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Role of Duplex Scan in Endoleak Detection After Endoluminal Abdominal Aortic Aneurysm Repair*

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Objective: *to validate the role of duplex scan in endoleak detection in postoperative surveillance of endoluminal abdominal aneurysm repair (EAAR).*
Patients and methods: *between April 1997 and March 1999, 103 patients were eligible for duplex and computed tomography (CT) scan after EAAR. Mean follow-up was 8 months (range 1–24 months). The study protocol comprised concurrent examination with colour-duplex and CT scan at 1, 6, and 12 months after EAAR, for a total of 198 concurrent examinations. All duplex scan examinations were performed by two vascular surgeons with the same machine (ATL HDI 3000). Interobserver agreement in endoleak detection ($\kappa = 1$) and in type of endoleak ($\kappa = 0.7$) was evaluated in 50 random duplex examinations. Endoleak detection was examined comparatively in duplex and CT scan, the latter being the gold standard. Sensitivity and specificity tests together with negative- and positive-predictive values (NPV and PPV) were calculated.*
Results: *duplex scan was not feasible in one patient. On CT scan the endoleak rate was 4% at one month, 3% at 6 months, and 4% at one year. Overall, CT scan detected 12 endoleaks. With respect to endoleak detection, duplex scan revealed a great ability in ruling out false-negative results (sensitivity 91.7%, NPV 99.4%), but overestimated the presence of endoleak (specificity 98.4%, PPV 78.6%). Regarding type of endoleak, the ability of duplex scan to identify the source of endoleak was low (sensitivity 66.7%).*
Conclusions: *duplex scan, if validated, appears to be a reliable means for excluding the presence of endoleak after EAAR.*

Key Words: Aneurysm; Aorta; Endoleak; Duplex scan.

Introduction

Follow-up is one of the most significant issues associated with endoluminal abdominal aortic aneurysm repair (EAAR). Long-term surveillance of the endoluminal procedure is not sufficient to assess safety and performance of the technique. Patients are required to undergo frequent examinations to exclude aneurysm expansion, leakage, or rupture. Contrast-enhanced computed tomography (CT), angiography, and angio RM are the imaging techniques commonly employed in follow-up of EAAR. Shortcomings associated with these techniques include invasiveness, use of contrast media with potential renal function impairment, costs, and patient compliance. Duplex scan represents the first-line diagnostic tool in follow-up of peripheral vascular procedures, yet its potential in follow-up of EAAR, with advantages related to low cost, non-invasiveness, and applicability in the majority of patients, has scarcely been examined.[1–3]

Several parameters are needed to evaluate the outcome of EAAR, yet ruling out the presence of endoleak is a critical issue in that, if present, risk of aneurysm rupture persists. In an attempt to simplify follow-up after EAAR, we designed a protocol to validate the role of duplex scan in postoperative surveillance.

Patients and Methods

Between April 1997 and March 1999, 154 patients underwent EAAR at the Unit of Vascular Surgery, Policlinico Monteluce in Perugia, Italy. The AneuRx stent graft was employed in 144 procedures, the Gore Excluder in 9 procedures, and the Talent graft in one.

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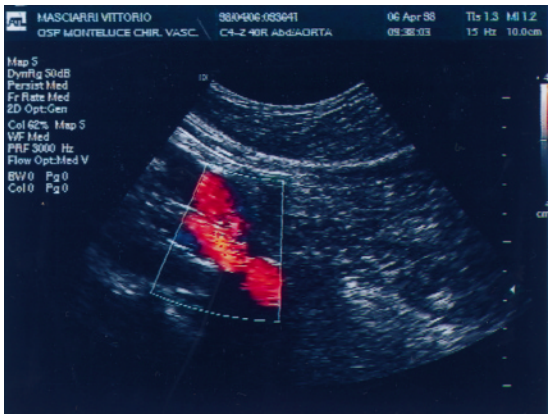

Fig. 1. Longitudinal section of abdominal aortic endografting: Colour flow is visualised within and out of the endograft in continuity of the inferior mesenteric artery, suggestive of a non-graft-related endoleak.

