

Reconciling the Data for DES Implantation

A Cardiologist's Point of View

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From balloon dilatation to local drug delivery

- POBA** (*plain old balloon angioplasty*)
- BMS** (*bare-metal stent*)
- DES** (*drug-eluting stent*)



Off and On label lesions but ON LABEL patient

Patients with numerous comorbidities, unfavorable lesion morphology and unstable clinical presentations constitute a **high risk population**.

FDA (7.12.2006) concluded that concerns about thrombosis do not outweigh the benefit of DES **when implanted for approved indications**.

The FDA panel also observed that at least **60%** of current DES use is off label, and **off label use is associated with increased events**.

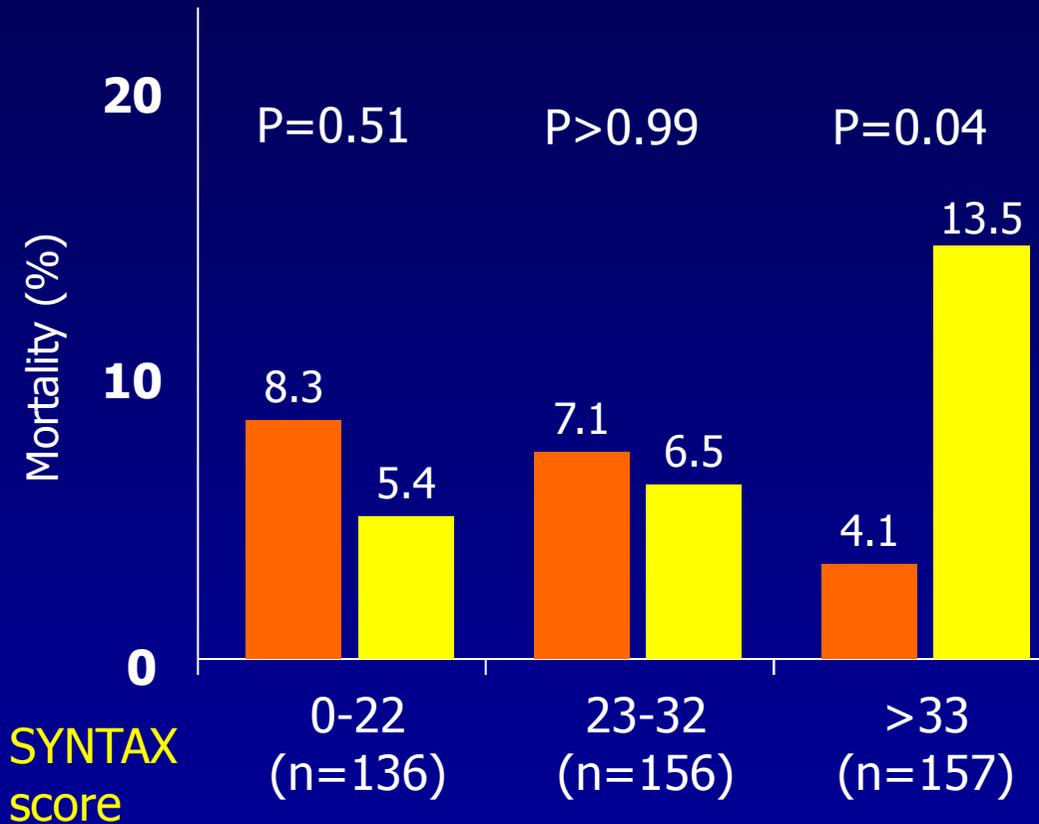
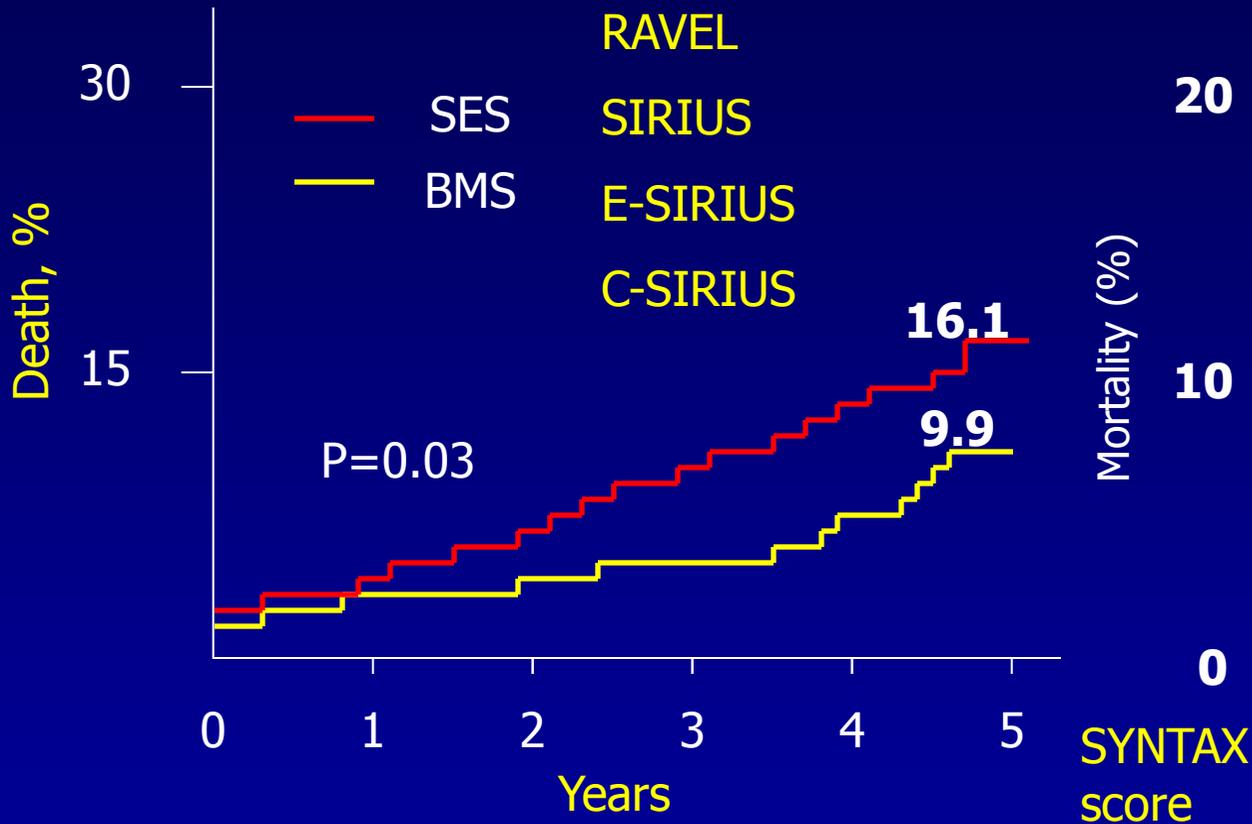
However, they acknowledge that with more complex patients there is an expected increased risk in adverse events and noted that FDA *"does not regulate how DES are used by individual clinicians in the practice of medicine"*.

