

A Comparative Study of Mechanical and Homograft Prostheses in the Pulmonary Position

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Background. Homografts (HGs) are considered the gold standard for pulmonary valve replacement. However, to avoid further operations, the use of mechanical valves (MVs) might be considered, especially in patients who had had multiple prior operations or require an additional MV in another position.

Methods. Data of 19 patients with MVs were compared with 19 patients with HGs, matched for age, sex, and follow-up time. Development of gradient and regurgitation were analyzed using hierarchical multilevel modeling. Mean follow-up time was 5.8 ± 2.6 years.

Results. The initial pressure gradient was significantly lower in HGs compared with MVs (11.7 mm Hg vs 19.2 mm Hg, $p = 0.006$), but the annual increase was significantly higher in HGs compared with MVs (4.0 mm Hg/year vs 1.1 mm Hg/year, $p = 0.008$). The initial regurgitation grade was significantly higher in HGs compared with MVs (0.81 vs 0.37, $p < 0.001$), and the annual

increase was also significantly higher in HGs compared with MVs (0.09 grade/year vs -0.01 grade/year, $p < 0.001$). Reintervention was required in 3 HGs (stenosis), and in 2 MVs (thrombosis after irregular anticoagulation, dysfunction due to ingrowth of tissue). Freedom from reintervention was not significantly different between both groups ($p = 0.32$).

Conclusions. The hemodynamic performances of MVs are superior to HGs because gradient and regurgitation develop significantly slower. However, this does not lead to lower reintervention rates. Because reoperations of MVs can be prevented by appropriate surgical technique and strict anticoagulation, MVs should be considered for the pulmonary position, especially in patients who require anticoagulation treatment for additional MVs or rhythm disturbances.

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Homograft (HG) reconstruction of the right ventricular outflow tract has become a classic surgical approach as a part of total correction of numerous congenital lesions. With this technique, successful repair of pulmonary atresia with ventricular septal defect, complex forms of tetralogy of Fallot, common arterial trunk, transposition of the great arteries with pulmonary stenosis, and other forms of complex congenital heart disease have become possible [1–3]. However, due to the lack of growth potential and the limited durability of cryopreserved valves or xenograft conduits, reoperations for conduit exchange are inevitable. Because most of the initial operations are performed in infancy, many of the patients who are scheduled for conduit exchange in adulthood have already undergone multiple prior oper-

ations. To avoid further operations, the use of mechanical valves (MVs) might be considered [4–6]. However, strict anticoagulation is required for patients with MVs in the pulmonary position. Therefore, patients who need oral anticoagulation for rhythm disturbances or due to MVs in other positions may, in particular, benefit from pulmonary valve replacement with MVs. Even so, MVs are rarely used for pulmonary valve replacement due to the potentially higher incidence of thrombosis in the low pressure system [7, 8]. Until now, data of less than 150 patients have been reported [6]. To clarify whether there is a rationale for the use of MVs in the pulmonary position, we sought to compare the development of gradient, regurgitation, and the reintervention rates in groups of patients with HGs and MVs matched by age, sex, and follow-up time.

Patients and Methods

Study Population

Between 1998 and 2005, 19 patients underwent pulmonary valve replacement with MVs. For each patient, a control patient who received a HG was selected. The controls had the same gender, a similar age at the time of

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Table 1. Population Characteristics

