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FMRP
Flanders Medical Research Program

A.Z. Sint-Blasius, Dendermonde
Marc Bosiers
Koen Deloose
Joren Callaert

Imelda Hospital, Bonheiden
Patrick Peeters
Jürgen Verbist

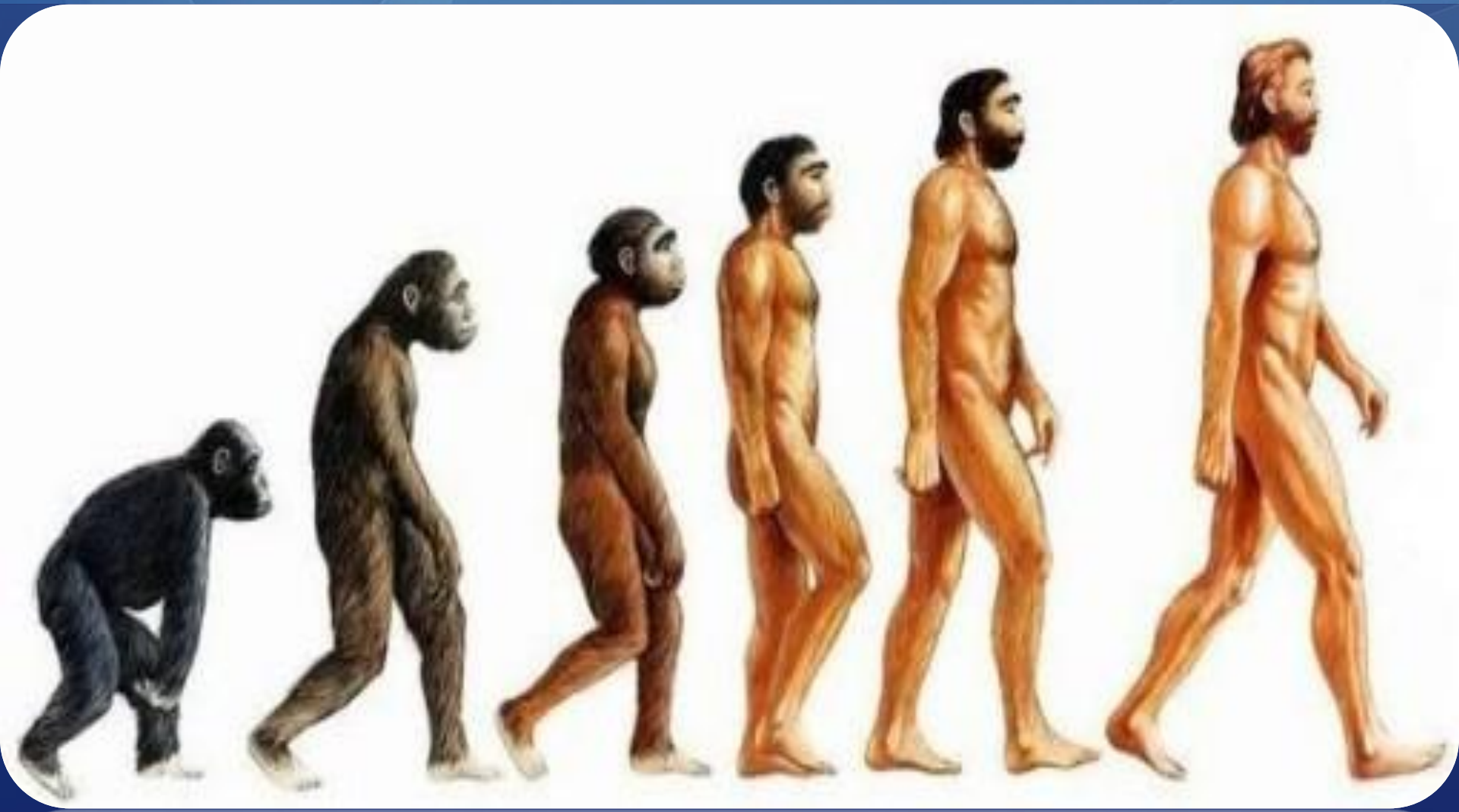
OLV Hospital, Aalst
Lieven Maene

R.Z. Heilig Hart, Tienen
Koen Keirse

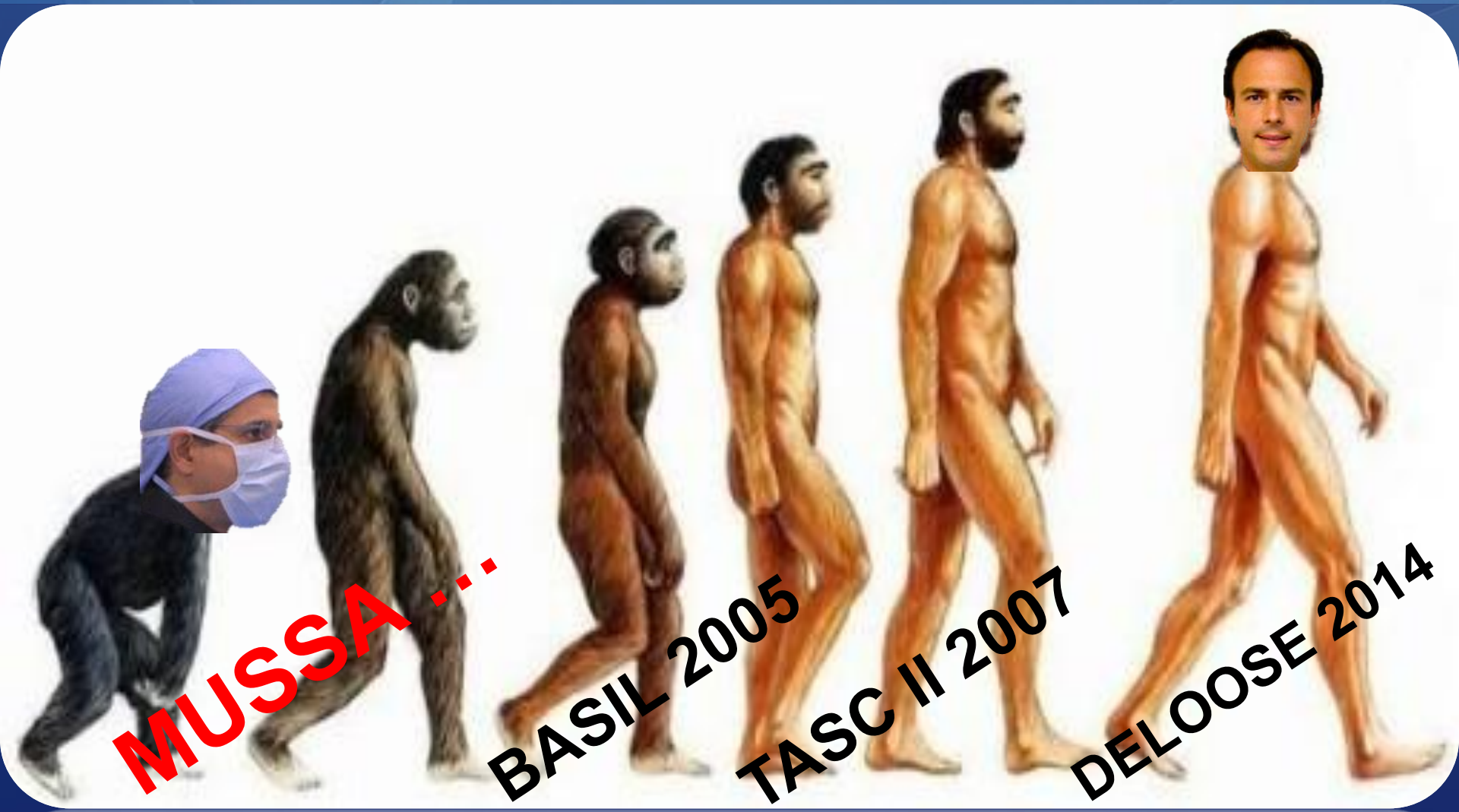
Critical Limb Ischemia : ENDOVASCULAR is the first choice strategy

Koen Deloose, MD

Evolution of human being…



Evolution of CLI treatment…



In the beginning…there was bypass surgery….

"…for patients with CLI, **surgical bypass grafting** has been the **gold standard**, with a 5-year limb salvage rates > 80% …"

- Horrocks M. et al Ann Vasc Surg 2003
- Akbari CM et al. J Vasc 2000
- Hunnink M.G.et al Med. Decis. Making 1994

But are venous CLI-bypasses that great???

