Results of Clinical Research to improve EVAR

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Results of Clinical Research to improve EVAR

Resultaten van Klinisch Onderzoek ter verbetering van EVAR

(met een samenvatting in het Nederlands)

Proefschrift

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geboren op 31 oktober 1976 te Zeist

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Voor mijn vader

Chapter 1

Introduction

INTRODUCTION

The term aneurysm is derived from the Greek word *aneurysma*, meaning "a widening." Arterial aneurysms have been recognized since ancient times. One of the earliest texts known, the Ebers Papyrus (2000 BC), contains a description of a traumatic aneurysm of the peripheral arteries.

By current reporting standards, an aneurysm is a permanent localized (i.e., focal) dilation of an artery that has at least a 50% increase in diameter compared with the expected normal diameter of the artery in question.[1] Arterial dilatation of less than 50% of normal is termed ectasia. The normal arterial diameter depends on many factors, including age, gender, and race. The normal diameter of the infrarenal part of the abdominal aorta is 1.19 to 2.16 cm for women and 1.41 to 2.39 cm for men.[2-4] For practical reasons, however, most reports document an aneurysm of the infrarenal aorta when diameter reaches 3 cm or more.[5;6]

Abdominal aortic aneurysm is a common disease entity, affecting men 4 times more often than women.[6;7] The estimated prevalence ranges from 1.0% to 11%, depending mainly on the gender and age of the investigated population.[6-8]

Modern techniques of aneurysm repair were made possible by Alexis Carrel (1873-1944), who showed in animals that a segment of the aorta could be replaced by a segment of another artery or vein. Carrel won the Nobel Prize for his work in 1912. However, it was not until 60 years and 9 days ago, on March 29, 1951, that Charles Dubost (1914-1991) performed the first successful replacement of an aortic aneurysm. Although his patient survived for 8 years, morbidity and mortality were quite high in the early days. However, with refined operative technique and improved patient care, the mortality rate dropped to 3% to 5%, as it still remains today.[9-11] The advances notwithstanding, open aneurysm repair continues to cause substantial morbidity and requires a prolonged hospital admission and intensive care stay as well as a long recovery period. In addition, a significant number of patients are deemed high-risk candidates for open repair because of significant comorbidities.

All of these issues provided a major incentive for the development of less invasive procedures. In 1991, Parodi et al. in Argentina and Volodos et al. in the Ukraine both reported a technique for endovascular aneurysm repair (EVAR).[12;13] Since then, treatment of aneurysms of the abdominal aorta shifted from open repair to the less invasive endovascular repair.

Today, only 2 decades after the first endovascular procedures were performed, more than 60% of patients are treated endovascularly.[14] In the beginning of the EVAR era, the procedure was mainly offered to patients unfit for open repair and to older patients with significant comorbidities. Since its introduction in 1991, there have been a lot of disbelievers of EVAR because the initially good short-term results were not sustained in the longer-term.

In August and October 2004, the short-term results of 2 randomized controlled trials were published.[15;16] The United Kingdom EVAR 1 Trial, randomized 1082 elective patients to receive EVAR (n = 543) or open aneurysm repair (n = 539). Thirty-day mortality in the EVAR group was 1.7% versus 4.7% in the open repair group ($p = 0.009$). Secondary interventions were more common in patients allocated to EVAR (9.8% versus 5.8%, $p = 0.02$). Unfortunately, 75% of secondary interventions in the EVAR group were classified as "corrections of endoleak and other surgery," without further clarification.

The Dutch Randomised Endovascular Aneurysm Management (DREAM) trial randomized 345 patients to EVAR (n = 171) or open aneurysm repair (n = 174). The operative mortality rate was 4.6% in the open-repair group and 1.2% in the EVAR group ($p = 0.10$). The combined rate of operative mortality and severe complications was 9.8% in the open-repair group and 4.7% in the EVAR group ($p = 0.10$). Compared with open repair, EVAR resulted in significantly better perioperative outcomes, such as a lower rate of systemic complications, less blood loss, a briefer duration of surgery, a lower rate of use of postoperative mechanical ventilation, and shorter hospital stays, all reflecting the less invasive nature of EVAR.

The long-term results of both randomized controlled trials were published in 2010.[17;18] Neither study showed significant differences between the open-repair and EVAR groups in the mortality rate from any cause: there was a 46% mortality rate in both groups by the end of 8 years of follow-up in the EVAR 1 trial and a 30% rate for open repair vs 31% for EVAR at 6 years after randomization in the DREAM trial. In addition, overall aneurysm-related mortality in the EVAR 1 trial was 7% in both groups by the end of 8 years of follow-up, which was not a statistically significant difference. Freedom from secondary interventions in both studies were, however; significantly lower in the EVAR groups.

The believers of EVAR might say that the significantly higher rate of secondary interventions in these 2 randomized controlled studies was partly due to the use of older-generation devices, less knowledge about aneurysm morphology, and less sophisticated intraoperative fluoroscopic imaging. As our experience with endografting grows, the introduction of new technology should result in improved outcomes. However, many studies that have evaluated long-term results have included patients treated with older generation stent grafts. EVAR technology is unfolding faster than it can be tested, so the current long-term outcomes may not reflect the results that can be obtained with newer generation devices.

The disagreements between the believers and nonbelievers of EVAR will not be resolved with the current knowledge of EVAR versus open aneurysm repair. Currently, however, patients seem to prefer endovascular repair rather than open repair, and most vascular centers offer EVAR as the first treatment option.[19;20]

The ongoing improvements and refinements in stent graft design (low profile delivery systems, flexible stent grafts and improved proximal fixation) will eventually lead to a better stent graft with increased durability.

Today, EVAR is not just reserved for older patients or patients with significant comorbidities. There is a clear trend to offer the younger patient an endovascular procedure as the first treatment because there is growing evidence that especially this younger patient group has the greatest benefit of EVAR.[21-23] Durability of EVAR is of major importance in younger patients because they have a substantially longer life expectancy after aneurysm repair.[22]

Besides the trend to treat younger and healthier patients endovascularly, due to ongoing improvements in stent grafts technique and design, the indications for EVAR has extended to patients with short infrarenal aortic necks or even juxtarenal aneurysms, ruptured aneurysms, and para-anastomotic aneurysms after previous open repair.[24-27]

With the expected ongoing increase of EVAR as the first option over open aneurysm repair of primary or para-anastomotic aneurysms, there is a need for clinical research that focuses on the long-term results of currently used stent grafts. In addition, to improve EVAR durability, information is needed that focuses on aneurysm morphology and stent graft fixation characteristics that influence durability.

OUTLINE OF THE THESIS

In **Chapter 2** a general overview is presented of the most important aneurysm morphologies that have an influence on EVAR durability. Some of the stent graft fixation characteristics are also mentioned. **Chapter 3** describes the long-term clinical results of the transrenal fixating Talent stent graft system. This stent graft was FDA-approved in 2008 but had already received CE approval in Europe in 1998. We report the follow-up since July 2000. In **Chapter 4** renal function after EVAR is described. Patients who were treated by means of transrenal fixating stent grafts were compared with patients treated by infrarenal fixating stent grafts.

Chapter 5 describes the value of computed tomography angiography early after EVAR. In **Chapter 6** the influence of aneurysm diameter and proximal aortic neck diameter on clinical outcome of endovascular abdominal aneurysm repair is described. The data up to 4 years of follow-up were obtained from a multicenter European collaboration database. In **Chapter 7** the importance of iliac fixation on long-term EVAR durability is highlighted. **Chapter 8** reviews the technical options for dealing with unfavorable iliac anatomy, including ectatic, aneurysmal, and short iliac arteries. Also the importance of iliac fixation is briefly mentioned.

In **Chapter 9** the midportion of the stent graft is investigated. The short-term results of endovascular repair of para-anastomotic aneurysms after previous open aortic prosthetic reconstruction is described in **Chapter 10** and the long-term results in **Chapter 11**. Finally, **Chapter 12** provides a summary of the thesis and the general discussion regarding the findings of this thesis.

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Chapter 2

Anatomic and fixation risk factors for EVAR-related complications

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In the past decade, endovascular abdominal aortic aneurysm repair (EVAR) has emerged as a good alternative treatment for infrarenal aneurysms of the abdominal aorta (AAA).
In the first years after its introduction in 1991, EVAR was used in patients who were not good candidates for open AAA repair. Especially for those patients with high cardiopulmonary comorbidities who could not undergo open AAA repair due to the high surgical risk, introduction of EVAR led to a reasonable treatment modality. An endovascular stent graft can be introduced under local anesthesia, without cross clamping of the aorta, and is therefore a great improvement in treating patients who could not tolerate open AAA repair.

The relative high mortality rate of open AAA repair and the even higher rate of significant major morbidities compared with EVAR has gained enormous popularity for EVAR. Because EVAR has a low mortality rate and is less invasive, there is a trend for treating patients with suitable anatomy by EVAR instead of offering them the classical open repair. To date, more than half of all patients with an AAA are treated with endovascular repair. By anatomic criteria alone, >65% of infrarenal AAAs can be treated with the endovascular devices currently available commercially or through the US Food and Drug Administration-approval clinical trials.[1]

Two randomized controlled trials in 2004 showed a significant short-term benefit for EVAR over open AAA repair in 30-day mortality and morbidity rates.[2;3] The short-term results of the British EVAR Trial 1 showed a reduction of 30-day operative mortality by two-thirds compared with open repair.[2] All-cause mortality was similar in the 2 groups 4 years after randomization, although there was a persistent reduction in aneurysm-related death in the EVAR group of 4% vs 7%.[4]

In comparison, the Dutch Randomised Endovascular Aneurysm Management (DREAM) trial showed a 30-day mortality rate of 1.2% in the EVAR group and 4.6% in the open-repair group.[3] The combined rate of operative mortality and severe complications was 9.8% in the open-repair group and 4.7 % in the EVAR group.

The more recent results of the Veterans Affairs Open versus Endovascular Repair (OVER) trial[5] showed patients in the EVAR group had reduced median procedure time, blood loss, transfusion requirement, duration of mechanical ventilation, hospital stay, and intensive care unit stay. Perioperative mortality (30-day or in-hospital) was lower for EVAR compared to open-repair (0.5% vs 3.0%).

Although the randomized controlled trials show an early benefit for EVAR, there are no studies describing the long-term follow-up after EVAR with the newest generation devices so far. Only when long-term results of EVAR become available will it be possible to make a reasonable consideration about long-term results after EVAR and open repair. Our study group reported results with the AneuRx stent graft in 2008 and showed that after 9 years, freedom from aneurysm rupture after EVAR was 91%, but freedom from secondary interventions was only 48%.[6] Although most secondary interventions were endovascular, further developments in stent graft (fixation) techniques will have to focus on lowering these numbers of secondary interventions. In this chapter, we will describe the latest insights into the anatomic risk factors that influence outcome after EVAR and some of the stent graft fixation characteristics that influence the success after EVAR.

ANATOMIC AAA CHARACTERISTICS

AAA diameter

Aneurysm size is the primary determinant of the risk of aneurysm rupture. In attempts to identify factors predictive of rupture, only aneurysm size has been recognized as reliable. Thus to date, the size of the aneurysm has been the principal parameter to decide when to operate (Figure 1.).

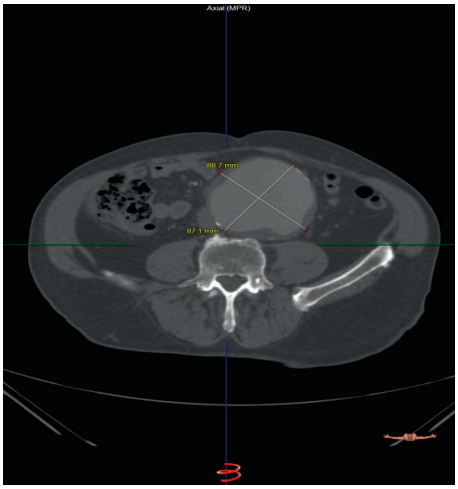

Figure 1. Large diameter AAA

The threshold in which the operative risk is less than the risk of rupture for the entire AAA patient population, set in most reports and guidelines, is 5.0 - 5.5 cm. The aneurysm configuration is also taken into account, because saccular aneurysms tend to be more prone to rupture at sizes of <5.5 cm, and these aneurysms must be treated earlier in the dilatation disease process.

Although patients with small aneurysms have a better short-term and long-term outcome after EVAR, the precise relationship between AAA size and outcome is not fully understood. Zarins et al. showed that 5 years after EVAR, patients with small aneurysms (<5.5 cm) had a lower AAA-related death rate (1% vs 6%), a higher survival rate (69% vs 75%), and a lower secondary intervention rate (25% vs 32%) than patients with large aneurysms (≥5.5 cm).[7] These finding were sustained by Peppelenbosch in 2004.[8] They found that the midterm outcome of large aneurysms after EVAR was associated with increased rates of aneurysm-related deaths, unrelated death, and rupture. Patients with large aneurysms were significantly older, had more comorbidity, and had a shorter and wider AAA neck. But even with multivariate analyses, AAA size was an independent predictor for worse outcome after EVAR.

The exact mechanics of an inferior outcome in patients treated for larger AAAs is not fully understood. Most important, AAA size may represent a marker for other negative anatomic anatomy, including a short and wide AAA neck, thrombus lining the AAA neck, and neck angle. Previous studies have demonstrated a correlation between aneurysm size and these parameters.[9-11] A European Collaborators on Stent-Graft Techniques for Abdominal Aneurysm Repair (EUROSTAR) report in 2005 documented the effect of preoperative aneurysm and aortic neck diameter on clinical outcome after EVAR. A total of 1317 patients were included during a 7-year period. Patients with the largest AAA size and AAA neck size had a significantly higher mortality rate, as were rates for rupture and conversion.[12] Although most studies describing the relation between AAA size and outcome after EVAR corrected for these negative AAA neck characteristics, other parameters must be influencing the outcome after EVAR.

A subject of interest is that the space of possible sideways stent graft movement in a larger AAA sac might be much greater than in small AAAs. This effect of a lateral displacement of the stent graft within a large AAA sac can cause friction in the proximal fixation zone, especially in highly rigid stent grafts. The friction in the proximal fixating part of the prosthesis can therefore lead to an increase in proximal migration and type IA endoleaks. Rafii et al. investigated this lateral movement of stent grafts within the AAA sack during follow-up and found that lateral stent graft movement of >5 mm during follow-up was associated with an increased risk of late adverse events and a higher risk of AAA rupture and conversion to open repair.[13] Besides, lateral stent graft displacement was at least as good a predictor of these complications as longitudinal stent graft migration. To date, the Rafii et al. report is the first that describes the sideways displacement of stent grafts during follow-up, and more reports regarding this particular subject are expected soon.

Aortic neck diameter

The diameter of the aortic neck has been of paramount importance for proper stent graft fitting. Until 2006, the largest stent grafts available were 32 mm in diameter, which meant many patients were not anatomically suitable for EVAR. With the appearance of larger grafts, up to 36 mm in

proximal diameter, more patients could be treated endovascularly. With the newest generation devices, however, sealing and fixation can be achieved in aneurysms that previously would have been rejected for EVAR because of their anatomy.

Large studies, however, have shown less good results after treating patients with wide infrarenal AAA necks. Waasdorp et al. showed a negative effect of aneurysm neck diameter on clinical end points such as mortality, conversion to open repair, and AAA rupture in patients with large AAA necks (>26 mm).[12] The patients with a large AAA (>60 mm) combined with a large AAA neck (>26 mm) had significantly worse clinical outcomes, with a mortality rate of 73%, conversion rate of 14%, and rupture rate of 13% at 60 months of follow-up.

The combination of a large AAA and a large, unfavorable AAA neck has been described.[7;9;14] In 2003, Cao et al. showed that patients with large aneurysms and aortic necks are at high risk for proximal aortic neck dilatation after endoluminal repair of AAA.[15] During a mean follow-up of 24 months, 28% of patients showed aortic neck dilatation, defined as a diameter change of >3 mm between the first postoperative CT scan and subsequent CT scans during follow-up. Univariate analysis in this study showed a significant association between preoperative aortic neck diameter and aortic neck dilatation, device migration and type I endoleak. The phenomenon of aortic neck dilatation after EVAR had already been described in 1996 by May et al. and was later confirmed by Malina et al. in 1997 and Sonesson et al. in 2008.[16-18] Both groups measured the proximal neck at the level of the stent and showed increases of 2 mm after 12 months and 3 to 4 mm after 18 months of follow-up. In 2001 Stanley at al. reported in a review of 238 patient records, that short neck length, contour, and neck diameter were the most important criteria relating to the development of endoleak.[19]

Overall, there is increasing evidence that the larger the aneurysm neck diameter, the worse the clinical outcome. With the increasing use of endovascular devices, partly by the availability of large-diameter devices, the risk of an EVAR-related complication might increase.

Aortic neck length

The aneurysm neck anatomy is an important variable determining if a patient can be offered EVAR. The introduction of fenestrated and branched endografts has meant that the infrarenal aortic neck length is no longer the predominant reason to deny a patient EVAR. Short necks, offering small proximal attachment lengths and seal zones, are thought to place patients at high risk for attachment site leaks and migration during follow-up. The suitability for EVAR, based on the manufacturers' instructions for use (IFU), requires a specific length of infrarenal aorta free of aneurysm and severe infrarenal aortic angulation. Initially, the proximal neck criteria for EVAR included a neck length ≥15 mm, a neck diameter ≤26 mm, and an aortic neck angulation of ≤45°, with thrombus or calcifications lining less than half the aortic circumference.

In the 2004 Elkouri et al. investigation of the morphologic suitability of AAA for EVAR,[20] one of the main reasons for exclusion for EVAR was the infrarenal aortic neck length. The infrarenal aortic neck in 50% of patients was <15 mm, making them unsuitable for EVAR in those years. In the early days of EVAR, it was generally held that a minimum of 15 mm of infrarenal nonaneurysmal aorta was needed for a secure endograft fixation. The findings of Elkouri et al were confirmed by Arko et al., who found that the primary anatomic reason for ineligibility for EVAR was a short infrarenal neck in 44% of patients.[21]

However, with the liberal use of endovascular stent grafting and evolving device technology, such as suprarenal fixation and larger diameter grafts, this technique continues to evolve to allow additional patients to be treated with EVAR who would not have previously been candidates. For example, the introduction of the Talent stent graft system (Medtronic Inc, Santa Rosa, Calif) in 1996, led to a recommendations of a minimum of infrarenal aorta free of aneurysm of only 10 mm.

Over the years in which patients have been treated by EVAR, numerous reports have described the comparable results of patients with and without hostile aortic necks. Nevertheless, most of these reports only described the short-term results, whereas we know that EVAR-related fixation

problems, such as proximal type I endoleaks and migration, are time-dependant and often occur many years after the primary endovascular repair. In 2000 Greenberg et al. reported their short-term experience with treating patients with short proximal necks (<10 mm).[10] They found short-term success with proximal fixation in a proximal neck measuring <10 mm. Endoleak rates were identical in the patients with a proximal neck <10 mm and those with longer necks during the first 30 days after EVAR. In the 2006 report of Choke et al., patients with a hostile neck (including an aortic neck length of <10 mm) were compared with patients without a hostile neck,[22] and there were no significant differences in the incidence of primary technical success, intraoperative adjunctive procedures, early and late type I endoleak, secondary interventions, aneurysm sac expansion, or 30-day mortality.

Although these reports show initially good short-term results for patients with short hostile necks, longer follow-up studies all show a negative effect of aortic neck length on EVAR-related complications.[23-26] Leurs et al. documented a clearly negative influence of infrarenal neck length on outcome after EVAR.[23] Their study enrolled 3499 patients from the EUROSTAR registry who were divided in 3 groups according to the infrarenal neck length: >15 mm (group A), 11 to 15 mm (group B), and ≤10 (group C). Proximal endoleak ≤30 days occurred in 10.9% in group C and in 2.6% in group A. Within 48 months of follow-up, the incidence of proximal endoleaks was significantly higher in groups B (9.6%) and C (11.3%) compared with group A (3.4%). Five years earlier, Mahan et al. had already found a significant correlation between the occurrence of proximal endoleak and aortic neck length.[24] More recently, AbuRahma et al. published their results describing the correlation between aortic neck length and early and late outcome in EVAR patients.[26] Kaplan-Meier methods showed a significant difference in freedom from proximal type I endoleak at 3 years of 80% in the patient group with ≥15 mm necks, and 53% for patients with <10 mm aortic neck length.

The recent evidence shows that patients with short infrarenal necks can be offered EVAR with relative good short-term results. However, short aortic necks are clearly associated with increasing incidence of type I endoleak. This must be taken into account when offering EVAR to patients with relative short infrarenal necks.

Aortic neck pulsation

CT-Angiography is used as the standard preoperative imaging modality to assess dimensions for stent graft sizing and aneurysm repair. Although most vascular centers use preoperative 3-dimensional imaging technique and central lumen line measurement, electrocardiogram gated dynamic CT-scans are not routinely used. The diameter measurements are therefore measured somewhere between the diastole (minimal diameter) and systole (maximum diameter) of the cardiac cycle.

Aortic compliance and cardiac pulsatility naturally result in conformational changes during the cardiac cycle (Figure 2.).[27;28] The diameter variation of the proximal aneurysm neck of individual patients ranges from less than 1 mm to up to 4 mm or more during the cardiac cycle.[29] More severe pulsatility in the aneurysm neck is likely to increase the demand on the fixation and sealing zone of the stent graft. Patients with greater aneurysm neck pulsatility are therefore probably more prone to stent graft sealing and fixation related complications after EVAR than patients with less pulsatility.

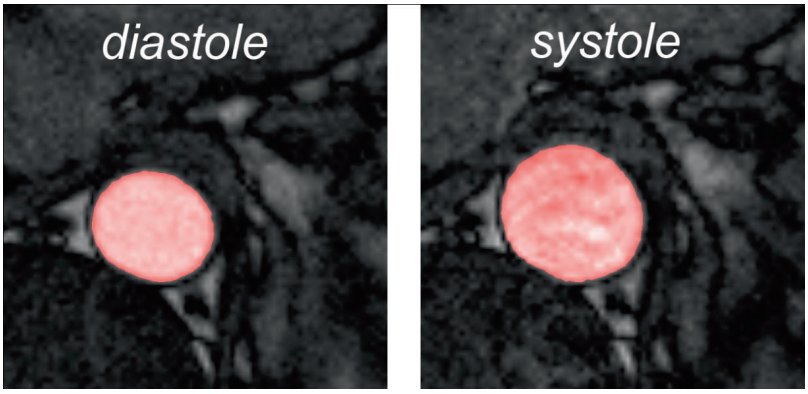

Figure 2. Aortic pulsatile distension

In 2006, van Herwaarden et al. published their results about conformational changes during the cardiac cycle.[30] They investigated the change in aortic neck diameter during the cardiac cycle at three levels in the aortic neck. Significant diameter changes during the cardiac cycle were observed at all three levels. Pre-EVAR mean aortic neck diameter changed up to 8.9% compared with post-EVAR changes of up to 11.5%.

Similar results were reported by Pol et al. who described an 8.5% diameter increase at the proximal neck during the cardiac cycle.[31]

In 2007, Arko et al. also showed significant diameter changes in the aortic neck in both the lateral axis and the anterioposterior (AP) axis.[32] Additionally, the infrarenal aortic neck deformed anisotropically during the cardiac cycle. The greatest movement was in the AP direction.

This finding was later sustained by Van Prehn et al. who investigated the asymmetrical pulsatile distention in 15 volunteers.[33] At the infrarenal level, mean changes over the minor axis versus major axis were 22% and 25% respectively.

Because AAA exclusion depends on a tight seal in the aortic neck, fixation zone enlargement during the cardiac cycle could result in intermittent or constant pressurization of the AAA or migration of the stent graft.

To investigate this potential complication, van Keulen et al. investigated the relation between stent graft migration (≥ 5mm) and preoperatively measured pulsatility of the proximal aortic neck.[34] The pulsatility of the aortic neck was compared between patients with and without proximal stent graft migration 3 years after EVAR. Baseline patient characteristics, AAA morphology, and the degree of stent graft oversizing were not statistically different between the two groups. Patients with stent graft migration after EVAR had significantly higher preoperative aneurysm neck pulsatility during the cardiac cycle than patients without stent graft migration.

Overall, the aortic dimensions at the level op the proximal aortic neck change during the cardiac cycle. This phenomenon is preserved after EVAR. Therefore maximum aortic neck diameter using dynamic imaging tools may not be similar to the maximum diameter with static imaging, and a standard regimen of 10% to 15% oversizing may be inadequate for some patients.

Aortic neck angle

Ideally, stent grafts were designed to fit to patients' aortic anatomy, rather than force the fixating part of the nonaneurysmal aorta to conform to the stent graft. Over the years of the EVAR era, numerous stent graft designs have evolved from shock-absorbing noncolumnar flexible grafts to more rigid grafts, at both ends of the spectrum. The more rigid stent grafts will force the fixating part of the aorta more to the stent grafts than will the highly flexible grafts.

To date, there has been no predisposition for one stent graft rather than the other, and therefore, numerous stent grafts are currently in use. This implies that the IFU will be different for different stent grafts. For example, the maximum treatable aortic neck angle is ≤75° for the highly flexible Endurant stent graft and ≤60° for the less flexible Talent stent graft. Although the IFU regarding the maximum acceptable neck angulation is clearly described in all IFU recommendation brochures, the most accurate method of measuring the aortic neck angle is far from clear from current literature. There have been wide variations in measuring the proximal aortic neck angulation: from the aortic neck angle between the lowermost renal artery to the beginning of the AAA, to the aortic neck angle within the first 30 mm from the lowermost renal artery (Figure 3.). Van Keulen et al. reported a technique to objectively quantify the angulation of the aneurysm neck, which was easy to perform and reliable. Their method showed good intraobserver and interobserver variability and should therefore be the standard when measuring and reporting aortic neck angulation.[35]

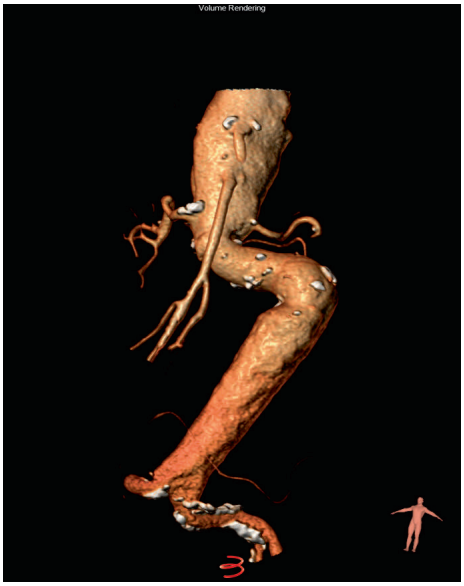

Figure 3. AAA with substantial aortic neck angulation

Thus far, no clinical papers have described the exact influence of the proximal aortic neck angulation on the clinical outcome of EVAR. In most clinical reports describing the aortic neck angulation, patients were classified into 2 subgroups according to the degree of neck angulation: a group with a good neck angulation and a group with bad neck angulation. The most frequent cut-off point between patients with a bad and good aortic neck in current literature is a neck angulation of 60°, although there are reports that have a cut-off of 45° or have divided the patients into 3 or 4 subgroups according to the degree of neck angulation. The inconsistent reporting of different neck angulation between published studies makes comparison between different studies difficult.

From former studies we know that infrarenal neck angulation is associated with other complex morphologic characteristics such as maximum AAA diameter, aortic neck length and diameter, and suprarenal aortic angulation.

In 2002 Sternberg et al. claimed aortic neck angulation was one of the most important determinants for adverse events after EVAR.[36] They investigated 148 patients who were treated electively for an infrarenal AAA with a mean follow-up after implantation of 26.6 months. Patients were divided into 3 groups according to the level of neck angulation: mild angulation (<40°), moderate angulation (40°-59°) and severe angulation (≥60°). The risk of patients experiencing one or more adverse events was 70%, 54%, and 17% in those with severe, moderate, and mild angulation of the aortic neck. Patients with moderate or severe aortic neck angulation, compared with those with mild angulation, had a significantly higher mortality rate ≤30 days (20% vs 0%), acute conversion to open repair (20% vs 0%), aneurysm expansion (9.1% to 20% vs 1.7%), device migration (20% to 30% vs 3.3%), and type I endoleak (23.8% to 8.3% vs 0%). An important finding was that baseline patient's characteristics and aneurysm morphology, such as age, aortic neck length and diameter, and AAA size, were not different between the investigated groups. Therefore Sternberg et al. strongly recommended reserving some caution in using EVAR to treat patients with moderate to severe neck angulation.

The correlation between aortic neck angulation and adverse outcomes after EVAR has been documented in other reports:

• Albertini et al. investigated the risk factors for proximal perigraft endoleak and graft migration.[37] Neck angulation was significantly greater in patients with proximal perigraft endoleak (mean neck angulation of 50° ± 16°) or graft migration (mean neck angulation of 54° ± 20°) compared with patients who had none of these adverse events (mean neck angulation of 37° ± 18°).
• Boult at al. searched for predictors of midterm success after EVAR.[38] Their results were published in 2006 and showed that along with a large AAA size and short infrarenal aortic neck, neck angulation of ≥45° was also a predictor for clinical failure or need for repeat intervention.
• More recently in 2007, Hobo et al. published their results regarding a large group of 5183 patients.[39] The influence of severe infrarenal neck angulation on complications at the proximal aortic neck after EVAR was investigated. They compared patients with and without severe neck angulation. Severe neck angulation was defined as a >60° angle between the infrarenal aortic neck and the longitudinal axis of the aneurysm. In the short-term (before discharge), proximal type I endoleak (OR, 2.32; 95% CI, 1.60-3.37; $p < 0.0001$) and stent graft migration (OR, 2.17; 95% CI, 1.20-3.91, $p = 0.0105$) were observed more frequently in patients with severe neck angulation. Over the long-term, patients with severe neck angulation had higher incidences of proximal neck dilatation ≥4 mm (HR, 1.26; 95% CI, 1.11-1.43; $p = 0.0004$), proximal type I endoleak (HR, 1.80; 95% CI, 1.25-2.58, $p = 0.0016$), and need for secondary interventions (HR, 1.29; 95% CI, 1.00-1.67; $p = 0.0488$).

Overall, the published reports about aortic neck angulation and adverse events all show a correlation between increasing neck angulation and early or late adverse events. For this reason, the IFU for all commercially available endografts have clear guidelines on maximal angulation of the aortic neck, and patients who are treated outside of the IFU clearly have a higher risk for EVAR-related complications.

Aortic neck thrombus

Thrombus in the aortic neck has been recognized as an important predictive factor for adverse events in EVAR (Figure 4A and 4B.). Many reports about anatomic AAA characteristics and EVAR describe the amount of thrombus lining the aortic neck. Proximal aortic neck thrombus is suggested to influence fixation and sealing and has therefore been an exclusion criterion for clinical trials studying EVAR.

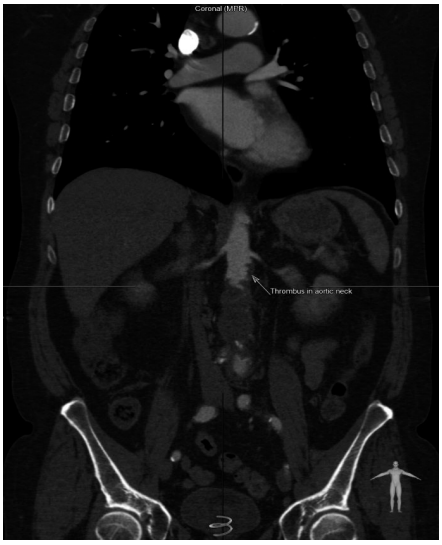

Figure 4A. Aortic neck thrombus

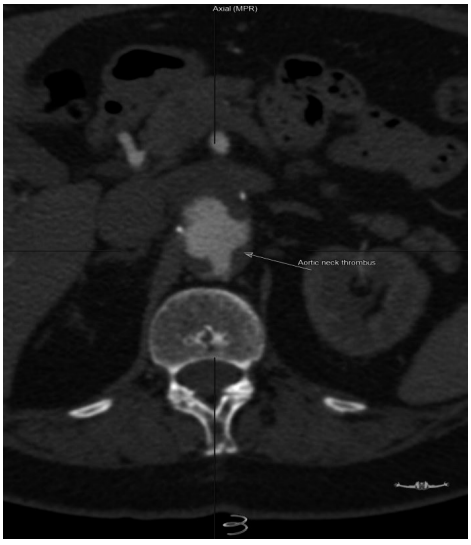

Figure 4B. Aortic neck thrombus

The presence of thrombus within the infrarenal aortic neck is considered a contraindication for EVAR because:

•The presence of thrombus in the aortic neck may prevent a seal and therefore may cause proximal type I endoleak. Moreover, lyses of thrombus after exclusion of the AAA by the stent graft may cause late endoleak or migration.

•There may be an ineffective purchase of the stent graft in the thrombus, causing migration of the graft during follow-up. Ivancev et al. reported that nearly 20% of graft migrations occurred in patients with a thrombus-lined aortic neck.[40]

• There is concern about manipulation with guidewires, catheters, and devices in a thrombus-lined aortic neck. Excessive manipulation may cause distal or renal embolization. In 1997 Thompson et al. showed that endovascular AAA repair is accompanied by a nearly threefold increase in thromboembolic events compared with open repair.[41]

Because many aortic necks contain some form of thrombus, most reports categorize the amount of thrombus lining the aneurysm neck depending on how much thrombus is present. However, there is no overall definition of what a thrombus-lined neck is. Cao et al. defined neck thrombus as a continuous parietal layer of thrombus at least three-fourths of the circumference in one section of the aneurysm neck.[15] Jordan et al. described a hostile thrombus-lined aneurysm neck as having >3 mm of thrombus around 60% of the circumference of the proximal seal zone.[42] In another report, Dillavou et al. defined significant neck thrombus as thrombus covering >50% of the circumference of the aortic diameter in the proximal neck.[43] This definition was also used in the reports of Chisci et al. and Fairman et al., but not in the report of Gitlitz et al., who described the early clinical experience in 19 patients with an irregular flow-limiting defect in the aortic neck occupying >75% of the aortic circumference.[44-46]

Because of these differences in definition, the incidence of aortic neck thrombus and the exact influence on the outcome of EVAR is difficult to establish. The incidence of aortic neck thrombus varies between 7% and 74%, depending on how neck thrombus is defined.[47] For example, Oriel et al. found an incidence of 74% among 277 patients considered for EVAR but involving more than half the neck circumference in 66% of patients and >2 mm thick in only 15% of patients.[47]

Most IFU, however, advise that patients with extensive thrombus in the aortic neck be rejected for EVAR but do not give recommendations about the exact amount of thrombus. Although aortic neck thrombus has long been assumed to be a risk factor for adverse events after EVAR, there are increasing reports that show good results when aneurysms with thrombus-lined aortic necks are treated. An early report of Carpenter et al., published in 2001, investigated the effect of exclusion criteria on patient selection for EVAR.[1] Only 10% of patients were excluded for EVAR

due to the presence of extensive mural thrombus in the aneurysm neck. Because of refinements in endograft design in the past decade, with active transrenal fixation capabilities, lower-profile devices, and careful patient selection, an increasing number of patients with hostile aortic necks with thrombus will be offered EVAR.

Dillavou et al. reported their results after treating patients with good aortic necks and bad necks (neck length ≤10 mm, focal bulge in the neck >3 mm, >2-mm reverse taper within 1 cm below the renal arteries, neck thrombus ≥50% of circumference, and angulation ≥60° within 3 cm below the renal arteries).[43] With an average follow-up of 18 months, comparisons of the patients with good necks and bad necks were, respectively, perioperative mortality (0% vs 1.1%), late mortality (5.2% vs 4.4%), all endoleaks (19.1% vs 17.6%), proximal endoleaks (0.8% vs 2.1%), and graft migration (0% for both groups). These results were not statistically different.