It seems that DES are effective but are they safe?

Off and On label lesions but ON LABEL patient

Diabetic On Label ¹

Diabetic ²



The clinician sticks to the hard end points. Meta analysis suggest increased death in diabetic even **when on Label! One can easily speculate that off label rates are worse or not?**

1. JACC 2009;54:894-902

2. TCT 2009

Clinical decision for stent implantation

Will the **clinical indication** affect stent selection?

Moreover, there are differences between eluting stents. Are there any **factors indicating different DES implantation**? (low EF, insulin treated diabetes, AMI etc)

In addition, what is the optimal duration of dual antiplatelet therapy. We don't have the answer but what **factors predispose longer than 1 year treatment**?

NextGen Stents

Currently we are using 1st and 2nd generation stents. Although DES are implanted since 2001, 3rd generation is on the way...

Numerous trials randomized or not have demonstrated the efficacy and the durable anti-restenotic effect.

What do we expect from a novel DES? Safety...? or even better performance?

Clinical Questions 1

- Diabetics; outcome, type of stent, treatment *Eur Heart J, 2009*
- DES; Elderly and very elderly *Am Heart J, 2008*
- Obese patients have worse outcomes after DES *Heart, 2009*
- CRP and outcome prediction in DES *Circulation. 2009*
- Treatment with statins; which, where, how long, dose
- Risk factors for DES thrombosis (diabetes, insulin, smoking, age, type of stent etc) *Circ Cardiovasc Intervent. 2009*
- Long-term survival worse in patients with renal impairment, even with DES *Circ Cardiovasc Intervent. 2009*

Clinical Questions 2

- **Antiplatelet treatment when need for GI endoscopy** *JACC, 2009*
- **Surgical complications more likely in patients with DES; Heparin (LM) treatment** *JACC, 2009*
- **What about dual antiplatelet therapy and how long** *JACC, 2009*
- **How long is long-term** *Circulation, 2007*
- **What about DES, very late stent thrombosis, hypersensitivity and vessel remodeling** *Circulation, 2009-10*

Clinical Questions 3

- DES safety equivalent to BMS in both on- and off-label use
JACC Interv, 2009
- DES show superior efficacy, similar safety compared to BMS
in off-label use *JACC Interv, 2009*

Clinical Questions 4

- Are there pathologic differences between different DES?
- Are there clinical differences between different DES?
- DES Improve outcomes, but Increased PCI volume adds millions in cost *Circulation, 2009*

17.00 - 18.30 COURSE: Update on DES

Course Director: Arampatzis Ch.

