LUTONIX Korean Registry

Preliminary data

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Background

- DCB is one of the default strategy for femoropoliteal disease.
- LEVANT randomized trial showed reduced restenosis rate compared to conventional balloon angioplasty.
- Lutonix global registry showed excellent safety and efficacy up to 2 years.

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 **100 subjects** at up to 9 sites.
Inclusion Criteria	Rutherford Clinical Category ≤ 4, Stenotic or obstructive vascular lesions
Exclusion Criteria	Not specific
Selected Endpoint	**Primary Effectiveness:** Freedom from target lesion revascularization(TLR) at 12 months. **Primary Safety:** 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.

Participating Centers (N=100)

No.	Site	Investigator
1	Asan Medical Center	Seung-Whan Lee
2	ChungNam Nat'l Univ. Hosp.	Jae-Hwan Lee
3	KangBuk Samsung Hosp.	Jong-Young Lee
4	Soonchunhyang Univ. Bucheon Hosp.	Yoon-Haeng Cho
5	Hallym Univ. Hosp.	Hyun-Sook Kim
6	Inje Univ. Paik Hosp.	Han-Young Jin
7	MyungJi Hosp.	Yun-Hyeong Cho
8	YoungNam Univ. Hosp.	Woong Kim
9	Busan Veterans Hosp.	Su-Hong Kim

Baseline DCB Demographics

Class.	Description	Korean registry (N=100)	Global registry (N=691)
Age(Years)	Mean (SD)	68.5±10.54	68.2±9.8
Gender	Male	84 (84%)	67.9%
	Female	16 (16%)	32.1%
Risk Factor	DM	67 (67%)	39.5%
	Dyslipidemia	31 (31%)	70.0%
	Hypertension	73 (73%)	84.9%
	Cigarette smoking	58 (58%)	36.9%
Rutherford Grade	Class 1~2	37%	20.6%
	Class 3	44%	66.9%
	Class 4	19%	7.4%
	Class 5~6	-	1.6%

