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Differences in Safety Profile Between Second Generation Drug-eluting Stents. Subgroup Analysis at 2 Years From the ESTROFA-2 Spanish Registry.

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Background: The ESTROFA-2 registry provided 2 years incidence and predictors of thrombosis with the zotarolimus-eluting stent (ZES) Endeavor Sprint TM and the everolimus-eluting stent (EES) Xience V TM in 4,768 patients. In the present analysis we compare the safety profile of both stents in different clinical and lesional subsets.
Methods: We obtained and compared the incidence of thrombosis for both stents in several subgroups based on age, sex, diabetes, clinical setting, ejection fraction, stent length, stent diameter and lesion characteristics. After propensity score matching we obtained the hazard ratios for thrombosis for each stent model in every subgroup. A multivariate analysis was performed in these matched subgroups in order to identify predictors for thrombosis. This registry is supported by the Spanish Working Group on Interventional Cardiology.
Results: From 2005 to 2008, 4,768 pts have been included in 34 centers, 2549 treated with ZES and 2,219 treated with EES. Among all the analyzed subgroups only in bifurcations a significantly different incidence was found. Incidence of definite + probable thrombosis was 3.3% at 1 year and 3.9% at 2 years for 470 pts treated with ZES and was 1.1% at 1 and 2 years for 464 pts treated with EES (p=0.02). Again, in the matched groups only in the bifurcation subgroup the risk was significantly different (HR for ZES 5.4;CI 95%1.2-25:p=0.02). In the bifurcation matched subgroup the use of ZES resulted an independent predictor for thrombosis (adjusted HR 4; CI 95% 1.1-13: p=0.03). The use of two stents techniques tended to be more frequent in thrombosis cases (27.5% vs 13.8%: p= 0.06), however this approach was comparable in both stent groups (12.8% with EES y 14.9% with ZES: p=0.4).
Conclusions: In a real practice setting EES and ZES have shown a similar safety profile, except in pts with bifurcations treated. In these cases the use of ZES is associated to a significantly higher incidence of stent thrombosis.

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Treatment and Long-Term Follow-up of Patients Experiencing Definite Stent Thrombosis Post-Drug Eluting Stent Implantation

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Background: The treatment and clinical follow-up (FU) of patients undergoing stent thrombosis (ST) post drug-eluting stents (DES) implantation remains controversial. We report the long-term FU of patients with definite ST post implantation of DES in the real-world clinical practice.
Methods: The DESIRE Registry is a large, prospective, non-randomized clinical trial evaluating the long-term clinical follow-up of patients undergoing elective or urgent percutaneous coronary intervention (PCI) with DES as the default strategy in a single center. From 05/02 to 02/10, 3,320 pts (4,925 lesions) were treated with 5,320 DES. Clinical FU was performed at 1, 6 and 12 months, and annually up to 8 years (median = 3,8 years). ST was defined according to the Academic Research Consortium criteria, including definite ST as clinical presentation of acute coronary syndrome with angiographic confirmation of stent occlusion (or pathological evidence of stent occlusion).
Results: During the clinical FU up to 8 years (completed in 98%), the overall incidence of ST was 1.6% (52/3,320), including 34 cases (65%) of definite ST (with angiographic confirmation). The mean time from index procedure to the occurrence of definite ST (n=34) was 1.8±1.9 years [10 cases in the subacute phase (<30 days); 8 cases in the late phase (1-12 months); 16 cases in the very late phase (>1 year)]. The treatment of the ST event was: PCI with balloon angioplasty only in 14 cases; PCI with bare metal stent in 8 cases; PCI with DES in 1 case; unsuccessful attempt to PCI (unable to successfully cross the lesion with a guidewire and/or restore flow in the target lesion) in 3 cases; coronary artery bypass graft surgery in 1 case; thrombolytic therapy in 3 cases, and conservative treatment in 4 cases. In the late clinical follow-up (post ST) (mean time: 24 months), 56% of patients were asymptomatic, 21% had cardiac death, 9% non-cardiac death, 12% stable angina, and 2% presented with cardiac heart failure. In addition, the mean time from ST to cardiac death was 3 months.
Conclusions: Pts experiencing definite ST post DES implantation with angiographic confirmation may benefit from reperfusion therapy in the majority of cases; however, such event is still associated with high mortality in the long-term follow-up.

