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ORIGINAL ARTICLE

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Durability of bioprostheses for the tricuspid valve in patients with congenital heart disease

Melchior Burri[a,†]*, Manfred O. Vogt[b,†], Jürgen Hörer[a,c], Julie Cleuziou[a], Jelena Kasnar-Samprec[a], Andreas Kühn[b], Rüdiger Lange[a,d] and Christian Schreiber[a]

[a] Department of Cardiovascular Surgery, German Heart Center Munich at the Technical University Munich, Munich, Germany
[b] Department of Paediatric Cardiology and Congenital Heart Disease, German Heart Center Munich at the Technical University Munich, Munich, Germany
[c] Pôle des Cardiopathies Congénitales, Hôpital Marie Lannelongue, Le Plessis-Robinson, France
[d] DZHK (German Center for Cardiovascular Research) – partner site Munich Heart Alliance, Munich, Germany

* Corresponding author. Department of Cardiovascular Surgery, German Heart Center Munich at the Technical University Munich, Lazarettstraße 36, 80636 Munich, Germany. Tel: +49-89-12182904; fax: +49-89-12184123; e-mail: burri@dhm.mhn.de (M. Burri).

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Abstract

OBJECTIVES: Only little data exist on the durability of bioprostheses in the tricuspid position in patients with congenital heart disease (CHD). The aim of the study was to determine the reoperation rate and the valve function after primary implantation.

METHODS: Between 1990 and 2013, 51 patients with CHD underwent tricuspid valve (TV) replacement with a bioprosthesis. The median age at operation was 32 years (range: 8–69). The underlying morphology was Ebstein's anomaly in 62% of the patients. Implanted valves included 38 pericardial and 13 porcine valves. All available echocardiographic examinations ($n = 714$) and clinical data were retrospectively reviewed. Dysfunction was defined as an at least moderate regurgitation or a mean diastolic gradient ≥9 mmHg. Freedom from death, reoperation and prosthetic valve dysfunction was estimated using the Kaplan–Meier method.

RESULTS: The 30-day mortality rate was 9%. The estimated survival rate was 86% at one and 80% at ten years. The freedom from reoperation at 1, 5 and 10 years was 100, 86 and 81%, and that from prosthesis dysfunction detected by echocardiography at 1, 5 and 10 years was 89, 66 and 58%, respectively. The main reason for dysfunction was insufficiency (89%). Valve implantation at an age below 16 years was associated with earlier reoperation and dysfunction (the 5-year freedom rate from reoperation/dysfunction was 70%/30% compared with 89%/78% in the rest of the patients, $P = 0.016/0.0009$).

CONCLUSIONS: Serial echocardiography shows a high rate of dysfunction of TV bioprosthesis in patients with CHD, which already occurred a few years after implantation. In patients below 16 years of age, most prostheses are dysfunctional within 5 years.

Keywords: Congenital heart disease • Tricuspid valve • Heart valve prosthesis • Bioprosthetic

INTRODUCTION

Recently, Guenther *et al*. [1] published a low reoperation rate of 24% after 10 years for patients with acquired heart disease (AHD) and tricuspid valve replacement (TVR) with a biological prosthesis. Even lower reoperation rates have been reported by other groups [2–6]. However, during the past years, we have observed a significant number of younger patients requiring replacement of a bioprosthesis in the tricuspid position quite soon after implantation. This led us to question whether published data on patients with AHD are valid in patients with congenital heart disease (CHD). Up to now, only a little data exist regarding durability of bioprostheses in the tricuspid position in patients with CHD. We therefore retrospectively reviewed serial echocardiographic examinations of patients with CHD who underwent biological TVR at our institution.

[†]The first two authors contributed equally to this study.

METHODS

The institutional review board approved the study and waived the need for informed consent from the parents or patients due to lack of any patient identifiers and the retrospective nature of the study. All patients with CHD who underwent initial TVR with a bioprosthesis at the German Heart Center Munich between 1990 and 2013 were analysed. Patients with a tricuspid valve (TV) in the systemic position (single ventricle, congenitally corrected transposition of the great arteries, transposition of the great arteries after an atrial switch operation) were excluded.

