European Journal of Vascular and Endovascular Surgery 43 (2012) 276–281

Contents lists available at SciVerse ScienceDirect

European Journal of Vascular and Endovascular Surgery

journal homepage: www.ejves.com

Surveillance Imaging Modality does not Affect Detection Rate of Asymptomatic Secondary Interventions following EVAR

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WHAT THIS PAPER ADDS

- This research compared an endovascular aortic aneurysm repair (EVAR) follow-up protocol based on colour duplex ultrasound (CDU) plus plain abdominal radiography (XR) and computed tomography (CT) angiography (CTA) on demand versus a CTA-based protocol still considered the gold-standard technique of surveillance. Our study reports that CDU can be used in the follow-up of patients after EVAR, as it is safe and picks up a similar rate of asymptomatic secondary interventions as a CTA-based surveillance protocol. We do not advocate eliminating CTA completely from surveillance protocols, but would limit its use to circumstances in which it can provide further details for problems first detected by CDU examination. This approach could reduce costs, the risk of contrast nephropathy and patients' exposure to radiation. Thus, nearly 70% of CTAs have been eliminated from our surveillance protocol.
  In our opinion, surveillance should be simplified, adopting CDU as the main follow-up modality and only applying CTA as required in certain circumstances.

ARTICLE INFO

Article history:
Received 4 July 2011
Accepted 28 November 2011
Available online 10 January 2012

Keywords:
EVAR
Follow-up
Asymptomatic secondary intervention
Complications

ABSTRACT

Objectives: Literature reports that surveillance imaging following endovascular aortic aneurysm repair (EVAR) gives rise to asymptomatic secondary interventions (SI) in 1.4–9% of cases. This retrospective study aimed to evaluate whether the modality of surveillance imaging influences the detection rate of asymptomatic SI.
Materials and methods: Two EVAR surveillance protocols were compared at the same vascular centre. Protocol I, performed from January 2003 to December 2006, consisted of colour duplex ultrasound scan (CDU) plus CT angiography (CTA) 1 month after procedure and every 6 months thereafter. Protocol II, performed from January 2007 to June 2010, consisted of CDU plus CTA 1 month after operation and CDU plus plain abdominal films (XR) every 6 months thereafter. In the second protocol, CTA was carried out only during follow-up in specific conditions. The term 'asymptomatic SI' was used when the necessity for SI was detected by imaging alone on an elective basis, prior to development of any symptoms.
Results: Enrolment included 376 and 341 consecutive patients with a mean follow-up of 1148 days (range 1–3204 days) and 942 days (range1–1512 days) in Protocols I and II, respectively ($p < 0.001$). Freedom rates from aneurysmal rupture, freedom from SI and detection rate for asymptomatic SI at 3 years were 98.3% and 98.7% ($p = 0.456$), 82% and 83.5%($p = 0.876$) and 8.8% ($n = 33/376$) and 8.5%($n = 25/341$) ($p = 0.49$) in Protocols I and II, respectively. Estimated comparison of the costs, radiation exposure and contrast used at 3 years in Protocol I versus Protocol II showed that Protocol II allowed for a three-, four- and six fold reduction in overall costs, radiation exposure and contrast used, respectively ($p < 0.0001$).
Conclusions: The detection rate of asymptomatic SI following EVAR is not affected by the type of surveillance imaging. A surveillance schedule based primarily on CDU and XR appears to be justified.

Lifelong follow-up is recommended for all patients following endovascular aortic aneurysm repair (EVAR),the primary goal being prevention of aneurysmal sac rupture. Various follow-up

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doi:10.1016/j.ejvs.2011.11.020

modalities are employed including plain abdominal radiography (XR), colour duplex ultrasonography (CDU), computed tomography angiography (CTA), magnetic resonance imaging (MRI), contrast-enhanced CDU and sac pressure measurement.[1–3]

