Innovations in Aortic Valve Replacement

A Comprehensive Overview of the Intuity Rapid Deployment Valve

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Abstract: Rapid deployment/sutureless (RDS) valves have recently emerged as an innovative surgical solution, providing an alternative to traditional methods of surgical aortic valve replacement (SAVR) by eliminating the need for suture placement and tying. This innovation leads to a reduction in aortic crossclamp and cardiopulmonary bypass times, enhancing the efficiency of the procedure. Among the 2 available RDS valves, the Edwards Intuity valve in particular has been demonstrated to be a particularly promising substitute in the field of SAVR. The Intuity valve distinguishes itself from other RDS and conventional valves by yielding superior outcomes, such as a significant reduction in mortality, increase in the longevity of the valve, and a marked decrease in both mean and peak transvalvular pressure gradients. These benefits collectively contribute to its appeal as a favorable new solution. However, further investigation is needed to conclusively determine the long-term outcomes and safety of RDS valves. Nevertheless, the utilization of the Intuity valve presents an exciting solution to the existing limitations of conventional and minimally invasive SAVR, especially for patients afflicted with severe aortic stenosis.

Key Words: aortic valve replacement, rapid deployment valve, Intuity, clinical outcomes, cardiac surgery

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Historically, patients with severe aortic stenosis (AS) who were older, frail, had multiple comorbidities, or a decreased left ventricular ejection fraction were often considered unsuitable for surgical aortic valve replacement (SAVR).[1,2] Transcatheter aortic valve implantation (TAVI) was developed as an alternative for these patients and has demonstrated favorable outcomes, including a 26.8% decrease in mortality compared to conservative management amongst inoperable patients.[2–4] On the other hand, TAVI is associated with higher rates of vascular complications, paravalvular leak, stroke, and long-term valve durability.[5–10]

Rapid deployment/sutureless (RDS) aortic valves have emerged as a relatively new surgical option that eliminates the need for suture placement and tying. The concept of sutureless valves originated in the early 1960s but was discontinued due to severe complications such as paravalvular leakage and valve-related thromboembolisms.[11] RDS valves are pericardial aortic prostheses that anchor within the aortic annulus using no more than 3 sutures, although it is worth mentioning that in clinical practice, the use of more than 3 sutures is a common occurrence.[12,13] They can be implanted using either full sternotomy or minimally invasive approaches, such as right anterior minithoracotomy (RAMT) or upper ministernotomy, according to surgeon preference.[14] The RDS valve prostheses aim to reduce aortic crossclamp and cardiopulmonary bypass time due to the sutureless nature of the valves. After cardioplegia and subsequent aortotomy, the diseased aortic valve leaflets are excised, and the annulus is decalcified. The RDS valves are then sized and implanted using delivery systems, facilitating a faster operation.[2,15]

The Edwards Intuity valve (developed by Edwards Lifesciences, Irvine) is one of the 2 types of RDS valves that are currently available on the market (the other being the Perceval valve developed by LivaNova, London, UK). This pericardial, stented aortic bioprothesis requires 3 guiding sutures for its implantation. Once implanted, the valve features intra-annular and subannular balloon-expandable cloth-covered frames that expand the left ventricular outflow tract and stabilize the valve in position.[16] The Intuity valve has shown superior outcomes compared to other RDS valves, including improved durability and a significant reduction in mean and peak aortic valve pressure gradients.[17,18] This review aims to summarize the latest literature on the utility of the Intuity prosthetic valve in SAVR, comparing its performance and outcomes with those of conventional valves and other RDS valves.

APPLICATION OF RAPID DEPLOYMENT/SUTURELESS VALVES

Conventional Surgical Aortic Valve Replacement

Conventional SAVR refers to SAVR done through a median sternotomy using either biological or mechanical prostheses and remains the gold standard for AS patients at low-to-medium surgical risk.[19,20] The American Heart Association guidelines recommend conventional SAVR over TAVI in patients younger than 65 years of age, primarily due to concerns regarding long-term valve durability of TAVI.[21] However, the suitability of conventional SAVR in high-risk patients remains unclear and is discussed further below.

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Rapid deployment valves have had a significant impact on minimally invasive and complex cardiac surgery. There is mounting evidence supporting the safety and efficacy of the Intuity bioprosthetic valve. There is also data suggesting that the valve has shown a decreased need for permanent pacemaker implantation in comparison to other rapid deployment valves. Therefore, it should be considered for deployment in the appropriately selected patients to reduce the risk of requiring a permanent pacemaker.

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Technological advancements have led to the introduction of RDS valves, representing a minimally invasive alternative that eliminates the need for suture placement and tying.[2] Moreover, the deployment and delivery mechanisms of RDS valve prostheses are exceptionally swift following excision of the diseased valve.[22] Consequently, RDS valves display potential for use in conventional SAVR for high-risk patients, as supported by recent data.

