

## CLINICAL RESEARCH STUDIES

# Predictive factors and clinical consequences of proximal aortic neck dilatation in 230 patients undergoing abdominal aorta aneurysm repair with self-expandable stent-grafts

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**Objective:** Several studies have suggested that proximal aortic neck dilatation (AND) is a frequent event after balloon-expandable endografting. Yet few data are available on AND after repair with self-expandable stent grafts. To investigate incidence, predictive factors, and clinical consequences of AND, computed tomography (CT) scans obtained at intervals during follow-up of 230 patients who had undergone endoluminal abdominal aortic aneurysm (AAA) repair with self-expandable stents were reviewed.

**Subjects:** Between April 1997 and March 2001, 318 patients underwent endoluminal AAA repair with a self-expandable endograft at our unit. CT scans obtained at 1 and 12 months after surgery and yearly thereafter were prospectively stored in a computer imaging data base. Two hundred thirty patients were available for minimum 1-year assessment. Two vascular surgeons with tested interobserver agreement reviewed 686 CT scans. Diameter of the proximal aortic neck was measured as the minor axis of the first CT section that contained at least half of the proximal portion of the endograft. For endografts with suprarenal attachment the first scan below the lowest renal artery was considered. Diameter change of 3 mm or more between the CT scan at 1 month and subsequent evaluations was defined as AND. Nine possible independent predictors of AND were analyzed with Cox regression analysis.

**Results:** Median follow-up was 24 months (range, 12-54 months). In 2 patients, AAA ruptured during follow-up. CT scans for 65 patients (28%) showed AND. Thirteen patients with AND (5.6%) underwent repeat intervention, including positioning of the proximal cuff in 8 patients and late conversion to open repair in five patients. Of the nine variables examined with multivariate analysis, only 3, ie, presence of neck circumferential thrombus (hazard ratio [HR], 2.51; 95% confidence interval [CI], 1.26-5.01;  $P = .008$ ), preoperative proximal neck diameter (HR, 1.21; 95% CI, 1.07-1.35;  $P = .001$ ), and preoperative AAA diameter (HR, 1.03; 95% CI, 1.00-1.06;  $P = .046$ ) were positive independent predictors of AND, whereas the other 6, ie, neck angulation more than 60 degrees, neck length, suprarenal fixation, oversizing more than 15%, endoleak at 30 days, and increased AAA diameter during follow-up, showed no significant correlation. Probability of AND at 48 months was  $59 \pm 6.1$  at analysis with the Kaplan-Meier method.

**Conclusions:** AND is a frequent sequela of endoluminal repair in the mid-term. Severe AND developed in a small percentage of our patients, compromising integrity of AAA repair. Patients with large aneurysms and aortic necks and patients with aortic neck circumferential thrombus are at high risk for aortic neck enlargement after endoluminal repair of AAA. (*J Vasc Surg* 2003;37:1200-5.)

The status of the proximal aneurysm neck after endoluminal abdominal aortic aneurysm (AAA) exclusion is criti-

cal in determining fixation and durability of the stent-graft. Endovascular graft fixation depends on the integrity and long-term structural stability of the aorta near the site of graft deployment. Graft migration, aneurysm sac reperfusion, and rupture may occur if the native aorta degenerates, becomes dilated, or lengthens. To date, knowledge of the status of the aortic neck at the level of proximal endograft attachment is limited.

To investigate incidence, predictive factors, and clinical consequences of aortic neck dilatation (AND), computed tomography (CT) scans obtained at intervals during follow-up of 230 patients who had undergone endoluminal AAA repair with self-expandable commercially available stent-grafts were reviewed.

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Competition of interest: none.

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## PATIENTS AND METHODS

Between April 1997 and March 2001, 318 consecutive patients underwent endoluminal AAA repair with a commercially available self-expandable stent-graft at Unità Operativa di Chirurgia Vascolare, Policlinico Monteluce, Perugia, Italy. Perioperative mortality was 1%.

CT scans were obtained at 1 and 12 months after surgery and yearly thereafter, and plain abdominal x-ray films and duplex scans were obtained 1 month after surgery and every 6 months thereafter. CT scans, plain x-ray films, and duplex scans; patient demographic data, risk factors, and anatomic features; operative details; and follow-up events were prospectively collected in a computer database. Only patients with minimum follow-up of 1 year were included in the present study. Seventeen patients died within 1 year of surgery, 5 underwent immediate conversion to open repair, 5 did not undergo CT during follow-up because of chronic renal failure, and in 61 patients adequate CT scanning was not feasible. Thus 230 patients were available for minimum 1-year CT assessment, for a total of 686 CT scans. No patients were lost to follow-up.

