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ORIGINAL ARTICLE

Transcatheter Aortic Valve Replacement With the HLT Meridian Valve

Results of the RADIANT Trial

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BACKGROUND: While most self-expanding transcatheter valves are repositionable, only one fully retrievable valve is currently available. The Meridian valve is a new self-expanding valve with full retrievability properties. The objective of our study was to evaluate the early feasibility, preliminary safety, and efficacy of transcatheter aortic valve replacement with the HLT Meridian valve (HLT, Inc).

METHODS: This was a multicenter early feasibility study including patients with severe aortic stenosis at high surgical risk undergoing transfemoral transcatheter aortic valve replacement with the 25-mm Meridian valve. All serious adverse events were adjudicated by an independent clinical events committee according to Valve Academic Research Consortium-2 criteria. Echocardiography data were assessed by an independent echocardiography core laboratory.

RESULTS: A total of 25 patients (mean age, 85±6 years; 80% of men) were included. The valve was successfully implanted in 22 (88%) patients (annulus too large and extreme horizontal aorta in 2 and 1 unsuccessful cases, respectively). Valve retrieval because of an initial nonadequate positioning was attempted and successfully performed in 10 (40%) patients. Echocardiography post-transcatheter aortic valve replacement showed a low mean residual gradient (10±4 mm Hg) and the absence of moderate-severe aortic regurgitation (none-trace and mild aortic regurgitation in 76% and 24% of patients, respectively). Mortality at 30 days was 8%, with no cases of disabling stroke, valve embolization, or major/life-threatening bleeding complications. At 6-month follow-up, the cumulative mortality rate was 12%, with no changes in echocardiographic parameters and no cases of valve dysfunction. The majority of patients (89%) were in New York Heart Association class I-II at 6 months.

CONCLUSIONS: Transcatheter aortic valve replacement with the Meridian valve was feasible and associated with acceptable early and 6-month clinical results. Valve retrieval after full valve deployment was successfully performed in all attempted cases, and valve performance was excellent, with low residual gradients, no cases of moderate-severe aortic regurgitation, and none-trace residual aortic regurgitation in the majority of patients.

CLINICAL TRIAL REGISTRATION: URL: https://www.clinicaltrials.gov. Unique identifier: NCT02838680 (RADIANT-Canada); NCT02799823 (RADIANT-US).

VISUAL OVERVIEW: A visual overview is available for this article.

Key Words: aorta ■ aortic valve stenosis ■ humans ■ transcatheter aortic valve replacement

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WHAT IS KNOWN

- While most current self-expanding transcatheter valve systems are repositionable and partially retrievable, there is only one system with full retrievability capabilities currently available.

WHAT THE STUDY ADDS

- This study showed the feasibility of transcatheter aortic valve replacement with a new full retrievable transcatheter valve system (Meridian valve).
- Full valve retrieval was successfully performed in all attempted cases, and valve performance was excellent, with no cases of moderate-severe aortic regurgitation.
- The possibility to assess valve performance and potential interaction with coronary ostia before final valve release may be important in the future, particularly in low-risk patients where open heart surgery would be an option in case of suboptimal valve performance.

Transcatheter aortic valve replacement (TAVR) is a well-recognized therapy for the treatment of patients with severe aortic stenosis at intermediate to prohibitive surgical risk.[1] The progressive expansion of TAVR in recent years has occurred in parallel with iterations of transcatheter valve and delivery systems and has translated into significant improvements in transcatheter valve positioning, valve performance, and overall TAVR results.[1,2] However, while most current self-expanding transcatheter valve systems are repositionable and partially retrievable, there is only one system with full retrievability capabilities currently available (Lotus Edge; Boston Scientific, Boston, MA).[2,3] As such, there is limited availability regarding the possibility for a transcatheter valve to be evaluated (final positioning, valve performance, potential interaction with coronary arteries) in its final position and full expansion before final release. Thus, both final frame expansion and potential movements of the valve system at the time of final release may result in changes in final positioning (from minor displacement up to valve embolization), valve performance (leaks), or coronary artery obstruction.

The HLT Meridian valve (HLT, Inc, Minneapolis, MN) is a novel self-expanding transcatheter valve system that can be fully expanded and implanted in its final position and subsequently retrieved if needed. This would allow for an accurate assessment of valve positioning and performance in addition to any interaction with coronary arteries before final release, knowing that the position and shape of the valve will not change after final release. The objective of this study was to evaluate the early feasibility of TAVR with the Meridian valve in patients with severe aortic stenosis at high surgical risk.

