Stent graft migration after endovascular aneurysm repair: Importance of proximal fixation

Christopher K. Zarins, MD, a Daniel A. Bloch, PhD, a Tami Crabtree, MS, a Alan H. Matsumoto, MD, b Rodney A. White, MD, a and Thomas J. Fogarty, MD, a Stanford and Torrance, Calif; and Charlottesville, Va

Objective: We reviewed the incidence of stent-graft migration after endovascular aneurysm repair in a prospective multicenter trial and identified factors that may predispose to such migration.

Methods: All patients who received treatment during the course of the multicenter AneuRx clinical trial were reviewed for evidence of stent-graft migration over 5 years, from 1996 to 2001. Post-deployment distance from the renal arteries to the proximal end of the stent graft and the proximal fixation length (length of the infrarenal neck covered by the stent graft) were determined in patients for whom pre-procedure and post-procedure computed tomography scans were measured in an independent core laboratory.

Results: Stent-graft migration was reported in 94 of 1119 patients, with mean time after device implantation of 30 ± 11 months. Freedom from migration was 98.6% at 1 year, 93.4% at 2 years, and 81.2% at 3 years (Kaplan-Meier method). Subset (n = 387) analysis revealed that initial device deployment was lower in 47 patients with migration, as evidenced by a greater renal artery to stent-graft distance (1.1 ± 0.7 cm), compared with 340 patients without migration (0.8 ± 0.6 cm; P = .006) on post-implantation computed tomography scan. Proximal fixation length was shorter in patients with migration (1.6 ± 1.4 cm) compared with patients without migration (2.3 ± 1.4 cm; P = .005). There was significant variation in migration rate among clinical sites (P < .001), ranging from 0% to 30% (median, 8%), with a greater than twofold difference in migration rate between the lowest quartile (6%) and the highest quartile (15%) clinical sites. Univariate and multivariate analysis revealed that renal artery to stent-graft distance (P = .001) and proximal fixation length (P = .005) were significant predictors of migration, and that each millimeter increase in distance below the renal arteries increased risk for subsequent migration by 5.8% and each millimeter increase in proximal fixation length decreased risk for migration by 2.5%. Pre-implantation aortic neck length, neck diameter, degree of device oversizing, correct versus incorrect oversizing, device type (stiff vs flexible), placement of proximal extender cuffs at the original procedure, and post-procedure endoleak were not significant predictors of migration. Migration was treated with placement of extender modules in 23 patients and surgical conversion in 7 patients; 64 patients (68%) with migration have required no treatment.

Conclusions: Stent-graft migration among patients treated in the AneuRx clinical trial appears to be largely related to low initial deployment of the device, below the renal arteries, and short proximal fixation length. Significant variation in migration rate among clinical sites highlights the importance of the technical aspects of stent-graft deployment. Advances in intraoperative imaging and deployment techniques that have been made since completion of the clinical trial facilitate precision of device placement below the renal arteries and should increase proximal fixation length. Whether this, together with increased iliac fixation length, will result in lower risk for migration remains to be determined in long-term follow-up studies. (J Vasc Surg 2003;38:1264-72.)

Endovascular procedures to treat infrarenal abdominal aortic aneurysm (AAA) are effective in preventing aneurysm rupture, with reduced patient morbidity and mortality compared with open surgical repair.1-3 However, migration of endoluminal devices noted after successful endovascular repair raises concerns about long-term durability of endovascular repair.4-6 Migration has been noted with all current endovascular devices and configurations, including those with modular design, unibody design, infrarenal fixation, suprarenal fixation, hook and barb fixation, longitudinal columnar support, and flexible designs.4-10 Risk for migration increases over time, and can result in loss of device fixation proximally, distally, or at modular junctions, with subsequent aneurysm rupture.11-15 The purpose of this investigation was to determine the incidence and significance of stent-graft migration in the multicenter US AneuRx clinical trial with follow-up to 5 years and to identify factors that may predispose to stent-graft migration.

