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REVIEW ARTICLE

Multimodality imaging assessment of endoleaks post-endovascular aortic repair

¹SASAN PARTOVI, MD, ¹THOMAS TRISCHMAN, BS, ²VASILEIOS RAFAILIDIS, MD, ³SUVRANU GANGULI, MD, ⁴FABIAN RENGIER, MD, ⁵HAROLD GOERNE, MD, ⁵PRABHAKAR RAJIAH, MD, FRCR, ⁶DANIEL STAUB, MD, ¹INDRAVADAN J PATEL, MD, ³GEORGE OLIVEIRA, MD and ³BRIAN GHOSHHAJRA, MD

¹Department of Radiology, Section of Vascular and Interventional Radiology, University Hospitals Cleveland Medical Center, Case Western Reserve University, Cleveland, OH, USA

²Department of Radiology, AHEPA University General Hospital, Aristotle University of Thessaloniki, Thessaloniki, Greece

³Department of Radiology, Division of Cardiovascular Imaging, Massachusetts General Hospital, Harvard Medical School, Boston, MA, USA

⁴Department of Diagnostic and Interventional Radiology, University Hospital Heidelberg, Heidelberg, Germany

⁵Department of Radiology, Division of Cardiothoracic Imaging, UT Southwestern Medical Center, Dallas, TX, USA

⁶Department of Vascular Medicine, University Hospital Basel, University of Basel, Basel, Switzerland

Address correspondence to: Dr Sasan Partovi

E-mail: sxp509@case.edu

ABSTRACT

Endoleaks are a common complication of endovascular aortic repair (EVAR). As a result, patients require lifelong imaging surveillance following EVAR. In current clinical practice, evaluation for endoleaks is predominantly performed with CT angiography (CTA). Due to the significant cumulative radiation burden associated with repetitive CTA imaging, as well as the repeated administration of nephrotoxic contrast agent, contrast-enhanced ultrasound (CEUS) and magnetic resonance angiography (MRA) have evolved as potential modalities for lifelong surveillance post-EVAR. In this paper, multimodality imaging, including CTA, CEUS and MRA, for the surveillance of endoleaks is discussed. Further, new CTA techniques for radiation reduction are elaborated. Additionally, imagery for three cases of aortic endoleak detection using CTA and five cases using MRA are presented. Imaging for different types of endoleaks with CTA, MRA and CEUS are presented. For lifelong endoleak surveillance post-EVAR, CTA is still regarded as the imaging modality of choice. However, advancements in CEUS and MRA technique enable partial replacement of CTA in certain patients.

INTRODUCTION

Endoleaks are a common complication in post-endovascular aortic repair (post-EVAR) patients. During EVAR, a graft is placed in the aorta with its margins extending further both proximally and distally than the aneurysm sac. Ideally, this should stop blood from flowing within the aneurysm sac. An endoleak is defined as continuous blood flow within the aneurysm sac that the graft placed during EVAR was intended to exclude. According to the most recent estimates, endoleaks occur in approximately 26% of EVAR patients.¹ If undetected, an endoleak may progress and cause aneurysm sac expansion or rupture, which can be fatal.

In [Table 1](#) the five types of endoleak are described, along with the estimated percentage distribution of each type. In [Figure 1](#), visual representations of the blood flow patterns that define each type of endoleak are provided. From a clinical standpoint, Type I and III endoleaks are

viewed as high-flow endoleaks. Hence, they have a high risk of progressing and causing aneurysm sac rupture, and therefore require urgent treatment. Type II endoleaks are the most common type of endoleak and account for over 50% of all endoleaks. Type II endoleaks are generally low-flow. As a result, the hemodynamics are more benign and the risk of progression is not considered as high. Once detected, Type II endoleaks are not typically treated, but are instead followed-up with serial imaging to monitor change and progression.³ In general, treatment for Type II endoleaks is warranted if the aneurysm sac expands more than 5 mm. However, the decision of whether or not to treat a Type II endoleak is complex and depends on individual factors as well as institutional protocols.^{4,5} Endoleaks can occur at any time following EVAR, from immediately post-procedure to decades later. Consequently, lifelong surveillance to assess for endoleaks and to monitor the status of existing endoleaks is indicated following EVAR.

