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ABSTRACT

Endovascular aneurysm sealing (EVAS) using the Nellix™ System was introduced in clinical practice with the aim of reducing the incidence of complications such as migration, endoleaks and reinterventions following conventional endovascular aneurysm repair (EVAR). Although, initial efficacy data on this device have been encouraging, EVAS has also demonstrated to undergo adverse events.

Herein, we report a case of Nellix graft explant due to endobags shrinkage after bubbles air reabsorption leading to proximal type I A endoleak and stent migration. The focus of this article is on the importance of a more assiduous surveillance of this new device, in particular in those cases with air into the endobags immediately after the procedure; this surveillance should be aimed to timely identify complications which can otherwise lead to consequences that require open conversion.

INTRODUCTION

Type I endoleaks (ELs) are one of the most frequent complications after endovascular abdominal aortic repair (EVAR) with an incidence of 5% to 25%, related to aneurysm growth and rupture and usually require treatment.

In 2013, EndoVascular Aneurysm Sealing (EVAS), using the Nellix system (Endologix, Irvine, CA, USA) was introduced in Europe to treat infrarenal abdominal aortic aneurysms (AAAs)[1] with the aim of reducing the risk of complications, particularly any type of endoleaks and secondary interventions following EVAR.

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EVAS is as a novel approach to AAA repair that is conceptually very different from EVAR since it addresses the principles of complete anatomic apposition to achieve sealing of AAA without any active fixation means.

Although long-term data from the international studies have not been published after five years from its introduction in clinical practice, preliminary and mid-term results had showed good outcomes with a low rate of device-related adverse events, with a 3% reported incidence of type 1A ELs. [2,3,4]

However, the polymer-filled endobags of Nellix device obliterates the aneurysmal sac, forming a cast of the lumen of the aorta and iliac arteries, and therefore the type 1A ELs following EVAS may significantly differ in characteristics and behavior from those after EVAR. This explains the need for a specific classification of these endoleaks as suggested by van den Ham et al, who included in this classification the possibility of AAA pressurization with no visible endoleak. [5]

The peculiar characteristics of these endoleaks may imply different outcomes in terms of aneurysm rupture and stent-graft migration, which are still poorly understood.

Herein, we report a case of Nellix graft explant due to a type I A endoleak and migration to discuss the main concerns of these complications.

CASE REPORT

This is a report of a 72-years-old male patient admitted at the department of Vascular Surgery on December 2013, for an abdominal aortic aneurysm (AAA) associated with a right common iliac artery (CIA) aneurysm (Fig. 1). The previous year, the patient had been

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affected by arterial hypertension (WHO II), hypercholesterolemia and was submitted to percutaneous transluminal angioplasty (PTCA) and stenting with drug eluting stent (DES) of the obtuse marginalis artery for an acute coronary syndrome (ACS). The patient was deemed at high risk for open surgery due to his age and co-morbidities.

The preoperative CTA showed an infrarenal AAA with a maximum diameter of 54 mm, with poor parietal thrombus apposition. The thrombus index (TI) calculated dividing maximum aneurysm sac diameter for the maximum flow lumen diameter was 1.38.

The neck length was 24 mm, measured from the left renal artery (4 mm lower than the right renal artery), its proximal and distal diameters respectively of 22 and 25 mm the suprarenal and infrarenal neck angle was of 35 and 45 degrees, respectively, with no thrombus or calcification.

The right CIA had a maximum diameter of 30 mm, and a length 57 mm, with patent internal iliac artery, the pre-bifurcation diameter was of 13 mm. The length between the lower renal artery and the iliac bifurcation was of 163 mm.

The left CIA had a maximum diameter of 21 mm, and a length 35 mm, with no patency of internal iliac artery and angulated origin of external iliac artery, with a diameter of 10 mm. The length between the lower renal artery and the iliac bifurcation was of 141 mm (Fig. 2).

The aorto-iliac anatomy was within the instructions for use (IFU) for the Nellix device (Endologix Inc., Irvine, California, USA) at the time.

The Nellix device was chosen to prevent the risk of type II endoleaks related to the patency of four pairs of lumbar arteries and of the inferior mesenteric artery emerging from the aneurysmal sac.

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Thus, the patient underwent the EVAS procedure using a 160x10 mm and a 140x10 mm module Nellix devices with 70 mL of polymer with an intrasac pressure of 210 mmHg. A pre-filling with saline solution was performed. On the left axis, to smooth the angle and to avoid any possible limb occlusion, the Nellix stent was extended using a Gore Viabahn stent graft (50x10 mm) landed in external iliac artery. Completion angiography demonstrated proper positioning of the device with total aneurysm sealing.

