TCT-50

Impact of a bifurcation culprit lesion in ST elevation myocardial infarction: procedural success, clinical outcome and 5-year follow-up.

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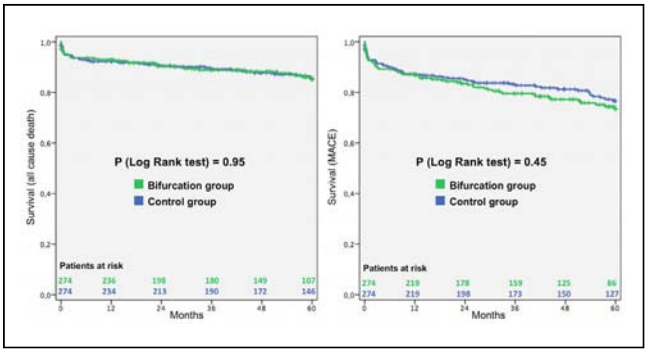
BACKGROUND Coronary artery bifurcation is a challenging scenario for percutaneous coronary intervention (PCI). We aimed to assess the impact of a bifurcation culprit lesion in the setting of primary PCI for ST elevation myocardial infarction (STEMI).

METHODS From 2747 STEMI patients (January 2004 to January 2015) undergoing primary or rescue PCI (<24h from symptoms) at our institution, we selected those with a bifurcation culprit lesion (BIF group: culprit lesion involving or adjacent [≤5 mm] to a sidebranch ≥2 mm). Left main or surgical graft lesions, and facilitated PCI patients were excluded. A total of 274 (10%) patients met inclusion criteria. From the remaining population, using propensity score matching, a control group of 274 non-bifurcation STEMI patients was selected. Variables included in the propensity score were age, sex, diabetes, previous MI, culprit vessel, number of diseased vessels, rescue PCI, and time from symptoms onset to PCI. MACE was composed of all-cause death, MI, CABG or target vessel revascularization. Follow-up data for the 548 patients was collected until 5 years after index PCI (mean 42.9±21.4 months).

RESULTS Baseline characteristics showed no differences after propensity score matching (mean age 62±14 BIF vs. 63±13 control, p=0.75; male 79% BIF vs. male 79% control, p=1; rescue PCI 17.5% BIF vs. 16.1% control, p=0.65). In the BIF group, the sidebranch was wired in 66.1% and provisional stenting was the preferred approach (84%); two-stent techniques were used in 8.7% and no stent (balloon or thrombectomy alone) in 7.3%. Compared to controls, more patients in the BIF group underwent any kind of balloon dilatation (73% BIF vs. 59% control, p=0.001) and received a drug eluting stent (63% BIF vs. 54% control, p=0.04). Procedural time and contrast use was higher in the BIF group (70±29 minutes vs. 62.8±28.9 minutes, p=0.004 and 256.2±87.9 ml vs. 221.1±82.3 ml, p<0.001). Main branch angiographic success was similar (93.4% BIF vs. 93.8% control, p=0.86), although in the BIF group global success (including sidebranch) was 84.7%. Thirty-day events were similar (mortality 4.7% BIF vs. 5.1% control, p=0.84, RR 0.96 [0.64 - 1.43]; MACE 7.3% BIF vs. 7.0% control, p=0.88, RR 1.03 [0.75 - 1.41]). Mean 5-year survival (54.2±1 months BIF vs. 54.1±1 months control) and MACE-free survival (49.2±1.3 months BIF vs. 50.6±1.2 months control) were similar (Figure). Individual components of MACE showed no statistical differences, although TVR and CABG were numerically more frequent in the BIF group.



CONCLUSION Primary PCI in a bifurcation culprit lesion is technically more complex, with increased procedural time and contrast use. However, main branch angiographic success is similar, and there are no differences in prognosis compared to non-bifurcation culprit lesions.

CATEGORIES CORONARY: PCI Outcomes

TCT-51

In hospital and one month outcomes of 983 patients implanted with bioresorbable vascular scaffolds for Acute Coronary Syndroms ; subgroup of the prospective, all comers, controlled, multicenter, FRANCE ABSORB Registry.

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BACKGROUND Aims : before agreing for reimbursment of the Absorb (ABBOTT) Bioresorbable Vascular Scaffold (BVS), French Health Authorities required a prospective, multicentered, controlled registry with five years follow up, including all BVS implanted in France. According to a supposed higher thrombosis risk of BVS over metallic stents, we investigated the subgroup of patients implanted in the setting of Acute Coronary Syndroms ; we report in hospital and 30 days outcomes of these patients

METHODS From September 2014 to April 2016, 2089 patients entered the Registry "France Absorb", held by the GACI group of the French Society of Cardiology, opened in 87 centers nationwide. Of these, 983 were implanted for STEMI (350), NSTEMI (425) or unstable angina (208).

