Endovascular aortic aneurysm repair surveillance may not be necessary for the first 3 years after an initially normal duplex postoperative study

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Objective: **We have previously shown that duplex ultrasonography (DU) may replace computed tomography angiography (CTA) as the primary surveillance tool for endovascular aortic aneurysm repair (EVAR). Current Society for Vascular Surgery practice guidelines suggest that if CTA does not document endoleak, aneurysm sac enlargement, or limb stenosis by 12 months after EVAR, surveillance studies may be performed annually. The purpose of this study was to determine whether the time to the second surveillance DU study can be safely postponed to 3 years after EVAR if the initial study finding is normal.**

Methods: **Between 1998 and 2013, DU surveillance was performed in our accredited noninvasive vascular laboratory at 1 week, 6 months, and annually after 410 EVARs (follow-up: mean, 35 months; range, 0.5-151 months). DU was used to measure sac diameter, intrasac endoleak peak systolic velocities (PSVs), and PSVs within endograft limbs. If an endoleak, limb stenosis, or increase in sac size was documented, DU surveillance was performed more frequently or CTA was performed, followed by intervention if appropriate.**

Results: **On the basis of DU surveillance, 113 patients (28%) were diagnosed with either endoleak or graft limb stenosis during the follow-up period. There were 95 patients (23%) with 118 endoleaks (15 [13%] type I, 90 [76%] type II, 11 [9%] type III, 2 [2%] type IV). There were 18 (4%) patients with limb stenosis defined as PSV >300 cm/s. Intervention was performed in 32 (28%) of the 113 patients with endoleak or limb stenosis, or in 8% of the total group (32 of 410), during the follow-up period of 0.5 to 151 months. Only 2.2% of the patients (7 of 325) with an initially normal finding on post-EVAR DU went on to develop endoleak or limb stenosis that required intervention during 3-year follow-up compared with 25% of patients (21 of 85) with an initially abnormal finding on post-EVAR DU ($P = .0001$).**

Conclusions: **These findings suggest that follow-up DU surveillance can be postponed until 3 years after EVAR if the initial result of surveillance DU is normal (no endoleak, sac enlargement, stenosis), with minimal risk of an adverse clinical event. (J Vasc Surg 2014;60:558-62.)**

The first endovascular aortic aneurysm repair (EVAR) was described in 1991.[1] By 2013, approximately 75% of the reported 63,000 abdominal aortic aneurysms (AAAs) were repaired by EVAR in the United States.[2] Registry data suggest that 13% to 22% of EVARs will need reintervention.[3,4] Therefore, it has been recommended that all EVARs need lifetime surveillance.[5,6] Surveillance protocols can add significant financial burden and patient inconvenience after the initial procedure. Therefore, it would be beneficial to identify a subset of post-EVAR patients who could be monitored less often. Likewise, a subset of patients may need more frequent monitoring if they are at a higher risk to require reintervention.

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The current Society for Vascular Surgery practice guidelines suggest that if the initial surveillance study does not document endoleak, aneurysm sac enlargement, or limb stenosis at 1 and 12 months after EVAR, surveillance studies may be performed annually thereafter.[5] The purpose of this study was to determine whether the time interval until the second surveillance duplex ultrasonography (DU) study can be safely postponed to 3 years after EVAR if the initial study finding is normal.

METHODS

Between 1998 and 2013, 410 patients who underwent EVAR by the vascular surgery service at Pennsylvania Hospital were observed by evolving DU surveillance protocols. DU surveillance after EVAR was performed in our Intersocietal Committee of Accredited Vascular Laboratory-accredited noninvasive vascular laboratory. Before 2004, our protocol consisted of computed tomography angiography (CTA) and DU within 2 weeks of discharge, at 6 and 12 months, and then annually after EVAR. From 2004 to 2009, CTA and DU were ordered within 2 weeks of discharge, then DU alone was used for surveillance at 6 and 12 months, then annually after EVAR.[7,8] Since 2009, we have used DU alone for surveillance obtained at 1 week after EVAR, then at 6 and 12 months, then annually after EVAR if no abnormalities were detected.

