Advantages of balloon expandable covered bridging stents in F/B/EVAR procedures: which one is best and why

Mauro Gargiulo

Vascular Surgery
University of Bologna - DIMES
University Hospital Policlinico S.Orsola
Bologna, Italy
mauro.gargiulo2@unibo.it
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Disclosure

Speaker name: **Mauro Gargiulo**

X I have the following potential conflicts of interest to report:

- Receipt of grants/research support
- Receipt of honoraria and travel support
- Participation in a company-sponsored speaker bureau
- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company

X Principal Investigator Expand Registry VBX 17-04

X Consulting: Cook Medical, WL Gore & Associates, Medtronic
Advantages of balloon expandable covered bridging stents in F/B/EVAR procedures: which one is best and why

Agenda

- BECS for Fenestrations and Branches: current indications
- The ideal BECS
- BECS available on the market
- Take-home messages
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• Take-home messages
1. Fenestration

*BECS is the choice!!*
2. Branches

**Table 4. Multivariate analysis of variables associated with occlusion or reintervention**

<table>
<thead>
<tr>
<th>Variable</th>
<th>HR</th>
<th>CI</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self expanding stent</td>
<td>0.95</td>
<td>0.41–2.2</td>
<td>.91</td>
</tr>
<tr>
<td>(versus balloon expandable)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Renal branch</td>
<td>3.51</td>
<td>1.7–7.35</td>
<td>.001</td>
</tr>
<tr>
<td>(versus visceral branch)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current smoker</td>
<td>0.99</td>
<td>0.045–2.14</td>
<td>.97</td>
</tr>
<tr>
<td>Diabetes</td>
<td>0.56</td>
<td>0.18–1.7</td>
<td>.311</td>
</tr>
<tr>
<td>Length of primary stent</td>
<td>1.00</td>
<td>0.96–1.02</td>
<td>.76</td>
</tr>
<tr>
<td>Diameter of primary stent</td>
<td>0.96</td>
<td>0.83–1.10</td>
<td>.14</td>
</tr>
</tbody>
</table>

**Conclusion:** There appears to be no difference in occlusion or reintervention rate for branch vessels treated with balloon expandable compared with self-expanding stents. Renal events appear to outnumber visceral events in this population.
2. Branches

Independent predictors of of loss of primary patency were:
- Renal artery target
- Small vessel diameter
- Viabahn VBX BESGs

Independent predictors of TAI:
- Large stent diameter
- Viabahn VBX BESGs
BECS for Fenestrations and Branches: current indications

2. Branches

Bologna Experience

**Endovascular repair of thoraco-abdominal aortic aneurysms by fenestrated and branched endografts**
Enrico Gallitto*, Gianluca Faggioni, Rodolfo Pini, Chiara Mascelli, Stefano Ancetti, Cecilia Fenelli, Andrea Stella and Mauro Gargiulo

**Risk Factors**

<table>
<thead>
<tr>
<th>TVV-s occlusion</th>
<th>Sig</th>
<th>OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal artery</td>
<td>.017</td>
<td>13.3</td>
<td>1.6 - 110.3</td>
</tr>
<tr>
<td>Branch design</td>
<td>.015</td>
<td>7.3</td>
<td>1.47 - 36.8</td>
</tr>
</tbody>
</table>

**Renal Artery Orientation Influences the Renal Outcome in Endovascular Thoraco-abdominal Aortic Aneurysm Repair**

Enrico Gallitto*, Gianluca Faggioni, Rodolfo Pini, Chiara Mascelli, Stefano Ancetti, Mohammad Abarrah, Andrea Stella, Mauro Gargiulo

Type B ($p = .05; OR 3.5; 95% CI 1.1–15.7$) or D ($p = .008; OR 10.9; 95% CI 2.8–50.8$) RA orientation and branches ($p = 0.06; OR 5.7; 95% CI 1.6–20.3$) were independent predictors of composite RA events on multivariable analysis.

