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Section Editors

Surgical Aortic Valve Replacement—Clinical Update on Recent Advances in the Contemporary Era

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THE ADVANCES IN surgical aortic valve replacement (AVR) have continued steadily, including the growing clinical experience with minimally invasive AVR.[1] The rapid dissemination of transcatheter AVR has further accelerated the evolution of surgical AVR with the advent of sutureless valve prostheses that can be deployed rapidly to facilitate shorter myocardial ischemic and cardiopulmonary bypass times.[2] This expert review will focus on these 2 major innovations in surgical AVR in the contemporary era in which transcatheter AVR continues to challenge the traditional indications and techniques for interventional management of aortic valve disease.[3,4]

MINIMALLY INVASIVE AORTIC VALVE REPLACEMENT

The first minimally invasive aortic valve replacement (MIAVR) was performed in 1993 via right thoracotomy.[5] In 1996, techniques for MIAVR included a variety of access approaches such as partial midline sternotomy, transverse sternotomy, and parasternal approaches.[6] Thereafter, clinical trials soon demonstrated outcome advantages such as shorter hospital stay and lower costs.[7,8] Furthermore, the unique anesthetic considerations for MIAVR also were realized at this time, including the advent of the percutaneous pulmonary artery vent and the coronary sinus cannula for administration of retrograde cardioplegia.[9,10] In the contemporary era, the predominant approaches for surgical access in MIAVR are the upper hemisternotomy (UHS) and the right anterior thoracotomy (RAT) (Figs 1–4).[10–12]

Careful procedural planning is imperative in MIAVR, because unique considerations depend on the selected surgical access approach.[10–12] In the setting of a RAT approach, significant pulmonary pathology such as prior resections and severe lung disease may increase overall perioperative risk.[10–12] In the setting of a UHS approach, MIAVR should be approached very cautiously in patients with severe chest wall deformities such as kyphoscoliosis and pectus excavatum.[10–12] Patients with risk factors for dense adhesions, such as prior cardiac surgery, should have preoperative chest computerized tomography to assess the risks of surgical entry (Figs 1 and 5).[10–12] Furthermore, computed tomographic angiography facilitates detailed vascular imaging in candidates for central aortic cannulation and peripheral femoral cannulation for cardiopulmonary bypass (CPB) (Fig 6).[10–12] Femoral arterial cannulation for CPB is typically via the common femoral artery with the cannula tip in the external femoral artery to preserve perfusion of the internal iliac artery (Fig 7). Arterial cannulation is typically via the Seldinger technique, including visualization of the wire in the descending thoracic aorta by transesophageal echocardiography (TEE). Furthermore, no tourniquets are placed around the femoral artery to allow antegrade perfusion of the lower extremity.[10–12] Monitoring for ischemia of the ipsilateral lower extremity can be conducted via pulse oximetry or near-infrared spectroscopy. If ischemia is detected, an antegrade perfusion cannula can be placed and connected to the arterial circuit for dedicated lower limb perfusion.[10–12]

Femoral venous cannulation for CPB is also via the Seldinger technique with visualization of the wire in the superior vena cava.[10–12] The advancement of the venous cannula also can be performed with TEE guidance to prevent trauma to the right atrial appendage, the coronary sinus, the tricuspid valve, and the atrial septum, including traumatic enlargement of a patent foramen ovale.[10–12] Besides antegrade cardioplegia via the ascending aorta, retrograde cardioplegia also can be delivered via a percutaneous coronary sinus catheter placed under TEE guidance by the anesthesia team via the right internal jugular vein (Figs 2 and 3).[10–12] The maintenance of left ventricular decompression during CPB for MIAVR may not be possible via the right superior pulmonary vein (standard access for left ventricular venting in cardiac surgery) because surgical access is by

