Controversies in Endovascular Peripheral Arterial Disease—Open vs. Endovascular
Endovascular strategies are superior

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Clinical Question  when I consider EVT

• When Considering EVT 3 considerations:
  — (1) What is the likelihood of technical success?
  — (2) What is the projected patency?
  — (3) Will any important collateral vessels or bypass targets be jeopardized in the attempt?

CLINICAL CONSIDERATIONS

• Lesion characteristics
  — Lesion length, morphology and location
    • Stenosis Vs Occlusion
    • Car++
    • Acute Stent occlusion Vs ISR
    • Aortoiliac,FIA,Fem pop, BK

• Patient Attributes
  — CAD, Cardiomyopathy, Stroke, DM, HTN, COPD, CKD
  — Risk of general anesthesia

• Quality and availability of venous conduit
• Patient preference
• Indication for intervention
  — IC, CLI or ALI
Key Definitions in EVT

- Definitions of long-term durability of endovascular procedures
  - **Primary patency**: exempt from restenosis of the target lesion during follow-up.
  - **Primary assisted patency**: patency of the target lesion following endovascular reintervention at the target vessel site in case of symptomatic restenosis.
  - **Secondary patency**: patency of the target lesion after treatment of a re-occlusion of the index lesion.
  - **Target lesion revascularization (TLR)**: reintervention at the index lesion site.
  - **Target vessel revascularization (TVR)**: if another lesion at the target vessel site but not the index lesion itself needs to be treated during follow-up this intervention.


TASC II lesion classification

Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II)
Surgical options for AIOD include direct aortic reconstructions (aortofemoral bypass [AFB], aortoiliac bypass, aortoiliac endarterectomy), which have proven to be most durable but also have significant morbidity and mortality.

In patients with suitable anatomy or those deemed to be at high risk for aortic surgery, or both, extra-anatomic bypasses (axillary-femoral [AxFB], iliac-femoral [IFB], femoral-femoral bypass [FFB]) are less morbid alternatives but are also less durable.
**AOID**

- EVT as primary treatment for more **focal** disease and **traditional surgery** for more **diffuse** disease.
- Improvements in technology and EVT have resulted in replacing open surgical bypass as a primary treatment for both focal and advanced AIOD in many cases.

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L. Norgren and W. R. Hiatt et al. TASC II Inter-Society Consensus on Peripheral Arterial Disease
EVT in Aortoiliac Disease

- Early and Late outcomes of Treatment of TASC C/D lesions Meta-analysis (2000-2010)

![Table Image]

5-year primary patency was 64%
Secondary patency 83%
Excellent Technical Success
EVT Mortality 2.9% vs. ABF 4.4%


EVT in Aortoiliac Disease

- Mortality for endovascular interventions in the aorta can range from 1% to 3%, and morbidity ranges from 5% to 20%, with aortic rupture a possibility
- Importantly, one should be prepared for potential aortic rupture when embarking on treatment for an aortic lesion with interventional therapy.
- Renal dysfunction has been reported in 2% to 10% of patients.
- Intensive care unit stay, blood transfusion requirements, and infection rates are generally lower with EVT than with open aortic reconstructions

Iliac artery interventions

- Primary stenting is the main stay
- SE Vs BE depending on lesion location and characteristics
  - Ca++/ostial/CI→ favors BE stent
  - E.I favors SE stent
- Covered stents Vs BE stents
- **Key consideration when CFA is involved**, CF endarterectomy with iliac stenting(Hybrid) offers an alternative to traditional aortofemoral grafting

![Graph Image]

Summary of Evidence

AOID

• TASC A/B lesions: EVT definitely the mainstay and Less risky
• TASC C/D lesions: EVT is an excellent alternative to surgery and if restenosis occurs very easy to re-intervene.
• IF CFA disease involved or highly complex disease, hybrid approach (stent the easier iliac and Fem-Fem)+/- CFEA if needed especially if patient has xple comorbidities

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Infrainguinal disease Facts and Challenges

• BK disease usually does not cause IC
• Unilateral calf claudication is well tolerated and can be managed conservatively (Ex, pharm)
• TASC II recommendation
  – For TASC A/B lesions → EVT
  – For TASC C/D lesions → surgical
• However patient more and more demand less invasive therapies and Surgical options are reserved for failed EVT
Forces Exerted in SFA

