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# 1-Year Outcomes After Transfemoral Transcatheter or Surgical Aortic Valve Replacement

## Results From the Italian OBSERVANT Study

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## ABSTRACT

**BACKGROUND** There is a paucity of prospective and controlled data on the comparative effectiveness of transcatheter aortic valve replacement (TAVR) versus surgical aortic valve replacement (SAVR) in a real-world setting.

**OBJECTIVES** This analysis aims to describe 1-year clinical outcomes of a large series of propensity-matched patients who underwent SAVR and transfemoral TAVR.

**METHODS** The OBSERVANT (Observational Study of Effectiveness of SAVR-TAVI Procedures for Severe Aortic Stenosis Treatment) trial is an observational prospective multicenter cohort study that enrolled patients with aortic stenosis (AS) who underwent SAVR or TAVR. The propensity score method was applied to select 2 groups with similar baseline characteristics. All outcomes were adjudicated through a linkage with administrative databases. The primary endpoints of this analysis were death from any cause and major adverse cardiac and cerebrovascular events (MACCE) at 1 year.

**RESULTS** The unadjusted enrolled population (N = 7,618) included 5,707 SAVR patients and 1,911 TAVR patients. The matched population had a total of 1,300 patients (650 per group). The propensity score method generated a low-intermediate risk population (mean logistic EuroSCORE 1: 10.2 ± 9.2% vs. 9.5 ± 7.1%, SAVR vs. transfemoral TAVR; p = 0.104). At 1 year, the rate of death from any cause was 13.6% in the surgical group and 13.8% in the transcatheter group (hazard ratio [HR]: 0.99; 95% confidence interval [CI]: 0.72 to 1.35; p = 0.936). Similarly, there were no significant differences in the rates of MACCE, which were 17.6% in the surgical group and 18.2% in the transcatheter group (HR: 1.03; 95% CI: 0.78 to 1.36; p = 0.831). The cumulative incidence of cerebrovascular events, and rehospitalization due to cardiac reasons and acute heart failure was similar in both groups at 1 year.

**CONCLUSIONS** The results suggest that SAVR and transfemoral TAVR have comparable mortality, MACCE, and rates of rehospitalization due to cardiac reasons at 1 year. These data need to be confirmed in longer term and dedicated ongoing randomized trials. (J Am Coll Cardiol 2015;66:804–12) © 2015 by the American College of Cardiology Foundation.

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Severe aortic stenosis (AS) is common; it affects 2% to 4% of adults >75 years of age (1). Although surgical aortic valve replacement (SAVR) is an effective therapy for this condition, operative mortality and morbidity can be significant, particularly in the elderly. Paradoxically, this means that the operation can often be prohibitive, and therefore, inadvisable in the population with the highest prevalence of aortic valve disease. The introduction of transcatheter aortic valve replacement (TAVR) offers an effective and less invasive alternative to SAVR in this extremely complex population. In 2007, Conformité Européenne mark approval was granted to both the Edwards SAPIEN (Edwards Lifesciences, Irvine, California) and Medtronic CoreValve (Medtronic, Minneapolis, Minnesota) prostheses; approval since then has been extended to many more transcatheter valves. There now exists a considerable body of clinical, quality-of-life, and economic evidence from registries and from 2 randomized trials supporting a role for TAVR as an alternative to open surgery in high-risk patients with severe AS (2–7). Reflecting this evidence, current guidelines recommend performing TAVR in patients who are considered inoperable or who are at high risk for SAVR (8).

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Recent observations suggest that European centers adopting TAVR are selecting patients at lower surgical risk than recommended by current international guidelines (8,9). Nevertheless, there is still a paucity of prospective and controlled data that report on the comparative effectiveness of TAVR versus SAVR in a real-world setting (10–13).

The OBSERVANT (Observational Study of Effectiveness of SAVR-TAVI Procedures for Severe Aortic Stenosis Treatment) trial is an Italian observational outcome study for the comparative effectiveness of SAVR-TAVR procedures for the treatment of severe AS. Preliminary data that showed 30-day outcomes from the OBSERVANT study on 266 matched patients were previously reported (10). The present analysis aims to describe 1-year clinical outcomes of a large series of propensity-matched patients from a real-world setting who underwent transfemoral TAVR and SAVR.

## METHODS

**STUDY DESIGN AND PATIENT POPULATION.** Patient eligibility criteria, study design and data collection modalities have been previously described (10). Briefly, OBSERVANT was a national observational, prospective, multicenter cohort study that enrolled consecutive AS patients who underwent TAVR or SAVR at 93 Italian centers (34 hemodynamic centers and 59 cardiac surgery centers) between December 2010 and June 2012, and was run by the Italian National Health Institution in cooperation with the Italian Ministry of Health, the National Agency for Regional Health Services, Italian Regions, and Italian scientific societies and federations representing Italian professionals involved in the management of AS. Hospitals invited to participate were those where a procedural (SAVR and/or TAVR) treatment could be offered to AS patients (Online Appendix for the complete list of executive working group members, participating centers, and investigators).

**ABBREVIATIONS AND ACRONYMS**

**AS** = aortic stenosis

**CABG** = coronary artery bypass grafting

**MACCE** = major adverse cardiac and cerebrovascular event(s)

**PPM** = permanent pacemaker

**RCT** = randomized controlled trial(s)

**SAVR** = surgical aortic valve replacement

**TAVR** = transcatheter aortic valve replacement

The study protocol complies with the Declaration of Helsinki and has been approved by the Local Ethics Committee (ASL 2 Melegnano) of the coordinating Institution (Policlinico San Donato). All patients gave an informed consent to the scientific treatment of their data on an anonymous form.

For the purposes of the present analysis, patients who underwent an associated procedure or a transaortic and/or transapical TAVR and patients who reported having a porcelain aorta, hostile thorax, and those who underwent combined coronary artery bypass grafting (CABG) or percutaneous coronary intervention were excluded.

**ENDPOINTS AND FOLLOW-UP.** The primary endpoints of this analysis were death from any cause, and major adverse cardiac and cerebrovascular events (MACCE) at 1 year. MACCE were defined as the composite of death from any cause, stroke, myocardial infarction, percutaneous coronary intervention and CABG. Pre-specified secondary endpoints included cerebrovascular accidents, acute myocardial infarction, repeat hospitalization due to cardiac reasons, and acute heart failure.

The incidence of some selected periprocedural complications (acute kidney injury, vascular complications, high-degree conduction disturbances requiring permanent pacemaker [PPM] implantation, and requirement for blood transfusions) was also considered. Echocardiographic criteria post-procedure (prosthesis performance and paravalvular regurgitation) were defined according to the Valve Academic Research Consortium definitions (14). The endpoint definitions are reported in the Online Appendix.

An administrative follow-up has been set up for each enrolled patient through a record linkage with the National Hospital Discharged Records (HDR) database (for in-hospital events) and with the Tax Registry Information System (TRIS) (for information