TCT-81

Six Versus Twelve Months of Dual Antiplatelet Therapy After Implantation of Biodegradable Polymer Sirolimus-Eluting Stent: A Randomized Substudy of the I-LOVE-IT 2 Trial

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BACKGROUND There are no reports on a large-scale randomized trial exploring optimal dual antiplatelet therapy (DAPT) duration after biodegradable polymer sirolimus-eluting stent (BP-SES) implantation. We sought to report the 18month follow-up of randomized substudy of the prospective I-LOVE-IT 2 trial, which compared safety and efficacy between patients receiving 6- vs. 12-month DAPT after implantation of a novel BP-SES.

METHODS In the prospective randomized I-LOVE-IT 2 trial, 1829 patients who were allocated to the BP-SES group were also randomized to receive either 6-month (n=909) or 12-month DAPT (n=920). The endpoints of this substudy included 18-month TLF, and 18-month net adverse clinical and cerebral events (NACCE), a composite of all-cause death, all MI, stroke, and major bleeding (Bleeding Academic Research Consortium [BARC] type ≥3 bleeding).

RESULTS At 18 months, there was no difference in TLF between 6-month DAPT and 12-month DAPT groups (7.5% [68/909] vs. 6.3% [58/920], Log-rank p=0.32). The 18-month incidence of NACCE were also similar between the groups (7.8% [72/909] versus 7.3% [67/920], Log-rank p=0.60), or its individual endpoint components. Landmark analyses also showed that there was no significant difference of NACCE through 6-18 months between the groups (Log-rank p = 0.32). No definite/probable stent thrombosis occurred between 6 and 18 months in either group; however, there was arithmetically higher all-cause mortality in the 12-month group compared to the 6-month group (0.7% vs. 1.3%, p=0.16) in the same time interval.

CONCLUSIONS The present study indicated noninferiority in safety and efficacy of 6- vs. 12-month DAPT after implantation of a novel BP-SES and low 18-month stent thrombosis in both treatment arms.

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Coronary artery disease, Drug-eluting stent, sirolimus, Dual antiplatelet therapy

TCT-82

Single versus Dual Anti-Platelet Therapy in Transcatheter Aortic Valve Replacement: a Meta-Analysis of Safety and Efficacy Outcomes

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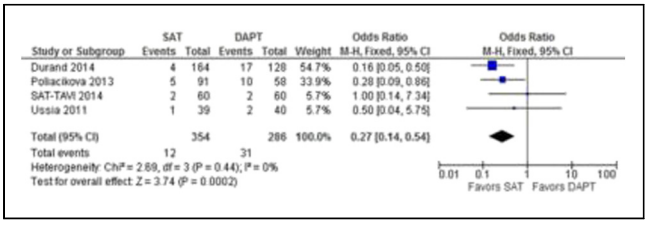
BACKGROUND Major bleeding episodes or strokes can occur in up to 25% of transcatheter aortic valve replacement (TAVR). Although guidelines recommend dual antiplatelet therapy (DAPT) up to 6 months, they also recognize there is a lack of evidence comparing antiplatelet strategies in TAVR. Previous studies were not powered for individual, but rather composite end-points. We aimed to perform a meta-analysis comparing single antiplatelet therapy (SAT) to DAPT in TAVR.

METHODS PubMed, EMBASE, Cochrane, and conference abstracts were searched for observational and randomized studies that directly compared SAT to DAPT in patients undergoing TAVR. Odds-ratios of safety and efficacy outcomes were computed using random or fixed-effects models. Heterogeneity was examined with Cochran Q test and I2 statistics. Meta-analysis statistics were performed with Review Manager 5.1.

RESULTS Four studies and 640 patients were included, of whom 354 (55%) received SAT. In the DAPT group, two antiplatelet agents were given for up to 6 months (Table 1). In a 30-day follow-up, SAT was associated with a decreased incidence of major vascular complications (OR 0.53; p=0.07), any vascular complication (OR 0.42; p<0.01), major bleeding (OR 0.27; p<0.01; Figure 1), life-threatening bleeding (OR 0.41; p=0.02), and any bleeding episode (OR 0.44; p=0.03). There were no significant differences between SAT and DAPT in all-cause mortality (p=0.57), cardiovascular mortality (p=0.99), major stroke (p=0.42), or any stroke/TIA (p=0.64). Similar results were observed in the 6 month follow-up.

	Design	Total population / SAT vs. DAPT	Mean age	Male	Second antiplatelet	Duration of DAPT	Follow-up	Valve
Durand 2014	Prospective cohort	292 / 164 vs 128	83.6 y	48%	Clopidogrel	1 mo	30 days	CoreValve, SAPIEN
Poliacikova 2013	Retrospective cohort	149 / 91 vs 58	82 y	54%	Clopidogrel	6 mo	30 days, 6 mo	CoreValve
SAT-TAVI 2014	RCT	120 / 60 vs 60	81.1 y	33%	Clopidogrel or ticlopidine	6 mo	30 days, 6 mo	SAPIEN XT
Ussia 2011	RCT	79 / 39 vs 40	81 y	46%	Clopidogrel	3 mo	30 days, 6 mo	CoreValve



CONCLUSIONS This meta-analysis suggests that SAT is safer than DAPT in terms of vascular complications and major or life-threatening bleeding episodes after TAVR. Further, our results indicate that a single antiplatelet agent is as effective as DAPT in the prevention of cerebrovascular events. Our study is hypothesis-generating; larger randomized trials are warranted to confirm these findings.

CATEGORIES STRUCTURAL: Complications

KEYWORDS Antiplatelet therapy, Complication, TAVR

HYPERTENSION THERAPIES AND RENAL DENERVATION

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TCT-83

Long-term (24-month) blood pressure results of catheter-based renal artery denervation: SYMPLICITY HTN-3 Randomized Controlled Trial

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BACKGROUND In previous unblinded trials of renal denervation (RDN), the reduction in blood pressure (BP) was stable or further increased over time. The SYMPLICITY HTN-3 trial is the first randomized blinded controlled trial of RDN (N=364) vs. sham control (N=171) where both the patient and BP assessor were blinded to treatment allocation until assessment of the 6-month primary endpoint. Patient behavior specific to drug adherence was believed to be one important factor underlying the marked 6-month BP reduction seen in the control arm, supported by changes in ambulatory and office BP measurement at 12 months when subjects were unblinded. Long-term (24-month) outcomes will provide further insights into whether BP trends seen in both the RDN and control cohorts at 12 months persist or are accentuated.

METHODS The SYMPLICITY HTN-3 trial enrolled subjects with office systolic BP ≥160 mm Hg despite being on an average of ~5 antihypertensive medications, including a diuretic, at least 3 of which were at maximally tolerated doses. While the 6-month primary safety endpoint was met, office and ambulatory BP did not differ between RDN and sham groups in part due to marked BP reduction in the control group. After 6 months, subjects were unblinded and those in the sham group meeting eligibility requirements could undergo RDN (crossover group) while some subjects chose not to undergo RDN or were not eligible (non-crossover group).