A post-operative CTA demonstrated the placement of Nellix stents, aligned 4 mm lower than the left renal artery, without endoleak (Fig. 3), although air bubbles were detected in both endobags (Fig. 4).

The patient was enrolled in our follow-up protocol for EVAS including Duplex Scanning (DUS) before discharge, at 3, 6, 12 months after the procedure and annually thereafter; an MRI or CTA control was carried out at 6, 12 and 24 months of follow-up and after this period only if DUS showed complications or was not diagnostic. The three years follow-up DUS showed high-flow type 1a endoleak with aneurysm growth; as a consequence of these US findings, a confirmation CTA was performed which also showed the proximal caudal migration (>10mm), lateral bending of both stents, inhomogeneities of the mural thrombus and both proximal neck and distal right landing zone enlargement. The aortic aneurysm and the right common iliac maximum diameters were 90 mm and 40 mm, respectively (Fig. 5).

The use of the MRI in the follow-up protocol of the patients undergoing EVAS was mainly aimed at studying the behavior of the mural thrombus and the aneurysm wall. Despite no signs of any complication were detected at that time during the first two years of follow-

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up, on the retrospective analysis of the 2-year MRI scans there was measured neither significant sac enlargement nor significant proximal caudal migration. However on MR imaging, a small sickle shaped enhancement between the two endobags was detected suggesting the presence of a low-flow endoleak that was initially buffered by the Nellix system with subsequent apposition of new thrombus (Fig. 6).

Open conversion was deemed absolutely necessary. Via transperitoneal approach, the proximal aortic control was obtained by cross-clamping the infrarenal aorta. Opening the aneurysmal sac, a thick parietal thrombus was noted; both endobags were undamaged although the polymer was predominantly dislocated in the proximal extremity rather than in the distal one of each endobag (Fig. 7a).

Aorto-bi-iliac reconstruction was performed with a bifurcated Dacron graft sewn to the infrarenal aorta proximally and the iliac vessels distally. The left iliac Viabahn stent was so tenaciously adherent to the arterial wall, thus the distal anastomosis was performed to the residual distal stent frame after cutting its proximal segment (Fig. 7b).

The post-operative course was uneventful and the patient was discharged in good clinical condition, on the sixth post-op day. One-year CTA control after Nellix explantation showed the patency of the aorto-iliac bypass (Fig. 7c).

DISCUSSION

Endovascular aneurysm repair (EVAR) is currently the first line therapy for abdominal aortic aneurysms. Although initially utilized in patients deemed high risk for open repair,

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EVAR is now widely applied in most patients with suitable aneurysm morphology and anatomy, regardless of the patient's surgical risk.[6]

Nonetheless, long-term data demonstrate high reintervention rates after EVAR, resulting in higher costs compared with surgical repair.[7]

Endoleaks are the most frequent complication requiring secondary intervention, after EVAR.[8]

On this backdrop, EVAS with the Nellix device has been designed to minimize the risk of device-related adverse events including all types of endoleaks and endograft migration.

The analysis of the two-year results of the FORWARD IDE trial have reported a freedom from all-cause mortality of 94%, a freedom from type IA endoleaks of 97.5% and a type I endoleak prevalence of 1.9%.[9]

Consistently with these data, the Italian IRENE retrospective observational study reported a freedom from aneurysm-related reintervention of 98.3% at 1 month and of 94.7% at 12 months of follow-up; the rates of early and late type IA endoleak were 0.3% and 1.4%, respectively and the reintervention incidence was 3.7%, that included 1.4% of surgical open conversions.[10]

Although the low reported incidence of type 1A endoleak after Nellix EVAS, these endoleaks are one of the major concerns of EVAS because they are mostly high-pressure leaks and may lead to late rupture of aneurysms.

