

# Endovascular repair of abdominal aortic aneurysm: a single-center results analysis\*

Correção endovascular do aneurisma da aorta abdominal: análise dos resultados de único centro

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**Abstract Objective:** To evaluate immediate and mid-term outcomes in a series of patients submitted to endovascular repair of infrarenal abdominal aortic aneurysm in a reference center for cardiovascular medicine. **Materials and Methods:** The present retrospective study included a series of patients treated in the period from January 2009 to July 2010, and evaluated demographic characteristics, technical success, therapeutic success, morbimortality, immediate complications and perioperative reintervention rate in a one-year follow-up. **Results:** The authors evaluated 102 consecutive patients with a mean age of  $72 \pm 9$  years (79% were men). Technical success was observed in 97.1% of cases, and therapeutic success, in 81%. Perioperative mortality was 0.9% and one-year mortality rate was 7.8%. Reintervention was necessary in 18.8% of the patients during follow-up. **Conclusion:** The outcomes observed in the present study justify performing such a procedure in patients with suitable anatomy.

**Keywords:** Aneurysm; Vascular graft; Atherosclerosis.

**Resumo Objetivo:** Avaliar os resultados clínicos imediatos e em médio prazo do tratamento endovascular em pacientes portadores de aneurisma da aorta abdominal em um centro de referência para doenças cardiovasculares. **Materiais e Métodos:** Estudo retrospectivo de uma série de pacientes submetidos a tratamento endovascular de aneurisma da aorta abdominal, no período de janeiro de 2009 a julho de 2010. Foram avaliados as características demográficas, o sucesso técnico, o sucesso terapêutico, a morbimortalidade, as complicações e a taxa de reintervenções perioperatórias imediatas, e após um ano de acompanhamento. **Resultados:** Foram analisados 102 pacientes consecutivos com idade média de  $72 \pm 9$  anos, sendo 79% deles do sexo masculino. Houve sucesso técnico em 97,1% e êxito terapêutico em 81% dos casos. A mortalidade perioperatória foi de 0,9% e a anual, de 7,8%. Foram necessárias reintervenções em 18,8% dos pacientes durante o seguimento. **Conclusão:** Em nosso estudo, os resultados obtidos justificam a realização desse procedimento nos pacientes com anatomia adequada.

**Unitermos:** Aneurisma; Prótese vascular; Arteriosclerose.

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## INTRODUCTION

Infrarenal abdominal aortic aneurysms (AAA) occur in 1% of the women and in 6% of men aged above 64. Aneurysm rupture is fatal in 80% to 90% of the cases, as pre-hospital deaths are taken into consideration<sup>(1)</sup>. Considerable advances have been observed in the treatment of such a disorder. Undoubtedly, the endovascular technique, initially presented by Parodi and later developed by many researchers, has allowed the delivery of treatment for patients who would otherwise be at high risk if they were submitted to conventional

open surgical treatment. Nowadays, with the accumulated experience and the development of safer and more flexible endografts, the endovascular treatment can be considered both for patients presenting surgical risk and those with anatomical characteristics favorable for conventional open surgical treatment<sup>(2)</sup>.

Endovascular repair is precisely indicated for patients presenting high surgical risk, the elderly, and for those cases where there are anatomical difficulties for the open surgery approach (hostile abdomen).

The open surgical repair is considered effective and definitive, with graft failure rate of only 0.3% per year. However, such a technique presents non-negligible morbimortality rates, many times requiring pro-

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longed recovery periods, sometimes reaching several months in the event of complications. On the other hand, the rate of reintervention in the endovascular treatment is not negligible, and is actually higher as compared with the open surgery approach<sup>(3-6)</sup>.

The present study is aimed at evaluating immediate and medium-term clinical outcomes in a series of patients submitted to endovascular repair of AAA in a reference center for cardiovascular medicine.

## MATERIALS AND METHODS

### Type of study

The present retrospective, longitudinal and observational study was developed at Instituto Dante Pazzanese de Cardiologia, São Paulo, SP, Brazil, in the period from January 2009 to July 2010, evaluating the outcomes of 102 patients submitted to endovascular repair of AAA.

