

A Closer Look at the Benefit of the **LUTONIX[®] DCB** in Diabetic and Hemodialysis Patients in Japan PMS

Yoshimitsu Soga, MD, PhD, FACC
Kitakyushu, Japan

Disclosure

Speaker name: Yoshimitsu Soga

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)
- do not have any potential conflict of interest

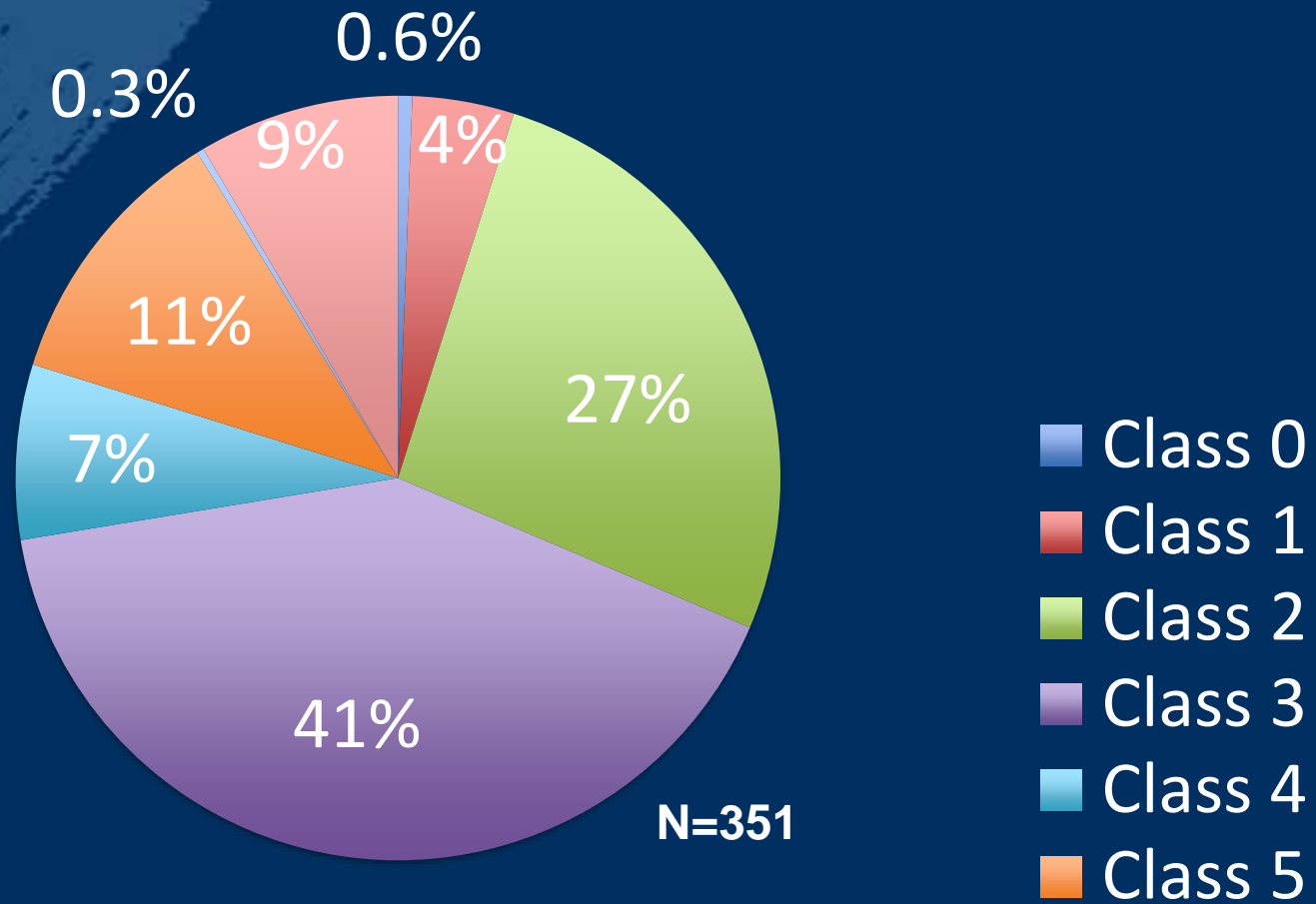
Study Synopsis

Study Design	Post-approval registry
Study Device	LUTONIX[®] 035 Drug Coated PTA Dilatation Catheter
Objective	To confirm whether the safety and efficacy equivalent to LUTONIX[®] 035 DCB for SFA demonstrated per protocol in the LEVANT Japan study
Primary Endpoint	Primary patency at 6 and 12 months
Number of Subjects/Sites	351 subjects 28 sites Current report 100 patients 6 month results
Follow-up	1, 6, and 12 month post index procedure

