CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE
CONTROVERSIES & UPDATES IN VASCULAR SURGERY
JANUARY 17-19 2013
MARRIOTT RIVE GAUCHE & CONFERENCE CENTER PARIS, FRANCE

Endovascular Repair of Tibial Arteries: Those Who Know How To Do It Have No Doubts

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CACVS
January, 2013

Faculty Disclosure

Peter Schneider

I disclose the following financial relationships:

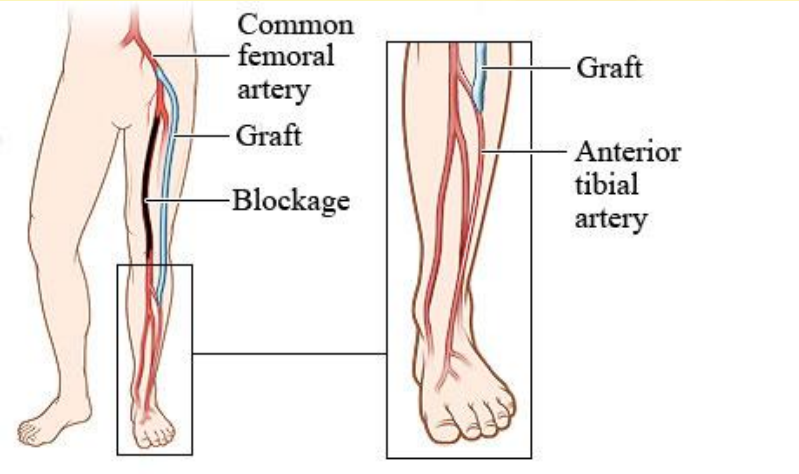
Consultant for Abbott (non-paid), Medtronic (non-paid)

Royalty from Cook (modest)

Receive research support from Abbott, Gore, Medtronic, Cordis (non-paid)

Performance of Tibial Bypass Grafts

	1month	1 year	2 years	3 years	4 years
Primary Patency					
Reversed saphenous vein	92%	77%	70%	66%	62%
In-situ bypass	94%	82%	76%	74%	68%
Limb salvage					
Reversed saphenous vein	95%	85%	83%	82%	82%
In-situ bypass	96%	91%	88%	83%	83%

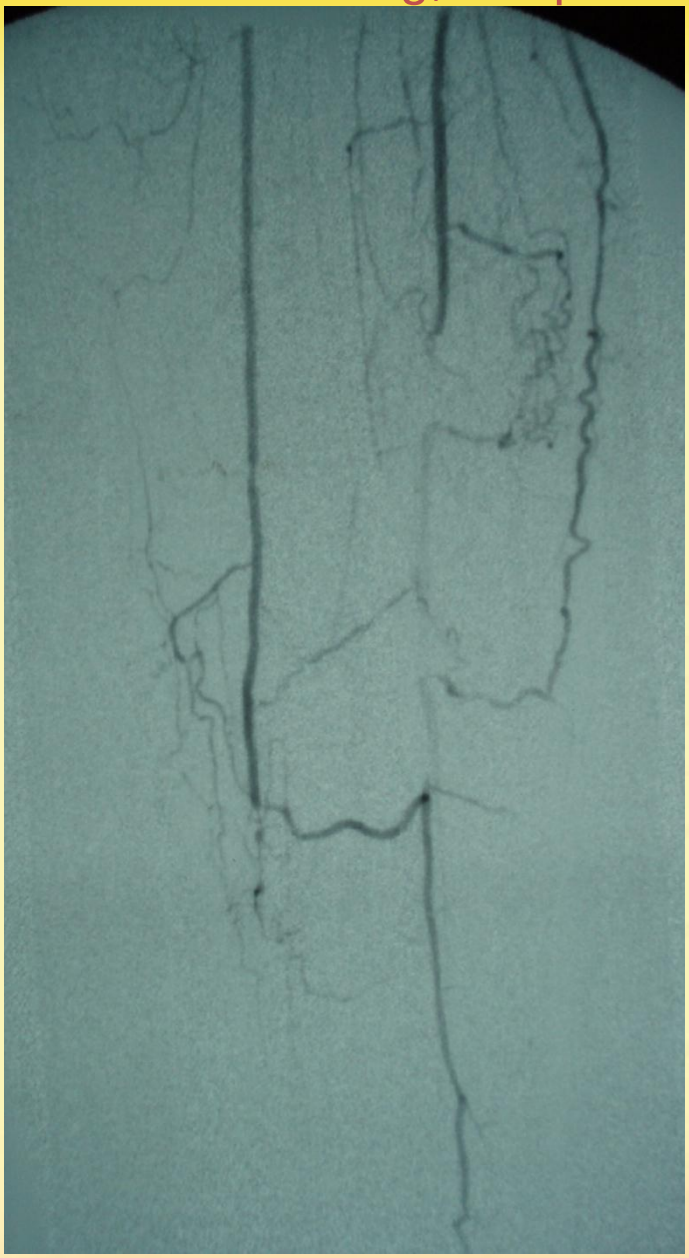


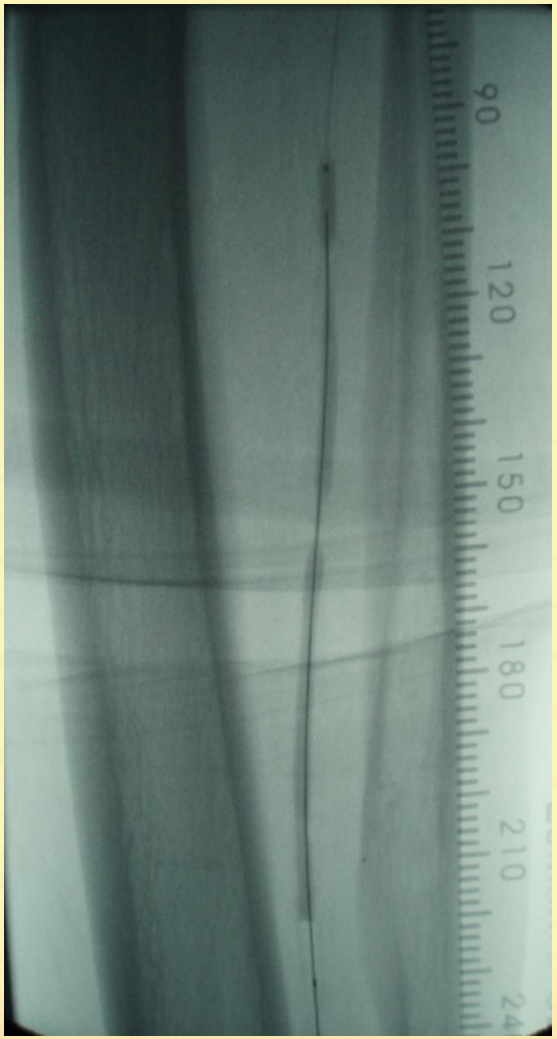
Mills J. Surgical revascularization of infrainguinal occlusive disease. Includes all series 1981-2009 Rutherford 7th ed. 2010

The biggest incision made in surgery today is for bypass to the tibial arteries!

