Endoleak after endovascular aneurysm repair: Duplex ultrasound imaging is better than computed tomography at determining the need for intervention

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Objective: **Color duplex ultrasound (CDU) imaging is a noninvasive alternative to computed tomography (CT) for the detection of endoleak. This study compared CT and CDU imaging in the detection of endoleaks requiring intervention after endovascular aneurysm repair (EVAR).**
Methods: **All EVARs performed at our institution from 1996 to 2007 were retrospectively reviewed. CDU and CT scans ≤3 months were paired and the presence of an endoleak and its type were recorded. Clinical follow-up was reviewed and interventions for endoleak were recorded. Interventions were performed for type I, for type II with sac enlargement, and for type III endoleaks. The first analysis of clinical test outcomes used the findings of CT scan as a gold standard and the second used the findings at time of intervention as a gold standard.**
Results: **During the time period reviewed, 496 patients underwent EVAR, and 236 of these had CDU and CT follow-up studies paired ≤3 months of each other. Mean follow-up was 17 months (range, <1-111 months). We reviewed 944 studies or 472 pairs. Eighteen patients (7.6%) required intervention for 19 endoleaks: six type I, 11 type II, and two type III. Early endoleak (≤1 month) requiring reintervention was detected in 1 vs late endoleak (mean, 28 months; range, 0.6-88 months) in 18. All type I and III endoleaks were treated with endovascular cuff or limb extension placement. Three type II endoleaks were treated with open ligation, and coil or glue embolization was used in eight. CDU imaging detected endoleaks requiring intervention in 89% of cases, whereas CT detected endoleak in 58% (*P* < .05). The ability to correctly identify the type of endoleak as confirmed at time of intervention was 74% with CDU imaging vs 42% by CT (*P* < .05). CDU, for the detection of endoleak requiring intervention, had a sensitivity of 90%, specificity of 81%, negative predictive value (NPV) of 99%, and positive predictive value (PPV) of 16%, while CT had a sensitivity of 58%, specificity of 87%, NPV of 98%, and PPV of 15%.**
Conclusions: **CDU imaging has a high sensitivity in detecting endoleaks requiring intervention, is better at identifying the type of endoleak, and is an excellent test for graft surveillance after endovascular aneurysm repair. Compared with CT scan, CDU imaging in our experience is the preferred test on which to base an intervention for endoleak. (J Vasc Surg 2009;50:1012-8.)**

Endovascular aneurysm repair (EVAR) has become the main treatment of abdominal aortic aneurysms (AAA) during the last decade. Although EVAR has shown decreased morbidity and mortality compared with open AAA repairs, the procedure has also been associated with different rates and types of postoperative complications such as endoleaks.[1-3] These complications can result either in reintervention or in the need for closer surveillance. Hence, long-term surveillance after EVAR has become paramount to identify these complications and allow for secondary interventions to maintain an optimal outcome after EVAR.

A contrast-enhanced computed tomography (CT) scan has been the gold standard for postoperative surveillance of EVAR. CT surveillance, however, is associated with the cumulative risks of contrast nephrotoxicity, radiation exposure, and cost.[4] Recent studies have shown an increased risk of radiation-induced cancer after repeated exposures from CT scans.[5-8] On the other hand, surveillance with color duplex ultrasound (CDU) imaging does not have either of these risks. Although CDU imaging has been used for preoperative AAA surveillance, its role with EVAR surveillance is still debated.[9] There have been conflicting studies on its efficacy compared with CT scan.[10-12] The ultimate success of a screening test is to accurately predict the disease process and guide appropriate interventions.

We reviewed all articles evaluating CDU surveillance for endografts using CT scan as a gold standard. We performed a retrospective review of our experience with CDU and CT surveillance to detect endoleaks and whether this correctly correlated with the actual findings at the time of reintervention after EVAR. We compared both imaging studies to a common measure, the endoleak detected at the time of intervention.

PATIENTS AND METHODS

A retrospective review was performed on patients with AAAs who underwent elective treatment with EVAR from

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July 11, 1996, through March 31, 2007. Only patients with paired imaging studies (CDU and CT) ≤3 months of each other were included. The analysis excluded patients with symptomatic or ruptured AAA and isolated iliac aneurysms. Patient demographics, clinic notes, preoperative CT/CDU scans, operative reports, types of EVAR devices, CT and CDU surveillance studies were reviewed after approval by the Institutional Review Board.

