2023年 年度採択 Research Proposal 報告

Impact of hospital volume on procedural failure in endovascular treatment for patients with acute limb ischemia: a report from nationwide endovascular therapy registry in Japan

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COI Disclosure

Speaker name: Takuya Haraguchi, 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

Acute limb ischemia

the sudden onset or acute deterioration of clinical symptoms of lower limb ischemia within the last 14 days

Norgren LJ Vasc Surg. 2007;45:S5-S67.

6P: Pain, Pallor, Paralysis, Pulseless, Paresthesia, Poikilothermia

Stage	Description and Prognosis	Findings		Doppler Signal	
		Sensory Loss	Muscle Weakness	Arterial	Venous
I	Limb viable, not immediately threatened	None	None	Audible	Audible
II	Limb threatened				
IIa	Marginally threatened, salvageable of promptly treated	Minimal (toes) or none	None	Often inaudible	Audible
IIb	Immediately threatened, salvageable with immediate revascularization	More than toes, associated with pain at rest	Mild or moderate	Usually inaudible	Audible
III	Limb irreversibly damaged, major tissue loss or permanent nerve damage inevitable	Profound, anesthetic	Profound, paralysis (rigor)	Inaudible	Inaudible

Creager MA. N Engl J Med. 2012;366(23):2198-2206.

Embolism 46%

Thrombus due to LEAD 24%

Complex morphology 20%

Stent or Graft 10%

Howard DP. Circulation 2015; 132: 1805-1815.

Mortality 10-40%/1yr

Amputation 12-50%/1yr

D.T. Baril. J Vasc Surg 2014;60:669-77

Background

A COMPARISON OF RECOMBINANT UROKINASE WITH VASCULAR SURGERY AS INITIAL TREATMENT FOR ACUTE ARTERIAL OCCLUSION OF THE LEGS

KENNETH OURIEL, M.D., FRANK J. VEITH, M.D., AND ARTHUR A. SASAHARA, M.D.,
FOR THE THROMBOLYSIS OR PERIPHERAL ARTERIAL SURGERY (TOPAS) INVESTIGATORS

ABSTRACT

Background Recent controlled trials suggest that thrombolytic therapy may be an effective initial treatment for acute arterial occlusion of the legs. A major potential benefit of initial thrombolytic therapy is that limb ischemia can be managed with less invasive interventions.

Methods In this randomized, multicenter trial conducted at 113 North American and European sites, we compared vascular surgery (e.g., thrombectomy or bypass surgery) with thrombolysis by catheter-directed intraarterial recombinant urokinase; all patients (272 per group) had had acute arterial obstruction of the legs for 14 days or less. Infusions were limited to a period of 48 hours (mean [±SE], 24.4±0.86), after which lesions were corrected by surgery or angioplasty if needed. The primary end point was the amputation-free survival rate at six months.

Results Final angiograms, which were available for 246 patients treated with urokinase, revealed recanalization in 196 (79.7 percent) and complete dissolution of thrombus in 167 (67.9 percent). Both treatment groups had similar significant improvements in mean ankle–brachial blood-pressure index. Amputation-free survival rates in the urokinase group were 71.8 percent at six months and 65.0 percent at one year, as compared with respective rates of 74.8 percent and 69.9 percent in the surgery group; the 95 percent confidence intervals for the differences were −10.5 to 4.5 percentage points at six months (P=0.43) and −12.9 to 3.1 percentage points at one year (P=0.23). At six months the surgery group had undergone 551 open operative procedures (excluding amputations), as compared with 315 in the thrombolysis group. Major hemorrhage occurred in 32 patients in the urokinase group (12.5 percent) as compared with 14 patients in the surgery group (5.5 percent) (P=0.005). There were four episodes of intracranial hemorrhage in the urokinase group (1.6 percent), one of which was fatal. By contrast, there were no episodes of intracranial hemorrhage in the surgery group.

Conclusions Despite its association with a higher frequency of hemorrhagic complications, intraarterial infusion of urokinase reduced the need for open surgical procedures, with no significantly increased risk of amputation or death. (N Engl J Med 1998;338:1105-11.)

ACUTE arterial occlusion of the legs is associated with a substantial risk of limb loss and death despite surgical intervention primarily consisting of thrombectomy or bypass grafting.[1-3] Percutaneous, catheter-directed infusion of thrombolytic agents has been used as an alternative to open surgery in such cases.[4-6] Thrombolysis can restore arterial flow by dissolving an occluding thrombus and can be followed by endovascular or relatively simple open procedures to correct any lesions unmasked by thrombolysis. Instead of a complex open procedure, a smaller elective procedure is performed under optimal conditions.[7]

Despite the theoretical advantages of thrombolysis, the safety and efficacy of the procedure remain controversial. Since it may restore flow more slowly than immediate surgical revascularization, tissue ischemia may progress to infarction before the artery has recanalized.[8] Hemorrhage is a potential complication.[9] The balance between the potential benefits of catheter-directed thrombolysis and the risk of associated complications can be assessed only through large, controlled trials. In a preliminary randomized, dose-ranging trial of thrombolysis using recombinant urokinase and involving 213 patients with acute lower-limb ischemia, we found that a regimen of 4000 IU of urokinase per minute for 4 hours, followed by an infusion of 2000 IU per minute for up to 44 additional hours, produced complete clot lysis in 71 percent of patients.[10] Mortality rates and amputation-free survival rates in this group were similar to those in the surgical control group, but patients treated with thrombolysis required significantly fewer major surgical procedures. Three of 144 patients (2.1 percent) treated with urokinase had intracranial bleeding, although the one fatal complication occurred 10 days after the completion of urokinase therapy and after the initiation of warfarin therapy.

The Thrombolysis or Peripheral Arterial Surgery trial was a randomized, multicenter study designed to compare the efficacy (as assessed by amputation-free survival) and safety of catheter-administered uro-

From the Department of Surgery, University of Rochester School of Medicine and Dentistry, Rochester, N.Y. (K.O.); the Department of Surgery, Albert Einstein School of Medicine, Bronx, N.Y. (F.J.V.); and the Department of Medicine, Harvard Medical School, Boston (A.A.S.). Address reprint requests to Dr. Ouriel at the Department of Surgery, University of Rochester, 601 Elmwood Ave., Rochester, NY 14642.

