Dynamics of Endovascular Aneurysm Repair

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Dynamics of Endovascular Aneurysm Repair

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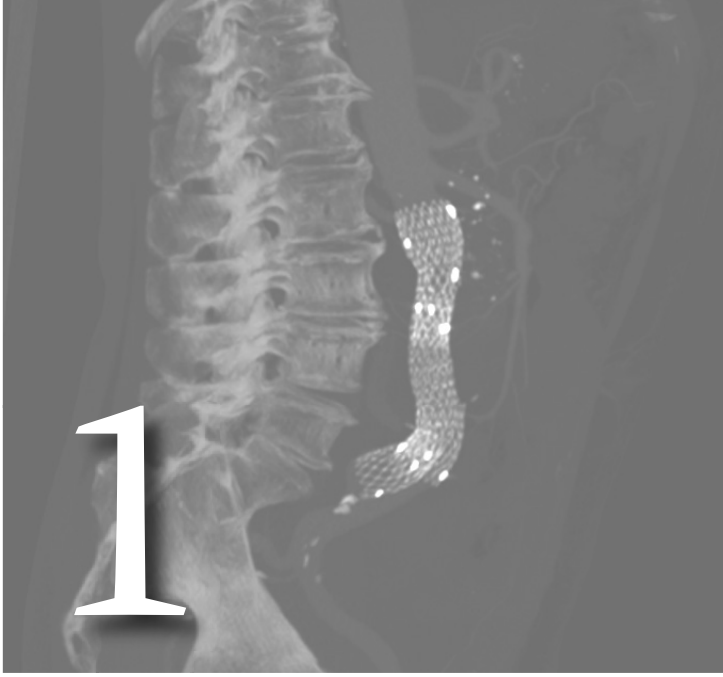
There is no disease more conducive to clinical humility than aneurysm of the aorta

Sir William Osler

Voor Maud

Dynamics of Endovascular Aneurysm Repair



Chapter 1

General introduction

Introduction

Aneurysm derives from the Greek word *ανευρυσμα*, which means widening. It can be defined as a permanent and irreversible localized dilatation of a vessel. For the infrarenal aorta, the first definition of an aneurysm was given by McGregor et al. in 1975.[1] They defined an abdominal aortic aneurysm (AAA) as an aorta with an infrarenal diameter greater than 30 mm.[1] However, the normal aortic diameter can vary from 1.4 to 3.0 cm,[2] depending on the individual's gender, age, and body weight.[3] In 1991, the Society for Vascular Surgery and the International Society for cardiovascular Surgery Ad Hoc Committee on Standards in Reporting therefore proposed as a criterion for AAA an infrarenal diameter that exceeds 1.5 times the expected normal diameter.[4] Another criterion is that the dilatation should affect all three layers of the vascular tunic; otherwise, the dilatation is called a pseudoaneurysm.

Epidemiology

Abdominal aortic aneurysm is a common disease, with an estimated prevalence of 1.3% to 8.9% in men and 1.0% to 2.2% in women.[5-9] The natural course of aneurysms is to expand and eventually rupture, which is associated with high mortality and morbidity rates. Most patients with ruptured AAAs die before they arrive at the hospital or before surgery can be performed.[10,11] Because operative mortality rates for emergent AAA repair are high, only 10% to 25% of individuals with a ruptured AAA survive this life-threatening disease.[11,12]

Therapy

In 1952, Dubost et al. introduced an open surgical technique for AAA repair.[13] Since then, open aortic surgery evolved and became the gold standard for the treatment of AAAs. However, this open technique consists of a laparotomy, with a temporary need for aortic cross-clamping while the proximal and distal anastomosis are sewed. This technique is accompanied by severe morbidity and mortality.

In 1991, Parodi et al.[14] in Argentina and Volodos et al.[15] in the Ukraine both reported a technique for endovascular aneurysm repair (EVAR). This procedure consists of an endovascular prosthesis that is placed into the aorta via the femoral or iliac arteries. The main advantage of EVAR compared with open reconstruction is that it eliminates the need to cross clamp the aorta. EVAR gained an enormous popularity worldwide because it appeared less invasive than open repair, had less blood loss, a shorter hospital stay, and improved perioperative mortality rates.[16-20]

Short-term results were excellent,[21-23] but during follow-up, specific complications such as endoleaks, kinking, and migration of the endografts, and even aneurysm rupture were described. The durability of EVAR was therefore firmly criticized by disbelievers. In 2001, the authors of the lead article of the *British Journal of Surgery* even disqualified EVAR as a "failed experiment" because of its higher costs, the specific complications during follow-up, and a persistent risk of aneurysm rupture.[24]

In 2004, the first results of multicenter randomized trials reported[19,20] that EVAR had favorable results compared to open repair. After 1[25] and 4 years of follow-up,[26] however, both groups had similar rates of all-cause mortality, although aneurysm-related death after EVAR was still less after 4 years.[26]

EVAR can only be justified as a regular or even preferable treatment when long-term results are durable and at least comparable with results of open aneurysm repair in randomized trials. However, EVAR has now been performed for only 15 years and is still evolving. Therefore, the first long-term results from randomized trials are still to be awaited, and can only be expected after 2007. Besides, when these results become available, the generation of endovascular devices used in these trials, will probably be outdated.

Aims and Outlines

The aims of this thesis are (1) to evaluate our single-center mid-term and long-term results with the AneuRx endograft (Medtronic AVE, Santa Rosa, CA, USA), and (2) to gain insight in the origin of EVAR-related complications to overcome them in future.

In **Chapter 2,** a general overview on EVAR with a review of literature is presented. **Chapter 3** contains mid-term results with the AneuRx device. In **Chapter 4,** the feasibility of endovascular repair of paraanastomotic aneurysms after previous open aneurysm repair is described. Experiences with late conversions after EVAR are reported in **Chapter 5,** and long-term results with the AneuRx device are reported in **Chapter 6**. In **Chapter 7,** dynamic magnetic resonance angiography is introduced to study dynamic conformational changes of the aneurysm neck. Elastic properties of the aneurysm and aneurysm neck before and after EVAR are reported in **Chapter 8.** These dynamic studies are executed to enhance knowledge on the proximal fixation zone to improve results of EVAR in future. Finally, the content of this thesis is summarized, discussed, and put into perspective in **Chapter 9.**

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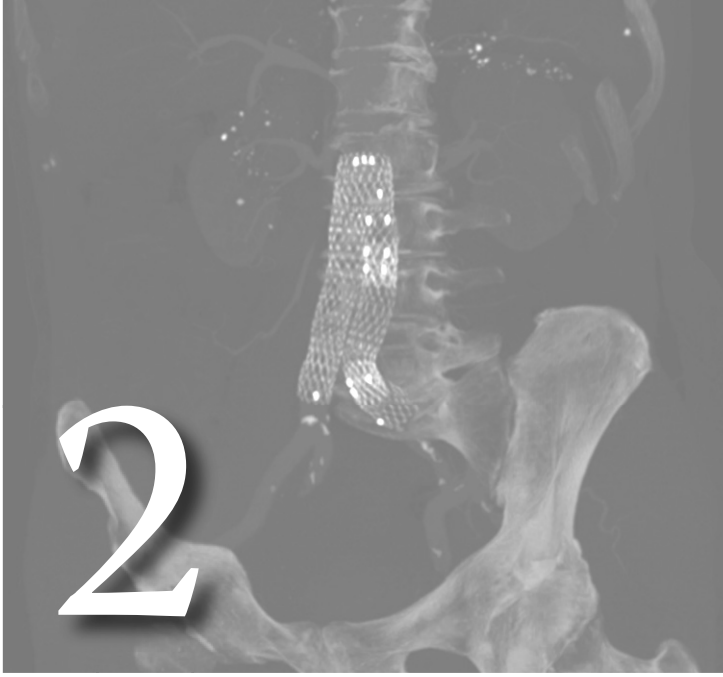

Chapter 2

Endovascular repair of infrarenal abdominal aortic aneurysms

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Introduction

Aneurysms of the infrarenal abdominal aorta (AAA) are common, with estimated prevalence rates of 1.3% to 8.9% in men and 1.0% to 2.2% in women.[1-5] The natural course of aneurysms is to expand and eventually rupture. Ruptured abdominal aneurysms account for 1.3% of deaths in men older than 65 years of age.[6]

In 1952, Dubost et al. initiated the era of corrective surgery for AAAs by performing an aneurysmectomy and using a homologous graft to restore aortic blood flow.[7] Since then, open aortic surgery evolved and became the gold standard for the treatment of AAAs. Currently, the early (30-day) mortality for elective open AAA repair has decreased to 5% or less.[8,9] A further decrease in mortality is not expected in invasive, open procedures.

In 1986, Balko et al. introduced an alternative and less invasive technique for AAA repair.[10] They reported exclusion of artificially created aortic aneurysms in sheep by using a nitinol and polyurethane stent-graft composite, which was inserted through the common femoral arteries. Three years later, Mirich et al. reported a comparable study in dogs, with percutaneously introduced endovascular grafts.[11] The first endovascularly repaired AAAs in humans were reported from Argentina by Parodi et al.[12] and the Ukraine by Volodos et al.[13], both in 1991. The benefits of endovascular aneurysm repair with a minimally invasive transfemoral approach, and without the need for aortic crossclamping, seemed obvious, and the technique gained an enormous popularity. At first, endografts in an aortic tube configuration were used, but those have been abandoned in favor of the bifurcated and aortouniiliac devices that are being used.

This chapter is a review of the evolution, short-term and long-term results, and state-of-the art data on endovascular aneurysm repair for infrarenal AAAs.

Indication

The decision whether to repair an AAA is based upon risk analysis. Because aneurysm size is the greatest risk factor for rupture, size is the most important feature in this analysis. The 1-year incidence of probable rupture by initial AAA diameter is 9.4% for AAAs of 5.5 to 5.9 cm, 10.2% for AAAs of 6.0 to 6.9 cm (19.1% for the subgroup of 6.5 to 6.9 cm), and 32.5% for AAAs of 7.0 cm or more[14]. When a patient's expected mortality because of aneurysm rupture during surveillance exceeds the peri- and postoperative mortality of aneurysm repair, aneurysm repair might be performed.

For open repair, two randomized trials showed no advantage for surgery over surveillance in patients with abdominal aortic aneurysms with a diameter between 4.0 and 5.5 cm.[15, 16] However, for endovascular aneurysm repair (EVAR), the EUROSTAR collaborators reported excellent outcome in a large group (n = 1962) of patients with aneurysms of 4.0 to 5.4 cm.[17] This might imply an advantage of EVAR over surveillance in smaller

aneurysms, which was reported by Zarins et al.[18] They compared the results of all patients with a small AAA (5.5 cm diameter or less) treated with a stent-graft in the multicenter AneuRx clinical trial from 1997 to 1999 with results of the surveillance patient cohort of the UK Small Aneurysm Trial.[18] However, the first randomized trial that compares EVAR versus surveillance in patients with small aneurysms started in September 2004, and the first results are expected to be published in 2007.[19]

Patient selection

Although EVAR is considered to be a minimally invasive procedure, the patient's physical condition should allow an open aneurysm repair in case an acute conversion is necessary. Further criteria for patient selection apply for anatomic details of the aorta, iliac, and femoral arteries. These criteria differ for the commercially available devices. In several of the original clinical trials of EVAR, the minimum acceptable proximal neck length was 15 mm between the most caudal renal artery ostium and the onset of the aneurysm.[20] Maximum acceptable diameter of the aneurysm neck depends on the available sizes of the device. For grafts approved by the United States Food and Drug Administration (FDA), the largest diameter currently available in Europe is 36 mm. For secure proximal fixation, a 10% to 20% degree of oversizing is recommended; therefore, the largest diameter neck that can be reliable treated with a FDA-approved graft is 32 mm. Angulation of the aneurysm neck, which is defined as the angle between the aortic neck and the main longitudinal flow axis of the aneurysm,[21] is a relative contraindication to EVAR when it exceeds 60 degrees.[22] Other relative contraindications for EVAR are the presence in the aortic neck of significant thrombus or circular calcification, which may interfere with both appropriate proximal sealing and secure proximal fixation of the stent-graft.[22]

Acceptable iliac artery morphology is essential to obtain delivery device access into the aorta, seal the aneurysm to prevent distal attachment site endoleaks, and maintain adequate perfusion to the pelvis.[22,23] Iliac artery tortuosity, intraluminal diameter, calcification, and the presence of iliac aneurysms are critically important factors.[24] The minimum required diameter of the iliac arteries and the maximum allowed degree of tortuosity depend on the size of the device's delivery system and on its flexibility. Especially in female patients, this could play a role in device selection because iliac arteries are significantly smaller in women.[25]

The size of the infrarenal AAA is not a limitation for EVAR. Several reports, however, have shown worse results with significantly more complications such as proximal type I endoleaks, device migration, death, and conversion to open surgical repair in patients with larger aneurysms.[17,26-28] In two reports from the EUROSTAR collaborators, the authors even concluded that large aneurysms (>6 cm) and large proximal necks (>26 mm) may require a more rigorous surveillance schedule because of the higher incidence of endoleaks, proximal migration, and death.[17, 28]

Other reasons for worse long-term results in larger excluded aneurysms are likely more complex anatomies, shorter proximal necks, and higher tortuosity.[26,29] In addition, exclusion of larger aneurysms may give more remodelling (shrinkage and kinking), which is associated with late migration of the stent-graft.

Technique

For preoperative graft sizing and planning, most preoperative imaging protocols use spiral computerized tomography angiography (CTA) with central luminal lining and, when needed, three-dimensional (3D) reconstructions.[30,31] In the future, these static techniques will probably be replaced by dynamic utilities such as dynamic CTA or dynamic magnetic resonance angiography (MRA) because the aneurysm neck exhibits significant changes in area and diameter during each cardiac cycle.[32]

During the endovascular intervention itself, high-quality fluoroscopy with a dual screen and road-mapping capability is required. Devices can be mobile or ceiling-mounted. EVAR can be performed in a fully equipped operating theatre or in an angiography suite that is designed and equipped to serve as an operating theatre when conversion to open aneurysm repair is needed.

EVAR is mostly performed in patients who are under general or spinal anesthesia, but local anaesthesia is also feasible.[33,34] The patient is placed in the supine position on an angiography-compatible table with, when preferred by the surgeon, a radiopaque ruler underneath. The operating field is prepared and draping is configured.
Both femoral arteries are exposed by using a vertical or oblique incision at the groins. The femoral arteries are punctured with a needle, and a soft guidewire is advanced into the aorta. All changes in guidewire or endograft position are performed under fluoroscopic guidance. For endograft delivery, the soft guidewire on the ipsilateral site is changed for a stiff wire, such as a Back-up Meier (Boston Scientific) or Lunderquist (Cook). On the contralateral site, the soft guidewire is changed for an angiography catheter. An angiogram is obtained, and the levels of the renal arteries are marked. To make precise infrarenal positioning possible, optimal, central, imaging of the renal arteries is important. Every effort, therefore, should be made to position the C-arm exactly perpendicular to the aorta, with the renal arteries centered on the screen.

Systemic heparin (5000 IU) must be administered before introduction of the stent-graft. Most systems have a marker that aids appropriate rotation of the device so that the short stump for the contralateral limb will open opposite the contralateral iliac artery orifice. Once positioned appropriately, the main section is deployed. Then, from the contralateral site, a wire must be passed through the contralateral limb stump in the main body of the stent-graft. The contralateral bifurcation limb can be advanced and deployed over this wire. It is important to mark the internal iliac artery and avoid unnecessary occlusion. In most systems, dilatation of the proximal and distal anchoring zones and the connection sites with a soft latex balloon is advised.

Finally, a completion angiography is performed to check for stent-graft position, patency of renal and internal iliac arteries, and to look for endoleaks. When the angiography findings are acceptable, the sheaths are removed and the arteriotomies and wounds are closed.

Perioperative complications, morbidity, and mortality

EVAR has proven to be a less invasive procedure compared with conventional, open surgery, with shorter procedure duration, reduced blood loss, and shorter hospital stay.[35-39] A meta-analysis of three randomized clinical trials[37-39] showed a 30-day mortality rate of 1.6%, which was significantly lower than the 30-day mortality rate of 4.7% for open repair (odds ratio, 0.33; 95% confidence interval, 0.17-0.64).[40] Further, EVAR was associated with a lower incidence of perioperative pulmonary complications, hemorrhage, graft infection, and colonic ischemia, whereas the incidence of graft thrombosis was higher compared with open repair (Table I).[40]

Table I. Deaths and complications reported in randomized controlled trials that compared endovascular aneurysm repair with open aneurysm repair.*

	No. of procedures†		
	EVAR	**Open**	**Odds ratio‡**
30-day mortality	12 of 759 (1.6)	33 of 709 (4.7)	0.33 (0.17, 0.64)
Complications			
Cardiac	12 of 228 (5.3)	12 of 193 (6.2)	0.81 (0.35, 1.86)
Renal	2 of 171 (1.2)	2 of 174 (1.1)	1.02 (0.14, 7.31)
Pulmonary	5 of 171 (2.9)	19 of 174 (10.9)	0.25 (0.09, 0.67)
Colonic ischemia	1 of 171 (0.6)	2 of 174 (1.1)	0.51 (0.05, 5.63)
Hemorrhage	3 of 171 (1.8)	6 of 174 (3.4)	0.50 (0.12, 2.03)
Graft infection	1 of 171 (0.6)	2 of 174 (1.1)	0.51 (0.05, 5.63)
Graft thrombosis	11 of 171 (6.4)	5 of 174 (2.9)	2.32 (0.79, 6.84)
Local wound complications	6 of 171 (3.5)	6 of 174 (3.4)	1.02 (0.32, 3.22)

*From Drury et al. Systematic review of recent evidence for the safety and efficacy of elective endovascular repair in the management of infrarenal abdominal aortic aneurysm. Br J Surg 2005;92:937-46.
Values in parentheses are †percentages and ‡95% confidence intervals

The specific perioperative complications of EVAR are:

(a) Access failure. This is mostly caused by tortuosity, angulation, calcification, or too small diameters of the iliac and femoral arteries. Some tortuosity and angulation can be overcome with the use of super-stiff guidewires that can be used to stretch the iliac arteries. In some cases the "push and pull technique", in which the device is pushed while the super-stiff wire is pulled, can help to overcome a troublesome access route. Careful handling is required when this technique is used to prevent

damage to the vessels. To avoid access problems, percutaneous transluminal angioplasty can be used to treat localized stenoses of the common or external iliac artery before introduction of the device. When stenotic disease remains a problem despite percutaneous transluminal angioplasty, an iliac conduit can be constructed for delivery of the stent-graft. A conduit is a prosthetic graft that is sewed to the common or external iliac artery via a retroperitoneal incision. After the stent-graft is deployed this conduit can be anastomosed to the common femoral artery to bypass the stenotic external iliac artery.[41]

(b) *Inadvertent occlusion of vessels.* Too proximal placement of the stent-graft may result in graft fabric blocking one or even both renal arteries. Similarly, placement that is too distal or a graft that is too long may occlude one or both internal iliac arteries. Bilateral internal iliac artery occlusion almost always causes buttock claudication or sometimes even colonic ischemia and should be avoided. Precise preoperative sizing by using central luminal lining and optimal intraoperative imaging are therefore essential.

(c) *Distal embolization.* This can be due to atheroma or thrombus. Several precautions are advised to minimize the risk of embolic complications. First, patients should start taking platelet inhibitors before hospital admission. Further, heparin (5000 IU) is administered before any arterial vessel is clamped or before the stent-graft is introduced. Manipulation of stiff guidewires and the device itself should be minimized during introduction and especially during stent-graft deployment. Additionally, the femoral arteries could be clamped before catheter manipulation and stent-graft deployment to minimize the risk of distal embolization.

(d) *Primary endoleaks*. An endoleak is defined as the persistence of contrast medium outside the lumen of the endoluminal graft but within the aneurysm sac[42] and is classified according to its origin (Table II).[43] Because endoleaks transmit systemic blood pressure to the aneurysm sac, the aneurysm is not excluded and is therefore at risk for rupture. On completion angiography at the end of the operation, the incidence of primary endoleaks varies from 12% to 44%.[44-46] Most of the leaks seen on completion angiography are type II leaks, which are often self-limiting; however, primary type I and type III endoleaks need to be corrected before the procedure is finished.[43] Most inadequate seals can be corrected by balloon angioplasty, by additional stent-graft components, or self-expandable stents such as the "giant" Palmaz stents. Sometimes, a primary type I endoleak resists endovascular repair. In these cases, surveillance is advised in literature,[47] because most of these endoleaks seal spontaneously.[48] The spontaneous resolution of type I endoleaks may only be temporary, however. Mialhe et al. reported that 20% of type I endoleaks that seal spontaneously reopen at 12 to 18 months.[49] Thus, in case of a persistent primary type I endoleak, immediate conversion or conversion within a short time frame has to be considered.[43,50,51] Type IV endoleaks are only seen at completion angiography when the patient is fully anticoagulated. These endoleaks are self-limiting, and treatment is not needed.[50]

Table II. Classification of endoleaks.*

		Description
Endoleaks (type)		**Source of perigraft flow**
I		Attachment site leaks†
	A	Proximal end of endograft
	B	Distal end of endograft
	C	Iliac occluder (plug)
II		Branch leaks†† (without attachment site connection)
	A	Simple or to-and-from (from only 1 patent branch)
	B	Complex or flow-through (with 2 or more patent branches)
III		Graft defect†
	A	Junctional leak or modular disconnect
	B	Fabric disruption (mid-graft hole)
	Minor	(<2 mm; eg, suture holes)
	Major	(≥ 2 mm)
IV		Graft wall (fabric) porosity (<30 days after graft placement)
Endotension (earlier type V)§		
	A	With no endoleak
	B	With sealed endoleak (virtual endoleak)
	C	With type I or type III leak‡
	D	With type II leak‡

*From Veith FJ et al. Nature and significance of endoleaks and endotension: summary of opinions expressed at an international conference. J Vasc Surg 2002;35:1029-1035.

† Some type I and type III leaks also may have patent branches opening from AAA sac and providing outflow for leak.

††From lumbar, inferior mesenteric, hypogastric, renal or other arteries.

§Endotension (strict definition) is defined here as increased intrasac pressure after EVAR without visualized endoleak on delayed contrast CT scans. In generic sense, endotension is any elevation of intrasac pressure and occurs with type I, type III, and most type II leaks and endotension in the strict sense.

‡Detectable only on opening aneurysm sac.

Complications and morbidity during follow-up

Post-procedural, a stent-graft not only needs to withstand the biomechanical forces of pulsatile aortic blood flow to exclude the aneurysm from the circulation but it also has to deal with the forces from the altering aortoiliac morphology. Close follow-up of patients after EVAR is advisable; however, the optimal follow-up protocol and the best imaging modality have yet to be fully defined. Current imaging options are selective angiography,

MRA, CT scanning, and color duplex ultrasonography. CT scanning has been accepted as the gold standard.[43] Further adjuvant plain radiographs are useful to check the graft integrity and to control for kinking and migration.

The most important complications during follow-up after EAVR are *(a)* endoleaks, *(b)* stent-graft migration, *(c)* graft thrombosis, and *(d)* aneurysm rupture.

(a) *Endoleaks* are seen in 15% to 52% of patients after EVAR.[42,48, 52-58] Type I endoleaks are associated with growth of aneurysm size and even aneurysm rupture,[43, 46, 59] and their incidence after EVAR increases with time from 3.5% at 1 month to 6.8% after at least 12 months.[40, 47] The spontaneous sealing of type I endoleaks has been described,[45,48] but this may be only temporary and in the minority of the cases.[8] At present, it is generally accepted that all type I endoleaks need to be treated.[43]

Type II endoleaks are the most common type of endoleak to occur during follow-up. The incidence varies from 27% to 37% at discharge,[60, 61] 8% to 14% at 1 month, 5% to 32% at 12 months, and 13% to 26% at 24 months.[40, 47, 61-63] They are more likely to be seen in patients with a large inferior mesenteric artery or multiple, paired lumbar arteries.[64] The long-term significance of type II endoleaks is unknown. Aneurysm rupture in patients with a type II endoleak has been described,[59, 65-67] but the risk of aneurysm rupture in patients with a type II endoleak is not increased compared to patients without any endoleak.[46] Nevertheless, because the long-term significance of type II endoleaks is unknown, surveillance is crucial in the wait-and-see policy for type II endoleaks. On behalf of the EUROSTAR collaborators, Van Marrewijk et al. advised that patients with type II endoleaks should be followed with regular imaging.[46] Interventions should be done only if the aneurysm size significantly increases.[46]

Type II endoleaks are mostly treated by selective catheterization of feeding vessels and embolization with coils or glue (Figure 1).[68] Concerns have been raised regarding the long-term durability of transarterial embolization. Chuter et al. reported an immediate technical success rate of 72%, but only 1 (9%) of 11 branch endoleaks remained resolved during follow-up.[54] All embolized vessels remained occluded in the series of Haulon et al., but they reported new type II endoleaks in 11% of patients after coil embolization.[69]

Another method is direct percutaneous translumbar embolization (Figure 2).[70,71] Baum et al. compared this technique with transarterial embolization.[72] In their series, transarterial embolization was unsuccessful in 80% owing to recanalization of the original endoleak cavity compared with 8% of patients in the translumbar treated group ($P = 0.0001$).[72]

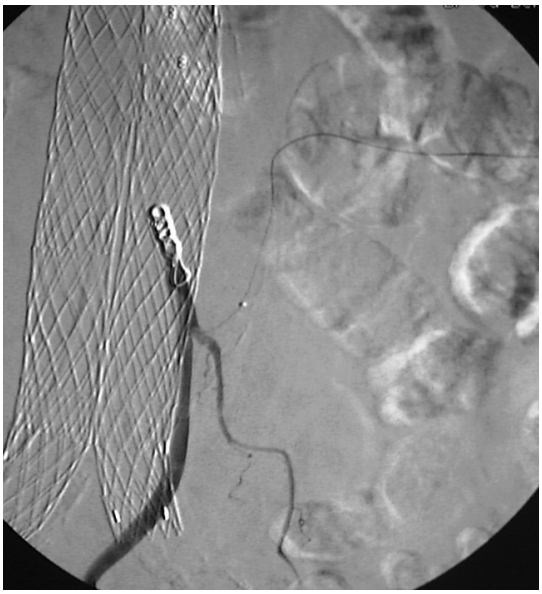

Figure 1. Angiogram of coiling of a type II endoleak.

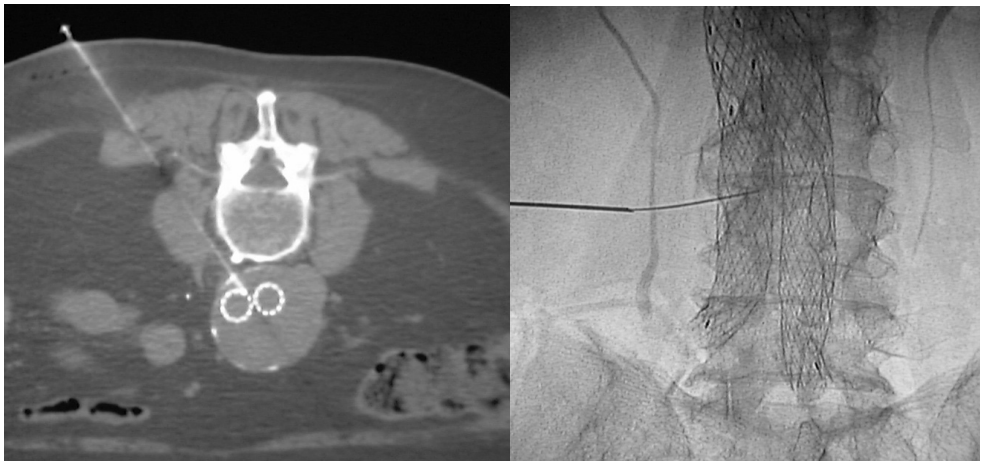

Figure 2. Computed tomography image (left) and fluoroscopy image (right) of direct percutaneously translumbar embolization.

A more effective treatment for a type II endoleak is ligation or clipping of the feeding vessel, which can be performed by using laparoscopy[73] or laparotomy.[74] Because these are operative and thus invasive techniques, ligation or clipping of the feeding vessels should be reserved for patients with aneurysm growth after EVAR with a type II endoleak that has resisted transarterial and/or direct translumbar embolization.

Type III endoleaks significantly increase the risk of aneurysm rupture.[48,59] Most type III endoleaks can be treated endovascularly with extender cuffs or even with an entire new stent-graft inside the old one.[75] If endovascular treatment is not possible or unsuccessful, open conversion is indicated.

Type V endoleak (endotension) is defined as continuing expansion of aneurysm after EVAR, without evidence of endoleak.[76] This complication is seen in 2% to 5% of patients after EVAR.[56,58,77,78] Possible explanations for persistent pressurization of the aneurysm were described by Dubenec et al. (Table III), and include pressure transmission through thrombus or through the stent-graft material, blood flow that is below the sensitivity limits of detection (with current imaging techniques), or accumulation of fluid within the aneurysm sac by graft infection, or hygroma.[79] Hygroma is a cystic collection of serous fluid described by Risberg *et al.*[80] In hygroma, a translucent, highly viscous and gelatinous fluid is found after either open aneurysm repair or EVAR, and both the coagulation and fibrinolytic systems within the sac seem activated. Intrasac pressure can be half the systemic blood pressure,[80] and persistent aneurysm growth or even rupture because of hygroma is described.[81] Because endotension causes aneurysm growth, some authors advocate treatment.[51,82,83]

The absence of a detectable cause makes endovascular repair impossible. Reported less-invasive treatments are puncture of the aneurysm sac, with removal of the aneurysm sac contents,[82] or (laparoscopic) fenestration of the aneurysm sac.[82,83] Puncture proved to be insufficient,[82] however, and reported results after fenestration are contradictory, with only a short-term follow-up.[82, 83] At the moment, therefore, open conversion is the only convenient treatment for endotension.[47] However, the risk of death and severe complications of open conversion[84] may be greater than the risk of a watchful waiting policy in case of endotension. Several other reports support a nonoperative approach in the clinically asymptomatic patient with aneurysm enlargement after EVAR, when endoleaks are excluded by well-performed imaging techniques.[47,81]

Table III. Possible mechanisms of endotension. (from S.R. Dubenec et al. Endotension A review of current views on pathophysiology and treatment. J Cardiovasc Surg 2003;44:553-7)

Possible mechanisms of endotension
Pressure transmission to AAA sac around the ends of the graft
– Layer of thrombus between the graft and aortic wall (or iliac artery wall)
– Graft displacement that exposes a layer of thrombus in the aortic neck
– Endoleak channel sealed by thrombus
– Undetected endoleak
– Intermittent endoleak channel
– Very low-flow endoleak channel
Pressure transmission through the graft wall
– High graft porosity
– Microleak through graft interstices
– Transudation of fluid through graft fabric
– Graft pulsatility/ wall movements
Pressure transmission from branch vessels
– Thrombus over orifice of inferior mesenteric or lumbar arteries
Pressure build-up from fluid accumulation
– Graft infection
– Thrombus fibrinolysis/ hygroma
– Genetic modulation
– Enzymatic activity
– Others
AAA Enlargement without elevated pressure
– Genetic modulation
– Enzymatic activity
– Graft infection?
– Growth factors?
– Others

(b) Stent-graft migration is defined significant if displacement of more than10 mm is noted or if migration leads to symptoms or requires therapy.[85] Migration occurs when the displacement forces on the stent-graft exceed the strength of fixation at the proximal and distal attachment zones. A short, proximal aortic neck, an increase of neck angulation, size of the initial neck diameter, growth of neck diameter, more than 30% proximal graft oversizing, and too distal initial device deployment in relation to the renal arteries have all been shown to increase the risk of migration.[86-91] The quality of the distal, iliac fixation might also influence the risk of migration.[91,92]

Risk for migration increases over time and can result in loss of device fixation proximally, distally, or in between modular components, with subsequent aneurysm rupture. The EUROSTAR registry has proven the association between stent-graft migration and aneurysm rupture.[59] In an analysis of 6341 patients after EVAR with a mean follow-up of 21 months (range, 0-108), van Marrewijk et al. reported significant migration in 5% of all patients.[93] The annual incidence rate was 2.8% overall, but for different devices was 0.5% (EVT/Ancure stent-graft) to 5.0% (Vanguard device). Risk of migration was lowest for devices designed with hooks or barbs for better proximal fixation. Devices without hooks or barbs depend on radial force and on columnar strength for fixation. From these devices, the Talent graft performed best on migration, with a 2.4% annual incidence rate.[93] Both the Talent and Zenith devices have a bare stent for deployment across the renal arteries (Figure 3), which enhances the area of the proximal anchoring zone.