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One Year Clinical Outcome of a Large, Unselected Patient Population Treated with a New Generation Drug Eluting Stent: NOBORI 2 Study

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Aims: Drug eluting stents (DES) with biodegradable polymer are the promising new treatment option for patients with coronary artery disease. We conducted a large study to assess, in a real life setting, the outcomes of patients treated with Nobori, a new generation DES, coated only abluminally with a matrix of biodegradable polymer and Biolimus A9.
Methods: In total 3068 consecutive patients eligible for treatment with drug eluting stent in 125 centres across Europe and Asia were treated with Nobori DES are enrolled in the NOBORI 2 study. Patients were stratified in: On-label and Off-label groups, the latter composed of patients mainly outside of the indications proven in pivotal trials. Primary endpoint is target lesion failure (TLF), a composite of cardiac death, MI and target lesion revascularization (TLR) at 1 year, with numerous safety and efficacy secondary endpoints. Data are extensively monitored and at 12 months 97% of patients were available for FU. All adverse events are adjudicated by an independent clinical event committee .
Results: In this real-world population 71.4% of patients were treated for Off-label indications. The most frequent Off-label use was acute MI, bifurcation, occlusion, in-stent restenosis, SVG. Patients in Off-label use were more frequently male, had higher incidence of unstable angina and history of MI. Lesions in Off-label group were more complex, more frequently ostial, thrombotic and calcified. By QCA assessment lesions in Off-label group were significantly longer, with higher %DS. At 12 months follow-up primary endpoint of TLF was reached in 99 patients (4.5%) in Off-label group and 13 patients (1.5%) in On-label group (p<0.001). In Off-label group 26 patients (1.2%) died, 41 patients (1.9%) suffered MI and 50 patients (2.3%) underwent re-PCI of the target lesion. In On-label group 5 patients (0.6%) died, 5 patients (0.6%) suffered MI and 4 patients (0.5%) underwent re-PCI of the target lesion. Stent thrombosis rate was 0.7% in Off- and 0.5% in On-label treated patients (p=NS), all stent thromboses were early except two (0.1%) in Off-label group and one (0.1%) in On-label group.
Conclusions: Across subsets of challenging lesions and high-risk patients excellent one year TLF and particularly late stent thrombosis have been observed. The results of this largest so far series of consecutive patients give further indication of potential benefit of Nobori DES for treatment of patients with CAD.

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A Comparison of Everolimus- and Sirolimus-eluting Stents in Patients with Obstructive Coronary Artery Disease: A Retrospective Analysis of the Washington Hospital Center Registry

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Background: The safety and efficacy of second-generation drug-eluting stents have been well established in both randomized clinical studies and registries. Compared to the paclitaxel-eluting stent [Taxus, Boston Scientific, USA], the everolimus-eluting stent [EES] [Abbot Laboratories, USA] has been shown to be associated with reduced rates of target lesion revascularization [TLR]. Currently, however, there is limited information regarding the performance of the EES compared to the sirolimus-eluting stent [Cypher, Johnson & Johnson, USA] in routine clinical practice.
Methods: The study cohort comprised 5,338 consecutive patients who underwent coronary artery stent implantation with either the Cypher stent [4,736] or the EES [602] for the full spectrum of obstructive coronary artery disease. Patients who received a bare metal stent, a Taxus stent or two different drug-eluting stents were excluded. The primary end point was major adverse clinical events [MACE] defined as all-cause mortality, Q-wave myocardial infarction [MI] or TLR at 6 months. The secondary end point was the composite of all-cause mortality or Q-wave MI.
Results: The two groups were well matched for the conventional risk factors for coronary artery disease. Following multivariable analysis, the cohorts did not differ in the 6-month rate of the primary end point [hazard ratio=1.06; 95% confidence interval=0.76-1.49; p=0.72]. There were no differences in any of the components of the secondary end point: all-cause mortality [hazard ratio=0.76; 95% confidence interval=0.45-1.29; p=0.31], and all-cause mortality or Q-wave MI [hazard ratio=0.78; 95% confidence interval=0.46-1.33; p=0.36]. Definite stent thrombosis rates were low and did not differ between groups [0.2% vs. 0%; p>0.5].
Conclusion: This study suggests that the use of EES in routine clinical practice is both safe and effective but offers no advantage in terms of hard end points over the Cypher stent.

