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How long is too long to wait for groundbreaking aortic valve replacement surgery?

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Severe aortic stenosis (AS) has a grave prognosis with 25-50% of patients dying within a year once symptoms develop. Transcatheter aortic valve replacement (TAVR) represents a paradigm shift in the therapeutic options for these patients. Because of cost and availability issues, there are often waiting times for this procedure. Investigators have found that even modest increases in wait times have a substantial impact on the effectiveness of TAVR in individuals who need it the most: otherwise inoperable patients and high-risk surgical candidates. Creating benchmarks for appropriate wait times should be a priority, say investigators in the *Canadian Journal of Cardiology*.

AS, a narrowing of the aortic valve opening that restricts normal blood flow to the body, is the most common heart valve disease in developed countries. Its impact on public health and health care resources is expected to become increasingly significant as the population ages. Traditionally, surgical aortic valve replacement has been the sole option for these patients. However, because of their advanced age and other health issues, a substantial proportion of severe AS patients are either very high risk for conventional surgery or inoperable.

TAVR is rapidly emerging as the recommended or preferred therapy for these patients because the replacement valve is implanted via blood vessels accessed through a small incision in the groin or heart access between the ribs, eliminating the need for a large chest incision. More

than 50,000 TAVR procedures have been performed in over 40 countries.

The landmark Placement of Aortic Transcatheter Valves (PARTNER) studies, which evaluated TAVR with the Edwards SAPIEN heart valve system in two patient cohorts, have fueled the worldwide growth in this procedure. In the PARTNER B study, TAVR was compared with conservative medical therapy in patients who were not surgical candidates. The investigators found a 20% absolute risk reduction in one-year mortality. In the PARTNER A study, investigators compared TAVR with conventional surgery for high-risk surgical candidates and found that TAVR was "noninferior" (noninferiority trials are intended to show that the effect of a new treatment is not worse than that of established therapy in an active control by more than a specified margin).

However there is a lack of data about what is an acceptable wait time for patients for whom TAVR is recommended. A team of investigators from the University of Toronto and the Institute for Clinical Evaluative Sciences in Toronto used mathematical modelling to simulate the results from the PARTNER randomized trial with increasing TAVR wait times.

The investigators found that even modest increases in TAVR wait times would have a substantial impact on the effectiveness of TAVR in inoperable patients and high-risk surgical candidates. Although TAVR would result in fewer deaths in patients deemed inoperable regardless of wait time, the magnitude of benefit decreased dramatically with longer wait times. In the high-risk surgical candidates, at TAVR wait times beyond 60 days, TAVR was less effective compared with conventional surgery, despite the high risk of conventional surgery, undermining the whole rationale for TAVR. "To our knowledge, our study is the first in the literature to evaluate the effect of delayed access to TAVR, and provides insight into the importance of wait time on outcomes," says

lead investigator Harindra C. Wijeysundera, MD, PhD, of the Schulich Heart Centre, University of Toronto.

"Our findings have implications for care delivery to severe AS patients who are TAVR candidates," continues Wijeysundera. "Because of the importance of wait-time monitoring, detailed information should be collected on the time of referral for TAVR work-up, the time at which diagnostic work-up is complete, and the time at which a patient is accepted for the procedure. Data on delays in any of these intervals should be made available to programs in a timely fashion, so that cases can be triaged. This is especially important for the patients in whom surgery is an option. The clinical decision of when high-risk surgery is preferable over TAVR should incorporate the program's current TAVR wait time and the associated potential wait-time mortality. Creating such benchmarks for appropriate wait times should be a priority."

In an accompanying editorial John Webb, MD, and colleagues from the Centre for Heart Valve Innovation, St Paul's Hospital, Vancouver, caution that the analysis by Wijeysundera and colleagues is based on relatively older data that no longer reflects current patient characteristics or the markedly improved clinical outcomes of the contemporary TAVR experience.

However, they agree that "the proposed model is an important contribution to the fledgling debate on the required mechanisms to monitor and report the effects of waiting for TAVR, 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. 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 TAVR."

More information: "Impact of Wait Times on the Effectiveness of Transcatheter Aortic Valve Replacement in Severe Aortic Valve Disease: A Discrete Event Simulation Model," by Harindra C. Wijeysundera, MD, PhD, William W.L. Wong, PhD, Maria C. Bennell, MSc, MPH, Stephen E. Fremes, MD, Sam Radhakrishnan, MD, Mark Peterson, MD, PhD, and Dennis T. Ko, MD, MSc, DOI: dx.doi.org/10.1016/j.cjca.2014.03.009

Editorial: "Monitoring Wait Times for Transcatheter Aortic Valve Implantation: A Need for National Benchmarks," by Sandra Lauck, RN, PhD, Dion Stub, MBBS, PhD, and John Webb, MD, DOI: dx.doi.org/10.1016/j.cjca.2014.05.006

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