Device migration after endoluminal abdominal aortic aneurysm repair: Analysis of 113 cases with a minimum follow-up period of 2 years

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Purpose: **Device migration (DM) has been shown to cause late failure after endoluminal abdominal aortic aneurysm (AAA) repair. To establish the incidence rate and the predictive factors of distal migration of the proximal portion of the endograft, computed tomographic (CT) scans performed at different time intervals during follow-up examination of 113 patients were reviewed.**

Patients and Methods: **Between April 1997 and March 1999, 148 patients underwent endoluminal AAA repair with a modular endograft with infrarenal fixation (Medtronic-AVE AneuRx, Santa Rosa, Calif) at our unit. CT scans performed at 1, 6, and 12 months after surgery and yearly thereafter were prospectively stored in a computer imaging database. Patient demographics, risk factors, operative details, and follow-up events were prospectively collected. No patients were lost to follow-up examination. Twelve patients died within 2 years of surgery, four patients underwent immediate conversion to open repair, and adequate CT measurements were not feasible in 19 cases, which left 113 patients available for a minimum 2-year assessment and 418 CT scan results reviewed. Two vascular surgeons, blinded to patient identity and history with tested interobserver agreement ($\kappa = 0.64$), separately reviewed axial reconstructions of CT scans. DM was defined as changes of 10 mm or more in the distance between the lower renal artery and the first visible portion of the endograft at follow-up examination. Ten possible independent predictors of DM were analyzed with multivariate Cox proportional hazards regression model.**

Results: **One AAA rupture, which was successfully treated, occurred at a mean follow-up period of 28 months (range, 24 to 46 months). Seventeen patients (15%) showed DM. Eight patients (47%) with DM underwent reintervention: a proximal cuff was positioned in six patients and late conversion to open repair was performed in two patients. Of the 10 variables analyzed with Cox proportional hazards regression model, AAA neck enlargement of more than 10% after endoluminal repair (hazard ratio, 7.3; confidence interval, 1.8 to 29.2; $P = .004$) and preoperative AAA diameter of 55 mm or more (hazard ratio, 4.5; confidence interval, 1.2 to 16.7; $P = .02$) were positive independent predictors of DM. The probability of DM at 36 months was 27% according to life table analysis.**

Conclusion: **DM occurred in a significant portion of our patients, yet aggressive follow-up examination and a high reintervention rate prevented aneurysm-related death. According to our data, dilatation of the infrarenal aortic neck is an important factor that contributes to the distal migration of stent grafts, and patients with large aneurysms are at high risk for DM. (J Vasc Surg 2002;35:229-35.)**

At present, the assurance of a lasting satisfactory outcome after endoluminal abdominal aortic aneurysm (AAA) repair is a complex issue that requires life-long periodic imaging to ensure the proper positioning of the endograft and the maintenance of decompression of the aneurysmal sac. The factors evaluated during imaging follow-up examination after endoluminal AAA repair generally include assessment of the AAA diameter and presence of an endoleak. Additional parameters have been analyzed to define long-term performance of the endoluminal procedure and include stent integrity, proximal stent graft configuration, AAA volume, and device migration (DM).[1-7] DM has been shown to be significantly associated with aneurysm rupture,[8] yet quantitative assessment of DM is not routinely performed.

This study is based on data from patients with a minimum follow-up period of 24 months after endoluminal AAA repair. Computed tomographic (CT) scan images provided quantitative assessment of the distance between the proximal portion of the endograft and the lowest renal artery at each time interval. The aim of this report was to establish the incidence rate, the predictive factors, and the clinical consequences of DM in 113 patients after AAA exclusion with the AneuRx endoprosthesis (Medtronic AneuRx, Santa Rosa, Calif).

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Competition of interest: nil.