TOPAS registry, RCT

Urokinase (CDT -48hrs) n=272

vs Vascular surgery n=272

UK 4,000IU/min -4hr, 2,000IU/min 4hr- max 48hr
Mean 3.5±0.11 million IU (24.4±0.86 hours)

79.7% recanalization
67.9% complete dissolution of thrombus

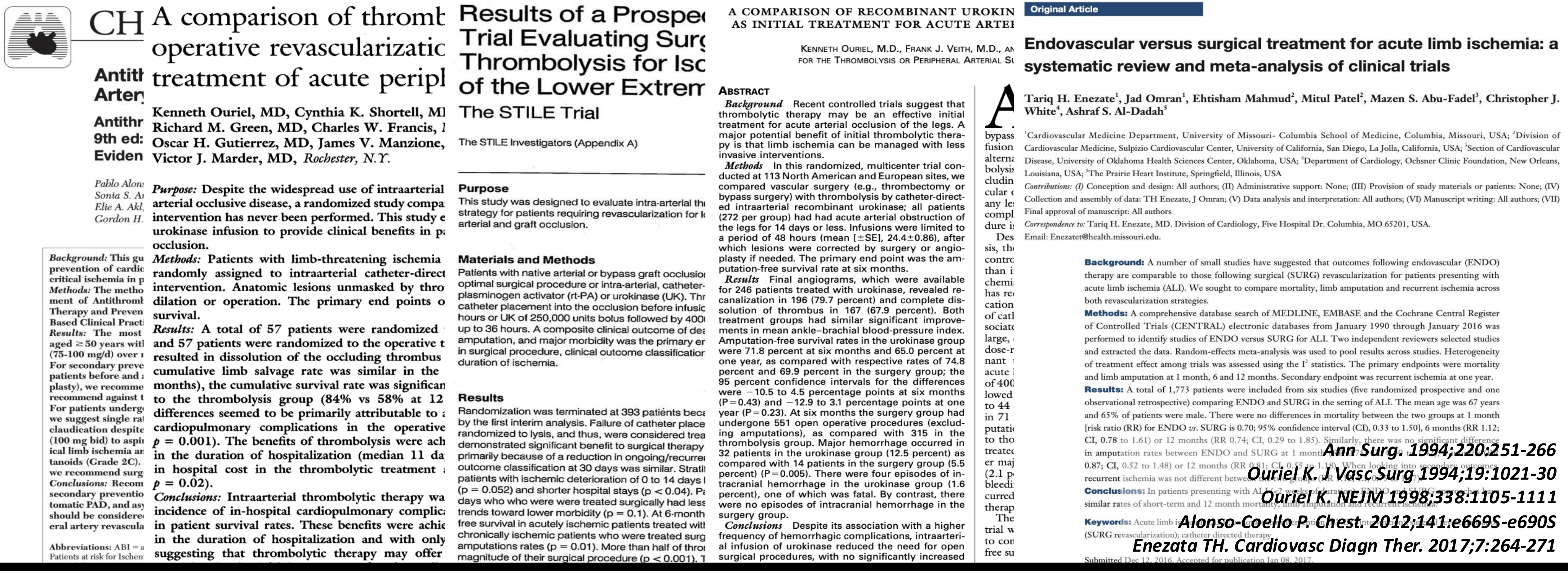
AFS/6, 12M: 71.8, 65.0% vs 74.8%, 69.9%

Major bleeding 12.5% vs 5.5% (p=0.005)

Urokinase reduced the need for surgical procedures with no significantly increased risk of AFS.

Ouriel K, Veith FJ, Sasahara AA. Thrombolysis or Peripheral Arterial Surgery (TOPAS) Investigators. N Engl J Med. 1998;338(16):1105-1111.

