State-of-the-Art Treatment of Proximal Endograft Failure After EVAR

Feasibility of Fenestrated Anaconda™ implantation for the treatment of existing or impending type Ia endoleak after EVAR.

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Over the last 2 decades, endovascular treatment of infrarenal abdominal aortic aneurysms (AAAs) has gained broad acceptance. Endovascular aneurysm repair (EVAR) offers reduced perioperative morbidity and mortality, and the ongoing improvements in graft design have reduced reintervention rates and improved long-term results. However, recent studies suggest that an increased risk for late failure remains after EVAR. Failure of the proximal seal is among the most critical concerns and can result in a secondary type I endoleak (Figure 1), aneurysm progression, and rupture. Although this can be the consequence of disease progression and stent graft fatigue, it may also be related to poor preoperative planning (short neck, undersized graft diameter) or incorrect intraoperative graft deployment. Regardless of the mode of failure, a loss of proximal seal represents a significant complication, and salvage of a failed EVAR procedure can be especially demanding in cases with a short or no infrarenal neck.

ENDOVASCULAR TREATMENT OPTIONS

Improvement of Proximal Anchoring

Devices designed for improving graft alignment to the aortic wall include the uncovered Palmaz stent (Cordis, a Cardinal Health company) and Heli-FX EndoAnchors (Medtronic). The use of an uncovered Palmaz stent to extend the proximal anchoring and increase the radial force of the endograft has been described for the treatment of primary type I endoleaks as well as for secondary procedures. Although 95% to 100% primary technical success rates have been reported, long-term results were disappointing. Arthurs et al reported a loss of proximal sealing zone in 35% and sac enlargement in 45% of cases upon a median follow-up of 53 months in 31 patients. According to the authors, continued aortic degeneration accounted for the loss of proximal seal zone, which the balloon-expandable Palmaz stent is not designed to address. Also, the use of bare-metal stents is limited to cases without significant endograft migration.

Figure 1. One year after EVAR for symptomatic AAA with an infrarenal neck of 14 mm, a type Ia endoleak was diagnosed by CTA (A, B). The patient was scheduled for FEVAR with four fenestrations, and completion angiography showed good perfusion of the renal and visceral arteries with no endoleak (C, D). Postoperative CTA was performed on postoperative day 6 and confirmed complete resolution of the endoleak and optimal perfusion of all four target vessels (E).
EndoAnchors have also been used to improve graft alignment to the aortic wall.\textsuperscript{12,13} For secondary interventions to treat a type I endoleak, a procedural failure rate of up to 20% has been reported despite the use of an additional aortic cuff in 65% of cases.\textsuperscript{12} After a relatively short follow-up interval of 9 months, 9% of patients had to undergo a secondary procedure for the same endoleak.

**Extension of the Proximal Landing Zone**

Cranial extension of the sealing zone may be the more sensible approach to improving endograft alignment, especially in cases in which proximal failure is associated with a diseased juxtarenal aortic neck. Greenberg et al first described the use of renal or visceral artery stents parallel to the aortic endograft,\textsuperscript{14} a technique that was originally intended to preserve aortic branch vessels in aortic anatomies with a short or nonexistent infrarenal sealing zone. This technique allows an extension of the aortic seal zone into the paravisceral segment, using covered self-expanding or balloon-expandable stent grafts.\textsuperscript{14,15} Although initial results demonstrated the technical feasibility of this technique, recent publications have reported 30-day procedure-related major complication rates of 25% to 40%.\textsuperscript{16-20} Data on the use of the chimney technique for redo cases are very limited. Donas et al reported on 18 interventions for the treatment of proximal seal failure, with a reintervention rate of 22% (n = 4) within 17 months.\textsuperscript{21}

Fenestrated endografts can be specifically designed to extend the proximal sealing zone of an abdominal aortic endograft into the pararenal and paravisceral segment. In contrast to the parallel graft technique, these devices allow for an anatomic reconstruction of this critical aortic segment, and existing results demonstrate an improved patency rate for visceral target vessels. Data on the use of fenestrated endografts for the treatment of proximal sealing failure after standard EVAR are limited. Katsargyris et al reported a technical success rate of 92% and a target vessel perfusion rate of 94% in 26 patients using the fenestrated Zenith device (Cook Medical).\textsuperscript{22} At an average follow-up of 26 months, reinterventions were necessary in four (15%) patients, and target vessel patency was 100%. Martin et al compared patients undergoing redo EVAR cases with patients undergoing primary fenestrated or branched interventions.\textsuperscript{23} Unfortunately, the authors did not differentiate between branched and/or fenestrated Zenith devices. For 52 patients undergoing rescue procedures, the technical success rate was 85%, and the target vessel perfusion rate was 92%. Although a follow-up interval and target vessel patency were not reported, the total reintervention rate was 27%.
Results Using the Fenestrated Anaconda™ Device

