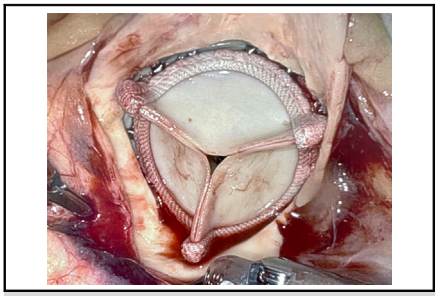
Outcomes following initial multicenter experience with robotic aortic valve replacement: Defining a path forward

Vinay Badhwar, MD,[a] Daniel Pereda, MD, PhD,[b] Feras H. Khaliel, MD,[c] Robinson Poffo, MD,[d] Ali Darehzereshki, MD,[a] J. Hunter Mehaffey, MD, MSc,[a] Tristan D. Yan, MD, PhD,[e] Serguei Melnitchouk, MD, MPH,[f] Arnar Geirsson, MD,[g] Arman Arghami, MD,[h] Jose L. Navia, MD,[i] Goya V. Raikar, MD,[j] Alberto C. Weber, MD,[k] Danny Ramzy, MD,[l] Štěpán Černý, MD, PhD,[m] Jan Vojáček, MD, PhD,[n] Robert L. Smith, MD,[o] Johannes Bonatti, MD,[p] Vinod H. Thourani, MD,[q] and Lawrence M. Wei, MD[a]

In the current era of available minimally invasive transcatheter and surgical options for the initial management of symptomatic aortic valve disease, patients and providers may seek alternatives to a traditional sternotomy approach for surgical aortic valve replacement (SAVR). Although the controversies surrounding the optimal approach for low- to intermediate-risk patients are being worked out through the continued examination of longitudinal evidence,[1-4] one thing remains certain: The longitudinal outcomes of open SAVR have been consistent over time.[4-6] Although alternative anterior chest wall options exist for a minimally invasive approach to aortic valve surgery,[7,8] in an effort to maintain the technical aspects of traditional prosthetic SAVR but further reduce invasiveness, lateral minithoracotomy endoscopic robotic aortic valve replacement (RAVR) has been established.[9,10]

The objective of this review was to report the initial 200 international cases performed, provide a status update on the progress of multicenter RAVR adoption, and present recommendations on program development and training.



RAVR.

CENTRAL MESSAGE

RAVR approaches conventional SAVR via a minimally invasive lateral approach with additional flexibility for concomitant procedures.

TECHNIQUE

The development, implementation, and technical details of RAVR have been described previously.[9-11] To summarize, before induction of double-lumen endotracheal anesthesia, patients receive upper-extremity arterial monitoring and intrathecal injection of 0.1 mg morphine sulfate. Cardiopulmonary bypass (CPB) is initiated via peripheral cannulation established through the right common femoral artery and vein, and the right internal jugular vein. All patients receive a 5F distal perfusion catheter in the superficial femoral artery connected to the ipsilateral arterial cannula. An aortic root vent is then placed through the 3-cm working incision followed by a left ventricular vent through the right superior pulmonary vein via a separate chest wall stab incision. The da Vinci Xi robot (Intuitive Surgical) is used with the camera port through the working incision (arm 2). Three additional ports include DeBakey forceps (arm 1), long-tip grasping

