Optimalization of endovascular aortic aneurysm repair by dynamic imaging studies

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CONTENTS

INTRODUCTION

Over the last two decades, endovascular (thoracic) aortic repair ((T)EVAR) has become an established alternative to open repair for several aortic diseases. This thesis was planned to contain research on endovascular treatment of aortic pathology at two different anatomical areas. Part 1 of the thesis contains research to improve the endovascular treatment of Abdominal Aortic Aneurysms and Part 2 aims to enhance the knowledge and treatment of acute dissections of the Descending Thoracic Aorta.

PART 1

Aneurysms of the infrarenal abdominal aorta (AAA) are common, with estimated prevalence rates of 1.3% to 8.9% in men and 1.0% to 2.2% in women.[1-5] The natural course of aneurysms is to expand and eventually rupture. To avoid aneurysm rupture, open aneurysm repair was introduced in 1952 by Dubost et al.[6]

The decision whether to repair an AAA is based upon risk analysis. When a patient's expected mortality caused by aneurysm rupture during surveillance exceeds the peri- and postoperative mortality of aneurysm repair, aneurysm repair may be performed.

In 1991, Parodi et al. in Argentinia[7] and Volodos et al. in the Ukraine[8] introduced an alternative and less invasive technique for repair of AAAs, the EVAR. The benefits of EVAR initially seemed obvious, with a minimally invasive transfemoral approach and without a need for aortic cross-clamping. This technique gained an enormous popularity. Nowadays, the benefits of EVAR versus open repair during short-term and midterm follow up have extensively been established[9-11] and these early results are even improving. However, long-term efficacy seems inferior to open repair because of concerns about long-term durability and lack of improvement of durability, despite the introduction of newer generation stentgrafts.[12,13]

Complications during long-term follow-up after EVAR frequently occur in the proximal aneurysm neck, which is the area of proximal fixation and sealing of the stentgraft. In 2006, we hypothesized that repetitive aortic wall movements during the cardiac cycles have a major impact on the durability of EVAR, which should have implications for patient selection and evolution of stentgraft design.[14] These aortic wall movements ("pulsatility") were subject of research in Part 1 of this thesis. **Chapter 2** contains a review of the available knowledge of thoracic aortic aneurysm (TAA) and AAA dynamics before and after EVAR. **Chapter 3** contains research on the effect of different stentgrafts on the aortic pulsatility and in **Chapter 4** we investigate whether patients with complications after EVAR (stentgraft migration) had more pronounced aortic pulsatility than patients without complications during follow-up. In **Chapter 5**, the dynamic pulsatility of the iliac arteries is studied. The iliac arteries are the distal sealing and fixation areas of aortic stentgrafts and could therefore also have an impact on durability after EVAR.

Other areas that could lead to improvement of the outcome after EVAR are patient selection and the planning of the EVAR procedure in case of challenging anatomy. In **Chapter 6**, a new, standardized method to measure proximal aneurysm neck angulation is presented. This improves patient selection and increases comparability of results between different series of patients with challenging anatomy. **Chapter 7** contains tips and tricks for optimization of planning of the procedure and stentgraft deployment in patients with challenging aneurysm neck morphology. **Chapter 8** describes the effect of the EVAR procedure on angulated aneurysm necks, and in **Chapter 9**, the additional value of aneurysm volume measurements over diameter measurements is studied. **Chapter 10** contains the results of the first 100 patients after EVAR with a new, latest generation stentgraft, performed in three high-volume Vascular Surgery Centers.

PART 2

Stanford type B Aortic Dissections, were also a planned subject of research. Type B dissections are detected less frequently than AAAs with a reported incidence of 3 to 8 per 100,000[15]. The current consensus entails that acute, uncomplicated Type B dissections should be treated conservatively and that acute, complicated pathology (eg, malperfusion or refractory pain) should be treated by endovascular sealing of the dissection flap at the entry[16]. However, with a non-operative approach for uncomplicated type B dissections, the survival rate after 1 month and 3 years is only 91% and 77%, respectively[15,17]. Hence, the indication, timing, and results of the conservative and operative treatment are still matter of debate and depend on the natural course of the disease in individual patients. Therefore, it was planned to investigate the prognostic value of morphologic characteristics of Acute Type B dissections.

Since Acute Type B dissections are seen less frequently, (international) collaborations between high-volume institutions are essential for performing research in this area. For many years, the Departments of Vascular Surgery of the Yale University School of Medicine in New Haven, Connecticut, USA, the Erasmus Medical Center in Rotterdam, the Antonius Hospital Nieuwegein and the University Medical Center Utrecht and the Departments of Cardiovascular Surgery of the University of Milano, Italy and the Antonius Hospital Nieuwegein have build an effective research collaboration focusing on diagnostic imaging and treatment of aortic diseases. These efforts have resulted in successful PhD graduations[18-22] and international publications in high-impact factor peer-reviewed journals.

The author of this thesis started this project at the University Medical Center Utrecht in April 2009. In 2010, he went to New Haven, Connecticut, for a one-year research fellowship to work on the second part of this thesis. In February 2011, he traveled to Milano, for a three-month research fellowship. On February 11th he became involved in a tragic car accident, that caused his death on February 12th, 2011. He was 26 year old.

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AORTIC ARCH BIOMECHANICS: DIFFERENCES DEPENDING ON THE PATHOLOGY

J.W. van Keulen, J.A. van Herwaarden, B.E. Muhs, F.L. Moll

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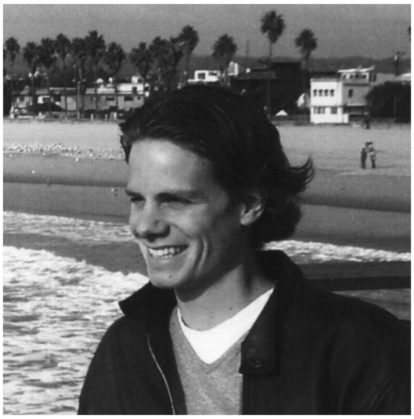
The aortic arch not only is an interesting and separate part of the aorta due to its embryology, but also due to its morphology, proximity to the heart, side branches and different pathologies that can possibly affect it. The biomechanics in the aortic arch play an important role in the endovascular treatment of diseases of the aortic arch and its side branches. The pulsatility of the aorta and its side branches per cardiac cycle, the heartbeat dependent out-of-plane movement of the aorta and its side branches and all other morphologic arch factors might play an important role in the endovascular treatment of several diseases of the aortic arch. An overview of the embryology of the aortic arch, the aortic arch dynamics and biomechanics and its potential influences on different pathologies and its endovascular treatments is given in this chapter.



2 april 1984 - 12 februari 2011

In memoriam,

Jasper van Keulen (26 years old) was a medical doctor doing his PhD thesis on Dynamics of the Aortic Arch, the Descending and Abdominal Aorta, at the departments of vascular surgery of the University Utrecht, the Netherlands and the Yale University, USA. For his study, he was collecting patient data on Thoracic Aorta Dissections when he died in a car accident close to Milan, Italy on 12th February 2011. As a researcher, Jasper had the exceptional ability to take a novel research question from concept to publication with an amazingly short time period. For those, who had the opportunity to get to know Jasper as a colleague, they respectfully remember his devotion to his family, natural likeability, compassion, loyalty and sense of humour. A promising career has come to an abrupt stop and a beloved colleague has gone.
On behalf of the co-authors, Frans Moll, UMC Utrecht, the Netherlands.

INTRODUCTION

The ascending aorta, aortic arch and descending aorta are not only clinical subdivisions of the aorta, but are from the early embryologic beginning actual distinct parts of the aorta. The ascending aorta and aortic arch arise from fetal pharyngeal arches derived from neural crest cells, while the descending thoracic and abdominal aorta are formed by dorsal migration of the endocardial mesenchyme.[1-5] Some believe these differences in development account for the distinctive pathophysiology in the aortic arch and descending thoracic and abdominal aorta.[6]
The aortic arch not only is an interesting and separate part of the aorta due to its embryology, but also due to its morphology, proximity to the heart, side branches and different pathologies that can possibly affect it. Congenitally and genetically determined diseases, inflammatory diseases, degenerative diseases, and dissections and aneurysms can all affect the aortic arch and its side branches. Moreover, all these different pathologies require different (endovascular) treatments.
The biomechanics in the aortic arch play an important role in the endovascular treatment of diseases of the aortic arch and its side branches. The pulsatility of the aorta and its side branches per cardiac cycle, the heartbeat dependent out of plane movement of the aorta and its side branches and all other morphologic arch factors might play an important role in the endovascular treatment of several diseases of the aortic arch.[7] An overview of the embryology of the aortic arch, the aortic arch dynamics and biomechanics and its potential influences on different pathologies and its endovascular treatments is given in this chapter.

EMBRYOLOGY: AORTIC ARCH DEVELOPMENT

The first pharyngeal arches develop after 2224 days of embryologic development and these arches are supplied by arteries, the pharyngeal arch arteries. Between days 26 and 29, the second, third, fourth and sixth aortic arches arise bilaterally, all within their respective pharyngeal arches.[1-4] All these pharyngeal arteries arise from the aortic sac, a vascular expansion at the cranial end of the truncus arteriosus. On the dorsal side, these pharyngeal arch arteries are connected to a then still bilaterally present (left and right) dorsal aorta. The dorsal aortae remain separated and do not fuse in the thorax until during the 4th week of gestation. The right and left caudal thoracic aorta then fuse and thereby form 1 midline dorsal aorta. The left and right cranial dorsal aortae remain separated.[1-4]
Six pairs of pharyngeal arches usually develop, but they are not all present at the same time. The first two arches already regress as the later arches rise. On day 28, when the first arch is regressing, the third and fourth aortic arches arise. Remnants of the first pharyngeal arches form parts of the maxillary arteries, and may also contribute to the formation of the external carotid arteries. Remnants of the second pharyngeal arches form the stems of the stapedial arteries. By day 35, the dorsal aortic segments connecting the

third and fourth arch arteries disappear on both sides of the body (the third arch arteries thus remain only connected to the aortic sac), and the third arch arteries give rise to the right and left common carotid arteries, and the proximal portion of the internal carotid arteries.[1-4]
After seven weeks, the right dorsal aorta loses its connection with both the caudally fused midline dorsal aorta and the right sixth arch, but remains connected to the right fourth arch. The definitive right subclavian artery is derived from the right fourth pharyngeal arch artery and a short segment of the right dorsal aorta, and the right seventh intersegmental artery. Intersegmental arteries are side branches of the dorsal aorta, and the left 7th intersegmental artery ultimately forms the left subclavian artery.[1-4]
The left fourth pharyngeal artery remains connected to the dorsal aorta and the aortic sac. The left fourth arch artery will then form the aortic arch, together with a small segment of the aortic sac and the most cranial part of the descending aorta.[1-4]
The fifth pharyngeal arch arteries are rudimentary vessels that soon degenerate in 50%, and in the other 50% these arteries do not even develop.[1-4]
The connection of the right sixth arch artery and the dorsal aorta disappears after seven weeks, and this artery forms the right pulmonary artery. The left sixth arch artery remains complete, and forms the left pulmonary artery and the ductus arteriosus.[1-4]
The part of the aortic sac connected to the right fourth artery will form the branchiocephalic artery. Moreover, the proximal aorta from the aortic valve to the left carotid artery arises from the aortic sac. The left dorsal aorta will develop in into the descending thoracic aorta.[1-4]

ARCH DYNAMICS

Heartbeat dependent expansion of the aortic arch and displacement of its side branches may be important factors in the endovascular management of several diseases of the arch and its side branches.

Aortic arch dynamics

In a study investigating six patients with thoracic aortic aneurysms (TAA), the mean distension 1 cm proximal to the brachiocephalic trunk was found to be 1.8 mm per heartbeat (range 1.1 - 2.5).[7,8] The mean pulsatility 1 cm proximal to the left subclavian artery (LSCA) was 1.5 mm (range 0.9 - 2.3), and 1 cm distal to the LSCA 1.5 mm (range 1.1 - 1.7) per heartbeat.[7,8] This distension in all these patients was also measured after thoracic stentgraft placement, and was found to be comparable to the preoperative distension and had not changed.[7,8]
The distension in the ascending thoracic aorta was earlier studied in patients with an abdominal aortic aneurysm (AAA).[9] These studies found the mean distension to be 4.9 mm (range 2.3 - 7.5 mm) 5 mm distal from the coronary arteries, 3.9 mm (range 2.4 - 6.2 mm) halfway along the ascending aorta and 2.0 mm (range 3.0 - 6.8 mm) 5 mm proximal to the brachiocephalic trunk.[9] In another study, also investigating the aortic heartbeat dependent distension in AAA

patients, the dynamics in the aortic arch and descending thoracic aorta were studied.[10] The pulsatility 1 cm proximal to the LSCA was found to be 2.7 mm per heartbeat (range 1.8 - 3.4 mm), 1 cm distal to the LSCA 2.8 mm (range 2.2 - 3.6 mm), 3 distal to the LSCA 3.1 mm (range 2.1 - 5.1 mm) and 3 cm proximal to the celiac artery 2.6 mm (2.0 - 3.2 mm).[10] The pulsatility of the thoracic aorta as shown in several studies should be taken into account when sizing, selecting and designing aortic stentgrafts, though the actual clinical value of the dynamics is unknown.

The aorta is not only shown to expand significantly per heartbeat, but the aorta also moves as a whole in the thorax per heartbeat.[9] It was shown in 15 AAA patients that 5 mm distally to the coronary arteries, the center of the aorta moves 6.1 mm out of plane[9]. More distally, this movement of the aorta in thoracic cavity is less outspoken, and halfway the ascending aorta the displacement was shown to be 3.6 mm while proximal to the brachiocephalic artery it was shown to be 2.3 mm.[9]

Aortic side branches dynamics

The movement of the center of the brachiocephalic trunk, left common carotid artery and LSCA per heartbeat was investigated in 15 patients at 10 mm and 20 mm from their origin of the aortic arch[9]. These side branches of the aortic arch were shown to displace significantly per heartbeat at both levels. The brachiocephalic trunk was shown to displace 1.9 and 1.8 mm at respectively 10 and 20 mm of its origin.[9] The left common carotid artery displaced 2.4 and 1.8 mm and the LSCA 1.9 and 1.9 mm at respectively 10 and 20 mm of its origins.[9] These movements of the side branches should be taken into account when placing stents in these side branches of the arch to treat, for instance stenosing diseases.

DIFFERENT PATHOLOGIES

Arterial stenosis

Aortic atherosclerosis is the most common disease of the aorta, although it mainly affects the abdominal tract.[11] Atherosclerosis of the aorta can lead to stenosis, aortic dilatation or thrombus formation, plaque ulceration or systemic embolism.[11]

Atherosclerosis of the side branches of the aortic arch is a rather common problem, and can be treated in various ways.[12-14] Endovascularly, percutaneous transluminal angioplasty (PTA) with or without stent placement can be performed.

The results of PTA with or without stent placement for brachiocephalic trunk stenosis in a total of 72 patients have been published recently.[14] Transfemoral PTA, with or without stent placement, was shown to yield acceptable results with a technical success rate of over 90%, no deaths or major neurological complications, and a primary patency rate of 70% after 96 months.[14] There is, however, no evidence that stenting is superior to PTA alone for brachiocephalic trunk stenosis.

Carotid artery angioplasty and stenting (CAS) are alternatives to carotid endarterectomy (CEA) for the treatment of carotid artery stenosis. The 30-day results of the international carotid stenting study (ICSS) reported that patients randomized to CEA had a significantly lower procedural risk than patients randomized to stenting (8.5% after CAS versus 5.1% after CEA).[15] The 30-day outcomes for carotid artery stenting from 2 prospective studies, on the other hand, showed that the stroke rate in patients aged <80 years was only 5.3% and the authors concluded that CAS might be preferable over CEA in selected subgroups.[16] These selected subgroups still have to be identified and there is currently no level I evidence supporting the routine use of carotid artery stenting in standard risk symptomatic patients.[17]

The exact role of carotid artery stenting in the treatment of carotid artery stenosis is unknown and ongoing clinical trials will likely provide additional evidence on the use of carotid artery stenting.[18,19]

PTA and stenting of the left subclavian artery have shown to be good treatment options for stenosis or even occlusion of this artery.[20-23] The technical success rate of PTA or stenting of the LSCA is over 90%, with few complications. The primary patency rates after PTA or stenting of the LSCA are around 70-90% after 1 to 5 years.

The placement of a stent in highly calcified lesions or in patients with significant residual stenosis after earlier PTA might be preferable over PTA alone. Self expandable or balloon expandable stents can both be used to treat focal atherosclerosis in the aortic side branches. The risk of stent fracture might, however, be larger for balloon expandable stents than for self expandable stents.[24,25] Fractures of balloon expandable stents might be the result of a potentially harmful effect of balloon inflation of the device, which possibly has a negative impact on the (micro) structure of the stent.[24,25]

The most optimal stent design is, however, currently not known and is probably not the same for different plaques in different locations. A stent design that minimizes unnecessary chronic trauma to arteries is, to prevent restenosis, likely to be preferable. In order to minimize these stresses, a more compliant stent might be desirable in calcium rich, rigid plaques.[26] In softer plaques, however, a more rigid stent design could be implanted.[26] On top of this, to prevent instent restenosis, stents with an active coating might be used. These so called drug eluting try to locally stop proliferation and hyperplasia of vascular cells, thereby eventually preventing in stent restenosis.[27]

We believe that, given the earlier described movement of the side branches of the aorta, it is important to entirely place a stent in the affected aortic arch side branch, if possible. This should be done to minimize the chance of breakage of a stent at the site of side branch attachment to the aortic arch[24] (*Figure 1*).

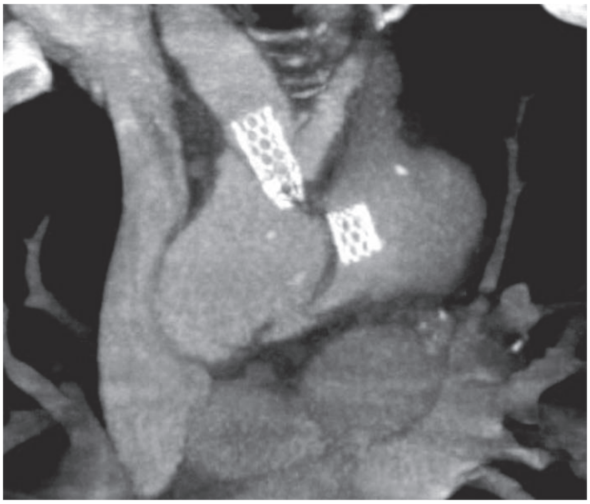


Figure 1: *A coronal reconstruction of a computed tomography angiography is shown. This is an image of a patient wherein a stent placed in the brachiocephalic artery broke during follow-up.*

Takayasu arteritis, which is a noninfectious vasculitis, often involves the aortic arch and its main branches and can lead to lumen stenosis or obstruction. The stenosis or obstruction in a Takayasu arteritis is the result of a panartritis, which eventually results in thickening of the vessel wall. The most optimal endovascular treatment of aortic arch side branch stenosis due to Takayasu arteritis is currently unknown.[28]

Dilating diseases

Degenerative, congenital or inherited, and inflammatory aortic diseases can all lead to aortic aneurysms. Thoracic aortic aneurysms can be treated by endovascular placement of a stentgraft. The morphology of an aortic arch is important in the planning and sizing of an endovascular exclusion of an aortic aneurysm. The angulation of the arch, proximal diameter, distal diameter and the length of the sealing and fixation zones are all important factors for endovascular repair. Moreover, aortic dynamics should be taken into account when designing and (over) sizing stentgrafts.

Stentgrafts that allow distension, for instance Zor Mshaped stents, might therefore be preferable over stents that allow less distension, as for instance ring stents. A stentgraft that is placed in the aortic arch should also be highly flexible, to allow for optimal apposition in the angulated arch. Moreover, when performing a fenestrated procedure, one should take the movement of the aortic side branches and its potential results during follow-up into account.

Dissections

Aortic dissections can be clinically subdivided into those involving the ascending aorta (Stanford type A) and those sparing the ascending aorta (Stanford type B). Here, we will focus on type B aortic dissections. Only the complicated acute type B dissections require direct intervention and endovascular stentgraft placement is a viable option in those patients. In patients with dissections, there are some specific problems to be taken into account. First, sizing is difficult in patients with a dissection since the actual size of the affected true lumen is unknown. On top of this is sizing in dissection patients most often performed with the use of static CTA or MRA images. The intimal flap is, however, shown to move significantly per heartbeat.[29] Second, the aortic wall is likely to be more fragile in patients with a dissection than in patients with an aortic aneurysm. Less oversizing, less radial force of stentgrafts and an absence of anchoring pins may therefore possibly lead to better results.[30] Moreover, a stentgraft in dissection patients will most likely have sealing over the entire length of the stentgraft, while in an aneurysm the stentgraft only has proximal and distal sealing and fixation zones. Stentgrafts specifically designed for the treatment of acute type B dissections are therefore required and there are some of these stentgrafts on the market. Stentgrafts with an absence of a proximal bare stentring, and entirely bare stents have been developed and are currently available for the treatment of aortic dissections.

CONCLUSION

Aortic arch biomechanics affect different aortic pathologies and endovascular treatments in different ways. The actual clinical consequences of these aortic arch biomechanics are not known but are likely to play an important role in the endovascular treatment of different pathologies

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2

DYNAMICS OF THE AORTA BEFORE AND AFTER ENDOVASCULAR ANEURYSM REPAIR: A SYSTEMATIC REVIEW

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ABSTRACT

Objective: An overview of the knowledge of thoracic (TAA), and abdominal aortic aneurysm (AAA) dynamics, before and after endovascular repair, is given.

Methods: Medline, EMBASE and the Cochrane database were searched for relevant articles. After inclusion and exclusion, 25 relevant articles reporting on aneurysm dynamics remained, allowing for comparison. Results provided in the included studies were assumed (statistically) significant if they were larger than the repeatability of the used method.

Results: The sample size of dynamic studies is limited and translational studies are missing. Magnetic resonance angiography (MRA) and computed tomographic angiography (CTA) were shown to have lower inter-observer variabilities than ultrasonography (US). The distension of several relevant stent-graft-landing zones during the cardiac cycle in both the abdominal and thoracic aorta are significant (mean diameter change of the AAA neck in the included studies ranged from 0.9 mm to 2.4 mm; mean area change of the thoracic aorta ranged from 4.8% to 12.7% at various levels). This distension remained preserved after stent-graft placement. Preoperatively, the renal arteries displace per heartbeat. Significant movement of the aorta in the anteroposterior (AP) and lateral direction, during the cardiac cycle, was observed.

Conclusion: The aorta exhibits a wide variety of morphologic changes throughout the cardiac cycle. CTA and MRA are reliable modalities to investigate aortic shape changes during the cardiac cycle. Significant changes per heartbeat are reported in the AAA neck and thoracic aorta. The renal artery displaces per heartbeat. The clinical relevance of dynamic imaging has not been proven yet, but dynamic changes of the aorta have to be taken into account in stent-graft selection and future stent-graft design.

Since being first described in 1991, endovascular aneurysm repair (EVAR) has become the preferred treatment for abdominal aortic aneurysms (AAAs) in properly selected patients.[1] The thoracic counterpart of the AAA, the thoracic aortic aneurysm (TAA), was treated endovascularly (TEVAR) for the first time in 1994 by Dake et al.[2] Although the reported complication rates of TEVAR are higher than those of EVAR, TEVAR has favourable results when compared to open thoracic aneurysm repair.[3] Currently, the primary challenge in aortic stent-grafting is to improve stent-graft durability, as there is a risk of late EVAR failure - aneurysm rupture or conversion - of 2-3% per year.[4,5]

When selecting patients for EVAR and TEVAR, careful preoperative assessment of aortic morphology is mandatory. The proximal and distal landing zones are especially relevant to achieve a durable result.[5-7] In most clinical practices, the modality of choice for preoperative evaluation is computed tomographic angiography (CTA), although magnetic resonance angiography (MRA) can also be used.[8] In general, the CTA protocols used acquire static images of the aorta, which, with the current highspeed CT acquisition times, could be at any random moment during the cardiac cycle. However, dynamic ECG-triggered CTA, ECG-gated MRI, ultrasonography (US) and intravascular ultrasound (IVUS) studies have reported that the aorta changes significantly during the cardiac cycle.[9-17]

The use of static images to visualise a dynamic aortic environment could lead to preoperative over-or undersizing of a stent graft. This could possibly be an explanation for the fact that postoperative stent-graft-related complications (e.g., type I endoleaks and migration) are still being observed.[11] Therefore, the use of dynamic imaging could lead to better stent-graft sizing and subsequently, an improved outcome. In addition, dynamic imaging is slowly providing insight into the causative mechanisms of stentgraft-related complications. More knowledge in this field could improve future stent-graft results and durability. The use of dynamic imaging also yields valuable information for improvement of stent-graft design. Besides prevention of complications, another application of dynamic imaging could be to provide insight into whether an aneurysm is excluded successfully.[16,18,19]

We hypothesise that the cardiac-dependent aortic distension is significant at several for (T) EVAR-relevant levels, which may possibly have clinical consequences. The purpose of this study is to show the current state, use and possible consequences of dynamic imaging of the aneurysmal aorta. By means of a systematic review, an overview of the knowledge of thoracic and abdominal aortic dynamics in patients with aortic aneurysmal disease, both before and after endovascular repair, is given.

METHODS

The search strategy and data collection in this study are based on the search strategy and data collection guidelines of the Meta-analysis Of Observational Studies in Epidemiology (MOOSE).[20]

Search strategy

Medline, EMBASE and the Cochrane databases were searched on 25 September 2008. No publication date or language restrictions were applied. The following search query was used in Medline: "(((Abdominal [TIAB] OR Thora* [TIAB] OR thoracoabdominal [TIAB] OR Aortic [TIAB]) AND (aneurysm* [TIAB] OR endograft* [TIAB] OR endoprosthe* [TIAB])) OR AAA [TIAB] OR TAA [TIAB]) AND (dynamic* [TIAB] OR ((ECG [TIAB] OR EKG [TIAB] OR electrocardiogram [TIAB]) AND (triggered [TIAB] OR Gated [TIAB])) OR ecgtriggered [TIAB] OR ekg-triggered [TIAB] OR ecg-gated [TIAB] OR ekg-gated [TIAB] OR Cine* [TIAB] OR motion OR movement [TIAB] OR distensibility [TIAB] OR distention [TIAB] OR pulsatility [TIAB] OR pulsation [TIAB])". "[TIAB]" is the abbreviation used for Title/ Abstract in Medline, and demands the presence of the preceding text in either the title or the abstract of the article. This search in Medline generated 751 articles. The same search strategy was used in EMBASE (only "[TIAB]" had to be exchanged for ":ti, ab"), rendering 672 articles.

Medline and EMBASE search strategy yielded a total of 1423 possibly relevant articles. The Cochrane library was manually searched, yielding no relevant articles. Duplicates were removed manually, and 879 potentially relevant articles remained (Fig. 1). We did not systematically search for unpublished data or abstracts.

Data collection

Titles and abstracts of 879 articles were independently read and examined by two observers. Inclusion criteria were: (1) examination of aortic or aortic side branch dynamics before or after endovascular aortic aneurysm repair or (2) examination of aortic dynamics in patients with aortic aneurysmal disease. Thirty-two full-text versions of studies that matched the inclusion criteria were obtained.

All full-text articles were examined by two observers. Studies were excluded if they met one of the exclusion criteria. The exclusion criteria were (1) non-systematic reviews, (2) non-human studies and (3) dynamic imaging for visualisation and detection of pathology other than aneurysmal disease (e.g., dissection and endoleak). Disagreements between the observers were resolved by discussion.

After criticising the full-text version of 32 articles, 23 studies that met the inclusion and exclusion criteria remained. Four articles were excluded because in these studies dynamic imaging was used for visualisation of pathology other than aneurysmatic aortic disease.[21-24] In addition, one non-human study[25] and one non-systematic review[17] were excluded. Another article was excluded because no full-text version could be retrieved.[26] Finally, two studies were excluded because the authors did not report on patients with aortic aneurysms.[27,28] Reference lists of all included articles were searched manually, yielding two more eligible articles (Fig. 1).[9,29]

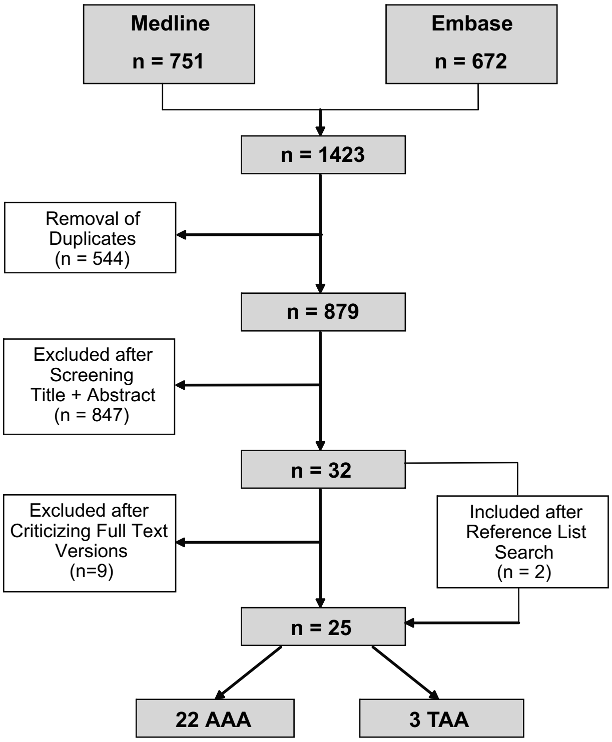

Figure 1: *Flowchart of the systematic review.*

Data extraction

Data were collected independently by two authors. The following characteristics were, if available, extracted out of the 25 included studies: data on author, publication year, study design, number of patients, age and sex of patients, aneurysm size, radiological modality, method, time and levels of measurement, difference between minimum and maximum expansion of the aorta, distensibility, used stent types, p values and reproducibility of the used method.