CDU or CT examinations within a week of each other were scheduled at 1, 3, 6, and 12 months, and annually thereafter. We adhered to our CDU imaging protocol previously reported by Sato et al.[12] After an overnight fast, patients were placed supine and studied with a low frequency (range, 2.5-5 MHz) curved array, phased array, or mechanical sector, and pulsed Doppler scan transducer. The endograft, proximal and distal fixation points, and the AAA sac were imaged in B-mode. The size of the AAA sac was measured.

The CDU scan was performed in sagittal and transverse views to evaluate the AAA sac for the presence of flow outside the graft. Perigraft leaks were identified when reproducible, pulsatile color Doppler scan flow images were present outside the graft and within the AAA sac. Focus was directed at the superior and inferior stent attachment, the anterior mid-AAA sac (inferior mesenteric artery), and the posterior mid-AAA sac (lumbar arteries). CDU scan evidence of an endoleak required the identification of perigraft Doppler scan signals with color flow and was confirmed with spectral analysis and mapping of blood flow pattern (Fig).

All CDU examinations occurred in a peripheral vascular laboratory accredited by the Intersocietal Commission for the Accreditation of Vascular Laboratories and were performed by vascular technicians with RVTS certification after being proctored by senior technicians. The results were read by vascular surgeons.

CT scan surveillance was performed using a GE Lightspeed plus 16-slice scanner (GE Healthcare, Waukesha, Wis) using 2.5-mm acquisition slice. Omnipaque 350 contrast (120 mL; GE Healthcare) was injected at a rate of 4 to 5 mL/s using SmartPrep software (GE Healthcare). The arterial phase acquisition was obtained by an average delay of 25 seconds after injection. The delayed phase was obtained at 70 seconds after completion of first scan. CT scan reconstruction used a 0.625-mm format.

Interpretation of CT scan results was performed by radiology, whereas vascular surgery interpreted CDU results. Vascular surgeons made clinical decisions by reviewing both imaging modalities and the patient's clinical findings. Endoleaks were categorized as type I, type II, type III or indeterminate. The CDU examination was considered inadequate if the endograft graft was poorly or incompletely seen secondary to patient habitus or obscured by bowel gas. In this study, only adequate CDU studies were examined. Studies were adequate if they visualized (1) the AAA residual sac, (2) the proximal and distal fixation points, and (3) the endograft and bilateral limbs. An internal review of CDU for EVAR surveillance revealed a 1% rate of inadequate studies.

The types of reinterventions, findings at reintervention, and the paired imaging studies obtained ≤3 months before reintervention were evaluated. The type of endoleak reported at the time of intervention was compared with the predicted type of endoleak by imaging studies. The type of endoleak found at the time of intervention was determined by angiography or open surgical findings. Early endoleaks and reinterventions were defined by detection or intervention ≤30 days of EVAR deployment. Late endoleaks and reinterventions were defined by detection or intervention after 30 days of EVAR deployment.

Commercially available and investigational devices were used during the study period. They included 160 AneuRx (Medtronic, Santa Rosa, Calif), 55 Ancure/EVT (Guidant, Indianapolis, Ind), 13 Zenith (Cook, Indianapolis, Ind), 5 Powerlink (Endologix, Irvine, Calif), 2 Excluder (W. L. Gore & Associates, Flagstaff, Ariz), and 1 Quantum (Cordis, New Brunswick, NJ).

Data were analyzed using XLStat software (Addinsoft USA, New York, NY). Continuous data are expressed as mean with standard deviation and were compared using the *t* test. Noncontinuous data are expressed as percentages and were compared by using the *z* test comparison for proportions. $P < .05$ was considered statistically significant. CDU/CT surveillance analysis was performed in two segments. First, CDU/CT were analyzed in a two-by-two grid for sensitivity, specificity, negative predictive value (NPV), and positive predictive value (PPV). CT scan was used as a gold standard. The second analysis (reintervention analysis) used the type of endoleak detected at the time of reintervention as the gold standard for both CDU imaging and CT.

RESULTS

Surveillance analysis. From July 11, 1996, through March 31, 2007, 496 consecutive patients underwent an EVAR procedure. Paired CDU and CT imaging studies were obtained in 236 patients, of which 202 (86%) were men. The mean age at the time EVAR was 72 years (range, 51-90 years). The study population compromised 211 whites (89%), 20 African Americans (8%), 4 Asians (2%), and 1 Hispanic.

