



The Japanese SPINCAH Registry Confirms That Open Bypass are Superior to Endovascular Treatment in CLTI Patients When Ischemia and Infection are Advanced

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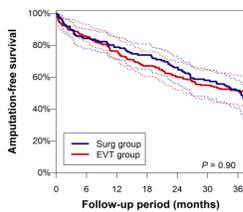
COI disclosure

The authors have no financial COI to disclose regarding this presentation.

CLTI Patients demographics –difference among countries

Study Name	BASIL trial	PREVENT III	CRITISCH registry	SPINACH registry	BEST CLI	BASIL II
Country (Year)	UK (2005)	USA (2005)	Germany (2015)	JAPAN (2017)	2022	2023
Type of study	multicenter RCT	multicenter RCT	multicenter registry	multicenter registry	multicenter RCT	multicenter RCT
Revascularization	Bypass vs EVT	Bypass	Bypass vs EVT	Bypass vs EVT	Bypass vs EVT	Bypass vs EVT
Subject	SLI	CLI	CLI	CLI	CLI	CLI with Infrapopliteal
No. Pts	452	1404	1200	548	1830	345
Comorbidities						
Diabetes	42%	64%	47%	74%	72%	69%
CAD	36%	48%	45%	45%	43%	
CVD	21%	20%	12%	12%	13%	17%
On dialysis	0%	12%	9%	53%	11%	4%
Infrapopliteal Revasc.	25%	67%	39%	Bypass 77% EVT 75%	Bypass 56% EVT 30%	100%

Three-Year Outcomes of Surgical Versus Endovascular Revascularization for Critical Limb Ischemia
The SPINACH Study (Surgical Reconstruction Versus Peripheral Intervention in Patients With Critical Limb Ischemia)

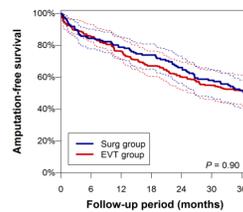


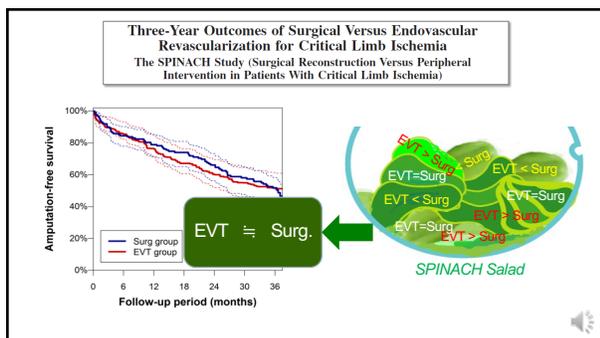
Covariates for propensity score

- Age, Gender, Ambulatory status, QOL
- Comorbidities and their management (including DM, renal failure)
- Contralateral limb status
- TASC Classification
- Foot lesion severity
- UT classification
- Wiffl W grade, I grade, II grade
- Plan for infra-popliteal revascularization

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Three-Year Outcomes of Surgical Versus Endovascular Revascularization for Critical Limb Ischemia
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Protocol paper of SPINACH Registry

