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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

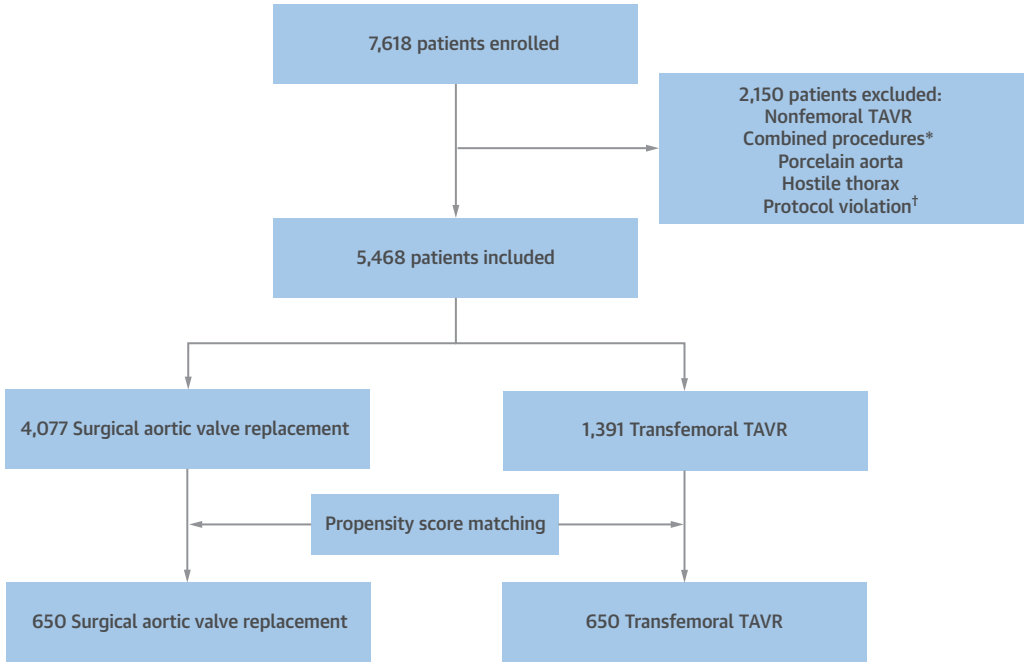
on life status). This approach guarantees a very low percentage of patients lost to follow-up.

DATA QUALITY ASSESSMENT. Specific quality assessment activities have been arranged to evaluate the reliability of the OBSERVANT database. In particular, independent observers, following specific standard operating procedures, monitored the participating hospitals to assess the completeness of the enrolled cohort and to compare the collected data to those reported in the original clinical charts.

STATISTICAL ANALYSIS. The data are shown stratified by procedure (SAVR and/or transfemoral TAVR). Continuous variables are presented as mean ± SD, and are compared using Student *t* test for the descriptive analysis. Categorical variables are presented as counts and percentages, and are compared with the chi-square test or Fisher exact test, as appropriate.

Because observational studies do not provide randomization, the propensity score method was applied to select 2 groups of patients who underwent SAVR and TAVR, respectively, and who had similar baseline characteristics. The propensity score was developed using logistic regression (15). Adopting a nonparsimonious approach, all measured potential confounders were used in the regression procedure. The propensity score includes the following variables: age; sex; previous percutaneous coronary intervention; previous balloon aortic valvuloplasty; previous cardiac surgery; diabetes; chronic obstructive pulmonary disease; smoking; previous myocardial infarction; peripheral arteriopathy; creatinine; critical preoperative state; unstable angina; neurological dysfunction; pulmonary hypertension (systolic pulmonary arterial pressure >60 mm Hg); chronic liver disease; active neoplastic disease; New York Heart Association functional class; frailty score [Geriatric Status Scale (16)]; left ventricular ejection fraction; coronary artery disease; urgency status; and mitral regurgitation. Pairs of TAVR and SAVR patients with the same probability score (nearest neighbor method; caliper = 0.2 × SD[logitPs]) were matched. To evaluate the balance between the matched groups, the following tests were used: Student *t* test for paired sample for continuous variables; the McNeimar test for dichotomous variables; and the Stuart-Maxwell test for categorical variables. Standardized differences of baseline variables before and after matching are shown in Online Figure 1. SAVR and TAVR periprocedural outcomes in the subgroup of the matched patients were compared using the same statistical tests.

