Results of the Anaconda endovascular graft in abdominal aortic aneurysm with a severe angulated infrarenal neck

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Objective: **Proximal neck anatomy of an abdominal aortic aneurysm (AAA), especially a severe angulated neck of more than 60 degrees, predicts adverse outcome in endovascular aneurysm repair. In the present study, we evaluate the feasibility of the use of the Anaconda endovascular graft (Vascutec, Terumo, Inchinnan, Scotland) for treating infrarenal AAA with a severe angulated neck (>60 degrees) and report the midterm outcomes.**

Methods: **In total, nine Dutch hospitals participated in this prospective cohort study. From December 2005 to January 2011, a total of 36 AAA patients, 30 men and six women, were included. Mean and median follow-up were both 40 months.**

Results: **Mean infrarenal neck angulation was 82 degrees. Successful deployment was reached in 34 of 36 patients. Primary technical success was achieved in 30 of 36 patients (83%). There was no aneurysm-related death. Four-year primary clinical success was 69%. In the first year, eight clinical failures were reported including four leg occlusions which could be solved using standard procedures. After the first year, three patients with additional failures occurred; two of them were leg occlusions. Four patients needed conversion to open AAA exclusion. In six of 36 patients, one or more reinterventions were necessary. Three of them were performed for occlusion of one Anaconda leg and two were for occlusion of the body.**

Conclusions: **The use of the Anaconda endovascular graft in AAA with a severe angulated infrarenal neck is feasible but has its side effects. Most clinical failures occur in the first year. Thereafter, few problems occur, and midterm results are acceptable. Summarizing the present experiences, we conclude that open AAA repair is still a preferable option in patients with challenging aortic neck anatomy and fit for open surgery. (J Vasc Surg 2014;59:1495-501.)**

Since its introduction, endovascular aneurysm repair (EVAR) has gained widespread adoption as a routine treatment alternative for patients with abdominal aortic aneurysm (AAA). However, it has become clear that the failure of EVAR depends both on features of AAA anatomy and endovascular graft characteristics. The proximal AAA neck anatomy, especially a severe angulated neck of more than 60 degrees, predicts adverse outcome in EVAR.[1-5] However, this opinion has been challenged recently.[6]

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*A full list of MANSA study participants can be found in the Appendix (online only).

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Learning from the experience with first-generation endovascular grafts, and because of technological advances, the latest generations of commercially available endovascular grafts have been clearly improved. Modification and redesigning of the endovascular graft with specific attention to flexibility, proximal fit, and sealing intended to decrease the chance of type I endoleak and endovascular graft migration.[7-9] As a consequence, indications outside instructions for use (IFU) were sought in patients with hostile neck anatomy unfit for open repair.[10-16]

The Anaconda endovascular graft (Vascutec, Terumo, Inchinnan, Scotland) was designed with the intention of addressing some of the failure modes observed in the 1990s. Hypothetically, because of the zero body columnar strength design and the high flexibility of the system during placement, it should be feasible to utilize the Anaconda in AAAs with severe infrarenal angulations.[17]

In the present study we evaluated the feasibility and midterm outcomes of the Anaconda endovascular graft for treating infrarenal AAA with a severe angulated neck.

METHODS

In total, nine Dutch hospitals participated in this prospective cohort study. From December 2005 to January 2011, a total of 36 AAA patients, 30 men and six women, were included. Mean and median follow-up were both 40 months (range, 0-69 months).

Study design. Patients with an AAA and an infrarenal neck angulation of 60 degrees or more were eligible for inclusion in the Multicenter Angulated Neck Study with the Anaconda endovascular graft (MANSA). Table I presents an enumerative description of all the inclusion and exclusion criteria for the MANSA study. The study protocol was approved by the institutional review board. Aneurysm anatomy was defined through the use of Eurostar criteria.[18]

Each patient underwent a detailed preoperative screening to evaluate suitability for inclusion in the study. The information collected consisted of a general health analysis including the Society of Vascular Surgery/International Society of Cardiovascular Surgery (SVS-ISCVS) risk scores for diabetes mellitus, smoking, hypertension, hyperlipidemia, and cardiac, carotid, renal, and pulmonary disease, as well as American Society of Anesthesiologists (ASA) classification and ankle-brachial index. Preoperative AAA assessment included detailed spiral computed tomography (CT) scanning and angiography as described in a previous study with the Anaconda endovascular graft (ANA-004 study).[19]

Study hypothesis and definitions. The primary objectives of the MANSA study were to examine the technical and clinical success of the Anaconda endovascular graft for the treatment of AAA with a severe angulated infrarenal neck. The outcome parameters were outlined in detail in ANA-004 and were in line with the previous published guidelines for reports concerning EVAR by Chaikof et al.[20]

Clinical success is reported as short-term clinical success (30 days) and midterm clinical success (up to 4 years of follow-up).

