Three-year outcomes of surgical vs. endovascular revascularization for critical limb ischemia: The **S**urgical reconstruction vs. **P**eripheral **IN**tervention in p**A**tients with critical limb is**CH**emia (**SPINACH**) study

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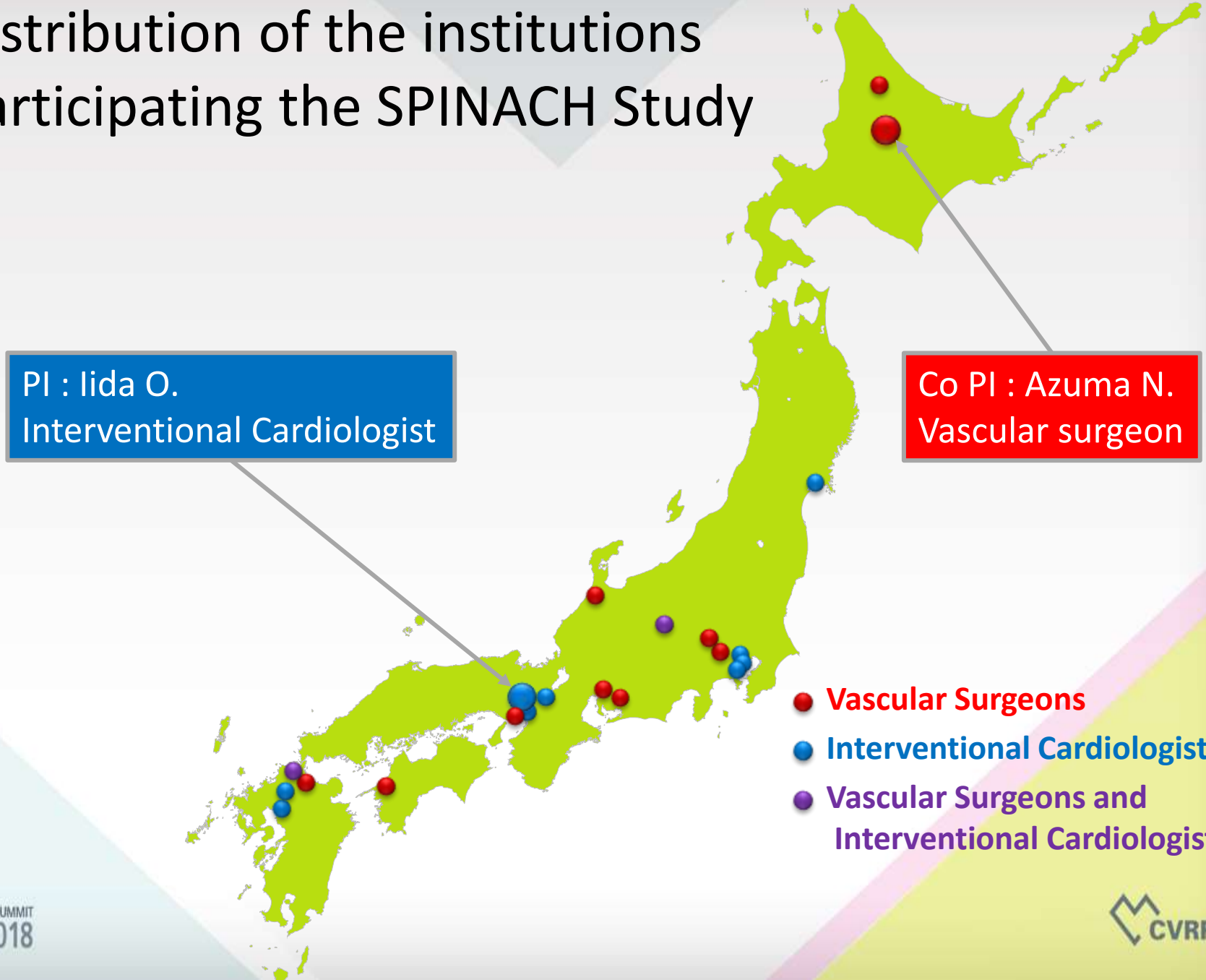
Methods (1)

Objective

- To compare clinical outcomes between surgical reconstruction (Surg) and endovascular therapy (EVT) for patients with critical limb ischemia (CLI) in today's real-world settings.

