CHAPTER 8

Early results with the custom-made Fenestrated Anaconda aortic cuff in the treatment of complex abdominal aortic aneurysm

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Abstract:

The objective of this study was to investigate the feasibility of a specific custom-made fenestrated aortic cuff in the treatment of complex abdominal aortic aneurysms (AAAs). Between 2013 and 2016, a total of 57 custom-made Fenestrated Anaconda (Vascutek, Inchinnan, Scotland, UK) aortic cuffs were placed in 38 centers worldwide. All centers were invited to participate in this retrospective analysis. Postoperative and follow-up data included the presence of adverse events, necessity for reintervention, and renal function. Fifteen clinics participated, leading to 29 cases. Median age at operation was 74 years (interquartile range [IQR], 71-78 years); five patients were female. Two patients were treated for a para-anastomotic AAA after open AAA repair, 19 patients were treated because of a complicated course after primary endovascular AAA repair, and 8 cases were primary procedures for AAA. A total of 76 fenestrations (mean, 2.6 per case) were used. Four patients needed seven adjunctive procedures. Two patients underwent conversion, one because of a dissection of the superior mesenteric artery and one because of perforation of a renal artery. Median operation time was 225 minutes (IQR, 150-260 minutes); median blood loss, 200 mL (IQR, 100-500 mL); and median contrast volume, 150 mL (IQR, 92-260 mL). Primary technical success was achieved in 86% and secondary technical success in 93%. The 30-day morbidity was 7 of 29 with a mortality rate of 4 of 29. Estimated glomerular filtration rate remained unchanged before and after surgery (76 to 77 mL/min/m²). Between preoperative and median follow-up of 11 months, estimated glomerular filtration rate was reduced statistically significantly (76 to 63 mL/min/m²). During follow-up, 9 cases had an increase in aneurysm sac diameter (5 cases >5 mm); 14 cases had a stable or decreased aneurysm sac diameter; and in 2 cases, no aneurysm size was reported. No type I endoleak was reported, and two cases with a type III endoleak were treated by endovascular means during follow-up. Survival, reintervention-free survival, and target vessel patency at 1 year were 81%±8%, 75%±9%, and 99%±1%, respectively. After 2 years, these numbers were 81%±8%, 67%±11%, and 88%±6%, respectively. During follow-up, the two patients with a type III endoleak needed endograft-related reinterventions. Treatment with this specific custom-made fenestrated aortic cuff is feasible after complicated previous (endovascular) aortic repair or in complex AAAs. The complexity of certain AAA cases is underlined in this study, and the Fenestrated Anaconda aortic cuff is a valid option in selected cases in which few treatment options are left.
Introduction

For decades, the treatment of an abdominal aortic aneurysm (AAA) consisted of open repair through laparotomy. During follow-up after open repair, a proximal paraanastomotic aneurysm may develop, which occurs in up to 3%. Once it has developed, the rupture risk is between 15% and 55%. Open redo surgical treatment of an extended AAA has a procedural mortality of 14% in asymptomatic patients. Endovascular aneurysm repair (EVAR) has emerged as a viable alternative in proximal para-anastomotic AAA, without reported procedural mortality and an annual reintervention risk of 17%.

EVAR has favorable early results over open AAA repair in primary cases but is associated with a higher reintervention rate in the long term because of endoleak, migration, and device failure. A short, conical, and angulated infrarenal aortic neck increases the chance of type IA endoleak and endograft migration. Subsequently, it may lead to AAA sac expansion and rupture.

In primary AAA or thoracoabdominal aneurysm (TAA) cases with a narrow or otherwise healthy distal aorta, a bifurcated or uni-iliac endograft might not be the most suitable. All three entities, proximal para-anastomotic aneurysm, complicated EVAR, and primary cases, could be treated with an aortic cuff. The length of the remaining infrarenal sealing zone may be a problem, with placement of the cuff near the level of the visceral arteries potentially overstenting these arteries. Placement of a fenestrated aortic device, possibly combined with thoracic endovascular aortic repair (TEVAR), could overcome overstenting of visceral arteries in an overly short neck.

