FENESTRATED ANACONDA™ ENDOGRAFT FOR JUXTA- AND PARARENAL AORTIC ANEURYSMS: PRELIMINARY EXPERIENCE

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Fenestrated Anaconda™ endograft for juxta- and pararenal aortic aneurysms: preliminary experience

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Aim. The Fenestrated Anaconda™ endograft (Vascutek, Inchinnan, UK) is a new device that could be used to treat challenging aortic aneurysms involving the abdominal visceral vessels (AAA). In this single-centric report we analyze the perioperative and 6-month results of the Fenestrated Anaconda™ endograft for treating juxta- and pararenal AAA. Methods. Patients undergoing fenestrated endovascular aneurysm repair (FEVAR) using Fenestrated Anaconda™ endograft between May 2012 and July 2013 were prospectively enrolled. Clinical, morphological, intra- and postoperative data were collected. FEVAR planning was performed on the computed tomography angiography (CTA) using dedicated software for advanced vessel analysis (3mensio Vascular, 3mensio Medical Imaging, Bilthoven, The Netherlands). All patients performed a CTA and a contrast-enhanced ultrasound at 1 and 6 months. Endpoints were technical success (TS), perioperative and 6-month clinical success (CS), renal function worsening (creatinine ≥30% of preoperative value), visceral vessel patency and type I/III endoleaks. Results. Between May 2012 and July 2013, 5 patients (mean age 78.4±6.1 years, ASA III/IV: 4/1) underwent FEVAR using Fenestrated Anaconda™ endograft for juxtarenal (3 cases) and pararenal (2 cases) AAA. In 2 cases the neck angle was ≥45° and in 3 cases there was a severe iliac angle (≥60°). A total of 19 vessels were accommodated with 15 fenestrations (celiac trunk: 1; superior mesenteric arteries: 4; renal arteries: 10) and 4 valleys/scallops (celiac trunks: 3; superior mesenteric arteries: 1). In all cases the endograft was repositioned during the procedure and 6/19 visceral vessels were cannulated through left brachial access. TS was achieved in 4/5 patients (proximal type I endoleak). All the target visceral vessels were successfully treated. Thirty-day CS was 80% (transient renal function worsening). No permanent re-

Fenestrated endograft has evolved to extend the proximal sealing zone from the infrarenal to the suprarenal aorta allowing the visceral vessels to be incorporated into the repair.¹,² The endovascular aneurysm repair using fenestrated endograft (FEVAR) is nowadays a widely accepted alternative to open repair (OR) for treating aortic aneurysms involving the abdominal visceral vessels. Larger studies and long-term data are needed to confirm this treatment as safe and effective. Key words: Endovascular procedures - Aortic aneurysm - Outcome assessment, health care.
Fenestrated Anaconda™ endograft (Vascutek, Inchinnan, UK) is a new generation device that can be repositioned during the deployment and allows cannulation of the abdominal visceral vessels from a brachial approach. These features could be an important adjunct to treat cases with hostile anatomy, considered unsuitable for other fenestrated devices. No large monocentric experience has yet been published regarding the use of Fenestrated Anaconda™ endograft.

The aim of the present report is to analyze our preliminary results of the Fenestrated Anaconda™ endograft for treating juxta- and pararenal AAA.

**Materials and methods**

**Patient selection**

Between May 2012 and July 2013 patients with asymptomatic juxtarenal or pararenal AAA underwent FEVAR using Fenestrated Anaconda™ endograft and were prospectively enrolled in a dedicated database. Indications for Fenestrated Anaconda™ endograft included: AAA with maximum diameter >50 mm and proximal infrarenal neck length <5 mm in patients considered at high risk for OR. Severe angulation of the proximal neck, iliac axis and abdominal visceral vessels was not considered among the exclusion criteria. Exclusion criteria were: symptomatic patients; AAA with maximum diameter >70 mm; iliac artery obstruction or visceral vessels with diameter <4 mm or severe stenosis. Patients signed an informed consent form. Clinical (demographic, cardiovascular risk factors, comorbidity) and preoperative aortic-iliac parameters were collected. Intra- and perioperative data were analyzed. All patients underwent preoperative evaluation of the AAA by a thoracoabdominal computed tomography angiography (CTA) <3 months from the procedure with axial cuts thickness <2 mm.