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The PLUS-ONE First-in-Man (FIM) Study: Safety and Efficacy of Low-Dose Paclitaxel and the COBRA-P Drug-Eluting Stent System with a Novel Biodegradable Coating in *de novo* Coronary Lesions

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Aims: First generation DES have markedly reduced restenosis and late stent thrombosis rates. However, there is a major interest in developing new DES with greater deliverability, radiopacity and improved safety profile. The Cobra-P stent is a novel second generation DES that combines a cobalt chromium stent platform with a low dose of paclitaxel, incorporating a bioabsorbable sol-gel matrix coating to achieve therapeutic efficacy. As potential advantages, it provides a very low drug dose as compared to the Taxus stent (8 µg on Cobra vs. 120 µg Taxus) and a non-polymeric coating that fully erodes within 6 months. We sought to evaluate safety and efficacy of this novel device in reducing neointimal hyperplasia as assessed by QCA and IVUS.
Methods and Results: A total of 54 subjects with *de novo* lesions up to 20 mm in length, located in native coronaries from 3.0 to 3.75 mm were included in two cohorts, 30 patients with 30 lesions in group A (4 µg paclitaxel) and 24 patients with 30 lesion in group B (8 µg paclitaxel). Dual anti-platelet therapy was maintained for a minimum of 6 months. Angiography and IVUS were done at baseline and at 4 months. The primary endpoint was MACE at 4 months defined as cardiac death, MI (Q wave and non-Q wave), and ischemia-driven TLR. Secondary endpoints included QCA lumen loss and in-stent neointimal volume by IVUS at 4-month follow- up, as well as MACE at hospital discharge, 30-days and 4-month, in-stent and in-segment binary restenosis rate (%) by QCA. The mean reference vessel diameter was 2.58±12 and 2.57mm. All 54 patients were clinically followed up to 1 year. Fifty-

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two (52) patients and 58 lesions were evaluated by angiography and IVUS at 4 months.
MACE at four-month was 3.3 and 0 respectively and remained unchanged at one year follow-up. Four month in-stent late loss was similar in both groups: 0.36±0.30mm and 0.34±0.27mm respectively. In-segment late loss was 0.20±0.33 mm and 0.33±0.33 mm respectively. Serial IVUS analysis was available for 28 patients and 28 lesions in group A and 23 patients and 28 lesions in group B. The neointimal volume was 13.5±9.5 mm^2 and 13.5±9.5 mm^2 respectively. There was no stent thrombosis.
Conclusion: In this FIM study, implantation of the Cobra-P low dose(LD)PES with a bioabsorbable sol gel coating was proven to be feasible and safe. Minimal neointimal proliferation was observed as well as an acceptable MACE rate at 4-months and 1 year. Additional large clinical trials should be considered to confirm the promising early results.

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Long Term Outcome Following Treatment Of Drug Eluting Stent Restenosis

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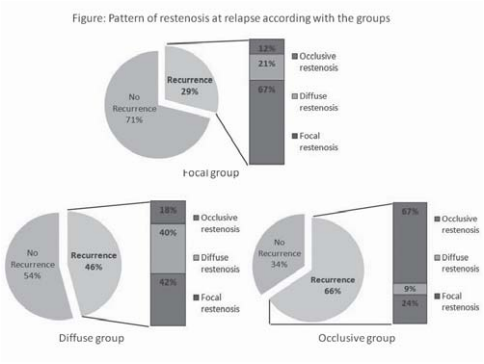
Background: Long-term outcomes following percutaneous treatment of drug-eluting stent restenosis (DES-ISR) are unclear.
Methods: Retrospective analysis of 481 consecutive de novo DES-ISR lesions (392 patients) treated percutaneously between August'02 and July'07. We divided lesions based on the pattern of restenosis: focal (305; 63.4%), diffuse (120; 24.9%), occlusive (56; 11.6%).
Results: Majority (65%) of patients had angina or ischemia on presentation and 13% an ACS. Angiographic follow-up was available in 65.5% of lesions. In comparison to the focal group (29.1%), angiographic restenosis was significantly higher in the diffuse (45.8%; p=0.007) and occlusive groups (65.6%; p<0.0001). The pattern of DES-ISR predicted the pattern of recurrence (See Figure). During a median follow-up of 2.97 years (IQR 2.37-3.89), MACE occurred in 32.8% with no differences between the focal, diffuse and occlusive (30.9%, 38.7%, 31.1%; p=0.38). Diffuse restenosis was associated with a significantly higher TLR rate compared to focal (27.1% vs. 15.8%; p=0.008). A disparity between restenosis (65.6%) and TLR (18.5%) rates for occlusive DES-ISR suggests that in the occlusive group many recurrences were not treated. Diffuse restenosis (HR 2.05, 95% CI 1.30-3.22; p=0.02) and previous CABG were the only independent predictors of TLR. For recurrent restenosis, both diffuse (HR 2.19, 95% CI 1.42-3.38; p<0.0001) and occlusive (HR 4.86, 95% CI 2.82-8.34; p<0.0001) patterns of restenosis as well as previous CABG were predictive.