In a retrospective study of 979 patients, Ranucci et al[23] demonstrated that RDS valves induced a greater clinical benefit in patients with a left ventricular ejection fraction ≤40% and diabetic patients, due to reduced aortic crossclamp time. These findings suggest that RDS-SAVR may be particularly advantageous for populations at high risk of systolic dysfunction. A meta-analysis by Phan et al[24] revealed that the use of the RDS valve allowed for half the regular aortic crossclamp and cardiopulmonary bypass time, with improved prognosis in elderly and high-risk patients. This finding of improved aortic crossclamp and cardiopulmonary bypass time, both of which are independent risk factors for postoperative morbidity and mortality,[25,26] is consistent among several studies.[22,24,27,28] Additionally, Berretta et al[2] proposed that RDS-SAVR may be especially helpful in high-risk patients who need SAVR with concomitant cardiac surgery or complex operations, in order to minimize operation duration and maximize results.

While the original sutureless valve was invented in the early 1960s, subsequent advancements have let to the creation of the Edwards Intuity valve. Unlike other RDS valves, the Edwards Intuity valve uses a sealing frame to anchor and seal the valve following resection of the diseased native aortic valve.[29] Fixation of the valve relies on contact with the walls of the left ventricular outflow tract, necessitating a smooth, pliable, and stable surface area in the region immediately below the valve leaflet insertion.[29]

Several studies have examined the safety, feasibility, and efficacy of the Edwards Intuity valve in SAVR.[29–33] One such study is the TRITON trial (Surgical Treatment of Aortic Stenosis with a Next Generation Surgical Aortic Valve, ClinicalTrials.gov identifier: NCT01445171[30]) conducted in 2013. A total of 146 patients were studied (mean age 75.5 ± 6.7 years), with 69.9% of patients undergoing conventional SAVR via median sternotomy, 29.5% via an upper hemisternotomy, and 0.7% via a RAMT. The procedure was found to be successful in 97.3% of patients. Furthermore, valve-related mortality was found to be just 1.9%, with 75.0% of the remaining patients showing continued improvement and 21.9% remained in the same NYHA class. Additionally, only 1 out of 146 patients (0.8%) developed valve-related conduction abnormalities postoperatively. Furthermore, 1 out of 146 patients (0.9%) developed a paravalvular leak (>1+). Early valve-related mortality (≤30 days) was 1.4%, while late mortality (>30 days) was 1.9%. The TRITON trial identified that patients who underwent Edwards Intuity valve implantation had significantly reduced aortic crossclamp and cardiopulmonary bypass times in comparison to conventional aortic valve replacement, as well as improved cardiac hemodynamic performance as measured on echocardiography. However, the TRITON trial also reported that while the ≤30-day valve-related postoperative permanent pacemaker implantation rate in patients with no previous conduction abnormalities (n = 102) was 0%, it was an alarming 17.9% in those with previous conduction abnormalities (n = 39). The same parameters measured at >30 days showed valve-related postoperative permanent pacemaker implantation in patients with no baseline conduction abnormalities to be increased by only 1%, and 0% among those with previous conduction abnormalities. This rate is quite high in contract to the rate of 5% reported by the European trials on the Edwards Intuity valve.[34] While the exact reason for this finding is unclear, it may be owed to the high prevalence (nearly 30%) of preoperative conduction abnormalities present in patients enrolled in the study.

Similar outcomes were reported by the TRANSFORM (Multicenter Experience With Rapid Deployment Edwards Intuity Valve System for Aortic Valve Replacement) trial conducted by Barnhart et al,[31] which had a 95% technical success rate. In the TRANSFORM trial, 59% of patients underwent a full sternotomy, while the other 41% underwent a minimally invasive procedure. Furthermore, early valve-related mortality (≤30 days) was 0.5%, and late valve-related mortality was 0.99%. At 1-year postoperatively, the mean pressure gradient was 10.3 mm Hg, while moderate and severe paravalvular leak was as low as 1.2% and 0.4%, respectively. Akin to the TRITON trial, the TRANSFORM trial also concluded that the Edwards Intuity valve showed reduced aortic crossclamp and cardiopulmonary bypass times and has exceptional hemodynamic performance. However, the TRANSFORM trial also reports a new pacemaker implantation rate of 11.9%—again a relatively high rate.