DU measured sac diameter, intrasac endoleak peak systolic velocities (PSVs), and PSVs within the endograft limbs. We have shown that CTA and DU measurements of aneurysm sac diameter after EVAR were equivalent.[7] Limb stenosis was defined as PSVs >300 cm/s within the endograft limbs.[9] If endoleak or limb stenosis was detected, DU surveillance was performed more frequently, CTA was obtained, or direct endovascular intervention was performed. If sac diameter increased by 0.5 cm, CTA was obtained. There was a high correlation of endoleaks seen in our noninvasive vascular laboratory's DU compared with CTA.[7]

DU was performed with the patient in the supine position after fasting overnight. Imaging of the aorta was performed from the celiac artery to the femoral arteries in the longitudinal and transverse axes. Measurements of the aorta were made in the transverse axis at the level of the celiac artery, at the level of the renal arteries, at the maximal aneurysm diameter, and just proximal to the aortic bifurcation. The entire aorta was scanned for any evidence of endoleaks. B-mode imaging and spectral Doppler were used to record any endoleaks. PSVs were recorded throughout the endograft and adjacent attachment sites with B-mode imaging and spectral Doppler.

DU scans after EVAR were performed by experienced vascular laboratory technologists. Our DU was equipped with 10.4 software (Philips HD-11, Philips DHI-5000, Philips HDI-3000; Philips, Bothell, Wash). All patients were prospectively maintained in our computer registry (Access; Microsoft Corp, Redmond, Calif). Statistical analysis was performed with a Fisher exact test, with P values $< .05$ considered statistically significant.

RESULTS

From September 1998 to June 2013, there were 410 patients who underwent EVAR at Pennsylvania Hospital by the vascular surgery service and were observed with postoperative DU surveillance (mean, 35 months; range, 0.5-151 months). There were 56 Ancure (Endovascular Technologies, Menlo Park, Calif), 139 AneuRx (Medtronic, Minneapolis, Minn), 8 Talent (Medtronic), 39 Endurant (Medtronic), 61 Excluder (WL Gore and Associates, Flagstaff, Ariz), 78 Zenith (Cook Medical Inc, Bloomington, Ind), and 29 Powerlink (Endologix, Irvine, Calif) grafts used during this 15-year period. The average age of this cohort was 73 years (range, 54-91 years), and 77% were men. The average diameter of AAA repaired was 5.8 cm (range, 4.4-9.8 cm).

On the basis of DU surveillance, 113 (28%) patients were diagnosed as having an endoleak (95 patients [23%] with 118 endoleaks: 15 [13%] type I, 90 [76%] type II, 11 [9%] type III, 2 [2%] type IV) or graft limb stenosis (18 patients [4%], based on PSV >300 cm/s) during the follow-up period (Table I). Intervention was performed in 32 (28%) of the 113 patients with endoleak or limb stenosis, or in 8% of the total group (32 of 410), during the follow-up period of 0.5 to 151 months. Only 2.2% of patients (7 of 325) with an initially normal finding on post-EVAR DU went on to develop endoleak, limb stenosis, or kinking that required intervention during 3-year follow-up compared with 25% of patients (21 of 85) with an initially abnormal finding on post-EVAR DU ($P = .0001$) (Table II).

Table I. Types of endoleaks and graft limb stenoses detected by duplex ultrasonography (*DU*)

DU surveillance after EVAR (mean, 35 months; range, 0.5-151 months)			
	Endoleaks detected	*Graft limb stenosis*	*Abnormalities detected*
Type I	15 (13%)	18	
Type II	90 (76%)		
Type III	11 (9%)		
Type IV	2 (2%)		
Total	118 in 95 patients	18 in 18 patients	113 of 410 (28%)

EVAR, Endovascular aortic aneurysm repair.

Of the 95 patients diagnosed with endoleaks, 20% of patients (19 of 95) had intervention for 30 endoleaks. These interventions included nine repairs for type I endoleaks, 14 repairs for type II endoleaks, five repairs for type III endoleaks, and two repairs for type IV endoleaks. There was no correlation with the type of endograft used and type of endoleak detected. Proximal endovascular cuffs, Palmaz stents, and distal limb extensions were used to repair type I endoleaks. Type II endoleaks were intervened on if they were thought to have caused a sac growth rate of 0.5 cm or more. Two patients with type II endoleaks had open surgery with oversewing of lumbar vessels. All other type II endoleaks were treated with selective angiography and coil embolizations or translumbar embolizations/polymerization. Type III and type IV endoleaks were treated with relining of the endograft. The average time to reintervention for all 19 patients with endoleaks was 38 months (range, 6-96 months). Nine of these patients had an initially abnormal finding on DU surveillance, with the average time to reintervention being 35 months (range, 6-64 months). Of the 10 patients who had an initially normal finding on DU surveillance, the average time to reintervention was 41 months (range, 8-96 months).