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As stated by Holden et al., a type I endoleak may be very subtle due to the device design and difficult to differentiate from contrast in the endobag.[11]

In EVAS, the type 1A ELs detected on completion angiography or on the first postoperative imaging control are usually the result of incomplete procedural seal at the proximal neck or within the aneurysm sac. Later type I endoleaks are related to several factors, including degeneration and dilation of the neck and changes in either aortic or device morphology (i.e. endobags shape) with loss of seal.[12]

This complication may also be related to suboptimal deployment of Nellix system, resulting in an insufficient coverage at the proximal aortic neck.[13]

As previously reported, the maximum diameter of the aneurysm may remain unchanged despite a persisting Type 1 endoleak, when it fills the limited space between the endobags and has an outflow via the inferior mesenteric artery or lumbar arteries which reduces the pressurization of the aneurysmal sac and the risk of AAA rupture.[14,15]

Due to the absence of active proximal fixation of EVAS, a persistent type I endoleak with no outflow via collateral vessels may cause continued pressurization and significant increase of the proximal segment of the aneurysm resulting in proximal caudal migration of the stents within the aneurysm sac.

However, the treatment of type I Els is always advisable assuming that they have the potential for sac enlargement and ultimately rupture.

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Distraction forces may act at the proximal level of the Nellix device differently from a standard endovascular device and drive the endobags through the sac thrombus causing migration. As suggested_by Argani et al, the Nellix endograft is exposed to external factors, that during day-to-day activities cause oscillating movements which, in time, may contribute to endograft instability and migration. [16]

This may result in the loss of the proximal sealing and a subsequent endoleak developing alongside the endobag within the aortic neck.[17] A higher deployment of the Nellix system would have probably ensured a safer interface between the bag and the aortic wall and potentially prevent bag slippage and distal migration of device components.

The etiology of the late type 1A endoleaks reported in this article has not been fully cleared and it was retrospectively researched analyzing and comparing post-operative and subsequent follow-up imaging, including both CTA and MRI scans.

It was probably due to two sequential factors: the loss of seal in the proximal neck with subsequent continued aneurysm growth and distal translocation of the stents within the aneurysm sac.

During the first year of follow-up, the imaging controls did not show any complications with the exception of the presence of air bubbles inside the endobags on the 1-month post-operative CTA.

According to literature, a small amount of air inadvertently introduced during the procedure, could be often seen on early post-operative contrast CT images; in a minority of cases, these air bubbles can persist at the 1-month stage but usually should not be

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visible after 3 or 6 months, because it diffuses across the endobag and is replaced by fluid, probably from the periaortic extracellular space.[18]

In the reported case, the 1-year CT scans demonstrated the shrinkage of both endobags; to confirm this, the total prosthetic volume calculated using the Osirix volume rendering tool, was 102.37 cm^3 and it was reduced of 4,92% when compared to the early post-operative CT. With the same method, we calculate the volume of the air bubbles that was 4,13 cm^3 and was comparable with the lacking volume.

Based on these findings and in accordance with the literature, we hypothesize that the endobags shrinkage was caused by reabsorption of the air bubbles that were not replaced by fluid or polymer expansion.

In addition, according to what was suggested by McWilliams et al. [19], the Hounsfield Unit measurement demonstrated a reduction in radiodensity of the polymer inside the endobags, from +189 to +100 HU.

No proximal caudal migration, proximal neck enlargement or distal landing zone dilatation were associated to the endobag shrinkage on both CT and MRI subsequent controls.

The post-operative imaging of Nellix failure may be challenging and sac pressurization and rupture may occur in the absence of a visible endoleak, as confirmed by Harrison et al. [20]

During the third year of follow-up, the DUS and the subsequent contrast CT control clearly showed a high-flow type IA EL combined with a dramatic distal dislocation of the two stents and enlargement of the aneurysm sac.

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We have not reliably identified the cause of these complications; anyhow, it is conceivable that shrinkage of endobags caused the loss of the proximal sealing of the Nellix system and consequent endoleak alongside the endobag within the aortic neck which was initially unrecognized; the decrease in volume of endobags led to a reduction of the support for the stents and their caudal dislocation.

In fact, as demonstrated by mechanical and computational fluid dynamic tests, the less the stents are surrounded by polymer, the less resistant they are to lateral bending. Also, vice versa the less thrombus is present in the aneurysmal sac, the more polymer can be introduced, providing support for the stents, because both blood flow downward force on the polymer-filled endobags and lateral acceleration force within curvatures in the stent-grafts could contribute to loss of proximal stent-graft attachment, which could cause a type Ia endoleak to open adjacent to the endobag.[21,22]

Although proximal Nellix-in-Nellix extension possibly with chimneys can be used to treat caudally migrated endograft and consequent type Ia endoleak [23], but this approach should be reserved to high-risk patients because the long-term efficacy remains still unproven. [24] Thus, open conversion is the safest choice.

