21st CardioVascular Summit
TCTAP2016

3-year results of the OLIVE registry:

A prospective multicenter study in patients with critical limb ischemia

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Epidemiology of patients with Critical Limb Ischemia (CLI)

1-year outcome in Pt with CLI

Limb morbidity and mortality

- Alive with two limbs 45%
- **Amputation** 30%
- **Mortality** 25%

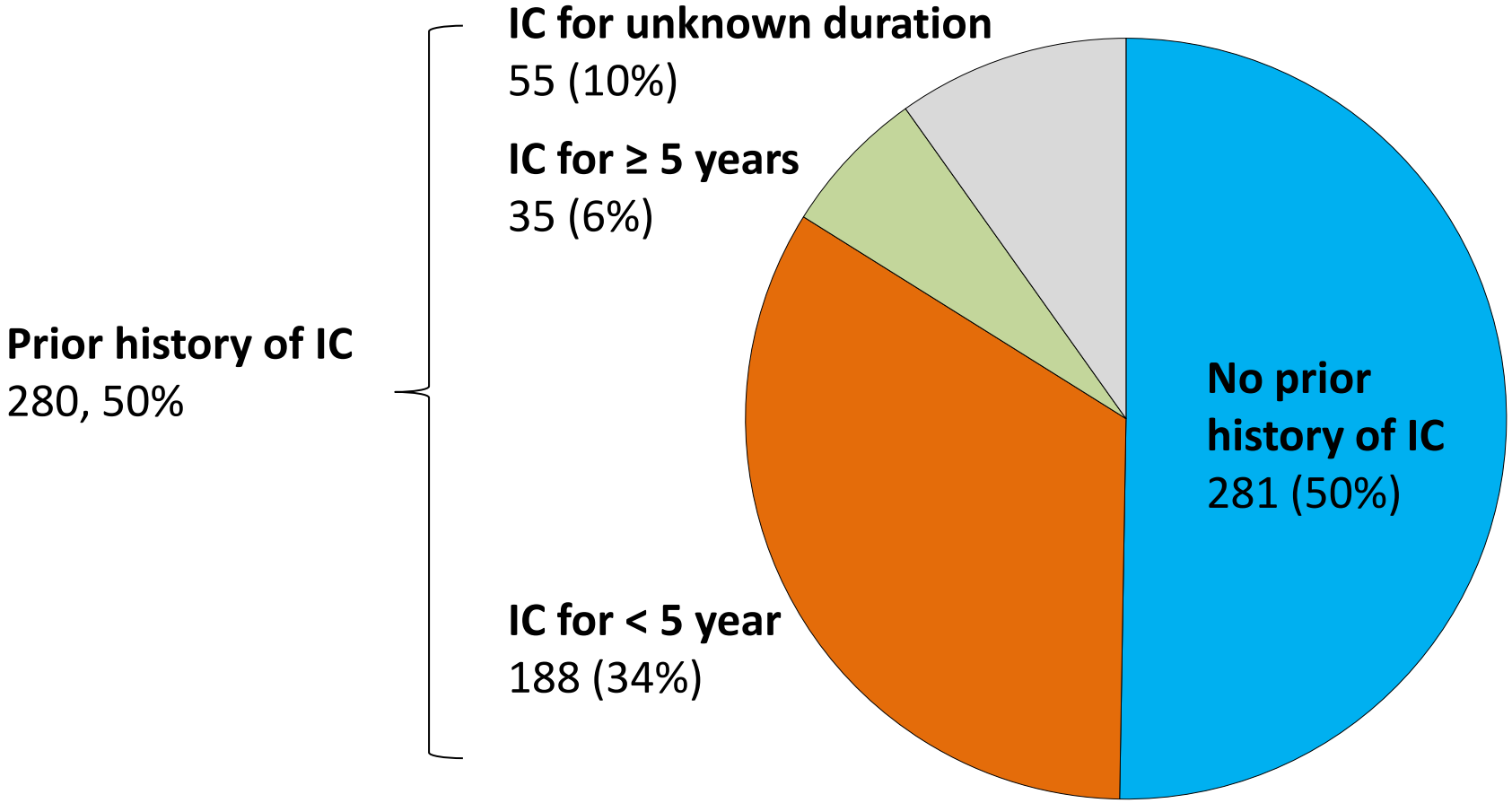
Critical Limb Ischemia

Acute coronary syndrome

- **More than half the patients** with below-knee major amputation for ischemic disease had absolutely no symptoms of leg ischemia as recently as **6 months before**

Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II)