The optimal protocol for imaging and timing EVAR follow-up is debatable as well as the balance of advantages and disadvantages for each modality. Follow-up includes measurement of aortic aneurysm diameter, detection and classification of endoleaks, detection of morphologic details of the stent graft, graft occlusion, graft infection and other minor details.[1–3] A recent systematic review reported that >90% of EVAR patients under follow-up do not benefit from surveillance since imaging alone initiates asymptomatic secondary interventions (SI) ranging from 1.4% to 9%.[4] The aim of this retrospective study was to evaluate whether different modalities of surveillance imaging could influence the detection rate of asymptomatic SI following EVAR. In particular, an EVAR follow-up protocol based on CDU + XR and CTA on demand versus a CTA-based protocol, still considered the gold-standard technique of surveillance, were compared.[1–3] Other aims were to evaluate the freedom from aneurysm rupture and SI, patients' compliance to protocol, cost, radiation exposure and contrast savings at 3 years. Three-year follow-up has been reported as a good indicator for the efficiency of a surveillance regimen.[5]

Materials and Methods

Patient selection

Consecutive patients operated for asymptomatic AAA larger than 5 cm were included in the study. All patients were treated from January 2003 to June 2010 at a single University tertiary referral centre. Patients were divided into two protocols. Patient data are listed in Table 1. Anatomical suitability for EVAR included proximal neck diameter <30 mm, angulation <75° and length >12 mm. For distal implantation, at least one common iliac artery with a distal diameter <24 mm was required. Patients with significant renal insufficiency (serum creatinine >2.5 mg/dl) but not on dialysis, and those with a documented contrast allergy were excluded from the study. The local Ethics Committee approved the study and patients gave informed consent before the procedure.

Surgical procedure

All patients were treated in an operating theatre equipped with a portable fluoroscopy unit (GE-OEC 9800; GE Medical Systems, Salt Lake City, UT, USA).

All stent grafts were aortobiiliac devices, but a variety of stent grafts were used (Table 2). The stent grafts were routinely 10–15% oversized. Bilateral femoral cut-down was performed in all patients. Primary type I endoleaks were treated intra-operatively with a giant Palmaz stent or proximal stent-graft extension.[6]

Follow-up protocols

The population was divided into two follow-up protocols.

Protocol I. From January 2003 to December 2006, all consecutive EVAR patients were scheduled for a 1-month postoperative follow-up consisting of CTA, CDU and clinical check-up. The same examinations were performed every 6 months thereafter. The change of surveillance regimen was dictated by the need to reduce costs and provide a safer (reduced radiation exposure and contrast agent use) less invasive follow-up for patients.

Protocol II. From January 2007 to June 2010, all consecutive EVAR patients were scheduled for a 1-month postoperative follow-up consisting of CTA, CDU, XR and clinical check-up. Thereafter, clinical check-up, CDU and XR were performed every 6 months. A further CTA was performed when at least one of the following elements were present: (a) aneurysmal sac growth >5 mm within 6 months of follow-up, (b) onset or persistence of any kind of endoleak and (c) suspected material fatigue/migration observed on XR.

CDU was performed by experienced vascular surgeons, using an ATL HDI 5000 or IU 22 ultrasound system (Philips Medical Systems, Bothell, WA, USA) with 2.5–5 MHz probes. After overnight fasting, a sagittal or transverse scan of the supine patient was performed using the probe. B-mode imaging was used initially to identify the aorta, while the maximum diameter of the aneurysmal sac was measured in the transverse plane. The patency of renal arteries was confirmed using spectral Doppler ultrasound. The aorta was scanned from the proximal attachment site of the endograft to the distal point. Using colour and spectral Doppler ultrasound, the stent was assessed for perigraft flow, graft stenosis, thrombosis, kinking and endoleaks, according to the reporting standards for EVAR.[7] Consistent centring of the radiograph and precise positioning of the patient were carefully controlled and changes in correlations between anatomical landmarks and stent-graft position were recorded during follow-up to detect structural failures or significant graft migration.[2]

Table 1
Patient data. SD: standard deviation, CAD: coronary artery disease, CHF: congestive heart failure, COPD: chronic obstructive pulmonary disease, renal insufficiency serum creatinine > 1.5 mg/dl, ASA : American Society of Anesthesiology.

