

Reinterventions after endovascular abdominal aortic aneurysm repair

John D. Kakisis¹, Konstantinos G. Moulakakis¹, George Sfyroeras¹, Andreas M. Lazaris¹, Christos D. Liapis¹, Stavros Spiliopoulos², Elias Brountzos², George Geroulakos¹

¹Department of Vascular Surgery, School of Medicine, National and Kapodistrian University of Athens, "Attikon" University Hospital, Athens, Greece

²2nd Department of Radiology, School of Medicine, National and Kapodistrian University of Athens, "Attikon" University Hospital, Athens, Greece

Abstract:

Objectives: To record all the complications after endovascular abdominal aortic aneurysm repair (EVAR) treated invasively, to summarize the treatment methods that were used and assess the safety and efficacy of these methods.

Patients and Methods: Between 1/2010 and 12/2017, 628 patients underwent EVAR. Patients were followed by CT angiography on the 1st and 12th postoperative month and annually thereafter by color duplex. The records of all patients undergoing reoperation, either open or endovascular, were reviewed from a prospectively kept database.

Results: One hundred and eight reinterventions were performed in 90 patients (14.3%). The most frequent cause of reoperation was type II endoleak: 43 reoperations in 35 patients (5.6%). Of these reoperations, 21 were transarterial (9) or translumbar (12) embolizations, 20 were open surgical ligations and 2 were interventions for complications of embolization. Technical success of transarterial embolization was 78% and of translumbar 67%. The second cause of reintervention was endograft limb occlusion (32 re-operations in 23 patients, 3.6%). Of these reinterventions, 13 were stentings (92.3% technical success), 17 bypasses and 2 thrombectomies with angioplasty. The third cause of re-intervention was type I endoleak (18 reinterventions in 17 patients, 2.7%). All Ib endoleaks (6 patients) were treated by extension of the endograft to the common or external iliac artery, while Ia (11 patients) endoleaks were treated by open conversion (5), proximal cuff (3), Palmaz stent (3) or embolization (1). More rare causes of re-intervention included endograft infection (8 patients), type III endoleak (3), aneurysm rupture (1) and sigmoid (2) or buttock ischemia (1).

Conclusions: The most frequent complication after EVAR requiring intervention was type II endoleak followed by endograft limb occlusion and type I endoleak. About half of these complications were treated by endovascular means with a success rate of 67-100% whereas the other half required open surgical repair.

Once considered as a surgical alternative for high risk patients with abdominal aortic aneurysms (AAAs), endovascular AAA repair (EVAR) has now outnumbered open AAA repair in most vascular centers, being applied in most patients in whom it is technically feasible, irrespective of surgical risk. That is due to the well documented low perioperative mortality ranging between 0.5-1.7%, whereas the respective rate in patients submitted to open repair is about 3-fold higher, ranging between 1.3-4.7%.¹⁻⁴ Nevertheless, reinterventions remain the Achilles heel of the technique, with a reported incidence of up to 38% after 12 years of follow-up, with the respective incidence in patients submitted to open AAA repair being less than 21%.⁵ Endoleaks, migration, limb occlusion, aneurysm rupture, endograft infection, graft-enteric fistula, bowel ischemia and access site problems represent the wide spectrum of complications that may require reintervention.

The aim of our study was to record all the complications

after EVAR that required interventional treatment, to summarize the treatment methods that were used and assess the safety and efficacy of these methods.

PATIENTS AND METHODS

The medical records of all patients undergoing EVAR in our Department between January 2010 and December 2017 were retrospectively reviewed to identify patients who underwent any type of reintervention. The initial decision between open and endovascular repair was based on anatomic suitability, medical fitness and patient's preference. The selection of endograft type was an individual surgeon's decision and was based on the anatomic characteristics of the aneurysm and the instructions for use of the various endografts. Informed consent was obtained from all patients that their anonymous data could be used in the future for research purposes.

All patients were followed with routine physical examination and computed tomography angiography (CTA) on the 1st and 12th postoperative month and, in the absence of endoleak, with duplex ultrasound (DUS) imaging and physical examination yearly thereafter. In the presence of type II endoleak, patients were followed with DUS every 6 months.

