

Midterm Results of a Single-Center Experience with Commercially Available Devices for Endovascular Aneurysm Repair

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Abstract

Purpose: To review the outcome of endovascular abdominal aortic aneurysm repair (EVAR) using commercial stent graft devices.

Methods: Retrospective review of 167 EVAR procedures using different commercial devices at a single center between 1999 and 2003. Analysis included preoperative patient morbidities, operative and hospitalization data, postoperative complications, procedural outcome and midterm patient survival. Data are expressed as mean \pm SD and total number (%). P-values \leq 0.05 were considered significant.

Results: A total of 153 men and 14 women (mean age 75.0 ± 7.3 years, range 53.1–89.2 years) underwent EVAR. Technical success rate was 97.0%. Postoperative intensive care unit stay was 0.05 ± 0.24 days and hospital stay was 4 ± 1.84 days. Postoperative complications occurred in 25 patients (15.0%). Two patients had to be readmitted within 30 days. Median follow-up time was 16.0 months (0–48 months). Overall mortality rate was 9.6% and did not depend on the type of endograft used ($p=0.287$). No early or aneurysm-related deaths or aneurysm ruptures occurred. Clinical success rate was 91.6% (153 patients). Graft limb thrombosis occurred in 5 patients (3.0%), all with the AneuRx device ($p=0.041$). Graft migration was seen in 3 devices (1.8%). There were 36 endoleaks (20.4%), specifically 30 branch vessel (type II) and 6 junctional (type I) endoleaks. Early endoleaks occurred in 21 patients (12.5%) and late endoleaks in 15 (9.0%). Twenty-two patients (13.0%) required secondary procedures (75.0% catheter-based vs. 25.0% surgical). Three patients (1.8%) underwent conversion to open aortic repair, 2 (1.0%) within the first year after EVAR. Aneurysm sac stabilization or shrinkage (≥ 5 mm reduction in transverse aneurysm diameter) occurred in 98.2% of patients; aneurysm shrinkage rate was 39.6% at 1 year, 68.74% at 2 years and 79.96% at 3 years after the procedure. Time to aneurysm shrinkage was longest with the AneuRx (1.96 ± 0.18 years) and Talent (1.67 ± 0.53 years) devices, compared to the Zenith (1.01 ± 0.13 years), Ancure (0.95 ± 0.14 years) and Excluder (0.25 ± 0.17 years) stent grafts ($p=0.0001$).

Conclusion: Endovascular aortic aneurysm repair using commercially manufactured devices is safe and effective, especially in patients at high risk for open aneurysm resection. While evolving endovascular experience has significantly decreased complication and secondary intervention rates, close long-term follow-up remains mandatory to detect late complications. Elective and unbiased use of all available surgical and interventional procedures is required to maintain long-term clinical success after EVAR.

Key Words: Abdominal aortic aneurysm, EVAR, commercial endograft, endograft migration, complication rate, secondary procedures, improved outcome, stent grafts.

List of Abbreviations

AAA: abdominal aortic aneurysm
ASA: American Society of Anesthesiologists

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CI: confidence interval
CT: computed tomography
EF: ejection fraction
EVAR: endovascular abdominal aortic aneurysm repair
FDA: Food and Drug Administration
FEV1: forced expiratory volume at 1 second
ICU: intensive care unit
IDE: investigational device exemption
MI: myocardial infarction
PVB: paravertebral blockage
SD: standard deviation
VC: vital capacity

Introduction

ENDOVASCULAR ABDOMINAL aortic aneurysm repair (EVAR) was introduced thirteen years ago (1) to prevent rupture of abdominal aortic aneurysm (AAA) in patients at very high risk for open surgical repair. Compared to open surgery, it requires shorter operative, intensive care and total hospital time; has lower postoperative morbidity; and allows for an earlier postoperative return to function (2–5). Such favorable results have made EVAR an attractive method for elective AAA repair (6–10), especially for octogenarian patients (11). With increasing device versatility, EVAR is currently the preferred treatment option for the majority of AAA patients (12).