	Mechanical Valve (n = 19)	Homograft (n = 19)	p Value
Mean patient age (years)	25.4 ± 9.8 (10–44)	24.6 ± 9.5 (10–39)	0.810
Patient gender (male)	6	6	1.0
Mean follow-up time (years)	6.1 ± 2.9	5.4 ± 2.2	0.452
Diagnosis			
Tetralogy of Fallot	13	12	1.0
Common arterial trunk	4	3	1.0
Pulmonary stenosis	1	2	
Pulmonary atresia	0	1	
Transposition of the great arteries	0	1	
Aortic stenosis	1	0	
2 or more prior operations	9	3	0.079
1 prior operation	1	7	
2 prior operations	9	9	
3 prior operations	4	1	
4 prior operations	4	1	
5 prior operations	1	1	
Body surface area (m ²)	1.7 ± 0.2	1.7 ± 0.2	0.713
NYHA functional class > II	3	4	0.677
Mean perfusion time (minutes)	132 ± 50	105 ± 54	0.134
Aortic cross-clamp	13	7	0.182
Mean ischemic time (minutes)	100 ± 31	81 ± 31	0.214
Mean valve size inner orifice (mm)	18.4 ± 1.0	23.8 ± 2.2	<0.001
Mean size of the mechanical valves ^a (mm)	23.7 ± 1.6		
Additional procedures			
Pulmonary artery patch plasty	5	4	1.0
Valvuloplasty tricuspid	0	2	
Valve replacement tricuspid	4	0	0.105
Valve replacement aortic	5	0	0.046
Valvuloplasty mitral	1	0	
VSD or residual VSD closure	3	1	

^a As indicated by the manufacturer.

NYHA = New York Heart Association; VSD = ventricular septal defect.

implantation, and had undergone surgery at almost the same time to provide similar follow-up intervals (Table 1). This study was approved by the ethics committee of the Technical University Munich. Individual consent for the study was obtained from each patient (project number: 2448/09).

Operative Data

All patients were operated on through a median sternotomy with cardiopulmonary bypass and moderate hypothermia (28°C to 32°C). Aortic cross-clamping was used in 20 patients to facilitate the intracardiac repair of associated lesions (Table 1). The remaining patients underwent surgery on the beating heart. The distal part of the bileaflet-valved conduit (St. Jude Medical, St. Paul, MN), was cut just above the valve level and was sutured to the prosthetic ring proximally with a 5-0 Prolene suture (Ethicon, Somerville, NJ). Then, an end-to-end anastomosis between the main pulmonary artery and the conduit was performed. The ventricular end of the tube was cut obliquely, thus creating a “roof” to cover the

ventriculotomy. For an optimal bileaflet valve function, it was always attempted to place the prosthesis in a 90-degree position to the ventricular septum [4]. Prior to implantation, the HGs were extended with a Dacron tube graft of appropriate diameter at the proximal end. The pulmonary artery of the HG was cut just above the valve level and sutured to the main pulmonary artery. The ventricular end of the tube was cut obliquely to enlarge the ventriculotomy according to the technique used for the MV. The HGs were provided by the homograft bank of the Department of Cardiovascular Surgery, German Heart Center Munich at the Technical University. The procurement of raw material, processing, and preservation was performed according to our center-specific protocol.

An additional mechanical valve (4 tricuspid and 5 aortic) was implanted in 9 patients who underwent pulmonary valve replacement with a MV. Four patients who received a MV were on anticoagulation therapy for rhythm disturbances. Patients who underwent pulmonary valve replacement with a HG did not require additional valve replacement (Table 1). There were no significant differ-

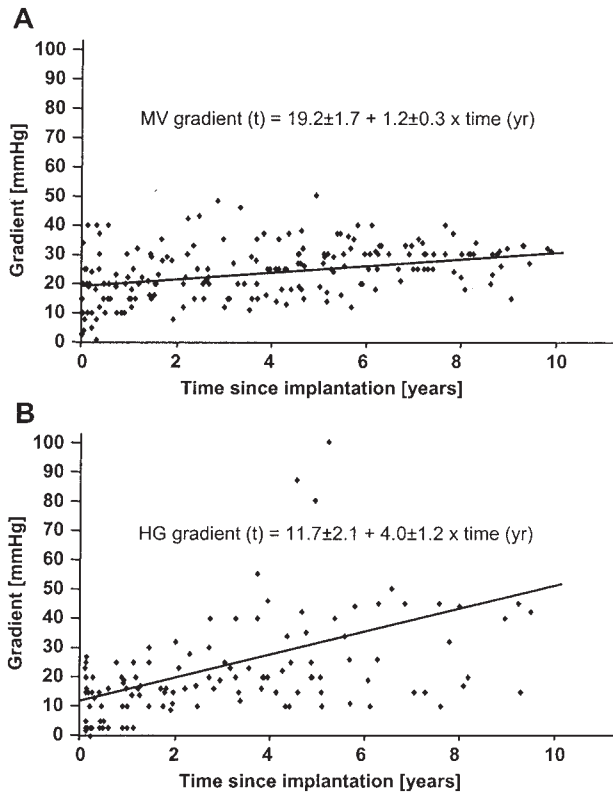


Fig 1. Estimates of the development of gradients of mechanical valves (A; MV) compared with homografts (B; HG) in the pulmonary position.

ences in perfusion time and aortic cross-clamp time between both groups.

