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Is a rigid tricuspid annuloplasty ring superior to a flexible band when correcting secondary tricuspid regurgitation?

Tie-Yuan Zhu, Jian-Gang Wang and Xu Meng*

Department of Cardiac Surgery, Beijing Anzhen Hospital, Capital Medical University, Beijing, China

* Corresponding author. Division of Cardiac Surgery, Beijing Anzhen Hospital, No. 2 Anzhen Road, Chaoyang District, Beijing 100029, China. Tel: +86-10-64456984; fax: +86-10-64453010; e-mail: mxu@263.net (X. Meng).

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Abstract

A best evidence topic in adult valvular surgery was written according to a structured protocol. The question addressed was 'Is a rigid tricuspid annuloplasty ring superior to a flexible band when correcting secondary tricuspid regurgitation (TR)?' A total of 166 papers were found using the reported search, of which, 13 presented the best evidence to answer the clinical question. The authors, country, journal, date of publication, patient group studied, study type, relevant outcomes and results of these papers are tabulated. All the 13 papers were retrospective studies, from which 4 were case–control studies comparing the rigid ring annuloplasty approach with the flexible band technique, eight case series and one case report. From the first three case–control studies, we conclude that more progression to moderate-to-severe TR in the flexible band group than rigid ring group. However, the fourth paper reported that both rigid and flexible systems provide acceptable early tricuspid valve repair results, but the use of a rigid ring increases risk of subsequent ring dehiscence. Another rare complication about the rigid ring was described by Galiñanes *et al*. We conclude that although there are relatively less risk of ring dehiscence or ring fracture in the flexible group, the rigid ring, particularly the new three-dimensional MC3 ring, is inclined to be better than the flexible band in terms of a sustained effect for maintaining stable postoperative regurgitation grade according to the current available evidences. However, due to the limited controlled studies and their retrospective design, the results should be confirmed by prospective studies with a large number of patients.

Keywords: Tricuspid valve • Tricuspid valve insufficiency • Annuloplasty ring

INTRODUCTION

A best evidence topic was constructed according to a structured protocol. This protocol is fully described in the *ICVTS* [1].

THREE-PART QUESTION

In [patients with secondary tricuspid regurgitation combined with left-sided valvular diseases requiring a tricuspid valve repair with an annuloplasty ring], is a [rigid ring superior to a flexible ring] in terms of improvement in [tricuspid valve competence]?

CLINICAL SCENARIO

During the period of surgical rotation, you change to another operating team in your department in the new year, and after a few days, during the operating process, you find that the new senior doctor performs tricuspid annuloplasty using a rigid ring rather than a flexible one after the mitral valve replacement, however, your former senior doctor told you previously that a flexible ring could accommodate the physiological motion of annulus during implantation. You pose a question and are told that it is the latest annuloplasty ring and can give better results. You decide to check the literature before discussing with him.

SEARCH STRATEGY

Medline from 1950 through March 2013 using the Pubmed interface: [(Title/Abstract) tricuspid valve repair OR (Title/Abstract) tricuspid annuloplasty] AND [(Title/Abstract) rigid ring OR (Title/Abstract) flexible ring OR (Title/Abstract) Carpentier-Edwards ring OR (Title/Abstract) Cosgrove-Edwards ring OR (Title/Abstract) MC3 ring OR (Title/Abstract) Duran ring]

SEARCH OUTCOME

A total of 166 papers were found using the reported search, from which 13 represented the best evidence on this topic and are summarized in Table 1.

DISCUSSION

Several studies [2, 3] have proved that tricuspid regurgitation secondary to the left-sided valvular diseases needs to be corrected.

