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DCB in my practice: How the evidence influences my strategy



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Disclosure

Speaker name: Yang-Jin Park

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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)

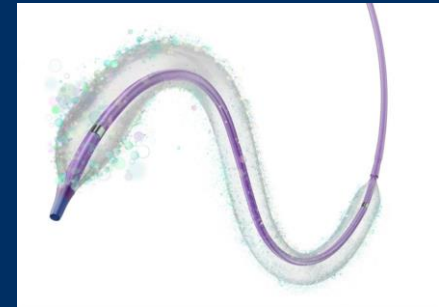
- I do not have any potential conflict of interest



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Drug Coated Balloons

- **Improved outcomes of DCB over PTA**
 - RCTs: IN.PACT Admiral, Lutonix, Stellarex
 - Published many DCB Trials or Registries
 - Single center experiences
- **Safety and efficacy:**
 - proved in many studies
- **Long-term data: limited**
 - 5YR results of IN.PACT admiral released recently (VIVA2018)





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Drug-coated balloons (DCB)

FDA approved

Device	Company	Coating	Drug dose ($\mu\text{g}/\text{mm}^2$)
IN.PACT™ Admiral,	Medtronic Vascular, Santa Clara, CA, USA	Paclitaxel-urea	3.5
Lutonix® 035 DCB	BARD, Murray Hill, NJ, USA	Paclitaxel-polysorbate/sorbitol	2.0
Stellarex®	Spectranetics, Colorado Springs, CO USA	Paclitaxel-polyethylene glycol	2.0



Lutonix®



IN.PACT®



Stellarex®



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RCTs of DCB in FP lesions

		1-Year	2-Year	3-Year	4-Year	5-Year
Primary Patency >	IN.PACT DCB	87.5% ¹	79.0% ¹	69.5% ²	Not assessed after 3 years	
	Lutonix DCB	73.5% ³	58.6% ⁴	—	—	—
	Stellarex DCB	82.3% ⁵	72.1% ⁶	—	—	—
CD-TLR >	IN.PACT DCB	2.4% ⁷	9.1% ⁸	15.2% ⁹	23.4% ¹⁰	25.5%
	Lutonix DCB	12.3% ³	18.0% ⁴	—	—	—
	Stellarex DCB	7.9% ⁵	—	—	—	—



DCBs: Unmet needs in daily practice

- Complex FP lesions
 - Heavy calcifications
 - Drug delivery, needs for scaffolds d/t post-balloon dissections
 - Long CTO lesions >25cm
 - Elastic recoils
 - Flow limiting dissections
 - Needs for scaffolds
- Limited data of:
 - Long-term durability: Restenosis rates
 - Efficacy mainly in claudicants, not in CLI
 - ISR lesions



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DCBs in “Real-World” Registries

	Global ¹	Long Lesion ²	Long Lesion ³	CTO ⁴	ISR ⁵	Clinical ⁶	ILLUMENATE Global ⁷ Stellarex
Key Inclusion Criteria	RCC ≤4 SFA & PA	RCC 2-4 SFA & PA Lesions ≥14cm	RCC 2-4 SFA & PA Lesions ≥15cm	RCC 2-4 SFA & PA CTOs	RCC 2-4 SFA & PA ISR	RCC 2-4 SFA & PA	RCC 2-4 SFA & PA
Key Patient Characteristics							
Age (years)	68.3y	67.6y	69.5y	67.5y	67.8y	68.6y	68.2y
RCC ≥4 (%)	9.0%	6.1%	16.7%	11.1%	10.0%	11.0%	8.6%
Men (%)	67.6%	73.7%	66.2%	69.0%	69.5%	67.8%	73.0%
DM (%)	39.5%	36.4%	41.0%	29.6%	35.1%	39.9%	33.7%
Key Lesion Characteristics							
Length (cm)	10.1cm	21.3cm	26.4cm	22.9cm	17.2cm	12.1cm	7.5cm
CTO (%)	31.2%	52.1%	60.4%	100.0%	34.0%	35.5%	31.3%
Ca ²⁺ (%)	50.2%	78.9% ²	71.8%	71.0%	59.1%	68.7%	56.2% ⁷
12-mo Outcomes							
1° Patency (%)	NR	68.9%	91.1%	85.3%	88.7%	NR	81.4%
FFTLR/CD-TLR(%)	94.3%	87.8%	94.0%	89.1%	92.9%	92.6%	94.8%
Bail-out Stent (%)	25.2%	39.8%	40.4%	46.8%	14.5%	25.3%	17.3%
Amputations (%)	0.5% (3/632)	NR	0.0%	0.0%	0.0%	0.2% (3/1311)	0.3% (1/371)



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Experiences in Samsung Medical Center Seoul, Korea



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Purpose

- To evaluate outcomes (safety and efficacy) of endovascular treatment using drug-coated balloon (DCB) for femoropopliteal artery lesions in a single-center