The data from the included articles are presented as results per individual study; a pooled analysis is not performed. The differences per heartbeat between the minimum and maximum aortic area, diameter or circumference are presented in absolute values or percentages (of the minimum value). Movement of the renal arteries is presented as displacement of the centre of mass of the renal arteries. Results provided in the included studies were assumed (statistically) significant if they were larger than the reported repeatability of the used method. It is important to acknowledge that if mean or median changes are not assumed significant, then maximum changes can be.

RESULTS

Twenty-two of the included studies investigated dynamic movement of the abdominal aorta, and three of the thoracic aorta. Ten of all these studies evaluated abdominal aortic changes both before and after (T)EVAR. All other studies described aortic movements only before or after aneurysm repair.

US, IVUS, CTA and MRA

The inter-observer variability (IV) of the different used modalities is shown in Tables 1-4. IVs of US for abdominal aortic diameters of 10%[19],16%[19] and 22%[16] were described. Reported IVs of intravascular US for diameters were 0.9 mm and 1.0 mm.[30] CTA had reported IVs for abdominal aortic diameter (area) of 1.62 mm (6.6 mm^2)[14] and 3.84 mm (20.8 mm^2).[14] In the thoracic aorta, the reported IVs of CTA were 0.7 mm (36.5 mm^2),[39] 1.0 mm (44.8 mm^2)[37] and 1.1 mm (61.4 mm^2).[38] For MRA, Vos et al. reported a reliability coefficient of 0.81 for MRA, while others reported IVs for diameters measured on MRA of 0.27 mm,[18] 1.0 mm[11] and 1.8 mm.[11]

Dynamic changes of the proximal AAA neck

Five studies were designed to study the influence of stent grafts on aortic neck distension during the cardiac cycle.[11-14,30] Results of all individual studies are shown in Table 1. A summarisation of the preoperative results 1 cm below the most distal renal artery can be found in Table 5 .

The results of these studies are rather homogeneous. Before EVAR, the mean (or median) distension 1 cm below the most distal renal artery was significant, if reported, in most studies. The mean (or median) aortic diameter increase per heartbeat at this level was more than 1.6 mm in all studies. Maximum diameter increases of 14.0%[14] and 12.0%[11] at this level were described. Measured values in between, or above, the renal arteries did not show striking differences with values 1 cm below the most distal renal artery.[11-14] Postoperatively, the mean (or median) distension 1 cm below the most distal renal artery was at least 2.0 mm, and significant, in all studies. These values were not significantly different from pre-EVAR values in all studies.[11,12,14]

Arko et al. studied the displacement of the AAA neck per heartbeat. There was significant displacement in both the AP (mean 1.7 mm; standard deviation (SD) ±0.6, range: 0.6-2.7) and lateral direction (mean 0.9 mm; SD ±0.5, range: 0.3-1.5).[30] Flora et al. demonstrated earlier in four patients that during open surgery the AAA neck moves in the lateral (range: 1.0-1.5 mm) and longitudinal direction (range: 0.6-1.0 mm).[40]

Table 1: Aortic distension at the level of the AAA neck. The change (mm) is the difference between the minimum and maximum given value (diameter or circumference) per cardiac cycle. All given values are mean, unless stated otherwise.

Author	AAA (n)	Method	Measured	Measured at	B/A EVAR	Stent type	Minimum diameter (mm)	Change (mm)	Range	P value B/A	Reproducibility
Teutelink, 2006[13]	10	CTA	Circumference	Middle of aneurysm neck	B	-	-	2.2a	-	-	-
Herwaarden, 2006[11]	11	MRA	Diameter	X: 3 cm above RA Y: Between RA Z: 1 cm below RA	B	Talent/ Excluder	X: 23.6 Y: 23.2 Z: 23.4	X: 2.0 Y: 1.6 Z: 1.6	X: 0.7-4.2 Y: 0.3-3.6 Z: 0.6-3.6	NS	IV 1.0 mm
					A		X: 22.8 Y: 22.4 Z: 22.9	X: 2.4 Y: 1.9 Z: 2.2	X: 1.0-4.6 Y: 0.4-4.2 Z: 0.8-4.5		IV 1.8 mm
Arko, 2007[30]	25	IVUS	Diameter	1 cm below RA	B	e	Lateral: 25.0 AP: 24.7	Lateral: 0.9 AP: 1.7	-	-	IV Lateral 0.9 mm IV AP 1.0 mm
Teutelink, 2007[14]	15	CTA	Diameter	X: 2 cm above RA Y: 1 cm below RA	B	Talent 11/ Excluder 4	X: 24.0 Y: 21.0	X: 1.0 Y: 2.0	X: max 11% Y: max 14%	NS	IV 3.84 mm
					A		X: 23.0 Y: 22.0	X: 2.0 Y: 2.0	X: max 11% Y: max 15%		IV 1.62 mm
Herwaarden, 2006[12]	11	MRA	Diameter	X: 3 cm above RA Y: Between RA Z: 1 cm below RA	B	Talent 7/ Excluder 4	Median X: 24.0 Median Y: 23.7 Median Z: 21.8	Median X: 1.8 Median Y: 1.4 Median Z: 1.7	-	NS	IV 1.0 mm
					A		Median X: 22.4 Median Y: 22.7 Median Z: 22.2	Median X: 2.1 Median Y: 1.7 Median Z: 2.4	-		IV 1.8 mm

B = before, A = after, RA = renal artery, IV = inter-observer variability. Max = maximum increase. Talent (Medtronic, Minneapolis, MN, USA), Excluder (Gore, Flagstaff, AZ, USA).
[a] Exact values not stated in article.

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Table 2: Aortic distension at the level of the maximum AAA diameter. The change is the difference between the minimum and maximum given value (diameter, circumference or area) per cardiac cycle. All given values are median, unless stated otherwise.

Author	AAA (n)	AAA diameter (mm)/ Area (cm^2)	Method	Measured	Stent type	B/A EVAR	Change	P value B/A	Reproducibility
Ganten, 2008[31]	67	Mean 48 (SD 13)	CTA	Diameter	-	B	Mean 1.5 mm (SD 0.8)	-	-
Teutelink, 2006[13]	10	-	CTA	Circumference	-	B	Mean 2.8 mm	-	-
Lindblad, 2004[19]	111	55 (IQR 51-64)	US	Diameter	-	B[a]	0.96 mm (IQR 0.74-1.32)[a]	<0.0001	B IV 16%
						A[a]	0.24 mm (IQR 0.07-0.41)[a]		A IV 10%
Vos, 2003[32]	7	61 (R 46-75)	MRA	Area	AneuRx/Talent	B	0.25 cm2 (R 0.07-0.29)	0.79	-
						A	0.18 cm2 (R 0.08-0.42)		
Vos, 2002[10]	21	ED area 28 cm^2 (IQR 22-31)	MRA	Area	-	B	0.25 cm2 (IQR 0.1-0.4)		RC 0.81
Malina, 1998[16]	47	52 (R 38-84)	US	Diameter	15 Chuter/ 32 Ivancev-Malmo	B	1.0 mm (R 0.8-1.3)	<0.001	IV 22%
						A[a]	0.3 mm (R 0.2-0.4)[a]		
Faries, 2003[18]	16	Mean 64 (R 57-72)	MRA	Diameter	16 Talent	B	Mean 3.51 mm (SD 0.79)	<0.001	IV 0.27 mm
						A[a]	Mean 0.12 mm (SD 0.09)[a]		
Long, 2004[33]	35	Mean 39 (SD 9)	US	Diameter	-	B	Mean 0.81 mm (SD 0.46)	NA	[b]
Herwaarden, 2006[12]	11	56.5 (R 47.4-71.5)	MRA	Diameter	Talent 7/Excluder 4	B	1.0 mm	NS	B IV 1.0 mm
						A	1.5 mm		A IV 1.8 mm

B = before, A = after, SD = standard deviation, IQR = interquartile range, R = range, NS = not significant, IV = inter-observer variability, ED = end diastolic, RC = reliability coefficient.

[a] Subgroup without EL.

[b] Mean difference diameter change intraobserver (RC = 2SD = 95% limit of agreement); Acquisition: 24 μm (RC562); 23 μm (457); 4.3 μm (583); Mean difference diameter change intraobserver: Reading -1 μm (RC 327); -21 μm (RC 374). AneuRx, Talent (Medtronic, Minneapolis, MN, USA), Excluder (Gore, Flagstaff, AZ, USA).

Table 3: Elastic modulus (EP, N/cm²) and stiffness (b, arbitrary units). All given values are median, unless stated otherwise.

Author	AAA (n)	Method	Measured at	B/A EVAR	Minimum diameter (mm)	N/cm²	β (AU)	P value B/A	Reproducibility
Sekhri, 2004[15]	20	US	X: AAA neck Y: inflection point Z: mid sac	B	X: 26.9 (R 19.5-41.9) Y: 32.0 (R 22.3-48.2) Z: 55.5 (R 33.5-74.0)	X: 13.0 (R 6.4-19.4) Y: 24.2 (R 13.9-39.8) Z: 26.4 (R 11.9-49.5)	X: 8.7 (R 4.6-12.6) Y: 16.3 (R 9.9-23.7) Z: 17.9 (R 8.5-37.8)	-	-
Long, 2004[33]	35 11	US	Dmax AAA	B	39 (SD 9)	Mean: 39.4	Mean: 28.8	-	[b]
Herwaarden, 2006[12]		MRA	W: 3 cm above RA X: Between RA Y: 1 cm below RA Z: Dmax AAA	B	W: 24.0 X: 23.7 Y: 21.8 Z: 55.5	W: 10.2 X: 13.1 Y: 11.6 Z: 42.0	W: 6.8 X: 8.2 Y: 8.1 Z: 27.9	EP Y, β Z significant	-
				A	W: 22.4 X: 22.7 Y: 22.2 Z: 54.3	W: 8.2 X: 9.3 Y: 7.9 Z: 37.0	W: 6.5 X: 7.7 Y: 6.5 Z: 35.8		-
Wilson, 2003[9]	210	US	Dmax AAA	B	Dmax 47.8 (IQR 41.0-53.5)	29.3 (IQR 20.6-43.8)	20.2 (IQR 15.0-29.5)	-	IV EP 21.2% IV β 17.6%
Wilson, 1999[34]	60	US	Dmax AAA	B	Dmax 43 (R 29-67)	24.2 (R 5.5-94.6)	17.7 (R 4.0-57.3)	-	-
Wilson, 1998[29]	89	US	Dmax AAA	B	Dmaxa 45.0 (R 28.8-77.1)	27.9 (R 0.55-9.46)[a]	18.2 (R 4.0-71.6)[a]	-	-
Macsweeney, 1992[35]	30	US	Dmax AAA	B	Dmax R 30-100	31.3 (R 10.0-84.0)	-	-	E_p CR 15
Wilson, 2001[36]	28	US	Dmax AAA	B	Dmax 44 (IQR 40-51)	30.0 (IQR 22.0-49.0)	-	-	IV EP 21.2% IV β 17.6%

B = before, A = after, IV = inter-observer variability, R = range, IQR = interquartile range, RA = renal artery, Dmax = maximum diameter, CR = coefficient of repeatability, NS = not significant.

[a] Only non-operated and non-ruptured patients.

[b] Mean difference diameter change intraobserver (RC = 2SD = 95% limit of agreement); Acquisition: 24 μm (RC562); 23 μm (457); 4.3 μm (583); Mean difference diameter change intraobserver: Reading -1 μm (RC 327); -21 μm (RC 374).

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Table 4: Distension in the thoracic aorta. The change is the difference between the minimum and maximum area per cardiac cycle. All given values are mean.

Author	AAA (n)	Method	Measured	Measured at		Change	P value B/A	Reproducibility
Muhs, 2006[37]	10	CTA	Area	W: 1 cm proximal to LSA X: 1 cm distal to LSA Y: 3 cm distal to LSA Z: 3 cm proximal to celiac trunk		W: 33.1 (4.8%; R 2.7-6.9%) X: 33.2 (5.0%; R 3.9-6.9%) Y: 36.0 (5.5%; R 3.0-10.8%) Z: 37.9 (7.0%; R 3.2-11.2%)	-	IV 44.8 mm^2
Prehn, 2007[38]	15	CTA	Area	W: 5 mm distal to CA X: 5 mm proximal to branchiocephalic trunk Y: halfway up the ascending aorta		W: 92.9 (12.7%; R 4.3-21.8%) X: 58.6 (7.5%; R 4.1-11%) Y: 47.5 (5.6%; R 1.9-11.4%)	-	IV 61.4 mm^2
Prehn, 2008[39]	6	CTA 6 Relay stents	Area	V: 1 cm proximal to branchiocephalic trunk W: 1 cm proximal to LSA X: 1 cm distal to LSA Y: 1 cm proximal to proximal origin of stent graft Z: 3 cm distal to proximal origin of stent graft	B	V: 51.4 (6.3%; R 3.3-14.9%) W: 34.4 (6.2%; R 2.2-12.0%) X: 33.2 (6.3%; R 4.4-8.5%) Y: 42.6 (6.8%; R 3.4-17.5%) Z: 35.9 (6.6%; R 2.6-12.4%)	NS	IV 36.5 mm^2
					A	V: 64.5 (7.8%; R 3.0-13.7%) W: 37.7 (6.2%; R 4.4-10.0%) X: 29.6 (5.9%; R 3.0-12.3%) Y: 52.2 (7.5%; R 2.5-20.2%) Z: 27.7 (4.7%; R 2.6-6.8%)		

B = before, A = after, NS = not significant, IV = inter-observer variability, R = range. Relay (Bolton Medical, Sunrise, FL, USA).

Dynamic changes of aortic side branches

Two studies reported on the movement of the renal arteries in patients with an AAA, both before and after EVAR.[41,42] In the first study (n = 15), Muhs et al. showed that the centre of mass displacement of the renal arteries was up to 3 mm (mean 2.0 mm, SD ±0.6), measured 1.2 and 2.4 cm from the renal ostia before EVAR.[41] Infrarenal stent grafts decreased the displacement of the renal arteries 1.2 cm from the renal ostia (mean 1.4 mm SD ±0.7 (decrease of 31%)). The movement of the renal arteries 2.4 cm from the renal ostia was unaffected by EVAR. The repeatability of the used method was not quantified in this study.

In the second study (pre-EVAR n = 8, post-EVAR n = 16), by Muhs et al. as well, the influence of transrenal, infrarenal and fenestrated stent grafts on renal artery motion were compared.[42] In contrast with the first study, neither transrenal nor infrarenal stent grafts altered renal artery motion. Fenestrated EVAR, with the placement of renal stents, reduced the renal artery motion by greater than 300% (mean 0.3 mm, SD ±0.1). The repeatability of the used method was not quantified in this study.

Table 5: A summarisation of the aortic distension (mean) 1 cm below the most distal renal artery and the distension in the thoracic aorta (mean).

Proximal AAA neck		
Author	Diameter Change (mm)	Range (mm)
Herwaarden, 2006[12]	1.6	0.6 - 3.6
Arko, 2007[30]	Lateral: 0.9 AP: 1.7	-
Teutelink, 2007[14]	2.0[a]	Max 14%
Thoracic aorta		
Author	Area change (mm^2)	Range (mm^2)
Prehn, 2008[39]	V:51,4	V: 31.8 - 94.2
	W: 34.4[a]	W: 12.9 - 57.2
	X: 33.2[a]	X: 22.9 - 48.5
	Y: 42.6	Y: 22.6 - 60.4
	Z: 35.9[a]	Z: 18.9 - 56.7

The diameter or area change is the difference between the minimum and maximum given values (diameter or area) per cardiac cycle.

[a] Indicates the mean difference to be repeatability.

Dynamic changes of the AAA Sac

Nine studies reported on dynamic changes of the abdominal aortic aneurysm sac.[10,12,13,16,18,19,31-33] Results of these studies are shown in Table 2.

Before EVAR, the reported median (or mean) distension of the maximum aneurysm diameter (or area) in the included studies ranged between almost negligible[32] and more than 5% in the included studies.[18] Most studies, however, reported a median (or mean) distension of approximately 1 mm. The majority of reported median (or mean) differences were within the IV of used methods.[12,16,19,32]

After EVAR, the median (or mean) distension of the sac had decreased in three studies compared to preoperative values (from 1.0 mm to 0.3 mm[16]; from 3.51 mm to 0.12 mm[18] and from 0.96 mm to 0.24 mm[19]). On the contrary, two other studies did not report a decrease of the median AAA distension after EVAR.[10,12] Again, most found studies reported values within the variation of measurements.[12,16,19,32]
Finally, one study evaluated the displacement of the aneurysm sac as a whole during the cardiac cycle.[32] The AP movement of the aneurysm decreased from a median of 1.0 mm (range: <0.5-1.29 mm) before EVAR to within pixel size after EVAR (median <0.5 mm; $p = 0.04$). Before EVAR, the median craniocaudal translation was 1.01 mm (range: <0.5-1.51 mm), and increased significantly after EVAR to a median of 1.69 mm (range: 1.1-1.99 mm; $p = 0.02$).[32] No reproducibility of the used method was given.

AAA distensibility

Eight studies used compliance to describe aortic wall motion during the cardiac cycle.[9,12,15,29,33-36] Compliance is the relationship between stress (pressure on aortic wall) and strain (deformation of aortic wall). Aortic wall distensibility, a way to measure aortic wall compliance, is expressed as the elastic modulus (E_p).[43] Both stiffness (β) and elastic modulus are inversely related to arterial wall distension and compliance.[34] The formulas of stiffness and elastic modulus are given in Appendix 1. Results of studies measuring E_p or β are shown in Table 3.

AAA distensibility - changes of the proximal AAA neck

Two studies measured E_p and β between the renal arteries and the upper limit of the aneurysm.[12,15] E_p was 11.6 and 13.0 while β was 8.1 and 8.7.[12,15] Only one of the two studies measured E_p and β post-EVAR. Post-EVAR, E_p shifted from 11.6 to 7.9 and β from 8.1 to 6.5.[12]

AAA distensibility - dynamic changes of the AAA Sac

The distensibility of the AAA sac was studied in eight articles.[9,12,15,29,33-36] Individual results per study can be found in Table 3. Before EVAR, the median E_p ranged in the included studies from 24.2 to 42.0 N cm^{-2}.[9,12] Median β ranged from 17.7 to 28.8.[9,12,33]

Dynamic changes of thoracic aorta

There were three studies that described dynamic changes of the thoracic aorta.[37-39] One study described changes in patients with TAA, both before and after TEVAR. The study populations of the two other articles consisted of patients with known AAAs, while none of the patients had a TAA. Results are shown in Table 4 and a summarisation of the study describing the pulsatility in patients with TAA can be found in Table 5.
In the study describing changes in patients with TAA, significant distension at several surgically relevant thoracic landmarks was found. The mean differences between the minimum and maximum aortic area per heartbeat in this study group, reported from proximal to distal, were 6.3%, 6.2% and 6.3%. Postoperatively, there was significant distension at several levels.[39]

Van Prehn et al. and Muhs et al. observed the distension of the thoracic aorta in patients with AAA.[37,38] Both studies measured the aortic distension at other levels in the thoracic aorta. Mean area changes of the ascending aorta, reported from proximal to distal, were 12.7%, 7.5% and 5.6%.[38] Only the mean distension most proximal to the heart was significant. Mean area changes of the aortic arch and descending thoracic aorta, reported from proximal to distal, were 4.8%, 5.0%, 5.5% and 7.0%.[37] None of those found values was significant.

DISCUSSION

In this systematic review, an overview of the current knowledge of aortic aneurysm dynamics is given. The AAA neck diameter, the proximal stent-graft-landing zone, increases significantly per heartbeat. In all included studies, the mean preoperative aortic diameter increase at this level was at least 1.6 mm; and maximum diameter increases of 14% and 12% are described. The use of static images for stent-graft sizing techniques, acquired anywhere in the cardiac cycle, might result in incorrect sizing. Stent-graft sizing, based on submaximal aortic diameters, might lead to inadequate stent-graft sizes and subsequent improper proximal fixation, stentgraft migration and (intermittent) proximal type I endoleaks. It is shown that the mean aortic distension of the AAA neck is maintained after EVAR in all the included studies, making appropriate stent-graft sizing possibly even more important. It seems important to know whether the different types of stent-graft design are able to adapt to the continuous pulsatile aortic shape changes to remain in close contact with the aortic wall during the cardiac cycle to provide adequate stent-graft fixation and seal.

This systematic review also presents the dynamic changes of the AAA sac. Three studies suggested that the distension of the aneurysm sac decreases after EVAR in patients with well-excluded aneurysm sacs.[16,18,19] Two other studies did not find a decreased wall motion after EVAR.[12,32] Most of the included studies reported values of aneurysm sac distension within the variation of measurements. In other words, the measured distention is likely to be caused by measurement variability rather than pulsatile expansion. Besides, the degree of distension is reported to be comparable in patients with and without endoleak.[12,19] It is for these reasons that aneurysm sac distension does not allow reliable detection of patients with endoleak.

Regarding the results of TAA dynamics, it is shown that the thoracic aorta expands significantly at relevant levels per heartbeat too. Since the diameter of the thoracic aorta is larger than the diameter of the abdominal aorta, equal relative changes will result in larger absolute changes. This larger absolute aortic distension in the thorax might be a cause for the higher complication rate seen in TEVAR compared to EVAR.[3] However, this statement is purely hypothetical and clinical trials are necessary to support this hypothesis.

A disadvantage of this study is the inclusion of studies wherein different modalities have been used to measure different parameters at different levels. It is for this reason that our data could not be pooled. Ultrasound was the first modality to be used to assess pulsatile aortic wall movement during the cardiac cycle. However, the use of ultrasound is known to have some disadvantages. First, the use of ultrasound is restricted to patients with AAA, and is not applicable in patients with TAA. Second, the inter-observer variability of ultrasound is high compared to IVUS, CTA and MRA.[16,19] This is probably because ultrasound is a highly operator-dependent modality. Third, the distension of the abdominal aneurysm sac cannot be measured by ultrasound in a significant number of patients because of obesity and bowel gas.[9] The use of CTA has advantages such as high spatial resolution and acquisition of a volumetric dataset within a single breath hold, which enables retrospective construction of any chosen reformatted plane. The drawbacks of CTA are the radiation dose and the need for intravenous contrast, which can be nephrotoxic. Besides, after EVAR, stent grafts can cause artefacts (scattering) on CTA, which possibly makes measurements less reliable. MRA and IVUS have lower IV. IVUS is an invasive modality, which makes it less suitable as a (preoperative) screening tool. MRA, in contrast, offers a non-invasive method and is a reliable method of measuring the aortic distension in the cardiac cycle.[11,12,18] However, this is at the expanse of longer acquisition times, when compared to CTA. Besides, not all - although most - stent grafts are suitable for MRA.[44]

All studies included in this systematic review, irrespective of the modality used, are limited in their measurements. First, most studies measured maximum aneurysm diameters. Measurement of maximum diameters potentially overestimates distension of the aorta, because it has been observed that the pulsatile aortic expansion is asymmetrical.[11] Second, the measurements in all studies were two-dimensional at predetermined aortic levels. While the in-plane aortic movement is measured in this manner, there is no compensation for the craniocaudal out-of-plane movement. Three-dimensional volumetric analysis during the cardiac cycle could overcome this problem. Finally, all studies are limited by the small sample size used.

Despite all the observations presented in this article, the clinical relevance of aortic dynamics has not yet been proven. All the presented studies are observational studies, and none of them confirms a relationship between dynamic imaging, sizing and complication rates. However, it is imaginable that the significant aortic distension at stent-graft-landing zones might influence both short-and long-term outcomes after (T)EVAR. It is possible that (intermittent) proximal type I endoleaks or stent-graft migration might be caused by sizing based on images of the aorta acquired during the diastole. Further, when assuming sizing has been performed correctly, there still remains aortic movement, which may compromise stentgraft durability. As there seems to be an inter-individual variation in the degree of distension, the clinical relevance is probably highest in the patients with a high degree of distension. Future studies and clinical trials are necessary to study the influence of aortic dynamics on clinical outcome.

The value of dynamic preoperative imaging for improvement of patient and device selection and ultimately improvement of EVAR outcome has to be studied.

CONCLUSIONS

MRA, CTA and IVUS are reliable modalities for dynamic imaging of the aorta, although IVUS is invasive. The distension of the thoracic aorta and the AAA neck during the cardiac cycle is significant at several levels (mean diameter change of the AAA neck of 0.9-2.4 mm, mean area change of the thoracic aorta ranged from 4.8% to 12.7%). This distension is maintained after EVAR or TEVAR. The renal arteries displace per heartbeat with a mean of 1.2-2.0 mm. Dynamic imaging is not able to illustrate whether an aneurysm is excluded successfully or not, since pulsatility in the aneurysm sac is negligible. The clinical relevance of dynamic imaging has not been established yet, and future research into this area is merited.

Appendix 1

The formula for elastic modulus (E_p) is:

$$E_p\ (N{=}m^2) = K\,\frac{P_{sys} - P_{dias}}{(D_{sys}\ D_{dias})\,/D_{dias}}$$

The formula for stiffness (β) is:

$$\beta = \frac{\ln(P_{sys} / P_{dias})}{(D_{sys} - D_{dias})\,/D_{dias}}$$

K = 133.3, a constant to convert E_p from mmHg to N/m^2.
P = arterial blood pressure. D = aortic diameter.[12]

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3

THE INFLUENCE OF DIFFERENT TYPES OF STENT GRAFTS ON ANEURYSM NECK DYNAMICS AFTER ENDOVASCULAR ANEURYSM REPAIR

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ABSTRACT

Objective: Dynamic imaging provides insight into aortic shape changes throughout the cardiac cycle. These changes may be important for proximal aortic stent graft fixation, sealing and durability. The objective of this study is to analyse the influence of different types of stent grafts on dynamic changes of the aneurysm neck.

Methods: Pre-and postoperative electrocardiography (ECG)-gated computed tomographic angiography (CTA) scans were obtained in 30 abdominal aortic aneurysm (AAA) patients, 10 each from three different types of stent grafts (Talent, Endurant, and Excluder). Each dynamic CTA dataset consisted of eight reconstructed images over the cardiac cycle. Aortic area and radius changes during the cardiac cycle were determined at two levels: (A) 3 cm above and (B) 1 cm below the lower most renal artery. Radius changes were measured over 360 axes, and plotted in a polar plot. An ellipse was fitted over the plots to determine radius changes over the major and minor axis for assessment of the asymmetric aspect and most prominent direction of distension.

Results: Baseline characteristics did not differ significantly between the three groups. Preoperatively, the aortic area increased significantly ($p < 0.001$) over the cardiac cycle in all patients at both levels: (A) mean increase 8.3 ± 4.1% (2.0-17.3%); (B) mean increase 5.9 ± 4.2% (1.9-12.4%). The postoperative aortic area increase over the cardiac cycle did not differ significantly from preoperative increases: (A) mean increase 9.9 ± 2.2% (4.4-20.0%); (B) mean increase 7.7 ± 2.4% (3.8-12.4%). The difference between radius change over the major and minor axis was significant both pre-and postoperatively for all three stent grafts, indicating asymmetric distension. Suprarenal, the distension showed a tendency to right-anterior and infrarenal to left-anterior. The distension and direction of the aortic expansion was preserved after stent grafting. There were no differences between the three types of stent grafts regarding their impact on the aortic distension or direction of this distension.

Conclusion: The aorta expands significantly and asymmetrically throughout the cardiac cycle. After implantation of abdominal aortic stent grafts, the aortic distension and direction of distension remain equally preserved in all three groups. The three stent graft types studied seem to be able to adapt to the asymmetric dynamic aortic shape changes.

INTRODUCTION

The purpose of endovascular aneurysm repair (EVAR) is successful exclusion and depressurisation of an abdominal aortic aneurysm (AAA) sac by placement of a stent graft.[1] Adequate proximal sealing and fixation of a stent graft is regarded especially important in achieving a durable result after EVAR.[2] Therefore, the appropriate stent graft selection, size and design are of great value.

Stent graft selection and sizing is most commonly based on static computed tomographic angiography (CTA) scans. With the current high-speed CTA acquisition times, these images might be acquired at any time in the cardiac cycle, ranging from systole to diastole. This is important since the cardiac induced aortic wall motion, in both patients with and without AAAs, is significant at several for EVAR relevant levels.[2-5] Heartbeat-dependent diameter changes complicate stent graft sizing and selection, and the use of static CTA images alone might lead to improper stent-graft selection and sizing.

Next to this significant aortic pulsatility, it has also been noted that the expansion of the aortic aneurysm's neck in patients with an AAA is anisotropic.[2,3] Recently, this asymmetric expansion has been quantified, by both intravascular ultrasound and ECG-gated magnetic resonance imaging (MRI) studies.[3,6] In a previous study from our group, the direction of the aortic expansion above the renal arteries, the landing zone for suprarenal bare stents, showed a tendency to right anterior. Below the renal arteries, however, the tendency of the expansion was not to right, but to left-anterior.[6] It is imaginable that there might be a relationship between the (asymmetric) aortic distension and the incidence of proximal fixation-and sealing-related complications. Proximal (intermittent) type I endoleaks and stent graft migration might be prevented by the use of stent grafts that are able to adapt to the cardiac-induced aortic shape changes. Nevertheless, the extent of adaptation of (currently in-use) stent grafts to, and the influence on the aortic motions are largely unknown.

The examination of potential differences between stent grafts might lead to altered stent graft selection, and equally important, to changes in design of future stent grafts. Next to the influence on aortic area and diameter changes, it is equally important whether a stent graft is able to adapt to, or has influences on, the direction of the aortic expansion.[6] The ability or inability of a stent graft to adapt to aortic shape changes might change physiologic haemodynamic flow patterns and influence the durability results of EVAR.

The purpose of this study is to use ECG-gated CTA scans to examine aortic shape changes (area and diameter) and the asymmetric aspect of these changes at different levels in the aneurysm neck, both pre-and postoperatively, for three different types of stent grafts. Consequently, we examine the influence of these stent grafts on aortic wall motions.

