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Case Report

Endovascular Conversion after Endovascular Aneurysm Sealing (EVAS): Hybrid Treatment of a Case of Late Type IA Endoleak

Vito Gallicchio[1§], Danilo Barbarisi[1§], Rosaria Sciarrillo[2*], and Loris Flora[1]

[1]Vascular Surgery, Hospital of National Importance San Giuseppe Moscati, Italy
[2]Department of Science and Technologies, University of Sannio, Italy
[§]Co-first authors (Vito Gallicchio and Danilo Barbarisi contributed equally to this work)4Department of Cardiology, UT South western, Dallas, USA
5Department of Imaging Sciences, King's College London, UK

***Corresponding author**
Rosaria Sciarrillo, Department of Science and Technology, University of Sannio, via de Sanctis snc, 82100 Benevento, Italy

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- Endovascular Aneurysm Sealing
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Abstract

Endovascular aneurysm sealing (EVAS) with the Nellix device has been a different solution for Abdominal Aortic Aneurysm (AAA) repair. The incidence of type 1a endoleaks after Nellix EVAS was researched in short-term and long-term follow-up. To avoid eventual sac rupture, early diagnosis and classification are important. We then describe a successful endovascular hybrid treatment of a type 1a endoleak, five years after Nellix EVAS implantation.

An 83-year-old patient, who submitted to endovascular aneurysm sealing (EVAS) on 2018, presented a type IA endoleak 5 years later, with enlargement of the aneurysmal sac (maximum diameter 82mm). We envisaged a hybrid endovascular correction consisting of implantation of a custom-made 4-branch-device and the placement of aortouniliac endoprosthesis, which was then completed by packing a right>left femoral-femoral crossover bypass in PTFE 8mm and left iliac axis occlusion with Amplatzer Vascular Plug II. He underwent angiography with coil embolization of the channels, obtaining a positive result. At 1 month, he is endoleak free, with a stable aneurysmal diameter.

Key points
- A Case of Late Type IA Endoleak After Endovascular Aneurysm Sealing
- We report a successful endovascular hybrid treatment of a type 1a endoleak
- At 1 month, patient is free from endoleak, with a stable aneurysmal diameter

INTRODUCTION

The Nellix System (Endologix Inc, Irvine, California), marketed in 2013, is a new approach to aneurysm exclusion using an endograft anchored to the sac in an effort to decrease complication and reintervention rates. The EVAS is engineered to fully infiltrate the aneurysmal sac and, as a result, decrease the incidence of endoleaks.

The Nellix system for EVAS involved two cobalt chromium-coated polytetrafluoroethylene stents, both with an integrated endobag. One Nellix stent is located through each femoral artery and unfolded adjacent to the inferior renal artery and proximal to the internal iliac artery by inflating the Nellix balloons.

After creating a flow lumen through the stents, the aneurysm was sealed by instilling an aqueous polyethylene glycol-based polymer into the endobags. EVAS planning included calculation of stent length and aortic flow lumen volume (for polymers). Aortic flow lumen (for estimating polymer volume) is determined between the renal artery and iliac artery [1].

Early published reports with the Nellix system demonstrated high technical performance success with ranging failure rates [2-6].

The global EVAS FORWARD registry, including 277 patients, recorded early type IA endoleak in eight cases, presumably owing to inappropriate use of the proximal sealing zone and inadequate filling of the endobands [5].

The IDE EVAS FORWARD study, after 2 years, showed a leading cause incidence of migration of 6.0%, prompting a root cause investigation, leading to refinement of the anatomical guidance within the Instructions for Use (IFU) according to proximal diameter constraints and restrictions on the quantity of thrombus within the aneurysm [6].

In the EVAS FORWARD IDE study, patients were differentiated based on technical procedural performance and revised anatomical operating instructions. The success of endovascular management of abdominal aortic aneurysm is connected with both anatomical characteristics and the adequacy

of the procedure used. In fact, statistical and clinical findings have demonstrated that complications related to the Nellix device are the absence of an acquired proximal or distal seal (<10 mm) and low or misaligned stent placement. The lack of type IA endoleaks at 3 years emphasizes the relevance of patient recruitment and the selection of the right procedural methods employed to obtain excellent results [7].

