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Long-Term Health Benefit of TAVR in Patients With Chronic Lung Disease

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ABSTRACT

OBJECTIVES This study sought to characterize the long-term effect of chronic lung disease (CLD) on mortality, clinical outcomes, quality of life, and health benefits after transcatheter aortic valve replacement (TAVR) with a self-expanding bioprosthesis.

BACKGROUND The long-term effect of CLD after TAVR is unknown.

METHODS Prevalence and severity of CLD was determined at baseline in high- and extreme-risk patients with aortic stenosis from the CoreValve US Pivotal Trial. Clinical outcomes and health status were assessed using the Kansas City Cardiomyopathy Questionnaire overall summary score (KCCQ-OS). A favorable health benefit was defined as alive with a KCCQ-OS ≥60 and stability (<10-point decrease) or improvement in the KCCQ-OS from baseline.

RESULTS CLD was present in 55% (20% mild, 13% moderate, 22% severe) of the 1,030 patients studied. All-cause mortality was higher in patients with moderate and severe CLD at 1 year (19.6% mild, 28.1% moderate, 26.9% severe CLD vs. 19.2% non-CLD; $p = 0.030$) and 3 years (44.8% mild, 53.0% moderate, 51.9% severe vs. 37.7% non-CLD; $p < 0.001$). New York Heart Association functional class improved in more than 80% of patients with CLD at 1 and 3 years. All patients had a nearly 20-point improvement in KCCQ-OS at 1 and 3 years. However, only 43.3% of patients with CLD had a favorable health benefit at 1 year and 22.5% at 3 years.

CONCLUSIONS Moderate and severe CLD increases 1- and 3-year mortality after TAVR. Although functional status and quality of life were improved in CLD at 1 and 3 years after TAVR, a favorable health benefit was only achieved in selected patients. (Safety and Efficacy Study of the Medtronic CoreValve System in the Treatment of Symptomatic Severe Aortic Stenosis in High Risk and Very High Risk Subjects Who Need Aortic Valve Replacement; NCT01240902) (J Am Coll Cardiol Intv 2017;■:■-■)

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ABBREVIATIONS AND ACRONYMS

CLD = chronic lung disease

DLCO = percent predicted diffusing capacity of the lungs for carbon monoxide

FEV_1 = forced expiratory volume in 1 s

KCCQ = Kansas City Cardiomyopathy Questionnaire

NYHA = New York Heart Association

STS = Society of Thoracic Surgeons

TAVR = transcatheter aortic valve replacement

Chronic lung disease (CLD) is common in patients with severe aortic stenosis treated by transcatheter aortic valve replacement (TAVR) or surgical aortic valve replacement (1-3). Although many patients are considered for TAVR based on the severity of their lung disease, CLD has been associated with increased early and 1-year mortality after TAVR (4-6). In addition, the clinical symptoms of CLD and aortic stenosis overlap and some patients do not improve symptomatically after resolution of the aortic stenosis. Thus, it is unclear whether patients with severe aortic stenosis and severe CLD achieve long-term clinical benefits after TAVR.

Recent reports from the CoreValve US Pivotal Trial showed that TAVR with a self-expanding bioprosthesis improved quality of life and health status in surviving patients at 1 year (7,8). It remains unanswered whether patients with CLD achieved similar improvements in their quality of life.

The aims of these analyses were to evaluate the long-term effect of CLD on clinical outcomes and quality of life and health benefits after TAVR. Improvement in quality of life is of particular importance because the underlying lung disease may compromise the symptomatic benefits seen after TAVR.

METHODS

Patients with severe aortic stenosis enrolled in the CoreValve US Pivotal Extreme Risk or High Risk Trial and treated with TAVR between 2011 and 2014 were included in this analysis (3,9). TAVR was performed with a CoreValve self-expanded bioprosthesis via an iliofemoral, subclavian, or direct aortic approach (3,9).

Inclusion and exclusion criteria were previously described (3,9). Patients with symptomatic (New York Heart Association [NYHA] functional class II or greater) severe aortic stenosis considered at extreme or high risk for surgery were eligible. Extreme-risk patients were considered to have a surgical risk of death or irreversible morbidity ≥50% at 30 days. High-risk patients were considered to have a ≥15% surgical mortality rate at 30 days. Severe aortic stenosis was defined as an aortic valve area ≤0.8 cm^2 or aortic valve index ≤0.5 cm^2/m^2 and either a mean aortic valve gradient >40 mm Hg or a peak aortic valve velocity >4.0 m/s at rest or with dobutamine. Principal exclusion criteria were a gastrointestinal hemorrhage within the prior 3 months, a major stroke within the prior 6 months, or a life expectancy <1 year because of comorbidities.

ASSESSMENT OF CLD SEVERITY. The severity of CLD was categorized using the Society of Thoracic Surgeons (STS) adult database classification (10). The STS database categorizes CLD as mild, moderate, or severe CLD (10). Mild CLD was defined as forced expiratory volume in 1 s (FEV_1) between 60% and 75% of predicted, and/or on chronic inhaled or oral bronchodilator therapy. Moderate CLD was defined as FEV_1 50% to 59% of predicted, and/or on chronic steroid therapy aimed at lung disease. Severe CLD was defined as FEV_1 <50% predicted, and/or room air Pao_2 <60 mm Hg or room air $Paco_2$ >50 mm Hg. Percentage predicted FEV_1 was calculated using the Hankinson et al. (11) formula. Percentage predicted diffusing capacity of the lungs for carbon monoxide (DLCO) was documented by the investigational site.

CLINICAL OUTCOMES. Clinical outcomes at 30 days, 1 year, and 3 years were evaluated by STS CLD severity at baseline. Outcomes evaluated included all-cause and cardiovascular mortality, stroke, major adverse cardiovascular and cerebrovascular events (composite of any death, any stroke, myocardial infarction, or reintervention), aortic valve-related rehospitalizations, and changes in NYHA functional class over time.

QUALITY OF LIFE AND HEALTH BENEFIT. Quality of life outcomes were evaluated at baseline, 1 year, and 3 years using the Kansas City Cardiomyopathy Questionnaire (KCCQ) (12). The KCCQ is a 23-item self-administered questionnaire that assesses symptoms, functional status, and quality of life in patients with heart failure, including those with severe, symptomatic aortic stenosis (12). The KCCQ assesses specific health domains (physical limitation, symptoms, quality of life, social limitation, and self-efficacy), the first 4 of which are combined into an overall summary score. Values for all KCCQ domains and the summary score range from 0 to 100, with higher scores indicating less symptom burden and better quality of life. The KCCQ overall summary score generally correlates with NYHA functional class as follows: class I, KCCQ 75 to 100; class II, 60 to 74; class III, 45 to 59; and class IV, 0 to 44 (13,14). Changes in the KCCQ overall summary score of 5, 10, and 20 points correspond to small, moderate, or large clinical improvements, respectively (13,14). We used a composite outcome of survival and quality of life to evaluate health benefit at 1 and 3 years. A favorable health benefit was defined as all of the following at 1 and 3 years: 1) alive; 2) KCCQ overall summary score ≥60 (roughly