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EDITORIAL COMMENT

Is Transcatheter Aortic Valve Replacement a Durable Therapeutic Strategy?*

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Transcatheter aortic valve replacement (TAVR) has rapidly become standard therapy for many patients for whom open surgery is considered "high risk." However, recent favorable experience in lower surgical risk patients suggests that TAVR may assume a much broader role. For this to be true, a "TAVR first" strategy would need to satisfy the needs of younger patients with lesser morbidity in whom durability assumes greater importance.

Bioprosthetic valves degenerate with time. Wear and tear, calcification, pannus formation, endocarditis, and thrombosis are the most common mechanisms of failure. Durability is determined by numerous physical factors (e.g., tissue characteristics, anticalcification treatments, leaflet and valve design, and transvalvular gradients) as well as clinical factors (e.g., patient age and various metabolic abnormalities). An optimal surgical bioprosthesis in an optimal patient may last in excess of 20 years. Unfortunately, many surgical bioprostheses fail much earlier (**Figure 1**). The potential for early failure was evident in the recent Global Valve-in-Valve registry in which the median age of failed surgical bioprostheses treated with transcatheter heart valve (THV) implantation was only 9 years (1).

The durability of THV frames has been of some concern, particularly given previous experience with fractures of some large-vessel stents and valved pulmonary conduits. Fortunately, midterm durability of more durable SAPIEN (Edwards Lifescience, Irvine, California) and CoreValve (Medtronic, Minneapolis, Minnesota) aortic frames has been well documented in vitro and in vivo (2–4).

It is reasonable to anticipate that THV leaflets might be at greater risk of early failure than surgical valve leaflets. Predisposing factors include leaflet trauma from compression within the delivery catheter or balloon dilation, suboptimal leaflet coaptation or leaflet-frame contact due to asymmetrical or incomplete frame expansion, and suboptimal implantation (5). The pursuit of lower profile delivery catheters has led to the use of thinner leaflet tissue, with the potential for reduced durability. Departure from established valve design principles and processes opens the potential for new modes of failure. Just as with surgical valves, the durability of all transcatheter valves may not be equal. Will next-generation THVs be as durable as those we have begun to trust, or will there be disappointments?

Because of these concerns, the requirements for approving THVs have been more rigorous than those applied to surgical valves. In vitro durability is routinely evaluated in accelerated wear testers for the equivalent of 5 years under varying conditions (e.g., transvalvular pressure gradients, noncircular expansion), and generally for much longer.

What do we know about real-world aortic THV durability? There have been scattered reports of valve failure due to leaflet degeneration (5–7). The predominant mechanism of failure has been progressive leaflet calcification resulting in progressive restenosis, whereas sudden and catastrophic regurgitation due to leaflet tears has been rare (5–7).

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In this issue of *JACC: Cardiovascular Interventions*, Barbanti et al. (8) add greatly to our knowledge by reporting sustained clinical outcomes 5 years after self-expandable CoreValve implantation. Valve performance was excellent, with signs of mild to

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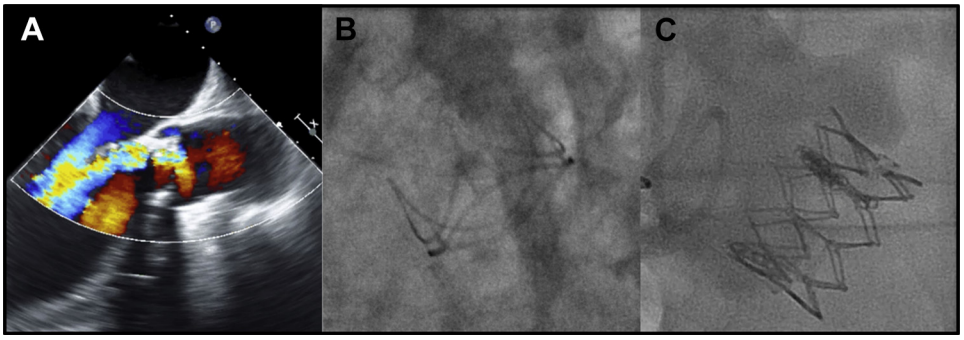
FIGURE 1 Early Failure of a 1-Year-Old Surgical Valve