Jordan et al. reported EVAR results for 78 patients with a hostile neck. Among these patients, 41% had severe neck thrombus (>3 mm of thrombus around 60% of the circumference of the proximal seal zone).[42] The 1-year all-cause mortality rate was 6.4%, with 100% freedom from aneurysm-related mortality. Secondary procedures were performed ≤1 year in 5 patients (6.4%) for treatment of type I endoleak. Reduced or stable aneurysm sac diameter at 1 year was observed in 96% of patients.

In 2003 Cao et al. published their results regarding the predictive factors and clinical consequences of proximal aortic neck dilatation and found, by means of multivariate analysis, the presence of circumferential neck thrombus was a positive independent predictor for aortic neck dilatation.[15] In contrast with the study of Cao, Albertini et al. did not find aortic neck thrombus was a predictive factor for proximal type I endoleak or migration after EVAR.[37] They documented 31 proximal graft endoleaks and 15 migrations in the investigated group of 184 patients. Thrombus or atheroma was lining the aortic neck in 44% of patients. There was no difference in the number of patients with thrombus lining the aortic neck between the patients in the proximal endoleak or migration group compared with the patients who did not have one of these events.

Because there is no overall standard for the definition of neck thrombus, the published reports are difficult to compare. Aortic neck thrombus is recognized as a risk factor for complications after EVAR, but some series have published good results when treating AAAs with aortic neck thrombus. However, the published series did not have long-term results, and vascular interventionists are still waiting for definitive results to see to what extent aortic neck thrombus influences the long-term clinical outcome after EVAR.

AAA neck calcification

Like aortic neck thrombus, the exact role of calcification of the aortic neck (Figure 5.) on EVAR durability is not fully clear from published research data. However, many studies about aneurysm neck anatomy and its influence on EVAR durability describe calcification of the aneurysm neck as a predictor for decreased clinical success.

Calcification of the aortic neck could be implicated through two reasonable mechanisms. Calcified aortic necks might be very rigid and irregularly shaped, and hence less able to fit closely around the endograft and achieve a tight hemostatic seal. In addition, the calcified aortic surface might constitute a wall without much grip of the stent graft, upon which the endograft could migrate during follow-up.

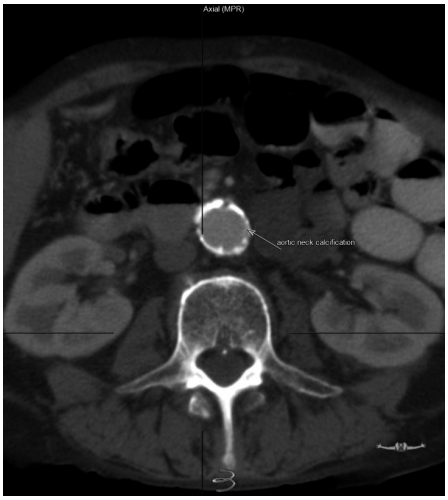

Figure 5. Aortic neck calcification

Although Chaikof et al. proposed calcification classification scores, this classification is not uniformly used in clinical practice.[48] Therefore, it is hard to compare different studies and outcomes to finally define the exact role of a calcified aortic neck on EVAR durability.
The proposed classification score of Chaikof et al. divides patients into 3 groups according to the amount of calcified aortic plaque in the aortic neck region: 1, calcification <25% of circumference; 2, calcification 25% to 50% of circumference; 3, calcification >50% of circumference. Although the classification is a good step toward the goal of assessing the amount of calcification in the aortic neck, making different reports easier to compare, the classification score is far from ideal and is not useful for research because most patients will be categorized in the first group. What about the patient with a long aortic neck with only a short distance of >50% calcification of the circumference and the rest of the aortic neck clear from calcification? Or the patient with extensive patchy calcification throughout the entire aortic neck, but all <25% of circumference? These patients are hard to put into a category. A more accurate measurement would be to count the absolute amount of calcified plaque area compared with the total aortic neck area. With current software package developments, the ability to make these refined calculations is expected soon.

Because most reports about aortic neck calcification do not uniformly define the amount of calcification in the same way, the incidence of neck calcification is not clear. Tournoij et al. divided 100 patients according to the classification model of Chaikhof et al[49] and 60% had calcium at the aneurysm neck. They investigated the amount of calcification at 6 different levels in the aortic neck. At the renal artery level, 34% had calcification in the aortic wall, although this was <25% of the circumference. Only 5% of the patients had calcification in 25% to 50% of the circumference of the aortic wall. No patients had calcification of the wall of >50% of the circumference. Distribution of calcium was predominant at the posterior wall and bilateral sites in the aortic neck.

In another report, Arko et al. investigated the number of patients acceptable for EVAR,[21] and 7% were defined as not acceptable for EVAR due to calcified aortic neck. The exact definition for calcified aortic neck was not indicated, however.

As mentioned, the effect of calcification on EVAR durability is thought to occur through two mechanisms: an effect on sealing of the proximal stent graft in the aortic neck and the fixation in the aortic neck. The effect of calcified aortic neck on device migration was investigated by Lambert et al.[50] In this experimental model on human cadavers, they showed that the pullout force was significantly decreased when the aortic neck was calcified. This observation was clinically investigated by Sampaio et al., who studied the risk factors for device migration in 109 patients treated with AneuRx devices.[51] Due to the small numbers of migration (n = 9) they failed, however, to find any significant association between neck calcification and migration probability.

The influence on proximal endoleak was investigated by the same group a year later.[52] Their second report documented a clear influence of aortic neck calcification on proximal type I endoleak. In most of the investigated 202 patients, a relatively small amount of the aortic neck was lined with calcification. The median portion of calcification was 16.8%, and less than half of the wall was calcified in 90% of the patients. Aortic neck calcification was associated with an increased risk of proximal type I endoleak. With a 25% increase in the percentage of neck calcification, the probability of developing this complication increased 2.2 times.

In 1998 Wain et al. published their report about the risk factors for endoleak among 47 patients treated during a 5-year interval.[53] Of 47 included patients, 7 (15%) had severe neck calcification (4-quadrant aortic neck calcification). The rate of endoleaks was increased, but not in a statistical fashion, in patients with severe aneurysm neck calcification compared with the rate in patients who did not have this feature.

Overall, aortic neck calcification has been recognized as a risk factor for proximal type I endoleak and migration after EVAR; however, it is not clear on what scientific observations this has been reached. The few reports that have focused solely on this particular subject lack convincing evidence on the effect the calcification has on EVAR durability.

STENT GRAFT FIXATION CHARACTERISTICS

Proximal stent graft fixation length

Proximal stent graft fixation in the aortic neck has been the Achilles' heel of EVAR durability. In our opinion, with the current available endovascular devices, this part of the fixation is still the most important. The association between proximal fixation length and achievement of an effective proximal fixation and seal is intuitive. Providing a larger area of contact to obtain a hemostatic seal or increasing the friction forces makes endograft displacement less likely. Proximal fixation length is highly correlated to the initial preoperative aortic neck length. Sampaio et al. showed a highly significant correlation between the neck length and the proximal fixation length: for each additional millimeter in neck length, the average overlapped distance increased 0.97 mm.[52]

With a proper placement of the graft just beneath the lowest renal artery, we might expect that the described EVAR-related complications in patients with short aortic necks (proximal type I endoleak and migration) can be extrapolated directly to the fixation distance of the proximal graft in the infrarenal aortic neck. Unfortunately, in the earlier days of EVAR, the placement of the graft below the renal artery ostia was not as strict as is the treatment goal today. Substantial improvements in intraoperative fluoroscopic imaging and device implantation techniques have evolved in the last decade, making EVAR more durable. Current technical improvements include the high-resolution image intensifier, with magnification and angulation of the C-arm. The C-arm needs to be angulated orthogonally to the aortic neck and orthogonally to the armpit of the most distal renal artery. By optimally positioning the C-arm, the stent graft can be deployed just below the lowermost renal artery, allowing for maximal sealing and fixation of the stent graft in the aneurysm neck.

The refinements in technique and in the deployment of the endograft that are now routine were used only rarely in the past. This is one of the explanations why there were significant differences in migration rates among the centers included in the AneuRx trial.[54] In this particular study, migration occurred in patients whose endograft had been placed at a mean distance of

1.1 cm below the lowermost renal artery. In comparison, the mean distance from the lowermost renal artery to the top of the stent graft in the no-migration group was 0.8 cm, which is still a substantial distance.

Even though low positioning of the stent graft in the aortic neck may successfully exclude the aneurysm, the long-term durability of fixation might be at risk. In our opinion, with the current knowledge and the refinements of imaging techniques, the treatment goal is to place the top of the (covered portion of the) endograft ≤2 mm of the lowermost renal artery to make sure that the whole fixation part of the aortic neck is used.

The knowledge about the value of a long fixation in the aortic neck on EVAR durability has gained from experimental cadaver studies as well as from clinical reports.

Bosman et al. described their results on the proximal fixation strength of the newest generation of stent grafts.[55] In this in vitro study, the force to dislodge the graft from the bovine aorta was measured for 3 different grafts and showed a higher displacement force was needed when the proximal graft fixation length increased from 20 to 25 mm. This finding had already been described by Lambert et al., who showed a significant higher pullout force when increasing the proximal fixation length of the endograft: the mean longitudinal distraction load was 409 g for an aneurysm neck of 20 mm, 277 g for 15 mm, and 218 g for 10 mm.[50]

In 2003 Zarins et al. described the importance of proximal fixation.[54] This multicenter AneuRx clinical trial included 1119 patients from 1996 to 2001. Patients were reviewed for evidence of stent graft migration over 5 years. Stent graft migration was observed in 94 of 1119 patients (8.4%), with a mean time after device implantation of 30 ± 11 months. Subgroup analysis showed that the proximal fixation length was significantly shorter in patients with migration (1.6 ± 1.4 cm) than in patients without migration (2.3 ± 1.4 cm). Univariate and multivariate analysis showed that proximal graft fixation length was a significant predictor of migration. Each millimeter increase of distance in the proximal fixation length decreased risk for migration by

2.5%. The importance of a long proximal fixation length was confirmed in later reports, which all showed a clear influence of proximal stent graft fixation on migration during follow-up.[56;57]

The incidence of proximal type I endoleak and proximal fixation length has not been the study goal of many reports, but investigators who described the importance of proximal fixation length all showed an increased risk of proximal endoleak in patients with short proximal fixation lengths. In a 2004 study of 257 patients, Sampaio et al. showed a significant increase in proximal type I endoleak when aortic neck fixation lengths decreased.[52] The mean overlap of the stent graft in the aortic neck was 15.6 mm and 29.3 mm, respectively, for the groups with and without a proximal type 1 endoleak. The reports from in vitro studies and clinical research show a clear correlation between the length of proximal stent graft fixation and the occurrence of graft migration or endoleak, or both. The final goal should therefore be to make sure all of the available aortic neck length is used for fixation. Especially when other anatomic characteristics of the aortic neck are not ideal for EVAR (angulated and wide necks), covering as much aortic neck as possible decreases EVAR-related complications during follow-up.

Proximal stent graft fixation technique

The success of EVAR depends on many factors, of which a secure proximal fixation is critical. A short infrarenal proximal landing zone has often excluded patients from EVAR. A bare spring graft component extending proximally to the graft fabric was developed to obviate these anatomic constraints and increase the number of eligible patients. Because the bare spring is fixated across the renal arteries, patients who were not suitable for EVAR because of a short infrarenal aortic neck length could now be treated in an endovascular way. For patients with long aortic necks (>15 mm), adding a bare spring to the covered stent graft adds surface attachment and therefore the pullout force of the stent graft increases. Eventually, the increased pullout force will influence migration in a positive way, making EVAR more durable on the long-term.

An uncovered stent placed above the covered stent graft is one of the most important modifications in stent graft design, and was originally proposed by Lawrence et al. in experimental animal studies.[58] Because the suprarenal aorta segment is usually less afflicted by the degenerative process and less likely to dilatate over time, this part of the aorta forms a ideal fixation part for the stent graft.[59]

In the earlier days of EVAR, the belief of placing an uncovered stent across the renal artery origins was to harm the renal arteries. Malina et al. reported a median 6-month follow-up of 18 patients with transrenal fixation of the proximal segment using Gianturco Z stent grafts.[60] Spiral CT and angiography showed continued patency of all 25 renal arteries affected, with no evidence of renal artery compromise and stable creatinine levels. Reports that describe the adverse renal effects of suprarenal vs. infrarenal fixated endografts does not show evidence for increased renal adverse events in patients undergoing transrenal fixation.[61;62]

The first clinical reports about transrenal fixating grafts showed good short- and medium-term results and led to an increase in transrenal fixating devices over infrarenal fixating devices in the past decade. More than half of treated patients today receive a transrenal fixating stent graft. Most of the currently available grafts have a bare nitinol or stainless steel spring of 15 to 22 mm in length that is positioned across the renal arteries during the endovascular procedure. Soon after the introduction of these stent grafts, the proximal bare spring was adjusted to even give more proximal fixation strength. Today, a wide range of different grafts are available, from bare rings to fixating barbs and hooks, or combinations of these, but the optimum design of mechanism of aortic fixation is not known.

In 2006 Leurs et al. published their results on the risks for migration after EVAR.[63] In this large patient cohort of the EUROSTAR registry, 4233 patients with an AAA >4 cm underwent EVAR, and proximal migration was found in 192 (4.5%). Among many variables such as a wider neck and AAA diameter, shorter necks and proximal endoleak, the absence of suprarenal fixation was a significant predictor for migration.

As mentioned, the addition of hooks and barbs has added even more proximal fixation strength. Malina et al. reported that stent graft fixation can be enhanced by at least 10-fold by adding barbs that perforate the entire aortic wall.[64] However, that even the best fixating stent graft cannot match the pullout force of a hand-sewn anastomoses was showed by Resch et al.[65] A force of 150 N applied to the hand-sewn graft resulted in tearing of the aorta, without the sutures breaking. In comparison, the median displacement force was only 25 N for the Palmaz stent; one of the investigated stents with the highest fixation. Ballooning the stent after deployment improved fixation in some cases, and hooks and barbs improved the fixation of self-expandable grafts.

The fixation strength of different types of endografts with different types of proximal fixation characteristics has been investigated in experimental in vitro studies. In 2003 Veerapen et al. published their results on the proximal fixation characteristics of different types of stent grafts and found a mean dislodgement force ranging from 6.5 to 26.5 N among the investigated grafts.[66] Not surprisingly, the self-expandable stent with the longest uncovered part (22 mm), the most hooks (12), and the longest barbs (5 mm) had the best resistance to dislodgement. An additional balloon-expandable stent (i.e., Palmaz) placed at the proximal attachment site greatly improved endograft fixation, regardless of the type of stent graft. Recently, Melas et al. described their results of aortic and iliac fixation of 7 endografts in an experimental model using human cadaveric aortas.[67] Endografts with hooks or barbs displayed a significantly higher displacement force compared with devices with no such fixation modalities. Balloon dilatation also produced a significant increase in displacement force in devices with or without hooks or barbs. Surprisingly, suprarenal support did not enhance proximal fixation, although there was a tendency for higher fixation forces in suprarenal support devices (median, 22.6 N) compared with infrarenal devices (median, 16.2 N).

Stent graft migration can cause proximal type I endoleak by means of a decreased fixation zone in the aortic neck. If proximal fixation strength can be increased by means of transrenal fixation, risk of proximal endoleak will decrease. The influence of transrenal vs. infrarenal endograft fixation on type I endoleak was investigated by Shames et al.[68] There were no significant differences in the rate of proximal type I endoleak between the transrenal and infrarenal devices, but the investigated group was small (42 patients), and mean follow-up was short (6 months). However, the Marin et al. study of the effect of transrenal fixation on proximal type I endoleaks[69] showed significantly more proximal aortic endoleaks in the infrarenal stent graft group (38%) than in the transrenal stent graft group (11%) at a mean follow-up of 10.3 months.

The proximal fixation length is definitively increased by extending the stent graft cephalad across the renal arteries. However, the hemostatic seal of the prosthesis below the renal arteries might not improve, when treating patients with short aortic necks. Only the covered portion of the stent graft offers a tight sealing of the graft in the infrarenal aortic neck. Treatment of a patient with an infrarenal aortic neck length of 5 mm means the seal is only ≤5 mm. From former studies we know that the infrarenal part of the aorta is susceptible to dilatation during follow-up.[59;70;71] Cao et al. investigated proximal aortic neck dilatation (>3 mm) in 230 patients treated with a self-expandable endograft.[15] With a median follow-up of 24 months, CT scans for 65 patients (28%) showed aortic neck dilatation. Kaplan-Meier analysis showed the probability of aortic neck dilatation at 48 months was 59% ± 6.1%. Taking into account that most stent grafts are oversized 15% to 20%, aortic neck dilatation exceeding 15% to 20% of the preoperative neck diameter will influence the hemostatic seal and cause proximal type I endoleak.

Thus, there is enough evidence that transrenal fixation is safe, renal adverse events do not exceed the adverse events seen after treatment by infrarenal fixating grafts, and the fixation strength is increased by extending the graft in a cephalad direction with a bare stent. Some caution is needed, however, when patients with very short infrarenal necks are treated because the risk for proximal type I endoleak might increase during longer follow-up.

Distal stent graft fixation length

Migration of endovascular stent grafts has been related to the secure proximal device fixation in the aortic neck. It was not until 2005 that the proximal stent graft fixation was seen as the Achilles' heel of stent graft fixation. The importance of distal fixation to the iliac arteries in relation to stent graft migration has received little attention. The importance of iliac fixation was first brought to light in an analysis of ruptures among patients treated during the course of the AneuRx clinical trial.[72] Late AAA rupture occurred in 7 of 1067 included patients, and 2 of these patients had inadequate iliac fixation.

Most IFU recommend a minimal iliac fixation length of 20 to 30 mm, but no studies have routinely assessed the distance of iliac fixation in clinical practice, and so the IFU recommendations are not based on clinical evidence. In 2005 Arko et al. reported the importance of iliac fixation to decrease stent graft migration.[73] Their in vivo study analyzed the displacement forces needed to initiate stent graft migration in ovine infrarenal AAAs. The force needed to displace a fully supported stent graft was increased by 67% by maximizing iliac fixation length. The peak displacement force to initiate migration was 30.2 ± 5.5 N in animals with a maximum iliac fixation length and 18.1 ± 3.7 N in those with a minimum iliac fixation length. One year later, Heikkinen et al. published the first clinical report on the importance of iliac fixation.[57] During a mean follow-up of 23 months, 10% of 173 included patients had stent graft migration ≥10 mm. Patients without migration had a longer iliac fixation length (30 ± 12 mm) than those with migration (22 ± 8 mm). Migration was observed only in patients with intermediate or bad iliac fixation, and no patients with good iliac fixation experienced stent graft migration during the follow-up period, even if there was suboptimal proximal fixation.

In 2007 Benharash et al. published similar results.[74] They showed that iliac fixation is important in preventing migration of both suprarenal and infrarenal aortic endografts that have longitudinal columnar support. This finding was sustained in 2008 by Waasdorp et al., who described their results on the importance of iliac fixation.[56] They investigated patients treated with a Talent endoprosthesis with a mean follow-up of almost 3 years, and proximal endograft migration of ≥10 mm occurred in 21% of patients. The migration group had significantly shorter proximal

and distal (iliac) fixation lengths. Multivariate regression analysis showed proximal and distal endograft fixation lengths were significant predictors for endograft migration during follow-up. Waasdorp et al. recommended extension of the endograft beyond the recommended IFU length of 3 cm in patients with relative short proximal fixation lengths.

The proposed explanation for the finding that iliac fixation length has a clear impact on EVAR durability might be that the iliac stent graft limbs serve as the foundation of the endograft. The consequence of repeated downward pulsation of blood flow in the face of weakness of resistance forces can result in proximal migration of the endograft. This phenomenon will be more pronounced in endografts with a high columnar strength. Because the previously mentioned studies only investigated 2 types of endograft, the exact role of iliac fixation in other grafts will have to be investigated before definitive recommendations about the ideal iliac fixation length can be given.

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Chapter 3

Long-term results of Talent endografts for endovascular abdominal aortic aneurysm repair

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ABSTRACT

Background: Since the introduction of endovascular aneurysm repair (EVAR), long-term follow-up studies reporting single-device results are scarce. In this study, we focus on EVAR repair with the Talent stent graft (Medtronic, Santa Rosa, Calif).

Methods: Between July 2000 and December 2007, 365 patients underwent elective EVAR with a Talent device. Patient data were gathered prospectively and evaluated retrospectively. By American Society of Anesthesiologists category, 74% were III and IV. Postoperative computed tomography (CT) scanning was performed before discharge, at 3, 12 months, and yearly thereafter. Data are presented according to reporting standards for EVAR.

Results: The mean proximal aortic neck diameter was 27 mm (range, 16-36 mm), with a neck length <15 mm in 31% (data available for 193 patients). Deployment of endografts was successful in 361 of 365 patients (99%). Initially, conversion to laparotomy was necessary in four patients. Primary technical success determined by results from CT scans before discharge was achieved in 333 patients (91%). Proximal type 1 endoleaks were present in 28 patients (8%) during follow-up, and 14 of these patients needed additional treatment for type 1 endoleak. The 30-day mortality for the whole Talent group was 1.1% (4 of 365). Follow-up to 84 months is reported for 24 patients. During follow-up, 122 (33%) patients died; in 9, death was AAA-related (including 30-day mortality). Kaplan-Meier estimates revealed primary clinical success rates of 98% at 1 year, 93% at 2 years, 88% at 3 years, 79% at 4 years, 64% at 5 years, 51% at 6 years, and 48% at 7 years. Secondary interventions were performed in 73 of 365 patients (20%). Ten conversions for failed endografts were performed. Life-table yearly risk for AAA-related reintervention was 6%, yearly risk for conversion to open repair was 1.1%, yearly risk for total mortality was 8.9%, and yearly risk for AAA-related mortality was 0.8%.

Conclusion: Initially, technical success of endovascular aneurysm repair (EVAR) using the Talent endograft is high, with acceptable yearly risk for AAA-related mortality and conversion. However, a substantial amount of mainly endovascular reinterventions is necessary during long-term follow-up to achieve these results.

INTRODUCTION

Endovascular aneurysm repair (EVAR) is widely accepted as an alternative for open repair. EVAR has proven to be a less invasive procedure compared with conventional, open repair surgery, with shorter procedure duration, reduced blood loss, shorter hospital stay and significantly lower 30-day mortality rate.[1,2] The drawback of EVAR is that secondary interventions are needed mainly to treat endoleaks, migration, graft disconnection, stent fractures, and graft thrombosis. Since the introduction of EVAR, many devices are now available for use, and commercially available devices have changed rapidly throughout the years, with improved flexibility and more secure proximal fixation. It is assumed that the ongoing improvements in graft design will lead to better long-term outcome and durability. Therefore, long-term follow-up studies are needed to evaluate the devices, although we have to keep in mind that long-term follow-up studies include EVAR procedures performed in the beginning of the EVAR era. In the past, we reported our experience with the AneuRx (Medtronic, Santa Rosa, Calif) stent graft.[3,4] The Talent (Medtronic) stent graft is one of the most-used devices worldwide and combines suprarenal fixation with high radial force and columnar strength. Long-term results of treatment with the Talent device are scarce and limited to small study populations.[5,6] In this article, we report the 7-year results of the Talent graft gathered in two tertiary referral vascular medical centers. Data were collected prospectively and are retrospectively analyzed. Data are presented according to reporting standards for EVAR.[7]

PATIENTS AND METHODS

Patients were included from two hospitals, The St. Antonius Hospital, Nieuwegein, The Netherlands, and Stanford University Hospital, Stanford, California, USA. Between July 2000 and December 2007, 365 patients underwent elective EVAR with the Talent graft. All aneurysms were infrarenal, and aneurysmatic extension to the iliac arteries were not excluded. Patients who were treated for a ruptured abdominal aortic aneurysm (AAA) were excluded from the study. Inclusion for endovascular treatment was based on the individual surgeons' decision. Exact data of anatomy and referral conditions were not available for all patients, but in both medical centers many patients had been referred by other surgeons after they were turned down for EVAR at

other hospitals because of high-risk surgery (American Society of Anesthesiologists (ASA) score ≥3), and/ or challenging anatomy (ie, infrarenal angulation >60 degrees, short neck length <15mm and >90 degrees iliac tract).

Data from all patients were recorded prospectively in a vascular database. The prospective data collection was coordinated between the two sites to capture similar data points, including the time intervals of the computed tomography (CT)-scans during follow-up. The database contains patient characteristics, graft characteristics, procedural characteristics, data concerning hospital stay, and follow-up data as readmissions, complications, occurrence of endoleaks, and all-cause mortality. Surveillance of patients after EVAR occurred at the outpatient department by regular clinical examination and CT scanning to rule out EVAR related complications like endoleaks at regular time intervals, including before discharge, at 3, 12 months, and yearly thereafter. Ultrasound and X-rays were not used routineously for surveillance during the inclusion period of this study. In case of a negative CT scan but clinical high suspicion (ie increase of AAA diameter) magnetic resonance angiography (MRA) with a specific setting for detecting (small) endoleaks or a selective angiography was performed. A radiologist and a vascular surgeon reviewed all follow-up CT scans for proper stent graft position, fixation, aneurysm diameter, and endoleak appearance. In case of long distance between patient's home and our hospital, CT scans were performed locally. Scans were sent over for reviewing. If a patient did not appear for a regularly scheduled follow-up visit, the general practitioner was contacted for information about the patient's condition.

According to the standards for EVAR, the following parameters of clinical outcome were reported[7]:

Survival outcomes: Overall survival and 30-day mortality, freedom from AAA related death, and freedom from AAA rupture.

Technical success: Relates to peri-procedural events that occur from the initiation of the procedure and extend through the first 24-hour postoperative period. *Primary technical success* is defined by

an intention-to-treat basis and requires the successful introduction and deployment of the device in the absence of surgical conversion or death, type I or III endoleaks, or graft limb obstruction. A technical success thus implies the following qualifying details:

1. Successful access to the arterial system using a remote site (ie, the femoral, external iliac, common iliac, or brachiocephalic arteries, with or without use of a temporary or permanent prosthetic conduit to access these arteries);
2. Successful deployment of the endoluminal graft with secure proximal and distal fixation;
3. Absence of a type I or III endoleak;
4. Patent endoluminal graft without significant twist, kinks, or obstruction

Definition of clinical success: Clinical success should be reported on an intention-to-treat basis and requires successful deployment of the endovascular device at the intended location without death as a result of aneurysm-related treatment, type I or III endoleak, graft infection or thrombosis, aneurysm expansion (increase of native aneurysm diameter >5 mm, or AAA volume >5%), aneurysm rupture, or conversion to open repair. Moreover, the presence of graft dilatation of ≥20% by diameter, graft migration, or a failure of device integrity classifies a case as a clinical failure.

Primary clinical success is clinical success without the need for an additional or secondary surgical or endovascular procedure. *Assisted primary or secondary clinical success* is clinical success achieved with the use of an additional endovascular or surgical procedure.

Statistical analysis.

Data were analyzed using the SPSS 13.0 statistical software (SPSS Inc, Chicago, Ill, USA). Kaplan-Meier curves and life tables were created with SPSS. We used nonparametric tests for continuous variables (Mann-Whitney test, Kruskal-Wallis test) and χ^2 and the Fisher exact test for categoric variables. When significant differences were found with the Kruskal-Wallis test, Dunn's post hoc test was applied. Additionally, binary logistic regression analyses were used for multiple testing. Values of $P < .05$ were considered statistically significant.

RESULTS

Patient baseline characteristics are reported in Table I. Mean follow-up was 40 months (range, 1-106 months). For this study, we report follow-up to 84 months for 24 patients.

Table I. Patient baseline characteristics

Variable	*Mean (range)*	*SD*
Age, year	74 (52-94)	7.7
Proximal graft diameter, mm	30 (24-36)	3.4
Maximum AAA diameter, mm	61 (31-125)	12
Neck diameter, mm	27 (16-35)	3.4
Neck length, mm	26 (6-77)	14
Pre-op creatinine, µmol/L	107 (44-577)	48
Hospital LOS, days	4.3 (1-67)	7
Follow-up, months	40 (1-106)	26
	No.	*%*
Aortic neck length <15mm	60/193	31
Neck angulation ≥ 60°	20/101	20
Neck diameter ≥ 30mm	72/257	28
Patients at each center		
Stanford	136	37
St. Antonius	229	63
Bifurcated graft	318	87
Aortic-monoiliac graft	40	11
Tube graft	7	2
Graft diameter ≥ 32mm	86/195	44
Coiling hypogastric artery	27	7
ASA class III and IV	270	74
Male	326	88

AAA, Abdominal aortic aneurysm; *ASA*, American Society of Anesthesiologists; *LOS*, length of stay; *SD*, standard deviation

Technical success

Deployment of endografts was successful in 361 of 365 patients (99%). Initially, four patients required conversion to laparotomy. One conversion was to solve a large preoperative distal migration of the just placed stent graft in a patient with a large angulated neck, and in three patients, it was impossible to introduce the main device despite endovascular percutaneous transluminal angioplasty (PTA) procedures of the common iliac arteries. Primary technical success, based on results from CT scans before discharge, was achieved in 333 patients (91%). Primary proximal type 1 endoleaks were present in 28 patients (8%), and 14 (50%) of these 28 needed additional treatment during follow-up. The median time to treatment was 13 months. Treatment for these persistent primary types 1 endoleaks were; 8 proximal extension cuffs, 2 uni-iliac aortic stent grafts (AUI), 3 aortic neck plications and 1 conversion to open repair. Causes of primary type 1 endoleak were; suboptimal placement in 4, migration in 7, three suboptimal stent graft appositions. In 10 patients, type 1 endoleak resolved spontaneously within a maximum of 9 months after appearance, with no migration or enlargement of the native aneurysm during follow-up. In these patients follow-up with CT scan was intensified to 3 months intervals. No significant difference was determined between the limited numbers of patients with and without a spontaneous seal of a proximal type 1 endoleak in terms of neck angulation, diameter and neck length. Details of extent of proximal neck thrombus and calcification were not recorded.
Four patients, with an early type 1 endoleak, died soon after the initial operation of non-AAA related causes (two of cardiac failures, one of multiorgan failure, and one of pneumonia).

Survival

Outcome is presented in Table II, including AAA related mortality and all cause mortality. Of the 365 patients overall, 122 (33%) died during follow-up. Estimated overall survival at 84 months by Kaplan-Meier curve was 50.4% (Fig 1).

Table II. Thirty-day and long-term outcomes

Outcome	*No.*	*%**
30-day outcome		
30-day mortality	4	1.1
Successful graft deployment	361	99
Primary technical success	332	91
Long-term outcome		
Mortality		
Overall	122	33.4
Aneurysm-related, including 30-d	9	2.5
Cardiac	46	12.6
Pulmonary	18	4.9
Carcinoma	13	3.6
Renal	6	1.6
Unknown	19	5.2
Other	11	3.0
Aneurysm rupture during follow-up	4	1.1
Explantation of Talent by laparotomy	10	2.7
Median follow-up		
Primary clinical success	261	71
Assisted primary clinical success	296	81

* Percentage of all included patients (365)

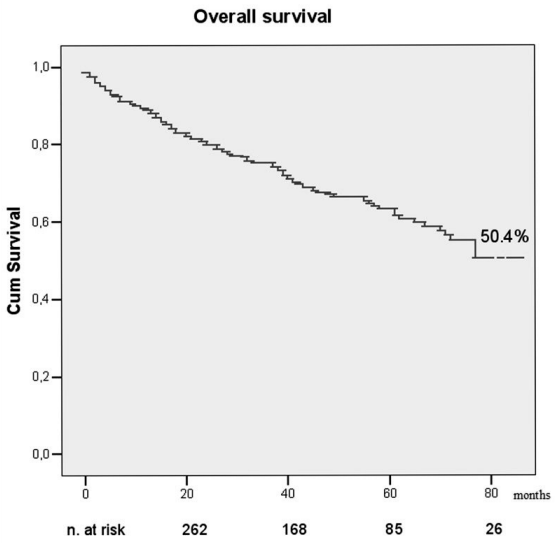

Figure 1. Survival curve for all-cause mortality during follow-up. Standard errors of displayed data on curves did not exceed 10%.

The freedom of AAA-related death is presented as a Kaplan-Meier survival curve (Fig 2). The Kaplan-Meier estimate for freedom of AAA-related death was 92% at 84 months. Nine AAA-related deaths (2.5%) occurred during follow-up. Four patients (1.1%) died within the first 30 days (above mentioned). The other five patients died of complications of secondary interventions. One patient had non-successful treatment of a type 1 endoleak. Eventually, the AAA ruptured and patient died during open repair. The other patient underwent an open procedure after complicated femoro-femoral crossover bypass and died due to myocardiac infarction in the ICU department. The other three patients, ASA class IV, died of rupture after unsuccessful secondary interventions for endoleaks and migration.

Four aneurysm ruptures (1.1%) occurred during follow-up. At 84 months, the Kaplan-Meier estimate for rupture-free survival is 96.5%.

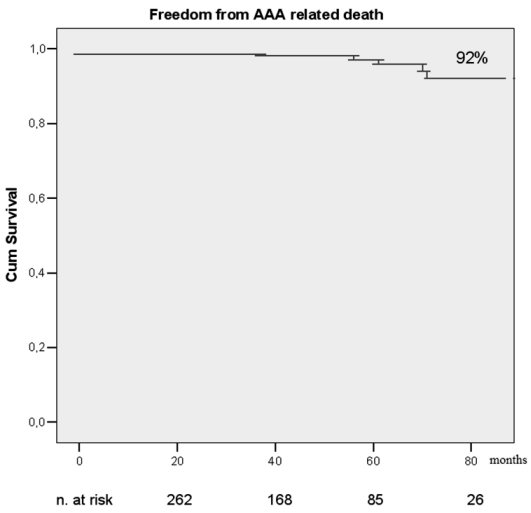

Figure 2. Survival curve for abdominal aortic aneurysm (AAA) related mortality during follow-up. Standard errors of displayed data on curves did not exceed 10%.

Clinical success

Primary clinical success was achieved in 261 of 365 patients (71.5%) at a mean follow-up of 40 months. Data are displayed in Fig 3. Kaplan-Meier estimates revealed primary clinical success rates of 98% at 1 year, 93% at 2 years, 88% at 3 years, 79% at 4 years, 64% at 5 years, 51% at 6 years, 48% at 7 years, and 46.9% at 84 months. Primary assisted clinical success rate was 81% (296 of 365) at a mean follow-up of 40 months, with a Kaplan-Meier estimate of 64.1% at 84 months. For the 104 patients who did not meet the criteria for primary clinical success, 73 patients underwent 73 additional procedures and 14 secondary procedures. An overview of the indications for reinterventions and the procedures performed are reported in Table III. The 14 secondary interventions comprised 4 conversions to laparotomy, 4 proximal extension cuffs, 2 femoro-femoral crossover bypasses, 1 embolectomy, 1 PTA, 1 aortic neck wrapping, and 1 exploration to staunch a hemorrhage. In only two patients with endograft limb occlusions was thrombolysis used. In most of the patients with endograft (limb) occlusions an additional morphological problem with the endograft limb was seen, like kinking or migration. These problems had to be treated with renewed stent grafts, or femoro-femoral crossover bypass, and were combined with open thrombectomy, instead of thrombolysis.

Table III. Indications for reinterventions and type of interventions

Variable	*Cases*
	(No.)
Indications for reinterventions	
Migration	11
Type 1 endoleak	21
Type 2 endoleak	9
Type 3 endoleak	1
Graft thrombosis/kinking	16
Infection	4
Postoperative hemorrhage	1
Rupture of aneurysm	1
Iliac stenoses	3
Renal artery stenoses	3
Unspecified	3
Interventions	
Additional cuff placement	18
Coiling	8
Thrombolysis/Thrombectomy/PTA	20
Femfem crossover bypass	5
Laparotomy, endograft explant	6
Abscess drainage	2
Staunch hemorrhage	1
Aortic mono-iliac endoprosthesis	6
Surgical control of lumbar endoleak	1
Aortic neck wrapping	5
Laparotomy for mesenterial ischemia	1

PTA, percutaneous transluminal angioplasty.

