THE ROLE of DCB in Korean Practice

LUTONIX® 035 DCB Korean Registry Data Update

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

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Disclosure

Speaker name: Je Hwan Won

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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

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 real world clinical practice of femoropopliteal lesions
Number of Patients/ Sites	Approximately 150 subjects at up to 7 sites. Enrollment is expected to last 12-18 months
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.**

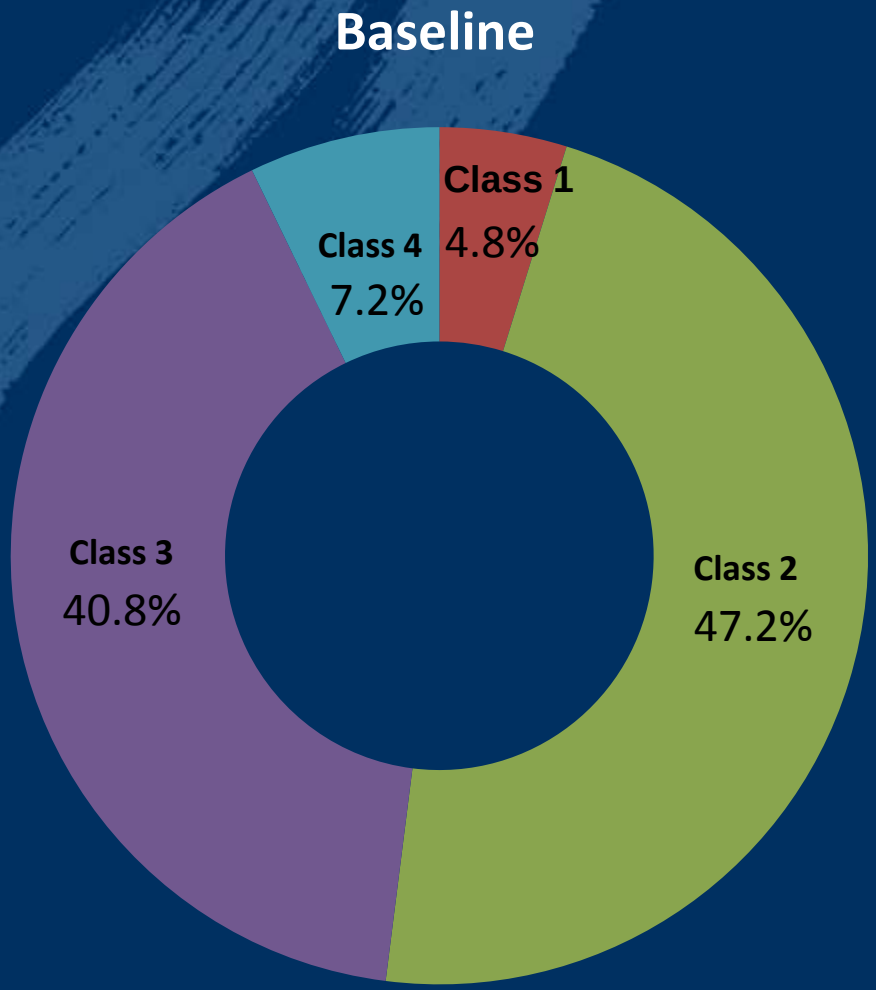
Patient Demographic and Medical History

Class.	Description	Lutonix Korea Registry (N=134)
Age(Years)	Mean (SD)	69.7±10.59
Gender	Male	115 (85.8%)
	Female	19 (14.2%)
Risk Factor	DM	72 (53.7%)
	Dyslipidemia	13 (9.7%)
	Hypertension	91 (67.9%)
	Cigarette smoking	46 (34.3%)
	Current	30 (22.4%)
	Former	16 (11.9%)
	Congestive heart failure (CHF)	3 (2.2%)
	Stroke	13 (9.7%)
Cardiovascular Disease	Coronary artery disease (CAD)	19 (14.2%)
	Myocardial infarction (MI)	5 (3.7%)
	Transient ischemic attack (TIA)	1 (0.7%)
	Valvular heart disease	1 (0.7%)
	Deep vein thrombosis (DVT)	3 (2.2%)
	Other	11 (8.2%)
Renal Disease	Chronic Kidney Disease	17(12.7%)
Other Disease	Cancer	13(9.7%)

Lesion Characteristics

Class.	Decription	Lutonix Korea Registry (N=134, 155 limbs)
Target Lesion Length (mm)	**Mean (SD)**	**122.9 (96.19)**
	Min - Max	8 - 450
Type	Stenosis	91 / 155 (58.7%)
	Occlusion	**64 / 155 (41.3%)**
	De Novo	111/ 155 (71.6%)
	restenotic (no ISR)	35/155 (22.6%)
	In-Stent Restenosis	9/ 155 (5.8%)
Location	Proximal 1/3 of SFA	67 / 155 (43.2%)
	Mid 1/3 of SFA	84 / 155 (54.2%)
	Distal 1/3 of SFA	84 / 155 (54.2%)
	Popliteal P1	**34 / 155 (21.9%)**
	Popliteal P2	**14 / 155 (9.0%)**
	Popliteal P3	**6 / 155 (3.9%)**
Initial Lesion Stenosis (%)	Mean (SD)	87.4 (16.065)
	Min - Max	26-100
Degree of Calcification	None	41 / 155 (26.5%)
	Mild	72 / 155 (46.5%)
	Moderate	**24 / 155 (15.5%)**
	Severe	**18 / 155 (11.6%)**
Reference Vessel Diameter (mm)	Mean (SD)	5.35(0.614)
	Min - Max	3.8 - 7

