Fate of Endoleaks after Endoluminal Repair of Abdominal Aortic Aneurysms with the EVT® Device

M. Makaroun*, A. Zajko2, H. Sugimoto1, M. Eskandari1 and M. Webster1

Division of 1Vascular Surgery and 2Interventional Radiology, University of Pittsburgh Medical Center, Pittsburgh, PA, U.S.A.

Objective: We aim to describe our medium-term follow-up of 20 patients with an endoleak following repair of their abdominal aortic aneurysms (AAA) using the Endovascular Technologies (EVT) device.

Design: the experience of one centre in a prospective multicentre phase II trial.

Materials and methods: 55 patients with an endovascular repair of their AAA and at least 6 months' follow-up were reviewed. Intraoperative angiograms, next day duplex scans and computed tomography (CT) images were used to detect endoleaks. Follow-up with CT and duplex was performed at 3, 6, 12 and 24 months. Persistent endoleaks at 6 months were evaluated by angiography and treated by endovascular coiling.

Results: there were three immediate conversions to open procedures. Twenty of 52 (38%) patients had an endoleak identified initially. One patient died from a myocardial infarction and three were not evident any longer by discharge CT. Sixteen endoleaks (31%) were present at discharge. Nine resolved spontaneously by 3–6 months and seven were still persistent at 6 months (14%). Six patients underwent coiling of their leak, all with successful radiographic seal after 1–3 sessions.

Conclusions: endoleaks are frequent after endovascular AAA repair, but the majority close spontaneously. Coiling of the leaks and radiographic seal can be achieved in all cases still persistent at 6 months. Whether this method is clinically effective awaits further follow-up.

Key Words: Abdominal aortic aneurysm; Endovascular repair; Treatment; Complications; Endoleak.

Introduction

Endovascular repair of abdominal aortic aneurysms (AAA) has delivered on many of its early promises. It clearly can be technically successful and applied widely.1–4 The incisions are small, patient acceptance is high, and blood loss and hospital stay are significantly reduced.1,2 The Achilles heel of the procedure remains, however, the incomplete exclusion of the aneurysmal sac from the circulation, with persistent perfusion of the aneurysm, a condition termed "endoleak".5,6 The significance of such endoleaks has been initially underestimated, since many seemed to resolve spontaneously, which led to many being observed for long periods.4 It soon became evident, however, that poorly excluded aneurysms can continue to grow and rupture.5,8 The natural history of endoleaks remains poorly understood: some remain stable and in some the sac becomes smaller. The sites of origin and behaviour of such leaks might be different among the various systems being presently investigated in the treatment of AAA. The proper management also remains unclear, with conversion to standard open repair the only certain cure.

The aim of our review is to document the fate of such endoleaks after one type of endovascular grafting system, and the effectiveness of an aggressive policy to proceed with angiography and coiling of all persistent endoleaks at six months.

Patients and Methods

From February 1996 to September 1998, we have repaired 62 aneurysms using the endovascular grafting system (EGS®) produced by Guidant Endovascular Technologies, Inc. (EVT, Menlo Park, CA, U.S.A.). All procedures were performed in the operating room by a vascular surgeon with a vascular radiologist acting as first assistant. Patient selection and techniques used
have been previously described. Anatomic requirements included a proximal neck that is at least 15 mm in length and less than 26 mm in diameter for all patients, and a 12 mm distal neck for a tube configuration. A bifurcated device required suitable bilateral undilated segments of common iliac artery. An aortoiliac configuration with femorofemoral bypass was used when unilateral iliac disease existed. Films were reviewed centrally prior to enrolment of any patient.

Fifty-five patients were treated by March 1998 and have at least six months’ follow-up. They constitute the basis of this report. All patients were part of a phase II prospective multicentre evaluation of the EGS system, under an investigational device exemption from the Food and Drug Administration. The research project was approved by the University of Pittsburgh institutional review board and reviewed annually. All patients signed a research-informed consent.

Follow-up was performed according to the multicentre protocol. Evaluation of aneurysm exclusion was performed intraoperatively by an aortogram. Prior to discharge, a duplex ultrasound examination and a contrast-enhanced computed tomographic (CT) scan were obtained, usually on the first postoperative day. Any patient not completely excluded on any of the three studies was considered to have an endoleak. Follow-up duplex and CT scans were repeated at 3, 6 and 12 months and yearly thereafter.