METHODS

Records for all patients who received treatment at 19 clinical sites (see Appendix) over the course of the US
AneuRx clinical trial, from 1996 to 1999, were reviewed for evidence of stent-graft migration with follow-up through August 2001. This review included all patients who received treatment during Phase I (n = 40), Phase II (n = 424), and Phase III (n = 639) of the clinical trial, as well as all patients who did not meet inclusion criteria for the trial but received the AneuRx stent graft on a compassionate-use basis (n = 90). Details of the study design and patient eligibility have been published.\(^1\) Selection criteria included abdominal aortic aneurysm with infrarenal neck length of at least 10 mm and neck diameter between 18 and 26 mm, with maximum distal iliac diameter of 15 mm. Patients were evaluated with pre-procedure and post-procedure contrast material–enhanced computed tomography (CT), with scheduled follow-up imaging at 1, 6, and 12 months and at yearly intervals thereafter. Additional CT scans were obtained at more frequent intervals as clinically indicated. Abdominal x-ray films (kidneys, ureters, bladder) were obtained at scheduled follow-up visits, and stent-graft location and configuration in relation to the vertebral bodies and femoral heads were noted. Follow-up angiograms were obtained as clinically indicated, and were compared with the post-deployment completion angiogram for evidence of migration. The presence or absence of migration was reported by each clinical site at each follow-up patient visit. Migration was defined as any postimplantation movement or displacement of the stent graft in relation to the native aorta or renal arteries, as documented on CT scans, abdominal x-ray films, angiograms, or pathologic analysis. Migration rate and factors that may predispose to migration, and clinical outcome were evaluated in 1119 patients with more than one postimplantation imaging study to allow assessment of migration.

Preoperative, postoperative, and follow-up clinical and imaging data from each clinical site were reported to a centralized data registry and audited by external monitors. Primary clinical end points included aneurysm rupture (intraoperative, perioperative, postoperative), aneurysm-related death (any death within 30 days of the primary procedure or a secondary procedure, or related to aneurysm rupture or to the device), surgical conversion (perioperative and late open surgical aneurysm repair), and overall survival (death from any cause).

An independent core laboratory evaluated preoperative and postoperative CT scans and abdominal x-ray films from 13 clinical sites during Phase II of the trial, and was blinded to patient information. In this subset of 387 patients the distance from the lowermost renal artery to the beginning of the aneurysm and the distance from the lowermost renal
artery to first appearance of the stent graft was determined from serial axial CT scans. The proximal fixation length (length of infrarenal neck covered by the stent graft) was calculated by subtracting the distance from the lowermost renal artery to the top of the stent graft from the length of the infrarenal aortic neck (Fig 1). The minor axis of the infrarenal neck was used to record neck diameter, but no quantification of neck angulation was made by the core laboratory. Thus, in patients with angulated necks the length of circumferential fixation of the stent graft to the aortic neck would be overestimated with this technique (Fig 1, C). Although the preoperative iliac length and diameter were measured by the core laboratory, there was no recording of post-deployment iliac stent position by the laboratory. Thus, in patients with angulated necks the quantitation of neck angulation was made by the core laboratory. In patients with angulated necks the problem could not be solved by using the minor axis of the infrarenal neck to record neck diameter, but no quantification of neck angulation was made by the core laboratory. Thus, in patients with angulated necks the quantitation of neck angulation was made by the core laboratory. In patients with angulated necks the quantitation of neck angulation was made by the core laboratory. In patients with angulated necks the quantitation of neck angulation was made by the core laboratory. In patients with angulated necks the quantitation of neck angulation was made by the core laboratory. In patients with angulated necks the quantitation of neck angulation was made by the core laboratory. In patients with angulated necks the quantitation of neck angulation was made by the core laboratory.
patients at risk at the beginning of the 2-year to 3-year interval. There was no significant difference in Kaplan-Meier migration analysis between the overall clinical trial patient cohort and the subset of Phase II patients with core laboratory data.

**Device design.** There was no significant difference in migration rate between the 174 patients who received the early “stiff” bifurcation design (migration in 10 of 95 patients at 3 years) and the 1019 patients who received the current “flexible” bifurcation design (migration in 7 of 98 patients at 3 years; difference not significant).