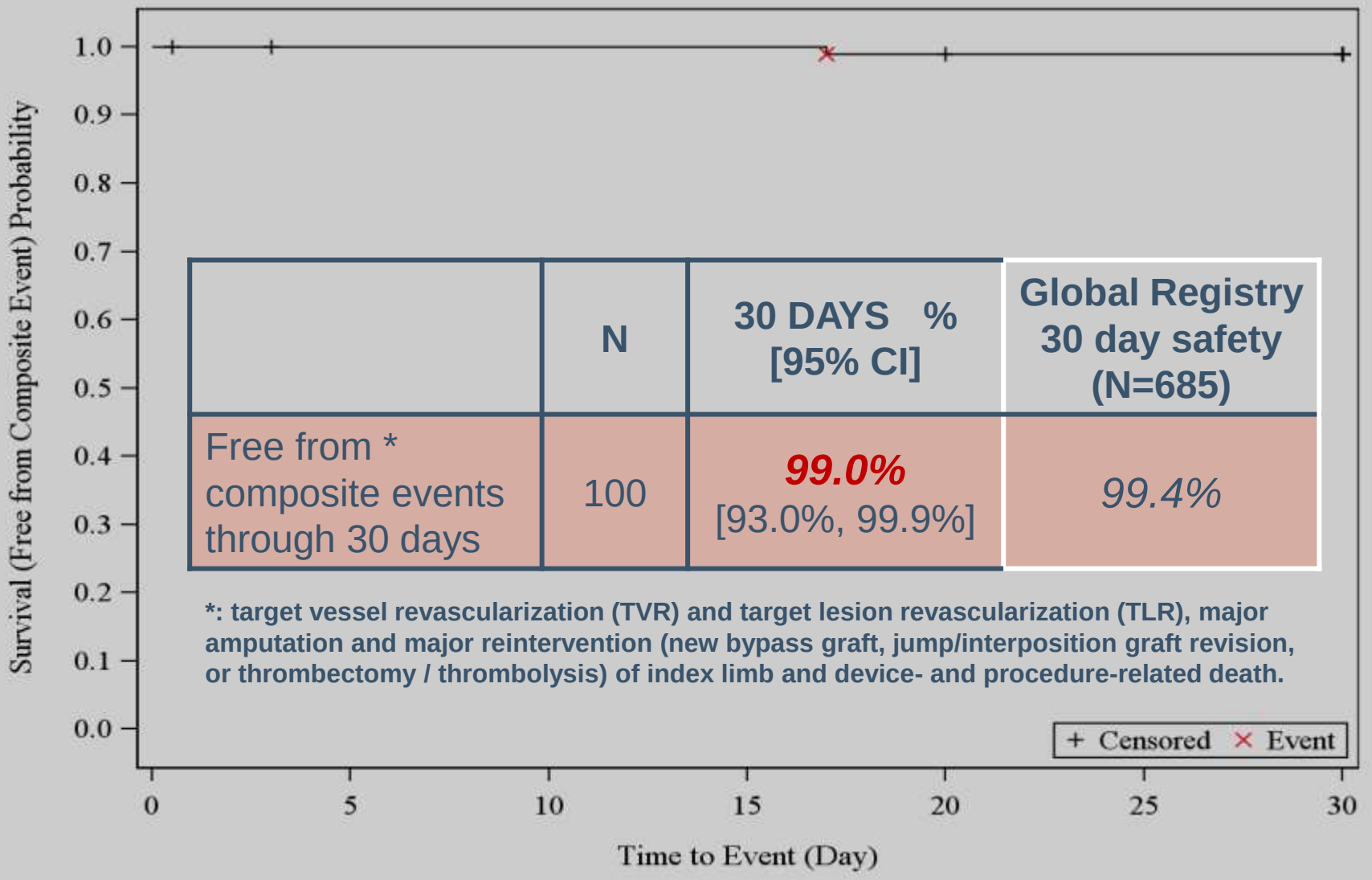
DCB Angiographic Demographics

Classification	Korean registry (N=100, 157 limbs)	Global registry (N=691)
Target Lesion Length (mm)	105.7 (59.72)	101.2
Calcification	65/157 (41.4%)	50.2%
Chronic Total Occlusion	75 / 157 (47.8%)	31.2%
Lesion Locations		
SFA	129 / 157 (82.2%)	70.0%
Proximal Popliteal	14 / 157 (8.9%)	16.8%
Mid & Distal Popliteal	14 / 157 (8.9%)	13.1%
Bail-out Stenting	6 / 157 (3.8%)	25.2%

Pretreatment and bailout stenting

Variables	N=100	Comment
Pretreatment		
Balloon angioplasty	**96**	
Atherectomy	**10**	
Others	**1**	**Cutting balloon**
Post-DCB treatment		
Balloon angioplasty	**8**	
Bail-out stenting	**6**	**5 BMS/ 1 Covered stent**

Primary Safety Endpoint



	N	30 DAYS % [95% CI]	Global Registry 30 day safety (N=685)
Free from * composite events through 30 days	100	***99.0%*** [93.0%, 99.9%]	*99.4%*

