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Application of Baseline Clinical and Morphological Parameters for Prediction of Late Stent Graft Related Endoleaks after Endovascular Repair of Abdominal Aortic Aneurysm

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WHAT THIS PAPER ADDS

Late stent graft related endoleaks (srEL) are a life threatening complication after endovascular aneurysm repair and knowledge of predisposing factors is sparse. This study demonstrated that older patients, those of female sex, and those with a larger left iliac sealing diameter seem to be at higher risk of developing late srEL. If it is to help refinement of surveillance protocols, this information requires independent confirmation by a larger study cohort.

Objectives: To evaluate the influence of baseline clinical and morphological parameters on the occurrence of a late stent graft related endoleak (srEL; types 1 and 3) after endovascular aneurysm repair (EVAR).

Methods: This is a retrospective case control study of patients who were routinely followed up after EVAR of abdominal aortic aneurysms. Pre-interventional, pre-discharge, and last available multislice computed tomography angiogram (MSCTA) of 279 patients were analysed. Stent graft related endoleaks detected by follow up MSCTA at least six months after EVAR were specified as late srEL. Baseline demographic characteristics and morphological variables were derived from the pre-interventional and pre-discharge MSCTA. Univariable and multivariable analysis with a Cox proportional hazards model were used to determine baseline factors associated with the occurrence of a late srEL.

Results: Twenty-four (8.6%) of 279 patients suffered a late srEL, during a mean MSCTA follow up of 30.9 ± 25.8 (23.5, IQR 10.6–42.8) months. In the univariable analysis, age (hazard ratio [HR] 1.09; $p = .001$), female sex (HR 3.25; $p = .014$), right iliac sealing diameter (HR 10.04; $p = .03$), left iliac sealing diameter (HR 8.65; $p = .001$), infrarenal aortic neck angulation (HR 1.02; $p = .011$), and suprarenal fixation level (HR 3.47; $p = .014$) were significantly associated with an increased incidence of late srEL. Age (HR 1.08; $p = .012$), female sex (HR 2.72; $p = .049$), and left iliac sealing diameter (HR 4.48; $p = .033$) proved to be risk factors significantly associated with a higher incidence of late srEL in multivariable analysis.

Conclusions: Older patients, those with female gender, and those with larger left iliac sealing diameters seem to experience higher rates of late srEL. Independent confirmation of these must be addressed in larger studies.

Keywords: Aortic aneurysm, Abdominal, Endoleak, Risk factors, Safety management, Stent graft
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INTRODUCTION

Application of endovascular aneurysm repair (EVAR) for abdominal aortic aneurysm (AAA) has steadily increased in the last decade.[1,2] As experience has increased, EVAR has become more commonly used outside the defined anatomical instructions for use.[3–5] In addition to complex anatomical conditions, the progressive nature of aortic disease leaves these patients at higher risk of repair failure.[6] Stent graft related endoleaks (srEL) are a life threatening complication and the most common cause of aneurysm rupture after EVAR.[7,8] The highest rate of stent graft related complications and consecutive re-interventions is reported within the first 30 days, and remains high during the first six months after EVAR.[9] Larger aneurysm sac and iliac diameters, various aspects of neck morphology, and age have been identified as risk factors for srEL during this interval.[9–14] After a period of six months, there is a clear drop

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Table 1. Characteristics of patients studied for stent graft related endoleaks after endovascular repair of abdominal aortic aneurysm

Characteristic	All patients (n = 279)	Early endovascular aneurysm repair (EVAR) failure (n = 50)	No early EVAR failure (n = 229)
Hypertension	275 (98.6)	50 (100)	225 (98.3)
Hyperuricaemia	94 (33.7)	18 (36.0)	76 (33.2)
Hyperlipidaemia	229 (82.1)	49 (98.0)	180 (78.6)
History of stroke	44 (15.8)	7 (14.0)	37 (16.2)
Peripheral artery occlusive disease – Fontaine stage	50 (17.9)	7 (14.0)	43 (18.8)
Stage I	3 (1.1)	1 (2.0)	2 (0.9)
Stage IIa	8 (2.9)	0	8 (3.5)
Stage IIb	30 (10.8)	6 (12.0)	24 (10.5)
Stage III	3 (1.1)	0	3 (1.3)
Stage IV	6 (2.2)	0	6 (2.6)
Atrial fibrillation	50 (17.9)	12 (24.0)	38 (16.6)
Cardiac pacemaker	14 (5.0)	3 (6.0)	11 (4.8)
Coronary heart disease	138 (49.5)	25 (50.0)	113 (49.3)
History of myocardial infarction	102 (36.6)	15 (30.0)	87 (38.0)
Diabetes mellitus	54 (19.4)	14 (28.0)	40 (17.5)
Insulin dependent diabetes mellitus	7 (2.5)	0	7 (3.1)
Non-insulin dependent diabetes mellitus	47 (16.8)	14 (28.0)	33 (14.4)
Renal insufficiency, mild to moderate	87 (31.2)	18 (36.0)	69 (30.1)
Haemodialysis	4 (1.4)	1 (2.0)	3 (1.3)
Active smoking	132 (47.3)	24 (48.0)	108 (47.2)
History of cancer	60 (21.5)	12 (24.0)	48 (21.0)

Data are given as n (%). EVAR = endovascular aneurysm repair.

in stent graft related complications, with an apparent further increase after two years.[9] However, considering the costs and radiation exposure, efforts have been made to streamline surveillance strategies, which aim to leave a negligible number of patients at risk of late srEL.[13,15] Therefore, knowledge of the predisposing factors associated with occurrence of late srEL could help to refine individual patient surveillance. The objective of this study was to evaluate the influence of baseline clinical and morphological parameters on the occurrence of late srEL.

