

ART With A Single Antiplatelet Therapy Strategy

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Introduction

In this prospective randomized study, whether an ART with a single antiplatelet therapy strategy (aspirin alone) was associated with morbidity and increased patient morbidity compared to the dual antiplatelet strategy (aspirin and thienopyridines). Transcatheter aortic valve replacement (TAVR) has emerged as an important treatment option for patients with aortic stenosis (AS). The SOCIAL and CoreValve tests showed that TAVR was superior to medical therapy in treating inoperable patients with severe AS and non-surgical lower than in April (SAVR) in patients with severe AD who were high-risk and intermediate. These TAVR tests have prominently positioned as an alternative to SAVR, but the clinical benefits of TAVR should be assessed in balance with peri-procedural complications, in particular strokes and coagulation (Table 1), which are associated with increased morbidity and mortality.

Methods Study Design

The retrospective investigation was performed in a singular focus planned associate review was going for continuous enrollment of all patients experiencing TAVR systems at the Heart Center Segeberger Kliniken, Bad Segeberg, Germany. Information accumulation was affirmed by the nearby morals board of trustees and educated, composed assent was gotten from all patients. The present investigation incorporates 514 back-to-back patients who experienced TAVR between September 2007 and December 2014 at the Heart.

Focus Segeberger Kliniken, Germany. Twenty patients were avoided from this investigation in light of antithrombotic medicines other than DAPT or OAC or because of system-related demise. TAVR was performed in all patients with CE-checked gadgets. TAVR methods were led using trans-femoral, trans-subclavian, trans-apical or trans-aortic get to destinations. Gadget achievement was characterized by the Valve Academic Research Consortium 2 (VARC-2) agreement record, which is a specialized composite endpoint including active vascular get to, conveyance and arrangement of the gadget and fruitful recovery of the transportation framework; rectify position of the device in the correct anatomical area; expected execution of the prosthetic heart valve (aortic valve zone [AVA] > 1.2 cm², mean aortic valve inclination < 20 mm Hg, or pinnacle speed < 3 m/s, without direct or severe prosthetic valve aortic spewing forth as surveyed by post-interventional transthoracic echocardiography [TTE]) and having just one pipe embedded in the best possible anatomical area.

Patients were classified into two gatherings given the antithrombotic treatment set up after TAVR. The DAPT aggregate comprised 315 (61.3%) patients treated with a mix of oral headache medicine and clopidogrel for three months taken after long-lasting ibuprofen treatment. The OAC amass included 199 (38.7%) patients treated with a blend of an oral anticoagulant and clopidogrel for three months taken after by OAC alone (Fig. 1). In patients treated with associative percutaneous coronary mediation (PCI) and medication eluting stent implantation antithrombotic treatment with DAPT or blend of OAC + clopidogrel was sought after for up to 6 months.

Development And Study Endpoints

All patients in the registry had a pre-characterized clinical and transthoracic echocardiographic (Vivid 7 Ultrasound Machine and an M4S lattice exhibit area transducer GE Medical Systems, Milwaukee, WI, USA) follow-up at 30 days, six months and one year. Extra transesophageal echocardiography (TEE) assessment was performed in instances of exacerbating indications or suspected valve thrombosis, characterized as valve brokenness (mean transvalvular angle > 20 mm Hg, a decrease of the AVA to < 1.2 cm² or new onset more than gentle transvalvular spewing forth) or recently evident portable mass suspicious of thrombus, independent of brokenness, and without the disease.

Moreover, a multidetector figured tomography (MDCT) examination was performed to affirm the finding of suspected valve thrombosis. CT scan was finished with a moment-era second source CT scanner (Somatom Definition Flash, Siemens Healthcare, Forchheim, Germany). Differentiate upgraded ECG-gated obtaining of the aortic root was performed after infusion of iodinated balance operator with the area of intrigue put in the ascending aorta and central areas of 0.6 mm. All information was exchanged to a devoted post-handling workstation (Syngo Multimodality Workplace, Siemens Healthcare, Forchheim, Germany) for examination. Pictures were assessed for hypoattenuating zones with or without decreased portability of at least one handout identifiable in two distinct projections. Valve thrombosis was ordered in light of the planning of finding after TAVR as intense (0–10 days), subacute (11–30 days), or late (> one month).

