Below the Knee Interventions

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DISCLOSURES....

Company	Relationship
AstraZeneca	Speaker
Gilead	Speaker
Covidien	Honoraria
Osprey	Consultant

Below the Knee Circulation....



Below the Knee Circulation....



Why should we care about below the knee disease?

Why we need to care about BTK disease...

Ms. M.A. 46 year old woman with diabetes who presented with an antero-lateral MI at an outlying hospital and was treated with thrombolytic therapy followed by PCI.









The patient is referred to me for limb salvage... Extensive necrosis and osteomyelitis.



















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Could we have prevented this amputation?

What can we learn from this case?



WAF

Medicare: Geographic Variation in Lower Extremity Amputation for PAD (2000-2008)



Republished from Schuyler-Jones W, et al. J Am Coll Cardiol. 2012;59;E1670, with permission from Elsevier.

CLI Epidemiology

Hospital Discharge Rates for Nontraumatic Lower-Extremity Amputations, 1988-2009



In 2009, the rate per 1000 people with diabetes:

- 3.1 age < 65 years
- 3.5 age 65-74 years
- 3.7 among people aged ≥ 75 years
- 4.5 vs 2.3 age-adjusted rate for blacks vs whites

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Texas CLI Tsunami





Prevalence of Diabetes, US and Texas, 1995 - 2008*



*Source: CDC Behavioral Risk Factor Surveillance System, Statewide BRFSS Survey, 2008, for persons who are eighteen years of age and older, and include both Type 1 and Type 2 Diabetes. Persons with diabetes include those who report that they have been told by a doctor that they have diabetes.



CLI Epidemiology: Amputations in Texas





2003-07, in the fee-for-service Medicare population: 3 x higher rate of amputations in McAllen Texas than the national average



What a Texas town can teach us about health care.

by <u>Atul Gawande</u> (The NewYorker 2009)

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Modified from Goodman DC et al Dartmouth Atlas Project 2010

In Texas we....





Amputations are not benign....



Amputation sites will not heal without adequate vascular supply



Medicare: Underuse of Revascularization and Angiogram in Year Prior to Major Amputation

N = 20,464 Patients with PAD who underwent major leg amputation (2003-2006)





Goodney PP, et al. Circ: Cardiovasc Qual Outcomes. 2012;5:94-102.

ACS-NSQIP: 30-Day Morbidity and **Mortality of Major Amputation for CLI**

N = 4250 patients with major amputation from 2005 through 2008



Hasanadka R, et al. J Vasc Surg. 2011;54:1374-1382.

Surgery

Survival After Amputation



5-Year Survival: Above Knee vs Below Knee



Subramaniam B, et al. Anesth Analg 2005;100:1241-1247.





Revascularization Reduces Amputation



Balar NN, et al. Endovascular Today. 2011:61-64.

5-Year Mortality for CLI Higher than Common Cancers



a. http://seer.cancer.gov/statfacts/html/prost.html; b. http://seer.cancer.gov/statfacts/html/breast.html; c. Kaul P, et al. *Circulation*. 2004;110:1754-1760; d. Weitz JI, et al. *Circulation*. 1996;94:3026-3049; a. http://seer.cancer.gov/statfacts/html/color



Circulation. 2004;110:1754-1760; d. Weitz JI, et al. Circulation. 1996;94:3026-3049; e. http://seer.cancer.gov/statfacts/html/colorect.html; f. Hartmann A, et al. Neurology. 2001;57:2000-2005; g. Ljungman C, et al. Eur J Vasc Endovasc Surg. 1996;11:176-182.





Revascularization reduces mortality...



Surgical versus Endovascular Revascularization...







Considerations of surgical versus endovascular revascularization...

Limitations of Surgical Bypass

✓ Patient co-morbidities
 ✓ Suitable autologous vein
 ✓ Suitable target vessel
 ✓ Bypass patency

"Traditional" limitations of endovascular therapy

✓ Calcification
 ✓ Chronic total occlusions and long lesions
 ✓ Poor target vessels
 ✓ Restenosis

Bypass vs Angioplasty

Meta-analysis of infrapopliteal angioplasty for chronic critical limb ischemia

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Marcello Romiti, MD,^a Maximiano Albers, MD,^a Francisco Cardoso Brochado-Neto, MD,^a Anai Espinelli S. Durazzo, MD,^b Carlos Alberto Bragança Pereira, PhD,^c and Nelson De Luccia, MD,^b Santos and São Paulo, Sao Paulo, Brazil



Meta-analysis (Romiti et al.) 30 studies

Data from Romiti et al J Vasc Surgery 2008

Bypass vs Angioplasty

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Limb Salvage Rate (Meta-Analysis)

Data from Romiti et al J Vasc Surgery 2008

Is long term patency important?