From the [a]Department of Cardiovascular and Thoracic Surgery, West Virginia University, Morgantown, WVa; [b]Department of Cardiovascular Surgery, Hospital Clinic, University of Barcelona, Barcelona, Spain; [c]Division of Cardiac Surgery, King Faisal Specialist Hospital & Research Center, Riyadh, Saudi Arabia; [d]Department of Cardiovascular Surgery, Hospital Moriah, Sao Paulo, Brazil; [e]Department of Cardiothoracic Surgery, The Royal Prince Alfred Hospital, Sydney, Australia; [f]Division of Cardiac Surgery, Massachusetts General Hospital, Boston, Mass; [g]Division of Cardiac, Thoracic and Vascular Surgery, New York-Presbyterian Columbia University Medical Center, New York, NY; [h]Department of Cardiovascular Surgery, Mayo Clinic, Rochester, Minn; [i]Department of Thoracic and Cardiovascular Surgery, Cleveland Clinic Florida, Weston, Fla; [j]Division of Cardiothoracic Surgery, Medical College of Wisconsin, Pleasant Prairie, Wis; [k]Department of Cardiovascular Surgery, Herzzentrum Hislanden, Zurich, Switzerland; [l]Division of Cardiac Surgery, McGovern Medical School, UTHealth, Houston, Tex; [m]Department of Cardiac Surgery, University Hospital Motol, Prague, Czech Republic; [n]Department of Cardiac Surgery, University Hospital, Hradec Kralove, Czech Republic; [o]Division of Cardiac Surgery, Baylor Scott & White Health, Plano, Tex; [p]Department of Cardiothoracic Surgery, University of Pittsburgh, Pittsburgh, Pa; and [q]Department of Cardiothoracic Surgery, Piedmont Healthcare, Atlanta, Ga.

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Address for reprints: Vinay Badhwar, MD, Department of Cardiovascular and Thoracic Surgery, West Virginia University, 1 Medical Center Dr, PO Box 8059, Morgantown, WV 26506-8059 (E-mail: vinay.badhwar@wvumedicine.org).

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forceps (arm 3), and scissors/needle driver (arm 4) with patient positioning and port locations nearly identical to those used for robotic mitral valve (MV) surgery (Figure 1). A transthoracic aortic crossclamp is then applied, and antegrade cardioplegic solution is delivered via the aortic root or directly via the coronary ostia in the setting of moderate or greater aortic insufficiency.

Under full robotic assistance, a transverse aortotomy at or above the sinotubular junction is extended down to the midpoint of the noncoronary sinus to provide excellent visualization of the aortic valve (Figure 2, *A*). The robotic curved scissors and long-tip grasping forceps (Intuitive Surgical) are used in all cases to facilitate the total debridement of leaflets and all calcific debris with precise tableside assistance. In more than 200 cases, a rongeur or any other similar instruments to debride the annulus have not been required. Circumferential interrupted 2-0 braided polyester sutures are robotically placed from the ventricular side starting from the left noncommissure and proceeding circumferentially clockwise. Switching to a left-handed suture placement once approaching the right noncommissure facilitates tableside suture management and eliminates potential inadvertent instrument trauma to the aortotomy. Once annular suture placement is complete, sizing is performed using conventional SAVR sizers. The sutures are passed through the sewing ring of the prosthesis by the tableside assistant, and the valve is navigated through the working incision after it has been separated from the handle to facilitate careful delivery and annular placement. Suture fasters (Core-Knot; LSI Solutions) facilitate securing the valve in place (Figure 2, *B*). The aortotomy is then closed using 4-0 polypropylene suture in 2 layers in a standard fashion. All patients receive atrial and ventricular pacing wires and silastic chest drains. The heart is then reanimated, the crossclamp is released, the robot is undocked, and the patient is weaned from CPB, decannulated, and closed.

TRANSPARENT DISSEMINATION AND OUTCOME REPORTING

After the initial development of RAVR and the first case performed on January 10, 2020, at West Virginia University (WVU), an international team of experienced robotic and nonrobotic valve surgeons was assembled for the purpose of reviewing the operative technique and all early results, and to help ascertain the optimal manner in which to disseminate RAVR in a safe and transparent manner. In November 2022, this group of leaders met in Morgantown, West Virginia, for a multi-day symposium with multiple live cases and data sharing. The objective of these sessions was to assimilate feedback on technique, approach, and patient selection. Consensus on training pathways for RAVR dissemination was attained that included initial procedural homogeneity, shared reporting, and a stepwise approach for surgeons to safely build a program to align with existing training recommendations.[12]