Background

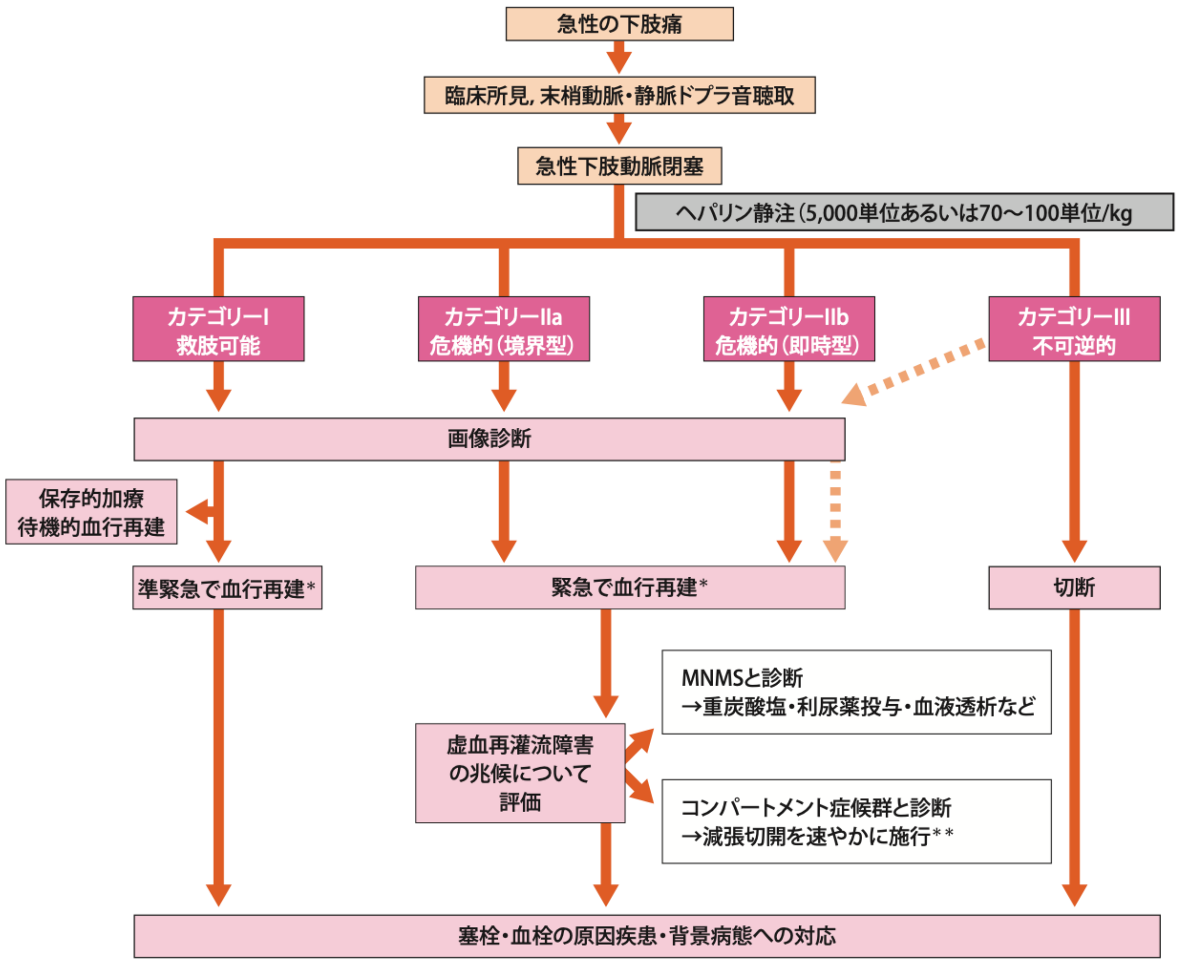


ALI has had a *30-day mortality rate of 23-29%.*

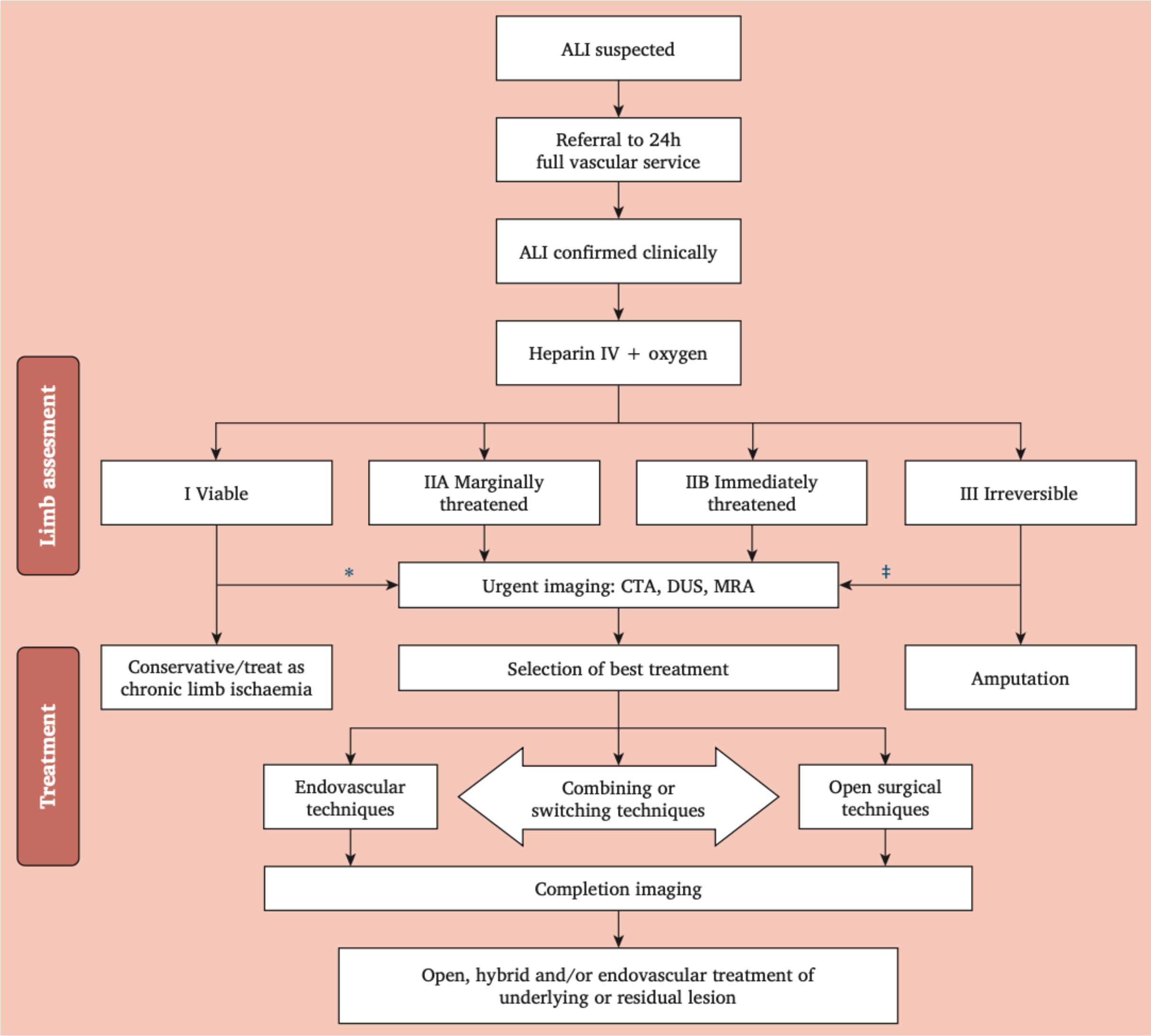
Mortality, limb amputation, or recurrent ischemia had

***no significant differences with EVT vs SR* from recent studies and meta-analysis.**

Guideline on the management of ALI



* 血栓塞栓除去手術は, 血管造影が可能な手術室でオーバーザワイヤー血栓除去カテーテルを用いて透視下で行う
** 内圧測定に関して, 減張切開を行うカットオフ値に関して一定の見解はない

