

Outcomes of De Vega versus Biodegradable Ring Annuloplasty in the Surgical Treatment of Tricuspid Regurgitation (Mid-term Results)

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ABSTRACT

Purpose: The aim of this study was to compare De Vega semicircular annuloplasty and a new biodegradable ring annuloplasty technique in patients requiring surgical intervention for tricuspid valve disease with concomitant disease of the mitral valve.

Methods: Between January 2004 and May 2008, 129 consecutive patients underwent annuloplasty procedures to correct tricuspid valve regurgitation during a concomitant mitral valve operation requiring replacement. Additionally, 24 patients underwent aortic valve replacement (AVR), 11 underwent coronary artery bypass grafting (CABG), 5 underwent AVR plus CABG, 3 underwent mitral valve replacement plus atrial septal defect (ASD) closure, and 2 underwent ASD closure. The patients in this study were assigned to 2 groups: Kalangos ring annuloplasty was performed in 67 patients (group 1), and De Vega semicircular annuloplasty was performed in the remaining 62 patients (group 2).

Results: Both tricuspid valve repair techniques produced a low rate of complications; however, the number of patients who developed residual tricuspid regurgitation was significantly lower in group 1.

Conclusion: The biodegradable ring annuloplasty technique may be used easily and safely in moderate and severe cases of tricuspid regurgitation; however, larger clinical series are necessary to confirm our promising results.

INTRODUCTION

Different methods have been used for the surgical treatment of tricuspid regurgitation. The surgical approach usually involves symmetric and moderate reduction and reconstruction for annulus dilatation and deformation. Annuloplasty should preserve the physiological function of the annulus.

Multiple clinical studies have shown the superiority of remodeling annuloplasty to other repair techniques. The

Kalangos biodegradable ring, which was recently developed for mitral and tricuspid annuloplasty, has the advantages of flexibility, remodeling, and preservation of both the growth potential of the native annulus and the 3-dimensional dynamic geometry [Yavuz 2007]. Among the several techniques described for tricuspid valve repair, the most commonly used technique is De Vega semicircular annuloplasty, which was developed by De Vega and Cabrol to reduce the amount of intracardiac prosthetic material, to provide annular flexibility, and to reduce the risk of injury of the conduction system [De Vega 1972]. Another repair technique, the Kay-Boyd tricuspid annuloplasty technique, is also used, however [Kay 1965; Boyd 1974]. This technique uses a biodegradable ring with a curved "C" segment consisting of a poly(1,4-dioxanone) polymer that is dyed a blue color and equipped with a stainless steel needle located at each extremity. This ring allows remodeling of the posterior mitral annulus or the anteroposterior tricuspid annulus, with gradual formation of fibrotic tissue during hydrolytic biodegradation. The biodegradable ring was developed for pediatric annuloplasty to preserve the growth potential of the child's heart [Blackstone 1979; Kalangos 2006].

This prospective randomized trial compares the results of biodegradable tricuspid ring annuloplasty and De Vega tricuspid annuloplasty for the surgical treatment of functional tricuspid regurgitation (FTR).

