



# The sutureless and rapid-deployment aortic valve replacement international registry: lessons learned from more than 4,500 patients

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The treatment options for patients with aortic valve disease have considerably expanded over the last decade. The remarkable advances in catheter-based technology, the popularizing of minimally invasive (MI) surgery, and the introduction of new valve technologies, such as sutureless and rapid-deployment (SURD) valves have led to a paradigm shift in the management of aortic valve pathologies. Yet, given their recent introduction, the current evidence on sutureless and rapid-deployment aortic valve replacement (SURD-AVR) has been limited thus far. The Sutureless and Rapid-Deployment Aortic Valve Replacement International Registry (SURD-IR) was established in 2015 by a consortium of 18 research centers to assess safety, efficacy, short- and long-term outcomes of SURD-AVR interventions. The present keynote lecture aims to assess and comment on the real-world evidence for SURD-AVR surgery generated from the SURD-IR.

**Keywords:** Sutureless valve; rapid-deployment valve; aortic valve replacement (AVR); Sutureless and Rapid-Deployment Aortic Valve Replacement International Registry (SURD-IR)



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## Introduction

The treatment options for patients with aortic valve disease have significantly expanded over recent years. The tremendous growth of transcatheter aortic valve implantation (TAVI) procedures, the increased popularity of less invasive approaches for surgical aortic valve replacement (SAVR) and the introduction of new valve technologies, such as sutureless and rapid-deployment (SURD) valves, have led to a paradigm shift in the management of aortic valve pathologies (1,2).

The sutureless concept of aortic valve implantation was introduced in the early 1960s to simplify the implantation technique and shorten cardiopulmonary bypass (CPB) duration (3). However, this approach fell out of favor due to several drawbacks, including frequent valve-related thromboembolic complications and severe paravalvular leakages (4). More recently, with the advent of bovine pericardial valve prostheses, new SURD valve prostheses have been developed based on the modern experience

with TAVI. Given the recent introduction and the short observational interval, the current literature on sutureless and rapid-deployment aortic valve replacement (SURD-AVR) interventions is limited to small multicenter clinical trials or single center series, that do not adequately reflect the real-world situation and do not allow for a thorough evaluation of procedural and clinical results of SURD valve technologies. To overcome these limitations and provide more convincing evidence for SURD-AVR surgery, the Sutureless and Rapid-Deployment Aortic Valve Replacement International Registry (SURD-IR) was established in 2015 with the aim of evaluating safety, efficacy, short and long-term outcomes of SURD-AVR (5).

The present keynote lecture aims to assess and comment on the real-world evidence on SURD-AVR surgery, generated from the SURD-IR.

## SURD-IR design

The SURD-IR is a multicenter retrospective and



Figure 1 SURD-IR participating centers.

prospective registry founded by a consortium of research cardiac centers, namely the International Valvular Surgery Study Group (IVSSG) (5). Currently, patients are enrolled from 18 sites in Europe, Australia and Canada (Figure 1). The study population is defined as patients undergoing SURD-AVR intervention, using any available SURD valve prosthesis, either by conventional sternotomy or a less invasive approach. Valve prosthesis types included Perceval S (Livanova PLC, London, UK) EDWARDS INTUITY/INTUITY Elite (Edwards Lifesciences, Irvine, California, USA) and Enable 3F (Medtronic, Minneapolis, USA). However, since the Enable 3F valve was recalled from the market, patients who received this prosthesis were excluded from the registry.

Details of site selection and invitation have been

previously published (5). Briefly, centers that had published reports on more than 50 SURD-AVR cases were initially invited to participate in the present database, as this was hypothesized to represent experienced centers with quality data collection. Further institutions recommended by the IVSSG Research Steering Committee were also invited to participate in the registry. Ethics approval was obtained at each site. Participating SURD-IR centers enrolled between 40 and 735 patients and collected information on patient demographics, comorbidities, functional status, imaging studies, surgical data, post-operative course, clinical and hemodynamic outcomes. Following electronic data submission, each dataset was evaluated to ensure that all patients were over 18 years old. All variables between datasets were assessed, with identical variables collated

into a centralized database. Isolated variables reported by less than 25% of centers were excluded from analysis. Individually missing data and center-specific non-reported data were coded separately. Clinically important absent data were queried with the submitting center. Data were analyzed for clinical face validity and internal validity. Submitted clinical data were compared against published data for inconsistencies.