Clinical Follow-Up

All patients were regularly followed up at 3-, 6-, or 12-month intervals at the outpatient Department of Pediatric Cardiology at the German Heart Center Munich. Patients with MVs had 203 echocardiographic examinations (mean 10.7 ± 5.7 , maximum 19), and patients with HGs had 127 examinations (mean 6.7 ± 3.5 , maximum 13, $p = 0.014$). Total echocardiographic follow-up was 115 patient-years for patients with MVs, and 103 patient-years for patients with HGs, respectively.

Echocardiographic Data Acquisition and Measurements

Regurgitation was graded by mapping the dimensions of the regurgitation jet with pulsed and color flow Doppler echocardiography, analogously to the semiquantitative method described by Perry and colleagues [9]. The width of the proximal pulmonary regurgitation jet and the density and deceleration rate of the spectral Doppler flow signal were included in the assessment of regurgitation severity. This was graded from 0 to 4 (0, none; 1, mild; 2, moderate; 3, moderately severe; 4, severe). Additionally, trace (trivial) regurgitation, defined as a very tiny regurgitation jet near the detection limit, was included in the

analyses as grade 0.5. Maximum velocities across the pulmonary valve were obtained by continuous Doppler. Pressure gradients across the right ventricular outflow tract were calculated by the modified Bernoulli equation. Measurements were accomplished by experienced pediatric sonographers. All tracings were digitally stored as raw data with the EchoPAC system (version 6.4.1; General Electric Vingmed, Horten, Norway). The final review of all records was accomplished by one of the authors (Manfred Vogt).

Oral Anticoagulation Self-Management

Patients under oral anticoagulation self-management were instructed to measure every second day for the first two weeks until they got stable international normalized ratio (INR) values within the therapeutic range. Then they were allowed to measure twice a week. Self-management was performed with the CoaguChek system (Roche Diagnostics GmbH, Mannheim, Germany) [10].

Statistical Analysis

Frequencies are given as absolute numbers and percentages. Continuous data are expressed in terms of the mean and SD. The Fisher exact test was performed to detect significant differences between groups. For comparison of continuous variables between two groups, the t test was used (two-tailed tests were used for all analy-

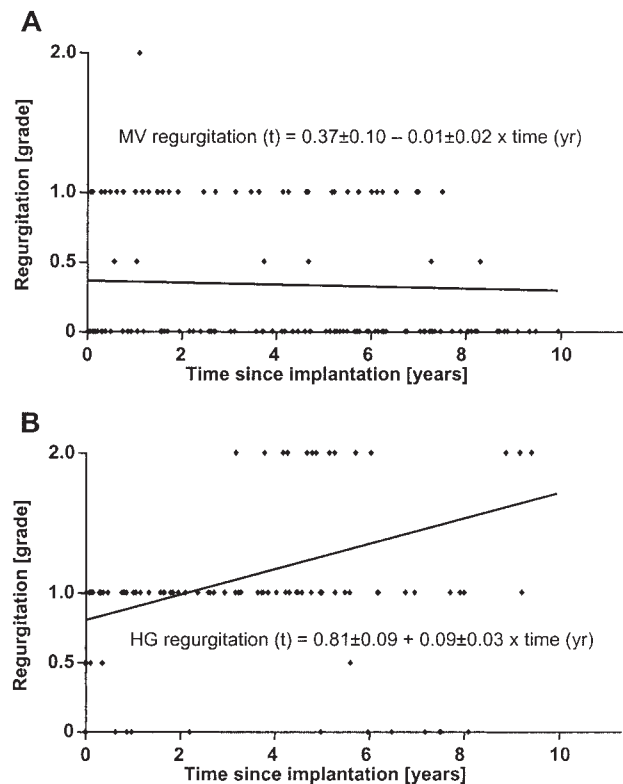


Fig 2. Estimates of the development of regurgitation of mechanical valves (A; MV) compared with homografts (B; HG) in the pulmonary position.