**Device oversizing.** The preoperative aortic neck diameter measured on CT scans was compared with the diameter of the implanted stent graft to assess the degree of stent-graft oversizing in relation to stent-graft migration. Migration occurred in 25 of 222 patients (11%) with less than 10% oversizing, 62 of 800 patients (8%) with 10% to 30% oversizing, and 6 of 60 patients (10%) with more than 30% oversizing. There was no significant difference in migration between patients with “correct” oversizing (10-30%, 8% of patients) compared with patients with “incorrect” oversizing (<10% or >30%, 11% of patients; difference not significant). The relation between migration and degree of stent-graft oversizing is shown in Fig 3.

**Proximal extender cuffs.** Proximal aortic extender cuffs were used in 202 of 1119 patients (18%) at stent-graft implantation. One extender cuff was placed in 13% of patients, two extender cuffs in 3% of patients, and three or more extender cuffs in 1% of patients. Proximal extender cuffs were often needed during the trial when intraoperative migration of the bifurcation module occurred while withdrawing the delivery system. Postoperative migration was not significantly affected by the need to place a proximal extender cuff at initial treatment or the number of extender cuffs used. Migration in patients with no proximal extender cuffs was 8%, in those with one extender cuff was 7%, in those with two extender cuffs was 16%, and in those with three or more extender cuffs was 9%.

**Proximal stent-graft fixation.** Core laboratory analysis of the subset of 387 patients revealed no significant difference in infrarenal neck length between the 47 patients with migration (2.7 ± 1.3 cm) and the 340 patients without migration (3.1 ± 1.4 cm). However, in patients with migration the distance from the lowest renal artery to the proximal end of the stent graft was 38% greater (1.1 ± 0.7 cm) than in patients without migration (0.8 ± 0.6 cm; P = .006), indicating lower initial deployment of the stent graft (Table II). This resulted in a 30% shorter fixation length of the stent graft to the infrarenal neck in patients with migration (1.6 ± 1.4 cm) compared with patients without migration (2.3 ± 1.4 cm; P = .005).

Migration rate was 19% in patients with fixation length less than 1.0 cm (17 of 89 patients), 17% in patients with fixation length 1.0 to 1.5 cm (8 of 46 patients), and 9% in patients with fixation length greater than 1.5 cm (22 of 252 patients).

Migration rate in patients with fixation length less than 1.5 cm was twofold greater than in patients with fixation length greater than 1.5 cm (P = .005). Migration rate in patients with fixation length less than 1.0 cm was twofold greater than in patients with fixation length greater than 1.0 cm (P = .02). The Kaplan-Meier estimate of risk for migration at 3 years with fixation length less than 1.5 cm was 22%, and migration risk with fixation length greater than 1.5 cm was 14% (P = .007, log-rank test). The Kaplan-Meier estimate of risk for migration at 3 years with fixation length less than 1.0 cm was 23%, and migration risk with fixation length greater than 1.0 cm was 15% (P < .05, log-rank test).

**Migration rate and clinical site.** There were significant differences in migration rate (P < .001, ANOVA) among the 13 Phase II clinical sites, ranging from 0% to 30% (mean, 12% ± 9.3%). Migration rate for the lowest quartile was 6%, median migration rate was 8%, and migration rate for the highest quartile was 15% (Fig 4). The number of patients who underwent treatment at these sites ranged from 6 to 73 (mean, 30 ± 20), with no clear relationship between number of patients and migration rate at that site. Treatment was administered at these same 13 sites in 989 of 1119 patients (88%) in the study. The number of patients receiving treatment at these sites during the entire clinical trial ranged from 10 to 179 (mean, 76), with 3-year freedom from migration rate, according to Kaplan Meier analysis, ranging from 68% to 100% among sites. There was no relationship between number of patients treated at a clinical site and Kaplan-Meier freedom

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**Table II. Proximal stent graft fixation: Core laboratory CT measurements**

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Migration (n = 47)</th>
<th>No migration (n = 340)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neck length (cm)</td>
<td>2.7 ± 1.3</td>
<td>3.1 ± 1.4</td>
<td>NS</td>
</tr>
<tr>
<td>Renal artery to proximal end of stent graft (cm)</td>
<td>1.1 ± 0.7</td>
<td>0.8 ± 0.6</td>
<td>.006</td>
</tr>
<tr>
<td>Proximal fixation length (cm)</td>
<td>1.6 ± 1.4</td>
<td>2.3 ± 1.4</td>
<td>.005</td>
</tr>
</tbody>
</table>