Table 1. Types of endoleak and associated characteristics

Type of endoleak	Source of leak	Treatment protocol	Percentage of endoleaks ^{2,3}
Type I	Type Ia – proximal end of endograft Type Ib – distal end of endograft	Intervention required urgently upon recognition	12%
Type II	Retrograde flow from patent collateral vessels into excluded aneurysm sac	Observation and surveillance until resolved or aneurysm sac expansion; intervention required with aneurysm sac expansion	76%
Type III	Type IIIa – endograft modular component leak Type IIIb – endograft fabric leak	Intervention required immediately/urgently upon recognition; with current generation endografts overall rare incidence	3%
Type IV	Increased porosity of endograft fabric	Self-limited, no treatment required	3%
Indeterminate/Type V	Unidentified source with sac expansion or flow within the excluded visualized. Debatable entity, may relate to a very low-flow endoleak undetected with imaging.	Unclear, often requires intervention	6%

Traditionally, the standard imaging modality used to monitor EVAR patients for endoleaks is CT angiography (CTA). In recent years there has been increasing interest in exploring other modalities, namely standard B-mode ultrasound combined with color-duplex ultrasound (CDUS), contrast-enhanced ultrasound (CEUS) and magnetic resonance angiography (MRA). Based on the most recent literature, the accuracy of CEUS in detecting endoleaks is comparable to that of CTA.⁶ In current clinical practice, the majority of endoleak assessments are still performed with CTA, but CEUS may soon gain a role in the surveillance algorithm for detection and monitoring endoleaks in post-EVAR patients. Limitations associated with CEUS include operator dependency and the lack of long-term established experience with contrast ultrasound agents. There have been several suggestions regarding the possible role for CEUS in the imaging surveillance algorithm post-EVAR. Some suggest using CEUS as an adjuvant in cases with indeterminate results on CTA. Others have proposed alternating the use of CEUS with CTA annually after the first year post-EVAR to lower cumulative radiation exposure and to decrease administration of contrast-induced nephrotoxicity. Lastly, CEUS has been proposed as first-line surveillance

imaging modality in post-EVAR patients with chronic kidney disease.^{7–10}

In this article, surveillance for endoleaks post-EVAR using various imaging modalities is discussed in the context of the available literature. Further, our own experience is shared based on representative cases for each modality.

CT ANGIOGRAPHY

Due to its wide availability, high spatial resolution and high diagnostic accuracy, the current modality of choice to detect and monitor endoleaks is CTA. Institutional CTA protocols vary with regard to timing, but typically include a triple-phase approach with a pre-contrast phase, an arterial phase and a delayed phase. The arterial phase is particularly useful for visualizing arterial vasculature and identifying Type I and Type III endoleaks, while the delayed phase is most sensitive for identifying Type II endoleaks.¹¹ The timing of the arterial phase is based on the bolus tracking technique with start of imaging when the contrast bolus reaches the most proximal abdominal aorta at the diaphragm level. Opinions vary across different institutions regarding what the most appropriate

Figure 1. Visual representations of the blood flow patterns that define each type of endoleak.

Figure 2. CTA arterial phase image (a) demonstrates a leak at the distal end of the endograft with contrast visualized within the excluded aneurysm sac (arrow). Volume rendered image (b) confirms extraluminal contrast surrounding the distal segment of the graft (arrow). These findings are consistent with a Type Ib endoleak. CTA, CT angiography.

delay duration is following contrast injection to obtain delayed phase imaging. Delay durations range from 2 to 5 min. Generally, the aforementioned protocol is preferred over portal venous imaging, which is typically performed 70 to 90 s post-iodine contrast injection.

