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Original Article

Clinical and echocardiographic results of the Kalangos biodegradable tricuspid ring for moderate and severe functional tricuspid regurgitation treatment

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Abstract: Introduction: The Kalangos Biodegradable Tricuspid Ring (Kalangos Biodegradable Tricuspid Ring®, Biorig SA, Lonay, Switzerland) is a biodegradable prothesis in the treatment of functional tricuspid regurgitation (FTR). In this study, we aimed to determine the clinical and echocardiographic results of this prosthesis for moderate and severe FTR treatment and compare this technique with the results of semicircular DeVega annuloplasty. Materials and methods: From January 2005 through January 2010 we retrospectively studied the data on 64 consecutive patients underwent annuloplasty procedures for FTR treatment. The patients were assigned to 2 groups: (1) Kalangos BTR annuloplasty was performed in 32 patients, and (2) Semicircular DeVega annuloplasty was performed in the 32 patients. All patients were evaluated clinically and by echocardiography preoperatively, at the end of the 1st week, 3rd and 6th month following surgery. Results: No complications related to the prosthesis or the procedures within the follow-up period were recorded. At the follow-up period, systolic pulmonary arterial pressure and tricuspid valve area diameter were found to be significantly lower than the preoperative values in both groups ($p < 0.0001$). At the follow-up period residual tricuspid regurgitation and the Tei index (Myocardial performance index) was significantly lower in group 1 compared to group 2 ($p < 0.05$). Three-quarters of the annuloplasty ring had degraded in the postoperative 6-months period. Discussion: We conclude that Kalangos BTR is an efficient and safe prosthesis with easy implantation technique for FTR treatment, with encouraging midterm results.

Keywords: Functional tricuspid regurgitation, tricuspid annuloplasty, echocardiography

Introduction

Various repair techniques have been advocated for the treatment of functional tricuspid regurgitation (FTR) [1]. These techniques include the use of flexible and rigid prosthetic rings, three-dimensional rings, flexible prosthetic bands, artificial chordae with polytetrafluoroethylene sutures, stitch annuloplasty such as semicircular De Vega or simple lateral Kay annuloplasty, and novel techniques such as edge-to-edge technique or cover technique [2]. Prosthetic ring annuloplasty has become a standard technique over years for the treatment of functional tricuspid regurgitation [3]. The tricuspid rings in routine clinical use have disadvantages such as the risk of infection and thromboemboli because of their structures and implantation techniques. Kalangos Biodegradable Tricuspid Ring (Kalangos BTR) is a relatively novel ring with many structural and technical advantages. It is biodegradable, three dimensionally flexible, and resistant to infections and embolic complications because of its sub-endocardial implantations. Easy handling and implantation are other advantages, which result in shortening of the in-flow or occlusion time [4]. In this study, we aim to determine the clinical and echocardiographic results of this prosthesis for FTR treatment and compare this technique with the results of semicircular DeVega annuloplasty.

Material and methods

From January 2005 through January 2010 we retrospectively studied the data on 64 consecutive patients underwent annuloplasty proce-

Table 1. Preoperative and demographic variables of the groups

	Group 1	Group 2	*P* value
Mean age (years)	43.5 ± 14	45.1 ± 12	> 0.05
Male/Female	22/10	23/9	> 0.05
NYHA class	3.1	3.2	> 0.05
Moderate TR	14 (43.8%)	15 (46.8%)	> 0.05
Severe TR	18 (56.2%)	17853.1%)	> 0.05
Mean value of TR	$3.44^0/4^0$	$3.53^0/4^0$	> 0.05
EF %	47 ± 13	49 ± 11	> 0.05
PAP (mmHg)	70 ± 14	68 ± 18	> 0.05
Tei index (RV)	0.62 ± 0.24	0.61 ± 0.19	> 0.05

EF: Ejection fraction, PAP: pulmonary artery pressure.

Table 2. Concomitant cardiac surgical procedures

Procedure	Group 1	Group 2
MVR	17	18
AVR + MVR	10	8
MVR + CABG	3	4
AVR + MVR + CABG	1	2
MVR + ASD repair	1	-
Total	32	32

MVR: Mitral Valve Replacement, AVR: Aortic Valve Replacement, CABG: Coronary Artery Bypass Grafting, ASD: Atrial Septal Defect.

dures to correct moderate and severe tricuspid valve regurgitations during a concomitant surgical procedure. This study was approved by the Institutional Review Board and written informed consent was obtained from all patients.

