Original article

Follow-up after endovascular aortic aneurysm repair can be stratified based on first postoperative imaging

H. Baderkhan[1], O. Haller[2], A. Wanhainen[1], M. Björck[1] and K. Mani[1]

[1]Department of Surgical Sciences, Section of Vascular Surgery, Uppsala University, Uppsala, and [2]Department of Radiology, Gävle Hospital, Gävle, Sweden

Correspondence to: Dr H. Baderkhan, Department of Surgical Sciences, Section of Vascular Surgery, Uppsala University, 75185 Uppsala, Sweden (e-mail: baderkhan@hotmail.com)

Background: Lifelong postoperative surveillance is recommended following endovascular aneurysm repair (EVAR). Although the purpose is to prevent and/or identify complications early, it also results in increased cost and workload. This study was designed to examine whether it may be possible to identify patients at low risk of complications based on their first postoperative CT angiogram (CTA).

Methods: All patients undergoing EVAR in two Swedish centres between 2001 and 2012 were identified retrospectively and categorized based on the first postoperative CTA as at low risk (proximal and distal sealing zone at least 10 mm and no endoleak) or high risk (sealing zone less than 10 mm and/or presence of any endoleak) of complications.

Results: Some 326 patients (273 men) with a CTA performed less than 1 year after EVAR were included (low risk 212, 65·0 per cent; high risk 114, 35·0 per cent). There was no difference between the groups in terms of sex, age, co-morbidities, abdominal aortic aneurysm (AAA) diameter, preoperative AAA neck anatomy, stent-graft type or duration of follow-up (mean(s.d.) 4·8(3·2) years). Five-year freedom from AAA-related adverse events was 97·1 and 47·7 per cent in the low- and high-risk groups respectively ($P < 0·001$). The corresponding freedom from AAA-related reintervention was 96·2 and 54·1 per cent ($P < 0·001$). The method had a sensitivity of 88·3 per cent, specificity of 77·0 per cent and negative predictive value of 96·6 per cent to detect AAA-related adverse events. The number of surveillance imaging per AAA-related adverse event was 168 *versus* 11 for the low-risk *versus* high-risk group.

Conclusion: Two-thirds of patients undergoing EVAR have an adequate seal and no endoleak on the first postoperative CTA, and a very low risk of AAA-related events up to 5 years. Less vigilant follow-up after EVAR may be considered for these patients.

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Introduction

Endovascular aneurysm repair (EVAR) is used increasingly for the treatment of abdominal aortic aneurysm (AAA)[1], and constitutes more than 50 per cent of repairs performed in many countries[2]. Although EVAR has a clear short-term survival benefit compared with open repair[3–5], the risk of graft failure mandates regular follow-up to allow timely identification and management of complications. Annual rupture rates of 0·7–1·4 per cent[6,7] and annual reintervention rates of 4–18 per cent have been identified in various studies[7–9]. Current guidelines[10,11] recommend annual imaging surveillance, whereas surveillance programmes vary significantly among institutions in frequency and imaging modality used[12]. CT angiography and ultrasonography are the two dominant modalities used for surveillance following EVAR. With an increasing number of EVAR procedures, this surveillance results in increasing costs and use of resources, as well as radiation and contrast exposure[13,14] and negative effects of repeated follow-up on the patients' well-being[15].

Stratification of post-EVAR follow-up based on the risk of graft failure would increase the efficacy of follow-up programmes and reduce unnecessary patient exposure to examinations. Risk factors associated with higher post-EVAR adverse events include intraoperative complications and adjunctive procedures[16], hostile anatomy or use of stent-grafts outside instructions for use[17,18], and lack of sac shrinkage in the postoperative interval[19]. The presence of an adequate sealing zone and no endoleak

on the first postoperative CT angiogram (CTA) has been shown[20] to predict a low risk of complications for up to 5 years after EVAR in a limited single-centre cohort of patients treated with a specific type of stent-graft. This finding enables the construction of an appealing follow-up algorithm, in which the first postoperative CTA could guide future EVAR follow-up frequency.

In the present study, the generalizability of the above study[20] was assessed. It was hypothesized that the risk of AAA-related adverse events and reinterventions could be predicted based on the presence of adequate seal and endoleaks on the first postoperative CTA, and that this examination could be used for stratification of follow-up after EVAR.