We found 51 patients who underwent TVR with a bioprosthesis. Basic diagnosis and procedural data are presented in Table 1; implanted valve types are specified in Table 2. After operative treatment, patients were anticoagulated with phenprocoumon for 3–6 months ($n = 29$) or persistently ($n = 9$). The reason for persistent prescription of phenprocoumon after operation/intervention

Table 1: Patient characteristics and operative data

Diagnosis	
Ebstein's anomaly	32 (63%)
Tricuspid valve dysplasia	5 (10%)
Endocarditis after VSD repair	4 (8%)
Pulmonary stenosis	3 (6%)
Other	7 (13%)
Demographics	
Age at operation (years)	32 (3.8–69)
Weight at operation (kg)	64 (16–118)
Isolated tricuspid valve replacement	34 (67%)
Additional procedure	
Failed tricuspid valve repair	23 (45%)
Antiarrhythmic surgery	9 (18%)
Mitral valve repair	4 (8%)
Mitral valve replacement	2 (4%)
Aortic valve replacement	1 (2%)
Other	5 (10%)
Previous cardiac surgery	40 (78%)
Previous tricuspid valve surgery	
Repair (no ring)	32 (63%)
Repair (with ring)	3 (6%)
Procedural information	
On ECC, no aortic clamping	15 (30%)
ECC time (min)	124 (48–252)
Aortic clamping time (min)	51 ± 43
Implanted valves	
Perimount (bovine pericardial)	38 (75%)
Mosaic (porcine)	7 (13%)
Intact (porcine)	5 (10%)
Hancock (porcine)	1 (2%)
Effective orifice area	
EOA[a] (cm^2)	2.8 (1.6–2.8)
iEOA[a] (cm^2/m^2)	1.6 (1.0–2.9)

ECC: extracorporal circulation; EOA: effective orifice area; iEOA: indexed effective orifice area; VSD: ventricular septal defect.
[a]Data missing in 5 patients.

Table 2: Prosthesis type and size ($n = 51$)

Manufacture valve size (mm)	21	25	27	29	31	33	35
Perimount ($n = 38$)	1	2	2	3	6	24	0
Mosaic ($n = 7$)	0	2	0	0	1	4	0
Intact ($n = 5$)	0	0	0	0	3	0	2
Hancock ($n = 1$)	0	0	0	0	0	1	0

was either atrial flutter ($n = 5$), another mechanical valve ($n = 1$), severely reduced ejection fraction ($n = 1$), history of pulmonary thrombo-embolism ($n = 1$) or intravenous atrial pacemaker leads ($n = 1$). Thirteen patients were not anticoagulated due to contraindications or complicated postoperative courses.

The median follow-up time was 5.4 years (range: 1 day–19 years, 291 patient-years). Eight patients (16%) were lost to follow-up in 2012/2013. Two of these patients, originating from foreign countries, were lost to follow-up early (21 and 28 days), but the remaining six had a median follow-up length of 4.1 years. All echocardiographic examinations, obtained during regular appointments at the German Heart Center Munich or at the referring cardiologist, were taken from the charts. A total of 714 echocardiographic examinations were included in the analysis. Echocardiographic examinations before valve replacement, at hospital discharge and at the latest follow-up examination were reanalysed by two experienced paediatric cardiologists (Manfred O. Vogt, Andreas Kühn) to standardize interpretation of the echocardiographic evaluations. All patients had a standardized echocardiographic examination at hospital discharge and 90% had at least one more echocardiographic evaluation in the first postoperative year. Echocardiographic data during the late follow-up were absent in 4 patients (8%).

Insufficiency was graded as none (0), minimal (1), mild (2), moderate (3) and severe (4), based on the width of the vena contracta of the regurgitant jet (four-chamber view and parasternal short-axis view). Intermediate descriptive findings between two grades were given the according half values (i.e. mild-to-moderate was assigned the value 2.5). Grades 3 and 4 were considered as a significant tricuspid insufficiency and per definition led to an enlarged right atrium. Tricuspid stenosis was evaluated by the diastolic atrioventricular mean gradient. Prosthesis dysfunction was defined as insufficiency ≥3, and/or diastolic mean gradient of ≥9 as proposed by Blauwet *et al.* [7].