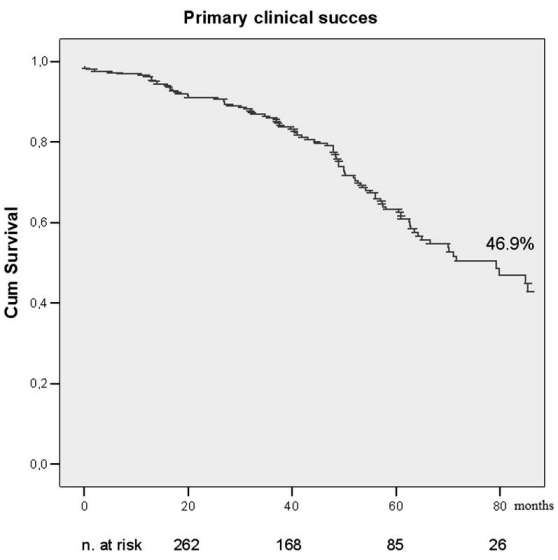

Figure 3. Primary clinical success presented as a survival curve during follow-up. Standard errors of displayed data on curves did not exceed 10%.

The remaining 31 of the 104 patients did not have a reintervention. Of the patients who did not receive additional treatment, 1 patient refused therapy for a type 1 endoleak, 2 had minor stent graft migrations, 1 had a small type 3 endoleak, and 4 patients died within 30 days. 23 patients had AAA expansion >5 mm without presence of endoleaks or stent graft migration. These patients are in extensive follow-up with late phase CT and MRA scanning to detect the possible cause of AAA expansion.

Patients who did not reach clinical success criteria were compared with primary clinical successful patients. Compared were baseline AAA diameter, proximal aortic neck length, proximal aortic neck diameter, proximal endograft size (<32 mm versus ≥32 mm), ASA class, graft length and configuration (bifurcation, AUI, tube graft), and age. Mann-Whitney testing did not reveal statistical significances between the groups, including graft configuration and proximal diameter. However, there was a tendency (P = .07) for increasing age, larger AAA diameters, shorter proximal aortic necks among patients who did not meet clinical success. Additionally, binary logistic regression analyses revealed larger AAA diameter was associated with clinical failures (P < .05).

Ten open conversions for failed endografts were performed, including initial conversions. The life-table yearly risk for AAA-related reintervention was 6%, yearly risk for conversion was 1.1%, and yearly risk for AAA-related mortality was 0.8%.

DISCUSSION

EVAR is widely accepted as a treatment for AAA. The long-term data of the Comparison of Endovascular Aneurysm Repair with Open Repair in Patients with Abdominal Aortic Aneurysm (EVAR-1) trial and the Dutch Randomized Endovascular Aneurysm Management (DREAM) trial were recently published.[8,9] The long-term all-cause mortality did not differ between open surgery and the EVAR group. However, there was an initial benefit for EVAR due to a lower AAA-related mortality. EVAR-1 and other randomized trials were not designed to investigate the different EVAR devices, endograft capabilities and limitations, and device specific results.[1,2] In daily practice, it is therefore useful that long-term data of frequently used EVAR devices, like the Talent device, are available.

Long-term results with other stent grafts have been published in the recent years. In 2009 Bos et al. described their 5-year results with the Gore Excluder (W.L. Gore, Flagstaff, Ariz) stent graft.[10] They showed an excellent long-term result with a 70% survival at 5-years with a 13% reinterventions rate and no AAA ruptures during follow-up. Abbruzzese et al. analyzed the long-term device specific outcomes of the Cook Zenith (William A. Cook PTY LTD, Brisbane, Australia), Gore Excluder and Medtronic AneuRx stent grafts and published comparable long-term outcomes.[11] Overall 5-year survival rate was 61% with a reintervention rate of 20% and a 5-year AAA rupture rate of 1.1%. However, data are difficult to compare since the criteria for reporting standards for EVAR, published by Chaikof et al. are not used consequently.

Long-term results of the Talent graft are limited to a few studies.[5,12] Through the years, indications for EVAR have changed. In the beginning, EVAR was more likely to be used as a therapy in patients who were unfit for open surgery. The studied population in this report also had severe co-morbidities, reflected by the ASA classification presented in Table I. Besides high number of ASA 3 and 4 patients, a substantial part of patients was treated with EVAR in presence of challenging

anatomy of the proximal neck (neck angulation ≥ 60 degrees, neck diameter ≥ 30 mm or neck length < 15 mm, Table I). The overall mortality rate reported for this cohort is comparable with other series.[12,13] Although long-term all-cause mortality is high in the current study, the 30-day mortality data of our cohort are good and even lower than in other series for EVAR and substantially lower than open repair.[1,2,8,12] The EVAR-1 and DREAM trial showed an operative (30-day) mortality rate for the open repair group of 4.7 and 4.6%, respectively.[1,2] Aneurysm-related death and rupture in our study were limited and at least comparable to results reported in the randomized trials and registries.[13-15] However, some under-registration of ruptured AAA could have occurred because postmortem examinations were not regularly performed.

Implantation and deployment of the graft was successful in 99% of the patients. Despite the Talent graft design with the ability of transrenal fixation by a 15-mm-long uncovered stent, still primary technical success was limited to 91%, mainly due to type 1 proximal endoleaks. An explanation for this could be the treating of a considerable number of patients with challenging AAA morphology, such as large and angulated (≥60 degrees) aortic necks. Detailed information about aortic neck length and diameters were available for 193 patients and information about neck angulation in 101 patients. The Talent graft was used to treat 60 patients with neck length <15 mm, which is likely to be a risk for a proximal type 1 endoleak. The presence of a perioperative detected type 1 endoleak is clinically relevant.

Perioperative additional procedures to solve a type 1 endoleak discovered on the completing angiography must be attempted. However, as described in the Results, some endoleaks will spontaneously seal. In this cohort, 14 of 28 patients (50%) needed additional treatment for persistent type 1 endoleak during follow-up.
If no migration was seen, no AAA diameter or volume growth was noticed, and the position of the proximal endograft was optimal with regard to the lowermost renal artery a watchful waiting policy was applied. In case of endograft migration with < 1 cm fixation left, native AAA diameter or volume growth, elective endovascular reintervention was scheduled. In most of the patients who needed an open reintervention procedure the intervention was postponed after persistent EVAR related complications were diagnosed at a second control CT scan at 6 or 9 months.

During follow-up, clinical success was accomplished in almost half of the patients. A substantial number of patients underwent additional procedures. Most of these procedures were performed endovascularly, which limits patient co morbidity. Besides the mentioned number of endoleak problems, graft thrombosis and kinking were also issues. At the completion angiography of all patients no kinking of the endograft limbs were predictable. Our data are consistent with other publications.[5,12] During the follow-up years, reinterventions had to be performed consistently through all years. Regarding the Kaplan Meier curve, a substantial increase in reinterventions could be observed in later years of follow-up. Therefore, regular and long-term clinical and radiologic surveillance is mandatory after a successful EVAR procedure.

This study is not without some limitations. Due to the retrospective character of this study, we do miss anatomical data like the pre-operative proximal suprarenal and infrarenal neck angulation in a substantial part of the patients and the existence of aneurysmal degeneration of the common iliac arteries.

Similar to all long-term follow up studies for EVAR, we included patients over a long time interval. This means that a substantial number of patients were treated in the early days of our experience with the Talent device. Although we did not observe a decrease in EVAR related complications over the years, there have been improvements in experience of EVAR at both institutions that will have been of influence in the study outcome. On the other hand, in both institutes >500 EVAR procedures were performed with other devices before the Talent stent graft had been introduced.

The graft itself has been evolved over the years (improved proximal fixation, a lower profile and available in larger diameters up to 36 mm). These refinements in graft design could have influenced our results over the years.

Moreover, as the study progressed, the treatment boundaries were extended over the years, and patients with shorter and wider necks and increased angulation were treated, sometimes with violation of the instructions for use. This counteracts with the improvement in stent graft fixation characteristics.

One should also be aware that most of the included patients were referred by other hospitals and were denied for open as well for EVAR on bases of their anatomic characteristics and co-morbidity in these (less experienced) centers, which might introduce a selected patient group therefore.

CONCLUSION

In this cohort with a high number of patients with severe co-morbidity, overall mortality post EVAR was substantial during follow-up. Technical success and clinical outcome are comparable to other manuscripts focussing on use of single EVAR devices. The current study showed (again) that the policy of treating higher risk patients with a suboptimal AAA anatomy for EVAR repair has its drawbacks including regularly and persistent follow-up, and substantial need for reinterventions which increases with follow-up duration.

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Chapter 4

Renal function after endovascular aortic aneurysm repair: a single-center experience with transrenal versus infrarenal fixation

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ABSTRACT

Purpose: To describe the short-term consequences of endovascular aortic aneurysm repair (EVAR) on renal function after infrarenal (IR) versus transrenal (TR) stent-graft fixation.

Methods: Between December 1996 and January 2006, 369 consecutive patients were treated with EVAR. All patients had an AneuRx or a Talent stent-graft implanted using IR (AneuRx) or transrenal (Talent) fixation. Post-EVAR, a standardized follow-up scheme included computed tomography (CT) scanning and serum creatinine measurements at 2 days, 3 months, and 12 months. Postoperative renal dysfunction was defined as a >20% decrease in serum creatinine clearance compared to baseline, the presence of new-onset dialysis, or both. Of the 369 patients, 309 (291 men; mean age 71±7 years, range 63–82) had complete 1-year follow-up and were included in this study. An IR stent-graft was placed in 190 patients, and a TR stent-graft was placed in the remaining 119 patients.

Results: At discharge, renal dysfunction occurred in 3.7% of the patients in the IR group versus 5.9% in the TR group (p=NS) and rose significantly to 13.7% in the IR group (p=0.001) and 15.1% in the TR group (p=0.02) at the 1-year follow-up. However, no significant difference was noted between the IR and TR groups at either time point. At the 1-year follow-up, at least 50% of renal dysfunction was caused by obstructions of (accessory) renal arteries and renal infarctions. During the follow-up interval, 3 (0.97%) of 309 patients underwent new-onset dialysis.

Conclusion: Both infrarenal and transrenal fixation techniques in EVAR will lead to a significant rise in renal dysfunction during the first year. A few patients with dysfunction will require dialysis.

INTRODUCTION

In the early days of endovascular aneurysm repair (EVAR), patients with favorable aortic morphology of the proximal landing zone (≥1.5 cm long, infrarenal, straight aortic neck) were mainly selected for treatment. Over the last decade, new stent-grafts have been designed that allow transrenal instead of pure infrarenal fixation so that patients with less favorable proximal aortic neck morphology can be treated. Currently, almost 60% of patients with abdominal aortic aneurysms (AAAs) can be treated endovascularly with conventional stent-grafts, not including fenestrated and branched devices, which widen the application further.[1]

A secure, proximal stent-graft fixation is essential and might prevent migration or proximal type I endoleak. The juxtarenal and suprarenal areas of the aorta are less susceptible to dilatation and thus may be a more durable fixation site for a stent-graft compared with the infrarenal aorta.[2;3] Nevertheless, it must be taken into account that transrenal fixation adds only to fixation; it does not necessarily improve the seal at the site. Although the impact of transrenal stentgraft fixation on renal function has been documented, most studies describe small patient groups or offer results from multiple types of stent-grafts and multicenter research projects.[4-9]

The aim of this single-center study was to answer two questions: what is the short-term impact of EVAR on renal function and does transrenal stent-graft fixation lead to more renal impairment compared with infrarenal stent-graft fixation? We therefore compared the results of the transrenally affixed Talent stent-graft with the infrarenal AneuRx stent-graft

METHODS

Study Design

Between December 1996 and January 2006, all patients with an AAA >55 mm in diameter or those with a >45-mm AAA that was rapidly growing (>5 mm in the past year) with suitable AAA morphology were offered EVAR at our tertiary referral hospital. During this period, 2 types of stent-grafts were used. From December 1996 to August 2003, the infrarenally affixed AneuRx

stent-graft (Medtronic Vascular, Santa Rosa, CA, USA) was implanted. As the transrenally implanted devices, such as the Talent stent-graft (Medtronic Vascular), became available, they were applied in AAAs with wide and short proximal aortic necks. Basically, patients with severe infrarenal thrombus and calcification were not considered to be candidates for EVAR, with the exception of patients with severe cardiopulmonary comorbidity. After acquiring experience with the Talent device, this policy changed, and all morphologically suitable AAAs were treated with transrenal devices. During the last 2.5 years of the study period, no AneuRx devices were implanted.

Patients were eligible for this retrospective analysis if they had elective EVAR during the study period and had survived to their 1-year follow-up without conversion to open repair.

Furthermore, data on serum creatinine and appropriate imaging studies had to be available at 4 time points: preoperatively, at discharge, and at 3 months and 1 year after treatment. Patients with a ruptured AAA or isolated iliac aneurysm were not eligible for analysis.

Patient Sample

During this 9-year study period, 369 consecutive patients underwent primary elective EVAR. Of these, 60 (16.3%) patients were excluded from analysis owing to (1) 1-year follow-up not yet attained (22, 6.0%), (2) conversion to open repair within 1 year after EVAR (10, 2.7%), or (3) death within 1 year after initial operation (28, 7.6%). None of the deaths was related to the AAA or EVAR. In the remaining 309 patients (291 men; mean age 71±7 years, range 63–82) an infrarenally (IR) affixed stent-graft was used in 190 and a transrenally (TR) positioned stent-graft in 119. Demographic data, aneurysm morphology, and vascular risk factors for both groups are summarized in Table 1. There were no patients with perioperative hemodynamic instability. Two patients with bilateral stenotic renal arteries in combination with an absolute serum creatinine concentration >130 mmol/L (one in each group) were treated with angioplasty and stent placement prior to EVAR.

Table I. Patient demographic data, characteristics of aneurysm morphology, and preoperative risk factors

	IR group (AneuRx) (n = 190)	*TR group (Talent) (n = 119)*	*p*
Age, y	71.3 ± 7.0	71.7 ± 7.6	NS
Men	177(93%)	114(96%)	NS
Diabetes	13(7%)	7(6%)	NS
Hypertension	51(27%)	32(27%)	NS
Renal insufficiency	23(12%)	13(11%)	NS
Coronary artery disease	130(69%)	79(66%)	NS
COPD	43(23%)	30(25%)	NS
Aneurysm diameter, mm	59.1 ± 10.7	62.5 ± 13.4	NS
AAA neck diameter, mm	23.8 ± 2.6	25.6 ± 3.0	< 0.001
AAA neck length, mm	25.5 ± 12.8	30.5 ± 13.1	NS
ASA ≥ 3	88(46%)	70(59%)	NS
Contrast volume, ml	152 ± 56	160 ± 65	NS

Continuous variables are presented as mean ± the standard deviation; categorical variables are given as the count (percentage).
IR: infrarenal, TR: transrenal, NS: not significant, COPD: chronic obstructive pulmonary disease, AAA: abdominal aortic aneurysm, ASA: American Society of Anaesthesiologists classification.

Preprocedural Evaluation

Serum creatinine concentration was measured preoperatively before patients underwent computed tomographic angiography (CTA) to evaluate AAA morphology. Scans were obtained with a multislice CT scanner (Tomoscan SR 7000; Philips Medical Systems, Best, The Netherlands) set to a slice collimation of 1.5 mm and a pitch of 1.5 for optimum volume coverage. Nonionic intravenous contrast was used in all patients, and the scan protocol did not change over the years. During the first 2 years, digital subtraction angiography with calibration catheters was performed in the preoperative workup at least 2 weeks before EVAR.

Stent-Graft Implantation

Patients with renal dysfunction at baseline were protected by prehydration with a 0.45% saline infusion (1 mL/kg/h) from 12 hours before to 12 hours after EVAR and N-acetylcysteine (2 1200-mg doses per day) for 3 days starting on the first preoperative day.

All procedures were performed under general or locoregional anesthesia in an operating theater by a vascular team consisting of a vascular surgeon and an interventional radiologist. Two vascular surgeons and 2 interventional radiologists were involved in all procedures. The EVAR technique is described extensively in other reports.[10;11]

Stent-graft oversizing was a maximum 10% to 15% of the diameter of the aorta, extensive mural thrombus was considered a contraindication to EVAR, and the proximal edge of the graft fabric was positioned 1 to 2 mm below the distal border of the most distal renal artery on fluoroscopy. Generally, as little contrast as possible was used during EVAR.

The only difference between the patients treated in the beginning of our EVAR program and the patients treated more recently was that fluoroscopy was used in combination with intravascular ultrasound (IVUS) initially; today, IVUS is abandoned.

Accessory renal arteries were covered only if their diameter was <1.5 mm and they perfused <20% of the kidney according to selective arteriography at the time of EVAR.

Otherwise, intentional covering of the accessory renal artery was not done.

Follow-up

After EVAR, each patient underwent a standardized surveillance protocol that included a physical examination and CTA at 2 days, 3 months, and 1 year; serum creatinine concentration was measured before CTA at each scanning session. The intraoperative angiograms and postoperative CTAs were examined to identify the cause of any renal impairment in terms of renal infarcts, progressive renal cysts, (accessory) renal artery stenosis or occlusions, or a combination of these factors. Renal artery stenosis or occlusion caused by (partial) positioning of the covered part of the stent-graft over the renal artery ostia were classified as renal artery stenosis or occlusion.

Definitions and Statistical Analyses

Preoperative renal dysfunction was defined as an absolute serum creatinine concentration >130 μmol/L or dialysis, or both. Postoperative renal dysfunction was defined as a >20% decrease in serum creatinine clearance (SCC) compared to baseline or the presence of new-onset dialysis, or both. Serum creatinine clearance was calculated using the Cockcroft-Gault formula.

To analyze progression of renal insufficiency in a control group, renal function was measured during the first postoperative year in 30 patients who had been treated endovascularly for an isolated thoracic aortic aneurysm (TAA).

A subanalysis of the long-term consequences of EVAR-induced renal dysfunction was performed with the most recent SCCs of all patients with proven renal dysfunction at the 1-year follow-up. Baseline patient demographic data, preoperative AAA characteristics, risk factors as defined by the reporting standards of the Society for Vascular Surgery and the American Association for Vascular Surgery,[12;13] and postoperative follow-up data were prospectively gathered and compared between the IR and TR fixation groups.

Continuous variables are expressed as the mean ± the standard deviation, and categorical data are presented as counts and proportions. After testing for normal distribution, statistical analyses were performed using the Student *t* test for continuous variables and the chi-square test for categorical variables. Differences were considered significant at $p<0.05$.

RESULTS

Aneurysm neck diameter was significantly larger in the TR group (25.6±3.0 versus 23.8±2.6 mm, $p<0.001$). All other variables revealed no difference between the groups.

Preoperative renal insufficiency was seen in 11.8% of the patients in the IR group and 11.1% in the TR group (p=NS). There were no significant differences between the IR and TR groups with regard to stent-graft oversizing or endograft position relative to the most distal renal artery. The mean amount of contrast used during EVAR has not changed significantly over the years (mean 105±36 mL). Median hospital stay was 2.4 days (range 2–60).

Mean preoperative SCC levels (Table 2) were similar between the groups (IR 70.9± 20.0 versus TR 72.2±22.2 mL/min; p=0.58). At discharge, no significant decrease of mean SCC was seen in the IR and TR groups compared with baseline, and there was no difference in mean SCCs between the groups (Table 2). At the 1-year follow-up, a significant decrease of mean SCC had occurred in both groups versus baseline (IR 70.9±20.0 versus 66.3±21.9 mL/min, p=0.04; TR 72.2±22.2 versus 68.7±24.1 mL/min, p=0.02), but no significant difference between the groups could be found.

Table II. Comparison of the serum creatinine clearance levels for the infrarenal (IR) and transrenal (TR) stent-graft fixation groups

	Preoperative	*At discharge*	*3 Months*	*1 Year*
IR, ml/min	70.9 ± 20.0*	73.6 ± 22.7	64.4 ± 22.0	66.3 ± 21.9*
TR, ml/min	72.2 ± 22.2**	74.6 ± 25.6	69.9 ± 23.2	68.7 ± 24.1**
p	NS	NS	NS	NS

Data are presented as mean ± standard deviation.
NS: not significant
* p = 0.04
** p = 0.02

At discharge, 7 (3.7%) of 190 patients in the IR group and 7 (5.9%) of 119 patients in the TR group had new renal dysfunction (Table 3). At 1-year, significantly more patients in both groups had renal dysfunction compared with the numbers at discharge: 26 (13.7%) in the IR group (p=0.001) and 18 (15.1%) in the TR group (p=0.02). No significant difference was noted between the groups in terms of renal dysfunction frequency at discharge and after 1 year. Renal dysfunction at 1 year occurred more often in patients with a preoperative serum creatinine >130 μmol/L compared to patients with no preoperative renal insufficiency (20% versus 13.5%, respectively; p<0.05). No patients required dialysis during their hospital stay. Two patients in the IR group required dialysis during 1 year of follow-up, temporary in 1 patient and permanent in the other.

In the control group with thoracic aortic aneurysms, no significant decrease in SCC was observed at 1 year (72.1±23.0 versus 71.4±21.9 mL/min, p=0.90). No patients had renal dysfunction at discharge. Renal dysfunction was observed in only 1 (3.4%) of 30 patients after 1 year of follow-up.

Table III. Patients with renal dysfunction in the infrarenal (IR) and transrenal (TR) stent-graft fixation groups

	At discharge	*3 Months*	*1 Year*
IR (n = 190)	7 (3.7)*	16 (8.4)	26 (13.7)*
TR (n = 119)	7 (5.9)**	10 (8.4)	18 (15.1)**
p	NS	NS	NS

Data are given as the count (percentage).
* p=0.001
**p=0.02

As to the causes of postoperative renal dysfunction (Table 4), aside from obstruction of the (accessory) renal artery and renal infarction, no morphological causes could be found in almost half of the patients. No renal arteries were stented intra- or postoperatively.

Sensitivity and specificity of our CTA measurements concerning renal artery stenosis were >90%, which is in accordance with other contemporaneous studies.[14;15] At the 1-year follow-up, 14.3% of the patients in the IR group and 4.3% of the TR patients had new or progressive renal cysts in 1 or both kidneys.

Table IV. Causes of renal dysfunction in the infrarenal (IR) and transrenal (TR) stent-graft fixation groups

	IR At discharge (n = 7)	*IR at 3 Months (n = 16)*	*IR at 1 year (n = 26)*	*TR At discharge (n = 7)*	*TR at 3 Months (n = 10)*	*TR at 1 year (n = 18)*
Occluded renal artery	3 (42.9)	4 (25)	6 (23.1)	1 (14.3)	1 (10.0)	3 (16.7)
Occluded accessory renal artery	1 (14.3)	2 (12.5)	3 (11.5)	0	3 (30.0)	3 (16.7)
Stenosed renal artery	0	0	1 (3.8)	0	2 (20.0)	6 (33.3)
Renal infarct	2 (28.6)	3 (18.8)	4 (15.4)	3 (42.9)	4 (40.0)	4 (22.2)
No explanation	1 (14.3)	7 (43.8)	12 (46.2)	3 (42.9)	0	2 (11.1)

Data are given as the count (percentage).

Five (2%) of the patients with normal renal function post-EVAR (2 IR and 3 TR, p=NS) had a renal infarct; in another 5 (2%) patients (3 IR and 2 TR, p=NS), progressive renal cysts were seen. No (accessory) renal artery stenoses or occlusions were diagnosed in the patients with normal renal function during follow-up.

To examine the long-term consequences of EVAR-induced renal dysfunction, we collected the most recent SCC values of the 44 patients with renal dysfunction at the 1-year follow-up (26 IR patients and 18 TR patients). After a mean follow-up of 36 months, SCC remained stable in 13 (30%) of the 44 patients. Of the 31 patients (70%) with progressive renal dysfunction, only 1 required dialysis (IR group).

To determine if increasing operating team experience over the course of the study period influenced these observations, the first versus the last cohort of 50 patients treated with EVAR during the inclusion period were compared; no significant differences were found concerning renal dysfunction post-EVAR or after 1 year of follow-up.

DISCUSSION

A secure proximal fixation of an abdominal stent-graft is one of the most important necessities for durable long-term aneurysm exclusion. In published registries, up to 70% of patients are currently being treated with transrenally affixed stent-grafts (EUROSTAR Data Registry Center).[16] It could be hypothesized that transrenally placed stent-grafts impair renal inflow more often than pure infrarenally placed stent-grafts and thus will lead to more renal dysfunction. Most of the reports that have been published about the effect of transrenal stent-graft fixation on renal function are multicenter studies or describe a mixture of different stent-grafts in a small number of patients. Recently, Parmer et al.[17] published a multicenter study with an approximate 10% postoperative renal impairment rate, but the stent-graft that was used is not among the most frequently implanted models.

We describe a single-center study with a large number of patients, none of whom were lost to follow-up. Renal dysfunction was defined on the basis of absolute values and changes in SCC, which Alric et al.[5] described as adequate to assess renal dysfunction.

Moreover, SCC is simpler and less costly to employ than other modalities, such as renal scintigraphy.

All the studied patients had a minimum postoperative hospital stay of 2 days. Patients with a significant rise in serum creatinine on postoperative day 1 or 2 were kept in the hospital for hydration until the SCC was on the decline. Acute tubular necrosis can develop as much as 72 hours after the use of nephrotoxic contrast agents, but, in most cases, serum creatinine starts to rise before that time. Therefore, we believe that the number of patients with acute tubular necrosis starting at the third postoperative day or later would be few.

The results in the current study are (1) a significant rise in the number of patients with renal dysfunction in the first year of follow-up, which seems to be a progressive process according to the results depicted in Tables 3 and 4, and (2) no significant differences in SCC changes and renal dysfunction between the infrarenal and transrenal fixation techniques. These observations are consistent with other publications.[5;8;17-19] Surowiec et al.8 investigated renal function after EVAR in patients who were free from preoperative renal insufficiency or direct postoperative renal disease; they reported that renal impairment developed in 36% in the IR group and in 25% in the TR group at 36 months. Both findings support the search for common reasons of renal impairment unrelated to the level of endograft fixation.

One could propose that the unfolding of the stent-graft above the level of the renal artery ostia, followed by manipulation with unfolded proximal stents, causes multiple thromboemboli and infarctions in the kidneys. Atheroemboli to the kidney are known to initiate a localized arteritis, resulting in renal dysfunction presenting weeks to months after EVAR.[20] To minimize dislocation of atheroembolic fragments, excessive manipulations of the proximal part of the stent-graft during placement have to be avoided.

Another explanation for the delayed renal impairment in both groups could be because of thrombogenicity. Tepe et al.[21;22] studied thrombogenicity of various endovascular stent-grafts and demonstrated that nitinol-containing stents induce platelet activation.

Because the AneuRx and Talent stent-grafts both contain nitinol, and this nitinol is very close to the renal arteries in both implantation techniques, thrombus can form, leading to renal infarction or renal artery obstruction. Even late occlusion of an accessory renal artery might cause renal dysfunction, as was the case in 6 of our patients.

As Al-Said et al.[23] also observed, we saw the appearance of progressive renal cysts during follow-up. Multiple renal cysts might be associated with renal dysfunction, but more evidence on this subject is necessary. Another non-anatomical cause of late renal dysfunction could be the repeated administration of contrast.[24] Over the years of our study, no essential change in the perioperative imaging protocol took place. The mean amount of contrast used during the EVAR procedures was minimal and did not change significantly. Besides, all blood samples were taken before CTA, so SCC at the 1-year follow-up was determined 9 months after the last administration of contrast. The fact that no decrease in SCC was observed in the control group at 1 year and only 3.4% of these patients developed renal dysfunction under the same CTA protocol means that contrast-induced nephrotoxicity is a less plausible cause of renal dysfunction over the long term. To minimize the chance of contrast-induced renal dysfunction, one must critically evaluate the excess contrast versus potential value of such a strict CTA protocol and look for alternatives, such as magnetic resonance angiography or duplex ultrasound scanning.[25;26] The surplus value of a pre-discharge CTA seems to be minimal and without major clinical consequences, which will be the aim of a future study. For the past year, we have skipped this pre-discharge CT scan, but none of these patients is included in this study because the follow-up was too short.

Although ~15% of patients in both subgroups had renal dysfunction after 1 year, only 2 patients required dialysis (1 temporary). Of the 44 patients with renal dysfunction at 1 year, only 1 patient needed dialysis after a follow-up of 36.4 months. In total, 3 (0.97%) of the 309 patients needed new-onset dialysis, which is comparable to other studies.[17]

Limitations

Besides the retrospective analysis of the prospectively gathered data, another limitation of this study could be the fact that more transrenal fixations were performed during the last part of the inclusion period. However, the type of stent-graft was not selected on the basis of patient or aortic characteristics; after 2003, all consecutive patients were treated with transrenal fixation.

It could be argued that the operating team gained more experienced over the course of the study period, but our subgroup analysis of the first versus the last cohort of 50 patients treated with EVAR during the inclusion period uncovered no significant differences in renal dysfunction post-EVAR or after 1 year.

CONCLUSION

Both infrarenal and transrenal fixation techniques in EVAR will lead to renal dysfunction in ~15% of patients over 1 year of follow-up. Only a small proportion might be assigned to natural deterioration of renal dysfunction. Fortunately, <1% of these patients will need long-term dialysis. Possible causes of renal dysfunction are thromboembolic complications due to device manipulation, thrombogenicity of the endografts, or perhaps progressive renal cysts.

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Chapter 5

Early computed tomographic angiography after endovascular aneurysm repair: worthwhile or worthless?

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ABSTRACT

This study evaluated the value of computed tomographic angiography (CTA) early after an endovascular aneurysm repair (EVAR) in relation to CTA 3 months after EVAR. We retrospectively reviewed all elective EVAR patients with available postprocedural and 3- month follow-up CTAs who were treated between 1996 and 2006. CTAs were analyzed for EVAR-related complications in terms of endoleaks, migration, and stent graft thrombosis. Secondary procedures and other complications within a 4-month time interval after EVAR were noted and analyzed for any association with the postprocedural CTA. During the study period, 291 patients (275 men), with a mean age of 71 years, underwent elective EVAR. All had postprocedural and 3-month follow-up CTAs, which detected 93 (32%) endoleaks (8 type I, 84 type II, 1 type III) and 1 stent graft thrombosis. These findings resulted in four secondary interventions (one interposition cuff, two extension cuffs, one conversion). All reinterventions were successfully done in an elective setting. During the first 3 postoperative months, five other reinterventions were required for acute ischemia in four patients (three Fogarty procedures, one femorofemoral crossover bypass) or groin infection in one patient. Eight patients died, but none of the deaths were related to abdominal aortic aneurysm or EVAR (four cardiac, two pulmonary, one gastric bleeding, one carcinoma). At 3 months, 43 endoleaks (3 type I, 40 type II), 3 stent graft thromboses, and 1 stent graft migration were seen. In two patients (0.7%), a new endoleak was diagnosed compared with the postprocedural CTAs. In 287 (99%) of 291 patients, the postprocedural CTA did not influence our treatment policy in the first 3 months after EVAR. More than half of the early endoleaks were self-limiting, and new endoleaks were seen in only two patients (< 1%) at the 3-month follow-up CTA. After an uneventful EVAR procedure, it is safe to leave out the early postprocedural CTA.

INTRODUCTION

During the last decade, endovascular aneurysm repair (EVAR) offered a true alternative treatment option to open surgery for abdominal aortic aneurysm (AAA) exclusion. With the newest generation of stent grafts, up to 60% of infrarenal AAAs can be excluded technically by an endovascular procedure.[1] Although EVAR outweighs open aneurysm repair in terms of short-term mortality and morbidity, this technique has its own unique complications, with incidence rates of up to 40%. Therefore, lifetime follow-up is recommended.[2]

To date, computed tomographic angiography (CTA) seems to be the preferred modality to detect EVAR-related complications such as migration, endoleaks, and stent graft thrombosis.[3] The most frequently advised post-EVAR follow-up scheme is described by the European Collaborating Group on Stent-Graft Techniques for Abdominal Aortic Aneurysm Repair (EUROSTAR) investigators and includes a CTA within 1 month of the procedure.

Many centers, however, still perform the first control CTA even sooner, that is, before discharge.[3-5] The extra value of an early postprocedural CTA before discharge from the hospital might be questionable. The disadvantages of such an early postprocedural CTA include nephrotoxicity owing to radiographic contrast agents, prolongation of hospital stay, and the diagnosis of EVAR related complications that often have a benign, self-limiting course. Therefore, we studied the value of these early post-EVAR CTAs in almost 300 patients.

PATIENTS AND METHODS

During a 9-year single-center study period from December 1996 to January 2006, 369 consecutive patients (350 men), with a mean age of 71 years (range 39–92 years), were treated by EVAR for an infrarenal AAA. During this period, two types of stent grafts were used: the infrarenal fixating AneuRx stent graft and the transrenal fixating Talent stent graft (both from Medtronic AVE, Santa Rosa, CA). Indications for endovascular surgery were an AAA of at least 45 mm in diameter with suitable aneurysm morphology for endovascular repair. The study excluded patients who underwent endovascular repair for a ruptured AAA, a para-anastomotic aneurysm, or a solitary iliac aneurysm.

Before inclusion, all patients underwent CTA. From the start of the study until November 2000, a single-slice CT scanner was used with a section thickness of 3 mm (Philips Tomoscan SR 7000, Philips Medical Systems, Best, the Netherlands). After November 2000, a multidetector-row CT scanner was used with a section thickness of 1.5 mm (Philips IDT CT scanner, Philips Medical Systems). Nonionic intravenous contrast was used in all patients.

Surgery was performed under general anesthesia by a team consisting of a vascular surgeon and an interventional radiologist. The details of surgery, including the amount of used contrast material, were noted in a prospectively gathered database. The key indices relating to these surgeries were the length of operation, amount of blood loss, technical and clinical success, and EVAR-related in-hospital complications.

Before hospital discharge, each patient underwent dual-phase CTA. After hospital discharge, each patient entered a regular follow-up program consisting of a clinical visit and radiographic surveillance with renewed dual-phase (early and delayed) CTA examinations at 3 and 12 months and annually thereafter. For the current study, all postprocedural and 3-month CTAs were reassessed by one of the interventional radiologists and one of the vascular surgeons to monitor the stent graft position, presence of migration, endoleaks, stent graft thrombosis, aneurysm diameter changes, and thromboembolic complications.

Stent graft thrombosis was defined as a complete thrombosis of the main body of the stent graft or one or both of its legs. Endoleak was classified into types I to IV, as described in 2002 by Veith and colleagues.[6] Stent graft migration was defined as a distal stent graft displacement of at least 5 mm compared with the stent graft position on the first postprocedural CTA.

AAA enlargement was defined as an aneurysm growth ≥ 5 mm and AAA shrinkage was defined as aneurysm shrinkage of ≥ 5 mm; both were compared with the measurements on the former CT scan. The protocol in our institution for the treatment of endoleaks confirmed at the predischarge CT scans was as follows: (a) type I endoleaks: endovascular surgical reintervention with extension cuffs or aortouni-iliac devices was performed when the distance between the lowest renal artery and the proximal part of the stent graft was ≥ 5 mm at the predischarge CT scan, and no elective open conversion was done for type I endoleaks during the first 3 months postprocedure; (b) type II endoleaks: treatment (basically coil embolization) was given only in

cases of symptomatic (painful) or growing aneurysms; and (c) type III endoleaks: treatment was always with interposition cuffs and ballooning.

The medical records of all patients were evaluated to assess EVAR-related complications. All secondary interventions were noted from discharge to a follow-up of 1 month after the 3-month postprocedural CTA. All secondary interventions were evaluated for any association with the findings on the early postprocedural and 3-month CTAs.