- **5% mortality rates**
- 10-20% of bypasses develop **incisional wound complications**
- Large prospective NSQIP analysis of >2500 patients revealed bypass has **~20% peri-procedural complication rate, and 49% readmission rate at 6 months** (65% are bypass related)
- Meta-analysis showed 12% **decline in ambulation** and 15% **loss of independent living** post bypass surgery
- 30-40% of bypasses develop **stenoses/occlusions with in 1 year**
- 20-80% of successful patent bypasses have recurrent or **persistent ulcers or wounds** at 1 year

La Muragglia et al. Eur J Vasc Endovasc Surg 2012; 43(5):549-55
Conte et al. Seminars of Vascular Surgery 2012 25:108-114
Goodney et al. J Vasc Surg 2011 : 54(1) ; 100-108

But are venous CLI-bypasses that great???

Optimum Outcomes Rare with Surgery

- OHSU experience with bypass for CLI
  - Mean postoperative follow-up 42 months
  - 88% independent at home
- Wound complications common
- Repeat operations required in 54%
- Only 14.3% had the "ideal surgical result"
  - Uncomplicated operation
  - Long-term symptom relief
  - Maintenance of functional status
  - No recurrence or repeat operations

Nicoloff AD, et al. Patient recovery after infrainguinal bypass grafting for limb salvage. *J Vasc Surg* 1998;27(2):256-63

But are venous CLI-bypasses that great???

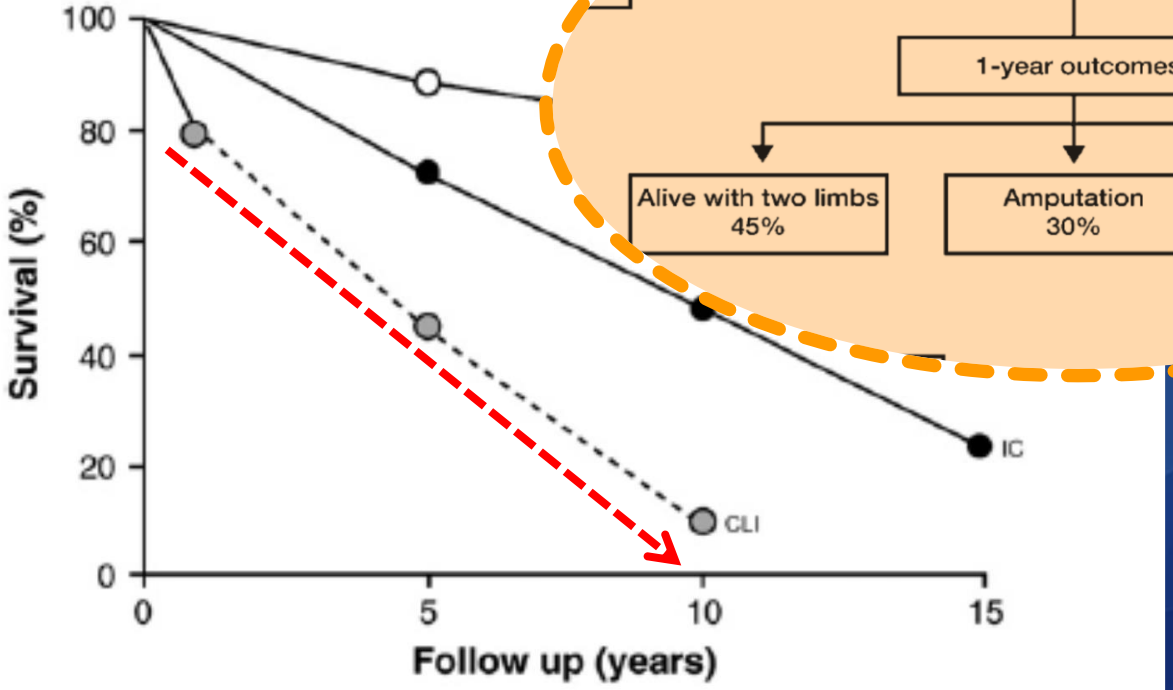
- No distal target
- No suitable vein
- Infected distal anastomosis area
- Very fragile population…

But are venous CLI-bypasses that great???

- Young healthy vein boys

- Old fragile no-vein men

…and old fragile no-vein men…



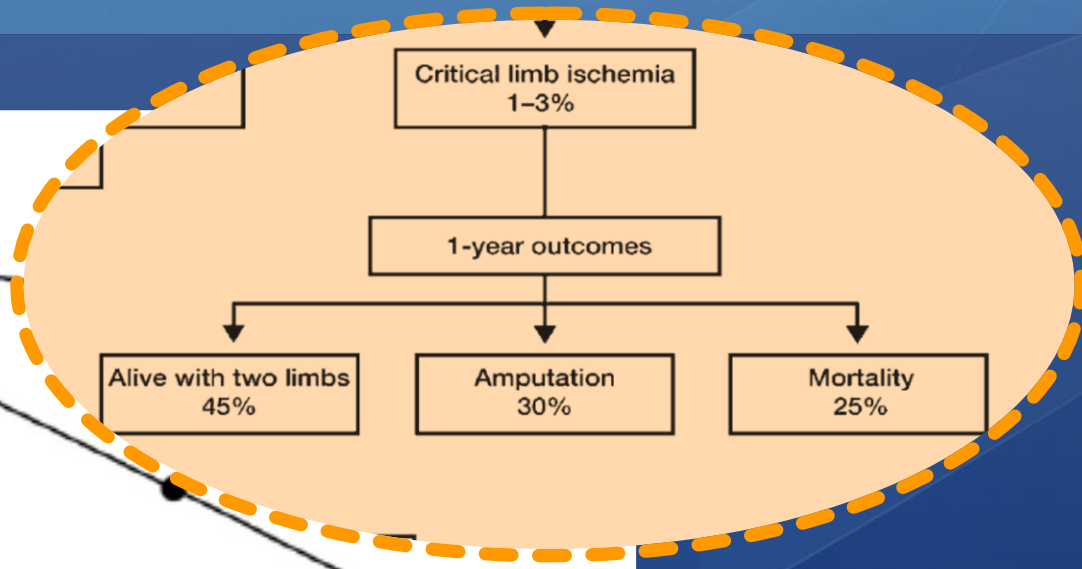


Fig. A8. Survival of patients with peripheral arterial disease. IC – intermittent claudication; CLI – critical limb ischemia.

Evolution of CLI treatment…

…a trend to a shift…BASIL Trial…

"In patients presenting with severe limb ischaemia due to infrainguinal disease and who are suitable for surgery and angioplasty, a bypass-surgery-first and a balloon-angioplasty-first strategy are associated with broadly similar outcomes in terms of amputation-free survival !.." **Basil trial participants**

Lancet 2005; 366: 1925–1934

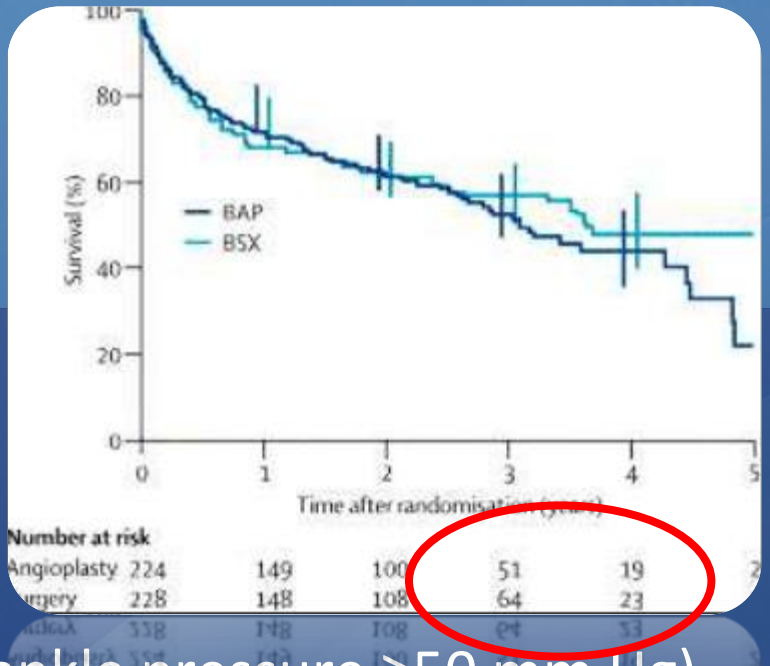
The BASIL Trial…

Recommendation BASIL

"CLI patients predicted to live >2 years,
with useable vein, should have bypass surgery :

- long-term results = good
- rate of endovascular failure = high
- result surgery after failed endovascular approach = significantly worse than for primary surgery"

