PHARMACOLOGY

Tuesday, October, 13, 2015, 2:00 PM-4:00 PM

Abstract nos: 75 - 82

TCT-75

Cangrelor Improves Ischemic Outcomes In Patients With Multivessel Disease And Single Vessel Disease Undergoing PCI: Insights From The CHAMPION PHOENIX Trial

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BACKGROUND Cangrelor, an intravenous, rapidly acting P2Y12 inhibitor, is superior to clopidogrel in reducing ischemic events in PCI patients with stable ischemic heart disease and acute coronary syndromes. We examined the safety and efficacy of cangrelor in relation to the extent of coronary artery disease.

METHODS We studied a prespecified modified intention to treat population of patients with single vessel and multivessel coronary disease. The primary efficacy outcome was the composite of death, myocardial infarction (MI), ischemia-driven revascularization (IDR), and stent thrombosis (ST) at 48 hours. Kaplan Meier analysis of the primary outcome was performed through 30 days. The safety outcome was non-CABG GUSTO severe bleeding at 48 hours.

RESULTS Among 10,921 patients, 5,296 (48%) had single vessel disease (SVD) and 5,625 (52%) had multivessel disease (MVD). Patients with MVD were older (65 vs. 63 years), less often female (25% vs. 31%), and more often had diabetes (31% vs. 25%), hypertension (82% vs. 77%), and prior MI (25% vs. 16%). At 48 hours, MVD patients had higher rates of death/MI/IDR/ST (6.3% v 4.2%, p=<0.001), but not GUSTO severe bleeding (0.1% vs. 0.2%, p=0.71) compared with SVD patients. Consistent with outcomes in the overall population, cangrelor resulted in fewer death/MI/IDR/ST events compared with clopidogrel in patients with SVD (3.9% v 4.5%; OR 0.88, 95% CI 0.67-1.15) and with MVD (5.4% vs. 7.3%; OR 0.73, 95% CI 0.59-0.91), p-interaction=0.31. 30-day Kaplan-Meier estimates of death/MI/IDR/ST are shown in Figure 1. Bleeding rates were not different between cangrelor and
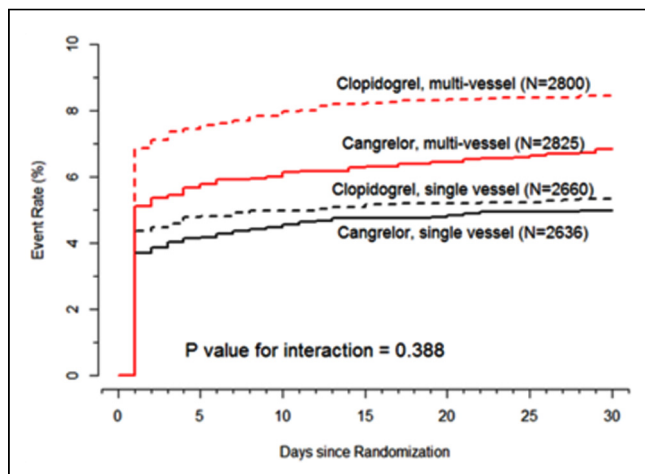
clopidogrel in either SVD or MVD patients (SVD: OR 3.04; 95% CI 0.61-15.06; MVD: OR 0.74; 95% CI 0.17-3.32; p-interaction 0.21).

CONCLUSIONS Patients with MVD compared to SVD had higher risk of ischemic complications after PCI but not severe bleeding. Cangrelor reduced ischemic complications compared with clopidogrel with consistent reductions in higher risk MVD patients and lower risk SVD patients with no significant increase in severe bleeding.

CATEGORIES CORONARY: PCI Outcomes

TCT-76

Six Versus Twelve Months of Dual Antiplatelet Therapy After Percutaneous Coronary Intervention With Biodegradable Polymer Sirolimus-Eluting Stents for Bifurcation Lesions: Insights From the I-LOVE-IT 2 Trial

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BACKGROUND Optimal duration of dual antiplatelet therapy (DAPT) after percutaneous coronary intervention (PCI) for complex coronary lesions and patients is still controversial. There is no randomized study investigating shorter (6 months) vs. standard (12 months) duration of DAPT after PCI for bifurcation lesions. We sought to report the 18-month results of the bifurcation substudy from the I-LOVE-IT 2 trial, which compared safety and efficacy between patients receiving 6- vs. 12-month DAPT after implantation of a novel biodegradable polymer sirolimus-eluting stent (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) pre-stenting; among them there were 717 patients (349 in 6-month DAPT group and 368 in 12-month DAPT group, respectively) with bifurcation lesions. The major endpoints were target lesion failure (TLF, a composite of cardiac death, target vessel myocardial infarction [TV-MI], or clinically indicated target lesion revascularization [CI-TLR]) and net adverse clinical and cerebral events (NACCE, a composite of all-cause death, all MI, stroke, or major bleeding [Bleeding Academic Research Consortium ≥ type 3]) at 18 months. Landmark analyses at 6 months were used to derive event rates between 6 and 18 months of follow-up.

RESULTS The demographic, lesion or procedural characteristics were similar between groups. Eighteen-month TLF rate was numerically higher in the 6-month DAPT group compared to the 12-month DAPT group (9.3% vs. 5.5%, p=0.055), which was mainly driven by an increased CI-TLR between 6 and 18 months (3.5% vs. 1.1%, p=0.03) in the 6-month DAPT group when patients have discontinued DAPT. There were no significant differences in NACCE, death, MI, stroke, and stent thrombosis (ST) at 18 months or between 6 and 18 months period of follow-up. However, there was a non-significant tendency of lower all bleeding events in favoring 6-month DAPT strategy according to the landmark analysis (1.2% vs. 3.3%, p=0.056). Major clinical outcomes were shown in table.

Table. Major Clinical Outcomes

	0-18 Months			6-18 Months (Landmark)		
	6-month DAPT Group n = 349	12-month DAPT Group n = 368	P	6-month DAPT Group n = 347	12-month DAPT Group n = 367	P
TLF	9.3 (32)	5.5 (20)	0.055	4.0 (14)	1.6 (6)	0.052
NACCE	8.7 (30)	6.6 (24)	0.30	2.6 (9)	3.0 (11)	0.74
All-cause Death	2.0 (7)	1.7 (6)	0.71	1.4 (5)	1.4 (5)	1.00
Cardiac Death	1.2 (4)	0.8 (3)	0.72	0.6 (2)	0.5 (2)	1.00
All MI	5.8 (20)	4.1 (15)	0.31	1.2 (4)	0.5 (2)	0.44
TV-MI	4.9 (17)	3.0 (11)	0.20	0.9 (3)	0.3 (1)	0.36
Stroke	2.0 (7)	1.7 (6)	0.71	1.2 (4)	1.4 (5)	1.00
Any Revascularization	6.1 (21)	5.5 (20)	0.74	4.9 (17)	3.3 (12)	0.27
TVR	4.4 (15)	3.0 (11)	0.35	3.5 (12)	1.4 (5)	0.07
CI-TLR	4.4 (15)	2.5 (9)	0.17	3.5 (12)	1.1 (4)	0.03
All Bleeding	4.1 (14)	6.1 (22)	0.23	1.2 (4)	3.3 (12)	0.056
Major Bleeding	0.3 (1)	0.6 (2)	1.00	0.3 (1)	0.3 (1)	1.00
Definite/Probable ST	0.6 (2)	0.3 (1)	0.62	0	0	-

CONCLUSIONS The present study indicates that 6 months of DAPT might be insufficient in patients after PCI (even with novel BP-SES) for