One-Year Outcomes with a Self-Expanding, Repositionable Transcatheter Heart Valve in Severe Aortic Stenosis Patients: PORTICO-I

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ABSTRACT
Background: The new self-expanding, repositionable transcatheter heart valve (THV) system was designed for treatment of severe, symptomatic aortic stenosis in patients with high surgical risk.
Objectives: To report 1-year outcomes of transcatheter aortic valve replacement (TAVR) with new THV system.
Methods: This ongoing, international, multicenter study evaluated patients with severe, symptomatic aortic stenosis implanted with the THV via transfemoral access and follow-up at 30 days, 1 year and annually through 5 years. The primary endpoint is all-cause mortality at 1 year; secondary endpoints include clinical outcomes and echocardiographic measurements, both adjudicated.
Results: A total of 941 patients (82.4 ± 5.9 years, 65.7% female, STS score: 5.8%) were enrolled and underwent an implant at 61 sites in Europe, Australia and Canada. At 1 year, Kaplan-Meier estimates for all-cause mortality, cardiovascular mortality, disabling stroke rates and myocardial infarction are 12.1%, 6.6%, 2.2% and 2.5%, respectively. Mean aortic transvalvular gradient and aortic valve area were 8.66mmHg and 1.75cm^2 respectively. Paravalvular leakage was moderate or higher in 2.6% of patients with no severe leakage. New pacemaker rates were 18.7% and 21.3% for pacemaker naïve patients at 30 days and 1 year, respectively. Functional class, exercise capacity and quality of life improved significantly from baseline to 1 year.
Conclusion: Transcatheter aortic valve replacement with the new THV in patients at increased surgical risk is associated with low 1-year mortality and stroke rates. Favorable hemodynamic results at 1 year are observed with low transvalvular pressure gradient and incidence of significant PVL.

KEY WORDS: Clinical research**,** Degenerative valve**,** Aortic stenosis**,** TAVR

Clinical Trial Registration Number: NCT01802788

CONDENSED ABSTRACT
Outcomes at 1 year are reported from on ongoing study using the new THV system for treatment of severe, symptomatic aortic stenosis. A total of 941 patients (82.4±5.9 years, STS score: 5.8%±4.8%) were enrolled. Kaplan-Meier estimates for all-cause mortality, cardiovascular mortality, disabling stroke rates and myocardial infarction at 1 year are 12.1%, 6.6%, 2.2% and 2.5%, respectively. Significant improvements in valve area and transvalvular pressure gradient remained stable through 1 year. Moderate or higher PVL was present in 2.6% of patients. The new THV system remains safe and effective at 1 year in patients at increased surgical risk.

ABBREVIATIONS
AKI: acute kidney injury
AS: aortic stenosis
CEC: clinical event committee
EuroSCORE: European System for Cardiac Operative Risk Evaluation
NYHA: New York Heart Association
PVL: Paravalvular Leakage
STS or STS PROM: Society of Thoracic Surgeons Predicted Risk of Operative Mortality score
TAVR: transcatheter aortic valve replacement
THV: transcatheter heart valve

VARC: Valve Academic Research Consortium

INTRODUCTION

Safety and efficacy outcomes of transcatheter aortic valve replacement (TAVR) using the new self-expanding, repositionable transcatheter heart valve (THV) system (Figure 1) for treatment of severe, symptomatic aortic stenosis (AS) have been reported from relatively small studies and over limited follow-up periods [1,2,3]. The PORTICO I study was initiated to collect comprehensive long-term, real-world experience from implanters' early commercial experience with this device. This ongoing multicenter study enrolled a large population of patients at increased risk of surgical mortality and will follow this cohort ≤5 years after valve implantation. Favorable 30-day safety and efficacy outcomes of this cohort has been reported [4]. This manuscript reports on the primary study endpoint of 1-year all-cause mortality and provides 1-year secondary endpoint results on safety events, valve hemodynamic performance and characterizes the clinical benefit of receiving a new THV system.

