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Published in:
EUROPEAN JOURNAL OF CARDIO-THORACIC SURGERY

DOI:
10.1016/j.ejcts.2006.02.069

Publication date:
2006

ELSEVIER

European Journal of Cardio-thoracic Surgery 30 (2006) 28—34

EUROPEAN JOURNAL OF CARDIO-THORACIC SURGERY

www.elsevier.com/locate/ejcts

Pulmonary valve replacement with a mechanical prosthesis. Promising results of 28 procedures in patients with congenital heart disease☆

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Received 25 September 2005; received in revised form 11 February 2006; accepted 13 February 2006

Abstract

Objective: Pulmonary valve replacement is performed increasingly late after correction of Tetralogy of Fallot. Most reports deal with pulmonary allografts as the valvar substitute of choice, although late deterioration and reoperation(s) are the rule. Mechanical valves are scarcely reported and if so only because of complications. Although life-long anticoagulation therapy is indicated for mechanical prostheses, the chance of subsequent re-operations can be expected to be low. We report the results of 28 mechanical valve replacements in the pulmonary position. **Methods:** A mechanical valve was implanted in 27 of 79 patients indicated for pulmonary valve replacement. Tetralogy of Fallot was the most common basic lesion. The results and follow-up were reviewed retrospectively, where death and re-operation were primary end points. Routine outpatient follow-up, including trans-thoracic echocardiography, was performed. **Results:** Twenty-eight pulmonary valve implantations were done in 27 patients. Thirty-day hospital mortality was 1/28 (3.6%), because of a cerebro-vascular accident. One patient died late (2.8 years postoperatively). Median age was 33 years and the median interval between primary repair and insertion of the prosthesis was 26 years. Freedom from re-operation at 1 year was 100%. One valve had to be replaced 14 years after implantation because of malfunction due to ingrowth of endomyocardial fibrosis. No thrombo-embolic events were observed. **Conclusions:** Our series do not confirm the bad reputation of mechanical valvar prostheses in the pulmonary position. On the contrary they perform well and result in a much lower re-operation rate than can be expected and in fact is reported after allograft usage. No thrombo-embolic complications were noted. In our experience pulmonary mechanical valve prostheses do well.

Keywords: Congenital heart disease; Pulmonary valve; Tetralogy of Fallot; Heart valve; Mechanical; Reoperation

1. Introduction

Pulmonary valve replacement is performed in an increasing number of patients for pulmonary regurgitation causing right ventricular failure, mostly late after correction of Tetralogy of Fallot [1,2]. These patients have right ventricular failure and often have ventricular rhythm disturbances, but can be treated fairly easily by pulmonary valvar replacement. Rarely patients present with symptoms of pulmonary stenosis.

Most surgeons replace the pulmonary valve with an allograft [3], although xenografts are also employed [4,2]. However, these valvar substitutes both deteriorate over time, making (potentially multiple) reoperations necessary, each associated with morbidity and mortality [5—7]. Additionally, patients usually do not relish the prospect of multiple re-operations. Replacement with a mechanical valvar prostheses most likely reduces the number of reoperations but has a less favourable reputation, despite a paucity of papers on results, let alone sizable series of patients (Table 1) [8—15].

We offered implantation of a mechanical valvar prosthesis primarily to our adult patients, in order to minimise the expected total amount of operations. Our aim is to report the medium term results of this policy.

2. Materials and methods

Between 1987 and June 2005, 79 patients underwent a pulmonary valve replacement for a congenital heart defect.

☆ Presented at the joint 19th Annual Meeting of the European Association for Cardio-thoracic Surgery and the 13th Annual Meeting of the European Society of Thoracic Surgeons, Barcelona, Spain, 25—28 September 2005.

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doi:10.1016/j.ejcts.2006.02.069

Table 1
Survey of the literature on mechanical PVR

Author	Year	mPVR	Age	Failure	Interval/follow-up	Anticoagulant therapy
Ilbawi et al. [8]	1986	8	2–10	6	1–6 months after PVR	Salicylates and dipyramidol
Miyamura et al. [9]	1987	5	13–30	1	10 months after PVR	'Adequate' warfarin therapy
Kiyota et al. [10]	1992	11	?	3	?	?
Rosti et al. [11]	1998	8	6–17	0	3 months–9 years	Coumadine (INR 2.0)
Nurozler and Bradley [12]	2002	5	1–20	4	1–18 years	Aspirin[a]
Iscan et al. [13]	2003	1	10	0	15 years	None
Reiss et al. [14]	2003	32	3–43	3	Mean follow-up 6.5 years	Dicoumarol (INR ?)
Haas et al. [15]	2005	14	10–38	0	1–5 years	Dicoumarol (INR 3–4.5)

[a] Warfarin was started after first thrombo-embolic event.

