Transcatheter Aortic Valve Replacement Results in Improvement of Pulmonary Function in Patients With Severe Aortic Stenosis

Richard C. Gilmore, BA, Vinod H. Thourani, MD, Hanna A. Jensen, MD, PhD, Jose Condado, MD, José Nilo G. Binongo, PhD, Eric L. Sarin, MD, Chandan M. Devireddy, MD, Bradley Leshnower, MD, Kreton Mavromatis, MD, Amjad Syed, MD, Robert A. Guyton, MD, Peter C. Block, MD, Amy Simone, PA, Patricia Keegan, NP, James Stewart, MD, Mohammad Rajaei, MD, Brian Kaebnick, MD, Stamatios Lerakis, MD, and Vasilis C. Babaliaros, MD

Divisions of Cardiothoracic Surgery and Cardiology, Structural Heart and Valve Center, Cardiothoracic Surgery Clinical Research Center, Emory University School of Medicine, Atlanta; and Department of Biostatistics and Bioinformatics, Rollins School of Public Health, Emory University, Atlanta, Georgia

Background. **Chronic obstructive pulmonary disease (COPD) has been identified as a risk factor for morbidity and mortality after transcatheter aortic valve replacement (TAVR). We hypothesized that a portion of pulmonary dysfunction in patients with severe aortic stenosis may be of cardiac origin, and has potential to improve after TAVR.**

Methods. **A retrospective analysis was made of consecutive TAVR patients from April 2008 to October 2014. Of patients who had pulmonary function testing and serum B-type natriuretic peptide data available before and after TAVR, 58 were found to have COPD (26 mild, 14 moderate, and 18 severe). Baseline variables and operative outcomes were explored along with changes in pulmonary function. Multiple regression analyses were performed to adjust for preoperative left ventricular ejection fraction and glomerular filtration rate.**

Results. **Comparison of pulmonary function testing before and after the procedure among all COPD categories showed a 10% improvement in forced vital capacity (95% confidence interval: 4% to 17%) and a 12% improvement in forced expiratory volume in 1 second (95% confidence interval: 6% to 19%). There was a 29% decrease in B-type natriuretic peptide after TAVR (95% confidence interval: −40% to −16%). An improvement of at least one COPD severity category was observed in 27% of patients with mild COPD, 64% of patients with moderate COPD, and 50% of patients with severe COPD. There was no 30-day mortality in any patient group.**

Conclusions. **In patients with severe aortic stenosis, TAVR is associated with a significant improvement of pulmonary function and B-type natriuretic peptide. After TAVR, the reduction in COPD severity was most evident in patients with moderate and severe pulmonary dysfunction.**

(Ann Thorac Surg 2015;100:2167–73)

Chronic obstructive pulmonary disease (COPD) is a common comorbidity in patients with aortic stenosis, with an incidence greater than 20% among patients undergoing transcatheter aortic valve replacement (TAVR) [1–8]. Moreover, patients with pulmonary dysfunction undergoing TAVR tend to have worse outcomes compared with patients not having pulmonary dysfunction [9]. However, evaluation of postprocedure pulmonary function after TAVR has not been well characterized, and the interrelationship of severe aortic stenosis, heart failure, and COPD remains incompletely understood.

We evaluated the impact of TAVR on pulmonary dysfunction and changes in B-type natriuretic peptide (BNP) in an attempt to further characterize this relationship. We speculated that a portion of documented pre-TAVR pulmonary dysfunction may stem from cardiac origin rather than pulmonary disease, and has the potential to improve after intervention for aortic stenosis. That would help redefine patient selection for TAVR, especially in cases where pulmonary dysfunction leads to hesitancy in referrals for treatment.

Accepted for publication June 1, 2015.

Presented at the Poster Session of the Fifty-first Annual Meeting of The Society of Thoracic Surgeons, San Diego, CA, Jan 24–28, 2015.

Address correspondence to Dr Thourani, Emory Hospital Midtown, Medical Office Tower, 6th Flr, 550 Peachtree St NE, Atlanta, GA 30308; e-mail: vthoura@emory.edu.

Dr Devireddy discloses a financial relationship with Medtronic.