Cross Tibial Occlusions

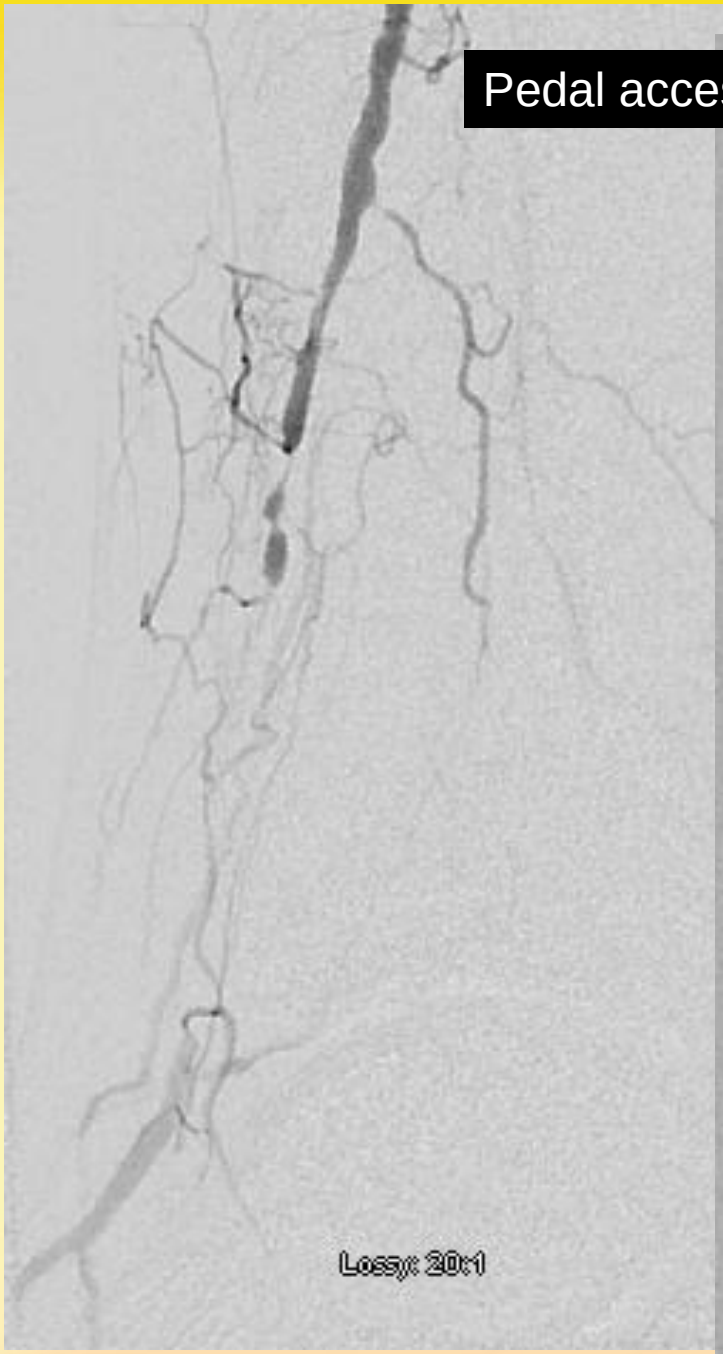
Long, low profile tibial balloons

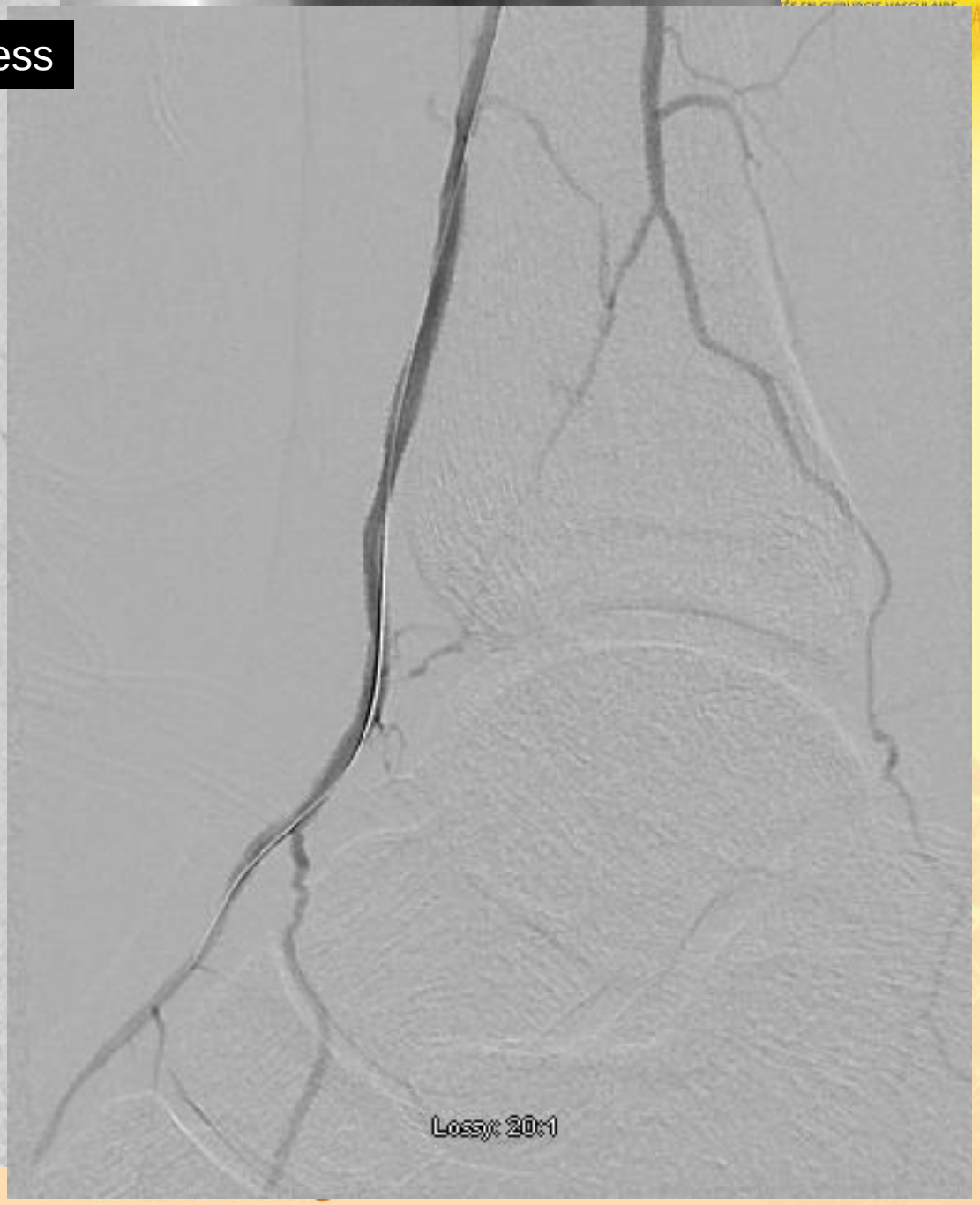




Complete foot revascularization

Pedal access



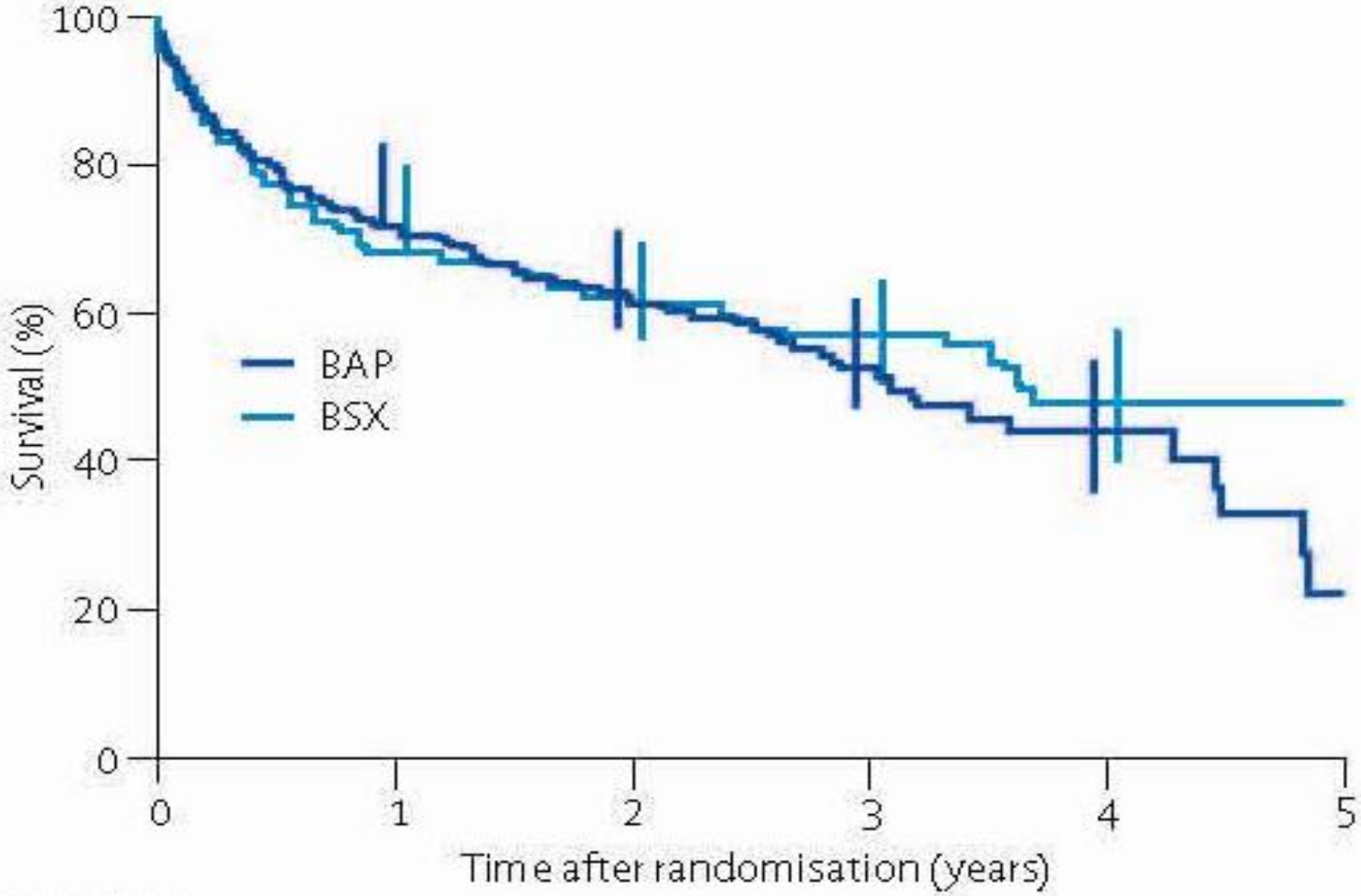


Tibial Angioplasty Starting Points

- PTA and bypass have not been directly compared.
- Lack of RCT or other fair comparative data.
  - Substantial amount descriptive data.
  - Similar to that which is available for bypass.
  - The quality of available data is not adequate to prove the efficacy of tibial angioplasty.

