



Patient Enrollment : US vs. OUS

RCT	Region	PTX-Coated Device Group	Uncoated Device Group
Zilver PTX RCT	US	64% (246/386)	36% (140/386)
	OUS	61% (54/88)	39% (34/88)
LEVANT 2	US	66% (199/301)	34% (102/301)
	OUS	67% (117/175)	33% (58/175)
IN.PACT SFA	US	67% (121/180)	33% (59/180)
	OUS	66% (99/150)	34%(51/150)
ILLUMENATE RCT	US	67% (183/273)	33% (90/273)
	OUS	63% (17/27)	37% (10/27)

Missing Rates: US vs. OUS (Panel Pack Data)

Study	Year	Geography	n/N	Missing Rate	p-value
LEVANT 2	5	US	51/301	0.169	0.24
		OUS	22/175	0.126	
Zilver PTX RCT	5	US	167/386	0.433	0.001
		OUS	11/88	0.125	
IN.PACT SFA	5	US	27/180	0.150	0.19
		OUS	31/150	0.207	
ILLUMENATE	3	US	55/273	0.201	0.007
		OUS	12/27	0.444	

- Based on Panel Pack data
- No consistent pattern of missing data: US vs. OUS



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)

Baseline Comparisons: Mortality vs Survival (AT Population, Panel Pack Data)



	Dead	Alive	p-value
ZILVER PTX RCT	N=64	N=232	
Age (years)	71.8 ± 10.1	67.1 ± 9.1	0.0019
Total Target Lesion Length (mm)	67.0 ± 52.3	53.5 ± 40.1	0.0459
Region (% US)	85.9% (55/64)	70.7% (164/232)	0.0153
Diabetes Mellitus	56.3% (36/64)	39.7% (92/232)	0.0223
History of Heart Failure	20.3% (13/64)	9.9% (23/232)	0.0310
Hyperlipidemia	79.7% (51/64)	67.7% (157/232)	0.0656
Rutherford Category above 3	15.6% (10/64)	7.4% (17/231)	0.0513
LEVANT 2	N=71	N=332	
Total Target Lesion Length (mm)	70.1 ± 38.7	61.3 ± 41.4	0.0359
Smoking			0.0547
Active	28.2% (20/71)	35.2% (117/332)	
Previous	60.6% (43/71)	45.2% (150/332)	
Never	11.3% (8/71)	19.6% (65/332)	
Renal Insufficiency (% Baseline Serum creatinine ≥ 1.5 ng/dl)	14.1% (10/71)	3.8% (12/312)	0.0026
History of CABG	22.5% (16/71)	13.3% (44/332)	0.0644
Statins	66.2% (47/71)	80.4% (267/332)	0.0116
IN.PACT SFA I & II	N=39	N=233	
Renal Insufficiency (% Baseline Serum creatinine ≥ 1.5 ng/dl)	17.9% (7/39)	6.6% (15/229)	0.0259
ILLUMENATE RCT	N=27	N=206	
Age (years)	72.8 ± 7.9	68.4 ± 9.8	0.0221

Baseline Comparisons: Mortality vs Survival (AT PTX Patients, Panel Pack Data)



Demographic and Baseline Characteristic	Patients Died	Patients Alive	P-value
Zilver PTX RCT:	N=48	N=137	
Age (years)	71.2 ± 9.5	67.0 ± 8.5	0.0101
Region			0.0374
US	85.4% (41/48)	70.1% (96/137)	
OUS	14.6% (7/48)	29.9% (41/137)	
Diabetes Mellitus	56.3% (27/48)	43.1% (59/137)	0.1318
CAD	31.3% (15/48)	19.7% (27/137)	0.1119
LEVANT 2	N=54	N=212	
Target Lesion Length (mm)	67.0 ± 35.5	61.1 ± 42.8	0.1125
BMI < 30 kg/m ²	63.0% (34/54)	67.5% (143/212)	
Renal Insufficiency			0.0362
Baseline Serum creatinine ≥ 1.5 ng/dl	11.1% (6/54)	3.5% (7/199)	
Baseline Serum creatinine < 1.5 ng/dl	88.9% (48/54)	96.5% (192/199)	
Statins at Baseline	66.7% (36/54)	80.2% (170/212)	0.0442
IN.PACT SFA	N=30	N=148	
Renal Insufficiency			0.0351
Baseline Serum creatinine ≥ 1.5 ng/dl	20.0% (6/30)	6.9% (10/145)	
Baseline Serum creatinine < 1.5 ng/dl	80.0% (24/30)	93.1% (135/145)	
ILLUMENATE RCT	N=17	N=139	
Age (years)	72.8 ± 7.5	67.5 ± 10.1	0.0298
Diabetes Mellitus	76.5% (13/17)	51.8% (72/139)	0.0710
History of Heart Failure	23.5% (4/17)	9.4% (13/139)	0.0939