The presence of death was verified by checking the digital medical record of the patients and by calling the general practitioner of all treated patients at the end of the study period.

Analyses of data were performed using SPSS version 11.1 software (SPSS Inc, Chicago, IL). Quantitative data were expressed as mean ± standard deviation and range.

RESULTS

During the study period, 369 patients underwent endovascular exclusion of an infrarenal AAA. Of these patients, 291 had both a postprocedural and 3-month follow-up CTA, all of which were included in the study. Most of the 78 excluded patients (n = 51) had their follow-up in other hospitals owing to logistic reasons. These patients had no 3-month follow-up but had 6-month CT scans. In the remaining 27 patients, the predischarge CT-scan was not performed owing to logistic reasons in our own institution. The baseline patient demographics of the 291 included patients are summarized in Table 1. The mean length of operations was 110 minutes (55–245 minutes), and the mean blood loss was 330 mL (80–1100 mL). In two patients (0.6%), thrombectomy of the superficial femoral artery had to be done during the operation. In Table 2, the detected complications related to the stent graft are summarized for the postprocedural and 3-month CTAs.

Table 1. Patient Demographics

Variable	*Percentage or Mean ± SD (Range)*
Age (yr)	72.4 ± 7.2 (40-92)
Male:female ratio	96:4
AAA diameter (mm)	60 ± 11.3 (37-102)
ASA classification	
I	4
II	20
III	44
IV	32
Comorbidity	
Cardiac	22
Pulmonary	40
Renal	30

AAA = abdominal aortic aneurysm; ASA, American Society of Anesthesiologists.

Table 2. Complications related to endovascular aneurysm repair seen on computed tomographic angiography

Complication	*Postprocedure (n)*	*3 mo (n)*
Endoleak type		
I	8	3
II	84	40
III	1	0
IV	0	0
Stent graft thrombosis	1	3
Migration	-*	1

*Cannot be given because this is the first postprocedural CTA.

The postprocedural CTAs detected 1 stent graft thrombosis and 93 endoleaks (32%), consisting of 7 proximal type I, 1 distal type I, 84 type II, and 1 type III endoleaks. These findings resulted in four secondary procedures (1%). Two type I endoleaks (one distally and one proximally) were treated with extension cuffs within 2 weeks after the initial operation. One interposition cuff was placed for a type III endoleak within 1 week after the initial operation. A patient with a large type II endoleak and an AAA > 10 cm underwent coiling of two paired lumbar arteries, which

was not successful. Because of progressive abdominal pain, surgical conversion with explantation of the stent graft was done within 2 months after the initial operation. All secondary procedures were performed in an elective setting.

Six of eight type I endoleaks were managed conservatively. Five patients had a small endoleak with a small (< 55 mm) preoperative AAA diameter. One patient with a small distal type I endoleak, who already had an overstenting of the internal iliac artery on the contralateral side, was treated conservatively.

In the 3-month time interval between the postoperative and 3-month CTA, four acute reinterventions were required because of thromboembolic complications (three Fogarty procedures, one femorofemoral crossover bypass), and one groin infection was explored. These interventions were done irrespective of the findings on the postprocedural CTA. None of the four patients treated for thromboembolic complications had signs of stent graft kinking or obstructed iliac arteries on the predischarge CTA, indicating a higher risk for thromboembolic complications.

Eight patients died within 3 months after EVAR. None of the deaths was related to the AAA or EVAR (four cardiac, two pulmonary, one gastric bleeding, and one carcinoma). Four of eight patients (50%) underwent autopsy, which confirmed the clinical diagnosis. No AAA ruptures occurred in the first 3 months after EVAR.

On the 3-month CTAs, 43 endoleaks (3 proximal type I, 40 type II), 3 stent graft thromboses, and 1 proximal stent graft migration were seen. In two patients, a new type II endoleak was diagnosed compared with the postprocedural CTA.

During 3 and 12 months of follow-up, two of the proximal type I endoleaks were successively treated by a proximal extension cuff. One patient with a type I endoleak had AAA shrinkage compared with the postprocedural CTA and was treated conservatively. Of the 40 patients with a type II endoleak on the 3-month CTA, 37 had a stable AAA (n = 32) or AAA shrinkage (n = 5) and were under a watchful waiting policy. AAA growth was observed on the 3-month CTA in three patients with a type II endoleak. These type II endoleaks were treated successfully by coil embolization (n = 2) or thrombin injection (n = 1).

All patients who needed a secondary intervention were treated in an elective setting. No patients needed an urgent intervention within a 1-month time interval after the 3-month CTA.

Five of 291 included patients had an AAA growth within the first 3 months of follow-up (mean AAA diameter of 47 mm postprocedure to 58 mm at 3 months). Three of these patients had a type II endoleak and two had a type I endoleak on the postprocedural CTA.

No AAAs ruptured during the first 6 months of follow-up. Thirteen patients (5%) had a prolonged hospital stay for intravenous fluid administration to return creatinine clearance to preoperative levels.

DISCUSSION

In the last decade, EVAR has become one of the leading treatment methods for exclusion of infrarenal AAAs. Despite its less invasive character, this technique has unique complications, as described in many reports that have focused on the results of EVAR.[7-11] Because most of these complications will occur asymptomatically, regular post-EVAR radiographic follow-up is mandatory to detect and treat these complications. The optimal follow-up frequency and the best imaging modality are not fully defined to date. It must be taken into account that new generation devices will lead to less device-related complications compared with the first-generation devices and less intensive radiologic follow-up might be justified in the near future. For instance, the use of the described AneuRx device has strongly declined.

The EUROSTAR reports advise examinations to start within the first month of follow-up and not during hospital stay, but the protocol in many centers still calls for a postprocedural CTA before hospital discharge.[3-5]

The CTA has long been accepted as the standard as it readily identifies a broad spectrum of postprocedural complications, including endoleak, migration, device fracture, aortic branch occlusion, delivery route dissection or injury, and retroperitoneal hematoma. With the introduction of dynamic magnetic resonance angiography and refined color duplex ultrasonography, the optimal imaging modality might become a matter of debate.[12-14] However, neither of the competing techniques can assess the full spectrum of abnormalities that CTA is

able to examine. In the current study, the early postprocedural follow-up scheme was the subject of interest, and the type of follow-up modality was beyond the scope of our study.

One of the reasons for performing an early postoperative CTA will be to establish the position of the device at the time of deployment to evaluate eventual future migration. However, of the 291 patients we studied, only 1 (0.3%) had proximal migration of > 5 mm in the first 3 months post-EVAR. All others had no or minimal migration of < 2 mm on the 3-month CTA; therefore, the baseline stent graft position can be reliably settled at the 3-month scan.

Another important issue is the time interval between the preoperative CT examination and the EVAR procedure itself. Most of the preprocedural CTAs (74%) of the studied patients were performed within 8 weeks prior to the EVAR. Only 11% of the patients had a preprocedural CT scan older than 4 months. In these particular patients, an early postprocedural study might provide a more effective baseline for comparison with the scans during a longer follow-up. This should not be a predischarge CT-scan but might be a 1-month postprocedural scan.

An important drawback of the early postoperative CTA is the use of nephrotoxic agents. It is, however, hard to measure the sole influence of the CTA because all patients receive contrast agents during the operation. In our study population, 5% had a prolonged hospital stay for intravenous fluid administration to normalize creatinine clearance, part of which might be caused by the extra amount of agents needed for CTA.

Another cause could be the occurrence of thromboembolic renal complications. Although we could not prove to what extent the predischarge CTA deteriorates renal function after EVAR, efforts should be made to minimize the amount of nephrotoxic contrast periprocedurally.

In our study, the data of the early postprocedural CTA did not influence postoperative treatment policy in 99% of EVAR patients. Only four patients were treated for EVAR-related complications found on the early postprocedural CTA. Another five (2%) interventions were done in the 3-month interval after successful EVAR, but all were done for clinical symptoms such as critical leg ischemia and groin infection. The early postprocedural CTA was therefore of no clinical value in discovering these postoperative complications.

At the intraoperative angiographies, 80 of 93 (86%) of the endoleaks from the predischarge CT scans were already diagnosed. This includes 6 of 8 type I endoleaks seen on the predischarge

CT scans. In case of intraoperatively detected type I endoleaks, these were all judged to be small, with no need for intraoperative conversion to an open procedure or endovascular revision.

More than half of all endoleaks diagnosed on the early CTA resolved within 3 months after EVAR without intervention. This overdiagnosis is a psychological burden for most of these patients. In addition, only two (1%) new endoleaks appeared in the 3-month period, and both were benign type II endoleaks.

Two of eight type I endoleaks were treated in the first postoperative month with endovascular reintervention. Although it is recommended to treat type I endoleaks as

they appear in association with the growth of aneurysms, spontaneous sealing of type I endoleaks has been described.[15;16] In our studied patient population, six of eight type I endoleaks were managed in a conservative manner because the AAA diameter and endoleak in these patients were relatively small. Type I endoleaks resolved spontaneously in three of six conservatively managed patients. More data from other studies are necessary to outline a thorough policy in case of early detected type I endoleaks.

Although the current study shows that the early postoperative CTA did not influence our treatment policy in the first 3 months post-EVAR in most of the 291 treated patients, possible bias has been introduced by the retrospective character of the study. The interpretation of the 3-month CTA could have been influenced by the information available from the predischarge CTA. A prospective randomized trial would be necessary to exclude this bias.

A limitation of this study might be the fact that it cannot set the course of the most ideal follow-up schedule in the first year post-EVAR. For this reason, the frequently used follow-up protocol including 1-, 6-, and 12-month CT scans (three scans) should be prospectively compared with a 3- and 12-month follow-up protocol (two scans). The 1-month scan could be preferred over the 3-month scan for those patients in whom the preoperative CTA is too old for settlement of AAA diameter or if the AAA diameter is so large that any kind of endoleak would propose a major risk for AAA rupture. However, the main benefit of this study is the fact that the predischarge CT scan can safely be abandoned from all possible follow-up protocols.

Last but not least, it is important to note that no patients needed an urgent intervention after the 3-month postoperative scan. If the indication for secondary reintervention was set, it could be performed in an elective setting. Therefore, none of the 99% patients would have been exposed to unwarranted hazards if the early CTA had been skipped.

CONCLUSIONS

In 287 (99%) of 291 patients, the postprocedural CTA did not influence our treatment policy in the first 3 months after EVAR. More than half of the early endoleaks were self-limiting, and new endoleaks were seen in only two (<1%) patients at the 3-month follow-up CTA. Hospital stay was prolonged in 5% of the patients owing to temporary worsening of their creatinine clearance. After an uneventful EVAR procedure, the early postprocedural CTA can be left out.

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Chapter 6

Aneurysm diameter and proximal aortic neck diameter influence clinical outcome of endovascular abdominal aortic repair: a four-year EUROSTAR experience

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ABSTRACT

Objective: To evaluate the effect of preoperative aneurysm and aortic neck diameter on clinical outcome after infrarenal abdominal endovascular aneurysm repair (EVAR).

Methods: Data of patients in the European Collaborators Registry on Stent-Graft Techniques for Abdominal Aortic Aneurysm Repair (EUROSTAR) registry base who underwent EVAR with Talent stent grafts were analyzed. Patient characteristics and clinical outcome were compared among four groups defined by preoperative abdominal aortic aneurysm (AAA) and proximal aortic neck diameter: A, AAA ≤60 mm and neck ≤26 mm; B, AAA >60 mm and neck ≤26 mm; C, AAA ≤60 mm and neck >26 mm; and D, AAA > 60 mm and neck >26 mm.

Results: Over a 7-year period, 1,317 patients underwent EVAR. Patients in groups B and D were significantly older and had a higher American Society of Anesthesiologists score compared with groups A and C (P = 0.002 and 0.003, respectively). Mortality rate was highest in group D (P = 0.002), as were rupture and conversion rates (P = 0.015 and 0.037, respectively).

Conclusion: This study demonstrates that patients with an AAA >60 mm and a proximal aortic neck >26 mm have worse clinical outcome after EVAR.

INTRODUCTION

Over the last 5 years, endovascular abdominal aneurysm repair (EVAR) has proven to be a less invasive alternative to open surgery, with reduced perioperative morbidity and mortality rates and decreased intensive care unit and hospital stay.[1-6] It even led to earlier return to functioning compared with conventional aneurysm repair. Ten years ago, when the first stent grafts were designed to exclude abdominal aortic aneurysms (AAAs), self-expandable nitinol stents were mostly used for graft fixation and support.

Compared with the proximal graft diameters being used in conventional open surgical repair, varying from 16 to 22 mm, the assumption was made that a maximum proximal stent graft diameter of 28 mm would cover most of the aortic neck diameters. This includes the necessity to oversize 10% to 20%, which is a prerequisite for durable fixation because the diameter obtained with computed tomography angiography is frozen somewhere between the systolic and diastolic phases of the pulsation.

Rather soon, it became obvious that a substantial subset of patients had infrarenal aortic neck diameters >26 mm, and at that time, most commercially available stents could not accommodate those sizes. The exception was the Talent stent graft (Medtronic, Santa Rosa, CA), which was supplied in stent diameters up to 34 mm and thus provided a treatment option for a proximal aortic neck diameter up to 30 mm. It was unclear whether this patient group had a "preaneurysmatic" neck prone for stent graft migration or simply a larger native arterial system.

Another thesis in EVAR is that patients with smaller aneurysms have a better outcome compared to patients with AAA diameters >60 mm. Although many studies describe the success of EVAR,[1-7] most reports neglect to examine the influence of aneurysm size and proximal aortic neck diameter on midterm clinical outcome, which is the aim of our study. Because the European Collaborators Registry on Stent-Graft Techniques for Abdominal Aortic Aneurysm Repair (EUROSTAR) data collection allows the evaluation of both subsets of patient groups for the long-term outcome of the Talent stent graft system, we placed the patients into four groups, depending on the aneurysm size and proximal aortic neck diameter.

PATIENTS AND METHODS

Data of all patients who had undergone elective EVAR with a Talent stent graft were analyzed retrospectively. Data were collected prospectively during a 7-year period in the EUROSTAR collaboratory study (Talent report, EUROSTAR Data Registry Centre, Feb. 2004, Eindhoven, The Netherlands).

All patients included in the study had an infrarenal AAA, with or without an iliac aneurysm, suitable for elective endovascular treatment. Inclusion criteria were based on morphologic criteria as described earlier[8,9]: a proximal aortic neck length of ≥10 mm, proximal aortic neck diameter of ≤30 mm, proximal aortic neck angulation of <60 degrees, iliac artery angulation of <90 degrees, and iliofemoral vessel diameter of at least 8 mm.

Baseline patient characteristics, including cardiopulmonary comorbidity, American Society of Anesthesiologists (ASA) score, and aneurysm morphology were prospectively recorded by each participating institution and submitted prior to inclusion to the EUROSTAR Data Registry Centre for data analysis. Patients with a solitary iliac aneurysm, pseudoaneurysm, or former conventional or endovascular abdominal aortic surgery were excluded from the study.

To assess the influence of aneurysm size and proximal aortic neck diameter on outcome after EVAR, patients were placed in four groups defined by preoperative aneurysm size and proximal aortic neck diameter (Table I).

Table I. Division of patients in four groups according to aneurysm diameter and proximal aortic neck diameter

	AAA (mm)	Neck (mm)
Group A	≤ 60	≤ 26
Group B	> 60	≤ 26
Group C	≤ 60	> 26
Group D	> 60	> 26

A commercially available Conformité Européene (CE)-approved Talent device was implanted in all patients: 88% received a bifurcated device, 10% an aortouniiliac device, and 2% an unsupported tube device. In Europe, all products, including medical products, must comply with these CE guidelines before they come onto the market, analogous to the U.S. Food and Drug Administration.

Most procedures were performed in the operating theater by a team consisting of an experienced vascular surgeon and an interventional radiologist. Each patient was given prophylactic antibiotics and systemic heparin periprocedurally.

During follow-up, all patients were monitored according to a standardized protocol. Follow-up visits were scheduled at postoperative months 1, 3, 6, 12, 18, and 24, and annually thereafter.

Findings at follow-up visits, including clinical examination and complementary roentgen diagnostic evaluations, were recorded on data forms, which were sent to the EUROSTAR Data Registry Centre.

Clinical end-points were defined as overall death (EVAR- and non-EVAR- related), rupture, and conversion to open repair.

Statistical Analysis

Results were reported as mean or median ± standard deviation (SD), range and percentage. The chi-square test was used to analyze patient characteristics. Life table analyses and log rank tests were used to compare long-term outcome in the study groups. All follow-up data was right-censored; patients with incomplete follow-up contributed to survival as long as they were in follow-up. Multivariate Cox proportional hazard models were used to determine whether baseline and follow-up variables were independently associated with adverse outcomes. Statistical significance was considered at $p < 0.05$. All statistical analyses were performed with Statistical Analysis System (SAS) software, version 8.00 (SAS Institute, Cary, NC).

RESULTS

Patient Characteristics

Between October 1996 and January 2004, 1,317 patients were treated with a Talent stent graft. Patient characteristics for groups A-D are shown in Table II. Mean age at time of operation was 71.5 ± 8.0 years (36-92).

Groups B and D consisted of significantly more patients older than 70 years compared with groups A and C (A, 59%; B, 67%; C, 58%; and D, 71%; p = 0.002) and had a significantly higher ASA score than did the other groups (ASA classification ≥ 3: 47%, 56%, 47%, and 60%, respectively; p = 0.003).

There was no significant gender difference among the four groups (percentage male in A, 95%; B, 94%; C, 96%; and D, 97%).

Table II. Baseline patient characteristics

Total (1317)	*Group A (616)*		*Group B (279)*		*Group C (249)*		*Group D (173)*		
	n	*%*	*n*	*%*	*n*	*%*	*n*	*%*	*p value*
Age (years)	71.1	-	73.5	-	71.4	-	74.0	-	<0.001
> 70 year	363	59	187	67	144	58	123	71	0.002
Men	586	95	262	94	240	96	167	97	NS
ASA ≥ 3	288	47	157	56	118	47	103	60	0.003
Diabetes	89	14	37	13	45	18	30	17	NS
Smoking	151	24	78	28	62	25	48	28	NS
Hypertension	123	20	56	20	47	19	26	15	NS
Cardiac history	172	28	95	34	85	34	76	44	<0.001
Renal insuff	129	21	61	22	67	27	55	32	0.020
Pulm history	111	18	59	21	65	26	55	32	<0.001
Obesity	160	26	89	32	85	34	57	33	NS
Unfit open repair	129	21	78	28	62	25	69	40	<0.001
Unfit for narcosis	61	10	36	13	25	10	40	23	<0.001
Max AAA (mm)	52	-	71	-	54	-	73	-	*
Neck diam (mm)	23	-	23	-	29	-	30	-	*
Neck length (mm)	28	-	26	-	27	-	23	-	NS

* *Cohort membership criterion.* NS, *not significant.*

Significantly more patients in group D had pre-existing cardiac co-morbidity compared with the other three groups (28%, 34%, 34%, and 44%, respectively; $p < 0.001$) and renal insufficiency (21%, 22%, 27%, and 32%, respectively; $p = 0.02$) and were more often unfit for narcosis and open repair (10%, 13%, 10%, and 23% respectively; $p < 0.0001$ and 21%, 28%, 25% and 40%, respectively; $p < 0.0001$).

Groups C and D suffered more often from preexisting pulmonary problems compared with groups A and B (in groups A-D 18%, 21%, 26%, and 32%, respectively; $p < 0.001$).

Operative Procedure and Hospital Stay

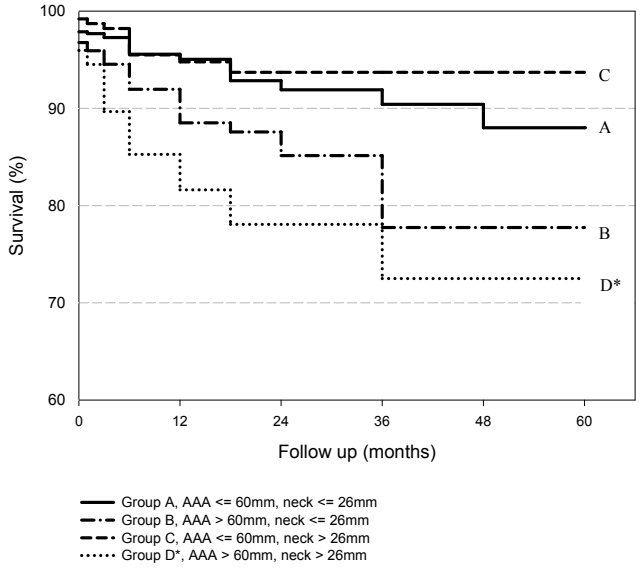
Mean time of all operations was 134 ± 61 minutes (range 30-660). The duration of the procedure was significantly longer in groups B and D compared with groups A and C ($p < 0.05$). Hospital stay was 6.7 ± 7.7 days (range 0-90) and was not significantly different among the four groups.

Postoperative Follow-up

Median follow-up was 17 months (range 0-48). Life table analysis of mortality rates (EVAR- and non-EVAR-related) is shown in Figure 1. The mortality rate of group D was significantly higher than the other groups ($p = 0.002$). Freedom from conversion was significantly lower in group D compared with other groups ($p = 0.037$, Fig. 2). Figure 3 reveals a significantly higher rupture rate in group D after 4 years of follow-up compared with the other groups ($p = 0.015$).

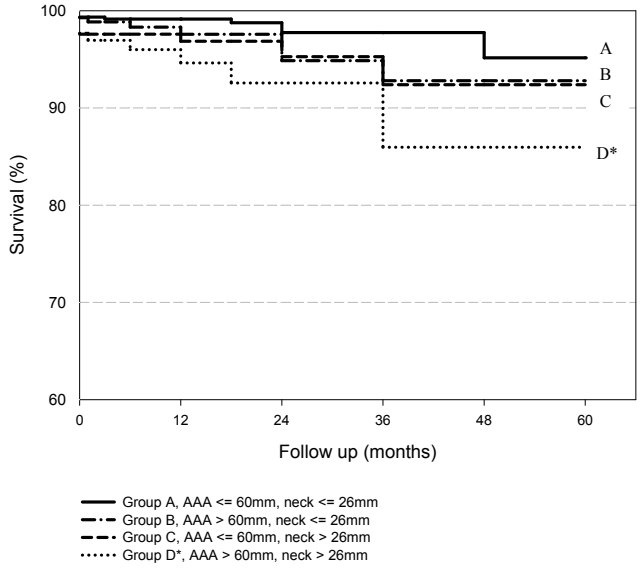
Proximal migration, one of the major EVAR-related complications, appeared significantly more frequently in groups B and D versus A and C ($p < 0.05$, Table III). Proximal type I endoleak occurred significantly more frequently in group D compared with the other three groups ($p = 0.036$, Table III). The incidence of endoleaks other than proximal type I was not significantly different among the four groups (A: 19%; B: 20%; C:19%; D: 18%, $p = 0.06$). Sixty-five percent of patients with an endoleak needed secondary intervention during the study period.

Figure 1. Life table analysis of mortality rates for groups A-D.



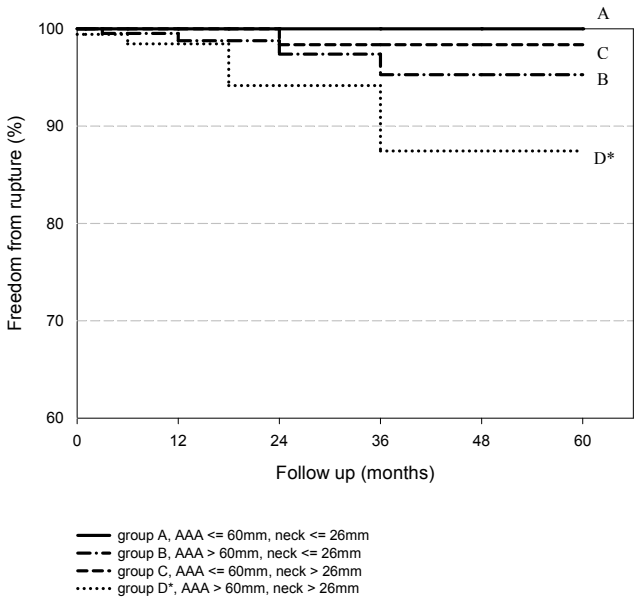
* D versus A-C, p = 0.002.

Figure 2. Life table analysis of conversion rates for groups A-D.



* D versus A-C, p = 0.037.

Figure 3. Life table analysis of rupture rates for groups A-D.



* D versus A-C, $p = 0.015$.

Table III. EVAR-related complications

	Proximal migration (%)	Type I endoleak (%)
Group A	2.5	2.8
Group B	5.7 *	5.0
Group C	1.5	5.6
Group D	5.3*	8.7**

* More proximal migration in B and D versus A and C, $p < 0.05$
** More type I endoleak in D compared with the other groups, $p < 0.05$

DISCUSSION

Conventional surgical repair of infrarenal aortic aneurysms is associated with substantial morbidity and mortality in patients with cardiopulmonary comorbidity.[10-12] Because of the observation that >35% of older patients at high operative risk with an AAA >55 mm will rupture when surgery is deferred, the less invasive EVAR technique is of great value in this patient population.[13] Potential advantages of endovascular repair include reduction in perioperative complications, hospital stay, and blood loss.[2] In two recently published randomized controlled trails, treatment by EVAR reduced 30-day mortality by 66% compared with open repair: 1.2% and 1.7% in the EVAR group versus 4.6% and 4.7% in the conventional repair group.[5,14]

In the early 1990s, large-diameter aneurysms and aneurysms with a short, severely angulated or wide infrarenal aortic neck were considered unsuitable for endovascular exclusion. With the new generation of devices, however, sealing and fixation are achievable in aneurysms that previously would have been rejected for endovascular repair because of their anatomy.

In this study, we focused on patients with a Talent stent graft because it is designed to treat infrarenal aneurysms with a proximal fixation zone that is relatively short, wide, or both. In many reports, transrenal graft fixation has been used successfully to attach endovascular grafts in patients with short infrarenal aortic necks.[15-18]

Over the last decade, numerous reports have been published about aneurysm morphology and its association with adverse outcome measures.[19,20] A few studies demonstrated a negative correlation between preoperative aneurysm size with midterm outcome after endovascular treatment.[21,22] Until now, however, no report has been published describing the influence of the proximal aortic neck diameter in combination with AAA diameter on clinical outcome.

Groups B and D were at significantly higher operative risk (ASA classification ≥3) compared with groups A and C. Patients in group D (combination of an AAA diameter >60 mm and a proximal aortic neck >26 mm) were at the highest operative risk, with a significantly higher ASA score, higher percentage of patients unfit for open repair, and more patients older than 70 years. These conditions could be partly responsible for the higher mortality rate of group D versus the other groups during follow-up.

Although cardiac, pulmonary, and renal problems are often correlated with smoking, diabetes mellitus, obesity, and hypertension, we could not prove any significance among the 4 groups. Operation time was higher in groups B and D and can be explained by the more complex aneurysm morphology with larger AAA size, which makes catheterization more difficult.

Multivariate analysis showed that overall conversion and rupture were independent risk factors for mortality ($p < 0.05$). Two of the main reasons for conversion and rupture post-EVAR are proximal migration and proximal type I endoleak, and both complications were significantly correlated with conversion and rupture ($p < 0.05$). Proximal migration was significantly higher in groups B and D compared with groups A and C. This was probably due to morphologic changes of the native aneurysm after EVAR, which makes the endograft prone for migration.

That group D had significantly more proximal type I endoleak than the other groups in combination with the high prevalence of type I endoleak in group C, strongly indicates that large, proximal aortic neck diameters are hard to seal sufficiently at the time of EVAR and during follow-up. Proximal neck length in group D tended to be smaller compared with the other groups, although this was not significant ($p = 0.055$). Moreover, the mean neck length of group D (23 mm) was larger than the favorable proximal neck inclusion criteria of 15 mm, as described by Fairman et al.[23] Therefore, the influence of neck length on clinical outcome could not be demonstrated.

In this study, we showed that patients with an AAA >60 mm in combination with a proximal aortic neck of >26 mm have worse clinical outcome after EVAR at a median follow-up of 17 months compared with AAAs of ≤60 mm, small aortic necks, or both. The higher mortality rate can be partly explained by adverse patient characteristics like age, ASA score, and unfitness for open repair.

However, the above-mentioned morphological criteria led also to significantly higher conversion and rupture rates after an initial successful EVAR. The latter was mainly due to proximal migration and proximal type I endoleak, which occur most frequent in patients with large AAAs and wide proximal aortic necks, respectively.

To overcome conversion or even rupture during follow-up in this group of high-risk patients, early detection of endoleak or migration is necessary. This group of patients might need an intensified surveillance schedule during follow-up after EVAR.

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Chapter 7

The association between iliac fixation and proximal stent-graft migration during EVAR follow-up: mid-term results of 154 Talent devices

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ABSTRACT

Objective. This study investigated the importance of iliac fixation to secure endograft fixation.

Materials and methods. Computed tomography (CT) scans of patients who underwent endovascular aneurysm repair with an endoprosthesis of great columnar strength (Talent™ stent graft) were analyzed retrospectively. Patients were enrolled consecutively between June 2000 and January 2007 and prospectively followed up with serial CT imaging. The superior mesenteric artery was used as a reference point to determine endograft migration (centerline endograft displacement of ≥10 mm). Proximal and distal fixation lengths were defined as the length of the endograft that was in full apposition to the aortic neck or common iliac arteries, respectively.

Results. Proximal endograft migration occurred in 32 of 154 patients (21%) at a follow-up duration of 32 ± 14 month; 13 migrations required treatment (8%). Migration was more frequent in patients treated with aorto-uniiliac devices than bifurcation devices ($P < 0.008$). The migrator and non-migrator groups had similar demographic and abdominal aortic aneurysm (AAA) characteristics. The migrator group had significantly shorter proximal (30 ± 12 mm vs. 41 ± 13 mm, $P < 0.001$) and distal endograft fixation lengths (31 ± 18 mm vs. 47 ± 15 mm, $P < 0.001$). By multivariate regression analysis, proximal and distal endograft fixations were significant predictors for endograft migration at follow-up ($P < 0.001$).

Conclusion. Iliac endograft fixation, along with proximal fixation, is a significant predictor for endograft migration.

INTRODUCTION

Migration is an issue for all types of endograft.[1;2] This unique phenomenon after endovascular aneurysm repair (EVAR) has been extensively described in many reports, with a prevalence ranging from less than 3% up to 28%, depending upon which stentgraft was used, the morphological abdominal aortic aneurysm (AAA) characteristics and the length of study follow-up time.[3-5] The proximal aortic neck length, diameter and angle seem to have great influence on the risk of proximal endograft migration after EVAR.[3;4;6-8] The other risk factors that have been studied are maximum aneurysm diameter, endograft configuration (aortic tubes vs. bifurcation grafts), the type of proximal endografts fixation (hooks and barbs), and the extent of endograft oversizing.[9-14]

Thus far, most attention has been paid to optimise proximal endograft fixation in reducing endograft migration. Currently, there is a wide range of different concepts of endograft design, with shock-absorbing non-columnar stent grafts vs. more rigid grafts at both ends of the spectrum. It might be assumed that the more rigid grafts experience high forces on the graft material in case of changes in AAA and iliac configuration during follow-up, especially in tortuous anatomies. Kinking or even breakdown of the stent grafts might occur then. The importance of distal endograft fixation has received little attention. Especially in endografts with a high columnar or axial strength, similar to the Talent device (Medtronic Vascular, Santa Rosa, CA, USA), one might assume that the extent of distal stability (i.e., iliac fixation) has an influence on the stent graft stability itself, much the same as a foundation beneath a building.

To date, two clinical reports have described the additional value of adequate distal endograft fixation in minimising post-EVAR migration in endografts with a high columnar strength.[15;16] Heikkinen and co-workers proved that iliac fixation, despite suboptimal proximal aortic neck anatomy, is important in preventing proximal migration in infrarenal aortic endografts that have longitudinal columnar support. In addition, closer placement of the distal end of the endograft to the iliac bifurcation seems to be protective against migration. These results were shown by Benharash and co-workers, who investigated transrenal endografts with longitudinal support.[16]

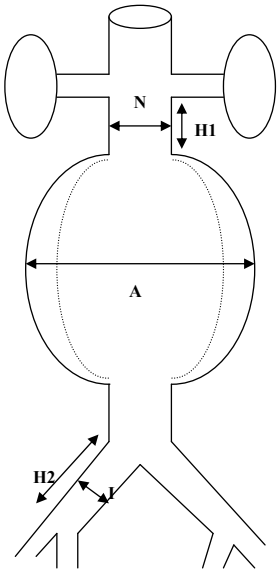
The follow-up time in both studies were relatively short.[15;16] As endograft migration is time dependent and might even occur many years after the index procedure, the aim of this study is to analyse the long-term association between iliac fixation and proximal endograft migration.[5]

MATERIALS AND METHODS

The patients analysed in this study were selected from a cohort of 290 patients with infrarenal abdominal aortic aneurysms (AAAs) who received primary treatment with a Talent bifurcated or aorto-uniiliac endograft. Patients were enrolled consecutively between June 2000 and January 2007 at the Stanford University Medical Center and the St. Antonius Hospital, Nieuwegein, and prospectively monitored with serial imaging and clinical follow-up. Although patients were prospectively monitored initially, the data for this study were collected in a retrospective manner. Patients were included if they had preoperative and early postprocedural (<3 months after the index procedure) digital computed tomography (CT) scans and a second postprocedural follow-up CT scan with a minimum interval of 1 year post-EVAR. The second postprocedural CT scan analysed was the latest available CT scan at follow-up, or the latest CT scan before a secondary procedure had been performed to resolve complications related to the endograft or the AAA.

Baseline patient characteristics, including cardiopulmonary co-morbidity, American Society of Anesthesiologists (ASA) score, and aneurysm morphology are summarized in Table I. Preoperative morphologic aneurysm measurements are depicted in Fig I. Maximum AAA diameter was measured on the preoperative CT scan. Aortic neck diameter was the maximum aneurysm neck diameter on the preoperative CT scan between the caudal portion of the lowest renal artery and the beginning of the AAA. Aortic neck length was the distance from the caudal portion of the lowest renal artery to the beginning of the AAA. When the aortic neck was not a straight tube, the distance between the lowest renal artery and the aneurysm neck portion that reached 85% of the proximal endograft diameter was used because endografts were 15% oversized compared with the aortic neck diameter.

Figure I. Preoperative morphologic measurements.



N AAA neck diameter

H1 AAA neck length

A Maximum AAA diameter

H2 Iliac artery length

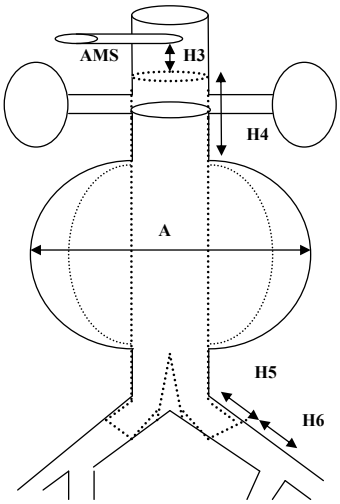
I Iliac artery diameter

The CT scans were performed with intravenous non-ionic contrast on a multi-detector-row CT scanner. The slice thickness was 1.5 mm, with delayed imaging to detect endoleaks.

Three-dimensional (3D) image analyses were performed on a TeraRecon (TeraRecon Inc., San Mateo, CA, USA) or 3Mensio workstation (3Mensio Medical Imaging, Bilthoven, The Netherlands) with maximum-intensity projection, center line and orthonormal views, thus allowing for measurement of angles and curvilinear distances. All reported diameters were measured perpendicular to the center line axis, and the reported lengths were curvilinear distances measured along the center line of vessels.