MATERIALS AND METHODS

Study design

This was a retrospective, single centre study of patients with infrarenal AAA and elective EVAR. The institutional review board approved the study protocol, and waived the need for written, informed consent.

Study population

The institutional database was screened for patients who underwent elective endovascular AAA repair with a bifurcated stent graft between May 2002 and July 2014.

There were 462 patients who were eligible for analysis. Exclusion criteria were: non-availability of standardised multislice computed tomography angiograms (MSCTA) (1) within three months before EVAR (n = 38), (2) predischarge within one week after the procedure (n = 0), and (3) after a time interval of at least six months (n = 145). This left 279 patients (28 female) with a mean age of 73.5 ± 8.2 (74.5, IQR 67.9–79.5) years for final analysis (Table 1).

Measurements and definitions

Routinely performed MSCTA follow up examinations (for acquisition parameters see supplementary material) were retrospectively screened for the presence of types 1 or 3 srEL, as described by Chaikof *et al.*[16] Stent graft related endoleaks that occurred at least six months after EVAR were specified as late srEL, which was defined as the endpoint. The influence of baseline clinical and morphological parameters were analysed on the probability of a late srEL.

Additionally, MSCTA follow up examinations were evaluated for the presence of EVAR failure, including: (1) srEL, (2) limb stenosis or occlusion, (3) stent graft migration, defined as an increase of the renal artery to stent graft distance (RSD) of >5 mm,[1] (4) re-intervention on type 2 endoleaks which were causing continuous aneurysm sac enlargement > 5 mm,[16] and (5) stent graft infection. EVAR failures were defined as early, occurring within six months, and late occurring at least six months after EVAR. For subgroup analysis, patients were divided according to the presence/absence of an early EVAR failure.

Baseline clinical parameters included age (at the time of EVAR), sex, and body mass index. Baseline morphological parameters included anatomical variables measured on preprocedural MSCTA, device dependent variables collected from the pre-interventional MSCTA and/or the stent graft

procedure, and early post-interventional variables assessed on the pre-discharge MSCTA. Measurements were performed with syngo.via imaging software (Siemens, Healthineers, Erlangen, Germany).

Anatomical variables determined in accordance with the Society for Vascular Surgery standards for EVAR[17] included: (1) aneurysm sac diameter; (2) maximum diameter of the proximal anchoring zone; (3) iliac sealing diameters; and (4) proximal and distal neck lengths. Supra- and infrarenal aortic neck angulation were measured based on the 2D methodology described by van Keulen *et al.*,[18] and adapted for measuring along a semi-automatically drawn centre lumen line (CLL). Assessment of the psoas muscle area (PMA) was performed as described by Indrakusuma *et al.*[19] The areas of both psoas muscles were added and corrected for patient height with the formula (left PMA + right PMA)/(height^2).[20] This variable was designated as height corrected PMA.

The presence of thrombus >2 mm thick at the circumference of the proximal anchoring zone was evaluated and classified as follows: (1) no thrombus; (2) thrombus <25%; (3) thrombus 25—50%; or (4) thrombus ≥50%. The presence of calcification was categorised according to the same classification. On the basis of the measured anatomical variables, compliance requirements with the manufacturer's instructions for use (IFU) were analysed, and rated as within or outside the IFU. Details of implanted devices are given in Table 2.

The IFUs required neck lengths (≥10—15 mm), minimum neck diameters (16—19 mm), maximum neck diameters (<30—32 mm), infrarenal aortic neck angulations (≤90°), distal neck lengths (≥10—20 mm), minimum iliac diameters (>7.5—10 mm), and maximum iliac diameters (<14—27 mm). Additionally, the IFU of the Zenith stent graft included suprarenal aortic neck angulation (≤45°), and the IFU of the Endurant stent graft excluded patients with neck thrombus or neck calcification >25% of the circumference and/or >2 mm thickness.

Device dependent variables included: (1) proximal oversizing factor; (2) distal oversizing factors; (3) proximal fixation level (suprarenal/infrarenal); and (4) implantation side of the modular limb (right/left).

Early post-procedural variables included: (1) the presence of a type 2 endoleak (T2EL), and (2) the RSD. RSD was measured along a semi-automatically drawn CLL as described by Bastos Goncalves *et al.*[15] It was defined as the distance between the lowest renal artery and the lowest stent graft fabric marker.