The analysis reviewed 472 paired imaging studies or 944 studies. The mean interval between CDU and CT scans was 18 days (range, 0-90 days), and 33% of paired studies were performed ≤4 days of each other. A CT scan was obtained before CDU scan 69% of the time (n = 325), a CDU study was obtained before the CT scan 15% of the time (n = 71), and both studies were obtained on the same day 16% of the time (n = 76). There were no statistically significant differences in these intervals in patients with endoleaks vs those without endoleaks, nor in patients requiring an intervention vs those without an intervention. The mean follow-up time was 17 months (ranged, <1-111 months).

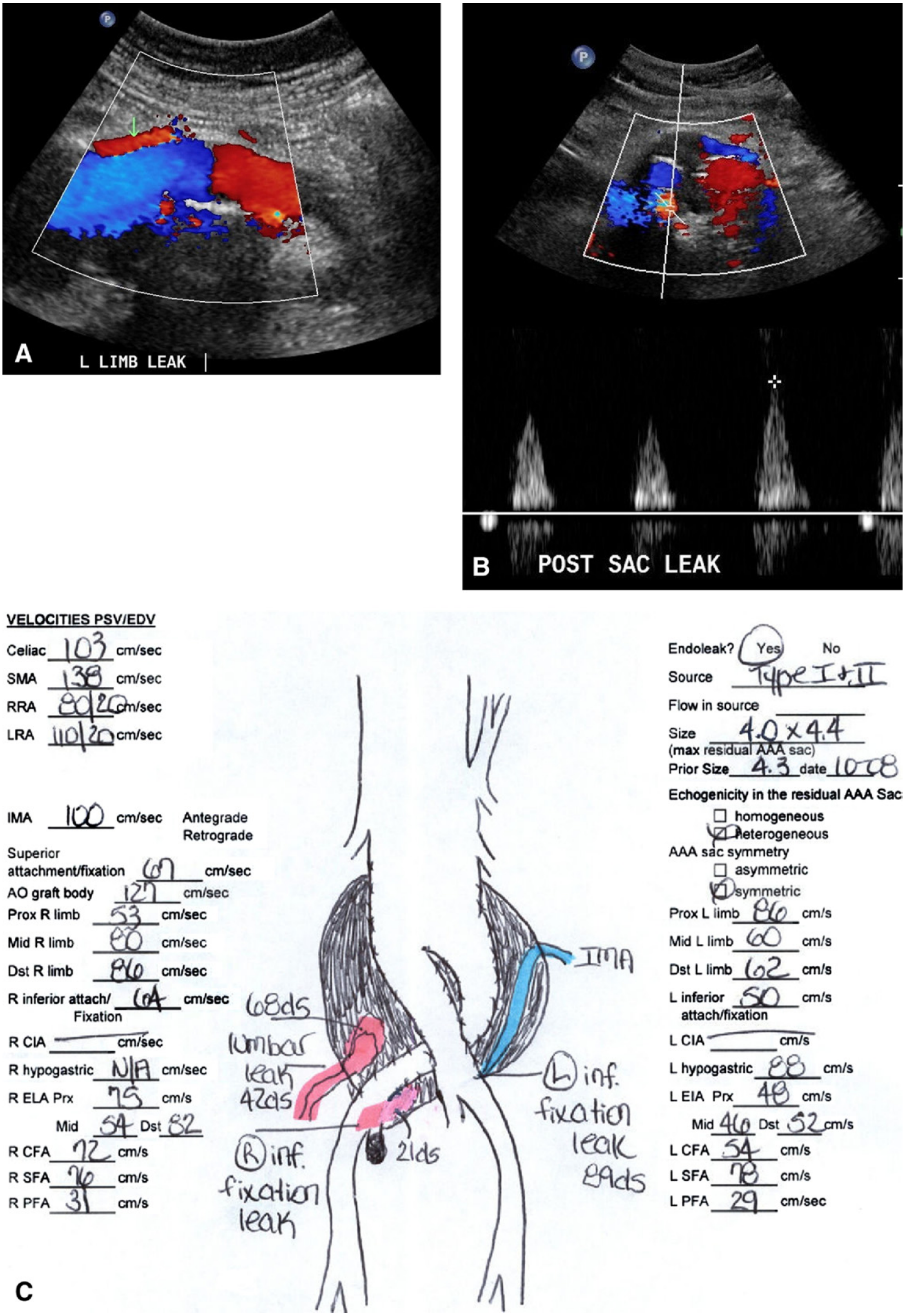

Fig. An example of **(A)** a type I and **(B)** type II endoleak in one patient by color duplex ultrasound imaging with **(C)** attached worksheet.