As programs commenced RAVR, outcome reporting and transparent data tracking were thought to be of critical importance to adhere to patient safety and quality. To support data sharing, this international RAVR consortium agreed to contribute to a central database including preoperative characteristics, operative details, postoperative events, and 30-day and 1-year echocardiographic and heart failure data. The multi-institutional collaborative database was created and housed at WVU to prospectively follow all patients undergoing RAVR in accordance with institutional and international country-specific management of

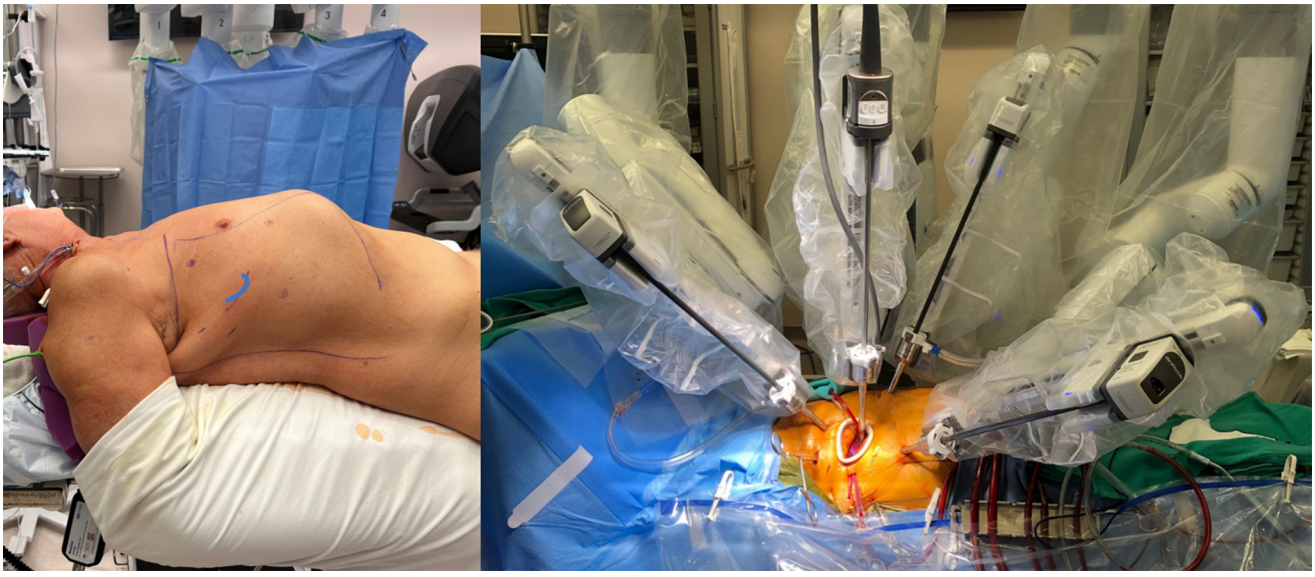

FIGURE 1. RAVR platform. RAVR with 3-cm working incision in fourth intercostal space at the level of the anterior axillary line.

