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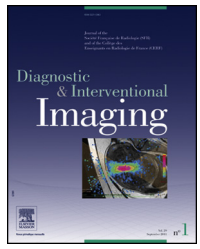

REVIEW / *Cardiovascular*

Aortic stent-grafts: Endoleak surveillance

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Abstract Endoleaks have been referred to as the ''Achilles heel'' of endovascular aortic aneurysm repair (EVAR) and are the most common complication of this procedure. An endoleak can maintain a high systemic blood pressure within the aneurysm sac, potentially leading to rupture. Follow-up is therefore mandatory to detect and classify possible endoleaks. Computed tomography (CT) remains the gold standard for follow-up, but provides no hemodynamic information on endoleaks and has the disadvantages of exposing patients to iodine contrast and X-ray radiation. Exposure to radiation could be reduced in various ways, by simplifying the triphasic protocol using dual-energy CT imaging, limiting the amount of radiation per slice using iterative reconstruction, and reducing the follow-up schedule that could be altered to include non-ionizing radiation imaging techniques. Contrast-enhanced ultrasound (CEUS) is an interesting alternative to CT, as is magnetic resonance (MR) imaging that can be used as an alternative or for complementary imaging. Long-term follow-up schedules are currently based on repeated CT. However, more recently alternative follow-up protocols have been proposed for patients with no endoleaks nor increase in aneurysmal sac size. These new protocols consist of CT imaging at 1 month and 1 year after treatment, subsequently followed by CEUS. Nevertheless, the mechanical structure of the stent-graft must still be verified by CT. The use of patient-specific risk-adjusted follow-up protocols, based on preoperative imaging and the first postoperative results, is gradually becoming more and more widespread.

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Why is it essential to diagnose and classify endoleaks?

Endoleaks occur when the aneurysmal sac continues to be pressurized following the placement of an aortic stent-graft. They are often referred to as the ''Achilles heel'' of the endovascular approach to both abdominal endovascular aortic repair (EVAR) and thoracic endovascular aortic repair (TEVAR) procedures.

In 1998, White et al. [1] classified endoleaks into five types:

- type 1: leak between the stent and the aortic or iliac wall. There are four type-1 subtypes:
  - 1a—proximal leak,
  - 1b—distal leak,
  - 1c—exclusion zone formed by an iliac plug with aorto-uni-iliac devices,
  - 1d—''gutter''-like leak following fenestrated EVAR or chimney/periscope techniques;
- type 2: aneurysm sac filling via a branch vessel (for abdominal EVAR: patency of the inferior mesenteric or lumbar artery);
- type 3: leak at the junction of stent-graft segments. Three type-3 subtypes have been described:
  - 3a—hole or defect within the stent-graft,
  - 3b—leak between two modular components,
  - 3c—defective stent-graft material;
- type 4: leak across the graft due to its porosity;
- type 5: ''Endotension'' leak—no evidence of a leak site can be found but the aneurysmal sac continues to expand.

Depending on the time to occurrence, endoleaks are described as early-onset, late-onset or recurrent.

Endoleaks that cause aneurysmal sacs to be under persistent systemic pressure increase the risk of rupture [2].

Based on the 6787 patients of the Eurostar registry, the incidence of type-1 and -3 endoleaks was 6%, whereas that of type-2 endoleaks was 5% [3]. The frequency of type-5 endoleaks is less well documented although it was estimated at 3.1% in the cohort of 160 patients studied by Mennander et al. [4].

The risk of rupture induced by post-EVAR type-1 and -3 endoleaks has long been considered as significant [5].

The risk of rupture related to type-2 endoleaks is less clear. Reinterventions are more frequent with this kind of endoleak, but, as shown by Van Marrewijk et al. who analyzed 3595 cases from the Eurostar database, neither post-EVAR rupture nor conversion to open surgery are significantly associated with type-2 endoleaks [6]. Among the five cases of type-5 endoleaks studied by Mennander et al., 3 were followed by rupture of the aneurysm [4].

How can endoleaks be detected?

Angiography

Historically, angiography was used to detect endoleaks and assess both antegrade and retrograde flow. Nowadays however, non-invasive techniques are implemented with the same results. In current clinical practice, angiography is used to assess the success of endoleak treatment immediately after its implementation; it is no longer used as a detection technique or as part of follow-up.