Conclusions: DES-ISR identifies a high-risk cohort that is at increased risk of events, in particular repeat revascularization, during long-term follow-up. The initial pattern of restenosis is the most important predictor of recurrent restenosis or the need for subsequent re-intervention.

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Five Years Follow-up of DIABETES Trial: The final results

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Background: The DIABETES (DIABETes and sirolimus Eluting Stent) trial is a prospective, multicenter, randomized, controlled trial aimed to demonstrate the efficacy of sirolimus-eluting stent (SES) implantation as compared to bare metal stent (BMS) in diabetic patients (pts). The aim of this study was to assess the 5-year clinical follow-up of the pts included in this trial.
Methods: From January to November 2003, 160 pts (222 lesions) were included in the trial: 80 pts were randomized to SES and 80 pts to BMS. Pts were eligible for the study if they were identified as non-insulin or insulin-dependent diabetics, with significant coronary stenoses in ≥1 vessel. There was a sub-randomization according to the type of diabetes. Dual antiplatelet therapy (aspirin indefinitely and clopidogrel for 1 year) was routinely prescribed.
Results: Five-year clinical follow-up (mean 57±18 months) was obtained in 96.2% of the patients included in the trial. The TLR rate at 5-years was still significantly lower in the SES group (7.8% vs. 37.7%, p<0.001), whereas myocardial infarction and cardiac death rates were similar between groups (5.2% vs 10.4;P=0.36), (3.9% vs 5.2%, p=1), respectively. Between 2 and 5 years very few events have been recorded. In the SES group 1 pt suffered from sudden cardiac death, this patient had stent mallaposition at 9 months and another pt presented a possible stent thrombosis 13 days after aspirin withdrawal. In the BMS group 1 pt died due to end-stage heart failure and 1 pt suffered definitive stent thrombosis. Independent predictors of MACE at 5 years were: SES implantation [0.12 (0.05-0.28);p<0.001], multivessel disease [4.3(1.4-13.06);p=0.008], multivessel stent implantation [1.94 (1.04-3.63);p=0.03], peak of CPK after the procedure [1.01(1.004-1009);p<0.001)] and creatinine levels [2.3(1.3-3.9);p=0.004].
Conclusions: SES implantation in diabetic pts continues to demonstrate the efficacy at 5 years. No safety concern has been observed in the SES group as compared to BMS group at long term follow-up.

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Impact of Second Generation versus First Generation Drug-eluting Stents on Significant Myonecrosis following Percutaneous Coronary Intervention in Non-Acute Myocardial Infarction Patients

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Background: The effect of 2nd generation drug-eluting stents (DESs, Zotarolimus, Endeavor™/Everolimus, Promus™ or Xience™) versus 1st generation DES (Sirolimus, Cypher™/Paclitaxel, Taxus™) on significant myonecrosis following percutaneous coronary intervention (PCI) in non-acute myocardial infarction (AMI) patients (pts) is largely unknown.
Method: A total 996 consecutive non-AMI pts who underwent PCI with DESs were divided into two groups. Myonecrosis group (N=152 pts) consists of pts who had either CK-MB > 15 U/L or Trop-I > 0.3 ng/mL (3 times or more upper normal) post-PCI within 24 hours period while No-Myonecrosis group (N=844 pts) consists of pts who had CK-MB ≤15 U/L and Trop-I ≤0.3 ng/mL.
Results: A total 544 (64.5%) pts received 1st generation DESs in No Myonecrosis group whereas 34 (24.4%) pts received 2nd generation DESs in the Myonecrosis group. Pts in Myonecrosis group were found to have worse angiographic characteristics than pts in No Myonecrosis group (Table).On multivariate analysis, there was a trend toward higher incidences of significant myonecrosis in pts receiving 1st generation DESs as compared to 2nd generation DESs (OR 1.602; 95% CI 0.943-2.720, P=0.081).