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PATIENTS AND METHODS

Between April 1997 and March 1999, 148 patients underwent endoluminal AAA repair with a modular endograft with infrarenal fixation (Medtronic AneuRx) at the

Table I. Demographics and risk factors of 113 patients

Patient characteristics	*No. of patients*
Mean age (years)	69.8 ± 6.8
Hypertension	71 (62%)
Diabetes	6 (5%)
Hypercholesterolemia	45 (40%)
Coronary artery disease*	55 (48%)
Cerebrovascular disease†	11 (10%)
COPD	55 (48%)
Renal insufficiency‡	12 (11%)

*Previous myocardial infarction, angina, or electrocardiographic evidence of myocardial ischemia.
†Previous stroke, transient ischemic attack, or carotid endarterectomy.
‡Preoperative serum creatinine level >1.5 mg/dL.
COPD, Chronic obstructive pulmonary disease.

Table II. Anatomic features of 113 patients

Anatomic features	*No. of patients*
Mean AAA diameter (mm)	51.4 ± 9.1
AAA diameter ≥55 mm	22 (15%)
Neck angulation >60 degrees	7 (6%)
Neck diameter ≥25 mm	24 (21%)
Neck length ≤10 mm	11 (10%)
Neck thrombus	12 (11%)

AAA, Abdominal aortic aneurysm.

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The AneuRx stent graft is a modular endovascular device of woven polyester fabric graft with a self-expanding nitinol exoskeleton. The self-expanding nitinol stent rings provide both radial and columnar structural support throughout the length of the graft that promote its fixation. CT scans were performed at 1, 6, and 12 months after surgery and yearly thereafter. Plain abdominal x-rays performed after surgery, at 6 months, and then yearly were prospectively stored in a computer imaging database. Patient demographics, risk factors, anatomic features, operative details, and follow-up events were prospectively collected in a computer database. Only patients with a minimum follow-up period of 2 years were included in this study. Twelve patients died within 2 years of surgery for non–graft-related causes, four patients underwent immediate conversion to open repair, five patients did not undergo CT scanning during follow-up examination because of chronic renal failure, and adequate CT measurements were not feasible in 14 patients, which left 113 patients for a minimum 2-year CT scan assessment and a total of 418 CT scans. No patients were lost to follow-up examination. The risk factors and anatomic features of the study population are summarized in Tables I and II. A bifurcated device was inserted in 111 cases, whereas a tube device was used in the remaining two cases. The proximal portion of the device was oversized 15% ± 6% as compared with the infrarenal neck diameter. In particular, in 27 patients (24%), oversizing was less than 10%, in 71 patients (63%), oversizing was between 10% and 20%, and in 15 patients (13%), oversizing was more than 20%. A stiff body device was used in 32 cases, and a flexible body device was used in 81 cases. Initial AneuRx stent graft modules were manufactured with a single-unit nitinol bifurcation stent, 5 cm in length, coupled proximally and distally to individual 1 cm–long nitinol rings joined end to end. After April 1998, the entire length of the bifurcation stent body was constructed with individual 1 cm–long nitinol rings joined end to end. The segmented body construction resulted in a flexible bifurcated graft for the full length of the stent graft and eliminated the stiff, unbending 5 cm–long proximal bifurcation segment.[9]

All spiral and conventional CT scans of patients included in the study were performed with slice reconstruction at 3 or 5 mm. Changes of 10 mm or more in the distance between the lower renal artery and the first visible portion of the endograft on the axial reconstruction of the CT scan were defined as DM (Figs 1 to 3). CT scan performed 1 month after surgery was the starting point for subsequent CT evaluation of DM. In patients who needed positioning of a proximal aortic cuff at the time of operation or during the follow-up period, DM was evaluated with the consideration of the position of the aortic cuff and not of the main body of the endograft. The patients in whom the proximal cuff disconnected from the main body during the follow-up period were not included in the group of patients with DM and were analyzed separately. AAA diameter was measured with axial reconstruction of CT scans with the consideration of the minor diameter of the larger section of the AAA.[10] Neck diameter was measured with the consideration of the minor diameter on the CT scan slice immediately below the lower renal artery. The shortest diagonal was considered to avoid overestimation of aortic diameter as the result of tortuosity. For the evaluation of neck enlargement, the preoperative neck diameter and the diameter in the last CT scan available in the follow-up period were compared. A continuous parietal layer of thrombus at least one quarter the circumference in one slice was defined as neck thrombus. Angle neck measurement was reported for neck-to-aneurysm median axis (with CT scan with three-dimensional reconstruction when available, angiography, or magnetic resonance angiography) and was divided in three grades according to suggested standards.[11] A secondary intervention for DM was performed when the landing zone in the aortic neck was less than 10 mm or when DM was associated with a secondary endoleak or AAA enlargement.