As demonstrated in many studies, the evidence for endoleaks is poor in the short term, whereas the results achieved in the medium term are not encouraging. Stenson et al. [8], shared single-center data from 295 patients who were treated with Nellix with a median follow-up of 2.4 years. In these cases, an overall rate of failure of 33.2% at 2 years after the endovascular procedure was reported. This study also report an overall rupture rate of 5.4 percent, a 5-year migration rate of 43.5 percent, a 5-year sac expansion rate of 38.7 percent, and a type IA endoleak rate of 38.6 percent in patients chosen with an elective regimen. Then numerous adverse events, the device was voluntarily withdrawn from the market by the manufacturer and continued to monitor clinical experiences related to the Nellix system and provide updates on relevant information obtained as follow-up monitoring. The technical approach consisted mainly of Nellix endograft explantation; as reported the successful explantation of the Nellix endograft in a 77-year-old man undergoing endovascular sealing (EVAS) in 2015 for an asymptomatic 58 mm abdominal aortic aneurysm [9]. Besides, Lorido et al. [10], report the case of a 66-year-old man who presented to the emergency department complaining of indefinite back pain for at least 7 days who had been treated three years earlier with a Nellix graft for a 6-cm juxtarenal aneurysm. The patient was successfully treated with a t-Branch graft (Cook Medical, Bloomington, Ind), a thoracoabdominal multi-branch device.

Volpe et al. [11], show a case of late type IA endoleak presenting 2 years after EVAS in an 87-year-old man, who had undergone a corrective endovascular procedure by proximal extension through two covered Nellix stent grafts, with an associated triple chimney.

Thus, postoperative follow-up of Nellix stent grafts is most important as late complications may occur and therefore, subsequent open conversions may be necessary.

We report a case of late type IA endoleak 5 years after EVAS and discuss hybrid treatment with endovascular conversion, given the patient's numerous comorbidities. This study is in accordance with the latest clinical practice guidelines,

CASE PRESENTATION

An 87-year-old man with hypertension, dyslipidaemia, and chronic ischemic heart disease due to acute myocardial infarction treated with coronary angioplasty (PTCA) in 2020 with combination therapy of clopidogrel and aspirin, who successfully underwent EVAS in 2018, came to came to our hospital for observation. A CT scan showed the presence of a type IA endoleak, probably due to the presence of an aneurysmal sac (maximum diameter 82 mm) (Figure 1).

Therefore, our goal was endovascular treatment of type IA endoleaks after standard EVAS in order to attain a safe sealing both proximally in the native aorta and distally in the preexisting endograft.To address these problems in endovascular repair of type IA endoleaks, we presented a hybrid endovascular conversion without surgical explantation of the Nellix prosthesis because of the patient's numerous co-morbidities.

Under general anaesthesia, Nellix's right leg had to be readjusted with a custom-made 4-branch-graft (Cook Medical, Bloomington, IN, USA). The graft is formed by a nitinol skeleton and branches lined with a low-profile polyester tissue. It has a maximum proximal diameter of 32 mm, which has been tapered to 16-20 mm at the level of the renal arteries and to a minimum of 10 mm at the level of the ipsilateral iliac limb. The taper under the renal arteries (RA) does not exceed 20 mm in length. In addition, an internal stainless steel stent is incorporated at the distal end of the endograft in case of distal tapering to ≤16 mm. The graft has 4 proximal sealing stents with a total length of 58 mm to the caudal end of the first branch. the branches include 8-mm branches for the celiac artery (CA) and superior mesenteric artery (SMA) and 6-mm branches for the RA. The device is imaged in an 18F inner diameter sheath and has single-diameter reducing laces (Figure 2).

After introduction of the custom-made device (Cook Medical, Bloomington, IN, USA), a Talent aortouniliac endoprosthesis (Medtronic Inc, Santa Rosa, USA) at the right iliac bifurcation and an Amplatzer Vascular Plug (AVP) (Vascular Plug Amplatzer, AGA Medical Corporation, Golden Valley, MN, USA) downstream of the aneurysm in order to achieve an "endovascular ligation" of the left branch of the Nellix stent graft (Figure 3).