Values represent mean ± SD.
from migration estimate at 3 years. The Kaplan-Meier estimate of freedom from migration at 3 years ranged from 68% to 90% (mean, 77%) at the three sites with the largest patient enrollment (mean number of patients treated, 141), where 67% of patients had fixation length greater than 1.5 cm. The Kaplan-Meier estimate of freedom from migration at 3 years ranged from 89% to 96% (mean, 93%) for the three sites with the lowest patient enrollment (mean number of patients treated, 20), where 87% of patients had fixation length greater than 1.5 cm.

**Predictors of migration.** Univariate cox proportional hazard results revealed that proximal fixation length ($P = .005$) and renal artery to stent-graft distance ($P = .001$) were significant predictors of risk for stent-graft migration. Factors that were not significant predictors of migration at univariate and multivariate analysis included age, gender, risk factors and comorbid conditions, pre-implantation aortic aneurysm size, pre-implantation aortic neck length, pre-implantation aortic neck diameter, degree of device oversizing or undersizing, correct versus incorrect oversizing, device type (stiff vs flexible), use of extender cuffs at implantation, and post-procedure endoleak. Multivariate analysis including both proximal fixation length and renal artery to stent-graft distance yielded $P$ values of .04 and .01, and hazard ratios of 0.975 and 1.058, respectively. These results indicate that both of these factors are independently predictive of migration and that each millimeter increase in length of fixation decreases the hazard of migration by 2.5% and each millimeter increase in renal artery to stent-graft distance increases the hazard of migration by 5.8%. However, there were significant differences in migration rate among clinical centers. Adjusting the multivariate model for clinical center results in $P = .007$ for stent-graft fixation, with a hazard ratio of 0.967, and $P = .058$ for renal artery to stent-graft distance, with a hazard ratio of 1.044.

**Clinical outcome.** Among the 94 patients with stent-graft migration, one patient had aneurysm rupture and underwent successful open surgical repair. Seven aneurysms ruptured among the 1025 patients (0.7%) with no stent-graft migration (not significant). Six patients underwent elective surgical conversion because of migration, with type I endoleak, with or without aneurysm enlargement; and one patient underwent emergent surgical conversion because of rupture. Twenty-three of 94 patients with migration (24%) underwent secondary endovascular treatment, with placement of proximal modular stent-graft extenders, with or without distal stent-graft extenders. Thus 30 of 94 patients (32%) with migration underwent treatment. There were no treatment-related or aneurysm-related deaths. Sixty-four patients (68%) with migration have not required treatment or secondary procedures, and continue to be monitored with clinical follow-up and serial imaging studies.

**Treated versus untreated migration.** There was no significant difference between patients with migration, with (n = 30) or without (n = 64) treatment, with regard to age, gender, risk factors, or comorbid conditions. There were no significant differences in preoperative aneurysm size, aortic neck diameter, or aortic neck length between treated patients and untreated patients (Table III). Proximal fixation length was shorter in patients with treatment (1.0 ± 1.2 cm) compared with patients without treatment (1.9 ± 1.4 cm; $P < .05$) patients. Treated patients had larger aneurysms at the last follow-up (6.1 ± 1.2 cm vs 5.5 ± 1.1 cm; $P < .005$) and had more endoleaks (53% vs 11% of patients; $P < .0001$), particularly type I endoleak, compared with untreated patients. There was no difference in time to discovery of migration in treated patients (21 ± 9 months) compared with untreated patients (23 ± 12 months), and no difference in duration of implant between patients with treated migration (34 ± 10 months) and untreated migration (37 ± 11 months). There have been no deaths related to the aneurysm, stent graft, or migration among either treated or untreated patients, and no difference in 3-year survival (Kaplan-Meier analysis) between patients with treated migration (100%) and untreated migration (93%; not significant).

