Mechanical valves in the pulmonary position: An international retrospective analysis

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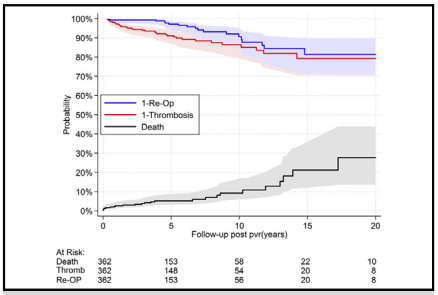
ABSTRACT

Objective: Life expectancy of patients with congenital heart disease has improved over the past decades, increasing the need for a durable pulmonary prosthetic valve. Biological valves in various forms have become the valve of choice for pulmonary valve replacement (PVR), but structural valve deterioration is unavoidable in the long term. Use of a mechanical valve could be an alternative, but data on long-term outcomes are sparse.

Methods: We retrospectively collected and analyzed data on 364 patients with mechanical valves implanted in the pulmonary position between 1965 and 2014. The data originate from medical centers in Barcelona (Spain), Graz (Austria), Groningen (the Netherlands), Munich (Germany), Rochester (United States), Seoul (Republic of Korea), and Tehran (Iran).

Results: Median follow-up duration was 4.26 years (range, 0-27 years), mean age at implantation was 27.16 ± 12.2 years. Tetralogy of Fallot was the most common primary cardiac diagnosis, with a subgroup of 69.8%. Freedom from valvular thrombosis was 91% (95% confidence interval [CI], 87%-94%) at 5 years and 86% (95% CI, 81%-91%) at 10 years post-PVR. With a success rate up to 88%, thrombolysis was a successful therapy. Freedom from reoperation was 97% (95% CI, 94%-99%) at 5 years post-PVR and 91% (95% CI, 85%-95%) at 10 years.

Conclusions: Mechanical PVR is associated with a limited risk of valvular thrombosis. Thrombolysis was an effective treatment in the majority. (J Thorac Cardiovasc Surg 2017;154:1371-8)



Cumulative incidence analyses for death, reoperation, and valvular thrombosis.

Central Message

MPVR is associated with a limited risk of valvular thrombosis. When this happened, thrombolysis was an effective treatment in the majority of patients.

Perspective

Literature on the long-term behavior of the different pulmonary prosthetic valves is scarce, especially on mechanical valves. With this study, we highlight the medium- to long-term performance of mechanical valves in the pulmonary position. Our results show a limited risk of valvular thrombosis and promising results for thrombolytic treatment. A mechanical valve can be a valid option for pulmonary valve replacement in selected patients.

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Pulmonary valve replacement (PVR) is among the most common procedures in patients with right-sided congenital heart disease.[1,2] No valve prostheses have been designed specifically for the pulmonary position, for which reason aortic valve prostheses (both tissue and mechanical) are usually used in the pulmonary position. Exceptions are

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Abbreviations and Acronyms

INR = international normalized ratio
IOD = inner orifice diameter
LVEF = left ventricular ejection fraction
MPVR = mechanical pulmonary valve replacement
PVR = pulmonary valve replacement
TAPSE = Tricuspid Annular Plane Systolic Excursion
ToF = tetralogy of Fallot

Scanning this QR code will take you to a supplemental video, appendix, and tabel for the article.

jugular venous xenograft valves that are available in a limited size range of 12 to 22 mm diameter and pulmonary allografts (homografts). Aortic tissue prosthetic valves in various models and allografts have been the valves of choice for particularly adult PVR[2] because of a low risk of thrombosis without the need for anticoagulation. However, tissue valves have a limited lifespan caused by structural valve degeneration,[3,4] which seems to occur earlier in the pulmonary than in the aortic position, rendering reinterventions unavoidable in all but elderly patients.

Mechanical prosthetic valves have been the gold standard for left-sided valve replacement in patients younger than age 60 years and could be a viable alternative to bioprostheses for patients in need of a PVR, particularly for patients with high surgical risk and patients already using anticoagulation agents. However, there are serious concerns about the higher risks of valvular thrombosis in right-sided mechanical valves as well as the bleeding risk resulting from lifelong anticoagulation use.

