Role of IVUS and Benefits in DES Era

Can We Reach Optimal DES Expansion

With Conventional Stent Delivery System in Long Diffuse Lesion?

Proven Safety and Best Practice in BES

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Ajou University Medical Center
Suwon, Korea

Angioplasty Summit 2007-TCT Asia Pacific

Wednesday, April 25 ~ Friday, April 27, 2007
The Convention Center of Sheraton Grand Walkerhill Hotel, Seoul, Korea
Are Drug-Eluting Stents Changing Your Daily Practice?

After 24 months of DES for all patients, the point of no return has been reached and we will not come back to bare stent.

Thank you
DES Penetration in Ajou University Medical Center

Ajou University Database
Angioplasty Summit 2007
DES changes our pattern of PCI

We are getting more aggressive...

Complex Lesions
Long Diffuse Lesions
Small Vessels
Diabetic Patients
DES Mania .. Metal Jacket
However, Diffuse Restenosis

Pre PCI

Post DES

8 months FU

8 months FU
Stent thrombosis

Pre PCI

Post DES
Stent thrombosis

4 days after DES

Cutting and HP
Stent thrombosis

4 days after SAT#1

CABG
Stent thrombosis

Post DES IVUS
Aneurysm formation

Pre

Crushing
Aneurysm formation

6 months

19 months
Aneurysm formation

19 months Post HPB/Kissing

24 months
When is IVUS appropriate?

- Diagnostic procedures

- High risk patients patient and lesion subsets
  - Diabetic patient
  - Ostial lesion
  - Long lesion
  - Small vessel
  - Bifurcation lesion including LM disease

- Treatment of in-stent restenosis

- DES failure
How does one use IVUS during DES implantation

• Identify the proximal and distal reference segments

• Measure
  – The vessel size to select stent size
  – The lesion length to select stent length

• After stent deployment, assess
  – Final stent area, apposition, lesion coverage, and other complications

• Determine whether additional work is required to optimize stent dimensions, completely cover the lesion, or treat complications
Evaluation of Stenosis Severity
Left Main Disease

No expert can be perfect with visual assessment...
Visual Angiographic Assessment of Left Main Disease

• To assess the accuracy of visual angiographic assessment of intermediate (40–80% diameter stenosis by angiography) or equivocal left main coronary artery stenoses by experienced interventional cardiologists when taking FFR as the gold standard.

• Angiograms were then reviewed by 4 experienced interventionalists blinded to FFR

• Lesions were visually assessed and their significance classified as ‘significant’, ‘not significant’, or ‘unsure’.

_M Lindstaedt et al. Int J Cardiol; 2007 (in press)_
Relation between FFR and each reviewer's (A–D) visual assessment of 51 intermediate or equivocal left main stenoses

Agreement of concordant classifications (n=25) and discordant classifications (n=26) of reviewers A–D with FFR values

- **Correct** = concordant classifications identical to functional significance by FFR
- **Incorrect** = concordant classifications different from functional significance by FFR
- **Discrepant** = divergent classifications by reviewers

*M Lindstaedt et al. Int J Cardiol; 2007 (in press)*
Visual Angiographic Assessment of Left Main Disease

• None of the 4 reviewers achieved correct classification in more than 50% of cases.

• Even on the basis of the most generous of these definitions, there was a concordance of only 49% (25 of 51 lesions) among the reviewers.

• An unanimously correct lesion classification was achieved in only 29% (15 of 51 lesions) of all cases.

• Visual assessment resulted in poor sensitivity 38%, specificity 58%, positive predictive value mean 39%, and negative predictive value mean 57%.

• The functional significance of intermediate and equivocal left main stenoses should not be based solely on angiographic assessment even by experienced interventional cardiologists.

Ischemic cut point of FFR and IVUS parameters

IVUS MLD and MLA of 2.8 mm and 5.9 mm$^2$, respectively, strongly predict the physiological significance of an LMCS.
Evaluation of Stent Expansion Bifurcation Lesion

No expert can be perfect with visual assessment...
Any Difference?

