Endograft migration one to four years after endovascular abdominal aortic aneurysm repair with the AneuRx device: A cautionary note

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Background: **Positional stability of the endograft is essential for long-term durability after endovascular abdominal aortic aneurysm repair (EAR). However, the cumulative risk of delayed endograft migration has been sparsely reported.**
Method: **A total of 91 patients studied underwent EAR with the AneuRx endograft with a minimum 1 year from implantation. Data from a prospective database were assessed for proximal endograft migration, defined as ≥5 mm change from the initial endograft position. Multiple anatomic characteristics were also examined. Sixty-nine patients were alive, with complete follow-up at 1 year, with a mean time from implantation of 33.2 ± 1.1 months. Data are mean ± SEM.**
Results: **Endograft migration occurred in 15 patients, giving a cumulative event rate of 7.2% (5/69) at 1 year, 20.4% (10/49) at 2 years, 42.1% (8/19) at 3 years, and 66.7% (2/3) at 4 years post-EAR ($P = .01$). Although the initial aortic neck diameter did not differ between the groups (21.5 ± 0.6 mm vs 21.8 ± 0.3 mm, $P = .61$), significant ($P < .05$), late aortic neck enlargement was seen in patients with migration (25.0 ± 1.6 mm, 26.2 ± 1.2 mm, and 27.0 ± 1.0 mm at 1,2, and 3 years, respectively) but not in nonmigrators. Regression analysis demonstrated a statistically significant ($P < .05$) correlation between endograft oversizing and late aortic neck dilation. Overall migration risk was 29.2% in patients oversized >20% and 18.6% in patients oversized ≤20%. Aortic neck angulation (23.4 ± 6.6 degrees vs 23.5 ± 3.3 degrees, $P = .99$), aortic neck length (25.9 ± 2.5 mm vs 27.0 ± 1.6 mm, $P = .74$), initial endograft/aortic neck overlap (18.6 ± 2.6 mm vs 19.4 ± 1.4 mm, $P = .80$) and size of abdominal aortic aneurysm (55.5 ± 1.5 mm vs 54.9 ± 1.4 mm, $P = .84$) were similar between migrators and nonmigrators, respectively. Secondary endovascular treatment with aortic cuffs was required in five patients with device migration.**
Conclusions: **Device migration after EAR with the AneuRx endograft occurred with significant frequency, the incidence of which increased with the length of follow-up. Late aortic neck dilation was significantly associated with migration. Oversizing of the endograft of >20% may accelerate this late aortic neck dilation. However, the etiologies of endograft migration were likely multifactorial, as the majority (8/15) of patients experiencing migration were oversized <20%. Although endovascular repair of these migrations is usually possible, the long-term durability of these secondary procedures is unknown. Careful surveillance for this endograft failure mode must be an essential component of post-EAR follow-up. (J Vasc Surg 2002;36:476-84.)**

Endovascular repair of infrarenal abdominal aortic aneurysms (AAAs) has grown rapidly since Parodi reported the first case over a decade ago.[1] Although initial prototypes had fairly high early failure rates,[2] second- and third-generation endografts have demonstrated excellent short-term results.[3,4] As such, the quest for long-term durability is now becoming the *holy grail* of endovascular aneurysm repair (EAR).

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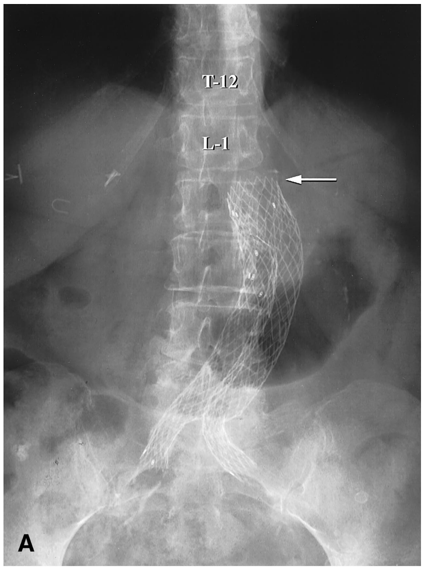
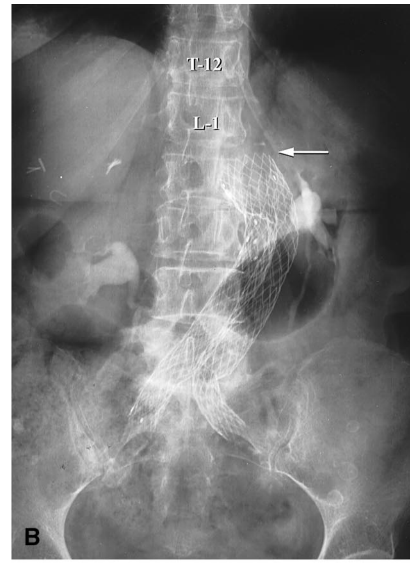
Midterm reports of EAR have generally sounded a cautionary note, demonstrating a significant incidence of late problems that require intervention.[5,6] Failure modes after EAR have included modular component separation,[7,8] stent and/or hook fractures,[9] fabric erosion,[10] and "micro leaks" presumably causing endotension and aneurysm expansion.[11] Because positional stability of the endograft is essential for long-term durability, proximal endograft migration is another important potential failure mode (Figs 1 *A*, *B*, and *C*). In order for EAR to challenge open AAA repair in patients who have a long life expectancy, these failure modes must be identified and minimized. The purpose of our study was to examine the incidence and risk factors for one particular failure mode, that of proximal endograft migration.