Statistical analysis

Normally distributed, continuous data were presented as the mean ± SD and 95% CI. Potential differences between groups were tested using an analysis of variance (ANOVA), or the *t* test, as appropriate. Non-normally distributed data, or ordinal variables, were described by medians and interquartile ranges (IQRs). Possible differences between groups were tested with the Wilcoxon Mann Whitney *U* test, and the Kruskal Wallis test, as appropriate. Dichotomous variables were described in absolute numbers and percentages, and possible differences between groups were tested by the chi square test or the Fisher exact test, as appropriate. Association between baseline parameters and early EVAR failure were tested using logistic regression analysis with calculation of OR with 95% CI. Multivariable logistic regression analysis was conducted using backward selection of parameters, with a limit of $p < .1$ required to enter and to stay in the model. The univariable Cox proportional hazards model, with calculation of OR with 95% CI, was used to investigate the influence of baseline clinical and morphological parameters on the probability of late srEL free survival. A multivariable Cox proportional hazards model was conducted using a backward selection of parameters, with a limit of $p < .1$ required to enter and to stay in the model. The association between variables, which stayed in the model, was tested in a general linear model. The Kaplan—Meier life table method was used to determine freedom from late srEL. Comparison of survival between patients with and without an EVAR failure was analysed for significance using the logrank test.

All tests were two sided; significance was assumed at $p < .05$. The *p* values are given as calculated and should be interpreted with care, considering α error accumulation. All

Table 2. Implanted stent grafts in patients studied for stent graft related endoleaks after endovascular repair of abdominal aortic aneurysm

Device	Company	All stent grafts ($n = 279$)	Early endovascular aneurysm repair (EVAR) failure ($n = 50$)	No early EVAR failure ($n = 229$)
Talent	Medtronic Vascular, Santa Rosa, CA, USA	64 (22.9)	24 (48.0)	40 (17.5)
Excluder	W.L. Gore & Associates, Flagstaff, AZ, USA	97 (34.5)	9 (18.0)	88 (38.4)
Zenith	Cook Medical, Bloomington, IN, USA	34 (12.2)	7 (14.0)	27 (11.8)
Endurant	Medtronic, Inc., Minneapolis, MN, USA	69 (24.7)	9 (18.0)	60 (26.2)
Anaconda	Vascutek, Renfrewshire, UK	5 (1.8)	0	5 (2.2)
Aorfix	Lombard Medical Technologies, Oxfordshire, UK	1 (0.4)	0	1 (0.4)
Powerlink	Endologix, Inc., Irvine, CA, USA	1 (0.4)	0	1 (0.4)
Treovance	Bolton Medical, Sunrise, FL, USA	8 (2.9)	1 (2.0)	7 (3.1)

Data are given as *n* (%). EVAR = endovascular aneurysm repair.

statistical analyses were performed using SPSS for Windows (version 24.0; IBM Corporation, Somers, NY, USA).

RESULTS

Fifty (17.9%) of 279 patients suffered from early EVAR failure after a mean time of 14.2 ± 27.1 (95% CI 6.5–22.0; 7, IQR 5–11) days. Information on early EVAR failures, and association of baseline parameters with early EVAR failure is given in the supplementary material. Baseline clinical parameters, separated for patients with/without an early EVAR failure, are given in Table 3.

Twenty-four (8.6%) of 279 patients suffered from a late srEL, during a mean MSCTA follow up of 30.9 ± 25.8 (23.5, IQR 10.6–42.8) months. Overall, cumulative freedom from late srEL rates after one, three, and five years was 97.9%, 92.0%, and 82.1%, respectively (Fig. 1). There were eight (2.9%) type 1a endoleaks that resulted in rupture in two

Table 3. Baseline clinical and morphological parameters of patients and their abdominal aortic aneurysms studied for stent graft related endoleaks after endovascular repair of abdominal aortic aneurysm.