**Fenestrated Anaconda™ endograft**

The Fenestrated Anaconda™ endograft is a custom-made device based on the design of the standard ONE-LOK Anaconda with some adjunctive modifications. The endograft is a modular device composed of a fenestrated main body and two iliac legs. The peaks of the ring stents are placed in the suprarenal aorta in lateral position (the endograft is rotated of 90° in contrast with the conventional device) allowing flow to the superior mesenteric artery (SMA) or celiac trunk (CT) which sit in the anteriorly oriented valley (Figure 1). The depth of the scallop/valley can be increased and a dedicated fenestration can be designed in cases where the distance between SMA or CT and renal arteries is <5 mm. The fenestrations are placed in the unsupported region of the endograft and therefore their positioning is not compromised by any stent or wire. The endograft can be easily repositioned even after its complete unsheathing to change the orientation and height and therefore correct any error between the fenestrations and the visceral vessels ostia. The absence of a proximal top cap in the endograft allows cannulation of the abdominal visceral vessel from a brachial access.

**Preoperative planning**

Planning for the Fenestrated Anaconda™ endograft was performed from CTA. Multiplanar, 3D and center lumen line reconstructions were performed using a dedicated postprocessing software for vessel analysis (3mensio Vascular, 3mensio Medical Imaging, Bilthooven, The Netherlands). A preliminary endograft plan was designed by our vascular surgeons with experience in EVAR and FEVAR technology. It was then confirmed by the Fenestrated Anaconda Planning Center and before implantation a prototype model was deployed into an aortic-iliac plastic reconstruction created from the CTA data to check the correct positioning of the fenestrations. Planning, manufacturing and sterilization time was 4-6 weeks.

**Endograft implantation**

The procedures were performed in the operating theatre with a mobile angiographic C-arm (OEC 9800 Plus, GE Healthcare, Salt Lake City, USA). Arterial and urinary catheters were placed preoperatively for monitoring purposes. Intravenous cefuroxime (2 g) and heparin (5000 IU) were administered prior the procedure. Bilateral common femoral artery and proximal left brachial artery cut-down were performed under general anesthesia.

The fenestrated module was introduced through the right common femoral artery. According to bone landmarks, angiography and orientation of the fenestration markers, the device was positioned and deployed. Through the left common femoral artery, using the dedicated magnet system, the controlateral
gate was cannulated and a 18-20 or 22F Cook introducer (according to the number of fenestrations) was inserted in the distal segment of fenestrated module to advance a 7F Flexor introducer (Cook Medical, Bloomington, IN, USA) near the renal fenestrations. Using a 0.035 floppy guidewire and a dedicated angiographic catheter, the renal and visceral arteries were cannulated through its fenestration. An angiographic Glidcath catheter (Terumo Medical Corp., Somerset, NJ, USA) was advanced into the artery to change the floppy guidewire with a Rosen wire (Cook Medical). The 7F introducer was then advanced into the artery. The same procedure was performed for all the target arteries. Advanta™ stent-graft (Atrium, Hudson, NH, USA) were advanced into the fenestrated arteries and deployed after complete fenestrated module release. When the target vessels could not be cannulated from the left femoral access, brachial access was employed (Figure 2). The fenestrated endograft was collapsed and repositioned when vessel cannulation through the fenestration was hampered by a deployment mistake (Figure 3).

The implantation was then completed with the iliac leg extension limbs, ballooning of the docking zone/iliac legs and a final angiography performed in 3 different projections to verify the correct position of the endograft, the absence of endoleak and the patency of the renal and abdominal visceral vessels. Patients were monitored in Intensive Care Unit for 48 hours after the procedure.
**Follow-up**

After the procedure, patients entered in a dedicated follow-up protocol. Before the discharge, they underwent laboratory evaluation of renal, hepatic and pancreatic function, thoracoabdominal CTA and a contrast-enhanced ultrasound (CEUS). These exams were repeated at 1 and 6 months of follow-up.

