State of EVAR in the US

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Abdominal aortic aneurysm (AAA) rupture results in considerable morbidity, mortality, and costs to society. The rate of aneurysm rupture and death could exceed 60% within 3 years of diagnosis.[1] Surgical repair was first reported in 1952[2] and was the only effective treatment for AAAs until the first endovascular aneurysm repair (EVAR) by Parodi et al in 1991.[3] Since then, there has been a significant increase in the amount of AAAs treated by endovascular means. The number of AAAs repaired in the US has grown from 34,237 performed in 1980 to 46,542 performed in 2000.[4] The 1990s saw a steady increase in the number of EVARs, such that by the year 2000, more than half of all AAA repairs were performed with an endograft.[5,6] The share of EVARs performed has increased even more and may currently approach 75%.

PATIENT SELECTION

Endografts were initially offered to patients who had aneurysms with a significant risk of rupture but could not undergo an open repair. Since then, the percentage of patients offered EVAR who also qualify for open repair has increased significantly. Studies report lower perioperative morbidity and mortality rates for patients undergoing EVAR versus open repair. Both low- and high-risk patients benefit from endografts because of lower complication rates and shorter hospital stays.[7] Intraoperative blood loss has been shown to be reduced, and intensive care unit stays are shorter.[8] Patients with chronic renal insufficiency not requiring dialysis have undergone EVAR with nonionic contrast without increased risk of worsening renal failure or death when adequate renal protection was performed.[9] Thus, EVAR may be the procedure of choice in high-risk patients, including those in renal failure. However, controversy exists in the treatment of low-risk younger patients. The proven durability of an open AAA repair may be preferable in this setting when compared to the higher reintervention rates associated with endografts.[10] The high mortality rates of 40% to 50% associated with open repair of ruptured AAAs are also being challenged by EVAR. Mehta et al[11] reported a mortality rate of 18% with emergent endovascular repair of both hemodynamically stable, as well as unstable, patients using a standardized protocol.

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ANATOMIC CRITERIA

The main criteria limiting the use of endografts are anatomic considerations. The long-term success of EVAR is dependent upon strict anatomic criteria,[10,12] which 20% to 69% of patients have been reported to meet.[13-16] Men are more likely than women to conform to these criteria,[15] indicating that lower-profile devices are needed. Proximal and distal fixation sites, as well as access issues, are the main anatomic constraints. The aortic neck, the segment from the renal arteries to the start of the aneurysm, is of great importance in determining suitability for EVAR. Factors contributing to type I endoleak include a short neck (≤15 mm), large diameter neck (≥28 mm), reverse tapered necks, increased angulation (≥60°), thrombus, and calcification.[17-19] Generally, 15% to 20% oversizing of stent grafts is done to decrease the occurrence of type I endoleaks and stent migration.[20] Suprarenal fixation may also contribute to achieving an adequate proximal seal by anchoring the stent above the renal arteries.[21,22] Evaluation of suprarenal fixation has indicated that it may be utilized without compromising renal function.[23]

Although the anatomic constraints of the aortic neck sometimes preclude endograft placement, difficulties in

iliac artery morphology can often be overcome with technical adaptations. A minimum landing zone of 10 mm is generally required in the common iliac artery for an adequate seal. If an iliac artery aneurysm is present, the ipsilateral hypogastric artery may be coiled with the subsequent landing site extended into the external iliac artery. The contralateral hypogastric artery should be preserved, if possible, to prevent buttock claudication or colon ischemia. To preserve the hypogastric artery, a "bell-bottom" technique can be utilized. The use of a short aortic extension cuff placed in the distal common iliac artery attachment zone has been reported with common iliac arteries ≥20 mm.[24] To achieve delivery sheath access, the external iliac artery should be ≥7 mm. For unilateral occluded iliac systems, an aorto-uni-iliac stent graft with cross-femoral bypass grafting can be performed. Furthermore, adjunctive retroperitoneal procedures, such as iliofemoral bypass, hypogastric artery revascularization, and iliac artery conduits, can be achieved.

STENT GRAFT DESIGNS

Stent grafts were initially a one-piece design, as used in open surgical repair. However, because of differences in individual anatomy, the modular bifurcated design has become popular. The most widely used commercially fabricated endovascular devices today include the AneuRx (Medtronic, Inc., Santa Rosa, CA), the Zenith (Cook Medical, Bloomington, IN), the Excluder (Gore & Associates, Flagstaff, AZ), and the Talent (Medtronic) stent grafts.

The Medtronic AneuRx stent graft was the first modular device and has the most clinical data in the US. The system includes a bifurcated main body and a contralateral iliac limb. Its self-expanding, thin polyester graft material is supported by diamond-shaped nitinol structural elements that supply radial force for sealing without barbs or hooks. Its Xpedient delivery system allows delivery in tortuous anatomy and does not require an introducer sheath. Its main body delivery system has a 21-F outer diameter, and the contralateral limb is 16 F. It is available for aortic diameters of 20 mm to 28 mm and iliac artery diameters of 12 mm to 16 mm.

The Cook Zenith endograft has multiple self-expandable stainless steel Z stents inside a dense woven polyester graft. It achieves suprarenal fixation of a bare transrenal stent with barbs that hook proximal to the renal arteries to limit migration. It can be delivered via an 18-F or 22-F outer diameter delivery system for the main body and a 14-F or 16-F system for the contralateral iliac limb. It can accommodate aortic neck diameters from 22 mm to 32 mm and iliac diameters of 8 mm to 24 mm. The Zenith graft has greater use in academic and tertiary care medical centers.