The records of all patients and all pre- and postoperative diagnostic studies of patients with endoleaks were reviewed. Preoperative variables were compared between the group of patients who developed endoleaks and those who did not. The preoperative size of the AAA, size of the native artery at the attachment sites, degree of calcification (minimal, moderate or circumferential) and/or mural thrombus presence were noted. The angulation of the necks was measured and the status of preoperatively patent branches of the AAA was determined. The site of the endoleak origin was classified from information obtained from all three diagnostic modalities used in the immediate postoperative evaluation. The classification was kept unchanged for the rest of the analysis. The size of the aneurysmal sac on follow-up was measured from CT scans.

The multicentre protocol left the endoleak management decisions including the type and timing of intervention to individual investigators and their patients. We observed our patients for six months for spontaneous resolution. All persistent endoleaks then underwent angiographic evaluation with obliteration of the leak using standard metallic coils (Cook, Bloomington, IN, U.S.A.) as suggested by Kato. The inflow, outflow and the entire cavity in the aneurysmal sac were packed with variable-size coils by accessing the endoleak around the attachment system involved (Fig. 1 A and B). Follow-up CT scans were then obtained 6–8 weeks later to assess the results of the procedure (Fig. 2 A and B). Aneurysms that were not yet completely excluded underwent the same procedure until complete exclusion from circulation was ascertained on both angiography and CT scanning.

Results

Forty-seven men and eight women had an attempted endovascular repair of their AAA. The deployment of the endograft was successful in 52 of the 55 patients, for an immediate technical success rate of 95%. One of the three immediate conversions was early in our experience and due to a proximal attachment system endoleak that was judged too severe to observe. Fifteen tube, 35 bifurcated and 5 aortoiliac configurations were used. Twenty of 52 patients (38%) had evidence of an endoleak on at least one of the postoperative studies. One high-risk patient with an endoleak died from a massive myocardial infarction on the third postoperative day, the only operative death in the series.

Predictability of endoleaks

Pre-procedure variables were compared between patients who developed an endoleak and those who did not. The incidence of leaks was higher in the tube (7/15) and aortoiliac (3/5) than in the bifurcated (10/35) configurations. This difference was not statistically significant because of small groups. There was no significant difference noted between groups in aneurysm size (56 vs. 55.7 mm), proximal neck diameter (23.3 vs. 23.6 mm) or distal attachment site diameter. Degree of calcification score and presence of mural thrombus were not different between groups. The presence or absence of large branches on the preoperative angiogram, such as lumbars, accessory renal, or inferior mesenteric arteries (IMA) was not clearly predictive of endoleaks either. Mean neck angulation to the flow channel of the AAA was not significantly different between patients with an endoleak and patients with no leak (28° vs. 19°). All endoleaks associated with the proximal attachment system, however, including the patient who was converted in the OR, had an angulation of the proximal neck in excess of 35° to the main flow channel of the AAA. The likelihood of developing a proximal
attachment system endoleak was 50% (8/16) if the angle on preoperative angiography exceeded 35°.

Spontaneous resolution

Three patients had their endoleaks identified only on the post-deployment intraoperative angiography. These were not present on the postoperative duplex or CT scans performed 24 hours later and are presumed to have spontaneously sealed in the interim. None of the follow-up studies showed a recurrence of these endoleaks.

Sixteen of 51 (31%) patients were thus discharged from the hospital with an endoleak. By the 3-month follow-up evaluation, only nine remained open. At six
over one year of follow-up, until the third coiling attempt was successful in sealing the sac. All other remained stable or decreased in size. All spontaneously sealed endoleaks except one have decreased in size. Two have completely collapsed around the graft at one-year follow-up.

**Endoleak by site**

**Proximal attachment system.** Six endoleaks were thought to originate mainly from the proximal attachment system. All were associated with a significant neck to flow channel angulation: 37, 52, 45, 52, 42, and 55 degrees. All six resolved spontaneously with no intervention (Fig. 4A and B). One additional patient, initially thought to have mostly a distal attachment leak and classified as such, was also found to have a proximal endoleak later. He also had a significant neck angulation of 35°, but required a staged coiling procedure to completely seal the sac.

**Distal bifurcated attachment system.**

Six patients had an endoleak classified on initial post-operative studies as arising from the distal attachment of a bifurcated graft. One died on the third day and the remaining five endoleaks persisted to the 6-month follow-up period. All six patients had iliac arteries that were ectatic with a diameter exceeding the size of the limb in at least one area above the attachment site. Four have been treated by coiling and one is awaiting treatment.

**Other endoleak sites.**

Two endoleaks were from the distal tube attachment site. One sealed spontaneously and the other was coiled when it persisted. Three of four endoleaks, suspected to arise from branch flow, spontaneously resolved. One IMA was coiled at eight months. Two endoleaks of indeterminate origin sealed on their own.