Which is the best revascularization for critical limb ischemia: Endovascular or open surgery

Beard J. J Vasc Surg 2008;48:I15



Number at risk

Angioplasty	224	149	100	51	19	2
Surgery	228	148	108	64	23	7

Recommendations for Critical Limb Ischemia: Endovascular and Open Surgical Treatment for Limb Salvage

J. Am. Coll. Cardiol. published online Sep 29, 2011

Class IIa

Balloon angioplasty →

1. For patients with limb-threatening lower extremity ischemia and an estimated life expectancy of 2 years or less or in patients in whom an autogenous vein conduit is not available, balloon angioplasty is reasonable to perform when possible as the initial procedure to improve distal blood flow (54). *(Level of Evidence: B)* — New recommendation

Bypass →

2. For patients with limb-threatening ischemia and an estimated life expectancy of more than 2 years, bypass surgery, when possible and when an autogenous vein conduit is available, is reasonable to perform as the initial treatment to improve distal blood flow (54). *(Level of Evidence: B)* — New recommendation

Journal of the American College of Cardiology
© 2011 by the American College of Cardiology Foundation and the American Heart Association, Inc.
Published by Elsevier Inc.
Vol. 58, No. 19, 2011
ISSN 0735-1097/$36.00
doi:10.1016/j.jacc.2011.08.023

PRACTICE GUIDELINE

2011 ACCF/AHA Focused Update of the Guideline for the Management of Patients With Peripheral Artery Disease (Updating the 2005 Guideline)

A Report of the American College of Cardiology Foundation/
American Heart Association Task Force on Practice Guidelines

Developed in Collaboration With the Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society for Vascular Medicine, and Society for Vascular Surgery

Tibial Bypass: SVS Optimal Performance Goals

Table Vb. *Summary of efficacy outcomes (one year) for overall CLI cohort and suggested OPG for each endpoint*

Outcome	*Point (95% CI)*	*Efficacy OPG*
MALE + POD	76.9% (74.0-79.9)	71%
AFS	76.5% (73.7-79.5)	71%
RAS	46.5% (42.3-51.2)	39%
RAO	61.3% (58.0-64.9)	55%
Limb salvage	88.9% (86.7-91.1)	84%
Survival	85.7% (83.3-88.1)	80%

AFS, Amputation-free survival; *CI*, confidence interval; *CLI*, critical limb ischemia; *MALE*, major adverse limb event; *OPG*, objective performance goals; *POD*, perioperative death; *RAO*, any reintervention or above ankle amputation of the index limb; *RAS*, any reintervention, above ankle amputation of the index limb, or stenosis.

Suggested objective performance goals and clinical trial design for evaluating catheter-based treatment of critical limb ischemia

Michael S. Conte, MD,[a] Patrick J. Geraghty, MD,[b] Andrew W. Bradbury, MD,[c] Nathanael D. Hevelone, MPH,[d] Stuart R. Lipsitz, ScD,[e] Gregory L. Moneta, MD,[f] Mark R. Nehler, MD,[g] Richard J. Powell, MD,[h] and Anton N. Sidawy, MD,[i] *San Francisco; Calif; St. Louis, Mo; Birmingham, United Kingdom; Boston, Mass; Portland, Ore; Aurora, Colo; Hanover, NH; and Washington, DC*

J Vasc Surg 2009;50:1462

Evidence for Tibial Angioplasty

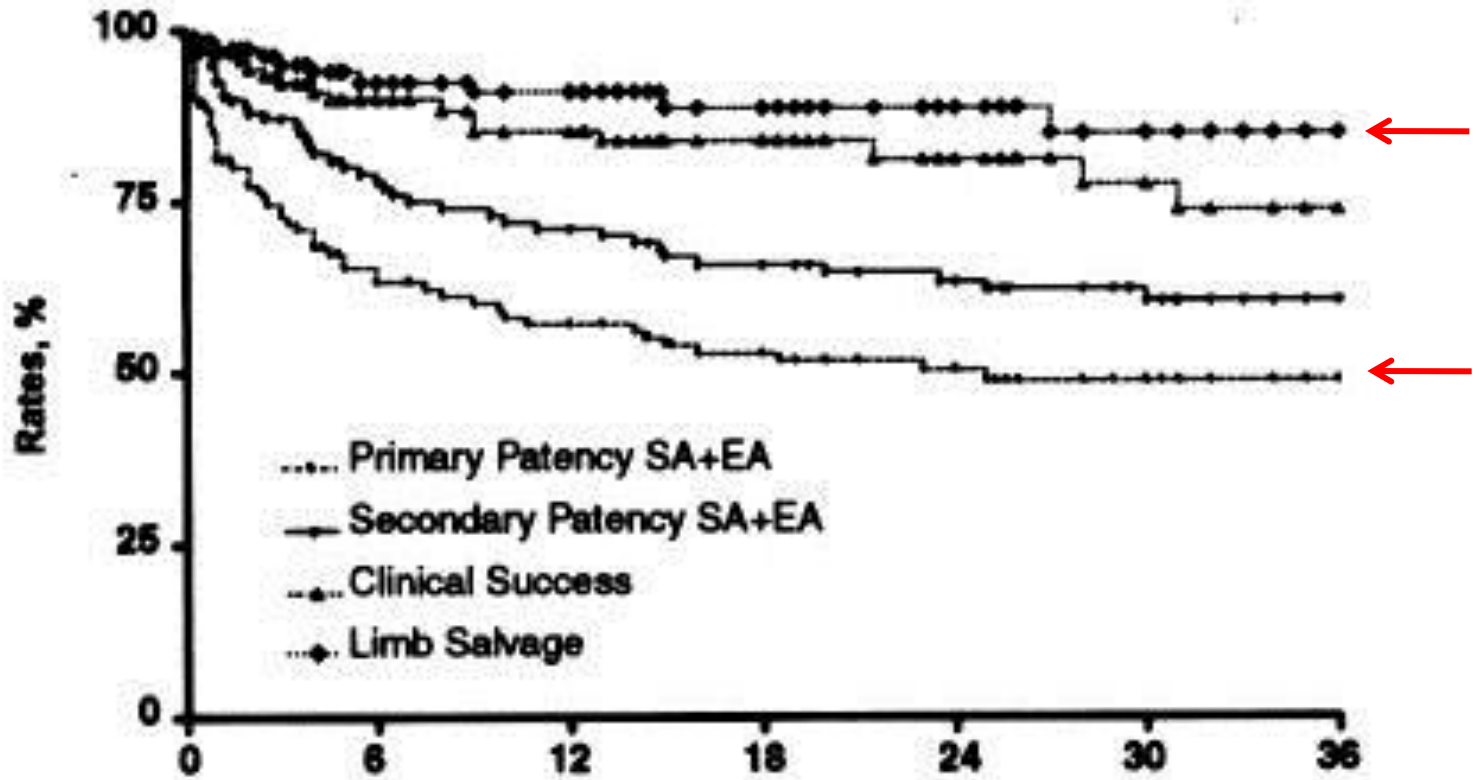
Meta-analysis of infrapopliteal angioplasty for chronic critical limb ischemia

Table II. Meta-analysis results of crural percutaneous transluminal angioplasty and popliteal-to-distal bypass[a]

Result	*1 month*	*6 months*	*1 year*	*2 years*	*3 years*
Primary patency					
PTA	77.4 ± 4.1	65.0 ± 7.0	58.1 ± 4.6	51.3 ± 6.6	48.6 ± 8.0
Bypass	93.3 ± 1.1	85.8 ± 2.1	81.5 ± 2.0	76.8 ± 2.3	72.3 ± 2.7
P	<.05	<.05	<.05	<.05	<.05
Secondary patency					
PTA	83.3 ± 1.4	73.8 ± 7.1	68.2 ± 5.9	63.5 ± 8.1	62.9 ± 11.0
Bypass	94.9 ± 1.0	89.3 ± 1.6	85.9 ± 1.9	81.6 ± 2.3	76.7 ± 2.9
P	<.05	<.05	<.05		
Limb salvage					
PTA	93.4 ± 2.3	88.2 ± 4.4	86.0 ± 2.7	83.8 ± 3.3	82.4 ± 3.4
Bypass	95.1 ± 1.2	90.9 ± 1.9	88.5 ± 2.2	85.2 ± 2.5	82.3 ± 3.0
Patient survival					
PTA	98.3 ± 0.7	92.3 ± 5.5	87.0 ± 2.1	74.3 ± 3.7	68.4 ± 5.5
Bypass	NA	NA	NA	NA	NA