NO ... ??
Kissing #1
LAD 3.0x20mm  8atm
DIG 2.5x20mm   8atm
Inflation: Simultaneous
Deflation: Simultaneous

Kissing #2
LAD 3.0x20mm  8atm
DIG 3.0x13mm   8atm
Inflation: DIG→LAD
Deflation: Simultaneous

Kissing #3
LAD 3.0x20mm  14atm
DIG 3.0x13mm   8atm
Inflation: DIG→LAD
Deflation: Simultaneous

Any Difference?
Yes, Big Difference on IVUS

Catheter in LAD
6.3 mm²
Catheter in Diagonal
5.3 mm²
Evaluation of Stent Expansion
Long Diffuse Lesion

No expert can be perfect with visual assessment...
Why is optimal DES expansion and apposition important ..

- Uniform stent apposition facilitates uniform drug absorption into endothelial tissue $^{2,3,4,5}$
- Incomplete apposition may contribute to thrombosis formation & SAT’s$^1$
- Stent underexpansion may increase risk for restenosis and target vessel revascularization (TVR) $^{6,7}$

4. Leon, M. The basic “tips and tricks” for DES implantation; TCT 2003 presentation
5. The TAXUS Stent Directions for Use
Predictors of Restenosis and Target Vessel Revascularization after SES Implantation

Clinical variables
- Diabetes

Angiographic variables
- Small reference vessel diameter
- Ostial location
- Non–left anterior descending artery lesion
- In-stent restenosis

Procedural variables
- Long stent length
- Small stent diameter or minimal stent area (MSA) by IVUS
Predictors of Drug-Eluting Stent Thrombosis

Clinical variables
- Diabetes
- Renal failure
- Low ejection fraction

Angiographic variables
- Bifurcation lesions

Procedural variables
- Use of multiple stents
- Use of long stents
- Small final stent area (MSA) by IVUS
- Stent underexpansion
- Residual reference segment stenosis

Postprocedural variables
- Premature discontinuation of antiplatelet therapy
What is the smallest acceptable minimum stent area?

**Bare Metal Stents**

F/U MLA > 4.0 mm² (%)

- Minimum stent area (mm²)
  - 6.5* predictive value = 56%


**Cypher**

F/U MLA > 4.0 mm² (%)

- Minimum stent area (mm²)
  - 5.0** predictive value = 90%

(Angioplasty Summit 2007)
Predictors of angiographic restenosis in 550 patients with 670 native artery lesions patients treated with Cypher Stents

(Hong et al. Euro Heart J 2006;27:1305-10)
Optimal stent deployment* is only achieved in 29% of patients with current stent delivery systems; usually due to inability of stent delivery balloon to expand fully the stent to nominal size (n=256).

*MSD≥90% of average reference lumen diameter

“With post-dilatation using non-compliant balloons, the frequency of achieving optimum stent deployment doubles and there are significant increases in MSA – maximum stent apposition.

These data stress the continued need for adjunctive balloon post-dilatation with appropriate stent expansion balloons.”¹

POSTIT Trial, Brodie et al, Catheterization and Cardiovasc Int 2003;59:184
DES Expansion with Incremental Delivery Pressures

Table 3
Comparison of postintervention IVUS parameters at different delivery pressures