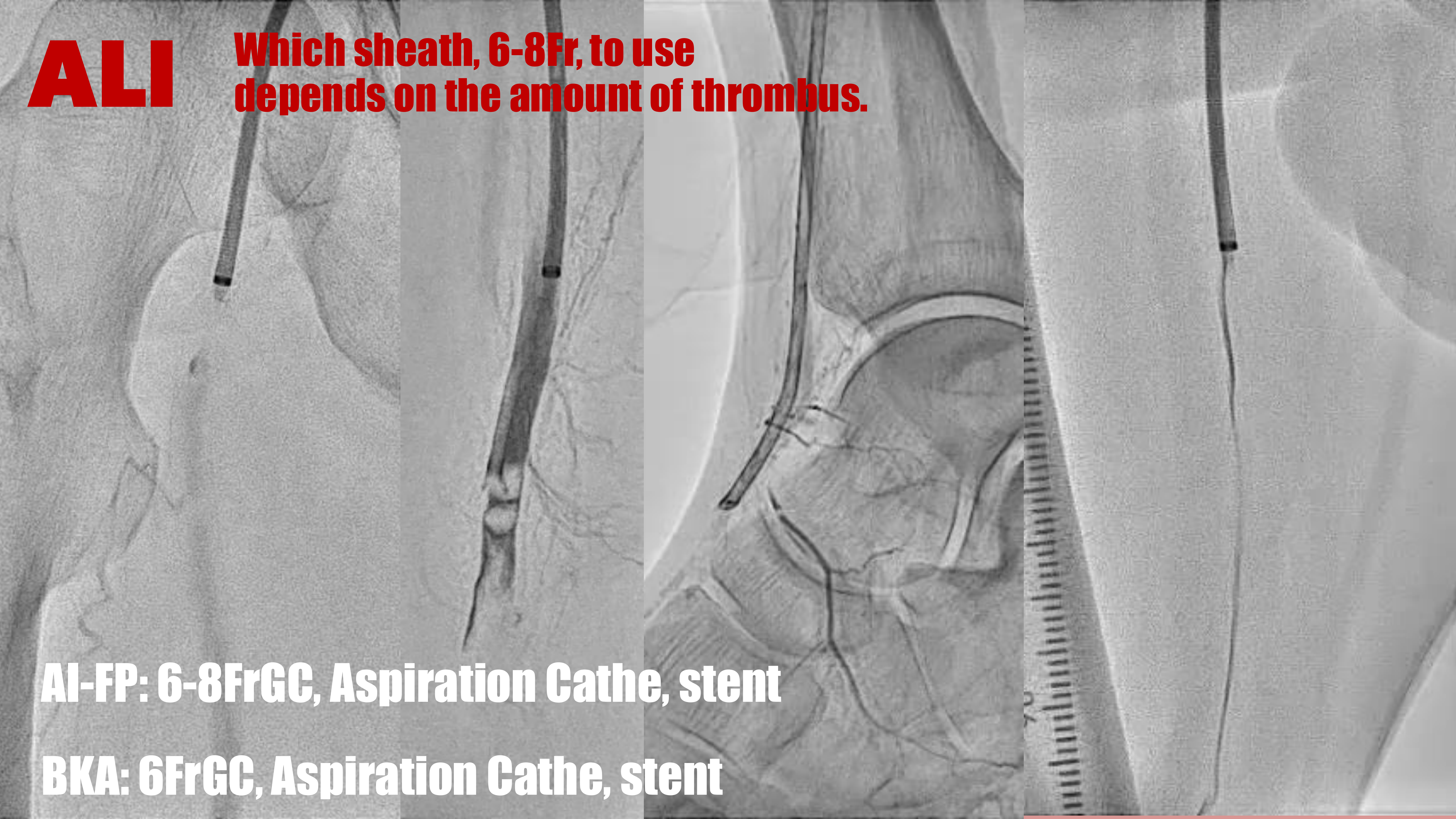


JCS/JSVS 2022 Guideline on the Management of Peripheral Arterial Disease

Björck M. Eur J Vasc Endovasc Surg. 2020;59(2):173-218.

ALI

Which sheath, 6-8Fr, to use depends on the amount of thrombus.



AI-FP: 6-8FrGC, Aspiration Cathe, stent

BKA: 6FrGC, Aspiration Cathe, stent

Background

1-year limb outcomes and mortality, n=70 from Edo registry, 2011-2013

EVT	27 (38.6)
Surgery	30 (42.9)
Angiography-guided Fogarty catheter thrombectomy	17 (24.3)
Blind Fogarty catheter thrombectomy	7 (10.0)
Bypass surgery	4 (5.7)
Angiography-guided Fogarty catheter thrombectomy + endarterectomy	1 (1.4)
Angiography-guided Fogarty catheter thrombectomy + bypass surgery	1 (1.4)
Hybrid (all angiography-guided)	13 (18.6)
Fogarty catheter thrombectomy + EVT	12 (17.1)
Fogarty catheter thrombectomy + bypass surgery + EVT	1 (1.4)
Adjunctive systemic thrombolysis	3 (4.3)
Adjunctive catheter-directed thrombolysis	2 (1.8)

39%, 43%, and 19% underwent EVT, surgery, and hybrid thrombectomy, respectively, in primary revascularization strategy. Limb ischemia was categorized into four classes at initial evaluation: SVS/ISCVS class I (19%), IIa (51%), IIb (30%), and class III (0%).

	All-cause death	Major amputation	MACE	MALE + POD	Bleeding	Major amputation + all-cause death
~1 month	9 (12.9)	4 (5.7)	10 (14.3)	20 (28.6)	2 (2.9)	11 (15.7)
1–6 months	9 (12.9)	0	8 (11.4)	4 (5.7)	2 (2.9)	8 (11.4)
6–12 months	2(2.9)	0	3(4.3)	4 (5.7)	0	2 (2.9)
1 year	20 (28.6)	4 (5.7)	21 (30.0)	28 (40.0)	4 (5.7)	21 (30)

Predictors of all-cause death:

Higher age, female, CKD, lower Alb, Higher CRP

The 1-year rates

All-cause death 29%, Major amp. 6%, MALE 40%

Small number, non-current devices and techniques.

M. Higashitani. CVIT2021;36:226-236

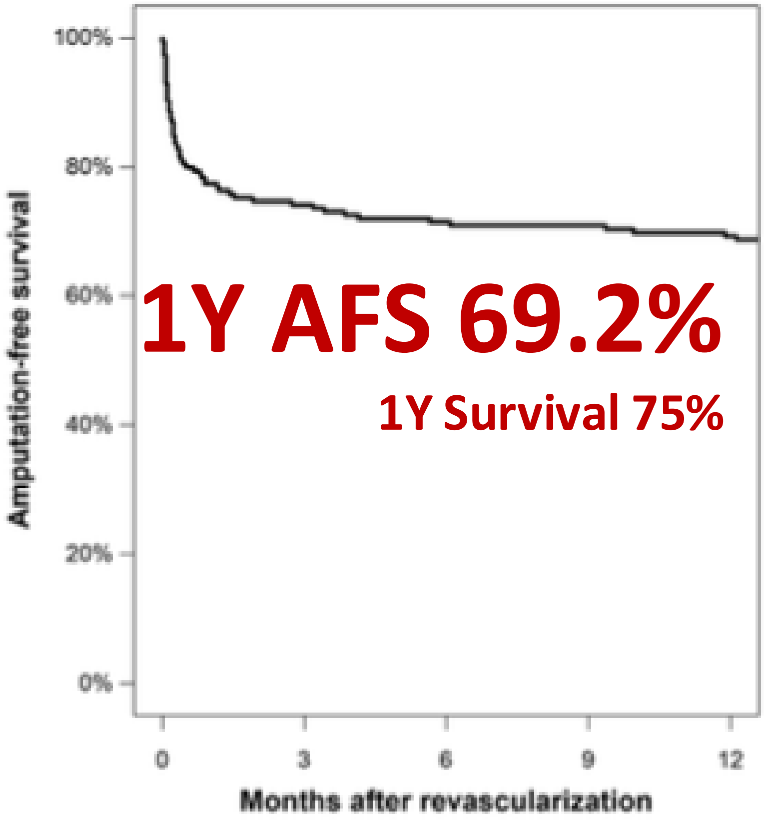
Background

1-year clinical outcomes and prognostic factors, n=185 from RESCUE ALI study including surgical, endovascular, and hybrid revascularization, 2015-2021

Tan M. Circ J. 2024;88(3):331-338.

