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Clinical outcomes with the state-of-the-art PCI for the treatment of bifurcation lesions: a sub-analysis of the SYNTAX II study

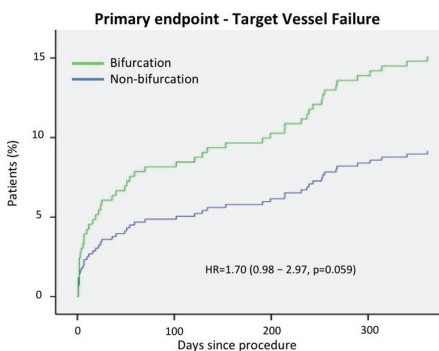
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Background: Bifurcation lesions augments SYNTAX score thus increasing risk and clinical outcomes after percutaneous coronary intervention (PCI). Its impact has been explored in multiple studies. However, clinical outcomes regarding bifurcation treatment with the new generation stent and all the interventional cardiologist armamentarium have not been tested in the context of a multicenter, all-comers study.

Purpose: To determine the impact of bifurcation treatment on clinical outcomes with state-of-the-art PCI (heart team decision-making using the SYNTAX score II, physiology guided coronary stenosis assessment, thin strut bioresorbable polymer drug-eluting stent and intravascular ultrasound – IVUS – guidance).

Methods: A sub-analysis of the SYNTAX II study stratified by the treatment of > 1 bifurcation vs non-bifurcation lesions. The primary endpoint was the occurrence of target vessel failure (TVF) defined as cardiac death, target-vessel myocardial infarction (TVMI) and ischemia-driven target vessel revascularization (IDTVR). Four hundred and forty-seven subjects were included (bifurcation lesions n=159 and non-bifurcation n=288).

Results: True bifurcations were observed in 61.6%, and Medina 1,1,1 was observed in 34% of patients in the bifurcation group. Two-stent techniques were used in 23% patients; the most commons were: Culotte 27%, Minicrush 21.6%, Trouser legs and seats 18.9% and TAP 13.5%. In the bifurcation group, final kissing balloon was performed in 36.5%. At one year, the TVF occurred in 50 patients, with a trend towards higher rate in the bifurcation group (15.1% vs. 9.0%, hazard ratio [HR] of 1.70, CI 95% 0.98 to 2.97, p=0.059). Cardiac death (1.9% vs. 0.7%, HR 2.70, CI 95% 0.45 to 16.17, p=0.28), clinically-driven TVR (6.9% vs. 4.5%, HR 1.54, CI 95% 0.69 to 3.45, p=0.29), and TVMI (7.5% vs. 4.2%, HR 1.82, CI 95% 0.82 to 4.04, p=0.14) did not differ between the bifurcation and non-bifurcation groups. TVF occurred in 13.5% patients with 2-stent technique and in 15.5% subjects with 1-stent technique (p=0.50).



Conclusion: Bifurcation treatment in patients with three vessel disease undergoing state-of-the-art PCI was associated with a trend towards higher incidence of TVF compared with non-bifurcation lesions.

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Vascular healing responses to paclitaxel coated balloon or everolimus eluting stent treatment in vessels with in-stent restenosis

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Purpose: To compare OCT-based vessel healing patterns after paclitaxel coated balloon (PCB) or everolimus eluting stent (EES) treatment of coronary in-stent restenosis (ISR).

Methods: The present study included cases from the RIBS IV and RIBS V, 2 prospective multicenter, controlled, randomized clinical trials that compared PCB vs EES in patients with DES-ISR (RIBS-IV) or BMS-ISR (RIBS-V). The trials included an OCT substudy that comprised OCT evaluation at baseline and at 6–9 months follow up.

Results: Sixty-four patients were included in the OCT substudy at baseline (30 treated with PCB and 34 with EES). Patients were randomized to treatment with PCB or EES. There were no differences in the baseline or angiographic characteristics of patients treated with PCB or EES. Both groups had the same proportion of DES and BMS ISR.

Baseline OCT analysis did not show differences in the characteristics of the ISR regarding restenotic tissue structure, presence of neoatherosclerosis, microvessels, intraluminal material, irregular lumen shape, peristrut low intensity area or macrophages. Quantitative evaluation did not show differences in the restenotic tissue area or burden between patients treated with PCB or EES.