The patients were assigned to 2 groups: (1) Kalangos BTR annuloplasty was performed in 32 patients (22 females/10 males, age: 43.5 ± 14 years) and (2) Semicircular DeVega annuloplasty was performed in the remaining 32 patients (23 females/9 males, age: 45.1 ± 12 years). 15 patients in group 1 (46.9%) and 14 patients in group 2 (43.8%) were in atrial fibrillation preoperatively. The exclusion criteria were as follows: congenital or organic tricuspid valve lesion (commissural fusion, leaflet and/or chordae thickening, valvular and/or annular calcification). There was one in hospital mortality in group 2 due to lower cardiac output (2.9%) and this patient excluded from the study. The echocardiographical measured tricuspid leaflet thickness was > 2 mm. Tricuspid valvular diameter was < 3.4 cm in diastolic phase and diastolic doming. All patients were evaluated preoperatively, at the postoperative 1st week, 3rd and 6th months by TTE. Demographic data of the study groups were shown in **Table 1**.

Echocardiography

TTE was performed with a Vivid 7 Doppler Echocardiographic unit (Vivid 7, GE Vingmed Ultrasound, Horten, Norway) with 3.5 Mhz transducer probe. All echocardiograms were performed by an experienced investigator. The echocardiographic evaluation was performed at left lateral decubitis position from parasternal long and short axis views and apical two and four views appropriate to American Echocardiography Association report [5]. Ejection fraction (EF) was determined by modified Simpson method [5]. The mitral inflow velocity was traced and the following variables were measured: peak velocity of early (E) and late (A) filling and deceleration time (DT) of the E-wave velocity. LV longitudinal functions were assessed by pulsed TDI. The diastolic indices of myocardial early (Ea) and atrial contraction (Aa) peak velocities and myocardial systolic weave (Sa) velocity was measured with pulsed TDI. Myocardial performance was measured with Tei index as the sum of the isovolumetric contraction time (IVCT) and isovolumetric relaxation time (IVRT) divided by ventricular ejection time (ET). Preoperative and postoperative RV functions were evaluated with Tei index (IVCT + IVRT/ET) [7].

FTR jet flow was evaluated from apical, subcostal and parasternal views. Pulmonary Artery Pressure (PAP) was measured with continuous-wave Doppler and the maximum peak tricuspid regurgitation velocity (V) was recorded from any view that was used to determine RV systolic pressure with the simplified Bernoulli equation (PAP = 4V2 + RAP) [8]. Preoperative and postoperative tricuspid valve area was measured by the pressure half-time method. Mean diastolic gradients were measured by continuous wave Doppler echocardiography. A transvalvular gradient between 2-5 mmHg was defined as moderate tricuspid valvular stenosis and a transvalvular gradient > 5 mmHg was defined as severe tricuspid valvular stenosis [9].

Surgical intervention

A median sternotomy and aorta-bicaval cannulation were performed under standard general

anesthesia. Cardiac arrest was achieved by antegrade and intermittent antegrade cold blood cardioplegia during surgery, and antegrade warm blood cardioplegia was given before declamping. Before tricuspid annuloplasty, all indicated concomitant procedures were performed. Tricuspid annuloplasty was performed using an in-flow occlusion technique on the beating heart. For the mitral valve, left atriotomy approach was used. A right atriotomy was also performed for tricuspid annuloplasty.

Patients undergoing tricuspid annuloplasty with a ring underwent a Kalangos BTR inserted technique in 32 patients and semicircular DeVega annuloplasty technique in 32 patients. Kalangos BTR inserted technique: After the meticulous inspection for valvular regurgitation and leaflet coaptation, the anterior leaflet area was measured, and the size was decided upon. Starting from the anteroseptal commissure, the Kalangos BTR was inserted around the annulus subendocardially, up to the posteroseptal commissure, taking care of the coronary sinus and AV node. The implantation was completed by fixation of the anteroseptal and posteroseptal commissures. Semicircular DeVega annuloplasty technique: Single polypropolene suture from the anteroseptal to the posteroseptal commissure with a pledget at each end.