While these trials support the notion that RDS valves, specifically the Edwards Intuity valve, may be safer for elderly, high-risk, and conventional SAVR-ineligible patients, their safety in patients with preexisting conduction abnormalities must be evaluated. It is proposed that in patients with baseline conduction abnormalities, the Edwards Intuity valve's balloon-expandable frame may cause greater radial force inside the LVOT than a conventional valve, thereby increasing the likelihood of pacemaker implantation. Further research is needed to address why this valve seems to be associated with such a risk.

Minimally Invasive Aortic Valve Replacement

Minimally invasive SAVR (MI-SAVR) encompasses various techniques, with the majority of cases employing upper hemisternotomy or RAMT approaches.[35] While the use of upper hemisternotomy is on the rise, RAMT remains less common.[36] Both methods minimize surgical trauma and enhance surgical exposure for valve replacement.[37] MI-SAVR is associated with reduced intraoperative bleeding, shorter intensive care unit and hospital stays, and a shorter duration of postoperative mechanical ventilation. However, some have found that it may lead to longer operative times.[35] In this regard, the use of RDS valves holds the promise of mitigating the prolongation of operative times associated with MI-SAVR. Despite this potential advantage, the use of MI-SAVR with RDS valves has for a long time been limited within the cardiac surgery community due to the lack of long-term clinical trials conclusively demonstrating their benefit over other valve types for particular patient populations.[36,38]

However, evidence supporting the use of RDS valves in MI-SAVR has accrued in recent years. Wiedemann et al[14] reported excellent surgical outcomes with the Intuity prosthetic valve in MI-SAVR using a RAMT approach and reported survival rates of 99%, 98%, and 93% at 6 months, 1-year, and 3 years, respectively. Furthermore, Glauber et al[39] report a survival rate of 91.54% at the 5-year mark, with 5 explants reported, 3 of which were due to endocarditis, while the other 2 were due to nonstructural valve dysfunction. In another study by Berretta et al,[38] 1935 patients underwent sutureless and rapid deployment AVR, of which 1418 (73.3%) underwent MI interventions. An upper ministernotomy was the approach used in 56.4% (n = 800) of patients, and anterior right thoracotomy in the other 43.6% (n = 618). Of those 1418 patients, Perceval valves were used in 1011 (71.3%) and Intuity valves were used in 407 (28.7%) patients. The study shows a total pacemaker implantation rate of 9% that significantly decreased over the course of the observational period from 20.6% to 5.6% ($P = 0.002$). Furthermore, the study showed that the Perceval valve was associated with a shorter intraoperative period, while the Intuity valve showed better postoperative hemodynamic parameters.

The TRITON trial discusses similar outcomes of MI-SAVR. A minimally invasive approach was used in 30.1% of patients, with 48.8% of them being isolated AVR. The TRITON trial concluded similar deductions; the Edwards Intuity valve provides valuable utility in minimally invasive surgery, while simultaneously reducing aortic crossclamp and cardiopulmonary bypass times.[30] In the TRANSFOR trial on the other hand, 41% of patients underwent minimally invasive surgery, demonstrating an aortic crossclamp time of 63.1 ± 25.4 minutes, and a cardiopulmonary bypass time of 84.6 ± 33.5 minutes, with the Edwards Intuity valve in MI-SAVR. These were found to be shorter aortic crossclamp and cardiopulmonary bypass times in comparison to the MI-SAVR comparators from the Society of Thoracic Surgeons database, which showed an aortic crossclamp time of 82.9 minutes, and a cardiopulmonary bypass time of 111.4 minutes.[31]

Other comprehensive studies have also extensively explored the utilization of RDS in MI-SAVR procedures.[39,40] Considering this, Beretta et al.[38] suggested that large-scale evidence supports the preference for utilization of RDS valves as the primary approach in MI-SAVR. However, it is noteworthy to add that, to date, most studies exploring the utilization of RDS in MI-SAVR procedures have been noncontrolled and often noncomparative studies. Further research is needed to determine the exactness of the superiority of RDS valves in MI-SAVR.

Concomitant Procedures

RDS valves provide a surgical alternative for patients who might otherwise be ineligible for surgery due to extended operative times.[41] Procedures that often require longer-than-anticipated operative times include those performed on patients undergoing simultaneous procedures alongside SAVR. For instance, in cases of severe AS and concurrent coronary artery disease, both SAVR and coronary artery bypass grafting may need to be performed. The application of the RDS valves in such procedures may allow for a decrease in aortic crossclamp and cardiopulmonary bypass times.

