Late Nellix failure in a juxtarenal abdominal aortic aneurysm treated with conversion to open repair: A case report and narrative review of the Nellix system

Nikolaos Moulatsiotis-Voreakis[1], Stavros K. Kakkos[1], Spyros Papadoulas[1], Emmanouil Barbaressos[1], Christos Pitros[1], Anastasia Zotou[2], Evgenia Dimou[2], Maria Kyriakopoulou[3], Vasiliki Taki[3]

[1] Department of Vascular Surgery, University of Patras Medical School, Patras, Greece
[2] Department of Anesthesiology & Intensive Care, University of Patras Medical School, Patras, Greece
[3] Department of Radiology, University of Patras Medical School, Patras, Greece

Abstract:

The EndoVascular Aneurysm Sealing (EVAS) System had been introduced as an alternative solution for the treatment of abdominal aortic aneurysms (AAAs). Unlike endovascular aneurysm repair (EVAR), EVAS with the Nellix device (Endologix, Irvine, Calif, USA) was based on sealing the aneurysm's lumen, by means of two polymer-filled endobags, with the AAA being excluded by two stent grafts. In spite of promising early-term results, late surveillance of the patients treated with EVAS, bore testament to a large number of type Ia endoleaks and sac enlargement, mainly due to device migration, a fact that obliged the company to withdraw Nellix on May 10th, 2022. We present a case of a seventy-six-year-old male, who developed an asymptomatic type Ia endoleak and sac enlargement because of migration of a Nellix endograft placed for a AAA eight years ago at another institution. The patient was considered fit for surgery and had conversion to open repair with transrenal aortic cross-clamping, explantation of the device, common femoral artery endarterectomy, bilaterally, and placement of an aortobifemoral graft on the grounds of significant iliac occlusive disease, which caused moderate intermittent claudication symptoms and precluded intra-abdominal reconstruction. Postoperative course was uneventful and our patient was discharged on the sixth postoperative day. On one-month and one-year follow-up there were no complications, the graft was patent and our patient enjoyed resolution of his claudication symptoms. Due to the high percentage of Nellix device failure, the severity of its complications (e.g. increased risk of rupture) and the large number of patients who underwent the procedure until EVAS withdrawal, holistically informing and surveilling these patients is crucial to achieve in-time diagnosis and proper treatment.

Key Words: Case Report, Narrative Review, EVAS, Nellix, Type Ia Endoleak, Aortobifemoral bypass, Open Conversion.

CASE

A 76 year-old male with a history of 5.6 cm AAA, had an EVAS procedure (Nellix system, Endologix, Irvine, Calif, USA) eight years ago at another institution. He was referred to our outpatient clinic due to aneurysm's sac enlargement, as shown on Computed Tomography Angiography (CTA) scanning during follow-up. He had also moderately severe intermittent claudication (IC) symptoms, affecting both legs, with the right leg being mostly affected. Past medical history included arterial hypertension, dyslipidemia, diabetes mellitus type II, insomnia and smoking (stopped seven years ago). Medications included ramipril 2.5 mg, hydrochlorothiazide 12.5 mg and monoxidine 0.2 mg once daily, metformin 850 mg twice daily, cilostazol 200 mg twice daily and zolpidem 10mg, clopidogrel 75mg and omeprazole 20mg once daily.

Author for correspondence:

Nikos Moulatsiotis-Voreakis

Department of Vascular Surgery, University of Patras Medical School, Patras, Greece
E-mail: nikosmoulvor@gmail.com
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On physical examination, palpation of epigastrium, revealed a non-tender, pulsatile mass, which represented the aneurysm. The only palpable artery of the lower extremities was the left femoral artery and his ABI was abnormal, especially on the right lower extremity, where the symptoms of IC were more intense (Figure 1). Auscultation also revealed

Figure 1: On patient physical examination, there was a pulsatile abdominal mass (aneurysm) and the only palpable artery of the lower extremities was the left femoral artery.

a systolic bruit over the left carotid artery. The rest of cardiovascular (ejection fraction, cardiac contractility and stress response), pulmonary (auscultation, spirometry), renal (urinalysis, creatinine) and remaining laboratory examination and testing was normal.

