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Risk Factors of Endoleak Following Endovascular Repair of Abdominal Aortic Aneurysm. A Multicentric Retrospective Study

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Abstract. *Endoleak (EL) represents the most common complication following endovascular abdominal aortic aneurysm repair (EVAR). Unfortunately, the long-term results of EVAR and its durability have been questioned, and EL are variably associated with a risk of late failure. The aim of this retrospective study was to identify risk factors for this complication of aneurysm-endograft complex in patients who underwent EVAR. A group of 104 consecutive patients (99 men, 5 women; median age, 74 years; range, 50-89 years) were enrolled in the study. Both preoperative and follow-up imaging studies were obtained using helical computed tomography scanning at 1, 6, 12, 24, 36 months after EVAR and blindly reviewed by a surgeon and a radiologist. Twenty-seven (25.9%) patients developed EL during follow-up, of which 10 (37%) were primary (<30 days from EVAR), and 17 (63%) were secondary EL. Age and smoking did not affect the EL onset, while a body mass index >25 and a history or presence of arterial hypertension represented significant ($p<0.05$) risk factors. Moreover, both greatest diameter and maximum length of the aneurysm were significantly higher ($p<0.01$) in patients who developed EL. No relationship was found with the anatomical features of the aortic neck (i.e. length and diameter), and between the initial size of the aneurysm and the dimension at the time of EL. In conclusion, in our study, being overweight, arterial hypertension and the initial size of the aneurysm represent risk factors for EL development.*

Endovascular aneurysm repair (EVAR) represents an effective treatment for several abdominal aortic aneurysms. Compared to a traditional open technique, EVAR has been shown to significantly reduce both intraoperative and postoperative complications. However, the long-term results of EVAR and its durability have been questioned because this treatment is associated with a number of aneurysm- or graft-related immediate and late complications (1, 2). Endoleak (EL), defined as arterial perfusion outside the stent graft lumen and within the aneurysmal sac, represents the most common complication following EVAR (3). Its prevalence ranges widely, and may reach 40% of cases (4). The aim of this retrospective study was to identify risk factors for EL in patients with abdominal aortic aneurysms who underwent EVAR.

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Patients and Methods

Study population. A group of 104 consecutive patients with infrarenal abdominal aortic aneurysms who successfully underwent an elective EVAR procedure were enrolled in the study. Patients who required early- or post-operative conversion to open surgery were excluded. There were 99 men and 5 women, with an overall median age of 74 years (range 50-89 years). The physical status was defined according to the American Society of Anesthesiologists (ASA) classification (5). Once they had given their informed consent, each patient underwent both preoperative and follow-up (1, 6, 12, 24, 36 and 60 months) imaging studies using computed tomography (CT) scanning. All patients were followed-up for at least 24 months.

CT scanning. Helical CT examination was performed with a single-slice CT scanner (Somatom Emotion, Siemens Medical Solutions, Germany) using the following scan parameters: 110 to 130 kV, 140-160 mA/s, collimation 3 mm, pitch 2, reconstruction slice thickness 1.5 mm, rotation time 0.8 s. Iodinated non-ionic contrast medium (140 to 160 mL, 350 mg I/mL) was injected at 3.5 to 4 mL/s into an antecubital vein by a power-injector at 250-300 psi.

Aortic angiographic images acquisition started 5 s after the contrast medium administration and once the region of interest in the aortic lumen reached a threshold trigger of 120 Hounsfield units (bolus tracking). Patients were examined during a breath hold or shallow breathing. The angiography CT protocol included a delayed scanning, about 120 s after contrast medium injection, acquired in a similar manner and by increasing slice thickness to 5 mm. Images

Table I. *Patient and aneurysm characteristics.*

Characteristics	Number or value	Percentage
Demographics		
Men	99	95.2%
Women	5	4.8%
Age (years)		
Overall (mean±SD)	72.9±7.8	-
<65 years	25	24.0%
66-75 years	48	46.2%
>75 years	31	29.8%
Body mass index >25 kg/m^2	27	26.0%
Smoking		
Smoking past	36	34.6%
Smoking present	25	24.1%
No smoking	43	44.3%
Smoking past or present	61	58.7%
Arterial blood pressure		
Hypertensive	43	41.3%
Normotensive	61	58.7%
ASA grade		
I-II	14	18.0%
III	37	47.4%
IV-V	27	34.6%
Aneurysm size (mm)		
Mean±SD		
Greatest diameter	55.5±11.2	-
Maximum length	82.7±21.9	-
Aortic neck diameter	25.3±2.8	-
Aortic neck length	31.6±12.5	-

