Lessons learned from the European Experience

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• I have received speaker’s honoraria from
  – Abbott Vascular
  – St Jude Medical
GHOST-EU
n = ~1,500, International Registry

Capodanno Eurointervention 2014
High complexity

Acute >>> late

Incomplete expansion

Inter-operator variability

December 13-15, 2015
Tel-Aviv, Israel
Malapposition

Foin JACC int 2015
Malapposition

<table>
<thead>
<tr>
<th>Malapposition at 12 Months</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Malapposition detected (% of patients/% of struts)</td>
<td>21(26%), 156(1.1%)</td>
</tr>
<tr>
<td>Number of malapposed struts, n</td>
<td>12.4±15 (1-58)</td>
</tr>
<tr>
<td>Malapposed struts per patient %</td>
<td>7.1±8.1(0.5-26.3)%</td>
</tr>
<tr>
<td>Mean incomplete strut apposition area, mm²</td>
<td>4.1±3.7(0.5-11.1)</td>
</tr>
<tr>
<td>BVS with at least 1% malapposed struts</td>
<td>18</td>
</tr>
<tr>
<td>&gt;5% malapposed struts</td>
<td>9</td>
</tr>
</tbody>
</table>

≠ PRAGUE 19 (~1mm²)

= PRAGUE 19 BVS STEMI

1. Spasm at implantation

2. Thrombus resorption
Late Thrombosis?

1. Address Spasm
2. Imaging / Thrombus
3. Potential additional issue, but
4. No evidence for major concern

In-BVS-Thrombosis

Kaplan-Meier estimate, %

Days

Patients at risk

0

1305

200

1098

400

798

600

433

800

102
**Ostial lesions**

1. **Prolong DAPT?**

<table>
<thead>
<tr>
<th></th>
<th>Univariate</th>
<th>Multivariable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>P</td>
<td>HR[95%CI]</td>
</tr>
<tr>
<td>Vessels treated</td>
<td>0.125</td>
<td>1.76 [0.86-3.60]</td>
</tr>
<tr>
<td></td>
<td>0.692</td>
<td>1.23 [0.45-3.39]</td>
</tr>
<tr>
<td>...</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ostial lesion</td>
<td>0.074</td>
<td>2.35 [0.93-5.96]</td>
</tr>
<tr>
<td></td>
<td><strong>0.049</strong></td>
<td><strong>2.59 [1.01-6.64]</strong></td>
</tr>
</tbody>
</table>

**Probability without event (%)**

Logrank $P=0.072$

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<table>
<thead>
<tr>
<th></th>
<th>Ostial lesions</th>
<th>Non-ostial lesions</th>
<th>$p$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baseline</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RVD, mm</td>
<td>2.92 [2.60-3.40]</td>
<td>2.87 [2.51-3.20]</td>
<td>0.283</td>
</tr>
<tr>
<td>MLD, mm</td>
<td>0.85 [0.57-1.36]</td>
<td>0.70 [0.35-1.05]</td>
<td>0.009</td>
</tr>
<tr>
<td>% stenosis</td>
<td>67 [51-79]</td>
<td>75 [62-87]</td>
<td>0.008</td>
</tr>
<tr>
<td><strong>Final result</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RVD, mm</td>
<td>3.20 [2.95-3.50]</td>
<td>3.00 [2.70-3.40]</td>
<td>0.004</td>
</tr>
<tr>
<td>MLD, mm</td>
<td>2.72 [2.35-3.00]</td>
<td>2.69 [2.33-3.00]</td>
<td>0.477</td>
</tr>
<tr>
<td>Acute gain, mm</td>
<td>1.67 [1.24-2.28]</td>
<td>1.97 [1.50-2.43]</td>
<td><strong>0.028</strong></td>
</tr>
<tr>
<td>Residual stenosis, %</td>
<td>30 [23-41]</td>
<td>26 [20-37]</td>
<td><strong>0.035</strong></td>
</tr>
</tbody>
</table>

MLD: minimum lumen diameter; RVD: reference vessel diameter
GHOST-EU

n = ~1,500, International Registry

Acute >>> late

Incomplete expansion

Inter-operator variability

Capodanno Eurointervention 2014
**DES vs BVS**

**Predilation with small balloon**
- No imaging
- Choose large BVS, Implant following IFUs
- No postdilation

**Choose large BVS and accept 10-20% residual stenosis**

**Sizing with NC balloon (1:1:1), 2 angiographic planes**

1. Vessel Expansion

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ICI meeting 2015
December 13-15, 2015
Tel-Aviv, Israel
2. BVS Expansion (and footprint)

Eyeballing? IVUS? OCT?
- The larger the better?
- Postdilate to size

„Small“ BVS
- Limited platelet-strut interactions

„Small“ BVS with postdilation
- Reduced force per surface
- Limited platelet-vessel interactions (Vessel damage)