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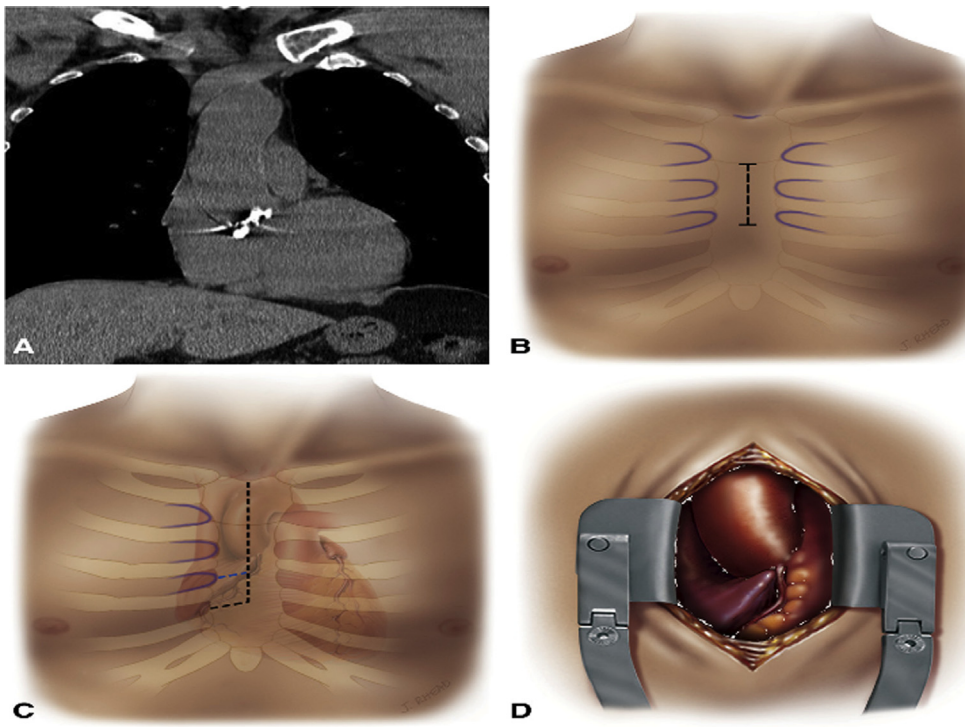

Fig 1. Upper hemisternotmy incision. (A) Preoperative chest computed tomography to identify the location of the aortic valve in relation to the sternum. (B) Skin incision for upper hemisternotomy. (C) J incision at the level of the third and fourth intercostal spaces. (D) Surgical exposure through an upper hemisternotomy; the ascending aorta and the right atrial appendage are clearly visible.[10]

definition very limited.[10–12] In this situation, the anesthesia team has the option to float a pulmonary artery vent (EndoVent, Edwards Life Sciences, Irvine, CA) via the right internal jugular vein (Fig 4).[10–12] Despite limited surgical access, selective lung ventilation via double-lumen endotracheal tube is not required for MIAVR, even with a RAT approach, as the right lung is mechanically retracted posteriorly without the need for 1-lung ventilation.[10–12] High-volume centers also emphasize a fast-track perioperative approach for patients undergoing MIAVR.[10–14] Anesthetic management is titrated toward early tracheal extubation and rapid recovery, with minimization of narcotics, dexmedetomidine for sedation, and multimodal perioperative analgesia, including liposomal local anesthetics such as bupivacaine.[10–14] The successful conduct of MIAVR requires close perioperative teamwork with essential contributions from the anesthesia team.[13,14]

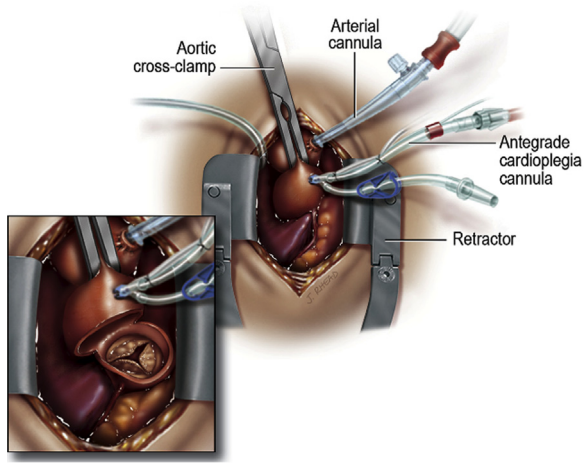

Fig 2. Upper hemisternotomy incision with central cannulation for cardiopulmonary bypass. The arterial cannula is in the ascending aorta above the aortic cross-clamp. The antegrade cardioplegia cannula is in the ascending aorta below the aortic cross-clamp. The venous cannula in this setting either can be placed directly in the right atrium via the right atrial appendage or can be placed via the femoral vein to facilitate surgical exposure of the aortic valve through this minimally invasive incision.[10]

