Early and Late Effects of Aortic Root Enlargement: Results From A Multicenter, Prospective Clinical Trial

Objective: Surgeons try to avoid prosthesis-patient mismatch (PPM) by implanting the largest possible valve into a given annulus. However, aortic root enlargement and/or annular enlargement (ARE) are sometimes required to insert an appropriately sized valve and avoid PPM. The effects of ARE on early and late mortality following surgical aortic valve replacement (SAVR) remain controversial. We reviewed clinical data collected prospectively from a large multinational, multicenter clinical trial evaluating a novel pericardial bioprosthesis to determine the impact of ARE on mortality and hemodynamic performance 5 years after implant.

Methods: Patients with moderate or greater aortic stenosis or regurgitation requiring SAVR were enrolled at 25 centers in North America (NA) and 13 centers in Europe (EUR). Standardized follow-up was prescribed, including serial echocardiography assessed by a core lab.

Results: Among 603 patients with detailed intraoperative data, 90 (14.9%) underwent an ARE procedure at the discretion of the surgeon. Mean valve size implanted in patients who did not undergo ARE was larger than in patients who underwent ARE (23.7 vs 23.1 mm, p=0.026). The proportion of subjects with no, moderate, or severe patient-prosthesis mismatch (PPM) at 12 months was comparable between the ARE group and the no ARE group (Table), and the average effective orifice area index (EOAi) was similar in both the ARE group and the no ARE groups (0.79 ± 0.22 vs 0.75 ± 0.17, p=0.15). The rates of ARE were generally similar in NA (69/420, 16.4%) and in EUR (21/183, 11.5%, p=0.12). The 30 day mortality was similar between ARE and no ARE groups, regardless of geographical region. Additional procedural data and clinical outcomes including mortality, NYHA functional classification, and hemodynamic performance through 5 years of follow-up will be available at time of presentation.

Conclusions: ARE procedures were conducted frequently in this large clinical trial. The incidence of PPM was generally similar between subjects receiving an ARE and subjects not receiving an ARE. Procedural data and clinical outcomes including mortality, NYHA functional classification, and hemodynamic performance through 5 years of follow-up will be available at the time of presentation.

Vivek Rao (1), Michael Reardon (2), Michiel Vriesendorp (3), Marc Ruel (4), Himanshu Patel (5), Fang Liu (6), Robert Klautz (7), (1) Toronto General, Toronto, ON, (2) Houston Methodist Hospital, Houston, TX, (3) LUMC, Leiden, Netherlands, (4) University of Ottawa Heart Institute, Ottawa, ON, (5) Michigan Medicine, Ann Arbor, MI, (6) Medtronic Inc, Minneapolis, MN, (7) Leiden University Medical Center, Leiden, ZH

Table. Prosthesis-patient mismatch (PPM) in patients who did or did not undergo aortic root, STJ, or annular enlargement (ARE)

PPM	**ARE (N=84)**	**No ARE (N=438)**	**p value**
			0.19
None	13 (15.5%)	86 (19.6%)	
Moderate	32 (38.1%)	180 (41.1%)	
Severe	39 (46.4%)	172 (39.3%)	