METHODS

From September 1997 to December 2000, 94 patients with infrarenal AAAs were evaluated and scheduled for repair with an AneuRx endograft (Medtronics/AVE Inc, Sunnyvale, Calif) at the Ochsner Clinic Foundation Hospital. Preoperative contrast-enhanced computed tomo-





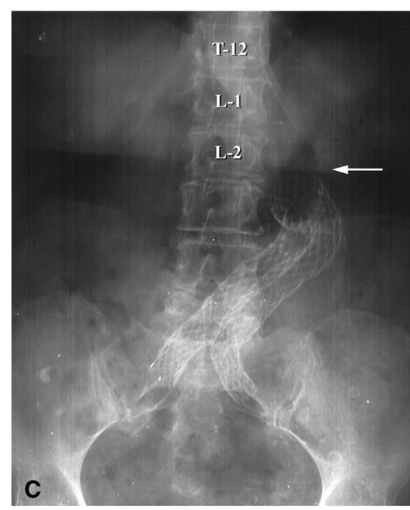


Fig 1. **A**, Postoperative plain abdominal radiograph demonstrating endograft position at the L1-L2 level (*arrow*). **B**, Plain abdominal radiograph demonstrating endograft position at the L1-L2 level (*arrow*) 1-year post implantation. **C**, Plain abdominal radiograph demonstrating endograft position at the L2-L3 level (*arrow*) 2 years post implantation.

graphic (CT) scanning and selective use of arteriograms were employed to select individuals with appropriate anatomy. The majority of patients were enrolled in phase II/III US Food and Drug Administration (FDA) trials and thus met those inclusion criteria.[3] Specific details regarding our operative team, experience with intraoperative imaging, and preference towards regional anesthesia have been published previously.[12] Postoperative follow-up consisted of a 1 to 2 week, 1-month, 6-month, 12-month and then yearly clinic visit unless indications demanded more frequent attention. Radiographic surveillance included a contrast-enhanced CT scan (2.5-mm axial images) and plain abdominal radiographs at each follow-up visit. Surveillance imaging of individuals who elected to have follow-up elsewhere was requested from the primary physician. Anatomic and outcome data from each follow-up visit were collected and recorded in our vascular section database. Query of this prospectively maintained database supplemented with a retrospective review of medical records was performed to retrieve all patient demographics, anatomic characteristics, and outcome data.

Definitions. Endograft migration was detected on axial CT scans by identifying changes in graft positioning in relation to the lowest renal artery. Specifically, the distance from the inferior aspect of the most caudad renal artery to the first axial cut with any appreciable endograft was measured. In accordance with the Lifeline Registry guidelines, migration was considered to be movement of the endograft ≥5mm.[13] Changes in neck diameter were detected by comparing follow-up CT images to the preoperative scan. Aortic neck diameter was measured from the external edges (adventitia-to-adventitia) by using manual calipers. All anatomic measurements were made from hard copy films. In a minority of cases, an accurate preoperative record was unavailable so the initial postoperative CT scan was used as the baseline (n = 4). Postoperative aortic neck diameters were measured at the first image that contained a portion of the endograft. In patients who experienced endograft migration, comparisons were made to postoperative scans to identify the original level of the endograft for subsequent neck diameter measurements. To avoid false measurements related to neck angulation, minor axis diameters were used. Measurement of the angle between the infrarenal aortic neck and the longitudinal axis of the aneurysm was measured with a protractor from either angiograms or three-dimensional CT reconstructions.[12] Overlap of the aortic neck by the endograft was calculated by subtracting the initial postoperative neck length (distance measured on CT

Table I. Patient cohort stratified by year from implantation

Years of follow-up	*1*	*2*	*3*	*4*
Initial patient cohort	91	70	34	6
Exclusions				
Death	10	10	6	1
Delayed conversion*	0	2	1	0
Incomplete data	12	9	8	2
Final patient cohort	69	49	19	3

*Total delayed conversions equal 2; one patient suffered a rupture and one had a persistent endoleak with aneurysm expansion.

