Duplex ultrasound imaging alone is sufficient for midterm endovascular aneurysm repair surveillance: A cost analysis study and prospective comparison with computed tomography scan

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Objective: **Early in our experience with endovascular aortic aneurysm repair (EVAR) we performed both serial computed tomography scans and duplex ultrasound (DU) imaging in our post-EVAR surveillance regimen. Later we conducted a prospective study with DU imaging as the sole surveillance study and determined cost savings and outcome using this strategy.**

Methods: **From September 21, 1998, to May 30, 2008, 250 patients underwent EVAR at our hospital. Before July 1, 2004, EVAR patients underwent CT and DU imaging performed every 6 months during the first year and then annually if no problems were identified (group 1). We compared aneurysm sac size, presence of endoleak, and graft patency between the two scanning modalities. After July 1, 2004, patients underwent surveillance using DU imaging as the sole surveillance study unless a problem was detected (group 2). CT and DU imaging charges for each regimen were compared using our 2008 health system pricing and Medicare reimbursements. All DU examinations were performed in our accredited noninvasive vascular laboratory by experienced technologists. Statistical analysis was performed using Pearson correlation coefficient.**

Results: **DU and CT scans were equivalent in determining aneurysm sac diameter after EVAR ($P < .001$). DU and CT were each as likely to falsely suggest an endoleak when none existed and were as likely to miss an endoleak. Using DU imaging alone would have reduced cost of EVAR surveillance by 29% ($534,356) in group 1. Cost savings of $1595 per patient per year were realized in group 2 by eliminating CT scan surveillance. None of the group 2 patients sustained an adverse event such as rupture, graft migration, or limb occlusion as a result of having DU imaging performed as the sole follow-up modality.**

Conclusion: **Surveillance of EVAR patients can be performed accurately, safely, and cost-effectively with DU as the sole imaging study. (J Vasc Surg 2009;50:1019-24.)**

Despite many clinical benefits and widespread use, enthusiasm for endovascular abdominal aneurysm repair (EVAR) has been tempered by long-term concerns. To date, computed tomography (CT) has been the preferred modality to detect EVAR-related complications such as migration, endoleak, and stent graft thrombosis.[1] The recommended practice of performing CT scans at 1, 6, and 12 months, and annually thereafter is included in the instructions for all marketed devices, which were carried through from regulatory trials.[2] Limited data have been published concerning the efficacy of this regimen.

The need for lifelong surveillance for potential complications has also called into question the cost-effectiveness of EVAR.[3-8] A recent study reported that >65% of postoperative EVAR costs are due to CT scanning alone.[9] Medicare reimbursement often fails to meet hospital costs of EVAR.[4] Hospitals and health care systems, already faced with escalating costs, may find that financial considerations will influence use of EVAR. Although CT remains the most commonly used modality for post-EVAR surveillance, cost is not the only drawback. Radiation exposure after repeated examinations is a significant consideration.[10] Contrast nephropathy and allergy are another concern: contrast nephropathy affects 7% to 12% of patients after CT angiography.[11,12]

For these reasons, alternative surveillance methods, such as duplex ultrasound (DU) imaging, have been explored. Recent studies have confirmed that DU surveillance is a safe and effective modality for analyzing infrarenal abdominal aortic aneurysm (AAA) sac dimensions, endoleak detection, and graft patency.[1,13-17]

Because of the disadvantages of CT scans and our confidence in our noninvasive vascular laboratory, we began to prospectively use DU as the sole imaging study after EVAR, aside from a single CT scan in the immediate postoperative period. We analyzed AAA sac diameter, presence of endoleak, and graft patency, and compared the utility of using DU scanning alone vs both DU and CT scanning as surveillance tools. In addition, we performed a cost analysis for the two different protocols.

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METHODS

From September 21, 1998, to May 30, 2008, 250 patients underwent EVAR on the vascular surgery service at Pennsylvania Hospital in Philadelphia. Five types of endografts were used during this time-period: Ancure (Endovascular Technologies, Menlo Park, Calif) early in our experience and later AneuRx (Medtronic, Minneapolis, Minn), Excluder (W.L. Gore and Associates Inc, Flagstaff, Ariz), Zenith (Cook Medical Inc, Bloomington, Ind), and Powerlink (Endologix, Irvine, Calif).