Since the introduction of MIAVR, the evidence base has rapidly grown.[15–25] Multiple clinical trials have demonstrated the outcome benefits associated with MIAVR, such as significant reductions in bleeding, transfusion, duration of mechanical ventilation, and length of stay in the intensive care unit and hospital.[15–25] Furthermore, high-volume centers also have demonstrated that MIAVR facilitates a more rapid recovery with less postoperative pain and improved cosmetic results.[15–25] Beyond these outcome advantages, the question remains whether MIAVR also can reduce mortality and major morbidity such as stroke. Bakir et al, in a 2006 study of 506 patients, showed no statistical differences in stroke with MIAVR.[26] In a large study of 1,000 patients undergoing MIAVR in 2008, Tabata et al reported an operative mortality of 1.9% and an actuarial 5-year survival of 84%, both of which are comparable to AVR with median sternotomy.[17] A recent meta-analysis (N = 683,286: 172 studies) demonstrated that isolated conventional AVR has low morbidity and mortality, although mortality increased significantly with advanced age (60 years 3.3%; 60-69 years 2.7%; 70-79 years 3.8%; ≥80 years 6.1%:

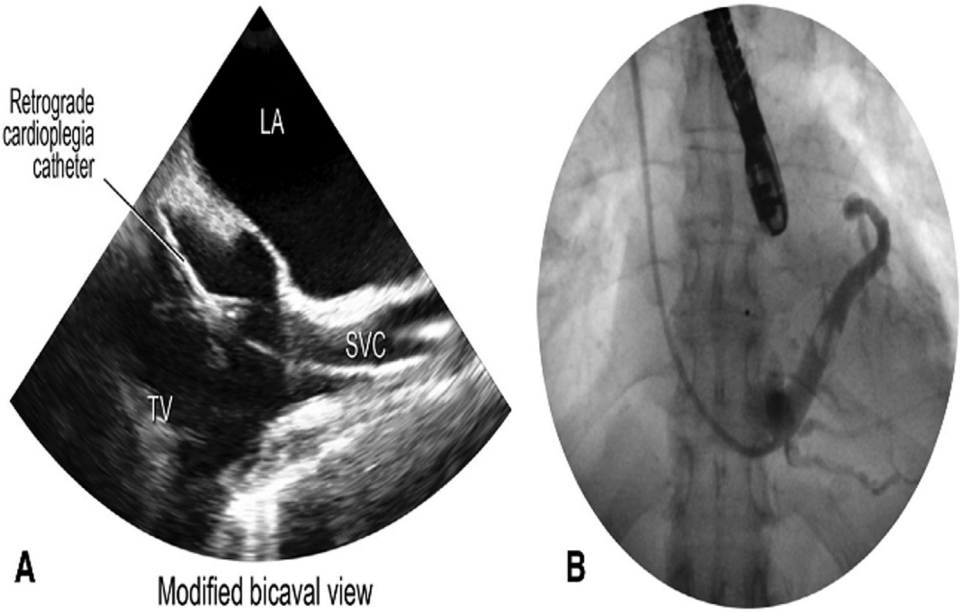

Fig 3. Placement of the percutaneous coronary sinus cannula. (A) Guidance with transesophageal echocardiography in the midesophageal bicaval view. (B) Guidance with fluoroscopy–the transesophageal echocardiography probe is also clearly visible.[10] LA, left atrium; SVC, superior vena cava; TV, tricuspid valve.

$p < 0.001$).[27] Further analysis revealed that there was a trend to lower mortality associated with MIAVR (MIAVR 2.3%; 95% confidence interval [CI] 1.8%-2.9%: N = 4,367 *v* conventional AVR 3.5%; 95% CI 2.8%-4.1%: N = 11,076: p = 0.088).[27] A second meta-analysis (N = 12,786: 50 comparative studies) focused exclusively on MIAVR but noted that the overall quality of the evidence was low with limited statistical power and wide heterogeneity among the clinical trials.[28] In this meta-analysis, MIAVR as compared to conventional AVR, significantly reduced transfusion burden, intensive care unit stay, hospitalization, and renal failure with an equivalent mortality risk.[28] These investigators suggested that further high-quality randomized trials were indicated to evaluate with greater confidence the outcome effects of MIAVR.[28] In an effort to address this evidence gap, a third meta-analysis (N = 4,670: 18 studies) assessed the clinical impact of MIAVR with a pooled analysis of 18 propensity-matched observational trials and 6 randomized controlled trials.[29] In this meta-analysis, MIAVR as compared to conventional AVR significantly reduced duration of mechanical ventilation (7.5 hours *v* 11.1 hours: p = 0.07) and hospital stay ($p < 0.01$) with equivalent effects on transfusion (odds ratio 0.77; 95% CI 0.51-1.14;