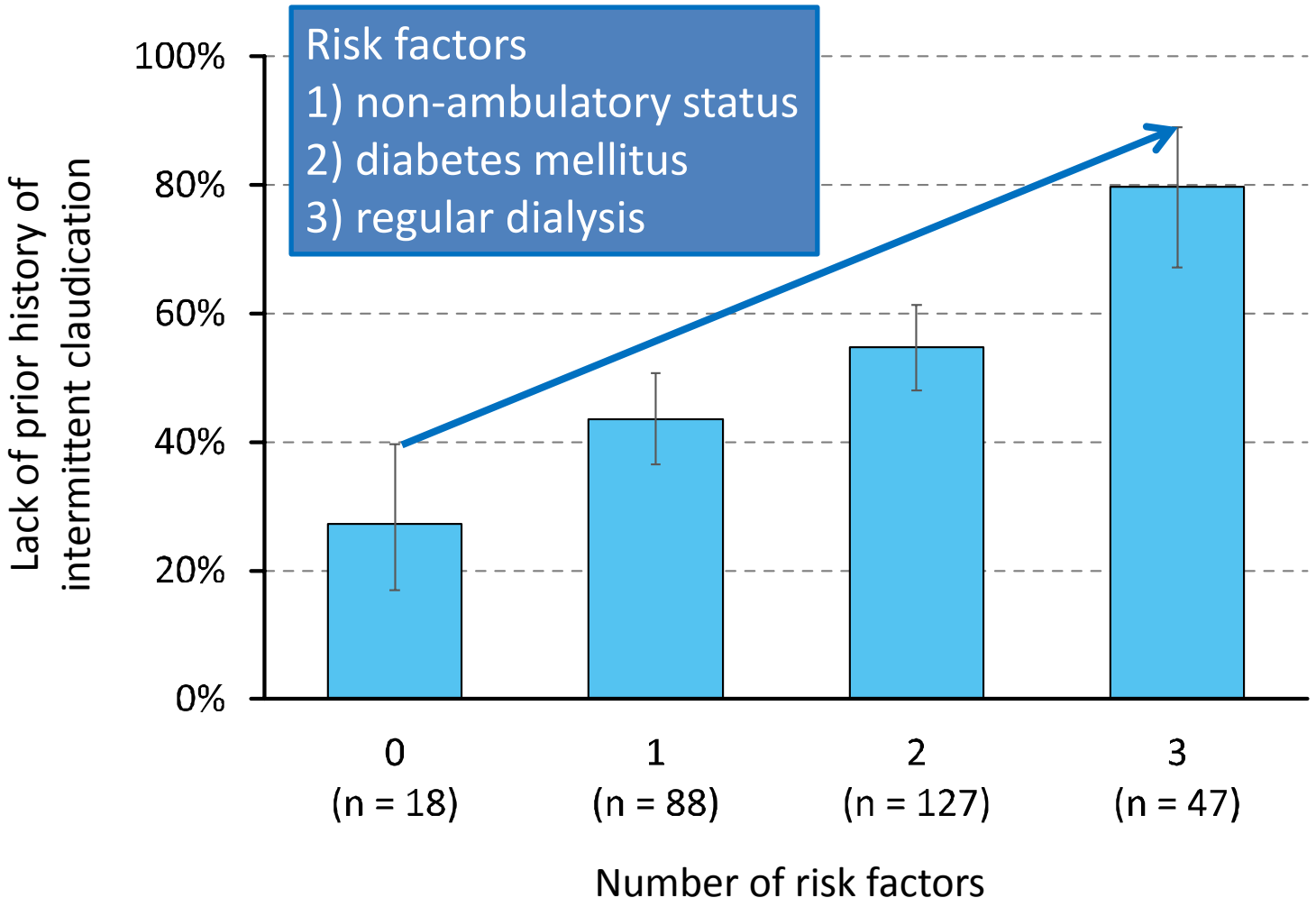
Prevalence of a prior history of intermittent claudication in CLI patients registrated SPINACH study



In patients with a prior history of intermittent claudication, the majority had a duration of less than 5 years.

Takahara M, et al. J Atheroscler Thromb. 2015;22:718-25.

Prevalence of the absence of a prior history of IC in CLI patients classified according to clinical features



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Revascularization Selection for Patients with CLI

Bypass therapy (BSX)

Endovascular therapy (EVT)

