MECHANICAL VALVES IN THE PULMONARY POSITION: A REAPPRAISAL

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Objectives: To evaluate midterm results of mechanical valves in pulmonary position in patients with pulmonary regurgitation and right ventricular dysfunction as an alternative to bioprostheses. **Patients:** Mechanical valves (six tilting disc valves and two bileaflet valves) were implanted in eight patients previously operated on for tetralogy of Fallot ($n = 7$) and truncus arteriosus ($n = 1$), with severe right ventricular dysfunction caused by massive pulmonary regurgitation. **Results:** All patients survived prosthesis implantation and are currently well. At follow-up (3 months to 9 years), they do not show signs of valve failure, and right ventricular function has dramatically improved in all but one, who still shows moderate ventricular hypokinesia. **Conclusion:** After operative correction of congenital heart defects in selected patients who show severe dysfunction of the right ventricle caused by pulmonary regurgitation/stenosis, mechanical valves may represent an alternative to bioprosthetic valves. The selection of the valve type is still a matter of debate. However, according to literature data, complications seem to have occurred only in patients with bileaflet mechanical valves in the pulmonary position, whereas no thromboembolic episodes or valve failure is reported in subjects with tilting disc valves in the right ventricular outflow. Tilting disc valves might perform better in the right ventricular outflow than bileaflet valves. (J Thorac Cardiovasc Surg 1998; 115:1074-9)

Continuing improvement of survival of young infants and children with complex congenital heart malformations has raised concerns about the quality of their future life and the need for further operations. In particular, the reliability and duration of biologic valves is a matter of debate.¹⁻⁵

Although mechanical valves are routinely implanted in "left-sided" positions and experience is growing with these techniques, children less commonly undergo mechanical valve replacement on the "right side" of the heart. In severely dilated and hypokinetic right ventricles with pulmonary valve dysfunction, a competent prosthetic valve with an

expected long life span is preferable. This cannot be achieved with the commonly used biologic prostheses (porcine or homograft), which may undergo progressive deterioration.³⁻⁶

However, reported results with prosthetic mechanical valves in the pulmonary position are inconsistent, and most authors recommend routine replacement of "biologic prostheses."^{1, 2}

We report our experience, with midterm follow-up of mechanical valves in the pulmonary position and a review of the available literature on this controversial issue.

Patients and methods

In two unrelated pediatric cardiac surgery departments between January 1988 and July 1997, eight patients underwent implantation of a mechanical valve in the pulmonary position for severe pulmonary regurgitation and right ventricular dysfunction. Five of eight had been previously operated on for complete correction of the malformation in other institutions and were referred to our centers by their own pediatric cardiologists.

Their clinical characteristics are summarized in Table I. Seven of them had tetralogy of Fallot (TOF), in two cases with absent pulmonary valve; one had truncus arteriosus type 1. Their mean age at operation was 10.1 years (range

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Received for publication July 18, 1997; revisions requested Sept. 17, 1997; revisions received Dec. 1, 1997; accepted for publication Dec. 9, 1997.

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0022-5223/98 \$5.00 + 0 12/1/88055

Table 1. Clinical features of the seven patients who underwent placement of a mechanical valve in pulmonary position

Patient (year of birth)	Diagnosis	Previous operations	Year of last operation	Valve size	Type of valve	Notes	Pressure gradient at valvular level (mm Hg)
1. (1988)	Fallot's tetralogy	1988—valvotomy 1990—correction	1994	21	St. Jude Medical	Well	23
2. (1986)	Fallot's tetralogy	1989—correction	1992	23	Sorin	Mild reduction of exercise tolerance. Dilated right ventricle	25
3. (1969)	Fallot's tetralogy with pulmonary agenesis	1980—correction	1989	25	Sorin (+Hancock conduit)	Well	20
4. (1978)	Fallot's tetralogy	1979—BT shunt 1980—correction (+Hancock conduit)	1988	21	Sorin (+Hancock conduit)	Well	20
5. (1977)	Fallot's tetralogy	1981—correction	1988	25	Duromedics	Well	NA
6. (1975)	Fallot's tetralogy	1978—correction (+Hancock conduit)	1988	23	Sorin (+ Dacron conduit)	Well	38
7. (1982)	Truncus type I	1982—correction (valved conduit)	1989	21	Björk-Shiley (+ Dacron conduit)	Well	NA
8. (1985)	Fallot's tetralogy	1985—BT shunt 1988—correction (+Hancock conduit) 1992—patch plasty of the RVOT	1997	23	Sorin	Well	30

