VANQUISH study

Viab**A**hn ste**N**t graft placement for SFA disease re**QU**iring

Invention**S**, a prospective observational multicenter co**H**ort study

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COI Disclosure

Speaker name :

Osamu Iida, MD

I have the following potential conflicts of interest to report:

- ■ Consulting: NIPRO, Canon
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ■ Other(s) Honoraria : Medtronic, Boston Scientific, Gore, NIPRO, Canon, Kaneka, Cook
- ☐ I do not have any potential conflict of interest

Heparin-Bonded Endoluminal Bypass Therapy

What's known (robust evidences)

Clinical trials indicate that heparin-bonded endoluminal bypass therapy achieves durable patency in complex femoropopiteal (FP) lesions, whereas the risk of thrombotic occlusion might attenuate the performance.

J Am Coll Cardiol. 2013;62:1320-7.

JACC Cardiovasc Interv. 2017;10:2320-31.

J Vasc Surg. 2017;66:130-42.

What remains unknown (clinical questions)

1) How high is the primary patency rate in the real-world settings?

2) What are the predictors for loss of patency in the real-world population?

3) Does prothrombotic state influence the primary patency rate?

Objective

The aim of VANQUISH study was 1) to evaluate the 1-year primary patency rate after FP heparin-bonded endoluminal bypass in today's real-world settings and 2) to explore risk factors for loss of primary patency.

Methods

Scheme

This was **a preliminary analysis of the VANQUISH study***, enrolling patients undergoing FP heparin-bonded endoluminal bypass in the real-world settings between March 2017 and December 2018.
Currently, we analyzed the participants enrolled by March 2018.

*VANQUISH study: ViabAhn steNt graft placement for SFA disease reQUiring InterventionS, a prospective observational multicenter coHort study

Subjects

289 limbs of **252** patients with symptomatic FP artery disease.

Intervention procedure

GORE® *VIABAHN*® stentgraft (W.L. Gore, *Flagstaff*, AZ) placement under intravascular ultrasound (IVUS) evaluation.*

*IVUS was used to maximize the device performance, through (1) precisely assessing the target vessel, (2) choosing an optimal device size, and (3) appropriately landing the device.

Methods

Evaluation of platelet reactivity at baseline

P2Y12 reaction units (PRU)*, evaluated using the VerifyNow P2Y12 assay (Accumetrics, San Diego, CA).

*The literature suggests that PRU of >208 U represents insufficient suppression of platelet reactivity.

Stone WG, et al. Lancet 2013; 382: 614–23

Endpoints

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

*Restenosis was defined as a DUS-evaluated peak systolic velocity ratio >2.4 or angiography-evaluated stenosis (≥50% of the arterial diameter).