	Overall (n = 279)	Early endovascular aneurysm repair (EVAR) failure (n = 50)	No early EVAR failure (n = 229)	p
Baseline clinical variables				
Sex – female	28 (10.0)	11 (22.0)	17 (7.4)	.002*
Age – years	73.47 ± 8.15 (72.51–77.43)	75.12 ± 7.30 (73.05–77.20)	73.12 ± 8.29 (72.04–74.19)	.115
Body mass index – kg/m^2	27.88 ± 4.71 (27.32–28.43)	27.20 ± 4.56 (25.19–28.50)	28.02 ± 4.74 (27.46–28.64)	.268
Baseline anatomical variables				
Aneurysm sac diameter – mm	60.4 ± 9.88 (59.21–61.5)	62.1 ± 11.5 (58.9–65.4)	60.0 ± 9.5 (58.8–61.2)	.173
Proximal neck length – mm	29.1 ± 13.2 (27.5–30.6)	23.0 ± 13.1 (19.2–26.7)	30.4 ± 12.9 (28.7–32.1)	.001*
Proximal neck diameter – mm	24.4 ± 3.2 (24.1–24.8)	25.8 ± 3.7 (24.7–26.8)	24.1 ± 3.1 (23.7–24.5)	.001*
Right iliac sealing diameter – mm	12.6 ± 2.5 (12.3–12.9)	12.8 ± 2.7 (12.0–13.6)	12.5 ± 2.3 (12.2–12.8)	.457
Right iliac neck length – mm	18.1 ± 5.5 (17.5–18.8)	18.6 ± 4.1 (17.4–19.7)	18.0 ± 5.7 (17.3–18.7)	.512
Left iliac sealing diameter – mm	12.3 ± 2.7 (12.0–12.6)	13.2 ± 3.5 (12.2–14.2)	12.1 ± 2.3 (11.8–12.4)	.012*
Left iliac neck length – mm	19.2 ± 5.4 (18.6–19.9)	19.8 ± 5.7 (18.2–21.4)	19.1 ± 5.4 (18.4–19.8)	.446
Suprarenal aortic neck angulation – °	28.73 ± 21.11 (26.25–31.22)	29.80 ± 21.37 (23.72–35.87)	28.50 ± 21.10 (25.76–31.25)	.695
Infrarenal aortic neck angulation – °	36.29 ± 25.39 (33.30–39.28)	53.24 ± 29.57 (44.83–61.64)	32.59 ± 22.83 (29.62–35.56)	.001*
Height corrected psoas muscle area – cm^2/m^2	5.39 ± 1.42 (5.22–5.55)	4.80 ± 1.28 (4.43–5.16)	5.51 ± 1.42 (5.33–5.70)	.001*
Neck thrombus				
0%	124 (44.4)	18 (36)	106 (46.3)	.266
<25%	46 (16.5)	9 (18.0)	37 (16.2)	
25–50%	63 (22.6)	9 (3.2)	54 (23.6)	
≥50%	46 (16.5)	14 (28.0	32 (14.0)	
Neck calcification				
0%	237 (84.9)	38 (76.0)	199 (86.9)	.051
<25%	30 (10.8)	7 (14.0)	23 (10.0)	
25–50%	10 (3.6)	4 (8.0)	6 (2.6)	
≥50%	2 (0.7)	1 (2.0)	1 (14.4)	
Instruction for use (IFU), outside	61 (21.9)	17 (34.0)	44 (19.2)	.022*
Device dependent variables				
Proximal oversizing – %	16.37 ± 8.76 (15.34–17.40)	12.46 ± 13.58 (8.60–16.31)	17.23 ± 7.06 (16.31–18.14)	.001*
Right distal oversizing – %	17.05 ± 9.71 (15.91–18.20)	19.03 ± 17.81 (13.97–24.09)	16.92 ± 6.57 (16.06–17.77)	.112
Left distal oversizing – %	18.49 ± 10.80 (17.21–19.76)	18.92 ± 19.88 (13.27–24.57)	18.68 ± 7.21 (17.74–19.62)	.756
Fixation level – suprarenal	174 (62.4)	40 (80.0)	134 (58.5)	.004*
Implantation side of modular limb – left	206 (73.8)	30 (60.0)	176 (76.9)	.014*
Early post-procedural variables				
Type 2 endoleak	128 (45.9)	23 (46.0)	105 (45.9)	.985
Lumbar	62 (22.2)	13 (26.0)	49 (21.4)	
Lumbar + internal mesenteric artery (IMA)	35 (12.5)	5 (10.0)	30 (13.1)	
IMA	28 (10.0)	5 (10.0)	23 (10.0)	
Acessory renal artery	3 (1.1)	0	3 (1.4)	
Renal artery to stent graft distance (RSD) – mm	2.83 ± 4.67 (2.28–3.38)	6.60 ± 6.70 (4.70–8.50)	2.00 ± 3.62 (1.53–2.48)	.001*

Data are presented as n (%) or mean ± SD (95% CI). Percentages given in parentheses relate to the total number of the subdivision given in the corresponding column. SD = standard deviation; CI = confidence interval; EVAR = endovascular aneurysm repair; IFU = instruction for use; IMA = internal mesenteric artery; PMA = psoas muscle area; RSD = renal artery to stent graft distance; p = patients with vs. without late stent graft related endoleak (srEL).

* Indicates a significant difference.

