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STRUCTURAL

"One-Stop Shop"

Safety of Combining Transcatheter Aortic Valve Replacement and Left Atrial Appendage Occlusion

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ABSTRACT

OBJECTIVES The aim of this study was to investigate the safety and efficacy of combining transcatheter valve replacement (TAVR) and left atrial appendage occlusion (LAAO) versus TAVR alone.

BACKGROUND Patients with severe aortic stenosis and atrial fibrillation undergoing TAVR are at increased risk for stroke and bleeding complications.

METHODS A cohort of 52 patients undergoing concomitant TAVR and LAAO were compared with 52 patients undergoing isolated TAVR. A primary safety endpoint at 30 days, a clinical efficacy endpoint from day 30 to last follow-up, and an LAAO efficacy endpoint from the first post-interventional day to the last follow-up were chosen.

RESULTS The mean age of the study population was 85 ± 5 years. The mean CHA_2DS_2-VASc score and HAS-BLED score were 3.9 ± 1.1 and 2.6 ± 0.9, respectively. The mean Society of Thoracic Surgeons score was 7.8 ± 5.5. The median follow-up duration of the study population was 9.4 months (range 0 to 48 months). The primary safety endpoint occurred in 10 patients in the concomitant group and in 7 patients in the isolated TAVR group (19% vs. 14%; 95% confidence interval: 0.59 to 4.06). The clinical and LAAO efficacy endpoints were achieved in 81 (79%) (75% vs. 82%; 95% confidence interval: 0.49 to 2.92) and 75 (73%) patients (69% vs. 76%; 95% confidence interval: 0.54 to 2.51), respectively.

CONCLUSIONS This pilot study shows that concomitant TAVR and LAAO is feasible and seems to be safe among patients with severe aortic stenosis and atrial fibrillation. Larger trials and longer follow-up are needed to confirm the safety and efficacy of such an approach. (J Am Coll Cardiol Intv 2016;9:1487–95) © 2016 by the American College of Cardiology Foundation.

Over the past decade, transcatheter aortic valve replacement (TAVR) has emerged as the preferred treatment modality for patients with severe aortic stenosis at high surgical risk and is now expanding to lower risk patients (1-3). Atrial fibrillation (AF) occurs in more than 10% of octogenarians and is the most common arrhythmia in the TAVR population. It is associated

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ABBREVIATIONS AND ACRONYMS

ACP = Amplatzer Cardiac Plug
AF = atrial fibrillation
CI = confidence interval
LAA = left atrial appendage
LAAO = left atrial appendage occlusion
OAC = oral anticoagulation
STS = Society of Thoracic Surgeons
TAVR = transcatheter aortic valve replacement
TEE = transesophageal echocardiography
TIA = transient ischemic attack

with substantial morbidity and mortality, particularly due to early and late embolic stroke (4-7), bleeding complications (8), and impaired overall outcomes (7,8).

SEE PAGE 1496

To prevent thromboembolic strokes in patients with AF, oral anticoagulation (OAC) is the standard treatment for patients with CHA_2DS_2-VASc scores of ≥1 (9). However, OAC carries a substantial risk for major bleeding complications (10). The combination of OAC with antiplatelet agents after TAVR potentiates the risk for major bleeding complications (11). In patients with AF undergoing TAVR, bleeding complications were reported to be as high as 50%, and in those who experience bleeding complications during the first year, 1-year mortality is doubled (8). Therefore, the increased risk for serious bleeding precludes the use of OAC in a significant proportion (30% to 50%) of eligible patients because of relative or absolute contraindications or physician or patient preference (12).

Balancing the risk for embolic and bleeding events in this high-risk population represents a major clinical challenge. Left atrial appendage occlusion (LAAO) offers nonpharmacological stroke protection, obviating the need for OAC. It may therefore be an attractive treatment for the AF TAVR population (13,14) (**Figure 1**).

We investigated the safety and short-term efficacy of combined procedures (TAVR and LAAO) versus TAVR alone in a contemporary TAVR population with AF.

METHODS

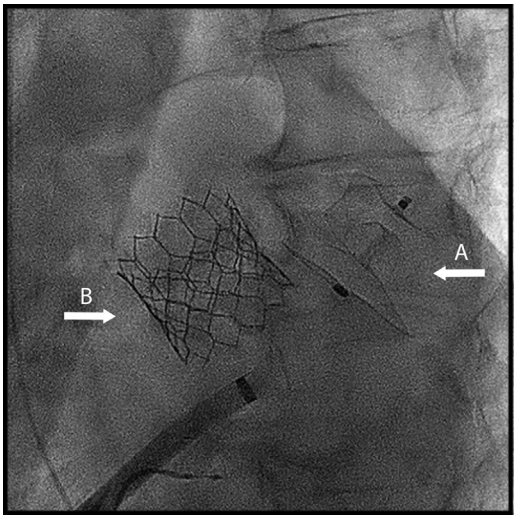
PATIENTS. This was an observational study of consecutive patients undergoing TAVR at the university hospitals of Zurich (463 patients) and Bern (707 patients) from February 2011 to June 2015. The decision of whether to perform concomitant LAAO was random, on the basis of patients' wishes and operators' and treating cardiologists' preferences. All patients had severe aortic stenosis (mean transaortic systolic pressure gradient of ≥40 mm Hg or aortic valve area of <1.0 cm^2 or <0.6 cm^2/m^2) and were deemed appropriate candidates for TAVR as assessed by the local heart team. All patients had AF with CHA_2DS_2-VASc scores of ≥1. Patients were dichotomized into a "concomitant group" (TAVR and LAAO during the same procedure) and an "isolated TAVR group" (TAVR alone and medical therapy for stroke prevention). All patients gave written informed consent for the procedure and data collection. Patients were followed within the nationwide Swiss TAVR registry, which was approved by the local ethics committees.

DEVICE. The Amplatzer Cardiac Plug (ACP) (St. Jude Medical, Plymouth, Minnesota) is made of nitinol mesh and filled by polyester to enhance endothelialization and to prevent blood flow through the device. The ACP consists of a lobe with tiny anchoring hooks and a sealing disc. The lobe and disc are connected by a thin, stretchable waist. The ACP is available in lobe sizes from 16 to 30 mm, requiring a 9- to 13-F TorqVue delivery sheath (St. Jude Medical). The second-generation ACP (Amulet) has a recessed screw on the disc to prevent clot formation. Additionally, the lobe comes in larger size ranges (16 to 34 mm) and requires a 12- or 14-F sheath. The larger sizes also feature more anchoring hooks.

PROCEDURE. TAVR was performed using either a transfemoral procedure or, in case of limiting peripheral arterial disease, transapical, subclavian, or direct aortic access. Balloon-expandable as well as self-expandable valve systems were used. Prosthesis size was selected on the basis of annular measurements by multislice computed tomography or transesophageal echocardiography (TEE).

In patients with concomitant interventions, LAAO was performed during the same sitting, usually after TAVR. Pre-procedural imaging of the left atrial appendage (LAA) comprised TEE in all patients. Procedural guidance, for both TAVR and LAAO, was

FIGURE 1 Fluoroscopic Image of a Combined Procedure



(A) Amulet 25-mm left atrial appendage occluder. **(B)** Edwards SAPIEN 3 26-mm transcatheter heart valve.