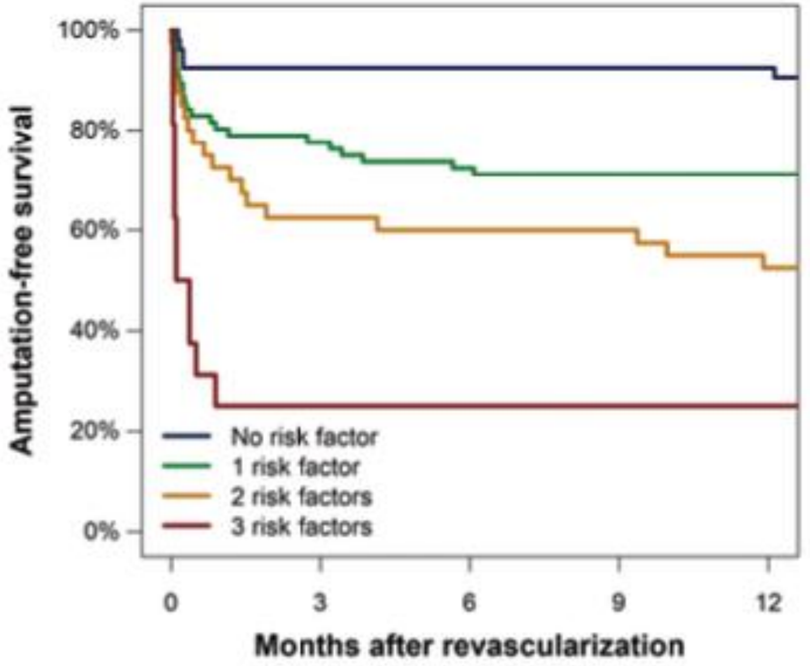
Table 1. Baseline Characteristics of the Study Patients With ALI

	Overall population (n=185)	Surgical revascularization (n=79)	Hybrid revascularization (n=40)	Endovascular revascularization (n=66)	P value
Male sex	107 (58%)	44 (56%)	27 (68%)	36 (55%)	0.42
Age (years)	76±14	73±16	75±14	79±11	0.007
≥70	136 (74%)	50 (63%)	29 (73%)	57 (86%)	0.007
Smoking	88 (48%)	42 (53%)	16 (40%)	30 (45%)	0.65
Diabetes mellitus	69 (37%)	24 (30%)	15 (38%)	30 (45%)	0.17
Chronic renal failure[a]	14 (8%)	4 (5%)	5 (13%)	5 (8%)	0.35
Hemodialysis	18 (10%)	4 (5%)	4 (10%)	10 (15%)	0.07
Valvular heart disease	6 (3%)	3 (4%)	0 (0%)	3 (5%)	0.17
Congestive heart failure	31 (17%)	13 (16%)	6 (15%)	12 (18%)	0.67
Atrial fibrillation	64 (35%)	29 (37%)	11 (28%)	24 (36%)	0.32
History of LEAD	62 (34%)	28 (35%)	11(28%)	23 (35%)	0.43
History of ALI	25 (14%)	8 (10%)	8 (20%)	9 (14%)	0.14
Current malignancy	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
Oral medication					
Aspirin	48 (26%)	19 (24%)	7 (18%)	22 (33%)	0.07
P2Y12 inhibitor	42 (23%)	14 (18%)	9 (23%)	19 (29%)	0.11
Cilostazol	20 (11%)	11 (14%)	4 (10%)	5 (8%)	0.22
Anticoagulant	40 (22%)	25 (32%)	9 (23%)	6 (9%)	<0.001
Statin	36 (19%)	18 (23%)	3 (8%)	15 (23%)	0.04
Time from onset (h)	38±69	41±78	49±82	27±45	0.12
Time from onset ≥24 h	79 (43%)	31 (39%)	18 (45%)	30 (45%)	0.45
Non-severe ALI (Rutherford category I and IIa)	136 (74%)	63 (80%)	33 (83%)	40 (61%)	0.02
Rutherford category I	67 (36%)	39 (49%)	20 (50%)	8 (12%)	
Rutherford category IIa	69 (37%)	24 (30%)	13 (33%)	32 (48%)	
Severe ALI (Rutherford category IIb and III)	49 (26%)	16 (20%)	7 (18%)	26 (39%)	0.02
Rutherford category IIb	43 (23%)	15 (19%)	6 (15%)	22 (33%)	
Rutherford category III	6 (3%)	1 (1%)	1 (3%)	4 (6%)	
De novo lesion	149 (81%)	63 (80%)	32 (80%)	54 (82%)	0.81
Occlusion site					
Aorta	8 (4%)	6 (8%)	2 (5%)	0 (0%)	0.02
Iliac artery	48 (26%)	30 (38%)	14 (35%)	4 (6%)	<0.001
CFA	54 (29%)	31 (39%)	13 (33%)	10 (15%)	0.001
SFA	127 (69%)	53 (67%)	31 (78%)	43 (65%)	0.18
Pop	125 (68%)	49 (62%)	25 (63%)	51 (77%)	0.04
IP	109 (59%)	35 (44%)	21 (53%)	53 (80%)	<0.001
Area of occluded lesion					
Suprapopliteal limited lesion	47 (25%)	24 (30%)	14 (35%)	9 (14%)	0.02
Popliteal to infrapopliteal limited lesion	37 (20%)	12 (15%)	5 (13%)	20 (30%)	0.03
Supra- to infrapopliteal lesion	101 (55%)	43 (54%)	21 (53%)	37 (56%)	0.72
No runoff of the below the knee artery before procedure	108 (58%)	36 (46%)	26 (65%)	46 (70%)	0.003
Aortic plaque	22 (12%)	16 (20%)	0 (0%)	6 (9%)	0.002
Left ventricular thrombosis	3 (2%)	0 (0%)	2 (5%)	1 (2%)	0.21
TEVAR/EVAR thrombosis	4 (2%)	4 (5%)	0 (0%)	0 (0%)	0.06
In situ thrombosis	29 (16%)	6 (8%)	7 (18%)	16 (24%)	0.02
Failed stent	6 (3%)	1 (1%)	1 (3%)	4 (6%)	0.40
Failed bypass	19 (10%)	11 (14%)	4 (10%)	4 (6%)	0.12



1Y AFS 69.2%

1Y Survival 75%



Number at risk	0	3	6	9	12
No risk factor	53	51	51	51	51
1 risk factor	76	60	56	55	55
2 risk factors	40	26	25	25	22
3 risk factors	16	5	5	5	5
Estimate ± SE					
No risk factor	100.0±0.0%	92.5±3.6%	92.5±3.6%	92.5±3.6%	92.5±3.6%
1 risk factor	100.0±0.0%	77.6±4.8%	72.4±5.1%	71.1±5.2%	71.1±5.2%

Rutherford category IIb and III ischemia, supra- to infrapopliteal lesions, and technical failures
were identified as independent risk factors for 1-year AFS.

