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Outcomes after Implantation of the ACURATE Neo and Portico Transcatheter Heart Valves for the Treatment of Severe Aortic Stenosis

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Abstract

Introduction: Among others the ACURATE neo and the Portico self-expanding transcatheter heart valves are widely used to treat severe aortic stenosis. So far, a direct comparison of the hemodynamics of these two valves is lacking. We want to fill this gap by a retrospective analysis of hemodynamic performance and the occurrence of new conduction disturbances.

Methods and results: Prospectively collected data at the University Hospital Zurich and the Heart Center Lucerne between December 2012 and April 2018 were analyzed. A total of 318 consecutive patients undergoing implantation of an ACURATE neo or a Portico valve formed the study population. The ACURATE neo was implanted in 144 patients (44% male) and the Portico in 174 patients (47% male). Patients receiving the ACURATE neo were older (82 ± 6 vs. 80 ± 7, p=0.03), had a higher LVEF (58 ± 12% vs. 54 ± 14%, p= 0.01) and a higher mean transvalvular pressure gradient at baseline (49 ± 17 vs. 41 ± 17 mmHg, p<0.001). There was no difference in annular size between the two groups (a perimeter of 75.3 ± 8.6 vs. 75.4 ± 5.2 mm, p=0.94).

Incidence of > mild paravalvular leak was low in both groups (3.4% in Portico vs. 5.6 % in ACURATE neo, p=0.42) at 30 days. The mean transvalvular pressure gradient after implantation of ACURATE neo was comparable to Portico (7 ± 4 mmHg vs. 8 ± 4 mmHg, p=0.05). New pacemaker insertion was significantly less frequent in the ACURATE neo group (2.5% vs. 10.9%, p=0.01).

Conclusion: Hemodynamic outcomes between the intra-annular Portico and the supra-annular ACURATE neo valve were similar with low transvalvular pressure gradients observed after implantation of both valves. Pacemaker rates after ACURATE neo implantation was lower

Keywords: Transcatheter aortic valve implantation (TAVI); Self-expandable valve; ACURATE neo-Portico

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Introduction

Transcatheter aortic valve implantation (TAVI) has been established as the treatment of choice in a broad patient population with aortic stenosis ranging from low-risk to inoperable patients [1,2]. Currently, the main limitations of TAVI are paravalvular leaks (PVL) and the need for new pacemaker implantation [3,4]. Furthermore, long-term outcome data (beyond 10 years) are currently missing.

The ACURATE neo (Boston Scientific, Marlborough, MA, USA) is a second-generation self-expanding, non-repositionable, supra-annular, porcine pericardial leaflet valve system. The Portico (Abbott, Abbott Park, IL, USA) is a second-generation self-expanding, repositionable, intra-annular, bovine pericardial leaflet valve system.

Data directly comparing the two valves are currently missing. Given the two different concepts (intra- *vs.* supra-annular

valve fixation; repositionable *vs.* non-repositionable) such a comparison is of interest, as the design of the valve potentially impacts hemodynamics and conduction disturbances.

The aim of the present study was therefore to compare the hemodynamic performance and the incidence of permanent pacemaker implantation of the ACURATE neo and the Portico valve.

Materials and Methods

Study design and population

Consecutive patients with severe aortic stenosis, defined as an aortic valve area of <1.0 cm^2 or a mean transvalvular pressure gradient >40 mmHg or maximal velocity of >4.0 m/s, treated at the University Hospital Zurich and Heart Center Lucerne between December 2012 and April 2018, using either a Portico or ACURATE neo valve prosthesis, were included in the present analysis. Patients undergoing TAVI with other valve types than Portico and ACURATE neo were not eligible for inclusion.

Patients gave written informed consent to the procedure and to data collection, approved by the local ethics committees (Swiss TAVI Registry (PB_2016-00394)).

