Featured Article

Establishing a robotic aortic valve replacement program in Spain: growing opportunities for Europe

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Background: The natural history of aortic valve disease commonly eventuates in percutaneous or open surgical treatment. Percutaneous treatment has been expanding its indication from high-risk patients to low- and moderate-risk patients; however, there are certain groups of patients who are not good candidates for percutaneous treatment, such as those with bicuspid valve disease or pure aortic regurgitation patients. Robotic surgery, as an evolution from traditional approaches, has been gradually expanding its indications in cardiac surgery. The use of a lateral approach, common to robotic mitral procedures, may become a valid alternative for several patients undergoing aortic valve procedures.

Methods: This was a retrospective study analysing prospectively collected data of all patients who have undergone robotic aortic valve replacement (RAVR) in our university hospital from December 2021 to October 2024.

Results: Since December 2021, 25 consecutive patients have undergone RAVR. Sixty-eight percent of the cohort were males and the median age was 66 years [interquartile range (IQR), 58.5–71.8 years]. Severe aortic stenosis was the predominant lesion in 76% of patients, and degenerative calcification was the aetiology in 52% of patients. Median cardiopulmonary bypass time was 129 minutes (IQR, 113–145.5 minutes) and median ischemic time was 91 minutes (IQR, 78–105 minutes). Three patients required a re-exploration for bleeding, which was performed through the same approach, and one patient suffered an ischemic cerebro-vascular accident (CVA) with complete recovery. Median intensive care unit (ICU) length of stay and hospital length of stay were 1 and 4 days, respectively.

Conclusions: Our initial experience shows that expanding a robotic program to include RAVR is feasible, safe, and can provide excellent clinical outcomes in selected patients.

Keywords: Robotic surgery; aortic valve disease; minimally invasive surgery

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Introduction

Aortic valve disease is among the most prevalent cardiovascular conditions in Western countries, with its incidence steadily increasing due to population aging and advancements in diagnosis and disease awareness. Aortic stenosis (AS), in particular, has emerged as the most common primary valve pathology necessitating surgical or transcatheter intervention in Europe and North America (1). Over the past decade, this field has undergone significant advancements, driven by innovations in both therapeutic approaches and patient management. The appearance and consolidation of transcatheter aortic valve replacement (TAVR) has revolutionized the management of inoperable and very high-risk patients with AS. Over time, its indications have expanded to include intermediate- and low-

risk populations, as well as patients with other conditions such as degeneration of previously implanted bioprosthetic valves, bicuspid AS, and aortic regurgitation.

In Europe, the 2021 European Society of Cardiology/European Association for Cardio-Thoracic Surgery (ESC/EACTS) guidelines (2) for managing valvular heart disease recommend surgical aortic valve replacement (SAVR) for symptomatic AS patients aged <75 years who are at low surgical risk and TAVR for patients aged ≥75 years or younger patients who are at intermediate to high risk. There is considerable variation in the rates of aortic valve replacement and the adoption of TAVR versus SAVR between European countries, as shown in a recent study by Rudolph *et al.* (3). In this multinational European study, the rate of aortic valve replacement (all types) varied from 508 patients per million (PPM) in Germany to 174 PPM in Poland in 2020, with TAVR increasing over the last years (from 61% in Switzerland and Finland to 25% in Poland), particularly in the elderly. In patients younger than 75 years, the rate of patients treated with TAVR increases with age: 10% of cases between 60–64 years, 17% of cases between 65–69 years and 30% in the 70–74 years.

On the surgical side, the expansion in adoption of minimally invasive approaches (such as partial sternotomy or right anterior minithoracotomy) and the development of new biological valves, designed for longer durability and optimized for future valve-in-valve TAVR, may further improve the surgical treatment of these patients (4). One of the most innovative advances in surgery in recent years has been the development of robotic systems that allow surgeons to perform surgical procedures with a level of precision and reduced invasiveness not seen before. In the cardiovascular field, robotic surgery is used for coronary revascularization and intracardiac procedures such as mitral and tricuspid valve repair or replacement, atrial fibrillation ablation, and closure of atrial septal defects. Most intracardiac robotic procedures can be performed using the same lateral thoracic approach that serves as a common platform for robotic cardiac surgery. This approach has consistently shown to produce excellent outcomes, as compared to the conventional approach through median sternotomy, in terms of reduced complications, faster recovery, and improved cosmesis.

