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# **Research Article**

# Common Iliac Anatomy as a Limiting Factor for the Implantation of Anaconda<sup>®</sup> Aortic Endoprostheses

Mayor Díaz A<sup>1</sup>; Segura Carrasco R<sup>1</sup>; Zafra Angulo J<sup>1</sup>; Morillo Jiménez V<sup>1</sup>; Plaza Pelayo C<sup>1</sup>; San Norberto García E<sup>2</sup>; Fernández Heredero A<sup>1</sup>; Riera Del Moral L<sup>1\*</sup>

<sup>1</sup>Angiology and Vascular Surgery, La Paz University Hospital, Madrid, Spain. <sup>2</sup>Angiology and Vascular Surgery, Valladolid University Clinical Hospital, Valladolid, Spain.

\*Corresponding Author: Riera Del Moral L Angiology and Vascular Surgery, La Paz University Hospital, Paseo de la Castellana 261, 28003 Madrid, Spain. Email: luis.riera@salud.madrid.org

# **Article Information**

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# Abstract

**Introduction:** Endovascular Abdominal Aortic Aneurysm Repair (EVAR) remains a challenge for vascular surgeons. There are different models of endografts, including the Anaconda model (Terumo<sup>®</sup>).

Complex iliac anatomy seems to be a risk factor for the appearance of complications after surgery such as endoleaks or branch occlusions.

**Objectives:** To analyse the anatomy of the iliac arteries that receive a distal anchoring of the Anaconda endograft and to determine if it could be a predictive factor for the development of type Ib endoleak. In addition, the study aims to examine the iliac anatomy and its potential relationship to the development of branch occlusion.

**Methodology:** A retrospective cohort study was conducted, including all patients diagnosed with AAA who underwent surgery between 2011 and 2020, with implantation of the Anaconda endograft model at our hospital. The anatomy of the arteries where type Ib endoleak and branch occlusion occurred was compared with those where it did not occur.

**Results:** The iliac arteries that developed type Ib endoleak showed a higher tortuosity index (P=0.047), a smaller angulation, and a larger diameter and length. The iliac arteries where branch occlusion occurred had a lower tortuosity index and length, as well as a larger diameter.

**Conclusion:** The occurrence of type Ib endoleak is related to a higher tortuosity index of the iliac artery. Furthermore, a positive tendency suggests that the occurrence of branch occlusion may be predisposed by a larger diameter of the iliac artery.

**Keywords:** Vascular surgery; Abdominal aortic aneurysm; Anaconda endograft; Endoleak; Branch occlusion.

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#### Introduction

Endovascular Repair of Abdominal Aortic Aneurysms (EVAR) has changed the paradigm of treating Abdominal Aortic Aneurysms (AAA), with various commercial devices available in the market.

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EVAR is associated with significantly lower early mortality than open surgery. However, this benefit does not persist during long-term surveillance, and there is also a higher reintervention rate compared to conventional surgery [1-3].

Among the technical complexities of EVAR is the anatomy of the iliac arteries [4]. The anatomy of the iliac arteries is crucial for achieving device access to the aorta, sealing the aneurysm from systemic intraluminal pressure and maintaining perfusion to the pelvis and adjacent areas [4].

Chaikof et al. establishes and categorizes iliac anatomical characteristics that pose a risk factor for complications after EVAR. Diameter, calcification, tortuosity, and length were the selected anatomic factors. Among them, tortuosity and iliac angulation stand out [4]. Moreover, the Tortuosity Index (TI) is considered more representative of aorto-iliac anatomy than angulation alone [5].

The Anaconda<sup>™</sup> endograft (Terumo<sup>®</sup>) has a unique design of a spiral ringed metallic skeleton that allows better adaptability. It is considered effective in terms of survival, thrombosis, migration, and reintervention [6,7]. However, some studies consider the main drawback of this model to be the occlusion of iliac branches [8].