At the end of endovascular correction, after verifying the success of the hybrid procedure, the surgery was completed with a bypass femoral-femoral "crossover" right > left in Intergard 8mm prosthesis (Figure 4).

The patient had no complications in the postoperative course and was discharged six days later with regular ultrasound follow-up.

The patient was treated immediately with dual antiplatelet therapy (Aspirin 100 mg and Clopidogrel 75 mg). At 1 month, the patient was healthy, and CT confirmed stable transverse diameter of the aneurysm and absence of endoleaks/gutters (Figure 5). The patient continued to be followed up.

DISCUSSION

A high incidence of failure is associated with endovascular aneurysm sealing (EVAS). The frequency of endoleaks is low in the short term, while in the medium term their frequency is not very encouraging. In fact, due to the structural features of the endoprosthesis, the management of proximal endoleaks and their migration differs from that after conventional EVAR. In addition, complications after EVAS are difficult to treat compared with traditional EVAR precisely because of the presence of

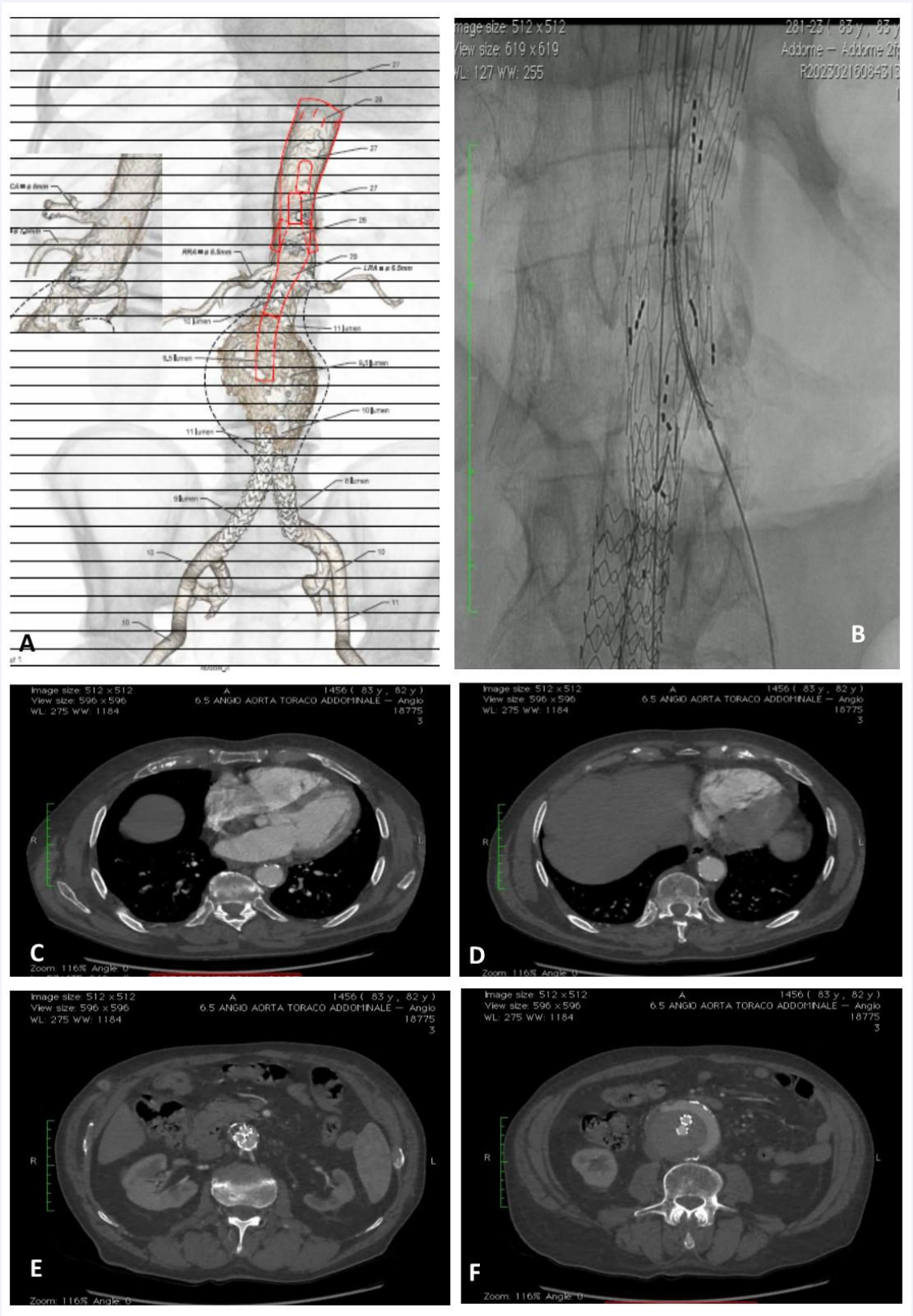

Figure 1 (A) (B) Preoperative CT image demonstrating a voluminous infrarenal abdominal aortic aneurysm with a transverse diameter of 82mm; (C, D, E, F) persistent type Ia endoleak in different CT image views.