Original Article

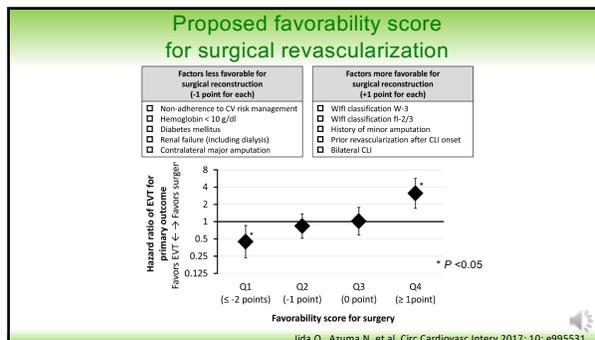
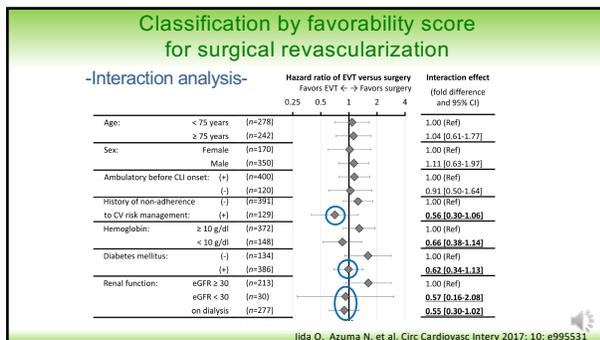
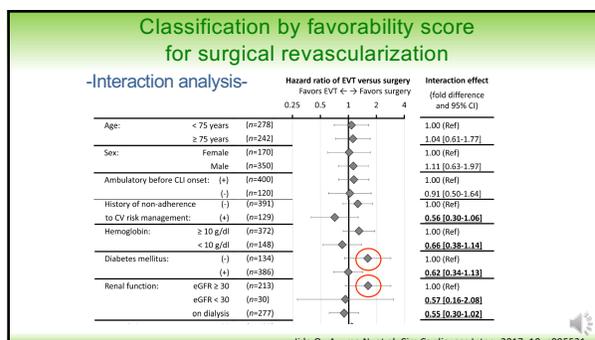
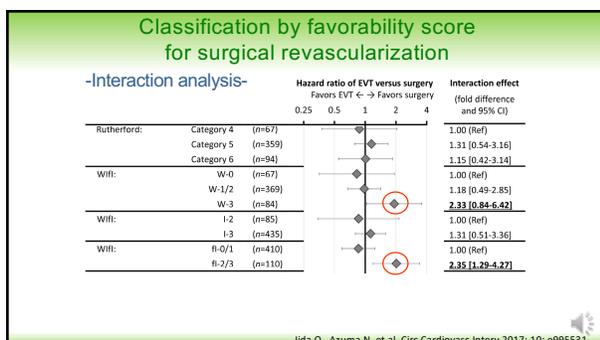
Vascular

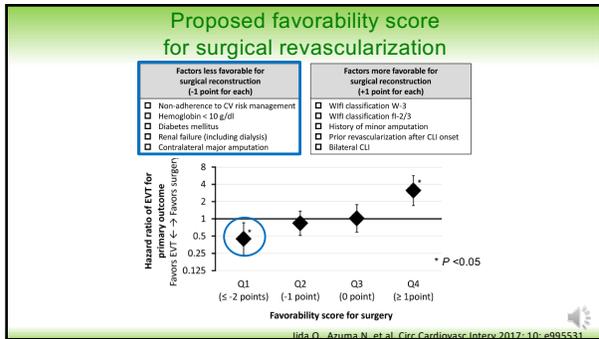
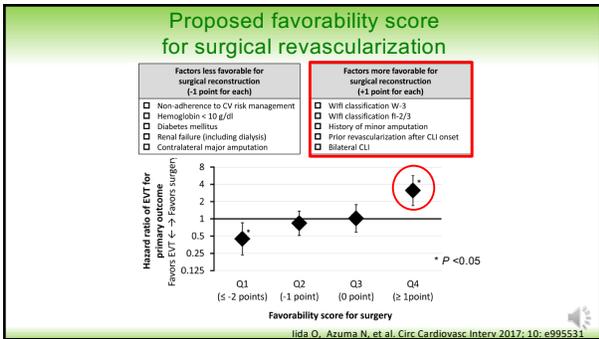
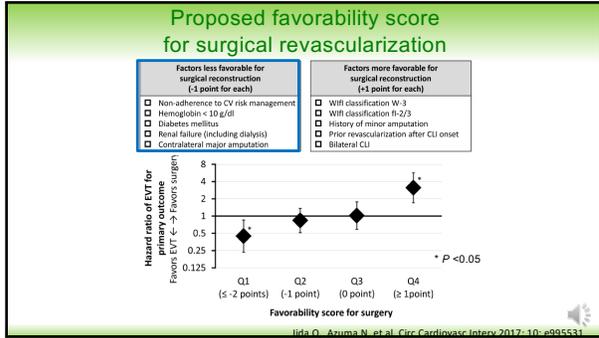
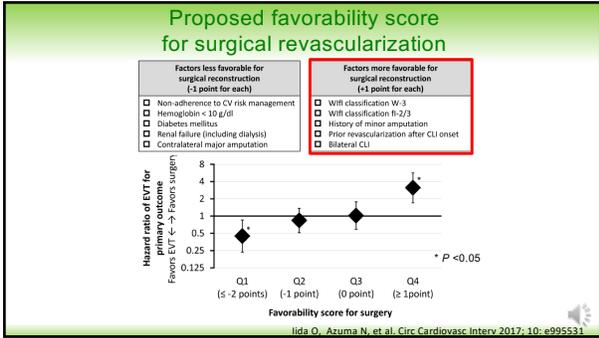
Surgical reconstruction versus peripheral intervention in patients with critical limb ischemia – a prospective multicenter registry in Japan: The SPINACH study design and rationale