Author for correspondence:

John D. Kakisis

Department of Vascular Surgery, "Attikon Hospital"
1 Rimini street - Haidari 12462 - Athens, Greece

E-mail: kakisis@med.uoa.gr

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Outcome measures

The main outcomes that were recorded included the type, the cause and the success rate of reinterventions. A reintervention was defined as any open surgical or endovascular procedure that was performed after the initial EVAR procedure and was either directly or indirectly related to it. Technical success was defined as uncomplicated completion of the preplanned procedure with elimination of the problem for which it was performed.

RESULTS

During the study period, 628 patients underwent EVAR in our Department with commercially available endografts: Gore Excluder (n=187), Cook Zenith (n=251), Vascutek Anaconda (n=118), Medtronic Endurant (n=54), Bolton TREO (n=6), Jottec E-Vita (n=4), Cordis Incraft (n=4), Trivascular Ovation (n=3) and Endologix AFX (n=1). The majority of the procedures were elective (606 procedures, 96.5%), whereas 22 (3.5%) procedures were performed for ruptured AAAs. The median follow-up time was 48 months (range: 1-96). Follow-up compliance over the first year was 100%, whereas 72 patients (11.5%) were lost to follow-up at some time point thereafter. Of these, 90 patients (14.3%) underwent 108 reinterventions. The causes of reinterventions along with their incidence are depicted in Table 1.

Cause of reintervention	Number of reinterventions	Number of patients	% patients
Endoleak type II	43	35	5.6
Endograft limb occlusion	32	23	3.6
Endoleak type I	18	17	2.7
Endograft infection	8	8	1.3
Endoleak type III	3	3	0.5
Sigmoid ischemia	2	2	0.3
Buttock ischemia	1	1	0.2
Aneurysm rupture	1	1	0.2
Total	108	90	14.3%

Table 1. Causes and incidence of reinterventions

Endoleak type II

Forty three reinterventions were performed in 35 patients (5.6%) for the management of a type II endoleak that caused asymptomatic expansion of the aneurysm sac >5mm. Mean aneurysm sac expansion was 10.8 ± 2.5 mm and the mean maximum diameter of the aneurysm at the time of embolization was 6.7 ± 1.3 cm. Mean time from EVAR to embolization was 30.7 ± 19.8 months.

Twenty one patients were treated by embolization either transarterial (9 patients) or translumbar (12 patients). The transarterial route was the access of choice in patients in whom the inferior mesenteric artery (IMA) was patent (8 patients). Embolization was performed via the common femoral artery. The IMA was catheterized from the superior mesenteric artery (SMA) via the marginal artery (Figure 1). In one patient with a large middle sacral artery (MSA) feeding a type II endoleak, the MSA was accessed from the left internal iliac artery (IIA) via the iliolumbar artery. In all 9 patients, the endoleak nidus within the aneurysm sac was reached with the use of microcatheter. Digital Subtraction Angiography (DSA)

was performed to depict the inflow and outflow arteries and embolization followed with n-butyl-cyanoacrylate (Glubran 2, GEM SRL, Viareggio, Italy) and lipiodol mixture (1:3 to 1:5).

