In-Stent Restenosis: What Works Best?

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Disclosures

- Cook Medical - scientific advisor DCB program
- Medtronic – scientific advisor DCB program

Restenosis: The Continuing Challenge for Vascular Intervention

- Most severe in the peripheral vasculature
- Limited Current Strategies
  - Cutting balloons
  - Covered stents
  - Brachytherapy
  - Atherectomy
  - Drug-eluting stents, balloons
    - Promising data in early studies
    - Gene and cell-based therapies
- Remains the greatest unmet need in Vascular Intervention

Growing impact of restenosis on the surgical treatment of peripheral arterial disease. Jones DW et al; JAHA 2013 Nov 25; 2(6)

RESTENOSIS IS THE NEW VASCULAR EPIDEMIC

72% relative increase in secondary bypass procedures

p < 0.001

N=3,504 patients who underwent an Index LE Bypass in VSGNE Database
Advanced SFA Disease: Treatment Failure is Common

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Estimated 2-yr Patency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>POBA</td>
<td>20-30</td>
</tr>
<tr>
<td>PTA+ BMS (or DES)</td>
<td>30-60</td>
</tr>
<tr>
<td>Atherectomy +/- adjunct</td>
<td>30-50</td>
</tr>
<tr>
<td>Endoluminal stent graft</td>
<td>40-60</td>
</tr>
<tr>
<td>Fem-Pop Bypass Grafting</td>
<td></td>
</tr>
<tr>
<td>Vein (AK or BK)</td>
<td>70-80</td>
</tr>
<tr>
<td>Prosthetic (AK)</td>
<td>65-80</td>
</tr>
<tr>
<td>Prosthetic (BK)</td>
<td>40-60</td>
</tr>
</tbody>
</table>

Fem-Pop ISR Treatment Options

- POBA/Cutting balloon
  - DCB not yet available in US
- Repeat stenting: BMS or DES
- Atherectomy +/- stent or covered stent
- Covered stent
- Open bypass

ISR Treatment: Factors to Consider

- Clinical status: CLI vs claudication vs Asx
  - No good data to support prophylactic reintervention
- Patient risk for open surgery, presence of GSV
- Failure pattern- timing and frequency
- Anatomic pattern
  - Stenosis vs occlusion
  - Lesion length and reference vessel diameter
  - Risk to collateral vessels, extension into popliteal
  - Potential effects on downstream surgical options
- Costs and resources
- NO LEVEL 1 DATA (Several RCTs in the works)
  - Provider bias esp regarding when to convert to open
What we are all trying to avoid...

- Mean stent length 163mm
- PSV>2.4; >50% angio
- 35% early ISR (<6 mo)
- All treated by repeat PTA alone
- Antiplatelet monotherapy

In-Stent Restenosis: Lesion Severity and Outcomes of Repeat PVI

**Drug-Eluting Balloons for the Treatment of the Superficial Femoral Artery in Stent Restenosis**

2-Year Follow-up

- N=39
- Final dilation using IN.PACT PTX balloon
- DAPT

VirgaV et al JACC Int 2014

**Covered Stents for Fem-Pop ISR**

- Several small retrospective series (<30 pts)
- Repeat failure rates 18-37% at mid term FU
- May be a useful approach in selected patients depending on clinical and anatomic scenario
- Concerns regarding collateral coverage and clinical deterioration if Viabahn fails, and possible major impact on subsequent open bypass

**Treatment of Femoropopliteal In-Stent Restenosis With Paclitaxel-Eluting Stents**

- Zilver PTX Global Registry
- N=108
- Lesion length 133mm
- 43% TASC C/D
- 31% occlusions
- DAPT indefinite

Zeller T et al JACC Int 2013; 6:274-81

**Clinical consequence of bare metal stent and stent graft failure in femoropopliteal occlusive disease**

Shunt M. Vartanian, MD,* Paul C. Johnston, MD,* Joy P. Walker, MD,* Sara J. Ringer, MD,* Charles M. Eichler, MD,* Linda M. Reilly, MD,* Jade S. Hirananto, MD,* and Michael S. Covic, MD,* San Francisco, Calif and Denver, Colo

- Table V. Summary of major late clinical events in both cohorts
- Freedom from any reintervention
- Number at risk (N)
  - SG 63
  - SG 24
  - SG 18
  - SG 9
  - SG 54
- Freedom from any reintervention (%) at 9 months
  - SG 81
  - SG 71

4/3/2014
Impact of Treatment Failure on Surgical Options in PAD

- Many advocate “endovascular first” treatment strategies
  - Presumed harmless as long as bypass targets remain intact
  - Stakes may increase with each PVI
- However, prior work has suggested that bypass following a failed prior peripheral endovascular intervention (PVI) is associated with poorer outcomes

Open Bypass for Fem-Pop ISR

- Little data in the literature
- Inflammation frequently extends beyond the stent
- Often requires below-knee anastomosis
- Multiple endo reinterventions may have led to loss of distal runoff, more severe ischemia
- Limited data suggests failure rates may be higher in secondary LEB compared to primary LEB
- Vein conduit strongly preferred
- Surveillance- unclear if ISR and VG stenosis propensity share related risk factors e.g. genetic
ISR Treatment Algorithm

• **Critical Limb Ischemia**
  – Class I lesion: repeat PTA +/- DES (DCB?)
  – Class II lesions: covered stent vs Open LEB
    • Open bypass favored for disease extent into popliteal, more advanced tissue loss, in a suitable candidate
  – Class III lesions: open LEB favored

• **Claudication**
  – Carefully consider risk/benefit of reintervention
    • Initial treatment length, timing and frequency of failures
    • Location of initial intervention- avoid extending into popliteal especially mid and distal
    • Contralateral disease/symptoms
  – Lesion considerations as above

• **Asymptomatic**
  – BE VERY SELECTIVE