However, growing experience has revealed that the durability of initial aneurysm exclusion is challenged over time by the pulsatile aortic blood flow and post-EVAR changes in aortic morphology. Related late adverse events after EVAR include endograft migration and kinking, separation of modular devices, and stent and graft fabric fatigue (13–18). Therefore, EVAR currently mandates long-term or even life-long follow-up (14–16) to avoid late aneurysm rupture (13). These problems are mirrored in high secondary procedure rates (19.6–29%) over midterm follow-up as reported in early endograft experiences (19–21). However, many of the device designs used in these early series failed to achieve recognition by the Food and Drug Administration (FDA). The endovascular armory, as well as the understanding of aortic remodeling, have been steadily refined since then. We report on recent developments and outcomes in EVAR, and our EVAR experience with commercial FDA-approved and investigational devices placed in patients between 1999 and 2003.

Patients and Methods

We did a retrospective review of all consecutive patients undergoing endovascular repair of infrarenal aortic or aorto-iliac artery aneurysms at our institution between June 1999 and December 2003. This study was approved by our Institutional Review Board; informed written consent was obtained from all patients prior to EVAR. The studied group comprised patients with commercial endograft designs (Table 1). Patients with custom-made devices and patients with previous endovascular treatment at outside institutions were excluded. Primary study endpoints included aneurysm-related survival, freedom from rupture, and freedom from secondary procedures (including conversion). Secondary study endpoints were overall survival, freedom from endograft migration, any type of endoleak, aneurysm enlargement, and postoperative complications. Data were abstracted from our prospective electronic endovascular database, and occasionally, additional information was obtained from paper medical records.

Patient Selection

Endovascular repair was offered to patients considered to be at high risk for open aortic surgery. This was defined as presence of significant cardiac comorbidities (e.g., stable angina, reversible or fixed perfusion deficit on stressed cardiac scan, myocardial infarction [MI] < 6 months prior to surgery, ejection fraction [EF] < 35%) or pulmonary comorbidities (e.g., vital capacity [VC] < 1.85 L, forced expiratory volume at 1 sec [FEV1] < 1.2 L, or < 35% of predicted, pulmonary hypertension, home oxygen use), known intolerance to general anesthesia, or hostile abdomen. A patient's preference was another reason for offering endovascular treatment.

TABLE 1
Commercial Stent-Graft Devices Placed

	Total	Male	Female	1999*	2000	2001	2002	2003
AneuRx (Medtronic, AVE, Minneapolis, MN)	90	85	5	8	28	23	15	16
Zenith (Cook, Inc., Bloomington, IN)	45	38	7	0	18	14	6	7
Ancure+ (Guidant, Inc, St. Paul, MN)	12	12	0	0	2	5	3	2
Talent (Medtronic, AVE, Santa Rosa, CA)	18	16	2	0	1	0	3	14
Excluder (W.L. Gore, Inc., Flagstaff, AZ)	2	2	0	0	0	0	0	2
Total	167	153	14	8	49	42	27	41

* Only November–December 1999 included.

+ device withdrawn from market in June 2003 by company.

Anatomical Suitability

Aneurysm configuration, proximal neck length and angulation, and iliac measurements were obtained by computed tomography (CT) angiography with 3 mm cuts, followed by 3-dimensional reconstruction. Circumferentially calcified small iliac arteries (< 7 mm diameter), a proximal neck with circumferential mural thrombus, extensive angulation (> 60 degrees to the main aortic axis), or an inverted funnel shape (> 10% increase in diameter over 15 mm length) were considered anatomic exclusion criteria. A proximal mid-neck diameter of less than 32 mm was acceptable for the Talent device, 28 mm or less for the Zenith, and less than 25 mm for the remaining devices. These differences originate from the different levels of proximal endograft anchorage: While the Zenith and Talent devices utilize transrenal fixation with bare proximal stents, the Ancure, AneuRx and Excluder devices anchor below the level of the renal arteries. Follow-up included physical examination, biplanar abdominal plain radiography and helical CT angiography at 1, 6 and 12 months post-procedure, and every 6–12 months thereafter. Once the maximum aneurysm sac diameter had decreased to approximately that of the stent-graft, the CT was substituted for ultrasound surveillance.

