Dr. Yosuke Hata

Further risk stratification by systemic factors in WIfI Stage 4 but not in Stage 1-3 in chronic limb-threatening ischemia

Q1:自己紹介をお願いします

関西労災病院循環器内科の畑陽介です。飯田先生の指導の元、
日々身を削る勢いで研鑽を積んでおります。

Q2:受賞された予選、決勝の感想は？

決勝でプレゼンテーションさせていただき、
結果発表の時に浦澤先生に名前を呼び間違えられたことが印象的です。

Q3:勝ち抜くためのTipsをいくつかお教えください

- シンプルな英語、シンプルなスライドで勝負しました。
- 関西労災では毎週抄読会を英語で行っており、そこでの練習が効きました。

Q4:発表された内容、論文化されましたか？

EJVESにアクセプトされました。
Eur J Vasc Endovasc Surg. 2019 Oct;58(4):548-555.

*JET HPに発表時のスライドを掲載しています

Further risk stratification by systemic factors in WIfI (Wound, Ischemia, and foot Infection classification system) Stage 4 but not in Stage 1-3 in chronic limb-threatening ischemia

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COI Disclosure

Speaker name :

Yosuke Hata, MD

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

WIfI (Wound, Ischemia, and foot Infection) Classification System

The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk stratification based on Wound, Ischemia, and foot Infection (WIfI)

Joseph L. Mills, Sr, MD,[a] Michael S. Conte, MD,[b] David G. Armstrong, DPM, MD, PhD,[a] Frank B. Pomposelli, MD,[c] Andres Schanzer, MD,[d] Anton N. Sidawy, MD, MPH,[e] and George Andros, MD,[f] on behalf of the Society for Vascular Surgery Lower Extremity Guidelines Committee, *Tucson, Ariz; San Francisco and Van Nuys, Calif; Brighton and Worcester, Mass; and Washington, D.C.*

A predictive tool to stratify limb prognosis in patients with chronic limb-threatening ischemia (CTLI)

Table 7. Assessment of the risk of amputation: the WIFI classification (for further details see Mills et al[317]).