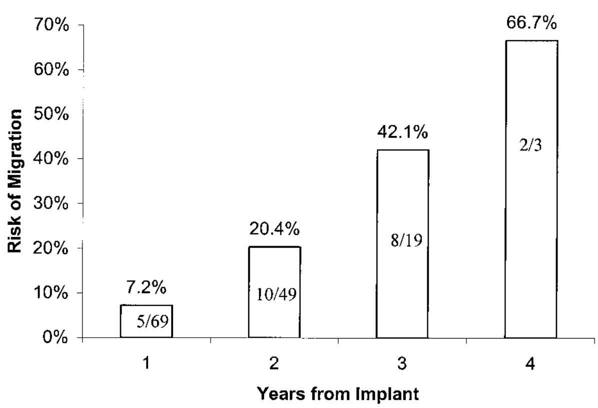


Fig 2. Cumulative risk of endograft migration.

scan from the lowest renal artery to the endograft) from the preoperative aneurysm neck length. Percentage of endograft over-sizing was calculated by the following formula: ([endograft diameter/aortic neck diameter]-1) × 100. The attending surgeon reviewed all images at the time of follow up.

Patients were evaluated for endograft migration at 1, 2, 3, and 4 years post endograft implantation. To assess for temporally related risk factors for migration, subgroup analyses were performed on patients stratified to four different categories on the basis of time from implantation. To avoid confounding variables, any individual experiencing migration was excluded from further subgroup analysis after the event date. However, patients who migrated earlier (ie, at 1 or 2 years) but had follow-up at a later date (ie, at 3 years) were included in calculations of cumulative risk of migration.

Statistics. Cumulative risk of endograft migration was assessed by use of χ^2 analysis. Differences in patient age, aneurysm size, aortic neck diameter, neck length, and neck angulation, endograft oversize, and endograft/aortic neck overlap were tested for significance by using two-tailed *t* tests. Bivariate and linear regression analyses were used to test for relationships between endograft over-sizing and changes in aortic neck diameter. Correlations between degree of over-sizing and late aortic neck dilation were tested with a one-way analysis of variance (ANOVA). Data are presented as mean ± standard error.

RESULTS

A total of 94 patients were studied in an intent-to-treat protocol. AneuRx modular bifurcated endografts were successfully implanted in 91 (96.8%) patients; three (3.2%) patients underwent conversion to an open repair. Five patients who were undergoing successful deployment of endografts were treated with the early "stiff-body" prototype. The average patient age was 72.6 years, and the mean aneurysm size was 55.0 ± 1.1 mm. Of the 89 patients, 81 (88%) of the patients were male and 11 (12%) were female. Of the 91 patients with successful deployments, 10 died within the first year, leaving an initial cohort of 81 patients with a minimum of 1-year follow-up. The causes of death within the first year were cardiac (n = 4), respiratory (n = 2), cancer (n = 2), and unknown (n = 2). Details regarding exclusion of additional patients during each follow-up period are presented in Table I. A total of 69 patients were available for analysis, with a mean time from implantation of 33.2 ± 1.1 months.

Endograft migration. A total of 15 patients were found to have endograft migration of ≥5 mm. One of these patients had been treated with the "stiff-body" device, whereas the remaining 14 were treated with the currently available AneuRx device. The mean migration distance was 8.8 ± 1.0 mm (range, 5-15 mm). The risk of migration increased with the length of follow-up (Fig 2). Cumulative endograft migration rate was 7.2% (5/69), 20.4% (10/49), 42.1% (8/19), and 66.7% (2/3) at 1, 2, 3, and 4 years post implantation, respectively (P = .01). New episodes of migration were seen during each subsequent year of follow-up. Five patients experienced migration within the first year of follow-up, six within the second year, three in the third year, and one in the fourth year.

Five patients with migration underwent treatment, all with placement of proximal aortic cuffs. Two of these patients had developed type I proximal endoleaks, one of whom experienced rapid aneurysm enlargement (15 mm over 6 months). Patients treated for migration had an average migration distance of 13.3 ± 1.8 mm. The ten remaining patients migrated an average of 7.0 ± 0.6 mm and are currently being managed by close observation.

Anatomic characteristics of all patient cohorts are presented in Table II. There was a trend towards greater endograft over-sizing in migrators (23.5 ± 3.6% vs 18.2 ± 1.4%) that did not achieve statistical significance (P = .11). Size of AAA, aortic neck length and diameter, aortic neck angulation, and endograft-aortic neck overlap were similar between the two groups. Subgroup analysis of migrators at 1 year (Table III), however, demonstrated a trend towards shorter endograft overlap (12.3 ± 4.3 mm vs 19.7 ± 1.2 mm, P = .12). Migrators at years 2 and 3 (Tables IV and V) had no significant differences or trends in endograft overlap when compared to nonmigrators.