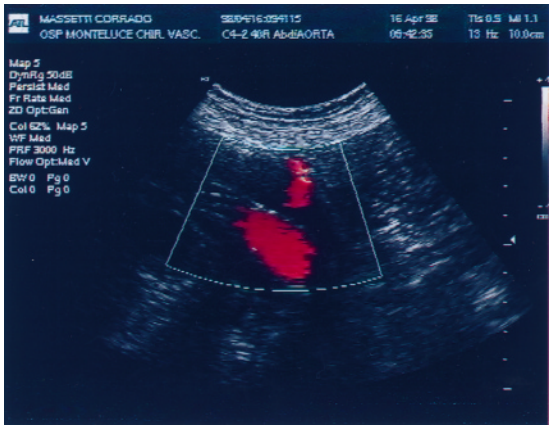

Fig. 2. Colour duplex scan: Longitudinal section of abdominal aortic endografting: simultaneous visualisation of colour signal within and out of the proximal neck of the aneurysm, suggestive of a graft-related endoleak.

Perioperative and late mortality occurred in 1% and 2% of patients, respectively; 2% of the patients required conversion to open repair. On CT scan the endoleak rates at 1, 6, and 12 months after surgery were 5%, 5%, and 3%, respectively. After surgery, patients were entered in a follow-up protocol consisting of colour-duplex and CT-scan examinations scheduled at 1, 6, and 12 months after surgery, and every 6 months thereafter. At discharge only duplex-scan examination was performed. In the case of an endoleak that appeared to be graft-related, or associated with an increase of the aneurysm diameter, or that persisted for over one year, digital subtraction angiography was performed. Compliance with the study protocol was not achieved in 51 patients for different reasons including perioperative death (two patients), conversion to open repair (four patients), duplex scan performed in a different centre in patients from out of town, and patient refusal. In addition, CT scan was not performed in patients with renal insufficiency or in need of a different imaging technique (i.e. angiography in patients subjected to adjunctive peripheral revascularisation), or patient compliance. Three patients (2%) were excluded from the study protocol because of inadequate duplex visualisation of the abdominal aortic aneurysm (AAA) sac due to obesity or intestinal gas. Overall, 103 patients were eligible for inclusion in the study protocol, for a total of 198 concurrent examinations. All patients underwent repair with a bifurcated modular graft. Mean follow-up of the study cohort was 8.5 months (range 1–24 months).

Colour-duplex ultrasound was performed with an ATL 3000 HDI system (Advanced Technology Laboratory) with a C4-2 MHz curved array transducer. Low frequencies were used and colour Doppler settings were optimised to avoid excessive overgain (i.e. colour artefacts that may fill the colour box) or undergain (i.e. absence of colour flow within the aortic graft). The scanhead was applied in both the transverse and longitudinal views to obtain colour and Doppler optimisation. The entire AAA sac, proximal and distal necks, the aorta, iliac and femoral arteries were systematically imaged and measurements were performed on both sagittal and transverse views. The presence of perigraft endoleaks was suspected when a reproducible colour signal outside the endograft and within the aneurysmal sac was visualised. All suspected endoleaks were further evaluated with the Doppler signal to avoid colour artefacts. When the presence of both the Doppler and colour signal outside the endograft and within the aneurysmal sac were observed, the presence of an endoleak was assessed. In the presence of endoleak, the location, flow direction, and extent of AAA sac involvement were recorded. Reperfusion of the aneurysmal sac in continuity with a lumbar artery or inferior mesenteric artery, without other source of aneurysmal refilling, was defined as non-graft-related endoleak (Fig. 1). Aneurysmal colour refilling originating from the proximal, distal, or mid-graft portion of the endograft was defined as graft-related endoleak (Fig. 2).

Two vascular surgeons (PDR and BP), with extensive vascular ultrasound experience (>5 years), performed all duplex-scan examinations. To determine inter-observer variability in duplex-scan endoleak detection and type of endoleak, a random sample of patients in the present series was examined by both physicians. Fifty patients from the study cohort were enrolled in the reproducibility study and examined independently on the same day by the two investigators who were blinded to their respective control values until conclusion of the study. No adjustments of transducer

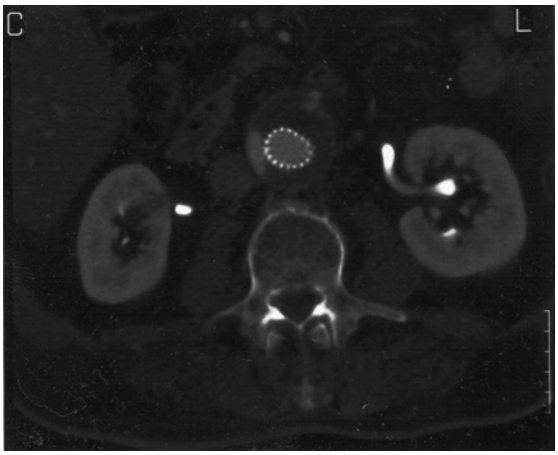

Fig. 3. CT scan of AAA following endoluminal repair. There is an extravasation (endoleak) of contrast into the aneurysmal sac.

selection, scan direction, or Doppler/colour settings were made by the two investigators. Duplex investigation required an average of 10–15 min per patient. The interobserver variability was randomly tested in different stages of follow-up, including the duplex studies performed at discharge.

