Ring-stents supported infrarenal aortic endograft fits well in abdominal aortic aneurysms with tortuous anatomy

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Aim. Abdominal aortic aneurysms (AAA) with severe angulation of the neck or of the iliac arteries are often unsuitable for endovascular repair with conventional endografts. We evaluated the performance of a ring-stent abdominal endograft (Anaconda™ Vascutek, Terumo, Scotland) in a consecutive series of infrarenal AAA.

Methods. Preoperative, procedural and follow-up data of patients treated with Anaconda™ endograft between September 2005 and September 2009 were prospectively enrolled. Patients were divided in Group A (proximal neck angle ≥60° or iliac arteries angle ≥90°) and Group B (all others). Main endpoints were technical and clinical success (primary and assisted) and late outcome in the two groups. Results were compared by Kaplan-Meier life table analysis with log-rank test (Mantel-Cox).

Results. One hundred twenty-seven patients, with a mean age of 73.5±6.9 years, have been included in this series. Mean aneurysm size was 56.7±10.4 mm. A severe angulation of the proximal aortic neck or/and of the iliac arteries was present in 44 cases (Group A), absent in 83 cases (Group B). The mean follow-up was 18.2±16.3 months. Overall primary technical success was achieved in 100% of the patients. At twenty-four months survival, primary and assisted clinical success were 94.2%, 88.2% and 91.3% in Group A and 80.3%, 83.7% and 95.2% in Group B respectively. No significant differences were found between the two groups. The only factor significantly associated with decreased survival was preoperative renal insufficiency. Iliac limb patency 24 months after EVAR in severely and non-severely angulated iliac axis was 96.7% and 98.1% respectively, with no significant difference between the groups. Only one proximal type I endoleak was detected in a patient with severe angulation of proximal aortic neck. No significant correlation between proximal type I endoleak and severe neck angulation was found.

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Conclusion. Aneurysms with severe neck or iliac arteries angulation can be treated by a ring-stent endograft with results similar to those of AAA with more favourable anatomy.

Keywords: Aortic aneurysm, abdominal - Iliac artery - Aortic diseases.

Endovascular treatment (EVAR) of abdominal aortic aneurysms (AAA) offers a less invasive alternative to open repair, and randomized trials have shown significant benefit in terms of early mortality in EVAR compared with conventional open repair.1-3 However EVAR can also be associated with a high risk of late complications, such as persistent endoleaks and increasing aneurysm size.1-3 Hostile anatomy, either of the proximal aortic neck or of the iliac arteries, remains one of the major limitations of EVAR. Particularly, aortoiliac tortuosity has an important role in the endograft choice and in the outcome of patients submitted to EVAR. Some clinical experiences showed that the presence of a hostile neck with severe angulation is a predictor of adverse events.4,6 Furthermore an unfavourable anatomy with severe angulations of the iliac axes is crucial for device access as well as for possible thrombotic complications of the iliac legs.7 Although more and more endovascular devices are currently becoming available with increasing technological advancements, the “ideal” endograft has
not been designed yet and limitations are still present in any device. It is widely accepted that the type of endograft should be chosen according to the aortoiliac morphology. However, in cases with tortuous anatomy some authors suggest the employment of a supported endograft with suprarenal fixation \(^8\) while others report good results with infrarenal unsupported endograft with active fixation.\(^3,6,9\)

The Anaconda™ endograft (Vascutek, Terumo, Scotland) is an infrarenal stent-graft, supported only by ring stents. It features a number of characteristics including its ability to be repositioned. The ring stent design enables it to adapt well to aortoiliac morphology. In a recent personal experience this endograft showed good results in cases with severe angulation of the proximal aortic neck and of the iliac arteries.\(^10\) The aim of this study was therefore to compare the performance of this endograft in cases with and without severe aortoiliac tortuosity.

**Materials and methods**

Preoperative, procedural and follow-up data of patients with AAA treated with Anaconda™ endograft between September 2005 and September 2009 were prospectively recorded.

**Anaconda™ endograft characteristics**

The Anaconda™ endograft has been previously described.\(^11\) This endograft has infrarenal fixation; the proximal sealing is obtained by two saddle-shaped nitinol stents and four pairs of hooks. In case of aortic neck dilatation, the stents adapt with a flattening effect of the saddle and the hooks prevent distal dislocation.

