BVS – Real-world evidence – what did we learn

CK Naber
Contilia Heart and Vascular Centre
Elisabeth Krankenhaus Essen, Germany
Conflict of interest

Speaking for Abbott, Elixir, REVA and Biotronik

Advising Abbott, Elixir and REVA

Contributing to trials of Abbott, Elixir and REVA
We learned a lot in 10+ years

30,000+ Patients Studied
12 RCTs
> 20 Registries

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Higher thrombosis rates in clinical trials

Stent/Scaffold Thrombosis Rates at 2 Years

What do real world data tell us?

- Early and Late ST compared to DES?
- Very Late ST compared to DES?
- Does ST translate into clinical outcome?
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GHOST EU: Implantation technique

*Adjusted for multivariate propensity score model
Brugaletta, S., GHOST-EU PSP Analysis, TCT 2016.
MICAT: Improved implantation improves outcomes

Nitrates

Sizing with ballon (1:1:1), 2 angiographic planes

Low threshold for OCT

Implant following IFUs

NC postdilation (+0.5mm)

Do not accept MLD<2.5/2.9mm MLA<4.9/6.6mm²

Puricel S et all, 4 Cities – J Am Coll Cardiol 2016; 67(8):921-31
GABI-R: experience improves outcomes

Patients treated in 2013/2014

Patients treated in 2015/2016

C. Hamm – Gabi-R, DGK 2017
GABI-R: impact of technique

6 months FU

Bifurcations excluded

C. Hamm – Gabi-R, DGK 2017
UK Registry: impact of technique

Predilatation, sizing according to reference diameter, high pressure postdilatation $\geq 16$ atm in 65.8%

Independent QCA analysis:
- 5/14 in vessels <2.5mm [1.8, 2.3mm]
- 2/14 undersized

A. Baumbach – UK Registry EuroPCR 2017
## UK Registry: avoid small vessels

### Multivariate analysis – risk for thrombosis

<table>
<thead>
<tr>
<th>Variable</th>
<th>Coding for Binary Variables</th>
<th>Coefficient (SE)(^1)</th>
<th>P-value(^2)</th>
<th>Odds Ratio(^1) [95% CI]</th>
<th>Maximum Rescaled R-Square(^3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTERCEPT</td>
<td></td>
<td>-4.49</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Scaffold Size</strong></td>
<td>2.5 vs. &gt;2.5mm</td>
<td>1.18 (0.48)</td>
<td>0.0136</td>
<td>3.27 [1.28, 8.37]</td>
<td>0.04</td>
</tr>
</tbody>
</table>

Model Checking Statistics, P-value of Hosmer and Lemeshow Goodness-of-Fit Test

| C-Statistic (the Area Under the ROC Curve): 0.64 |

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\(^1\) Coefficient (SE)
\(^2\) P-value
\(^3\) Maximum Rescaled R-Square
ST in large volume registries

Importance of dedicated implantation technique

1.7%**
1.5%
1.6%
1.0%
0.9%
1.0%
0.2%
0.0%
1.0% in 13/14
0.6% in 15/16
0.2%

UK REGISTRY
FRANCE ABSORB
REPARA
RAI REGISTRY
IT DISAPPEARS
GABI-R
BVS STEMI STRATEGY

ST rates @ 1y
ST rates @ 6mos
ST rates @ 30d

UK REGISTRY
1.1% in small vessel/undersized scaffolds
0.7% in properly sized vessels
## Treatment of Diffused Disease in IT-DISAPPEARS

