Aortic stenosis is the most common valvular heart disease in developed countries; its impact on public health and health care resources is expected to become increasingly significant as the population ages. The rapid emergence of transcatheter aortic valve implantation (TAVI) as the recommended or preferred therapy for many patients with aortic stenosis is challenging clinicians, administrators, and policy makers to ensure adherence to evidence-based indications and access to services within safe and appropriate times. Recently, the findings of the CoreValve US Pivotal Trial demonstrated a significant reduction in mortality and morbidity in high-risk patients who had TAVI compared with a randomized surgical cohort; this further confirmed the findings of the Placement of Aortic Transcatheter Valves (PARTNER) study, which showed a 20% absolute risk reduction in 1-year mortality in inoperable patients, noninferior outcomes in high-risk surgical candidates, and a significantly lower procedural mortality in even higher risk patients who underwent transfemoral TAVI rather than surgery. Clinical trials are currently under way to examine the role of newer improved devices in patients at lower surgical risk. Outcomes with TAVI continue to improve and indications will likely broaden. This paradigm shift in the management of valvular heart disease is creating significant new pressures on clinical resources and casts questions regarding how to best monitor patient access, support health care planning, and inform funding models.

In the current issue of the Canadian Journal of Cardiology, Wijeysundera et al. report on the development of a discrete event simulation model using the PARTNER data available for inoperable and high-risk patients to estimate the hypothetical effectiveness of TAVI according to 7-wait-time fixed-queue scenarios ranging from 10-180 days. Statistical modeling determined that there was a 27% difference in wait-time mortality between inoperable patients who waited 10 days and those who waited 180 days; longer wait time was associated with a lasting negative effect of 9.9% between the 2 groups at 1 year. Further, high-risk patients experienced similar deterioration while waiting for either surgery or TAVI; when their wait exceeded 60 days, TAVI patient mortality was comparably worse than an estimated surgical cohort who waited for a fixed 2-week period. The analysis by Wijeysundera et al. is limited by multiple assumptions and is based on relatively older data drawn from a first-generation device clinical trial of highest risk patients that no longer reflects current patient characteristics or clinical outcomes of the contemporary TAVI experience. The proposed model is, however, an important contribution to the fledgling debate on the mechanisms required to monitor and report the effects of waiting for TAVI, the establishment of wait-time benchmarks, and the pivotal need to support health care planning in anticipation of the increasing availability of transcatheter options for the management of valvular heart disease.

**Measuring Wait Times for TAVI in Contemporary Patients**

The applicability of the model and the confirmation of the findings in “real world” clinical data hinge on the accurate capture of wait times and the comparability across risk-stratified patient groups. The authors discuss how the “inception point” defined in the study fails to measure the patient’s complete trajectory from the time of the initial referral to the date of the procedure and does not capture the cost of the time spent under assessment. As outlined in the Canadian Cardiovascular Society Position Statement on TAVI, appropriate recommendations for TAVI and surgical eligibility ideally involve multidisciplinary and multimodality evaluation to inform the heart team’s consensus decision. The logistic and expertise complexity of case selection can be more challenging than procedure planning. In preparation for TAVI, the patient must be seen in consultation with a cardiologist and surgeon and typically undergoes cardiac catheterization, transthoracic echocardiography, computed tomography, and functional assessment. Each of these requirements may create potential time delays related to
multiple factors, including scheduling and availability of specialty services, staging of contrast administration, and burden of patient travel to attend repeated appointments. Preprocedure bottlenecking can be further compounded by local sites’ standardized practices (eg, routine use of transesophageal echocardiography, carotid ultrasonography, and pulmonary function testing) or individualized additional assessment requirements (eg, anesthesia or geriatric medicine consultation). Similarly, current metrics may underestimate the wait time for the surgical treatment of aortic stenosis by a factor of 3.2, whereas surgical wait time in the model by Wijeysundera et al. remained constant at 15 days. This “time under assessment” (and the concomitant monitoring of “deaths under assessment”) is an important marker of program efficiency, multidisciplinary collaboration, and potential barriers to patient access. Patients with severe aortic stenosis can deteriorate rapidly and may experience worse outcomes on the wait list and after the procedure because of the time needed for the heart team to recommend treatment. Defining and monitoring this time is essential to inform program and therapy evaluation (Fig. 1).

