Mid-term follow-up of pulmonary valve bioprostheses in adults with congenital heart disease

Konjenital kalp hastalığı olan yetişkinlerde pulmoner kapak biyoprotezlerin orta dönem izlemi

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As the long-term results of the surgical treatment for congenital heart disease (CHD) have been improved, the number of adult patients with CHD is increasing. Tetralogy of Fallot (TOF) is the most common form of cyanotic CHD (1) and according to favorable outcome of TOF total correction nowadays we are facing with an increasing number of patients with residual pulmonary regurgitation (PR) (2).

The deleterious effects of longstanding PR on right ventricular (RV) size and function, resulting in an increased risk for severe arrhythmias and sudden death, have been well documented (3) which is the reason for increasing number of pulmonary valve replacement (PVR) in patients with repaired TOF. In adult patients with TOF, controversy remains on the type of prosthetic valve and optimal timing of PVR. Most surgeons replace the pulmonary valve with an allograft or xenografts and have suggested good medium term follow up (4). However, these tissue valves both deteriorate over time and making multiple reoperations necessary, each associated with morbidity and mortality. We aimed to review the mid-term results of bioprosthetic pulmonary valve implantation in patients with a previous corrective surgery resulting severe PR.

Since 2003 to July 2008, seventy-eight patients with history of TOF repair or pulmonary valvotomy underwent bioprosthesis PVR. After clinical evaluation based on classification of functional class by the New York Heart Association, (NYHA), all patients underwent a complete two-dimensional (2D) and Doppler study. Any regurgitation equal or more than moderate was defined as significant. Peak systolic pressure gradient across the pulmonary bioprostheses was estimated by continuous wave Doppler echocardiography, using the modified Bernoulli equation and graded as severe stenosis (peak gradient >64 mmHg), moderate stenosis (peak gradient 36-64 mmHg) and mild stenosis (peak gradient less than 36 mmHg) based on the latest guideline for assessment of valve stenosis (5). Mean±SD of age of our patients was 27±8.7 years (range 9 to 54 years) and female/male was 46/32. Median age of prosthesis (time interval between PVR and echocardiographic examination) was 2 years (ranged from 1 month to 5 years) and 68 patients (87.2%) were between 0.5-5 years of the age of prosthesis.

Patients' clinical data are presented in Table 1. Right ventricle enlargement was observed in 91% of patients and only 7 patients (9%) had normal RV size. Similarly almost all of the patients (98.7%) had degrees of RV dysfunction. Forty-eight patients (62.5%) had degrees of left ventricular dysfunction. Sixteen patients (20.5%) had moderate or higher pulmonary prosthetic valve insufficiency. Peak pressure gradient was ≥ 36 mmHg in 24 patients (30.8%).

Thirty-four patients (43.6%) had at least one kind of malfunctioning pulmonary bioprostheses: 24 patients with stenosis (30.8%), 16 (20.5%) with insufficiency and 6 (7.7%) with both. Most patients were asymptomatic; only fourteen patients (17.9%) had clinical symptoms at the time of examination.

Overall freedom from bioprosthesis dysfunction (defined as freedom from significant stenosis or regurgitation) was 56.4% after 5 years. We found more severe RV enlargement in patients with bioprosthesis malfunction (p=0.053) compared to normally

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Table 1. Clinical findings in patients with pulmonary valve bio-prosthesis (n=78)

Variables	n (%)
Symptoms	14 (17.9)
Underlying disease	
TF	61 (78.2)
PS	17 (21.8)
Age of prosthesis	
<6 months	10 (12.8)
6 months-5 years	68 (87.2)
Prosthesis insufficiency	
No	37 (47.4)
Mild	25 (32.1)
Moderate	12 (15.4)
Severe	4 (5.1)
Increased peak pressure gradient	
Mild (<36 mmHg)	54 (69.2)
Moderate (36-64 mmHg)	19 (24.4)
Severe (>64 mmHg)	5 (6.4)
Left ventricular function	
Normal	30 (38.5)
Mild dysfunction	40 (51.2)
Moderate dysfunction	7 (9)
Severe dysfunction	1 (1.3)
Size of right ventricle	
Normal	7 (9)
Mild enlargement	13 (16.7)
Moderate enlargement	30 (38.5)
Severe enlargement	28 (35.9)
Right ventricular function	
Mild dysfunction	27 (34.6)
Moderate dysfunction	31 (39.8)
Severe dysfunction	20 (25.6)
Prosthesis malfunction	
Peak pressure gradient (≥36 mmHg)	24 (30.8)
Prosthesis insufficiency (≥moderate)	16 (20.5)
Overall malfunction	34 (43.6)

