IntraVascular ultrasOund suppoRted endovascular therapy in superficial femoral arterY disease: 12-months results from the IVORY-study

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Objective

- ✓ To evaluate clinical outcomes of intravascular ultrasound (IVUS)-supported endovascular therapy (EVT) for the femoropopliteal (FP) artery disease in today's real-world settings

IVORY @ 33 centers in JAPAN

Methods

Subjects

2,014 limbs of 1,762 patients with symptomatic PAD in whom IVUS-assisted FP EVT was planned between Nov 2015 and Jun 2017.

Endpoints

Perioperative complications (POC)

One-year primary patency, i.e., freedom from restenosis

Statistical analysis

For missing data (1% on POC and 21% on primary patency), multiple imputation method was adopted.

The risk factors for POC and one-year restenosis were explored by the generalized linear mixed model with a logit link treating the inter-institution & subject variability as random effects.

Baseline Characteristics

Patient	
Male sex	69%
Age (years)	74 ± 9
Smoking status	
Past smoking	44%
Current smoking	27%
Diabetes mellitus	59%
Chronic renal failure	36%
Chronic heart failure	15%
Medication kept during F/U	
Aspirin	71%
Thienopyridine	67%
Cilostazol	27%
Statin	52%
Anticoaglant	14%

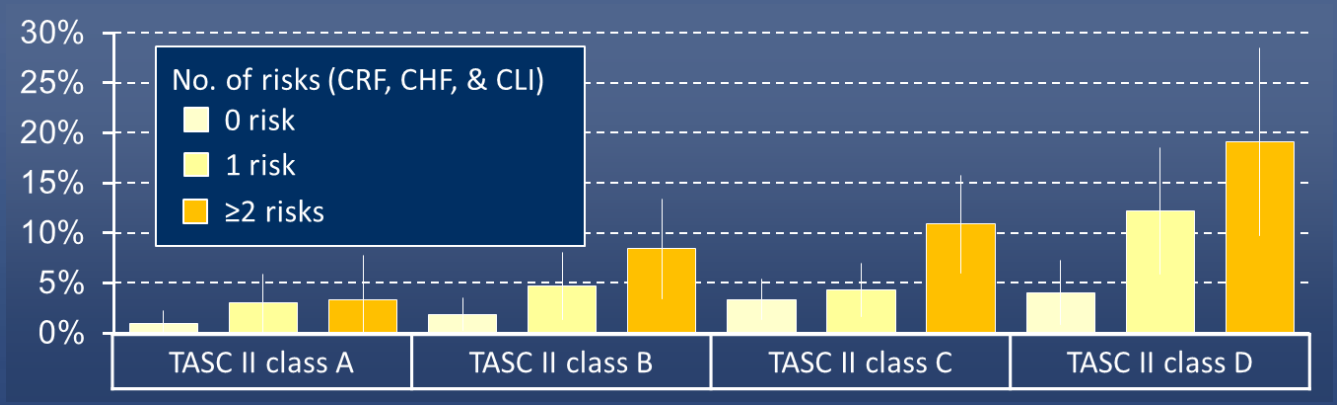
Limb	
Critical limb ischemia	25%
TASC II class A/B/C/D	22%, 28%, 35%, 16%
de novo/post-PTA/In-stent lesion	87%, 2%, 11%
Distal reference vessel diameter	5.0 ± 1.0 mm
Lesion length	16 ± 10 cm
Chronic total occlusion	39%
Calcification: None/Unilateral/Bilateral	33%, 33%, 35%
Popliteal lesion	27%
Poor below-the-knee runoff (0 or 1)	38%
Treatment strategies	
Stent implantation	67%
Full-covered stenting	54%
Drug-eluting stent or stent graft use	17%
Drug-coating balloon use	0.4%
Lumen gained after treatment	
IVUS-assessed minimum lumen area	15 ± 5 mm^2

Perioperative complication (POC)

- ✓ The proportion of POC in the overall population was estimated at: **5%** (95% CI: 4 to 6%).
- ✓ Independent risk factors for POC were:

	Adjusted odds ratio
Chronic renal failure (CRF)	1.79 [1.14-2.81] (P=0.012)
Chronic heart failure (CHF)	1.97 [1.21-3.22] (P=0.006)
Critical limb ischemia (CLI)	2.06 [1.30-3.26] (P=0.002)
TASC II classification	1.66 [1.30-2.12] (P<0.001)

- ✓ The proportion of POC in subgroups stratified by risk factors was:



One-year primary patency

- ✓ The proportion of 1-year patency in the overall population was estimated at:
- ✓ 64% (95% CI 62 to 67%).
- ✓ Independent risk factors for loss of patency (restenosis) were:

	Adjusted odds ratio for 1-year restenosis
FP lesion characteristics	
Distal reference vessel diameter (per 1-mm decrease)	1.34 [1.14-1.59] (P=0.001)
Lesion length (per 10-cm increase)	1.32 [1.12-1.55] (P=0.001)
Chronic total occlusion	
Endovascular procedures	
Full-covered stenting	0.42 [0.31-0.58] (P<0.001)
Drug-eluting stent or stent graft use	0.51 [0.34-0.77] (P=0.001)
Post-procedural characteristics	
Minimum lumen area (per 10-mm^2 increase)	0.70 [0.54-0.92] (P=0.009)
Medication kept during FU	
Statin use	0.64 [0.49-0.82] (P=0.001)

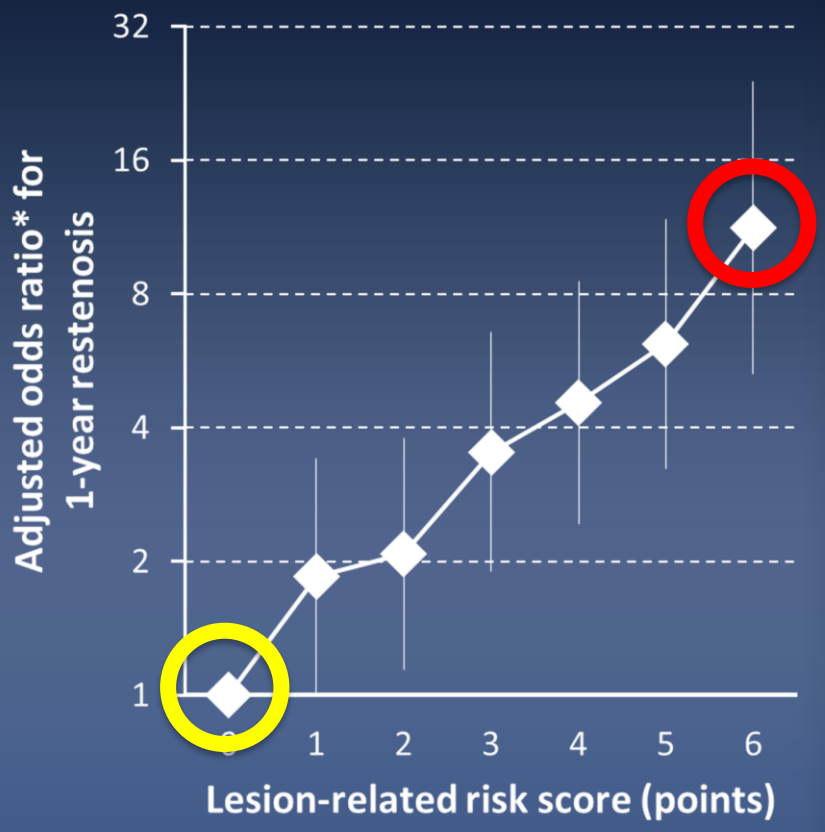
Lesion-related risk score for restenosis