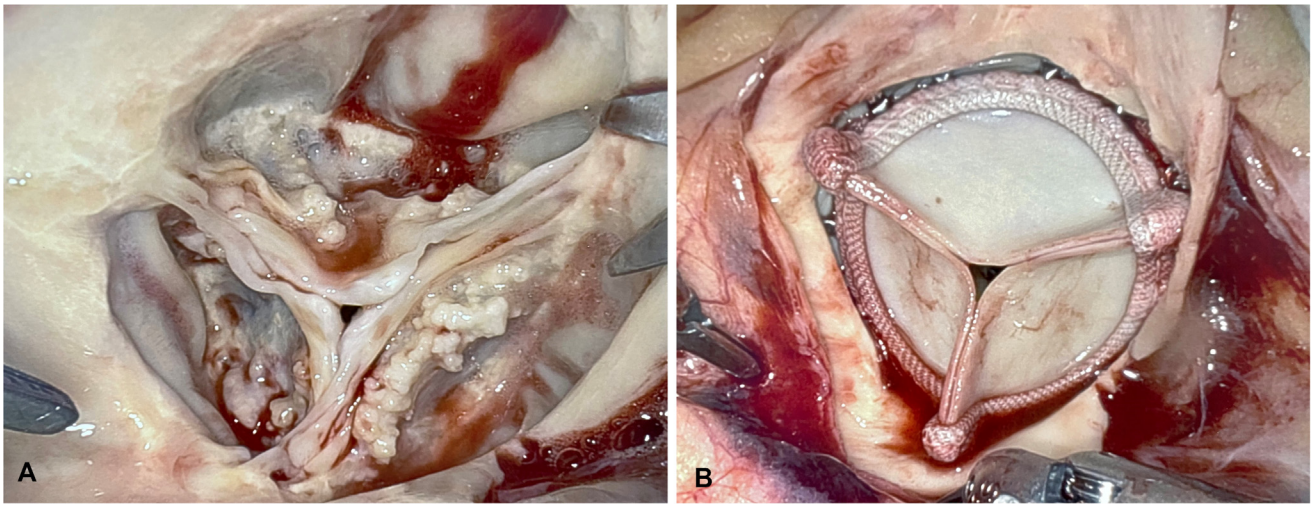

FIGURE 2. Robotic valve exposure and implantation. A, Robotic visualization of native trileaflet aortic valve. B, Bioprosthetic RAVR.

protected health information. All sites agreed to share their data for the total experience from all centers, with the aim of reporting data from any site completing 3 or more roll-in cases. WVU Health Sciences Institutional Review Board approval was obtained with waiver of consent for analysis of deidentified data (Protocol #1709755537, approval May 15, 2022, reapproved August 18, 2023). Categorical variables are presented as counts and percentages, and continuous variables are shown as mean ± SD or median [25th, 75th percentiles] based on normality. Baseline characteristics, intraoperative and postoperative, 30-day, and 1-year outcomes were reported. All analyses were performed using SAS Version 9.4 (SAS Institute, Inc).

CURRENT OUTCOMES

Patient Characteristics

All consecutive adult patients (age >18 years) who underwent RAVR at centers performing 4 or more cases between January 2020 and September 2023 were included for analysis. A total of 212 patients underwent RAVR at 4 high-volume robotic cardiac programs around the world. These included WVU, 180 patients (V.B. and L.M.W.); Barcelona, Spain, 15 patients (D.P.); Riyadh, Saudi Arabia, 11 patients (F.H.K.); and Sao Paulo, Brazil, 6 patients (R.P.), each providing a minimum of 30 days of follow-up. Patients had a median age of 67 years, were predominantly male (66.0%), and had a median Society of Thoracic Surgeons predicted risk of mortality of 1.7%. The majority of patients had severe aortic stenosis (89.7%) with approximately half of patients having bicuspid valves and 39.2% with moderate or worse aortic regurgitation (Table 1).

Outcomes

The median CPB time was 166 minutes with a crossclamp time of 117 minutes. Biological prostheses were implanted in 151 patients (71.2%), and mechanical prostheses were implanted in 61 patients (28.8%). The median valve size was 23 mm. A total of 23 patients (10.8%) underwent root enlargement procedures to allow placement of a larger valve, and 16.5% of patients received other concomitant procedures including left atrial appendage obliteration (LAAO) with or without biatrial cryothermic Cox Maze, patient foramen ovale closure, transaortic septal myectomy, MV repair, or MV replacement (Table 2). There were no operative conversions to sternotomy. The postoperative median mean aortic valve gradient was 9 mm Hg, and no patients had more than trace paravalvular regurgitation (Table 2).