Despite the advances seen in other areas, robotic aortic valve replacement (RAVR) has not evolved at the same pace and its use has remained minimal for the last years, mostly limited to isolated cases using a different anterior approach and sutureless prostheses (5-7). However, more recently, a few groups have developed and reported their initial experience using the same lateral approach (8,9). Badhwar *et al.* (10) have recently published the largest clinical series reporting the results of RAVR in more than 200 patients using conventional surgical valves, with excellent clinical results (10). At Hospital Clínic, we performed our first RAVR using this lateral approach in 2021 (8), shortly following a previous case of resection of an aortic valve fibroelastoma (11). Now, we aim to present our initial cohort of RAVR using the lateral approach, a pioneer program in Europe.

Methods

This was a retrospective study analysing prospectively collected data of all patients who have undergone RAVR in a tertiary university hospital from December 2021 to October 2024 (n=25). During the study period, our centre has performed a median of 950 major cardiac cases, a median of 110 isolated aortic valve replacements, and a mean of 150 TAVR each year.

Inclusion/exclusion criteria

All adult patients visited in the outpatient clinic for symptomatic AS or insufficiency, for whom isolated SAVR without concomitant procedures was planned, were screened, and the surgical approach was left at the preference of the main surgeon. Exclusion criteria: need for concomitant procedures, previous cardiac surgery, previous TAVR, cardiac surgery or surgery in the right chest, need for emergency surgery, left ventricular ejection fraction <30%, active endocarditis, severe thoracic deformities, ascending aorta >40 mm, severe calcification of the ascending aorta or the aortic root, and severe peripheral vascular disease or venous anomalies precluding peripheral cannulation.

Interventions

All procedures were performed with the da Vinci Xi system (Intuitive Surgical®, CA, USA) using the same approach we use for mitral surgery, and that has been previously described in detail (8,12). Briefly, an 8-mm camera trocar was inserted in the 4th intercostal space (ICS) between the midclavicular and the anterior axillary lines, and the remaining ports were introduced under endoscopic vision: the right arm trocar was inserted in the 6th ICS, and the