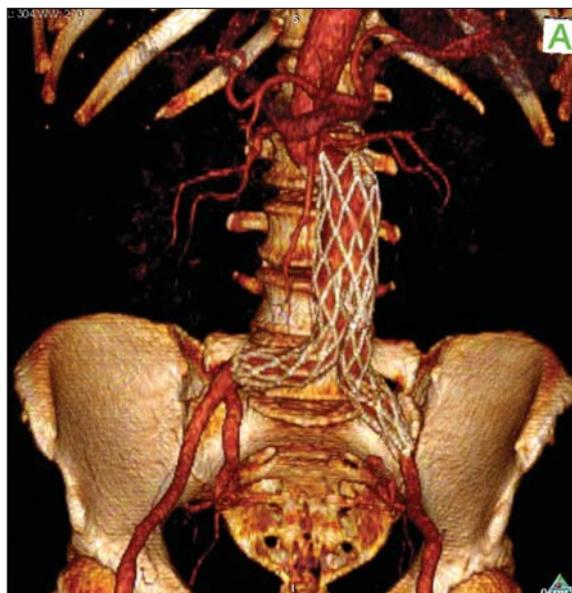
### Inclusion and exclusion criteria

The present study included both symptomatic and asymptomatic women and men with indication for endovascular repair of abdominal aortic aneurysms with > 55 mm in diameter for the male or 50 mm for the female patients, as well as for type I or type III endoleak repair in previously treated patients.

Patients with proximal aneurysmal neck < 15 mm in length, presence of thrombus or calcification > 50% of the neck diameter, aneurysmal neck angulation > 65°, aortoiliac bifurcation > 90°, external iliac arteries diameter < 7 mm, serum creatinine levels > 2.0 mg/dl or creatinine clearance < 30 ml/min were excluded from the study (Figure 1).

The patients who met the inclusion criteria were considered as having favorable anatomy and were consecutively referred for endovascular treatment. Anesthesia and/or cardiovascular risks were not taken into consideration for inclusion/exclusion of patients.

In all of the cases, the diagnosis and therapeutic planning were based on computed tomography angiography, with preoperative arteriography being the optional diagnostic method.



**Figure 1.** One-month tomographic follow-up of AAA repair. Aneurysmal neck with angulation of 60° and aortoiliac bifurcation with angulation of 65°.

### Surgical technique

All the procedures were performed in the Hemodynamics Laboratory of Instituto Dante Pazzanese de Cardiologia, in São Paulo, SP, Brazil.

The patients were treated under general inhalation anesthesia. Antimicrobial prophylaxis was performed with 1.5 g of cefuroxime, at the moment of the anesthetic induction. The preferred approach was through the common femoral artery, either unilateral or bilaterally according to the type of intervention or endograft to be deployed. In the cases where such an approach was not feasible the external iliac artery was approached by means of retroperitoneal access.

The radiographic control was performed by an Artis flat panel apparatus (Siemens; Munich, Germany). The following devices were utilized: Anaconda™ (Vascutek, Terumo; Inchinnan, Scotland), Aorfix™ (Lombard Medical Technologies PLC; Oxfordshire, UK), Apollo® (Nano; Florianópolis, SC, Brazil), Endurant™ (Medtronic; Minneapolis, MN, USA), Excluder® (Gore Medical; Flagstaff, AZ, USA), PowerLink System® (Endologix; Irvine, CA, USA), Talent® (Medtronic; Minneapolis, MN, USA), and Zenith Flex® (Cook Medical; Bloomington, IN, USA). All the patients underwent intraoperative arteriography. The immediate postoperative management of all the patients was carried out in the intensive care unit.

### Postoperative follow-up

The patients were followed-up on an outpatient basis 15, 30, 180 and 360 days after the repair. After the first year, the follow-up was performed once a year. Computed tomography angiography was performed on the 1st and on the 12th month of the outpatient follow-up. Color Doppler ultrasonography was utilized in cases where CT angiography was contraindicated.

### Outcomes and definitions

Primary and secondary outcomes were defined as follows:

1 – Technical success: when the objective of deploying the endograft in the affected area was achieved, with or without endoleaks or other events that could influence the favorable evolution of the aneurysm.

2 – Therapeutic success: when the endograft deployment occurred without endoleaks or other events that could affect the favorable evolution of the aneurysm.

3 – Perioperative mortality: number of deaths recorded within the first 30 days after the procedure.

4 – Annual mortality: number of deaths occurred within the 12-month follow-up.

5 – Perioperative complications: a) intraoperative complications – those occurring in the hemodynamics room during the intervention; b) in-hospital complications – those complications occurring during hospital stay, out of the hemodynamics

room and within 30 days after the intervention.