Background

In-Hospital outcomes after EVT from J-EVT registry, 2015-2018

	ALI (n = 2,398)	Chronic symptomatic PAD (n = 74,171)	P value
Female sex	39.7%	28.6%	< 0.001
Age (years)	76.6 ± 11.8	73.9 ± 9.3	< 0.001
Mobility			< 0.001
Self-ambulatory	49.7%	75.9%	
In wheelchair	28.6%	20.1%	
Bedridden	21.7%	4.0%	
Diabetes mellitus	35.4%	57.0%	< 0.001
Hypertension	66.4%	77.3%	< 0.001
Dyslipidemia	32.4%	49.2%	< 0.001
Current smoking	22.9%	34.1%	< 0.001
Regular dialysis	13.7%	26.3%	< 0.001
Coronary artery disease	22.0%	39.6%	< 0.001
Cerebrovascular disease	16.8%	13.5%	< 0.001
Suprapopliteal lesion	76.1%	86.4%	< 0.001

Patients with ALI were older and had a higher prevalence of female sex, impaired mobility, and history of cerebrovascular disease,

	ALI	Chronic symptomatic PAD	P value
In-hospital complications (overall)	6.1% [5.2% to 7.2%]	2.0% [1.9% to 2.1%]	< 0.001
In-hospital mortality	2.3% [1.7% to 3.0%]	0.2% [0.2% to 0.3%]	< 0.001
Urgent surgery	0.5% [0.3% to 0.9%]	0.1% [0.1% to 0.2%]	< 0.001
Bleeding requiring transfusion	1.4% [1.0% to 2.0%]	0.5% [0.5% to 0.6%]	< 0.001
Distal embolism	0.7% [0.4% to 1.1%]	0.2% [0.2% to 0.2%]	< 0.001
Blood vessel rupture	0.5% [0.3% to 0.9%]	0.3% [0.3% to 0.4%]	0.29
Acute occlusion	0.8% [0.5% to 1.3%]	0.1% [0.1% to 0.1%]	< 0.001
Contrast-induced nephropathy	0.1% [0.0% to 0.4%]	0.0% [0.0% to 0.1%]	0.23

In-hospital complications:
ALI 6.1% vs Chronic symptomatic PAD 2.0% (p<.001)

In-hospital complications of risk factors:
Bedridden, History of CAD, Suprapopliteal lesions

The current study demonstrated that ALI patients with significant comorbidities show a higher proportion of in-hospital complications after EVT.

T. Tsujimura. JAT 202128:1145-1152

Background

The official journal of the Japan Atherosclerosis Society and the Asian Pacific Society of Atherosclerosis and Vascular Diseases

Original Article

J Atheroscler Thromb, 2019; 26: 000-000. http://doi.org/10.5551/jat.51631

Impact of Hospital Volume on Clinical Outcomes after Aortoiliac Stenting in Patients with Peripheral Artery Disease

Osamu Iida[1], Mitsuyoshi Takahara[2], Yasutaka Yamauchi[3], Yoshiaki Shintani[4], Teruyasu Sugano[5], Yoshito Yamamoto[6], Daizo Kawasaki[7], Hiroyoshi Yokoi[8], Akira Miyamoto[3], Toshiaki Mano[1] and Masato Nakamura[9], on behalf of the OMOTENASHI investigators

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[7]Cardiovascular Division, Department of Internal Medicine, Morinomiya Hospital, Osaka, Japan
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[9]Division of Cardiovascular Medicine, Toho University, Ohashi Medical Center, Tokyo, Japan

Aim: To investigate the impact of institutional volume on clinical outcomes after aortoiliac (AI) stenting in patients with symptomatic peripheral artery disease (PAD).

Methods: We analyzed the clinical database from the Observational prospective Multicenter registry study on the Outcomes of peripheral arTErial disease patieNts treated by AngioplaSty tHerapy in the aortoIliac artery (OMOTENASHI) registry. The volume of each institution was evaluated as the number of endovascular therapy (EVT) procedures performed in 2 years (2014–2015). High-volume centers were defined as being in the highest tertile of the procedural volume (≥ 611 EVT procedures in 2 years). Clinical outcomes, treatment strategies, and endovascular procedures were compared between high- and low-volume centers using a propensity score matching.

Results: The propensity score matching extracted 236 pairs of patients (as many patients treated at high-volume centers and 519 patients treated at low-volume centers), with no remarkable intergroup differences in the baseline characteristics. Patients treated at high-volume hospitals had a significantly lower 12-month restenosis rate than that of patients treated at low-volume hospitals (6.5% vs. 15.8%, $P=0.032$), although comparable outcomes between the two groups included the technical success rate (99.6% vs. 99.8%, $P=0.58$) and the rate of 30-day major adverse events (0.4% vs. 0.8%, $P=0.59$).

Conclusion: Institutional volume was associated with the 12-month restenosis rate after AI stenting for PAD, although comparable perioperative outcomes were also observed between high-volume and low-volume hospitals.

Key words: Endovascular treatment/therapy, Aortoiliac lesion, Institutional volume, Restenosis

Iida O. J Atheroscler Thromb. 2020;27(6):516-523.