Fifty-three of these patients were 18 years or older and in 24 patients (24/53 = 45%) a mechanical valve was implanted in the pulmonary position. These 24 patients are the subject of this study. Early in our experience three children underwent implantation of a mechanical pulmonary valvar prosthesis in a 'bail out' situation because an allograft was not available at the time and we added them to this study group, making for a total of 27 patients (Table 2). One patient had to have a re-replacement of a mechanical valve 14 years after the first implantation, because of malfunction, due to ingrowth of fibrous tissue (Fig. 1). Tetralogy of Fallot was the most frequent underlying congenital heart defect (19 patients). Other underlying diagnoses were pulmonary atresia with intact ventricular septum (2 patients), isolated pulmonary stenosis (2 patients), truncus arteriosus (2 patients), Tetralogy of Fallot combined with AVSD (1 patient) and a failing allograft after a Ross procedure (1 patient). Patients either had massive pulmonary regurgitation (20 of 27 patients) and were symptomatic with diminished exercise tolerance, rhythm disturbances and right ventricular failure or had pulmonary stenosis (7 of 27 patients) after pulmonary valvotomy or a previous right ventricle (RV) to pulmonary artery (PA) conduit insertion. The age at mechanical valve insertion ranged from 6 to 65 years (median 33 years). The interval between primary correction and mechanical valve insertion ranged from 3 to 37 years (median 26 years).

Table 2
Patient characteristics

No.	Age	Diagnosis	Year of mPVR	No. of sternotomies	Beating heart	CPB before sternotomy	Additional procedures	Valve brand	Valve diameter	Pacemaker	NYHA class at last follow-up
1	6	AVSD/ToF	1987	2	No	No		Durom	21	Yes	II
2	21	ToF	1989	2	No	No	tvp	SJM	23	Yes	II
3	54	ToF	1992	2	No	No		SJM	25	No	I
4	11	ToF	1992	3	No	No	tvp	Carbo	21	Yes	II
5	33	Truncus	1992	4	No	No	avr/tvp	Carbo	25	No	I[a]
6	11	ToF	1998	2	No	No	mvr	SJM	23	Yes	II
7	37	ToF	1999	3	Yes	Yes	Coronary fistula	SJM	27	Yes	I
8	38	ToF	1999	3	Yes	Yes	tvp	Carbo	27	No	I
9	42	ToF	2000	4	Yes	Yes	tvp	Carbo	23	icd	I
10	41	ToF	2000	4	No	Yes	avr/tvp	Carbo	23	icd	I
11	33	ToF	2000	3	Yes	Yes		SJM	23	No	I
12	35	ToF	2001	2	Yes	Yes	tvp + pacemaker	SJM	25	Yes	I
13	44	PS	2001	2	Yes	No		SJM	21	No	I
14	36	PA-IVS	2001	3	Yes	Yes	tvp	SJM	23	No	I
15	29	ToF	2001	2	Yes	Yes	tvp	SJM	25	No	I
16	29	PA-IVS	2001	3	Yes	Yes	tvp	SJM	25	No	I
17	33	ToF	2001	3	Yes	Yes	Maze	SJM	25	icd	II
18	31	AI/Ross	2001	3	No	No	mvr/tvp	SJM	23	No	I
19	21	AVSD/ToF	2001	3	Yes	No		SJM	23	Yes	II[b]
20	24	ToF	2002	2	Yes	No		SJM	23	No	I
21	33	ToF	2003	2	Yes	Yes		ATS	21	No	I
22	18	Truncus	2004	3	No	Yes	False retrosternal aneurysm	SJM	23	No	II
23	26	ToF	2004	2	No	No	Reconstruction VCSS tunnel	ATS	25	No	I
24	65	PS	2004	2	Yes	No	tvp	ATS	23	No	—[c]
25	34	ToF	2004	2	Yes	No		ATS	25	No	II
26	27	ToF	2005	2	Yes	Yes		SJM	23	No	I
27	28	ToF	2005	2	Yes	No		SJM	25	No	II
28	38	ToF	2005	2	Yes	No		ATS	25	icd	I

ToF: Tetralogy of Fallot; PA-IVS: pulmonary atresia with intact ventricular septum; AI: aortic insufficiency; PS: pulmonary stenosis; tvp: tricuspid valve repair; avr: aortic valve replacement; mvr: mitral valve replacement; Durom: Duromedics; SJM: St. Jude Medical; Carbo: Carbomedics; ATS: ATS Medical; mPVR: pulmonary valve replacement with a mechanical prosthesis; VCSS: persistent left caval vein.