The BASIL Trial…

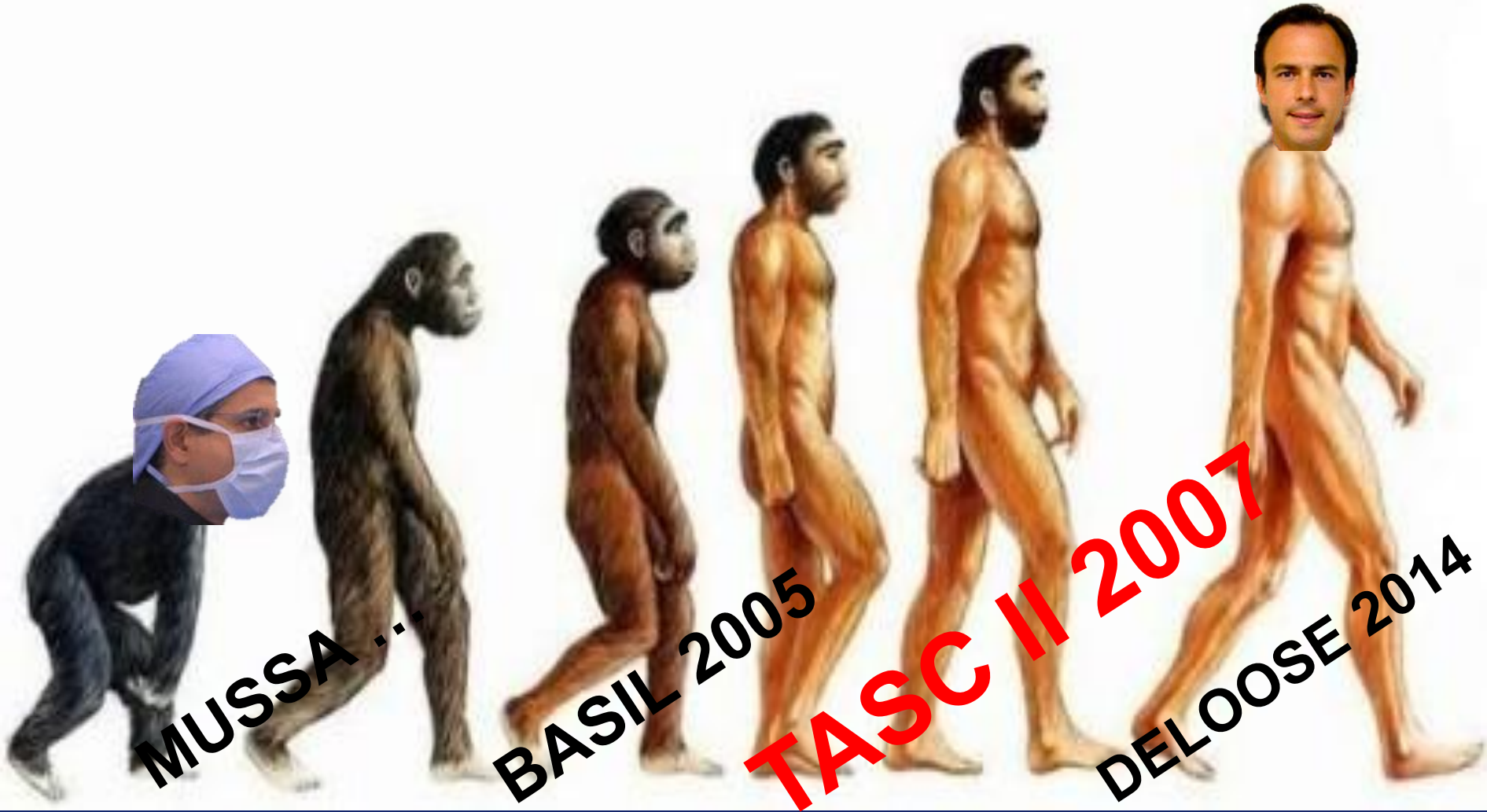


Problems with BASIL…

- SLI instead of CLI (inclusions ankle pressure ≥50 mm Hg)
- Exclusion patients with ESRD
- Almost no BTK lesions included
- high primary procedural failure rate (20%)
- Failed angioplasties are doing worse (bias+++)
- limited range of EVT strategies (balloon angioplasty only)
- Post hoc long term (24 m) analysis with low patient numbers
- Outdated in 2014…

Evolution of CLI treatment…

Evolution of CLI treatment…



TASC II recommendations…

Recommendation 35: Choosing between techniques with equivalent short- and long-term clinical outcomes

- In a situation where endovascular revascularization and open repair/bypass of a specific lesion causing symptoms of peripheral arterial disease give equivalent short-term and long-term symptomatic improvement, endovascular techniques should be used first [B]

Conclusion TASC II 2007 :

There is increasing evidence to support a recommendation for angioplasty in patients with CLI and infrapopliteal artery occlusion where in-line flow to the foot can be re-established and where there is medical co-morbidity.

Norgren L et al, EJVES 2007;33:S1-S75

Supported by more and more papers…

- Cambria et al. J Vasc Surg 2006

"…**In this series**, there was **no periprocedural mortality** and the **rate of major morbidity was 3%, which is a dramatic improvement over the recently reported rate of 10% morbidity and 3% mortality after infrainguinal bypass** with autogenous vein…."

Cambria RP et al. J Vasc Surg 2006

And more papers…

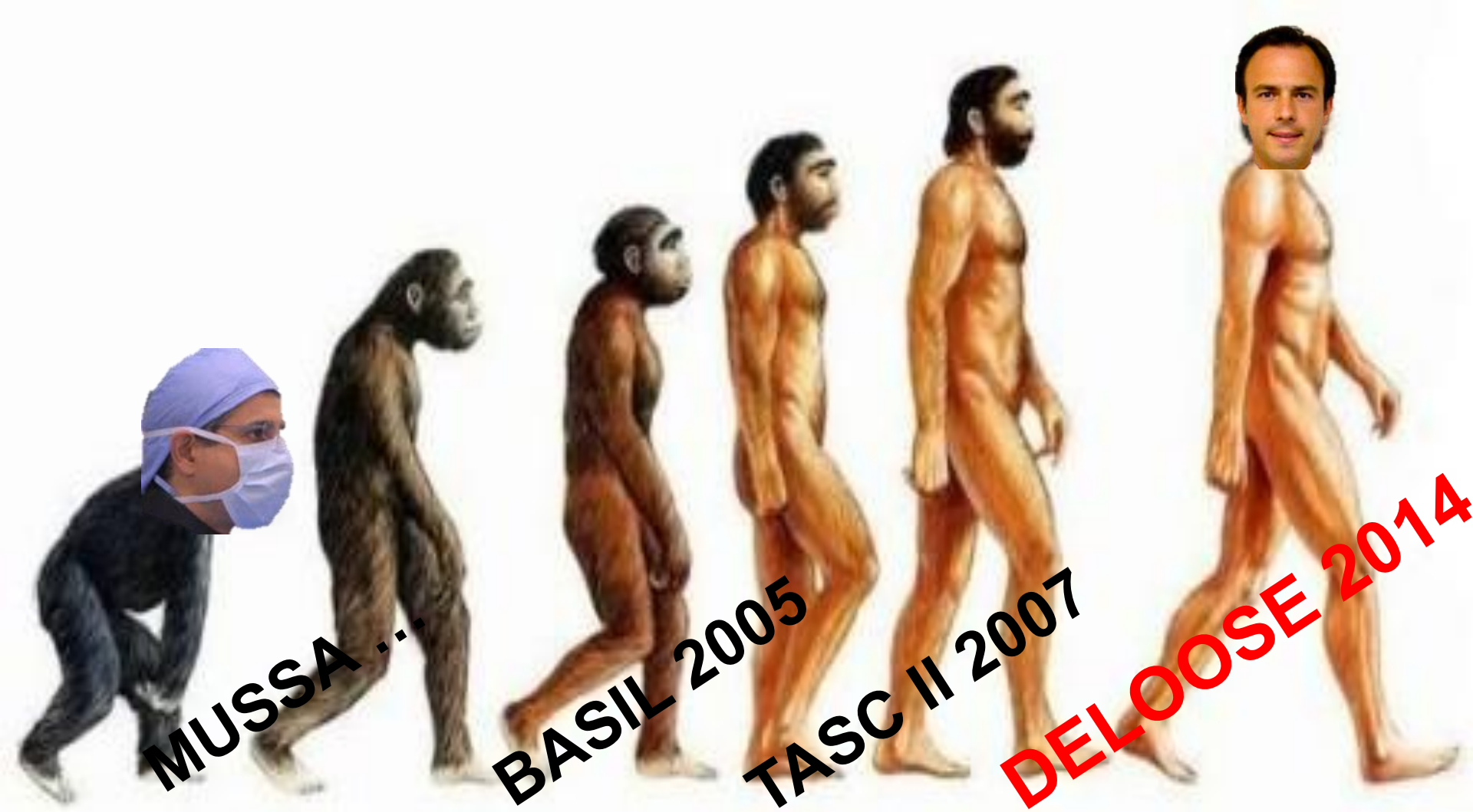
- **Meta-analysis of 30 studies**
- **n = 2653 limbs treated**

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.

