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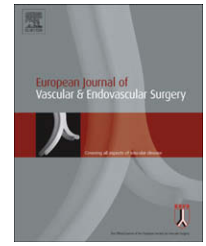


# Is There a Benefit of Frequent CT Follow-up After EVAR?

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**KEYWORDS**
Abdominal aortic aneurysm (AAA);
Endovascular aneurysm repair (EVAR);
Computed tomography (CT);
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**Abstract** *Objective:* Imaging follow-up (FU) after endovascular aneurysm repair (EVAR) is usually performed by periodic contrast-enhanced computed tomography (CT) scans. This study aims to evaluate the effectiveness of CT-FU after EVAR.
*Methods:* In this study, 279 of 304 consecutive patients (261 male, aged 74 years (interquartile range (IQR): 70—79 years) with a median abdominal aortic aneurysm (AAA) diameter of 58 mm (IQR: 53—67 mm)) underwent at least one of the yearly CT scans and plain abdominal films after EVAR. All patients received Zenith stent-grafts for non-ruptured AAAs at a single institution. Patients were considered asymptomatic when a re-intervention was done solely due to an imaging FU finding. The data were prospectively entered in a computer database and retrospectively analysed.
*Results:* As a follow-up, 1167 CT scans were performed at a median of 54 months (IQR: 34—74 months) after EVAR. Twenty-seven patients exhibited postoperative AAA expansion (a 5-year expansion-free rate of $88 \pm 2\%$), and 57 patients underwent 78 postoperative re-interventions with a 5-year secondary success rate of $91 \pm 2\%$. Of the 279 patients, 26 (9.3%) undergoing imaging FU benefitted from the yearly CT scans, since they had re-interventions based on asymptomatic imaging findings: AAA diameter expansion with or without endoleaks ($n = 18$), kink in the stent-graft limbs ($n = 4$), endoleak type III due to stent-graft limb separation without simultaneous AAA expansion ($n = 2$), isolated common iliac artery expansion ($n = 1$) and superior mesenteric artery malperfusion due to partial coverage by the stent-graft fabric ($n = 1$).
*Conclusions:* Less than 10% of the patients benefit from the yearly CT-FU after EVAR. Only one re-intervention due to partial coverage of a branch by the stent-graft would have been delayed if routine FU had been based on simple diameter measurements and plain abdominal radiograph. This suggests that less-frequent CT is sufficient in the majority of patients, which may simplify the FU protocol, reduce radiation exposure and the total costs of EVAR. Contrast-enhanced CT scans continue, nevertheless, to be critical when re-interventions are planned.
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Endovascular aneurysm repair (EVAR) has been subject to intensive follow-up programs since its introduction. In contrast to open repair, EVAR relies on the remote insertion of a stent-graft without disrupting the physical integrity of the aneurysm wall. This has allowed the use of the aneurysm diameter as one of the main surrogate indicators of successful EVAR. Preventing expansion of the aneurysm sac is, therefore, defined as one of the principal aims of EVAR.[1]

Imaging follow-up after EVAR evaluates usually not only the aneurysm size, but also the endoleak status, stent integrity and migration of the stent-graft. Imaging protocols, particularly when stainless-steel-based stent-grafts are used, involve periodic contrast-enhanced spiral computed tomography (CT) scans and plain abdominal films. This intensive imaging follow-up provides a great amount of information, but the relevance of the information acquired has not been evaluated in relation to improving results obtained with successive generations of stent-grafts.[2,3] An increasing number of periodic examinations may therefore be required before an adverse event needing re-intervention is identified. However, repeated contrast-enhanced CT scans involve risks to the renal function[4] and have a carcinogenic potential.[5] Moreover, imaging follow-up has been shown to be a contributor to the high costs associated with EVAR.[6,7] The optimisation of the follow-up protocol after EVAR is therefore essential, especially considering that any benefit will be amplified by the increasing use of this technique in the treatment of abdominal aortic aneurysms (AAAs)[8,9] in recent years.

This study aims to evaluate the outcome of CT follow-up in patients who underwent EVAR of AAA with a recent generation of stent-grafts.

## Methods

### Patients and procedures

This study included 304 consecutive patients who were treated for non-ruptured AAA with the standard Zenith stent-graft (Cook Europe A/S, Bjaeverskov, Denmark) between May 1998 and February 2006.

