Percutaneous Treatment of Saphenous Vein Grafts

Michael S. Lee, MD, FACC, FSCAI
Assistant Director, Interventional Cardiology Research
UCLA School of Medicine
SVG Intervention

- 300,000 new CABG/year*
- 10% of PCI case volume

*MedPar Data
SVG Angiographic Patency

Fitzgibbon et al. JACC 1996;28:616
Typical SVG disease progression

**First month**
- Thrombosis
- Intimal hyperplasia

**1-7 years**
- Build-up of atherosclerosis with superimposed thrombus

**7-10 years**
- Occlusion
- Friable atheroma and thrombi are bulky and particularly prone to distal embolization during PCI, leading to a significant increase in the risk of death or MI
Saphenous Vein Graft PCI

- Is associated with worse outcomes compared with PCI of native coronaries
  - **Acute complications**
    - Periprocedural MI
    - No-reflow
  - **Long-term**
    - Restenosis
- Patients often have comorbid conditions, extensive disease, and LV dysfunction
CK-MB Rise in SVG PCI

Rates After Successful SVG Intervention

\[ n=1056 \text{ consecutive SVG interventions} \]

- 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
- Patients with major CK-MB rise had 2.5x the mortality as those with normal CK-MB

Hong, et al., Circulation. 1999;100:2400-2405.
Causes of Microvascular Obstruction

- Distal embolization from PCI causes microvascular obstruction via plugging, with secondary spasm and platelet aggregation.

No-Reflow Has Lasting Consequences

• Complicates 10–15% of SVG PCI\(^1\)
• 31% rate of AMI\(^2\)
• Increases in-hospital mortality by 10-fold\(^2\)
• Atheroembolization is a key contributor\(^3\)

1 Sdringola, et al., Cathet Cardiovasc Intervent. 2001
Saphenous Vein Graft Intervention

State-of-the-Art 2011

Michael S. Lee, MD,* Seung-Jung Park, MD,‡ David E. Kandzari, MD,§
Ajay J. Kirtane, MD, SM,∥ William F. Fearon, MD,† Emmanouil Brilakis, MD,¶
Paul Vermeersch, MD,# Young-Hak Kim, MD,‡ Ron Waksman, MD,** Julinda Mehilli, MD,††
Laura Mauri, MD,‡‡ Gregg W. Stone, MD∥

Los Angeles, and Palo Alto, California; Seoul, South Korea; Atlanta, Georgia; New York, New York;
Dallas, Texas; Antwerp, Belgium; Washington, D.C.; Munich, Germany; and Boston, Massachusetts

Saphenous vein grafts are commonly used conduits for surgical revascularization of coronary arteries but
are associated with poor long-term patency rates. Percutaneous revascularization of saphenous vein grafts
is associated with worse clinical outcomes including higher rates of in-stent restenosis, target vessel revas-
cularization, myocardial infarction, and death compared with percutaneous coronary intervention of native
 coronary arteries. Use of embolic protection devices is a class I indication according to the American Col-
lege of Cardiology/American Heart Association guidelines to decrease the risk of distal embolization, no-
reflow, and periprocedural myocardial infarction. Nonetheless, these devices are underused in clinical prac-
tice. Various pharmacological agents are available that may also reduce the risk of or mitigate the
consequences of no-reflow. Covered stents do not decrease the rates of periprocedural myocardial infarc-
tion and restenosis. Most available evidence supports treatment with drug-eluting stents in this high-risk
lesion subset to reduce angiographic and clinical restenosis, although large, randomized trials comparing
drug-eluting stents and bare-metal stents are needed. (J Am Coll Cardiol Intv 2011;xx:xxx) © 2011 by the
American College of Cardiology Foundation
Should embolic protection be used for SVG Intervention?
### SVG PCI

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
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</thead>
<tbody>
<tr>
<td>Embolic protection device use when technically feasible</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>GP IIb/IIIa inhibitors</td>
<td>III - No Benefit</td>
<td>B</td>
</tr>
<tr>
<td>PCI for chronic SVG occlusions</td>
<td>III - Harm</td>
<td>C</td>
</tr>
</tbody>
</table>

2011 ACCF/AHA/SCAI Guideline for PCI (and Coronary Revascularization)
Rationale for Embolic Protection

- Embolization is common and is associated with 8-10 fold increase in mortality
- Although risk factors can be identified, embolization cannot be reliably predicted
Material capture is common and independent of patient demographics, clinical presentation, and lesion characteristics.