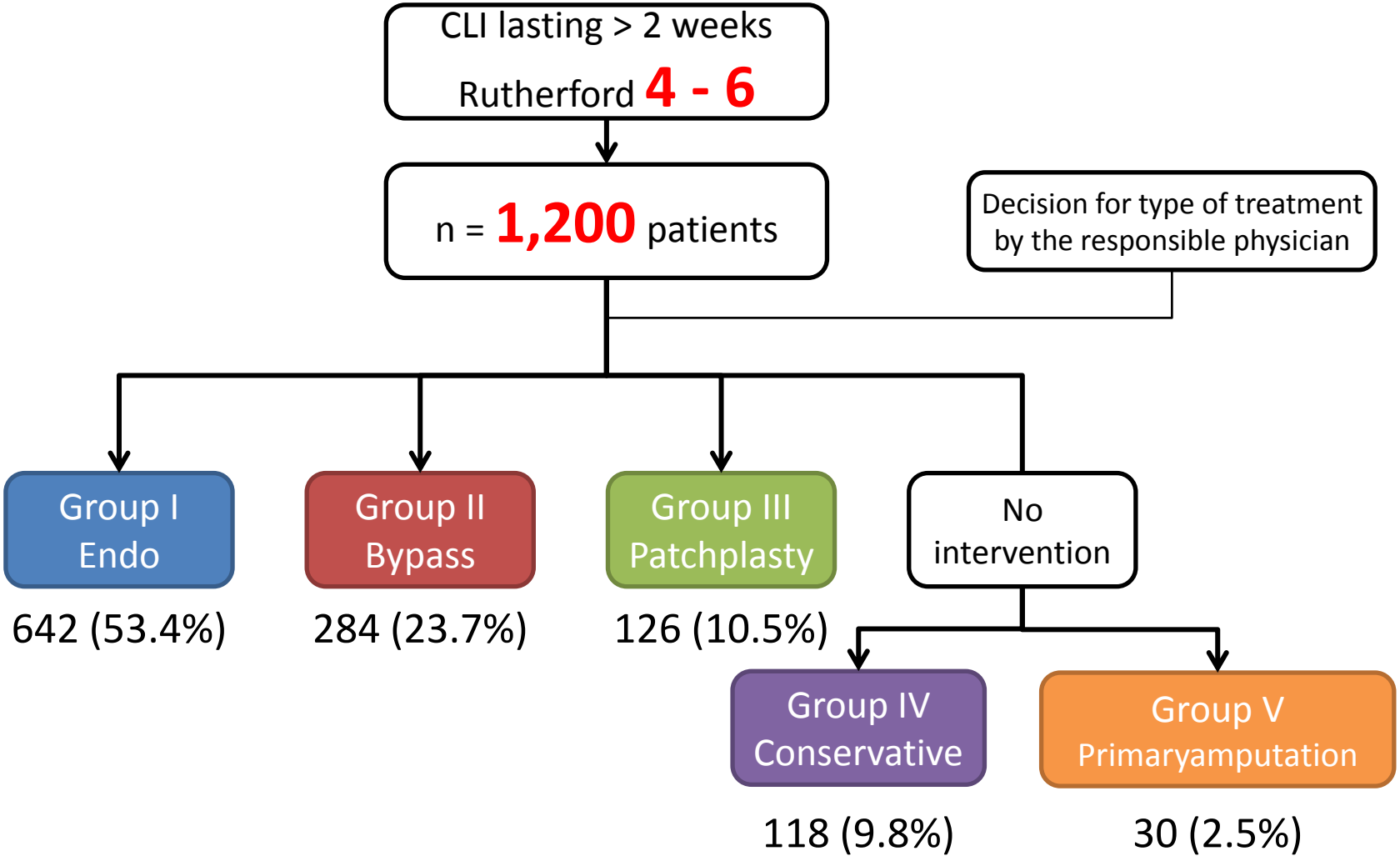
CRITISCH registry assesses first-Line treatment strategies for CLI

CRITISCH Interdisciplinary Registry for Critical Limb Ischemia

Subjects:	CLI patients lasting more than 2 weeks
Follow-Up:	2 years per subject
Study Design:	Observational
Intervention:	Surgical bypass (vein or prosthetic)
	Endovascular (Angioplasty +/- stent)
	Patchplasty/Hybrid treatment (Femoral artery patchplasty +/- profundoplasty +/- endovascular treatment)
	Conservative treatment (no vascular intervention)
Primary Endpoint:	**2-year amputation-free survival**
	(defined as the time until an above-ankle amputation of the index limb or death, or both)

Bisdas T, et al. J Vasc Surg. 2015;62:965-973.

Overview of recruitment procedure (first-line treatment of choice)



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In-hospital end points

	Group I, Endo	Group II, Bypass	Group III, FAP	Group IV, Conservative	Group V, Amputation	P value
Composite end point	24(4)	17(6)	8(6)	9(8)	-	0.172
Amputation	**20(3)**	**10(4)**	5(4)	6(5)	-	0.67
Death	**6(1)**	**8(3)**	4(3)	4(3)	3(10)	0.003
Hemodynamic failure	**81(13)**	**24(8)**	11(9)	107(91)	-	<0.001
MACCE	23(4)	15(5)	8(6)	6(5)	4(13)	0.097
Reintervention	**50(8)**	**33 (14)**	11(9)	6(5)	1(3)	0.015
Type of reintervention						
Endovascular	32(64)	6(9)	5(45)	1(17)	0	
Open surgery	18(36)	30(91)	6(55)	5(83)	1(100)	
Minor amputation	80(12)	39(14)	7(6)	5(4)	-	