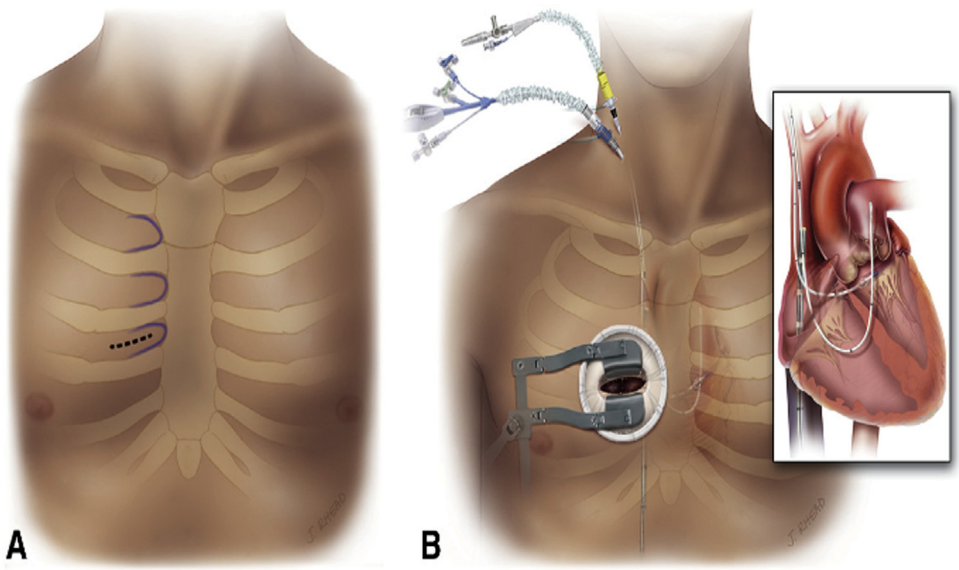

Fig 4. Right anterior thoracotomy incision. (A) Right third intercostal space. (B) Surgical exposure–the right panel insert demonstrates the vascular positions of the percutaneous cannulae, namely the coronary sinus cannula and the pulmonary arterial vent.[10]

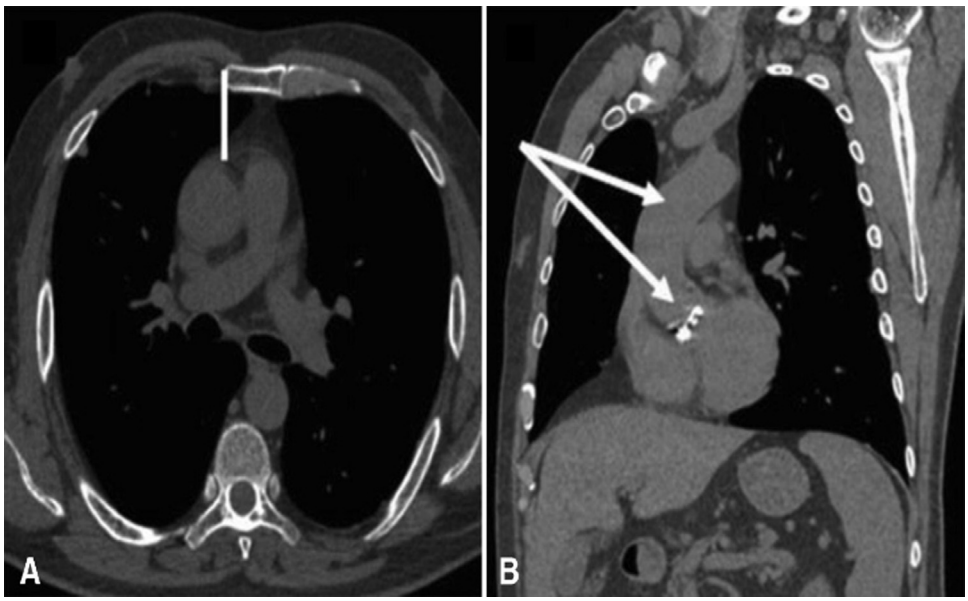

Fig 5. Preoperative chest computed tomography. (A) Axial plane. (B) Sagittal plane–preoperative chest computed tomography can facilitate the identification of the distance from the sternum to the right ventricle and the location of the aortic valve in relation to the sternum. These anatomic factors guide the planning and choice of surgical access in minimally invasive AVR.[10]