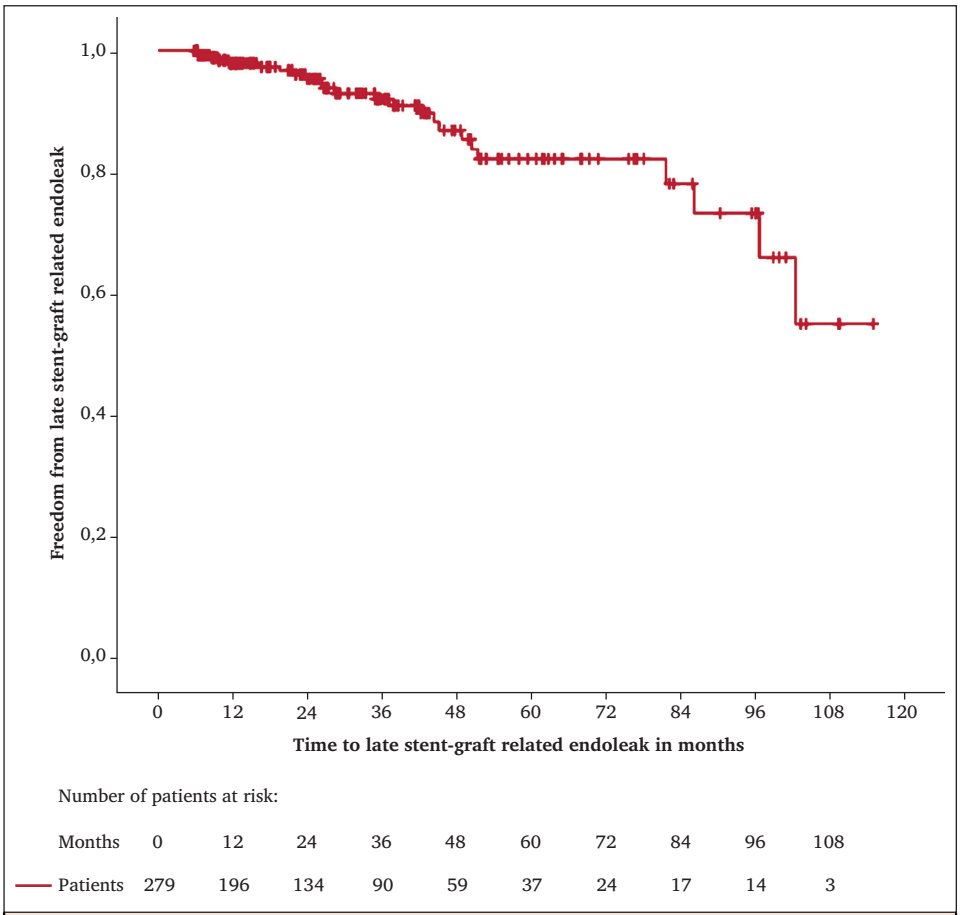

Figure 1. Freedom from late stent graft related endoleaks after endovascular repair of abdominal aortic aneurysm.

male patients, 45 and 42 months after treatment. Ruptures were caused by migration of a Talent stent graft in one case, and an Excluder stent graft in the other case. Successful redo-EVAR was performed by implantation of an aorto—uni-iliac device in the first, and a bifurcated endoprosthesis in the second patient. The first patient had no imaging between the pre-discharge and the MSCTA on the event day. In the second patient, migration from neck dilation without loss of proximal sealing was evident in the MSCTA examination 40 months after EVAR. However at that time, the migration was ignored and the need for an immediate re-intervention not correctly addressed. The other six type 1a endoleaks were treated by implantation of a Palmaz XL stent (Cordis Corp, Miami Lakes, FL, USA; $n = 2$), proximal extensions (Endurant, Medtronic, Inc., Minneapolis, MN, USA; $n = 2$), and implantation of custom made fenestrated stent grafts (Cook Medical, Bloomington, IN, USA; $n = 2$). Furthermore, six (2.2%) patients had a type 1b endoleak on the modular limb (two right, four left), and three (1.1%) on the ipsilateral (right) limb, which were treated by extension of the iliac limb into the external iliac artery after coil occlusion of the internal iliac artery. Seven (2.5%) type 3 endoleaks, caused by disconnection of the modular limb (one right, five left), and a defect in graft fabric ($n = 1$) were over stented. Further information on implanted stent grafts, instructions for use, and late EVAR failures is given in the supplementary material.

Patients with early EVAR failure had a significantly higher rate ($p = .001$) of late srEL ($n = 14$, 28.0%) compared with those without ($n = 10$, 4.4%). Freedom from late srEL rates in patients with vs. without an early EVAR failure after one, three, and five years was 89.0%, 64.5%, and 52.8%, vs. 99.5%, 97.1%, and 88.4%, respectively ($p < .001$, Fig. 2).

Age (hazard ratio [HR] 1.09; $p = .001$), female sex (hazard ratio [HR] 3.25; $p = .014$), right iliac sealing diameter (HR 10.04; $p = .03$), left iliac sealing diameter (HR 8.65; $p = .001$), infrarenal aortic neck angulation (HR 1.02; $p = .011$), and suprarenal fixation level (HR 3.47; $p = .014$) were significantly associated with an increased incidence of late srEL in the univariable analysis. Proximal neck diameter (HR 2.63; $p = .098$) was also part of the multivariable analysis, but was not significantly associated with an increased incidence of late srEL. Multivariable analysis (Table 4) revealed that age (HR 1.08; $p = .012$), female sex (HR 2.72; $p = .049$), and left iliac sealing diameter (HR 4.48; $p = .033$) were risk factors significantly associated with a higher incidence of late srEL.