Definition of Success

Technical success was defined as successful vascular access, device deployment with no type I or III endoleak, and graft patency through the first 24-hour postoperative period. Clinical success was defined as absence of the following: AAA related death, any type I or III endoleak, AAA diameter enlargement > 5 mm, > 20% graft dilation, graft migration, device failure, aneurysm rupture, or early or late conversion to open repair. Due to inter-study and inter-observer differences, aneurysm shrinkage was defined as a decrease of 5 mm or more compared to preoperative values and sac enlargement as increase in transverse aneurysm diameter of 5 mm or more between any two studies.

Death was classified as operative death (within 30 days of surgery) or late death, either aneurysm related (secondary to aneurysm rupture or any primary or secondary procedure) or unrelated. Endograft migration was defined as caudal graft dislocation of more than 10 mm.

Endoleak Classification

Endoleaks were categorized as periprosthetic (type I: inadequate sealing of the attachment

zone), branch vessel (type II: retrograde flow via an aortic side branch), or transgraft (type III: direct graft fabric defect or disconnection of modular graft components) endoleaks, or a blush of contrast inside the aneurysm sac through graft fabric porosity (type IV) (22, 23). Aneurysm enlargement in the absence of demonstrable perfusion was defined as endotension (type V). For time-to-endoleak analysis, all patients with detectable endoleak during follow-up were counted as positive for endoleak, regardless of whether the endoleak subsided, was treated, or persisted at the time of the last available follow-up CT study. Immediate treatment was recommended for all type I and III endoleaks. Uncomplicated type II endoleaks were observed, but treated in the presence of transverse aneurysm diameter increase of 5 mm or more if the patient experienced pain, or based upon the diameter of the AAA.

Statistical Analysis

Data are expressed in total numbers and percentages or mean values \pm standard deviation (SD) and range. Dichotomous variables were compared with Chi-2 analysis and Fisher's exact tests. Numeric data were tested for normal distribution using the one-sample Kolmogorov-Smirnov test and parametric or non-parametric tests applied as indicated. Cumulative survival, time-to-endoleak and time-to-secondary-procedure were estimated using log-rank tests and the Kaplan Meier estimator. Statistical analyses were conducted with SPSS software (Version 10.0; SPSS Inc., Chicago, IL), and for all tests statistical significance was assumed if $p \leq 0.05$.

Results

Between November 1999 and December 2003, commercial endografts (Table 1) were used by 167 patients (91.6% male and 8.4% female). Mean transverse diameter of the treated aneurysms was 56.32 ± 8.78 mm (range 32–84 mm, one patient with a small AAA [< 50 mm] also had bilateral common iliac artery aneurysms). Patient comorbidities are outlined in Table 2. Patient assignment to a specific device was based upon anatomic suitability and, if the device was still investigational at time of treatment, our ability to treat high-risk patients based upon inclusion in an FDA-approved clinical trial (Talent).

General anesthesia was used in 89.8% of cases, while paravertebral blockage (PVB) (24) with conscious sedation was used in 7.2%, spinal anesthesia in 2.4%, and local anesthesia in 0.6%.

TABLE 2
Preoperative Patient Demographic and Medical Comorbidity Data

	Mean	SD
Age (years)	75.0	7.3
Weight (kg)	84.85	16.12
Height (cm)	174.15	8.46

	n	% of Patients
Age ≥ 80 years	43	25.7
Use of nicotine	76	45.5
<i>Past</i>	55	32.9
<i>Current</i>	21	12.6
Hypertension	115	68.5
Diabetes mellitus	21	12.6
<i>Insulin dependent</i>	9	5.4
Hyperlipidemia	93	55.7
<i>Drug controlled</i>	78	46.7
Carotid artery disease	42	25.1
<i>History of TIA / stroke</i>	9	5.4
<i>Acute stroke / permanent deficit</i>	4	2.4
Coronary artery disease	97	58.1
<i>Unstable angina,</i>	7	4.2
<i>MI < 6 months ago</i>		
Ejection fraction < 50%	61	31.8
Oral anticoagulation	17	10.2
Pulmonary	71	42.5
<i>VC < 1.85 l, FEV1 < 1.2l,</i>	8	4.8
<i>< 35 % predicted,</i>		
<i>pO2 > 45 mm Hg,</i>		
<i>home oxygen use</i>		
Renal	20	12.0
<i>Creatinine > 6.0, dialysis,</i>	2	1.2
<i>post-transplant</i>		
Cancer	11	6.6
ASA score		
2	14	8.4
3	131	78.4
4	21	12.6

