# Predictive factors for endoleaks after thoracic aortic aneurysm endograft repair

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**Background:** Our prospective investigation aimed to determine and analyze the incidence and the determinants of endoleaks after thoracic stent graft.

**Methods:** Sixty-one patients affected by thoracic aortic aneurysms were treated between January 2000 and March 2008. The study cohort contained 54 men, with a mean age of 63.6 ± 17.9 years. The follow-up imaging protocol included chest radiographs and triple-phase computed tomographic angiography performed at 1, 4, and 12 postoperative months and annually thereafter.

**Results:** Median follow-up was 32.4 months (range: 1–96 months). Endoleaks were detected in 9 (14.7%) patients, of which 7 were type 1. Five endoleaks were detected at 30 postoperative days, and the other 4 developed with a mean delay of 12 months. Endovascular or hybrid interventions were used to treat the endoleaks. Secondary technical success rate was 100%. Multivariate analysis demonstrated that the diameter of the aneurysmal aorta (odds ratio 1.75, 95% confidence interval 1.07–2.86) and the coverage of the left subclavian artery (odds ratio 12.05, 95% confidence interval 1.28–113.30) were independently associated with endoleak development. The percentages of patients in whom reinterventions were unnecessary were 94.6% ± 3.0%, 88.3% ± 4.5%, and 85.4% ± 5.2%, at 1, 2, and 5 years, respectively. The actuarial survival estimates at 1, 2, and 5 years were 85.2% ± 4.6%, 78.1% ± 5.4%, and 70.6% ± 6.4%, respectively.

**Conclusions:** The diameter of the aneurysmal aorta and the position of the landing zone are independent predictors of endoleak occurrence after thoracic stent-graft procedures. A careful follow-up program should be considered in patients in whom these indices are unfavorable, because most of the endoleaks may be successfully and promptly treated by additional endovascular procedures.

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Endovascular techniques have evolved rapidly and become an accepted alternative to open aortic aneurysm repair. They have also generated new complications including stent-graft (SG) migration and endoleak formation and therefore altered the way patients are followed after repair.[1] Unlike the minimal imaging required after open surgical repair, patients having endovascular repair of thoracic aortic aneurysms (TEVAR) require lifelong postoperative surveillance imaging.[2]

Although the detection and management of endoleaks after abdominal endovascular aortic aneurysm repair have been well described, few reports have been published about endoleaks after TEVAR.[3-6] This investigation was performed to evaluate the incidence and the determinants of endoleaks after TEVAR. The outcomes of secondary interventions in patients with endoleaks were also evaluated.

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## METHODS

### Population and Management

Between January 2000 and March 2008, 61 patients had endovascular repair for thoracic aortic aneurysm (TAA). Thoracoabdominal aneurysms and acute type B dissections were not considered in this analysis. TAAs included atherosclerotic or dissecting aneurysms (n = 52, ruptured n = 4) and traumatic aneurysms (n = 9, chronic n = 2). The study cohort contained 54 men, with a mean age of 63.6 ± 17.9 years (range: 17–87 years). All elective patients had preoperative evaluation with echocardiography and spirometry; computed-tomography angiography (CT-A) of the brain was performed when the lesion involved the aortic arch or the distal portion of the arch in order to assess the integrity of the circle of Willis and the dominance of the vertebral arteries. Three different devices were used: Talent (Medtronic Vascular, Santa Rosa, Calif), Excluder (W. L. Gore and Associates, Flagstaff, Ariz), and TX-1/TX-2 (Cook, Bloomington, Ind). The type of SG has been chosen according to the aneurysm anatomic characteristics and type of lesion. Generally, self-expanding SGs without bare stents were used for traumatic aneurysms and proximal or distal extremity bare stents in the proximity of the epiaortic branches or abdominal visceral vessels.

The study protocol was in compliance with the local Institutional Review Board and received full approval. All patients gave their consent to participate.

### Follow-up and Imaging Characteristics

After intervention, the follow-up imaging protocol included chest radiographs and triple-phase CT-A performed at 1, 4, and 12 months after SG

**Abbreviations and Acronyms**

| | |
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| CI | = confidence interval |
| CT | = computed tomography |
| CT-A | = computed-tomography angiography |
| LSA | = left subclavian artery |
| OR | = odds ratio |
| SG | = stent graft |
| TAA | = thoracic aortic aneurysm |
| TEVAR | = endovascular repair of thoracic aortic aneurysm |

