
Abstract:
Transcatheter aortic valve implantation was developed to provide a therapeutic option for patients considered to be ineligible for, and to mitigate mortality and morbidity associated with, high-risk surgical aortic valve replacement. The Edwards SAPIEN Aortic Bioprosthesis European Outcome (SOURCE) Registry was designed to assess initial post commercial clinical transcatheter aortic valve implantation results of the Edwards SAPIEN valve in consecutive patients in Europe. Cohort 1 consists of 1038 patients enrolled at 32 centers. One-year outcomes are presented. Patients with the transapical approach (n=575) suffered more comorbidities than transfemoral patients (n=463) with a significantly higher logistic EuroSCORE (29% versus 25.8%; P=0.007). These groups are different; therefore, outcomes cannot be directly compared. Total Kaplan Meier 1-year survival was 76.1% overall, 72.1% for transapical and 81.1% for transfemoral patients, and 73.5% of surviving patients were in New York Heart Association (NYHA) class I or II at 1 year. Combined transapical and transfemoral causes of death were cardiac in 25.1%, noncardiac in 49.2%, and unknown in 25.7%. Pulmonary complications (23.9%),
renal failure (12.5%), cancer (11.4%), and stroke (10.2%) were the most frequent noncardiac causes of death. Multivariable analysis identified logistic EuroSCORE, renal disease, liver disease, and smoking as variables with the highest hazard ratios for 1-year mortality whereas carotid artery stenosis, hyperlipidemia, and hypertension were associated with lower mortality. The SOURCE Registry is the largest consecutively enrolled registry for transcatheter aortic valve implantation procedures. It demonstrates that with new transcatheter aortic techniques excellent 1-year survival in high-risk and inoperable patients is achievable and provides a benchmark against which future transcatheter aortic valve implantation cohorts and devices can be measured.

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