Delivery Science Grants Program

Predicting Adverse Outcomes and Poorer Quality of Life After TAVR is Challenging in Real World Populations Alan S. Go, MD, Edward M. McNulty, MD, Jacob Mishell, MD; Samuel T. Savitz, PhD; Andrew Rassi, MD; Andrew P. Ambrosy, MD

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| Challenge | The current literature provides inadequate guidance regarding **which subgroups of patients are the most or least likely to benefit from TAVR in terms of both clinical outcomes and quality of life,** especially given the moderate number of selected patients enrolled in the published RCTs. Additional evidence-based guidance may enable physicians to provide a more realistic outlook for patients who are being considered for TAVR and support system-level efforts to provide targeted management and follow-up interventions to patients at high risk for adverse clinical and patient-centered outcomes after TAVR. |
| Existing Evidence | TAVR is a minimally-invasive procedure to treat severe aortic valve stenosis. Before the introduction of TAVR, the standard treatment approach was to perform open heart surgical aortic valve replacement (SAVR) to remove the diseased valve and implant a replacement valve.  Due to the expanding indications for TAVR, there has been a dramatic increase nationally in both the number of sites performing TAVR and the number of TAVR procedures captured in The Society of Thoracic Surgeons and American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) Registry; within KPNC, the annual number of procedures has grown rapidly from 49 in 2012 to 450 in 2018. While many patients who receive TAVR have favorable outcomes, a recent study found that nearly 38% of TAVR patients experienced unfavorable outcomes (i.e., death or persistent low quality of life) at 1-year following the procedure.14 Questions were raised with the KPNC Cardiac Outcomes Leadership Team and Structural Heart |
| Target Population | KPNC members aged ≥18 years who received TAVR between January 1, 2013 and December 31, 2019. |
| Intervention or Exposure | Severity of risk for negative outcomes associated with TAVR defined by Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database risk score at time of TAVR |
| **Outcomes/Key Findings** | * **STS risk score was not independently predictive of death or favorable quality of life at 30 or 365 days.** * **STS risk score was weakly predictive of hospitalization at 30 days and ED visits at 365 days, as well as total utilization over all follow-up.** * Of 1565 TAVRs performed within KPNC, 22% of patients were classified as low risk, 62% as intermediate risk, and 13% as high risk based on the STS Risk Score. STS Risk Score was unavailable for 3% of the cohort. * Patients with a higher STS Risk Score tended to be older, women, and were more likely to have a prior history of cardiac surgery and a substantially higher burden of cardiac and non-cardiac comorbidities. * Most TAVR procedures were performed in a hybrid operating room, and transfemoral access was obtained in ~93% of overall cases and in >95% of low risk patients. * Overall, among those who had available baseline quality of life, >90% of patients were alive and had either a favorable quality of life measurement or experienced an improvement in quality of life at 30 days post-TAVR. This is significantly better than what has been reported at the national level. * All-cause hospitalizations (6.8% of patients) and all-cause ED visits (15.3% of patients) at 30 days were relatively high across the entire risk spectrum. * Predictive risk models showed high discrimination for death and HF-related utilization at 30 days, and for HF-related ED visits only at 365 days.   TAVR valve characteristics were not associated with restenosis during follow-up. |
| **Resulting Action/Change** | See figure of analytic cohort and tables of associated risk score and outcomes below. |

**Higher STS Risk Score Not Significantly Associated with Outcomes at 30 days**

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| **​30-day outcomes** | **Death\*​** | **Hospitalization\*​** | **ED visit\*​** | **HF hospitalization\*​** | **HF ED visit\*​** | **Quality of life not improved\*\*​** |
| STS <3​ | (reference)​ | (reference)​ | (reference)​ | (reference)​ | (reference)​ | (reference)​ |
| STS 3-8​ | 0.95 (0.27-3.36)​ | 1.47 (0.73-2.98)​ | 0.96 (0.61-1.50)​ | 1.12 (0.15-8.60)​ | 0.82 (0.32-2.13)​ | 0.80 (0.30-2.12)​ |
| STS >8​ | 1.42 (0.35-5.81)​ | 1.01 (0.29-3.57)​ | 0.81 (0.41-1.63)​ | 0.29 (0.03-3.16)​ | 0.83 (0.28-2.43)​ | 1.00 (0.24-4.16)​ |
| STS missing​ | 0.00 (0.00-0.00)​ | 2.70 (0.69-10.60)​ | 0.87 (0.29-2.64)​ | 1.68 (0.09-31.76)​ | 0.57 (0.08-4.07)​ | 4.28 (0.62-29.49)​ |

\* Adjusted hazard ratio and 95% confidence interval​

\*\* Adjusted odds ratio and 95% confidence interval

**Higher STS Risk Score Not Significantly Associated with Outcomes at 365 days**

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| **​365-day outcomes** | **Death\*​** | **Hospitalization\*​** | **ED visit\*​** | **HF hospitalization\*​** | **HF ED visit\*​** | **Quality of life not improved\*\*​** |
| STS <3​ | (reference)​ | (reference)​ | (reference)​ | (reference)​ | (reference)​ | (reference)​ |
| STS 3-8​ | 0.90 (0.44-1.84)​ | 1.16 (0.83-1.61)​ | 1.19 (0.91-1.55)​ | 1.69 (0.61-4.71)​ | 1.56 (0.90-2.70)​ | 0.80 (0.38-1.71)​ |
| STS >8​ | 0.73 (0.29-1.83)​ | 1.24 (0.76-2.02)​ | 1.26 (0.86-1.85)​ | 0.82 (0.19-3.43)​ | 1.54 (0.79-3.02)​ | 0.60 (0.19-1.92)​ |
| STS missing​ | 0.56 (0.10-3.17)​ | 1.46 (0.64-3.29)​ | 1.12 (0.60-2.07)​ | 2.18 (0.35-13.53)​ | 1.63 (0.53-4.98)​ | 1.09 (0.07-18.20)​ |

\* Adjusted hazard ratio and 95% confidence interval​

\*\* Adjusted odds ratio and 95% confidence interval