Aortic neck dilation. Aortic neck dilation during follow up differed significantly between groups (Fig 3). Although preoperative neck diameters were not different,

Table II. Anatomic characteristics independent of time from implantation

Characteristic	*Overall (n = 69)*	*Migrators (n = 15)*	*Nonmigrators (n = 54)*	P
M:F (n)	12.8:1	6.5:1	17:1	NA
Age (y)	72.6 ± 0.7	71.3 ± 1.5	73.0 ± 0.8	.33
Aneurysm size (mm)	55.0 ± 1.1	55.5 ± 1.5	54.9 ± 1.4	.84
Preoperative neck diameter (mm)	21.7 ± 0.3	21.5 ± 0.6	21.8 ± 0.3	.61
Graft oversize (%)	19.5 ± 1.4	23.5 ± 3.6	18.2 ± 1.4	.11
Preoperative neck length (mm)	26.7 ± 1.3	25.9 ± 2.5	27.0 ± 1.6	.74
Graft overlap (mm)	19.2 ± 1.2	18.6 ± 2.6	19.4 ± 1.4	.80
Neck angulation (degree)	23.5 ± 2.9	23.4 ± 6.6	23.5 ± 3.3	.99

Data are mean ± SE.

Table III. Aneurysm characteristics 1-year post implantation

Characteristic	*Migrators (n = 5)*	*Nonmigrators (n = 64)*	P
Aneurysm size	54.4 ± 2.5	55.1 ± 1.2	.88
Preop neck diameter	21.8 ± 1.4	21.7 ± 0.3	.94
Graft oversize (%)	20.4 ± 5.8	19.4 ± 1.4	.84
Preop neck length	27.2 ± 5.4	26.7 ± 1.4	.92
Graft overlap	12.3 ± 4.3	19.7 ± 1.2	.12
Neck angulation (degree)	27.5 ± 13.0	23.2 ± 3.0	.71
Neck diameter (1 y)	25.0 ± 1.6	22.6 ± 0.3	.05*
Neck change (1 y)	2.8 ± 1.8	0.6 ± 0.3	.08

*Statistically significant. Data are mean ± SE. Data are in millimeters unless otherwise indicated.

Table IV. Aneurysm characteristics 2 years post-implantation

Characteristic	*Migrators (n = 6)*	*Nonmigrators (n = 39)*	P
AAA Size	57.5 ± 2.8	54.1 ± 1.5	.39
Preop neck diameter	21.0 ± 1.1	21.5 ± 0.3	.58
Graft oversize	27.0 ± 6.9	19.8 ± 1.7	.16
Preop neck length	22.0 ± 3.8	27.7 ± 1.8	.25
Graft overlap	17.7 ± 2.7	19.6 ± 1.7	.66
Neck angulation (degree)	25.7 ± 10.1	20.9 ± 3.7	.62
Neck diameter (2 y)	26.2 ± 1.2	22.7 ± 0.4	<.05*
Neck change (2 y)	4.8 ± 1.7	1.3 ± 0.4	<.05*

Data excludes four patients who migrated within the first year post implantation. Data are mean ± SE. Data are in millimeters unless otherwise indicated.
*Statistically significant.

Table V. Aneurysm characteristic 3 years post implantation

Characteristic	*Migrators (n = 3)*	*Nonmigrations (n = 11)*	P
AAA size	52.7 ± 2.7	51.7 ± 3.4	.89
Preop neck diameter	21.3 ± 0.7	20.5 ± 0.8	.56
Graft oversize (%)	28.2 ± 1.0	18.6 ± 3.9	.24
Preop neck length	29.3 ± 5.0	26.5 ± 2.9	.65
Graft overlap	24.3 ± 7.4	18.3 ± 2.4	.32
Neck angulation (degree)	8.5 ± 8.5	31.0 ± 8.1	.25
Neck diameter (3 y)	27.0 ± 1.0	22.4 ± 0.7	<.05*
Neck change (3 y)	5.7 ± 0.9	2.1 ± 0.9	.07

*Statistically significant.
Data excludes five patients who migrated within the first 2 years post implantation. Data are mean ± SE. Data are in millimeters unless otherwise indicated.

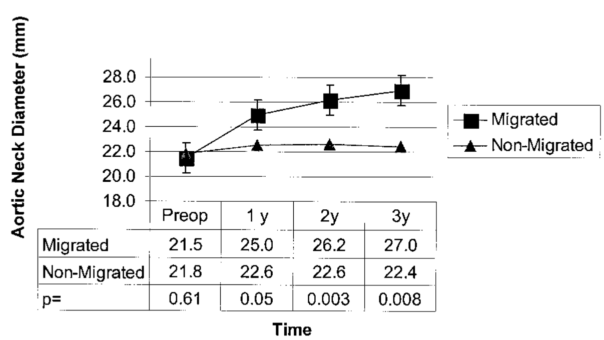


Fig 3. Changes in aortic neck diameter over time in patients with and without endograft migration.

migrators at 1 year had significantly larger neck diameters (25.0 ± 1.6 mm) than did nonmigrators (22.6 ± 0.3 mm), $P = .05$. This significant difference continued in follow-up of patients at 2 and 3 years. It is of interest that individuals who migrated within the second year demonstrated no difference in aortic neck size at 1 year when compared to nonmigrators.