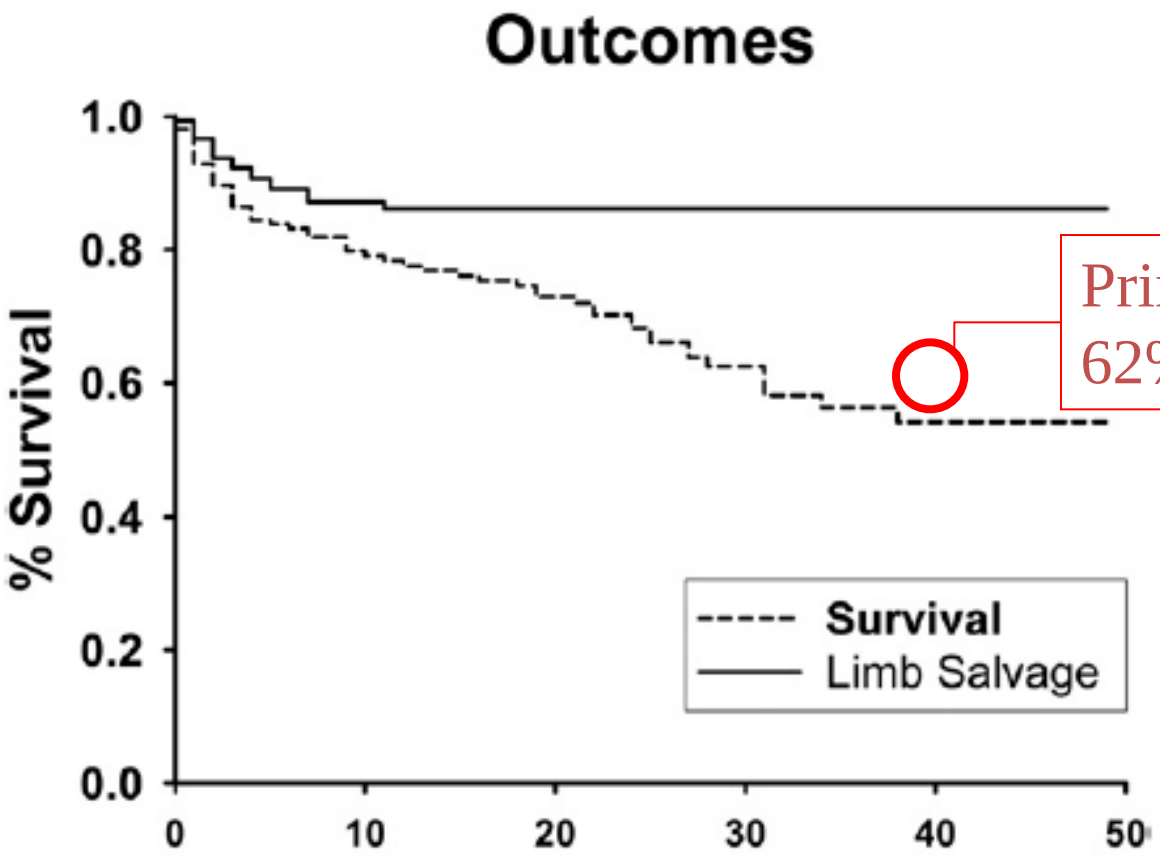
NA, Estimates not available; *PTA*, percutaneous transluminal angioplasty.
[a]Values are pooled estimate and standard error.

Tibial Angioplasty in Diabetics with CLI



Subjects at Risk							
Primary patency	124	66	57	45	35	21	6
Secondary patency	124	79	70	60	52	42	20
Clinical success	124	67	56	38	29	21	8
Limb salvage	124	87	56	38	29	21	7

Alexandrescu et al. J Endovasc Ther 2008;15:580



Primary patency=
62% at 40 months

Conclusions: Infrapopliteal angioplasty can be performed safely with favorable results in patients with limited longevity. Primary patency is related to disease extent. Secondary interventions may be necessary to maintain clinical success. These data indicate that PTA should be considered as initial therapy for infrapopliteal occlusive disease in patients with lower extremity ischemia. (J Vasc Surg 2009;50:799-805.)

Predictors of failure and success of tibial interventions for critical limb ischemia

Nathan Fernandez, MD, Ryan McEnaney, MD, Luke K. Marone, MD, Robert Y. Rhee, MD, Steven Leers, MD, Michel Makaroun, MD, and Rabih A. Chaer, MD, *Pittsburgh, Pa*

Conversion to bypass: 6%

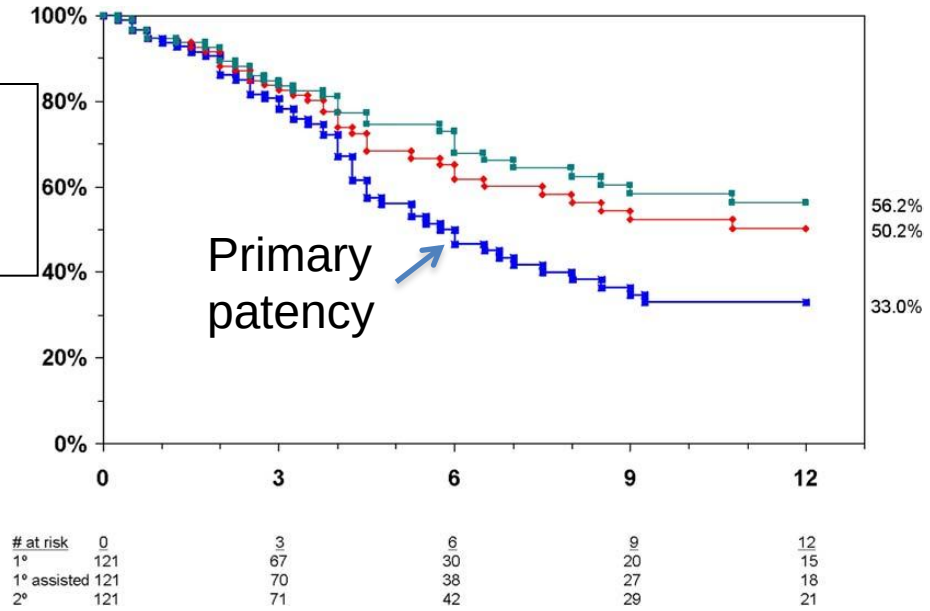


Fig 1. Patency in limbs undergoing tibial interventions (n = 121).