The AneuRx stent-graft (Medtronic, Santa Rosa, Calif) was implanted in 176 procedures, the Excluder endograft (W. L. Gore and Associates, Flagstaff, Ariz) in 26 procedures, the Zenith graft (William Cook Europe, Bjaeverskov, Denmark) in 14 procedures, the Talent graft (World Medical/Medtronic, Sunrise, Fla) in 13 procedures, and the EndoLogix (Bard, Irvine, Calif) in 1 procedure. Endograft configuration included 3 tubes, 223 bifurcations, and 4 aortouniliac grafts, combined with contralateral iliac occlusion and femoral-femoral bypass grafting.

All spiral and conventional CT scans of patients included in the study were obtained with section reconstruction at 3 or 5 mm. Proximal aortic neck was measured as the outer diameter in the minor axis of the first CT section that contained at least half of the proximal portion of the endograft. The shortest diagonal diameter was selected for analysis to avoid overestimation of aortic dimension due to vessel tortuosity.<sup>1</sup> For endografts with suprarenal attachment the first scan below the lowest renal artery was considered for analysis. All CT scan measurements were obtained with interactive computerized software (Corel Draw 6.0) on magnified images (Fig 1).

The CT scan obtained 1 month after surgery was the starting point for subsequent CT evaluation of AND. Neck diameter change of 3 mm or more between the CT scan at 1 month and subsequent evaluations was defined as AND. Device migration was defined as change 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, as described in a previous study.<sup>2</sup> A continuous parietal layer of thrombus at least three-fourths the circumference in one section was defined as neck thrombus. Angle neck measurement was reported for neck-to-aneurysm median axis, at CT with three-dimensional reconstruction, when available, angiography, or magnetic resonance angiography, and was classified in three grades, according to sug-

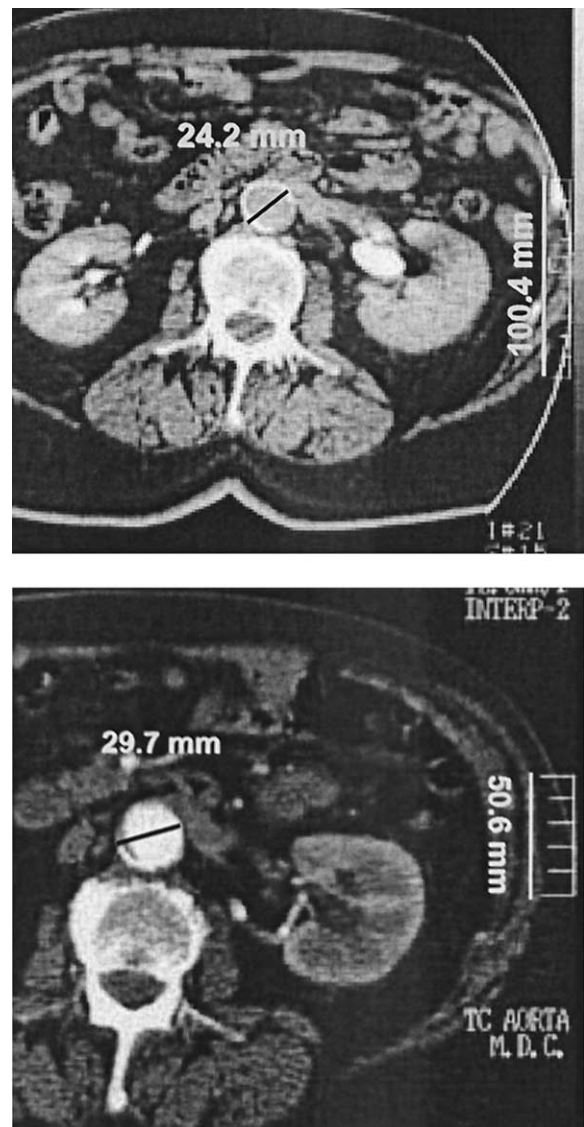


Fig 1. CT scans obtained at 1 month (*top*) and 24 months (*bottom*) after endograft placement show aortic neck dilatation of 24.2 and 29.7 mm.

gested standards.<sup>3</sup> Two vascular surgeons blinded to patient history and outcome, with previously tested interobserver agreement ( $\kappa = 0.64$ ), separately reviewed axial reconstructions of CT scans.<sup>2</sup>

**Statistical analysis.** Univariate analysis was performed with the  $\chi^2$  or Fisher exact test. Multivariate analysis (Cox regression analysis) was used to determine the influence of nine variables on AND: proximal neck length, proximal neck diameter, neck thrombus, neck angulation more than 60 degrees, AAA diameter, graft oversizing more than 15%, suprarenal fixation, AAA growth ( $\geq 3$  mm) during follow-up, and presence of any endoleak at 30 days. The Kaplan-Meier method was used to assess probability of AND. Statistical analysis was conducted with SPSS software (SPSS

**Table I.** Degree of AND in 65 patients

Degree of AND (mm)	No. of patients	Percent
3	29	45
4	21	32
5	6	9
6	7	11
7	1	1
8	—	—
9	1	1

AND, Aortic neck dilatation.