Methods

The study involved two Swedish institutions (Uppsala University Hospital and Gävle Hospital) with experience in EVAR, each performing more than 50 aortic procedures annually (including standard and complex EVAR, as well as open repair). The study was performed in accordance with the STROBE guidelines[21] for observational studies. The study complied with the Helsinki declaration on research ethics, and local procedures for ethical approval were followed.

Patients

All patients treated with EVAR from January 2001 to December 2012 at the two centres were identified based on the prospective Swedish vascular registry (Swedvasc) and local surgical registries. Inclusion criteria were: presence of infrarenal aortic or aortoiliac aneurysm treated with standard EVAR (no chimneys or fenestrations), and a CTA of adequate quality taken within 1 year of the operation. Patients with isolated iliac aneurysms, with previous abdominal aortic surgery, and those with a complex endovascular repair were excluded, as were those with only duplex surveillance during the first postoperative year.

Data collection

Data from each institution were anonymized and entered into a study-specific database, which included: clinical baseline characteristics, anatomical parameters in the preoperative and first postoperative CTA, procedural characteristics including endograft model, endograft configuration and intraoperative complications. Follow-up data included all surveillance imaging, complications, reinterventions and mortality. Survival data were based on cross-matching with the population registry using the Swedish unique personal identification number, resulting in 100 per cent accurate survival follow-up. All CTAs were scrutinized by a single experienced vascular surgeon or radiologist at each centre, and endpoints were registered. CTA readers were blinded to the outcome. Anatomical measurements were performed with central luminal line reconstructions using dedicated software (3mensio Vascular™, Pie Medical Imaging, Bilthoven, The Netherlands; and Aquarius iNtuition™, TeraRecon, Foster City, California, USA). Measurements on the preoperative CTA included assessment of aneurysm size, aortic neck (diameter, length, α and β angulation), iliac diameter and stenosis. Measurements obtained on the first postoperative CTA included: the distance from the lowermost renal artery to the beginning of the covered part of the endograft; the length of the proximal sealing zone (where the main body of the endograft is closely attached to the aortic neck); and the length of the distal sealing zone (where the endograft limb is closely attached to the common or external iliac artery). The presence of endoleaks was assessed, and classified according to the White and May system[22].

Definitions

Based on the first postoperative CTA, patients were categorized as at either low risk (proximal and distal sealing zone at least 10 mm and no endoleak) or high risk (sealing zone less than 10 mm proximally or distally and/or presence of any endoleak) of complications. Sealing zone was defined as the length of the aortic neck or iliac vessels (common iliac artery, CIA; or external iliac artery, EIA) covered by the stent-graft, that is, where the stent-graft was circumferentially in contact with the vessel wall (as opposed to the available neck), and patients were grouped based on measurements performed on a centre-line reconstruction of the vessel. If the sealing zone was less than 10 mm in any of the landing zones, the patient was classified as high risk.

AAA-related adverse events were defined as stent-graft migration greater than 10 mm, aneurysm rupture, endoleak type I or III, undefined endoleak, sac expansion of 5 mm or more in the presence of a type II endoleak or with no clear endoleak. Type II endoleaks without sac expansion were not regarded as AAA-related adverse events. AAA-related reinterventions were defined as any intervention performed to manage or prevent these adverse events. Maldeployment was defined as the intentional or unintentional placement of the stent-graft with its proximal edge more than 5 mm below the lowest renal artery, as assessed

on the first postoperative CTA (irrespective of preoperative morphology of the aneurysm).

In a sensitivity analysis, the data were also reanalysed based on a definition of the low-risk group including only patients with a sealing zone of at least 15 mm proximally and distally, and no endoleak. Additionally, combined AAA- and iliac limb-related complication and reintervention rates (including iliac limb thromboses and reinterventions) were determined by Kaplan–Meier analysis.

Surveillance programmes

All patients were followed up regularly by either CTA or ultrasound imaging. In Uppsala, follow-up was by duplex ultrasonography 1 month after surgery, CTA at 6 months and ultrasound imaging at 12 months, followed by biannual CTA and ultrasound imaging. In Gävle, the follow-up programme was with CTA at 1, 6 and 12 months, and then annually. Ultrasound imaging replaced CT angiography for many patients in the later years of the study in both centres. The rate of ultrasound examinations for follow-up increased slightly during the study period.

Endpoints

The primary study endpoint was freedom from any AAA-related adverse event. Secondary endpoints were freedom from different types of AAA-related adverse event and freedom from AAA-related reintervention.