Conversion to open repair of AAA after EVAS with Nellix system has rarely been reported and the explant due to a type IA endoleak and device migration has been even rarer.

Lee et coll. has been the first to discuss two Nellix endograft explants required for endoleak and proximal caudal migration of the stent frames.[25]

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Explantation of conventional endografts can be technically difficult due to suprarenal fixation stents and barbs. Conversely, in this case the absence of proximal active fixation system made the late explantation easy and quick to perform, without any wall damage at the level of aortic neck. At contrary of other endografts, we did not observe any periaortic inflammation and fibrosis provoked by the Nellix device at the time of its explantation. This is in line with our previously reported findings of no perioartic reaction to Nellix endograft graft demonstrated with MRI controls.[26]

CONCLUSION

The preliminary and mid-terms results of the real-world multicenter studies have demonstrated that EVAS with Nellix is a promising technique for treating AAAs. This device platform provided acceptable procedure-related mortality with low overall complication and reintervention rates. However, the more recent data highlight that migration is one of the main causes of EVAS failure. This complication may appear late, even after years of apparent stability. Therefore, the safety of EVAS remains under scrutiny.

Post-operative surveillance of Nellix stent grafts is crucial to identify features of failure but evaluation of complications after a Nellix procedure can be challenging.

The focus of this article is on the early recognition and treatment of type IA endoleaks before they lead to the migration of the stent frames. Another crucial point is that the initial presence of air bubbles within the endobags may not be harmless since their

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reabsorption can lead to modification of their volume and shape with subsequent loss of Nellix device sealing and proximal type I endoleak.

The reported case reinforces the current evidence that EVAS with the Nellix device needs a careful and rigorous surveillance which should include Duplex ultrasound controls combined with a yearly MRI or CT imaging. This multimodality protocol of follow-up is aimed to timely identify complications such as type I endoleaks and migration requiring surgical conversion when misconceived.

In case of open conversion, the Nellix explantation is easier than other devices', due to the absence of proximal fixation means and the lack of periaortic inflammation.

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Figures legend:

Fig. 1 Aneurysm morphology in 3D reconstruction
Fig. 2 The preoperative aneurysm sizing report
Fig. 3 Post-operative CTA with no endoleak detectable, in coronal scans (a) and in sagittal scans (b)
Fig. 4 Post-operative CTA showing the presence of air bubbles inside the endobags, and the comparison with 1 years CTA
Fig. 5 Three-years follow-up scans showing type 1s3 endoleak, in 3D reconstruction (a), sagittal reconstructions (b), coronal scans (c). In d, the aneurysmal sac maximum diameter is shown
Fig. 6 MRI findings: comparison between 6 months (a), 1 year (b) and two years (c)
Fig. 7 Intraoperative pictures: at the aneurysmal sac opening, thick parietal thrombus and intact endobag are shown (a). After manipulation and explantation, the endobags presented a yin-yang conformation with more polimer at the proximal extremities and less at the distal ones. Aorto-bisiliac bypass (c)