Imaging studies are typically performed shortly after the EVAR device implantation procedure, and again 30 days post-procedure, 6 months post-procedure and annually thereafter. Since endoleaks can occur at any time following endograft placement, annual CTA surveillance is indicated for life. Aneurysm sac size and volume measurements are typically compared with measurements from prior imaging. Endoleaks are essentially visualized as contrast accumulation within the excluded aneurysm sac. The faster contrast accumulates in the excluded aneurysm sac, the more likely it is that urgent treatment will be required. Early contrast detection during the arterial phase indicates a high-flow state, and if there is aneurysm sac expansion, it requires urgent attention. Late contrast detection in 5 min delayed images suggests low-flow endoleak, which may warrant only observation or follow-up imaging without the need for treatment.

One interesting proposal for endoleak evaluation is to initially capture non-contrast CT images only. These images are utilized to measure excluded aneurysm sac size and volume, and these measurements are compared to prior examinations. If the excluded aneurysm sac is stable in size and the patient is asymptomatic, the examination is not continued with arterial and delayed phase imaging. The drawback of this approach is that it requires either a real-time interpretation of the non-contrast phase by the reading radiologist while the patient remains waiting on the CT examination table, or else two separate CT appointments. Another proposal involves alternating annual CT examinations with and without contrast. With this method, a CT examination with contrast agent is administered 1 year, and a non-contrast CT examination is performed the following year. If a drastic change in size of the aneurysm sac is detected during the non-contrast examination, the patient will be called back for a follow-up examination with contrast agent.

CTA has an estimated sensitivity and specificity of 83 and 100%, respectively, for detecting endoleaks.⁷ The drawbacks of CTA are that administration of iodine-based contrast agents may be contraindicated in chronic kidney disease patients due

Figure 3. CTA non-contrast phase (a) demonstrates patient is status post-aortic bi-iliac stent graft repair. Arterial phase (b) demonstrates contrast enhancement abutting the left common iliac artery limb of the endograft (arrow). Delayed phase (c) depicts a large amount of contrast within the aneurysm sac. These findings are consistent with a Type Ib endoleak from the left common iliac limb. The large amount of contrast accumulation on delayed imaging is suggestive of a high-flow endoleak and therefore is suggestive of the need for urgent treatment. CTA, CT angiography.

Figure 4. Pre-contrast phase CTA image (a) demonstrates placement of the endograft within an excluded infrarenal aortic aneurysm. Portal venous phase CTA image (b) demonstrates enhancement of an area in the posterior aspect of the excluded aneurysm sac (arrow) related to an endoleak via a lumbar artery. These findings are consistent with a Type II endoleak. CTA, CT angiography.

to risk of contrast-induced nephropathy. Further, with young or middle-aged patients, lifelong monitoring with CTA confers a significant amount of radiation exposure. Finally, lifelong annual CTA monitoring is associated with a significant financial burden.

In recent years, radiation reduction and contrast reduction protocols for CTA imaging have been developed. If patient body habitus allows, voltage can be reduced from 120 kVp to as low as 70 kVp, which reduces radiation exposure.^{12,13} Using iterative reconstruction rather than filtered-back projection further decreases the radiation exposure per CTA examination.^{14,15}

Spectral CT enables calculation of virtual non-contrast images from post-contrast images, potentially eliminating the need for the non-contrast phase from the CTA protocol and decreasing radiation exposure.^{16,17}

Another option to reduce the radiation and contrast dose involves the use of dual energy, which is also known as spectral/multienergetic CT. Using image datasets obtained at two different energy levels with one of the currently available technologies, such as dual source, rapid kVp switching, dual layer, dual spin, or split beam, multiple spectral images such as iodine-map, virtual non-contrast, effective atomic number and virtual

Figure 5. Spectral CT (a and b) demonstrates contrast enhancement within the superior portion of the aneurysm sac near the origin of the inferior mesenteric artery (arrows) in a patient with a fusiform infrarenal abdominal aortic aneurysm status post-aortic bi-iliac endograft repair. Retrospective creation of a virtual non-contrast phase image (c) using spectral CT does not demonstrate hyperdensity in this area, and therefore the source of the hyperdensities in a and b are true contrast extravasation. These findings are consistent with a Type II endoleak, most likely originating from the IMA.