<table>
<thead>
<tr>
<th>Variable</th>
<th>SES (n=46)</th>
<th>PES (n=41)</th>
<th>P value</th>
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</thead>
<tbody>
<tr>
<td>14 atm</td>
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</tr>
<tr>
<td>Min stent CSA (mm²)</td>
<td>5.0±1.4</td>
<td>5.6±2.1</td>
<td>.15</td>
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<tr>
<td>Max stent CSA (mm²)</td>
<td>6.9±1.9</td>
<td>8.0±2.4</td>
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<tr>
<td>Min stent diameter (mm)</td>
<td>2.34±0.33</td>
<td>2.40±0.50</td>
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<tr>
<td>Max stent diameter (mm)</td>
<td>2.93±0.37</td>
<td>3.35±0.50</td>
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<tr>
<td>Axial stent symmetry</td>
<td>0.73±0.11</td>
<td>0.69±0.13</td>
<td>.08</td>
</tr>
<tr>
<td>Radial stent symmetry</td>
<td>0.80±0.09</td>
<td>0.72±0.09</td>
<td>&lt;.0001</td>
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<tr>
<td>Underexpansion</td>
<td>37/46 (80.4%)</td>
<td>26/41 (63.4%)</td>
<td>.08</td>
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<tr>
<td>20 atm</td>
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<tr>
<td>Min stent CSA (mm²)</td>
<td>6.4±1.7</td>
<td>6.0±2.0</td>
<td>.30</td>
</tr>
<tr>
<td>Max stent CSA (mm²)</td>
<td>8.0±1.9</td>
<td>8.4±2.3</td>
<td>.44</td>
</tr>
<tr>
<td>Min stent diameter (mm)</td>
<td>2.64±0.34</td>
<td>2.51±0.44</td>
<td>.16</td>
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<tr>
<td>Max stent diameter (mm)</td>
<td>3.20±0.38</td>
<td>3.45±0.48</td>
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<tr>
<td>Axial stent symmetry</td>
<td>0.82±0.11</td>
<td>0.70±0.10</td>
<td>.0004</td>
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<tr>
<td>Radial stent symmetry</td>
<td>0.83±0.08</td>
<td>0.73±0.08</td>
<td>&lt;.0001</td>
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<tr>
<td>Underexpansion</td>
<td>22/46 (47.8%)</td>
<td>9/26 (34.6%)</td>
<td>.28</td>
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</tbody>
</table>

* Stent Underexpansion by MUSIC criteria
The DES achieved only 75% of predicted MSD and 66% of predicted MSA.

This was similar form SES and PES.

Furthermore, 24% of SES and 28% of PES did not achieve a final MSA of 5.0 mm², a consistent predictor of DES failure.

Table IV. IVUS quantitative assessment

<table>
<thead>
<tr>
<th></th>
<th>SES (n = 133)</th>
<th>PES (n = 67)</th>
<th>P</th>
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<tbody>
<tr>
<td>Reference segment</td>
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<td></td>
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<tr>
<td>Minimal stent diameter (mm²)</td>
<td>75.6 ± 10.3</td>
<td>74.6 ± 11.0</td>
<td>.5</td>
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<tr>
<td>IVUS/manufacturer’s predicted stent diameter (%)</td>
<td>66.0 ± 16.2</td>
<td>65.4 ± 18.1</td>
<td>.4</td>
</tr>
<tr>
<td>IVUS/manufacturer’s predicted stent cross-sectional area (%)</td>
<td></td>
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</table>
Compliance of current DES delivery system
Balloon compliance and dilation force

Compliant/Semi-Compliant

- High dilation force
- More vessel injury

Non Compliant

- Low dilation force and Stent Underexpansion

\[ F = \frac{\text{Pressure} \times \text{Diameter}}{2 \times \text{Wall Thickness}} \]
Balloon compliance and dilation force

Inflation pressure and dilatation force

Inflation pressure = 10 atm

Dilation force varies from

$10 \times \frac{3}{2} \times 0.5 = 30 \text{ atm}$

to

$10 \times \frac{1}{2} \times 1.5 = 3.3 \text{ atm}$
Long Diffuse Lesion
FFR and IVUS-guided DES Implantation

• PCI with current semi-compliant stent delivery system (SDS) in long diffuse lesion may result in stretching of the balloon around the lesion rather than concentrating the force at the lesion and cannot achieve optimal stent expansion at culprit site.

• Visual angiographic estimation of stenosis may poorly correlate with anatomic and physiologic significance.
Long Diffuse Lesion
FFR and IVUS-guided DES Implantation

• Evaluate the incidence of suboptimal stent expansion with current drug SDS in long diffuse lesion.

• Evaluate effectiveness of post-stent adjuvant high-pressure non-compliant balloon dilatation.

• Identify the factors which was related with the suboptimal stent expansion.
Long Diffuse Lesion
FFR and IVUS-guided DES Implantation

**Inclusion Criteria**
- 41 consecutive angina patients, 47 de novo lesions
- \% DS on QCA >50% with evidence of myocardial ischemia
- Stent length > 32mm
- Informed consents for IVUS and FFR measurement.