The patients receiving fenestrated and/or branched stent-grafts and those undergoing EVAR of ruptured AAAs, pseudo-aneurysms and aortic ulcers were excluded. Anatomical suitability for EVAR included proximal neck diameter $\leq 30$ mm, angulation $\leq 90°$ and length $\geq 12$ mm. For distal implantation, at least one common iliac artery with a distal diameter $\leq 20$ mm was required. Table I describes the patient characteristics and stent-grafts used.

**Table I** Patients' characteristics and stent-graft configuration

| | Median (IQR) | n (%) |
|---|---|---|
| **Age** | 74 (70–79) | |
| **Gender (Male/Female)** | | 261 (86 %)/ 43 (14 %) |
| **AAA diameter (mm)** | 58 (53–67) | |
| **AAA-related symptoms** | | |
| Asymptomati | | 54 (18 %) |
| Symptomatic | | 250 (82 %) |
| **Stent-graft configuration** | | |
| Bifurcated | | 278 (91 %) |
| Aorto-uniiliac | | 24 (8 %) |
| Aorto-aortic | | 2 (1 %) |

All stent-grafts used were Zenith (Cook Europe A/S, Bjaeverskov, Danmark).

### Follow-up after EVAR

Postoperative follow-up included clinical assessment at 1 and 12 month(s) after EVAR. The imaging follow-up consisted of periodic contrast-enhanced CT scans and plain abdominal films. The periodicity of the examinations changed during the study period, but all protocols included at least yearly imaging. The CT scans were obtained at 1, 3 and 6 month(s) postoperatively and every half year thereafter until the year 2000. Subsequently, the CT scans were performed at 1 month and yearly thereafter. Since 2002, the need for a 1-month CT scan was left to the discretion of the operator.

The AAA diameters were measured in axial CT scans perpendicular to the maximum diameter in order to avoid errors caused by vessel tortuosity. The AAA shrinkage or expansion was defined when the diameter decreased or increased by 5 mm or more, respectively.[1]

Considering the changes in our follow-up protocol, yearly CT scans were assumed for the analysis of the outcome. The end-points for the follow-up included the following: freedom from AAA expansion and rupture or AAA-related death and the performance of re-interventions on an elective basis before the development of symptoms. Benefit from CT follow-up was assumed whenever adverse events were identified at an earlier stage than if routine imaging follow-up had not been performed. Asymptomatic patients undergoing re-interventions prompted by a CT finding without AAA expansion would not have been offered a re-intervention based solely on clinical symptoms and simple diameter measurements. Primary clinical success was defined according to the reporting standards.[1] The definition of secondary success was simplified by assuming all re-interventions that allowed the maintenance of clinical success, independently of the technique used (endovascular or open).

### Study setting, data collection and presentation

The study was conducted at a university tertiary referral centre. Data from all patients undergoing EVAR of AAA were prospectively entered into a database. Patients fulfilling the inclusion criteria were retrospectively selected for the study. The study was approved by the local ethical committee and the patients gave their informed consent before the procedures.

The values for continuous variables are shown as median (interquartile range (IQR)). Survival was calculated using life-tables and is presented as mean $\pm$ standard deviation. Survival plots were based on Kaplan–Meyer curves. Non-parametric tests were used for comparisons, with a significance level of $p < 0.05$. The SPSS 16.0.1 software (SPSS Inc., Chicago, IL, USA) was used.

## Results

### Study population

Of the 304 patients, 279 were available for the yearly CT follow-up (Fig. 1). Two of the 25 patients who could not undergo a 1-year CT follow-up had been converted to open repair. One conversion was successfully done intra-operatively due to an incomplete stent-graft deployment in a severely angled suprarenal aorta that impaired the deployment of the top cap. The other conversion to open repair followed the development of an aorto-duodenal fistula 2 months after EVAR of a rapidly expanding painful AAA. This patient died in-hospital 1.5 months after the conversion and was therefore considered as an AAA-related death.

### Mortality

The other 23 patients who could not undergo 1-year postoperative CT scan had died: nine within 30 days (3%) and 14 at 1—12 months of unrelated causes. During the rest of the study period (more than 1 year of follow-up), there was only one additional AAA-related death due to AAA rupture in a patient unfit for re-interventions (see below). The overall survival rate at 1, 3 and 5 years was 92 ± 2%, 80 ± 3% and 67 ± 3%, respectively (110 deaths), and mean survival after EVAR was 91 ± 7 months. The freedom from AAA-related mortality at the same time points was, respectively, 97 ± 1%, 96 ± 1% and 96 ± 1%.