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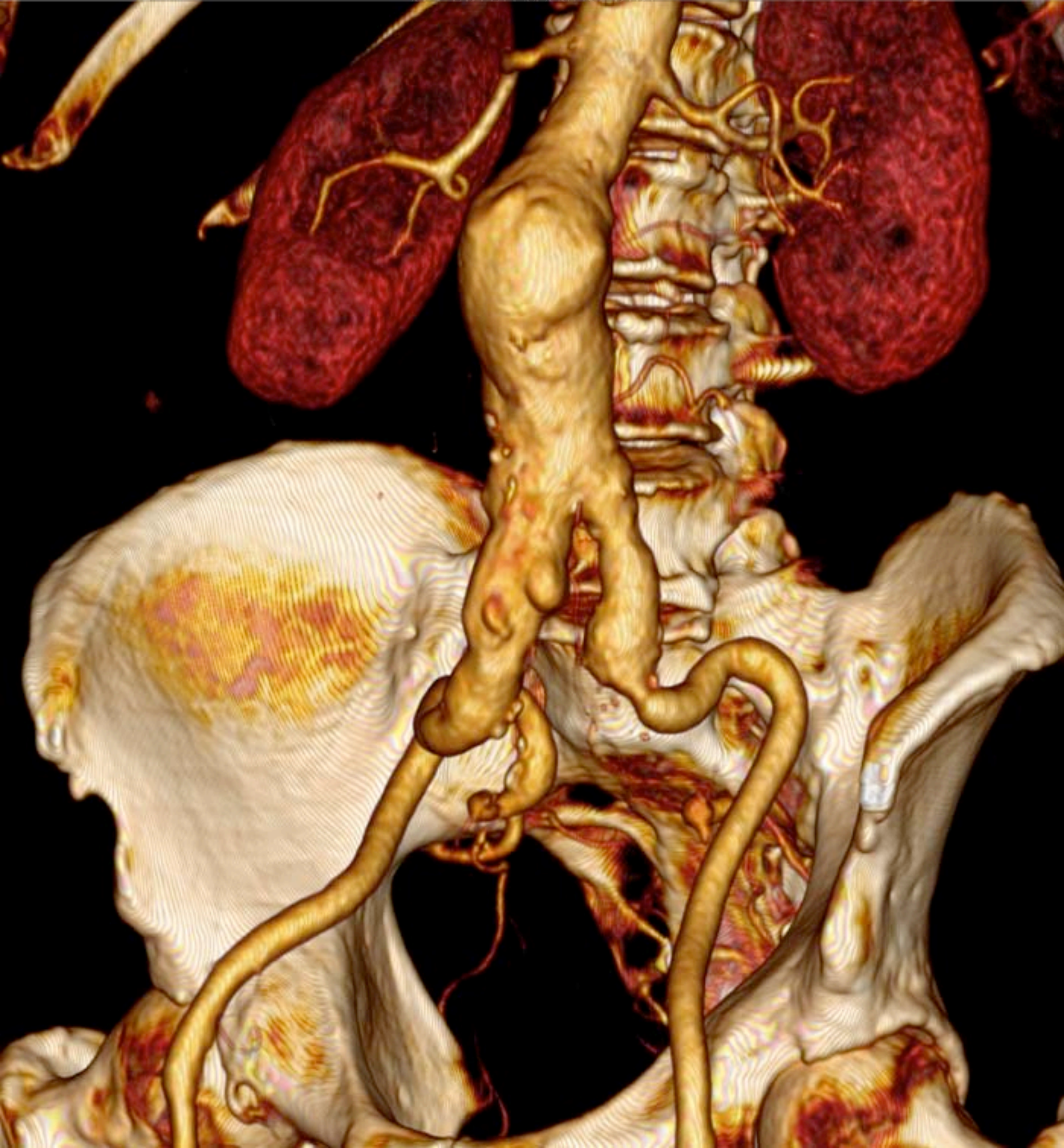