Statistical analysis

Data analysis was performed using IBM SPSS® Statistics 21 (IBM, Armonk, New York, USA). Data were assessed for normality with histograms and the Shapiro–Wilk test. Continuous variables are presented as mean(s.d.) values, and categorical variables as counts and percentages. Comparisons between the groups were performed using contingency table analysis with Pearson χ^2 tests for categorical variables and *t* tests or the Mann–Whitney *U* test for continuous variables.

The effects of potential predictors on AAA-related adverse events and reinterventions were assessed by univariable logistic regression. All demographic and anatomical variables that achieved $P < 0{\cdot}200$ on unadjusted analysis were introduced into a multivariable logistic regression model. Selection bias was explored by comparing baseline characteristics, overall mortality, follow-up time, AAA-related adverse events and reintervention rates between patients included and excluded from the study. Kaplan–Meier methodology was used to estimate survival, freedom from AAA-related adverse events and reinterventions for each group, with the log rank test. $P < 0{\cdot}050$ was considered statistically significant.

Stratification of patients undergoing EVAR into low- and high-risk groups for adverse events during the 5-year follow-up was further evaluated by calculating the sensitivity, specificity and negative predictive values for detection of AAA-related adverse events. The κ coefficient was used to evaluate interobserver agreement in classifying patients to each group: 30 patients (20 in the low-risk and 10 in the high-risk group) were selected randomly by one of the authors not involved in the measurements, and classified by two independent evaluators, who measured sealing zones and assessed the presence of endoleaks.

Results

In 2001–2012, a total of 454 patients were treated with EVAR in the two participating institutions. Some 128 patients lacked an adequate postoperative CTA within 1 year of aortic repair, and 326 (273 men) were included in the study (*Table S1*, supporting information). For 18 patients the primary CTA examination was without contrast, and information on endoleak was obtained from duplex examination performed within 3 months of the CTA.

Evaluation of the first postoperative CTA resulted in categorization of 114 (35·0 per cent) of the patients to the high-risk group, based on presence of a short sealing zone or endoleak. Baseline characteristics are presented in *Table 1*. There were no differences between the groups regarding sex, age, co-morbidities, duration of follow-up (mean(s.d.) 4·8(3·2) years), aneurysm diameter or aortic neck anatomy. Analysis of preoperative AAA morphology compared with instructions for use (IFU) of the stent-graft used found that 69·8 per cent of patients in the low-risk group were operated on inside IFU *versus* 56·0 per cent in the high-risk group ($P = 0{\cdot}016$). Patients in the high-risk group had significantly larger mean iliac landing zone diameters.

Perioperative data, as well as adverse events and reinterventions occurring before the first CTA examination, are presented in *Table 2*. The high-risk group had a higher rate of stent-grafts deployed more than 5 mm below the lowest renal artery (42·1 per cent *versus* 21·2 per cent in the low-risk group; $P < 0{\cdot}001$), as well as a significantly increased rate of AAA-related adverse events and reinterventions at 30 days after surgery. Survival data were available for all patients. Seventeen (5·2 per cent) of the 326 patients (9 low risk, 8 high risk) were lost to imaging follow-up after a median of 15·5 (range 0–70) months.

Table 1 Baseline characteristics

	Low-risk group ($n = 212$)	High-risk group ($n = 114$)	P‡
Age (years)*	75(7)	75(7)	0·874§
Sex ratio (M : F)	179 : 33	94 : 20	0·644
Duration of follow-up (years)*	4·6(3·3)	5·0(3·1)	0·316§
Time to first postoperative CTA (days)†	58 (0–355)	41 (0–311)	0·232¶
Co-morbidities			
Cardiac disease	102 of 206 (49·5)	47 of 111 (42·3)	0·222
Pulmonary disease	44 of 207 (21·3)	15 of 110 (13·6)	0·097
Renal disease	16 of 208 (7·7)	12 of 111 (10·8)	0·348
Hypertension	123 of 207 (59·4)	66 of 114 (57·9)	0·790
Diabetes	22 of 206 (10·7)	15 of 111 (13·5)	0·453
Cerebrovascular disease	28 of 206 (13·6)	13 of 111 (11·7)	0·634
Peripheral artery disease	23 of 205 (11·2)	9 of 111 (8·1)	0·381
Preoperative aneurysm anatomy			
Preoperative aneurysm size (mm)*	63·4(12·7)	64·7(14·7)	0·445§
Aortic neck diameter (mm)*	25·4(4·0)	26·0(4·0)	0·169§
Aortic neck length (mm)*	23·8(13·8)	22·0(13·9)	0·260§
Suprarenal angulation (°)*	20·9(17·3)	21·1(18·5)	0·923§
Infrarenal angulation (°)*	41·7(15·6)	44·4(20·0)	0·190§
Iliac landing zone diameter (mm)*			
Right	14·3(3·7)	16·2(5·4)	0·002§
Left	14·2(3·6)	15·6(3·7)	0·003§
Common iliac stenosis			
Right	18 of 198 (9·1)	7 of 111 (6·3)	0·389
Left	14 of 200 (7·0)	5 of 111 (4·5)	0·379

