The Future of Vascular Disease Therapeutics

Percutaneous Atherectomy and Tibio-Pedal Access

The Art of Body Floss

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Objectives

1. Appreciate the scope of PAD and Amputation.
2. Define the goals of therapy
3. Recognize the available options for treatment
4. Understand the mechanism of action for orbital atherectomy
5. Learn about the value of tibia-pedal artery access for peripheral interventions.

Disclosures:
- Cardiovascular Systems Inc., Medical Education Faculty Consultant
Introduction and demographics of amputation

Peripheral arterial disease (PAD), atherosclerosis, is present in up to 29% of the US population.

Critical Limb Ischemia (CLI) was diagnosed in more than 2.5 million Americans in 2003.

Patients with critical limb ischemia have an overall poor prognosis:
- 1 year mortality = 25%
- 5 year mortality = 50%

Patients presenting with CLI:
- Initial Treatment
  - 50% revascularized
  - 25% medical management only
  - 25% receive a primary amputation
- 1 year later
  - 25% CLI resolved
  - 30% alive with amputation
  - 20% continue to have CLI
  - 25% have died
Introduction and Demographics of Amputation

- 25% of patients with the worst stage of PAD will have an amputation
- Approximately 120,000 LE amputations are performed annually in the US
- The lifetime direct healthcare cost for an amputee patient is $794,027.
- When aggregated for the total number of LE amputations, the expected lifetime cost is roughly $95.2 billion.

Introduction and Demographics of Amputation

- Following an initial LE amputation,
  - 27% will have 1 or more re-amputations within 1 year
  - 40% progressed to a higher level of limb loss within a year
  - 62% if patient has DM
  - 55% of those with PAD will have the other limb amputated within 2-3 years.

How Endovascular Surgeons Are Trained

- Endovascular approach first, open surgery second.
- Requirements for a successful revascularization
  - Inflow, Conduit, Outflow
  - "Faucet, hose, sprinkler"
- Role of Outflow in Wound Healing
  - More flow to the wound should result in better wound healing
  - Endovascular technique allows attempts at three vessel treatments and may reach vessels too small for open surgery
- Role of Stents in Endovascular Surgery
  - Primarily "sail-out", with exceptions
  - DO NOT cover your Surgical Zones, aka "no stent territories"
Endpoints

- Patency
- Amputation free survival
- Wound healing
- Functional status
- Quality of Life

The Challenge of Calcium:

Patient Implications of Calcium: Contributes to Lower Success Rates

- 74% of flow limiting dissections occur in calcium

- 1 yr. patency of ballooned arteries drops to 36%
  - Limb salvage drops to 56% at 1 year

- Increased Adverse Events
  - Decreased Balloon Success
  - Decreased Stent Success
  - Non-Orbital Technologies Result in Higher Risk
  - Non-orbital atherectomy technologies not optimized for performance in calcium
    - Stent malapposition
    - 22% bail out stent rate

4. TCT 2008, Abstract, D. Scheinert, MD, Department of Clinical and Interventional Angiology, Heart Center and Park Hospital, University of Leipzig Hospital
6. Review of Atherectomy devices. Information on file at CSI.
Intervention in Unseen Calcium Can Result in Dissection

- Significant subintimal dissection confirmed by IVUS
  - Up to 74% dissections related to calcified plaque
  - Dissections significantly larger in calcified vs. non-calcified plaque (p<0.002)
- Need for bail-out stenting
- Deep vessel injury leading to high restenosis rates
  - 38.6% binary restenosis at 12 mos in FAST Trial

Balloon Angioplasty Can Cause Dissections

Pre-Procedure Calcified Lesion

Balloon Inflation 8 atm of Inflation

Post Balloon Dissection Occurred
High Pressure Inflation Does Not Always Enable Balloon Expansion

Results May Vary

20 atm Balloon Inflation

- Pre-Procedure Calcified Lesion
- Post Dilatation PTA
- Stent Lacked Radial Force

Stent Radial Force May Be Inadequate

Pre-Procedure Calcified Lesion
Stent Malapposition
Calcium Prevented Sufficient Apposition
Post Dilatation PTA 12 atm of Inflation

Health Care Economics Implications: Calcium Increases Costs

Day of Case
- Increased lab time to manage adverse event $100/minute
- Increased bail-out stent rate at $700-$1,500/each

Durability
- Increased re-intervention rate at $28,000/each

Wound Healing
- Average cost to heal wound $17,096
- Amputation cost $48,152
- Annual cost to manage amputee $49,000
- Annual cost of nursing home $80,000

References:
1. Reimbursement Principles Inc. Data on record at CSI
2. Average price paid for stents. Compiled from review of 100 UB40 case expense worksheets. Data on file at CSI.
Calcium Can Be Predicted

Independent Calcium Prediction Variables

1. ABI > 1.3
2. Critical Limb Ischemia
3. Diabetes: Especially if neuropathy present
4. Calcium found on forefoot X-Ray
5. History of tobacco use
6. Creatinine > 1.7
7. Glomerular Filtration Rate (GFR) ≤ 60


Which Patients are More Likely to Have Calcium?

