

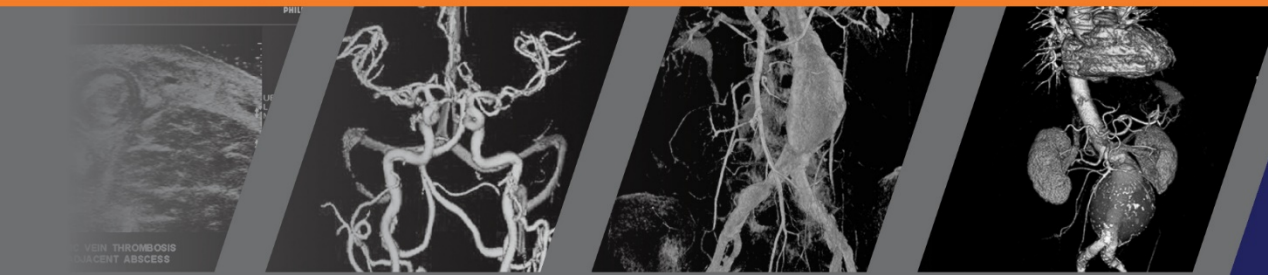
# 2019 MID-ATLANTIC CONFERENCE

## 9th ANNUAL CURRENT CONCEPTS IN VASCULAR THERAPIES

# 2019

Hilton Virginia Beach Oceanfront  
Virginia Beach, Virginia

MAY 2-4



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## 9th ANNUAL CURRENT CONCEPTS IN **VASCULAR THERAPIES**

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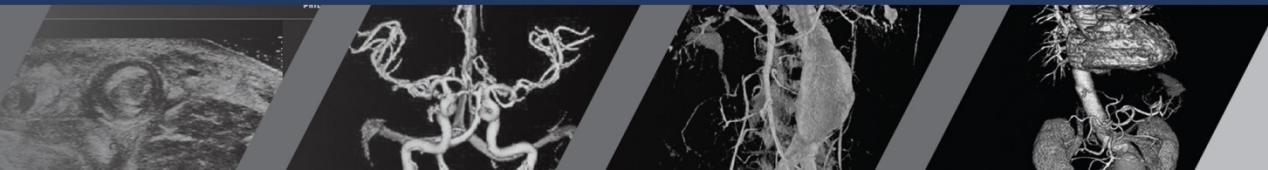


- Tarkten A. Pharr, MD, FACS
- Sentara Vascular Specialists
- Sentara Albemarle Medical Center

Debate 3: 55 Year Old  
Smoker with 2 Block  
Claudication and SFA  
Occlusion **Should Be  
Offered Endovascular  
Therapy**

# Debate 3: Percutaneous Therapy

- No Disclosures



# Debate 3: Percutaneous Therapy

- Pertinent facts and questions regarding the management pathway for this hypothetical patient:
  - PAD is a strong predictor of adverse cardiovascular and overall outcome<sup>1</sup>
  - What is the expected longevity of this 55 yo active smoker with claudication?
  - What is the expected outcome of each option: medical therapy, endovascular therapy, traditional open surgery?
  - What are the risks and costs of each chosen therapeutic pathway?
  - If endovascular is chosen, what is the best modality?

1. Diehm, C, et al. Mortality and vascular morbidity in older adults with asymptomatic versus symptomatic PAD. *Circulation* 2009; 120:2053.





# Debate 3: Percutaneous Therapy

- Natural History of Claudication (Symptomatic PAD)<sup>1</sup> over 5 years:
  - Only about a quarter of patients with IC (intermittent claudication) will ever significantly deteriorate, so roughly 70-80% remain stable<sup>2</sup>
  - Only 1 to 3.3% of patients with IC need major amputation over a 5 year period<sup>1</sup>
  - Difficult to predict the risk of deterioration in a *recent* claudicant.<sup>1</sup>
  - Changing ABI is possibly the best predictor of those needing intervention
  - **Death in 15-30% (75% due to cardiovascular disease) over 5 years<sup>2</sup>**
  - The importance of PAD as a marker for coexistent CAD cannot be overstated<sup>2</sup>
  - In addition to high M&M, patients with IC have a poor quality of life and high rates of depression. The adverse impact of IC on the patient's physical and emotional well-being appears to be directly related to walking ability<sup>2</sup>
- 1. Norren, L., et al. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II), JVS, Jan 2007, pg. S5A-S67A
- 2. Harris, Linda, et al. Epidemiology, risk factors, and natural history of peripheral artery disease, Up to Date, Feb. 2019