Previous cases with the Zenith fenestrated cuff (Cook Medical, Bloomington, Ind) appeared to be successful after failed EVAR, but there were restrictions in neck anatomy with use of this device. Vascutek

Figure 1: Left-anterior view of the custom-made Fenestrated Anaconda™ cuff with two fenestrations and fully augmented proximal ring configuration. The stitching on the left peak hook indicates the location of the proximal ring hook markers. Permission for use granted by Vascutek Ltd. Inchinnan, Scotland, UK.
(Inchinnan, Scotland, UK) developed the custom-made Fenestrated Anaconda aortic cuff (Figure 1), applicable in more angulated necks up to 90 degrees compared with the 60-degree angulated neck limitation with the Zenith fenestrated cuff.\textsuperscript{16}

No results have been reported yet for the Fenestrated Anaconda cuff, but the design potentially leads to higher technical success for patients with complex aortic anatomy. This study investigated the feasibility of the Fenestrated Anaconda aortic cuff for complex AAA repair.

Methods

Design

Between 2013 and 2016, a total of 57 patients in 38 European hospitals were treated with the Fenestrated Anaconda cuff for a proximal para-anastomotic aneurysm after failed EVAR or as primary treatment, and all were eligible for inclusion. An aortic cuff in primary treatment could be used solely in case of a narrow distal aorta or as part of TAA repair. All treatment sites were asked to participate in this retrospective study. Patients were excluded if they underwent implantation of an aortic uni-iliac or bi-iliac endograft.

Retrospective research of patients’ files is not under the scope of the Dutch Act on Medical Scientific Research Involving Human Beings (WMO). The Institutional Review Board approved the protocol, data collection, and study design (M16.200104); therefore, informed consent of the patients was not required. The manufacturer provided a list of clinics, without patient information, where Fenestrated Anaconda cuffs were implanted. Once participating, patients’ data were retrospectively collected by the treating clinician and filled into an online case report form without any patient-identifiable information (OpenClinica, version 3.11; OpenClinica LLC, Waltham, Mass). Data were analyzed anonymously by the investigators.

Data collection. Patients’ comorbidities were gathered, specifically cardiac, pulmonary, and renal disease and American Society of Anesthesiologists (ASA) class.\textsuperscript{17} The patient’s clinician assessed the AAA anatomy by multi-slice spiral computed tomography angiography (CTA), and a neck was considered short when an infrarenal length from lowest renal artery to aneurysm was <10 mm and infrarenal sealing would be insufficient. Measurements included landing zone angulation, defined straight in 0 degrees, counting toward 90 degrees in more angulation.

Information about the operation was gathered for type of anesthesia, type and location of
access, operation time, contrast material volume, estimated blood loss, successful cannulation of target vessels, operative mortality and morbidity, and procedural technical success. Procedural primary technical success was defined as an exclusion of the aneurysm, deployment of the planned endograft, and successful stenting of target vessels but without type I or type III endoleak at completion angiography and without conversion or mortality within 24 hours of surgery. In case an unplanned procedure was successfully performed, technical success was defined as a secondary technical success. Postoperative information was gathered during the 30-day postoperative period and follow-up, including laboratory findings, duplex ultrasound or CTA, target vessel patency, endoleak, and reinterventions.

**Technical details**
The cuff was designed by Vascutek and customized to the patient according to preoperative CTA measurements. The Fenestrated Anaconda endograft is typically oversized 10% to 25%, depending on landing zone angulation. The design’s proximal and distal diameters typically vary between 19 and 34 mm, with a length up to 120 mm. The endograft consists of two proximal nitinol rings that default to their single-plane configuration, and oversizing creates two opposing valleys and peaks apposing the aortic wall. These rings contain three or four pairs of hooks to attach to the aortic wall. In standard design, the rings are parallel; but by converging the rings from dorsal to anterior, placement is allowed between a proximal celiac artery and superior mesenteric artery (SMA), still enabling adequate sealing. Below the proximal rings, the unsupported part can theoretically hold an unlimited number of nitinol-reinforced fenestrations. The implantation procedure has been described in more detail before.

