Use of a sutureless aortic valve in reoperative aortic valve replacement

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ABSTRACT

Objectives: Management of degenerated bioprosthetic aortic valves remains a challenge. Valve-in-valve transcatheter aortic valve replacement (AVR) has limited utility in the presence of small annuli/prosthetic valves. Sutureless valves may offer an advantage over traditional redo AVR by maximizing effective orifice area due to their unique design as well as ease of implant.

Methods: Twenty-two patients undergoing redo AVR received a sutureless valve in our institution over the past 5 years. All patients were determined to be poor candidates for valve-in-valve transcatheter AVR due to a combination of small annulus size, low coronary heights, and/or underlying valve characteristics (ie, mechanical valves).

Results: Median time from implant to redo AVR was 8 years. One patient died within 30 days. In the 13 patients who had a 21 mm or smaller valve explanted, 5 small, 7 medium, and 1 large Perceval valves were implanted (all with larger internal diameters than the explanted valve). The average postoperative gradient of the cohort valves was 14.8 mm Hg compared with 38.8 mm Hg preoperatively.

Conclusions: In addition to their ease of use and rapid deployment, sutureless bioprosthetic aortic valves offer significant physiological advantages in patients with degenerated prosthetic aortic valves and small anatomical annuli. It can also simplify the surgical approach to redo AVR following a Bentall procedure. If long-term durability is confirmed, sutureless valves should be considered in a broader population of patients for both redo and primary aortic valve replacement surgery. (JTCVS Techniques 2022;13:31-9)

CENTRAL MESSAGE

During redo AVR, the unique design of a sutureless valve allows for placement of a larger valve compared with the explanted valve, improving gradients, future ViV prospects, and patient outcomes.

PERSPECTIVE

The growth in TAVR has helped spur an increase in bioprosthetic valve use. When these valves degenerate, ViV TAVR has been useful, but in patients with small aortic annuli, the procedure is associated with increased mortality due to PPM. Sutureless valves have been shown to have excellent hemodynamics and no episodes of PPM in ViV TAVR, prompting our team to study their use in redo SAVR.

See Commentary on page 40.

The landscape of aortic valvular surgery has changed significantly over the past 20 years. The introduction of transcatheter aortic valve replacement (TAVR) has revolutionized treatment of aortic valve disease, proving to have superior survival to surgical aortic valve replacement (SAVR) in high-risk patients, and be at least as safe as SAVR in...
Abbreviations and Acronyms
AI = aortic insufficiency
AVR = aortic valve replacement
PPM = patient–prosthesis mismatch
SAVR = surgical aortic valve replacement
STS = Society of Thoracic Surgeons
TAVR = transcatheter aortic valve replacement
ViV = valve-in-valve

Sutureless valve use simplifies the redo AVR procedure by avoiding the need for suture placement in a reoperative annulus. In addition, in previous Bentall procedures, redo sutureless valve implantation can avoid the need for reoperative root replacement and coronary reimplantation, instead allowing for explantation of the previous valve alone with sutureless valve deployment in its place. The unique caged valve design simplifies deployment and maximizes effective orifice area but also serves as an excellent scaffold for future ViV TAVR. In fact, a small subset study from the Valve-In-Valve International Data registry revealed excellent hemodynamic outcomes in ViV TAVR postsutureless valve placement, with no episodes of significant PPM or coronary obstruction noted to date.16 Here, we illustrate our experience with sutureless valve placement during reoperative AVR, with the belief that due to their unique hemodynamics and rapid deployment, this operation will yield positive outcomes in 2 challenging patient populations: (1) small preexisting AVR and (2) those with a previous Bentall procedure.

METHODS
Patient Cohort
We used a retrospective database containing all patients who underwent redo AVR with sutureless valve placement from January 2016 to June 2021, excluding those who had prosthetic endocarditis. All patients had a Perceval placed. Over the 5-year study period, all patients were initially evaluated by the heart team, with preoperative computed tomography assessment. These patients were deemed poor candidates for ViV TAVR due to a combination of small annulus size, low coronary heights, and/or underlying valve characteristics (ie, mechanical valves). The final patient cohort included 22 patients. All patients then underwent reoperative median sternotomy, explant of the previous surgical valve, and subsequent Perceval implantation. Follow-up was complete in all patients but one.

