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Evolution of Minimally Invasive Surgical Aortic Valve Replacement at a Veterans Affairs Medical Center

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Summary

Objective: The majority of minimally invasive surgical aortic valve replacements (MIAVR) are performed at high-volume cardiac surgery centers. However, outcomes at lower-volume federal facilities are not yet reported in the literature, and not captured in the national Society of Thoracic Surgeons (STS) database. Our study objective was to describe the evolution of MIAVR at a Veterans Affairs Medical Center (VAMC).

Methods: A single-center retrospective cohort study was performed of 114 patients who underwent MIAVR for isolated aortic valvular disease between January 2011 and August 2018. Preoperative STS risk factors were determined and perioperative outcomes were analyzed.

Results: By 2016, 100% of isolated surgical aortic valve replacement were performed as MIAVR at our VAMC. Introduction of automatic knot-fastening devices, single-shot del Nido cardioplegia, and rapid deployment valves decreased aortic cross clamp times from median of 96 (IQR:84–103) to 53 minutes (38–61, $p<0.001$, Kruskal-Wallis). Thirty-day mortality was 0.9%. Median length of hospital stay was 9 days (7–13). Postoperative atrial fibrillation occurred in 54% of patients, stroke occurred in 1.8% of patients, and 7.1% of patients required permanent pacemakers. Transition to rapid deployment valves decreased post-operative mean pressure gradient from median 14mmHg (10–17) to 7mmHg (4.7–10, $p<0.001$, Mann-Whitney). At median 1.5-year follow-up echocardiogram, mean gradient was 10.8mmHg with mild paravalvular leak rate of 1.8%.

Conclusions: Facilitating technologies decreased operative times during MIAVR adoption at our VAMC. For patients with isolated aortic valve pathology, MIAVR can be performed with low morbidity and mortality at lower-volume federal institutions, with outcomes comparable to those reported from higher volume centers.

Keywords

aortic valve replacement; mini-sternotomy; minimally invasive; low-volume center

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Introduction

Aortic valve replacement is the only effective treatment for severe aortic stenosis (AS).[1] Prior to transcatheter aortic valve replacement (TAVR), operative therapy via median sternotomy was the standard of care for surgical patients.[1,2] First described in 1996, minimally invasive aortic valve replacement (MIAVR) was developed as an alternative to traditional median sternotomy.[3] MIAVR, performed through smaller incisions, results in reduced pain and surgical trauma, and accelerated postoperative recovery.[3–6] Despite a strong shift towards minimally invasive surgical techniques, driven in part by patient preference, technical challenges associated with operating in a limited field have precluded universal adaptation of MIAVR, and as a result, the majority of these procedures are performed at high-volume cardiac centers.[7,8] Thus, current literature is dominated by experiences from these larger centers, and MIAVR results from lower-volume centers are unknown. Furthermore, the outcomes of MIAVR at relatively lower-volume federal facilities, such as Veterans Affairs (VA) medical centers, are also unknown, since their outcomes are excluded from the national Society of Thoracic Surgeons (STS) database.

Age is the primary risk factor for aortic stenosis, affecting up to 1 in 8 patients over the age of 75.[9] Thus, with more than half of the veteran population reported to be 65 years or older, effective treatment of aortic stenosis is a priority.[10,11] In an effort to meet the healthcare demands of an aging veteran population and increase veterans' access to innovative surgical techniques, the MIAVR program at the San Francisco Veterans Affairs Medical Center (SFVAMC) was established in January 2011. This single-center retrospective cohort study describes a report of an MIAVR program at a VA facility.

Methods

This study was approved by Committee for Human Research at UCSF Medical Center and Institutional Review Board of SFVAMC.

Patients

The cardiac surgery database at our VAMC was retrospectively reviewed to identify patients who underwent isolated surgical aortic valve replacement between January 2011 and August 2018. During our study period, the annual cardiac surgery volume was ~165 cases per year, of which ~15–20 cases were isolated aortic valve replacements. The principal surgeon had ~10 years' experience, performing 150 adult cardiac cases annually at the initiation of the MIAVR program, and was primary surgeon for 98% MIAVR cases. A total of 128 patients were identified during this period, 114 received partial sternotomy for MIAVR and 14 underwent planned full median sternotomy for isolated aortic valve replacement. Prior to surgery, all patients underwent left heart cardiac catheterization, trans-thoracic echocardiography (TTE), and electrocardiogram-gated computed tomography angiography (CTA) to plan the surgical approach. Baseline demographics, operative characteristics, early mortality, and perioperative outcomes were obtained from reviewing the VA Computerized Patient Record System (CPRS), using definitions set forth by the STS Adult Cardiac Surgery Database Data Collection Training Manual Version 2.81. Preoperative data were

then summarized using a risk model developed by the STS to estimate predicted risk of mortality (PROM, or the risk of death at 30 days post-procedure).[12]