The original surveillance protocol was modeled from that suggested by EVAR regulatory trials, registries, and device manufacturers.[2] Before July 1, 2004, our protocol consisted of CT and DU scanning ≤2 weeks of discharge, at 6 and 12 months, and then yearly (group 1). After this date, we obtained one CT and DU scan ≤2 weeks of surgery and then performed DU examinations at 6 and 12 months and then yearly if no problems were detected (group 2). Some patients had CT scans at other institutions besides ours and were included in the analysis, but all patients in this series had follow-up DU scans performed in our vascular laboratory in Philadelphia or at a satellite office in southern New Jersey by the same technologists. If CT or DU suggested an endoleak, an expanding AAA sac diameter, or a significant stenosis in the limb of a graft, more frequent or invasive studies and intervention were done when necessary.

All patients were included in a prospectively maintained computerized registry (Access, Microsoft Corp, Redmond, Wash). Hospital, office, and noninvasive vascular laboratory records were reviewed to determine AAA post-EVAR sac diameters, endoleak rate, and graft patency. Graft limb stenosis was defined as stenosis or kinking based on a focal elevated peak systolic velocity three times higher than the normal adjacent site.

A true-positive study was defined as one where concomitant (performed ≤1 month of each other) CT and DU examinations confirmed an endoleak or graft stenosis or where concomitant studies disagreed but subsequent CT, DU scans, or arteriography during follow-up confirmed the abnormality found on the original study. A false-positive study was defined as a study that suggested a problem that was discordant with the concomitant alternative study, and with subsequent CT, DU imaging, or arteriography not confirming the problem. A false-negative study was one in which the imaging study missed a problem but other concomitant or subsequent studies confirmed an abnormality. Questionable findings were those in which a problem was identified by one study but no other studies were performed ≤1 month to confirm or contradict the finding, and no subsequent studies were performed. False-positive and false-negative statistics were compared with the Fischer exact test, with $P < .05$ considered significant.

CT scanning was performed using a standardized endograft protocol with delayed dual spiral imaging before and after (60- and 120-second delays) administration of a 175- to 200-mL bolus of intravenous contrast. Multiple axial images were taken using 2-mm slices with a 1.5-mm reconstruction algorithm throughout the abdomen and pelvis.

DU examination was performed in our accredited vascular laboratory (International Committee of Accredited Vascular Laboratory) by one of three certified technologists. DU imaging equipment equipped with 10.4 software did not change over the study period (Philips HD-11, Philips HDI-5000, Philips HDI-3000; Bothell, Wash). During DU examinations, the aorta was scanned in long-axis and in cross-sectional views from the diaphragm distally to the common femoral arteries. Residual aneurysm sac diameter was measured. Arterial flow hemodynamics were documented throughout the endograft using spectral Doppler velocity measurements. Color Doppler imaging was adjusted for optimum sensitivity for lower velocities.

The entire endograft and aneurysm sac were scanned to detect any endoleaks. Endoleaks were classified as occurring at the proximal or distal attachment sites (type I), at graft module junctions (type III), or secondary to patent aortic branch vessels (type II), such as the inferior mesenteric artery or lumbar arteries, which demonstrated collateral filling and back-bleeding into the aneurysm sac. Presence or absence of endoleaks by DU imaging was based primarily on real-time B-mode image data with spectral Doppler recordings.

CT and DU measurements of AAA sac diameter were compared using the Pearson correlation coefficient, with $P < .05$ considered significant. All statistical analysis was performed using SPSS software (SPSS Inc, Chicago, Ill).

Charges for CT and DU EVAR surveillance were compared using 2008 health system charges and 2008 Medicare reimbursements. Our health system charges for a complete CT scan with EVAR protocol included abdominal ($4052) and pelvic ($4052) views for a total charge of $8104. Our health system charges for aortic DU EVAR protocols were $360 per study. Medicare reimbursements were $949 for a complete CT scan with EVAR protocol and $232 for a DU study.

RESULTS

Of the 250 patients who underwent EVAR during the study period, 51 were excluded from analysis primarily because our noninvasive vascular laboratory was not able to perform surveillance DU studies due to incompatibility with third-party payer reimbursements, inadequate follow-up intervals, or data points were insufficient to make meaningful comparisons. The remaining 199 patients comprised group 1 (82 patients) and group 2 (117 patients). The average age of patients was 73 years (range, 63-82 years), and 80% were men. The average diameter of the AAAs treated with EVAR was 5.8 cm (range, 4.4-9.7 cm). AneuRx (Medtronic, Minneapolis, Minn) grafts were the most commonly placed endografts in our series (36%; Table I). Very rarely we needed to perform CT scans instead of DU imaging for extremely obese patients, but these patients were not included in this report.