Seven of the 10 patients with initially normal findings on DU surveillance who underwent reintervention did so within 3 years. In this subset, there were two type I endoleaks, four type II endoleaks, and one limb stenosis. All patients had successful endovascular treatment. The mean time to reintervention in this subset of patients was 21 months (range, 8-36 months) (Table III).

Of the 18 patients who had limb stenosis on the basis of the preceding criteria, 13 underwent endovascular or open surgical treatment (all with initially abnormal findings on DU). Six of these patients had reintervention to maintain patency. Seven patients had reintervention for limb thrombosis. Open surgery was performed in three patients, including femorofemoral bypass (two) and axillofemoral bypass (one). The remaining 10 patients had endovascular reintervention that included catheter-directed thrombolysis

Table II. Rates of intervention after endovascular aortic aneurysm repair (*EVAR*)

	Post-EVAR				
	Totals	*Interventions on patients with initially abnormal findings on DU*	*Interventions on patients with initially normal findings on DU*		
	#	*At 3 years*	*At 2 years*	*At 3 years*	*At 4 years*
Abnormal findings on DU with interventions	28% (32/113)				
Initially abnormal findings on DU	21% (85/410)	25% (21/85)			
Initially normal findings on DU	79% (325/410)			2.2% (7/325)	
Total cohort	8% (32/410)	5.1% (21/410)	1.0% (4/410)	1.7% (7/410)	1.7% (7/410)

DU, Duplex ultrasonography.

Table III. Interventions on patients with initially normal findings on duplex ultrasonography (DU)

Patient	*Type of endoleak*	*Limb stenosis*	*Time of intervention, months*	*Type of intervention*
1	Type I		8	Palmaz stent
2	Type II		12	Translumbar embolization
3	Type II		13	Translumbar embolization
4	Type II		24	Selective angiography, coil embolization
5	Type I		29	Proximal cuff
6		Right limb	36	Balloon angioplasty and stent
7	Type II		36	Selective angiography, coil embolization
8	Type III		68	Relining of endograft limb
9	Type I		84	Extension of distal limb, coil embolization of hypogastric artery
10	Type II		96	Translumbar embolization

alone, mechanical-chemical thrombolysis, balloon angioplasty with or without stent, or stent graft. There was no correlation between the type of endograft used and rate of limb stenosis. The average time to intervention for limb stenosis was 43 months (range, 1-120 months).

Therefore, we would have missed 1.0% (4 of 410), 1.7% (7 of 410), and 1.7% (7 of 410) at 2-, 3- and 4-year follow-up, respectively, of all patients who would have potentially benefited from useful reintervention for an endoleak or limb stenosis if follow-up surveillance DU was postponed.

DISCUSSION

The treatment algorithm for AAAs has dramatically shifted during the past decade. In 2013, approximately 75% of all AAAs were repaired with EVAR in the United States.[2] Surveillance after open surgical repair has not been considered necessary because the AAA was definitively excluded. However, occasional patients may develop anastomotic or other aneurysms that are not detected on physical examination.[10] Therefore, current Society for Vascular Surgery guidelines recommend CT surveillance every 5 years after open surgical repair.[5]

The need for long-term surveillance after endovascular repair is more widely appreciated. Patients undergoing EVAR for AAA remain at small but persistent risk for aneurysm rupture. The EUROSTAR (European Collaborators on Stent/graft Techniques for aortic Aneurysm Repair) and OVER (Open vs Endovascular Repair) registries found an annual rate of AAA rupture of 0.7% to 1.4% after EVAR.[3,11] Therefore, it has been recommended that post-EVAR patients undergo lifelong surveillance.[5]

The optimal type and frequency of post-EVAR surveillance remain undefined. Others have recommended that CTA be used as the primary imaging modality because it may be more specific at identifying abnormalities such as endoleak, sac expansion, limb stenosis, and kinking after EVAR. However, we have shown the DU and CTA are equivalent in determining sac size as well as in detecting endoleaks.[7] We have also shown that DU is effective in detecting limb stenosis or kinking after EVAR.[9] Therefore, we believe that DU is as efficacious as CTA for post-EVAR surveillance.