implantation and annually thereafter. CT-A was performed using a 64-detector row (Aquilion, Toshiba, Zoetermeer, Netherlands); initially, nonenhanced computed tomography (CT) images were obtained, then 80 to 90 mL (350/400 mg of iodine/mL) of a nonionic intravenous contrast material (Iomeron, Bracco, Milano, Italy) were administered at a rate of 4 mL/s and followed by a bolus of 40 mL of saline solution by using a power injector (Envision CT Injector, Medrad, Pittsburgh, Pa). Arterial and venous phase acquisitions were then performed. Arterial phase imaging was performed by using bolus tracking. Arterial phase CT data acquisition was initiated when the attenuation of a region of interest positioned in the ascending aorta reached +150 Hounsfield units. Venous phase acquisition was initiated 90 seconds after the arterial phase. The nonenhanced CT arterial and venous phase acquisitions were initiated at the level of the upper portion of the neck and continued to the level of the celiac trunk. For nonenhanced CT arterial and venous phase acquisitions, a 0.50-mm detector configuration was used. Each phase data acquisition was performed in less than 10 seconds. The postprocessing (multiplanar reconstructions, maximum intensity projection, 3-D images, and virtual angioscopy) was performed on a workstation (Vitrea, Vital Images, Plymouth, Minn). The patients were evaluated for the presence of an endoleak, type of sac reperfusion, aneurysm expansion, and endoleak intervention. Endoleaks were defined by a specific team of radiologists blinded to the performed procedures. The CT-A examinations were subsequently reevaluated on workstations by a team of a vascular surgeon and an interventional radiologist, using multiplanar reformatting capabilities and MIP/MPR/3-D reconstruction to identify and classify the type of endoleak.

## Definition

The intervention was classified as emergency when surgery was performed within the first 24 hours after admission.[7] The elective procedures performed on the same admission day were not considered emergent. Primary technical success was defined as successful deployment of the SG without any type of endoleak at the end of the intervention, and secondary technical success was defined as the persistent exclusion of the aortic disease after the second intervention (either endovascular or hybrid repair) without occurrence of any other type of endoleak. A hybrid repair, as well as ''debranching,'' was intended as a combination of surgical and endovascular procedure. Location of the aortic disease was defined according to the classification proposed by Criado and colleagues[8] in terms of landing zones. Type 1 endoleaks were classified on the basis of the location in contiguity with the proximal (type A) or distal (type B) attachment site. Endoleaks were classified as type 2 endoleak if the endoleak sac could not be seen communicating with the distal or proximal attachment site or if there was delayed enhancement of the endoleak sac. Type 3 endoleak was defined by the junctional separation of two SGs. Grading of the aortic arch atheroma was defined according to a previously reported modified classification[9]: grade I (normal), smooth and continuous aortic intimal surface; grade II, intimal thickening 3 to 5 mm; grade III, atheroma protruding < 5 mm into aortic lumen; grade IV, atheroma protruding > 5 mm into aortic lumen, and ulcerated or pedunculated. During the follow-up, period shrinking was defined a size reduction of 5 mm between 2 consecutive radiologic controls. For all patients, the mean changes in maximal aortic diameter were calculated by comparing the baseline aortic diameter with the maximal diameter at last follow-up, irrespective of endoleak treatment.

## Data Analysis

Clinical data were prospectively recorded and tabulated with Microsoft Excel (Microsoft Corp, Redmond, Wash). Continuous variables were tested for normal distribution by the Kolmogorov-Smirnov test and compared between groups with unpaired Student *t* test for normally distributed values; otherwise, the Mann-Whitney *U* test was employed. In case of dichotomous variables, group differences were examined by chi-square or Fisher exact tests as appropriate.

A stepwise logistic regression model was developed to identify patient and procedural variables associated with endoleak development. The model was built using variables that demonstrated a $P$ value < .20 in univariable analysis. The strength of the association of variables with the endoleak was estimated by calculating the odds ratio (OR) and 95% confidence interval (CI). The discrimination of the model was obtained by calculating the area under the receiver operating characteristic curve; the calibration of the model, by the Hosmer-Lemeshow goodness-of-fit test. Survival rate and freedom from reinterventions were estimated by means of the Kaplan-Meier method.

Results are expressed as mean ± standard deviation for continuous variables and frequencies for the categorical ones. Statistical analysis was computed with SPSS, release 13.0 for Windows (SPSS Inc, Chicago, Ill).

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# RESULTS

## Clinical Univariable Data

Among the 61 TEVAR cases, emergency procedures were performed in 20 patients (31.7%). Endoleaks were detected in 9 (14.5%) subjects, of which 7 (77.8%) were type 1 (4 type A, 3 type B). None of the patients had more than 1 endoleak type. Endovascular or hybrid intervention was used to treat the endoleaks in all but 1 patient; 1 type 1A endoleak spontaneously thrombosed. Five endoleaks (type 1A, n = 4 and type 2, n = 1) were diagnosed during the initial postoperative CT-A at 30 days. Four endoleaks developed late; mean delay of endoleak appearance was 12 months (median: 9, range: 6–24 months). Patients with endoleak and patients without it were comparable in terms of clinical characteristics (Table 1). Briefly, age distribution was similar (72.2 ± 5.1 vs 62.1 ± 19.0 years, $P = .176$) as well as mean standard EuroSCORE (European System for Cardiac Operative Risk Evaluation) (8.4 ± 2.2 vs 8.8 ± 3.7, $P = .751$). No statistical differences were noted in terms of distribution of the aortic diseases. Four patients (44.4%) in the endoleak group and 10 (18.8%) among those without endoleak have had previous thoracic or abdominal aortic surgery.

## Morphological Univariable Data

No differences were detected regarding the extension and morphology (saccular or fusiform) of the aneurysm ($P = .077$ and $P = .478$, respectively). No differences were also observed regarding the surgical access and the SG used ($P = .796$ and $P = .724$, respectively). In contrast, the