Values in parentheses are percentages unless indicated otherwise; values are *mean(s.d.) and †median (range). CTA, CT angiogram. ‡χ^2 test, except §t test and ¶Mann–Whitney U test.

Long-term outcome

Within 5 years of surgery seven AAA-related adverse events had occurred in the low-risk group compared with 53 in the high-risk group (3·3 *versus* 46·5 per cent; $P < 0·001$). This corresponds to a sensitivity of 88·3 per cent, a specificity of 77·0 per cent and a negative predictive value of 96·6 per cent for the method to detect AAA-related adverse events. The reintervention rate at 5 years was 1·9 *versus* 38·6 per cent respectively ($P < 0·001$) (*Table 3*). A short distal sealing zone was the strongest predictor of AAA-related adverse events and reinterventions (*Table 4*). Patients with a distal sealing zone of less than 10 mm had a larger iliac diameter than those with a distal sealing zone of 10 mm or above (mean(s.d.) 19(6) *versus* 15(4) mm; right side $P = 0·026$, left side $P < 0·001$).

Twenty-three patients (7·1 per cent of the whole cohort, 20·2 per cent of the high-risk group) had a combination of short sealing zone and endoleak. In these patients, the 5-year reintervention rate was 87 per cent (20 of 23) and 5-year freedom from AAA-related adverse events was 0 per cent.

Kaplan–Meier analyses of freedom from AAA-related adverse events and reinterventions for low- and high-risk patients are presented in *Figs 1* and *2*. Adverse events and reinterventions throughout the follow-up period (including those occurring beyond 5 years) are shown in *Table S2* (supporting information). Kaplan–Meier analysis of overall survival in the two groups is given in *Fig. 3*.

Analysis of adverse events and imaging follow-up

Seven patients in the low-risk group suffered AAA-related adverse events within 5 years of EVAR (*Table S3*, supporting information), one rupture was a result of graft infection. There were 53 AAA-related adverse events in the high-risk group. Fifteen new endoleaks (not present at initial examination) occurred during follow-up, all of which were in patients with a short sealing zone. In contrast, no new endoleaks occurred in patients with an adequate seal in either the low- or high-risk group.

Three ruptures occurred in the high-risk group. The first patient, who had a type II endoleak from the beginning with adequate sealing, developed a type Ib endoleak and rupture after 5 years, and was managed successfully with limb extension. This patient later had a type Ia endoleak, which was treated with a proximal cuff. The second patient had a type Ia endoleak on the first postoperative CTA at 2 months after EVAR; this was misinterpreted as a type II endoleak and could not be verified in the next CTA 8 months later. The patient presented after 1·5 years with a rupture, which was managed initially with a proximal cuff