METHODS

The RADIANT trial (Transfemoral Replacement of Aortic Valve With HLT Meridian Valve Early Feasibility Trial) was a multicenter early feasibility study that enrolled and treated 25 patients who had TAVR with the Meridian valve in 2 centers in Canada (RADIANT-Canada: NCT02838680) and 2 centers in the United States (RADIANT-US: NCT02799823) between December 2016 and March 2018. Patients included in the study had severe calcific aortic stenosis and were considered at high surgical risk (either determined by a Society of Thoracic Surgeons Predicted Risk of Mortality score ≥8% or heart team criteria). Patients with unicuspid or bicuspid valves, prior aortic valve surgery (valve in valve), and those with severe aortic, mitral, or tricuspid regurgitation were excluded. The study was approved by the Ethics Committee of each participating center, and all patients provided signed informed consent to be included of the study. The authors will make the data, methods used in the analysis, and materials used to conduct the research available to any researcher for purposes of reproducing the results or replicating the procedure.

HLT Meridian Valve

The Meridian valve consists of a self-expanding valve with 3 leaflets of porcine pericardium and a braided liner to reduce paravalvular leak (Figure 1). The valve leaflets are attached to a nitinol wireform that flexes with each closure to reduce leaflet stress at commissures. The only valve size available at the time of the study was the 25-mm valve, which was indicated for mean aortic annulus diameters ≥24 and ≤26 mm. The height of the support structure is 17 mm. The valve is implanted through transfemoral approach using an 18F (outside diameter) delivery system (Pathfinder II delivery system; Figure 1). The valve is attached to the delivery system with 3 lever wire connectors that ensure the possibility of valve retrieval after valve implantation. Valve deployment is performed using the deployment dial in 2 main steps (Figure 2). First, the support structure is unsheathed until ≈3/4 of the frame is formed. Full deployment of the valve is then achieved by inversion of the valve through a forward movement of the delivery system while continuously unsheathing the rest of the valve. After full valve deployment, the valve remains attached to the 3 lever wire connectors and can be retrieved if necessary. After verifying the appropriate valve position, valve performance, and lack of interference with surrounding structures (coronary arteries), the valve is released by detaching the 3 lever wire connectors. No rapid pacing is required for valve deployment.

Valve sizing was based on preprocedural aortic annulus measurements obtained by 3-dimensional computed tomography. The only valve size available for this study was 25 mm, and a mean annulus diameter between 24 and 26 mm was considered adequate.

Clinical and Echocardiography Data

All data (baseline, procedural, 30-day, follow-up) were collected prospectively in a dedicated database and systematically

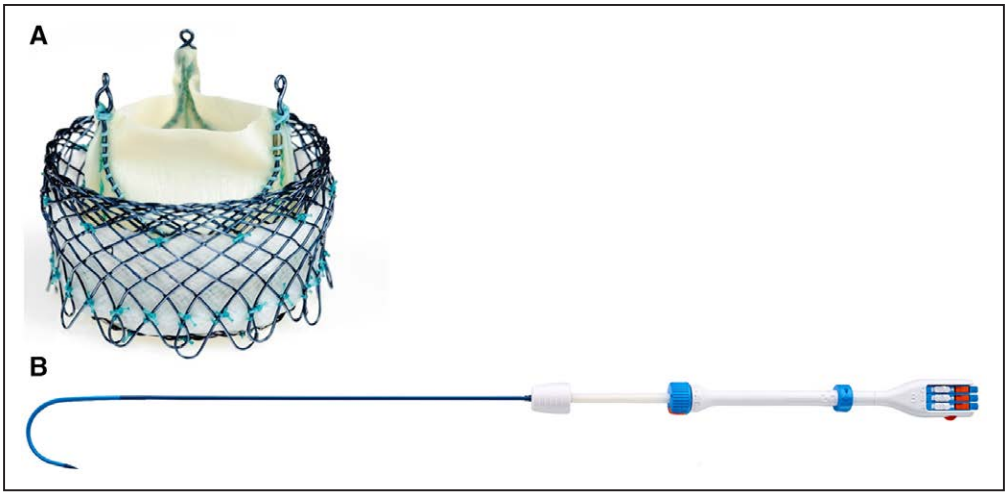

Figure 1. The HLT transcatheter aortic valve system.
A, The Meridian valve. **B**, The Pathfinder II delivery system.