RESULTS 1 251 BVS covered 1 117 lesions. 78% were men ; mean age was 52 (19-87). 18% had a past history of coronary artery desease, 12% suffered Diabetes and 54% were current smokers. 65% had single vessel desease ; mean left ventricular ejection fraction was 57%. Radial approach was performed in 91%. 88% of the lesions were classified B1/B2/C. Mean BVS length was 22.5 +/- 8.5 mm (12-84). BVS nominal diameter was 2.5 mm in 21%, 3.0 in 40% and 3.5 in 39%. No stent delivery failure. 69% post dilatation rate with non compliant balloons. Heparin used in 97% of cases, Bivalirudin in 2%. All patients, except 1%, were discharged with dual antiplatelet therapy. In hospital and one month outcomes : 4 patients (0.4%) died, 2 in hospital (one stent thrombosis) and 2 within 30 days. At 30 days 12 patients (1.2%) experienced stent thrombosis.

CONCLUSION This prospective all comers registry suggests that BVS implantation can be safely realized in acute coronary syndroms with an acceptable risk of major events, provided rigouros implantation rules are respected. The registry patients young age and the high rate of acute coronary syndroms included (47%) attest the present indications of BVS chosen by French Interventionnal Cardiologists.

CATEGORIES CORONARY: Stents: Bioresorbable Vascular Scaffolds

TCT-52

Proportion and Morphological Features of Restenosis Lesions with Acute Coronary Syndrome in Different Timings of Target Lesion Revascularization after Sirolimus-Eluting Stent Implantation

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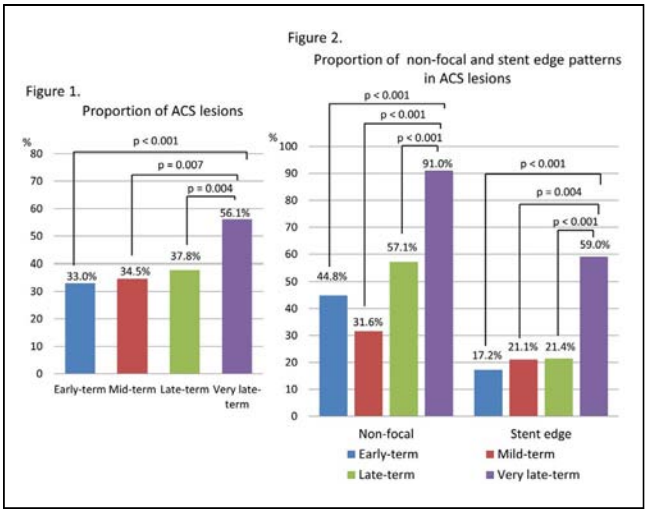
BACKGROUND Target lesion revascularization (TLR) is consistently observed after sirolimus-eluting stent (SES) implantation. Acute coronary syndrome (ACS) can be also occurred due to the early, late, and very late SES restenosis lesions. However, the proportion and morphological features of restenosis lesions with ACS in various timings of TLR are unknown.

METHODS From 2002 to 2007, SES was implanted in 4097 lesions (2101 patients). Among them, clinically driven TLR (for asymptomatic proven ischemia, effort angina, and ACS) was required in 88 lesions in

early (<1 year), 55 lesions in mid (1 to 2 years), 111 lesions in late (2 to 5 years), and 139 lesions in very late term (5 to 14 years). The median period from SES implantation to TLR was 206 days (interquantile range [IQR] 114 to 254 days) in early TLR, 604 days (IQR 462 to 637 days) in mid TLR, 1334 days (IQR 1023 to 1600 days) in late TLR, and 2458 days (IQR 2144 to 3015 days) in very late TLR. Morphological pattern was divided into focal or non-focal and stent edge or body patterns.

RESULTS The proportion of ACS in the TLR lesions substantially increased from late-term to very late-term (Figure 1), and it was significantly higher in the very late TLR lesions (56.1%) than in the early (33.0%, p<0.001), mid (34.5%, p=0.007), and late TLR lesions (37.8%, p=0.004). Both diffuse lesions and stent edge patterns in the ACS lesions were observed more frequently during the very late-term compared to the early, mid, and late-term (Figure 2).