The Fenestrated Anaconda™ (Vascutek Ltd.) is a custom-made device based on the Anaconda™ AAA Stent Graft System (Vascutek Ltd.) that allows treatment of juxtarenal, pararenal, and suprarenal AAAs. Proximal sealing is achieved by two ring stents. Proximal fixation is achieved by nitinol hooks attached at the peaks and valleys of the ring stents. Depending on the configuration of the visceral segment, the anterior valley hook can be omitted or reduced in size, and the ring stents can be configured with an augmented valley to allow for sealing between closer visceral vessels. The deployment system allows precise positioning as well as repositioning of the endograft even after complete unsheathing. Cannulation of the fenestrations and respective target vessels can be achieved via inguinal, subclavian, or axillary access. The manufacturing process of this custom-made graft includes the production of a three-dimensional model of the aorta, as well as a nonsterile prototype that allows a test implantation by the treating physician so that changes can be requested for the production of the final sterile device, if necessary.

Although some have reported on the application of the Fenestrated Anaconda™ device for treating the proximal seal after EVAR in individual cases, our recent report on the technical results of rescue fenestrated EVAR (FEVAR) after failed EVAR compared to primary FEVAR was the first to systematically address this issue.

Among 94 patients treated with the Fenestrated Anaconda™ device, 12 patients with prior EVAR were treated for a pathology of the proximal neck, including type I endoleak in seven cases (Figure 1), stent migration with no apparent endoleak in two cases (Figure 2), and progressive aortic disease immediately cranial to the proximal sealing zone including the visceral segment in three cases. Previous EVAR devices included the Excluder AAA endoprosthesis (Gore & Associates; n = 4), Talent Occluder (Medtronic; n = 1), Endurant AAA stent graft system (Medtronic; n = 4), Powerlink system (Endologix, Inc.; n = 2), and the Zenith graft (n = 1). One patient had already undergone a temporarily successful treatment with proximal cuff extension plus EndoAnchors. Deployment of fenestrated endografts in redo cases proved to be challenging—increased friction between the Fenestrated Anaconda™ graft and the old graft in situ hindered accurate graft deployment, and cannulation of visceral arteries was complicated by bare-metal stents placed with previously implanted stent grafts crossing the ostium (Figure 3). This was reflected by reduced primary technical success rates when compared to primary interventions (58.3% vs 87.8%; P = .02). However, functional success rates, defined as successful exclusion of the aneurysm without type I or type III endoleak or loss of organ function, were comparable between the two groups (91.7% in redo and 95.1% in primary cases, respectively).

Intraoperative mortality was 0% and there was no conversion to open surgery. Thirty-day mortality was 0% in redo cases and 6.1% in patients with primary FEVAR (P = .5). Major systemic complications including perioperative stroke, myocardial infarction, spinal cord ischemia, and renal insufficiency were comparable between redo cases, and primary FEVARs (8.3% vs 8.5%). Postoperative imaging was performed by CTA (n = 89) or, in cases of renal insufficiency, contrast-enhanced ultrasound (n = 5). After an average follow-up of 10 months, two cases of iliac limb occlusion were observed, but imaging did not reveal any cases of visceral connecting stent occlusions. The reintervention rate was 16.7% in redo cases compared to 11% after primary FEVAR (P = .57).
CONCLUSION

Treatment of patients after failed EVAR procedures and with no or insufficient infrarenal aortic neck is demanding. Due to limited midterm success rates, secondary anchoring of a failed infrarenal EVAR should be reserved for selected cases. The primary aim should be to extend the proximal sealing zone into a healthy aortic segment to prevent early failure of these complex redo cases. Fenestrated endografts allow for an anatomic reconstruction of juxtarenal, pararenal, and suprarenal aneurysmal aortic disease. Although redo procedures using fenestrated devices are associated with an increased risk of failure to cannulate the visceral target vessels compared with primary FEVAR interventions, secondary technical and functional success rates are satisfactory at > 90%. Increased primary failure rates seemed to be commonly attributable to space restrictions inside the old endografts and especially to difficulties accessing target vessels as a result of bare-metal stents crossing the ostium of a target vessel. Importantly, these difficulties did not result in increased perioperative complication rates or impaired short-term results. Whether there is a negative impact on long-term reintervention rates or patient morbidity and mortality remains to be evaluated.

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