monitored (external monitoring of all data was performed in all cases). Patients were followed at 30-day, 6-month, and 12-month follow-up and yearly thereafter ≤5 years. All events were classified according to Valve Academic Research Consortium-2 criteria[4] and adjudicated by an independent clinical events committee. Echocardiography examinations were performed at baseline, at hospital discharge, at 30-day, 6-month, and 12-month follow-up, and yearly thereafter up to 5 years. Echocardiography data were evaluated by an independent echocardiography core laboratory. The primary end point was all-cause mortality at 30-day follow-up. Secondary end points included successful valve implantation, device success, procedural and follow-up mortality, and valve performance acutely and at follow-up.

Statistical Analyses

Categorical variables are presented as n (%) and numerical variables as mean (SD) or median (25th–75th range) depending on variable distribution. Effective orifice area and mean aortic gradient were analyzed from baseline to 6 months using a generalized linear mixed model. Baseline, 1-month, and 6-month data were used as the factor levels of the fixed effect part of the model. Subject was used as the random effect in the model, and an unstructured (working) correlation matrix was used to account for any correlation between repeated assessments within a subject. Least square means were used to estimate the average at each visit, which were then compared in a pairwise fashion to discern where the differences existed. The paired comparisons were adjusted

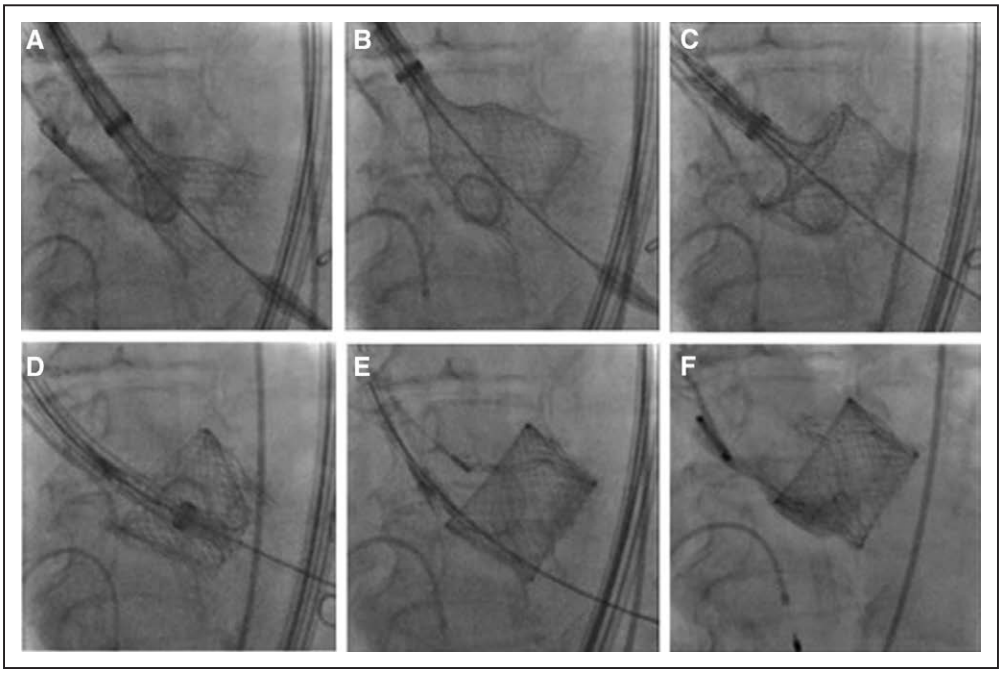

Figure 2. Fluoroscopic images of the Meridian valve deployment.
A, Initial deployment of the support structure. **B**, Support structure formed. **C**, Initial valve inversion. **D**, Valve inversion completed. **E**, Valve in final position, fully functioning. The valve is still attached to the 3 lever wire connectors and can be fully retrieved. **F**, Final valve release.