**Exclusion Criteria**
- Restenotic lesion
- Acute myocardial infarction or prior myocardial infarction
- LV dysfunction: LVEF < 55%
- Left main disease
- Significant cardiac arrhythmia hampering physiologic study

*SJ Tahk, MH Yoon, et al. Aspen 2007*
Long Diffuse Lesion
FFR and IVUS-guided DES Implantation

Pre PCI  Stenting with SDS  Adjunctive High Pressure
(at RBP: 16-18 atm) (Quantum at 20-22 atm)

if Post Stent FFR<0.95

Pressure measurement: RADI Medical System, Uppsala, Sweden
IVUS: 40MHz Atlantis™ SR Pro, Galaxy 2 Ultrasound Imaging System, Boston Scientific Corporation, Natick, MA, USA

63 y-o Male, Unstable Angina

MLD  0.72 mm
DS   77.0%
Lesion length 38 mm

MLA  1.15 mm²
%AS  87.6%
Plaque Burden 89.3%
69 y-o Male Stable Angina

MLD 0.58 mm  MLA 0.94 mm²
DS 81.0%  %AS 87.7%
Lesion length 61 mm  Plaque Burden 90.3%

SH Han

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MLA: 3.85 mm²

MLA: 3.84 mm²
72 y-o Stable Angina

MLD  0.70 mm  MLA  2.15 mm$^2$
DS   77.0%  %AS   72.7%
Lesion length  40 mm  Plaque Burden  80.5%

HJ Lee

Ajou University Medical Center

Angioplasty Summit 2007
Results

47 Lesions

Stenting with Current SDS at RBP

FFR ≥ 0.95

9 Lesions (19.1%)

FFR < 0.95

38 Lesions (80.9%)

MLA 7.2±1.4 mm² MLA < 5.5 mm²: (2) *
%DS 13.7±12.1 %

MLA 5.5±1.5 mm² MLA < 5.5 mm²: (22) *
%DS 26.3±12.5 %

Adjunctive High Pressure

FFR ≥ 0.95 (n=16)

25 Lesions (53.2%)

FFR < 0.95 (n=22)

22 Lesions (47.8%)

MLA 7.1±1.3 mm² MLA < 5.5 mm²: (3) **
%DS 5.9±2.2 %

MLA 5.8±1.5 mm² MLA < 5.5 mm²: (10) **
%DS 9.7±6.1 %

* 24/47 (52.7%) lesions could not reach MLA>5.5mm² on IVIS with SDS at RBP
** 13/47 (27.7%) lesions could not reach MLA>5.5mm² on IVIS after HP dilatation

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<table>
<thead>
<tr>
<th>Criteria</th>
<th>Post Stent</th>
<th>Post HP</th>
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</thead>
<tbody>
<tr>
<td>FFR &gt; 0.95</td>
<td>9 (19.1%)</td>
<td>25 (53.2%)</td>
</tr>
<tr>
<td>IVUS MSA &gt; 5.5mm²</td>
<td>23 (47.3%)</td>
<td>38 (72.3%)</td>
</tr>
<tr>
<td>IVUS MUSIC*</td>
<td>12 (25.5%)</td>
<td>14 (29.8%)</td>
</tr>
</tbody>
</table>

* Final lumen CSA > 80% of the reference (or > 90% if minimal lumen CSA was < 9 mm²)
Late Loss and “Headroom” to Restenosis in Patients FFR≥0.95

Vessel Size 3.2 mm
Minimal Stent Diameter 3.0 mm

Headroom to Restenosis
1.5 mm after Post PCI

1.3 mm
1.1 mm
0.9 mm

0.5 mm in BMS
RV Size 3.0 mm

MLD<1.5 mm = Restenosis

DES1 MLL 0.2 mm
DES 2 MLL 0.4 mm
DES3 MLL 0.6 mm
Late Loss and “Headroom” to Restenosis in Patients FFR<0.95

Vessel Size 3.2 mm
Minimal Stent Diameter 2.3 mm

DES1 MLL 0.2 mm
DES2 MLL 0.4 mm
DES3 MLL 0.6 mm

Headroom to Restenosis
0.7 mm after Post PCI
0.5 mm
0.3 mm
0.1 mm
-0.3 mm in BMS
RV Size 3.0 mm