Weisz, et.al. JACC Vol. 43, (suppl A); 72A-73A
Distal occlusion + aspiration (Percusurge)

Distal filters

Proximal occlusion + aspiration
Occlusion and Aspiration

**Advantage**
- Easy to cross lesion
- Captures smaller particles and “humoral” mediators
- Easy device retrieval

**Disadvantage**
- Difficult to image during stenting
- Balloon injury
- Transient occlusion/ischemia
- May not catch particles near balloon and not get full evacuation
- Cumbersome operation
SAFER (Saphenous Vein Graft Angioplasty Free of Emboli Randomized) Trial

801 patients with SVG Disease
Mean graft age 10.4 yrs (range 7-13)

GuardWire Plus
n=406

Conventional Guidewire
n=395

Endpoint: 30-day MACE

# SAFER Trial

*Primary Endpoint*

<table>
<thead>
<tr>
<th></th>
<th>With protection (n=406)</th>
<th>No protection (n=395)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>MACE out to 30 days</em></td>
<td>9.6%</td>
<td>16.5%</td>
<td>*p=0.004</td>
</tr>
<tr>
<td>All MI</td>
<td>8.6%</td>
<td>14.7%</td>
<td>*p=0.008</td>
</tr>
<tr>
<td>Q-wave MI</td>
<td>1.2%</td>
<td>1.3%</td>
<td>NS (p=1.00)</td>
</tr>
<tr>
<td>Non Q-wave MI</td>
<td>7.4%</td>
<td>13.7%</td>
<td>*p=0.004</td>
</tr>
<tr>
<td>Death</td>
<td>1.0%</td>
<td>2.3%</td>
<td>NS (p=.171)</td>
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<tr>
<td>Emergent CABG</td>
<td>0.0%</td>
<td>0.5%</td>
<td>NS (p=.243)</td>
</tr>
<tr>
<td>TLR</td>
<td>1.0%</td>
<td>2.0%</td>
<td>NS (p=.257)</td>
</tr>
</tbody>
</table>

*Baim DS, et.al., Circulation. 2002;105:1285-1290.*
Proxis

Benefits
- Nothing crosses the lesion prior to protection
- Protection of main vessel and side branches
- Captures large and small particles
- Can handle large embolic loads

Proximally Deployed
-Proxis™

-Target Lesion with Stent
Filters

**Advantage**
- Maintain Flow
- Visualization during procedure
- Non-ischemic
- Intuitive operation

**Disadvantage**
- May not capture all particles <100 micron
- Does not control secretions of humoral factors
FIRE Trial
30-Day MACE

FilterWire EX® System (n=332)
GuardWire Plus® System (n=319)

P = 0.0016 (non-inferiority for MACE with 5.5% delta)

AngioJet Thrombectomy
30-Day Clinical Results
Stopped early (349 vs 500) by DSMB!

VEGAS 2 Trial

Death MI MACE

Angiojet

Urokinase

P=NS

P<0.001

P<0.001

1.7%
3.0%
13.9%
30.8%
33.1%
0%
10%
20%
30%
40%

VEGAS 2 Trial

30-Day Clinical Results
Stopped early (349 vs 500) by DSMB!

VEGAS 2 Trial

30-Day Clinical Results
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VEGAS 2 Trial

30-Day Clinical Results
Stopped early (349 vs 500) by DSMB!
Is there any role of GP IIb/IIIa receptor antagonists in SVG Intervention?
Lack of Benefit of GPIIb/IIIa Inhibitors in SVG PCI

Pooled Analysis of 5 Randomized Trials

Death, MI, Revascularization

- 30 Days: 13% (Placebo), 16% (IIb/IIIa)  
  - P = 0.18

- 6 Months: 33% (Placebo), 39% (IIb/IIIa)  
  - P = 0.07

Roffi et al. Circulation 2002
Conclusion

IIbIIIa inhibitors offer NO benefit in SVG intervention
223 consecutive patients underwent SVG intervention
Non-randomized, single center, retrospective analysis

Operator discretion

BMS (201 stents)
\[ n=84 \text{ patients} \]

DES (289 stents: 211 SES, 78 PES)
\[ n=139 \text{ patients} \]

Clinical Outcomes at 9 Months

- Death: 1% (n=139), 4% (n=84), P=0.03
- MI: 4%, 4%, P=0.04
- TVR: 20% (n=139), 37% (n=84), P=0.003

75 patients with 96 lesions localized in 80 diseased SVG. Prospective, randomized, double-blind, non industry sponsored, single center, trial.