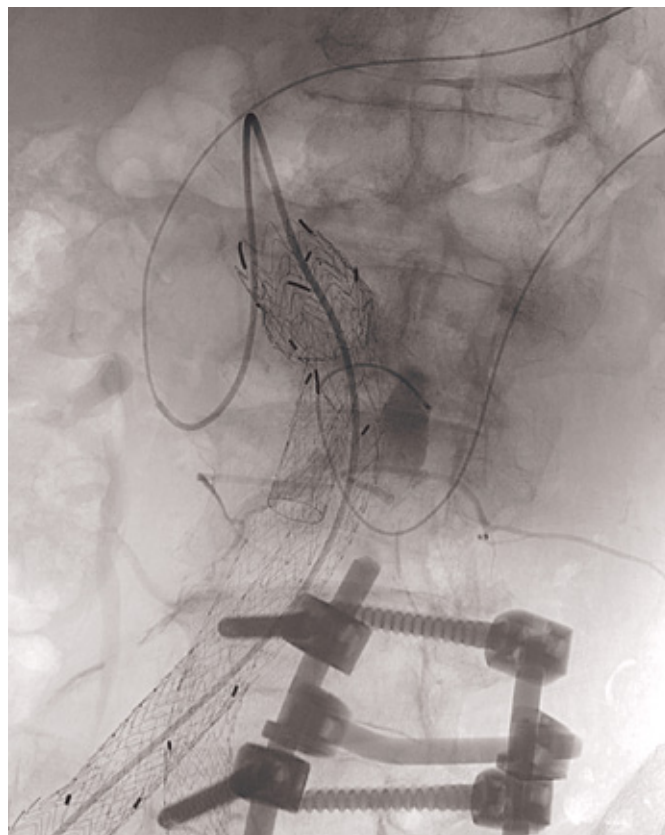


Figure 1. Transarterial embolization of a type II endoleak. A Simmons catheter is inserted through the right common femoral artery to the superior mesenteric artery and a microcatheter through the middle colic artery, the left branch of the middle colic artery, the superior branch of the left colic artery, the left colic artery and the inferior mesenteric artery to the endoleak nidus, where glue was infused.

Translumbar embolization was performed from a left-sided translumbar approach under CT guidance. The patient was then transferred prone to the angiosuite table and the procedure was completed there under fluoroscopic guidance. A standard angiographic catheter was introduced into the sac at the point of the endoleak and embolization was performed as described in the previous paragraph.

Technical success of transarterial embolization was 78% (7 out of 9 patients). In one patient, the type II endoleak persisted after completion of the procedure and was treated with open surgical ligation at a second stage. In another patient, shortly after the embolization procedure, sigmoid necrosis developed and was treated by left colectomy and proximal colostomy (Hartman operation). The continuity of the colon was restored three months later.

Technical success of translumbar embolization was 67% (8 out of 12 patients). In 4 patients, a persisting type II endoleak was observed after the completion of the embolization procedure and was treated with open surgical ligation.

In total, 21 patients required open surgery, with the surgical technique of choice being ligation of the lumbar arteries (18 patients) with preservation of the endograft and tight

suturing of the aneurysm sac around it. In 2 patients the endograft was replaced by a Dacron tube graft because of displacement of the endograft during manipulations to expose and ligate the orifice of the lumbar arteries. One more patient required 2 open surgical reinterventions for the treatment of sigmoid necrosis, as already mentioned.

Endograft limb occlusion

Overall, 32 reinterventions for 31 endograft limb occlusions were performed in 23 patients (3.6%) during the study period. One patient had 2 reinterventions in the same limb to restore perfusion, whereas 8 (1.3%) patients were treated for sequential (in different time) bilateral limb occlusion.

There was one case of limb occlusion during the first post-operative week, three cases of endograft limb occlusion between the first and the fourth post-operative week, while in the remaining 27 cases (87%) limb occlusion occurred after 2-96 months.

The majority of these reinterventions (29/32; 90.6%) were performed for short-distance buttock claudication (Rutherford-Becker classification 3), whereas 3 reinterventions (9.4%) were performed for the treatment of rest pain. Although the exact cause of limb occlusion could not always be determined with certainty, in 12 cases (38.7%) an ipsilateral iliac artery angulation of $>60^\circ$ was noted, in 10 cases (32.3%) an excessive endograft limb over sizing $>15\%$ and in 20 (64.5%) cases an iliac calcification of $>50\%$ of the vessel circumference. In 5 patients (16.1%), however, no causal factor could be identified.

Thirteen limb occlusions were treated by either stent grafts (9 cases) or nitinol bare stents (4 cases) (Figure 2).