MSD 2.65 mm
MSA 5.5 mm²
Mean Late Loss and Risk of Restenosis

<table>
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<tr>
<th>Mean Late Loss (mm)</th>
<th>Predicted Binary Angiographic Restenosis (%)</th>
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<tbody>
<tr>
<td>40.0</td>
<td>40.0</td>
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<tr>
<td>35.0</td>
<td>35.0</td>
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<td>30.0</td>
<td>30.0</td>
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<td>25.0</td>
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<tr>
<td>20.0</td>
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<td>15.0</td>
<td>15.0</td>
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<tr>
<td>10.0</td>
<td>10.0</td>
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<tr>
<td>5.0</td>
<td>5.0</td>
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<tr>
<td>0.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

Mean RVD 2.79, Minimal SD 2.67, Headroom 1.275
Mean RVD 3.20, Minimal SD 2.32, Headroom 0.720, - 0.55

Mauri L, Orav JE, Kuntz RE. Circulation 2005; 111: 3435-3442

Ajou University Medical Center  Angioplasty Summit 2007
## Angiographic and Procedural Findings

<table>
<thead>
<tr>
<th></th>
<th>Group A (FFR ≥ 0.95, n=9)</th>
<th>Group B (FFR &lt; 0.95, n=38)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Stent</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MLD (mm)</td>
<td>0.57 ± 0.11</td>
<td>0.59 ± 0.19</td>
<td>0.921</td>
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<tr>
<td>DS (%)</td>
<td>81.1 ± 4.5</td>
<td>81.5 ± 5.4</td>
<td>0.872</td>
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<tr>
<td>Post-Stent</td>
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</tr>
<tr>
<td>MLD (mm)</td>
<td>3.09 ± 0.23</td>
<td>2.32 ± 0.46</td>
<td>0.012</td>
</tr>
<tr>
<td>DS (%)</td>
<td>13.8 ± 12.1</td>
<td>26.3 ± 12.5</td>
<td>0.014</td>
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<tr>
<td>Reference Diameter (mm)</td>
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<tr>
<td>Proximal</td>
<td>3.40 ± 0.17</td>
<td>3.42 ± 0.25</td>
<td>0.776</td>
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<tr>
<td>Distal</td>
<td>2.95 ± 0.14</td>
<td>3.0 ± 0.29</td>
<td>0.641</td>
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<tr>
<td>Lesion length (mm)</td>
<td>42.8 ± 10.4</td>
<td>52.3 ± 12.2</td>
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<tr>
<td>Stent number</td>
<td>1.64 ± 0.50</td>
<td>1.95 ± 0.55</td>
<td>0.096</td>
</tr>
<tr>
<td>Stent length (mm)</td>
<td>46.4 ± 13.9</td>
<td>56.9 ± 15.3</td>
<td>0.047</td>
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</table>

## IVUS Findings

<table>
<thead>
<tr>
<th></th>
<th>Group A (FFR≥0.95, n=9)</th>
<th>Group B (FFR&lt;0.95, n=38)</th>
<th>p Value</th>
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<tr>
<td><strong>Pre-stent</strong></td>
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<tr>
<td>MLA (mm^2)</td>
<td>2.65 ± 0.68</td>
<td>1.75 ± 0.69</td>
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<tr>
<td>AS (%)</td>
<td>71.3 ± 9.8</td>
<td>80.0 ± 10.6</td>
<td>0.030</td>
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<tr>
<td><strong>Post-stent</strong></td>
<td></td>
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<tr>
<td>MLA (mm^2)</td>
<td>7.16 ± 1.64</td>
<td>5.57 ± 1.57</td>
<td>0.005</td>
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<tr>
<td>AS (%)</td>
<td>23.3 ± 12.3</td>
<td>36.2 ± 19.7</td>
<td>0.059</td>
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<tr>
<td>Ref Lumen Area (mm^2)</td>
<td>10.0 ± 3.4</td>
<td>8.9 ± 1.9</td>
<td>0.176</td>
</tr>
<tr>
<td>VA at Lesion (mm^2)</td>
<td>13.0 ± 4.2</td>
<td>10.8 ± 2.5</td>
<td>0.041</td>
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<tr>
<td>Plaque Burden</td>
<td>78.7 ± 6.3</td>
<td>83.7 ± 6.5</td>
<td>0.042</td>
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<tr>
<td>Ref Vessel Area (mm^2)</td>
<td>14.6 ± 4.4</td>
<td>13.3 ± 2.9</td>
<td>0.284</td>
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<tr>
<td>Remodeling Index</td>
<td>0.92 ± 0.22</td>
<td>0.82 ± 0.16</td>
<td>0.140</td>
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# Independent Predictor for Suboptimal Stent Expansion
*(FFR<0.95 or FFR≥0.95)*