[a] Died late.

[b] Patient 19 is Patient 1.

[c] Died.

Fig. 1. Duromedics valve explanted 14 years after implantation due to valve malfunction caused by ingrowth of fibrous tissue.

2.1. Operative details

All these redo operations were performed through a median sternotomy and subsequent canulation of the ascending aorta and caval veins in 15 patients. In the remaining 13 patients cardiopulmonary bypass was established before redo sternotomy with canulation of femoral artery and vein. Aortic cross clamping was only used when additional procedures made this necessary. Whenever possible and after excluding the existence of any residual septal defects the operation was performed at 37 °C on a beating heart with caval tapes snared. The right ventricular outflow tract (RVOT) was opened by removing the transannular patch or by removing the existing conduit. If necessary, obstructive muscular bands were removed from the RVOT. Over time various valvar prostheses were used at the discretion of the surgeon: 1 Duromedics®, 17 St. Jude Medical®, 5 Carbomedics® and 5 ATS® valvar prostheses were used. Usually about two thirds of the circumference of the prosthetic valve was sutured to the infundibular septum, at the insertion of the original pulmonary valve. To allow for a prosthetic valve of adequate size the remaining 'roof' was constructed with a diamond shaped patch (synthetic or xenograft), covering the RVOT as well as the pulmonary trunk. For the remaining one third of the circumference the patch was sutured to the valvar prosthesis.

2.2. Follow-up

No patients were lost to follow-up, and all were seen on a regular basis by a cardiologist specialised in congenital heart disease. Follow-up time ranged from 2 months to 18 years (mean 5.5 years). Special attention was paid to RV function and prosthetic valvar performance by transthoracic and/or transesophageal echocardiography.

2.3. Statistics

Seventy percent of confidence limits were calculated where applicable (70% CL).

3. Results

All patients survived the operation (70% CL: 0–6.7%). No patients had pulmonary emboli at least none were clinically manifested. Our oldest patient (65 years) died of an ischaemic (probably embolic) cerebro-vascular accident on day 5 after the operation. Cardiac function of the latter patient at the time of this complication was unimpaired. This single early death, that was in all likelihood unrelated to the specific procedure, results in a 30-day mortality of 3.6%; 70% CL 0.5–11.6%. One patient died 2.8 years after the operation of pulmonary haemorrhage due to an INR of >7. One patient had to have her prosthetic valve replaced by another, due to valve malfunction by fibrous tissue ingrowth (Fig. 1). Details of all procedures are summarised in Table 2. The sternotomy was the second in succession in 15 procedures (53%), the third sternotomy in 10 procedures (36%) and the fourth sternotomy in 3 (11%). No complications did occur at any of these redo sternotomies. In 13 of 28 (46%) procedures cardiopulmonary bypass was installed before sternotomy or during sternotomy (one patient). In 18 of 28 (64%) procedures pulmonary valvar implantation was performed at normothermy on the beating heart. In 12 of 28 (43%) procedures an additional tricuspid valve repair was performed. Other additional procedures were aortic valve replacement (two patients), mitral valve replacement (two patients), repair of a retrosternal false aneurysm of the RVOT (one patient) and a 'maze' procedure (one patient).

RV dilatation (due to pulmonary insufficiency) was present in 20 cases and improved in 15 patients; in 2 patients RV dimensions remained the same; one patient died postoperatively; in 2 patients follow-up was to short to judge. No postoperative pulmonary regurgitation was found, apart from minor early diastolic intravalvar regurgitation, considered to be normal for valvar prostheses. All surviving patients (25) perform well (17 patients are NYHA class I, 8 patients are NYHA class II) and improved in exercise tolerance after the operation. All surviving patients are on coumadine medication and are advised to maintain an INR of 2.5–4.

4. Discussion

Despite the unfavourable reputation, we showed that mechanical pulmonary valvar replacement can be performed with promising early and midterm results. These results are not surprising from a theoretical standpoint, since flow through these prostheses is essentially the same as through an aortic valvar prosthesis, albeit that pressures are obviously much lower.