PAD Patients with Metabolic Disorders Leading to Calcified Plaque and Media

- Advanced Age
- Diabetics
- Kidney Disease

- 40.3M 65+yrs old in U.S. (1)
- 85+ age group is fastest growing in U.S.
- Up to 26M in U.S. (2) Diabetes is fastest growing health problem in U.S.
- Up to 21M in U.S. (3) Diabetes is leading cause of kidney disease

Angiography Routinely Underestimates Calcium

Calcium? Yes!
General List of Therapeutic Options

- conservative management
- risk factor management
- walking
- Cilostazol
- endovascular interventions
  - angioplasty
  - stent
  - atherectomy
- open surgical procedures
  - endarterectomy
  - bypass with vein graft
  - bypass with synthetic graft
  - bypass with biograft
  - gene therapy
  - angiogenesis

List of Options for Atherectomy

- directional (Turbohawk)

- rotational (Rotoblader)

- orbital (Diamondback)
List of Options for Atherectomy

- photoablative (Laser)
- aspirational (Pathway)
- hybrid (Phoenix)
- contact (Crosser)

Orbital Atherectomy Mechanism of Action

The Orbital Atherectomy Mechanism of Action is based on two elements

1. Differential Sanding
2. Centrifugal Force
Differential Sanding Targets
Diseased Tissue

- 30 micron grit for optimal "catch" of hard plaque surfaces
- Diseased tissue provides resistance and allows grit to "sand" away plaque
- Elastic healthy tissue "gives" and is not affected by diamond surface
- Orbit motion creates smooth, even surface

Diamond Grit

The Physics of the MOA:
Centrifugal Force

Centrifugal Force = Mass x Rotational Speed²

Radius of the Orbit

Solid Crown Mass > Classic Crown Mass

- Solid Micro Crown: tapered design of Solid Crown, but less mass and a shorter surface for additional flexibility
- Classic Crown: Shorter sanding surface for increased flexibility
- Solid Crown: Longer sanding surface created more overall crown mass; tapered design for frontal sanding
Rotational Speed

- Speed exponentially impacts Centrifugal Force
- An increase in speed exponentially increases Centrifugal Force

- Classic Crown Speeds: 60, 90, 140K RPM
- Solid Crown Speeds: 60, 90, 120K RPM

Orbit Radius

- Offset Center of Mass Creates Orbital Motion
- Orbital motion produces 360° of contact
- As Orbit Radius increases, Centrifugal Force decreases for inherent safety

Tibio-Pedal Artery Access
Background

- Patients with critical limb ischemia typically have many co-morbidities.
- By virtue of the disease these patients are predisposed to complications:
  1. Groin access complications
  2. Acute Kidney Injury
  3. Radiation exposure to the patient and the operator
  4. In case of complications, significant recovery time

Background

- Tibio-pedal arterial access is one of the cornerstones of advanced endovascular therapies for patients with CLI
- Familiarity with ultrasound imaging and especially understanding the spacial relationships of localizing needle entry and manipulating wires under ultrasound is ESSENTIAL to successful access and treatment of these difficult patient anatomies.

Technique

- Linear 15i7 MHz hockey stick probe for tibio-pedal access
Anterior Tibial Artery Access
The tibial vessels are accessed in the following fashion:

• The orientation of the foot is adjusted depending on the target tibial vessel.
• In cases of the dorsalis pedis (DP) or the distal anterior tibial artery (AT), the foot is maintained in natural orientation with the heel of the foot on the table with slight dorsiflexion.

Posterior Tibial Artery Access
• To access the posterior tibial artery (PT) the foot is rotated laterally and the leg will be bent slightly at the knee level for patient comfort.

Technique
• Assessing the ideal spot for retrograde tibiopedal arterial access site is mainly done by ultrasound.
• This decreases the likelihood of venous puncture, venous sheath placement, AV fistulas, and tibial artery spasm.
Technique

- As we move the probe cranially, it is easy to visualize how the tibial veins start to separate from the tibial arteries, allowing easier cannulation of the tibial vessels in a spot where the veins are not located in the planned needle trajectory.
- However, while moving cranially, keep in mind the four major anatomical compartments below the knee.
- These compartments lay within the gastrocnemius muscle and most of the time end at the insertion points of the distal gastrocnemius heads.

Technique

- Avoid accessing beyond the gastrocnemius heads in order to decrease the likelihood of a complication which may result in compartment syndrome, which in turn can lead to emergent surgical intervention and in rare occasions even amputation.
- Arterial access below the gastrocnemius heads, allows the operator to have complete control to address potential bleeding complications during and after tibial access procedures.
- A vascular technologist is very beneficial during the access process, but is not required if the interventionist is skilled in ultrasound localization.

