EVAR in Community Hospitals

A community hospital approach to establishing a successful EVAR program.

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Abdominal aortic aneurysm (AAA) is the 10th leading cause of death in the US. Ninety-five percent of those deaths are due to infrarenal AAAs. Eight-five percent of AAAs occur in men, however, AAAs tend to rupture in women at an overall smaller diameter. Risk factors for AAAs include age, smoking history, family history of AAAs, and generalized atherosclerotic vascular disease. As aneurysms enlarge, the risk of rupture increases. Historically, when an AAA reaches a diameter of 5 cm, open repair is considered because at that diameter the risk of death from rupture over a year exceeds the risk of operative repair. Despite the fact that the morbidity of endoluminal stent graft repair for AAAs is much lower than for open surgery, we continue to use a diameter of 5 cm as the threshold for endoluminal stent graft repair as well as open repair. If the patient is believed to be symptomatic from the aneurysm, causing back or abdominal pain, distal emboli, or if the size increases rapidly (>0.5 cm growth in a year), consideration for possible endoluminal stent graft repair is done on an individual basis.

TABLE 1. UVRMC AAA DATA

Total patients treated	145
Open repairs	29
Endoluminal stent graft	116
Ratio of endografts to open repair	4:1

TABLE 2. PATIENTS TREATED WITH ENDOLUMINAL STENT GRAFT

Male patients	106
Female patients	10
Age range	51-94 years
Aneurysm size range	3.2* to 10 cm
Iliac aneurysms	4.7 to 11.3 cm

**Ruptured*

APPLICATION OF COMPLEX NEW TECHNOLOGIES AT THE COMMUNITY HOSPITAL LEVEL

Endovascular aortic aneurysm repair (EVAR) has rapidly gained wide acceptance as the procedure of choice for a significant percentage of patients with AAAs. At most large community hospitals, there was little delay in adoption of this new technology. In some cases, community hospitals introduced this new technology ahead of academic medical centers. In the past, complex new medical techniques often took years to filter down to the community hospital level. This has changed during the past several years with more rapid dissemination of technology. There are three primary forces that have accelerated the early adoption of new technology: (1) improved communication and education within the medical community, often with the support of medical specialty societies and with the intent of improving patient care, with a secondary interest in establishing these new techniques as legitimate core components of the specialty; (2) aggressive industry-sponsored education and training programs

designed to speed acceptance of new medical equipment and products; and (3) patient demand for new technologies with an increasingly well-informed public. In some cases, medical device manufacturers market new technologies directly to the public. In other cases, the research-savvy public locates the information in traditional medical resources. Physicians, medical specialty societies, and other groups are providing easier access to patient education materials.

MULTISPECIALTY INTEGRATION: A ROADMAP FOR SUCCESS

We present our approach to EVAR in a midsize community hospital as one example of a safe and effective system for providing this recent technology. Utah Valley Regional Medical Center (UVRMC) is a 400-bed community hospital serving a referral area of approximately 450,000. Most medical specialties are represented, including a well-established interventional radiology group with eight fellowship-trained interventional radiologists. A single vascular surgeon joined the medical staff in 2000. The vascular surgeon had completed peer training and had performed EVAR cases as staff at a university medical center before joining the community hospital medical staff. One interventional radiologist completed industry-sponsored training in the same time period.

The referral base for vascular surgery without interventional radiology includes all hospital beds within the county, for a total of 659 beds. Interventional radiology provides services to a significantly larger referral base where there is a radiology presence either electronically or with people actually on site. The referral base with interventional radiology increases the total beds for interventional vascular services to 1,132, significantly increasing the overall referral base.

A visiting vascular surgeon with extensive experience in EVAR proctored the first three cases at our hospital. We found this helpful, especially with our support staff not familiar with the technique, although we had taken them through a dry run.