Pre-determined viability endpoints of this review were characterized as all-cause demise, myocardial localized necrosis (MI), stroke and clinical valve thrombosis at 30 days, six months and one year. The key viability endpoint was a composite of all at one year. The key well-being endpoint was the event of life-debilitating or significant sleeping at one year. Singular endpoints were characterized by the VARC-2 criteria for occasion definition.

Measurable Investigation

Constant information is accounted for as mean $\pm$ standard deviation (SD) for regularly circulating factors and as the middle with interquartile extends for non-ordinarily appropriated elements. All out factors are accounted for as some patients (% of patients). Typically and non-ordinarily circulated

factors were looked at utilizing the Student's t-test or the Mann-Whitney U test appropriately. Correlations between independent factors were performed using the χ^2 or Fisher's correct test, wherever fitting. Keeping in mind the end goal to recognize whether the counter thrombotic treatment methodology was prescient of all-cause mortality, cardiovascular mortality, stroke, significant dying, or consolidated adequacy and wellbeing endpoints multivariable twofold calculated relapse investigation was performed. Factors that achieved a p-esteem < 0.1 on univariate paired relapse examination were incorporated into the model. Factors are balanced for age, sex, body mass record (BMI), AF and arranged PCI. All tests were two followed, and a p-estimation of < 0.05 was considered as actually noteworthy. Every one of the examinations was reviewed and performed utilizing STATA from 14 (STATA Corp., TX, USA) or (SPSS, Release 22; SPSS Inc, Chicago, IL).

Results

A sum of 514 consecutive patients that experienced TAVR at the showed Foundation were incorporated into this review. The mean age of the review populace was 80.4 years; 43.7% were guys, with an average strategic EuroScore of 18.49%. In both gatherings, patients had severe aortic stenosis. Echocardiographic attributes did not contrast fundamentally in either gathering. The mean ($\pm$ SD) inclination was 46 ± 16.8 mm Hg in the DAPT collection and 44 ± 16.8 mm Hg in the OAC conference ($p = 0.27$). The ordered AVA was 0.41 ± 0.2 cm²/m² and 0.39 ± 0.2 cm²/m² ($p = 0.28$). The two gatherings had comparable pattern attributes (Table 1), with the exception of a higher rate of AF in the OAC gathering (10.5 versus 69.2%; $p < 0.01$) and a higher rate of arranged PCI in patients experiencing TAVR in the DAPT gathering (40.1 versus 28.3%; $p = 0.01$). Procedural attributes did not vary between either gathering (Table 2). At release, 315 (61.3%) patients got DAPT and 199 (38.7%) a blend of OAC and clopidogrel ($n = 188$ phenprocoumon, $n = 7$ rivaroxaban, $n = 4$ dabigatran) taking after TAVR (Fig. 1).

Results At 30 Days

At 30 days, all-cause mortality happened in an aggregate of 18 patients (3.5%), 11 (3.5%) in the DAPT gathering and 7 (3.5%) in the OAC gathering ($p=0.98$) (Table 3). Cardiovascular mortality accounted for 3.5% of the patients in the DAPT gathering and 2.5% in the OAC gathering ($p = 0.61$). There was no huge distinction between either gather in the frequency of MI (0.9% versus 0.5%, $p = 1.0$), stroke (3.8% versus 3.5%, $p = 0.86$) or valve thrombosis (0.3% versus 0%, $p = 1.0$) at 30 days. Additionally, security endpoints did not contrast between either gathering: life-debilitating dying (7.3% versus 9.5%, $p = 0.36$) and significant dying (16.8% versus 15.1%, $p = 0.60$).

Results At Six Months

At six months, all-cause mortality was accounted for in 25 (7.9%) patients in the DAPT gathering and

24 (12.1%) patients in the OAC meeting ($p = 0.15$) (Table 4). There was no noteworthy distinction between DAPT and OAC bunches in the frequency of MI (1.6% versus 0.5%, $p = 0.41$) and stroke (4.5% versus 4.1%, $p = 0.83$). In spite of the fact that valve thrombosis was just detailed in the DAPT gathering, there was no critical contrast (1.9% versus 0%, $p = 0.08$) between the groups following six months. Consolidated adequacy (15.3% versus 14.6%, $p = 0.8$) and security (24.4% versus 26.1%, $p = 0.64$) endpoints at six months did not contrast essentially (Table 4).