The Anaconda<sup>™</sup> system has the following instructions for use in infrarenal AAA repair [9]: Proximal aortic neck length ≥15 mm in segments with non-significant calcification or non-significant mural thrombosis. Native proximal aortic neck diameters of 17.5 to 31.0 mm. Infrarenal proximal aortic neck angulation ≤90°. Adequate iliac or femoral access. Native iliac artery diameters of 8.5 to 21.0 mm. Distal fixation length ≥20 mm.

#### **Hypothesis & objectives**

The hypothesis of our study is that a complex anatomy of the iliac arteries favors the occurrence of complications such as type Ib endoleaks and branch occlusions in patients treated with Anaconda<sup>M</sup>.

Our main objective is to attempt to clarify whether complex iliac anatomy is a predictive factor for the occurrence of type Ib endoleaks and branch occlusions. To achieve this, it is necessary to study the anatomical characteristics of the iliac arteries that receive a distal anchoring of the Anaconda<sup>™</sup> endograft.

#### **Patients & methods**

This is a retrospective cohort study that included all patients undergoing scheduled AAA intervention between 2011 and 2020 through the implantation of the Anaconda<sup>™</sup> aortic endograft model at our center.

All patients meeting the inclusion criteria (Patients undergoing elective EVAR with the Anaconda<sup>™</sup> model between 2011-2020) and none of the exclusion criteria (Patients treated with other endograft models or those without preoperative angioTC) were included. All data were obtained retrospectively from medical records and angioCT scans performed before and after the procedure. This study was approved by the ethical committee of the University Hospital La Paz (HULP PI 5472).

#### **Methods**

Retrospectively, various data related to aortic aneurysmal pathology, routine medication at the time of intervention, and complications during follow-up were collected from medical records.

Preoperative and postoperative angioCT scans were also downloaded, essential for measuring anatomical variables using the EndoSize program.

The measurement base included the following points:

P1: Aortic segment corresponding to the exit of the SMA (superior mesenteric artery). P2: Aortic segment corresponding to the exit of the renal arteries. P3: Aneurysm neck. P4: Aortic bifurcation. P5: Right common iliac artery bifurcation. P5': Right common iliac artery bifurcation. P6': Left common iliac artery at its origin. P6: Left common iliac artery bifurcation. P6': Right femoral artery before its bifurcation. P8: Left femoral artery before its bifurcation.

Considering these points, the following measurements were taken in both iliac arteries:

Iliac angle: angle formed by the common iliac artery and the external iliac artery. Common iliac artery diameter. Common iliac artery length. Renal-iliac axis: length of the path between P4-P7/P8. Aorto-iliac axis (L1): length of the path between P4-P7/P8. Straight iliac length (L2): distance P4-P7/P8 in a straight line. Tortuosity index, defined according to Chaikof et al. [4] as the ratio of the distance along the centerline between the common femoral artery and the aortic bifurcation to the straight-line distance from the common femoral artery to the aortic bifurcation. Maximum diameter of the aneurysmal sac, diameter, and length of the proximal neck.

#### Variables

#### **Principal variables:**

- Aorto-iliac anatomy: Common iliac artery diameter and length. Iliac angle. Renal-iliac axis. Aorto-iliac axis. Straight iliac length. Tortuosity index (IT).

- Type Ib endoleak: Presence/absence. Reintervention. Disappearance.

- Branch occlusions: Presence/absence. Reintervention. Time in years from the intervention until the occurrence of branch occlusion. Disappearance.Variables

#### Secondary variables:

-Demographic variables: age and sex

-Clinic variables: A Personal history: Smoking. Hypertension (HTA). Diabetes mellitus (DM). Dyslipidemia (DL). Chronic Obstructive Pulmonary Disease (COPD). Ischemic heart disease (CI). Cerebrovascular Disease (ECV). Peripheral arterial disease (EAP). Chronic Kidney Disease (CKD). Medication at the time of the intervention: Acetylsalicylic acid (ASA) or Disgren. Clopidogrel or Ticlopidine. ASA + Clopidogrel. Anticoagulation.

Anatomic variables: Aneurysm size: Maximum diameter (mm), neck diameter (mm), neck length (mm).

Permeability: Inferior Mesenteric Artery (AMI). Lumbar arteries. Right hypogastric artery. Left hypogastric artery.