p = 0.19), pain scores (p = 0.20), atrial fibrillation (p = 0.67), stroke (p = 0.79), and perioperative mortality (odds ratio 0.70; 95% CI 0.46-1.06; p = 0.09).[29] Despite this pooled analysis of higher quality evidence, further randomized trials still are required to evaluate the outcome advantages associated with MIAVR.

Besides the outcome advantages of MIAVR as compared to conventional AVR, the ideal surgical approach for MIAVR is also still a matter of debate. A recent clinical trial explored in MIAVR whether the RAT approach yielded superior clinical outcomes as compared with the UHS approach.[30] In this single-center observational clinical trial (N = 406 MIAVR: 251 RAT; 155% UHS: 2005-2011), the RAT approach was associated with significant reductions in atrial fibrillation (p = 0.01), duration of mechanical ventilation (p = 0.003), intensive care unit stay (p = 0.001), and hospital stay (p = 0.0001).[30] Furthermore, a large multicenter analysis demonstrated that the RAT approach for MIAVR significantly reduced overall costs as compared to sternotomy-based approaches, including UHS.[31] Further trials are indicated to explore the full extent of further outcome improvement related to choice of surgical access approach for MIAVR.

The outcome effects of MIAVR with both RAT and UHS as compared to conventional AVR also have been more recently explored in higher-risk settings such as advanced age and previous AVR.[32–37] The evidence base to date has demonstrated that MIAVR with either surgical approach is a safe and reasonable alternative in these higher-risk AVR populations.[34–37] A recent single-center propensity-matched (N = 105: 1997-2011) analysis demonstrated that in octogenarians presenting for repeat AVR, MIAVR was associated significantly with reduced mortality both at 1 and 5 years (p = 0.28).[37] In this analysis, independent predictors of mortality included extreme age (hazard ratio 1.150; 95% CI 1.052-1.256; p < 0.002), full sternotomy (hazard ratio 2.162; 95% CI 1.149-4.071;

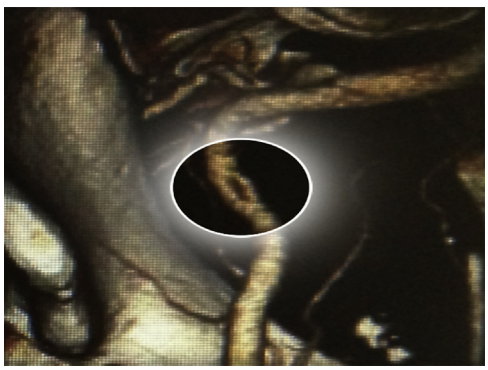

Fig 6. Preoperative chest computed tomography. Angiography with computed tomography in a patient scheduled for minimally invasive aortic valve replacement demonstrates iatrogenic dissection of the external iliac artery after cardiac catheterization.[10]

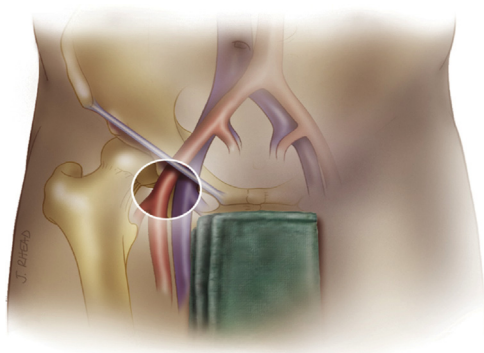

Fig 7. Technique for exposure of femoral vessels. Anterior exposure of the femoral artery and vein in preparation for vascular cannulation for cardiopulmonary bypass.[10]

Fig 8. The 3F Enable self-expanding sutureless aortic bioprosthesis.[39]

$p < 0.017$), and reoperation for bleeding (hazard ratio 7.983; 95% CI 2.666-23.904; $p < 0.001$).[37] Although further trials are still required, it is likely that MIAVR has major outcome advantages in higher-risk AVR cohorts as compared to conventional AVR.