The Anaconda™ endograft can also be completely repositioned. Movements of rotation, advancement, and retraction can be performed. This opportunity is particularly useful in angled necks, thus adapting the release of the endograft to the different angiographic projections.

Another main feature of Anaconda™ endograft is the magnet system for the catheterization of the contralateral leg. This feature is very useful especially in tortuous aorto-iliac anatomy. The support of the iliac legs is provided due to separate nitinol rings that appear to have an ideal flexibility.

**Patient selection**

A proximal aortic neck between 16 and 31.0 mm in diameter and longer than or equal to 15 mm is required for infrarenal AAA treatment with Anaconda™ endograft. Iliac arteries with a diameter between 8 and 21 mm in the landing zone are suitable.

Patients with an asymptomatic AAA greater than 50 mm in diameter, a symptomatic AAA (with contained rupture) or an infrarenal aortic dilatation associated with iliac aneurysms greater than 30 mm were enrolled in this study. Patients with acute AAA rupture, circumferential calcification or thrombus of the aortic neck or inadequate delivery system (18 F and 22 F) arterial access were excluded from the study. Severe angulation or tortuosity of the proximal aortic neck or of the iliac arteries were not considered as exclusion criteria.

Patients were divided into two groups: Group A included patients with severe angulation of the proximal neck (≥60°) and/or of the iliac arteries (≥90°), and Group B all other patients.

Approval of the Ethical Committee of our Hospital was not necessary, since the endograft is marketed under CE licence. All patients gave written consent.

**Endpoints**

Primary endpoints were survival, technical and clinical success (primary and assisted)\(^12\) in the two groups of treatment.

Secondary endpoints were primary and assisted iliac limb patency and freedom from proximal type I endoleaks. These secondary endpoints were compared between the two groups taking separately into account iliac axis angulation and proximal aortic neck angulation.

**Planning of the implant and follow-up (pre- and postoperative imaging)**

The procedure was planned through a multi-slice 16 layer CTA scan (G.E. Light Speed) starting from 2 cm above the celiac axis to the femoral artery bifurcation.

The data regarding the proximal aortic neck (diameter, length, angle, presence of calcification or thrombus) and the iliac arteries (diameter, angle, presence of calcification or wall thrombus) were collected and entered in a database.

Aortic neck angulation was defined as the angle
between the flow axis of the proximal aortic neck and the longitudinal axis of the aneurysm. A severely angulated iliac axis was defined as the presence of an angle equal or higher than 90° in almost one segment of the common iliac artery. Angles were measured on CTA 3D reconstruction considering the plane passing through the flow line.

All of the patients treated with Anaconda™ endograft underwent a strict follow-up protocol with a CTA, Contrast Enhanced Ultrasound (CEUS) and Doppler ultrasound (DUS) scan at 1, 3, 6 and 12 months after the procedure and yearly thereafter. Anteroposterior and latero-lateral diameters of the aneurysm were measured, and the presence of possible endoleaks detected. Variations in AAA diameters, device migration, endoleak and iliac limb thrombosis were considered.

**Statistical analysis**

Continuous data are expressed as mean ± standard deviation and discrete variables are given as counts (percentages). A descriptive analysis of frequencies was performed on qualitative variables. Patients were dichotomized into two groups in relation to proximal neck angulation (stratified as <60° and ≥60°) and/or iliac arteries angulation (stratified as <90° and ≥90°). The homogeneity of the two groups was analyzed using the nonparametric Mann-Whitney U test for continuous variables and with the Fisher exact test for categorical variables.

The Kaplan-Meier method was used to evaluate survival, technical success and primary and assisted clinical success. Univariate analysis of survival and primary and assisted clinical success was calculated.
in relation to groups (A and B), risk factors (hypertension, coronary artery disease, renal insufficiency, and COBP) and ASA preoperative risk. Variables from each analysis were entered into a multivariate Cox proportional hazards model and the outcomes (hazard ratio, HR) tested for significance with the log-rank test.

The Kaplan-Meier method and univariate analysis of primary and assisted iliac leg patency was only calculated in relation to iliac arteries angulation. Logistic regression of proximal and distal type I endoleak were calculated in relation to neck and iliac angulation respectively.