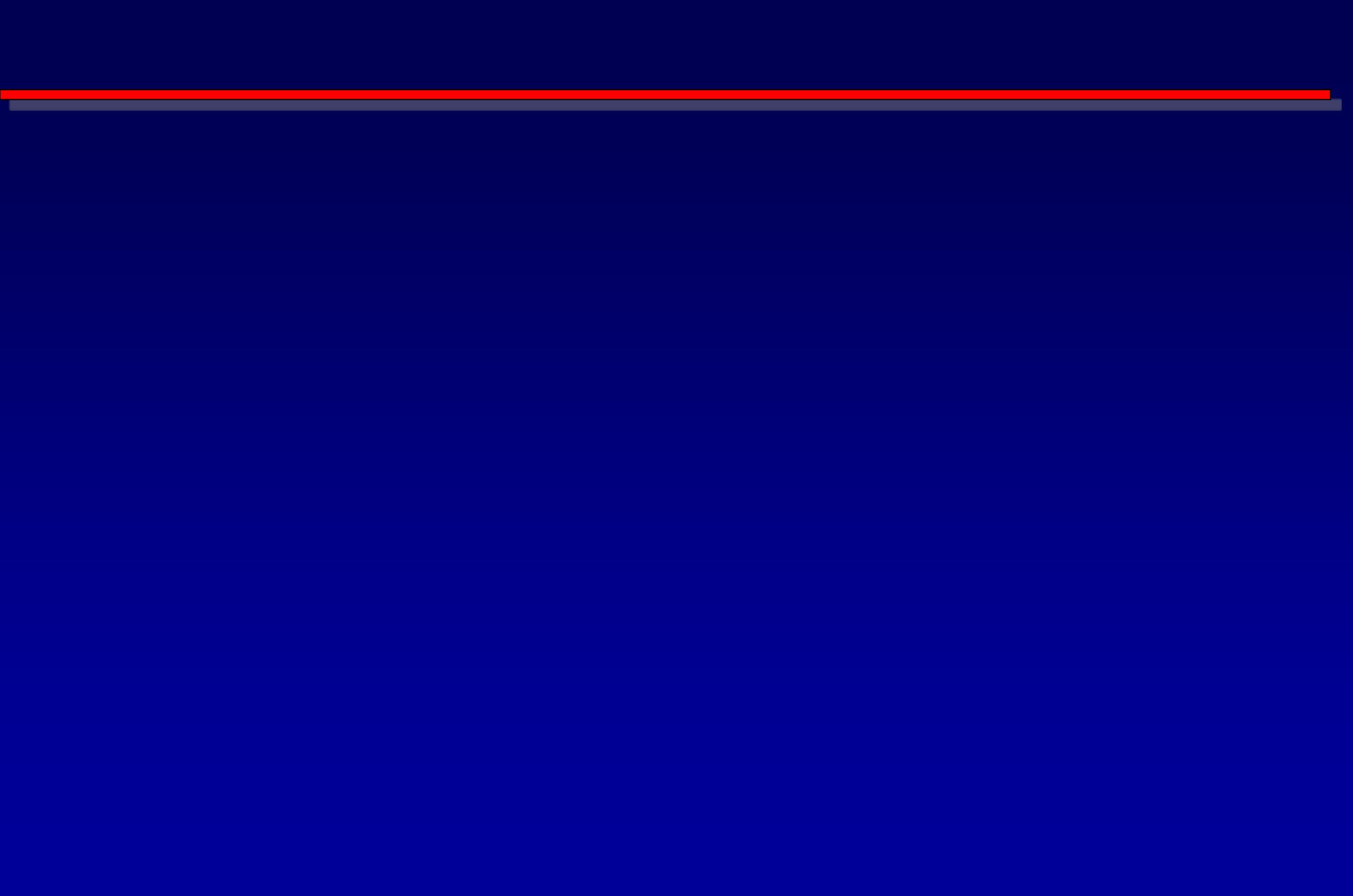
Chairmen: Arampatzis Ch., Psirropoulos D.

-Reconciling the data; expanding use of DES for percutaneous coronary interventions - *Tzifos V.*

-Patient and lesion selection to enhance the long-term benefit of DES implantation - *Saia F.*

-Latest clinical trials on DES implantation. Current trends and future perspectives - *Lemos P.*

-Balancing safety and efficacy on DES implantation for coronary revascularization procedures - *Katritsis D.*



Clinical Questions 4

- **Are there pathologic differences between different DES?**
- **How to choose a DES from the Multiple Commercially Available Formulations?**
- **GP IIb/IIIa Inhibitors in ACS and PCI**
- **Are there clinical differences between different DES?**