**DISCUSSION**

Documentation of aortic endograft migration after successful aneurysm exclusion has raised substantial concern regarding the long-term durability of endovascular procedures to treat AAA. Continuous downward displacement forces are exerted on all aortic devices by the

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**Table III. Treated versus untreated migration**

<table>
<thead>
<tr>
<th></th>
<th>Treated (n = 30)</th>
<th>Untreated (n = 64)</th>
<th>P</th>
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</thead>
<tbody>
<tr>
<td>AAA diameter (cm)</td>
<td>5.7 ± 1.1</td>
<td>5.8 ± 1.0</td>
<td>NS</td>
</tr>
<tr>
<td>Neck diameter (cm)</td>
<td>2.2 ± 0.2</td>
<td>2.3 ± 0.3</td>
<td>NS</td>
</tr>
<tr>
<td>Neck length (cm)</td>
<td>2.3 ± 1.5</td>
<td>2.8 ± 1.4</td>
<td>NS</td>
</tr>
<tr>
<td>Fixation length (cm)</td>
<td>1.0 ± 1.2</td>
<td>1.9 ± 1.4</td>
<td>&lt;.05</td>
</tr>
<tr>
<td>AAA diameter at migration (cm)</td>
<td>6.1 ± 1.2</td>
<td>5.5 ± 1.1</td>
<td>&lt;.05</td>
</tr>
<tr>
<td>Endoleak rate (%)</td>
<td>53</td>
<td>11</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Time to migration (mo)</td>
<td>21 ± 9</td>
<td>23 ± 12</td>
<td>NS</td>
</tr>
<tr>
<td>Duration of implant (mo)</td>
<td>34 ± 10</td>
<td>37 ± 11</td>
<td>NS</td>
</tr>
</tbody>
</table>

AAA, Abdominal aortic aneurysm; NS, not significant.
pulsatile nature of blood flow,17 with cumulative effects over time. Thus it is not surprising that migration has been noted with all endovascular aortic devices and with prosthetic aortic grafts placed at open surgery.18 There is no evidence of permanent tissue bonding between the aorta and implanted prosthetic devices, and prevention of distal migration of aortic devices appears to depend on the continuing integrity of fixation mechanisms over both the short and long terms. Mechanical fixation of the AneuRx stent graft depends on radial and frictional forces of the stent graft applied to the aortic neck, iliac arteries, and modular junction, along with longitudinal columnar support provided by the stent graft. This study provides evidence for the importance of proximal fixation length in preventing migration. Although iliac fixation length and columnar strength are also important, data regarding these factors are beyond the scope of this study.

AneuRx stent-graft migration has been reported from European centers in which patients received treatment during the same time frame as the US AneuRx clinical trial (1996-1999), with migration rates similar to those found in the clinical trial patients. Tutein Nolthenius et al19 reported 128 patients who received the AneuRx stent graft, of which 77 patients had minimum follow-up of 12 months. Stent-graft migration occurred in 6 patients, with a 2-year migration rate of 10% at life table analysis and 42 patients at risk at 2 years. This is similar to the 7% migration rate at 2 years at Kaplan-Meier analysis in our study. The report by Cao et al4 of 148 patients noted migration in 17 of 113 patients followed up for 2 or more years. Migration rate at life table analysis was 21% at 3 years, with 27 patients at risk at this time point. This is similar to the 3-year Kaplan-Meier migration rate of 19% found in our analysis. A higher migration rate was reported by Conners et al,5 who reported AneuRx device migration in 15 of 91 patients with a minimum of 1 year of follow-up, and found a cumulative migration rate at χ² analysis of 42% (8 of 19 patients) at 3 years. This variability in migration reported by individual centers outside the trial is consistent with our finding of a significant difference in migration rate at various centers in the multicenter clinical trial.

Stent-graft migration may result from a variety of causes, which may act together or individually, including patient selection, preoperative characteristics of the aneurysm and aortic neck, characteristics and properties of the endovascular device, precision of device deployment, postoperative morphologic changes in the aneurysm, aortic neck enlargement, and endoleak.20-24 AneuRx stent-graft migration has been attributed to preoperative aneurysm size,4 device oversizing,5 post-implantation aortic neck enlargement,6 and use of a stiff device early in the clinical trial.6 These were not found to be significant predictors of migration in this study.