**Data analysis**
Discrete variables were presented with frequencies and percentages. Continuous variables were presented with median and interquartile range (IQR) because of the small sample size, and Wilcoxon signed rank test was used. Overall survival, reintervention rate, and target vessel patency were subjected to Kaplan-Meier analysis. Survival analysis confidence interval was taken at 95%, and statistical significance was set at $P < .05$. SPSS (version 22; IBM Corp, Armonk, NY) was used for statistical analysis.
Results

Fifteen clinics composing the Fenestrated Anaconda Cuff Study Group agreed to participate, resulting in 29 cases. Fenestrated Anaconda cuffs were implanted in six clinics in one patient, in another six clinics in two patients, in two clinics in three patients, and in one clinic in five patients. The remaining 28 cases were performed in 23 clinics that did not respond or did not want to participate.

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<th>TABLE I: PREOPERATIVE CHARACTERISTICS OF PATIENTS TREATED WITH THE FENESTRATED ANACONDA AORTIC CUFF</th>
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ASA, American Society of Anesthesiologists; COPD, chronic obstructive pulmonary disease; CVD, cerebrovascular disease, which could be transient ischemic attack or cerebrovascular accident; GOLD, Global Initiative for Chronic Obstructive Lung Disease. Variables are reported as number (%).

Characteristics of the patients

Median age at time of operation was 74 years (IQR, 71-78 years), and five patients were female. Estimated glomerular filtration rate (eGFR) was 75 mL/min/1.73 m2 (IQR, 58-89 mL/min/1.73 m2). One patient had an eGFR of 12 mL/min/1.73 m2 and was dialysis dependent preoperatively. Cardiac disease included coronary heart disease in eight cases and arrhythmia in six cases. All risk factors are summarized in Table I. The ASA class 2 patients were not treated open because of a combined TEVAR (n=1), a hostile abdomen (n=2), cardiac history favoring EVAR (n=4), or clinician’s preference (n=2).

Previous operation characteristics

Two patients required a fenestrated cuff because of a paraanastomotic AAA at 27 and 36 months after open AAA repair. Nineteen patients had undergone previous EVAR with an infrarenal endograft; 8 were treated with the Anaconda, 10 with the Endurant (Medtronic, Santa Rosa, Calif), and 1 with the Aorfix (Lombard, Oxfordshire, UK). Four of these endografts migrated distally, creating a type IA endoleak in three cases. One case had proximal AAA growth. The remaining 14 cases had a type IA endoleak without migration. Time between EVAR and fenestrated cuff placement was 41.5 months (IQR, 33-60 months). In six patients, the indication was primary repair of a juxtarenal-pararenal aneurysm. In two cases, the fenestrated cuff was the distal part of TEVAR for a primary TAA.
Aneurysm characteristics
Overall maximum diameter of the AAA was 62 mm (IQR, 44-73 mm). Location of the aneurysm was considered short-neck infrarenal (n = 7), juxtarenal (n = 17), suprarenal (n = 3), or type IV TAA (n = 2). Landing zone diameter was 24 mm (IQR, 23-28 mm). Proximal landing zone angle was 8 degrees (IQR, 0-35 degrees), with a maximum angle in one patient of 65 degrees. Significant aortoiliac tract stenosis or occlusion was present in three patients.

Implanted endograft specifics
A total of 76 fenestrations were used, with a mean of 2.6 fenestrations per endograft. The combination and number of fenestrations are summarized in Table II. One case had fenestrations for the celiac artery and the left renal artery only. This patient had an occluded SMA and was deliberately overstented by the aortic cuff. Seventeen endografts had standard and 12 had augmented proximal rings. The numbers of hooks were 16 four pairs and 13 three pairs.