Why mechanical pulmonary valvar replacement has such an unfavourable reputation is somewhat of a mystery. Series of any substantial size and follow-up are lacking. Nonetheless the number of grown-up congenital heart disease (GUCH) patients is increasing to significant numbers. As we know now a large number of patients with 'corrected' Tetralogy of Fallot is at risk of failure of their right ventricle [16], mostly because of pulmonary regurgitation (PR) induced by a transannular patch [1]. Particularly, in the long term, PR leads to diminished exercise capacity

and rhythm disturbances, due to RV dilatation and dysfunction. This condition can be treated easily by surgical introduction of a competent valvar prosthesis in the pulmonary position.

The Guidelines for the Management of Patients with Valvular Heart Disease [3] by the American College of Cardiology and the American Heart Association do not recommend any particular surgical technique but state that 'pulmonary valve replacement' is usually performed with a homograft, but '*follow-up data are too preliminary to develop recommendations at this time*' (1998). To offer these patients a hopefully last operation, a mechanical valve is a viable option in our opinion. Until recently [15] there was almost no support for this strategy in the literature, on the contrary, implantation of mechanical valves is advised against because of hearsay evidence of pulmonary thrombo-embolic complications. By reviewing the very scarce literature (Table 1) on mechanical pulmonary valvar replacement we conclude that only few series are reported and that those studies were hardly more than case histories, except for a few. We conclude that there is insufficient evidence against the use of mechanical pulmonary valvar prostheses, although the experimental work of Kiyota et al. [10] must be taken into account. This study reports in vitro experiments on leaflet closure of mechanical bileaflet valves in low-pressure circumstances and conclude that forces in the pulmonary system are insufficient to close both semi-discs at all times and that as a result pulmonary regurgitation remains, in this experimental setting. Although the authors advocate in vitro assessment of mechanical valves in a low-pressure system, we could not find any subsequent report on these views. On the contrary, our clinical echocardiography studies did not show any evidence of regurgitation of the mechanical valvar prosthesis, apart from the normal early diastolic jets that also can be seen after placement of a mechanical valve in the aortic position.

The drawback of the need for anticoagulation is counterbalanced by the prospect of the likely absence of re-operations due to valve malfunction as compared to biological valvar substitutes. Both risks, however, are unequal in nature and in time, for which reason they need to be described carefully.

The reported freedom from reoperation of allografts in the right ventricular outflow tract varies in different papers. The most favourable figures are 89% actuarial freedom from reoperation at 10 years and 80% at 20 years [17]. Other papers report 81% at 5 years and 70% at 7 years [6]. Second and third replaced allografts fare worse [5], so that the interval between reoperations becomes shorter over time. Preservation techniques of allografts and subsequent rejection-like phenomena play a role, as yet not fully elucidated [18]. Multiple re-operations are to be anticipated in this strategy, when taking the otherwise good life expectancy of these patients into account, a prospect most patients do not relish.

Xenografts can also be used in the right ventricular outflow tract, and have a reported 10-year survival of 85% [7]. Essentially, xenografts have the same drawback as allografts do, resulting in multiple reoperations. Furthermore, one has to bear in mind that patients most likely become increasingly symptomatic for a considerable period before yet another reoperation is performed.

The risk of thrombo-embolic and bleeding complications in patients on oral anticoagulant therapy for mechanical heart valves has been thoroughly analysed by Cannegieter et al. [19]. The linear risk of cerebral emboli was 0.68 per 100 patient-years, whilst the risk of peripheral emboli was much lower at 0.03 per 100 patient-years; most likely due lack of detection of the latter. These embolic risks must theoretically be similar for pulmonary mechanical valvar prostheses. The emboli of the size causing a disabling cerebro-vascular accident, cause only a minor pulmonary embolus, possibly even of a subclinical nature. Thus, the embolic risk of a mechanical pulmonary valvar prosthesis seems to be slight. The risk of thrombosis of the valve must also be minimal when anticoagulation is adequate. Whether or not the immobilised valve that we replaced in our current series of patients is due to fibrosis secondary to a thrombotic process is a matter of speculation. Most likely, however, by the very nature of the pathology it was excessive fibrosis that was induced by the vascular prosthesis that was used to cover the valve and the outflow tract.

Bleeding complications in the Cannegieter paper [20], whether intracranial or spinal, were reported to be 0.57 per 100 patient-years. In contrast, the risk of major extracranial bleeding was more than three times larger at 2.1 events per 100 patient-years. The patients in this study had a target INR of 3.6—4.8. Patients younger than 50 years had a very low risk of thrombo-embolic event 0.1 per 100-patient years. In this study, however, there were no patients with a mechanical valve in the pulmonary position.