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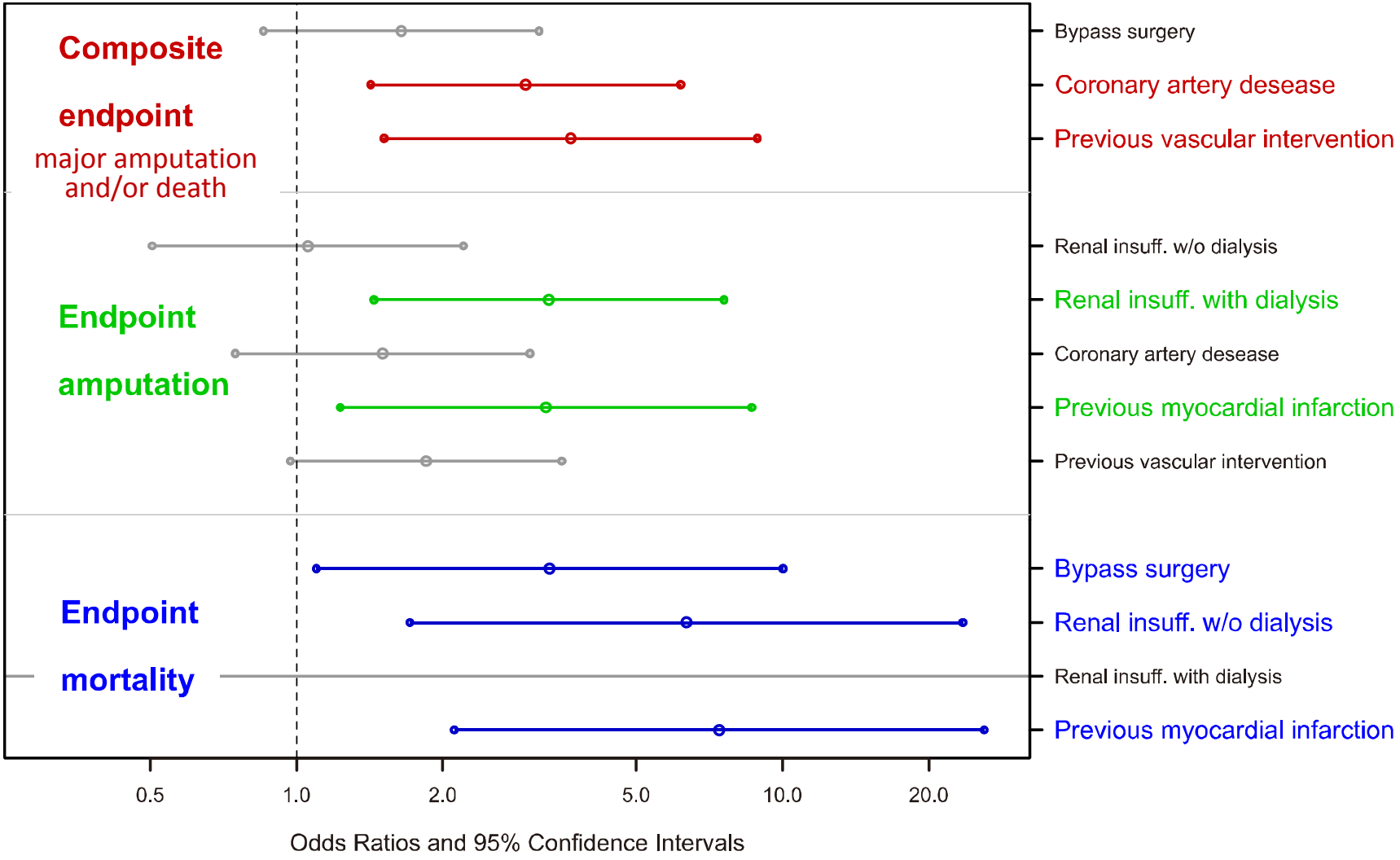
Risk factors of all in-hospital end points