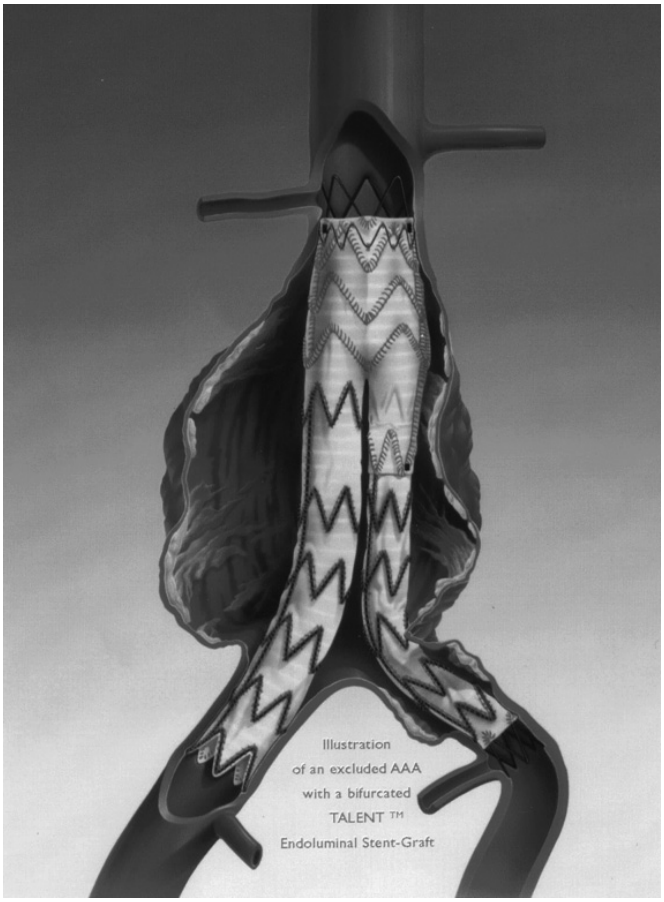

Figure 3. Talent™ stent-graft with a proximal bare stent to enhance the proximal anchoring zone.

Better results might be expected from fenestrated endografts with incorporation of the renal arteries or even the superior mesenteric artery. The first series of EVAR with fenestrated stent-grafts are now being reported.[94-97] In 2005, Verhoeven et al. published pooled data on reported series with a mean follow-up of 11 ± 2 months (range, 1-24).[98] Results were promising, with 99% technical success, 3% type I endoleaks, no renal failure requiring dialysis, and no migration of stent-grafts. However, longer follow-up will be necessary to review the durability of fenestrated endografts.

Plain abdominal radiography following a standardized protocol can detect migration. Especially valuable are lateral projections, with the bone landmarks of the spine used as reference points.[99] However, CT scanning with determination of device movement in relation to a vascular anatomic landmark, such as the superior mesenteric artery, might even be more adequate in the screening for and quantification of stent-graft migration.[100]

The clinical significance of stent-graft migration is debatable. One opinion is that stent-graft migration can lead to sudden loss of "seal," with immediately disastrous consequences and, therefore, should be treated as soon as possible after detection. No evidence for this can be found in the literature. In general, patients with stent-graft migration undergo close surveillance and reintervention is performed when endoleaks occur, when the sealing zone becomes less than 10 mm or when the aneurysm size increases. In the AneuRx clinical trial, migration was reported in 8.4% of 1194 patients, with a mean time of 30 ± 11 months after implantation.[91] There was no significant correlation between stent-graft migration and the presence or absence of endoleak.[91]

In the AneuRx clinical trial, 68% of the patients with device migration have not required treatment thus far.[91] Conners et al. and Cao et al. reported similar experiences with reintervention rates of 33% and 47% in patients with migration.[101, 102] When treatment is required, this can usually be performed endovascular. This was possible in 77% in the AneuRx trial[91] and in 75% in Cao et al. study.[102] Conners et al. were able to use endovascular extender cuffs in 100% of patients with migration who needed treatment.[101] Durability after endovascular treatment of migration is yet unknown. Migration of the main device might continue, with possible component separation in future.

(c) *Graft thrombosis* is the third most common reason for readmission to the hospital after EVAR.[103] Drury et al. report incidence rates of 2.5% for acute occlusions and 3.9% for thrombosis as a delayed event.[40] From the EUROSTAR registry database, the reported overall annual incidence rate for occlusion is 3.2%, with a 1.1% to 5.3% range between different devices.[93] Supported and unsupported grafts have different risks of occlusion.[104,105] This because the lack of device support predisposes the graft to angulate and kink, resulting in stenosis and, therefore, in risk for graft thromboses. Even in a short follow-up period, a 15-fold difference is reported between unsupported and supported stent-grafts.[106]

Anatomic factors can also potentially lead to endograft limb occlusion. Tortuous iliac artery anatomy, preexisting iliac stenosis, and a high degree of angulation predispose the endograft to kinking, which can result in limb occlusion. Deployment of the endograft limb in the external iliac artery is another proven risk factor,[105, 107] probably because of the tortuosity between the origin of the common iliac and the external iliac artery as well as the smaller size of the external iliac artery or compromised runoff via this limb caused by the loss of hypogastric artery outflow. Women are at higher risk for graft limb occlusion, probably because their iliac arteries have smaller diameters.[106, 108] Furthermore, dissection of the femoral or iliac arteries, either preexisting or as complication of stent-graft implantation, can cause limb occlusion.

When graft limb thrombosis occurs, patients typically complain of acute onset of pain and paresthesis in the affected leg. Fortunately, most patients do not have motor dysfunction that would necessitate an immediate surgical revascularization.

Several approaches have been advocated in literature for the management of graft limb occlusion. Standard surgical thrombectomy might be hazardous, as it might dislodge or separate the modular endograft, which is mostly held in place by radial force or self-expanding stents.[109,110] To avoid graft manipulation, several surgeons performed femorofemoral bypass grafting, which restores perfusion of the affected limb. However, overall 5-year patency rate of femorofemoral bypasses is 59% to 92%,[111,112] which might be inferior to restoration of flow in the endograft limb. Three techniques are available for endovascular treatment of graft limb occlusions: rheolytic thrombectomy, thrombolytic therapy, and endovascular recanalization, with or without stenting. These methods can be used alone or combined. An endovascular approach is successful in more than 80% of cases,[113] and when the mechanical cause of the occlusion has been treated, a 100% rate of secondary patency might be achieved.[110]

(d) *Aneurysm rupture* as a complication is the ultimate failure, because prevention of rupture is the main goal of EVAR. Reported incidences of rupture after EVAR are low and vary between 0.2% and 1% annually.[59,93,113-121] Identified causes for rupture include migration, type I and type III endoleaks, kinking, proximal neck diameter of more than 26 mm, aneurysm diameter of more than 6 cm, and poor proximal or distal fixation.[28, 119,120] Noncompliance with standard follow-up schedules has also been identified as a factor contributing to late rupture.[116, 120] However, the absence of complications before rupture in some patients who regularly attended follow-up, highlights the difficulty of predicting rupture after EVAR.[120]

For treatment of rupture after EVAR, most patients undergo emergency open conversion, with mortality rates of 38% to 50%,[114,116,120,121] but secondary endovascular grafting can also be considered. From the EUROSTAR database, Fransen et al. reported aneurysm rupture after EVAR in 34 patients (0.8%),[120] of whom 7 were treated with renewed endovascular grafting, with a 71% survival rate. Conventional open repair of aneurysm rupture was performed in 19 patients, with a survival rate of 47%.[120]

Mortality after EVAR

First multicenter randomized trials for assessing the value of EVAR against open repair are the British Endovascular Aneurysm Repair trials (EVAR I and EVAR II) and the Dutch Randomised Aneurysm Management (DREAM) trial. Mid-term results of these trials are now available. EVAR I showed similar all-cause mortality rates for open and endovascular repair 4 years after randomization in patients who were otherwise fit for open repair. Aneurysm-related death was 4% in the EVAR group, which was significantly lower than the 7% in open repair ($P = 0.04$).[122] The DREAM trial showed comparable survival 2 years after randomization. The advantage of EVAR for aneurysm-related death was seen after 1 month in this trial, but this was not sustained after 2 years.[123]
The EVAR II trial compared results between EVAR and best medical treatment in patients who were unfit for open repair. Overall mortality in these patients after 4 years was as high as 64%. There was no significant difference between the EVAR group and the group that had no intervention for all-cause mortality ($P = 0.25$) and aneurysm-related death ($P = 0.43$).[124]

Mid-term results of these multicenter randomized trials validate the use of EVAR as a treatment for infrarenal AAAs in fit patients. The EVAR II study shows that in very sick patients, a ruptured aneurysm is usually not the cause of death, and thus, offering these patients EVAR is not advocated.

Quality of life after EVAR

EVAR, with its smaller wounds, less blood loss, and shorter hospital stay, is considered a less invasive procedure compared with open aneurysm repair: Therefore, a better quality of life after EVAR compared with open aneurysm repair might be expected. The DREAM and EVAR-I trials did compare quality of life after open repair and EVAR. On behalf of the DREAM trial participants, Prinssen et al. reported the impact on the quality of life of both EVAR and open repair.[125] Both groups had decreased quality of life, especially in the first 3 weeks after the intervention. In the physical domains category, this decrease in quality of life parameters is significantly more manifest in the open repair group. After 3 months, this difference between the EVAR and open repair groups had disappeared, and what is most remarkable, after 6 months, patients reported an even better quality of life after open repair than after EVAR. In fact, patients scored better after open repair than preoperatively. The authors hypothesized that people experience a relatively better quality of life after a period of severe illness or major surgery.
EVAR-I trial participants reported almost comparable results[122]. From 0 to 3 months, the open repair group had a diminished quality of life, which had recovered by 3 to 12 months. By 12 to 24 months after randomization, there was no difference between the groups.

Endovascular repair of ruptured abdominal aortic aneurysms

In 1994, Yusuf et al. were the first to report an emergency endovascular repair of a ruptured aortic aneurysm.[126] In theory, the advantages of the endovascular technique in ruptured aneurysms are the facts that the abdominal wall is kept closed and the retroperitoneal hematoma is unreleased, which hamper further blood loss because of the tamponade effect. It also provides the possibility of avoiding general anaesthesia in hemodynamically unstable patients.[127] To diminish the period of bleeding in ruptured aneurysms, the use of an aortouniiliac endograft with a contralateral occluder and femorofemoral crossover bypass is advocated.[128] An aortouniiliac device can be deployed relatively simply, and the possible time-consuming cannulation of a contralateral gate is avoided.

A disadvantage of EVAR for ruptured aneurysms is the need for a preoperative CTA to monitor aneurysm morphology to evaluate feasibility of EVAR. Therefore, an important requirement for emergency EVAR is prompt availability of CT facilities. Because of morphologic features, EVAR is only feasible in 40% to 62% of patients who present with a ruptured AAA.[128-130] The required CTA might induce a potentially dangerous treatment delay for patients who are unsuitable for endovascular repair. For patients suitable for endovascular repair, the decrease in mortality, morbidity, and hospital length of stay has been reported in nonrandomized series.[129,131-133] It is possible, however, that results of open repair in hospitals that perform EVAR for ruptured aneurysms become worse, because all patients are delayed in treatment as a result of the pre-operative CTA, and the patients with a more challenging morphology will persist in the open repair group. Multicenter randomized studies are necessary to answer the question if endovascular aneurysm repair improves overall mortality in the treatment of ruptured abdominal aortic aneurysms.

Summary

In the last decade, EVAR has gained worldwide popularity for treatment of infrarenal abdominal aortic aneurysms. EVAR proved to be less invasive compared with open repair, and the outcome of first randomized trials validated the use of EVAR in fit patients. EVAR is related to specific complications, however. This requires knowledge of techniques and pitfalls, adequate patient selection, efficient logistics, angiography suite experience, and close patient surveillance.

In the future, new stent-graft technologies will probably make EVAR more applicable and more durable. First results with fenestrated grafts are promising for applicability of EVAR in patients with short aneurysm necks, and less migration rates are expected. Development in EVAR will continue, and long-term results of multicenter randomized trials will eventually make clear if there are patients in who open aneurysm repair is indicated and which patients will benefit most from this challenging technique.

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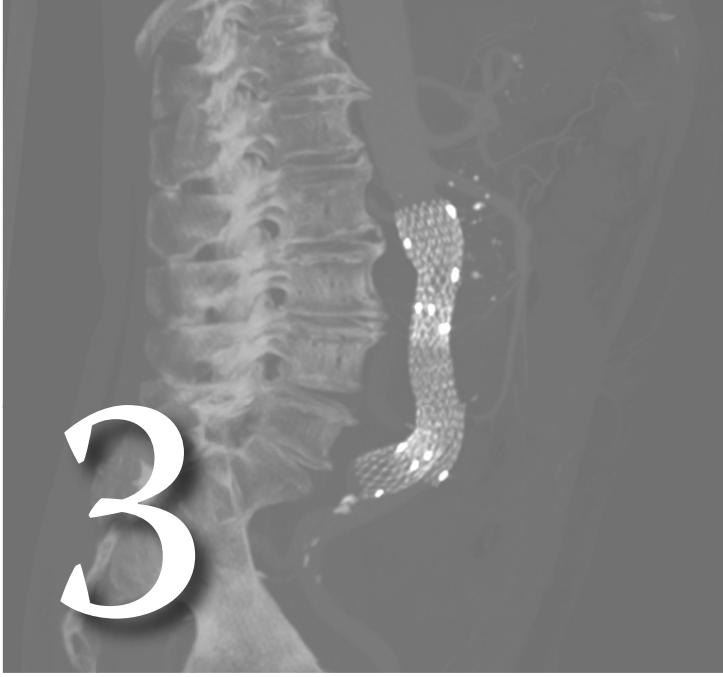

Chapter 3

Three year single centre experience with the AneuRx aortic stent graft

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Abstract

Objectives: To report the mid-term single-centre experience with the AneuRx self-expandable nitinol stentgraft for endovascular aneurysm repair.

Patients and Methods: Between December 1996 and January 2000 a total of 128 patients were treated with an AneuRx bifurcated stentgraft. Of these, 77 patients had a minimum follow-up of 12 months. Patient operative and follow-up data were prospectively gathered.

Results: Two (3%) conversions were necessary. Median hospital stay was 3 days. One superficial wound infection occurred. Periprocedural (30 days) mortality was 5% (four patients). Three graft occlusions were noted of which two required treatment. Fifteen patients developed 18 endoleaks (six type 1, eight type 2 and four type 3). Type 1 and type 3 endoleaks were treated by extender cuffs. Four type 2 endoleaks were treated with embolization or direct lumbar puncture. Two-year freedom from endoleak was 76%. Graft migration occurred in six cases, resulting in a 2-year freedom from migration of 90%, kinking only once.

Conclusions: Endovascular AAA treatment is feasible and so far mid-term results are without major problems. Extensive follow-up is essential as secondary problems may occur later. Long-term results are to be awaited.

Introduction

Since the first endovascular aneurysm repair in humans by Parodi in 1991[1] many different stentgrafts have been designed.[2–12] it is still not clear which system provides the best long-term results. Of all the commercially available products the longest experience is with the EVT (currently named Ancure device) of Guidant Corporation and the Vanguard of Boston Scientific Corporation. Mid-term fixation stability results of the EVT device were published earlier.[13,14] Most reports on the AneuRx device are descriptions of short-term results.[15-17] The longest described experience is the FDA study published by Zarins et al.[18] In many reports results are described of multicentre studies or with mixed data from registries. Advantage of these multicentre studies is the relatively large amount of patients included in a relatively short time span. Disadvantage is the variety of centres, each with different experience and a large number of treating physicians. Each centre has to go through its own learning curve and this may influence outcome. In our opinion, although the numbers may be a little smaller, single centre experiences can be very valuable. The aim of this study is to describe our experience with the AneuRx stentgraft.

Patients and Methods

As the AneuRx stentgraft has a maximum diameter of 28 mm and a delivery system of 21 Fr, inclusion criteria were a minimum diameter of the access vessels of 7 mm and a maximum diameter of the infrarenal neck of 25-26 mm. Pre-operative evaluation included contrast enhanced helical CT scan (Philips Tomoscan SR 7000, Philips Medical Systems, Best, The Netherlands) and intra-arterial or intravenous DSA (Philips Integris C 3000, Philips Medical Systems, Best, The Netherlands). During implantation fluoroscopy, angiography (Philips OPC 9, Philips Medical Systems, Best, The Netherlands) and intravascular ultrasound (IVUS) with the Hewlett Packard HP 500 machine (Hewlett-Packard, Andover, Massachusetts, U.S.A.) and a 6.2 Fr/12.5 MHz IVUS monorail catheter (Sonicath, Meditech- Boston Scientific Corporation, Maple Grove, MN, U.S.A.) were used. Preoperatively, all patients received 1500 mg cefuroxime intravenously and a bilateral vertical groin incision was performed. For intraoperative angiography and IVUS measurements a 7 Fr introducer sheath was inserted by puncture in the common femoral artery followed by a transverse arteriotomy in the common femoral artery to introduce the delivery system of the stentgraft. After measurements, but before introduction of the delivery system, 5000 IU of heparin were given intravenously. A superstiff Backup Meier guidewire (Schneider Corporation – currently Boston Scientific Corporation, Bülach, Switzerland) was used. After deployment of the stentgraft and after satisfying completion angiography the arteriotomies were closed with a running Prolene 5.0 (Ethicon Inc., a Johnson & Johnson Company, Somerville, NJ, U.S.A.) suture. The wound was closed with a running Vicryl 4.0 (Ethicon) subcutaneous suture and a Vicryl Rapide 4.0 intracutaneous suture. No drains were left *in situ*. Follow-up consisted of early phase contrast enhanced CT scanning pre-discharge (day 2) and at 3 months and 12 months postoperatively and annually thereafter. At 6 months duplex scanning was performed. Endoleaks were classified according to the classification proposed by White et al.[19-21]

As the short-term one year results were published earlier, the focus of this study is on the mid-term results and behaviour of the stentgraft. Therefore, only patients with at least 12 months of follow-up were included in this study. Between December 1996 and January 2000 128 patients were treated with an AneuRx bifurcated stentgraft. A total of 77 patients had a minimum follow-up of 12 months. Of this group 75 were men and two women. Mean age was 70 (range 51–87) years. American Society of Anesthesiologists (ASA) classification was 54% ASA 2, 42% ASA 3, 4% ASA 4. Forty-five patients had a follow-up of 24 months and 11 patients of 36 months. All patients were operated under general anesthesia by a team consisting of one vascular surgeon and one interventional radiologist. In total only three different vascular surgeons and three different interventional radiologists were involved in all procedures. Intraoperative problems, hospital stay, wound complications, early and late graft occlusion, endoleak, graft migration, graft kinking and secondary interventions were prospectively noted. All data were put in the Eurostar registry and results of these data are published in this paper.

Results

During follow-up one patient was lost to follow-up, because of terminal pulmonary disease. Four (5%; 95% confidence interval: 1–13%) patients died within 30 days of the operation. Another 10 patients died within 1 year after the procedure, one died during the second and none died the third year of follow-up. None of deaths were device or aneurysmal disease related. Fifty-three percent had cardiac related deaths, 47% died because of progression of co-existing disease (cancer or pulmonary dysfunction) or general condition (elderdom).

Intraoperative problems

Deployment of the graft was technically successful in all but three cases. In two (3%; 95% CI: 0-9%) cases intraoperative conversion was necessary. In one of these cases it appeared impossible to insert the deployment system past a bilateral very narrow and calcified external and common iliac artery. Predilatation could not resolve this problem. Conversion was performed uneventfully. In the other patient after deployment of the main segment of the modular stentgraft it appeared impossible to manipulate a guidewire past a very narrow distal aneurysmal neck. The deployed limb of the main graft already occluded the lumen of the distal neck. Efforts by using a brachial approach to manipulate the guidewire between graft and arterial wall were unsuccessful. At conversion attempts were made to manipulate the guidewire with manual assistance past the occluded lumen, but appeared impossible. Uneventful full conversion was completed. In a third case deployment was performed suprarenal and laparotomy was performed with the intention to perform a conversion. After laparotomy but before exposing and clamping the aorta it was decided to try to resolve the problem with endovascular techniques. We managed to pull the stentgraft to a just infrarenal position by inflating a 25 mm. aortic balloon just above the flow divider of both limbs. With gently pulling forces it was possible to manipulate the stentgraft in the right position and a full conversion could be avoided. In this patient no postoperative renal impairment occurred.

Hospital stay

All patients underwent an in hospital predischarge spiral CT scan. Median hospital stay was 3 days (range 1-44). Delayed hospital stay of more than 5 days occurred in 13 patients. Four patients because of fever without objective signs of infection, one patient had a small endoleak which was observed and resolved on duplex scanning on day 6, in one patient a *de novo* lung cancer was diagnosed and analyzed, one patient had persistent hypertension and cardiac problems requiring in-hospital treatment, one patient had a superficial wound infection, one patient required a laparotomy because of renal artery occlusion by the stentgraft which was finally resolved with endovascular technique (see also sector intraoperative problems), one patient had neuralgia which prolonged hospital stay, one patient developed diverticulitis which was treated conservatively. Finally in two no explanation for prolonged stay could be found in the patient's records.

Wound complications

In all but one patient the groin incisions healed uneventfully. In one patient a superficial wound infection occurred. This was treated by removal of skin stitches and antibiotics. No deep infection or graft infection occurred, neither at follow-up.

Graft occlusion

At follow-up three limb graft occlusions were noted. One patient with a pre-existing tight iliac artery stenosis and extensive collateral circulation developed a limb occlusion with only slight increase of claudication symptoms. It was decided to accept this occlusion without further treatment. The other patient developed an acute occlusion of one limb 6 months after graft implantation, which was treated with fibrinolysis using urokinase. After successful fibrinolysis a narrowing of the graft was found at a pre-existing stenosis in the common iliac artery. This was treated with PTA and the vessel is patent up to now. Primarily at implantation this stenosis was recognized but considered as insignificant. This appears to have been a misjudgment. One patient required successful thrombectomy. This resulted in a primary patency of 98%, and secondary patency of 99% after 2 years.

Endoleak

For endoleak detection contrast enhanced spiral CT scan was used. In case a type-1 or type-3 endoleak was found, the patient was scheduled for repair or intervention on a short time basis. In type-2 and type-4 endoleak our policy is either to perform an embolization or use a wait and see policy. In seven patients (6%) six type-1 endoleaks were found (one at 6 months, three at 1 year and two at 2 year follow-up) and four type-3 endoleaks were found (one at 3 days, two after 1 year and one after 2 years). Three patients had both a type-1 and type-3 endoleak. In two patients it was discovered at the same time (after 1 year), in the other there was a time interval of 1.5 years between the two interventions. In one patient within one week after operation an extender cuff was placed at the connection between main body and iliac limb because of inappropriate placement of the iliac limb that was not noted at the time of operation. These type-1 and type-3 endoleaks were treated with either extender cuffs or interposition grafts (Fig. 1). All reinterventions were successful.

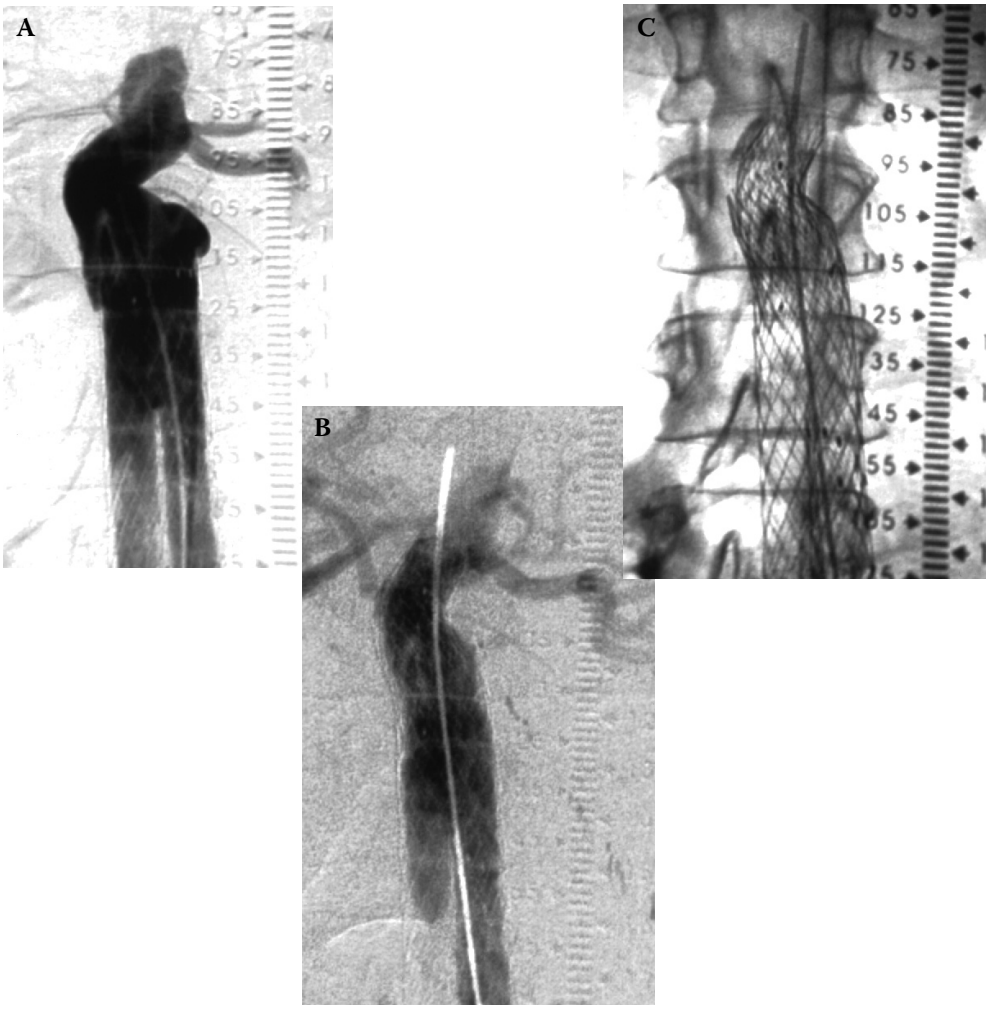

Figure 1. Example of a type 1 proximal endoleak treated by placing a proximal aortic extender cuff. Proximal endoleak is clearly visible on angiogram (A). After placement of the proximal aortic cuff, a good sealing is created up to the renal arteries (B). Plain X-rays show the skeleton of the stentgraft after (C) placement of the proximal cuff.

A total of eight type 2 endoleaks were noted. Four patients are being evaluated. In four patients with a type-2 endoleak successful treatment was performed. Two patients were treated with direct CT guided translumbar puncture in the aneurysm and open lumbar artery and α-amino capronic acid was injected (Fig. 2).

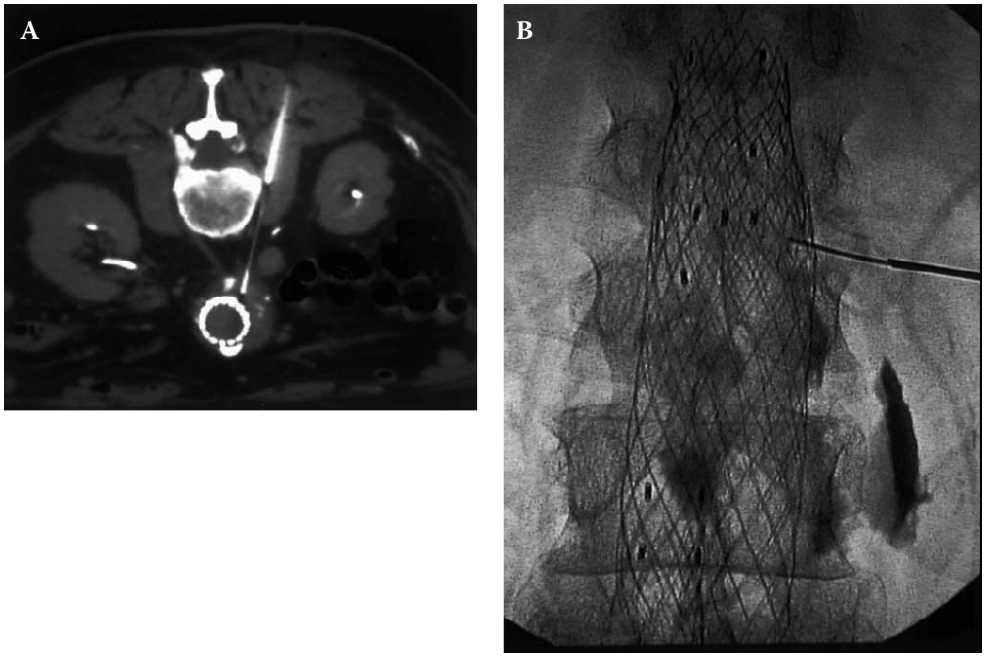

Figure 2. Example of treatment of type 2 endoleak by means of direct puncture. CT-guided direct puncture of the aneurysm sac is performed at the level of the endoleak (A) in prone position. Patient is transported to the angiosuite and contrast is injected which is visualised as collections in the aneurysm sac (B). After the position of the needle is verified a siccative agent (in this case capronic acid) is injected to thrombose the endoleak.