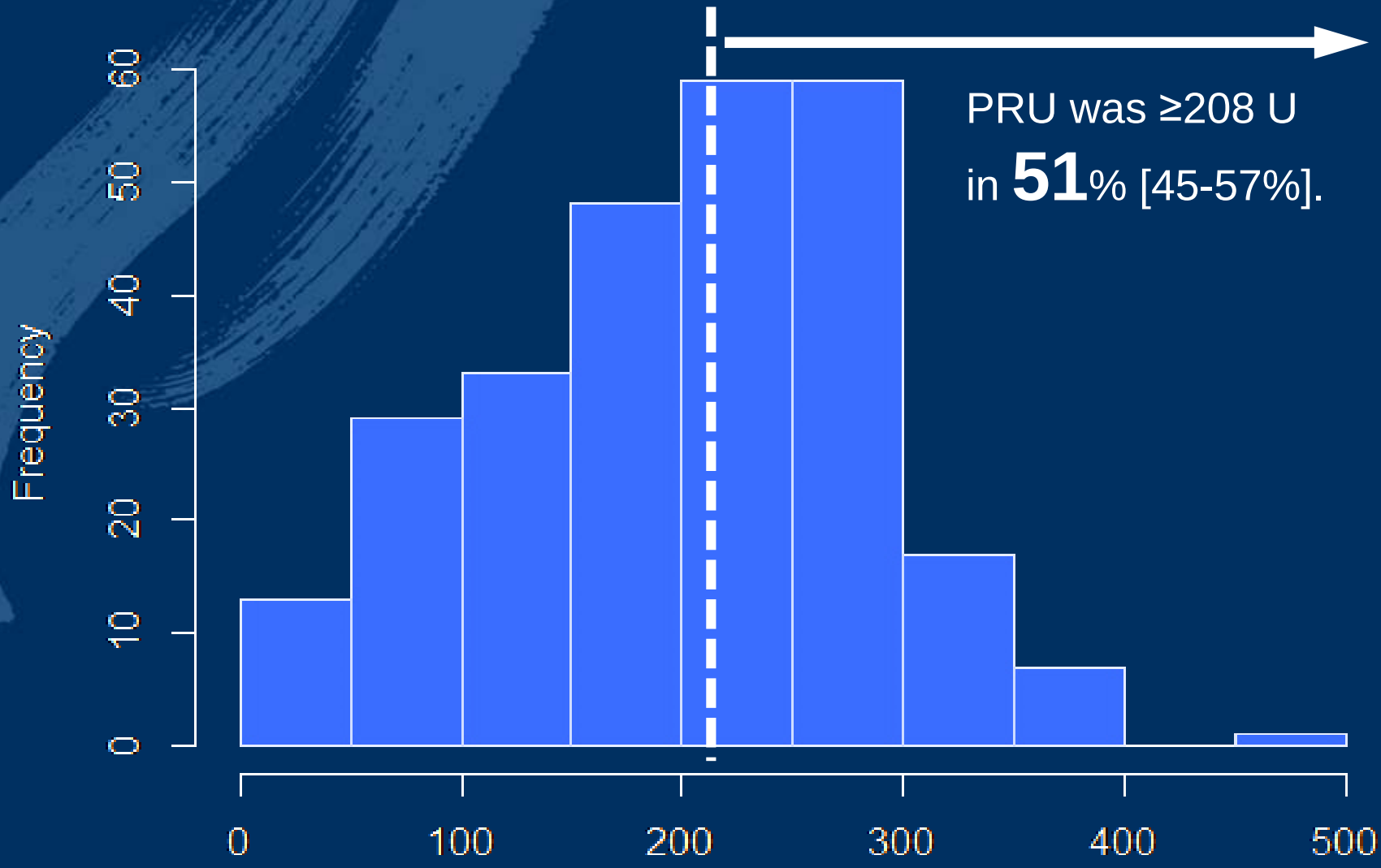
Statistical analysis

For missing data, multiple imputation method was adopted.
The risk factors for one-year restenosis was explored by the generalized linear mixed model with a logit-link function, treating the inter-institution & subject variability as random effects.

Baseline Characteristics

Patient characteristics (n=252)	Male sex	70%
	Age (years)	75 ±8
	Smoking	21%
	Diabetes	57%
	Chronic renal failure	36%
Limb characteristics (n = 289)	Critical limb ischemia	24%
	ABI	0.55±0.22
	TASC II class C/D	91%
	Reference vessel diameter (RVD), distal (mm)	5.1±0.8
	Lesion length (cm)	26±8
	Chronic total occlusion	67%
	Severe calcification (PACCS grade 4)	26%
	In-stent restenosis/occlusion	20%
	Full-covered Viabahn implantation	80%

Distribution of P2Y12 Reaction Unit (PRU)



Crude Odds Ratio for 1-Year Restenosis

Male sex	0.73 [0.38-1.41]
Age (per 10 years)	0.95 [0.65-1.39]
Smoking	1.31 [0.60-2.84]
Diabetes	0.75 [0.40-1.43]
Chronic renal failure	1.28 [0.63-2.61]
Critical limb ischemia	1.86 [0.90-3.83]
TASC II classification	1.44 [0.88-2.34]
Distal RVD (per 1 mm)	**0.56 [0.36-0.86]***
Lesion length (per 10 cm)	1.61 [0.90-2.89]
Chronic total occlusion	1.69 [0.79-3.60]
PACSS classification	1.18 [0.95-1.45]
In-stent restenosis	1.38 [0.63-3.04]
Full coverage	0.54 [0.23-1.25]