Since our first EVAR case in late 2000, our case volume has nearly doubled each year. We attribute this increase to (1) consideration of higher-risk patients and patients with less favorable anatomy as our experience level has increased; (2) increased physician awareness of the procedure. Patients are now referred who might not otherwise have been referred for an open surgical repair due to age and comorbidities considered by the primary care physician to be contraindications. Some of our rapid increase in caseload may represent a backlog of such patients and may not be sustainable; (3) increasing public awareness of the disease and the procedure; (4) screening programs such as Lifeline, Legs for Life, and other community screening programs; and (5) improved device options, allowing wider application of the technique.

TABLE 3. ANCILLARY PROCEDURES PRIOR TO SURGERY

Angiography	22
Embolization of hypogastric artery	15
Renal stenting	15
Angioplasty	6

TABLE 4. ANCILLARY PROCEDURES PERFORMED DURING SURGERY

Hypogastric embolization in the OR	0
Renal arteries stented	7
Access angioplasty	6

TABLE 5. DEVICE SELECTION FOR EVAR

Devices	No. of Devices	Mean No. of Components Used
AneuRx	75	2.8
Excluder	32	2.9
Zenith	9	3
Ancure*	1	1

**Guidant Corporation, Indianapolis, IN*

TABLE 6. ENDOLUMINAL STENT GRAFT RESULTS

One vascular surgeon and one interventional radiologist (December 2000 to November 2005)

Total cases	116
Failures	0
Conversions	0
Deaths*	0

**One 86-year-old failure-to-thrive patient at 30 days after the procedure. May be our first procedure-related mortality.*

TABLE 7. RESULTS

Device	Failures	Conversions	Migrations	Deaths From AAA
AneuRx	0	0	0	0
Excluder*	0	0	0	0
Zenith	0	0	0	0

**Required use of an AneuRx inside a floating Excluder.*

TABLE 8. WHY NO MIGRATIONS?

Not enough patients
Good patient selection
Good coverage of abnormal vessel from inferior renal to hypogastric in most cases
Team approach utilizing best skills of vascular surgery and interventional radiology
Careful sizing of stents and components

TABLE 9. GRAFT PROCEDURES AFTER STENTING

Type I leaks	3
Total type II leaks	11
Number treated	5
IMA*	3
Lumbar arteries†	2

SMA, superior mesenteric artery; IMA, inferior mesenteric artery.

**The inferior mesenteric arteries were treated with coil embolization by using a microcatheter to navigate from the SMA to the IMA via the marginal artery of Drummond.*