Table 2. Reinterventions

Patient	Diagnosis	Valve	Time to Failure	Cause of Failure	Type of Reintervention
1	Common arterial trunk	Homograft	5 years	Stenosis	Transcatheter valve implantation in pulmonary position
2	Aortic stenosis	Mechanical valve	4 years	Thrombosis	Conduit exchange with mechanical-valved conduit
3	Transposition of the great arteries	Homograft	5 years	Stenosis	Conduit exchange with mechanical-valved conduit and aortic root replacement with mechanical prosthesis
4	Tetralogy of Fallot	Mechanical valve	9 years	Nonstructural dysfunction	Conduit exchange with porcine-valved conduit aortic valve replacement with mechanical prosthesis
5	Tetralogy of Fallot	Homograft	9 years	Stenosis	Transcatheter valve implantation in pulmonary position

ses). In order to perform appropriate longitudinal analysis of HG and MV function over time, as proposed by the guidelines of reporting mortality and morbidity after cardiac valve interventions [11], the echocardiographic data were analyzed by using the multilevel hierarchical linear model. This model provides a linear regression line with an intercept and slope for each individual patient. The intercept (\pm standard error of the mean [SE]) corresponds to the initial value (gradient in mm Hg, regurgitation in grade) at the end of surgery; the slope (\pm SE) represents the annual progression of these measures. The probability of freedom from events was estimated according to the Kaplan-Meier method. The time of the pulmonary valve replacement was designated as time zero. Freedom-from-event curves were compared using the log-rank test. Statistical analysis of clinical variables and initial fitting was performed using SPSS 16.0 (SPSS Inc, Chicago, IL).

Results

Gradient

The best fitting models to study the development of the gradient (Fig 1) were linear models with the terms

$$\text{MV gradient (t)} = 19.2 \pm 1.7 + 1.2 \pm 0.3 \times \text{time (year) for the MV,}$$

and

$$\text{HG gradient (t)} = 11.7 \pm 2.1 + 4.0 \pm 1.2 \times \text{time (year) for the HG.}$$

The initial MV gradient at the time of implantation was 19.2 mm Hg with a significant annual increase of 1.2 mm Hg/year ($p < 0.001$), and the initial HG gradient was 11.7 mm Hg with a significant annual increase of 4.0 mm Hg/year ($p = 0.001$). The initial gradient was significantly lower in HGs compared with MVs ($p = 0.006$), but the annual increase was significantly higher in HGs compared with MVs ($p = 0.008$). Hence, after 3 years, the estimates of the gradients are higher for the HG, compared with the MV.

Regurgitation

The best fitting models to study the development of the regurgitation (Fig 2) were linear models with the terms MV regurgitation (t) = $0.37 \pm 0.10 - 0.01 \pm 0.02 \times \text{time (year)}$ for the MV, and HG regurgitation (t) = $0.81 \pm 0.09 + 0.09 \pm 0.03 \times \text{time (year)}$ for the HG. The initial MV regurgitation grade was 0.37 with no significant annual change ($-0.01/\text{year}$, $p = 0.73$), and the initial HG regurgitation grade was 0.81 with a significant annual increase of 0.09/year ($p = 0.003$). The initial regurgitation and the annual increase were significantly higher in HGs compared with MVs ($p < 0.001$ both).