**Endpoints and definitions**

Endpoints were technical success (TS), perioperative (30-days) and 6-month clinical success (CS), renal function worsening, visceral vessels patency and type I/III endoleaks.

TS was defined as the correct deployment of the endograft, without intraoperative mortality, type I/III endoleak, failure in the target vessels cannulation/patency and iliac limb steno-obstructive complications at the completion angiography. CS was defined as effective AAA repair without perioperative (30 days) mortality and morbidity. The renal function worsening was defined as the reduction of glomerular filtration rate (GFR) ≥30% of the baseline value at 30 days. The GFR was calculated with the Chockcroft-Gault formula. The treated visceral vessels pat-

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Figure 2.— Brachial access.

Figure 3.— Collapsing and repositioning of the fenestrated endograft in case of difficult vessel cannulation through the fenestration due to error of deployment.
ency and type I/III endoleaks were evaluated at the completion angiography, at the discharge, and at 1 and 6 months by CTA and CEUS.

Results

Between May 2012 and July 2013, 5 patients (male: 100%, mean age 78.4±6.1 years, ASA III/IV: 4/1) underwent FEVAR using Fenestrated Anaconda™ endograft for juxtarenal (3 cases) and pararenal (2 cases) AAA. Demographic, cardiovascular risk factors and comorbidities are summarized in Table I. The mean preoperative creatinine value was 1±0.5 mg/dL (range: 0.7-1.6 mg/dL).

The mean AAA diameter and neck length were 56±4 mm (range: 50-70 mm) and 2±2 mm (range: 0-4 mm), respectively. The mean native suprarenal aortic diameter was 27±4 mm (range: 23-31 mm). In two cases there was a severe proximal neck angle (>45°) and in 3 cases there was a severe iliac angle (≥60°). The main aortic-iliac morphological features are summarized in Table II. The mean main body oversize was 16±5% (range: 10-22%).

Five Anaconda™ aortic-bis-iliac fenestrated endografts were used: 1 (20%) with 2 fenestrations, 3 (60%) with 3 fenestrations and 1 (20%) with 4 fenestrations. A total of 19 vessels were accommodated with 15 fenestrations (celiac trunk: 1; superior mesenteric arteries: 4; renal arteries: 10) and 4 valleys/scallops (celiac trunks: 3; superior mesenteric arteries: 1). In all cases the endograft was repositioned and type I/III endoleaks were evaluated at the completion angiography, at the discharge, and at 1 and 6 months by CTA and CEUS.

### Table I.—Cardiovascular risk factors and comorbidities.

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>N.</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>5</td>
<td>100</td>
</tr>
<tr>
<td>COPD</td>
<td>4</td>
<td>80</td>
</tr>
<tr>
<td>Coronary disease</td>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>Chronic renal failure (creatinine &gt;1.3 mg/dL)</td>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>Diabetes</td>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>PAOD</td>
<td>1</td>
<td>20</td>
</tr>
</tbody>
</table>

COPD: chronic obstructive pulmonary disease; PAOD: peripheral arterial occlusive disease.

### Table II.—Clinical and aortic-iliac morphological features.

<table>
<thead>
<tr>
<th>Pts</th>
<th>Age (years)</th>
<th>ASA</th>
<th>AAA type</th>
<th>AAA diameter (mm)</th>
<th>Proximal neck angle (°)</th>
<th>Common iliac angle (°)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>82</td>
<td>III</td>
<td>J</td>
<td>52</td>
<td>35</td>
<td>&lt;60</td>
</tr>
<tr>
<td>2</td>
<td>72</td>
<td>III</td>
<td>J</td>
<td>50</td>
<td>30</td>
<td>120</td>
</tr>
<tr>
<td>3</td>
<td>77</td>
<td>III</td>
<td>J</td>
<td>56</td>
<td>75</td>
<td>75</td>
</tr>
<tr>
<td>4</td>
<td>87</td>
<td>IV</td>
<td>P</td>
<td>70</td>
<td>30</td>
<td>90</td>
</tr>
<tr>
<td>5</td>
<td>74</td>
<td>III</td>
<td>J</td>
<td>51</td>
<td>50</td>
<td>&lt;60</td>
</tr>
</tbody>
</table>

J: juxtarenal AAA; P: pararenal AAA.