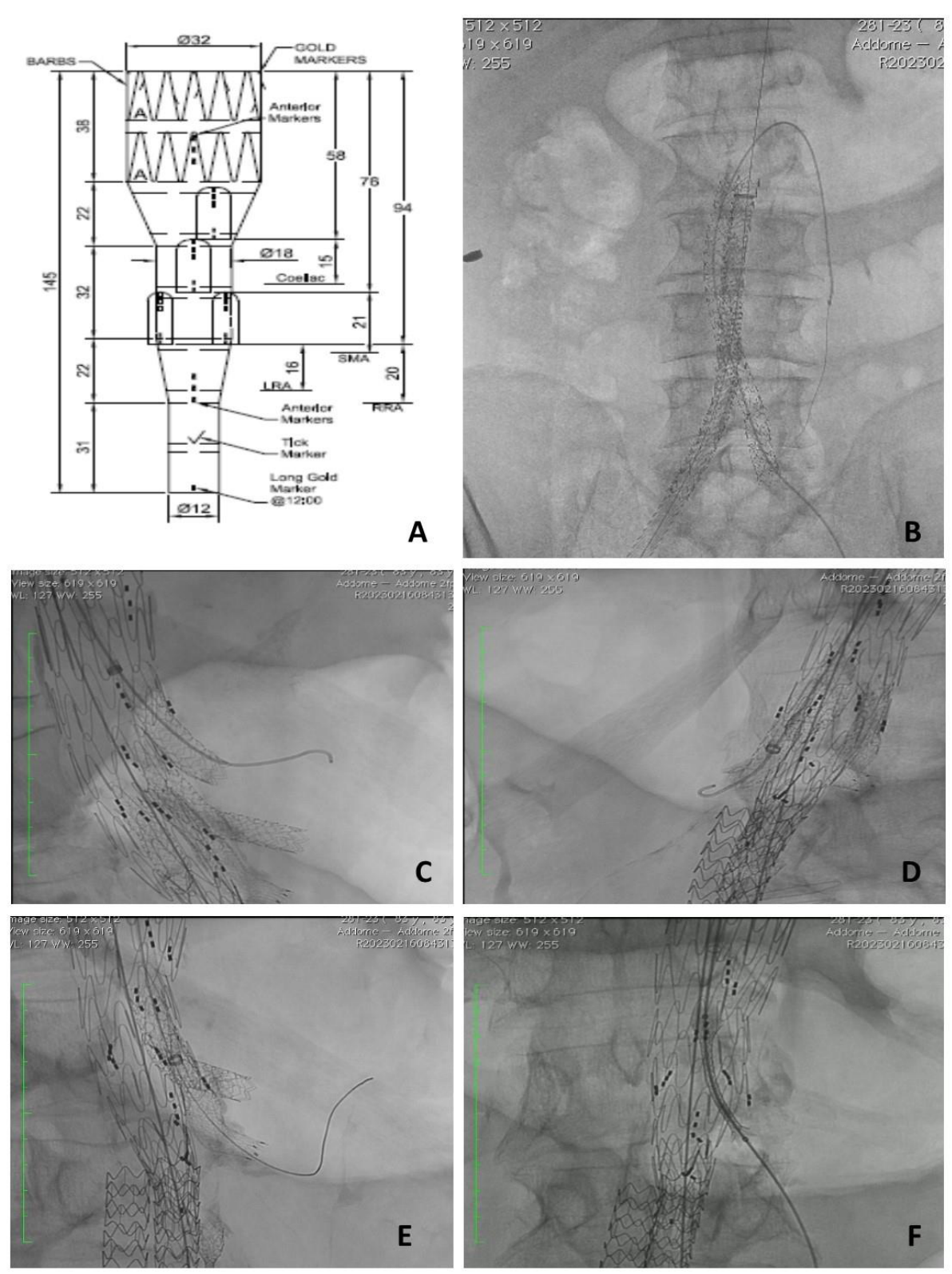

Figure 2 (A) Customized endograft shape and size with four directional branches for superior mesenteric artery (SMA) and celiac trunk (CT) and two internal branches for renal arteries. LRA, left renal artery; RRA, right renal artery; (B, C, D, E, F) Intraoperative angiographic image. Image showing the result after its introduction into the right leg of Nellix.