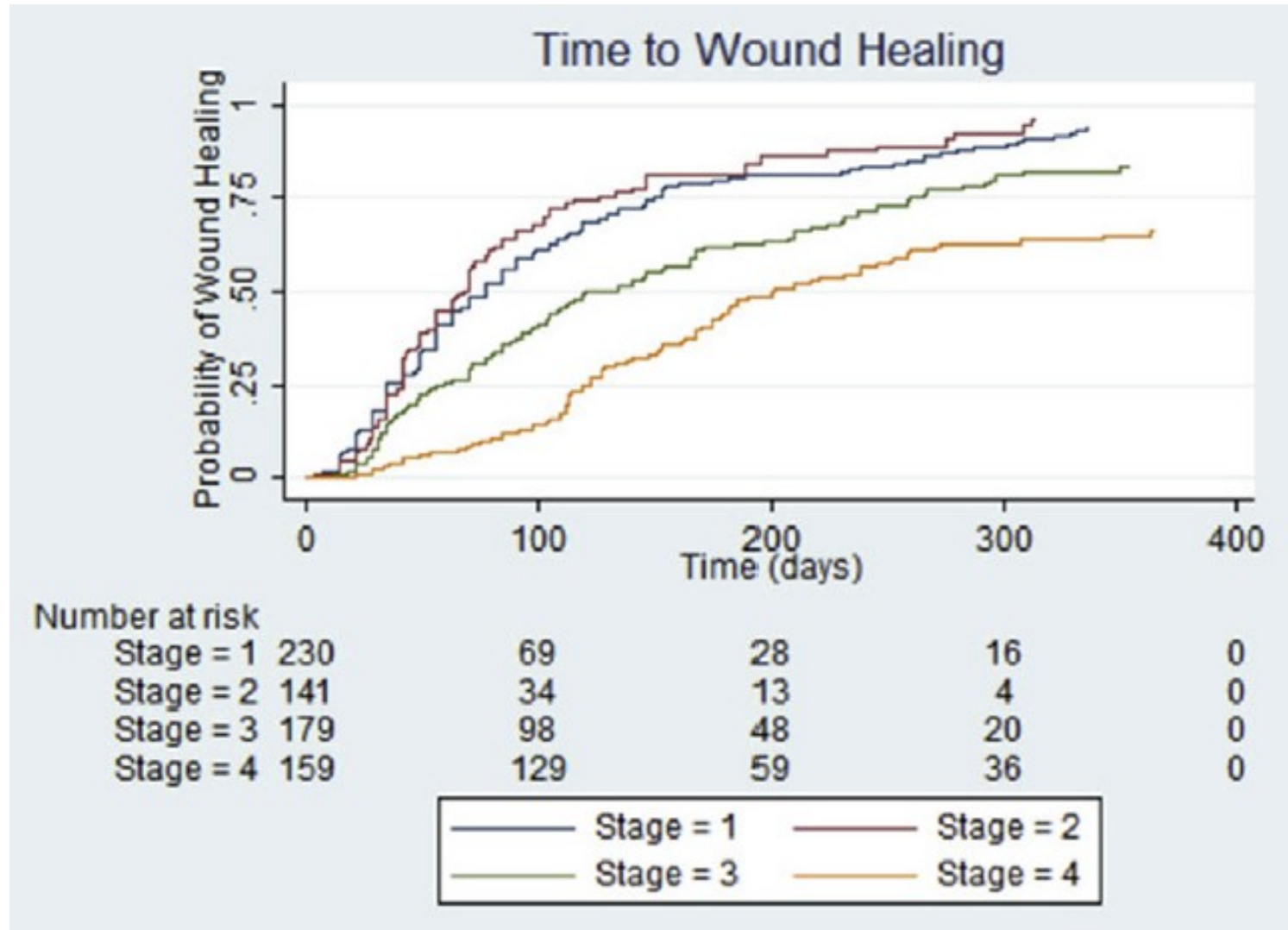| Component	Score	Description		
W (Wound)	0	No ulcer (ischaemic rest pain)		
	1	Small, shallow ulcer on distal leg or foot without gangrene		
	2	Deeper ulcer with exposed bone, joint or tendon $\pm$ gangrenous changes limited to toes		
	3	Extensive deep ulcer, full thickness heel ulcer $\pm$ calcaneal involvement $\pm$ extensive gangrene		
I (Ischaemia)		ABI	Ankle pressure (mmHg)	Toe pressure or $TcPO_2$
	0	≥ 0.80	> 100	≥ 60
	1	$0.60-0.79$	$70-100$	$40-59$
	2	$0.40-0.59$	$50-70$	$30-39$
	3	< 0.40	< 50	< 30
fI (foot Infection)	0	No symptoms/signs of infection		
	1	Local infection involving only skin and subcutaneous tissue		
	2	Local infection involving deeper than skin/subcutaneous tissue		
	3	Systemic inflammatory response syndrome		

Stage 4 (High risk)

W: 2 # Ischemic wound in 3rd-5th toes

I: 3 # Ankle-brachial index < 0.40

fI: 2 # Accompanied with osteomyelitis

	Ischemia – 0				Ischemia – 1				Ischemia – 2				Ischemia – 3			
W-0	VL	VL	L	M	VL	L	M	H	L	L	M	H	L	M		H
W-1	VL	VL	L	M	VL	L	M	H	L	M	H	H	M	M	H	H
W-2	L	L	M	H	M	M	H	H	M	H	H	H	H	H	H	H
W-3	M	M	H	H	H	H	H	H	H	H	H	H	H	H	H	H
	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3

Mills JL Sr, et al. J Vasc Surg 2014;59:220-234.
Aboyans V, et al. Eur J Vasc Endovasc Surg 2018;55:305-368.

