

# Endovascular Treatment of Abdominal Aortic Aneurysms with Complex Anatomy: Preliminary Results of a Second-Generation Stent Graft with a Dual-Ring Design

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## ABSTRACT

**Background:** Endovascular treatment has revolutionized the therapeutic approach to abdominal aortic aneurysms due to its low morbidity and mortality rates. Despite technological advances, there are still anatomical limitations to the use of stent grafts. This study aimed to evaluate the immediate clinical results in patients with complex abdominal aortic aneurysms treated with a second-generation stent graft. **Methods:** This was an observational, prospective, non-randomized, single-centre study with a series of patients who underwent endovascular repair of complex infra-renal abdominal aortic aneurysms using a stent graft with a dual-ring stent design (Anaconda™, Vascutek – Terumo, Inchinnan, Scotland). Clinical and angiographic characteristics, technical and therapeutic success rates, morbidity and mortality, and perioperative re-intervention rates were evaluated. **Results:** Between February 2010 and December 2011, 108 consecutive patients with aortic aneurysms were treated; 16 had complex abdominal aortic aneurysms treated with the Anaconda™ AAA Stent Graft System. The mean age was  $76 \pm 7$  years and 75% were males. Technical success was observed in 94% of the cases and therapeutic success was achieved in 75% of the cases. There was one postoperative death. The most prevalent perioperative complications were surgical wound bleeding (2/16) and peripheral embolism (2/16). Reinterventions were required in 12.5% of the patients during follow-up. **Conclusions:** In this study, the second-generation Anaconda™ Stent Graft System was effective and provided satisfactory immediate results in the treatment of complex infra-renal abdominal aortic aneurysms.

**DESCRIPTORS:** Aortic aneurysm, abdominal. Blood vessel prosthesis. Arteriosclerosis. Atherosclerosis.

## RESUMO

### Tratamento Endovascular dos Aneurismas da Aorta Abdominal com Anatomia Complexa: Resultados Preliminares com a Segunda Geração de Endoprótese com Arcabouço Metálico Circular

**Introdução:** O tratamento endovascular dos aneurismas da aorta abdominal tem revolucionado o tratamento dessa afecção, em decorrência das baixas taxas de morbidade e mortalidade. Apesar dos avanços tecnológicos ocorridos nas endopróteses, ainda existem limitações anatômicas para o emprego da técnica. Este estudo teve por objetivo avaliar os resultados imediatos do tratamento de pacientes portadores de aneurisma da aorta abdominal com anatomia complexa com uma endoprótese de segunda geração. **Métodos:** Estudo observacional, prospectivo, não randomizado, realizado em um único centro, em uma série de pacientes submetidos a tratamento endovascular de aneurismas da aorta abdominal infrarrenais complexos, com prótese com arcabouço metálico disposta em anéis (Anaconda™ – Vascutek, Terumo, Inchinnan, Escócia). Foram avaliados as características clínicas e angiográficas, o sucesso técnico, o sucesso terapêutico, a morbidade e a mortalidade, e a taxa de reintervenção perioperatória. **Resultados:** Foram analisados, no período de fevereiro de 2010 a dezembro de 2011, 108 pacientes consecutivos portadores de aneurisma da aorta, dos quais 16 eram portadores de aneurisma da aorta abdominal com anatomia complexa tratados com a prótese Anaconda™. A média de idade foi de  $76 \pm 7$  anos e 75% eram do sexo masculino. Houve sucesso técnico em 94% e êxito terapêutico em 75% dos casos. Ocorreu um óbito no pós-operatório. As complicações perioperatórias mais prevalentes foram sangramento da ferida operatória (2/16) e embolia periférica (2/16). Foram necessárias reintervenções em 12,5% dos pacientes durante o seguimento. **Conclusões:** Neste estudo, a segunda geração da endoprótese Anaconda™ foi efetiva e apresenta resultados imediatos satisfatórios no tratamento do aneurisma da aorta abdominal infrarrenal de anatomia complexa.

**DESCRIPTORES:** Aneurisma da aorta abdominal. Prótese vascular. Arteriosclerose. Aterosclerose.

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For many years, surgical treatment has been the standard therapy for patients with abdominal aortic aneurysm.<sup>1</sup> Since the introduction of the endovascular repair technique by Parodi et al.<sup>2</sup> in 1991, which aimed to decrease intra- and postoperative morbidity and mortality, the materials used for this treatment have been constantly improved. These improvements have led to better medium and long-term results.<sup>3</sup>

Endovascular repair is preferably indicated for high-risk surgical patients due to clinical comorbidities or for those patients with anatomic difficulties for an open surgical approach (hostile abdomen). Despite aggressive technological development, the ideal endograft has not yet been designed, and there are still technical limitations regarding the percutaneous procedure due to local anatomic variation, which hinders the adequate exclusion of the aneurysm.