Rutherford Classification Distribution



Rutherford Category	Distribution (N=134)
0	0
1	4.8%
2	47.2%
3	40.8%
4	7.2%
5	0

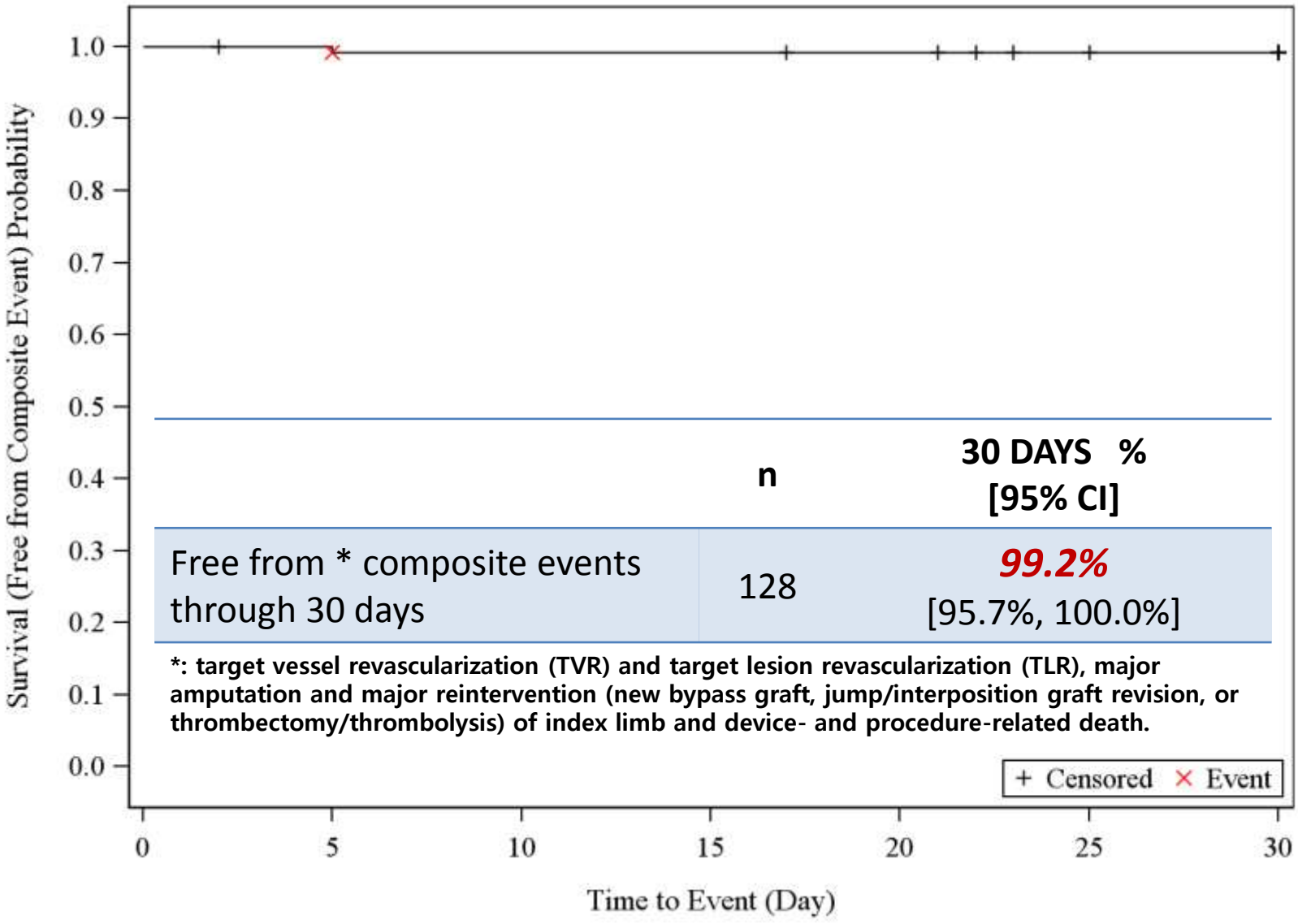
Procedural characteristics

- Pre-dilatation : 90%
- Post-dilatation : 22%
- **Provisional stenting rate : 11.2%**
- Device success : 100%
- Procedural success* : 89 %

*: Attainment of ≤30% residual stenosis in the treatment area after DCB without major adverse events prior to hospital discharge. (Major adverse events include death, stroke, MI, emergent surgical revascularization, significant distal embolization in the target limb, and thrombosis of the target vessel)