Table I. Demographics and devices used for group 1 and group 2, broken down into patients with and without an endoleak

Variable [a]	*Group 1 (n = 82)*		*Group 2 (n = 117)*		*Total (n = 199)*
	No endoleak	*Endoleak*	*No endoleak*	*Endoleak*	
Age, y	72.71 ± 7.35	74.14 ± 6.81	71.91 ± 8.59	75.10 ± 7.68	72.93 ± 7.93
Sex, male	46 (80.70)	22 (84.62)	63 (77.78)	29 (80.56)	160 (80.00)
Aneurysm size, cm	5.8 ± 0.84	6.0 ± 1.07	5.7 ± 1.22	6.0 ± 1.26	5.8 ± 1.11
Device					
AneuRx	15 (26.79)	11 (40.74)	31 (38.27)	14 (38.89)	71 (35.50)
Excluder	8 (14.29)	2 (7.41)	15 (18.52)	8 (22.22)	33 (16.50)
Cook	9 (16.07)	4 (14.81)	29 (35.80)	14 (38.89)	56 (28.00)
Ancure	24 (42.86)	10 (37.04)	0 (0.00)	0 (0.00)	34 (17.00)
Endologix	0 (0.00)	0 (0.00)	6 (74.10)	0 (0.00)	6 (3.00)

[a]Age and aneurysm sac size are presented as an average with standard deviation, and sex and device type are shown as number and percentage of the total group.

Table II. Patients with false-negative (endoleak was missed) and false-positive (endoleak detected when none existed) detection of endoleak by computed tomography or duplex ultrasound imaging

Modality	*False − No. (%)*	*False + No. (%)*
Computed tomography	11 (5.5)	2 (1.0)
Duplex ultrasound	5 (2.5)	5 (2.5)
Total	16 (8.0)	7 (3.5)

For the 199 patients in this study, 50 (25%) had 54 endoleaks. Four patients, two in each group, had both type I and type II endoleaks, there were eight type I endoleaks (5 in group 1, 3 in group 2), and 46 type II endoleaks (18 in group 1, 28 in group 2). There were 16 endoleaks (6 in group 1, 10 in group 2) detected using one imaging modality that were not confirmed by the other study ≤1 month or because the other modality was not performed at all. The primary reason for lack of confirmatory studies were findings of small type II endoleaks documented by the DU examination without apparent sac expansion. In these circumstances, CT scans were not obtained because no action would likely be taken. Of the 21 endoleaks found in the operating room and at the immediate postoperative CT scan, three resolved by 3 months, one by 6 months, and four by 9 months. Four patients were lost to follow-up by 9 months, leaving nine of 21 endoleaks that persisted at 9 months after EVAR.

An endoleak was missed in 16 patients who had false-negative scans: eight in group 1 (2 DU, 6 CT) and eight in group 2 (3 DU, 5 CT; Table II). Most of these patients had type II endoleaks that did not require intervention. A single type I endoleak was missed by CT scan but found by DU imaging in group 1, which subsequently required an extension cuff. The false-negative rate for CT scans was 5.5% (11 of 199), and the false-negative rate for DU studies was 2.5% (5 of 199; $P = .126$). Thus, there was no significant difference in false-negative scans by CT and DU, although a trend existed favoring DU imaging.

A false-positive examination suggested an endoleak when none existed in seven patients, five in group 1 (4 DU, 1 CT) and two in group 2 (1 DU, 1 CT). Most of the results suggested type II endoleaks, but concomitant studies did not confirm the findings. One type I endoleak was suggested by DU imaging and subsequently ruled out by aortogram; thus, the false-positive rate was 1.0% (2 of 199) for CT and 2.5% (5 of 199) for DU imaging ($P = .253$), which was not significantly different (Table II). DU sensitivity for detecting endoleak was 0.710 and specificity was 0.990, whereas CT sensitivity was 0.731 and specificity was 0.991.

In addition, six possible endoleaks (1 in group 1 and 5 in group 2) were detected by one modality but were not confirmed by subsequent DU scans or CT. The group 1 patient was lost to follow-up; the group 2 patients had small type II endoleaks on DU imaging with no CT performed.

