Medicine Grand Rounds
April 19, 2011

Advances in Interventional Therapies for Peripheral Arterial Disease

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Disclosures

• We will be discussing off-label applications of FDA approved devices.

• Consultant – Medtronic

• Advisory Board – Boston Scientific
Advances in Interventional Therapies for PAD

• Cardiologists and PAD
• Endovascular Intervention for PAD
  – Anatomic Considerations
  – Angioplasty & Stenting compared to Surgery
• Why do Endovascular Interventions Fail?
  – Restenosis Biology
  – Lessons from Coronary Restenosis
• Novel therapies in Peripheral Intervention
  – Stent Design
  – Local Drug and Cell Delivery
A Typical Case....

CC/ID: 57 yo male with prior CABG with progressive bilateral claudication
HPI: Worsening symptoms for past year now unable to keep up with his grandkids

• PMH/PSH:
  – CAD s/p CABGx 4 with LIMA to LAD→D1, SVG to OM, SVG to PDA
  – Prior Gastric Bypass
  – DM2
  – HTN
  – Dyslipidemia
• SH: Active tobacco
• FH: Mother with premature CAD, PAD

• Intolerant of ASA due to gastric bypass
• Meds:
  – Vitamin B12 500 mcg daily
  – Plavix 75 mg daily
  – omeprazole 20 mg daily
  – fluoxetine 40 mg daily
  – iron 150 daily
  – ramipril 10 mg daily
  – metoprolol XL 100 mg daily
  – Vytorin 80/10 mg daily
A Typical Case....

Physical Exam:
Neck: Carotids 2+, no bruits
Chest: CTA&P
CVS: Quiet precordium, RRR S1 S2 no M/R/G
Abd: Soft, no bruits
Ext: dependent rubor with elevation pallor.
Pulses:
  Femoral  1+/1+ no bruits
  Popliteals Trace/1+
  DP        mono/biphasic
  PT        mono/biphasic
Noninvasive Evaluation: ABI, PVRs, Exercise

Exercise Pressure Measurement

<table>
<thead>
<tr>
<th></th>
<th>Rest</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>R Ankle (PT)</td>
<td>89</td>
<td>53</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>L Ankle (PT)</td>
<td>124</td>
<td>86</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>R Brachial</td>
<td>130</td>
<td>143</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>R ABI</td>
<td>0.68</td>
<td>0.37</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>L ABI</td>
<td>0.95</td>
<td>0.60</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

0.68 → 0.37

0.95 → 0.60
What Now?

- Continue risk factor modification
- Counsel on smoking cessation
- Prescribe exercise
- Do we need to revascularize and how?
Lower Extremity Claudication: The Tip of the Iceberg

- Patients >55 y.o.
  - Intermittent Claudication: 5%
    - Claudication: Stable: 73%
    - Claudication: Progressive: 16%
    - LE Surgical Revascularization: 7%
  - Non-fatal CV Event: 20%
  - 5-year Mortality: 30%
  - 75% CV Death
- CV M&M
  - Amputation: 4%

Overlap of Pan Vascular Disease

Patients with one manifestation often have coexistent disease in other vascular beds.

Therapies for PAD

Preventing Death, MI, Stroke
- Antiplatelets
- Cholesterol lowering – statins
- ACE Inhibitors

Reducing Symptoms
- Exercise
- Cilostazol
- Endovascular interventions
- Surgery

Saving Limbs
- Endovascular interventions
- Surgery
Who is Doing Peripheral Interventions These Days?

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Peripheral Arterial Disease: Indications for Intervention

- Claudication
  - Disabling
  - Lifestyle limiting

- Critical Limb Ischemia
  - Tissue loss/ischemia
  - Rest pain
  - Refractory infection

ANGINA
ACS
ACC/AHA Guidelines for the Management of Patients with Peripheral Arterial Disease

1. Endovascular procedures are indicated for individuals with a vocational or lifestyle-limiting disability due to intermittent claudication when clinical features suggest a reasonable likelihood of symptomatic improvement with endovascular intervention and (a) there has been an inadequate response to exercise or pharmacological therapy and/or (b) there is a very favorable risk-benefit ratio (e.g., focal aortoiliac occlusive disease). (Level of Evidence: A)
Peripheral Arterial Disease: Surgical Revascularization is Not Without Risks

- Complications
  - Mortality 2-5%
  - Myocardial Infarction 1.9-3.4%
  - Hemorrhage 2%
  - Graft Thrombosis 2-7%
  - Wound Infection 8-19%
  - Surgical Revision >20%