The Gore Excluder stent is made of expanded polytetrafluoroethylene with an outer self-expanding nitinol support structure. It is wrapped around the delivery system with thread that is pulled to deploy the device. It employs infrarenal anchors to inhibit migration, and its delivery system is flexible. The Excluder requires an introducer sheath. The main body utilizes an 18-F inner diameter sheath, and the contralateral limb is introduced with a 12-F inner diameter sheath. The Excluder has the largest overall market share in the US.

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Finally, the Talent stent graft is made of multiple self-expandable nitinol stents attached with sutures to the inside of a thin Dacron graft. The nitinol stents in the iliac limbs are placed outside of the graft. It accommodates 22-mm to 32-mm aortic necks and 8-mm to 20-mm iliac arteries. It is delivered via a 20-F to 24-F outer diameter main body sheath and an 18-F outer diameter iliac limb sheath. An advantage of this system is its ability to treat AAAs with larger aortic necks. However, this device is not yet FDA-approved in the US.

Greater than 90% of these grafts are implanted by vascular surgeons, with fewer performed by interventional cardiologists or radiologists. Access can be achieved with surgical exposure of the femoral artery, although a total percutaneous method has been performed with suture closure devices. However, there is a significant complication rate associated with percutaneous placement. The future role of the various specialties is likely to continue with current trends.

EVAR 1, EVAR 2, AND DREAM TRIALS

The growing number of endografts placed makes it an attractive component of practice. The EVAR 1, EVAR 2, and DREAM trials have added further level I evidence that may suggest a shift from open to endovascular management of AAAs larger than 5.5 cm.[25-27] The DREAM and EVAR 1 trials compared open to endovascular repair, and both found a lower initial mortality rate, although with significantly higher reintervention rates and hospital costs. EVAR 1 also demonstrated a persistent reduction in AAA-related deaths at 4 years. The EVAR 2 trial randomized patients unfit for operative repair between EVAR and nonoperative management. It found no survival advantage of EVAR and noted higher reintervention rates and hospital costs. However, the

statistical significance of this comparison is not conclusive. Thus, endovascular repair of AAAs is associated with higher reintervention rates and costs that, in the US, are borne primarily by Medicare (44% to 93%) or HMOs (25% to 56%),[28-30] in addition to private insurance. However, the advantage of lower short-term mortality rates has made endovascular repair of large AAAs an attractive option to open repair. Overall, the results of EVAR 1, EVAR 2, and DREAM trials have had a limited impact on current practice. FDA approval of devices is still a significant but perhaps appropriate barrier, as are costs of endograft development and placement.

POSTPROCEDURE SURVEILLANCE

Surveillance methods after EVAR are necessary for evaluation of potential complications including aneurysm expansion, endoleak, graft migration, graft limb thrombosis, and degeneration of the fabric structure.[31,32] The optimal imaging modality and frequency of surveillance remain incompletely defined. The typical postoperative imaging modality employed after endograft AAA repair is spiral CT scanning.[33,34] This is performed usually at 1 month, 6 months, 12 months, and then annually postoperatively. Pre- and postcontrast helical CT of the abdomen and pelvis are performed. If endoleaks are identified, further evaluation is generally warranted.[34,35] However, not all patients who rupture after EVAR demonstrate an increase in aneurysm sac diameter, highlighting the limitations of spiral CT alone in identifying patients with risk for rupture.[31]

Three-dimensional CTA with volumetric analysis has been studied as an alternative or adjunctive imaging modality to identifying increases in aneurysm sac size after EVAR. Some studies have found volumetric analysis to be more accurate in determining sac size change.[36] Three-dimensional CTA has also been used to correlate mechanical wall stress with the risk for AAA rupture.[37]

Other imaging modalities that do not rely on iodinated contrast material have been studied. These include duplex ultrasound with or without contrast enhancement and cine MRA. Contrast-media–enhanced duplex ultrasound has been shown to improve detection of endoleak[38] and may be useful for patients with contraindications to contrast material. Cine MRA has been used to quantify aneurysm wall motion during the cardiac cycle and to correlate it with endoleak.[39] However, both modalities need further comparative investigation, and neither can currently replace helical CT for surveillance after EVAR. Experimental models have also been developed, which focus on measurements of intrasac pressure as a marker for successful repair. The CardioMEMS (Atlanta, GA) wireless pressure sensor has been implanted within excluded aneurysm sacs as a potential method of diagnosing type II endoleaks.[40]

FUTURE TRENDS

In the future, EVAR will likely be more widely applied due to technical advancements in endograft designs, which will allow anatomic criteria to be broadened. Development of grafts that can be delivered through smaller devices may permit total percutaneous placement and insertion through smaller iliac arteries. Fenestrated and branch graft techniques are also being developed in which renal and mesenteric vessels are catheterized and preserved by insertion of side grafts. This can be used to achieve endograft repair of juxtarenal aneurysms. Fixation devices, including the endostaple,[41] which uses a stapler to attach the graft to the artery for a better seal, are also being developed. Furthermore, screening of AAAs has been shown to reduce aneurysm-related mortality.[42,43] Thus, technical improvements in graft and delivery design, advancements and expansion of surgical experience, and developments in pre- and postoperative surveillance methods, will likely result in the increased application of EVAR in the US. ■

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