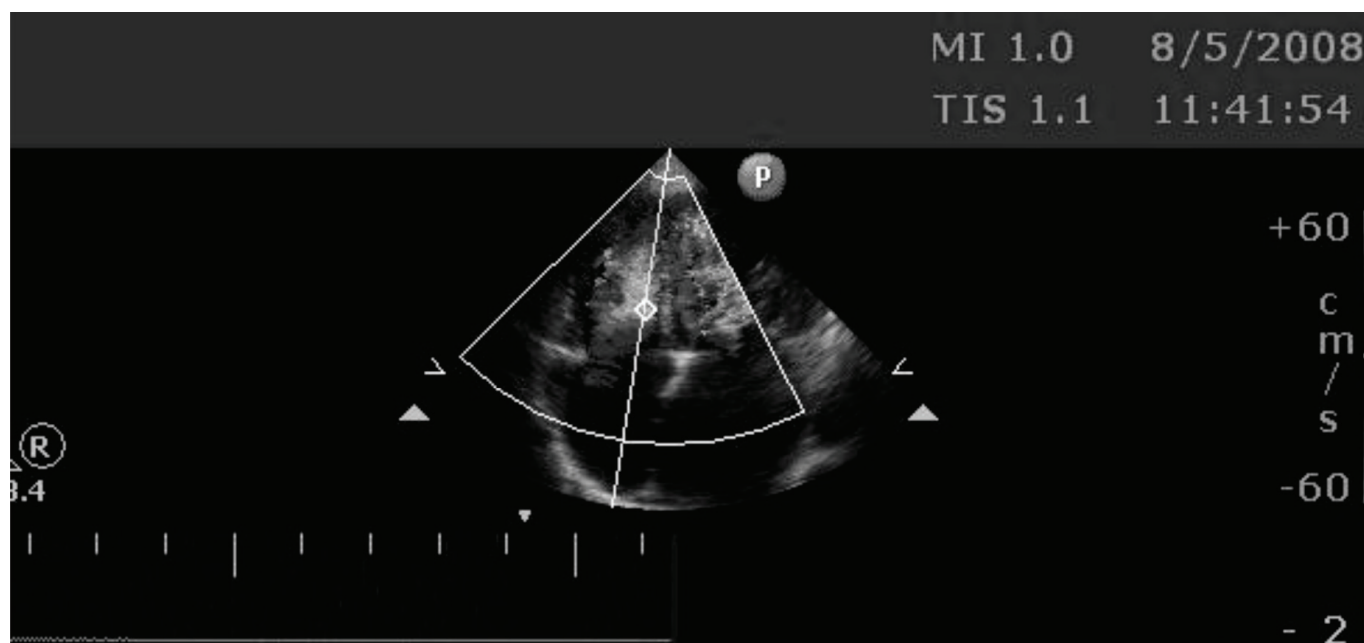
MATERIALS AND METHODS

Between January 2004 and May 2008, 129 patients underwent tricuspid valve repair concomitant with mitral valve replacement or repair and/or other cardiac procedures, such as aortic valve replacement and coronary artery bypass grafting, in the cardiothoracic surgery department of our hospital. Of these patients, 67 (51.5%) underwent annuloplasty with a biodegradable ring (group 1), and 62 patients (48.5%) underwent their surgery with the De Vega tricuspid annuloplasty technique (group 2). Patients were followed with transthoracic echocardiography (TTE) at 1, 12, 18, and 24 months postoperatively. Patients were followed-up for a mean ($\pm$ SD) of 25.8 ± 7 months (range, 20-36 months). The operations were performed by 2 senior surgeons.

The degree of FTR was determined via the apical 4-chamber view during systole as well as by measuring the

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Transthoracic echocardiography image of tricuspid regurgitation.

Doppler color flow jet area of the right atrium (Figure). FTR was graded from 1 to 4 (ie, mild, moderate, moderate to severe, and severe). The myocardial performance index (MPI) is a numeric value that can be obtained from cardiac time intervals. The MPI is defined as the sum of isovolumetric contraction time (ICT) and the isovolumetric relaxation time (IRT), divided by ejection time (ET), and can be calculated for each ventricle individually. The MPI is higher in severe FTR, and it decreases as FTR improves. It is a visual method for evaluating right ventricle functions.

The patients were followed up at 1, 12, 18, and 24 months postoperatively and were evaluated for effort capacity according to the New York Heart Association (NYHA) class, pulmonary artery pressure (PAP), FTR, MPI, tricuspid stenosis, and the right ventricular end-diastolic diameter.

Operative Technique

A median sternotomy approach was used in all patients. Aortic arterial and bicaval venous cannulation was used in the patients. Antegrade and retrograde cardioplegia cannulas were used in all patients. The vent cannula was inserted through the right superior pulmonary vein.

Rectal temperatures were lowered to the target temperature of 30°C to 32°C during cardiopulmonary bypass. After cross-clamping of the aorta, the patients were placed on continuous nonpulsatile perfusion. Isothermic blood cardioplegia was used in all cases. The hematocrit was kept between 20% and 25% during cardiopulmonary bypass. The pump flow rate was maintained at 2 to 2.2 L/min per m², and the mean arterial pressure was kept at 50 to 60 mm Hg during cross-clamp application.