Imaging

The pre-operative CTA depicted the Nellix (Endologix, Irvine, Calif) device, which appeared displaced and migrated resulting in a type Ia endoleak (Figure 2a, 2b), more accurately corresponding to Is2 endoleak, according to van den Ham classi-

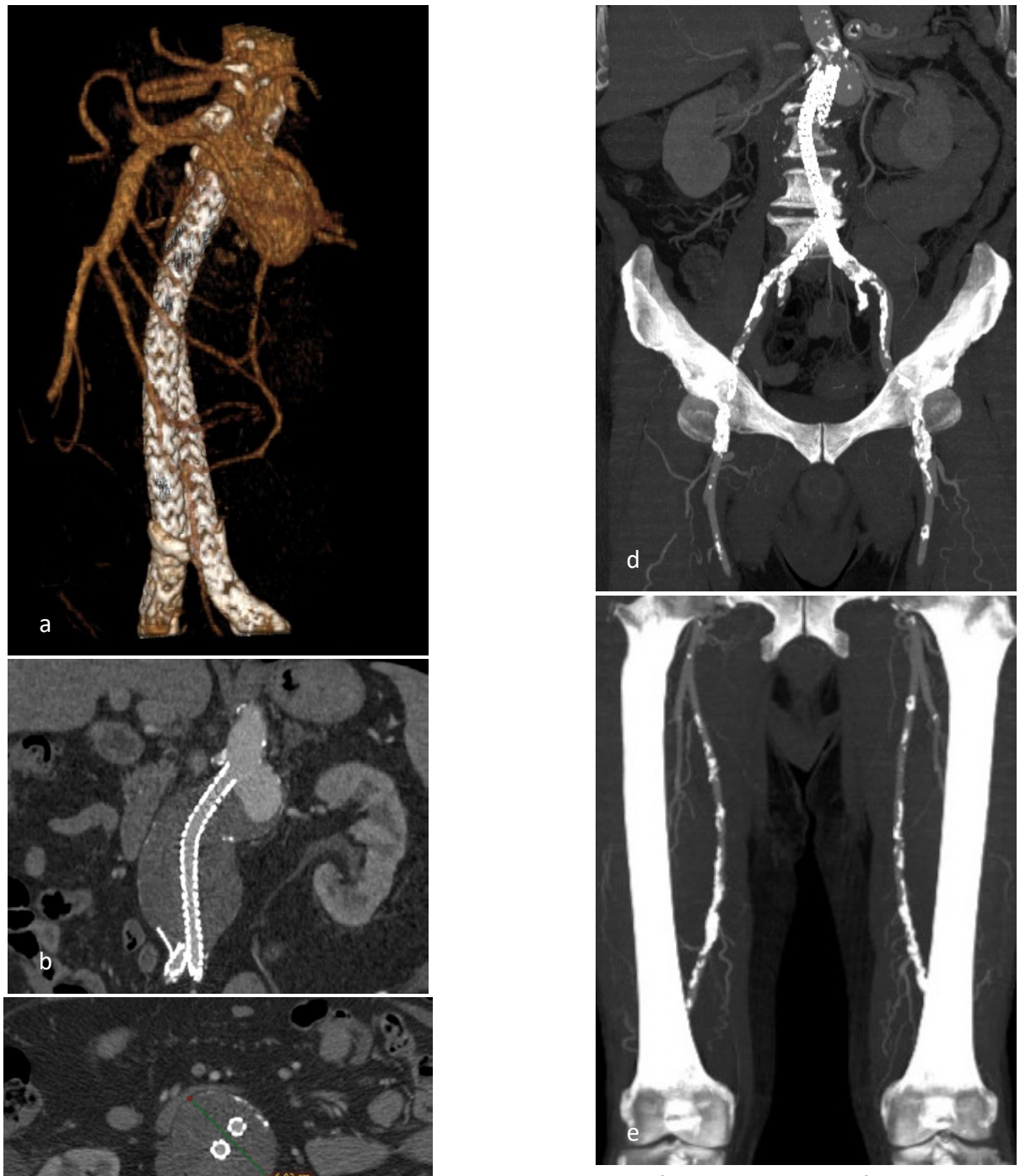

Figure 2: This figure shows results of computed tomography angiography (CTA) scanning (a) Three-dimensional and (b) CT reconstruction, depicting the type Ia endoleak. (c) Axial plane section of the CTA Scan, showing the aneurysm sac expansion to 6.8 cm. (d & e) CTA reconstruction of the lower extremity runoff revealed severe atherosclerotic lesions of the iliac and femoral axes.

fication, causing a juxtarenal bulging aneurysm neck dilatation and expansion of the aneurysmatic sac to the maximum diameter of 6.8 cm (Figure 2c).

The CTA also revealed extensive atherosclerotic lesions with severe stenosis (>90%) of the common and external iliac arteries bilaterally and occlusion of the left internal iliac, right common femoral and superficial femoral arteries bilaterally (Figure 2d, 2e).

As part of the preoperative evaluation and in correlation with the finding of the physical examination, a carotid duplex doppler ultrasound was performed, which revealed approximately 50% stenosis of the common carotid arteries, extending into the internal carotid arteries bilaterally.

Surgical Treatment

The patient was considered fit for open surgery and explantation of the device, which is the treatment of choice according to the most recent guidelines (Figure 3). The presence of severe common femoral atherosclerotic lesions required femoral endarterectomy bilaterally to ensure adequate runoff to the