- Thrombosis : 0%

Primary Safety Endpoint

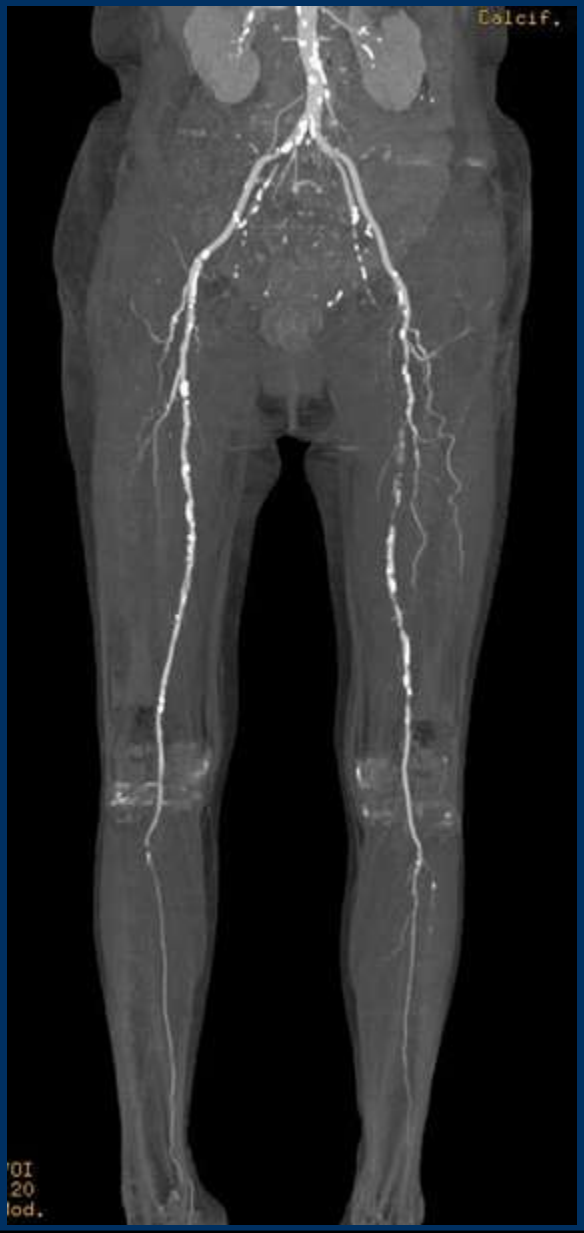


	n	30 DAYS % [95% CI]
Free from * composite events through 30 days	128	***99.2%*** [95.7%, 100.0%]

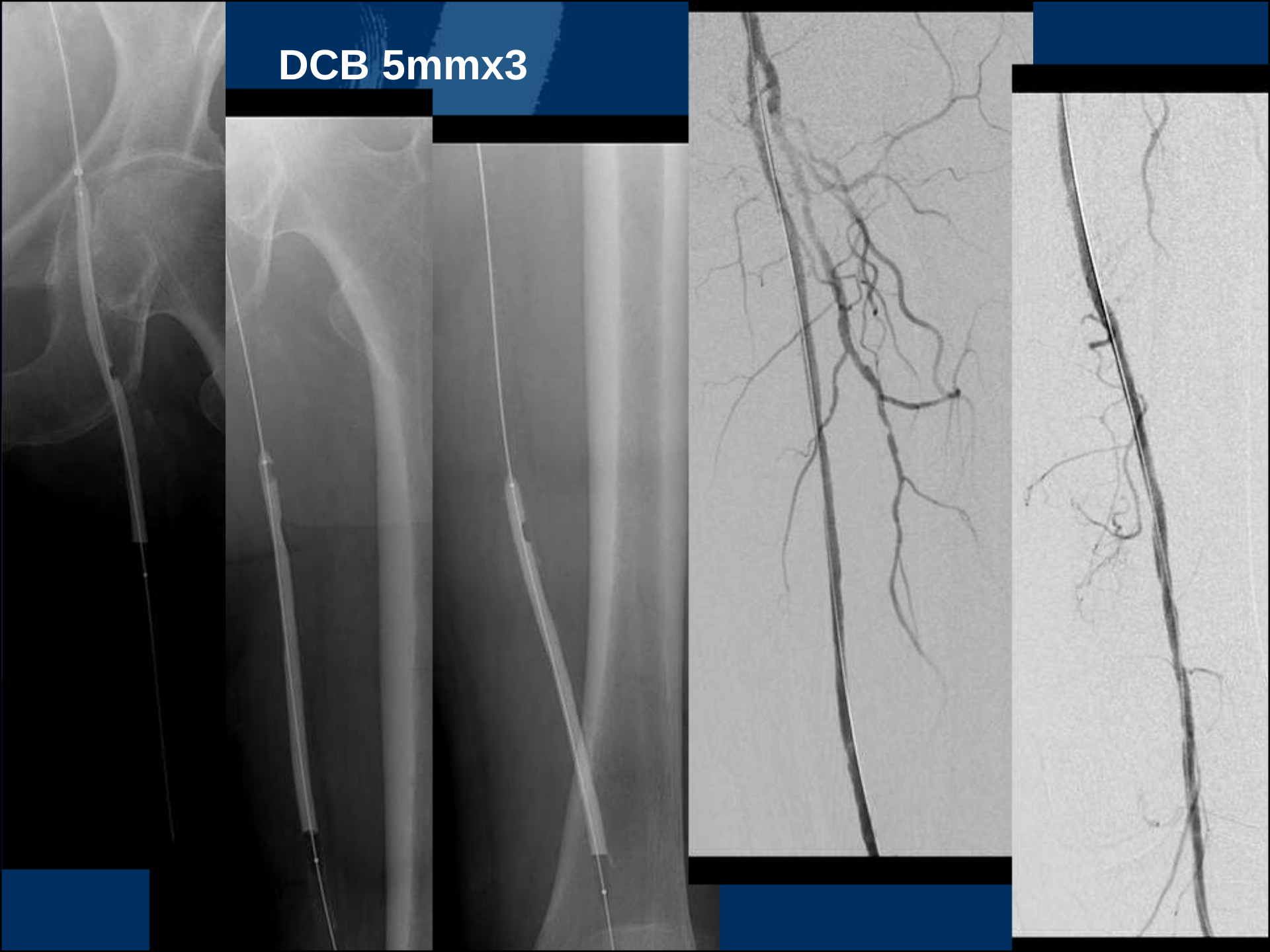
***: target vessel revascularization (TVR) and target lesion revascularization (TLR), major amputation and major reintervention (new bypass graft, jump/interposition graft revision, or thrombectomy/thrombolysis) of index limb and device- and procedure-related death.**