Postoperative endograft fixation characteristics are illustrated in Fig. II. The inferior border of the superior mesenteric artery (SMA) was used as a reference point to determine endograft migration when the early post-procedural and the latest follow-up CT scans were compared. The distance from the distal border of the SMA to the uncovered portion of the Talent endograft (e.g. the circumferential top of the bare stent) was used to measure endograft migration (distance H3 in Fig. II). Endograft migration was defined as a distal migration of 10 mm or more during follow-up. Patients were placed in the migrator group if migration was 10 mm or more and in the non-migrator group if migration was less than 10 mm during follow-up. Proximal and distal endograft fixation and the distance from the distal part of the endograft to the iliac bifurcation were measured on the postprocedural CT angiograms (CTAs).

Figure II. Postoperative endograft fixation measurements (first proximal 15 mm of endograft is uncovered, the so-called bare stent).



AMS Superior mesenteric artery

H3 Distance AMS to top of stent graft

H4 Proximal stent graft fixation

A AAA diameter

H5 Distal stent graft fixation

H6 Distance bottom of stent graft to hypogastric artery

Factors considered as potentially influencing proximal migration included infrarenal aortic angulation, graft oversizing and amount of thrombus of the proximal aortic neck.

Proximal and distal endograft fixation was defined as the part of the proximal and distal portion of the endograft that was in full apposition with the aortic neck or iliac arteries- that is for the proximal part of the Talent device, it is the uncovered bare stent (15 mm) plus the first proximal part of the covered stent graft. The endograft to iliac bifurcation distance was the distance from the distal circumferential portion of the stent graft to the cranial portion of the hypogastric artery origin. When the left and right distal endograft fixation or the distance to the hypogastric arteries differed, the mean distances were used.
The primary outcome measure of the study was proximal migration of the stent graft. For comparison, patients were placed in non-migrator or migrator groups, which have been previously defined.

Statistical Analysis

Continuous data are presented as the mean ± standard deviation (SD) and range. Discrete variables are given as counts and percentages. For comparison of values between groups, the Student's *t*- test was used for continuous variables and the chi-square test for binary variables. Multivariate logistic regression was done to test for predictors of migration. The five most significant parameters analysed between the two groups with the Student's *t*-test or the chi-square test were then analyzed in a multivariate model. The risk of migration for different proximal and iliac fixation lengths were calculated from the results of the multivariate model. On the basis of multivariate outcome, the risk of migration for six different proximal endograft fixation groups as a function of iliac fixation lengths was calculated. Statistical significance was considered at $P < 0.05$. All statistical analyses were performed with SPSS 15.0 software (SPSS Inc., Chicago, IL, USA).

RESULTS

Of the 290 patients treated by Talent EVAR, 136 patients (47%) did not meet the inclusion criteria and were not eligible for analyses. The excluded patients had no follow-up period that met the criteria of inclusion (n = 17) or missed one of the necessary CT scans (n = 52). Moreover, CT scans could not be collected in 22, CT scans were not digitally recorded in 32, and the inferior quality of the CT scans precluded 3D reconstructions in 13. Nine of 154 patients (6 %) received an aorto-monoiliac endograft, and the other 145 patients (94 %) received a bifurcated endograft. The mean follow-up period was 32 ± 14 months, (range, 12-58 months).

Migration. Among the 154 included patients, proximal migration (≤10 mm endograft displacement) of the endograft occurred in 32 (21%) during follow-up. The mean length of migration was 22 ± 16 mm (range, 10-71 mm) in the migrator groups vs. 2 ± 2 mm (range, 0-9 mm) in the non-migrator group ($P < 0.001$). Migration was significantly more frequent in patients with longer follow-up (mean follow-up was 28 ± 13 months in the non-migrator group and 36 ± 13 months in the migrator group, $P = 0.006$). In the migrator group, 25 of 32 patients (78%) were followed up for more than 2 years.

A subgroup analysis revealed a significant difference in occurrence of migration between the patients treated with a bifurcated endograft and patients treated with a uniiliac endograft ($P = 0.008$). Migration occurred during follow-up in five of nine patients (56%) treated by means of an aorto-uniiliac endograft vs. 19% in the bifurcation group.

Baseline patient and AAA characteristics. No significant differences in age, sex distribution, ASA score, co-morbidities, maximum AAA diameter, aneurysm neck diameter and neck angle were revealed between the migrator and non-migrator groups (Table I). However, aortic neck length was significantly shorter in the migrator group (17 ± 11 mm vs. 26 ± 15 mm, $P = 0.001$).

Endograft fixation characteristics. The proximal length of endograft fixation (uncovered bare stent plus first part of the covered stent graft) was significantly different among the migrator

and non-migrator groups (30 ± 12 vs. 41 ± 13 mm, $P < 0.001$). Distal endograft fixation was significantly longer in the non-migrator group compared with the migrator group (47 ± 15 mm vs. 31 ± 18 mm, P < 0.001) and did not change significantly during follow-up (non-migrator group 47 ± 15 mm vs. 45 ± 16 mm, migrator group 31 ± 18 mm vs. 28 ± 14 mm). In eight patients (5 %) the iliac fixation length was less than 20 mm and all of them had migration of the stent graft. Distance from the circumferentially distal end of the endograft to the hypogastric artery was not significantly different between the two groups (non-migrator group, 11 ± 10 mm vs. migrator group, 15 ± 15, $P = 0.08$). In 88 patients (57 %) one or both legs of the stent graft were not extended up to the hypogastric arteries.

Table I. Baseline patient characteristics and endograft fixation in migrator vs. non-migrator group

Clinical characteristics	***Migrator group***	***Non-migrator group***	***P-value***
	(n = 32)	*(n = 122)*	
Age (yr)	71	73	NS
Male sex (%)	93	92	NS
ASA ≥ III (%)	58	56	NS
Co-morbidities			
Cardiac (%)	29	34	NS
Pulmonary (%)	33	27	NS
Diabetes (%)	6	11	NS
Hypertension (%)	28	27	NS
Aneurysm characteristics			
Max AAA (mm)	62 ± 9	61 ± 13	NS
Aneurysm neck diameter (mm)	27 ± 4	27 ± 3	NS
Aneurysm neck length (mm)	17 ± 11	26 ± 15	0.001
Aneurysms neck angle (°)	30 ± 16	30 ± 17	NS
Iliac aneurysm (n)	0	12 †	NS
Endograft fixation			
Prox fixation length (mm)	30 ± 12	41 ± 13	<0.001
Dist fixation length (mm)	31 ± 18	47 ± 15	<0.001

† Hypogastric artery overstented in eight patients.

Predictors of migration. Multivariate logistic regression analysis to test for predictors of proximal migration revealed proximal length of endograft fixation, preoperative aortic neck length, and distal endograft fixation along with follow-up time as significant predictors (Table II).

Table II. Multivariate logistic regression analysis for migration 10 mm or more.

Factor	*Estimate*	*SE**	*Odds ratio*	*P value*
Aortic neck length (mm)	0.028	0.29	1.029	0.0324
Prox. Fixation length (mm)	–0.124	0.039	0.884	0.001
Dist. Fixation length (mm)	–0.086	0.023	0.918	0.000
FU period (months)	0.89	13.487	1.093	0.000
Monoiliac-bif endograft	1.087	1.278	2.966	0.258

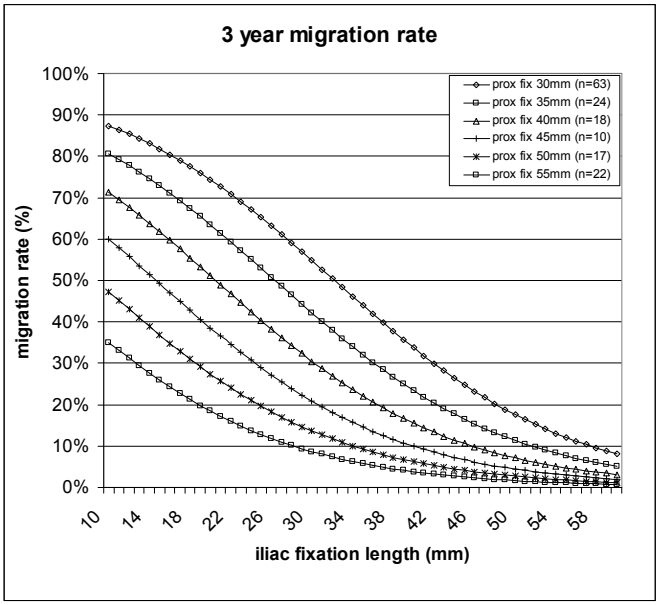
* Standard error.

Infrarenal aortic angulation, amount of graft oversizing, and amount of thrombus in the proximal aortic neck were no significant predictors, but differences between the groups were small. Multivariate logistic regression analysis revealed no predictive value for endograft configuration (uniiliac vs. bifurcated endografts). Based on the results of multivariate logistic regression analysis, the risks of migration for six different proximal fixation groups were calculated for iliac fixation distances (Fig. III). Group 1 had short proximal fixation lengths (30 mm) and group 6 had long proximal fixation lengths (55 mm). The iliac fixation length was especially important in the group with short proximal endograft fixation, as shown in Fig. III. Of the treated patients, 63 out of 154 (41 %) had a relatively short proximal fixation (that is <35 mm, uncovered bare stent plus covered proximal part of the stent graft) and 39 out of 154 patients (25 %) had a relatively long proximal fixation (≥50 mm, again uncovered bare stent plus covered proximal part of the stent graft). When iliac fixation was relatively short, (mean iliac fixation <30 mm) migration rates of almost 60% at 3 years of follow-up were determined, indicating the importance of good iliac fixation in selected patients with short proximal fixation length.

During a mean clinical follow-up time of 41 ± 11 months there has been no AAA ruptures in the migrator group. In the migrator group 13 needed surgical revision; nine patients were treated with aorto-uniiliac endografts and femoro-femoral crossover bypass, one patient was treated

with aortic neck banding and three patients needed endograft explantation. Nineteen patients are under regular observation as proximal fixation is still >15 mm and no endoleaks (not even type II endoleaks) occur. In the non-migrator group only two patients have been diagnosed with complex type II endoleaks with growth of the native aneurysm; both patients have been successfully treated with intra-arterial embolisation.

Figure III. Three-year migration rate.



DISCUSSION

In the last decade of EVAR, numerous articles have been published concerning the importance of optimal proximal endograft fixation, but only a few studied the importance of distal iliac endograft fixation in preventing endoprosthesis migration.[15;16] Only the reports of Heikkinen and Benharash et al. showed a highly important role for iliac fixation in preventing endograft migration; however, both had short-term follow-up.[15;16]

The proposed explanation for this phenomenon could be that the iliac limbs are the foundation of the endograft. The consequences of repeated downwards pulsation of blood flow in the face of weakness of resistance forces can result in proximal migration of the endograft. The iliac limbs are the pilings or support structure of the endograft, which is less susceptible to migration when distal iliac fixation is good. We think that this phenomenon will be especially important in endografts with a high columnar strength, similar to the studied Talent endograft, as the continuous blood flow is transmitted throughout the whole stent graft system. We believe it is important for new-generation stent grafts to have a more flexible configuration and thus a less rigid device. The decrease of columnar strength has to be compensated, for instance, by more secure proximal fixation such as anchoring pins or barbs, or maybe additional endoluminal stapling of the proximal part of the device.

The current study substantiated the importance of sufficient iliac fixation and showed that iliac fixation is of major importance in patients in whom the proximal fixation site is not optimal. Although not as important as proximal fixation, iliac fixation is of major importance in patients with short proximal aortic necks. The shorter the proximal fixation, the longer the iliac fixation has to be to prevent future endograft migration. Because the renal arteries limit proximal endograft fixation length in endografts without fenestrations, the only way to achieve more fixation is to extend the endograft at the bottom of the common iliac arteries all the way to the hypogastric arteries. In Fig. III we have shown that even when the iliac fixation already exceeds 3 cm, it is still more beneficial to extending the iliac limbs further.

From these findings, we can say that the iliac fixation is a determinant for proximal stent graft stability. As the proximal fixation zone is also a major determinant of migration, we are not able to determine an ideal iliac fixation length. As recommended by the manufacturer, the minimum iliac fixation length is 20 mm. In the current study eight patients (5 %) had an iliac fixation of less that 20 mm. All of them had migration of the stent graft. Although this finding suggest that we have to extend the limbs of the stent graft at least 20 mm into the iliac arteries, another 24 patients (16%) had migration of the stent graft although iliac fixation was more than 20 mm.

In cases where the durability of the proximal attachment zone is in doubt, we think the best way to achieve the best fixation is to extend the iliac limbs all the way to the hypogastric arteries.

In the current study, five of nine aorto-monoiliac Talent endografts showed evidence of migration. Although the number of patients treated by means of a monoiliac endograft was not large enough to give definite conclusions about the durability of this endograft configuration, this trend toward higher migration rates in this selected patient group deserves attention. Studies have described good results using monoiliac endografts, but we think larger studies are needed that focus on this selected patient group to definitively prove the durability of this configuration.[17;18]

Contrary to our expectations, we did not find a significant role for aortic neck diameter and angle when the two studied groups were compared. Numerous reports have described an association between large aortic neck angle and diameter and risk of migration.[3;7;8] A reasonable explanation for this is that the mean neck length of the studied patients was relatively long and the neck angles were small compared with other studies.

A limitation of this study is the fact that we did not determine the influence of proximal aortic neck elongation as a confounding factor for migration. Even in open AAA repair, suturing a prosthetic graft in the infrarenal aorta, the appearance of caudal graft displacement can occur due to continuing neck elongation.[19] Litwinski et al. showed that postoperative elongation of the infrarenal aortic neck after EVAR may create the radiographic perception of migration without necessarily causing a loss of the proximal stent graft fixation.[20]
A remarkable finding in this study was that more than 10 patients were found to have proximal migration that was not described in radiology CTA reports. All of these measurements were done on axial CTA views without 3D reconstructions with central lumen line measurements. Secure measurements regarding migration and distance measurements can only be performed accurately when the aorta is considered as a straight tube and thus with perpendicular views. Especially in cases where the abdominal aorta is tortuous or there is much angulation, precise morphologic measurements can only be done accurately with 3D central lumen line reconstructions.

In the current study the proximal migration rate of 21% at a mean follow-up of 32 months is high compared to other studies .[3-5] One of the explanations could be that we measured all the variables on the CT scans, including migration rate, with 3D central lumen line reconstructions at the 3D workstation. Most of the referred studies, done in the past decade, did not use this type of exact measurements. The 3D reconstructions allow most accurate measurements, especially in patients in which the aortic neck is very tortuous. Secondly, >55% of the included patients were referred from other hospitals due to serious cardiopulmonary co-morbidity and hostile abdomens. Of the patients described in this study, 41% had a proximal fixation of less than 35 mm including the first 15 mm of uncovered part of the endograft and the mean aneurysm neck of the migrator group was only 17 mm. As has been known from other reports, the length of the aneurysm neck is a predictor for migration.[6;8]

The question that arises from this study is what should be the iliac fixation length in order to give the most optimal distal fixation. We showed that even in patients with a long proximal fixation, more distal iliac fixation offers some benefit. Patients with short aortic necks do have the most benefit. Furthermore, it is clear from this study that short proximal and distal fixation length is a major reason for graft migration during follow-up. Again, violating the instructions for use concerning minimal proximal and distal fixation length has been associated with worse outcome in the long run.

CONCLUSION

Our results confirm that the iliac fixation is a highly significant predictor of migration during follow-up after a successful EVAR procedure with an endoprosthesis with great columnar strength, similar to the studied Talent stent grafts. The optimum iliac fixation length cannot be determined from this retrospective study and is dependent on the proximal endograft fixation length. Although patients with short proximal endograft fixation benefit the most from a longer iliac fixation length, we showed that even when proximal fixation is long (≥30 mm), extending the iliac limbs even further will be beneficial in preventing migration. We therefore think that the iliac limbs have to be extended up to the hypogastric arteries, irrespective of achieved proximal fixation length.

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Chapter 8

Technical options for the ectatic, aneurysmal or short common iliac artery with EVAR

Book Chapter

Christopher K. Zarins, MD and Evert J. Waasdorp, MD

Zarins CK, Waasdorp EJ. Endovascular treatment of complicated aortoiliac arteries. 2008
Chapter 31, Page 351-355

INTRODUCTION

Successful endovascular aneurysm repair requires secure proximal and distal endograft fixation in order to exclude the aneurysm from the circulation and prevent aneurysm rupture. The importance of infrarenal aortic neck anatomy and proximal endograft fixation is well recognized. A variety of technical options are available to deal with variations in aortic neck anatomy, including infrarenal and suprarenal fixation mechanisms, with or without penetrating hooks and barbs and a good selection of device diameters to allow precise oversizing of the endograft. However, relatively little attention has been paid to issues of iliac fixation. Endograft iliac limb diameters are fixed in relationship to proximal endograft diameter and device size selection is based on the proximal neck diameter. This may result in suboptimal sizing for the iliac artery. While iliac artery diameter and stenoses are well recognized factors in aortic access and successful device deployment, the importance of iliac fixation in preventing long term endograft migration has only recently been recognized.[1] The purpose of this chapter is to highlight the importance of iliac fixation on the long-term durability of EVAR and to review the technical options for dealing with unfavorable iliac anatomy, including ectatic, aneurysmal and short iliac arteries.

Importance of iliac fixation

The importance of iliac fixation in preventing stent graft migration was first reported by Heikkinen et al. in 2006[1], almost a decade after the first reports of endograft migration appeared.[2] While a great deal of attention has been focused on issues related to proximal endograft fixation to the aortic neck, little attention has been paid to distal iliac fixation.[2-5] Heikkinen et al. showed that while proximal aortic fixation was an important factor in endograft migration, no migration was observed in patients who had good iliac fixation.[1] Even in the face of suboptimal aortic fixation, no migration occurred unless there was also bad iliac fixation. Quantitative assessment of proximal and iliac fixation lengths using 3-dimensional CT image analysis revealed shorter proximal and distal fixation lengths in patients who experienced endograft migration. Multivariate analysis revealed that while both proximal and distal fixation lengths were independent predictors of migration, poor iliac fixation was the single most important predictor of endograft migration over a 2 year period.[1]

Subsequent studies have shown that iliac fixation is also important in preventing migration of endografts with suprarenal fixation. Benharash et al. found that migration could occur with both infrarenal and suprarenal endografts, and that migration in both groups occurred only in patients with poor iliac fixation.[6] Despite the inclusion of a large number of patients with short, angulated and large diameter necks, no patient with good iliac fixation experienced endograft migration even if proximal fixation length was suboptimal. It should be noted that the infrarenal and suprarenal devices used in this study had longitudinal columnar support and no penetrating hooks or barbs. Also, only common iliac fixation was studied, with exclusion of patients with extension of the iliac limb to the external iliac artery.[6] Whether iliac fixation plays an important role in devices with penetrating hook fixation mechanisms remains to be determined.

Distal endograft fixation to the common iliac artery can be defined in terms of iliac endograft contact length and proximity of the distal end of the device to the hypogastric artery. Both factors were shown to be important in preventing migration.[1;6] Thus the technical challenge in maximizing iliac fixation is to maximize the contact length of the endograft to the common iliac artery and to extend the endograft as close to the orifice of the internal iliac artery as possible, without occluding the vessel. If this is not possible, the endograft should be extended to the external iliac artery to achieve distal fixation.

Pre and post operative imaging

Although iliac artery diameter is carefully evaluated on pre-operative imaging studies, iliac length is less often considered in selecting patients for endovascular repair. This may in part be due to the fact that while axial CT images are usually adequate to evaluate the infrarenal aortic neck and iliac diameters, curvature and tortuosity of the iliac arteries makes iliac length measurement cumbersome and at times unreliable. Accurate measurement of iliac artery length usually requires 3-dimensional reconstructions with centerline length measurements. It is important to note that iliac artery length measurements may change during the implant procedure due to the insertion of stiff guidewires and sheaths. Post-implantation determination of iliac fixation length is more complex and thus is rarely assessed in current clinical practice. Thus, the easiest and most

reliable measure of adequacy of iliac fixation is proximity of the distal end of the stent graft to the hypogastric artery and this measure should be incorporated into routine post-implantation follow-up image assessments.

Technical options to achieve optimal iliac fixation

Optimal iliac fixation is achieved if there is full endograft apposition to the common iliac artery with the distal end of the stent graft within 1 cm of the hypogastric artery orifice (Figure 1). This may present a challenge in cases where the common iliac artery is ectatic, angulated, aneurysmal or short in length. Technical options to deal with these conditions include, the use of a variety of iliac endograft extenders including straight limb extenders, flared limb extenders, aortic extender cuffs and coil embolization of the internal iliac artery and extension of the endograft to the external iliac artery. Treatment options also include revascularization of the internal iliac with a bypass or endograft to preserve pelvic blood flow and aortouniiliac endografting with cross-femoral bypass. Since introduction of stiff guidewires and sheaths and deployment of the primary endograft modules may alter iliac length and angulation, intra-operative angiography is essential to precisely define the distal endograft fixation points. Angulation of the C-arm image intensifier is usually needed to clearly define the iliac bifurcation (right anterior oblique for the left iliac bifurcation and left anterior oblique for the right iliac bifurcation). This allows precise placement of extender modules to within 1 cm of the internal iliac artery for maximum fixation length.

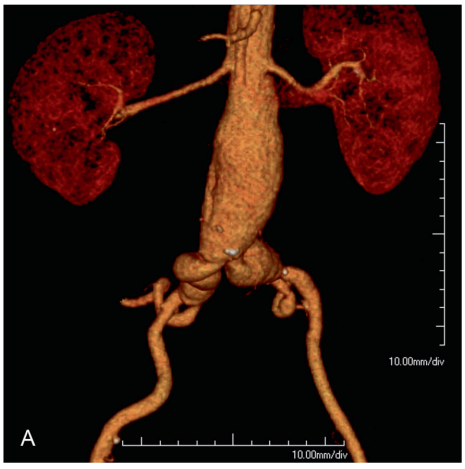
Ectatic iliac arteries

Non-aneurysmal common iliac arteries which are larger in diameter than normal are considered to be ectatic. This does not exclude endovascular aneurysm repair and good results have been reported in patients with ectatic iliac arteries.[7;8]

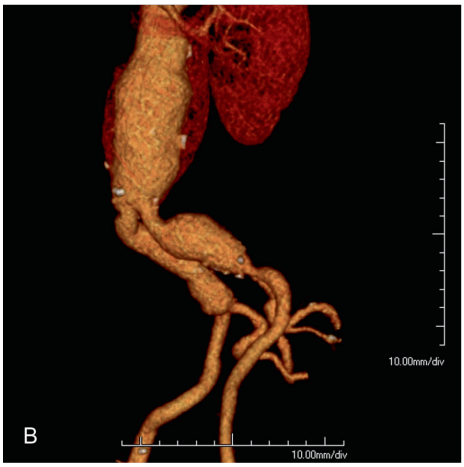
The upper limit of "normal" for most patients is an iliac diameter of approximately 14 mm. Iliac arteries with a diameter in the 16-20 mm range are generally considered to be ectatic. However, the common iliac artery often is non-uniform in diameter, with segments of stenosis and segments of ectasia (Figure 1). Secure iliac fixation usually requires approximately 10% oversizing of the endograft. In cases of iliac ectasia, the iliac limb is often undersized because the

endograft is selected based on the proximal aortic neck diameter and the iliac limb diameter is fixed. In such cases, a shorter primary bifurcation module may be selected to allow upsizing the iliac limb in the iliac fixation zone using larger diameter iliac extender, a flared iliac extender or an aortic extender cuff. The contralateral iliac limb can be upsized, or a flared iliac limb can be used to achieve appropriate oversizing in the ectatic iliac. The narrowed or stenotic proximal iliac segments can be dilated after endograft placement. Care must be exercised in dilating the distal end of the endograft to avoid rupture of the iliac artery.

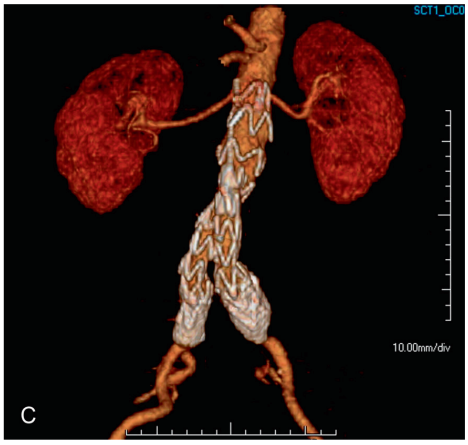
Figure 1. 3-dimensional surface reconstruction of CT angiogram.



A: Frontal projection gives the appearance of short, ectatic and aneurysmal iliac arteries bilaterally.



B: Lateral projection demonstrates sufficient length of iliac artery with bilateral common iliac aneurysms.

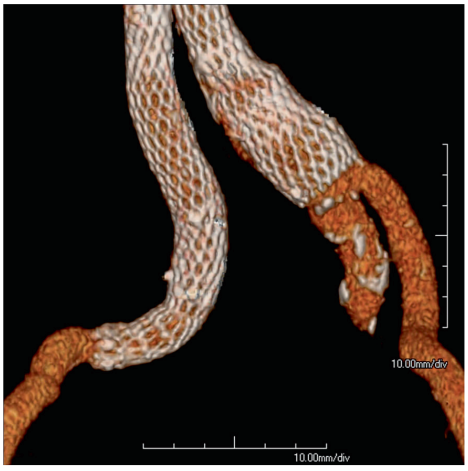


C: Endovascular aneurysm repair with placement of bilateral aortic extender modules in order to completely cover the aneurysmal iliac artery. This preserves flow to both internal iliac arteries. On the left, the iliac artery returns to a normal caliber just above the bifurcation. Magnification and oblique imaging of each iliac bifurcation was used to precisely position the distal end of the aortic extender within 5 mm of the internal iliac artery.

Aneurysmal iliac arteries

Common iliac arteries larger than 20 mm are considered to be aneurysmal. Aneurysmal common iliac arteries 20-26 mm in diameter can often be treated in the same manner as ectatic iliac arteries, using appropriately oversized endograft modules. Large diameter and flared iliac limbs ranging from 20 to 28 mm are available as well as aortic extender modules with diameters up to 28 mm. These can be used to line the inside of the iliac aneurysm and thus prevent the risk of rupture (Figure 2). These endograft modules should be extended as close to the orifice of the internal iliac artery as possible. In cases where common iliac artery diameter exceeds 28-30 mm, or if the common iliac aneurysm extends to involve the orifice of the internal iliac artery, the internal iliac artery can be coil embolized and the endograft limb extended to the external iliac artery (Figure 2). [9;10] However, occlusion of the internal iliac artery can lead to hip and buttock claudication and significant disability.[11;12] Therefore, we prefer to maintain flow in the internal iliac artery with a hypogastric artery bypass whenever possible.[13]

Figure 2. Patient with bilateral iliac artery aneurysms. The aneurysmal left iliac artery was covered with a flared iliac limb which was extended to the level of the hypogastric artery to provide maximum fixation length. This preserved flow to the internal iliac artery. On the right side, coils were placed in the internal iliac artery and the iliac limb was extended to the external iliac artery.



Short iliac arteries

Short common iliac arteries, particularly when combined with an aortic aneurysm that includes the aortic bifurcation, thus widening the space between the iliac artery orifices, may provide insufficient distal fixation length for long-term endograft stability. In cases where an iliac fixation length of 2.5 cm cannot be achieved due to short iliac arteries, extension of the endograft to the external iliac artery should be considered. Alternatively, an aortouniiliac endograft configuration can be used with occlusion of the short iliac artery with a blocker and cross-over femoral artery bypass. In cases of widely angulated iliac arteries, the two limbs of the endograft can be crossed to enhance distal iliac fixation (Figure 1C). Crossing the iliac limbs enhances longitudinal columnar support and minimizes kinking of the iliac limbs.

CONCLUSION

Secure distal iliac fixation, along with good proximal fixation, is needed for long-term durability of endovascular aneurysm repair. Endografts should be placed just below the renal arteries and extended to cover the entire length of the common iliac artery in order to maximize fixation length. Flared iliac extenders or aortic extenders should be used in cases of ectatic and aneurysmal iliac arteries to maximize iliac fixation.

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Chapter 9

Sideways displacement of the endograft within the aneurysm sac is associated with late adverse events after endovascular aneurysm repair

Submitted

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ABSTRACT

Objective: Previous studies have shown the importance of proximal and distal endograft fixation. There is little information on the middle, unsupported section of endograft within the aneurysm sac. We quantified sideways movement of the endograft within the aneurysm sac and correlated it to late adverse events.

Methods: Patients who underwent endovascular abdominal aortic aneurysm (AAA) repair with a suprarenal or infrarenal endograft between January 1997 and December 2007 were analyzed for sideways endograft movement. Patients were included if they had a digital preoperative computed tomography angiogram (CTA), a postoperative CTA within 3 months after the index procedure, and at least one follow-up CTA thereafter with a minimal time interval of 6 months. The endograft position within the aneurysm sac was quantitated on cross-sectional images using a fixed vertebral body reference point. Patients with change in endograft position ≥5 mm were placed in the sideways displacement (SD) group and compared with patients with no displacement (ND; <5 mm change in position). The relationship between sideways endograft movement and EVAR-related complications were noted for AAA rupture, AAA-related death, conversion, secondary procedures, AAA growth (≥5 mm), proximal migration (≥10 mm), and new onset of type I or III endoleaks.

Results: The study included 144 patients (mean age, 76 ± 7.6 years). Mean follow-up time was 43 ± 27 months. Fifty patients (35%) had sideways endograft movement ≥5 mm during follow-up. Baseline AAA diameter was larger (SD 60 ± 9 mm vs ND 57 ± 9 mm, $P < .05$) and proximal and iliac endograft fixation lengths were shorter (SD 18 ± 8 mm vs ND 24 ± 11 mm, $P < .05$; and SD 35 ± 14 vs ND 42 ± 16 mm, $P < .05$) in patients with sideways endograft displacement. There was no significant difference between the groups in AAA rupture and AAA-related death (one fatal AAA rupture, ND group). SD patients had a higher surgical conversion rate (10% vs 0%, $P = .002$), more secondary procedures (44% vs 6%, $P < .001$), more AAA sac enlargement (42% vs 10%, $P < .001$), more endograft migration (66% vs 5%, $P < .001$), and more type I or III endoleaks (36% vs 3%, $P < .001$).

Conclusion: Positional stability of the endograft within the aneurysm sac is critical for the long-term success of EVAR. Sideways movement of the endograft within the aneurysm sac is associated with an increased risk of late adverse events.

INTRODUCTION

The goal of endovascular treatment of an aneurysm of the abdominal aorta (AAA) is to exclude the aneurysm from the bloodstream and thereby eliminate the risk of rupture.
Despite improvements in endograft design, implantation technique, patient selection, and early results, there are persistent concerns regarding the long-term durability of endovascular AAA repair (EVAR).[1-4] Endograft migration leading to new-onset endoleaks is of particular concern and may result in AAA rupture, the need for secondary procedures, or surgical conversion during follow-up. Until recently, most studies of endograft stability after EVAR focused on the proximal anchoring site of the endograft.[5,6] These studies have shown that secure proximal endograft fixation is needed to ensure long-term durability of the endograft.

Unfortunately, endograft instability, as evidenced by proximal endograft migration, is sometimes difficult to see on the sequential follow-up computed tomography (CT) scans due to tortuosity of the aneurysm neck and inadequate timing of the contrast infusion. Although sophisticated 3-dimensional (3D) CT image reconstruction can overcome these difficulties, 3D imaging software is often not available, and these measurements are time-consuming and therefore are not very useful in clinical practice.

We recently described that in addition to proximal endograft fixation, distal (eg, iliac) endograft fixation plays a significant role in the long-term durability and clinical success of EVAR.[7;8] CT imaging with 3D reconstructions is even more important in evaluating distal endograft fixation because iliac fixation lengths can only accurately be measured using 3D reconstructions with central lumen line measurements.

The behavior of the midportion of the endograft within in the aneurysm sac has received little attention until recently, when Rafii et al[9] reported that lateral or sideways movement of the endograft was an indicator of endograft instability. Their study showed that 5-mm lateral movement of the endograft within the aneurysm sac at 1 year was associated with an increased risk of late adverse events. Endograft movement could be detected on simple cross-sectional CT images without the need for 3D imaging and without the need of contrast injection. This initial

study described a small group of patients with one endograft and relatively short follow-up. The purpose of our investigation was to determine whether sideways movement of the endograft within the aneurysm sac is related to endograft migration and late clinical adverse events in a large patient population with long-term follow-up.

PATIENTS AND METHODS

Patients with asymptomatic infrarenal AAA who underwent elective EVAR at Stanford University Medical Center between January 1997 and December 2007 and who were entered into a prospective, Institutional Review Board (IRB)-approved, image-based follow-up protocol were reviewed. Patients were treated with a suprarenal or infrarenal endograft (Talent or AneuRx stent graft system; Medtronic Vascular, Santa Rosa, Calif). Patients were included in this study if the following digital contrast CT scans were available: preoperative CTA, a postoperative CTA within 3 months of the index procedure, and at least one follow-up CTA with a minimum interval of 6 months from the first postoperative CT scan. Patients were excluded from the study if digital images were unavailable or of insufficient quality for 3D image processing and quantitation measurements. Follow-up CT scans performed at other institutions were included, if available, and uploaded into our workstation for analysis. The follow-up CT scan used to quantitate sideways displacement was one of the last digital CT scans available before a secondary procedure was done to resolve endograft- or AAA-related complications. All clinical records and follow-up information of selected patients were retrospectively reviewed.

Secondary procedures with an influence on endograft configuration were classified as any combination of proximal, distal, or interposition endograft extenders or implantation of a new bifurcated or aortouniiliac endograft within the former endoprosthesis. Partial or total explantation of the endoprosthesis and aortic neck plication were classified as conversion procedures and were noted separately in addition to secondary endovascular procedures. Patients who had an indication for a secondary procedure and who were advised to undergo a secondary procedure, but refused, were counted as having had a secondary procedure for statistical analysis.

Baseline patient characteristics and comorbidities, American Society of Anesthesiologists (ASA) score, and aneurysm morphology were documented. Maximal AAA diameter was measured on the preoperative and direct postprocedural CT scan. When the postprocedural AAA diameter was increased compared with the preoperative size, the largest AAA diameter was taken as the baseline measurement. Aortic neck diameter was measured on the preoperative CT scan halfway between the caudal portion of the lowermost renal artery and the beginning of the AAA. Aortic neck length was the distance from the caudal portion of the lowermost renal artery to the beginning of the AAA.

CT scans included images with and without intravenous nonionic contrast that were performed on a multidetector-row CT scanner with a slice thickness of 1.5 mm. Delayed imaging was used to detect endoleaks.

The 3D image analyses were performed on a workstation (TeraRecon Inc, San Mateo, Calif) with maximum-intensity projection, centerline, and orthonormal views, thus allowing for measurement of curvilinear distances. All reported diameters were measured perpendicular to the centerline axis, and the reported lengths were curvilinear distances measured along the centerline of vessels.

The inferior border of the superior mesenteric artery was used as a reference point in determining endograft migration when the postprocedural and the follow-up CT scans were compared. The distance from the superior mesenteric artery to the beginning of the first 360° appearance of the endograft was used to measure endograft migration. Endograft migration was defined as a distal migration of ≥10 mm during follow-up and any migration that needed a secondary intervention.

Proximal and distal endograft fixation and the distance from the distal part of the endograft to the iliac bifurcation were measured on the postprocedure CTA. Proximal and distal endograft fixation was defined as the part of the proximal (covered and uncovered portion) and distal portion of the endograft that was in full 360° apposition with the aortic neck or iliac arteries,

respectively. The endograft-iliac bifurcation distance was the distance from the distal portion of the endograft to the origin of the hypogastric artery. In patients treated by bifurcation devices, mean distances were taken. In patients treated by means of aortouniiliac endografts, the total length of the monoiliac limb was taken.