Surgical Technique

Surgical approach was planned using each patient's respective pre-operative CTA to characterize ascending aorta and arch anatomy, plan intercostal space level for mini-sternotomy, and size the aortic annulus. Based on CTA findings, surgical access was performed via upper mini-sternotomy to the third or fourth intercostal space in 106 patients. Due to low lying, horizontally oriented heart, a partial lower midline sternotomy was used in 8 patients. Cardiopulmonary bypass (CPB) was initiated via central cannulation and surgical aortic valve replacement was carried out according to procedures previously described.[4,13–15] The technique at our institution evolved over time with the assistance of facilitating technologies. The COR-KNOT (LSI Solutions, Victor, New York, USA) automatic knot-fastening device was introduced in 2012 to more efficiently tie knots given spatial constraints at the aortic annulus, and replaced manual knot-tying of the valve to the annulus. In 2014, single-dose del Nido cardioplegia replaced high potassium blood crystalloid cardioplegia, minimizing the need for re-dosing cardioplegia and retrograde delivery. Patient temperature was permitted to drift to 35.5 degrees Celsius on CPB with no active cooling performed. The majority of MIAVR patients received bioprosthetic Carpentier-Edwards Model 3300TFX Perimount heart-valves (Edwards Lifesciences LLC, Irvine, California, USA), with few receiving mechanical valves (St. Jude Medical Inc, St. Paul, Minnesota, USA). After October 2016, MIAVR patients received the bioprosthetic Edwards Intuity Model 8300AB Rapid Deployment heart-valve (Edwards Lifesciences LLC).

Statistical Analysis

Continuous variables were expressed as median with interquartile range (IQR). Categorical variables were described using frequencies. For comparison of continuous variables, the Mann-Whitney-Wilcoxon test or the Kruskal-Wallis test was used. For comparison of categorical variables, the Chi-squared (χ^2) test was used. Statistical significance was classified as p <0.05. All statistical analyses were performed using Stata version 15 (StataCorp LLC, College Station, Texas, USA).

Results

Institutional Learning Curve

MIAVR through a mini-sternotomy was planned in 114 patients with isolated aortic valve disease. The percentage of MIAVR planned for isolated aortic valve surgery over time is illustrated in Fig. 1. No formalized training was undertaken prior to initiating the program though the primary surgeon visited a high volume minimally invasive valve surgeon to visualize their technique. By 2016, 100% of patients requiring isolated aortic valve replacements were performed as MIAVR at this VAMC. Introduction of facilitating surgical technologies decreased operative times and assisted the learning curve. The additive effect of each new technology is illustrated in Fig. 2. Aortic cross-clamp (AXC) times decreased from a median of 96 minutes (IQR: 84–103) to 53 minutes (38–61, p<0.001, Kruskal-Wallis).

Cardiopulmonary bypass (CPB) times also decreased accordingly from a median of 157 minutes (134–182) to 75 minutes (59–81, p<0.001, Kruskal-Wallis).

Patients

Cohort baseline characteristics are reported in Table 1. Median age of patients who underwent MIAVR was 69 years old (65–73). The majority of patients fell into STS PROM low-risk category (PROM <4%), with median STS PROM of 1.3 (0.9–1.8). Shortly after introduction of MIAVR, TAVR was introduced at our institution and became the procedure of choice for inoperable and high-risk patients with gradual transition to intermediate-risk surgical patients. For MIAVR patients, 34% had diabetes mellitus, 31% were New York Heart Association class III/IV, and 1.7% had prior stroke. Isolated aortic stenosis was the most common valve pathology in patients undergoing MIAVR, occurring in 53% of patients. 9.6% of patients presented with isolated aortic regurgitation and 37% of patients presented with mixed aortic valve disease. Median pre-operative aortic valve area was 0.7cm^2 (0.6–0.9) with mean transvalvular pressure gradient of 46mmHg (40–54).

Outcomes

Postoperative outcomes for all patients who underwent MIAVR are depicted in Table 2. Of 114 total patients, 64 received a stented bioprosthetic Carpentier-Edwards MagnaEase valve (Edwards Lifesciences LLC), 44 received a rapid deployment bioprosthetic Edwards-Intuity valve (Edwards Lifesciences LLC), and 6 received a mechanical valve (St. Jude Medical Inc). There were three unplanned concomitant procedures performed: 1 patient underwent ascending aortic aneurysm wrap, 1 patient underwent aortic root enlargement, and 1 patient had a thymic mass excised. Thirty-day mortality was 0.9%; 1 patient expired after left ventricular (LV) perforation from the LV vent and myocardial infarction requiring left ventricular assist device. Afterwards, LV vent size was reduced, and TEE guidance used for depth of placement without subsequent complication. For 113 patients, early post-operative course was complicated by reoperation for bleeding in 3 patients (2.6%). Median postoperative length of hospital stay was 9 days (7.0–13). Across all patients, a mean of 1 unit of packed red blood cells was given (SD: 1.8). 11 patients required only intraoperative transfusion, 11 patients required only postoperative transfusion, while 18 patients required both intra- and postoperative transfusion. Post-operative atrial fibrillation lasting longer than one hour or requiring medical intervention to treat occurred in 61 patients (54%). Stroke occurred in 2 patients and transient ischemic attack occurred in 1 patient in the postoperative period, accounting for event rates of 1.8% and 0.9%, respectively. Eight patients (7.1%) developed complete heart block that necessitated permanent pacemaker placement after MIAVR. No patients experienced acute renal failure. Mild to moderate paravalvular leak (PVL) was documented in 3.6% of patients on post-operative TTE prior to discharge from index admission, and post-MIAVR mean pressure gradient was 11mmHg (7.0–15). Eight patients (7.1%) were readmitted within 30 days of discharge: 3 for pericardial effusion, 3 for symptomatic arrhythmia, 1 for pneumonia, and 1 for congestive heart failure.