In two patients embolization of the inferior mesenteric artery was performed by selective catheterization via the superior mesenteric artery and Riolan's arcade (Fig. 3).

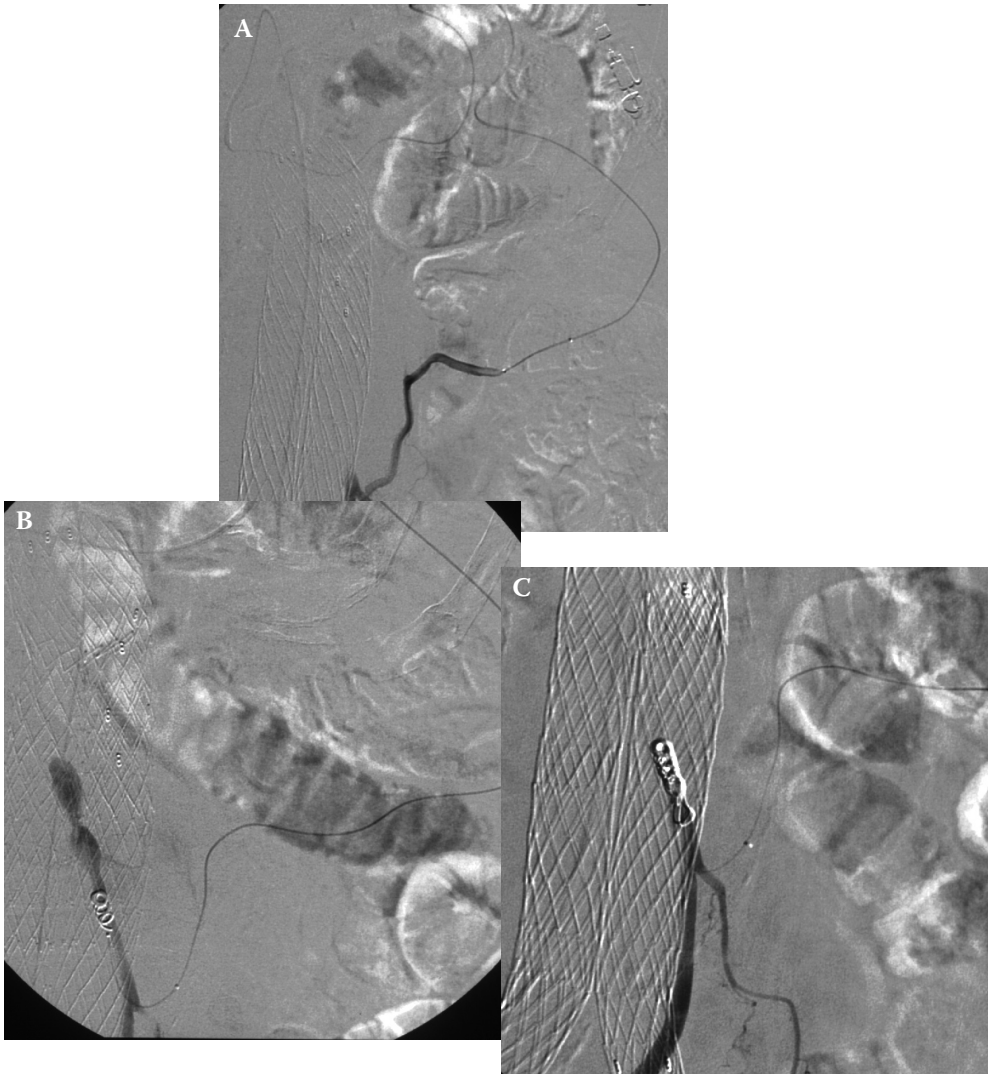

Figure 3. Example of treatment of type 2 endoleak by means of selective embolization. Selective embolization by means of catheterising the SMA and Riolan's arcade. Contrast is injected and the endoleak is visualised (A), first coils are deployed at the origin of IMA near the aneurysm sac but the endoleak is still visible (B). Finally after deploying extra coils the leak is fully sealed (C).

All secondary interventions were successful without recurrence of endoleak at the treated site at follow-up. No mortality was seen in association to reinterventions. No delayed ruptures of the aneurysm were seen. Two-year freedom from endoleak was 76% (Fig. 4).

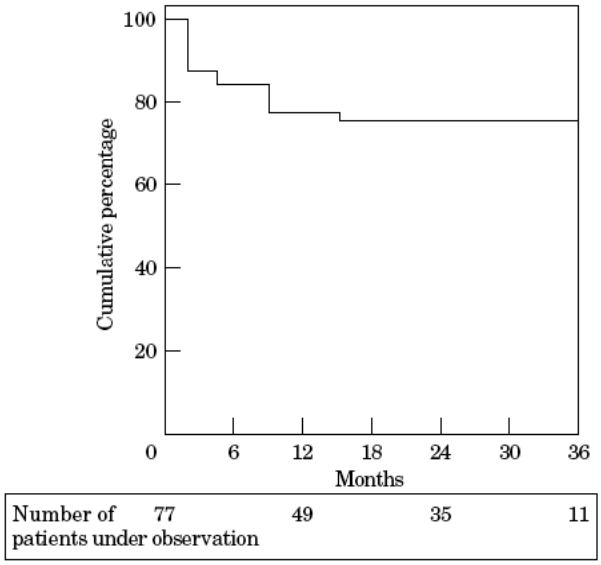

Figure 4. Life table: freedom from endoleak.

Graft migration

Graft migration could be demonstrated in six patients (Fig. 5). In two patients a slight displacement at the proximal attachment sight was seen resulting in an endoleak. These were treated with an aortic extender cuff. In both patients the preoperative neck diameter was 26mm and they were treated in the beginning of this series. Our policy since then is to include only patients with a maximum diameter of 25 mm. In one patient one iliac limb "popped" out of the common iliac artery into the aorta 6 months after the operation. In this patient the distal limb was placed too proximal in the common iliac artery resulting in only 5-mm attachment zone. At operation this was accepted but after shrinkage of the aneurysm it proved to be a too short anchoring zone and dislocation occurred. This was treated with an extender cuff.

In three other patients in whom a proximal endoleak occurred no displacement of the graft could be demonstrated.

In three patients an additional interposition stentgraft was placed at a connection of the modular system. Dislocation at the connection occurred probably because of shrinkage of the aneurysm, twice after 1 year and once after 2 years. Two-year freedom from migration was 90% (Fig. 5).

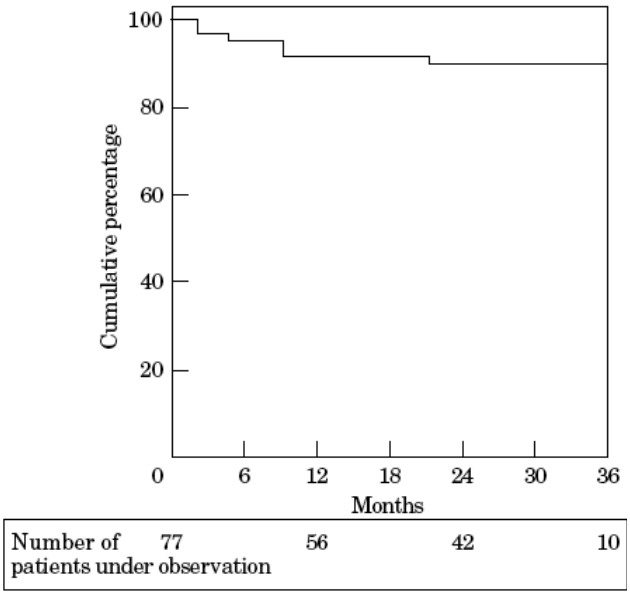

Figure 5. Life table: freedom from migration.

Graft kinking

Kinking of the graft occurred in only one patient. This happened after shrinkage of the aneurysm and resulted in a limb kink that was successfully treated by PTA.

Discussion

The high mortality and therefore "lost to follow-up" reflects the fact that most patients had serious comorbidity. Despite this, most patients were discharged within 3 days of surgery. Morbidity was low. In general, the patients themselves were very enthusiastic about their fast recovery.

Both conversions could have been prevented. In one case the inclusion criteria were not strictly followed. In the other case inexperience with this problem was the reason for conversion. Since this second case, it is our policy (in the presence of a tight distal aortic neck) to make sure to have a contralateral guidewire or catheter in the aneurysm before deploying the main device of the stentgraft. Using this contralateral guidewire it is possible to guarantee access to the short limb of the ipsilateral placed main body and deploy the iliac limb.[22] Usually after deployment of the iliac limb it is necessary to dilate the distal aortic neck slightly with the kissing balloon technique. In this way we managed to prevent conversion in two other similar cases.
In general, a prolonged hospital stay was due to postoperative problems which were non-device related.

Graft occlusions occurred only three times. In two cases a pre-existing iliac artery stenosis existed. We now tend to be more liberal in dilating the stentgraft if we notice a not fully deployed segment of the stentgraft, especially in pre-existing stenoses. Endoleak in this series is in accordance with other publications.[23-25] In our opinion, type-1 and type-3 endoleaks need to be treated immediately to eliminate the risk of rupture. In many cases it is possible to resolve the problem with an endovascular or minimal invasive technique. Adequate interventional experience is required however.
Graft migration did occur with this type of stentgraft. It seems that proximal stentgraft migration leading to proximal endoleak is less frequent than dislocation at then connections. In both patients with proximal graft migration the preoperative neck diameter was 26mm and they were treated early in this series. Our policy since then is to include only patients with a maximum diameter of 25 mm. Accurate preoperative measurements based on good quality images are the key to success. Intraoperative IVUS measurements can be of additional value.[26] If at the distal landing zone only a short contact area between stentgraft and iliac artery exists, an extender cuff should be placed immediately. With this policy we could have prevented at least one re-intervention. The same applies for the connection zone of a modular system. With the AneuRx stentgraft this overlap should be at least 2 cm at the connection between main graft and contralateral limb and at least 1–1.5 cm between limbs and extender cuffs. At connection sites of the modular system we tend to perform a routine balloon dilatation to guarantee proper sealing.

As described in other series,[27-30] shrinkage of an excluded aneurysm can cause kinking of the stentgraft. In our series we found this kinking in only one patient,[27-30] possibly because the stentgraft is fully supported over its whole length. Secondary interventions were necessary in 11 patients and occurred even after 2 years. This stresses the importance of

performing extensive follow-up as the long-term results are not known.
As with other devices, the endovascular treatment of AAA's is not without problems, but most can be solved with a minimal invasive technique. These compatible extender cuffs are a worthwhile item of the AneuRx stentgraft system. It increases flexibility and offers bailout options, but on the other hand can introduce future problems at the connection site as a result of dislocation. The recently developed conversion kit offers even greater flexibility to handle late incompletenesses or in some cases offers a bailout opportunity in case of an initial failure. Our mid-term experience and the general lack of knowledge in the long-term stresses the importance of performing extensive follow-up. Also it is important to put all data in a central registry like Eurostar. Only in this way we can learn of earlier mistakes and improve the results for future endovascular treatments.

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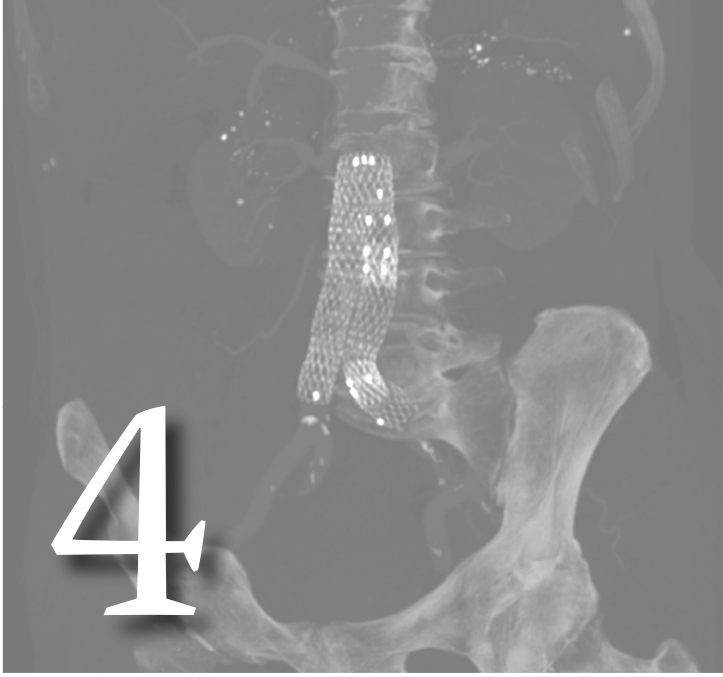

Chapter 4

Endovascular repair of paraanastomotic aneurysms after previous open aortic prosthetic reconstruction

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Abstract

The aim of this study was to evaluate the effectiveness of endovascular repair of anastomotic and true aortic and iliac aneurysms occurring after prior polyester graft repair for abdominal aortic aneurysms (AAA) or aortoiliac obstructive disease. Between July 1999 and January 2003, 14 patients underwent endovascular treatment of aortic pseudoaneurysms (n = 6) or iliac aneurysms (2 patients with pseudoaneurysms and 6 patients with true aneurysms) occurring 4 to18.4 years (mean 8.8 years) after open aortic surgery. No patient had symptoms or positive parameters for infection of the original polyester graft.

Eleven patients, including one patient with both a proximal anastomotic and a true iliac aneurysm, were treated with AneuRx (n = 8), Talent (n = 2), or Quantum LP (n = 1) bifurcated stent grafts. Three patients with an infrarenal anastomotic pseudoaneurysm were treated with a tube stent graft (Talent [n = 2] and AneuRx [n = 1]). Endovascular stent grafts were successfully inserted in all patients. Procedure-related complications or death were not seen. During a median follow-up of 12 months (range, 3-40) all anastomotic and/or true aneurysms treated with bifurcated stent grafts maintained excluded. However, two out of three patients, treated with a tube graft for proximal anastomotic aneurysm exclusion, were converted. In both patients the tube stent graft did not migrate from the level of the renal arteries but fixation failed between the stent graft and the previous polyester graft, creating endotension in the thrombus of the aneurysm sac. In one of these patients the old anastomotic aneurysm ruptured 16 months after stent graft placement and the patient died 1 day after conversion because of mesenterial ischemia. At 1 year follow-up the second patient was converted successfully after enlargement of his anastomotic aneurysm due to similar disconnection between the stent graft and the polyester graft.

From this experience with endovascular stent grafts, we conclude that these can be used successfully to exclude anastomotic or true aneurysms after open aortic surgery. Exclusion of aneurysms at the proximal anastomosis with tube stent grafts is apparently not durable because of the insecure distal fixation in polyester grafts. Endovascular repair with bifurcated stent grafts, however, seems to be effective at mid-term follow-up.

Introduction

Conventional abdominal aortic prosthetic reconstruction for repair of an abdominal aortic aneurysm (AAA) or aortoiliac obstructive disease is generally a durable procedure. However, reoperations are technically challenging procedures that require dissection through previous scarred operative sites in patients who are likely to have more comorbidity than that with primary aortic surgery. As a result, mortality and morbidity rates of aortic redo surgery are higher than those associated with primary prosthetic reconstructions.[1-5] Most reoperations are needed because of anastomotic aneurysms or because of true iliac aneurysms.[6] Endovascular repair of pseudoaneurysms and of true iliac aneurysms after aortic prosthetic reconstructions is reported several times in the literature as case reports on four patients or less[7-12] or as a series of patients treated with several different custom-made or homemade devices.[13,14] We present our experience in endovascular repair of anastomotic aneurysms and true iliac aneurysms in 14 patients, after previous open reconstruction with polyester aortic tube and bifurcated grafts, with commercially available stent graft devices.

Patients and Methods

Patients

Between July 1999 and January 2003, 14 male patients with an aortic or iliac pseudoaneurysm or a true aneurysm of the iliac artery after previous aortic prosthetic reconstruction were treated with an endovascular stent graft (Table 1). The patients mean age was 72.8 years. Thirteen patients had undergone previous aortic surgery because of an AAA and one patient had been treated for occlusive disease. All patients were initially treated with polyester grafts. In 10 patients a tube graft was used, and 4 patients were treated with a bifurcated graft.

Five patients had developed one aortic pseudoaneurysm at the proximal (n = 4) or distal (n = 1) anastomosis. One patient developed a pseudoaneurysm at the iliac anastomosis and seven patients had uni- or bilateral true iliac aneurysms. Furthermore, one patient had a pseudoaneurysm at the distal aortic anastomosis combined with true iliac aneurysms at both sides. The diameters of the aneurysms ranged from 2.7 to 11.5 cm for the aortic pseudoaneurysms and from 2.1 to 7.5 cm for the true iliac aneurysms.

The paraanastomotic aneurysms, which were true iliac aneurysms, anastomotic aneurysms of the iliac artery, or aortic anastomotic aneurysms, were detected at a median interval of 7 years (range, 4-18) after the initial reconstruction. In most patients the paraanastomotic aneurysms were detected because of a surveillance protocol that included physical examination and ultrasonography 1, 3, and 5 years after open aortic surgery and every 2 years thereafter. In three patients paraanastomotic aneurysms were found at presentation with abdominal or back pain. None of the patients in this series were treated for a ruptured paraanastomotic aneurysm. Furthermore, none of the patients had symptoms (history of fever or leukocytosis) or computed tomographic (CT) characteristics that were suggestive of graft infection.

Table 1 Clinical characteristics

Patient no.	Age (years)	Primary disease	Initial prosthesis	Pseudo- or true aneurysm	Location	Latency time (years)	Size (cm)	Stent graft
1	76	RAAA	Tube	True	RCIA	6.4	3.4	AneuRx bif.
2	61	RAAA	Tube	Pseudo	Prox. anast.	4	5.5	AneuRx tube
3	77	AAA	Tube	Pseudo	Distal anast.	14.6	2.7	AneuRx bif.
4	72	AAA	Tube	True	RCIA/LCIA	6.7	7.5/6	Talent bif.
5	62	AAA	Tube	True	LCIA	6	3.6	AneuRx bif.
6	77	RAAA	Aortobiiliac	Pseudo	Prox. anast.	5.1	11.5	Talent tube
7	69	AIOD	Aortobifemoral	Pseudo	Prox. anast.	13.5	7	Talent tube
8	79	AAA	Tube	Pseudo	Distal anast.	14.7	5.5	AneuRx bif.
				True	RCIA/LCIA		2.3/2.4	
9	66	RAAA	Aortobiiliac	Pseudo	RCIA	5.7	Unknown	AneuRx bif.
10	76	AAA	Tube	True	RCIA/LCIA	5.1	2.1/3.4	AneuRx bif.
11	65	AAA	Tube	True	RCIA/LCIA	8.2	5/3	AneuRx bif.
12	60	AAA	Tube	True	RCIA/LCIA	4.2	2.5/3	AneuRx bif.
13	82	AAA	Tube	True	RCIA/LCIA	8	3.5/2.8	Talent bif.
14	78	AAA	Aortobifemoral	Pseudo	Prox. anast.	18.4	4.9	Quantum bif.

AAA, abdominal aortic aneurysm; AIOD, aortoiliac occlusive disease; bif.,ifurcated graft; LCIA, left common iliac artery; Prox. anast.; proximal anastomosis; RAAA, ruptured AAA; RCIA, right common iliac artery

Through preoperative risk assessment, four patients were classified as American Society of Anesthesiologists (ASA) class II, eight patients as ASA III, and two patients as ASA IV, on the basis of pre-existing disease. Medical histories of the patients included either chronic obstructive pulmonary disease (n = 2), hypertension (n = 12), or prior myocardial infarction, coronary artery surgery, percutaneous transluminal coronary angioplasty (PTCA), or cardiac failure (n = 7).

Devices

Three patients with a proximal anastomotic aneurysm were treated with an AneuRx (Medtronic, Sunnyvale, CA, USA) (n = 1) or Talent custom-made (Medtronic, Sunnyvale, CA, USA) (n = 2) tube graft. Eight patients (1 distal aortic anastomotic aneurysm, 1 iliac anastomotic aneurysm, 5 true iliac aneurysms, and 1 patient with a distal anastomotic aneurysm and true iliac aneurysms at both sides) were treated with AneuRx bifurcated stent grafts and two patients (both with iliac aneurysms at both sides) were treated with a Talent bifurcated stent graft. In one patient with a proximal anastomotic aneurysm, a Quantum LP (Cordis Corp., Warren, NJ) bifurcated stent graft was used.

Operative Technique

Anatomical characteristics were preoperatively evaluated by contrast-enhanced spiral CT scans and digital subtraction angiography (DSA). All procedures were performed in an operating room by a team including a vascular surgeon and an interventional radiologist. Ten patients were treated under general anesthesia and four patients received regional anesthesia. All stent grafts were inserted through an open femoral arteriotomy. In patients with an aneurysm of the proximal anastomosis, the endovascular device was proximally anchored above the lesion in the native aorta. In cases of a difficult aortic neck, a Talent device was used that allowed for transrenal fixation (Fig.1). Distally the stent graft was anchored in the previous polyester grafts when an endovascular tube graft was used or in native iliac arteries when a bifurcated stent graft was used. For endovascular repair of aneurysms of the distal aortic anastomosis or iliac aneurysms, the stent graft was proximally fixated in the previous polyester graft and distally below the lesion in the common iliac or external iliac artery (Fig. 2). Distal anchoring in the common iliac artery was favorable, but if the aneurysms extended to the iliac bifurcation or into the external iliac artery, the stent graft was distally fixated in the external iliac artery. Preoperative embolization of the hypogastric artery to prevent retrograde flow into the aneurysm was performed only if the aneurysm extended into the external iliac artery.

Surveillance Protocol

Postoperatively, patients were monitored according to a regular endovascular aneurysm repair (EVAR) protocol. Surveillance included basic laboratory testing for renal function, physical examination, and three phase contrast-enhanced spiral CT scans before discharge, at 3 and 12 months, and yearly thereafter.

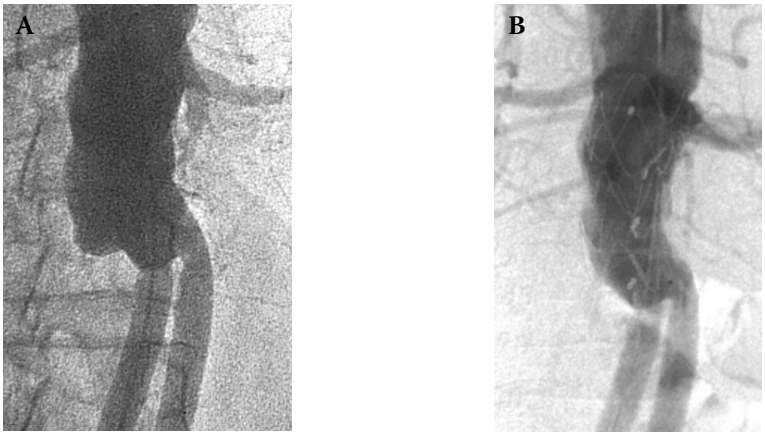

Figure 1. Angiogram before (A) and after (B) insertion of Talent tube graft for proximal anastomotic aneurysm. Because of a wide aorta at the level of the renal arteries, transrenal fixation of the stent was performed.

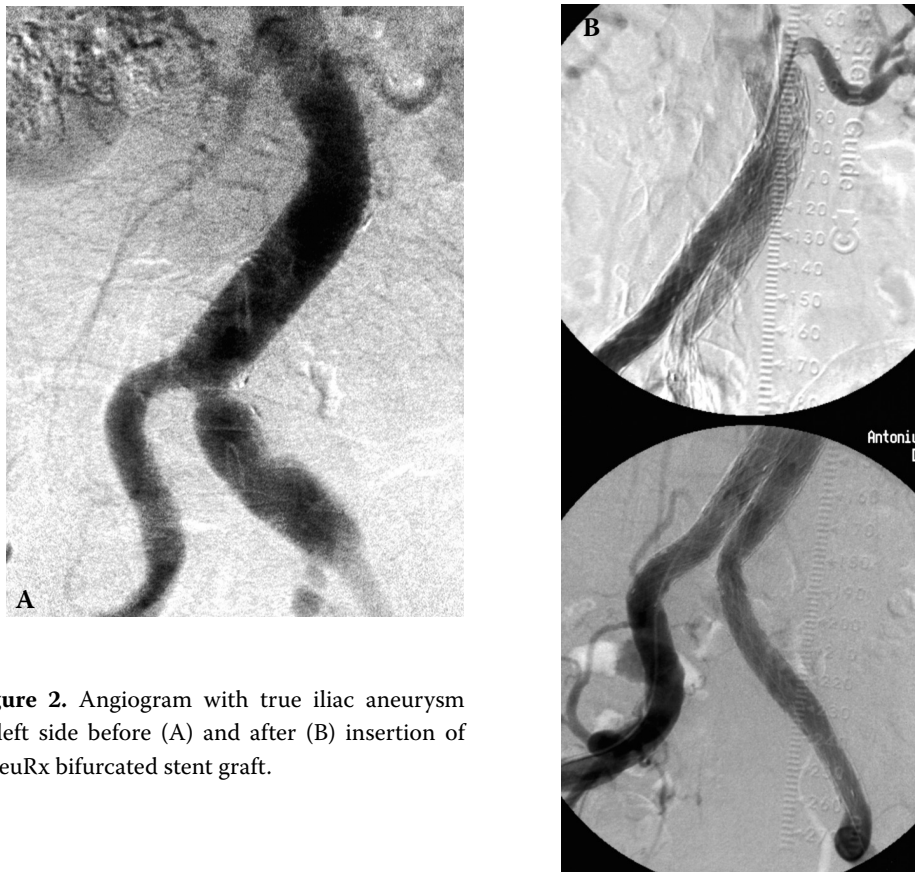

Figure 2. Angiogram with true iliac aneurysm at left side before (A) and after (B) insertion of AneuRx bifurcated stent graft.

Results

Surgery

Stent graft deployment was successful in all patients. There was no operative mortality and no complications occurred during operation. On completion angiography, all aneurysms were excluded and all renal arteries were patent. Also, all hypogastric arteries with planned preoperative patency remained patent. The median duration of the operation was 113 min (range, 80-270) and median blood loss was 350 mL (range, 50-1900).

Hospital Stay

Patients were admitted the day before surgery. Postoperatively, all patients went to a regular or medium care unit. They were put on a normal diet and started mobilizing on the first postoperative day. Pre-discharge CT scans were performed on the second postoperative day (fourth day in hospital) and patients were discharged, if possible, directly thereafter.

Postoperative stay was complicated in one patient, who suffered from a pulmonary infection on the third postoperative day. He was treated with antibiotics intravenously and was discharged in good health on the eighth postoperative day. Median hospital stay was 4 days (range, 2-10).

Follow-up

Median follow-up was 12 months (range, 3-40). Conversion to open repair during follow-up was performed in two patients. One patient developed aneurysmal rupture and was treated for a proximal anastomotic aneurysm with a diameter of 11.5 cm 5 years after he was operated on for a ruptured AAA. At the level of the lowest renal artery the diameter of the aorta was 3 cm. Length of the aneurysm neck was 2.7 cm. The aneurysm was excluded with a transrenal fixated Talent tube graft (36 × 60 mm), which was distally anchored in the previous polyester bifurcated graft (it was 18 mm originally, and dilatated over the years to a diameter of 26 mm) with an overlap of approximately 2 cm. Perioperative angiography and a pre-discharge CT scan demonstrated that the anastomotic aneurysm was successfully excluded. A CT scan performed 12 months following endovascular graft placement documented no sign of endoleak. In addition, the diameter of the treated aneurysm remained unchanged. An additional DSA was performed, which showed no sign of endoleak. A wait-and-see policy was followed and the next CT scan was planned for 6 months later. Sixteen months after stent graft placement, the patient collapsed and was admitted to our hospital. Upon arrival, he was in hypovolemic shock and immediately transported to the operating room for laparotomy. The anastomotic aneurysm had ruptured and when this aneurysm was opened, blood flow was seen through the overlap between the endovascular graft and the polyester bifurcated prosthesis. After stent graft explantation, the aneurysm was re-excluded with a new polyester tube graft anastomosed distally to the old polyester bifurcated graft. Because hemodynamic instability persisted, a second laparotomy was performed the following day. Severe mesenteric ischemia ensued and the decision to refrain from further treatment was made. Several hours later, the patient died.

The second patient who was converted was treated because of a proximal anastomotic aneurysm (diameter 7 cm) 13 years after aortic prosthetic reconstruction for occlusive disease. The diameter of the aorta at the level of the lowest renal artery was 2.9 cm and the length of the aneurysm neck was 5.3 cm. The anastomotic aneurysm was initially successfully excluded with a transrenal fixated Talent tapered tube graft (36-32 × 105 mm). Distally, the stent graft was anchored in the previous polyester graft with an overlap zone of 2.8 cm. After 3 months, the aneurysm diameter showed shrinkage and no abnormalities were seen. After 12 months, a CT scan showed enlargement of the anastomotic aneurysm without migration or sign of endoleak. DSA was performed, which showed complete luxation of the endovascular tube graft out of the previous polyester bifurcated graft. The stent graft was explanted and the anastomotic aneurysm successfully excluded with a new bifurcated graft distally anastomosed to the legs of the old bifurcated graft.

A third patient needed secondary intervention. This patient was treated for true iliac aneurysms 6 years after aortic reconstruction for an AAA with a tube graft. A Talent bifurcated graft was inserted, which successfully excluded both iliac aneurysms. After 3 months, the patient presented with acute lower extremity pain. CT documented complete occlusion of the Talent graft. Thrombectomy was performed but was complicated by a reocclusion directly postoperatively. The cause for occlusion could not be identified and the decision was made to perform an axillobifemoral bypass, which proceeded uneventfully.

In 11 other patients the follow-up (range, 3-40 months) was uncomplicated. In particular, there was no evidence for migration, endoleak, or occlusion and no superficial wound or graft infection. Secondary interventions were not needed in these patients.