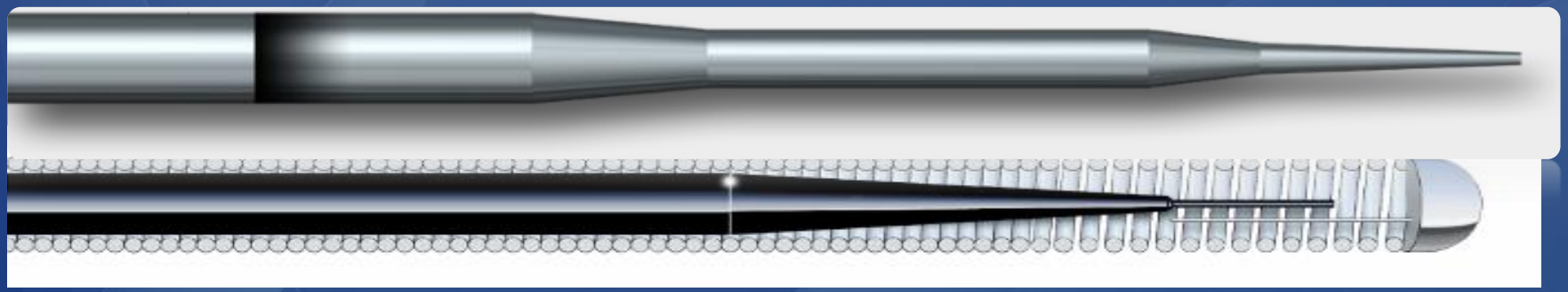
Romiti et al. J Vasc Surg 2008;47:975-81

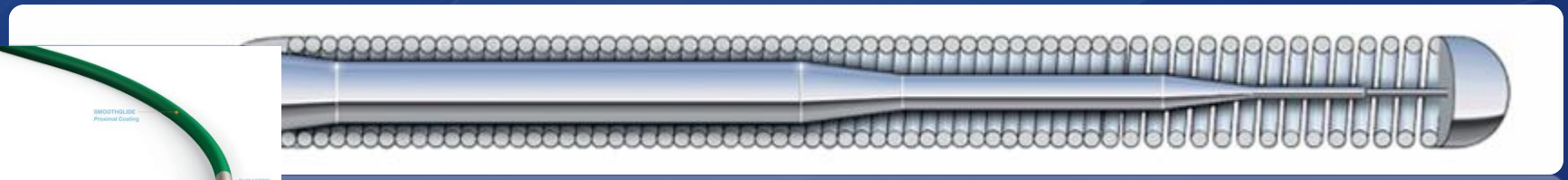
Evolution of CLI treatment…



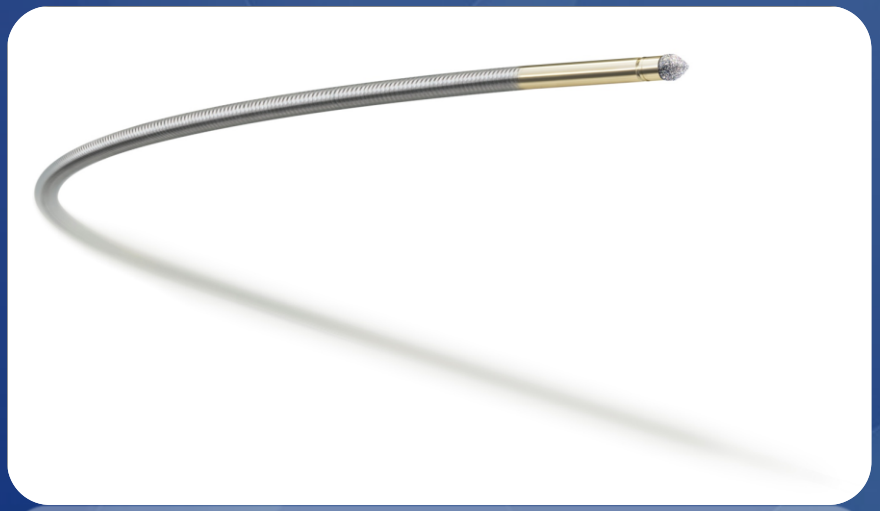
Nowadays…there is modern endovascular surgery….

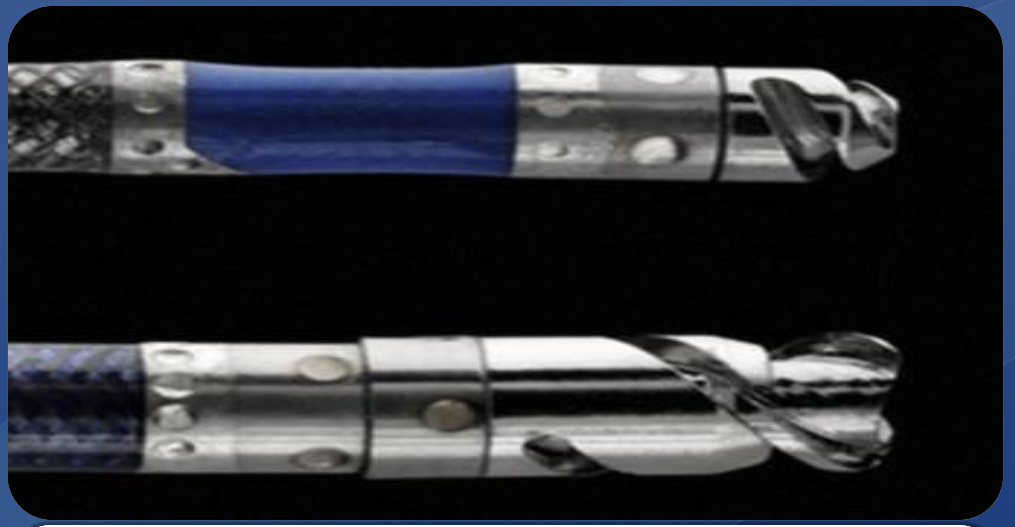
…more and more improvements in the endovascular approach… guide wires

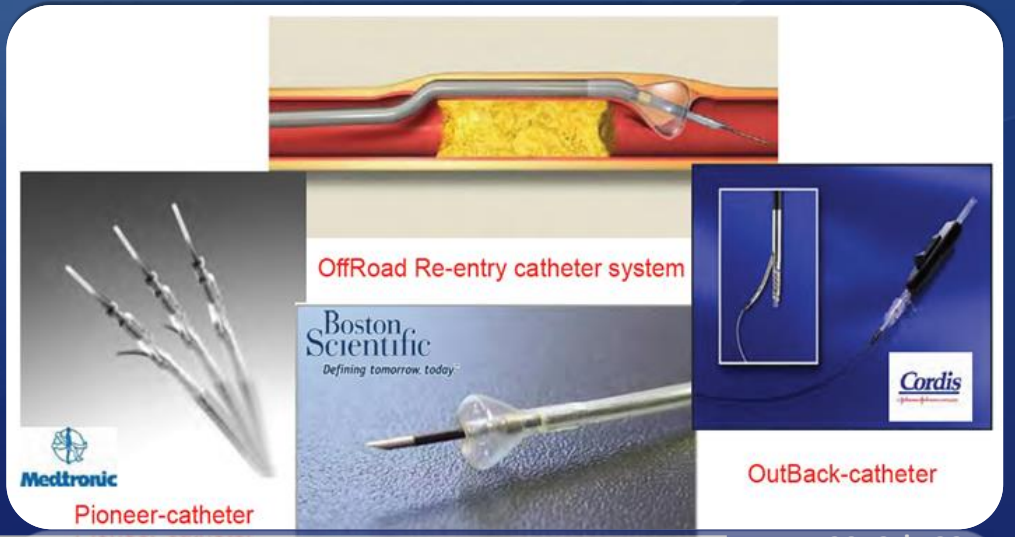




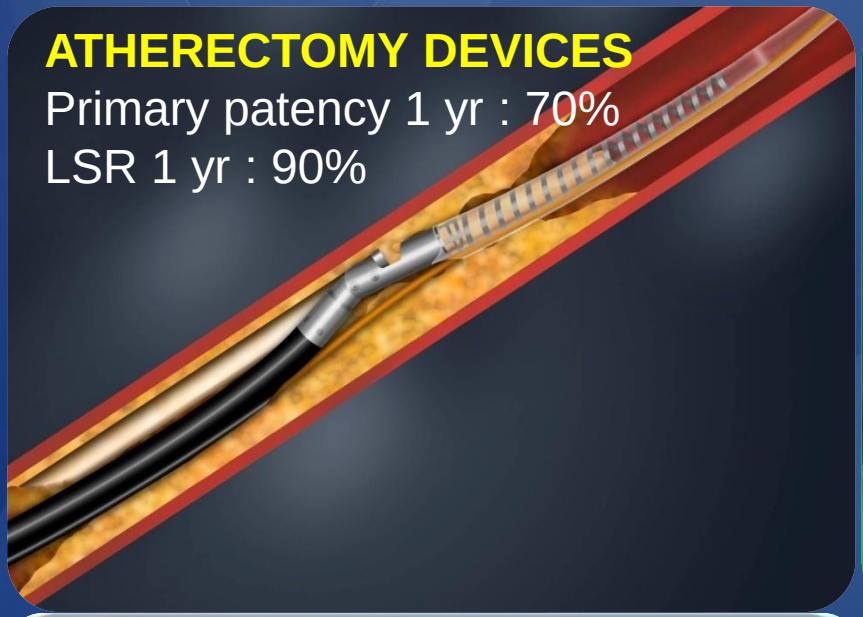
…more and more improvements in the endovascular approach… CTO devices