On multivariable analysis, type B RA orientation ($p = .03; OR 5.5; 95% CI 1.1–31.1$) and branches ($p = .03; OR 7.3; 95% CI 1.1–47.9$) were independent risk factors for in-hospital RA loss.
BECS for Fenestrations and Branches: current indications

2. Branches

Bologna Experience

The Combined Use of a Distal Self-Expandable and Proximal Balloon-Expandable Stent Graft in Bridging Hostile Renal Arteries in Thoracoabdominal Branched Endografting

Ann Vasc Surg 2020
2. Branches

Bologna Experience

BECS for Branches:

- Celiac trunk, Superior Mesenteric Artery
- Renal Artery:
  - type A-C renal artery anatomy
  - type B-D renal artery anatomy: BECS (proximal) + SECS (distal)
Advantages of balloon expandable covered bridging stents in F/B/EVAR procedures: which one is best and why

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- BECS for Fenestrations and Branches: current indications
- The ideal BECS
- BECS available on the market
- Take-home messages
Ideal features

✓ Navigability / Pushability / Low profile
✓ Visibility
✓ Precise deployment
✓ Conformability / Adaptability
✓ Radial force
✓ Flaring attitude
✓ Long term patency / fracture and kinking resistance

Balloon-expandable covered bridging stents (BECS) in FEVAR and BEVAR procedures
Advantages of balloon expandable covered bridging stents in F/B/EVAR procedures: which one is best and why

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<th>Structure materials</th>
<th>Diameter (mm)</th>
<th>Length (mm)</th>
<th>Compatible sheath size (Fr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>iCAST / V12</td>
<td>Stainless steel encapsulated in 2 layers of PTFE</td>
<td>5-10</td>
<td>16-59</td>
<td>6 (5-6 mm diameters, 12, 22 length), 7</td>
</tr>
<tr>
<td>(Maquet / Getinge, Mijdrecht, the Netherlands)</td>
<td></td>
<td></td>
<td>(5 length options for 5-7mm stents)</td>
<td></td>
</tr>
<tr>
<td>BeGraft</td>
<td>Cobalt Chromium inside PTFE covering</td>
<td>5-10</td>
<td>18-58</td>
<td>6 (up to 8mm diameter), 7</td>
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<td>Lifestream</td>
<td>Stainless steel encapsulated in ePTFE</td>
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<td>6 (up to 6mm diameter), 7, 8</td>
</tr>
<tr>
<td>(Bard, Tempe, AZ, USA)</td>
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<td></td>
<td>(4 length options for 6-8mm stents)</td>
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<td>Cobalt Chromium inside ePTFE covering</td>
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<tr>
<td>VBX</td>
<td>Separate rings of Stainless steel attached externally to CBAS Heparin surface PTFE</td>
<td>5-11</td>
<td>15-79</td>
<td>7 (up to 8 mm diameter), 8</td>
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Balloon-expandable covered bridging stents in Fenestrations and Branches: **Structural features**
Balloon-expandable covered bridging stents in Fenestrations and Branches

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Preliminary Outcomes of the LifeStream Balloon-Expandable Covered Stent in Fenestrated and Branched Thoracoabdominal Endovascular Repairs

- **Pts** 18
- **BECS** 43
  - fenestration 32
  - branches 11
- **30days results**
  - fenestration TAI 15%
  - branches TAI 0%

**Conclusion:** This single-center preliminary experience with the LifeStream balloon-expandable covered stent in fenestrated/branched stent-grafts for TAAA repairs demonstrated good patency; however, an unexpectedly high rate of type IIIc endoleaks was observed. These endoleaks were resolved with reintervention or during the index procedure by proximal relining with a bare balloon-expandable stent, achieving adequate perifenestration sealing.
Balloon-expandable covered bridging stents in Fenestrations and Branches

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- **Pts**: 40
- **BECS for fenestration**: 82

95% Patency

Fig. 3 Kaplan-Meier analysis curve for target vessel patency.
Balloon-expandable covered bridging stents in Fenestrations and Branches

iCAST / V12
(Maquet / Getinge, Mijdrecht, the Netherlands)

BeGraft
(Bentley InnoMed, Hechingen, Germany)

VBX
(WL Gore & Associates, Medical Inc, Flagstaff, AZ, USA)