Statistical significance was defined as a two-tailed P<0.05. The calculations were performed by using SPSS for Windows software (version 13; SPSS, Chicago, IL, USA).

**Results**

**Patients**

In the study period 293 patients with infrarenal aorto-iliac aneurysm were treated with EVAR; in the same period 127 patients (43.3%) were considered suitable for treatment with Anaconda™ endograft.

The mean age was 73.5±6.9 years (range 55-89), 120 were male and 7 female.

Fourty-four (34.6%) patients had severe angulation of the aortic neck (21 cases – 16.5%) (Figure 1) and/or the iliac arteries (27 cases - 21.3%) (Group A).

In four cases the severe angulation was both in the aortic neck and in the iliac arteries. The latter subgroup was not analyzed because of the small number of patients. Eighty-three (65.4%) patients had no severe angulation of the aortic neck and iliac arteries (Group B).

Preoperative comorbidity, risk factors and demographic characteristics are reported in Table I and were similar in both study groups (A and B).

One hundred-twenty patients had an infrarenal AAA; 7 patients had an iliac aneurysm with diameter greater than 30 mm associated with a small AAA (5 in Group A, 2 in Group B). The characteristics of the aneurysm are reported in Table II and were similar in the two groups. Two AAAs had a contained rupture (both in Group B) and one was inflammatory (in Group A).

Intraoperative data such as operative time, fluoroscopy time, contrast volume and blood transfusion are reported in Table III.

The mean follow-up was 18.2±16.3 months (range 1.1-53.1) and did not differ significantly between Group A and Group B.

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**Table I.** — Risk factors.

<table>
<thead>
<tr>
<th>Group</th>
<th>N (44)</th>
<th>% (A)</th>
<th>N (83)</th>
<th>% (B)</th>
<th>Total N (127)</th>
<th>% (total)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age &gt;75 yrs</td>
<td>24</td>
<td>54.5%</td>
<td>48</td>
<td>57.8%</td>
<td>72</td>
<td>56.7%</td>
<td>NS</td>
</tr>
<tr>
<td>CAD</td>
<td>18</td>
<td>40.9%</td>
<td>47</td>
<td>56.6%</td>
<td>65</td>
<td>51.2%</td>
<td>NS</td>
</tr>
<tr>
<td>COBP</td>
<td>24</td>
<td>54.5%</td>
<td>45</td>
<td>54.2%</td>
<td>69</td>
<td>54.3%</td>
<td>NS</td>
</tr>
<tr>
<td>RI (Scr ≥1.5 mg/dl)</td>
<td>10</td>
<td>22.7%</td>
<td>17</td>
<td>20.5%</td>
<td>27</td>
<td>21.3%</td>
<td>NS</td>
</tr>
<tr>
<td>Hypertension</td>
<td>29</td>
<td>65.9%</td>
<td>62</td>
<td>74.7%</td>
<td>91</td>
<td>71.7%</td>
<td>NS</td>
</tr>
<tr>
<td>ASA II</td>
<td>4</td>
<td>9.1%</td>
<td>7</td>
<td>8.4%</td>
<td>11</td>
<td>8.6%</td>
<td>NS</td>
</tr>
<tr>
<td>ASA III</td>
<td>35</td>
<td>89.5%</td>
<td>65</td>
<td>78.3%</td>
<td>100</td>
<td>78.7%</td>
<td>NS</td>
</tr>
<tr>
<td>ASA IV</td>
<td>5</td>
<td>11.4%</td>
<td>11</td>
<td>13.5%</td>
<td>16</td>
<td>12.6%</td>
<td>NS</td>
</tr>
</tbody>
</table>

CAD: coronary artery disease; COBP: chronic obstructive bronchopulmonary disease; RI: renal insufficiency; Scr: serum creatinine.