Association between WIfI stages and wound healing in CLTI patients

Hicks CW, et al. J Vasc Surg 2018;68:1096-1103.

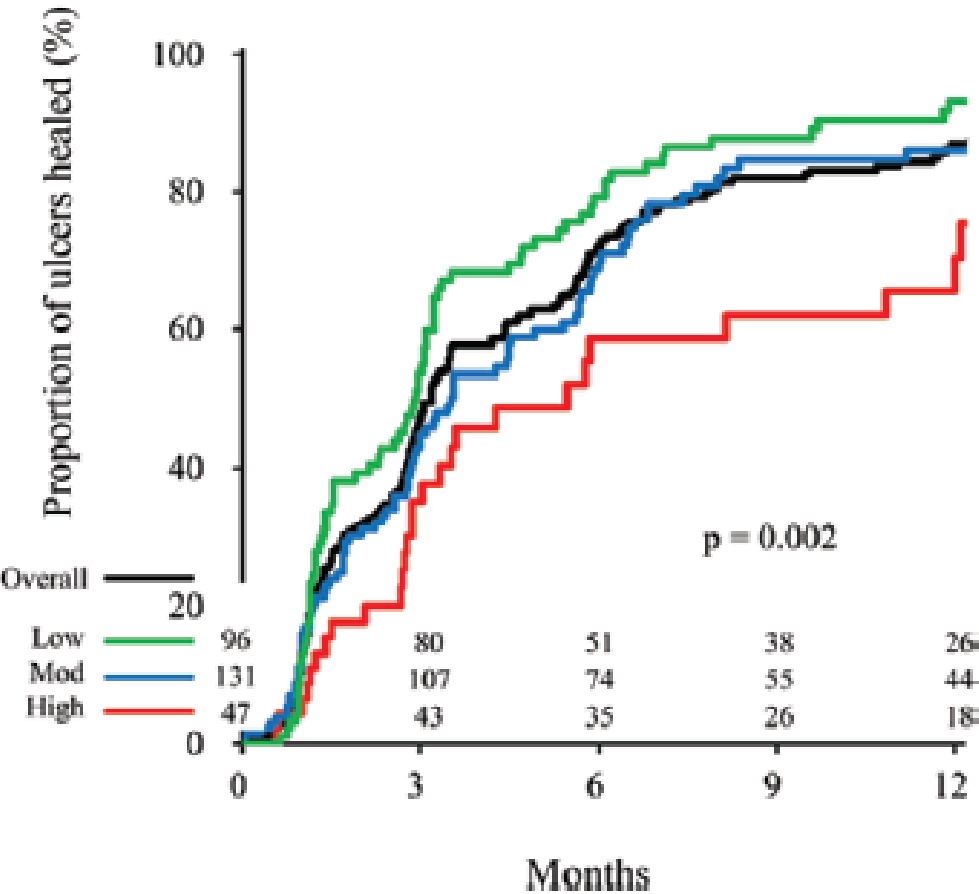# Impact of systemic factors for wound healing in CLTI patients

Table 4. Multivariable Analysis for Predictors of Amputation-Free Survival, Major Adverse Limb Events, and Unhealed Wounds After Endovascular Treatment

	HR (95% CI)	P Value
AFS		
BMI <18.5	2.22 (1.23–4.01)	0.008
Statin administration	0.59 (0.30–1.13)	0.11
Anemia	1.80 (0.97–3.32)	0.06
Heart failure	1.73 (1.02–2.91)	0.04
Wound infection	1.89 (1.07–3.32)	0.02
MALE		
Hemodialysis	1.98 (1.23–3.20)	0.005
Heart failure	1.69 (1.08–2.66)	0.02
Rutherford classification 6	2.25 (1.36–3.74)	0.002
One straight line to foot	0.55 (0.23–1.28)	0.16
Time to wound healing		
BMI <18.5	0.54 (0.31–0.96)	0.03
Hemodialysis	0.79 (0.58–1.09)	0.15
Wound infection	0.60 (0.36–0.98)	0.04