METHODS

Patients

Pre-and postoperative retrospective ECG-gated CTA scans of 30 patients with AAAs (27 men, median age 72 years, range 55-90 years) were obtained for three different types of stent grafts (10 Talent (Medtronic, Minneapolis, MN, USA), 10 Endurant (Medtronic) and 10 Excluder (Gore, Flagstaff, AZ, USA)). We selected 10 consecutive patients, meeting the inclusion criteria, for the three different stent graft types out of our vascular database. Patients had to meet the following inclusion criteria: (a) AAA neck length of more than 20 mm, (b) angulation between the suprarenal abdominal aorta and AAA neck (α) of <45° and angulation between the AAA neck and the AAA sac (β) of <45° and (c) aneurysm neck diameter of <30 mm.

Imaging

All CTA scans were performed on a 64- or 256-slice helical CT scanner (Philips Medical Systems, Best, the Netherlands; values for 256-slice scanner are stated between brackets) with a standardised acquisition protocol. Scan parameters were: slice thickness 0.9 mm (0.9), increment 0.7 mm (0.7), collimation 64 × 0.625 mm (128 × 0.625) and pitch 0.25 (0.2). Field of view was 250 × 250 mm (250 × 250) and the reconstructed matrix size was 512 × 512 (512 × 512) resulting in a voxel size of 0.5 × 0.5 × 0.9 mm (0.5 × 0.5 × 0.9). Radiation exposure parameters were 120 kVp (120) and 300 mA (250), resulting in a CT dose index ($CTDI_{vol}$) of 17.6 mGy (16.5). Intravenous non-ionic contrast (120 ml) (Iopromide, Schering, Berlin, Germany), followed by a 60-ml saline chaser bolus, was injected at a rate of 6 ml/s. The scan was started using bolus triggering software with a threshold of 100 HU over the baseline. Images were acquired from the coeliac trunk to the ischial tuberosities. Retrospective ECG-gated reconstructions were made at eight equidistant time points over the cardiac cycle. All images were acquired during a single breath-hold phase.

Analysis

Multiplanar reconstructions of the eight images per cardiac cycle were made perpendicular to the centre lumen line of the aorta. Reconstructions were made at two levels: 3 cm above the most distal renal artery (level A), and 1 cm below the most distal renal artery (level B).

The reconstructed dynamic images were analysed using Dynamix software (Image Science Institute, University Medical Center, Utrecht, the Netherlands). First, a region of interest of the dynamic images was manually selected. The region of interest of the eight images per cardiac phase was supersampled (with a factor of 8) by using linear interpolation in the left-right and antero-posterior direction. In-plane supersampling was performed to obtain smoother segmentation of the aortic lumen. Second, semiautomatic segmentation of the aortic lumen was performed. A seeding point was placed manually inside the aortic lumen and a minimum intensity value of the lumen pixels was defined. A region-growing algorithm was applied thereafter to automatically segmentate the aorta. The segmentations were reviewed and minor corrections were made manually, if necessary.

After segmentation of the aortic lumen, areas and minimum/maximum diameters were calculated. Diameter measurements were performed from the outer to the outer vessel wall, through the centre of mass (COM) of the aortic lumen over 180 axes (with an angular increment of 1°) during the cardiac cycle. The difference between the average minimum and average maximum diameter and area of the different phases are presented (pulsatility).
The direction of the aortic distension was calculated by a process which has been described before.[4,6] Radius changes were measured through the COM of the aortic lumen over 360 axes (with an angular increment of 1°) and plotted as a function of angle. With the use of Direct Least Square Fitting of Ellipses in Matlab computing software (Version 7.5, The Mathworks Inc., Natick, MA, USA) an ellipse was fitted over this plot.[7] The radius change over the major (Ra) and minor (Rb) axis and the angle of the major axis of this ellipse were automatically calculated. This angle indicates the deviation of the major axis from the antero-posterior direction. Zero degree was defined as the antero-posterior direction, a deviation of +90 corresponds to left and a deviation of -90 corresponds to right. The mean orientation of all patients is calculated with the orientation anterior. All these anterior orientations are also mirrored in the posterior direction, due to the periodicity of the elliptical radial system. Asymmetry of the aortic expansion is calculated by dividing the radius change over the major axis (Ra) by the radius change over the minor axis (Rb).
A second observer also performed all segmentations for calculation of the inter-observer repeatability of the used methods, which was calculated according to Bland and Altman.[8]
Data on area, diameter and radius are presented as mean ± standard deviation (SD) and range. Data on asymmetry ratio are presented as median with interquartile range (IQR) and range. Statistical analysis of changes in area, diameters and radius changes were performed using the Student's *t* test for paired data. The three different patient groups were compared with the use of the Student's *t* test for unpaired data. Statistical significant difference was assumed at $p < 0.05$.

RESULTS

Thirty AAA patients meeting our inclusion criteria were included, with the following baseline characteristics: mean aneurysm diameter of 5.6 ± 0.8 cm (range: 4.4-7.9), mean aneurysm neck length of 3.5 ± 1.3 cm (2.1-7.0), mean α angle of 18 ± 10° (0-40), mean β angle of 24 ± 11° (0-44) and a mean aneurysm neck diameter of 23.6 ± 3.4 mm (18.1-30.0). The postoperative CTAs were acquired after a median of 2 days (1-7). There were no significant differences between the baseline characteristics of the three groups.

Aortic diameter

The aortic diameter demonstrated significant changes during the cardiac cycle in all patients at both measured levels, in both pre-and postoperative CTAs ($p < 0.001$).

Preoperatively, the mean diameter change 3 cm above the most distal renal artery (level A) in patients with a Talent stent graft was 6.4 ± 2.0% (range 4.2-9.8%) and 1 cm below the most distal renal artery (level B) 5.5 ± 1.3% (3.9-8.3%). In patients with an Excluder stent graft, the mean diameter change at level A was 5.8 ± 1.8% (2.2-9.1), and at level B, 5.4 ± 2.0% (2.2-9.3). In the Endurant group, the mean diameter change at level A was 6.7 ± 2.4% (2.7-10.6) and 5.5 ± 1.3% (3.3-7.6) at level B. The corresponding absolute values can be found in Table 1. The mean diameter and mean diameter change was not significantly different between the three groups ($p > 0.1$).

Postoperatively, the mean diameter change 3 cm above the most distal renal artery (level A) in patients with a Talent stent graft was 6.8 ± 2.0% (4.9-10.5), and 1 cm below the most distal renal artery (level B) 6.4 ± 1.0% (5.1-7.8). In patients with an Excluder stent graft, the mean diameter change at level A was 6.7 ± 2.5% (4.0-11.8), and at level B 5.8 ± 0.8% (4.9-7.2). In the Endurant group, the median diameter change at level A was 7.9 ± 1.8% (6.1-10.8) and 6.3 ± 1.4% (3.8-8.6) at level B. The corresponding absolute values can be found in Table 1. In all three groups, and in all patients, there were no statistical differences between pre-and post-EVAR mean diameter changes at any of the measured levels ($p > 0.1$). The mean diameter change was not significantly different among the three groups ($p > 0.1$). The inter-observer variability for diameter changes was 0.9 mm.

Aortic area

The aortic area changed significantly during the cardiac cycle in all patients at the two measured levels, in both pre-and postoperative CTAs ($p < 0.001$).

Preoperatively, the mean area change 3 cm above the most distal renal artery (level A) in patients with a Talent stent graft was 8.5 ± 4.9% (2.3-17.3), and 1 cm below the most distal renal artery (level B) 5.8 ± 1.4% (3.6-8.0). In patients with an Excluder stent graft, the mean aortic area increase per cardiac cycle was 8.1 ± 3.5% (2.8-15.8) at level A and 6.0 ± 2.3% (2.0-10.6) at level B. The mean aortic area increase at level A in the Endurant group was 8.2 ± 4.4% (2.0-17.1) and 5.8 ± 3.0% (1.9-12.4) at level B. The absolute values of the minimum and maximum areas can be found in Table 2. The mean area and mean area increase did not differ significantly between the three groups ($p > 0.1$).

Postoperatively, the mean area increase at level A in patients with a Talent stent graft was 9.9 ± 4.0% (4.6-17.9), and 7.9 ± 2.2% (3.8-11.1) at level B. The mean aortic area increase in patients with an Excluder device at level A was 9.3 ± 4.6% (4.8-19.5) and 6.7 ± 1.6% (4.7-10.3) at level B. In the group with an Endurant stent graft, the mean aortic area increase at level A was 10.6 ± 4.4% (4.4-20.3) and 8.4 ± 2.9% (4.0-12.4) at level B. The corresponding absolute values can be found in Table 2. There were no statistically significant differences between the pre-and postoperative aortic area increase per heartbeat ($p > 0.1$). The mean area change was not significantly different among the three groups ($p > 0.1$). The interobserver variability for area changes was 24.3 mm^2.

Table 1: Absolute values of the mean diameter (mm). The maximum and minimum diameter and the diameter change per cardiac cycle are shown. There were no statistically significant differences between the pre-and postoperative values in all 3 groups at both levels.

	Talent		excluder		Endurant	
	Pre - EVAR	Post - EVAR	Pre - EVAR	Post - EVAR	Pre - EVAR	Post - EVAR
Suprarenal						
Diameter change	1.5 ± 0.5	1.8 ± 0.3	1.4 ± 0.4	1.6 ± 0.6	1.6 ± 0.6	1.9 ± 0.4
Maximum diameter	24.7 ± 1.8	24.4 ± 1.8	25.1 ± 2.4	25.1 ± 2.6	25.8 ± 2.6	25.5 ± 1.8
Minimum diameter	23.2 ± 1.7	22.8 ± 1.7	23.7 ± 2.4	23.5 ± 2.4	24.1 ± 2.3	23.7 ± 1.7
Infrarenal						
Diameter change	1.2 ± 0.3	1.5 ± 0.3	1.1 ± 0.4	1.2 ± 0.3	1.2 ± 0.3	1.4 ± 0.3
Maximum diameter	23.9 ± 2.3	24.1 ± 2.3	22.1 ± 1.9	22.0 ± 2.6	23.4 ± 1.7	23.9 ± 2.0
Minimum diameter	22.7 ± 2.2	22.6 ± 2.1	20.9 ± 1.8	20.8 ± 2.4	22.2 ± 1.7	22.5 ± 2.0

Table 2: Absolute values of the mean area (mm^2). The maximum and minimum area and the area change per cardiac cycle are shown. There were no statistically significant differences between the pre-and postoperative values in all 3 groups at both levels.

	Talent		Excluder		Endurant	
	Pre- EVAR	Post - EVAR	Pre - EVAR	Post - EVAR	Pre - EVAR	Post - EVAR
Suprarenal						
Area change	36 ± 19	40 ± 13	37 ± 19	42 ± 24	39 ± 24	47 ± 18
Maximum area	470 ± 69	459 ± 68	491 ± 99	490 ± 100	513 ± 107	502 ± 70
Minimum area	434 ± 68	419 ± 68	454 ± 92	448 ± 88	473 ± 93	454 ± 70
Infrarenal						
Area change	24 ± 6	33 ± 12	21 ± 9	23 ± 8	22 ± 9	33 ± 11
Maximum area	441 ± 86	448 ± 85	375 ± 62	375 ± 94	415 ± 59	441 ±75
Minimum area	417 ± 84	415 ± 75	353 ± 59	351 ± 88	393 ± 63	408 ± 72

Direction of distension

The results are shown in Figs. 1-4. There was a significant difference between radius change over the major and minor axes in all patients at all levels studied ($p < 0.01$).

Suprarenal (level A)

The results of the suprarenal level A are shown in Fig. 1 and 2.
Preoperatively in the Talent group, the mean radius change over the major axis was 1.0 ± 0.3 mm (0.7-1.5) and 0.8 ± 0.2 mm (0.5-1.1) over the minor axis. The mean orientation of the major distension axis was -16.5 ± 31.9° (-73 -27), which indicates right-anterior. Median asymmetry ratio was 1.38 (IQR 1.25-1.45, range 1.12-1.72). Postoperatively, the mean radius change over the major axis was 1.2 ± 0.4 mm (0.7-2) and 0.8 ± 0.1 mm (0.6-1.0) over the minor axis in this group. The mean orientation of the major distension axis was -24.8 ± 34.5° (-84.0-20.6). Median asymmetry ratio was 1.34 (IQR 1.20-1.67, range 1.02-2.15).
In the Excluder group, the preoperative mean radius change over the major axis was 1.0 ± 0.3 mm (0.5-1.5) and 0.8 ± 0.2 mm (0.4-1.0) over the minor axis. The mean orientation of the major distension axis was 7.4 ± 46.9° (-75-85). The median asymmetry ratio was 1.31 (IQR 1.21-1.45, range 1.08-1.53). Postoperatively, the mean radius change over the major axis was 1.1 ± 0.3 mm (0.7-1.7) and 0.9 ± 0.3 mm (0.6-1.6) over the minor axis. The mean orientation of the major distension axis was -0.8 ± 44.9° (-68-74). The median asymmetry ratio was 1.35 (IQR 1.22-1.51, range 1.06-1.71).
The preoperative mean radius change over the major axis in the Endurant group was 1.2 ± 0.4 mm (0.6-1.8) and 0.9 ± 0.3 mm (0.5-1.2) over the minor axis. The mean orientation of the major distension axis was -26.2 ± 24.0° (-62.7-12.7). The median asymmetry ratio was 1.33 (IQR 1.22-1.38, range 1.09-1.95). Postoperatively, the mean radius change over the major axis was 1.3 ± 0.3 mm (0.7-1.8) and 1.0 ± 0.2 mm (0.7-1.5) over the minor axis. The mean orientation of the major distension axis was -19.9 ± 28.0° (-54.4-30.2). The median asymmetry ratio was 1.35 (IQR 1.25-1.49, range 1.09-1.68). For all three stent graft groups together, the preoperative mean orientation of the major distension axis was -11.8 ± 38.2° (-75.4-84.5) and postoperative -15.1 ± 37.9° (-84.0-74.1), which both indicates right-anterior.

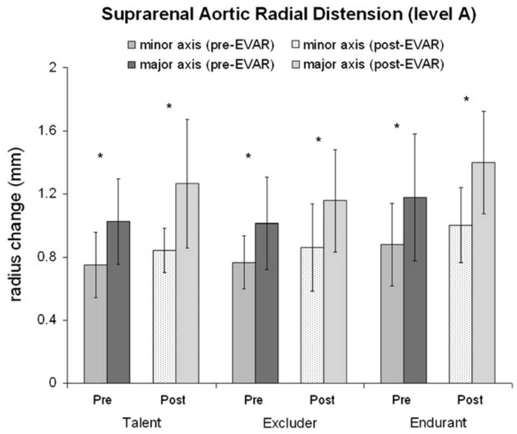

Figure 1: *The mean radial distension (mm) in the 3 different groups at level A is presented with the standard deviation (error bars). At each level, the radius change over the minor and major axis differed significantly both pre-and postoperatively (*p < 0.05). Pre = pre-operative. Post = postoperative.*

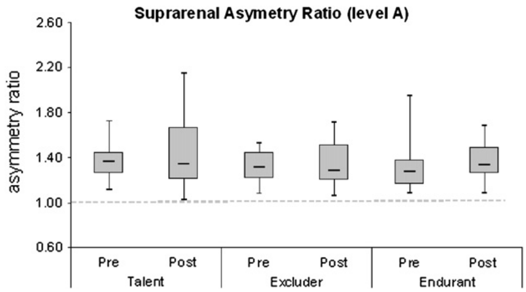

Figure 2: *Box plot showing the asymmetry ratio in the 3 different groups at level A. Asymmetry ratio is calculated as radius change over the major axis divided by radius change over the minor axis (Ra/Rb). The dashed line is a ratio of 1.0, which represents symmetric expansion. Pre = pre-operative. Post = postoperative.*

Infrarenal (level B)

The results of level B are shown in Figs. 3 and 4.

Preoperatively, the mean radius change over the major axis was 0.9 ± 0.2 mm (0.4-1.4) and 0.7 ± 0.1 mm (0.4-0.9) over the minor axis in the Talent group. The mean orientation of the major distension axis was 16.4 ± 47.7° (-76.1-68.7), which indicates left-anterior. Median asymmetry ratio was 1.34 (IQR 1.17-1.38, range 1.05-1.65). Postoperatively, the mean radius change over the major axis was 1.1 ± 0.2 mm (0.8-1.6) and 0.8 ± 0.2 mm (0.6-1.1) over the minor axis in this group. The mean orientation of the major distension axis was 21.7 ± 60.5° (-76.8-82.5). Median asymmetry ratio was 1.31 (IQR 1.19-1.40, range 1.08-1.59).

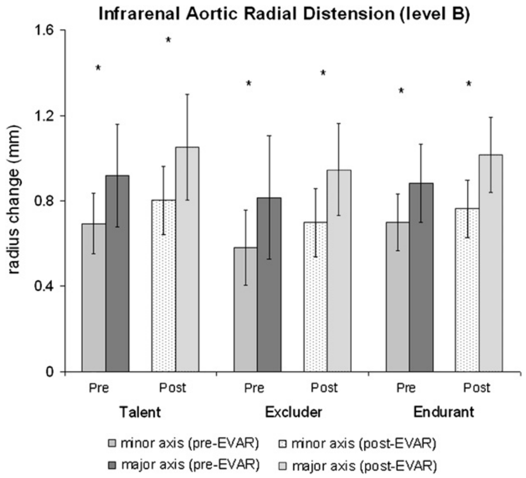

Figure 3: *The mean radial distension (mm) in the 3 different groups at level B is presented with the standard deviation (error bars). At each level, the radius change over the minor and major axis differed significantly both pre-and postoperatively (*p < 0.05). Pre = pre-operative. Post = postoperative.*

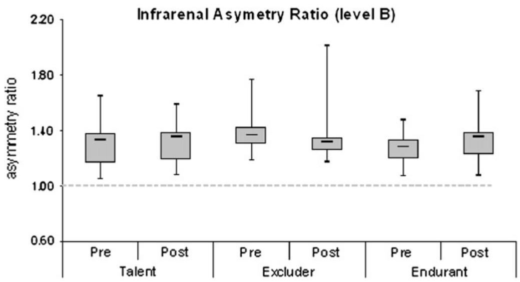

Figure 4: *Box plot showing the asymmetry ratio in the 3 different groups at level B. Asymmetry ratio is calculated as radius change over the major axis divided by radius change over the minor axis (Ra/Rb). The dashed line is a ratio of 1.0, which represents symmetric expansion. Pre = pre-operative. Post = postoperative.*

In the Excluder group, the preoperative mean radius change over the major axis was 0.8 ± 0.3 mm (0.4-1.3) and 0.6 ± 0.2 mm (0.3-0.9) over the minor axis. The mean orientation of the major distension axis was 31.8 ± 29.5° (-12.7-88.6). The median asymmetry ratio was 1.37 (IQR 1.29-1.43, range 1.19-1.77). Postoperatively, the mean radius change over the major axis was 0.9 ± 0.2 mm (0.6-1.3) and 0.7 ± 0.2 mm (0.5-1.0) over the minor axis. The mean orientation of the major distension axis was 0.4 ± 47.8° (-80.2-68.1). The median asymmetry ratio was 1.37 (IQR 1.25-1.35, range 1.18-2.01).

The preoperative mean radius change over the major axis in the Endurant group was 0.9 ± 0.2 mm (0.7-1.3) and 0.7 ± 0.1 mm (0.6-1.0) over the minor axis. The mean orientation of the major distension axis was 0.4 ± 40.5° (-75.1-83.5). The median asymmetry ratio was 1.27 (IQR 1.22-1.34, range 1.07-1.47). Postoperatively, the mean radius change over the major axis was 1.0 ± 0.2 mm (0.7-1.3) and 0.8 ± 0.1 mm (0.6-0.9) over the minor axis. The mean orientation of the major distension axis was 7.0 ± 53.8° (-64.9-81.5). The median asymmetry ratio was 1.34 (IQR

1.22-1.38, range 1.08-1.68). For all three stent graft groups together, the preoperative mean orientation of the major distension axis was 16.2 ± 42.0° (-76.1-88.6), and postoperative 12.2 ± 55.0° (-80.2-82.5), which both indicates left-anterior. The inter-observer variability for radius change was 0.5 mm. Inter-observer variability for the direction of the major axis was 62°.

DISCUSSION

In this study, we found that three current in-use stent grafts seem to be able to adapt to the pulsatility of the abdominal aorta. Preoperatively, the aorta expands significantly and asymmetrically during the cardiac cycle at several levels that are relevant for EVAR. After the implantation of the studied stent grafts, the degree as well as the direction of the distension remains equal compared with preoperative values.

To the best of our knowledge, this is the first study comparing the influence of different stent graft types on aortic wall motion. We observed that the placement of several stent graft types did not influence the aortic expansion per heartbeat and found no differences between the several stent graft types. In relatively small studies, it was shown before that the placement of an aortic stent graft did not influence the aortic area or diameter distension per heartbeat.[2,5,9] However, those studies did not compare different stent graft types nor investigated the direction of the aortic distension.

We have evaluated the direction of this distension both pre-and postoperatively, and found both the pre-and postoperative distension to be asymmetric. Asymmetric aortic distension was noted in previous studies.[2,3,10] Only two studies previously quantified the asymmetric distension,[3,6] one of which used the same ellipse-fitting procedure as applied in this study.[6] In this previous dynamic MRI study, it was noted that the suprarenal aortic distension showed a tendency to right-anterior, while in the case of infrarenal, there was a tendency to left-anterior. It is important to acknowledge that the aortic expansion is asymmetric. The stent grafts implanted in the aorta must be able to adapt to this asymmetric distension. Therefore, the most proximal part of the stent grafts should probably be flexible and compliant and self-expandable with a high radial force.

The levels that we studied are both relevant landing zones for EVAR. The suprarenal level, measured 3 cm proximal to the most distal renal artery, might be the landing zone for suprarenal bare extensions. The infrarenal level, 1 cm below the most distal renal artery, is a relevant landing zone for most stent grafts. At those levels, the aortic area and diameter changes were measured per heartbeat.

Two of the three studied stent grafts have a proximal transrenal bare extension (<3 cm) for suprarenal fixation. This suprarenal fixation does not seem to influence the aortic suprarenal dynamics. Further, no other differences between the several stent graft types where found. It is possible that the three included stent grafts are too much similar in their proximal shape and fixation techniques.

Our study has some limitations. Although we were able to correct for the in-plane movement of the aorta, we could not correct for movement out of plane. Moreover, the influences of the stent grafts on aortic dynamics were studied a relatively short time after implantation of the stent grafts. It is not unimaginable that the aortic motions might be altered several years after the implantation of a stent graft. Further, all measurements in this study were performed semi-automatically and minor manual adjustments were required in about 30% of all scans. A major limitation of this study is the inter-observer variability for the measurement of the direction of the major axis and radius changes. The reported inter-observer variabilities signify that our results should be interpreted with care (inter-observer variability for radius change 0.5 mm; for direction of the major axis 62°; for area change 24.3 mm^2). Although the inter-observer variability for radius change, regarding the voxel size of 0.5 × 0.5 × 0.9 mm, seems very large, one should not forget that we were able to measure subvoxel changes (changes within the spatial resolution). This was accomplished by upsampling of the images by a factor of 8 in both the *x* and *y* directions. Finally, although all CTAs used in this study are performed for regular follow-up, we should not forget the radiation exposure to patients caused by a CTA. The radiation exposure parameters of our dynamic protocol are comparable with those of static protocols, but we should take into account that the radiation burden of EVAR patients is substantial.[11,12]

The three studied stent grafts do not seem to influence the aortic distension or direction of distension. Although the current observations are valuable, we cannot conclude that the three stent grafts adapt perfectly to the asymmetric aortic expansion. Nevertheless, it is promising that the three studied stent grafts, with a standard oversizing regime of 15-20% (according to local protocol), do not seem to alter the aortic dynamics at the studied levels. Since the stent grafts are oversized that much, it is very likely they would change the distension, or the direction of the distension, if they would not adapt to the heartbeat-dependent aortic changes. Nevertheless, it is likely that the asymmetric distension of the aorta applies different forces on the stent grafts than symmetric expansion would do. The continuous asymmetric pulsatile aortic expansion may result in mechanical stress on the grafts, which subsequently may have consequences for EVAR durability. Therefore, the consequences of a pulsatile asymmetric expansion on symmetrically shaped stent grafts on the long term have to be studied, and are awaited with interest.

CONCLUSION

In this study, we have shown that the aorta expands significantly and asymmetrically throughout the cardiac cycle at several relevant levels for EVAR. The asymmetric aortic distension is preserved after the placement of three different types of stent grafts. The three studied stent grafts do not alter the aortic shape changes throughout the cardiac cycle, but probably adapt to these changes equally.

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PULSATILE DISTENSION OF THE PROXIMAL ANEURYSM NECK IS LARGER IN PATIENTS WITH STENT GRAFT MIGRATION

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ABSTRACT

Purpose: The proximal abdominal aortic aneurysm (AAA) neck expands significantly during the cardiac cycle, both before and after endovascular aneurysm repair (EVAR). Clinical consequences of this pulsatility were anticipated but have never been reported. This study investigated whether there is a relation between stent graft migration and preoperatively measured pulsatility of the proximal aneurysm neck.

Methods: EVAR patients with a preoperative dynamic computed tomography angiography (CTA), an immediate postoperative, and a CTA at 3 years after EVAR were included. The preoperative dynamic CTAs consisted of eight images per heartbeat. Aortic diameter and area changes per heartbeat were measured at two levels: (A) 3 cm above and (B) 1 cm below the most distal renal artery. Postoperatively, the distance between the most distal renal artery and the most proximal stent graft ring was measured. Two patient groups were distinguished according to whether migration during follow-up occurred (group 1) or had not occurred (group 2). The aneurysm neck dynamics of the two groups were compared by using the t-test for unpaired data and multivariable logistic regression analyses were performed. Mean values are presented with the standard deviation.

Results: Included were 26 patients (19 Talent, 6 Excluder and 1 Lifepath). Stent graft migration of 25 mm occurred in 11 patients (group 1). The pulsatility of the AAA neck in these patients was compared with the pulsatility in 15 patients with no graft migration (group 2). There were no significant differences in aortic neck characteristics (angulation, length and diameter) or degree of stent graft oversizing between the two groups. At level A in group 1 versus group 2, the diameter increase during the cardiac cycle was 2.0 ± 0.3 versus 1.7 ± 0.3 mm and the aortic area increase was 49 ± 15 versus 33 ± 12 mm^2. At level B in group 1 versus group 2, the diameter increase per heartbeat was 1.8 ± 0.3 versus 1.6 ± 0.4 mm, and the area increase was 37 ± 10 versus 25 ± 15 mm^2. The heartbeat-dependent diameter and area changes at both levels were significantly higher in group 1 compared with group 2. Multivariate regression analysis showed suprarenal aortic pulsatility was a significant predictor for stent graft migration after 3 years.

Conclusion: The preoperative heartbeat-dependent aneurysm neck distension is significantly associated with stent graft migration after 3 years. The aortic pulsatility in patients with stent graft migration is significantly higher than the pulsatility in patients without stent graft migration.

INTRODUCTION

Adequate fixation and complete sealing of a stent graft in an abdominal aortic aneurysm (AAA) neck is considered one of the most crucial aspects of endovascular aneurysm repair (EVAR).[1] Inadequate proximal fixation or sealing might lead to stent graft migration, thereby compromising the results of EVAR.[1,2] Several morphologic features of the proximal aneurysm neck, including neck length, diameter and angulation, are related to stent graft sealing and fixation-related complications.[3-6]

The proximal sealing and fixation zone of a stent graft in the aneurysm neck expands significantly per heartbeat, both preoperatively and postoperatively.[7,8] Preoperatively, this aortic pulsatility could complicate the process of stent graft selection and sizing, which is most commonly based on static computed tomography angiography (CTA) images. Postoperatively, stent grafts should be able to withstand and adapt to millions of repetitive heartbeat-dependent aortic wall movements to prevent stent graft migration.

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.[8] 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 more aneurysm neck pulsatility are therefore probably more prone to stent graft sealing and fixation related complications after EVAR than patients with less pulsatility. Although aneurysm neck pulsatility has been studied before, to our knowledge, the relation between aneurysm neck pulsatility and EVAR outcome has never been studied.

It is, therefore, the purpose of this study to investigate whether there is a relation between the preoperative aneurysm neck pulsatility and stent graft migration. Our hypothesis is that heartbeat-dependent aneurysm neck distension is larger in patients with stent graft migration than in patients without stent graft migration.

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METHODS

Patients

From our prospectively collected AAA database, we selected all AAA patients with a preoperative dynamic CTA, an immediate postoperative (≤7 days after EVAR) and a CTA at 3 years after EVAR. These three CTA scans were available for 26 AAA patients (21 men, median age 73 years, range, 50-82 years). The stent graft characteristics and clinical course of these patients during follow-up were investigated.

Imaging

The dynamic preoperative and static postoperative CTA scans were performed on a 64-slice or 256-slice CT scanner (Philips Medical Systems, Best, The Netherlands; values for the 265-slice scanner stated between parentheses) with a standardised acquisition protocol.

Scan parameters were: slice thickness, 0.9 mm (0.9 mm); increment, 0.7 mm (0.7 mm); collimation, 64 x 0.625 mm (128 x 0.625 mm); and pitch 0.25 (0.2). Field of view was 250 x 250 mm (250 x 250 mm), and the reconstructed matrix size was 512 x 512 (512 x 512), resulting in a voxel size of 0.5 x 0.5 x 0.9 mm (0.5 x 0.5 x 0.9 mm). Radiation exposure parameters were 120 kVp (120 kVp) and 300 mAs (250 mAs), resulting in a CT dose index ($CTDI_{vol}$) of 17.6 mGy (16.5 mGy). Intravenous nonionic contrast (120 ml; Iopromide, Schering, Berlin, Germany), followed by a 60-ml saline chaser bolus, was injected at a rate of 6ml s^{-1}. The scan was started using bolus-triggering software with a threshold of 100 HU over baseline. Retrospectively, electrocardiogram-gated reconstructions were made at eight equidistant time points covering the cardiac cycle on the (preoperative) CTAs. All scans were acquired during a single breath-hold.