Effect of Transitioning to Rapid Deployment Valves

In October 2016, our practice transitioned to using the rapid deployment bioprosthetic Edwards-Intuity valve (Edwards Lifesciences LLC), which requires only 3 sutures, for

MIAVR. The impact of this transition on postoperative outcomes is examined in Table 3. Generally, implantation of rapid deployment valves led to an increase in selected valve size from 23mm (21–25) to 25mm (25–27, p<0.001, Mann-Whitney test), and a decrease in post-operative mean pressure gradients. While there were increased rates of permanent pacemaker implantation from 5.8% to 9.1% after rapid deployment valve adoption, this was not statistically significant (p=0.59, χ^2). In the rapid deployment valve cohort, moderate PVL was reported in 4.5% of patients postoperatively, compared with 0% of patients with sutured bioprosthetic stented or mechanical valves (p=0.08). Mild PVL occurred in 0% of patients with rapid deployment vs. 2.9% of patients with sutured bioprostheses or mechanical valves (p=0.27). Postoperative atrial fibrillation was comparable between the two cohorts, occurring in 52% of patients prior to the transition and 57% of patients afterwards (p=0.63, χ^2). Most notably, postoperative mean transvalvular pressure gradient decreased from 14mmHg (10–17) to 7mmHg (4.7–10) (p<0.001, χ^2). Transitioning to rapid deployment valves did not impact length of hospital stay, or rates of postoperative neurologic events.

Late Follow-up

Late follow-up outcomes are presented in Table 4, collected based on guidelines set forth by Akins and colleagues.[16] For 113 patients, median follow-up time was 2.6 years (IQR: 1.1–4.1 years, range: 0–7.6 years), with 361.5 patient-years (py). Figure 3 illustrates Kaplan-Meier survival data. Of these patients, 1 experienced late structural valve deterioration, resulting in an event rate of 2.8 cases/1000 py, and was found to have moderate aortic regurgitation on echocardiogram 6 years after MIAVR. One patient (2.8 cases/1000 py) was diagnosed with late endocarditis. Four patients (11 events/1000 py) experienced late bleeding events. A total of 8 patients (22 events/1000 py) experienced late thromboembolism. Of note, no patients required reoperative valve replacement. These data were collated and are summarized in a composite curve that illustrates actuarial freedom from any late complication, including structural valve deterioration, endocarditis, bleeding events and thromboembolism (Figure 4). Actuarial freedom from late complication events was 92.9%±0.03% (89 patients at risk) at 1 year, 89.5%±0.04% (60 patients at risk) at 2 years, and 73.1%±0.08% (19 patients at risk) at 5 years. Two patients experienced more than one complication included in the composite events category over time. The composite curve is calculated based on the time to first complication experienced by each patient.

The results from follow-up echocardiograms are summarized in Table 5 and were available for 83 patients. Median time from discharge to latest follow up echocardiogram was 1.5 years (0.5–3.2), with mean pressure gradient of 10.8mmHg (8–13). No PVL was seen in 98.2% (111) of patients on late follow up. The two patients with immediate postoperative moderate PVL had improved to mild PVL at 1 year follow up. Additionally, at 3.1 years post-MIAVR 8 patients were found to have trace aortic regurgitation, 6 patients had mild aortic regurgitation, and 1 patient had mild stenosis of the prosthetic valve.

Discussion

Given that the experience of relatively lower-volume federal facilities is not represented in the STS database, we report a study of MIAVR outcomes in the VA population. We have used our single-center experience to examine outcomes and inform clinical practice for veterans not only at our VA facility, but also for those at other VA centers nationwide. This cohort study demonstrates several notable findings. The introduction of facilitating technologies expedited the transition from traditional full-sternotomy and towards mini-sternotomy for MIAVR as the routine approach for isolated surgical aortic valve replacement. Much of the controversy surrounding more widespread adoption of MIAVR revolved around technical difficulty and prolonged operative times.[17] In addition to making this technically challenging procedure available to the VA patient population, these technologies, in conjunction with increased experience, allowed for operative time optimization, resulting in significantly shortened AXC and CPB times. Because this is a retrospective study, it is difficult to quantify the relative contribution of an enabling technology versus increasing operator experience with regards to the improved performance measures and outcomes. Despite this, we maintain that the use of the facilitating technologies and techniques allowed MIAVR to be more technically feasible for surgeons at our facility. Though the experience of the principal surgeon increased with every case, assisting surgeons rotated off service after ~10 cases. As a result, the learning curve was partially reset with every new assisting surgeon joining the service. Despite this, operative times still decreased likely reflective of increasing primary surgeon experience coupled with the introduction of facilitating technologies. Adoption of similar technologies would likely facilitate the development of MIAVR programs at other VA centers across the country.

We have demonstrated that MIAVR can be performed successfully with low morbidity and mortality at a lower-volume federal facility. Our postoperative outcomes are comparable to those reported by higher volume cardiac surgery centers.[18,19] Hirji and colleagues report the single-center experience of 1,029 patients who underwent MIAVR, citing an operative mortality rate of 1.3%, a postoperative stroke rate of 2.1%, 0.09% rate of new onset renal failure, a 1.3% rate of reoperation for bleeding, and a mean postoperative length of stay of 6 days.[18] Our median AXC and CPB times of 53 minutes and 75 minutes, respectively, were within range of Hirji *et al.'s* reported times of 62 minutes and 81 minutes. Another group, led by Johnston and colleagues, examined a cohort of 1,193 patients who received MIAVR and report similarly favorable outcomes in their study.[19] Of these 1,193 patients, operative mortality was reported to be 0.84%, stroke occurred in 1.3% of patients, renal failure was found in 0.59% of patients, and reoperation for bleeding occurred in 5% of patients. Our median length of hospital stay appears prolonged at 9 days, compared to 6 days, as reported by Hirji *et al.* Because our VA facility services a geographically vast catchment area, social and logistical factors such as long transport distances and transportation availability as well as social factors including homelessness, result in the prolongation of hospital stays despite patients being medically cleared for discharge. The rate of postoperative atrial fibrillation also appeared to be high in our cohort. VA patients are generally older, with a high incidence of smoking, excess alcohol use, among other risk factors, and tend to have more comorbidities than the general population which are not necessarily reflected by STS