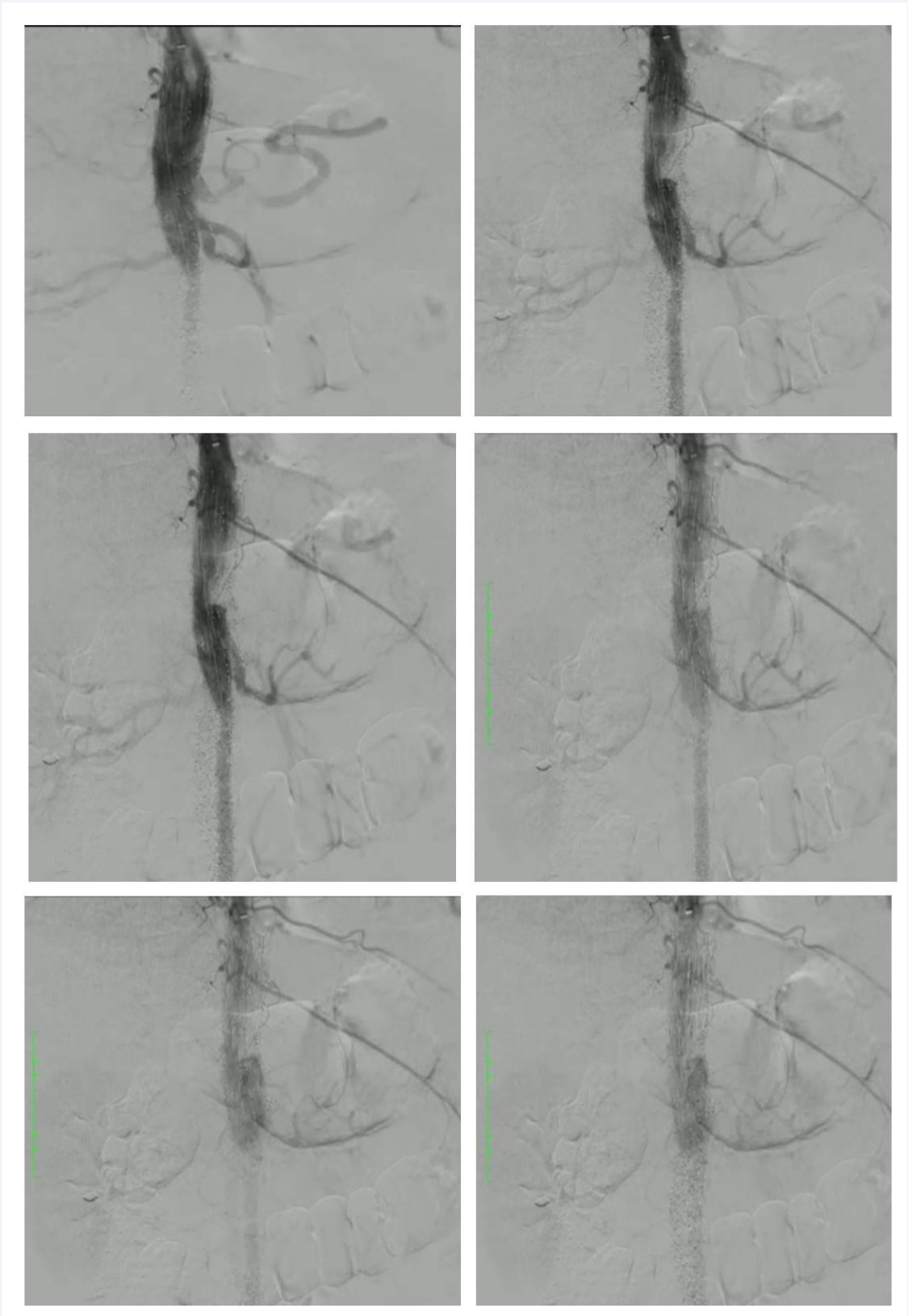

Figure 3 The Talent aortouniliac endoprosthetic device is delivered at the right iliac bifurcation and. the Amplatzer Vascular Plug is delivered at the left branch of the Nellix stent graft.