### End-points

Over 190 variables were collected for each patient. Variables of interest for the SURD-IR involved: (I) clinical data variables, including age, sex, NYHA class, CCS class, comorbidities, indications for surgery, baseline echocardiographic and hemodynamic data and patient history; (II) risk assessment variables, including Logistic EuroSCORE, EuroSCORE II, STS PROM risk and major organ system compromises; (III) operative details, including surgical approach, concomitant procedures, type of prosthesis, prosthesis size and operative times; (IV) technical outcomes, including immediate procedural success (defined as successful first implant of the valve, not requiring repeated cross-clamping), occurrence of first implant failure, valve migration/embolization, conversion to sutured AVR, post-implantation aortic valve regurgitation and pressure valve gradients; (V) hospital outcomes, including mortality and cause of death, echocardiography and hemodynamic parameters, perioperative blood transfusion, postoperative complications (cardiac, renal, respiratory, neurologic, infective, gastrointestinal and wound complications), cardiac and aortic valve re-interventions and duration of ICU and hospital stay; (VI) follow up data, including mortality and cause of death, cardiac and/or neurological complications, echocardiography and hemodynamic data and occurrence and cause of aortic valve reintervention.

## Evidence from SURD-IR

### Demographics and risk profile

A total of 4,759 patients undergoing SURD-AVR over a 12-year period between 2007 and 2019 were enrolled in the SURD-IR. Of these, 123 (2.6%) received an Enable 3F valve and were excluded from the registry. The SURD-IR study population consisted of near octogenarians (mean age 76 years, 32.8% >80 years), with a considerable burden of comorbidities that translated into a median

Logistic EuroSCORE of 8.1% (IQR, 5.1–12.6%). However, consistent with the current worldwide trends in conventional SAVR described in several national registries (6,7), data from the SURD-IR revealed a change in patient characteristics, with a significant decrease in estimated surgical risk over time (8). This is likely due to both the exponential growth in TAVI case volumes that had the highest penetration in elderly and higher risk patients (1,6,7) and the increasing adoption of biological valves in younger, lower risk patients (9,10). Indeed, the overall mean age of the SURD-IR cohort decreased from 78.4 to 73.4 years over time. Accordingly, the rate of younger patients (<65 years of age) who underwent SURD-AVR increased from 1.5% to 12.6% (8).

### Peculiar patient subgroups

#### *Bicuspid aortic valve (BAV)*

In the SURD-IR, 191 patients (5.6%) presented with a BAV. However, using SURD valves in BAV is controversial; inserting a SURD prosthesis in a non-circular BAV annulus may result in reduced sealing and paravalvular regurgitation. Nevertheless, during SURD-AVR, unlike TAVI, calcium removal may be effective in reducing paravalvular leaks and promoting a more circular adaptation of the annulus to the valve. It has been suggested that BAV does not represent a contraindication in all cases, but only in patients with BAV type 0 [as described by Sievers *et al.* (11)] (12). However, available data in these anatomical settings have been limited thus far and robust clinical trials are needed to validate the performance of SURD valves in patients with BAV (13,14). The results of SURD-IR patients with BAV is reported in a focused analysis published in this special issue.