scores. As such VA patients may be at a higher risk for the development of postoperative atrial fibrillation.[20–22] Additionally, the incidence of postoperative atrial fibrillation was measured per STS guidelines, defined as any episode lasting longer than one hour and/or requiring medical intervention in a patient who did not have pre-operative atrial fibrillation. Patients with postoperative atrial fibrillation were typically treated with amiodarone for rhythm control per protocol, pending no contraindications. For most patients, postoperative atrial fibrillation had resolved by time of clinic follow-up. Taken together, our experience supports the expansion of MIAVR programs to other VA facilities and lower-volume cardiac surgery centers affiliated with academic surgery programs.

With the advent of the rapid deployment and sutureless valves, surgeons now have a solution to the technical difficulty and increased AXC and CPB times previously associated with MIAVR.[17] Because our study describes the evolution of the MIAVR program at our VA facility over time, including the transition from sutured valves to rapid deployment valves, our data were able to capture trends in perioperative outcomes that appeared to correlate with the introduction of rapid deployment aortic valves. As predicted, our data demonstrated a decrease in AXC and CPB times after switching to rapid deployment valves. Our data were also notable for mean pressure gradients <10 mmHg, which mirror the hemodynamics of TAVR valves.[23,24] With the establishment of formal definitions for structural heart valve deterioration (SVD) in the era of TAVR, more attention is now being paid to postoperative valve gradients as measures of hemodynamic performance. Per definition, a mean gradient ranging from 20mmHg to 40mmHg is considered moderate SVD.[25] Achieving measurably lower mean gradients with rapid deployment valves can provide assurance to surgeons and patients of optimal valve performance.

Sutureless and rapid deployment valve technology similar to TAVR, led to an increase in pacemaker implantation by 3% as well as slightly higher PVL rates compared to traditional sutured valves.[15] Santarpino and colleagues reported their experience with the Perceval S sutureless aortic valve (LivaNova PLC, London, United Kingdom) with relatively lower mean AXC and CPB times of 40 and 68 minutes, respectively, and mean postoperative mean pressure gradient of 11.6mmHg in their MIAVR cohort study.[26] We did not find a statistically significant difference in the rate of permanent pacemaker implantation between sutured valves and rapid deployment valves. However, it was not feasible to obtain adequate study power for this comparison, given our study duration and case volume. Nevertheless, the increase in rate of permanent pacemaker implantation from 5.8 to 9.1% requires ongoing follow-up. This 3% increase comes as a tradeoff for decreased operative times, smaller surgical incision, lower CPB/AXC times, and improved hemodynamic performance. Other studies have also shown similar higher rates of permanent pacemaker implantation following sutureless or rapid deployment valve insertion and our rate of 9.1% appears consistent with literature reported ranges.[27–30] In a study of 565 patients, Dalen and colleagues report a permanent pacemaker implantation rate of 9.3% in their cohort that underwent MIAVR with a Perceval S sutureless valve, compared to 1.8% in the cohort that underwent median sternotomy with a stented valve.[29] Barnhart and colleagues conducted a prospective, non-randomized multicenter single-arm trial of 839 patients who received the Edwards Intuity valve, reported a permanent pacemaker implantation rate of 11.9%.[30] An increase in permanent pacemaker implantation is not unexpected since the anchoring forces from

the valve's stent may compress the conduction system, similar to TAVR devices.[31] Overall, the use of rapid deployment valves resulted in improved postoperative hemodynamics and was associated with equivalent morbidity compared to sutured valves, though there was a suggestion of increased risk of PVL. Compared to our 4.5% rate of moderate and 0% rate of mild PVL in the rapid deployment cohort, Dalen and colleagues report no moderate/severe PVL and 2.2% mild PVL in the sutureless group.[29] At one-year post-operative echocardiogram, patients in Barnhart and colleagues' rapid deployment cohort demonstrated moderate and severe PVL rates of 1.2% and 0.4% respectively.[30] Di Eusanio and Phan cite a meta-analysis reporting pooled PVL rates of 2–4% in patients who underwent sutureless or rapid deployment valve MIAVR, noting that the occurrence of PVL tended to be a function of the MIAVR learning curve, decreasing with increased operator experience.[32] Hanedan and colleagues, in their cohort of patients who received either a Perceval S sutureless valve or an Edwards Intuity rapid deployment valve, cited PVL rates of 1.6–15.8% and reported that severe postoperative PVL correlated with poor patient outcomes. These authors propose that chief contributory factors to PVL include stenotic remnants of the native aortic valve, residual annular calcification, and incorrect valve sizing and positioning.[33] We found this to be reflective of our experience, given that the two cases of moderate PVL found on immediate post-operative echocardiogram occurred in the first and eighth patients to undergo rapid deployment valve MIAVR. We utilized our TAVR experience to preoperatively estimate valve size. Using preoperative CTA to measure aortic annulus area, and adopting true sizing rather than under-sizing, we reduced PVL with experience. Intra-operative sizing was still performed to confirm pre-operative measurements. Using these techniques, no further cases of PVL exceeding trace levels were found on immediate post-operative echocardiogram imaging. At 1-year echocardiographic follow-up, the moderate PVL for those two patients had improved to mild PVL. With the change in sizing technique adopted, and excellent results demonstrated thereafter with increased program experience, the risk of significant postop PVL was mitigated.