METHODS

Study design

The prospective, single-arm, non-randomized, multicenter PORTICO I study was conducted to assess acute and long-term clinical outcomes of the new self-expanding, repositionable Portico THV system (Abbott, Plymouth, Minnesota) for the treatment of severe, symptomatic AS. The design of the study and procedural aspects have been described in detail elsewhere [4]. In brief, the study included patients with symptomatic, severe AS that were evaluated by the Heart Team and deemed to have high surgical risk according the Society of Thoracic Surgeons Predicted Risk of Operative Mortality (STS) score, logistic European System for Cardiac Operative Risk Evaluation score (logistic EUROScore), or other individual risk factors such as frailty and comorbidities not captured by the risk scores. All patients underwent transfemoral TAVR using

the THV system [5]. The appropriate valve size was selected from the 4 available sizes (23, 25, 27 and 29 mm sizes) covering an aortic annulus diameter between 19 and 27 mm based on preprocedural multi-slice computed tomography (CT). It was recommended to perform balloon pre-dilatation, after which the valve could be deployed without rapid pacing. The valve could be re-sheathed and repositioned if indicated. Post-dilatation under rapid pacing was allowed to improve sealing and full device expansion if deemed necessary by the operator.

Postprocedural antithrombotic protocol was at the physician's discretion. Follow-ups are scheduled at 30-days, 1-year and annually through 5-years post-implant. This paper reports the primary and secondary outcomes of PORTICO I patients through 1-year.

The study was conducted in compliance with the Declaration of Helsinki and approved by ethics committees and local authorities. All patients provided written informed consent prior to participation. This study was sponsored by Abbott (formerly St. Jude Medical).

Endpoints

The primary endpoint of the study was all-cause mortality at 1 year. Secondary clinical endpoints assessed at 1 year included cardiovascular mortality, myocardial infarction, stroke, THV function, functional classification, 6-minute walk test and Quality of Life assessment. An independent clinical events committee (CEC) adjudicated all safety endpoints according to VARC-2 consensus [6]. Valve hemodynamics were assessed by transthoracic echocardiography at baseline and at subsequent follow-ups. The 30-day and 1-year results were evaluated by an independent core laboratory (MedStar Health Research Institute, Washington DC, USA).

Statistical analysis

Continuous variables were summarized by mean ± standard deviation (SD) or median and interquartile range. Categorical variables were summarized using frequencies and percentages.

Paired Student t tests (e.g. echocardiographic data, 6-min walk test, etc.) and the Wilcoxon sign rank test (e.g. NYHA functional class) were used to compare outcomes at follow-up relative to baseline. Time to event variables were analyzed using Kaplan–Meier method and Cox proportional hazard model. The 1 year Kaplan-Meier survival analyses used 36 5 days as a strict cut-off. For example, the patients that had a 1-year follow-up visit conducted on or before 365 days are not considered at risk at 1 year.

A 30-day landmark analysis for selected safety outcomes was performed by calculating Kaplan-Meier estimates over the period from day 31 to 1year post-TAVR, excluding patients who experienced the safety event within the first 30 days.

Cox proportional hazard regression modeling was used to identify variables associated with 1-year mortality. Baseline, procedural and limited event variables were included. Variables with univariate p-values < 0.2 were subsequently included in multivariable analysis. Statistical significance was indicated by a p-value <0.05. All statistical analyses were performed using SAS v9.4 (SAS Institute, Cary, North Carolina).