<table>
<thead>
<tr>
<th>Procedure and complication</th>
<th>1998, %</th>
<th>2007, %</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endo revascularization</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac</td>
<td>1.6</td>
<td>0.8</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Postoperative stroke</td>
<td>0.2</td>
<td>0.1</td>
<td>.04</td>
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<tr>
<td>Respiratory</td>
<td>0.8</td>
<td>0.7</td>
<td>.21</td>
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<tr>
<td>Hemorrhage</td>
<td>9.9</td>
<td>6.7</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Infection</td>
<td>1.7</td>
<td>1.3</td>
<td>.02</td>
</tr>
<tr>
<td>Open revascularization</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postoperative stroke</td>
<td></td>
<td></td>
<td></td>
</tr>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemorrhage</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major amputation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac</td>
<td>1.6</td>
<td>1.4</td>
<td>.42</td>
</tr>
<tr>
<td>Postoperative stroke</td>
<td>0.3</td>
<td>0.1</td>
<td>.05</td>
</tr>
<tr>
<td>Respiratory</td>
<td>2.6</td>
<td>2.2</td>
<td>.09</td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>8.9</td>
<td>7.8</td>
<td>.09</td>
</tr>
<tr>
<td>Infection</td>
<td>3.7</td>
<td>4.6</td>
<td>.005</td>
</tr>
<tr>
<td>Major amputation + revascularization</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac</td>
<td>4.4</td>
<td>3.5</td>
<td>.19</td>
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<tr>
<td>Postoperative stroke</td>
<td>0.45</td>
<td>0.4</td>
<td>.78</td>
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<tr>
<td>Respiratory</td>
<td>6.5</td>
<td>6.2</td>
<td>.75</td>
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<tr>
<td>Bleeding</td>
<td>28.1</td>
<td>16.7</td>
<td>.0004</td>
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<tr>
<td>Infection</td>
<td>9.1</td>
<td>7.2</td>
<td>.11</td>
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<tr>
<td>Open + endo revascularization</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac</td>
<td>3.2</td>
<td>2.1</td>
<td>.02</td>
</tr>
<tr>
<td>Postoperative stroke</td>
<td>0.1</td>
<td>0.4</td>
<td>.08</td>
</tr>
<tr>
<td>Respiratory</td>
<td>2.7</td>
<td>3.4</td>
<td>.17</td>
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<tr>
<td>Bleeding</td>
<td>16.3</td>
<td>13.6</td>
<td>.03</td>
</tr>
<tr>
<td>Infection</td>
<td>3.0</td>
<td>3.2</td>
<td>.83</td>
</tr>
</tbody>
</table>

Aortoiliac Occlusive Disease: Comparing Open vs Endovascular Approaches

OPEN SURGICAL
- Excellent long-term patency rate
  - 85%-90% at 5 years
- Requires general anesthesia
- 1%-3% mortality rate

ENDOVASCULAR
- High procedural success rates (90%)
- Excellent long-term patency (≥70% at 5 years)
- Less morbidity/mortality
- Factors associated with a poor outcome:
  - Long segment occlusion
  - Multifocal stenoses
  - Eccentric calcification
  - Poor runoff
TASC II AortoIliac lesions

Endovascular Treatment of Choice
- Type A

Preferred Endovascular Treatment
- Types B

Preferred Surgical Treatment
- Types C

Surgical Treatment of Choice
- Type D

Norgren L et al. JVS. 2007:S5A–S67A
Endovascular Therapy for Aortoiliac Occlusive Disease is Feasible and Effective Across All Degrees of Stenosis

Femoropopliteal Disease: Comparing Open vs Endovascular Approaches

OPEN SURGICAL
- 40%-75% 5 year patency rate depending on conduit
- Limb salvage rates are 70% at 5 years
- 1%-3% mortality rate

ENDOVASCULAR
- Excellent procedural success
- Reported patency varies widely
  - 30%-80% at 1 year
- Role of primary stenting for femoropopliteal disease remains incompletely defined however there are emerging data supporting this strategy
Table 3. The 5-year patency of different types of conduits

<table>
<thead>
<tr>
<th>Type</th>
<th>Patency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vein</td>
<td>74–76%</td>
</tr>
<tr>
<td>ePTFE Graft</td>
<td>39–52%</td>
</tr>
</tbody>
</table>