**Table II.** — Aneurysms characteristics in Group A and Group B.

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean (range)</th>
<th>Group</th>
<th>Mean (range)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAA diameter (mm)</td>
<td>58.9±12.8</td>
<td>55.0±8.2</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Neck diameter (mm)</td>
<td>22.6±2.5</td>
<td>23.5±2.6</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Neck length (mm)</td>
<td>24.5±7.8</td>
<td>25.7±9.8</td>
<td>NS</td>
<td></td>
</tr>
</tbody>
</table>

**Table III.** — Intraoperative data.

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean (range)</th>
<th>Group</th>
<th>Mean (range)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating time (minutes)</td>
<td>129.3 (82-225)</td>
<td>121.3 (75-208)</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Fluoroscopy time (minutes)</td>
<td>40 (27-115)</td>
<td>36 (25-106)</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Contrast medium (Iomeron 300)</td>
<td>95.5 (60-255)</td>
<td>90.8 (53-198)</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Units of blood transfused (300 mL)</td>
<td>1.6 (0-4)</td>
<td>1.2 (0-4)</td>
<td>NS</td>
<td></td>
</tr>
</tbody>
</table>
Primary technical success, overall survival and clinical success

All patients were treated successfully with no intraoperative death, procedure abortion, surgical conversion, persistent type I and type III endoleak or graft limb occlusion. Primary technical success was achieved in 100% in both study groups.

No aneurysm-related deaths were observed during follow-up in both study groups. There was one cardiac-related death in Group A. Twelve deaths occurred in Group B, either for cardiac disease (8 cases), cancer (2 cases), post-operative multi-organ failure (1 case) and acute respiratory insufficiency (1 case). Survival rates at 24 months of follow-up were 94.2% in Group A and 80.3% in Group B (Figure 2) (P=NS).

ASA risk did not significantly affect survival at 24 months on univariate and multivariate analysis. By univariate and multivariate analysis, the only factor significantly correlated with shorter survival was preoperative renal insufficiency (HR=8.863 [95% CI=2.404-32.681], P=0.001).

Primary clinical success at 24 months was 88.2% in Group A and 83.7% in Group B (Figure 3) (P=NS). No aneurysm rupture occurred during follow-up. This result was also confirmed for the other analyzed variables.

Complications and treatment

Thrombosis occurred in 4 of the 254 iliac limb at risk (1/35 in severely angulated iliac axis; 3/219 in non-severely angulated iliac axis); all of these complications occurred within nine postoperative months. Iliac limb patency at 24 months from EVAR was 96.7% and 98.1% respectively in severely and non-severely angulated iliac axis (Figure 4) (P=NS). There was no significant difference on univariate analysis between the groups.

Cause for iliac limb thrombosis was an extrinsic compression from the aortic wall on the iliac limb or docking zone in two cases without severe iliac angulation. One case was treated by thrombolytic therapy and percutaneous angioplasty with good result. In the second case the thrombolytic therapy was ineffective, and the patient underwent surgical conversion.

One case of iliac limb thrombosis occurred in another patient without severe iliac angulation because of...
the incomplete expansion of the last distal stent of the iliac limb; the thrombosis was triggered by significant postoperative hypotension. The patient died on postoperative day 24 of a myocardial infarction.

One case occurred in a patient with severe iliac angulation: iliac limb thrombosis was due to recoiling of a calcified plaque at the distal portion of iliac limb in external iliac artery. The patient had moderate claudication and was left untreated because of high surgical risk.

Assisted patency at 24 months was 96.7% and 98.7% respectively in severely and non-severely angulated iliac axis with no significant difference.

A renal artery thrombosis due to dislocation of the lateral portion of the saddle-shaped proximal stent was incidentally detected one year after EVAR in an asymptomatic patient with normal renal function.

Spinal cord ischemia occurred in a patient with aorto-bi-iliac aneurysm treated by an endograft extended to both external iliac arteries and with surgical revascularization of the right hypogastric artery.

One proximal type I endoleak, not visible at completion angiography, was detected in the second postoperative day in a patient with severe angulation of the proximal aortic neck. The patient died from cardiac complications and therefore was not treated. This patient, the only one with a proximal type I endoleak, had a severe angulation of the aortic neck. No significant relationship between proximal type I endoleak and severe neck angulation was found at logistic regression.

One patient in Group B showed a distal type I endoleak 6 months after surgery and was treated successfully with an iliac extension. No distal type I endoleak was observed in patients with severe iliac angulation. There was no significant relationship with distal type I endoleak and cases of severe neck angulation. No type III endoleaks were detected in both groups.

Two patients showed an increased aneurysm diameter at 6 (Group B) and 24 months (Group A). In the first patient a 6 mm AAA diameter increase was associated with a distal type I endoleak, which was successfully treated. The second patient, who had 6 mm increase in diameter 2 years after the procedure, showed a persistent type II endoleak.