RESULTS

Procedural Results

TAVR was attempted in 941 patients (age at implant: 82.4 ± 5.9 years, 65.7% female, STS score: 5.8 ± 4.8%). Approximately one-third of patients (33.7%) also had two frailty indexes. Demographics and baseline characteristics are presented in Table 1. Procedural data are summarized in Table 2. Thirty-day outcomes of this cohort have been previously reported in detail [4] and are therefore only briefly summarized as follows. A single self-expanding, repositionable THV was successfully implanted in 903 of 941 patients (96.0%) while 2 valves were implanted in 19 patients (2.0%). In the remaining 19 patients (2.0%) no HV was implanted,

due to implantation of another commercial TAVR device (n=12, 1.3%), conversion to surgery (n=4, 0.4%) and procedural death (n=3, 0.3%). The reasons for implanting another commercial valve include: a second THV was required to reduce PVL, unstable or migrated self-expanding, repositionable THV, Portico mal-positioned, and annulus size not suitable for the patient. The 19 patients in which a THV was attempted but not implanted were monitored for adverse events through 30-day post-TAVR and then withdrawn. In the PORTICO I study there was no screening committee. The selection of the patients and the annulus sizing was left to the standard of care at each institution. All sites were trained on the PORTICO I inclusion and exclusion criteria and adherence to the criteria was monitored. Thirty-day and 1-year assessments were completed for 828 and 717 patients, respectively representing follow-up visits on more that 92% of active patients at each visit (Figure 2). At 1 year, there were 585 patients with echocardiographic assessments deemed suitable for evaluation by the core lab.

Safety outcomes

Adverse events rates at 30 days and at 1 year after TAVR are shown in Table 3. KM event rates for all-cause mortality and cardiovascular death at 30 days were 2.7% (95% CI: 1.8%,3.9%) and 2.5% (95% CI: 1.6%-3.7%), respectively. At 1 year these were 12.1% (95% CI: 10.1%-14.5%) and 6.6% (95% CI: 5.1%-8.4%), respectively (Central Illustration A).

Table 4 shows a 30-day landmark analysis conducted to further examine the safety rates solely after the peri-procedural period (i.e. from 31 to 365 days). For this latter period the KM event rates were 9.7% (95% CI: 7.9%-11.8%) and 4.2% (95% CI: 3.0%-5.8%) for respectively all-cause and cardiovascular mortality.

In total, 108 deaths were reported during the first year (cut-off at 365 days) after TAVR; of which, 58 were classified as cardiovascular deaths. The most common cause of

cardiovascular deaths within the first 30 days were procedural complications (n=13). After 30 days, the most common causes of cardiovascular death were sudden cardiac death SCD (n=11) and heart failure (n=10) (Table 5).

Within the first year after TAVR disabling strokes occurred in 20 patients, resulting in a Kaplan-Meier 1-year estimate of 2.2% (95% CI: 1.4%-3.4%). Through 1 year, 25 patients experienced an MI, resulting in a Kaplan-Meier estimate of 2.5% (95% CI: 1.7%-3.8%). Most cases of disabling stroke or myocardial infarction occurred within the first month after the index procedure, in 15 and 16 patients respectively.

Minor increases in other events rates (e.g. AKI, bleeding, new-onset AF and pacemaker implantation) occurred between 30 days and 1 year. Among patients with no pacemaker at baseline, a pacemaker was implanted in 18.7% (n=161) at 30 days, and in 21.3% (n=178) at 1 year after TAVR.

Table 4 further shows the risk for a disabling stroke rate of 0.6%, an acute MI rate of 0.9% and pacemaker implantation rate of 2.8% in the period after 30 days up to 1 year.
Five patients needed reintervention due to worsening of PVL severity. All of these had been prepared with a pre-BAV during their initial implant. One patient had their self-expanding, repositionable THV system replaced with a surgically implanted valve at 29 days post implant, a VinV procedure was performed in 3 pts (at 15, 83 and 256 days post procedure) and one patient (in whom post-dilatation was not performed during implant) required a post BAV 160 days later. All treatments were successful.

After implant, there have been no reports of infective endocarditis, coronary occlusion, valve thrombosis nor of structural valve failure that needed intervention through 1 year.

