A new generation of transcatheter aortic valves

Age is a predictor of degenerative aortic valve disease, with around 10% of adults over 80 years of age affected with aortic stenosis, compared with 0.2% in the age group 50–59 years.[1] Patients with severe symptomatic disease are at increased risk of heart failure and death; if left untreated, patients have a very poor prognosis, with a 2-year mortality rate of 50–60% and a 3-year survival rate of less than 30%.[2] When indicated, aortic valve replacement can be done surgically or via a transcatheter approach. Surgical aortic valve replacement (SAVR) remains the preferred option in patients with low to intermediate risk of intraoperative mortality or morbidity, while transcatheter aortic valve implantation (TAVI) is indicated in high- and extreme-risk patients unsuitable for surgery, and can be considered for other high-risk patients.[1] Studies indicate that TAVI is superior to SAVR in terms of survival rates in high-risk,[3] and non-inferior in intermediate-risk patients,[4 5] although the two procedures are associated with different perioperative risks. Rates of major bleeding, acute kidney injury and new onset AF are higher with SAVR, whereas vascular complications, stroke, aortic insufficiency and pacemaker requirement occur more frequently with TAVI.[3-7] TAVI devices continue to evolve, aiming to optimise valve positioning and minimise complications, such as pacemaker requirement, stroke risk, heart block and site access difficulties.

fig. 1

Medtronic CoreValve Evolut R™

The CoreValve Evolut™ system (Medtronic Inc., Minneapolis, MN, USA), first used in 2012, brought improvements in fit (particularly in angulated anatomy), due to a reduced outflow height and total valve height of 45 mm. An alpha-amino oelic acid treatment was applied, with the aim of helping to prevent calcification of the valve leaflets in the short and long term, by its binding to aldehyde groups in the pericardial tissue, thereby enhancing the valve's durability.[8]

The most recent device to be launched is the CoreValve Evolut R™ (Medtronic Inc.), available in 23, 26 and 29 mm diameters (figure 1), which is suitable for treating patients with annulus sizes 18-26 mm. A larger valve to treat an annulus size of up to 30 mm is under development. The device comprises a self-expanding nitinol frame, with an extended inflow tract skirt.[9] Radial force of the inflow is more consistent across a range of annulus diameters than that seen with the original CoreValve®, which improves sealing and reduces paravalvular leak.[10] The EnVeo R™ (Medtronic Inc.) is a next generation delivery catheter (figure 2), designed for use with Evolut R, that has a 14 Fr equivalent delivery profile (true 18 Fr outer diameter), representing a 4 Fr reduction and one of the smallest delivery catheter diameters.[11, 12] In addition, the capsule allows a partially deployed valve (up to 80%) to be resheathed or recaptured, allowing for repositioning if required.[11] In the pivotal CE study, 60 high- or extreme-risk patients (mean age 82.8 years) underwent TAVI using the CoreValve Evolut R (98% via transfemoral implantation). At Day 30, no deaths or strokes had occurred. The mean aortic valve gradient was significantly reduced from 49.1±13.0 mmHg at baseline to 9.2±3.9 mmHg 24-hours post-procedure, and 8.1±3.3 mmHg at Day 30 ($p<0.0001$). Pacemaker implantation rate was 11.7%, and 8.3% of patients experienced major vascular complications. Acute kidney injury

fig. 2

Medtronic Enveo R™ delivery catheter

stage 2 or 3 was experienced by 1.7% of patients. Repositioning of the valve was successful on all attempts (22 attempts in 15 patients). No patient developed severe paravalvular regurgitation (PVR), and 3.4% of patients experienced moderate PVR.[13]

The Sadra® Lotus™ valve (Boston Scientific, Natick, MA, USA) is another nitinol frame device, with an additional sealing membrane on the prosthesis skirt that helps minimise paravalvular leak. Delivery is via a retrograde approach using an 18–20 Fr delivery system, and the device can be recaptured or repositioned if required.[14] In the REPRISE II study, 120 high-risk patients (mean age 84.4 years) underwent successful implantation of the Lotus valve system, with a resulting mean gradient of 11.5 mmHg. Pacemaker implantation was required in 28.6% of patients (n=34), and Day 30 mortality rate was 4.2%. Disabling stroke and moderate PVR occurred in 1.7% and 1.0% of patients, respectively, at Day 30. No patients experienced severe PVR. Repositioning and retrieval was successful in all attempts (n=32).[15]

The SAPIEN 3 valve (Edwards Lifesciences, Irvine, CA, USA) is a balloon-expandable valve, incorporating a cobalt chromium frame with an internal skirt on the inflow, and an additional outer sealing cuff to improve paravalvular sealing and minimise regurgitation. It is delivered via the Commander catheter (Edwards Lifesciences Inc.), which is accommodated in a 14–16 Fr expandable sheath that enlarges as the valve passes through the sheath. The CE study was a prospective, single-arm multi-centre study, in which 150 high- or intermediate-risk patients (mean age 83.6±5.0 years) underwent TAVI using the SAPIEN 3 (Edwards Lifesciences Inc.). Transfemoral approach was used in 64% of procedures. At Day 30, mortality rate was 2.1%, stroke rate was 1%, pacemaker implantation rate was 12.5%, and 1% of patients experienced acute kidney injury (stage 2 or 3) in patients undergoing transfemoral implantation (n=96). Overall, transaortic mean gradient fell significantly from 45.2±14.5 mmHg at baseline to 10.6±4.7 mmHg at Day 30 ($p<0.0001$). No patient developed severe PVR and 3.5% of patients developed moderate PVR.[16]

The Portico™ aortic valve (St Jude Medical, Inc., St Paul, MN, USA) is another self-expanding nitinol stent, with a non-flared annulus and porcine pericardial sealing cuff, designed for implantation at the annular level with minimal protrusion into the left ventricular outflow tract, which may help reduce conduction defects and pacemaker requirement. It is available in 23, 25, 27 and 29 mm sizes, and is suitable for annuli 19–27 mm. Delivery can be transfemoral using an 18–19 Fr catheter, or transapical using a 24 Fr catheter without the need for an introducer sheath. Resheathing, repositioning or retrieval are possible. The CE study was a prospective, non-randomised, multi-centre trial. Out of 103 patients assessed at Day 30, mortality rate was 2.9%, pacemaker implantation rate was 9.7%, disabling stroke rate was 2.9%, and acute kidney injury occurred in 7.8% of patients (1.9% stage 3). Average mean gradient fell significantly from 45.5 mmHg at baseline to 8.8 mmHg at Day 30. No patient experienced severe PVR, and 4% of patients experienced moderate PVR.[17]

At present, TAVI is primarily considered suitable for high-risk patients who cannot undergo surgery. A new generation of devices is being developed with the aim of improving safety and simplifying delivery through a range of measures, including reduction in the size of delivery catheter required, increased flexibility to allow for repositioning or retrieval of the catheter so that achieving optimal positioning is more feasible, and measures to minimise complications associated with TAVI, such as paravalvular leak and pacemaker requirement. Trials of these devices in patients have already begun, and have shown promising results; achieving improved outcomes in these parameters may expand the population for whom TAVI is considered suitable.

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