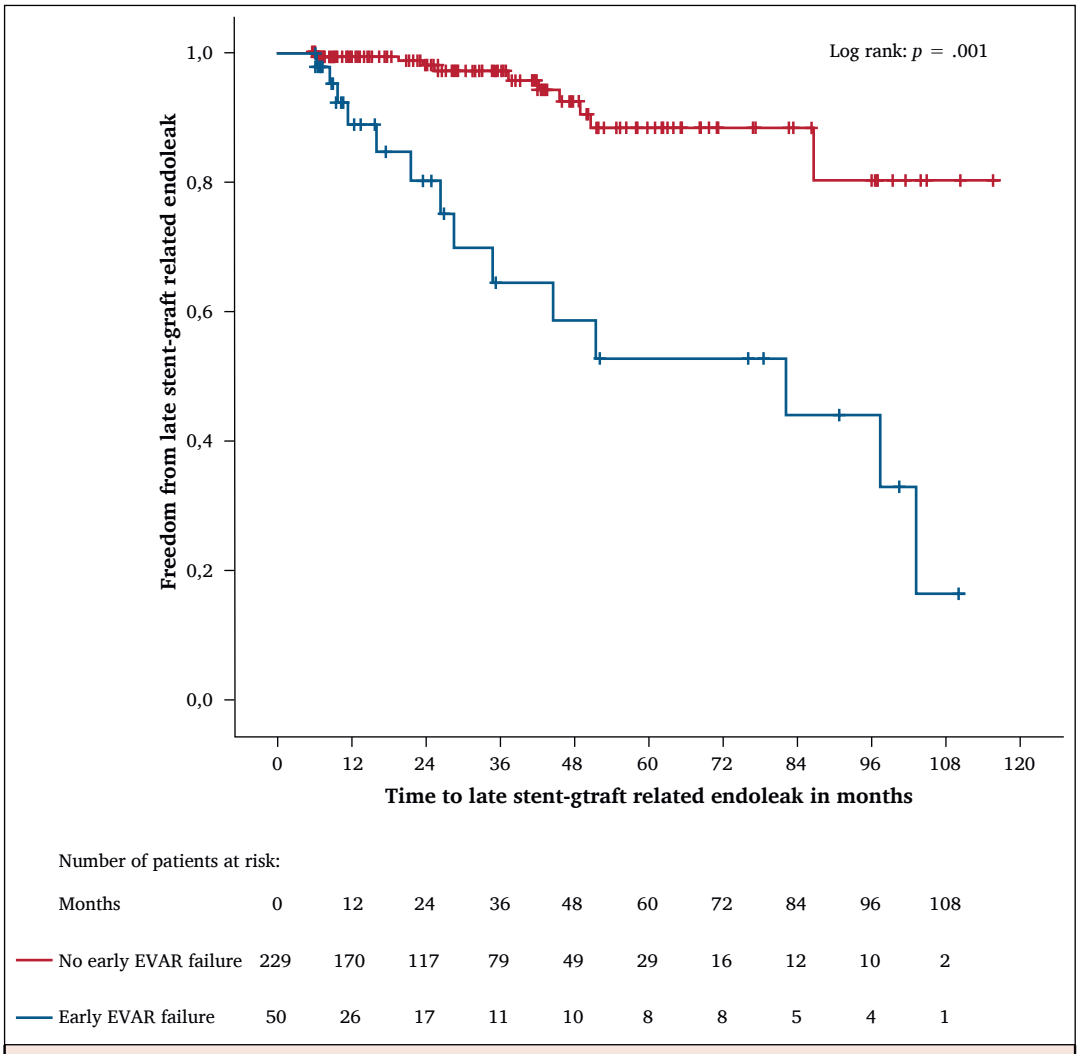

Figure 2. Freedom from late stent graft related endoleaks after endovascular repair of abdominal aortic aneurysm compared between patients with and without early endovascular aneurysm repair (EVAR) failure.

Table 4. Influence of baseline variables on the probability of late stent graft related endoleak free survival, after endovascular repair of abdominal aortic aneurysm in 279 patients included in the multivariable Cox regression analysis

Co-variable	Events/patient	Univariable analysis		Multivariable analysis	
		Hazard ratio (95% CI)	*p*	Hazard ratio (95% CI)	*p*
Baseline clinical variables					
Age, years		1.09 (1.04–1.16)	.001	1.08 (1.02–1.14)	.012*
Sex					
Male – n (%)	18/251 (7.2)	Reference		Reference	
Female – n (%)	6/28 (21.4)	3.25 (1.27–8.33)	0.014	2.72 (1.01–7.36)	.049*
Baseline anatomical variables					
Proximal neck diameter – cm		2.63 (0.81–8.61)	.098	3.37 (0.89–12.71)	.074
Right iliac sealing diameter – cm		10.04 (2.15–46.85)	.003	1.70 (0.26–11.09)	.577
Left iliac sealing diameter – cm		8.65 (2.30–32.58)	.001	4.58 (1.14–18.50)	.033*
Infrarenal aortic neck angulation – °		1.02 (1.00–1.03)	.011	1.01 (0.99–1.03)	.206
Device dependent variable					
Fixation level, suprarenal		3.47 (1.28–9.40)	.014	1.60 (0.54–4.79)	.398

Hazard ratios for continuous variables represent increase in hazard per unit increase in covariable. *p* values were calculated by the Wald test. CI = confidence intervals.
* Indicates a significant result (p<0.05).