Freedom from prosthesis dysfunction was defined as time until the first occurrence of a prosthesis dysfunction. For each patient, echocardiographic data were plotted as shown in Fig 1. The plotted echocardiographic data for each patient can be found in the Supplementary Material. Isolated findings of prosthesis dysfunction, followed by multiple echocardiographic examinations without dysfunction, were considered to be outliers and were excluded from the analysis (altogether five values).

The systolic pressure gradient between the right ventricle (RV) and the right atrium was estimated by the insufficiency jet over the TV and was averaged for each patient over the follow-up period.

To exclude prosthesis dysfunction due to patient/prosthesis mismatch, we indexed the effective orifice area (iEOA) from the literature [8] to each patient's body surface. Data of the effective orifice area were available for 46 valves (90%). Supplementary Material contains a more detailed table of the implanted valve size related to the body weight.

Statistics

Descriptive statistics are described as frequencies and percentages for categorical variables. Continuous variables are expressed as the mean ± standard deviation if normally distributed, or median and range if abnormally distributed. Confidence interval (CI) is reported as 95% CI. Probability of freedom from death, reoperation and freedom from prosthesis dysfunction were calculated using the Kaplan–Meier method, and curves were compared using the log-rank test. In calculations for prosthesis dysfunction and reintervention, death was stated as censoring. All statistical calculations were performed using the R environment (version 3.1.1). All authors had full access to the data and take full responsibility for its integrity.

RESULTS

The estimated survival rate was 86% (CI: 77–96%) at 1 year, and 80% (CI: 69–93%) at 5 and 10 years (Fig. 2A). The early mortality rate (<30 days) was 8%. Causes of 30-day mortality were sepsis ($n = 2$), right heart failure ($n = 1$) and gastrointestinal bleeding ($n = 1$). Causes for late death were heart failure ($n = 1$), lung emboli ($n = 1$) or were unknown ($n = 3$).