Interobserver variability for interpretation of the presence and type of endoleak was assessed with kappa (κ) statistics, in which the degree of agreement between the different physicians was defined using the scale of Landis and Koch:[4] less than 0.00, poor; 0.00 to 0.20, slight; 0.21 to 0.40, fair; 0.41 to 0.60, moderate; 0.61 to 0.80, substantial; and 0.81 to 1.0, almost perfect.

In the present study contrast-enhanced CT scan was considered the gold standard in endoleak detection and classification, and was performed with 5-mm-thick slices in 162 studies (82%) and with 3-mm-thick slices in the balance, from above the superior mesenteric artery to the level of the origin of the common femoral artery. Spiral or axial CT scans (78 and 120, respectively) were obtained at different time intervals according to the study protocol. Spiral CT was acquired with a collimation of 5 mm and table speed of 5 mm (pitch = 1). An average of 140 cc of iso-osmotic, non-ionic iodinated contrast media was injected 25 seconds before imaging acquisition. All CT scans were centrally reviewed by the same vascular surgeon (FV) who established the presence or absence of endoleak. Endoleak was diagnosed in the presence, in the axial reconstruction, of contrast outside the lumen of the endoluminal graft and within the aneurysmal sac (Fig. 3). Medium contrast within the aneurysmal sac that appeared in continuity with the proximal or distal implant zones was interpreted as a graft-related endoleak, whereas a small amount of contrast medium near the entry of a patent inferior mesenteric or lumbar artery, implying retrograde flow, was interpreted as a non-graft-related endoleak. The interpretation of all colour-duplex and CT scans was blinded to all concurrent and prior studies.

Sensitivity and specificity tests together with negative and positive-predictive values (NPV and PPV) and accuracy of colour-duplex scan versus the gold standard (CT) were calculated.

Table 1. Demographics and anatomical features of 103 patients.

Mean age (years)		70.1 ± 6.7	
Mean AAA diameter (mm)		50.2 ± 8.3	
		No.	%
ASA[16] IV		19	19
Eurostar classification[17]	A	18	17
	B	62	61
	C	7	7
	D	7	7
	E	8	8

Results

Demographics and anatomical and clinical information of the study population are reported in Table 1. Ninety-one per cent of the study population were males. Major complications occurred in six patients (6%) and included a non-disabling stroke during a secondary endovascular procedure (this patient had a brachial wire), occlusion of the endograft limb (warranting a femoral–femoral bypass in one case and regional fibrinolysis in another), renal infarction due to covering of the right renal artery by the endograft treated with nephrectomy, asymptomatic occlusion of a renal artery, and intraoperative rupture of a common iliac artery treated with an iliofemoral bypass. Late death occurred in 3 patients (3%) and was caused by pulmonary embolism in a patient undergoing hip replacement, by cancer, and by myocardial infarction.

Interobserver agreement using colour-duplex scan, tested in the 50 random patients entered in the reproducibility study, revealed a κ classification of "almost perfect" (κ = 1) for assessment of the presence of endoleak and of "substantial agreement" (κ = 0.7) in defining the type of endoleak, according to the scale of Landis and Koch.[4]

At discharge, 25 endoleaks were detected at duplex scan. Five of these were classified as graft-related: 4 were immediately corrected by positioning a graft extension, and in the remaining case the patient refused any additional treatment. Of 198 concurrent CT and colour-duplex-scan examinations, 102 were

performed 1 month after surgery, 64 at 6 months and 32 at 12 months of surgery. Overall a total of 12 endoleaks were detected on CT scan: 50% were graft-related. Duplex scan performed concurrently with the CT examinations revealed 14 endoleaks, 4 of which were graft-related. With respect to the presence of endoleak, CT and colour-duplex scans were conflicting in 4 cases (2%), with a resulting colour-duplex-scan sensitivity of 91.7%, specificity of 98.4%, PPV of 78.6%, NPV of 99.4%, and accuracy of 98%. In detail, duplex scan failed to show one endoleak (1 false negative) and revealed 3 endoleaks not confirmed by CT scan examination (3 false positives). Digital subtraction angiography performed on these 4 patients revealed the absence of endoleak in all cases.