Bivariate analysis demonstrated a highly significant correlation between endograft over-sizing and aortic neck dilation at 1 and 2-years post implantation ($P < .05$). Figs 4 and 5 are linear regression plots demonstrating the relationship of endograft over-sizing and aortic neck dilation. Patients with >20% over-sizing had significantly greater late changes in aortic neck diameter when compared to those with <20% (Fig 6). When patients were categorized by percentage of endograft over-sizing, eight were over-sized ≤20% and seven by >20%. Observed migration within these categories of over-sizing was 18.6% and 29.2%, respectively.

DISCUSSION

Endovascular aneurysm repair has proven to be a reliable alternative for patients with extensive comorbid illness,

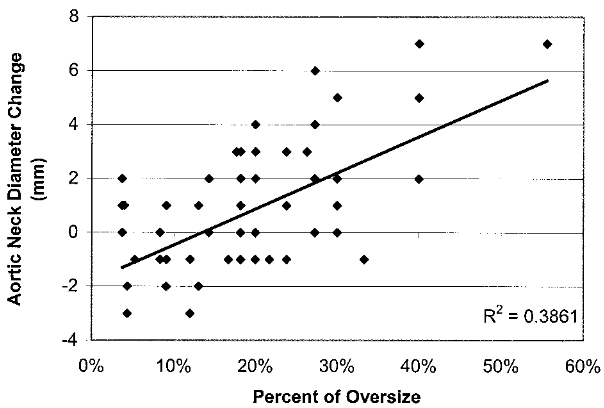


Fig 4. Correlation of over-sizing and neck diameter change 1 year post implantation.

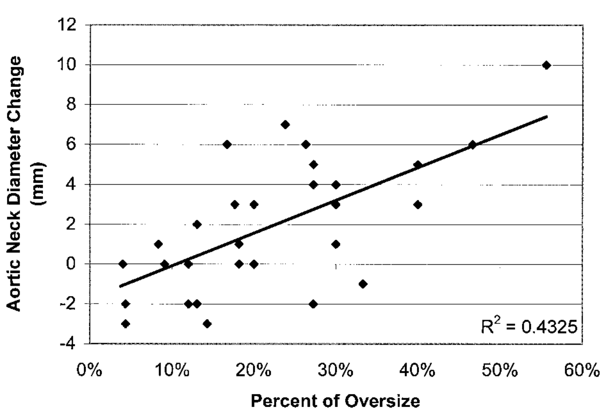


Fig 5. Correlation of over-sizing and neck diameter change 2 years post implantation.

which is believed to preclude them from a conventional aneurysm repair. High rates of successful implantation as well as reductions in blood loss, length of hospital stay, and rates of subsequent aneurysm rupture in the short- to midterm make this procedure ideal for patients with limited life expectancies. Chuter et al[14] demonstrated this advantage in a group of high-risk patients by achieving a 1.7% perioperative mortality rate in a patient cohort that exhibited 81%, 34%, and 49% rates of coronary insufficiency, congestive heart failure, and chronic obstructive pulmonary disease, respectively. Bush and colleagues[4] offered another example of success in this high-risk population when they found comparable success rates at 2 years in patients stratified as either low-risk or increased-risk for intervention based on preexisting medical conditions. Reports such as these have paved the way for acceptance of this technique in the high-risk patient. However, as Bush et al caution in closing remarks "advocating endovascular treatment for the patient who is at low risk for the standard operative intervention remains problematic." The reason for such a warning is based on the fact that the long-term durability of these devices is unknown.

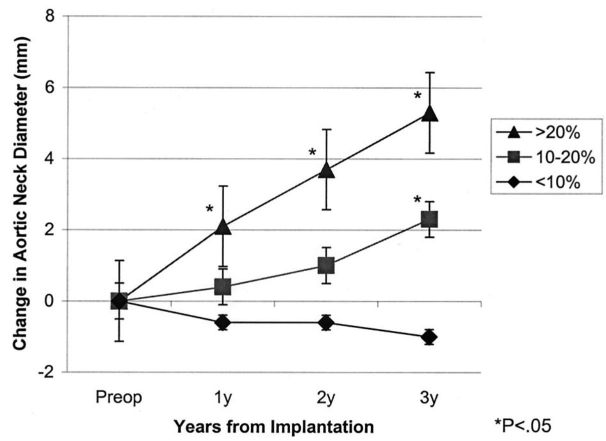


Fig 6. Effect of endograft oversizing on changes in aortic neck diameter over time.

Early problems related to endograft design led to structural modifications that improved success rates, but recent reports of mid- to long-term failures have raised questions regarding endograft durability. Hölzenbein et al[6] reported a prospective follow up analysis of 173 patients with a midterm reintervention rate of 26.6%; 46% of the reinterventions were required within the first year and 74% were required within the second year, suggesting a possible long-term durability problem.

Although a reduction in reinterventions was experienced with second-generation endografts, no comparison was made among different endograft designs. Currently there are a number of different endograft designs that vary in method of attachment, metallic composition, and modular component structure. If valid arguments are to be entertained regarding the long-term durability of particular endografts, focused studies looking for causes of failure need to be conducted and must be endograft specific.