We found that low deployment of the stent graft, below the renal arteries, and short proximal fixation length were significant predictors of subsequent stent-graft migration. Low deployment may be the result of poor patient selection, suboptimal imaging of the renal arteries during deployment (poor image quality, angulation, lack of magnification, movement, or parallax) or of downward displacement of the primary bifurcation module during retraction of the delivery system. Our finding of significant differences in post-deployment migration rate among clinical centers suggests that the technique and precision of implantation are important to long-term effectiveness of this device. Indeed, for each millimeter increase in distance of the stent graft below the renal artery, the hazard of migration increases by 5.8%, and for each millimeter increase in proximal fixation length the hazard of migration decreases by 2.5%. Preoperative aortic size, aortic neck length, degree of device oversizing or undersizing, device type (stiff vs flexible), use of proximal extender cuffs at device implantation, and post-procedure endoleak were not significant predictors of migration. This is not to say that these factors are not clinically important; they simply do not appear to predict subsequent stent-graft migration.

Cao et al4 similarly used univariate and multivariate analysis to study AneuRx stent-graft migration, and found no relation to device oversizing, preoperative aortic neck diameter, length, angulation, thrombus, use of a stiff device, or presence of endoleak. In contrast to our results, these authors did not find that deployment of the device more than 10 mm below the renal artery was a significant factor for migration, but identified neck enlargement greater than 10% and preoperative aortic diameter greater than 5.5 cm as independent risk factors for stent-graft migration.

Our finding that short proximal fixation length of the stent graft to the infrarenal neck was a significant predictor of the likelihood of subsequent stent-graft migration is consistent with clinical observations that poor stent-graft fixation is a primary cause of clinical failure, resulting in aneurysm rupture and need for secondary treatment or conversion to open surgical repair.10,11,15,16,20,21,25,26 However, it should be noted that poor fixation can also occur at the modular junction and iliac arteries, which were not quantitatively studied in this core laboratory analysis. The method used in this study to calculate length of achieved fixation involved measuring the axial distance from the lowermost renal artery to the top of the stent graft, as seen on post-implantation CT scans, and subtracting it from the length of the infrarenal neck as measured on axial CT scans. Although this method may give an accurate estimate of fixation length when the aneurysm and aortic neck are straight, it is likely that effective fixation length is overestimated if the aneurysm and aortic neck are significantly angulated (Fig 1). Thus, true fixation length may have been shorter than was calculated in this study. With significant neck angulation, the superior aspect of the stent graft may be in close proximity to the renal artery, and the inferior aspect of the stent graft may have little contact with the aneurysm neck, resulting in ineffective fixation and seal. In this study we had no meaningful data on neck angulation for analysis. However, short angulated necks with poor stent-graft fixation are significant factors in aneurysm rupture15 and predictors of adverse clinical events.20,22 This
suggests that patients with angulated necks may require longer infrarenal necks, compared with patients with straight necks, for secure stent-graft fixation.

There were significant differences in migration rates among clinical sites, being low at some sites and high at other sites. Furthermore, we found no relation between migration and number of patients treated at each site, and migration rate for each center did not appear to change over the course of the clinical trial. In this regard, it should be noted that the primary end point for procedural success during the trial was complete aneurysm exclusion with no endoleak. Migration, however, is a late event, and often does not appear for several years after implantation. Critical information regarding long-term success of endovascular aneurysm repair became known only after completion of the clinical trial and therefore could not affect the learning curve during the trial. Aneurysm rupture after successful AneuRx device implantation was first reported in 1999 and published in 2000, after all patients included in this report had already undergone treatment. Failure analysis of patients with rupture identified the primary cause of aneurysm rupture to be poor fixation of the stent graft in the aortic neck, iliac arteries, or bifurcation junction gate, rather than presence or absence of endoleak. A morphologic analysis by Fillinger et al provided information that aortic neck length and angulation, as well as proximal and distal fixation length, are significant predictors of adverse clinical events and the need for secondary procedures. This information was provided to clinical investigators, and was included in training sessions for new users of the device after US Food and Drug Administration approval. Thus, although patient selection criteria for the clinical trial included patients with a 1.0-cm infrarenal neck length, the current manufacturer’s instructions for use recommends a 1.5-cm infrarenal aortic neck length and avoidance of neck angulation greater than 45 degrees. On the basis of knowledge gained thus far, it is not known whether this “learning curve,” after completion of the trial, has resulted in centerspecific reduction or overall reduction in migration rate.