1 composite event within 30 days

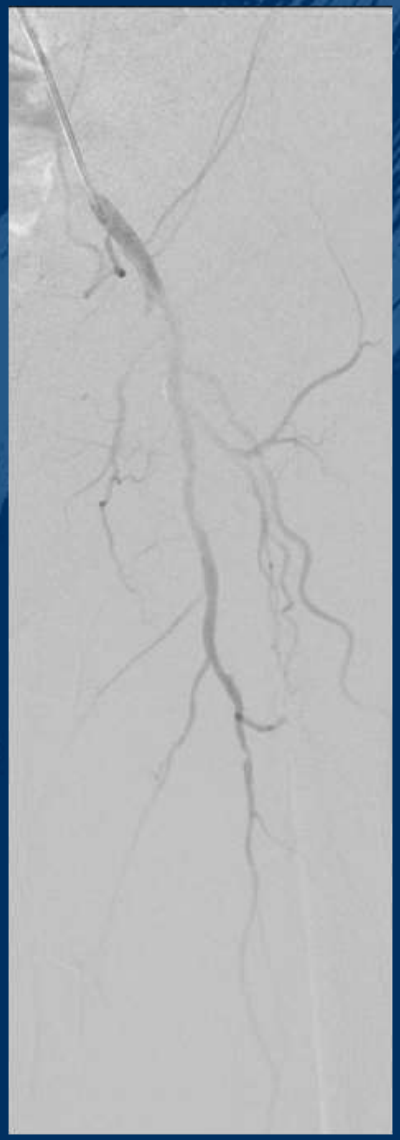
- F/78
- DM, HT
- Claudication (50m)
- ABI (0.79/0.50)
- Lesion : TASC D, moderate calcification
- Primary treatment: DCB only