Sideways endograft displacement was measured on the axial CT images on the same TeraRecon workstation, which also allows for simple 2D axial measurements. The absolute distance from a fixed point on one of the lumbar vertebra to the endograft was taken at the point of the maximal AAA diameter. The first postoperative CT scan was used as the baseline vertebra-endograft measurement, and the follow-up CT scans were measured at the same axial fixed point on the same lumbar vertebra (Fig 1). The distance from the anterior middle portion of the vertebral spine and the point between both endograft legs was measured on the postoperative and follow-up CT scans and analyzed for differences in path lengths (Fig 1).

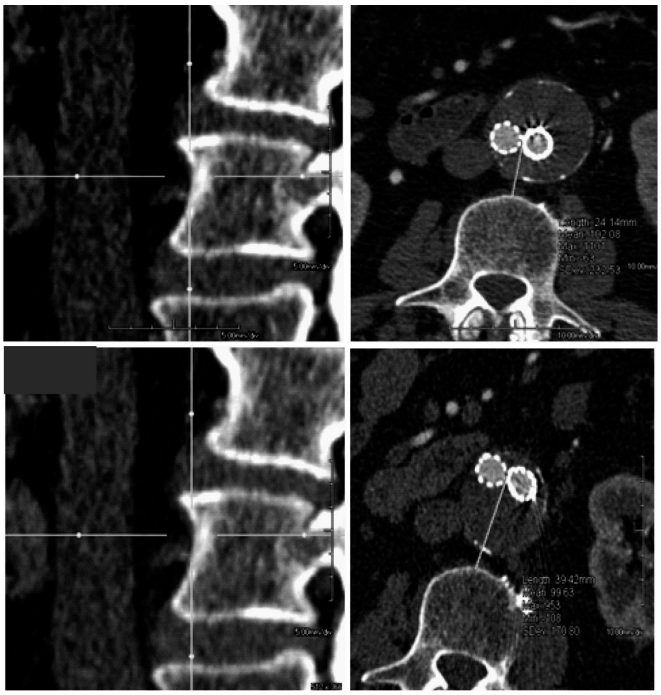

Figure 1. 2D sideways displacement of the endograft during follow-up (fixed axial vertebra level)

The measurements were done by an investigator who was blinded for the clinical outcome. To analyze interobserver variability for sideways endograft movement, 25 randomly selected patients were measured by a second investigator in a blinded fashion. To assess intraobserver variability, 25 randomly selected patients were measured by the primary investigator twice in a randomly selected sequence. The interval between the first and second measurements was at least 2 weeks.

For comparison of groups, patients were divided in a nonsideways displacement (ND) group and a sideways displacement (SD) group, depending on the distance of sideways endograft movement. Patients were placed in the SD group if there was sideways endograft displacement of ≥5 mm on the follow-up CT scan compared with the first postoperative CT scan. Apart from the previously mentioned latest digital available CTA scan, we tried to collect earlier follow-up CTA scans after EVAR for the SD group.

To analyze the association of the sideways endograft displacement with clinical and radiologic outcomes, the following outcomes were noted: AAA rupture, surgical conversion, secondary procedures as mentioned earlier in this section, and AAA-related death. The radiologic parameters that were noted were AAA growth, defined as a growth of ≥5 mm during follow-up, and new onset of type I or III endoleaks, or both. Stable AAA diameter was defined as an AAA diameter with <5 mm decrease and <5 mm increase. AAA shrinkage was defined as a decrease in AAA diameter of ≥5 mm during follow-up.

Because sideways endograft movement will be related to proximal endograft migration (≥10 mm compared with the postoperative CT scan) in these investigated stiff endografts, proximal migration was investigated but not defined as a study end point. The correlation between sideways endograft movement and proximal migration was investigated.

Statistical Analysis

Continuous data are presented as the mean ± standard deviation and range. Discrete variables are given as counts and percentages. For comparison of values between groups, *t* tests were used for continuous variables and the χ^2 test for binary variables. Differences between the ND and SD groups in clinical and radiologic end points were analyzed using χ^2 tests and the Kaplan-Meier method. The interobserver and intraobserver variability for sideways endograft movement were analyzed by calculating the Pearson correlation coefficient of the different measurements. Significance was assumed at $P < .05$. All statistical analyses were performed with SPSS 15.0 software (SPSS Inc, Chicago, Ill).

RESULTS

Baseline measures

A total of 144 patients met the inclusion criteria and were included in the study. Patient demographics and aneurysm morphology are summarized in Table I. Age at the time of operation was 76.2 ± 7.6 years (range, 56-94 years). All patients had an asymptomatic infrarenal aortic aneurysm. Maximal diameter of the AAA was 58.5 ± 9.7 mm (range, 36-105 mm), aortic neck diameter was 26.7 ± 4.0 mm (range, 15-34 mm), and aortic neck length was 22.5 ± 13.0 mm (range, 5-64 mm).

Postoperative endograft fixation measurements are summarized in Table I. Proximal endograft fixation length was 22.2 ± 10.3 mm (range, 2-51 mm), and distal iliac fixation length was 39.5 ± 15.6 mm (range, 2-94 mm). Mean clinical follow-up was 43.3 ± 27.2 months (range, 6-108 months).

Sideways displacement

Sideways displacement of the endograft ≥5 mm on the latest available CTA scan was seen in 50 patients (35%), and these patients were included in the SD group. Sideways endograft displacement for 94 patients (65%) was <5 mm during follow-up and they were included in the ND group.

Table I. Patient demographics, preoperative aneurysm morphology, and post-implantation measurements

Variable	*Total group (n=144)*	*SD group ≥5 mm (n = 50)*	*ND group <5 mm (n = 94)*	P
Demographics				
Age (year)	76.2 ± 7.6	74.9 ± 7.7	77.2 ± 7.3	.15
Women, No. (%)	13 (9.0)	5 (10)	8 (8.5)	.18
Cardiac comorbidity, No. (%)	85 (59)	31 (62)	54 (57)	.50
Respiratory comorbidity, No. (%)	55 (38)	20 (40)	35 (37)	.23
Follow-up time (months)	43.3 ± 27.2	53.0 ± 30.1	38.3 ± 24.3	.002
ASA score >2, No. (%)	68 (47.2)	23 (46)	45 (47.9)	.16
Preimplantation				
AAA size (mm)	58.5 ± 9.7	60.2 ± 9.0	57.0 ± 8.7	.04
AAA-neck length (mm)	22.5 ± 13.0	22.7 ± 13.6	22.4 ± 12.8	.90
AAA-neck diameter (mm)	26.7 ± 4.0	25.9 ± 3.9	27.0 ± 4.1	.10
Postimplantation				
Proximal fixation length (mm)	22.2 ± 10.3	17.9 ± 8.0	24.6 ± 10.7	<.001
Iliac fixation length (mm)	39.5 ± 15.6	34.8 ± 14.5	42.2 ± 15.7	.008
Distance to hypogastric art (mm)	13.0 ± 12.0	15.4 ± 11.4	11.7 ± 12.2	.09

Baseline patient characteristics were not significantly different between the ND and SD groups (Table I). However, there were significant differences between the groups in baseline AAA morphology, postoperative endograft fixations lengths, and length of the follow-up time. Patients in the SD group had larger baseline AAA diameter (60.2 ± 9.0 vs 57.0 ± 8.7 mm, $P = .04$). There were no differences between the SD and ND groups in aortic neck length (22.7 ± 13.6 vs 22.4 ± 12.8 mm) or diameter (25.9 ± 3.9 vs 27.0 ± 4.1 mm).

The SD group had significantly shorter postoperative proximal (17.9 ± 8.0 vs 24.6 ± 10.7 mm, $P < .001$) and distal endograft fixation lengths (34.8 ± 14.5 vs 42.2 ± 15.7 mm, $P = .008$). The distance from the end of the endograft to the origin of the hypogastric arteries was not different between the two groups (15.4 ± 11.4 vs 11.7 ± 12.2 mm).

We successfully collected earlier follow-up CTA scans in 33 of 50 patients in the SD group, and in 25, sideways endograft movement ≥5 mm had already been documented on an earlier CTA scan after EVAR. However, eight patients in the SD group had <5 mm sideways movement of the endograft earlier on in the follow-up after EVAR.

Clinical end points

The clinical end points for both groups are summarized in Table II. AAA rupture was rare and occurred in only one patient. This patient was in the ND group, had a persisting type I endoleak with aneurysm enlargement, and refused recommended secondary treatment. This was the only AAA-related death in this study. None of the patients who had a secondary intervention or conversion died within 30 days after the secondary procedure. There was no difference in the rupture rate or AAA-related death rate between the two groups (*P* = .46)

Table II. Clinical and radiologic outcomes

Variable	*SD group ≥5 mm (n = 50)*	*ND group <5mm (n= 94)*	P
Radiologic			
Absolute prox migration (mm)	15.1 ± 13.5	3.2 ± 3.7	<.001
Prox migration ≥10 mm, No. (%)	33 (66)	5 (5.3)	<.001
Absolute lateral displacement (mm)	9.6 ± 7.0	1.9 ± 1.7	<.001
AAA diameter change (mm)	+2.6 ± 10.4	–2.7 ± 8.1	.001
AAA growth ≥5mm, No. (%)	21 (42)	9 (9.6)	<.001
New-onset endoleak type I/III, No. (%)	18 (36)	3 (3.2)	<.001
Clinical			
AAA ruptures, No. (%)	0 (0)	1 (1.1)	.47
Secondary procedures, No. (%)	22 (44)	6 (6.4)	<.001
Conversions, No. (%)	5 (10)	0	.002
AAA-related death, No. (%)	0	1 (1.1)	.47

Secondary procedures were more frequent in the SD group than in the ND group. A secondary procedure was required in 22 patients (44%) in the SD group and in 6 (6%) in the ND group to resolve endograft-related problems (*P* < .001).

Kaplan-Meier estimates showed a freedom from secondary interventions of 98%, 94%, and 94% for the ND group and 89%, 78%, and 56% for the SD group at 12, 36, and 60 months (P = .01, Fig 2). The list of secondary interventions in each patient group is listed in Table III. Most secondary interventions were proximal extension cuffs for proximal type I endoleaks or migration.

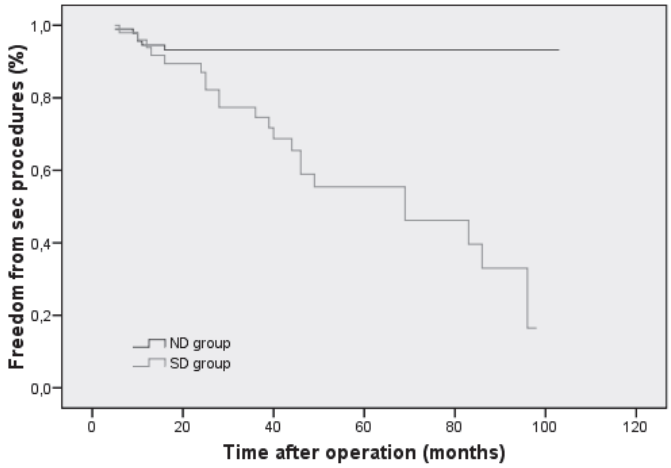

Figure 2. Freedom from secondary interventions

Table III. Secondary interventions in the ND and SD groups

Variable	**ND group (N = 94)**	**SD group (N = 50)**
	No. (%)	No. (%)
Prox extension cuff	3 (3)	11 (22)
Dist extension cuff	2 (2)	3 (6)
Interposition cuff	0	1 (2)
Prox and dist ext cuff	0	5 (10)
New endograft	0	1 (2)
Refuses sec intervention	1 (1)	1 (2)
Aortic neck wrapping*	0	4 (8)
Explantation*	0	1 (2)

* Are considered as conversion operations

Surgical conversion procedures were more frequent in the SD group than in the ND group. Five patients in the SD group (10%) compared with no patients in the ND group underwent conversion to open repair (P = .002). Kaplan-Meier estimates showed a freedom from conversion of 100% in the ND group and 100%, 98%, and 87% in the SD group at 12, 36, and 60 months (P = .015, Fig 3).

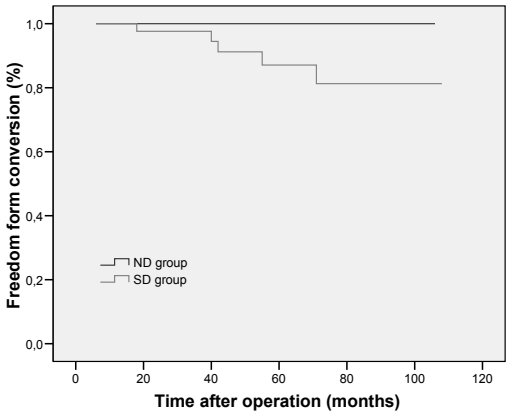

Figure 3. Freedom from conversion in the ND and SD group

Radiologic end points

The radiologic end points are summarized in Table II. Of the 144 included patients, AAA diameter was stable in 73 patients (51%), AAA shrinkage was seen in 41 (28%), and AAA enlargement was seen in 30 (21%). AAA enlargement occurred in 21 SD patients (42%) vs 9 ND patients (10%; P < .001).

Patients in the SD group had more new type I and III endoleaks compared with the ND group. New-onset type I or III endoleak was noted in 18 SD patients (36%) vs 3 ND patients (3.2%; P < .001). Kaplan-Meier estimates showed a freedom from new endoleaks of 98%, 97%, and 97% in the ND group and 98%, 79%, and 61% in the SD group at 12, 36, and 60 months (P < .001, Fig 4).

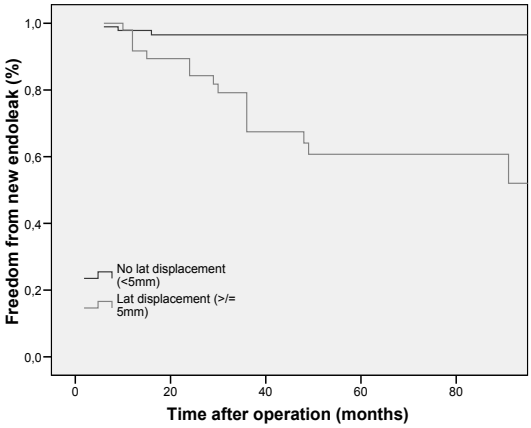

Figure 4. Freedom from new onset endoleak type I or III.

Proximal endograft migration was correlated to sideways endograft movement. Of the 38 patients who had proximal migration >10 mm, 33 (87%) had sideways movement of the endograft ≥5 mm. Of the 50 patients with sideways movement, only 33 (66%) had proximal migration of the endograft.

Interobserver and intraobserver variability

There was a highly significant association between the interobserver and intraobserver measurements regarding the sideways displacement of the endograft during follow-up. The interobserver and intraobserver Pearson correlation coefficients were 0.98 and 0.99, respectively ($P < .001$). The measurements of the 25 patients are depicted in Fig 5.

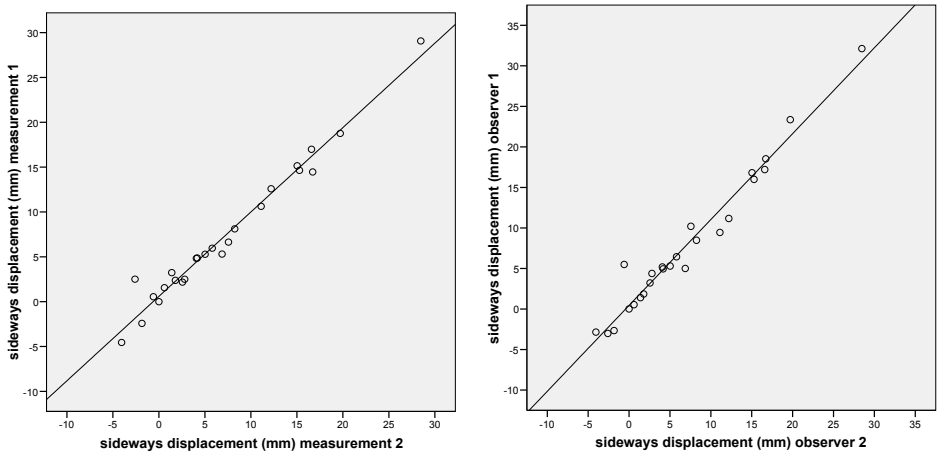

Figure 5. Intraobserver (right figure) and interobserver (left figure) variability plot for sideways endograft movement

DISCUSSION

The current study identified original data of 144 patients. Sideways displacement of the endograft during follow-up occurred in more than one in three patients. There was a strong association between sideways endograft displacement and most adverse events in the investigated patient population. To our knowledge, this study represents the largest cohort of patients to be systematically studied for evidence of sideways movement of the midportion of the endograft in the AAA sac over time.

The role of the midportion of the endograft on the durability of EVAR has received little attention thus far. The midportion of the endograft, because of its unsupported position within the aneurysm sac, can have significant sideways movement during follow-up, particularly in large-diameter aneurysms and in endografts with an unsupported body.

Larger AAA diameters are associated with worse long-term outcome after EVAR, but the mechanism of this phenomenon has never been understood.[10-12] Even after successful initial

endovascular repair with good proximal endograft fixation and no endoleak, a large aneurysm diameter is a significant predictive factor in long-term success after EVAR. In the current study, we showed that patients with sideways endograft movement had larger initial AAA diameter. The larger intrasac aneurysm space may have facilitated sideways movement of the unsupported midportion of the endograft within the AAA sac, thus causing endograft failure in the proximal or distal fixation zone. This could be the explanation why patients with large AAA diameters have worse long-term outcomes after EVAR. However, we also found evidence in this study group of significant sideways displacement in patients with small aneurysms. Sideways displacement occurred during follow-up in 11 of 54 patients (20%) with a small AAA (<55 mm). The incidence rose to 39% in patients with larger AAAs (≥60 mm). Thus, there is a clear association of sideways endograft movement and increasing AAA size; however, a relatively small AAA does not preclude sideways endograft movement.

Patients in the SD group had a significantly shorter proximal and distal endograft fixation length. As shown in this study, sideways endograft movement and migration was strongly correlated with the proximal end of the endograft. Prior studies have shown that a short proximal or short distal endograft fixation length, or both, is associated with an increased risk for proximal migration.[5,7,8] Therefore, the association between sideways endograft movement and shorter proximal and distal fixation lengths is no surprise. Downward movement of the proximal portion of the endograft is intimately associated with sideways movement of the midportion of the endograft if the distal fixation point does not move, because the length of the endograft does not change. In this study, we were not able to determine which is the primary event.

Proximal endograft migration was correlated with sideways endograft movement in this study. Of the 38 patients who had proximal migration >10 mm, 33 (87%) had sideways movement of the endograft.

Two patients with proximal migration did not have sideways movement of ≥5 mm, but the graft configuration was completely different at the same vertebra level on the follow-up CTA scan

(Fig 6). Although sideways displacement was <5 mm at the same vertebral level, these endografts were displaced at another vertebra level lower in the AAA sac during follow-up. On the other hand, of the 50 patients with sideways movement, only 33 (66%) had proximal migration of the endograft. An explanation of why the endograft was not displaced in the proximal anchoring zone in 17 patients is that the graft could be displaced at the distal anchoring zone or that measuring sideways displacement is probably more accurate than the proximal migration measurements in these patients. It is very likely that if sideways movements are noticed without proximal migration, the endograft must have been displaced somewhere else. Unfortunately, we did not measure distal iliac stent graft movement in the study and therefore can only speculate that there was distal movement of the stent grafts.

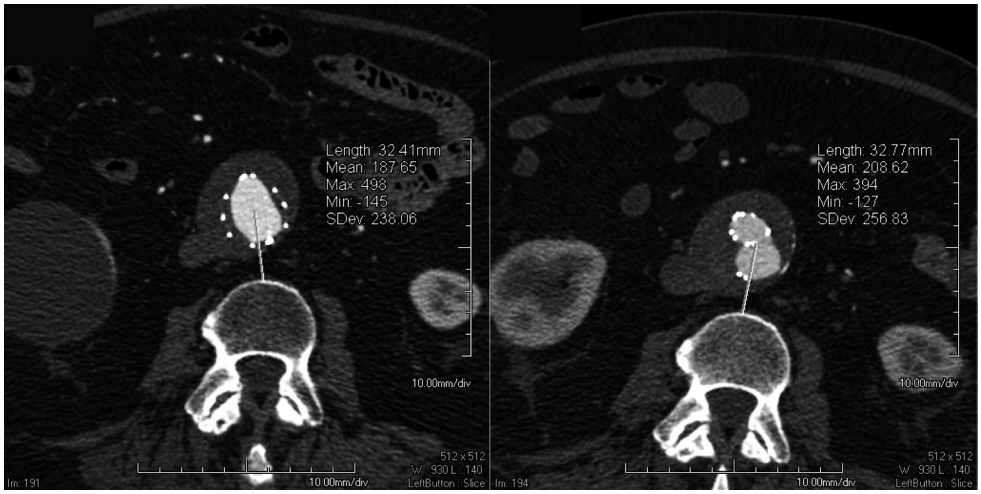

Figure 6. Proximal endograft migration without sideways displacement

As described in the Results, we successfully collected earlier CT scans of 33 of 50 patients in the SD group and determined that in 76% of these patients, sideways endograft movement (≥5 mm) had already occurred earlier on after EVAR. Owing to our study protocol, we think that with the current study we showed that sideways displacement is a very accurate measuring parameter, strongly correlated with adverse events. However, earlier follow-up CT scans could be collected in only 33 of 50 patients with SD, so the predictive value of sideways displacement could not be elucidated in the current study because numbers are too small.

The magnitude and direction of displacement forces acting on aortic endografts in vivo has been studied by Figueroa et al using 3D computational modeling techniques.[14,15] These investigators found that pulsatile displacement force acting on an endograft is in a sideways direction with respect to the axis of the blood flow rather than in the downstream direction of blood flow. In these patient-specific models, 72% of the total displacement force on the endograft was directed sideways in these patient-specific models. Increased curvature of the endograft increases sideways displacement force, as does increased endograft diameter and increased blood pressure. These findings are consistent with our finding of sideways endograft movement in the aneurysm sac over time.

Simple 2D measurements were done to document sideways movement of the endograft. The simple 2D sideways displacement measurement was a quick measurement that could be done within 60 seconds when comparing the postoperative endograft-vertebra distance with the follow-up distance and could be done on CT scans without the use of contrast media. We described a low interobserver and intraobserver variability with a highly significant correlation coefficient. Keeping in mind that 33 of 38 patients (87%) with proximal migration had sideways movement of the endograft and another 2 patients (5%) had a totally different endograft configuration at the same axial vertebra level, the simple and reproducible axial sideways movement measurement probably can probably replace the time-consuming proximal endograft migration measurement during follow-up after EVAR. The use of this measurement technique for evaluating endograft positional stability should be further evaluated in prospective studies and with other endografts to increase our understanding of long-term durability of EVAR.

Limitations

Because we included a large number of patients, conclusion can be drawn with relatively high statistically validity. However, the study has some limitations.

First, we included only patients with at least 6 months of follow-up to be able to determine positional changes over time. Thus, the analyses excluded patients with postoperative events occurring within 6 months after the index procedure. This may have had an effect on measures

such as overall AAA-related mortality. Because endograft migration and sideways displacement is a time-dependent event, we selected a standard time frame that coincides with the prospectively determined routine imaging follow-up protocol. Measuring sideways displacement during follow-up requires at least two CT scans to measure the difference in vertebra-endograft distance.

The second limitation is that almost half of the treated patients were tertiary referral patients, many with AAA anatomy not ideal for endovascular repair (AAA neck <15 mm, AAA neck angle >60°, extensive AAA neck thrombus/calcification, tortuosity of iliac arteries) but unfit for open repair. This may have increased the risk of endograft movement and migration. In addition, some patients, particularly those with less complex anatomies, were monitored with CT imaging done at the local referral center, with reports and images brought by the patient at follow-up visits. Some images were not suitable for quantitative image analysis for this study. Thus, missing comparative data may have introduced a selection bias for more complicated patients who underwent all follow-up imaging studies at our institution.

Another factor that could have influenced our results was that the CT scans were static scans. The measurements of all parameters occurred somewhere during the diastole and systole of the cardiac cycle. Although dynamic changes are investigated in the AAA neck, the dynamic changes of the sideways endograft movement at the point of maximal AAA diameter during the cardiac cycle has not been investigated so far.[16,17] We set the threshold for sideways movement at ≥5 mm because we think some dynamic sideways displacement may occur during the cardiac cycle. This problem should be investigated on dynamic CT scans and will be an investigation goal for our study group.

Another limitation is that we only measured the vertebra-endograft position over time and did not determine the change of endograft position in the AAA sack. Asymmetrical shrinkage or growth of the AAA during follow-up can therefore influence the vertebra-endograft position, without a change of the position of the endograft in the AAA sack.

CONCLUSIONS

This study highlights the importance of the midportion of the endograft, which is unsupported within the aneurysm sac. Significant sideways movement of the endograft is associated with endograft migration, whereas lack of movement indicates endograft stability. Sideways movement of the device within the aneurysm sac is associated with late adverse events; conversely, lack of movement is correlated with long-term success.

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Chapter 10

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 months) 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.

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., bifurcated graft; LCIA, left common iliac artery; Prox. anast., proximal anastomosis; RAAA, ruptured AAA; RCIA, right common iliac artery

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.

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 (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.

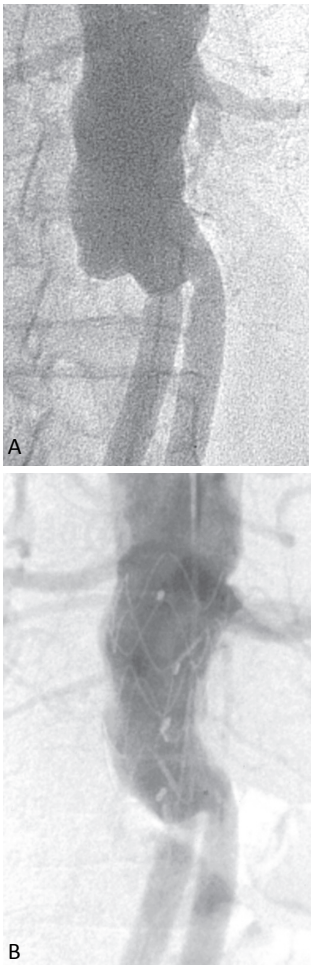

Figure 1. Angiogram before (**A**) and after (**B**) insertion of Talent tube graft for proximal anastomotic aneurysm. Because of a wide aorta at the level of the renal arteries, transrenal fixation of the stent was performed.

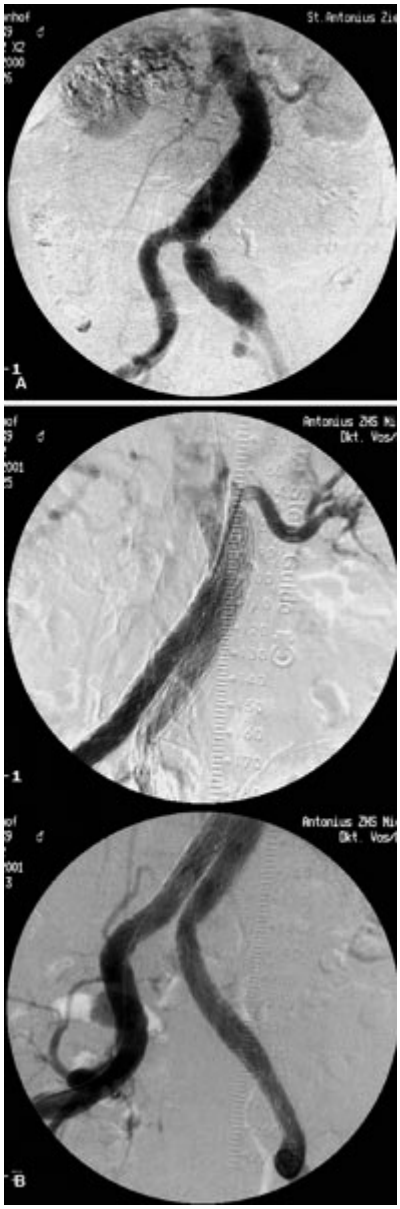

Figure 2. Angiogram with true iliac aneurysm at left side before (A) and after (B) insertion of AneuRx bifurcated stent graft.

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 explanation, 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 11

Endovascular paraanastomotic aneurysm repair after previous conventional aortic prosthetic reconstruction, a durable alternative to open surgical repair

Submitted

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ABSTRACT

Introduction: Anastomotic pseudoaneurysms and true paraanastomotic aneurysms after initial open abdominal aortic prosthetic reconstruction often need reintervention because they are at risk for rupture. However, open surgical reinterventions in frequently high-risk patients are technically challenging procedures with high mortality and morbidity rates. In the present multicenter study, we describe the long-term clinical course in an expanded number of patients who underwent endovascular repair of paraanastomotic aneurysms after previous open reconstruction.

Materials and Methods: The study included all patients who were treated with an endovascular stent graft between July 1999 and July 2009 for an aortoiliac anastomotic pseudoaneurysm or a true paraanastomotic aneurysm after previous aortic prosthetic reconstruction for aneurysmal or occlusive disease in one of the four participating centers. Main outcomes were long-term complications, reinterventions and conversion rate, mortality, and hospital length of stay.

Results: An endovascular stent graft was used to treat 58 patients (53 [91%] men; mean age 71**±9** years) with 80 aortic or iliac pseudo or true paraanastomotic aneurysms, or both. Bifurcated stent grafts were used in 32 patients, endovascular tube grafts in 8, aortouniiliac stent grafts in 7, and iliac extension grafts in 11. Stent graft deployment was successful in 55 patients, for a technical success rate of 95%. Median hospital admission was 3 days (range, 1-122 days). The 30-day and in-hospital mortality rates were 3.4% (n=2) and 6.9% (n=4), respectively. The 30-day clinical success rate was 91% (n=53). Median follow-up was 41 months (range, 0-106 months). The cumulative and procedural-related mortality during follow-up was 19% (n=11) and 10% (n=6), respectively. During follow-up, computed tomography angiography revealed nine endoleaks (3 type I and 6 type II endoleaks) in eight patients and endotension in two patients. The overall reintervention and conversion rate during follow-up was 26.9% (n=15) and 6.9% (n=4), respectively. Life-table analysis showed reduced freedom from reintervention for aortouniiliac and tube stent grafts. Type I endoleaks were observed in 25% of patients with endovascular aortic tube grafts for proximal anastomotic aneurysms.

Conclusions: The present study shows that endovascular repair of paraanastomotic aortic and iliac aneurysms after initial prosthetic aortic surgery is a safe and durable alternative to open

reconstruction. On the long-term, fewer complications occurred after procedures with bifurcated stent grafts compared with procedures with tube grafts, aortouniiliac or iliac extension stent grafts.

INTRODUCTION

Conventional aortic prosthetic reconstruction for repairs of abdominal aortic aneurysm (AAA) or aortoiliac obstructive disease is considered to be a durable procedure and is still widely performed. A typical complication after conventional aortic prosthetic reconstruction is paraanastomotic aneurysm formation. Paraanastomotic aneurysms after previous open reconstruction may present as continuing dilatation of the aortoiliac arteries adjacent to the anastomosis (true paraanastomotic aneurysms) or as disruption of the anastomosis leading to pseudoaneurysm formation (false paraanastomotic aneurysms).[1] The reported incidence varies widely. In a retrospective 15-year follow-up study of 208 patients, proximal and distal aortic paraanastomotic aneurysms occurred in 6 (2.9%) and 18 patients (8.7%), respectively.[2] In the Comparison of Endovascular Aneurysm Repair with Open Repair in Patients with Abdominal Aortic Aneurysm (EVAR-1) trial, 1.2% of the 519 patients who underwent open repair sustained an anastomotic pseudoaneurysm (n=1) or true iliac dilatation (n=5) after previous open repair at an average follow-up of 3.3 years.[3]

Most open reinterventions after initial abdominal aortic prosthetic reconstruction are for repairs of anastomotic pseudoaneurysms and true paraanastomotic aneurysms because they are at risk for rupture.[2,4] However, these open surgical reinterventions are technically challenging, with high mortality rates of 21% to 70% and morbidity rates of 70% to 83%, which are considerably higher than those associated with primary prosthetic reconstructions.[5-8]

Endovascular paraanastomotic aneurysm repair (EVPAR) allows for local or regional anesthesia without requiring dissection through the scars of previous operations and might be preferred instead of renewed open repair.[9] Except for case reports, a few small case series have suggested that endovascular exclusion of noninfected paraanastomotic aneurysms after previous abdominal aortoiliac surgery is feasible, with low perioperative mortality and morbidity.[9-15] Earlier, we

showed that endovascular paraanastomotic aneurysm repair is effective with bifurcated stent grafts.[9] However, larger series with longer-term follow-up are necessary to confirm the long-term effectiveness of this approach.[9,10,12]

In the present multicenter study, we describe the long-term clinical course in an expanded number of patients who underwent EVPAR after previous open reconstruction.

MATERIALS AND METHODS

Patients

Four Dutch centers participated in the study (AmcP, UMCU, St AHN, CHE). The study included all patients who were treated with an endovascular stent graft between July 1999 and July 2009 for an aortic or iliac false paraanastomotic or true paraanastomotic aneurysm after previous aortic prosthetic reconstruction for aneurysmal or occlusive disease. The short-term follow-up of 14 patients included in the current study has been described previously.[9]

Variables analyzed included age, gender, comorbidities, initial aortic pathology, graft configuration at the initial open reconstruction, time between initial open prosthetic reconstruction and endovascular repair, paraanastomotic aneurysm characteristics, stent graft configuration at endovascular repair, hospital admissions, survival, complications, reinterventions (freedom from reinterventions), and conversion rate during follow-up.

Diagnostics and operative technique

All patients underwent a preoperative contrast enhanced spiral computed tomography angiography (CTA) scan with a slice thickness of 1.5 to 3 mm or digital subtraction angiography (DSA), or both, to confirm the presence of a paraanastomotic aneurysm and to evaluate its anatomic characteristics. Criteria for intervention of paraanastomotic aneurysms were 1.5 times the diameter of the nondiseased aorta or iliac artery at that segment, symptoms of acute onset of abdominal or back pain combined with pain at aneurysm palpation (symptomatic paraanastomotic aneurysm), and signs of (contained) rupture on preoperative CTA or DSA.[16]

Criteria for endovascular repair were proximal aortic neck length of >10 mm between the lowest renal artery and the beginning of the aneurysm, proximal aortic neck or iliac artery angulation <90°, lack of circumferential calcification or thrombus of the aortic neck or iliac arteries, and adequate iliac-femoral access to the paraanastomotic aneurysm. Endovascular repair was preferentially performed in anatomically suitable paraanastomotic aneurysms. The exclusion criterion for endovascular repair was anatomic unsuitability for endovascular repair.

General, regional, or local anesthesia were used. Groin incisions with open femoral arteriotomy were performed to gain access to the common femoral artery. Endovascular devices used were AneuRx (Medtronic, Sunnyvale, CA), Endurant (Medtronic, Sunnyvale, CA), Excluder (Gore, Arizona, US), Quantum LP/Fortron (Cordis Corp., Warren, NJ), Relay (Bolton Medical, Sunrise, FL), Talent (Medtronic, Sunnyvale, CA), Valiant (Medtronic, Sunnyvale, CA) and Zenith (Cook Vascular, Bloomington, IN). Tube grafts, aortouniiliac stent grafts, and bifurcated stent grafts were used. The device type was chosen according to anatomic suitability, preferences of the vascular surgeon, availability of the type of stent graft of suitable caliber at the time of the procedure in each participating center, and paraanastomotic aneurysm location and configuration, including aortic neck diameter and length, as well as the presence of iliac stenosis or occlusion.

Tube grafts were used exclusively for proximal paraanastomotic aneurysms, whereas bifurcated or aortouniiliac stent grafts were used to treat patients with proximal or distal paraanastomotic aneurysms, or both. Aortouniiliac stent grafting was combined with a femorofemoral crossover bypass to restore blood flow to the contralateral leg and with an occluder in the contralateral common iliac artery to prevent backbleeding into the aneurysm sac. In patients with a single paraanastomotic iliac aneurysm and a proximal iliac sealing zone of at least 0.5 cm, exclusion was obtained by placement of an endovascular iliac extender graft.

