Eur J Vasc Endovasc Surg (2018) 56, 40–47

Endovascular Aortic Repair Follow up Protocol Based on Contrast Enhanced Ultrasound Is Safe and Effective☆

Emiliano Chisci [a,*], Linda Harris [b], Azzurra Guidotti [a], Angelica Pecchioli [a], Clara Pigozzi [a], Enrico Barbanti [a], Leonardo Ercolini [c], Stefano Michelagnoli [a]

[a] Department of Surgery, Vascular and Endovascular Surgery Unit, Usl Toscana Centro, "San Giovanni di Dio" Hospital, Florence, Italy
[b] Division of Vascular Surgery, University at Buffalo, State University of New York, NY, USA
[c] Cardiovascular Department Vascular and Endovascular Surgery Unit "S. Donato" Hospital, Arezzo, Italy

WHAT THIS PAPER ADDS

This 4 year retrospective analysis showed that a CEUS based protocol is safe and effective for EVAR surveillance. AAA related mortality, re-intervention, sac shrinkage, and endoleak rate detection was similar to a CTA based EVAR surveillance regimen. In this centre, CDU + CEUS have become the primary follow up modalities leaving CTA as a secondary imaging modality in case of non-diagnostic examinations, dubious imaging and to plan secondary interventions. Moreover, in the last 4 years the use of CTA was reduced by 90%, thereby decreasing unnecessary radiation exposure for patients.

Objectives: The aim of this study was to define the safety and effectiveness of a contrast enhanced ultrasound (CEUS) based follow up for endovascular aortic repair (EVAR) surveillance at a mid-term period (4 years).
Methods: At the tertiary referral centre EVAR surveillance was based on plain abdominal radiograph and duplex ultrasound (CDU), with computed tomography angiography (CTA) reserved for any non-diagnostic imaging during the period 1999–2011 (Group A). From 2012, CEUS was performed when (a) any endoleak was detected at CDU, (b) sac growth $>$ 5 mm within 6 months, and routinely for (c) patients with renal insufficiency (above Stage 3 chronic kidney disease), or (d) iodine contrast allergy (Group B).
Results: A total of 880 patients (mean age 75.6 $\pm$ 8.4 years; 824 male) who underwent EVAR between 1999 and 2015 and with a minimum of 1 year follow up were included. Six hundred and nineteen patients were in Group A (70%) and the remaining 261 in Group B (30%). Median follow up was 48 months (interquartile range 24–84). During the study period 318 CEUS scans were performed with no related complications. Indications for CEUS were the following: (a) 160 (50%) endoleak presence, (b) 34 (11%) significant sac expansions, (c) 91 (29%) renal insufficiency (Stage 3 or above CKD), and 33 (10%) iodine contrast allergies. CEUS was compared with CTA, with additional confirmation by angiographic and operative findings in the case of repair in the first 100 patients. CEUS had 100% sensitivity and 100% specificity in classifying endoleaks. No differences in endoleak, re-interventions and sac shrinkage percentage were seen between the two groups at 4 years. A 4 year analysis of CTA use found a 90% reduction with the introduction of CEUS.
Conclusions: The introduction of a CEUS based protocol for EVAR follow up was safe and effective and it was similar to the previous CTA based follow up protocol with regard to identification of endoleaks in a mid-term period. Moreover, CEUS allowed for 90% reduction of CTA, thereby decreasing radiation exposure for patients.

Article history: Received 19 October 2017, Accepted 7 March 2018, Available online 17 April 2018
Keywords: Endovascular aortic repair follow-up, Contrast-enhanced ultrasound, Computed tomography angiography, Endovascular aortic repair, Endoleaks, Abdominal aortic aneurysm

INTRODUCTION

A protocol for imaging and timing for endovascular aortic aneurysm repair (EVAR) follow up, with reduced radiation and contrast dose, is still under investigation. Various follow up modalities are employed aiming to measure residual aortic sac diameter, detect and classify endoleaks, detect morphological details of the stent graft, graft occlusion, graft infection, and other minor details.[1–3] The primary goal of follow up is to prevent aneurysm rupture. Contrast enhanced ultrasound (CEUS) is one of the more recent modalities of

☆ Presented as oral presentation at the Plenary Session 6 at the Vascular Annual Meeting 2017, San Diego, CA, USA, June 2, 2017.

* Corresponding author. Department of Surgery, Vascular and Endovascular Surgery Unit, "San Giovanni di Dio" Hospital, Via Torregalli, 3, 50124, Florence, Italy.
E-mail address: e.chisci@gmail.com (Emiliano Chisci).