The assisted clinical success at 24 months after EVAR was respectively 91.3% in Group A and 95.2% in Group B (P=NS).

Discussion

Endovascular AAA repair has shown a clear benefit over conventional open surgery in terms of early mortality, morbidity rate and invasiveness. However, a hostile aorto-iliac anatomy may prevent successful endovascular repair. Morphology of the proximal aortic neck should be considered in patient selection for EVAR. Many authors have reported difficulties in endovascular treatment of aneurysm with hostile-neck anatomy, such as severe neck angulation, short neck and neck thrombosis. However, an increasing number of patients with an unfavourable neck anatomy is submitted for EVAR every year. This may lead to a greater incidence of major complications, such as type I endoleaks and graft migration, with poorer early and late results. Severe angulation of the infrarenal aortic neck was associated with early proximal type I endoleak and endograft migration in the series by Hobo et al.; this result was sustained at follow-up for proximal type I endoleak. Other authors reported similar results in patients with angulated aortic necks using different types of endograft.

Severe angulations of the iliac axes is also a critical problem in EVAR, leading to limb graft occlusion or inability to access the abdominal aorta. It is widespread opinion that the ideal endograft is not yet available and that the endograft should be selected according to the aorto-iliac anatomy of every single patient, in order to reduce the risk of graft-related complication. The endograft should warrant good proximal sealing and flexible adaptability to aorto-iliac anatomy in cases with tortuous anatomy.

Suprarenal fixation has been proposed as a solution for angulated aortic necks. Some authors believe that suprarenal fixation gives the best protection against type I endoleak and graft migration in aortic neck angulation, because of a better fixation to the healthy suprarenal aorta. In this context Cowie et al. reported no migrations or renal complications in their series.

Some authors suggest that unsupported grafts adapt more easily to tortuous vessels, however the lack of the endograft skeleton may increase the rate of type I endoleaks and of limb kinking and thrombosis. In their series Ouriel et al. showed a higher rate of limb occlusion in patients treated with an unsupported endograft (Ancure). In order to avoid this compli-
cation Faries et al. suggest the extensive use of graft limb stenting with that device.

On the other hand, the rigid structure of supported endografts reduces the risk of limb thrombosis but has a poorer adaptability to tortuous anatomy. This leads to a higher rate of late dislocation of proximal and distal components. Furthermore, the longitudinal stents of the iliac limbs may determine graft kinking in tortuous iliacs.

The endograft in our study introduces some innovative solutions for both proximal neck and iliac angiulations. Neck length was not considered because this graft requires an aortic neck longer than or equal to 15 mm.

In fact, both passive and active proximal infrarenal fixation are present in this device. The high radial force of the device and the active fixation given by the hooks provide a better stability, thus reducing the incidence of proximal type I endoleak or endograft migration. The fully unsupported main body, absence of longitudinal stents on the iliac legs and the separate nitinol ring support provide good flexibility and avoid the risk of endograft kinking, as it adapts well to tortuous aorto-iliac anatomy. For these reasons some authors suggest the use of this endograft for the endovascular treatment of isolated iliac and popliteal aneurysms, which are submitted to dynamic solicitation and angulation.

However, the absence of a longitudinal stent makes extrinsic compressions on the endograft possible. This adverse effect can be caused by a narrow and strongly calcified aortic bifurcation that was the cause of iliac leg thrombosis in one of our cases. Thus we frequently perform dilatation and balloon-expandable stenting.

In our series, patients were divided into two groups according to Chaikof’s criteria for aortic neck and iliac angles. All patients were closely followed-up and only one case of proximal type I endoleak was detected in a patient with a severe aortic neck angulation; no significant relationship between proximal type I endoleak and severe neck angulation was therefore found. Neither late proximal type I endoleaks nor endograft migration occurred. Iliac leg occlusion occurred in three out of four patients with a severe iliac angulation. All events occurred during the first nine months after EVAR. Despite that, we did not find a statistically significant difference in iliac leg patency between angulated and non-angulated iliac axis.

Conclusions

In conclusion, the mid-term data analysis supports the use of Anaconda in cases with severe angulation of both the proximal infrarenal aorta and the iliac arteries. This endograft has good proximal sealing and good performance in iliac tortuosities, with a low incidence of thrombosis.

References

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