RVOT, Right ventricular outflow; BT, Blalock-Taussig; NA, not available.

6 to 17 years). They previously had a mean of 1.6 operations (range 1 to 4).

The decision to place a prosthetic valve was based on several reasons: (1) In almost all, the right ventricle was severely dilated and hypokinetic; (2) in five patients with stenosed valved conduits, the right ventricle had to manage high pressures (mean 170 mm Hg; range 60 to 220 mm Hg); (3) it was necessary to definitely relieve the right ventricle from such a volume/pressure overload.

In all, a mechanical valve was implanted in the pulmonary position. This option was chosen because they were old enough to anticipate a long time before the need for reoperation as a result of patient-valve mismatch with somatic growth and to minimize the risks of reoperations caused by valve degeneration as occurs with bioprostheses. In six patients a tilting disc valve (Sorin Biomedica spa, Saluggia, Italy, in five children and Björk-Shiley [Shiley, Inc., Irvine, Calif.] in one child) was used. In five of these patients the valve was sutured within a Dacron conduit after institution of moderately hypothermic cardiopulmonary bypass to connect the right ventricle with the main pulmonary

artery. In two patients a bileaflet valve was placed in the pulmonary position.

Results

All patients survived and were discharged home in a good condition after an uneventful early post-operative period with anticoagulants (warfarin sodium [Coumadin]). They are currently receiving anticoagulants to maintain an international normalized ratio of 2.0.

The mean duration of follow-up is 6.4 years (range 3 months to 9 years). All patients are clinically well and lead normal lives. Only a 10-year-old girl with moderately dilated and hypokinetic right ventricle has a mild reduction in exercise tolerance. All are in sinus rhythm and periodic Holter studies did not show any significant arrhythmia. Cross-sectional echocardiography and Doppler ultrasonographic cardiac evaluations show complete recovery of right ventricular function in six patients. In the

last patient to have an operation the follow-up duration is too short to allow recovery of right ventricular function, although a marked improvement has been observed after the operation. In one patient the ventricular wall is still moderately hypertrophied, and in another patient the right ventricle is moderately dilated and hypokinetic. In all patients only mild pressure gradients have been detected at the valvular level (range 20 to 38 mm Hg; Table I). Serial echocardiography did not show any evidence of valve failure, paravalvular leak, or both. No tissue growth (pannus) within the valve anulus has been detected during the follow-up period.

No patient showed hemolytic anemia or thrombotic phenomena, and none reported bleeding complications caused by anticoagulant therapy.

Discussion

Valve replacement in children represents a special problem and deserves particular considerations because of the characteristics of these patients. In children, prostheses should have a long life and an orifice large enough to avoid "outgrowing" of the child and patient-valve size mismatch. Also, anticoagulation has been claimed as a risk factor in these active subjects.

Although wide experience has been gathered about "left-sided" prostheses and current guidelines support the use of mechanical valves in the aortic position, because of their extended functional life free of complications, the issue of which type of valve would perform better in the pulmonary position is still controversial and there is a need to establish precise criteria for the selection of patients and valve type. In general, most authors recommend porcine xenografts and homografts for the reconstruction of a competent pulmonary valve.^{1,2} This attitude has been supported by the publication of several papers reporting thrombotic complications in patients with mechanical valves in the pulmonary position, with a rate of complications ranging from 25% to 56%.^{1,2,7-10}

Patients with severely dysfunctional right ventricles are relatively uncommon because of the good operative results attained in the past decades. However, a small proportion of these patients will have disability develop from pulmonary regurgitation after correction of TOF. Because of the increased postoperative and long-term survival of these patients, one may expect that the problem of a young and active adult with a TOF corrected early in life, who has become symptomatic or shows laboratory

signs of right ventricular dysfunction, will have increasing frequency.