Table. Variables predicting post-PCI significant myonecrosis

Variable, n (%)	No Myonecrosis Group (n=844 pts)	Myonecrosis Group (n=152 pts)	P-Value
Age	65.41±10.26	68.80±10.95	0.001
Multivessel disease	182 (21.6)	51 (33.6)	0.002
Bifurcation lesion	339 (40.2)	75 (49.3)	0.040
Ostial Lesion	213 (25.2)	55 (36.2)	0.007
Calcified Lesion	134 (15.9)	35 (23.0)	0.035
Sirolimus/Paclitaxel	544 (64.5)	118 (77.6)	0.001
Zotarolimus/Everolimus	300 (35.5)	34 (22.4)	
Echo EF (%)	55.20±7.96	52.13±10.97	0.002
Baseline CK-MB	2.76±1.58	3.76±2.44	0.002
Baseline Glucose	128.83±53.00	141.63±58.46	0.016
Baseline BNP level	542.43±2189.53	730.19±4904.83	0.008
Baseline Creatinine	0.98±0.82	1.31±1.37	0.005
Procedure time	40.66±32.42	59.20±38.38	<0.001
Lesion Length	23.57±10.23	25.35±13.76	0.047
Pre-MLD	0.59±0.38	0.52±0.35	0.002
Clopidogrel Loading Dose	344.45±170.00	315.88±178.17	0.091

Conclusion: Worse baseline angiographic and procedural features was associated with higher incidences of post-PCI myonecrosis and there was a trend toward higher incidences of significant myonecrosis following PCI with 1st generation DESs as compared to 2nd generation DESs in Non-AMI pts.

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Cost Analysis of Four Major Drug-Eluting Stents in Diabetic Populations

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Background: Patients with diabetes are at increased risk for restenosis versus patients without diabetes. Recent studies reported differences in drug-eluting stent (DES) safety and efficacy in diabetic patients, however, there is no single trial that compares all major DES. The study objective was to combine trials and conduct a cost analysis comparing CYPHER™, ENDEAVOR™, TAXUS™, and XIENCE™ from a US payer perspective.
Methods: Upon literature review, studies were chosen that randomized two or more DES and included a diabetic subpopulation. Included studies were ISAR-DIABETES, SIRTAX, Kim 2008, DiabeDES, DES-Diabetes, ZEST, and SPIRIT IV and only diabetic patient data were analyzed. First, one-year TLR (target lesion revascularization) rates for TAXUS were derived by combining data from all trials and weighting by sample. Then, a relative risk (RR) for CYPHER vs. TAXUS was calculated by conducting a meta-analysis in RevMan (Cochrane Collaboration, 2008). For ENDEAVOR and XIENCE, RRs vs. TAXUS were available from single studies. The RRs were then multiplied by the combined TLR risk for TAXUS to estimate combined TLR risks for each stent. These imputed estimates were added to the budget-impact model, along with reported usage and reimbursement rates for diagnosis-related groups (DRGs) from the US CMS (DRG's 247-251 and 233-236). DES budgets were calculated, assuming 100% utilization for each stent and 200,000 diabetic Medicare beneficiaries receiving index PCI with DES.
Results: One-year TLR rates were approximately 3.4% for CYPHER, 7.1% for XIENCE, 7.6% for ENDEAVOR, and 8.3% for TAXUS. By substituting CYPHER instead of DES with higher TLR, results predicted annual cost savings of $144 million (vs XIENCE), $163 million (vs ENDEAVOR), and $193 million (vs TAXUS) per population, corresponding to $719, $817, and $964 per patient respectively.
Conclusions:
Pooled results showed that CYPHER has lower TLR risk in patients with diabetes compared with other major DES. When outcomes from randomized, head-head trials of diabetic patients are combined, differences in one-year TLR rates translate into large potential cost savings to the US payer. Further study is required to assess budget impact when considering safety outcomes such as stent thrombosis.

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