In patients with a proximal paraanastomotic aneurysm of the abdominal aorta, the (covered portion of) the endovascular device was proximally anchored just below the lowest renal artery for optimal sealing in the native aortic neck above the lesion. In case of an endovascular tube

graft, the distal fixation was in the previous graft, with overlap of the endovascular device and the previous graft of at least two stent rings. For a bifurcated or aortouniiliac stent graft, the common iliac artery was used as distal landing zone in most patients. In patients with a paraanastomotic aneurysm near the hypogastric artery, the stent graft was extended in the external iliac artery after embolization of the hypogastric artery. According to the instructions for use all stent grafts were oversized at least 10% to 20%.

Surveillance protocol

Postoperatively, all electively treated patients went to a regular ward or medium care unit where they were fed a normal diet and started ambulating on the first postoperative day. Some patients who were endovascularly treated for a ruptured paraanastomotic aneurysm initially went to an intensive care unit for close monitoring. Postdischarge surveillance after EVPAR included basic laboratory testing for renal function, physical examination, and dual-phase (arterial and delayed phase) CTA scans before discharge or within 3 months, at 12 months, and yearly thereafter. In patients with significant renal insufficiency (GFR<40 ml/min), a renal protection protocol consisting of prehydration and administration of acetylcysteine was used before and after CTA. Otherwise, non-contrast CT scanning combined with contrast-enhanced ultrasonography was performed at the discretion of the vascular surgeon and scheduled at the same time intervals as the regular EVAR protocol.

Statistical analyses

Data were collected and analyzed using SPSS 15.0 software (SPSS Inc, Chicago, IL). Categoric variables are presented as frequency and percentages. Continuous variables are presented as mean ± standard deviation for a normal distribution, or as median and range for a skewed distribution. Survival and freedom from reintervention after endovascular repair of anastomotic aneurysms was evaluated using Kaplan-Meier curves, log-rank tests, and annual risk with related standard error (SE).

RESULTS

Patients

From July 1999 to July 2009, 58 patients (53 men [91%]; mean age of 71**±9** years) with 80 aortic or iliac pseudo or true paraanastomotic aneurysms, or both, were treated with an endovascular stent graft. Of these, 54 patients (93%) were initially treated for aneurysmal disease and 4 (7%) for occlusive aortoiliac disease. Twenty-eight patients were conventionally treated with a tube graft to exclude an AAA and 30 with a previous bifurcated prosthesis or bifurcated bypass. Baseline characteristics and clinical details of these patients are described in Table 1. In patients with a previous tube graft, 42 paraanastomotic aneurysms were present, including pseudoaneurysms at the proximal (n=9) or distal (n=7) anastomosis, and true iliac aneurysms at one (n=6) or both sides (n=10). In patients initially treated with a conventional bifurcated prosthesis, 38 paraanastomotic aneurysms were present, including pseudoaneurysms at the proximal aortic anastomosis (n=10), at one (n=19) or both (n=3) distal iliac anastomosis, and unilateral (n=1) or bilateral (n=1) true iliac aneurysms. Diameters of the aneurysms ranged from 3.4 to 11.0 cm for aortic pseudoaneurysms, from 1.5 to 8.3 cm for iliac pseudoaneurysms, and from 2.1 to 7.5 cm for true iliac aneurysms.

In 40 patients, the paraanastomotic aneurysms were detected by a routine surveillance protocol that included ultrasound imaging 1 year after open aortic surgery and every 3 or 5 years thereafter. In five patients, the paraanastomotic aneurysms were incidentally detected by diagnostic imaging that was performed for purposes other than surveillance after open AAA repair. Eight patients presented with a symptomatic paraanastomotic aneurysm, and five presented with a ruptured paraanastomotic aneurysm. None of the patients in this series had symptoms or signs at CT suggesting graft infection.

Through preoperative risk assessment of pre-existent disease, 17 patients were classified as American Society of Anesthesiologists (ASA) II, 22 patients as ASA III, and 19 patients as ASA IV. At baseline, cardiovascular and pulmonary comorbidity was present in 50 (86%) and 21 (36%) patients, respectively.

Table 1. Baseline characteristics and clinical details after initial open conventional tube and bifurcated graft. Data are presented as number (%) or as median (IQR).

Variables	*Tube graft (n = 28)*	*Bifurcated graft (n = 30)*	*All (n = 58)*
Baseline characteristics			
Age	68 (62-78)	74 (65-78)	73 (63-78)
Male	26 (93%)	27 (90%)	53 (91%)
Comorbidity	25 (89%)	26 (87%)	51 (88%)
Cardiovascular[a]	25 (89%)	25 (83%)	50 (86%)
Pulmonary	8 (29%)	12 (40%)	20 (35%)
Renal	5 (18%)	6 (20%)	11 (19%)
Serum creatinine level (μmol/L)	95 (91-115)	116 (98-165)	115 (95-161)
ASA class	3 (2-4)	3 (2-4)	3 (2-4)
I	0 (0%)	0 (0%)	0 (0%)
II	9 (32%)	8 (27%)	17 (29%)
III	12 (43%)	10 (33%)	22 (38%)
IV	7 (25%)	12 (40%)	19 (33%)
Latency time, years[b]	7 (4-11)	16 (12-21)	13 (6-18)
Clinical details			
Number of PAA	42	38	80
Proximal pseudo PAA	9	10	19
Proximal true PAA	0	0	0
Distal pseudo PAA	7	25	32
Distal true PAA	26	3	29

ASA, American Society of Anesthesiologists; PAA, paraanastomotic aneurysm
[a] Other than previous aneurysmal or occlusive aortic disease.
[b] Time between initial open prosthetic surgery and endovascular paraanastomotic aneurysm repair.

Endovascular Intervention

The median interval between the initial open reconstruction and EVPAR was 12.5 years (range, 1-25 years). Endovascular repair was performed under general anesthesia in 38 patients, spinal anesthesia in 17, and under local anesthesia in 3. An endovascular tube graft was used in 8 patients, a bifurcated stent graft in 32, an aortouniiliac stent graft in 7, and an iliac extension graft in 11 (Figure 1). Devices that were used are listed in Table 2. Median procedure time was 120 minutes (range, 45-355 minutes) and median blood loss was 250 mL (range, 30-1900 mL).

The median radiation time was 23 minutes (range, 3-66 minutes), and median contrast dose administration was 87 mL (range, 20-150 mL).

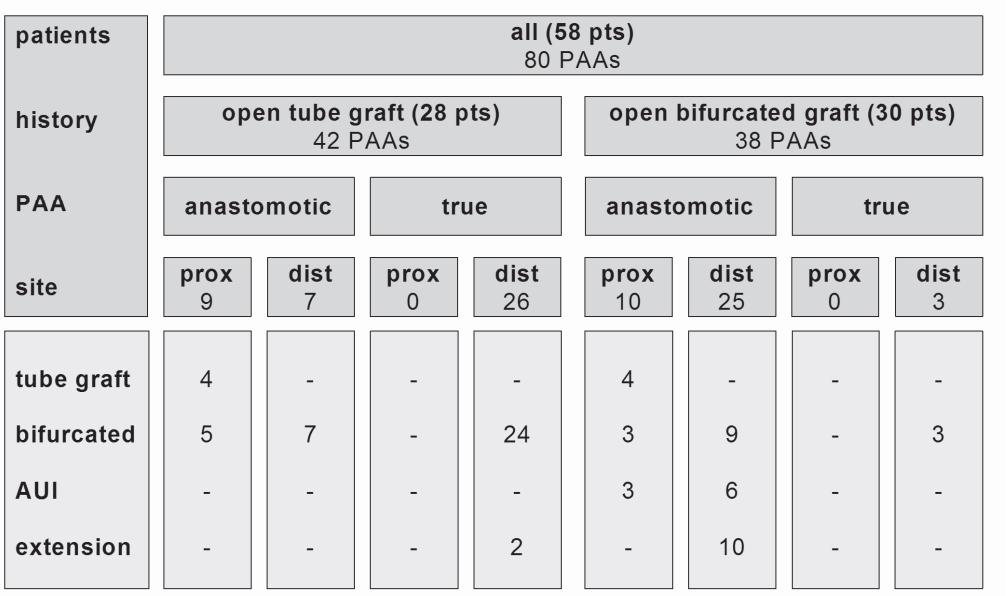


Figure 1. Flowchart showing the types of stent graft (yellow) used for different localizations of (false) anastomotic and true paraanastomotic aneurysms after previous open tube or bifurcated graft (blue).

Table 2. Types of endovascular stent grafts that were used.

Device	*Tube graft*	*Bifurcated graft*	*Aortouniiliac graft*	*Extension*
AneuRx	1	8	0	1
Talent	3	19	7	6
Endurant	0	1	0	0
Valiant	1	0	0	0
Zenith	1	1	0	1
Quantum LP	0	1	0	0
Gore excluder	1	2	0	3
Relay	1	0	0	0
Total	8	32	7	11

None of the patients died during the EVPAR procedure. Stent graft deployment was successful in 55 patients (technical success rate, 95%). One patient needed an adjunctive surgical procedure. In this patient, access to the retroperitoneum was gained to ligate the contralateral limb of the previous open bifurcated graft after successful aortouniiliac endoprosthesis placement for a ruptured proximal paraanastomotic aneurysm. In three patients (5%), primary stent graft deployment was unsuccessful, of whom one needed an additional laparotomy. In this patient, the short contralateral leg of the bifurcated stent graft was deployed accidentally in the ipsilateral limb of the primary existing bifurcated graft. The bifurcated stent graft was then converted into an aortouniiliac stent graft by extending the graft to the right external iliac artery. Subsequently, a suitable endovascular occluder was not available, so a laparotomy was performed for ligation of the right hypogastric artery and the left common iliac artery to prevent back bleeding into the aneurysm sac. A femorofemoral crossover bypass was placed to restore blood flow in the left leg.

The secondary technical success rate was 97%. In the two other patients with unsuccessful stent graft deployment, one (n=1) or both (n=1) renal arteries were inadvertently overstented during stent graft deployment. No type I or III endoleaks were observed at completion angiography.

Other events during EVPAR were type II endoleaks at angiography at the end of the procedure in four patients, of which one type II endoleak was still present on predischarge CTA. Furthermore, the left hypogastric artery in one patient was inadvertently covered by the stent graft.

Hospital stay

Median hospital stay was 3 days (range, 1-122 days). The in-hospital and 30-day mortality rates were 6.9% (n=4) and 3.4% (n=2), respectively, all in patients with successful stent graft deployment. Two of these four patients were treated for a ruptured paraanastomotic aneurysm. Causes of death were pulmonary insufficiency (day 8), progressive cardiac failure (day 8), pulmonary insufficiency combined with a sepsis (day 55), and sepsis after repetitive infections and occlusion of a femorofemoral crossover bypass (day 122). This last patient underwent several reinterventions for critical limb ischemia.

The 30-day clinical success rate was 91% (n=53). In five patients, 30-day clinical success was not achieved due to death (n=2), overstenting of both renal arteries causing progressive renal insufficiency (n=1), distal type I endoleak present on predischarge CTA (n=1) for which close observation was initiated, and hemodynamic shock (n=1) due to rupture of the left external iliac artery after paraanastomotic aneurysm repair for which an extension cuff was placed successfully. An abdominal compartment syndrome developed in this last patient due to a retroperitoneal hematoma and abdominal decompression was required the next day.

Follow-up

Median follow-up was 41 months (range, 0-106 months). No patients were lost to follow-up. The cumulative mortality during hospital stay and follow-up was 19% (n=11). Overall, median follow-up until death was 13 months (range, 0-106 months). Patient survival is illustrated using a Kaplan-Meier curve (Figure 2), which shows the annual risk of mortality was 4.0%. Two of seven deaths during follow-up were procedure-related. In one patient, slight aneurysm expansion (3 mm) without signs of an endoleak was observed on CTA at 12 months after endovascular treatment for a proximal paraanastomotic pseudoaneurysm using a tube stent graft. A wait-and-see policy was followed, but this resulted in acute aneurysm rupture at 18 months needing acute reintervention including explantation of the endovascular graft and placement of an open bifurcated prosthesis. The patient died the next day due to bowel ischemia. The other patient, whose renal artery was overstented during the endovascular procedure, suffered from postoperative progressive hemodialysis-dependent renal insufficiency. At 51 months, successful conversion to open repair was performed for a type Ia endoleak. However, this patient decided to stop undergoing hemodialyses and died at 106 months of follow-up.

The overall complication rate during follow-up after discharge was 22% (n=13). Two patients died due to procedure-related complications, as described above. Hydronephrosis occurred in one patient as the result of external ureter compression by a paraanastomotic aneurysm in the iliac artery. In the other 10 patients (17%), reinterventions were performed for stent graft occlusion in 4 patients that needed thrombectomy or thrombolysis, followed by percutaneous

transluminal angioplasty (PTA) in 3 patients and replacement with a synthetic prosthesis in 1 patient; infection of a femorofemoral crossover bypass that was replaced by a venous bypass in 1, access site infection and bleeding of a patch in the groin in 2, type B dissection for which an aortouniiliac stent graft was placed in 1, distal type I endoleak (which was already detected on predischarge CTA as described previously) of a bifurcated stent graft for which an iliac extension graft was placed in 1, and endotension for which the stent graft was converted to a bifurcated prosthesis in 1.

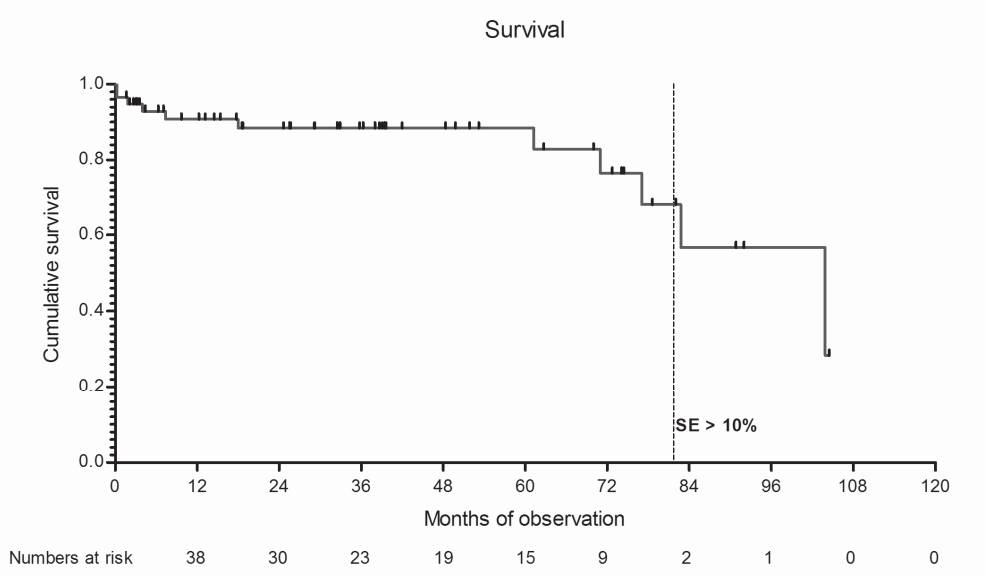
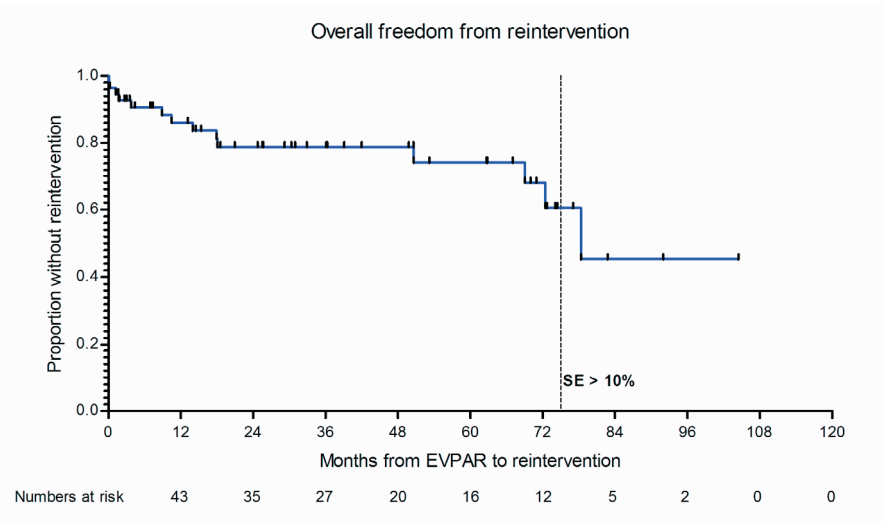


Figure 2. Kaplan-Meier curve showing survival after endovascular paraanastomotic aneurysm repair. The dashed line indicates when the standard error exceeds 10%.

During total follow-up, including hospital stay, reintervention was performed in 15 patients (25.9%) at a median of 11 months (range, 0-80 months). Figure 3A shows the Kaplan-Meier curve for freedom of reintervention after endovascular paraanastomotic aneurysm repair. The overall annual risk of reintervention was 5.8% (SE, 0.088). The log-rank test for equality of intervention distributions between different stent graft configurations is visualized in Figure 3B, showing a significantly larger proportion of tube and aortouniiliac stent grafts needing

reintervention during follow-up (*P*<.001). The annual reintervention risk was 3.2% (SE, 0.098%) for bifurcated stent grafts, 16.6% (SE, 0.239%) for tube grafts, 66.4% (SE, <0.001%) for aortouniiliac stent grafts, and 19.1% (SE, 0.152%) for distal iliac extension grafts.

A)



B)

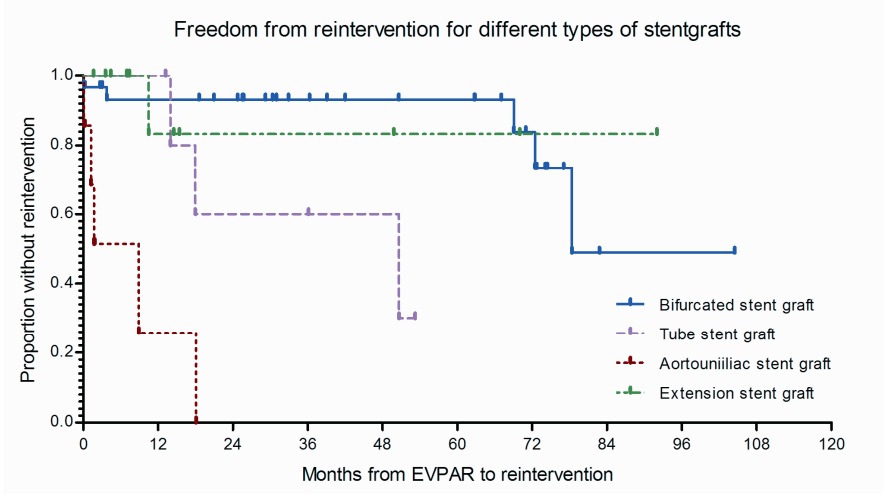


Figure 3. Kaplan-Meier curve showing freedom from reintervention after EVPAR for (A) all stent grafts and (B) the different types of stent grafts that were used. In 2A, the dashed line shows when the standard error exceeded 10%.

Four patients (6.9%) required conversion to open repair at a median follow-up of 16 months (range, 4-51 months). Two patients needed conversion for endotension, which caused an aneurysm rupture in one patient. In one patient, an endovascular tube graft was replaced by an open tube graft at 51 months after EVPAR for persistent type Ia endoleak. Finally, an axillobifemoral prosthesis was placed in one patient for occlusion of a bifurcated stent graft at 4 months after placement for bilateral true iliac paraanastomotic aneurysms. Mortality was 50% (2 of 4) in patients who underwent conversion to open aneurysm repair vs 0% (0 of 5) in patients who underwent an endovascular reintervention (*P*=.167).

During follow-up, CTA revealed nine endoleaks (1 type Ia, 2 type Ib, and six secondary type II endoleaks) in eight patients. In one patient, type Ia endoleak was observed after migration of the previously described bifurcated stent graft, which was converted to an aortouniiliac stent graft during EVPAR. Type Ib endoleak was observed in two patients at the distal fixation side of the endovascular tube graft, resulting in replacement of the stent graft by an open tube graft in one patient, as described above. Of the six secondary type II endoleaks, two disappeared spontaneously during follow-up, and the other four received close observation. None of these patients needed reintervention and AAA did not grow. Furthermore, endotension was observed in two patients treated with an endovascular tube graft for a proximal paraanastomotic aortic aneurysm, resulting in conversion to open surgical repair in one patient and acute aneurysm rupture in the other patient, as described previously.

DISCUSSION

The reported incidence of paraanastomotic aneurysms after previous conventional aortic reconstruction varies widely, from 0.5 to 15%.[17,18] This is probably an underestimation, because most patients who undergo open aortic repair do not receive regular imaging surveillance follow-up. Paraanastomotic aneurysms are associated with high rupture rates. The reported rupture rate ranges from 15% to 55% in patients who did not undergo revision surgery.[19-21] Pseudoaneurysms might be even more unpredictable in terms of rupture risk compared with true paraanastomotic aneurysms,[1] with a mortality rate of 61% in the absence of an intervention.[6]

EVPAR allows for local or regional anesthesia without requiring dissection through the scars of previous operative sites.[9] However, EVPAR has some drawbacks, including inadequate proximal or distal fixation zones[22], showing the importance of accurate pre-operative sizing and planning, and potential stent graft deformation in patients with previous end-to-side anastomoses.

Several case series describing endovascular management of paraanastomotic aortic and iliac aneurysms have considered this treatment as feasible and safe,[9-15,23,24] especially when compared with mortality rates of 21% to 70% and morbidity rates of 70% to 83% reported for open paraanastomotic aneurysm reconstruction.[5-8] However, the available series describing endovascular repair included a small number of patients, and follow-up time is relatively short. The report by Sachdev et al included 53 patients with paraanastomotic aneurysms treated with endovascular repair at a mean follow-up of 18.1 months, excluding patients who were lost to follow-up.[16] However, they studied a mixture of thoracic and abdominal paraanastomotic aneurysms. One report compared 16 open repairs with 10 EVPAR procedures in patients who were candidates for endovascular repair, showing higher morbidity and complication rates after open repair than with endovascular repair.[25] Furthermore, blood loss, procedural time, and hospital length of stay were significantly reduced for endovascular repair. The results of the present study focus on durability of endovascular repair with different types of stent grafts for paraanastomotic aneurysms, with extended follow-up time and more patients.

The present study, with a follow-up up to 106 months, showed endovascular management of paraanastomotic aortic and iliac aneurysms is a feasible and durable alternative to open reconstruction. In 95% of patients treated with EVPAR after previous open aortic reconstruction, stent graft deployment was successful (primary technical success rate). Perioperative mortality and morbidity rates in patients (70% with ASA class ≥III) were acceptable, with an intraoperative mortality of 0%, 30-day mortality of 3.4%, and in-hospital mortality of 6.9%. Exclusion was successfully maintained during follow-up, without signs of endoleak, in 86% of the paraanastomotic aneurysms.

Furthermore, the endovascular reconstruction was less durable in patients treated with aortouniiliac and tube stent grafts for proximal paraanastomotic aortic aneurysms (Figure 3B). The main causes for reintervention in aortouniiliac stent grafts were infections of the femorofemoral crossover bypass and stent graft occlusion. In patients treated with an endovascular tube graft, the main cause of reintervention was endoleak type I, caused by insecure distal anchoring of the endovascular stent graft in the previous polyester graft, or endotension. Therefore, when endovascular tube grafts are used for proximal anastomotic aneurysms, the distal fixation site has to be long enough for secure distal anchoring of the tube graft in the previous polyester prosthesis. Or when the proximal anchoring site is short, efforts have to be done to implant a bifurcated stent graft. Follow-up showed the proximal fixation site of the aortouniiliac or bifurcated stent grafts in the previous polyester graft was secure, probably due to the longitudinal columnar support in these types of stent grafts. Stent grafts that were fixated proximally and distally in the native aorta or iliac vessels were all secure.

In patients who needed conversion to open repair after EVPAR, there was a clear trend towards a higher mortality rate compared with patients who underwent an endovascular reintervention.

Several patients in the present study who had paraanastomotic aortoiliac aneurysms with relatively small diameters were treated with endovascular repair. Indications for treatment in these patients were symptoms or rupture of the aneurysm, or aneurysm growth during routine follow-up after primary open prosthetic reconstruction.

CONCLUSIONS

The present multi-center study confirms that EVPAR after initial prosthetic aortic surgery is a feasible and safe alternative to open reconstruction with low perioperative mortality and morbidity. At long-term follow up, treatment with bifurcated stent grafts showed to be durable with low reintervention rates. Aortouniiliac stent grafts and endovascular tube grafts appeared less durable, requiring more reinterventions. Based on the long-term results of EVPAR in this

serie of 58 patients, endovascular exclusion of paraanastomotic aneurysms with bifurcated stent grafts can be considered as the first-choice treatment option.

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Chapter 12

Summary and General Discussion

SUMMARY AND GENERAL DISCUSSION

Chapter 1 is the introduction of this thesis and presents a brief overview of how the treatment of aneurysm of the abdominal aorta (AAA) has developed since the first open repair was done in 1951. Additionally, the shift to the less invasive endovascular treatment is described alongside the newer utilities of endovascular aneurysm repair (EVAR) to treat patients with suboptimal aortic neck anatomy and even those with late complications after a previous open AAA repair. The developments and the use of newer and better stent grafts continue like never before and will lead to improvement of the endovascular treatment.

Chapter 2 describes some of the most mentioned anatomic risk factors for EVAR-related complications. The risk factors that have a negative effect on EVAR durability are summarized and briefly described together with some of the stent graft fixation characteristics that influence EVAR durability. The current literature presents strong evidence that most of these risk factors clearly affect EVAR durability. However, for some risk factors, such as aortic neck thrombus and calcification, evidence in the current literature was not convincing. Although these two risk factors are described to play a role in EVAR durability, their exact role on long-term outcomes still must be investigated.

In **Chapter 3,** the 7-year clinical results of EVAR with the Talent stent graft are described. This study was a collaboration between a vascular center in Europe and in the USA. The data for this chapter were gathered at St. Antonius Hospital, Nieuwegein, The Netherlands, and Stanford Medical Center, Stanford, California, USA. Sixty-three percent of patients were included in The Netherlands and 37% in the USA. The Talent stent graft became Communauté Européenne (CE)-approved in Europe in 1998, and 2 years later, the graft was introduced in the St. Antonius Hospital, Nieuwegein. Beginning with the first EVAR procedure with this graft, all data were prospectively captured in a vascular database.

Between July 2000 and December 2007, 365 patients underwent elective EVAR with the Talent stent graft. Overall, the included patients had many comorbidities reflecting in the high American Society of Anesthesiologist (ASA) score, with 74% classified ASA ≥3. Deployment of endografts

was successful in 99% of patients. Even though a high number of patients were at ASA ≥3, 30-day mortality was 1.1%. This 30-day mortality rate is comparable to the reported 0.5% - 1.7% in the three randomized controlled trials and other rates reported in large prospective population studies.[1-5]

Of the 365 patients overall, 122 (33%) died during follow-up. Most patients died of cardiac or pulmonary causes, which illustrate the severe comorbidities of the investigated patient group. Nine AAA-related deaths (2.5%) occurred during follow-up, of which 4 patients died within 30 days (1.1%). At a mean follow-up of 40 months, 73 of 365 patients (20%) underwent a secondary procedure. Most secondary interventions were done for proximal migration (n = 11), proximal type 1 endoleak (n = 21), and graft thrombosis or kinking (n = 16).

In the last decade of EVAR, the use of transrenal fixating stent grafts has increased over the use of infrarenal fixating devices.[6] In the St. Antonius Hospital, the infrarenal fixating AneuRx device was used beginning in 1996 and was replaced by the transrenal fixating Talent device in 2000. Concerns about the renal side effects of this transrenal fixation prompted us to investigate possible renal deterioration after EVAR in both the infrarenal (IR) and transrenal (TR) fixation groups. The results of this study are described in **Chapter 4**. Postoperative renal dysfunction was defined as a >20% decrease in serum creatinine clearance compared with baseline. The aim of this study was to investigate the short-term effect of EVAR on renal function and compare the TR and IR fixation groups. During a 9-year study period, 309 patients underwent EVAR with 190 receiving an IR stent graft and 119 receiving a TR-positioned graft. At discharge, renal dysfunction occurred in 3.7% of the patients in the IR group versus 5.9% in the TR group (p = NS) and rose significantly to 13.7% in the IR group (p = 0.001) and 15.1% in the TR group (p = 0.02) at the 1-year follow-up. No significant differences were observed between the IR and TR groups at both time-points.

No morphologic causes for the substantial amount of renal dysfunction could be found in almost half of the patients. One of the proposed nonanatomic causes for renal dysfunction could be the repeated administration of contrast used during sequential follow-up imaging with CT angiography (CTA). The predischarge CTA could especially harm renal function by adding an extra contrast dose shortly after the endovascular procedure.

In **Chapter 5** the value of predischarge CTA was investigated in 291 EVAR patients treated between 1996 and 2006. All patients had CTA before discharge and at 3 months, which detected 93 endoleaks and 1 stent graft thrombosis. The predischarge CTA findings in the 291 patients resulted in only 4 secondary interventions, comprising 1 interposition cuff, 2 extension cuffs, and 1 conversion. Thus, the early predischarge CTA data did not influence postoperative treatment policy in 99% of EVAR patients. More than half of all early endoleaks were self-limiting, and new endoleaks were seen in only two patients (<1%) at the 3-month follow-up CTA. The surplus value of an early CTA can be questioned after an uneventful EVAR procedure, especially when this uneventful procedure was done in a patient with favorable aneurysm (neck) anatomy.

Chapter 6 describes two of the unfavorable anatomic parameters when treating patients endovascularly. Patients with large-diameter aneurysms and wide aneurysm necks are compared with patients with small sizes of these characteristics. The effect on EVAR durability was analyzed during a 7-year period in the EUROSTAR collaborative study.

In the past, large-diameter aneurysms and aneurysms with a wide infrarenal aortic neck were considered unsuitable for endovascular exclusion. With the newer-generation devices, however, sealing and fixation are achievable in aneurysms that previously would have been rejected for endovascular repair because of their anatomy.

Patients who had a large aneurysm (>60 mm) in combination with a wide aortic neck (>26 mm) had a significantly higher overall mortality rate, conversion rate, and rupture rate compared with patients with smaller aneurysms and aortic necks. These patients also had significantly more proximal type 1 endoleak and proximal migration.

Migration is an issue for all types of stent grafts. Prevalence ranges from less than 3% up to 28%, depending on which stent graft is used, the length of follow-up, and the morphology of the AAA.[7-9] Most attention has been paid to a good proximal stent graft fixation in preventing migration after EVAR.

Chapter 7 describes that distal (iliac) fixation is also important in preventing migration after EVAR. Among the 154 included patients, migration of ≥10 mm occurred in 32 (21%).

Multivariate analysis to test for predictors of migration revealed that preoperative aortic neck length, proximal fixation length, distal stent graft fixation length, and follow-up time were significant predictors.

As described in Chapter 7, iliac fixation is importation to obtain EVAR durability. However, technical problems can arise when the common iliac arteries are ectatic, aneurysmal, or short. In **Chapter 8** the technical options are described for dealing with these kinds of unfavorable iliac anatomy.

In the former chapters, the proximal fixation zone (aortic neck) and the distal (iliac) fixation zone were both described. The middle part of the stent graft has not been given much attention so far. In 2009 Rafii et al.[10] were the first to describe this issue in a clinical paper. They showed that lateral endograft movement of the endograft within the aneurysm sac was associated with an increased risk of late adverse events.

In **Chapter 9,** this sideways stent graft movement during EVAR follow-up is described.
Of the 144 included patients, 50 (35%) had sideways movement of the stent graft within the AAA sac of ≥5 mm, and these patients were included in the sideways displacement (SD) group. Patients in the SD group had significantly more secondary procedures compared with patients with <5 mm sideways movement (ND group). Secondary procedures were required in 22 patients (44%) in the SD group and in 6 (6%) in the ND group. Surgical conversions were significantly higher in the SD group. At 60 months of follow-up, 13% of patients in the SD group versus no patients in the ND group underwent surgical conversion. Freedom from new-onset type 1 or type 3 endoleak was significantly higher in the SD group. At 60 months of follow-up, freedom from new onset type 1 or type 3 endoleak was 61% in the SD group and 97% in the ND group. It has to be mentioned that this chapter was a first step in evaluating the stent graft movement in this part of the aneurysm, and further research is clearly needed to confirm the predictive value.

As knowledge about EVAR increases, the indications for EVAR have been extended throughout the years, from treating patients with ideal aneurysm anatomy to patients with suboptimal anatomy. The endovascular approach has even led to treatment of patients with paraanastomotic aneurysms occurring after prior open repair for AAAs or aortoiliac obstructive disease.

In **Chapter 10** we describe the application of EVAR to treat these paraanastomotic aneurysms. Paraanastomotic aneurysm after previous open repair may present as continuing dilatation of the aortoiliac arteries adjacent to the anastomosis (true paraanastomotic aneurysms) or as a disruption of the anastomosis that leads to pseudoaneurysm formation (false paraanastomotic aneurysms).[11] False paraanastomotic aneurysms are at an especially high risk for rupture. Open repair of paraanastomotic aneurysms is challenging, with mortality rates up to 70%.[12-15]

In our series of 14 patients, paranastomotic aneurysms were successfully excluded with EVAR without perioperative mortality. A pulmonary infection complicated the postoperative stay of one patient. No conversions were performed in 11 patients who were treated with bifurcated stent grafts, but a secondary intervention was necessary in 1 patient at a median follow-up of 12 months. Exclusion of paraanastomotic aneurysm with tube grafts was not durable, however. The proposed mechanism is the difference in compliance of previous polyester grafts compared with the native aortic wall. The polyester graft gives less fixation to the self-expandable nitinol stent graft.

In summary, we state that endovascular exclusion of paraanastomotic aneurysm by endovascular bifurcated grafts is feasible, with low perioperative mortality and morbidity rates. However, larger series with long-term follow-up are necessary to confirm the long-term effectiveness of this approach.

Chapter 11 reports the further investigation of EVAR to treat paraanastomotic aneurysm in a group of 58 patients with an extended median follow-up of 41 months. Bifurcated stent grafts were used in 32 patients, tube grafts in 8, aortouniiliac grafts in 7, and iliac extension grafts in 11. Stent graft deployment was successful in 55 patients (95%). Median hospital length of stay was 3 days, and the 30-day mortality rate was 3.4%. The overall and procedurally related mortality during follow-up was 19% and 10%, respectively. The overall reintervention and conversion rate during follow-up was 26% and 6.9%, respectively.

Reintervention rates were significantly higher during follow-up for patients treated with tube and aortouniiliac stent grafts compared with patients with bifurcated grafts. The annual reintervention risk was 3.2% for bifurcated grafts, 16.6% for tube grafts, and 66.4% for aortouniiliac stent grafts. From the long-term results of this large series of 58 patients, we conclude that endovascular exclusion of paraanastomotic aneurysm with bifurcated stent grafts can be considered the first-choice treatment option.

GENERAL DISCUSSION

Aneurysm of the abdominal aorta (AAA) is an increasing health problem, ranking as the 13th leading cause of death in Western countries and responsible for almost 1% of all deaths.[16] AAA frequently affects older men, and the increase in AAA prevalence with age is well documented.[17-21] The prevalence of AAA by age, investigated in >10,000 men aged older than 50, is 3% for men aged 60 years and rises to >10% in men aged 80 years old.[19] The expected increase of people aged >65 years from 15% currently to 26% in 2040 (National Population Prognosis 2009, Central Bureau of Statistics), will inevitably lead to an increase in AAA prevalence.