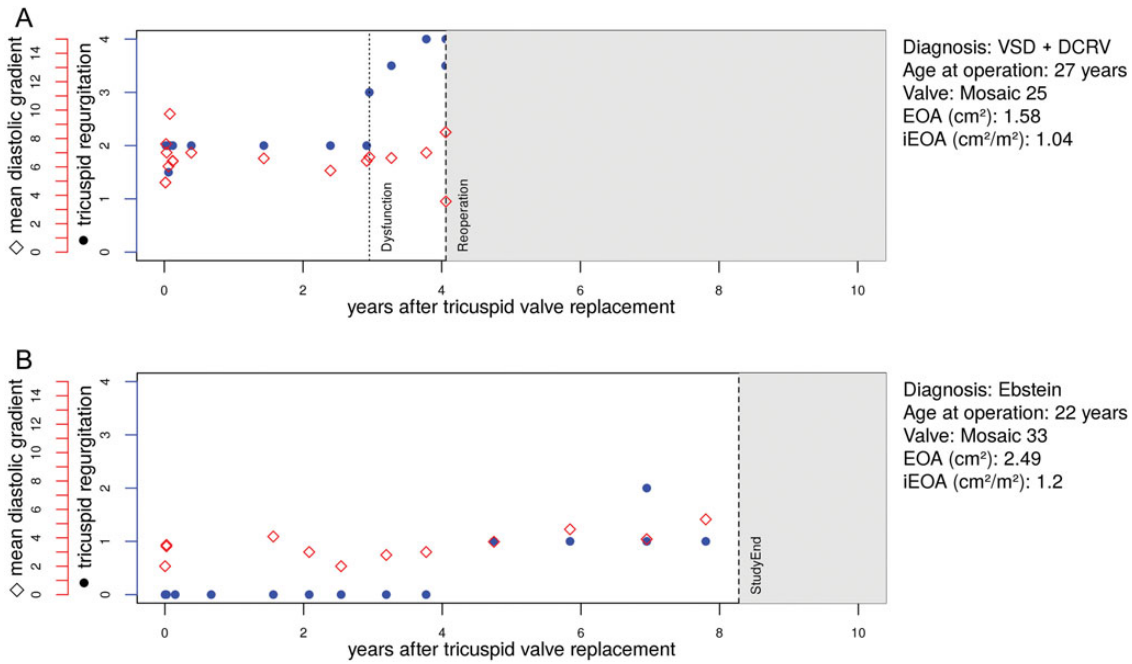

Figure 1: Two samples of postoperative echocardiographic evaluation. Blue dots indicate insufficiency; red diamonds indicate stenosis. In the first patient (**A**), valve dysfunction was present 3.1 years after implantation and reoperation was performed 1.3 years afterwards. The second patient (**B**) had a well-functioning valve at the end of the study period. DCRV: double-chambered right ventricle; EOA: effective orifice area; iEOA: indexed effective orifice area; VSD: ventricular septal defect.

The freedom from reoperation was 100% (CI: 100–100%) at 1 year, 86% (CI: 75–98%) at 5 years and 81% (CI: 67–97%) at 10 years (Fig. 2B). The freedom from prosthesis dysfunction was 89% (CI: 80–99%) at 1 year, 66% (CI: 53–83%) at 5 years and 58% (CI: 44–77%) at 10 years (Fig. 2C). Prosthesis dysfunction was stenosis and insufficiency in 17%, isolated insufficiency in 72% and isolated stenosis in 11%. The location of the insufficiency was transvalvular in 20 cases and paravalvular in 2 cases. Both freedom from reoperation and freedom from dysfunction was significantly lower in patients below 16 years of age (the 5-year freedom rate from reoperation: 78 vs 89% in patients older than 16 years, $P = 0.016$; the 5-year freedom rate from dysfunction: 30 vs 78% in patients older than 16 years, $P < 0.001$, Fig. 3). Valves smaller than 28 mm diameter ($n = 7$) showed dysfunction earlier than the bigger one (the 5-year freedom rate from reoperation: 50 vs 93%, respectively, $P < 0.001$; the 5-year freedom rate from dysfunction: 0 vs 81%, respectively, $P < 0.001$). There was no significant difference in prosthesis dysfunction between patients with iEOA in the lowest quartile (<1.3 cm^2/m^2) and the remaining patients (the 5-year freedom rate from dysfunction: 67 vs 65%, respectively, log-rank: $P = 0.58$). There was no significant difference in valve dysfunction between patients after pericardial valve implantation compared with patients after porcine valve implantation (the 5-year freedom rate from dysfunction: 64% in pericardial valves, versus 73% in porcine valves, log-rank: $P = 0.25$). Three patients required prolonged postoperative cardiopulmonary support by either veno-atrial extracorporal membrane oxygenation or intra-aortic balloon pump. Of 51 patients, 16 received a pacemaker after valve replacement. Bleeding was documented in 1 patient and 1 patient had a pulmonary embolism. One patient had brain damage due to hypoxia. No case of endocarditis or valve thrombosis was documented. For the total patient population, the maximum systolic transvalvular gradient for RV pressure estimation was at a median of 22.4 mmHg (min: 8.5 mmHg, first quartile: 19.1 mmHg, third quartile: 27 mmHg, max: 50 mmHg).

In the 8 patients who required reoperations, 1 subsequent replacement was performed in 4 patients, 2 subsequent replacements in 3 patients and 3 subsequent replacements in 1 patient. Of these 13 reoperations, 7 were conventional valve implantations with bioprosthesis and 6 were interventional (transvenous) valve implantations. Indication for valve replacement was based on isolated valve dysfunction in 3 cases. In addition to prosthesis dysfunction, a reduced RV function (4 cases), an impaired exercise tolerance (2 cases) and a combination of both (4 cases) contributed to the decision for reoperation. The median age at reoperation was 26 years (range: 11–38). There was no 30-day mortality in patients undergoing a reoperation. Aortic clamping was required in 5 of 7 patients undergoing conventional reoperation; the mean cross-clamp time was 53 ± 23 min. The estimated 5-year freedom rate from reoperation after a subsequent conventional valve replacement was 83% (CI: 58–100%), and that from dysfunction was 17% (CI: 3–100%, Fig. 4). In the short follow-up (median 309 days, range 88 days–2.7 years) of the patients who received an interventional valve, 1 patient required a reoperation after 1.9 years.