Table II. *Type of devices used.*

Type of device	Number of patients	Percentage
Talent	38	36.5%
Excluder	27	26.0%
AneuRx	25	24.0%
Vanguard	4	3.9%
Other type	10	9.6%

Table III. *Potential factors associated with endoleak.*

	Parameter		
Patients characteristics	No endoleak (N=77)	Endoleak (N=27)	P-value
Age (years)			
Overall (mean±SD)	71.8±4.2	73.0±6.5	0.27
<65 years	19	6	0.84
66-75 years	38	10	0.49
>75 years	20	11	0.30
Body mass index >25 kg/m^2	13	14	0.01
Smoking past	26	10	0.83
Smoking present	15	10	0.16
Smoking past or present	41	20	0.35
No smoking	36	7	0.20
Arterial hypertension	25	19	0.04
Aneurysm characteristics (mean±SD)			
Greatest diameter	46.4±8.3	60.7±14.2	<0.001
Maximum length	70.1±19.1	90.0±27.6	<0.001
Aortic neck diameter	23.0±3.0	22.9±1.8	0.87
Aortic neck length	27.5±11.3	27.1±6.4	0.86

were processed at the work-station and assessed on multiple planar reconstruction (MPR) and maximum intensity projection (MIP) reconstructions for measurements.

Statistical analysis. The reported data are expressed as mean±standard deviation (SD). Differences between means (*i.e.* age, aneurysm size) were tested by ANOVA and unpaired Student's *t*-test or, when non-normally distributed, the Mann-Whitney *U*-test. The Chi-square (χ^2) test corrected by Yates and the Fisher exact test, when required, were used for comparisons of fractions (*i.e.* smokers *vs.* non-smokers, hypertensive *vs.* normotensive patients). Pearson's correlation coefficient (R) calculation was also used to evaluate the linear relationship between pairs of variables. The differences were considered significant at a <0.05 *p*-value.

Results

Table I shows patient and aneurysm characteristics, while Table II shows the type of stent-graft device used. No deaths were observed during the procedure, while 6 patients died during follow-up of causes unrelated to the surgical procedure.

Twenty-seven (25.9%) patients developed EL, of which 10 (37%) were primary (<30 days from EVAR) and 17 (63%) were secondary EL. Neither age nor smoking affected the onset of EL, while a body mass index >25 and a history or presence of arterial hypertension represented significant risk factors (Table III). Moreover, both the preoperative greatest diameter and maximum length of the aneurysm were significantly higher in patients who developed EL. There was no relationship between the initial size of the aneurysm and the length and diameter of the aortic neck at the time of EL. In most patients the complication occurred within the first 12 months from EVAR. Figure 1 shows the cumulative risk of EL during follow-up.

Discussion

The prevalence of EL in patients who underwent EVAR ranges between 8% and 44% (6-9). In the EUROSTAR study 12% were type I, III, or multiple EL and 7.8% were type II