6 – Reintervention rate: interventions performed for the maintenance of satisfactory endograft function and exclusion of the aneurysmal sac, or for the resolution of complications associated with the intervention.

**Secondary outcomes**

1 – Length of hospital stay: time elapsed between hospital admission and patient’s discharge.

2 – Procedural time: time elapsed between anesthesia induction and surgical site closure.

**Endoleaks**

1 – Initial or primary endoleak: those endoleaks originated during the initial procedure or diagnosed within the first 30 days.

2 – Secondary endoleaks: those diagnosed after 30 days from the initial procedure.

**RESULTS**

The follow-up comprised 102 patients submitted to infrarenal AAA repair. The mean age of the patients was 72 ± 9 years, and 79% of them were men. The predominant risk factor was hypertension in 100 patients (99%), 23 (22%) were diabetic patients, 23 (22%) were smokers, 47 (46%) were former smokers, and 51 (50%) patients presented dyslipidemia. Obesity with body mass index > 40 was present in 5 patients of the studied population.

Amongst the comorbidities, a high incidence of ischemic cardiomyopathy (57.8%) was found, and in a lesser degree, chronic renal failure (14.7%). A significant percentage of patients with previous endovascular repair of aortic aneurysm were also found (12.7%) (Table 1).

Most patients (76%) underwent elective treatment (asymptomatic abdominal aneurysms) while 24% were emergencially treated because of alarm symptoms of alarm symptoms (abdominal pain or tomographic signs of imminent aneurysm rupture). Presence of aneurysm was the indication for treatment in 88.2% of the cases, while management of endoleak after

**Table 1** Comorbidities in the studied population (total number = 102 patients).

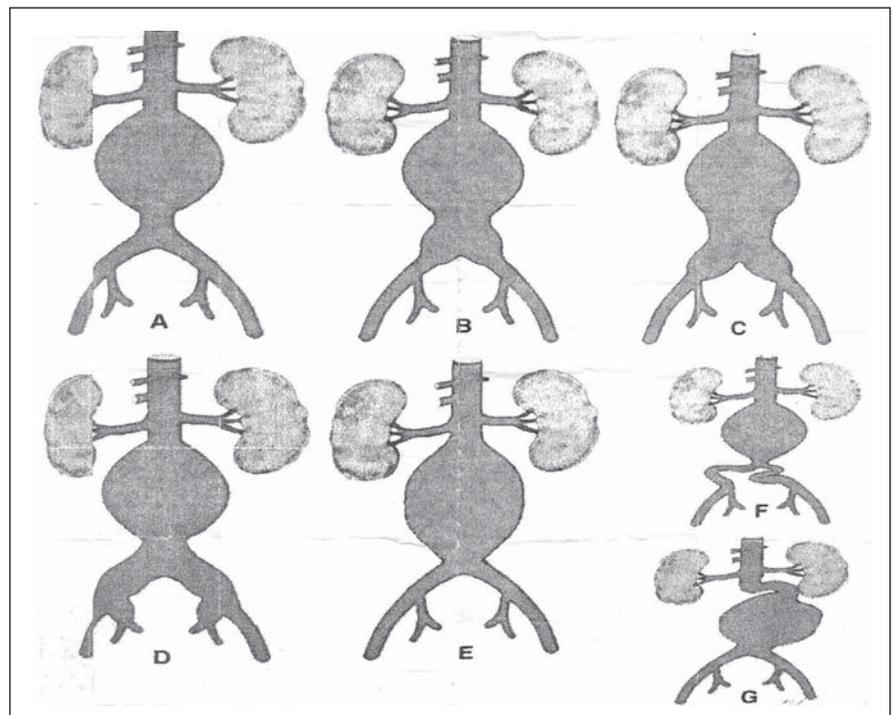
Comorbidities	Number of patients	Percentage
Previous myocardial infarction	20	19.6%
Myocardial revascularization	16	15.6%
Chronic renal failure	15	14.7%
Coronary failure	14	13.7%
Previous aortic endograft	13	12.7%
Previous coronary angioplasty	9	8.8%
Chronic obstructive pulmonary disease	9	8.8%
Cancer	6	5.8%
Carotid disease	6	5.8%
Previous aortic surgery	5	4.9%
Hypothyroidism	5	4.9%
Cerebrovascular accident	3	2.9%
Valvulopathies	3	2.9%
Chronic cardiac arrhythmia	3	2.9%
Congestive heart failure	3	2.9%
Hepatitis B	1	0.9%
ASA score ≥ 3	46	45%

ASA, American Society of Anesthesiology.

endovascular repair of AAA was the indication in 11.8% of the cases.