Table 1: Best evidence papers

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key results	Comments
McCarthy *et al.* (2004), J Thorac Cardiovasc Surg, USA [2] Cohort study (level 2b)	430 patients Carpentier-Edwards rigid ring = 139 patients Cosgrove-Edwards flexible band = 291 patients	Freedom from 3+ or 4+ TR in 1 month, 1 year, 5 years and 8 years	Rigid 3+: 90, 90, 89 and 89%; 4+: 94.8, 94.5, 94 and 94%, $P = 0.7$ Flexible 3+: 90, 88, 88% and NA; 4+: 94.7, 94, 94% and NA, $P = 0.05$	Retrospective nature of the study More progression to moderate-to-severe TR in the flexible ring than rigid ring
Izutani *et al.* (2010), Heart Int, Japan [10] Retrospective study (level 2b)	117 patients Cosgrove-Edwards flexible band = 35 patients MC3 rigid ring = 82 patients TR grade preoperation: Flexible: 2.80 ± 0.67 Rigid: 2.68 ± 0.70	30-day mortality Late death TR at discharge Follow-up TR at latest evaluation Freedom from 2+ or 3+ TR	Flexible: 4 (11.4%) vs rigid: 2 (2.4%), $P = 0.12$ Flexible: 2 (5.7%) vs rigid: 4 (4.9%), $P = 0.86$ Flexible: 0.71 ± 1.0 Rigid: 0.22 ± 0.60, $P = 0.006$ Flexible: 34.6 ± 9 months Rigid: 21 ± 7 months Flexible: 0.80 ± 0.95 Rigid: 0.36 ± 0.77, $P = 0.04$ Flexible: 68.6% Rigid: 87.8%, $P = 0.002$	Retrospective nature of the study Rigid ring annuloplasty is more effective for decreasing TR in immediate and mid-term periods
Navia *et al.* (2010), J Thorac Cardiovasc Surg, USA [11] Cohort study (level 2b)	1636 patients Flexible ring = 1052 patients Rigid ring = 584 patients	Freedom from 3+ or 4+ TR at 5 years 6 years free of TV reoperation	Standard or 3D rigid ring: 90 or 86% Flexible ring: 84% Rigid: 96% Flexible: 94%	Retrospective nature of the study Rigid ring, standard or 3D, provides less increase of TR across time
Pfannmüller *et al.* (2012), J Thorac Cardiovasc Surg, Germany [15] Retrospective study (level 2b)	820 patients Cosgrove-Edwards flexible band = 415 patients Carpentier-Edwards rigid ring = 405 patients	30-day mortality 5-year survival TR at discharge Risk of dehiscence	Flexible: 11.9% vs rigid: 8.4%, $P > 0.05$ Flexible: 60.3% vs rigid: 64.7%, $P > 0.05$ Total 0.7 ± 0.7, no difference between groups Flexible: 0.9% vs rigid: 8.7%, $P < 0.01$	Retrospective nature of the study Both groups provide acceptable early tricuspid valve repair results, use of a rigid ring increases risk of subsequent ring dehiscence
Onoda *et al.* (2000), Ann Thorac Surg, Japan [5] Case series (level 4)	45 patients Capentier-Edwards rigid ring Patients: Male: 13 (29%) Age: 54.6 (32–69) NYHA class: 39 (95.1%) III/IV Preoperative TR: 3.6 ± 0.5	30-day mortality Late death 5-year survival 10-year survival TR at discharge Follow-up (95.6%) TR at follow-up 10-year freedom from reoperation Ring-related complications	2 (4.4%) 10 (22.2) 86.7% 68.3% NA 96.7 ± 48.5 months 0.7 ± 0.8 97.5% 1 patient (reoperation due to suture rupture)	Retrospective nature of the study without comparison Long-term follow-up for the rigid ring The rigid ring annuloplasty improves the TV function and clinical status on a long-term basis

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Table 1: (*Continued*)

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key results	Comments
Filsoufi *et al.* (2006), Ann Thorac Surg, USA [6] Case series (level 4)	75 patients MC3 rigid ring Patients: Male: 34 (45%) Age: 64 ± 14 NYHA class: 64 (85%) III/IV LVEF: 49 ± 14% Preoperative TR: 3.1 ± 0.9	30-day mortality TR at discharge Follow-up TR at follow-up Ring-related complications Reoperation for TV	4 (5.3%) 0.3 ± 0.4 Median 16 months 0.3 ± 0.5 None None	Retrospective nature of the study without comparison MC3 ring effectively corrects secondary TR with excellent early and mid-term clinical outcomes
Jeong *et al.* (2010), Circ J, South Korea [7] Case series (level 4)	103 patients MC3 rigid ring Patients: Male: 37 (36%) Age: 52 ± 13 LVEF: NA SPAP: 48.4 ± 15.0 Preoperative TR: 2.5 ± 0.8	30-day mortality TR at discharge Follow-up TR at follow-up Ring-related complications	1 (1%) 0.8 ± 0.8 Median 15 months 0.9 ± 0.8 None	Retrospective nature of the study without comparison MC3 ring provides stable mid-term clinical and echocardiographic results for TR
Yoda *et al.* (2011), Interact CardioVasc Thorac Surg, Japan [8] Case series (level 4)	136 patients with MC3 rigid ring Patients: Male: 80 (59%) Age: 64.7 ± 11.8 LVEF: 54.1 ± 7.9% SPAP: 43.0 ± 14.1 Preoperative TR: 2.3 ± 1.0	30-day mortality Late death Survival rates at 3 months, 1 year and 4 years TR at discharge Follow-up TR at follow-up Ring-relateed complications	8 (5.9%) 3 (2.2%) 97.1 ± 0.15 93.4 ± 0.02 and 90.7 ± 0.28% 0.9 ± 0.5 18 ± 9.6 months 1.0 ± 0.4 None	Retrospective nature of the study without comparison The MC3 rigid ring provides good mid-term results for functional TR
De Bonis *et al.* (2012), J Card Surg, Italy [9] Case series (level 4)	140 patients with MC3 rigid ring Patients: Male: 80 (57.1%) Age: 63.8 ± 11.6 NYHA class: 71 (50.7%) III/IV LVEF: 56.4 ± 10.1% SPAP: 52.5 ± 14.4 Preoperative TR: 3.0 ± 0.5	30-day mortality 3-year survival TR at discharge Follow-up TR at follow-up 3-year freedom from TR ≥3+ Ring-related complications	5 (3.5%) 94.8 ± 2.1% 0.4 ± 0.6 22 ± 9.5 months 0.6 ± 0.6 94.3 ± 4.89 None	Retrospective nature of the study without comparison MC3 ring annuloplasty provides satisfactory early results which remain stable at mid-term follow-up
Galiñanes *et al.* (1986), Ann Thorac Surg, Spain [16] Case report (level 5)	3 cases of fracture of Carpentier-Edwards ring after tricuspid annuloplasty	Man (age: 41) AVR + MVR + TVP, reoperation after 51 months Woman (age: 51) AVR + MVR + TVP, reoperation after 22 months	Reopertation for all patients using prosthetic valve replacement for the tricuspid position No hospital death of the 3 patients	Fracture of the Carpentier-Edwards rigid ring in tricuspid position is rare Reoperation can be done in this special situation