deep femoral arteries bilaterally, while to overcome the bilateral iliac artery occlusive disease, we had to perform aortobifemoral by-pass grafting. Moreover, we had to consider reperfusing the right internal iliac artery (RIIA) to preserve adequate supply to the pelvis.

During the procedure, because of the juxtarenal pathology described above, the aorta had to be crossed-clamped transrenally. The aortotomy revealed the Nellix device, blatantly dysfunctional, with shrinkage of its endobags, likely as a result of polymer dissolution (Figure 4). The extraction of the device proved easy, while difficulties potentially can be present, especially at its distal portion, where the bare-stent graft limbs can form adhesions with the vessel's wall causing intimal flaps when manipulations are inept.

After meticulous dissection and endarterectomy of the common femoral arteries bilaterally, a bifurcated 24x12 mm PTFE aortobifemoral graft (Gore Medical, Flagstaff, AZ, USA) was used and anastomosed end-to-end to the aorta proximally (Figure 5) and side-to-end to the common femoral arteries distally. The initial plan of graft to RIIA by-pass procedure intending its revascularization, was abandoned intra-operatively, because of adequate back-flow to the common iliac and the right internal iliac arteries.

Recommendation 2		
Explantation of failing Endovascular Aneurysm Sealing Nellix prostheses (Endologix) is recommended as the preferred treatment in surgically fit patients.		
Class	**Level**	**References**
I	C	Consensus

Figure 3: ESVS AAA Guidelines Update concerning the treatment of patients with failed Nellix device, published on March 2023, reproduced with permission from Elsevier.