All preoperative and postoperative CTA data sets were transferred to a 3 Surgery 4.0 workstation (3Mensio Medical Imaging B.V., Bilthoven, The Netherlands) for analysis. The dynamic images were analysed using a custom-made dynamic extension tool for this software.

Preoperative dynamic CTA analysis

An aortic centre lumen line (CLL) was automatically constructed by placement of a proximal start and distal end point in the aortic lumen. Aortic CLL spline points were thereafter manually checked and corrected, if necessary.

Multiplanar reconstructions of the eight images per cardiac cycle were made perpendicular to the aortic CLL at two levels: 3 cm above the most distal renal artery (level A) and 1 cm below the most distal renal artery (level B).

A semi-automatic segmentation of the aortic lumen of the eight images per cardiac cycle was performed at those levels. A seeding point was placed manually inside the aortic lumen, and a region-growing algorithm was applied thereafter to automatically segment the aorta. The segmentations were reviewed and minor corrections were made manually, if necessary. After segmentation of the aortic lumen, areas and minimum/maximum diameters were calculated. Diameter measurements were performed through the centre of mass of the aortic lumen over 180 axes (with an angular increment of 1°) during the cardiac cycle. The pulsatility was calculated as the difference between the minimum and maximum area and average minimum and maximum diameter over 180 axes.

The following AAA characteristics were measured on the preoperative CTA scans as well: AAA neck length, calcification and thrombus in the AAA neck, suprarenal and infrarenal angulation of the AAA neck, maximum AAA diameter and AAA volume. The aortic neck length was measured along the CLL from the most distal renal artery to the most proximal side of aneurysmal dilatation. The thrombus and calcification lining the aortic neck wall were visually quantified 10 mm below the most distal renal artery. The aortic neck angulation and AAA volume were measured according to earlier published protocols.[9,10] Diameters were measured perpendicular to the CLL.

Postoperative CTA analysis

A reconstructed stretch view of the aorta was generated around a semi-automatically constructed aortic CLL on all postoperative CTAs. The distance between the most distal renal artery and the most proximal stent graft ring was measured on the reconstructions on the direct postoperative CTA and also on the CTA performed 3 years after EVAR. Stent graft migration was defined as a migration of the most proximal stent graft ring of ≥5 mm during this 3-year follow-up. Patients with an intervention for stent graft migration during follow-up or stent graft migration of ≥5 mm after 3 years were designated as group 1 and those with no stent graft migration were group 2.

The diameter of the aorta 10 mm below the most distal renal artery was measured on the direct postoperative CTA and on the CTA performed 3 years after EVAR. The difference between these diameters is defined as the postoperative aneurysm neck dilatation. Maximum AAA diameters and AAA volumes were measured on CTAs performed after 3 years. Diameters were measured perpendicular to a CLL.

Statistics

Data on area and diameter change per heartbeat are presented as mean ± standard deviation and range. Statistical analysis of changes in area and diameters per heartbeat was performed using the *t*-test for paired data. The AAA characteristics, postoperative aneurysm neck dilatation, minimum area, minimum diameter and area and diameter changes per heartbeat in the two groups were compared by using the *t*-test for unpaired data. Univariable and multivariable logistic regression analyses were performed to assess the association between AAA characteristics, postoperative aneurysm neck dilatation, minimum area, minimum diameter, area and diameter changes per heartbeat and dichotomous data on stent graft migration. All significant parameters after univariable analyses were added to the multivariable analysis. Statistical significance was assumed at $P < 0.05$.

The distance between the renal arteries and the most proximal stent graft ring was measured twice by the first observer and once by a second observer. Intraobserver and interobserver variability of area and diameter measurements were calculated according to Bland and Altman.[11] All measurements were performed blinded of migration outcome and independently from the other observations.

RESULTS

The study included 26 asymptomatic AAA patients with the following baseline characteristics: mean aneurysm diameter, 60 ± 9 mm (range, 44-78 mm); mean aneurysm neck length, 3.5 ± 1.3 cm (range, 1.1-6.0 cm); mean suprarenal angulation, 26° ± 18° (range, 0-94°); and mean infrarenal angulation, 43° ± 17° (range, 5-68°). Stent grafts used were the Talent (Medtronic, Minneapolis, MN, USA) in 19 patients, the Excluder (Gore, Flagstaff, AZ, USA) in six patients and the Lifepath (Edwards Lifesciences, Irvine, CA, USA) in one patient. The mean stent graft oversizing was 21 ± 6% (range, 9-35%). The mean postoperative aneurysm neck dilatation during the 3-year follow-up was 1.5 ± 1.9 mm (range, 0-5 mm). The mean decrease in maximum AAA diameter after 3 years was 3 ± 10 mm (range, 12-30 mm) and the mean AAA volume decrease was 23 ± 65 ml (range, -88-182 ml).

Group 1 consisted of patients with an intervention for stent graft migration during follow-up or stent graft migration of ≥5 mm after 3 years. Nine patients had ≥5mm stent graft migration after 3 years, and two other patients had an intervention to treat stent graft migration during follow-up. An aortic extension cuff was placed endovascularly in one patient after 2 years, and an open AAA repair was performed in another patient 2 years after EVAR. Group 1 thus consisted of 11 patients and group 2 consisted of the other 15 patients. The subdivision of the 26 patients into the two groups was the same using the first or the second measurements of the first observer or the measurements of the second observer.

An overview of the baseline characteristics of the patients in groups 1 and 2 can be found in Table 1. There were no patients with calcifications lining >25% of the aneurysm neck. One patient in both groups had a thrombus lining 25-50% of the aneurysm neck. There were no significant differences between the baseline characteristics of the two groups and there was no significant postoperative aneurysm neck dilatation in both groups.

Table 1: The abdominal aortic aneurysm (AAA) characteristics of the patients in both groups (group 1 = stent graft migration; group 2 = no stent graft migration). There were no significant differences between the baseline characteristics of the 2 groups, as can be seen.

	Group 1	Group 2	*P* value
Number of patients *(n)*	11	15	
AAA diameter (mm)	60.4	59.7	0.9
Stent graft type			
Talent	10	9	
Excluder	1	5	
Lifepath		1	
AAA neck length (mm)	33.2	37.2	0.5
Suprarenal Angulation (°)	32	21	0.1
Infrarenal Angulation (°)	49	39	0.1
Stentgraft Oversizing (%)	20%	22%	0.6
Neck dilatation during FU (mm)	1.7	1.4	0.5
Diameter decrease (mm)	1.5	4.4	0.2
Volume decrease (ml)	23.4	22.1	0.5

Mean aortic diameter

The preoperative aortic diameter demonstrated significant changes during the cardiac cycle in all patients at both measured levels ($P < 0.001$).

The mean diameter change 3 cm above the most distal renal artery (level A) was 8.3 ± 1.5% (range, 6.0-11.8%) in patients of group 1 (migration) and 7.3 ± 1.3% (range, 5.8-9.3%) in patients of group 2 (no migration). The mean diameter change 1 cm below the most distal renal artery (level B) was 8.4 ± 1.4% (range, 6.6-11.2%) in group 1 and 6.9 ± 1.1% (range, 4.8-8.6%) in group 2. The corresponding absolute values and *p*-values related to group comparisons can be found in Table 2. The differences between the mean minimum diameters of the two groups at both levels were not significant. The mean diameter change at both levels was significantly higher in group 1 (patients with migration) than in group 2. The intraobserver repeatability for diameter changes was 0.9 mm, and the interobserver variability was 0.6 mm.

Table 2: Absolute values of the mean diameter change (mm) per cardiac cycle. The heartbeat-dependent diameter increase at both levels was significantly higher in patients of group 1 than in patients of group 2. There were no statistically significant differences between the mean minimum diameters of the 2 groups.

	Group 1	Group 2	*P* Value
Suprarenal			
Diameter change	2.0 ± 0.3	1.7 ± 0.3	0.03
Minimum diameter	24.2 ± 2.0	23.3 ± 1.7	0.2
Maximum diameter	26.2 ± 1.9	25.0 ± 1.9	
Infrarenal			
Diameter change	1.8 ± 0.3	1.6 ± 0.4	0.04
Minimum diameter	21.8 ± 2.1	22.3 ± 3.4	0.7
Maximum diameter	23.7 ± 2.1	23.8 ± 3.7	

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Mean aortic area

The mean area change 3 cm above the most distal renal artery (level A) was 10.3 ± 3.6% (range, 5.7-15.6%) in patients of group 1 and 7.4 ± 2.3% (range, 3.7-12.3%) in patients of group 2. The mean area change 1 cm below the most distal renal artery (level B) was 9.5 ± 2.7% (range, 5.8-14.5%) in group 1 and 6.0 ± 2.6% (range, 3.0-11.1%) in group 2. The corresponding absolute values can be found in Table 3. There were no significant differences between the mean minimum areas of the two groups at both levels. The mean area change at both levels was significantly higher in group 1 (patients with migration) than in group 2. The intraobserver repeatability for area changes was 17 mm^2 and the interobserver repeatability for area changes was 26 mm^2.

Table 3: Absolute values of the mean area change (mm^2) per cardiac cycle. The heartbeat-dependent area increase at both levels was significantly higher in patients of group 1 than in patients of group 2. There were no statistically significant differences between the mean minimum areas of the 2 groups.

	Group 1	Group 2	*P* Value
Suprarenal			
Area change	48 ± 15	33 ± 12	<0.01
Minimum area	479 ± 76	445 ± 64	0.2
Maximum area	528 ± 77	478 ± 70	
Infrarenal			
Area change	39 ± 10	25 ± 15	0.03
Minimum area	393 ± 71	415 ± 127	0.6
Maximum area	430 ± 74	440 ± 138	

Logistic regression

Univariable logistic regression analyses showed that the mean diameter and area change at both levels were significantly associated with stent graft migration after 3 years. The AAA characteristics, postoperative aneurysm neck dilatation, stent graft oversizing and the diameter and volume decrease after 3 years were not statistically significantly associated with stent graft migration after 3 years. In multivariable logistic regression analysis, the suprarenal area change per heartbeat was the only significant independent predictor of stent graft migration after 3 years (odds ratio, 1.1; 95% confidence interval (CI), 1.013-1.21; $P = 0.04$).

DISCUSSION

This study shows that the preoperative aneurysm neck pulsatility is significantly associated with stent graft migration after 3 years and is significantly higher in patients with stent graft migration than in patients without stent graft migration. We believe that this study is the first to confirm a relation between aneurysm neck dynamics and stent graft fixation-related problems during follow-up. Previous dynamic studies have shown, similar to this study, that the aneurysm neck pulsatility at several for EVAR relevant levels is significant.[8] A correlation between preoperative pulsatility of the aneurysm neck and stent graft fixation and sealing has been suspected from the findings in these previous studies.

Most AAA patients undergo static CTA imaging preoperatively, and we are currently not able to predict from these images which patients will have a large heartbeat-dependent aneurysm neck distension. Although an earlier study found that the aneurysm neck pulsatility in young healthy persons is larger than in AAA patients, we do not know whether younger AAA patients have a larger pulsatility than older AAA patients.[8,12] It would, however, be useful to be able to preoperatively measure, which patients have a higher aneurysm neck pulsatility: A dynamic CTA could be obtained for stent graft selection and sizing, and therapy could possibly be adapted to the dynamics in the aneurysm neck.

The most optimal treatment option for AAA patients with a large aneurysm neck pulsatility is not known. An open repair instead of an endovascular repair in these patients might be considered. Moreover, if EVAR is considered the treatment of choice in a patient with a high pulsatility, the stent graft choice or oversizing might be adapted in these patients; for instance, a stent graft with an active proximal fixation technique, such as hooks or barbs, might be considered. Besides, a longer aneurysm neck might be required for stent graft fixation to prevent future complications. Additionally, a more liberal oversizing regimen in patients with a high pulsatility might be considered.

The multivariate analysis performed in this study showed that the aortic suprarenal area increase was significantly associated with stent graft migration. The aortic pulsatilities at several levels in the aorta are correlated to each other, and only the pulsatility at the level of the most significant difference was an independent predictor for stent graft migration after 3 years.

A limitation of our study might be that the relation between preoperative aneurysm neck dynamics and postoperative stent graft migration was investigated. The decision to investigate the preoperative aneurysm neck dynamics was made for several reasons. First, the post-operative aneurysm neck dynamics are comparable with the preoperative dynamics.[2] The implantation of the Talent and Excluder stent grafts do not seem to influence the movement of the aortic wall, either in heartbeat-dependent distension or in direction of distension.[2] Second, it is our experience that the investigation of the postoperative pulsatility is less reliable than the measurement of the preoperative pulsatility. The measurement of the postoperative pulsatility is influenced negatively by scattering of the stent graft. Third, the relation between preoperative aneurysm neck pulsatility and postoperative stent graft migration might be of help in decisions on EVAR suitability in the future. Future studies investigating whether there are absolute pulsatility values, which make postoperative complications either more likely or unlikely, can therefore be of great value in EVAR planning.

Another limitation might be that a higher migration rate in our study was found compared to other studies.[1] We, however, believe that this is mainly caused by the definition of migration. In our study, migration was defined as a migration of ≥5 mm, whilst other studies use a migration of ≥10 mm as a definition of migration.[13]

The intraobserver and interobserver variability of the preoperative aortic area and diameter measurements in this study were small, making the dynamic results reliable. On top of this, it is important to note that the distance between the most distal renal artery and the proximal stent graft ring was measured three times, independently and blinded. The classification of the included patients in the two groups was completely the same using these different measurements.

The patients included in this study were treated with three different types of stent grafts, both with and without suprarenal bare stents. The Excluder and Lifepath stent graft were, however, used in a very small number. It is therefore impossible to make a useful comparison between the several stent grafts used in this study.

A stent graft design should be able to adapt to - and withstand - the continuous pulsatile and asymmetric distension of the aorta. It is therefore likely that not only patients with short, angulated, calcified and thrombosed aneurysm necks, but also patients with higher aneurysm neck dynamics are more prone to stent graft migration than others.[3-6] A more firm proximal fixation of a stent graft, not only relying on radial force but also with hooks or barbs, might possibly prevent stent graft migration. Moreover, the use of dynamic images might optimise the preoperative process of patient selection and stent graft sizing.

CONCLUSION

Aortic heartbeat-dependent pulsatility is significantly associated with stent graft migration. Patients with stent graft migration 3 years after EVAR have significantly higher preoperative aneurysm neck pulsatility during the cardiac cycle than patients without stent graft migration.

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5

PULSATILITY IN THE ILIAC ARTERY IS SIGNIFICANT AT SEVERAL LEVELS: IMPLICATIONS FOR EVAR

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ABSTRACT

Purpose: To evaluate the pulsatility of the iliac arteries and compare their distension at several levels that might influence preoperative stent-graft sizing and the long-term durability of stent-graft sealing and fixation.

Methods: Preoperative dynamic computed tomographic angiography (CTA) scans of 30 patients (24 men; median age 75 years, range 60–85) with an abdominal aortic aneurysm and patent iliac arteries were included. The CTAs consisted of 8 images per heartbeat. Bilateral diameter and area changes per heartbeat were measured semi-automatically in the common iliac artery (CIA) at 3 levels: (A) 0.5 cm after the aortic bifurcation, (B) in the middle of the CIA, and (C) 0.5 cm proximal to the iliac bifurcation. Pulsatility was defined as the largest difference in area and average diameter change over 180 axes per heartbeat. Pulsatility at the 3 levels was compared, and the intraobserver variability of the method was calculated according to Bland and Altman.

Results: The mean area increases in the CIAs at levels A, B, and C were 12.5% (16.3 mm^2), 11.2% (13.6 mm^2), and 9.6% (12.6 mm^2), respectively, and the mean iliac diameter increases were 9.2% (1.1 mm), 8.5% (1.0 mm), and 8.1% (1.0 mm). The iliac distension was statistically significant at all levels. The iliac distension at level A was statistically significantly larger than the distension at level C. The intraobserver variability was 13.3 mm^2 for area and 0.6 mm for diameter measurements.

Conclusion: The pulsatility in the iliac arteries is statistically significant at several levels relevant to endovascular aneurysm repair. The distension of the iliac artery possibly decreases more distally, which might encourage the extension of stent-grafts to the internal iliac artery.

INTRODUCTION

Adequate fixation and sealing of a stent-graft in an aneurysm neck is important in achieving good results after endovascular aneurysm repair (EVAR). A stent-graft should fit both the proximal and distal sealing and fixation zones perfectly, and a mismatch between the stent-graft and these zones might lead to type I endoleaks or stent-graft migration.

Much attention has been paid to the proximal landing zone, and patients with more hostile proximal aneurysm neck characteristics are more prone to proximal stent-graft sealing- and fixation-related problems.[1–4]

Although the proximal sealing and fixation zone of stent-grafts is probably the most important zone, the significance of the distal landing zone in the iliac arteries should not be underestimated.

Distal type I endoleaks are one of the most common reasons for reinterventions, with an incidence of 2% to 4% during follow-up after EVAR.[5–7] Furthermore, a longer iliac fixation length and deployment of a stent-graft close to the iliac bifurcation prevents migration in stent-grafts with columnar support.[8–10] It was shown earlier that the higher the pulsatility in the proximal aneurysm neck, the greater the chance of stent-graft migration during follow-up.[11] This finding could be extrapolated to the hypothesis that the distal sealing and fixation of a stent-graft in a more pulsatile part of a vessel may be undesirable as well *[Movie: An example of the common iliac artery (CIA) distension 0.5 cm after the aortic bifurcation. The view in this video is perpendicular to the left CIA]*.

The purpose of this study was to evaluate and compare the pulsatility of the iliac arteries at several significant levels relevant to EVAR. Our hypothesis was that the heartbeat-dependent CIA distension is significant but might decrease more distally and closer to the iliac bifurcation.

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METHODS

Study Design and Patient Sample

Preoperative dynamic computed tomographic angiography (CTA) scans of patients with an abdominal aortic aneurysm (AAA) were randomly selected from our prospectively collected EVAR database. The sample size was based on earlier published studies of aortic dynamics.[12] Because pulsatility of the iliac arteries was expected to be smaller than in the proximal aneurysm neck, a larger sample of 30 AAA patients (24 men; median age 75 years, range 60–85) was selected. These patients had bilateral patent internal iliac arteries and no CIA aneurysm, defined as a diameter ≥20 mm in the middle of the artery. The mean aneurysm diameter was 59 ± 9mm (range 44–85), and all EVAR procedures were performed between 2007 and 2010.

Imaging

The CTA scans were performed on a 64-slice or 256-slice MDCT scanner (Philips Medical Systems, Best, The Netherlands) with a standardized acquisition protocol (values for the 256-slice scanner given in parentheses). Scan parameters were slice thickness 0.9 mm (0.9 mm); increment 0.7 mm (0.7 mm); collimation 64×0.625 mm (128×0.625 mm); and pitch 0.25 (0.2). Field of view was 250×250 mm (250×250 mm), and the reconstructed matrix size was 512×512 (512×512), resulting in a voxel size of 0.5×0.5×0.9 mm (0.5×0.5×0.9 mm). Radiation exposure parameters were 120 kVp (120 kVp) and 300 mAs (250 mAs), resulting in a CT dose index ($CTDI_{vol}$) of 17.6 mGy (16.5 mGy). Intravenous nonionic contrast (120 mL; Iopromide, Schering, Berlin, Germany), followed by a 60-mL saline chaser bolus, was injected at a rate of 6 mL/s. The scan was started using bolustriggering software with a threshold of 100 HU over baseline. All images were acquired during a single breath-hold. Electrocardiogram-gated reconstructions were made at 8 equidistant time points over the cardiac cycle on the (preoperative) dynamic CTAs.

Analysis

All CTA datasets were transferred to a 3Surgery 4.0 workstation (3Mensio Medical Imaging B.V., Bilthoven, The Netherlands), and the dynamic images were analyzed with the use of a custom-made dynamic extension tool for this software (3Mensio Medical Imaging B.V.). Multiplanar reconstructions of the 8 images per cardiac cycle were made perpendicular to an aortoiliac center lumen line (CLL) at 3 levels in both CIAs: (A) 0.5 cm after the aortic bifurcation, (B) in the middle of the CIA, and (C) 0.5 cm proximal to the iliac bifurcation. Length measurements were performed alongside the aortoiliac CLL.

A semi-automatic segmentation of the iliac lumen of the 8 images per cardiac cycle was performed at these 3 levels. A seeding point was placed manually inside the iliac lumen, and a region-growing algorithm was applied thereafter to automatically segment the iliac arteries. The segmentations were visually inspected, and minor manual corrections were made if necessary.

After segmentation of the iliac lumen, areas and minimum and maximum diameters were calculated. Diameter measurements were performed through the center of mass of the iliac lumen over 180 axes (with an angular increment of 1°) during the cardiac cycle. Because vessel pulsatility is asymmetrical,[13] it was calculated as the difference between the minimum and maximum area and average minimum and maximum diameter over 180 axes to give an overview of the average pulsatility per heartbeat of the entire vessel.

Statistical Analysis

Data on area and diameter change per heartbeat are presented as mean ± standard deviation [95% confidence interval (CI) and range]. Mean values of the right and left CIA area and diameter measurements are first presented together. The mean right and left CIA area and diameter measurements are thereafter presented separately as well.

Statistical analysis was performed with the measurements of the right and left iliac arteries separately. Changes in area and diameters per heartbeat and the relative pulsatility at the 3 studied levels were compared with the *t* test for paired data. The pulsatility in the right and left CIAs was also compared. Statistical significance was assumed at $p<0.05$.

Measurements were performed twice by the first observer and once by a second observer; the results of the first measurements of the first observer are presented. Intraobserver and interobserver variability of area and diameter measurements were calculated according to Bland and Altman.[14] Statistical analyses were performing using SPSS software (SPSS, Chicago, IL, USA).

RESULTS

Mean Iliac Diameter

The iliac diameter (Table 1) demonstrated statistically significant changes during the cardiac cycle in all patients at all 3 measured levels ($p<0.001$). The mean diameter change for the left and right iliac arteries together was 9.2 ± 2.1% (CI 8.6 - 9.7%, range 5.5–15.4%) 0.5 cm below the aortic bifurcation (level A), 8.5 ± 2.0% (CI 8.1 - 9.1%, range 4.7–13.6%) in the middle of the CIA (level B), and 8.1 ± 1.8% (CI 7.6 - 8.5%, range 4.9–13.6%) 0.5 cm before the iliac bifurcation (level C). There was no statistically significant difference between the mean diameter change in the right and left CIA at the 3 levels.

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The mean diameter change 0.5 cm below the aortic bifurcation (level A) in the right iliac artery was 9.2 ± 1.9% (CI 8.5 - 9.9%, range 6.7–13.5%), in the middle of the right CIA (level B) 8.1 ± 1.7% (CI 7.5 - 8.9%, range 4.9–12.4%), and 0.5 cm before the right iliac bifurcation (level C) 8.2 ± 1.8% (CI 7.6 - 8.9%, range 5.6–12.4%). The relative distension at level A was statistically significantly larger than at level B ($p=0.03$) and at level C ($p=0.01$). The difference between the relative distension at level B and C was not significant ($p=0.6$).

The mean diameter change 0.5 cm below the aortic bifurcation (level A) in the left iliac artery was 9.1 ± 2.3% (CI 8.2 - 9.9%, range 5.5–15.4%), in the middle of the left CIA (level B) 8.9 ± 2.3% (CI 8.1 - 9.8%, range 4.7–13.3%), and 0.5 cm before the left iliac bifurcation (level C) 7.9 ± 1.9% (CI 7.2 - 8.6%, range 4.9–13.6%). The relative distensions were statistically significantly larger at level A ($p=0.01$) and at level B ($p=0.04$) than the distension at level C. There was no significant difference between the relative distension at levels A and B ($p=0.7$). The intraobserver variability for diameter changes was 0.6 mm, and the interobserver variability was 0.9 mm.

Table 1: Absolute Maximum and Minimum Diameters and the Diameter Change per Heartbeat

	Level A, mm	Level B, mm	Level C, mm
Both iliac arteries			
Diameter change	1.1 ± 0.4	1.0 ± 0.2	1.0 ± 0.2
Minimum	12.7 ± 3.5	12.4 ± 2.6	12.8 ± 2.1
Maximum	13.8 ± 3.7	13.4 ± 2.7	13.8 ± 2.2
Right iliac artery			
Diameter change	1.2 ± 0.4	1.0 ± 0.2	1.0 ± 0.3
Left iliac artery			
Diameter change	1.1 ± 0.3	1.1 ± 0.2	1.0 ± 0.2

Data are presented as means 6 standard deviation. The heartbeat-dependent diameter increase at level A was bilaterally statistically significantly higher (p<0.05) than the increase at level C.

Mean Iliac Area

The iliac area (Table 2) demonstrated significant changes during the cardiac cycle at all 3 measured levels (p<0.001). The pooled mean area change for the left and right iliac arteries was 12.5 ± 5.4% (CI 11.1 - 13.9%, range 3.0–29.9%) 0.5 cm below the aortic bifurcation (level A), 11.2 ± 4.2% (CI 10.1 - 12.2%, range 3.8–21.9%) in the middle of the CIA (level B), and 9.6 ± 64.0% (CI 8.5 - 10.6%, range 3.8–20.4%) 0.5 cm before the iliac bifurcation (level C). There was no significant difference between the mean area change in the right and left CIAs at all 3 levels.

The mean area change 0.5 cm below the aortic bifurcation (level A) in the right iliac artery was 12.9 ± 5.2% (CI 11.0 - 14.8%, range 5.2–23.0%), in the middle of the right CIA (level B) 10.8 ± 3.5% (CI 9.5 - 12.1%, range 4.4–18.8%), and 0.5 cm before the right iliac bifurcation (level C) 10.4 ± 4.1% (CI 8.9 - 11.9%, range 3.9–20.4%). The relative distension at level A was statistically significantly larger than at level B (p=0.05) and at level C (p=0.02). The difference between the relative distension at levels B and C was not significant (p=0.7).

The mean area change 0.5 cm below the aortic bifurcation (level A) in the left iliac artery was 12.0 ± 5.6% (CI 9.9 - 14.1%, range 3.0–29.9%), in the middle of the left CIA (level B) 11.5 ± 4.7% (CI 9.7 - 13.2%, range 3.8–21.9%), and 0.5 cm before the left iliac bifurcation (level C) 8.7 ± 3.8% (CI 7.3 - 10.1%, range 3.8–19.9%). The relative distension at level A was statistically significantly larger than at level C (p=0.02). Moreover, the relative distension at level B was statistically significantly larger than the distension at level C (p=0.02). The difference between the relative distension at levels A and B was not significant (p=0.7). The intraobserver variability for area changes was 13.3 mm^2, and the interobserver variability was 19.2 mm^2.

Table 2: Absolute Maximum and Minimum Areas and the Area Change per Heartbeat

	Level A, mm^2	Level B, mm^2	Level C, mm^2
Both iliac arteries			
Area change	16 ± 11	13 ± 5	13 ± 6
Minimum	140 ± 95	132 ± 54	138 ± 46
Maximum	157 ± 103	146 ± 57	150 ± 49
Right iliac artery			
Area change	18 ± 13	13 ± 5	13 ± 6
Left iliac artery			
Area change	14 ± 6	14 ± 5	12 ± 5

Data are presented as means 6 standard deviation. The heartbeat-dependent diameter increase at level A was bilaterally statistically significantly higher (*p*,0.05) than the increase at level C.

DISCUSSION

The diameter increase per heartbeat ranged from 8.1% to 9.2% at several levels in the iliac arteries, which should be taken into account when sizing stent-grafts. After the placement of a stent-graft, these dynamics of the iliac tract might influence the durability of successful stent-graft fixation and sealing.

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Stent-grafts should be able to adapt to the movements of the native vessels literally millions and millions of times. Failure of the stent-graft to adapt to these movements might lead to stent-graft migration or endoleaks during follow-up. Earlier investigations of the proximal aneurysm neck demonstrated that a larger pulsatility is related to stent-graft migration.[15] Therefore, stent-graft fixation closer to the iliac bifurcation, in a slightly less pulsatile environment, might possibly be preferable over fixation in a more pulsatile environment.[8–10] However, a pulsatility difference of only 0.1 to 0.2 mm per heartbeat between the proximal and distal iliac arteries is very small, and although there is a statistically significant difference between the investigated levels, we are unsure whether this difference is of clinical value.

Previous studies have shown that the iliac artery expands significantly per heartbeat.[15,16] These studies measured the iliac distension at only 1 level in the iliac artery and are therefore not comparable to our study. Teutelink et al.[16] investigated iliac pulsatility and found the measured distension in the middle of the CIA comparable to our values. Conversely, the mean relative iliac diameter distension in the CIA in another study was ~14% larger than in this study; it was, however, suggested that the measurement method that was used might explain this larger distension.[15,17] The minimum and maximum iliac diameters in that study were measured manually over 1 axis. Comparing minimum and maximum diameters of different axes is not accurate and presenting the distension over 1 axis increases the likelihood of measurement errors.

In our study, the diameter measurements were performed semi-automatically and over 180 axes; pulsatility was defined as the mean difference between the minimum and maximum diameter over these 180 axes. By calculating the differences over 180 axes we not only provide the average distension of the entire vessel, but we also minimize the risks of presenting imprecise measurements. We believe that the observer variability related to manual diameter measurements and determining iliac diameters over only 1 axis clarify the differences between the studies.[15,17]

Limitations

Several limitations of our study are important when interpreting the results. The clinical consequences of iliac distension after EVAR are unknown. Moreover, distension might not be the only factor that possibly influences stent-graft migration. The longitudinal upward and downward movement of the iliac arteries, in addition to distension, likely influences iliac fixation. However, we are currently not able to reliably investigate these iliac movements because of the severe tortuosity and angulations of the iliac vessels. Besides influencing iliac fixation, the longitudinal movement of the iliac arteries is also likely to influence our measurements. We were not able to correct for out of plane movement of the arteries in this study. However, when studying coronal and sagittal dynamic images of the iliac arteries, the movement seems to be minimal near to the aortic and iliac bifurcations. The influence of longitudinal movement thereby seems to most likely affect the measurements performed in the middle of the iliac artery.