Distribution of the institutions participating the SPINACH Study



Methods (2)

Endpoint

- Primary endpoint: 3-year amputation-free survival (AFS)
- Secondary endpoints: 3-year 1) freedom from major adverse limb event (MALE), 2) freedom from major amputation and/or any re-intervention

Statistical analysis

- The propensity score matching was performed to minimize the intergroup difference in baseline characteristics

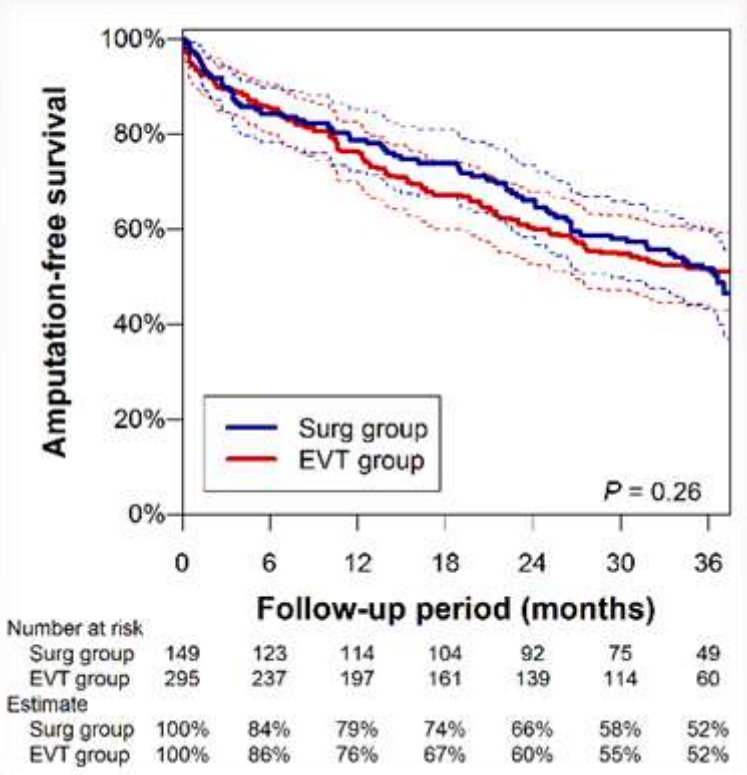
Results

- 550 CLI patients in whom revascularization was planned were registered.
  - One patient who was later diagnosed with vasculitis
  - One patient who later voluntarily withdrew from the study were excluded.
- The remaining 548 CLI patients (n = 351 in the EVT group and n = 191 in the Surg group.) were followed, and 80% of patients (n=437) completed the 3-year follow-up.
- During the follow-up period, 47 patients underwent major amputation and 237 patients died.

Baseline Characteristics

	Before matching			After matching		
	Surg (n=197)	EVT (n=351)	Std diff (%)	Surg (n=149)	EVT (n=295)	Std diff (%)
Male sex	72%	66%	13.1	72%	71%	2.0
Age (years)	72±9	74±10	16.0	72±9	73±9	7.5
Non-ambulatory before CLI onset	18%	**26%**	20.5	18%	17%	2.0
Diabetes mellitus	73%	74%	2.7	75%	75%	0.5
Renal failure on dialysis	51%	55%	7.9	54%	55%	1.8
BTK revascularization intended	77%	75%	4.6	79%	76%	6.7
Rutherford classification						
Category 4	15%	12%	10.4	14%	15%	2.0
Category 5	65%	70%	10.9	66%	68%	3.0
Category 6	20%	18%	4.0	19%	17%	5.5
UT classification, class 3	**36%**	23%	26.9	32%	29%	6.6
Infection (%)	**53%**	36%	33.9	49%	45%	7.2
Disease-specific QOL (VascuQOL)	2.5±1.1	2.4±1.1	3.2	2.5±1.1	2.4±1.0	3.8
Generic QOL (SF-36)						
Physical functioning	6±19	1±17	29.5	4±17	3±18	4.0
Role physical	20±16	16±15	20.5	19±15	18±16	4.0
General health	36±11	34±10	20.9	34±10	35±10	7.8
Social functioning	29±16	25±15	24.5	29±16	28±15	8.6
Role emotional	26±16	21±16	29.9	26±16	25±17	4.6

