated.

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None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: The study was approved by the ethics committee of Qingdao Fuwai Hospital (No. 002/2009) and written informed consent was obtained from all patients.

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