The SOURCE Registry: what is the learning curve in trans-apical aortic valve implantation?

Abstract:
Trans-apical aortic valve implantation (TA-AVI) has been shown to be a reproducible technique. Early results from the SAPIEN Aortic Bioprosthesis European Outcome (SOURCE) Registry identified major access complications associated with high 30-day mortality. Using the SOURCE Registry, we analyze the learning curve for TA-AVI over the first 2 years after commercialization. The SOURCE Registry gathered data for 2 consecutive years at European centers following commercialization of the Edwards SAPIEN bioprosthesis, totaling 2339 patients (1038 in COHORT 1 and 1301 in COHORT 2). Only data from centers that provided all of their consecutively treated patients were included in this study. We compared the 30-day results of TA-AVI from COHORT 1 (C-1: January/2008-January/2009) with the 30-day results of COHORT 2 (C-2: February/2009-January/2010). This analysis is based on a total number of 575 TA-AVIs in C-1 and 819 TA-AVIs in C-2. Mean age (C-1: 80.7 years, C-2: 80.5 years) and logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE) (C-1: 29.1%, C-2 27.3%) were not significantly different. Valve malposition (C-1: 1.6%, C-2: 1.2%), valve migration/embolization (C-1: 0.5%, C-2: 1.0%), and major access complications (C-1: 2.1%, C-2: 1.8%) were in total less frequent, but not statistically significant lower in C-2. However, the reduction of aortic
regurgitation $>2^+$ immediately following the procedure (C-1: 4.52%, C-2: 2.1%, \(p=0.011\)) and conversion rate to open surgery (C-1: 3.7%, C-2: 1.5%, \(p=0.0315\)) reached statistical significance. Postoperative complications included dialysis (C-1: 7.0%, C-2: 5.7%, \(p=\text{ns}\)), pacemaker implantation (C-2: 7.7%, C-2: 6.7%, \(p=\text{ns}\)), stroke (C-1: 2.4%, C-2: 2.6%, \(p=\text{ns}\)), and myocardial infarct (C-1: 0.7%, C-2: 0.4%, \(p=\text{ns}\)). The total 30-day mortality was 10.8% and not significantly different between the two groups (C-1: 10.8%, C-2: 10.7%, \(p=\text{ns}\)). Although the incidence of technical intra procedural complications has trended downward, reflecting the learning curve for TA-AVI, 30-day mortality was unchanged, likely due to patient co-morbidities not captured by preoperative risk variables.