CT Versus Color Duplex Ultrasound for Surveillance After EVAR

An analysis of the correlation between the two modalities.

BY ALI F. ABURAHMA, MD

During the last several years, endovascular repair of AAAs (EVAR) has become a viable option. FDA approval of commercially available endovascular exclusion devices, such as Ancure (Guidant, Indianapolis, IN), AneuRx (Medtronic, Inc., Santa Rosa, CA), Excluder (Gore & Associates, Flagstaff, AZ), and Zenith (Cook Incorporated, Bloomington, IN) has led to an increasing number of endovascular repairs of infrarenal AAAs. With the increased use of endovascular techniques for AAA repair, follow-up surveillance is increasingly important. Although endovascular techniques for AAA repair harbor obvious initial advantages over traditional open AAA repair, potential adverse events unique to endovascular grafts warrant lifelong surveillance. Two of these potential events include graft endoleak and increasing or changing aneurysm size. Whereas most experts agree that lifelong follow-up of endovascular graft patients is necessary, the method of follow-up continues to evolve.

Computed tomography (CT) and color duplex ultrasound (CDUS) have been used to evaluate patients after EVAR. Some studies have suggested that CDUS may be as effective as CT for detection of endoleak and diameter changes, whereas others maintain that CT is superior to CDUS as a modality for follow-up of patients undergoing EVAR.

This study was conducted to examine the role of CT versus CDUS[1-3] in the follow-up of patients with endovascular grafts for AAAs, and to compare both modalities for detecting endoleak and their accuracy in measuring AAA diameters after endovascular repair.[4]

PATIENT POPULATION AND METHODS

Patients with an AAA who underwent endovascular repair using three commercially available devices (Ancure, AneuRx, and Excluder) were analyzed. A preoperative work-up of these patients included CDUS and CT.

CT Scanning

Helical CT was performed using the Philips System (Shelton, CT). Both noncontrast and contrast studies were performed. After intravenous administration of 125 mL of Optiray 350 (Mallinckrodt, a Tyco Healthcare Company, St. Louis, MO), axial images of the abdominal aorta were obtained and were reformatted in 3D multiple rotational projections, and sagittal and coronal projections. Measurements were made with electronic calipers. CT scans were obtained using 3-mm slice thick-

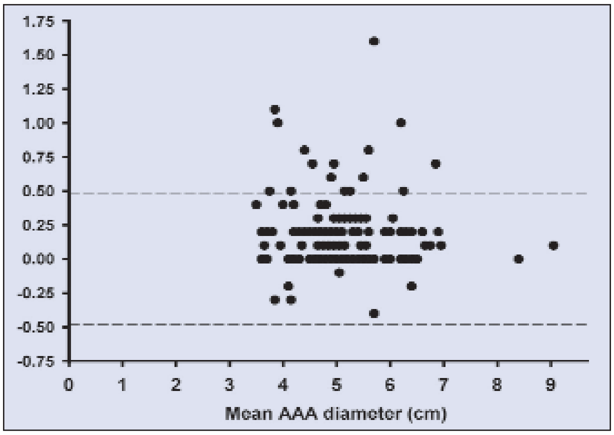

Figure 1. All CT and CDUS AAA diameter readings (178 preoperative and 189 postoperative, 367 pairs).

ness throughout the scan, which started 1 cm above the celiac trunk and ended at the femoral bifurcation.

CDUS

All CDUS scans were performed in an accredited vascular laboratory by a registered vascular technologist. The studies were reviewed by a board certified vascular surgeon and registered vascular technologist. The CDUS exams were performed using the ATL 5000 HDI Philips System. Transverse and anteroposterior imaging were performed from the level of the suprarenal aorta, above the graft, and through the distal iliac or femoral arteries. Doppler spectral analysis and color Doppler evaluation of the endovascular graft was performed to identify any evidence of abnormal flow or a leak in the excluded aneurysm.

Our follow-up protocol included serial CT scans and CDUS at 1 month and every 6 months thereafter. CT scans and CDUS exams were considered concurrent if they were done within 7 days.

Primary or early endoleak was defined as a leak detected within 30 days of the procedure, and late endoleak was defined as a leak observed beyond 30 days after the procedure. A leak was determined using CT scans based on extravasation of contrast material between the prosthesis and the aneurysm wall, or by CDUS, if the flow and spectral signals were outside the prosthesis.