On top of this, it is still unknown which factors influence the distension of arteries. Investigation of the influence of age, atherosclerosis, calcification, length, and diameters of vessels on the aortic distension can be of great value. It might, for instance, be that patients with larger aneurysms have a lower pulsatility compared with patients with smaller aneurysms. By investigating this, it might become clear which patients have the largest distension, so the use of dynamic imaging for stent-graft sizing and EVAR planning in these patients might be more important than in others. Finally, the observer variability should not be forgotten. Although the measurements in this study were performed semi-automatically, the observer variability resulted from minor manual corrections considered necessary in patients with thrombus or calcification at the measurement levels. The intraobserver variability for diameter measurements was, however, only 0.6 mm, and there were no patients with a CIA pulsatility <0.6 mm.

The incidence of distal type I endoleaks is considerable and might be related to preoperative suboptimal stent-graft sizing.[6,7] Stentgrafts should be adequately oversized distally, thereby compensating for the iliac heartbeat-dependent distension.[15] Studies investigating a possible relationship between iliac distension and endoleaks or stent-graft migration now have to be performed.

CONCLUSION

The pulsatility in the iliac arteries is statistically significant at several EVAR-relevant levels. The distension of the iliac artery possibly decreases more distally, which might encourage the extension of stent-grafts to the internal iliac artery.

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6

VALIDATION OF A NEW STANDARDIZED METHOD TO MEASURE PROXIMAL ANEURYSM NECK ANGULATION

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ABSTRACT

Purpose: This study presented and validated a new standardized method for the measurement of the aortic angulation in patients with abdominal aortic aneurysms (AAA) and quantified the observer variability.

Methods: A standardized method to quantify aortic angulation was introduced. To measure aortic angulation, a center lumen line (CLL) of the aorta was made, and a three-dimensional (3D) aortic reconstruction was obtained. The 3D reconstruction was turned 360° perpendicular to the CLL in the middle of the flexure. The sharpest angle of the CLL was considered the true angle of the aortic axis. The computed tomography angiography data sets of 20 patients scheduled for endovascular aneurysm repair (EVAR) were obtained. The angles between the suprarenal aorta and the aneurysm neck (α) and between the aneurysm neck and sac (β) were measured. Two observers independently measured the angles. Differences of each pair of measurements were plotted against their mean and intraobserver and interobserver variabilities were calculated according to Bland and Altman.

Results: The intraobserver mean difference for angle α was -0.2° (-0.5%), with a repeatability coefficient (RC) of 6.4° (20.2%), and 0.6° (1.4%) for angle β, with a RC of 6.2° (13.4%). The interobserver mean difference for angle α was -1.5° (-4.5%), with a RC of 6.9° (22.0%), and -0.2° (-0.4%) for angle β, with a RC of 7.4° (16.0%). No significant differences were observed between the observers.

Conclusion: The presented technique to objectively quantify the angulation of the aneurysm neck is easy to perform and reliable. This method showed good intraobserver and interobserver variability and should therefore be the standard when measuring and reporting aortic angulation.

INTRODUCTION

Endovascular aneurysm repair (EVAR) has become a widely accepted therapy for abdominal aortic aneurysms (AAA). EVAR has several advantages compared with open aneurysm repair, and the short-term results of EVAR are superior.[1] To achieve good results with EVAR, patient selection is a very important element. Only then can the risk of EVAR-related complications be minimized, thereby improving both the short-term and long-term results of this procedure.[2,3] The morphology of the aneurysm neck is considered especially important in this process.[4,5]
The angulation of the proximal aneurysm neck is considered one of the most important morphologic characteristics with major negative effects on the results of EVAR, including type I endoleaks, stent graft migration, secondary interventions, and conversion.[2,3,6-9] For this reason, the instructions for use for all commercially available endografts have clear guidelines on maximal angulation of the aortic neck. The reporting standards for EVAR also contain recommendations regarding the investigation of the aneurysm neck morphology.[10]
Strangely enough, there is currently no consensus on how to measure and quantify the aortic neck angulation exactly. Thus far, most studies investigating the relationship between neck angulation and outcome after EVAR have used various techniques, but none have assessed the observer variation of the methods they used.[2,3,6,8,9]
A recent study of observer variability for the measurement of angulation of aneurysm necks on three-dimensional (3D) computed tomography angiography (CTA) reconstructions[11] concluded that there was substantial observer variability. Therefore, it is mandatory that other techniques be investigated to minimize observer variability.

6

Confounders of aortic angle measurements

The regularly used methods for angle measurement are operator dependent and not standardized. To improve the angle measurement technique, it is important to acknowledge that the aorta can angulate in several directions (dimensions) simultaneously. Parts of the aorta are overlapping if a 3D reconstruction of an angulated aorta is only viewed in one direction; therefore, angulation itself can be a cause for overestimation or underestimation of the aortic angle. To minimize the influence of angulation itself on angle measurements, an angle should be measured perpendicular to the aortic lumen in the middle of the flexure, as shown in Fig 1. Precise 3D navigation of an aortic reconstruction is complex. It is hard to navigate a 3D reconstruction precisely 360° around a specific point in a plane perpendicular to the aorta without aid in navigation.
Another reason for imprecise aortic measurements is widening or narrowing of an aneurysm or aneurysm neck. This widening or narrowing results in the inner and outer curvature angles being possibly different from each other, as can be seen in Fig 2. The mean aortic angle is the angle of the center of a vessel. A new standardized aortic angle measurement technique should take these problems into account and neutralize them in order to be precise.

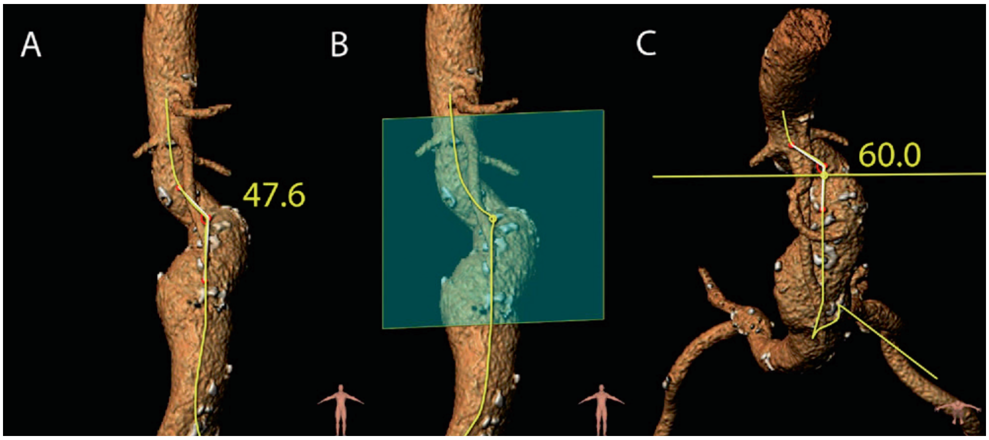


Figure 1: A, *An anteroposterior view of the aorta shows the measurement of the infrarenal aortic angulation.* ***B,*** *A plane perpendicular to the center lumen line (CLL) in the middle of the infrarenal angle is added.* ***C,*** *The exact same angle is measured as in Panel A, but now with a view perpendicular to the CLL in the middle of the angle (indicated by the* yellow line *perpendicular to the CLL). Note the more severe angle measured on the right. The difference is caused by the horizontal movement of the aorta, which is unnoticed because of aortic overlap in Panel A. Thus, the angle measured on the left is an underestimation.*

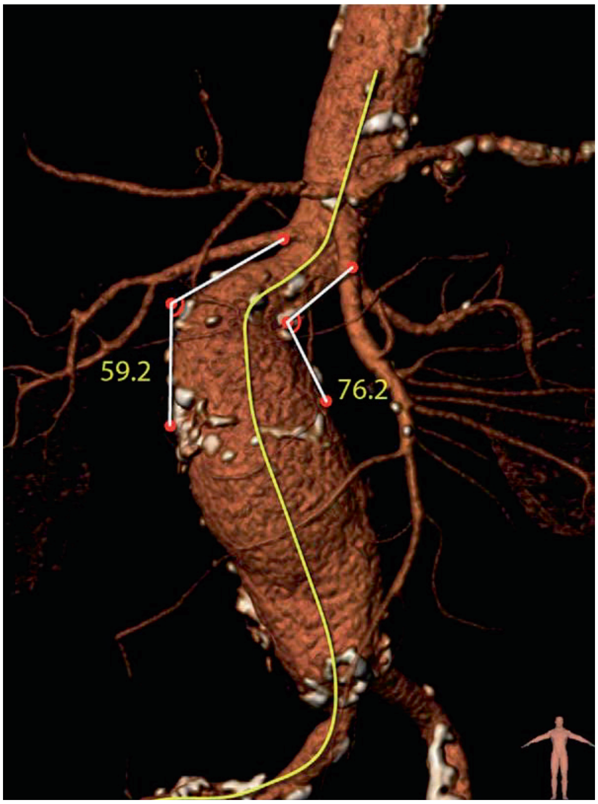


Figure 2: *The influence is shown of asymmetric widening of the aorta on aortic angles. The angle of the inner curvature is more severe than the angle of the outer curvature.*

The purpose of this study is to present a new standardized measurement technique for aortic neck angles and to quantify the observer variability of this technique. Our hypothesis is that this technique is more precise than previously used methods, and has lower observer variability.

METHODS

Aortic neck angulations were determined by two observers on CTA data sets of 20 AAA patients (17 men) who were a mean age of 72 years (range, 62-85 years). The data sets of these 20 patients, who were scheduled for EVAR, were randomly selected from our hospital EVAR database. All images were acquired between 2004 and 2006.

Image acquisition

All CTA scans were acquired on a 64-slice CT-scanner (Philips Medical Systems, Best, The Netherlands) with a standardized acquisition protocol (scan parameters: 9-mm slice thickness, 0.7-mm increment). Intravenous nonionic contrast (120 mL; Iopromide, Schering, Berlin, Germany), followed by a 60-mL saline chaser bolus, was injected at a rate of 6 mL/s. The scan was started using bolus-triggering software with a threshold of 100 HU over baseline. The acquired data sets were transferred to a workstation (3Surgery 4.0; 3Mensio Medical Imaging B.V., Bilthoven, The Netherlands) for measurement of the aortic neck angles.

Angle measurement technique

The aortic angulations in this study are measured according to the following standardized method:

First, a 3D CTA reconstruction of the aorta is acquired.

Second, an aortic center lumen line (CLL) is drawn semi-automatically. An aortic CLL is calculated automatically after start and endpoint of the CLL are placed in the aortic lumen. The position of CLL spline points is checked manually on transverse, orthogonal, and sagittal planes. A spline point that is not in the middle of the aorta on one of these planes is corrected manually. Thus, the CLL is actually a center vessel line that needs correction if a vessel is lined by, for instance, thrombus or calcification.

Third, a view perpendicular to the CLL in the middle of the angle is visually acquired. The middle of the angle is defined as the inflection point of the lumen of the suprarenal aorta and the aneurysm neck for the suprarenal angle (α) and the inflection point of the lumen of the aneurysm neck and the AAA sac for the infrarenal angle (β).

Fourth, the 3D reconstruction of the aorta is turned 360° around the middle of the angle. While turning the 3D reconstruction, the view is kept perpendicular to the CLL. The most severe angle over the 360° in the middle of the angle is measured with the use of electronic callipers without predefined length of the rays. The length of the rays along the CLL, however, is as long as possible. An overview of the consecutive steps is given in Fig 3.

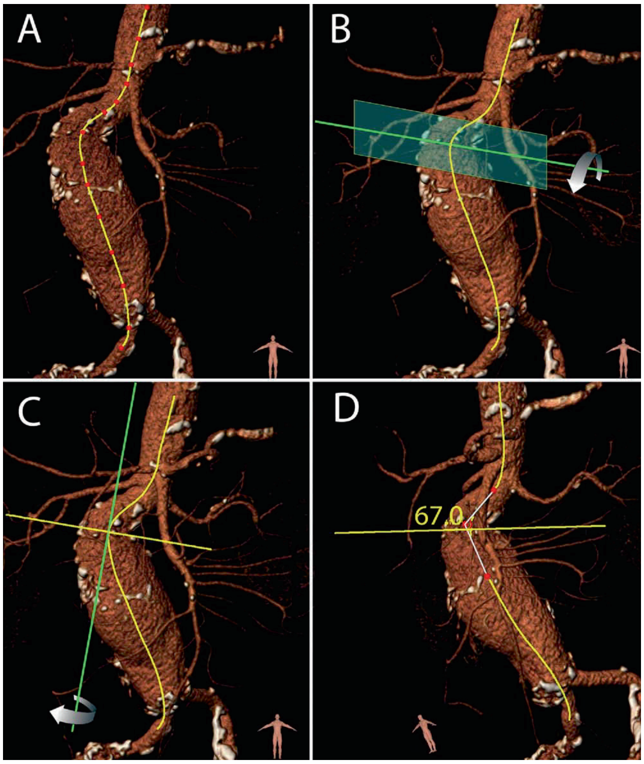


Figure 3: *The consecutive steps for aortic angle measurements are shown.* ***A,*** *The construction of the center lumen line (CLL) is performed semi-automatically. CLL spline points (red points) are checked and can be corrected manually, if necessary.* ***B,*** *An anteroposterior view of the aorta with a plane perpendicular to the middle of the infrarenal angle is seen. The arrow indicates that the three-dimensional reconstruction should be rotated along the green line to obtain a view perpendicular to the middle of the infrarenal angle.* ***C,*** *A view perpendicular to the middle of the infrarenal angle is seen (indicated by the yellow line perpendicular to the CLL). The arrow indicates that the three-dimensional reconstruction should be rotated 360° around the green line for measurement of the aortic angle.* ***D,*** *Measurement of the most severe angle over the 360° in the middle of the angle with the use of electronic callipers.*

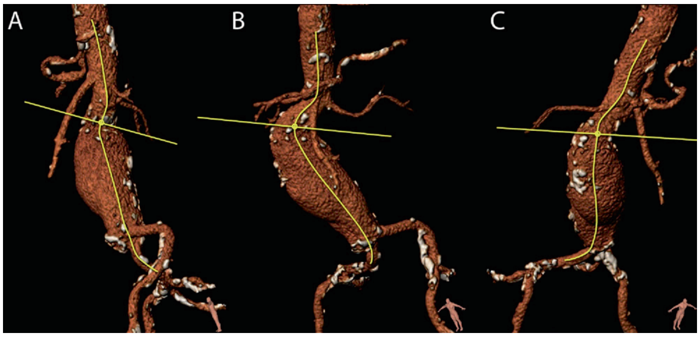


Figure 4: *Three-dimensional reconstructions of the aorta are shown. An aortic center lumen line (CLL) is created (yellow line) in all reconstructions. The view in all reconstructions is perpendicular to the middle of the infrarenal angle (indicated by the yellow line perpendicular to the CLL).* ***A, B*** *and* ***C,*** *Note the differences in angle while the three-dimensional reconstruction is turned 360° around this point. The most severe angle of the CLL is noted as the true angle.*

An example of a view perpendicular to the aorta is given in Fig 1, *C.* It is important to realize that the 3D reconstruction is not turned 360° around the craniocaudal axis, but around the axis of the CLL of the aorta (Fig 4). This step urges the observer to inspect the aorta from every different viewpoint and helps to navigate in a 3D model. A reconstructed plane perpendicular to the CLL makes navigation perpendicular to the CLL easier and will be seen as a flat line if the view is perfectly perpendicular to the aorta (Fig. 1 and 4).

Evaluation

Two investigators performed the angle measurements independently and in a random order. All measurements were performed according to the measurement technique described above. The suprarenal (α) and infrarenal (β) angles were measured on all CTAs. The suprarenal angle (α) is the angle between the flow axis of the suprarenal aorta and the flow axis of the AAA neck. The infrarenal angle (β) is the angle between the flow axis of the aneurysm neck and the flow axis of the AAA sac (Fig 5). A completely straight aortic neck corresponds to 0° angulation, and more angulation corresponds to higher degrees of angulation.

The results of the two observers were compared to assess the interobserver variability. For determination of the intraobserver variability, one observer measured all aortic angles twice, with an interval of 2 weeks. The intraobserver and interobserver variabilities for the angle measurement technique were calculated using the Bland and Altman method.[12] The differences between two measurements were plotted against the mean values of these measurements. The standard deviation (SD) of the mean difference was calculated. The mean difference between two measurements was considered the center of agreement. The limits of agreement were defined as 1.96 SD above and below the center of agreement. The repeatability coefficient (RC) was calculated by squaring the differences of two measurements, adding them, dividing them by *n,* taking the square root and multiplying this number by 1.96.[12]

The different measurements of the observers were compared by a *t*-test for paired data. Statistical significance was assumed at $P < 0.05$. Data are presented as mean ± SD. The mean difference, SD, and RC are also presented as percentages of the first measurements of observer 1.

6

RESULTS

The results are summarized in the Table. For observer 1, the mean α angle was 31.5° ± 19.1° (range, 7.4°-91.8°) for the first measurement and 31.7° ± 19.3° (range, 8.0°-92.4°) for the second measurement. For observer 2, the mean α angle was 32.3° ± 19.5° (range, 7.2°-95.6°). For observer 1, the β angle was 46.1° ± 16.6° (range 22.7°-77.3°) for the first measurement and 45.5° ± 16.5° (range, 20.1°-74.2°) for the second measurement. For observer 2, the β angle was 46.3° ± 15.2° (range, 24.6°-75.2°).

The differences of measurements plotted against the mean of measurements for the interobserver and intraobserver variability can be found in Fig. 6 and 7. The intraobserver mean difference for angle α was – 0.2° (–0.5%), with an RC of 6.4° (20.2%), and 0.6° (1.4%) for angle β, with an RC of 6.2 (13.4%). One α angle measurement difference was outside the limits of agreement. All other measurement differences were within the limits of agreement. No significant differences were observed between the two measurements of observer 1.
The interobserver mean difference for angle α was –1.5° (–4.5%), with an RC of 6.9° (22.0%), and –0.2° (–0.4%) for angle β, with an RC of 7.4° (16.0%). One measurement difference for the β angle was outside the limits of agreement. All other measurement differences were within the limits of agreement. No significant differences were observed between the two observers.

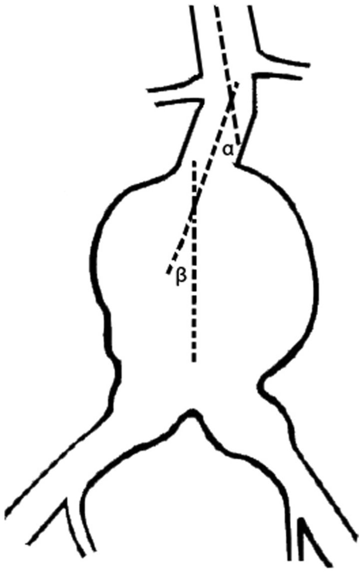


Figure 5: *The angle between the longitudinal axis of the suprarenal aorta and the longitudinal axis of the abdominal aortic aneurysm (AAA) neck (α) and the angle between the longitudinal axis of AAA neck and the longitudinal axis of the AAA sac (β) are shown.*

Table. Assessment of interobserver variability and repeatability coefficients

Difference, deg[a]			
Variable	Mean	SD	RC, deg[a]
Angle α			
Intraobserver	-0.2 (-0.5)	3.3 (10.6)	6.4 (20.2)
Interobserver	-1.5 (-4.5)	3.3 (10.4)	6.9 (22.0)
Angle β			
Intraobserver	0.6 (1.4)	3.2 (6.9)	6.2 (13.4)
Interobserver	-0.2 (-0.4)	3.9 (8.4)	7.4 (16.0)

RC, Repeatability coefficient, SD, standard devation.

[a]Data in parentheses reflect the percentage of the first measurement.

DISCUSSION

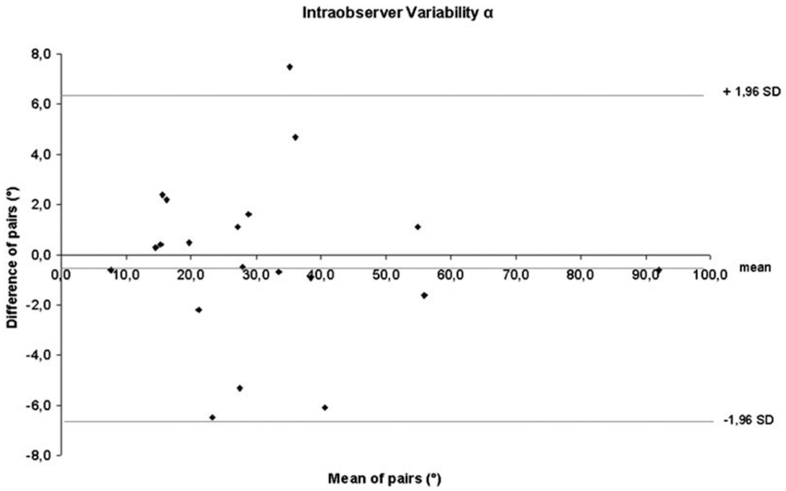
We have presented in this study a technique to quantify aortic angles as well as its observer variability. The interobserver variability of this technique is 6.9° for α (22.0%) and 7.4° for β (16.0%). This makes this measurement technique far more reliable than other reported techniques.[8,11] The relative repeatability coefficients decrease, while absolute angles increase (mean α angle 32.3°, mean β angle 46.1°). The introduced method is therefore also reliable in more severely angulated aneurysm necks.

A previously validated angle measurement technique reported an interobserver variability of 19.4° (49%) and a mean measurement deviation between two observers of 32.1% ± 24.8% (12.8° ± 9.9°).[11] The interobserver variability using that method was therefore substantial, and the authors stated that other technical approaches had to be studied.

There are several reasons that probably make the technical approach used in this study more reliable. The technique we have described is more standardized than the previously used methods. This standardization lessens the influence of several clear confounders. The use of a CLL minimizes the influence of widening and narrowing of the aorta and thus inner-outer curvature differences. Moreover, we have experienced that the use of an aortic CLL makes the location of the angles of the aorta more obvious. Besides, 360° navigation perpendicular to a specific point on this CLL urges the observer to inspect the 3D model of the aorta from all sides. This minimizes the influence of inaccurate 3D navigation and aortic overlap in this reconstruction.

The current restrictions for the use of stent grafts in angulated aneurysm necks are based on studies that determined the influence of angulated necks on EVAR outcome and on laboratory studies performed by stent graft manufacturers. We believe that angulated aneurysm necks negatively influence EVAR results, because several studies, using different measurement techniques, concluded that these results are influenced by angulations. However, it is at least remarkable that all studies determining the influence of angulations on outcome have used different, nonvalidated angle measurement techniques.[2,3,7-9] This makes the results of these studies less reliable and should be taken into account.

Nevertheless, accurate and reliable measurement of aortic angles is important. A reliable measurement technique of aortic angles helps to identify high-risk EVAR patients preoperatively. Identification of these patients might have consequences: an open procedure might be considered or a specific stent graft that is more dedicated to angulated necks might be used. Besides, it is imaginable that the post-EVAR surveillance scheme will be stricter in these patients. Adequate preoperative investigation of the aortic angles might therefore prevent or permit early detection of EVAR-related complications. Moreover, the use of a standardized aortic angle measurement technique is important to compare the results of several studies and stent grafts. This is especially relevant as the number of patients with angulated necks who are being treated by EVAR is increasing with the introduction of stent grafts especially designed to treat patients with hostile necks.[13] Inclusion criteria for EVAR are widening, and in our center, for example, most patients with angulations of up to 90° undergo EVAR if the aneurysm neck length is ≥15 mm.



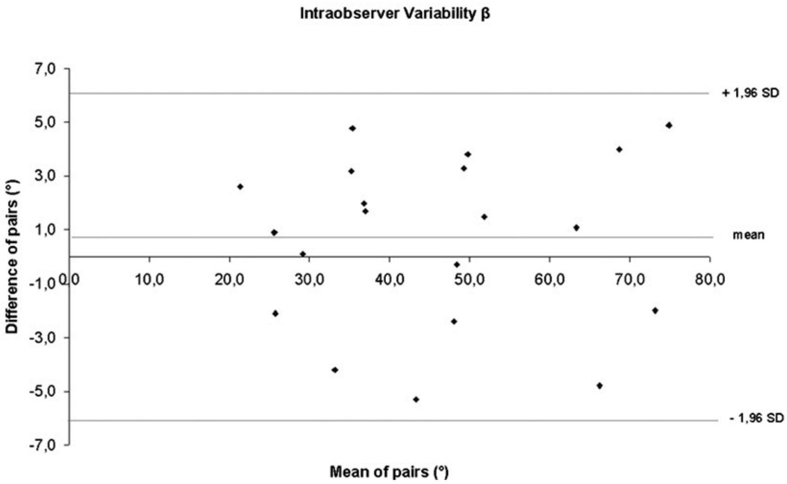


Figure 6: *Bland and Altman plots show observer variability of both angles. The mean of pairs is plotted against the difference of pairs. The mean difference is close to zero, and the limits of agreement, set as 1.96 standard deviations* (SD), *are acceptable.*

A different way to measure aortic angles is by a technique called trigonometry.[14] For trigonometry, X, Y, and Z values (coordinates) are needed on several CTA slices. With the use of these values, angles can be calculated with the use of several formulas. A major disadvantage of this technique is the combination of several individual measurements (of coordinates) and calculations. This makes this measurement technique less likely to be used in clinical practice. It is time-consuming and is therefore not the most optimal way to measure aortic angles.

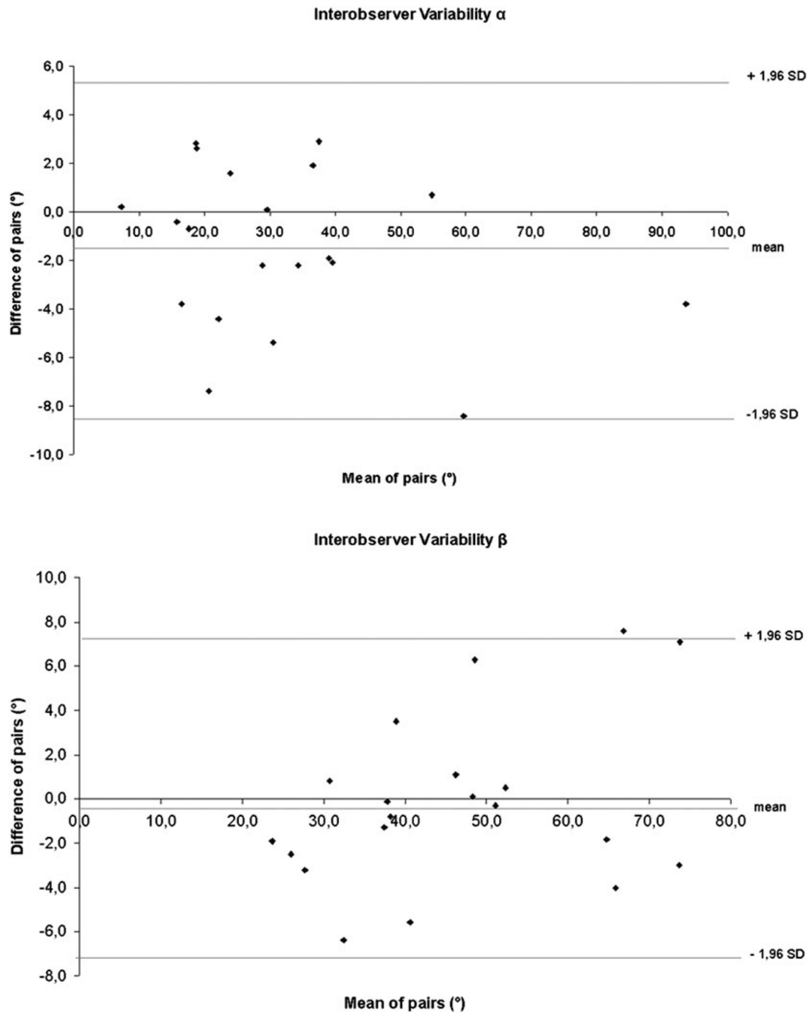


Figure 7: *Bland and Altman plots show interobserver variability of both angles. The mean of pairs is plotted against the difference of pairs. The mean difference is close to zero, and the limits of agreement, set as 1.96 standard deviations* (SD)*, are acceptable.*

We have measured the observer variability of two aortic angles. The angle between the axis of the AAA sac and the infrarenal aortic neck is the most important landing zone for most EVAR devices, but the angle between the suprarenal aorta and the infrarenal neck is becoming more important with the use of stent grafts with suprarenal fixation and branched or fenestrated stent grafts. The relation between these two angles is also of value. Opposing angles will result in opposing forces on the most proximal part of the stent grafts, possibly influencing the sealing and fixation zone of the stent graft even more.

This study has some limitations. First, the aortic angle measurement technique introduced in this study can only be performed with the use of CTA postprocessing software. CTA postprocessing software is currently, however, widely available and (almost) all postprocessing software is able to perform these angle measurements.
Second, the construction of a CLL makes the method for angle measurements applied in this study a little more time consuming than other methods. Nevertheless, the construction of a CLL usually takes no longer than several minutes because it is often done automatically and is also necessary for reliable diameter measurements and stent graft sizing.[15]
Third, navigation perpendicular to a CLL can be difficult in some CTA postprocessing systems. The visual navigation perpendicular to the CLL might be easier with the use of a reconstructed plane (Fig. 1 and 3). Moreover, the determination of the middle of an angle in a gradual angle may account for small differences between two observers.
Finally, a 2D measurement is only an estimation of a 3D angle. This might lead to overestimation or underestimation of an aortic angle, but we could not correct for this problem.
The observer variability in this study was acceptable: the mean difference between two independent measurements was close to zero. Besides, the limits of agreement were satisfactory and were <8°. Although the repeatability coefficients were up to 22% (6.9°), we believe they are satisfactory, especially when the absolute degrees of angulation are being compared. Moreover, it was satisfactory to see that the RC was comparable for both the α and β angles, although the β angle was larger than the α.