At one year, all-cause mortality had happened in an aggregate of 74 (14.4%) patients. 39 (12.4%) passings were accounted for in the DAPT gathering and 35 (17.6 %) in the OAC collection (Fig. 2). Despite the fact that a pattern towards a higher death rate could be seen in the OAC gathering, this expansion did not achieve factual essentialness ($p = 0.09$). Besides, there was no distinction in MI (2.9% versus 0.5%, $p = 0.09$) and stroke (5.2% versus 4.1%, $p = 0.67$) rates between the DAPT and OAC gatherings. Following one year, 8 (2.5%) instances of valve thrombosis were recorded in the gathering of patients on antiplatelet treatment, while in patients on OAC, no valve thrombosis was accounted for (2.5% versus 0%, $p = 0.02$). Joined key viability (21.5% versus 19.7%, $p = 0.61$) and security (25.1% versus 27.8%, $p = 0.53$) endpoints at one year did not contrast between the gatherings (Fig. 3). A balanced calculated relapse investigation affirmed that notwithstanding a pattern towards an expansion taking all things together causes mortality following one year was seen in patients under OAC, there was no general huge distinction in the event rates of the predefined endpoints (Fig. 3). In any case, OAC diminished the danger of valve thrombosis-free of age, sex, BMI, AF and whether organized PCI was performed (OR 0.53; 95% CI 0.23–0.76).

In the present examination, transcatheter heart valve (THV) thrombosis was accounted for in 8 patients with a mean age of 78.7 years. Middle and interim to the finding of THV thrombosis were 181 (interquartile go 176–263) days and 196 days, individually. THV thrombosis was thought to be subacute in 1 and late in 7 patients (Table 5). Each of the eight instances of THV thrombosis happened in the DAPT gathering. While two patients were still under DAPT (headache medicine/clopidogrel), six patients were under ibuprofen monotherapy at the point in time of the finding of THV thrombosis. Instances of valve thrombosis included seven patients who had experienced TAVR with an inflatable expandable THV and one tolerant treated with a self-expandable THV. Three cases of THV thrombosis happened in patients who underwent TAVR for the treatment of declined surgical bioprosthesis (valve-in-valve). Declining dyspnoea was the main clinical sign of THV thrombosis and was seen in 5 patients. In the other three patients, no clinical side effect could be ascribed to the event of THV thrombosis. No instance of stroke, MI or fringe embolism could be related to THV thrombosis.

Lifted transvalvular angles were the main finding in all patients on TTE examination. The pinnacle and mean transaortic angles at the season of the finding of THV thrombosis were 61 mm Hg and 39 mm Hg, individually. TEE was performed in all patients with suspected THV thrombosis. TEE discoveries included limited handout versatility ($n = 3$), thrombotic mass ($n = 3$) and thickened flyers ($n = 4$) (Table 5). In 1 case, TEE was uncertain. CT examination was performed in 4 patients and showed hypoattenuating injuries of the pamphlets and limited flyer movement predictable with THV

thrombosis. All patients determined to have THV thrombosis were treated with VKA in restorative measurements.

Three patients were dealt with likewise with clopidogrel. Under oral anticoagulation follow-up, TTE examinations reported a reduction of the transvalvular slopes in all patients. Follow-up CT was performed in 3 patients 1 (n = 2) and 2 (n = 1) months after the start of anticoagulant treatment, affirmed the determination of the hypoattenuating injuries and flyer thickening with the rebuilding of pamphlet movement. After the determination of THV thrombosis, OAC was stopped in 3 patients, while VKA treatment proceeded in 5 patients. No repeat of THV thrombosis was accounted for.

Discussion

This individual tracer screening test analyzed the results of two antithrombotic regimens after TAVR intake. After a subsequent 1-year period, no significant total endpoint feasibility and safety contrasts were observed between an antithrombotic in the light of the DAPT initial phase of 3-6 months of the technique as suggestions indicated the existing rule.

What's more, OAC. However, clinical valve thrombosis occurred after TAVR at the DAPT meeting and was effectively treated by the OAC foundation.