The median length of stay was 5 days. Morbidity included 4.7% with prolonged ventilation, 1.4% with renal failure, and 0.9% with stroke. The new permanent pacemaker rate for the full cohort was 2.8% (5/178) and 2.5% (4/162) after isolated RAVR ± root enlargement. There were no vascular complications. The 30-day reoperation rate was 7.5%, all for evacuation of hemothorax and none for valvular reasons, and all reoperations were performed within 12 to 24 hours via the same robotic working incision. One patient required temporary postcardiotomy extracorporeal membrane oxygenation (ECMO) and there were two 30-day operative mortalities (0.9%).

The patient requiring ECMO was a 59-year-old frail woman presenting with acute multivalvular bacterial endocarditis and severe mitral annular calcification associated with anasarca, hypotension, and peripheral splenic emboli. She underwent RAVR with attempted concomitant repair of an anterior MV leaflet perforation followed by robotic

TABLE 1. Baseline demographics and patient characteristics

Variable	(n = 212)
Age, y	67 (60-72)
Gender (male)	140 (66.0%)
Race (White)	199 (93.9%)
BMI (kg/m^2)	30.1 (26.7-34.7)
Atrial fibrillation	35 (16.5%)
Hypertension	174 (82.1)
Diabetes mellitus	164 (77.4%)
Peripheral artery disease	10 (4.7%)
Coronary artery disease	25 (12.4%)
End-stage renal disease	6 (2.8%)
Cerebrovascular accident	31 (14.6%)
Permanent pacemaker	34 (16.0%)
Ejection fraction (%)	60 (55-65)
NYHA	
I	22 (10.4%)
II	74 (34.9%)
III	106 (50.0%)
IV	10 (4.7%)
Mitral regurgitation moderate or greater	19 (10.3%)
Tricuspid regurgitation moderate or greater	56 (27.8%)
Aortic regurgitation	
0	35 (16.8%)
1+	21 (10.0%)
2+	71 (34.0%)
3+	55 (26.3%)
4+	27 (12.9%)
Severe aortic stenosis	184 (86.8%)
Aortic valve gradient (mm Hg)	42 (35-50)
Unicuspid/bicuspid aortic valve	97 (48.3%)
Predicted risk of mortality (%)	1.7 ± 1.3
Predicted risk of major morbidity or mortality (%)	10.7 ± 6.9

BMI, Body mass index; *NYHA*, New York Heart Association.

TABLE 2. Operative characteristics and postoperative outcomes

Variable	(n = 212)
CPB time (min)	166 (149-203)
Crossclamp time (min)	117 (105-148)
Valve type (mechanical)	61 (28.8%)
Valve size	
19	6 (2.8%)
21	69 (32.6%)
23	88 (41.5%)
25	40 (18.9%)
27/29	9 (4.2%)
Root enlargement	23 (10.8%)
Conversion to sternotomy	0 (0%)
Concomitant surgery	35 (16.5%)
LAAO only	7 (3.4%)
Cox Maze with LAAO	18 (8.8%)
PFO	8 (3.9%)
Transaortic myectomy	3 (1.5%)
MV repair	7 (3.4%)
MV replace	7 (3.4%)
Aortic valve gradient (mm Hg)	9 (6, 11)
Paravalvular leak	
0	208 (98.1%)
1+	4 (1.9%)
2+	0 (0%)
3+	0 (0%)
4+	0 (0%)
LOS (d)	5 (4-7)
Cardiogenic shock	1 (0.5%)
Prolonged ventilation (>24 h)	10 (4.7%)
Renal failure requiring dialysis	3 (1.4%)
Stroke	2 (0.9%)
Reoperation	16 (7.6%)
Vascular complication	0 (0%)
Permanent pacemaker	5 (2.9%)
Operative mortality	2 (0.9%)

CPB, Cardiopulmonary bypass; *LAAO*, left atrial appendage obliteration; *PFO*, patent foramen ovale; *MV*, mitral valve; *LOS*, length of stay.