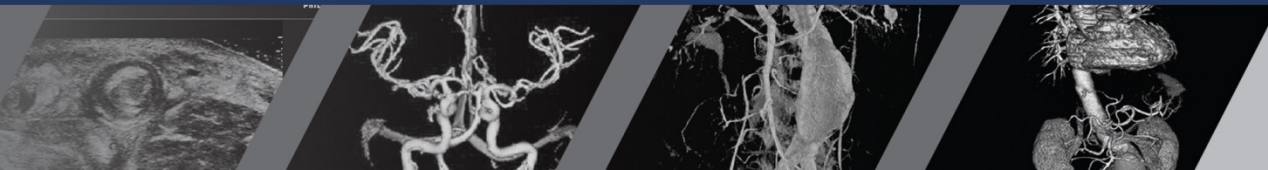


# Debate 3: Percutaneous Therapy

- More about the CV risk over time in this cohort:<sup>1</sup>
  - 5 yr morbidity and mortality (all causes): 15-30%
  - 10 yr morbidity and mortality 50%
  - 15 year morbidity and mortality 70%

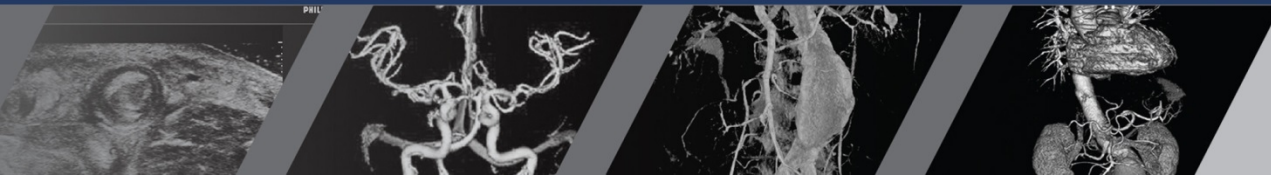
This is what we are looking at for this 55 yo patient

1. Norgren, L. et al. Inter Society Consensus for the Management of Peripheral Arterial Disease (TASCII), Journal of Vascular Surgery, January 2007, pg. S5A-S67A



# Debate 3: Percutaneous Therapy

- So, have a 55 yo patient, actively smoking, 2 block claudication. What are our shared (Doctor/provider//patient) goals?
  - Maximize risk factor modification treatment (to treat systemic burden of disease), educate patient for best outcome, regardless of course prescribed
  - What are the patient's expectations? This may vary widely, changing potentially what is offered, as the risk/benefit profile will vary, patient to patient
  - Maximize Quality of life/Productivity @ age 55 into the future
  - Do No Harm!



# Back to the debate: what to do

## Medical:

- no procedural complications
- minimal chance of progression if strictly adherent (stay at two blocks)
- can always reassess
- Most success is had with patients without DM or renal dysfunction<sup>1</sup>

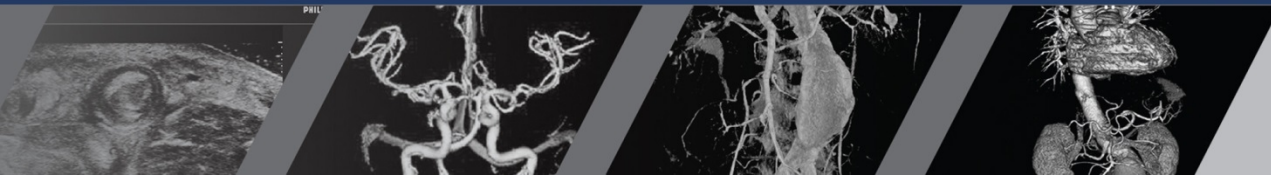
## Endovascular:

- minimally invasive
- outpatient
- minimal recovery period
- can be repeated, if necessary
- patency rates of primary procedures varying, but increasing incrementally as technology and techniques improve

## Femoral popliteal BPG, rGSV or in situ:

- 65% primary patency rate at 5 years<sup>2</sup>
- Cumulative graft patency at 5 years was 88% (so including all reinterventions)
- estimated that vein graft stenosis develops in 20-30% of infrainguinal vein bypasses during the first year, which can lead to graft thrombosis and failure, necessitating an intervention of some type<sup>2</sup>

