

TAXUS[®] Express^{2™}

Clinical Programs

Boston
Scientific

Clinical Trial
and Registry
Summary



TAXUS VI

Randomized International Complex Trial (continued)

TAXUS VI Trial Data (9-Month) Effectiveness Measures

	TAXUS [®] Express [®] Paclitaxel-Eluting MR Stent (n=219)	Control* (n=227)	p-Value
Clinical Procedural Success	92.7% (203/219)	95.2% (216/227)	0.3232
Target Vessel Revascularization	9.1% (20/219)	19.4% (44/227)	0.0027
Target Lesion Revascularization	6.8% (15/219)	18.9% (43/227)	0.0001
CABG	0.9% (2/219)	1.8% (4/227)	0.6857
PCI	5.9% (13/219)	17.6% (40/227)	0.0001
TVR, Non-TLR	3.2% (7/219)	0.9% (2/227)	0.1004
CABG	0.9% (2/219)	0.0% (0/227)	0.2406
PCI	2.7% (6/219)	0.9% (2/227)	0.1688
TVF	16.0% (35/219)	22.0% (50/227)	0.1174
Stent Thrombosis			
Analysis Segment	12.4% (26/210)	35.7% (74/207)	<0.0001
In-Stent	9.1% (19/209)	32.9% (68/207)	<0.0001
Analysis Segment Restenosis	12.4% (26/210)	35.7% (74/207)	<0.0001
MLD (mm), In-Stent			
Post Procedure	2.59 ± 0.407 (209)	2.57 ± 0.367 (207)	0.6274
Follow-Up	2.20 ± 0.604 (209)	1.58 ± 0.661 (207)	<0.0001
MLD (mm), Analysis Segment			
Post Procedure	2.21 ± 0.520 (210)	2.18 ± 0.482 (207)	0.5732
Follow-Up	1.97 ± 0.575 (210)	1.51 ± 0.627 (207)	<0.0001
Diameter Stenosis, In-Stent (%)			
Post Procedure	8.1 ± 10.43 (209)	7.7 ± 9.99 (207)	0.6419
Follow-Up	22.2 ± 19.15 (209)	42.8 ± 20.90 (207)	<0.0001
Diameter Stenosis, Analysis Segment (%)			
Post Procedure	22.6 ± 11.67 (210)	22.8 ± 10.20 (207)	0.9019
Follow-Up	30.4 ± 17.38 (210)	45.4 ± 19.66 (207)	<0.0001
Late Loss, In-Stent (mm)	0.39 ± 0.560 (209)	0.99 ± 0.585 (207)	<0.0001
Late Loss, Analysis Segment (mm)	0.24 ± 0.567 (210)	0.66 ± 0.619 (207)	<0.0001

Safety Measures

In-Hospital MACE	6.8% (15/219)	4.8% (11/227)	0.4219
Out-of-Hospital MACE to 9 Months	9.6% (21/219)	19.4% (44/227)	0.0046
MACE to 9 Months, Overall	16.4% (36/219)	22.5% (51/227)	0.1208
TLR to 9 Months	6.8% (15/219)	18.9% (43/227)	0.0001
TVR (Non-TLR) to 9 Months	3.2% (7/219)	0.9% (2/227)	0.1004
TVR to 9 Months	9.1% (20/219)	19.4% (44/227)	0.0027
TVF to 9 Months	16.0% (35/219)	22.0% (50/227)	0.1174
Stent Thrombosis	0.5% (1/219)	1.3% (3/227)	0.6236
In-Hospital	0.0% (0/219)	0.4% (1/227)	1.0000
Out-of-Hospital to 30 Days	0.5% (1/219)	0.9% (2/227)	1.0000
31–180 Days	0.0% (0/219)	0.0% (0/227)	
181–300 Days	0.0% (0/219)	0.0% (0/227)	
In-Hospital MACE	6.8% (15/219)	4.8% (11/227)	0.4219
Out-of-Hospital MACE to 300 Days	9.6% (21/219)	19.4% (44/227)	0.0046

*Control for TAXUS VI is the Express Stent.

