Single Center Experience Performing Transcatheter Aortic Valve Replacement with the Mechanically-Expandable LOTUS Edge Platform in High-Risk Patients with Symptomatic Severe Aortic Stenosis

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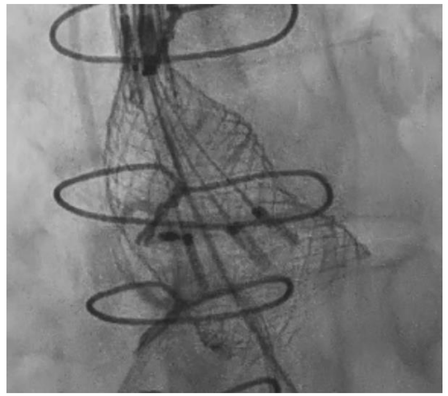
Introduction

We present our initial single-center experience with TAVR using the commercially available mechanically-expandable, fully-repositionable LOTUS Edge platform (Boston Scientific). Transcatheter aortic valve replacement (TAVR) has become the preferred therapeutic option for patients with symptomatic severe aortic stenosis (AS) at high risk for surgical aortic valve replacement.



Methods

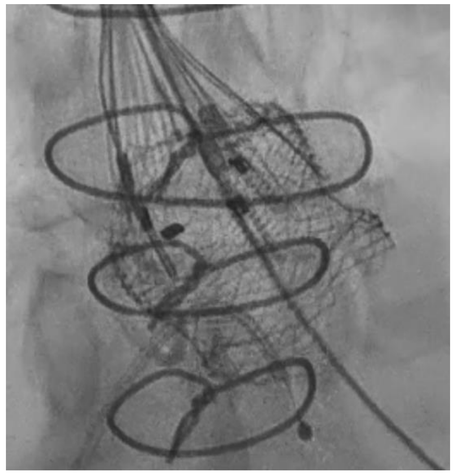
We retrospectively reviewed consecutive patients with symptomatic severe AS who underwent TAVR with LOTUS Edge at our institution between August 28, 2019 and March 11, 2020. All patients were considered to be at high-risk for SAVR by a multidisciplinary heart team using an integrated assessment that combined the Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) score plus frailty, organ system dysfunction and procedure-specific impediments based on the Reprise III trial inclusion criteria. Clinical, procedural and echocardiographic data were collected by chart and echocardiographic database review. Clinical outcomes were reported following the Valve Academic Research Consortium 2 (VARC-2) criteria.

Results

During the study period, 35 patients underwent TAVR with LOTUS Edge. The mean age was 76.9±9.1 years, 54.3% of patients were women, and the mean STS-PROM score was 8.9 ± 2.2. The mean baseline mean ejection fraction was 45%, mean aortic valve area was 0.7 ± 0.6 cm(2), and the mean transvalvular pressure gradient was 51.5 ± 16.2 mmHg. All patients were. successfully implanted with a LOTUS Edge valve using a percutaneous femoral approach, and 30-day clinical follow-up was available for all patients. The mean 30-day transvalvular aortic pressure gradient was 10.6 ± 5.7 mmHg, and the mean valve area was 1.8 ± 0.6 cm(2). A total of 97% patients had none or trace perivalvular leak at 30 days and 91% of patients were New York Heart Association functional class I or II. Of note was the absence of significant paravalvular leak even in patients with difficult anatomy. At 30-days, VARC-2 results showed the all-cause mortality rate was 5.7% (2 of 35 patients, 1 patient with worsening right ventricular failure and acute respiratory failure and 1 patient with massive pulmonary embolism), disabling stroke rate was 0%, major vascular complication rate was 5.7% (2 of 35 patients). There were no procedural related deaths. A total of 17.6% (6 of 34 patients with no prior pacemaker) underwent new permanent pacemaker implantation at 30-days

Conclusions

Our initial experience suggests that TAVR using LOTUS Edge is a reliable option to surgery in high-risk AS patients with low incidence of complications and high success rates. Despite our limited number of patients, our data is consistent with results of clinical trials like Reprise III, however, so far we have noted a reduced need for new permanent pacemaker.



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