TIA = transient ischemic attack, MI = myocardial infarction, VC = vital capacity, FEV1 = forced expiratory volume at 1 sec, ASA Score = American Association of Anesthesiologists Score.

Mean operation time was 180.4 ± 62.9 min. Intraoperative blood loss was 401.4 ± 392.0 mL. During the procedure, 21.6% of the patients received cell-saved autologous blood (89.0 ± 184.8 mL), while only 4.2% required packed red blood cell transfusion (0.2 ± 0.7 units). Total amount of intraoperative intravenous fluids was 3208.0 ± 1271.5 mL. Length of hospital stay was 4.0 ± 1.84 days (2–16 days), and while 95.8% of the patients required no postoperative intensive care, 3.6% of all patients were admitted to the intensive care unit (ICU) for 1 day and 0.6% for 2 days (overall mean 0.1 ± 0.2 days).

Initial endograft deployment was successful in all patients, and 24-hour technical success was

97.0%. Technical failure included partial coverage of a renal artery (1.2%), postoperative early graft limb thrombosis (0.6%), and postoperative type I endoleak (1.2%). At the end of follow-up, overall clinical success was 91.6%.

Primary Study Endpoints and Patient Survival

During the observed study period (mean 16.0 ± 13.0 months, range 0.1–48 months), there were no aneurysm-related deaths or aneurysm ruptures (0.0%).

The estimated cumulative overall survival for the observed time interval was 92.1% at 1 year, 84.7% at 2 years and 84.7% at 3 years. Postoperative survival was the same for all endograft groups ($p = 0.287$).

Secondary procedures after EVAR are listed in Table 3. Overall cumulative reintervention rate was 14.1% at 1 year, 15.6% at 2 years and 23.5% at 3 years (Fig. 1), with an estimated freedom from reinterventions at 1, 2, 3 years of 85.0%, 84.4%, 74.1% for the AneuRx, 83.1%, 83.1%, 83.1% for the Zenith, and 77.9%, 77.9%, 77.9% for the Ancure device groups, respectively (Kaplan Meier method, $p = 0.883$). One reintervention (7.1%) was required in the Talent and none (0.0%) in the Gore group. Conversion to open surgery (1.8%) was performed for aortic rupture during proximal aortic stent deployment (day 30), progressive suprarenal aneurysm formation (day 113) and en-

TABLE 3
Secondary Procedures (Interventional and Surgical) following EVAR

	Intervention Surgery		
Patients (%)	22 (13.2%)*	18 (72%)	7 (28.0%)
Type of Procedure	n	%	
Surgical conversion	3	10.7	x
Bypass (cross-over)	1	3.6	x
Graft limb thrombectomy	1	3.6	x
Inguinal wound revision	2	7.1	x
Angioplasty ± stent	5	17.9	x
Additional proximal cuff	4	14.3	x
Additional distal extension	2	7.1	x
Embolization (coils/glue)			
of type II endoleak	10	35.7	x
TOTAL	28+	100.0	21 (75%) 7 (25%)

* 3 patients underwent both interventional and surgical secondary procedures.

+ 1 patient underwent four unsuccessful attempts for embolization of a type II endoleak.