FIGURE 1 Patient Flowchart



*Concomitant surgical and/or percutaneous revascularization and intervention on other valves. †Centers in which the monitoring process reported the nonconsecutiveness of the enrollment. TAVR = transcatheter aortic valve replacement.

With regard to long-term outcomes, hazard ratios (HRs) for death from any cause, MACCE at 1 year, and time-to-event curves were calculated using Cox proportional hazard models, taking into account pairing of data.

Problems related to the linkage keys resulted in 25 pairs of TAVR and SAVR patients who were not linked with the administrative databases and were definitively lost to follow-up. Nevertheless, for the survival analysis, they were considered censored at the time of discharge after being hospitalized for the procedure.

Cumulative incidence functions of stroke, acute myocardial infarction, repeat hospitalization for acute heart failure, and repeat hospitalization for cardiac reasons were estimated using a competing-risks regression by the method of Fine and Gray. This method uses a semiparametric regression for survival data in the presence of competing risks, positing a model for the subhazard function of a failure event of primary interest. In these analyses, death was considered a competing event because patients under observation might have died, making it impossible for the event of interest to occur. This competing-risks regression was carried out by the Stata statistical package (StataCorp, College Station, Texas) with the stcrreg procedure. All statistical analyses were performed using the Stata statistical package (version 13, StataCorp).

TABLE 1 Baseline Clinical Characteristics After PS Matching

	SAVR (n = 650)	TAVR (n = 650)	p Value
Age, yrs	80.3 ± 5.1	80.5 ± 6.2	0.323
Female	387 (59.5)	383 (58.9)	0.822
Smoking history	71 (11.5)	62 (10.1)	0.417
BMI, kg/m^2	26.9 ± 4.5	26.5 ± 4.8	0.095
Diabetes mellitus	165 (25.4)	161 (24.8)	0.798
Creatinine, mg/dl	1.2 ± 0.8	1.2 ± 0.7	0.823
Long-term dialysis treatment	3 (0.5)	9 (1.4)	0.083
Albumin, mg/dl	3.7 ± 0.9	3.5 ± 0.8	0.006
Hemoglobin, mg/dl	12.3 ± 1.6	11.7 ± 1.7	<0.001
Previous AMI	75 (11.5)	72 (11.1)	0.795
Unstable angina	18 (2.8)	21 (3.2)	0.622
COPD	141 (21.7)	154 (22.3)	0.790
Oxygen dependency	11 (1.7)	36 (5.6)	0.001
Neurologic dysfunction*	37 (5.7)	38 (5.8)	0.904
Chronic liver disease†	23 (3.5)	19 (2.9)	0.527
Active neoplastic disease	16 (2.5)	17 (2.6)	0.853
Peripheral arteriopathy	126 (19.4)	124 (19.1)	0.886
Pulmonary hypertension	88 (14.6)	88 (14.6)	1.000
Previous cardiac surgery	65 (10.0)	62 (9.5)	0.778
Previous vascular surgery	18 (2.8)	22 (3.4)	0.527
Frailty score, moderate-severe	88 (13.5)	85 (13.1)	0.801
Previous PCI	85 (13.1)	94 (14.5)	0.455
Previous BAV	15 (2.3)	24 (3.7)	0.128
Critical preoperative state	24 (3.7)	17 (2.6)	0.274
NYHA functional class III	318 (48.9)	324 (49.8)	0.790
NYHA functional class IV	70 (10.8)	61 (9.4)	
Logistic EuroSCORE 1, %	10.2 ± 9.2	9.5 ± 7.1	0.104
Logistic EuroSCORE 2, %	5.1 ± 6.2	4.9 ± 5.1	0.485

Values are mean ± SD or n (%). *Any previous neurological event (cerebrovascular accident or transient ischemic attack). †Child-Pugh classes B and C.

AMI = acute myocardial infarction; BAV = balloon aortic valvuloplasty; BMI = body mass index; COPD = chronic obstructive pulmonary disease; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; PS = propensity score; SAVR = surgical aortic valve replacement; TAVR = transcatheter aortic valve replacement.

