From the Society for Vascular Surgery

Clinical outcome and morphologic determinants of mural thrombus in abdominal aortic endografts

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Objective: **Endograft mural thrombus has been associated with stent graft or limb thrombosis after endovascular aneurysm repair (EVAR). This study aimed to identify clinical and morphologic determinants of endograft mural thrombus accumulation and its influence on thromboembolic events after EVAR.**

Methods: **A prospectively maintained database of patients treated by EVAR at a tertiary institution from 2000 to 2012 was analyzed. Patients treated for degenerative infrarenal abdominal aortic aneurysms and with available imaging for thrombus analysis were considered. All measurements were performed on three-dimensional center-lumen line computed tomography angiography (CTA) reconstructions. Patients with thrombus accumulation within the endograft's main body with a thickness >2 mm and an extension >25% of the main body's circumference were included in the study group and compared with a control group that included all remaining patients. Clinical and morphologic variables were assessed for association with significant thrombus accumulation within the endograft's main body by multivariate regression analysis. Estimates for freedom from thromboembolic events were obtained by Kaplan-Meier plots.**

Results: **Sixty-eight patients (16.4%) presented with endograft mural thrombus. Median follow-up time was 3.54 years (interquartile range, 1.99-5.47 years). In-graft mural thrombus was identified on 30-day CTA in 22 patients (32.4% of the study group), on 6-month CTA in 8 patients (11.8%), and on 1-year CTA in 17 patients (25%). Intraprosthetic thrombus progressively accumulated during the study period in 40 patients of the study group (55.8%). Overall, 17 patients (4.1%) presented with endograft or limb occlusions, 3 (4.4%) in the thrombus group and 14 (4.1%) in the control group ($P = .89$). Thirty-one patients (7.5%) received an aortouni-iliac (AUI) endograft. Two endograft occlusions were identified among AUI devices (6.5%; overall, 0.5%). None of these patients showed thrombotic deposits in the main body, nor were any outflow abnormalities identified on the immediately preceding CTA. Estimated freedom from thromboembolic events at 5 years was 95% in both groups ($P = .97$). Endograft thrombus accumulation was associated with >25% proximal aneurysm neck thrombus coverage at baseline (odds ratio [OR], 1.9; 95% confidence interval [CI], 1.1-3.3), neck length ≤15 mm (OR, 2.4; 95% CI, 1.3-4.2), proximal neck diameter ≥30 mm (OR, 2.4; 95% CI, 1.3-4.6), AUI (OR, 2.2; 95% CI, 1.8-5.5), or polyester-covered stent grafts (OR, 4.0; 95% CI, 2.2-7.3) and with main component "barrel-like" configuration (OR, 6.9; 95% CI, 1.7-28.3).**

Conclusions: **Mural thrombus formation within the main body of the endograft is related to different endograft configurations, main body geometry, and device fabric but appears to have no association with the occurrence of thromboembolic events over time. (J Vasc Surg 2015;61:1391-8.)**

The surgical management of abdominal aortic aneurysms (AAAs) has progressively shifted toward endovascular aneurysm repair (EVAR) as the primary treatment[1] for moderate- and high-risk patients. Limb thrombosis and endograft occlusion are infrequent but potentially devastating complications that have limited the clinical success of EVAR[2,3] and have been associated with preceding endograft mural thrombus accumulation.[4,5] However, the evidence for this is scarce and potentially biased.

Endograft mural thrombus formation has been detected as early as 1 week after endograft deployment, and its course is still not completely understood.[4] Optimal management of asymptomatic thrombotic formation within abdominal aortic stent grafts has not been determined; although most experts defend conservative surveillance,[6] oral anticoagulation therapy has also been reported.[7] There is a clear need for further evidence to support either conduct.

Our hypothesis was that thrombus accumulation within the main body of the endograft is not associated with the occurrence of thromboembolic events.

METHODS

We designed a retrospective case-control study based on a prospectively maintained observational database of

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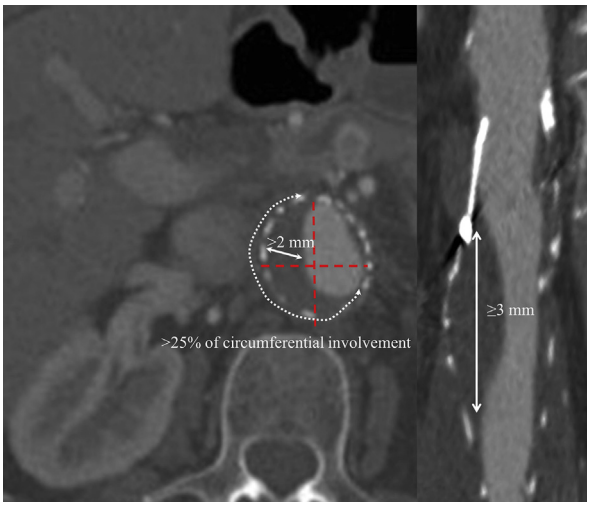

Fig 1. Study case selection: Inclusion criteria.

all patients undergoing EVAR in a high-volume center in The Netherlands. The study complies with the Helsinki statement on research ethics, and no informed consent was required according to institutional guidelines on research ethics.