In the TRITON trial by Kocher et al[30] which assessed the efficacy and safety of the Edwards Intuity valve in patients undergoing SAVR, 24.7% of procedures were conducted concomitantly with coronary artery bypass grafting, while another 16.4% of procedures were performed alongside other operations, such as Maze procedure, mediastinal tumor excision, or repair of an atrial septal defect. These complex RDS-SAVR procedures (ie, Edwards Intuity valve SAVR with concomitant surgery) once again revealed reduced aortic crossclamp and cardiopulmonary bypass times (60 ± 19 and 96 ± 30 minutes, respectively) as compared to conventional (ie, non-RDS) SAVR with concomitant surgery (87 and 113 minutes, respectively).[30] These results support the hypothesis that the Edwards Intuity valve may be a more favorable prosthesis choice for patients requiring multiple procedures.

On the other hand, a 2-center clinical trial conducted by Bottio et al[42] comparing the efficacy of RDS-SAVR using the Edwards Intuity valve plus myocardial revascularization versus standard SAVR plus myocardial revascularization revealed that no significant difference was found in the 5-year mortality between standard and RDS-SAVR. Further research is needed to determine whether the use of the Edwards Intuity valve in patients requiring concomitant surgeries provides significant long-term benefit over non-RDS valves. Several patients with severe AS may also present with concurrent mitral valve disease and require dual valve replacement. This poses a great risk, as chances of the 2 valve prostheses interfering with 1 another are high due to their proximity, particularly when both are implanted within the same procedure. This scenario was first studied in a case series by Ferrari et al[43] in 2014, who performed concomitant aortic and mitral valve repair/replacement on 2 patients. Both procedures deployed the Edwards Intuity valve for SAVR and were found to be successful with minimal interference from the valve on the mitral prosthesis (in the first case) and mitral ring (in the second case). A later study by Bechtel et al[44] further supported this finding, showing the success of RDS-SAVR using the Edwards Intuity valve with concomitant mitral valve surgery in 16 patients. Furthermore, in 2017, Schlömicher et al[45] demonstrated that RDS-SAVR using the Edwards Intuity valve system in patients undergoing combined aortic and mitral valve surgery also displayed consistently lower aortic crossclamp and cardiopulmonary bypass times, with a 1-year survival of 81%.

These results suggest that the indications for RDS valves could potentially be expanded to include patients with concomitant mitral valve disease, as well as those requiring concomitant procedures for other reasons. However, it is worth mentioning that the currently available literature has limitations due to the lack of studies on the long-term outcomes in these patient populations.

Bicuspid Aortic Valves

The utility of RDS valves in patients with a bicuspid aortic valve (BAV) remains unclear. One major concern is the potential occurrence of paravalvular leak due to the asymmetric anatomy of the aortic root and the increased risk of valve dislocation.[46] Literature on the safety and efficacy of RDS valves in BAV patients presents conflicting findings. For instance, Miceli et al[46] reported that using RDS valves in BAV is safe, with a 30-day mortality of 1.6%. On the other hand, Miceli et al[46] showed that using RDS valves in these patients may increase the risk of postoperative complications, such as aortic regurgitation, atrial fibrillation, atrioventricular block, and the need for a pacemaker. Another study conducted by Coti et al[47] reported significantly better mortality rates in BAV patients in comparison to tricuspid aortic valve patients, but also observed a higher incidence of moderate to severe paravalvular regurgitation during long-term follow-up. This observation raises an important consideration regarding the potential trade-off between favorable early outcomes (including lower risk of operative mortality and shorter operative times) on the 1 hand, and the increased occurrence of paravalvular regurgitation associated with the use of RDS valves in BAV patients on the other hand. Given that the elliptic aortic annulus in BAV patients presents a challenge for RDS valves, and as the approach using RAMT gains traction for MI-SAVR, Sá et al[48] have detailed their specific surgical technique. Their focus lies on the procedural intricacies in the context of the 2-sinus BAV laterolateral phenotype. Further investigation is warranted to fully understand the implications of this increased frequency and its impact on the overall efficacy and long-term prognosis of BAV patients undergoing RDS valve implantation. Consequently, the use of RDS valves in BAV patients is still a matter of debate.

OUTCOMES OF THE EDWARDS INTUITY RAPID DEPLOYMENT VALVE

Several studies have demonstrated the results of Edwards Intuity valve to be superior to those of conventional SAVR (as well as other RDS valves). **Table 1** gives a concise summary of seminal studies describing several key outcomes of the Edwards Intuity valve. Comparisons of these outcomes to conventional SAVR can be found in the subsections below.