Conventional X-ray imaging

Monitoring the mechanical structure of the stent-graft is still an essential part of follow-up. Typically, stent-graft migration and possible mechanical defects (kinking, dilation, fracture, module or branch disconnection, etc.) can be visualized clearly on anteroposterior and oblique projections. However, endoleaks cannot be visualized directly using this imaging modality.

In practice, following accurate thresholding, current multislice CT techniques (from 16 slices) enable volume reconstruction and therefore, analysis of metal structures. Hence, conventional X-ray imaging techniques are no longer used to detect endoleaks [7].

Computed tomography

Endoleak detection using CT is relatively simple. It is based on detecting, after administration of contrast agent, a perigraft flow that reflects the flow of contrast out of the stent-graft and into the aneurysm. The radiologist must locate the site of the endoleak precisely, and determine whether it involves the ends of the stent-graft (type-1) and other collateral vessels (type-2). Such leaks may be detected either in the early arterial phase (type-1 and -3 endoleaks) or during the delayed phase (type-2 endoleaks and minor leaks) [8] (Figs. 1—4).

Three main disadvantages are associated with CT imaging.

Determining the direction of flow

Although of great importance for endoleak classification and determining the therapeutic approach to be used, the direction of flow within the aneurysmal sac and/or in collateral vessels is sometimes difficult to detect with conventional CT imaging. For example, opacification of a lumbar artery can reflect both a type-2 endoleak (retrograde flow) and a type-1 endoleak combined with antegrade flow into a lumbar artery. As demonstrated by Sommer et al., this problem can be overcome by using a time-resolved CT angiographic protocol to examine the patient. Indeed, the authors recommended a protocol consisting of 12 low-dose phases, with a scan frequency of 5 seconds and a scan range of 27 cm [9]. This protocol resulted in the characterization of type-1 endoleaks with an early enhancement time of 0.28 seconds ($\pm$0.83), and type-2 endoleaks with a delayed enhancement time of 9.17 seconds ($\pm$3.59). However, patient exposure to radiation with this protocol was high with a total dose of 14.6 mSv.

Administration of iodinated contrast agent

Approximately 80—120 ml of iodinated contrast agent is injected when performing CT angiography to detect endoleaks. In a cohort of 398 patients monitored following EVAR, 83% showed a glomerular filtration rate of less than 90 ml/min [10]. In such renally-impaired patients, clinicians should either attempt to use lesser amounts of contrast

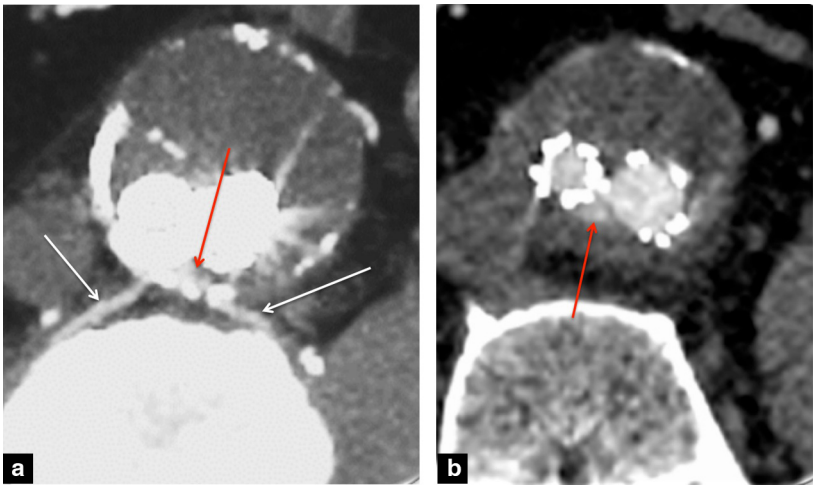

Figure 1. Two lombar arteries (white arrows) responsible of a type-2 endoleak (red arrow): a: axial slice showing the lombar arteries responsible of the type-2 endoleak; b: axial slice showing the endoleak and aneurysmal sac reinjection.