Patients with an allograft or xenograft therefore have an estimated risk of reoperation of 15—20% at 10 years [20,7], an interval that is expected to decrease. Since our patients had a median age of 33 years at the time of their PVR, and assuming a normal life expectancy, 45—60% of them will need multiple reoperations, each time associated with a mortality risk of 2—10%. In contrast, patients with a mechanical valve have a risk of reoperation of 4% at 14 years (this study) and have a cumulative reoperation risk during their lifetime of 8%.

It is difficult to compare these risks because of their disparate nature. In our opinion both circumstances, mechanical PVR and allograft-PVR or xenograft-PVR, probably do not differ in the incidence of complications, but do in mode of complication. Where patients that need re-do operations risk mortality, even more then once, patients that use anticoagulant medication suffer more from morbidity, albeit during their entire lifetime. Furthermore, we do realise that fatal thrombo-embolic or bleeding complications do occur occasionally. In fact our only late death until now occurred of a major pulmonary bleed due to coumadine over dosage.

Anticoagulant therapy is thus an important issue. Most of the reports advising against the use of mechanical valves mention either no anticoagulant therapy or inadequate prophylaxis such as aspirin or aspirin and dipyramidol. Only those studies that employ coumadine anticoagulant therapy, maintaining an INR of more than 2.0, report absence of thrombo-embolic incidents. As is the case with every other use of mechanical valves adequate anti-thrombotic therapy is mandatory. We advocate maintaining an INR of 2.5—4.0. In this respect there is no restriction to self-management of the

level of anticoagulation. Finally, it is not only speculation that well-trained patients control their INR level better than health professionals or specialised laboratories do [21].

5. Conclusion

Replacement of the pulmonary valve with a mechanical valve prosthesis can be performed with promising early and midterm results. The unfavourable reputation of PVR with a mechanical (bileaflet) valve prosthesis must be reconsidered in the light of our findings. Our experience is in keeping with that of others, but consists of more patients and a longer follow-up. Crucial is anti-thrombotic therapy with coumadines, maintaining an INR of 2.5–4. On the condition that this can be managed, fewer reoperations can be expected. Patients that comply with this condition can safely be offered replacement of their pulmonary valve with a mechanical valve prosthesis. Complications due to anti-thrombotic therapy will occur but must be weighed against the complications of multiple re-operations. Therefore, mechanical valvar replacement of the pulmonary valve is a viable option in our opinion.

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Appendix A. Conference discussion

Dr B. Maruszewski (*Warsaw, Poland*): My comment is that, what is the choice nowadays for the pulmonary valve replacement? You have xenograft, you have allograft, you have mechanical valve. If we all believe that homogenous tissue will calcify, so we provide patient with second operation in the future, there is still a choice between the mechanical valve, but also the new generation of xenografts, the valves that are covered with the agents that reduce the calcification.

So this is my comment. And actually I have to say I never put the mechanical valve in the right ventricle outflow tract and I'm not prepared to do it. But what we have done, we have switched from about 800 homografts, that we put in this position in the past, to the freestyle valve, since Magdi Yacoub has reported very good long-term results, and there is no reason why we should not use this valve on the right side of the heart. And there is a report that was presented on the CHHS meeting in Buenos Aires that over 80 of these valves have already been implanted. So I think having in mind the anticoagulation and the risk of complications, I think we should really consider this valve as the other choice.

Dr Waterbolk: I like to comment on the use of xenografts. Every time newer generations of these valves are presented, but it has to be seen how they will last in the end. And furthermore these patients have a long time to live assuming a normal life expectancy.

Dr B. Murzi (*Massa, Italy*): I would like to know, first, which kind of valve you used, monocusp or bileaflet valve?

Dr Waterbolk: All these valves are bileaflet valves.

Dr Murzi: I have seen that you presented the paper that was from Milan. And we did that paper and we observed that in the literature most of the valve that thrombosed were the bileaflet valves that had four struts. And there were no reports of tilting valve that was in the pulmonary position. So we are using, when we have to put a mechanical valve on the right ventricle of inflow tract, we use tilting valve because of that.

And I totally agree with you that when you have a patient that has been operated five or six times, probably deciding to have a valve that can last for all the life could be a good idea.

Dr Waterbolk: Well, this series shows that the bad reputation of the bileaflet valve is, as far as we are concerned, not right.

I like to make another comment. We give the patients themselves the opportunity to think over the prospect of redo operations or the prospect of lifelong anticoagulation and let them decide themselves.