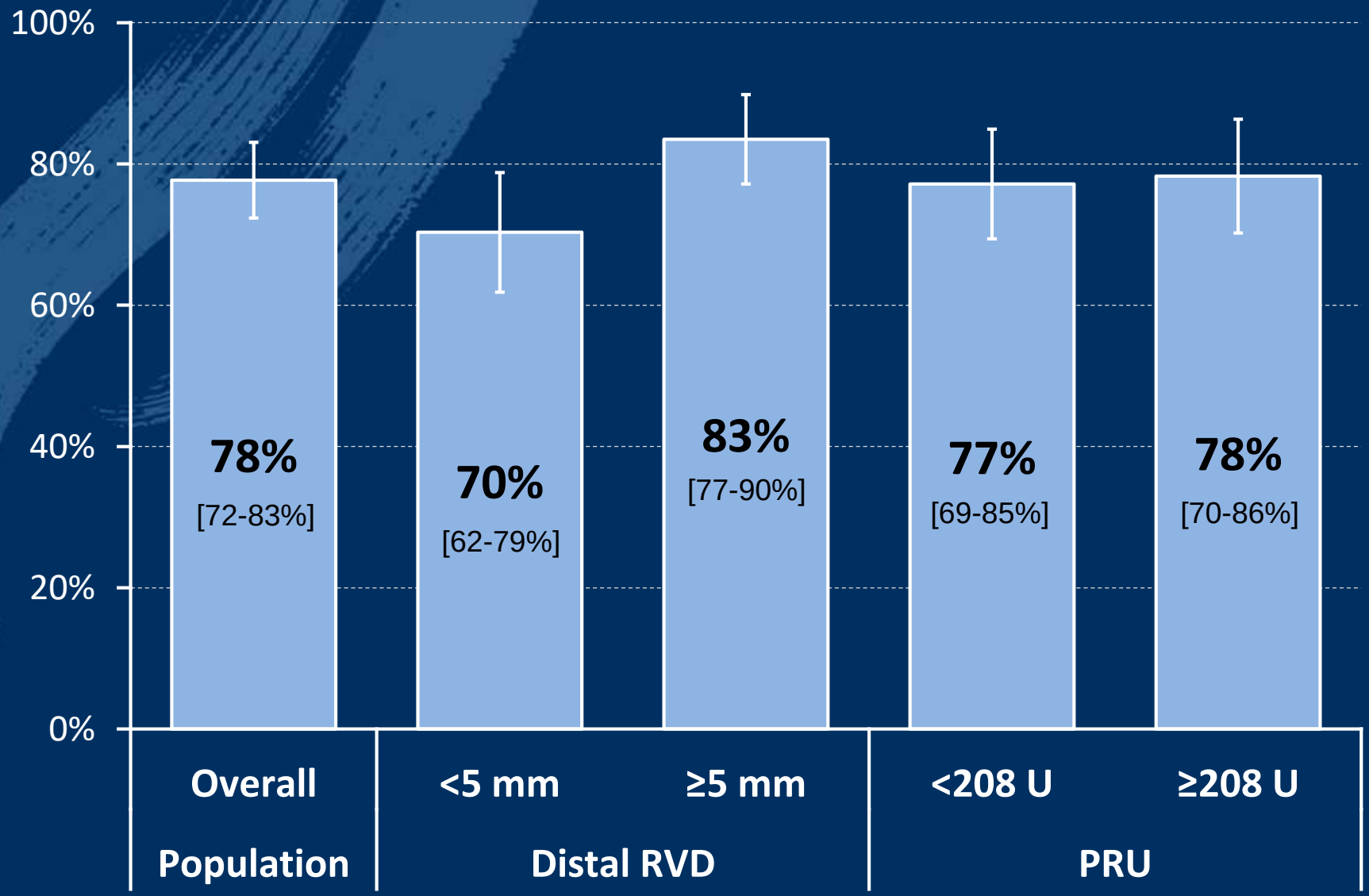
Platelet Reactivity

PRU (per 100 U)	1.02 [0.66-1.57]

IVUS Findings

Pre-EVT	
Min EEM area (per 10 mm^2)	**0.61 [0.41-0.89]***
Post-EVT	
Distal stent area (per 10 mm^2)	**0.44 [0.24-0.80]***
Distal EEM area (per 10 mm^2)	**0.63 [0.43-0.93]***
Prox stent area (per 10 mm^2)	0.73 [0.51-1.05]
Prox EEM area (per 10 mm^2)	0.91 [0.73-1.12]
Subintimal route	0.90 [0.41-1.95]
Edge dissection	1.85 [0.39-8.73]

1-Year Primary Patency Rate



Conclusions

The current preliminary analysis of the VANQUISH study demonstrated that …

- Primary patency at 1 year after IVUS-supported FP stentgraft placement was **78**% [72-83%].
- **PRU-evaluated platelet reactivity** was **NOT** associated with the restenosis risk, whereas **a smaller vessel** was a risk factor for loss of patency.

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