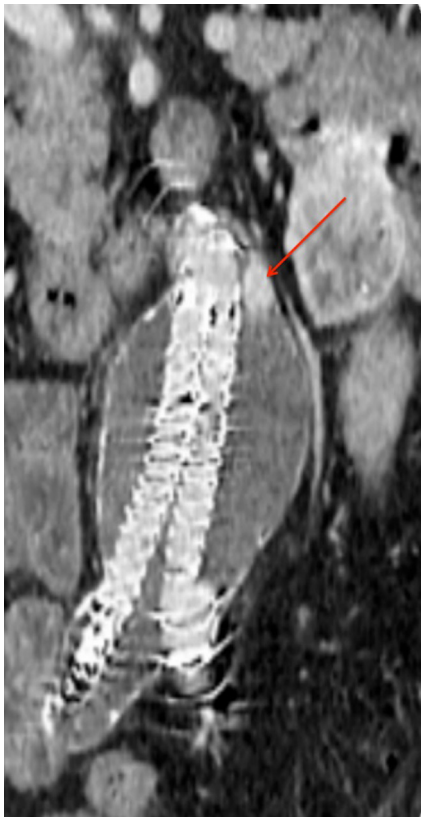

Figure 2. Large type-1 endoleak.

agent or completely eliminate its use by implementing an alternative method of diagnosis.

Exposure to radiation

Long-term follow-up protocols based on CT imaging mean that patients are exposed to non-negligible amounts of radiation. When attempting to assess the risk associated with radiation exposure, White et al. estimated that the summed radiation received during initial diagnosis, stent-graft placement and the CT follow-up protocol at 1, 3, 6 and 12 months and then yearly in patients aged 70 years, incurred a risk of radiation-induced cancer of 0.42% (1 patient in 240) [11]. If the patient was only 50 years old at the time of stent-graft placement, this risk was 0.73% (1/140 patient). Extrapolating this risk of radiation-induced cancer to elderly patients is probably excessive, but reducing exposure to radiation should still remain a priority. Three different manners of reducing exposure to radiation have been proposed:

- eliminating one of the three phases. Several researchers have suggested eliminating either the arterial phase, unenhanced phase [12] or the delayed phase [13], although this has had no real impact on clinical practice for the moment. Bley et al. suggested selecting patients needing to receive contrast based on aneurysmal sac volume as determined on non-enhanced images [14]. According to Stolzmann et al., a 61% decrease in exposure to radiation could be achieved without significantly changing endoleak detection performances by using new dual-energy dual-source CT systems that produce virtual non-contrast images [15];
- limiting the dose of radiation per slice. Various iterative reconstruction algorithms now allow the use of lower doses compared with the filtered back projection algorithms [16—19]. Reductions of up to 40 and 60% are observed compared with first-generation (VISIR: GE; IRIS: Siemens) and second-generation algorithms (ASiR: GE; iDOSE: Philips; SAFIRE: Siemens; AIDR/AIRDR3: Toshiba), respectively. A manufacturer (GE) offers now third-generation iterative reconstruction features. In a recent prospective monocentric study (Pérignon et al., submitted to Eur. Radiol.), we compared 2nd-generation ASiR and 3rd-generation Veo iterative reconstruction on a GE Discovery CT750 system in a cohort of 76 patients. Patients underwent three phases with ASiR, and two phases with low-dose Veo, based on a 50% reduction of the computed tomography dose index (CTDI). For endoleak detection, the sensitivity and specificity of Veo were 96% and 100%, respectively; no endoleaks were missed. The images were of identical subjective quality,

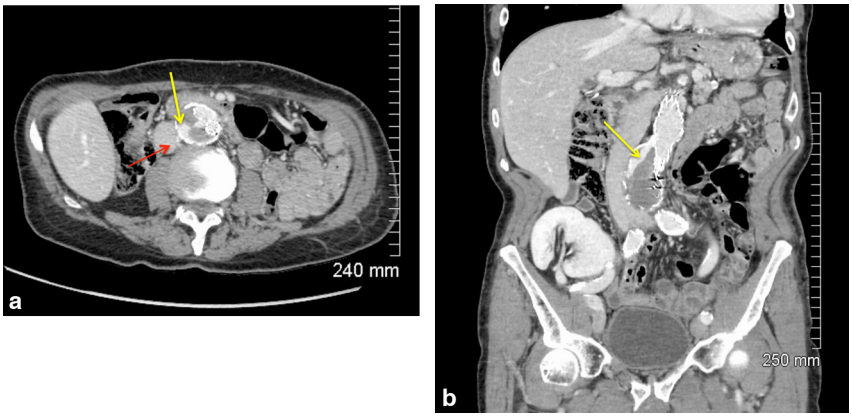

Figure 3. Type-2 endoleak by lombar reinjection with significant aneurysmal diameter expansion: interventionnal procedure is required: a: axial slice showing the endoleak, lombar artery (red arrow) and type-2 endoleak (yellow arrow); b: coronal slice, type-2 endoleak (yellow arrow).