Most cardioembolic events after TAVR were considered to happen in the primary days after TAVR. In this review, the 30-day death rate for all causes, stroke, and IM was similar to what is already distributed at the next test point of testing and even across the record country. DAPT or OAC post-intervention has produced comparable rates of myocardial infarction, stroke and death for all cause up to 6 months after TAVR, then underlining the vitality of both useful regimens. After six months, patients who meet fixed DAPT in anti-tumor therapy (headache medication), while the anticoagulant sought in the OAC group due to concomitant diseases, in particular, paroxysmal or life. One year later, TAVR, a single-drug monotherapy for a headache, also provided comparative results when compared to OAC compared to predetermined evaluation criteria. Therefore, actual results agree with previous reviews strongly support DAPT interference after a 3-6 month TAVR in patients who have no other sign for DAPT, for example, end-of-coronary heart disease (<12 Months) O coronary stent implant (<6 months)]. It is interesting to note that after one year of independently altering an FA event and different factors, a pattern could be observed to increase mortality from all causes at the OAC meeting. review given the limited size of the revision population and also the correction mode, this perception requires clarification of the vigils.

In replacement of moderately young perinatal aortic valve period, he developed an increasing number of reports describing the post-TAVR thrombotic subacute cases clinically appropriate application and delayed movement delayed movement MDCT recognized may be related to subclinical replacement valve thrombosis.

This valve and post-TAVR work rotate broken thrombosis reports created about the clinical relevance

of this wonder. In this review, thrombosis of the valve given the echocardiographic examination routine to follow up with 1.5% of the total population and as regularly as 2.5% in patients initially treated with DAPT was analyzed. The conclusion depended on echocardiographic parameters that showed a significant increase in transvalved angulation or thrombotic mass weight and asserted by the results revealing MDCT thickening of the flaps and reduced brochure movements. THV thrombosis showed an aggravation of dyspnea in 5 out of 8 patients and was not related to any clinical manifestation in 3 patients.

In patients with THV thrombosis, DAPT was switched to OAC for not less than three months; follow-up ranges were shortened. By echocardiography and also the clinical examination reported the reconstruction of the valve capacity under OAC by reducing pelvic and medical transvaginal course on the valve prosthesis, the determination of thrombotic mass and a further change of clinical side effects to all patients. Interestingly, rather than collecting DAPT, no thrombosis valve cases were analyzed in any of the patients in OAC and calculated the relapse test showed that OAC was associated with a risk primarily to reduce THV thrombosis. This perception agrees with current editorial reports suggest that OAC treatment still prevents platelet thrombosis.

Reduced aortic leaf movement can speak of subclinical valve thrombosis. Further studies are needed with a specific end goal to represent this patient subgroup better and distinguish indicators show potential patients who may benefit from OAC after separating different signs for TAVR anticoagulant therapy.

Hemorrhagic disadvantages are continuous and significant side effects or life-wasting after TAVR checks, about 20-30% and 15%, individually [16, 17, 29]. Despite the fundamental components, disabling or debilitating discharge life is a critical indicator of great and late mortality in patients undergoing TAVR. Drainage indicators have been distinguished for a couple of encounters [30, 31]. Including vascular tonsils or into processed tonsils, female sex, and pallor series have been detailed most of the time. While periprocedural drainage is driven primarily by anatomical and specialized contemplations, greater drainage and subsequent post-mining life indicate that time is predominantly linked to the patient's drainage vulnerability, the current antithrombotic operator used.

In this research, the criterion of being composed occurred mainly within the first six months after TAVR at both meetings. This perception unequivocally suggests that DAPT is OAC mixing with a self-agonizing drug alone, for example, clopidogrel results in a sharp increase in complexity bleeding after TAVR in a population of patients at high risk of loss due to morbidity and lightness. At one year, the composite safety criterion frequency was only slightly greater in both meetings when compared to the 6-month time point and was identified primarily in the manner following a 6-month high thienopyridine treatment stopped in patients without A sign for the further treatment of long-distance clopidogrel, for example, ACS. Past reviews and records have announced a fleeting risk identified with the confusion of drainage being the clearest in the first three months since the beginning of the VKA plus a single anti-drug or DAPT treatment. A new meta-search that excludes OAC patients has shown that monotherapy head pain while being as efficient as DAPT in predicting thromboembolic

complexity and post-intervention, has been better than DAPT on difficulties.