Mortality and Stroke

Numerous studies have reported promising clinical outcomes of RDS-SAVR with the Edwards Intuity valves pertaining to mortality and stroke rates.[14,24,50] In a meta-analysis of clinical trials involving Edwards Intuity valves, the pooled proportions of long-term outcomes revealed an 8.9% all-cause mortality rate and a 3.7% cardiac-related mortality rate after 5 years.[28] These results are favorable compared to previous data, such as the 15.0% 5-year all-cause mortality rate reported by Williams et al[28] for conventional SAVR. A separate study reported a 2.6% 30-day mortality rate among patients receiving Edwards Intuity valves,

TABLE 1. Summary of Studies That Have Reported the Clinical Outcomes Associated With the Intuity Rapid Deployment Valve

Author, Year	Title	Journal	Surgical Approach	Sample Size	Findings
Wiedemann et al (2021)[14]	Anterior right thoracotomy for rapid deployment aortic valve replacement	The Annals of Thoracic Surgery	Anterior right thoracotomy	165	In-hospital mortality (0.6%), 6-month mortality (1%), 1-year mortality (2%), 3-year mortality (7%), Early (≤30 days) stroke (3%), Late (>30 days) stroke (1.2%), Trace or mild paravalvular leak (8.4%), Moderate or severe paravalvular leak (1.8%), Permanent pacemaker implantation (10.3%), Mean pressure gradient 12.8 ± 5.3 mm Hg, Peak pressure gradient 22.2 ± 8.9 mm Hg, Structural valve deterioration (0%)
Werner et al (2022)[49]	Long-term durability after surgical aortic valve replacement with the trifecta and the Intuity valve - a comparative analysis	European Journal of Cardiothoracic Surgery	Full sternotomy (400), Hemisternotomy (179), Anterolateral thoracotomy (193)	772	30-day mortality (0.91%), 30-day stroke (N/A), Permanent pacemaker implantation (9.07%), Mean pressure gradient at: • 1 month: 12.3 ± 5.4 mm Hg • 1-year: 11.1 ± 4.4 mm Hg • 3 years: 11.4 ± 4.7 mm Hg • 5 years: 13.6 ± 9.1 mm Hg Peak pressure gradient N/A, Structural valve deterioration at 5 years (1.04%) and at 7–8 years (1.6%)
Ono et al (2022)[17]	Early outcomes of Intuity rapid deployment aortic valve replacement compared with conventional biological valves in Japanese patients	Circulation Journal	Median Sternotomy, right minithoracotomy	95	In-hospital mortality (2%), 1-year mortality (4%), In-hospital disabling stroke (1%), 1-year stroke (1%), Paravalvular leak: • Trivial (87%) • Mild (12%), • Moderate (1%) Permanent pacemaker implantation (3%), Mean pressure gradient at 1 week 12.7 ± 5.2 mm Hg, and at 1-year 11.6 ± 4.7 mm Hg, Peak pressure gradient at 1-year N/A, Structural valve deterioration (N/A)
Gotzmann et al (2019)[20]	Hemodynamic comparison of sutureless and rapid deployment valves with conventional bioprostheses	The Thoracic and Cardiovascular Surgeon	N/A	33	Immediate mortality within 72 hours (0%), Stroke (0%), Paravalvular leak • Trace/Mild (9.4%) • Moderate (6.3%), • Severe (0%) Permanent pacemaker implantation (9.1%), Mean pressure gradient 10.79 ± 4.78 mm Hg, Peak pressure gradient 19.76 ± 9.56 mm Hg, Structural valve deterioration (N/A)

(Continued)

TABLE 3. *(Continued.)*

Author, Year	Title	Journal	Surgical Approach	Sample Size	Findings
Bening et al (2017)[22]	Rapid deployment valve system shortens operative times for aortic valve replacement through right anterior minithoracotomy	Journal of Cardiothoracic Surgery	Right anterior minithoracotomy	43	30-day mortality (4.7%), 30-day stroke (N/A), Paravalvular leakage (0%) Permanent pacemaker implantation (2.3%), Mean pressure gradient 9.2 ± 1.7 mm Hg, Peak pressure gradient 14.3 ± 8 mm Hg, Structural valve deterioration (N/A)
Rahmanian et al (2018)[27]	Rapid deployment aortic valve replacement: excellent results and increased effective orifice areas	The Annals of Thoracic Surgery	Median Sternotomy (155), Upper partial sternotomy (8)	163	In-hospital mortality (1.8%), Postoperative cerebrovascular accidents (1.8%), Minimal paravalvular leakage of no clinical significance seen in 2 patients, Permanent pacemaker implantation (9.2%), Mean pressure gradient 9.2 ± 4.9 mm Hg, Peak pressure gradient 17.3 ± 9.0 mm Hg, Structural valve deterioration (N/A)
Kocher et al (2013)[30]	1-year outcomes of the surgical treatment of aortic stenosis with a next-generation surgical aortic valve (TRITON) trial: a prospective multicenter study of rapid deployment aortic valve replacement with the Edwards Intuity valve system	The Journal of Thoracic and Cardiovascular Surgery	Full Sternotomy (102), Upper Hemisternotomy (43), Right anterior minithoracotomy (1)	146	Early (≤30 days) all-cause mortality (2.1%) Early (≤30 days) valve-related mortality (1.4%), Late (>30 days) all-cause mortality (7.5%), Late (>30 days) valve-related mortality (1.9%), 30-day stroke (N/A), Early paravalvular leak (1.4%), Late paravalvular leak (0.9%) Permanent pacemaker implantation (5%), Mean pressure gradient at: • 3 months 8.8 ± 3.0 mm Hg • 1-year 8.4 ± 3.4 mm Hg Peak pressure gradient at • 3 months 16.7 ± 6.0 mm Hg • 1-year 15.8 ± 5.7 mm Hg Structural valve deterioration (0%)
Barnhart et al (2017)[31]	TRANSFORM (multicenter experience with rapid deployment Edwards INTUITY valve system for aortic valve replacement) US clinical trial: performance of a rapid deployment aortic valve	The Journal of Thoracic and Cardiovascular Surgery	Full sternotomy (495), Upper ministernotomy (275), Right anterior thoracotomy (69)	839	All-cause mortality at 30 days (0.8%), Valve-related mortality at 30 days (0.5%), All-cause mortality at 1-year (3.0%), Valve-related mortality at 1-year (1.1%), 30-day stroke (2.6%), Permanent pacemaker implantation (11.9%), Mean pressure gradient at 1-year 10.3 ± 3.8 mm Hg, Peak pressure gradient (N/A), Structural valve deterioration (0%)