Discussion

The reported incidence of paraanastomotic aneurysms varies widely in recent literature. For anastomotic aneurysms, early after the operation an incidence as low as 3% has been reported;[6] however, this incidence increases up to 13.3% in series with longer follow-up.[15,16] The reported incidences of pseudoaneurysms assessed by life-table analysis are 20% and 22.8 % at 15 years.[15,16] True aneurysms are less frequently seen after aortic surgery, with a reported incidence of 4% at 10 years.[16]

The natural history of paraanastomotic aneurysms can be complicated by rupture, thrombosis, embolism, and pressure on or erosion into adjacent structures.[1,4,5] Surgery for ruptured paraanastomotic aneurysms has poor results, with reported mortality rates ranging from 24 to 70%[1-4,17] and morbidity ranging from 70 to 83%.[1,3] Elective open repair of anastomotic or true aneurysms after earlier aortic prosthetic reconstruction is also challenging. Patients are several years older than at the time of primary reconstruction, and dissection through previous scarred operative sites is obligatory. Therefore, mortality rates for elective open repair of paraanastomotic aneurysms are relatively high, ranging

from 3 to 17%,[1-5,17] with only two reports having a mortality rate <8% in asymptomatic patients.[3,17]

Since morbidity and mortality rates in open paraanastomotic aneurysm repair are high compared with those for primary aortoiliac reconstructions, endovascular repair of these lesions could provide an extra advantage for these patients. In recent literature, there have been several reports on endovascular repair of paraanastomotic aneurysms,[7-13] however, most articles are case reports and only two reports are based on series of more than four patients.[13,14]

Yuan et al. described their experience with endovascular grafts for aortoiliac anastomotic aneurysms in 10 patients.[13] They reported successful exclusion of anastomotic aneurysms using homemade devices in all patients, without complications or perioperative mortality.

The largest series was reported by Faries et al.[14] Their experiences in endovascular repair of failed prior endovascular (n = 14) or conventional (n = 33) AAA repair is described with several different commercially available and physician-made devices. In this series, morbidity and mortality were low, but techniques and results were not differentiated between patients treated for complications after open or endovascular AAA repair. We describe the first series of patients treated for paraanastomotic aneurysms with only commercially available stent graft devices.

Deployment of devices in previous aortic grafts was possible in all patients, with successful exclusion of all anastomotic and true paraanastomotic aneurysms. In our moderate group of most patients being assigned to ASA III, we had no perioperative mortality and a morbidity rate of only 7%, because of a pulmonary infection in one patient. In patients treated with bifurcated stent grafts, all paraanastomotic aneurysms maintained excluded. Migrations of the stent graft or endoleaks were not seen. Conversions were not performed and the secondary intervention rate was 9% because of a late complete occlusion of the stent graft in one patient.

The conversion rate was high for patients treated with tube grafts for proximal aortic anastomotic aneurysms. In two out of three patients the endovascular reconstruction was not durable, resulting in an increase in aneurysm diameter in one patient and aneurysm rupture in the other. In both patients the distal anchoring of the stent graft in the previous polyester graft was insecure. All stent grafts in our series were oversized 10-20%. Proximal and distal fixations of stent grafts that were proximally and distally anchored in the native aorta or iliac vessels were uncomplicated. Also, fixations of bifurcated stent grafts anchored proximally in a previous polyester grafts were uncomplicated. However, the distal fixation of a tube graft in a previous polyester graft was insufficient in two out of three cases. The three stent graft systems that we used have a self-expandable nitinol frame. Fixation in these grafts depends on radial expansion of the stent graft against native vessel wall or a previous graft due to oversizing. Because of differences in compliance of previous polyester grafts compared with that of native aortic wall, fixation through only radial expansion force was insufficient. In patients in whom iliac pseudoaneurysms, true aneurysms, or a distal aortic anastomotic aneurysm were treated, the bifurcated stent

grafts were proximally anchored in a previous polyester graft. These fixations proved to be secure during follow-up, probably because fixation in bifurcated grafts is not only dependant on radial force but also on longitudinal columnar support.
In our hospitals we have discontinued the use of endovascular tube grafts for distal fixation in previous polyester grafts and now use only bifurcated stent grafts. If anatomic characteristics make insertion of a bifurcated graft impossible, we consider the use of an aortouniiliac device, which also provides longitudinal columnar support.

Conclusions

Endovascular exclusion of noninfected paraanastomotic aneurysms occurring after previous aortic surgery is feasible. Perioperative mortality and morbidity are low, which is a significant advantage over standard open repair. Exclusion of paraanastomotic aneurysms by insertion of a bifurcated stent graft is effective initially, although longer follow-up is necessary. Exclusion with an endovascular aortic tube graft, however, appears not to be durable because of insecure distal fixation between the stent graft and previous prosthesis. For patients after conventional or endovascular treatment of AAA or paraanastomotic aneurysms, lifelong surveillance is necessary.

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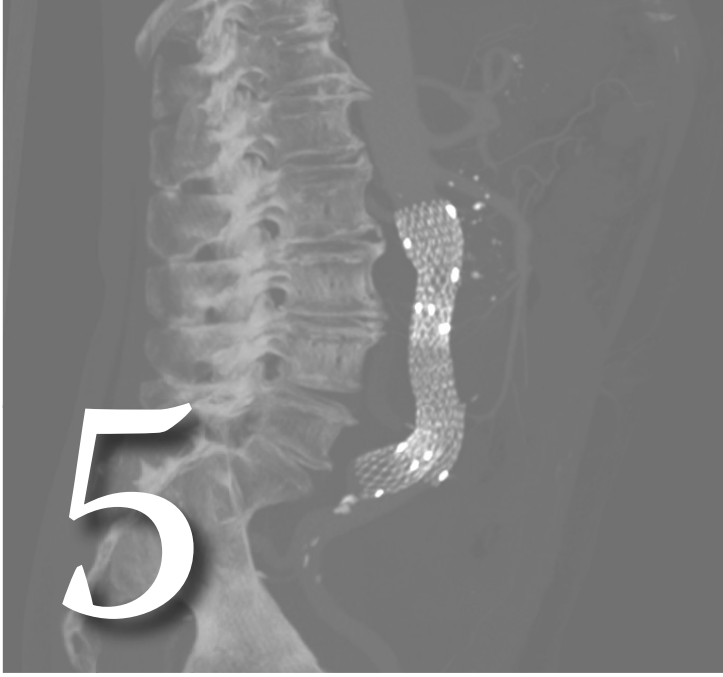

Chapter 5

Clinical outcome and technical consideration of late removal of abdominal aortic endografts: 8-Year single-center experience

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Abstract

During an 8-year period, 355 patients underwent endovascular repair of mainly true (97%) infrarenal aneurysms. After a mean follow-up of 48 months, 11 (3.1%) patients required conversion to open repair and 10 were eligible for open surgical intervention. Via a midline incision, explantation of the endograft was performed by using an infrarenal aortotomy. Explantation was done for rupture in four patients (40%), with a marked difference in mortality rates between acute (50%) and elective (0%) explantations.

The main reason for explantation was proximal type I endoleak caused by (1) malposition of the device, (2) proximal migration of the endograft, and (3) dislodgment of a tube endograft that followed former central reconstruction. Proximal migration is most worrisome and demands preventive endovascular reintervention.

The mortality and morbidity rates of elective explantation are acceptable. When delayed conversion is indicated, priority has to be given to operate on these patients.

Introduction

Since the early 1990s, the endovascular repair of abdominal aortic aneurysms (EVAR) has proliferated at a dramatic pace. In most vascular centers, endoluminal stent-graft placement has become the preferential treatment, with excellent immediate technical and clinical results.[1,2] Despite initial successful exclusion of the aneurysm sac, recurrent graft surveillance is required. Endovascular grafts can fail in a number of ways, including migration, dislodgment, or infection, which can lead to renewed arterial perfusion of the aneurysm (endoleaks) with considerable risk of rupture.[3,4] The frequency of these major complications seems to increase with longer follow-up.[5,6] Although most of the problems can be solved with endovascular techniques, some cannot, and endograft explantation is necessary.

We began performing EVAR procedures in 1996, and in the last 12 months of follow-up, we were faced with a growing number of endograft failures that required surgical explantation. We report the technical considerations and clinical outcome of these challenging cases to provide insight in how to successfully overcome this increasing problem in the vascular field.

Methods

Between December 1996 and August 2004, 355 patients (mean age 71.2 ± 7.2 years; 334 men) underwent endovascular treatment of an infrarenal nonruptured abdominal aortic aneurysm (AAA) (n = 342), an isolated iliac artery aneurysm (n = 3), or a proximal anastomotic aneurysm after former central open reconstruction (n = 10). One hundred eighty-nine (53%) patients were treated with AneuRx devices and the others with Talent devices (both Medtronic AVE, Santa Rosa, CA). Both systems have been described in detail.[7] The mean American Society for Anesthesiology (ASA) score was 2.5 ± 0.6, and 48% of the patients had an ASA score of 3 or 4. Severe cardiac comorbidity (including recent myocardial infarction, cardiac decompensation, or former coronary artery bypass grafting) was recorded in 32.6% of the patients, chronic obstructive pulmonary disease in 10.1%, and combined cardiopulmonary disease in 26.6% of the patients. Fifty-two patients (14.6%) had a case history of at least two abdominal operations.

At least 1 week before the endovascular procedure, a spiral computed tomographic (CT) scan was performed. All procedures were performed in the operating room with general (72%) or epidural (28%) anesthesia. The endovascular procedures were performed with standardized techniques by a team that consisted of an experienced vascular surgeon and an interventional radiologist.[8]

Follow-up consisted of clinical examination and CT scans at 3 and 12 months postprocedure and yearly thereafter. Proximal or distal endograft migration associated with an endoleak or aneurysm diameter enlargement > 5 mm was considered significant

and a reason for reintervention. The definitions of White and colleagues were used to classify endoleaks.[9,10]

Medical records and radiographic files of those patients who required endograft explantation were identified for further analysis. Late explantation was defined as conversion to open repair more than 24 hours after EVAR.

Results

Of the 355 patients who underwent endovascular treatment, 71 (20%) needed reintervention. Most (85%) of these reinterventions were renewed endovascular procedures with placement of proximal or distal extender cuffs. After a mean follow-up of 48 months (range 3–96 months), 11 patients required conversion to open repair. One of them, an 80-year-old man, was ineligible for an explantation procedure because of severe cardiopulmonary comorbidity. His aneurysm (maximum diameter 57 mm; proximal neck 23 mm) had been repaired in October 1999 with an AneuRx bifurcation device. Completion angiography showed good sealing of the proximal and distal parts of the endoprosthesis and no signs of endoleak. Follow-up CT scans at 1, 2, and 3 years demonstrated no endoleak and shrinkage of the aneurysm diameter to 45 mm. In January 2004, the device appeared to be fully migrated into the aneurysm sac. During the last year of follow-up, the proximal neck dilated from 23 to 26 mm, whereas the aneurysm diameter had grown to 58 mm.

The characteristics of the other 10 patients who needed conversions are listed in Table 1. All patients were men, and all of the primary endovascular procedures were performed electively. Comorbidities included coronary artery disease (60%), chronic obstructive pulmonary disease (40%), hypertension (80%), and diabetes mellitus (20%). Six (60%) of the patients had a solitary abdominal aneurysm (mean size 71 mm; range 53–99 mm), and one had an isolated iliac artery aneurysm. Three patients (3, 4, and 5) underwent endovascular repair of a proximal anastomotic aneurysm after a previous open procedure. A Talent tube graft had been used to perform these three procedures.

Reasons for explantation

In patients 1 and 2, malposition of the device was the reason for conversion. Patient 1 had a proximal Talent extender cuff implantation in November 2002 to prevent further proximal migration of an AneuRx endoprosthesis that had been implanted in September 1998. During deployment of the cuff, one of the bare struts was at right angles to the aortic wall. The same thing happened to patient 2 during deployment of his Talent main device. During follow-up, a type I endoleak persisted with growth of the aneurysm. Figure 1 shows the proximal part of the explanted endograft of patient 1 with a clear dent at the top.

Table 1. Patient Characteristics for Explantation After Endovascular Repair

Patient	Age (yr)	Endograft	Implantation Date	Interval to Explantation (mo)	Indication for Explantation	Elective/ Acute	Complication
1	57	Talent (cuff)	11/2002	1	Malposition	E	None
2	67	Talent	1/2001	4	Malposition	E	Temporary renal insufficiency
3	66	Talent	7/1999	50	Type I endoleak	E	Pneumonia
4	80	Talent	8/2000	18	Type I endoleak	A	Death
5	72	Talent	12/2000	14	Type I endoleak	E	None
6	68	AneuRx	1/1998	43	Proximal migration	A	None
7	74	AneuRx	5/1999	50	Proximal migration	A	Death
8	87	AneuRx	1/2000	48	Proximal migration	A	Urosepsis
9	73	AneuRx	7/2003	1	Thrombosis	E	Compartment syndrome
10	56	Talent	9/2003	5	Type II endoleak	E	Splenectomy

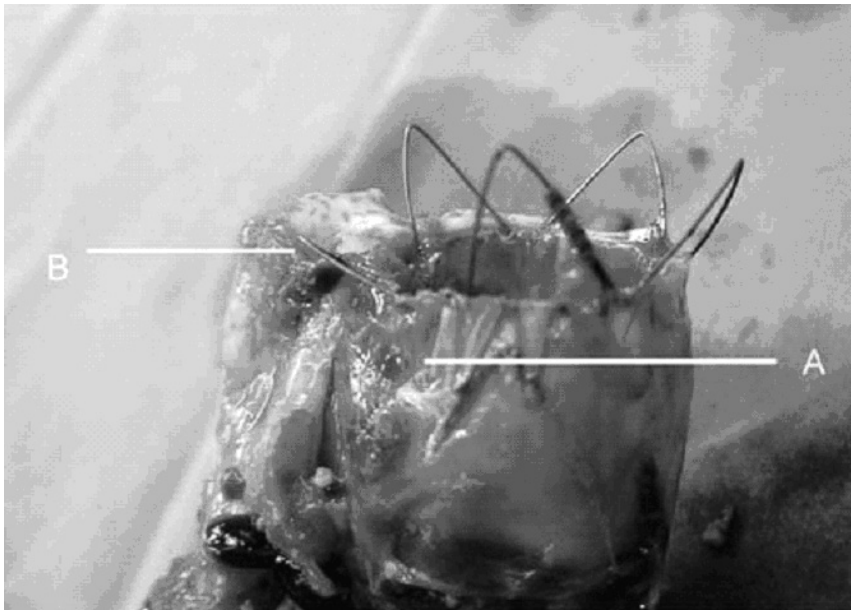

Figure 1. Detail of the proximal part of an explanted Talent graft for malposition. There is a dent in the main device (arrow A) owing to malposition of the bare strut on top (arrow B).

All patients with endovascular repair for a proximal anastomotic aneurysm after former central reconstruction (3, 4, and 5) had type I endoleaks at the time of conversion. These endovascular procedures were all done with an unsupported Talent tube graft covering at least 2 cm of the proximal part of the former Dacron prosthesis, but with a maximum covered length of 4.5 cm. The infrarenal necks were 1.2, 1.3, and 1.7 cm long, respectively. At completion angiography directly after the endovascular procedures, no signs of endoleaks were seen.

Patients 6, 7, and 8 needed explantation because of proximal migration of the endograft that resulted in complete dislodgment into the aneurysm sac. In retrospect, the diameters of the native aorta at the proximal fixation zone of the endoprosthesis were dilated between 5% and 9%, which must have been the reason for migration.

Patient 9 suffered from an ischemic right leg at the second day after implantation of an AneuRx bifurcation endograft. During this procedure, a percutaneous transluminal angioplasty (PTA) was done for a stenosis in the right common iliac artery just distally from the endograft. Angiography confirmed thrombosis of the right iliac AneuRx limb and the native common and external iliac artery. After successful thrombolysis, a repeat PTA of the stenosis with additional stent placement was performed. Three weeks later, acute rethrombosis of the whole endograft occurred that led to critical ischemia of both legs. Because of this recurrence and the severity of the ischemia, the endograft was explanted and a central reconstruction was done with an aortobifemoral prosthesis.

Patient 10 suffered from an inflammatory AAA with a diameter of 8.5 cm. CT scan 3 months postimplant showed a type IIB (complex) endoleak[11] with six patent lumbar arteries and growth of the aneurysm to 9.2 cm. Transarterial coil embolization was attempted but did not succeed owing to the patient's complex anatomy. Because of the growth and clinical symptoms (pain), reconstruction was done with an aortobiiliac graft with all anastomoses in noninflammatory tissue.

Surgical technique

No early (< 24 hours post-EVAR) conversion was done, and the mean time between EVAR and explantation was 28 ± 21 months. All 10 procedures were performed under general anesthesia by an experienced vascular surgeon.

Via a midline incision, supraceliac cross-clamping was performed for proximal control and clamping of the iliac arteries below the endograft was done for distal control. All grafts could be rather easily removed through an infrarenal aortotomy. No severe periaortic fibrotic reaction was seen, nor was pannus ingrowth of the devices. After inspection, testing for backbleeding, and flushing of the renal arteries, the proximal clamp was moved to the infrarenal position. The mean suprarenal clamp time was 27 minutes (range 11–35 minutes), and the mean perioperative blood loss was 2,430 mL (range 1,200–5,500 mL). The operation time of the successful explantations ranged from 150 to 300 minutes (mean 220 minutes). Two patients underwent reconstruction with a tube graft, five with

an aortobiiliac graft, and one (patient 9) with an aortobifemoral prosthesis. The explanted endografts were thoroughly checked for their macroscopic integrity postprocedure. No macroscopic fabric holes were seen. Broken sutures were found in all explanted devices, which has been reported.[12] However, no structural microscopic analysis of the endografts was performed.

The mean length of stay at the intensive care unit was 5 ± 2 days in case of elective procedures and 33 ± 18 days for the acute conversions; the in-hospital stay was 9 ± 3 days versus 37 ± 19 days. However, the number of patients is too small to draw any firm conclusions. Explantation was performed for aneurysm rupture in four cases (patients 4, 6, 7, and 8). Seven patients had complications during or after explantation. Two of the four patients with a ruptured AAA died. One (patient 7) died durante operationem of myocardial infarction owing to hypovolemic shock. The other (patient 4) died in the intensive care unit from multiorgan failure on postoperative day 2. Another patient with a ruptured AAA suffered from gastritis and urosepsis, which were both treated successfully with antibiotics.

Patient 9 had a compartment syndrome in his left leg 24 hours after central revascularization. The compartments were released by dermatofasciotomy without further sequelae. The other complications were temporary renal failure (serum creatinine levels more than three times the admission value), pneumonia, and iatrogenic spleen damage that necessitated a splenectomy. At a mean follow-up of 20 ± 11 months, all patients who survived the explantation did not have any further complications.

Discussion

In our series of 355 patients treated with endovascular grafts, no immediate conversion (< 24 hours after implantation) was necessary. The late conversion rate of 3.1% is similar to the results of other series with long-term follow-up.[13-15] The mortality rate for acute conversions in patients with aortic rupture was 50%. Of the six patients who needed elective conversion, the mortality rate was 0% and the morbidity rate was 67%; however, all complications were without permanent sequelae.

As in other clinical trials, the main reason for late conversion to open repair was persistent endoleak, particularly proximal type I, and proximal migration.[16-18] The majority of the conversions reported in these series (n = 25) had to be done for nonruptured aneurysms (n = 18, 72%), with good midterm results. No thorough comparison can be made because of the variety of operation techniques and indications for explantation.

In our patients, three principal causes for this type of endoleak existed.

The first is malposition of the device (patients 1 and 2) during deployment. Little is known about the incidence of this specific problem. Jacobowitz and colleagues reported

an incidence of ± 0.5%, similar to our findings.[19] If the malposition is in the midportion of the device, percutaneous transluminal balloon angioplasty might solve this problem. When bare struts are part of the malposition (as in our two patients), little can be done to overcome this problem other than explantation because of the risk of perforating the aortic wall during balloon angioplasty.

Second, all patients who were treated with an unsupported tube endograft for a proximal anastomotic aneurysm after former open repair (3 of 10 patients) developed progressive type I endoleaks. In the long term, fixation of these short proximal extender cuffs is not sufficient, probably because of inadequate longitudinal columnar support.[20] To overcome this problem, more rigid and supported devices should be used, such as an aortouniiliac device with contralateral occlusion of the common iliac artery and a crossover bypass, or extender cuffs with a longer transrenal fixation crown. The remaining seven patients who developed a proximal anastomotic aneurysm after open repair were successfully treated with an aortouniiliac device, contralateral iliac occlusion, and femoral crossover bypass. At a mean follow-up of 19 months, no endoleaks or other complications occurred.

Third, and most worrisome, three explantations (patients 6, 7, and 8) were necessary because of complete proximal dislodgment of the endografts. In retrospect, the dilation of diameters of the native aorta at the proximal fixation zone of the endoprosthesis during the last follow-up had increased as much as 9% compared with findings from preoperative CT scans. Proximal migration during follow-up was no more than 5 mm, with still adequate sealing of at least 8 mm. These findings are especially seen more frequently with longer follow-up and raise the question of whether all of these patients need preventive endovascular revision. At the least, follow-up intervals should be reduced from 12 months to 6 months when aorta dilation or discrete migration is noticed. If dilation or migration persists, renewed endovascular intervention should be performed before complete dislodgment occurs.

Patient 10 illustrates the potential danger of type II endoleaks, as described by other investigators.[21,22] The treatment of first choice is transarterial coil embolization, which did not succeed owing to the patient's complex anatomy. Because of the inflammatory component, we chose central reconstruction with extensive débridement and omental wrapping of the Dacron graft instead of laparoscopic branch clipping.
In our opinion, supraceliac clamping is the procedure of choice during explantation. Especially in case of endografts with transrenal fixation, even suprarenal clamping can damage the renal arteries by crushing the prosthesis, making it difficult to explant the juxtarenal part of the endograft. After explantation of the endograft, thorough control of the patency of the renal arteries and even the superior mesenteric artery has to be done and can be easily performed. After this, the clamp has to be switched to the infrarenal position. In our series, only one patient suffered from temporary renal insufficiency postoperatively.

Partial or even complete preservation of the endograft can be considered. Advantages could be shorter duration of the operation and less traumatic surgery. Especially in case of type II endoleaks without an inflammatory aortic component, complete preservation of the endograft is possible. In these situations, opening of the aneurysm sac, removing of the thrombus, and oversewing of bleeding lumbar arteries will suffice.[23] In fact, these steps can be done by means of a laparoscopic approach.[24] Hitherto, the number of patients are small with short- or midterm follow-up. In case of proximal migrated endografts, the distal part can be preserved and sewn to a new tube graft (eventually as a sleeve). We believe that in case of proximal type I endoleak, complete explantation of the endograft is the safest surgical intervention for the patient and prevents possible disastrous distal migration of the endograft during follow-up.

In summary, late explantation of aortic endovascular devices was necessary in 3.1% of 355 patients. A substantial number (20%) of procedures was needed for malposition of the device itself, which is hard to prevent. Other main difficulties were proximal neck dilation and the use of short endovascular tube extensions for the treatment of a proximal anastomotic aneurysm after former open surgery. The first problem demands persistent, short, periodic radiologic surveillance of the endoprosthesis and probably preventive endovascular reintervention in case of continuing migration or dilation. Endovascular revisions of proximal anastomotic aneurysms after open surgery should consist of an aortouniiliac prosthesis with additional crossover bypass for sufficient longitudinal columnar support.

The combination of temporary supraceliac clamping and an infrarenal aortotomy appears to be a safe technique for adequate removal of endografts without damage of native visceral and renal arteries.

There was a marked difference in mortality rates between acute (50%) and elective (0%) conversions. Taking into account the considerable comorbidity of the patients, the complication rate of elective open reconstruction after EVAR is acceptable, with no major permanent sequelae. It is our opinion that when delayed conversion is indicated, priority has to be given to operate on these patients.

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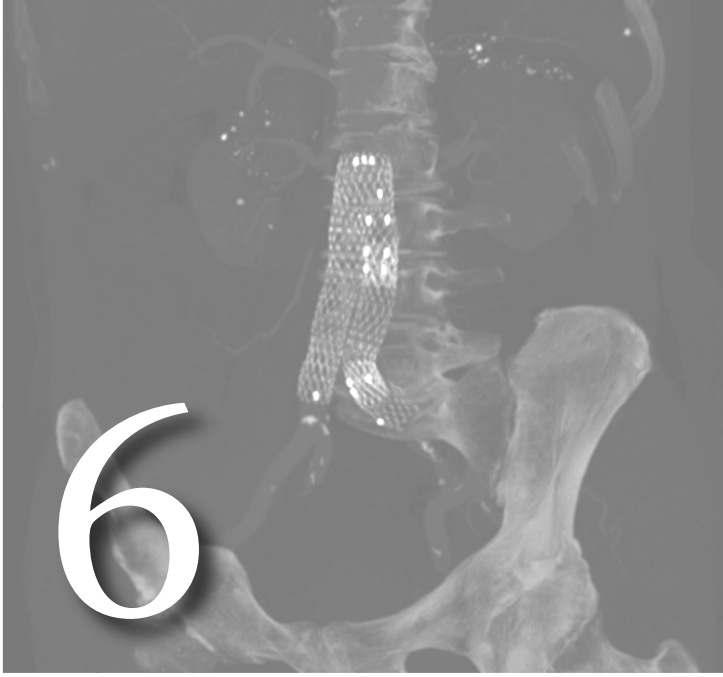

Chapter 6

Long-term single centre results with AneuRx endografts for endovascular abdominal aortic aneurysm repair

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Abstract

Background: Stent-grafts for endovascular repair (EVAR) of infrarenal abdominal aortic aneurysms (AAAs) have been commercially available for 10 years. The first randomized trials showed good short-term and mid-term results, but results on long-term durability of EVAR are lacking. This study evaluates long-term single-centre results with the AneuRx stent-graft.

Methods: Between December 1996 and August 2003, 212 patients were treated with an AneuRx stent-graft for an infrarenal AAA. Postoperatively, patients enrolled a fixed follow-up protocol and data were prospectively captured into a database. Data analysis was performed on May 1st, 2006. For statistical analysis the Kaplan-Meier method and log-rank testing were used.

Results: Graft deployment was successful in 98.6%. Thirty-day mortality was 2.4%. Median hospital stay was 4.3 ± 5.5 days. Mean follow-up was 52.0 ± 29 months. Follow-up was ≥12 months in 189 patients, ≥24 months in 173 patients, ≥60 months in 92 patients, ≥84 months in 35 patients, and ≥108 months in 5 patients. One patient was lost to follow-up. Patient survival was 88% at 1 year, 69% at 5 years, and 56% at 9 years. In 13 patients (6.1%), mortality was aneurysm related. In 67 (31.6%) patients, at least one secondary procedure was performed. Freedom from secondary interventions was 91% at 1 year, 65% at 5 years, and 48% at 9 years. Most of these reinterventions (68.7%) were needed for fixation-related complications, and most of these complications (75%) encompassed the area of the proximal aneurysm neck. Aneurysm rupture after EVAR occurred in 7 patients (3.3%). Freedom from aneurysm rupture was 100% after 1 year, 97% after 5 years, and 91% after 9 years. Primary clinical success was 89% at 1 year, 57% at 5 years, and 37% at 9 years. With secondary interventions, this improved to a primary assisted clinical success of 97% at 1 year, 91% at 5 years, and 73% at 9 years.

Conclusion: As an alternative to open repair, EVAR with the AneuRx device has low perioperative mortality and acceptable long-term results. At expense of regular surveillance and an annual secondary intervention rate of 6%, the risk of major complications is low. Most complications that needed a secondary intervention occured in the proximal aneurysm neck. Therefore, this proximal landing zone was identified as the Achilles' heel of success.

Introduction

Endovascular aneurysm repair (EVAR) has become widely accepted as an alternative for open abdominal aortic aneurysm (AAA) repair. Compared with open aneurysm repair, EVAR has proven to be less invasive, with a shorter procedure duration, reduced blood loss, and shorter hospital stay.[1-5] A recent meta-analysis of three randomized clinical trials[3-5] showed a 30-day mortality rate of 1.6%, which was significantly lower than the 30-day mortality rate of 4.7% for open repair (odds ratio, 0.33; 95% confidence interval, 0.17 to 0.64).[6] During follow up, however, EVAR is associated with specific complications such as endoleaks, migration, fabric tear, graft disconnection, stent fracture, graft thrombosis, and even aneurysm rupture.
The first EVAR was performed in 1991,[7] and commercially available devices were first introduced in 1993; therefore, long-term results are lacking so far. Only when long-term results of EVAR become available, a reasonable consideration between EVAR and conventional open repair can be made. We report our single-centre results with the AneuRx (Medtronic AVE, Santa Rosa, CA, USA) stent-graft implanted since 1996.

Patients and Methods

Between December 1996 and August 2003, 212 patients were treated with the AneuRx stent-graft in our hospital. Data from these patients were captured prospectively in a vascular database. This database collected information on patient characteristics, preoperative arterial anatomy based on computed tomography angiography (CTA), procedural data, graft characteristics, data on hospital stay and in-hospital complications, occurrences of late complications (endoleaks, endotension, migration, graft occlusion, graft infection and failure of device integrity), reinterventions, aneurysm rupture, conversion to open repair, death, and aneurysm related death. End points for data collection were explantation of the graft or death.

Surveillance of patients included laboratory testing for renal function, physical examination, and contrast-enhanced spiral CTA scans before discharge, at 3 and 12 months, and annually thereafter. A radiologist and vascular surgeon reviewed all images for proper device position, adequate proximal and distal fixation, endoleaks, and maximum aneurysm diameter.

Secondary interventions were planned for all persistent type I or III endoleaks and for type II endoleaks if the maximum diameter of the native aorta increased >5 mm/year. Further, secondary interventions were planned for symptomatic stent-graft occlusions and in case of migration that led to type I endoleak, aneurysm expansion, or insufficient proximal fixation (<10 mm overlap).

According to the reporting standards of EVAR,[8] the clinical outcomes reported were early and late survival rate, aneurysm-related death, rupture-free survival rate, freedom from

secondary interventions, and clinical success (primary, primary assisted, and secondary). Primary clinical success was defined as successful deployment of the stent-graft at the intended position without death as a result of aneurysm-related treatment, type I or III endoleak, graft infection or occlusion, aneurysm expansion (diameter ≥5 mm), graft dilation (diameter ≥20%), graft migration (≥1 cm), failure of device integrity, aneurysm rupture, and conversion to open repair. If endovascular or surgical secondary interventions were needed (except for stent graft explantation), this was defined as respectively primary assisted and secondary clinical success.[8]

Analysis of data was based on the intention-to-treat principle. Patients in whom EVAR failed and who underwent immediate or late (>24 hours postoperative) conversion to open surgery were included in the analysis. Data acquisition was stopped on May 1st, 2006 for this report.

Continuous variables are presented as mean ± SD. Statistical analysis was performed with SPSS 12.0.1 (SPSS, Chicago, Ill, USA). The Kaplan-Meier method was used to assess the cumulative rates of survival, freedom from secondary interventions, migration, and aneurysm rupture and to assess primary, primary assisted, and secondary success. The log-rank test was used for estimating the effect of variables on clinical outcome. To identify predictors for secondary interventions, migration, and for primary clinical success, Cox proportional hazard models were used. Significance was assumed at $P < .05$.

