Matched Comparison of Self-Expanding Transcatheter Heart Valves for the Treatment of Failed Aortic Surgical Bioprosthesis

Insights From the Valve-in-Valve International Data Registry (VIVID)

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Background—Transcatheter valve-in-valve implantation is an established therapy for high-risk patients with failed surgical aortic bioprosthesis. There are limited data comparing outcomes of valve-in-valve implantation using different transcatheter heart valves (THV).

Methods and Results—Patients included in the Valve-in-Valve International Data registry (VIVID) and treated with self-expanding THV devices were analyzed using centralized core laboratory blinded to clinical events. St. Jude Medical Portico versus Medtronic CoreValve were compared in a 1:2 fashion after propensity score matching. A total of 162 patients, Portico- (n=54) and CoreValve- (n=108) based valve-in-valve procedures comprised the study population with no significant difference in baseline characteristics (age, 79±8.2 years; 60% women; mean STS [Society of Thoracic Surgery] score 8.1±5.5%). Postimplantation, CoreValve was associated with a larger effective orifice area (1.67 versus 1.31 cm^2; *P*=0.001), lower mean gradient (14±7.5 versus 17±7.5 mm Hg; *P*=0.02), and lower core laboratory–adjudicated moderate-to-severe aortic insufficiency (4.2% versus 13.7%; *P*=0.04), compared with Portico. Procedural complications including THV malpositioning, second THV requirement, or coronary obstruction were not significantly different between the 2 groups. Survival and stroke rates at 30 days were similar, but overall mortality at 1 year was higher among patients treated with Portico compared with CoreValve (22.6% versus 9.1%; *P*=0.03).

Conclusions—In this first matched comparison of THVs for valve-in-valve implantations, Portico and CoreValve demonstrated differences in postprocedural hemodynamics and long-term clinical outcomes. Although this could be related to THV design characteristics, the impact of other procedural factors cannot be excluded and require further evaluation. **(*Circ Cardiovasc Interv*. 2017;10:e004392. DOI: 10.1161/CIRCINTERVENTIONS.116.004392.)**

Key Words: aortic valve ■ bioprosthesis ■ hemodynamic ■ transcatheter aortic valve replacement

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WHAT IS KNOWN

- Transcatheter valve-in-valve (ViV) implantation is a safe and effective strategy among high-risk patients with degenerated surgical bioprosthesis.
- Residual stenosis is a major limitation of aortic ViV procedures.

WHAT THE STUDY ADDS

- In comparison to Portico, CoreValve was associated with larger postimplantation effective orifice area, lower gradients, and lower rate of regurgitation after ViV.
- In this first matched comparison of transcatheter heart valves in ViVs, the 30-day clinical outcomes were comparable, but the Portico group exhibited a higher 1-year mortality compared with CoreValve.

Transcatheter valve-in-valve (ViV) implantation has become an established therapeutic strategy for the management of high-risk patients with failed surgical aortic bioprostheses.[1–3] Most candidates for ViV implantation can be treated with either balloon-expandable or self-expanding transcatheter heart valves (THV). Although certain clinical and anatomic features affect the choice of THV in an individual patient,[4–6] supra-annular self-expanding valves (CoreValve) are associated with favorable hemodynamic profile compared with balloon-expandable THV.[2,7,8] However, it is unclear how it compares to another self-expanding design with an intra-annular THV position (Portico). In this study, we compare the hemodynamic and clinical outcomes of the 2 most commonly used self-expanding THV systems, CoreValve (Medtronic, Inc, Minneapolis, MN) and Portico (St. Jude Medical, Inc, St. Paul, MN) after aortic ViV implantations.

Methods

The design and details of the Valve-in-Valve International Data Registry (VIVID) have been reported previously.[2] Briefly, the VIVID registry is a collaboration of centers from Europe, the Americas, Australia, New Zealand, and the Middle East for prospective collection of data for ViV implantation procedures. Data are collected using detailed case report forms, and any inconsistency is resolved with local investigators and on-site data monitoring. All patients had provided written informed consent for the ViV implantation procedure, and the Registry was approved by the local ethics committee. All Portico cases within the VIVID registry were matched with comparable CoreValve ViV implantation cases using propensity score matching. Each Portico case was matched with 2 CoreValve cases in a 1:2 fashion to enhance the statistical power. Variables used for propensity score determination included age, sex, STS (Society of Thoracic Surgery) mortality score, procedural access, surgical valve label size, and surgical valve design (stentless versus stented). In addition, groups were matched for surgical valve true internal diameter (true ID). All ViV implantation procedures in the present study were performed for failed surgical bioprostheses at the aortic position according to local standards and practices.

Definitions

The Portico is a self-expanding THV with bovine pericardial leaflets sewn into nitinol frame at an annular level surrounded by a porcine pericardial skirt.[9] The CoreValve is a self-expanding THV with porcine pericardial leaflets sewn into nitinol frame at a supra-annular position surrounded by an outer skirt of porcine pericardium.[10] The mechanism of bioprosthetic valve failure (ie, stenosis, regurgitation, or combined) was determined based on preprocedural echocardiography. True internal diameter of surgical valves was derived according to valve type and label size.[4,11] Procedural complications included coronary obstruction, THV malpositioning, need for a second THV, and device success. Prosthesis–patient mismatch was based on post–ViV implantation effective orifice area (EOA), ≤0.85 and ≤0.65 cm^2/m^2 for any and severe mismatch, respectively.[12] Clinical outcomes determined included all-cause mortality at 1 and 12 months. Other outcomes included 30-day rate of stroke, acute kidney injury, major bleeding, and major vascular complication according to the updated Valve Academic Research Consortium criteria.[13]

Core Laboratory Echocardiographic and Fluoroscopic Analysis

Echocardiographic and cine angiographic images after THV implantation were reviewed in a centralized core laboratory to determine the severity of postimplantation aortic insufficiency (AI) in a blinded manner at St. Michael's Hospital, Toronto, Canada. AI was adjudicated independently using semiqualitative parameters defining the AI jet features, including number of jets, width of jet origin, jet path along the stent, proximal flow convergence, vena contracta, jet density on continuous-wave Doppler, pressure half time and flow reversal in the abdominal aorta. In addition, the circumferential extent of the aortic insufficiency on short axis was ascertained (<10, 10–30, >30% for mild, moderate, or severe AI, respectively). The AI assessment was also supplemented by evaluation of postimplantation aortic root angiography using established angiographic criteria.[14]

THV depth assessment was performed at St. Paul's Hospital, Vancouver, Canada. Postimplantation angiographic images were analyzed using centralized core laboratory assessment blinded to clinical events. THV depth was expressed in millimeter(s) reflecting the distance of THV distal frame in relation to the surgical valve frame as previously described.[15]

Statistical Analysis

Categorical variables were reported as frequencies and percentages, and continuous variables as means and SDs or medians and interquartile ranges. Propensity score matching was applied to identify a cohort of patients with similar baseline characteristics. The propensity score was developed by a logistic regression model using a nonparsimonious approach. Portico and CoreValve patients having the same probability score (nearest neighbor method; calliper=0.25×SD [logitPs]) were matched in a 1:2 fashion. After matching, continuous variables with a normal distribution were compared using the paired sample *t* test; otherwise, the Wilcoxon rank-sum test was used. Differences for matched categorical variables were analyzed with the McNemar test. A 2-sided *P* value of <0.05 was considered to be of statistical significance. Kaplan–Meier method was used to calculate the time-to-event curves compared by stratified log-rank test, and hazard ratio was derived from Cox proportional model. All statistical analyses were performed using SAS version 9.2 (SAS Institute, Cary, NC).