DISCUSSION

In our study population, the 5-year freedom rate from dysfunction of a tricuspid bioprosthesis was 66%. The rate of freedom from reoperation was 86 and 81% at 5 and 10 years, respectively. These results are in contrast to published data on the durability of bioprosthetic TV valves in patients with AHD where a rate of freedom from reoperation of 76–96% at 10 years is reported [1, 5, 9]. But patients with AHD undergoing TVR differ from those with CHD; they are often in congestive heart failure, and the survival rate may be as low as 37% after 10 years [1]. Only sparse data exist on the durability of the TV in patients with CHD: Brown *et al.* [10] reported on the results after bioprosthetic TV replacement in CHD patients with Ebstein's anomaly ($n = 333$), while Said *et al.* [11]

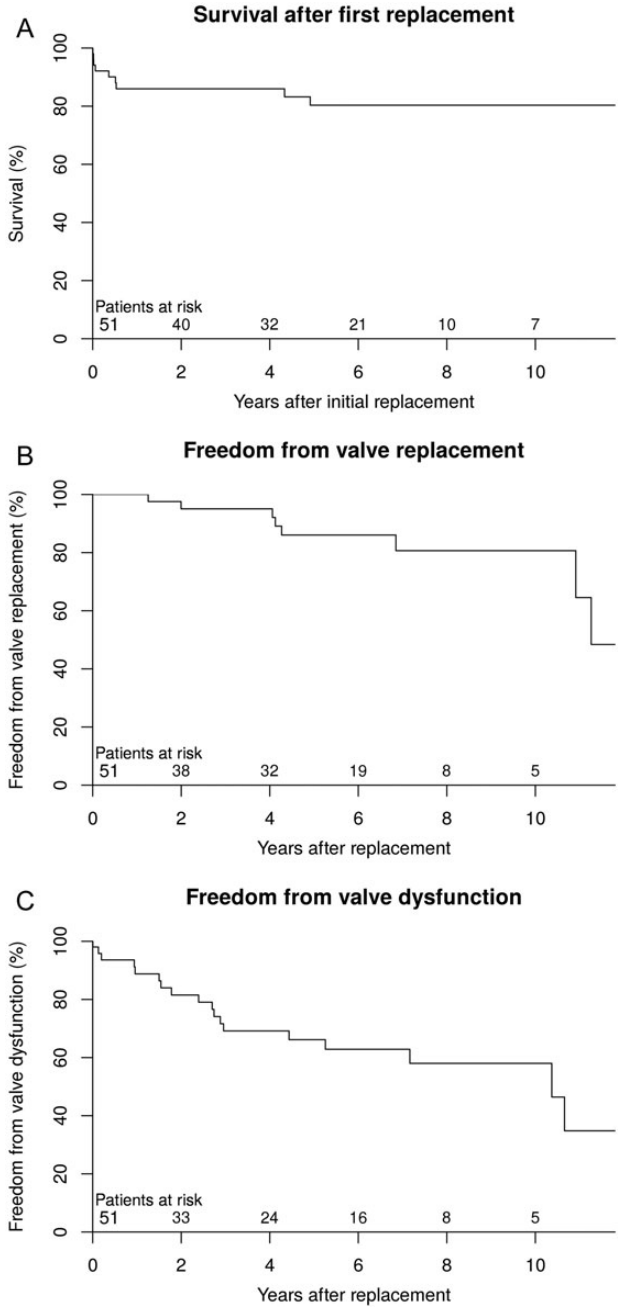

Figure 2: Survival (**A**), freedom from reoperation (**B**) and freedom from dysfunction (**C**) after first tricuspid valve replacement with a bioprosthesis in patients with congenital heart disease.