- multivariate logistic regression models -



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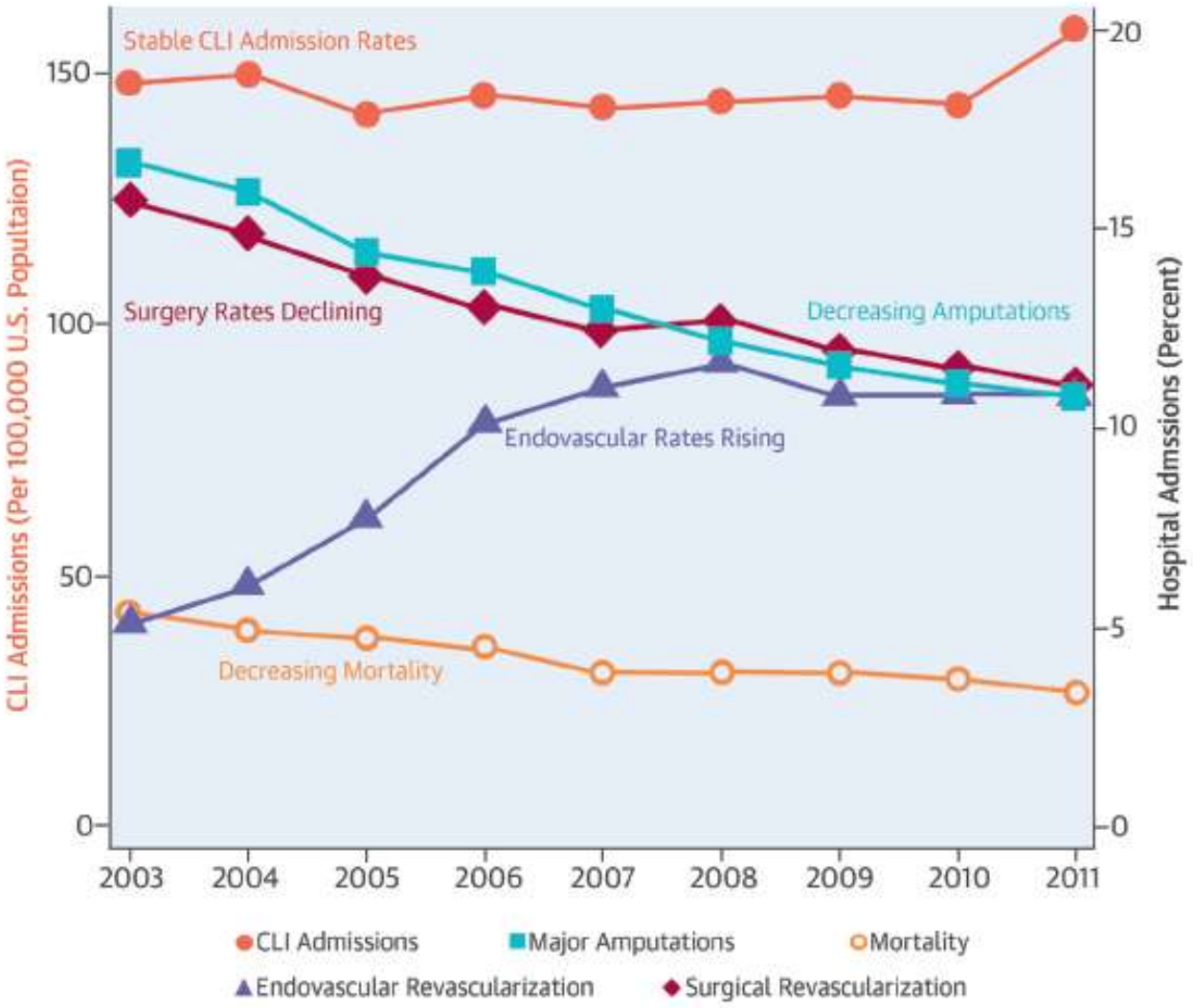
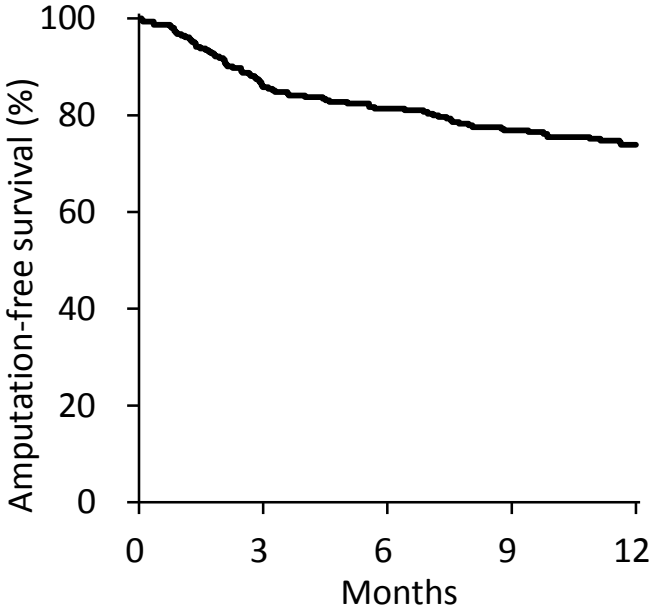
U.S. Trends of Hospital Admission and Outcomes among CLI Patients



Agarwal S, et al. J Am Coll Cardiol. 2016 in press.

Primary Endpoint:
Amputation-free survival



AFS were 86±2%, 81±2%, 77±3%, and 74±3% at 3, 6, 9, and 12 months, respectively.