RESULTS

BASELINE CHARACTERISTICS AND PROCEDURAL DATA OF THE PRE-MATCHING POPULATION. A total of 7,618 consecutive patients with severe AS who underwent SAVR (n = 5,707) or TAVR (n = 1,911) were enrolled in the OBSERVANT study. In TAVR patients, transfemoral access was used in 1,564 (81.8%), transapical access in 259 (13.6%), trans-subclavian access in 73 (3.8%), and direct aortic access in 15 (0.8%). Patients excluded from the present analysis are listed in the patient flowchart in Figure 1. A total of 5,468 patients (4,077 SAVR and 1,391 transfemoral TAVR) formed the pre-matching population, and their baseline demographic and clinical characteristics are listed in Online Table 1. The mean logistic EuroSCORE 1 was 4.9 ± 5.5% and 13.6 ± 11.4% in the SAVR and TAVR groups, respectively ($p < 0.001$) (Online Figure 2). The mean logistic EuroSCORE 2 was 2.5 ± 3.4% in the SAVR group and 6.8 ± 7.2% in the TAVR group ($p < 0.001$). Echocardiographic findings before intervention of the pre-matching population are listed in Online Table 2. All TAVR procedures were performed using the third-generation, self-expanding CoreValve ReValving System (Medtronic Inc.) (N = 839; 60.4%) or the balloon-expandable Edwards SAPIEN XT (Edwards Lifescience) (N = 549; 39.6%) under local anesthesia (with or without additional sedation and/or analgesia) or general anesthesia and endotracheal intubation, under fluoroscopic guidance and transesophageal echocardiography, according to individual institutional practice, in a standard cardiac catheterization laboratory or hybrid room, with surgical backup. The choice of SAVR technique and type of prosthesis used were left to the cardiac surgeon's discretion and individual institutional practice.

PROPENSITY-MATCHED GROUPS. Patient population. From the entire cohort, 650 pairs of patients who underwent SAVR and transfemoral TAVR with similar baseline demographic and clinical characteristics were obtained using the propensity score method

(Tables 1 and 2). All computed post-match standardized differences were <0.10 (Online Figure 1).

The use of the propensity score method generated a matched population with a mean logistic EuroSCORE 1 of 9.8 ± 8.3%, with scores of 10.2 ± 9.2% for the SAVR group versus 9.5 ± 7.1% for the TAVR group (p = 0.104). The mean logistic EuroSCORE 2 was 5.1 ± 6.2% for the SAVR group and 4.9 ± 5.1% for the TAVR group (p = 0.485). The procedure was performed in an emergency setting in 4.0% of SAVR patients and 3.1% of TAVR patients (p = 0.339). In the TAVR group, CoreValves or Edwards SAPIEN XT valves were implanted in 358 (55.1%) and 274 (44.9%) patients, respectively. SAVR patients had more prolonged hospitalization compared with TAVR patients (12.6 ± 13.4 days vs. 8.8 ± 8.5 days; p < 0.001).

Acute echocardiographic outcomes. TAVR yielded a slightly lower mean post-procedural aortic valve gradient than SAVR (13.6 ± 6.7 mm Hg vs. 10.3 ± 5.6 mm Hg, respectively; p < 0.001). However, TAVR was associated with a higher incidence of paravalvular regurgitation, with a higher rate of aortic regurgitation (grade ≥2) compared with SAVR (2.0% for SAVR vs. 9.8% for TAVR; p < 0.001).

Clinical outcomes. In the matched population, in-hospital mortality during the index admission was 3.4% in SAVR patients and 2.0% in TAVR patients (p = 0.423). Twenty-four SAVR patients (3.8%) and 20 TAVR patients (3.2%) died at 30 days (p = 0.546). Major periprocedural adverse events, including acute renal failure (10.9% vs. 6.1%; p = 0.004) and a higher requirement for blood transfusion (3.6 ± 3.6 red blood cells units vs. 2.3 ± 2.2 red blood cells units; p = 0.002) were more frequently reported in the SAVR group, whereas major access site complications (0.5% vs. 7.9%; p < 0.001) and a high-degree atrioventricular block that required PPM implantation (3.6% vs. 15.5%; p < 0.001) were higher in the TAVR group. There were no differences with respect to cerebrovascular accidents (2.2% vs. 1.3%; p = 0.180), acute myocardial infarction (0.8% vs. 0.5%; p = 0.479), and cardiac tamponade (3.9% vs. 4.1%; p = 0.886) between the 2 groups (Table 3).