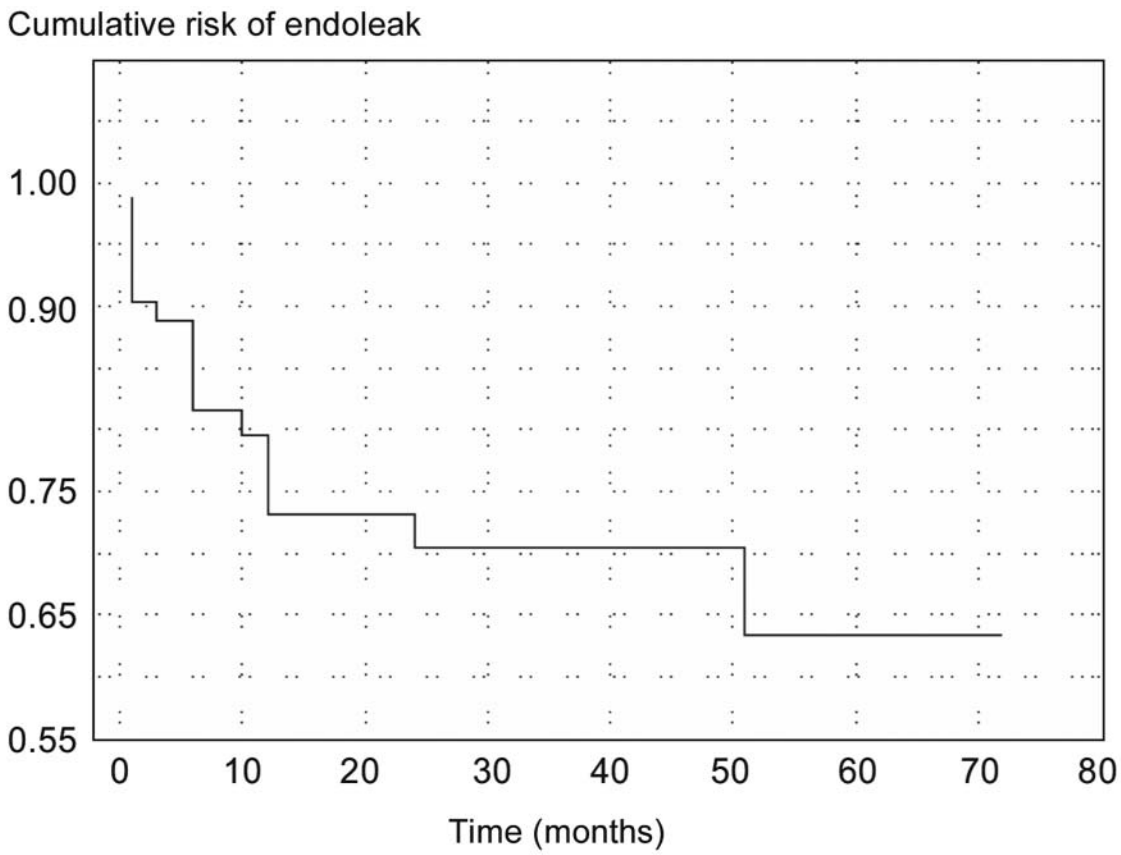

Figure 1. *Cumulative risk of endoleak during follow-up. In most of the patients this complication occurred within the first 12 months after the surgical procedure.*

EL (10). In several studies the risk of EL remains significant for patients with larger aneurysm diameters and for ex-smokers. Mohan *et al.* (11) in a multicentric study found that smoking, age (>75 years) and an aneurysm diameter larger than 50 mm were significantly associated with EL, with a relative odds ratio ranging from 1.72 and 1.47. Moreover, they demonstrated a strong correlation between the diameter of the aortic neck and the device used, suggesting that oversizing by 10-20% may reduce the frequency of EL. We also found a relationship between EL and both the diameter and length of the aneurysm, but no relationship to the aortic neck diameter and length. Because aortic wall distensibility decreases with age, earlier in men than in women, a correlation between aneurysm diameter and both gender and aging has long been reported (12, 13). Neither age nor smoking represented risk factors in our experience, while both arterial hypertension and being overweight did. A variety of self-expanding stent-grafts were used, but no significant relationship between the occurrence of EL and the type of device was found in the EUROSTAR study (11).

A number of risk factors different from those usually reported (*i.e.* age, size of the aneurysm at presentation) have been considered, enclosed atherosclerotic factors, platelet aggregation, variation in patient selection, and surgical experience (*i.e.* learning curve) (11, 14). Lambert *et al.* (15) showed a relationship between the lack of radial force of the proximal stent, the maximum neck diameter of the aneurysm, and risk of perigraft EL. Moreover, in an experimental study, the role of blood flow as a displacing force involved in the pathophysiological mechanism of graft migration has been hypothesized (16, 17). Finally, the variable which may have the most significant association with proximal perigraft EL is the neck angulation, while other adverse anatomical features of the proximal aortic neck do not seem to have the same importance in the mechanism leading graft migration (18).

In conclusion, in our study, neither the anatomical features of the aortic neck (*i.e.* length and diameter) nor the age of the patients represented risk factors for EL development. The risk was not significantly higher in smokers, while being overweight, arterial hypertension, and the initial size (*i.e.* greatest diameter and maximum length) of the aneurysm should be considered significant risk factors.

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