CONCLUSION

The technical approach for aortic angle measurements described in this study is easy to perform and repeatable. The variability in measured angulation was very low among the observers. This standardized measurement technique may be an improved method to optimize patient selection. Besides, when EVAR studies are reported, standardized measurements for aortic angulations might contribute to a better way to compare results.

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7

TIPS AND TECHNIQUES FOR OPTIMAL STENT GRAFT PLACEMENT IN ANGULATED ANEURYSM NECKS

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ABSTRACT

An increasing number of patients with severely angulated abdominal aortic aneurysm (AAA) necks are being treated by endovascular aneurysm repair (EVAR). Optimal preprocedural planning and investigation of the AAA morphology is essential to achieve a successful EVAR in these patients. In this article, we discuss specific problems that can be encountered during preoperative planning in relation to periprocedural stent graft deployment in patients with angulated AAA necks and offer potential solutions for these problems.

INTRODUCTION

The proximal aneurysm neck is considered the Achilles' heel of the endovascular aneurysm repair (EVAR) procedure.[1] The length, diameter, and angulation are regarded as important morphologic features of the proximal aneurysm neck,[2,3] and more hostile aneurysm necks are related to adverse EVAR outcomes.[2,4-6] However, with the introduction of newer stent grafts and with increasing experience in the use of endovascular devices, patients with shorter, more severely angulated and wider aneurysm necks are also considered eligible for EVAR.[7]
Angulation of the proximal aortic aneurysm neck makes adequate proximal stent graft fixation and sealing more difficult. For an optimal position of the stent graft body, it is important that adequate planning has been performed. Preprocedural computed tomography angiography (CTA) measurements, the choice of stent graft size, and the plan for deployment are all heavily influenced by the angulation of the aneurysm neck.
The purpose of this article is to draw attention to the specific preoperative preparation for EVAR in patients with angulated abdominal aortic aneurysm (AAA) necks. Problems that can be encountered during preoperative planning and stent graft deployment in patients with angulated AAA necks are discussed, and potential solutions for these problems are given.

MEASUREMENTS AND PLANNING

In patients with angulated AAA necks, a CTA must be obtained preoperatively for adequate planning of the EVAR procedure, although magnetic resonance angiography (MRA) can also be used. The morphology of the access vessels, the aneurysm, and the proximal and distal stent graft landing zones must be examined with the use of these imaging techniques.

Aortic center lumen line

An aortic center lumen line (CLL) of the aorta should be constructed with the use of dedicated software. A reconstructed stretch view of the aorta can thereafter be generated around this CLL. This stretch view allows for optimal diameter measurements perpendicular to the CLL and length measurements alongside this CLL. The angulations in the proximal aortic aneurysm neck must also be quantified with the use of a volumetric 3-dimensional reconstruction of the aorta, according to an earlier published protocol.[8]

Investigation of the aneurysm neck

Patients with angulated aneurysm necks are more likely to have additional adverse morphologic neck features than other AAA patients.[9] The aneurysm neck should therefore be investigated for its shape, length, and diameter as well as for the presence of thrombus, calcification, and bulging.

The investigation of the AAA neck length is a complicated part of this process. While measuring the aneurysm neck length on a reconstructed view along the CLL, one should realize that the length of a virtually stretched aneurysm neck is being measured. The actual aneurysm neck length is most likely not equal to the functional neck length in patients with angulated necks. The functional neck is defined as the length of the neck that can be adequately used for fixation and sealing of the stent graft. Angulation in an aneurysm neck, however, hampers the effort to use the entire neck for stent graft fixation and sealing.

An inner and outer curvature exists in an angulated aneurysm neck, with the shorter inner curvature probably being the limit of the functional neck (Fig 1). A stent graft can only use the entire length of the neck for fixation and sealing if the aneurysm neck is straightened. Periprocedural straightening of an aneurysm neck thus increases the functional neck, which is therefore desirable.

It is important to estimate the straightening possibilities during the procedure because this may optimize the sealing zone for the stent graft and also possibly influences the stent graft sizing process. Whether the aneurysm will straighten during EVAR depends on many factors, however, and is therefore hard to predict.

One factor is the patient's anatomy. Calcification of the aneurysm neck, the length of the neck, the presence and morphology of lumbar arteries in the AAA neck, and the angle between the neck and the common iliac arteries all determine the possibility of straightening the aneurysm. Another important factor is the stiffness of the guidewire introduced during the procedure. A stiff wire is more likely than a less stiff wire to straighten the tortuosity of the access vessels and the AAA neck.

The length of an aneurysm neck probably is the most important anatomic factor determining the straightening possibilities during the procedure. A guidewire in a long aneurysm neck is forced to follow the track of the aneurysm neck and take the inner-outer curvature route. In a short aneurysm neck, however, the guidewire will take the inner-inner curvature route, which is almost straight; therefore, the longer the angulated aneurysm neck, the more it can be straightened during the procedure.

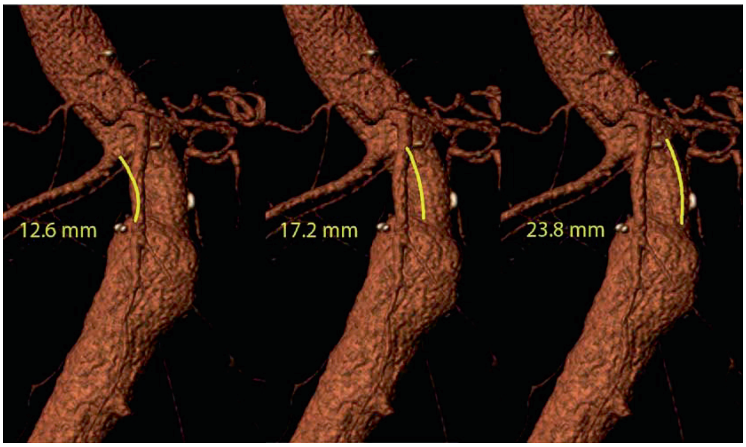

Figure 1: *The yellow lines in the aneurysm neck are lumen lines. The center lumen line is projected in the middle, a lumen line in the inner curvature of the aneurysm neck is on the right, and a lumen line in the outer curvature of the neck is on the left. The center lumen line length indicates the true length of the neck, but will probably not be the functional neck.*

Stent graft sizing

The instructions for use of most stent grafts recommend oversizing the body of a stent graft 10% to 20% compared with the preoperative aortic neck diameter. These recommendations are based on straight aneurysm necks and thus symmetric placement of the stent graft.

In an angulated aneurysm neck, however, the stent graft size needs to be determined after the investigation of the morphology of the neck and the estimation of the periprocedural angulation. It is important to realize that there is a possibility that a stent graft can be positioned asymmetrically in an angulated aneurysm neck. This asymmetric deployment can occur because of the asymmetric positioning of a guidewire in an angulated aneurysm neck, which is caused by the curves in the neck and the stiffness of the wire and the delivery system.

The differences between symmetric and asymmetric positioning are shown in Fig. 2 and 3. The following explanation describes the possible consequences of asymmetric positioning on stent graft sizing by giving a simple example:

Imagine a patient with an aneurysm neck diameter of 25 mm (circumference, 78.5 mm). A symmetrically placed stent graft with a diameter of 30 mm would fit perfectly in this aneurysm neck (20% oversizing). If this stent graft is not placed symmetrically, but at an angle of 20° to the aneurysm neck, the oversizing will be less. The area that has to be covered by the stent graft will be elliptically shaped and more aortic wall will have to be covered. In this situation, the circumference of the ellipses will be 81.2 mm, which corresponds to a circle with a diameter of 25.8 mm, and the oversizing will be 16% instead of 20%. If the stent graft is placed at an angle of 40% to the aneurysm neck, which is not uncommon in severely angulated necks, then the circumference of the ellipse of the neck increases to 92.0 mm, which resembles a circle with a diameter of approximately 29.2 mm (circumference, 92.0 mm). In this situation, a stent graft of 30 mm is only oversized 2.4% (Fig 4).

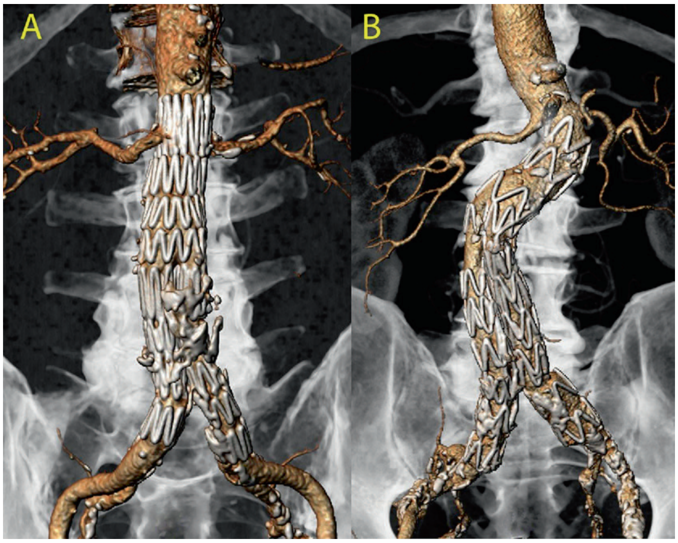

Figure 2: A, *A symmetrically deployed stent graft is shown in a straight aneurysm neck.* ***B,*** *An example of an asymmetrically positioned stent graft is shown in an angulated aneurysm neck.*

Figure 3: *This is an enlargement of the aneurysm neck that is shown in Fig 2, B. The stent graft is placed asymmetrically compared with the aneurysm neck. The asymmetric placement of stents grafts may have serious consequences.*

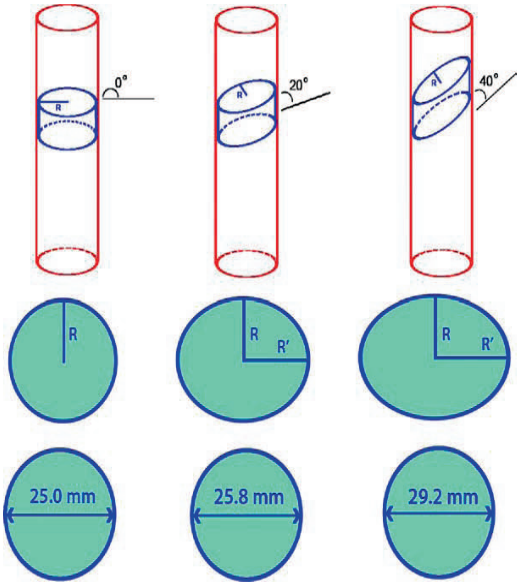

Figure 4: *Drawings show the consequences of asymmetric stent graft placement. The radius/diameter of a plane not perpendicular to aorta increases the more oblique it is placed to the perpendicular plane, thereby influencing the degree of oversizing.*

We therefore believe that stent grafts should be oversized >20% (based on diameter measurements perpendicular to the aorta) if asymmetric placement can be expected. Because the appropriate diameter of a stent graft depends on the preprocedural straightening of an aneurysm neck and the position of a guidewire in the neck, stent grafts with different proximal diameters should be available during EVAR procedures in angulated necks. Furthermore, the interventionalist should anticipate stent graft deployment over very stiff and less stiff guidewires, which may influence the symmetry of the stent graft placement.

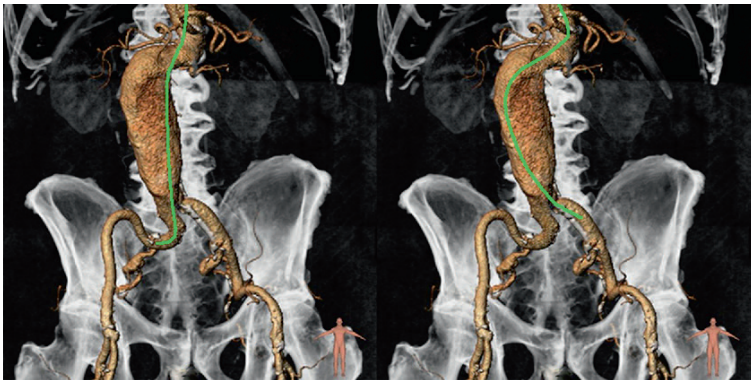

Figure 5: *The green lines are expected guidewire routes.*
Left, *A guidewire is introduced in the right groin.* ***Right,*** *A guidewire is introduced in the left groin. The access site for the guidewire influences the route of the guidewire.*

Access site determination

Once stent graft sizes are determined, the preferable access site for the main device is chosen. This, apparently, depends on the diameter and calcification of the access vessels and on the morphologic characteristics of the AAA neck. The angulation of the iliac vessels should not be forgotten, however. The tortuosity of the iliac vessels, and especially the aortoiliac angle, influences the direction of the guidewire and, thus, of the stent graft. The straightening of the aneurysm neck, which determines the length of the functional neck, and the final track of the guidewire, which determines whether the stent graft can be deployed in line with the aorta or asymmetrically, are therefore also dependent on the access site for the main device (Fig 5). Therefore, the interventionalist should anticipate the introduction of the stent graft from either groins when planning the procedure.

C-arm positioning

Another important aspect of preoperative planning is the determination of the most optimal C-arm position, with a view perfectly perpendicular to the origin of the lower most renal artery. A suboptimal positioned C-arm will cause overlap of vascular structures. By optimally positioning the C-arm, the stent graft can be deployed just below the lower most renal artery, allowing for maximal sealing and fixation of the stent graft in the aneurysm neck (Fig 6 and 7). The most optimal C-arm position depends on the clock position of the ostium of the lowermost renal artery and the angulation of the aneurysm neck, which can be determined preoperatively. The C-arm needs to be angulated orthogonally to the aortic neck and orthogonally to the armpit of the most distal renal artery. This most optimal position of the C-arm can be different during the procedure than expected preoperatively, as the aneurysm neck possibly straightens out more or less than expected. We have found that although the angulation of the AAA neck can change perioperatively, the clock position of the renal arteries does not change under the influence of an introduced guidewire or stent graft. Moreover, the most optimal C-arm position can be checked and fine-tuned during the procedure if stent grafts with more than two markers at the proximal end are used. If a stent graft has more than two proximal markers at one level, then all markers are visible in a straight line in the most optimal C-arm position.

We therefore advise that a stent graft should be introduced under fluoroscopy, with the C-arm in the standard anterior-posterior position, up to the expected location of the lower most renal artery. The C-arm is thereafter angulated in the preoperatively determined most optimal position, taking the neck angulation and clock position of the renal arteries into account. Angiography is then performed, and deployment of the stent graft is started at the desired position. After deployment of the proximal stent ring(s), the C-arm position can be corrected in the cranial-caudal direction, if necessary, by using the proximal markers of the stent graft. A new angiogram is thereafter advised for fine-tuning of the stent graft position and full stent graft deployment thereafter.

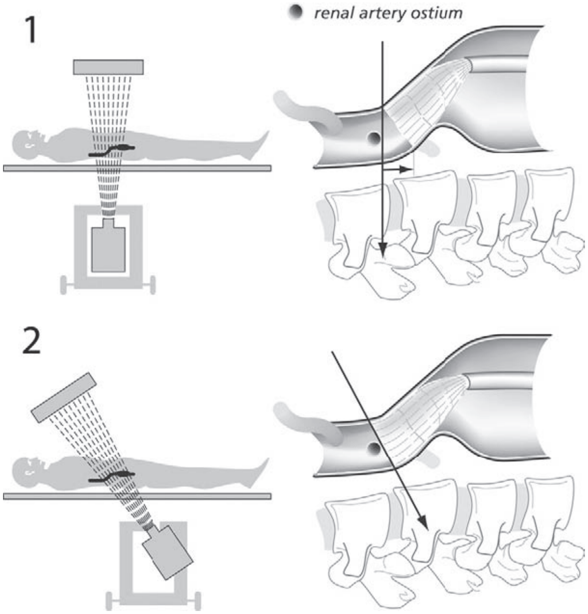

Figure 6: *Inaccurate positioning of the C-arm underestimates the length of the abdominal aortic aneurysm (AAA) neck.* ***Panel 1,*** *A neutral position of the C-arm is shown in the images on the top. Although the stent graft position seems visually right, the stent graft position is suboptimal, and the entire neck is not used for stent graft fixation and sealing.* ***Panel 2,*** *A C-arm position orthogonal to the aortic angulation (cranial-caudally angulated) is shown. The entire AAA neck is used.*

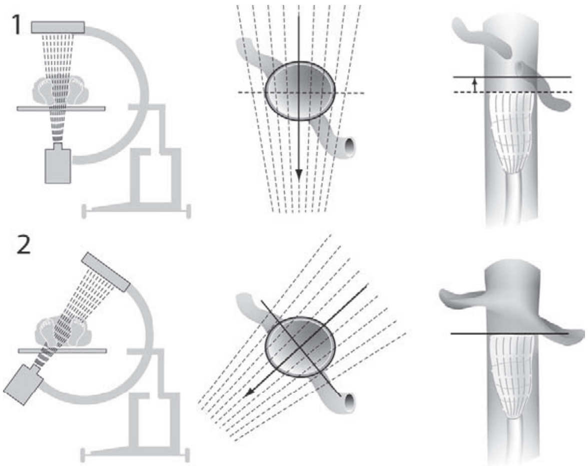

Figure 7: *Inaccurate positioning of the C-arm underestimates the length of the abdominal aortic aneurysm (AAA) neck.* ***Panel 1,*** *A C-arm position in neutral position is shown. Again, the stent graft position seems visually optimal.* ***Panel 2,*** *Lateral angulation of the C-arm provides a view orthogonal to the clock position of the renal arteries. This view allows the entire use of the AAA neck for stent graft fixation and sealing.*

DISCUSSION

EVAR is increasingly being used as an alternative for open repair in patients with hostile proximal aneurysm neck anatomy. More patients with a hostile neck are considered suitable for EVAR and exclusion criteria are narrowing.[10] Nonetheless, inferior EVAR outcomes have been reported in patients with severely angulated proximal aneurysm necks.[2,4-6] EVAR is far more complex if the proximal aneurysm neck is angulated, and more stent grafts are deployed at suboptimal positions in these circumstances. If this is acknowledged and the potential obstacles in patients with angulated aneurysm necks are recognized, one can adapt to these. By doing this, the results of EVAR in patients with angulated aneurysm necks can be improved.

The functional neck length and the possibility of enlarging this neck by straightening the aneurysm neck, can be investigated by adequate preoperative investigation and planning. Besides, it can be necessary to adapt the stent graft size (oversize the stent graft >20% based on diameter measurements perpendicular to the aorta) in angulated aneurysm necks. A potential drawback of this oversizing is the possible relationship between oversizing and neck dilatation and stent graft migration. Until now, however, no relation between oversizing and neck dilatation has been confirmed.[11] Moreover, oversizing of up to 25% seems to decrease the risk of proximal endoleaks.[11] We believe that oversizing of stent grafts should be at least 20% in some patients with angulated aneurysm necks.

If asymmetric stent graft placement is considered a possibility, it is advisable to have several stent graft sizes available during the endovascular procedure. The degree of oversizing of the stent graft can be adapted to the straightening of the aneurysm neck, the (asymmetric) position of the guidewire, and the access site of the main device.

Straightening of an angulated aneurysm neck is desirable and can be achieved by the introduction of a very stiff guidewire. However, a stiff guidewire will probably be placed asymmetrically in an angulated neck. To prevent asymmetric deployment, a second stiff guidewire can be introduced for the delivery of the stent graft. If the stent graft introduced over the second guidewire is in an optimal place for deployment, the guidewire over which the stent graft is introduced can be replaced by a less stiff wire. This will result in a more symmetric placement of the stent graft. Nevertheless, one should note that changing a guidewire is not allowed in all stent grafts according to the instructions for use.

In patients with angulated aneurysm necks, it is important for several reasons that most of the aneurysm neck can be used as the functional aneurysm neck: First, the radial forces of a stent graft can only be used for sealing and fixation if it is placed appropriately to the aortic wall. In a more angulated neck, the length of the stent graft alignment to the aneurysm neck will be shorter than in a straight aneurysm neck.

Second, the greater the curvature of a tube, the greater the change in velocity of fluid (blood flow velocity) that circulates in this tube. The force applied against the wall of a tube by a fluid (blood flow) is proportional to the square of the change in velocity in angulated necks, thus resulting in an increased displacement force.[6]

Finally, appropriate positioning, sealing, and fixation are all the more important in patients with an angulated aneurysm neck, because angulated aneurysm necks are related to other adverse anatomic characteristics.[9]

We believe, as was discussed, that appropriate oversizing of stent grafts in patients with angulated aneurysm necks is important. The asymmetric positioning of a stent graft can lead to (intermittent) proximal type I endoleaks or stent graft migration. This problem can be partly overcome by the deployment of a stent graft with suprarenal fixation. Suprarenal fixation diminishes the problem of asymmetric fixation because the angle between the suprarenal and infrarenal aorta is usually smaller than the angle between the infrarenal aorta and the AAA sac. This advantage is particularly present if the proximal bare stent is deployed first (non-bare-stent-captured device), but the fine-tuning of the positioning in these stent grafts is generally considered to be more difficult.

CONCLUSION

Specific problems come along with the endovascular exclusion of an AAA in a patient with an angulated aneurysm neck. Accurate preoperative measurements, planning, and perioperative attention help to identify, recognize, and adapt to these problems. Doing this can improve the results of EVAR.

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8

AORTIC NECK ANGULATIONS DECREASE DURING AND AFTER ENDOVASCULAR ANEURYSM REPAIR

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ABSTRACT

Purpose: To investigate whether suprarenal and infrarenal aortic neck angles change immediately after endovascular aneurysm repair (EVAR) or during follow-up. A change in aortic angulation influences the proximal stent-graft sealing and fixation zone, thereby possibly influencing the long-term results of EVAR.

Methods: Forty-three EVAR patients (39 men; mean age 73 years, range 62–85) with preoperative, postoperative, and 1, 2, and 3-year follow-up computed tomographic angiography (CTA) data were selected from our center's vascular database. The suprarenal and infrarenal angulations on all CTAs were measured using a standardized 3-dimensional centerline method, which has a repeatability coefficient of 6.4° (20.2%) for the suprarenal angle and 6.2° (13.4%) for the infrarenal angle. Repeated measures analysis was used to test the effect of angulation over time, followed by a post-hoc analysis.

Results: The mean suprarenal angulation was 28°±16° preoperatively, 22°±16° postoperatively, 19°±15° after 1 year, 17°±14° after 2 years, and 16±13° after 3 years (mean difference 5°,9°,11°, and 12°, respectively). The aortic suprarenal angle decrease was significant (all $p<0.01$) compared with the preoperative measurements at all time points. The mean infrarenal angulation was 50°±18° preoperatively and changed to 41°±15° postoperatively, to 39°±14° after 1 year, to 38°±14° after 2 years, and to 36°±14° after 3 years (mean difference 8°,11°,11° and 13°, respectively). The infrarenal aortic angle decrease was significant (all $p<0.01$) compared with the preoperative measurements at all time points.

Conclusion: The aortic suprarenal and infrarenal angles decrease during EVAR and in the years after this procedure.

INTRODUCTION

Endovascular aneurysm repair (EVAR) has evolved from an alternative for open aneurysm repair to an established therapy for abdominal aortic aneurysm (AAA) in patients with suitable anatomy. While EVAR has several advantages over open aneurysm repair in appropriately selected patients,[1,2] hostile proximal aneurysm neck anatomy is still considered a major anatomical limitation. Neck angulation, neck length, and thrombus or calcification lining the aneurysm neck are determinants for EVAR-related complications.[3–5] Among these, angulation is possibly the most important characteristic of the aneurysm neck. The influence of angulation on EVAR outcome has been assessed in several studies and found to be an important factor for the success of EVAR.[3–8] Aortic neck angulations impact the stent-graft sealing and fixation zone and are therefore related to proximal type I endoleaks and stent-graft migration.[3–8] These problems related to stent-graft sealing and fixation can occur up to several years after the EVAR procedure.[9,10]

The inclusion and exclusion criteria for EVAR have changed over time. Inclusion criteria for EVAR have broadened with increasing experience and the introduction of newer stent-graft devices and techniques.[11] Aneurysms that were considered ineligible for EVAR in the past are now being treated endovascularly, and the number of severely angulated aneurysm necks that are being treated by stent-graft placement is increasing.[12] Despite this, it is still unclear whether open or endovascular repair is the best option in patients with hostile aneurysm neck anatomy.[13]

Although more and more severely angulated aneurysm necks are being treated endovascularly, the influence of EVAR on the morphology of these angulated proximal aneurysm necks is still unknown. During EVAR, it is possible that an angulated aneurysm neck is stretched under the influence of an introduced guidewire, the delivery system, and/or the stent-graft. Moreover, the presence of an aortic stent-graft or shrinkage of an aneurysm sac might change the aortic angulations over time, which might influence the proximal stent-graft fixation and sealing zone. Thus, the aim of this study was to investigate our hypothesis that the aortic angles change after the EVAR procedure and during follow-up.

METHODS

Patients

Between June 2004 and the end of 2006, 172 patients underwent EVAR in our hospital. All patient data were entered prospectively into a database, which was interrogated to select all AAA patients with preoperative, direct postoperative (within 30 days), and 1-, 2-, and 3-year follow-up digital computed tomographic angiography (CTA) data. The search using these inclusion criteria identified 43 patients (39 men; mean age 73 years, range 62–85). Of these, 11 were treated with an Excluder stentgraft (W. L. Gore and Associates, Flagstaff, AZ, USA) and 32 with a Talent device (Medtronic Vascular, Santa Rosa, CA, USA).

Image Acquisition

All CTA scans were acquired on a 64-slice CT scanner (Philips Medical Systems, Best, The Netherlands) with a standardized acquisition protocol. Scan parameters were 0.9mm slice thickness, 0.7-mm increment, and 64×30.625 collimation. Radiation exposure parameters were 120 kVp and 300 mAs, resulting in a CT dose index ($CTDI_{vol}$)of 17.6 mGy. Intravenous nonionic contrast (120 mL of Iopromide; Schering, Berlin, Germany) was injected at a rate of 6 mL/s followed by a 60-mL saline chaser bolus. The acquired datasets were transferred to a workstation (3Surgery; 3Mensio Medical Imaging B.V., Bilthoven, The Netherlands) for angle, diameter, and volume measurements.

Measurement Technique

The aortic angulations on all preoperative and postoperative CTAs were investigated using a previously described standardized measurement technique.[14] All measurements were performed in a random and blinded manner. First, a volume-rendered 3D CTA reconstruction of the aorta was acquired. Second, an aortic center lumen line (CLL) was drawn semi-automatically (configured after the placement of a start- and endpoint in the aortic lumen). The positions of the CLL spline points were then checked manually on transverse, orthogonal, and sagittal planes. A spline point that was not in the middle of the aorta on one of these planes was corrected manually. Third, a view perpendicular to the CLL in the middle of either the suprarenal or infrarenal angle was acquired. Fourth, the 3D reconstruction of the aorta was turned 360° while keeping the view perpendicular to the aortic CLL. The most severe angle over 360° was thereafter measured with an electronic caliper. The intraobserver repeatability coefficient of this method was documented as 20.2% (6.4°) for the suprarenal angle and 13.4% (6.2°) for the infrarenal angle.[14]

Aortic neck lengths were measured alongside the CLL on all preoperative CTAs. Neck lengths were measured from the most distal renal artery to the most proximal side of aneurysmal dilatation.[15] Maximum aneurysm sac diameters and volumes were measured on the preoperative and 1-, 2-and 3-year follow-up scans. Diameters were measured perpendicular to the CLL, and volumes were measured according to an earlier published protocol.[16,17]

Statistic Analysis

Repeated measures analysis was used to measure the main effect of the aortic angles. If there was a significant main effect, a posthoc analysis with Bonferroni adjustment was performed. All postoperative angle measurements were compared with preoperative measurements, and the direct postoperative aortic angulation was compared with the values after 1, 2, and 3 years. Measurements are given as the mean 6 standard deviation (range); differences between mean values are presented as the mean 6 standard error. Statistical significance was assumed at $p<0.05$. Statistical analysis was performed using SPSS software (version 15; SPSS Inc., Chicago, IL, USA).

RESULTS

The mean preoperative aneurysm neck length was 31±17 mm (10–75 mm). The mean aneurysm diameter was 61±8 mm (41–77 mm) preoperatively, 57±9 mm (41–76 mm) after 1 year, 54±10 mm (32–79 mm) after 2 years, and 55±11 mm (33–78 mm) after 3 years. The mean volume of the AAA sac was 191±65 mL (103–420 mL) preoperatively, 160±62 mL (66–354) after 1 year, 160±62 mL (66–345 mL) after 2 years, and 162±69 mL (62– 345 mL) after 3 years.

The mean suprarenal angulation (Table) of 28°±16° (7°–88°) preoperatively changed to 22°±16° (2°–82°) postoperatively, to 19°±15° (4°–82°) after 1 year, to 17°±14° (2°–80°) after 2 years, and to 16°±13° (2°–74°) after 3 years. The mean difference between the preoperative suprarenal angulation and the angulation at each time point was 5.4°±1.1°, 9.0°±1.2°, 10.5°±1.5°, and 11.9°±1.4°, respectively, which corresponds to 19%±4%, 32%±4%, 35%±5%, and 42%±5%, respectively.

Because there was a significant main effect of the suprarenal angle, a post-hoc analysis was performed. Compared with the preoperative suprarenal angulation, the aortic angle decreased significantly postoperatively and after 1, 2, and 3 years (all $p<0.01$). Compared with the postoperative suprarenal angle, the angle decreased significantly after 1, 2, and 3 years (all $p<0.01$).