**Primary endpoint**
- 6-month in-stent late loss

**Secondary endpoints (all at 6 months follow up):**
- Binary angiographic restenosis (in-stent/in-segment)
- Clinical events (death, MI, TLR, TVR)

**RRISC Trial**

Reduction of Restenosis In Saphenous vein grafts with Cypher stent

75 patients with 96 lesions localized in 80 diseased SVG. Prospective, randomized, double-blind, non industry sponsored, single center, trial.

**Randomized**

- BMS
  - n=37
- Cypher stent
  - n=38

Vermeersch et al. JACC 2006
## 6-month MACE

<table>
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<tr>
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<th>BMS n=37</th>
<th>SES n=38</th>
<th>P value</th>
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<tbody>
<tr>
<td><strong>In-hospital</strong></td>
<td></td>
<td></td>
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<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
<td>0.99</td>
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<tr>
<td>Repeat revascularization</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Periprocedural MI</td>
<td>1 (2.7%)</td>
<td>2 (5.3%)</td>
<td>0.99</td>
</tr>
<tr>
<td><strong>Between discharge and 6 months</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>1 (2.6%)</td>
<td>0.99</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>0</td>
<td>1 (2.6%)</td>
<td>0.99</td>
</tr>
<tr>
<td><strong>TLR (per-patient)</strong></td>
<td>8 (21.6%)</td>
<td>2 (5.3%)</td>
<td><strong>0.047</strong></td>
</tr>
<tr>
<td><strong>TVR (per-patient)</strong></td>
<td>10 (27%)</td>
<td>2 (5.3%)</td>
<td><strong>0.012</strong></td>
</tr>
<tr>
<td><strong>Cumulative 6-month MACE</strong></td>
<td>11 (29.7%)</td>
<td>6 (15.8%)</td>
<td>0.15</td>
</tr>
</tbody>
</table>

Vermeersch et al. JACC 2006
DES vs. BMS in Saphenous Vein Graft Lesions

DELAYED RRISC Trial
N=75

Survival

TLR

Log Rank = 0.0007

P=.55

Vermeersch et al., JACC 2007
## Stent Thrombosis
*(ARC criteria)*

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<th>SES n=38</th>
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<tr>
<td>Definite</td>
<td>0</td>
<td>2 (5.2%)</td>
<td>0.49</td>
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<tr>
<td></td>
<td></td>
<td>1 fatal at 13 mo</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 non fatal at 30 mo</td>
<td></td>
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<tr>
<td>Probable</td>
<td>0</td>
<td>0</td>
<td>-</td>
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<tr>
<td>Possible</td>
<td>0</td>
<td>3 (7.9%)</td>
<td>0.30</td>
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<tr>
<td></td>
<td></td>
<td>1 sudden death at 7.5 mo</td>
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<tr>
<td></td>
<td></td>
<td>1 sudden death at 11.5 mo</td>
<td></td>
</tr>
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<td></td>
<td></td>
<td>1 sudden death at 35 mo</td>
<td></td>
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<tr>
<td>Total</td>
<td>0</td>
<td>5 (13.1%)</td>
<td>0.02 Log Rank</td>
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</table>
DES vs. BMS in Saphenous Vein Graft Lesions

SOS Trial
N=80

All-cause Death

Target Lesion Revascularization

Cardiac death
7% (PES) vs. 13% (BMS)
HR 0.62 [0.15-2.6]; P=0.51

Brilakis et al., JACC Intv 2011
ISAR-CABG

Is Drug-Eluting Stenting Associated With Improved Results in Coronary Artery Bypass Grafts?

