Strategies for PCI of SVG

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OPTIONS FOR IMPROVED OUTCOMES IN SVG PCI

Direct Stenting

Embolic Protection

Vasodilators

Thrombus Management

Stent Sizing Issues

?
PCI of SVG’s
Which lesions embolize?

1. Cannot predict which lesion will embolize.
2. Cannot predict how severe the embolization will be.
3. Significant embolization occurs in 5-20% of SVG’s.

(Predictors: ↑ plaque mass, positive remodeling, degeneration index).
SAFER Trial – Comparison of PercuSurge to Routine Stenting in SVG’s

801 Patients Randomized

30 Day MACE

Routine: 16.5%

PercuSurge: 9.6%

Reduced 42%
P<0.001

Baim et al. Circulation 2002; 105: 1285
SAFER Trial: Predicted Rates of MACE Between Control and Treatment

Treatment with distal embolic protection provides benefit across all risk levels.

Giugliano G.R, et. al. on behalf of the SAFER Trial Investigators. AJC 2005;95:173-177
Short Lesions benefit from protection as much as Long Lesions. SAFER Trial.

GuardWire® System versus Control

- Lesion Length (mm)
  - <10: 73%
  - 10-14.8: 51%
  - 14.8-22: 30%
  - >22: 22%

% MACE
### Fire Trial: Randomized Filter

**Wire vs. PercuSurge in SVG PCI**

650 patients in 65 sites

<table>
<thead>
<tr>
<th></th>
<th>FW</th>
<th>GW</th>
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<tbody>
<tr>
<td>TIMI 3 Flow</td>
<td>95.7%</td>
<td>97.7%</td>
</tr>
<tr>
<td>Device Success</td>
<td>95.5%</td>
<td>97.2%</td>
</tr>
<tr>
<td>Death</td>
<td>0.9%</td>
<td>0.9%</td>
</tr>
<tr>
<td>MI</td>
<td>9.0%</td>
<td>10.0%</td>
</tr>
<tr>
<td>QMI</td>
<td>0.9%</td>
<td>0.6%</td>
</tr>
<tr>
<td>30 day MACE</td>
<td>9.9%</td>
<td>11.6%</td>
</tr>
</tbody>
</table>

**Conclusion:** FW not inferior to GW

Stone et al. J Am Coll Cardiol 2003; 41: 43A
Example of SVG unsuitable for distal protection

Best Strategy for Embolic Protection in this Patient is Proxis
The PROXIMAL Trial: Proximal Protection During Saphenous Vein Graft Intervention Using the Proxis Embolic Protection System

A Randomized, Prospective, Multicenter Clinical Trial

Laura Mauri, MD, MSc, FACC,*† David Cox, MD, FACC,‡ James Hermiller, MD, FACC,§ Joseph Massaro, PhD,† Joyce Wahr, MD,‖ Sew Wah Tay, PhD,‖ Michael Jonas, MD,* Jeffrey J. Popma, MD, FACC,* Jim Pavliska, BS,‖ Dennis Wahr, MD, FACC,‖ Campbell Rogers, MD, FACC*
### Proximal Trial: Proxis vs. Filter or PercuSurge in SVG PCI

594 randomized patients

<table>
<thead>
<tr>
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<th>Prox</th>
<th>Distal</th>
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<tbody>
<tr>
<td>Death</td>
<td>0.7%</td>
<td>1.0%</td>
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<tr>
<td>Non QMI</td>
<td>7.9%</td>
<td>6.4%</td>
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<tr>
<td>QMI</td>
<td>0.7%</td>
<td>1.7%</td>
</tr>
<tr>
<td>30 day MACE</td>
<td>9.2%</td>
<td>10.0%</td>
</tr>
</tbody>
</table>

Conclusion: Proxis not inferior to GW or FW
Role of Embolic Protection

- Beneficial across all patient subsets in 6 studies; plaque volume and SVG degeneration strongest predictors of MACE (Coolong et al Circulation 2008;117:790-97)

- No better than direct stenting in 188 patients at Washington Hospital Center in an observational study (Okabe et al CCI 2008;72:799-803)

- Used in <25% of 19,546 SVG PCI in the ACC-NCDR Registry (Mehta et al AJC 2007;100:114-118)
PCI in SVG Disease is often Complicated by Myocardial Infarction