Independent predictors for AFS

Variables	HR (95%CI)	P value
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
Heat failure	1.73(1.02-2.91)	0.04
Wound infection	1.89(1.07-3.32)	0.02

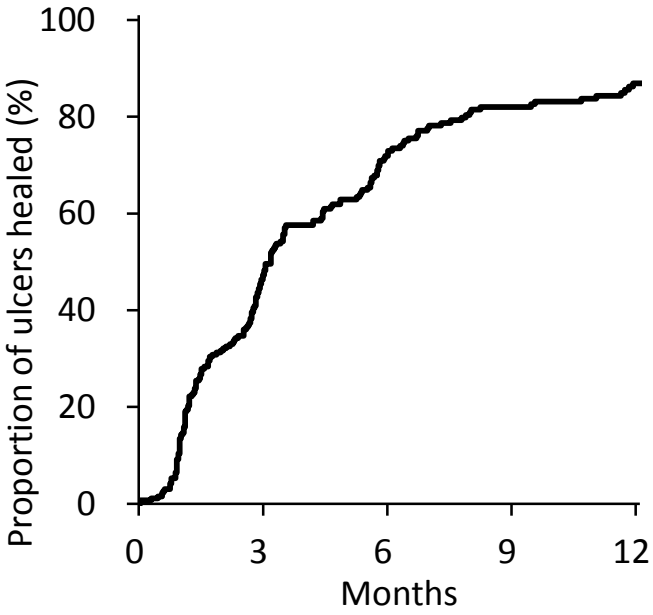

BMI <18.5


Heat failure


Wound infection

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

Secondary Endpoint:
Time to wound healing



Median time requiring complete wound healing was **97±10 days**.

The proportion of not-healed patients was 54±3%, 29±3%, 18±3%, and **14±3%** at 3, 6, 9, and 12 months, respectively.

Factors predicting failure to achieve healing after 97 days

Variables	HR (95%CI)	P value
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