Results

Cohort Characteristics

A total of 162 patients undergoing ViV implantation were included in the present analysis. Using the propensity score approach, 54 patients receiving Portico were matched with 108 patients out of 779 patients receiving CoreValve within the VIVID Registry (Figure 1). The baseline characteristics and procedural details of the study population are shown in Table 1. Standardized differences after propensity score were <0.1 for all baseline variables. Average age for the study population was 79±8.2 years, 60% were women, and the mean STS

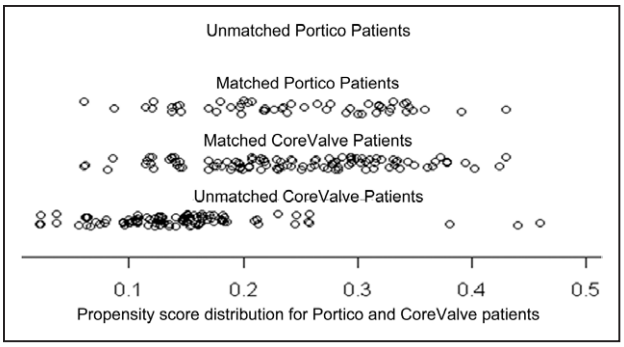

Figure 1. Propensity matching for Portico and CoreValve patients. All Portico patients were appropriately matched with CoreValve cases from the Valve-in-Valve International Data registry.

score was 8.1±5.5. There were no significant differences in comorbidities, preoperative left ventricular systolic function, hemodynamic data, and surgical valve characteristics between the 2 groups. Pure aortic insufficiency as the mode of bioprosthetic valve failure was present in one third of patients for both groups with comparable baseline EOA and mean transaortic gradient. Peripheral arterial access was used in 93%, general anesthesia in 60%, and transesophageal guidance in 50% of patients. THV size of 23 mm was the most common device used for ViV implantation in both groups.

Hemodynamic and Procedural Outcomes

The outcomes of interest are summarized in Table 2. Post–ViV implantation hemodynamics identified a larger EOA (1.67 versus 1.31 cm^2; P=0.001), lower mean gradient (14±7.5 versus 17±7.5 mm Hg; P=0.02), and a lower rate of severe prosthesis–patient mismatch (19.5% versus 40%; P=0.03) for CoreValve-treated compared with Portico-treated patients. The observed difference in EOAs between the 2 THVs was more significant for implantations within smaller (ID <21 mm; 1.67 versus 1.25 cm^2; P=0.001) compared with larger surgical valves (ID ≥21 mm; 1.6 versus 1.5 cm^2; P=0.1) for CoreValve versus Portico, respectively. Site-reported rates of significant postimplantation AI were higher in Portico compared with CoreValve group (18% versus 5%; P=0.02). Core laboratory–adjudicated moderate-to-severe AI was observed in 13.7% of Portico and 4.2% of CoreValve THV patients (P=0.04). The rate of procedural complications including THV malpositioning, need for second THV, or coronary obstruction was not significantly different between the 2 groups. At 1 year, hemodynamic data were available for 46 CoreValve and 18 Portico patients. EOAs and mean transaortic gradients for the CoreValve and Portico were 1.52±0.39 and 1.38±0.6 cm^2 (P=0.45) and 13.1±7.2 and 16.8±10.6 mm Hg (P=0.15), respectively.

Clinical Outcomes

At 1 month, 2 patients in the Portico group (one related to left ventricular wire perforation and second related to ischemic stroke) and 1 patient in the CoreValve (because of coronary obstruction) had died. There were no differences in major bleeding, major vascular complication, and stage II–III acute kidney injury between the 2 groups. New pacemaker implantation was required for 1 patient (2.1%) in Portico and 7 patients (7.3%) in the CoreValve group (P=0.27). Median length of stay was 7 days and similar for the 2 groups. Within 1 year,

Table 1. Baseline and Procedural Details of Study Patients

	Portico (n=54)	CoreValve (n=108)	*P* Value
Patient characteristics			
Age, y	79.3±7.2	78.8±8.7	0.72
Female sex, n (%)	35 (65)	61 (58)	0.40
Height, cm	164±9.6	165±9.6	0.53
Weight, kg	72.6±14.5	73.5±15.8	0.73
Body mass index, kg/m^2	26.9±4.8	26.8±5.0	0.94
Body surface area, m^2	1.81±0.23	1.83±0.21	0.67
STS score, %	7.4±4.2	8.4±6.1	0.30
NYHA III–IV class, n (%)	50 (92.6)	99 (91.7)	0.82
Diabetes mellitus, n (%)	13 (24.1)	32 (29.6)	0.46
Prior stroke, n (%)	9 (16.7)	16 (14.8)	0.76
Renal insufficiency, n (%)*	31 (57.4)	55 (50.9)	0.44
Previous Pacemaker, n (%)	6 (11.1)	20 (18.5)	0.23
LVEF, %	54.6±10.9	51.5±12.7	0.20
Surgical valve characteristics			
Bioprosthesis label size			0.21
<21, n (%)	1 (1.9)	8 (1.9)	
21–25, n (%)	51 (94.4)	90 (83.3)	
>25, n (%)	2 (3.7)	10 (9.3)	
True internal diameter, mm			0.74
<21 mm, n (%)	30 (57.7)	50 (54.3)	
21–23 mm, n (%)	15 (28.8)	25 (27.2)	
>23 mm, n (%)	7 (13.5)	17 (18.5)	
Aortic valve area, cm^2	0.94±0.45	0.92±0.44	0.83
Mean gradient, mm Hg	35.8±18	33.8±18	0.54
Degeneration mode			0.25
Regurgitation, n (%)	19 (35.2)	33 (30.6)	
Stenosis, n (%)	14 (25.9)	42 (38.9)	
Combined, n (%)	21 (38.9)	33 (30.6)	
Stentless bioprosthesis, n (%)	5 (9.3)	15 (13.9)	0.40
Age of bioprosthesis, y	10 (6–12)	9 (7–13)	0.41
Procedural characteristics			
Peripheral arterial access	50 (92.6)	101 (93.5)	0.58
THV size, mm			
23 mm, n (%)	41 (76)	46 (43)	
25 or 26 (mm), n (%)†	11 (21)	46 (43)	
General anesthesia, n (%)	30 (59)	68 (63)	0.73
TEE guidance, n (%)	27 (53)	52 (48)	0.61
Pre dilation, n (%)	14 (28)	15 (14)	0.05
Post dilation, n (%)	15 (28)	18 (17)	0.15

All values are mean±SD unless noted otherwise. GFR indicates glomerular filtration rate; LVEF, left ventricular ejection fraction; NYHA, New York heart Association classification; STS, Society of Thoracic Surgery; TEE, transesophageal echo; and THV, transcatheter heart valve.

*GFR <60 mL/min.

†Portico and CoreValve are available in the following sizes: 23, 25, 27, and 29 mm and 23, 26, 29, and 31 mm, respectively.

Table 2. Procedural, Hemodynamic, and Clinical Outcomes

	Portico (n=54)	CoreValve (n=108)	*P* Value
Procedural outcomes			
Coronary obstruction, n (%)	0 (0)	2 (1.9)	0.55
THV malposition, n (%)	2 (3.7)	10 (10)	0.22
2nd THV implantation, n (%)	1 (1.9)	7 (6.5)	0.27
Procedural complications, n (%)*	2 (3.7)	11 (11.3)	0.08
Postimplantation hemodynamics			
Effective orifice area, cm^2, (n)	1.31±0.47 (40)	1.67±0.56 (82)	0.001
Mean gradient, mm Hg, (n)	17±7.5 (51)	14±7.5 (98)	0.02
Prosthesis–patient mismatch			
Any, n (%)	31 (77.5)	25 (30.5)	0.01
Severe, n (%)	16 (40)	16 (19.5)	0.03
Aortic insufficiency (core laboratory adjudicated)			0.04
None/mild, n (%)	44 (86.3)	97 (95.8)	
Moderate/severe, n (%)	7 (13.7)	4 (4.2)	
Clinical outcomes—1 mo			
Death, n (%)	2 (3.7)	1 (1)	0.27
Major stroke, n (%)	1 (1.9)	1 (0.9)	0.11
Major vascular complication, n (%)	1 (1.9)	4 (3.7)	0.5
Major bleeding, n (%)	6 (11.1)	6 (5.6)	0.22
Stage II–III acute kidney injury, n (%)	2 (3.7)	9 (8.4)	0.34
Pacemaker implantation, n (%)	1 (2.1)	7 (7.3)	0.27
Length of stay, d, median (IQR)	7.5 (4–12)	8 (5–10)	0.91
Clinical outcomes—1 y			
Death, n (%)†	11 (22.6)	8 (9.1)	0.03

All values are n (%), unless noted otherwise. IQR indicates interquartile range; and THV, transcatheter heart valve.

