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12 Months Comparison of the Lutonix[®] Korean SFA Registry vs Global SFA Registry

Prospective, Multicenter, Post-Market Registry Assessing the
Clinical Use and Safety of the
Lutonix[®] Drug Coated Balloon in Femoropopliteal Arteries

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Disclosure

Speaker name: Jae Kyu Kim. MD, PhD

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest



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Lutonix[®] Korean Registry

Prospective, Multicenter, Post-Market Registry
Assessing the Clinical Use and Safety of the
LUTONIX[®] 035 Drug Coated Balloon in Femoropopliteal Arteries



Study Design

Study Design	A Prospective, Multicenter, Single Arm, Post-Market Registry
Objective	To assess the clinical use and safety of the Lutonix [®] Drug Coated Balloon Catheter in a heterogeneous patient population in real world clinical practice.
Number of Patients/Sites	Approximately 249 subjects at up to 16 sites in Korea
Inclusion Criteria	Rutherford Clinical Category ≤ 4 , Stenotic or obstructive vascular lesions
Exclusion Criteria	Inadequate distal outflow
Selected Endpoint	<u>Primary Effectiveness:</u> Freedom from target lesion revascularization (TLR) at 12 months <u>Primary Safety:</u> Freedom at 30 days from the composite endpoint*

*Target vessel revascularization (TVR) and target lesion revascularization (TLR), major amputation and major reintervention (new bypass graft, jump/interposition graft revision, or thrombectomy/thrombolysis) of index limb and device- and procedure-related death.



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16 Participating Centers (N=249)

No.	Dept.	Site	Investigator
1	IR	Chonnam Nat'l Univ. Hosp.	Jae-Kyu Kim
2		Ajou Univ. Hosp.	Je-Hwan Won
3		Seoul Nat'l Univ. Hosp.	Hwan-Jun Jae
4		Inha Univ. Hosp.	Yong-Sun Jeon
5		Seoul St. Mary's Hosp.	Ho-Jong Chun
6		Konkuk Univ. Hosp.	Sang-Woo Park
7		Keimyung Univ. Dongsan Hosp.	Young-Hwan Kim
8	IC	Asan Medical Center	Seung-Whan Lee
9		Chungnam National University Hospital	Jae-Hwan Lee
10		Kangbuk Samsung Hospital	Jong-Young Lee
11		Soonchunhyang University Hospital Bucheon	Yun-Hang Cho
12		Hallym University Sacred Heart Hospital	Hyun-Sook Kim
13		Inje University Busan Paik Hospital	Han-Young Jin
14		Myongji Hospital	Youngsung Suh
15		YeungNam University Medical Center	Ung Kim
16		Busan Veterans Hospital	Su-Hong Kim



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Baseline DCB Demographics

Class.	Description	Korean registry (N=249)
Age(Years)	Mean (SD)	69.1 ± 10.44
Gender	Male	212 (85.1%)
	Female	37 (14.9%)
Risk Factor	DM	148 (59.4%)
	Hypertension	177 (71.1%)
	Cigarette smoking	106 (42.6%)
	Dyslipidemia	49 (19.7%)
Rutherford Grade	Class 1~2	27.0%
	Class 3	9.4%
	Class 4	1.2%
	Class 5~6	-



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DCB Angiographic Demographics

Classification	Korean registry (N=249) Number of Lesions=338
Target Lesion Length (mm)	115.2 (79.42)
Calcification	256 / 338 (75.7%)
Chronic Total Occlusion	143 / 338 (42.3%)
Lesion Locations	
SFA	248 / 338 (73.3%)
Proximal Popliteal	53 / 338 (15.6%)
Mid & Distal Popliteal	37 / 338 (10.9%)