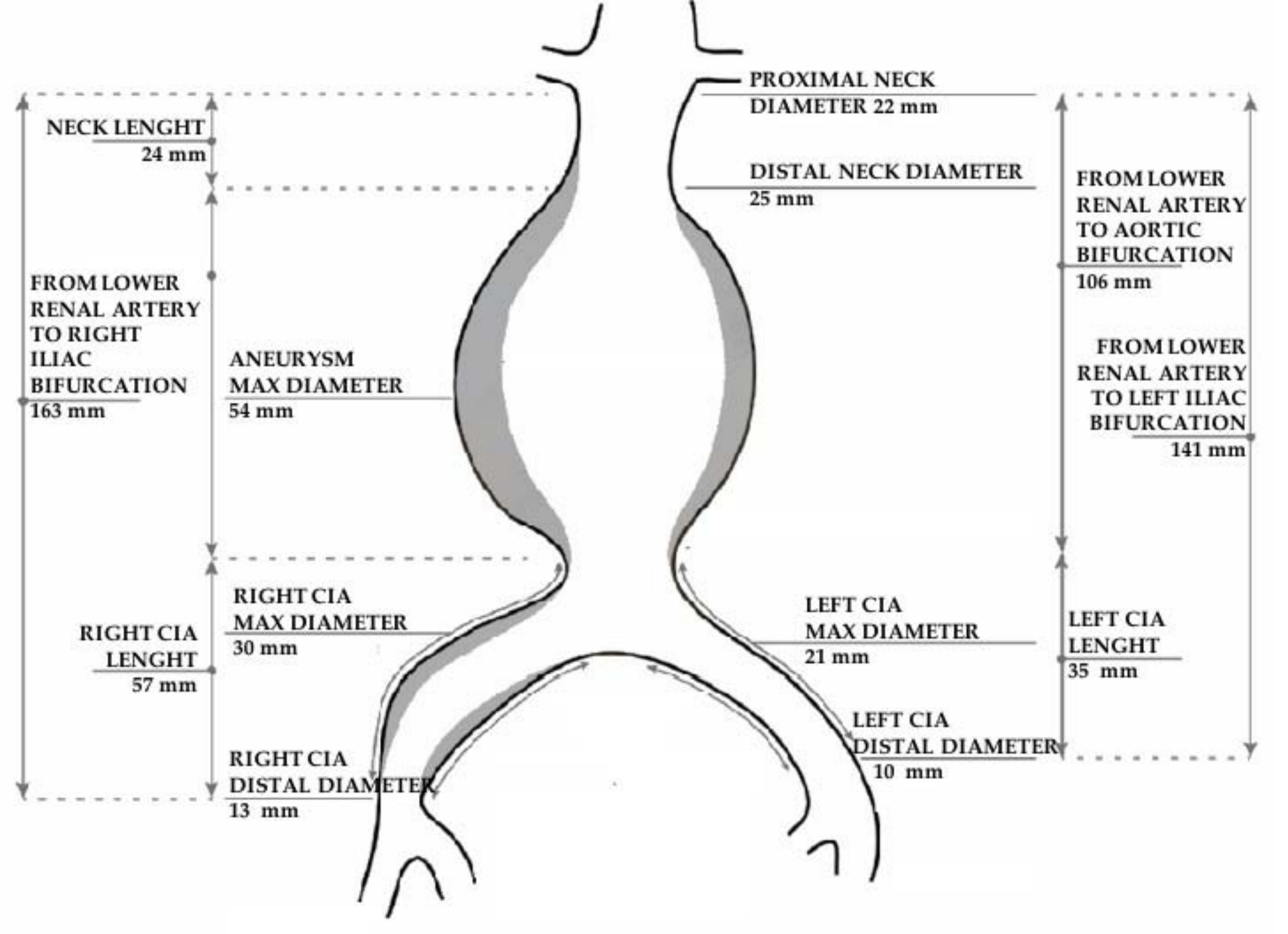
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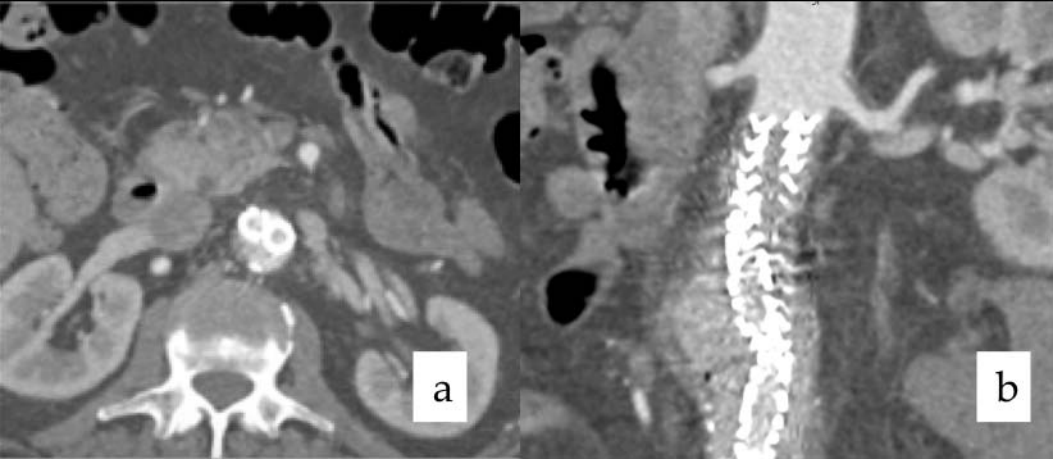
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