CONCLUSION ACS due to SES failure became more common during the very late phase. Diffuse and stent edge restenosis was the main morphology of very late stent-related ACS beyond 5 years after SES implantation. Our findings suggest that the mechanisms of very late SES failure differ from those of late SES failure within 5 years after implantation.

CATEGORIES CORONARY: Acute Coronary Syndromes

ADJUNCT PHARMACOLOGY II: ACUTE AND CHRONIC ANTITHROMBOTIC TREATMENTS

Abstract nos: 53 - 56

TCT-53

Thromboembolic event rate is elevated with lower adherence to warfarin and NOACs

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BACKGROUND Non-vitamin K antagonist oral anticoagulants (NOACs) obviate the need for frequent blood testing, and showed equivalent or better thromboembolic event rates than warfarin in controlled trials of patients with non-valvular atrial fibrillation (NVAF). With interventional procedures emerging as an alternative to chronic anticoagulation, we sought to determine if the findings from NOAC clinical trials are similarly observed in everyday practice.

METHODS This real-world retrospective study used MarketScan® administrative claims for U.S. patients with private or Medicare supplemental insurance and a linked prescription drug plan from 2010 to 2014. Inclusion criteria were a prescription in 2012 or 2013 for warfarin or a NOAC, diagnosis of NVAF and at least one year of prior claims history. Patients were excluded if there was previous heart surgery, CHA2DS2-VASc <2, or anemia. Adherence was measured as the fraction of days covered by a prescription for anticoagulants. Patients with <40% adherence, who may have had a temporary indication, were excluded. Those remaining were classified as having higher (>80%) or lower (40-80%) adherence. Thromboembolic event rate, including any inpatient hospitalization with diagnosis of ischemic stroke or systemic embolism, was tabulated separately for patients with warfarin and NOACs, and hazard of events was evaluated with multivariable Cox regression.

RESULTS The study cohort included 158,325 patients (age 74±11 years, 44% female) followed for 300,614 pt-yrs, with 43,368 (27%) prescribed NOACs. Thromboembolic event rate was 2.41 per 100 pt-yrs for warfarin and 1.93 for NOACs. Only 52% of those prescribed warfarin and 69% of those prescribed NOACs achieved higher (>80%) adherence. Compared to warfarin with higher adherence, the HR for thromboembolic events was 1.46 (p<0.001) for pts with lower adherence to warfarin, and 1.68 (p<0.001) for those with lower adherence to NOACs. The latter group experienced 3.17 events per 100 pt-yrs.

Group	No. of pts	Events/100 pt-yrs	% w/ event at 1 yr	Adj. HR* [95% CI]	P value
Warfarin, higher adherence (>80%)	59,642	1.90	1.72%	1.00 (reference)	-
Warfarin, lower adherence (40-80%)	55,315	2.95	2.54%	1.46 [1.38, 1.55]	<0.001
NOAC, higher adherence (>80%)	29,993	1.50	1.36%	0.84 [0.77, 0.91]	<0.001
NOAC, lower adherence (40-80%)	13,375	3.17	2.85%	1.68 [1.53, 1.84]	<0.001

CONCLUSION A sizeable fraction of patients taking oral anticoagulants do not achieve adherence above 80%. For those with lower adherence, thromboembolic event rate is 46% higher for warfarin and 68% higher for NOACs than for patients with higher adherence to warfarin.

CATEGORIES CORONARY: Pharmacology/Pharmacotherapy

TCT-54

LEADERS FREE OAC : Biolimus A9 coated versus bare metal stents in patients requiring oral anticoagulation. A pre-specified subgroup analysis of the LEADERS FREE trial

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BACKGROUND The optimal choice of stent and antithrombotic therapy for patients (pts) at high bleeding risk (HBR) remains controversial because of concerns regarding long-term dual antiplatelet therapy (DAPT). Recently, the LEADERS FREE trial documented that a polymer-free Biolimus A9- Drug Coated Stent (DCS) was superior to a bare-metal stent (BMS) in HBR pts when used with a 1-month course of dual antiplatelet therapy.The present pre-specified subgroup analysis focuses on pts included in LEADERS FREE for reason of concomitant (OAC) planned to continue after PCI.

METHODS Among 2466 pts randomized in the LEADERS FREE trial, we studied a pre-specified sub-group of 879 pts (35.6%) for whom continued long term OAC after the index PCI was planned. Adjudicated primary safety (cardiac death, myocardial infarction, stent thrombosis) and efficacy endpoints (clinically driven TLR) and bleeding events (BARC defined) during a 390 day follow-up period were evaluated. Of the 879 pts, 448 pts received DCS and 431 pts BMS.The groups were