Taken together, these perceptions may challenge the present work on prescribing DAPT for 3–6 months after TAVR, yet these outcomes should be affirmed by the moment, continuous planned randomized trials. On the administration of antithrombotic treatment after TAVR in patients on OAC, facilitate information announcing is justified. In this review examination, patients on OAC were treated with clopidogrel for no less than three months after TAVR, as indicated by popular suggestions [4]. Since most of the draining occasions happened in this gathering within the initial six months, the net advantage of including a platelet inhibitor on top of OAC might be addressed. Concerning DAPT, imminent randomized trials are required to characterize the most suitable antithrombotic post-TAVR treatment in patients on OAC. Finally, while the more popular direct oral anticoagulants have turned out to be more secure and, at any rate, as proficient as VKA in anticipation of thromboembolic occasions in patients with fundamental non-valvular AF, their part in patients experiencing TAVR stays to be characterized.

Conclusion

TAVR – is the transformation and development of treatment for patients with severe aortic stenosis. Cases of peri-procedure stroke and exhaustion related to dramatic horror and death in patients with the mark. Deep holes remain in our lack of adjunctive antithrombotic treatments to increase the risk of thromboembolic changes and cases of leakage in the lower and TVR. Agreements and recommendations for modern judicial standards require anticoagulation with unfractionated heparin vnutriprotsedurnoy and to maintain ACT extends 250–300, and are administered to patients after the mark, to achieve DAPT for 1–6 months with clopidogrel, without leaving pharmacological treatment of headaches. There is a need for a fantastic clinical synthesis to advise the standards and apply the best treatment protocol that is taken after TVAR. Numerous clinical studies on adjuvant antiplatelet therapy and anticoagulant therapy after TAVR. Several randomized clinical trials provide clinically vital, highly anticipated clinical research in the perfect pharmacological system, strength and duration of antithrombotic treatment after TVAR. The future clinical examination would also require the creation of equipment hazard expectations used to detect the net benefits and risks of adjuvant antithrombotic therapy in this heterogeneous patient population.

References

Ross Jr J, Braunwald E. Aortic stenosis. *Circulation* 1968;38:61–7.[2] Turina J, Hess O, Sepulcri F, Kräyenbuehl HP. The natural course of aortic valve disease. *Eur Heart J* 1987;8:471–83.

Bonow RO, Carabello BA, Chatterjee K, et al. 2008 Focused update incorporated into

The ACC/AHA 2006 Guidelines for the Management of Patients with Valvular Heart Disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines

(Writing Committee to Revise the 1988 Guidelines for the Management of Patients with Valvular Heart Disease): endorsed by the Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. *Circulation* 2008;118(15): e523-661.

Schwarz F, Baumann P, Manthey J, et al. The effect of aortic valve replacement on survival. *Circulation* 1982;66:1105-10.

[5] Lund O. Preoperative risk evaluation and stratification of long-term survival after valve replacement for aortic stenosis: reasons for earlier operative intervention. *Circulation* 1990;82:124-39.

[6] O'Brien SM, Shahian DM, Filardo G, et al. The Society of Thoracic Surgeons 2008 Cardiac surgery risk models: part 2—isolated valve surgery. *Ann Thorac Surg* 2009;88(Suppl.): S23-42.

[7] O'Brien SM, Shahian DM, Filardo G, et al. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 3—valve plus coronary artery bypass grafting surgery. *Ann Thorac Surg* 2009;88(Suppl.): S43-62.

Miyazaki Y, Suwannasom P, Satomi Y, et al. Single or dual antiplatelet therapy after PCI. *Nat Rev Cardiol* 2017;14:294-303.

Kappetein AP, Head SJ, Genereux P, et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. *J Am Coll Cardiol* 2012;60:1438-54.

Hioki H, Watanabe Y, Koizumi K, et al. Pre-procedural dual antiplatelet therapy in patients undergoing transcatheter aortic valve implantation increases risk of bleeding. *Heart* 2017;103: 361-7.

Shibori Y, Mizote I, Maeda K, et al. Clinical outcomes and bioprosthetic valve function after transcatheter aortic valve implantation under dual antiplatelet therapy vs. aspirin alone. *Circ J* 2017; 81:397-404.