In group 1, 23 endoleaks were demonstrated in 21 of 82 patients (26%) during follow-up: five type I and 18 type II (2 patients had both types I and II). Overall, 10 of the 21 patients (48%) with endoleaks in group 1 underwent surveillance without intervention and 11 (52%) required endovascular intervention, comprising seven cuffs or extension limbs to treat type I endoleaks and six coil embolizations to seal type II endoleaks.

In group 2, 31 endoleaks were demonstrated in 29 of 117 patients (25%): 3 type I and 28 type II (2 patients had both types I and II). Overall, 26 of 29 patients (90%) with endoleaks in group 2 underwent surveillance without intervention and three (10%) required endovascular intervention, which consisted of one percutaneous balloon angioplasty of a previously placed proximal cuff to treat a type I endoleak and one coil embolization to seal a type II endoleak. One patient in group 2 who had a type I endoleak was not treated due to a recent diagnosis of advanced cancer. No patients in either group experienced a ruptured aneurysm after EVAR during the follow-up period.

Surveillance of graft patency using CT and DU imaging was also compared. For the 199 patients in this study, limb migrations or stenosis occurred in seven (4%) that threatened overall endograft patency. Two graft migrations (both

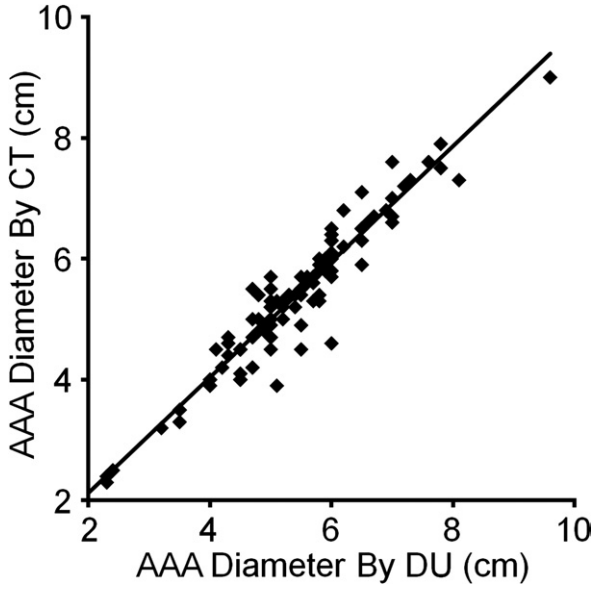

Fig 1. Diameters of aneurysm sacs during surveillance after endovascular abdominal aortic aneurysm *(AAA)* repair are shown in 114 data points from 75 patients comparing computed tomography (*CT*, y axis) and duplex ultrasound (*DU*; x-axis) scans performed ≤1 month of each other. The Pearson correlation coefficient was 0.956, which was statistically significant ($P < .001$).

AneuRx) were both correctly identified by DU and CT (true-positive examinations) and treated with extension cuffs.[18] Five limb stenoses or kinks were identified, one by both CT and DU findings and the other four by DU studies only. Although DU imaging identified these graft-threatening lesions, which were later successfully treated, these studies were not confirmed or refuted by concomitant imaging studies ≤1 month, but instead four of the five lesions underwent elective intervention. The operative findings confirmed the DU findings in all cases. Of these five patients, two were treated with femoral-femoral bypasses, two with balloon angioplasty with stenting, and one with axillary-femoral bypass. The five limbs identified as failing grafts due to stenosis or kinks had peak systolic velocities of 308, 399, 515, 521, and 530 cm/s. These five endograft limbs were two AneuRx, two Ancure, and one Zenith. Four of the five limbs underwent prophylactic intervention, but one graft limb in a high-surgical-risk patient was initially observed. This graft later occluded and thrombosed, resulting in severe ischemia that required urgent intervention. No aneurysm-related deaths occurred during the follow-up, but two patients died secondary to myocardial infarction.

Aneurysm sac diameters after EVAR were compared between DU and CT studies that were performed ≤1 month of each other in group 1. Available for comparison were 114 data points from 75 patients in group 1 (Fig 1). A statistically significant Pearson correlation coefficient of 0.956 ($P < .001$) was established showing DU and CT provided similar findings. Therefore, DU imaging in our study predicted aneurysm sac diameters as precisely as CT, and could be reliably used to determine whether to intervene based on expanding sac size.