***: 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.**

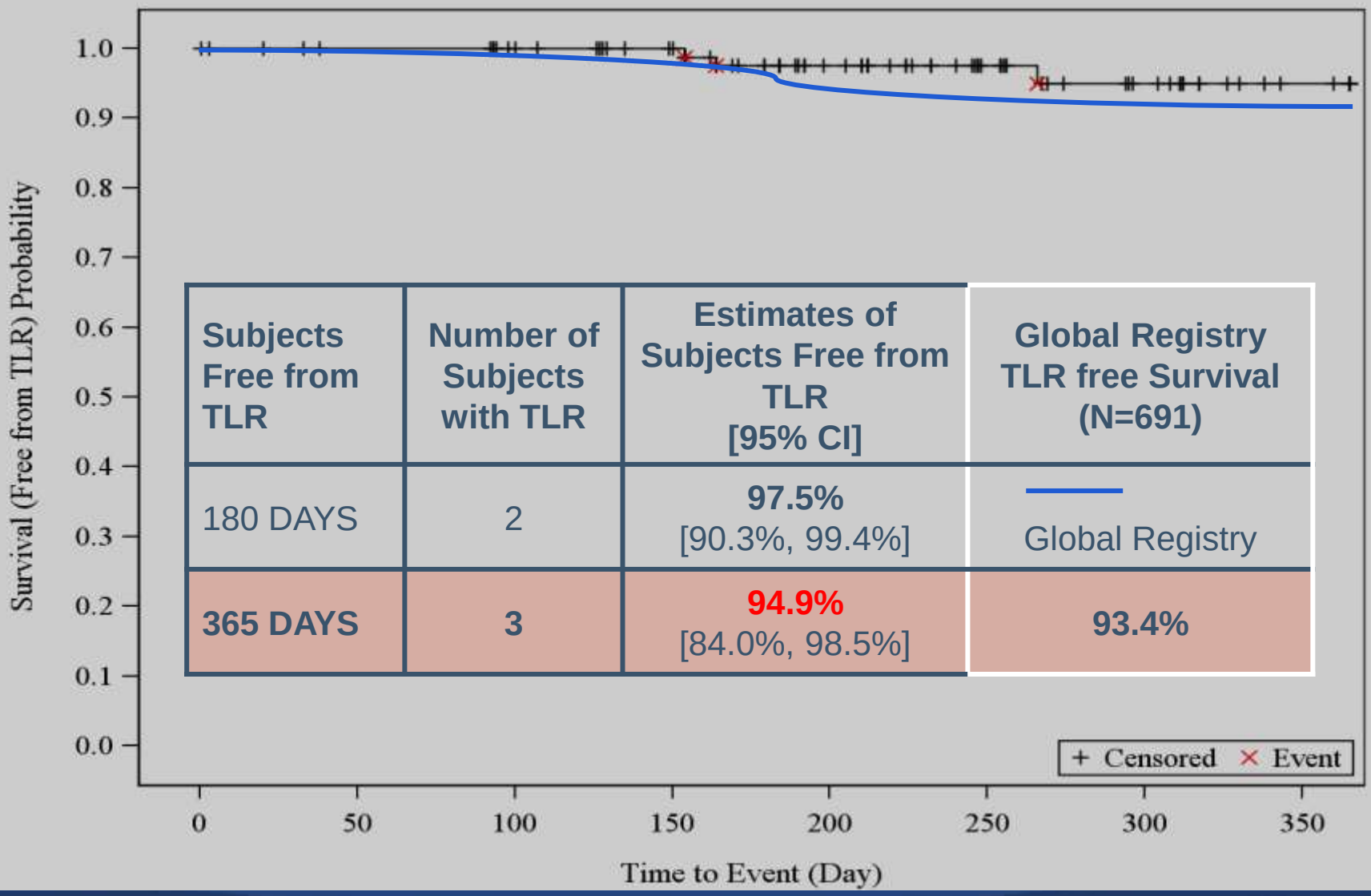
Primary safety endpoint at 1 month

Variables	N=100	Comment
TVR	**1**	LT SECOND TOE WOUND and 100% Stenosis
TLR	**-**	
Major reintervention	**-**	
Death	**-**	
Procedure-related	**-**	
Device-related	**-**	
Major index limb amputation	**-**	
* Minor index limb amputation *: was not in the list of primary safety endpoint	**1**	LT 4th toe ray amputation

1 composite event within 30 days

- **Primary treatment: Pre-dilatation + DCB only + Post-dilatation**
  - 70% residual stenosis
- **Re-intervention @ 17 days**
  - Reason for Re-Intervention: LT SECOND TOE WOUND and 100% Stenosis
  - Location: Target vessel and non-target lesion
  - Treatment: PTA, Stenting

Primary Efficacy Endpoint at 1 year



Subjects Free from TLR	Number of Subjects with TLR	Estimates of Subjects Free from TLR [95% CI]	Global Registry TLR free Survival (N=691)
180 DAYS	2	**97.5%** [90.3%, 99.4%]	Global Registry
365 DAYS	**3**	**94.9%** [84.0%, 98.5%]	**93.4%**

Lutonix Global SFA Real-World Registry

12 months results

MEASURE	% (n / N)
30-day Safety[1]	**99.4%** (681/685)
Free from TLR	**93.4%** (605/648)
Clinical Primary Patency[2]	83.1% (510/614)

[1] Freedom at 30 days from TVR, major index limb amputation, and device-and procedure-related death

[2] Secondary endpoint. Clinical primary patency of the target lesion was reported by the investigator based on presenting symptoms and clinical exam.