Czerwinski-Jelonkiewicz K, Zembala M, Dąbrowski M, et al. Can TAVI patients receive aspirin monotherapy as patients after surgical aortic bioprosthesis implantation? Data from the Polish Registry—POL-TAVI. *Int J Cardiol* 2017;227: 305-11.

Mangieri A, Jabbour RJ, Montalto C, et al. Single antiplatelet therapy in patients with contraindication to dual antiplatelet therapy after transcatheter aortic valve implantation. *Am J Cardiol* 2017;119:1088-93.

Durand E, Blanchard D, Chassaing S, et al. Comparison of two antiplatelet therapy strategies in patients undergoing transcatheter aortic valve implantation. *Am J Cardiol* 2014;113:355-60.

Ussia GP, Scarabelli M, Mulè M, et al. Dual antiplatelet therapy versus aspirin alone in patients undergoing transcatheter aortic valve implantation. *Am J Cardiol* 2011;108:1772-6.

Stabile E, Pucciarelli A, Cota L, et al. SAT-TAVI (single antiplatelet therapy for TAVI) study: a randomized pilot study comparing double to single antiplatelet therapy for transcatheter aortic valve implantation. *Int J Cardiol* 2014;174:624-7.

Hassell ME, Hildick-Smith D, Durand E, et al. Antiplatelet therapy following transcatheter aortic valve implantation. *Heart* 2015;101:1118-25.

Gandhi S, Schwalm JD, Velianou JL, Natarajan MK, Farkouh ME. Comparison of dual- antiplatelet therapy to mono antiplatelet therapy after transcatheter aortic valve implantation: systematic review and meta-analysis. *Can J Cardiol* 2015;31:775-84.

Nombela-Franco L, Webb JG, de Jaegere PP, et al. Timing, predictive factors, and prognostic value of cerebrovascular events in a large cohort of patients undergoing transcatheter aortic valve implantation. *Circulation* 2012;126:3041-53.

Van Mieghem NM, Schipper ME, Ladich E, et al. Histopathology of embolic debris captured during transcatheter aortic valve replacement. *Circulation* 2013;127:2194-201.

Kahlert P, Al-Rashid F, Dottger P, et al. Cerebral embolization during transcatheter aortic valve implantation: a transcranial Doppler study. *Circulation* 2012;126:1245-55.

Rodés-Cabau et al. 9 Antithrombotic Therapy Post-TAVR fibrillation in the Atrial Fibrillation Clopidogrel Trial With Irbesartan for Prevention of Vascular Events (ACTIVE W): a randomised controlled trial. *Lancet* 2006;367:1903-12.

Puri R, Auffret V, Rodés-Cabau J. Bioprosthetic valve thrombosis. *J Am Coll Cardiol* 2017;69: 2193-211.

Chakravarty T, Sondergaard L, Friedman J, et al. Subclinical leaflet thrombosis in surgical and transcatheter bioprosthetic aortic valves: an observational study. *Lancet*. In press.

Hassig S, Manager N, Dwyer MG, et al. Effect of a cerebral protection device on brain lesions following transcatheter aortic valve implantation in patients with severe aortic stenosis: the CLEAN- TAVI randomized clinical trial. *JAMA* 2016;316: 592-601.

Kapadia SR, Kodali S, Makkar R, et al. Protecting against cerebral embolism during transcatheter aortic valve replacement. *J Am Coll Cardiol* 2017;69:367-77.

Auffret V, Regueiro A, Del Trigo M, et al. Predictors of early cerebrovascular events in patients with aortic stenosis undergoing transcatheter aortic valve replacement. *J Am Coll Cardiol* 2016;68:673-84.

APPENDIX

DAPT (n = 315) OAC (n = 199) p							
	All cause death		25 (7.9%)	24 (12.0%)	0.15		
Cardiovascular death			16 (5.0%)	14 (7.0%)	0.12		
Myocardial infarction			5 (1.6%)	1 (0.5%)	0.41		
Stroke, all			14 (4.4%)	8 (4.0%)	0.83		
Transcatheter heart valve thrombosis			6 (1.9%)	0 (0%)	0.08		
Combined efficacy endpoint			48 (15.2%)	29 (14.6%)	0.86		
Major bleeding			55 (17.5%)	33 (16.5%)	0.80		
Combined safety endpoint			76 (24.1%)	51 (25.6%)	0.64		