Continued

Table 1: (*Continued*)

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key results	Comments
		Woman (age: 52) MVR + TVP, reoperation after 3 years		
Gatti *et al.* (2001), Ann Thorac Surg, Italy [12] Case series (level 4)	22 patients Cosgrove-Edwards flexible ring Patients: Male: 5 (22.7%) Age: 66.5 ± 10.9 NYHA class: 3.7 ± 0.6 21 (95.5%) III/IV LVEF: 49% ± 12% SPAP: 49.9 ± 14.6 Preoperative TR: 3.5 ± 0.5	30-day mortality Late death At discharge NYHA class TR grade Follow-up NYHA class TR grade Ring-relateed complications	2 (9.7%) 1 (4.8%) 1.6 ± 0.6 0.5 ± 0.5 19.9 ± 9.7 months 1.3 ± 0.5 0.3 ± 0.5 None	Retrospective nature of the study without comparison The Cosgrove flexible ring provides satisfactory early results which remain stable at short-term follow-up
Gatti *et al.* (2007), Interact CardioVasc Thorac Surg, Italy [13] Case series (level 4)	53 patients Koehler flexible band Patients: Male: 17 (32.1%) Age: 66.2 ± 8.5 NYHA class: 31 (58.5%) III/IV 2.7 ± 0.8 LVEF: 56.1% ± 7.9% SPAP: 21.9 ± 16.1 Preoperative TR: 2.2 ± 0.6	30-day mortality Late death 4-year survival At discharge NYHA class TR grade Follow-up NYHA class TR grade Ring-related complications	3 (5.7%) 1 (1.9%) 91.7% NA NA 19.2 ± 14 months 1.4 ± 0.6 0.8 ± 0.6 None	Retrospective nature of the study without comparison with other approaches The Koehler flexible band proved effectively corrected secondary TR, and provided satisfactory short-term results
Jung *et al.* (2010), Circ J, South Korea [14] Case series (level 4)	219 patients Duran flexible ring Patients: Male: 65 (29.7%) Age: 54.2 ± 12.7 NYHA class: 108 (49.3%) III/IV, mean 2.5 LVEF: 55.9% ± 10% SPAP: 97 (44.1%) Preoperative TR: 3.4 ± 0.7	30-day mortality Late death 1-year, 5-year and 8-year survival At discharge NYHA class TR grade Follow-up NYHA class TR grade Ring-related complications	3 (1.4%) 21 (9.6%) 95, 86.2 and 79.9% Mean 1.1 1.2 ± 0.7 Mean 35.8 months 1.4 ± 0.6 1.0 ± 0.7 1 patient (reoperation due to ring dehiscence)	Retrospective nature of the study without comparison with other approaches The Duran flexible ring is safe and durable according to a mid-term results

NYHA: New-York Heart Association; SPAP: systolic pulmonary artery pressure; LVEF: left ventricular ejection fraction; TR: tricuspid regurgitation. The echocardiographic severity of TR was graded as none (0), mild (1), moderate (2), moderate-to-severe (3) and severe (4). Data were presented as mean ± standard deviation.