Conclusions

The results of this study will contribute to existing guidelines on the selection of the most appropriate revascularization procedure for the treatment of CLI. In other words, this study will attempt to provide a proposed patient model suitable for bypass surgery as the first line of treatment and a patient model suitable for EVT as the first strategy.

Azuma N, et al. *VASCULAR* 2014; 22: 411-20





Initial Success Rate*

Table 2. Perioperative Outcomes in Matched Population

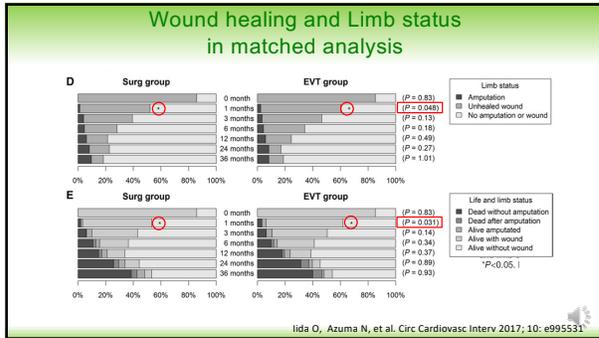
	Surg Group	EVT Group	P Value
Initial technical success, %			
Anatomic	97 (94-99)	91 (87-94)	0.006
Hemodynamic	88 (84-93)	81 (77-86)	0.032
Perioperative adverse event, %			
Death	2.7 (1.0-4.4)	3.3 (1.2-5.2)	0.71
Myocardial infarction	0.7 (0.0-1.1)	0.1 (0.0-0.4)	0.54
Cerebrovascular disease	1.3 (0.0-2.2)	1.2 (0.0-2.4)	0.93
Acute renal failure	1.3 (0.0-2.2)	2.0 (0.3-3.6)	0.54
Major amputation	2.7 (1.0-4.4)	3.1 (1.1-5.1)	0.71
Major adverse limb event	4.7 (2.1-7.3)	5.7 (2.8-8.4)	0.62
Surgical site infection	4.7 (2.1-7.2)	0.0 (0.0-0.0)	0.001

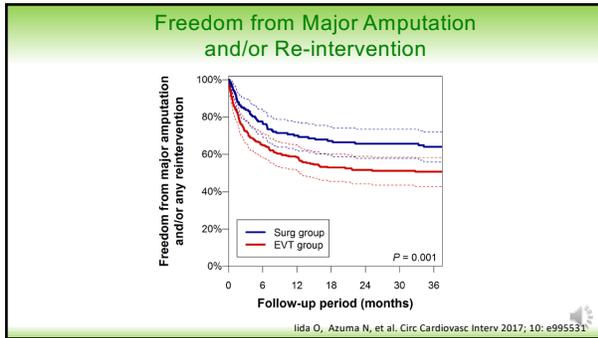
***Definition of initial success**

Anatomic success: at least one straight line reaching the foot for EVT and as a patent bypass graft perfusing blood directly to the foot for surgical revascularization.