DAPT (n = 315) OAC (n = 199) p				
	5 (1.6%)	1 (0.5%)	0.41	
	14 (4.4%)	8 (4.0%)	0.83	
	6 (1.9%)	0 (0%)	0.08	
	48 (15.2%)	29 (14.6%)	0.86	
	55 (17.5%)	33 (16.5%)	0.80	

Age (years)WomenHypertensionDiabetes mellitus Peripheral vascular disease Porcelain aortaCongestive heart failure*Previous myocardial infarctionPrevious strokePrevious transient ischemic attackPrevious coronary artery bypass grafting Previous cardiac surgery†Previous percutaneous coronary intervention Chronic obstructive pulmonary diseaseLiver cirrhosisChronic kidney failurePermanent atrial fibrillationPrevious aortic valvuloplastyPrevious pacemakerNew York Heart Association class III and IV Echocardiographic findings Mean gradient (mm Hg)Aortic valve area (cm2)	76 (24.1%)	51 (25.6%)	0.64	
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Table 1							
Baseline clinical and echocardiographic characteristics							
Variable	Overall		DAPT		Aspirin		p Value
	(n 79)		(n 40)		(n 39)		
Age (years)	81 4		80 6		81 4		0.68
Women	43	(54%)	20	(50%)	23	(59%)	0.44
Hypertension	66	(84%)	35	(88%)	31	(80%)	0.96
Diabetes mellitus	21	(27%)	13	(33%)	8	(21%)	0.35

Peripheral vascular disease	7	(9%)	3	(8%)	4	(10%)	0.43
Porcelain aorta	2	(3%)	1	(3%)	1	(3%)	0.72
Congestive heart failure*	32	(41%)	18	(45%)	14	(36%)	0.65
Previous myocardial infarction	11	(14%)	7	(18%)	4	(10%)	0.31
Previous stroke	6	(8%)	2	(5%)	4	(10%)	0.28
Previous transient ischemic attack	4	(5%)	2	(5%)	2	(5%)	0.68
Previous coronary artery bypass grafting	6	(8%)	2	(5%)	4	(10%)	0.28
Previous cardiac surgery [†]	3	(4%)	2	(5%)	1	(3%)	0.55
Previous percutaneous coronary intervention	21	(27%)	12	(30%)	9	(23%)	0.35
Chronic obstructive pulmonary disease	17	(22%)	10	(25%)	7	(18%)	0.60
Liver cirrhosis	1	(1%)		0	1	(3%)	0.47
Chronic kidney failure	11	(14%)	6	(15%)	5	(13%)	0.92
Permanent atrial fibrillation	10	(13%)	4	(10%)	6	(15%)	0.29
Previous aortic valvuloplasty	42	(53%)	24	(60%)	18	(46%)	0.45
Previous pacemaker	5	(6%)	4	(10%)	1	(3%)	0.22

New York Heart Association class III and IV	49	(62%)	26	(65%)	23	(59%)	0.60
Echocardiographic findings							
Mean gradient (mm Hg)	53 17		52 6		57 18		0.23
Aortic valve area (cm ²)	0.6 0.2		0.6 0.2		0.6 0.3		0.70
Left ventricular ejection fraction (%)	52 12		51 12		54 8		0.49
Logistic EuroSCORE (%)	21 13		23 15		21 16		0.60
Society of Thoracic Surgeons score (%)	7.3 4		8 5		7 3		0.37

Variable	Overall		DAPT		Aspirin		p
	(n 79)		(n 40)		(n 39)		Value
Procedural variables							
Procedure time (minutes)	45 26		44 23		47 23		0.70
Fluoroscopy time	22 13		22 13		22 13		0.48
(minutes)							
Approach							

Transfemoral	77	(97%)	38	(95%)	39	(100%)		
Trans-subclavian	2	(3%)	2	(5%)		0		
Device								
CoreValve Revalving	35	(44%)	23	(56%)	12	(31%)		
system 26-mm								
CoreValve Revalving	44	(56%)	17	(43%)	27	(69%)		
system 29-mm								
Procedural success	74	(94%)	38	(95%)	36	(92%)	0.49	
Postdilation	4	(5%)	1	(3%)	3	(8%)	0.30	
Valve-on-valve	3	(4%)	2	(5%)	1	(3%)	0.51	
Valve-in-valve		0		0		0	—	