There were no differences between patients treated with PCB or EES regarding procedural characteristics (balloon to artery ratio, pressure, length of the new PCB/EES). Acute angiographic result was better with EES (acute gain was higher 1.82 ± 0.5 vs 1.18 ± 0.4 mm $p=0.004$, minimum lumen diameter (MLD) was larger 2.53 ± 0.4 vs 1.96 ± 0.3 mm $p<0.001$, % diameter stenosis (%DS) was lower 4 ± 12 vs $19 \pm 10\%$ $p<0.001$). At angiographic follow up MLD was larger in EES (2.11 ± 0.8 vs 1.76 ± 0.5 mm $p=0.047$) but there were no differences in %DS or restenosis rate.

Follow up OCT showed a larger mean lumen area in the EES group as compared with the PCB group (6.03 ± 1.5 vs 5.24 ± 1.3 , $p=0.043$) with no differences in the minimum lumen area. Regarding vessel healing, tissue coverage burden was higher in patients treated with PCB vs those treated with EES (26 ± 13 vs $19 \pm 11\%$ $p=0.031$). The group treated with EES had more frequently struts not covered by tissue than the patients treated with PCB 21 (72%) vs 12 (44%) $p=0.034$. Tissue covering struts at follow up had more frequently a high backscattering structure in the group treated with PCB 21 (78%) vs 16 (55%) $p=0.07$. There were no significant differences in other characteristics of the tissue coverage such as the presence of microvessels or peristrut low intensity areas. Evaginations were observed in 2 patients treated with EES but were not visible in any of the patients treated with PCB ($p=0.17$).

Conclusions: Compared with EES treatment, ISR treated with PCB showed a more favourable healing pattern with a larger neointimal proliferation of high backscattering tissue and a lower frequency of uncovered struts. Yet, larger OCT-defined neointimal proliferation in PCB-treated ISR did not translate into higher angiographic restenosis rates.

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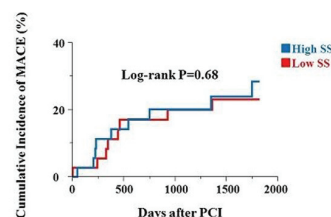
Impact of SYNTAX score on 5 years clinical outcomes in patients treated with cobalt-chromium everolimus-eluting stent for unprotected left main disease

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Background: Impact of SYNTAX score (SS) on long-term clinical outcomes after cobalt-chromium everolimus-eluting stent (CoCr-EES) implantation for unprotected left main disease (ULMD) remains unclear.

Methods: Between February 2010 and May 2011, 1064 consecutive patients with 1440 lesions were treated only with CoCr-EES implantation. Of these, the SS was calculated in 74 patients with 74 lesions for ULMD. Patients were divided into two groups: two groups for SS (low SS [6–15], n=37; and high SS [16–48], n=37). We assessed the cumulative 5-year incidences of major adverse cardiac events (MACE), defined as a composite of cardiac death, myocardial infarction, definite stent thrombosis, and clinically driven target lesion revascularization (CDTLR) based on SS groupings.

Results: Baseline patients and lesion characteristics were similar between low SS and high SS groups. No significant differences were observed with regard to lesion location (distal bifurcation lesion; 62.2% vs. 81.1%, $p=0.07$) and number of stent strategy (single stent strategy; 56.8% vs. 56.8%, $p=1.0$) between the two groups. Cumulative 5-year incidence of MACE rate was not significantly different between the two groups (23.1% vs. 28.4%, $p=0.68$). The cumulative incidence of cardiac death, myocardial infarction, stent thrombosis and CDTLR were similar between the two groups (5.7% vs. 9.4%, $p=0.63$; 8.8% vs. 0%, $p=0.09$; 2.7% vs. 0%, $p=0.90$; 14.8% vs. 26.5%, $p=0.33$, respectively).



Days	0	365	1095	1825
High SS group				
No of lesions at risk	37	31	25	16
Cumulative incidence		11.3%	20.1%	28.4%
Low SS group				
No of lesions at risk	37	32	28	21
Cumulative incidence		11.2%	20.0%	23.1%

Figure. Kaplan-Meier Plot of Cumulative Incidences of MACE Through 5-Year Follow-up

Conclusions: For ULMD patients, SS has no significantly impact on 5 years clinical outcomes after CoCr-EES implantation.