610 patients with *de novo* SVG lesions

- DES (Cypher/Taxus/BP Sirolimus) n=303
- BMS n=307

6 to 8-month repeat angiogram (encouraged)

12-month clinical follow-up
Primary Endpoint: Death/MI/TLR

Cumulative Incidence (%)

- **DES**: 22.1%
- **BMS**: 15.4%

**P = 0.03**

**RR 0.65 [0.45-0.96]**
Target Lesion Revascularization

Cumulative Incidence (%)

- DES: 13.1%
- BMS: 7.2%

Months After Randomization

P = 0.02
RR 0.52 [0.30-0.90]
TVR Rate for SVG Patients Treated with DES vs. BMS

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<td>138 344</td>
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<td>Ellis et al.</td>
<td>175 175</td>
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<td>DELAYED RR1508</td>
<td>37 84</td>
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<td>Hoffman et al.</td>
<td>60 60</td>
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<td>Lee et al.</td>
<td>139 84</td>
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<td>Ge et al.</td>
<td>61 89</td>
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<td>SOS</td>
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Favors DES Favors BMS

Lee MS. Am J Cardiol 2010.
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<td>1429 1871</td>
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**Death Rate for SVG Patients Treated with DES vs. BMS**

Lee MS. Am J Cardiol 2010.
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<tr>
<th>Study name</th>
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<td>43</td>
<td>1.31</td>
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<tr>
<td>van Twisk et al.</td>
<td>122</td>
<td>128</td>
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<tr>
<td>Okabe et al.</td>
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<td>344</td>
<td>9.45</td>
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<tr>
<td>BASKET</td>
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<td>Kaplan et al.</td>
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<td>33</td>
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<td>0.02</td>
<td>1.46</td>
<td>2.81</td>
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<td>106</td>
<td>119</td>
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<td>2.47</td>
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<td>141</td>
<td>170</td>
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<td>0.21</td>
<td>1.34</td>
<td>14.83</td>
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<tr>
<td>Vignali et al.</td>
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<td>Minutello et al.</td>
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<td>50</td>
<td>3.69</td>
<td>0.40</td>
<td>33.89</td>
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<td>DELAYED RRIS CH</td>
<td>38</td>
<td>37</td>
<td>4.17</td>
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<tr>
<td>Ge et al.</td>
<td>61</td>
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0.1 0.2 0.5 1 2 5 10

Favors DES  Favors BMS

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<td>SOS</td>
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<td>39</td>
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<tr>
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<td>444</td>
<td>663</td>
<td>0.41</td>
<td>0.15</td>
<td>1.11</td>
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</table>

**Odds ratio and 95% CI**

- Assali et al.: <
- van Twisk et al.: <
- Okabe et al.: <
- Bansal et al.: <
- DELAYED RRISC: <
- SOS: <

Lee MS. Am J Cardiol 2010.
Comparison of *Sirolimus*-Eluting Stents With *Paclitaxel*-Eluting Stents in Saphenous Vein Graft Intervention (from a Multicenter Southern California Registry)

Michael S. Lee, MD* a,b,c,d,e, Patrick P. Hu, MD a,b,c,d,e, Joseph Aragon, MD a,b,c,d,e, Atman P. Shah, MD a,b,c,d,e, Jared Oyama, MD a,b,c,d,e, Jashdeep Dhoot, MD a,b,c,d,e, Zahid Iqbal, BA a,b,c,d,e, Nathaniel Jones, BS a,b,c,d,e, William Penny, MD a,b,c,d,e, Jonathan Tobis, MD a,b,c,d,e, Ehtisham Mahmud, MD a,b,c,d,e, and William French, MD a,b,c,d,e

This study was designed to compare the safety and efficacy of sirolimus-eluting stents (SESs) to paclitaxel-eluting stents (PESs) in percutaneous intervention of saphenous vein graft (SVG) lesions. SVGs develop atherosclerosis at high rates and often require repeat revascularization. Percutaneous intervention with drug-eluting stents has become the preferred method of revascularization due to higher restenosis with bare metal stents and increased morbidity and mortality with repeat coronary artery bypass grafting. We sought to compare the rate of major adverse cardiac events and stent thrombosis between SESs and PESs in patients undergoing SVG intervention. A multicenter analysis of 172 patients with SVG lesions treated with SESs or PESs was performed. The 30-day and 1-year clinical outcomes of 102 patients receiving SESs were compared to those of 70 patients receiving PESs. There was no significant difference in baseline demographic, angiographic, and procedural characteristics between the SES and PES treatment groups. There was no statistical difference in major adverse cardiac events at 30 days and at 1 year (hazard ratio [HR] 1.58, 95% confidence interval [CI] 0.77 to 3.23, log-rank p = 0.21). There was also no difference in survival (HR 1.28, 95% CI 0.39 to 4.25, log-rank p = 0.69) or target vessel revascularization (HR 2.54, 95% CI 0.84 to 7.72, log-rank p = 0.09). In conclusion, this multicenter analysis of real-world patients demonstrated that SESs and PESs have similar clinical outcomes when used in SVG intervention. © 2010 Published by Elsevier Inc. (Am J Cardiol 2010;xx:xxx)
MACE-Free Survival Comparing SES vs. PES