Figure 6. CTA arterial phase imaging (a) shows leaking of contrast from the left leg of the endograft (arrow), into the surrounding soft tissues. These soft tissues appear ill-defined with foci of gas due to perigraft abscess formation (asterisk). Volume rendering image (b) reveals damage of graft structure with small out-pouching (arrow) visible. This is indicative of a Type III endoleak. CTA, CT angiography.

monoenergetic images can be obtained. The virtual non-contrast images of a dual-energy CT have attenuation values and accuracy similar to true non-contrast images and hence can be used to eliminate the true non-contrast phase from multiphasic studies, which can result in up to 40% reduction in radiation dose.^{18–22} However, some studies have shown lower attenuation of calcium and stents using dual-energy CT.^{20,23} Further radiation dose reductions of up to 64% can be achieved by using virtual images derived from the venous phase of dual-energy CT to replace the arterial phase.^{18,19,21} With this method, the highest sensitivity for endoleak detection was shown to be at 55 keV using virtual monoenergetic images.²⁴

Another strategy involves using risk stratification categories based on EVAR device type, patient characteristics and findings on initial CTA. Data from a previously published study using the Excluder Endoprosthesis (WL Gore & Associates, Flagstaff, AZ) revealed that if the CTA immediately after endograft placement shows adequate seals and no evidence of endoleaks, there is a much lower overall risk of subsequently developing an endoleak. Some of these patients may not need another surveillance CTA for up to 5 years post-procedure.²⁵

Figures 2 and 3 demonstrate the value of CTA in detecting a high-flow Type I endoleak, which requires treatment. Figure 4

visualizes CTA findings associated with a Type II endoleak. Figure 5 demonstrates a spectral contrast-enhanced CT with virtual creation of non-contrast images, confirming a Type II endoleak. Type II endoleaks are typically low-flow endoleaks and therefore observation is sufficient. If the aneurysm sac continues to grow on follow-up imaging, then treatment is indicated. Figure 6 demonstrates CTA findings associated with a Type III endoleak.

Although CTA has long been the modality of choice for non-invasive assessment of endoleaks post-EVAR, there has been increasing interest in exploring alternate modalities. In particular, standard B-mode ultrasound including CDUS, CEUS and MRA all have been proposed for endoleak surveillance post-EVAR and will be discussed in subsequent sections.

ULTRASOUND, COLOR-DUPLEX ULTRASOUND AND CONTRAST-ENHANCED ULTRASOUND

Compared to other imaging modalities, ultrasound with its associated high temporal resolution has the inherent advantage of being able to visualize and evaluate blood flow in a real-time pattern, thus providing functional hemodynamic information. Additionally, similar to CT and MRI, the i.v. administration of a contrast agent with ultrasound can increase its ability to detect blood flow patterns and associated anomalies. This has been rendered feasible with the introduction of microbubbles as ultrasonographic contrast agents. CEUS is now regarded as a valuable complementary ultrasonographic technique based on society guidelines.^{26,27} CEUS is especially valuable in detecting low-flow endoleaks. With optimized techniques, there is sufficient duration of vessel opacification, thereby enabling observation of blood flow patterns multiple times. This characteristic of ultrasound contrast agents is related to the ability to disrupt the microbubbles using a high mechanical index pulse, thus allowing the microbubbles to reflow within the field-of-view. SonoVue (Bracco, Milan, Italy) is the most widely used contrast agent in Europe with registered applications including cardiac, macrovascular, liver and breast lesion characterization. A similar contrast agent, Lumason (Bracco, Milan, Italy), recently received Food and Drug Administration approval for the characterization of liver lesions in the United States. These two ultrasound contrast agents are composed of sulfur hexafluoride with a phospholipid shell. Other commercially available ultrasound contrast agents