Baseline DCB Demographics

	Japan PMS (N=351)
Age, Mean \pm SD (n)	74 \pm 8.2 (351)
Gender, % (n/N)	
Male	72.4% (254/351)
Female	27.6% (97/351)
Smoking, % (n/N)	68.4% (240/351)
Current Smoker, % (n/N)	19.4%(68/351)
Dyslipidemia, % (n/N)	58.7% (206/351)
Hypertension, % (n/N)	80.1% (281/351)
Diabetes, % (n/N)	61.3% (215/351)
Chronic Renal Disease, % (n/N)	41.3% (145/351)
Hemodialysis, % (n/N)	27.1%(95/351)

Baseline Rutherford Category



Lesion Characteristics

Description	Japan PMS (293pts, 295 lesions)
Lesion Location, % (n/N, lesions)	
Femoral Artery	89.8% (265/295)
Popliteal Artery	10.2% (30/295)
Total Target Lesion Length (mm), Mean \pm SD (n, pts)	93.8 \pm 46.8 (283)
Average RVD (mm), Mean \pm SD (n, pts)	4.75 \pm 0.92 (278)
Calcification, % (n/N, lesions)	64.6% (184/285)
Severe Calcification, % (n/N, lesions)	30.9% (88/285)
TASC, % (n/N, lesions)	
A	46.5% (132/284)
B	50.7% (144/284)
C	2.8% (8/284)
CTO, % (n/N, pts)	18.3% (51/278)

Procedure information

TIPS	Japan PMS
Balloon Transit Time < 30 seconds, % (n/N, balloons)	95.0% (397/418)
Balloon Inflation Time ≥ 120 seconds, % (n/N, balloons)	98.3% (413/420)
Inflation Pressure ≥ Nominal Pressure, % (n/N, balloons)	98.6% (414/420)
Final % Diameter Stenosis , Mean ± SD (n, pts)	22.9 ± 12.7 (276)
Bailout stenting , % (n/N, pts)	0.9% (3/351)

30-Day Safety

	% (n/N) [95% CI]
30-Day Safety*	97.7% (256/262) [95.1%, 99.2%]

*Freedom from composite safety events are target limb re-intervention, unscheduled target limb amputation and target limb related death during the follow-up period.