(Continued)

TABLE 3. *(Continued.)*

Author, Year	Title	Journal	Surgical Approach	Sample Size	Findings
Pelce et al (2014)[33]	5-year outcomes of rapid deployment aortic valve replacement with the Edwards Intuity valve	Journal of Cardiac Surgery	Full sternotomy (170)	170	All-cause mortality at 1-year (2.4%), All-cause mortality at 5 years (12.4%), Cardiovascular mortality at 1-year (1.8%), Cardiovascular mortality at 5 years (4.7%), 1-year stroke (4.1%) 5-year stroke (7.0%), Paravalvular leak • Mild (2.4%) • Moderate (0.6%) Permanent pacemaker implantation (3.5%), Mean pressure gradient at: • 30 days: 12.3 ± 4.6 mm Hg • 1-year: 11 ± 4.7 mm Hg • 5 years: 11.2 ± 4.4 mm Hg Peak pressure gradient (N/A), 1-year structural valve deterioration (26.5%), 5-year structural valve deterioration (28.9%)
D'Onofrio et al (2022)[50]	Clinical and hemodynamic outcomes of rapid deployment aortic bioprostheses	Seminars in Thoracic and Cardiovascular Surgery	Full sternotomy (985), Ministernotomy (638) Minithoracotomy (64)	1687	30-day mortality (1.8%). 1-year mortality (5.3%), Cardiovascular mortality at 1-year (2.8%), Stroke (2.4%), Permanent pacemaker implantation (6.3%), Mean pressure gradient 10 (8–13) mm Hg, Peak pressure gradient 18 (14-23) mm Hg, Structural valve deterioration (N/A) Paravalvular leak (5.2%) • Mild (4.7%) • Moderate (0.5%) • Severe (0%)
Liakopoulos et al (2018)[51]	Direct comparison of the Edwards Intuity elite and Sorin Perceval S rapid deployment aortic valves	The Annals of Thoracic Surgery	Median sternotomy (107), Upper minimal J-sternotomy (10)	117	All-cause mortality at 30 days (2.6%), Valve-related mortality (0.9%), Stroke (0.9%), Paravalvular leak • Mild (1.7%) • Moderate/severe (0%) Permanent pacemaker implantation (8.5%), Mean pressure gradient at discharge 10 ± 5 mm Hg, Peak pressure gradient at discharge 18 ± 9 mm Hg, Structural valve deterioration (0%)
Andreas et al (2016)[52]	Conventional versus rapid deployment aortic valve replacement: a single-center comparison between the Edwards magna valve and its rapid deployment successor	Interactive Cardiovascular and Thoracic Surgery	Full sternotomy (47), Hemisternotomy (27), Anterolateral thoracotomy (42)	116	All-cause mortality at 30 days (0.9%), 1-year (5%), and 5 years (10%), Stroke (0%), Permanent pacemaker implantation (9%), Mean pressure gradient 14 ± 4 mm Hg, Peak pressure gradient (N/A), Structural valve deterioration (0%), Paravalvular leak: • Trivial (6%) • Mild (3%) • Moderate (2%) • Severe (0%)

(Continued)