SUTURELESS AORTIC VALVE REPLACEMENT

The evolution of MIAVR has progressed steadily so that in the contemporary era, it is a mature technique with either the RAT or UHS approach.[10–14] The advent of sutureless AVR (SUAVR) prostheses that can be deployed rapidly has resulted in significant reductions in operative time for MIAVR, with the possibility that this technique could be the new alternative to transcatheter aortic valve replacement in high-risk patients.[14,38,39] Recent meta-analysis of 12 observational studies (MIAVR 40.4%) demonstrated that SUAVR had a mortality of 2.1% at 30 days and 4.9% at 1 year.[39] Furthermore, the pooled incidences of the following outcomes were as follows: stroke 1.5%; valve degeneration 0.4%; and paravalvular leak 3.0%.[39] Given the safety and efficacy of SUAVR, they likely will be integrated into the menu of therapeutic options for patients with aortic stenosis.

SUTURELESS AORTIC VALVE PROSTHESES

The prostheses for SUAVR are biologic pericardial valves that can be anchored within the aortic annulus with no more than 3 sutures.[38] There are currently 3 commercially available prostheses (Figs 8–10):[40–42] the 3F Enable (Medtronic, Minneapolis, MI), Perceval S (Sorin, Suluggia, Italy), and Intuity Elite (Edwards Lifesciences, Irvine, CA).[38,39,43,44] The 3F Enable and Perceval S SUAVR are contained within nitinol.[38,39,43–45] The Intuity valve has a stainless steel frame that is expanded by a balloon catheter system and requires three sutures.[38,39,43–45] Although these current SUAVR options offer rapid deployment in the aortic annulus as their main innovation, they still share the following similarities with conventional AVR prostheses: surgical access via full sternotomy or via an MIAVR approach such as RAT or UHS; the requirement for CPB and aortic cross-clamping; aortotomy with complete excision of the diseased native valve for complete aortic

