Reccurrent Stenosis in the SFA: Treatment Strategies

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Restenosis After SFA Interventions

- Restenosis is the “Achilles heel” of SFA interventions and is common
- Stents prevent elastic recoil, but intimal hyperplasia results in (diffuse) ISR
- No proven endovascular treatment for ISR
- Prevention and treatment of restenosis remain one of the major challenges of vascular surgery today

More Interventions = More Restenosis

Endo: 115% Increase
Bypass: 31% Decrease

Hong, Ann Vasc Surg 2011

Disclosures

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- Cook, Inc. - research funding
- EV3 – consultant
- Bard – consultant
POBA – “Plain Old Balloon Angioplasty”

High Incidence of Restenosis

PTA vs. Nitinol Stents: 1 Year Patency

ABSOLUTE Trial
N = 104
Mean Lesion Length
4.5 cm

FAST Trial
N = 244
Mean Lesion Length
4.5 cm

RESILIENT Trial
N = 206
Mean Lesion Length
4.5 cm

ABSOLUTE
Schillinger
NEJM 2006

FAST
Krankenberg
Circulation 2007

RESILIENT
Laird
Circ Cardiovasc Interv 2010

Vascular Interventions Cause Vascular Injury

• Balloon angioplasty
  – Endothelial loss
  – Stretch injury
  – Fissure/dissection
  – Platelet adherence

• Stents
  – Laceration by struts
  – Platelet adherence
  – Mechanical strain
  – Foreign body

Vascular Injury Response Restenosis
Restenosis After Angioplasty and Stenting

Time Course and Phases of Restenosis

VIENNA: Angiographic Restenosis at 6 Months

<table>
<thead>
<tr>
<th>N</th>
<th>PTA</th>
<th>Stent</th>
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<tbody>
<tr>
<td>12mo restenosis rate (ITT)</td>
<td>101</td>
<td>63%</td>
</tr>
<tr>
<td>24mo restenosis rate (ITT)</td>
<td>98</td>
<td>69%</td>
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Risk Factors

- DM
- Renal Failure
- Lesion length
- TASC C&D
- CRP
- Poor runoff
- Calcification
Reintervention for SFA Restenosis & ISR

- PTA
- Cutting balloon
- Cryoplasty
- Atherectomy
- Reline with bare stent
- Reline with covered stent
- Drug coated balloon (DCB)
- Drug eluting stent (DES)

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Ineffective

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Promising

PTA is Ineffective Treatment of ISR

Dick Radiology 2008
Cryoplasty for Arterial Restenosis


“Cryoplasty is of no value in patients with restenosis … with half the procedures failing within 6 months and all of them within the 1st year.”

Atherectomy: Role for SFA Disease and Restenosis Unclear

Scheinert et al. JACC 45:312-315 (2005)

Stent Fractures & Restenosis

Schrinert et al. JACC 45:312-315 (2005)
Results: Treatment of ISR with Covered Stents

- 24 limbs in 22 patients (2006 to 2010)
- Nitinol diffuse in-stent restenosis
  - 21 (87%) native SFA/popliteal arteries
  - 3 (13%) vein fem-pop bypass grafts
  - 7 (29%) stent occlusion
  - 6 (25%) debulking with laser atherectomy
  - 75% TASC C (n=11) OR TASC D (n=8)
- All completely relined with Viabahn covered stents
- Median F/U: 595 days
A) Survival
62%

B) Primary Patency

C) Primary Assisted Patency
79%

D) Secondary Patency
Drug-Eluting Devices for the SFA

- Drug-Coated balloons (DCB)
  - Thunder
  - Fem-Pac
- Drug-Eluting Stents (DES)
  - SIROCCO (Sirolimus)
  - STRIDES (Everolimus)
  - Zilver PTX (Paclitaxel)

Zilver® PTX® Drug-Eluting Stent

- Designed for the SFA
- CE Marked
- Paclitaxel only
  - No polymer or binder
  - 3 µg/mm² dose density
- Zilver® Flex™ Stent Platform
Restenosis: Treatment Considerations

- Is reintervention required?
  - Surveillance finding vs. clinical failure
  - Stable claudication
  - Limb threat; have wounds healed

- Stenosis vs occlusion
  - Acute: thrombolysis/mechanical thrombectomy
  - Chronic: redo revascularization
Restenosis: Treatment Considerations

- Focal vs. diffuse process
  - Focal: PTA
  - Diffuse: reline with covered stent
  - DCB and DES in the near future
- Stent fractures
  - Reline with covered stent (or bare stent)
- Repeated failures
  - Consider surgical bypass

Conclusions

- Restenosis after SFA interventions is common and remains an ongoing major challenge
- Literature on clinical management of restenosis is limited; additional study is needed
- Patency rates for reintervention are lower than for primary interventions

Conclusions

- Relining with covered stents may be used to successfully treat diffuse in-stent restenosis
- Drug technology will be available soon & may be useful for prevention & treatment of restenosis after SFA interventions
- Most failures can be managed with repeat endovascular approaches, but surgical options should be considered