Table 2 Perioperative data

	Low-risk group (n = 212)	High-risk group (n = 114)	P*
Operative data			
Local anaesthesia	58 of 150 (38·7)	29 of 71 (41)	0·757
Aortouni-iliac configuration	4 (1·9)	3 (2·6)	0·699
Iliac branched device	5 (2·4)	4 (3·5)	0·725
Associated iliac aneurysm	40 of 211 (19·0)	22 (19·3)	0·940
Rupture	14 (6·6)	9 (7·9)	0·664
Endografts			
Excluder®	45 of 208 (21·6)	27 (23·7)	0·610
Endurant®	49 of 208 (23·6)	29 (25·4)	0·639
Zenith®	94 of 208 (45·2)	48 (42·1)	0·698
Talent®	14 of 208 (6·7)	7 (6·1)	0·871
Other	6 of 208 (2·9)	3 (2·6)	1·000
Intraoperative complications and reinterventions			
Any AAA-related adverse event	33 (15·6)	21 (18·4)	0·508
Type Ia endoleak	19 (9·0)	14 (12·3)	0·344
Type Ib endoleak	5 (2·4)	1 (0·9)	0·669
Undefined endoleak	4 (1·9)	1 (0·9)	0·661
Unintentional coverage of renal artery	1 (0·5)	1 (0·9)	1·000
Graft limb stenosis or thrombosis	3 (1·4)	4 (3·5)	0·245
Any adjunctive procedure	15 (7·1)	12 (10·5)	0·281
Proximal cuff/Palmaz™ stent	12 (5·7)	8 (7·0)	0·626
Thrombectomy	1 (0·5)	3 (2·6)	0·125
Renal stenting	1 (0·5)	1 (0·9)	1·000
Postoperative outcome			
30-day			
Mortality	0 (0)	2 (1·8)	0·122
AAA-related adverse event	0 (0)	12 (10·5)	< 0·001
Type Ia endoleak	0 (0)	5 (4·4)	0·005
Type Ib endoleak	0 (0)	6 (5·3)	0·002
Undefined endoleak	0 (0)	1 (0·9)	0·351
Graft limb thrombosis	5 (2·4)	0 (0)	0·166
AAA-related reintervention	1 (0·5)	5 (4·4)	0·021
Proximal cuff/Palmaz™ stent	0 (0)	2 (1·8)	0·122
Limb extension	1 (0·5)	3 (2·6)	0·126
Thrombolysis	1 (0·5)	0 (0)	1·000
Before first CTA			
AAA-related adverse event	0 (0)	3 (2·6)	0·042
Type Ia endoleak	0 (0)	2 (1·8)	0·122
Undefined endoleak	0 (0)	1 (0·9)	0·350
Graft limb stenosis or thrombosis	2 (0·9)	0 (0)	0·544
AAA-related reintervention	1 (0·5)	1 (0·9)	1·000
Proximal cuff/Palmaz™ stent	0 (0)	1 (0·9)	0·349
Limb extension	1 (0·5)	0 (0)	1·000
Thrombolysis	1 (0·5)	0 (0)	1·000

Values in parentheses are percentages. Excluder®: W. L. Gore, Flagstaff, Arizona, USA; Endurant® and Talent®: Medtronic, Minneapolis, Minnesota, USA; Zenith®: Cook, Bloomington, Indiana, USA; Palmaz™: Cordis, Miami Lakes, Florida, USA. AAA, abdominal aortic aneurysm; CTA, CT angiogram. *χ^2 test.

and later with conversion to open repair. He died 3 years after this last operation. The third patient also had a type II endoleak from the beginning. Follow-up imaging revealed graft migration after 3 years; the patient presented with rupture, which was managed with a proximal cuff. A further cuff was required after a few months because of continued sac expansion. The patient died 1 year later.

A total of 1343 surveillance imaging examinations were performed during follow-up in the low-risk group (533 CTA, 632 duplex, 79 non-contrast CTA, 87 abdominal X-ray and 12 other – contrast-enhanced ultrasonography, intravascular ultrasonography, diagnostic angiography). This resulted in 168 imaging examinations per AAA-related adverse event (8 adverse events in whole follow-up interval) in this group. In the high-risk group, 652 examinations were performed (265 CTA, 345 duplex, 30 non-contrast CTA, 4 abdominal X-ray and 8 other), resulting in 11 imaging examinations per adverse event

Table 3 Five-year frequency of abdominal aortic aneurysm-related adverse events and reinterventions after endovascular aneurysm repair, categorized as low or high risk based on first postoperative CT angiogram

	Low-risk group (n = 212)	High-risk group (n = 114)	P‡
Overall outcome			
AAA-related adverse event	7 (3·3)	53 (46·5)	< 0·001
AAA-related reintervention	4 (1·9)	44 (38·6)	< 0·001
Any endoleak	4 (1·9)	48 (42·1)	< 0·001
Rupture	1 (0·5)	3 (2·6)	0·125
Detailed outcome*			
Type Ia endoleak	0 (0)	24 (21·1)	< 0·001
Type Ib endoleak	0 (0)	13 (11·4)	< 0·001
Type III endoleak	0 (0)	5 (4·4)	0·005
Undefined endoleak	1 (0·5)	2 (1·8)	0·281
Type II with expansion	3 (1·4)	13 (11·4)	< 0·001
Expansion without clear endoleak	2 (0·9)	4 (3·5)	0·189
Graft migration	0 (0)	2 (1·8)	0·122
Graft limb thrombosis†	12 (5·7)	4 (3·5)	0·391
Proximal cuff/Palmaz™ stent	1 (0·5)	23 (20·2)	< 0·001
Relining	0 (0)	4 (3·5)	0·014
Limb extension	0 (0)	11 (9·6)	< 0·001
Coil or glue embolization	3 (1·4)	9 (7·9)	0·005
Conversion to open surgery	1 (0·5)	4 (3·5)	0·052
Conversion to aortouni-iliac repair	0 (0)	1 (0·9)	0·350
Thrombolysis†	6 (2·8)	1 (0·9)	0·428