Procedural characteristics

Pre-procedural work-up included a transthoracic echocardiogram and a gated-CT scan. Transthoracic echocardiography studies were performed by experienced certified personnel. Studies were analysed according to the American Society of Echocardiography (ASE) and the European Association of Echocardiography (EAE) recommendations and performed using commercially available ultrasound systems (Philips iE33 or Epic, Philips Healthcare, Andover, MA, USA; GE Vivid 7 or E9 or E95, GE Healthcare, Milwaukee, WI, USA). Basic echocardiographic parameters were retrieved from baseline echocardiographic reports. LV ejection fraction (LVEF) was measured by Simpson's biplane method.

The vast majority of transcatheter aortic valve implantation procedures were performed *via* the transfemoral approach (95.4% in Portico and 95.1% in ACURATE neo) in local anaesthesia and under fluoroscopic guidance only. Pre-dilatation of the native aortic valve was done in the majority of cases (86.2% in Portico and 95.1% in ACURATE neo). At 30 days a transthoracic echocardiogram and a clinical follow-up were performed.

Statistical analysis

Continuous variables are expressed as mean ± SD or medians with interquartile ranges (IQR), and were compared using 1-way ANOVA, Student's t-test, Kruskal-Wallis or Mann-Whitney tests, as appropriate. Categorical data are presented as frequency (percentages) and were compared using the Fisher exact or the chi-square test. All statistical analyses were performed with SPSS 22 and p-values < 0.05 were considered as statistically significant.

Study endpoints

At 30 days, mean transvalvular pressure gradient, severity of paravalvular leaks and incidence of permanent pacemaker implantation were recorded. Further endpoints analyzed at baseline and at 30 days included functional capacity, as defined by New York Heart Association classification, and changes in left ventricular ejection fraction.

Results

A total of 318 patients (45% male, age 81 ± 7) were included. The Portico was used in 174 patients (47% male, age 80 ± 7) and the ACURATE neo in 144 patients (44% male, age 82 ± 6). The ACURATE neo population had a higher STS PROM (4.6 ± 4.2 *vs.* 4.3 ± 2.7) than the Portico group.

Baseline clinical and echocardiographic data are listed in **(Tables 1 and 2)**. Outcome data after transcatheter aortic valve implantation with the Portico and ACURATE neo valve systems are listed in **(Tables 3 and 4)**.

Hemodynamic outcomes

Mean trans-valvular pressure gradient decreased from 40.6 ± 16.5 to 7.7 ± 3.5 mmHg in the Portico and from 48.7 ± 17.3 to 7.1 ± 3.9 mmHg in the ACURATE neo group (p < 0.001 for both valves compared to baseline). A para-valvular leak >mild was rare in both groups (3.4% in Portico *vs.* 5.6% in ACURATE neo, p=0.42) **(Figure 1)**.

Table 1: Baseline characteristics. Patients receiving an ACURATE neo valve were older and in worse functional class, while patients receiving the Portico valve were more often in atrial fibrillation and previous stenting/PCTA were more frequent.

Characteristics	Portico (N=174)	ACURATE neo (N=144)	p-value
Age - years	80.3 ±7.2	82.0 ± 6.2	0.028
Male sex (%)	82/174 (47.1)	63/144 (43.8)	0.573
STS Risk Score	4.3 ± 2.7	4.6 ± 4.2	0.435
Previous MI (%)	15/174 (8.6)	13/144 (9.0)	1
PTCA/Stenting (%)	43/174 (24.7)	20/144 (13.9)	0.017
CABG (%)	12/174 (6.9)	6/144 (4.2)	0.338
Atrial fibrillation (%)	56/174 (32.2)	277138 (19.6)	0.014
NYHA ³II (%)	135/174 (77.6)	136/142 (95.8)	<0.001
Cardiovascular risk factors (%)			
Diabetes mellitus	41/174 (23.6)	29/144 (20.1)	0.499
Hypertension	126/174 (72.4)	118/144 (81.9)	0.047

Note: STS Risk Score: Society of Thoracic Surgeons Risk Score; Previous MI: Previous Myocardial Infarction; PTCA: Percutaneous Transluminal Coronary Angioplasty; CABG: Coronary Artery Bypass Grafting; NYHA: New York Heart Association

Table 2: Echocardiographic and CT data at baseline. Left ventricular ejection fraction and mean transvalvular pressure gradient were lower in the Portico group.