Results

Of the 212 enrolled patients, 197 (92.9%) were men and 15 were women. Age at time of operation was 71.3 ± 7.0 years. The American Society of Anesthesiologists (ASA) guidelines were used preoperatively to assess the physical status of the patients, of whom 114 (53.7%) were classified as ASA score II, 90 (42.5%) were ASA score III, and eight (3.8%) were ASA score IV.
All patients had an infrarenal aortic aneurysm. Mean diameter of the aneurysm sac was 59.1 ± 10.6 mm. The proximal neck length was 25.5 ± 12.8 mm, with a mean neck diameter of 23.8 ± 2.6 mm. The aneurysm was asymptomatic in 211 patients (99.5 %). One patient had a symptomatic aneurysm but was hemodynamically stable at the time of operation.

Mean follow-up was 52.0 ± 29 months. Follow-up was ≥12 months in 189 patients, ≥24 months in 173 patients, ≥60 months in 92 patients, ≥84 months in 35 patients and ≥108 months in 5 patients. One patient was lost to follow-up because he moved to an unknown address.

Early outcome
Deployment of the graft was successful in 209 (97.2%) of 212 patients. Of the three patients in whom deployment failed, immediate conversion was necessary in two patients (0.9%). In one patient, this was because of inability to pass a bilateral stenotic external and

common iliac artery. In the second patient, the contralateral limb could not pass a very narrow distal aortic neck after the main body of the stent-graft was already deployed. In a third patient, the stent-graft was deployed above both renal arteries. After a laparotomy was performed, the problems were solved with endovascular techniques. Details on these three cases were reported earlier.[9]
The mean hospital stay was 4.3 ± 5.5 days. Five patients (2.4%) died ≤30 days after the primary operation. Four patients died because of cardiac complications (one after conversion) and one patient died from multiple organ failure after a new operation for diverticulitis 20 days after EVAR.

Early postoperative complications occurred in 21 (9.9%) patients. According to the reporting standards for endovascular aortic aneurysm repair, complications were grade 1 in 10 patients (4.7%), grade 2 in nine patients (4.2%). and grade 3 in two patients (0.9%).

Late mortality and aneurysm related death

During follow-up, 63 patients (29.7%) died. Causes of death were cardiac disease in 25 (39.7%), malignancy in 12 (19.0%), pneumonia in 6 (9.5%), unknown in 6 (9.5%), aneurysm rupture in 4 (6.3%), and other causes in 10 (15.9%). Mortality was aneurysm related in 13 patients (6.1%). In addition to the five aforementioned patients who died perioperatively, four died because of aneurysm rupture, two after stent-graft occlusion (patients requested no further treatment), one from colon ischemia after placement of a proximal extender cuff to treat a proximal type I endoleak, and one due to massive hemorrhage during laparoscopic clipping of a type 2 endoleak. Patient survival rates were 88% at 1 year, 78% at 3 years, 69% at 5 years, 64% at 7 years, and 56% at 9 years follow-up (Fig 1). Freedom from aneurysm-related death was 97% at 1 year, 96% at 3 years, 93% at 5 years, 90% at 7 years and 90% at 9 years follow-up (Fig 2).

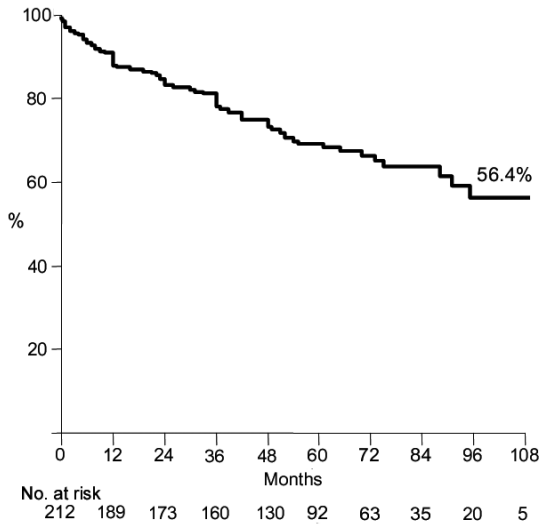

Figure1. Survival in patients undergoing endovascular aneurysm repair. Standard errors of displayed data on curve did not exceed 10%.

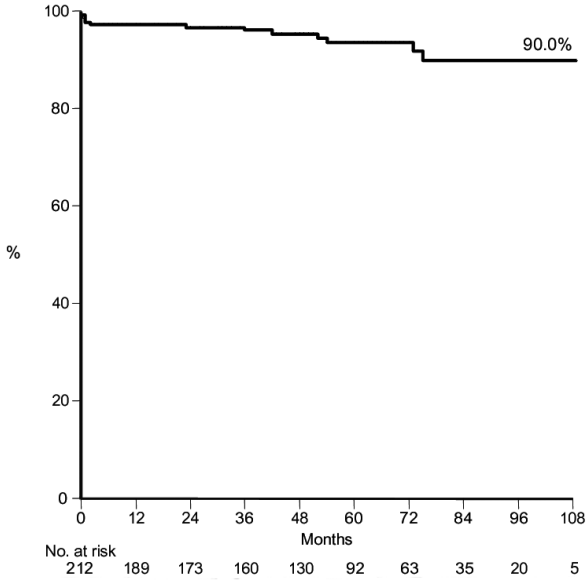

Figure 2. Freedom from aneurysm-related death. Standard errors of displayed data on curve did not exceed 10%.

Secondary procedures

After the primary operation, 67 patients (31.6%) had to have at least one secondary procedure. One reintervention was performed in 47 patients, two reinterventions were performed in 13 patients, three reinterventions were performed in five patients, and four reinterventions were performed in two patients. Indications for these reinterventions are summarized in Table I.

Table I. Indications for secondary interventions

Indication for re-intervention	Number of cases
Type I endoleak, proximal (without migration)	12
Type I endoleak, distal	10
Type II endoleak	25
Type III endoleak, proximal	17
Type III endoleak, other	7
Migration, without endoleak	17
Migration, causing type I endoleak	5
Symptomatic occlusion	3

Kaplan-Meier estimates showed a freedom from secondary interventions of 91% at 1 year, 78% at 3 years, 65% at 5 years, 52% at 7 years, and 48% at 9 years follow-up (Fig 3). Twenty-five interventions (25.3%) were performed for repair of type 2 endoleaks, and 22 of these (coiling or thrombin injection) were performed in the angiography suite of the Department of Interventional Radiology. The other 74 reinterventions were performed in the operating room. Sixty-eight (67.7%) reinterventions were needed for fixation-related complications (endoleaks, or migration). All of these reinterventions were catheter based. Three (3.1%) reinterventions were for persistent type II endoleaks, which were done by laparoscopic clipping of lumbar arteries. Three other reinterventions were for stent-graft occlusions, which were treated by embolectomy (n = 1) and femorofemoral (n = 1) and axillobifemoral (n = 1) bypass grafting. The 30-day mortality rate for all secondary procedures was 2.1% (n = 2).

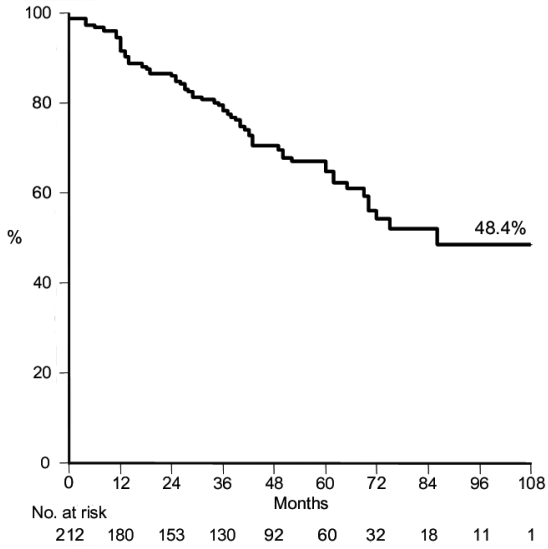

Figure 3. Freedom from secondary interventions. Standard errors of displayed data on curve did not exceed 10%.

Multivariate analysis revealed that EVAR performed before 2000, proximal neck diameter, and maximal preoperative aneurysm diameter significantly influenced the hazard for secondary interventions ($P < .05$), but proximal neck length, primary use of extender cuffs, and ASA class I/II or class III/IV did not.

Maximum aneurysm diameter

Follow-up CT scans from 204 patients were available. After a mean follow-up of 53.4 ± 28.4 months, a decrease (>5 mm) in maximum aneurysm sac diameter was seen in 80 patients (39.2%). In 109 patients (53.4%), the maximum aneurysm sac diameter did not change, and in 15 patients (7.4%), aneurysm expansion (>5 mm) was detected.

A type I endoleak was detected in five patients with aneurysm expansion. Four were treated by placement of an extender cuff, and elective conversion was successfully performed in

the other. One patient with aneurysm expansion had a type III endoleak, and this patient had an endovascular reintervention within a short time. In two patients, a type II endoleak was detected as the probable cause for aneurysm expansion. In one of these patients, the type II endoleak sealed spontaneously, and the aneurysm diameter stabilized. The other patient died of massive hemorrhage during laparoscopic clipping of the involved lumbar arteries due to iatrogenic caval vein injury.

In one patient, migration was thought to be the cause of aneurysm expansion. This patient was treated by placement of a proximal extender cuff. In the other six patients, aneurysm expansion was probably caused by endotension, because no endoleak could be detected. One of these patients died during conversion when the aneurysm ruptured. In one other patient, conversion was successful. In three patients, a wait-and-see policy was adopted. The sixth patient rejected further follow-up because of a preterminal condition.

Graft migration

Proximal graft migration was detected in 26 patients (12.3%) after a mean follow-up of 42.0 ± 17.3 months. In five patients, migration caused a proximal type I endoleak and in one patient, it probably caused aneurysm expansion. In 16 other patients, migration caused insufficiency of the proximal anchoring zone (<10 mm sealing). A secondary intervention was also performed in these patients. In 16 patients, proximal fixation was secured by placement of an extensor cuff, in six other patients a Talent (Medtronic AVE, Santa Rosa, CA, USA) aortouniiliac device was placed. In all cases, migration was solved by endovascular techniques. Freedom from migration was 100% at 1 year, 92% at 3 years, 85% at 5 years, 75% at 7 years, and 75% at 9 years (Fig 4).

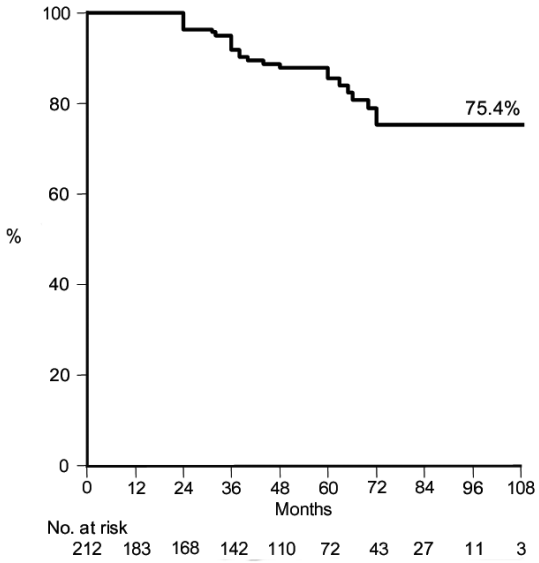

Figure 4. Freedom from migration. Standard errors of displayed data on curve did not exceed 10%.

Multivariate Cox regression analysis revealed that preoperative length of the aneurysm neck and preoperative AAA diameter were not independent predictors for migration, whereas neck diameter was (P = .002). Hazard rates indicated that each millimeter increase in preoperative neck diameter increased the hazard of migration by 1.7.

Aneurysm rupture

Six patients (2.8%) in our series were referred to a hospital with a ruptured aneurysm after EVAR. Another patient had a type II endoleak and aneurysm expansion and an indication for conversion was made; however, because of her age and condition, the patient declined further intervention and died at home. Her general practitioner confirmed a ruptured aneurysm as the probable cause of death. Therefore, aneurysm rupture probably occurred in seven patients (3.3%). Details on these cases are listed in Table II. Freedom from aneurysm rupture was 100% at 1 and at 3 years, 97% at 5 years, and 91% at 7 and 9 years (Fig 5).

Table II. Details on patients with aneurysm rupture

#	Age (years)	Complication during FU	Re-intervention	Sac Diameter	FU to rupture	Intervention	Outcome
1	68	Type III endoleak	Interposition cuff	Expansion	73	Conversion	Died during operation
2	62	None	None	Stable	41	Conversion	Survived
3	72	Migration with Type I	Extender cuff	Stable	42	Extender cuff	Survived
4	80	Type II	Trombine	Expansion	75	none	Died
5	76	None	None	Stable	54	Conversion for ruptured internal iliac aneurysm	Died post-operation
6	82	Type I and III endoleak	None (patients' decision)	Expansion	48	Conversion	Survived
7	83	Wound infection	None	Decrease	42	Conversion	Died during operation

Late conversion

Late conversion to open repair was necessary in 11 patients (5.2%). Five of these patients were reported before.[10] Indication for late conversion was type I endoleak in three patients, and one patient each had type III endoleak, endotension, and stent-graft occlusion. In all these cases, earlier attempts were made to treat these endoleaks or occlusion endovascular. In five patients, aneurysm rupture was the indication for conversion. Perioperative mortality was 0% for elective conversions. After aneurysm rupture, two of five patients survived, two patients died during conversion, and one died ≤30 days postoperatively. This resulted in a 30-day mortality rate of 60% for conversion for aneurysm rupture in our series.

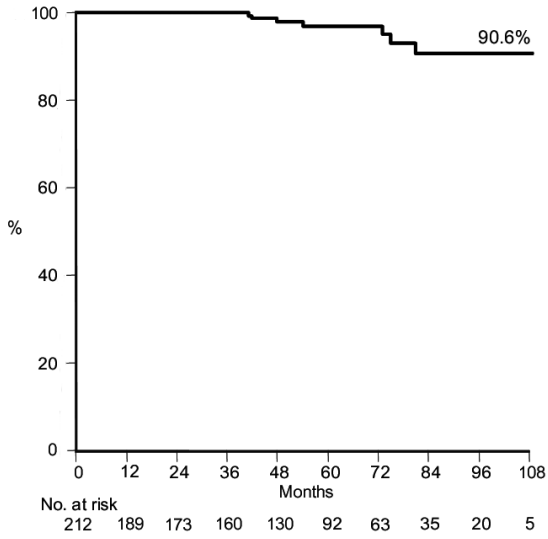

Figure 5. Freedom from aneurysm rupture. Standard errors of displayed data on curve did not exceed 10%.

Clinical success

Kaplan-Meier estimates showed a primary clinical success of 89% at 1 year, 75% at 3 years, 57% at 5 years, 43% at 7 years, and 37% at 9 years, and a primary assisted clinical success of 97% at 1 year, 95% at 3 years, 91% at 5 years, 77% at 7 years, and 73% at 9 years. Because of laparoscopic clipping of lumbar arteries in three patients with type II endoleaks, performance of a femorofemoral bypass in two patients, and an axillobifemoral bypass in one patient, the secondary clinical success rates, estimated by Kaplan-Meier analysis, were 97% at 1 year, 97% at 3 years, 91% at 5 years, 81% at 7 years, and 78% at 9 years (Fig 6).

Multivariate Cox proportional hazard analysis results revealed that preoperative aneurysm neck diameter, preoperative maximal aneurysm diameter, and EVAR performed before 2000 were independent predictors for primary clinical success (P = .015, .009, and .033 respectively), whereas age, aortic neck length, ASA II or III/IV and use of extender cuffs at implantation did not influence primary clinical success.

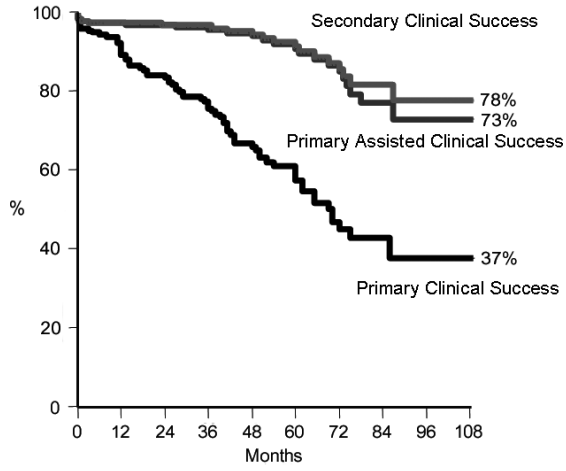

Figure 6. Kaplan Meier estimates of primary, primary assisted and secondary success. Standard errors of displayed data on curves did not exceed 10%.

Discussion

In 1999, the AneuRx stent-graft system and the Ancure stent-graft (Guidant/EVT, Menlo Park, CA, USA) were the first EVAR devices approved by the United States Food and Drug Administration (FDA). Although the Ancure stent-graft has been withdrawn from the market temporally, the AneuRx device has been used continually for 10 years. To our knowledge, we are the first to present results with a follow-up period up to 9 years.

Early results of the EVAR 1 and the Dutch Randomized Endovascular Aneurysm Management (DREAM) trials have established the 30-day mortality advantage for EVAR vs open aneurysm repair.[4,5] In the EVAR 1 trial, 30-day mortality in the EVAR group was 1.7% vs 4.7 % in the open repair group. The DREAM trial reported a 30-day mortality rate in the EVAR group of only 1.2% vs 4.6% in the open repair group. In our series, 30-day mortality was 2.4%, which gives the impression of being relatively high, but it is still less compared with open surgery. An explanation for this phenomenon is patient comorbidity in our studied population. In both of the randomized trials, patients were only included when they were fit for both EVAR and open repair, whereas our study also included patients who where not fit for open repair. In the DREAM trial only 8.1% of patients in the EVAR group was considered as ASA class III and none of the patients as ASA class IV, but almost half of the patients (46.2%) in our series were classified as ASA III or IV. Only one of the patients in our series who died perioperatively was ASA II (30-day mortality rate 0.9% for ASA II patients).

Four years after randomization, the EVAR trial participants reported no differences in all-cause mortality between EVAR and open aneurysm repair, but the reduction in aneurysm-related death was sustained.[11] Several more years are needed until long-term results from randomized trials are available, but stent-graft durability will be the crucial factor in

determining if EVAR will ever be a judicious alternative for open aneurysm repair.
Migration, which has been noted with all of the frequently used endovascular devices,[12] might lead to proximal endoleak, graft kinking, graft limb thrombosis, and even late aneurysm rupture.[13,14] Since migration was reported after mid-term follow-up,[9] it became a major concern for durability of the AneuRx device.[15] The AneuRx device has no barbs or hooks, and mechanical fixation depends completely on radial and frictional forces of the device applied on the aortic neck, iliac arteries, and modular junction along with longitudinal columnar support provided by the stent-graft itself.

In a special analysis, migration was studied among the 1119 patients of the multicenter US AneuRx clinical trial.[16] Freedom from migration was 81.2% at 3 years, with a significant variation among 13 different clinical sites, which suggested that operative technical details played a role in determining migration.[16] In our series, freedom from migration was 92% at 3 years. More important, the annual incidence rate of approximately 3% has been sustained up to 9 years after operation and even tends to decrease during longer follow-up. A multivariate analysis found the only positive predictor for migration was preoperative neck diameter, whereas in other studies neck length was also identified as predictor for migration.[17,18] An explanation for this could be that we did not use the entire neck length as a fixation zone in the early years. Because the company's first recommendation was a minimum neck length of only 10 mm and migration was an unknown complication, it was unusual to deploy the stent-graft precisely below the renal arteries. After we identified migration as a possible complication from early data analysis,[9] we changed our inclusion criteria (neck length ≥15 mm) and our technique of stent-graft placement. From that moment, we started to deploy the stent-graft just below the renal arteries for maximal proximal fixation, extended all stent-grafts just above the hypogastric arteries for maximal distal fixation, created a generous overlap of modular components, and started to balloon dilate all anchoring and connection sites to guarantee proper sealing.

After the Talent AAA endografts system became available, which is a fairly comparable stent-graft system but with the ability of transrenal fixation due to a 15-mm-long uncovered stent at the proximal end, we have tended to use this device in patients with adverse aneurysm neck anatomy. These early changes may have contributed to the relatively low incidence of migration compared with most other reports.[16-19]

In all cases of migration that needed a secondary procedure, proximal fixation could be secured with endovascular techniques by placement of a proximal extender cuff (custom-made AneuRx [n = 3] or custom-made Talent [n = 13] or placement of an aortouniiliac Talent stent-graft). Also, for other complications, secondary interventions were mostly catheter-based or percutaneous (injection of thrombin into type II endoleaks). Consequently, the 30-day mortality rate for secondary interventions (2.1%) was comparable with that for primary intervention.
Freedom from secondary interventions was 91% at 1 year, 78% at 3 years, 65% at 5 years, 52% at 7 years, and 48% at 9 years. In 2005, van Marrewijk et al.[12] reported from the EUROSTAR experiences an annual risk for secondary interventions of 6.3% for patients

with an AneuRx device. At 7 years of follow-up, our annual incidence rate seems higher; however, this might also be explained by the liberal inclusion criteria and technique of EVAR that we used in the early years. For patients treated after 1999, freedom from secondary interventions was 94% at 1 year, 84% at 3 years, and 76% at 5 years, which means an annual risk of about 5%. This is in accordance with Habo et al,[20] who on behalf of the EUROSTAR collaborators, reported a decrease in secondary interventions for patients treated after 1999.

Secondary intervention was needed for type II endoleaks in 25 patients, but in 68 patients (71%) interventions were needed for fixation-related complications between stent-graft and aortic or iliac vessel or between modular components. In 51 of these patients, complications occurred in the proximal aortic neck (Fig 7), which identifies this zone as the Achilles' heel for durability after EVAR. This area should be of special interest to improve EVAR durability. New, dynamic imaging tools are emerging that will enhance our knowledge on proximal fixating zone configuration and behavior.[21-23] Together with more advanced proximal fixation techniques from newer stent-graft designs, results on EVAR will further improve to finally calm ongoing debate.

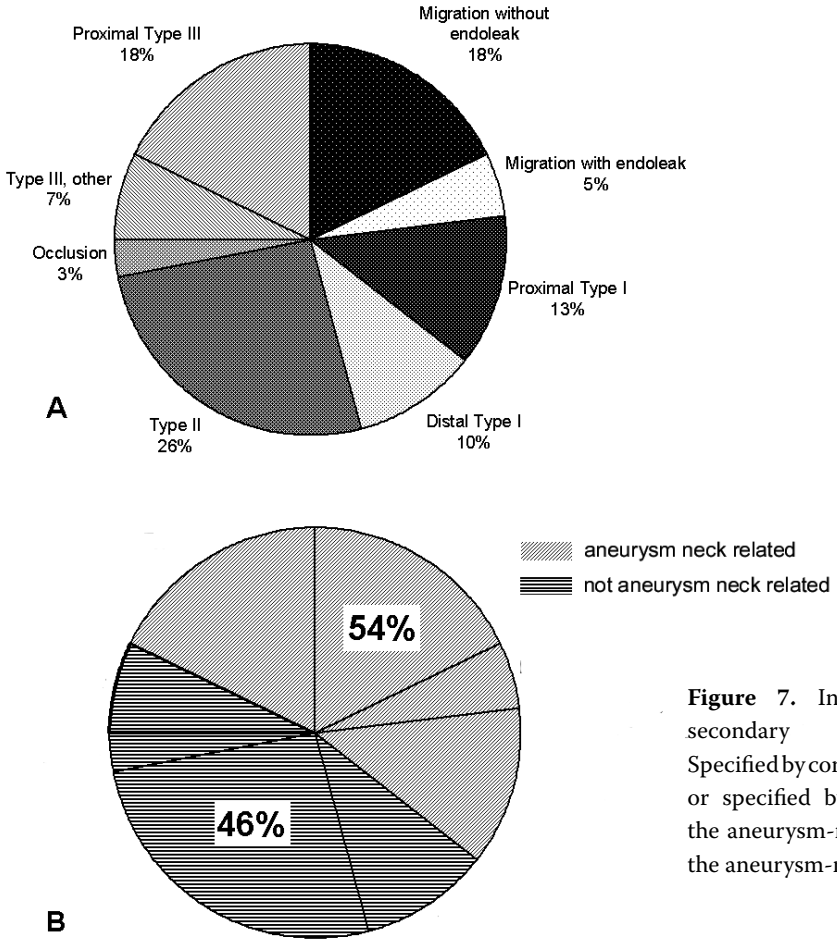

Figure 7. Indications for secondary interventions. Specified by complication (**A**), or specified by location: in the aneurysm-neck or not in the aneurysm-neck (**B**).

Conclusions

As an alternative to open repair, EVAR with the AneuRx device has low perioperative mortality. At expense of regular surveillance and an annual secondary intervention rate of 6%, risk on major complications was low. Late conversion was performed in 5.2% of patients, and the annual incidence of aneurysm rupture was 1%. During long-term follow-up, the annual risk on aneurysm-related death was stable at around 1%, and the total survival rate was 56% after 9 years. The aneurysm neck was identified as the Achilles' heel of durability, and results improved when experience increased and endografts were placed flush distal to the renal arteries. These long-term results with this first FDA-approved device appear acceptable in this population, in which almost half of the patients were ASA III or IV. With enhanced knowledge on dynamics of the proximal fixation zone in near future and advanced, more adapted, proximal fixation techniques, a durable advantage of EVAR over open repair can really be expected.

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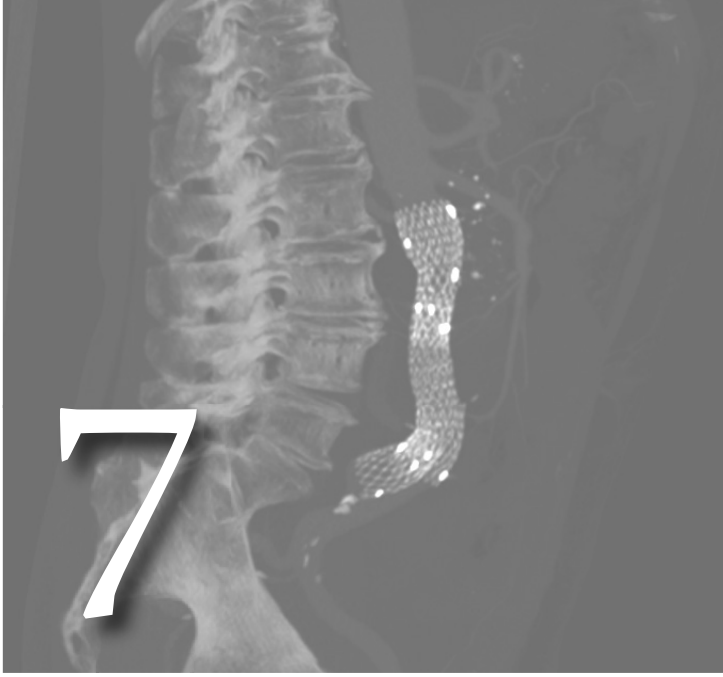

Chapter 7

Dynamic magnetic resonance angiography of the aneurysm neck: Conformational changes during the cardiac cycle with possible consequences for endograft sizing and future design

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Abstract

Objective: Proper proximal fixation and stent-graft sealing within the aneurysm neck are critical for endovascular aneurysm repair (EVAR) durability. Computed tomography angiography (CTA) is the gold standard for preoperative sizing of endograft diameters, but the accuracy of these measurements is uncertain because they rely on static images of a dynamic process. The aortic configuration and diameter may change during the cardiac cycle. We studied these phenomena using dynamic electrocardiograph-triggered magnetic resonance angiography (MRA).

Methods: Eleven consecutive EVAR patients were included. Dynamic MRA was used to perform preoperative and postoperative measurements. Changes were measured in transverse aortic sections 10 mm below the lowest renal artery (level A), at the level of the renal arteries (level B), and 3 cm above the lowest renal artery (level C). Data were analyzed using image segmentation software. Aortic area and diameter changes along 256 axes were determined.

Results: Dynamic MRA demonstrated significant aortic area changes during the cardiac cycle before and after EVAR at all three measured levels. Pre-EVAR aortic area significantly increased per cardiac cycle: 8.4% at level A; 9.3% at level B; and
13.3% at level C ($P < .001$ for all levels). Post-EVAR aortic area increased 9.7% at level A, 9.6% at level B, and 15.8% at level C per cardiac cycle ($P < .001$ for all levels).
Significant diameter changes during cardiac cycles were also observed at all three levels. Pre-EVAR mean diameter changed up to 8.9% ($P < .001$) compared with post-EVAR aortic changes of up to 11.5% ($P < .001$). EVAR had no effect on change in aortic area and diameter. Dynamic MRA also demonstrated that pulsatile aortic distension was not equal in all axes, but rather occurred as an asymmetrical expansion and contraction.

Conclusion: In patients with (atherosclerotic) aneurysm disease, the aortic dimensions at the level of and proximal to the aneurysm neck change during the cardiac cycle. This phenomenon is preserved after EVAR. Therefore, maximum
diameter using dynamic MRA may not be similar to the maximum diameter with static CTA in all patients, and a standard regimen of 10% to 15% oversizing of an endograft based on static CTA images may be inadequate for some patients.
Further studies using dynamic MRA to evaluate effects of different endografts are anticipated, with possible consequences for endograft designs.

Introduction

Endovascular aneurysm repair (EVAR) has emerged from its infancy in 1991 to become the preferred treatment modality for appropriately selected patients with abdominal aortic aneurysms (AAA).[1] Properly selected patients with AAAs treated with EVAR can expect improved outcomes, a shorter hospital stay, and less surgical morbidity in the early postoperative period compared with conventional open surgery.[2,3] Patient selection has been based primarily on anatomic considerations, with most attention directed towards proper sizing of the endograft within the infrarenal aneurysm neck.[4,5] Most preoperative imaging protocols use computerized tomography angiography (CTA) with three-dimensional (3D) reconstructions for sizing and planning.[6,7] However, several centers have reported successful use of magnetic resonance angiography (MRA) in preoperative EVAR planning with similar results to that of CTA.[8,9]

Regardless of modality, the resulting images are static images, irrespective of the obvious fact that the human aorta exists in a dynamic environment. Aortic compliance and cardiac pulsatility naturally result in conformational changes during the cardiac cycle.[10,11] With the current high-speed multislice CT scans, the time it takes to scan the neck of an aneurysm only takes a fraction of the cardiac cycle. The static images acquired may represent the aortic neck during diastole (minimum diameter) or systole (maximum diameter), or somewhere in between. Subsequent sizing decisions are then made from these image measurements. The presence of significant pulsatile aortic neck variation may have serious implications for EVAR design, durability, and desirability. A potential risk of improper endograft sizing, with subsequent graft migration, intermittent type I endoleak, and poor patient outcome, exists.