MV replacement, both with mechanical valves. Crossclamp time was 335 minutes. Peripheral venoarterial ECMO was used perioperatively. The patient was decannulated on postoperative day 3, extubated on day 5, and discharged to rehabilitation on day 18. The first mortality occurred in a 61-year-old man with severe rheumatic multivalvular disease with a preoperative ejection fraction of 40% on guideline-directed medical therapy, 80% systemic pulmonary hypertension, persistent atrial fibrillation, class III heart failure, and morbid obesity. The patient underwent bioprosthetic RAVR and concomitant mitral replacement and biatrial Cox Maze. Crossclamp time was 230 minutes. He made an uneventful initial recovery and was nearing discharge when he had an acute hypoxic respiratory event followed by cardiac arrest due to a suspected pulmonary embolus. The second mortality was in a 63-year-old morbidly obese man with severe aortic stenosis and root calcification with remote percutaneous coronary intervention but without obstructive anatomy who underwent RAVR with a 25-mm mechanical prosthesis and aortic root endarterectomy. Crossclamp time was 161 minutes. The patient developed postoperative atrial fibrillation and was discharged home on postoperative day 6 in sinus rhythm on warfarin and amiodarone. His warfarin was therapeutic, and he was reportedly doing well. He was found dead at his home on postoperative day 17.

At 30-day postoperative follow-up, all patients had New York Heart Association class I to II. Of the 201 patients (95%) with evaluable transthoracic echocardiograms at

30 days, the median mean aortic valve gradient was 10 mm Hg, and all but 1 patient had no to trace valvular or paravalvular regurgitation (Table 3). As of September 2023, 109 patients had completed 1-year clinical and echocardiographic follow-up with a median mean aortic valve gradient of 11 mm Hg, all with trace to no prosthetic or paravalvular stenosis or insufficiency except 2 patients (1.1%) having mild-moderate aortic prosthetic insufficiency. To date, only 1 patient required valve reoperation at 2.5 years postoperatively for early symptomatic structural valve degeneration in a Trifecta bioprosthesis (Abbott).

TABLE 3. 30-day and 1-year outcomes

30-d outcomes	(n = 201)
Readmission, any	23 (11.4%)
NYHA	
I	124 (93.2%)
II	9 (6.8%)
III	0 (0%)
IV	0 (0%)
Aortic valve gradient (mm Hg)	9.7 (7.3-13.6)
Paravalvular leak	
0	192 (95.5%)
1+	8 (4.0%)
2+	1 (0.5%)
3+	0 (0%)
4+	0 (0%)
1-y outcomes	**(n = 109)**
Aortic valve gradient	10.0 (8.2-13.4)
Perivalvular leak	
0	103 (94.5%)
1+	4 (3.7%)
2+	2 (1.8%)
3+	0 (0%)
4+	0 (0%)

NYHA, New York Heart Association.

INTERNATIONAL EXPERIENCE AND TRAINING RECOMMENDATIONS

As of September 2023, four centers represented by the above outcomes were actively performing RAVR. Seven additional centers have already commenced RAVR and were within their first 3 roll-in cases. These include programs in Sydney, Australia (T.D.Y.), Hradec Králové, Czech Republic (S.C. and J.V.), Boston, Massachusetts (S.M.), Rochester, Minnesota (A.A.), Weston, Florida (J.L.N.), Milwaukee, Wisconsin (G.V.R.), and Houston, Texas (D.R.). Teams that have trained and are preparing for initial cases include programs in Dallas, Texas (R.L.S.) and Zurich, Switzerland (A.C.W.). Approximately 20 others have received initial RAVR training and are in various stages of preparation.