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Primary Safety Endpoint

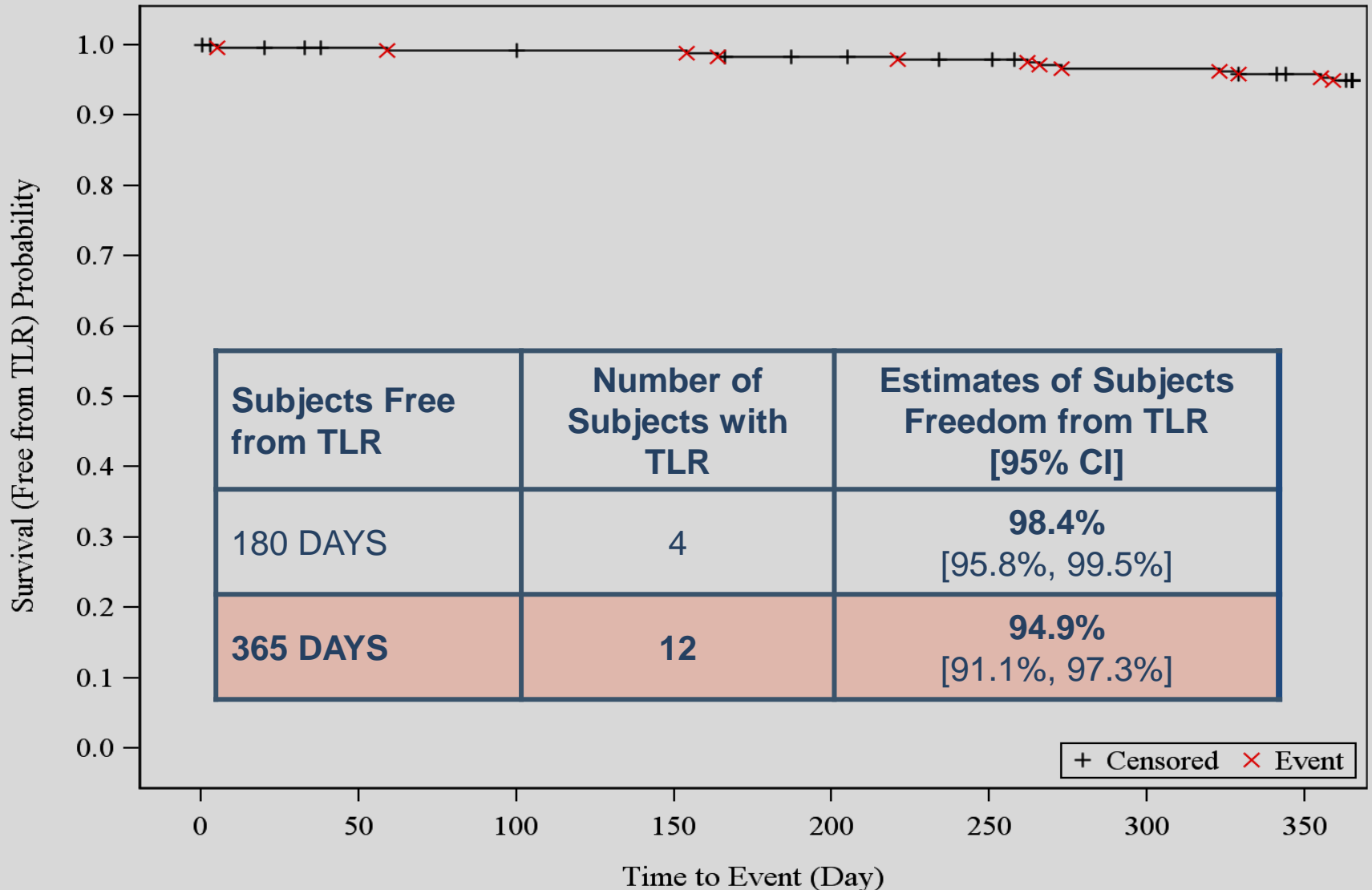
	(n/N)	30 Days, % [95% CI]
Freedom from Composite Events Through 30 Days*	247/249	99.2% [96.8%, 99.8%]

*Target vessel revascularization (TVR) and target lesion revascularization (TLR), major amputation and major reintervention (new bypass graft, jump/interposition graft revision, or thrombectomy / thrombolysis) of index limb and device- and procedure-related death.



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Primary Efficacy Endpoint at 12 months





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Comparison

Global SFA Registry

Prospective, Multicenter, Post-Market Registry

Assessing the Clinical Benefit and Outcomes of the Lutonix 035" Drug Coated Balloon in heterogenous, real-world patient population in Femoropopliteal arteries

Korean SFA Registry

Prospective, Multicenter, Post-Market Registry

Assessing the Clinical Use and Safety of the Lutonix 035" Drug Coated Balloon in Femoropopliteal arteries



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Baseline DCB Demographics

	Global registry (N=691)	Korean registry (N=249)
Age, Mean \pm SD (n)	68.2 \pm 9.8 (691)	69.1 \pm 10.46
Male gender, % (n/N)	67.9% (469/691)	212/249 (85.1%)
Obesity	24.7% (164/665)	-
Current Smoker	36.9% (254/689)	106/249 (42.6%)
Dyslipidemia	70.0% (484/691)	19.7%
Diabetes	39.5% (273/691)	148/ 249(59.4%)
Hypertension	84.9% (587/691)	71.1%
Rutherford Glade Class 1~2	20.6% (142/689)	27.0%
Rutherford Glade Class 3	66.9% (461/689)	9.4%
Rutherford Glade Class 4	7.4% (51/689)	1.2%
Rutherford Glade Class 5~6	1.6% (11/689)	-