The mean infrarenal angulation of 50°±18° (23°–97°) preoperatively decreased to 41°±15° (19°–89°) postoperatively and was 39°±14° (17°–70°) after 1 year, 38°±14° (15°–73°) after 2 years, and 36°±14° (14°–70°) after 3 years. The mean difference between the preoperative infrarenal angulation and the angulation at these time points was 8.1°±1.5°, 10.7°±1.8°, 11.3°±1.8° and 12.8°±2.0° respectively, which corresponds to 14.0%±3.0%, 20.0%±3.6%, 21.9%±3.6%, and 24.7±4.0%, respectively.

The post-hoc analysis found that compared with the preoperative infrarenal angulation, the early postoperative angulation and the angulation after 1, 2, and 3 years had decreased significantly (all $p<0.01$). Compared with the postoperative infrarenal angle, the angle remained unchanged after 1 ($p=0.8$), 2 ($p=0.4$), and 3 ($p=0.1$) years.

Table 1. Suprarenal and Infrarenal Angulation During Follow-up after Endovascular Aneurysm Repair

	Baseline	Postoperative	Year 1	Year 2	Year 3
Suprarenal angulation, °	28 ± 6	22 ± 6	19 ± 15	17 ± 14	16 ± 13
Mean difference versus baseline, °		5 ± 1	9 ± 1	11 ± 2	12 ± 1
Infrarenal angulation, °	50 ± 18	41 ± 15	39 ± 14	38 ± 14	36 ± 14
Mean difference vesus baseline °		8 ± 2	11 ± 2	11 ± 2	13 ± 2

Angulations are presented as the mean ± standard deviation; differences between angle measurements are presented as the mean ± standard error.

DISCUSSION

To the best of our knowledge, no one has until now demonstrated that suprarenal and infrarenal aortic angulations decrease under the influence of the EVAR procedure. Moreover, this decrease of aortic angulations continues in the years after this procedure, which may impact the proximal stent-graft sealing and fixation zone.

The largest decrease in aortic angulations was seen directly after the EVAR procedure. An aneurysm neck is stretched during EVAR, and the aneurysm neck apparently does not completely regain its original position after the placement of a stent-graft. Several factors may influence the possibility of straightening, notably, the neck anatomy (i.e., calcification, length, and the presence and morphology of lumbar arteries in the neck) and the characteristics of the guidewire.[12] The continuing aortic angle decrease during the first few years after EVAR is, however, also relevant. This observation might indicate that patients with severely angulated aneurysm necks are more prone to proximal sealing/fixation and fixation zone related complications in the first few years. Theoretically, the risk of these complications might decrease with decreasing angulations.

Shrinking aneurysm sacs might be the reason for decreasing aortic angulations during follow-up after EVAR. The design and configuration of stent-grafts might also influence the aortic angulations, and there may be a difference in the degree of angulation decrease between several stent-graft types. In this relatively small patient group, however, we found no major differences between the 2 self-expanding stent-grafts used in this cohort. Nevertheless, there are important differences in the designs of the stent-grafts implanted in these patients. Notably, the Talent stent-graft has columnar support and a proximal suprarenal bare stent for suprarenal fixation, while the Excluder does not. It would nonetheless be interesting to study whether different types of stent-grafts have different effects on aortic angulations.

The decrease of proximal aortic angulations possibly results in other changes of aortic morphology. A decrease in angulation of the infrarenal or suprarenal aorta may result in more severe angulations distally in the stent-graft. However, we were not able to reliably quantify the angulations in the iliac arteries because these vessels are elongated over a larger track.

Limitations

First, this study was not designed to investigate a relationship between postoperative angulations and clinical outcome, but it would be very interesting to examine the potential relationship between decreasing angulations and stent-graft sealing and fixation related complications. Second, the number of patients included for this study was limited. Moreover, only patients with at least 3-year follow-up were eligible.

All of the studies that have previously investigated the influence of aortic angulations on EVAR outcome measured these angulations preoperatively. Although most of these studies concluded that the aortic angulation had a negative influence on the outcome after EVAR, there are some conflicting data.[3–8] Considering our findings, it might be interesting to link the postoperative aortic angulations to clinical outcome. The correlation between postoperative angulation and EVAR-related problems might be stricter than between preoperative angulation and EVAR results.

The outcome of patients with angulated aneurysm necks after EVAR is probably influenced negatively because optimal stentgraft placement is more difficult in angulated aneurysm necks. On top of this, patients with severe aortic angulations after the EVAR procedure might be more at risk for EVAR related complications. A stricter surveillance scheme may thus be advocated in these patients. On the other hand, patients with severely decreased aortic angulations after EVAR might be reclassified as no longer having an increased risk of EVAR-related complications. The postoperative surveillance scheme may therefore be less strict in these patients and comparable to patients with less angulated aneurysm necks. The adaptation of a postoperative surveillance scheme to the patient's needs is relevant because the radiation burden during regular follow-up of EVAR patients is already significant.[18]

CONCLUSION

Aortic neck angulations decrease during the EVAR procedure and this decrease continues in the years after this procedure.

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POTENTIAL VALUE OF ANEURYSM SAC VOLUME MEASUREMENTS IN ADDITION TO DIAMETER MEASUREMENTS AFTER ENDOVASCULAR ANEURYSM REPAIR

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ABSTRACT

Purpose: To investigate the value of aneurysm sac volume measurement in addition to diameter measurements based on computed tomographic angiography (CTA) after endovascular aneurysm repair (EVAR).

Methods: Interrogation of a vascular database identified 56 patients (51 men; median age 77 years, range 59–92), 28 with an endoleak and 28 without, who had digital CTA data available at baseline (first postoperative scan) and at 1 and 2 years after EVAR. Total aneurysm volume, transverse maximum diameter (TMD), and orthogonal maximum diameter (OMD; perpendicular to the aortic center lumen line) were compared for all patients and between those with and without endoleak. Differences of 5% for volume and 5 mm for diameters were considered a significant change. Kappa statistics were used to compare measurements.

Results: Volumetry detected aneurysm growth in 32 (24%) of 131 scans, which was reflected by TMD in 12 (38%) and by OMD in 14 (44%). Eighteen scans with increasing aneurysm volume were measured in patients with endoleaks, which was documented by TMD in 6 (33%) and by OMD in 8 (44%). Fourteen volume increases were measured in patients without endoleak; both TMD and OMD documented only 43%. Volumetry detected aneurysm shrinkage in 71 (54%) of 131 scans (detected by TMD in 38 [54%] and by OMD in 37 [52%]). Thirty-two volume decreases were measured in patients with an endoleak, noted by TMD in 18 (56%) and OMD in 14 (44%). Thirty-nine scans showed decreasing volumes in patients without endoleaks; the TMD corresponded in 20 (51%) and the OMD in 23 (59%). The kappa agreements for volume increase were 0.42 (TMD) and 0.35 (OMD) and for volume decrease 0.48 (TMD) and 0.47 (OMD); different thresholds of change produced similar moderate range kappa values (0.3–0.6).

Conclusion: Volumetry detects sac size changes that are not reflected in diameter measurements. Vice versa, diameters can increase without a total volume increase, which might indicate a variety of morphological aneurysm changes. The agreement between volume and diameter measurements using different cutoff values is equally moderate. Volume measurements should be performed in addition to diameter measurements.

INTRODUCTION

In many centers, the preferential treatment of an abdominal aortic aneurysm (AAA) is endovascular placement of a stent-graft.[1] The purpose of endovascular aneurysm repair (EVAR) is preventing aneurysm rupture by excluding the aneurysm sac from the circulation.[2] Shrinkage or growth arrest of the excluded aneurysm sac in combination with appropriate stent-graft position and the absence of endoleak are generally considered a successful treatment.

Follow-up imaging after EVAR is necessary to confirm appropriate stent-graft position, to detect complications (e.g., endoleaks and material fractures), and to assess changes in aneurysm size. Computed tomographic angiography (CTA) is the most commonly used modality for surveillance.[3] In most protocols, aneurysm size changes after EVAR are assessed by maximum diameter measurements. However, the inter- and intraobserver variabilities of diameter measurements are large, and variations of ≥5 mm have been observed.[4,5] Thus, diameter measurements are not precise, and only large differences can be expected to reflect real changes in size.

Intuitively and physically, total aneurysm volume measurements are more insightful than diameter measurements as they assess the entire 3-dimensional (3D) aneurysm sac structure.[6–9] Although most physicians appreciate the additional value of volume measurements, literature on volume measurements remains scarce, and the clinical implications and benefits of volume measurements have to be studied. In the past, a major disadvantage of volume measurements was the amount of time needed to perform these measurements. However, recently introduced fast CTA postprocessing software, as applied in the current study, substantially reduces the time needed for volume measurements.[10,11]

Volume measurements are known to be more precise than diameter measurements.[12] Therefore, volumetry might be able to determine AAA size changes that are not noticed by diameter measurements. The aim of this study was to compare aneurysm volumetry to aneurysm diameter measurements, measured in both the transverse and orthogonal (perpendicular to the aortic center line) planes after EVAR.

METHODS

Patient Samples

Between 1999 and 2006, 248 patients underwent EVAR in our hospital. All patient data were entered prospectively into a vascular database, which was interrogated to identify all patients with a reported endoleak and digital CTA data available within the 30-day postoperative period and at 1 and 2 years after EVAR. Twenty-eight patients (25 men; median age 77 years, range 59–92) met these criteria. A cohort of 28 EVAR patients (26 men; median age 77 years, range 70–91) without an endoleak (on early and late-phase images) who also had CTAs available at 1 and 2 years after EVAR were selected for comparison. CTA scans after 3 years, when available (n=19), were selected for analysis as well. Of the total 56 patients in the study, 27 were treated with a Talent bifurcated stent-graft (Medtronic CardioVascular, Santa Rosa, CA, USA), 14 with an Excluder bifurcated device (W.L. Gore & Associates, Flagstaff, AZ, USA), and the remaining 15 with 7 other types of bifurcated stent-grafts.

Scan Protocol

All scans were performed on a 64-slice helical CT scanner (Philips Medical Systems, Best, The Netherlands) with a standardized acquisition protocol. Scan parameters were: slice thickness 0.9 mm, increment 0.7 mm, collimation 64×0.625 mm, and pitch 0.25. Field of view was 250×250 mm, and the reconstructed matrix size was 512×512, resulting in a voxel size of 0.5×0.5×0.9 mm. Radiation exposure parameters were 120 kVp and 300 mAs, resulting in a CT dose index ($CTDI_{vol}$)of 17.6 mGy. Intravenous nonionic contrast (120 mL of Iopromide; Schering, Berlin, Germany), followed by a 60-mL saline chaser bolus, was injected at a rate of 6 mL/s. The scan was started using bolus triggering software with a threshold of 100 HU over baseline. Early and late arterial phase scans were obtained; the latter were made 50 seconds after reaching the threshold of 100 HU. All scans were loaded into a graphical workstation (EasyVision workstation; Philips Medical Systems) and checked for the presence of endoleaks by a radiologist and a vascular surgeon; interobserver disagreement was resolved by consensus. The acquired raw (DICOM) datasets were imported in a 3Surgery workstation (3Mensio Medical Imaging B.V., Bilthoven, The Netherlands) for diameter and volume measurements.

CTA Data Assessment and Measurements

Postoperative scans ("baseline" for the purposes of this analysis) were taken within several days after EVAR; 1-, 2-, and 3-year follow-up scans were taken at a median of 350 days (range 111–529), 709 days (range 363–976), and 1089 days (n=19, range 774–1767), respectively. One observer (J. v K.) performed all measurements on the 187 scans obtained. For each dataset, an aortic center lumen line (CLL) was semi-automatically constructed by choosing proximal start and distal endpoints in the aortic lumen, after which the CLL was automatically calculated. If necessary, small corrections were made manually.

Maximum aortic diameter measurements were obtained in the transverse plane [transverse maximum diameter (TMD)] and in a reconstructed plane perpendicular to the aortic CLL [orthogonal maximum diameter (OMD); Fig. 1]. All diameter measurements were performed manually and independently from each other. Diameters were measured between the outer walls of the aorta at any level (CTA slice thickness 0.9 mm). In the reconstructed planes perpendicular to the CLL, the largest axis was measured as diameter. In the transverse planes, the influence of aortic angulations was considered. If there was completely no angulation, the largest axis was measured as the diameter. In cases with aortic angulation, the TMD was measured in an axis perpendicular to the angulation.

Volume measurements were taken from exactly distal to the origin of the most distal renal artery to 5 mm above the native aortic bifurcation. Volume measurements were performed semi-automatically using a previously described process.[11] In brief, a stretch view of the aorta along the CLL was generated. Both aneurysm sac outer walls were drawn on this view, which was repeated for 4 different angles (views). The aneurysm sac borders in the stretch view were then projected on reconstructed slices perpendicular to the CLL. For each reconstructed slice, the 8 border control points were connected by spline interpolation. The final segmentation on the reconstructed slices was checked and corrected manually per slice, if necessary. Finally, the total volume was computed, taking into account the original voxel locations.[11] The intraobserver variability for volume measurements using this system was 4.2% compared to an interobserver variability of 5.9%.[11]

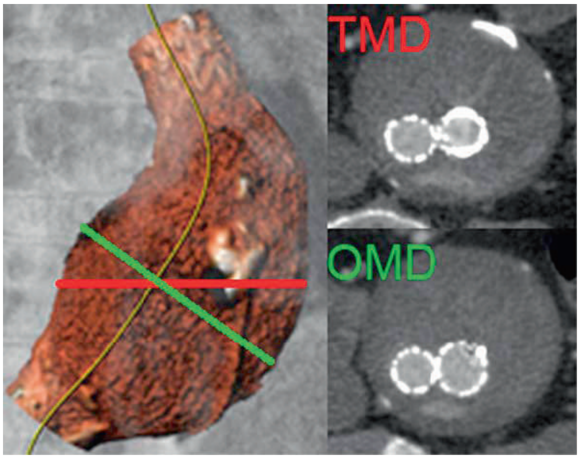

Figure *Maximum aortic diameter measurements were taken in the transverse plane (TMD) on axial CTA slices and on a reconstructed plane perpendicular to the center lumen line (CLL, yellow line) for the orthogonal diameter measurement (OMD). Diameter measurements were made independently from each other.*

Statistical Analysis

Aneurysm sac volumes and transverse and orthogonal diameters after 1, 2, and 3 years (131 CTAs) were compared to postoperative baseline measurements from 56 CTAs. For 3D volume, a change of 5% was considered significant, based on repeatability coefficients of this method.[11] For diameters, a change of 5 mm was considered significant, based on the reporting standards for EVAR[2] and previously reported intraobserver variabilities.[4,5,12]

Significantly increasing and decreasing volumes were set out in tables against diameter measurements. The agreements between diameter and volume measurements, between TMD and OMD measurements, and for aneurysm growth (increased versus stable/decreased measurements) and aneurysm shrinkage (decreased versus stable/increased measurements) were estimated using kappa statistics. Additionally, the influence of different cutoff values for significance (3 mm for diameter and 10% for volume) on the agreement was studied.

A kappa value of 1.0 indicates perfect agreement, 0.8 to 1.0 excellent agreement, 0.6 to 0.8 good agreement, 0.4 to 0.6 moderate agreement, 0.2 to 0.4 fair agreement, and <0.2 poor agreement.[13] Analyses were performed using SPSS software (version 16.0; SPSS Inc., Chicago, IL, USA).

RESULTS

Aneurysm Sac Characteristics

At baseline, the median aneurysm volume was 189.4 mL (range 41.1–551.8); in follow-up, the volumes were 174.0 mL (42.3–509.4) after 1 year, 175.7 mL (43.9–634.3) after years, and 171.0 mL (110.9–474.0) after years in 19 scans. The median maximum diameters measured in the transverse plane were 64.8 mm (range 34.0–91.6) at baseline, 62.2 mm (32.6–112.8) after 1 year, 60.7 mm (29.3–117.3) after 2 years, and 60.3 mm (49.4– 110.1) after 3 years (n=519). The median OMD was 63.8 mm (range 33.1–106.1) at the baseline, 61.2 mm (33.6–112.9) after 1 year, 61.4 mm (28.5–116.5) after 2 years, and mm (45.7–110.2) after 3 years (n=19).
There were 8 patients with a type I endoleak (Table 1); 6 leaks were first reported on the baseline postoperative scan. Of the 18 type II endoleaks, most (n=17) were first noticed on the baseline scan, 1 was seen after 1 year; 2 seen on the baseline scan recurred after 2 years. Two type III endoleaks were observed after 2 and 3 years, respectively.

Table 1. Number of Endoleaks and Time of Appearance on CTA

	Baseline*	Year 1 (n=556)	Year 2 (n=556)	Year 3 (n=519)
Endoleak type	23	11	13	4
I(n=8)	6	1	2	0
II(n=18)	17	10	10	3
III (n=2)	0	0	1	1

* First postoperative scan.

Volume Versus Diameter Measurements

Volume increase was measured in 32 (24%) of the 131 scans available for comparison with the baseline scan (Table 2). TMD reflected 12 (38%) of these 32 increasing volumes and OMD 14 (44%). Eighteen scans with increasing aneurysm volume were measured in patients with endoleaks, which was documented by TMD in 6 (33%) and by OMD in 8 (44%). Fourteen volume increases were measured in patients without endoleak, of which both TMD and OMD documented only 6 (43%).
A volume decrease was measured in 71 (54%) of the 131 CTAs; TMD detected the aneurysm sac decrease in 38 (54%) and OMD in 37 (52%). Thirty-two volume decreases were measured in patients with an endoleak, noted by TMD in 18 (56%) and OMD in 14 (44%). Thirty-nine of the 71 scans with decreasing volumes were measured in patients without endoleaks, which was noted by TMD in 20 (51%) and OMD in 23 (59%).

Table 2. Aneurysm Sac Increase or Decrease by Volumetry and Diameter Measurements

	Year 1	Year 2	Year 3
Aneurysm Sac Increase			
All patients – total scans	56	56	19
Volume increase	13 (23%)	14 (25%)	5 (26%)
Detected with TMD	4	6	2
Detected with OMD	5	6	3
TMD increase	5 (9%)	8 (14%)	2 (11%)
Volume stable or decreased	1	2	0
OMD increase	9 (16%)	12 (21%)	4 (21%)
Volume stable or decreased	4	6	1
Endoleak patients – total scans	28	28	10
Volume increase	8 (29%)	8 (29%)	2 (20%)
Detected with TMD	3	2	1
Detected with OMD	4	3	1
TMD increase	4 (14%)	4 (14%)	1 (10%)
Volume stable or decreased	1	2	0
OMD increase	5	7	1
Volume stable or decreased	1	4	0
Kappa TMD (0.42 overall)	0.36	0.44	0.50
Kappa OMD (0.35 overall)	0.33	0.30	0.57
Aneurysm Sac Decrease			
All patients – total scans	56	56	19
Volume decrease 30 (54%)	28 (50%)	13 (68%)	
Detected with TMD	14	17	7
Detected with OMD	15	14	8
TMD decrease	15 (27%)	18 (32%)	7 (37%)
Volume stable or increased	1	1	0
OMD decrease	16 (29%)	15 (27%)	8 (42%)
Volume stable or increased	1	1	0
Endoleak patients – total scans	28	28	10
Volume decrease	13 (46%)	12 (43%)	7 (70%)
Detected with TMD	6	8	4
Detected with OMD	4	6	4
TMD decrease	7 (25%)	9 (32%)	4 (40%)
Volume stable or increased	1	1	0
OMD decrease	5 (18%)	7 (25%)	4 (40%)
Volume stable or increased	1	1	0
Kappa TMD (0.48 overall)	0.41	0.57	0.42
Kappa OMD (0.47 overall)	0.45 ¤	0.46	0.50

TMD: transverse maximum diameter, OMD: orthogonal maximum diameter.

In scans with no volume increase, OMD showed a significant increase in 11 patients (5 with endoleak and 6 without), while TMD increased in 3 cases (all with endoleak). Diameters measured in both the transverse and orthogonal plane decreased in 2 scans, while total aneurysm sac volume was not reduced.

Table 3 displays the volume increases detected by diameter measurements and the diameter increases that were not detected by volume measurements when using different cutoff values. When comparing aneurysm increase versus stable/decreased measurements by volumetry and diameter (Table 4), the kappa values were 0.42 for TMD and 0.35 for OMD. For aneurysm decrease versus stable/increased measurements, the kappa values were 0.48 for TMD and 0.47 for OMD. Applying different thresholds for diameter and volume change resulted in similar kappa values (0.32≤kappa≤0.56) for aneurysm increase versus stable/decreased values and similar kappa values (0.45≤kappa≤0.60) for aneurysm decrease versus stable/increased measurements. The agreement between OMD and TMD was 0.48 for aneurysm growth (increased versus stable/decreased measurements) and 0.87 for aneurysm shrink-age (decreased versus stable/increased measurements).

Table 3. Influence of Cutoff Points for Diameter and Volume Measurements

	Volume Increase Detected by Diameter Measurement			
	5 mm and 5%	3 mm and 5%	5 mm and 10%	3 mm and 10%
TMD	12/32 (38%)	17/32 (53%)	8/17 (47%)	11/17 (65%)
OMD	14/32 (44%)	23/32 (72%)	9/17 (53%)	13/17 (76%)
	Diameter Increase Not Detected by Diameter Measurement			
	5 mm and 5%	3 mm and 5%	5 mm and 10%	3 mm and 10%
TMD	3/15 (20%)	7/24 (29%)	7/15 (47%)	13/24 (54%)
OMD ¤	11/25 (44%)	13/36 (36%)	16/25 (64%)	23/36 (64%)

TMD: transverse maximum diameter, OMD: orthogonal maximum diameter.

Table 4. Agreement (Kappa Values) for Detecting Volume Growth or Shrinkage Using Different Cutoff Values

Increasing Volumes/Diameters vs. Stable/Decreasing Volumes/Diameters				
	5 mm and 5%	3 mm and 5%	5 mm and 10%	3 mm and 10%
TMD	0.42	0.50	0.41	0.53
Year 1	0.36	0.51	0.22	0.51
Year 2	0.44	0.47	0.56	0.56
Year 3	0.50	0.57	0.27	0.48
OMD	0.35	0.56	0.32	0.48
Year 1	0.33	0.43	0.13	0.39
Year 2	0.30	0.51	0.43	0.59
Year 3	0.57	0.87	0.28	0.23
Decreasing Volumes/Diameters vs. Stable/Increasing Volumes/Diameters				
	5 mm and 5%	3 mm and 5%	5 mm and 10%	3 mm and 10%
TMD	0.48	0.54	0.52	0.59
Year 1	0.41	0.44	0.37	0.560
Year 2	0.57	0.68	0.62	0.46
Year 3	0.42	0.42	0.60	0.25
OMD	0.47	0.60	0.45	0.55
Year 1	0.45	0.55	0.37	0.57
Year 2	0.46	0.64	0.42	0.36
Year 3	0.50	0.59	0.69	0.38

A kappa value between 0.4 and 0.6 indicates moderate agreement.

DISCUSSION

Intuitively, volume measurement of the aneurysm sac provides more information about aneurysm morphology than diameter measurement. However, the amount of evidence supporting volumetry remains scarce and is based on studies performed with outdated CT scanners and acquisition protocols. Therefore, there is a need for more studies to investigate the potential additional value of volumetric measurements.[6–9] In the present study, we compared aneurysm volumetry to transverse and orthogonal diameter measurements.

To our knowledge, there are currently no studies confirming a correlation between volume measurements and clinical outcome. However, this is of great interest since missing aneurysm sac growth after EVAR on diameter measurements might be dangerous, as it could indicate unsuccessful treatment of an aneurysm that continues to be at risk for rupture. Additional imaging and surveillance can be contemplated in patients with increasing volumes that are not confirmed by increasing diameters.

In our study, 63% of the volume increases in patients with type II endoleaks were missed by transverse diameter measurements and 50% by orthogonal diameter measurements. In those patients with type II endoleaks (in which there is still no consensus about reintervention), volumetry may provide a useful parameter to discriminate between type II endoleaks that either do or do not need re-intervention. Volume decreases were missed on a large scale by both transverse and orthogonal diameter measurements. In cases where aneurysm sac decrease after diameter measurement is doubtful, volume measurement could lead to earlier reassurance. Although the clinical relevance of volumetry has not been proven yet, volumetric reassurance may prevent additional imaging and re-intervention.

A limitation of our study is that the majority of endoleaks in this study were noted only on the baseline scan or on 1 follow-up image; therefore, definite conclusions regarding the relationship between endoleak and aneurysm sac morphology cannot be drawn. Further, one might argue about the cutoff values used to determine a significant change in sac size. However, the cutoff values of 5 mm for diameters and 5% for volumes were based on repeatability coefficients and SVS reporting standards.[2,4,5,11] In addition, we have analyzed our results using different cutoff points for volumes and diameters. The cutoff points of 3 mm for diameters and 10% for volumes demonstrate that there still remains only fair to moderate agreement between diameter and volume measurements with both higher and lower thresholds.

It is of great interest that in some cases diameters increase while volume does not. The measurement of orthogonal diameters showed a significant increase without volume increase in 11 scans, while transverse diameter measurement differed from volume in only 3 scans. Diameter measurements are taken on a single slice level and therefore depend heavily on slice selection. On the other hand, a 5-mm level of significant change should account for such variations. Thus, it appears that there is a wide variety of changes in aneurysm morphology.

What is the significance of a volume that is not increasing while a diameter is? Increase of diameter is associated with high intraaneurysm pressure, [14] and the pressure measured in the aneurysm sac of patients with endoleak is distributed non-uniformly.[15] Unevenly distributed pressure and non-uniform strain might help explain why certain aneurysms have apparent locally expanding diameters without increasing total volumes. From this perspective, local diameter increase in the absence of volume change could be dangerous since it might indicate locally increased pressure on the wall. Therefore, we believe diameter measurements are still very important in EVAR surveillance, and volume measurements should be performed in addition to diameter measurements to have high quality assessment of both the entire aneurysm sac and the local diameters as well. Future studies are merited to assess the correlation between diameter and volume measurements after EVAR and clinical outcome.

CONCLUSION

Volumetry detects aneurysm sac changes that are not detected by orthogonal and transverse diameter measurements. Vice versa, diameters can increase without a total volume increase. The agreement between volume and diameter measurement is fair to moderate. Therefore, we advise that volume measurements be performed in addition to diameter measurements.

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ONE-YEAR MULTICENTER RESULTS OF 100 ABDOMINAL AORTIC ANEURYSM PATIENTS TREATED WITH THE ENDURANT STENT GRAFT

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ABSTRACT

Objective: The Endurant (Medtronic, Minneapolis, Minn) is a new stent graft specifically designed to make more patients anatomically eligible for endovascular aneurysm (EVAR). This study presents the 1-year results of 100 consecutive patients with abdominal aortic aneurysms (AAAs) treated with the Endurant stent graft in real-life practice.

Methods: All clinical preoperative, operative, postoperative, and 1-year follow-up data of patients with the Endurant stent graft from three tertiary centers were prospectively collected. Patients underwent computed tomographic angiography (CTA) preoperatively, at 1 month, and at 1-year post-EVAR. The first 100 patients with an implantation date at least 1 year before our date of analysis and complete information were included. Clinical data, AAA characteristics, presence of endoleaks, graft migration, and other EVAR-related complications were noted. All values are stated as mean ± SD (range).

Results: This study included 100 patients with AAAs (88 men) with a mean age of 73 ± 8 years (47 to 87 years), an AAA size of 61 ± 10 mm (31 to 93 mm), an AAA volume of 210 ± 122 mL (69 to 934 mL), a proximal neck length of 33 ± 14 mm (9 to 82 mm), and an infrarenal angulation of 44 ± 25° (0°-108°). Nineteen of the 100 included patients had at least one anatomic characteristic that was considered a violation of the instructions for use (IFU) of the Endurant stent graft. A primary technical success was achieved in 98% of the patients (one additional stent placement in renal artery was required; one unplanned aorto-uni-iliac device placed), with no primary type I or III endoleaks or conversions. A secondary technical success was achieved in all cases. The 30-day mortality was 2% and the first postoperative CTA documented 16 endoleaks (16%; 16 type II). One-year follow-up showed three iliac limb occlusions (3%), one infected stent graft (causing a type Ia endoleak), and five endovascular reinterventions (5%; three to treat iliac limb occlusions, one proximal extension cuff; and one stent in the renal artery). The 1-year all-cause mortality rate was 12% (12 patients) and the AAA-related mortality was 3%. The mean AAA size was significantly smaller after 1 year (diameter, 54 ± 11.8 [32-80] mm; $P < 0.01$; volume, 173 ± 119 [42-1028] mL; $P < 0.01$), and one graft migration >5 mm and 13 endoleaks were noted (12 type II, 1 type I [neck dilatation]).

Conclusion: The treatment of patients with AAAs with the Endurant stent graft seems to be successful and durable during the first year after EVAR. Despite the wider inclusion criteria for the Endurant, and with 19% of our patients treated outside the IFU, the AAA-related mortality, number of type I or III endoleaks, and reintervention rates are comparable to the results of other stent grafts.

INTRODUCTION

Endovascular aneurysm repair (EVAR) has evolved to become an established therapy for patients with abdominal aortic aneurysms (AAAs) with suitable anatomy since its introduction in the early 1990s.[1] By far, not all patients with AAAs are, however, considered anatomically suitable for EVAR and the anatomic inclusion criterion of the different commercially available stent graft devices are comparable.[2,3] Especially short or angulated proximal aneurysm necks and tortuous, small or calcified iliac arteries are related to adverse EVAR outcomes.[4,5] Further technical improvements of stent grafts and delivery systems are needed to treat these patients safely by EVAR.

The Endurant stent graft (Medtronic, Minneapolis, Minn) is a new stent graft, specifically designed to broaden the EVAR treatment range. The anatomic inclusion criteria for the Endurant stent graft, according to its instructions for use (IFU), are wide compared to other stent grafts. Patients with shorter aneurysm necks and more severe suprarenal and infrarenal angulations are considered suitable for treatment with the Endurant stent graft (Table I).