*Composite of coronary obstruction, malposition, and need for second THV.

†Kaplan–Meier survival analysis.

11 patients in Portico and 8 patients in CoreValve groups had died (*P*=0.03; Figure 2). Use of Portico for ViV implantation was associated with higher 1-year mortality (Hazard ratio, 1.13; 95% confidence interval, 1.01–1.27).

The cause of death among the CoreValve was procedural (1 case), intracranial bleeding (2 cases), heart block (1 case), and unknown in the remaining cases. The mortality in the Portico group was procedural (1 case), ischemic stroke (1 case), endocarditis (1 case), intracerebral bleeding (1 case), pneumonia (2 cases), cancer (1 case), fall (1 case), and unknown in the in the remaining patients.

Implantation THV Depth Analysis

Patients in the CoreValve and Portico groups had comparable implantation depth distribution (Figure 3). The median (25% to 75% interquartile range) implantation depth for CoreValve and Portico were 5.7 mm (2.6–8.2) and 6.8 mm (4.9–10.2), respectively. In addition, no significant difference in implantation depth was noted among those with or without moderate-to-severe postimplantation AI (*P*=0.81; Figure 3).

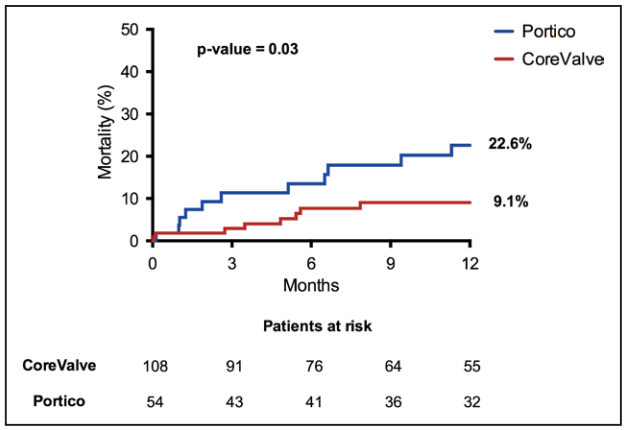

Figure 2. Kaplan–Meier curves for 1-y mortality after Portico vs CoreValve for valve-in-valve implantation.

Transcatheter and THV Operators Experience

CoreValve and Portico cases were contributed by 29 centers, 13 for CoreValve (Germany [4], Italy [3], Canada [2], United Kingdom [2], France [1], and Israel [1]) and 16 for Portico (Canada [6], Germany [3], Italy [2], and Netherlands [2], Australia [1], Belgium [1], United Kingdom [1]). CoreValve operators were the same ones for Portico in 4 centers. Operators at enrolling centers were surveyed. Operators in the CoreValve group had performed a median (25% to 75% interquartile range) of 500 (640–810) transcatheter aortic valve implantation, 32 (16–44) ViV implantation procedures, and 316 (225–393) CoreValve cases. Operators in the Portico group performed 510 (362–905) transcatheter aortic valve implantation, 35 (21–54) ViV implantation procedures, 35 (10–69) Portico, and 300 (20–371) cases of CoreValve implantations.

Discussion

This report describes the first matched comparison of hemodynamic and clinical outcomes of different THVs used for ViV implantation procedures with detailed core laboratory imaging analyses. The main findings of the present study are (1) Portico was associated with a higher postimplant mean gradient, higher rate of prosthesis–patient mismatch, and core laboratory adjudicated moderate-to-severe AI. (2) Portico use was associated with a trend for lower rate of a composite of procedure complications but with higher 1-year mortality compared with CoreValve.

ViV implantation has become the mainstay of treatment for failed surgical aortic bioprosthesis in patients at high or prohibitive risk of redo valve surgery.[2,3] Most candidates for ViV implantation may be suitable for treatment with either balloon-expandable or self-expanding THV,[4,16,17] but certain patient characteristics may be better managed by a specific THV than others.[1,18] Initial results from Portico implantation for the treatment of patients with severe native aortic stenosis were promising[9,19] with potential for advantage in patients at high risk of procedural complications.[20,21] However, the present comparison

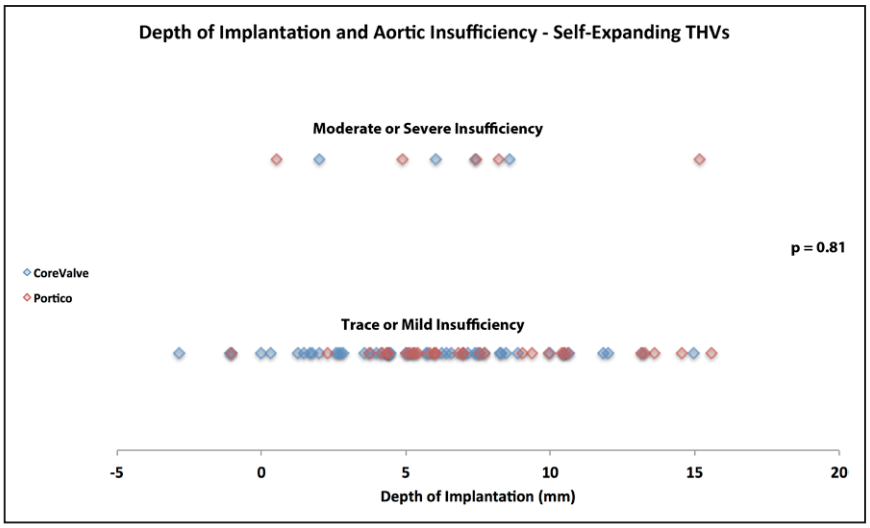

Figure 3. Depth of implantation and postimplantation aortic insufficiency. Note the comparable implantation depth distribution between the 2 transcatheter heart valves (THVs). Similar distribution is also noted among those with or without significant amount of postimplantation aortic insufficiency.

showed that CoreValve resulted in greater EOA, lower mean gradient, and lower rate of prosthesis–patient mismatch compared with Portico. Annular size is an important determinant of EOA.[22] Annular area in ViV interventions is determined by the space available within the failed surgical bioprosthesis, which can be further compromised by the implanted THV. At adequate implantation depth, CoreValve allows unconstrained leaflet function, which likely accounts for the differences in hemodynamic performance. The inclusion of many patients (nearly half) with smaller degenerated bioprosthesis (true ID < 21 mm) might have amplified the observed postimplantation hemodynamic finding, which is supported by the pronounced hemodynamic difference we observed between the THVs among smaller, compared with larger, surgical bioprosthesis subgroups.

Portico was associated with significantly higher rate of postimplantation AI, predominantly paravalvular compared with the CoreValve, a finding that was confirmed by independent blinded analysis (Figure 4). AI post–ViV implantation is uncommon and may be related to clinical or technical factors. There were no differences in the surgical valve size, internal diameter, or the mode of degeneration between the 2 THV groups, and the rate of postdilatation was comparable. In addition, no major disparity in THV implantation depth was found between the 2 platforms (Figure 3). The possibility of surgical paravalvular leaks was considered and only suspected in 2 cases (1 Portico and 1 CoreValve). Variation in THV frame's cell size and its impact on radial strength cannot be excluded as a potential reason for the observed findings. In addition to THV design, including the leaflet location in relation to the aortic annulus, other factors with mechanisms that we may or may not currently understand should be considered. For instance, it is important to note that THVs larger than 23 mm were used more frequently among the CoreValve patients compared with the Portico group, 54% versus 24%, respectively. It is possible that the manufacturer's sizing recommendations for the Portico are suboptimal and might have contributed to the postimplantation hemodynamic differences, although unlikely to be the sole explanation. Optimal THV sizing for ViV implantation is not well established, and the effect of THV oversizing within a rigid confined space is not necessarily beneficial and can be detrimental.[22] Despite our careful matching here accounting for the surgical bioprosthesis true ID, baseline difference in THV sizes was unavoidable because of the different manufacturers recommendations and the different label sizing between the 2 platforms (26, 29, and 31 mm for CoreValve and 25, 27, and 29 mm for Portico).