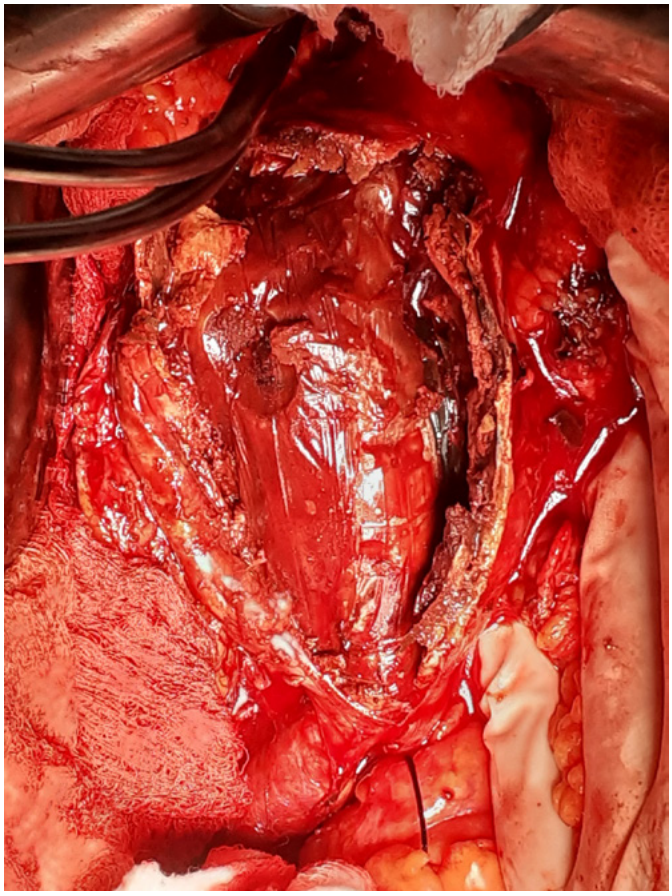

Figure 4: Intraoperative picture of the Nellix device inside the aneurysm lumen. The device endobags are clearly shrank providing inadequate sealing.

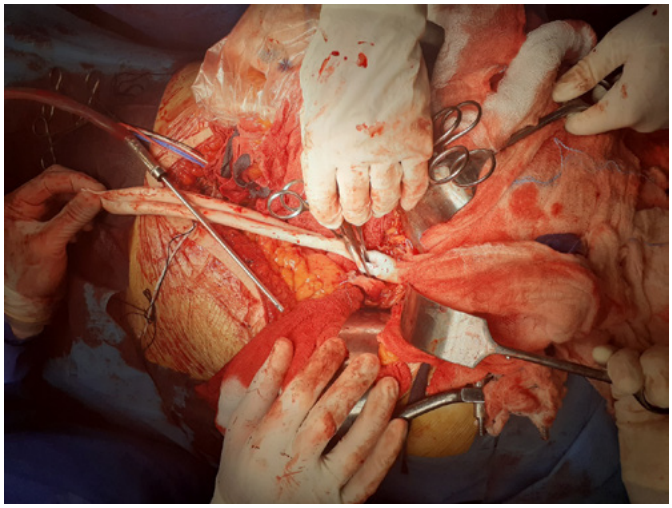

Figure 5: Proximal end-to-end anastomosis between the bifurcated PTFE (24mm x 12mm) graft (Goretex) and the juxtarenal abdominal aorta.

Post-Operatively, One-Month & One-Year Follow-Up

Postoperatively, a transient acute kidney injury, with elevation of creatinine levels (from 0.8 mg/dL pre-operatively to 1.8 mg/dL) due to the transrenal cross-clamping occurred and gradually resolved, reaching normal on 6th postoperative day,

when the patient was discharged uneventful.

On the one month follow up, all wounds had healed, the graft was clinically patent with the patient having a full complement of lower extremity pulses, enjoying relief from his claudication symptoms. On one-year follow up the patient had an ABI_{right}=1 and ABI_{left}=1.1, clearly improved from his last measurement and compatible with his clinical status.

DISCUSSION

The EndoVascular Aneurysm Sealing System (EVAS, Endologix Inc, Irvine, CA, USA) , was introduced as an alternative, to the conventional EVAR , method of endovascular exclusion of an aneurysm sac, sealing its lumen by polymer-filled polyurethane endobags[1].

IFU

Its initial instructions for use (2013)[2] were similar to the most EVAR devices;

- Aortic proximal neck diameter between 18 mm and 32 mm
- Minimum aortic proximal neck length of 10mm
- Aortic neck angulation <60°
- Common iliac arteries diameter between 8 mm and 35 mm.
- Blood lumen diameter of the aortic sac <70 mm.

