## MP2-4

## Feasibility, usefulness, function and durability of a pulmonary valved conduit evaluated in a growing, long-term lamb model

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Objectives: We evaluate a tissue engineered valved conduit connecting the right ventricular outflow tract to the pulmonary artery bifurcation during long-term follow up and growth up to 24 months. Methods: In total, 19 female Swiss white mountain lambs (27–38 kg at surgery) were operated, using left lateral thoracotomy and cardiopulmonary bypass. The native pulmonary valve and the complete pulmonary trunk were resected. The conduit was constructed out of a de-cellularized porcine small intestinal submucosa extracellular matrix biologic scaffold and was implanted in orthotopic position. Follow-up transesophageal/-thoracic 2D Doppler echocardiography and laboratory values (LDH, hemoglobin, hematocrit, white blood cell count) were performed directly after surgery and after 1,3,6,12,15,18 and 24 months.

Results: Seven animals died perioperatively, 3 animals died due to asphyxiation pneumonia (at postoperative day 23) and infective endocarditis (day 20 resp. 256). In 9 animals, long-term function of the implanted conduit was assessed. Mean follow-up time so far is 17 months (range 20 days – 24 months). Seven animals were already sacrificed at 24 months (n=4), at 15 months (n=1), 12 months (n=1) and 9 months (n=1). Mean body weight at last follow up was 58.8 kg (28-72). 2D echocardiography revealed good function of the conduit with mean±SD systolic pressure gradient 7.1±1.3 mmHg and maximum moderate regurgitation. LDH increased from a pre-operative 976±78.2 to 1100±181.8 U/I [n.s.]. CT scan prior to termination (n=7) revealed no severe calcification or dilatation of the conduit. Subsequent histologic evaluation revealed a variable degree of incorporation to native tissue between individual valve leaflets. Most valves were moderately populated by stromal cells and showed endothelialisation (confirmed by CD31 immunohistology) and mild inflammation

within the valve. Small foci of chondroid and osseous metaplasia were occasionally observed, predominantly at the suture sites rather than within the leaflets.

Conclusions: The implantation of a valved RV-PA-conduit in a growing lamb model is feasible, useful and leads to a stable valve function up to 2 years. The animals demonstrated, after the initial recovery phase from surgery, good physical development but remain at risk for endocarditis (16%). The function of the valved conduit was satisfactory during long-term follow up.