#### *Small aortic annulus*

Some advocate SURD-AVR in patients with a small aortic annulus because of the excellent hemodynamic performance of SURD prostheses. When compared with conventional SAVR, SURD-AVR is associated with reduced valve gradients, larger effective orifice areas and lower incidences of patient-prosthesis mismatch (15,16). SURD-IR investigators analyzed hemodynamic performance and clinical outcomes in patients with a small (S group) versus large (L group) aortic annulus (17). In-hospital results and five-year survival were similar between the two groups. At discharge, mean pressure gradients were  $12.8 \pm 5.8$  in the S group and  $14.4 \pm 6.8$  mmHg in the L group ( $P=0.21$ ), while indexed effective orifice areas were  $0.88 \pm 0.18$  and

0.86±0.22 cm<sup>2</sup>/m<sup>2</sup> (P=0.6), respectively. Severe patient-prosthesis mismatch occurred in 10.5% (S group) and 14.3% (L group) of cases (P=0.65). These findings confirmed that SURD-AVR can be a favorable solution to reduce the risk of patient-prosthesis mismatch in patients with a small aortic annulus.

A subgroup analysis of SURD-IR patients who underwent isolated AVR indicated that valve pressure gradients were significantly lower for the INTUITY valve compared with the Perceval S valve (18). This was also reported in more recent series (19) and may be related to the subannular balloon-expandable stent frame of the INTUITY valve, which could lead to widening of the left ventricular outflow tract and more laminar flow through the prosthesis (20).

### ***Infective endocarditis***

Few patients (n=43, 1%) with acute valve endocarditis were enrolled in the SURD-IR. Currently, the use of SURD prostheses in the case of endocarditis is still under investigation; SURD-AVR should be performed with caution in such patients with frail and inflamed perivalvular tissue and is contraindicated in cases with annular abscess or destruction (21).

### **Prosthetic valve choice**

In the SURD-IR, valve prosthesis selection is dependent on surgeon choice and institutional practice. Among 4,636 patients, the Perceval S was implanted in 3,135 (67.6%) patients and the EDWARDS INTUITY or INTUITY Elite in 1,501 (32.4%) patients. Analysis of patient characteristics revealed differences between valve groups. The Perceval S prosthesis was more frequently implanted in high-risk patients compared with the Intuity valve (22). Accordingly, younger patients were more likely to receive an INTUITY valve than a Perceval S valve. In a series of 1,418 isolated SURD-AVR, 13% of the INTUITY patients were younger than 65 years compared with 4.6% of Perceval S patients (P<0.001) (18). Although this finding reflected real-world surgical practice, it should be interpreted with caution as it is not supported by any evidence. Clinical trials demonstrated excellent mid-term outcomes in both patients receiving Perceval S valves and patients receiving INTUITY valves (23-27); nevertheless, given their recent introduction, no robust data on the durability and performance of these prostheses in the long-term have been reported so far. Thus, we may speculate that SURD-IR surgeons had better long-term expectations

in durability from the INTUITY valve (compared with Perceval S), likely based on the assumption that it is of similar durability to the standard Carpentier-Edwards Perimount Magna Ease.

A recent comparative analysis between anterior right thoracotomy (ART) and ministernotomy (MS) access (28) revealed that the Perceval S valve was more frequently applied in the ART group when compared with the INTUITY valve (41.6% vs. 18.6%; P<0.001). This is likely favored by (I) the collapsed design of the Perceval S prosthesis that increases visualization and simplifies valve positioning via limited ART access, and (II) the shortened operative times observed in Perceval S patients. In fact, Perceval S valve implantation demonstrated significantly shorter cross-clamp and CPB times compared with INTUITY valve implantation. In isolated procedures, the reported cross-clamp time is about ten minutes shorter in patients receiving Perceval S, regardless of the surgical approach. However, this was not associated with any differences in clinical outcomes with regard to mortality and postoperative complications (18,19).