Data are expressed as mean±SD
PS - pulmonary stenosis, TOF - tetralogy of Fallot

Table 2. Prosthesis malfunction in association with patients' clinical findings

Variables	Malfunction		*p
	No (n=44)	Yes (n=34)	
Age, years	27.1±9.0	27.7±8.4	0.807
Sex, F/M	30/14	16/18	0.060
Type of prosthesis			0.577
Biologic	43 (97.7)	32 (94.1)	
Homograft	1 (2.3)	2 (5.9)	
Age of prosthesis, years	2.3±1.3	2.2±1.5	0.727
Underlying disease, n (%)			0.820
TF	34 (77.3)	27 (79.4)	
PS	10 (22.7)	7 (20.6)	
Right ventricular enlargement, n (%)			0.053
Mild	9 (20.5)	4 (11.8)	
Moderate	16 (36.4)	14 (41.2)	
Severe	13 (29.5)	15 (44.1)	
Right ventricular dysfunction, n (%)			0.974
Mild	14 (31.8)	13 (38.2)	
Moderate	20 (45.5)	11 (32.4)	
Severe	10 (22.7)	10 (29.4)	
Peak pressure gradient, mmHg	22.3±7.3	47.0±21.0	<0.001
Mean pressure gradient, mmHg	13.0±4.7	28.2±15.2	<0.001
PV VTI, m/s	54.8±12.6	84.6±24.6	<0.001
RVOT VTI, m/s	23.3±10.1	29.3±11.6	0.029
RVOT/PV VTI	0.45±0.18	0.36±0.16	0.061
TAPSE, mm	1.4±0.31	1.5±0.34	0.441
S_m , m/s	6.4±1.9	6.3±1.6	0.695

Data are expressed as mean±SD and number (percentage)
F - female, M - male, PS - pulmonary stenosis, PV - pulmonary valve, RVOT - right ventricular outflow tract, Sm - systolic velocity of tricuspid annulus, TAPSE - tricuspid annulus plane systolic excursion, TOF - tetralogy of Fallot, VTI - velocity time integral

functioning bioprostheses. Prosthesis malfunction data are summarized in Table 2. In bioprosthesis group, most of the events occurred in second and third years. In this study, the 5-year freedom from structural failure of pulmonary bioprostheses (mean follow up 24 months) was 56.4%. Fiore et al. (6) reported 19% bioprostheses dysfunction in a mean follow up 20±27 months and in another study on mixed population of children and adults who underwent PVR, the rate of freedom from further valve replacement has been suggested 81% for 5 years and 58% for 10 years (7). We found that our pulmonary valve bioprostheses had significantly less freedom from structural failure compare to previous studies. In our study, freedom from significant dysfunction at 5-year (56.4%) was comparable to 10-year (58%) durability of pulmonary bioprostheses in the other studies. Graham et al. (8) reported average valve durability approximately 11 years (50% replacement at 11 years) in a multicenter study with 93 adult patients with previous PVR and mean follow up 3 years.

We found significant difference between normally functioning and malfunctioning bioprostheses in the following data: mean pressure gradient (13.0±4.7 vs 28.2±15.2 mmHG) (Fig. 1),

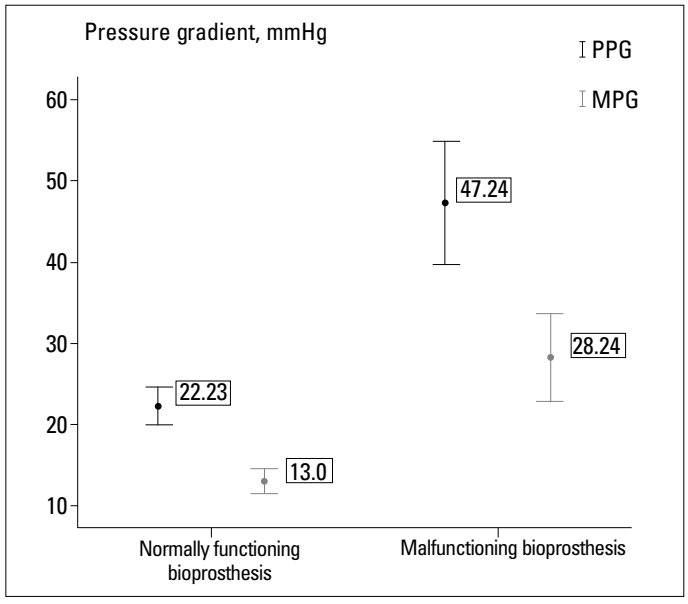

Figure 1. Comparisons of pressure gradients between patients with or without malfunctioning pulmonary bio-prostheses
MPG-mean pressure gradient, PPG-peak pressure gradient

PV velocity-time integral (VTI) (54.8±12.6 vs 84.6±24.6 cm) and RV outflow tract VTI/ PV VTI (0.45±0.18 vs 0.36±0.16) with values p<0.001. The normal values for pulmonary bioprostheses are consistent with our previous study and other similar studies (9).

In general, most authors recommend porcine xenografts and homografts for the reconstruction of a competent pulmonary valve, that the late deterioration and reoperations are the rule (10). The issue of which type of valve would perform better in the pulmonary position is still in debate. Mechanical prostheses have less favorable reputation due to lifetime anticoagulation therapy and higher risk of right sided mechanical pulmonary thrombosis, but the chance of subsequent re-operations especially in patients wishing no further surgery or patients with significant right ventricular dysfunction can be expected to be low. We might consider mechanical valves for the pulmonary position, especially in patients with significant ventricular dysfunction or patients who require anticoagulation treatment for rhythm disturbances. However it needs another comprehensive study with long- term follow up.

Conflict of interest: None declared.

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