†Lumbar type II leaks were treated with coils and gl

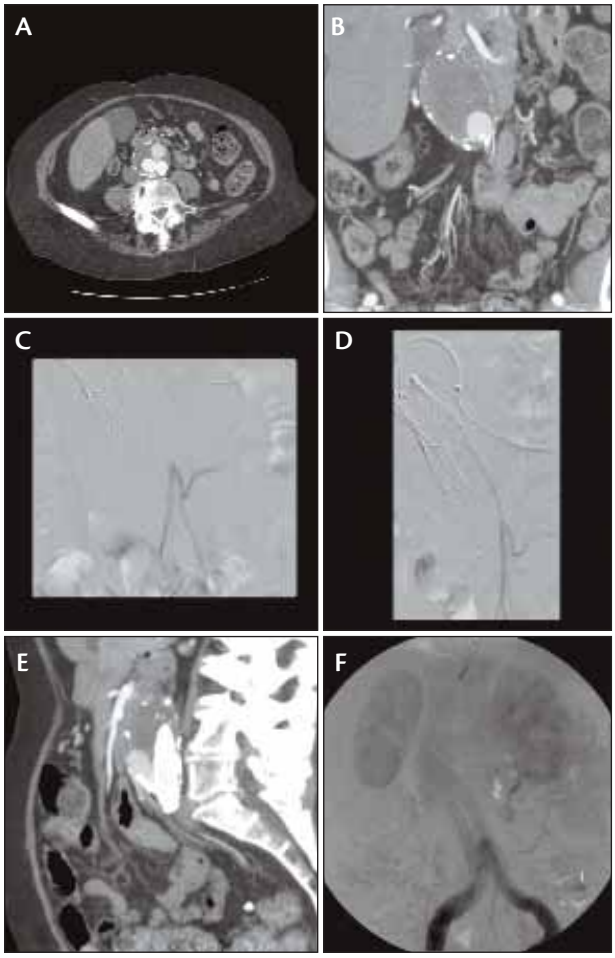

Figure 1. CT scan shows what was thought to be a type II endoleak (A). A coronal CT reconstruction showing the inferior mesenteric artery (IMA) contributing to the endoleak (B). Contrast in the IMA and branches. Flow is out of the aneurysm sac (C). Angiogram with a microcatheter injected well up in the aneurysm sac. Flow in the IMA branches is, again, out of the aneurysm sac rather than in, indicating that this is the exit site (D). Sagittal CT scan reconstruction with the IMA in contact with the endoleak (E). A true type I endoleak along the right iliac limb fills the endoleak and flows into the IMA branches (F).

TEAM APPROACH TO EVAR

The Team

A vascular surgeon and an interventional radiologist are involved in all elective cases at our institution. Because of the limited number of these cases and a long learning curve to master the subtleties of the procedure, we have limited participation to a single interventional radiologist and vascular surgeon. Surgical scrub technologists trained in guidewire and catheter management assist with the procedure and an interventional radiology technologist operates the imaging and power injector equipment. When needed, intravascular ultrasound is operated by a cath lab technologist. A variety of anesthetic techniques have been used, including local, regional, and general anesthesia.

Independent Case Planning

The interventional radiologist and vascular surgeon independently review the preoperative CT scan. We rarely do preoperative angiography unless it is needed for coil embolization of hypogastric arteries or other specific indications. Independent measurements and device selection are compared and debated. We use all currently approved devices, which we believe is important to offering the best possible device for a particular patient anatomy.

The three commercially available brands in the US are the

AneuRx (modular aortobilateral iliac device, aortic cuffs/extenders, iliac cuffs/extenders, and iliac limbs; Medtronic, Santa Rosa, CA), the Excluder (modular aortobilateral iliac device, aortic cuffs/extenders, iliac cuffs/extenders, and iliac limbs; Gore & Associates, Flagstaff, AZ), and the Zenith (tri-modular aortobilateral iliac device, aorto-monoiliac device conversion kit; Cook Incorporated, Bloomington, IN). We have not found any one device to be best for all applications.

Technique

All procedures are done in the vascular OR using a four-way floating carbon fiber top angiographic table and portable imaging equipment (OEC 9800 12-inch image intensifier with digital subtraction and road mapping; GE Medical Systems, Waukesha, WI). We maintain a full range of guidewires, catheters, stents, and sheaths in the OR. In addition, we have immediate availability of all devices maintained within the interventional radiology laboratory. We use standardized order sets for preoperative and postoperative care. We use a standardized sodium bicarbonate infusion protocol for patients at increased risk of contrast nephropathy,[1] which includes patients with creatinine levels >1.4, history of contrast nephropathy, clinical signs of dehydration, diabetes, and other risk factors. Our standard contrast agent is iodixanol 270 mg I/mL. Anesthetic technique is decided in consultation with our anesthesiologist. Arterial line monitoring is routine. Central venous access is decided on a case-by-case basis. Standard techniques are used for vascular access and graft deployment. Cell Saver (Haemonetics, Corp., Braintree, MA) was used for early cases due to sheath-related blood loss but is no longer routinely used.

Postoperative care is provided at an intermediate level where arterial line monitoring can be continued if needed. ICU-level care has only been used for patients with emergency repair for leak or rupture. Our standard follow-up protocol has included a first postoperative CT scan with and without contrast at 3 months, then annually for lifetime. Exceptions to this follow-up are made for patients with known endoleaks of concern or other conditions requiring more aggressive monitoring. We have used a computer database system (Management Plus, American Computer Software, Madison, WI) to generate automated recall notices but are currently transitioning to Stent Graft Tracker software (Medtronic, Inc., Minneapolis, MN).