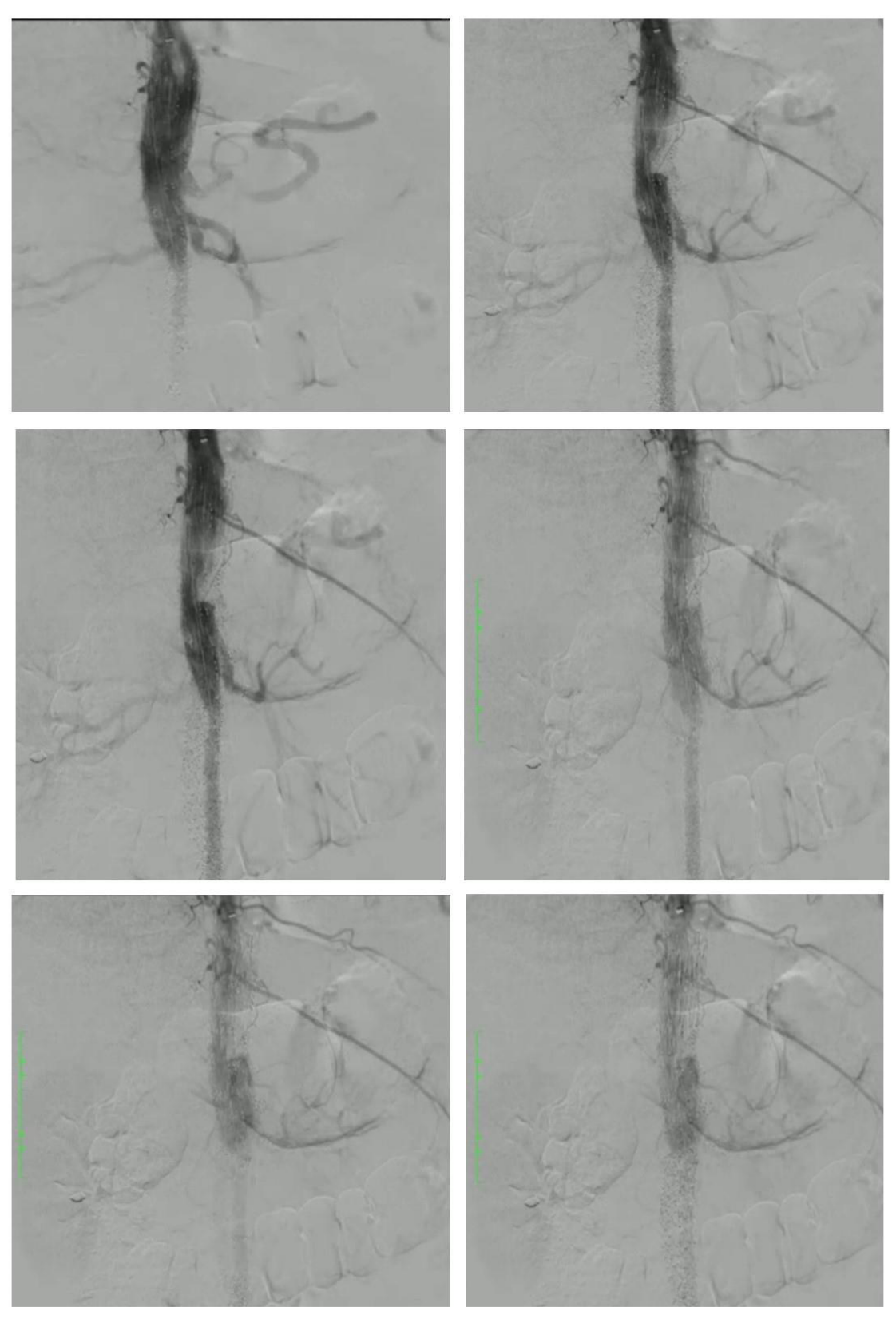

Figure 4 A bypass femoral-femoral "crossover" right > left in Intergard 8mm prosthesis