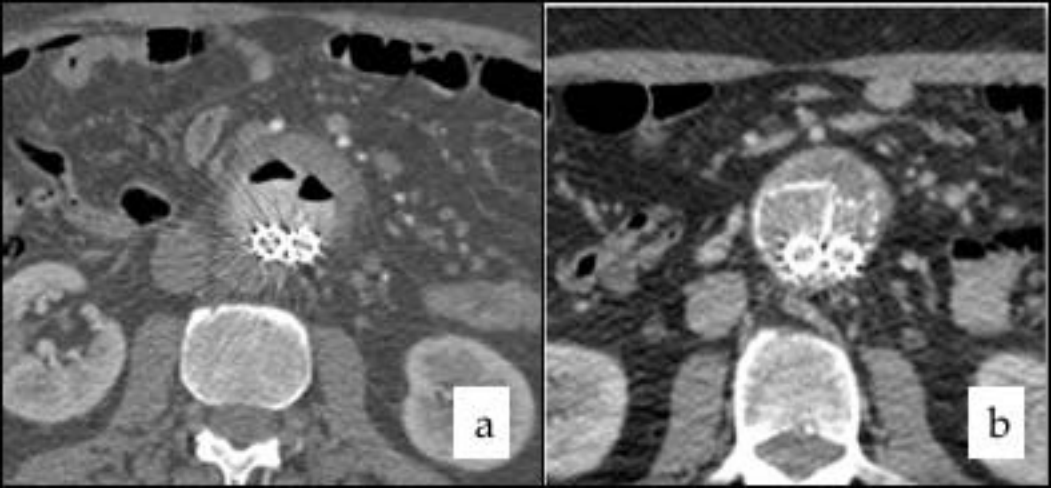
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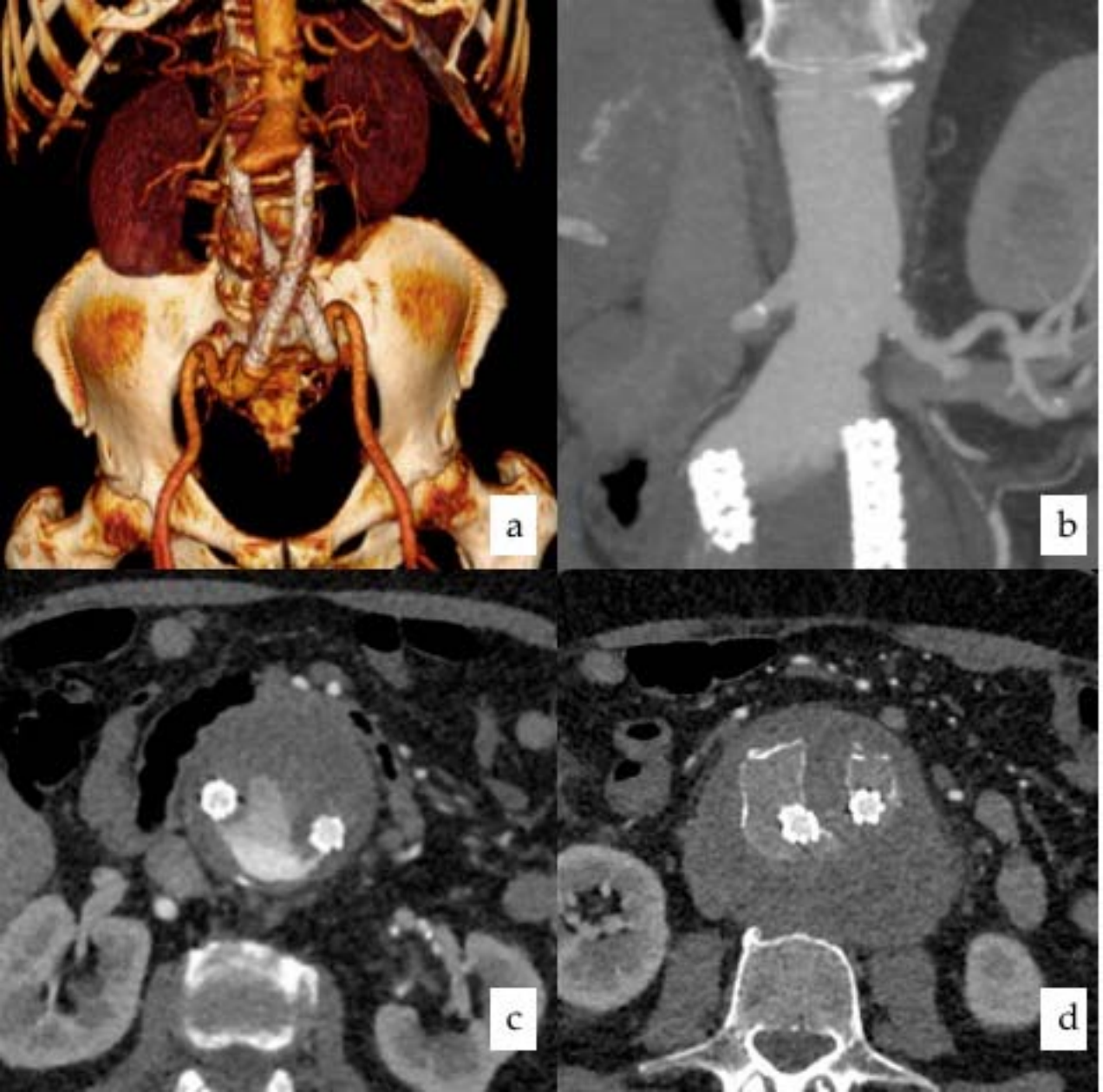
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