After this early experience, a consensus from the international RAVR consortium recommended 2 general pathways tailored for surgeons with (A) established robotic mitral experience (>50 cases) with a minimum of 5 MV replacements or (B) surgeons with extensive conventional open or minimally invasive SAVR or root surgery experience (>250 cases) but no prior robotic experience (Table 4). After participating in initial RAVR training and case observation and before commencing RAVR, experienced robotic surgeons in pathway A are recommended to start with 5 lateral anterior axillary line minithoracotomy thoracoscopic or direct-vision SAVR procedures using shafted instruments in good candidates unlikely to need advanced root procedures or enlargements. The aim of this optional effort is to gain situational comfort for exposure and closure of the aortotomy via the lateral approach. Experienced aortic valve surgeons without robotic experience in pathway B are recommended to train their teams on the robotic mitral platform and first perform 10 robotic MV replacements to become familiar with the interface and lateral approach before moving on to a suggested minimum of 5 lateral thoracoscopic or direct-vision SAVR procedures as in pathway A. The table-side assistant may be another surgeon or advanced practice provider, based on the comfort and experience of the surgical team. Upon RAVR commencement, and similar to recent consensus recommendations on robotic cardiac surgery training,[12] it is further suggested that for a program's first 25 cases, each step of the RAVR operation be compartmentalized and timed for internal quality improvement purposes (aortotomy, valvectomy, suture placement, suture tying, aortotomy closure).[9]

PERSPECTIVE

Several excellent options for minimally invasive SAVR exist, each with different advantages but also select opportunities. Upper hemi-sternotomy provides excellent visualization for a conventional SAVR implant technique with minimal need for cannulation alterations, other than perhaps the optional adjunct of percutaneous femoral venous drainage. Right anterior thoracotomy permits SAVR via direct visualization or endoscopic video assistance, often facilitated using sutureless valves.[7,8,13-15] Although both of these are effective approaches with reproducibility and comparable outcome to full sternotomy, both require anterior chest wall incisions involving the sternum or pectoralis musculature with rare rib or internal thoracic artery division, respectively. Neither option readily permits the addition of concomitant operative procedures (eg, mitral, tricuspid, biatrial surgical ablation). Although the right anterior thoracotomy approach remains an excellent option for certain centers, it has yet to gain widespread use because of the common need for sutureless valves, perceived anterior incisional morbidity, and limited opportunity for root enlargement.[15] Given the promulgation of transcatheter aortic valve replacement (TAVR) into lower-risk cohorts with short- and mid-term randomized

TABLE 4. Training recommendations

Pathway A prior robotic MV experience (>50 cases)	Pathway B aortic valve experience (>250 cases) but no prior robotic experience
Team experience with 5 robotic MV replacements within 2 y of RAVR	Team robotic training and initial experience with 10 robotic MV replacements
Team training with case observation at an existing RAVR program	Team training with case observation at an existing RAVR program
5 minimally invasive lateral thoracotomy direct-vision of video-assisted SAVR	5 minimally invasive lateral thoracotomy direct-vision of video-assisted SAVR
Initial 10 cases isolated RAVR only before expanding to concomitant procedures	Initial 25 cases isolated RAVR only before expanding to concomitant procedures
Track compartmentalized times for aortotomy, valvectomy, suture placement, knot securing, and aortotomy closure	Track compartmentalized times for aortotomy, valvectomy, suture placement, knot securing, and aortotomy closure

MV, Mitral valve; *RAVR*, robotic aortic valve replacement; *SAVR*, surgical aortic valve replacement.

evidence of noninferiority to SAVR in highly selected cohorts, patients and providers seek additional alternatives for minimally invasive therapy that avoid anterior chest entry with increasing frequency.[1-4,9]

With a fourth intercostal space anterior axillary line 3-cm working incision and port placements nearly identical to those used in robotic MV surgery, the RAVR platform not only permits complete valvectomy and even left ventricular outflow tract debridement when necessary, its utility provides for the performance of conventional SAVR with the option of additional intracardiac concomitant procedures. This added flexibility permits RAVR to be applied to an increased cohort of patients who may benefit from more than isolated SAVR. As part of the current experience outlined in this review, several firsts are reported. The first RAVR was performed on January 10, 2020. Concomitant to RAVR, the first biatrial Cox Maze with LAAO was performed on May 1, 2020,[16] to avoid patient-prosthesis mismatch the first concomitant root enlargement with patch augmentation was performed on May 12, 2020,[17,18] the first MV repair and biatrial Cox Maze and LAAO was performed on July 24, 2020,[19] MV replacement for aortic and mitral stenosis was performed on March 16, 2021, and the first transaortic septal myectomy for hypertrophic cardiomyopathy was performed on December 8, 2022. Many of these concomitant procedures or combinations thereof have become routine with growing RAVR team experience.