Once the repair of the left-system pathologies had been completed, the left atrium was vented with the pulmonary venting cannula, the cross-clamp was removed, and blood

was circulated in the heart chambers. This procedure allows the heart to reperfuse and facilitates prompt separation from bypass once the atrium is closed. The right atrium was opened while the inferior and superior vena cavae were cannulated and snared. The tricuspid valve was measured for the appropriately sized ring, and the biodegradable ring was implanted. Selection of the correct ring size is based on the surface area of the anterior leaflet. De Vega annuloplasty was performed with 4-0 pledgeted Prolene suture, and the tricuspid valve was narrowed with double-line suture until normal coaptation was achieved. This constriction was performed with Hegar dilators of the appropriate diameter according to a body mass index table [Blackstone 1979]. The right atrium was oversewn with continuous 5-0 Prolene suture.

Statistical Analysis

Data are presented as the mean $\pm$ SD. Differences between proportions were assessed by the chi-square test; differences between subgroups were compared by 1-way analysis of variance. Logistic regression was used to analyze the correlation of variables. Statistical analysis was performed with SPSS for Windows (version 11.5; SPSS, Chicago, IL, USA). A *P* value $<.05$ was considered statistically significant.

RESULTS

Demographic data and risk factors were evaluated preoperatively, and the 2 groups were similar (Tables 1 and 2). Nineteen patients (29.8%) in the biodegradable ring group (group 1) and 22 patients (40.3%) in the De Vega annuloplasty group (group 2) presented with preoperative atrial fibrillation. The mean preoperative NYHA score was 3.3 (out of 4) in group 1 and 3.5 in group 2.

Table 1. Preoperative and Demographic Characteristics of Patients*

Parameters	Group 1	Group 2	P
Age, y	38.5 ± 12	39.1 ± 11	NS
Sex, n			
Female	41 (61.2%)	40 (64.5%)	NS
Male	26 (38.8%)	22 (35.5%)	NS
MAP, mm Hg	98 ± 17	96 ± 18	NS
Heart rate, /min	82 ± 15	85 ± 13	NS
Rhythm (AF/SR), n	19/21	22/18	NS
Mean NYHA class	3.3	3.5	NS
FTR, n			
Medium	35 (52.2%)	32 (51.6%)	NS
Severe	32 (47.8%)	31 (48.4%)	NS
Mean	3.34 (of 4)	3.43 (of 4)	NS
LVEF, %	44 ± 12	45 ± 12	NS
MPI index (RV)	0.64 ± 0.23	0.63 ± 0.18	NS
PAP, mm Hg	71 ± 14	69 ± 16	NS
Right ventricular end-diastolic diameter, mm	36.4 ± 4.8	36.1 ± 4.2	NS

*Data are presented as the mean ± SD where indicated. NS indicates not statistically significant; MAP, mean arterial pressure; AF, atrial fibrillation; SR, sinus rhythm; NYHA, New York Heart Association; FTR, functional tricuspid regurgitation; LVEF, left ventricular ejection fraction; MPI, myocardial performance index; RV, right ventricle; PAP, pulmonary artery pressure.

The PAP was 71 ± 14 mm Hg in group 1 and 69 ± 16 mm Hg in group 2. The PAP showed a rapid decrease postoperatively. At the end of the 24-month follow-up period, the PAP was 37 mm Hg in group 1 and 41 mm Hg in group 2 (Table 3). At 1 month postoperatively, the FTR ratio was 1.64 (out of 4) in group 1 and 1.68 in group 2. The FTR ratio also decreased during follow-up, and at the end of the 24 months it was 1.37 in group 1 and 1.47 in group 2.

The MPI was 0.61 in group 1 and 0.60 in group 2 at the end of 1 month, but the MPI also decreased by the end of the 24-month follow-up period to 0.40 and 0.50, respectively. The right ventricular end-diastolic diameter (RVEDD) was 36.4 mm in group 1 and 36.1 mm in group 2 at the end of 1 month. The RVEDD decreased to 30.2 mm in group 1 and 34.1 mm in group 2 at the end of the 24-month follow-up.

