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Outcomes of Surgical Aortic Valve Replacement: The Benchmark for Percutaneous Therapies

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ABSTRACT

Historically, many patients with severe senile calcific aortic valve stenosis (AS) were not offered surgery, largely due to the perception that the risks of operation were prohibitive. Such patients have subsequently been formally designated as 'high risk' or 'inoperable' with respect to their suitability for surgical aortic valve replacement (SAVR) in the evolving lexicon of heart valve disease. The recent availability of transcatheter aortic valve replacement (TAVR) represents an alternative treatment option, and permits the opportunity to re-examine algorithms for assessing operative risk. As the experience with TAVR grows, expanded use in new patient populations can be anticipated. While TAVR in high risk AS patients has demonstrated benefits, the emerging indication in intermediate AS is less clear and conclusions will necessarily await the availability of results from ongoing clinical trials. This article will discuss current outcomes for SAVR among high- and intermediate-risk patients with AS as a barometer in assessing the results of nascent percutaneous therapies.

"The feasibility of an operation is not the best indication for its performance."

[Lord Cohen of Birkenhead]

Severe calcific aortic stenosis (AS), a common heart valve condition of elderly patients in the developed world, is associated with an increased mortality once symptoms appear.[1–3] Without aortic valve replacement (AVR), patients with severe AS have a dismal prognosis with a one-year mortality of 30%–50%.[3–5] Surgical aortic valve replacement (SAVR) has been shown to improve symptoms and prolong survival, with very low morbidity and mortality even in patients who have undergone prior cardiac operations.[6]

Since the introduction of percutaneous pulmonary valve implantation in 2000[7] and subsequent aortic valve implantation in 2002,[8] technological advances in transcatheter aortic valve replacement (TAVR) have affirmed its emergence as an effective, alternative treatment modality to conventional SAVR in select patient populations.[9] Recent randomized controlled trials have demonstrated that TAVR offers similar rates of survival and symptoms improvement as SAVR in high-risk and inoperable patients at 2 years of follow-up.[10] As TAVR experience grows, expanded use in new patient populations can also be anticipated. When considering therapeutic options for the majority of patients with AS however, particularly for those at intermediate risk of death after SAVR (Society

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Abbreviations and Acronyms

ADL = activity of daily living

AS = aortic stenosis

AVR = aortic valve replacement

EuroSCORE = European System for Cardiac Operative Risk Evaluation

PROM = predicted risk of mortality

SAVR = surgical aortic valve replacement

STS = Society of Thoracic Surgery

TAVR = transcatheter aortic valve replacement

of Thoracic Surgeons [STS] predicted risk of mortality [PROM], 4%–8%), uncertainty exists regarding the best treatment option, and many unresolved clinical issues must be addressed before dispersion into lower risk patient populations is warranted. To understand the contemporary results of SAVR in the latest clinical trials and retrospective studies, we will explore current risk stratification schemes for high or intermediate risk patient populations with AS. We will then discuss current outcomes in SAVR with particular emphasis on intermediate risk populations.

Assessment of operative risk

Recent publications detailing the results of TAVR in high risk and inoperable patients from both Europe and North America[11–14] have prompted a significant shift in the management of these populations of AS patients. In order to determine which patients might benefit from these therapies, accurate prediction of relative surgical perioperative morbidity and mortality, is paramount, yet remains challenging. In the absence of a designated risk model specifically validated for TAVR candidates, currently used surgical scoring systems have been reported to overestimate actual periprocedural risk. The key question that arises during each patient evaluation is whether TAVR will incrementally benefit the patient with severe AS who is still deemed operable for conventional SAVR by the experienced heart valve surgeon, but estimated to have a "high early post-surgical risk" according to current risk stratification schemes.

Are the current risks scoring systems helpful in defining operability?

While the use of surgical risk calculators has become commonplace in daily clinical practice,[15,16] it has been demonstrated that standard risk calculators may become less accurate in the patient with a more extensive array of comorbidities. Paradoxically, it is in precisely this population that the greatest need for an accurate mechanism of risk stratification exists. The most frequent scoring systems used to assess and risk stratify TAVR patients have been the Society of Thoracic Surgeons (STS) risk score and logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE). The 2011 updated STS risk score now includes new variables that are relevant to high-risk SAVR. These include liver disease (Model for End-stage Liver Disease score), previous radiation therapy, oxygen dependence, porcelain aorta, and frailty (assessed by the 5-m walk test)[17] The logistic EuroSCORE was commonly believed to overestimate the surgical risk for TAVR patients, and the EuroSCORE divided by 3 was deemed as the accepted "true risk" comparable to the STS score. The recently revised EuroSCORE II includes insulin-dependent diabetes, creatinine clearance, and procedural categories as components for risk calculation, and is thought to more accurately reflect the risk scoring of TAVR patients. Due to the fact that EuroSCORE in particular may overestimate peri-procedural risk, it has been recommended that it not be utilized in isolation to ascertain SAVR risk.[18] The STS Adult Cardiac Surgery Database predicted risk of mortality (PROM) thus remains the most frequently employed and best-validated risk calculator model utilized in cardiac surgery, and even in recent comparisons.[19–22]

Predictive models are most relevant to the specific population from which they are derived. This is a feature that deserves special consideration when attempting to universalize the risk associated with either SAVR or TAVR. Important to note is the fact that operative mortality in cardiac surgery has also steadily diminished over time, particularly during the past decade, thus rendering risk prediction algorithms outdated when compared to actual results obtained in contemporary practice. Combined with the fact that currently utilized scoring algorithms necessarily utilize historic cohorts of surgical patients to construct and validate models, it is becoming increasingly well understood that relying on such systems alone may dangerously mislead patients and clinicians. Denying life saving, effective and low risk surgical therapy to patients on the basis of a potentially anachronistic risk score alone is thus cautiously avoided in most high volume structural heart programs with a healthy and well balanced "heart team". While scoring systems have largely centered upon ascertainment of the risk of mortality, significant morbidity may also occur following either SAVR or TAVR. Existing scores largely are incapable of integrating and quantifying risk associated with certain comorbidities (such as pulmonary hypertension), selected anatomic conditions (such as porcelain aorta and adherent coronary grafts), and clinical conditions (such as functional debility). It is therefore critical that a full understanding of patient goals and preferences with respect to extending survival and reducing morbidity related to treatment is attained.

Frailty in cardiovascular disease has been associated with poorer outcomes, and objective evaluation of this condition has been incorporated into the assessment of TAVR candidates in a standardized way for the first time in the history of heart valve therapy. Recently, a modified Fried frailty index composed of 4 criteria has been developed at Columbia University. Frailty was defined has having ≥2/4 criteria among: (1) ≥2/6 activity of daily living (ADL) impairment, (2) serum albumin <3.5 g/dL, (3) grip strength <30 kg for male and <18 kg for female, and (4) 15-ft walk test ≥7 s. Each criterion is scored in quartiles (0–3) and total score ranges from 0 to 12 with 12 being the most frail. The study showed that a frailty score >5 had a >3-fold increase in 1-year mortality after TAVR.[23] In another report, the use of a multidimensional geriatric assessment was found helpful in predicting the 30-day and 1-year mortality and major