Thirty-day outcomes were similar, but 1-year mortality was higher in the Portico compared with the CoreValve-treated patients. The exact mechanism of higher 1-year mortality in Portico is unclear. Postimplantation AI is an important determinant of long-term mortality after transcatheter native aortic valve therapy.[23,24] Despite the higher postimplantation AI among the Portico, this group had a comparable 1-year survival to the remaining cohort, which has multiple explanations. First, the study was not powered for mortality particularly in smaller subgroups. Second, unlike patients undergoing transcatheter aortic valve implantation, significant AI at baseline is frequently encountered among ViV implantation candidates.[2] In fact, two thirds in each THV group in our analysis had ≥moderate AI at baseline as mode of degeneration. This might have served to attenuate the hemodynamic impact of postimplantation AI and alter its prognostic implications. The latter is theoretical at this stage and requires further evaluation. Predilatation, a potential confounder,[25] was more frequent in the Portico group, but its relation to long-term outcomes post–ViV implantation is unknown. Premature THV degeneration or thrombosis could not be assessed, and their contribution to the 1-year outcomes here cannot be excluded. Prosthesis–patient mismatch was significantly higher among Portico patients, which may adversely affect long-term outcomes after aortic valve replacement. However, the relationship between prosthesis–patient mismatch after THV implantation remains poorly understood.[12] It is important to note that the observed 1-year mortality rate for the CoreValve patients in the present study was similar to early experience with CoreValve ViV implantation.[2,17,26] Although death reported here was mostly attributed to noncardiac causes, this has to be taken with caution given the lack of clinical outcomes adjudication.

Implanting operators in each cohort had comparable well-established experience. Operators experience includes the expertise in transcatheter ViV implantation (transcatheter ViV experience) and the familiarity with a specific THV (THV

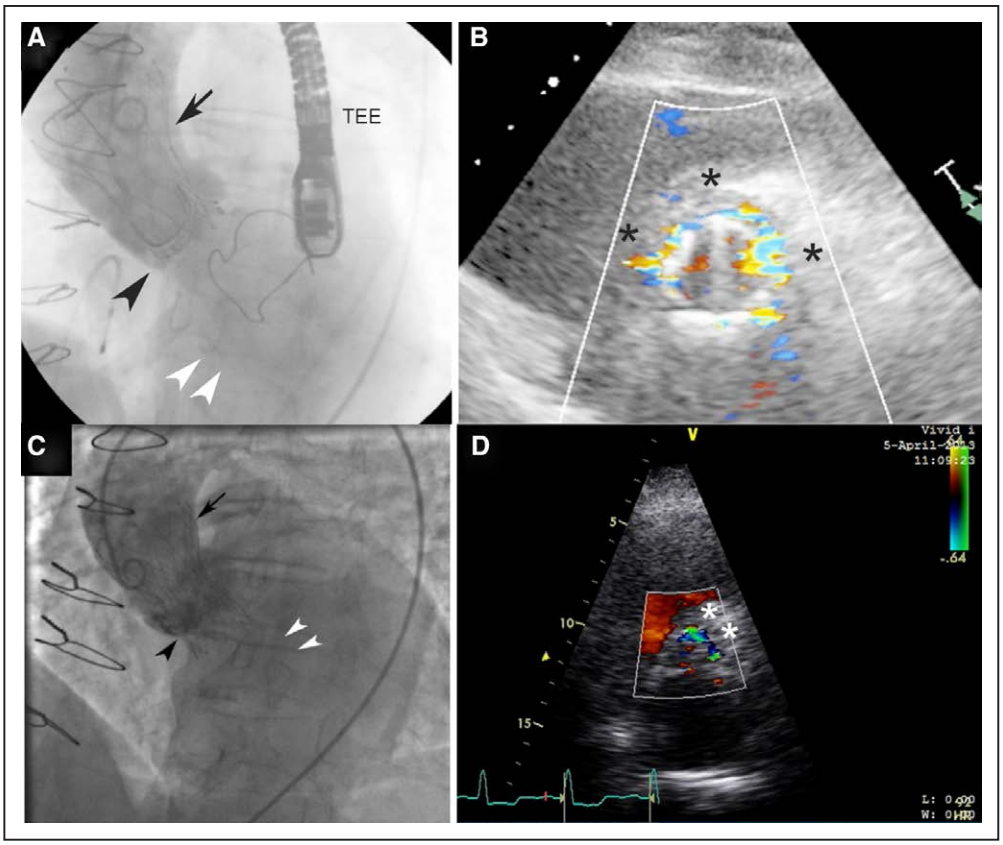

Figure 4. Aortic insufficiency after Portico for ViV procedure. **A**, Portico (black arrow) implanted for a failed Carpentier Edwards bioprosthetic valve (black arrowhead) under transesophageal echo (TEE) guidance. **B**, Severe aortic insufficiency evident on aortic angiogram (white arrowheads) that was paravalvular in location by echocardiography (asterisks). **C**, Portico (black arrow) implanted for a failed St. Jude Toronto stentless porcine bioprosthetic valve (black arrowhead). **D**, Moderate aortic insufficiency evident on aortic angiogram (white arrowheads) that was paravalvular in location by echocardiography (asterisks).

experience). Although the THV experience with Portico was relatively less established than CoreValve given the temporal variation in market's availability (more recent with former), it is clear that the Portico cohort had the advantage of evolved operators transcatheter ViV experience. Furthermore, we did not observe significant difference in procedural parameters such as THV embolization, second THV deployment, or vascular complications, indirect markers of operator experience. In addition, the 30-day outcomes were similar between the 2 THV groups, suggesting limited influence of operator and procedural factors on observed findings.

Limitations

Despite the inclusive multicenter nature of VIVID registry, reporting bias cannot be excluded. Clinical outcomes within the registry are self-reported by the enrolling center and not centrally adjudicated. In this analysis, however, mortality cases and related pathogenesis were individually verified with each center. Imaging-related outcomes such as aortic insufficiency or implantation depth were adjudicated independently. Even though the current analysis included a comprehensive matching of patient and surgical valve characteristics and core laboratory analysis of echocardiographic results, the presence of residual confounding despite propensity score matching cannot be excluded. Matching by country or center was initially considered but proved to be challenging as it had limited the matching pool and therefore the ability to account for other baseline characteristics. In addition, inclusion of early Portico experience in centers performing ViV implantation procedures is a potential confounder. Information on the frequency of THV repositioning/recapturing attempts was lacking, and the 1-year hemodynamic data were only partially available. A comparison among other repositionable THV platforms used in ViV implantation (Lotus, DirectFlow, and Evolut R) is needed to further understand relationship between THV selection and clinical outcomes.

Conclusions

In this first matched comparison of THVs for ViV interventions, Portico was associated with worse postprocedural hemodynamics compared with CoreValve. Clinical outcomes at 30 days were similar, but overall mortality at 1 year was higher in Portico compared with CoreValve patients. Although this can be related to THV design characteristics, the impact of other procedural factors cannot be excluded and requires further evaluation.

Disclosures

Dr Dvir reports consulting for Edwards Lifesciences and Medtronic. Dr Webb reports consulting for St. Jude Medical. Dr Sinning reports receiving speaker honoraria and research grants from Medtronic, Edwards Lifesciences, Direct Flow Medical, and Boston Scientific. Dr Barbanti reports consulting for Edwards Lifesciences. Dr Latib reports consulting for Medtronic and Direct Flow Medical. Dr Horlick reports consulting and program support from Edwards Lifesciences, Medtronic, and St.

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Background—Transcatheter valve-in-valve implantation is an established therapy for high-risk patients with failed surgical aortic bioprosthesis. There are limited data comparing outcomes of valve-in-valve implantation using different transcatheter heart valves (THV).