Data Procurement
Institutional review board approval (STUDY 00008264, approved October 10, 2019) was obtained for the study, which waived the need for patient consent. All patient data were obtained from the electronic medical record, including necessary outside records if available. Basic demographics, preoperative data, intraoperative data, and both short- and medium-term outcomes were obtained. Mortality was noted using both the electronic medical record as well as a statewide database containing all death records. All demographics and outcomes were defined based upon Society of Thoracic Surgeons (STS) reporting standards.12 STS risk was determined using the online calculator.16 A representative video was recorded in one of our operating rooms of Perceval valve implantation in a previous Freestyle root replacement (Video 1).

End Points and Data Analysis
End points obtained from data analysis were preoperative, first clinic visit, and 1-year hemodynamic parameters such as mean gradient and peak velocity, along with internal diameters of the explanted and implanted annuli also had a 41.2% rate of significant PPM (mean gradient ≥20 mm Hg), nearly 2 times the rate in the rest of the cohort. Therefore, ViV TAVR is an imperfect solution for select patients with degenerated AVR, specifically those with small annuli and small preexisting valve sizes.

 Surgeless valve use simplifies the redo AVR procedure by avoiding the need for suture placement in a reoperative annulus. In addition, in previous Bentall procedures, redo sutureless valve implantation can avoid the need for reoperative root replacement and coronary reimplantation, instead allowing for explantation of the previous valve alone with sutureless valve deployment in its place. The unique caged valve design simplifies deployment and maximizes effective orifice area but also serves as an excellent scaffold for future ViV TAVR. In fact, a small subset study from the Valve-In-Valve International Data registry revealed excellent hemodynamic outcomes in ViV TAVR postsutureless valve placement, with no episodes of significant PPM or coronary obstruction noted to date. Here, we illustrate our experience with sutureless valve placement during reoperative AVR, with the belief that due to their unique hemodynamics and rapid deployment, this operation will yield positive outcomes in 2 challenging patient populations: (1) small preexisting AVR and (2) those with a previous Bentall procedure.

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valves. Internal diameters and estimated ViV TAVR implant size were obtained from a ViV TAVR sizing database. Other minor end points include 30-day perioperative outcomes and 1-year follow-up, which were obtained as discussed previously. Outcomes were then stratified by explant valve type. Means were obtained for continuous data, with percentages for categorical data. The median was used for “Average Time Since First AVR” due to evident skewing of that data. All means reported in the tables include standard errors. All categorical percentages include the corresponding number of patients in parentheses.

RESULTS
Preoperative Characteristics
Demographic data and preoperative characteristics are listed in Table 1. The average age of the patient cohort was 64.1 years, with an average STS risk of mortality of 2.30%. 4 (18.18%) of patients in the cohort had a previous Bentall. 6 (27.27%) had at least moderate preoperative aortic insufficiency. Based upon the hemodynamics listed, all had severe stenosis and/or significant aortic insufficiency (AI), with an average mean gradient of 38.8 mm Hg and peak velocity of 4.04 m/s. The average mean gradient of those with isolated prosthetic valve stenosis was 45.7 mm Hg. The median time from previous SAVR to redo SAVR with Perceval implantation was 8 years, suggesting early degeneration for the valves in the cohort. The breakdown of valve sizes prior to explant is shown in Figure 1, A. The vast majority of the patients in the cohort had small valve sizes, with 20 (90.9%) having a 23-mm valve or less. Of 22 patients, 4 (18.2%) had mechanical valves and 18 (81.8%) had a bioprosthetic valve (2 of which were aortic homografts). Thus, 16 patients had stented bioprosthetic aortic valve pathology.

TABLE 1. Representative demographics of the patient cohort, along with preoperative valve characteristics

| Characteristic          | Value          |
|-------------------------|----------------|
| Age, y                  | 64.1 ± 3.1     |
| BMI                     | 29.7 ± 1.5     |
| Afib                    | 36.4% (8)      |
| HTN                     | 77.3% (17)     |
| DM                      | 27.3% (6)      |
| CKD                     | 13.6% (3)      |
| Previous Bentall        | 18.2% (4)      |
| STS risk score          | 2.3% ± 0.2%    |
| Median y after first AVR| 8              |
| Pre MG, mm Hg           | 38.8 ± 2.2     |
| Pre PV, mm Hg           | 4.04 ± 0.12    |
| AI (moderate or greater)| 27.3% (6)      |

BMI, Body mass index; Afib, atrial fibrillation; HTN, hypertension; DM, diabetes mellitus; CKD, chronic kidney disease; STS, Society of Thoracic Surgeons; AVR, aortic valve replacement; MG, mean gradient; PV, peak velocity; AI, aortic insufficiency.