Table 1. Baseline Clinical Characteristics of the Study Population

Variable	n=25
Age, y	85±6
Women	5 (20)
NYHA	
II	9 (36)
III	16 (64)
COPD	3 (12)
Cerebrovascular disease	7 (28)
Coronary artery disease	18 (72)
Coronary artery bypass grafting	6 (24)
Renal insufficiency	9 (36)
Frailty	11 (44)
STS score, %	5.1±3.2
Echocardiography at baseline	
LVEF, %	58±13
Mean aortic gradient, mm Hg	34±8
EOA, cm^2	0.80±0.13

Data are presented as n (%) or mean±SD. COPD indicates chronic obstructive pulmonary disease; EOA, effective orifice area; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; and STS, Society of Thoracic Surgeons.

Table 2. Procedural Data and 30-Day Outcomes

Variable	n=25
Procedural characteristics	
Transfemoral approach	25 (100)
Conscious sedation	10 (40)
Pre-TAVR balloon dilation	8 (32)
Post-TAVR balloon dilation	11 (44)
Valve retrieval attempts	10 (40)
Successful valve retrieval attempts	10 (40)
Implant success	22 (88)
Valve embolization	0
Coronary obstruction	0
30-d results	
Mortality	2 (8)
Stroke	2 (8)
Disabling stroke	0
Nondisabling stroke	2 (8)
Life-threatening or disabling bleeding	0
Major vascular complications	0
Myocardial infarction	0
Pacemaker	5 (20)*
Echocardiography at 30 d	
LVEF, %	61±12
Mean aortic gradient, mm Hg	11±4
EOA, cm^2	1.64±0.34

Data are presented as n (%) or mean±SD. EOA indicates effective orifice area; LVEF, left ventricular ejection fraction; and TAVR, transcatheter aortic valve replacement.

*Fourteen percent (3/22) among those patients who finally received the Meridian valve.

using the Tukey-Kramer method to account for multiplicity in testing. Data were analyzed as intention to treat, except for echocardiography data and follow-up data, which included only those patients who were implanted with the Meridian valve. $P<0.05$ was considered significant. The analyses were performed with a SAS system 9.3 or higher.

RESULTS

The main baseline characteristics of the study population are shown in Table 1. Mean age of the patients was 85±6 years, 80% were men, and the mean Society of Thoracic Surgeons Predicted Risk of Mortality score was 5.1±3.2%.

The main procedural and 30-day results are shown in Table 2. All procedures were performed through transfemoral approach (40% under conscious sedation; full percutaneous vascular closure in 84%), and balloon valvuloplasty before valve implantation was used in a minority (36%) of cases. Initial valve deployment and implantation was successfully performed in all cases. However, initial valve positioning was not considered optimal in 40% of the patients (because of valve positioning too high or low), and valve retrieval was successfully performed in all cases without complications. Finally, the valve was implanted in a correct position in all patients but 3 (88%). In these 3 patients, the procedure was completed using another valve system (Sapien 3 in 2 cases; Evolut R in 1 case). Unsuccessful valve implantation was due to a valve sizing issue in 2 cases (annulus diameters in the upper range limit for the 25-mm Meridian valve) and an extreme horizontal aorta preventing correct positioning of the valve in 1 case. There were no cases of valve embolization, coronary obstruction, or procedural death. Echocardiography data post-TAVR showed a low mean residual gradient (10±4 mm Hg) and a large valve area (1.9±0.3 cm^2) along with the absence of moderate-severe aortic regurgitation (AR; none-trace, 76%; mild, 24%). The median hospital length of stay was 3 days (Q1–Q3 range, 1–6 days).

At 30-day follow-up, the rates of death and nondisabling stroke were 8% and 8%, respectively, with no cases of disabling stroke (Table 2). There were no cases of major vascular complications, bleeding, or myocardial infarction. Mortality at 30 days was due to 2 apparent sudden death episodes occurring 6 and 8 days after TAVR both due to suspected arrhythmic death. One patient developed new-onset left bundle branch block combined with first-degree atrioventricular block post-TAVR and had no permanent pacemaker implantation. This patient developed extreme bradycardia in hospital on day 6 while on telemetry and could not be