Predictors of all-cause mortality

Multivariate analysis identified pre-existing kidney disease, heart failure, history of MI, mitral regurgitation, NYHA class IV and length of hospitalization after the index procedure as independent predictors of 1-year mortality (Table S1). Implantation of a pacemaker within 30 days post-TAVR had no effect on 1-year all-cause mortality (p=3) (Figure 3). Moderate or higher PVL at discharge is not associated with a higher mortality risk at 1 year (p=0.5186).

Valve hemodynamics

Echocardiographic assessments of valve hemodynamics are summarized in Figure 4 (valve area, mean transvalvular gradient, unpaired data) and Figure 5 (PVL, unpaired data). Hemodynamic outcomes for patients with data available at all data points through 1 year are reported in the paired analysis (Central Illustration B, C). In the paired analysis, TAVR was associated with a significant increase in valve area at 30 days over baseline (0.72 ± 0.37 cm^2 to 1.79 ± 0.48 cm^2, $p < 0.0001$) which remained stable through 1 year (1.74 ± 0.49 cm^2, $p = 0.058$) (Central Illustration B). Similarly, the mean aortic transvalvular gradient significantly decreased from 49.73 ± 15.80 mmHg at baseline to 8.60 ± 3.80 mmHg at 30 days ($p < 0.0001$) and remained stable through 1 year (8.75 ± 4.22 mmHg, $p = 0.325$). Moderate or higher PVL was present in 2.6% of the patients at 1-year post-TAVR, with no severe PVL (Central Illustration C). The paired PVL analysis (n = 524) (Table 6) shows that the majority of patients with mild PVL at 30 days remained mild at 1 year (287/358, 80.2%), 64 (17.9%) improved from mild to none/trace, and 7 (1.9%) patients changed from mild to moderate between 30 days and 1 year.

Functional assessments

Compared to baseline, the study cohort showed an overall improvement in NYHA functional class at 30 days post-TAVR. The improvement was sustained through the 1-year assessment ((number of patients per follow-up).

Figure 6). The signed rank test (p-value <0.0001), shows a significant improvement in NYHA functional class at 1 year compared to baseline in the paired NYHA analysis (Central Illustration D). Compared to baseline, the 6-minute walk test improved significantly at 1 year (250.3 ± 117.0 m vs. 285.9 ± 112.2; p<0.0001). Similar improvements were also seen in QoL EQ-VAS at 1 year (62.2 vs 69.0 p<0.0001).

DISCUSSION

With 941 attempted patients, the present study comprises the largest 1-year multicenter data set from a cohort implanted with the self-expanding, repositionable THV. Overall, the study outcomes confirm the high safety, hemodynamic performance and clinical improvement provided by the THV system at 1 year. Specifically, a low mortality and disabling stroke rate given the higher risk patients enrolled, low and stable transvalvular pressure gradients and low rate of more than mild significant PVL through 1 year.

Early safety

Procedural mortality (0.3%), and 30-day rates of all-cause mortality (2.7%) and disabling stroke (1.6%) were relatively low and similar to outcomes reported from other TAVR cohorts implanted with the self-expanding, repositionable valve [1,2] or other contemporary transcatheter aortic valves [7,8,9,12].

1-year outcomes

In this study, TAVR with the self-expanding, repositionable valve was associated with low 1-year all-cause and cardiovascular mortality rates of 12.1% and 6.6%, respectively. These rates

compare well with those reported from smaller series with the self-expanding, repositionable valve [1,3] and larger studies with the CoreValve and Sapien 3 THV systems in comparable cohorts [7,10,11,12].

Only few additional safety events occurred between 30 days and 1-year post-TAVR, as demonstrated in the landmark analysis set at 30 days. In this analysis, the probability for all-cause mortality between 30 days and 1 year is 9.7%, for cardiovascular death 4.2%, for disabling stroke 0.6%, for AMI 0.9% and for new pacemaker implant 2.8%. With events occurring in only 5 patients after the 30-day post-procedural period, a relatively low rate (2.2%) of disabling stroke at 1 year was achieved. Stroke rates were similar to outcomes reported from the SURTAVI [7], SOURCE 3 [13] and SAVI-TF [14] studies, with similar overall risk scores. After the post-procedural period, 9.7% of the patients died, mainly SCD and deaths due to heart failure. While the univariate analysis identified multiple predictors of mortality at 1 year, the multivariate analysis confirmed 6 independent predictors; 5 of which are baseline risk factors common in the high surgical risk population and the 6th being a longer hospitalization period following the index procedure. Many of these associations are consistent with those, reported from other studies [13].