Reproducibility study. Two vascular surgeons (Drs Verzini and Parlani) who were blinded to patient identity and history reviewed separately all available CT scans to assess the presence of DM. The blinding procedure was necessary for objective evaluations. Interobserver variabil-

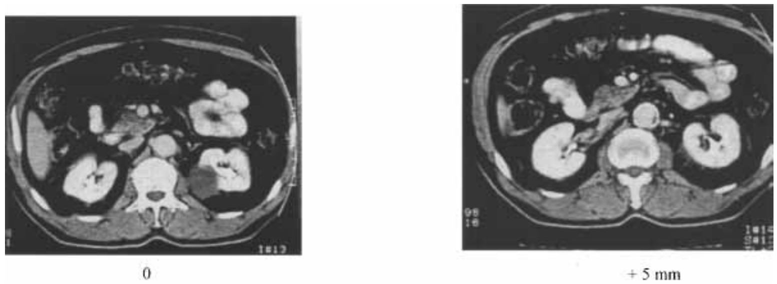

Fig 1. Computed tomographic scan at 1 month after endoluminal procedure as starting point for measurements of renal-device distance. Endograft is positioned at 5 mm below renal arteries.

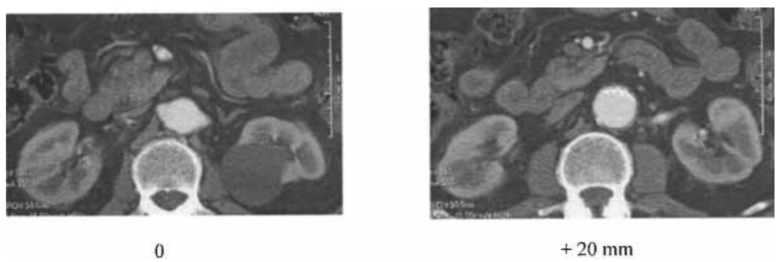

Fig 2. Computed tomographic scan at 36 months in same patient as in Fig 1. First axial reconstruction shows proximal portion of endograft is 20 mm below renal arteries.

ity for interpretation of the presence of graft migration was assessed with κ statistic. The degree of agreement between the two physicians was defined with the scale of Landis and Koch:[12] poor, less than 0.00; slight, 0.00 to 0.20; fair, 0.21 to 0.40; moderate, 0.41 to 0.60; substantial, 0.61 to 0.80; and almost perfect, 0.81 to 1.0. Disagreement was found in 11 cases, with a resulting κ value of 0.64 (Table III). In all cases of disagreement, the CT scans were jointly reviewed and consensus was reached by discussion.

Statistical analysis. The influence of the following 10 variables on DM was tested with univariate (χ^2 test or Fisher exact test) and multivariate (Cox proportional hazards regression model) analysis: AAA proximal neck diameter of 25 mm or more, AAA neck length of 10 mm or less, neck thrombus, neck angulation more than 60 degrees, AAA diameter of 55 mm or more, graft deployment of more than 10 mm below the lower renal artery, neck enlargement of 10% or more after endoluminal repair, the use of a stiff device, graft oversizing of more than 15%, and presence of any endoleak at 30 days. The life table method was used for the assessment of probability of DM. Statistical analysis was conducted with SPSS software (SPSS Inc, Chicago, Ill). *P* values of .05 or less were considered statistically significant.

RESULTS

Of 113 patients with a mean follow-up period of 28 months (range, 24 to 46 months), 17 (15%) showed endoleak at 24 months. Sixty-nine patients (61%) showed a mean decrease of 8 mm in maximum aneurysmal diameter, in 34 patients (30%), the AAA diameter was unchanged, and in 10 patients (9%), the AAA diameter increased a mean of 4.6 mm. Plain abdominal radiographic results did not reveal stent fractures in any of these patients.