Performance Goals and Endpoint Assessments for Clinical Trials of Femoropopliteal Bare Nitinol Stents in Patients With Symptomatic Peripheral Arterial Disease

PTA Patency--Trials

<table>
<thead>
<tr>
<th>Ranges of lesion length</th>
<th>12-month patency</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.0–6.5 cm</td>
<td>28% (8/29)</td>
</tr>
<tr>
<td>6.6–11.0 cm</td>
<td>38% (12/32)</td>
</tr>
<tr>
<td>11.1–15 cm</td>
<td>16% (4/25)</td>
</tr>
</tbody>
</table>

PTA Patency--Literature

<table>
<thead>
<tr>
<th>Author</th>
<th>Diabetes</th>
<th>Smoking</th>
<th>Hypertension</th>
<th>#Run-off vessels</th>
<th>Mean lesion</th>
<th>Combined</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pokrajac, 2004 (N = 46)</td>
<td>48% (22)</td>
<td>15% (7)</td>
<td>80% (37)</td>
<td>52% (24)</td>
<td>10.3</td>
<td>38% (78)</td>
</tr>
<tr>
<td>Zdanowski, 1999 (N = 17)</td>
<td>29% (5)</td>
<td>35% (6)</td>
<td>24% (4)</td>
<td>29%</td>
<td>10.0</td>
<td>38% (78)</td>
</tr>
<tr>
<td>Minar, 2000 (N = 56)</td>
<td>52% (29)</td>
<td>23% (13)</td>
<td>48% (27)</td>
<td>52% (24)</td>
<td>10.5</td>
<td>38% (78)</td>
</tr>
<tr>
<td>Van Der Zaag, 2004</td>
<td>16% (5)</td>
<td>39% (12)</td>
<td>55% (17)</td>
<td>23% (12)</td>
<td>10.5</td>
<td>38% (78)</td>
</tr>
<tr>
<td>Schillinger, 2006</td>
<td>32% (17)</td>
<td>36% (19)</td>
<td>89% (47)</td>
<td>77% (41)</td>
<td>10.5</td>
<td>38% (78)</td>
</tr>
</tbody>
</table>

37% (71/191)

Cath Cardiovasc Interv 2007;69:910
SFA Stenting is Superior to Angioplasty Alone

32% Crossover due to inadequate PTA result

Schillinger et al., NEJM 2006
Randomized SFA Stent Trials Demonstrate Favorable Patency Compared to PTA

<table>
<thead>
<tr>
<th>Trial name</th>
<th>Method</th>
<th>N (stent)</th>
<th>Lesion Length (cm)</th>
<th>Patency 12 mo (%)</th>
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<tbody>
<tr>
<td>FAST</td>
<td>Luminexx vs. PTA</td>
<td>123</td>
<td>4.5</td>
<td>68 vs 61</td>
</tr>
<tr>
<td>RESILIENT</td>
<td>Lifestent vs. PTA</td>
<td>137</td>
<td>6.2</td>
<td>80 vs 34</td>
</tr>
<tr>
<td>VIENNA</td>
<td>Absolute vs PTA</td>
<td>46</td>
<td>11.2</td>
<td>63 vs 37</td>
</tr>
<tr>
<td>ASTRON</td>
<td>Astron vs PTA</td>
<td>34</td>
<td>9.8</td>
<td>66 vs 39</td>
</tr>
</tbody>
</table>

Four Year Results with SFA Stent Grafts vs Fem-Pop Bypass Demonstrate Similar Primary Patency

## Percutaneous Revasc of SFA/Pop

### Factors affecting long-term patency

<table>
<thead>
<tr>
<th>factor</th>
<th>better</th>
<th>worse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication</td>
<td>claudication</td>
<td>limb salvage</td>
</tr>
<tr>
<td>Diabetes</td>
<td>absent</td>
<td>present</td>
</tr>
<tr>
<td>Smoker</td>
<td>no</td>
<td>yes</td>
</tr>
<tr>
<td>Vessel caliber</td>
<td>large</td>
<td>narrow</td>
</tr>
<tr>
<td>Disease</td>
<td>focal</td>
<td>diffuse</td>
</tr>
<tr>
<td>Lesion length</td>
<td>&lt;7cm</td>
<td>&gt;7cm</td>
</tr>
<tr>
<td>Patency</td>
<td>stenosis</td>
<td>occlusion</td>
</tr>
<tr>
<td>Calcification</td>
<td>mild</td>
<td>heavy</td>
</tr>
<tr>
<td>Runoff</td>
<td>preserved</td>
<td>compromised/poor</td>
</tr>
</tbody>
</table>