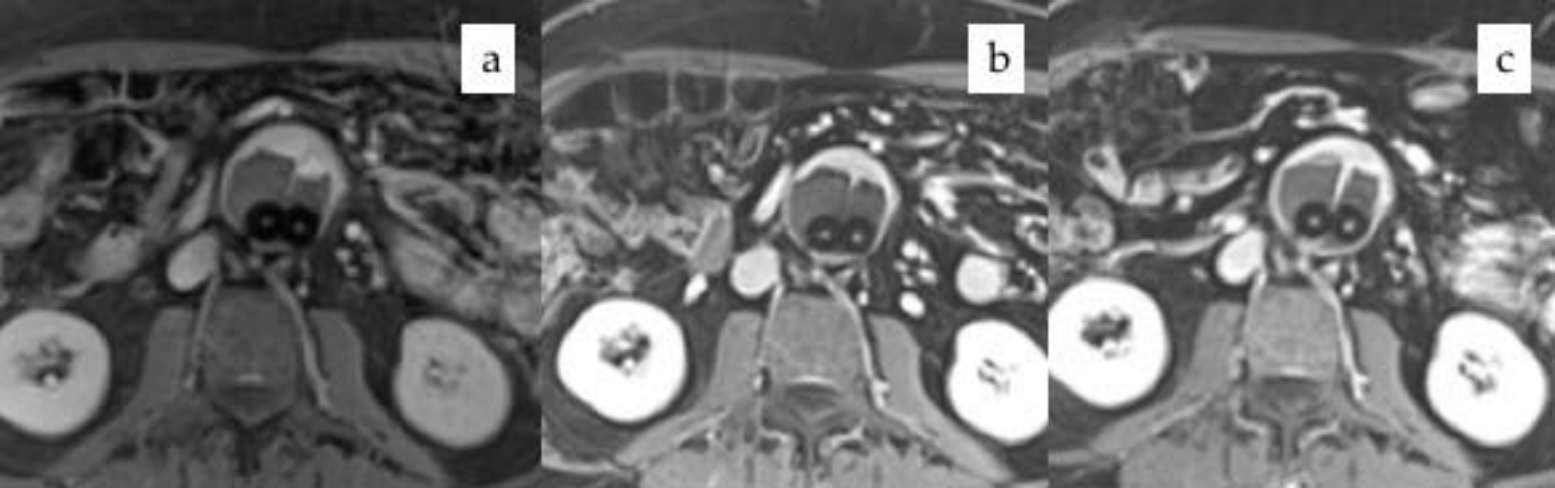
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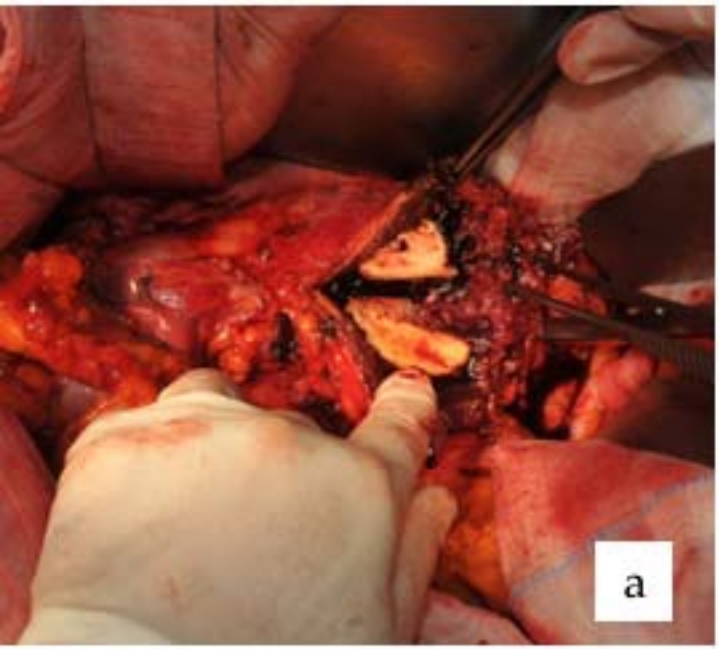
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