TAVR with self-expanding, repositionable THV system was associated with functional improvement at 30 days, with 87% of the patients in NYHA class I/II vs. 36% at baseline. This improvement was sustained through 1 year.

At 1 year post-TAVR, 21.3% of pacemaker naïve patients at baseline had received a new pacemaker, the vast majority of these being implanted by 30 days. This rate is higher than reported previously from other studies with the Portico valve [1,3] and similar to the 1-year new pacemaker implant of 19.7% for Evolut R (Medtronic, Dublin, Ireland) in 1,040 patients with median STS score of 5.5% [12]. This study previously confirmed that preexisting conduction

disturbances at baseline, RBBB and AV block I/II and QRS >120ms are significant predictors for pacemaker implantation post implant (4). A new pacemaker implant within 30 days had no effect on mortality at 1 year.

Valve hemodynamics

Significantly improved hemodynamic performance, as reported from this cohort at 30 days [4] was sustained through 1 year after TAVR. In particular, the valve achieved low transvalvular pressure gradients and the degree of PVL was remained stable from 30 days to 1 year post-TAVR, with no severe PVL at either assessment. The PVL status of 458 of the 524 (87.4%) patients with paired echo data, remained the same or improved between 30 days and 1 year. As suggested by other authors [10,15], improving PVL outcomes over time suggest remodeling of the interface between the aortic annulus and the self-expanding valve. These outcomes compare well with those from other balloon-expandable and self-expanding valves [7,11,15]. Aspects that may have promoted these favorable outcomes include accurate sizing using multi-slice CT, the re-sheathing and repositioning capability of the self-expanding, repositionable THV system, and that pre-dilatation, was performed in the majority of the procedures. Pre-dilatation is commonly used and not associated with further complications (13) but facilitates gradual and uniform valve deployment during implantation. While pre-dilatation has been suggested to affect the risk of early stroke [16], the frequent use of pre-dilatation in the present study does not allow testing of this relationship, since the self-expanding, repositionable THV achieved a relatively low rate of disabling stroke, both at 30 days and at 1-year post-TAVR. Finally, there was no evidence of moderate PVL impacting 1-year mortality in this cohort, although the low rate of clinical significant PVL in the present study did not allow to be fully evaluate this.

The predictor analysis showed that pre-existing comorbidities were the primary drivers for 1-year mortality. As expected, patients who are sicker at baseline have a higher risk of dying within 1 year. Interestingly, the only procedure related factor reaching a level of significance after the multivariate analysis was the days from implant to discharge.

Limitations

This study was conducted as a real-world post-approval study, involving non-randomized and possibly biased selection of patients to be treated with the self-expanding, repositionable TAVR system. Initial enrolment was relatively slow, due to only small valve sizes being commercially available. Data was obtained from centers with variable experience and patient load, providing a cross-section of centers performing TAVR and included the initial learning curve in most institutions.

Conclusions

The self-expanding, repositionable THV system is safe and significantly improves hemodynamic performance in patients suffering from severe, symptomatic AS. At 1 year after implant, relatively low mortality and stroke rates were observed, with single digit transvalvular gradients and a low degree of greater than mild PVL. Clinical benefit is also demonstrated through an observed improvement in functional class, exercise capacity and quality of life.

PERSPECTIVES

What is known? THV has been introduced to treat patients with aortic stenosis and increased surgical risk. The self-expanding repositionable THV is the first re-sheathable system. Previously reported pre-CE Mark studies established its safety and performance profile.