After the tricuspid anuloplasty, the competence of the tricuspid valve was checked with the help of saline injection into the right ventricle. The operation was terminated after closure of right atrium and implantation of epicardial pacemaker leads. 24, 26, 28, 30, 32, and 34 size rings implanted in 1, 3, 11, 12, 4, and 1 patients, respectively (mean size: 29. 1 ± 2.09). Concomitant surgical procedures were performed in 15 patients in group 1 and 14 patients in group 2 (**Table 2**). TV repair was performed after other concomitant cardiac procedures were completed, usually with the aortic cross-clamp in place. Mean postoperative hospitalization was 8 ± 2.3 (6-17) days. All of the patients were anticoagulated with warfarin.

Statistical analysis

SPSS 13.0 Statistical Software (SPSS Inc., Chicago, IL, USA) was used for all statistical analysis. The patients' preoperative and postoperative TTE parameters were compared between the groups and the results were also compared in the groups. Chi-square and one-way ANOVA tests were used to determine the statistical differences between the two study groups. Wilcoxon test was used to evaluate the differences in the same group during the time period. $P < 0.05$ was considered statistically significant. All values reported are mean ± SD.

Results

Age, gender, mean arterial pressure, cardiac rhythm, heart rate, NYHA class, left ventricular EF and sPAP did not statistically significant differ between the two study groups. Preoperatively, severe FTR has been detected in 14 patients in group 1 and in 15 patients in group 2. Preoperative Tei index was measured as 0.62 ± 0.24 in group 1 and 0.61 ± 0.19 in group 2 ($p > 0.05$). Aortic cross-clamp time was 48 ± 9 min. in group 1 and 47 ± 8 min. in group 2. Tricuspid repair periods were 15 ± 4 min in group 1, and 14 ± 4 min in group 2, but did not statistically significant between the study groups. St. Jude Medical mechanical bi-leaflet valve was used for mitral valve replacement.

At the 1st week control TEE, systolic pulmonary arterial pressure and tricuspid valve area diameter were significantly lower than the preoperative values in both groups (PAP decreased from 70 ± 14 mmHg to 57 ± 12 mmHg in group 1 and from 68 ± 18 mmHg to 56 ± 15 mmHg in group 2; $p < 0.05$). Tricuspid valve area showed a statistically significant decrease at the 1st week [4.15 ± 0.35 (preoperative) to 3.15 ± 0.45 (post-operative) in group 1; 4.12 ± 0.37 (preoperative) to 3.05 ± 0.48 (post-operative) in group 2], but did not statistically significant difference between the groups. In group 1, FTR severity was decreased from 3.44°/4° to 1.69°/4° and group 2 from 3.53°/4° to 1.71°/4° ($p < 0.05$). Concomitantly, we calculated the Tei indices of the groups and we achieved a statistically significant decrease in both groups (In group 1; from 0.61 ± 0.24 to 0.59 ± 0.14 and in group 2; from 0.61 ± 0.19 to 0.59 ± 0.28). There was not a statistically significant difference in between the groups in terms of the TTE variables evaluated in the postoperative 1st week.

At the 3rd month control TEE, sPAP value was decreased to 46 ± 16 mmHg in group 1 and 48 ± 17 mmHg in group 2; but there was no significant difference between the groups. Despite

Table 3. Postoperative echocardiographic results of the groups

	Group 1	Group 2	P
Preoperative			
sPAP (mmHg)	70 ± 14	68 ± 18	NS
Mean FTR degree (°)	3.44/4	3.53/4	NS
Tei index	0.62 ± 0.24	0.61 ± 0.19	NS
1st WEEK			
PAP (mmHg)	57 ± 12	56 ± 15	NS
Mean FTR degree (°)	1.69/4	1.71/4	NS
Tei index	0.59 ± 0.14	0.59 ± 0.28	NS
3rd MONTH			
NYHA class	2.2	2.4	NS
Mean FTR degree (°)	1.75/4	1.87/4	< 0.05
PAP (mmHg)	46 ± 16	48 ± 17	NS
Tei index	0.48 ± 0.20	0.54 ± 0.22	< 0.05
6th MONTH			
NYHA class	2.1	2.4	NS
Mean FTR degree (°)	1.84/4	2.22/4	< 0.05
PAP (mmHg)	45 ± 9	46 ± 12	NS
Tei index	0.47 ± 0.29	0.55 ± 0.24	< 0.05