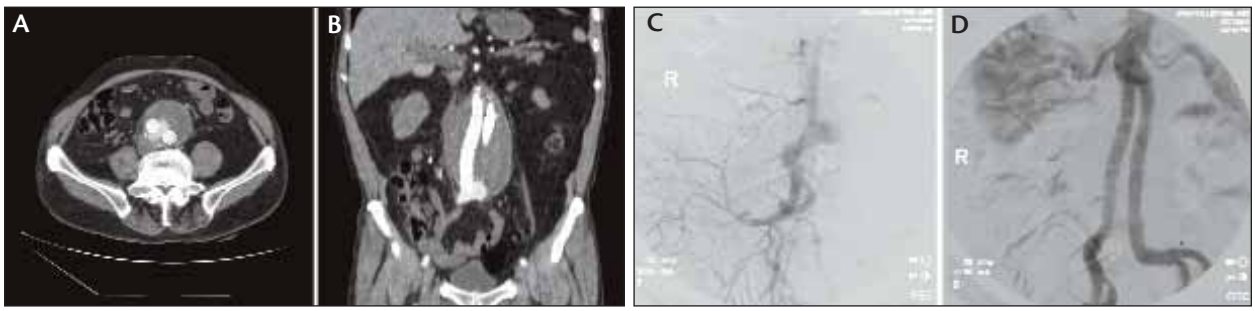

Figure 2. Axial CT scan with coronal reconstruction shows a type I endoleak along the right iliac limb of the stent graft (A, B). A retrograde injection into the right femoral artery shows the type I endoleak identified filling retrograde along the right iliac limb of the stent graft (C). The completed extension of the right common iliac endoluminal stent graft down to the hypogastric artery completely eliminates the type I endoleak (D).

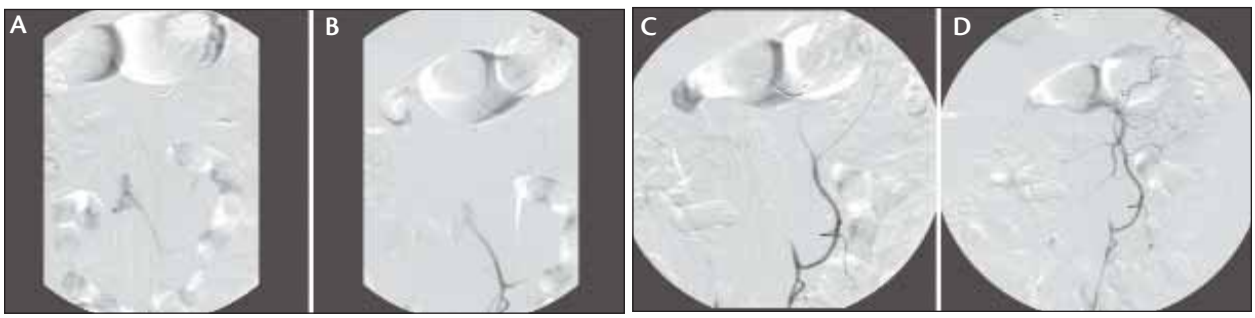

Figure 3. These images show placement of a microcatheter from the superior mesenteric artery (SMA) to the IMA by way of the marginal artery of Drumond, with the contrast injected filling the type II endoleak (A, B). An IMA angiogram after placement of proximal IMA coils eliminates flow into the aneurysm sac (C, D).

EVAR RESULTS AT A COMMUNITY HOSPITAL

During a 64-month interval (December 2000 through April 2006), 145 patients were treated for AAAs (Table 1). Repairs performed included 116 EVAR and 29 open repairs (112 patients were male, 33 were female; mean age for open repair, 71.7 years; mean age for EVAR, 76.6 years; mean preoperative aneurysm size based on CT scan, 5.7 cm for open repair and 5.9 cm for EVAR). EVAR procedures were elective in 111 cases and urgent in five cases (Table 2). Open repair procedures were elective in 16 cases and urgent in 12 cases. Fifteen patients who underwent EVAR required preoperative coil embolization procedures. Fifteen EVAR patients had renal arteries stented prior to the procedure and seven patients received renal artery stents at the time of EVAR (Tables 3 and 4).