	Protocol I ($n = 376$)	Protocol II ($n = 341$)	P value
Diameter (mm)			
Mean (SD)	64 (6)	61 (8)	<0.001
Range	50–99	50–112	
Iliac aneurysm	86 (23%)	61 (18%)	0.119
Bilateral iliac aneurysm	41 (11%)	48 (14%)	0.241
Age			
Mean (SD)	76.8 (8.7)	77.5 (7.0)	0.239
Range	67–90	66–92	
Gender			
Male/female	327/49 (87%/13%)	286/55 (84%/16%)	0.285
CAD	241 (64%)	208 (61%)	0.436
CHF	31 (8%)	31 (9%)	0.788
COPD	229 (61%)	201 (59%)	0.017
Renal insufficiency	169 (45%)	167 (49%)	0.315
Hypertension	278 (74%)	245 (72%)	0.586
Diabetes	124 (33%)	120 (35%)	0.586
Hypercholesterolemia	214 (57%)	203 (59%)	0.527
ASA			
I	–	–	
II	49 (13%)	41 (12%)	0.426
III	286 (76%)	252 (74%)	
IV	41 (11%)	48 (14%)	

Table 2
Type of stent graft implanted in the two protocols.

Stent graft	Protocol I $N = 376$	Protocol II $N = 341$	p
Talent			
Medtronic CardioVascular, Santa Rosa, CA, USA	242 (64%)	144 (43%)	<0.0001
Zenith			
Cook Europe A/S, Bjaeverskov, Denmark	51 (13%)	16 (5%)	<0.0001
Endurant			
Medtronic CardioVascular, Santa Rosa, CA, USA	–	168 (49%)	–
Anaconda			
Vascutek, Terumo, Inchinnan, Scotland, GB	17 (4%)	4 (1%)	<0.05
Excluder			
W.L. Gore & Associates, Flagstaff, AZ, USA	64 (19%)	9 (2%)	<0.0001

CTA imaging was performed using a GE multidetector CT scanner (GE Medical Systems, Milwaukee, WI, USA) with a 3-mm acquisition slice. A tri-phasic CT scan was performed on all patients at 30 days. The 30-day postoperative CT scan findings were compared to the 30-day CDU results and to the 30-day XR findings (Protocol II). The findings of this first postoperative CTA scan were considered the baseline images for the entire follow-up. In Protocol I, the 6-month CTAs were biphasic, adding the delayed phase only if required, while in Protocol II CTA scan was tailored to the diagnostic queries that arose following CDU. In the case of suspected structural problems, material fatigue, type I or III endoleaks, a non-contrast and arterial phases were performed. With suspected type II endoleak, arterial and delayed phases were performed. In the enhanced CT, approximately 120 ml of Iodixanol 320 mg I $ml^{-1}$was used (Visipaque ™ 320 mg I ml^{-1}, GE Healthcare, Buckinghamshire, UK). To avoid errors caused by vessel tortuosity, the diameter measurements were defined as the smallest axis of the largest axial slice at CTA, XR and CTA scans were analysed using an image-data post-processing software program available at the imaging station (Advantage Windows 3.1 or 4.1; Sun Microsystems, Mountain View, CA, USA).

Definitions and endpoints

The number of CTA, CDU and XR scans performed in both protocols and the number of CTA scans deemed necessary in Protocol II were assessed.

Primary technical success was assessed on an intention-to-treat basis and defined as successful implantation of a stent graft in the absence of surgical conversion, mortality, type I or III endoleaks or graft occlusion in the first 24-h postoperative period. The clinical endpoints were in accordance with the reporting standards for EVAR[7] and included 30-day mortality and late freedom from abdominal aortic aneurysm (AAA)-related death.

Number/rate of asymptomatic and symptomatic SIs were noted. The term 'asymptomatic SI' was used when the necessity for SI was detected by imaging alone on an elective basis, prior to development of any symptoms. The term 'symptomatic SI' was used when the necessity for SI was driven by symptoms and triggered a diagnostic check-up. Indications for SI were noted. Complications included any endoleaks, AAA expansion (defined as increase >5 mm in postoperative diameter within 6 months of follow-up), migration of the main graft (>1 cm at CT scan or XR), graft infection, graft thrombosis, conversion to open repair, postoperative renal impairment (permanent elevation of serum creatinine >30% over baseline and dialysis-free survival), bowel ischaemia and myocardial infarction (defined as elevation of either creatinine kinase or CK-MB to more than 2 times the upper limit of normal and troponin $T > 0.1$ ng ml^{-1}, usually in the context of chest pain or electrocardiogram changes).