Reintervention

Reinterventions were required in 3 patients (patients 1, 3, and 5) with HGs due to stenosis, and in 2 patients (patients 2 and 4) with MVs due to thrombosis or non-structural dysfunction (Table 2). Patient 2 had undergone both tricuspid and pulmonary valve replacement with mechanical prostheses at the fourth operation after a Ross-Konno operation. After 4 years he presented with thrombosis of the pulmonary valve due to irregular oral anticoagulation medication. Patient 4 had undergone staged correction of tetralogy of Fallot with a mechanical right ventricle to pulmonary artery conduit in adulthood. After 4 years she presented with nonstruc-

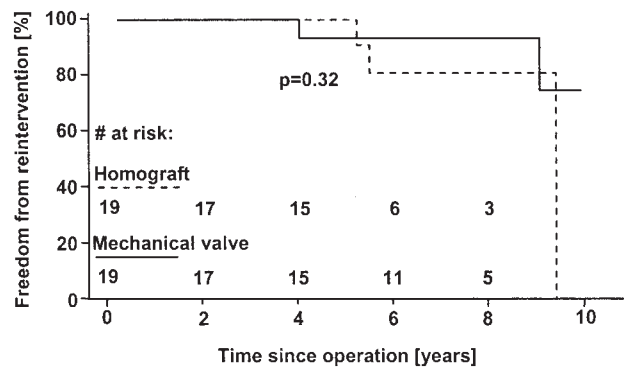


Fig 3. Estimated freedom from reintervention of homografts compared with mechanical valves in the pulmonary position.

tural dysfunction of the pulmonary valve due to ingrowth of endovascular tissue. The freedom from re-intervention was not significantly different between both groups ($p = 0.32$) (Fig 3). During follow-up, no thrombosis or bleeding was observed in the remaining patients.

Anticoagulation Management

All patients with MVs were treated with dicoumarol at an INR target area between 3 and 4.5. Cross-sectional INR values (3 measurements per patient) could be obtained from 13 patients with MVs. Mean INR value was significantly higher in patients who performed INR self-management ($n = 9, 3.6 \pm 0.4$) compared with patients who were instructed by their doctors ($n = 4, 2.6 \pm 0.7, p = 0.009$).

Comment

Our results show that a MV provides better hemodynamic performance compared with a HG within a mean follow-up of 5.8 years in comparable patients. However, this advantage is defeated by the risk of thrombosis and nonstructural dysfunction. Therefore, both types of prostheses yield similar reoperation rates.

The present study has two major advantages compared with previous reports on MV and HG performance. (1) Because the development of a potential pressure gradient and regurgitation is a process that evolves with time, the study of repeat longitudinal echo data in the present analysis may be more appropriate to describe MV and HG performance compared with the analysis of actuarial estimates of freedom from events [6, 11–13]. The comparability of freedom from event curves may be biased by differences in the indications for reintervention. (2) The present study compares MVs and HGs in two patient populations that do not differ in relevant demographic, clinical, and surgical parameters. Due to the selection of a similar HG patient for each MV patient from a large group of patients who underwent HG reconstruction of the pulmonary outflow tract, the development of gradient and regurgitation could be studied as a function of prosthesis specific factors in the absence of recipient specific risk factors such as age at the time of implantation or the implantation site [12, 14].

The analysis of serial echocardiographic data of the present study reveals that MVs show low initial, and no substantial, increase in gradient and regurgitation with time. This is important because normal right ventricular dimensions and function are preserved by a competent pulmonary valve and a low outflow tract gradient. In contrast, HGs show significant increase in gradient and regurgitation with time. In this regard, MVs are the better prostheses for pulmonary valve replacement.

However, MVs in the pulmonary position have been described to exhibit a higher incidence of thrombosis in the low pressure system. This assumption was based on two small case series, published in the 1980s by Ilbawi and colleagues [7], and Miyamura and colleagues [8], which included only 8 and 5 patients, respectively. These studies reported failure rates due to valve thrombosis of

37% and 20%, respectively. A recent larger series, however, has put another complexion on the matter; Waterbolk and colleagues [6] observed no thromboembolic complications in 27 patients. Rosti and colleagues [15] found no signs of valve failure at 3 months to 9 years of follow-up in 8 patients. In the series published by Reiss and colleagues [5] only 2 of 32 patients (6%) required reoperation for thrombosis. In the present series, 1 patient (5%) required a reoperation for thrombosis of the MV.