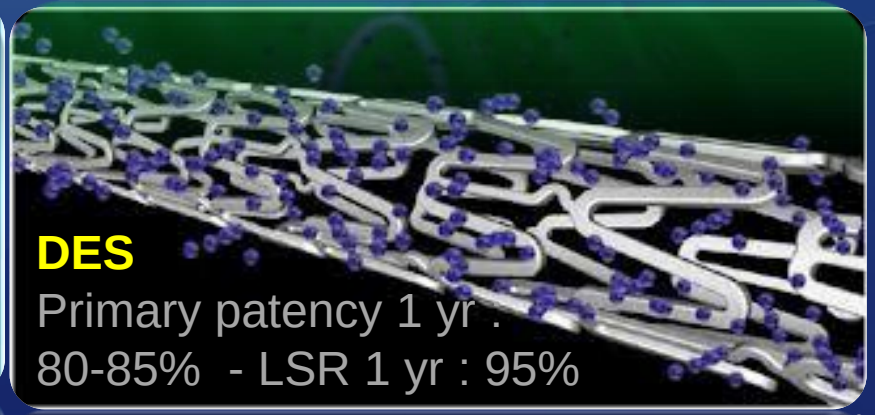
…more and more improvements in the endovascular approach… **treatment devices**



ATHERECTOMY DEVICES
Primary patency 1 yr : 70%
LSR 1 yr : 90%

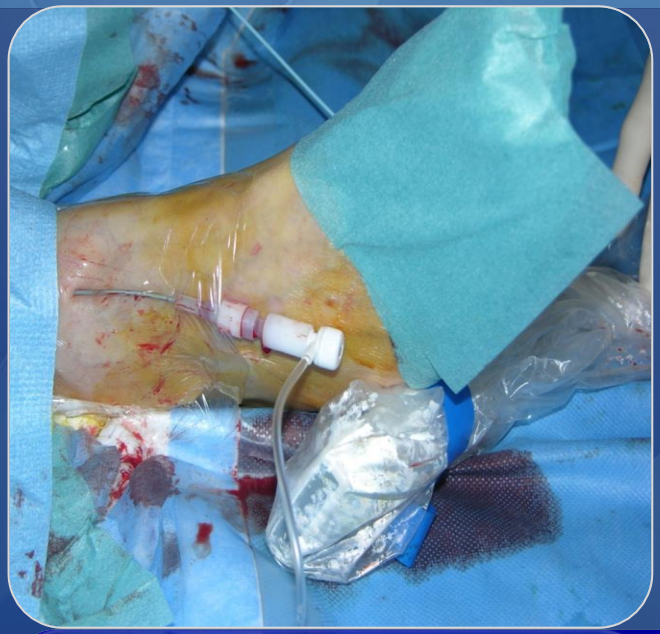
DCB
Primary patency 1 yr : 80%
LSR 1 yr : 95%

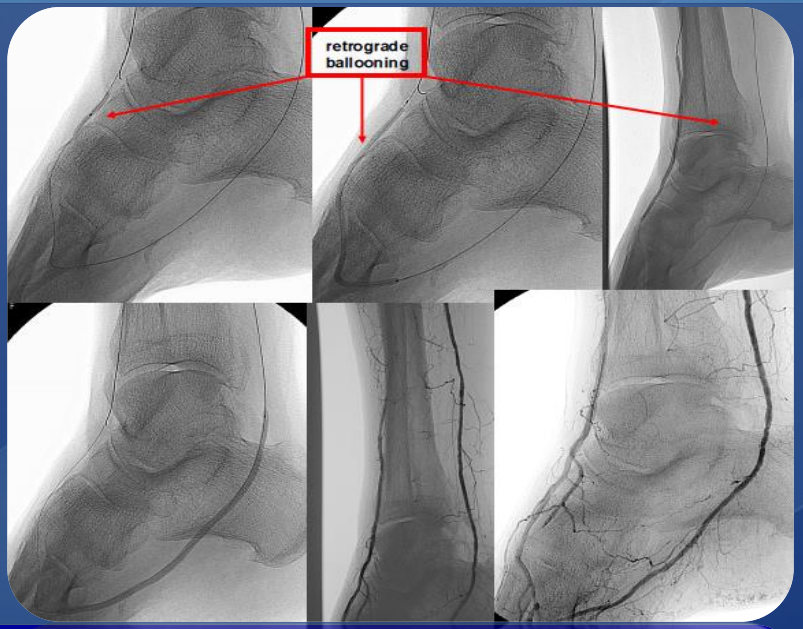
RESORBABLE SCAFFOLDS
Primary patency 1/2 yr : 85%
LSR 1 yr : na