Device description. The Anaconda AAA Stent Graft System is a three-piece endovascular graft. The stents were made of multiple-element nitinol stents internally covered with woven polyester graft material. The top of the endovascular graft consists of a dual-ring stent design, resembling the Anaconda snake. The proximal ring stent is anchored in an infrarenal position by four pairs of nitinol hooks, which prevent device migration. The body is unstented, resulting in zero column strength and adaptability in angulated proximal vascular anatomy. The iliac legs are fully supported with independent nitinol ring stents, which prevent kinking and provide flexibility with fixation in tortuous distal iliac and femoral anatomy. The delivery device of the main body has an outer diameter of 20.4F or 22.5F (6.8-7.5 mm), depending of the stent graft neck diameter used. The delivery system for the iliac legs has an outer diameter of 18.3F (6.1 mm). The Anaconda AAA Stent Graft System can be fully repositioned by use of the control collar of the delivery system handle. The cannulation of the contralateral gate of the body is facilitated with a magnet system that uses a preloaded magnet wire to assist in the cannulation and deployment of the contralateral iliac leg.

Operative procedure. All surgery was performed electively with a radiolucent table under fluoroscopic guidance. The endovascular graft was selected according to AAA anatomy, with special attention for at least 20%-30% oversizing of the prosthetic body in relation to the infrarenal neck diameter. The procedure was carried out under local (n = 9), epidural (n = 26), or general (n = 1) anesthesia, by means of standard surgical exposure of femoral arteries with the use of surgical cut-down and arteriotomy. For anticoagulation during the procedure, intravenous heparin (100 IU/kg body weight) was given in accordance with standard endovascular procedures. A second heparin dose was given when the EVAR procedure exceeded 2 hours of operative time.

First, on both sides, a stiff .035 wire (Backup Meier; Boston Scientific, Natick, Mass) was introduced up to the aortic arch. When iliac and aortic angulations could not be straightened with the use of stiff wires, one or two endovascular sheaths (Cook Medical Europe Ltd, Limerick, Ireland) were used. The zero columnar strength of the body caused by the unstented segment is problematic in the severely angulated distal part of the infrarenal aortic neck. To prevent infolding of the body, the starting point of the release of the iliac legs in the body was therefore close to the proximal body stent rings at a distance above the level of the aortic rim and angulation. In this way, the body is supported in this crucial place and kinking or infolding was diminished.

If applicable, the legs were extended to the common iliac bifurcation. All necessary operative details, overall outcome of the procedure, as well as any adverse event during operation were recorded.

Follow-up protocol. The study included postoperative follow-up at discharge and at 3, 6, 12, 18, and 24 months and yearly thereafter to assess clinical success or failure. Each patient underwent postoperative CT scanning

Table I. Inclusion and exclusion criteria

Inclusion criteria
Patient willing and available to comply with follow-up requirements
Patient can comply with instructions and gives informed consent
Life expectancy >2 years
AAA >50 mm in diameter
Symptomatic small AAA
Infrarenal proximal neck diameter 18-31.5 mm
Infrarenal proximal neck length ≥15 mm
Infrarenal aortic angulation >60°
Distal iliac fixation site diameter <16 mm and >30 mm in length
Access vessels >7.5 mm in diameter
Exclusion criteria
Ruptured or symptomatic AAA
Juxtarenal or suprarenal extension of aneurysm
Low operative risk for open repair
Presence of serious concomitant medical disease or infection
Known allergy to contrast medium, nitinol, or polyester
Inability to preserve at least one hypogastric artery
Connective tissue disease
ASA grade IV or V
Need for surgical reconstruction of other visceral arteries
Presence of >50% continuous calcification of proximal neck
Presence of >50% thrombus in proximal neck

AAA, Abdominal aortic aneurysm; *ASA,* American Society of Anesthesiologists.