Figure 7. Color Doppler ultrasound (a) of the infrarenal aorta 5 years after endovascular aneurysm repair shows enlargement of the aneurysm sac but no visible endoleak. Additional CEUS, (b) with contrast mode (left) and conventional B-mode (right) simultaneously, 52 s after bolus injection of contrast agent reveal Type II endoleak from a lumbar artery (arrow). CEUS (c) after percutaneous trans-abdominal direct sac injection of Onyx (Medtronic, Minneapolis, MN) for embolization of the endoleak reveals no evidence of enhancement within the aneurysm sac. CEUS, contrast-enhanced ultrasound.

Figure 8. Time-resolved MRA images from early to late phases (a–d). The very early (a) and early (b) phases after contrast media injection illustrate filling of the descending aorta without contrast in the aneurysm sac (a, b, circles, corresponding to the location of the circles in c and d). The mid (c) and late (d) phases demonstrate a Type II endoleak (arrow in circle) via lumbar feeder and internal iliac branch feeders (right arrow in c, right two arrows in d). MRA, magnetic resonance angiography.

are Optison (GE Healthcare, Milwaukee, WI), composed of perflutren with an albumin shell and Definity (Bristol-Myers Squibb, Billerica, MA), composed of octafluoropropane with a phospholipid shell. Unlike CT and MR contrast agents, ultrasonographic contrast agents are not contraindicated in renal failure, and these ultrasound contrast agents have an excellent safety profile.^{27,28}

CEUS is a well-suited imaging modality for endoleak surveillance due to its specific strengths. First, it can safely be performed annually for long-term follow-up after EVAR without concern for nephrotoxicity and without the use of ionizing radiation. Endoleaks represent a complex dynamic phenomenon and prior studies highlight the ability of CEUS to accurately classify endoleaks.^{29,30} The high temporal resolution associated with real-time evaluation enables detailed characterization of endoleaks. Drawbacks of CEUS include its operator-dependent nature, and that it requires experience and specialized equipment. Further,

aorta visualization may be suboptimal due to bowel gas and increased body habitus in some situations.

Studies evaluating conventional unenhanced ultrasonographic techniques, including CDUS, for the identification of endoleaks after EVAR have yielded varying results, with an estimated sensitivity of 33–86% and a specificity of 63–93%. These studies concluded that ultrasound is an adequate first-line modality but unable to replace the reference method of CTA.^{6,7,31–33} Other studies have investigated the added value of CEUS in the detecting and characterizing endoleaks when used in addition to standard B-mode ultrasound and CDUS. Early CEUS studies showed a sensitivity of up to 100% and specificity of 65%, respectively, outperforming CDUS at correctly diagnosing Type I and Type II endoleaks.^{34,35} CEUS has consistently shown improved diagnostic accuracy compared to unenhanced conventional ultrasound, with sensitivities in the range of 80–100% and specificities

Figure 9. Pre-contrast phase (a, b) and arterial phase (c, d) MRA demonstrate enhancement of aneurysm sac posteriorly (arrows), which is consistent with Type II endoleak likely from lumbar feeders. MRA, magnetic resonance angiography.