These patients are usually treated with pulmonary homografts or porcine xenografts to avoid anticoagulation. Bioprostheses in the pulmonary position seem to have a good outcome, with a prolonged survival compared with those in the aortic position. In the series reported by Bando and colleagues,³ 94% of homografts were still functioning well after 5 years. However, 24% of these valves were already moderately or severely calcified 5 years after operation, and 10% of these children had to be reoperated for homograft failure. Other authors have reported unsatisfactory results with bioprosthetic valves: Bull and colleagues⁴ had to perform second operations for conduit obstruction or conduit valve malfunctioning in 23 of 173 (13.3%) children and calculated that only 15% to 27% of patients will be free of severe complications (death or obstruction of the conduit) 10 years after the operation. These results led them to suggest that homografts and heterografts in various types of conduits may not represent a permanent solution for many children with complex congenital heart defects. Similar results have been reported by Cleveland and colleagues,⁵ who observed a rate of conduit failure of 15% after 3 years, with an actuarial freedom from reoperation of 55% at 5 years. They had to reoperate on 50% of the patients within 8 years because of failure of the biologic valve.

However, with the progressively increasing survival of these patients, one should try to avoid reoperations, reducing the risks of operation and attaining cost-containment. Indeed, reoperations carry an increased burden of risk. Vogt and colleagues¹¹ estimated that 80% of patients with right ventricular outflow reconstruction will be free of reoperation 18 years after initial correction of TOF. The likelihood of reoperation increases if a conduit had been previously used. These authors observed a mortality rate of 9.3% at the first reoperation and 16% at the second reoperations. However, these rates seemed to decrease with time. Patients with the higher risk of reoperation for right ventricular outflow tract reconstruction are probably those who underwent "heavy" reconstructive surgery at the initial operation and in whom conduits or transannular patches were used.

These considerations have prompted us to evaluate the results of mechanical valves in the pulmonary position in our patients and to review the available literature.

Table II. Mechanical valves in pulmonary position

First author	Reference	Year	Nonfailing monodisc valves	Failing monodisc valves	Nonfailing bileaflet valves	Failing bileaflet valves
Cartmill	12	1974	9 (7 survived)	0	0	0
Misbach	15	1983	2	0	0	0
Pass	9	1984	0	0	3	1
Goor	17	1984	7	0	0	0
Ilbawi	1	1986	0	0	10	6
Miyamura	7	1987	0	0	3	2
Ilbawi	2	1987	0	0	6* (No. in tricuspid?)	8/14* (No. in tricuspid?)
Kawachi	14	1991	0	0	7	1
Kiyota	8	1992	0	0	8	3
Fiane	6	1996	1	0	0	0
Burger	10	1997	0	0	0	1
Present study			6	0	2	0
Total			25	0	39	22

Data are disaggregated by valve type and the occurrence of complications (valve failure, thrombosis, need of reoperation).

*The data reported in this paper do not allow precise disaggregation by valve position (tricuspid or pulmonary).

All our eight patients who received a mechanical valve in the pulmonary position are doing well and are free of complications related to valve failure or thromboembolic phenomena, although they are receiving anticoagulants. The duration of follow-up is sufficiently long to reassure us about the good results of the operation. This is also supported by the improvement showed by all the children and by the echocardiographic parameters. It should be noted that six children received a tilting disc valve, whereas a bileaflet valve was used in only two.