No infections or thrombotic complications occurred in the groups of our series. According to our postoperative 12-, 18-, and 24-month TTE findings, the function of the tricuspid annulus sphincter was better preserved in group 1. Whereas only 4 patients (5.9%) had 3° recurrence failure in the tricuspid valve in group 1, group 2 had 9 patients (14.5%) with 3° recurrence failure and 2 patients (3.2%) with 4° recurrence failure. In these patients, persistent pulmonary hypertension, long-term valve disease, and right ventricle dysfunction were considered as risk factors.

Table 2. Concurrently Performed Cardiac Procedures*

Procedure(s) Performed	Group 1, n	Group 2, n
MVR or MV repair	46	38
MVR + AVR	11	13
MVR + CABG	5	6
MVR + AVR + CABG	2	3
MVR + ASD	2	1
ASD	1	1

*MVR indicates mitral valve replacement; AVR, aortic valve replacement; CABG, coronary artery bypass grafting; ASD, atrial septal defect.

DISCUSSION

Seventy percent to 85% of patients with tricuspid valve regurgitation have functional-type regurgitation [Simon 1980; King 1984]. Generally, the regurgitation depends on annular dilatation and the reduction in the systolic annular constriction [Come 1985]. Similar dilatation is seen in the mural annular segment and particularly in the posterior annulus (80%) [Carpentier 1974]. Isolated tricuspid valve regurgitation is a rare clinical entity. Functional tricuspid valve regurgitation is closely related to the functions of left-side valves, especially mitral valve functions. When the left-side valve dysfunction is fixed, tricuspid valve regurgitation often resolves and sometimes disappears. Functional tricuspid valve regurgitation has been shown to recover in 47% of patients because of postoperative pulmonary resistance [Pasque 1987]. In addition, postoperative functional capacity, which is related to inadequate repair or negligence of the tricuspid valve, is based on the results of mitral valve surgery [Pasque 1987]. Because the tricuspid valve is functioning in a low-pressure system, inaccurate results can be tolerated. A marginal example of this condition is that in the presence of a normal pulmonary pressure and normal right ventricular functions, total excision of the tricuspid valve is possible in patients with tricuspid endocarditis [Pasque 1987].

Severe or moderate FTR must be corrected surgically owing to the high postoperative morbidity and mortality rates [Simon 1980; King 1984]. There are numerous surgical methods for the treatment of FTR, all of which are aimed at proportional and symmetric reduction and reconstruction of the annulus dilatation and deformation. Different methods have been used for the surgical treatment of tricuspid regurgitation, including replacement with a prosthetic heart valve, suture, and ring annuloplasty. Ring annuloplasty is divided into 2 groups according to whether a flexible or rigid annuloplasty ring is used. Early and late results of tricuspid annuloplasty are superior to those of valve replacement. Heart valve replacement should be avoided as long as possible [Ege 2002]. Tricuspid valve replacement is limited to patients with valve destruction due to infective endocarditis; however, replacement is not often recommended because it increases the risk of thrombus formation associated with low pressure and valve malfunction [Breyer 1976; Simon 1980].

Table 3. Postoperative Results*

	Group 1	Group 2	P
Month 1			
NYHA class	2.9	2.8	NS
PAP, mm Hg	50.3	51.8	NS
FTR	1.64 (of 4)	1.68 (of 4)	NS
MPI	0.61	0.60	NS
Tricuspid stenosis, n	—	—	NS
RVEDD, mm	36.4	36.1	NS
Month 12			
NYHA class	2.0	2.1	NS
PAP, mm Hg	40	41	NS
FTR	1.43 (of 4)	1.58 (of 4)	<.05
MPI	0.44	0.51	<.05
Tricuspid stenosis, n	—	3	<.05
RVEDD, mm	34.1	35.7	<.05
Month 18			
NYHA class	1.8	2.0	NS
PAP, mm Hg	38	40	NS
FTR	1.38 (out of 4)	1.51 (out of 4)	<.05
MPI	0.42	0.50	<.05
Tricuspid stenosis, n	—	3	<.05
RVEDD, mm	31.3	34.3	<.05
Month 24			
NYHA class	1.6	1.8	NS
PAP, mm Hg	37	41	NS
FTR	1.37 (out of 4)	1.47 (out of 4)	<.05
MPI	0.40	0.50	<.05
Tricuspid stenosis, n	—	3	<.05
RVEDD, mm	30.2	34.1	<.05