In our analysis of 91 patients with the AneuRx endograft, a significant rate of distal migration was observed that increased over time and did not appear to plateau. Upon evaluation of migration from a temporal standpoint, we determined that our patients experienced event rates of 7.2%, 20.4%, 42.1%, and 66.7% at 1 year, 2 years, 3 years, and 4 years post implantation. Because of the very small number of patients available for 4-year review (n = 3), the risk of migration at this long-term time-point must be considered preliminary. Further long-term follow up with larger cohorts of patients will be needed to assess whether a plateau in the incidence of this failure mode occurs.

Endograft migration with the AneuRx device has been reported previously. In the seminal report of multicenter FDA trial data of this device by Zarins et al,[3] 6.1% (2/33) of patients experienced migration of the proximal endograft at 1 year, similar to our 1-year migration rate of 7.2%. Cao and colleagues[15] reviewed 113 patients with a minimum of 2 years follow-up after EAR with the AneuRx device. In this study, 10 mm was employed as the minimum distance to define migration. A total of 17 patients (15%) had endograft migration with use of this strict definition, giving an event rate of approximately 20% at 24 months and 27% at 36 months by life-table analysis. These late rates of endograft migration were similar to those found in the present study.

Measurement of migration. Evidence of migration in this study was quantified by measuring the distance from the lowest renal artery to the top of the endograft from axial 2.5-mm cuts of CT scans. In patients with significant neck angulation, this method likely *underestimated* true length of device migration. This fact may help explain why aortic neck angulation was not higher in the migrator group. Although the maximum migration distance reported by axial CT measurement in this study was 15 mm, examination of plain radiographs in some patients (Fig 1, *A-C*) suggested that the true migration distance was significantly longer. However, we could not accurately quantify such measurements from plain abdominal radiographs. Measurement of true center-line lengths with multiplanar CT reconstructions may provide more precise length measurements.[16]

Treatment of migration. Treatment of endograft migration has been addressed primarily with the addition of aortic cuff(s). In the study of Cao et al,[15] patients with endograft migration had placement of aortic cuffs in six patients and open conversion in two patients. In a report from the Stanford group, Lee et al[17] examined 67 patients treated with the AneuRx endograft with a minimum of 1-year follow-up (mean, 18 months). In this patient cohort, seven (10.4%) were treated for migration with aortic cuffs. No estimation of an overall (including untreated) migration rate was made. In the current study, five patients (7.2%) were treated with placement of aortic cuffs.

Although treatment of these proximal migrations with aortic cuffs is usually possible, the secondary durability of this approach is unknown. It is possible that continued downward migration of the main device could continue, causing component separation. There are at least 10 reported cases of AneuRx main body separation from aortic cuff(s) that were placed at the initial implant.[7,8,16-18] These component separations occurred 1 to 3 years after implantation. Although firm treatment recommendations cannot be made on the basis of such anecdotal data, patients treated for migration with aortic cuffs warrant very close observation for further migration and/or component separation. In such instances, plain radiographs may be more sensitive in detecting component separation that CT scanning.[7]

Migration risk factors. Risk factors for endograft migration were found by Cao et al[15] to be an initial aortic neck diameter of $\geq$25 mm, preoperative AAA size of >55 mm, and aortic neck enlargement of >10%. We did not find significant differences in either initial neck diameters or AAA size between migrators and nonmigrators. However, our data agreed with the finding that migrators had significant dilation of the aortic neck.

The etiology of endograft migration in dilating aortic necks is intuitive, relating to the loss of friction seal as the neck enlarges. However, the underlying reason(s) for aortic neck dilation is uncertain. Reports on changes in neck size after EAR have been conflicting.[19-20] In this current study, there was a significant relationship between degree of endograft over-sizing and subsequent aortic neck dilation. There is a plausible explanation for this relationship. The AneuRx endograft uses radial force to create wall friction that contributes to stability of the endograft within the aorta. This radial force exerts a constant outward pressure on the aortic wall. Over time this constant outward force may exhaust the elastic recoil of the degenerating aortic wall and result in enlargement of the aneurysm neck. As the aneurysm neck dilates, the endograft approaches its maximal diameter. This in turn translates into a reduction in outward force and ultimately a reduction in the friction that maintains the endograft in position. By excessive oversizing (>20%), the aneurysm neck is exposed to a higher radial force generated by the larger endograft. This may accelerate the natural phenomenon of aneurysm neck dilation.

The decision to oversize the endograft by more than 20% was typically based on the presence of short and/or angulated aortic necks. We felt that the additional radial force might be beneficial with unfavorable aortic neck anatomy. Criado et al[21] have also reported routine oversizing of >20% in patients with challenging neck anatomy. Our long term data, however, suggest that this practice may be counterproductive.

It is important to underscore that the majority (8/15) of migrators were *not* oversized >20%. The causes of endograft migration are likely multifactorial and are not solely a consequence of generous over-sizing. In the subgroup analyses of patients who had migrated by their 1-year follow up, there was a trend toward a shorter initial endograft–aortic neck overlap. This decreased overlap could have contributed to early (1 year) migration. No such trend was seen with later migrators, however.