A recent meta-analysis on mechanical PVR (MPVR) showed an average valvular thrombosis occurrence of 2.2% at an average mean follow-up of 73 months (range, 8-180 months).[5] However, this study was limited by a stark heterogeneity between studies and no time-related analysis was possible. A large study on the long-term functionality of MPVR is missing in the current literature.

The objective of this study was to evaluate medium- to long-term results of MPVR, using a large multicenter database combining updated data from the 7 largest studies worldwide from 2009 to 2015,[6-12] with a focus on valvular thrombosis as a primary end point. Thrombolysis, reoperation, and death were chosen as secondary end points because death is more associated with cardiac failure than with the prosthetic valve, whereas thrombolysis and reoperation are the result of the primary end point.

METHODS

Study Design

This study was designed as a multicenter retrospective study to observe the long-term functionality of a first MPVR. The primary end point was first valvular thrombosis, whereas secondary end points were thrombolysis, reoperation, and mortality. To minimize patient-related factors (such as thrombophilia), follow-up of second mechanical valves introduced at reoperation were not further analyzed. All corresponding authors of articles with a minimum of 15 mechanical pulmonary valves published between May 2009 and May 2015[6-12] agreed to participate in this retrospective chart review study, where the data were to be completed and updated from the time of their original publication. Patients diagnosed with carcinoid heart disease were excluded from the study due to the poor prognosis associated with carcinoid heart disease. Data transfer agreements are in place between all institutions and the University Medical Center Groningen.

Data Collection

All data were de-identified and compiled at the time of collation into the clinical database. Institutional review board approval was obtained by each separate institution before the collection of the data. Applicable legislation in the Netherlands stipulates that retrospective anonymized chart research is not subjected to institutional review board review. Ethics review was not deemed necessary upon question of individual ethics review boards. Data were collected retrospectively, using electronic and paper patient records. No identifiers were linked to patients in this collective database. Centers from the following towns contributed to this study: Barcelona, Spain; Graz, Austria; Groningen, The Netherlands; Munich and Lübeck, Germany; Rochester, Minnesota; Seoul, Republic of Korea; and Tehran, Iran. Data were collected and entered by the individual centers in a predetermined data submission file. We used the following parameters:

- Patient characteristics: age, gender, original diagnosis, previous surgeries, concomitant medication, and previous pregnancies.
- Procedural information: prosthetic valve brand, model and labeled size, date of implantation, concomitant procedures, complications, antithrombotic regimen, tricuspid annular plane systolic excursion (TAPSE), left ventricular ejection fraction (LVEF), and postoperative valve flow velocity, determined by continuous wave Doppler echocardiography.
- Follow-up information: valvular thrombosis, death, cause of death, valve replacement, thrombolysis of valvular thrombosis, date of the last follow-up visit, and pregnancies.

Transthoracic echocardiography was recorded within 1 year postoperatively. Local protocols were followed for obtaining and evaluating the echocardiographic images. Right ventricular systolic dysfunction was defined as TAPSE $\leq$ 16. Moderately impaired left ventricular systolic dysfunction was defined as a LVEF $\leq$ 45% and severe dysfunction as a LVEF < 30%. The variable "thrombosis" also includes pannus because the difference is often not obvious.

Labeling of prosthetic heart valves has changed over the years, although not all manufacturers adhere to the applicable International Standards Organization standards. The tissue annulus diameter of the patient is meant to reflect the labeled size. Thus, the labeled size reflects the inner orifice diameter (IOD) in supra-annular valves and the outer diameter in intra-annular valves. To take into account as many aspects as possible, we collected the IOD of all prosthetic valves from the manufacturer's specifications. Thus, IOD was chosen instead of the in vitro determined effective orifice area because of additional inconsistencies in the applicable methods used for measuring the effective orifice area. All data files were merged into 1 database and prepared for analysis at the University Medical Center Groningen.