With respect to type of endoleak, of the 11 endoleaks detected both by CT and colour-duplex scan, there was discordance in 2 cases. Based on the 2 colour-duplex-scan examinations, reperfusion of the aneurysmal sac appeared in continuity with the inferior mesenteric artery and the 2 endoleaks were classified as non-graft-related. Inversely, in these 2 patients CT scan revealed accumulation of the majority of the contrast media in the area of the proximal implant zone, suggesting the presence of a graft-related endoleak in accordance with digital subtraction angiography obtained subsequently. Thus, the ability of colour-duplex scan to identify the source of endoleak showed a sensitivity of 66%, specificity of 100%, PPV of 100%, NPV of 71%, and accuracy of 82%.

Discussion

Follow-up after EAAR is as crucial as it is difficult to attain. Cuypers *et al.*, in a recent study reporting the EUROSTAR experience, showed that the ratio between observed and expected data was acceptable up to 12 months after operation, but declined to a disappointing 40% at 18 months.[5] Likewise, in the Italian AneuRx Register (RITA), which comprises the experience of 23 Italian centres with the AneuRx stent graft and has a lighter follow-up than EUROSTAR (differently from EUROSTAR, no imaging follow-up is obtained in the RITA registry at the three-month interval after surgery), 44% of follow-up data are incomplete at 6 months after surgery, reaching a discouraging 56% at one year (unpublished data). These data are representative of the difficulties related to postoperative management of EAAR. Several reasons may explain these disappointing figures, one being that, from the patient's perspective, the operation appears minimally invasive, thereby not justifying frequent verification of technical success. The possibility of decreasing frequency and invasiveness of follow-up, without detracting from reliability, may help to achieve adequate surveillance of EAAR. The present study confirmed that colour-duplex scan is a sensitive means for excluding the presence of endoleak and, when suggestive of the absence of endoleak, was accurate in 99.4% of the cases. Despite these encouraging figures on the performance of colour-duplex, there is still much to be done before the role of invasive monitoring techniques can be substantially reduced.

Lindholt *et al.* recently published a study on the validity of ultrasonographic scanning for AAA screening by measuring the maximal anterior–posterior diameter, and reported an estimated diagnostic sensitivity and specificity of 98.9% and 99.9%, respectively.[6] These and other data[7] indicate that there is potential for colour-duplex ultrasound in all facets of EAAR surveillance, also considering that the use of ultrasound contrast agents, not employed in the present experience, may improve diagnostic confidence and further refine overall anatomical evaluation.[8–10]

Given the subjectivity of ultrasound evaluation, related to operator dependency, it is of paramount importance that the duplex technique be validated in each centre so that reproducibility can be guaranteed. In our opinion, validation implies not only testing interobserver variability but also comparing the technique with a gold standard. In fact, regardless of a possible excellent interobserver agreement, there may be scarce concordance with the gold standard due to non-optimal duplex equipment. In the present study, CT scan was considered the gold standard, in agreement with others[1] and in line with the extensive use of CT scan in assessing outcome of EAAR in most centres.[11–14] In this regard, White *et al.* suggested that CT scanning may be more sensitive than angiography in the detection of endoleak.[15] In our opinion, angiography has a crucial role in endoleak evaluation, especially in defining the source of the endoleak. Although we do not use it in routine follow-up of EAAR, in the presence of a graft-related endoleak, of endoleak associated with aneurysm expansion, or persisting for over 1 year, angiography is performed.

Based on our data, colour-duplex alone is not reliable in follow-up of EAAR, also considering that we have focused on one of the technical aspects needed to evaluate outcome of EAAR, i.e. the ability of colour-duplex scan to identify endoleak. However, in the case of negative colour-duplex evaluation, CT scan may be postponed to the next follow-up appointment. Absence of endoleak does not necessarily mean that the risk of rupture has been avoided. Other important parameters

for monitoring EAAR patients are the evaluation of the aneurysm diameter and shrinkage.