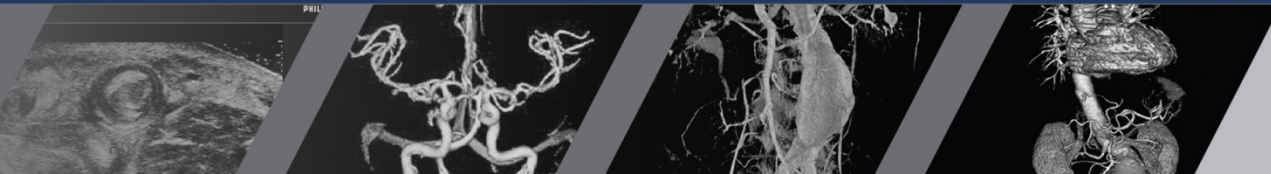
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# Debate 3: Percutaneous Therapy

- So, they have maximized medical therapy:
  - Is a standalone therapy, but also cornerstone of good endovascular and/or surgical outcome
  - Smoking abstinence
  - Supervised walking program
  - Statin, antithrombotic, BP, DM, anticoagulant, etc
- But, our hypothetical patient comes back in 3 months, no better, frustrated, feels nonproductive. Now what?



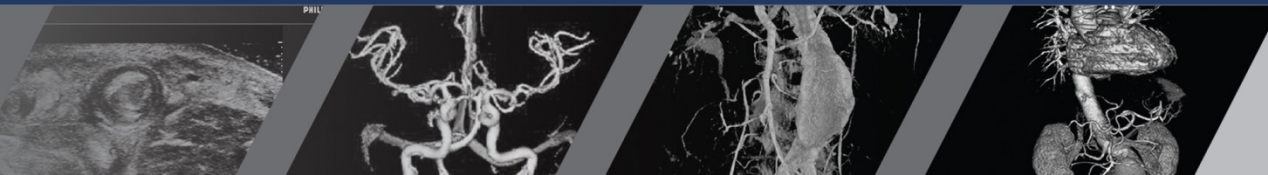
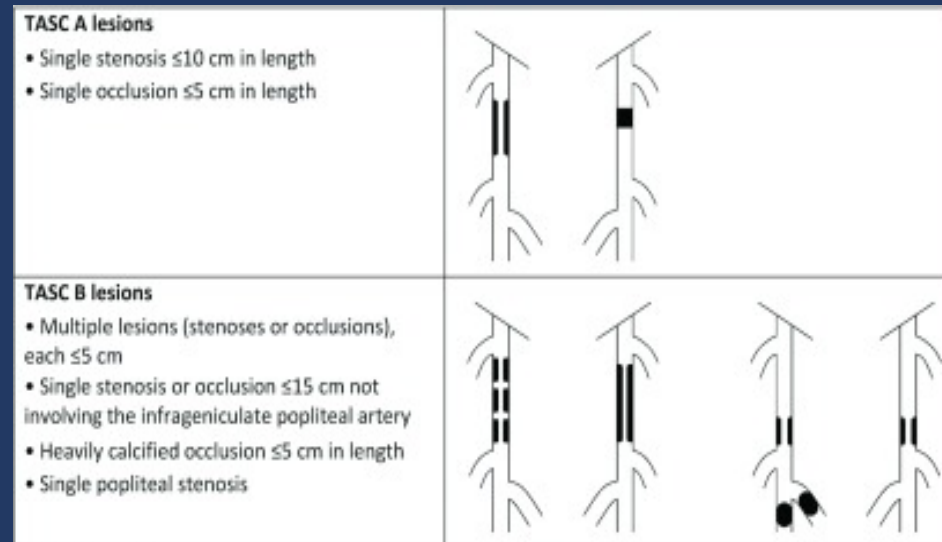
# Debate 3: Percutaneous Therapy

- So we have a 55 yo active smoker with a 15—30% chance of mortality in 5 years, and quality of life diminished with 2 block claudication, but 70-80% chance this will remain unchanged (possible less than this, as still smoking)
- So if any consideration made to intervening, has to make sense from risk/reward standpoint
- First rule of medicine: Do No Harm
- Two very important details impacting outcome and potential course of action recommended in this patient:
  - Will this patient continue to smoke?
  - What does the SFA occlusion look like?



# Debate 3: Percutaneous Therapy

- **Not all SFA lesions are equal**
  - TASC Classification for SFA disease:
    - Type A:
      - Single stenosis  $\leq 10$  cm in length
      - Single occlusion  $\leq 5$  cm in length
    - Type B:
      - Multiple lesions (stenosis or occlusions), each  $\leq 5$  cm
      - Single stenosis or occlusion  $\leq 15$  cm, not involving the infrageniculate popliteal artery
      - Single or multiple lesions in the absence of continuous tibial vessels to improve inflow for a subsequent distal bypass
      - Heavily calcified occlusion  $< 5$  cm in length
      - Single popliteal stenosis