New, dynamic imaging tools are emerging to assess preoperative and postoperative aortic dynamics. With these tools, the effect of placing endografts of varying columnar strength into a relatively mobile, pulsatile aortic environment can be evaluated in an effort to improve stent-graft durability and results. The purpose of this study was to use high-resolution electrocardiograph (ECG)-gated cine MRA to characterize aortic pulsatility during the cardiac cycle at important anatomic aortic landmarks in preoperative and postoperative AAA patients undergoing EVAR.

Patients and Methods

Patients

Eleven consecutive patients were selected for EVAR and recruited into the study. All were men, with a median age of 74 years (range, 63 to 78 years). The study design and protocol were approved by the institutional medical ethics committee. Informed consent was obtained from all participants.

Imaging

All scans were performed on a 1.5-T MR scanner (Gyroscan Intera, Philips Medical Systems, Best, the Netherlands). After initial multistack abdominal survey scans, a balanced fast field echo survey scan was performed to localize the renal arteries and aortic aneurysm. Transverse high-resolution scans with retrospective ECG gating were then obtained perpendicular to the long axis of the aorta at three levels. Level A was 1 cm below the lowest renal artery, level B was between the renal arteries, and level C was 3 cm above the lowest renal artery (Fig 1). The acquired voxel size was 2.1 x 0.78 x 6.0 mm^3, with a field of view of 400 x 320 mm^2 and using a scan percentage of 267% in the anteroposterior direction. The reconstructed voxel size was 0.78 x 0.78 x 6.0 mm^3, obtained with a reconstructed matrix of 512 x 512 pixels. Scan duration for obtaining a data set of 16 heart phases within each cardiac cycle was approximately 4 minutes at each level.

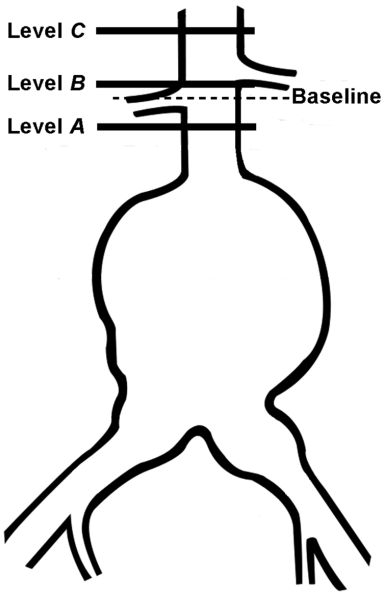

Figure1. Levels at which transverse dynamic MRA scans were obtained. Level A, 1 cm below the lowest renal artery; level B, between the renal arteries; levelC, 3 cm above the lowest renal artery.

Preoperative imaging MR scans were acquired in all patients the day before surgery. Sizing measurements were performed perpendicular to the central lumen line using preoperative static CTA with 20% oversizing according to institutional protocol. EVAR was performed by one surgeon using the Talent (Medtronic, Santa Rosa, CA, USA) or Excluder (W. L. Gore & Assoc, Flagstaff, AZ, USA) stent-graft systems. Postoperative MR scans were obtained 1 day after surgery (Fig 2). Preoperative and postoperative scans were technically successful, and cine loop images were obtained for all levels in each study patient. Image quality was considered to be excellent for all 11 patients.

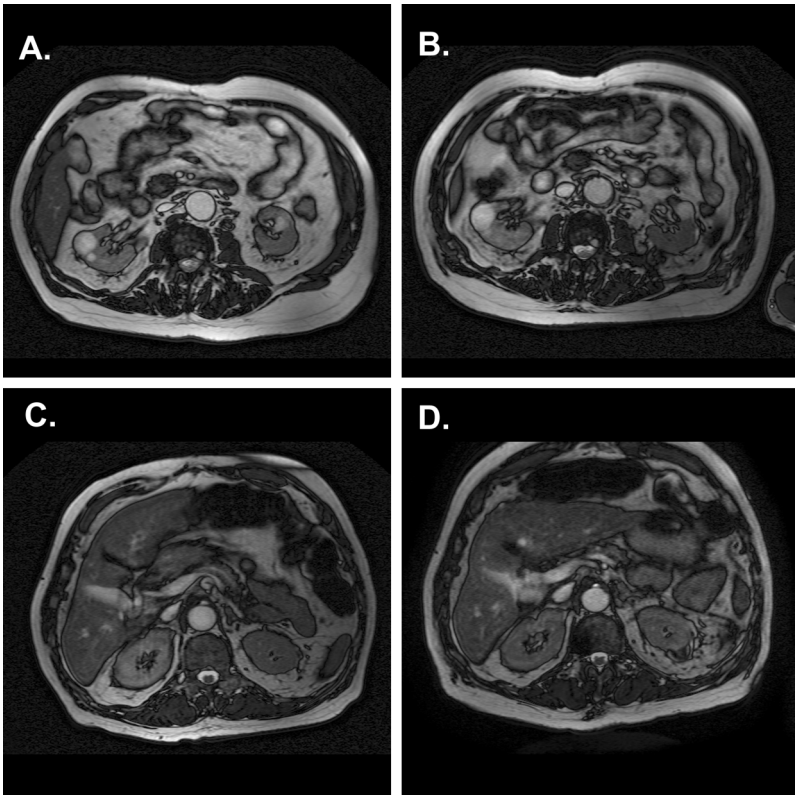

Figure 2. Preoperative and postoperative representative magnetic resonance angiography images at level A (**A** and **B**) and level C (**C** and **D**). The presence of the endograft does not affect image quality. The left side demonstrates preoperative images. The right side demonstrates postoperative images.

Analysis

Dynamix software (Image Sciences Institute, Utrecht, the Netherlands) was used to analyze the dynamic scans. This software was developed to perform automated segmentation and measure changes in area and diameter at predetermined aortic levels (Fig 3). Each segmentation was independently reviewed manually by two blinded observers, and minor adjustments in the segmentation for small irregularities were required in approximately 35% of the images. Areas and minimum and maximum diameter along 256 axes, equally-spaced and through the center of mass of the aortic lumen, were also calculated during cardiac cycles.

Statistical analysis of changes in area and diameters were performed using a Student's t-test for paired data. Significance was assumed at $P < .05$. Data on area and diameter were expressed as mean ± standard deviation. Analysis of measurement method comparison data according to Bland and Altman were performed to analyze repeatability and to compare measurements by two observers as well as comparing dynamic MRA and CTA data.[12]

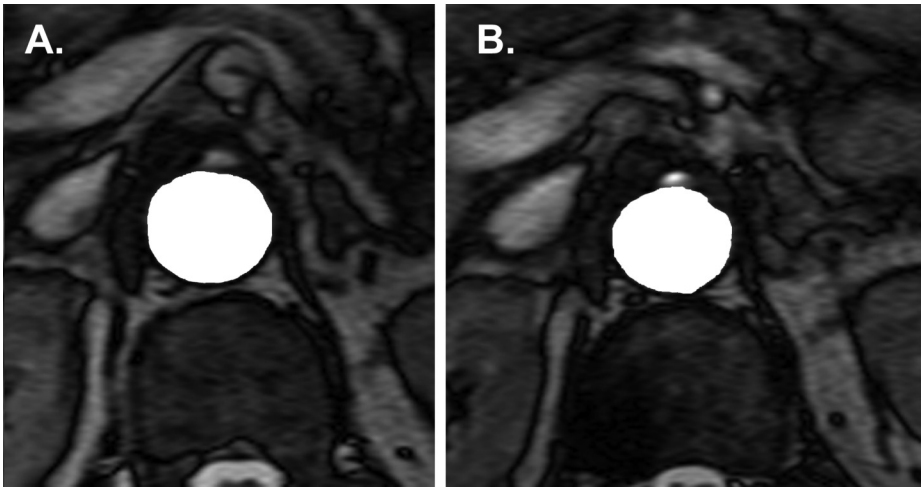

Figure 3. Representative preoperative (**A**) and postoperative (**B**) images with the segmentation overlay shown.

Results

Aortic area

Preoperative aortic area changed significantly during each cardiac pulsation at each of the three anatomic levels: above, at the level of, and below the renal arteries. At level A (within the aneurysm neck), the aortic area changed from 476 ± 144 mm^2 to 512 ± 143 mm^2 per cardiac cycle (P< .001); at level B (between the renal arteries), it changed from 471 ± 70mm^2 to 514 ± 71mm^2 (P< .001); and at level C (3 cm above the renal arteries), it changed from 475 ± 86 mm^2 to 535 ± 88 mm^2 (P< .001) (Fig 4). This corresponded to a pre-EVAR aortic area increase of up to 13.3% per cardiac cycle. The intraobserver repeatability coefficients were 22 mm^2 for observer 1 and
16 mm^2 for observer 2. The interobserver repeatability coefficient was 29 mm^2. Intraobserver and interobserver variability showed no significant differences within or between the observers.

The postoperative aortic area also changed significantly during each cardiac cycle: from 472 ± 185 mm^2 to 516 ± 194 mm^2 at level A, from 439 ± 66 mm^2 to 480 ± 66 mm^2 at level B, and from a low area of 437 ± 87 mm^2 to a maximum area of 503 ± 90 mm^2 at level C (P< .001 for all levels) (Fig 4). This corresponded to a post-EVAR aortic area increase of up to 15.8% per cardiac cycle, which was not statistically different from pre-EVAR aortic area changes. Endograft placement did not significantly alter mean area change at any of the levels (Fig 5). The intraobserver repeatability coefficients were 39 mm^2 for observer 1 and 36 mm^2 for observer 2. The interobserver repeatability coefficient was 55mm^2. Again, intraobserver and interobserver variability showed no significant differences within or between the observers.

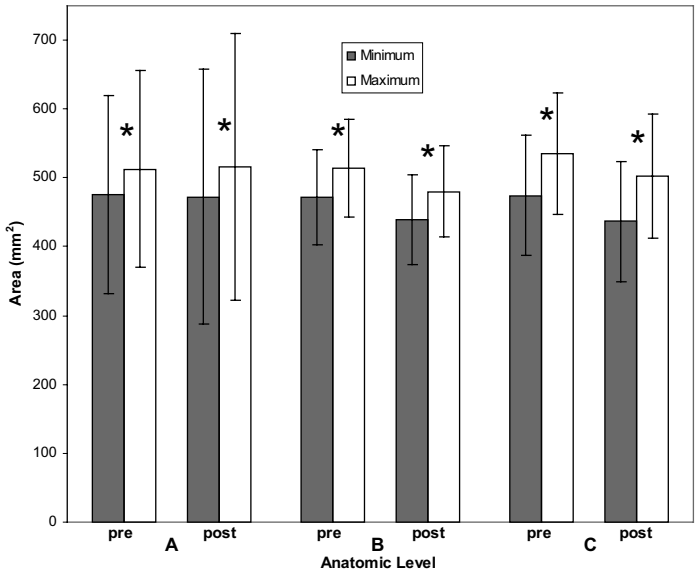

Figure 4. Minimal and maximal aortic area during cardiac cycles measured preoperatively and postoperatively at three anatomic levels (A, B, and C). Data are means ± SD. *P < .05.

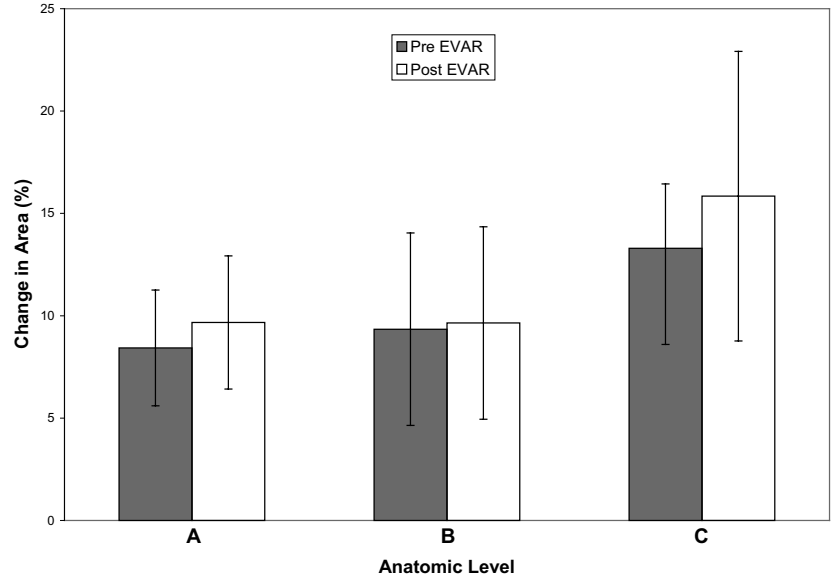

Figure 5. Preoperative and postoperative mean changes in aortic area during cardiac cycles at three anatomic levels (A, B, and C). Data are means ± SD.

Aortic diameter

Aortic diameters changed significantly during the cardiac cycle at all measured levels. Preoperatively, mean aortic diameter changed from 23.4 ± 3.6 mm to 25.0 ± 3.5 mm at level A (P< .001), from 23.2 ± 1.8 mm to 24.8 ± 1.8 mm at level B (P< .001), and from 23.6 ± 2.2mm to 25.6 ± 2.2 mm at level C (P<.001) (Fig 6). At level A, mean diameter changes over 256 axes ranged between 0.6 ± 0.3 mm and 3.6 ± 0.6 mm. Similar diameter changes were observed at level B (0.3 ± 0.4 mm to 3.6 ± 1.0 mm) and at level C (0.7 ± 0.2 mm to 4.2 ± 0.9 mm). The intraobserver repeatability coefficients were 0.6 mm for observer 1 and 0.8 mm for observer 2. The interobserver repeatability coefficient was 1.0 mm. Intraobserver and interobserver variability showed no significant differences within or between the observers.

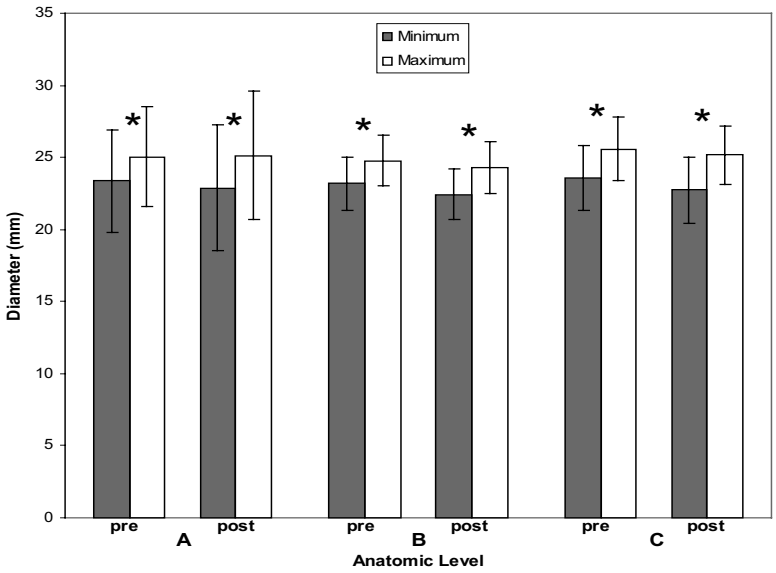

Figure 6. Preoperative and postoperative minimum and maximum aortic diameters in 256 axes obtained during cardiac cycles at three anatomic levels (A, B, and C). Data are means ± SD. *P < 0.05.

Postoperatively, mean aortic diameter also changed significantly during each cardiac cycle. At level A, it changed from 22.9 ± 4.4 mm to 25.1 ± 4.4 mm; at level B, it changed from 22.4 ± 1.8 mm to 24.3 ± 1.8 mm; and at level C, it changed from 22.8 ± 2.3 mm to 25.2 ± 2.0 mm (P< .001 for all levels) (Fig 6). Within the 256 different axes, diameters changed between a minimum of 0.8 ± 0.5 mm and a maximum of 4.5 ± 1.0 mm at level A, between 0.4 ± 0.5 mm and 4.2 ± 0.8 mm at level B, and between 1.0 ± 0.4 mm and 4.6 ± 0.8 mm at level C. This change corresponded with an increase in aortic diameter of up to a 22%. Post-EVAR diameter changes were not different from pre-EVAR changes. Stent-graft placement did not significantly alter mean diameter change at any of the levels (Fig 7). The intraobserver repeatability coefficients were 1.7 mm for observer 1 and 1.0 mm for

observer 2. The interobserver repeatability coefficient was 1.8 mm. Again, intraobserver and interobserver variability showed no significant differences within or between the observers.

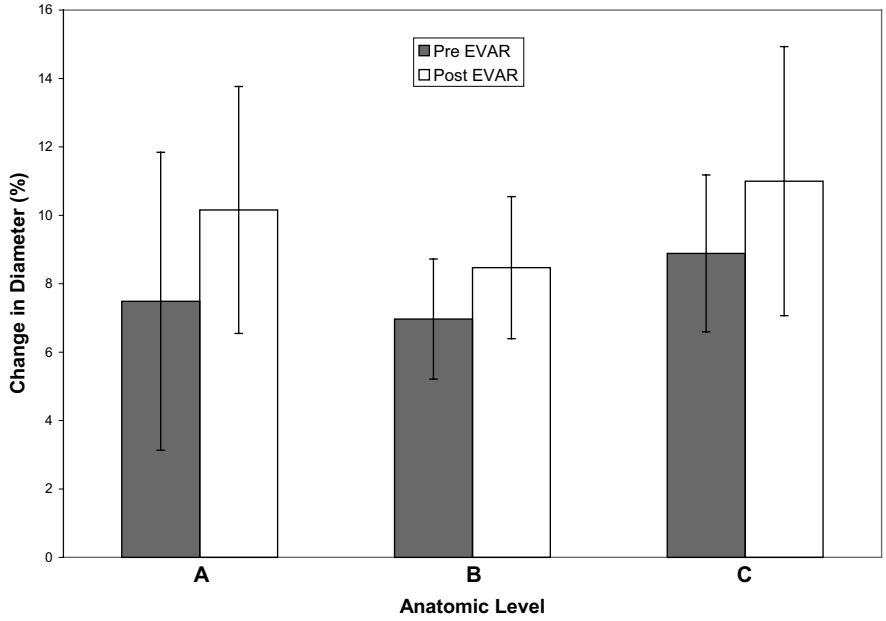

Figure 7. Preoperative and postoperative mean changes of aortic diameters in 256 axes during cardiac cycles at three anatomical levels (A, B, and C). Data are means ± SD.

Aortic diameter using dynamic MRA vs static CTA (before EVAR)

The mean maximum diameter for the 11 patients before EVAR showed no significant differences comparing dynamic MRA and static CTA (mean difference, 0.9 mm ± 2.6 mm; P = .29). In one patient, however, a significantly higher maximum diameter (6.6 mm) was seen with dynamic MRA, even exceeding a 20% oversizing of the maximum aortic diameter based on static CTA. During followup, a proximal type I endoleak developed in this patient. A type I endoleak was also seen in one other patient. The maximum diameter in this patient showed no significant difference when measurements with dynamic MRA and static CTA were compared.

Discussion

To our knowledge, this is the first publication of the use of cine MRA to study the dynamic effects on the aneurysm neck before and after endograft placement for the treatment of AAAs. High spatial resolution allows precise imaging and subsequent measurements. By using retrospective ECG gating, time-resolved images at clinically relevant aortic

levels can be acquired, resulting in cine MRA loops with 16 images per cardiac cycle. We therefore have achieved excellent temporal and spatial resolution. This new powerful tool allows one to view dynamic changes in the aorta with every beat of the heart. The potential implications of this tool could be enormous to vascular surgeons and engineers contemplating endograft design, durability, and potential pitfalls.

This imaging method has some limitations. In addition to the standard contraindications to MRA, only patients with a specific type of endograft can be evaluated with dynamic MRA. All of our patients received the Talent or Excluder devices, which are compatible with MRA. Our institution has previously evaluated the MRI characteristics of various endografts.[13] Of those studied, the AneuRx (Medtronic), Talent, Excluder, and Quantum LP (Cordis, Warren, NJ) stent-grafts appear to be amenable to MRI evaluation, whereas the ferromagnetic properties of the Zenith (Cook, Bloomington, Ind) and Lifepath (Edwards Lifesciences, Irvine, Calif) devices resulted in large susceptible artifacts that precluded adequate image quality.[13] Therefore, patients with Zenith and Lifepath endografts are not currently candidates for this new imaging tool.

All measurements were performed at predetermined, clinically relevant anatomic levels. We chose 3 cm above the lowest renal artery, at the level of the renal arteries, and 1 cm below the lowest renal artery. These levels corresponded to native aorta, aorta with suprarenal fixation, and aneurysm neck with endograft fabric, respectively. However, aortic wall motion obviously occurs at all levels and in all directions. This study is limited in evaluating only the three abovementioned levels in two dimensions. Three-dimensional movements might make the analyzed cross-sectional area in our study move slightly out of plane during the cardiac cycle. Theoretically, this could have some influences on our results. Three-dimensional volumetric analysis could give further interesting results, but this technique, which measures movement in all possible planes within a reasonable scan duration, is not yet available in our hospital. Aortic dynamics may play a role in the design of future endografts. Pulsatile forces with each heartbeat over a patient's lifetime can result in literally millions of repeated stress events placed upon an implanted endograft. Clinicians have witnessed stent fractures, fabric erosions, suture breakage, and endograft erosions through native arteries.[14-18] Although this report does not evaluate endograft durability, it does characterize and quantify the dynamic environment in which endografts are placed. As the frontiers of endografts design are pressed forward with the development of fenestrated and branched endografts, the devices and the dynamics become increasingly complex.[3,19,20] Cine MRA is a new tool that could be used to evaluate and potentially improve future designs.

Computer analysis enabled us to determine the greatest change in diameter at each predetermined aortic level, simultaneously along 256 axes, equally-spaced and through the center of mass of the aortic lumen during the cardiac cycle. At the same level and during the same cycle, aortic diameter can change by as much as 4.2 mm or as little 0.3 mm, depending on which axis is being viewed. This may imply an asymmetrical expansion of the aorta during systole.

Data analysis showed a significant change in aortic diameter and in aortic area, both preoperatively and postoperatively during the cardiac cycle at each level. In the studies by Vos et al,[21] pulsatile aneurysm wall motion was negligible before and after EVAR. The measurements in their studies were performed at the level of the aneurysm sac, however, not at the level of the undilated aorta proximal to the aneurysm.[21,22] Furthermore, in our study intraobserver and interobserver repeatability coefficients were relatively low. This could be the result of the high quality of the images and the use of Dynamix software that offered automated segmentation. Because the preoperative and postoperative changes in aortic diameter and area exceeded the above-mentioned repeatability coefficients, these changes can be considered significant and are therefore clinically relevant.

No significant differences were seen between the preoperative change in aortic area or diameter (pulsatility) and the changes after EVAR. During the postoperative measurements, however, mean arterial blood pressure was significantly lower, which could have influenced these results.

Although stent grafts were oversized by 20%, endografts placement did not significantly alter the change in aortic area or in maximum aortic diameter at any of the levels, and two-dimensional pulsatile aortic wall motion was preserved. This contrasts with previous studies that showed a reduction in aortic diameter and pulsatile wall motion after EVAR.[10,23] However, in these studies evaluations were performed by ultrasound imaging,[10] or on a small group of patients being evaluated before EVAR compared with a large group of patients with endoleaks after EVAR.[23]
Again, measurements (before and after endograft placement) in both studies were performed at the level of the aneurysm sac[10,23]. In fact, to our knowledge, our study is the first to use dynamic MRA in quantifying aneurysm pulsatility at three levels encompassing the aneurysm neck, as mentioned earlier. Previous studies on aneurysm neck wall movement were either not dynamic,[24] were invasive, contained only small groups of patients, or were in vitro measurements.[25]

The preoperative maximum aneurysm neck diameter comparing dynamic MRA and static CTA showed a significantly higher diameter in one patient that exceeded an oversizing of 20% based on static CTA. A proximal type I endoleak developed in this patient during follow-up. Endograft oversizing of 20% based on static CTA may not have been adequate in this patient.

Conclusion

This study introduces the feasibility of cine MRA imaging on dynamic aortic wall motion before and after EVAR at the level of the undilated aorta proximal to the abdominal aneurysm. Understanding the dynamic properties in this area could have important affects on stent-graft fixation and design. Patients with AAAs selected for EVAR demonstrate changes in aortic diameter with each cardiac cycle. The native aorta exhibits significant pulsatility, and this phenomenon is preserved after endograft implantation. Morphologic changes are very complex, but this study gives early insight into changing aortic morphology per cardiac cycle. Future studies using dynamic MRA to determine rupture risk, effects of different endografts, volumetric analysis, and even consequences for endograft efficacy and durability are anticipated.

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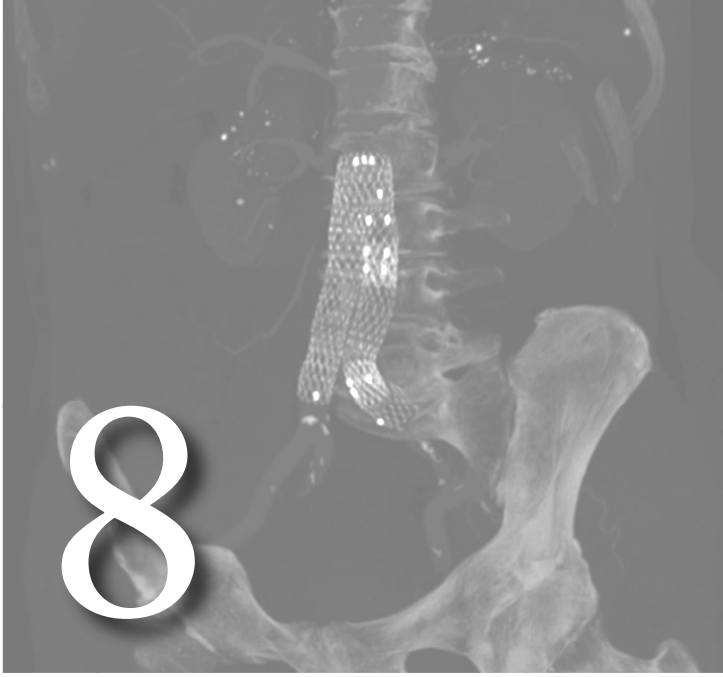

Chapter 8

Aortic compliance following EVAR and the influence of different endografts: Determination using dynamic MRA

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Abstract

Purpose: To utilize dynamic magnetic resonance angiography (MRA) to characterize aortic stiffness (β) and elastic modulus (Ep) as indexes of wall compliance during the cardiac cycle and determine any influence of different endograft designs or the presence of endoleaks on these indexes.

Methods: Eleven consecutive patients (11 men; median age 74 years, range 63–78) with abdominal aortic aneurysm (AAA) selected for endovascular repair were scanned pre- and postoperatively. Aortic area and diameter changes during the cardiac cycle were determined using dynamic MRA at 4 levels: 3 cm above the renal arteries, between the renal arteries, 1 cm below the renal arteries, and at the level of maximum aneurysm sac diameter. Ep and β were calculated. Data are presented as median (range); $p<0.05$ was considered significant.

Results: Preoperatively, Ep and β were significantly higher at the level of the aneurysm sac compared to all other levels ($p<0.05$). Following EVAR, stiffness increased at this level ($p<0.05$). After implantation, patients with an Excluder endograft demonstrated Ep and β measurements at the aneurysm neck that were 94% and 60% higher, respectively, compared to those with a Talent ($p<0.05$) endograft. The presence of an endoleak had no effect on Ep or β.

Conclusion: This study introduces the feasibility of dynamic MRA imaging-based calculations of aortic elastic modulus and stiffness. AAA patients demonstrate increased Ep and β at the level of the aneurysm sac. EVAR results in increased aneurysm sac Ep and β. Stent-graft design seems to alter Ep and β within the aneurysm neck, which may have consequences for endograft durability. The presence of an endoleak does not seem to have an effect on Ep or β.

Introduction

Abdominal aortic aneurysm (AAA) repair has undergone an enormous evolution since the introduction of endovascular aneurysm repair (EVAR) nearly 2 decades ago.[1] Since that time, several well controlled clinical trials have proven the benefit of an endovascular approach in well-selected patients.[2,3] EVAR is now considered the preferred treatment modality for many. In conjunction with physicians and industry, stent-graft design has evolved rapidly, resulting in several endovascular devices approved for human implantation.

New treatment modalities may change the physiological paradigm, resulting in unforeseen dilemmas that can complicate clinical decision making. EVAR presents choices and complications previously unknown with standard open repair. A choice of commercially available endografts and the potential complication of endoleaks are two ways in which this modality differs from the traditional approach.

In contrast to open repair, the aneurysm sac remains, and intrasac pressure often persists following successful endovascular exclusion.[4-7] The presence of endoleaks complicates matters further, with debate continuing regarding the clinical significance of backbleeding vessels into the aneurysm sac. Efforts are currently underway to use implantable pressure sensors to monitor successful aneurysm exclusion, but these methods are invasive, will likely be expensive, and have not been validated in human trials.[8-10] Earlier studies have utilized ultrasonic echo-tracking scans in an effort to determine aortic compliance and stiffness before and after EVAR.[11,12] However, pressure from the transducer may affect dispensability, and high-quality ultrasound is limited in postoperative EVAR patients because of artifacts from the stent-graft skeleton. To our knowledge, the effect of using endografts of different design on aortic stiffness and compliance has not been evaluated.

New dynamic imaging tools are emerging to assess pre- and postoperative aortic dynamics. With these tools, the effect of placing endografts of varying columnar strength and flexibility into a relatively mobile, pulsatile aortic environment can be evaluated in an effort to improve stent-graft durability and results.

The purpose of this study was to utilize a high-resolution electrocardiographically (ECG)-gated dynamic MRA technique to characterize aortic stiffness and elastic modulus as indexes of wall compliance during the cardiac cycle. Pre- and postoperative measurements at important anatomical aortic landmarks in AAA patients undergoing EVAR were performed using two different stent-graft designs.

Patients and Methods

Eleven consecutive patients (11 men; median age 74 years, range 63-78) with AAA selected for EVAR were recruited into the study. The study design and protocol were approved by the institutional medical ethics committee. Informed consent was obtained from all participants.

Preoperative sizing measurements were performed using static computed tomographic angiography (CTA). According to institutional protocol, all stent-grafts were 20% oversized. EVAR was performed by one surgeon using the Talent (Medtronic Vascular, Santa Rosa, CA, USA; n=7) or Excluder (W.L. Gore & Associates, Flagstaff, AZ, USA; n=4) stentgraft systems. All devices were implanted with the fabric starting immediately below the lowest renal artery. Prior to discharge, stentgraft position and appearance of endoleaks were assessed by static CTA, including delayed phase imaging, according to our hospital's EVAR protocol.

