

Comprehensive Meta-Analysis of DES vs. BMS Randomized Trials and Registries

Analysis performed by:

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The safety and effectiveness of the TAXUS[®] Express² Stent have not been established in patients with diabetes, lesions >28 mm in length, in-stent restenosis, or present with an acute myocardial infarction.

Meta-analysis DES vs. BMS

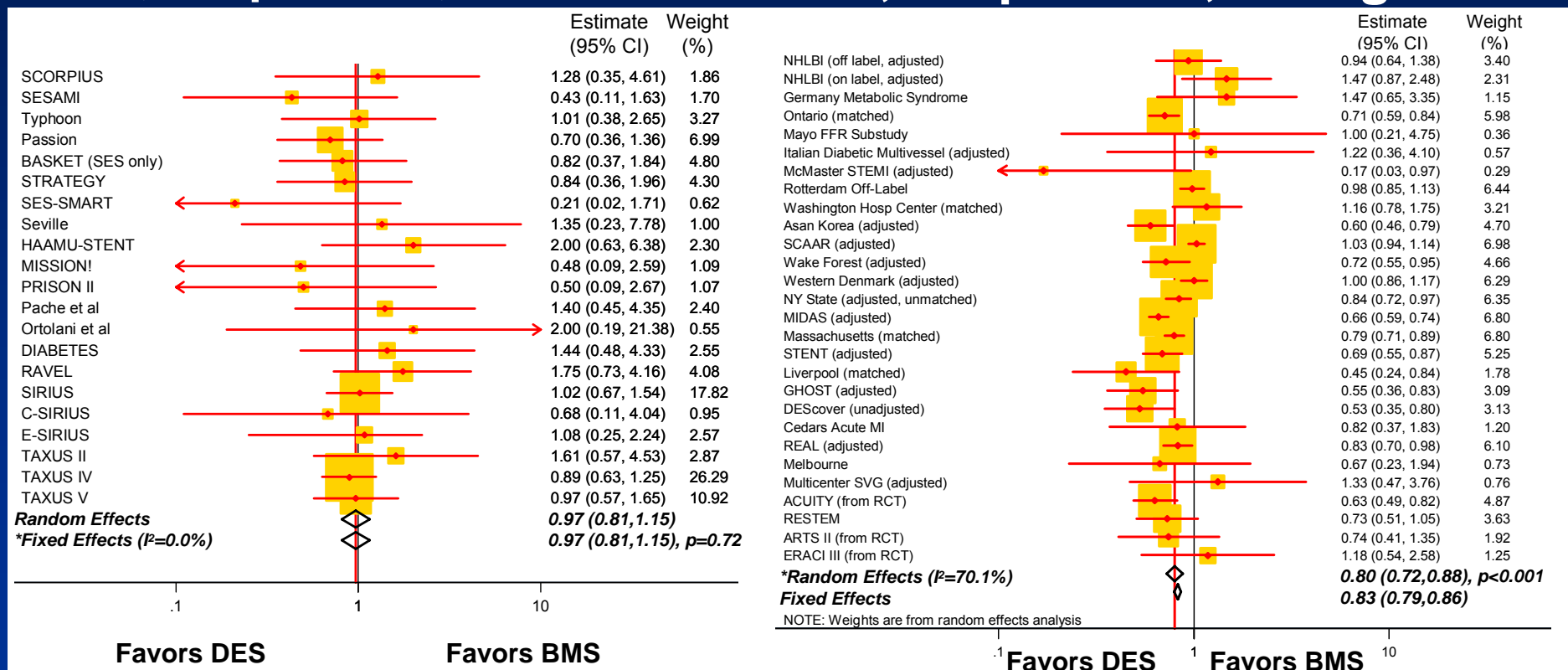
Study Objective:	To assess the long-term safety and efficacy of DES compared to BMS.
Study Design:	Comprehensive systematic review of all high quality DES vs. BMS publications and major medical meeting presentations (RCT and registries). Pre-specified data criteria: ≥ 100 pts, reported mortality, MI and/or TVR, and ≥ 1 year of follow up.
Follow up:	≥ 1 year
Number of Patients Enrolled:	Total of 52 studies representing 180,749 patients 22 randomized controlled trials n=9,470 30 observational registries n=171,279
Data Presented By:	Gregg W. Stone MD, and Ajay Kirtane, MD, ACC 2008

Meta-analysis DES vs. BMS

Mortality RCT and Registry Analysis

Mortality: All RCTs
8,867 patients, 21 trials**

Mortality: All Registries
161,232 patients, 28 registries**



<1.0 ⇒ Favors DES; * = significant

**All-cause mortality data was available in 21 of 22 RCTs and 28 of 30 Registries.

Presented by Gregg W. Stone MD and Ajay Kirtane MD, ACC 2008. Point estimates are represented by red circles; Confidence intervals by red lines and Weight by yellow boxes (based on primary model); No significant effect of number of patients (total or DES patients) or diabetic patients by meta-regression; Random effects used except if I²<25. The safety and effectiveness of the TAXUS® Stent have not been established in patients with diabetes, lesions >28 mm in length, in-stent restenosis, or present with an acute myocardial infarction.