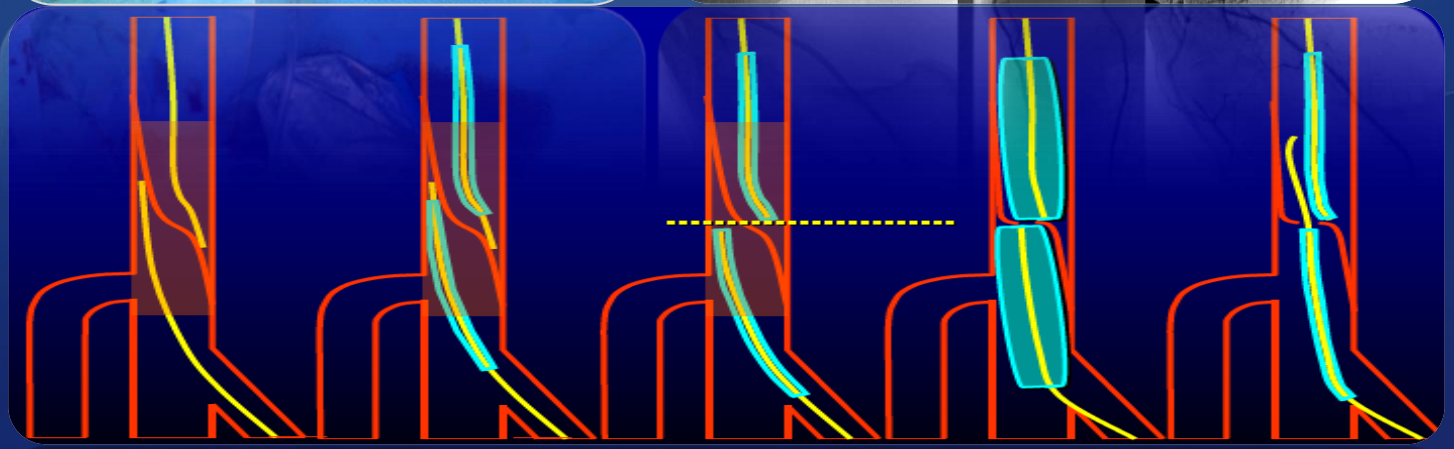


DES
Primary patency 1 yr :
80-85% - LSR 1 yr : 95%

…more and more improvements in the endovascular approach… techniques

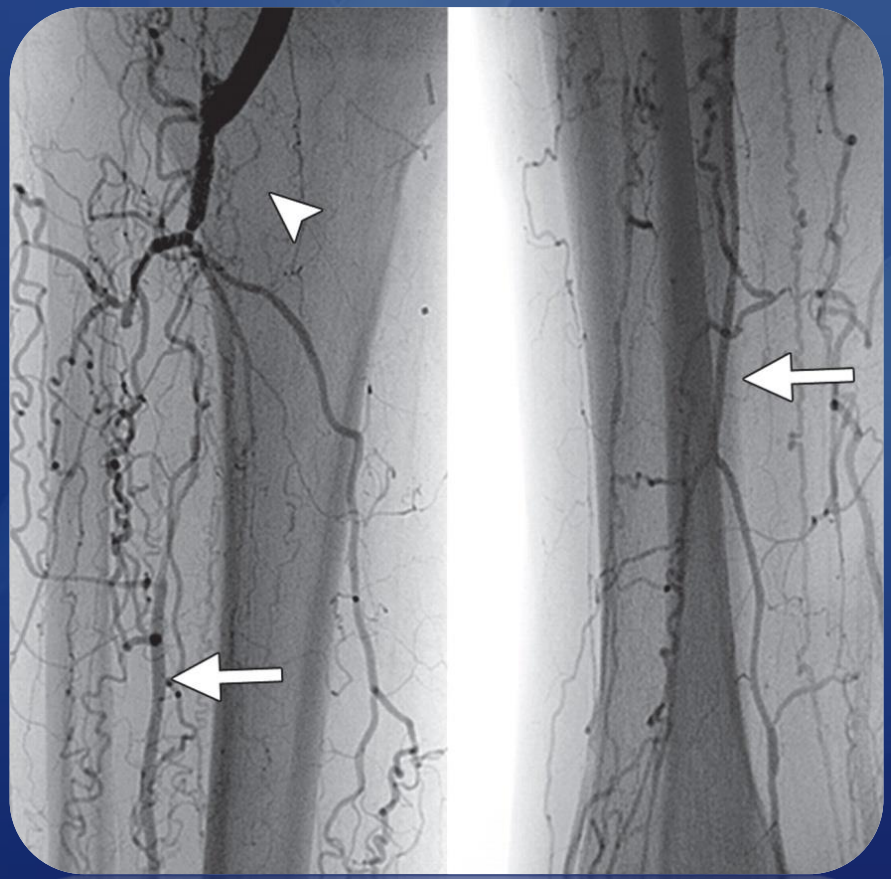


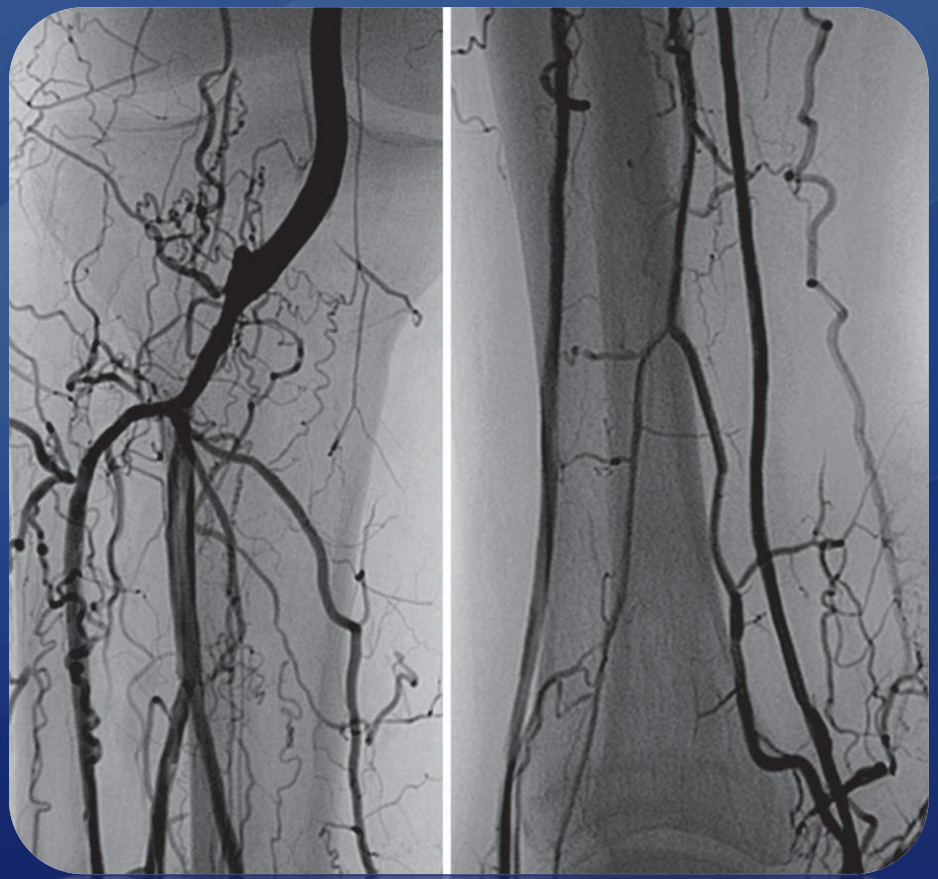




…more and more improvements in the endovascular approach… techniques

Multiple vessel recanalization





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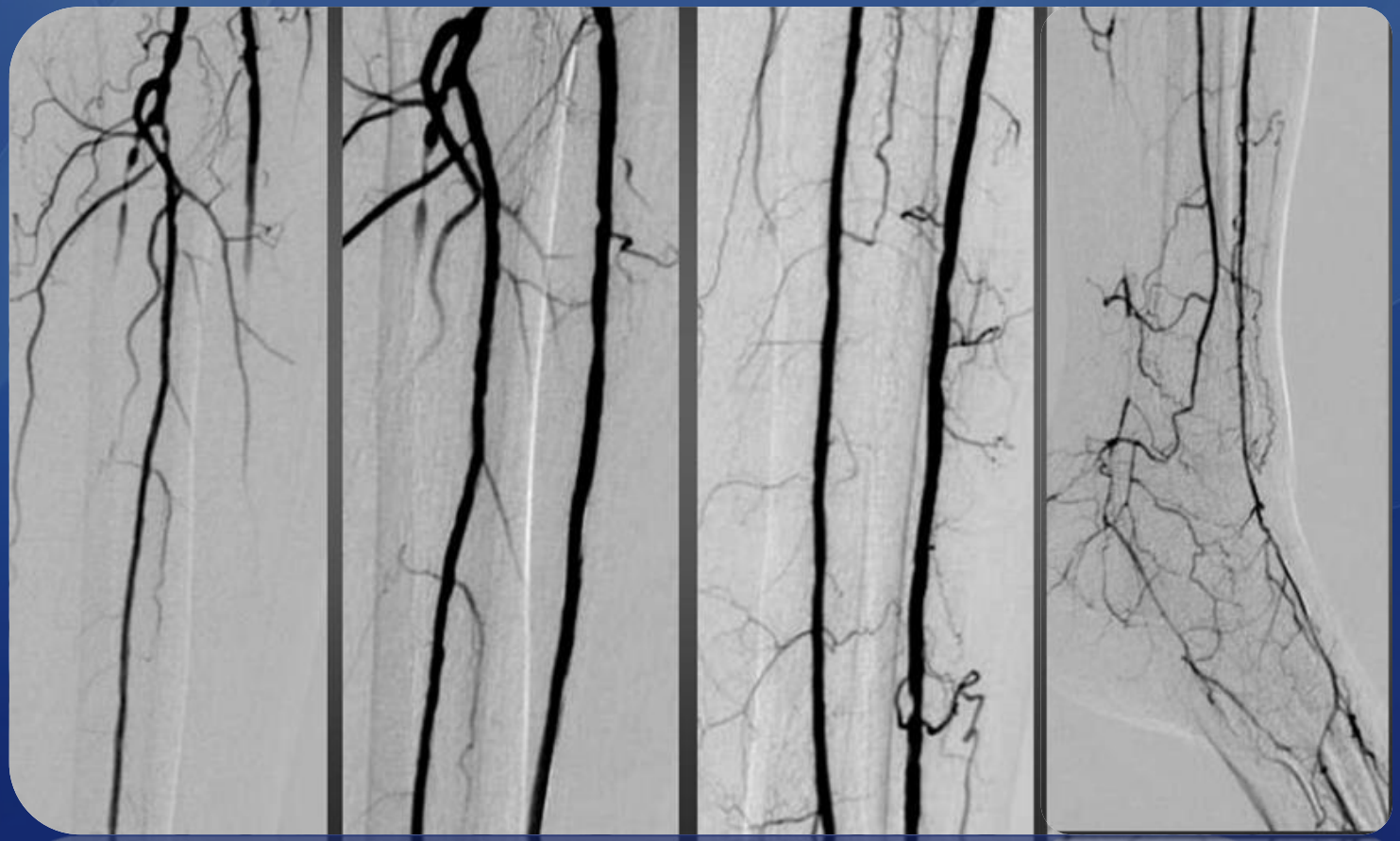

