Current transcatheter heart valves (THVs) have been developed primarily for patients with aortic stenosis. Most incorporate metallic frames that rely on high radial force to anchor the implant within a stenotic and calcified native valve. However, aortic regurgitation (AR) typically results from abnormalities of the aortic cusps or root, often without associated calcification. In patients with pure or predominant AR, it may not be possible to securely anchor a THV, with the potential for paravalvular regurgitation, malposition, or embolization.

Noncalcific AR is much less common than calcific aortic stenosis; patients are typically younger and the clinical course is more insidious. Moreover, patients with pure AR often have an aortopathy, associated with progressive dilation of the aortic root. This may itself mandate aortic surgery and may contraindicate THVs that depend on radial force for anchoring.

For these reasons, open surgical valve replacement remains the treatment of choice for pure AR. However, in some patients with comorbidities, such as severe left ventricular dysfunction or advanced age, a less invasive approach may be appealing. We will briefly review the available THV options (Table 1).

**ANCHORING IN THE ASCENDING AORTA**

The CoreValve (Medtronic, Minneapolis, Minnesota) has been used with some success in the absence of valvular calcification. The very long frame anchors not only in the aortic annulus, but also extends up to the supracrural aorta, improving stability. Several registries document the feasibility in patients with pure AR (1-3). In high surgical risk patients with pure AR, the 30-day mortality rate has ranged from 9.3% to 23%, the stroke rate from 0% to 4.7%, and the need for new pacemakers from 7.5% to 27.3%. Residual AR that is greater than mild remained in 20.9% to 23%. In the largest series to date (n = 43), a second THV was needed in 18.6% of patients, and 2.3% required conversion to open surgery (1). The reported survival rate at 1 year ranged from 64% to 79%. Although these outcomes are less desirable than reported with aortic stenosis, the CoreValve may represent a useful alternative when surgery is not an option (Figure 1).

**REPOSITIONABLE VALVES**

The CoreValve’s successor, the Evolut R (Medtronic), represents an attractive advance. This THV can be partially, but not fully, deployed and yet be recaptured in its delivery catheter and repositioned or removed if needed. Taking repositionability a step further, the inflatible Direct Flow THV (Direct Flow Medical Inc., Santa Rosa, California) and the mechanically expanded Lotus THV (Boston Scientific, Natick, Massachusetts) can be fully deployed, assessed, and, if necessary, repositioned or removed. In this issue of *JACC: Cardiovascular Interventions*, Schofer et al. (4) report the use of the Direct Flow THV in 11 high-risk patients with pure AR. AR was reduced to mild or less in all, although in 1 patient, an unstable THV required surgical valve replacement. At 30 days, the mortality rate was 9% with no strokes (4). Experience with the Lotus THV in pure AR is also favorable, but even more limited (5).
SELF-POSITIONING GEOMETRY

Some THVs incorporate self-seating geometry that facilitates optimal positioning within the annulus. The aortic and ventricular inflatable bladders of the Direct Flow THV may assist in positioning and anchoring. Similarly, the Acurate THV (Symetis SA, Ecublens, Switzerland) has a narrower waist, which may facilitate seating, along with a frame that extends into the aorta to facilitate coaxial alignment. Wendt et al. (6) reported successful implantation in 8 patients with pure AR with a reduction in AR to mild or less in all, with no deaths, major strokes, or pacemakers.

ARCHES, FEELERS, AND GRASPERS

Other valves have taken self-positioning a step further, incorporating design elements that use the leaflets of the native valve to assist in THV positioning and fixation.

The Engager (Medtronic) incorporates 3 nitinol wire “arches” that, using a transapical approach, are exposed in the aorta and withdrawn until they contact the 3 native cusps; at this point, the self-expanding THV is unsheathed and expanded. Experience with this device in pure AR is limited to isolated reports (7).

JenaValve (JenaValve Technology, Munich, Germany) incorporates 3 nitinol wire “feelers” that, using a transapical approach, are similarly exposed in the aorta and withdrawn until these contact the native cusps. As the self-expanding frame is unsheathed, the native leaflets are actively “clipped” between the feelers and the THV frame, providing additional fixation. Seiffert et al. (8) reported their experience in 31 high-risk patients with pure AR. Transcatheter aortic valve replacement was initially successful in all but 1, in whom a second THV was required. AR was reduced in mild or less in all. At 30 days, the mortality rate was 12.9%, with no patients experiencing strokes and new pacemakers implanted in 6.4%. The survival rate at 6 months was 80.7%. Schlingloff et al. (9) reported their experience with 10 patients with similar high procedural success and low paravalvular AR rates, but with a higher 30-day mortality rate of 20%.

J-Valve (JieCheng Medical Technology, Suzhou, China), takes this approach further with mobile nitinol wire leaflet “graspers” that may allow for fine positioning and active fixation to the leaflets. In this issue of JACC: Cardiovascular Interventions, Wei et al. (10) report their experience in 6 high-risk patients. In combination with another report by Zhu et al. (11), this totals 13 patients with pure or predominant AR reduced to mild or less in all, with no strokes, pacemakers, or mortality at 30 days.

BALLOON-EXPANDABLE

Prototypic balloon-expandable tubular valves have been avoided in the setting of pure AR. However, a 2-stage docking system has been effectively used by our group and others in a small number of patients (12). The Helio transcatheter aortic dock (Edwards Lifesciences, Irvine, California) consists of a nitinol frame placed in the aortic root behind the native leaflets within which a balloon-expandable THV is then deployed. The native leaflets are compressed between the dock and THV, providing secure fixation (and paravalvular sealing). A theoretical advantage is the potential to resist progressive annular dilation.

THE IDEAL VALVE?

Surgery remains the gold standard for pure AR, although current THVs may offer an option for some
patients. The association of AR with progressive aortic dilation represents a particular concern as to the durability of a conventional THV procedure. Desirable features of future THV treatment for pure AR might include the following: 1) minimally invasive implantation; 2) facilitated active positioning; 3) repositioning; 4) an effective seal; 5) a range of sizes suitable for enlarged annuli; 6) durability; and 7) fixation mechanisms that constrain, rather than dilate, the aortic annulus. Options for AR continue to improve, but compromise remains.

Reprint requests and correspondence: Dr. John Webb, St. Paul’s Hospital, 1081 Burrard Street, Vancouver, British Columbia V6Z 1Y6, Canada. E-mail: john.webb@vch.ca.
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