### CT follow-up, AAA diameter and AAA rupture

The 279 patients available for follow-up underwent 1167 CT scans at a median of 54 months (IQR: 34—74 months) postoperatively. Five patients abandoned the yearly CT follow-up at a median of 44 months (IQR: 18—68 months) (5-year compliance to follow-up of 99 ± 1%).

AAA expansion was identified in 27 patients at 25 months (IQR: 24—46 months) postoperatively (expansion-free rate at 1, 3 and 5 years was, respectively, 100 ± 0%, 94 ± 2% and 88 ± 2%). AAA expansion was neither related to the preoperative presence of symptoms ($p > 0.05$), nor to the configuration of the stent-graft ($p > 0.05$).

As described below, 20 of the patients with expanding AAAs underwent 26 re-interventions (Fig. 2). The remaining seven patients with expanding AAAs did not receive any re-intervention, since in six patients the medical condition was considered too poor (including the two patients mentioned below with AAA rupture), and one patient refused the proposed re-intervention and abandoned the imaging follow-up.

Four patients developed AAA rupture after EVAR. One of these patients had initially a shrinking AAA, but ruptured after a separation of the stent-graft limb at 54 months postoperatively (type III endoleak). The other three patients had expanding aneurysms at follow-up CT scans and ruptured at 32, 34 and 73 months after EVAR. One rupture occurred while waiting for an elective procedure for endotension and an acute re-intervention was performed (see below). The other two patients were considered unfit for re-interventions. One of them died upon rupturing (AAA-related death), while the other patient survived with a contained rupture until he eventually died of unrelated cause 2 years later. The causes of rupture in these last two patients were, respectively, separation of the bare top stent (type I endoleak) and endotension due to poor proximal sealing zone.

### Re-interventions

The re-intervention-free survival at 1, 3 and 5 years was 92 ± 2%, 84 ± 2% and 77 ± 3%, respectively. Seventy-eight re-interventions were performed in 57 patients at a median of 16 (IQR: 3—39) months after EVAR (Fig. 4 provides a schematic representation of the distribution of re-interventions

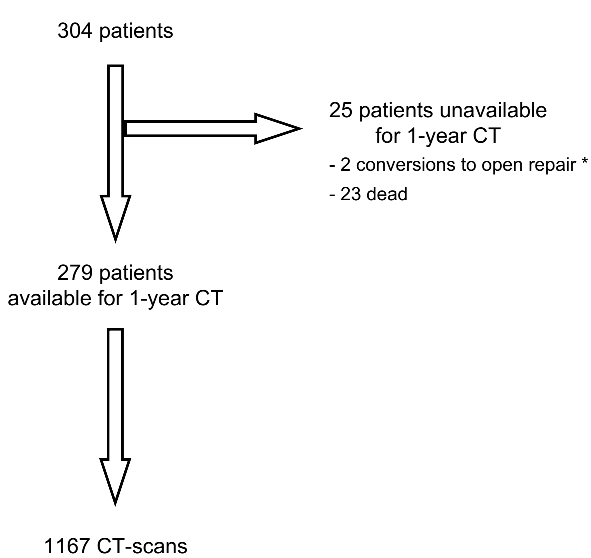



**Figure 1** Schematic representation of patients included in EVAR follow-up protocol. *, one of the conversions to open repair was performed due to an aorto-duodenal fistula and the patient died 1.5 months later (AAA-related death). All other deaths after 30 days but less than 1 year after EVAR were not related to AAA.

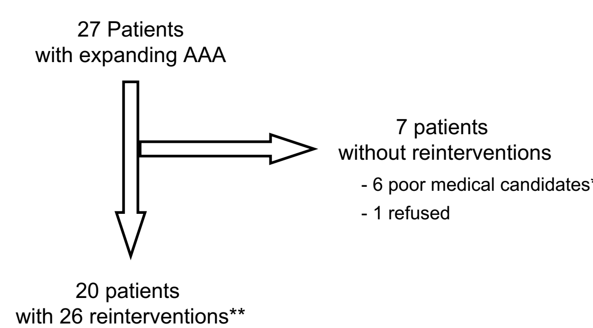



**Figure 2** Schematic representation of patients with AAA expansion after EVAR. *, two of the patients that did not undergo re-interventions due to poor medical conditions developed contained ruptures. In both cases, AAA expansion had been identified during the previous CT follow-up. One of these patients died due to rupture (AAA-related death), while the other died of an unrelated cause 2 years later. **, two of the re-interventions were done due to AAA rupture.

according to symptoms and is available as extra material in the internet-based version). Forty patients underwent a single re-intervention, while 13 patients needed two re-interventions and four patients required three.