# Debate 3: Percutaneous Therapy

## TASC II Classification (SFA):

### Type C lesions:


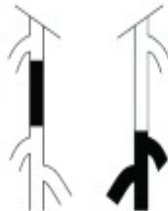
-Multiple stenosis **or** occlusions totaling **> 15 cm** with or without heavy calcification

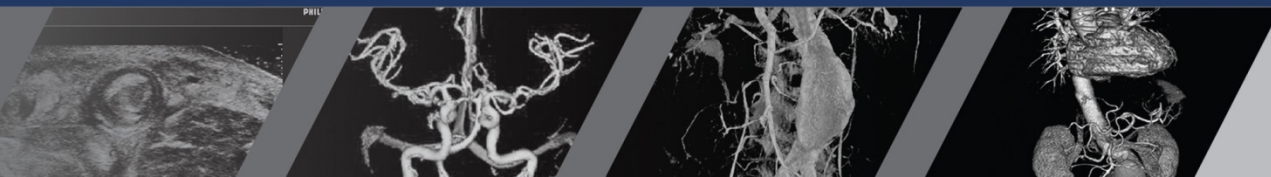
-Recurrent stenosis or occlusions that need treatment after **two** endovascular interventions

### Type D lesions:

Chronic total occlusion of CFA or SFA (>20 cm, involving the popliteal artery)

Chronic total occlusion of popliteal artery and proximal trifurcation vessels

<b>TASC C lesions</b> <ul style="list-style-type: none"><li>• Multiple stenoses or occlusions totaling &gt;15 cm with or without heavy calcification</li><li>• Recurrent stenoses or occlusions after failing treatment</li></ul>	
<b>TASC D lesions</b> <ul style="list-style-type: none"><li>• Chronic total occlusions of CFA or SFA (&gt;20 cm, involving the popliteal artery)</li><li>• Chronic total occlusion of popliteal artery and proximal trifurcation vessels</li></ul>	

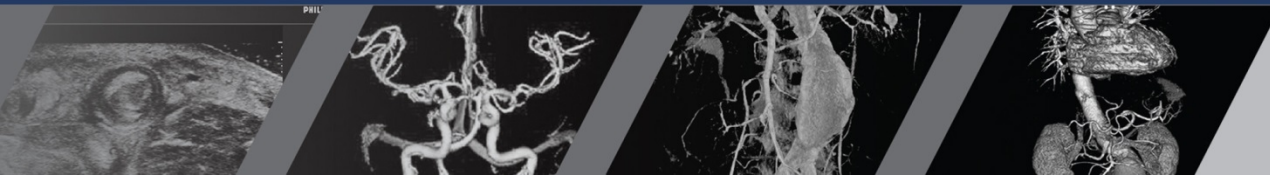




# Debate 3: Percutaneous Therapy

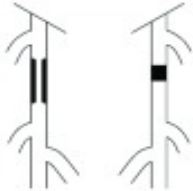
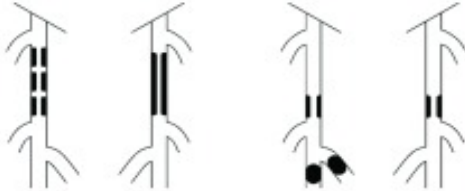

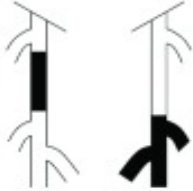
- What does the data say about efficacy of percutaneous intervention in these SFA TASC A to D lesions?
  - A paucity of well controlled randomized clinical trials
  - Technological evolution/advancements may quickly result in out of date comparisons
  - In practical terms, management of fempop (SFA) disease is as follows:
    - Endovascular first strategy, depending on lesion complexity, availability of autologous conduit, patient condition, and center experience.
    - Bypass reserved for complex, extensive lesions, provided that the patient's health status suggests > 2 year survival

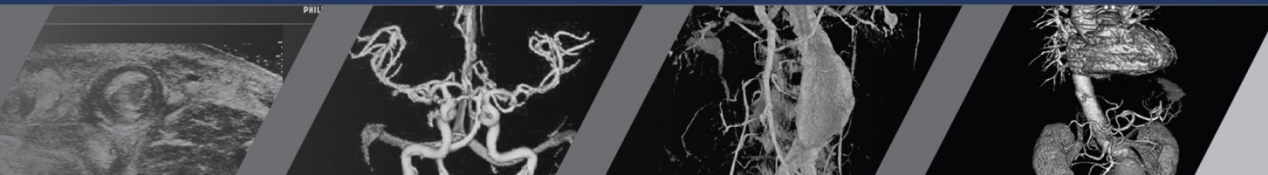
Jaff, MR, et al, An Update on Methods for Revascularization and Expansion of the TASC Lesion Classification to Include Below the Knee Arteries: A supplement to the Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II), Ann Vasc Dis. 2015; 8(4): 343-357.