Courtesy: Kenneth Rosenfield, MD
TASC II Recommended Therapy of Femoral Popliteal Artery Stenosis/Occlusion

Endovascular Treatment of Choice

- ≤10 cm
- ≤5 cm

Preferred Endovascular Treatment

- Types B

Preferred Surgical Treatment

- ≤5 cm, Type A
- Types C

Surgical Treatment of Choice

- >20 cm, Type D

Norgren L et al. JVS. 2007:S5A–S67A
Now back to our case…..

- After 3 months of medical therapy and exercise, our patient is no better
- He continues to have disabling claudication
- He wants to know if we can “do something”
- For TASC D lesions, surgical therapy is considered preferred, but…..
CT Angiogram

Segmental SFA Disease
Angiography reveals 20cm SFA CTO
Treated with Overlapping Stents
Before and After
Followup ABI

1.11 → 0.67
1.23 → 0.84
Tibial Occlusive Disease
Angioplasty + Stenting

- Small case series
- Feasible, safe
- Little long-term data
- Provides another therapeutic alternative in this complex patient population
Durability of Endovascular Procedures

Primary Patency (%, 95% CI)

- Femoropopliteal Stent
- Iliac Stent
- Iliac PTA
- Femoropopliteal PTA
- Infrapopliteal PTA

CI=confidence interval; PTA=percutaneous transluminal angiography

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Time Course of Vascular Response to Injury

A. Platelet/Fibrin

B. Inflammation

C. Proliferation

D. Remodeling

R_x
ASA/Clopidogrel
IIb/IIIa Inhibitors

Molecular/Pharmaceutical
Anti-inflammatory Drugs

Antiprolif Drugs

Stents

All Stents Cause EC Denudation

Luminal surfaces of iliac rabbit arteries 1h post balloon expansion

Slotted tube design
Corrugated ring design

S – strut locations
E – remnant EC
M – medial SMC

Stents That Cause Less Injury Have Lower Restenosis Rates

Rogers & Edelman, Circ 1995
Neointimal thickness is proportional to stent imposed mechanical strain & thereby depends on stent design (strut spacing)
Superficial Femoral Artery: A Challenge For Revascularization

But new endovascular devices designs are designed specifically for this hostile environment...
Knee flexed

Courtesy of Gary Ansel
<table>
<thead>
<tr>
<th>Grade</th>
<th>Clinical Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No strut fractures</td>
</tr>
<tr>
<td>I</td>
<td>Single tine fracture</td>
</tr>
<tr>
<td>II</td>
<td>Multiple tine fractures</td>
</tr>
<tr>
<td>III</td>
<td>Stent fracture(s) with preserved alignment of the components</td>
</tr>
<tr>
<td>IV</td>
<td>Stent fracture(s) with mal-alignment of the stent components</td>
</tr>
</tbody>
</table>
Stent Fractures and Mechanical Stress
Left SFA Stent
The Clinical Impact of Stent Fractures

- 93 patients/121 limbs underwent systematic investigation for stent fracture
- All stents were Nitinol
- Mean follow-up 10.7 months
- Mean length of treated segment: 15.7 cm
- 45/121 limbs with fracture (37.2%)
- 64/261 stents with fracture (24.5%)

Scheinert, JACC.2005; 45:312-5
FESTO database

• Clinical importance of stent fractures
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New Stent Designs Undergo More Rigorous Bench Testing

Compression – Radial Force

Torsion

Flexibility
IDEV Supera Stent
Supera Demonstrates High Primary Patency Rates with No Fractures

N=107

No Fractures!

<table>
<thead>
<tr>
<th></th>
<th>Primary Patency</th>
<th>Secondary Patency</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 month</td>
<td>93.1% (SE 2.5)</td>
<td>99.0% (SE 0.10)</td>
</tr>
<tr>
<td>12 month</td>
<td>84.7% (SE 3.6)</td>
<td>94.8% (SE 0.23)</td>
</tr>
<tr>
<td>18 month</td>
<td>76.1% (SE 4.5)</td>
<td>93.5% (SE 0.26)</td>
</tr>
<tr>
<td>24 month</td>
<td>76.1% (SE 4.5)</td>
<td>91.9% (SE 0.30)</td>
</tr>
</tbody>
</table>