The 3-year Amputation-free Survival in primary matched analysis

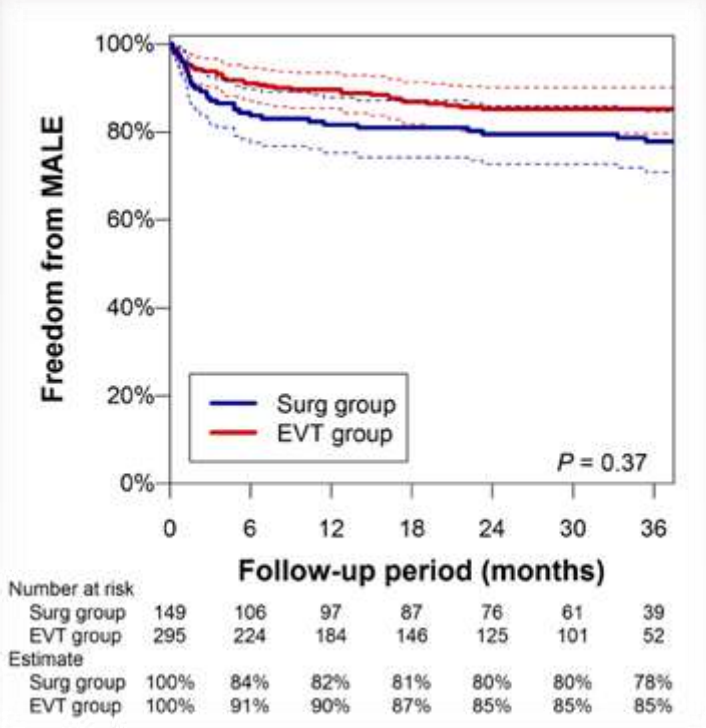


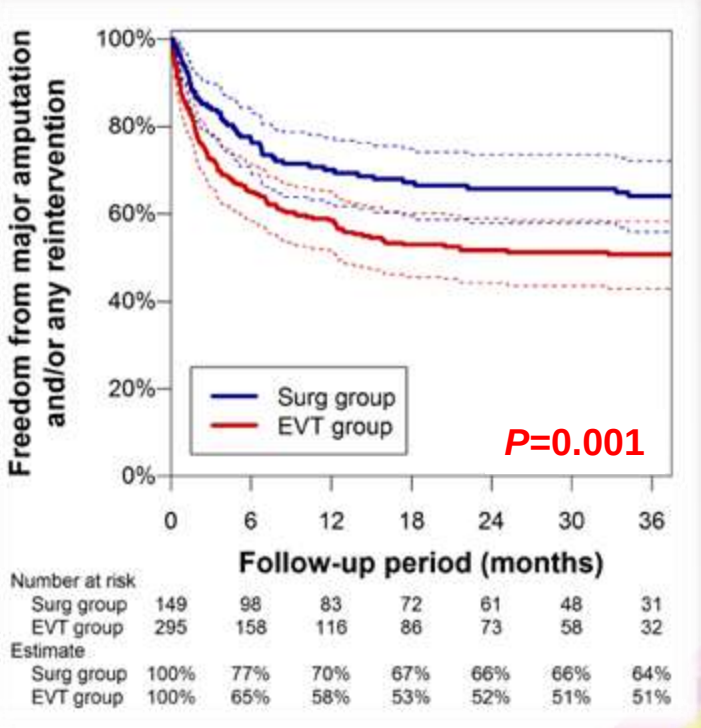
Covariates for propensity score

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

The 3-year AFS rate was not different between the groups (52% [95% CI: 43–60%] in the Surg group versus 52% [44–60%] in the EVT group; *P*=0.26).