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TAXUS VI

Randomized International Complex Trial (continued)

TAXUS VI Trial Data (9-Month) Subgroup Analysis

	TAXUS® Express® Paclitaxel-Eluting MR Stent (n=219)	Control* (n=227)	p-Value
Diabetes (Med. Treated)			
MACE	15.4% (6/39)	28.0% (14/50)	0.2037
TVR	7.7% (3/39)	22.0% (11/50)	0.0826
TLR	2.6% (1/39)	22.0% (11/50)	0.0103
In-Stent Restenosis	8.1% (3/37)	40.5% (17/42)	0.0015
Analysis Segment Restenosis	10.8% (4/37)	47.6% (20/42)	0.0005
Late Loss – In-Stent	0.39 ± 0.552 (37)	1.16 ± 0.550 (42)	<0.0001
Late Loss – Analysis Segment	0.19 ± 0.425 (37)	0.81 ± 0.587 (42)	<0.0001
Diabetes (Non-Insulin Req)			
MACE	16.7% (4/24)	30.0% (9/30)	0.3428
TVR	4.2% (1/24)	23.3% (7/30)	0.0633
TLR	4.2% (1/24)	23.3% (7/30)	0.0633
In-Stent Restenosis	8.7% (2/23)	45.8% (11/24)	0.0078
Analysis Segment Restenosis	8.7% (2/23)	54.2% (13/24)	0.0013
Late Loss – In-Stent	0.35 ± 0.611 (23)	1.22 ± 0.598 (24)	<0.0001
Late Loss – Analysis Segment	0.14 ± 0.413 (23)	0.88 ± 0.636 (24)	<0.0001
Diabetes (Insulin Req)			
MACE	13.3% (2/15)	25.0% (5/20)	0.6722
TVR	13.3% (2/15)	20.0% (4/20)	0.6804
TLR	0.0% (0/15)	20.0% (4/20)	0.1186
In-Stent Restenosis	7.1% (1/14)	33.3% (6/18)	0.1037
Analysis Segment Restenosis	14.3% (2/14)	38.9% (7/18)	0.2349
Late Loss – In-Stent	0.45 ± 0.453 (14)	1.09 ± 0.487 (18)	0.0006
Late Loss – Analysis Segment	0.27 ± 0.448 (14)	0.72 ± 0.519 (18)	0.0140
Diabetes (HbA1c ≤ 7%)			
MACE	8.3% (1/12)	38.5% (5/13)	0.1602
TVR	8.3% (1/12)	23.1% (3/13)	0.5930
TLR	0.0% (0/12)	23.1% (3/13)	0.2200
In-Stent Restenosis	0.0% (0/12)	16.7% (2/12)	0.4783
Analysis Segment Restenosis	8.3% (1/12)	33.3% (4/12)	0.3168
Late Loss – In-Stent	0.23 ± 0.504 (12)	0.91 ± 0.590 (12)	0.0058
Late Loss – Analysis Segment	0.22 ± 0.422 (12)	0.60 ± 0.534 (12)	0.0667
Diabetes (HbA1c > 7%)			
MACE	19.2% (5/26)	25.0% (7/28)	0.7471
TVR	7.7% (2/26)	21.4% (6/28)	0.2531
TLR	3.8% (1/26)	21.4% (6/28)	0.1021
In-Stent Restenosis	12.0% (3/25)	48.0% (12/25)	0.0121
Analysis Segment Restenosis	12.0% (3/25)	52.0% (13/25)	0.0054
Late Loss – In-Stent	0.47 ± 0.567 (25)	1.25 ± 0.513 (25)	<0.0001
Late Loss – Analysis Segment	0.17 ± 0.434 (25)	0.91 ± 0.553 (25)	<0.0001
Patients Receiving Multiple Study Stents			
MACE	10.8% (9/83)	25.3% (21/83)	0.0254
TVR	4.8% (4/83)	25.3% (21/83)	0.0003
TLR	3.6% (3/83)	24.1% (20/83)	0.0002
In-Stent Restenosis	8.6% (7/81)	41.9% (31/74)	<0.0001
Analysis Segment Restenosis	11.1% (9/81)	45.9% (34/74)	<0.0001
Late Loss – In-Stent	0.41 ± 0.453 (81)	1.10 ± 0.586 (74)	<0.0001
Late Loss – Analysis Segment	0.23 ± 0.434 (81)	0.80 ± 0.623 (74)	<0.0001
Long Lesions (≥ 26 mm)			
MACE	13.3% (6/45)	26.3% (10/38)	0.1679
TVR, Overall	6.7% (3/45)	26.3% (10/38)	0.0174
TLR, Overall	4.4% (2/45)	26.3% (10/38)	0.0097
Late Loss (mm) – Analysis Segment	0.26 ± 0.441 (43)	0.89 ± 0.630 (34)	<0.0001
	(-0.75, 1.74)	(-0.20, 2.36)	
Late Loss (mm) – In-Stent	0.41 ± 0.472 (43)	1.16 ± 0.613 (34)	<0.0001
	(-0.58, 1.74)	(0.05, 2.49)	
Binary Restenosis Rate – Analysis Segment	9.3% (4/43)	52.9% (18/34)	<0.0001
Binary Restenosis Rate – In-Stent	7.0% (3/43)	50.0% (17/34)	<0.0001
Patients Receiving Multiple Overlapping Study Stents			
MACE	9.5% (6/63)	24.6% (15/61)	0.0316
TVR	1.6% (1/63)	24.6% (15/61)	<0.0001
TLR	1.6% (1/63)	23.0% (14/61)	0.0002
In-Stent Restenosis	4.8% (3/62)	45.5% (25/55)	<0.0001
Analysis Segment Restenosis	8.1% (5/62)	50.9% (28/55)	<0.0001
Late Loss – In-Stent	0.43 ± 0.443 (62)	1.13 ± 0.582 (55)	<0.0001
Late Loss – Analysis Segment	0.24 ± 0.426 (62)	0.86 ± 0.617 (55)	<0.0001