Courtesy: Sven Braunlich, MD. Presented at LINC 2011
UH CMC H-M HVI SFA Stent Protocol: SUPERB

- IDEV Supera Stent
- Local PI: Sahil Parikh
- Symptomatic patients with SFA stenoses
- Study design also looks at fracture rates
What about local drug delivery?
Stent Based Drug Delivery Makes Sense
But Drug Properties are Important

Hwang, et al., Circ, 2001

Strut Distribution

Homogenous  Inhomogenous

Compound

Hydrophilic

Hydrophobic

% Concentration

Hwang, et al, Circ, 2001
DES Inhibit Neointimal Hyperplasia in Experimental Models in the Peripheral Circulation


BMS Polymer Paclitaxel

Rabbit Iliac Arteries

7 Days 56 Days
Paclitaxel: A Model Hydrophobic Drug

- Distribution is a function of partitioning
- Slows transmural transport, localizes drug
- Enhanced dosing
- Partitioning is rate limiting factor for distribution

Radial concentration variability due to non-uniform presence of binding sites

Stent Based Drug Delivery is Complex and Impacted by Fluid Dynamics

Balakrishnan, et al. Circ 2005

Governing Equations and Boundary Conditions

\[ Eq1 \quad \frac{\partial v_z}{\partial z} + \frac{\partial v_r}{\partial r} = 0 \]
\[ Eq2 \quad \frac{\partial^2 v_z}{\partial z^2} + \frac{\partial^2 v_z}{\partial r^2} = \frac{\partial P}{\partial z} \]
\[ Eq3 \quad \frac{\partial^2 v_r}{\partial z^2} + \frac{\partial^2 v_r}{\partial r^2} = \frac{\partial P}{\partial r} \]
\[ Eq4 \quad v_z(r,-L_p) = 1 - r^2, \quad v_r(r,-L_p) = 0 \]
\[ Eq5 \quad P(L_p,r) = 0 \]
\[ Eq6 \quad Pe \left( \frac{\partial C_f}{\partial z} + \phi \frac{\partial C_f}{\partial r} \right) = \frac{\partial^2 C_f}{\partial z^2} + \frac{\partial^2 C_f}{\partial r^2} \]
\[ Eq7 \quad 0 = \frac{\partial^2 C_f}{\partial z^2} + \frac{\partial^2 C_f}{\partial r^2} \]
\[ Eq8 \quad C_f(-L_p,r) = 0 \]
\[ Eq9 \quad \frac{\partial C_f}{\partial z} \bigg|_{z=L_p/R} = 0 \]
\[ Eq10 \quad \frac{\partial C_f}{\partial r} \bigg|_{r=W_p/R} = 0 \]
\[ Eq11 \quad D_{f,0} \frac{\partial C_f}{\partial r} \bigg|_{r=0} = \frac{\partial C_f}{\partial r} \bigg|_{r=0} \]
\[ Eq12 \quad \frac{\partial C_f}{\partial z} \bigg|_{z=-L_p/R,L_p/R} = 0 \]
\[ Eq13 \quad C_f = 1 \quad \text{on} \quad \Gamma \cap \Omega_{\text{lumen}} \]
\[ Eq14 \quad C_i = 1 \quad \text{on} \quad \Gamma \cap \Omega_{\text{issue}} \]
Different Release Kinetics Deliver Similar Coronary Efficacy

Paclitaxel Coated Balloon

Cumulative % released

Days

Adapted from Moses, CIT
Arterial Drug Uptake is a Function of Presentation Kinetics and Drug Properties

Parikh, et al. (Submitted)
Durable Reduction in Coronary TLR with DES
9 Prospective, Double-Blind, Randomized Trials: Freedom From Ischemic TLR (*Meta-Analyses by CRF*)

Drug Eluting Balloons demonstrate lower restenosis rates in clinical trials.

Paclitaxel Eluting Balloon PTA Demonstrates Superior Patency and MAVE at 6 Months compared to PTA

![Graph showing comparisons between MOXY and PTA at 6 months for different endpoints such as TLR, TVR, Thrombosis, Death, and Composite Clinical Endpoints.]

DES are Superior to PTA or BMS in SFA stenoses

Zilver PTX Trial:
Paclitaxel eluting stents vs standard of care (PTA +/- BMS)

Event-free Survival: Freedom from CEC-adjudicated death, amputation, and target lesion revascularization, or worsening Rutherford score (by 2 classes or to class 5 or 6)

TLR Rates of DES in the SFA are NOT the same as the Coronary Bed

What Questions Remain for DES/DEB?