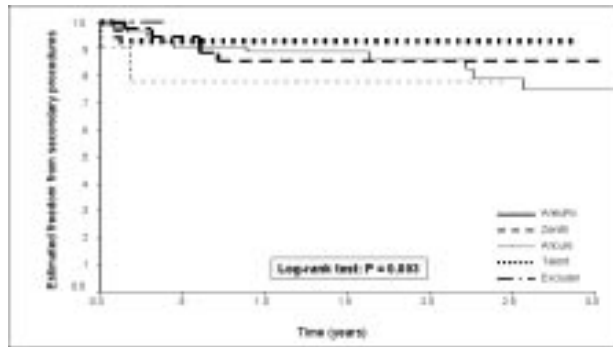


Fig. 1. Freedom from secondary procedures after deployment of commercial EVAR devices.

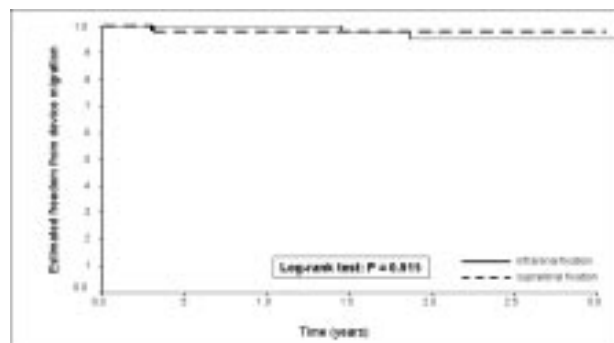


Fig. 2. Cumulative freedom from endograft migration for infrarenally (n = 104; drawn line) and suprarenally (n = 63; interrupted line) anchored devices (p=0.915).

dotension (day 935). Type II endoleak embolization was successful in 71.4% of attempted cases.

Secondary Study Endpoints

EVAR-related adverse events are shown in Table 4. Graft migration occurred in 1.2% of pa-

tients. With no differences with respect to endograft fixation, the overall cumulative migration rate at 1, 2 and 3 years was 0.0%, 5.1% and 5.1%, respectively (Fig. 2). Any type of endoleak at any time (16.7% type I, 83.3% type II) occurred in 21.6% of patients during follow-up. Cumulative probability of endoleak development was 15.5% at 1 year, 23.9% at 2 years and 32.2% at 3 years (Kaplan Meier method). The type of endograft used did not influence overall endoleak occurrence (p=0.804). Overall, 25.0% of the endoleaks resolved spontaneously, 30.6% were treated, and 47.2% were still present at the time of the latest available CT scan (all type II).

Aneurysm measurement during follow-up revealed maximum transverse aneurysm diameter decrease in 47% and aneurysm size stabilization in 51.2% of patients, accounting for a freedom from further aneurysm enlargement in 164 of 167 patients (98.2%) at the end of follow-up. Aneurysm enlargement was encountered in 1.2% of patients. Cumulative occurrence of shrinkage was 39.6% at one year, 68.7% at two years and 80.0% at three years follow-up. Time to occurrence of aneurysm shrinkage was longer in patients with AneuRx (1.96 years; standard deviation [SD] 0.18; 95% confidence interval [CI] 1.5997–2.3230) and Talent devices (1.67 years; SD 0.53; 95% CI 0.6438–2.7284), but shorter in Zenith (1.01 years; SD 0.13; 95% CI 0.7466–1.2635), Ancure (0.95 years; SD 0.14; 95% CI 0.6686–1.2281) and Excluder stent-grafts (0.25 years; SD 0.17; 95% CI 0.0–0.5876) (p=0.0001).

Early postoperative systemic complications occurred in 15.0% of patients. These included pneumonia (2.4%), respiratory insufficiency (0.6%), atrial fibrillation (1.8%), myocardial infarction (0.6%) and congestive heart failure (0.6%), as well as ileus (1.2%), bleeding duodenal ulcer (0.6%) and pancreatitis (0.6%). Multi-organ

TABLE 4
Aneurysm and Graft Related Adverse Events during Follow-up for Commercial Devices