DISCUSSION

The present study investigated potential baseline risk factors for the development of late stent graft related endoleaks. In the multivariable analysis, increasing age, female sex, and larger left iliac sealing diameter proved to be risk factors associated with a higher incidence of late srELs. Additionally, freedom from late srEL was significantly longer in patients without early EVAR failure.

The incidence of late srELs in the present study was 8.6%, which is in line with previously reported percentages (3.9—10.6%).[10,12—14] From patient anatomy, the pre-operative aneurysm sac diameter is a well known risk factor for early srELs[9,21] and different late aortic complications, including srEL,[13] which is not supported by the present results. The iliac artery diameter proved to be associated with a higher rate of stent graft related complications at any time.[1,9] Apart from vessel diameter, different authors have identified the docking area of the modular stent graft limb as a vulnerable region, which seems to be exposed to the highest mechanical stress[22] and surface movement.[23] The present results demonstrated a left sided predominance of late srEL, and revealed left iliac sealing diameter as a significant predictor in the multivariable analysis. The predilection for disease in the left iliac sealing zone may be explained by differences in aorto-iliac geometry and consecutive variations in local haemodynamics.[24] These findings lead to the suspicion that mechanical stress to the predominantly left sided modular limb may accelerate natural evolution of aneurysmal disease in the iliac sealing zone, and in the worst case, may cause disconnection of stent graft components.

The proximal anchoring zone is of crucial importance, and different anatomical aspects of proximal neck morphology were found to be associated with the incidence of late type 1 endoleaks. On this matter, neck length was found to be a risk factor,[4,12] which could not be proven by the results of AbuRahma *et al*.[25] Comparable rates for early and late type 1 endoleaks were reported for supra- and infrarenal stent graft fixation, even in short necks <1.5 cm.[26] Severe aortic neck angulation ($>60^{\circ}$) was found to be associated with a higher incidence of late type I ELs,[10] which was questioned by AbuRahma *et al.*[25] The growing experience of interventionalists with EVAR procedures has resulted in an increasing number of patients with complex aneurysms treated outside the recommended IFUs.[3—5] In a recent meta-analysis, including patients with hostile neck anatomy, some authors asserted that EVAR performed outside the IFU is associated with a higher incidence of late srELs.[11] However, in another meta-analysis,[11] type 1 endoleaks that occurred 30 days after EVAR were defined as late events, which may nuance any comparison with the present results. In addition to hostile neck parameters, the presence of any endoleak on the initial post-operative CT scan was identified as an independent predictor of re-interventions or adverse events after EVAR.[15,27] However, in these studies, more than two thirds of endoleaks were type 2 endoleaks, which are rarely associated with an unfavourable outcome.[28] In the present patient cohort, none of the assessed parameters was associated with a higher incidence of late srELs in the multivariable analysis. The occurrence of type I ELs within the first six months seems to be primarily caused by hostile neck anatomy (supplementary material: Association of baseline parameters with early EVAR failure), which is reflected in a high rate of stent graft related complications during this period.[9] After this time interval, there is a clear drop in stent graft related complications, with a relapsing increase after two years,[9] particularly in patients with early EVAR failure,[29] which is in line with the present results. Besides existing anatomical parameters, this rise potentially could be caused by the natural evolution of aneurysmal disease.[6] Atherosclerotic disease progression negatively influences wall compliance and aneurysm morphology.[30] This mechanism has an especially negative effect on females, who are anatomically disadvantaged by a higher rate of hostile necks, smaller iliac artery diameters, and faster aneurysm growth.[10,31] In this context, a recent retrospective study demonstrated that women were more likely than men to develop endoleaks (especially types 1 and 3) in long-term follow up,[32] which is in line with the present results. Another factor clearly associated with atherosclerotic disease progression is age.[33] Age $\geq$80 years was associated with sac expansion as an indirect sign of device failure after EVAR in an analysis of more than 10,000 patients.[5] Furthermore, several authors reported an association between early EVAR complications and increasing age.[9,34] Focusing on the incidence of late srEL, this observation was also made in the present study. Considering the increasing life expectancy[35] and the increased number of EVAR treatments in older patients,[2] it seems that this risk factor will become more and more important in the future. Although results of this study do not enable a broad statement on surveillance strategy after EVAR, given the low late srEL rate in patients without early EVAR failure, the present findings might support the proposed strategy of yearly ultrasound surveillance in patients with normal CT imaging one year after EVAR.[16]

This study has several limitations. First, data were evaluated in a retrospective manner and a relatively small number of patients were included. Second, a large number of patients ($n = 145$) had to be excluded because of lack of MSCTA follow up $\geq$ 6 months. As there is no information on possible late complications of these patients, possible selection bias cannot be ruled out completely. Third, performance of the pre-discharge MSCTA mostly within one week might have contributed to the high number of early EVAR failures. Fourth, inclusion of second generation devices and rudimentary planning in the early period of the study may have negatively affected outcome. Fifth, because of the magnitude of included variables, considering the small number of events, the Cox model may not be as robust, and significant predictors of this exploratory analysis must be interpreted with great caution.