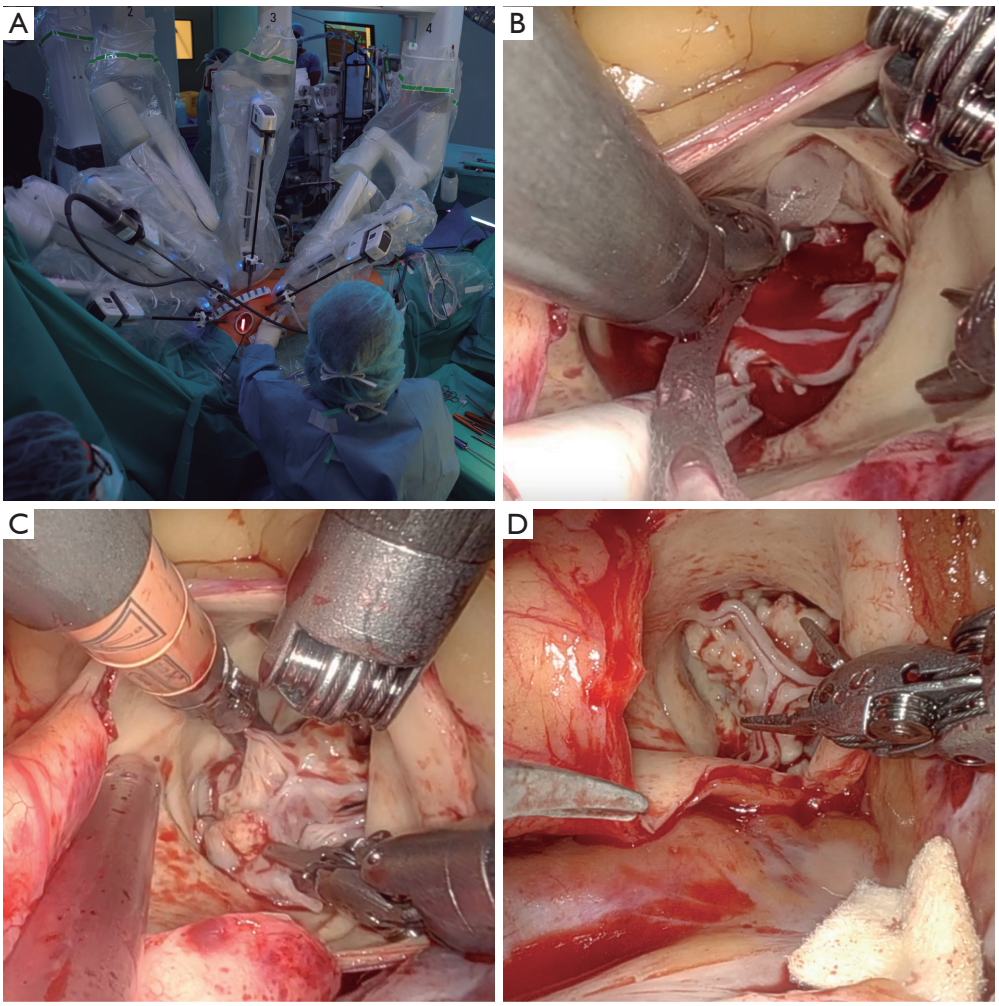

Figure 1 (A) shows how the trocars are placed in the chest. (B) shows direct administration of ostial crystalloid cardioplegia with a regular balloon. (C,D) displays the excellent exposure of the aortic valve, either bicuspid or tricuspid.

left arm in the 3rd ICS, and finally, the trocar for a third instrument was inserted in the 5th ICS medial to the mid-clavicular line. Lastly, a 2–3 cm minithoracotomy was performed lateral to the camera port and in the same ICS to serve as a working port and to introduce the prosthesis (*Figure 1A*). Cardiopulmonary bypass (CPB) was established using right femoral cannulation using a single venous multiperforated femoral cannula using a small cut-down incision. Myocardial protection was achieved using transthoracic aortic cross-clamping and antegrade delivery of crystalloid cardioplegia, either in the aortic root or directly at the coronary ostia in cases with significant aortic regurgitation (*Figure 1B*). A left ventricular vent was placed through the right superior pulmonary vein. The aortic valve was inspected and removed through a "J-shaped" aortotomy (*Figure 1C,1D*). After decalcifying the aortic annulus, the valve was sized and interrupted pledgetted U-stitches were placed in the ventricular aspect of the annulus for a supra-annular implantation of the prosthesis (*Figure 2A*). The stitches were passed through the prosthesis outside the chest, and it was then placed in its final position with the aim of the robotic instruments (*Figure 2B*). After ensuring the proper positioning, all sutures were tied using the Cor-Knot® device (LSI Solutions, NY, USA). The aortotomy was closed using a double layer, running 4/0 non-absorbable suture (*Figure 2C*). Once the aortotomy was closed, temporary pacing wires were placed in the right ventricular free wall, deairing maneuvers started, and the aortic clamp was released. The vents were removed and the cannulation sites repaired. The pericardium is then closed leaving a

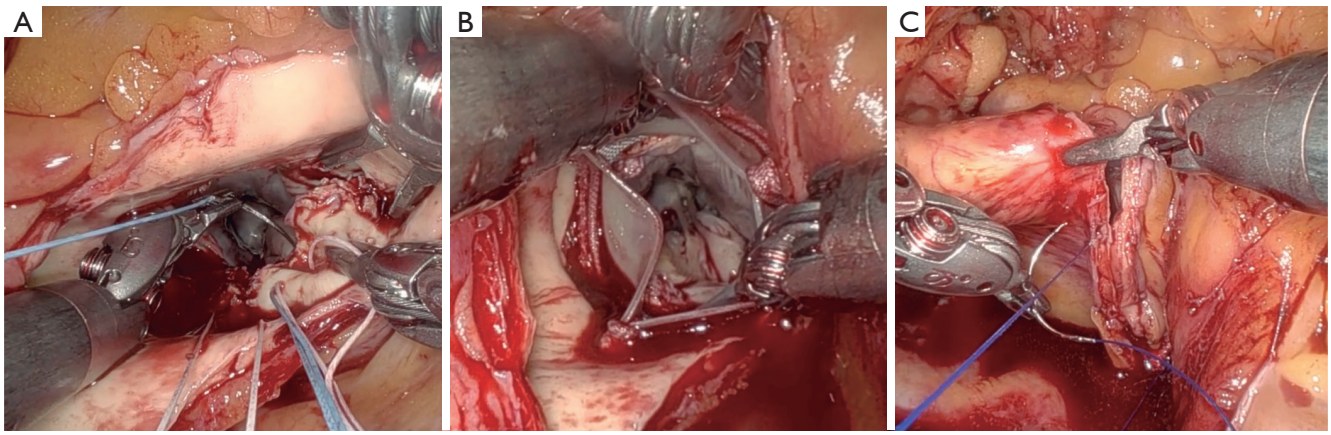

Figure 2 (A) shows the placement of the non-coronary sinus stitches, with the pledgets in the ventricular aspect of the annulus for supra-annular implant. (B) shows the final positioning of the prosthesis in the native annulus and a direct inspection of the left ventricular outflow tract. In (C) we can see how the aortotomy is closed with a double polypropylene suture.

chest tube introduced from the right arm trocar into the pleural and pericardial cavities.