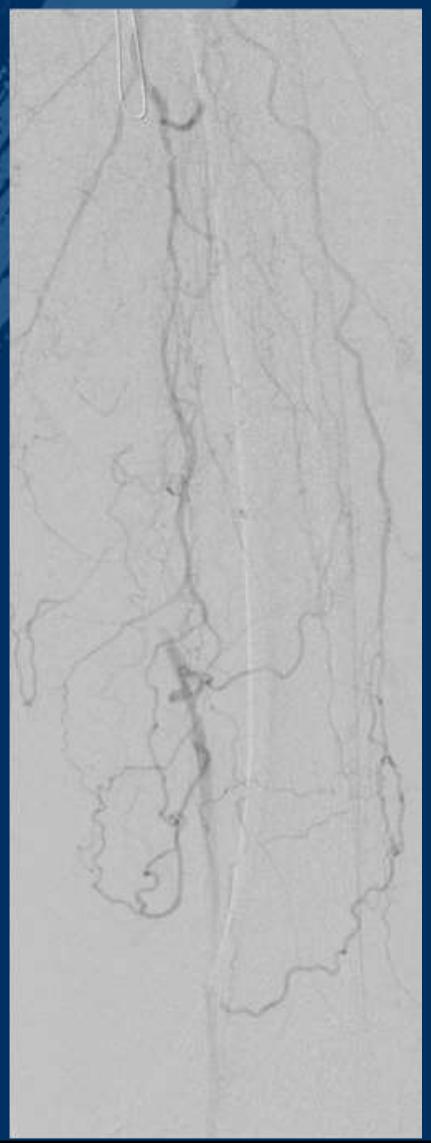


DCB 5mmx3

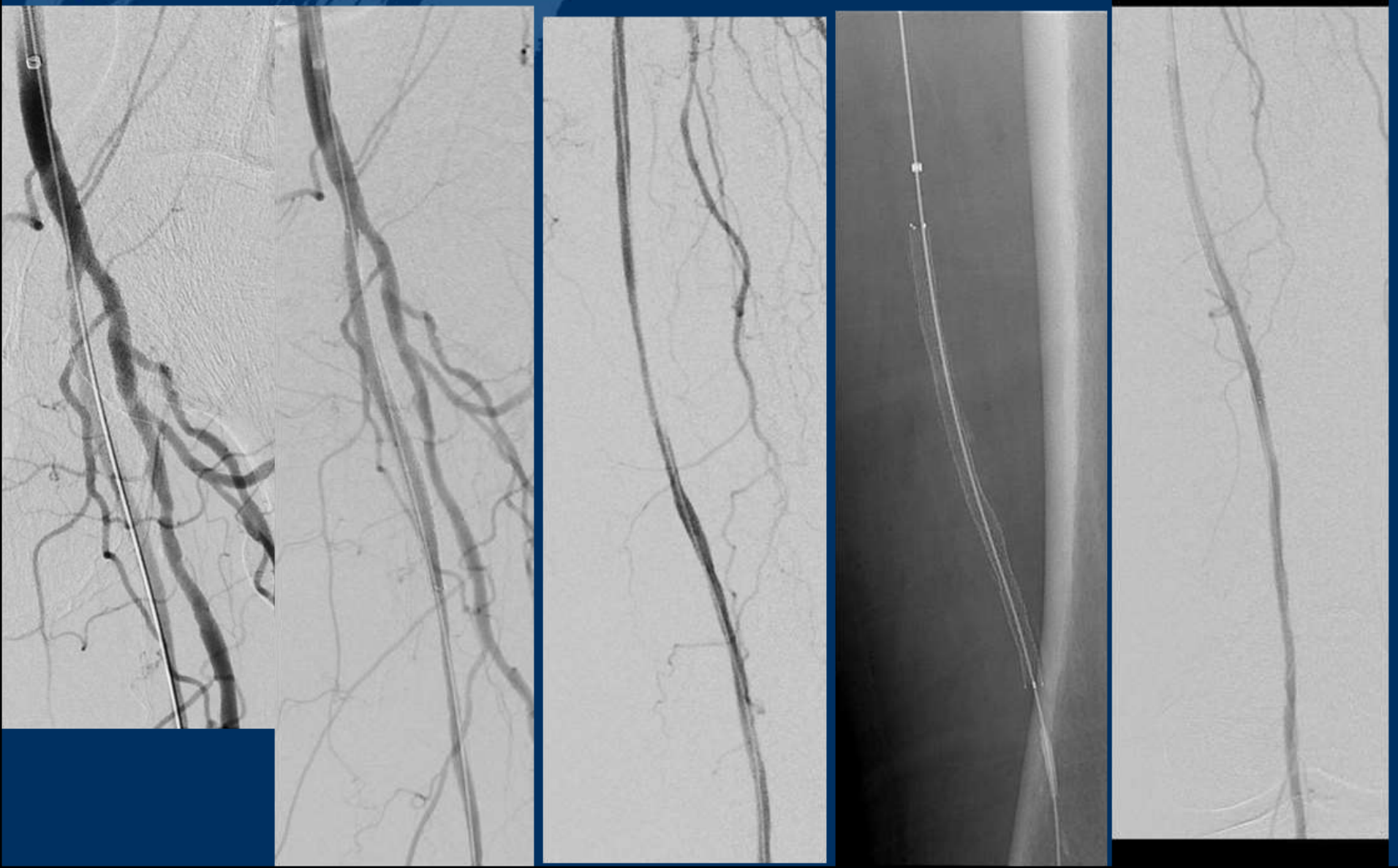


Symptoms: non subsided after procedure
Re-intervention @ 5 days





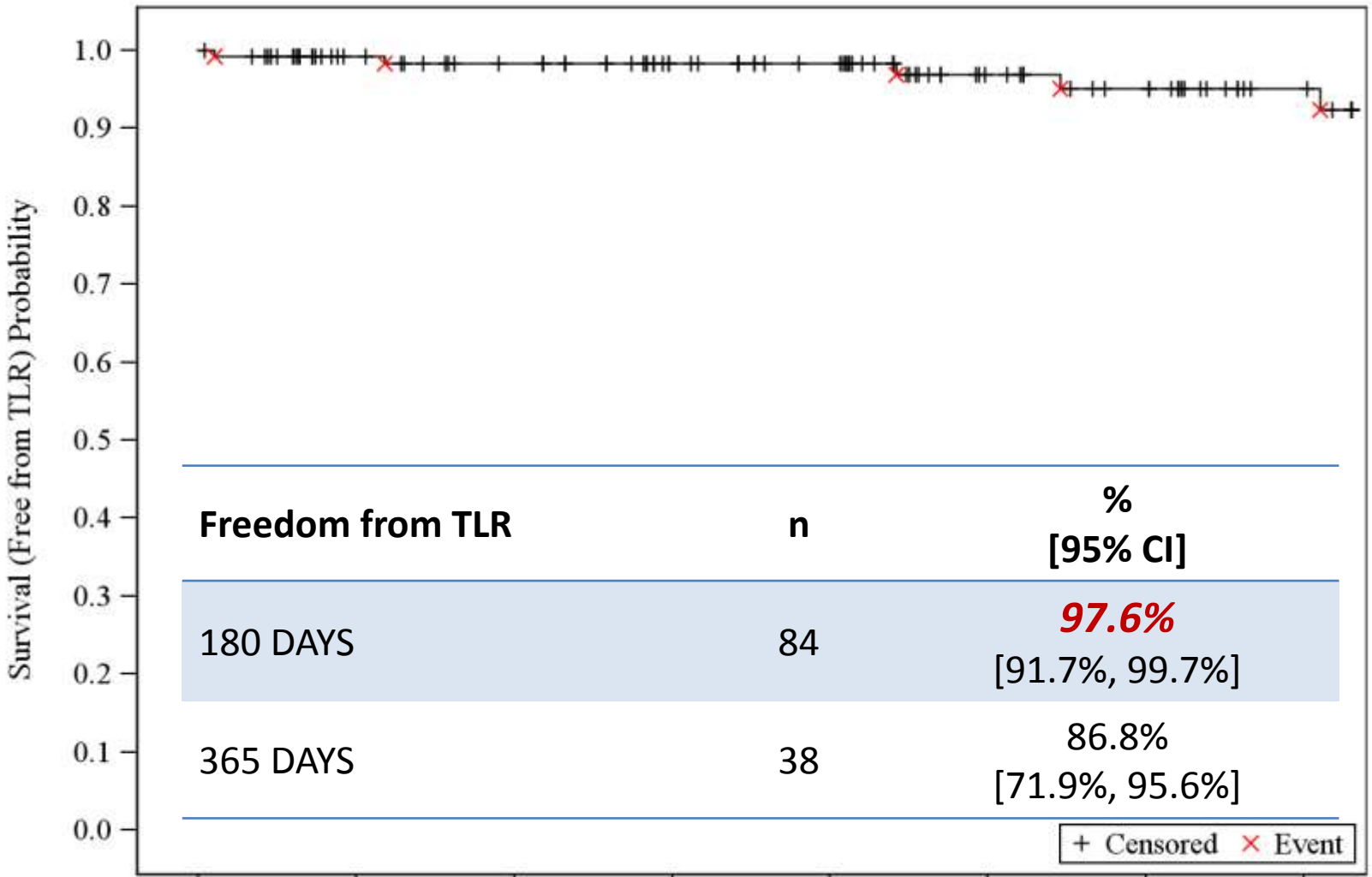
Two spot stenting @ proximal stump and distal reentry site