Patients' compliance to each study protocol was defined as the percentage of patients not lost to follow-up.

Cost, radiation exposure and contrast savings were estimated for both protocols in a 3-year follow-up.

Study design

Data were collected prospectively in a computerised database. All data were analysed retrospectively for the two groups on an intention-to-treat basis.

Statistical analysis

Normal distribution and homogeneity of variance were confirmed by the Kolmogorov–Smirnov and Levene's tests, respectively. Data are expressed as mean and standard deviation (SD) or as absolute frequency and percentage (%). The Chi-square or Fisher's exact test were used for all comparisons of proportions. The continuous variables were compared using the Student's t test. Survival analysis was performed according to Kaplan–Meier and significance was calculated with a log-rank test for pairwise comparisons. A p value < 0.05 (two tailed) was considered statistically significant. All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) package, version 13.0 (SPSS Inc., Chicago, IL, USA).

Results

Consecutive patients enrolled during the study periods were 376 in protocol I and 341 in protocol II. Mean follow-up was 1148 days (range: 1–3204 days) and 942 days (range: 1–1512 days) in Protocol I and II, respectively ($p < 0.001$). There were only two significant differences in the patients' characteristics between the two protocols: the distribution of chronic obstructive pulmonary disease (61% in Protocol I vs. 59% in Protocol II; $p = 0.017$) and the mean aneurysm size, which was larger in Protocol I ($p < 0.001$). Balloon expandable stents (Palmaz) and proximal extensions for intra-operative proximal type I endoleak were used in nine and 12 patients and in 7 and 15 patients in Protocol I and II, respectively ($p = 0.45$).

In Protocol I, the total number of CTAs was 3657 and CDUs 5478 while in Protocol II 489 and 3856 of these examinations were performed, respectively. The number of XR performed in Protocol II was 1094 while the number of CTAs deemed necessary was 148 (30%). Of these, 96 (65%) were due to aneurysmal sac growth >5 mm within 6 months of follow-up, 44 (30%) to the onset or persistence of any endoleak and eight (5%) to suspected material fatigue/migration at XR. Moreover, CDU revealed 14 cases of kink/stenos is that were further investigated by CTA.

In Protocol I, accuracy of CDU compared to CTA was 94.4% (positive predictive value of 88.9% and negative predictive value of 95.3%). The detection rate of findings in Protocol I is shown in Table 3. In Protocol II, positive CTA following abnormalities detected on CDU was present in 131/144 (91%). In particular, CTA did not describe correctly six low-flow type II endoleaks and five stenosis/kinks at the level of the iliac limb due to the artifacts from calcium and metal skeleton. In two cases even a not technically well-performed CTA, with no late phase scan did not detect a type II endoleak. When CTA was negative, CDU was considered the most reliable modality of further follow-up. Angiography was used as the last diagnostic tool (only in one case, low-flow type II endoleak). Clinical outcomes are reported in Table 4. There were no statistically significant differences between Protocol I and II in the rates of primary technical success, 30-day mortality, late AAA-related mortality or cardiac, renal or pulmonary complications. This confirms the safety of Protocol II versus Protocol I. In particular,

Table 3
Detection rate of findings in Protocol I from CTA as compared to CDU that lead to asymptomatic SI.SI: Secondary intervention; CDU: colour duplex ultrasound; CTA computed tomography angiography.

Indications for asymptomatic SI	Total	Detected by CDU n (%)	Detected by CTA n (%)	p	Detected by both modalities
Stent-graft limb kink	5	5 (100)	4 (80)	1	5 (100)
Type I endoleak	4	3 (75)	4 (100)	1	4 (100)
Type II endoleak	21	18 (86)[a]	16 (76)[a]	0.697	20 (95)[a]
Type III endoleak	2	2 (100)	2 (100)	1	2 (100)
Access site-related problems	1	1 (100)	1 (100)	1	1 (100)
Sac expansion	27	26 (96)	27 (100)	1	27 (100)
Total	60	55 (92)	54 (90)	1	59 (98)

[a] Low flow type II endoleak with sac expansion erroneously classified as endotension by CTA and CDU. Angiography was required.