All devices used during the time period of this study were FDA-approved devices, although in only one case (Ancure) was the device used before the product was taken off the market. Each product has unique features, and with careful, thoughtful patient evaluation, the device best suited for any given anatomy may be selected. We believe our ability to understand and use all of the devices has led to our success rate and lack of complications (Table 5).

Thirty-day mortality was 8% for open repair and 1% for EVAR. One-year mortality with 98% follow-up was 12% for open repair compared to 2% for EVAR. Length of stay was a mean of 2.4 days for EVAR compared to 16.4 days for open repair. Reintervention was required in one open repair patient for ventral hernia and for seven EVAR patients (five coil embolizations for type II endoleaks, one femoral-femoral bypass for a unilateral limb occlusion, and one graft extension for late type I distal endoleak with rupture). No EVAR cases required conversion to open surgical repair. Blood transfusions included a mean of 1.4 units for open repair and 0.1 units for EVAR.

General anesthesia was used for open repair in all cases. EVAR was done with general anesthesia in 82%. Regional anesthesia was used in 16% of the patients, and local anesthetic alone was used in 2%.

ENDOLUMINAL STENT GRAFT RESULTS

From December 15, 2000, to April 30, 2006, 116 cases were successfully treated with endoluminal stent grafts. There were no conversions. Our follow-up data show no migrations, and we have had no deaths from AAA repair. We currently have one 86-year-old failure to thrive at 30 days postoperatively; the patient remains in renal failure and may not survive. This may be our first procedure-related mortality (Tables 6 and 7).

The literature reports significant migrations of the endoluminal stent grafts over time. We believe that our lack of migrations is in part due to a decision early on to cover from the lowest renal artery to the hypogastrics in most cases. It may be that we do not have enough patients. Part of our success may well be good patient selection. We believe that the team approach, utilizing the best skills of vascular surgery and interventional radiology in carefully selecting and sizing stents and components, has improved our success in this area (Table 8).

Type II endoleaks remain the Achilles' heel of endoluminal stent grafts. The search for endoleaks requires constant vigilance with, at a minimum, yearly follow-up by means of carefully performed CT scans. Follow-up CT scans remain the standard for the detection of endoleaks, with all other imaging modalities being adjunctive. However, in any given case, one of the other modalities may be helpful. This is particularly true of angiography, which on occasion is necessary to differentiate a type I endoleak from a type II endoleak (Figure 1A through C). Careful attention to the technique of CTA is essential. We use the following protocol: (1) a spiral multislice CT scanner (16 slice) with 2-mm scan slices; and (2) the patient is first examined with nonenhanced images, followed by enhancement with 120 mL of Isoview 370 (Bracco, Princeton, NJ) at an injection rate of 4 mL/s. Delayed images through the aneurysm at approximately 100 seconds after injection (range, 75 to 125 seconds) will occasionally pick up endoleaks that the initial CT angiography will not demonstrate. Careful attention to window and leveling, including liver windows, are good for subtle endoleaks.

All modalities are subject to observer error. CT angiography is the most reproducible of the imaging modalities. Observer error is less if the interventional radiologist who placed the endoluminal stent graft reads the study.

We had three type I endoleaks. One occurred during deployment when the main body failed to attach to the infrarenal aorta and pulled down into the aneurysm sac during deployment. This required placement of a second endoluminal stent graft within the first, which then allowed good infrarenal attachment and successful completion of the case.

In our series of 116 cases, significant type I or type II endoleaks occurred in 12% of the EVAR cases. Of the 11 type II endoleaks identified, five have been treated and one remains persistent after the initial treatment. Of the five