At 1 year, the rate of death from any cause was 13.8% in the transcatheter group compared with 13.6% in the surgical group (HR: 0.99; 95% confidence interval [CI]: 0.72 to 1.35; p = 0.936) (Central Illustration, panel A). Similarly, there were no significant differences in the rates of MACCE, which were 17.6% in the surgical group compared with 18.2% in the transcatheter group (HR: 1.03; 95% CI: 0.78 to 1.36; p = 0.831) (Central Illustration, panel B). The cumulative 1-year incidence of cerebrovascular events, acute myocardial infarction, and rehospitalization due to cardiac reasons and acute heart failure, as assessed by the competing risk regression approach, was similar in both groups (Table 4, Figure 2), whereas the PPM implantation rate was remarkably higher in the TAVR group (Table 4).

DISCUSSION

The principal findings of this study of a propensity-matched population was that transfemoral TAVR was comparable to surgical replacement with respect to 1-year rates of death from any cause, MACCE, and repeat hospitalization due to cardiac reasons.

TABLE 2 Echocardiographic Characteristics After PS Matching

	SAVR (n = 650)	TAVR (n = 650)	p Value
Left ventricular ejection fraction, %	54.2 ± 11.2	53.6 ± 11.4	0.349
Left ventricular ejection fraction ≤30%	20 (3.1)	16 (2.5)	0.499
Mitral regurgitation			
Mild	367 (56.5)	348 (53.5)	0.753
Moderate	138 (21.2)	143 (22.0)	
Severe	14 (2.2)	16 (2.5)	
Aortic valve pattern			
Aortic valve area, cm^2	0.7 ± 0.2	0.7 ± 0.3	0.097
Peak gradient, mm Hg	82.1 ± 23.9	82.7 ± 22.1	0.655
Mean gradient, mm Hg	51.1 ± 15.9	51.0 ± 14.5	0.918
Annulus diameter, mm	21.3 ± 2.1	22.2 ± 2.2	<0.001

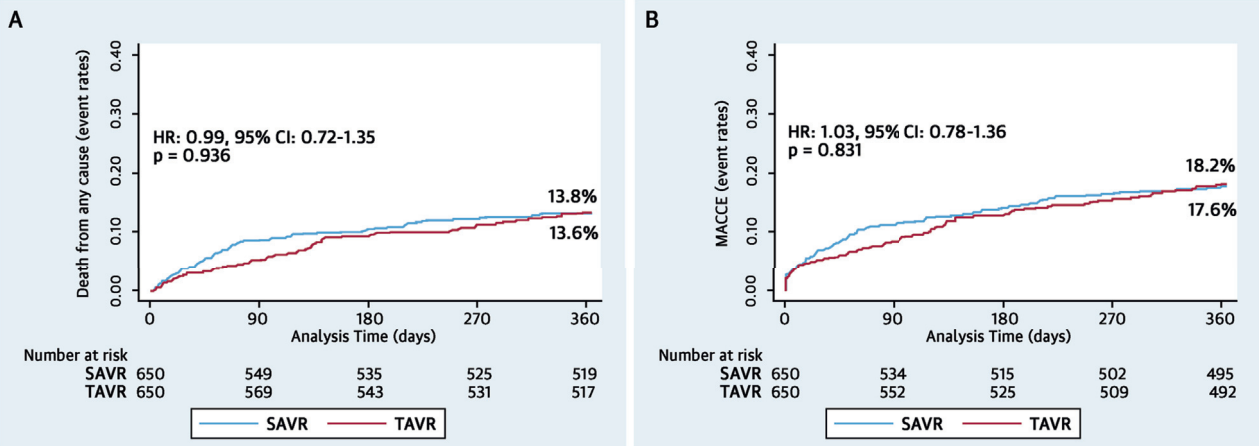
Values are mean ± SD or n (%).
Abbreviations as in Table 1.