Table 4
Clinical outcomes. AAA: abdominal aortic aneurysm; SI: Secondary interventions.

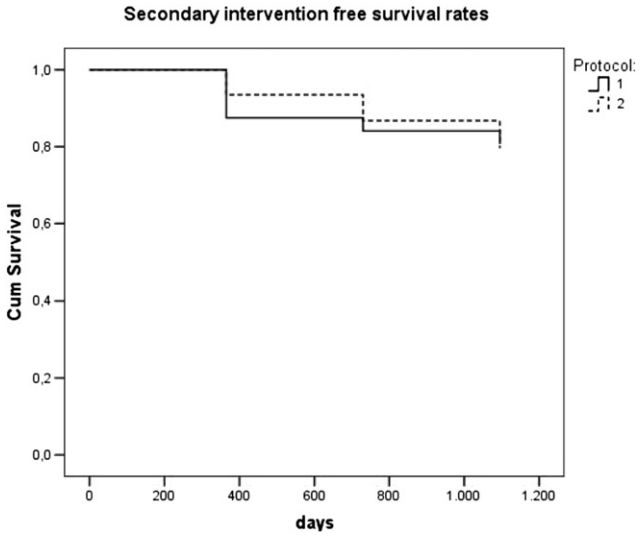
	Protocol I ($n = 376$)	Protocol II ($n = 341$)	p value
Primary technical success	367 (97.6%)	334 (97.9%)	0.956
30-day mortality	8 (2.1%)	6 (1.7%)	0.932
3-year freedom from AAA-related mortality	94.9% (19 deaths)	95.6% (15 deaths)	0.814
3-year overall survival	83% (64 deaths)	84% (55 deaths)	0.764
Early proximal type I endoleak (<30 days)	2 (0.5%)	1 (0.3%)	1.000
Late proximal type I endoleak (>30 days)	4 (1.1%)	4 (1.2%)	1.000
Distal type I endoleak	1 (0.3%)	0	1.000
Type II endoleak	57 (15%)	45 (13.2%)	0.519
Type III endoleak	3 (0.8%)	3 (0.9%)	1.000
SIs	68 (18%)	56 (16.4%)	0.625
Sac expansion (>5 mm)	54 (14.4%)	43 (12.6%)	0.565
Migration (>1 cm)	2 (0.5%)	1 (0.3%)	1.000
Conversion to open repair	3 (0.8%)	1 (0.3%)	0.626
Aneurysm rupture	2 (0.5%)	1 (0.3%)	1.000
Renal impairment			
Permanent (>30% over baseline)	33 (8.7%)	29 (8.5%)	0.997
Need for dialysis	0	0	–
Myocardial infarction	16 (4.2%)	13 (3.8%)	0.912
Graft infection	0	0	–
Limb occlusion	10 (2.6%)	8 (2.3%)	0.977
Bowel ischaemia	2 (0.5%)	0	0.501

freedom from aneurysm rupture at 3 years was 98.3% for Protocol I and 98.7% ($p = 0.456$) for Protocol II. Two ruptures occurred in Protocol I and one in Protocol II. All ruptures occurred in patients lost to follow-up who had a preoperative aneurysm larger than 7 cm and a nearly or late type Ia endoleak. The ruptures occurred at 44, 1067 and 508 days after EVAR. In one case, type I endoleak was caused by proximal migration of the prosthesis due to the rupture of the suprarenal stent. All ruptures were treated by emergency conversion to open repair. A case of impending rupture due to a massive type II endoleak was also treated by emergency conversion to open repair (another case was treated endovascularly by coil embolisation of the sac).

A total of 124 SIs were performed at 3 years ($n = 58$; 8.1% asymptomatic, $n = 66$; 9.2% symptomatic). Three-year asymptomatic SI rate was 8.8% ($n = 33/376$) in Protocol I and 8.5%($n = 25/341$) in Protocol II ($p = 0.49$). Symptomatic SIs were relatively more frequent within 30 days ($n = 25/28$; 90%) while asymptomatic SIs ($n = 55/96$; 58%) were more likely to occur after 30 days.