One Year Outcomes of 101 BeGraft Stent Grafts used as Bridging Stents in Fenestrated Endovascular Repairs

Performance of BeGraft and BeGraft + Stent-Grafts as Bridging Devices for Fenestrated Endovascular Aneurysm Repair: An In Vitro Study

First Preliminary Experience of Gore Viabahn Balloon-Expandable Endoprosthesis as Bridging Stent in Fenestrated and Branched Endovascular Aortic Repair

Performance of Viabahn Balloon Expandable Stent (VBX) Compared to Self-Expandable Covered (SES) Stents for Branched Endovascular Aortic Repair

Outcomes of bridging stent grafts in fenestrated and branched endovascular aortic aneurysm repair

J Endovasc Ther 2019

Motta F et al. JVS 2020

Vasc Endovasc 2019
Balloon-expandable covered bridging stents in Fenestrations and Branches: **Biomechanical properties**

<table>
<thead>
<tr>
<th></th>
<th>Median pullout* forces - 6 mm</th>
<th>Median pullout* forces – 8 mm</th>
<th>Shear stress° 6mm</th>
<th>Shear stress° 8 mm</th>
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<td></td>
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<tr>
<td>iCAST / V12</td>
<td>16.6 N</td>
<td>15.8 N</td>
<td>14.7 N</td>
<td>20.2 N</td>
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<tr>
<td>BeGraft +</td>
<td>30.4 N</td>
<td>21.8 N</td>
<td>15.28 N</td>
<td>20.72 N</td>
</tr>
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<td></td>
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<td></td>
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</tr>
<tr>
<td>VBX</td>
<td>27.1 N</td>
<td>20.1 N</td>
<td>12.5 N</td>
<td>23.9 N</td>
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* Pullout: perpendicular displacement

° Shear stress: axial displacement

After flaring no damage or fracture
Balloon-expandable covered bridging stents in Fenestrations and Branches

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- High resistance to dislocation  
- Proven long-term results | - Rigid device with a risk of vessel angulation  
- Sheath size not compatible with Preloaded FEVAR |
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| **BeGraft** *(Bentley InnoMed, Hechingen, Germany)* | - High resistance to dislocation  
- Good trackability  
- High flexibility  
- Is compatible with 6Fr sheath | - Lack long-term results  
- Fenestration: Risk of catheter friction and guidewires entanglement during device re-cannulation |
Aortic custom-made Stent-Graft with Preloaded Catheters
Steerable sheath for cannulation of Target Visceral Vessels in Branches

Steerable Sheath for Cannulation and Bridging Stenting of Challenging Target Visceral Vessels in Fenestrated and Branched Endografting

Enrico Gallitto,1 Gianluca Foggio,1 Luca Berioglio,2 Giovanni Pratesi,3 Giacomo Isernia,4 Martina Goretti,1 Arnaldo Ippoliti,1 Massimo Lentii,2 Roberto Chiola,2 and Mauro Gargiulo,1 Bologna, Milan, Genova, Pernagia, and Rome, Italy

Ann Vasc Surg 2020
Balloon-expandable covered bridging stents in Fenestrations and Branches

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<tr>
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<td>- Lack long-term results</td>
</tr>
<tr>
<td></td>
<td>- High flexibility</td>
<td>- Risk of kinking in the non stented segments</td>
</tr>
<tr>
<td></td>
<td>- Good trackability</td>
<td>- Learning curve</td>
</tr>
<tr>
<td></td>
<td>- Wide range of lengths up to 79</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Possibility for different diameter adaptation by post-dilation</td>
<td></td>
</tr>
</tbody>
</table>
Advantages of balloon-expandable covered bridging stents (BECS) in FEVAR and BEVAR procedures: Which one is best and why

Take-Home Messages

• I don't think there is a BECS for all occasions

• **Fenestration:** *iCAST/V12, VBX, BeGraft* according to the surgeon's preferences, the aortic endograft device (preloaded) and target artery anatomy

• **Branch:** *iCAST/V12, VBX, BeGraft* according to the surgeon's preferences, cannulation of branch from brachial or femoral access, target artery and target artery anatomy