Although, after the increase of late incidents of Nellix migrations, endoleaks (mainly type Ia) and sac enlargements, the company attempted a modification of the IFU (October 18th, 2016)[2,3,4]:

- Reducing the limit of the maximum proximal aortic neck diameter to 28 mm (trying to prevent type Ia endoleaks and device migrations),
- Restricting the blood lumen´s diameter (8-35mm) measurement, outside the distal zone (aiming the reduction of type Ib endoleaks) and
- Inserting a maximum aortic aneurysm diameter to maximum aortic blood lumen diameter ratio <1.4

Complications of the EVAS System

The Nellix device was introduced as having a unique mechanism for reducing the incidence of endolealks, especially type II [6,7] (whose prevalence may reach 25% of all endoleaks in some cases[5]), by restricting back-flow from the IMA, lumbar and renal accessory arteries via direct sealing. EVAS was initially associated with high technical success rates (98-100%)[1] and low 30-day[8] and one-year[9] complication rates. However, significant adverse effect rates were observed during mid- and late-term surveillance (usually an average of two years after the intervention)[10,11,12].

The most common Nellix complication, that subsequently provoked device failure and aneurysm sac growth, was stent-graft migration, frequently coexisting with limb separation (>5mm)[13,14]. The Society for Vascular Surgery (SVS) has defined stent migration as stent movement of >10mm, or any stent displacement leading to symptoms (endoleaks, sac enlargement, etc)[15]. The most important factor that either causes or allow and intensify especially proximal migration (which is the most often), is the lack of proximal active fixation site to the aortic wall (absence of struts, anchors, barbs, hooks or crowns). Therefore, stability and adhesion of the device to the proximal aortic neck relies only on the polymer-filled endobag sealing[15]. As a consequence, alterations of either the aortic anatomy or the device itself could result in sealing deficits, thus, caudal translocation, endobag separation (>5mm), endoleaks (mainly type Ia) and late aneurysm sac growth. In regard to the polymer/endobag complex, in many cases of open surgical conversion, degradation of PEG and endobag shrinking had been noticed. This dissolution decreases the area of sealing surface and the immobilization of the stent-grafts (especially to the proximal aortic neck, where the paucity of fixation coexists), allowing for caudal migration[16] of the device and resulting to endoleak type Ia and sac growth. It has been reported that not only stent-graft migration can cause the growth of the AAA (due to inadequate sealing and leakage of the blood circulation inside the sac), but it could also be a result of progression of the aneurysmatic disease at the first place. These measurements brought out possible expansion concerning the whole aneurysm, or partially, away from the maximum cross-sectional area and accompanied by changes in shape or volume, without noticed differences in maximum diameter. Another potential cause of this fact is the existence of aneurysmatic regions that underlie different radial force and pressure, which the landing zones exert (e.g. because of polymer dissolution or endobag weakness). This disunion indicates a closer and more detail examination of the AAA anatomy and characteristics, during the follow-up screening and imaging. Histologically, it has been reported that, in some cases, elastolysis existed, likely because of a triggered biological response and interaction between the endobags and the aortic wall[17].

As aforementioned, the most frequent event that follows the device´s proximal migration is type Ia endoleak. The diagnosis of this complication may be challenging, even in CT or DSA, mainly due to the increased density and opacity of the endobags, making it difficult to be spotted. The only detail that implies the presence of a type Ia endoleak is an arcuate and slightly linear area, enhanced by the flow of contrast, between the device´s endobags and the aortic wall[21]. Van den Ham et al. proposed a comprehensive classification of the type Ia endoleaks following EVAS failure[18], depending on the site and the extend of the contrast medium inside the aortic sac:

- Is1: The slit or gutter leakage is observed at the neck, not reaching the aneurysm sac.
- Is2: The endoleak reaches and fills partially or totally the aneurysm sac.
- Is3: The flow is present between the endobags.
- Is4: There is no visible source of endoleak and it is similar to type V post-EVAR endoleak (endotension).