Methods and Results—Patients included in the Valve-in-Valve International Data registry (VIVID) and treated with self-expanding THV devices were analyzed using centralized core laboratory blinded to clinical events. St. Jude Medical Portico versus Medtronic CoreValve were compared in a 1:2 fashion after propensity score matching. A total of 162 patients, Portico- (n=54) and CoreValve- (n=108) based valve-in-valve procedures comprised the study population with no significant difference in baseline characteristics (age, 79±8.2 years; 60% women; mean STS [Society of Thoracic Surgery] score 8.1±5.5%). Postimplantation, CoreValve was associated with a larger effective orifice area (1.67 versus 1.31 cm^2; *P*=0.001), lower mean gradient (14±7.5 versus 17±7.5 mm Hg; *P*=0.02), and lower core laboratory–adjudicated moderate-to-severe aortic insufficiency (4.2% versus 13.7%; *P*=0.04), compared with Portico. Procedural complications including THV malpositioning, second THV requirement, or coronary obstruction were not significantly different between the 2 groups. Survival and stroke rates at 30 days were similar, but overall mortality at 1 year was higher among patients treated with Portico compared with CoreValve (22.6% versus 9.1%; *P*=0.03).

Conclusions—In this first matched comparison of THVs for valve-in-valve implantations, Portico and CoreValve demonstrated differences in postprocedural hemodynamics and long-term clinical outcomes. Although this could be related to THV design characteristics, the impact of other procedural factors cannot be excluded and require further evaluation. **(*Circ Cardiovasc Interv*. 2017;10:e004392. DOI: 10.1161/CIRCINTERVENTIONS.116.004392.)**

Key Words: aortic valve ■ bioprosthesis ■ hemodynamic ■ transcatheter aortic valve replacement

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WHAT IS KNOWN

- Transcatheter valve-in-valve (ViV) implantation is a safe and effective strategy among high-risk patients with degenerated surgical bioprosthesis.
- Residual stenosis is a major limitation of aortic ViV procedures.

WHAT THE STUDY ADDS

- In comparison to Portico, CoreValve was associated with larger postimplantation effective orifice area, lower gradients, and lower rate of regurgitation after ViV.
- In this first matched comparison of transcatheter heart valves in ViVs, the 30-day clinical outcomes were comparable, but the Portico group exhibited a higher 1-year mortality compared with CoreValve.

Transcatheter valve-in-valve (ViV) implantation has become an established therapeutic strategy for the management of high-risk patients with failed surgical aortic bioprostheses.[1–3] Most candidates for ViV implantation can be treated with either balloon-expandable or self-expanding transcatheter heart valves (THV). Although certain clinical and anatomic features affect the choice of THV in an individual patient,[4–6] supra-annular self-expanding valves (CoreValve) are associated with favorable hemodynamic profile compared with balloon-expandable THV.[2,7,8] However, it is unclear how it compares to another self-expanding design with an intra-annular THV position (Portico). In this study, we compare the hemodynamic and clinical outcomes of the 2 most commonly used self-expanding THV systems, CoreValve (Medtronic, Inc, Minneapolis, MN) and Portico (St. Jude Medical, Inc, St. Paul, MN) after aortic ViV implantations.

Methods

The design and details of the Valve-in-Valve International Data Registry (VIVID) have been reported previously.[2] Briefly, the VIVID registry is a collaboration of centers from Europe, the Americas, Australia, New Zealand, and the Middle East for prospective collection of data for ViV implantation procedures. Data are collected using detailed case report forms, and any inconsistency is resolved with local investigators and on-site data monitoring. All patients had provided written informed consent for the ViV implantation procedure, and the Registry was approved by the local ethics committee. All Portico cases within the VIVID registry were matched with comparable CoreValve ViV implantation cases using propensity score matching. Each Portico case was matched with 2 CoreValve cases in a 1:2 fashion to enhance the statistical power. Variables used for propensity score determination included age, sex, STS (Society of Thoracic Surgery) mortality score, procedural access, surgical valve label size, and surgical valve design (stentless versus stented). In addition, groups were matched for surgical valve true internal diameter (true ID). All ViV implantation procedures in the present study were performed for failed surgical bioprostheses at the aortic position according to local standards and practices.

Definitions

The Portico is a self-expanding THV with bovine pericardial leaflets sewn into nitinol frame at an annular level surrounded by a porcine pericardial skirt.[9] The CoreValve is a self-expanding THV with porcine pericardial leaflets sewn into nitinol frame at a supra-annular position surrounded by an outer skirt of porcine pericardium.[10] The mechanism of bioprosthetic valve failure (ie, stenosis, regurgitation, or combined) was determined based on preprocedural echocardiography. True internal diameter of surgical valves was derived according to valve type and label size.[4,11] Procedural complications included coronary obstruction, THV malpositioning, need for a second THV, and device success. Prosthesis–patient mismatch was based on post–ViV implantation effective orifice area (EOA), ≤0.85 and ≤0.65 cm^2/m^2 for any and severe mismatch, respectively.[12] Clinical outcomes determined included all-cause mortality at 1 and 12 months. Other outcomes included 30-day rate of stroke, acute kidney injury, major bleeding, and major vascular complication according to the updated Valve Academic Research Consortium criteria.[13]

Core Laboratory Echocardiographic and Fluoroscopic Analysis

Echocardiographic and cine angiographic images after THV implantation were reviewed in a centralized core laboratory to determine the severity of postimplantation aortic insufficiency (AI) in a blinded manner at St. Michael's Hospital, Toronto, Canada. AI was adjudicated independently using semiqualitative parameters defining the AI jet features, including number of jets, width of jet origin, jet path along the stent, proximal flow convergence, vena contracta, jet density on continuous-wave Doppler, pressure half time and flow reversal in the abdominal aorta. In addition, the circumferential extent of the aortic insufficiency on short axis was ascertained (<10, 10–30, >30% for mild, moderate, or severe AI, respectively). The AI assessment was also supplemented by evaluation of postimplantation aortic root angiography using established angiographic criteria.[14]

THV depth assessment was performed at St. Paul's Hospital, Vancouver, Canada. Postimplantation angiographic images were analyzed using centralized core laboratory assessment blinded to clinical events. THV depth was expressed in millimeter(s) reflecting the distance of THV distal frame in relation to the surgical valve frame as previously described.[15]

Statistical Analysis

Categorical variables were reported as frequencies and percentages, and continuous variables as means and SDs or medians and interquartile ranges. Propensity score matching was applied to identify a cohort of patients with similar baseline characteristics. The propensity score was developed by a logistic regression model using a nonparsimonious approach. Portico and CoreValve patients having the same probability score (nearest neighbor method; calliper=0.25×SD [logitPs]) were matched in a 1:2 fashion. After matching, continuous variables with a normal distribution were compared using the paired sample *t* test; otherwise, the Wilcoxon rank-sum test was used. Differences for matched categorical variables were analyzed with the McNemar test. A 2-sided *P* value of <0.05 was considered to be of statistical significance. Kaplan–Meier method was used to calculate the time-to-event curves compared by stratified log-rank test, and hazard ratio was derived from Cox proportional model. All statistical analyses were performed using SAS version 9.2 (SAS Institute, Cary, NC).

Results

Cohort Characteristics

A total of 162 patients undergoing ViV implantation were included in the present analysis. Using the propensity score approach, 54 patients receiving Portico were matched with 108 patients out of 779 patients receiving CoreValve within the VIVID Registry (Figure 1). The baseline characteristics and procedural details of the study population are shown in Table 1. Standardized differences after propensity score were <0.1 for all baseline variables. Average age for the study population was 79±8.2 years, 60% were women, and the mean STS

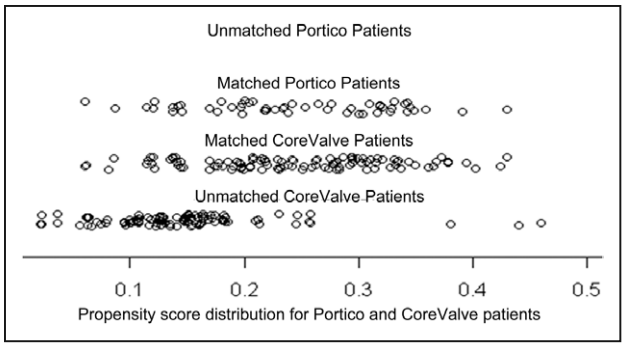

Figure 1. Propensity matching for Portico and CoreValve patients. All Portico patients were appropriately matched with CoreValve cases from the Valve-in-Valve International Data registry.

score was 8.1±5.5. There were no significant differences in comorbidities, preoperative left ventricular systolic function, hemodynamic data, and surgical valve characteristics between the 2 groups. Pure aortic insufficiency as the mode of bioprosthetic valve failure was present in one third of patients for both groups with comparable baseline EOA and mean transaortic gradient. Peripheral arterial access was used in 93%, general anesthesia in 60%, and transesophageal guidance in 50% of patients. THV size of 23 mm was the most common device used for ViV implantation in both groups.