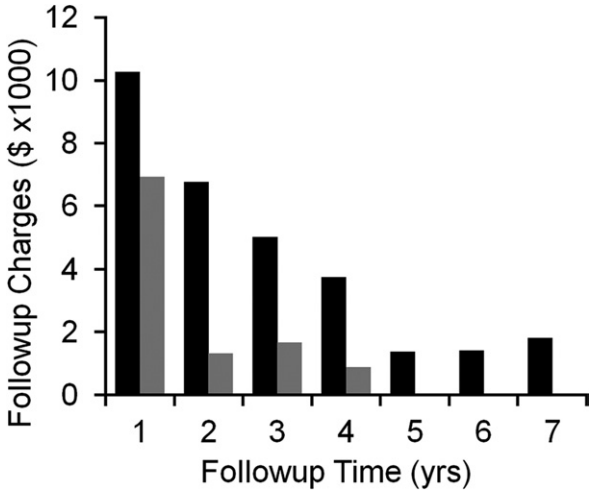

Fig 2. Follow-up charges for group 1 *(black bars)* and group 2 *(gray bars)* are compared based on 2008 health care system pricing (y axis) per patient for each year of follow-up (x axis) after endovascular aneurysm repair and are not cumulative.

Average follow-up with graft surveillance in group 1 patients after EVAR was 3.5 years (range, 0-9 years). Hospital system charges for surveillance studies in group 1 patients, which included 204 CT scans and 550 DU studies, were $1,851,216. Medicare reimbursement for these studies was $321,196. Average follow-up with graft surveillance in our more recently enrolled patients in group 2 was 1.6 years (range, 6 months-4 years). Hospital system charges for surveillance studies for group 2 patients, which included 102 CT scans and 390 DU studies, were $967,008. Medicare charges for group 2 patients were $187,278. Had DU alone been used for graft surveillance of group 1, charges for EVAR surveillance would have been reduced by $534,356 and Medicare reimbursements by $66,163. Charges per patient (y axis) for each year after EVAR (x axis) for group 1 patients were compared with group 2 patients (Fig 2). Charges are high for group 1 patients receiving both CT and DU scans, particularly in the early follow-up period. Decreased charges of $1595 per patient per year or $198 per patient per year using Medicare reimbursements were realized by eliminating CT scan surveillance in group 2. The payor mix for our patients included private insurance, 55%; Medicare, 31%; Medicaid, 8%; and patient pay, 6%.

DISCUSSION

Although previous authors have compared DU and CT scans for surveillance after EVAR, CT scan remains the gold standard to assess aneurysm diameter, presence of endoleak, and graft patency.[13-17,19] The benefits of CT as an imaging modality compared with DU imaging include that it is highly reproducible, less influenced by body habitus,

and offers faster image acquisition. However, among the limitations of CT scans are repeated radiation exposure, potential contrast-related complications, including allergy and renal insufficiency, and high costs.

We have shown that cost savings is substantial when DU imaging alone is used for midterm follow-up vs the accepted approach that requires multiple CT scans. Bendick et al[16] reported that eliminating CT as a surveillance tool after EVAR would represent a 3-year cost savings of >$16,000 per patient.[16] In fact, new surveillance paradigms have already been suggested to reduce the charges associated with EVAR, and to our knowledge, ours is the first prospective study comparing the different surveillance regimens.[19] Kim et al[20] estimated that current reimbursement for long-term EVAR surveillance and secondary procedures using traditional protocols average a net loss of $2235 per patient.

Although hospital system charges vary by institution, Medicare reimbursement schedules are fixed and often used as a benchmark for private insurance payors to determine what a fair market value should be for an imaging study. Reimbursement is not always at the Medicare level and can influence charges. Cumulative reimbursement for the hospital will be less if our protocol is followed, because fewer CT scans will be performed and hospital administrators may not favor this cost-saving strategy.

Inflation and decreasing reimbursements over time affect cost and charges, which makes a true cost analysis difficult. We performed our cost analysis using 2008 health care system charges to reflect the potential cost savings for the current economic climate and with today's health care system, which is significantly different than that of 1998, when our study began. Regardless, the cost savings are substantial when CT and DU are compared for EVAR surveillance.

AAA size reduction over time has been used as a surrogate marker for successful exclusion, thrombosis of the aneurysm sac, and decreased risk of rupture.[21] We showed that CT and DU imaging were equivalent for measuring AAA sac size after EVAR (Fig 1). This finding reassured us that DU imaging alone could potentially serve as the only surveillance study for EVAR patients, at least in terms of identifying sac expansion.