Table I. Overall endoleak detection of color duplex ultrasound vs computed tomography scan[a]

	Color duplex ultrasound		
	Positive	*Negative*	*Totals*
CT scan			
Positive	48	27	75
Negative	62	335	397
Totals	110	362	472

CT, computed tomography.
[a]Sensitivity, 64%; specificity, 84%; positive predictive value, 44%; negative predictive value; 93%.

Table II. Overall endoleak detection at time of reintervention for (A) color duplex ultrasound imaging and (B) computed tomography scan

	Intervention		
	Yes	*No*	*Totals*
A			
CDU[a]			
Positive	17	88	105
Negative	2	365	367
Totals	19	453	472
B			
CT scan[b]			
Positive	11	61	72
Negative	8	392	400
Totals	19	453	472

CDU, Color duplex ultrasonography; *CT,* computed tomography.
[a]Sensitivity, 90%; specificity, 81%; positive predictive value, 16%; negative predictive value, 99%.
[b]Sensitivity, 58%; specificity, 87%; positive predictive value, 15%; negative predictive value, 98%.

Overall, 137 endoleaks (29% of paired studies) were detected by CT or CDU scan. There were 8 type I endoleaks, 123 type II endoleaks, 4 type III endoleaks, and 2 indeterminate endoleaks (one detected by CDU only and the other detected by CT only). During the surveillance, 91 patients (39%) were found to have an endoleak, comprising 25 endoleaks ≤30 days (18%) compared with 112 late endoleaks (82%). CDU imaging detected 110 endoleaks compared with 75 by CT, which was significant ($P < .01$). There was moderate agreement between the two tests for detection of endoleak by association analysis ($\kappa = 0.42$).

The CDU sensitivity, specificity, PPV, and NPV for overall endoleak detection were 64%, 84%, 44%, and 93% (Table I). CDU imaging showed a trend toward better detection of type I endoleaks compared with CT scan (CDU, 7 of 8 vs CT, 4 of 8; $P = .10$). CDU and CT performed equally well for type III endoleak detection (CDU, 3 of 4 vs CT, 4 of 4; $P = .29$). The CDU sensitivity, specificity, PPV, and NPV for type I endoleaks were 75%, 99%, 43%, respectively, and for type III endoleaks, 99% and 75%, 100%, 100%, and 99%. CDU performed better than CT at detection of type II endoleaks (CDU, 99 of 123 vs CT, 66 of 123; $P < .05$). CDU sensitivity, specificity, PPV, and NPV for type II endoleaks were 64%, 86%, 42%, and 94%, respectively.

Reintervention analysis. To better compare the clinical utility of these two modalities, the endoleak confirmed at time of reintervention was used as the gold standard to compare CDU imaging and CT. Eighteen patients (7.6%) required interventions for 19 endoleaks, comprising six type I, 11 type II, and two type III. One early (≤1 month) endoleak reintervention occurred vs 18 late (mean, 28 months; range, 0.6-88 months) endoleak reinterventions. All type I and III endoleaks were treated with endovascular cuff or limb extension placement. Type II endoleaks underwent intervention if there was aneurysmal sac enlargement or large aneurysmal sac with failure to regress. Three type II endoleaks were treated with open ligation, whereas coil or glue embolization was used in eight.

CDU detected an endoleak requiring intervention in 89% of cases, whereas CT detected endoleak in only 58% ($P < .05$). The ability to correctly identify the type of endoleak as confirmed at time of intervention was 74% with CDU compared with 42% by CT ($P < .05$). CDU missed one type I and one type II endoleaks. CDU also incorrectly detected type II endoleaks for one actual type I and two type III endoleaks. CT scan missed two type I and six type II endoleaks and incorrectly detected type II endoleaks for one actual type I endoleak and two type III endoleaks. For the detection of endoleak requiring intervention, CDU imaging had a sensitivity of 90%, specificity of 81%, NPV of 99%, and PPV 16%, whereas CT had a sensitivity of 58%, specificity of 87%, NPV of 98%, and PPV of 15% (Table II, *A* and *B*).