Limitations

Despite the merits of this study, it also has several limitations. First, we report an observational, single-center, nonrandomized study that included a relatively small volume of patients over a long study period. Additionally, because the patient population serviced by the VA health system lacks the diversity of the general population, in particular, a paucity of women, this inherent bias impacts the generalizability of our results. Secondly, as acknowledged in our discussion, multiple confounding variables may have influenced our results, most notably the difficulty in differentiating the impact of new technology from the effect of increased experience. Third, though we were able to obtain follow-up data for all 113 patients who survived the index procedure, our median follow-up was 2.6 years, which may have limited our ability to observe differences in survival over a longer time period in this population.

Conclusions

We present outcomes from an MIAVR program at a low-volume VA medical center. Operative times decreased with increasing surgeon experience in conjunction with use

of facilitating technologies. This study addresses a critical gap in the literature and demonstrates that despite comparatively lower case volumes, clinical outcomes for minimally invasive surgeries at VA facilities can be equivalent to those reported by larger cardiac centers. Additionally, these data serve to increase health outcomes transparency for populations and cardiac surgery centers that are otherwise omitted from the national STS databases.

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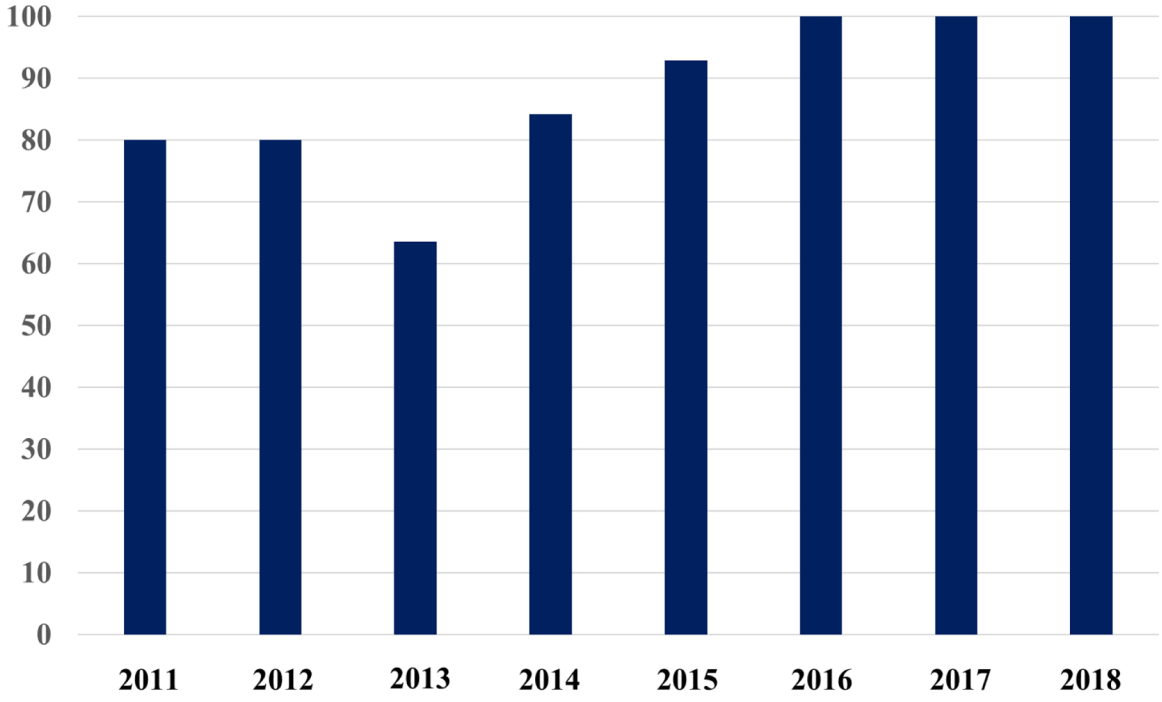

Figure 1.
Percentage of aortic valve replacements performed minimally invasively.

(a)

	No Technology	Cor-Knot	Del Nido Cardioplegia	Rapid Deployment Valve	p-value
Aortic Cross Clamp (min), median (IQR)	96 (84-103)	84 (73-90)	67 (61-80)	53 (38-61)	<.001
Cardiopulmonary Bypass (min), median (IQR)	157 (134-182)	129 (113-144)	96 (86-110)	75 (59-81)	<.001

Figure 2a.
Effect of facilitating technologies on operative times.