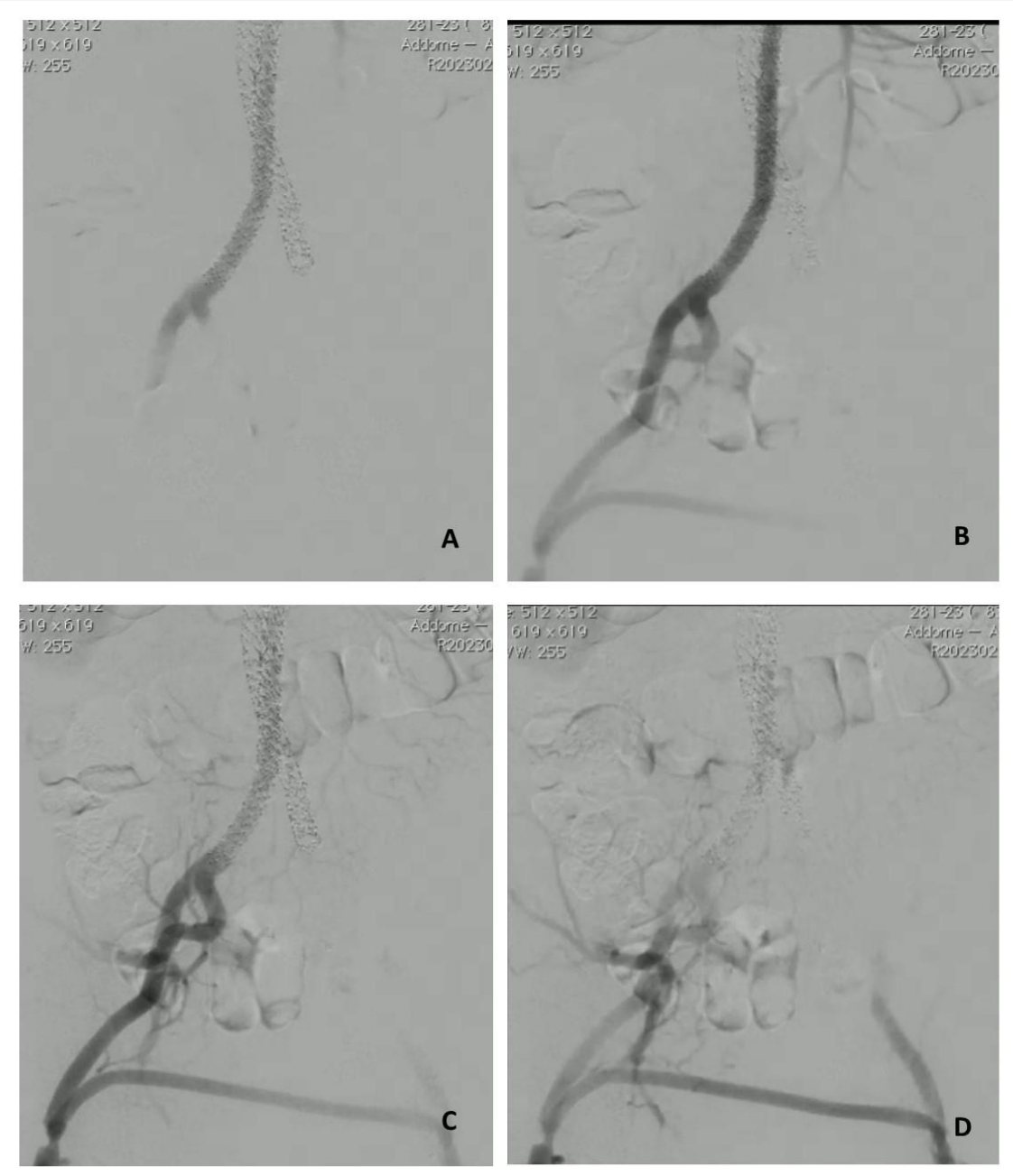

Figure 5 Computed tomography at 1 month demonstrating a stable transverse diameter of the aneurysmal and no endoleak/ gutters.