HR 1.58, 95% CI 0.77 to 3.23, log-rank p=0.21

<table>
<thead>
<tr>
<th>Patients at risk</th>
<th>0 days</th>
<th>180 days</th>
<th>365 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>SES</td>
<td>102</td>
<td>86</td>
<td>73</td>
</tr>
<tr>
<td>PES</td>
<td>70</td>
<td>61</td>
<td>57</td>
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</tbody>
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Impact of Chronic Renal Insufficiency on Clinical Outcomes in Patients Undergoing Saphenous Vein Graft Intervention With Drug-Eluting Stents: A Multicenter Southern Californian Registry

Michael S. Lee,† MD, Patrick P. Hu, MD, Joseph Aragon, MD, Atman Shah, MD, Ravi Bhatia, Nathaniel Jones, BA, MD, William Penny, MD, William French, MD, Jonathan Tobis, MD, and Ehtisham Mahmud, MD

Objectives: To evaluate the clinical outcomes in patients with chronic renal insufficiency (CRI) who undergo saphenous vein graft (SVG) intervention with drug-eluting stents (DES). Background: Patients with CRI have higher rates of major adverse cardiac events (MACE) after percutaneous revascularization. SVG intervention is associated with increased rates of MACE compared with percutaneous revascularization of native arteries. However, the impact of CRI on SVG intervention with DES has not been well characterized. Methods: Consecutive patients who underwent SVG intervention with DES at six medical centers from April 2003 to December 2007 were included in this analysis. Results: A total of 172 patients, 39 patients with CRI and a serum creatinine ≥1.5 mg dL⁻¹, and 133 patients without CRI, underwent SVG intervention with DES. Patients with CRI were more often older, diabetic, and had a longer mean total stent length. At 1 year, patients with CRI had a higher MACE rate (35.9% vs. 15.8%, hazard ratio [HR] 2.48, 95% confidence interval [CI] 1.26 to 4.88, log rank P = 0.009), mainly driven by higher mortality (20.5% vs. 9.8%, HR 3.41, 95% CI 1.10–10.58, log rank P = 0.024). There was a trend toward higher rates of target vessel revascularization in the CRI group (21.8% vs. 10.3%, HR 2.42, 95% CI 0.94–6.24, log rank P = 0.059). Stent thrombosis rates were not different between patients with and without CRI (2.5% vs. 3.0%, P = 0.8). Multivariable analysis revealed that CRI was the only significant predictor of 1-year MACE (HR 2.2, 95% confidence interval 1.1–4.3; P = 0.03). Conclusions: Patients with CRI who underwent SVG intervention with DES had higher risks of MACE and death compared with patients with preserved renal function. Further treatment strategies are needed in this high-risk group who undergo SVG intervention with DES. © 2010 Wiley-Liss, Inc.
Fig. 1. Kaplan-Meier estimates of the probability of MACE-free survival in patients with and without chronic renal insufficiency.

HR 2.48, 95% CI 1.26 to 4.86, log rank p=0.009

Fig. 2. Kaplan-Meier estimates of the probability of survival in patients with and without chronic renal insufficiency.

HR 3.41, 95% CI 1.10 to 10.58, log rank p=0.024
Conclusions

- The behavior of SVG disease is substantially different from native CAD—with higher incidence of procedural complications and long-term failure.
- Glycoprotein IIb/IIIa antagonists are ineffective in SVG intervention, presumably due to their ineffectiveness against atheroemboli.
- Embolic protection in SVG PCI can dramatically reduce 30 day MACE rates and should be used in SVG PCI.
- Data continue to show that DES is preferred over BMS.
- Perhaps hybrid revascularization may be considered.
Thank You!