I: new mechanisms?
II: dose?
III: duration?
IV: kinetics?

A. Thrombus
B. Inflammation
C. Proliferation
D. Remodeling

DAYS AFTER INJURY
Inhibitors of Syk Reduce Inflammation, Thrombosis, and Neointimal Hyperplasia in Vascular Injury Models

Courtesy: Daniel I. Simon, MD
What about Cell Therapy?
TISSUE ENGINEERED ENDOTHELIAL CELLS

Viability Assay

AcLDL Uptake

Tissue Culture

Gelfoam®

In Vivo

Influence Arterial Repair

Viability Assay

AcLDL Uptake

Graph: Time (days) vs. Cell Number (10^5)

0 2 4 6 8 10

0 7 14

Cell Number/10^5

Time (days)
TISSUE ENGINEERED IMPLANTS INHIBIT INTIMAL HYPERPLASIA

Rat Carotid Balloon Injury 14 Days

Control Artery: Balloon Injury

Tissue Engineered Implant: Balloon Injury+Gelfoam+BAEC

EC Implants Inhibit Neointimal Hyperplasia in a Porcine SFA model

Nugent, et al. JVIR, 2009
Other Evolving Techniques: Atherectomy Devices

Silverhawk

Jetstream

Diamondback

LASER
Intravascular Imaging of PAD

- Angiographic assessment of vascular pathology is often inadequate.
- Coronary intervention studies demonstrate that "geographic miss" due to reliance on angiography predicts restenosis.
- Intravascular imaging in PAD remains an underutilized technique.
- IVUS has 100-200\(\mu\)m resolution while OCT has 10\(\mu\)m resolution.
Endovascular Therapy for Lower Extremity Arterial Disease

• Potential Advantages
  – Low risk of wound infection
  – Very low mortality rates
  – Potential cost advantage
  – Repeatable
  – Preferred by patients

• Controversies and unanswered questions
  – Is therapy better than natural history of disease?
  – Is therapy durable?
  – Do results justify lowering threshold to intervene?
  – Will therapy complicate other options in future?
Conclusions

• Internists and Cardiologists MUST be engaged in the management of PAD as we are in the management of CAD
• Endovascular therapy for LE PAD should be considered FIRST LINE therapy in most cases
• Restenosis REMAINS a vexing problem, and the leading mode of failure of SFA intervention
• New therapies with alternate stent designs and local drug and cellular delivery are promising
• New targets for therapy MUST be developed to move the field forward, however regulatory hurdles are limiting our progress
Endovascular Medicine & Intervention Service

• **PURPOSE**: To provide inpatient and outpatient consultative services, teaching, and assistance in management for the full spectrum of vascular diseases.

• **CLINICAL ISSUES ADDRESSED**
  – Coronary Artery Disease and Coronary Intervention
  – Cerebrovascular Disease
  – Peripheral Arterial Disease
  – Aortic Disease
  – Renal Artery Disease
  – Mesenteric Vascular Disease
  – Complex Venous Thromboembolic Disease (acute or chronic including IVC filters)
  – Pulmonary embolism
  – Antiplatelet therapy for primary/secondary prevention and periprocedural management of dual antiplatelet therapy
  – Access Site Complications after invasive procedures, including management of hematoma, pseudoaneurysm (i.e. ultrasound-guided thrombin injection), A-V fistula
Endovascular Medicine & Intervention Service

- Arteriography and Endovascular Intervention:
  - Carotid, Vertebral and Subclavian
  - Lower Extremity Vessels: Iliac, Femoral, Below-the-knee
  - Renal
  - Mesenteric

- Venous Angiography and Intervention
  - IVC Filter placement and retrieval
  - Thrombolysis (systemic or catheter directed including suction embolectomy)
  - Angioplasty

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Factors Influencing Threshold for Intervention: “Inflow” versus “Outflow”

**Principles**

- Fix inflow first
- Prox revasc = Tech success
- Distal revasc = Tech difficulty
- Restenosis
- For healing ulcers, must restore straight-line flow to foot

**Restenosis rates**

- Aorta <10%
- Iliac 10%-20%
- Superficial femoral/popliteal artery 20%-70%
- Tibioperoneal 30%-75%

Courtesy: Kenneth Rosenfield, MD
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Endovascular Medicine and Intervention Pager #38686
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