Hemodynamic and Procedural Outcomes

The outcomes of interest are summarized in Table 2. Post–ViV implantation hemodynamics identified a larger EOA (1.67 versus 1.31 cm^2; *P*=0.001), lower mean gradient (14±7.5 versus 17±7.5 mm Hg; *P*=0.02), and a lower rate of severe prosthesis–patient mismatch (19.5% versus 40%; *P*=0.03) for CoreValve-treated compared with Portico-treated patients. The observed difference in EOAs between the 2 THVs was more significant for implantations within smaller (ID <21 mm; 1.67 versus 1.25 cm^2; *P*=0.001) compared with larger surgical valves (ID ≥21 mm; 1.6 versus 1.5 cm^2; *P*=0.1) for CoreValve versus Portico, respectively. Site-reported rates of significant postimplantation AI were higher in Portico compared with CoreValve group (18% versus 5%; *P*=0.02). Core laboratory–adjudicated moderate-to-severe AI was observed in 13.7% of Portico and 4.2% of CoreValve THV patients (*P*=0.04). The rate of procedural complications including THV malpositioning, need for second THV, or coronary obstruction was not significantly different between the 2 groups. At 1 year, hemodynamic data were available for 46 CoreValve and 18 Portico patients. EOAs and mean transaortic gradients for the CoreValve and Portico were 1.52±0.39 and 1.38±0.6 cm^2 (*P*=0.45) and 13.1±7.2 and 16.8±10.6 mm Hg (*P*=0.15), respectively.

Clinical Outcomes

At 1 month, 2 patients in the Portico group (one related to left ventricular wire perforation and second related to ischemic stroke) and 1 patient in the CoreValve (because of coronary obstruction) had died. There were no differences in major bleeding, major vascular complication, and stage II–III acute kidney injury between the 2 groups. New pacemaker implantation was required for 1 patient (2.1%) in Portico and 7 patients (7.3%) in the CoreValve group (*P*=0.27). Median length of stay was 7 days and similar for the 2 groups. Within 1 year,

Table 1. Baseline and Procedural Details of Study Patients

	Portico (n=54)	CoreValve (n=108)	*P* Value
Patient characteristics			
Age, y	79.3±7.2	78.8±8.7	0.72
Female sex, n (%)	35 (65)	61 (58)	0.40
Height, cm	164±9.6	165±9.6	0.53
Weight, kg	72.6±14.5	73.5±15.8	0.73
Body mass index, kg/m^2	26.9±4.8	26.8±5.0	0.94
Body surface area, m^2	1.81±0.23	1.83±0.21	0.67
STS score, %	7.4±4.2	8.4±6.1	0.30
NYHA III–IV class, n (%)	50 (92.6)	99 (91.7)	0.82
Diabetes mellitus, n (%)	13 (24.1)	32 (29.6)	0.46
Prior stroke, n (%)	9 (16.7)	16 (14.8)	0.76
Renal insufficiency, n (%)*	31 (57.4)	55 (50.9)	0.44
Previous Pacemaker, n (%)	6 (11.1)	20 (18.5)	0.23
LVEF, %	54.6±10.9	51.5±12.7	0.20
Surgical valve characteristics			
Bioprosthesis label size			0.21
<21, n (%)	1 (1.9)	8 (1.9)	
21–25, n (%)	51 (94.4)	90 (83.3)	
>25, n (%)	2 (3.7)	10 (9.3)	
True internal diameter, mm			0.74
<21 mm, n (%)	30 (57.7)	50 (54.3)	
21–23 mm, n (%)	15 (28.8)	25 (27.2)	
>23 mm, n (%)	7 (13.5)	17 (18.5)	
Aortic valve area, cm^2	0.94±0.45	0.92±0.44	0.83
Mean gradient, mm Hg	35.8±18	33.8±18	0.54
Degeneration mode			0.25
Regurgitation, n (%)	19 (35.2)	33 (30.6)	
Stenosis, n (%)	14 (25.9)	42 (38.9)	
Combined, n (%)	21 (38.9)	33 (30.6)	
Stentless bioprosthesis, n (%)	5 (9.3)	15 (13.9)	0.40
Age of bioprosthesis, y	10 (6–12)	9 (7–13)	0.41
Procedural characteristics			
Peripheral arterial access	50 (92.6)	101 (93.5)	0.58
THV size, mm			
23 mm, n (%)	41 (76)	46 (43)	
25 or 26 (mm), n (%)†	11 (21)	46 (43)	
General anesthesia, n (%)	30 (59)	68 (63)	0.73
TEE guidance, n (%)	27 (53)	52 (48)	0.61
Pre dilation, n (%)	14 (28)	15 (14)	0.05
Post dilation, n (%)	15 (28)	18 (17)	0.15

All values are mean±SD unless noted otherwise. GFR indicates glomerular filtration rate; LVEF, left ventricular ejection fraction; NYHA, New York heart Association classification; STS, Society of Thoracic Surgery; TEE, transesophageal echo; and THV, transcatheter heart valve.

*GFR <60 mL/min.

†Portico and CoreValve are available in the following sizes: 23, 25, 27, and 29 mm and 23, 26, 29, and 31 mm, respectively.

Table 2. Procedural, Hemodynamic, and Clinical Outcomes

	Portico (n=54)	CoreValve (n=108)	*P* Value
Procedural outcomes			
Coronary obstruction, n (%)	0 (0)	2 (1.9)	0.55
THV malposition, n (%)	2 (3.7)	10 (10)	0.22
2nd THV implantation, n (%)	1 (1.9)	7 (6.5)	0.27
Procedural complications, n (%)*	2 (3.7)	11 (11.3)	0.08
Postimplantation hemodynamics			
Effective orifice area, cm^2, (n)	1.31±0.47 (40)	1.67±0.56 (82)	0.001
Mean gradient, mm Hg, (n)	17±7.5 (51)	14±7.5 (98)	0.02
Prosthesis–patient mismatch			
Any, n (%)	31 (77.5)	25 (30.5)	0.01
Severe, n (%)	16 (40)	16 (19.5)	0.03
Aortic insufficiency (core laboratory adjudicated)			0.04
None/mild, n (%)	44 (86.3)	97 (95.8)	
Moderate/severe, n (%)	7 (13.7)	4 (4.2)	
Clinical outcomes—1 mo			
Death, n (%)	2 (3.7)	1 (1)	0.27
Major stroke, n (%)	1 (1.9)	1 (0.9)	0.11
Major vascular complication, n (%)	1 (1.9)	4 (3.7)	0.5
Major bleeding, n (%)	6 (11.1)	6 (5.6)	0.22
Stage II–III acute kidney injury, n (%)	2 (3.7)	9 (8.4)	0.34
Pacemaker implantation, n (%)	1 (2.1)	7 (7.3)	0.27
Length of stay, d, median (IQR)	7.5 (4–12)	8 (5–10)	0.91
Clinical outcomes—1 y			
Death, n (%)†	11 (22.6)	8 (9.1)	0.03

All values are n (%), unless noted otherwise. IQR indicates interquartile range; and THV, transcatheter heart valve.

*Composite of coronary obstruction, malposition, and need for second THV.

†Kaplan–Meier survival analysis.