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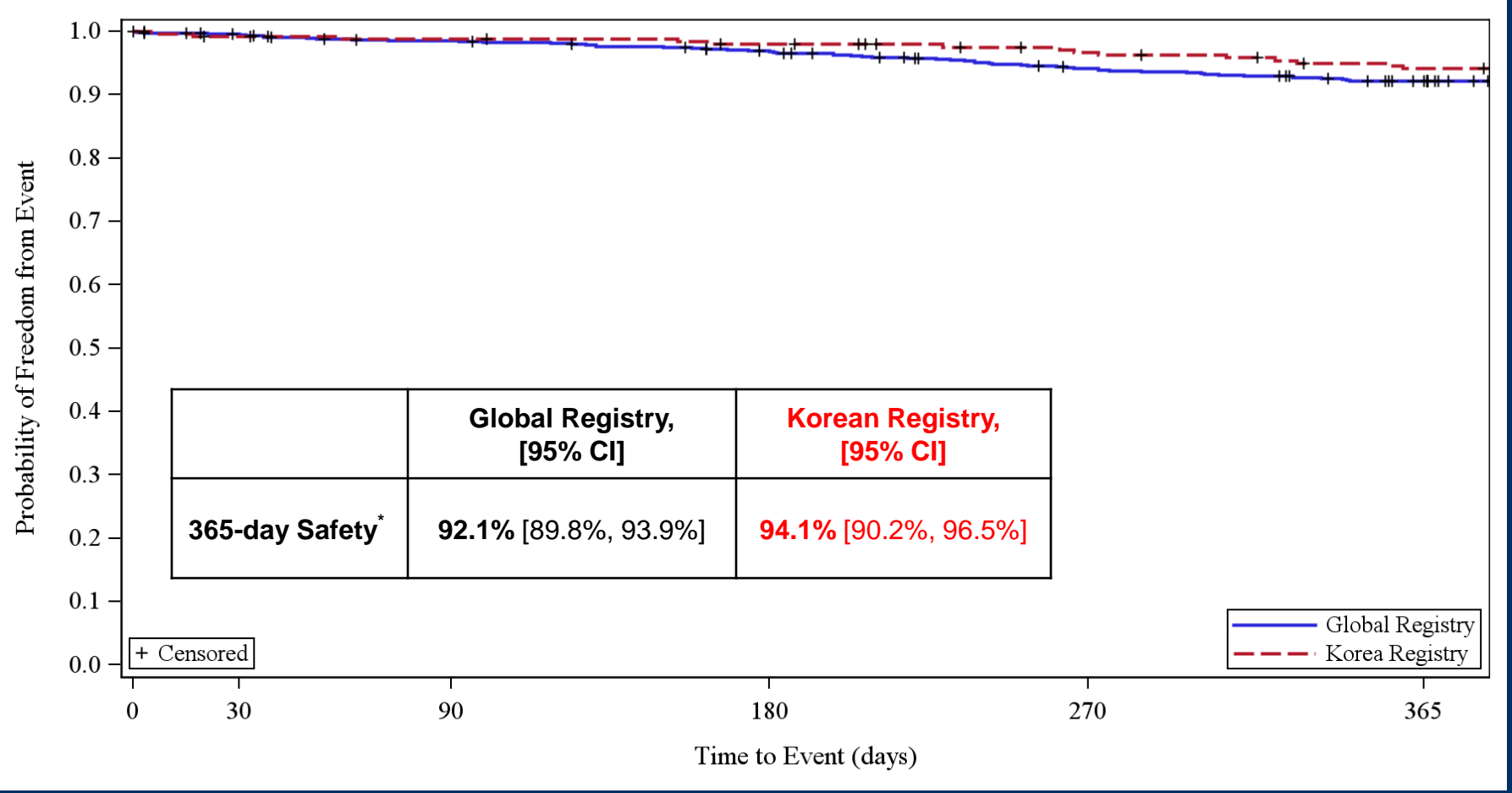
DCB Angiographic Demographics

Classification	Global registry (N=691)	Korean registry (N=249)
> Two lesions treated	15.6% (108/691)	
Total Lesion Length (mm)	101.2 ± 84.2 (685)	115.2
Treated Length (mm)	136.6 ± 89.7 (689)	
Calcification	50.2% (238/474)	256 / 338* (75.7%)
Chronic Total Occlusion	31.2% (214/686)	143 / 338 (42.3%)
Lesion Locations		
SFA	70.0% (483/690)	73.3%
Proximal Popliteal	16.8% (116/690)	15.6%
Mid & Distal Popliteal	13.1% (91/690)	10.9%
Final %Diameter Stenosis	14.6 ± 18.6 (680)	
Bail-out Stenting	25.2% (174/690)	8.8%
Dissection	18.4% (127/690)	2.8%