Statistical Methods

CT scanning was the gold standard in determining the sensitivity, specificity, positive predictive value, and negative predictive value of CDUS for detecting endoleak. The kappa statistic was used to determine the level of agreement in identifying endoleaks between CDUS and CT scans. The Pearson correlation coefficient was used to determine the degree of association between CT scans and CDUS AAA size measurements preoperatively and after EVAR. Aneurysm maximal diameter was compared on serial examinations to assess for growth or shrinkage of the AAA. Both unpaired and paired *t* tests were used to examine the difference between CT and CDUS before and after repair. A P value <.05 was considered significant. To show how far apart the results of the two methods were, the Bland-Altman method was used to establish the limits of agreement by calculating the mean difference ± 1.96 times the standard deviation, thus expecting 95% of differences between measurements by CT and CDUS to lie between those limits of agreement.

RESULTS

One hundred seventy-eight patients were included in this study (device distribution was 86 Ancure, 55 AneuRx, 37 Excluder). The mean age of the group was 74 years (range, 49-89 years). Follow-up ranged from 1 to 53 months (mean, 16 months). Three hundred sixty-seven paired studies (CT and CDUS) were available for analysis.

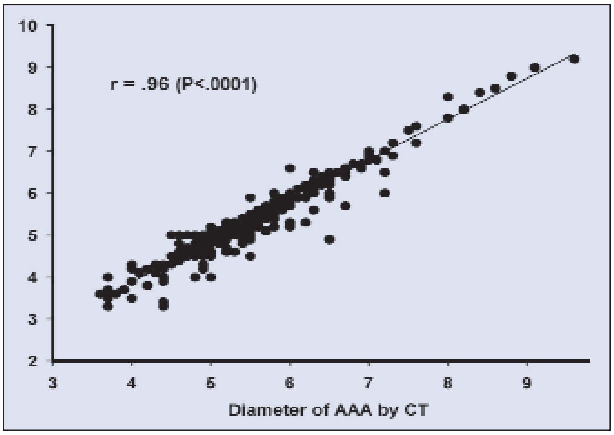

Figure 2. Bland-Altman plot of postoperative CT and CDUS AAA diameter measurements (n=189).

Correlation of CT Scans and CDUS for AAA Size

The mean diameter of AAAs was larger on CT scanning than on CDUS (5.45 vs 5.3; P=.02). Maximal diameter as measured by CT scans and CDUS correlated closely, as noted in Figure 1 for all studies (preoperative and postoperative combined; r=.96; P<.0001). Overall, 93% of paired studies (CT scans and CDUS) were somewhat similar (≤5 mm difference; 341 of 367; 93%). In 26 of 367 (7%), the CT scans were >.5 cm than CDUS.

Figure 2 shows the Bland-Altman plot of postoperative CT scans and CDUS measurements, which demonstrated consistent variability in all AAA diameters, with the CT scan usually exceeding the CDUS measurement. The mean difference was .154 cm (95% CI; .119 to .190 cm). The upper limit of agreement was .624 cm (95% CI; .573 to .695 cm). The lower limit of agreement was -.326 (95% CI; -.265 to -.387 cm). The limits of agreement were created to show that 95% of the CDUS measurements should be between 0.326 cm below and 0.634 cm above those of CT. However, only 94.2% of the subjects were within these limits, and 11 of the 189 were outside of the established limits of agreement.

Prediction of Endoleak

Overall, there were 34 endoleaks in 31 patients; 26 (14.6%) were early endoleaks and eight (4.5%) were late endoleaks. Three patients had both early and late endoleaks. The 26 early endoleaks included 11 (6.2%) type I, 13 (7.3%) type II, and two (1.1%) type IV endoleaks, whereas the eight late endoleaks included five

(2.7%) type I and three (1.6%) type II endoleaks. There were 12 endoleaks with the Ancure device (seven early and five late), 13 endoleaks with the AneuRx device (11 early and two late), and nine endoleaks with the Excluder (eight early and one late). The proportion of endoleaks by device was not different (*P*=.13). The sensitivity, specificity, positive predictive value, and negative predictive value of CDUS in detecting early endoleak were 65%, 100%, 100%, and 94% (kappa coefficient = .76). The sensitivity, specificity, positive predictive value, and negative predictive value in detecting late endoleaks were 75%, 98%, 60%, and 99% (kappa coefficient = .65). Overall, the sensitivity, specificity, positive predictive value, and negative predictive value of CDUS in detecting all endoleaks were 68%, 99%, 85%, and 97% (kappa coefficient = .73). CDUS was more likely to predict type I endoleaks than type II endoleaks (14 of 16 [87.5%] for type I endoleak vs eight of 16 [50%] for type II endoleak; *P*=.046).