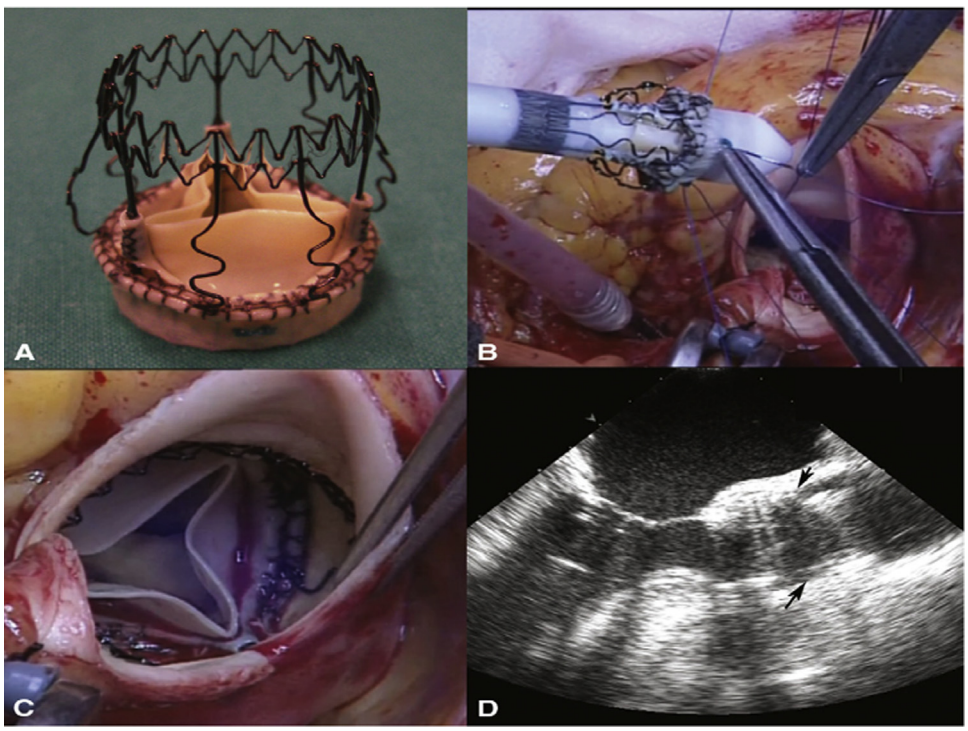

Fig 9. The Perceval S self-expanding sutureless aortic bioprosthesis. (A) The pericardial leaflets and the nitinol frame are illustrated in this panel. (B) The bioprosthesis is mounted on the holder and prepared for correct positioning within the aortic annulus. (C) The bioprosthesis is correctly deployed. (D) Transesophageal echocardiography demonstrates in the midesophageal long-axis aortic view that the Perceval S bioprosthesis is correctly positioned in the aortic annulus and aortic root (arrows).[40]

Fig 10. The Intuity Elite sutureless aortic bioprosthesis. The Intuity Elite bioprosthesis is shown before (left) and after deployment (right). The deployment of this sutureless aortic bioprosthesis requires balloon inflation.[41]

annular exposure; valve size selection as measured on CPB; and valve implantation under direct vision.[43–45] As outlined earlier, the rapid deployment of SUAVR offers the option for reduced operative times that may improve clinical outcomes.[38,43–45] Although the technology for SUAVR is similar in principle to transcatheter AVR (TAVR), there remain the following important differences between SUAVR and TAVR. The SUAVR approach provides for complete debridement of the aortic annulus that may reduce the risk for cerebral embolism. Furthermore, the direct visualization of the aortic annulus may allow for better seating of the AVR prosthesis with an atraumatic valve insertion that requires no crimping of valve leaflets for a potentially lower risk of paravalvular leak and enhanced valve durability.[38,39,43–45]

SUTURELESS VERSUS CONVENTIONAL AORTIC VALVE PROSTHESES

Multiple clinical trials have compared SUAVR to conventional AVR prostheses. A single-center trial (N = 120) demonstrated that SUAVR in elderly patients with small aortic annuli yielded equivalent clinical outcomes, including mortality.[46] A larger single-center trial (N = 515: 246 SUAVR) evaluated SUAVR as compared to conventional valves in MIAVR via RAT.[47] Although the CPB and cross-clamp times were significantly reduced in the SUAVR cohort, in-hospital mortality, stroke, and risk for permanent pacemaker were equivalent.[47] At a median follow-up of 21 months, survival was significantly higher in octogenarians (100% *v* 50%: p = 0.02), suggesting that SUAVR can further enhance the outcome advantages of MIAVR in this high-risk cohort.[47] In a single-center trial (N = 164: 82 matched pairs) from Germany, propensity analysis revealed that SUAVR was associated with significant reductions in operative time, blood transfusion, atrial fibrillation, duration of mechanical ventilation, intensive care unit stay, and overall cost.[48] A small randomized trial (N = 94: 46 SUAVR and 48 conventional AVR) demonstrated that SUAVR reduced operative time, with equivalent clinical outcomes, including quality of life.[49] In a multicenter European trial (N = 565: 182 SUAVR via UHS and 383 conventional AVR with full sternotomy), propensity-score matching demonstrated that SUAVR significantly reduced operative times and transfusion with equivalent mortality risk and higher risk for permanent pacemaker.[50]

The evidence suggests that SUAVR can further enhance the outcome advantages of MIAVR. A single-center trial (N = 593 RAT MIAVR: 51% SUAVR: 2004-2014) demonstrated excellent results with an in-hospital mortality rate of 1.5% with fast-tracking of most patients through the intensive care unit and hospital.[51] The CPB and aortic cross-clamp times were significantly reduced with application of SUAVR ($p < 0.0005$).[52] Given that a recent trial has demonstrated the durability of SUAVR at 5 years, it is likely that MIAVR with SUAVR will compete to be the new gold standard for surgical AVR, especially in higher-risk patient cohorts.[52,53] A recent consensus from an international panel of experts has addressed in detail the therapeutic niche of SUAVR for management of aortic valve disease.[45] Although a thorough discussion of this expert consensus paper is beyond the scope of this review, the recommendations for SUAVR are still based largely on opinion and limited clinical trials, given that this technology recently has entered clinical practice.[45] It is likely that the evidence base for future guidelines about SUAVR will have an even higher quality. The major innovations of MIAVR and SUAVR have resulted in a paradigm shift for surgical AVR that may affect the future balance between surgical and transcatheter valve interventions for aortic valve disease.[54–56] It remains essential that institutions and surgeons integrate the SUAVR technology into clinical practice in the setting of adequate education and proctoring in order to minimize the outcome effects of the learning curve inherent with this paradigm-shifting hardware.[45]