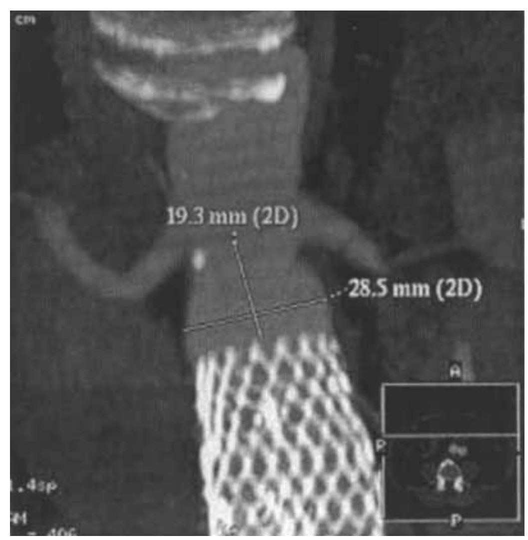

Fig 3. Longitudinal reconstruction of computed tomographic scan at 36 months confirms that renal-device distance is 20 mm. Device migration in this patient was estimated at 15 mm.

Seventeen patients (15%) showed DM on CT scan results (mean migration, 11.47 ± 2.9 mm). Graft-related events in these patients are displayed in Table IV. Eight patients (47%) with DM underwent complication-free reintervention: a proximal cuff was positioned in six

Table III. Interobserver variability in detection of device migration in 113 patients by two vascular surgeons

		Operator I	
		Yes	*No*
Operator II	*Yes*	13	6
	No	5	89

κ = 0.64.

patients and late conversion to open repair was performed in two patients. One patient died of myocardial infarction before scheduled endovascular correction. Proximal DM was not observed in any patient.

In our series of 113 patients, seven needed immediate positioning of a proximal cuff because of low deployment. None of these patients showed migration of the proximal cuff. In three of the patients, disconnection between the main body and the proximal cuff occurred during the follow-up period and caused type 3 endoleaks and AAA enlargement. The conditions of two of these three patients were successfully corrected with endovascular secondary procedures. The remaining patient had AAA rupture and underwent successful late conversion to open repair after 40 months from endografting.

The probability of DM at 36 months was 27% ± 1.33% according to life table results (Fig 4). Univariate analysis results indicated that an increase in neck diameter of more than 10% during the follow-up period was positively associated with DM ($P = .004$; Table V). Of the 10 variables analyzed with Cox proportional hazards regression model, AAA neck enlargement of more than 10% after endoluminal repair (hazard ratio, 7.3; confidence interval, 1.8 to 29.2; $P = .004$) and preoperative AAA diameter of 55 mm or more (hazard ratio, 4.5; confidence interval, 1.2 to 16.7; $P = .02$) were positive independent predictors of DM. No statistically significant correlation was found between oversizing of the endograft more than 15% and neck enlargement ($P = .7$).

DISCUSSION

Our results showed that 27% of our patients who underwent endoluminal AAA repair had probability of DM at 3 years after the operation and that in 47% of our patients with DM, secondary procedures were necessary for the prevention of harmful endograft-related events.

Few studies have focused on DM after endoluminal AAA repair.[2,3,5-7] For the investigation of this issue, a reasonably long follow-up period is mandatory. Because of the late occurrence of DM, it has been suggested that no conclusions can be drawn from studies with follow-up periods of less than 12 to 18 months.[5] The data from the Eurostar Registry showed that DM occurred at a mean of 19.8 months after endovascular repair (Peter Harris, unpublished data, 2001). In our experience, only the patients with a minimum follow-up period of 24 months were included. Life table results showed a sharp increase in DM at 24 months after surgery (Fig 1), which reinforces the hypothesis that DM is a late-occurring complication after endoluminal repair.

