

SYNTAX Trial 12-Month Outcomes in Subset of Patients with Diabetes

OBJECTIVE:	Study the roles of CABG and PCI using the TAXUS® Express® Stent in the contemporary management of patients with diabetes (subset analysis)
STENT:	TAXUS Express Stent
PURPOSE:	Safety and efficacy
DESIGN:	Prospective, randomized, consecutive all-comer patient enrollment, with limited exclusions: previous interventions, acute MI with CPK>2x, concomitant cardiac surgery
LESION:	<i>De novo</i> lesions in left main disease (isolated, +1, +2, +3 vessels) and three vessel disease (revascularization of all three vascular territories)
CONTROL:	Coronary artery bypass graft (CABG)
PRIMARY ENDPOINT:	Non-inferiority 12-month major cardiovascular or cerebrovascular event rate (MACCE†)
LOCATION & SITES:	62 E.U. sites and 23 U.S. sites
PATIENTS:	Medically Treated Diabetic n=452, Non-diabetic n=1,348 TAXUS Express Stent Medically Treated Diabetics n=227, TAXUS Express Stent Non-diabetics n=664 CABG Medically Treated Diabetics n=204, CABG Non-diabetics n=645
PRESENTER:	Keith D. Dawkins MD

Procedural Characteristics	TAXUS Express Stent (n=903)	CABG (n=897)	P value
Diabetic	28.2%	28.5%	0.89
Diet only	2.7%	3.9%	0.14
Medically Treated	25.6%	24.6%	0.64
Insulin Treated	9.9%	10.4%	0.72
Metabolic Syndrome	46.0%	45.5%	0.86
Waist > 40" male, >35" female	47.4%	45.8%	0.53
Triglycerides ≥150 mg/dL	32.3%	38.7%	0.007
HDL <40 male or <50 female	46.2%	52.5%	0.01
Blood Pressure ≥ 130/85 mmHg	68.9%	64.0%	0.03
Fasting Glucose ≥ 110 mg/dL	45.0%	40.1%	0.07
HbA1c ≥7%	14.9%	16.8%	0.29

Patient Characteristics	Non-diabetic (n=1,348)	Diabetic (n=452)	P value
Age, mean ± SD (years)	65.0 ± 9.9	65.4 ± 9.2	0.41
Male	79.9%	71.0%	<0.001
Metabolic Syndrome	37.4%	69.9%	<0.001
Hypercholesterolemia	76.7%	81.5%	0.03
Hypertension	72.6%	84.1%	<0.001
Current Smoker	21.7%	15.8%	0.006
Prior MI	33.2%	32.0%	0.65
Congestive Heart Failure	3.7%	7.4%	0.001
Poor Ejection Fraction	1.6%	2.9%	0.07
Peripheral Vascular Disease	8.2%	14.6%	<0.001
Prior Stroke	3.8%	6.0%	0.046
Creatinine >200 µmol/L	1.0%	2.9%	0.003
Additive euroScore, mean ± SD	3.7 ± 2.6	4.0 ± 2.7	0.03
Total Parsonnet Score, mean ± SD	7.5 ± 6.8	11.3 ± 6.4	<0.001
Total SYNTAX Score	28.6 ± 11.5	29.0 ± 11.2	0.52
Diffuse Disease or Small Vessels	10.2%	13.4%	0.06
No. Lesions, mean ± SD	4.3 ± 1.8	4.6 ± 1.8	0.003
Total Occlusion	22.7%	24.7%	0.38
3-Vessel Disease only	64.1%	71.0%	0.007

Data presented by Keith D. Dawkins MD, TCT 2008

† MACCE is defined as: all cause death, cerebrovascular accident (CVA/stroke), documented myocardial infarction (ARTS I definition NEJM 2001; 344: 1117-1124), any repeat revascularization (PCI and/or CABG)

The safety and effectiveness of the TAXUS® Express® Stent have not been established in patients with lesions located in an unprotected left main, multi-vessel disease, lesions requiring more than one stent or multiple overlapping stents, lesions located at a bifurcation, coronary artery reference vessel diameters <2.25mm or >4.00mm, lesions longer than 28mm, in patients with moderate or severe calcification or specifically in patients with diabetes.

Patient Characteristics (cont.)	Non-diabetic (n=1,348)	Diabetic (n=452)	P value
Left Main any	35.9%	29.0%	0.007
Left Main only	3.9%	2.2%	0.10
Left Main + 1 Vessel	5.6%	4.0%	0.19
Left Main + 2 Vessels	12.0%	11.1%	0.64
Left Main + 3 Vessels	14.4%	11.6%	0.13

12-month Clinical Event Rates According to Diabetic Status	TAXUS® Express® Stent	CABG	P value
MACCE Non-diabetic (n=1,348)	15.1%	11.8%	0.08
MACCE Diabetic (n=452)	26.0%	14.2%	0.003
Death/CVA/MI Non-Diabetic (n=1,348)	6.8%	6.8%	0.97
Death/CVA/MI Diabetic (n=452)	10.1%	10.3%	0.96

12-month Clinical Event Rates in Non-diabetics	TAXUS Express Stent (n=664)	CABG (n=645)	P value
MACCE	15.1%	11.8%	0.08
All Death	3.0%	2.6%	0.68
MI	4.8%	2.9%	0.08
CVA	0.5%	2.2%	0.006
Revascularization	11.1%	5.7%	<0.001

12-month Clinical Event Rates in Diabetics	TAXUS Express Stent (n=227)	CABG (n=204)	P value
MACCE	26.0%	14.2%	0.003
All Death	8.4%	6.4%	0.43
MI	4.8%	4.4%	0.83
CVA	0.9%	2.5%	0.26
Revascularization	20.3%	6.4%	<0.001



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