0003-4975/$36.00
http://dx.doi.org/10.1016/j.athoracsur.2015.06.008

Abbreviations and Acronyms

BNP = B-type natriuretic peptide
CI = confidence interval
COPD = chronic obstructive pulmonary disease
FEV_1 = forced expiratory volume in 1 second
FVC = forced vital capacity
OR = odds ratio
PFT = pulmonary function testing
TAVR = transcatheter aortic valve replacement

Material and Methods

Patient data were collected by querying the Emory University institutional adult cardiac database of The Society of Thoracic Surgeons (STS) for consecutive patients who underwent TAVR from April 2008 to October 2014. Of these, only patients with recorded pulmonary function tests (PFT) before (as long as 3 months before TAVR) and after the procedure (as long as 1 year after TAVR) were included in the study. Patients were divided according to pre-TAVR COPD category as defined by the STS national cardiac database based on forced expiratory volume in 1 second (FEV_1): none ($FEV_1 > 75\%$ predicted), mild (FEV_1 60% to 75% predicted), moderate (FEV_1 50% to 59% predicted), and severe ($FEV_1 < 50\%$ predicted). Patients with no COPD were excluded from further analysis.

Extracted records from the database included basic demographic information, preexisting comorbidities and other risk factors, and periprocedure and postprocedure clinical outcomes. The study was approved by the Emory University Institutional Review Board in compliance with Health Insurance Portability and Accountability Act regulations and the Declaration of Helsinki. The Institutional Review Board waived individual patient consent owing to the retrospective nature of the study.

Procedural Techniques

All TAVR procedures were performed using a balloon-expandable valve (Edwards Lifesciences, Irvine, CA). The procedure approach was left to the discretion of the attending physicians. Valves were implanted through a retrograde transfemoral, transaortic, or transcarotid approach or in an antegrade transapical fashion. Details of each procedure have been previously described [10].

The Viasys Body Plethysmograph Model 62-J (CareFusion Corp., San Diego, CA) was used to measure forced vital capacity (FVC) and FEV_1. Forced vital capacity is defined as the maximal amount of air that can be exhaled forcefully after a maximal inspiration or the most air a person can blow out after taking the deepest possible breath [11]. Conversely, FEV_1 is the volume of air exhaled during the first second of a forced expiratory maneuver. The CareFusion Vmax Program Manager (CareFusion, San Diego, CA) was used to electronically access and view each PFT.

Variables of Interest

Before analysis, 29 preprocedure risk factors were identified and harvested from the database. Standard STS definitions for each risk factor and outcome were used. Race was dichotomized as Caucasian or non-Caucasian. New York Heart Association heart failure class was dichotomized as class III/IV or I/II. Before and after procedure BNP values were obtained from the electronic medical record.

Primary outcomes examined were post-TAVR FEV_1, FVC, and BNP. Secondary outcomes fell into two categories: (1) periprocedure outcomes including the need for intraaortic balloon counterpulsation, procedural time, second valve implantation, need for balloon dilation, and paravalvular leak at the time of TAVR; and (2) short-term outcomes including total intensive care unit time, postoperative length of stay, postoperative ventilation time, and aortic valve mean gradient at 30 days after surgery.

Statistical Methods

Categoric variables were expressed as counts and proportions; group proportions were compared with the use of the χ^2 test or Fisher's exact test, as appropriate. Continuous variables were summarized using means and standard deviations, and one-way analysis of variance was used to compare group means. For variables that had skewed distributions, the median was also reported, and the variables were log transformed before performing one-way analysis of variance. To adjust for preoperative left ventricular ejection fraction and glomerular filtration rate, multivariable linear (or logistic, as appropriate) regression analyses were performed. A two-sided 5% statistical significance level was used throughout, without adjustments for multiple comparisons. All statistical analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC).

Results

Before and After Procedure Data

Preoperatively, 58 patients were identified as having mild (n = 26, 45%), moderate (n = 14, 24%), or severe (n = 18, 31%) COPD. Patient characteristics for all groups are shown in Table 1. The age ranged from 59 to 95 years (median 79), and 37 (64%) were male. As expected, patients in the moderate and severe COPD groups were more likely to have a higher STS predicted risk of mortality than patients with mild COPD ($p < 0.01$). Preprocedure imaging data were similar among groups (Table 2).

Table 3 shows procedural outcomes stratified by preprocedure COPD severity. The majority of the valves implanted were sizes 23 and 26. The TAVR was performed almost equally between transfemoral (31 patients, 53.4%) and alternative access (27 patients, 46.6%). No 30-day mortality was observed in the study cohort.

Post-TAVR Outcomes

Adjusted post-TAVR outcomes for total intensive care unit time, ventilation times, and overall length of stay are reported in Table 4. There was no significant difference in these variables between COPD categories.