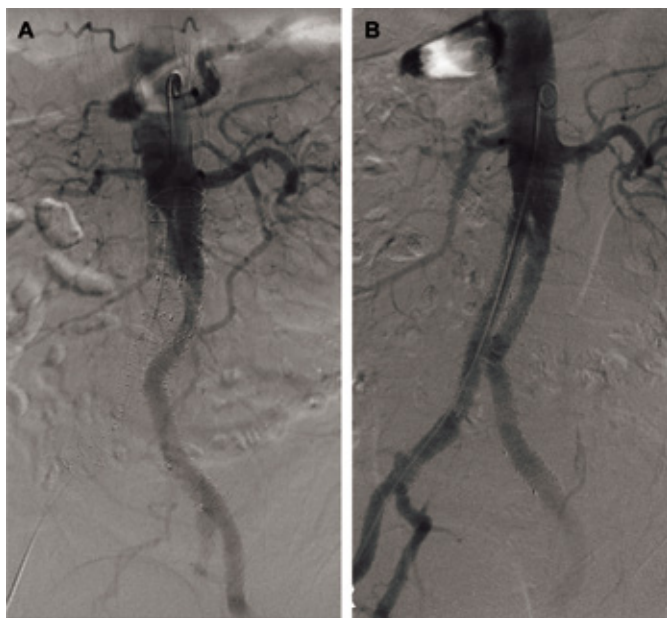


Figure 2. Endograft right limb occlusion (A), treated by percutaneous placement of two nitinol, self-expandable stents (B).

Median diameter of stent grafts deployed was 13.5mm (range: 10-13.5mm). Median diameter of bare self-expandable stents deployed was 12mm (range: 9-14mm). Mean number of stents used per limb was 2 (range: 2-3 stents). Mean occlusion length that had to be covered was 132.0 ± 17.1 mm). Technical success was 92.3% (12/13 cases). There was only

one technical failure to cross a long-standing, 12-months old occlusion, in a patient suffering from Rutherford 3 intermittent claudication. The patient was treated with a femorofemoral bypass.

Seventeen limb occlusions were treated by open surgery: femoro-femoral (10), aortobifemoral (4) or axillofemoral (3) bypass, whereas 2 more patients were treated by a hybrid approach consisting of open surgical thrombectomy plus intra-operative angioplasty to correct the underlying iliac stenosis.

Endoleak type I

Eighteen reinterventions in 17 patients (2.7%) were performed for the management of a type I endoleak. Six type Ib endoleaks, occurring 1-5 years after the initial EVAR procedure, were successfully treated by coil embolization of the internal iliac artery plus endograft extension to the external iliac artery (4) or by endograft extension to the common iliac artery in two patients with upward migration of the endograft limbs within the aneurysm sac. Two type Ia endoleaks were recognized in the first postoperative CTA and 5 after 1-4 years. All of the type Ia endoleaks were treated percutaneously by an aortic cuff (3), a Palmaz stent (3) or by coil and glue embolization (1). Aortic cuffs were placed when the distance between the lowest renal artery and the main body of the endograft was more than 5 mm. Palmaz stents were placed when the distance between the lowest renal artery and the endograft was less than 5 mm (Figure 3). Coil and glue embolization was performed when the Palmaz stent failed to seal the endoleak.

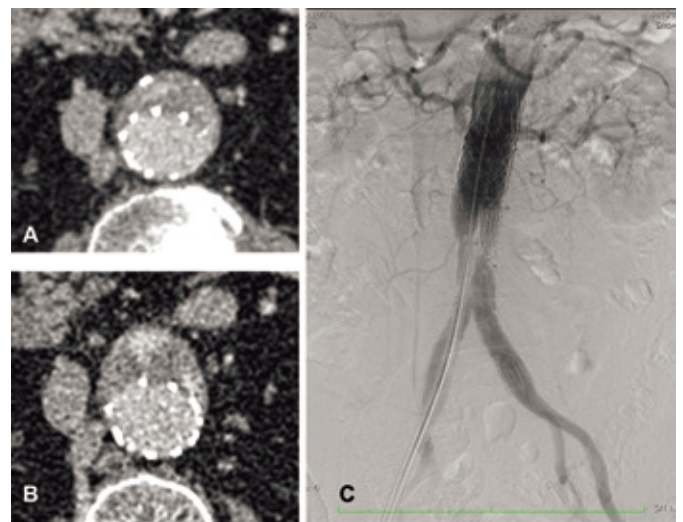


Figure 3. A, B: CTA revealing the presence of a type Ia endoleak. C: DSA revealing elimination of the endoleak by placement of a Palmaz XL stent.