### Table III.—Intraoperative adjunctive procedures and postoperative complications.

<table>
<thead>
<tr>
<th>Pts</th>
<th>Fenestrations</th>
<th>Intraoperative complications</th>
<th>Treatment</th>
<th>Resolution</th>
<th>Postoperative complications</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3</td>
<td>LRA cannulation</td>
<td>Ostial PTA</td>
<td>Yes</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
<td>LRA stent-graft dislocation</td>
<td>Bridging stent</td>
<td>Yes</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>LRA dissection</td>
<td>PTA-stenting, local UK</td>
<td>Yes</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>4</td>
<td>3</td>
<td>Endoleak Ia</td>
<td>Ballooning</td>
<td>No</td>
<td>Renal bleeding</td>
<td>Nephrectomy</td>
</tr>
<tr>
<td>5</td>
<td>4</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

LRA: left renal artery; UK: urokinase for fibrinolytic therapy.
during the procedure and 6/19 (31.6%) visceral vessels were cannulated from the left brachial access (celiac trunk: 1; superior mesenteric arteries: 4; renal arteries: 1). The endograft characteristics, intraoperative adjunctive procedures and postoperative complications are shown in Table III.

In patient N. 1, advancement of the 7F Flexor introducer (Cook Medical) into the left renal artery was not feasible. A percutaneous transluminal angioplasty of the fenestration and the ostium of renal artery was performed using a balloon catheter of 4x6 cm, completing the procedure. In patient N. 2, the stent-graft of the left renal artery was dislocated from the visceral vessel during the flaring manoeuvre. From the left femoral access, using a coaxial technique with a 0.018 and 0.035 floppy guidewire, the renal artery was cannulated and a bridging stent-graft was deployed between the previous stent-graft and the left renal artery.

TS was achieved in 4/5 patients. All the target visceral vessels were successfully cannulated and stented. In one pararenal AAA (patient N. 4) a low flow proximal type I endoleak was detected at the completion angiography. There was no intra-operative mortality. Mean procedure time was 404±30 min (range: 360-420 min), mean fluoroscopy time was 102±7.2 min (range: 96.6-114.2 min) and 240 mL of iodinate contrast (range: 200-250 mL) was used for case. The mean blood infusion was 360 mL (range: 0-600 mL). The mean post-operative creatinine value was 1±0.8 mg/dL (range: 0.9-4.1 mg/dL). There was no difference between pre- and postoperative creatinine value (P=NS).

An emergency nephrectomy was necessary in patient N. 4 on the second postoperative day due to a renal bleeding. The patient suffered from a transient renal function worsening that returned to baseline level at 30-day follow-up.

Thirty-day CS was 80%. There were no cases of renal, pancreatic and liver function worsening. At the CTA and CEUS evaluation no new type I/III endoleak was detected and all the visceral vessels treated were patent. Three type II endoleaks were detected without a significant AAA increase.

At 6-month follow-up 4 patients survived without any complications. All visceral vessels were patent and no type I or III endoleaks were detected. Patient N. 4 died at 5-month follow-up due to a respiratory failure (after a severe pneumonia). One type II endoleak sealed and 2 persisted without AAA sac enlargement.

Discussion

Endovascular aneurysm repair using FEVAR is nowadays a widely accepted therapeutic option for the treatment of AAA involving renal arteries and abdominal visceral vessels especially for patients at high risk for OR. Several studies reported FEVAR as a safe and effective treatment (high technical and clinical success) with good early/mid-term results.