DU has advantages compared with CTA. Our technologists can visualize physiologic as well as anatomic abnormalities, whereas CTA can detect only anatomic abnormalities. DU is also more cost-effective than CTA. Bendick et al[12] reported a cost savings of more than $16,000 per patient if a DU surveillance protocol was used compared with a CTA protocol during a 3-year period. Our group has also reported a cost savings benefit of approximately $1600 per patient per year with use of a primarily DU-only surveillance protocol.[7] In addition, DU does not require repeated radiation exposure that could potentially increase the risk of cancer as well as the risk of acute kidney injury due to contrast-induced nephropathy.[13]

We recommend CTA if a type I or type III endoleak occurs or for type II endoleak with >0.5 cm aneurysm sac expansion. CTA may sometimes be helpful in planning intervention for graft limb stenosis in some cases.[7-9]

Currently, the timing for post-EVAR surveillance is recommended at 1 and 12 months, then annually if no abnormalities are detected. If abnormalities are detected, it is recommended that the imaging interval be shortened to every 6 months.[5] We agree that an initial scan, preferably DU, should be done to establish a post-EVAR baseline. The initial DU study is performed in our office during the patient's first postoperative visit so that he or she does not have to return for another visit at 1 month. Our results suggest that if the initial scan does not show any abnormalities (ie, endoleak, limb stenosis), the interval until the second surveillance DU study may be safely postponed to 3 years after EVAR. Our data support this recommendation by showing that only 2.2% of patients who had normal findings on DU initially after EVAR later required reintervention. This is in stark contrast to a 25% reintervention rate after 3-year follow-up if the initial DU detected an abnormality. Patients who are treated outside of an endograft's instructions for use, even if their initial DU finding was normal, should most likely have surveillance annually 1 year after EVAR.

The mean time to reintervention was 41 months in the subset of patients with initially normal findings on DU. However, there were seven patients in this group who had re-intervention within 36 months, or 3 years, of EVAR. Although the rate of intervention after a DU scan with initially normal findings was only 2.2%, some clinicians might question if this is an acceptably low rate to omit surveillance until 3 years postoperatively. The potential adverse effects of omitting surveillance for 3 years after an initial normal study result after EVAR should be weighed against the costs and adverse effects of frequent CT scans or DU studies. DU surveillance after 3 years should most likely return to yearly surveillance because we do not have long-term data to support longer surveillance intervals.

Other groups have also suggested alternatives to current Society for Vascular Surgery recommended surveillance guidelines if the first post-EVAR surveillance study result is normal. Kirkpatrick[14] has recommended that if the 1-month post-EVAR CTA does not demonstrate an endoleak, less frequent CTA surveillance is needed. Sternbergh[15] noted that if the initial post-EVAR surveillance CTA does not demonstrate any abnormalities, the rate of freedom from reintervention at 5 years may be up to 85%. We aggressively pursued DU abnormalities during the 3 years after EVAR, and the incidence of reintervention would likely have been much less in our series had we not prophylactically intervened.

There are some limitations to this study. First, this study is a retrospective review of a prospectively maintained database during the past 15 years. Second, the average follow-up of the study was 35 months. Last, DU-only surveillance after EVAR is highly dependent on the vascular laboratory technologists. The accuracy of the DU examination can be time-consuming and dependent on the skill of the technologists; therefore, DU results will certainly vary between noninvasive vascular laboratories.

CONCLUSIONS

These findings show that post-EVAR patients with an initially normal DU surveillance study result are at significantly lower risk for reintervention than are patients with initially abnormal study results. We would suggest that surveillance DU studies may be postponed until 3 years after EVAR if the initial result of surveillance DU is normal (no endoleak, sac enlargement, or limb stenosis) with minimal risk of an adverse clinical event.

AUTHOR CONTRIBUTIONS

Conception and design: DT, KC
Analysis and interpretation: DT, MC, MD, KC
Data collection: DT, MC
Writing the article: DT, KC
Critical revision of the article: DT, MC, MD, KC
Final approval of the article: DT, MC, MD, KC
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