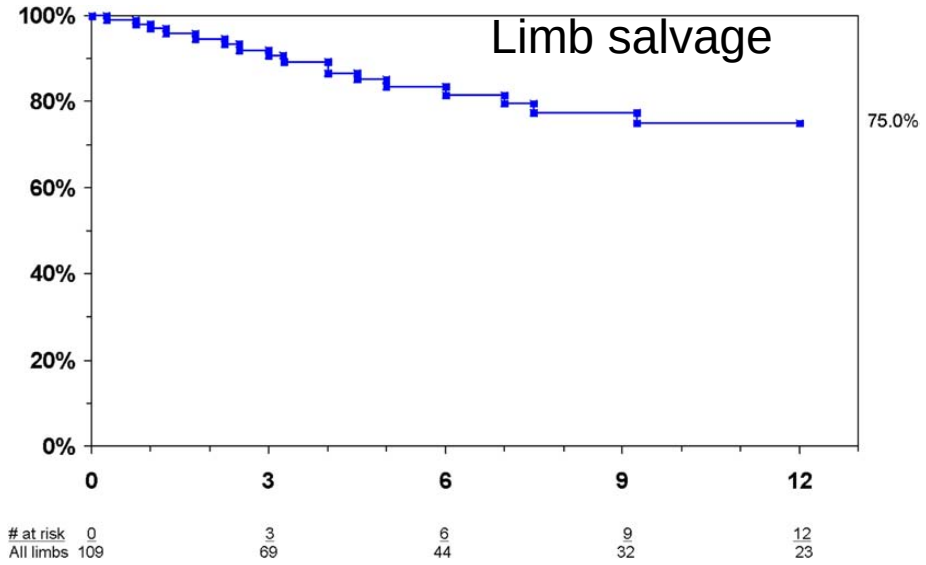
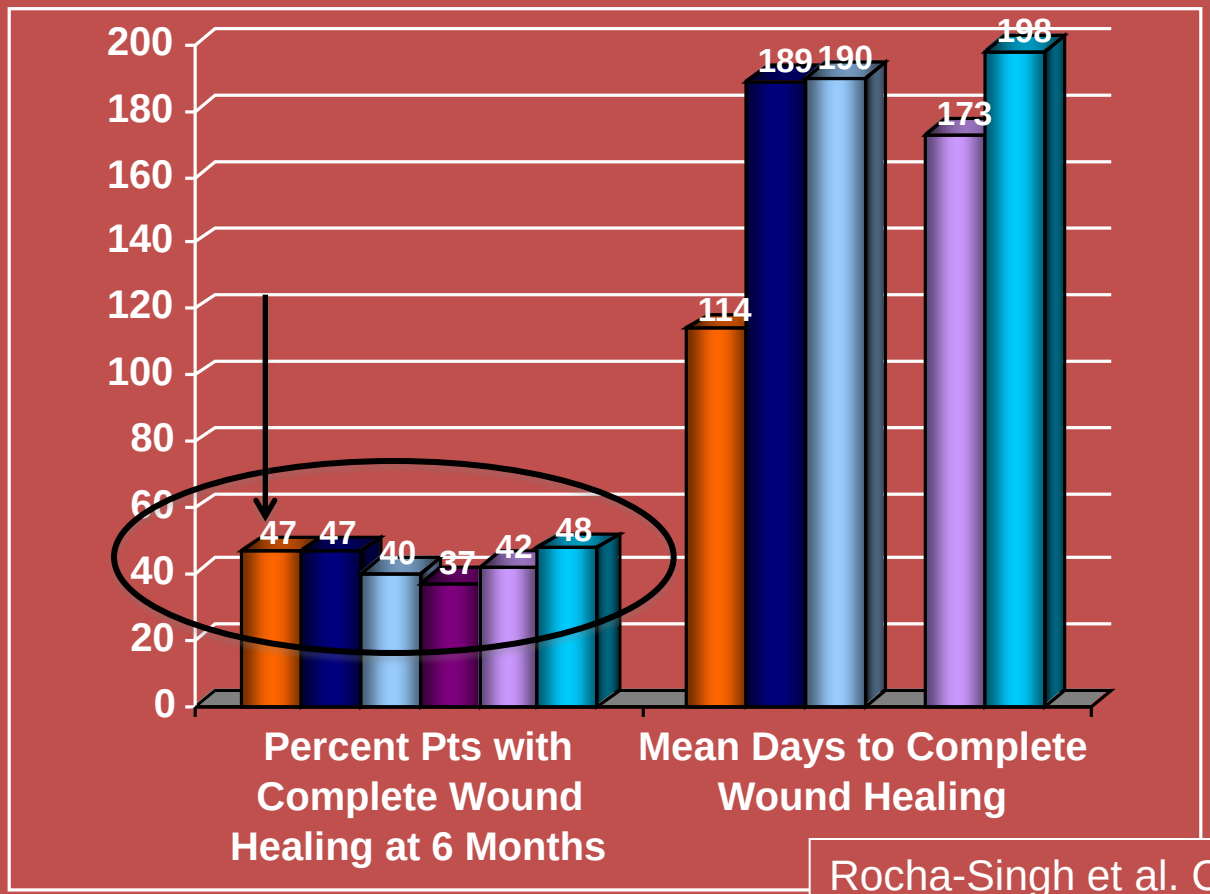


Fig 2. Cumulative limb salvage in at-risk limbs.

J Vasc Surg 2010;52;834

Wound Healing

Compare Tibial Angioplasty and Bypass



Rocha-Singh et al. Cath Cardiovasc Int 2011

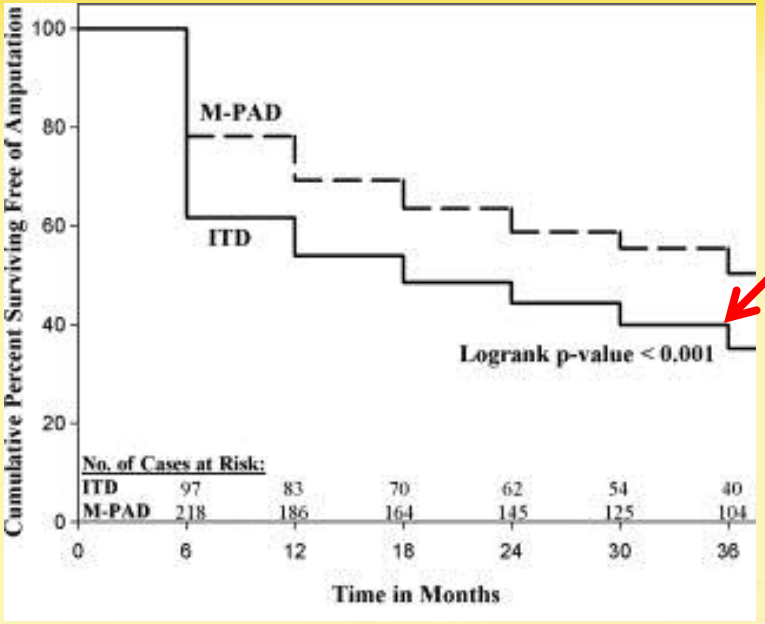
The time to healing was over 100 days for both therapies.

CLI= Complex systemic and local problem

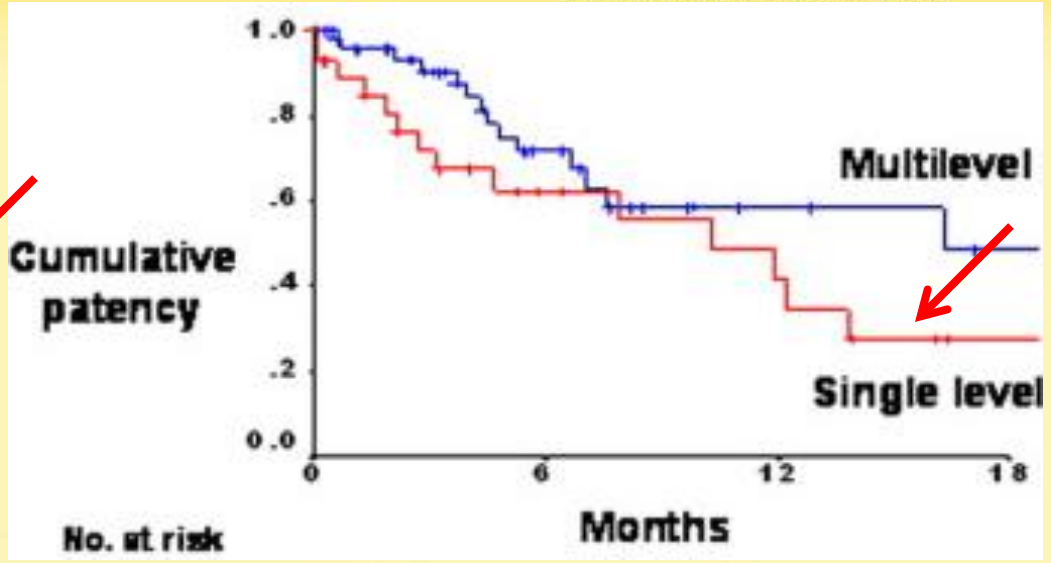
Perfusion
Diabetes
Infection
Wound management
Foot mechanics
Nutritional status
Physical and
mental function

Perfusion is only one of many factors. It may not be that important how it is established.

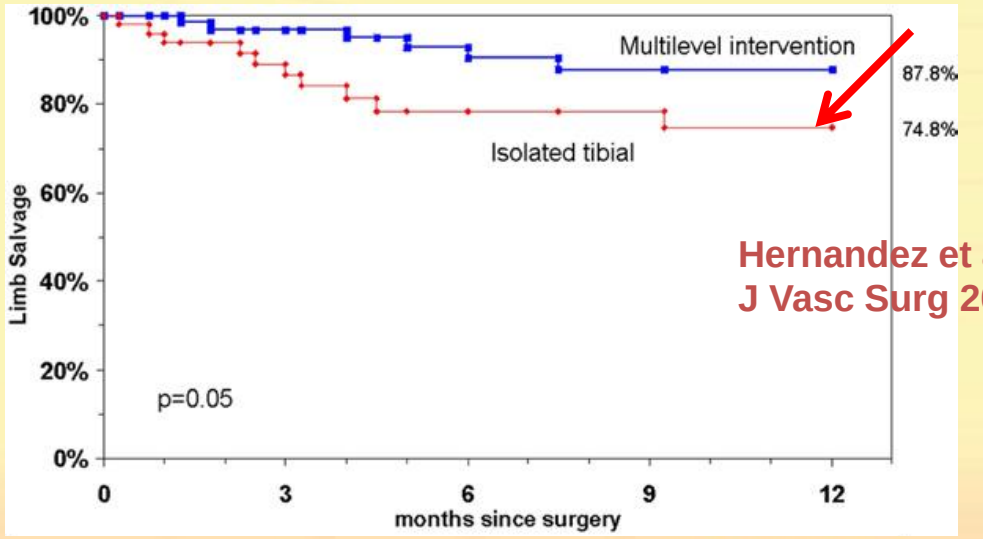
Patients With Isolated Tibial Disease Do Worse