Substantial improvements in intraoperative imaging and device implantation techniques have evolved since completion of the AneuRx clinical trial. Early technique involved using a tabletop ruler to reference the renal arteries, with no magnification or image intensifier angulation. Current techniques involve high-resolution image intensifiers, with magnification and angulation of the C-arm to

Fig 5. AneuRx stent graft placed during clinical trial, with complete aneurysm exclusion and no endoleak. Left, Low positioning of stent graft in aortic neck, with short proximal fixation length and short iliac fixation length, are evident on post-implantation CT scan (three-dimensional reconstruction). Right, Stent-graft migration with development of type I endoleak and aneurysm enlargement, noted at 23 months, were successfully treated with placement of proximal and distal extender cuffs. Current recommended clinical practice is to achieve fixation at initial endovascular treatment by positioning the device just below the renal arteries and using iliac modules, as needed, to extend the device to the level of the hypogastric arteries.
precisely locate the renal arteries during deployment. These techniques are now routinely used in most practices, but were used only rarely at some clinical sites during the trial. Improved techniques of buttressing or deployment of the opposite iliac limb before pulling the runners on the main bifurcation device, along with recent improvements in the delivery system (expedient delivery system introduced in 2002), have virtually eliminated downward migration of the primary bifurcation module during device deployment. This occurred commonly during the clinical trial, and frequently required deployment of a proximal aortic extender cuff to compensate for initial stent-graft deployment well below the renal arteries. Although the frequency of extender cuff use at each clinical site was not a predictor of subsequent migration, the current need for proximal extender cuffs at initial treatment appears to be substantially less than during the clinical trial. Distal extension of the stent graft with additional modules to the level of the iliac bifurcation is now commonly performed, but was rarely used during the clinical trial. Current awareness of the importance of stent-graft fixation has likely resulted in improved initial fixation of the stent graft compared with the practice during the clinical trial (Fig 5).

The clinical significance of stent-graft migration is variable. Most patients with migration in the AneuRx clinical trial (68%) have required no treatment thus far. More than half of the patients in the experience of Cao et al and two thirds of the patients in the study by Conners et al have not required treatment. In patients who require treatment, such as those with type I endoleak or aneurysm enlargement, usually a proximal aortic extender cuff can be placed, to the level of the lowermost renal artery. This was true in 77% of patients with stent-graft migration in the AneuRx trial, with only 23% of treated patients needing surgical conversion. Similarly, Cao et al were able to treat 75% of patients with migration with aortic extender cuffs, and open repair was required in only 2 patients. Conners et al and Tutein Nothernies et al were able to treat all migration with extender cuffs, with no need for surgical conversion. These good results are likely due to careful and ongoing surveillance, with prompt secondary treatment as clinically indicated. It is possible that over time more patients in whom migration has been identified will require secondary treatment.

The clinical experience of endovascular aneurysm repair with the AneuRx stent graft is favorable. Three-year Kaplan-Meier analysis of the primary end points in all 1193 patients treated during the course of the clinical trial reveals low aneurysm rupture rate (1.6%), low aneurysm-related death rate (3.1%), low surgical conversion rate (5.8%), and overall survival of 76.6%. 

CONCLUSION

Device migration after endovascular aneurysm repair with the AneuRx stent graft appears to be largely related to precision of deployment of the stent graft just below the renal arteries and the length of proximal fixation achieved after device deployment, rather than to preoperative neck length or aneurysm anatomy. This highlights the importance of the technical aspects of stent-graft deployment. Improved intraoperative imaging and deployment techniques, together with improved patient selection, may result in achieving increased length of proximal fixation at device implantation. This, together with improved distal iliac fixation, may lower migration rates. Most device migration can be treated with endovascular placement of modular stent-graft extenders. The long-term outcome after such treatment remains to be determined.