Values in parentheses are percentages. *Some patients had more than one adverse event or reintervention. †Graft limb thrombosis and thrombolysis not regarded as abdominal aortic aneurysm (AAA)-related adverse events and reinterventions in the analysis. ‡χ^2 test.

Table 4 Multivariable logistic regression analysis of predictors of abdominal aortic aneurysm-related adverse events and reinterventions within 5 years of endovascular aneurysm repair

	Unadjusted analysis		Adjusted analysis	
	Odds ratio	P	Odds ratio	P
AAA-related adverse events				
Short proximal sealing	10·42 (4·91, 22·10)	< 0·001	26·60 (10·15, 69·68)	< 0·001
Short distal sealing	14·95 (6·14, 36·37)	< 0·001	37·64 (12·71, 111·43)	< 0·001
Type II endoleak	2·62 (1·38, 4·96)	0·003	9·19 (3·83, 22·04)	< 0·001
AAA-related reinterventions				
Short proximal sealing	10·06 (4·71, 21·48)	< 0·001	24·66 (8·95, 67·99)	< 0·001
Short distal sealing	17·93 (7·40, 43·44)	< 0·001	42·88 (14·05, 130·84)	< 0·001
Type II endoleak	1·87 (0·92, 3·81)	0·084	6·84 (2·54, 18·42)	< 0·001

Values in parentheses are 95 per cent confidence intervals. AAA, abdominal aortic aneurysm.

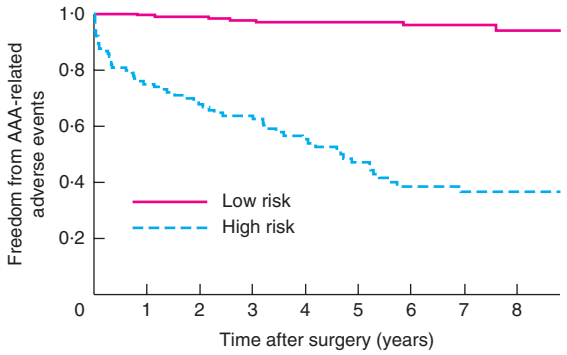
(total of 59 adverse events). The mean cost of one duplex or CTA examination in Sweden of approximately €400 indicates a surveillance cost of approximately €70 000 per AAA-related adverse event in the low-risk group and €4500 in the high-risk group.

Assessment of excluded patients

A total of 128 patients were excluded from the study owing to lack of adequate CTA imaging within 1-year after EVAR. To assess the risk of selection bias, these patients were evaluated for AAA-related adverse events and reinterventions. At a mean follow-up of 4·7 years, 18 (14·1) per cent of the excluded patients had experienced an AAA-related adverse event, compared with 67 (20·6 per cent) of the 326 patients included in the study (P = 0·111), and 19 (14·8 per cent) and 55 (16·9 per cent) of patients respectively had required a reintervention (P = 0·599). There were no significant differences between groups in baseline characteristics, duration of follow-up and overall mortality. Three patients in the excluded group presented with rupture at 2·5, 3 and 7 years after EVAR.

Assessment of interobserver variability

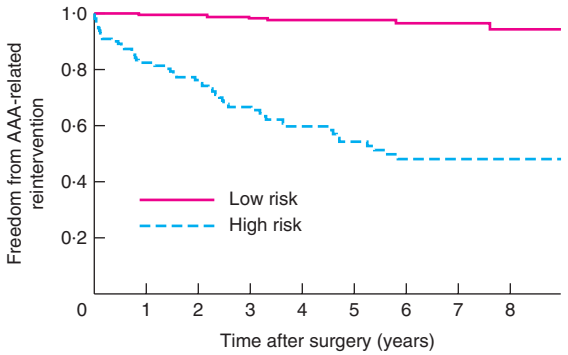
Interobserver variability assessment using κ coefficient showed a moderate degree of agreement (κ = 0·59). Five