Gray et al. Ann Vasc Surg 2010;24:349



Sadek et al. J Vasc Surg 2009;49:638



Hernandez et al.
J Vasc Surg 2011;54:722

Patients On Dialysis Do Worse

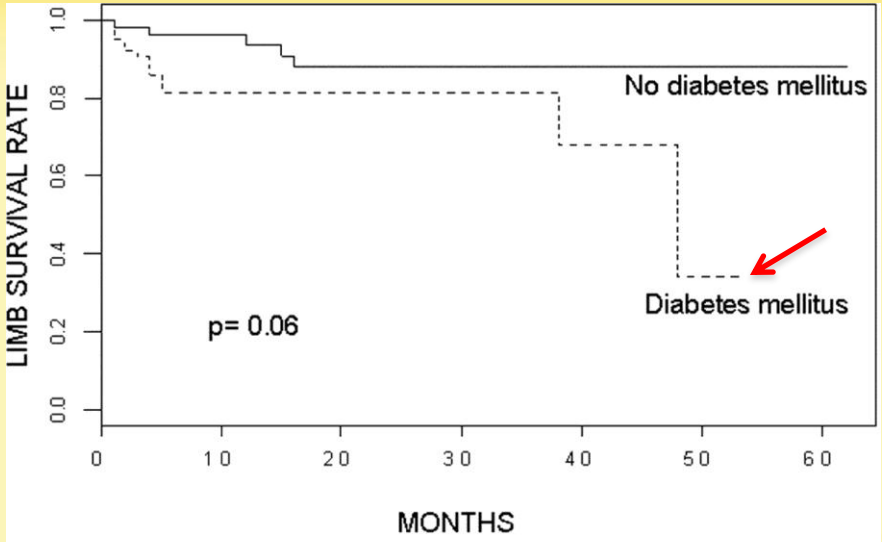


Table II. Independent predictors of primary amputation on multivariate analysis

	P	Odds ratio (95% CI)
Major tissue loss	0.002	5.5 (1.82-16.58)
ESRD	0.005	5.3 (1.62-17.60)
DM	0.03	3.0 (1.06-8.24)
Nonambulatory status	0.05	2.5 (1.01-6.25)

CI, confidence interval.

Abouzamzam et al.
Ann Vasc Surg 2007;21:548

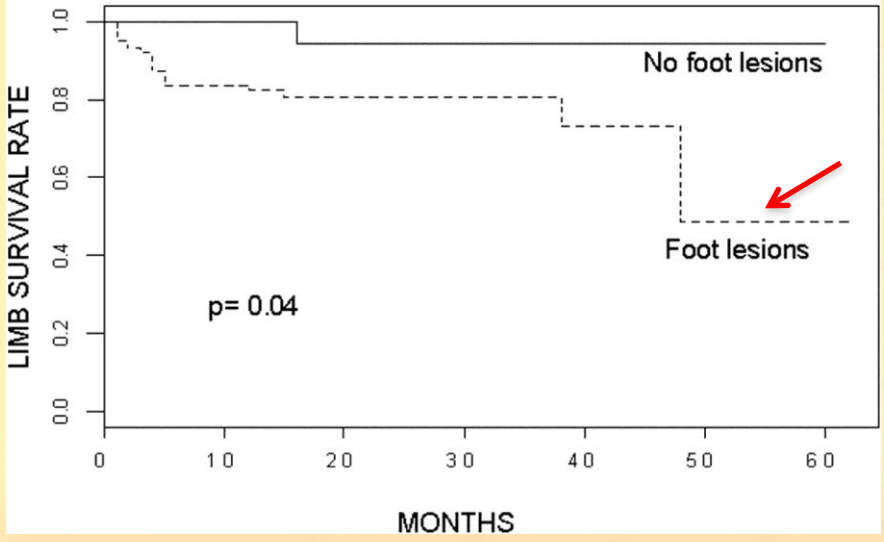


Table IV. Published series of infrainguinal bypass in renal failure.

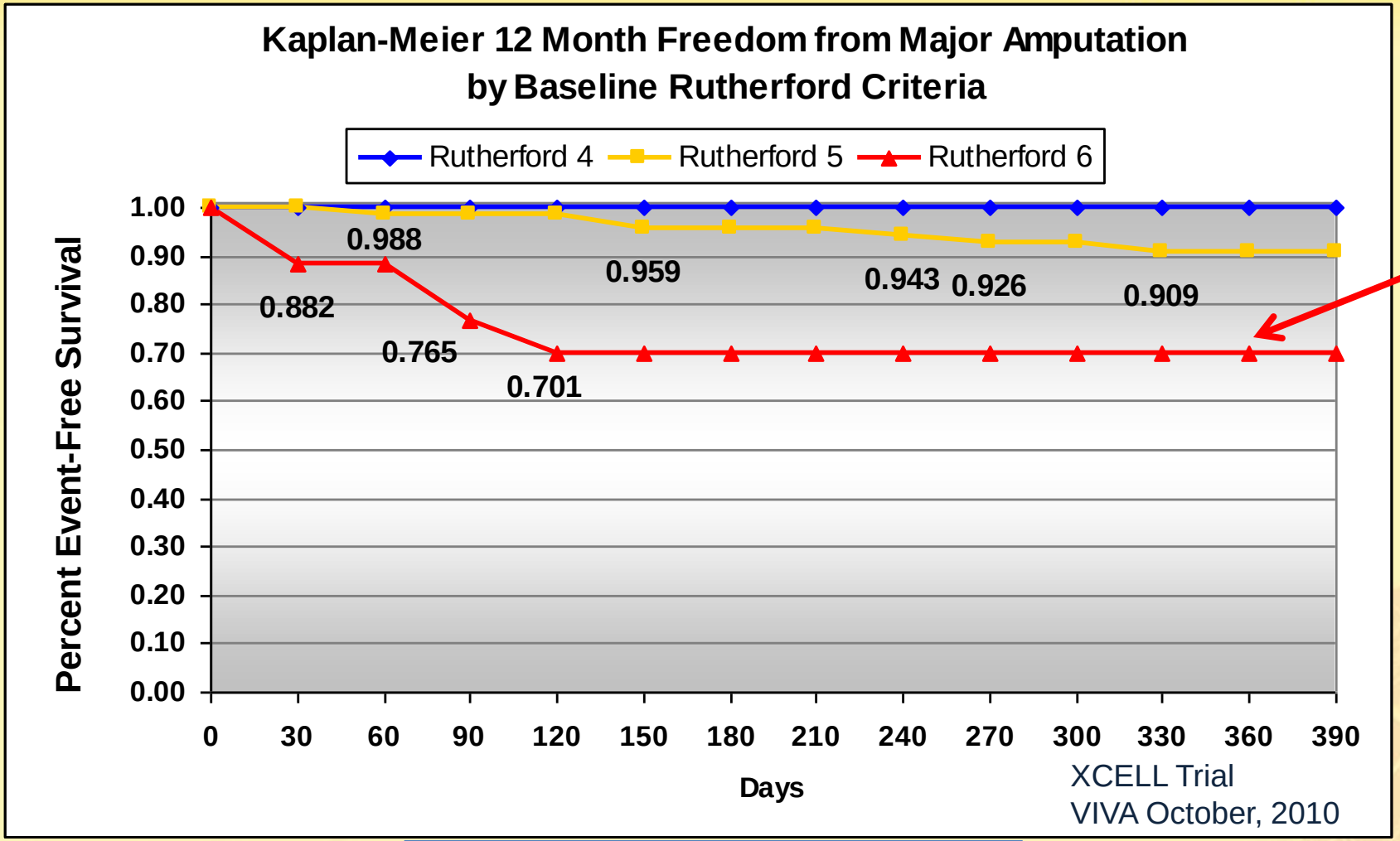
Authors	Number of Limbs	Early Mortality	Long-term Survival	Limb Salvage
Townley 2005	24	12%	35%*	66%*
Kimura[9] 2003	33	18%	45%†	83%†
Meyerson[11] 2001	82	4.9%	60%‡	59%‡
Ramdev[10] 2002	177	3%	50%‡	80%‡
Lantis[12] 2001	70	1.3%	51%§	76%§

* At 2-year follow-up.
† At mean follow-up of 22 months.
‡ At 3-year follow-up.
§ At 4-year follow-up.