The lower incidence of thromboembolic complications in a recent series may be attributed to INR self-management [5]. In the present series, the mean INR value was significantly higher in patients who performed INR self-management compared with patients who were instructed by their doctors. However, the only thromboembolic complication in the present series occurred due to irregular dicoumarol medication in a 16 year old boy, who performed INR self-management. At the time of initial diagnosis of MV thrombosis his INR was 1.1 so that he had obviously discontinued his oral anticoagulation. The present data suggest that no thromboembolic complications occur at a mean INR of 3.3. In addition, self-management of oral anticoagulant therapy may be potentially better as instructing the patient on the basis of INR measurements by the patient's family doctor [16], and provides improvement in quality of life [17]. But, does strict anticoagulation alone effectively prevent reoperations altogether?

The answer is no! Despite valve failure due to thrombosis, malfunction of MVs in the pulmonary position can be caused by ingrowth of fibrous tissue [6, 7]. In the present series, one patient required a reoperation due to a valve leaflet fixed by ingrowth of fibrous tissue. Hence, the incidence of nonstructural valve failure in recent series is around 4% to 5%, and therefore as high as the incidence of thrombosis. In contrast to thrombosis, the mechanisms of excessive fibrous tissue formation may presumably not be inhibited by medical treatment. However, the function of the MV may be influenced by technical considerations at implantation. Waterbolk and colleagues [6] suggested suturing the MV to the original insertion of the pulmonary valve. In contrast, the preferred technique at our institution is to extend a composite graft with an appropriate tube graft at the proximal end. The distal end of the graft is shortened and sutured to the pulmonary artery bifurcation. The proximal end of the graft is tailored obliquely and used to reconstruct the right ventricular outflow tract [4]. Hence, the MV is completely within the tube graft. In fact, the only case of nonstructural valve failure in the present series was observed in a patient in whom the MV was sutured into the native pulmonary outflow tract. Hence, strict anticoagulation and placing the MV into a conduit may effectively prevent reoperations altogether.

However, it is of note that patients who receive replacement of the pulmonary valve with a HG do not require oral anticoagulation therapy. Although we observed no bleeding complications in the present series in patients who received a mechanical prosthesis, the risk of bleeding complications may be lower for patients with a

HG compared with patients with a MV. In addition, anticoagulation during pregnancy is demanding, and the risk for miscarriage is markedly higher in women with MV compared with women with tissue valves [18]. Therefore, we dissuade from implanting MVs in women desiring future pregnancy.

In conclusion, MVs are the better choice for pulmonary valve replacement with regard to hemodynamic performance. Valve failure due to thrombosis can be prevented by strict anticoagulation management. Nonstructural valve failure may be avoided by appropriate surgical technique. Therefore, MVs should be considered for the pulmonary position, especially in patients who require anticoagulation treatment for additional MVs or rhythm disturbances.

The current study presents several limitations. The small patient number restricts the results of actuarial analyses. The mean regurgitation was depicted against time although regurgitation is not a continuous variable. However, it is easier for clinicians to interpret the mean increase per year compared with freedom from events, such as more than grade 2 of regurgitation.