### **Surgical approach**

The treatment of valve pathologies is increasingly focused on developing and popularizing minimally invasive (MI) procedures. When compared with conventional SAVR, minimally invasive aortic valve replacement (MI-AVR) has been associated with reduced postoperative complications, transfusion requirements, length of postoperative stay and increased patient satisfaction (29-32). However, notwithstanding these favorable results, the proportion of patients receiving MI-AVR in daily clinical practice remains disappointingly low, and most SAVR interventions are still performed via a full sternotomy (33). This is mainly due to the perception of increased technical difficulty of MI-AVR that may lead to prolonged operative durations. Because of the simplified and shortened valve implantation process, SURD valves are well suited to facilitate and promote MI-AVR. In the SURD-IR study cohort, almost 75% of isolated AVR were performed through less invasive approaches, with a marked increase to 85.5% in recent years (8,18). This increased adoption rate of MI-AVR interventions was almost four times as frequent as the observed rate in the German Aortic Valve Registry (GARY) (33). Moreover, as also reported by others (34-36), the increased rate of MI-AVR did not translate into considerably prolonged CPB and cross-clamp times using SURD valves. In patients who

received MI-AVR interventions, the mean CPB and cross-clamp times were 79.4 and 50.2 minutes, respectively (28). These values compared positively with those reported in the multicentric conventional AVR registries, such as the GARY (CPB time 84 minutes, cross-clamp time 60 minutes) and the Society of Thoracic Surgeons (STS) database (CPB time 104.9 minutes, cross-clamp time 77 minutes) (33,37). Thus, by decreasing operative duration and allowing for easier prosthesis implantation via limited access, SURD valves have overcome the main limitations of MI-AVR, and can be considered a primary indication for MI surgery.

Nowadays, two main MI approaches are performed, namely MS and ART. MS incision is the most widely used technique for MI-AVR. The lower prevalence of ART may be attributed to the fact that ART is a longer and more challenging procedure requiring more technical skill. Nevertheless, in the SURD-IR population, the rate of ART (43.6%) was considerably higher than those reported in previous series (29,38,39). Although the clinical relevance of this observation is debatable, as current evidence shows similar results between patients undergoing ART and MS (32), this strongly supports the assumption that SURD valves facilitate and help promote MI-AVR, regardless of the surgical approach. Recently, SURD-IR investigators compared patients who underwent MS to those who underwent ART and showed that the MS group had a higher risk profile compared with the ART group, and the latter was associated with significant longer operative times (28). Patients who underwent ART showed a decreased rate of postoperative adverse events as well as shorter postoperative lengths of stay. The observed differences between the access groups were likely related to both the higher surgical risk of MS and the advanced experience level of the surgeons performing ART.

The less invasive SURD-AVR also showed promising results in re-operative AVR. Findings from the SURD-IR revealed neither conversion to full sternotomy nor mortality, with an acceptable complication rate in 63 patients who underwent redo SURD-AVR through MS or ART (40). A major benefit of less invasive access in redo settings is that adhesion dissection of mediastinal tissue is minimized and, therefore, the risk of bleeding and cardiac or graft injury may be substantially reduced. However, further study is necessary to validate this assumption.

### Technical success and operative times

In large multicenter series, both valves yielded high

technical success rates ranging from 95% to 96.1% (26,35,41). Evidence from the SURD-IR confirmed this finding, with a successful implantation rate of 97.7% and no differences between valve types and surgical approaches (8,18). Furthermore, this rate significantly improved over time (from 95.5% to 98.6%) as a result of the growing experience of surgeons and refined surgical techniques. However, it must be mentioned that valve malpositioning emerged as a strong risk factor for in-hospital mortality (odds ratio, 16.2; 95% confidence interval, 2.55–10.8;  $P=0.003$ ) in patients who underwent isolated, MI SURD-AVR (18). The occurrence of valve malpositioning resulted in considerably longer CPB and cross-clamp times and a greater incidence of postoperative complications, such as low cardiac output state, respiratory failure and the need for dialysis.

During valve surgery, prolonged CPB and cross-clamp times are well established risk factors for mortality and morbidity (42). Because of the simplified and quicker deployment, SURD valves have been associated with substantially reduced procedural times (34,43,44). In fact, despite a higher rate of MI procedures, the SURD-IR series (45) reported significantly shorter CPB and cross-clamp times compared with conventional SAVR series. When compared with the STS database, a time benefit was found both in overall isolated AVR (79 and 51 *vs.* 106 and 78 min) and combined AVR + coronary artery bypass graft (CABG) (106 and 72 *vs.* 147 and 112 min) (45). A clinical advantage determined by shortened operative times with SURD may become more evident in elderly patients, patients carrying serious comorbidities, such as renal insufficiency, peripheral vasculopathy and myocardial dysfunction and patients requiring combined interventions. The latter hypothesis is currently being tested by the SURD-IR investigators.