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TAXUS VI

Randomized International Complex Trial (continued)

9-Month Data

IVUS 9-Month Data	TAXUS Express Paclitaxel-Eluting Stent (n=87)
% In-Stent Net Volume Obstruction	10.71 ± 10.78

2-Year Data

Safety Measures	TAXUS® Express® Paclitaxel-Eluting Stent (n=217)
MACE	21.4% (46/215)
Cardiac Death	0.5% (1/215)
MI	8.8% (19/215)
Q-Wave MI	1.4% (3/215)
Non-Q-Wave MI	7.4% (16/215)
TVR, Overall	14.0% (930/215)
TLR, Overall	9.8% (21/215)
TLR, PCI	9.3% (20/215)
TLR, CABG	0.5% (1/215)
Non-TLR, Overall	6.0% (13/215)
Non-TLR, PCI	5.6% (12/215)
Non-TLR, CABG	0.9% (2/215)
Stent Thrombosis	0.9% (2/216)
0–30 Days Post-Procedure	0.5% (1/217)
31–365 Days Post-Procedure	0.0% (0/217)
1–2 Years Post-Procedure	0.5% (1/216)
In-Hospital MACE	6.5% (14/217)
Out-of-Hospital MACE to 2 Years	15.5% (33/216)

	Control (n=92)	p-Value
	32.95 ± 15.13	<0.0001
	Control* (n=223)	p-Value
MACE	25.5% (55/216)	0.3632
Cardiac Death	1.4% (3/216)	0.6233
MI	6.9% (15/216)	0.4811
Q-Wave MI	1.4% (3/216)	1.0000
Non-Q-Wave MI	5.6% (12/216)	0.4424
TVR, Overall	22.2% (48/216)	0.0330
TLR, Overall	21.3% (46/216)	0.0013
TLR, PCI	19.4% (42/216)	0.0037
TLR, CABG	2.3% (5/216)	0.2155
Non-TLR, Overall	2.3% (5/216)	0.0578
Non-TLR, PCI	1.9% (4/216)	0.0447
Non-TLR, CABG	0.5% (1/216)	0.6233
Stent Thrombosis	0.9% (2/215)	1.0000
0–30 Days Post-Procedure	0.9% (2/223)	1.0000
31–365 Days Post-Procedure	0.0% (0/223)	
1–2 Years Post-Procedure	0.0% (0/215)	1.0000
In-Hospital MACE	4.0% (9/223)	0.2891
Out-of-Hospital MACE to 2 Years	23.6% (51/219)	0.0390

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INDICATIONS

The TAXUS[®] Express[™] 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.

Coronary Artery Stenting is contraindicated for use in:

- Patients in whom antiplatelet and/or anticoagulant therapy is contraindicated.
- 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.

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 Express² Paclitaxel-Eluting Coronary Stent System have not been established in the following patient populations:

- Women who are pregnant or lactating.
- Men intending to father children.
- Pediatric patients.
- Patients with unresolved vessel thrombus at the lesion site.
- Patients with coronary artery reference vessel diameters < 2.5 mm or > 3.75 mm.
- 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 multiple overlapping stents.
- Patients with longer than 1-Year follow-up.

Prior to use, please see the complete "Directions for Use" at www.taxus-stent.com for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events and Operator's Instructions.

CAUTION

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

TRADEMARKS

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