Goal of revascularization is wound healing and amputation free survival.

Rocha-Singh et al. XCELL trial:

Examined wound healing in CLI patients following

infrapopliteal stent placement

>120 patients with 128 wounds

>57 % healed at 6 months, 63% healed at 1 year



Rocha-Singh K. Catheterization and Cardiovascular Interventions 2012

Tips for success...

- Patient/Case selection
- Angiosome concept
- Case planning
- Advanced techniques
- Equipment selection

PATIENT/CASE SELECTION

Which patients should we be working on?

✓ REST PAIN

✓ TISSUE LOSS

CLAUDICATION?????

Which patients should we be working on?

SCAI Expert Consensus Statement for Infrapopliteal Arterial Intervention Appropriate Use

Bruce H. Gray,^{1*} DO, Larry. J. Diaz-Sandoval,² MD, Robert S. Dieter,³ MD, Michael R. Jaff,⁴ DO, and Christopher J. White,⁵ MD

"At the present time, patients with IP disease and claudication should be preferentially treated pharmacologically and a walking program before considering any revascularization procedure..."

Catheterization and Cardiovascular Interventions 2014

TABLE II. Clinical Scenarios in Which Treatment of Infrapopliteal Artery Disease May Be Considered

Appropriate Care	• Moderate-severe claudication (RC 2-3) with
653 - 65 M	two, or three-vessel IP disease (if the arterial
	target lesion is focal)

· Ischemic rest pain (RC4) with two, or three-

MY PERSONAL OPINION:

There is currently a lack of data both clinical and physiologic to support routine below the knee intervention for claudication

	 Ischemic rest pain (KC 4) with one, or two-
	vessel IP disease (to provide direct flow to
	the plantar arch and in two-vessel, to maxi- mize volume flow to foot)
	 Minor tissue loss (RC 5) with one-vessel IP disease (to provide direct flow to the plantar arch and to maximize volume flow to foot)
Rarely Appropriate Care	 Mild claudication (RC 1) with, one, two, or three-vessel IP disease
	 Moderate-severe (RC 2-3) claudication symptoms with one-vessel IP disease
	Martine France Lane (DCLC) might service 11D

Major tissue loss (RC 6) with one-vessel IP
 disease

CASE PLANNING

CASE PLANNING

• Study the angiogram...consider approach, equipment, potential problems



Goals of endovascular therapy: Angiosomes





Lida O. et al. Catheterization and Cardiovascular Interventions 75:830-836 (2010)

Goals of endovascular therapy: Angiosomes





Lida O. et al. Catheterization and Cardiovascular Interventions 75:830-836 (2010)

CASE PLANNING..... Access Choice

Approach	Pros	Cons
Contralateral	Most operators comfortable with this access	Poor supportEquipment length issuesWastes contrast
Ipsilateral antegrade	More supportCan reach plantar archBetter visualization	 May seem challenging at first Inexperience can lead to vascular complications
Retrograde crossing via transpedal approach	 Can help cross CTOs with poorly defined caps Crossing CTO distal cap is sometimes easier 	 Requires suitable pedal vessel Must prevent spasm and thrombosis
Tibopedal arterial minimally invasive (TAMI)	Single retrograde sheathTreat completely from below	 Requires suitable pedal vessel Limits equipment selection

Retrograde transpedal access technique

- Ultrasound guided is the way to go...avoid flouro guided access
- Dorsiflex and rotate out foot for PT
- Plantarflex foot for DP
- Peroneal access much more challenging due to hemostasis issues
- Minimize use of lidocaine and be liberal with nitrates



Figure 2. Duplex ultrasound-guided access into the dorsalis pedis artery. (A) Duplex ultrasound probe and 21-gauge needle in place. (B) Color duplex identifies the patent anterior tibial artery lumen. (C) Tip of the needle inside the vessel on ultrasound (red arrow).