By Multiple binary logistic regression analysis


<table>
<thead>
<tr>
<th>Step 1</th>
<th>Variable(s)</th>
<th>B</th>
<th>S.E.</th>
<th>Wald</th>
<th>df</th>
<th>Sig.</th>
<th>Exp(B)</th>
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<tr>
<td></td>
<td>PLAQ_C</td>
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<td>1.116</td>
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<td>.653</td>
<td>1.652</td>
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<td>REMOD_IX</td>
<td>−.120</td>
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<td>.966</td>
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<tr>
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<td>ST_LENGTH</td>
<td>.019</td>
<td>.041</td>
<td>.213</td>
<td>1</td>
<td>.645</td>
<td>1.019</td>
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<tr>
<td></td>
<td>Constant</td>
<td>4.057</td>
<td>3.453</td>
<td>1.380</td>
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<td>.240</td>
<td>57.780</td>
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</table>

a. Variable(s) entered on step 1: PLAQ_C, REMOD_IX, ECCENT, MINLA, ST_LENGTH.
# Independent Predictor for Suboptimal Stent Expansion (correlation with post-stent FFR)

## Coefficients

<table>
<thead>
<tr>
<th>Model</th>
<th>Unstandardized Coefficients</th>
<th>Standardized Coefficients</th>
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<th>Sig.</th>
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<td>Std. Error</td>
<td>Beta</td>
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<td>(Constant)</td>
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<td>.036</td>
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<td>.008</td>
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<td>.000</td>
<td>-.351</td>
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</tbody>
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*a. Dependent Variable: FFR_STEN*

*By Multiple linear regression analysis*

FFR vs. IVUS Minimal Stent Area

![Graph showing the relationship between Final FFR and Final MSA. The correlation coefficient is r=0.501, p<0.001.](chart.png)
The Relation between Final FFR and MSA (BCV of FFR for MSA ≥ 5.5 mm²)

BCV : 0.94
Sensitivity : 72%
Specificity : 79%
AUC : 0.78 (0.64-0.91)

Effect of HP Dilatation on Headroom to Restenosis
QCA Analysis

Reference Vessel Diameter

Head Room to Restenosis before HP

Head Room to Restenosis after HP

Reference Vessel Diameter

- FFR<0.95
- FFR>0.95
FFR and IVUS Criteria Reached were Inadequate with current SDS even with RBP

<table>
<thead>
<tr>
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<th>Post Stent</th>
<th>Post HP</th>
</tr>
</thead>
<tbody>
<tr>
<td>FFR&gt;0.95</td>
<td>9 (19.1%)</td>
<td>25 (53.2%)</td>
</tr>
<tr>
<td>IVUS MSA &gt;5.5mm²</td>
<td>23 (47.3%)</td>
<td>38 (72.3%)</td>
</tr>
<tr>
<td>IVUS MUSIC*</td>
<td>12 (25.5%)</td>
<td>14 (29.8%)</td>
</tr>
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</table>

* Final lumen CSA > 80% of the reference (or > 90% if minimal lumen CSA was < 9 mm² )

- Independent IVUS predictors for suboptimal stent expansion was IVUS minimal lumen area and stent length (lesion length).
- Best cut-off value of FFR for MSA>5.5mm² after HP dilatation was 0.94
Conclusion

• Routine adjunctive high-pressure balloononing of DES might be required to achieve optimal functional and anatomic stent expansion, in number of long diffuse coronary stenoses.

• FFR and IVUS-guided PCI could potentially improve the procedural precision and decrease the rate of target vessel failure in DES era. However, the role of physiologic and IVUS study in DES era needs more randomized trials.

DES Implantation in Long Diffuse Lesion

- Appropriate lesion preparation

- Adjunctive High Pressure Dilatation

Do not forget old lessons even in DES era.

- Do not believe your visual estimation

- Please do not avoid modern facilities of convenience