and their objective quality was even improved with Veo (SNR = 7.84 with VEO vs. 5.14 with ASiR; CNR: 5.26 vs. 3.11; $P < 0.0001$). Use of Veo resulted in a total reduction of the effective dose of 54% for a series of images compared to ASiR (4.17 mSv ± 1.43 vs. 9.06 mSv ± 3.2);

- reducing the follow-up schedule (i.e. less CT examinations). Until now long-term post-EVAR follow-up consisting of repeated CT examinations was considered to be essential to detect endoleaks and rule out a risk of rupture. Possible modifications to such protocols will be discussed below.

Ultrasound

Ultrasound examination, either contrast-enhanced or not, offers the following advantages: it does not induce renal toxicity, avoids exposure to radiation, and is widely available and relatively inexpensive (even if CEUS is not reimbursed in France).

Ultrasound is now considered to be as reliable as CT imaging for determining aneurysmal sac diameter [20].

With contrast-enhanced ultrasound, the direction of flow can now also be determined and hyper- (low risk) and hypodynamic endoleaks can be differentiated based on their wash-in and wash-out times [21].

Kharthikesalingam et al. performed a meta-analysis to compare various post-EVAR follow-up protocols [22]. These authors analyzed 25 different studies comparing the use of duplex Doppler ultrasound and CT imaging, for all endoleak types, and achieved a pooled sensitivity of 0.74 and a specificity of 0.94. The pooled sensitivity and specificity of 11 studies comparing CEUS and CT scanning were 0.96 and 0.85, respectively. When only type-1 and type-3 endoleaks were analyzed, the sensitivity and specificity reached 0.83 and 1 respectively with duplex ultrasound (pooled results of 13 studies), and 0.99 and 1, respectively with CEUS (pooled results of 8 studies).

Ultrasound is therefore beginning to replace CT as the gold standard imaging modality for post-EVAR follow-up. Nevertheless, this technique also has limits (obese patients, hernia, intestinal gases, etc.) and cannot be used for the post-TEVAR follow-up of thoracic aortic stent-grafts or to assess the mechanical structure of the stent-graft (Fig. 5).

Magnetic resonance imaging

The examination technique consists of a 3D MR angiography (MRA) after administration of a double dose of gadolinium (4 ml/kg). Dynamic contrast-enhanced time-resolved MRA datasets centered on the endoleak are acquired to assess contrast kinetics.

MR imaging offers the advantage of no exposure to radiation, causes less or no renal toxicity and suggests

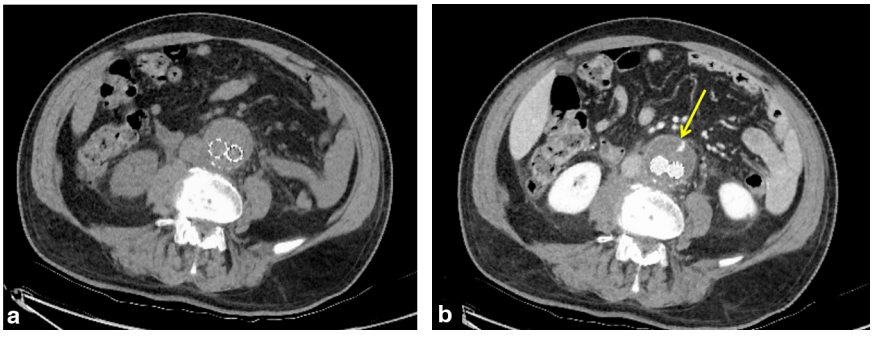

Figure 4. Follow-up computed tomography before and after contrast media injection: arterial phase, type-2 endoleak due to inferior mesenteric artery reinjection: a: axial slice before contrast media injection; b: same slice level after contrast media injection (arterial phase), type-2 endoleak (yellow arrow).