in the range of 82–100%. CEUS may thus be considered an excellent endoleak surveillance tool along with CTA. If abnormalities are detected with ultrasound imaging including CEUS and CDUS, then this can be followed-up with a triple-phase CTA protocol for further characterization and endovascular planning purposes.⁹ Meta-analyses have concluded that CEUS pooled sensitivity is approximately 91 to 98% and pooled specificity is approximately 78 to 88% for detection of endoleaks, even in the case of a delayed Type II endoleak.^{36,37} In keeping with these results, another recently published systematic review has shown that CEUS may outperform CTA for the detection of low-flow endoleaks but is equivalent to CTA in terms of classifying Type I

and Type III endoleaks.¹ Yet another meta-analysis concluded that CEUS is not significantly superior to CDUS in terms of diagnostic accuracy, although it did report a higher sensitivity for CEUS compared to CDUS.¹⁰ Apart from routine integration into post-EVAR imaging surveillance, CEUS has also served as a valuable modality for difficult cases that had discordance using other imaging modalities. In one investigation, CEUS was shown to help in equivocal cases to guide patient management towards intervention in 30% of patients in this study, vs safe return to surveillance protocol in the other 70% of patients.³⁸

Figure 10. Time-resolved MRA demonstrates a Type II endoleak by contrast accumulation within the aneurysm sac (arrow in a) via L2/L3 lumbar feeders (arrow in b).

Figure 11. MRA non-contrast image (a) shows bi-iliac component of endograft in place within excluded aneurysm sac (arrow). The corresponding gadolinium-enhanced image (b) demonstrates enhancement of the aneurysm sac (arrow), which is consistent with a Type II endoleak.

Figure 12. MRA demonstrates enhancement in the aneurysm sac (arrow in a), which is consistent with a Type I endoleak as seen on coronal MRA image (b).

Beyond subjective assessment, CEUS also has the capability for objective and quantitative analysis. In detail, it is possible to draw a region of interest within the excluded aneurysm sac or aortic lumen in order to create a time-intensity curve, visualizing the enhancement pattern in an objective, quantitative and reproducible manner. This capability has been applied in endoleak detection, yielding 99% sensitivity and 93% specificity, explained by the significantly increased enhancement of excluded aneurysm sacs containing an endoleak.³⁹

Figure 7 shows a case demonstrating the value of CEUS imaging in detecting endoleaks and CEUS use to assess treatment success after endoleak embolization procedure. The use of three-dimensional (3D) technology has been recently incorporated in clinical CEUS imaging, allowing for even higher sensitivity compared to the two-dimensional technique, and improving correlation with findings on CTA. In one study, 3D CEUS was the only technique that could detect inflow and outflow of an endoleak in every case while this was possible in 89% of cases with 2D CEUS and only in 67% of cases with CTA. These findings are congruent with the technique's reported superior endoleak characterization and classification ability.⁴⁰ Patients with fenestrated endografts have also been evaluated with 3D CEUS, resulting in equivalent diagnostic accuracy compared with CTA, both for measuring aneurysm diameter and volume, as well as for endoleak detection.⁴¹ In conclusion, there is some evidence to consider integrating CEUS into the surveillance algorithm for post-EVAR patients, but more studies are needed. Specifically, a

Figure 13. CT and MR correlation of a Type II endoleak. CTA (a) shows contrast enhancement within the posterior and right lateral portion of the aneurysm sac (arrow), which is confirmed and more easily visualized on post-gadolinium MRA image (arrow in b). CTA, CT angiography; MRA, magnetic resonance angiography.

randomized trial directly comparing CEUS with CTA is required. CEUS should not likely replace CTA; rather, CEUS can be viewed as complementary to standard B-mode ultrasound and CDUS in an attempt to reduce the number of lifelong CTA studies. CEUS may also be valuable for challenging cases as a problem-solving tool to guide patient management appropriately towards either treatment or short-term imaging follow-up.

MAGNETIC RESONANCE ANGIOGRAPHY

MRA using gadolinium contrast has been explored as a possible method to detect and monitor endoleaks in specific situations and to reduce radiation exposure. Importantly, MRA can only be used if patients have MR compatible endograft. Specifically, compatible grafts include those composed of nitinol, which is an alloy of nickel and titanium. MR non-compatible grafts include any variety of ferromagnetic material. MR contraindications also need to be considered, namely claustrophobia, the presence of other ferromagnetic indwelling devices such as pacemakers, as well as advanced kidney disease.