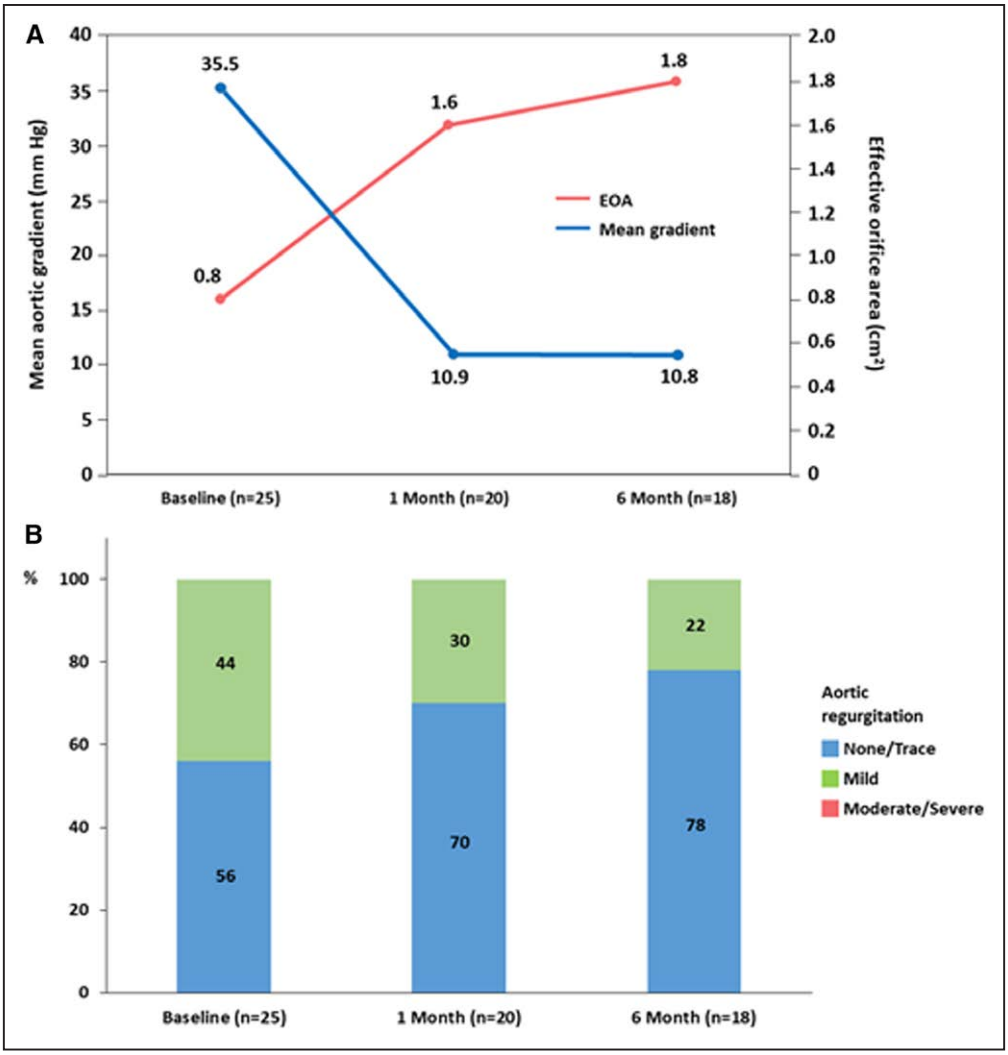

Figure 3. Echocardiography data at baseline, 30-d, and at 6-mo follow-up.
A, Mean transvalvular gradient and aortic valve area. *P*<0.001 between baseline and 30 d. *P*=NS between 30-d and 6-mo follow-up. **B**, The presence and severity of aortic regurgitation. EOA indicates effective orifice area.

resuscitated despite prompt cardiopulmonary resuscitation maneuvers. Autopsy confirmed appropriate position of the HLT valve, as well as absence of valve or coronary thrombosis. The second patient had preexisting sinus bradycardia, first-degree AV block, and left bundle branch block. He was discharged on day 2 and died in his sleep on day 8. The 2 stroke events occurred immediately after the procedure, one in a patient who required multiple valve retrieval attempts, and the other in a patient who had an optimal valve implantation at the first attempt. Permanent pacemaker implantation was required in 5 patients (20%), which included 2 patients who were converted to commercial valve implants. At 30-day follow-up, echocardiographic findings (Figure 3) showed a significant increase in effective orifice area and decrease in mean gradient versus baseline values (*P*<0.001 for both), and the majority of patients (80%) were in New York Heart Association class I-II (Figure 4).