Rutherford Classification Improvement

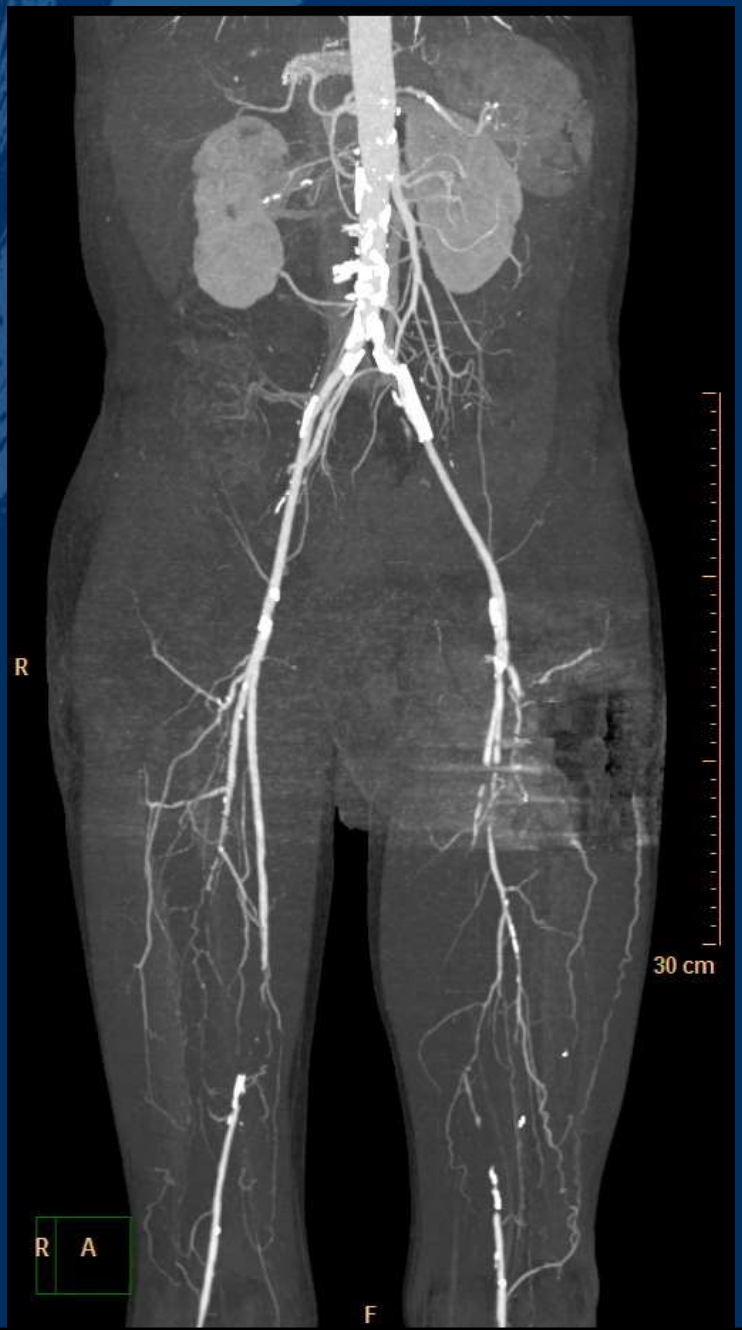
Lutonix Korea Registry (N=134)				
Rutherford Category	Baseline	1 Month	6 Month	12 Month
0	0	79.4%	90.0%	50.0%
1	4.8%	8.8%	0	0
2	47.2%	5.9%	5.0%	50.0%
3	40.8%	2.9%	5.0%	0
4	7.2%	0	0	0
5	0	2.9%	0	0