Methods I

- Single center retrospective cohort study
- Study period: 2013. 4. – 2018. 10.
- 226 patients (297 lesions, 253 limbs)
- Follow-up (mean \pm SD, range): 13.6 \pm 14.1 (1-65.8) months
- DCB in femoro-popliteal lesions
- Primary end-points
 - Primary patency: Binary restenosis $>50\%$ on DUS (PSVR >2.4) or TLR
 - Freedom-from TLR
- Secondary end-points
 - Freedom-from death
 - Freedom-from major amputation



Methods II

- Inclusion criteria
 - Atherosclerotic disease of the femoro-popliteal lesion
 - RC 3-6
 - PTA using drug-coated balloon (with or without stenting or atherectomy)
 - De-novo or restenosis (non-stented or in stent restenosis), stenosis of bypass graft
- Exclusion criteria
 - Non-atherosclerotic lesions
 - ex> acute thrombotic occlusion, TAO



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Patient Demographics and Comorbidities

Patients characteristics	N=226(%)
Age (years, median, IQR)	71.7 ± 9.1 (38-93)
Sex (male)	183 (81)
HTN	187 (82.7)
Smoking (ex or current)	92 (40.7)
DM	161 (71.2)
CAD	96 (42.5)
CKD (≥grade 3)	75 (33.2)
Hyperlipidemia	104 (46)



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Treatment Indication

Limbs	N=253 limbs (%)
Claudication	167 (66)
Rest pain	18 (7.1)
Tissue loss	68 (26.9)
Minor tissue loss	65 (82.7)
Major tissue loss	13 (17.3)
Lesions	N=297 lesions (%)
De-novo	62 (82.7)
Restenosis	13 (17.3)
Balloon angioplasty	6
Stenting	3
Surgical bypass	4
Location	
Common femoral artery	8 (2.7)
Superficial femoral artery	226 (76.1)
Popliteal artery	63 (21.2)



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Lesion Characteristics

Calcification $\geq 50\%$ in target lesion	87 (29.3)
Chronic total occlusion (CTO)	71 (23.9)
TASC classification	
A	75 (25.3)
B	169 (56.9)
C	40 (13.5)
D	13 (4.4)
No. of run off vessel	
0	7 (2.4)
1	69 (23.3)
2	105 (35.5)
3	115 (38.9)
Length (cm, median, IQR)	7 (4,13)
Preoperative ABI (median, IQR)	0.66 (0.5,0.8)



Treatment details

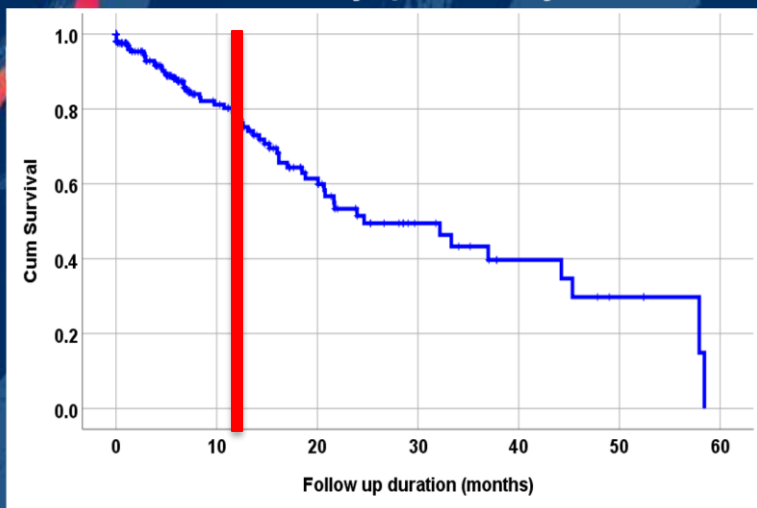
Treatment details	N(%)
DCB types	
IN.PACT	244 (82.2)
Lutonix	53 (17.8)
Concurrent use of Atherectomy	58 (19.5)
Stenting	26 (8.8)
Adjuvant	8
Bail out	18
Complication	
Dissection	46 (15.5)
Embolization	3 (1)
Hematoma	7 (2.4)
Pseudoaneurysm	1 (0.3)



Immediate outcomes

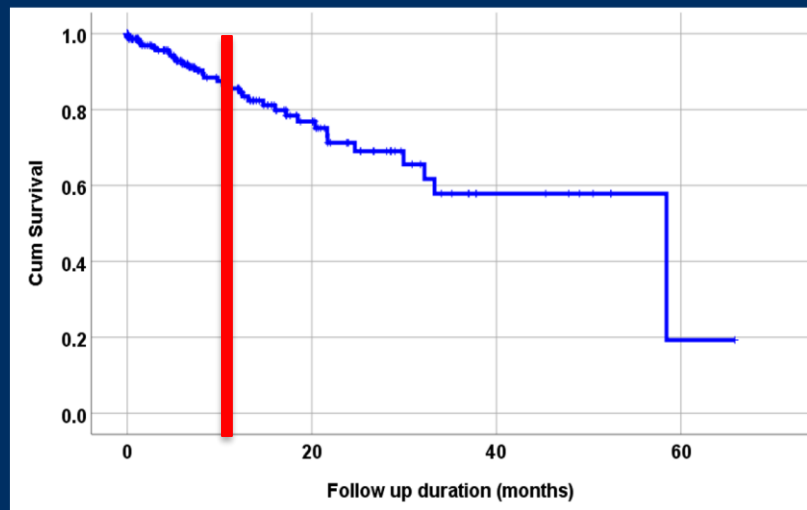
Outcomes	N(%)
Procedural success	294 (99)
30day mortality	0
Target limb major amputation	4 (1.6)
Intentional	4 (1.6)
Unplanned	0
Amputation level	
Toe	5 (35.7)
Foot	5 (35.7)
BK	4 (28.6)
AK	0
Post procedural ABI, median (IQR)	0.95 (0.8,1.02)