there was no significant difference between the study groups at 1st week control for tricuspid valve area (3.19 ± 0.50 in group 1, 3.06 ± 0.45 in group 2), at 3rd month control post-operatively tricuspid valve area showed a statistically significant decrease compared to the preoperative values. Additionally, in postoperative 3rd month TEE determined an improvement in patients' functional capacity as NYHA class of group-1 was 2.2 and group-2 was 2.4 ($p > 0.05$) and residual tricuspid regurgitation was statistically significantly lower in Kalangos BTR annuloplasty group than semicircular DeVega annuloplasty group. Furthermore, the Tei index of group 1 patients was significantly lower than group 2 patients (0.48 ± 0.2 vs. 0.54 ± 0.22; $p < 0.05$). Mild tricuspid valve stenosis was found in 2 patients in group 2. Measured transvalvular gradient was 2 mmHg in one of them and 3 mmHg in the other patient.

At the 6th month control TTE showed that sPAP was 45 ± 9 mmHg in group 1 and 46 ± 12 mmHg in group 2. sPAP did not statistically significant differ between the groups and 6th month' control. Tricuspid valve area significantly decreased compared to the preoperative values, but did not statistically significant differ between the groups at 1st-week and 3rd-month controls (3.17 ± 0.48 in group 1, 3.12 ± 0.42 in group 2). Similarly, there was not a statistically significant difference between the groups in terms of functional capacity. However; TTE showed that residual TR and the Tei index (0.47 ± 0.29 vs. 0.55 ± 0.24; $p < 0.05$) was statistically significant lower in group 1 compared to group 2. Three-quarters of the annuloplasty ring had degraded in the postoperative 6 months' period. Postoperative echocardiographic results of the study groups were shown in **Table 3**.

Discussion

The FTR is a dynamic entity that is governed by several pathophysiologic mechanisms like TV annular dilatation, annular shape, pulmonary hypertension, left or right ventricle dysfunction, right ventricle geometry, and leaflet tethering. With the decline of rheumatic heart disease, a large proportion of the TR encountered is functional rather than organic. FTR refers to the TR secondary to the left heart pathology or right heart pathology in the face of a normal TV leaflet morphology. Treatment options for FTR are primarily surgical [10]. Right ventricular failure due to FTR is an important cause of late morbidity and mortality in patients operated for valvular heart disease [5]. The ACC/AHA guidelines advices tricuspid annuloplasty in patients with moderate and severe functional tricuspid regurgitation [11]. Various types annuloplasty techniques have been performed for treatment of FTR, which includes the use of flexible and rigid prosthetic rings or three-dimensional rings (e.g. Puig-Massana Shileyring, Duran ring, Carpentier ring, etc.), flexible prosthetic bands (e.g. Cosgrove-Edwards flexible band), the use of artificial chordae with polytetrafluoroethylene sutures for anterior and septal leaflet pathology, stitch annuloplasty such as semicircular De Vega or simple lateral Kay annuloplasty, and novel techniques such as edge-to-edge technique or cover technique [2].

Semisircular De Vega annuloplasty is one of the suture annuloplasty techniques for FTR. It is a simple and quicker method with a lower cost than ring annuloplasty. However, sometimes when the suture annuloplasty techniques are used for the treatment significant FTR, outcomes might be unsuccessful because of the residual significant tricuspid regurgitation or tricuspid stenosis [12, 13].

The Kalangos BTR is a biodegradable "C-shape" ring made of blue-colored poly 1, 4-diaxanone polymer with two integrated sutures and stainless steel needles on either ends. Polydiaxanone is a well-known absorbable surgical suture material, and degrades within six months in the body [14]. Owing to simple design of Kalangos BTR, it could be implanted easy and fast, and reducing the in-flow occlusion time for tricuspid annuloplasty. The subendocardial implantation of the Kalangos BTR prevents the device from being in direct contact with the blood stream. This prevents thromboembolic complications and reduces the need for anticoagulation as is required in patients with conventional annuloplasty rings. Also, degradation of the material within six months reduces the risk of infection [15]. In our study, in both study groups, there was no any complication resulting from infection or thromboembolism.