REFERENCES

The positive aspects of this multicenter trial are that it is prospective, involves a large number of patients, and has had data from one of its phases analyzed by an independent core laboratory. The article is an important one, since the authors have previously identified poor fixation as the cause of most ruptures following endovascular repair with the AneuRx prosthesis. It is unfortunate, therefore, that migration at modular connections and between the prosthetic limbs and native iliac arteries was not addressed.

Since the article reports clinically significant events almost entirely on the basis of imaging findings, it is regrettable that details of imaging and methodology of measurement are not included in the text. It is well known that parallax error in plain radiographs makes detection of endograft migration by reference to bony landmarks on images obtained at different times an unreliable method. Similarly, in the absence of any information on the thickness of CT slices, the sensitivity of this modality in detecting migration is called into question. The criteria by which the core laboratory and clinical sites assigned the dichotomous endpoint of migration or no migration are missing, together with information on the intraobserver and interobserver error for measuring migration. Migration is defined by the authors as “any postimplantation movement or displacement of the stent graft.” If this statement is taken at face value, all 1025 patients categorized as having no migration would have had to have follow-up imaging with the endograft assigned the identical distance from the reference point as in the postdeployment images, accurate to the last millimeter. Information is also lacking on imaging data coming from participating clinical sites and not reviewed by the core laboratory. If these data were not obtained under any defined protocol and were produced by observers with variable skill levels, migration may have been underreported.

Although the stated objective of the article is to identify factors that may predispose to stent-graft migration, the relatively high incidence of migration itself tends to overshadow the culprit factors of low initial deployment of the device below the renal arteries and a short proximal fixation length. The incidence of migration documented in the article is a cause for some concern. Two of the clinical sites had migration rates of 30% (Fig 4), while the mean follow-up from implantation is limited to 23 months, which is just short of a marked increase in events, and that 70% of patients did not reach the 3-year follow-up time point. Since the cut-off date for this study was August 2001, surgeons and patients will await with interest the authors’ next report.

REFERENCES


INVITED COMMENTARY

James May, MD

The positive aspects of this multicenter trial are that it is prospective, involves a large number of patients, and has had data from one of its phases analyzed by an independent core laboratory. The article is an important one, since the authors have previously identified poor fixation as the cause of most ruptures following endovascular repair with the AneuRx prosthesis. It is unfortunate, therefore, that migration at modular connections and between the prosthetic limbs and native iliac arteries was not addressed.

Since the article reports clinically significant events almost entirely on the basis of imaging findings, it is regrettable that details of imaging and methodology of measurement are not included in the text. It is well known that parallax error in plain radiographs makes detection of endograft migration by reference to bony landmarks on images obtained at different times an unreliable method. Similarly, in the absence of any information on the thickness of CT slices, the sensitivity of this modality in detecting migration is called into question. The criteria by which the core laboratory and clinical sites assigned the dichotomous endpoint of migration or no migration are missing, together with information on the intraobserver and interobserver error for measuring migration. Migration is defined by the authors as “any postimplantation movement or displacement of the stent graft.” If this statement is taken at face value, all 1025 patients categorized as having no migration would have had to have follow-up imaging with the endograft assigned the identical distance from the reference point as in the postdeployment images, accurate to the last millimeter. Information is also lacking on imaging data coming from participating clinical sites and not reviewed by the core laboratory. If these data were not obtained under any defined protocol and were produced by observers with variable skill levels, migration may have been underreported.

Although the stated objective of the article is to identify factors that may predispose to stent-graft migration, the relatively high incidence of migration itself tends to overshadow the culprit factors of low initial deployment of the device below the renal arteries and a short proximal fixation length. The incidence of migration documented in the article is a cause for some concern. Two of the clinical sites had migration rates of 30% (Fig 4), while Kaplan-Meier analysis demonstrates an increasing incidence with time (18.8% at 3 years, Fig 2). Moreover, it should be noted that the mean follow-up from implantation is limited to 23 months, which is just short of a marked increase in events, and that 70% of patients did not reach the 3-year follow-up time point. Since the cut-off date for this study was August 2001, surgeons and patients will await with interest the authors’ next report.

REFERENCES