Meta-analysis DES vs. BMS

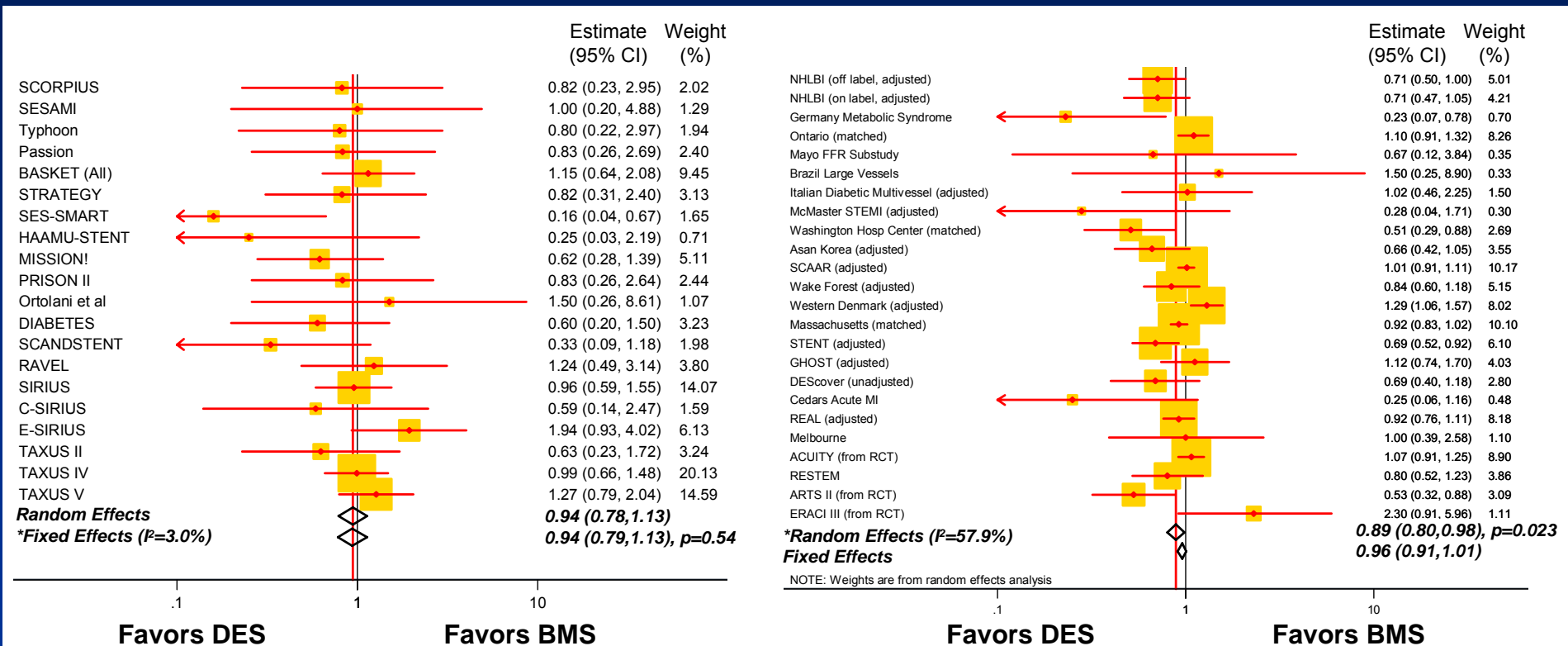
MI RCT and Registry Analysis

MI: All RCTs

8,850 patients, 20 trials**

MI: All Registries

129,955 patients, 24 registries*



<1.0 ⇒ Favors DES; * = significant

*** MI data was available in 20 of 22 RCTs and 24 of 30 Registries

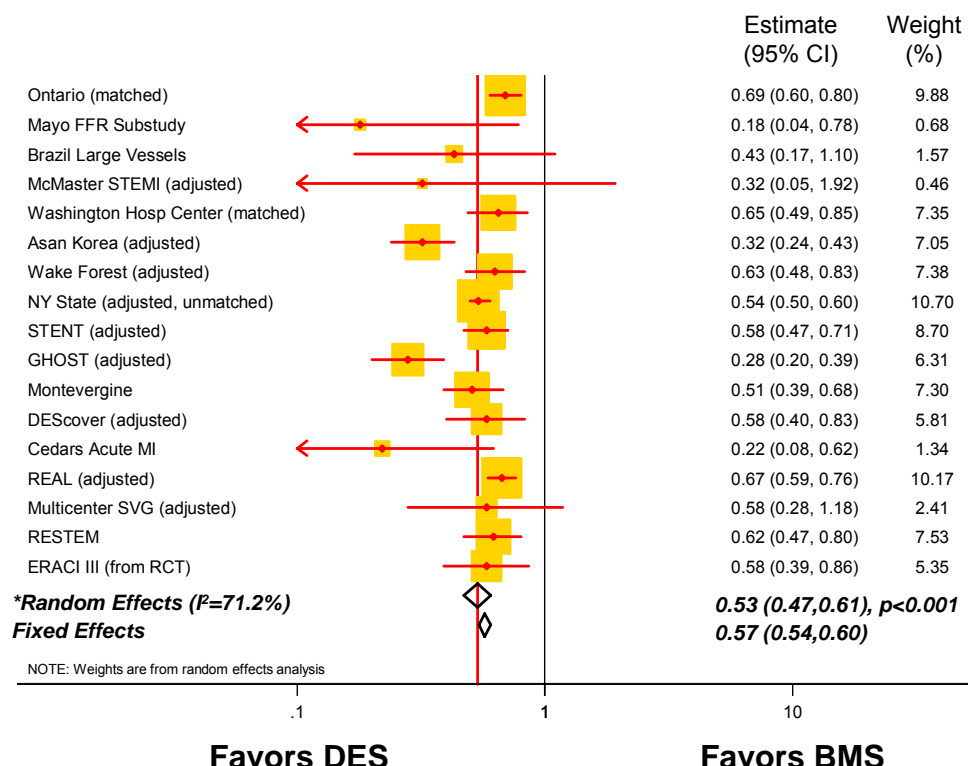
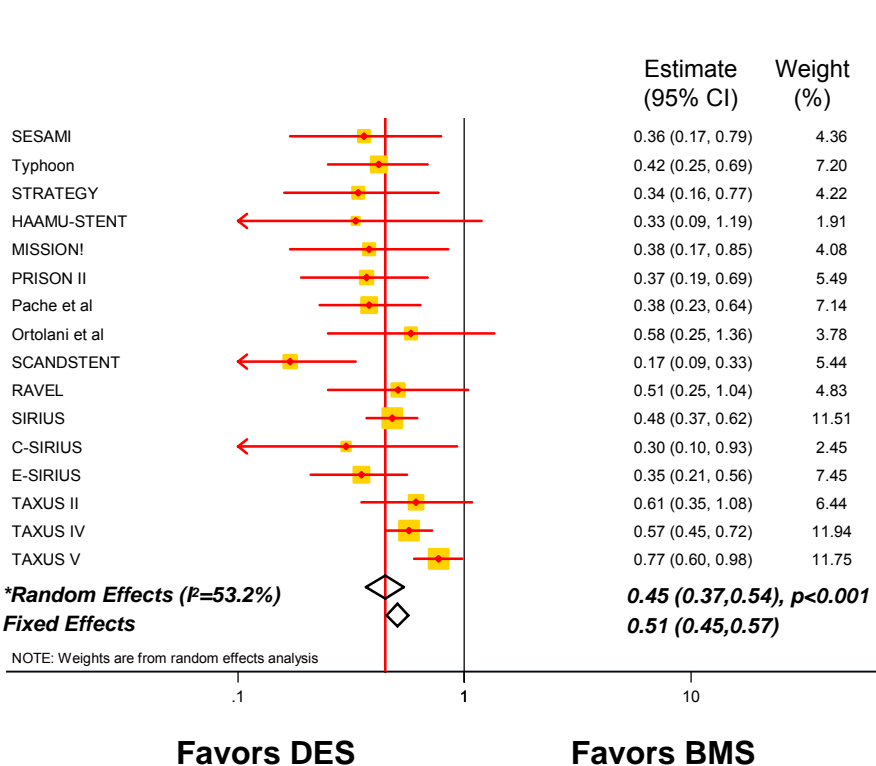
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Meta-analysis DES vs. BMS

TVR RCT and Registry Analysis

TVR: All RCTs
7,291 patients, 16 trials**

TVR: All Registries
73,819 patients, 17 registries**



<1.0 ⇒ Favors DES; * = significant

****TVR data was available in 16 of 22 RCTs and 17 of 30 Registries**

Presented by Gregg W. Stone MD and Ajay Kirtane MD, ACC 2008. Point estimates are represented by red circles; Confidence intervals by red lines and Weight by yellow boxes (based on primary model); No significant effect of number of patients (total or DES patients) or diabetic patients by meta-regression; Random effects used except if I2<25%. The safety and effectiveness of the TAXUS® Stent have not been established in patients with diabetes, lesions >28 mm in length, in-stent restenosis, or present with an acute myocardial infarction.