Procedural details and technical success
All procedures were performed under general anesthesia. In the cases in which bilateral groin access was used (n = 20), a cranial approach was added in 14. In all unilateral groin access cases (n = 9), cranial access was also used. The total of 23 cranial approaches were brachial (n = 7), axillary (n = 7), or subclavian (n = 9). Cutdown groin access was performed in 42 of the total 49. Operation time was 225 minutes (IQR, 150-260 minutes), blood loss was 200 mL (IQR, 100-500 mL), and contrast material (iodine 300 mg/mL) volume was 150 mL (IQR, 92-203 mL). Two patients underwent planned spinal drainage, and no spinal cord injury was reported.

During operation, the feature of collapse and redeployment was used in 9 of 28 cases and was unknown in 1 case. In all patients, balloon-expandable covered stents were used for the visceral arteries (Atrium ADVANTA V12 [Maquet Holding B.V. & Co KG, Rastatt, Germany; n = 25]; BeGraft [Bentley Innomed GmbH, Hechingen, Germany; n = 2]; LifeStream [Bard,
There were seven planned surgical adjunctive procedures in four patients. In two patients, an elective TEVAR was done, and in one of them, a left subclavian transposition was performed in the same session. In that same patient, an iliac conduit was used because of an external iliac artery stenosis. In one patient, bilateral femoral anastomotic aneurysm after open repair was present, and bilateral reconstruction was performed. One patient had an iliac aneurysm after EVAR, and the original iliac limb was extended to seal the iliac aneurysm.

In one patient, a dissection of the distal SMA necessitated a laparotomy with bowel resection and iliac-SMA bypass. Another patient needed laparotomy <24 hours after surgery because of perforated renal artery, successfully tamponading the bleeding. Consequently, these two cases were considered technical failures. In one patient, a renal stent was misplaced between the aortic cuff and aortic wall and was irretrievable. The stent was left in place and the renal artery was successfully stented with another covered stent. Two patients had an endoleak at completion angiography between the original infrarenal endograft and the fenestrated cuff and were treated in the same session with a standard Vascutek aortic extension cuff. Consequently, the primary technical success was 86%. With the additional measures, the aneurysm was excluded in all patients. All target vessels were successfully stented, and no endoleak was noted at final angiography, leading to a secondary technical success of 93%. Figure 2 shows preoperative and postoperative CTA images of a successfully implanted cuff after previous EVAR.

Postoperative results
Seven patients had a complicated course within 30 days postoperatively and four resulted in death. One of these patients was treated for a para-anastomotic aneurysm after open repair and postoperatively developed a hemorrhagic cerebrovascular accident (CVA). Another patient had an ischemic CVA after treatment of a primary AAA. This patient was preoperatively known to have cardiac arrhythmia, but a subclavian approach was also used, possibly leading to the ischemic CVA. One patient died 3 days after surgery of multiorgan failure after dissection of the SMA and subsequent laparotomy. The patient who underwent TEVAR and subclavian transposition underwent cholecystectomy at the second postoperative day and sigmoidectomy and small bowel resection at the third postoperative day because of ischemia, presumably of embolic cause. All branches were open at CTA. He died 11 days postoperatively of multiorgan failure.
In the same patient with the misplaced renal stent, an occlusion of the endograft was seen on the same day of the operation, possibly because of a small aortic lumen at the level of the stented vessels and torsion in the endograft after repositioning. A balloon thrombectomy was performed to increase lumen diameter; an additional cuff was placed within the original fenestrated cuff. This created a chimney-like appearance where the stents in the fenestrations were pushed upward between the two cuffs, maintaining flow to the target organs. The stents protruded sufficiently within the aortic lumen, and additional extension was not necessary. In addition, this patient had a dissection of the external iliac artery treated with a self-expanding covered stent. One patient had a groin infection that was treated with conservative measures. The patient already on dialysis preoperatively required dialysis postoperatively. Two patients had a small renal infarction, without stenosis in the corresponding renal artery. One of these
patients died of a hemorrhagic CVA, and the other had only minimal decline in eGFR from 83 to 77 mL/min/1.73 m². Overall, there was no significant difference between preoperative and postoperative eGFR (P = .619).