Adverse Events

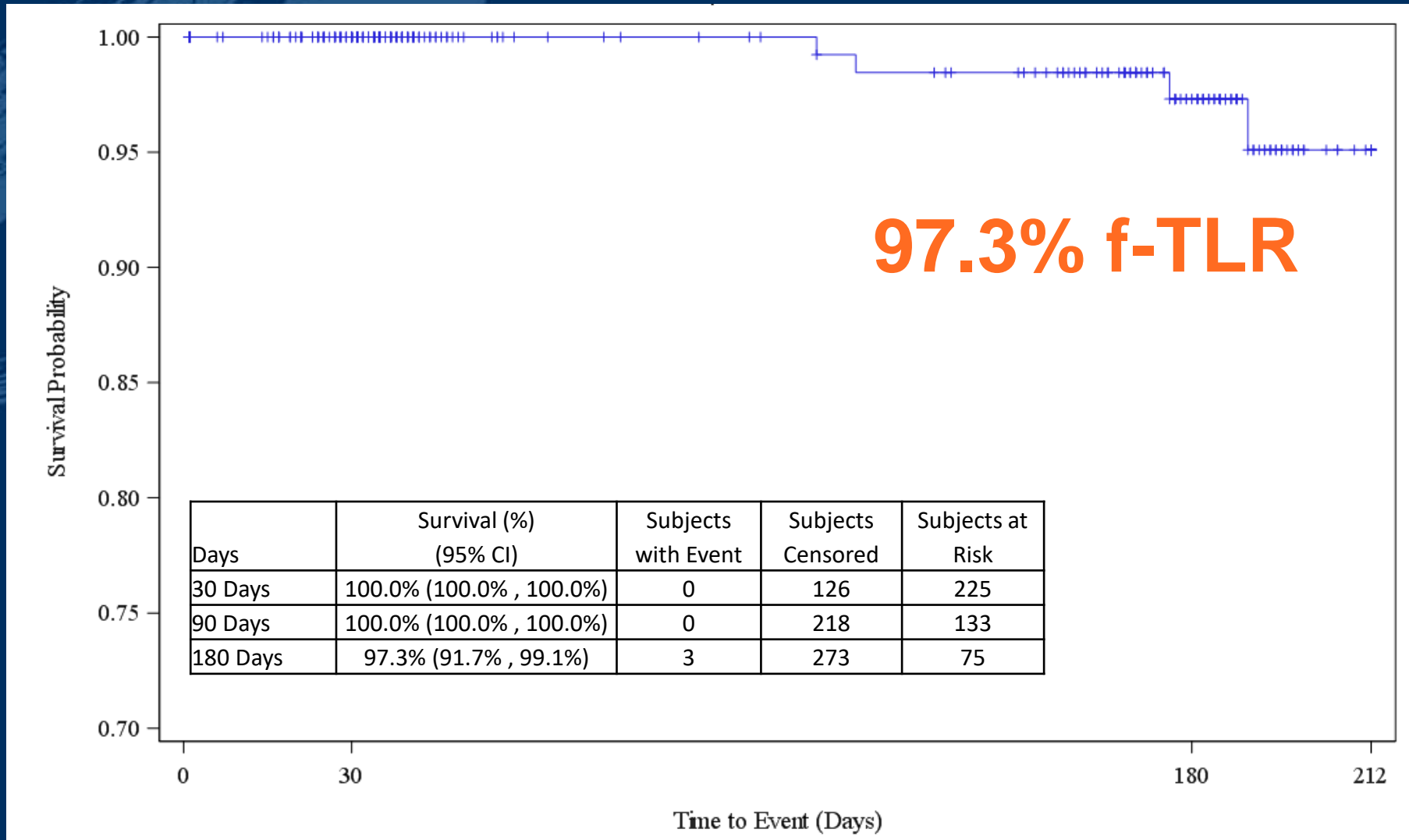
<Device Related AEs>

Description	Japan PMS (N=351)	Diabetic Subgroup (N=215)	Hemodialysis Subgroup (N=95)
Subjects with at least One AE	8 (2.3%)	6 (2.8%)	2 (2.1%)
Target Lesion	8 (2.3%)	6 (2.8%)	2 (2.1%)
Restenosis	8 (2.3%)	6 (2.8%)	2 (2.1%)