## Results

### In hospital mortality

Despite the increased risk profile of the SURD-IR study cohort, SURD-AVR yielded excellent clinical outcomes. Overall in-hospital mortality was 2.1%, with 1.3% and 3.7% contributed to patients undergoing isolated and combined SURD-AVR, respectively. When stratified according to the risk profile, early mortality was 0.8% in low-risk (logistic EuroSCORE <10%), isolated SURD-AVR and 2.2% in increased-risk patients (logistic EuroSCORE  $\geq$ 10%) (45). These results compare favorably with those reported in conventional SAVR registries (6,33,46) both in low- and

high-risk patients.

### Stroke

The occurrence of stroke was 3.2%, which considerably decreased over time, from 4% to 0.5% in the isolated SURD-AVR group, and from 4.7% to 2.4% in the combined group (8). It is likely that these findings were affected by the reduced patient risk profiles in the last years. However, recent data from the SURD-IR demonstrated that SURD-AVR is associated with satisfactory outcomes in patients of all risk categories (22). On this basis, we speculate that SURD valves, by facilitating less invasive approaches and accelerating the implantation process, provide good immediate results, mainly due to reduced surgical stress to patients; this may be especially true for those in the higher risk category.

### Pacemaker implantation

Concern exists regarding the increased incidence of conduction abnormalities following SURD-AVR (36,47-49). In the SURD-IR, the overall pacemaker implantation rate was 8.9% with no differences between valve types. However, SURD technologies have demonstrated to be strongly influenced by the “learning curve effect”, with improving outcomes over time (45). In the SURD-IR series, a substantial reduction in the pacemaker implantation rate was observed, from 20.6% to 5.6% (18). The latter compares satisfactorily with the rate reported after conventional SAVR, and is much lower than those reported after TAVI (6,33,50,51). Simple technical modifications of the SURD valve implantation technique may have contributed to this finding. In particular, a careful avoidance of valve oversizing and low valve positioning is crucial in preventing injuries of conduction tissue. Additionally, the accuracy of decalcification, the traction on the guiding sutures and the balloon pressure may also play a role (52,53). We believe that minimizing post-operative pacemaker implantation rates by optimizing the valve implantation process and identifying proper predictors for conduction disorders are essential to further improve SURD-AVR outcomes.

### Valvular leaks

Although SURD-AVR was associated with low rates of postoperative aortic regurgitation (AR) (severe AR 0.2%, moderate AR 1.2%, mild AR 6.1%), these values were

still higher than those reported in conventional SAVR interventions (45). However, over the 12 years of SURD-IR data collection, both the incidence (from 17.8% to 2.7%) and the severity (severe AR from 0.6% to 0, moderate AR from 3.1% to 1.1%, mild AR from 14.1% to 1.6%) of postoperative AR markedly decreased. This is likely due to the increased surgical experience of the valve implantation technique.

### Conclusions

With more than 4,500 patients enrolled, the SURD-IR is currently the largest independent registry on SURD aortic valves. The SURD-IR provides a real-world picture of SURD-AVR interventions and may refine the decision-making process in the search for the most appropriate treatment for patients with aortic valve pathologies. Evidence from the SURD-IR suggests that SURD-AVR is a safe and efficacious alternative to conventional SAVR, with satisfactory and constantly improving outcomes. When compared with SAVR, SURD-AVR allows for shorter CPB and cross-clamp times, promotes MI surgery and provides improved hemodynamic results. Long-term outcomes have yet to be analyzed in order to thoroughly evaluate the performance of these valve technologies over time.

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### Footnote

*Conflicts of Interest:* The authors have no conflicts of interest to declare.

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