Use of IVUS to Improve Procedural Outcomes

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St. Louis, MO
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Disclosures

• I, Corey Foster DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation
Introduction
When to Use IVUS

Pre-intervention

– Accurately measure vessel and lumen size to maximize stent dimensions
– Identify proximal and distal reference segment landing zones and accurately select stent length
– Determine when debulking should be considered

Post-intervention

– Maximize stent CSA relative to reference
– Ensure full lesion coverage
– Recognize, diagnose and treat complications
Interoperator and Intraoperator (In)Accuracy of Stent Selection Based on Visual Estimation

40 interventional cardiologists invited to review 25 angiographic images that were pre-scored using QCA; 5 images were repeats.

- Lesion lengths reported in the surveys were within -1 to +4 mm of QCA values 30.4% of the time; measurements were short in 51.1% and long in 18.5%
- Compared to QCA, proper stent length was accurately identified (with overlap of 2-4 mm) in 22.3% of the cases
- When looking at the same image, individual operators varied more than 3 mm in 38.5% of lesion length measurements and 37.5% of stent length selections

**Implications:** Visual estimation of coronary lesion length alone may not be optimal for stent selection as inter-, intra-operator variability is high.

Impact of lesion length and final minimum stent area (MSA) on restenosis

*No actual observations in this range

P. J. de Feyter et al. Circulation. 1999;100:1777-1783
Edge Restenosis

Post-stenting

Prox edge

Prox reference PB 60%

At 2-year f/u

Pre-PCI

Post-PCI

After 2 years

Prox edge

Prox reference

Greg Stone CRF Course 2014
IVUS-Guided Stent Sizing

0 ➔ 6.5mm ➔ 26.0mm

Lumen

Smallest reference lumen (prox or dist)

Largest reference lumen

Mid-wall (between lumen and media)

Media-to-media (typically discounted)

Reference

Increasingly aggressive

Gary Mintz, Greg Stone CRF Course 2012, 2014
Meta-analysis of 7 RCTs of IVUS vs Angio Guided BMS implantation (n=2,193 pts)

**IVUS guidance was associated with significantly larger post-PCI MLD (Δ0.12 mm (0.06, 0.18), p<0.0001), and lower rates of:**

- Angiographic restenosis (22.2% vs. 28.9%; OR 0.64, p=0.02)
- Repeat revascularization (12.6% vs. 18.4%; OR 0.66, p=0.004)
- Overall MACE (19.1% vs. 23.1%; OR 0.69, p=0.03)
- But no significant effect on MI (p=0.51) or mortality (p=0.18)

*Parise et al. Am J Cardiol. 2011;107:374-82*
IVUS-guided Implantation of DES to Improve Outcome: A Meta-analysis

24,849 patients from 3 randomized trials and 12 observational studies, 2005-2013.

<table>
<thead>
<tr>
<th>IVUS- vs Angiography-guided PCI</th>
<th>OR (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACE</td>
<td>0.79 (0.69-0.91)</td>
<td>0.001</td>
</tr>
<tr>
<td>All-cause Mortality</td>
<td>0.64 (0.51-0.81)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>MI</td>
<td>0.57 (0.42-0.78)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Stent Thrombosis</td>
<td>0.59 (0.42-0.82)</td>
<td>0.002</td>
</tr>
</tbody>
</table>

Conclusion: IVUS guidance is associated with significant reductions in PCI outcomes compared with angiography alone.

8,575 pts prospectively enrolled
No clinical or anatomic exclusion criteria
Successful and uncomplicated PCI with ≥1 non-investigational DES

Pre-specified IVUS vs no IVUS substudy

IVUS: 3349 pts
No IVUS: 5234 pts
Clinical FU at 30 days, 1 year, 2 years

How was IVUS used?

- Document Procedure (26%)
- Guide and Optimize Procedure (74%)

**“How IVUS changed the procedure?”**

- Larger Size of Stent/Balloon
- Higher Pressure
- Longer Stent
- Under-expansion
- Mal-apposition
- Additional Stent
- Post Dilation

Time-to-event curves through 1 year for definite/probable stent thrombosis (ST) (left), myocardial infarction (middle), and major adverse cardiac events (MACE) (right) according to intravascular ultrasound (IVUS) guidance vs angiography guidance.

Which of these LMCA lesions are significant and, therefore, should be treated? And which are not??