1078-5884/
https://doi.org/10.1016/j.ejvs.2018.03.006

EVAR follow up. It has no risk of contrast nephropathy, and no radiation exposure. The morbidity is very low as reported in recent clinical trials, where the most commonly observed adverse reactions were headache, injection site reaction, and nausea related to the contrast medium.[4–18]

The European Federation of Societies for Ultrasound in Medicine and Biology guidelines recommended the use of CEUS for the detection and characterisation of endoleaks following EVAR and follow up of endoleaks (recommendation level A; 1a).[19] Recently, the literature has reported that > 90% of EVAR patients under follow up do not benefit from surveillance, since imaging alone may lead to unnecessary interventions in 1.4–9% patients.[20–22] Therefore, the current role of a computed tomography angiography (CTA) based follow up has been questioned in favor of a less invasive protocol.[23] The aim of this study was to define the safety and effectiveness of a CEUS based follow up as endovascular aortic repair (EVAR) surveillance at a mid-term period (4 year analysis).

METHODS

Consecutive patients operated on for asymptomatic abdominal aortic aneurysm (AAA) larger than 5.5 cm were included in the current study. Patients with ruptured AAA as an indication for EVAR were excluded, as the surveillance protocol at the institution differs for these patients. All patients were treated from 1999 to 2015 at a single tertiary referral hospital. The patient characteristics, operative data, and follow up details were collected prospectively in a computerised database. All data were analysed retrospectively. The local ethics committee approved the study and patients gave informed consent before the procedure and during follow up to the technique used.

From 1999 to 2012 (Group A) all consecutive EVAR patients were scheduled for post-operative day 1 color duplex ultrasound (CDU) and plain abdominal radiography (X-ray), a 1 month post-operative follow up consisting of CTA, CDU, and clinical check up. The same examinations were performed every 6 months thereafter. In cases with sac shrinkage, CTA was then performed annually. From 2012 forward (Group B) EVAR follow up patients were scheduled for a 1 month post-operative follow up consisting of CDU, X-ray, and clinical check up. Thereafter clinical check-up and CDU were performed every 6 months. In Group B, CEUS was performed when any endoleak was detected at CDU, and in cases of significant sac growth >5 mm within 6 months (growth of both antero-posterior and latero-lateral diameter of the sac of at least 5 mm between two examinations within a 6-month interval). CTA was performed within 3 months following the procedure, but thereafter in cases of non-diagnostic imaging with CDU or CEUS imaging, and to plan a secondary intervention when endoleak was detected by CEUS, or at 4 year intervals. When patients were suffering from renal insufficiency Stage 3 or above chronic kidney disease (CKD) or iodine contrast allergy, CEUS was performed in place of CTA.

Sac shrinkage was considered in any case of reduction of both antero-posterior and latero-lateral diameter of the sac of at least 2 mm in the two last consecutive examinations (sac growth was >2 mm increase in diameter, with significant sac growth at >5 mm). Sac stability was considered if the sac shows the same or 1 mm modification in the antero-posterior and latero-lateral diameter of the sac during the entire follow up.

Contrast enhanced ultrasound imaging technique

CEUS was performed by an experienced (>100 procedures) vascular surgeon in an office based service, using an Esaote MyLab 60 or 90 (Esaote, Genoa, Italy) with 2.5–5-MHz probes. Currently all vascular surgeons of the unit can perform standard CDU and CEUS can be managed by three of them. All patients were screened and selected for one of the four indications mentioned previously. A standard CDU examination was always performed before CEUS. After overnight fasting, a sagittal or transverse scan of the supine patient was performed using the probe. B-mode imaging was used initially to identify the aorta, while the maximum diameter of the aneurysm sac was measured in the transverse plane. The patency of renal arteries was confirmed using spectral Doppler ultrasound. If the renal arteries could not be seen directly (especially when body mass index (BMI) > 30 or obese truncal body habitus) the perfusion of the kidney was investigated by CEUS to confirm adequacy. For this purpose, CEUS was helpful since it can show the perfusion of the kidney with a lot of detail. Direct visualisation of the renal arteries was not feasible in 5–10% of cases. The aorta was scanned from the proximal attachment site of the endograft to the distal point. Using color and spectral Doppler ultrasound, the stent was assessed for perigraft flow, graft stenosis, thrombosis, kinking, and endoleaks, according to the reporting standards for EVAR.[3]

Then CEUS was performed. The contrast used was a second generation agent (SonoVue; Bracco, Milan, Italy) made of sulfur hexafluoride filled microbubbles with flexible lipid shells, which is eliminated through the respiratory system. According to the instruction for use for SonoVue, its use is contraindicated in certain patient populations including those with unstable angina or a recent episode of acute coronary syndrome, and, as such, all patients were screened with regard to the contraindications prior to introduction of the contrast agent. The ultrasound machine was set up with a low mechanical index (0.2–0.3) to avoid early destruction of the microbubbles. Contrast techniques apply a low acoustic pressure to produce images based on non-linear acoustic interaction between the ultrasound systems and the microbubbles. The microbubbles oscillate and resound allowing continuous display of contrast enhancement on grayscale images. A 5 mL bolus of SonoVue was administered through an 18 gauge cannula placed in the antecubital fossa followed by a 5 mL normal saline flush. Similar to what is seen with angiography, immediate endoleak (e.g., simultaneous enhancement of both sac and graft) suggests a graft related Type I or III endoleak whereas a delay of greater than 5 s suggests a Type II endoleak.[13] Thrombotic material inside the graft can be seen as a