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Is there benefit of frequent CT follow-up after EVAR?

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Abstract

Objective: Imaging follow-up (FU) after endovascular AAA repair (EVAR) is usually performed by periodic contrast-enhanced computer tomography (CT) scans. The aim of this study is to evaluate the effectiveness of CT-FU after EVAR.

Methods: 279 of 304 consecutive patients (261 male, 74 (IQR: 70-79) years-old with a median AAA diameter of 58 (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 reintervention was done solely due to an imaging FU finding. Data was prospectively entered in a computer database and retrospectively analyzed.

Results: 1167 CT-scans were performed at a median of 54 (IQR: 34-74) months after EVAR. Twenty-seven patients exhibited postoperative AAA expansion (5-year expansion-free rate of 88 ± 2 %). Fifty-seven patients underwent 78 postoperative reinterventions with a 5-year secondary success rate of 91 ± 2 %. Twenty-six out of the 279 (9.3 %) patients undergoing imaging FU got a benefit from the yearly CT-scans, since they got reinterventions 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 get a benefit from yearly CT follow-up after EVAR. Only one reintervention 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 X-ray. This suggests that less frequent CT is sufficient in the majority of patients, which may simplify the follow-up protocol, reduce radiation exposure and total costs of EVAR. Contrast-enhanced CT scans continue, nevertheless, critical when reinterventions are planned.

Keywords: Abdominal aortic aneurysm (AAA), Endovascular aneurysm repair (EVAR), computed tomography (CT), follow-up

Introduction

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 scans (CT) 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 the 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 reintervention is identified. However, repeated contrast-enhanced CT-scans involve risks to the renal function⁴ 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 optimization of the follow-up protocol after EVAR is therefore essential, especially considering that the any benefit will be amplified by the increasing use of this technique in the treatment of abdominal aortic aneurysms (AAA)^{8,9} in recent years.

The aim of this study is 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

Three-hundred and four consecutive patients being treated for non-ruptured AAA with the standard Zenith stent-graft (Cook Europe A/S, Bjaeverskov, Danmark) between May 1998 and February 2006 were included in this study.

Patients receiving fenestrated and/or branched stent-grafts and patients undergoing EVAR of ruptured AAAs, pseudoaneurysms and aortic ulcers were excluded. Anatomic suitability for EVAR included proximal neck diameter ≤ 30 mm, angulation $\leq 90^\circ$ and length ≥ 12 mm. For distal implantation, at least one common iliac artery with a distal diameter ≤ 20 mm was required. Patient characteristics and stent-grafts used are described in table I.

Follow-up after EVAR

Postoperative follow-up included clinical assessment at 1 and 12 months 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. CT-scans were obtained at 1, 3, 6 months postoperatively and every half-year thereafter until the year 2000. Thereafter CTs 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.

AAA diameters were measured in axial CT-scans as the perpendicular to the maximum diameter in order to avoid errors caused by vessel tortuosity. AAA shrinkage or expansion were defined when 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 endpoints for the follow-up included: freedom from AAA expansion and rupture or AAA-related death, and the performance of reinterventions 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 reinterventions prompted by a CT finding without AAA expansion would not have been offered a reintervention 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 reinterventions that allowed the maintainance 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 center. 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 patients gave their informed consent before the procedures. Values for continuous variables are shown as median (interquartile range). Survival was calculated using life-tables and is presented as mean \pm standard deviation. Survival plots were done according to Kaplan-Meyer. Non-parametric tests were used for comparisons with a significance level of $p < .05$. SPSS 16.0.1 software (SPSS Inc, Chicago, USA) was used.

Results

Study Population

Two-hundred seventy nine of the 304 patients were available for the yearly CT follow-up (figure 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: 9 within 30 days (3 %) and 14 at 1 – 12 months of unrelated causes. During the rest of the study (more than 1 year of follow-up) there was only one more AAA-related death due to AAA rupture in a patient unfit for reinterventions (see below). The overall survival rate at 1, 3 and 5 years was $92 \pm 2 \%$, $80 \pm 3 \%$ and $67 \pm 3 \%$, 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 $97 \pm 1 \%$, $96 \pm 1 \%$ and $96 \pm 1 \%$.

CT follow-up, AAA diameter and AAA rupture

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

AAA expansion was identified in 27 patients at 25 (24 – 46) months postoperatively (expansion-free rate at 1, 3 and 5-years was respectively $100 \pm 0 \%$, $94 \pm 2 \%$ and $88 \pm 2 \%$).

AAA expansion was not related to the preoperative presence of symptoms ($p > .05$) nor to the configuration of the stent-graft ($p > .05$).