**Follow-up**

In the 25 patients alive after the postoperative period, the follow-up was 11 months (IQR, 3–21 months). In 23 patients, follow-up was beyond 1 month, and CTA was done in all. No aneurysm-related deaths were reported. One-year patient survival was 81%±8%, and 2-year patient survival was 81%±8% (Figure 3).

During follow-up, 3 of 25 patients presented with an endoleak. In one patient, a type III endoleak between the right renal artery stent and the fenestration was found at 6 months, and a persistent type II endoleak was found at 18 months. The type III endoleak was treated with an additional balloon-expandable covered stent, and the type II endoleak required transarterial embolization. A laparoscopic infrarenal single tape banding was performed at 25 months postoperatively because of continued aneurysm sac expansion. One patient had a type III endoleak between the fenestrated cuff and the original infrarenal endograft. A full endovascular relining was done at 13 months, with preservation of the stented target vessels. Another patient had continued AAA sac expansion despite the fenestrated cuff, without definite endoleak on CTA. At 20 months, a laparotomy with infrarenal neck banding was performed and the AAA sac was explored, identifying two fabric failures in the first infrarenal endograft. The first endograft was left in situ after suturing of the fabric tears.

One endograft migration was observed at 9 months postoperatively. It was treated with Aptus Heli-FX EndoAnchors (Medtronic) and a proximal extension with TEVAR. Total en-
dograft-related reintervention-free survival was 75%±9% at 1 year and 67%±11% at 2 years (Figure 4).

Two patients developed an occlusion of the SMA at 15 and 19 months, respectively. Another patient, without a stented SMA, had an occlusion at 15 months postoperatively. In all cases, collaterals preserved sufficient vascularization and no treatment was necessary. One-year target vessel patency was 99%±1%, and 2-year target vessel patency was 88%±6% (Figure 5).

Decline in eGFR was seen in comparing the preoperative (76 mL/min/m2) vs follow-up (63 mL/min/m2) values (P = .044) but not the postoperative (77 mL/min/m2) vs follow-up (63 mL/min/m2) values (P = .177). Median AAA size remained stable (P = .946). Ten patients had AAA shrinkage (of 5 to 32 mm), four had stable AAA size, four had a marginal increase in AAA-size (1 to 5 mm), and five had an increase of >5 mm in AAA size.

These patients were treated with a fenestrated cuff because of a type IA endoleak after prior EVAR. The mentioned patient with the type III and type II endoleak had an AAA sac expansion of 30 mm, and the mentioned patient with an endoleak between the cuff and the original EVAR had an AAA sac expansion of 6 mm. In three other cases, no explanation for the sac expansion (7, 10, and 11 mm, respectively) could be found, and close follow-up was done. In two patients, no aneurysm size was reported at 18 and 24 months of follow-up.
Discussion

This study shows the applicability of the Fenestrated Anaconda cuff in para-anastomotic AAA, as salvage after failed EVAR, or in specific primary complex AAA cases. The complication rate in our study of 24% is slightly higher than in primary treatment of complex AAAs with the Fenestrated Anaconda. Primary treatment was shown to have an early complication rate of 19% to 24%.20-23 Postoperative complication risk and mortality require limitation of the use of the Fenestrated Anaconda cuff to patients in whom open repair is not an option, and careful selection of patients is essential.

Primary infrarenal AAA has a 30-day mortality of approximately 5% in open repair and 1% in EVAR.7 The elective open approach for failed EVAR has a 30-day mortality rate of 3%.24 In the primary repair of complex AAA, fenestrated EVAR (FEVAR) has similar postoperative mortality compared with open repair of 4% but seems favorable in high-risk patients not eligible for open repair.25 The postoperative mortality of 14% (4/29) in our study is higher than the reported early mortality of 4% to 7%.20-22 A single incident will have a significant influence on complication rate because of the small sample size in our study. Nevertheless, the frequent use of the cranial approach to cannulate downward-oriented target vessels possibly led to one fatal CVA in one patient. FEVAR carries the additional risk of embolization to vital organs.26 Reinterventions probably increase this risk, possibly causing multiorgan failure in one of the patients. Twenty-one patients had an ASA 3 classification, and a high number of patients had stroke-related risk factors, such as smoking, hypertension, and cardiac disease (Table I).27 The preoperative characteristics possibly influenced the postoperative mortality.