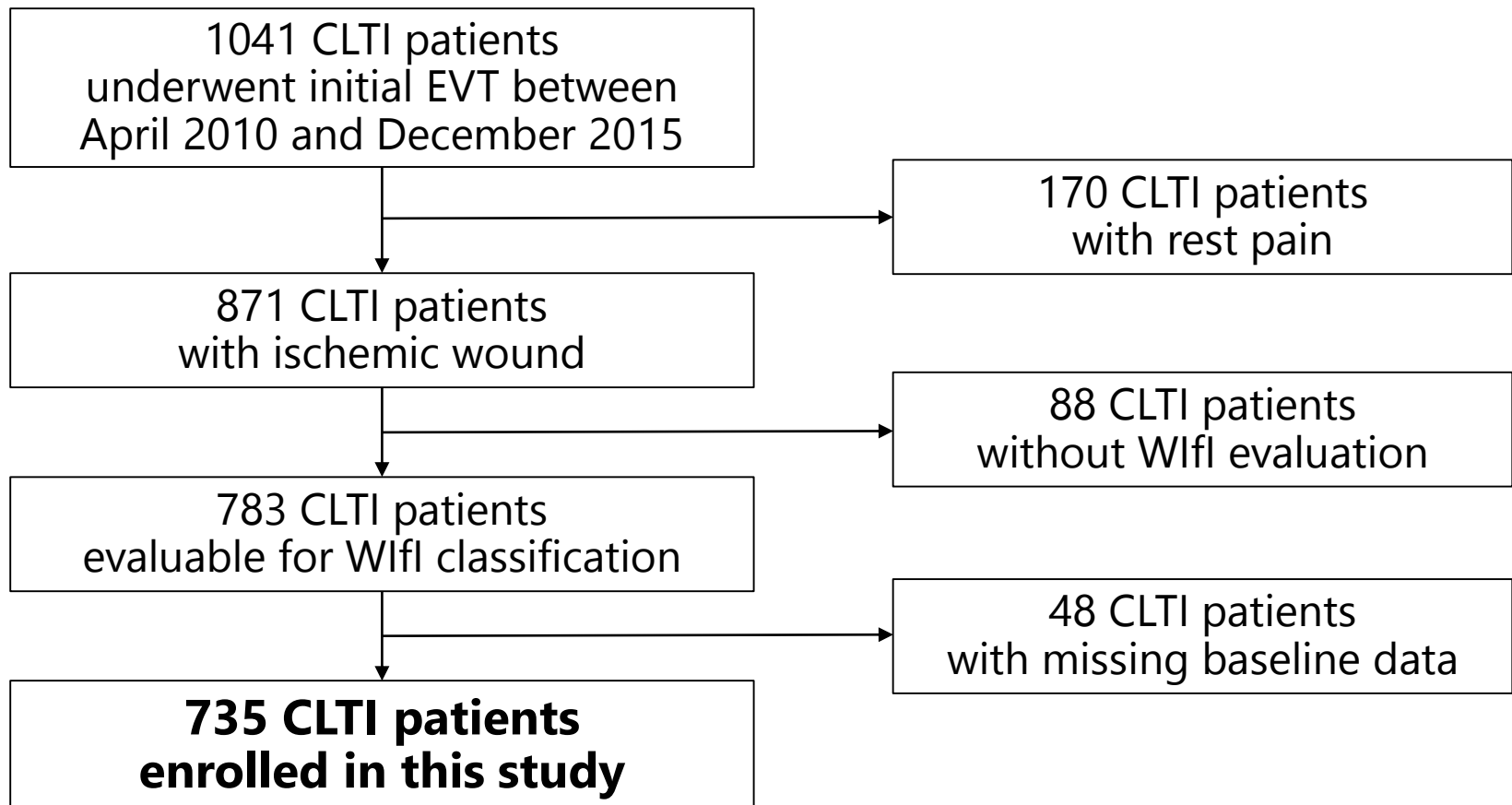*Iida O, et al. Circ Cardiovasc Interv. 2013;6:68-76.*

Objectives

The aim of this study was to investigate the prognostic impact of local and systemic patient characteristics on limb prognosis in CTLI undergoing endovascular therapy (EVT).