Most LMCA IVUS shows either insignificant disease or critical disease.
Clinical Impact of Intravascular Ultrasound Guidance in Drug-Eluting Stent Implantation for Unprotected Left Main Coronary Disease

Pooled Analysis at the Patient-Level of 4 Registries

1,670 patients DES-PCI; Propensity Matched

IVUS
505 pts

No-IVUS
505 pts
Impact of IVUS use in DES LM-PCI
n=1,110 pts propensity matched

ALL CAUSE DEATH, MI, TLR
P=0.006

CARDIAC DEATH, MI, TLR
P=0.03

All population
Distal Left Main

De la Torre Hernandez et al. J Am Coll Cardiol Intv 2014;7:244–54
Optimal Stent Cross Sectional Area after Left Main Stenting with 2 stents


ISR Rate

Underexpansion 24%
Complete Expansion 5%

Proximal LM
POC
LCX ostium
LAD ostium
Bifurcation Lesions Still a Challenge

- Require more time, anxiety, skill, and equipment (cost)
- Increased complications
  - peri-procedural MIs,
  - stent thrombosis, and
  - restenosis
- Suboptimal angiographic outcomes (esp. side branch ostium)
Long-Term Outcomes With Use of Intravascular Ultrasound for the Treatment of Coronary Bifurcation Lesions

Yogesh Patel, MD, Jeremiah P. Depta, MD, Eric Novak, MS, Michael Yeung, MD, Kory Lavine, MD, PhD, Sudeshna Banerjee, MD, C. Huie Lin, MD, PhD, Alan Zajarias, MD, Howard I. Kurz, MD, John M. Lasala, MD, PhD, Richard G. Bach, MD, and Jasvindar Singh, MD*

449pts

IVUS  No-IVUS

Medina 1,1,1(89%)  Medina 1,1,1(89%)

247 pts  202 pts

### IVUS in Bifurcation; n=449 pts

Mean Follow-up 2.5 Years

<table>
<thead>
<tr>
<th>Event</th>
<th>IVUS (N=247 pts)</th>
<th>NO IVUS (N=202 pts)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death or myocardial infarction</td>
<td>20 (8%)</td>
<td>42 (21%)</td>
<td>0.0002</td>
</tr>
<tr>
<td>Death</td>
<td>14 (6%)</td>
<td>24 (12%)</td>
<td>0.02</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>7 (3%)</td>
<td>24 (12%)</td>
<td>0.0002</td>
</tr>
<tr>
<td>Stent thrombosis</td>
<td>0 (0%)</td>
<td>5 (2%)</td>
<td>0.02</td>
</tr>
<tr>
<td>Periprocedural MI</td>
<td>16 (6%)</td>
<td>24 (12%)</td>
<td>0.06</td>
</tr>
<tr>
<td>Target vessel revascularization</td>
<td>19 (7%)</td>
<td>52 (24%)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Target lesion revascularization</td>
<td>15 (6%)</td>
<td>45 (21%)</td>
<td>&lt; 0.0001</td>
</tr>
</tbody>
</table>

## IVUS in Bifurcation; n=449 pts

### Propensity Score Analysis

<table>
<thead>
<tr>
<th>Event</th>
<th>Unadjusted OR (95% CI)</th>
<th>p-value</th>
<th>Adjusted OR (95% CI)</th>
<th>p-value</th>
<th>Matched OR (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death or MI</td>
<td>0.34 (0.18-0.61)</td>
<td>0.0002</td>
<td>0.38 (0.20-0.74)</td>
<td><strong>0.005</strong></td>
<td>0.34 (0.15-0.77)</td>
<td>0.009</td>
</tr>
<tr>
<td>Death</td>
<td>0.45 (0.21-0.93)</td>
<td>0.03</td>
<td>0.40 (0.18-0.88)</td>
<td><strong>0.02</strong></td>
<td>0.36 (0.12-1.07)</td>
<td>0.07</td>
</tr>
<tr>
<td>MI</td>
<td>0.22 (0.08-0.53)</td>
<td>0.0002</td>
<td>0.37 (0.14-0.98)</td>
<td><strong>0.04</strong></td>
<td>0.36 (0.12-1.0)</td>
<td>0.05</td>
</tr>
<tr>
<td>Peri. MI</td>
<td>0.51 (0.25-1.04)</td>
<td>0.07</td>
<td>0.45 (0.20-0.97)</td>
<td><strong>0.04</strong></td>
<td>0.44 (0.17-1.1)</td>
<td>0.08</td>
</tr>
<tr>
<td>TVR</td>
<td>0.25 (0.14-0.44)</td>
<td>&lt; 0.0001</td>
<td>0.28 (0.14-0.53)</td>
<td>&lt; <strong>0.0001</strong></td>
<td>0.29 (0.13-0.64)</td>
<td>0.002</td>
</tr>
<tr>
<td>TLR</td>
<td>0.23 (0.13-0.43)</td>
<td>&lt; 0.0001</td>
<td>0.27 (0.14-0.56)</td>
<td><strong>0.0003</strong></td>
<td>0.25 (0.11-0.58)</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Intravascular Ultrasound-guided Systematic Two-stent Techniques for Coronary Bifurcation Lesions and Reduced Late Stent Thrombosis

Shao-Liang Chen,¹ MD, FSCAI, FACC, Fei Ye,¹ MD, Jun-Jie Zhang,¹ MD, PhD, Nai-Liang Tian,¹ MD, Zhi-Zhong Liu,¹ MD, PhD, Teguh Santoso,² MD, Yu-Jie Zhou,³ MD, Tie-Ming Jiang,⁴ MD, Shang-Yu Wen,⁵ MD, and Tak W. Kwan,⁶ MD

