

Baseline Comparisons: US vs. OUS

Zilver PTX RCT



Demographic and Baseline Characteristic	US (N=386)	OUS (N=88)	P value
Age (years)	67.4 ± 10.1	69.5 ± 10.1	0.0640
Gender			0.0853
Male	63.0% (243/386)	72.7% (64/88)	
Female	37.0% (143/386)	27.3% (24/88)	
Hispanic	7.9% (26/328)	0.0% (0/88)	0.0024
Black	14.6% (48/328)	0.0% (0/88)	<.0001
Smoking			0.0928
Active	33.5% (129/385)	23.9% (21/88)	
Previous	53.2% (205/385)	55.7% (49/88)	
Never	13.2% (51/385)	20.5% (18/88)	
Hyperlipidemia	80.3% (310/386)	40.9% (36/88)	<.0001
CAD	22.0% (85/386)	6.8% (6/88)	0.0005
Obesity			<.0001
BMI ≥ 30 kg/m ²	36.3% (140/386)	10.2% (9/88)	
BMI < 30 kg/m ²	63.7% (246/386)	89.8% (79/88)	
History of MI	21.8% (84/386)	8.0% (7/88)	0.0024

Baseline Comparisons: US vs. OUS

LEVANT 2



Demographic and Baseline Characteristic	US (N=301)	OUS (N=175)	P value
Gender			0.0946
Male	60.1% (181/301)	68.0% (119/175)	
Female	39.9% (120/301)	32.0% (56/175)	
Black	8.9% (25/281)	0.0% (0/175)	<.0001
Smoking			0.0007
Active	30.2% (91/301)	42.3% (74/175)	
Previous	52.2% (157/301)	34.3% (60/175)	
Never	17.6% (53/301)	23.4% (41/175)	
Hypertension	91.0% (274/301)	84.6% (148/175)	0.0363
Hyperlipidemia	92.7% (279/301)	81.1% (142/175)	0.0003
Diabetes Mellitus	47.8% (144/301)	34.3% (60/175)	0.0040
CAD	59.8% (180/301)	31.4% (55/175)	<.0001
Obesity			0.0018
BMI \geq 30 kg/m ²	38.5% (116/301)	24.6% (43/175)	
BMI < 30 kg/m ²	61.5% (185/301)	75.4% (132/175)	
Renal Insufficiency			0.0964
Baseline Serum creatinine \geq 1.5 ng/dl	7.7% (23/299)	3.3% (5/150)	
Baseline Serum creatinine < 1.5 ng/dl	92.3% (276/299)	96.7% (145/150)	
Rutherford Category			0.0003
\leq 3	88.7% (267/301)	97.7% (171/175)	
$>$ 3	11.3% (34/301)	2.3% (4/175)	
History of MI	22.9% (69/301)	12.6% (22/175)	0.0054
History of PCI	20.9% (63/301)	9.7% (17/175)	0.0014
History of CABG	18.3% (55/301)	9.7% (17/175)	0.0118
Anti-thrombotic medication at Baseline	96.0% (289/301)	92.0% (161/175)	0.0922
Statins at Baseline	80.4% (242/301)	73.1% (128/175)	0.0688

Baseline Comparisons: US vs. OUS

IN.PACT SFA



Demographic and Baseline Characteristic	US (N=180)	OUS (N=150)	P value
Smoking			0.0015
Active	31.1% (56/180)	45.3% (68/150)	
Previous	37.2% (67/180)	20.0% (30/150)	
Never	31.7% (57/180)	34.7% (52/150)	
Hypertension	93.9% (169/180)	86.0% (129/150)	0.0237
Hyperlipidemia	91.1% (164/180)	75.3% (113/150)	0.0001
CHD	66.3% (116/175)	44.9% (66/147)	0.0001
Obesity			<.0001
BMI \geq 30 kg/m ²	38.3% (69/180)	12.7% (19/150)	
BMI < 30 kg/m ²	61.7% (111/180)	87.3% (131/150)	
Renal Insufficiency			0.0362
Baseline Serum creatinine \geq 1.5 ng/dl	10.6% (19/180)	4.1% (6/145)	
Baseline Serum creatinine < 1.5 ng/dl	89.4% (161/180)	95.9% (139/145)	
Anti-thrombotic medication at Baseline	96.1% (173/180)	89.3% (134/150)	0.0178
Statins at Baseline	0.0% (0/180)	70.0% (105/150)	<.0001
Beta Blocker at Baseline	0.0% (0/180)	55.3% (83/150)	<.0001
ACEI/ARB at baseline	0.0% (0/180)	68.7% (103/150)	<.0001

Baseline Comparisons: US vs. OUS

ILLUMENATE RCT



Demographic and Baseline Characteristic	US (N=273)	OUS (N=27)	P value
Black	19.9% (54/272)	0.0% (0/14)	0.0798
Diabetes Mellitus	52.7% (144/273)	25.9% (7/27)	0.0086
CAD	23.8% (65/273)	7.4% (2/27)	0.0539



Mortality Rates by Geography (Panel Pack Data)

			Paclitaxel		Control		
Study	Year	Geography	Mortality Rate	95% CI	Mortality Rate	95% CI	Difference (PTX – Ctrl)
LEVANT 2	5	US	0.22	(0.17, 0.29)	0.12	(0.07, 0.21)	0.10
		OUS	0.15	(0.10, 0.24)	0.12	(0.05, 0.24)	0.03
Zilver PTX RCT	5	US	0.23	(0.17, 0.30)	0.13	(0.08, 0.20)	0.10
		OUS	0.14	(0.07, 0.27)	0.06	(0.02, 0.23)	0.08
IN.PACT SFA	5	US	0.16	(0.10, 0.24)	0.06	(0.02, 0.16)	0.10
		OUS	0.14	(0.08, 0.23)	0.14	(0.06, 0.28)	0.00
ILLUMENATE	3	US	0.09	(0.05, 0.14)	0.12	(0.06, 0.21)	-0.03
		OUS	0.12	(0.03, 0.39)	0.00	NA	0.12

- Rates based on K-M estimates
- Based on Panel Pack data
- Mortality rate for paclitaxel coated device group: numerically higher US vs. OUS, except for ILLUMENATE (limited to 3-year follow-up)