endobags. Postoperative CT images may change over time, so complications may have a different CT appearance About type IA endoleak, some authors have distinguished four types, on by the localization of the contrast agent for the three first types, while the fourth type is characterized by the pressurization of the sac, with no obvious signs of endoleaks [12]. In fact, post-EVAS type IA endoleaks were classified in: an Is1-type endoleak was characterized by the presence of contrast between the endobag and the proximal neck wall, but without reaching the aneurysmal sac. Is2 type endoleaks are characterized by the presence of a contrast between the endobag and the aneurysmal wall or a thrombus within the aneurysmal sac; an Is3 type endoleak is characterized by the presence of a contrast or newly formed thrombus between the endobags within the aneurysmal sac; an Is4 type endoleak is characterized by pressurization of the sac without signs of endoleak or with the appearance of obvious secondary signs [12]. According to these authors [12], open surgery may be critical for types Is2 and Is3, especially after failure of endovascular treatment, whereas in a more recent study of 101 patients undergoing EVAS, the occurrence of type Ia

endoleak was in 19.8% and the first treatment option was open conversion in 70% of cases, taking into account that proximal extension and embolization could be a viable strategy to open conversion [13].

Based on this classification, our patient had type Is2 endoleaks in which there was an enlarged aneurysmal sac of 84 mm (before surgery), which was judged to be at high risk of rupture. Due to severe comorbidities, we opted for an endovascular correction recurring a hybrid conversion was carried out.

For our patient with a type Ia endoleak, the 4-branch device (Cook Medical, Bloomington, IN, USA) was used, consisting of a nitinol skeleton with 4 branches, covered with a low-profile polyester fabric loaded in an 18F sheath, and a Talent aortouniliac endoprosthesis (Medtronic Inc, Santa Rosa, USA) was used for exclude the Nellix stent grafts. Besides, the use of Vascular Plug Amplatzer (AGA Medical Corporation, Golden Valley, MN, USA) allowed occluding the left branch of Nellix stent. The main advantage, compared with other embolizing "devices" such as metal coils, is the possibility of using a single device for the occlusion of afferent and/or efferent to aneurysmal pathology therefore with a faster immediate result; in addition, the characteristics of the delivery system allow a more precise and controlled placement. Another advantage is by the fact that VPA, because of its morphological and structural features, results in fewer artefacts from hardening of the beam on angio-CT investigation compared with spiral metallic platinum coils, allowing accurate assessment highlighting exclusion of the aneurysm and full reintegration of endoleaks. Finally, a bypass femoral-femoral "crossover" right > left in Intergard 8mm prosthesis was implanted to revascularize the left side.

This case demonstrates the usefulness of hybrid conversion in the management of late AI endoleak occurring 5 years after EVAS regarding patient comorbidities.

CONCLUSIONS

Type 1A endoleak formation following Nellix EVAS has been much studied highlighting that the natural history of an untreated type 1 endoleak after EVAS could lead to sac rupture and death.

In our view, the key point of this case is the hybrid conversion in the management of a late type Ia endoleak that occurred 5 years after EVAS.

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Declaration of Conflicting Interests

The authors have declared no potential conflict of interest in relation to the research, authorship, and/or publication of this article.

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AUTHOR CONTRIBUTIONS

Conception and design: DB, VG

Analysis and interpretation: DB, VG, LF, RS

Writing the Manuscript: RS, DB, VG

Critical revision of the Manuscript: VG, DB, LF, RS

Final approval of the Manuscript: DB, VG, RS

Agreement to be Accountable: LF, RS, VG, DB

VG and DB contributed equally to this article and share co-first authorship.

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