The novel of healthcare is to optimize both quantity and quality of life for patients. Among select patients with severe symptomatic aortic stenosis, transcatheter aortic valve replacement (TAVR) can, on average, improve both survival and health status (ie, symptoms, functional status, and quality of life). However, the technology is currently limited to patients who are either ineligible or at high risk for open surgical aortic valve replacement. The result is that TAVR is used in older patients with multimorbidity and frailty. As such, success is far from guaranteed for each of these complex cases. Indeed, despite the overall benefits seen in the Placement of AoRtic TraNsCatheterER Valve (PARTNER) trial, ≈1 in 5 patients undergoing TAVR died within 6 months. An unmet need is to better determine, before TAVR, which individual patients are unlikely to achieve a “good” outcome.

Risk models offer the potential to move beyond the average effects presented in summary trial results by further risk stratifying patients on the basis of their individual characteristics. A number of TAVR risk models have been constructed, primarily to predict risk for death. However, for many of these patients (the average TAVR recipient is in his or her ninth decade of life), survival alone may not constitute a “victory.” Persistently poor or worsening patient health status, even among longer-term survivors, is unlikely to be perceived as a success for most patients and their families. Fortunately, the PARTNER trial collected data on a wide range of anticipated health status. Despite the obvious relevance to patients, few patient outcome models, predicting both survival and patient health status, are rarely captured in routine care. To integrate the Arnold risk model results for individual patients must become integrated with routine clinical work flow. They cannot inhibit or add significant time to patient care. Electronic health records are largely electronic versions of paper records, with critical clinical information not available as structured data. Additionally, patient health status measures such as the Kansas City Cardiomyopathy Questionnaire used in this study, are reproducible, valid, and clinically interpretable. The era of measuring and predicting patient-reported outcomes as part of clinical practice is just dawning and is bolstered by the study by Arnold and colleagues.

The results presented in the current study are eye opening. Overall, one third of the patients had a poor outcome at 6 months after TAVR: 19% had died, 12% had poor health status, and 2% had worsened health status. These individuals were more likely to have low body weights, low mean aortic valve gradients, oxygen-dependent lung disease, and poor baseline functional and cognitive status. When patients were categorized by the risk model with the use of these characteristics, poor outcome at 6 months after TAVR was seen in 55% of high-risk patients, 37% of intermediate-risk patients, and 18% of low-risk patients. Thus, the risk model was able to stratify risk of poor outcome after TAVR with the use of preprocedural patient factors.

This directly leads to the next critical question, “Is this risk model useful?” This is an open question. The vast majority of risk models—for any outcome and for any condition or procedure—have not been applied clinically. They remain more academic than practical. For risk models like the one developed by Arnold and colleagues to be helpful in clinical practice, the 3 “Ts” must be embraced: integration, interpretation, and interaction.

Integration

Risk model results for individual patients must become integrated with routine clinical work flow. They cannot inhibit or add significant time to patient care. Electronic health records should support this, but only rare examples of effective integration of clinical decision support tools exist. Most current electronic health records are largely electronic versions of paper records, with critical clinical information not available as structured data. Additionally, patient health status measures such as the Kansas City Cardiomyopathy Questionnaire are rarely captured in routine care. To integrate the Arnold TAVR risk model in clinical practice and monitor outcomes,
Clinicians will need to become familiar with the interpretation of risk model results and understand the limitations of model predictions. This is analogous to interpreting other clinical test results that inform treatment recommendations (eg, laboratory or diagnostic studies). However, interpretation of risk model estimates and patient health status data such as the Kansas City Cardiomyopathy Questionnaire have not yet become as familiar as creatinine clearance. Furthermore, the inherent uncertainty for any future event must be incorporated into the practical use of risk models. In split-sample validation, the C index for the Arnold TAVR model was 0.64, with nearly 1 in 5 “low-risk” patients having a poor outcome and nearly half of “high-risk” patients having a good outcome. The “holy grail” of such risk models could be the ability to determine preprocedural futility, thereby avoiding hopeless procedures and simplifying treatment decisions. The truth is that risk models will never say that an individual patient will or will not derive benefit from a procedure. In the case of TAVR, in which the alternative of medical therapy has a very high rate of poor outcome, even a risk model predicting a >50% chance of adverse outcome after TAVR may not change the decision by many patients and clinicians to move forward with the procedure. Such risk models can objectively calibrate expectations and help to anticipate possible future events.

Interaction

The most important aspect of risk models is the way that they interact with patients and their families. Even the best risk models cannot supplant the process of communicating prognosis. In addition, clinicians cannot let models outweigh clinical sense and consideration of patient preferences. This defines the need for shared decision making, which integrates evidence-based medicine and tailored risk estimates with individual patient preferences. Shared decision-making tools to help patients and clinicians to move forward with the procedure. Such risk models can objectively calibrate expectations and help to anticipate possible future events.

Disclosures

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References

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