**Discussion**

Several reports have established endoluminal repair of AAA as a viable alternative to the standard open surgical procedure. Endoleaks, however, remain the major drawback of the techniques and have been reported with all systems being investigated. The aetiology is obviously not uniform and neither is their natural history and management. Some endoleaks, mostly branch flow backbleeding into the sac, are an unavoidable side-effect of the technique, unless all

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*Fig. 3. Number of aneurysms excluded or with persistent endoleak at various follow-up stages. (□) Excluded; (■) endoleaks.*

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Persistence endoleaks

Seven endoleaks still evident at the 6-month follow-up were considered to be persistent. Six have undergone angiography and successful coiling of the leak, one awaits treatment. Angiography revealed the endoleak to originate from the IMA in one patient and the distal attachment of a tube graft in another without any outflow. Both were sealed after one attempt. The IMA was approached through the superior mesenteric artery. The other 4 patients had complex cavities connecting the distal attachment system to various outflow branches, and in one patient the proximal attachment system. All were coiled successfully. One patient required, however, 3 episodes of coiling for a satisfactory result. Another patient had a two-stage intervention, two months apart, because of the complexity of the cavity and outflow.

Pressure inside the sac was measured on two occasions and found to be 100 mmHg in one and 115 mmHg in the other, only around 20 mmHg lower than systemic pressures in both cases.

**AAA size on follow-up**

Among the patients with a persistent endoleak at six months, only one patient showed signs of enlargement
branches are embolised preoperatively, a somewhat daunting and potentially undesirable task. Although we attempted to embolise large branches initially, we quickly abandoned it because of additional cost, patient burden and, most importantly, ineffectiveness, since our first two embolisations did not prevent the development of endoleaks. It is noteworthy that our review failed to identify a direct relationship between patent branches on the preoperative angiogram and the development of endoleaks.

Other types of endoleaks are associated with the particular device used and are related to the attachment systems, modular joint area or fabric of the device. Hook and frame breaks initially identified with the old EVT device have been entirely corrected without any being reported in phase II. Endoleaks around attachment sites with poor sealing, however, remain a potential problem. We have identified a strong association between neck angulation and proximal endoleaks not previously emphasised, allowing anticipation of the possible problem and an insight into their causation. The endoleak tends to occur along the concavity of the angle because of reduced seal at the junction between the frame of the attachment system and the body of the graft. Angulation, however, should not be used to exclude patients from repair with the EVT device, since almost all of these endoleaks resolved spontaneously.

Another strong association was also noted between endoleaks around the distal bifurcated attachment systems and ectatic common iliac arteries. It appears that, for a seal to develop, a certain distance of apposition of the graft is important. It should therefore be stressed that proper measurements and the proper size selection are important in avoiding this problem, which proved to be the source of around two-thirds of the persistent endoleaks.

The frequency of endoleaks is important, since they imply incomplete exclusion of the aneurysmal sac, which can lead to continued expansion and possible rupture. Our endoleak rate of 38% is similar to most published experience with the EVT device. It is at least partially related to a very meticulous study design that uses multiple modalities very early to detect all possible leaks. The ultimate fate of these endoleaks, however, has not been well documented long term.

Spontaneous resolution of the endoleaks has been reported previously. Certain endoleaks seem to resolve much more readily than others. Most of our proximal attachment endoleaks, branch flow and indeterminate cases stopped spontaneously. Most distal attachment endoleaks, especially those related to a bifurcated device placed in ectatic iliac arteries, have persisted up to 6 months. The rate of closure seems to be high initially and decreases with time. By discharge our rate was 31% indicating a rapid seal of some of the endoleaks, with only 18% still present at 3 months. By 6 months, 63% of the endoleaks have resolved with only 14% of the patients still exhibiting the problem.

Interventions on endoleaks have been recommended very early because of risk of rupture if observed for a considerable period of time. The significant rate of spontaneous closure with no intervening complications in our patients certainly justifies a policy of observing these leaks for six months prior to any intervention. The decreasing rate of resolution, however, with the potential for disastrous complications led us to intervene on persistent endoleaks at six months.
The only obvious cure for a persistent endoleak is to convert the patient to a standard repair. At the request of the patients, we have attempted to resolve the problem with interventional means. Since the FDA-approved protocol did not allow additional placement of new grafts, we proceeded with coiling of the source, outflow and cavity of the endoleak as previously reported.\(^1,9\) This was successful in all cases in achieving obliteration and cavity of the endoleak as previously approved protocol did not allow additional placement of new grafts. Persistent endoleaks can be managed by interventional means successfully without any late conversions to standard repair. Whether this radiographic seal will be supported by clinical follow-up remains to be documented.

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References


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