Statistical analysis

Data regarding patient demographics, baseline characteristics, and perioperative outcomes were obtained from a prospectively maintained institutional database. Qualitative variables are presented as frequency and percentage. Quantitative variables are presented as median (interquartile range).

Results

Since the beginning of the program in December 2021 until October 2024, 25 consecutive patients underwent RAVR. Sixty-eight percent of the cohort were males and the median age was 66 years (IQR, 58.5–71.8 years). Severe AS was the predominant lesion in 76% patients, whereas 24% patients had isolated aortic regurgitation. Degenerative calcification was the main aetiology in 52% of cases. The valve morphology was bicuspid in 44% cases. All other preoperative data is presented in *Table 1*.

Intraoperative data

Regarding surgical times, median CPB time was 129 minutes (IQR, 113–145.5 minutes) and median ischemic time was 91 minutes (IQR, 78–105 minutes) (*Table 2*). Most patients (23, 92%) received a tissue valve, only 4 of them (17%) being a rapid deployment prosthesis (Edwards Intuity Elite®, Edwards Lifesciences; CA, USA) and the rest being conventional sutured valves. Size 23 mm was the most frequently used. One patient received a concomitant transaortic septal myectomy.

Postoperative outcomes

All procedures were completed successfully using the robotic platform, without any conversion to sternotomy. Also, there was no need for a second clamp time in this initial cohort. After the operation was completed, 36% (n=9) patients could be extubated in the operating room. Three patients (12%) underwent re-exploration for bleeding, which could be performed using the same approach through the working port in all cases; seven patients (28%) needed a blood transfusion during the hospital stay. No patients required a pacemaker implant in the postoperative period and one patient (4%) suffered a CVA with complete recovery at discharge. *Table 3* presents additional postoperative data. Median intensive care unit and hospital length of stay were 1 (IQR, 1–2.75) and 4 (IQR, 4–5) days, respectively. In-hospital survival was 100%. Six months after the procedure, all patients were alive and 23 (92%) were in functional class I [New York Heart Association (NYHA)]. Median mean gradient at 6 months was 11 mmHg (IQR, 8–15 mmHg) and the prosthesis had good function in all cases except one, which showed a moderate intravalvular leak.

Table 1

Baseline characteristics	Robotic group (n=25)
Age (years)	66 [58.5–71.8]
Gender (male)	17 [68]
Weight (kg)	76 [67–90]
Height (cm)	172 [163–179]
Hypertension	11 [44]
Diabetes mellitus	5 [20]
Dyslipidemia	10 [40]
Chronic kidney disease	4 [16]
Creatinine (mg/dL)	0.89 [0.8–1.07]
Previous stroke	0
Ischemic cardiomyopathy	1 [4]
NYHA class ≥ III	2 [8]
LV ejection fraction (%)	61.5 [56–65]
Aortic lesion	
Severe stenosis	19 [76]
Severe regurgitation	6 [24]
Etiology	
Bicuspid	11 [44]
Degenerative	13 [52]
Rheumatic	1 [4]
Aortic valve area (cm^2)	0.88 [0.75–0.95]
Mean aortic gradient (mmHg)	43 [37–46.3]
EuroSCORE II (%)	0.9 [0.76–1.3]

Data are presented as median [interquartile range] or n [%]. LV, left ventricle; NYHA, New York Heart Association.

Table 2

Postoperative data	Robotic (n=25)
CPB time (min)	129 [113–145.5]
Ischemic time (min)	91 [78–105]
Total surgical time (min)	240 [214.5–259]
Type of valve	
Mechanical	2 [8]
Tissue	23 [92]
Rapid deployment	4 [16]
Prosthesis size in mm	
19	4 [16]
21	8 [32]
23	11 [44]
25	2 [8]

Data are presented as median [interquartile range] or n [%]. CPB, cardiopulmonary bypass.

Table 3

Postoperative data	Robotic (n=25)
Conversion to sternotomy	0
Need of second clamp time	0
Reoperation for bleeding	3 [12]
Chest tube output 24 h (mL)	295 [155–645]
Need of transfusion	7 [28]
Extubation in the OR	9 [36]
Mechanical ventilation time (h)	4 [0–7]
Cerebrovascular accident	1 [4]
Acute kidney injury	2 [8]
Permanent pacemaker	0
Postoperative atrial fibrillation	2 [8]
ICU length of stay (days)	1 [1–2.75]
Hospital length of stay (days)	4 [4–5]
Survival at discharge	25 [100]
Mean gradient at 6 months (mmHg)	11 [8–15]
NYHA class I at last follow-up	23 [92]

Data are presented as median [interquartile range] or n [%]. ICU, intensive care unit; NYHA, New York Heart Association; OR, operating room.