What is new? This is the first and largest, multicenter post-market study of the THV representing early commercial experience. This real-world study has confirmed the safety and efficacy of the pre-market studies.

What is expected? These results provide important information on the new THV and are expected to help clinicians understand the performance profile of the device which is similar to other current TAVR technologies.

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FIGURE LEGENDS

Central Illustration: The primary outcomes with the New Self-Expanding, Repositionable Transcatheter Heart Valve

A: Kaplan-Meier estimates of survival from all-cause and cardiovascular death.

B: Mean transvalvular gradient (n=489) and aortic valve area (n=356).

C: Paravalvular leak (n=524). D: NYHA functional class (n=673).

Outcomes shown in panels B, C and D represent paired analyses only including patients with data at all follow-ups.

AVA = aortic valve area; NYHA = New York Heart Association functional class; PVL = paravalvular leak.

Figure 1: The New Self-Expanding, Repositionable Transcatheter Heart Valve

Figure 2: Study flow-chart

Patient disposition through 1 year after TAVR for all patients who underwent an attempted implantation. A total of 717 1-year visits were documented of 755 patients eligible for follow-up.

Figure 3: Survival Versus Pacemaker Implantation

Kaplan-Meier survival analysis for patients with a pacemaker at baseline, patients who received a pacemaker within 30 days post-TAVR and patients with no pacemaker at all.

Figure 4: Mean transvalvular gradient and Aortic valve area (AVA) (unpaired analysis)

Echocardiographic assessment of mean transvalvular gradient and aortic valve area (AVA) including data from all assessed patients.

Figure 5: Paravalvular Leak (PVL) (unpaired analysis)

Echocardiographic assessment of paravalvular leak (PVL) (number of patients per follow-up).

Figure 6: NYHA functional class (unpaired analysis)

NYHA functional class of all assessed patients (number of patients per follow-up).

Table 1: Demographic and baseline data (including all patients with an implant attempt; n=941)

Age (years)	82.4±5.9
Female gender	65.7
Coronary artery disease	50.3
Previous CABG	9.9
Previous PCI	22.5
History of myocardial infarction	11.9
Prior atrial fibrillation	17.2
Left Bundle Branch Block	5.0
Right Bundle Branch Block	3.6
Heart Failure	13.3
NYHA class III/IV	63.8
Diabetes	29.6
Hypertension	80.7
Prior stroke	6.1
Prior TIA	6.4
Peripheral artery disease	6.3
Permanent pacemaker	8.5
Moderate/severe mitral regurgitation	25.2
Hematologic disorders	10.6
Liver disease / cirrhosis	2.9
Chronic kidney disease	30.2

Chronic lung disease	15.0
Anticoagulant use	28.7
Logistic EuroSCORE I (%)	15.7±11.3
STS Score (%)	5.8±4.8
Frailty indexes	
5 m walking time (sec)	8.1±7.6
Grip strength (kg)	24.15±13.7
Serum Albumin (g/dL)	4.00±2.4
Mini mental status score	26.9±3.4
Unintentional weight loss >5 kg	
within the last year	11.2
Left ventricular systolic dysfunction	20.5
Left ventricular ejection fraction	57.4±11.6
Mean aortic valve gradient (mmHg)	49.74±15.32
Aortic valve area (cm^2)	0.70±0.3

Data in percentages or mean ± standard deviation

CABG, coronary artery bypass surgery; PCI, percutaneous coronary intervention

Table 2: Procedural data (including all patients with an implant attempt; n=941)	
Implant success	98.0
Single successful THV valve	96.0
Anaesthesia	
Conscious sedation/Local	75.5
General	24.4
Valve size	
23 mm	5.4
25 mm	29.0
27 mm	34.4
29 mm	31.2
Need for second valve	2.0
Procedural Mortality	0.3
Conversion to AVR	0.4
Other TAVR valve	1.2
Pre-dilatation	88.9
Post dilatation	43.3
Valve re-sheathed	41.4
Total procedure time (min)	76.5±35.0
Fluoroscopy time (min)	20.4±10.0
Contrast volume (mL)	162.6±93.1

