

TCT- 597 Two-Year Ischemic and Bleeding Outcomes After Coronary Intervention of Calcified vs. Non-Calcified Lesion Treated With Drug-eluting Stents: The ADAPT DES Study

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sirolimus, 8 frSES with 1 µg/mm² of sirolimus and 8 bare metal stents. Following 28 days, coronary angiography was performed, animals sacrificed and stented segments harvested for histopathological evaluation.

RESULTS In angiography at 28 days, the late lumen loss was lowest in the elevated dose SES (ed-frSES: 0.20±0.2 vs. frSES 0.80±0.5 vs. BMS: 0.96±0.5±0.5 mm, p<0.01). This was confirmed in the morphometric evaluation in histopathology as represented by significant and dose dependent decrease in percent area stenosis (ed-frSES: 22.4±12.7% vs. frSES: 35±10.7% vs. BMS: 47.5±12.5%; p<0.01). There was no peristrit inflammation in any of the groups. Endothelialisation score was numerically, however not meaningfully decreased in ed-frSES (ed-frSES: 2.93 vs. 3. vs. 3; p=0.05). Signs of fibrin were also noted in ed-frSES (ed-frSES: 0.4 vs. frSES: 0 vs. BMS: 0, p=0.05).

CONCLUSIONS Sirolimus dose dependent vascular response was reported. The elevated dose, fast releasing SES shows satisfactory vascular healing, similar to regular dose, fast release SES, with improved efficacy in restenosis inhibition.

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Porcine coronary artery, Sirolimus-eluting stent

TCT-597

Two-Year Ischemic and Bleeding Outcomes After Coronary Intervention of Calcified vs. Non-Calcified Lesions Treated With Drug-eluting Stents: The ADAPT-DES Study

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BACKGROUND Percutaneous coronary intervention (PCI) of coronary calcified lesions has been associated with worse clinical outcomes compared to non-calcified lesions. However, the impact of coronary calcifications (CC) two years after drug-eluting stent (DES) PCI is unknown. We sought to evaluate the frequency and impact of CC two years after DES PCI from the large ADAPT-DES registry.

METHODS ADAPT-DES was a prospective, multicenter “all-comers” registry of consecutive patients successfully treated with at least one DES. Two-year outcomes were analyzed according to the presence of CC as assessed by the enrolling site operator.

RESULTS A total of 8,578 patients underwent DES PCI; CC of at least one target lesion was present in 2,646 patients (30.8%). Patients with CC were older, more frequently had diabetes, hypertension, dyslipidemia, renal insufficiency, left main or LAD disease, and multivessel intervention, with more stents implanted. IVUS was used equally in both groups. Second-generation DES were implanted less frequently among patients with CC (60.5% vs. 64.7%, p=0.0002). At two years, CC patients had higher unadjusted rates of adverse ischemic and bleeding events (Table). By multivariable analysis, the presence of CC was a strong independent predictor of death (HR [95%CI] = 4.92 [1.29, 18.80]), myocardial infarction (HR [95%CI] = 1.67 [1.26-2.23],

p=0.0004), MACE (HR [95%CI] = 1.82 [1.37, 2.41], p<0.0001 and major bleeding (HR [95%CI] = 1.76 [1.44-2.16], p<0.0001).

	Calcified lesions (N=2,646)	Non-calcified lesions (N=5,932)	P-value
All-cause death	4.8% (124)	3.5% (192)	0.003
Cardiovascular	2.8% (73)	2.3% (124)	0.09
Non-cardiovascular	2.0% (51)	1.2% (68)	0.008
Myocardial infarction	6.4% (135)	4.0% (226)	<0.0001
ST definite/probable	1.2% (30)	1.1% (63)	0.82
Any revascularization	21.7% (574)	19.7% (1167)	0.03
Clinically-driven TVR	10.0% (264)	8.8% (525)	0.09
Clinically-driven TLR	5.8% (153)	5.4% (322)	0.50
Target vessel failure	18.2% (471)	14.2% (801)	<0.0001
MACE*	12.8% (329)	9.9% (556)	<0.0001
Major bleeding	14.0% (370)	6.2% (369)	<0.0001

Values are Kaplan-Meier estimates presented as % (n). TVR = target vessel revascularization; ST = stent thrombosis; TLR = target lesion revascularization; *MACE = major adverse cardiovascular events, defined as the composite of cardiac death, myocardial infarction, or ischemia-driven target lesion revascularization; target vessel failure = the composite of cardiac death, target vessel revascularization, and MI.

CONCLUSIONS Target lesion CC as assessed by the interventionalist is relatively frequent, being present in approximately one-third of patients undergoing PCI. CCA was strongly predictive of adverse ischemic and bleeding events 2 years after DES PCI.

CATEGORIES CORONARY: Stents: Drug-Eluting

TCT-598

Revascularization strategies for patients with multiple vessel disease and unprotected left main with a cobalt-chromium rapamycin eluting stent (ERACI IV Registry)

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BACKGROUND Multiple coronary artery disease (CAD) including diabetic patients (pts) remained a challenge for percutaneous coronary interventions (PCI). Introduction of newer generation of drug eluting stent (DES) significantly improved safety and efficacy compared with the previous ones although its value in pts with complex CAD in comparison with 1st generation DES is not established yet.

METHODS From March 2013 to February 2014, 225 pts with complex CAD undergoing DES implantation in 15 centers in Argentina were prospectively included. The registry was approved by local regulatory authorities and monitored by an independent safety committee. Primary endpoint was to assess the incidence of major adverse cardiovascular events (MACCE) defined as death, myocardial infarction (MI) stroke and unplanned new revascularization (TVR) using Firebird-2 (2nd generation chromo-cobalt rapamycin eluting stent, Microport Medical Co, Shanghai) vs. ERACI III population (DES arm) at long term follow-up. Inclusion criteria were indication of myocardial revascularization in 2, 3 major coronary arteries and/or unprotected left main disease (ULMD). Exclusion criteria were poor ejection fraction (<35%), recent ST elevation MI, previous DES, lesion diameter < 2.5 mm, renal failure and contraindications for dual antiplatelet therapy (DAPT). Stent thrombosis was analyzed. All revascularization was done by intention-to-treat-principle and operator’s advice was to treat only lesions ≥ 70% of diameter stenosis in vessels with, at least, 2.0 mm of reference diameter, to fulfill a modified in SYNTAX score. In ERACI IV the only DES allowed was Firebird-2, whereas in ERACI III 1st DES generation was used. All patients received DAPT for one year.

RESULTS Mean age of the 225 pts was 64.5 +/- 11.0 years, with 30.6% diabetics and 67.7% with 3 vessels or ULMD. Modified SYNTAX score was 22 +/- 11 and we implanted 1.7 +/- 1.8 Firebird-2 per patient, similar to the ERACI III DES arm (1.79), p=0.8. Stent length was 41.4 mm +/- 10.8 vs 36.1 mm +/- 8.9 in ERACI IV and ERACI III,