Characteristics	Portico (N =174)	ACURATE neo (N =144)	p-value
LVEF - %	54.0 ± 14.1	58.3 ± 11.8	0.004
Mean transvalvular pressure gradient - mmHg	40.6 ± 16.5	48.7 ± 17.3	<0.001
Perimeter Aortic Annulus - mm	75.3 ± 8.6	75.4 ± 5.2	0.941
Note: LVEF: Left Ventricular Ejection Fraction			

Table 3: Clinical outcomes at 30 days. New pacemaker implantation was more frequent in the Portico group and the functional outcome was worse. However there were no significant differences in terms of mortality, myocardial infarction, major bleeding and need of a second valve between the two groups

Characteristics	Portico (N =174)	ACURATE neo (N =144)	p-value
Mortality (%)	8/174 (4.6)	5/144 (3.5%)	0.778
Myocardial Infarction (%)	1/174 (0.6)	0/144 (0)	1
Major/Life-threatening Bleeding (%)	15/174 (8.6)	6/144 (4.2)	0.12
Second valve Implantation	3/174	1/143	0.63
NYHA ≥ II (%)	84/155 (54.2)	48/133 (36.1)	0.003
New PM Implantation (%)	19/155 (10.9)	3/117 (2.5)	0.006
Note: NYHA: New York Heart Association; New PM Implantation: New Pacemaker Implantation			

Table 4: Hemodynamic Outcomes at 30 days. Paravalvular leakage, mean transvalvular pressure gradient and ΔLVEF were similar in patients receiving the ACURATE neo and the Portico valve.

Characteristics	Portico (N=174)	ACURATE neo (N =144)	p-value
Paravalvular Leakage>mild (%)	6/174 (3.4)	8/144 (5.6)	0.417
Mean transvalvular pressure gradient - mmHg	7.7 ± 3.5	7.1 ± 3.9	0.05
ΔLVEF (Baseline to 30d) - % (total no.)	+2.4 (172)	+2.3 (136)	0.955
Note: NYHA: New York Heart Association			