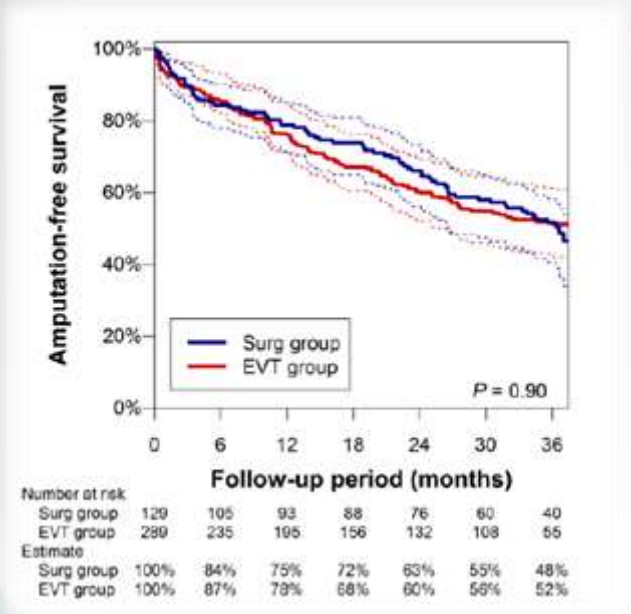
Freedom from MALE, major amputation, and any-reintervention in primary matched analysis

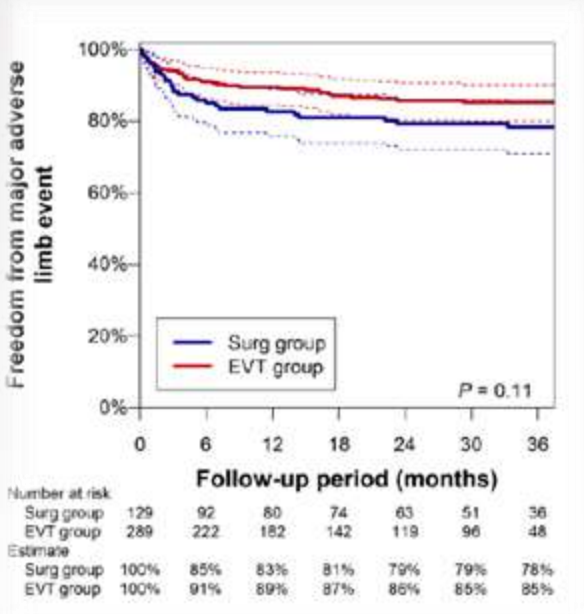


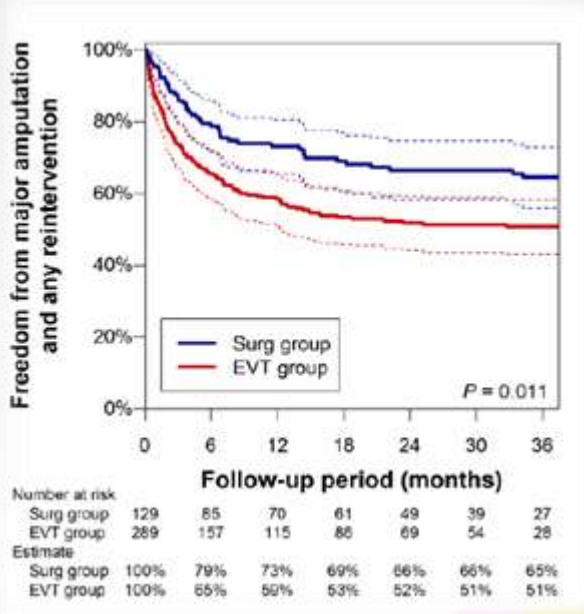


A significant intergroup difference was not observed in the 3-year freedom rate from MALE (78% versus 85%; *P*=0.37) but was in the 3-year freedom rate from major amputation and/or any re-intervention (64% versus 51%; *P*=0.001)