Three major studies (Comparison of EndoVascular Aneurysm Repair open repair in patients with abdominal aortic aneurysm – EVAR 1, Endovascular Aneurysm Repair and outcome in patients unfit for open repair of abdominal aortic aneurysm – EVAR 2, and Dutch Randomized Endovascular Aneurysm Management – DREAM)<sup>4-6</sup> have shown that perioperative morbidity and mortality rates (within 30 days after the procedure) were favourable for endovascular treatment; however, when mortality rates were compared with that of the surgical technique, they were similar after one year of aneurysm treatment. The reintervention rates were greater in the endovascular treatment group and varied from 14% to 26%. This fact motivated the development of more versatile and flexible endografts, which would better adapt to existing anatomic obstacles in the aneurysm neck and aortoiliac bifurcation, as well as promote better sealing of its connections. A better seal would help prevent undesired endoleaks and decrease reintervention rates.

The aim of this study was to conduct an analysis of the perioperative results achieved through the use of a second-generation stent graft with a dual-ring stent design (Anaconda™, Vascutek – Terumo, Inchinnan, Scotland) in the treatment of complex infra-renal abdominal aortic aneurysms.

## METHODS

This was an observational, prospective, non-randomized study conducted at a cardiovascular disease centre in the state of São Paulo between February of 2010 and December of 2011. During the study period, 108 consecutive patients with aortic aneurysms were percutaneously treated with the Anaconda™ second-generation stent graft; 16 patients had complex infra-renal abdominal aortic aneurysms.

### Inclusion and exclusion criteria

Patients with abdominal aortic aneurysm and indication for elective repair using the diameter criterion

(> 55 mm in men and > 50 mm in women) or due to the presence of symptoms were included in the study. The anatomical criteria for using the stent graft were the presence of angulation in the proximal aortic neck (defined as the angle between the greater axis of the aneurysm neck and the greater axis of the aneurysm) and/or aortoiliac bifurcation of > 60 degrees. The study excluded patients presenting with a proximal neck < 15 mm, thrombus, calcification > 50% of the neck circumference, diameter of external iliac arteries < 7 mm, serum creatinine > 2 mg/dL, or creatinine clearance < 30 mL/min.

### Techniques used

The diagnosis and treatment of abdominal aortic aneurysm were based on angio-tomography, employing a 64-channel multi-slice computed tomography scan with 1 mm slices in all cases. Preoperative arteriography was an optional diagnostic method. All computed tomography scans were reproduced using OSIRIX® software in 3D and multi-planar reconstruction (MPR) modes. Therefore, it was possible to obtain the diameters, angles, and lengths of the proximal aortic neck, aneurysm, and aortoiliac bifurcation (Figure 1).

Anaconda™ is a tri-modular stent graft consisting of a nitinol dual-ring design and coated with woven Dacron. The proximal part of the graft body consists of two nitinol rings that provide radial strength for passive sealing of the proximal neck. Active fixation is provided by four pairs of hooks (two anterior pairs and two lateral pairs), which are not required for suprarenal or juxta-renal fixation. The stent graft diameter must be 10% to 20% greater than the internal diameter of the proximal aortic neck. The main body is connected to a system of nitinol rings, which make it possible for the stent graft to be collapsed and repositioned. The iliac leg consists of a woven Dacron® prosthesis with a series of nitinol rings whose distance varies according to its diameter. The contralateral iliac leg is connected through catheterization and is facilitated by a magnetic guide wire connected to the body of the stent graft. Dilation with a compliant balloon during the operation is only recommended in the case of an initial endoleak, and should not be frequently performed.

All procedures were performed in a haemodynamic monitoring laboratory. Patients were treated under general inhalation anaesthetics. Antimicrobial prophylaxis was administered with 1.5 g of cefuroxime at the moment of anaesthesia induction. The preferred approach was by the bilateral common femoral artery through open surgical dissection. When this approach was not possible, the external iliac artery was accessed via a retroperitoneal approach.

Radiographic control was performed with the Artis® Flat panel detector (Siemens, Munich, Germany). When the location of the device was not considered

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