*NYHA indicates New York Heart Association; NS, not statistically significant; PAP, pulmonary artery pressure; FTR, functional tricuspid regurgitation; MPI, myocardial performance index; RVEDD, right ventricular end-diastolic diameter.

Even in severe rheumatic diseases, commissurotomy followed by ring annuloplasty is preferred to valve replacement [Breyer 1976]. The Kay technique, which is defined as tricuspid valve bicuspidalization via plication of the posterior leaflet, is more frequently recommended, although this technique does not protect the valve from annulus dilatation [Kay 1992]. The risk of thrombosis around the prosthesis is higher, and long-term and functional results have been demonstrated to be worse in the tricuspid position than in the mitral and aortic positions [Ege 2002]. We experienced no thrombosis problems in either of the groups in our series.

Although tricuspid valve correction procedures provide promising results, the fact that a variety of procedures are

currently used indicates that uniformly successful methods are not yet available. Postoperative hemodynamic evaluations show a lack of physiological improvement, a persistent residual diastolic gradient in 40% to 50% of cases, and residual tricuspid regurgitation in 30% to 40% of patients [Haerten 1978]. Current annuloplasty techniques have failed to provide a balance between potential tricuspid stenosis associated with a wide constriction of the annulus and persistent residual tricuspid regurgitation due to a limited constriction of the annulus. Use of a biodegradable ring, however, can achieve this balance via measurement of the length of the anterior leaflet and use of the appropriate ring. This approach allows a lower FTR ratio to be obtained in the postoperative follow-up.

Early and medium-term postoperative results after tricuspid valve repair by biodegradable ring annuloplasty have shown that the annulus function and flexibility of the tricuspid valve are retained [Kalangos 2006]. With respect to our patients, the mean MPI scores were 0.64 ± 0.23 and 0.63 ± 0.18 in groups 1 and 2, respectively. Although the postoperative TTE results demonstrated MPI improvement in groups 1 and 2 at 24 months (0.40 and 0.50, respectively), the 46.5% improvement in group 1 was superior to the 37.1% improvement in group 2 ($P < .05$). This result is also consistent with results described in the literature [Uluçay 2008].

According to our postoperative 12-, 18-, and 24-month TTE findings, the sphincter functions of the tricuspid annulus were better preserved in group 1. Whereas only 4 patients (5.9%) in group 1 had 3° recurrence failure in the tricuspid valve, group 2 had 9 patients (14.5%) with 3° recurrence failure and 2 patients (3%) with 4° recurrence failure. In these patients, persistent pulmonary hypertension, long-term valve disease, and right ventricle dysfunction were considered as risk factors.

Right ventricle end-diastolic diameters obtained from the echocardiographic evaluations were also compared. Although the 2 groups were not significantly different in the first month, a statistically significant difference in favor of the biodegradable ring was obtained at the 12-, 18-, and 24-month follow-ups.

Unlike conventional rings placed over the native annulus, the biodegradable ring is inserted into the tissue of the annulus; consequently, the ring has no contact with the systemic blood flow. The patient is thus protected from thromboembolic complications. Anticoagulation therapy for 3 months is considered appropriate for patients with a conventional ring until the ring becomes covered with endothelium; however, anticoagulation treatment is not used in patients who receive a biodegradable ring [Kalangos 2006]. In addition, the biodegradable ring does not consist of synthetic material; theoretically, it can also be used in cases of mitral valve failure [Kazaz 2005]. No infections or thrombotic complications occurred in the groups of our series. Mild to moderate tricuspid stenosis in 3 patients (4.8%) of the De Vega group, which the TTE results demonstrated at the 12-, 18-, and 24-month follow-ups, was considered a complication.