The aneurysms morphology was predominantly fusiform, being found in 98 of the patients (96.1%). The remaining four patients had saccular aneurysms (3.9%). The types of treated aneurysms were classified according to the classification uti-

lized in the EUROSTAR study, as follows: type A in 28 patients (27.4%); type B in 48 patients (47.0%); type C in 10 patients (9.8%); type D in 13 patients (12.7%); type E in 1 patient (1%). In 2 cases (2%), the indication was repair of abdominal aortic pseudoaneurysm (Figure 2). The mean diameter of the aneurysms was 61 ± 1.0 mm.



**Figure 2.** AAA classification –EUROSTAR study.

The bifurcated endograft was the most utilized model, in 98% of the cases, and the mono-iliac endograft was utilized in only 2 patients (2%). The most utilized devices were the following: 23 (22.5%) Talent, 19 (18.6%) PowerLink System, 19 (18.6%) Zenith Flex, 17 (16.7%) Excluder, 9 (8.8%) Endurant, 8 (7.8%) Anaconda, 5 (4.9%) Aorfix, 2 (2%) Apolo.

General inhalation anesthesia was utilized in all cases. Technical success was achieved in 97.1% of the cases. In 99 patients, the endograft could be deployed in the desired site. In three cases the endograft could not be advanced to the desired location because of technical or anatomic difficulties (presence of calcifications or tortuosity).

Therapeutic success was achieved in 81% of the cases, that is to say, in 83 patients the endograft was deployed without endoleaks or other events that could affect a favorable outcome of the intervention.

In 16 cases (15.7%) hypogastric artery embolization was required. Neither pelvic nor intestinal were observed in any case and erectile dysfunction was not reported during follow-up.

The rate of complications was 19%, and the most frequent intraoperative complications were the following: active bleeding in the surgical site in 6 cases (5.8%), femoral lesion in 3 cases (2.9%) peripheral embolism in 3 cases (2.9%) and renal artery occlusion in 2 cases (1.9%), without progression to renal failure in these patients. In-hospital postoperative complications were the following: infections in 4r cases (3.9%) [2 cases of surgical wound infection (50%) and 2 cases of respiratory tract infection (50%)], and acute renal failure in 2 patients (1.9%). The perioperative mortality rate was 0.9%. One patient submitted to emergency aortic repair died because of aneurysm rupture.

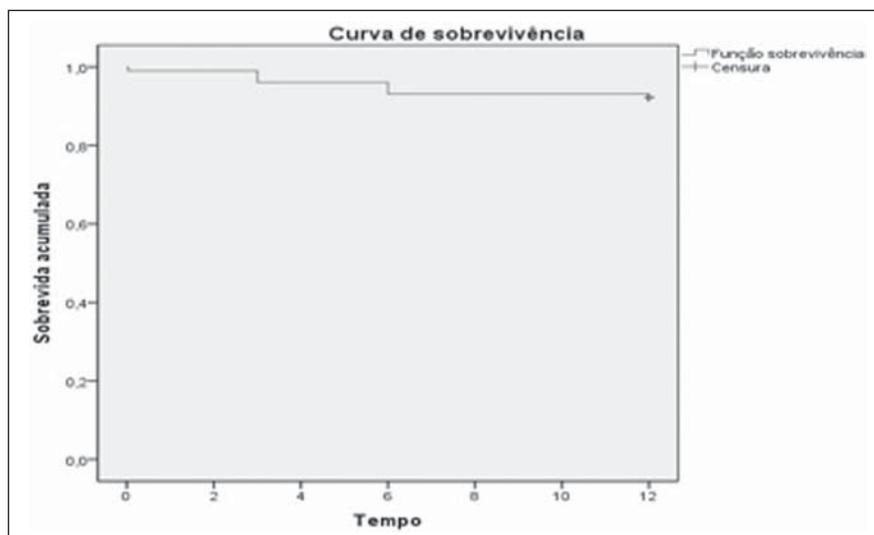
The total rate of endoleaks was 19.6%, with type I and III endoleaks being present in 16.6% of cases. No case of endograft migration was observed during follow-up. The rate of reintervention within one year was 18.8% resulting from management of types I and III endoleaks (Tables 2 and 3). The annual mortality rate observed during follow-up was 7.8%. One death occurred because of vascular causes (Figure 3).