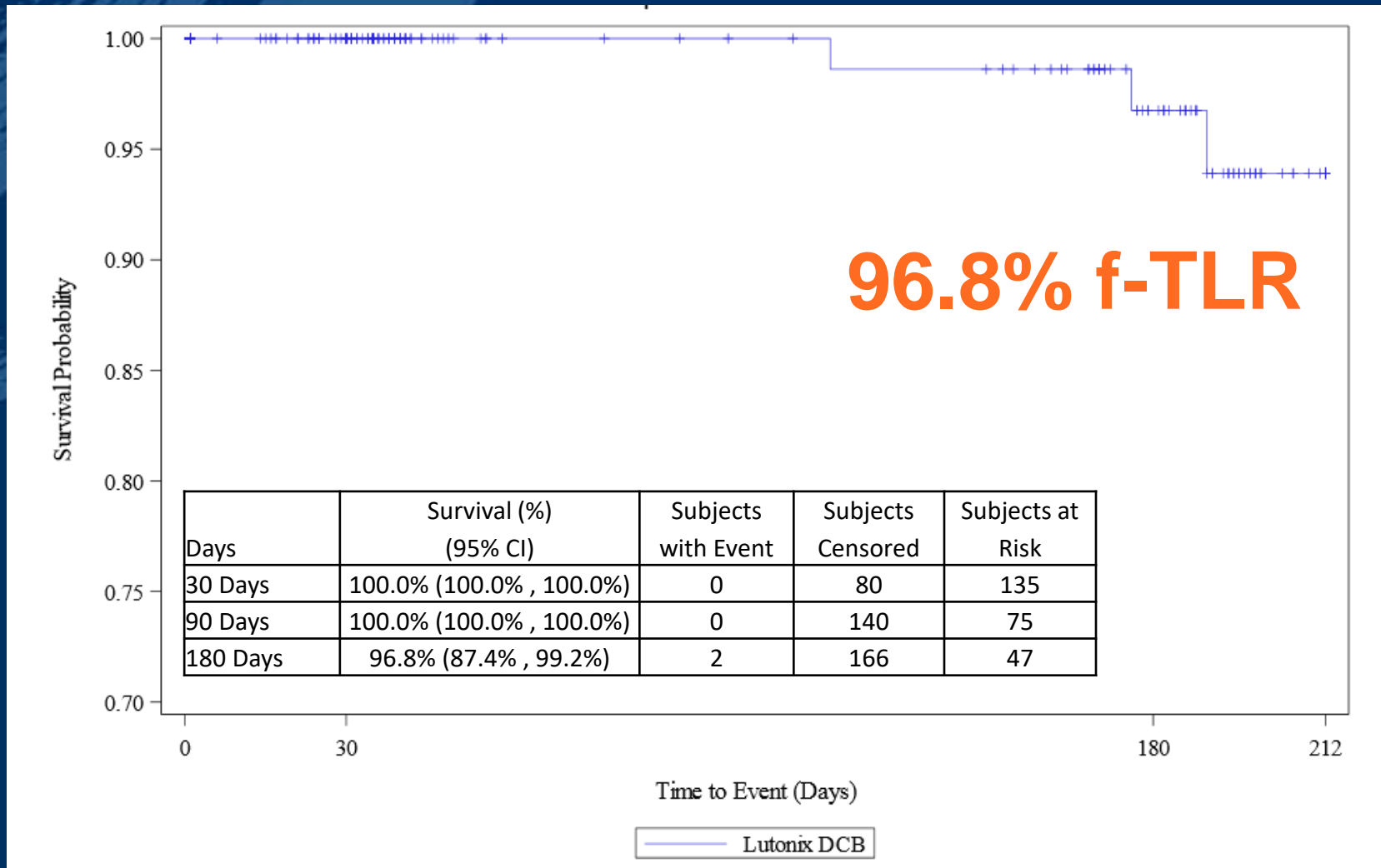
<Procedure Related AEs>

Description	Japan PMS (N=351)	Diabetic Subgroup (N=215)	Hemodialysis Subgroup (N=95)
Subjects with at least One AE	11 (3.1%)	6 (2.8%)	3 (3.2%)
Access Site Complication	2 (0.6%)	-	-
Hematoma / bleeding puncture site – major	1 (0.3%)		
Pseudo aneurysm	2 (0.6%)		
Target Lesion	4 (1.1%)	3 (1.4%)	2 (2.1%)
Restenosis	4 (1.1%)	3 (1.4%)	2 (2.1%)
Various	2 (0.6%)	1 (0.5%)	1 (1.1%)
Other	2 (0.6%)	1 (0.5%)	1 (1.1%)
Vessel specific complications in the leg(not target lesion or target vessel)	3 (0.9%)	2 (0.9%)	-
Perforation	1 (0.3%)	1 (0.5%)	
Stenosis	2 (0.6%)	1 (0.5%)	