What design features might minimize endograft migration? It was hypothesized that the columnar rigidity provided by fully supported endografts like AneuRx might prevent migration,[22] but our data and those of others have not found this to be the case. Experimental studies have demonstrated that the addition of barbs and/or hooks to the proximal endograft can significantly increase the displacement force required for endograft migration.[23] A self-expanding endograft with a friction seal only required 2.5 N for displacement, but a device with hooks and barbs required 22.5 N. Early clinical prototypes, mostly with the Ivancev-Malmo stent-graft system, had an unacceptable migration risk despite hooks and barbs.[24] However, other endograft designs with hook fixation have shown minimal migration.[25]

Surveillance and treatment recommendations. On the basis of the findings of this study, the following recommendations can be made. (1) The distance between the lowest renal artery and the endograft should be prospectively recorded from every CT scan and compared to the prior study. Patients with evidence of migration should have more frequent subsequent surveillance. (2) Aortic neck diameter should also be routinely measured in follow-up, and if dilation is seen, more frequent CT surveillance should be instituted, as these patients are at significantly elevated risk of subsequent migration. (3) Prophylactic therapy for significant endograft migration should be considered if the remaining endograft–aortic neck overlap is <5 to 10 mm. With further migration, these patients are at increased risk of acute repressurization of the aneurysm sac that could present as a symptomatic or ruptured aneurysm. (4) Patients treated for migration with aortic cuffs should undergo CT and plain radiograph surveillance at a minimum of every 6 months.

CONCLUSIONS

There was a significant risk of endograft migration after EAR with the AneuRx device, the incidence of which increased with time and did not appear to plateau. Late aortic neck dilation was correlated highly with device migration. Over-sizing of the endograft by >20% significantly increased the risk of late aortic neck dilation. Excessive radial forces associated with endograft over-sizing may contribute to proximal aneurysm neck dilation and subsequent endograft migration. However, it is doubtful that a single factor is responsible for endograft migration; the majority of patients who experience migration in this series were oversized by ≤20%. Although endovascular repair of endograft migration is usually possible, the long-term durability of these secondary procedures is unknown. Careful surveillance for this endograft failure mode must be an essential component of post-EAR follow-up.

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DISCUSSION

Dr L. Stevens (Knoxville, Tenn). Drs. Conners, Sternbergh, Money, and group presented the Ochsner Clinic experience with endograft migration and send a cautionary note. Ninety-four patients are analyzed between 1 and 4 years following endograft placement. Cumulative yearly migration rates of 7%, 20%, 42%, and 67% are reported. In this series, aortic neck angulation, aortic neck length, initial endograft-to-aortic neck overlap, and aneurysm sac size do not predict migration with statistical confidence. This study does, however, determine generous oversizing as a predictor of graft migration and notes dilating necks in migrating aneurysms. This presentation is timely and presses critical issues in aortic endografting. In this arena it is all about outcomes. Specifically targeted are effectiveness, durability, and mechanisms of graft failure. Quantum advance in device design coupled with unforgiving technical learning curves makes tracking outcomes critical yet challenging. This moving-target technology is evidenced by widely varying results according to series, device, and surgeon experience. In a multicenter phase-II FDA trial using the same AneuRx device, there was a 1.7% incidence of migration as measured by the core laboratory. Of these seven, none ruptured, none required conversion, three had no enlargement, and three were treated with secondary cuff placement. In a single-center experience of 128 AneuRx Dr Mall reports a 4.7% incidence of graft migration. Again, in this series there were no ruptures, no migrations requiring open conversion, and only three required cuff repair. Prediction of poor outcomes and migration is not device specific. Studies on Ancure, on Zenith by Brown, and on AneuRx by Fillinger all identify aortic neck angulation as a predictor of poor outcomes. Today's presentation shows no statistically significant impact of neck angulation on migration; however, this same Ochsner group recently presented and published in *Journal of Vascular Surgery* online that neck angulation is a predictor of poor outcomes including death, open conversion, aneurysm expansion, type-I endoleak, and graft migration. Certainly it is important to be cautious. Physicians are learning from early experience, clinical trials, and critical outcomes assessment as presented by these pioneering endovascular surgeons today. I find the outcomes literature for endovascular grafting encouraging and claim that most adverse events are predictable by anatomic criteria and preventable by meticulous planning, patient selection, and technical expertise. At the University of Tennessee in Knoxville, our experience in the research lab and the clinic highlights the importance of placing the graft in healthy vessel segments proximally near the renal arteries and distally well into the iliacs near the iliac bifurcation to secure graft fixation. I would like to congratulate the authors and have four questions for Dr. Sternbergh. First, what do you think is the clinical significance of graft migration? Have you had any ruptures in this series? Have you had to convert any to open for migration? Second, with results you reported here today, are you still implanting the AneuRx device, and, if so, why? Third, do you consider a hostile aortic neck, one with calcifications, mural thrombus, and angulation a risk factor for migration? And last, what planning considerations and technical maneuvers do you perform to prevent graft migration? Thank you.