Large BVS
BVS expansion

Oversizing BVS too large

(Vessel damage)
Larger footprint
Smaller pressure per surface unit
## 2. BVS Expansion (and footprint)

<table>
<thead>
<tr>
<th></th>
<th>%</th>
<th>P value</th>
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<tbody>
<tr>
<td><strong>BVS Thrombosis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% Stenosis</td>
<td>19±12</td>
<td></td>
</tr>
<tr>
<td>Maximum footprint, %</td>
<td>43±11</td>
<td></td>
</tr>
<tr>
<td><strong>Control</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% Stenosis</td>
<td>16±7</td>
<td>0.157</td>
</tr>
<tr>
<td>Maximum footprint, %</td>
<td>35±6</td>
<td>4.3*10^{-07}</td>
</tr>
</tbody>
</table>
Improved technique – Improved outcomes

Nitroglycerin

Sizing with NC balloon (1:1:1), 2 angiographic planes

Liberal use of imaging

Choose right BVS, Implant following IFUs

Postdilation (high ATM, +0.5mm)

Do not accept MLD<2.4/2.8mm

Puricel, JACC in press

Ishibashi, JACC int 2015
Conclusions

The results of the European experience suggest caution.

Evidence of safety (even in cohorts at risk) exist, however variability among centers exist.

Prof Minz ICI 2015:
- „Expansion is number 1 issue“
- „The larger the better“

Choices made at the time of implantation result in major differences in outcomes:

Accurate vessel preparation:
- Predilation: 10% incomplete expansion is not acceptable for 2.5mm BVS!

Achieve optimal lumen by
- Postdilation to minimum **2.4/2.8mm**
- Avoid Malapposition by sizing/imaging!
Percutaneous coronary intervention with everolimus-eluting bioresorbable vascular scaffolds in routine clinical practice: early and midterm outcomes from the European multicentre GHOST-EU registry

| Post-dilation | 0.92 (0.57-1.49) | 0.74 |

| No postdil | 3 | 303 | 112 | 84 |
| Post dil | 96 | 101 | 155 | 49 |
There is more to incomplete expansion

Incomplete vessel expansion → Impaired flow

Incomplete scaffold expansion → Reduced local pressure → Increased blood – BVS interactions

A

MLD: 2.65mm
BVS: 3.5mm
Footprint: 40%
Scaled residual stenosis: 24%

B

Footprint: 26%
### Implantation Technique

<table>
<thead>
<tr>
<th></th>
<th>Pre-procedure</th>
<th>After BVS implantation</th>
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<tbody>
<tr>
<td><strong>BVS Thrombosis</strong></td>
<td></td>
<td></td>
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<tr>
<td>MLD, mm</td>
<td>0.66±0.59</td>
<td>2.39±0.58</td>
</tr>
<tr>
<td>RVD, mm</td>
<td>2.77±0.58</td>
<td>2.93±0.58</td>
</tr>
<tr>
<td>% Stenosis</td>
<td>76±20</td>
<td>19±12</td>
</tr>
<tr>
<td>Maximum footprint, %</td>
<td>-</td>
<td>43±11</td>
</tr>
<tr>
<td>Scaled residual stenosis</td>
<td>-</td>
<td>0.21±0.18</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Control</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MLD, mm</td>
<td>0.68±0.51</td>
<td>0.849</td>
</tr>
<tr>
<td>RVD, mm</td>
<td>3.13±0.66</td>
<td>0.003</td>
</tr>
<tr>
<td>% Stenosis</td>
<td>77±16</td>
<td>0.660</td>
</tr>
<tr>
<td>Maximum footprint, %</td>
<td>-</td>
<td>35±6</td>
</tr>
<tr>
<td>Scaled residual stenosis</td>
<td>-</td>
<td>0.07±0.14</td>
</tr>
</tbody>
</table>

#### Graphs

- Sensitivity vs. 100-Specificity
- Max. footprint for 3.5 (blue) and 2.5-3.0 (red) BVS
- Positive predictive value, %
Implantation technique

**BVS Implantation technique**
1. Predilation with 3.0 noncompliant balloon
2. Assessment of effective dilation in two orthogonal planes
3. Implantation of a 3.0 BVS at max. 12ATM
4. Postdilation with a 3.0/3.25mm noncompliant balloon at 14-16ATM

**Standard Implantation technique**
1. Predilation with 2.5-3.5 semicompliant balloon
2. Implantation of a 3.5 BVS at 12-16ATM

**Soft plaque**
- Excessive BVS expansion
- VD 3.87mm
- Increased risk of vascular damage

**Calcific plaque**
- Incomplete BVS expansion
- e.g. MLD 2.9mm
- Footprint 35%

RVD 3.2mm
MLD 1.0mm

Final vessel diameter 3.2mm
Footprint 26%