Study design

➢ Retrospective observational study

➢ Study flow chart

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┌─────────────────────────────────┐
│ 1041 CLTI patients              │
│ underwent initial EVT between   │
│ April 2010 and December 2015    │
└─────────────────────────────────┘
                │              ┌─────────────────────────┐
                │─────────────▶│ 170 CLTI patients       │
                │              │ with rest pain          │
                ▼              └─────────────────────────┘
┌─────────────────────────────────┐
│ 871 CLTI patients               │
│ with ischemic wound             │
└─────────────────────────────────┘
                │              ┌─────────────────────────┐
                │─────────────▶│ 88 CLTI patients        │
                │              │ without WIfI evaluation │
                ▼              └─────────────────────────┘
┌─────────────────────────────────┐
│ 783 CLTI patients               │
│ evaluable for WIfI classification│
└─────────────────────────────────┘
                │              ┌─────────────────────────┐
                │─────────────▶│ 48 CLTI patients        │
                │              │ with missing baseline data│
                ▼              └─────────────────────────┘
┌─────────────────────────────────┐
│ 735 CLTI patients               │
│ enrolled in this study          │
└─────────────────────────────────┘
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Study endpoint

➤ Primary outcome measure: wound healing

➤ The predictors of wound healing were explored by Cox proportional hazards regression analysis.

Definitions

➢ Wound healing:
Complete epithelialization of all wounds without death or major amputation

➢ WIfI clinical stages
We used clinical stages for amputation risk.
Stage 1: very low risk,
Stage 2: low risk,
Stage 3: moderate risk,
Stage 4: high risk

Definitions

➢ Non-ambulatory status:
Wheel chair or bed ridden on admission

➢ Hypoalbuminemia:
Serum albumin < 3.0 g/dL in laboratory
examination before EVT

➢ Major amputation:
Limb amputation at proximal side from ankle

Statistical analysis

➢ Kaplan-Meier analysis

➢ Log-rank test

➢ Cox proportional hazards model

Patient characteristics

No. patients	735
Male	450 (61.2)
Age, years	73.9 ± 9.8
Body mass index (BMI), kg/m^2	21.4 ± 3.7
Non-ambulatory status	324 (44.1)
Hypertension	482 (65.6)
Dyslipidemia	230 (31.3)
Diabetes mellitus	491 (66.8)
Hemodialysis	398 (54.1)
Coronary artery disease	325 (44.2)
Ejection fraction (EF), %	61.5 ± 12.6
Serum albumin, g/dL	3.3 ± 0.6

Data given as n (%) or mean ± SD.

Limb characteristics

No. patients	735
Ankle-brachial index	0.63±0.21
Skin perfusion pressure, mmHg	
Dorsal surface	26.9±17.8
Plantar surface	29.9±17.1
Stage in WIfI classification	
1 (Very low risk)	142 (19.3)
2 (Low risk)	154 (21.0)
3 (Moderate risk)	168 (22.9)
4 (High risk)	271 (36.9)

Data given as n (%) or mean ± SD.

Arterial lesion characteristics

No. patients	735
Lesion distribution	
Aortoiliac-femoropopliteal	92 (12.5)
Isolated below the knee	320 (43.5)
Multi vessels	323 (43.9)
TASC 2 class C/D at any lesions	665 (90.4)
Chronic total occlusion	589 (80.1)
Lesion calcification	
None	239 (32.5)
Unilateral	151 (20.5)
Bilateral	345 (46.9)

Data given as n (%) or mean ± SD.
TASC: Trans-Atlantic Inter-Society Consensus Document on Management of Peripheral Arterial Disease.

