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Performance of CryoValve[®] SG Decellularized Pulmonary Human Heart Valve in Adult Patients Undergoing a Ross Procedure

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Objectives:

This study compared the mid-term performance of the CryoValve SG decellularized human pulmonary heart valve (SGPV) to the standard-processed CryoValve pulmonary heart valve (CV) implanted in adult patients undergoing a Ross procedure.

Method:

Between 2/2000 and 3/2004, 129 consecutive adult patients at four institutions received a SGPV during the Ross procedure. Patient age ranged from 18 to 63.6 years: mean age at implant was 39.2 years. Demographic, perioperative and hemodynamic data (peak transvalvular gradient and valvular insufficiency ≥ 1 year postoperative) were retrospectively collected. Adverse events were assessed using Kaplan-Meier methodology. Data were compared to 441 CV adult Ross patients. Age, gender, and mean follow-up were similar between SGPV and CV patient cohorts.

Results:

Follow-up was current for 99% of SGPV patients (606 patient-years) with hemodynamic data ≥ 1 year available for 112 patients (87%) at mean follow-up 4.0 years. Adverse event occurrence was low and actuarial freedom did not significantly differ between SGPV and CV patients. Hemodynamic performance at longest follow-up was improved in SGPV patients demonstrated by a significantly lower peak gradient: 15.5mmHG compared to 19.9mmHg in CV patients ($p=0.043$). Additionally, pulmonary insufficiency was improved with 98% SGPV patients having none to mild insufficiency compared to 93% in CV ($p=0.043$).

Conclusions:

At mid-term follow-up, Ross procedure patients receiving SGPV demonstrated improved hemodynamic performance compared to CV. Adverse events were similarly low for both heart valves. The data suggests that the decellularization process does not adversely impact valve function as compared to standard-processed cryopreserved heart valves, and may lead to improved hemodynamic outcomes.