The manufacturer’s IFU report some anatomical limitations that preclude a widespread use of FEVAR and that could reduce its outcome. Even if it’s possible to use FEVAR also in challenging anatomies, a proximal aortic neck angle >45°, an iliace angle >60/90°, and calcification or stenosis of the femoral-iliac axis and abdominal visceral arteries are considered as FEVAR contraindications.

Fenestrated AnacondaTM endograft is a new generation device that can be easily collapsed and repositioned during the deployment and which allows great accuracy in the deployment and the cannulation of abdominal visceral vessels also from a brachial approach. These features could be an important adjunct to treat cases with hostile anatomy, also considered unsuitable for others fenestrated devices. The unsupported main body of the Fenestrated AnacondaTM endograft allows great flexibility in order to conform the endograft to the aortic anatomy also in tortuous and angulated cases. Another advantage of the unsupported endograft design is unrestricted positioning of fenestrations.

No large studies regarding the use of Fenestrated AnacondaTM endograft can currently be found in the literature. The first published experience is by Bungay et al. Four patients with short neck and juxta-renal AAA were treated in two different centres. The endografts used were planned with two fenestrations for renal arteries and a scallop/valley was used to accommodate the SMA. The results were excellent with 100% of TS, no type I/III endoleaks, no visceral vessels loss and no mortality at 30 days. Rolls et al. reported the use of the Fenestrated AnacondaTM endograft in 13 patients with juxtarenal AAA and type IV thoraco-abdominal aortic aneurysm. Another published experience is by Dijkstra et al. who reported a Dutch multicenter experience (25 patients) using this device for short neck and juxtarenal AAA. Both these studies reported good technical success and perioperative clinical results but no mid-term follow-up data.

Our results compare favorably with these data. We
have reported the treatment of juxta- and para-AAA using 2-, 3- and 4-fenestration endografts. In our experience TS was not achieved only in one case where a slow flow type I endoleak was detected at the completion angiography. This patient was an 87-year-old man, ASA IV, with a pararenal AAA of maximum AAA and suprarenal aorta diameter of 70 mm and 31 mm, respectively. Due to the high risk of spinal cord ischemia and severe clinical conditions we decided not to perform an extensive aortic coverage but to use only a 3-fenestration design with 34 mm of main body diameter. The same patient had an acute bleeding in the second postoperative day and underwent an emergency nephrectomy. He died at the fifth month of follow-up due to a not-AAA-related cause. This is the only death occurred in our experience. Thirty-day results (no complications, visceral vessels patency, renal function) were excellent as compared to other published experiences. These results were also confirmed at 6 months of follow-up.

Both advantages (repositioning and visceral vessels cannulation from above) of the Fenestrated Anaconda™ System were employed in the present series. In all cases the endograft was collapsed and repositioned during the procedure and 6/19 visceral vessels to stent were easily cannulated from a brachial/axillary approach, after repeated unsuccessful attempts to cannulate them through femoral access. These aspects could suggest the use of the Fenestrated Anaconda™ endograft to treat juxta- and para-renal AAA despite challenging anatomies.

Some features of the endograft’s design could limit its use in selected cases. For example, the largest main body diameter and length of 34 mm and 90 mm respectively or the absence of branch configuration limit the use of this endograft in case of type I, II and III thoraco-abdominal aortic aneurysms. Particular care is required during the flaring manoeuvre of the visceral stent-graft. The unsupported body could be partially moved during this moment and the visceral stent-graft could be dislocated from the visceral vessels. For this reason, if possible (i.e. no presence of arterial early collateral trunks), we suggest to use a long stent-graft that ensures a good sealing into the visceral artery.

It should be kept in mind, however, that this is just a preliminary experience with a very small cohort and a 6-month follow-up.

Conclusions

The Fenestrated Anaconda™ endograft can be used to treat challenging AAA involving the abdominal visceral vessels. The device’s characteristics have the potential to increase the proportion of juxtarenal and para-renal AAA that are suitable for endovascular repair. Larger studies and long-term data are needed to confirm our preliminary experience.

References


Conflicts of interest.—The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.