	Total	AneuRx	Zenith	Talent	Ancure	Excluder
Patients (n)	167	90	45	18	12	2
Mortality rate (30 days) % (n)	0.0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Early endoleak rate % (n)	12.5 (21)	12 (11)	11 (5)	17 (3)	17 (2)	0 (0)
Late endoleak rate % (n)	9.0 (15)	13 (12)	7 (3)	0 (0)	0 (0)	0 (0)
Graft infection rate % (n)	0.0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Limb thrombosis rate % (n)	3.0 (5)	6 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Immediate conversion rate % (n)	0.0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
1-year surgical conversion rate % (n)	1.0 (2)	1 (1)	2 (1)	0 (0)	0 (0)	0 (0)

n = total number, conversion = conversion to open repair, early endoleak = endoleak detected on CT scan within 30 days after EVAR, late endoleak = de-novo endoleak arising later than 30 days after EVAR

failure and sepsis each occurred in 0.6% of all patients. Decrease in renal function with an increase in serum creatinine > 30% compared to baseline occurred in 7.2% of patients. Two patients (1%) with pre-existing end-stage renal disease resumed dialysis after surgery. After 334 inguinal incisions, wound infection (defined as positive cultures and need for antibiotic treatment) rate was 1.5%, and incidence of lymphoceles 3.3%. Two lymphoceles required treatment, one by aspiration and one by surgical revision. Re-hospitalization rate within 30 days was 1.0% for bilateral groin infections and shortness of breath and occurrence of a proximal type I endoleak after implantation of an AneuRx device (1).

Twelve patients (7.2%) experienced problems related to their iliac limbs, including 5 total (all in AneuRx patients; $p=0.041$) and 1 partial occlusion, 2 stenoses, 1 graft kinking, 1 iliac artery laceration with intimal flap, 1 distal type I endoleak and 1 bad anchorage of the distal sealing zone. Two limb occlusions (40%) needed further interventions, while 3 nearly asymptomatic patients refused reintervention and were treated medically.

Discussion

First described by DuBost (25), open surgical repair of abdominal aortic aneurysms (AAA) provides excellent long-term results and has a low operative mortality in elective settings (1.4–4.0%) (26–28). Endovascular abdominal aortic aneurysm repair (EVAR) is a newer treatment strategy for AAA, with dramatically reduced operative pain, morbidity and length of hospital stay compared to open surgery. More important, EVAR allows for AAA repair in patients with severe medical co-morbidities who would otherwise be unsuitable for open treatment options.

In the setting of elective repair of an asymptomatic AAA, however, the favorable early results of EVAR have to measure up against the excellent mortality and long-term results of the open approach. While mortality after EVAR is low (1.5–2.6%) (29, 30) and similar to that of open repair, long-term durability has been an area of great concern for patients who participated in early series. To achieve stable fixation within the diseased vasculature, the endograft needs proximal and distal segments of unaltered aorto-iliac vessel in order to have correct position and tight sealing of the excluded aneurysm. Patient's aorto-iliac anatomy was unsuitable for early endograft designs in up to 90% (bifurcated

grafts), while aorto-monoiliac grafts and transrenal fixation allowed for higher eligibility rates in 48–66%. The most common anatomic exclusion factor remains a proximal neck anatomy unsuitable for endograft anchorage. Narrow or tortuous iliac anatomy inadequate for device delivery is less frequent (12, 31, 32); however, early and more rigid device designs were often difficult to navigate through narrow or tortuous vessel segments, with increasing risk of access vessel laceration or even aneurysm rupture. EVAR series from 1994–1999 reported iliac access and femoral vessel complications in 9–13.9% (29, 33). Contemporary endografts are more flexible, with a long, tapered introducer tip to reduce shear forces during device advancement, and access-related morbidity declined substantially in a more recent series (34). In this series, only one iliac artery laceration (0.5%) occurred (Talent). Another vexing problem, especially with unsupported endograft designs (endograft fabric without internal or external supportive metal skeleton), was stenosis or thrombosis of the iliac limbs, resulting in reintervention rates as high as 38% (bifurcated Guidant graft) (35). These findings led to a more supported and rigid limb design, as used in modular stent-grafts. Surprisingly, all limb occlusions in our series occurred with the modular AneuRx endograft. Nevertheless, the resulting overall limb thrombosis rate of 3% (5% for AneuRx devices) is consistent with occlusion rates reported by other large series using the AneuRx graft, including a US multicenter trial (3% limb occlusion rate) (36). After successful graft deployment, postoperative remodeling of the excluded aneurysm can have major impact on the durability of the repair. Unlike open repair, continuing proximal aortic neck dilatation has been recognized as an important variable after EVAR (37, 38). During endograft deployment, the proximal device diameter is tailored to fit the aortic infrarenal diameter; ongoing dilatation compromises graft fixation and may lead to device migration and failure of aneurysm exclusion. Makaroun et al. reported progressive neck dilatation within 2 years in 20% of patients (39); endograft migration subsequently has been recognized to be time-dependent, similar to endoleak occurrence or postoperative survival after EVAR. Analysis of the AneuRx multicenter trial data found that low endograft deployment below the renal arteries and short proximal fixation zone length were more indicative of late migration than preoperative aneurysm morphology or proximal neck length (40).