Re-interventions due to endotension were performed in 12 patients (14 re-interventions). The cause for endotension was identified mostly as a failing proximal seal. Therefore, these patients underwent mainly endovascular procedures in the proximal neck, with the exception of three conversions to open surgery. Indications for the procedures during follow-up are provided in detail as extra material in the internet-based version of the journal.

### CT follow-up and re-interventions prompted by symptoms

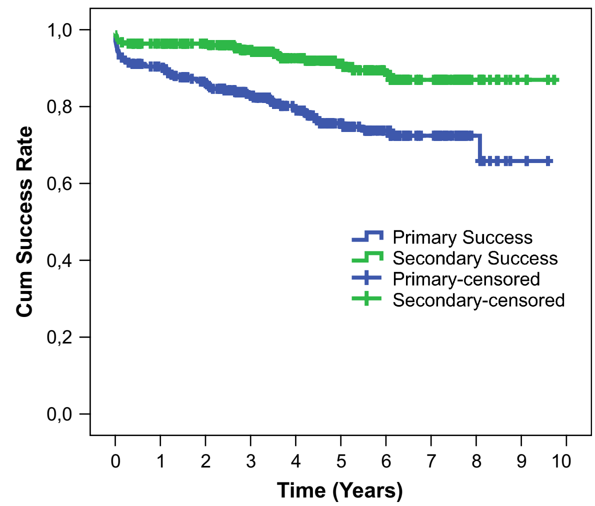
Of the 23 procedures performed due to the development of symptoms more than 1 month after EVAR, five were performed in patients where the adverse events had already been suspected in CT follow-up, but the appearance of symptoms precipitated acute re-interventions: one suffered rupture, as mentioned above, one aorto-enteric fistula, two stent-graft infection and one hydronephrosis caused by AAA inflammatory reaction. The adverse events leading to the other 18 re-interventions performed in symptomatic patients had not been suspected by the CT follow-up, since the CT scans were either negative ($n = 6$) or did not focus on the renal arteries and stent-graft limbs ($n = 5$). The remaining seven of the 18 re-interventions were done 1–12 months after EVAR and, therefore, no yearly CT scan was available.

## Clinical success and benefit from CT follow-up

The primary success rate at 1, 3 and 5 years was $90 \pm 2\%$, $83 \pm 2\%$ and $76 \pm 2\%$, respectively. The re-interventions (described below) allowed a secondary success rate at the same time intervals of $96 \pm 1\%$, $95 \pm 1\%$ and $91 \pm 2\%$, respectively (Fig. 3). This difference could be attributed to the benefit conferred by follow-up in 26 out of the 279 (9.3%) patients undergoing routine imaging examinations. The main findings in the CT scans of these patients were AAA diameter expansion with or without endoleaks ($n = 18$), kink in the stent-graft limbs ($n = 4$), endoleak type III due to stent-graft limb separation without simultaneous AAA expansion ($n = 2$), isolated common iliac artery expansion ($n = 1$) and superior mesenteric artery malperfusion ($n = 1$).

## Discussion

The follow-up protocols have remained relatively extensive since the introduction of EVAR in spite of the continuous stent-graft developments. The CT scan has been the method of choice for periodic assessments. Our study shows that the majority of the follow-up CT scans after EVAR do not lead to re-interventions. Furthermore, the excellent secondary clinical success rate is achieved by re-interventions that are based mostly on the expansion of the aneurysm or the development of symptoms. This suggests that asymptomatic patients may have a similar benefit from simple diameter measurements compared to the one conferred by the follow-up based on regular CT scans.




**Number at risk**

| | | | | |
|---|---|---|---|---|
| Primary Success | 258 | 169 | 85 | 33 |
| Secondary Success | 276 | 195 | 106 | 44 |

**Figure 3** Kaplan–Meyer analysis of primary (blue line) and secondary clinical success (green line). The numbers at risk refer to the time points immediately above in the figure, that is, 1, 3, 5 and 7 years follow-up.