The incidence rate of DM varies considerably among studies, with a range between 5% and 45%.[5,7] Different definitions of DM, design of the stent graft, and adequacy and length of the follow-up period may explain this wide interval. In this study, DM was defined as a change of 10 mm or more in the renal-device distance in the axial reconstruction of CT scan during the follow-up period. This interval, greater than that reported in most studies,[3,5-7] was less prone to subjective interpretation on the CT scan revision process. Indeed, substantial agreement was achieved between the two surgeons independently involved in CT scan measurements.

Thrombus at the aortic neck has been suggested to not permit a watertight seal of the stent graft against the aortic luminal surface, which thus allows endoleakage and noneffective exclusion of the AAA. Moreover, late lysis of the thrombus may allow channel formation around a previously intact seal of the device against the aortic wall, which would result in different stent graft–related events, including DM.[13-15] In this study, the presence of thrombus was tested as an independent predictor of DM, although multivariate analysis results showed that it did not play a significant role on DM. Other factors have been considered as possibly responsible for DM. Our data showed that neck enlargement and preoperative AAA diameter of 55 mm or more were positive independent predictors of DM. Many authors have reported the occurrence of neck enlargement after endoulminal AAA repair, but only a few have correlated this finding with DM.[5,16-21] Resch et al[5] in a study on 58 patients with a mean follow-up period of 29 months after endoluminal AAA repair reported that AAA neck enlargement was found in 50% of the patients with DM. Although their definition of DM and the type of device used differed from ours, these data confirm the central role of AAA neck enlargement in the development of DM.[5] We hypothesize that the effect of radial force on the AAA neck increased with oversizing of the endograft and represented a likely cause of neck enlargement. Prinssen et al,[21] in a study on durability of the proximal AAA endograft fixation in patients treated with the EVT/Ancure device (Guidant, Menlo Park, Calif), found a continuous aortic neck enlargement of 1 mm per year after endoluminal repair. The authors suggested that neck changes might vary with the type of attachment system used. Yet, infrarenal neck enlargement is now documented for stent grafts with hooks and barbs and for self-expandable stents, as shown in this study. Moreover, infrarenal neck enlargement has been reported also in patients who undergo conventional surgical AAA repair[22,23] and in patients who undergo endoluminal AAA repair with suprarenal fixation.[7] These data suggest that, in addition to the effect of radial force, oversizing, and attachment systems, a pathologic process of the aortic wall proximal to the AAA per se is involved, which leads to the loss of sealing between the device and the aortic wall. It is clear that the need for improved proximal fixation is urgent.

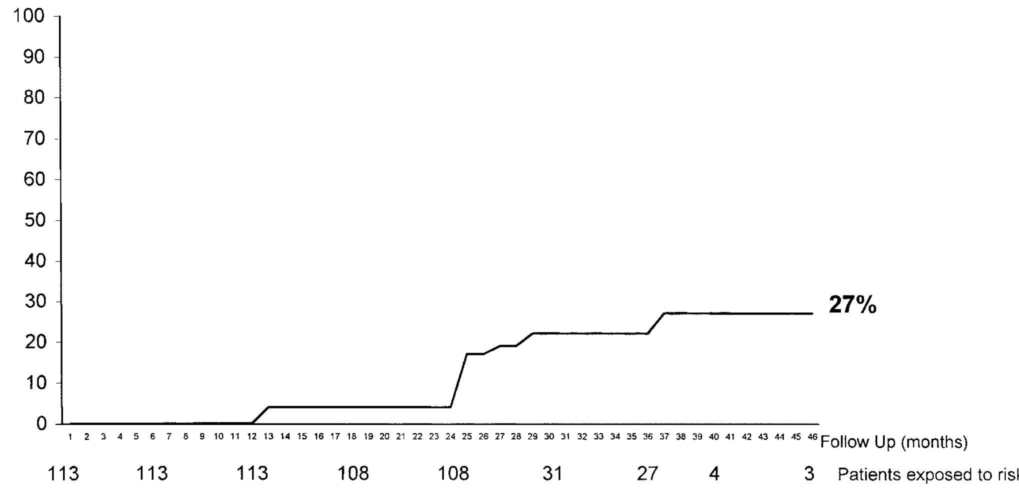

Fig 4. Probability of device migration of current study cohort. Numbers of patients at risk for different intervals are shown.

