Transcatheter aortic valve replacement (TAVR) has been shown to dramatically improve survival and quality of life for many patients with symptomatic severe aortic stenosis (AS) considered inoperable or at high risk for conventional surgical aortic valve replacement. In fact, recent analyses from 2 separate randomized controlled trials have reported that health-related quality of life improves earlier and faster among high-risk patients assigned to transfemoral TAVR, as compared with surgical aortic valve replacement. Nevertheless, it is becoming increasingly clear that not all patients assigned to TAVR benefit from the procedure. For example, in the CoreValve US Pivotal trial, extreme risk cohort (mean Society of Thoracic Surgeons [STS] score 10.4±5.6%), 39% of patients were deemed to have had a poor outcome after TAVR (22% death, 16% poor quality of life, and 1.4% quality of life decline). Similarly, in the Placement of Aortic Transcatheter Valves (PARTNER) trial (including both cohorts), 35% of patients were categorized as having a poor outcome after the procedure (19% death, 16% poor quality of life). In the recently published STS/American College of Cardiology/Transcatheter Valve Therapy (ACC/TVT) registry, patients with the combination of advanced age (85–94 years), dialysis dependency, and STS score ≥15% (n=77 patients) had a 1-year mortality rate of 54%. Similarly, Allende et al observed in a multicenter registry that severe AS patients with a combination of preexisting atrial fibrillation and dialysis therapy undergoing TAVR had a 1-year mortality rate of 71%. Hence, the evidence suggests that although most patients profit from TAVR, an unmet need exists for better risk stratification tools to avoid futile interventions among extreme-risk patients who are unlikely to benefit. In routine clinical practice, patient selection for TAVR relies mainly on surgical risk scores and the assessment of comorbidities. Indeed, some comorbidities, such as coronary artery disease, can be treated before or during the TAVR procedure in an effort to optimize clinical outcomes afterward. However, among elderly patients referred for TAVR, factors in addition to traditional risk stratification need to be considered because comorbidities and risk scores alone do not provide the complete picture of an individual’s state of health and functional status (Figure). For example, Stortecky et al and Schoenenberger et al observed that ≤40% of patients referred for TAVR had cognitive impairment as assessed by the mini-mental status examination, poor mobility as assessed by the timed-up-and-go test, disability as assessed by activities of daily living, or malnutrition as assessed by the mininutritional assessment. The investigators observed that each of these parameters predicted functional decline or death 6 months after the procedure even after adjustment for traditional surgical risk scores. The burden of a patient’s comorbidities and frailty parameters ultimately affect a patient’s quality of life. Therefore, health-related quality of life may serve as a useful surrogate marker for the combined effect of a patient’s age, AS severity, comorbidities, and frailty parameters. Although there have been several studies quantifying improvements in health-related quality of life as compared with baseline following TAVR, it remains unclear whether the status of baseline health-related quality of life per se may serve as a useful parameter for further risk stratification of patients before the procedure.

See Article by Arnold et al

In this issue of Circulation: Cardiovascular Interventions, Arnold et al set out to assess the usefulness of the Kansas City Cardiomyopathy Questionnaire (KCCQ) in predicting 1-year clinical outcomes after TAVR among real-world patients enrolled in the multicenter STS/ACC TVT registry. The KCCQ is a self-reported patient questionnaire that provides an assessment of symptoms and quality of life among patients with heart failure but is increasingly being applied to the severe AS patient population. Although the onset of dyspnea and other symptoms of heart failure presage the worst prognosis for patients with AS, the assessment of heart failure–related symptoms in routine clinical practice remains challenging. One advantage of the KCCQ questionnaire is that it is the patients themselves who provide the responses to their current health status. This is important because there seems to be a discrepancy between physician-estimated and patient-reported health status. For example, in the present study, 1 in 10 patients with poor health status (KCCQ overall summary score ≤25) were estimated by physicians to be in New York Heart Association I-II functional status, whereas conversely, over two-thirds of patients with self-reported good health status (KCCQ overall summary score >75) were classified by physicians as New York Heart Association III-IV. The investigators analyzed a large population of real-world patients who completed baseline KCCQ questionnaire forms (7769 out of 12,182 patients) enrolled in the multicenter STS/
ACC TVT Registry between November 2011 and June 2014. Included patients were stratified into KCCQ overall summary score quartiles depending on whether the reported health status was deemed very poor (28%), poor (38%), fair (24%), or good (10%). The key finding was that as compared with patients with good baseline health status, those with the poorest baseline health status had the worst in-hospital (prolonged hospital stay, increased requirement for dialysis, higher in-hospital mortality rates, lower likelihood to be discharged home) and 1-year (2-fold increased hazard of death) clinical outcomes, even after adjustment for relevant baseline clinical and demographic characteristics. Reassuringly, 70% of patients in the lowest KCCQ overall summary score quartile were still alive at 1 year, suggesting that very poor baseline health status per se should not be considered a contraindication for TA VR. Nevertheless, this figure was probably an overestimation because excluded patients were sicker and had significantly worse 1-year clinical outcomes as compared with the included patient population. Furthermore, no data were provided on quality of life improvement after TA VR, which is a major limitation because it is unclear from the present study what proportion of patients with very poor health status at baseline had a clinically meaningful improvement in quality of life after TA VR.

In conclusion, the study by Arnold et al confirms in a large population of real-world patients that quantifying baseline health status using the KCCQ questionnaire serves as a useful parameter to help further risk-stratify patients being considered for TA VR. After almost 14 years of TA VR in clinical use, the discussion of utility versus futility remains an ongoing issue. It appears obvious that a patient with multiple comorbidities and a high frailty score would ultimately have a poor functional status. Needless to say, advanced age and female sex may contribute substantially to this. To attempt an anatomically difficult TA VR intervention in this setting is most probably futile; on the other hand, a patient with no frailty and good functional status will overcome a procedural complication much faster and will most likely profit from the minimal-invasive approach. Risk assessment should include comorbidities, frailty status, and the age and sex of the patient. A straightforward, standard TA VR procedure may be indicated and utile in patients with poor functional status at baseline and good anatomic features. Conversely, anatomically complex interventions represent too high a risk in this setting and should be avoided. On the contrary, more intermediate risk patients will likely profit from TA VR in the future because of refined technological features and growing experience of the operators. A high level of clinical experience and detailed analysis of the anatomic factors of the aortic valvular complex will remain crucial.

Disclosures

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References


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Quality of Life and Survival After TAVR


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Crochan J. O'Sullivan and Peter Wenaweser

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