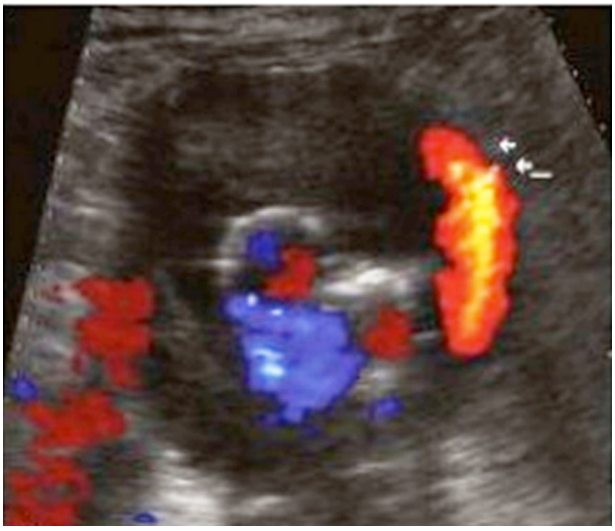

Figure 5. Abdominal aortic Doppler US follow-up after aneurysm treatment with endoprosthesis: Doppler US signal in the exclude aneurysm by a type-2 endoleak due to inferior mesenteric artery reinjection.

the direction of flow. Nevertheless, it has 3 main setbacks:

- classic MRI contraindications;
- potential safety issues, with two associated risks:
  - stent-graft migration, as addressed in vitro by van der Laan et al. [23]. Although nitinol-structure stent-grafts are not affected by this risk, other steel stent-grafts (older Zenith stents by Cook and Lifepath stents by Edwards) could migrate in magnetic field,
  - the second theoretical risk is that of stent heating [24]; although to our knowledge no such event has ever been reported at 1.5 Tesla;
- image artifacts:
  - magnetic susceptibility artifacts from ferromagnetic stent-grafts can distort the images making them uninterpretable. Such artifacts are observed with nitinol stent-grafts but to a much lesser degree,
  - RF shielding effects can cause decreased in-stent visualization and depend on stent geometry and conductance [24,25].

Up to present, MR imaging has not been used on a routine basis for stent-graft follow-up. A meta-analysis including 11 studies that compared MR with CT imaging (369 patients, 562 MRI examinations, 562 CT scans) demonstrated that the sensitivity was greater with MRI than CT, especially for detecting type-2 endoleaks [26]. The authors suggested that this modality be used in the event of aneurysmal sac growth with negative or uncertain CT results (Fig. 6).

Novel alternative follow-up modalities

Manometry

The risk associated with an endoleak being a rupture of the aneurysmal sac due to excessive pressure, monitoring sac pressure, represents an interesting approach for post-EVAR follow-up.

The limits of classic invasive manometry are obvious (introduction of an intrasac catheter during stent-graft placement, or measurement by direct puncture), however alternative manometric methods could be feasible.

For example in a study by Ellozy et al., a miniaturized pressure transducer was implanted within the aneurysmal sac during stent-graft placement, and pressure readings collected via a receiver placed on the patient's abdomen [27]. This device was tested over a 1-year period for post-EVAR follow-up in a series of 55 patients and enabled the detection of increased intrasac pressure in 4 out of 14 patients with type-2 endoleaks [28].

These results still need to be confirmed to demonstrate the reliability of the manometer. A possible limitation of this technique is that it does not provide any information on how pressure is distributed within the aneurysmal sac.

Monitoring D-dimer levels

Blood D-dimers are fibrin degradation products that are released during fibrinolysis. Increased D-dimer levels are typically observed after a recent thrombotic event.

Once exclusion of the aneurysm sac has been achieved by stent-graft treatment, a stable clot normally forms within the sac. However, if blood continues to flow in and out of the sac, fibrinolysis can occur and result in increased D-dimer levels. In a multicenter study on the post-EVAR follow-up of 74 patients, Serino et al. showed that, for type-1 endoleaks, D-dimer levels were significantly higher when the diameter of the aneurysmal sac remained unchanged or increased compared with patients for which the diameter of the sac decreased [29]. Such use of D-dimer levels in post-EVAR follow-up seems interesting, but to our knowledge these results have yet to be confirmed. Also, it should be noted that this method lacks in specificity since other events can cause an increase in D-dimer levels during follow-up.

Post-EVAR surveillance and when to intervene

The 2009 guidelines of the French National Authority for Health (Haute Autorité de la santé [HAS]) state that ''long-term surveillance of patients after placement of an abdominal stent-graft is mandatory. If such monitoring is not performed then treatment should be considered as incomplete. Monitoring is of the responsibility the surgeon who implanted the device and should occur according to a schedule discussed with the patient'' [30].