Patients. From 2000 to 2012, EVAR was performed in 473 patients with AAAs at the Erasmus University Medical Center, Rotterdam, The Netherlands. The type of repair offered was individualized according to anatomic features, health status, and history of previous abdominal surgery (hostile abdomen). The patient's preference was accounted for before informed consent was obtained. Patients with previous aortic surgery or without degenerative AAAs (ie, with isolated iliac aneurysms, mycotic aneurysms, and anastomotic or traumatic pseudoaneurysms) as well as patients for whom a postoperative computed tomography angiography (CTA) image could not be obtained were not included.

Patients presenting with in-graft thrombus with a thickness >2 mm and an extension of >25% of the main body's circumference on at least three consecutive 1-mm slices in any postoperative CTA scan were included in the thrombus group (Fig 1). For case selection, all postoperative CTA images were analyzed with center-lumen line reconstruction. The remaining patients formed the control group. Patients who received a stent graft other than the ones deployed in the thrombus group were also excluded from the study for homogeneity (two patients with Powerlink [Endologix, Irvine, Calif] stent grafts).

Postoperative surveillance. Institutional follow-up protocols have changed significantly during the time of the study. From the initial practice, which consisted of contrast-enhanced CTA at 1 month, 6 months, 12 months, and yearly thereafter, the 6-month CTA evaluation has been reserved only for patients with a high risk of complications. In addition and according to the treating physician's expectation, selected patients with an expected lower risk of complications or with renal function impairment have been alternatively followed up with color duplex ultrasound or noncontrasted CT.

Data management. Baseline clinical, anatomic, and intraoperative data were acquired at the time of surgery. All subsequent long-term follow-up data were prospectively obtained on outpatient visits or from the patient's record on regular consultation.

Image analysis and measurements. All measurements (diameters, lengths, angles, cross-sectional area, and volumes) were performed with semiautomatically generated center-lumen line reconstructions on a workstation with dedicated reconstruction software (3mensio Vascular 4.2; Medical Imaging B.V., Bilthoven, The Netherlands) and according to previous validated methodology.[8] All long-term imaging data were obtained by a single observer with experience in image analysis (N.O.).

A centered ellipse was assumed as the most approximate form to represent the cross-sectional area of the main body. For cross-sectional area calculation, the largest and lesser diameters were measured, and the respective radius was determined. Cross-sectional area was calculated as follows: Area = rA*rB*π (in which rA is the largest radius and rB the lesser radius, and π value was rounded to six decimal digits). For lumen reduction determination, the difference between the cross-sectional areas of the main body and the patent lumen was calculated at the point of maximum thrombus accumulation.

Definitions. Reporting was done in accordance with the guidelines of the Society for Vascular Surgery/American Association for Vascular Surgery Ad Hoc Committee for Standardized Reporting Practices in Vascular Surgery.[9] Cardiac status was defined and scored according to the Society for Vascular Surgery/American Association for Vascular Surgery medical comorbidity grading system.[10]

Thromboembolic events were defined as the composite of endograft occlusion, iliac limb occlusion, thromboembolic acute limb ischemia, and blue toe syndrome. Oversizing was determined from the ratio between the implanted main body diameter and the reference neck diameter in the first 15 mm of the infrarenal aneurysm neck. Neck length was defined as the distance between the distal point of the lowermost renal artery ostium and the beginning of the aneurysm.

Variation of the main body cross-sectional area was defined in percentage from the ratio between the maximum cross-sectional area assumed by the main body of the endoprosthesis and the minimum main body cross-sectional area identified in the first 10 mm of the stent graft.

End points. The primary end point of this study was freedom from thromboembolic events. In addition, clinical and morphologic variables were explored for association with significant thrombus accumulation within the endograft.

Statistical analysis. Categorical variables are presented as count and percentage and were compared by the Pearson χ^2 test. Continuous variables are presented as mean and standard deviation or median and interquartile range. Differences between groups were analyzed by the Mann-Whitney *U* test for independent nonparametric data and the Student *t*-test