No. at risk

Low risk	212	188	138	98	93
High risk	114	75	57	33	16

Fig. 1 Kaplan–Meier analysis of freedom from abdominal aortic aneurysm (AAA)-related adverse events in patients classified as at low and high risk of adverse events after endovascular aneurysm repair. $P < 0{\cdot}001$ (log rank test)



No. at risk

Low risk	212	190	138	98	44
High risk	114	83	61	38	18

Fig. 2 Kaplan–Meier analysis of freedom from abdominal aortic aneurysm (AAA)-related reintervention in patients classified as at low and high risk of adverse events after endovascular aneurysm repair. $P < 0{\cdot}001$ (log rank test)

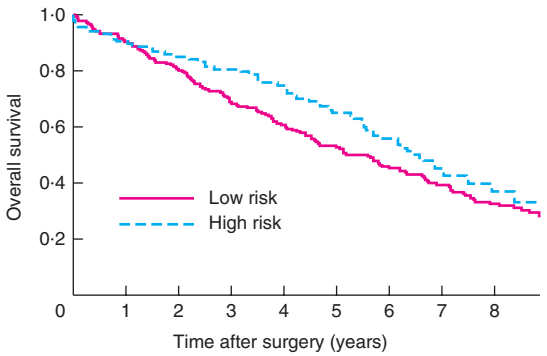
patients were classified differently by the two observers, in two instances due to differences in the assessment of the presence of endoleak and in three to differences in sealing zone measurements.

Sensitivity analyses

Categorization of patients into the low-risk group based on a minimum sealing zone of at least 15 mm and no endoleak (145 (44·5 per cent) of the 326 patients) resulted in four (2·8 per cent) AAA-related adverse events in the low-risk group compared with 56 (30·9 per cent) of the 181 patients in the high-risk group ($P < 0{\cdot}001$) within 5 years of the operation. This corresponds to a sensitivity of 93·3 per cent, specificity of 53·0 per cent and negative predictive value of 97·2 per cent to detect AAA-related adverse events. The AAA-related reintervention rate was 1·4 per cent (2 of 145) and 25·4 per cent (46 of 181) respectively ($P < 0{\cdot}001$).

Fifteen patients (4·6 per cent) had a first postoperative CTA without contrast, and information on endoleak was based on ultrasound examinations performed within 90 days of the CTA. A sensitivity analysis was performed by excluding these patients from the analysis of long-term outcome; there was no change in the overall results.

Analysis of the cohort for combined AAA- and iliac limb-related complications resulted in 9·6 per cent experiencing complications in the low-risk group and 55·9 per cent in the high-risk group at 5 years after EVAR ($P < 0{\cdot}001$). The combined AAA- and iliac limb-related reintervention rate at 5 years was 6·3 and 47·4 per cent respectively ($P < 0{\cdot}001$) (*Fig. S1*, supporting information).



No. at risk

Low risk	212	189	141	101	46
High risk	114	103	88	62	26

Fig. 3 Kaplan–Meier analysis of overall survival in patients classified as at low and high risk of adverse events after endovascular aneurysm repair. $P = 0{\cdot}077$ (log rank test)

Forty-six graft limbs were deployed in the right EIA (12 in the high-risk and 34 in the low-risk group), and 20 in the left EIA (5 and 15 respectively). In a subgroup analysis, patients with a distal landing zone in the EIA had an iliac limb complication rate of 15·5 per cent, compared with 7·3 per cent in patients with a distal landing zone only in the CIA ($P = 0{\cdot}046$). Graft limb thrombosis occurred in 12·1 and 3·6 per cent respectively ($P = 0{\cdot}009$), and type Ib endoleak in 3·4 and 4·4 per cent ($P = 0{\cdot}737$).

Twelve patients in the low-risk group developed graft limb thrombosis, seven of which were managed with thrombolysis. One patient underwent femorofemoral

crossover bypass. In four limbs the thrombosis resulted in mild or no claudication and was therefore managed conservatively, with no need for surgical intervention. In the high-risk group, four patients developed graft limb thrombosis. Three were managed with thrombolysis and one patient had a femorofemoral crossover bypass.