Lesion-related Risk Score for 1-year restenosis

Summing the following points

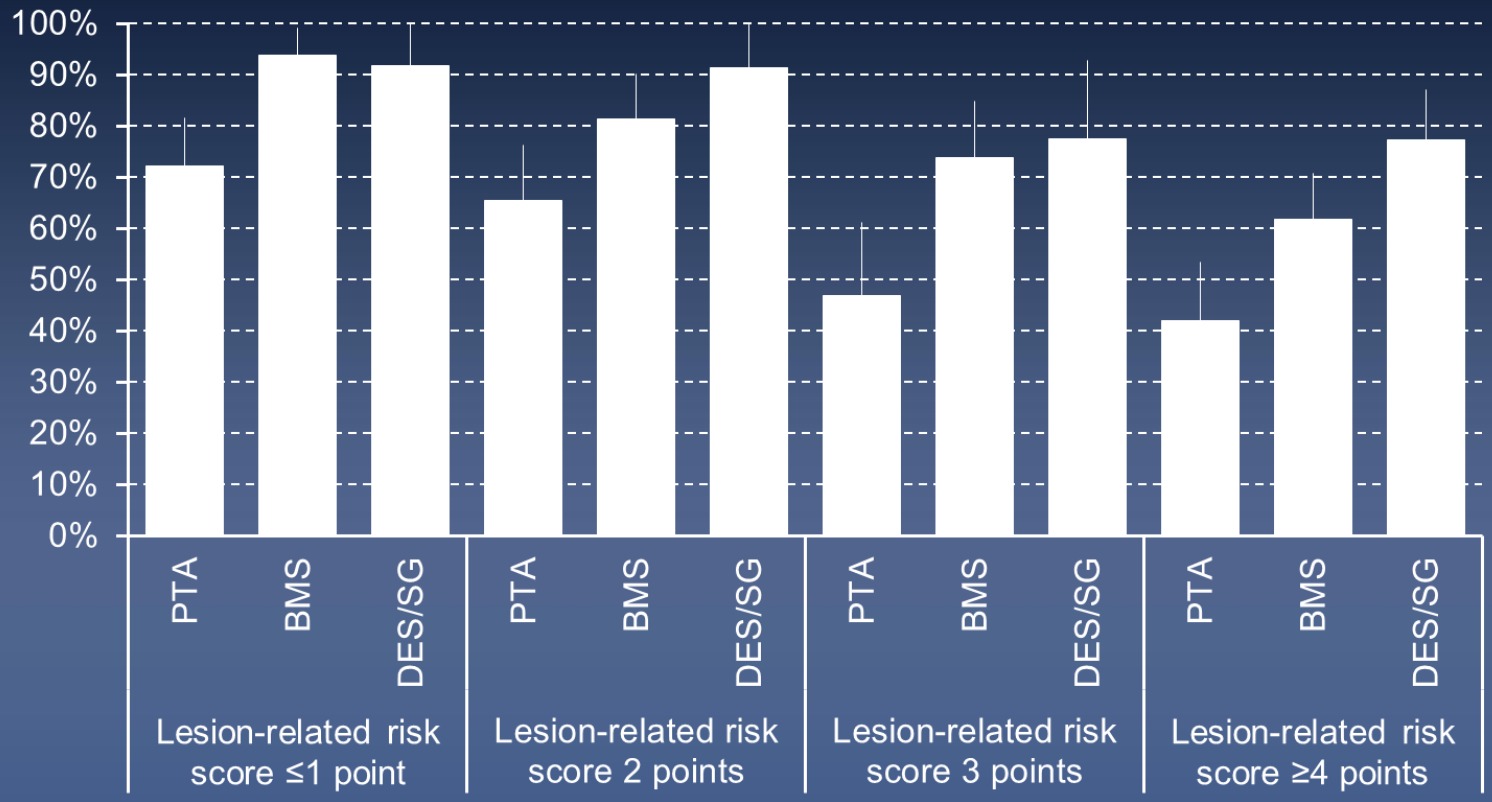
Lesion risk factor	Status	Point
Distal reference vessel diameter (1 pt/1-mm decrease)	≥5.5 mm	0
	4.5-5.5 mm	+1
	<4.5 mm	+2
Lesion length (1 pt/10-cm increase)	≤5 cm	0
	5-15 cm	+1
	15-25 cm	+2
	>25 cm	+3
Chronic total occlusion (1 pt/presence)	Absent	0
	Present	+1

(max: 6 points)



* Adjusted for stenting, DES/SG use, post-EVT minimum lumen area, and statin use.

Proportion of 1-year primary patency under continuous statin use



PTA, percutaneous transluminal angioplasty without stent implantation or drug-coating balloon
BMS, full-covered bare metal stent implantation without any use of drug-eluting stents or drug-coating balloon
DES/SG, full-covered drug-eluting stent or stent graft implantation without any use of bare metal stents or drug-coating balloon

Stent types and Restenosis Risk

- ✓ As a supplementary analysis, the following variables were entered in the model in replacement of the variable "drug-eluting stent or stent graft use"

	Prevalence in study population	Adjusted odds ratio* for 1-year restenosis
Misago use	5%	1.22 [0.67-2.24] (P=0.52)
INNOVA use	19%	0.92 [0.62-1.36] (P=0.67)
LIFESTENT use	8%	1.19 [0.73-1.95] (P=0.48)
Zilver PTX use	11%	0.70 [0.42-1.16] (P=0.16)
Eluvia use	1%	0.10 [0.01-0.80] (P=0.030)
Viabahn use	5%	0.28 [0.13-0.60] (P=0.001)

*Practically relative to S.M.A.R.T., Luminexx, and other BMS

Summary of IVORY study

- ✓ The IVORY study (n = 2,014) demonstrated the clinical outcomes of IVUS-supported FP EVT in today's real-world settings.
- ✓ The proportion of POC was estimated at 5% [95% CI: 4 – 6%], whereas that of 1-year primary patency was 64% [62 – 67%].
- ✓ Risk factors for POC were CRF, CHF, CLI, and TASC II classification.
- ✓ Factors associated with 1-yr restenosis were:

Lesion:	✓ Smaller vessel diameter ✓ Longer lesion ✓ Chronic total occlusion	☹ Restenosis risk↑
Tx Strategy:	✓ Full-covered stenting ✓ Drug-eluting stent, stent graft	☺
Gained lumen:	✓ Larger minimum lumen area	Restenosis risk↓
Medication:	✓ Statin use	

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