TABLE 3. *(Continued.)*

Author, Year	Title	Journal	Surgical Approach	Sample Size	Findings
Herry et al (2020)[59]	Pacemaker implantation after aortic valve replacement: rapid deployment Intuity compared to conventional bioprostheses	European Journal of Cardiothoracic Surgery	Full Sternotomy (256)	256	In-hospital Mortality (3.5%), Stroke (2.3%), Permanent pacemaker implantation (14.5%), Mean pressure gradient 11 ± 4 mm Hg, Peak pressure gradient (N/A), Structural valve deterioration (N/A), Paravalvular leak > mild (2.3%)
Ferrara et al (2021)[53]	Rapid deployment versus transcatheter aortic valve replacement in intermediate-risk patients: a propensity score analysis	Journal of Cardiac Surgery	Median Sternotomy (48)	48	2-year overall mortality (8.38%), 2-year disabling stroke (0%), Permanent pacemaker implantation at 2 years (11.11%), Mean pressure gradient 10.33 ± 3.42 mm Hg, Peak pressure gradient (N/A), Structural valve deterioration (N/A), Paravalvular leak ≥grade 2/4 at 1 month (0.0%)
Haverich et al (2014)[54]	3-year hemodynamic performance, left ventricular mass regression, and prosthetic-patient mismatch after rapid deployment aortic valve replacement in 287 patients	The Journal of Thoracic and Cardiovascular Surgery	N/A	287	30-day mortality (1.7%), Late mortality >30 days (3.7%), 30-day stroke (2.8%), Permanent pacemaker implantation (N/A), Mean pressure gradient at 1-year 9.0 ± 3.6 mm Hg and 3 years 8.7 ± 4.1 mm Hg, Peak pressure gradient (N/A), Structural valve deterioration (0%), Major paravalvular leak grade >2+ (0.7%)
Liakopoulos et al (2020)[72]	Rapid deployment aortic valve replacement with the Perceval S and Intuity elite	The Thoracic and Cardiovascular Surgeon	SAVR (209), Minimally invasive (43)	251	30-day mortality (2.4%), Cerebrovascular events (4.4%), with disabling stroke seen in 0.8%, Permanent pacemaker implantation (11.2%), Mean pressure gradient at discharge 12 ± 4 mm Hg, Peak pressure gradient at discharge 23 ± 8 mm Hg, Structural valve deterioration (N/A), Moderate or severe paravalvular leak (0.4%)

indicating positive clinical outcomes associated with these valves.[28] Furthermore, a comparison study demonstrated a lower 30-day mortality rate of 2.6% in patients receiving the Edwards Intuity valve compared to 5.1% in patients receiving the Perceval valve.[51] At the 5-year mark, Pelce et al[33] reported a 12.4% mortality rate with the usage of Edwards Intuity valves.

The superiority of Edwards Intuity valve is further supported by another study which documented a lower rate of stroke with the Edwards Intuity valve in comparison to conventional AVR (0% vs 1.6%; $P < 0.044$).[52] However, data reporting the rate of stroke in patients receiving the Edwards Intuity valve is conflicting. For example, Ensminger et al[55] documented a higher risk of stroke in RDS patients in comparison to conventional AVR (0.9% vs 2.2%; $P < 0.001$), while another study found no significant difference in stroke rates between RDS and conventional AVR patients.[56] Further research is necessary to determine the risk and incidence of stroke in RDS patients receiving the Edwards Intuity valve.

The incidence of valve-associated infection, a rare complication, is typically less than 1% among recipients of Edwards Intuity valves.[33] Reoperation rates are also low, with only 2.8% of patients requiring reoperation within 5 years postvalve implantation.[33] Severe bleeding is an important consideration for any surgical procedure, including SAVR. In a clinical trial involving 839 patients who received the Edwards Intuity RDS valve, only 3.5% experienced significant bleeding.[31] However, while Edwards Intuity valves have demonstrated positive outcomes in clinical trials and studies, it is important to note that individual patient outcomes may vary due to multiple factors. Continued monitoring and evaluation of the long-term outcomes of these valves are also necessary to ensure optimal patient care.

Pacemaker Rate, Paravalvular Leak, and Patient-Prosthesis Mismatch

Atrioventricular block necessitating pacemaker implantation can develop with SAVR utilizing the Edwards Intuity RDS valve. Studies have shown 30-day incidence rates of pacemaker implantation between from 5% to 8%.[24,30,57] In the study by White et al,[58] 6.8% of patients undergoing RDS-SAVR required a new pacemaker, compared to only 2.3% in the conventional SAVR group ($P = 0.009$).[58] In line with this, other studies have identified increased rates of atrial fibrillation and conduction abnormalities in patients undergoing RDS-SAVR.[52,55,59,60]