Discussion

Our study presents the initial results of a RAVR program using the same right lateral approach used for other intracardiac robotic procedures, the first of such studies in Europe. Despite this being an initial experience, our results show that:

- Starting a RAVR program is feasible and safe, in a centre with previous robotic cardiac surgery experience.
- RAVR allows the routine use of all types of conventional prostheses, both tissue and mechanical.

- ❖ RAVR is feasible in bicuspid valves and in cases with severe aortic regurgitation.

One of the common criticisms of minimally invasive surgery in general, and robotic surgery in particular, is the prolongation of surgical times (CPB and aortic cross-clamp). In our initial experience, we have observed longer surgical times as compared to our conventional surgery and mini-sternotomy cohorts. However, our surgical times are concordant with the largest published robotic series and other previous minimally invasive aortic valve replacement series (13). We expect our surgical times will continue to decrease as we perform more cases and the procedure is refined, as we have seen in our robot mitral repair cohort (11).

RAVR, using the lateral approach, offers some advantages over the other most-used minimally invasive alternatives for SAVR: the upper ministernotomy and the right anterior thoracotomy (RAT, usually on the 2nd ICS). As compared to the upper ministernotomy, this lateral robotic approach provides better cosmesis and completely avoids dividing the sternum and its potential complications (e.g., mediastinitis, sternal dehiscence, increased blood loss and postoperative pain), thus favoring faster recovery and eliminating the physical restrictions that are usually recommended after surgery to favor sternal healing. As compared to RAT, this approach also offers better cosmesis and reduces surgical aggression, avoids incisions over large muscular structures such as the pectoralis major, eliminates the need for costal retractors and reduces the size of the working port. In terms of the configuration of the robotic system, the exposure of the aortic valve provided with the lateral approach is excellent and provides a larger working space and range of movement for the robotic instruments as compared to RAT, avoiding internal and external conflicts between the robotic arms during the procedure. This better visualization is also considered key for minimizing the risk of postoperative atrioventricular block. Indeed, RAVR has shown a low incidence of postoperative pacemaker implantation, both in the published series or in a recent propensity-score study comparing RAVR with TAVR (14).

This approach for RAVR taps into the established advantages of the proven lateral approach, is comprised of the largest accumulated experience worldwide, and has become the routine technique for most robotic cardiac cases. The possibility of using this same configuration to treat the aortic valve may greatly expedite the surgeon's learning curve and facilitate the adoption of this procedure in all centers that are already performing robotic cardiac surgery. This would make RAVR a truly scalable, new indication for robotic cardiac surgery. Furthermore, RAVR may enhance the feasibility of establishing new robotic surgery programs in lower-volume centers, improving their sustainability by expanding the pool of eligible patients, and thereby increasing overall efficiency.

There is an increasing demand for minimally invasive options to treat the aortic valve, coming both from patients and physicians, and this will certainly continue to grow in the future in Europe and in America. TAVR has revolutionized the treatment of AS in high-risk and inoperable patients, and its indications continue to spread even into the low-moderate risk population. In fact, in Europe, some of the current recommendations in this regard are based solely on patient's age (2), with reports from current practice showing an indication creep favoring TAVR beyond these guidelines already occurring in all age subgroups (2). However, there is still a significant proportion of patients in all-risk categories that are not good candidates for TAVR for technical reasons, and could greatly benefit from RAVR, such as patients with pure aortic regurgitation, bicuspid AS, endocarditis, patients with low origin of the coronary arteries, or those in need of additional procedures.

As with most initial experiences, this study has two main limitations: first, the sample size is limited; second, there is a possibility of significant selection bias. We have been quite restrictive while including patients at this stage, as we excluded patients with very heavily calcified valves and extension to aortic root and/or the mitral valve, small annulus (<19 mm), patients with peripheral vasculopathy precluding femoral cannulation, and patients requiring concomitant procedures (other than septal myectomy).

We expect to expand our inclusion criteria as we perform more cases and advance through the learning curve of this very promising procedure. Our initial experience shows that expanding a robotic program to include RAVR is feasible and safe and can provide excellent clinical outcomes in selected patients. We believe the reproducibility of the lateral approach may ease the expansion of such programs to other European centers already performing robotic mitral procedures.

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Footnote

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