Follow-Up

At 6-month follow-up, a total of 3 patients (12%) had died, with 1 additional death occurring beyond 30 days (Table 3). There were no episodes of late stroke, valve dysfunction, or embolization at follow-up. Most (89%) patients remained in New York Heart Association class I-II at 6 months (Figure 4).

Echocardiography data demonstrated lack of significant changes in valve performance over time, including transvalvular mean gradient (*P*=0.99) and effective orifice area (*P*=0.39), as well as the absence of moderate-severe residual AR (Figure 3).

DISCUSSION

The results of this early feasibility study suggest that TAVR with the Meridian valve was feasible and associated with acceptable early and 6-month clinical results.

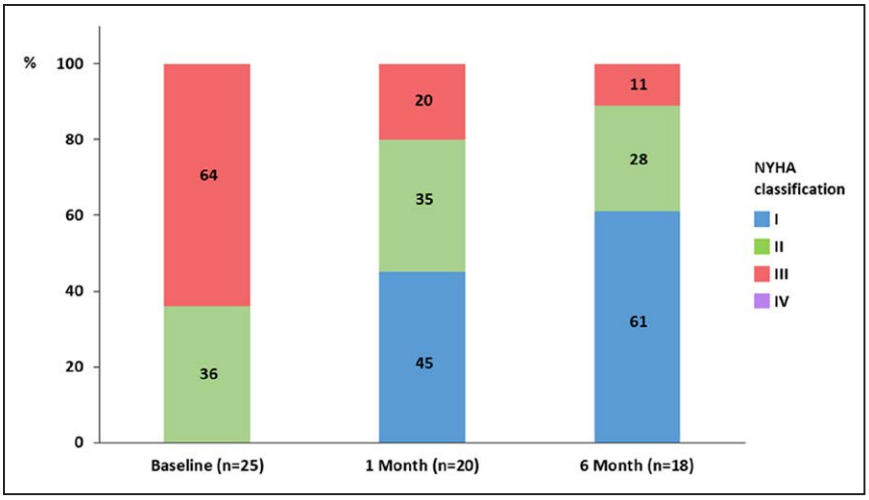

Figure 4. Changes in New York Heart Association (NYHA) class over time.

Valve retrieval after full valve deployment was successfully performed in all attempted cases, and valve performance appears to be excellent, with low residual gradients, none-trace residual AR in the majority of patients, and no cases of moderate-severe AR.

The procedural data from this initial experience with the Meridian valve provided novel and valuable information. First, the valve was successfully deployed in most cases, with no technical issues regarding the navigability of the delivery system or the unsheathing and valve inversion maneuvers to achieving final valve deployment. Second, valve retrieval after full valve deployment was successfully performed in all attempted cases, providing a high level of (in human) confidence regarding the retrievability properties of the system. Valve retrieval was performed in 40% of patients, mainly because of concerns about initial positioning of the valve. This was in large part related to the learning curve process, particularly with a self-expanding valve system that requires a 2-step process (initial support structure exposure followed by valve inversion) to achieve final valve deployment. One might expect less frequent valve retrieval over time, similar to the experience with a different retrievable valve (Lotus valve; Boston Scientific, Boston, MS), where a marked reduction in valve reposition and retrieval rates were observed after the initial clinical experience.[5,6] Also, the fact that only a single valve size was available in the present study represents an important limitation and may in large part explain the fact that a different and larger transcatheter valve system was finally implanted in 3 (12%) cases. Inexperience regarding optimal valve sizing and degree of oversizing (mean diameter ≤26 mm was allowed in this study for the 25-mm valve) may have also contributed. Finally, it is important to note that no cases of valve embolization or mortality during the implant occurred in this study despite the first clinical experience with a new valve system. Also, coronary permeability was evaluated in all cases before final valve release, and no cases of acute coronary obstruction were observed.