Table IV. Patients with migration during study period

Patient	*Timing of migration (months)*	*Migration (mm)*	*Changes in AAA diameter (mm)*	*Type 1 leak*	*Resolution*
1	24	15	+1	Yes	Conversion
2	24	10	+5	Yes	Proximal cuff
3	12	10	+2	Yes	Proximal cuff
4	24	20	+4	Yes	Proximal cuff
5	24	10	–12	No	Observation
6	24	15	–3	No	Proximal cuff
7	12	10	0	No	Observation
8	24	10	–18	No	Observation
9	28	15	–4	Yes	Died of MI before correction
10	30	10	–9	No	Observation
11	36	10	–6	No	Observation
12	24	10	0	No	Observation
13	24	10	–9	No	Observation
14	24	10	–15	No	Observation
15	24	10	+5	No	Proximal cuff
16	24	10	+1	Yes	Proximal cuff
17	24	10	+3	Yes	Conversion

AAA, Abdominal aortic aneurysm; *MI,* myocardial infarction.

Although previous study results have shown a relationship between large AAA and failure after endoluminal repair,[24,25] to our knowledge, the role of AAA diameter on DM has never been analyzed. In our study, AAA diameter of more than 55 mm was a positive independent predictor of DM. The data from the Eurostar Registry showed that endovascular repair for large aneurysms was correlated with postoperative graft migration (Peter Harris, unpublished data, 2001). Intuitively, the scarce adherence between the aneurysmal sac and the endograft in patients with large AAA may cause instability and facilitate endograft movement. According to our data, it is reasonable to recommend the use of this type of graft only to patients with AAAs less than 55 mm.

In the study by Resch et al,[5] patients with DM showed significantly shorter necks when compared with patients without DM.[5] In this study, univariate analysis results showed that aortic neck length of 10 mm or less had a trend towards causing DM (Table V). Yet, it has to be considered that few patients in this study had an aortic neck of 10 mm or less. A larger study might indeed show this and other factors to be important causes of DM.

White et al,[6] in a recent study on CT scan assessment of AAA morphology after endograft exclusion, reported an association between the use of a stiff body AneuRx device and DM. The authors hypothesized that the use of a stent graft with stiff body could have caused a lesser accommodation to tortuosity of the aortic neck after AAA exclusion, thereby rendering the stent graft more prone to movement. In this study, a relation between the use of a stiff device and DM was not found. In the study of White et al,[6] only 22 patients had the flexible device and the follow-up period beyond 1 year was limited. This may explain the discrepancy between our data and theirs.

Table V. Factors associated with device migration in 113 patients who underwent endoluminal abdominal aortic aneurysm repair

	Device migration		
	Yes (n = 17)	*No (n = 96)*	*P value*
AAA diameter ≥55 mm	6 (35%)	16 (17%)	.09
Neck angulation >60 degrees	1 (6%)	6 (6%)	1
Neck diameter ≥25 mm	5 (29%)	19 (20%)	.3
Neck length ≤10 mm	4 (23%)	7 (7%)	.06
Graft deployment >10 mm	7 (41%)	25 (26%)	.2
Increased neck diameter >10%	5 (29%)	4 (4%)	.004
Neck thrombus	1 (14%)	11 (11%)	.7
Endoleak at 30 days	2 (12%)	4 (4%)	.2
Graft oversizing >15%	9 (53%)	43 (45%)	.6
Stiff body device	3 (18%)	29 (30%)	.4

AAA, Abdominal aortic aneurysm.

The clinical implications of DM are substantial. In our cohort, 47% of the patients with DM underwent secondary procedures to prevent late AAA rupture. This invasive approach allowed us to avoid late AAA rupture and AAA-related death. The only case of AAA rupture, which was successfully treated, occurred in one patient with type 3 endoleak caused by disconnection between the main body and proximal cuff.