ALL SAEs adjudicated. Study monitored.

Lutonix Global SFA Real-World Registry

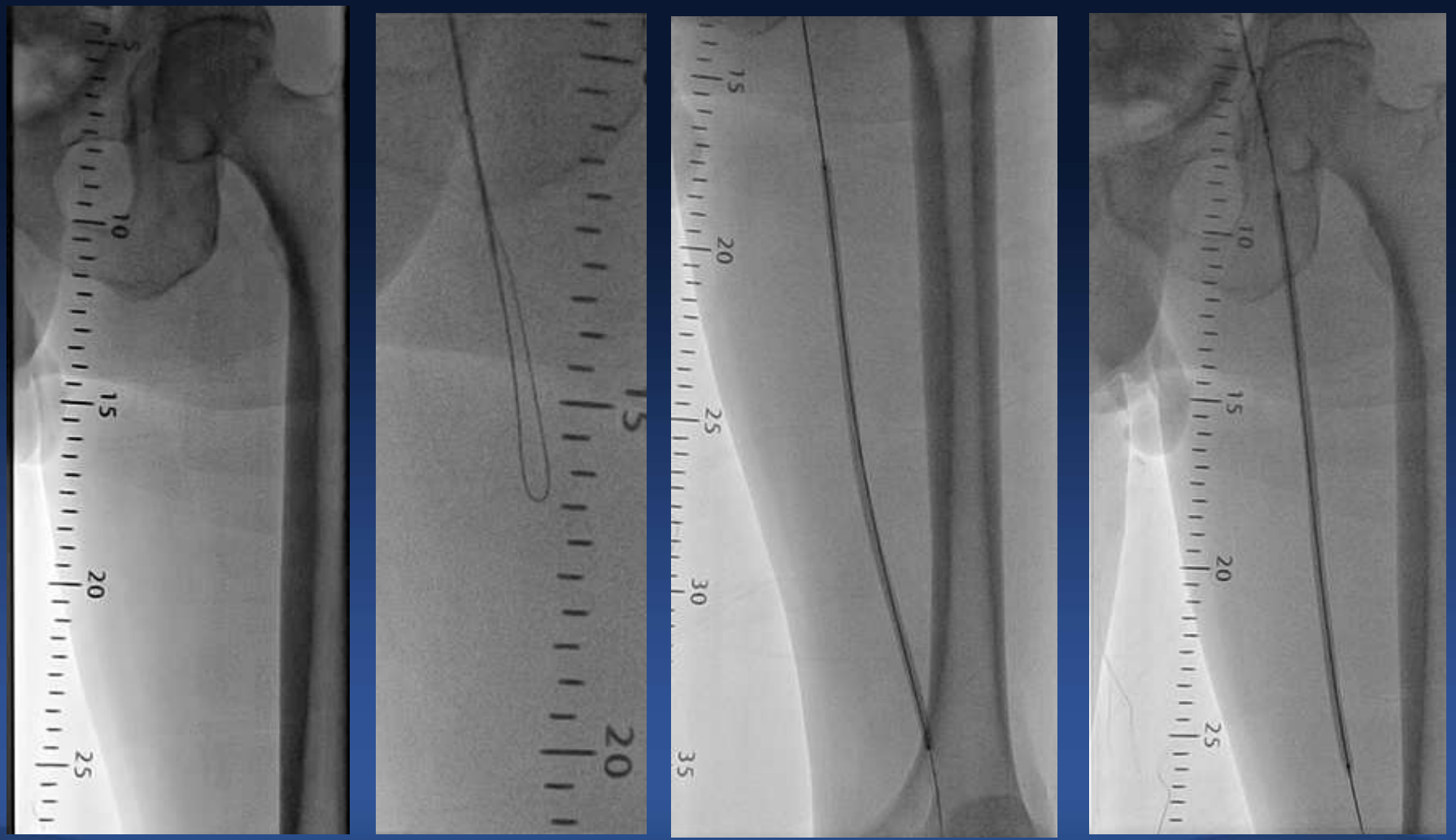
24 months results

MEASURE	% (n / N)
Free from TLR	**89.3%** (526/589)
Clinical Primary Patency[1]	73.5% (416/566)

[1] Secondary endpoint. Clinical primary patency of the target lesion was reported by the investigator based on presenting symptoms and clinical exam. .