Predictors for wound healing

	WIfI stage 1-3		WIfI stage 4	
	HR [95%CI]	p value	HR [95%CI]	p value
Female	1.03 [0.80-1.32]	0.82	1.22 [0.85-1.76	0.27
Age ≥ 80 years	1.21 [0.93-1.58]	0.15	1.03 [0.67-1.58]	0.90
Non-ambulatory status	0.79 [0.61-1.04]	0.09	**0.50 [0.35-0.71]**	**<0.001**
Diabetes mellitus	1.22 [0.94-1.58]	0.14	0.87 [0.59-1.28]	0.48
Hemodialysis	0.84 [0.66-1.07]	0.16	**0.54 [0.38-0.76]**	**0.001**
Coronary artery disease	0.96 [0.75-1.22]	0.71	0.88 [0.61-1.25]	0.47
BMI <18.5 kg/m^2	1.21 [0.94-1.56]	0.13	0.83 [0.53-1.23]	0.40
Hypoalbuminemia	0.87 [0.62-1.24]	0.45	**0.54 [0.36-0.81]**	**0.003**
EF < 50%	0.71 [0.49-1.02]	0.07	0.81 [0.49-1.35]	0.42

HR: Hazard ratio, CI: Confidential interval, p: p value
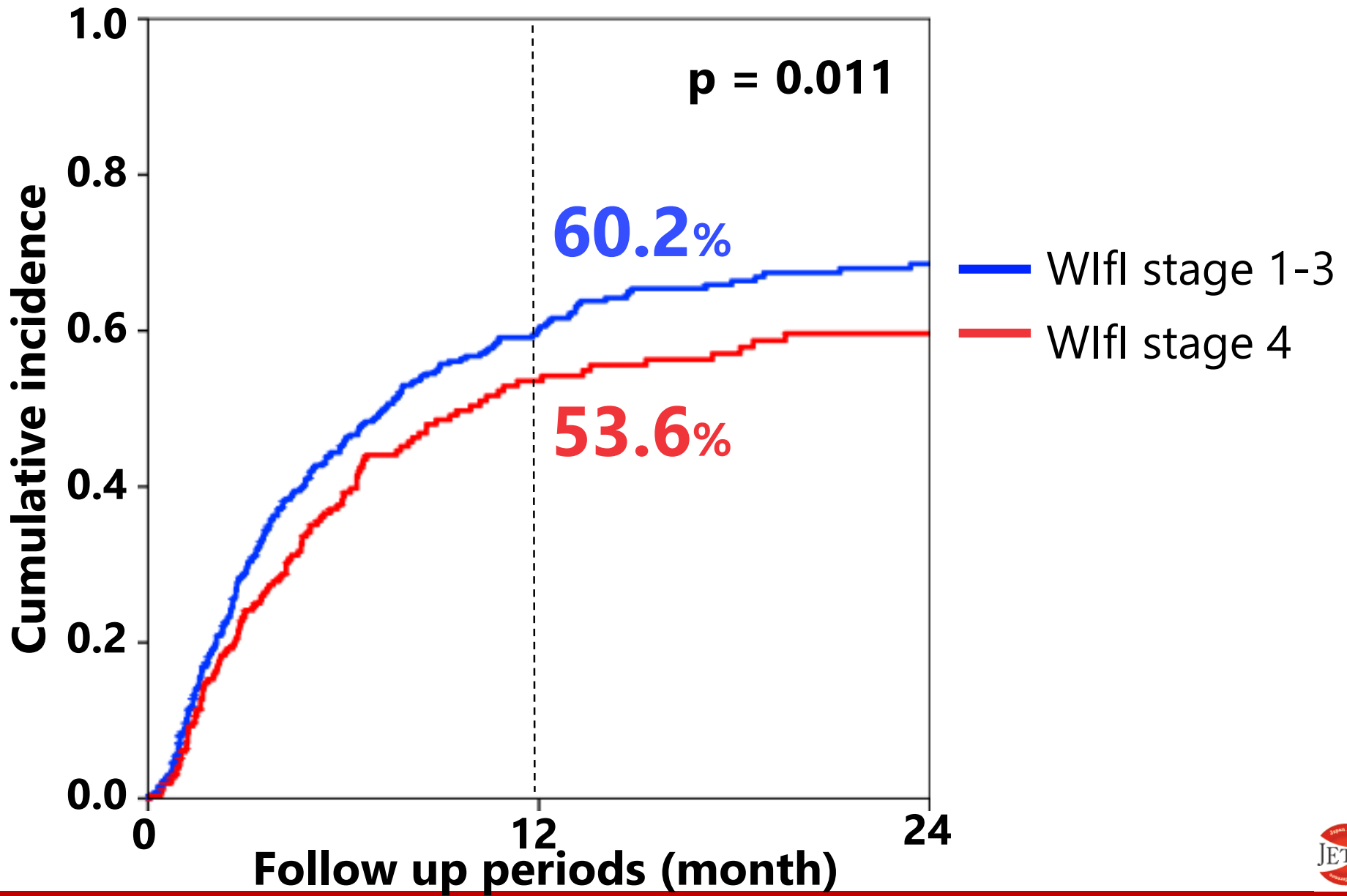
Wound healing rate
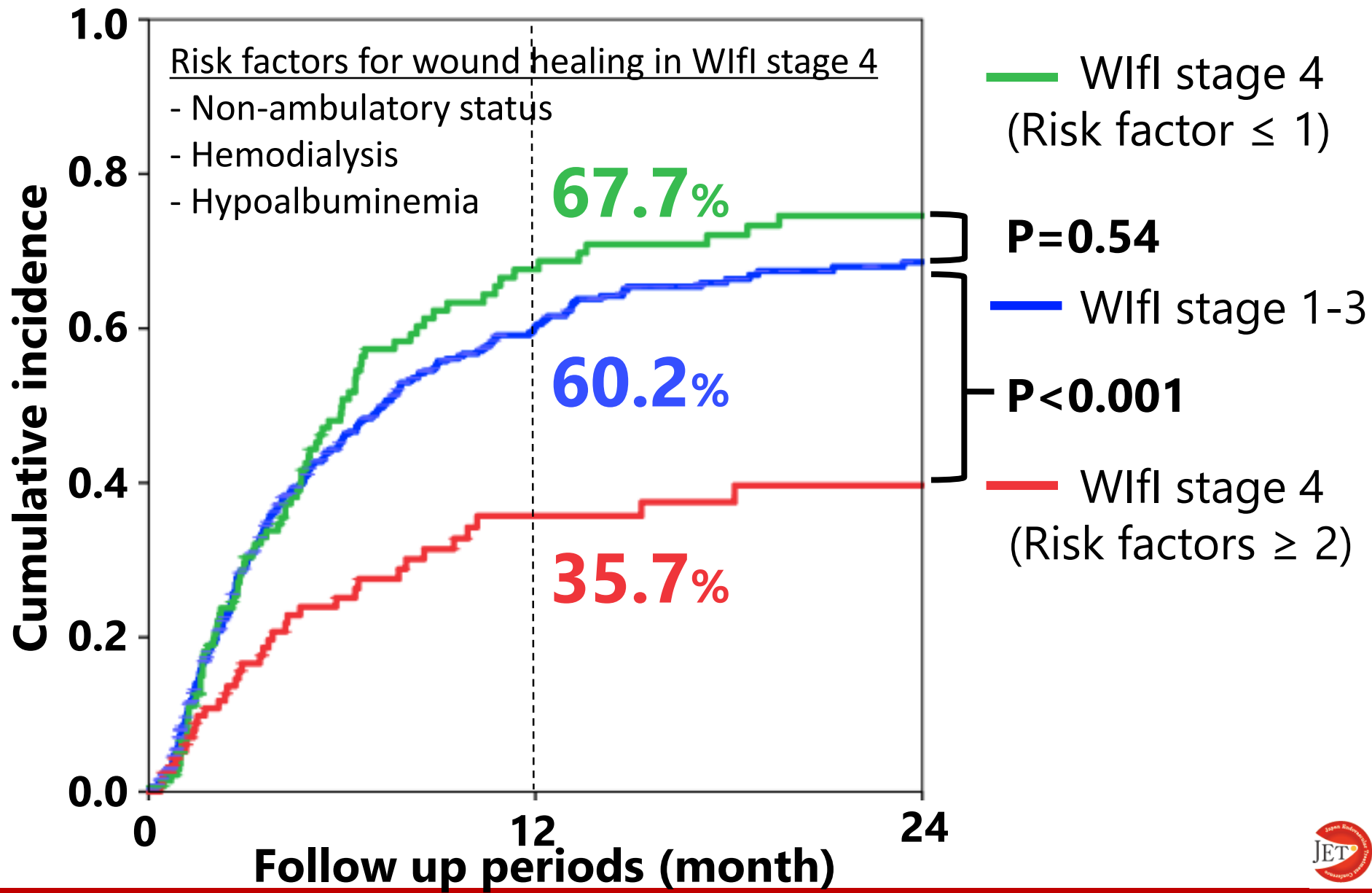
Summary