One of the major benefits of the Kalangos BTR is the preservation of the natural three dimensional elasticity of the annulus, while gradually replacing the foreign material by natural fibrous tissue. This fibrous tissue, however, does not prevent anteroposterior contraction as occurs with other design. This might have a positive impact on ventricular function. The clinical improvement indicated by echocardiographic findings (Tei index) in our patients might be not only treatment of valves, but also to the effective application of tricuspid ring annuloplasty. Kalangos and colleagues [16] published a retrospective echocardiographic study implanting Carpentier's ring and biodegradable ring to 213 patients; showed that when compared with the rigid rings, biodegradable rings have less gradient, better posterior leaflet mobility and faster recovery of the shortening fraction after surgery-important features for the short, medium and long term results of vale repairs.

FTR is closely associated with RV volume overload. Although the effects of RV volume and pressure overload on ventricular septal motion are different, the differential effect on LV function is still controversial [17]. Systolic and diastolic time intervals are closely linked to systolic and diastolic LV performance. Systolic time intervals have been found to be correlated closely with cardiac output, EF and also with the first derivative of isovolumetric LV pressure in patients with or without cardiac disease [18]. Tei and colleagues [7] reported a Doppler-derived index for assessment of overall LV function that combines systolic and diastolic time intervals. Tei index is also an important parameter evaluating RV functions, preoperative risk and postoperative prognosis [19]. In healthy subjects, Tei index is 0.39 ± 0.05. In patients with primary pulmonary hypertension Tei index can increase to 0.93 ± 0.34. In our study, the patients' Tei index values were calculated as 0.62 ± 0.24 for group 1, and 0.61 ± 0.19 for group 2, preoperatively. Clinical observation and echocardiography performed during the postoperative period revealed significant improvement in NYHA-class, the symptoms and severity of FTR and Tei index. Postoperative 1st-week echocardiographic examination revealed a significant decrease in Tei index and indicated improved cardiac functions. Furthermore, echocardiography performed at 3rd and 6th month after the operation revealed a statistically significant difference between group 1 and group 2 (Postoperative 6th month echocardiographic examination revealed that Tei index was decreased from 0.61 to 0.47 in group 1, from 0.62 to 0.55 in group 2. The differences between two study groups were statistically significant; $p < 0.05$). This result might have arises a positive impact on ventricular function of the Kalangos BTR.

Recurrence of left-sided valvular disease, advanced RV dysfunction, postoperative high pulmonary artery pressure, postoperative pulmonary artery resistance, and severity of preoperative TR were important factors for the development of residual or recurrent TR after tricuspid valve surgery [19, 20]. In our study, when we evaluated the patients at postoperative 3rd and 6th month by TTE, we found that tricuspid annular contraction was more preserved in group 1 patients. 4 patients in group 1 (12.5%) had 30 recurrent TR, whereas 9 patients (28.1%) had 30 recurrent TR and 2 patients (6.3%) had 40 recurrent TR at postoperative 6th month control. We thought that persistent pulmonary artery hypertension, RV dysfunction and the long period of time suffering severe FTR might be responsible for those recurrences.

As a result, biodegradable rings enhance the well-known benefits of valve repair. KBR, because of its biodegradable character, induces the fibrous tissue with structural function resulting in low infection and thromboembolic

risk. Furthermore, comparing with semicircular DeVega annuloplasty, we found that implanting Kalangos BTR in patients with deteriorated RV function because of long-lasting pulmonary hypertension preserves annular tricuspid functions and recurrence rate of FTR is much lower. Also we did not observe any evidence of tricuspid stenosis and noticed that the recovery of RV functions was more convincing. As a conclusion, Kalangos BTR is a promising prosthesis in patients with moderate and severe FTR, with encouraging mid-term results.

Disclosure of conflict of interest

All authors accepted there was no editorial and financial conflict of interest.

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