Graziani L et al.
Nephrol. Dial. Transplant. 2007;22:1144-1149

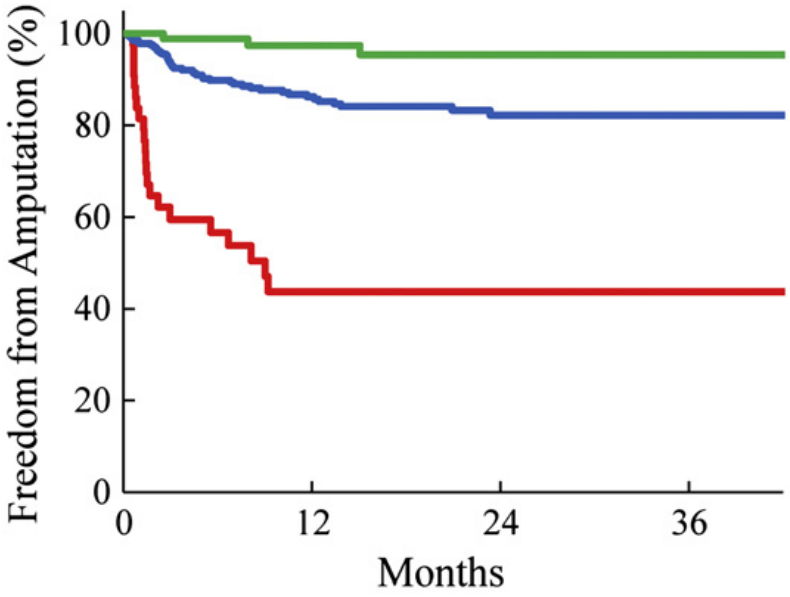
Townley et al.
Vasc Endovasc Surg 2006;40:362

Limb Salvage After Tibial Angioplasty: Worse in Rutherford 6 Patients



The degree of foot damage upon presentation drives results.

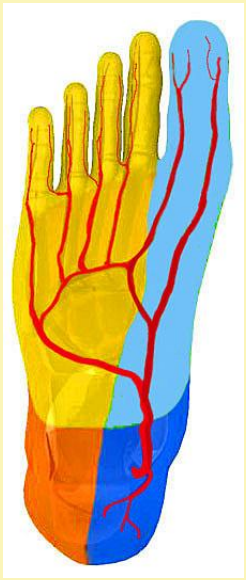
Risk Factors Determine Freedom from Amputation

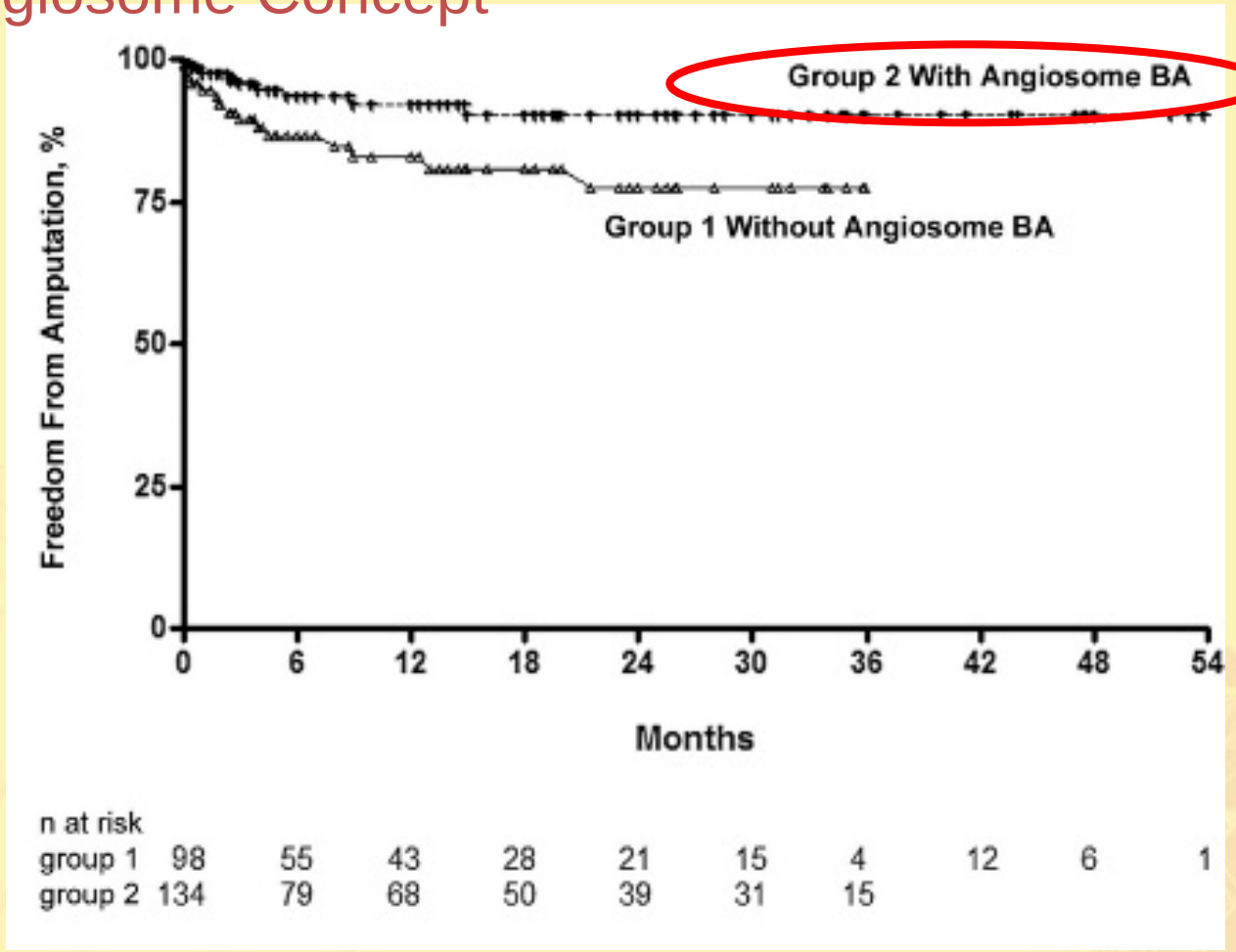


Months		0	12	24	36
at risk	Low	93	54	25	15
	Moderate	327	171	71	37
	High	45	11	7	2

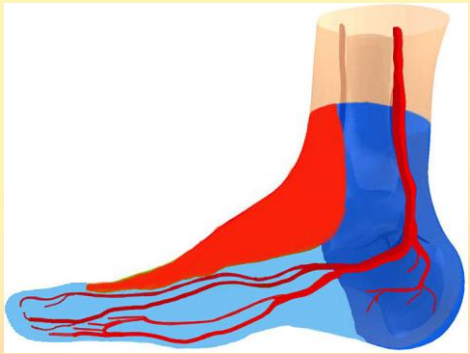
Iida et al. Eur J Vasc Endovasc Surg 2012;43:313

Comparison of BTK Angioplasty in Diabetics With and Without Use of the Angiosome Concept





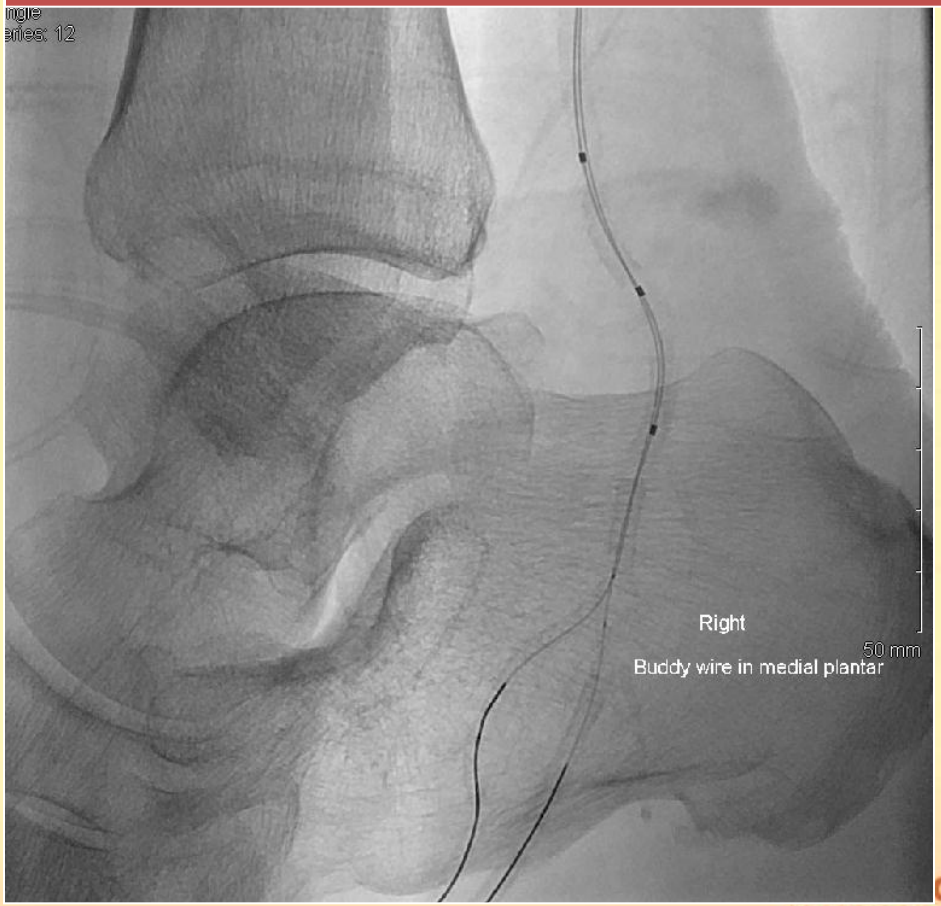
Alexandrescu et al. J Endovasc Ther 2011;18:376

