Midterm results of right ventricular outflow tract reconstruction with a tissue engineered pulmonary valve in 30 consecutive patients

Dohmen P M, Lembcke A, Holinski S, Dushe S, Pruß A, Stefanelli G, Konertz W

Objective
This study was performed to collect prospective safety and effectiveness data of a tissue engineered heart valve to reconstruct the right ventricular outflow tract during Ross procedure.

Methods
Since April 2000, 30 consecutive patients received a tissue engineered heart valve. Four weeks prior to the Ross operation a piece of forearm or saphenous vein was harvested, to isolate, characterize and expand endothelial cells. A pulmonary allograft or xenograft was decellularized, coated with fibronectin and seeded with autologous vascular endothelial cells, using a specially developed bioreactor. Follow-up was performed by clinical evaluation, transthoracic echocardiography, and multi-slice computed tomography.

Results
Patients mean age was 42.5 ± 14.6 years. Seeding cell density was $1.1 \times 10^5 \pm 0.5 \times 10^5$ cells/cm$^2$ with a viability of 90.0 ± 8.3 %. All patients survived surgery, however one patient died during follow up. One needed reoperated. Currently all patients are in NYHA class I. Transthoracic echocardiography evaluation of the tissue engineered heart valve showed a mean flow velocity of 0.8 ± 0.2 m/s at 4.5 years. Multi-slice computed tomography showed no calcification up to 4.5 years.

Conclusions
Tissue engineered heart valves showed excellent hemodynamic performance during midterm-term follow-up. Decellularization of heart valves and seeding with autologous vascular endothelial cells may decrease prevent degeneration of tissue valves.

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