In both low-risk trials of TAVR versus SAVR, the incidence of stroke in the surgical cohort was just over 2%.[2,3] Inclusive of all RAVR sites, the total incidence of stroke was only 0.9%. Despite retrograde arterial perfusion, transthoracic aortic clamping, and many patients requiring aggressive debridement of calcium, the ability to visualize and meticulously aspirate any and all calcific debris during the RAVR procedure may be but one explanation for the low stroke rates.

Need for new permanent pacemaker, ranging between 11% and 29% after TAVR and 4% to 8% after SAVR, is associated with reduced longitudinal outcomes including survival.[1-4,20-22] After RAVR, with a median valve size of 23 mm, the pacemaker implant rate for the total cohort was only 2.8%. Although this study was not designed to directly compare RAVR with SAVR, a possible reason for this potentially advantageous result may be the very clear visualization of the annular and subannular anatomy including the membranous septum and the ability to precisely place sutures to avoid impingement of related anatomy during prosthetic implantation. This may further explain why the incidence of paravalvular leak remained negligible across all RAVR sites.

Acknowledging the limitations of this experience being initial bias of case selection as programs commenced RAVR, we thought this was appropriate and justified as RAVR was introduced as a novel procedure in each institution with a focus on patient and team safety. This noted, as RAVR becomes routine for centers, the heart team approach has made RAVR an all-comer first option for patients of low to intermediate surgical risk instead of TAVR. Further acknowledging that this report represents early multicenter results, care was taken to not directly compare RAVR outcomes with SAVR or TAVR or other minimally invasive approaches because the aim was merely to note observations of this experience in the context of others.

FUTURE DIRECTIONS

Despite the exponential rise in TAVR over the past decade, numerous patient cohorts and pathoanatomies remain best served with SAVR. Although several excellent minimally invasive approaches to SAVR with conventional biological or mechanical prostheses exist, RAVR affords a lateral approach that avoids anterior skeletal or muscular disturbance while enabling the flexibility to add concomitant procedures determined to be in the best interest of the patient. As international multicenter reproducibility continues, RAVR may provide low- and intermediate-risk patients with a safe and effective minimally invasive option

to receive a traditional SAVR with known durable longitudinal outcomes.[4]

As collective experience with the RAVR platform continues to evolve, further options may be possible. One such possibility is the approach to robotic repair of primary aortic insufficiency due to due degenerative aortic valve leaflet prolapse.[23] Although longitudinal follow-up of initial patients is ongoing, this new option may provide younger patients with a potentially durable warfarin-free alternative performed robotically.

The present multicenter international experience highlights that in centers with established robotic experience, the RAVR procedure is reproducible and safe with excellent early results. As more centers initiate RAVR programs, a dedication to reproducible, quality patient care remains paramount and the recommendations for team training provided in this report aim to assist this endeavor.

Conflict of Interest Statement

Dr Pereda discloses nonfinancial support from Edwards Lifesciences. Dr Melnitchouk discloses consulting fees from Medtronic. Dr Ramzy discloses nonfinancial support from Edwards Lifesciences, Medtronic, and Abbott. Dr Cerny discloses consulting fees from Intuitive Surgical. Dr Smith discloses consulting fees from Edwards Lifesciences, Abbott, Medtronic, and Artivion. Dr Thourani discloses consulting fees from Abbott, Boston Scientific, CryoLife, Edwards Lifesciences, Jenavalve, Medtronic, and Shockwave. All other authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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