Technique

- The short and long access views of these vessels will reveal the access point.
- Retrograde tibial access identifies a hibernating lumen of these vessels not otherwise identified with traditional angiography due to proximal vessel occlusion.
- Tibial lesions also can be distal and easy to identify on US evaluation.
Technique

- Visualize the wire under US guidance while traveling inside the vessel.
- Once access is gained into the tibial vessel, the micro sheath is introduced into the vessel.

Final Step

- Inject contrast to confirm our intraluminal position.
- Inject 400-600 micrograms of nitroglycerin.
- 4 French micro sheath inserted into the tibial vessel.

Body Floss
Cases
Case TL

74 year old gentleman with a long standing history of diabetes, who presented with a gangrenous left 2nd toe.

HTN
Chf
Non smoker
Hgb A1c of 7
Previously healed left 3rd toe amputation

Pedal pulses non palpable
ABI non compressible
Left digital pressure 23 mm Hg
Arterial Duplex demonstrated diffuse calcification and monophasic distal waveforms
Comments Case TL

- Flush tibial occlusions seen from above can be crossed from below using Tibio-Pedal Access.
- Angiosoome directed therapy is important
- Lesions isolated to the tibial arteries can be treated from the foot without the additional risks of groin access.
Case 5

Tibio pedal access assisted interventions.

- 5a; Daniel Liston AT intervention
- 5b; Sandra Boland SFA intervention from the foot
- 5c; John Callaway
- 5d; James Hutchins

Case DL

- 85 year old gentleman with DM and severe RA
- referred for recurrent non healing foot and toe ulcers bilaterally
- non palpable pulses, ABI 0.6 right, 0.55 left with monophonic waveforms

Case DL

- Diagnostic angio showing flush occlusion of the right SFA with AK reconstruction and 3 vessel tibial disease with ATA/DP available for pedal access.
- patient unable to hold still in the cath lab, so rescheduled for Hybrid OR
Comments Case DL

1. Percutaneous angioplasty, 6 x 220 mm balloon, atherectomy, Diamondback 1.5 solid crown, and stent placement, Viabahn 6 x 150 mm, 6 x 150 mm, 6 x 150 mm, right superficial femoral artery (percutaneous fem-pop bypass).
2. Percutaneous atherectomy of the right anterior tibial artery, Diamondback 1.25 with post-angioplasty 3 x 200 mm balloon by retrograde tibial artery access.
3. Ultrasound-guided vascular access to the right common femoral artery for femoral cutdown access.
4. Ultrasound-guided vascular access to the left common femoral artery for femoral cutdown access.

Case SB

70 year old lady with a history of right SFA stents, coronary stents, ongoing tobacco use, hypertension and hypercholesterolemia is referred by her podiatrist for foot pain.

She has known spine disease s/p multiple injections without relief. She has no palpable pulses below the groin. no ulcers, worsened with exercise which she says is mostly limited by her back.

She has worsening bilateral LE rest pain especially on the left. ABI 0.45 right and 0.2 left, no ulcers.

CTA showing diffusely small vessels with iliac disease on the left and flush occlusion on the right SFA. Right tibial vessels are patent.
Comments Case SB
1. PECRA AT-VERSECTOPY, RIGHT SFA-POP, DIAMONDBACK 1.25, WITH 5X60MM PTA PROX,
4X120MM DISTAL.
2. RIGHT FEMORAL ANGIOGRAM, VIA PEDAL ACCESS.
3. ULTRASOUND-GUIDED ACCESS, RIGHT PTA AT THE ANKLE, 4FR, PRESSURE HEMOSTASIS.

Case JC
- 87 year old gentleman with bilateral dependent rubber and edema with a gangrenous right first toe tip.
- Popliteal pulses faintly palpable, not aneurysmal.
- Right ABI is 0.5 in the PT and 0.1 in the AT.
- Left ABI is 0.6 in PT and DP.
Case JC

• Antegrade access angio showing diffuse disease and TPT occlusion. PT reconstruction mid and distal tibia.
• Lateral plantar patent to arch
• Medial plantar very small and occludes mid foot
Comments Case JC
1. PERC ATHERECTOMY LEFT PTA, DIAMONDBACK 1.25 PEDAL, WITH 3X220MM PTA@6ATM
2. RIGHT TIBIAL ANGIOGRAM, NON SELECTIVE FROM LEFT PTA
3. ULTRASOUND GUIDED ACCESS, RIGHT POSTERIOR TIBIAL ARTERY, 4FR, PRESSURE
HEMOSTASIS
Conclusions:

- Amputation is still far too frequent and costly
- Orbital Atherectomy is designed to treat calcified vascular disease
- Tibio-Pedal artery access can produce successful interventions with low risk
- Advanced endovascular techniques continue to improve outcomes while reducing patient risk and discomfort.

Thank you

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