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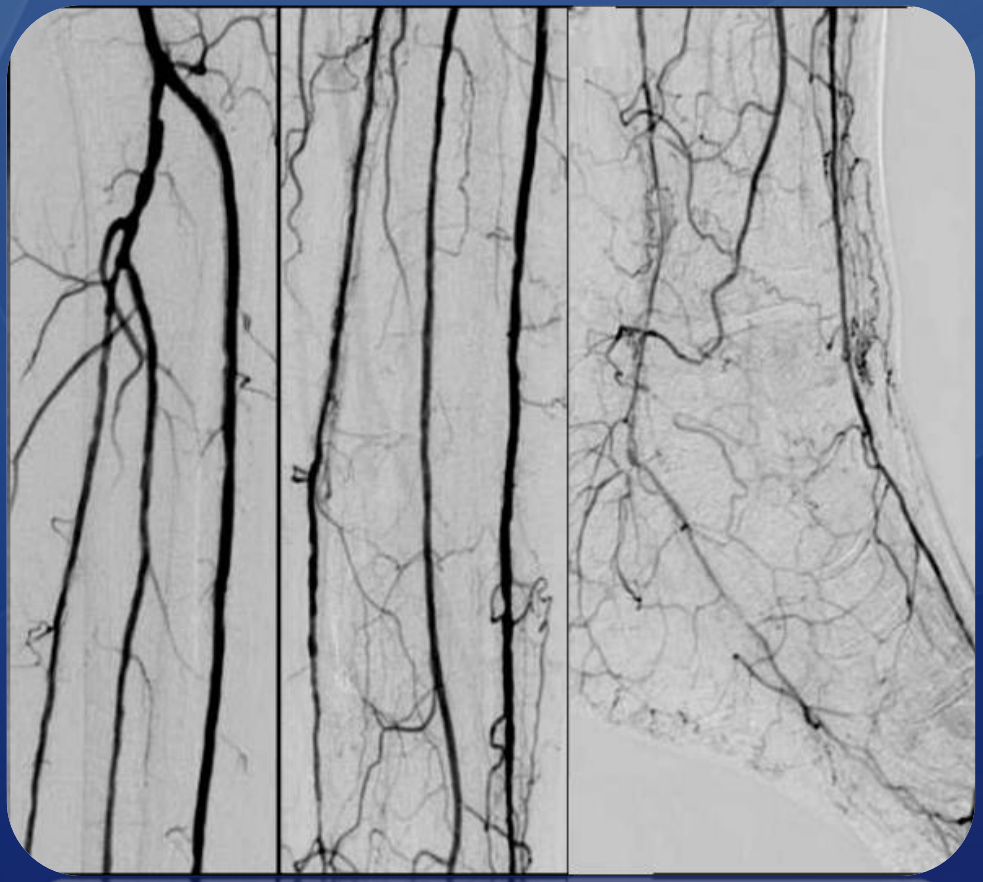
Multiple vessel recanalization



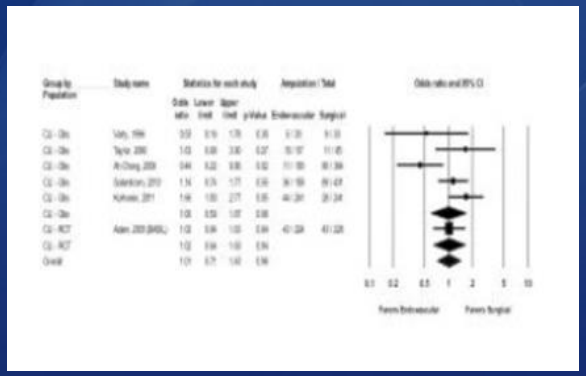
And also literature follows the evolution…

COMPARATIVE EFFECTIVENESS OF ENDOVASCULAR OR SURGICAL REVASCULARIZATION IN PATIENTS WITH CRITICAL LI

William Schuyler Jones; Rowena J. D
Subherwal; Brooke Heidenfelder; Eliz

[+] Author Information

J Am Coll Cardiol. 2013;61(10_S):. d



Background

Background | Methods | Results | Discussion

For patients with critical limb ischemia (CLI), the optimal revascularization method to preserve limbs, prevent death, and improve functional status is unknown. We systematically reviewed the literature assessing the comparative effectiveness and safety of endovascular and surgical revascularization in patients with CLI.

Methods

Background | Methods | Results | Discussion

Two investigators screened each abstract and full–text article for inclusion, abstracted the data, and performed quality ratings and evidence grading. Random–effects models were used to compute summary estimates of effects.

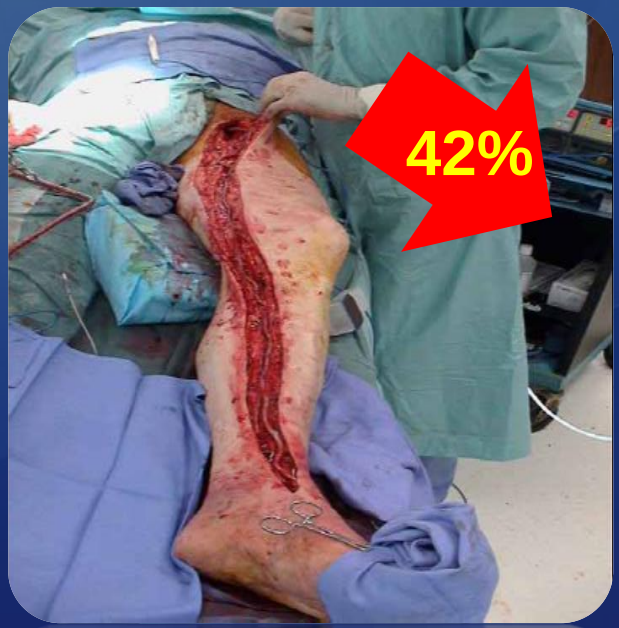
Results

Background | Methods | Results | Discussion

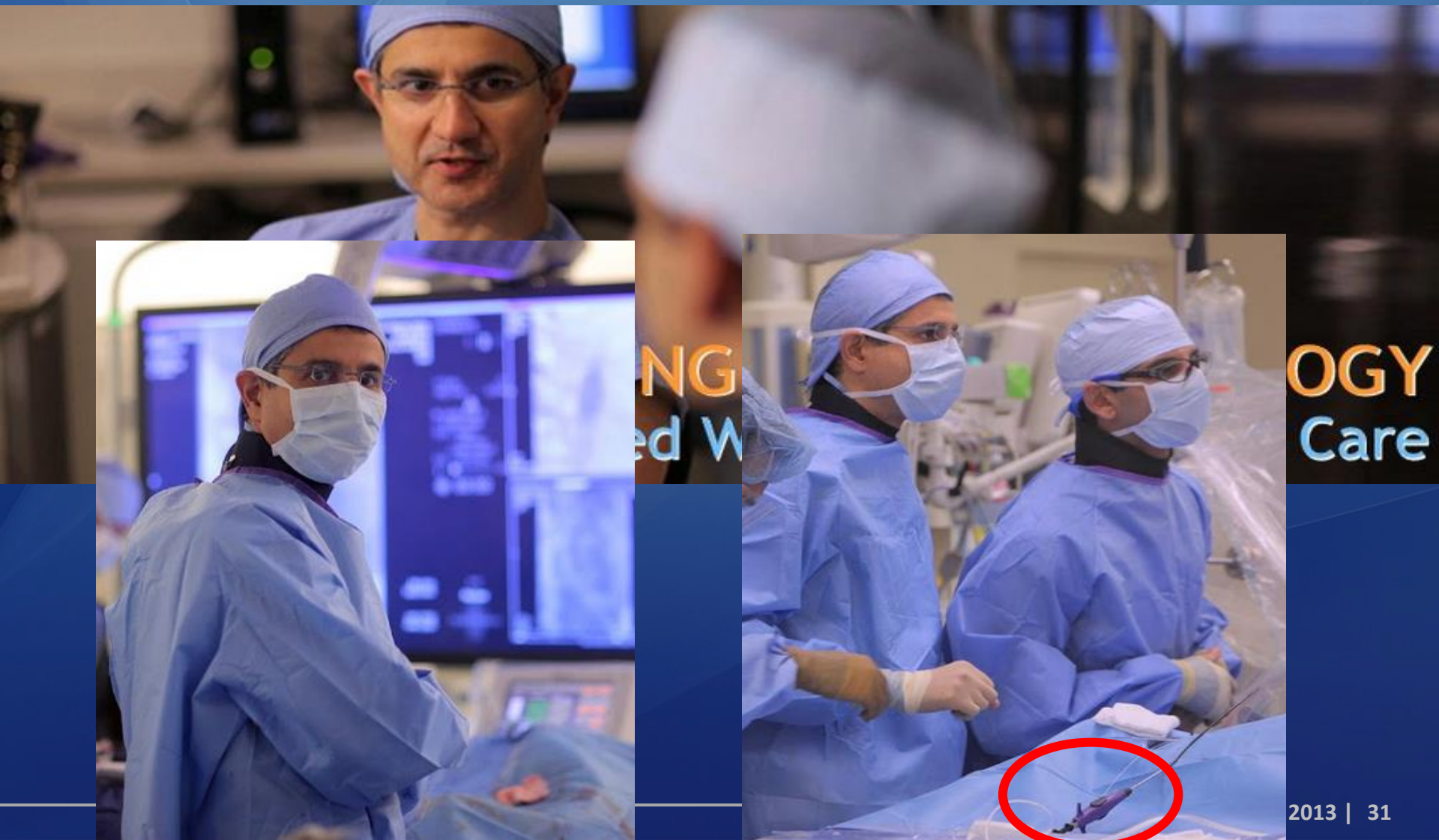
A total of 20 studies (1 randomized and 19 observational) in CLI patients evaluated the comparative effectiveness of endovascular and surgical revascularization therapies. Meta–analysis of the studies showed no difference in lower extremity amputation up to 3 years between endovascular and surgical revascularization [OR (95% CI); 1.01 (0.71–1.43), p=0.96; Figure 1].