# Statistic analysis

Descriptive statistics were conducted using absolute frequencies (n) and relative percentages (%) for the categories. For quantitative variables, the median was calculated as a measure of central tendency, and the  $25^{th}$  and  $75^{th}$  percentiles were used as a measure of dispersion.

Differences between groups of patients with and without endoleaks, as well as differences in the anatomy of iliac arteries where endoleaks and branch occlusions occurred compared to those where they did not, were analyzed using the Fisher's exact test for small sample sizes. Continuous variables were analyzed using the Mann-Whitney U test. Kaplan-Meier analysis was employed for the assessment of permeability and survival.

In all analyses, statistically significant differences were considered for study variables with p<0.05 (95% confidence interval).

# Results

The total number of patients operated on for AAA through EVAR in our center between 2011 and 2020 was 388, of which 61 patients were treated with the Anaconda™ model.

After applying the established criteria, 7 patients were excluded. Finally, 54 patients treated with the Anaconda<sup>™</sup> EVAR model were included. The specific analysis was conducted on 108 treated iliac arteries.

The distal iliac oversizing was less than 15% in all cases. All patients were male with a median age of 76.6 (69.4-80.8) years. The median maximum aneurysm diameter was 56 mm (52.8-60.3), neck diameter 22 mm (20.8-24.0), and neck length 35.5 mm (17.3-48.0).

The inferior mesenteric artery was not patent in 7 patients (13%), and the left hypogastric artery in 1 patient (1.9%). The right hypogastric artery and lumbar arteries were patent in all patients.

The median Common Iliac Artery (CIA) diameter was 13 mm (12.0-16.0), CIA length 67 mm (57.0-77.8), iliac angle 154.2° (137.1-162.5), renal-iliac axis 333.5 mm (319.0-350.0), aorto-iliac axis 223.5 mm (213.0-243.8), straight iliac length 175.5 mm (161.3-186.2), and an IT of 1.3 (1.2-1.4).

In follow-up, 22 patients (40.7%) presented endoleaks, including 1 with type Ia (1.9%), 4 with type Ib (7.4%), and 17 with type II (31.5%). No type III or IV endoleaks were found. Of the total patients with endoleak, 7 required some form of reintervention.

In the case of type Ia endoleak, no reintervention was performed due to the patient's high comorbidity, and the leak persisted. For type Ib endoleaks, reintervention was necessary in 3 cases, involving extending the iliac branch of the endoprosthesis on the leak side with the need for hypogastric embolization in one case. The leak disappeared in the treated cases. In the remaining case, conservative management was chosen due to high comorbidity.

Of the 17 patients with type II endoleak, 3 required reintervention due to sac growth equal to or greater than 1 cm; in these cases, the inferior mesenteric artery was embolized, but the leak only disappeared in 2 patients. Among the remaining 14 patients without reintervention, the leak disappeared in half.

On the other hand, 5 patients experienced branch occlusion during follow-up (9.2%). One case occurred in the immediate postoperative period, one within the first ten days of surgery, and the remaining cases within the first three years. The median time in years from the intervention to the occurrence of branch occlusion was 1.7(0.9-2.2). All cases required simple thrombectomy, and in one of them, a femoro-femoral bypass was also performed. At 3 years, patency was established at 90%, remaining so until the end of follow-up.

No statistically significant differences were found for sociodemographic variables, personal history, medication, aneurysm size, or pre-treatment patency of hypogastric arteries or the inferior mesenteric artery between the two groups.

Regarding the comparison of the anatomy of iliac arteries where type Ib endoleak appeared with those where it did not, no statistically significant differences were found in the studied anatomical characteristics, except for the IT variable. The IT was higher for arteries with type Ib endoleak, with a median of 1.55, compared to those where it did not develop, which had a median of 1.29 (P=0.047). A larger diameter, although not significant, was observed in cases of type Ib endoleak, with only one case associating with iliac aneurysm.

On the other hand, comparing the anatomy of iliac arteries where branch occlusion appeared with those where it did not, iliac arteries with occlusion had a shorter length and a larger diameter. The IT was practically similar in both groups. No statistical significance was obtained for any of these variables or for the rest of the variables related to iliac anatomy.