The tendency of the stent-graft limbs to kink and separate continued to be a problem after EVAR in this series. Kinking is expected to decrease in the future, since it seems to be prevented by liberal intra-operative stenting of the stent-graft limbs.[10] However, the risk for modular component separation justifies a regular control of the structural stability of the stent-graft. Plain abdominal films may suffice for this purpose. Furthermore, plain abdominal films are able to identify material fatigue such as stent fractures or bare stent separation. While the first of these complications does not seem to have clinical consequences with the Zenith stent-graft,[11,12] the second may be fatal as seen in one unfit patient in this series. The separation of the top bare stent is, nevertheless, a rare event and is expected to have been solved by the reinforcement of the suture line after the year 2002.[13]

Contrast-enhanced CT scans have been recommended for follow-up after EVAR, given its good reliability in the measurement of the AAA diameter and the identification of endoleaks.[1] The routine use of contrast-enhanced CT scans has, nevertheless, become more controversial. Recent studies show that CT scan can identify non-aneurysm-related incidental findings with clinical significance during the follow-up, but this is more common preoperatively.[14] Moreover, repeated CT scans with their inherent ionising radiation have been suggested to have a carcinogenic potential.[5] This risk may be less relevant in patients undergoing EVAR, considering their advanced age. However, aging may enhance the nephrotoxic effects of the iodine contrast.[4]

The present study indicates that periodic CT scans after EVAR benefitted less than 10% of the patients entering the follow-up program. Furthermore, simple AAA diameter measurements, together with control of the structure stability of the stent-graft, would identify the majority of asymptomatic patients requiring a re-intervention. In the present study, the use of simple aorto-iliac diameter measurements instead of contrast-enhanced CT scans would most likely only postpone the identification of a superior mesenteric artery malperfusion in a patient with a pelvic renal transplant, where both native renal arteries were covered by the stent-graft. Simple diameter measurements can be done by CT scans with selective contrast injection only when adverse events were suspected. CT scan allows also the measurement of the aneurysm volume, which has been suggested to be advantageous although it is still a time-consuming method.[15] However, this assessment also seems to be safely done by ultrasound,[16,17] which has the additional advantage of decreasing the costs associated with the imaging follow-up,[6,7] and thereby increasing the cost-effectiveness of EVAR.[18] Similar conclusions were made in a recently published study suggesting that postoperative CT scans may be abandoned after more than 1 year postoperatively in patients free from endoleaks.[19] Nevertheless, if ultrasound becomes the method of choice for the routine follow-up after standard infrarenal EVAR, contrast-enhanced CT scan continues to be fundamental whenever adverse events are suspected. This becomes even more relevant when the background risk for rupture is higher, that is, in patients with extremely large AAAs.

Some other issues need to be addressed in this study: Zenith stent-grafts were exclusively used and, therefore, the conclusions can only be applied to this endoprosthesis. Furthermore, during the study period, we have introduced fenestrated stent-grafts into our clinical practice. The good results of these endoprostheses in patients with challenging aneurysm necks[20,21] may further improve the results of EVAR. This effect is expected to occur even in patients receiving standard infrarenal stent-grafts, since these prostheses will be limited to patients with a good anatomy, as opposed to the current material where 20% of the patients had an aneurysm neck anatomy that did not comply with the recommendations of the manufacturer. These broad criteria for the acceptance for EVAR may be one of the reasons for the occurrence of endotension, which was usually associated with failure of the proximal seal.

This study excluded patients being treated for ruptured AAAs in order to avoid the inclusion of aneurysms without an intact wall, which may condition the remodelling after EVAR and thereby the diameter assessment. Moreover, and more importantly, in ruptured AAAs, the choice of the stent-graft is limited by the existing local stock and the emergency of the procedure, which may condition the clinical results later on.

One drawback of this study has been the changes in the frequency of the imaging follow-up during the study period. However, this does not seem to have greatly changed the results since the majority of the adverse events leading to re-interventions in symptomatic patients had not been suspected in the previous CT follow-up. This suggests the safety of yearly controls when current stent-grafts have been used.

In conclusion, less than 10% of the patients being followed up after EVAR of AAA with the Zenith stent-graft benefit from periodic CT follow-up, even when broad inclusion criteria for the aneurysm neck are applied. This benefit would most likely be sustained by a follow-up protocol based on the combined use of measurements of aneurysm diameter by simple ultrasound and plain abdominal films. This would simplify the follow-up protocol and also reduce the patients' exposure to radiation and nephrotoxic contrast. The CT scans should, nevertheless, continue to be used at 1 year after EVAR or whenever an adverse event is suspected and a re-intervention is planned.

## Conflict of Interest/Funding:

None.

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## Appendix

### Supplementary material

Supplementary data associated with this article can be found in the online version, at doi: 10.1016/j.ejvs.2008.12.019.

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