Data in percentages of all patients or in mean ± standard deviation

Table 3: Safety outcomes (including all patients with an implant attempt; n=941)

	30 days	1 year
All-cause mortality	2.7	12.1
Cardiovascular mortality	2.4	6.6
Stroke		
Disabling	1.6	2.2
Non-disabling	1.0	1.9
TIA	0.4	1.2
Myocardial infarction	1.6	2.5
AKI stage 2 or 3	3.0	4.2
Bleeding		
Life threatening	3.1	3.2
Major	8.5	8.7
Major vascular complication	5.5	5.7
New-onset atrial fibrillation	3.8	5.2
Overall pacemaker implantation*	17.1	19.5
New pacemaker implantation[§]	18.7	21.3

Data represents proportions at 30 days and Kaplan-Meier estimated event rates at 1 year (%).

*among patients regardless of pacemaker at baseline

[§]among patients without pacemaker at baseline.

Table 4: Landmark analysis of safety outcomes between 31 and 365 days (excludes patients with an event at 30 days; n=941) - % (n)

All-cause mortality	9.7 (82)
Cardiovascular mortality	4.2 (34)
Stroke	
Disabling	0.6 (5)
Non-disabling	0.9 (7)
TIA	0.7 (6)
Myocardial infarction	0.9 (9)
AKI stage 2 or 3	1.2 (10)
Bleeding	
Life threatening	0.1 (1)
Major	0.1 (1)
Major vascular complication	0.1 (1)
New-onset atrial fibrillation	1.4 (13)
Overall pacemaker implantation*	2.5 (17)
New pacemaker implantation[§]	2.8 (17)

*Among patients regardless of pacemaker at baseline

[§]Among patients without a pacemaker at baseline

Table 5: Causes of cardiovascular death over time – n/N (%)

	30 days	31 days - 1 year	Total to 1 year
Cardiovascular deaths	**23/58 (39.7)**	**35/58 (60.3)**	**58/58 (100)**
Main causes of cardiovascular death			
Sudden cardiac death	2/58 (3.4)	11/58 (19.0)	13/58 (22.4)
Procedural complication	13/58 (22.4)	0	13/58 (22.4)
Major vascular complication	8 /58 (13.8)	0	8/58 (13.8)
Coronary obstruction	3/585.2)	0	3/58 (5.2)
Hemipericaridium	1/58 (1.7)	0	1/58 (1.7)
Prosthetic valve dysfunction	1/58 (1.7)	0	1/58 (1.7)
Heart failure	1/58 (1.7)	10/58 (17.2)	11/58 (19.0)
Stroke	1/58 (1.7)	2/58 (3.4)	3/58 (5.2)
AKI	1/58 (1.7)	1/58 (1.7)	2/58 (3.4)
AV block	1/58 (1.7)	0	1/58 (1.7)
Endocarditis	0	1/58 (1.7)	1/58 (1.7)
Multi Organ failure	1/58 (1.7)	1/58 (1.7)	2/58 (3.4)
Other	3/58 (5.2)	3/58 (5.2)	6/58 (10.3)
Unknown	0	6/58 (10.3)	6/58 (10.3)

Table 6: Paired PVL Results from 30 days and 1 year

Paravalvular Aortic Regurgitation	1 Year: **NONE/TRACE**	1 Year: **MILD**	1 Year: **MODERATE**	1 Year: **SEVERE**
30 Days: **NONE/TRACE**	86 (16.4%)	59 (11.3%)	0 (0.0%)	0 (0.0%)
30 Days: **MILD**	64 (12.1%)	287 (54.8%)	7 (1.3%)	0 (0.0%)
30 Days: **MODERATE**	0 (0.0%)	14 (2.7%)	7 (1.3%)	0 (0.0%)
30 Days: **SEVERE**	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)