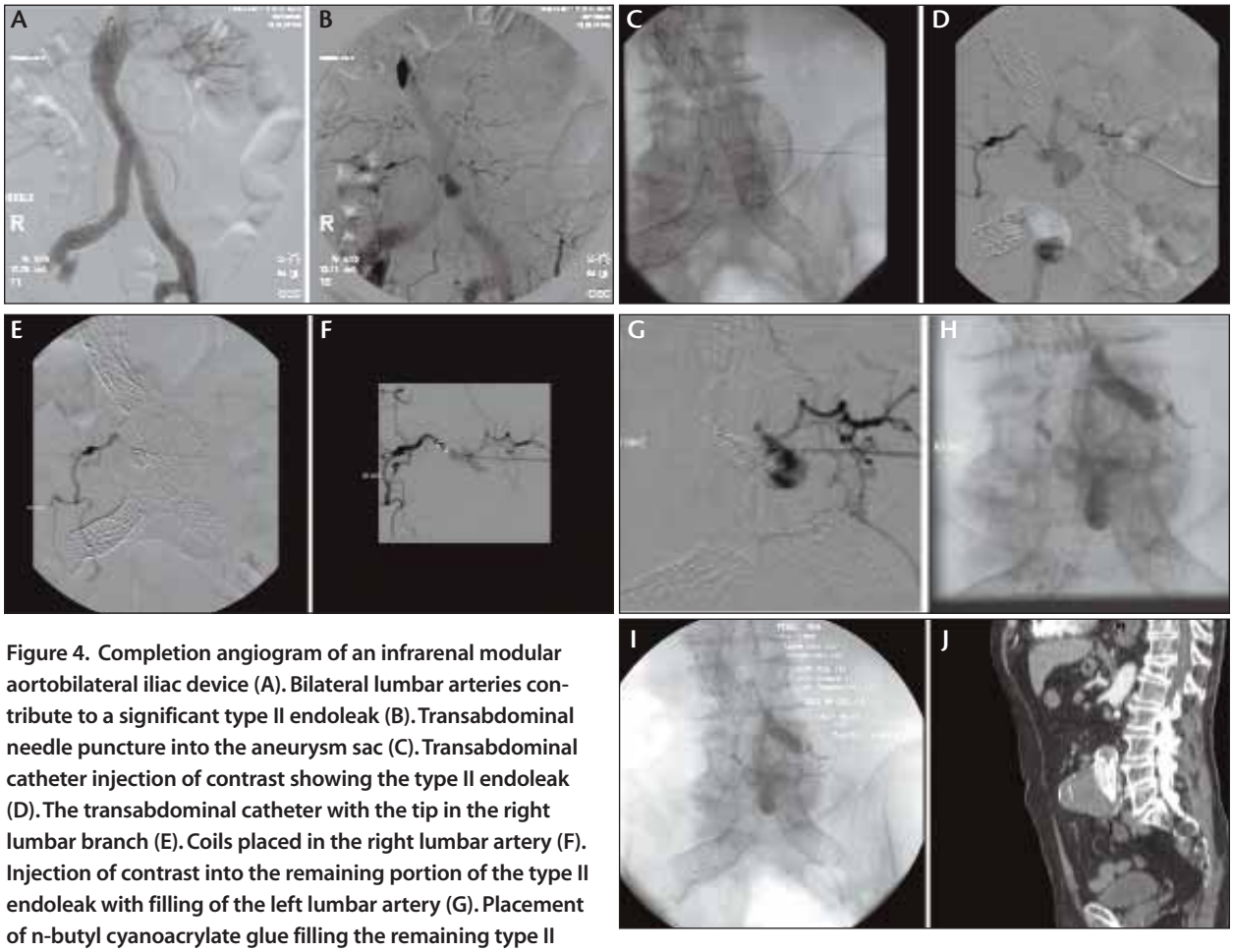

Figure 4. Completion angiogram of an infrarenal modular aortobilateral iliac device (A). Bilateral lumbar arteries contribute to a significant type II endoleak (B). Transabdominal needle puncture into the aneurysm sac (C). Transabdominal catheter injection of contrast showing the type II endoleak (D). The transabdominal catheter with the tip in the right lumbar branch (E). Coils placed in the right lumbar artery (F). Injection of contrast into the remaining portion of the type II endoleak with filling of the left lumbar artery (G). Placement of n-butyl cyanoacrylate glue filling the remaining type II endoleak cavities and all other branches supplying the endoleak (H). Complete obliteration of the type II endoleak nidus with coils and n-butyl cyanoacrylate glue (I). A sagittal reconstructed CT scan shows no residual endoleak (J).

treated endoleaks, three were primarily attributed to IMA flow and the other two were attributed to lumbar flow (Table 9).

