会長要望セッション02（ I-YB02）
右室流出路再建：インターベンションと外科治療

座長:櫻井 一（中京病院 心臓血管外科）
座長:杉山 央（聖隷浜松病院 小児循環器科）
コメンテーター:John P. Cheatham（ Nationwide Children's Hospital &The Ohio State University）
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[I-YB02-3]Primary Outcomes of The Harmony Transcatheter Pulmonary Valve Pivotal Trial

○藤本 一途[1], 坂口 平馬[1], 神崎 秀明[2], 小林 順二郎[3]（1.国立循環器病研究センター 小児循環器内科, 2.国立循環器病研究センター 心不全科, 3.国立循環器病研究センター 心臓血管外科）
Keywords:transcatheter pulmonary valve implantation, pivotal trial, self-expandable valve

Background: Harmony transcatheter pulmonary valve (TPV), a self-expandable, porcine pericardial valve, was designed to accommodate the larger right ventricular outflow tract (RVOT) of patients with congenital defects who develop severe pulmonary regurgitation (PR) after surgical repair. It is available in 22 and 25 mm. An Early Feasibility Study (EFS) of the 22-mm has shown favorable performance through 3 y.Methods: Harmony TPV Pivotal Trial, a prospective, nonrandomized study, is being conducted at 12 sites in the US, Canada, and Japan. Inclusion criteria include severe PR on echocardiography or PR fraction ≧30% by magnetic resonance imaging (MRI) and an indication for surgical placement of a right ventricle-pulmonary artery conduit or prosthetic PV. 40 patients received a TPV (22 mm, n=21; 25 mm, n=19). A modified 25-mm was subsequently implanted in 10 patients. The primary safety endpoint is freedom from procedure- or device-related mortality at 30 days. The primary effectiveness endpoint is acceptable hemodynamic function (mean RVOT gradient ≦40 mmHg on echo, PR fraction ＜20% on MRI, and no prior TPV reintervention) at 6 months. 30-day hemodynamic performance and safety data will be reported for the modified 25-mm.Results: Primary endpoints and 30-day outcomes for the modified 25-mm will be presented.Conclusions: This new data will expand on findings from the EFS, which showed favorable outcomes in patients with severe PR.*Presentation will include data submitted to the 2020 Scientific Sessions of the Society for Cardiovascular Angiography and Interventions.