MEDICAL UNIVERSITY OF VIENNA

Pulmonary Valve Replacement with Decellularized Homografts: a Single-center Experience

A. Andreeva, I. Coti, P. Werner, S. Scherzer, D. Zimpfer, A. Kocher, G. Laufer, M. Andreas

Department of Cardiac Surgery, Medical University of Vienna, Vienna, Austria

Baseline

Patients, n	51
Mean age at surgery, y	35.8 (10.2)
Sex, female, %	19.6
Weight, kg	77.3 (16.0)
Height, cm	175.0 (8.6)
Body mass index, kg/m^2	25.2 (4.5)
Mean EuroScore II	3.8 (3.1)
Diabetes, n (%)	0 (0)
Dyslipidemia, n (%)	6 (11.8)
Coronary artery disease, n (%)	4 (7.8)
Cerebrovascular disease, n (%)	0 (0)
Mean preoperative creatinine, mg/dl	1.1 (1.1)
Chronic lung disease, n (%)	5 (9.8)
Rhythm abnormalities, n (%)	15 (29.4)
Patients with previous valve replacement, n (%)	12 (23.5)
Patients with previous valve repair or valvuloplasty, n (%)	3 (5.9)
Patients with previous Ross procedure, n (%)	10 (19.6)

Operative data

Mean diameter of the implanted valve, mm	28.1 (2.8)
Mean bypass time, min	172.5 (70.6)
Mean cross-clamp time, min	143.2 (48.2)
Concomitant procedures, %	70.6

Follow-up

Mean follow-up, months	16.1 (17.2)
Cumulative follow-up, y	68.3
Explantation for valve degeneration, n (%)	2 (3.9)
Death, n (%)	1 (2.0)
Mean postoperative gradient, mmHG	9.2 (7.2)

Table 1. Overview of patient characteristics at baseline, implantation and follow-up. The standard deviation of the mean values is reported in parentheses.

Objective

The aim of this work was to analyze our single-center experience with decellularized pulmonary homografts in adult patients.

- Freedom from lifelong anticoagulation,
- low immunogenicity,
- good hemodynamic characteristics
- and a possible regeneration of the valve are potential major advantages of decellularized homografts.

Methods

We evaluated decellularized pulmonary homografts (DPH) in adult patients regarding safety, durability and hemodynamic performance according to current guidelines.

Each patient received a decellularized pulmonary homograft and has been followed up in our center after the surgery.

- **Safety** endpoint: rate of cardiovascular adverse events (all-cause mortality, bleeding, acute kidney injury, major stroke and major vascular complications).
- **Efficacy** endpoint: rate of homograft dysfunction including stenosis and insufficiency assessed by transthoracic echocardiography and repeat procedures for valve-related dysfunction.

The databank close was on September 11, 2020.

Results

- Since 2015, **51** patients received a DPH in our center
- Mean age 35.8 (10.2) years (range 18 to 58 years), 10 (19.6%) female.
- Twelve patients (23.5%) previously underwent pulmonary valve replacement, ten of them were Ross procedures.
- Mean diameter of the implanted DPH was 28.1 (2.8) mm.
- Concomitant procedures were performed in 38 (74.5%) patients, of which 32 (62.7%) were Ross-operations.
- One patient suffered a perioperative stroke
- The **perioperative mortality** was 2.0% **(n=1)** due to preexisting antiphospholipid antibody syndrome and associated bleeding.
- **Two** patients (3.9%) underwent a **reoperation** with homograft explanation due to **stenosis** at 11 and 14 months. One of these was associated to patch material.
- Mean postoperative gradient of the DPH was 9.2 (7.2) mmHg, pulmonary regurgitation (trace) occurred in 8 (15.7%) cases.
- Mean follow up was 16.1 months (17.2), with a maximum follow up of 59 months. The cumulative follow-up was 68.3 years.
- **No other adverse events** including late mortality, valve thrombosis or non-structural dysfunction have been observed.

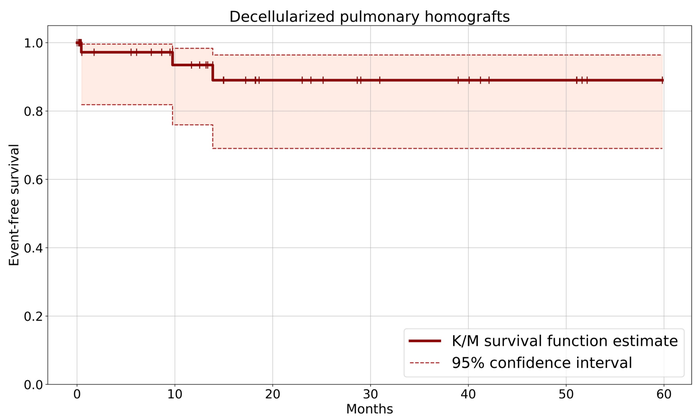

Figure 1. Kaplan-Meier event-free survival curve for the composite endpoint with 95% confidence interval.

Conclusions

- Early results showed a **low rate of complications** and valve degeneration in a complex patient population.
- Re-operation due to re-stenosis after implantation was observed.
- **Further studies are needed to evaluate the long-term performance** of the decellularized pulmonary homografts, which could be a safe and efficient alternative for the routine techniques of pulmonary valve replacements in young adults.