➢ We retrospectively analyzed 735 CLTI patients who underwent EVT.

➢ In WIfI stage 1-3, no systemic factors were significantly associated with delayed wound healing, whereas in WIfI stage 4, non-ambulatory status, hemodialysis and hypoalbuminemia were identified as independent risk factors for delayed wound healing.

➢ In Kaplan-Meier analysis, wound healing rate at one year were significantly better in WIfI stage 4 with fewer risk factors than WIfI stage 4 with more risk factors, and comparable to WIfI stage 1-3.

Conclusion

Non-ambulatory status, hemodialysis and hypoalbuminemia were additional risk factors for delayed wound healing in WIfI stage 4.
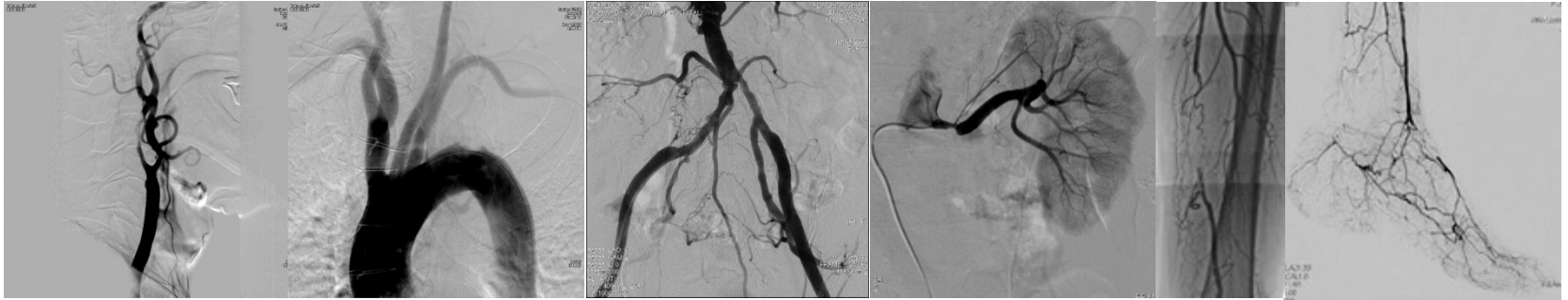
Thank you for your attention

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