(A) Severe regurgitation due to a leaflet tear. **(B)** Trifecta surgical valve (St. Jude Medical, St. Paul, Minnesota). **(C)** SAPIEN XT (Edwards Lifesciences, Irvine, California) transcatheter valve-in-valve implantation. Aortography shows no regurgitation.

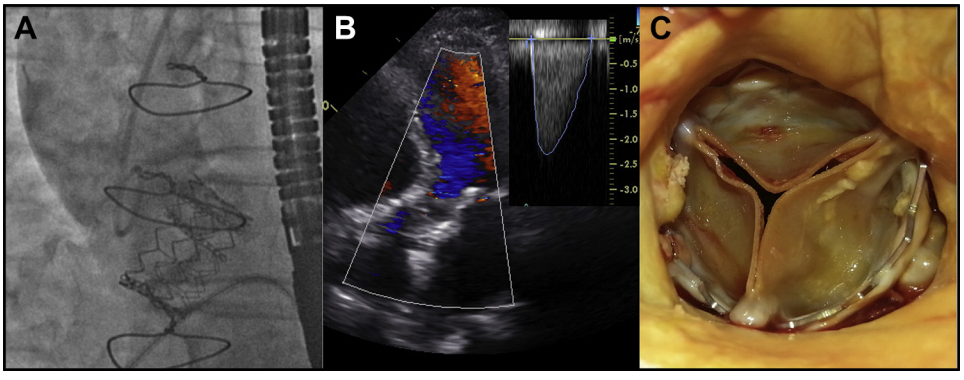
moderate prosthetic failure in only 2.8% and severe failure in only 1.4%. Our group previously reported similar sustained clinical and echocardiographic outcomes beyond 5 years for balloon-expandable SAPIEN and SAPIEN XT valves (9). Valve performance was excellent, with moderate late prosthetic stenosis seen in 3.4%, with no severe failure. Perhaps the most rigorous evaluation is from the 5-year follow-up of the PARTNER (Placement of AoRtic TraNscathetER Valve) trial. Structural failure of transcatheter valves was not observed. SAPIEN THVs had valve areas and gradients identical to those of surgical bioprostheses (10,11).

As a consequence of the population under study, follow-up beyond 5 years remains anecdotal (**Figure 2**). It is clear from multiple sources that the paucity of late survivors after TAVR is the consequence of the advanced age and comorbidities of the high-risk surgical population being treated, not valve failure (10–12).

What will happen when TAVR is applied to lower risk patients who may live long enough for their transcatheter valves to fail? Surgery may be an option for some. Removal of a purely annular valve (e.g., SAPIEN) can be relatively simple, although removal of a THV that extends into the ascending aorta (e.g., CoreValve) may require a more extensive procedure (5). However, favorable experience with THV implantation in failed surgical and transcatheter bioprostheses has demonstrated that TAVR may be more easily repeated than open surgery (13,14).

The durability of the currently available THVs appears adequate for the great majority of elderly

FIGURE 2 Midterm Durability of a Transcatheter Heart Valve



(A) A bovine pericardial SAPIEN valve (Edwards Lifesciences, Irvine, California) was implanted in 2006. **(B)** Seven years later, the transaortic mean gradient was 11 mm Hg with no aortic regurgitation. **(C)** The patient died in 2013 of unrelated causes. Postmortem examination revealed a durable valve with only minimal calcification.

patients with contraindications to surgery currently undergoing TAVR. Application in patients with longer anticipated survival will require a strategy incorporating THVs with demonstrable durability and repeatability.

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