Meta-analysis DES vs. BMS

Findings from 180,749 patients

- I. In 22 RCTs involving 9,470 patients randomized to DES or BMS and followed for ≥ 1 year, DES resulted in:
 - a. A non-significant 3% reduction in mortality - **HR 0.97 (0.81,1.15)**
 - b. A non-significant 6% reduction in MI - **HR 0.94 (0.79,1.13)**
 - c. A significant 55% reduction in TVR – **HR 0.45 (0.37,0.54)**

- II. In 30 Registries with 171,279 patients treated with either DES or BMS and followed for ≥ 1 year, DES resulted in:
 - a. A significant 20% reduction in mortality - **HR 0.80 (0.72,0.88)**
 - b. A significant 11% reduction in MI – **HR 0.89 (0.80-0.98)**
 - c. A significant 47% reduction in TVR – **HR 0.53 (0.47-0.61)**

TAXUS[®] Express[®] Stent System Abbreviated Statement

Indications

The TAXUS Express² Paclitaxel-Eluting Coronary Stent System is indicated for improving luminal diameter for the treatment of de novo lesions ≤ 28 mm in length in native coronary arteries ≥ 2.5 to ≤ 3.75 mm in diameter.

Contraindications

Use of the TAXUS Express² Paclitaxel-Eluting Coronary Stent System is contraindicated in patients with:

- Known hypersensitivity to paclitaxel or structurally-related compounds.
- Known hypersensitivity to the polymer or its individual components (see details in TAXUS Express² Stent System DFU).

Coronary Artery Stenting is contraindicated for use in:

- Patients who can not receive recommended anti-platelet and/or anticoagulant therapy.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or delivery device.

Warnings

- To maintain sterility, the inner package should not be opened or damaged prior to use.
- The use of this product carries the risks associated with coronary artery stenting, including subacute thrombosis, vascular complications, and/or bleeding events.
- Patients with known hypersensitivity to 316L stainless steel may suffer an allergic reaction to this implant.
- This product should not be used in patients who are not likely to comply with recommended antiplatelet therapy.

Potential Adverse Effects

Potential adverse events (in alphabetical order) which may be associated with the use of a coronary stent in native coronary arteries include but are not limited to: Aneurysm, Arrhythmias, Bleeding complications, Death, Distal Emboli, Emergent CABG, Myocardial Infarction, Myocardial Ischemia, Occlusion, Stent Delivery Failures, Target Lesion Revascularization, Thrombosis, Vascular complications, Vessel Dissection.

Potential adverse events not captured above that may be unique to the paclitaxel drug coating:

Alopecia, Allergic reaction to the drug or the polymer, Anemia, Blood product transfusion, Gastrointestinal symptoms, Hematologic dyscrasia, Hepatic enzyme changes, Histologic changes in vessel wall, including inflammation, cellular damage or necrosis, Myalgia/Arthralgia, Peripheral neuropathy.

The safety and effectiveness of the TAXUS[™] Express[®] Stent have not been established in the cerebral, carotid, or peripheral vasculature or the following patient populations:

- Patients with vessel thrombus at the lesion site.
- Patients with coronary artery reference vessel diameters < 2.5 or > 3.75 mm.
- Patients with coronary artery lesions longer than 28 mm or requiring more than one TAXUS stent
- Patients with lesions located in the saphenous vein grafts, in the unprotected left main coronary artery, ostial lesions, or lesions located at a bifurcation.
- Patients with diffuse disease or poor flow distal to the identified lesions.
- Patients with tortuous vessels (>60 degrees) in the region of the obstruction or proximal to the lesion.
- Patients with a recent acute myocardial infarction where there is evidence of thrombus or poor flow.
- Patients with in-stent restenosis.
- Patients with moderate or severe calcification in the lesion or a chronic total occlusion.
- Patients with multi-vessel disease.

Prior to use, please see the complete "Directions for Use" at [www. Taxus-stent.com](http://www.Taxus-stent.com) for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events and Operator's Instructions.

Cautions

Federal law restricts this product to sale by or on the order of a physician.

Trademark

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