CONCLUSION

The biodegradable ring annuloplasty technique provides annulus functions that are more physiological in patients

with an impaired right ventricle, less recurrence of tricuspid valve regurgitation, no occurrence of iatrogenic stenosis, and better right ventricle functions, according to the mid-term TTE findings. In conjunction with the resolution of the biodegradable ring to fibrotic tissue, the risk of infection and thrombogenicity decreases. In conclusion, we consider the novel annuloplasty technique with a biodegradable ring to be an easy, safe, and promising surgical method for moderate and severe FTR cases.

REFERENCES

- Blackstone EH, Kirklin JW, Pacifico AD. 1979. Decision-making in repair of tetralogy of Fallot based on intraoperative measurements of pulmonary arterial outflow tract. *J Thorac Cardiovasc Surg* 77:526-32.
- Boyd AD, Engelman RM, Isom OV, Reed GE, Spencer FC. 1974. Tricuspid annuloplasty: five and one-half years' experience with 78 patients. *J Thorac Cardiovasc Surg* 68:344-51.
- Breyer RH, McClenathan JH, Michaels LL, McIntosh CL, Morrow AG. 1976. Tricuspid regurgitation. A comparison of nonoperative management, tricuspid annuloplasty and tricuspid valve replacement. *J Thorac Cardiovasc Surg* 72:867-74.
- Carpentier A, Deloche A, Hanania G, et al. 1974. Surgical management of acquired tricuspid valve disease. *J Thorac Cardiovasc Surg* 67:53-65.
- Come PC, Riley MF. 1985. Tricuspid annular dilatation and failure of tricuspid leaflet coaptation in tricuspid regurgitation. *Am J Cardiol* 55:599-601.
- De Vega NG. 1972. Selective, adjustable and permanent annuloplasty. An original technic for the treatment of tricuspid insufficiency [in Spanish]. *Rev Esp Cardiol* 25:555-6.
- Ege E, Paç M. 2002. Tricuspid ve Pulmoner kapak hastalıklarında cerrahi yaklaşım. *T Klin Kardiyol* 15:136-41.
- Haerten K, Sepiel L, Loogen F, Herzer J. 1978. Hemodynamic studies after DeVega's tricuspid annuloplasty. *Circulation* 58:128-33.
- Kalangos A, Sierra J, Vala D, et al. 2006. Annuloplasty for valve repair with a new biodegradable ring: an experimental study. *J Heart Valve Dis* 15:783-90.
- Kay JH, Maselli-Campagna G, Tsuji KK. 1965. Surgical treatment of tricuspid insufficiency. *Ann Surg* 162:53-8.
- Kay JH. 1992. Surgical treatment of tricuspid insufficiency. *Ann Thorac Surg* 53:1132-3.
- Kazaz M, Celkan MA, Ustunsoy H, Başpınar O. 2005. Mitral annuloplasty with biodegradable ring for infective endocarditis: a new tool for the surgeon for valve repair in childhood. *Interact Cardiovasc Thorac Surg* 4:378-80.
- King RM, Schaff HV, Danielson GK, et al. 1984. Surgery for tricuspid regurgitation late after mitral valve replacement. *Circulation* 70:1193-7.
- Pasque M, Williams WG, Coles JG, Trusler GA, Freedom RM. 1987. Tricuspid valve replacement in children. *Ann Thorac Surg* 44:164-8.
- Simon R, Oelert H, Borst HG, Lichtlen PR. 1980. Influence of mitral valve surgery on tricuspid incompetence concomitant with mitral valve disease. *Circulation* 62:1152-7.
- Uluçay A, Tatlı E. 2008. Myokart performans indeksi. *Anadolu Kardiyol Derg* 8:143-8.
- Yavuz S. 2007. Should stitch annuloplasty really be abandoned for developed flexible prosthetic band or ring in functional tricuspid regurgitation? *Interact Cardiovasc Thorac Surg* 6:736.