Creatine Kinase > 3 times normal

Procedural AMI is the strongest predictor of late death

3. Circulation 1999; 100: 2400-2405
CKMB Release and Mortality.

WHC: Hong et al. Circulation 1999;100:2400-5

1052 patients with successful SVG PCI

- 47% had CK-MB rise, even after successful PCI
- 15% had major CK-MB rise
- Even minor CK-MB rise related to a significant late mortality increase
- Major CK-MB rise related to 144% increase in late mortality
CK release post PCI of De-Novo and ISRS in SVG

342 ISRS and 2555 De Novo SVG Lesions.
Prevention of No Reflow in SVG PCI
Variety of Distal Protection Approaches & Costs

**PercuSurge™**
- Cost ~ $1,195
- Extra Time ~ 20 min.
- Complexity ****

**FilterWire EX**
- Cost ~ $1,195
- Extra Time ~ 20 min.
- Complexity ***

**Prophylactic IC Nicardipine**
- Cost ~ $87/vial
- Extra Time ~ 2 min.
- Complexity *

Courtesy Tim Fishell, TCT 2007

Nicardipine = Cardene
Protection Devices for SVG’s. MACE Rates

Protection Devices:

- Effectively decrease distal embolization.
- Do not eliminate distal embolization.
- Should always be considered.
Is there a role for 2B3A inhibitors in SVG angioplasty?
## MACE and 2B3A in SAFER Trial

<table>
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<tr>
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<th>Percusurge</th>
<th>No Percusurge</th>
<th>p-Value</th>
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<tr>
<td>IIb/IIlla</td>
<td>10.1%</td>
<td>20.8%</td>
<td>0.003</td>
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<td>No IIb/IIlla</td>
<td>7.1%</td>
<td>12.4%</td>
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</table>

Baim DS, SAFER subset analysis presented November 18, 2002; AHA.
Second Conclusion

2B3A inhibitors offer NO benefit in PCI of SVG’s.
Technical Aspects.
Pre dilatation before stenting?

NO!
Always plan on direct stenting.
Predilatation often associated with distal embolization.
Technical Aspects.
Post dilatation after stenting?

- It is the most common cause of distal embolization.
- Do it only if severe stent under expansion is evident.
- Always with distal protection.
Direct Stent in SVG’s.
WHC: Leborgne et al. AHJ 2003;146:501-6

• 507 patients (672 lesions) with 12 m f/u.
• 229/672 lesions with direct stenting.
• Direct stenting had
  – Less CK MB >4x (13.6 vs 23. p<0.12)
  – Lower Maximum CK MB (9.5 vs 19.6  p<0.001)
  – Less NQMI (10.7 vs 18.4 p< 0.024)
  – Less TLR at 1 year (p<0.02)
  – Improved EFS at 12 months
Direct Stenting in the Safer Trial SVGs

Baim DS, SAFER subset analysis presented November 18, 2002; AHA.
Third Conclusion

• Direct Stenting is the technique of choice.
• Protection Device still beneficial.
Any role for Vasodilators in PCI of SVG’s?
Vasoconstrictors Released in PCI of SVG.

Concentration of Vasoconstrictor

- Serotonin: 9.7 ng/ml
- Endothelin: 1.6 pg/ml

Vessel Constriction Induced by SVG Aspirate. (TXA2, 5HT & ET Release)

Vessel Constriction with TXA2 and 5HT Blockers


Pharmacologic Agents Shown to Reverse No Reflow

**IC Diltiazem** 23/24 cases (95%) reversal to normal flow.
Mooney, et al 1995, AJC.

**IC Adenosine** with 92-94% reversal to normal flow

**IC Verapamil** -> 90% with improved flow.

**IC Nitroprusside** reversal in >90% of cases.

**IC Nitroprusside + Adenosine** reversal in >90% of cases.

**IC Nicardipine (Cardene):** prevents no reflow in 98% of pts.
Fishell et al. JIC 2007,19:58-62
CBF and IC Calcium Channel Blockers.
Fourth Conclusion

- Intracoronary vasodilators are effective to:
  - prevent no reflow
  - treat no reflow.
New Strategy

• Small Stent for Large SVG’s
Small Stents for Large SVG’s

Large Stent in Large Vein

Plaque extrudes through the stent into the lumen

Small Stent in Large Vein

Plaque stays behind the stent struts
2 years later
Small Stents in Large SVG’s. TLR at 1 year in 72 patients.