Twenty of the patients with expanding AAAs underwent 26 reinterventions as described below (figure 2). The remaining 7 patients with expanding AAAs did not receive any reintervention, since in 6 the medical condition was considered too poor (including the 2 patients mentioned below with AAA rupture) and one patient refused the proposed reintervention 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 3 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 reintervention was performed (see below). The other 2 patients were considered unfit for reinterventions. 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 2 last patients were, respectively, separation of the bare top stent (type I endoleak) and endotension due to poor proximal sealing zone.

Reinterventions

The reintervention-free survival at 1, 3 and 5 years was respectively, $92 \pm 2 \%$, $84 \pm 2 \%$ and $77 \pm 3 \%$. Seventy-eight reinterventions were performed in 57 patients at a median of 16 (3 – 39) months after EVAR (figure 4 provides a schematic representation of the distribution of

reinterventions according to symptoms and is available as extra material in the internet based version). Forty patients underwent a single reintervention, while 13 patients needed 2 and 4 patients required 3.

Reinterventions due to endotension were performed in 12 patients (14 reinterventions). The cause for endotension was identified mostly as a failing proximal seal. These patients underwent, therefore, mostly endovascular procedures in the proximal neck, with the exception of 3 conversions to open surgery. Indications for the procedures during follow-up are provided in detailed as extra material in the internet based version of the journal.

CT follow-up and reinterventions prompted by symptoms

Of the 23 procedures performed due to the development symptoms more than 1 month after EVAR, 5 were done in patients where the adverse events had already been suspected in CT follow-up, but the appearance of symptoms precipitated acute reinterventions: 1 contained rupture mentioned above, 1 aortoenteric fistula, 2 stent-graft infection and 1 hydronephrosis caused by AAA inflammatory reaction. The adverse events leading to the other 18 reinterventions performed in symptomatic patients had not been suspected by the CT follow-up since the CTs were either negative (n=6) or did not focus on the renal arteries and stent-graft limbs (n=5). The remaining 7 of the 18 reinterventions were done 1 to 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 respectively $90 \pm 2\%$, $83 \pm 2\%$ and $76 \pm 2\%$. The reinterventions (described below) allowed a secondary success rate at the same time intervals of $96 \pm 1\%$, $95 \pm 1\%$ and $91 \pm 2\%$, respectively (figure 3). This difference could be attributed to benefit conferred by follow-up in 26 out of the 279 (9.3 %) patients undergoing

routine imaging exams. 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

Follow-up protocols have remained relatively extensive since the introduction of EVAR in spite of the continuous stent-graft developments. CT 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 reinterventions. Furthermore, the excellent secondary clinical success rate is achieved by reinterventions 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.

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 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 ionizing radiation have been suggested to have 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 offered benefit to 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 reintervention. In the present study, the use of simple aortoiliac 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 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 also the advantage of decreasing the costs associated with the imaging follow-up^{6, 7} and thereby increase 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 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-scans continues fundamental whenever adverse events are suspected. This becomes even more relevant when the background risk for rupture is higher, ie, in patients with extremely large AAAs.

There are some other issues that 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 endoprosthesis in patients with challenging aneurysm necks^{20, 21} may improve even more 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 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 manufacture. 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. In this study we did not include 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 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 reinterventions 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 get a benefit of the 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 simple ultrasound aneurysm diameter measurements and plain abdominal films. This would simplify the follow-up protocol and also reduce patients' exposure to radiation and nephrotoxic contrast. CT scans should nevertheless continue to be used at 1 year after EVAR or whenever an adverse event is suspected and a reintervention is planned.

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Figure Legend

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 afterwards (AAA-related death). All other deaths after 30-days but less than one year after EVAR were not related to the AAA.

Figure 2 – Schematic representation of patients with AAA expansion after EVAR. * - 2 of the patients that did not undergo reinterventions 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 at the time of rupture (AAA-related death) while the other died of unrelated cause 2 years afterwards. ** - two of the reinterventions were done due to AAA-rupture.

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, ie, 1, 3, 5 and 7 years follow-up.

Figure 4 (for web based version) – Schematic representation of reinterventions after EVAR according to symptoms.

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		
Asymptomatic		250 (82 %)
Symptomatic		54 (18 %)
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).

Table II (for web based version)– Indication for reinterventions performed within one year after EVAR.

Indication for reintervention	n
Within 30 days after EVAR	
Access site related problems	5
Bowel ischemia	3
Limb ischemia caused by stent-graft limb	6
More than 30 days after EVAR	
<i>Asymptomatic</i>	
Stent-graft limb kink	1
EL type II in AAA with unchanged diameter	2
<i>Symptomatic</i>	
Limb ischemia	3
Limb ischemia with impending separation of the stent-graft limb	1
Aortoenteric fistula	1
Renovascular hypertension	1
Increasing creatinine	1

EL – endoleak.

