Perfusion-balloon valvuloplasty of aortic valve stenosis without rapid pacing: results of the TRUE-FLOW study

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THEME: Interventions for Valvular Disease
TOPIX(S): TAVI, Other valvular and structural interventions

AIMS
TRUE-FLOW was a prospective study designed to assess acute performance and safety of the TrueTMFlow Valvuloplasty Perfusion Catheter in providing stationary, effective, longer-term inflation of a stenotic aortic valve without rapid pacing.

METHODS AND RESULTS
Twenty-four patients undergoing TAVI for aortic valve stenosis were enrolled at the University of Leipzig - Heart Center (Leipzig, Germany) in this observational study. The test device (i.e., TrueTMFlow Valvuloplasty Catheter, Bard Peripheral Vascular) consisted of eight individual balloons encapsulated in a fiber-based non-compliant shell mounted on an over-the-wire catheter. The open chamber between the individual balloons was designed for blood flow, allowing for inflation with low hemodynamic resistance. The primary performance measure was stationary inflation of the balloon with clinically acceptable intraventricular pressure with or without rapid pacing. Safety was measured as freedom from device-related death, stroke, annulus rupture, coronary occlusion, or ventricular perforation during the dilation procedure. Baseline data were collected and pressure measurements were taken prior to inflation, at the time of balloon inflation, and immediately thereafter. Patients in the TRUE-FLOW study were 79.8 ± 4.3 years old; 70.8% were male with a mean STS score of 7.8 ± 5.9%. The ejection fraction prior to the procedure was 53.1% ± 13.9, and 54.2% of patients were classified as NYHA Class III. The total time of balloon inflation was 5.4 ± 2.3 sec, and all procedures except one (95.8%) were completed without rapid pacing. Movement of the balloon during inflation, while inflated, and during deflation were 4.2 ± 5.0, 2.0 ± 4.5 and 5.9 ± 6.1 mm, respectively. The mean pressure gradient between the left ventricle and the aorta before, during, and after inflation was 43.9 ± 18.9 mmHg, 38.3 ± 14.3 mmHg, and 29.0 ± 13.6 mmHg, respectively. The peak-to-peak gradient before, during, and after inflation was 54.9 ± 24.7 mmHg, 63.7 ± 24.1 mmHg, and 40.3 ± 18.5 mmHg while the mean ventricular end diastolic pressure was 17.8 ± 10.9 mmHg, 13.4 ± 11.3 mmHg, and 17.5 ± 10.5 mmHg, respectively. There were no reports of device-related safety events (i.e., death, stroke, annulus rupture, coronary occlusions, or ventricular perforation).

CONCLUSIONS
Data from this feasibility study demonstrate that the TrueTMFlow Valvuloplasty Catheter can treat aortic valve stenosis with minimal movement during inflation in the absence of rapid pacing (96% of cases), no increase in left-ventricular end-diastolic pressure, and with no device-related adverse events. Further studies are necessary to elucidate whether the avoidance of rapid pacing during valvuloplasty reduces ischemia of the myocardium, ischemia-related arrhythmias, and decompensations especially in patients with poor LV function.