DISCUSSION

The goal of surveillance or screening tests is to not miss a diagnosis or complication; that is, have a high sensitivity and NPV. The crux of this assessment lies in the chosen gold standard. For AAA screening and surveillance, CDU imaging has been the modality of choice.[9] For EVAR surveillance, a contrast CT scan as a comparison standard has been an arbitrary choice. Studies comparing CDU with CT scan for endoleak detection have produced mixed results. Sato et al[12] and d'Audiffret et al[13] both showed that CDU is an excellent screening test for endoleaks, with sensitivities of 97% and 96%, respectively. Elkouri et al,[10] however, found poor results for CDU endoleak detection, with a sensitivity of 25% and specificity of 89%. Most studies comparing CDU with CT for endoleak detection, however, show modest sensitivities of 52% to 81% and good NPV of 86% to 95%.[14-18] This study also shows a modest sensitivity of 64%, but an excellent NPV of 93%. Our results almost mirror the meta-analysis results of Sun,[19] which showed an overall sensitivity, specificity, PPV, and NPV value for endoleaks of 66%, 93%, 76%, and 90%, respectively.

Although CDU sensitivity for overall endoleak detection appears adequate at best, the decrease in sensitivity occurred for type II endoleaks. CDU sensitivity for type I and III endoleak detection is excellent. AbuRahma et al[18] found a similar pattern of worse outcomes for type II endoleak detection vs type I. This decreased sensitivity can be partially attributed to the statistics using CT scan as the gold standard. If CDU were used as the gold standard, then CT would have a sensitivity of 44%. This study also showed that CDU detected more type II endoleaks than CT by a ratio of 1.5:1. Other studies have confirmed the ability of CDU to better detect type II endoleaks than CT, with ratios varying up to 2:1.[11-13] Some studies have increased detection of type II endoleaks with ultrasound contrast.[20,21] Although contrast-enhanced CDU imaging may aid in decreasing missed type II endoleaks, it increases the amount of false-positive results, may be too sensitive, and increases the cost of the study, the time of the study, and the invasiveness of the study because patients require an intravenous catheter. Finally, these studies have been in small cohorts, and this experience has not been used more broadly to truly assess its efficacy.

Overall, it appears that CDU provides an excellent ability to detect type I and type III endoleaks, which are the most worrisome endoleaks that require reintervention. Our results also show that CT scans fail to show 50% of type I endoleaks. We believe this results from confusion of distal type I endoleaks for type II endoleaks with a static image from a CT scan, whereas CDU can provide a more dynamic picture illustrating the higher velocity flow associated with type I endoleaks. On the other hand, several studies have shown that both imaging modalities may miss type II endoleaks. Hence, neither CT nor CDU imaging will detect all type II endoleaks, nor do they need to detect all endoleaks. Fortunately, the fate of type II endoleaks usually follows a benign and often sporadic course. In addition, this fate is intertwined with aneurysmal sac size, which may ultimately serve as the main marker for EVAR surveillance. Therefore, type II endoleak detection may be less important than aneurysmal sac size.

The reintervention analysis is an attempt to compare CDU with CT by using a shared gold standard of endoleak confirmation at the time of reintervention. These results clearly show that CDU imaging not only performs better for endoleak detection than CT but also for identification of the type of endoleak. This analysis, however, was performed on a small subset of patients.

Which test is better? Neither test is or will be the perfect screening test for EVAR surveillance. CDU imaging does have limitations:

- It is operator-dependent, which may lead to disparate findings between the different technicians.
- Suboptimal examinations due to body habitus or bowel gas can compromise results. An internal review of our CDU examinations during 1 year showed about 1% of studies were inadequate; however, this will vary according to experience and patient population.
- Availability and time commitment restricts its broader use; whereas CT scanners are ubiquitous and fast.
- The ability of CDU to detect endograft migration is currently unknown.

The limitations of CDU must be weighed with its benefits. CDU offers no exposure to radiation, intravenous contrast, and cheaper cost. On the other hand, CT scan surveillance is more expensive and exposes patients to cumulative risks of radiation and intravenous contrast. Recent studies have raised awareness of the increased risk of cancer after repeated exposures from CT scans.[5-8] We have obtained both CT scans and CDU imaging for EVAR surveillance for several years. This provided a way to validate the use of CDU. Over time this practice has evolved, with some patients getting only CT scan, others CDU only, and still others obtaining both.

Our study has several limitations. First, its retrospective design contributed to incomplete data collection for some preprocedural and postprocedural variables. A retrospective study can also introduce selection bias into patient subsets. Our use of CDU, however, has been extensive and has never been used selectively.

Second, there was an average of 18 days between the CDU and CT scans. Although this time frame between tests is relatively small, the behavior of endoleaks, recurring and sealing, can be variable. This could lead to overestimation or underestimation of endoleak detection by each modality. Ideally, all scans would be perfectly paired each day and every patient would follow our protocol. In clinical practice, however, scheduling conflicts arise that limit the ability to obtain both imaging studies in the same day. This is retrospective study in which own surveillance protocol was followed as best as possible.