* 338 = number of lesions



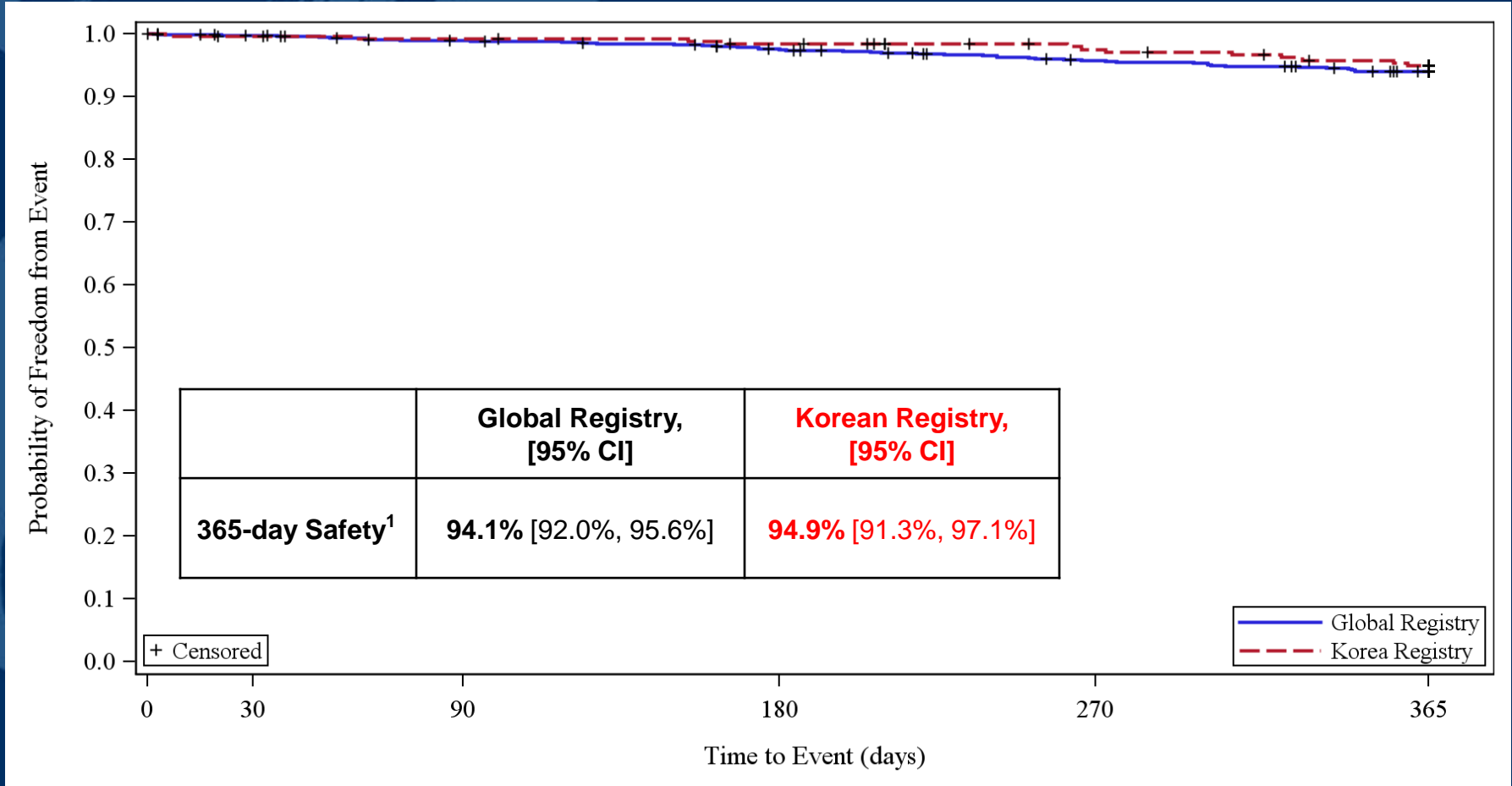
KM Safety at 12 Months



*Target vessel revascularization (TVR) and target lesion revascularization (TLR), major amputation and major reintervention (new bypass graft, jump/interposition graft revision, or thrombectomy / thrombolysis) of index limb and device- and procedure-related death.



LIN KM Freedom from TLR at 12 Months





Conclusions

- Lutonix[®] DCB Korean registry data shows a **99.2% safety through 30 days** and **a 95.0% freedom of TLR at 12 months**, respectively.
- The results of Lutonix[®] Korean registry **correspond very well to** the results of the Global registry.
- The Korean registry has a great significance since it shows the efficacy and safety of Lutonix[®] DCB for the **large Asian population**.



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