11 patients in Portico and 8 patients in CoreValve groups had died (*P*=0.03; Figure 2). Use of Portico for ViV implantation was associated with higher 1-year mortality (Hazard ratio, 1.13; 95% confidence interval, 1.01–1.27).

The cause of death among the CoreValve was procedural (1 case), intracranial bleeding (2 cases), heart block (1 case), and unknown in the remaining cases. The mortality in the Portico group was procedural (1 case), ischemic stroke (1 case), endocarditis (1 case), intracerebral bleeding (1 case), pneumonia (2 cases), cancer (1 case), fall (1 case), and unknown in the in the remaining patients.

Implantation THV Depth Analysis

Patients in the CoreValve and Portico groups had comparable implantation depth distribution (Figure 3). The median (25% to 75% interquartile range) implantation depth for CoreValve and Portico were 5.7 mm (2.6–8.2) and 6.8 mm (4.9–10.2), respectively. In addition, no significant difference in implantation depth was noted among those with or without moderate-to-severe postimplantation AI (*P*=0.81; Figure 3).

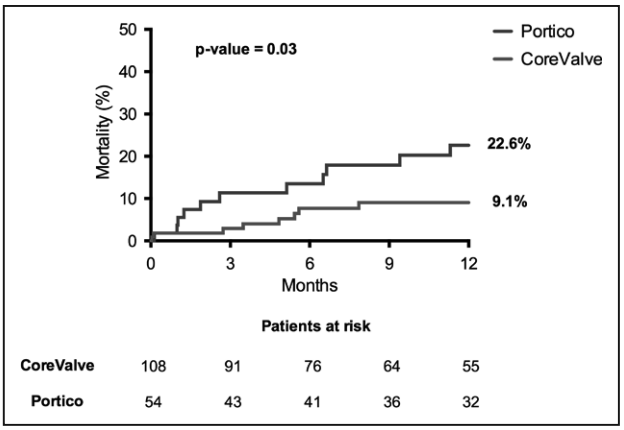

Figure 2. Kaplan–Meier curves for 1-y mortality after Portico vs CoreValve for valve-in-valve implantation.

Transcatheter and THV Operators Experience

CoreValve and Portico cases were contributed by 29 centers, 13 for CoreValve (Germany [4], Italy [3], Canada [2], United Kingdom [2], France [1], and Israel [1]) and 16 for Portico (Canada [6], Germany [3], Italy [2], and Netherlands [2], Australia [1], Belgium [1], United Kingdom [1]). CoreValve operators were the same ones for Portico in 4 centers. Operators at enrolling centers were surveyed. Operators in the CoreValve group had performed a median (25% to 75% interquartile range) of 500 (640–810) transcatheter aortic valve implantation, 32 (16–44) ViV implantation procedures, and 316 (225–393) CoreValve cases. Operators in the Portico group performed 510 (362–905) transcatheter aortic valve implantation, 35 (21–54) ViV implantation procedures, 35 (10–69) Portico, and 300 (20–371) cases of CoreValve implantations.

Discussion

This report describes the first matched comparison of hemodynamic and clinical outcomes of different THVs used for ViV implantation procedures with detailed core laboratory imaging analyses. The main findings of the present study are (1) Portico was associated with a higher postimplant mean gradient, higher rate of prosthesis–patient mismatch, and core laboratory adjudicated moderate-to-severe AI. (2) Portico use was associated with a trend for lower rate of a composite of procedure complications but with higher 1-year mortality compared with CoreValve.

ViV implantation has become the mainstay of treatment for failed surgical aortic bioprosthesis in patients at high or prohibitive risk of redo valve surgery.[2,3] Most candidates for ViV implantation may be suitable for treatment with either balloon-expandable or self-expanding THV,[4,16,17] but certain patient characteristics may be better managed by a specific THV than others.[1,18] Initial results from Portico implantation for the treatment of patients with severe native aortic stenosis were promising[9,19] with potential for advantage in patients at high risk of procedural complications.[20,21] However, the present comparison

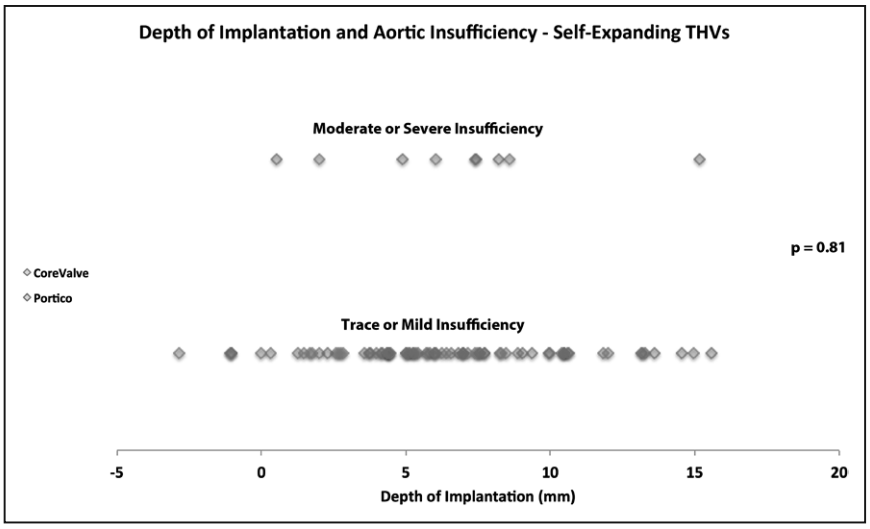

Figure 3. Depth of implantation and postimplantation aortic insufficiency. Note the comparable implantation depth distribution between the 2 transcatheter heart valves (THVs). Similar distribution is also noted among those with or without significant amount of postimplantation aortic insufficiency.

showed that CoreValve resulted in greater EOA, lower mean gradient, and lower rate of prosthesis–patient mismatch compared with Portico. Annular size is an important determinant of EOA.[22] Annular area in ViV interventions is determined by the space available within the failed surgical bioprosthesis, which can be further compromised by the implanted THV. At adequate implantation depth, CoreValve allows unconstrained leaflet function, which likely accounts for the differences in hemodynamic performance. The inclusion of many patients (nearly half) with smaller degenerated bioprosthesis (true ID < 21 mm) might have amplified the observed postimplantation hemodynamic finding, which is supported by the pronounced hemodynamic difference we observed between the THVs among smaller, compared with larger, surgical bioprosthesis subgroups.

Portico was associated with significantly higher rate of postimplantation AI, predominantly paravalvular compared with the CoreValve, a finding that was confirmed by independent blinded analysis (Figure 4). AI post–ViV implantation is uncommon and may be related to clinical or technical factors. There were no differences in the surgical valve size, internal diameter, or the mode of degeneration between the 2 THV groups, and the rate of postdilatation was comparable. In addition, no major disparity in THV implantation depth was found between the 2 platforms (Figure 3). The possibility of surgical paravalvular leaks was considered and only suspected in 2 cases (1 Portico and 1 CoreValve). Variation in THV frame's cell size and its impact on radial strength cannot be excluded as a potential reason for the observed findings. In addition to THV design, including the leaflet location in relation to the aortic annulus, other factors with mechanisms that we may or may not currently understand should be considered. For instance, it is important to note that THVs larger than 23 mm were used more frequently among the CoreValve patients compared with the Portico group, 54% versus 24%, respectively. It is possible that the manufacturer's sizing recommendations for the Portico are suboptimal and might have contributed to the postimplantation hemodynamic differences, although unlikely to be the sole explanation. Optimal THV sizing for ViV implantation is not well established, and the effect of THV oversizing within a rigid confined space is not necessarily beneficial and can be detrimental.[22] Despite our careful matching here accounting for the surgical bioprosthesis true ID, baseline difference in THV sizes was unavoidable because of the different manufacturers recommendations and the different label sizing between the 2 platforms (26, 29, and 31 mm for CoreValve and 25, 27, and 29 mm for Portico).