Dr Sternbergh. (New Orleans, La). Thank you for those comments. Let me start at the top of your questions.

One, what is the clinical significance of this? I think that it is very clinically significant if grafts are migrating. We can only have a long-term durable result if the endograft stays where you have placed it. If it migrates significantly, the ultimate end-result can be a catastrophic loss of seal, causing type-I endoleak aneurysm expansion, and in the worst case scenario, rupture. In our group of 15 patients in whom we have seen migration of 5 mm or greater, five of those have undergone treatment for this migration. Those have all been done with aortic cuffs. Two of those patients had developed type I leaks and one had developed a large expanding aneurysm. We have not had any ruptures in those patients who have migrated. We have had one rupture in our entire series of AneuRx patients, and this was a patient that had a known type-I leak who refused any follow-up and perhaps not surprisingly went on to rupture. That was not associated with migration.

Although we have only treated five of these 15 patients with migration, there are at least one or two patients who are probably going to require an open conversion because of device kinking, which may make an endovascular repair difficult.

Secondly you asked, are we still using this device? In the last 2 years we have been involved with clinical trials of next-generation devices, and the large majority (80%) of our experience in the last 2 years has been with other devices. However, we still are selectively using this endograft in patients with very favorable anatomy who are poor candidates for open repair.

Your third question was about hostile necks, and I think that is a very important question. As you pointed out, data that was presented at the SVS last summer by our group suggested a significant correlation of adverse neck anatomy, particularly neck angulation with late problems including migration (Sternbergh et al, J Vasc Surg 2002;35:482-6). It was very much to my surprise that when we accumulated an additional 10 people who migrated, the significance of aortic neck angulation fell out completely. Our data showed really no trends at all in those who migrated vs those who did not migrate in terms of neck angulation. Does that mean that I think we should be treating highly angulated necks? Absolutely not, and I still think that that is a very significant risk factor for a whole host of problems probably including migration, although our expanded data with more follow-up do not support that.

Dr Francis Robicsek (Charlotte, NC). It is a very interesting study and most probably whatever you said is appropriate, but I have some remarks regarding the methods. You related the neck of the graft to neighboring anatomic structures; however, the aorta may get longer and the spinal column may get shorter in this patient population. We tried to use a similar method when we worked on a study of elongation of Dacron grafts, and we found it somewhat unreliable. You are counting in millimeters. Wouldn't it be a much better method that when you put in the graft somehow to place some separate markers? I am not sure you can do it if you do not operate, but I call your attention. There is a potential fault with the method of relating to neighboring structures because everything moves there. The aorta can bend, may get longer, and unfortunately with advancing age the spinal column maybe gets shorter, and these may influence the measurements.

Dr Sternbergh. Thank you for your questions. All of our measurements were made in relation to the lowest renal artery. Our CT scanning protocol typically uses 2.5-mm cuts. That is one of the reasons we chose a 5-mm minimum to suggest that there really was significant migration. As a corollary we have had at least two or three patients who have migrated less than 5 mm by our measurement, somewhere between 3 mm and 4 mm, who have developed type I leaks and have required repair. They are not included in these data because they did not migrate 5 mm but are still clinically significant. I think that you can very accurately measure migration based on CT scanning and I would encourage everyone in the audience to make that a part of your usual surveillance. Frankly it was not something that we looked for very closely early in our experience. When we found people who had migrated at two years, we went back and looked at their one-year scans, and if you looked very closely, we found that there had been some migration that had not been detected.

Dr Tim Sullivan (Greenville, SC). Chip, I really appreciate you presenting this data. It may offer us some practical tips as to who we should be selecting for endovascular repair because I think that patient selection is key to long-term results.

The first question is, what is the maximum degree of neck angulation that you will consider for a patient for endovascular repair? The KUB that you presented, at least from back, here suggested that that patient did have a significant amount of angulation. We have tended to be very conservative in treating patients, with usually <40 or 45 degrees of neck angulation for endovascular repair.

Second, I seem to recall that one of your coauthors suggested in the past that the way to choose devices was to take careful measurements and then to pick a 28 graft. (laughter) I wonder, has this data changed your clinical practice in terms of oversizing?

Dr Sternbergh. Thank you for those questions, Tim. Our data on neck angulation suggest that the risk of poor outcomes increases significantly when you go beyond a 40-degree neck angulation, and it increases radically once you go over 60 degrees. I think that significant caution should be exercised in treating anybody with a neck angulation greater than 40 degrees.

Your second question in terms of oversizing, I think you are absolutely right. This was an unexpected finding when we were looking at the data to find that there appears to be a correlation of generous oversizing with late aortic neck dilation. Certainly on the basis of these data I think it is very important not to oversize more than 20%. One of the important take-home points, however, is that the majority of the patients who migrated in this series were *not* oversized more than 20%, so I think the reasons for migration are not as simple as too much oversizing, but are most likely multifactorial.