The main aim of post-EVAR surveillance is to avoid aneurysmal sac rupture by measuring sac diameter, and detecting and characterizing any potential endoleaks.

Other goals of post-EVAR surveillance are to detect other potential issues such as arterial access complications, renal artery occlusion, risk of infection, stent-graft migration, fracture or disconnection of modular components, and thrombosis.

It is now acknowledged that type-1 and type-3 (high pressure) endoleaks should be treated immediately [5]. Type-2 endoleaks are treated if the aneurysmal sac increases in size [31]. Monitoring is pursued if the diameter of the aneurysmal sac remains stable with or without a type-2 endoleak

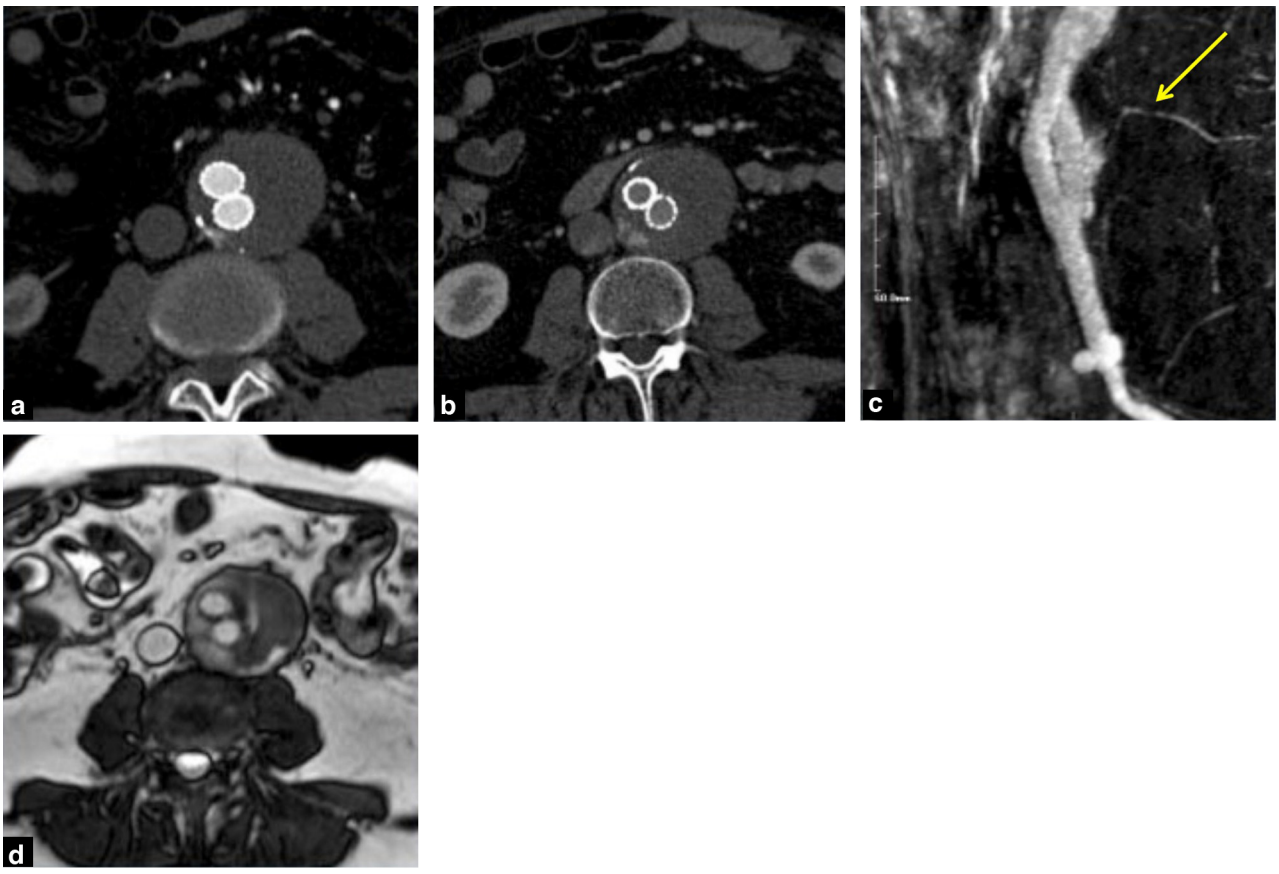

Figure 6. Correlation MDCT/MRI of a type-2 endoleak due to lombar reinjection: arterial phase (a) and portal phase (b) MDCT showing a type-2 endoleak due to lombar artery, with increased reinjection of the aneurysmal sac in the portal phase; c: MRI: arterial and portal phase 3D angio-MRI, better vizualization of the posterior reinjection and individualization of the lombar artery responsible of the type-2 endoleak (yellow arrow); d: MRI: axial T2 slice showing a flowing portion at the posterior portion of the aneurysm normally exclude.