# Debate 3: Percutaneous Therapy

- So back to the 55 y.o.
  - What is the TASC lesion in the SFA?
    - A: -Single focal stenosis  $\leq 10$  cm  
-Single occlusion  $\leq 5$  cm
    - B: -Multiple lesions (stenosis or occlusion), each  $\leq 5$  cm  
-Single stenosis or occlusion  $\leq 15$  cm not involving the infrageniculate popliteal artery  
-Single or multiple lesions in the absence of continuous tibial vessels to improve inflow for a distal bypass  
-Heavily calcified occlusion  $\leq 5$  cm in length (not depicted)  
-Single popliteal stenosis

<p><b>TASC A lesions</b></p> <ul style="list-style-type: none"> <li>• Single stenosis <math>\leq 10</math> cm in length</li> <li>• Single occlusion <math>\leq 5</math> cm in length</li> </ul>	
<p><b>TASC B lesions</b></p> <ul style="list-style-type: none"> <li>• Multiple lesions (stenoses or occlusions), each <math>\leq 5</math> cm</li> <li>• Single stenosis or occlusion <math>\leq 15</math> cm not involving the infrageniculate popliteal artery</li> <li>• Heavily calcified occlusion <math>\leq 5</math> cm in length</li> <li>• Single popliteal stenosis</li> </ul>	
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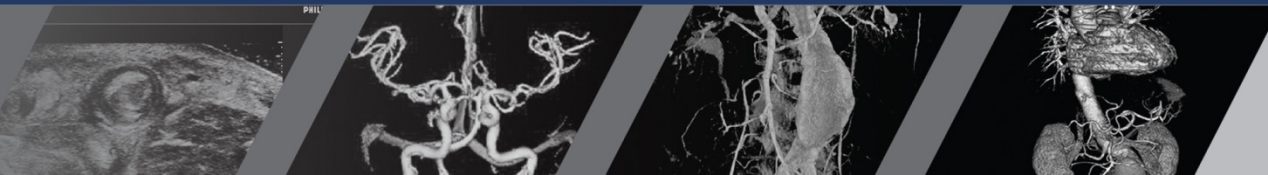


# Debate 3: Percutaneous Therapy

- More recently, metaanalysis by Katsanos:
  - Was a review of 28 RCT with 4663 patients, 24 of which were DCB, 4 were DES
  - Studies reviewed: \*ZILVER PTX (2011), THUNDER (2008), INPACT SFA (2015), FEMPAC (2008), LEVANT I (2012), LEVANT II (2015), ILLUMENATE EU (2017), CONSEQUENT (2017), ISAR-STATH (2017), ISAR-PEBIS (2017), IN.PACT SFA JAPAN (2018), ACOART I (2016), \*FINN-PTX (2018), \*BATTLE (2018), \*DEBATE in SFA (2018), DEBELLUM (2014), PACIFIER (2012), FAIR (2015), BIOLUX P-1 (2015), RANGER-SFA (2018) ILLUMENATE pivotal (2017), DEBATE-SFA (2013), LUTONIX JAPAN (2018), RAPID (2017)EFFPAC (2018), PACUBA (2016), FREEWAY (2017), DRECOREST (2018)
  - Increased risk of death following application of Paclitaxol coated balloons and stents in the Femoropopliteal artery
  - This was seen in the INPACT-DEEP (involved below the knee, CLI patients, compared with POBA)
    - Increased rates of major amputation
    - Increased late mortality (DEB and DES vs plain balloon angioplasty (POBA))
  - Actual causes unknown, further clinical investigation urgently warranted

\* Denotes DES study

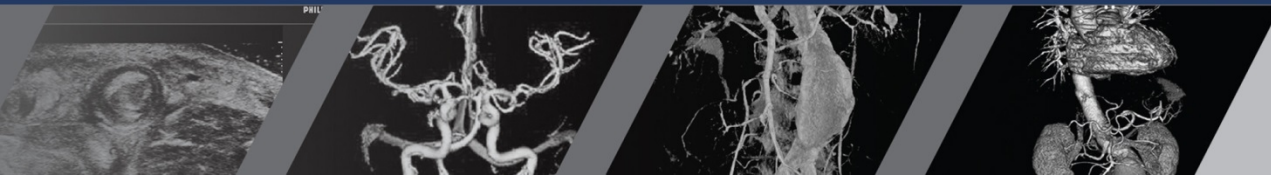
Katsanos, K, et al. Risk of Death Following Application of Paclitaxel-Coated Balloons and Stents in the Femoropopliteal Artery of the Leg: A Systematic Review and Meta-Analysis of Randomized Controlled Trials, Jour. Of Amer. Heart Assn, Dec. 6, 2018.