Good evidence [4] has been concluded to support ring annuloplasty over suture annuloplasty (such as De Vega's or Kay's technique). But there is no consensus regarding which ring annuloplasty is better in tricuspid valve repair.

The ring annuloplasty is a relatively new method in the clinical practice. Many current published papers are observational studies without comparison groups and lack long-term results. Only four papers that compare the two methods are available.

Rigid ring tricuspid annuloplasty

In 2000, Onoda *et al*. [5] performed a retrospective study with a 10-year follow-up for the Carpentier-Edwards rigid ring. Echocardiographic studies showed that tricuspid regurgitation (TR) was well controlled within grade 2+ in all survivors. Filsoufi *et al*. [6] and Jeong *et al*. [7] reported their retrospective studies about the MC3 ring. Echocardiography predischarge showed significant decrease in TR grade and the follow-up transthoracic echocardiography (TTE) demonstrated a stable result. Another two studies [8, 9] from Japan and Italy also gave excellent results in early and mid-term periods.

In our literature search, we found three case–control studies with regard to our subject. The first was reported by McCarthy *et al*. [2] in a cohort of 430 patients. Severity of regurgitation was stable across time with the rigid ring ($P = 0.7$) and increased slowly with the flexible band ($P = 0.05$). The result of the second study [10] was similar to that of the first one. TR grade at discharge and the follow-up period showed better results in the rigid group. The last study performed by Navia *et al*. [11] from Cleveland Clinic compared two large groups (rigid ring: 584; flexible band: 1052). By 5-year follow-up, patients with either standard or three-dimensional (3D) rigid prosthetic ring annuloplasty had the least increase across time compared with those receiving flexible rings.

Flexible band tricuspid annuloplasty

In 2001, Gatti *et al*. [12] evaluated the Cosgrove system for TR in 22 patients. All survivors were in NYHA class 1 or 2. Echo cardiography at discharge showed that TR grade decreased from 3.5 ± 0.5 to 0.5 ± 0.5, and at follow-up TR grade remained stable.

Gatti *et al*. [13] performed a study of 53 patients undergoing flexible band annuloplasty for secondary TR. Follow-up was 19.2 ± 14.0 months and TR significantly decreased from 2.2 ± 0.6 to 0.8 ± 0.6. Jung *et al*. [14] reported their outcomes using a Duran ring. Predischarge TEE showed decrease in TR from 3.4 ± 0.7 to 1.2 ± 0.7 and follow-up TTE result after ∼35.8 months was 1.0 ± 0.7.

One controlled study [15] reported by German surgeons investigated a large number of patients with either a flexible band ($n = 415$) or a rigid ring ($n = 405$). Follow-up mean duration was 21 months. Thirty-day mortality, 5-year survival and TR grade postoperative showed no differences between groups. Use of a rigid ring, however, was associated with significantly higher risk of dehiscence. Ten patients underwent reoperation for recurrent TR, 4 with ring dehiscence. The authors concluded that although both rigid and flexible systems provide acceptable early results, use of a rigid ring increases risk of subsequent ring dehiscence.

In addition, Galiñanes *et al*. [16] and Kay *et al*. [17] have reported 4 cases about a special complication. It is the fracture of the Carpentier rigid ring in the tricuspid position. Only 4 cases of this uncommon entity were found in the literature. So we can say it is extremely rare.

From the above observational studies, the 30-day mortality, late death rate were similar in the two groups. The echocardiography TR grade at predischarge and follow-up periods of rigid ring group varied from 0.22 ± 0.6 to 0.9 ± 0.5 and 0.3 ± 0.5 to 1.0 ± 0.4, while data in the flexible group which were slightly higher, were 0.5 ± 0.5 to 1.2 ± 0.7 and 0.3 ± 0.5 to 1.0 ± 0.7. But when it comes to the first three case–control studies (rigid ring: 805 patients vs flexible band: 1378 patients), it can be concluded that the rigid ring annuloplasty is more effective than flexible band for maintaining stable TR grade across time.

CLINICAL BOTTOM LINE

Both ring tricuspid annuloplasty methods have been proved to be safe, feasible and durable to correct secondary tricuspid regurgitation. Although there is relatively less risk of dehiscence or fracture in the flexible ring group, the rigid ring, particularly the new 3D MC3 ring, is inclined to be better than the flexible band in terms of a sustained effect for maintaining stable postoperative regurgitation grade according to the current available evidences. However, due to the limited controlled studies and their retrospective design, the results should be confirmed by prospective studies with a large number of patients.

Conflict of interest: none declared.

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