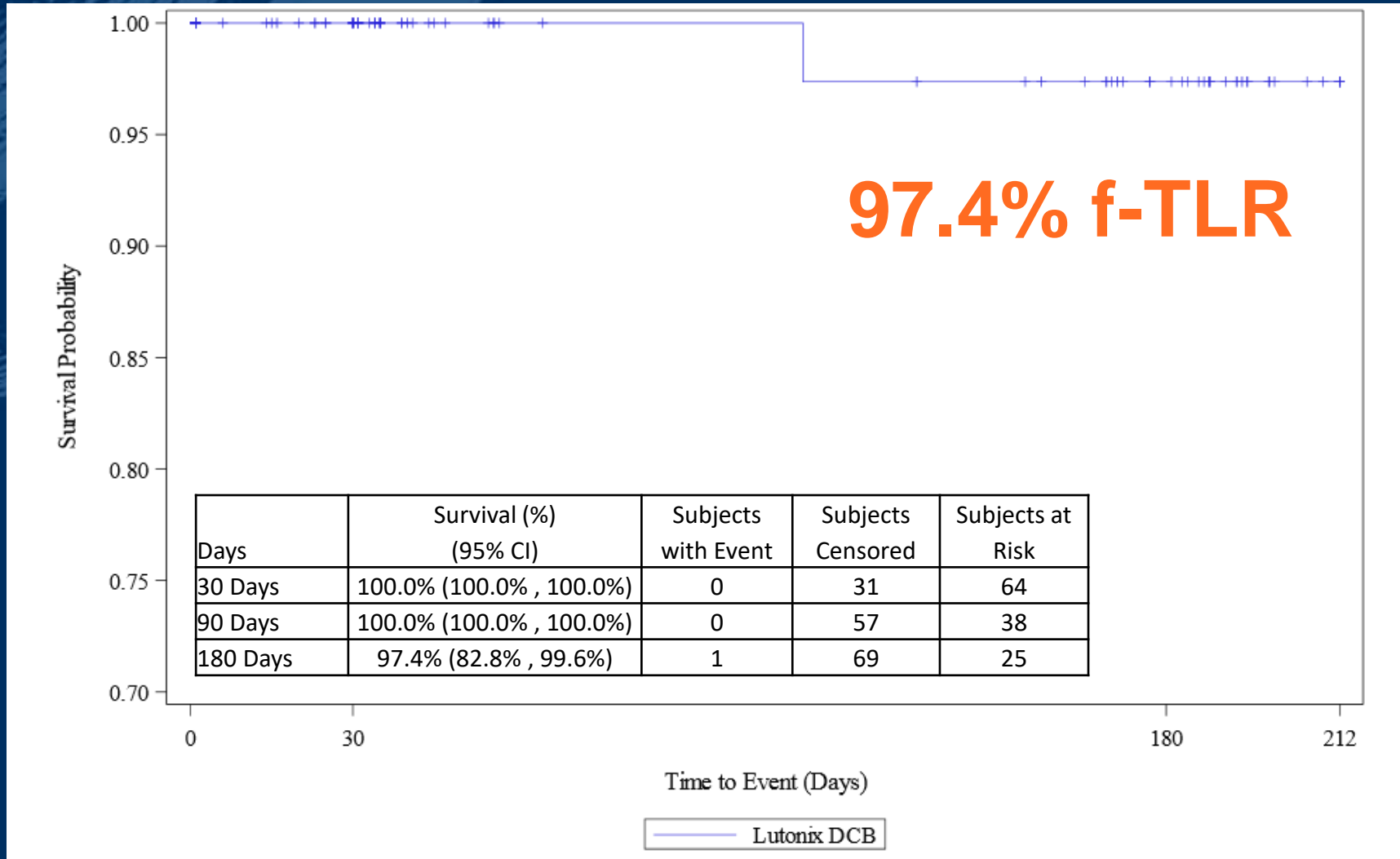
Freedom from TLR (KM 6 Month Endpoint)



Diabetic Subgroup (KM Clinically Driven TLR)



Hemodialysis Subgroup (KM 6 Month TLR)



Summary

- **LUTONIX Japan PMS** re-enforces the safety of the Lutonix DCB with 97.7% Freedom from composite safety events.
- Good procedure with proper DCB technique.
- **LUTONIX Japan PMS** resulted in 97.3% Freedom from TLR at 6 months.
- In Diabetic subgroup, **LUTONIX Japan PMS** resulted in 96.8% Freedom from TLR at 6 months.
- In Hemodialysis subgroup, **LUTONIX Japan PMS** resulted in 97.4% Freedom from TLR at 6 months.

A Closer Look at the Benefit of the **LUTONIX[®] DCB** in Diabetic and Hemodialysis Patients in Japan PMS

Yoshimitsu Soga, MD, PhD, FACC
Kitakyushu, Japan