HAEMODYNAMIC PERFORMANCE AND EARLY SAFETY AFTER RAPID DEPLOYMENT AORTIC VALVE REPLACEMENT: REAL-WORLD OUTCOMES OF 512 PATIENTS

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Objectives: Superior aortic valve haemodynamic performance may accelerate LV mass regression, enhance survival and functional status after surgical aortic valve replacement. This may be achieved by rapid deployment aortic valve replacement using a subannular balloon-expandable stent frame. We herein report haemodynamic outcomes at 3 months from a large series of patients enrolled in the FOUNDATION registry.

Methods: FOUNDATION is a prospective, multicentre, single-arm, post-market registry evaluating safety and effectiveness of rapid deployment aortic valve replacement using a stented trileaflet bovine pericardial bioprosthesis in patients with aortic stenosis. Patients were assessed peri-operatively for procedural times, technical and procedural success rates; and, at discharge, 30 days, 3 months, and 1 year for valve haemodynamic performance, safety, and NYHA.

Results: Between July 2012 and July 2014, 512 patients were operated in 27 centres in Europe. Mean age was 75.6 ± 6.5; female, 42.8%. Seventy-six (15.0%) 19 mm, 139 (27.5%) 21 mm, 165 (32.7%) 23 mm, 95 (18.8%) 25 mm, and 30 (5.9%) 27 mm sized valves were implanted. Safety outcomes at 30 days were as follows: All-cause mortality 3.3%, thromboembolic events 3.3%, major bleeding events 5.5%, explants 0.8%, and major PVL requiring surgical intervention 1.0%. Site-reported echocardiographic data by valve size is presented in the table below. Mean pressure gradients decreased postoperatively and continued to improve at 3 months. Mean EOA increased postoperatively and improvement was maintained at 3 months.

Conclusion: In this large real-world series of patients with aortic stenosis, rapid deployment aortic valve replacement demonstrated early safety and good haemodynamic performance at 3 months.