In the medical literature the placement of mechanical valves in the pulmonary position is reported in less than 90 patients, with apparently inconsistent results (Table II). Several authors have reported moderate to severe complications in patients with mechanical valves in the right side of the heart.^{1, 2, 6-9, 12-16} Common complications include thromboembolic phenomena, bleeding, and valve failure. In a comparison of St. Jude Medical (St. Jude Medical, Inc., St. Paul, Minn.) valves and bioprostheses in the pulmonary or tricuspid position, Kawachi and colleagues¹⁴ showed that bioprostheses have a good midterm outcome with a low rate of valve dysfunction, whereas St. Jude Medical valves are at high risk for complications. These mainly anecdotal reports led to recommend bioprosthetic valves in the "right heart." However, when these patients are disaggregated by valve type, it appears that complications occurred only in children with bileaflet

valves. As shown in Table II, no complications are reported in the patients with tilting disc valves in the pulmonary position, whereas thrombotic phenomena or valve failure occurred in 35% of children with St. Jude Medical valves. This probably depends on the different valve behavior, which may be explained by the structural features of the bileaflet valve; the "force threshold" they need for adequate functioning is probably higher than for monodisc valves, and this appears to be a critical issue in the low-pressure system in the "right heart."⁸ This low pressure probably allows the deposition of fibrin and the formation of microclots, predisposing to the growth of fibrous tissue within the valve anulus and in the hinges, impairing the movement of the leaflets.^{1, 7} It may be hypothesized that the better performance of tilting disc valves is due to the absence of structural links between the disc and the valve ring, where blood flow is slower and clotting with subsequent growth of pannus are favored. One may also hypothesize that the structural features of monodisc valves, with the central position of the leaflet pivot, where the blood flow is (presumably) less disturbed and turbulent and its velocity is higher, may reduce the risks of fibrin deposition, clotting formation, growth of fibrous tissue, and, therefore, of valve failure. Thus available clinical data suggest that tilting disc valves in the pulmonary position may perform better than bileaflet valves, especially because using valved

conduits may further increase their durability and reliability. Unfortunately, we lack experimental data on the behavior of tilting disc valves in a low-pressure circuit.^{12, 17}

Although these figures are small and long-term follow-up is lacking, we would agree with Dr. Ilbawi's recommendation about a "word of caution regarding right side placement"¹ of bileaflet mechanical valves; we would also suggest a thorough reevaluation of tilting disc valves in the pulmonary position. Should their reliability be confirmed, the use of mechanical valves in carefully selected patients might result in a satisfactory outcome, comparable at least to bioprostheses but possibly reducing the risk of reoperation because of calcification and stenosis. Anticoagulation carries some risk of thromboembolic events, which cannot be overlooked. Bradley and colleagues¹⁸ have recently reviewed their series and conducted an analysis of related papers: the risk of thromboembolic events in children with mechanical valves (mitral or aortic position) is about 4%. Obviously, these figures should enter the risks/benefits balance when considering this particular type of surgery. An important issue that should not be overlooked is future pregnancy in patients with prosthetic valves. Bioprostheses show an enhanced deterioration during pregnancy because of aggressive calcification and early replacement may add uncertain risks; on the other hand, in patients with mechanical valves, warfarin sodium and heparin carry some risks for both mother and fetus, but these drugs should not be discontinued during pregnancy. Surveillance of pregnant patients with mechanical valves, as well as of the fetus, should be very close.^{19, 20}

In conclusion in selected patients with severe dysfunction of the right ventricle because of pulmonary regurgitation, the use of a mechanical valve in the pulmonary position may be taken into consideration as an alternative option to bioprostheses to reduce the risk of reoperations. In addition, redo operations consume resources that, conversely, could progressively decrease with time. Our series is clearly small, and this is not a controlled study; therefore reliable statistics cannot be drawn. Larger prospective studies should be conducted before one may routinely consider mechanical valves as a safe alternative to bioprostheses in the pulmonary position. In the pulmonary position, tilting disc valves seem to function better than bileaflet valves.

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