TABLE 3 Periprocedural Clinical Outcomes of the Propensity Score-Matched Population

Outcomes	SAVR (n = 650)	TAVR (n = 650)	p Value
Valve migration	–	15 (2.3)	–
Stroke	14 (2.2)	8 (1.3)	0.180
Acute myocardial infarction	5 (0.8)	3 (0.5)	0.479
Renal failure	64 (10.9)	36 (6.1)	0.004
Cardiac tamponade	25 (3.9)	26 (4.1)	0.886
Permanent pacemaker	23 (3.6)	98 (15.5)	<0.001
Major vascular damage	3 (0.5)	48 (7.9)	<0.001
Infection			
Wound	10 (1.6)	6 (1.0)	0.191
Lung or other organs	24 (3.9)	29 (4.7)	
Sepsis	11 (1.8)	4 (0.6)	
Emergency PCI	0 (0.0)	6 (0.9)	–
Transfusions, no. of units	3.6 ± 3.6	2.3 ± 2.2	0.002
Mean gradient after procedure, mm Hg	13.6 ± 6.7	10.3 ± 5.6	<0.001
ICU stay, days	3.8 ± 7.7	3.2 ± 4.7	0.077
Hospital stay, days	12.6 ± 1.3	8.8 ± 8.5	<0.001
30-day mortality	24 (3.8)	20 (3.2)	0.546

Values are n (%) or mean ± SD.
ICU = intensive care unit; other abbreviations as in Table 1.

CENTRAL ILLUSTRATION **TAVR Versus SAVR: Time-to-Event Curves for the Primary Endpoints**



Tamburino, C. et al. J Am Coll Cardiol. 2015; 66(7):804–12.

Time-to-event curves are shown for **(A)** death from any cause and **(B)** MACCE. The event rates were calculated using Kaplan-Meier methods and compared by the log-rank test. CI = confidence interval; HR = hazard ratio; MACCE = major adverse cardiac and cerebrovascular event(s); SAVR = surgical aortic valve replacement; TAVR = transcatheter aortic valve replacement.

Despite the availability of head-to-head comparisons between TAVR and SAVR in randomized clinical studies, this observational study represents a useful support for the comparative effectiveness of these strategies in a real-world setting, generating results that are likely to be more generalizable than those from randomized controlled trials (16).

TABLE 4 **Clinical Outcomes of the Propensity Score-Matched Population at 1 Year**

Outcomes	SAVR (n = 650)	TAVR (n = 650)	p Value
Death from any cause*	82 (13.6)	83 (13.8)	0.912
Stroke†	29 (4.9)	37 (6.4)	0.243
Acute myocardial Infarction†	18 (3.8)	15 (3.1)	0.442
PCI†	3 (0.6)	10 (1.7)	0.055
CABG†	0 (0.0)	0 (0.0)	1.000
MACCE*‡	107 (17.6)	110 (18.2)	0.796
Repeat hospitalization for cardiac reasons†	134 (23.6)	127 (21.9)	0.473
Repeat hospitalization for acute heart failure†	112 (19.7)	110 (19.0)	0.722
Permanent pacemaker†	43 (7.3)	114 (18.5)	<0.001