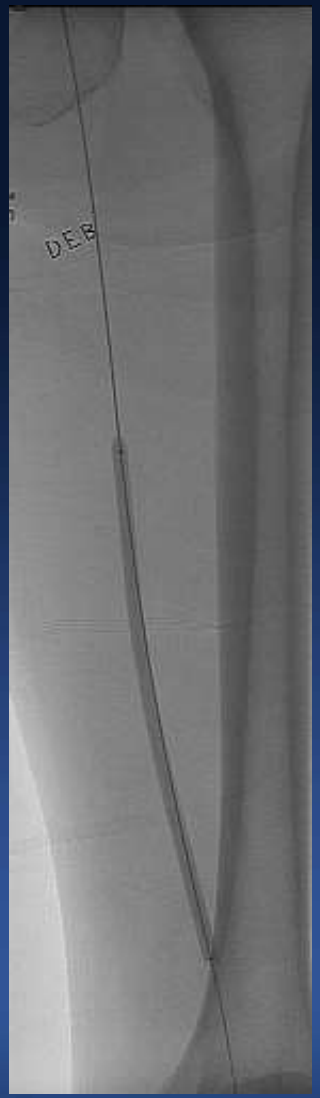
78/M claudication CTO

Pretreatment 5.0/220 balloon



Pre-DCB

Lutonix 5.0/150, 6.0/150 mm

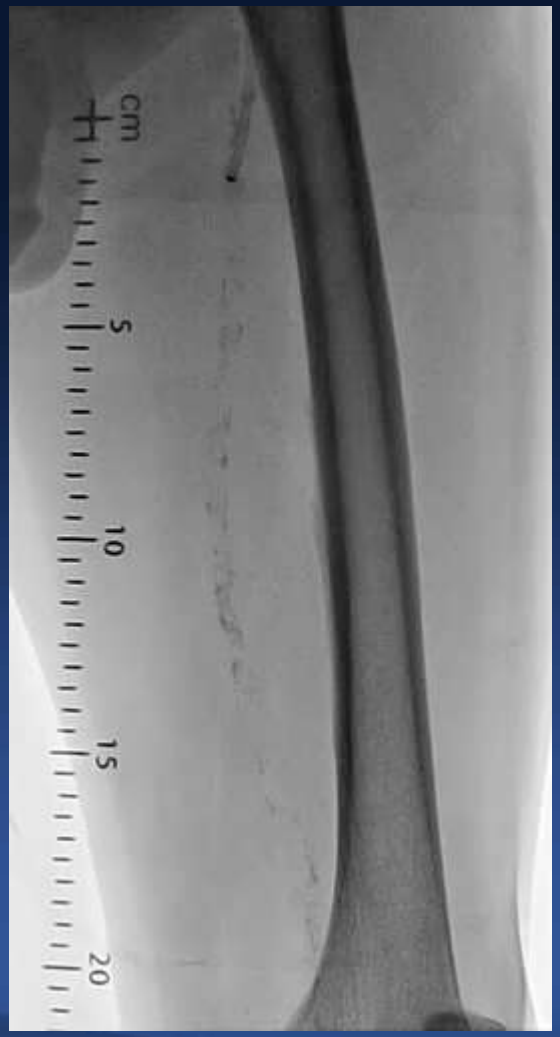


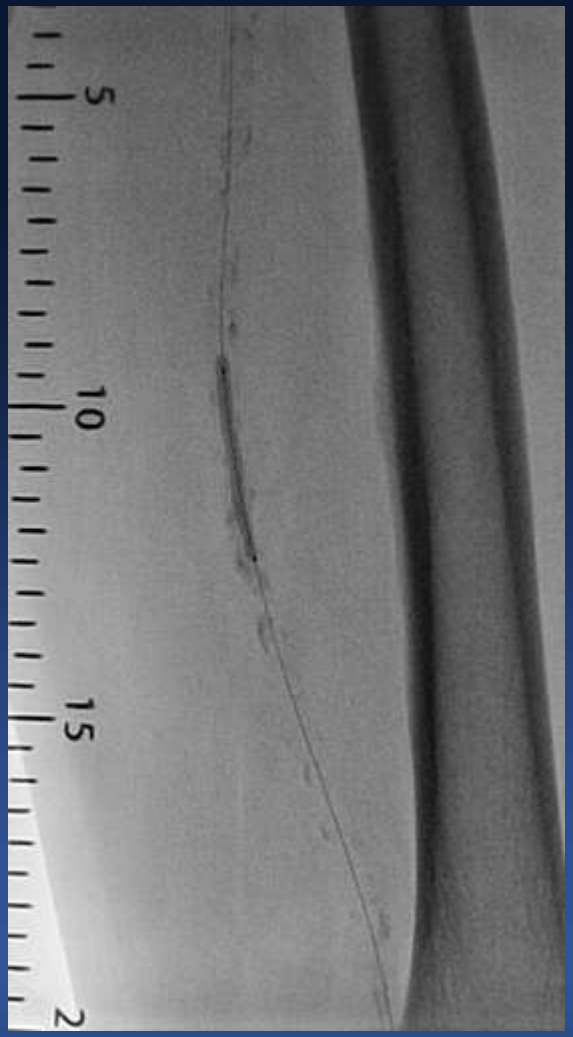
Final results

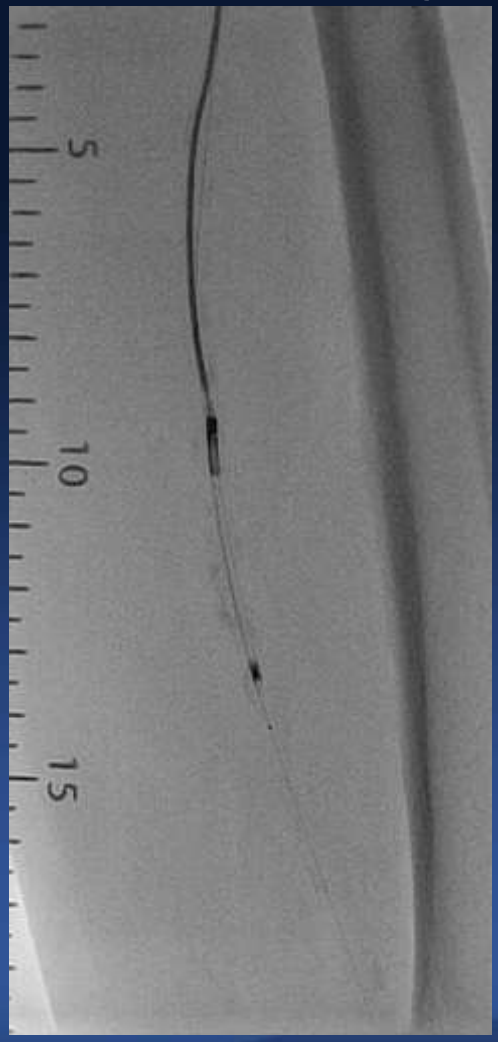
64/M claudication Heavy calcium