(but in the absence of a type-1 or -3 endoleak). Treatment must be considered when sac diameter increases.

Conventional post-EVAR follow-up consists of immediate postoperative CT imaging, then repeated CT scans at 1, 3, 6 and 12 months, and then yearly.

MR imaging is used for stent-grafts made from non- or weakly ferromagnetic materials when CT is contraindicated. Use of duplex Doppler ultrasound examination is still not established.

As discussed above, recent advances in the use of ultrasound and MR imaging, together with the risks related to exposure to X-ray radiation and contrast agent and the cost of CT imaging, tend to suggest that post-EVAR follow-up protocols will change in the not too distant future.

SVS Practice Guidelines 2009

The Society of Vascular Surgery (SVS) recommends the following post-EVAR follow-up protocol [32]:

- CT scan at one month and 12 months. Then, if no endoleak or no increase in aneurysmal sac size is observed, color Doppler ultrasound can be used for yearly surveillance as an alternative to CT scanning. CT examination must be carried out at 6 months if any abnormalities are detected at the 1-month visit;
- type-2 endoleaks are monitored using CT, then if the diameter of the aneurysmal sac remains constant or decreases, using Doppler ultrasound;
- any new endoleaks detected must be characterized, and type-1 and -3 endoleaks treated by exclusion;
- in renally-impaired patients, combined follow-up using Doppler ultrasound and non-contrast enhanced CT can be used as a suitable alternative to contrast-enhanced CT.

Among the issues that remain outstanding with these guidelines is the frequency of follow-up visits which will probably need adjusting in the future to define three different post-EVAR follow-up periods: 0—5 years, 5—10 years and 10—15 years. One should also bear in mind the benefit provided by surveillance of the rest of the arterial network in these patients with atheromatous disease.

Fig. 7 shows the protocol proposed by H. Rousseau in 2013 for the French Society for Cardiovascular Imaging (Société française d'imagerie cardiovasculaire [SFICV]) and modified from the North-American consensus described by Sternbergh et al. [33].

The main limitation of this protocol is that the mechanical structure of the stent-graft cannot be assessed when follow-up is based on ultrasound examination. The surveillance of stent-graft structure and its potential migration