Hemodynamic success: an increase in ankle-brachial index > 0.1 or an increase in SPP > 10mmHg.

Iida O, Azuma N, et al. Circ Cardiovasc Interv 2017; 10: e995531





The Association of Preoperative Characteristics with Reintervention Risk in Patients Undergoing Revascularization for Chronic Limb-Threatening Ischemia

Osamu Iida¹, Mitsuyoshi Takahara², Yoshimitsu Soga³, Aiko Kodama⁴, Hiroto Terashi⁵, and Nobuyoshi Azuma⁶, on behalf of the SPINACH investigators

Table 6. Sensitivity analysis for associations between baseline characteristics and reintervention risk (complete case analysis)

	Interaction of EVT versus surgical reconstruction (fold increase)	Unadjusted hazard ratio for reintervention	Adjusted hazard ratio for reintervention
EVT (versus surgical reconstruction)	---	1.52 (1.15-2.01)*	1.83 (1.25-2.68)*
Hemoglobin (per 1 g/dl)	0.96 (0.81-1.13)	0.92 (0.85-1.00)*	0.95 (0.87-1.05)
Renal function			
eGFR 30-60 ml/min/1.73 m ²	0.59 (0.23-1.51)	1.61 (1.02-2.54)*	1.48 (0.86-2.56)
eGFR < 30 ml/min/1.73 m ² on dialysis	0.92 (0.43-1.96)	1.94 (1.35-2.78)*	1.63 (1.06-2.52)*
Heart failure	1.06 (0.52-2.14)	1.62 (1.04-2.51)*	1.37 (0.95-1.98)
WHI classification: Wound	0.80 (0.58-1.09)	1.01 (0.88-1.16)	NI†
WHI classification: Ischemia	1.17 (0.43-3.15)	1.02 (0.71-1.47)	NI†
WHI classification: Foot infection	1.16 (0.83-1.63)	1.11 (0.95-1.30)	1.26 (1.04-1.53)*
History of revascularization after CLTI onset	0.68 (0.26-1.73)	1.65 (1.05-2.57)*	2.19 (1.21-3.97)*
Bilateral CLTI	0.89 (0.42-1.87)	2.01 (1.42-2.85)*	2.01 (1.31-3.09)*
TASC II aorto-ilio classification	0.80 (0.70-1.12)	0.95 (0.85-1.07)	NI†
TASC II femoro-popliteal classification	1.04 (0.87-1.24)	0.95 (0.88-1.03)	NI†
TASC II infra-popliteal classification	1.27 (0.94-1.71)	1.01 (0.87-1.17)	NI†
Tibial artery lesion	1.60 (0.66-3.83)	1.07 (0.71-2.00)*	1.41 (0.93-2.14)

Hazard ratios are presented together with the 95% confidence intervals. Asterisks indicate P<0.05. NI, not included.

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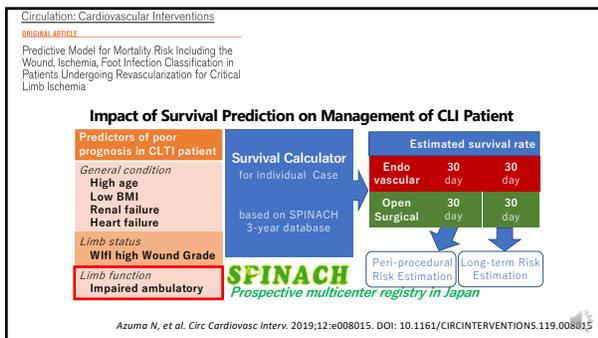
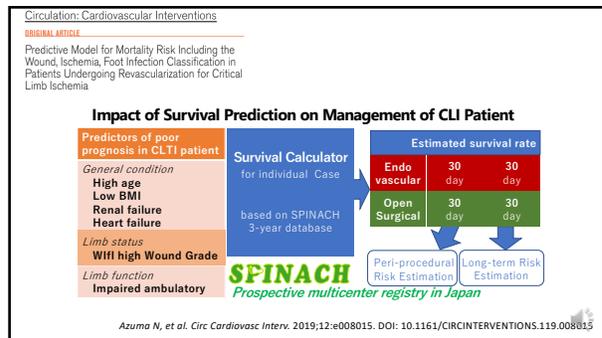
Ambulatory Status Over Time after Revascularization in Patients with Chronic Limb-Threatening Ischemia