<table>
<thead>
<tr>
<th></th>
<th>IT-DISAPPEARS 1415 lesions</th>
<th>ABSORB II 364 lesions</th>
<th>ABSORB III 1322 lesions</th>
<th>AIDA 1237 lesions</th>
<th>GHOST-EU 1549 lesions</th>
</tr>
</thead>
<tbody>
<tr>
<td>% patient ACS</td>
<td>59.8 %</td>
<td>20 %</td>
<td>26.9 %</td>
<td>53.5 %</td>
<td>46.5 %</td>
</tr>
<tr>
<td>Definite /Probable ST</td>
<td>0.9 %</td>
<td>0.9 %</td>
<td>1.5 %</td>
<td>1.7 %</td>
<td>1.8 %</td>
</tr>
<tr>
<td>Bifurcation</td>
<td>22.3 %</td>
<td>Excluded</td>
<td>Excluded</td>
<td>Excluded</td>
<td>23.1 %</td>
</tr>
<tr>
<td>Total BVS length (mm)</td>
<td>47.2 ± 22.9</td>
<td>13.8</td>
<td>20.5 ± 22.9</td>
<td>31.1 ± 19.6</td>
<td>28.5 ± 24.4</td>
</tr>
<tr>
<td>Pre-dilatation</td>
<td>97.9 %</td>
<td>100 %</td>
<td>100 %</td>
<td>96.9 %</td>
<td>97 %</td>
</tr>
<tr>
<td>Post-dilatation</td>
<td>96.8 %</td>
<td>61 %</td>
<td>65.5 %</td>
<td>74 %</td>
<td>50.5 %</td>
</tr>
<tr>
<td>Intravascular imaging</td>
<td>20.4 %</td>
<td>100 %</td>
<td>11.2 %</td>
<td>0 %</td>
<td>30.5 %</td>
</tr>
</tbody>
</table>

F. Bedogni – IT DISAPPEARS EuroPCR 2017
Treatment of STEMI in BRS STEMI STRATEGY

STEMI patients undergoing PCI, total n = 2,989

- RVD < 2.5 or ≥ 3.7 mm n = 596 (19.9%)
- Culprit bifurcation requiring 2-stent as intention, n = 118 (3.9%)
- STEMI onset > 12 hours n = 108 (3.6%)
- Contraindication for 12 months DAPT n = 56 (1.8%)
- Chronic oral anticoagulation n = 38 (1.3%)
- Saphenous vein graft culprit vessel n = 26 (0.8%)
- Planned Surgery n = 21 (0.7%)
- Dyalisis n = 16 (0.5%)
- Age more than 75 years n = 706 (23.6%)
- Severe tortuosity/calcifications n = 219 (7.3%)
- Cardiogenic shock n = 116 (3.8%)
- Stent thrombosis n = 61 (2.0%)
- Life expectancy < 3 years n = 47 (1.5%)
- Restenosis at a culprit site n = 32 (1.0%)
- Hybrid BVS/DES overlap n = 23 (0.7%)
- Operator’s decision n = 301 (10.0%)

BVS STEMI patients n = 505 (16.9%)
Treatment of STEMI in BRS STEMI STRATEGY
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Single centre short and long term results

**BVS MILAN EXPERIENCE**
264 patients
Latib, A., JIM 2017

- 53.2mm (average scaffold length per lesion)
- 43.9% (scaffold overlap per lesion)
- 74.8% (B2/C lesions)
- 46.8% (% of bifurcations)

**GHOST FERRAROTTO**
319 patients (mean FU @ 906 ± 265 days)
Tamburino, C., CRT 2017

- 21.2mm (average scaffold length per lesion)
- 13.5% (lesion length > 34mm)
- 51.2% (B2/C lesions)
- 49.5% (ACS patients)
Causes of late/very late scaffold thrombosis

Possible mechanical causes of late/very late scaffold thrombosis

Malapposition and late/very late scaffold thrombosis

Prospective study on 132 patients w/ OCT (150 scaffolds)

T. Gori, ACC 2017 and EuroPCR 2017
Technique and late/very late scaffold thrombosis

Series of 657 consecutive patients (925 scaffolds)

Proper technique substantially reduces short term and long term ScT risk

Acute or subacute

Late or very late

P=0.027
HR=0.29 [0.04-0.82]

P=0.010
HR=0.14 [0.03-0.62]

Time

Freedom from ScT

Optimal technique
Non-optimal technique

T. Gori, ACC 2017 and EuroPCR 2017
What do real world data tell us?

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Outcomes of scaffold registries in real world

Cardiac Death

TV-MI

TLR

*ALL MI
5y FU of first clinical BVS implant
Summary

Real-world learnings

• Scaffold thrombosis in real world registries is clearly linked to implantation technique

• Avoiding malapposition appears to be key to reproduce excellent results achieved by experienced implanters

• If this is respected there are promising results even in more complex populations like STEMI and diffused disease