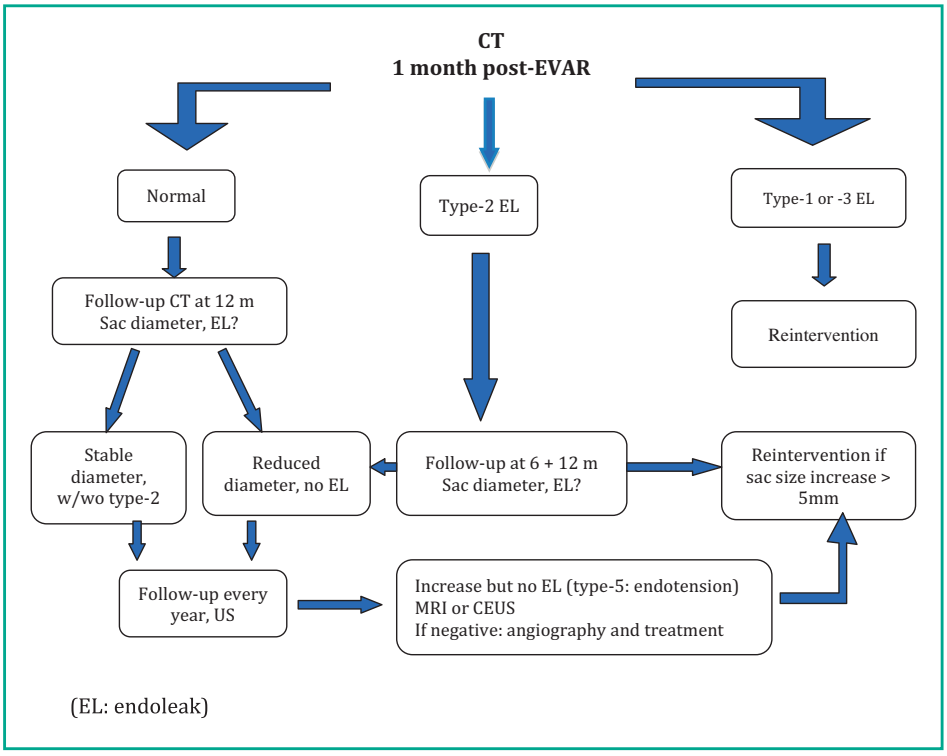

Figure 7. Follow-up protocol proposed by H. Rousseau in 2013 for the SFICV, modified from the North-American consensus [29].

being essential, this protocol would therefore benefit from complementary conventional X-ray imaging.

Prospects

Without doubt, the current consensus on post-EVAR follow-up will undergo changes in the not too distant future. It is now recognized that lethal post-EVAR complications are observed more frequently in inadequately-monitored patients than in patients who attend regular follow-up visits [34]. Long-term surveillance is also important as new endoleaks have been detected up to 7 years after EVAR [35].

Moreover, if the meta-analysis conducted in 2010 by Nordon et al. based on 32 studies including 17,987 EVAR patients demonstrated that 90% of patients did not benefit from follow-up, the remaining 10% of patients definitely did [36]. Sternbergh et al. also discussed the possibility of identifying at an early stage sub-populations of patients at a high risk of complications and specifically adjusting the follow-up protocol to take such risks into account [33]. This would mean defining various prediction criteria. Some of these prediction criteria are already established:

- preoperative criteria: aneurysmal sac diameter; short and angulated neck [37];
- postoperative criteria:
  - reduction of aneurysmal sac diameter: decreased sac size at 12 months is indicative of long-term success [38],
  - no endoleaks at 1 month: The Zenith multicenter trial conducted in the USA demonstrated that in such patients the aneurysm-related morbidity and mortality was lower than in patients with an endoleak at 1 month and that CT imaging at 6 months provided no additional benefit if CT results were normal at one month [33]. The Powerlink trial (Endologix) including 345 patients and 1591 CT scans showed that the negative predictive value of secondary post-EVAR CT imaging was 96.4%, whereas it was 97.6% for ultrasound [39],
  - finally, the absence of early-onset endoleaks and the presence of an adequate proximal and distal stent seal (> 10 mm) can be used to characterize a sub-population of low-risk patients, for whom follow-up is recommended at 5 years [40].

Conclusion

Type-1 and type-3 (high pressure) endoleaks should be treated immediately whereas type-2 endoleaks should only be treated if aneurysmal sac size increases. Monitoring is pursued if the diameter of the aneurysmal sac remains stable with or without a type-2 endoleak (but in the absence of a type-1 or -3 endoleak). If aneurysmal sac diameter increases, clinicians should strive to detect and characterize the endoleak, using another imaging modality if necessary, and treat it either using interventional radiology techniques or by conversion to open surgery.

CT imaging is the gold standard and enables clinicians to simultaneously detect endoleaks and assess the mechanical structure of the stent-graft. It should be performed at 1 and 12 months post-EVAR. Nonetheless, CT imaging has three main disadvantages: poor flow detection, administration of contrast agent, and exposure to radiation. Exposure to radiation could be reduced in several manners, notably via the use of new dual-energy CT systems (that eliminate

the need to perform non-contrast enhanced imaging), iterative reconstruction and adapting (reducing) the follow-up schedule based on individual patient requirements.

Optimized contrast-enhanced ultrasound is becoming for many clinicians the new gold standard for surveillance of post-EVAR patients without endoleaks from one year on. The need to ascertain stent-graft structure and non-migration in the long-term raises the possibility of adding conventional X-ray imaging to this protocol as a complement to CEUS examination.

MR imaging (for stent-grafts made of non-ferromagnetic material) is required if the size of the aneurysmal sac continues to increase and CT results are negative or uncertain.

A shift in practice is underway towards patient-adjusted protocols based on each individual patient's risk of complications that take into account preoperative imaging (sac diameter, short and angulated neck) and the initial postoperative results (reduction in sac diameter, absence of endoleaks on CT imaging at 1 month, and adequate proximal and distal sealing).

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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