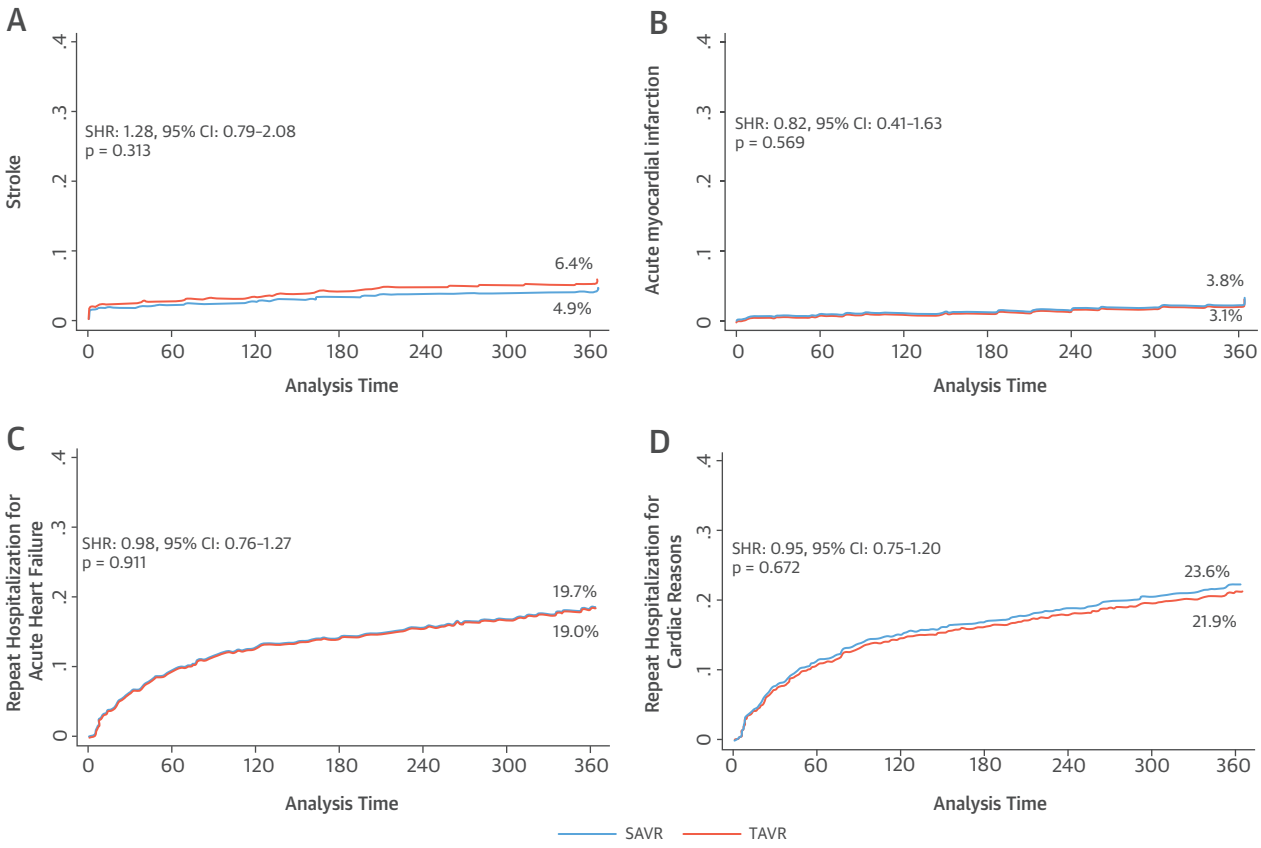
Values are n (%). *Data are reported as Kaplan-Meier estimates at the specific time point and do not equal the number of patients with events divided by the total number of patients in each treatment group. †Data are reported as competitive risk estimates at the specific time point and do not equal the number of patients with events divided by the total number of patients in each treatment group. ‡MACCE were defined as the composite of death from any cause, stroke, acute myocardial infarction, PCI, and CABG.

CABG = coronary artery bypass graft; MACCE = major adverse cardiac and cardiovascular events; other abbreviations as in Table 1.

In this study, the baseline characteristics of the transcatheter group characterize a population with a lower risk profile than those usually undergoing such a procedure (2-7). This observation might suggest that TAVR is increasingly offered not only to inoperable or high-risk patients, as recommended by clinical practice guidelines, but also to those with few or relative contraindications to surgery. If so, in view of the excellent short- and long-term results of SAVR in low-risk patients and the lack of evidence on very long-term durability of TAVR, this should be a worrying trend. However, risk stratification of patients treated with TAVR and enrolled in OBSERVANT was on the basis of the clinical judgment of local heart teams, rather than according to specific criteria, such as surgical risk score. Both versions of the EuroSCORE alone did not account for clinical characteristics that might have increased the level of patient risk perceived by the local heart teams, such as frailty, difficult anatomy, or comorbidities not captured by these 2 pre-procedural risk scores (e.g., end-stage liver diseases and autoimmune disorders).

The death rates from any cause at 30 days and at 1 year in our propensity-matched population were similar in the transfemoral TAVR and SAVR groups. Our results are in line with those reported in the PARTNER (Placement of Aortic Transcatheter Valve Trial) Cohort A trial in a high-risk population (3), whereas they differ from those reported by

FIGURE 2 Time-to-Event Curves for the Other Major Outcomes



(A) Cumulative incidence of stroke, **(B)** acute myocardial infarction, **(C)** repeat hospitalization for acute heart failure, and **(D)** repeat hospitalization for cardiac reasons. The event rates were calculated using a competing-risks regression and considering death as competing event. CI = confidence interval; SHR = subdistribution hazard ratio.