In conclusion, to the authors' knowledge, this is the first study to investigate a group of baseline risk factors that could possibly influence the occurrence of late stent graft

related endoleaks after EVAR. Older patients, those of female gender, and larger left iliac sealing diameters seem to be at higher risk of development of late srEL. These findings require independent confirmation by a larger study cohort, if they are to help refine surveillance protocols.

CONFLICT OF INTEREST

None.

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APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2018.11.002.

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COUP D'OEIL

Haemangioma of the Thumb

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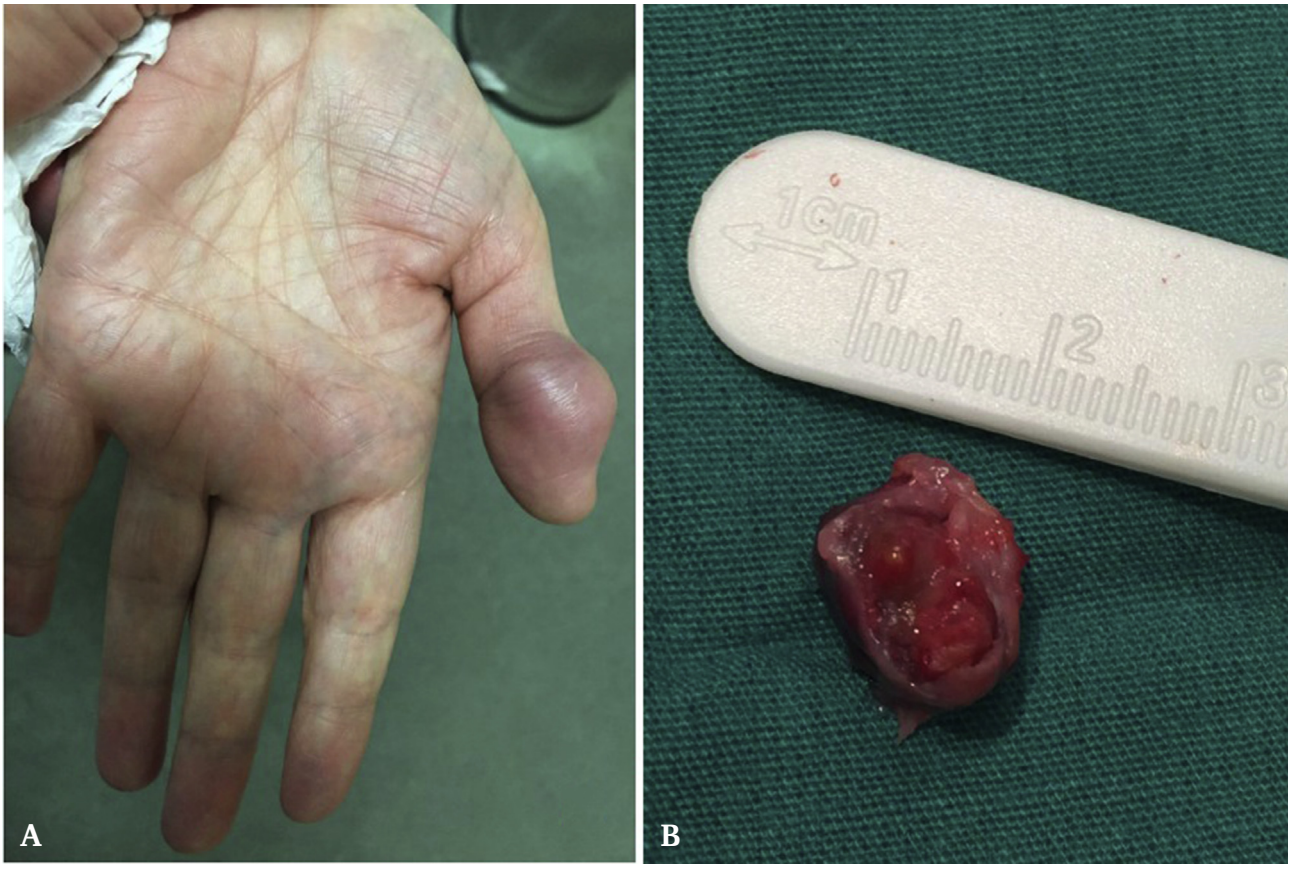

A 47 year old woman presented as an outpatient complaining of a three week history of painful lump in her left thumb (A). There was no history of trauma. There were normal palpable pulses over the radial and ulnar artery. Previous drainage by a general surgeon had revealed only blood, without resolution of the lump. Hence, the patient was referred for further diagnostic investigation and management. Magnetic resonance imaging revealed a 2 cm wide mass with contrast enhancement. The mass was removed under local anaesthesia (B); histological examination confirmed a haemangioma.

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