Inc, Chicago, Ill).  $P \leq .05$  was considered statistically significant.

## RESULTS

Of 230 patients available for minimum 1-year assessment, mean preoperative and 1-month postoperative proximal aortic neck diameter was 22.8 mm (range, 16-30 mm) and 23.3 mm (range, 16-31 mm), respectively. At a median follow-up of 24 months (range, 12-54 months), CT scans for 65 patients (28%) demonstrated AND (median AND, 4 mm; range, 3-9 mm). Degree of AND is displayed in Table I. Scans for 17 patients (15%) exhibited a decrease in proximal aortic neck diameter (median, 1 mm; range, 1-4 mm).

In 17 patients (15%), endoleak had developed by 12-month follow-up. Aneurysm diameter decreased by 3 mm or more in 150 patients (65%), was unchanged in 59 patients (25%), and increased by 3 mm or more in 21 patients (10%). In 2 patients the aneurysm ruptured during follow-up, unrelated to AND in both cases.

Late repeat interventions were performed in 18 of 230 patients (7.8%): 8 patients required conversion to open repair, and 10 underwent secondary proximal endoluminal correction. Indications for repeat intervention were often based on development of more than one concurrent complication. Reasons for conversion and endoluminal correction are given in Table II.

Late repeat intervention was more frequently necessary in patients with AND compared with patients without AND (13 of 65 vs 5 of 165; odds ratio [OR], 8.0; 95% confidence interval [CI], 2.5-29.16;  $P < .0001$ ). Repeat intervention was needed in 8 of 50 patients (16%) with AND smaller than 4 mm and in 5 of 15 patients (33%) with AND 5 mm or greater ( $P = .14$ ).

Of 52 patients with AND and no late repeat interventions, 22 had undergone follow-up subsequent to AND detection (mean, 18 months; range, 12-24 months) and were evaluated for further AND. Only in 3 patients (13.6%) did further AND of 3 mm or more develop after the initial AND detection on CT scans. The remaining 30 patients did not undergo CT after detection of AND. Probability of AND at 48 months was  $59\% \pm 6.1\%$  according to the Kaplan-Meier method (Fig 2).

Univariate analysis indicated that device migration (OR, 8.0;  $P = .0001$ ), type I endoleak (OR, 8.3;  $P = .009$ );

**Table II.** Indications for repeat intervention in 18 patients with and without AND\*

	AND	
	Yes (n = 5)	No (n = 3)
Open conversion (n = 8)		
AAA growth	2	2
Type I endoleak	3	—
Migration	3	1
Endovascular repeat intervention (n = 10)	(n = 8)	(n = 2)
AAA growth	2	1
Type I endoleak	1	—
Migration	6	1

AND, Aortic neck dilatation; AAA, abdominal aortic aneurysm.

\*One or more concurrent complications were cause for repeat intervention in the same patient.

and proximal neck diameter (OR, 3.1;  $P = .02$ ) were associated with AND (Table III). Rate of AAA growth in patients with and without AND is shown in Table III.

Of the nine variables examined with multivariate analysis, presence of neck circumferential thrombus (hazard ratio [HR], 2.51; CI, 1.26-5.01;  $P = 0.008$ ), preoperative neck diameter (HR, 1.21 per 1 mm increment; CI, 1.07-1.35;  $P = 0.001$ ), and preoperative AAA diameter (HR, 1.03 per 1 mm increment; CI, 1.00-1.06;  $P = 0.046$ ) were positive independent predictors of AND.

## DISCUSSION

Although several studies have documented aortic neck enlargement after endoluminal and open aortic surgery<sup>4-17</sup> and as a natural process related to aging,<sup>18-20</sup> data regarding incidence and consequences of this morphologic change after endoluminal repair with self-expandable commercially available stent-grafts is lacking. The present study enables analysis of AND in a large series of patients, with fairly long follow-up, in whom aortic dimensions were accurately measured.