SUTURELESS VERSUS TRANSCATHETER AORTIC VALVE PROSTHESES

The ongoing advances in TAVR have established its role for management of severe aortic stenosis in high- and intermediate-

risk patients in an ongoing trend that steadily challenges the role of surgical AVR, including MIAVR with SUAVR.[56–58] The progress with SUAVR has resulted in the rapid adoption of this technology into clinical practice.[40–42,59,60] A multicenter propensity-matched analysis (N = 76: 2008-2011) between SUAVR and transapical TAVR demonstrated equivalent mortality, stroke, risk for permanent pacemaker, dialysis, and valvular gradients, although the risk for paravalvular leak was significantly greater in the TAVR cohort (44.7% *v* 15.8%: p = 0.001).[59] A larger single-center propensity-matched analysis (N = 244: 2010-2012) demonstrated equivalent perioperative mortality, stroke, and risk for permanent pacemaker with a significantly greater risk for paravalvular leak in the TAVR cohort (13.5% *v* 0%: p = 0.027).[61] At a mean follow-up of 18.9 ± 10.1 months, survival was significantly better in the SUAVR cohort as compared to the TAVR cohort (97.3% *v* 86.5%: p = 0.015).[61] In this analysis, 62.3% of the SUAVR cohort had MIAVR and 40.2% of the TAVR cohort underwent transfemoral access for this procedure.[61] The investigators concluded that SUAVR has a role in selected high-risk patients with severe aortic stenosis (AS) in the context of clinical decision making by the multispecialty heart valve team.[61]

A third single-center analysis (N = 163 intermediate- to high-risk patients with severe AS: 55 conventional AVR; 53 SUAVR; 55 TAVR) demonstrated that TAVR was associated with a higher risk for permanent pacemaker ($p < 0.001$) and peripheral vascular complications ($p < 0.001$).[62] Furthermore, at 2 years, TAVR was associated with significantly less freedom from adverse cerebrovascular and cardiac events, including prosthetic regurgitation (p = 0.015).[62] In this analysis, the selection of a particular management intervention was guided by a multidisciplinary heart team, taking into account all clinical considerations including frailty, anatomy, and atheroma burden.[62] The investigators concluded that SUAVR may have a significant role in selected intermediate- to high-risk patients with severe AS.[62] A fourth single-center propensity-matched analysis (N = 74 high-risk patients with AS: 38 MIAVR with RAT and SUAVR; 38 TAVR: 2008-2013) demonstrated that clinical outcomes were equivalent in the short- and mid-term, with significantly less risk for paravalvular leak ($p < 0.001$) in the MIAVR cohort.[63] Overall, these clinical trials suggested that SUAVR has a role in high-risk operable patients with AS with overall equivalent outcomes and a significantly lower risk for paravalvular leak, given the advantages of aortic annular debridement and valve implantation under direct vision. Further trials are required to explore in more detail the outcome advantages of MIAVR with SUAVR in this setting.

CONCLUSIONS

Conventional AVR via full sternotomy and CPB is no longer the only option for surgical management of aortic valve disease. This traditional paradigm has been challenged by the advent of 3 major innovations: first, the less invasive surgical approaches of MIAVR with RAT and UHS emerging as the favored access approaches; second, the family of SUAVR that offer the surgeon the opportunity for rapid valve deployment with significant reduction in operative time; and, finally the ongoing progress in TAVR.[64,65] The rapid dissemination of TAVR for management of severe aortic stenosis from high-risk patients to intermediate-risk patients in the contemporary era suggests that this clinical drift coupled with ongoing advances will reach low-risk patients within the coming decade.[64] Given this trend, the roles of conventional AVR and MIAVR with SUAVR may be further challenged with respect to severe aortic stenosis. With respect to severe aortic insufficiency, there is currently less progress in the TAVR arena, suggesting that for this indication, the traditional paradigm of conventional AVR with CPB will be challenged less by TAVR and more by advances in aortic valve repair, as well as MIAVR with SUAVR.[64,65]

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