References

- Ross DN, Somerville J. Correction of pulmonary atresia with a homograft aortic valve. *Lancet* 1966;2(7479):1446–7.
- Dearani JA, Danielson GK, Puga FJ, et al. Late follow-up of 1095 patients undergoing operation for complex congenital heart disease utilizing pulmonary ventricle to pulmonary artery conduits. *Ann Thorac Surg* 2003;75:399–411.
- Lange R, Weipert J, Homann M, et al. Performance of allografts and xenografts for right ventricular outflow tract reconstruction. *Ann Thorac Surg* 2001;71(5 suppl):S365–7.
- Haas F, Schreiber C, Hörer J, Kostolny M, Holper K, Lange R. Is there a role for mechanical valved conduits in the pulmonary position? *Ann Thorac Surg* 2005;79:1662–8.
- Reiss N, Blanz U, Bairaktaris H, Koertke A, Körfer R. Mechanical valve replacement in congenital heart defects in the era of international normalized ratio self-management. *ASAIO J* 2005;51:530–2.
- Waterbolk TW, Hoendermis ES, den Hamer IJ, Ebels T. Pulmonary valve replacement with a mechanical prosthesis. Promising results of 28 procedures in patients with congenital heart disease. *Eur J Cardiothorac Surg* 2006;30:28–32.
- Ilbawi MN, Lockhart CG, Idriss FS, et al. Experience with St. Jude Medical valve prosthesis in children. A word of caution regarding right-sided placement. *J Thorac Cardiovasc Surg* 1987;93:73–9.
- Miyamura H, Kanazawa H, Hayashi J, Eguchi S. Thrombosed St. Jude Medical valve prosthesis in the right side of the heart in patients with tetralogy of Fallot. *J Thorac Cardiovasc Surg* 1987;94:148–50.
- Perry GJ, Helmcke F, Nanda NC, Byard C, Soto B. Evaluation of aortic insufficiency by Doppler color flow mapping. *J Am Coll Cardiol* 1987;9:952–9.
- Braun S, Spannagl M, Völler H. Patient self-testing and self-management of oral anticoagulation. *Anal Bioanal Chem* 2009;393:1463–71.
- Akins CW, Miller DC, Turina MI, et al. Guidelines for reporting mortality and morbidity after cardiac valve interventions. *Ann Thorac Surg* 2008;85:1490–5.
- Boethig D, Goerler H, Westhoff-Bleck M, et al. Evaluation of 188 consecutive homografts implanted in pulmonary position after 20 years. *Eur J Cardiothorac Surg* 2007;32:133–42.
- Tokunaga S, Masuda M, Shiose A, Tomita Y, Morita S, Tominaga R. Isolated pulmonary valve replacement: analysis of 27 years of experience. *J Artif Organs* 2008;11:130–3.
- Brown JW, Ruzmetov M, Rodefeld MD, Vijay P, Turrentine MW. Right ventricular outflow tract reconstruction with an allograft conduit in non-Ross patients: risk factors for allograft dysfunction and failure. *Ann Thorac Surg* 2005;80:655–64.
- Rosti L, Murzi B, Colli AM, et al. Mechanical valves in the pulmonary position: a reappraisal. *J Thorac Cardiovasc Surg* 1998;115:1074–9.
- Christensen TD, Andersen NT, Attermann J, Hjortdal VE, Maegaard M, Hasenkam JM. Mechanical heart valve patients can manage oral anticoagulant therapy themselves. *Eur J Cardiothorac Surg* 2003;23:292–8.
- Soliman Hamad MA, van Eekelen E, van Agt T, van Straten AH. Self-management program improves anticoagulation control and quality of life: a prospective randomized study. *Eur J Cardiothorac Surg* 2009;35:265–9.
- Shannon MS, Edwards MB, Long F, Taylor KM, Bagger JP, De Swiet M. Anticoagulant management of pregnancy following heart valve replacement in the United Kingdom, 1986–2002. *J Heart Valve Dis* 2008;17:526–32.

INVITED COMMENTARY

Valve choice for reconstruction of the right ventricular outflow tract (RVOT) is still a matter of debate among cardiac surgeons dealing with complex congenital lesions. Due to the fact that many of the patients are infants, children, or youngsters, the use of homografts or heterografts has become standard, even though age-dependent degeneration and the need for reoperation has been, and still is, an inherent risk of these grafts. Reports on the use of mechanical valves in the RVOT are scarce and mostly negative; therefore, their reputation may be worse than they are.

Hörer and colleagues [1] report a series of 19 patients with mechanical valve implantation in the pulmonary artery position. Outcome is compared with an identical number of patients who were matched for gender, age, and time of follow-up for pulmonary homograft im-

plantation. Unfortunately, important information regarding the homograft procurement, preparation, and storing, as well as selection criteria (ie, ABO compatibility) are lacking. Therefore, the results of this homograft group, characterized by increasing gradients and valve insufficiency due to tissue degeneration, are somewhat difficult to interpret. However, the main issue of this report is that with time, a bi-leaflet prosthetic valve conduit is equal to a pulmonary homograft. On first glance this may be provocative. Yet, the mean age of the patients was 25 years, and strict anticoagulation, even with a target international normalized ratio of 3.5 to 4.0 is relatively easy. Furthermore, self management of oral anticoagulation with the CoaguCheck System, as used in this series, provides excellent prophylaxis against bleeding and