**Table 2** Characteristics of primary endoleaks.

Endoleak types	Number of patients	Percentage
Total	21	19.6%
Type Ia	8	7.8%
Type Ib	2	1.9%
Type II	1	0.9%
Type IIIa	7	6.8%
Type IV	3	2.9%

**Table 3** Rate of secondary endoleaks, endograft migration and annual reintervention rate.

Endoleak types	Number of patients	Percentage
Total	8	7.8%
Type Ia	3	2.9%
Type II	2	1.9%
Type III	3	2.9%
Endograft migration	0	—
Annual reintervention rate	19	18.8%



**Figure 3.** Mid-term survival. Probability of survival estimate (Kaplan-Meier method). Time expressed in months.

The mean procedural time was 93 minutes (ranging from 65 to 130 minutes) and the mean hospital stay time was 5.2 days, with a variation of 9 days.

**DISCUSSION**

Over the past decade, the technique of endovascular repair of AAA has been developed as an alternative to open surgery. The impact of new devices and the two-decade experience from learning have led to the decrease in the operative mortality rate, as reported by several publications<sup>(7,8)</sup>.

The EVAR-I study<sup>(9)</sup> has demonstrated a decrease in perioperative mortality from 4.7% with open repair to 1.7% with endovascular repair, corresponding to a relative risk decrease of 65%. The EUROSTAR<sup>(10)</sup> study presented a 30-day mortality rate of 1.7% for minimally invasive treatment, while the DREAM<sup>(11)</sup> study presented a perioperative mortality rate of 4.6% for open surgery versus 1.2% for endovascular repair. Brazilian authors have reported a less significant decrease (6.5% versus 5.5% with conventional and endovascular repair, respectively)<sup>(12,13)</sup>.

In the authors' experience, the 30-day mortality rate was 0.9%. One patient died during intervention on a ruptured AAA. The operative mortality for ruptured AAA is above 40% for open surgery<sup>(14)</sup>. Large randomized studies comparing open surgery *versus* endovascular repair in this type of medical emergency are yet to be completed, such as the case of the IMPROVE study<sup>(15)</sup>.

The annual mortality rate in the present study was 7.8% (Figure 3). There was one death due to vascular causes related to aneurysm rupture. Ischemic cardiomyopathy was most frequent comorbidity in the present study population, with a high number of patients presenting previous myocardial infarction, myocardial revascularization and coronary angioplasty (Table 1). Cardiac deaths were predominant, with highest prevalence of cardiogenic shock and cardiac arrest.

The success of the endovascular technique depends on the continued exclusion of the aneurysmal sac<sup>(7)</sup>. The positioning and deployment of the endograft for such a purpose is not always achievable, hence the importance of complementary preoperative studies such as CT angiography and arteriography to evaluate the feasibility of the procedure. Such studies allow the analysis of the aneurysmal diameter, the anatomic evaluation of the proximal and distal necks and the definition of iliac and femoral accesses, which constitute indispensable practices in this type of intervention.

The rate of technical success was 97.1%, as in three patients the endograft could not be positioned and deployed because of underestimation of the degree of calcification and tortuosity of the access. In the EUROSTAR study<sup>(10)</sup> the endograft delivery system could not be appropriately advanced in 0.8% of the cases.

The primary objective of every endovascular repair of aortic aneurysm is to prevent the aneurysm rupture and the potentially associated death. Other objectives include the reduction of the aneurysm size and the absence of endoleaks as markers of continued rupture risk.

The rate of initial therapeutic success was 81%, measured as a function of the incidence of endoleaks in the primary proce-

dures. In the EUROSTAR study<sup>(10)</sup> the incidence of initial endoleaks was the following: type I endoleak, 4.4%; type II, 9%; type III, 2.4%. In the present study population, the rate of initial endoleaks was 19.6% corresponding to: type Ia, 7.8% (8 cases); type Ib, 1.9% (2 cases); type II, 0.9% (1 case); type III, 6.8% (7 cases); type IV, 2.9% (3 cases). Such high rate of endoleaks was analyzed in detail. The percentage of types I and III endoleaks was 16%. In the population with type I endoleaks, 6 patients presented a minimum degree of leakage, which had spontaneously resolved at the time of the 30-day follow-up. In 3 cases of type III endoleak, the same phenomenon was observed. This fact sensibly reduces the rate of reintervention due to endoleak to 11%, a rate that is similar to other reports. As the aneurysmal necks were evaluated in patients with type I endoleak, 4 patients were found with neck length between 15 and 17 mm, 2 patients with cone-shaped neck, and in 4 patients, the angulation was close to 65°.