Primary Efficacy Endpoint



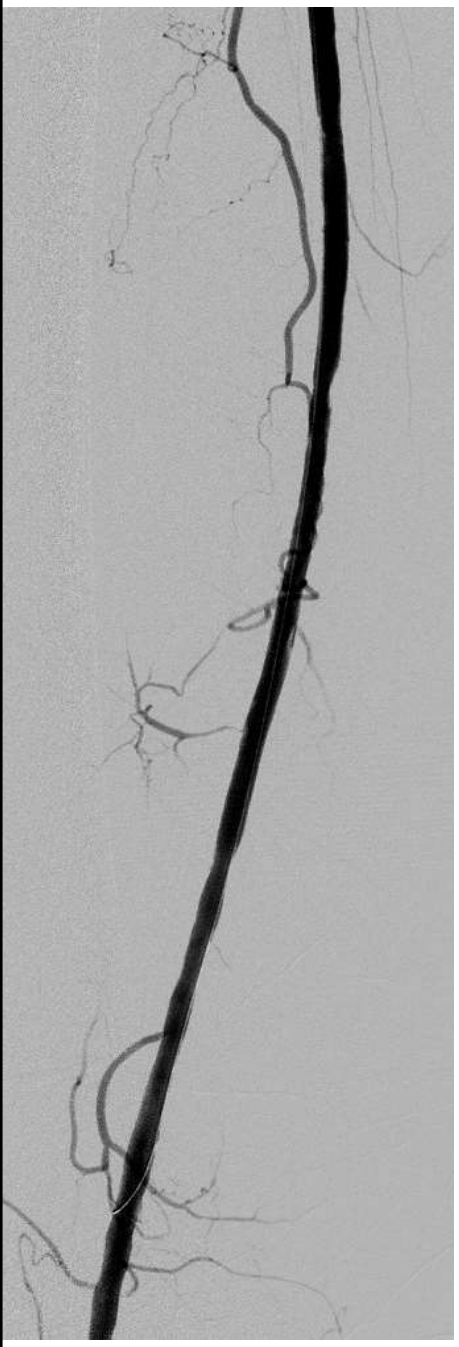
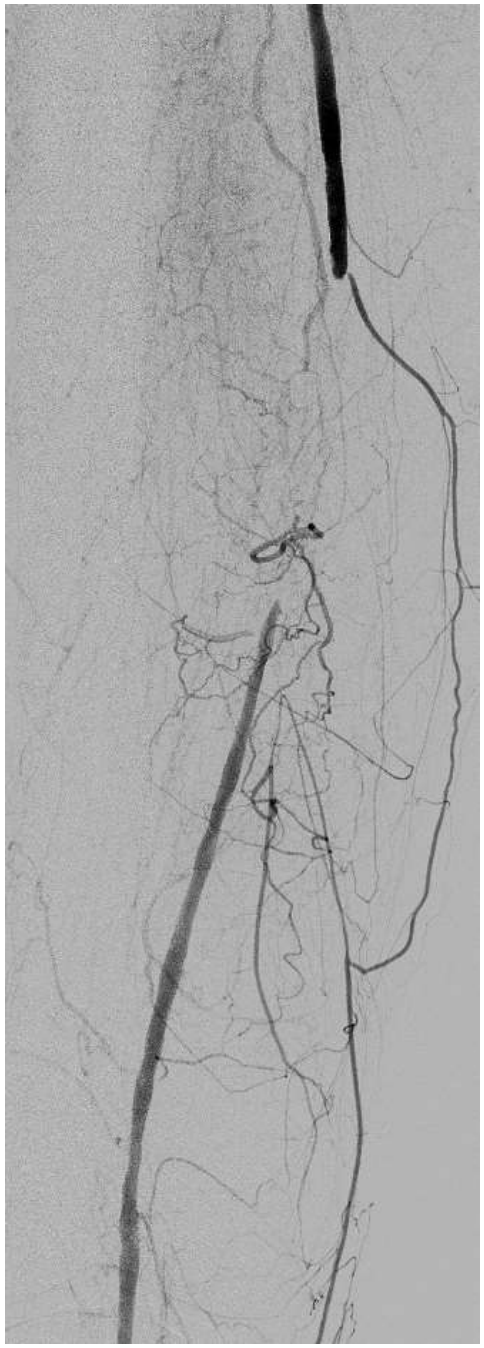
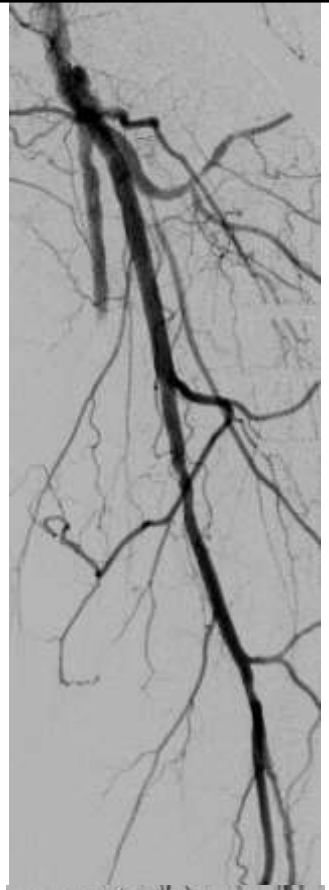
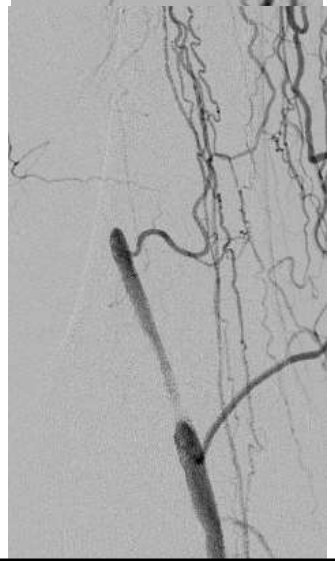
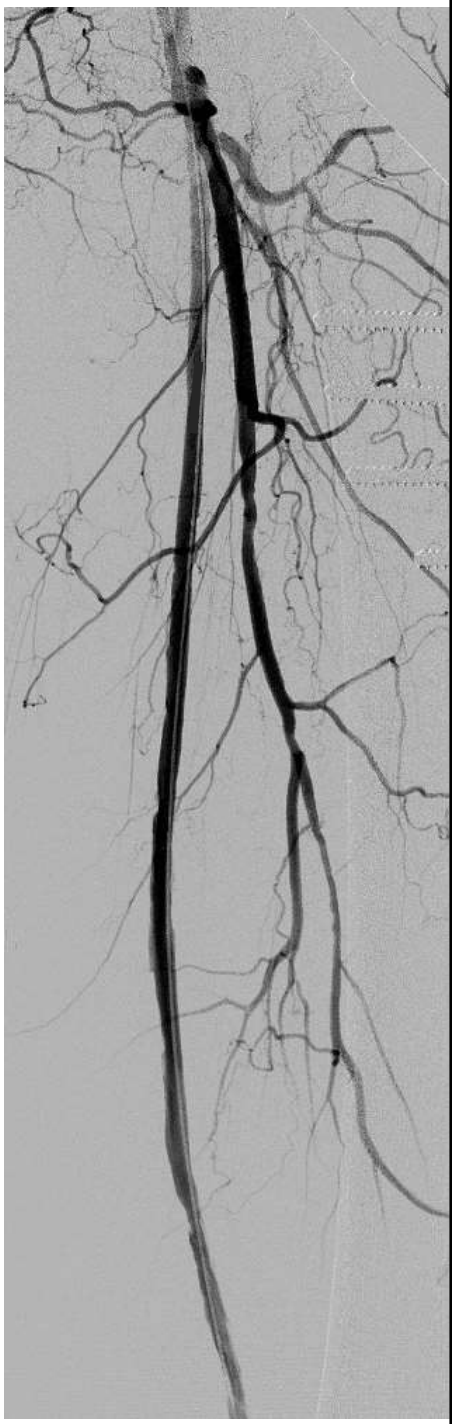
Freedom from TLR	n	% [95% CI]
180 DAYS	84	***97.6%*** [91.7%, 99.7%]
365 DAYS	38	86.8% [71.9%, 95.6%]