Intraoperative Data
Video 1 shows a representative redo AVR with a sutureless valve, in this instance in a previous Freestyle root with the Perceval. Pertinent intraoperative data are listed in Table 2. Cardiopulmonary bypass times and crosclamp

FIGURE 1. A, Size distribution among valves explanted. B, Pre- and postoperative MGs at the first clinic visit after discharge. Patients experienced significant improvement in their hemodynamics after redo valve replacement with a sutureless valve. MG, Mean gradient.

VIDEO 1. Representative operative video illustrating Perceval placement in a previous Freestyle root, with preoperative and postoperative hemodynamics noted. Video available at: https://www.jtcvs.org/article/S2666-2507(22)00136-5/fulltext.
times for the entire cohort were 112.7 and 69.4 minutes, respectively. Four patients received concomitant procedures: one ascending hemiarch, one zone 2 arch replacement with a mitral repair, one tricuspid replacement, and one who received a zone 2 arch with frozen elephant trunk. Cardiopulmonary bypass; XC, crossclamp.

Postoperative Outcomes

Perioperative/30-day outcomes are listed in Table 3. One patient died during the perioperative period. This specific patient was a salvage, urgent inpatient operation. Average length of stay was 8.4 days, only 1 patient had any acute kidney injury or hemodialysis requirements, and 4.3% of patients had any wound complication. Any documented atrial fibrillation occurred at a rate of 26.7%. Among patients who underwent isolated redo AVR explanting stented bioprosthetic valves, average bypass and crossclamp times were 86.5 and 58.9 minutes, respectively.

Among the subset that had a previous bioprosthetic stented SAVR, average length of stay was 8.3 days, and there were no mortalities, episodes of acute kidney injury or hemodialysis requirements, or any wound complications. This subset included the 2 strokes from the entire cohort, elevating the rate in this group to 13.3%. Any documented atrial fibrillation occurred at a rate of 26.7% (Table 3).

Postoperative hemodynamic data obtained at the first clinic visit are shown in Table 4. Mean time to first clinic visit was 14.4 days and was complete in all patients (excluding the sole mortality). One patient (6%) had 1+ AI or greater. Mean gradients had a notable decrease in the cohort, from an average of 38.8 mm Hg preoperatively to 14.8 mm Hg at the first postoperative clinic visit (Figure 1, B). Peak velocities decreased from an average of 4.04 m/s preoperatively to 2.6 m/s at the first postoperative clinic visit (Table 4). There was only 1 patient with significant PPM (mean gradient >20 mm Hg) in the entire cohort (4.8%). When the data are broken down into those who had bioprosthetic stented SAVRs explanted (Table 4), the mean gradient at the first clinic visit was 12.8 mm Hg, with a mean peak velocity of 2.5 m/s. In the subset of bioprosthetic explants, 1 patient (8.3%) had 1+ AI or greater, and only 1 patient had significant PPM (6.7%).

All patients that survived past 30 days had continued follow-up with either cardiology or cardiac surgery at 1 year, with no new mortalities. The mean gradient at 1 year for the cohort was 14.9 mm Hg, with a mean peak velocity of 2.5 m/s. The number of patients with AI or PPM remained unchanged.

**TABLE 2. Intraoperative data, including the entire cohort, those who had previous Bentall procedures, and those who just underwent isolated explants of stented bioprosthetic aortic valves**

|                  | Entire cohort | Isolated Bentall | Stented bioprosthetic explants |
|------------------|---------------|------------------|--------------------------------|
| CPB, min         | 112.7 ± 9.7   | 145.8 ± 30.1     | 86.5 ± 3.7                     |
| XC, min          | 69.4 ± 6.0    | 77.5 ± 15.7      | 58.9 ± 4.0                     |

Four patients (18.2%) in the cohort had concomitant procedures: one ascending hemiarch, one zone 2 arch replacement with a mitral repair, one tricuspid replacement, and one who received a zone 2 arch with frozen elephant trunk. CPB, Cardiopulmonary bypass; XC, crossclamp.