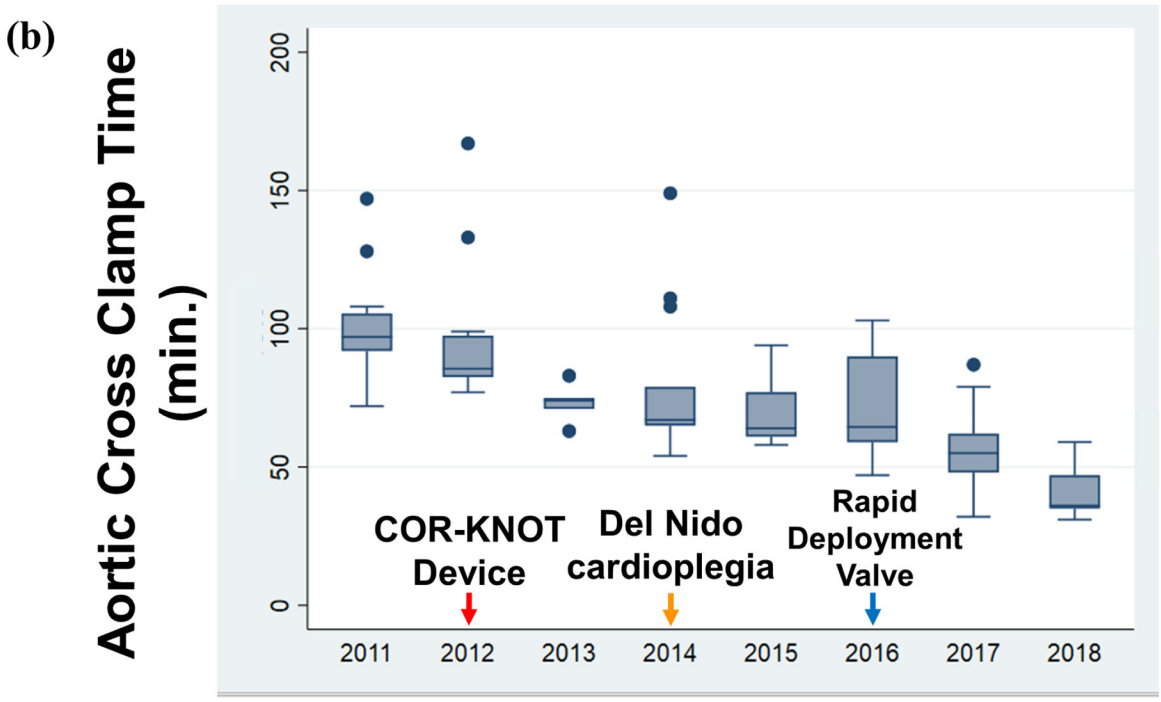

Figure 2b.
Chronological illustration of the effect of facilitating technologies on aortic cross clamp time

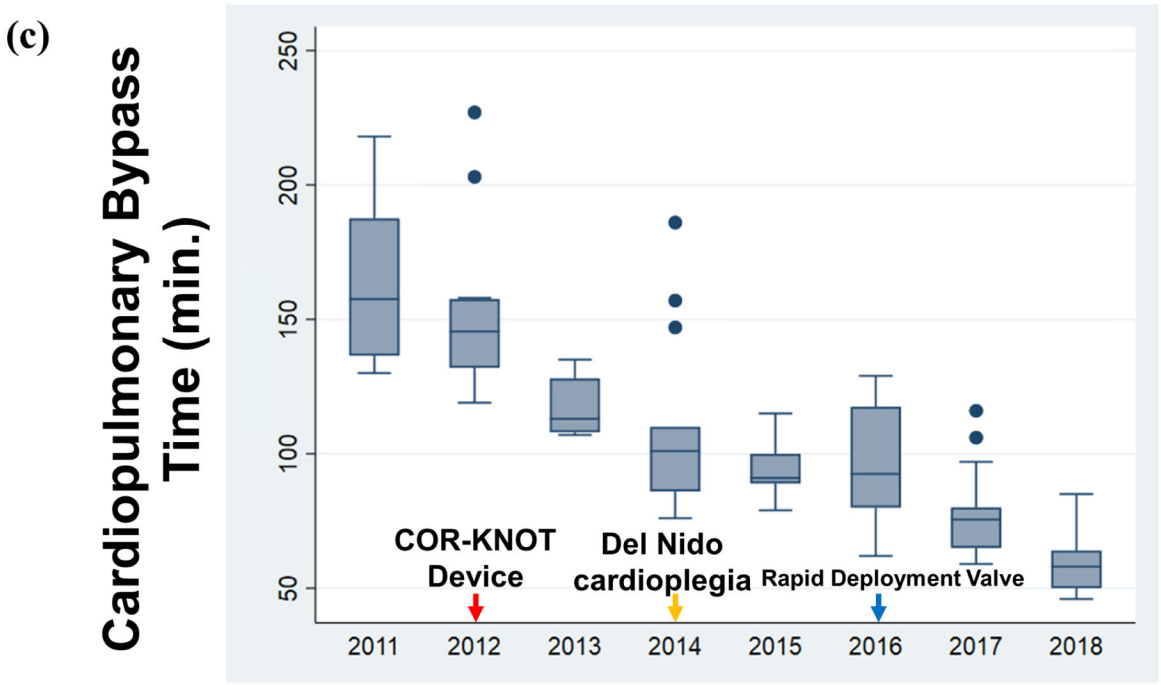

Figure 2c.
Chronological illustration of the effect of facilitating technologies on cardiopulmonary bypass time.