In summary, in our experience colour-duplex scan failed to show only one endoleak when compared to the gold standard. Conversely, it was less effective in defining type of endoleak. Given its high sensitivity and NPV, colour-duplex scan may be optimally applied as a screening test in follow-up of EAAR. When the presence of an endoleak is suspected, a more aggressive diagnostic approach is required.

From the data presented herein, it is evident that further investigation is needed to define the conclusive role of colour-duplex scan in postoperative surveillance of EAAR. Duplex-scan appears to be a reliable means for excluding the presence of endoleak after EAAR. In an attempt to decrease invasiveness and frequency of follow-up after EAAR, duplex scan may be a valuable tool for identifying patients in need of aggressive and invasive postoperative surveillance, thereby representing a key component in individualising follow-up.

References

1 Sato DT, Goff CD, Gregory ET *et al.* Endoleak after aortic stent graft repair: diagnosis by color duplex ultrasound scan versus computed tomographic scan. *J Vasc Surg* 1998; **28**: 657–663.

2 Heilberger P, Schun C, Ritter W, Weber S, Raithel D. Postoperative color flow duplex scanning in aortic endografting. *J Endovasc Surg* 1997; **4**: 262–271.

3 Giannoni MF, Bilotta F, Fiorani L, Fiorani P. Regarding "Reduction in aortic aneurysm size: early results after endovascular graft replacement". Letter. *J Vasc Surg* 1998; **27**: 981.

4 Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics* 1977; **33**: 159–174.

5 Cuypers PH, Buth J, Harris PL, Gevers E, Lahey R, on behalf of the EUROSTAR collaborators. Realistic expectations for patients with stent-graft treatment of abdominal aortic aneurysms. Results of a European multicentre registry. *Eur J Vasc Endovasc Surg* 1999; **17**: 507–516.

6 Lindholt JS, Vammen S, Juul S, Henneberg EW, Fasting H. The validity of ultrasonographic scanning as screening method for abdominal aortic aneurysm. *Eur J Vasc Endovasc Surg* 1999; **17**: 472–475.

7 Thompson MM, Boyle JR, Hartshorn T *et al.* Comparison of computed tomography and duplex imaging in assessing aortic morphology following endovascular aneurysm repair. *Br J Surg* 1998; **85**: 346–350.

8 Vogt KC, Jensen F, Schroeder TV. Does Doppler signal enhancement with Levovist improve the diagnostic confidence of duplex scanning of the iliac arteries? A pilot study with correlation to intravascular ultrasound. *Eur J Ultrasound* 1998; **7**: 159–165.

9 Calliada F, Campani R, Bottinelli O, Bozzini A, Sommaruga MG. Ultrasound contrast agents: basic principles. *Eur J Radiol* 1998; **27** (Suppl. 2): 157–160.

10 Langholz J. Investigation of peripheral arterial disease: the expanding role of echo-enhanced color flow Doppler and duplex sonography. *Eur J Ultrasound* 1998; **7** (Suppl. 3): 53–61.

11 Zarins CK, White RA, Schwarten D *et al.* AneuRx stent graft versus open surgical repair of abdominal aortic aneurysms: multicenter prospective clinical trial. *J Vasc Surg* 1999; **29**: 292–308.

12 Matsumura JS, Pearce WH, McCarthy WG, Yao JST, for the EVT Investigators. Reduction in aortic aneurysm size: early results after endovascular graft placement. *J Vasc Surg* 1997; **25**: 113–123.

13 Brewster DC, Geller SC, Kaufman JA *et al.* Initial experience with endovascular aneurysm repair: comparison of early results with outcome of conventional open repair. *J Vasc Surg* 1998; **27**: 992–1005.

14 May J, White GH, Waugh R *et al.* Adverse events after endoluminal repair of abdominal aortic aneurysms: a comparison between two successive periods of time. *J Vasc Surg* 1999; **29**: 309–316.

15 White JH, Yu W, May J, Chaufour X, Stephen MS. Endoleak as a complication of endoluminal grafting of abdominal aortic aneurysms: classification, incidence, diagnosis, and management. *J Endovasc Surg* 1997; **4**: 152–168.

16 American Society of Anesthesiology. *Basic Standards for Preanesthesia Care.* Park Ridge, IL: American Society of Anesthesiology, 1987.

17 Harris PL, Buth J, Miahle HO, Norgren L. The need for clinical trial of endovascular abdominal aortic aneurysm stent-graft repair: the EUROSTAR project. *J Endovasc Surg* 1997; **4**: 72–77.

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