The 30-day mortality rate of 8% appears higher than that reported in other studies including patients considered at intermediate-to-high surgical risk.[1,2,7] Although the mean Society of Thoracic Surgeons Predicted Risk of Mortality score of our study population was just above 5%, all patients had been considered at high risk by the Heart Team and were older than those included in most previous studies. Also, preprocedural frailty was common (44%) and likely contributed to high surgical risk despite a mean Society of Thoracic Surgeons Predicted Risk of Mortality score <8%. Frailty has been identified as a major risk factor for early and late mortality after TAVR.[8] Finally, the fact that the 2 deaths to 30 days were sudden and likely arrhythmic in origin merits further discussion. Both patients had left bundle branch block and first-degree atrioventricular block, which is a recognized risk factor for high-degree atrioventricular block and cardiovascular death in some studies.[9–11] Also, recent data from the MARE study (Ambulatory Electrocardiographic Monitoring for the Detection of High-Degree Atrio-Ventricular Block in Patients With New-Onset Persistent Left Bundle Branch Block After

Table 3. Late Safety Events (>30 Days; 6-Month Follow-Up)

Event	n=20
All-cause mortality	1 (5)
All stroke	0
Life-threatening or disabling bleeding	0
Embolization or migration	0
Endocarditis	1 (5)
Myocardial infarction	0
Valve thrombosis	0
New permanent pacemaker	1 (5)
Rehospitalization for heart failure	3 (15)

Data are presented as n (%).

Transcatheter Aortic Valve Implantation) using implantable loop recorders in patients with left bundle branch block post-TAVR showed a high rate of life-threatening bradyarrhythmias in these patients, particularly within the weeks after the procedure.[12] Finally, the learning curve process associated with the initial experience with a new valve system may have partially contributed to the relatively high early mortality rate.

Of note, the rate of conduction disturbances requiring pacemaker implantation with the Meridian valve in the present experience appears similar to that reported with other self-expanding valves.[13] Mounting evidence suggests that the occurrence of high-degree heart block and the need for a new pacemaker is strongly associated with the depth of implantation in relationship to the membranous septum.[13,14] With increasing experience with the Meridian valve, and especially because of the ability to reposition the valve, operators will likely be able to place the valve at predetermined depth levels and potentially decrease the occurrence of heart block. However, the potential for different progression-regression of conduction disturbances due to changes in the mechanical forces of the support structure specific to this valve should be further evaluated. Definitive conclusions are limited by small sample size, and further studies are needed.

Finally, while the overall stroke rate (8%) appears somewhat higher than reported in other studies,[1,2,15] the lack of disabling strokes compares favorably with most prior studies. The learning curve, and particularly the relatively high rate of valve retrieval attempts, may have contributed to increase the risk of periprocedural stroke. Importantly, no additional stroke events were observed beyond 30 days, suggesting a good safety profile during the follow-up period.

Echocardiographic valve performance, with low transvalvular gradients and low rates of residual AR (as evaluated by an independent echo core laboratory), appears similar if not better than reported for other newer transcatheter valve systems,[2,16] and no valve dysfunction or early valve degeneration was observed ≤6-month follow-up. In addition, the Meridian valve system incorporates a unique feature of flexible nitinol wires at the level of the valve leaflets to reduce valve leaflet stress and thus valve leaflet fatigue over time. Future studies with a longer term echocardiography follow-up are needed to determine whether these iterations may translate into improved valve durability.

Study Limitations

This study represented the initial experience with a new transcatheter valve system, and the number of patients included was limited. No computed tomography or transesophageal echocardiography studies were performed to detect subclinical valve thrombosis.

Following this initial experience, a multicenter, international Conformité Eurpéene (CE) mark trial including 200 patients with severe aortic stenosis at intermediate or high surgical risk is planned to initiate during the second half of 2019 and should be followed by a pivotal US FDA IDE trial (United States Food and Drug Administration - Investigational Device Exemption). In addition, several iterations of the Meridian valve system are being undertaken and will incorporate (1) improved valve inversion properties to facilitate valve positioning and reduce valve retrieval attempts, (2) a pericardial sealing liner to further reduce paravalvular leak, (3) a modified leaflet attachment to reduce stress at commissures, and (4) a specific (Trivent) anticalcification treatment to enhance valve durability. Further, an expanded valve size range (24, 26, and 28 mm) is planned. These valve iterations along with the increasing experience of operators/centers should translate into further improvement in clinical and echocardiographic results.

ARTICLE INFORMATION

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Disclosures

Dr Rodés-Cabau is consultant and proctor for HLT, Inc. Dr Kereiakes is a consultant for HLT, Inc, Boston Scientific Corp and Abbott Vascular, Inc. Drs Wilson and Kubo are employees of HLT, Inc. The other authors report no conflicts.

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