2.0/40 mm balloon

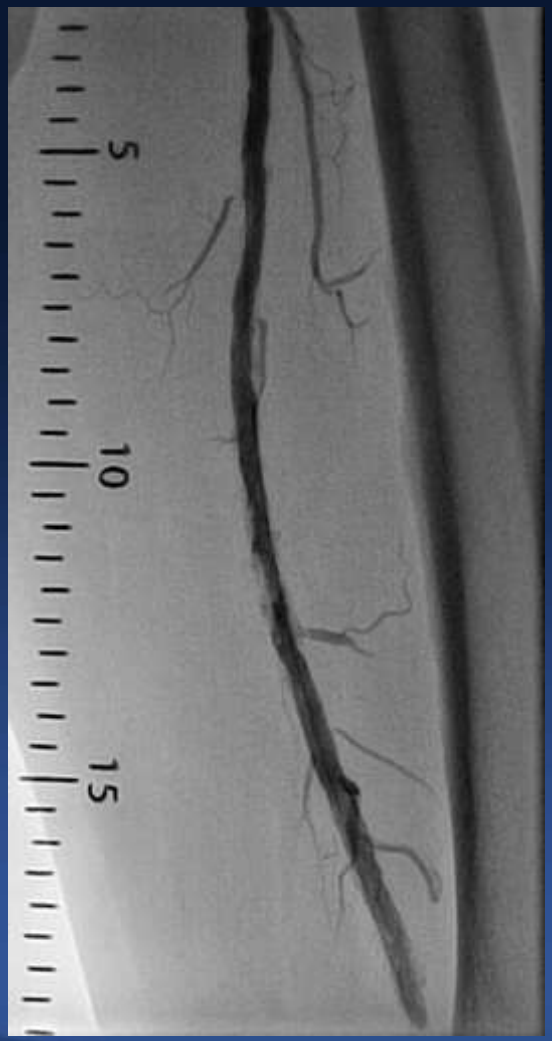
Atherectomy



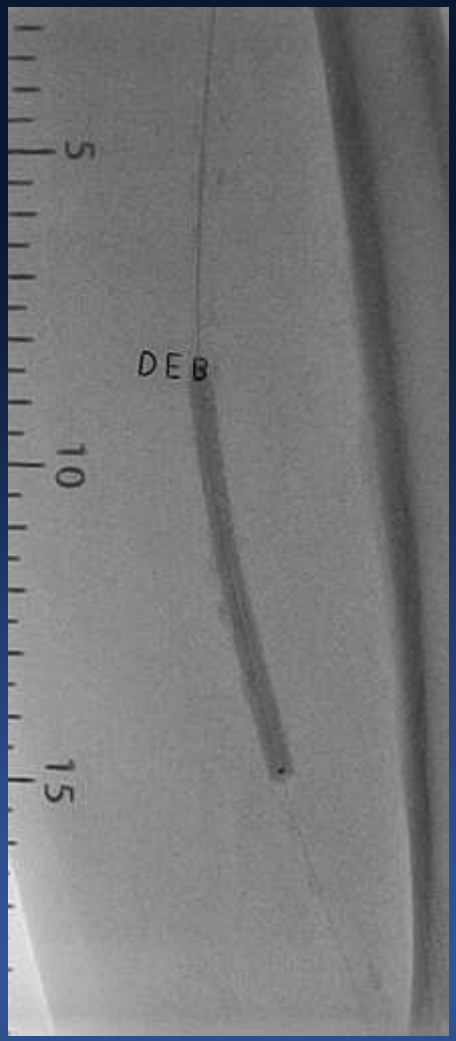




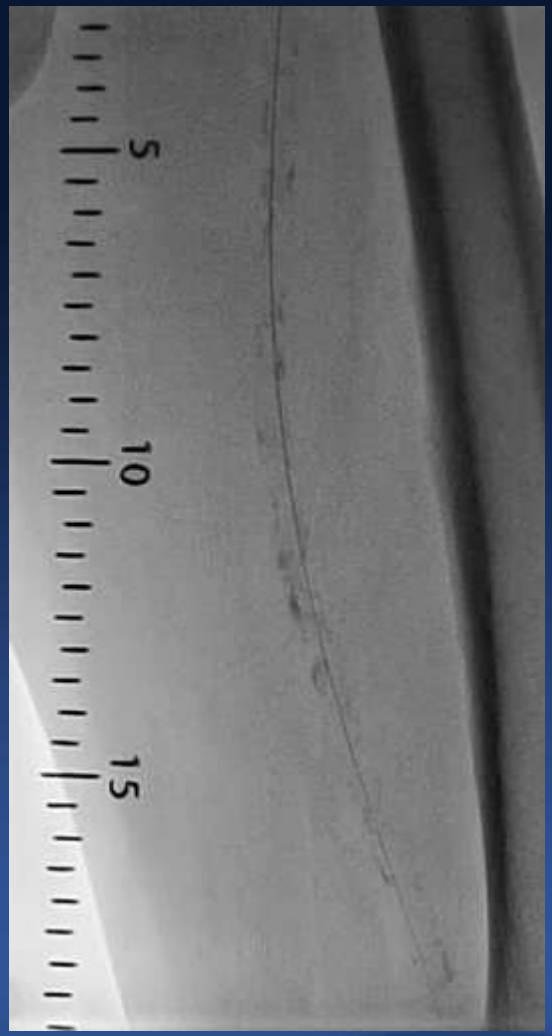
Post atherectomy



Lutonix 6.0/80 mm

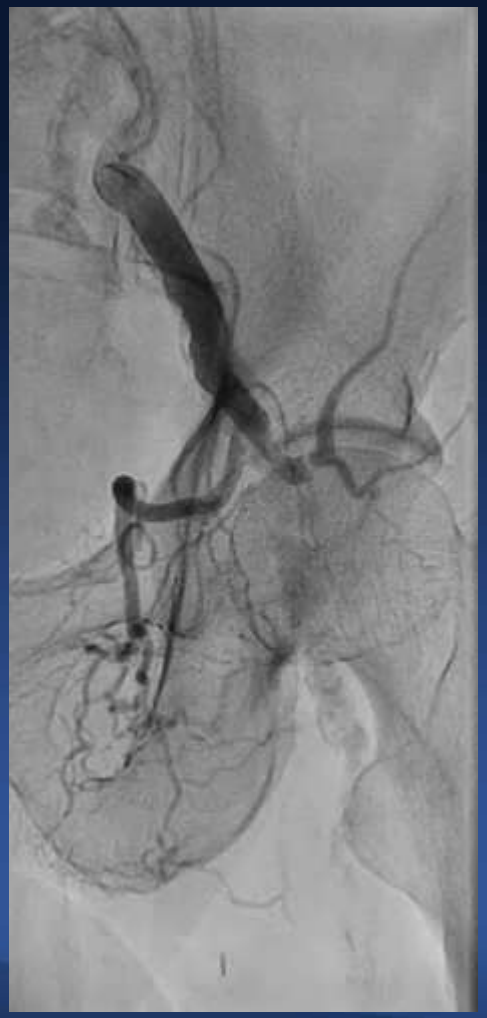


Final results



79/M claudication Heavy calcium