Aortic wall dispensability, which is a surrogate measure for aortic wall compliance,[13] was expressed as elastic strain modulus (Ep), which was calculated as:

$$E_p = K \frac{P_{sys} - P_{dias}}{(D_{sys} - D_{dias}) / D_{dias}} = KD_{dias} \frac{\Delta P}{\Delta D}$$

where K (133.3) is a constant that converts Ep from mm Hg to N/m^2, P is the arterial blood pressure, and D is the aortic diameter.[14] Stiffness (β), which describes the viscoelastic behavior of the aortic wall within a physiological pressure range, was calculated as[15]:

$$\beta = \ln\left(\frac{P_{sys}}{P_{dias}}\right)\frac{D_{dias}}{\Delta D}.$$

Measurement of the aortic diameters during the cardiac cycle was performed on dynamic MRA data. Preoperative MRA scans were obtained on the day before EVAR. Postoperative MRA scans were obtained 1 day after surgery. All scans were performed on a 1.5-T MR scanner (Gyroscan Intera, Philips Medical Systems, Best, The Netherlands). Transverse balanced gradient echo (bFFE) scans with retrospective ECG-gating were obtained perpendicular to the long axis of the aorta at 4 levels: level A was 3 cm above the lowest renal artery, level B was between the renal arteries, level C was 1 cm below the lowest renal artery, and level D was at the level of maximum aneurysm sac diameter (Fig.1). Images in 16 cardiac cycles were acquired, which allowed the viewing of cine loops showing the aortic expansion over time. The acquired voxel size was 2.1 x 0.78 x 6.0 mm^3, with a field of view of 400 x 320 mm^2 using a scan percentage of 267% in the anteroposterior direction. The reconstructed voxel size was 0.78 x 0.78 x 6.0 mm^3 obtained with a reconstructed matrix of 512 x 512 pixels.

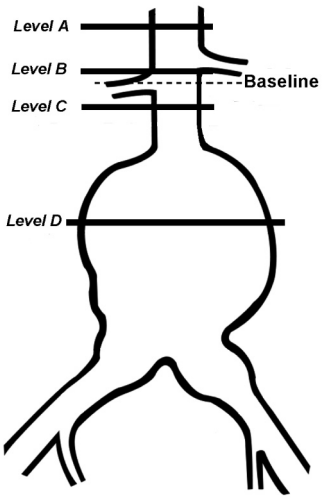

Figure 1. Levels at which transverse scans were obtained. Level A: 3 cm above lowest renal artery; Level B: Between renal arteries; Level C: 1 cm below lowest renal artery; and Level D: the level of maximum diameter of the aneurysm sac.

Analysis of the dynamic scans was performed using DynamiX software (Image Sciences Institute, Utrecht, the Netherlands) as described elsewhere.[16] Based on image grey values, aortic segmentations were automatically determined (Fig. 2). Segmentations were checked for artifacts, and if necessary, manually corrected. Minimal and maximal diameters were measured along 256 axes through the center of mass of the aortic lumen. Diastolic and systolic diameters averaged over all axes were used for calculation of mean elastic strain modulus (Ep) and stiffness (β) values. Blood pressure was measured with an automated brachial sphygmomanometer before the MR imaging session in the radiology department.

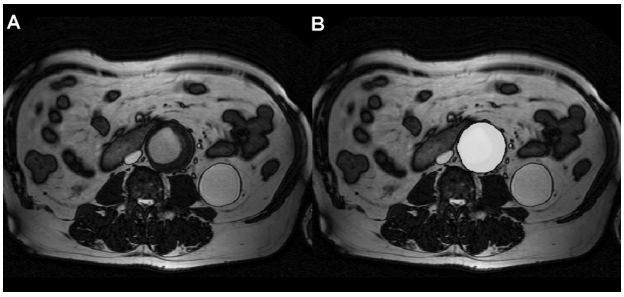

Figure 2. Representative preoperative images without (A) and with (B) automatically created segmentation of the aorta at the level of maximum aneurysm sac diameter.

Statistical Analysis

Data are presented as median (range). Statistical analysis was performed with SPSS (version 12.0.1; SPSS, Chicago, IL, USA). For comparisons of values between groups, the Mann-Whitney U test was used. For comparison of changes in groups with paired samples (pre- versus postoperatively), the Wilcoxon signed rank test was used. Significance was assumed at $p<0.05$.

Results

Preoperative elastic modules (Ep) and stiffness (β) were highest at the level of the aneurysm sac (Table 1). Compared to levels A, B, and C, Ep and β were significantly higher at the level of the aneurysm sac ($p<0.05$ for all levels; Fig. 3). However, no significant differences in Ep and β values were seen between levels A, B, and C.

Table 1 Blood Pressure (BP), Diameter (DM), Elastic Modulus (Ep), and Aortic Stiffness (β). Measurements Before And After Endovascular Aneurysm Repair

	Level A (n=11)		Level B (n=11)		Level C (n=11)		Level D (n=10)	
	Before	**After**	**Before**	**After**	**Before**	**After**	**Before**	**After**
Systolic BP, mm Hg	148 (106-188)	128 (98-164)	148 (106-188)	128 (98-164)	148 (106-188)	128 (98-164)	149 (106-188)	128 (98-164)
Diastolic BP, mm Hg	81 (70-100)	66† (57-87)	81 (70-100)	66† (57-87)	81 (70-100)	66† (57-87)	82 (70-100)	66† (57-87)
Systolic DM, mm	25.8 (21.9-28.8)	24.5† (21.4-28.0)	22.3 (20.7-26.1)	24.4 (20.8-26.9)	23.1 (20.0-30.3)	24.6 (20.1-35.4)	56.5 (47.4-71.5)	55.8 (45.9-72.1)
Diastolic DM, mm	24.0 (19.3-26.7)	22.4† (18.2-25.4)	23.7 (22.7-27.6)	22.7 (19.4-25.3)	21.8 (18.7-28.9)	22.2 (16.9-33.4)	55.5 (46.5-70.5)	54.3 (45.0-71.0)
Ep	10.17 (5.37-17.91)	8.16 (3.72-17.19)	13.13 (6.19-23.09)	9.32 (5.09-21.42)	11.55 (5.26-22.78)	7.92† (4.40-17.45)	41.97* (30.71-58.7)	36.95 (27.94-90.9)
N/cm²								
β	6.77 (4.03-9.73)	6.47 (3.66-10.62)	8.19 (4.65-13.68)	7.73 (4,79-14.10)	8.13 (4.54-13.50)	6.46 (4.10-11.49)	27.91* (23.6-34.6)	35.83† (23.5-59.8)

* $p<0.05$ versus level A before, versus level B before, and versus level C before.
† $p<0.05$ versus before endovascular repair.

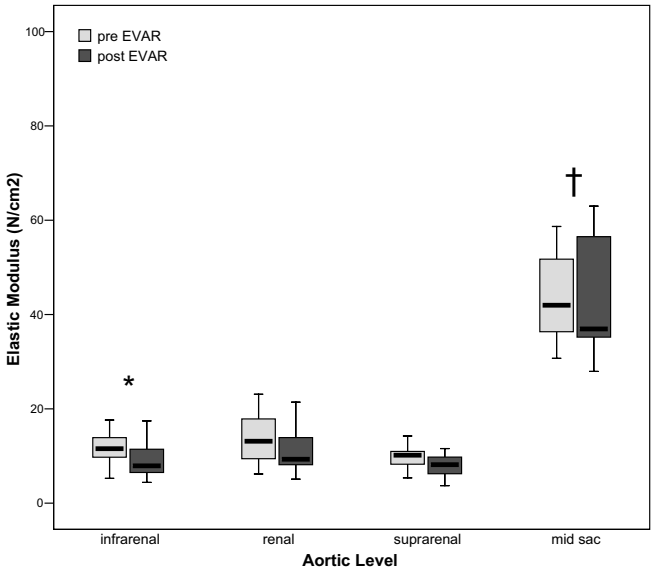

Figure 3. Box plot showing variations of elastic modules (Ep) at the 4 aortic levels before and after EVAR. * P<0.05 pre EVAR versus post EVAR. † P<0.05 mid sac versus the other 3 aortic levels.

One day following EVAR (Table 1), diastolic blood pressure had dropped significantly compared to preoperative values ($p<0.05$), whereas systolic blood pressure was not significantly decreased ($p=0.09$). Although stentgrafts were 20% oversized, placement of a stent-graft did not change systolic or diastolic aortic diameters at levels B, C, or D. However, at level A (3 cm above the lowest renal artery), both diameters decreased: systolic aortic diameter from 25.8 (21.9-28.8) to 24.5 (21.4-28.0) mm ($p<0.05$) and diastolic diameter from 24.0 (19.3-26.7) to 22.4 (18.2-25.4) mm ($p<0.05$). EVAR did not change Ep or β of the aortic wall at this level ($p=0.13$ and $p=0.67$, respectively). Also at level B, Ep and β were unchanged. In the aneurysm neck (level C), Ep decreased from 11.55 (5.26-22.78) to 7.92 (4.40-17.45) N/cm^2 ($p<0.05$; Fig. 3), whereas β did not change ($p=0.29$). At level D, maximal sac diameter, Ep was not influenced by EVAR ($p=0.39$), while β (Fig. 4) increased from 27.91 (23.57-34.63) to 35.83 (23.51-59.83; $p<0.05$).

Examining the data according to the stentgraft model, there were no differences in systolic blood pressure, diastolic blood pressure, Ep, or β between the groups before EVAR (Table 2). After EVAR, Ep and b were similar between the groups at levels A, B, and D (Ep: $p=0.65$, 0.32, and 0.41, respectively; for β, $p=0.65$, 0.41, and 0.41, respectively). However, in the aneurysm neck (level C) where the stent-graft is in contact with the native aorta and sealing occurs, Ep and β were significantly higher in patients who were treated with an Excluder stent-graft (Fig. 5). The median Ep was 12.86 (7.92-17.45) N/cm^2 after an Excluder stent-graft versus 6.63 (4.40-12.42) N/cm^2 after a Talent stent-graft ($p<0.05$). Median β was 9.35 (6.46-11.49) after an Excluder device versus 5.86 (4.10-9.93) after a Talent stent-graft ($p<0.05$).

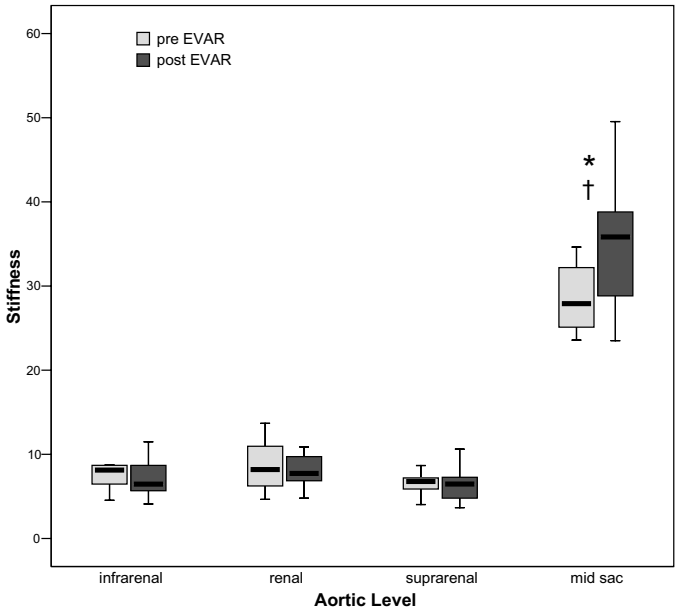

Figure 4. Box plot showing variations of stiffness (β) at the 4 aortic levels before and after EVAR. * P<0.05 pre EVAR versus post EVAR. † P<0.05 mid sac versus the other 3 aortic levels.

Table 2 Comparison of Blood Pressure (BP), Elastic Modulus (Ep), and Aortic Stiffness (β). Measurements After EVAR according to the Stent-Graft Model

	Level A		**Level B**		**Level C**		**Level D**	
	Talent (n=7)	**Excluder (n=4)**	**Talent (n=7)**	**Excluder (n=4)**	**Talent (n=7)**	**Excluder (n=4)**	**Talent (n=7)**	**Excluder (n=4)**
Systolic BP, mm Hg	128 (115-145)	152 (108-164)	128 (115-145)	152 (108-164)	128 (115-145)	152 (108-164)	128 (115-145)	152 (108-164)
Diastolic BP, mm Hg	65 (58-71)	74 (57-87)	65 (58-71)	74 (57-87)	65 (58-71)	74 (57-87)	65 (58-71)	74 (57-87)
Ep N/cm2	8.16 (3.72-11.58)	9.27 (4.32-17.19)	8.97 (5.76-14.17)	14.43 (5.09-21.42)	6.63* (4.40-12.42)	12.86* (7.92-17.45)	36.42 (29.4-62.2)	56.46 (27.9-90.9)
β	6.47 (3.66-9.26)	6.40 (4.06-10.62)	7.42 (5.67-10.88)	9.73 (4.79-14.10)	5.86* (4.10-9.93)	9.35* (6.46-11.49)	32.16 (23.5-49.5)	37.87 (26.3-59.8)

* p<0.05 between Talent and Excluder stent-grafts.

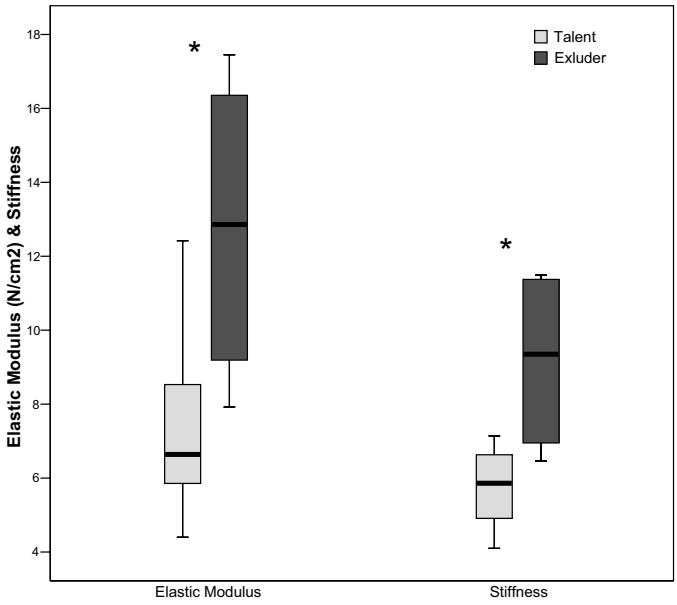

Figure 5. Box plot showing variations of elastic modulus (Ep) and stiffness (β) at the level of the aneurysm neck after placement of Talent and Excluder stent-grafts. * P<0.05 Talent versus Excluder.

Static CTA before discharge showed proper stent-graft position in all patients. In 6, no endoleak was seen. Among the 5 patients with endoleak, 2 exhibited small proximal type I endoleaks, and 3 had type II endoleaks. There were no significant differences in Ep (Fig. 6) or β (Fig. 7) between those patients with and without endoleak (Table 3).

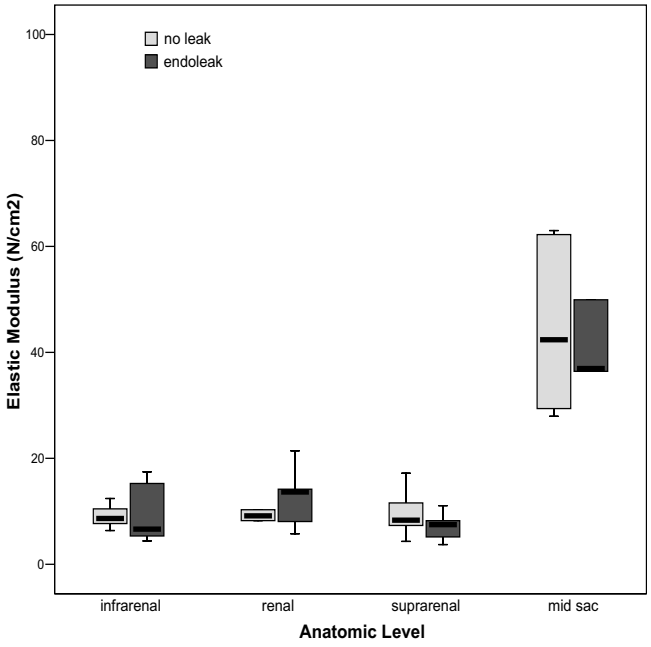

Figure 6. Box plot showing variations of elastic modulus (Ep) at the 4 anatomic levels in patients with endoleak and patients without endoleak.

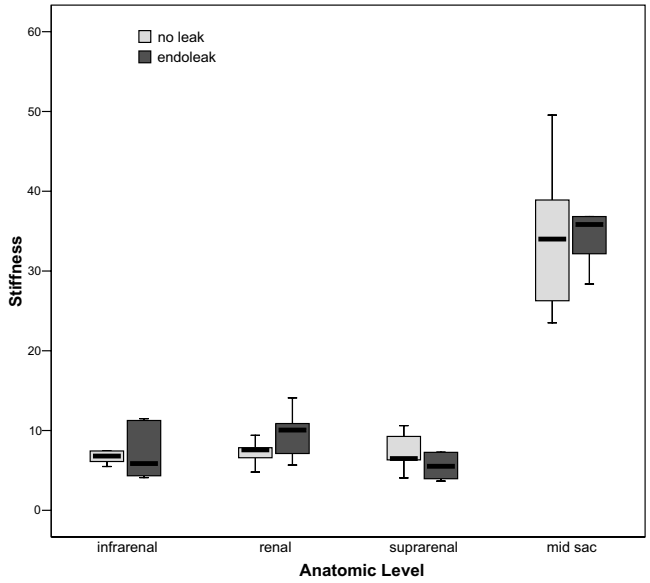

Figure 7. Box plot showing variations of stiffness (β) at the 4 anatomic levels in patients with endoleak and patients without endoleak.

Table 3 Comparison of Blood Pressure (BP), Elastic Modulus (Ep), and Aortic Stiffness (β) Between Patients With and Without Endoleaks (Measurements After EVAR)

	Level A		Level B		Level C		Level D	
	Without (n=6)	**With (n=5)**	**Without (n=6)**	**With (n=5)**	**Without (n=6)**	**With (n=5)**	**Without (n=6)**	**With (n=5)**
Systolic BP, mm Hg	125 (108-164)	140 (98-158)	125 (108-164)	140 (98-158)	125 (108-164)	140 (98-158)	125 (108-164)	140 (98-158)
Diastolic BP, mm Hg	67 (57-87)	65 (58-79)	67 (57-87)	65 (58-79)	67 (57-87)	65 (58-79)	67 (57-87)	65 (58-79)
Ep N/cm2	8.32 (4.32-17.19)	7.48 (3.72-11.06)	9.14 (5.09-15.22)	13.64 (5.76-21.42)	8.64 (6.37-12.42)	6.64 (4.40-17.45)	42.38 (27.9-63.0)	36.95 (36.4-90.9)
β	6.48 (4.06-10.62)	5.52 (3.66-7.28)	7.58 (4.79-9.40)	10.06 (5.67-14.10)	6.80 (5.49-9.93)	5.86 (4.10-11.49)	34.00 (23.5-49.5)	35.83 (28.4-59.8)

Discussion

Wall stiffness (inversely related to wall compliance) is characterized by Ep (elastic modulus) and β (stiffness). Our preoperative values of Ep and β, which were determined using dynamic MRA, compare with previously reported values for wall stress distribution, validating this as a method for Ep and β calculations.[12,17] Dynamic MRA has theoretical benefits exceeding other imaging modalities. It is entirely noninvasive in contrast to implantable pressure sensors. As opposed to ultrasound, dynamic MRA possesses the potential to

image the aortic arch to the femoral arteries. Aortic wall compliance can therefore be determined at any anatomical level without concern for poorly accessible locations, such as the suprarenal aorta. The applicability of this modality could be extended to include the proximal descending aorta, another area poorly visualized by ultrasound. Dynamic MRA reconstructions provide the added benefit of allowing compliance determinations to be performed in the axis perpendicular to the flow lumen, which is not always possible with ultrasound. The primary limitations of dynamic MRA are the expense, limited availability, and the incompatibility of some endografts.[18]

The use of dynamic MRA to determine pulsatile wall motion (PWM) of the aneurysm wall before and after EVAR was first reported by Vos et al.[19] in 2002. They concluded that PWM of the aneurysm wall is negligible and may therefore not be a potential tool to assess efficacy of EVAR. In 2003, Faries et al.[20] also reported a study in which AAA diameter changes were determined with dynamic MRA. In contrast, they observed a difference in aneurysm pulsatility between patients with or without endoleaks. Both studies, however, did not study the pulsatility proximal to the aneurysm, which is the most important area for stent-graft fixation. Furthermore, they did not mention any data on compliance characteristics.

Proponents of aneurysm sac pressure monitoring suggest that aneurysm exclusion results in a depressurized system with decreased pulsatile wall motion,[7,21,22] which is correlated to measurement of increased stiffness. However, others have noted that sac pressure can remain elevated following successful endovascular exclusion.[23,24] We measured an increased stiffness at the level of the aneurysm sac after EVAR, which supports the notion that the aneurysm sac is then less pressurized. The finding of increased sac stiffness following EVAR is intuitive, as once the aneurysm has been excluded by an endograft, greater pulse pressure is required to cause similar sac wall pulsatility as that seen before exclusion. In other words, the endograft is fulfilling its clinical requirement of decreasing the transmitted blood pressure on the sac wall. In principle, this should result in clinical success and prevention of rupture.

We were surprised to discover that identical Ep and β patterns are seen in the aneurysm sac whether or not an endoleak is present. Our study included 5 patients with endoleak (2 type I and 3 type II) compared to 6 without endoleak. It is possible that our study was not powered to detect the differences between those patients with endoleak and those without. However, if there were a large difference, the study should have been powered to detect the effect of endoleaks on sac wall Ep and β. Most of the endoleaks in our study were type II, which are known to have relatively benign clinical consequences. Our results might have been different had most of the endoleaks been type I. Another explanation for this may be that many more patients had (type II) endoleaks at the time of CTA, but they were too small to detect with this imaging modality. This seems logical, as the CTA was done very soon after the implantation procedure (before discharge), and it is well recognized that the completion angiogram after EVAR shows open lumbar arteries that will close off during the first few weeks postoperatively.[25]

Although neither endoleak nor EVAR resulted in changes to Ep or β within the aneurysm neck, the design of the stent-graft did influence compliance at the level of the neck. Comparing Gore Excluder versus Medtronic Talent, we discovered that the Excluder device resulted in increased Ep and β at the infrarenal level versus the Talent stent-graft. This level corresponded to the aneurysm neck, the level at which proximal sealing of the endograft in the aorta occurs. No difference was observed at the other 3 levels (aneurysm sac, renal, and suprarenal). This does raise interesting questions regarding stentgraft design. Undoubtedly, there are differences in both design and clinical outcomes when comparing various endografts.

One theory that might explain this detected difference relates to the two methods of aortic fixation of these endografts. At the level in which a difference was detected, the Excluder stent-graft has proximal attachment barbs that hook into the neck. Perhaps as the aorta expands with passage of the pressure pulse wave, the Excluder limits the expansion of the aorta by the constraining effect of these attachment barbs. In comparison, the Talent stent-graft uses radial force without attachment barbs to maintain the endovascular device in proper position. The radial forces of the stent-graft, together with the radial force caused by the blood pressure wave, may increase pulsatility, which might explain the decreased Ep and β measurements at the aneurysm neck after EVAR with the Talent stent-graft. This study lends support to the notion that not all endografts are created equal. The human implantation of manufactured stent-grafts of varying columnar strength and flexibility into the pulsatile aortic environment will have effects of varying degrees. Our results indicate that these various effects can be measured and quantified using a dynamic MRA technique. Any clinical relevance of these measurements has yet to be determined.

A final interesting observation was that the diameter decreased significantly at the level of the suprarenal aorta following EVAR. This decrease might be explained by the lower postoperative blood pressure. The fact that aortic diameters did not decrease at levels B and C might be explained by the presence of an oversized stent-graft at or just below these levels.

Conclusion

This study introduces the feasibility of dynamic MRA imaging–based calculations of elastic modulus and stiffness. Patients with AAAs selected for EVAR demonstrate Ep and β that differ significantly between aortic levels and are greatest at the level of the aneurysm sac. EVAR further increased Ep and β at the level of the aneurysm sac. Postoperatively, Ep and β values at the level of the aneurysm sac were unchanged by the presence or absence of endoleak. Stent-graft design alters Ep and β at the aneurysm neck, the site of endograft sealing, which may have serious consequences for endograft efficacy and durability.

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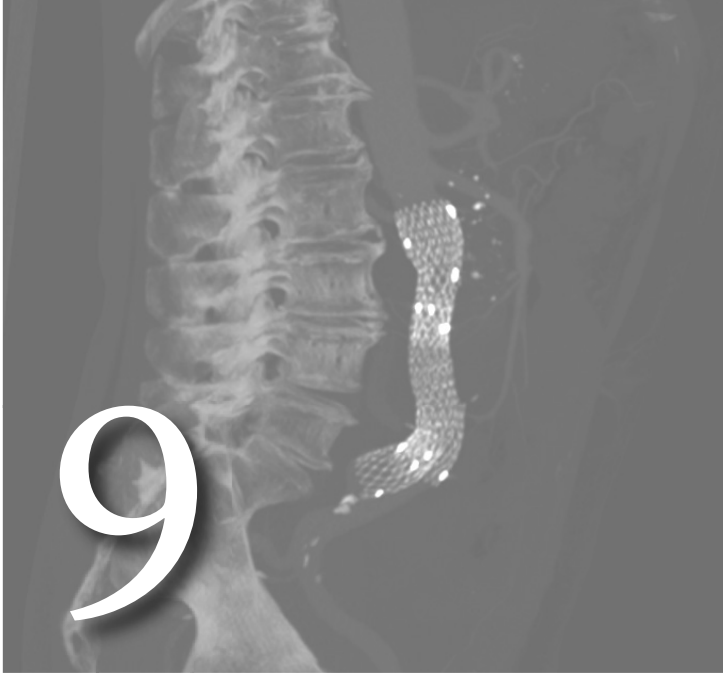
Chapter 9



Summary and general discussion

Endovascular aneurysm repair (EVAR) was first introduced in patients in 1991.[1,2] Five years later, this therapy was started at the St. Antonius Hospital, Nieuwegein, The Netherlands, with use of the AneuRx stent-graft system (Medtronic AVE, Santa Rosa, CA, USA), one of the first commercial available endoprosthesis. From the first EVAR procedure, all data were captured prospectively in a vascular database. In this thesis, the mid-term and long-term single-center EVAR experiences have been evaluated, and the dynamic features of the abdominal aorta have been studied.

In **Chapter 2** a general overview of EVAR is presented. The recent literature has been evaluated for a discussion on indications, patient selection, technique of EVAR, and perioperative and late mortality and morbidity. Attention is also paid to quality of life after EVAR, endovascular repair of ruptured aneurysms, and future perspectives.

Chapter 3 contains mid-term single-center results with the AneuRx device in the first 77 patients with a minimum follow-up of 12 months. The results were comparable with similar EVAR studies in literature, with low in-hospital morbidity and mortality rates, and a shorter hospital stay compared with results from open abdominal aortic surgery. Also assessed were the first EVAR-specific complications, such as failure of device deployment (n = 2), different types of endoleaks (n = 18), graft kinking with (n = 3) or without occlusion, and proximal migration (n = 5). To enhance durability, we altered our strategy with more strict anatomic inclusion criteria and endeavored to maximize fixation proximally, distally, and between modular components.

In **Chapter 4**, the application of EVAR to repair paraanastomotic aneurysms (PAA's) is described. PAA's are false anastomotic aneurysms after previous open aneurysm repair, or true aneurysms proximal or distal to an aortic tube or bifurcated prosthesis. PAA's might lead to rupture, thrombosis, embolism, and pressure on or erosion into adjacent structures.[3-5] Therefore, repair of these aneurysms is preferred if it can be accomplished with a low complication rate. However, open repair of PAA's has mortality rates of up to 17%,[3-8] with only two reports of mortality rates of less than 8%.[7,8]

In our series of 14 patients, PAA's were successfully excluded with EVAR without perioperative mortality and with morbidity (pulmonary infection) in one patient. Median follow-up was 12 months (range, 3 to 40 months). In 11 patients who were treated with bifurcated stent-grafts, no conversions were performed, and a secondary intervention was necessary in one patient.

Reconstructions of proximal aortic anastomotic aneurysms with endovascular tube grafts were not durable, however. This observation supports the theory that proximal fixation of bifurcated stent-grafts depends not only on radial force but also on longitudinal columnar support. We therefore currently only use bifurcated stent-grafts, or if this is not possible because of anatomic characteristics, we consider the use of an aortouniiliac device.

In summary, we state that endovascular exclusion of PAA's is feasible with low perioperative morbidity and mortality rates. Exclusion of PAA's by insertion of a bifurcated stent-graft seems effective initially, although longer follow-up is necessary.

In **Chapter 5,** stent-graft explantation is discussed. In our series of 355 consecutive patients treated with AneuRx or Talent endovascular stent-grafts, late conversion rate (>24 hours after implantation) was 3.1%, which is similar to the results of other series with long-term follow-up.[9-11] As in other clinical trials, the main reasons for late conversion to open repair were persistent endoleak, particularly proximal type I, and proximal migration.[12-14] Most complications that might lead to late conversion were located in the proximal aneurysm neck. In our opinion, the technique of explantation should consist of short supraceliac clamping, whereafter the transrenal fixating stent-graft or transrenal fixating extender cuffs can be removed through an infrarenal aortotomy. After this, the clamp can be switched to the infrarenal position.

The mortality rate for acute conversions (n = 4) in patients with an aortic rupture was 50%. Of the six patients who needed elective conversion, the mortality rate was 0% and the morbidity rate was 67% (n=4); however, all complications were without permanent sequelae. Taking into account the considerable comorbidity of the patients, the complication rate of elective open reconstruction after EVAR is acceptable. These results advocate timely and thus elective explantation if EVAR-related problems occur that cannot be solved with renewed endovascular techniques.

Chapter 6 focuses on the long-term single-center results with the AneuRx device which was used in 212 patients. The perioperative mortality rate was 2.4 %, which is acceptable in a series with 46% American Society of Anesthesiologists (ASA) class III or IV patients. Freedom from secondary interventions was 91% at 1 year, 78% at 3 years, 65% at 5 years, 52% at 7 years, and 48% at 9 years. These results indicate an annual risk for secondary interventions higher than the annual risk of 6.3%, which was reported from the EUROSTAR experiences for patients with an AneuRx device.[15] This might be explained by the liberal inclusion criteria, including short aneurysm necks (≤1 cm), and suboptimal use of anchoring zones in the early years. After we experienced fixation-related complications, we changed our inclusion criteria and also improved our technique of stent-graft placement. For patients treated after 1999, risk for secondary interventions was decreased to an annual risk of about 5%.