Table III (for web based version) – Indication for reinterventions more than one year after EVAR in symptomatic patients.

Indication for reintervention	n
AAA contained rupture	2*
Distal type I endoleak	2
Aortoenteric fistula	2
AAA infection	1
Acute limb ischemia and asymptomatic endotension	1
Limb ischemia	3
Increasing creatinine secondary to renal hypoperfusion	3
Bowel ischemia after SMA stent	1
Hydronephrosis	1

* - 1 type III endoleak and 1 endotension

Table IV (for web based version) – Indication for reinterventions prompted by imaging findings in the follow-up more than one year after EVAR in asymptomatic patients.

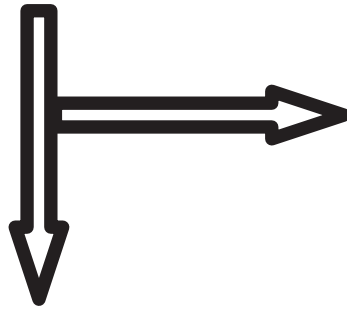
Indication for reintervention	n
Expanding AAA diameter	
Type I EL	2
Type II EL	7
Type III EL	1
Endotension	12
Unchanged AAA diameter	
Type II EL	7
Type III EL	1
Impending separation of stent-graft limb	1
Stent-graft limb kink	1
Isolated expansion of common iliac artery diameter	1
Shrinking AAA diameter	
Type II EL	1
Type III EL	1
Stent-graft limb kink	2
Partial coverage of the SMA ostium*	1

EL – Endoleak; SMA – superior mesenteric artery.

* - Patient with a renal transplant on the right external iliac artery where the native renal arteries were intentionally covered by the stent-graft. The 1-year postoperative CT scan revealed a partial coverage of the ostium of the superior mesenteric artery and the patient

received a stent. This patient had mild symptoms of bowel angina, but had not yet sought medical attention. He was, therefore, considered as “asymptomatic” to express the fact that the reintervention was based on the follow-up program finding.

304 patients



25 patients unavailable
for 1-year CT

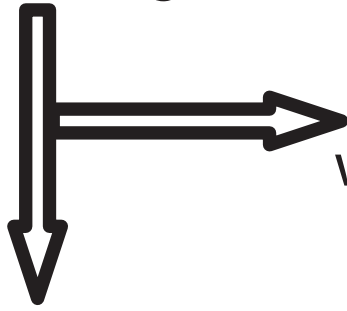
- 2 conversions to open repair *
- 23 dead