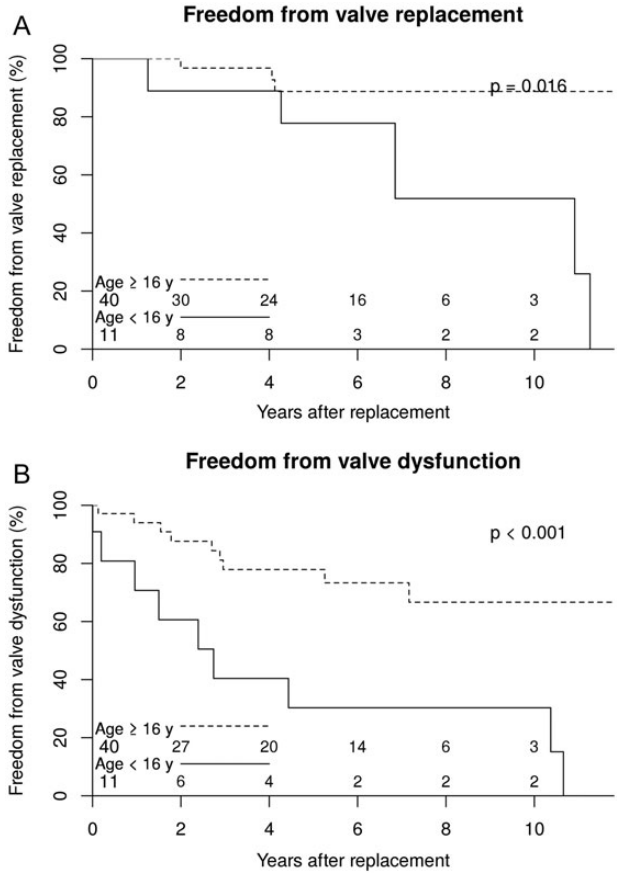

Figure 3: Freedom from reoperation (**A**) and prosthesis dysfunction (**B**) after bioprosthetic tricuspid valve replacement in patients with congenital heart disease depending on the patient's age.

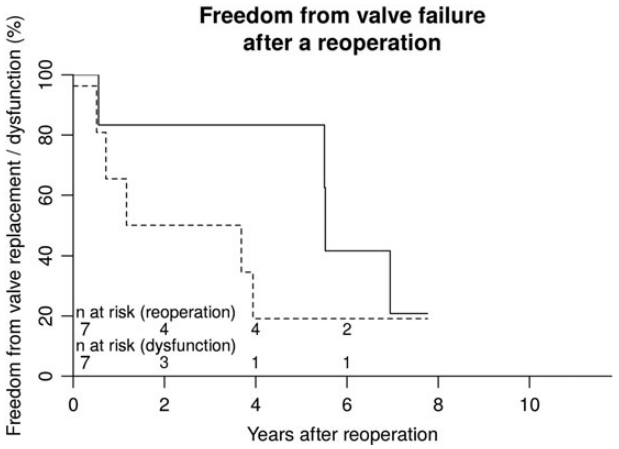

Figure 4: Freedom from reoperation and dysfunction after the exchange of a dysfunctional tricuspid valve bioprosthesis with a new one.

analysed patients without Ebstein's anomaly ($n = 92$). Results were comparable with our data regarding survival and reoperation but serial echocardiographic follow-up was not conducted. The Dutch Congenital Corvitia (CONCOR) registry [12] included only 11 patients after bioprosthetic TVR. In accordance with our report, 2 of these patients required reoperation soon (2.6 and 2.9 years) after implantation.

Our reported data suggest that valve dysfunction does not routinely lead to valve replacement as long as the RV response to pressure or volume overload does not lead to symptoms. Therefore, the 'freedom from reoperation' overestimates valve durability. Serial echocardiographic data help to overcome these limitations: patients with a failing valve who are at that moment not referred to surgery are detected and the particular time of dysfunction can be determined more accurately. As a result, the 'freedom from prosthesis dysfunction' curve lies considerably below the 'freedom from reintervention' curve. Serial echocardiographic data are rare for TV bioprostheses. We are aware of only one other study, published in 1996 by Kobayashi *et al.* [13]. They examined 60 patients undergoing TVR, comparing serial

echocardiographic examinations. Even though Kobayashi mainly included patients with AHD (62%), the results are in line with our study on two major points: first, prosthesis dysfunction was frequent (34% at 5 years and 63% at 10 years). Second, prosthesis dysfunction occurred in a linear way early after valve implantation.