The mean change in AAA diameter on CT was statistically significantly different in patients with late endoleak versus patients with no late endoleak (0.21 vs -0.65, respectively; *P*<.0001). Similarly, the change in AAA diameter on CDUS was statistically significantly different in patients with late endoleak than in patients with no endoleak (+0.28 cm vs -0.62 cm; *P*<.001).

Fate of Endoleak

Of 26 early endoleaks, 13 were type II endoleaks, 12 of which sealed spontaneously, and one persisted as a late endoleak and the patient is being observed. Eleven were type I endoleaks, of which two persisted as late endoleaks, one of which is being observed and the other patient was treated with proximal cuff extension. Of the eight late endoleaks, three also had early endoleak, whereas five only had late endoleak. Three of these late endoleaks were treated; two with proximal cuff extensions and one with a distal iliac cuff extension. One is being observed, and the other patient refused further treatment.

DISCUSSION

There is a need for an accurate, cost-effective means of postoperative surveillance for EVAR. CT scans have long been accepted as the gold standard for surveillance; however, recent improvements in duplex ultrasound technology have evolved and may offer some advantages.

Duplex ultrasound has been a well-known method of preoperative evaluation of aneurysms, as well as surveillance of small aneurysms before they require surgery. CDUS offers the advantages of lower cost, easier accessibility, and no need for ionizing radiation or nephrotoxic dye exposure. However, CT has other benefits, including faster image acquisition, it is less influenced by body habitus, and it is highly reproducible. CDUS is also more operator-dependent and can be affected by the patient's fasting status. In our study, we were able to demonstrate that CDUS is as effective as CT scanning in measuring aneurysm diameter after exclusion by an endovascular device,[1-3] however, CDUS was somewhat inferior to CT scanning in demonstrating endoleak, particularly type II endoleaks.

"CT scans have long been accepted as the gold standard for surveillance; . . . recent improvements in duplex ultrasound technology have evolved and may offer some advantages."

The sensitivity of CDUS in determining the diameter of the aneurysm after EVAR was adequate in our study.[4] There was a good correlation between CT and CDUS in determining AAA diameter changes over time. Therefore, detecting AAA diameter changes can be performed rather adequately by either method. In 93% of the cases, the diameters obtained with both modalities were within 5 mm of each other. These data would indicate that CDUS is an adequate method to monitor the aneurysm size after EVAR. It is well-known that an increase in the size of the aneurysm increases the risk for rupture and will probably require some type of intervention, such as a repeat endovascular procedure or conversion to an open technique to prevent rupture.

It is imperative to identify endoleaks after EVAR. Whereas type I and type III endoleaks may require immediate intervention, type II endoleaks, in the absence of aneurysmal dilation, may be followed with increased surveillance. This information indicates the necessity to identify endoleaks during postoperative surveillance. Our study indicated that CDUS, with a sensitivity of 67%, is not as effective as CT scanning in detecting endoleaks. CDUS was particularly inferior in identification of type II endoleaks (50%).

Other studies reported that CDUS was fairly reliable for surveillance of AAA diameter, but had a 42% sensitivity in detecting endoleaks. Other studies have reported sensitivities of 12% for unenhanced ultrasound scanning and 50% for enhanced power Doppler using contrast agents.[5]

Despite these limitations, several studies have documented excellent results using CDUS in endovascular graft surveillance.[6] Sato et al reported a sensitivity of 97%, with a negative predictive value of 98% in detection of

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endoleak.[3] It should be noted that in their study, and in reviewing several CDUS examinations from several different centers, they concluded that only 19% of these studies were technically adequate, suggesting that significant differences exist between various CDUS performed at different institutions. Therefore, it is critical for each medical center to evaluate the result of the CDUS and compare it to the CT scan prior to recommending the method of choice for follow-up in these patients.

Recently, several authorities have advocated the addition of contrast agents for increasing the sensitivity of CDUS for endoleak detection. McWilliams et al[6] concluded that the addition of Levovist (Berlex, Canada) improved the sensitivity of CDUS, but the number of false-positive results increased, which they attributed to overestimation of the endoleak to either the blooming of the color arising from adjacent vessels or to aneurysmal wall inflammation. Bendick et al[7] recently reported on the use of a different contrast agent (Optison, Mallinckrodt) combined with digitally encoded tissue harmonic imaging, which helps to suppress the artifacts associated with CDUS, and they found no false-positive studies.

CONCLUSION

Although CDUS has good correlation to CT in measuring the size of AAAs, it has a lower sensitivity in detecting endoleaks, particularly type II endoleaks. Therefore, CT scans should remain the primary imaging for the diagnosis of endoleak. ■

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