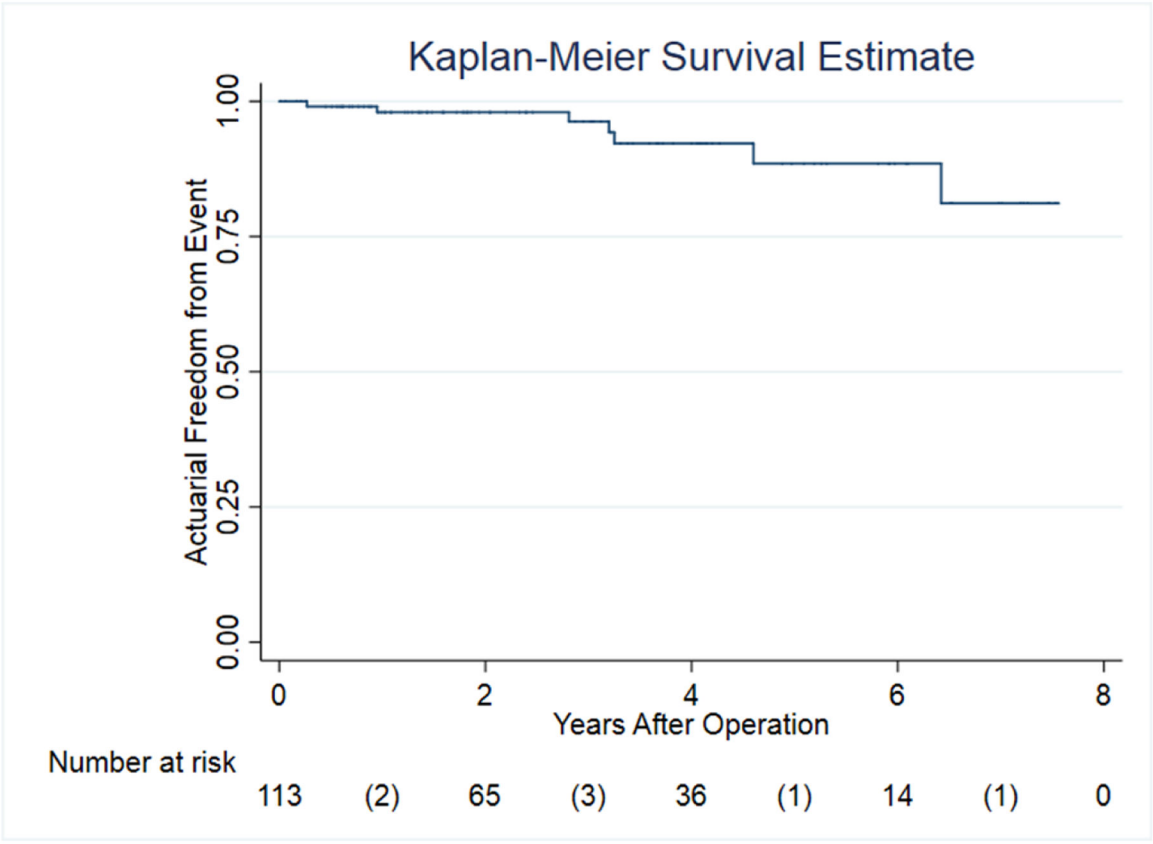

Figure 3.
Kaplan-Meier event curve for survival.
*Number in parentheses denotes number of failure events

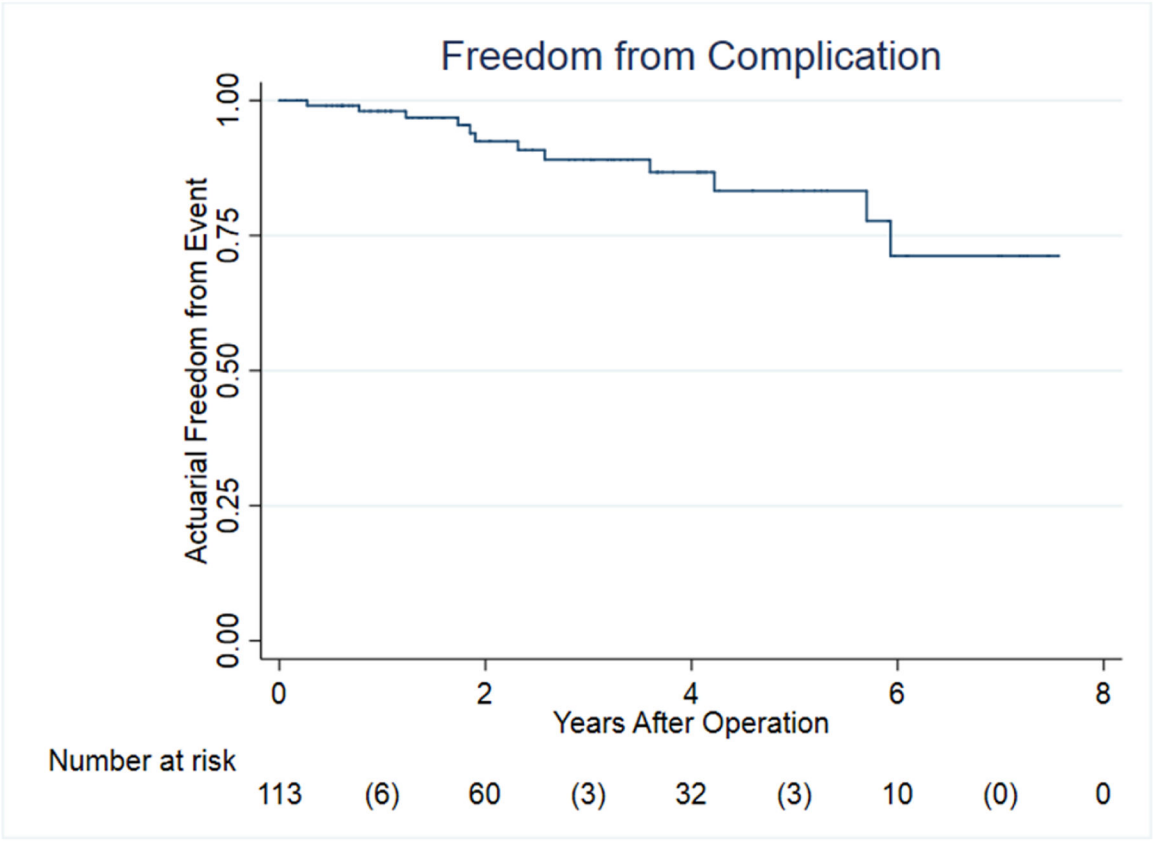

Figure 4.
Kaplain-Meier event curve for freedom from complication.
*Number in parentheses denotes number of failure events

Table 1.