Endoleak detection by DU imaging was as or more accurate than by CT because the false-negative rate for DU was 2.5% compared with 5.5% for CT. The five false-negative DU examinations were not vascular technologist-dependent. Aneurysm sac remodeling may explain why these five endoleaks were detected by DU imaging later during follow-up and not initially by CT, given that sac diameter in each case had changed by at least 0.5 cm in size. Perhaps with aneurysm sac remodeling, back bleeding vessels become more readily apparent. DU imaging may ultimately prove to be more sensitive than CT in detecting endoleaks given its ability to detect subtle flow characteristics within an aneurysm sac. Our technologists were able to document flow velocities in these endoleaks. Arko et al[22] reported that intrasac DU flow velocities may help in predicting whether type II endoleaks will seal spontaneously and therefore not require intervention, suggesting a peak systolic velocity of <80 cm/s as being safe. When type II endoleak peak systolic velocities are elevated >80 cm/s, we recommend more frequent DU follow-up.

When there is any question of sac expansion, or for persistent type II endoleaks with elevated velocities, we would recommend performing CT angiography. Our follow-up in group 2 patients was limited and does not reflect 3-year follow-up, when increasing risk of endoleak may occur. CT requires multiple scans at different contrast times to detect endoleaks and cannot predict which endoleaks will regress. Currently, sac pressure sensors are still largely experimental and confined to a few centers experienced with this technique.[23] Nonetheless, pressure sensors in the sac may prove more accurate and useful than CT or DU scanning in the future.[24,25]

We believe that DU imaging is more accurate than CT in detecting problems that threaten graft patency, such as migration, kinking, and stenosis. Color-flow images give physiologic as well as anatomic information that CT does not. DU imaging accurately predicted all seven cases where graft patency appeared threatened. The ability to quantify and compare serial examinations in a cost-effective, contrast-free, and radiation-safe manner suggests that DU imaging should be the gold standard for EVAR limb patency follow-up. In our opinion, use of plain x-ray films of the abdomen may be an outdated method to detect endograft problems. We believe that DU imaging can almost always accurately determine if structural defects are causing a flow-related problem and graft migration.

This study has some potential weaknesses. DU imaging is more operator-dependent than CT and is significantly affected by the patient's body habitus and fasting status. DU imaging with contrast may prove to be especially useful for obese patients but is not necessarily any better in most patients, especially considering the extra cost and more difficult technique required to use this method.[14,16]

Interobserver variability in technical factors can be another important limitation in the diagnostic value of DU imaging.[26] Several reports have shown that DU measurements of AAA diameter vary greatly compared with CT; in our vascular laboratory, they did not. We believe each vascular laboratory needs to do its own comparison of CT and DU imaging to determine accuracy.

The safety of DU imaging in post-EVAR surveillance should be tested in one's own noninvasive vascular laboratory before it is adopted as the sole study to make clinical decisions about patients after EVAR. There is a possibility that as more AAAs with shorter necks are treated, our findings showing the safety and efficacy of using DU imaging alone to monitor EVARs may be affected. If we were particularly concerned about short infrarenal aortic necks, we would recommend more frequent follow-up with DU and possibly CT angiography to better define the anatomy.

The accuracy of DU imaging to detect endoleak or limb stenosis may vary depending on different graft designs; however, in our experience, other secondary inter-

ventions such as coils or glue placed in the sac or accessory branches have more of an effect on the accuracy of DU imaging than the graft design. Our results were obtained by experienced, technically superb vascular technologists, and less experienced or skilled technologists may not achieve the same results.

CONCLUSION

The search for the optimal means of surveillance for complications of EVAR continues to evolve. CT and DU imaging can both detect AAA sac dimensions, endoleaks, and graft patency. The cost difference between the two imaging techniques is substantial. Our results demonstrate that DU surveillance during midterm follow-up after EVAR performed in an experienced vascular laboratory can accurately detect aneurysm size, endoleaks, and stenotic or kinked graft limbs while lowering the overall costs of surveillance. We do not advocate eliminating CT completely from surveillance protocols but would limit its use to those circumstances in which it could provide other details about problems first detected by the DU examination.

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AUTHOR CONTRIBUTIONS

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Critical revision of the article: BB, LD, KD, SB, MD, KC
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Statistical analysis: BB, LD, MD, KC
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