**TABLE 3. Postoperative outcomes in patients after redo AVRs with sutureless valves in the entire cohort and among those with stented bioprosthetic AVRs explanted**

| Perioperative outcomes | Entire cohort | Stented bioprosthetic explants |
|------------------------|---------------|--------------------------------|
| Mortality at 30 d      | 4.5% (1)      | 0% (0)                         |
| Length of stay, d      | 8.4 ± 0.9     | 8.3 ± 1.1                      |
| Discharge Cr           | 0.88 ± 0.1    | 0.73 ± 0.07                    |
| AKI/New HD             | 4.5% (1)      | 0% (0)                         |
| Wound complication     | 4.3% (1)      | 0% (0)                         |
| CVA                    | 9.0% (2)      | 13.3% (2)                      |
| Afib                   | 27.3% (6)     | 26.7% (4)                      |
| New PPM requirement    | 9.1% (2)      | 13.3% (2)                      |

Cr, Creatinine; AKI, acute kidney injury; HD, hemodialysis; CVA, cerebrovascular accident; Afib, atrial fibrillation; PPM, patient–prosthesis mismatch.

**TABLE 4. Hemodynamic parameters at first clinic visit amongst the entire cohort and amongst those with stented bioprosthetic AVRs explanted**

| Postoperative hemodynamics | Entire cohort | Stented bioprosthetic explants |
|----------------------------|---------------|--------------------------------|
| AI                         | 6.3% (1)      | 8.3% (1)                        |
| MG, mm Hg                  | 14.8 ± 1.6    | 12.8 ± 1.7                      |
| PV (m/s)                   | 2.6 ± 0.1     | 2.5 ± 0.2                       |
| EF                         | 63.4% ± 1.8%  | 64.1% ± 2.0%                    |
| PPM                        | 4.8% (1)      | 6.7% (1)                        |

AI, Aortic insufficiency; MG, mean gradient; PV, peak velocity; EF, ejection fraction; PPM, patient–prosthesis mismatch.
stented bioprosthetic valves, which constituted the majority of the small annuli in the study (Tables E1 and E2). Using a ViV TAVR sizing database, we determined the internal diameter for all explanted valves and the implanted Perceval valve. In addition, we used the same database to estimate the size of ViV Sapien 3 and Evolut valves that could be placed in both the explanted and implanted valves (Table 5, Tables E1 and E2). Quite notably, nearly every single patient ended up getting a larger internal diameter and ViV TAVR estimate with a sutureless valve compared with their explanted valve (Figure 2, B).

**DISCUSSION**

Sutureless aortic valves are widely used for their ease and speed of deployment, reducing crossclamp and cardiopulmonary bypass times. We have demonstrated straightforward use of these valves in the operating room, specifically in a previous Freestyle root (Video 1). This greatly simplifies usually much more complicated redo operations. However, these valves’ unique hemodynamic profile has not yet been widely described. Here, we have shown that sutureless valves (specifically the Perceval), due to a novel cage design and lack of a sewing ring, allow for the implantation of a larger-sized valve when performing redo AVR (Figure 3). This not only significantly reduces gradients when replacing degenerated surgical valves, but, due to the larger internal diameter of the Perceval implanted, can allow for a larger ViV TAVR valve in the future. This reduces the likelihood of PPM both in the Perceval and any future ViV reinterventions. This stands in contrast to the outcomes of ViV TAVR in patients with small bioprosthetic valves, who suffer greater gradients, early consequences of PPM, and reduced 1-year survival.

Despite their sutureless design and rapid deployment mechanism, there still exists a significant “learning curve” with the use of these valves. We noted concerning neurologic outcomes in the initial patients treated in this cohort, although our overall stroke rate is actually similar to reported rates for redo SAVR and ViV TAVR (9.0% in our small cohort, 9.7% in recent reports for both redo SAVR and ViV TAVR). One series of TAVR explants even quotes a cerebrovascular accident rate as high as 18.7%. Neurologic outcomes and hemodynamics seemed to improve with further use and familiarity with the device. We believe that proper sizing (namely avoidance of oversizing) was a critical aspect of this learning curve. Oversizing this valve can lead to improper function (overcrowding and “pin-wheeling” of the leaflets with incomplete opening), possibly leading to greater rates of PPM and early valve degeneration due to this incomplete valve opening. Furthermore, issues with sizing in the operating room may lead to multiple attempts at deployment, which may account for some of the neurologic events noted in the initial patients in this series. Still, stroke rates remain an Achilles’ heel of both ViV TAVR and redo SAVR. Our improvements in stroke rate with experience suggest that familiarity with and proper sizing of the Perceval valve in the reoperative setting can further evolve and improve these outcomes.