BMI <18.5


Wound infection


75% Rutherford 5


25% Rutherford 6

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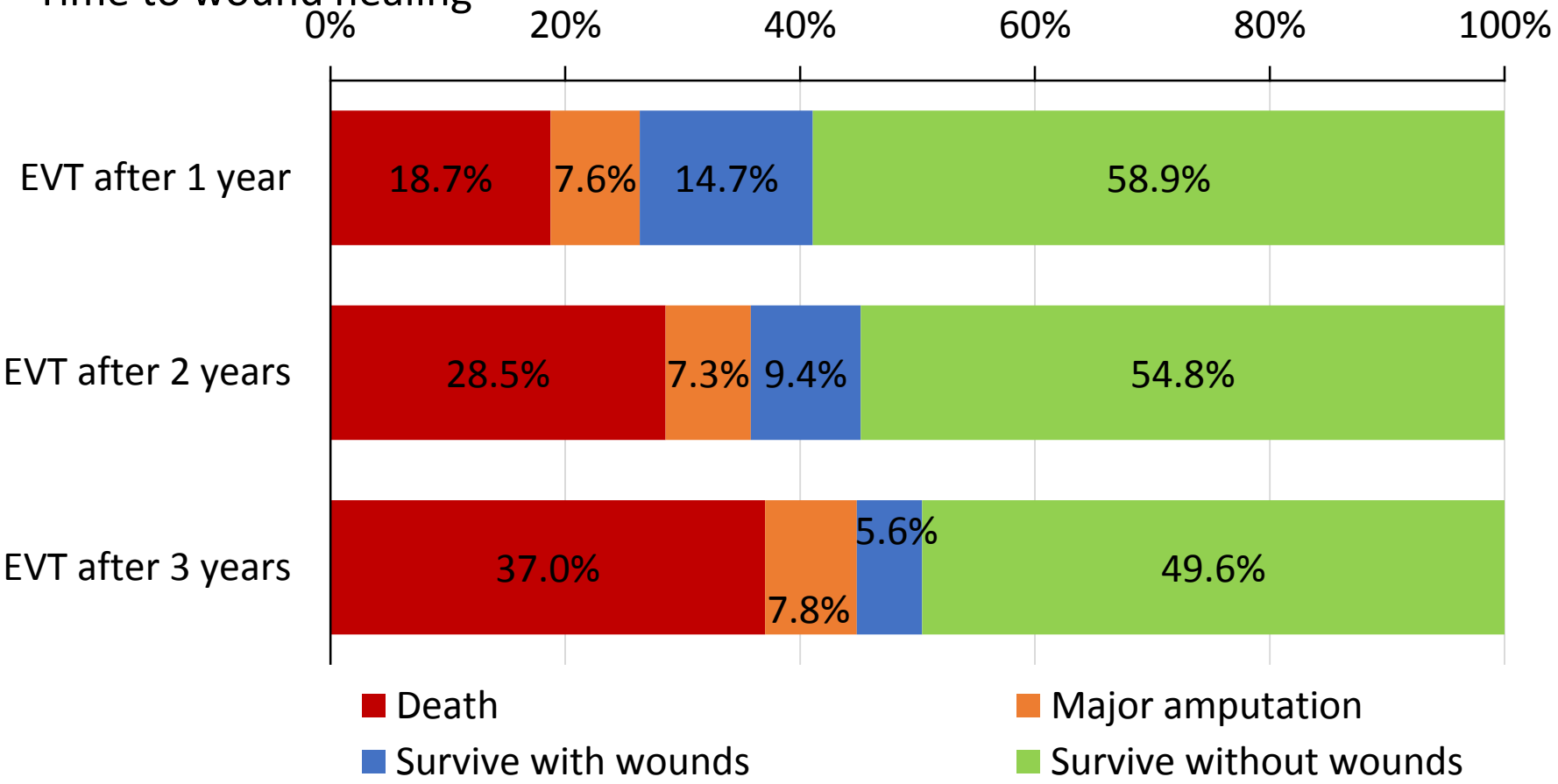
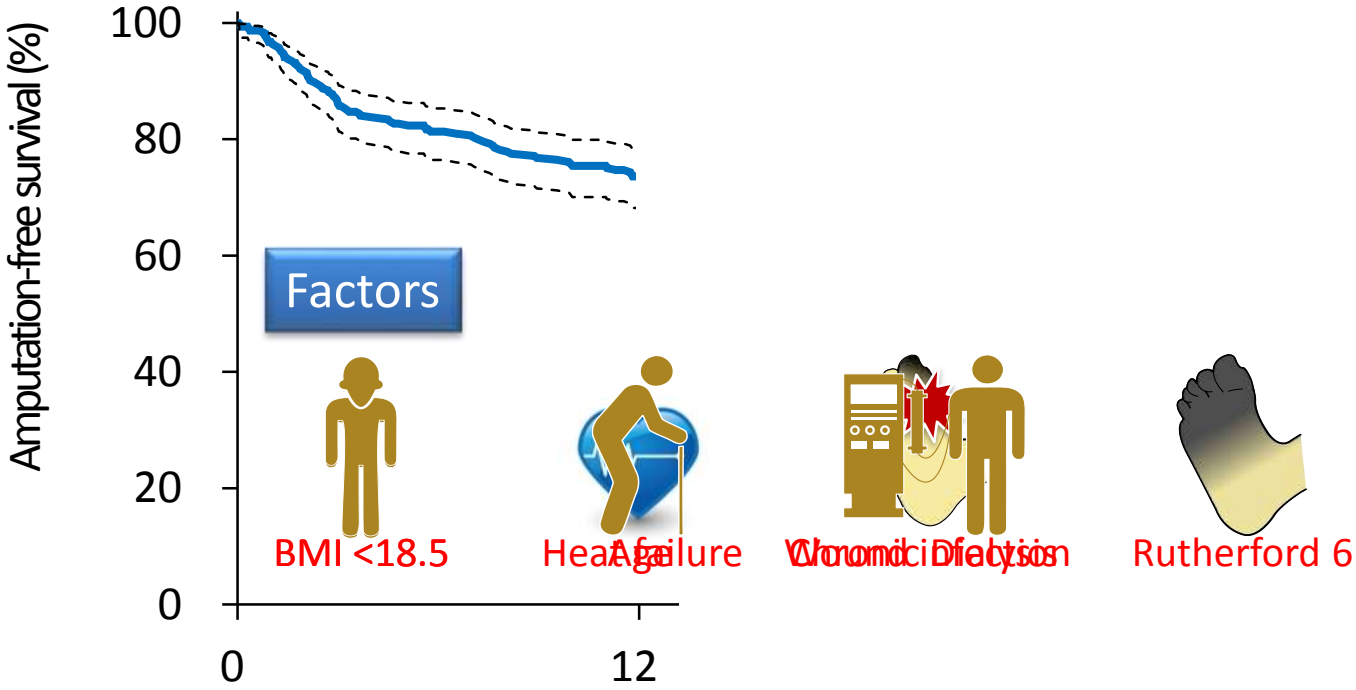
Secondary Endpoint:
Time to wound healing



Iida O, et al. JACC Cardiovasc Interv. 2015;8:1493-502.

OLIVE: 1-year and 3-year results

Primary Endpoint:
Amputation-free survival



	0	12
No. at risk	312	204
Rate (%)	100	73.6

Risk factors for amputation-free survival (AFS) in patients with CLI

in short period

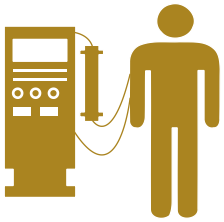
Heat failure

Wound infection

BMI <18.5

in long period

Age



Chronic Dialysis

Rutherford 6

BMI <18.5

Secondary Endpoint: Wound recurrence and its predictors

Stepwise analysis for recurrence of wound	OR	95%CI		Wald p-value
		Lower	Upper	
ALL				
Male Gender	1.61	0.74	3.52	0.23
Serum albumin<3.0g.dL	2.72	0.42	17.61	0.29
Diabetes mellitus	1.75	0.76	4.01	0.19
Hemodialysis	1.52	0.74	3.14	0.26
Isolated below-the knee lesions	**4.54**	**2.20**	**9.37**	**<.0001**
STEPWISE				
Diabetes mellitus	2.05	0.94	4.45	0.07
Isolated below-the knee lesions	**4.28**	**2.15**	**8.53**	**< 0.001**

Recurrence of wound until 3 years: **43.9 %**

Iida O, et al. JACC Cardiovasc Interv. 2015;8:1493-502.