During follow-up, three patients had an occlusion of the SMA (two stented cases, one unstented case), without clinical consequences. The incidence seems higher than with primary repair, and it was unclear why the SMA became occluded in these cases.22 All these cases were treated after EVAR, and the double aortic devices possibly influence the patient’s natural anatomy, consequently leading to occlusion.

There was a statistically significant decline of 13 mL/min/1.73 m2 between preoperative eGFR and follow-up eGFR, without any clinical consequences. Only one patient had a new postoperative stenosis of a renal artery, with a decline in eGFR of 15 mL/min/1.73 m2. In the other cases, the cause for eGFR decline was unknown and possibly not device related. The risk of declining renal function in FEVAR has been described before, and extra attention is
warranted in cases at risk of renal failure. The placement of a fenestrated cuff after previous (endovascular) AAA repair or in very complex primary cases can technically be more difficult, reflected by more fenestrations and cranial approaches, compared with regular FEVAR. The operation time and number of fenestrations in our study were similar to earlier published data about the Fenestrated Anaconda, reflecting the experience of the surgeons. The main difference between the three currently commercially available fenestrated cuffs is the maximum possible landing zone angle, depending on the endograft’s design. The circular Z-stents from the Zenith fenestrated limit the landing zone angle to 45 degrees, which can be increased in the JOTEC E-xtra Design (JOTEC, Hechingen, Germany) to 60 degrees. The unsupported graft below separate circular proximal rings allows a landing zone angle of 90 degrees in the Fenestrated Anaconda. Furthermore, the delivery system of the Fenestrated Anaconda allows collapse, redeployment, and cannulation of the target vessels from above, without releasing the main device. The Zenith fenestrated has proved to be a safe and effective option for migrated or type I endoleak EVAR. Our study is the first to show the applicability of the Fenestrated Anaconda cuff, and the results for the JOTEC E-xtra Design are still awaited. Choosing a fenestrated cuff should be dependent on the patient’s anatomy because of the limited available evidence for either of the fenestrated cuffs.

Several alternatives should be kept in mind for salvage of failed EVAR, such as the use of EndoAnchors to appose the endograft against the aortic wall. The use of a cuff with chimneys or a combination with EndoAnchors. The EndoVascular Aneurysm Sealing System (Endologix, Irvine, Calif) with chimneys may also be successful in patients with failed EVAR.

Complete relining of the previous EVAR or paraanastomotic AAA with a bifurcated or aortouni-iliac endograft is an alternative in certain cases to the aortic cuff and is preferred nowadays by multiple clinicians. This could have led to a selection bias in this study. Evidence for complete relining with a fenestrated endograft is still limited but shown to be equally challenging in one small cohort study. More research needs to be conducted to prove the feasibility of relining in specific cases. Despite great experience in each center with the fenestrated endografts, each center implanted one to five cuffs, and these small numbers per center will result in inexperience with this specific fenestrated cuff. For unknown reasons, 23 clinics did not participate in this study,
which could have led to a selection bias. Because of the diversity in cases and small sample size, our findings may not be generalizable to all situations in which fenestrated cuffs would be applicable.

The duration of follow-up information varied greatly, from the perioperative period to 44 months postoperatively. Consequently, long-term follow-up data were not available for every patient.

**Conclusion**

The Fenestrated Anaconda aortic cuff can be used to treat patients with a para-anastomotic aneurysm after open AAA repair, in a complicated course after infrarenal EVAR, and in primary complex AAA. The complexity of certain AAA cases is underlined by this study, and the Fenestrated Anaconda aortic cuff is an option in cases in which few treatment options are left.
The Fenestrated Anaconda Cuff Study Group

In order of the number of included cases; when the number of inclusions is equal, the order is alphabetical.

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