Percutaneous treatment was successful in 85.7% (6/7 patients). In one patient, placement of a Palmaz stent, followed by coil and glue embolization failed to eliminate the endoleak and the patient was treated by open conversion (Figure 4). In total, 5 conversions were performed for the management of a type Ia endoleak, in cases where endovascular treatment was either impossible or failed. Endovascular treatment was considered impossible when the diameter of the aortic neck had exceeded the diameter of the main body of the endograft.

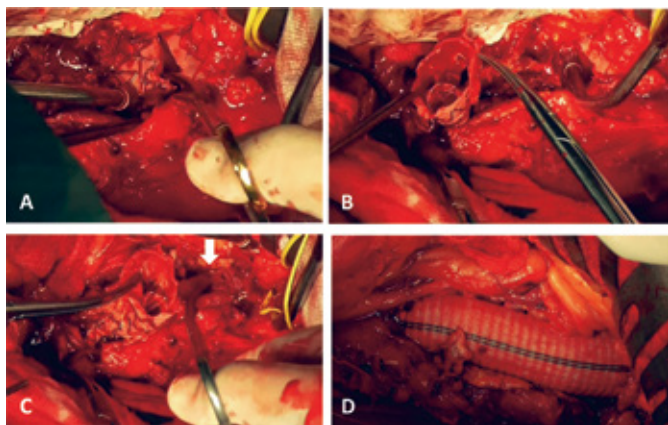


Figure 4. Open conversion due to type Ia endoleak. The main body of the endograft is cut between the first and the second stent (A, B). A Palmaz stent that had been placed in an attempt to seal the endoleak is being removed (C). The endograft is excised and replaced by a straight Dacron graft with the sutures of the proximal anastomosis passing through both the fabric of the remaining proximal stent and the aortic wall (D).

Endograft infection

Eight patients (1.3%) presented with fever, low back pain, leukocytosis, and increased C-reactive protein. A CTA showed the presence of gas in the aneurysm sac, verifying the diagnosis of endograft infection. The treatment of choice was endograft excision followed by either axillofemoral bypass (2 patients) or neoaortoiliac system (NAIS) procedure (3 patients). One of the 3 patients treated by NAIS died 1 month after the procedure because of vein graft rupture, probably due to recalcitrant infection by *Klebsiella pneumoniae*.

In the remaining 3 patients, a more conservative approach with preservation of the endograft was selected due to the poor clinical status of the patients. A laparotomy was performed, the aneurysmal sac was opened, the endograft was exposed and debridement of the area, local irrigation with antibiotics according to antibiogram and omentoplasty followed. One of these patients died on the 2nd postoperative day due to pulmonary embolism, whereas in the other 2 patients infection recurred 11 months and 3 years, respectively, after laparotomy, despite lifelong treatment with antibiotics.

Less common causes of reinterventions

Three type III endoleaks were diagnosed during the study period, all of which were invasively treated with either relining of the endograft (2 patients) or open conversion (1 patient).

One patient presented with aneurysm rupture and was submitted to open conversion.

Two patients developed sigmoid necrosis which was diagnosed on the first postoperative day. Both patients were submitted to left colectomy and proximal colostomy (Hartman operation) but they both died of multiorgan failure 1 and 3 days later.

One patient developed buttock ischemia with skin necrosis after intended coverage of the ipsilateral internal iliac artery (IIA), while the contralateral IIA was patent but heavily calcified. The patient was treated by external to internal iliac bypass via a retroperitoneal approach.

DISCUSSION

The results of our study, showing a 14.3% reintervention rate, confirm that secondary procedures after EVAR are still a problem despite the unequivocal improvements in endografts as well as in imaging and sizing methods. The EVAR trial 1, having recruited patients between 1999 and 2004, has recently shown a 26% reintervention rate after a mean follow-up of 12.7 years.⁶ Re-interventions occurred throughout the study follow-up, including in patients who were free from re-intervention after 2 years or even 5 years. These late reinterventions have led the authors of the EVAR trial 1 to the conclusion that it is not safe to stop follow-up for patients with EVAR. The OVER trial has also shown a high rate of reinterventions, with 22.1% of the patients having at least one reintervention after a mean follow-up of 5.2 years after EVAR.⁷ In the ACE trial, the percentage of reinterventions was 16% in the EVAR group, after a mean follow-up of 3 years.⁴ This percentage was significantly higher than the 2.4% reintervention rate in the open AAA repair group and has led the authors of the ACE trial to the conclusion that open repair of AAA remains a more durable therapeutic option.