Third, a wide variety of endografts were used during the study. The variability of performance between the different endografts may have confounded the outcomes. This, however, reflects a true clinical practice. And the ability of CDU imaging to monitor a variety of endografts despite their different characteristics reaffirms its utility in EVAR surveillance.

CONCLUSION

Duplex ultrasound imaging has a high sensitivity and negative predictive value in detecting endoleaks requiring intervention, is better at identifying the type of endoleak, and is an excellent test for graft surveillance after endovascular aneurysm repair. Compared with CT scan, our experience shows DU is the preferred test on which to base an intervention for endoleak.

AUTHOR CONTRIBUTIONS

Conception and design: GCS, JP
Analysis and interpretation: GCS, JP
Data collection: GCS, CS
Writing the article: GCS
Critical revision of the article: GCS, CS, GKS, FP, JP
Final approval of the article: GCS, GKS, FP, JP
Statistical analysis: GCS, CS

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Overall responsibility: GS, JP

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DISCUSSION

Britt Tonnessen, MD (*New Orleans, La*). Thank you for an excellent presentation on a topic of great interest to us all. In prior publications, the group from Norfolk has championed the use of Duplex ultrasound for the identification of endoleaks. Still, sensitivity of endoleak detection, measured up against CT, ranges from 12% to 97% in the literature. The most obvious rationale for this discrepancy is the variability among vascular laboratories and lack of a standardized protocol, as the authors emphasize.

In this robust retrospective study, the authors identified more endoleaks on US than on CT-particularly type II endoleaks. The crux of this manuscript is in the authors' contention that US is, in their hands, more frequently able to identify those patients who require a secondary procedure for their endoleak. They found a sensitivity of 90% for US versus 58% for CT. Just so that we do not lose total confidence in CT, a negative CT did successfully rule out endoleak requiring intervention 98% of the time.

One shortcoming of these data is that the examinations were not performed concurrently. Potentially, endoleaks may have resolved or appeared during the mean of 18 days between paired the studies, introducing the possibility of a type I statistical error.

Skepticism aside, many of us have already adopted Duplex ultrasound as part of our post-EVAR surveillance. Lack of a standardized regimen incorporating US has likely led to disparate practices. At this meeting last year, data was presented that showed that the absence of endoleak on the 1 and 12 month CT predicts low aneurysm related morbidity with one endovascular device. A more "relaxed" regimen of CT follow-up, incorporating Duplex, may be appropriate in this setting. Such algorithms need to be prospectively validated and standardized.

I have the following questions for the authors:

1. What is the current surveillance algorithm in Norfolk? Given the variability in ultrasound quality, do the authors believe that this algorithm should and can be widely adopted?
2. Migration is one post-EVAR complication that is time-dependent, often occurring late in the follow-up. Migration is best detected prior to the development of a type I endoleak. Particularly with devices reported to have high migration rates, how do you intend to follow these patients for migration?
3. If we assume that many of these endoleaks caught on US but not on CT were "low-flow" and not false positives, how did the authors decide when a type II endoleak was "clinically significant"? In other words, what was your threshold for intervention?

Gregory C. Schmieder, MD. Thank you for your questions. The first question is about our surveillance protocol. We recently adopted a protocol of duplex ultrasound at six months, twelve months, eighteen and twenty-four months; no routine CT scans. If there are any questions about an endoleak or we are concerned secondary to sac enlargement or some other finding, then a CT scan will be obtained. We use CT scans in a more isolated and directed approach. In regards to migration, this is one of the weak elements of a color duplex ultrasound exam. As you mentioned, however, the development of a Type 1 endoleak is the most concerning outcome from migration. As we have demonstrated, you can clearly detect Type 1 endoleaks very well with duplex color ultrasound. Also, we are currently looking at measurements of the distance from the renal artery to the stent grafts with duplex to see if we can truly get a good measurement using duplex ultrasound and that is a current ongoing study. The third question is how we determine when patients get reinterventions for Type 2 endoleaks which as you mentioned were detected more with ultrasound compared to CT scan. Most of that decision is based on clinical variables, such as sac size enlargement. Is there an absolute definitive number that we use at our institution? No. Some of it is surgeon-specific. Also, another indication for intervention is a persistent endoleak without sac regression in a large aneurysm, which has been shown in studies to have more adverse outcomes.