Biologic SAVR is known to be a safe and effective long-term strategy in low-risk patients older the age of 60 year. Given these data and the promising results in our patient cohort, we believe redo AVR with sutureless valve placement should be considered more broadly, discussed at multidisciplinary team conferences, and be shared with well-selected patients as a possible choice when discussing valve options, in addition to traditional stented bioprostheses, mechanical valves, and ViV TAVR.

Patients presenting with degenerated valves in the setting of previous Bentall procedure deserve special mention. Reoperations on these patients are significantly more
complex due to the presence of aortic graft at the root level. Previously, redo root replacement and coronary artery reimplantation is needed in many of these patients, which can be a hazardous and technically challenging procedure. However, several patients in this series demonstrate a viable alternative to reoperative Bentall. One simply opens the Bentall graft, sharply excises the existing valve (taking great care not to injure any underlying structures), debrides all annular and subannular pledgets, and then places a sutureless valve within the existing Bentall graft. Our data reveal promising results in this small subset, with no mortalities, strokes, or episodes of renal dysfunction. Thus, continued experience and follow-up will be needed to assess the long-term viability of this approach.

The major limitation in our study comes is our sample size. In addition, understanding long-term (>10 years) durability of sutureless valves is critical to establishing redo SAVR with these devices as a safe paradigm. Mid-term (1-10 year) results for the Perceval are promising, with a recent study citing an average mean gradient of 13 mm Hg and no reoperations for valve degeneration. These hemodynamic parameters have been noted across all Perceval sizes. With reduced rates of PPM, patients should experience prolonged valve longevity along with improved

| Valve type            | Valve size | Perceval implanted | ID of explant valve | ID of implant valve |
|-----------------------|------------|--------------------|---------------------|---------------------|
| St Jude Epic          | 21         | L                  | 19                  | 25                  |
| St Jude Trifecta      | 23         | XL                 | 21                  | 27                  |
| Carpentier-Edwards    | 19         | M                  | 18                  | 23                  |
| Carpentier-Edwards Magna Ease | 23 | L                  | 22                  | 25                  |

The ID of the Perceval implanted is much larger than that of the explanted valve. Sutureless valve implantation consistently allows for a larger Sapien 3 or Evolut ViV TAVR option compared with the explanted valve. ID, Internal diameter; L, large; XL, extra-large; M, medium; ViV TAVR, valve-in-valve transcatheter aortic valve replacement; S, small.

FIGURE 3. Graphical abstract summarizing the hemodynamic outcomes of our patient cohort after Perceval placement during redo AVR. Nearly all patients had a larger internal diameter (ID) valve implanted than what was explanted, which improved their gradients and allows for larger ViV TAVR implants in the future, altogether reducing the risk for PPM. AVR, Aortic valve replacement; EOA, effective orifice area.
survival years out from their operation. Finally, to optimize preoperative planning, especially in the decision to pursue redo AVR as opposed to ViV TAVR, we are participating in a multi-institutional study comparing and standardized computing tomography measurements to predict sutureless valve sizes in patients being evaluated for reintervention on degenerated prosthetic aortic valves.

TAVR will continue to grow in utility as techniques and outcomes improve. This, along with the rise of bioprosthetic SAVR, mandates feasible solutions to inevitable valve degeneration. ViV TAVR is an excellent strategy but is not without limitations. Patients undergoing redo SAVR, mandates feasible solutions to inevitable valve degeneration. ViV TAVR is an excellent strategy but is not without limitations. Patients undergoing redo SAVR, mandates feasible solutions to inevitable valve degeneration.