SI-free survival rates at 3 years were 82% in Protocol I and 83.5% in Protocol II (p=0.876)(Table 5). Table 6A reports the indications for SI in both protocols, divided into early (<30 days) and late (>30 days) and symptomatic or asymptomatic. Table 6B reports the type of stent graft in which a different SI occurred. No statistically significant differences were found between the two protocols in the detection rate of asymptomatic or symptomatic SI. Any comparison

Table 5
Kaplan–Meier plots of freedom from secondary interventions for protocol I and II. SI : Secondary interventions.



		1 year	2 years	3 years
Protocol I	Patients at Risk	368.5	305	257
	Events	46	12	7
	Freedom from SI	88.5%	84%	82%
Protocol II	Patients at Risk	338	277	184
	Events	22	20	9
	Freedom from SI	93%	87%	83.5%

Table 6
A. Indications and timing for any secondary intervention (SI).Asymp: asymptomatic; symp: Symptomatic; **B**. Causes for secondary intervention by the type of stent graft used.T: Talent; Z: Zenith; EX: Excluder; A: Anaconda; E: Endurant.

A

Indications for SI	Protocol I	Protocol II	p
Asymp/symp	33/35	25/31	0.802
Within 30 days after EVAR			
Early SI	17 Asymp 2*/15 symp	11 Asymp 1*/10 symp	0.602
Access site-related problems	8	5	0.827
Bowel ischaemia	1	–	1.000
Stent-graft limb kink	1*	1*	1.000
Limb occlusion	3	2	1.000
Limb ischaemia	2	–	0.501
Type I endoleak	2 (1*)	1	1.000
Type III endoleak	–	1	1.000
Blue toe syndrome	1	–	1.000
Renal infarct	–	1	1.000
More than 30 days after EVAR			
Late SI	51 Asymp 31*/20 symp	45 Asymp 24*/21 symp	0.621
Access site-related problems	5(1*)	4	1.000
Bowel ischaemia	1	–	1.000
Limb occlusion	2	4	0.408
Limb ischaemia	3	2	1.000
Stent-graft limb kink	5 (4*)	10 (6*)	0.050
Type I endoleak	5(3*)	4 (1*)	0.771
Type II endoleak	21*	17*	0.895
Impending rupture type II endoleak	1	1	1.000
Type III endoleak	3 (2*)	2	1.000
Rupture	2	1	1.000
Total	68	56	

B

Cause for secondary intervention	Protocol I	Protocol II
Access site-related problems	14 (11T, 2Z, 1EX)	9 (5T, 3E, 1Z)
Bowel ischaemia	2 (1T, 1Z)	–
Stent-graft limb kink	10 (7T, 2Z, 1EX)	17 (13T, 3E, 1Z)
Limb occlusion	5 (4T, 1Z)	6 (4T, 1Z, 1E)
Limb ischaemia	5 (3T, 1Z, 1EX)	2 (1T, 1E)
Type I endoleak	11 (9T, 1Z, 1 EX)	6 (3T, 3E)
Type II endoleak	21 (15T, 2Z, 1A, 3EX)	17 (7T, 1Z, 9E)
Impending rupture type II endoleak	1 (EX)	1 (T)
Type III endoleak	5 (3T, 1Z, 1EX)	3 (2T, 1E)
Rupture	2 (2T)	1 (T)
Blue toe syndrome	1 (Z)	–
Renal infarct	–	1 (E)

among stent grafts could be done since the sample size recorded is not adequate to evaluate a statistical significance. SIs were performed mainly by endovascular means (63% of cases). We had a significant number of access problems in the 30-day follow-up (symptomatic SIs). Some were related to bleeding at the level of the groin but the most frequent were related to occlusive problems (75%) due to dissection of very calcified plaques at the level of the external iliac artery or to the presence of a very diseased and calcified common femoral artery. The patients lost to follow-up were 18 (4.8%, Protocol I) and five (1.5%, Protocol II) with a higher level of patient compliance in Protocol II ($p = 0.018$).

On 3-year analysis ($p < 0.0001$), Protocol I cost approximately 3000 euro while Protocol II about 1000 euro (when any CTA was required). Each patient in Protocol I received an estimated dose of 151 m Sv while in Protocol II the estimated dose was 35 m Sv (when any CTA was required). The quantity of contrast medium used was one-sixth that used in Protocol II. Estimated comparison of Protocol I versus Protocol II showed a threefold reduction of overall costs for Protocol II ($p < 0.0001$).