Washington Hospital Center. Salah et al. 06

Minimum Stent Area (mm²) by IVUS
Small Stent in Large SVG. IVUS Findings.

WHC: WJ Hong et al. Am J Cardiol in press

![Stent/SVG diameter bar chart]

- Stent/SVG diameter:
  - <0.7: 21 lesions
  - ≥0.7: 188 lesions

- Stent malapposition:
  - 33 lesions (7/21)

- Plaque prolapse:
  - 40 lesions (76/188)

- p<0.001
- p=0.056
Small Stent in Large SVG. IVUS Findings.

WHC: WJ Hong et al. AJC in press 2009.

Stent/SVG diameter
- <0.7: 21 lesions
- ≥0.7: 188 lesions

- TLR: p=0.12
- TVR: p=0.089

(0/21) 11 (20/188) 12 (23/188)
- Vein grafts are often oversized.
- Stent size that matches the target native vessel provides adequate flow.
- Small stents in large saphenous veins decreases acute and longterm MACE.
No increase in restenosis if MLA >6mm².
Probably no need for protection device
Patient with NSTEMI
Oct 8th, 2009
Drug therapy initiated to attempt Thrombus resolution

- Was treated with:
  - ASA
  - Plavix
  - 2b3a infusion
  - Lovenox
5 days later

Contrast injection:
no flow

Distal contrast through
Microcatheter
In view of persistent abundant filling defects…

Patient received for 2 more days:
• Reopro intra-graft
• Reopro IV, Plavix, Lovenox, ASA.
2 days later…

Contrast injection through microcatheter
1.25mm balloon in severe stenosis.
2.5mm Xience Prime Stents deployed at Low Pressure
Minimal Touch to obtain flow and antithrombotic medical therapy for 48-72 hours may reduce significantly the thrombus burden.
Sixth Conclusion.

Optimal Medical Therapy is effective in SVG’s.

Additional mild or moderate lesions in SVG’s should be stented also.
• Do drug eluting stents offer and advantage in SVG’s?
DES vs BMS for SVG’s.

WHC: Okabe et al. AJC 2008; 102:530-4

138 cases with 183 lesions (sirolimus-eluting stents, n = 117; paclitaxel-eluting stents, n = 66) and the BMS group consisted of 344 cases with 478 lesions
3 year Outcome in SES for SVG.
Delayed RRISC Trial. Agostoni et al JACC 2007
DES vs BMS for SVG. 4 year f/u.  

### Non adjusted

**Survival of MACE (%)**

- **Logrank p = 0.035**
  - univariate HR: 0.66; 95% CI [0.45-0.98]
  - Adjusted HR: 0.77; 95% CI [0.51-1.16]

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### Adjusted

**Survival of MACE (%)**

- **Logrank p = 0.65**
  - Univariate HR: 0.89; 95% CI [0.52-1.51]
  - Adjusted HR: 1.09; 95% CI [0.63-1.90]

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TVR free Survival.

DES did not provide statistically significant benefit in any other subgroup including **diabetics** and patients with **long lesions**.
DES vs. BMS for SVG
Washington Hospital Center: Okabe et al. 2007

P < 0.001

P < 0.02

ns

MACE

ns

BMS 375 les.
DES 151 les.
Seventh Conclusion

• Advantage of DES vs BMS in large SVG’s is not settled at this point.
Do Covered Stents offer an advantage in SVG’s?
Endoluminal Stent Grafts

**Jomed**

*PTFE covered Balloon-expandable*

**SYMBOIOT-BSC**

*Self-expanding*
Symbiot III Randomized Trial
Jomed Covered Stent for SVG. Recovers Trial

300 patients randomized
Eight Conclusion

Existing Covered Stents have not shown any benefit for PCI of SVG’s.
Summary

• Distal or proximal protection is effective.
• 2b3a inhibitors offer no benefit.
• Pharmacological vasodilation is effective.
• Direct stenting is better.
• Small stent in large veins: A safe and provocative approach
• Role of DES and Covered Stents in SVG is not clear