There were no fatalities in the first 30 days post-intervention. Survival after the first year of treatment was 92.6%, 83.4% in the second year, and 72.2% at the end of follow-up, with a median survival time of 103 months (71-134).

# Discussion

This study has evaluated the receiving iliac anatomy of distal anchorage of Anaconda endoprostheses to assess whether hostile characteristics at the iliac level favor the occurrence of complications at that level, especially if increased tortuosity is related to the appearance of type Ib endoleaks and branch occlusions. Chaikof et al in their study on risk factors for complications after EVAR establishes that an iliac IT greater than 1.6 implies a high risk, between 1.6 and 1.25 a moderate risk, while an index less than 1.25 is considered absent risk of complications at the iliac level [4].

On one hand, we have studied the occurrence of endoleaks, with special attention to type Ib endoleaks, which are high-flow leaks due to a defect in the distal iliac anchorage, requiring correction during follow-up to avoid problems derived from AAA pressurization and growth [2]. According to the results obtained, the most frequent endoleaks are type II, with an incidence of 31.5%. Type Ib endoleaks are the second most frequent, with an incidence of 7.4%. In these cases, the obtained IT was moderate

to high risk, with a statistically significant difference compared to patients who did not present it.

In the systematic review and meta-analysis of Anaconda<sup>™</sup> results by Abatzis-Papadopoulos et al., they argue that type II endoleaks are the most frequent with an incidence of 17.4% and that type Ib endoleaks are less frequent, with an incidence lower than that obtained by us, 2.2%. They also compare these data with the occurrence of type Ib endoleaks in other commercial models such as Endurant or Gore Excluder, where the incidence is similar between 2.4-3.8%, respectively [8].

In Zuccon et al.'s systematic review, they also associate a high-risk IT with the occurrence of type Ib endoleaks, but additionally relate a Common Iliac Artery (CIA) diameter greater than 18 mm to this type of leaks. In our case, only one patient with type Ib endoleak exceeded this threshold, so we cannot establish a clear association [10].

On the other hand, regarding branch occlusions, Abatzis-Papadopoulos et al. concludes that the Anaconda<sup>™</sup> model has comparable results with other available models with a low incidence of complications, except for branch occlusions, whose occurrence they consider high with a frequency of 6.8%. In our case, the number of branch occlusions in our study was higher, with an incidence of 9.2%.

Our result is very similar to the study by Simmering et al., a retrospective analysis of anatomical and geometric variables in patients treated with Anaconda, where they conclude that this model has a higher rate of branch occlusions in medium-term follow-up compared to other models, with an incidence of 9.5% [11]. In contrast, with other devices such as Endurant or Gore Excluder, occlusions are around 2-4% [12,13].

The trend towards the occurrence of branch occlusions could be explained by the Concertina effect. This effect implies that after the implantation of Anaconda in tortuous or shorter iliac branches, the separate nitinol rings come together. This induces the invagination of graft tissue into the lumen. These folds can induce blood stasis that promotes thrombosis formation [11].

Generally, the average time for the appearance of branch occlusions is 6 months (14); in our study, the occurrence has been higher with a median time in years of 1.7.

Further research is needed to clarify the relationship between the tortuosity index and the occurrence of type Ib endoleaks and branch occlusions.

# Limitations

There is a limitation in accurately measuring the distance between two points in 3D without specialized imaging software to calculate the Tortuosity Index (IT). The measurement of IT was performed by a single author, and correlation analysis between multiple authors was not possible. The IT has not been calculated after EVAR. The characteristics of the external iliac axis concerning previous stenosis or calcification have not been taken into account.

# Conclusion

Complex iliac anatomy predisposes to complications after the implantation of Anaconda<sup>™</sup> endoprostheses.

Regarding type Ib endoleaks, a high IT is statistically significantly associated with the occurrence of type Ib endoleaks. As for branch occlusions, despite a high incidence, similar to other series treated with Anaconda<sup>m</sup>, we cannot establish a causal relationship.

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