Discussion

To our knowledge, this is the first paper dealing with the comparison of asymptomatic SI using two modalities of EVAR surveillance. It reports similar findings using a protocol based mainly on CDU plus XR and the other based on CTA.[1–3] Regarding the safety of the two protocols, there were no statistically significant differences in freedom from aneurysm rupture and SI rate. This study highlights the fact that the majority of SIs are initiated by symptoms rather than by a surveillance-imaging protocol, even when carefully performed or when follow-up is based predominantly on CDU and XR. Specifically, 8.1% of patients benefited from surveillance imaging following EVAR. Literature reports that imaging alone leads to a rate of asymptomatic SI ranging from 1.4% to 9%.[4,8–10] Therefore, the role of a CTA-based follow-up could be questioned in favour of a less invasive protocol in many patients.[9]

The primary goal of EVAR follow-up is to prevent expansion of the aneurysmal sac and rupture.[1–3,8] Aneurysmal sac reduction over time has been used as a surrogate marker for successful exclusion, thrombosis of the aneurysmal sac and a decreased risk of rupture.[11] In fact, an increase of the sac after EVAR has been linked to continued risk of rupture.[2] A CDU-based surveillance programme using increasing aneurysmal sac size as a trigger for SI showed no negative effects on aneurysm-related survival.[12] Some authors have reported that diameter measurements of the residual sac, as well as the detection of limb problems and endoleaks, could be evaluated by CDU with a high level of accuracy.[8,13–16] By contrast, AbuRahma[17] reported that CDU could not diagnose type II endoleaks with the same sensitivity as CTA, but affirmed that any type II endoleak that required SI would provoke an increase in the sac size, which can be correctly diagnosed by CDU. Therefore, an SI could be detected in time by CDU focussing on endoleaks or sac enlargement.

Chaer et al.[15] reported that CDU is safe as the sole long-term post-EVAR surveillance method in patients with shrunk or stable aneurysms, resulting in a 70% reduction of CTA scans. This finding is similar to our CTA reduction rate in Protocol II (about 70%). CTA scan in Protocol II was tailored to each patient to reduce unnecessary invasive examinations. Our study does not advocate eliminating CTA completely from surveillance protocols, but could limit its use to circumstances that provide further details about problems first detected on CDU and XR examination.[8,17] Alternative modalities of surveillance have also been reported.[2,4,18,19]

In our study, a 3-year analysis of cost, radiation exposure and contrast used allowed for a three to six fold reduction with Protocol II. Similarly, other studies reported a higher cost for CTA-based EVAR surveillance regimen over a CDU-based protocol.[16,20,21] The cost of current (CTA-based) EVAR surveillance regimens is significant, accounting for 30–35% of the total costs of EVAR follow-up over a 5-year period.[20] CT imaging accounts for more than two-thirds of the total costs of such surveillance protocols.[21] EVAR needs to demonstrate cost effectiveness and reducing surveillance costs is certainly an essential step. According to Nordon et al.,[4] surveillance is necessary and should be targeted to stent grafts and patients at high risk for complications (large aneurysms, short and/or angulated necks, early endoleaks and patients undergoing adjunctive intra-operative procedures), thus suggesting that the high costs of CTA-based surveillance may not be justified for all patients.[9,10] CDU can satisfy both the need to reduce costs and patients' demand for less invasive methods. Moreover, CDU has