Take Home Massages

From SPINACH registry

- ✓ Prevalence of the absence of prior intermittent claudication in patient with critical limb ischemia was 50%.

From CRITISH registry

- ✓ Patients who received BSX had an elevated rate of in-hospital death compared with EVT.
- ✓ CAD and previous MI were identified as risk factors for AFS.

From OLIVE 3-year results

- ✓ Wound recurrence at 3 years was 43.9%.
- ✓ CLI due to isolated BTK lesion was a wound recurrence predictor.

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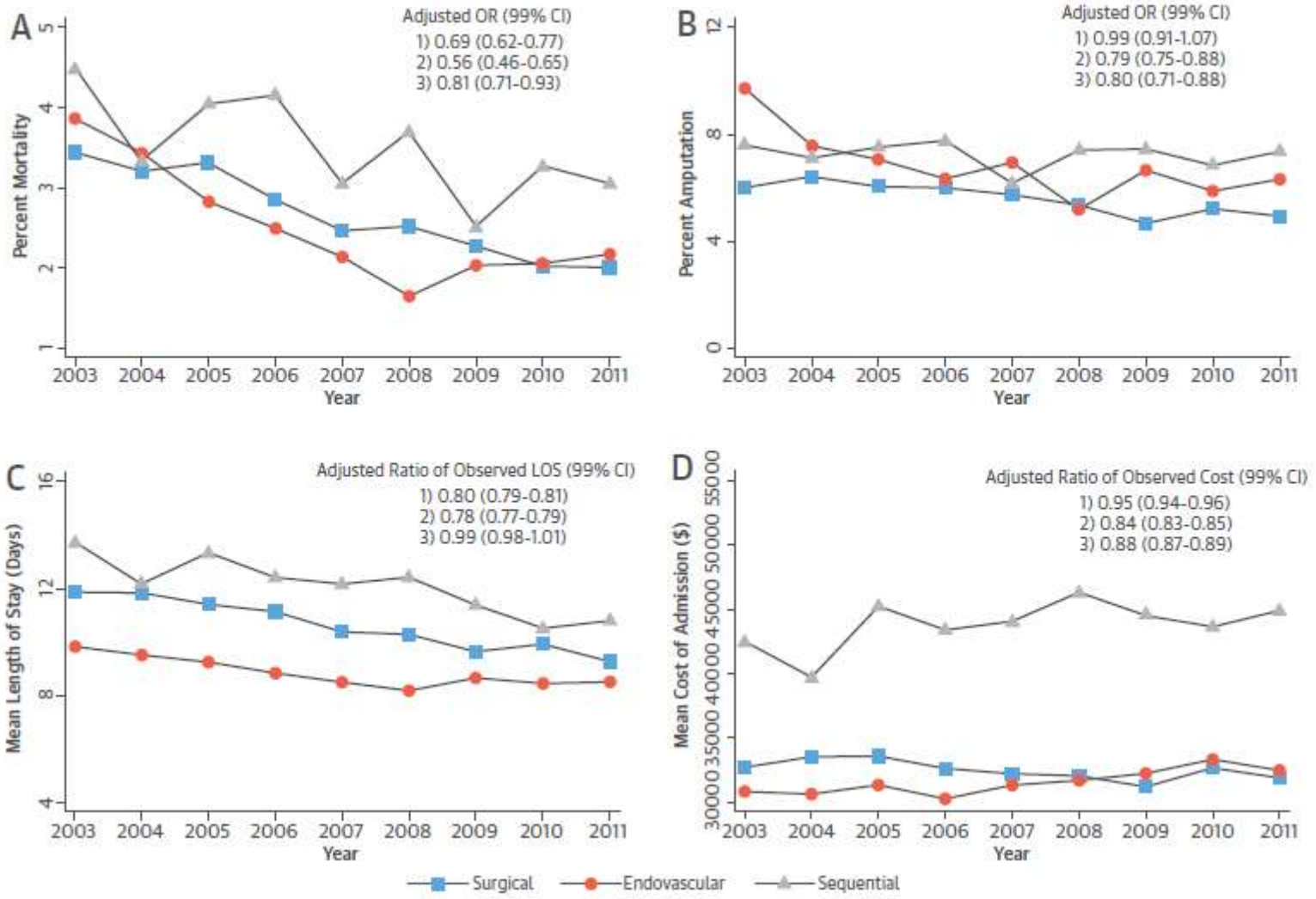

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