Self-expanding vs. balloon-expandable stents for iliac artery disease: Is either superior?

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Disclosure

Speaker name: Hans Krankenberg

I do not have any potential conflict of interest.
<table>
<thead>
<tr>
<th>Self-expanding stent (SE)</th>
<th>Balloon-expandable stent (BE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexible</td>
<td>High radial outward force</td>
</tr>
<tr>
<td>• Easy to adapt wall pulsatility</td>
<td>Can be placed more precisely</td>
</tr>
<tr>
<td>• Conform to various vessel diameters</td>
<td>• Heavily calcified lesions?</td>
</tr>
<tr>
<td>• Less Neointimahyperlasia</td>
<td>• Lesions prone to recoil?</td>
</tr>
<tr>
<td>• Tapering lesions?</td>
<td>• Ostial CIA lesions?</td>
</tr>
<tr>
<td>• Tortuous lesions?</td>
<td>• Kissing balloon?</td>
</tr>
<tr>
<td>• Longer lesions?</td>
<td>• Shorter lesions?</td>
</tr>
</tbody>
</table>

Following Feldman and Klein J Am Coll Cardiol Intv 2017;10:1705-7
ICE Trial

Prospective, multicenter, randomized, investigator initiated

660 patients

August 2010 – June 2013

R

Self-expanding stent (SE)
N = 340

Balloon-expandable stent (BE)
N = 320

Follow-up at 6 and 12 months
Clinical / Functional / Duplex US

## ICE Trial

### Lesion Characteristics

<table>
<thead>
<tr>
<th></th>
<th>SE</th>
<th>BE</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N</strong></td>
<td>340</td>
<td>320</td>
<td></td>
</tr>
<tr>
<td>CIA (%)</td>
<td>60.3</td>
<td>57.8</td>
<td><em>ns</em></td>
</tr>
<tr>
<td>EIA (%)</td>
<td>39.7</td>
<td>42.2</td>
<td><em>ns</em></td>
</tr>
<tr>
<td>DS (%)</td>
<td>85.1 ± 10.0</td>
<td>84.2 ± 9.6</td>
<td><em>ns</em></td>
</tr>
<tr>
<td>RVD (mm)</td>
<td>8.3 ± 1.1</td>
<td>7.7 ± 1.2</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Lesion length (mm)</td>
<td>41.1 ± 32.9</td>
<td>33.7 ± 26.5</td>
<td><em>0.005</em></td>
</tr>
<tr>
<td>Heavy calcification (%)</td>
<td>26.5</td>
<td>24.7</td>
<td><em>ns</em></td>
</tr>
<tr>
<td>Total occlusion (%)</td>
<td>18.2</td>
<td>14.7</td>
<td><em>ns</em></td>
</tr>
<tr>
<td>In-stent restenosis (%)</td>
<td>4.1</td>
<td>3.4</td>
<td><em>ns</em></td>
</tr>
</tbody>
</table>

ICE Trial
Primary endpoint
12-month binary binary restenosis

\[ P = 0.006 \]

- **Self-expanding stent**: 6.1%
- **Ballon-expandable stent**: 14.9%

ICE Trial

Primary patency at 12 months

Primary Patency Rate (%)

SE 94.5%
BE 87.0%
P = 0.026

Patients at risk
SE 340 233 229 228 196 194 192
BE 320 244 243 238 175 172 166

ICE Trial

12-month TLR

\[ P = 0.041 \]

- Self-expanding stent: 3.0%
- Balloon-expandable stent: 6.9%

**ICE Trial**

**Multivariable Analysis**

Association of binary restenosis with:

<table>
<thead>
<tr>
<th>Factor</th>
<th>Odds Ratio (95% CI)</th>
</tr>
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<tbody>
<tr>
<td>Study device (BE)</td>
<td>2.7 (1.30 - 5.65)</td>
</tr>
<tr>
<td>Age (&gt; 65 years)</td>
<td>0.64 (0.31 - 1.34)</td>
</tr>
<tr>
<td>CAD</td>
<td>1.86 (0.93 - 3.74)</td>
</tr>
<tr>
<td>In-stent restenosis</td>
<td>5.7 (1.49 - 21.4)</td>
</tr>
<tr>
<td>Heavy calcification</td>
<td>0.40 (0.15 - 1.07)</td>
</tr>
</tbody>
</table>
Lesion Subgroups

Treatment effect on 12-month restenosis rate

- Heavy calcification: 0.86 (0.19 - 4.00)
- No or moderate calcification: 0.31 (0.14 - 0.68)
- Lesion length > 30 mm: 0.51 (0.20 - 1.30)
- Lesion length ≤ 30 mm: 0.24 (0.08 - 0.71)
- In-stent restenosis: 0.27 (0.03 - 2.6)
- Occlusion: 0.38 (0.09 - 1.59)
- Stenosis: 0.38 (0.16 - 0.88)
- EIA: 0.27 (0.09 - 0.84)
- CIA: 0.45 (0.19 - 1.11)
- All lesions: 0.37 (0.18 - 0.75)

ICE Trial - Summary

- Treatment of IAOD with self-expanding stents as compared to balloon-expandable stents
  - resulted in a lower 12-month restenosis rate
  - a significantly reduced TLR rate
  - provided superior primary patency

- Multivariable analysis identified treatment with balloon-expandable stents and in-stent restenosis as predictors of binary restenosis

- None of the patient or lesion characteristics were found to interact with the treatment effect

- No safety concerns arose in both groups
VISIBILITY Iliac study
Prospective, observational, 17 centers, balloon-expandable stent*, 75 patients, 9-month FU

Ø Lesion length 2.9 cm; mod./severe Calcium 54%; CTO 8%

Primary patency 95.8%
TASC A/B 98.1%/ 92.9%
TASC C/D 83.3%

No difference (ns): gender, lesion loc., calcification, occlusion

Freedom from cd-TLR 95.8%

MAE 4.0%
( 5 cd-TLR in 3 patients)

DURABILITY Iliac study
Prospective, observational, 15 centers, self-expanding stent*, 75 patients, 9-month FU

Ø Lesion length 4.5 cm; mod./severe Calcium 67%; CTO 22%

9 months
Primary patency 95.8%

EIA vs. CIA: p=0.9045
TASC A vs. B-D: p=0.1048

9-month MAE: 1.3% (1 cd-TLR, no death, MI, or amputation)

* Protégé Everflex, Protégé GPS

Covered stent* (BE) vs. BMS (BE, 6% SE)

COBEST (RCT) trial: 5-year results
Iliac artery stenosis or occlusion: TASC B-D, 125 patients

Risk factors: Type of stent (HR 2.8), Rutherford category (HR 2.0)

* Advanta V12  
PTFE* covered stent (SE) vs. BMS (SE)
Iliac artery occlusions

Retrospective, 2 matched cohorts, 94 limbs, 3 years
Ø Lesion length 7/6 cm; mod./severe Calcium 47/41%; CTO 100%

Primary patency: Overall

**Favours CS:**
- Occlusion length > 3.5 cm: p=0.04
- Total lesion length ≥ 6.0 cm: p=0.04
- Calcification > 75% of arterial circumference: p=0.01

* Polytetrafluoroethylene: Viabahn, Fluency

Piazza et al. Eur J Vasc Endovasc Surg (2017) 54, 177e185
Conclusion

• Both SE and BE perform well in IAOD.
• The randomised ICE trial favours SE over BE.
• Covered stents (SE and BE) might add some benefit in ISR and heavily calcified lesions.
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