Paravalvular leak is another significant complication of SAVR and can lead to significant morbidity and mortality. A review article of 3993 patients showed that only 4.2% of individuals undergoing RDS-SAVR with the Edwards Intuity valve developed a paravalvular leak within 1-year postvalve implantation,[61] which is consistent with other reports.[30,53] Furthermore, Erfe et al[62] reported similar rates of moderate or greater paravalvular leak with RDS-SAVR and conventional SAVR (0.2% vs 0.1%, respectively, $P = 0.210$). A recently published meta-analysis with reconstructed time-to-event data of matched studies compared surgical AVR with RDS valves versus TAVI and showed that the pooled risk of 30-day mortality did not favor any group, but patients undergoing surgical AVR with RDS valves had a lower risk of paravalvular leak. No statistically significant differences were observed for 30-day stroke, AKI, major bleeding, permanent pacemaker implantation, prosthesis-patient mismatch, and postoperative aortic valve area. In the follow-up, the authors observed a higher risk of mortality with TAVI; however, the interpretation of these results warrant caution due to the fact that patients receiving RDS valves tended to be younger than TAVI patients.[63] Dokollari et al[64], reported a similar finding in their systematic review, with a lower paravalvular leak in Intuity valve recipients in comparison to TAVI (Intuity 0% and TAVI 2.17%).

Regarding patient-prosthesis mismatch, which occurs when the implanted prosthetic valve is too small for the patient's valve, the incidence is minimal among Edwards Intuity valve recipients; severe mismatch (ie, an indexed effective orifice area of $\leq 0.65\ cm^2/m^2$) only develops in 3% of patients and transvalvular pressure gradients are comparable to other prosthetic heart valves.[54] Since it is reported that prosthesis-patient mismatch increases perioperative, early-, mid-, and long-term mortality rates after surgical AVR, the lower rates of mismatch with RDS valves is of utmost importance to improve outcomes.[65] This suggests that the Edwards Intuity valve provides an appropriate prosthesis size for most patients, minimizing the risk of patient-prosthesis mismatch.

Thus, while the higher rates of pacemaker implantation should be seriously considered, the overall incidences of paravalvular leak and patient-prosthesis mismatch associated with the Edwards Intuity RDS valve remains relatively low. However, careful patient selection by considering comorbidities, intraoperative techniques, and postoperative surveillance using regular follow-ups are crucial in minimizing and managing these potential complications.

Durability

Several studies with follow-up times up to 10 years post-SAVR have provided evidence for the long-term structural and functional durability of the Edwards Intuity valve,[32,49] with a low incidence of structural valve degeneration.[30,66] In addition to clinical studies, researchers have utilized computer simulations and other modeling techniques, including finite element analysis, to evaluate the durability of the Edwards Intuity valve.[67,68] One such study demonstrated that the Edwards Intuity valve exhibited robust mechanical resilience during the cardiac cycle, suggesting its suitability for long-term use.[69] It is important to note that factors such as patient age, comorbidities, and surgical skill can influence the longevity of the valve. Furthermore, while these results are encouraging, comparisons to conventional SAVR remain unclear, particularly regarding durability in the very long term and the settings of exercise and endurance testing.[20]

COMPARISON TO PERCEVAL VALVE

Comparing different RDS valves, the Edwards Intuity valve demonstrates lower mean (10.79 ± 4.78 vs 15.48 ± 7.51 mmHg) and peak (17 ± 7 vs 22 ± 8 mmHg) transvalvular pressure gradients than the Perceval valve.[20] However, Liakopoulos et al[51] found similar peak or mean pressure gradients between the 2 groups, but a higher indexed orifice area in the Intuity group. Cardiopulmonary bypass times, aortic crossclamp times, 30-day mortality, need for pacemaker implantation, and incidence of cerebrovascular events were similar between the 2 groups.[51] Patients receiving the Perceval RDS valve demonstrate higher rates of increased rate of prolonged postoperative thrombocytopenia, while Intuity valve recipients experience only transient thrombocytopenia.[70,71] Further large-scale prospective studies are required to validate these findings and establish the potential superiority of the Edwards Intuity valve in this context.

CONCLUSION

Rapid deployment aortic valves have emerged as a surgical option that eliminates the need for suture placement and tying. The Edwards Intuity Elite valve, a type of RDS valve, has demonstrated to be a promising surgical option. In comparison to other RDS valves and conventional valves, the Intuity valve has shown to produce better results. These improvements include increased longevity, a considerable decrease in the mean and peak aortic valve pressure gradients, and a shorter duration of thrombocytopenia. While further studies are needed to determine the long-term outcomes and safety of RDS valves, the use of the Intuity valve offers a potential solution to the limitations of conventional SAVR and MI-SAVR for patients with severe AS.

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