Endoleak (reperfusion of the excluded aneurysm sac) formation after EVAR is also time dependent. The cumulative endoleak rate in this series of 23.9% at two years compares to other large series using multiple devices (29, 41), and unlike previous reports (42), we did not experience significant device-specific differences in endoleak rates. In the subgroup of endoleaks, however, the late (> 30 days after EVAR) endoleak occurrence was 3 times higher with the AneuRx device as compared to other devices. While this did not reach statistical significance, it was paralleled by slower aneurysm sac shrinkage in the AneuRx group. However, given the time-dependent manner of endoleak occurrence, we cannot exclude a type II error in our series, as the AneuRx device was the most commonly used, and those patients also had the longest postoperative follow-up. Device-specific differences in aneurysm involution rates have been reported previously, and in their large series from the Cleveland Clinic, Ouriel et al. also noted a trend towards an increased number of microleaks in AneuRx devices (41), which would support our results.

In earlier series, secondary procedures were reported in 29–38% of patients over midterm follow-up (35, 42). Improved device design and refined patient selection have significantly lowered secondary procedure rates. Contemporary results of second and third generation stent-grafts include lower re-intervention rates (15–20%) (16, 18). The midterm reintervention rate in this study compares favorably, with 11.9% of patients requiring an additional procedure.

Clearly, EVAR is a rapidly evolving technology, widely used by a variety of medical specialists (e.g., vascular surgeons, interventional radiologists, interventional cardiologists). However, of paramount importance is the commitment to ongoing follow-up by both physicians and patients, to ensure long-term aneurysm exclusion. EVAR is a new therapeutic option in the management of AAA, a potentially life-threatening condition, and rigorous long-term follow-up, if possible with prospective patient registries, has often been mandated (43). The recently reported nationwide EVAR experience from France from 1999–2003 (44), however, revealed how sobering real countrywide results for this new procedure can be. Thirty-day mortality (3.1%) and 1-year mortality (5.3%; 2.2% device and procedure-related) and complication rates (19.9%) were surprisingly high, with 31% of the aneurysms treated being smaller than 50 mm in diameter. In light of two large randomized studies (45, 46) demonstrating the low risk of spontaneous aneurysm rupture (<

1%) for such small aneurysms, these mortality rates seem even more unacceptable. Also, a complete lack of follow-up surveillance was reported for 18.6% of all patients. These data clearly indicate that EVAR can under no circumstances be considered a “single-session” treatment performed by interventionalists without commitment to or logistic abilities for ongoing patient care, regardless of specialty. With the optimum endograft design and mechanism of aortic fixation yet to be determined, responsible patient selection and reliable postoperative surveillance must ensure that the patient receives maximum benefit from this new technology.

Conclusion

EVAR is a frequently used, effective alternative to conventional open surgery, especially for selected patients with otherwise excessive operative risk. Rapidly evolving technology and growing experience continue to dramatically improve complication and secondary procedure rates, but favorable long-term outcome can only occur with meticulous follow-up, and early and elective secondary interventions. Unbiased and sophisticated use of all available endovascular procedures and devices, including staged use of endografts with different anchoring and landing zones, in combination with surgical procedures, is necessary to improve outcome and ensure durable aneurysm exclusion.

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