The total mortality rate in our series was 44% after 9 years. Causes of death were mostly cardiac disease (40%) or malignancy (19%), which illustrates the severe comorbidity of this patient population. The aneurysm-related death rate was relatively small, with an annual risk of about 1%.

One of the most important lessons in this long-term follow-up is that most secondary interventions were needed for fixation-related problems and that these complications mainly occurred in the proximal aortic anchoring zone. In fact, the proximal aneurysm

neck is likely to be the Achilles' heel for durability after EVAR. To improve EVAR outcome in future, it appears essential to get more insight into the dynamic behavior of this aneurysm neck. For this reason, we decided to start dynamic studies on the area of the proximal aneurysm neck by means of dynamic magnetic resonance angiography (MRA).

Chapter 7 describes the first study on dynamics of the proximal anchoring zone studied with dynamic MRA before and after EVAR in 11 patients. By using retrospective electrocardiographic (ECG) gating, time-resolved images could be acquired, resulting in cine MRA loops with 16 images per cardiac cycle.

We performed measurements at three, predetermined, clinically relevant anatomic levels of the aneurysm neck. These three levels corresponded to uncovered (suprarenal) native aorta, aorta with bare stents (between the renal arteries), and aneurysm neck with stent-graft fabric (infra-renal), respectively. We revealed that severe wall motion was present at all these levels.

It seems obvious that aortic dynamics may play a role in EVAR's durability. Pulsatile forces with each heartbeat over a patient's lifetime can result in literally millions of repeated stress events placed upon an implanted stent-graft. Although this study did not evaluate stent-graft durability, it characterized and quantified the dynamic environment in which stent-grafts are placed.

By computer analysis we could determine the greatest change in diameter simultaneously along 256 axes during the cardiac cycle at each predetermined aortic level. Preoperatively, mean diameter changes at each level were about 8%. However, these diameter changes differed between patients and even within each patient they varied over the studied axes. This means that aortic expansion during systole is not only significant, but it is also an asymmetrical phenomenon. Further, pulsatility of the aneurysm neck appeared not to be influenced by stent-graft placement.

In **Chapter 8,** wall stiffness (inversely related to wall compliance) of the aneurysm neck and the aneurysm wall (sac) were studied with dynamic MRA, before and after stent-graft placement in 11 patients. Wall stiffness was characterized by Ep (elastic modulus) and β (stiffness). We measured an increased stiffness at the level of the aneurysm sac after EVAR, which supports the notion that the aneurysm sac is less pressurized. The finding of increased aortic wall stiffness after EVAR is intuitive, because once the aneurysm has been excluded by a stent-graft, a greater pulse pressure is necessary to cause similar sac wall pulsatility compared to pulsatility before exclusion. In other words, the endograft is fulfilling its clinical requirement of decreasing the transmitted blood pressure on the aneurysmatic aortic wall.
In our study, neither EVAR nor endoleaks resulted in changes to Ep or β within the aneurysm neck, but stent-graft design did influence compliance at the level of the neck. Comparing the Excluder (W.L. Gore& Associates, Flagstaff, AZ, USA; n=4) versus the Talent (Medtronic Vascular, Santa Rosa, CA, USA; n=7) device, we discovered that the

Excluder device resulted in significantly higher Ep and β at the infrarenal aorta. No difference was observed at the other three levels (aneurysm sac, renal, and suprarenal); therefore, the difference in stiffness of the aneurysm neck between patients with an Excluder or a Talent stent-graft was probably caused by the differences in stent-graft design.

Future Perspectives

The EVAR 1 and DREAM trials have established the early mortality advantage for EVAR versus open repair,[16,17] and EVAR 1 data showed a persistent reduction in aneurysm-related mortality in EVAR patients at 4 years.[18] Only long-term results, however, will determine if EVAR can stand the comparison with conventional open repair. It is important to realize that EVAR just started in 1991 and is still in evolution.

In this thesis, we have shown that long-term results of the AneuRx device are acceptable in our group of patients. However, better results are needed to advocate EVAR instead of open repair in healthier and especially younger patients. Improvement of results of EVAR in the future can especially be achieved by more secure proximal fixation. This should improve durability of EVAR and will decrease the need for secondary interventions. We have shown in this thesis that the proximal anchoring zone of the stent-graft is not a rigid tube, but rather a dynamic, pulsatile structure. Unfortunately, static computed tomography angiography, the gold standard to determine a patient's anatomic suitability for EVAR, cannot determine this new dimension and therefore seems insufficient to judge anatomic suitability. We advocate additional use of dynamic imaging tools before EVAR to determine aortic dynamic changes during cardiac cycles.

New studies with dynamic imaging tools will have to reveal the relations between the dynamic features of aneurysm necks and their influence on stent-graft fixation and fixation-related complications during follow-up. We expect that proximal stent-graft fixation is less secure in patients with large (asymmetrical) pulsatility. In upcoming years, these dynamics will become important in the determination of suitability for EVAR and also in the determination of optimal stent-graft sizing. Optimal oversizing of the stent-graft will probably depend on pulsatility of the aneurysm neck. Necks that show large pulsatility might need more oversized stent-grafts compared with necks with less pulsatility. Moreover, it is also possible that the optimal fixation technique for a stent-graft depends on pulsatile parameters. A stent-graft design that relies for its fixation particularly on radial force may provide good fixation in patients with rigid aneurysm necks, whereas its outcome in patients with large pulsatility might be worse. Controversially, a stent-graft design that especially relies on barbs or hooks may have good fixation in the pulsatile necks, while penetration of barbs or hooks in more rigid aneurysm necks could be more difficult and therefore make its fixation less secure.

Further, in this thesis we showed that aortic neck pulsatility is asymmetrical. This feature might imply that fixation could be improved with adapted, asymmetrical stent-graft designs or by symmetrical stent-grafts that transform asymmetrically during the cardiac cycle. Stent-grafts with hooks could possibly perform better in patients with asymmetrical expansion compared with grafts without hooks. Perhaps larger, oversized stent-grafts or the use of multiple hooks that "catch" the aortic wall could reduce or even prevent asymmetrical expansion.

We also reported that stent-graft design could significantly alter aortic stiffness. Also, the clinical consequence of this observation will need to be determined by future studies. Aortic stiffness will probably have a relationship with the magnitude of neck dilatation during follow-up and therefore can affect durability.

Conclusion

Whether EVAR will ever be the preferable technique for repair of AAAs or paraanastomotic aneurysms is not yet predictable. This thesis has shown acceptable results during mid-term and long-term follow-up for patients with severe comorbidities. Proximal fixation of the stent-graft was identified as the Achilles' heel of EVAR and therefore should be of major interest for further investigation and improvement. We presented new information on dynamic features of the aneurysm neck before and after stent-graft placement. This information gains insight into a whole new area for further studies and will have its effects on inclusion criteria and stent-graft designs. Dynamics of EVAR can initiate further improvements of stent-graft fixation to make a giant leap ahead in EVARs evolution.

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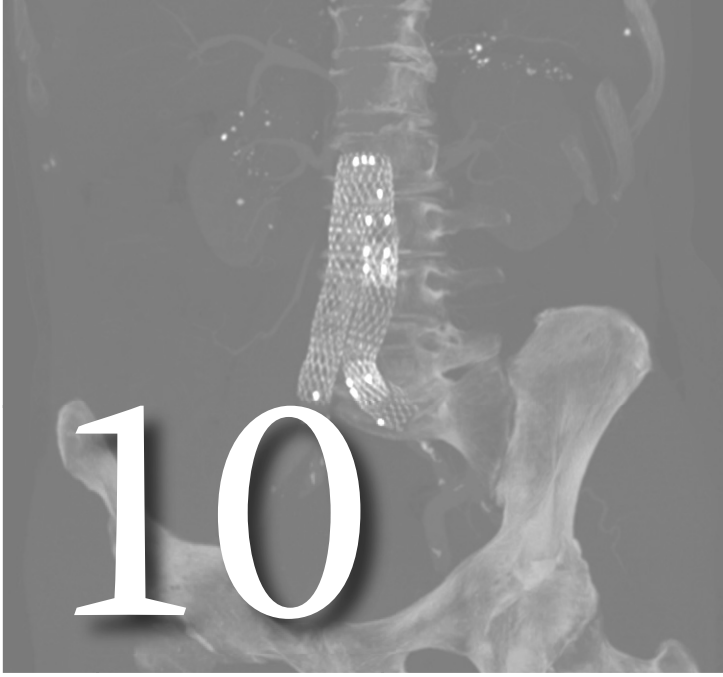

Chapter 10

Nederlandse samenvatting, toekomstperspectieven en conclusie

Het endovasculair uitschakelen van aneurysmata van de abdominale aorta (endovascular aneurysm repair, EVAR) werd in 1991 voor het eerst bij patiënten geïntroduceerd.[1,2] Vijf jaar later werd met deze behandeling begonnen in het St. Antonius Ziekenhuis te Nieuwegein, waarbij gebruik werd gemaakt van het AneuRx stent-graft systeem (Medtronic AVE, Santa Rosa, CA, USA). Dit was een van de eerste commercieel beschikbare endoprothesen. Vanaf de eerste EVAR procedure werden alle data prospectief verzameld in een database. In dit proefschrift worden de middellange en lange termijn resultaten na EVAR geëvalueerd en wordt het dynamische karakter van de aorta bestudeerd.

In **Hoofdstuk 2** wordt een algemeen overzicht van EVAR gegeven. In een review van recente literatuur worden de indicatie stelling, patiënten selectie, technieken van EVAR, mortaliteit en morbiditeit geëvalueerd. Tevens wordt aandacht geschonken aan de kwaliteit van leven na EVAR en de toekomstperspectieven van deze behandeling.

Hoofdstuk 3 bevat de middellange termijn resultaten van de AneuRx endoprothese bij onze eerste 77 patiënten met een minimale follow-up van 12 maanden. Vergelijkbaar met andere studies uit de literatuur, tonen onze resultaten een lage morbiditeit en mortaliteit durante opname en een kortere opnameduur in vergelijking met resultaten van studies na open (klassieke) aneurysma-chirurgie. Tevens worden EVAR-gerelateerde complicaties geëvalueerd, zoals het niet (goed) ontplooien van de prothese (n = 2), verschillende typen endolekkage (n = 18), afknikken van de prothese met (n = 3) of zonder occlusie, en migratie van de endoprothese (n = 5). Om de resultaten na EVAR te verbeteren, werden de inclusiecriteria strikter en werd gestreefd naar maximale fixatie proximaal, distaal en tussen de modulaire componenten in.

In **Hoofdstuk 4** wordt de toepassing van EVAR bij het uitschakelen van para-anastomotische aneurysma's (PAA's) beschreven. PAA's zijn naadaneurysmata na eerdere open (conventionele) uitschakeling van een aneurysma, of ware aneurysmata proximaal of distaal van een aortabuis- of bifurcatieprothese. PAA's kunnen leiden tot ruptuur, trombose, embolie en druk op of erosie van omliggende structuren.[3-5] Derhalve verdient het de voorkeur om deze aneurysmata uit te schakelen, mits dit bereikt kan worden met een laag complicatiepercentage. De mortaliteit van open uitschakeling van PAA's kan echter oplopen tot 17%.[3-8] Slechts twee studies vermelden een mortaliteit onder de 8%.[7,8]

In onze studie werden bij 14 patiënten PAA's succesvol uitgeschakeld middels EVAR zonder perioperatieve mortaliteit. Behoudens een longontsteking bij 1 patiënt, traden er geen perioperatieve complicaties op. De mediane follow-up bedroeg 12 maanden (3 tot 40 maanden). Bij 11 patiënten, behandeld met een bifurcatie endoprothese, was geen conversie noodzakelijk en een re-interventie was slechts nodig bij een patiënt.

Uitschakeling van naadaneurysmata van de proximale aorta-anastomose met endovasculaire buisprothesen bleek niet duurzaam. Deze bevinding ondersteunt de theorie dat proximale fixatie van bifurcatie endoprothesen niet alleen afhankelijk is van de radiaire krachten, maar ook van de longitudinale ondersteuning van de endoprothese.

Daarom gebruiken we tegenwoordig alleen bifurcatie-endoprothesen. Indien dit niet mogelijk is ten gevolge van anatomische karakteristieken, wordt het gebruik van een aorto-uniiliacale endoprothese overwogen.

Samenvattend kan gesteld worden dat endovasculair uitschakelen van PAA's uitvoerbaar is met lage perioperatieve morbiditeit en mortaliteit. Uitschakeling van PAA's middels implantatie van bifurcatie endoprothesen lijkt effectief, een langere follow-up is echter noodzakelijk.

In **Hoofdstuk 5** wordt de explantatie van endovasculaire prothesen kritisch bekeken. Onze patiëntengroep (n=355), behandeld met een AneuRx of Talent endoprothese, liet een late conversie percentage (>24 uur na implantatie) zien van 3.1%. Dit is vergelijkbaar met de resultaten van andere lange termijn studies.[9-11] Zoals in andere klinische trials betrof de voornaamste reden voor late conversie naar open aneurysma-chirurgie persisterende endolekkage (voornamelijk proximaal type I) en migratie van de endoprothese.[12-14] De meeste complicaties die een conversie tot gevolg hadden, bleken gelokaliseerd in de proximale aneurysma-nek. Wij zijn de mening toegedaan dat de preferente techniek van endoprothese explantatie bestaat uit het kortdurend supracoeliacaal afklemmen, waarna de (eventueel transrenaal gefixeerde) endoprothese of extensie cuff verwijderd kan worden middels een tomie in de infrarenale aorta. Hierna kan de aortaklem infrarenaal geplaatst worden

De mortaliteit van acute conversies (n=4) bij patiënten met een aortaruptuur bedroeg 50%. Bij de zes patiënten die electief geconverteerd werden, was er perioperatief geen mortaliteit en de morbiditeit was 67% (n=4); Echter, alle complicaties waren van tijdelijke aard. Met inachtneming van de aanzienlijke co-morbiditeit van de patiëntengroep, kan het percentage complicaties van electief open reconstructie na EVAR als acceptabel beschouwd worden. Deze resultaten bepleiten zorgvuldig geplande en dus electieve explantatie indien EVAR-gerelateerde problemen optreden die niet opgelost kunnen worden middels vernieuwde endovasculaire technieken.

In **Hoofdstuk 6** worden de lange termijn resultaten van de AneuRx endoprothese, toegepast bij 212 patiënten, geëvalueerd. De perioperatieve mortaliteit bedroeg 2,4%. Dit is een acceptabel percentage, aangezien 46% van de patiënten geclassificeerd was als ASA (American Society of Anesthesiologists) klasse III of IV. Het percentage patiënten dat vrij was van een re-interventie was 91% na 1 jaar, 78% na 3 jaar, 65% na 5 jaar, 52% na 7 jaar en 48% na 9 jaar. Deze percentages lagen hoger dan het jaarlijkse risico van 6,3% eerder gerapporteerd in de EUROSTAR resultaten met de AneuRx prothese.[15] Dit zou verklaard kunnen worden door de liberale inclusie criteria, zoals een korte aneurysmanek (≤1 cm), en suboptimaal gebruik van een eventueel langere aneurysmanek in de beginjaren. Na het vaststellen van fixatie gerelateerde complicaties, hebben we onze inclusie criteria aangepast en onze techniek van endoprothese plaatsing verbeterd. Voor patiënten die na 1999 werden behandeld, was het risico op re-interventies gedaald naar een jaarlijks risico van circa 5%.

De totale mortaliteit in onze serie patiënten bedroeg 44% na 9 jaar. De voornaamste doodsoorzaak was van cardiale origine (40%) of was een malignitiet (19%). Dit illustreert de ernstige co-morbiditeit binnen onze patiënten populatie. De aneurysma gerelateerde mortaliteit was relatief laag, met een jaarlijks risico van circa 1%.

De belangrijkste boodschap van deze lange termijn follow-up was dat de meeste re-interventies nodig waren wegens fixatie gerelateerde problemen en dat deze complicaties voornamelijk optraden in het gebied van de proximale fixatie van de endoprothesen. In feite lijkt de duurzaamheid van de fixatie van de endoprothese in de aneurysmanek de Achilleshiel van EVAR te zijn. Om de resultaten van EVAR in de toekomst te verbeteren, achten wij het essentieel om meer inzicht te verkrijgen in de dynamiek van de aneurysmanek. Derhalve, zijn we studies gestart met dynamische MRA (magnetic resonance angiography) naar de veranderingen van de aneurysmanek tijdens cardiale cycli.

Hoofdstuk 7 bevat de eerste dynamische studie naar veranderingen van de proximale aneurysmanek onderzocht met dynamische MRA voor en na EVAR in 11 patiënten. Op drie, klinisch relevante, anatomische niveaus proximaal van het aneurysma, werden metingen verricht. De drie niveaus waren gelokaliseerd 3 centimeter proximaal van de meest distale nierarterie, op het niveau van de nierarteriën, en 1 centimeter distaal van de meest distale nierarterie. De dynamische MRA toonde aan dat de aortawand op alle niveaus grote pulsatiliteit laat zien. Het lijkt duidelijk dat het dynamische karakter van de aorta een rol zou kunnen spelen bij de duurzaamheid van geplaatste endoprothesen. Hartslagen veroorzaken pulsatiele krachten en tijdens een patiëntenleven leidt dit letterlijk tot miljoenen herhaaldelijke stressmomenten op een geïmplanteerde endoprothese. Ondanks dat deze studie niet de duurzaamheid van endoprothesen bestudeerde, werd wel de dynamische omgeving waarin endoprothesen geplaatst worden gekarakteriseerd en gekwantificeerd.

Met behulp van computer analyse kon op elk vooraf bepaald niveau van de aorta, gedurende de hartcyclus, de grootste diameter verandering simultaan over 256 assen bepaald worden. Preoperatief bedroeg de gemiddelde diameter verandering circa 8% op alle niveaus. Maar deze pulsatiliteit varieerde behoorlijk tussen de verschillende patiënten en zelfs binnen één patiënt varieerde de diameterveranderingen behoorlijk over de verschillende gemeten assen. Diameterveranderingen van de aorta varieerde van 0.3 mm tot 4.2 mm op hetzelfde niveau en tijdens dezelfde hartcyclus, afhankelijk van welke as gemeten werd. Dit betekent dat het expanderen van de aorta niet alleen een significant, maar ook een asymmetrisch fenomeen is. Verder bleek dat de pulsatiliteit van de aneurysma-nek niet beïnvloed wordt door plaatsing van een endoprothese.

In **Hoofdstuk 8** worden de elastische eigenschappen (omgekeerd evenredig met compliance) van de aneurysma-nek en de aneurysma-zak onderzocht met dynamische MRA. Het onderzoek vond plaats voor en na endoprothese plaatsing bij 11 patiënten. De elastische kenmerken werden gekarakteriseerd door Ep (elasticiteitsmodulus) en β (stijfheid). Na EVAR werd op het niveau van de aneurysma-mantel een verhoogde stijfheid gemeten. Dit ondersteunt de gedachte dat er dan minder druk op de aneurysma-mantel

staat. Door de aanwezigheid van een endoprothese is een grotere polsdruk nodig is om dezelfde pulsatiliteit van de aortawand te bewerkstelligen als voor EVAR.
In deze studie resulteerde zowel plaatsing van een endoprothese, als aanwezigheid van een endoleak niet in veranderingen van elastische kenmerken van de aneurysma-nek. Het ontwerp van de endoprothese had echter wel invloed op de compliance. Bij een vergelijking tussen patiënten met een Excluder endoprothese (W.L. Gore& Associates, Flagstaff, AZ, USA; n=4) en patiënten met een Talent endoprothese (Medtronic Vascular, Santa Rosa, CA, USA; n=7), werd bij patiënten met een Excluder prothese een significant hogere Ep en β gevonden ter hoogte van de infrarenale aorta. Op de andere drie niveaus (aneurysma-zak, juxtarenaal en suprarenaal) werd geen verschil gevonden in elastische kenmerken. Het verschil in stijfheid ter hoogte van de aneurysma-nek tussen patiënten met de Excluder en de Talent endoprothese werd waarschijnlijk veroorzaakt door het verschil in ontwerp van de endoprothese.

Toekomstperspectieven

De EVAR 1 en DREAM studies hebben voor EVAR een voordeel in vroege mortaliteit aangetoond in vergelijking met de open aneurysma chirurgie.[16,17] De data van EVAR 1 lieten een blijvende reductie in aneurysma gerelateerde mortaliteit zien bij EVAR-patiënten na 4 jaar.[18] Alleen lange termijn resultaten zullen echter kunnen bepalen of EVAR de vergelijking met open aneurysma chirurgie kan doorstaan. Daarbij is het belangrijk om te realiseren dat EVAR pas sinds 1991 toegepast wordt en nog steeds in ontwikkeling is.

We hebben laten zien dat de lange termijn resultaten van de AneuRx endoprothese acceptabel zijn voor onze patiëntengroep. Echter, er zijn betere resultaten nodig om EVAR te promoten als alternatief voor open aneurysma chirurgie bij gezondere en vooral jongere patiënten. Een verbetering van de resultaten van EVAR in de toekomst zou bereikt kunnen worden door een verbetering in de proximale fixatie. Dit zou de duurzaamheid van EVAR verbeteren en de behoefte aan re-interventies verminderen. Onze studie bewijst dat de proximale aneurysma-nek, waar de endoprothesen verankeren, geen rigide buis is, maar een dynamische, pulsatiele structuur . Helaas kan pulsatiliteit niet geëvalueerd worden met behulp van statische CTA (computed tomography angiography), de gouden standaard voor het bepalen of een patiënt anatomisch gezien in aanmerking komt voor EVAR. Daarom, lijkt de statische CTA niet sufficiënt om de anatomische geschiktheid voor EVAR te bepalen. Wij pleiten voor additioneel gebruik van dynamische beeldvorming om de dynamische aorta veranderingen gedurende de hartcyclus te evalueren.

Nieuwe studies met dynamische beeldvorming zullen een verband moeten aantonen tussen de dynamische eigenschappen van de aneurysma-nek en de invloed op endoprothese-fixatie en fixatie-gerelateerde complicaties tijdens de follow-up. Wij verwachten dat proximale fixatie minder degelijk is bij patiënten met een grote (asymmetrische) pulsatiliteit. De komende jaren zullen deze dynamische kenmerken belangrijk worden bij bepalen of een patiënt geschikt is voor EVAR en voor het bepalen van de optimale

endoprothese. Optimale oversizing van een endoprothese zal waarschijnlijk afhangen van de pulsatiliteit van de aneurysma-nek; een nek met meer pulsatiliteit heeft waarschijnlijk een meer oversized endoprothese nodig vergeleken met een nek met minder pulsatiliteit. Bovendien is het mogelijk dat de optimale fixatie techniek van een endoprothese afhankelijk is van pulsatiliteit. Enerzijds zou een endoprothese ontwerp dat voor zijn fixatie vooral afhankelijk is van radiaire krachten, een goede fixatie kunnen bieden in een rigide aneurysma-nek, terwijl ditzelfde ontwerp misschien een slechter resultaat biedt bij een meer pulsatiele aneurysma-nek. Anderzijds zou een endoprothese ontwerp waarbij de proximale fixatie vooral berust op weerhaken een goede fixatie kunnen bieden bij een meer pulsatiele aneurysma-nek, terwijl deze fixatiehaken in een meer rigide aneurysma-nek de (wellicht hardere) wand moeilijker kunnen penetreren en daardoor misschien wel een minder degelijke fixatie bieden.

We hebben in dit proefschrift aangetoond dat de pulsatiliteit van de aneurysma-nek asymmetrisch is. Dit fenomeen zou kunnen impliceren dat fixatie van endoprothesen verbeterd kan worden met aangepaste, asymmetrische ontworpen endoprothesen of met symmetrische endoprothesen die asymmetrisch transformeren gedurende de hartcyclus. Een endoprothese met weerhaken zou wellicht betere resultaten kunnen bieden bij een aorta met asymmetrische pulsatiliteit vergeleken bij een endoprothese zonder haken. Misschien zou een grotere, oversized endoprothese of het gebruik van multipele weerhaken die juist de aortawand fixeren het asymmetrisch expanderen van de aorta kunnen reduceren of wellicht zelfs voorkomen.

In dit proefschrift werd ook aangetoond dat het ontwerp van een endoprothese de stijfheid van de aortawand significant kan veranderen. De klinische consequentie van deze bevinding zal nog nader bestudeerd moeten worden door toekomstige (dynamische) studies. Het is voorstelbaar dat stijfheid van de aortawand ter plaatse van de proximale aneurysma nek een relatie heeft met de omvang van dilatatie van de aneurysma-nek tijdens follow-up en zou dientengevolge een effect kunnen hebben op de duurzaamheid van EVAR.

Conclusie

Of EVAR de preferente techniek zal worden voor het uitschakelen van aneurysmata van de infrarenale aorta abdominalis is nog niet duidelijk. Dit proefschrift toont acceptabele resultaten van de middellange en lange termijn follow-up voor patiënten met ernstige co-morbiditeit. Proximale fixatie van de endoprothese werd geïdentificeerd als de achilleshiel van EVAR en zou derhalve het speerpunt voor verder onderzoek moeten vormen. Wij hebben nieuwe informatie naar voren gebracht over de dynamische kenmerken van de aneurysma-nek voor en na EVAR. Deze gegevens verschaffen inzicht in een geheel nieuw gebied voor toekomstige studies en zij zullen effect hebben op de inclusiecriteria en op ontwerpen van endoprothesen. Kennis van de dynamische veranderingen tijdens cardiale cycli kan verdere verbetering van de fixatie van endoprothesen initiëren om zodoende een grote stap voorwaarts in de evolutie van EVAR te bewerkstelligen.

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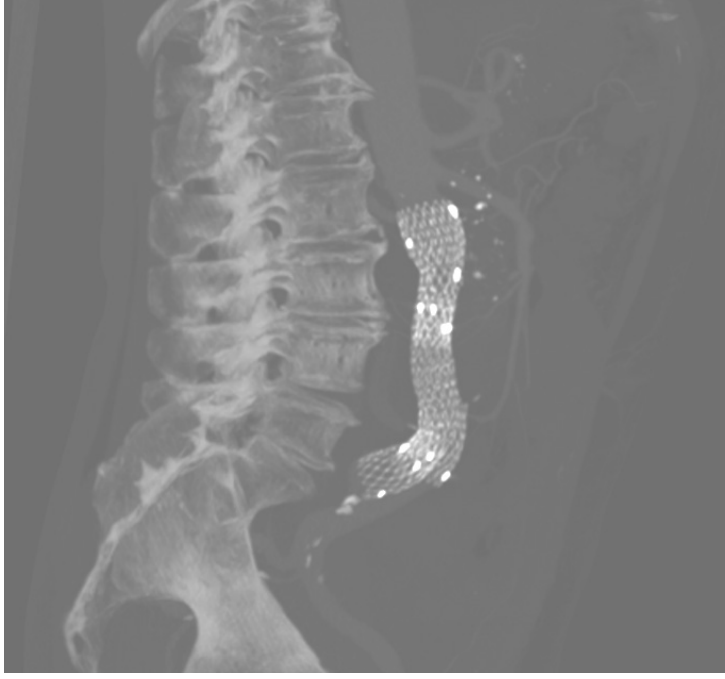

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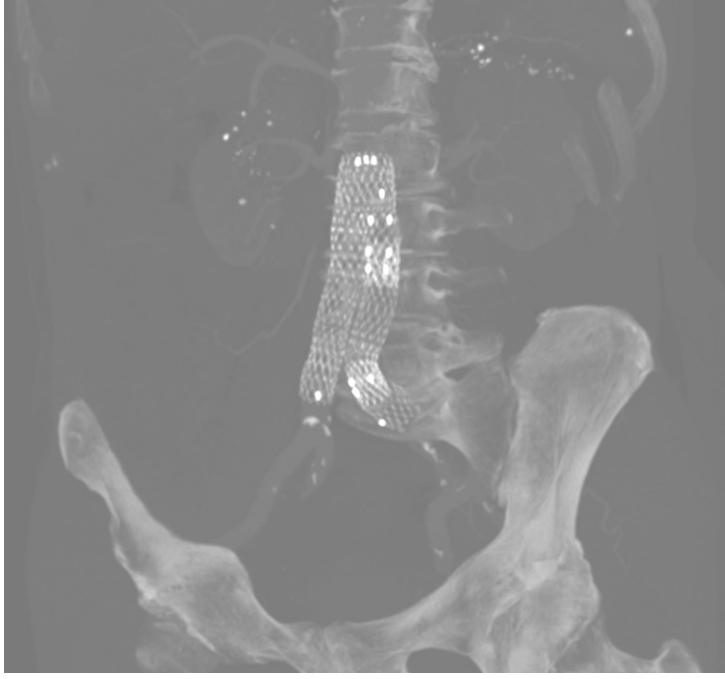

Curriculum vitae

De auteur van dit proefschrift werd op 8 november 1973 geboren te Nijmegen. Hij groeide op in Nijmegen en Groesbeek. In 1992 behaalde hij het VWO diploma aan de Nijmeegse Scholengemeenschap "Groenewoud". Aansluitend studeerde hij geneeskunde aan de Universiteit Utrecht. Vanaf 1995 tot 1998 deed hij, in zijn vrije tijd, de eerste ervaringen op met het doen van wetenschappelijk onderzoek op de afdeling Experimentele Cardiologie (Prof. dr C. Borst). Tijdens deze periode ontstond in het dierenlab de liefde voor een "snijdend" specialisme. Na het behalen van het doctoraalexamen in 1997 werd aangevangen met de co-schappen. Het co-schap chirurgie had plaats in het UMC Utrecht en het St. Antonius Ziekenhuis Nieuwegein. De (vaat)chirurgie veroverde zijn hart. Tijdens zijn co-schappen deed hij retrospectief onderzoek bij Prof. dr. Th.J.M.V. van Vroonhoven, naar de resultaten van de chirurgische behandeling van het geruptureerde aneurysma van de abdominale aorta. Het artsexamen werd behaald in 1999.
Aansluitend werkte hij 20 maanden als AGNIO chirurgie in het St. Antonius Ziekenhuis Nieuwegein. In deze periode startte hij met het bijhouden van de resultaten van EVAR met de AneuRx prothese, de basis voor dit proefschrift. De opleiding chirurgie begon hij in 2001. De opleiding heeft plaats in het St. Antonius Ziekenhuis Nieuwegein (opleider Dr. P.M.N.Y.H. Go) en het UMC Utrecht (opleider Prof. dr. I.H.M. Borel Rinkes). Naar verwachting zal hij de opleiding afronden eind 2006. Hierna zal hij zich als CHIVO (Chirurg In Vervolgopleiding) in het UMC Utrecht verder bekwamen in de vaatchirurgie (opleider Prof. dr. F.L. Moll).
In 2004 trouwde hij met Maud Lindeboom, met wie hij eind dit jaar een eerste kindje verwacht.