Altogether, the aging of the Western population, the increase in life expectancy, the probability of earlier detection of asymptomatic AAAs through screening programs,[22] and as a result of a greater trend toward consumer-directed health care,[23] we will encounter this disease more frequently in the upcoming decade. The expected increase in AAA prevalence will have its burden on the health care system.

The goal for the next decade in the vascular field of surgery, is to improve the treatment of this disease through several improvements in treatment:

- Further elucidate the pathogenesis of the dilatation process and gain more insight how to slow the degenerative process long before the AAA reaches critical size.
- When the AAA reaches a diameter that an intervention is needed, efforts must focus on making the treatment as durable as possible with a modality that is minimally invasive.

This thesis focuses on the second point of interest. Although, EVAR was developed to treat patients with high comorbidities and older patients, the increase in endovascular treatment of younger patients cannot be ignored. The overall longer life expectancy of younger patients will emphasize the field of minimally invasive AAA surgery.[24;25] Because younger patients live longer and reinterventions have to be performed consistently through the rest of their lifetime (Chapter 3), the need for durable endovascular devices is more critical than ever.

During 7 years of follow-up of the Talent device (Chapter 3), a stent graft that is still in use, 20% of secondary procedures were needed to obtain long-term AAA exclusion. These secondary procedures can occur even years after the primary EVAR, which means that life-long surveillance after EVAR is needed in most patients.

Although a significant number of secondary procedures were needed during the long-term follow-up of the Talent device, a major improvement in 30-day mortality and secondary procedures was noticed compared with the former AneuRx stent graft system in the same institute.[9] Thirty-day mortality decreased from 2.4% for the AneuRx to 1.1% for the Talent stent graft. Secondary procedures decreased almost 50%, from 31.6 % for the AneuRx versus 20% for the Talent stent graft. However, to continue this rising clinical improvement and obtain even better long-term results, with a decreased need for a stringent and expensive follow-up scheme, continuing improvement of stent grafts is warranted.

Not only is it important to put effort into optimizing stent graft durability, but the economic aspect of this minimally invasive treatment must also be taken into account. In these years where millions of Euros have to be saved on health care, an understanding of costs related to treatment and cost differences between treatment modalities is important for adequate allocation of resources.

The recently published long-term data from the EVAR 1 trial showed EVAR was more costly than open repair during 8 years of follow-up.[26] The higher operative costs were due to the increased cost of the stent graft. During postoperative follow-up, EVAR remained significantly more expensive due to the graft-related reinterventions and follow-up imaging. However, reintervention rates and costs for the open-repair group may have been underestimated because readmission data were not collected for abdominal hernias, gastrointestinal (GI), or other complications related

to open AAA repair. A reoperation rate after open AAA repair of more than 10% is reported for hernia repair and GI complications.[27]

Although a reduction in stent graft prices is anticipated with increasing use of the EVAR technique and increasing market competition, continuing stent graft improvements will eventually lead to more durable grafts, lower secondary procedure rates, less stringent follow-up schemes, and therefore to reduced costs.

The continuing concern of late adverse events after EVAR has led to widespread recommendations that all patients treated with EVAR should undergo lifelong surveillance with annual imaging studies. The ideal follow-up scheme and modality is debated, but to date, most vascular centers recommend a follow-up scheme consisting of a CTA scan before discharge, at 3 and 12 months, and annually thereafter. In this thesis we already proved that the predischarge CT scan is of little value in decision making after uncomplicated EVAR and can therefore be left out of the follow-up scheme. We have altered our follow-up scheme, but must mention that for research tools, this particular CTA may be worthwhile. Skipping the predischarge CT scan was a first step in compelling the stringent follow-up scheme, but we still do not know how to deal with later CT scans during follow-up. Although preoperative imaging studies can identify patients with an unfavorable morphologic anatomy that may predispose them to adverse events after EVAR, little attention has been paid to favorable postoperative image characteristics that identify patients who are at very low risk for adverse events and thus may require less strict follow-up or no follow-up at all.

Two decades after the introduction of EVAR and >300,000 of procedures further, it is time to introduce a patient-specific follow-up scheme after EVAR based on a prediction model. Such a prediction model should incorporate all factors known to affect the outcome being assessed, such as the adverse morphologic aspects of the AAA, stent graft fixation characteristics, and endoleak. The predictive role of sideways stent graft movement has to be further evaluated before we can use this in a prediction model. In addition, the role of fast AAA shrinkage after EVAR is an interesting area of attention. Especially in large-diameter AAA when shrinkage is asymmetrical, friction forces on the stent graft could cause a movement in the proximal or distal fixation site of device. This might lead to migration or type I endoleak. To our knowledge, this subject has not been investigated so far and needs further investigation.

In this thesis we described the influence of AAA and AAA neck diameter on complications after EVAR. The aortic neck length was not statistically different between the groups. Patients with a large AAA and a large AAA neck had a significantly higher risk of mortality, rupture, and conversion during 4-year follow-up after EVAR. These morphologic risk factors should therefore be included in this proposed prediction model.

Some of the most important stent graft fixation characteristics that were investigated are reported in Chapter 7. We clearly show that length of the proximal stent graft fixation and the length of iliac fixation are significant predictors for migration and should therefore also be included in the prediction model.

Although we investigated some of the adverse AAA morphologies and fixation characteristics, EVAR-related complications are caused by a combination of factors. In Chapter 2 we summarized the current literature about most of these factors that seemed to play a role in the durability of EVAR.

Much of the described adverse features were clearly recognized and investigated in former studies and can therefore used to put in a prediction model. The evidence of some of the apparently recognized risk factors for EVAR durability, however, is not very strong in the current literature. A good example is the influence of the amount of AAA neck thrombus and calcification in relation to EVAR durability. Although these features are mentioned as a contraindication for EVAR in most instructions for use, studies have described good results when treating patients with these features.[28;29] Prospective studies using well-defined criteria of AAA neck thrombus and calcification with longer follow-up time are needed to define the exact influence on EVAR durability.

An absolute necessity for future investigations is that we have to redefine some standards in EVAR. The ability to interpret future clinical reports about adverse morphologic features requires a uniform standard for analyzing and reporting these data. The rapid evolution of EVAR has led to new concepts and insights into factors that define success, and thus, this evolving technique needs evolving standards.

In 2002 the Ad Hoc Committee for Standardized Reporting Practices in Vascular Surgery of the Society for Vascular Surgery/International Society for Cardiovascular Surgery reported a scoring system for factors that modify the outcome of EVAR.[30] Although this report included a scoring

grade for AAA neck thrombus, calcification, and angulation, the proposed scoring grade has not been systematically used in most reports. In Chapter 2 we showed that many studies report the amount of AAA neck thrombus, calcification, and angulation in a variety of ways that make comparison of one report with another difficult, if not impossible. Overall, it is very important that we all measure and report all the adverse features in the same way. Only then can decent comparisons be tested and weak evidences be turned to strong conclusions.

In the 20 years of EVAR, this treatment modality has gained enormous popularity for the treatment not only of infrarenal AAAs but also for paraanastomotic aneurysm. Several reports of the endovascular treatment of these types of aneurysms have been published, but most of these reports were small case series.[31;32] We showed that the treatment of paraanastomotic aneurysm is safe, with high technical success and significantly lower mortality rates compared with open repair. The long-term results showed similar results, but from both reports we found that treatment of these aneurysms with aortic tube or aortouniiliac stent grafts is not durable. This finding may also have implications for primary EVAR.

In our study about the importance of iliac fixation, 9 patients (6%) received an aortouniiliac stent graft. Although this was not the primary study goal, a subgroup analysis revealed a significant difference in the occurrence of migration between patients treated with a bifurcated stent graft and patients treated with an aortouniiliac stent graft ($P = 0.008$). Migration occurred during follow-up in 5 of 9 patients (56%) treated with an aortouniiliac stent graft vs. 19% in the bifurcation group. To date, about 90% of grafts are bifurcated and the rest are aortouniiliac.[3] To our knowledge, the probable difference in long-term durability of these 2 stent graft configurations has never been described and would be a great subject of interest for future research.

FUTURE PERSPECTIVES

In this thesis we showed the Talent stent graft had acceptable long-term results; however, a significant number of secondary procedures were needed to obtain long-term success. In the next decade of EVAR we have to focus on durability of this less invasive procedure. This can be accomplished through several improvements:

● Improve patient selection

Like every new treatment modality, the boundaries of the EVAR will be approached or even passed. During the EVAR era, many reports have been published about the successes of treatment of patients with suboptimal AAA morphology. Although these articles reported many different outcomes and investigated a wide range of adverse morphologic features, they all shared a common feature: describing only the short- to median-term results. Because EVAR is still an evolving technique, we have to be cautious when treating patients at the boundaries of EVAR because we are still waiting for long-term results with the newest generation of stent grafts. To come to a better patient selection for EVAR, a prediction model would clearly help the current decision making of when to treat a patient by open AAA repair or by an endovascular technique.

● Improve stent graft sizing and procedural planning

In the early days of EVAR, most stent grafts were sized on 2-dimensional (2D) images of CT scans with 5-mm slice thickness. Measurements were done on light boxes using a pair of compasses. Today's imaging technique has developed at least as fast as the endovascular treatment. The introduction of dynamic electrocardiography-gated CT imaging makes it possible to measure AAA morphology changes during the cardiac cycle. The introduction of 3D imaging tools has also greatly improved imaging technique and sizing. In our opinion, an accurate measurement of the AAA and all anatomic fixation points for the stent graft in the aortic neck and iliac arteries can only be done with this kind of 3D imaging. With 3D processing of the CT images, diameter measurements can be made perpendicular to the centerline axis, and vessel lengths can be measured along the centerline. Van Keulen et al. recently investigated (unpublished submitted data) the difference between stent graft sizing measurements, with and without the use of a center lumen line, and found a significantly lower variability for the central lumen line method compared with the conventional 2D measurement method for both diameter and length measurements.

Reports about 3D computational techniques in predicting displacement forces acting on the future implanted stent graft have increased in recent years.[33;34] Refinement and validation of these computational methods will eventually lead to preoperative computational prediction models.

The combination of computational and clinical prediction models can add a great improvement in defining which patients will be a good candidate for EVAR or for a particular type of stent graft.

● Improve stent graft deployment

An anatomically ideal patient will still have a worse long-term outcome if the favorable AAA anatomy is not used. Good examples were the patients who experienced stent graft migration in the US AneuRx clinical trail conducted from 1996-1999, which had a mean distance of 1.1 cm from the lowermost renal artery to the beginning of the stent graft.[8]

In recent years there have been substantial improvements in intraoperative technique, including the high-resolution image intensifier with road mapping images and flat panel detectors. Along with technical improvements, stent graft delivery systems have improved throughout the years, which make a precise placement of the stent graft easier.

Along with these improvements in imaging and stent graft delivery, the endovascular skills of the vascular interventionists have also improved. Altogether, the stent graft deployment will be closer to the renal arteries, resulting in longer attachment and sealing zones, and this will have a profound effect on EVAR durability.

● Improve stent grafts

Although the stent grafts we use today are different from the grafts used in the early nineties, continuing improvements of stent graft characteristics will be expected. At the end of the development era, the ultimate stent graft will enhance all of the characteristics needed for a durable AAA exclusion. The currently used stent grafts rely on radial force and hooks and barbs for fixation, but some new technologies have an entirely different approach of fixation. One of these technologies is the fixation of the stent graft by an endovascular staple technique. The proximal part of the stent graft is endovascularly secured by staples that fixate the graft into the aortic neck. Although the 1-year follow-up in 21 patients with this stent graft fixating technique showed good results, the long-term results have to be awaited.[35]

Another different technical approach to endovascular aneurysm repair is filling the AAA sac with a stent graft that contains a polymer-filled endobag on the outside that conforms perioperatively to the specific shape of the AAA while providing anchoring and sealing. This would not only enhance fixation but also extend the patient population with adverse fixation anatomy for EVAR. These two concepts are only two of the many device developments that are expected in the next few years. Only future research will show which techniques will eventually evolve as the most durable option compared with the stent graft technique we use today.

As knowledge of EVAR durability increases, so does wider application of endovascular aortic procedures. The introduction of transrenal fixation devices widened the endovascular AAA treatment, but there are instances in which satisfactory endovascular exclusion cannot be obtained without sacrificing important side branches of the aorta. This has led to the development of branched or fenestrated devices. Aside from the improvements in straight infrarenal devices, these devices will also continue to develop. The first long-term results are very promising, with results comparable with treatment of infrarenal AAAs.[36-40] Until 2 years ago, these devices were custom-made; however, an increasing number of off-the-shelf devices are currently available. Eventually this technique will represent a further step in replacement of the entire aorta with endovascular grafts.

EVAR will continue to develop and eventually become the preferred treatment for all patients with this devastating disease. With the results of this clinical research we have tried to contribute to the improvement of EVAR.

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Chapter 13

Nederlandse Samenvatting

(voor niet-ingewijden)

ANEURYSMA VAN DE ABDOMINALE AORTA

Definitie

Het Griekse woord "aneurysma" betekent "verwijding" en wordt als medische term gebruikt voor een permanente lokale verwijding van een bloedvat.

Volgens de huidige richtlijnen spreken we van een aneurysma van de abdominale aorta (= buikslagader) (AAA) indien de diameter ten minste 1,5 maal groter is dan de verwachte diameter van het betreffende bloedvat. Een verwijding kleiner dan 50% wordt ectasie genoemd. De abdominale aorta is het deel van de grote lichaamslagader dat zich achter in de buikholte bevindt. De normale diameter van de abdominale aorta is afhankelijk van verschillende factoren zoals de leeftijd, geslacht en ras. De normale diameter van de infrarenale (het gedeelte onder de nierslagaders) aorta bedraagt voor vrouwen 1.19 cm – 2.16 cm en voor mannen 1.41 cm – 2.39 cm.

Voor de infrarenale aorta wordt om praktische redenen echter een aorta die groter is dan 3 cm aangemerkt als aneurysmatisch verwijd.

Prevalentie

De in de literatuur beschreven prevalentie van een AAA is afhankelijk van de gehanteerde definitie. Onder prevalentie wordt het aantal gevallen van een ziekte verstaan, dat op één specifiek moment aanwezig is. Mannen zijn vier maal vaker aangedaan dan vrouwen. De geschatte prevalentie ligt tussen de 1% en 11%, en is voornamelijk afhankelijk van de leeftijd en het geslacht van de onderzochte populatie. Een grote screeningsstudie onder >10.000 mensen vond een prevalentie van 3% in mensen boven de 65 jaar en meer dan 10% in mensen boven de 80 jaar.

De verwachte groeiende vergrijzing (mensen boven de 65 jaar) van de Westerse samenleving van momenteel 15% naar 26% in 2040, betekent dat wij in toenemende mate te maken zullen krijgen met deze ziekte.

Symptomen

Een AAA verloopt meestal asymptomatisch (zonder klachten). Dit is de reden waarom een AAA, in landen waar nog niet aan screening wordt gedaan, veelal per toeval ontdekt wordt tijdens onderzoek naar andere aandoeningen.

Indien er toch symptomen zijn dan zal het vaak gaan om een voelbare massa in de buik eventueel in combinatie met buik en/of rugpijn.

Het meest levensbedreigende risico van een AAA is een aneurysma ruptuur. Bij een ruptuur ontstaat er een scheur in de aorta. De symptomen bij een ruptuur zijn hevige buik en/of rugpijn, een voelbare massa in de buik en een lage of zelfs niet-meetbare bloeddruk. Dit is een medische urgentie en directe operatieve behandeling is gewenst. Slechts 50% van de patiënten met een geruptureerd AAA zal levend het ziekenhuis bereiken. Van deze patiënten zal vervolgens nog eens 50% uiteindelijk in het ziekenhuis overlijden. Kortom, 75% van de patiënten met een geruptureerd AAA zal aan deze ziekte overlijden.

De kans op ruptuur is vooral afhankelijk van de maximale aneurysma diameter. Dit is onder andere te verklaren door de wet van Laplace waarbij de diameter van de aorta de bepalende factor is voor de druk uitgeoefend op de wand van de slagader. Bij een aneurysma wil dit dus zeggen: hoe groter het aneurysma, hoe groter de druk en dus hoe groter het risico op ruptuur. Dit verklaart ook waarom er een snellere groei wordt gezien van AAA's met een grote diameter.

Het jaarlijkse risico op ruptuur is minder dan 2% voor AAA's kleiner dan 4 cm en stijgt naar > 20% voor AAA's groter dan 7 cm. Op basis van deze ruptuur risico's adviseren de huidige richtlijnen om een AAA te behandelen indien deze een diameter heeft bereikt van 5 tot 5.5 cm. Ook wordt geadviseerd om bij een hoge groeisnelheid van meer dan 1 cm/jaar het AAA te behandelen. Patiënten die niet aan deze criteria voldoen worden regelmatig vervolgd met een echo onderzoek ten einde eventuele groei te kunnen vervolgen. Uiteraard zal er ook de nodige aandacht moeten worden besteed aan het reduceren of staken van risico factoren zoals hypertensie en roken.

Behandeling

Ondanks het reduceren van risico factoren zal een aanzienlijk deel van de patiënten met een klein AAA, groei ondervinden en uiteindelijk operatieve behandeling moeten ondergaan. Met de huidige stand van zaken wordt een operatieve correctie geadviseerd voor patiënten met een AAA groter dan 5 tot 5.5 cm of een snelle groei.

Het beslissingsproces een AAA operatief te behandelen is echter veel complexer dan deze consensus doet vermoeden. Voor elke individuele patiënt zal een afweging moeten worden gemaakt waarbij rekening moet worden gehouden met de factoren die het risico op ruptuur beïnvloeden, het operatieve risico en de levensverwachting van de desbetreffende patiënt.

Tot 1991 werd het AAA hersteld door middel van een open uitschakeling van het AAA. Bij deze open uitschakeling wordt een laparotomie (open-buik operatie) uitgevoerd waarbij het verwijde stuk slagader wordt vervangen door een kunststof vaatprothese.

In 1951 voerde Charles Dubost (1914 – 1991) de eerste open operatie uit. Hoewel deze patiënt gedurende 8 jaar overleefde, was de operatie mortaliteit (sterfte) en morbiditeit (invaliditeit) aanzienlijk. Door verfijning van de operatie techniek en door de verbeterde postoperatieve zorg (zorg na de operatie) is de mortaliteit gedaald tot de huidige 3% tot 5%. Alhoewel deze operatie sindsdien de gouden standaard is om patiënten met een AAA te behandelen, blijft deze operatie techniek een aanzienlijke mortaliteit en morbiditeit houden.

Omdat we veelal te maken hebben met een patiëntenpopulatie die meerdere cardiopulmonale co-morbiditeiten (aandoening aan hart of longen) heeft, is een substantieel deel van deze patiënten niet geschikt om deze zware open operatieve uitschakeling van het aneurysma te ondergaan.

Ten einde deze slechte patiëntengroep toch te kunnen behandelen ging men op zoek naar andere behandelingsmogelijkheden. In 1991 berichtten Parodi et al. in Argentinië en Volodos et al. en in de Ukraine een alternatief voor deze open uitschakeling: de **endovasculaire behandeling van het abdominale aneurysma (EVAR)**.

Deze nieuwe endovasculaire behandeling is sindsdien niet meer weg te denken uit de behandeling van het AAA en heeft in de afgelopen 2 decennia een enorme ontwikkeling doorgemaakt. De endovasculaire behandeling bestaat uit het endovasculair (via de binnenzijde van het bloedvat)

inbrengen van een stentgraft (vaatprothese). In vergelijking met de conventionele open chirurgische behandeling, biedt deze techniek het voordeel dat het een minimaal invasieve procedure is die zelfs onder lokale verdoving kan worden gedaan. Dit brengt vanzelfsprekend voordelen met zich mee op het vlak van perioperatieve (rondom de operatie) morbiditeit en mortaliteit.

Niet elke patiënt kan worden behandeld door middel van deze endovasculaire techniek. Een vereiste voor het kunnen toepassen van deze techniek is onder andere, het hebben van een geschikte infrarenale aorta nek. De nek van het AAA is het normale (niet-verwijde) gedeelte van de aorta tussen de nierslagaders en het begin van het AAA. Ook dienen de bekkenslagaders voldoende ruim te zijn om de stentgraft door te kunnen opvoeren.
Met de huidige generatie stentgrafts kan > 60% van de patiënten behandeld worden door middel van deze techniek. Inmiddels is deze techniek verder verfijnd en zijn de indicaties verruimd tot de behandeling van juxtarenale AAA's en behandeling van para-anastomotische aneurysma's na eerdere open uitschakeling. Een juxtarenaal AAA is een aneurysma waarbij het deel van de aorta rondom de nierslagaders ook aneurysmatisch verwijd is. Een para-anastomotisch aneurysma is een aneurysma dat op de rand van een eerdere (via een open-buik operatie) ingehechte vaatprothese kan ontstaan in de aorta.

Ondanks de uitstekende korte en middellange termijn resultaten van EVAR, kent deze techniek ook complicaties welke uniek zijn voor deze behandeling. Eén van deze complicaties is het optreden van endoleak waarbij bloed tussen de wand van de aorta en de stentgraft het AAA in lekt (type 1 endoleak). Tevens kan de stentgraft in de loop van de jaren naar beneden zakken richting het AAA (migratie). Beide complicaties, welke zich kunnen voordoen jaren na de endovasculaire procedure, kunnen uiteindelijk lijden tot falen van de endovasculaire behandeling. Dit kan betekenen dat er een noodzaak is voor een tweede (secundaire) interventie.
Tevens heeft dit als consequentie dat patiënten na deze endovasculaire behandeling vaak langdurig onder controle moeten blijven om het optreden van eventuele complicaties nauwlettend te volgen.

In het huidige proefschrift worden een aantal kanten van de endovasculaire behandeling belicht. Zo worden de lange termijn resultaten beschreven van de Talent stentgraft, een vaatprothese die nog steeds veel wordt gebruikt. Tevens hebben wij bekeken wat voor effect het plaatsen van een stentgraft in de buurt van de nierslagaders heeft op de nierfunctie. Verder hebben we de waarde van de controle CT-scan kort na de endovasculaire procedure onderzocht.

De invloed van vele karakteristieken van de anatomie van de aorta, alsmede stentgraft fixatie karakteristieken hebben wij uitvoerig beschreven in meerdere hoofdstukken.

Tot slot beschrijven we de korte en de lange termijn resultaten van één van de nieuwe toepassingen van de endovasculaire aneurysma chirurgie, namelijk de behandeling van para-anastomotische aneurysma's na eerdere open uitschakeling.

Het doel van dit onderzoek is om door middel van dit klinisch onderzoek tot een verbetering te komen van de resultaten van EVAR.

Hoofdstuk 1 vormt de algemene introductie van het proefschrift.

Hoofdstuk 2 geeft een overzicht van de meest beschreven anatomische risico factoren die geassocieerd zijn met EVAR-gerelateerde complicaties. Tevens beschrijven we stentgraft fixatie karakteristieken die van invloed zijn op de duurzaamheid van EVAR. De huidige literatuur beschrijft een duidelijke negatieve invloed van tal van anatomische AAA en stentgraft fixatie karakteristieken op de duurzaamheid van EVAR; AAA diameter, nek diameter en lengte, pulsatiliteit van de nek (beweging van de nek tijdens de hartslag), nek-hoek, proximale (bovenzijde) stentgraft fixatie lengte en techniek, en distale (onderzijde) fixatie lengte.

Hoofdstuk 3 beschrijft de lange (7-jaars) resultaten van de Talent stentgraft. Deze studie was een samenwerkingsverband tussen het St. Antonius Ziekenhuis in Nieuwegein en Stanford Medical Center, Stanford, Californië, USA. Drieënzestig procent van de patiënten werden geïncludeerd in het St. Antonius Ziekenhuis.

Tussen juli 2000 en december 2007 ondergingen 365 patiënten een endovasculaire uitschakeling van het AAA met de Talent stentgraft.
De introductie (opvoeren tot op de juiste plaats) en de ontplooiing van de (samengevouwen) stentgraft was succesvol in 99% van de patiënten.
Ondanks de slechte conditie van de behandelde patiënten groep, was de 30-dagen mortaliteit 1.1%.
Van de 365 patiënten overleden er 122 (33%) gedurende de follow-up. De meeste patiënten overleden aan cardiale (hart) en/of pulmonale (long) oorzaken wat de slechte conditie van de behandelde groep nogmaals reflecteert. Negen patiënten (2.5%) overleden ten gevolge van een AAA-gerelateerde oorzaak, van wie 4 (1.1%) binnen 30 dagen na de ingreep.
Gedurende een gemiddelde follow-up van 40 maanden, ondergingen 73 van de 365 patiënten (20%) een secundaire procedure. De meeste secundaire procedures werden gedaan vanwege migratie (n = 11), proximale type 1 endoleak (n = 21) en trombose of knikken van de stentgraft (n = 16).

Er is een duidelijke toename in het gebruik van transrenaal fixerende stentgrafts in de afgelopen 10 jaar. Bij deze fixatie techniek komt het deel van de bovenzijde van de stentgraft dat niet bedekt is met stof, over de nierslagaders heen te liggen. Door deze manier van fixeren neemt de lengte van de fixatie toe en dientengevolge de kans op migratie van de vaatprothese af. In **Hoofdstuk 4** hebben wij de eventuele gevolgen van deze fixatie techniek op de nierfunctie onderzocht. Postoperatieve achteruitgang van de nierfunctie (nierinsufficiëntie) was gedefinieerd als een > 20% achteruitgang in creatinine klaring ten opzichte van de uitgangswaarde.
Het doel van deze studie was om het effect op de nierfunctie te analyseren tussen een groep patiënten die een infrarenale en een groep die een transrenale fixatie van de stentgraft onderging.
Gedurende een tijdsbestek van 9 jaar ondergingen 309 patiënten een endovasculaire uitschakeling van hun AAA. Van deze patiënten ondergingen 190 patiënten een infrarenale fixatie (IR) en 119 patiënten een transrenale fixatie (TR).
Bij ontslag na de EVAR procedure had 3.7% van de patiënten in de IR groep versus 5.9% in de TR groep nierinsufficiëntie. Na 1 jaar werd er een significante stijging in nierinsufficiëntie gezien in beide groepen: 13.7% in de IR groep en 15.1% in de TR groep.

Er was geen significant verschil tussen de IR en TR groep op beide tijdsmomenten.
Slechts in de helft van de patiënten met nierinsufficiëntie kon een anatomische oorzaak worden gevonden (zoals een afgesloten nierslagader). Een mogelijke niet-anatomische oorzaak voor nierinsufficiëntie kan de toediening van contrastmiddel zijn bij de CT-scan controle voor ontslag uit het ziekenhuis. Deze extra contrast dosis kort na de EVAR procedure (waarbij ook contrastmiddel gebruikt wordt) kan nadelige gevolgen hebben voor de nierfunctie.

De eventuele waarde van deze vroege CT-scan controle voor ontslag uit het ziekenhuis is beschreven in **Hoofdstuk 5**. De waarde van deze CT-scan werd onderzocht in een groep van 291 patiënten die tussen 1996 en 2006 middels EVAR werden behandeld. Alle geïncludeerde patiënten hadden een CT-scan voor ontslag alsmede na 3 maanden follow-up. Er werden 93 endoleaks en 1 stentgraft trombose gezien op de CT-scans bij ontslag. Dit resulteerde in slechts 4 secundaire interventies waaronder 1 interpositie cuff (tussenstuk), 2 extensie cuffs (verlengstuk) en 1 conversie naar open AAA uitschakeling. Een conversie betekent dat de endovasculair behandelde patiënt alsnog een open uitschakeling van het aneurysma moet ondergaan.
Dit betekent dat deze vroege CT-scan bij ontslag in 99% van de patiënten geen behandelingsconsequentie heeft gehad.
Meer dan de helft van alle endoleaks op de ontslag CT-scan waren verdwenen op de controle na 3 maanden. Een nieuw ontstane endoleak werd slechts in twee (< 1%) patiënten gezien op de 3 maanden controle CT-scan. Op basis van deze resultaten kan deze controle CT-scan voor ontslag uit het ziekenhuis bekritiseerd worden.

In **Hoofdstuk 6** wordt de invloed van twee anatomische AAA karakteristieken op de duurzaamheid van EVAR onderzocht. Patiënten met een groot AAA (>60 mm) en AAA nek (>26 mm) worden vergeleken met patiënten met een klein AAA (≤60 mm) en AAA nek (≤26 mm).
De data voor deze studie werden verkregen uit het bestand van de EUROSTAR studie. Er werden 1317 patiënten geïncludeerd welke in een tijdsbestek van 7 jaar een endovasculaire uitschakeling van hun AAA ondergingen.
Patiënten met een groot AAA in combinatie met een wijde AAA nek hadden een significant hogere mortaliteit, conversiekans en kans op AAA ruptuur in vergelijking met patiënten met een

klein AAA en AAA nek. Tevens had deze patiënten groep significant meer type 1 endoleak en migratie gedurende de follow-up.

De prevalentie van migratie is 3% tot 28% en is voornamelijk afhankelijk van het type stentgraft, de follow-up duur en de anatomische karakteristieken van het behandelde AAA.
Een goede duurzame stentgraft fixatie is een voorwaarde om migratie te voorkomen. In het onderzoek naar factoren die een invloed hebben om migratie heeft de nadruk vooral gelegen op het belang van een goede proximale stentgraft fixatie in de AAA nek. Dit is dus het gebied direct onder de nierslagaders.
In **Hoofdstuk 7** beschrijven we echter dat de distale fixatie (fixatie in de bekkenslagaders) ook belangrijk is teneinde het migratie risico te reduceren. In deze studie waarbij 154 patiënten werden geïncludeerd werd een migratie gezien (≥10 mm) in 32 patiënten (21%). Multivariate analyse liet zien dat de preoperatieve nek lengte, de proximale fixatie lengte, de distale fixatie lengte en de follow-up duur onafhankelijke voorspellers waren voor het optreden van migratie.
Op basis van deze gegevens lijkt het gewenst de stentgraft tot aan de afgang van de a. iliaca interna te verlengen. Dit is tot aan de eerste splitsing van de beide bekkenslagaders.

Echter, indien de bekkenslagaders kort, ectatisch of aneurysmatisch zijn is een adequate stentgraft fixatie lastig te bewerkstellingen. In **Hoofdstuk 8** worden de technische opties besproken om deze fixatieproblemen op de lossen.

In de voorgaande hoofdstukken werd zowel de proximale (net onder de nierslagaders) als de distale (in de bekkenslagaders) fixatie zone besproken. Het middengedeelte van de stentgraft heeft echter in de huidige literatuur weinig aandacht gekregen. In 2009 beschreven Rafii et al. als eerste het middengedeelte van de stentgraft in de AAA zak. Zijwaartse verplaatsing van de stentgraft in de AAA zak was geassocieerd met een verhoogd risico op late EVAR-gerelateerde complicaties.

Hoofdstuk 9 beschrijft de zijwaartse stentgraft verplaatsing in een groep van 144 patiënten. Vijftig patiënten (35%) hadden zijwaartse verplaatsing (≥5 mm) van de stentgraft gedurende de follow-up en deze patiënten vormden de zijwaartse verplaatsing groep (SD). Patiënten met <5 mm verplaatsing vormden de niet-zijwaartse verplaatsing groep (ND). Patiënten in de SD ondergingen significant meer secundaire procedures en conversies dan de ND groep (secundaire procedures: 44% versus 6%, conversies: 13% versus 0%).
Patiënten in de SD groep hadden significant meer nieuw-ontstane type 1 en/of 3 endoleaks in vergelijking met de ND groep (39% versus 3% na 60 maanden follow-up). Een type 3 endoleak is een lekkage van bloed tussen de verschillende onderdelen van een stentgraft door het AAA in. Zijwaartse stentgraft verplaatsing in de AAA zak lijkt duidelijk geassocieerd met late EVAR-gerelateerde complicaties. De voorspellende waarde van deze verplaatsing zal echter nog nader onderzocht moeten worden.

Door een voortschrijdend inzicht in de endovasculaire aneurysma chirurgie, zijn de indicaties in de afgelopen jaren verbreed. In het begin van het EVAR tijdperk werden met name patiënten met een goede AAA anatomie en patiënten met hoge co-morbiditeiten behandeld middels deze techniek. Heden ten dage worden er steeds meer patiënten behandeld met een minder goede anatomie en zelfs patiënten met para-anastomotische aneurysma's na eerdere open AAA uitschakeling.
Hoofdstuk 10 beschrijft de korte termijn resultaten van de behandeling van para-anastomotische aneurysma's middels EVAR. Open uitschakeling van deze aneurysma's kent een hoge mortaliteit tot wel 70%.
In deze studie werden 14 patiënten succesvol behandeld middels EVAR zonder peri-operatieve mortaliteit. Een behandeling met een endovasculaire bifurcatie prothese (broekprothese) bleek echter aanzienlijk duurzamer dan behandeling met een buisprothese.
De mediane follow-up duur in deze studie bedroeg echter slechts 12 maanden en gegevens van grotere series met een langere follow-up zijn gewenst.

Hoofdstuk 11 beschrijft de lange termijn resultaten van een grotere groep patiënten (behandeld voor een para-anastomotisch aneurysma) met een langere mediane follow-up duur van 41 maanden. In totaal werden er 58 patiënten behandeld. Tweeëndertig patiënten kregen een bifurcatie prothese, 8 patiënten een buisprothese, 7 patiënten een aorta-uni-iliacale prothese (buisprothese welke helemaal naar de bekkenslagader loopt) en 11 patiënten een iliacale extensie prothese (vaatprothese welke alleen in een bekkenslagader wordt geplaatst). Ontplooiing van de stentgraft was succesvol in 55 patiënten (95%). De gemiddelde opname duur bedroeg 3 dagen en de 30-dagen mortaliteit was 3.4%. Totale mortaliteit en procedure-gerelateerde mortaliteit gedurende de follow-up bedroeg 19% en 10%, respectievelijk.
Het totale reïnterventie risico bedroeg 26% en het conversie risico 6.9%. Reïnterventie risico was significant hoger in patiënten die behandeld waren met een buis of aorta-uni-iliacale prothese in vergelijking met patiënten die een bifurcatie prothese kregen. Het jaarlijkse reïnterventie risico bedroeg 3.2% voor bifurcatie protheses, 16.6% voor buisprotheses, en 66.4% voor patiënten behandeld met een aorta-uni-iliacale vaatprothese.
Op basis van de resultaten van deze grote studie waarbij 58 patiënten met een para-anastomotisch aneurysma werden behandeld, is de endovasculaire behandeling met een bifurcatie prothese de eerste keuze optie.

Hoofdstuk 12 geeft tot slot een visie op de toekomst van de ontwikkelingen in de endovasculaire behandeling van het aneurysma van de abdominale aorta.

Chapter 14

Publicaties

Dankwoord

Curriculum Vitae

PUBLICATIES

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CURRICULUM VITAE

Evert J. Waasdorp was born on October 31, 1976, in Zeist, The Netherlands. After graduating from High School (Revius Lyceum, Doorn), he started his study of Medicine at the University of Utrecht in 1995. In 2002 he obtained his Medical Degree from the University of Utrecht. The same year he started as a resident at the department of Surgery in the St. Antonius Hospital Nieuwegein, where he worked until July 2004. Surgical training started in July 2004 at the same hospital (Dr. P.M.N.Y.H. Go). In July 2008 he started the final two years of Surgical training at the department of Surgery in the Academic Hospital Utrecht (Prof. dr. I.H.M. Borel Rinkes). During his Surgical training he started scientific research which has become the basis for this thesis. He was invited to do research at the Stanford Medical Center, Stanford, USA (Prof. C.K. Zarins). He visited Stanford twice and collected the data for three Chapters of this thesis. This research forms the basis of a continuing fruitful collaboration. During the last year of his Surgical training he specialised in Vascular Surgery. This was completed in July 2010 when he became qualified as a General Surgeon. Since then he is in training for Vascular Surgery (Prof. dr. F.L. Moll), where he hopes to complete training in January 2012.