Endovascular treatment of arterial injuries with Bentleys BeGraft stent-graft system: preliminary results

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Disclosure

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I have the following potential conflicts of interest to report:

- [ ] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

☒ I do not have any potential conflict of interest
Endovascular therapy with implantation of covered stent has become a therapeutic option for treating arterial injuries providing a minimally invasive and effective alternative to surgery.

They provide:
- Immediate exclusion of the lesion
- Redirect flow through the vessel
- Minimize the risk of distal embolization

ANATOMIC SUITABILITY:
- Proximal artery lesions
- Adequate proximal and distal neck
- 5 to 10 mm length of artery before and after the lesion without arterial division
- Adequate caliber
Vessel path allowing for safe catheter navigation
SPLENIC PSEUDOANEURYSM FOLLOWING DCP

RIGHT FEMORAL ARTERY ACCESS

- 6-F, 45 cm sheath Flexor® Ansel1 Guiding Sheath (Cook Medical)
- Radifocus® Guidewire M Standard Type, Terumo
- 7x37 mm 75 cm catheter BeGraft Peripheral (Bentley)
HEPATIC PSEUDOANEURYSM WITH MASSIVE BLEEDING

LEFT BRACHIAL ARTERY ACCESS

- 5-F, 90 cm sheath Flexor® Shuttle® Guiding Sheath (Cook Medical)
- V-14™ Controlwire™ guidewire (Boston Scientific)
- 4x12 mm and 4x16 mm BeGraft Coronary (Bentley)
SMA BLEEDING FOLLOWING DCP

RIGHT FEMORAL ARTERY ACCESS

- 6-F, 45 cm sheath Flexor® Ansel2 Guiding Sheath (Cook Medical)
- Radifocus® Guidewire M Standard Type, Terumo
- 5x18 mm 75 cm catheter BeGraft Peripheral (Bentley)
RIGHT EIA BLEEDING AND LEFT CIA PSEUDOANEURYSM FOLLOWING BRICKER URETEROENTERIC ANASTOMOSIS

BILATERAL FEMORAL ARTERY ACCESS

- 6-F, 11 cm sheath Radifocus® Introducer II, Terumo
- Radifocus® Guidewire M Standard Type, Terumo
- 2x 8x37 mm 75 cm catheter BeGraft Peripheral (Bentley)
PERFORATION OF COMMON TRUNK AFTER PTCA THROUGH RIGHT RADIAL ACCESS

10.85 mm
RIGHT FEMORAL ARTERY ACCESS

- 10-F, 90 cm sheath Flexor® Shuttle® Guiding Sheath (Cook Medical)
- Radifocus® Guidewire M Standard Type (Terumo)
- 12x29 mm BeGraft Aortic (Bentley)
A retrospective analysis of all the data of the treated patients was performed.

Informed consent was obtained from patients who were deemed to be able to provide consent at the time of the procedure.

**PRIMARY ENDPOINTS**

- To evaluate the **efficacy** of the BeGraft peripheral stent graft intended as technical success in excluding the vessel lesion/defect.
- To evaluate the **safety** of the device in terms of peri-procedural (minor and major) complications related to the device, 30-day clinical success, recurrence of the lesion.

**SECONDARY ENDPOINT**

- To determine the **patency** of the device during the follow up.
JUNE 2015 - OCTOBER 2018
60 patients (age 67 ± 15 y, 39 males, 64%)

20/61 (32.8%) patients were haemodinamically unstable

**LESIONS = 64**

- Active bleeding 32 pts. (49.0%)
- Dissection 17 pts. (30.2%)
- Pseudoneurysm 12 pts. (15.1%)
- AVF 2 pts. (3.8%)
- Enteric-iliac fistula 1 pt. (1.9%)

**LESION LOCATION**

- common iliac a. 25
- hepatic a. 8
- external iliac a. 7
- superficial femoral a. 6
- common carotid a. 2
- celiac trunk 2
- renal a. 2
- profunda femoral a. 2
- tibial a. 2
- brachiocephalic a. 1
- gluteal a. 1
- subclavian a. 1
- ascending cervical a. 1
- brachial a. 1
- post. circumflex a. 1
- aorto-renal bypass 1
- fem-fem left-to-right bypass 1

After the procedure, a DAT was administered (clopidogrel 75 mg and aspirin 100 mg daily) for 3 months followed by aspirin (100 mg daily) to be used for the lifetime thereafter.
### RESULTS

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TECHNICAL SUCCESS:</strong></td>
<td>61/61 patients (74 stent-grafts)</td>
<td></td>
</tr>
<tr>
<td><strong>CLINICAL SUCCESS:</strong></td>
<td>60/61 patients (98.4%)</td>
<td></td>
</tr>
<tr>
<td><strong>MAJOR COMPLICATIONS:</strong></td>
<td>1 exitus (not related to the procedure)</td>
<td>1.6%</td>
</tr>
<tr>
<td><strong>MINOR COMPLICATIONS:</strong></td>
<td>1 CFA pseudoaneurysm</td>
<td>1.6%</td>
</tr>
<tr>
<td></td>
<td>1 closure device failure</td>
<td>1.6%</td>
</tr>
</tbody>
</table>

We did not notice any stent migration during follow-up.

After a mean FU of 587 ± 344 days (min 26, max 1238) all the implanted devices are patent, corresponding to a rate of no patency ≤2×10⁻² events per person-years (EPPY).
CONCLUSION

Endovascular treatment with BeGraft covered stents, with preservation of distal flow, is minimally invasive, safe and effective in the management of arterial injuries and emergencies.

The good trackability of the delivery systems, the small profile of the stent-grafts, their flexibility and conformability allow for the rapid treatment of the lesion even in case of tortuous anatomy.

In case of arterial injuries, the proper sizing of the stentgraft is essential to achieve technical and clinical success without complications/recurrences, therefore a wide range of stentgrafts is mandatory.

BeGraft Family is the broadest covered stenting platform in the market – globally!
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