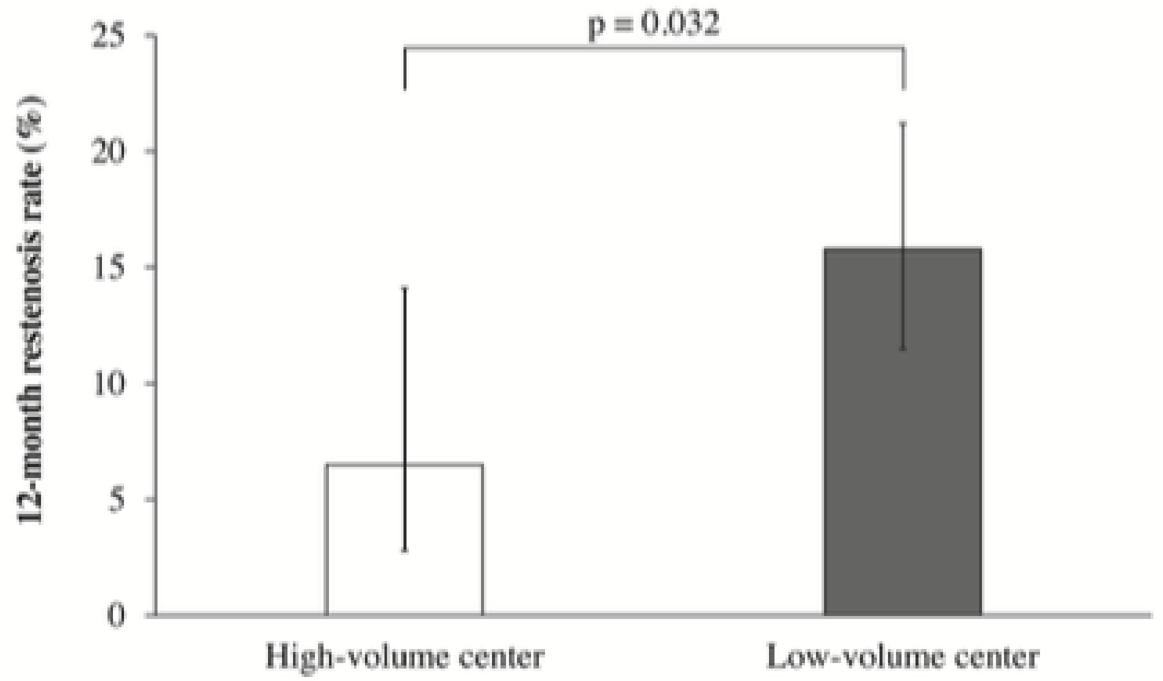


Fig. 1. Twelve-month restenosis rate between high- and low-volume centers

The incidence of 12-month restenosis was significantly lower in patients treated at high-volume centers (6.5% [2.8 to 14.1%] vs. 15.8% [11.5 to 21.2%], $P=0.032$).

Even in the AI field, the 12-month restenosis rate in high-volume centers was superior to low-volume centers.

Background

- ✓ Given that ALI has a worse prognosis than chronic LEAD, the clinical outcomes of EVT for ALI may be influenced by a hospital's procedural volume.
- ✓ However, whether hospital volume influences EVT outcomes in ALI remains unclear.
- ✓ This study aimed to determine the effect of hospital volume on procedural outcomes in patients with ALI. Identifying this association may improve the outcomes of patients with ALI when care is provided regionally in high-volume hospitals.

O. Iida

M. Takahara

2023

2024

Sep 28
Submit
Proposal form

Dec 25
Web
interview

Jan 4
Statistical
analysis

Feb 21, 2024
Paper ver.0

Mar-Apr
Editing
Review

Apr.16
1st submit to
Vascular Medicine

Jun.25
Reject

Jul
2nd submit to
Angiology

S. Kohsaka

H. Ishii

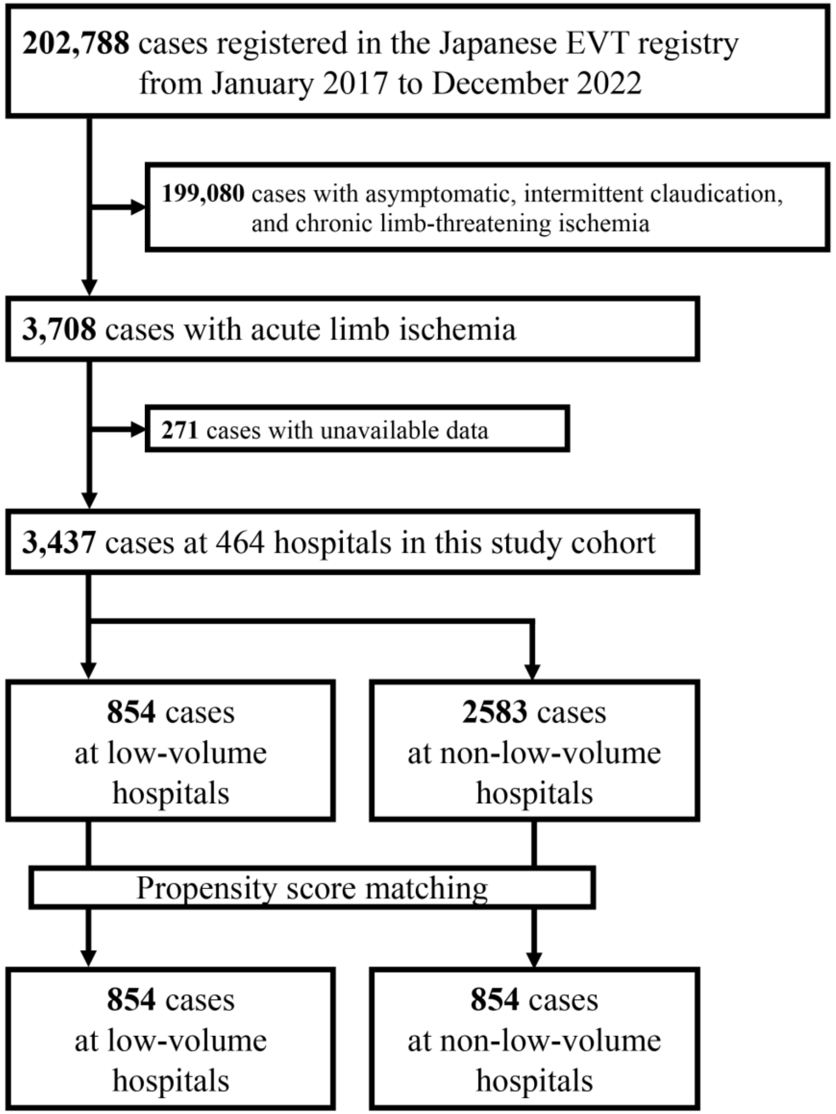
M. Nakamura

T. Amano

K. Kozuma

Method

Impact of hospital volume on procedural
ALI 3437 at 464 hospitals, 2017-2022



Low-volume (≤53) vs non-low-volume (≥54)

Primary outcome: Procedural failure

failure to achieve the success criteria of less than 30% residual stenosis and the absence of a flow-limiting dissection

Secondary outcome: Perioperative complications

major bleeding, emergency surgery, distal embolism, vessel rupture, acute occlusion, contrast nephropathy

Propensity score matching was adopted.
(sex, age, mobility, smoking, hypertension, dyslipidemia, diabetes mellitus, chronic renal failure, dialysis dependence, coronary artery disease, cerebrovascular disease, chronic obstructive pulmonary disease, aortoiliac revascularization, femoropopliteal revascularization, and infrapopliteal revascularization)

For sensitivity analysis, the association between hospital volume and perioperative outcomes was analyzed using the generalized propensity score (GPS) method.