Preoperative Characteristics

Patients, n	114
Age (y), median (IQR)	69 (65–73)
Gender	
Male, n (%)	112 (98)
Female, n (%)	2 (2)
STS Predicted Risk of Mortality (PROM) Score	
PROM Mortality Risk (%), median (IQR)	1.3 (0.9–1.8)
Smoking Status	
Current Smoker, n (%)	19 (17)
Prior Smoker, n (%)	71 (62)
Diabetic, n (%)	39 (34)
Hypertension, n (%)	92 (81)
Hyperlipidemia, n (%)	98 (86)
Dialysis, n (%)	0 (0)
Cerebrovascular Disease, n (%)	14 (12)
Past Cerebrovascular Accident, n (%)	2 (1.7)
New York Heart Association Class	
Class I, n (%)	20 (17)
Class II, n (%)	59 (52)
Class III, n (%)	34 (30)
Class IV, n (%)	1 (1)
Ejection Fraction (%), median (IQR)	63 (58–68)
Aortic Stenosis, n (%)	61 (53)
Aortic Regurgitation, n (%)	11 (9.6)
Mixed Disease, n (%)	42 (37)
Aortic Valve Area (cm), median (IQR)	0.7 (0.6–0.9)
Mean Pressure Gradient (mmHg), median (IQR)	46 (40–54)

Table 2.

Postoperative Outcomes

Valve Type	
Stented Bioprosthetic, n (%)	64 (56)
Mechanical, n (%)	6 (5.3)
Rapid Deployment Bioprosthetic, n (%)	44 (39)
Concomitant Procedures	
Aneurysm Wrap, n (%)	1 (0.9)
Aortic Root Enlargement, n (%)	1 (0.9)
Thymic Mass Excision, n (%)	1 (0.9)
Valve Size, (mm), median (IQR, range)	23 (23–25, 21–29)
Postoperative Length of Stay (days), median (IQR)	9 (7.0–13)
Total pRBCs Used (units), mean (SD, range)	1 (1.8, 0–10)
30-Day Mortality, n (%)	1 (0.9)
Stroke, n (%)	2 (1.8)
Transient Ischemic Attack, n (%)	1 (0.9)
Atrial Fibrillation, n (%)	61 (54)
Permanent Pacemaker, n (%)	8 (7.1)
Renal Failure, n (%)	2 (1.8)
Paravalvular Leak	
None, n (%)	97 (86)
Trace, n (%)	11 (9.7)
Mild, n (%)	2 (1.8)
Moderate, n (%)	2 (1.8)
Not reported, n (%)	1 (0.9)
Reoperation for Bleeding, n (%)	3 (2.6)
Readmission, n (%)	8 (7.1)
Post-operative MPG (mmHg), median (IQR)	11 (7.0–15)

Table 3.

Effect of Rapid Deployment Valve on Postoperative Outcomes

	Sutured Valves	Rapid Deployment Valve	p-value
Valve Size, (mm), median (IQR)	23 (21–25)	25 (25–27)	*< 0.001
Postoperative Length of Stay (days), median (IQR)	10 (7–13)	9 (7–12)	0.64
Stroke, n (%)	1 (14)	1 (2.3)	0.75
Transient Ischemic Attack, n (%)	1 (14)	0 (0)	0.42
Atrial Fibrillation, n (%)	36 (52)	25 (57)	0.63
Permanent Pacemaker, n (%)	4 (5.8)	4 (9.1)	0.59
Post-operative Mean Gradient	14 (10–17)	7.0 (4.7–10)	*< 0.001
Paravalvular Leak, n (%)			
None/Trace	66 (96)	42 (95)	0.64
Mild	2 (2.9)	0 (0)	0.27
Moderate	0 (0)	2 (4.5)	0.08
Not reported	1 (1.4)	0 (0)	

*= Denotes statistical significance

Table 4.

Late Follow-Up Outcomes

Total Follow-up, n (%)	113 (100)
Time to Follow-up (years), median (IQR, range)	2.6 (1.1–4.1, 0–7.6)
Structural Valve Deterioration, n (events per 1000 patient-years)	1 (2.8)
Endocarditis, n (events per 1000 patient-years)	1 (2.8)
Bleeding, n (events per 1000 patient-years)	4 (11)
Thromboembolism, n (events per 1000 patient-years)	8 (22)
Reoperation, n (events per 1000 patient-years)	0 (0)

Table 5.

Late Echocardiogram Follow-Up

Total Follow-up, n (%)	83 (73)
Time to Follow-up (years), median (IQR)	1.5 (0.5–3.2)
Mean Pressure Gradient (mmHg), median (IQR)	10.8 (8–13)
Paravalvular Leak, n (%)	
None	81 (98)
Trace	0 (0)
Mild	2 (2.4)
Moderate	0 (0)
Aortic Regurgitation, n (%)	
None	68 (82)
Trace	8 (9.6)
Mild	5 (6.0)
Moderate	1 (12)
Aortic Stenosis, n (%)	
None	82 (99)
Trace	0 (0)
Mild	1 (12)
Moderate	0 (0)