Endovascular Treatment of EVAS Complications

The initial treatment choices to deal with type Ia endoleaks and graft migration were both endovascular and open surgical (Open Conversion - OC), until the withdrawal of the device, when the first one was abandoned. Endovascular methods were preferred and indicated for unfit for OC patients[20], those with low life expectancy and in some urgent cases[19]. Due to EVAS peculiar anatomy, EVAR or FEVAR stent-graft extensions would not match for proximal sealing reinforcement. A common solution to overcome this problem, was the endovascular use of a Nellix extension device, placed in the top of the initial one, while the bare-stent distal limbs were inserted, deployed and stabilized into the main proximal ones (Nellix in Nellix Application - NiNa)[21,22]. In case of inadequate aortic neck length, the Nellix proximal extension required the use of chimney technique (for the Superior Mesenteric Artery and the Renal Arteries) to provide sufficient blood supply to the superior mesenteric and renal arteries[22,23,24]. In persistent cases of type Ia endoleaks, due to the presence of slits or gutters, coil or butyl-cyanoacrylate embolization[25] could potentially stop the leakage and the sac enlargement. In general, Is1 and Is2 endoleaks with correct location of the Nellix endograft, were usually treated with embolization (coils and onyx glue), while for Is3 and Is2 with caudal migration of Nellix stent-grafts, NiNa proximal extension with or without the use of chimney stent-grafts or open surgical conversion were preferred.

Even though endovascular techniques temporarily showed a decent block sealing of the endoleak, long-term surveillance proved a significantly low percentage of success, presenting recurrence of the endoleak and further sac growth. NiNa technique proved ineffective due to the unsolved stent-graft migration problem. Even if the proximal extension achieves transient sealing and endoleak reduction or exclusion, the initial Nellix device is not stabilized, hence the migration continues until the complications reappear.

EVAS Withdrawal and Open Device Explantation

On account of Nellix´s disappointing late results, the company decided its withdrawal on May 10th, 2022. Insecurity of Nellix usage preexisted, since 2019 AAA Guidelines, when its application was not recommended in clinical practice (IIIC). During an update (March 2023) on guidelines concerning EVAS, ESVS recommends the close surveillance of patients treated with Nellix and in case of device failure, the explantation of the prosthesis in fit for surgery patients (IA)[26].

Open surgical conversion and explantation of the Nellix device is the current treatment of choice in fit patients. During surgery, there are advantages, like the tractable removal of the device´s proximal part (due to lack of active fixation) and often the existence of a suitable area for cross-clamping (depending on the neck´s anatomy and length) and some points that could potentially cause serious complications. For example, in most cases, due to the features of the device's distal limbs (which are bare stents, deprived of endobags or graft coverage) and the late onset of the complications, adhesions can be formed, between the stents and the iliac attachment sites. As a result, abrupt or clumsy manipulation could cause vascular damage and later thrombosis or iliac dissection. Mortola et al concluded that constant and stable pulling of the stent-graft limb permits proper removal without harming the artery. Adhesions formation and fibrosis on the aortic wall could also coexist at the endobag attachment sites. Generally, due to an unregulated inflammatory response of the surrounding tissues[22], the device explantation and aneurysm isolation may be challenging. At any rate, the whole procedure of Nellix extraction should be under great care and mild manipulation.

CONCLUSION

In summary, Nellix failure may result in severe complications, such as sac enlargement and aneurysm rupture. The patients treated with EVAS should be closely informed and supervised to prevent imminent device failure and endoleaks. In case the failure is confirmed, fit patients should be treated with open conversion and extraction of the device. Concerning our case, patients with juxtarenal aneurysms due to Nellix failure and concomitant peripheral arterial occlusive disease have to be treated with caution to avoid unforeseen circumstances, like ischemic complications of the kidneys or the lower extremities. In any case, the necessity of timely diagnosis of the failure and the open conversion with explantation of the device in fit patients is crucial for their safety.

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