Drug-Eluting Stents
An Overview

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Disclosures

• Presenter: Adam Witkowski
• I have nothing to disclose
50 Year Anniversary of Myocardial Revascularization

History of POBA and Coronary Stents

- First Coronary Balloon Angioplasty – A. Gruentzig, 1977

- First Coronary Stenting – U. Sigwart, J. Puel, 1986
  To act as a scaffold, thus 1) preventing vessel closure during PTCA, and 2) reducing the incidence of angiographic restenosis, which had an occurrence rate of 30-40%.

  The First-in-Man feasibility study, conducted in Sao Paulo, Brazil and Rotterdam, the Netherlands showed the CYPHER® sirolimus-eluting stent (Cordis Corporation, Johnson & Johnson, Warren, NJ, USA) to be remarkably effective in eliminating the occurrence of restenosis. Circulation 2001; 103:192-5.

  As a strategy to minimize restenosis and requirement for reintervention.

- First Bioabsorbable Stent (BVS), poly-L-lactic acid (PLLA) – J. Ormiston, 1st implantation on March 7th, 2006
  In contrast to a permanent metal stent, a completely absorbable stent may allow the vessel to react normally to pulsatile flow, to positively remodel and to respond normally to factors released by endothelium.
Design of 2nd generation DES

- Alloy: cobalt-chromium, platinium-chromium, thin struts (<80 mc)
- Polymer: durable or bioabsorbable vs non-polymeric, drug-coated stents, drug-filled stents
- Drug: paclitaxel, sirolimus or sirolimus derivatives (EES, ZES, BES)
- Fully bioresorbable DES (3rd generation DES or 1st generation BRS?)
DES in ESC/EACTS Guidelines

- Second generation DES in STEMI: IA

- Second generation DES in NSTE-ACS: IA

- Second generation DES in SCAD: New-generation DES should be considered by default in all clinical conditions and lesion subsets

2014 ESC/EACTS Guidelines on Myocardial Revascularization
2015 ESC Guidelines on NSTE-ACS
2017 ESC Guidelines on STEMI

Antithrombotic treatment in SCAD patients undergoing PCI

2014 ESC/EACTS Guidelines on MR
Interventional Cardiology in Poland 2017

PCI

DES stents in 2016 by diagnosis and in comparison to 2015

STEMI
↑5.9% DES

NSTEMI
↑6.7% DES

UA
↑5.2% DES

SCAD
↑4.8% DES

Biodegradable Polymer BES vs Durable EES: COMPARE II 5 years

Objective
To report the 5 year clinical outcome of the biodegradable polymer biolimus-eluting stent (BES) with durable polymer everolimus-eluting stent (EES)

Study
Prospective, multicentre randomised non-inferiority trial (2:1)

Population
All-comers

Endpoints
MACE: cardiac death, MI, or TVR at 5 years

Patients: 2,707

BES 1,795

EES 912

Follow-up complete: 98% at 5 years

MACE 5 years
RR: 1.11 (95% CI 0.92-1.33) p=0.26

Conclusion
The clinical outcome after 5 year follow-up of BES implantation was non-inferior compared to EES implantation

LEADERS FREE
Polymer-free drug-coated stent (Biofreedom) vs BMS (Gazelle)
n=2,466 pts

- The primary safety end point, tested for both noninferiority and superiority, was a composite of cardiac death, MI, or stent thrombosis
- The primary efficacy end point was clinically driven TLR
- 1 month DAPT

P Urban et al. NEJM 2015

EXCEL Study

Death, Stroke, or Myocardial Infarction

Hazard ratio, 1.00 (95% CI, 0.79–1.26)
P = 0.98

PCI non inferior to CABG for LM disease

LM and SYNTAX<32
Xience stent, 28% BIMA
CABG vs PCI, n=1905
PEP= Death, MI, stroke

Stone et al, NEJM 201
**NOBLE Study**

Death, non-procedural MI, Stroke, Revascularization

PCI not non-inferior to CABG for LM disease (HR>1.35)

Left Main
Biomatrix stent (>90%)
CABG vs PCI, n=1201, 8% BIMA
PEP = Death, non-procedural MI, stroke +

Mäkikallio et al, Lancet 2016

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**ABSORB II: 3 years**

- Comparison of an everolimus-eluting bioresorbable scaffold with an everolimus-eluting metallic stent for the treatment of coronary artery stenosis
- The primary endpoint was superiority of the Absorb bioresorbable scaffold versus the Xience metallic stent in angiographic vasomotor reactivity after administration of intracoronary nitrate
- The co-primary endpoint is the non-inferiority of angiographic late luminal loss

PW Serruys et al. Lancet 2016
**ABSORB II: 3 years**

- Late loss significantly higher in Absorb (0.37 mm [0.45] vs 0.25 mm [0.25]; p for non-inferiority=0.78)
- The secondary endpoints of patient-oriented composite endpoint, Seattle Angina Questionnaire score, and exercise testing were not statistically different in both groups
- A device-oriented composite endpoint was significantly different between the Absorb group and the Xience group (10% vs 5%, hazard ratio 2.17 [95% CI 1.01–4.70]; log-rank test p=0.0425), mainly driven by target vessel myocardial infarction (6% vs 1%; p=0.0108), including peri-procedural myocardial infarction (4% vs 1%; p=0.16).

PW Serruys et al. Lancet 2016

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**AIDA: Bioresorbable Scaffolds versus Metallic Stents in Routine PCI**

- Randomised: EES vs BVS
- 924 vs 921 pts
- no significant difference in the rate of TVF between the patients who received a bioresorbable scaffold and the patients who received a metallic stent
- The bioresorbable scaffold was associated with a higher incidence of device thrombosis than the metallic stent through 2 years of follow-up

JJ Wyrzykowska et al. NEJM 2017
Stent Thrombosis With Drug-Eluting Stents and Bioresorbable Scaffolds
Evidence From a Network Meta-Analysis of 147 Trials (n=126,526 patients)

- Contemporary DES, including biocompatible DP-DES, BP-DES, and polymer-free DES, showed a low risk of definite or probable stent thrombosis at 1 year
- BVS had an increased risk of device thrombosis compared with CoCr-EES, PtCr-EES, and H-SES
- Data from extended follow-up are warranted to confirm the long-term safety of contemporary coronary devices.

Si-Hyuck Kang et al, J Am Coll Cardiol Intv 2016

Magmaris components
A combination of proven Orsiro elements and the benefits of a resorbable Magnesium Scaffold

- Backbone: Mg alloy
- Tantalum markers
- 6-crown & 2-link design
- 150μm strut thickness
- Coating: PLLA
- Proven resorption profile
- Proven technology identical to Orsiro coating
- Drug: Limus
- 1.4 μg/mm² same as for Orsiro
- Delivery system: RX, 0.014”
- 6F compatible
- Adapted from Orsiro system

Not CE marked – not yet available
Are DES really better?

This article was published on August 30, 2016, at NEJM.org.

Are DES really better?

This article was published on August 30, 2016, at
CONCLUSIONS

• Contemporary, second generation DES are highly effective and safe (low thrombosis rate)
• The use of DES is recommended over BMS in ESC/EACTS Guidelines
• The use in EU country is ≈ 90%
• Long DAPT (6-12 months) is usually not required
• Bioresorbable stents: BVS is out (higher thrombosis and MI rate than with metallic DES)
• Magnesium scaffold: promising, larger clinically-oriented trials required