Outcomes of Patients With Severe Chronic Lung Disease Who Are Undergoing Transcatheter Aortic Valve Replacement

Rakesh M. Suri, MD, DPhil, Brian C. Gulack, MD, J. Matthew Brennan, MD, MPH, Vinod H. Thourani, MD, Dadi Dai, PhD, Alan Zajarias, MD, Kevin L. Greason, MD, Christina M. Vassileva, MD, Verghese Mathew, MD, Vuyisile T. Nkomo, MD, MPH, Michael J. Mack, MD, Charanjit S. Rihal, MD, Lars G. Svensson, MD, PhD, Rick A. Nishimura, MD, Patrick T. O'Gara, MD, and David R. Holmes, Jr, MD

Cleveland Clinic, Cleveland, Ohio; Mayo Clinic, Rochester, Minnesota; Duke University, Durham, North Carolina; Emory University, Atlanta, Georgia; Washington University, St. Louis, Missouri, Southern Illinois University School of Medicine, Springfield, Illinois; Baylor University, Plano, Texas; Brigham and Women's Hospital, Boston, Massachusetts

Background. **In this study, we sought to determine the clinical outcomes after transcatheter aortic valve replacement (TAVR) among patients with chronic lung disease (CLD) and to evaluate the safety of transaortic versus transapical alternate access approaches in patients with varying severities of CLD.**

Methods. **Clinical records for patients undergoing TAVR from 2011 to 2014 in The Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry were linked to Medicare hospital claims (n = 11,656). Clinical outcomes were evaluated across strata of CLD severity, and the risk-adjusted association between access route and post-TAVR mortality was determined among patients with severe CLD.**

Results. **In this cohort (median age, 84 years; 51.7% female), moderate to severe CLD was present in 27.7% (14.3%, moderate; 13.4%, severe). Compared with patients with no or mild CLD, patients with severe CLD had a higher rate of post-TAVR mortality to 1-year (32.3% versus 21.0%; adjusted hazard ratio [HR], 1.48; 95% confidence interval [CI], 1.31 to 1.66), as did those with moderate CLD (25.5%; adjusted HR, 1.16; 95% CI, 1.03 to 1.30). The adjusted rate of mortality was similar for transapical versus transaortic approaches to 1 year (adjusted HR, 1.17; 95% CI, 0.83 to 1.65).**

Conclusions. **Moderate or severe CLD is associated with an increased risk of death to 1-year after TAVR, and among patients with severe CLD, the risk of death appears to be similar with either transapical or transaortic alternate-access approaches. Further study is necessary to understand strategies to mitigate risk associated with CLD and the long-term implications of these findings.**

(Ann Thorac Surg 2015;■:■–■)

Chronic lung disease (CLD) is a frequently encountered condition in patients with senile calcific aortic valve stenosis, and when CLD is severe, it is associated with poor outcomes after cardiac surgical procedures including surgical aortic valve replacement [1–6]. CLD has also been reported to coexist in 21% to 43% of patients enrolled in existing transcatheter aortic valve replacement (TAVR) registries [7–12]. Although patients with CLD who are oxygen (O_2) dependent or who have diminished mobility have been shown to have particularly poor outcomes after TAVR, this observation cannot be generalized within the overall population of patients with varying severities of pulmonary disease. A recent analysis from the PARTNER (Placement of AoRTic TraNscathetER Valve) Trial and Registry demonstrated that clinical improvement among patients with CLD was, in fact, not different from improvement in patients without this condition [13]. Additionally, at least three studies have failed to demonstrate that CLD was independently associated with post-TAVR mortality risk [11, 14, 15]. It thus remains uncertain whether, and to what degree, differing severities of CLD are associated with early and midterm survival after TAVR.

In all major international TAVR trials to date, a transfemoral (TF) –first strategy has been used. Patients with severe peripheral vascular disease and associated comorbidities who are allocated to "non-TF", alternative

Accepted for publication May 6, 2015.

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

Address correspondence to Dr Suri, Department of Thoracic and Cardiovascular Surgery, Cleveland Clinic, 9500 Euclid Ave, J4-1, Cleveland, OH 44195; e-mail: surir@ccf.org.

Dr Zajarias discloses a financial relationship with Edwards Lifesciences.