# Steady endovascular improvement with multiple modalities:

- Zilver PTX trial: Dr Dake (11/6/18): “after **5 yr**, Zilver PTX has sustained benefit compared to standard of care with 72.4% primary patency rate”
- DEB: **3 yr** results demonstrate DCB>standard PTA, with higher primary patency and lower TLR, resulting in similar functional improvements with reduce need for repeat interventions.<sup>1</sup>
- Interwoven nitinol biomimetic stent: at 2 and 3 years, freedom from TLR 84 and 82%, respectively
- Covered PTFE stent: 97% 3 yr **secondary** patency for complex lesions (**27 cm** average length, 93% CTO), 2014
- No single or combination of modalities has demonstrated superiority, and a paucity of true head to head trials, and many are employed concurrently

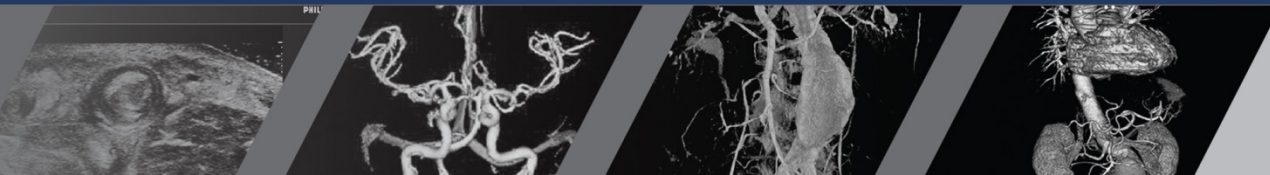
1. Schneider PA, et al. Treatment of Drug-Coated Balloons is Durable to 3 years in the Femoropopliteal Arteries: Long-Term Results of the IN.PACT SFA Randomized Trial. Circ Cardiovasc Interv. 2018.
2. Garcia, LA. et al. SUPERB final 3-year outcomes using interwoven nitinol biomimetic supera stent. Catherter Cardiovasc Interv. 2017.





# Debate 3: Percutaneous Therapy

- A brief nonexhaustive history of endovascular therapies:
  - First cardiac angioplasty: 9/16/77 Gruentzig (Munich)
  - First cardiac stent, 1986 , Puel and Sigwart
  - First FDA approved stent for PAD, 1988
  - Multiple off label stents used for the SFA
  - By 1999, 82% of coronary intervention involved stents, and this was the year of the first sirolimus stent, Dr Edouad Sousa
  - 2002-2004 FDA approval of sirolimus (Cypher) and (Taxus)paclitaxel coronary stents
  - Resilient Trial: Bard Lifestent vs. PTA: 81% vs. 36% @1 yr
  - Summit Study: Epic stent vs. pta: freedom from TLR @ 1 yr, 92%
  - Zilver BMS trial 2008 showed superiority to POBA at one year and beyond
  - Silverhawk Directional Atherectomy, 2008
  - 2009 Spectranetics Turbo Tandem excimer laser FDA approved
  - 2013 to 2018 Zilver PTX trial (91% 1 yr freedom from TLR), and 72.4% primary patency rate
  - Supera stent (SUPERB study): final outcome after 3 yr: patency 89% 1 yr, 84% @2 yr, 82% @ 3 yr
  - In.PACT SFA: primary patency 1 yr (87%), 2 yr (79%), 3 yr (69%)



# Back to the debate: what to do

## Medical:

- no procedural complications
- minimal chance of progression if strictly adherent (stay at two blocks)
- can always reassess
- Most success is had with patients without DM or renal dysfunction<sup>1</sup>

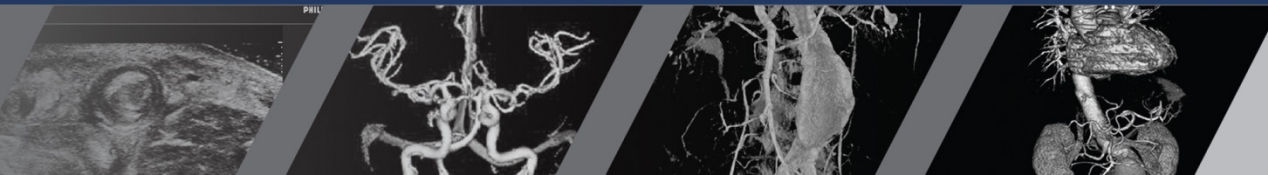
## Endovascular:

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## Femoral popliteal BPG, rGSV or in situ:

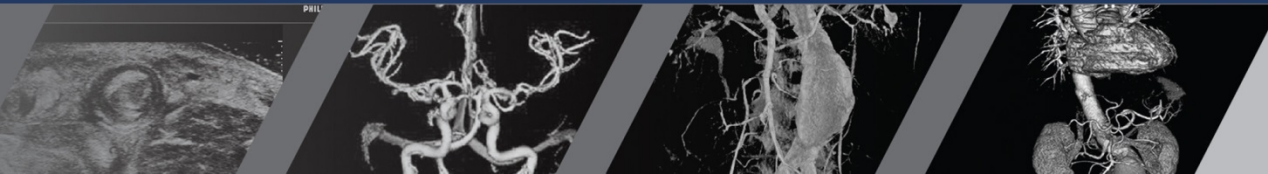
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2. Neschis, D, et al. Surgical Management of Claudication, UpToDate, current through 02/2019.



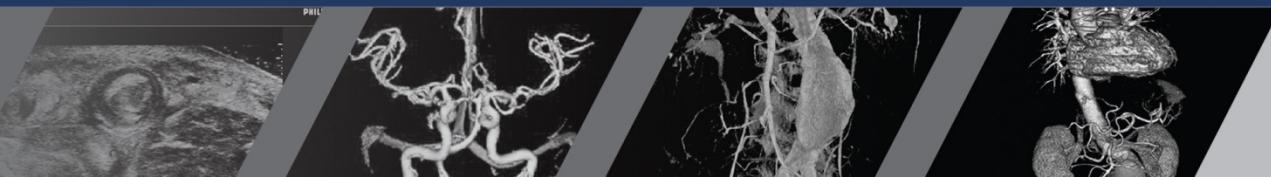
# What would you want?

- At 55 years of age, what are you willing to accept as far as level of function?
- Are you willing to accept 2 blocks, with possibly some improvement, with strict adherence to prescribed medical therapy and a structured walking program?
- Do you want more out of life, and at what risk?
- Do you want an open surgery, with attendant risks of pain, bleeding, graft failure, wound complication, and 65% patency rate at 5 yr, 82-93% assisted 5 yr patency rate (note: this means you required another procedure, open or endo, to achieve this)
- Do you want an outpatient endo procedure, little to no recovery period, minimal complication risk (EPD, closure devices), patency rates approaching open surgery (which frequently also needs “maintainance”)



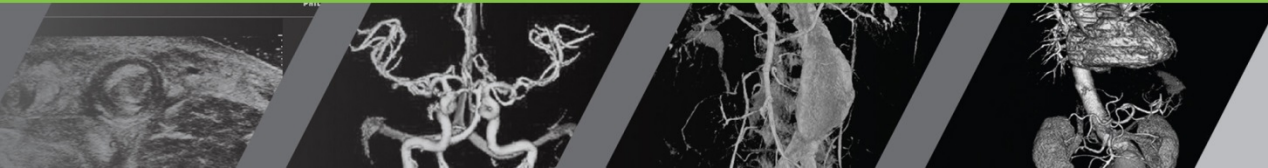
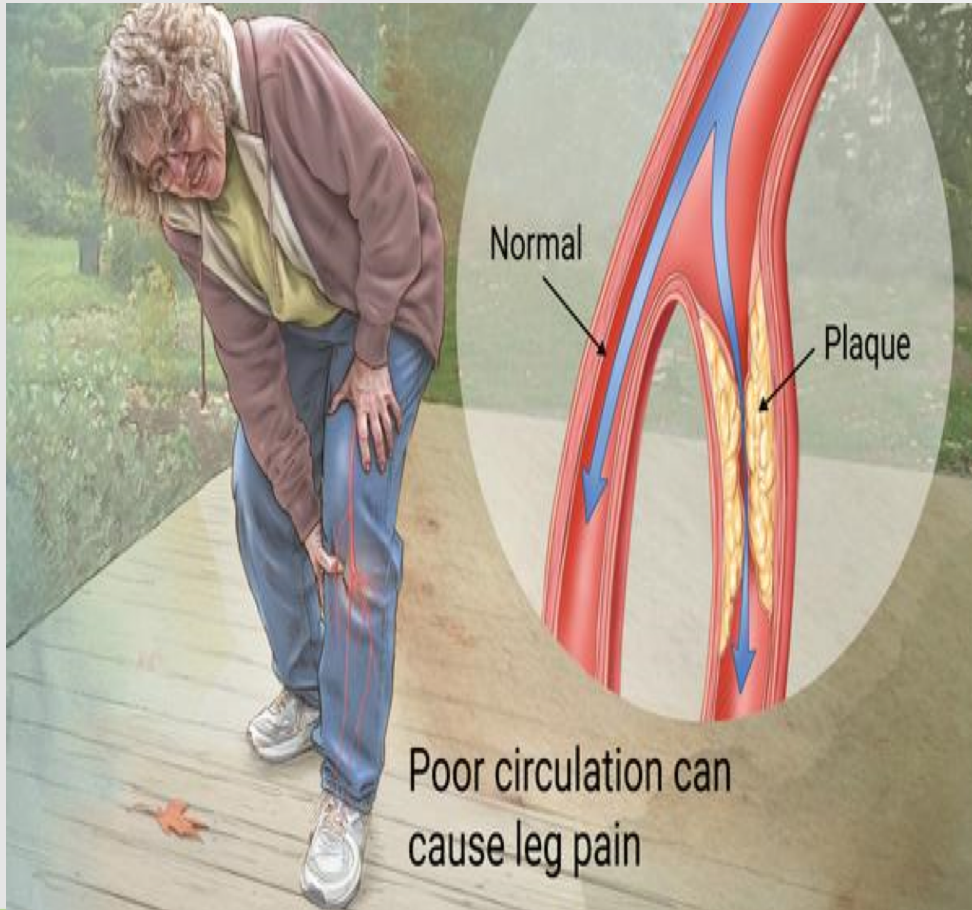
# Medical vs. Endo vs. Open Surgery