the CoreValve U.S. trial (4), in which survival at 1 year after TAVR was superior to that after SAVR (Online Figure 3). Putting the results of OBSERVANT into the perspective of these 2 RCTs, which compared SAVR versus TAVR, the following should be considered. The rate of 1-year death from any cause after isolated SAVR decreased consistently with the reduction of the logistic EuroSCORE in these 3 studies, which suggested that mortality after SAVR was predominantly affected by the coexisting comorbidities of the patients, rather than the procedure itself. However, although 1-year mortality after TAVR reported in OBSERVANT was remarkably lower than that reported in PARTNER A, because of the result of the reduced patient risk profiles and the integration of newer generation devices, mortality at 1 year was similar in the TAVR cohorts of the OBSERVANT and the U.S. CoreValve studies (13.1% vs. 14.2%, respectively), despite the large difference in risk profiles between these 2 populations (mean logistic EuroSCORE: 17.6% vs. 9.5%). A possible explanation was that a non-negligible proportion of both early and late deaths after TAVR might be attributable to procedure-related sequelae (i.e., vascular complications, paravalvular regurgitation), thus suggesting that a learning curve effect and improved patient selection for TAVR might have played an important role in determining this result.

Major procedure-related complications rates, such as neurological events and myocardial infarction, were similar in the transcatheter and surgical groups at 1 year. Compared with PARTNER A, we reported a lower incidence of stroke in the TAVR group, which was consistent with data from other recent TAVR registries (17). This might be related to the use of first-generation devices, which were characterized by higher diameter and minor flexibility in the PARTNER trial.

Finally, rehospitalization rates due to cardiac reasons and acute heart failure were similar in the surgical

and the transcatheter groups. These data could suggest substantial equipoise in terms of cost-effectiveness of the 2 procedures in the low- to intermediate-risk cohort, although more focused studies are warranted before definitive conclusions can be drawn.

STUDY LIMITATIONS. The present study had some strengths and limitations. First, evaluating the impact of a specific treatment using an observational study could lead to weaker conclusions than using an RCT because treatment was not randomly assigned and because of potential residual confounding. However, it has been argued that a well-conducted observational cohort study could provide the same level of internal validity as RCTs (18). Moreover, observational studies are carried out on real-world populations, and therefore, could reach higher levels of external validity compared with RCTs. In this analysis, to partly compensate for the baseline imbalance between groups, we applied a propensity approach that represented a widely used method for analyzing observational data (15). The high percentage of TAVR matched with SAVR procedures (47%) represented an excellent result for studies using this methodology. Nevertheless, residual confounding due to unrecorded risk factors could not be excluded. A specific strength of this study was the use of an administrative follow-up, which guaranteed an extremely low percentage of patients lost to follow-up, the independence of outcome observations, and the possibility of very long-term follow-up analyses in terms of survival, rehospitalizations, and costs related to patient management. Second, the TAVR intermediate-risk group was retrospectively selected using propensity matching with the SAVR group, with no prespecified threshold for patient inclusion. Third, Valve Academic Research Consortium criteria (14) were not used in this study. These definitions are specifically designed to define complications after TAVR; therefore, they might be misleading and were likely to result in overestimation of complications after SAVR. Fourth, the lack of a core laboratory to centrally assess echocardiographic parameters was another important limitation of this study. Finally, this analysis referred only to patients who underwent isolated SAVR and transfemoral TAVR. Whether these results could be applied in patients undergoing concomitant CABG and/or percutaneous coronary intervention or transapical and transaortic TAVR remains unknown.

CONCLUSIONS

The results of this study on a large propensity-matched cohort of real-world patients with severe AS and at low or intermediate surgical risk suggest that SAVR and transfemoral TAVR have comparable rates of mortality, MACCE, and rehospitalization due to cardiac reasons at 1 year. These data need to be confirmed in longer term and dedicated ongoing randomized trials (SURTAVI [Safety and Efficacy Study of the Medtronic CoreValve System in the Treatment of Severe, Symptomatic Aortic Stenosis in Intermediate Risk Subjects Who Need Aortic Valve Replacement] and PARTNER 2).

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PERSPECTIVES

COMPETENCY IN PATIENT CARE: For patients with AS at low or intermediate surgical risk on the basis of logistic EuroSCORE assessment, rates of all-cause mortality, major adverse cardiovascular events, and hospitalization for cardiac conditions at 1 year were similar in those who underwent TAVR versus SAVR.

TRANSLATIONAL OUTLOOK: Further studies are needed to identify patient characteristics other than high surgical risk scores that are associated with better long-term outcomes with TAVR than SAVR.

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KEY WORDS aortic stenosis, implantation, intermediate risk, transcatheter aortic valve

APPENDIX For a member list of the OBSERVANT research group, a list of endpoint definitions, and supplemental tables and figures, please see the online version of this article.