0003-4975/$36.00
http://dx.doi.org/10.1016/j.athoracsur.2015.05.075

Abbreviations and Acronyms

ACC = American College of Cardiology
CLD = chronic lung disease
CMS = Centers for Medicare and Medicaid Services
COPD = chronic obstructive pulmonary disease
FEV_1 = forced expiratory volume in 1 second
NYHA = New York Heart Association
PARTNER = Placement of Aortic Transcatheter Valve Trial
STS = The Society of Thoracic Surgeons
TA = transapical
TAo = transaortic
TAVR = transcatheter aortic valve replacement
TF = transfemoral
TVT = transcatheter valve therapy

access approaches have thus generally been at higher risk for postprocedural complications. In addition, among patients with severe CLD and with vascular anatomic features precluding safe ileofemoral passage of the collapsed transcatheter valve, it is unclear which "alternate" access route would be preferred when several options (left ventricular apex, subclavian, direct aortic) exist.

We sought to test the hypothesis that severity of CLD does not affect outcome after TAVR regardless of anatomic access route. We thus studied a real-world North American TAVR registry to determine (1) the association between CLD and in-hospital and 1-year outcomes after TAVR, (2) the midterm prognosis of particularly high-risk groups of patients with severe CLD (eg, pulmonary hypertension, O_2 dependency), and (3) outcomes across the two most common alternative access routes for patients with severe CLD in whom a TF access route is not possible.

Patients and Methods

The Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Registry

Developed jointly by The Society of Thoracic Surgeons (STS) and the American College of Cardiology (ACC), the Transcatheter Valve Therapy (TVT) Registry was created in partnership with the Food and Drug Administration, the Centers for Medicare and Medicaid Services (CMS), and the Duke Clinical Research Institute (Duke University, Durham, North Carolina). The TVT Registry was created to promote performance improvement, assist in postmarket device surveillance, aid the development of risk models, and assist in planning randomized controlled trials. These goals are supported by linking of the registry to Medicare data, which allow for the inclusion of long-term outcomes. Other data elements collected by registry participants include patients' demographics, comorbidities, procedural details, postoperative complications, and both 30-day and 1-year follow-up data [16]. Registry activities have been approved by a central Institutional Review Board, and the Duke University School of Medicine Institutional Review Board granted a waiver of informed consent and authorization for this study.

Patient Population

Patients who underwent TAVR as their index procedure for hospital admission from November 2011 to June 2014 that involved TF, transapical (TA), or transaortic (TAo) access were included in the initial study cohort. Patients with unknown CLD status were excluded, as were patients with an access site other than TF, TA, or TAo (Fig 1). Furthermore, patients who were less than 65 years old, did not have Medicare fee-for-service insurance, had a non-CMS eligible admission, could not be linked to Medicare, or had TAVR as a nonindex procedure were also excluded.

Data Definitions

Variable definitions followed STS/TVT Registry standards. CLD severity is stratified as (1) no CLD or mild CLD, (2) moderate CLD, or (3) severe CLD, according to the standard STS database definition [17] (https://www.ncdr.com/TVT/Home/DataCollection.aspx). Mild CLD was defined as forced expiratory volume in 1 second (FEV_1) 60% to 75% predicted, long-term use of inhaled or oral bronchodilator therapy, or both. Moderate CLD was determined on the basis of identification of FEV_1 50% to 59% of predicted, use of long-term steroid therapy for pulmonary disease, or both. Severe CLD was defined as an FEV_1 lower than 50% of predicted, room air partial pressure of arterial O_2 less than 60 mm Hg or room air

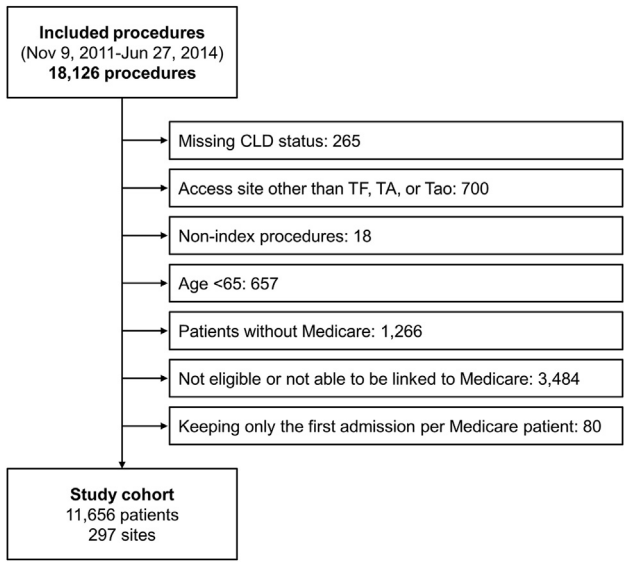

Fig 1. Consort diagram demonstrating development of the study population. (CLD = chronic lung disease; FFS = fee for service; TA = transapical; TAo = transaortic; TF = transfemoral.)