Thirty-day outcomes were similar, but 1-year mortality was higher in the Portico compared with the CoreValve-treated patients. The exact mechanism of higher 1-year mortality in Portico is unclear. Postimplantation AI is an important determinant of long-term mortality after transcatheter native aortic valve therapy.[23,24] Despite the higher postimplantation AI among the Portico, this group had a comparable 1-year survival to the remaining cohort, which has multiple explanations. First, the study was not powered for mortality particularly in smaller subgroups. Second, unlike patients undergoing transcatheter aortic valve implantation, significant AI at baseline is frequently encountered among ViV implantation candidates.[2] In fact, two thirds in each THV group in our analysis had ≥moderate AI at baseline as mode of degeneration. This might have served to attenuate the hemodynamic impact of postimplantation AI and alter its prognostic implications. The latter is theoretical at this stage and requires further evaluation. Predilatation, a potential confounder,[25] was more frequent in the Portico group, but its relation to long-term outcomes post–ViV implantation is unknown. Premature THV degeneration or thrombosis could not be assessed, and their contribution to the 1-year outcomes here cannot be excluded. Prosthesis–patient mismatch was significantly higher among Portico patients, which may adversely affect long-term outcomes after aortic valve replacement. However, the relationship between prosthesis–patient mismatch after THV implantation remains poorly understood.[12] It is important to note that the observed 1-year mortality rate for the CoreValve patients in the present study was similar to early experience with CoreValve ViV implantation.[2,17,26] Although death reported here was mostly attributed to noncardiac causes, this has to be taken with caution given the lack of clinical outcomes adjudication.

Implanting operators in each cohort had comparable well-established experience. Operators experience includes the expertise in transcatheter ViV implantation (transcatheter ViV experience) and the familiarity with a specific THV (THV

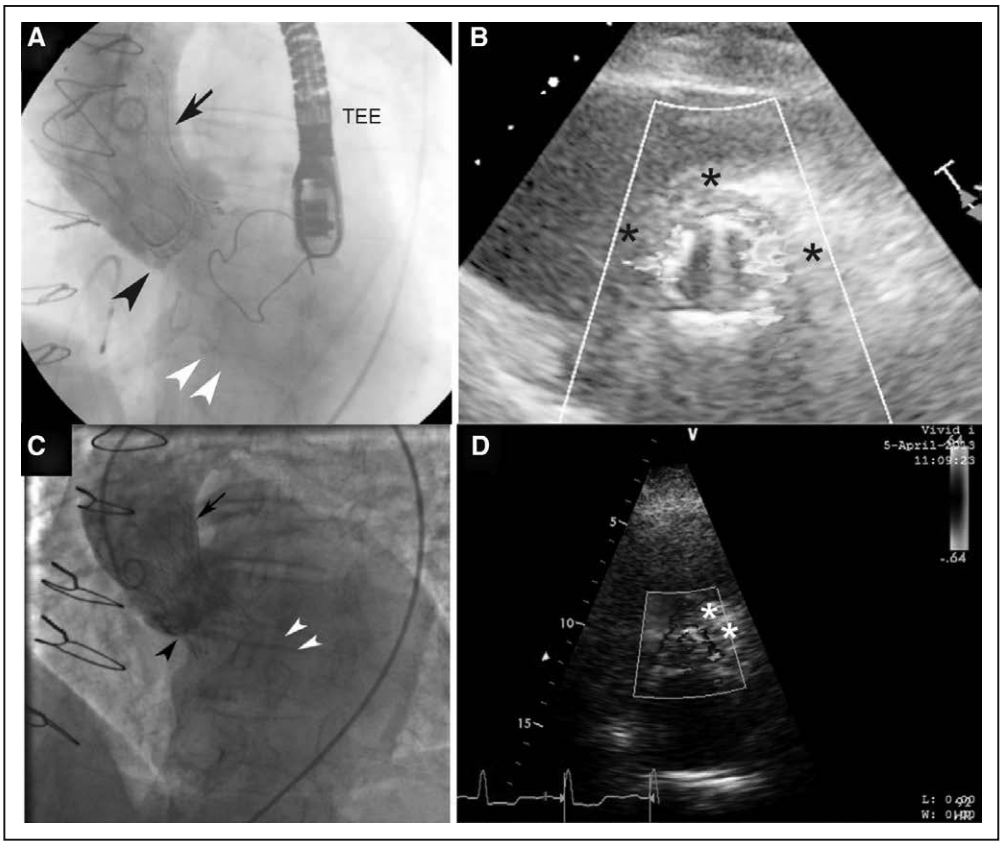

Figure 4. Aortic insufficiency after Portico for ViV procedure. **A**, Portico (black arrow) implanted for a failed Carpentier Edwards bioprosthetic valve (black arrowhead) under transesophageal echo (TEE) guidance. **B**, Severe aortic insufficiency evident on aortic angiogram (white arrowheads) that was paravalvular in location by echocardiography (asterisks). **C**, Portico (black arrow) implanted for a failed St. Jude Toronto stentless porcine bioprosthetic valve (black arrowhead). **D**, Moderate aortic insufficiency evident on aortic angiogram (white arrowheads) that was paravalvular in location by echocardiography (asterisks).

experience). Although the THV experience with Portico was relatively less established than CoreValve given the temporal variation in market's availability (more recent with former), it is clear that the Portico cohort had the advantage of evolved operators transcatheter ViV experience. Furthermore, we did not observe significant difference in procedural parameters such as THV embolization, second THV deployment, or vascular complications, indirect markers of operator experience. In addition, the 30-day outcomes were similar between the 2 THV groups, suggesting limited influence of operator and procedural factors on observed findings.

Limitations

Despite the inclusive multicenter nature of VIVID registry, reporting bias cannot be excluded. Clinical outcomes within the registry are self-reported by the enrolling center and not centrally adjudicated. In this analysis, however, mortality cases and related pathogenesis were individually verified with each center. Imaging-related outcomes such as aortic insufficiency or implantation depth were adjudicated independently. Even though the current analysis included a comprehensive matching of patient and surgical valve characteristics and core laboratory analysis of echocardiographic results, the presence of residual confounding despite propensity score matching cannot be excluded. Matching by country or center was initially considered but proved to be challenging as it had limited the matching pool and therefore the ability to account for other baseline characteristics. In addition, inclusion of early Portico experience in centers performing ViV implantation procedures is a potential confounder. Information on the frequency of THV repositioning/recapturing attempts was lacking, and the 1-year hemodynamic data were only partially available. A comparison among other repositionable THV platforms used in ViV implantation (Lotus, DirectFlow, and Evolut R) is needed to further understand relationship between THV selection and clinical outcomes.

Conclusions

In this first matched comparison of THVs for ViV interventions, Portico was associated with worse postprocedural hemodynamics compared with CoreValve. Clinical outcomes at 30 days were similar, but overall mortality at 1 year was higher in Portico compared with CoreValve patients. Although this can be related to THV design characteristics, the impact of other procedural factors cannot be excluded and requires further evaluation.

Disclosures

Dr Dvir reports consulting for Edwards Lifesciences and Medtronic. Dr Webb reports consulting for St. Jude Medical. Dr Sinning reports receiving speaker honoraria and research grants from Medtronic, Edwards Lifesciences, Direct Flow Medical, and Boston Scientific. Dr Barbanti reports consulting for Edwards Lifesciences. Dr Latib reports consulting for Medtronic and Direct Flow Medical. Dr Horlick reports consulting and program support from Edwards Lifesciences, Medtronic, and St.

Jude Medical, as well as program support from Gore. Dr Danenberg reports proctoring for Medtronic. Dr Hildick-Smith reports consulting for Boston Scientific, Medtronic, Edwards Lifesciences and St. Jude Medical. Dr Kim reports proctoring and consulting for St. Jude Medical. Dr Linke reports honoraria from Symetis, St. Jude Medical, Edwards Lifesciences and Boston Scientific, as well as ownership of stock in Claret Medical and consutling services for Medtronic. Dr Manoharan reports consulting for Medtronic, St. Jude Medical and Boston Scientific. Dr van Mieghem reports a research grant from Medtronic and participation in the steering committee of that same company. Dr Wijeysundera reports research grants from Edwards Lifesciences and Medtronic. The other authors report no conflicts.

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