These study results confirm that at present endoluminal AAA repair is a procedure in need of meticulous lifelong monitoring. At follow-up visits, confirmation of the decrease in AAA diameter and the absence of endoleaks should be accompanied by routine quantitative assessment of the renal-device distance. Improvement in attachment systems is a primary need in aortic endovascular surgery.

We conclude that DM after endoluminal AAA repair with the AneuRx stent graft is a frequent event that requires the surgeon to make a therapeutic decision. Aggressive follow-up examination and a high reintervention rate permitted the maintenance of clinical success of the endoluminal procedure in our patients. According to our data, dilatation of the infrarenal aortic neck is an important factor that contributes to the distal migration of stent grafts and patients with large aneurysms are at high risk for DM.

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DISCUSSION

Dr Richard M. Green (Rochester, NY). I am a little surprised at the blip at 2 years. Some years ago, we did an analysis of patients undergoing open repair using CT scan follow-up at 5 years and found that, first of all, neck dilatation was late in coming and second, it came only in those patients with original neck sizes of over 28 mm. I wonder how much of your migration is related to angulation of the neck, proximal neck angulation. I wonder, because I did not see it in your statistics, if you analyzed that as a variable?

Dr Piergiorgio Cao. You mean dilatation or migration due to angulation?

Dr Green. I am talking about migration of the device because of excessive angulation at the proximal neck.

Dr Cao. The role of angulation was examined with multivariate analysis. We analyzed as independent factors neck angulation equal and above 60 degrees, and we found no significant relationship on Cox multivariate analysis between angulation and migration.

Dr Ronald L. Dalman (Palo Alto, Calif). Was iliac anatomy considered in your multivariate analysis? Because this is a fully supported device that may receive longitudinal support from the distal attachment sites, presumably there are iliac factors (eg, aneurysms, tortuosity, or bifurcation disease) that may be relevant to device migration. I am curious why only the anatomy of the surgical neck was considered.

Dr Cao. We did not include iliac tortuosity as factors contributing to migration in our statistical model. We assumed that iliac tortuosity could not represent a factor predisposing to distal migration because of the significant columnar support of the AneuRx device. For this reason, we considered only aortic characteristics and aneurysm size as variables related to migration.

Dr Jon S. Matsumura (Chicago, Ill). I congratulate you on this study, as I have also had an interest in the proximal neck. Resch et al[5] and ourselves have also looked at a threshold of less than 10 mm and found distal migration of 40% to 45%. I think that might explain why you have this bump at 2 years: that is when the threshold of 10 mm is crossed.

You were able to identify migration before there were any symptoms and retreat the patients. How many of these increases in renal-to-device length were related to the top of an aortic cuff versus the top of the main trunk?

Dr Cao. No migrations occurred in patients with a proximal cuff. However, in three patients, disconnection between the proximal cuff and the main body occurred, without modification of the renal-to-proximal cuff distance. For this reason, these three patients were not considered as cases with device migration.

Dr Greg Kasper (Cincinnati, Ohio). I wonder if you have any data in your series measuring aortic length from the infrarenal to the aortic bifurcation. And what you may be observing, perhaps, is aortic elongation, not necessarily graft migration?

Dr Cao. Unfortunately, we do not have these data. However, this will be the topic of a future study.

Dr Peter Gloviczki (Rochester, Minn). I am wondering if you have seen proximal migration. We had a patient where we believed there was an early proximal migration of the graft, so I wonder if you have seen that at all?

Dr Cao. We could not find proximal migration in any of our cases.

Dr Timothy A.M. Chuter (San Francisco, Calif). I think your data are very important, given the known relationship between stent graft migration and risk of rupture.

I suspect your findings can be explained by a couple of specific features of the AneuRx device. First, the proximal stent is very rigid and expands very forcibly. It may be responsible for some of the increase in neck diameter you are seeing. Second, there are no barbs to attach the proximal end of the device to the aortic wall, hence the high rate of migration.

Dr Cao. In the AneuRx stent graft, there are two generations of stent graft, a stiff body and flexible body device. We considered the stiff body as a variable in the Cox regression analysis, and we could not find a relationship with migration.

Concerning the hooks and the barbs, they can be a factor of fixation. I agree with you.