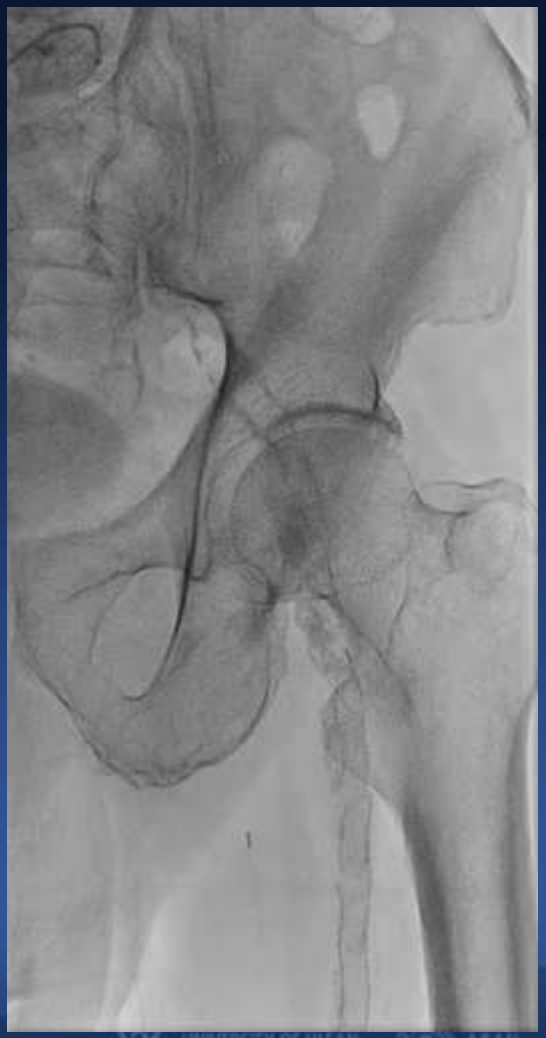
Baseline



Post-procedure, DCB with bailout stenting

Post-procedure, DCB with bailout stenting

1 yr fu angiography



Conclusions

- **Preliminary Lutonix DCB Korean registry data** shows acceptable safety at 1 month in terms of repeat revascularization, amputation, device-and procedure-related death

- **Preliminary Lutonix DCB Korean registry data** shows 97.5% at 6 months and further 94.9% at 1 year of freedom from TLR, respectively, which is consistent with global registry.

- Before DCB application, lesion preparation is important to make good outcome and patency


Thank You !!