MRA has the ability to produce high resolution images that can detect aneurysm sac expansion, device position changes, luminal patency and the presence of endoleaks. The main advantage of MRA compared to CTA is that with MRA it is possible to obtain multiple acquisitions following contrast media injection without increasing the radiation dose. MRA also offers the ability to analyze hemodynamics with techniques like computational fluid dynamics and 4D phase-contrast MRA.^{42–44} A recent meta-analysis showed MRA to be more sensitive than CTA at detecting endoleaks, especially Type II endoleaks, and suggested MRA be used in cases in which CTA findings are equivocal or show aneurysm sac expansion without definitive endoleak detection.⁴⁵ The estimated sensitivity and specificity of MRA for detecting endoleaks is 96 and 100%, respectively, with an estimated accuracy of 99%.⁷ In cases of endotension, where the aneurysm sac is expanding without detecting an endoleak using CTA or CEUS, MRA may be considered as a problem-solving tool. Due to the exquisitely high sensitivity of MRA for the detection of endoleaks, there is continuous debate whether the additional endoleaks detected using MRA are clinically significant.⁴⁶ Further analyses are needed to determine if the extra costs involved with MRA and increased likelihood of detecting endoleaks translates into superior outcomes. Therefore, based on current evidence, MRA should be used only as a problem-solving tool in selected patients.

Figures 8–14 show several example cases demonstrating the value and technique of MRA in detecting endoleaks.

The main drawbacks of MRA are lack of availability, specifically with regard to expertise, high associated cost, scan duration and susceptibility artifacts depending on the type of endograft. Another disadvantage of MRA is that it does not allow for direct visualization of the endograft. Consequently, assessment of device integrity cannot be performed, and so an additional X-ray image must be obtained for this purpose. For these reasons, MRA is not likely to be used in the near future as routine surveillance modality but may be considered for specific indications.

Figure 14. CT and MRI correlation of Type II endoleak. Coronal CTA image (a) and sagittal MRA images (b and c) show contrast accumulation within the excluded aneurysm sac. This patient has a past medical history of Marfan syndrome status post-thoracic endovascular aortic repair for chronically expanding aortic dissection. After progression of the dissection, aorta bi-iliac endograft extension was performed in this patient. CTA, CT angiography; MRA, magnetic resonance angiography.

CONCLUSION

Post-EVAR patients require lifelong imaging surveillance to detect complications such as endoleaks. Endoleaks are common post-EVAR, and can be fatal if they lead to aneurysm sac rupture. CTA is the current standard method to monitor post-EVAR patients due to its high reproducibility, high diagnostic accuracy and wide availability. However, serial CTA monitoring exposes patients to cumulative doses of radiation and nephrotoxic contrast agent. As a result, there has been interest in exploring alternative imaging modalities to monitor post-EVAR patients and detect endoleaks. In many studies and meta-analyses, CEUS has demonstrated similar or superior accuracy to CTA in detecting endoleaks, and may therefore be integrated in future post-EVAR routine surveillance protocols. Drawbacks of CEUS include its operator dependency and the requirement for specialized equipment. MRA is more sensitive than CTA at detecting endoleaks, but expertise at performing it is not widely

available. Additionally, only patients with non-ferromagnetic graft materials can undergo MRA studies. Therefore, MRA is unlikely to become the dominant imaging modality in routine post-EVAR surveillance. MRA can serve as a problem-solving tool for cases of suspected endoleak, as well as for patients who have undergone embolization procedures for endoleak treatment.

ETHICAL STANDARDS

All research on human subjects in this study has been carried out in accordance with the standards set out in the Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans. The research procedures involved in this study were reviewed by an Institutional Review Board, which determined this project is not human subject research, according to federal regulations. As such, it does not require Institutional Review Board oversight or approval.

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