In the present study, younger age at implantation and smaller size of prosthesis were both associated with early failure. While the durability of the bioprosthesis was almost similar to patients with AHD in patients over 16 years of age, reoperation and dysfunction were frequent in patients below 16 years of age. This is in line with studies that investigate the use of bioprostheses in other positions in younger patients: Saleeb *et al*. [14] recently reported aortic valve prosthesis failure in 82% of the implanted valves 3 years after implantation. Kopf *et al*. [15] reported that 16 of 18 implanted aortic and mitral valves were replaced within 6 years after implantation. Calcification of the leaflets leading to insufficiency was described as the main reason for replacement. Shinkawa *et al*. [16] reported a rate of freedom from prosthesis dysfunction of 74% after 5 years and of 33% after 10 years for bioprosthesis in the pulmonary position, with earlier dysfunction in younger patients.

In this study, there were patients who required a second, third or even a fourth prosthesis. The durability of prosthesis implanted in subsequent reoperations was not satisfying. In most patients who underwent exchange of a bioprosthesis, we observed dysfunction of the new prothesis only a few years later. But whether the durability of the second or third bioprosthesis really differs from the durability of the first bioprosthesis cannot be answered in this study, because the number of patients undergoing subsequent reoperations was small. The role of an interventionally implanted bioprosthesis for redo procedures also warrants further evaluation. The current experience with these interventions is limited [17].

What are the alternatives to replacement of the TV with a bioprosthesis? The use of mechanical prosthesis in the tricuspid position has neither improved the outcome in patients with AHD [4, 18], nor in patients with CHD [10, 18]. Brown *et al*. [10] compared patients with Ebstein's anomaly undergoing bioprosthetic and mechanical TV implantation. Freedom from reoperation was similar after 20 years, but overall survival was better when using a bioprosthetic valve. The authors concluded that bioprosthetic valves should be preferred in patients with Ebstein's anomaly. Bartlett *et al*. [19] investigated TVR in children below 6 years of age and equally did not find an advantage in freedom from reoperation when using mechanical valves. Because current options for TVR in patients with a CHD remain unsatisfactory, all efforts should be made to repair the native valve whenever possible. More recent repair techniques enable reconstruction in an increasing percent of patients with Ebstein's anomaly [20, 21], even after a previously failed repair [22].

In our study, the incidence of pacemaker implantation (31%) was relatively high compared with other studies that report incidence between 6 and 20% [1, 23]. Both concomitant maze procedures (18%) and the fact that 80% of operations were reoperations may have contributed to the higher incidence in our study.

The study has several limitations: It is a retrospective study, and some findings, like the examinations of the explants, could not be conducted. Furthermore, the retrospective design did not allow one to determine RV function, because most patients had Ebstein's anomaly and required specific echocardiographic examination to determine RV function [24]. Although we observed differences between subgroups (age, prosthesis size), it was not possible to determine which factors were decisive, because the patient number did not allow multivariate analysis.

CONCLUSION

In patients with CHD, biological TV prosthesis dysfunction increases in a linear way, beginning soon after implantation. In our cohort, 34% of the patients developed prosthesis dysfunction within 5 years. In patients below 16 years of age, dysfunction occurred even earlier and could be detected in two out of three implanted valves 5 years after operation. But the reoperations ensured improved valve function only for a short period. As these patients usually have a good life expectancy, reoperations are frequently needed. Other studies have shown that mechanical valves are not beneficial. Therefore, repair of the TV should be attempted whenever possible. Close observation and serial echocardiographic assessment of the bioprostheses are warranted to determine the right time for a surgical or interventional prosthesis replacement.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *EJCTS* online.

Conflict of interest: none declared.

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