

SYNTAX Trial 12-Month Outcomes in Subset of Patients with Three-Vessel Disease

OBJECTIVE:	Study the roles of CABG and PCI using the TAXUS® Express® Stent in the contemporary management of patients with *three-vessel disease (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 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:	TAXUS Express Stent n=546, CABG n=549 (3-vessel disease subset analysis)
PRESENTER:	Friedrich W. Mohr MD, PhD

Patient Characteristics	TAXUS® Express® Stent (n=546)	CABG (n=549)	P value
Age, mean ± SD (years)	65.1 ± 9.6	64.5 ± 9.6	0.32
Male	79.3%	81.1%	0.47
BMI, mean ± SD	28.1 ± 4.7	28.0 ± 4.2	0.88
Medically Treated Diabetes	28.0%	26.0%	0.46
Hypercholesterolemia	77.2%	78.3%	0.66
Hypertension	76.3%	77.3%	0.70
Current Smoker	18.9%	20.8%	0.42
Prior MI	34.2%	39.1%	0.10
Unstable Angina	27.8%	27.3%	0.85
Additive euroScore, mean ± SD	3.7 ± 2.5	3.7 ± 2.6	0.77
Total Parsonnet Score, mean ± SD	8.3 ± 6.3	8.0 ± 6.5	0.50
Total SYNTAX Score	23.8 ± 9.4	23.6 ± 8.8	0.72
Diffuse Disease or Small Vessels	28.9%	26.1%	0.29
No. Lesions, mean ± SD	4.4 ± 1.4	4.5 ± 1.4	0.38
Total Occlusion	33.0%	33.6%	0.83
Bifurcation	62.1%	65.9%	0.19
Trifurcation	3.5%	3.5%	0.99

Procedural Characteristics	TAXUS Express Stent (n=546)	CABG (n=549)	P value
Time to Procedure - Days‡, mean ± SD	7.6 ± 14.1	19.2 ± 28.1	<0.001
Procedural Duration – Hours‡‡, mean ± SD	1.8 ± 1.0	3.5 ± 1.0	<0.001
Post-procedural Hospital Stay – Days, mean ± SD	3.5 ± 4.8	9.3 ± 6.8	<0.001
Complete Revascularization**	51.7%	57.2%	0.07

Data presented by Friedrich W. Mohr MD, PhD, 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)

* Revascularization for all 3 vascular territories. ‡Allocation to procedure. ‡‡For PCI patients, includes time for staged procedure. **Per protocol: Complete revascularization is defined as the treatment of any lesion with more than 50% diameter stenosis in vessels ≥1.5 mm diameter as estimated on the diagnostic angiogram during the local Heart Team conference. Completeness of revascularization was assessed post procedure by the operator (Surgeon or Interventional Cardiologist)

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.

12-month Clinical Event Rates	TAXUS® Express® Stent (n=546)	CABG (n=549)	Pvalue
MACCE (<i>failed to meet the non-inferiority primary endpoint</i>)	19.1%	11.2%	<0.001
Revascularization	14.7%	5.4%	<0.001
All Death	4.4%	2.9%	0.18
CVA (Stroke)	0.8%	1.9%	0.09
MI	5.2%	2.6%	0.04
Death/MI/CVA	7.9%	6.4%	0.39
Symptomatic Graft Occlusion & Stent Thrombosis*	3.7%	3.3%	0.73

ITT population, Kaplan-Meier Rates, Fisher Exact Test, *Binary Rates

SYNTAX Score Tercile Three-Vessel Disease Subset	TAXUS Express Stent MACCE Rate	CABG MACCE Rate	Pvalue
Low (0 – 22), Number of Patients	17.3%, n=181	15.2%, n=171	0.66
Mean Baseline SYNTAX Score – Low Tercile	17.3 ± 3.8	17.3 ± 3.7	
Medium (23 – 32), Number of Patients	18.6%, n=207	10.0%, n=208	0.02
Mean Baseline SYNTAX Score – Medium Tercile	27.4 ± 2.9	27.5 ± 2.7	
High (≥33), Number of Patients	21.5%, n=155	8.8%, n=166	0.002
Mean Baseline SYNTAX Score – High Tercile	39.8 ± 6.0	41.0 ± 6.6	

Calculated by core laboratory, ITT population, Fisher Exact Test



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