The principal finding is that AND is common, occurring in more than a fourth of patients after endovascular aneurysm repair. In 77% of our patients AND was less than 5 mm and developed by 24 months after surgery. Furthermore, when we analyzed the rate of progression of AND, we found that in patients followed up after AND detection only 3 of 22 patients showed continuing neck enlargement at a mean follow-up of 18 months. However, as the group of patients with substantial follow-up after AND assessment was small (n = 22), the rate of progression of AND over time may be underestimated.

To prevent considering AND that developed immediately after surgery in patients undergoing endoluminal repair with self-expandable stent-grafts (in virtually all patients with self-expandable stent-grafts in which oversizing is performed, aortic neck diameter may increase slightly increase after implantation of the graft), we considered as the starting point for evaluation of aortic neck diameter the first CT scan obtained during follow-up, not the preoper-

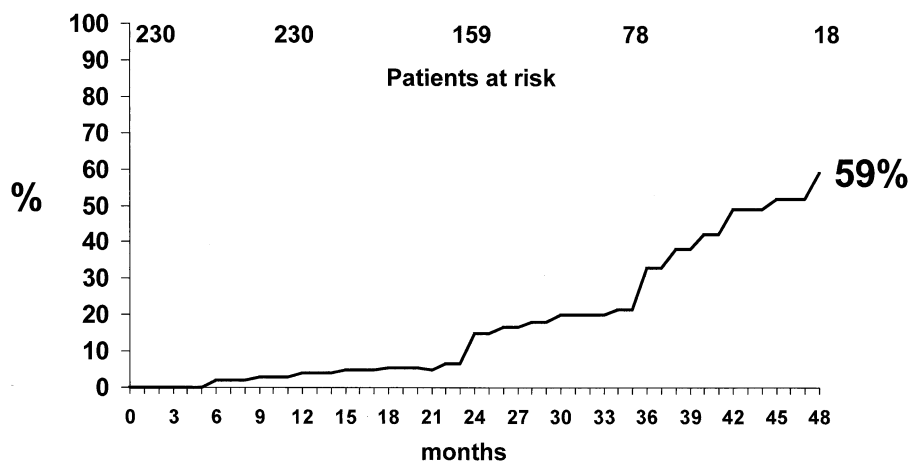


Fig 2. Probability of aortic neck dilatation. Number of patients at risk at different follow-up intervals is shown.

Table III. Clinical events in 230 patients with and without AND

	AND				Odds ratio	P
	Yes (n = 65)		No (n = 165)			
	n	%	n	%		
Proximal neck length ≤10 mm	18	27	34	21	—	.3
Proximal neck diameter ≥25 mm	9	14	8	4.8	3.1	.02
Neck thrombus	10	15	12	7	—	.08
Neck angulation >60 degrees	3	4.6	10	6	—	1
AAA diameter ≥55 mm	17	26	41	25	—	.9
Graft oversizing >15%	30	46	76	46	—	1
Suprarenal fixation	9	14	19	11.5	—	.6
Migration >10 mm	18	27	10	6	8.0	.0001
Type 1 endoleak	6	9	2	1	8.3	.009
AAA growth >3 mm	8	12	13	7	—	.3

AND, Aortic neck dilatation; AAA, abdominal aortic aneurysm.

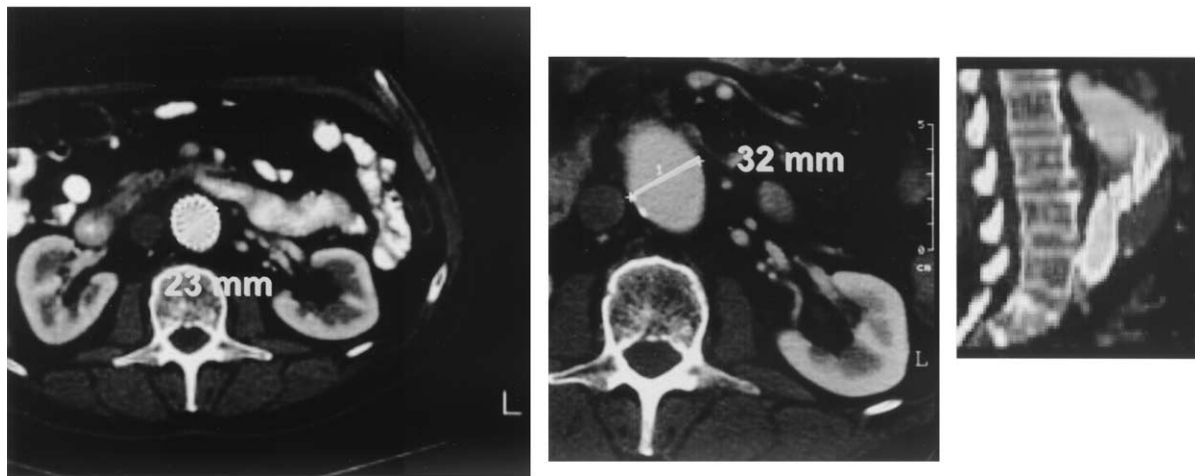
ative CT scan. In our series, mean increase in aortic diameter on the first postoperative CT scan, compared with the preoperative CT scan, was negligible (0.5 mm). If we consider mean graft oversizing between 15% and 20% in patients with mean neck diameter of 23 mm, we hypothesize that AND up to 4 mm may be risk-free because the enlargement is balanced by oversizing. On the other hand, enlargement of more than 5 mm may represent a serious risk for endoleak development or graft migration.<sup>8-10,21,22</sup> In this view, only AND of 5 mm or more is considered harmful and potentially compromising. AND 5 mm or greater developed in 15 patients, ie, 6.5% of our overall study population and 23% of our patients with AND. A possible and previously suggested solution<sup>11</sup> to “severe” AND may be to increase oversizing. In this regard, potential adverse effects caused by excessive oversizing should be considered, eg, damage to the aortic neck that may cause AND or possibility of graft folding or distortion.