M/57, both claudication



Right : TASC B

Left : TASC D

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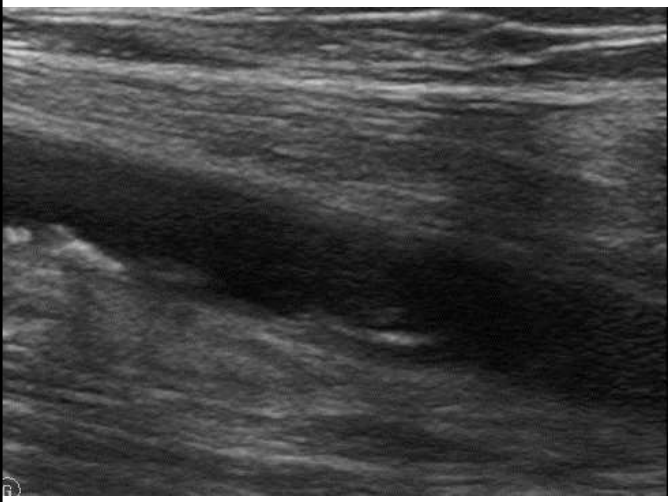

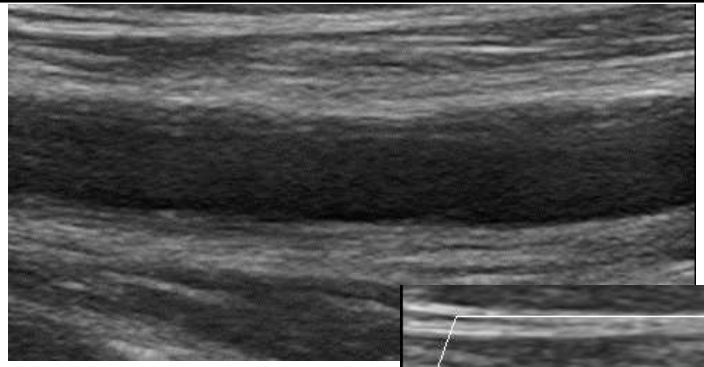

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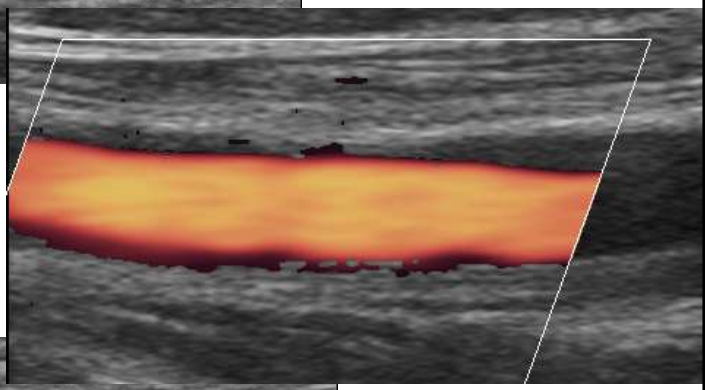

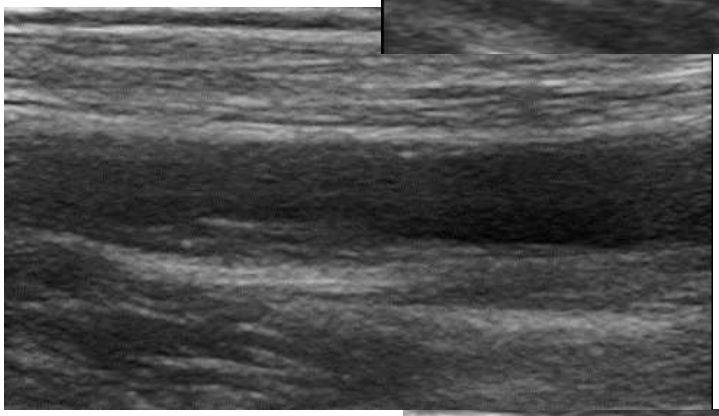

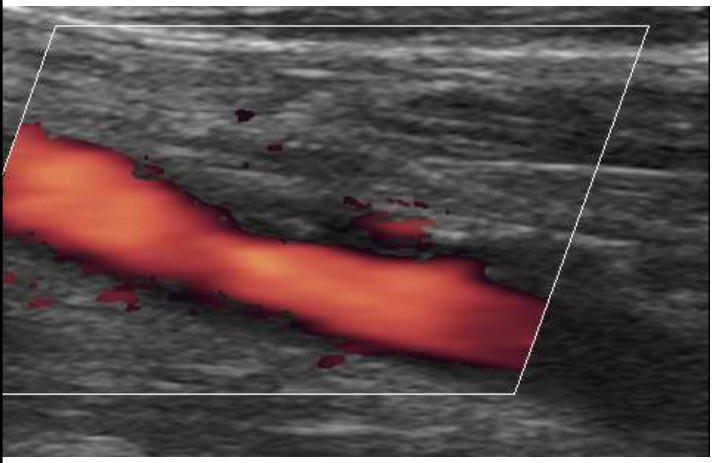

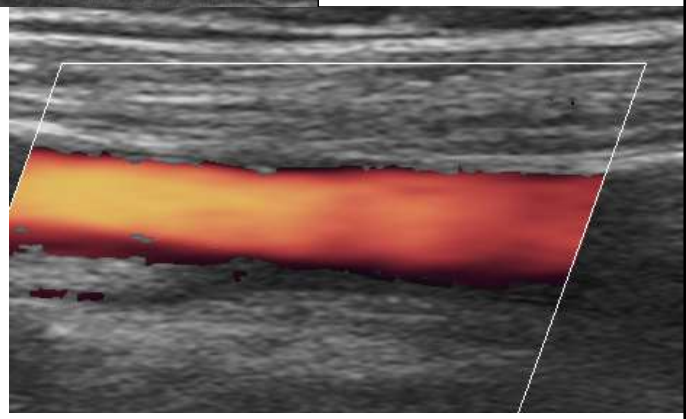

1 year follow up

Summary

- Lutonix DCB Korean registry data shows 97.6% at 6 months and further 86.8% at 1 year of freedom from TLR, respectively
- Provisional stenting rate was 11.2%, it also suggests that the DCB can reduce stenting rate and then preserves future treatment options in femoropopliteal lesions.

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