Akio Kodama¹, Mitsuyoshi Takahara², Osamu Iida³, Yoshimitsu Soga⁴, Hiroto Terashi⁵, Daizo Kawasaki⁶, Yuichi Izumi⁷, Shinsuke Mi⁸, Kimihiro Komori⁹ and Nobuyoshi Azuma⁶ on behalf of the SPINACH investigators.

Table 2. Association of baseline characteristics with ambulation loss

	Crude odds ratio	Adjusted odds ratio
Ambulatory with and before CLTI onset (vs. ambulatory without and)		
At 3 months	2.2 (1.3 to 3.6) (P<0.002)*	2.1 (0.9 to 4.6) (P=0.08)
At 12 months	3.1 (1.8 to 5.5) (P<0.001)*	3.1 (1.2 to 7.1) (P=0.009)*
At 24 months	3.1 (1.7 to 5.5) (P<0.001)*	2.9 (1.1 to 7.2) (P=0.025)*
At 36 months	2.1 (1.0 to 4.2) (P=0.04)*	2.2 (0.9 to 5.1) (P=0.08)
Ambulatory with and at revascularization (vs. ambulatory without and)		
At 3 months	1.2 (0.6 to 2.3) (P=0.65)	0.6 (0.2 to 1.6) (P=0.34)
At 12 months	1.8 (1.0 to 3.1) (P=0.04)*	0.8 (0.3 to 1.9) (P=0.61)
At 24 months	1.8 (1.0 to 3.1) (P=0.04)*	0.9 (0.4 to 2.2) (P=0.80)
At 36 months	1.3 (0.7 to 2.6) (P=0.43)	0.9 (0.4 to 2.1) (P=0.82)
WHI clinical stage 4 (vs. WHI clinical stage 2/3)		
At 3 months	2.0 (1.3 to 3.1) (P<0.001)*	2.1 (1.2 to 3.7) (P=0.010)*
At 12 months	2.1 (1.4 to 3.2) (P<0.001)*	2.9 (1.6 to 5.0) (P<0.001)*
At 24 months	1.4 (0.8 to 2.2) (P=0.15)	1.6 (0.9 to 2.8) (P=0.09)
At 36 months	1.3 (0.8 to 2.1) (P=0.21)	1.2 (0.7 to 1.9) (P=0.34)
Surgical reconstruction (vs. EVT alone)		
At 3 months	0.9 (0.6 to 1.4) (P=0.65)	0.9 (0.5 to 1.5) (P=0.79)
At 12 months	0.7 (0.4 to 1.0) (P=0.067)	0.6 (0.3 to 1.0) (P=0.038)*
At 24 months	0.5 (0.3 to 0.8) (P<0.001)*	0.5 (0.3 to 0.8) (P<0.001)*
At 36 months	0.8 (0.5 to 1.4) (P=0.42)	0.8 (0.5 to 1.0) (P=0.46)

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Take Home Message

- SPINACH study tried to find out patient model suitable for surgical revascularization and also patient model suitable for EVT.
- SPINACH study showed superiority of bypass surgery over EVT in CLTI patients with advanced ischemic wounds with/without advanced infection.
- Surgical reconstruction was superior to the EVT in terms of the following outcome measures: initial success rate, ulcer healing, low reintervention rate, and ambulatory function after revascularization.

Thank you for your kind attention



SPINACH Investigators