Primary patency



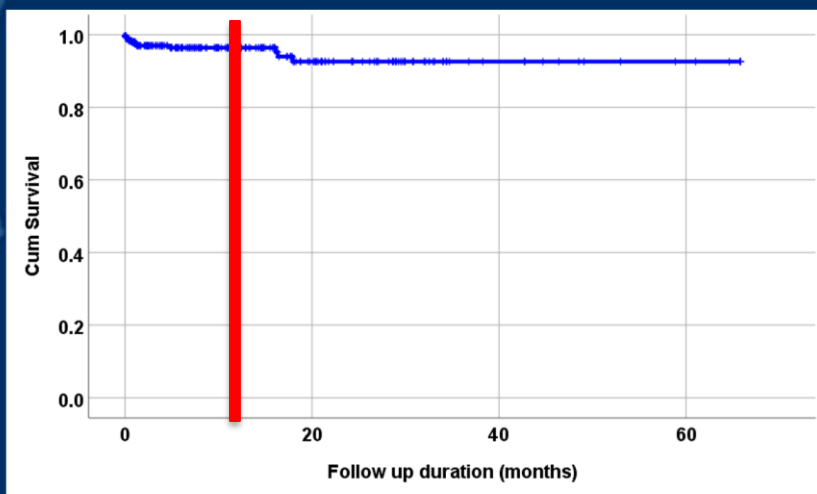
	1mo	6mo	12mo	24mo	36mo	48mo
No.at risk	182	114	81	26	12	5
Patency (%)	97.6	88.1	79.3	51.4	43.3	29.7

Freedom-from TLR



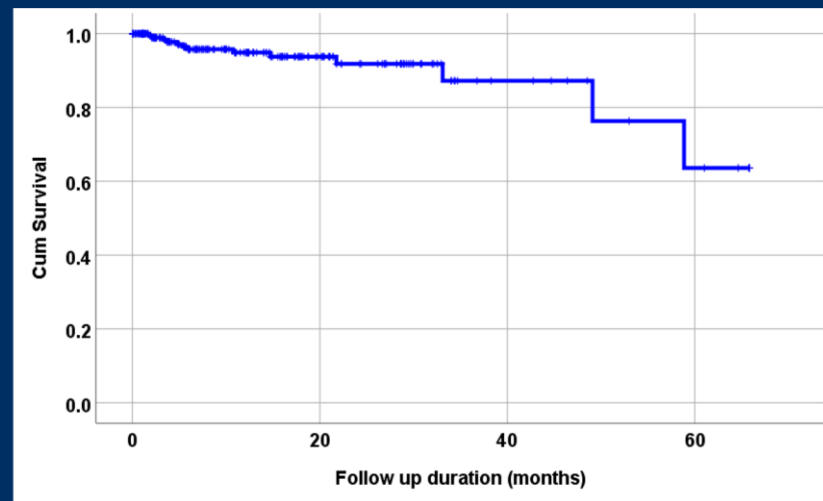
	1mo	6mo	12mo	24mo	36mo	48mo
No.at risk	182	117	86	32	13	7
FF TLR (%)	98.6	92	85.6	71.3	57.9	57.9

Freedom from major amputation



	1mo	6mo	12mo	24mo	36mo	48mo
No.at risk	221	150	109	48	15	9
FF-Amp (%)	97.9	96.4	96.4	92.6	92.6	92.6

Patients overall survival



	1mo	6mo	12mo	24mo	36mo	48mo
No.at risk	206	140	102	44	14	9
Survival (%)	100	95.8	94.9	91.8	87.2	87.2



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Risk factors of restenosis (multiple regression model)

	P-value	RR	95% CI
Lesion length (cm)	0.014	1.053	1.011, 1.097
Combined atherectomy use	0.004	2.806	1.384, 5.688
DCB type2	<0.001	3.701	1.902, 7.200



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Strength & Limitation

- Relatively large number of patients
- Guideline-based practice by vascular specialists in real clinical field
 - Balanced, multidisciplinary approach after conference
- Retrospective single center study
- Selection bias
 - Complex FP lesion were treated mainly by surgical bypass with autologous vein
 - TASC C/D, long CTO, severe calcification, ISR



Conclusions

- Drug coated balloons (DCBs) are a good option for the treatment for femoropopliteal occlusive disease.
- But, primary patency and target limb revascularization rate in real practice was not as good as that of RCT in this study.
- Evidence-based, lesion-specific, and individualized approach is essential part of treatment for the patients with FP lesions.



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