

SYNTAX Trial 12-Month Outcomes in Subset of Patients with Left Main Disease

OBJECTIVE:	Study the roles of CABG and PCI using the TAXUS® Express® Stent in the contemporary management of patients with left main* 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 left main disease (isolated, +1, +2, +3 vessels)
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=357, CABG n=348 (left main disease subset analysis)
PRESENTER:	Patrick W. Serruys MD, PhD

Patient Characteristics	TAXUS® Express® Stent (n=357)	CABG (n=348)	P value
Age, mean ± SD (years)	65.4 ± 9.8	65.6 ± 10.1	0.78
Male	72.0%	75.6%	0.28
BMI, mean ± SD	28.2 ± 4.9	27.7 ± 5.0	0.24
Medically Treated Diabetes	21.8%	22.4%	0.86
Hyperlipidemia	81.0%	75.4%	0.07
Hypertension	70.5%	76.5%	0.07
Current Smoker	17.9%	24.0%	0.0492
Prior MI	28.5%	25.4%	0.37
Unstable Angina	30.5%	29.0%	0.66
Additive euroScore, mean ± SD	3.9 ± 2.8	3.9 ± 2.9	0.91
Total Parsonnet Score, mean ± SD	8.9 ± 7.8	9.1 ± 7.4	0.77
Total SYNTAX Score	28.1 ± 12.4	26.7 ± 11.5	0.13
Diffuse Disease or Small Vessels	11.8%	12.9%	0.64
No. Lesions, mean ± SD	3.3 ± 1.8	3.2 ± 1.9	0.89
Left Main			
Left Main only	11.8%	14.1%	0.36
Left Main + 1 Vessel	18.8%	20.4%	0.58
Left Main + 2 Vessels	31.4%	30.5%	0.79
Left Main + 3 Vessels	38.1%	35.1%	0.40
Total Occlusion	17.9%	14.7%	0.24
Bifurcation	63.6%	62.4%	0.74
Trifurcation	13.2%	12.6%	0.84

Procedural Characteristics	TAXUS Express Stent (n=357)	CABG (n=348)	P value
Time to Procedure - Days†, mean ± SD	6.0 ± 11.0	14.7 ± 278	<0.001
Procedural Duration – Hours‡, mean ± SD	1.5 ± 0.8	3.3 ± 1.2	<0.001
Post-procedural Hospital Stay – Days, mean ± SD	2.9 ± 3.3	9.3 ± 7.8	<0.001
Complete Revascularization**	64.5%	72.5%	0.02

Data presented by Patrick W. Serruys 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)

* Isolated or in conjunction with 1, 2, 3-vessel disease. †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=357)	CABG (n=348)	Pvalue
MACCE (<i>failed to meet the non-inferiority primary endpoint</i>)	15.8%	13.6%	0.44
Revascularization	12.0%	6.7%	0.02
All Death	4.2%	4.4%	0.88
CVA (Stroke)	0.3%	2.7%	0.009
MI	4.3%	4.1%	0.97
Death/MI/CVA	7.0%	9.1%	0.29
Symptomatic Graft Occlusion & Stent Thrombosis	2.7%**	3.7%**	0.49

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

12-month Subgroup Analysis	TAXUS Express Stent MACCE Rate	CABG MACCE Rate	Pvalue
All Left Main (n=705)	15.8%	13.7%	0.44
Left Main Isolated (n=91)	7.1%	8.5%	1.00
Left Main + 1 Vessel Disease (n=138)	7.5%	13.2%	0.27
Left Main + 2 Vessel Disease (n=218)	19.8%	14.4%	0.29
Left Main + 3 Vessel Disease (n=258)	19.3%	15.4%	0.42

ITT population

SYNTAX Score Tercile Left Main Subset	TAXUS Express Stent MACCE Rate	CABG MACCE Rate	Pvalue
Low (0 – 22)	7.7%	13.0%	0.19
Mean Baseline SYNTAX Score – Low Tercile	15.7 ± 4.4	15.5 ± 4.3	
Medium (23 – 32)	12.6%	15.5%	0.54
Mean Baseline SYNTAX Score – Medium Tercile	27.0 ± 2.7	27.2 ± 3.0	
High (≥33)	25.3%	12.9%	0.008
Mean Baseline SYNTAX Score – High Tercile	43.8 ± 9.1	42.1 ± 7.6	

Calculated by core laboratory, ITT population, Fisher Exact Test



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