Discussion

The ability to identify patients with a low risk of complications after EVAR, who may be able to receive less vigilant surveillance, will benefit patients, healthcare providers and the health economy. This study suggests that follow-up after EVAR can be stratified based on the findings of the first postoperative CTA. Two-thirds of patients in the present cohort demonstrated adequate seal and no endoleak on the first postoperative CTA, and subsequently had a very low risk of AAA-related adverse events for up to 5 years following EVAR. These patients would thus derive no benefit from annual imaging, and delayed imaging in this substantial group would significantly reduce the follow-up workload.

This study confirms the results of a previous, smaller study using a single stent-graft[20]. The same definition of high risk was used in both studies. Although there was only moderate agreement between two independent reviewers in classifying patients as low or high risk, the diagnostic accuracy was excellent with a negative predictive value of 96·6 per cent. This suggests that stratification based on this definition is safe. Furthermore, this definition resulted in only one-third of all patients undergoing EVAR being classified as high risk, requiring a more vigilant follow-up regimen, whereas the majority could be followed less frequently with even fewer resources required.

In a sensitivity analysis, a more liberal definition of high risk was evaluated (a sealing zone of less than 15 mm and/or endoleak), which agrees better with the IFU of most EVAR devices. With this definition, more than half (55·5 per cent) of all patients were classified as high risk, requiring more frequent follow-up imaging, without significantly improving the diagnostic accuracy and safety (negative predictive value 97 per cent). Thus, the definition used in this paper would appear to be preferable.

Hostile AAA anatomy based on morphological variables identified on the preoperative CTA is the factor that has been studied most rigorously and connected to EVAR failure. An adequate neck length can be underutilized, for example when a stent-graft is deployed lower in the aortic neck than intended. This occurred in 48 (42·1 per cent) of the 114 patients classified as high risk in the present study, and in 93 (28·5 per cent) of the total cohort. Many of the morphological parameters associated with a hostile anatomy affect the sealing zone, and thus sealing zone assessment based on the first postoperative CTA may correct for potential problems created by hostile anatomy (severe angulation, excessive thrombus, focal calcification, conical neck and larger diameters than those required by device-specific IFU). Stratifying follow-up based on assessment of the utilized sealing zone on first postoperative CTA can correct for the risks associated with maldeployment of a stent-graft.

The high number of unnecessary imaging examinations performed in the low-risk group in this study indicates an important possibility for increased efficiency of the programme of follow-up after EVAR. A surveillance programme based on the risk stratification will save resources for the healthcare system, without jeopardizing patient safety. A possible protocol, which suggests delayed imaging for low-risk patients, is presented in *Fig. S2* (supporting information).

As the present study focused on patients treated with standard EVAR, no recommendation can be made regarding use of fenestrated endografts. However, patients with an inadequate seal have a high risk of late AAA-related events. A fenestrated EVAR solution would result in a better seal in these patients, potentially reducing the risk of late EVAR failure.

Iliac events occurred at a similar rate in the two groups, and the combined AAA- and iliac limb-related complication and reintervention rates remained significantly lower in the low-risk group. However, iliac limb thrombosis was more frequent in patients with a distal landing in the EIA. Although it is unclear whether a more vigilant follow-up protocol would prevent these events, the presence of distal stenosis should be assessed specifically and corrected in these patients.

The main limitation of this study is that, although patients were registered prospectively, analysis of imaging and adverse events was retrospective, with the risk of selection bias. The study assessed results in two centres over 12 years, during which progress in device development and clinical practice has occurred. Although EVAR procedures early in the study were performed with a mobile C-arm in a standard operating theatre, practice increasingly changed to procedures being performed in a hybrid theatre. Owing to the surveillance routine at one of the hospitals involving early duplex scanning and first CTA at 6 months, the median time to first postoperative CTA in the present cohort was 53 (range 0–355) days. This differs from the recommended guidelines[10,11] of performing an early CTA 1 month after EVAR, and may have affected the number of early endoleaks detected. Despite

the observed differences in outcome between the groups, the κ coefficient for adequate classification into risk groups showed a moderate degree of agreement. Standardization of postoperative imaging evaluation may be required to improve this.

A further limitation of the present analysis is the lack of standardized outcome reporting guidelines for EVAR. This is especially problematic for the definition of migration, which has been reported as either 5 or 10 mm. In the present study, the 10-mm definition for migration was used, as in previous studies[23,24].

Disclosure

The authors declare no conflict of interest.

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Supporting information

Additional supporting information can be found online in the supporting information tab for this article.