Review of literature

- Unlike CAD, AAA, carotid trials, very scarce (RCTs) to provide level I evidence in support of clinical decision making in PAD
- From 1980’s to 2004
  - Only 4 RCT surgery Vs PTA in FP disease
  - Total patients 102+255+56+452=763

Holm J. Eur J of Vasc Surg. 1991
Wolf GL. J Vasc Int Radiol. 1993
Van Der Zaag Eur J Of Endo Sur.
Adam D I Basil Trial investigator. Lancet 2005

Basil Trial

- 452 patients, who presented to 27 UK hospitals with severe limb ischemia due to infra-inguinal disease,
- PTA n=228 Vs Bsx n=224
- Primary endpoint AFS
- @ 2 years there was no difference in AFS between PTA or Bsx and Bsx was more expensive
- But beyond 2 years AFS and OS was favorable for BSx group
  - HR of AFS of 0.85 inc mean OS by 7.3 month
  - HR of OS of 0.61 inc mean by 5.9 months

BASIL Implication

- Patients with SLI expected to live:
  - < 2 years should PTA first because they are unlikely to get longer-term benefits of BSX and because BAP is significantly less expensive and morbid in the short term.
  - > 2 years should usually be offered BSX first; the strength of this recommendation appears to be greatest where vein is available as the conduit.
- Role of prosthetic BSX: Surgeons should make every effort to use vein and view prosthetic material as a last resort.
- Role of PTA: PTA failure → worst outcome if went after for BSX

Technology and Advances

- Since BASIL
  - Nitinol SE stents
  - Stent Grafts
  - DES
  - DEB
  - Atherectomy: Jetstream, Diamondback, Turbohawk
  - Laser
  - Reentry devices: Outback, Pioneer etc...
- Still No defined Gold Standard EV modality Unlike VG BSx “Gold Std”

Who needs Scaffolds:
- Ca++
- Significant recoil

IT IS ONLY LOGICAL THAT EVT DOES NOT STOP AT PTA

Who needs atherectomy
- Heavily Ca++ arteries that is resistant to PTA

50% of Patients have acute PTA failures
- Zilver PTX RCT arm 50% (120/238)
- Resilient trial 40% (29/72)
Stents Vs PTA

<table>
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<tr>
<th>TRIAL</th>
<th>N</th>
<th>STENT TYPE</th>
<th>MEAN LENGTH</th>
<th>PTA PATENCY</th>
<th>PTA/S PATENCY</th>
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<tr>
<td>RESILIENT</td>
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<td>LIFE STENT</td>
<td>6.5 CM</td>
<td>45% (12M)</td>
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<td>FAST</td>
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<td>LUMINEX</td>
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<td>VIENNA</td>
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<td>VARIOUS NITINOL</td>
<td>5.9 CM</td>
<td>47% (12M)</td>
<td>63%</td>
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</table>


VIBRANT Trial

- Viabahn Vs BMS
- Non heparin coated VIABAHN
- Lesion length 18cm +/- 8 cm fem-pop
- Primary patency at 3 years BMS 24.2% Vs VB 25.9%
- Primary assisted patency BMS 88.8% Vs VB 69.8%

Geraghty PJ J Vasc surgery 2013

- VIPER trial
- Single arm multicenter
- Heparin coated VIABAHN (second gen.)
- Lower profile 6F(5-6mm)&7F (7-8 mm),0.014/0.018".Longest 25cm
- 119 limb TASC C/D (72) Rutherford 3-5(88)
- LL=19cm 56% CTOs
- Patency Ratio<2.5 By Dupplex
- 12month
  - PP 73% secondary Patency 92%
• primary patency of stent graft 72%, 63%, 63%, and 59% with a secondary patency of 83%, 74%, 74%, and 74%
• The surgical femoral-popliteal group demonstrated a primary patency of 76%, 63%, 63%, and 58% with a secondary patency of 86%, 76%, 76%, and 71% at 12, 24, 36, and 48 months
• 18 thrombosed stent grafts 5 mechanical balloon thrombectomy, 1 IA Lysis, 11(61%) had to convert to F-P, 1 amputation
• 16 synthetic surgical graft failure 15/16 thrombosis, 33% declotted, 20% BK FP VG, 13% AK FP VG, 3 (20%) Pt conservatively 6 amputations
• Conclusion: Study supports use of stent grafts, especially if autologous vein grafts are not available.