Secondary matched analysis for patients presenting WIfI I-3 with rest pain and I-2/3 with ulcer/gangrene







Secondary matched analysis revealed that the 3-year AFS and freedom from MALE were not different between the groups, whereas the Surg group had a higher rate of freedom from major amputation and/or any re-intervention, representing similar tendency to primary matched analysis.

Classification by favorability score for surgical revascularization

Factors **less favorable** for surgical reconstruction (-1 point for each)	Factors **more favorable** for surgical reconstruction (+1 for each)
✓ Non-adherence to CV risk management	✓ WIfI Classification W-3
✓ Hemoglobin < 10 g/dL	✓ WIfI Classification fI2/3
✓ Diabetes mellitus	✓ History of minor amputation
✓ Renal failure (including Dialysis)	✓ Prior revascularization after CLI onset
✓ Contralateral major amputation	✓ Bilateral CLI

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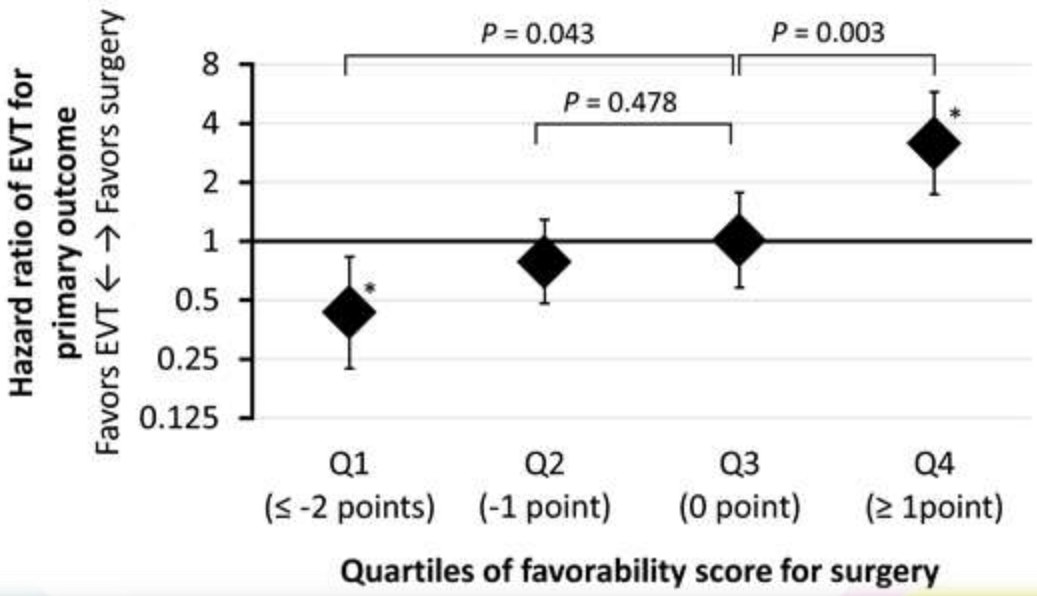

Conclusions

- The SPINACH study, cooperatively performed by vascular surgeons and interventional cardiologists, compared clinical outcomes between current optimal surgical reconstruction and EVT for CLI patients in real-world clinical settings.
- The 3-year AFS were not different between the two treatment strategies in the overall population.
- The subsequent interaction analysis suggested that CLI with severe wound status might be more suited for surgical reconstruction, while those with a poor general condition might benefit more from EVT in terms of AFS.

Thank you for your kind attention

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