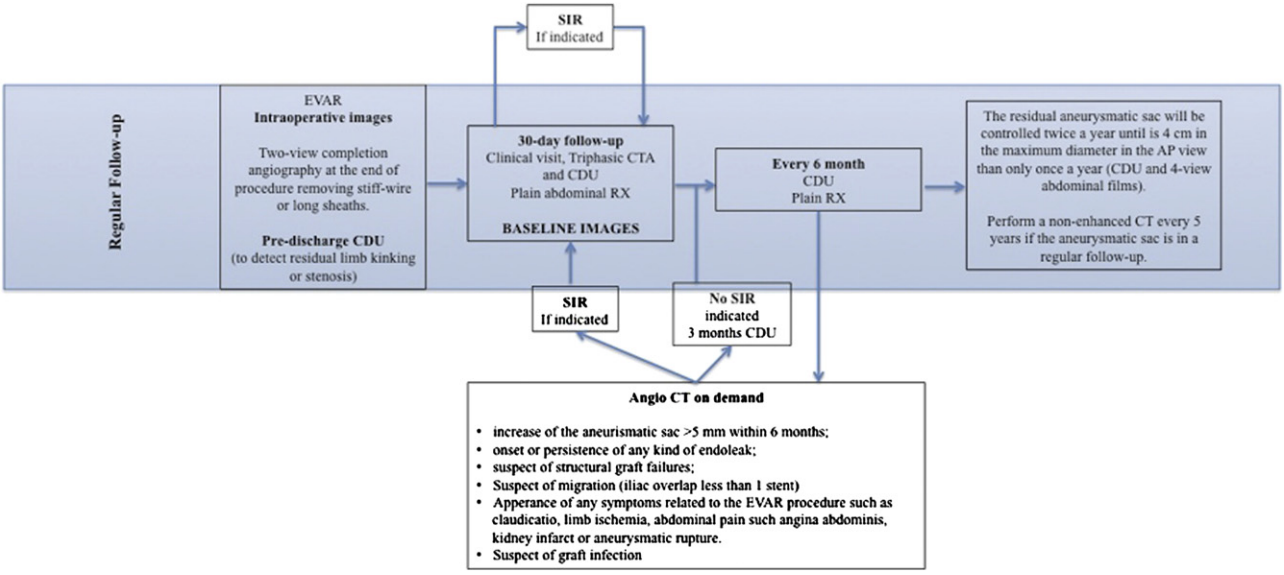


Figure 1. A proposed protocol of surveillance as currently performed in our center CDU: colour duplex ultrasonography; CTA: Computed tomography angiography; XR: plain abdominal radiography; SI: Secondary interventions.

zero potential morbidity[22] and no risk of contrast nephropathy or radiation exposure for patients.[23,24]

Symptomatic SI still occurs in daily practice and many are performed within 30 days of stent-graft deployment. According to various authors, incomplete immediate postoperative imaging leads to many early SIs.[4] Accurate intra-operative imaging, at least two-view completion angiography[4] or alternatively a Dyna-CT scan,[25] and a pre-discharge CDU can evaluate the completeness of aneurysm exclusion and the absence of kinks, compression or stenosis in a limb, allowing pre-emptive treatment thus reducing the need for surveillance and SI.[4,26]

According to our findings, the current post-EVAR surveillance regimen should be simplified, adopting CDU as the main follow-up modality. Component separation and structural stability could be effectively evaluated on XR.[2] CTA should only be applied when adverse events are suspected, remaining crucial, when SIs have to be planned.

The current EVAR follow-up protocol performed at our vascular center is outlined in Fig. 1. The 30-day images can be considered as the baseline value for surveillance and the key stage of the whole protocol.

Limitations

The main limitations of this study were the retrospective nature of the paper and the wide variety of endografts used as well as the shift from the use of Talent to Endurant grafts in Protocol II. Patient inclusion in Protocol I or II was not based on randomisation but on the surveillance practice followed at our institution at the time. The aneurysms in Protocol I were larger. Moreover, there was no specific assessment of the categories at high risk for complications. Lastly, CDU is an operator-dependent technique and some variables depend on patients' physical habits and the need for optimal patient preparation. However, developing technologies and extensive operator training have improved these limitations.[2]

Conclusions

Our study shows that detection rate of asymptomatic SI following EVAR is not affected by the type of surveillance imaging. The percentage of patients benefiting from surveillance was 8.1%, while 9.2% were treated because of symptoms. The reduced invasiveness, cost, radiation exposure and contrast used of the surveillance protocol based on CDU and XR appears to justify its use in long-term EVAR follow-up, as also patients' better compliance. CTA is necessary in planning SI or in solving diagnostic problems arising from a dubious CDU scan or XR.

Conflict of Interest/Funding

None.

Acknowledgements

We thank Ms Francesca Zannetti for language supervision and editing.

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