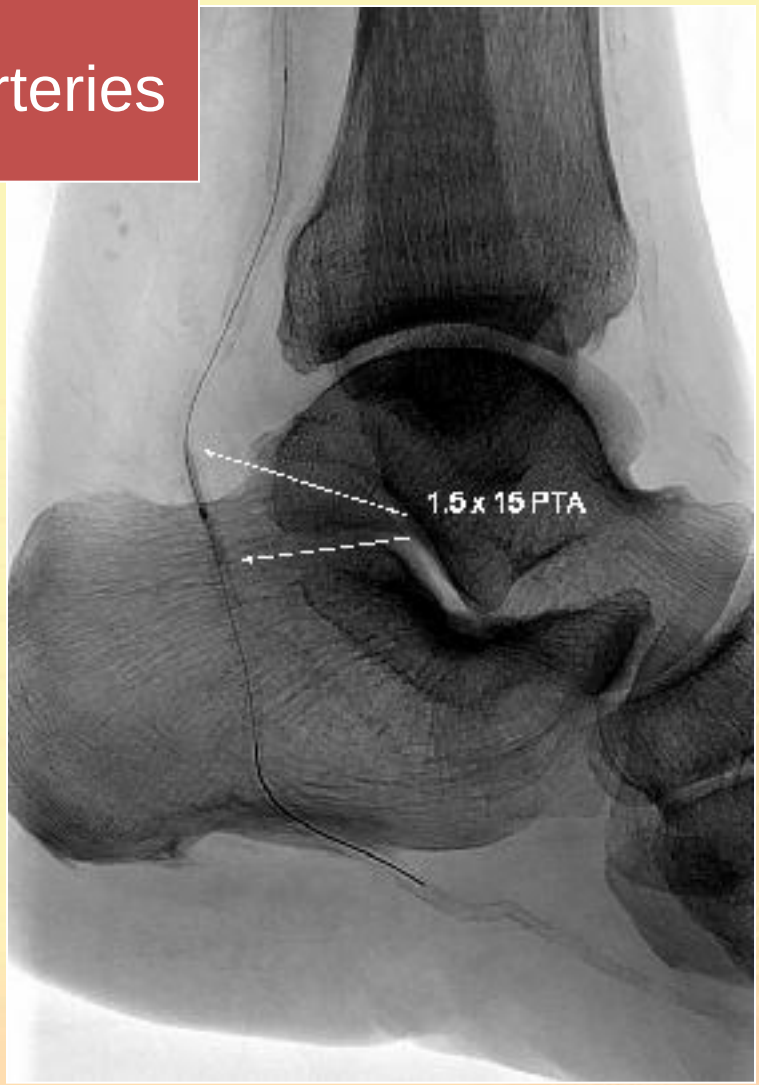


Angiosomal revascularization is an advantage of endovascular therapy

Below the Ankle Angioplasty Advantage of Endovascular Therapy

1331 patients with CLI
135 (10%) underwent PTA of pedal arteries
Manzi et al. J Cardiovasc Surg 2009;50:331





Drug Coated Balloon
Below-the-knee Lesions

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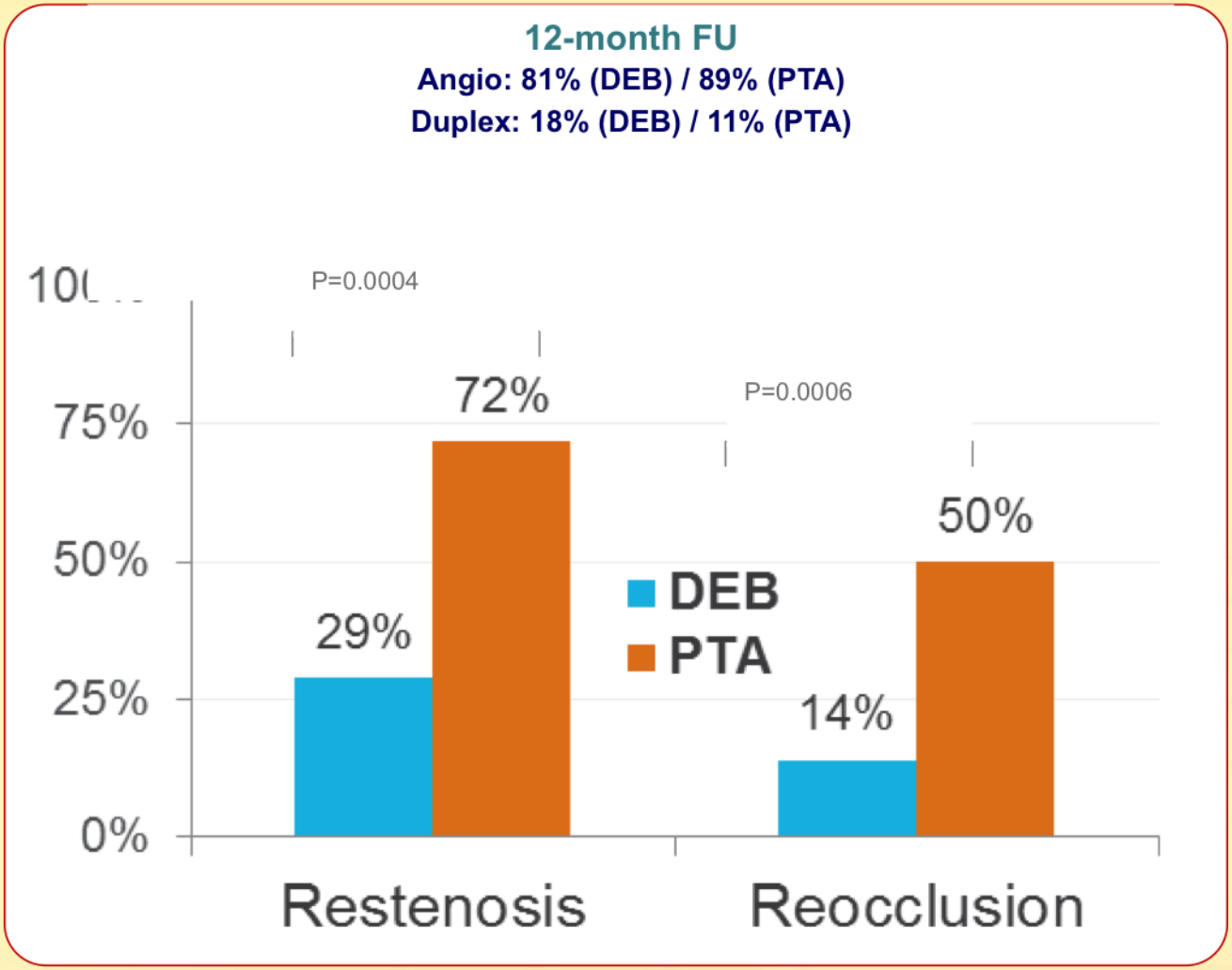


IN.PACT Amphirion vs. PTA in BTK-CLI

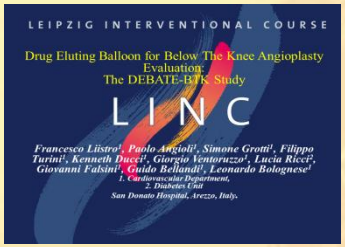
Prim. Endpoint:

12m Angiographic Restenosis Rate

120 patients

Lesion length = 12 cm

Occlusions = 80%



DEBATE Randomized Trial Liistro LINC Jan., 2012

Tibial Angioplasty

The patency rate of tibial angioplasty:

- Is typically lower than the limb salvage rate in each clinical series.
- Has mostly been assessed with duplex in published series and there is limited angiographic patency data available.
- Is lower in patients with renal failure.
- Is not always associated with limb salvage.
- Is lower in patients with isolated tibial disease than it is in patients with multilevel occlusive disease.

Tibial Angioplasty: Those Who Know How to Do It Have No Doubts

- Bypass better than PTA
  - Patency
  - Consider bypass for patients at high risk for limb loss
- Bypass and PTA similar
  - Limb salvage, wound healing
- PTA better than bypass
  - Lower morbidity, shorter hospital stay, treat below the ankle, treat multiple tibial arteries, multiple levels of disease, easier to treat correct angiosome

- Durability of angioplasty not yet good enough but may improve with drug coated balloons.