- In Summary:
  - This debate is occurring at a fixed point in time.....things will change, favoring endo
  - Currently TASC A and B can be offered as appropriate therapy, in the appropriate candidate (combined with medical optimization).
    - Failure of an endovascular intervention (i.e. closure) doesn't carry with it the down side that losing an open surgical bypass graft does.
    - Repeat intervention can usually be done safely
  - Human innovation will continue to develop new tools and improve existing technologies that are employed in the treatment of SFA disease
  - When we have options that are minimally invasive, with acceptable complication profile, can (or should) we encourage medical therapy only, with the potential that we are relegating these patients to a life with significant functional limitations placed on them?
  - Or recommend open surgery, which isn't without it's own significant risks in the short term and, as seen in the past, many times requires additional interventions to maintain durable patency and accompanying symptom relief?



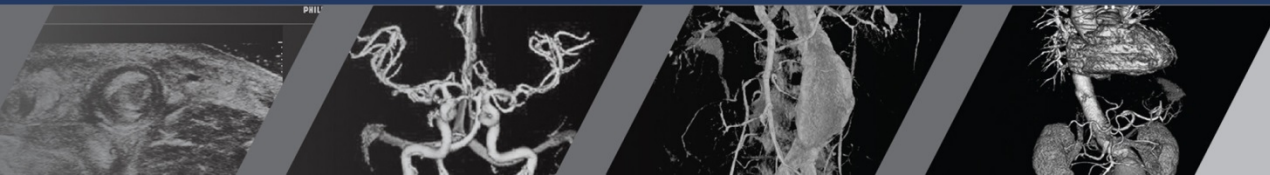


# Debate 3: Percutaneous Therapy



# Debate 3: Percutaneous Therapy

- Why Endo is a rational choice:
  - Minimal periprocedural risk
  - Outpatient procedure
  - Quick return to full function
  - redo if necessary, with sum of efforts equaling durable patency rates of open procedures (which also not infrequently require reintervention)
  - does not necessarily compromise surgical solutions, if done with this in mind (don't burn a bridge), so surgery can still be done if needed, with time 0 pushed back on the surgery, so overall limb salvage more likely
  - Costs likely comparable over time with single larger intervention (even if more than one procedure needed)
  - Allows return to productivity in the workplace, satisfaction in private life, less depression issues
  - Percutaneous technologies for use in the SFA will continue to improve, expanding indications for use (TASC C?, then D?)
  - There will always be a role for surgery, but endo provides a very useful tool to maximize patient outcomes with minimal morbidity and recovery times
  - No procedure in the SFA is curative, thus the chosen treatment (medical, endo, open) is always about extending patency/function as long as possible...remember, this patient cohort has a somewhat ominous CV outlook, but we want to maximize QoL, with as little risk as possible, for as long as possible



# Debate 3: Percutaneous Therapy