El Sayed et al Debakey Heart Journal 2013

Sheath Choice	Manufacturer	Description
Sheathless	N/A	Limits support and retrograde treatment options
Pinnacle Precision Sheath	Terumo	4.0 Fr ID/6.0 Fr OD
Micropuncture [®] Pedal Introducer Access Set with CheckFlo valve	Cook	2.9 Fr ID/4.0 Fr OD, can accommodate 1.25 micro CSI crown





Wire choices for crossing lesions....

Non-CTO lesion:

Workhorse 0.014" wire

Chronic Total Occlusions

- ➢ Wire escalation strategy
- Direct use of heavy tipped wire

Selected Equipment	Manufacturer	Characteristics
MiracleBros Wires, 0.14"	Abbott/Ashai	3-12 gram tip weight Hydrophobic coated
Approach, 0.014"	Cook	6-25 gram tip weight PTFE coated
Treasure 12, 0.018"	Asahi	12 gram tip weight Hydrophilic tip coating PTFE shaft coating
Astato 30, 0.018"	Asahi	30 gram tip weight Hydrophilic tip coating PTFE shaft coating
Astato XS 20, 0.014"	Asahi	20 gram tip load Hydrophilic tip coating PTFE shaft coating

Support catheters....

Support Catheters

0.014" 0.018" 0.035" 0.038"

Straight tip Tapered Angled tip

Catheter	Manufacturer
Quickcross	Spectranetics
Mini	Vascular Solutions
Trailblazer	Covidien
CXI	Cook
Navicross	Terumo
Finecross	Terumo

Crossing catheters....

Crossing Device	Manufacturer	Description
Viance	Covidien	Blunt manual probing/controlled dissection Can be used retrograde
KittyCat	Avinger	Manual or assisted blunt dissection
Ocelot	Avinger	Manual or assisted blunt dissection with OCT guidance
Peripheral Crosser	Bard	High frequency vibrations to penetrate tissue
TruePath	Boston Scientific	Diamond coated rapidly rotating tip
Frontrunner XP	Cordis	Blunt microdissection

Wire-Catheter vs Crossing Device XLPAD registry data....



Re-entry devices....

Re-entry Device	Manufacturer	Description
Outback	Cordis	Flouroscopic/Angiographic guided needle re-entry
Pioneer	Volcano	IVUS guided needle re-entry
Enteer	Covidien	Flouroscopic/Angiographic guided wire re-entry using a balloon to help align and direct wire
OffRoad	Boston Scientific	Flouroscopic/Angiographic guided wire re-entry using an angled balloon to help align and direct wire

Explosion of endovascular therapies for CLI have overcome traditional limitations...

2014

- Next generation balloons
- > Drug eluting balloons
- > Cryoplasty
- Drug eluting stents
- Orbital atherectomy
- Directional atherectomy

Dedicated devices and wires for Chronic total occlusions (CTOs)

- New techniques:
- subintimal tracking and re-entry
- retrograde CTO recanalization
- pedal access
- meta-tarsal/digital access





Treatment options

Balloon Angioplasty:

"standard PTA" [long] Specialty Balloons: Chocolate (Trieme) Angiosculpt (Angioscore) Cutting Balloon (Boston Sci)

Atherectomy:

- ➢ Orbital (CSI)
- Directional (Turbohawk, Covidien)
- Rotational w aspiration (Jetstream, Boston)
- Scientific)
- Rotational (Rotablator, Boston Scientific)
- Laser (Spectranetics)

Stenting:

Small diameter nitinol (Xpert, Abbott) Drug eluting coronary

CASE EXAMPLES...

58 year old diabetic female with neuropathy who has had a non-healing ulcer on the R foot.

ABI 1.2, TCOMs 40+ range



TCOMs look good. ABI seems ok. PAD??

- No inflow disease above the knee
- PT is occluded or absent







No PT reconstitution



What would you do?

Plantar arch reconstruction...

- Elected to reconstruct the plantar arch.
- Alternating wires (Miracle 3 gram with Asahi soft), CXI catheter and OTW coronary 1.5 balloon
- Approached plantar arch from AT and peroneal with dual wires
- PTA escalation 1.5, 2.0 mm diameter alternating from both vessels to open channel
- PTA with high pressure 2.0 long balloon across entire plantar arch