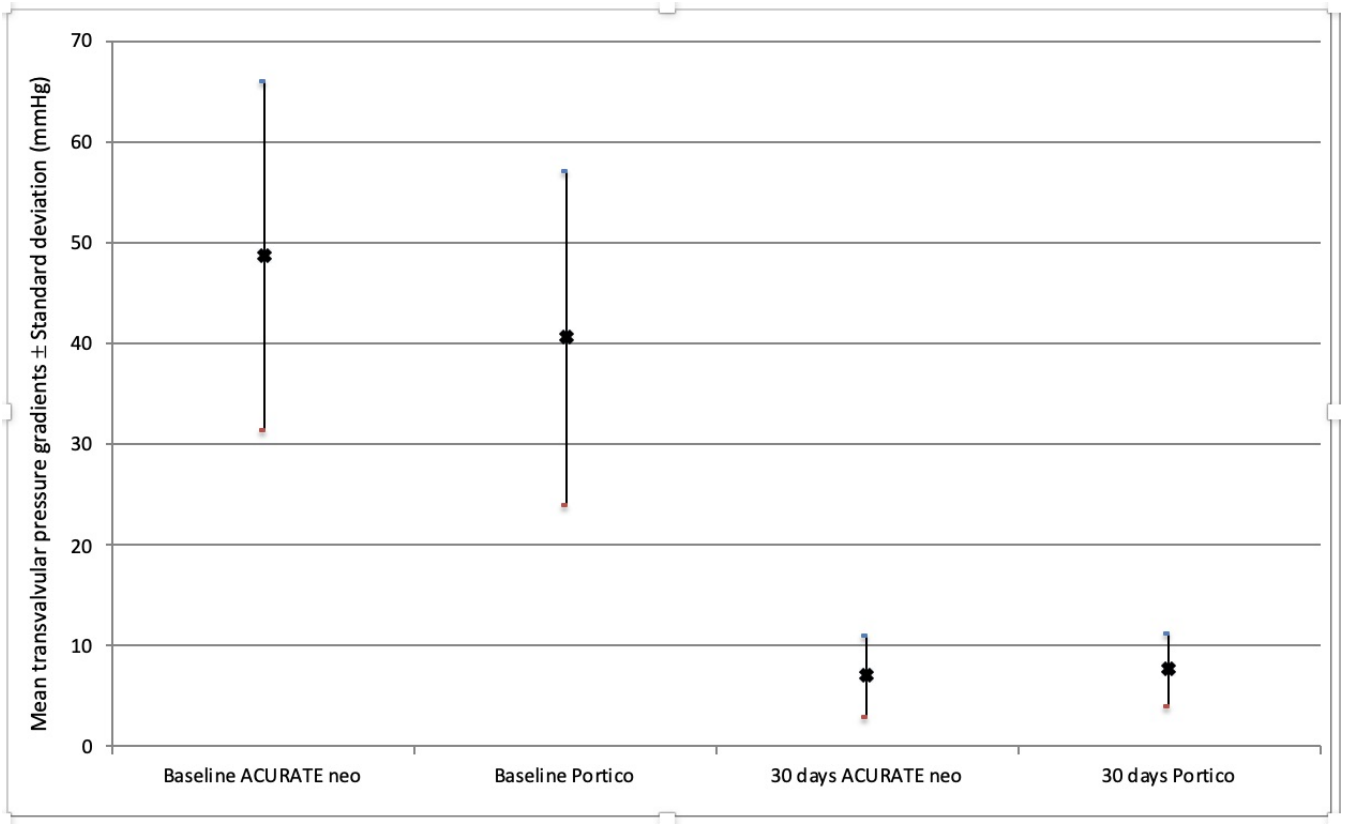

Figure 1 Mean transvalvular pressure gradients (mean and standard deviation) at baseline and 30 days. Both valve types showed a similar outcome in terms of mean transvalvular pressure gradients 30 days after implantation.

Clinical outcomes

Procedural outcomes were comparable between the two groups. Mortality at 30 days in the Portico and the ACURATE neo group was 4.6% *vs.* 3.5% (p=0.78) and major bleeding complications (major or life-threatening bleedings) occurred in 8.6% *vs.* 4.2% (p=0.12). Myocardial infarction was reported in only one patient (0.6% *vs.* 0% (p=1.0)). Implantation of a second valve was required in 4 patients (3 in the Portico group and 1 in the ACURATE neo group, p=0.63). The incidence of permanent pacemaker implantation was significantly higher in the Portico group compared to the ACURATE neo group (10.9% *vs.* 2.5%, p=0.01). A logistic regression model corrected for age, history of hypertension, atrial fibrillation and previous PTCA/Stenting showed that the Portico valve was associated with a five-fold increased risk of new permanent pacemaker implantation within 30 days (OR 5.184 (1.465-18.344); p=0.01).

At 30 days functional recovery was worse in the Portico group (NYHA ≥ II 54% *vs.* 36%, p=0.01). At baseline functional class NYHA ≥ II was more frequent in the ACURATE neo group, reflecting a better recovery of the ACURATE neo group.

Discussion

The main finding of this retrospective comparison between the two valve systems ACURATE neo and Portico was a significantly lower pacemaker rate after implantation of the ACURATE neo. There were no differences in hemodynamic outcome in terms of paravalvular leakages and transvalvular pressure gradients at 30 days follow-up. New permanent pacemaker rates after TAVI using earlier-generation valve systems ranged between 5% and 12% for balloon-expandable and between 24% and 33% for self-expanding devices [5]. With more precise implantation techniques resulting in prostheses being implanted more aortic, and thanks to improvements in prosthesis design, pacemaker rates have come down to 6.5% for balloon-expandable valves [2]. Pacemaker rates for self-expanding valves on the other hand, tend to remain higher [6, 7].