Variable	Overall population (before matching)					Matched population		
	Overall (n=3437)	Cases at low-volume hospitals (n=854)	Cases at non-low-volume hospitals (n=2583)	Standardized difference (%)	P value	Cases at low-volume hospitals (n=854)	Cases at non-low-volume hospitals (n=854)	Standardized difference (%)
Male sex	1997 (58.1%)	488 (57.1%)	1509 (58.4%)	2.6	0.54	488 (57.1%)	483 (56.6%)	1.2
Age (years)	77 ± 12	78 ± 12	77 ± 12	1.2	0.76	78 ± 12	77 ± 12	2.6
Non-ambulatory	1594 (46.4%)	407 (47.7%)	1187 (46.0%)	3.4	0.41	407 (47.7%)	405 (47.4%)	0.5
Smoking	864 (25.1%)	204 (23.9%)	660 (25.6%)	3.9	0.35	204 (23.9%)	198 (23.2%)	1.7
Hypertension	**2329 (67.8%)**	**554 (64.9%)**	**1775 (68.7%)**	**8.2**	**0.041**	**554 (64.9%)**	**566 (66.3%)**	**3.0**
Dyslipidemia	1293 (37.6%)	310 (36.3%)	983 (38.1%)	3.6	0.38	310 (36.3%)	310 (36.3%)	0.0
Diabetes mellitus	1203 (35.0%)	287 (33.6%)	916 (35.5%)	3.9	0.34	287 (33.6%)	287 (33.6%)	0.0
Chronic renal failure	**1286 (37.4%)**	**257 (30.1%)**	**1029 (39.8%)**	**20.5**	**<0.001**	**257 (30.1%)**	**253 (29.6%)**	**1.0**
Dialysis dependence	**485 (14.1%)**	**88 (10.3%)**	**397 (15.4%)**	**15.2**	**<0.001**	**88 (10.3%)**	**87 (10.2%)**	**0.4**
Coronary artery disease	784 (22.8%)	182 (21.3%)	602 (23.3%)	4.8	0.25	182 (21.3%)	169 (19.8%)	3.8
Cerebrovascular disease	557 (16.2%)	143 (16.7%)	414 (16.0%)	1.9	0.66	143 (16.7%)	124 (14.5%)	6.1
COPD	196 (5.7%)	41 (4.8%)	155 (6.0%)	5.3	0.22	41 (4.8%)	45 (5.3%)	2.1
Aortoiliac revascularization	804 (23.4%)	200 (23.4%)	604 (23.4%)	0.1	>0.99	200 (23.4%)	213 (24.9%)	3.6
Femoropopliteal revascularization	2448 (71.2%)	591 (69.2%)	1857 (71.9%)	5.9	0.14	591 (69.2%)	597 (69.9%)	1.5
Infrapopliteal revascularization	**1599 (46.5%)**	**337 (39.5%)**	**1262 (48.9%)**	**19.0**	**<0.001**	**337 (39.5%)**	**322 (37.7%)**	**3.6**

Clinical outcomes

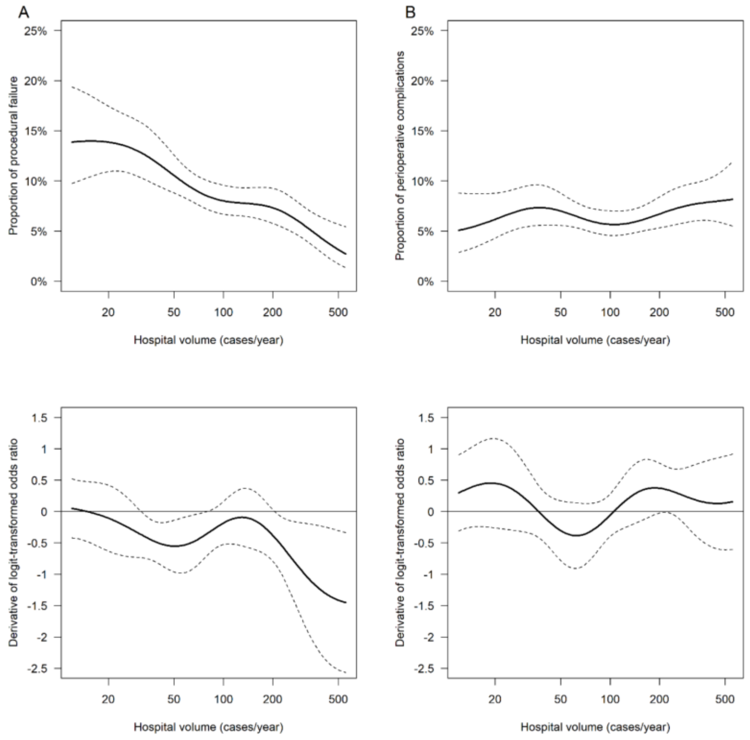
	Cases at low-volume hospitals (n = 854)	Cases at non-low-volume hospitals (n = 854)	P value
Procedural failure	100 (11.7%)	68 (8.0%)	P=0.008
Perioperative complication	56 (6.6%)	46 (5.4%)	P=0.35
Major bleeding	16 (1.9%)	11 (1.3%)	P=0.44
Emergency surgery	6 (0.7%)	2 (0.2%)	P=0.29
Distal embolism	15 (1.8%)	10 (1.2%)	P=0.40
Vessel rupture	0 (0.0%)	5 (0.6%)	P>0.99
Acute occlusion	0 (0.0%)	0 (0.0%)	P>0.99
Contrast nephropathy	1 (0.1%)	2 (0.2%)	P>0.99
Perioperative death	14 (1.6%)	12 (1.4%)	P=0.84

Procedural failure

Low-volume (≤53) non-low-volume (≥54)
11.7% vs. 8.0%, p = 0.008

Preoperative complication

6.6% vs. 5.4%, p = 0.35



	1st quartile (53 cases/year)	Median (97 cases/year)	3rd quartile (198 case/year)
Procedural failure			
Estimate	10.3% (8.6–12.1%)	8.1% (6.7–9.6%)	7.3% (5.8–9.3%)
Odds ratio			
vs. 1st quartile	(Reference)	0.78 (0.63–0.97) (P=0.022)	0.69 (0.51–0.95) (P=0.021)

EVT is recommended for ALI treatment, especially for higher severity levels, in non-low-volume hospitals than in low-volume hospitals.

Estimate	6.9% (5.5–8.5%)	5.7% (4.6–7.0%)	6.7% (5.3–8.4%)
Odds ratio			
vs. 1st quartile	(Reference)	0.83 (0.64–1.08) (P=0.16)	0.97 (0.70–1.34) (P=0.85)
vs. median	1.20 (0.93–1.56) (P=0.16)	(Reference)	1.17 (0.88–1.54) (P=0.28)
vs. 3rd quartile	1.03 (0.75–1.43) (P=0.85)	0.86 (0.65–1.13) (P=0.28)	(Reference)

Low-volume hospitals had a higher proportion of procedural failures than non-low-volume hospitals, whereas the incidence of perioperative complications was not significantly different between the two groups.

Impression

Limitation

- ✓ data variables
- ✓ data definition
- ✓ follow-up data
- ✓ hospital’s detailed information

**However, when reformulating the data,
it is necessary to think critically about how past data should be handled or how to add items that may increase the burden on doctors.**

**Data is limited,
therefore, you need to find the research you can do,
not research you want.**

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Impact of hospital volume on procedural failure in endovascular treatment for patients with acute limb ischemia: a report from nationwide endovascular therapy registry in Japan

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