Karen McQuade, MD, JOURNAL OF VASCULAR SURGERY Volume 52, Number 3

DES Vs PTA

• SIROCCO studies
  – Smart Stent Vs SES Smart Stent Cordis
  – SIROCCO II 36 pt %DS was 22.6% SES and 30.9% Smart BMS
  – SIROCCO II 93 pts
    • ISR 22.9% SES 21.1% BMS
• Zilver PTX (Cook)
  – Zilver PTX nitinol stent platform with a 3ug/mm polymer-free coating of paclitaxel on its outer surface.

DES and Infrainguinal disease

JACC Vol. 61, No. 24, 2013 Dake et al
Zilver PTX 2 years

Zilver Primary Patency by Duplex

Freedom from TLR
Zilver PTX Summary

- 2-year primary patency rate for the primary DES 74.8% group was:
  - superior optimal PTA 53.4%
  - superior to provisional BMS 57.3%
  - overall PTA 63% (optimal PTA (50%) + provisional BMS (25%) + provisional DES (25%) placement after acute PTA failure
- Freedom from TLR at 2 years
  - Single arm 80%
  - RCT Arm 86%
- 5 years Primary patency Zilver PTX
  - 66.4% Vs 43.4% BMS (provisional)
- Japanese post marketing
  - 967 pts 802 F/U 1 year primary patency 84% , Freedom from TLR 91%
SUPERA stent

- Vasculomimetic Technology: Minimizes COF, Compression resistant
- Indicated to improve luminal diameter in the treatment of patients with symptomatic de novo or restenotic native lesions or occlusions of the superficial femoral artery (SFA) and/or proximal popliteal artery with reference vessel diameters of 4.0 to 6.5mm, and lesion lengths up to 140mm.
- Single Arm Study
- Effectiveness: Primary patency at 12 months (PSV ratio <2.0): 86%
- Safety: Freedom from MAE (TLR, Death and amputation): 99.25%

SUPERA stent

- Mimics the natural structure and movement of the anatomy
  - Optimizes luminal gain: maintains a round open lumen in challenging anatomy
  - Provides strength and flexibility for a durable solution
    - > 4x compression resistance than standard nitinol stents
    - High fracture resistance
    - Minimal chronic outward force

Safety and efficacy demonstrated with the SuperA implant

1-year Results:
- Primary Patency 94.6% of 86.3%
- No stent fractures
- Significant improvement in TLR of 12 months versus baseline with 90% of patients having improved more than 1 Blalock/Ashman classification category at 12 months

2-year Results:
- 84% freedom from TLR
- 0.0% fracture
DCB technology

- IN.PACT SFA
  - ADMIRAL Paclitaxel DCB

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DCB

- LEVANT II
  - Lutonix DCB

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12-Month Primary Patency (K-M) for SFA Endovascular Therapies
• Retrospective study 2005-2010
• 1237 symptomatic PVD on med Rx
• N=104(8%) pt SFA/pop PTA /S(N=61) Vs Bsx (N=43)
• 77% TASC A/B uderwent EVT
• 73% TASC C/D underwent BSx(VG >3.5mm)
• F/U 1m, 3m, 6m, 12m by Duplex. Restenosis PSV >300 cm/sec or Ratio>3.0
• Re-intervention if >50% angiographic

National Trends EVT Vs Surgery

• EVT minimally invasive, hence more appealing
• In the past patients with CLI that are sick went for amputation, now are given options of EVT
• Even octogenarians have improved outcomes and lower mortality CW BSx
• Patients who have avoided claudication in the past due to the invasive nature of procedure are offered more options
• Poor target vessels, conduits, or factors for excess surgical risk

Conclusion

• NO RCT so far showing superiority of BSx to Current EVT options in F-P disease
  - NIH sponsored On Going BEST-CLI
• Current EVT options proven is Definitely Superior to PTA and emerging long term data appears to be consistent and durable
• With emerging technologies and options, incorporation of EV training in IC/Vascular Surgery programs and aging population make physicians more comfortable treating complex patients with EVT and hesitant to perform BSx.
• EVT should not limit further surgical options if needed and Interventionalists should be very conscientious about not burning surgical bridges if ultimately needed
• Regardless what the data dictates a good Surgeon/ Interventionalist should individualize their patients treatment options