In accordance with the findings of our study, a systematic review of 23 studies published between 2010 and 2017 and reporting on 83,307 patients showed that endoleak type II was the most common indication for re-intervention.⁸ Type II endoleaks occurred in 14-25.3% after EVAR, but the majority resolved without intervention. Reintervention was required in 3.5-22.5% of them. Consequently, about 2.6-7.3% of the patients submitted to EVAR required reintervention for a type II endoleak.^{9,10} The success rate of transarterial embolization is reported to be 20-80%.¹¹⁻¹⁴ The reason why transarterial embolization may fail to seal the endoleak is that these endoleaks are usually fed by a network of arteries instead of a single vessel. Embolization of the endoleak cavity and not only of the feeding artery is therefore recommended and is reported to increase the success rate of the transarterial embolization to 78%.¹⁵ Incomplete embolization of the endoleak cavity accounts for the remaining cases of failure to seal the endoleak.

Endograft limb occlusion is reported to occur in 2.6-7.4% of patients after EVAR.¹⁶⁻¹⁸ Several anatomical risk factors have been proposed including common iliac artery diameter, calcification, angulation and the presence of thrombus, whereas procedure related risk factors for limb thrombosis include endograft oversizing and extension to the external iliac artery.¹⁹⁻²⁰ In a previous study from our center on 579 patients treated by EVAR, we had shown that endograft limb occlusion was associated with iliac artery angulation $\geq 60^\circ$, perimeter calcification $\geq 50\%$ and $\geq 15\%$ endograft oversizing in the common iliac artery. No other risk factors for limb occlusion were recognized.^{21,22} Although frequently avoided for the fear of thromboembolic complications, percutaneous stenting is nowadays the treatment of choice in our department, with zero complications in the first 13 cases and only one failure to recanalise a chronic occlusion of more than 12 months old.²³

Type Ia endoleaks have been reported in 0.6%-13% of the patients after EVAR and are more frequent in patients with short and heavily calcified aneurysmal necks and large aneurysms.^{8,24} Aortic cuffs, when the distance between the lowest renal artery and the endograft is more than 5 mm, and Palmaz stents, when the distance is less than 5 mm, are associated

with a success rate of 86-100% in sealing the endoleak.^{25,26} Recently, self-expandable nitinol stents with a diameter of up to 36 mm have been manufactured and used for the treatment of type Ia endoleaks.²⁷ When aortic cuffs and Palmaz stents fail to seal the endoleak, coil and/or glue embolization is the next step, associated with a success rate of about 85%.^{28,29} The chimney graft technique,^{30,31} fenestrated cuffs³² and endostaples³³ represent additional options that are included in the minimally invasive armamentarium against a type Ia endoleak, whereas aortic neck banding³⁴ and open conversion³⁵ are the two open surgical alternatives for cases refractory to multiple attempts at endovascular repair.

The incidence of endograft infection ranges between 0.2-3%.³⁶ Although rare, it is a life-threatening disease with mortality rates ranging between 25-100%. Roughly one-third present as chronic sepsis, one-third as severe acute sepsis, and one-third as aortoenteric fistulas. The primary treatment objective in such cases is to remove the infected stent graft and to reestablish vascular continuity with an extraanatomic bypass or in situ graft replacement. Nevertheless, this approach is associated with high mortality rates, ranging from 28% to 83%, especially when undertaken in unstable, septic patients with severe comorbidities.^{37,38} Open laparotomy with debridement without removal of the endograft, or CT-guided percutaneous drainage, followed by lifelong antibiotic therapy, could be an alternative in such cases.³⁶

In conclusion, despite significant improvements in endograft design as well as in imaging and sizing methods, complications after EVAR continue to be a problem and required re-intervention in 14.3% of our patients. The most frequent complication requiring intervention was type II endoleak with an increasing aneurysm sac diameter, followed by endograft limb occlusion and type I endoleak. About half of these complications were treated percutaneously with a success rate of 67-100% whereas the other half required open surgical repair.

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