**Time for Wait-Time Benchmarks?**

The Canadian Institute for Health Information defines benchmarks as indicators of the amount of time clinical evidence shows is appropriate for a procedure. The Canadian Wait Time Alliance categorizes benchmarks as health system performance goals beyond which the best available evidence and clinical consensus indicate that the patient’s health is likely to be adversely affected. Previous researchers have proposed that benchmarks must reflect the time the patient is at risk for morbidity and mortality and should be applicable and reproducible across jurisdictions and easily tracked. The development of Canadian wait-time benchmarks for TAVI is required to promote patient safety and inform program planning and evaluation.

Setting Canadian benchmarks for TAVI will be filled with trials and tribulations. For the foreseeable future, risk scores and stratification, urgency ratings for patients undergoing elective TAVI and inpatients, and eligibility assessment requirements will remain somewhat “unstable” and require ongoing research and expert consensus. The availability of newer TAVI devices and techniques with improved outcomes and new indications may modify the TAVI patient population, whereas streamlined preprocedure assessment and reduced length of stay may impact the footprint of TAVI on cardiac programs and resources. Given these confounders, the road map to developing TAVI wait-time benchmarks may involve the following steps:

- **Accurate and timely data capture of date of referral, treatment decision (ie, acceptance on wait list), and procedure; monitoring and reporting of the time from referral to acceptance (time 1) and acceptance to procedure (time 2) to measure the patient’s full trajectory of care.**
- **Evaluation of adverse events during time 1 and time 2; study of the effects of wait time on 30-day and longer term outcomes.**
- **Provincial or national initiative (or both) to compare data and findings within TAVI programs and compared with surgical valve replacement.**
- **National consensus recommendations on risk-stratified wait-time benchmarks (time 1 and time 2).**

**Figure 1.** Pathway from referral to procedure for patients with aortic stenosis. Representing true total transcatheter aortic valve implantation (TAVI) wait time. TEE, transesophageal echocardiography; TTE, transthoracic echocardiography.
**Development of Wait-Time Management Provincial Systems**

Current indications for TAVI according to the Canadian Cardiovascular Society position statement include severe symptomatic aortic stenosis, high or excessive risk for surgical valve replacement, likelihood to derive survival and quality of life benefit for at least 1 to 2 years, and the heart team’s consensus recommendation for TAVI. The British Columbia model represents 1 potential example for wait-list management. TAVI sites report access issues regularly to Cardiac Services British Columbia, an agency of the Provincial Health Services Authority that is responsible for planning, coordinating, monitoring, evaluating, and funding the Provincial Transcatheter Heart Valve (THV) program in collaboration with the health authorities. A central referral system at each TAVI site of the Provincial THV program enables the ongoing evaluation of the denominator of referred patients, the distribution of treatment decisions, the number of patients undergoing eligibility assessment, and patients on the wait list (ie, accepted and “ready, willing, and able”), and the reporting of mortality at both time points. Along with the Provincial THV outcome evaluation program, this data informs health care planning to ensure patient access and quality of services.

**Conclusions**

The rapid emergence of transcatheter options for the management of structural heart disease is a transformative challenge for clinicians, administrators, and policy makers. Multiple new pressures are being exerted by the increasing availability of minimally invasive and expensive therapies; the implications for funding, siting of programs, planning, and allocation of health care resources are complex. Recent media stories about patients’ demanding TAVI despite not meeting indications may attest to new elements in the current debate. Ongoing close monitoring of the true wait times, adverse events, and long-term outcomes will inform a much needed thoughtful evaluation of evidence-based benchmarks for waiting for TAVI.

**Disclosures**

John Webb and Sandra Lauck are consultants to Edwards Lifesciences. John Webb and Dion Stub are consultants to St Jude Medical.

**References**