In one of their most important studies, Stanley et al. have analyzed the morphology of aneurysms as a predictor of endoleaks and complications, demonstrating that the presence of morphologies different from those recommended resulted in a four-fold increase in the occurrence of type I endoleaks, and the noncompliance with more than one recommendation multiplied such risk<sup>(16)</sup>. The authors of the present study have undoubtedly explored the limits of the therapeutic endovascular intervention.

According to May et al., intraoperative complications may be observed in approximately 20% of the patients treated by endovascular approach. Some complications are inversely related to the length of the aneurysmal neck, that is, the shorter the length of the neck, the more difficult it is to deploy the endovascular device<sup>(17)</sup>. Also the greater the number of comorbidities, the higher the probability of intra- and postoperative adverse events. The DREAM study, which has compared the operative mortality and complications in surgical treatments with endovascular repair within 30 days, concluded that the endovascular repair is preferable because of the lower rates of mortality and complications, and also be-

cause of the significant reduction of the incidence of systemic complications<sup>(11)</sup>. In the EVAR-I study, the rate of complications was 35%, while in the EVAR-II it was 33%<sup>(9,18)</sup>.

In the present casuistry, the total rate of complications was 19% within the 30-day periprocedural period. Intraoperative bleeding in the surgical site was present in 6 cases (in 5 cases, at the level of the inguinal region, and 1 case of retroperitoneal hematoma), and femoral injury in 3 cases. Such complications were the ones most frequently observed in the present study. Undoubtedly, the profile of the utilized materials, in association with unfavorable surgical practices, does influence such rate.

Reintervention is performed in order to maintain the endografts function and, in some cases, for the resolution of remote complications. According to Sampram et al.<sup>(19)</sup>, main indications for reintervention are the following: a) endoleaks; b) endograft migration; c) occlusion of iliac branches; d) postoperative hemorrhage; e) renal occlusion. Less frequently, distal embolization, infection and aneurysm rupture are observed.

In the present study, most of the reinterventions occurred for endoleaks related to the initial procedure (11%) and, to a lesser degree, for secondary endoleaks (7.8%) observed after the 30-day periprocedural period. The annual rate of reintervention was 18.8%. The EVAR-I study presented a reintervention rate of 20% in a four-year follow-up; and in the EVAR-II study, such a rate was 26%. On the other hand, the DREAM and EUROSTAR studies presented rates of 14.3% and 13.5%, respectively, in a three-year follow-up<sup>(9-11,18)</sup>. The DREAM study has shown that the rate of reintervention was threefold higher in the first nine months for the endovascular repair as compared with open surgery, with such rates becoming equal at the two-year follow-up<sup>(11)</sup>. In such a study, the main reason for reintervention was the onset of types I and II endoleaks.

Drury et al. have reported a reintervention rate for initial endoleak of 17.5%, with 3.5% being type I endoleaks and 14%, type II endoleaks. At 12 months, the endoleak rate was 21%, with increase in the number of type I endoleaks (6.8%) and type III

endoleaks, and decrease in the number of type II endoleaks. The annual rate of secondary reintervention was 16.2%<sup>(20)</sup>. In the present casuistry, the percentages of secondary endoleaks were the following: type I, 2.9%; type II, 1.9%; type III, 2.9%; maintaining the high indices of endoleak types I and III as causes for reintervention during one-year follow-up.

In the EUROSTAR study, with a five-year follow-up, the main indication for reintervention was the type II endoleak, followed by the type III<sup>(10)</sup>. One should highlight that, in the present study, the patient who presented type II endoleak did not undergo reintervention since no aneurysmal sac increase was detected at CT angiography, as well as in the cases of type IV endoleaks, where no further endoleak was observed during tomographic follow-up, thus being thus considered as spontaneous resolution.

## CONCLUSION

The results obtained by means of endovascular repair of AAA are associated with low indices of complications in the short and medium-terms. Such rates of complication and reintervention are similar to those obtained in other Brazilian and international reference centers. Such results support the performance of such procedure in patients with suitable anatomy.

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