628pts

IVUS

DK-Crush(59.6%)

324 pts

No-IVUS

DK-Crush(63.5%)

304 pts
IVUS-guided PCI for Bifurcation treated with 2-Stent Technique; n=628

<table>
<thead>
<tr>
<th>12 months</th>
<th>IVUS N=324</th>
<th>No IVUS N=304</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stent thrombosis</td>
<td>1.2%</td>
<td>6.9%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Definite</td>
<td>0.6%</td>
<td>5.3%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Probable</td>
<td>0%</td>
<td>1.6%</td>
<td>0.026</td>
</tr>
<tr>
<td>Possible</td>
<td>0.6%</td>
<td>0%</td>
<td>0.50</td>
</tr>
<tr>
<td>Death</td>
<td>2.2%</td>
<td>3.9%</td>
<td>0.54</td>
</tr>
<tr>
<td>Cardiac death</td>
<td>0.9%</td>
<td>3.3%</td>
<td>0.049</td>
</tr>
<tr>
<td>MI</td>
<td>4.6%</td>
<td>8.9%</td>
<td>0.038</td>
</tr>
<tr>
<td>TLR</td>
<td>8.6%</td>
<td>13.5%</td>
<td>0.056</td>
</tr>
<tr>
<td>TVR</td>
<td>10.2%</td>
<td>15.5%</td>
<td>0.055</td>
</tr>
<tr>
<td>MACE</td>
<td>15.7%</td>
<td>19.7%</td>
<td>0.21</td>
</tr>
</tbody>
</table>

Chen et al CCI. 2013;81(3):456-63
Role of IVUS for CTO Intervention
A total of 467 patients with CTO were initially screened. A total of 402 patients were finally enrolled after successful guidewire-crossing. Total 467 patients with CTO were initially screened

- Exclusion
  - Wiring failure; 61 patients
  - Refusal of study enrollment; 4 patients

IVUS-guided group (n=201)

Angiography-guided group (n=201)

Clinical follow-up for 12 months

# Primary endpoint; Composite of Cardiac death, MI, & TVR at 12 months

Yangsoo Jang et al. TCT 2014
Primary endpoint (Cardiac death, MI, TVR)

Cumulative incidence (%)

Follow-up duration (months)

<table>
<thead>
<tr>
<th>Follow-up duration (months)</th>
<th>Angiography-guided group</th>
<th>IVUS-guided group</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

HR = 0.35, 95% CI = 0.13 – 0.97

p = 0.035

Number at risk

<table>
<thead>
<tr>
<th>Group</th>
<th>Risk</th>
<th>Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angiography-guided</td>
<td>201</td>
<td>198</td>
</tr>
<tr>
<td>IVUS-guided</td>
<td>201</td>
<td>198</td>
</tr>
</tbody>
</table>

Yangsoo Jang et al. TCT 2014
Optical Coherence Tomography Versus Intravascular Ultrasound to Evaluate Coronary Artery Disease and Percutaneous Coronary Intervention

Stent underexpansion PLUS. . .
Geographical miss (major edge dissections, plaque burden >50%)

Stent underexpansion PLUS. . .
Findings not seen on IVUS
Minor malapposition
Minor tissue protrusion
Small edge dissections
## IVUS vs OCT RCT

70 pts – randomized to OCT vs IVUS guidance

<table>
<thead>
<tr>
<th></th>
<th>IVUS</th>
<th>OCT</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final inflation pressure</td>
<td>16.1±4.7</td>
<td>13.5±3.4</td>
<td>0.03</td>
</tr>
<tr>
<td>Final balloon diameter</td>
<td>3.2±0.4</td>
<td>3.4±0.6</td>
<td>0.3</td>
</tr>
<tr>
<td>Proximal edge</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plaque burden, %</td>
<td>37.1±10.1</td>
<td>45.7±10.9</td>
<td>0.001</td>
</tr>
<tr>
<td>MSA, mm²</td>
<td>7.1±2.1</td>
<td>6.1±2.2</td>
<td>0.04</td>
</tr>
<tr>
<td>Focal expansion, %</td>
<td>80±13</td>
<td>65±14</td>
<td>0.001</td>
</tr>
<tr>
<td>Distal Edge</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plaque burden, %</td>
<td>33.3±6.4</td>
<td>40.3±8.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Incomplete stent apposition, %</td>
<td>0.4±0.7</td>
<td>0.6±0.8</td>
<td>0.34</td>
</tr>
</tbody>
</table>

Conclusion

Although the definitive randomized trial has not yet been done, a burgeoning body of evidence suggests that by improving acute results, IVUS-guided stent implantation reduces stent thrombosis and improves event-free survival compared to angiographic guidance alone:

– Complex CAD
– Left Main PCI
– Bifurcation
– CTO