Incidence of AND in the present study is higher than that reported by others.<sup>12-13</sup> May et al<sup>12</sup> reported a high probability (0.943 at 7 years) of no enlargement of the

proximal AAA neck after endoluminal repair in a series of 51 patients. These authors hypothesized that there is a protective effect of the correctly positioned endograft just below the renal arteries toward AND.<sup>12</sup> The type of graft used was not reported, and therefore it is not possible to speculate on possible causes of AND.

Our data show that probability of AND after endoluminal repair of AAA is 59% at 4 years, and secondary interventions are required in a fifth of patients. Makaroun et al<sup>13</sup> found that AND occurs in about 20% of patients after endovascular aortic grafting and is rarely associated with graft migration. They did not perform actuarial analysis of data on occurrence of AND. AND rates were reported as simple proportions of crude numbers: 13% (42 of 314 patients) at 1 year, 21% (48 of 226 patients) at 2 years, and 19% (11 of 59 patients) at 3 years. If incidence of AND is considered a crude rate, our figures are comparable with those of Makaroun et al: 26% of aortic necks were enlarged at 3 years.

With respect to predictors of AND, Makaroun et al,<sup>13</sup> in conflict with our findings, showed that AAA size has no



**Fig 3.** One-month axial CT scan (*left*) and 24-month axial CT scans with longitudinal reconstruction (*right*) show aortic neck dilatation associated with graft migration and type I proximal endoleak.

clear effect on neck enlargement, whereas initial neck diameter is inversely related to later neck dilatation. These discrepancies may be due to bias in both study designs (nonrandomized design, small number of events) and, most likely, to type of endograft used (self-expandable vs balloon-expandable).

In the present study, although five types of devices were examined, only self-expandable stent-grafts were included. No significant differences in AND were found between patients undergoing repair with endografts with suprarenal or infrarenal attachment. Whether AND is caused by radial force or disease progression remains to be determined. However, that AND occurred at similar rates after endovascular grafting with suprarenal and infrarenal stents favors the theory of vessel degeneration.

The AAA neck is the main fixation point for aortic stent-grafts and is a key factor in long-term integrity of repair. The presence of thrombus or ectasia in the aortic neck, confirmed with multivariate analysis, together with the presence of large AAA, all markers of severe vessel degeneration, should be carefully considered in evaluating AAA anatomy suitable for endoluminal repair. Despite the significant incidence of AND, only 5.6% of our patients required AND-related repeat intervention.

In conclusion, AND is a frequent sequela of endoluminal repair at mid-term follow-up, and shows little tendency to progress. In a small percentage of our patients severe AND developed, compromising integrity of the repair (Fig 3). A larger cohort of patients with longer follow-up will be needed to fully understand the progression rate and true clinical effect of AND.

Patients with large aneurysms and aortic necks and patients with aortic neck circumferential thrombus are at high risk for aortic neck enlargement after endoluminal repair of AAA.

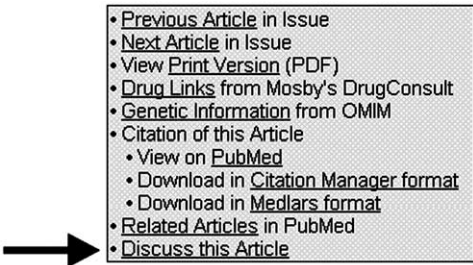
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