We have one basic rule as it relates to type II endoleaks—if the aneurysm sac enlarges, some type of intervention is mandatory. Type I endoleaks all require treatment upon discovery. The other two type I endoleaks were both at the right iliac limb. One required a simple extension of the limb. The second required a simple aortic cuff extension flaring the right distal iliac limb. Both type I endoleaks were successfully treated, and the patients currently remain stable (Figure 2A and B).

Five type II endoleaks have been treated. Three embolizations of the IMA using the SMA and collateral branches to the IMA for microcatheter embolization of the proximal IMA have been successful in two of the three cases (Figure 3A and B). One case remains persistent. The two persistent lumbar artery endoleaks were treated utilizing a transabdominal or translumbar approach into the region of the type II endoleak and then utilizing a combination of coils and glue (n-butyl cyanoacrylate liquid embolic system from Cordis Corporation, a Johnson & Johnson company, Miami, FL). This type of treatment has allowed us to treat not only the branch vessels entering into the endoleak, but also the nidus of the endoleak, which we believe will be the appropriate way to treat type II endoleaks in virtually all cases (Figure 4A through E).

OBSERVATIONS AND RECOMMENDATIONS

EVAR is a complex recent technology that can be safely and effectively delivered by community hospitals. Although total numbers of aneurysm ruptures in our region are inadequate to reach statistical significance, we have observed a steady decline in the frequency of aneurysm ruptures presenting to our hospital, which may be related to successful screening and intervention programs such as ours (Figure 5).

In our case, we have found significant advantages to a team approach to EVAR using a vascular surgeon and an interventional radiologist. We have found several instances in which the complimentary skill sets unique to the two specialties have led to solutions that either alone may not

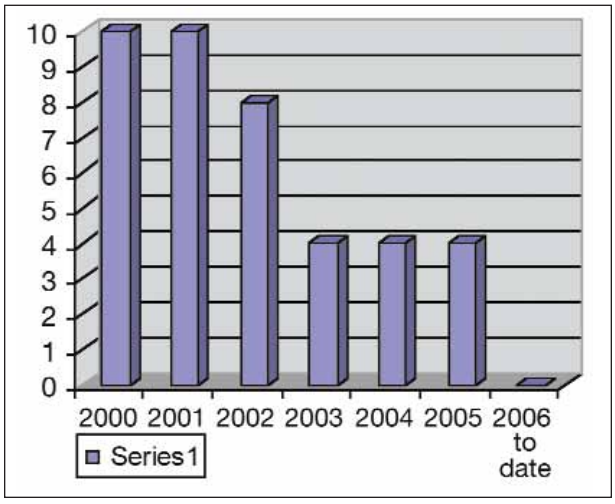

Figure 5. The number of AAA ruptures has decreased by more than 50% since 2000 and has remained relatively stable for the last 3 years. To date in 2006, we have had no ruptured AAAs. The endoluminal stent graft program appears to be diminishing the number of AAA ruptures.

have accomplished. This has created a win/win situation for all participants. For the patient, procedures are determined by best practices; there is no financial incentive, the procedures are performed by qualified physicians, and there is improved patient outcome and patient satisfaction. For vascular surgery, the volume of patients fed by multiple sites has increased. It has also created an opportunity for vascular surgery to increase endovascular skills in a cooperative, controlled environment. For interventional radiologists, our referral base has increased, and it has allowed us to become clinical consultants. Our interaction with referring physicians has improved, as has patient quality of care by better postprocedure care and follow-up. Perhaps, best of all, it has made a potentially stressful, challenging procedure fun. ■

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1. Merten GJ, Burgess WP, Gray LV, et al. Prevention of contrast-induced nephropathy with sodium bicarbonate: a randomized controlled trial. JAMA. 2004;291:2328-2334.