We found in our cohorts low rates of new pacemaker implantation – both for the Portico and the ACURATE neo valve. A new permanent pacemaker was required in 10.9% of patients receiving the intra-annular valve system Portico, whereas a new pacemaker rate of 18.7% at 30 days was reported in the PORTICO-I trial [6]. An even lower pacemaker rate was found for the cohort receiving the ACURATE neo valve (2.5%), achieving results as with balloon-expandable valves. This is lower than reported rates for other supra-annular valve systems- e.g. the Evolute valve (13.3%) [8]. Also the rates are lower than reported in other studies using the ACURATE neo valve (8.2% and 10.2%) [9]. The reasons for this are unknown and are speculative - however, routine cessation of negative dromotrope medication as well as aiming at an aortic implantation may explain the findings.

The current Portico valve does not feature a sealing cuff. We learned from our own unpublished data, that aggressive oversizing when using the Portico valve resulted in very low paravalvular leak rates. This has become routine practice at our institution. The downside of this practice may be a slightly higher pacemaker rate and may explain the differences observed between the ACURATE neo and the Portico valve in our cohort [10].

Conclusion

Our data do not support the suggested lower transvalvular pressure gradients when using supra-annular as compared to intra-annular prostheses. While both designs may have their advantages, vascular access, the presence of coronary artery disease as well as center experience may play an important role on valve choice. Furthermore, with expanding indications for TAVI and use of TAVI in younger patients, the suitability for valve-in-valve procedures should also be considered.

Study limitations

This study is a retrospective analysis, generated from real-world observational data. The local Heart Team decision-making process cannot be captured and may be a source of bias. This study focuses on short-term outcomes (30 days observational period) consequently conclusions on long-term hemodynamic differences between the two valve systems cannot be made.

Conflicts of interest

Dr Nietlispach Consultant and Proctor for Abbott Vascular and Edwards Lifesciences;

Dr Toggweiler Consultant and proctor for Boston Scientific, NVT GmbH and Abbott Vascular, has received institutional research grants from Boston Scientific and Fumedica AG and holds equity in Hi-D Imaging AG

References

1. Leon MB, Smith CR, Mack M, Miller DC, Moses JW, et al. (2010) Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med 363:1597-1607.
2. Mack MJ, Leon MB, Thourani VH, Raj Makkar, Kodali SK, et al. (2019) Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. N Engl J Med 380:1695-1705.
3. Tirado-Conte G, Armijo G, Nombelo-Franco L (2018) Head to head trancatheter heart valve comparisons: When theory becomes reality. Cardiovasc Diagn Ther 8:552-555.
4. Erkapic D, Kim WK, Weber M, Mollmann H, Berkowitsch A, et al. (2010) Electrocardiographic and further predictors for permanent pacemaker requirement after transcatheter aortic valve implantation. Europace 12:1188-1190.
5. Siontis GC, Juni P, Pilgrim T, Stortecky S, Bullesfeld L, et al. (2014) Predictors of permanent pacemaker implantation in patients with severe aortic stenosis undergoing TAVR: A meta-analysis. J Am Coll Cardiol 64:129-140.
6. Sondergaard L, Rodés-Cabau J, Hans-Peter Linke A, Fichtlscherer S, Schafer U, et al. (2018) Transcatheter aortic valve replacement with a repositionable self-expanding prosthesis: The portico-I trial 1-year outcomes. J Am Coll Cardiol 72:2859-2867.

7. Reardon MJ, Van Mieghem NM, Popma JJ, Kleiman NS, Sondergaard L, et al . (2017) Surgical or transcatheter aortic-valve replacement in intermediate-risk patient. N Engl J Med 376:1321-1331.

8. Petronio AS, Zucchelli G, Kovac J, de Jaegere P (2014) ADVANCE II: Best practices investigation in patients undergoing transcatheter aortic valve implantation with a self-expanding valve. Paper presented at: Annual Meeting of the EuroPCR. May 22, Paris, France.

9. Husser O, Kim W, Pellegrini C, Holzamer A, Walther T, et al. (2017) Multicenter comparison of novel self-expanding versus balloon-expandable transcatheter heart valves. JACC Cardiovasc Interv 10:2078-2087.

10. Manoharan G, Walton AS, Brecker SJ, Pasupati S, Blackman DJ, et al. (2015) Treatment of symptomatic severe aortic stenosis with a novel resheathable supra-annular self-expanding transcatheter aortic valve system. JACC Cardiovasc Interv 8:1359-1367.