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Key Words: aortic valve, TAVR, ViV TAVR, SAVR, small annulus
| Valve type                        | Valve size | Perceval implanted ID of explant valve | ID of implant valve | Recommended ViV TAVR size of explant (S3) | Recommended ViV TAVR size of implant (S3) |
|----------------------------------|------------|----------------------------------------|---------------------|------------------------------------------|------------------------------------------|
| Toronto SPV                      | 21         | S                                      | 21                  | 20/23                                    | 20/23                                    |
| Carpentier-Edwards               | 21         | M                                      | 19                  | 20/23                                    | 23                                       |
| Medtronic Mosaic                 | 21         | M                                      | 18.5                | 20                                       | 23                                       |
| St Jude Epic                     | 21         | L                                      | 19                  | 20/23                                    | 23                                       |
| Sorin CarboMedics Mitroflow      | 21         | S                                      | 17.3                | 20                                       | 20/23                                    |
| St Jude Trifecta                 | 23         | XL                                     | 21                  | 27                                       | 26/29                                    |
| St Jude Trifecta                 | 21         | S                                      | 19                  | 21                                       | 20/23                                    |
| St Jude Trifecta                 | 21         | M                                      | 19                  | 23                                       | 20/23                                    |
| Medtronic Mosaic                 | 25         | XL                                     | 21                  | 27                                       | 23                                       |
| St Jude Trifecta                 | 21         | M                                      | 19                  | 23                                       | 20/23                                    |
| Carpentier-Edwards Magna Ease    | 21         | M                                      | 19                  | 23                                       | 20/23                                    |
| St Jude Trifecta                 | 19         | S                                      | 18                  | 21                                       | 20                                       |
| St Jude Trifecta                 | 19         | S                                      | 18                  | 21                                       | 20/23                                    |
| Carpentier-Edwards               | 19         | M                                      | 18                  | 23                                       | 23                                       |
| Carpentier-Edwards Magna Ease    | 23         | L                                      | 22                  | 25                                       | 23                                       |
| St Jude Trifecta                 | 23         | L                                      | 21                  | 25                                       | 23                                       |

ID, Internal diameter; ViV TAVR, valve-in-valve transcatheter aortic valve replacement; SPV, stentless porcine valve; S, small; M, medium; L, large; XL, extra-large.
### TABLE E2. Complete table of each bioprosthetic valve explanted and implanted, along with the associated ID and ViV Evolut size\(^\text{19}\)

| Valve type                        | Valve size | Perceval Implanted ID of explant valve | ID of implant valve | Recommended ViV TA VR size explant (Evolut) | Recommended ViV TA VR size implant (Evolut) |
|-----------------------------------|------------|----------------------------------------|---------------------|---------------------------------------------|--------------------------------------------|
| Toronto SPV                       | 21         | S                                      | 21                  | 23                                          | 23                                         |
| Carpentier-Edwards                | 21         | M                                      | 19                  | 23                                          | 23                                         |
| Medtronic Mosaic                  | 21         | M                                      | 18.5                | 23                                          | 23                                         |
| St Jude Epic                      | 21         | L                                      | 19                  | 23                                          | 23                                         |
| Sorin CarboMedics Mitroflow       | 21         | S                                      | 17.3                | 21                                          | 23/29                                      |
| St Jude Trifecta                 | 23         | XL                                     | 21                  | 27                                          | 26                                         |
| St Jude Trifecta                 | 21         | S                                      | 19                  | 21                                          | 23                                         |
| St Jude Trifecta                 | 21         | M                                      | 19                  | 23                                          | 23                                         |
| Medtronic Mosaic                  | 25         | XL                                     | 21                  | 27                                          | 26                                         |
| St Jude Trifecta                 | 21         | M                                      | 19                  | 23                                          | 26                                         |
| Carpentier-Edwards Magna Ease     | 21         | M                                      | 19                  | 23                                          | 23                                         |
| St Jude Trifecta                 | 19         | S                                      | 18                  | 21                                          | 23                                         |
| St Jude Trifecta                 | 19         | S                                      | 18                  | 21                                          | 23                                         |
| Carpentier-Edwards                | 19         | M                                      | 18                  | 23                                          | 23                                         |
| Carpentier-Edwards Magna Ease     | 23         | L                                      | 22                  | 25                                          | 26                                         |
| St Jude Trifecta                 | 23         | L                                      | 21                  | 25                                          | 23/29                                      |

*ID, Internal diameter; ViV TA VR, valve-in-valve transcatheter aortic valve replacement; SPV, stentless porcine valve; S, small; M, medium; L, large; XL, extra-large.*