And also the community follows the evolution…

Between 1996 and 2006, the number of endovascular lower-extremity interventions in the Medicare population reportedly increased by **230%**, whereas the number of bypass procedures decreased by **42%**



And also my opponent follows the evolution…



And is very successfull in this new evolution…

▲ **Firas Mussa, MD**
New York University
Project title: *Patient-Centered Outcomes for Endovascular Interventions in Critical Limb Ischemia*

…And even promotes the endovascular approach in the literature…

AN INTERVIEW WITH …

Firas F. Mussa, MD, MS, FACS

Dr. Mussa shares his insights on the future of TEVAR for uncomplicated type B aortic dissection, percutaneous EVAR, and treatment options for CLI.

Will TEVAR be the treatment of choice for uncomplicated type B aortic dissection?

We are heading in that direction. Currently, TEVAR is associated with improved aortic remodeling at 2 years. In the near future, the 5-year results of the INSTEAD trial will be published. This will be a game changer as far as the role of TEVAR in uncomplicated type B aortic dissection. Furthermore, new imaging software dedicated to flow dynamics is going to play a critical role in selecting the appropriate patients for TEVAR. We will also witness a significant reduction in TEVAR-related complications such as stroke and retrograde dissection as a result. I am also very excited about the possible expansion of IRAD (International Registry of Aortic Dissection). This can facilitate data sharing and the development of modern treatment paradigms that can best help our patients.

As smaller devices become available, what kind of changes can we expect in terms of who is performing EVAR and how it is being performed?

I do not expect a major shift in who is performing EVAR just because the sheath size is getting smaller. This is mostly governed by referral patterns and institutional policies. With smaller devices, however, more vascular surgeons are likely to adopt percutaneous EVAR (PEVAR). I believe that vascular surgeons currently lag behind other specialists when it comes to using closure devices in general and for larger sheaths specifically. If this trend continues, I imagine that patients are going to demand the "no incision" aneurysm repair and create another shift in referral away from vascular surgeons. I also believe that PEVAR is associated with faster recovery, less blood loss, and ultra-short length of stay. I anticipate that in the near future, a cutdown will be the exception rather than the rule!

What are the current recommendations for open bypass versus endovascular repair for critical limb ischemia (CLI)?

As of today, for those who have a suitable autologous vein conduit and life expectancy that is more than 2 years, open bypass is superior, more durable, and possibly more cost effective than endovascular intervention. Unfortunately, many of our patients have less than 2 years life expectancy with no suitable vein, so endovascular intervention becomes the default first line of therapy. Having said that, I am an endovascular enthusiast and believe that the below-the-knee (BTK) vascular bed deserves special attention. We are seeing less balloon angioplasty as a standalone therapy for CLI and more drug-eluting stents, drug-coated balloons, atherectomy, retrograde tibial punctures, etc. My personal views are that vascular surgeons need to embrace and validate the newer technologies if they are to remain competitive in this field.

What can be done to avoid poor outcomes for open revascularization if an endovascular treatment has been performed previously?

It makes intuitive sense that repeat intervention is associated with biologically aggressive disease. We have shown that patients who undergo bypass after a failed initial endovascular intervention have worse limb salvage rates; this will be presented at the 2012 Eastern Vascular Society meeting. I think this might be related to the delay or reluctance in offering open bypass in favor of an endovascular approach. Not surprisingly, however, there remains a significant proportion of patients who are first treated with endovascular intervention requiring an open procedure at some point down the line. Anecdotally, the two most problematic patients are those with end-stage renal disease and/or diabetes. One is worse with endovascular (end-stage renal disease), and one is worse with open revascularization (diabetes). Furthermore, medical therapy has undergone significant transformation with high-dose statins and dual antiplatelets; the outcomes of both open and endovascular interventions have somehow improved.

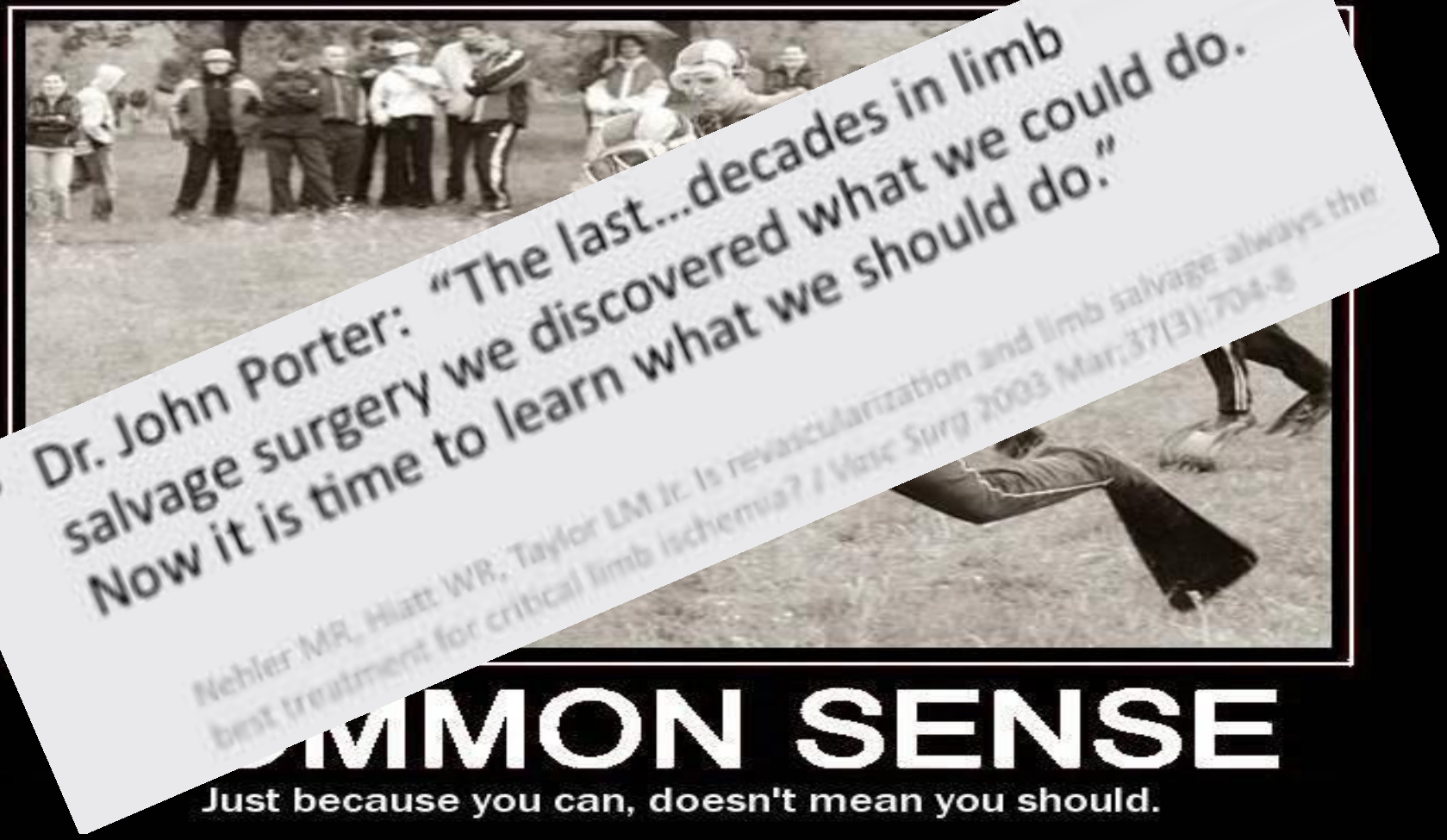
How does plaque characterization guide therapy for patients with asymptomatic carotid disease?

Using FDG-PET MR/CT fusion technology to study "vulnerable" plaque in patients with carotid disease is bound to take off. It picks up inflammation in macrophages inside the plaque as increased signal uptake and superimposes the images from PET with MR or CT scan. We have also shown that statins modify this process in the carotid artery in a dose-dependent manner. With the debate over intervention for asymptomatic carotid disease (CEA and CAS) nowhere near settled, I believe

(Continued on page 86)

cular intervention becomes the default first line of therapy. Having said that, I am an endovascular enthusiast and believe that the below-the-knee (BTK) vascular bed deserves special attention. We are seeing less balloon angioplasty as a standalone therapy for CLI and more drug-eluting stents, drug-coated balloons, atherectomy, retrograde tibial punctures, etc. My personal views are that vascular surgeons need to embrace and validate the newer technologies if they are to remain competitive in this field.

CONCLUSION


• Dr. John Porter: "The last...decades in limb salvage surgery we discovered what we could do. Now it is time to learn what we should do."
Nehler MR, Hiatt WR, Taylor LM Jr. Is revascularization and limb salvage always the best treatment for critical limb ischemia? J Vasc Surg 2003 Mar;37(3):704-8
MMON SENSE
Just because you can, doesn't mean you should.