279 patients
available for 1-year CT



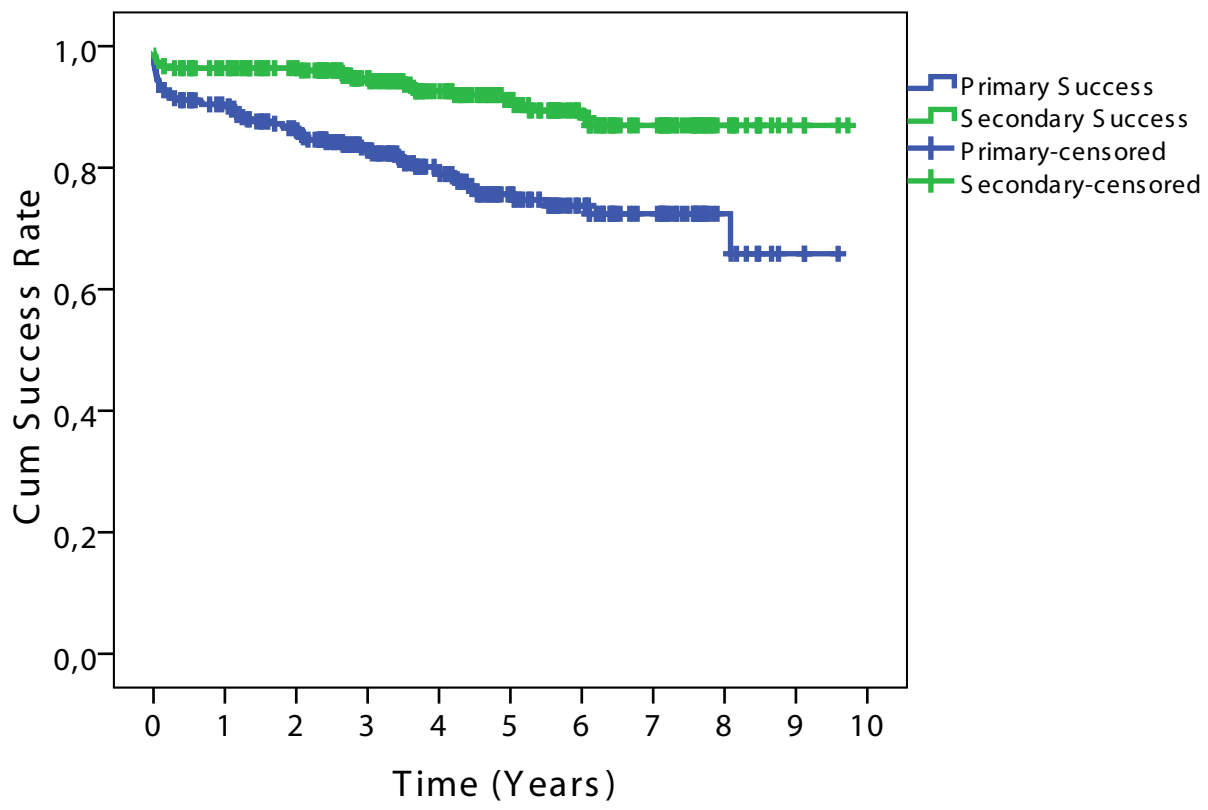
1167 CT-scans

27 Patients
with expanding AAA



7 patients
without reinterventions
- 6 poor medical candidates*
- 1 refused

20 patients
with 26 reinterventions**

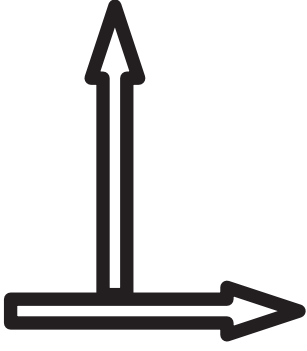


Number at risk

Primary Success	258	169	85	33
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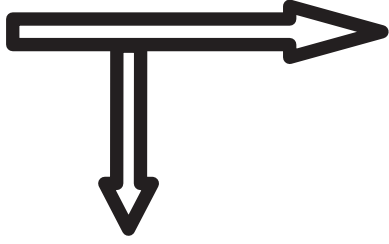
Secondary Success	276	195	106	44
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78 reinterventions



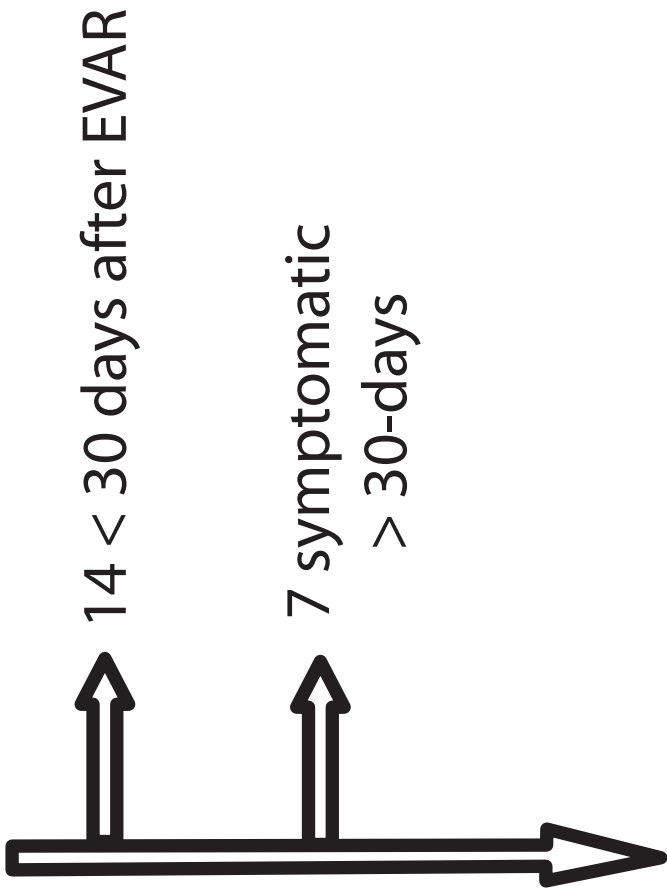
24 reinterventions
< 1-year after EVAR

54 reinterventions
> 1-year after EVAR



16 symptomatic
> 1 year

38 asymptomatic
> 1 year



14 < 30 days after EVAR
7 symptomatic
> 30-days

3 asymptomatic
> 30-days