The individual stents of the Endurant are designed in a sinusoidal M-shaped form with small amplitude, theoretically leading to optimal sealing in short and angulated aneurysm necks while possibly making it more forgiving for sizing issues. Small amplitude of stent graft rings is thought to allow for more flexibility, which may increase the sealing zone in angulated and short necks. Proximal "active fixation" is provided by a bare stent ring and anchoring pins. The stent graft has virtually no columnar strength and it is loaded into the hydrophilic Endurant delivery system with an outer diameter of 18F to 20F for the main device and 14F to 16F for the limb components.

Preliminary and short-term results in a small number of patients showed that the Endurant stent graft seems effective in the treatment of patients with AAAs.[6,7] Nevertheless, long term results of a larger study group in a real-life practice are mandatory. The purpose of this study was to investigate the 1-year results of 100 consecutive patients with AAAs treated with the Endurant stent graft system.

Table 1. Anatomic criteria according to the IFU of the Endurant stent graft

Proximal aneurysm neck diameter	19-32 mm
Infrarenal neck length	≥10 mm or ≥15 mm[a]
Suprarenal neck angulation	≤45° or ≤60°[a]
Infrarenal neck angulation	≥60° or ≥75°[a]
Iliac diameter	8-25
Distal fixation length	≥15 mm

[a]An infrarenal neck is considered suitable for the Endurant stent graft if the neck length is ≥10 mm in combination with a suprarenal angulation ≤45° and an infrarenal angulation of ≤60°. If the neck length is ≥15 mm, then a suprarenal angulation ≤60° and an infrarenal angulation of ≤75° are accepted.

METHODS

All clinical preoperative and peroperative data, as well as follow-up data of all patients with the Endurant stent graft of three teaching and tertiary referral hospitals were prospectively collected in a combined database. Patients underwent computed tomographic angiography (CTA) preoperatively, within 1 month after EVAR, and after 1 year, as part of a standardized protocol.

Inclusion

The implantation of the Endurant stent graft started December 2007 in our hospitals. This study included the first 100 elective patients with AAAs being at least 1 year after the treatment with a bifurcated Endurant stent graft system and not being lost to follow-up. Patients were included on an intention-to-treat basis and patients that were lost to follow-up were contacted by telephone but excluded for analysis. Suitability for EVAR treatment was judged by the treating physicians. The Endurant stent graft was the stent graft of primary choice for the treatment of infrarenal AAAs in all participating centers during the study period.
All available CTA datasets of included patients, being the preoperative, postoperative, 1-year follow-up, and any possible additional CTA, were transferred to a 3Surgery 4.0 workstation (3Mensio Medical Imaging BV, Bilthoven, The Netherlands) for analysis.

Preoperative analysis

The following characteristics of included patients were obtained preoperatively from our database: age, gender, American Society of Anesthesiologists (ASA) score, and laboratory tests for renal function (creatinine).
The AAA characteristics measured on the preoperative CTA scans were AAA neck length, AAA neck diameter, calcification and thrombus in the AAA neck, suprarenal and infrarenal angulation of the proximal AAA neck, maximum AAA diameter, AAA volume, diameter of the common iliac arteries, and diameter of the external iliac arteries.
Diameter and length measurements were performed with the use of a center lumen line (CLL). All diameters were measured from outer-wall to outer-wall. Aortic neck diameters were measured at the level of the lower border of the most distal renal artery and every 5 mm from this level until the start of the aneurysm. The calcification and thrombus in the aortic neck were measured at 10 mm below the most distal renal artery and were visually quantified and classified into groups of <25%, 25% to 50%, 50% to 75%, and >75% of the aortic circumference lined by thrombus or calcification. The aortic suprarenal and infrarenal neck angulations and AAA volumes were measured according to earlier published protocols.[8,9] Diameters of the common iliac arteries were measured 1, 3, and 5 cm distally of the aortic bifurcation, and the diameters in the external iliac arteries were measured 1 cm distally of the iliac bifurcation.

The morphology of the proximal aneurysm neck of the study patients was classified as within or outside the IFU of the Endurant stent graft. Moreover, for comparison, the proximal aneurysm neck morphology was also classified as within or outside the IFU of the Talent (Medtronic), Zenith (Cook, Bloomington, Ind), and the Excluder (Gore, Flagstaff, Ariz) stent grafts.

Perioperative and 1-month postoperative analysis

The following perioperative characteristics of the study patients were noted: type of anesthesiology, stent graft size, right or left groin used for main device entry, use of stent graft extensions, operation time, volume of contrast agent used, total minutes of fluoroscopy, estimated total blood loss, endoleaks at completion angiography, complications, and procedurally-related problems. Also noted were the postoperative hospital length of stay, laboratory tests (creatinine), and the course and possible complications or reinterventions.

The first postoperative CTA scans were evaluated for the existence of endoleaks, the patency of renal arteries, and for the distance from the lower border of the most distal renal artery to the most proximal stent graft ring. The CTA scans were also checked for any other EVAR-related abnormality, as stent graft kinking, twisting, or infection. All measurements were performed as on the preoperative CTAs.

One-year postoperative analysis

All complications, reinterventions, outpatient department visits, re-admissions, deaths, causes of death, and extra CTA scans were noted and analyzed. The following characteristics were investigated on the CTA performed 1 year after the EVAR procedure: AAA diameter, existence of endoleaks, patency of renal arteries, diameter of the AAA neck, distance from the most distal renal artery to the most proximal stent graft ring, and AAA volume. The CTA scans were also checked for any other EVAR-related abnormality. All CTA measurements were performed as on the preoperative CTAs. Causes of death in patients that died were investigated by contacting the treating general practitioner or medical specialist.

Statistics

The perioperative and postoperative outcomes are reported according to the Reporting Standards for Endovascular Aortic Aneurysm Repair.[10] Data are presented as mean ± SD and range. Statistical analysis of changes in creatinine, diameter, and volume was performed by using the *t* test for paired data. The Kaplan-Meier method was used to assess cumulative rates of survival, freedom from secondary interventions, or from type I or III endoleaks, and freedom from aneurysm-related death. Statistical significance was assumed at $P < 0.05$.

Table 2. Preoperative AAA characteristics

Parameter	*Mean ± SD (range)*		
Maximum diameter, mm	0.6 ± 9.6 (31-93)		
Volume, mL	209.9 ± 122 (69-934)		
Neck length, mm	33.3 ± 14 (9-82)		
Neck diameter, mm	25.5 ± 3.7 (19-34)		
Neck calcification, No.			
<25%	83		
25%-50%	13		
50%-75%	4		
>75%	0		
Neck thrombus, No.			
<25%	64		
25%-50%	20		
50%-75%	8		
>75%	8		
Suprarenal angulation, degree	24 ± 19 (0-96)		
Infrarenal angulation, degree	44 ± 25 (0-108)		
		Right	*Left*
Diameter of the CIA, mm			
1cm		18 ± 7 (10-56)	17 ± 6 (9-44)
3cm		18 ± 6 (6-44)	17 ± 4 (9-42)
5cm		18 ± 6 (10-41)	17 ± 4 (9-40)
Diameter of the EIA, mm		10 ± 2 (7-17)	10 ± 2 (5-18)

AAA, Abdominal aortic aneurysm; *CIA,* common iliac artery; *EIA,* external iliac artery.

RESULTS

Preoperative results

The first 100 patients with the Endurant stent graft out of our three centers with an implantation date at least 1 year before our date of analysis that were not lost to follow-up were included in this study. Four patients that were lost to follow-up and did not have their 1-year follow-up CTA scan were contacted by telephone, and follow-up visits were planned. These patients were excluded for analysis. All included patients were treated between December 2007 and March 2009.

The mean age of the 100 included patients (88 men) at the time of operation was 73 ± 8 years (range, 47-87 years) and the aneurysm characteristics measured on the preoperative CTAs can be found in Table 2. Nineteen of the 100 included patients with AAAs had at least one anatomic characteristic that was considered a violation of the IFU of the Endurant stent graft: there were three patients that had an aneurysm neck diameter exceeding 32 mm, one patient had a suprarenal neck angulation exceeding 60°, and 10 patients had an infrarenal neck angulation exceeding 75°. Moreover, there was one patient that had an aneurysm neck length of 9 mm, and one patient had an aneurysm neck length of 12 mm along with an infrarenal angulation exceeding 60°. On top of this, there were three patients that had more than one anatomic characteristic outside the IFU of the Endurant; all three patients had a suprarenal neck angulation exceeding 60° in combination with an infrarenal neck angulation exceeding 75°. The suitability of all 100 included patients according to the IFU criteria of other stent grafts can be found in Table 3.

More than 50% of the aortic aneurysm neck lumen was lined by thrombus or calcification in 20 of the 100 patients. Five of these 20 patients were also patients with at least one anatomic characteristic that was considered a contraindication according to the IFU.

The ASA guidelines were preoperatively used to assess the physical status of all included patients and six patients were classified as ASA score I, 45 as ASA score II, 48 as ASA score III, and one patient as ASA score IV. The mean preoperative serum creatinine value was 101 ± 45 μmol/L (range, 38-413 μmol/L; normal reference range, 74-120 μmol/L).

Table 3. IFU anatomic criteria of the Zenith, Excluder, Talent, and Endurant stent graft are given

Suitability of the 100 included patients according to the IFU of different stent grafts								
IFU parameter	*Zenith*	*n*	*Excluder*	*n*	*Talent*	*n*	*Endurant*	*n*
Neck diameter	18-28 mm	77	19-29 mm	86	18-32 mm	97	19-32 mm	97
Neck length	≥15 mm	96	≥15 mm	96	≥10 mm	99	≥10 mm or ≥15 mma	98
Suprarenal neck angulation	<45	88	Not specified		Not specified		≤45 Or ≤60[a]	96
Infrarenal neck angulation	<60	77	≤60	77	≤60	77	≤60 Or ≤75[a]	86
Total suitable		52		60		73		81

IFU, Instructions for use.

[a]An infrarenal neck is considered suitable for the Endurant stent graft if the neck length is ≥10 mm in combination with a suprarenal angulation ≤45° and an infrarenal angulation of ≤60°. If the neck length is ≥15 mm, then a suprarenal angulation ≤60° and an infrarenal angulation of ≤75° are accepted. The suitability of the proximal aneurysm neck of the 100 included patients according to these different IFU is shown.

Perioperative results

The EVAR procedure was performed with the patient under general anesthesia in 95 of the 100 patients and under locoregional anesthesia in five patients. The main body of the stent graft was inserted from the right side in 64 patients, and the deployment of the stent graft was successful and uncomplicated in 97 patients.

In one patient, however, the main device of a bifurcated stent graft was placed successfully, but the canalization of the contralateral limb failed due to severe aortoiliac angulation. To convert this bifurcation graft to an aorto-uni-iliac device, an aortic extension was placed in the main device over the flow divider, followed by an occluder in the contralateral common iliac artery, after which a femoralfemoral crossover bypass was constructed. In another patient, the most distal renal artery was unintentionally partially overstented by the main device, which was followed by successful stent placement in the renal artery during the same procedure. In a third patient, an internal iliac artery was unintentionally overstented. The anatomy of these three patients with complicated stent graft deployment was considered suitable for EVAR according to the IFU of the Endurant stent graft. A primary technical success of the EVAR procedure was achieved in 98% of the procedures and a secondary technical success in 100% of the patients. Additional interventions were performed during the EVAR procedures in nine patients; the type of interventions can be found in Table 4.

The mean operation time was 102 ± 33 minutes (range, 50-280 minutes), with a mean reported blood loss of 193 ± 130 mL (range, 10-800 mL), a mean volume of contrast agent used of 87 ± 20 mL (range, 35-150 mL), and a mean fluoroscopy time of 23 ± 14 minutes (range, 10-80 minutes). Completion angiography showed a type II endoleak in 24 patients and no type I or III endoleaks, conversions to open repair, or procedural deaths were noted.

Table 4. Additional interventions performed during the initial EVAR procedure

Additional procedures	*No. of patients*
PTA of the common iliac artery	3
Femoral desobstruction	1
Dacron patch plasty to treat femoral artery dissection	1
Bare stent placement in iliac artery and Dacron patch plasty in femoral artery to treat dissection	1
Interposition graft placement to treat femoral aneurysm	1
Renal artery stent	1

EVAR, Endovascular aneurysm repair; *PTA,* percutaneous transluminal angioplasty. The renal artery stent and the iliac extension in combination with an occluder were placed due to complicated stent graft deployment, as stated in the text.

One-month postoperative analysis

The mean postoperative hospital length of stay was 4 ± 5 days (median, 3; range, 1-45) and there were two endovascular reinterventions within 30 days after the initial operation. In one patient (treated inside the IFU of the Endurant stent graft), a covered stent was placed successfully in the renal artery one day postoperatively because it was suspected on immediate postoperative control CTA that thrombus from the AAA neck had partly occluded the renal artery during EVAR. The second patient (treated inside the IFU of the Endurant stent graft) that underwent reintervention died within 30 days after EVAR. Ventricular tachycardia developed one day postoperatively, and an iliac limb was obstructed after this low-flow state, which resulted in an ischemic leg. Endovascular therapy (embolectomy) to solve this occlusion failed, the patient rejected further treatment and died 15 days after EVAR.

One other patient (treated inside the IFU of the Endurant stent graft) died during the first 30 days after the initial procedure. An arterial occlusion developed in this patient's lower leg 10 days after EVAR, and heparin therapy was started. The patient suddenly became hemodynamically unstable 13 days after the operation and died. Autopsy showed that gastrointestinal bleeding was the cause of death.

No other EVAR-related complications were noted during the first postoperative month, and 98 control CTAs were performed within the first postoperative month. Sixteen endoleaks were seen (16 type II) on these CTAs and the mean aneurysm neck diameter was 26.4 ± 4.1 mm (range, 19-35 mm). The mean serum creatinine value after 1 month was

105 ± 50 μmol/L (range, 56-273; normal reference range, 74-120 μmol/L, unchanged compared to the preoperative values [$P = 0.5$], mean difference, 3.4 μmol/L) and no patients had become dialysis-dependent.

One-year postoperative analysis

Between 30 days and 1-year follow-up, three more patients underwent an endovascular reintervention. First, a proximal extension cuff was placed successfully in a patient with an infected stent graft who was considered unfit for open surgery. In addition to this, the infected content in the aneurysm sac in this patient was drained percutaneously. This patient, who was preoperatively considered eligible for EVAR according to the IFU of the Endurant stent graft, presented 38 days after the initial EVAR procedure with a short history of fever in combination with abdominal pain. A CTA was obtained, which revealed a type I endoleak, multiple air bubbles in the aneurysm sac indicating an aneurysm sac infection, and a contained AAA rupture. Compared to the earlier obtained CTA, the AAA had increased 11 mm in size and the aneurysm neck had disappeared, causing a type I endoleak. Second, an embolectomy, followed by placement of a self-expandable stent in the common iliac artery, was performed in a patient with an iliac limb occlusion 3 months after EVAR. Third, an embolectomy to solve an iliac limb occlusion was performed in another patient after 12 months. In addition to these three endovascular reinterventions, one patient developed an inguinal abscess that required operative drainage.

Ten patients died between the first 30 postoperative days and 1-year follow-up. The earlier-mentioned patient with an infected stent graft and aortic cuff placement died from sepsis caused by the infected stent graft, despite the given therapy. Other causes of death were malignancy in two patients, cardiac disease in two patients, sepsis caused by a gastrointestinal infection in one patient, and a preoperatively existent renal insufficiency in one patient. Two patients died from unknown causes, although death caused by a ruptured AAA was considered unlikely since both patients had an absence of endoleaks on earlier obtained CTAs.

On the 88 CTAs performed after 1 year, the mean AAA diameter had decreased significantly to 54.4 ± 11.8 mm (range, 32-80 mm; $P < 0.01$; mean difference -4.9 mm) and the mean AAA volume had decreased significantly to 174 ± 119 mL (range, 42-1028 mL; $P < 0.01$, mean difference -24.7 mL) when compared to the preoperative values. The mean aneurysm neck diameter had increased significantly to 28.3 ± 3.6 mm (range, 22-36 mm; $P < 0.01$; mean difference 2.0 mm) after 1 year when compared to the direct postoperative aneurysm neck diameter.

The CTAs obtained at 1 year documented 13 patients with an endoleak (1 type I, 12 type II). The patient with the type I endoleak was treated inside the IFU of the Endurant stent graft, and the type I endoleak was very likely caused by an aneurysm neck dilatation of 4 mm. The placement of a proximal extension cuff in this patient is planned.

In total, there were five patients with a diameter increase of more than five mm during follow-up (one patient with a type I endoleak, three patients with a type II endoleak, and one patient without endoleak). The patient with a type I endoleak had a volume increase of 42 mL, and the patients with a type II endoleak had a volume increase of 113 mL, 68 mL, and 30 mL, respectively. The patient without an endoleak had a volume decrease of 42 mL. The AAA diameter had decreased more than 5 mm during the first postoperative year in 41 of the 88 patients.

One patient had a stent graft migration of more than 5 mm after 1 year but with enough sealing and fixation length in the aneurysm neck left. This patient was treated inside the IFU of the Endurant stent graft.

The serum creatinine value after 1 year had increased significantly from 101 ± 45 μmol/L to 105 ± 34 μmol/L (range, 56-216 μmol/L; normal reference range, 74-120 μmol/L; $P < 0.01$; mean difference 9.9 μmol/L). The estimated freedom from secondary endovascular interventions and type I or III endoleaks after 1 year was 95% (95 of 100) and 98% (98 of 100), respectively (Fig 1). The estimated freedom from aneurysm-related death was 97% (97 of 100). The overall survival after 1 year was 88% (88 of 100; Fig 2).

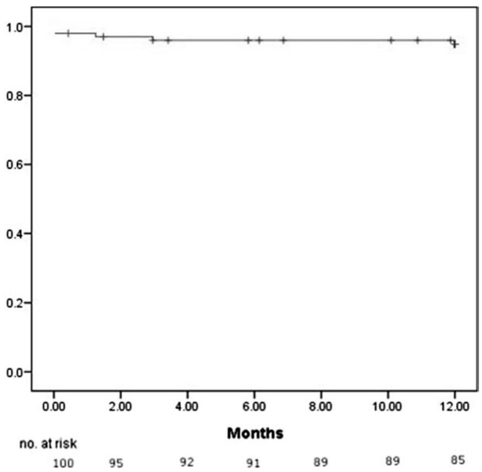

Figure 1: *Kaplan-Meier curve presents the freedom from secondary procedures during the first postoperative year.*

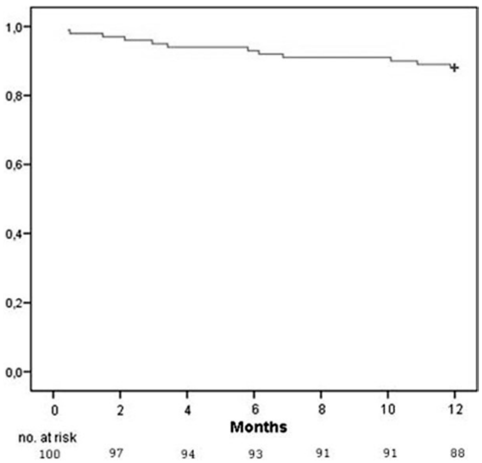

Figure 2: *Kaplan-Meier curve of the 1-year overall survival.*

DISCUSSION

The endovascular repair of AAAs has become an established therapy for patients with AAAs with a suitable aneurysm neck anatomy. Many patients are, however, still considered unsuitable for EVAR due to their anatomy.[2,5] One should be aware that these patients are often also considered as challenging patients in open surgery.[3] These patients might, therefore, actually benefit most from EVAR. The introduction of newer stent grafts with wider inclusion criteria, therefore, could be a step forward in treating these patients with AAAs.

In this study, the technical and clinical success rate of the EVAR procedure with the Endurant stent graft was high, and the 1-year secondary intervention rate (5%) was comparable to the rates of other stent grafts.[11] This is important as the inclusion criteria of the Endurant stent graft are wider compared to those of other stent grafts. On top of this, even 19% of the patients included in this study were treated outside the IFU of the Endurant stent graft. Although we are not able to conclude that the Endurant stent graft makes more patients eligible for EVAR, the wider inclusion criteria of the Endurant stent graft at least do not seem to decrease the 1-year follow-up results of patients treated by EVAR.

It has been recently shown that the long-term follow-up results of EVAR are comparable to those of open aneurysm exclusion, but the reintervention rate after EVAR was higher than the reintervention rate after open aneurysm exclusion.[12,13] Therefore, a major challenge is also to decrease the reintervention rates after EVAR.[12,13] It needs to be acknowledged that, although decreasing the reintervention rate after EVAR also is a major goal of new stent grafts, the reintervention rate in this patient group after 1 year was comparable to the reintervention rate of other stent grafts.[11,14,15]

Three access site-related problems were reported in this study, and the iliac limb occlusion rate was also 3%, which is slightly higher than in other stent grafts. In the past, while using other stent grafts for AAA treatment, we were used to treating iliac stenosis conservatively if patients were asymptomatic and if the stent graft outflow was symmetric on completion angiography. Nowadays, after analyzing the results of the Endurant stent graft, we have decided to treat all significant stenoses in the aortoiliac area detected on completion angiography by percutaneous transluminal angioplasty (PTA) to prevent future iliac limb occlusions. There is, however, no evidence for this preventive therapy and future results will have to show whether the Endurant stent graft has more access site and iliac artery-related problems during follow-up than other stent grafts.

Unintentional coverage of the internal iliac artery during stent graft deployment was seen in one patient at completion angiography. The patency of the internal iliac arteries in this study was observed preoperatively and at the completion angiography in all patients. Moreover, there were, during the 1-year follow-up, no patients that presented with symptoms of hypogastric artery occlusion.

The aneurysm neck in the 100 patients treated by the Endurant stent graft dilated from 26.4 ± 4.1 mm (range, 19-35 mm) to 28.3 ± 3.6 mm (range, 22-36 mm; $P < 0.01$) after 1 year. The cause of this neck dilatation is unknown but might be device-related or due to liberal oversizing of stent grafts.

The mean volume and diameter of the aneurysm sac of included patients had decreased significantly during the 1-year follow-up, indicating successful aneurysm exclusion. The mean diameter shrinkage of AAA sacs during the first year was more than 6 mm, with a median shrinkage of 4 mm (maximum shrinkage of 18 mm). The aneurysm sac shrinkage after treatment with the Endurant stent graft is larger when compared to the AAA shrinkage after the treatment with other stent grafts.[11] The cause of this aneurysm diameter decrease is not known but might indicate a decreased pressure in the aneurysm sac. A certain amount of shrinkage of the aneurysm sac in such a short time might, however, lead to changes in the configuration of the stent graft in the sac; nevertheless, this did not result in an impaired clinical outcome.

One of the limitations of this study is that no actual comparison between the Endurant and any other stent grafts can be made because the Endurant is the stent graft of primary choice in the cooperating centers, and no randomized trial was performed. Moreover, the inclusion criteria of the Endurant stent graft are wider than those of other stent grafts, thereby making a retrospective comparison less reliable. Despite these wider inclusion criteria, up to 19% of the patients in this series had at least one anatomic characteristic considered a violation of the IFU of the Endurant stent graft. The IFUs of other stent grafts, however, are stricter and even 27% to 48% of included patients that were treated outside the IFU of other stent grafts (Table 2). It needs to be said, in light of this, that probably not all violations of the IFU are equal, as short necks, for example, may be less well tolerated than some neck angulation. Moreover, when comparing the inclusion criteria of the different stent grafts (Table 3), there is a possibility of selection bias. Even though the Endurant stent graft is the stent graft of primary choice in cooperating centers, patients included in this study might be treated by the Endurant because they were unsuitable for other devices. Secondly, there were four patients lost to follow-up that could not be included for this study. Although all these patients were contacted and were still alive, it cannot be concluded that these patients have no EVAR-related complications. It might therefore be that these patients lost to follow-up might have influenced the outcome of the entire patient group, either negatively or positively. Last, there might be a learning curve involved in the use of the Endurant stent graft. We, as earlier discussed, nowadays preoperatively treat all significant stenoses in the aortoiliac area detected on completion angiography. Our centers, however, have extensively used the predecessor of the Endurant stent graft, and we do not believe the learning curve of the use of the Endurant stent graft will be of much influence on the results of this study.

The AAA-related mortality and reintervention rates during this first year were acceptable and comparable with other studies, although the inclusion criteria for the Endurant are wider.[11,16] All reinterventions were performed endovascularly, and all but one were successful. The aneurysm-related death rate was 3%, but on the other hand, the total 1-year related mortality rate of 12% was considerable. An overall survival rate of 88% at 1 year after EVAR is relatively low, indicating the need for remaining cautious while selecting patients for EVAR.

CONCLUSION

This study evaluates the 1-year results of 100 consecutive patients treated with the Endurant stent graft in a real-life situation. The treatment of patients with AAAs by the Endurant stent graft is successful and durable during the first year after EVAR. The wider inclusion criteria of the Endurant stent graft do not seem to influence the 1-year results negatively.

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IN MEMORIAM

IN MEMORIAM

Jasper in UMC Utrecht

Jasper als collega is een van de leukste dingen die je op de werkvloer kan overkomen. Altijd vrolijk, gedreven, enthousiast en bereid om naar je te luisteren. Toen hij enige jaren geleden als onderzoeker in het UMC Utrecht begon, had hij als student al enkele publicaties op zijn naam staan. Binnen een korte tijd heeft Jasper met ogenschijnlijk groot gemak zijn lijst van publicaties uitgebreid. Het leek alsof dit hem nooit enige moeite kostte.

Op zijn werkplek stonden twee computer schermen naast elkaar aan om zijn metingen op te verrichten. Echter, zodra er grote sportevenementen zoals het WK voetbal of de Tour de France bezig waren, werd één scherm opgeofferd om deze sportbeelden te volgen. Op het andere scherm ging hij vrolijk, in zijn typerende onderuit gezakte houding, verder met zijn metingen en enkele dagen later had hij alweer een eerste versie van een artikel geschreven.

Oftewel, de koning van het muli-tasken. Nooit zeuren en alles aanpakken. Klaar staan voor collega's om ze te helpen met het schrijven van artikelen, niets was teveel. Indien collega's problemen hadden en zij Jasper om advies vroegen, wist hij het *of* op te lossen *of* te relativeren (en dat laatste vaak zonder dat hij er erg in had). "Niks is zo belangrijk dat je je er echt druk over hoeft te maken, morgen is er gewoon weer een nieuwe dag."

Naast zijn wetenschappelijk bevlogenheid had hij veel interesse in alle sociale activiteiten met collega's. 's Ochtends liet hij iedereen de goals van een mooie voetbalwedstrijd zien, uiteraard voorzien van zeer gedetailleerd commentaar. Aan het einde van de dag bracht hij allerlei nummers ten gehore om de juiste sfeer er weer in te brengen. Daarnaast was hij betrokken bij het organiseren van de jaarlijkse Heelkunde Skitrip, het voetballen voor de chirurgencup en natuurlijk alle borrels; altijd aanwezig met een grote glimlach. Tijdens deze gelegenheden vond hij het leuk om lange, mooie discussies naar voren te brengen, waarbij hij vaak nog wat provoceerde om enige reactie bij zijn collega's uit te lokken.

Een groot charmeur, die met zijn vrolijkheid en enthousiasme alles voor elkaar kreeg. Het duizendpoot leven heeft hij ook in Amerika voortgezet waar hij met zijn brede lach en aanstekelijke betrokkenheid bij zijn collega's snel weer nieuwe vrienden maakte. Tevens heeft hij daar nog enkele van zijn Nederlandse collega's uitgenodigd voor een mini road trip. New York, Jersey shore, Atlantic City en Philly en dat alles in enkel twee dagen. Zulke impulsieve acties waren typisch voor Jasper. Altijd in voor alles.

Zijn tomeloze energie, loyaliteit en enthousiasme tijdens èn buiten zijn werk zullen ons dan ook altijd bijblijven. Fantastisch dat zijn zeer verdiende promotie op deze manier toch nog gestalte krijgt.

Alle (oud) arts-onderzoekers Heelkunde UMC Utrecht

IN MEMORIAM

Jasper's Life at Yale

Jasper arrived at Yale in August 2010. He was excited about this experience and hoping for adventure and for having a good time. The quality of his scientific work already exceeded that of many of his PhD graduated peers at that time. Looking back, it was impressive how he rapidly adapted and built an impressive network of friends, further expanded his scientific base and gained memorable experiences socializing with friends and traveling around the USA.

Jasper lived in a medical school graduate student dormitory, where he met many of his friends. The city of New Haven, where Yale University is located, is large enough to be a true city, yet small enough to be a friendly college town. Jasper frequently explored the downtown restaurants and nightlife together with his Dutch friends Frederik Jonker and Felix Schlosser, or went on a trip or a house party with many of his other friends.

At the start of the year, the sections of Vascular Surgery of Yale University School of Medicine in New Haven, Connecticut, and the University Medical Center Utrecht, The Netherlands, which share a continued relationship, conducted a symposium on aortic catastrophes. During the day, the international professors were on a tour of the Yale campus and Jasper was unexpectedly spotted wearing short pants. In the evening, we had an informal gathering at Dr Muhs's home. The professors were now all wearing short pants following Jasper's example. A barbeque took place with interesting conversations about the widest range of topics, and it went on till the early hours. One of the topics of the professors included the evolution of the Dutch abdomen in the USA

Jasper's research interests focused on the impact of the morphology of aortic dissections on their outcomes. He was especially interested in the effect of spiral shaped dissections compared with straight dissections, and on the impact of involvement of aortic side branches on outcomes of aortic dissections. This was unique, because he was the first to study and write about this specific topic.

Throughout his stay, he liked to compare American to Dutch culture. He joined a Yale deep sea fishing trip and noticed how his American friends were bragging about their extensive fishing experience and unrealistic expectations for the day. Jasper told them happily that he was going to catch just one fish, but... the biggest one. And so he did, he had the biggest catch of the day. This was one of many proud moments.

Keen as he was on meeting new people and socializing, he joined the Yale Medical School Soccer team, and within a few months after joining the team, they won the competition and became the Yale Competitive League Champions.

During a vascular surgery symposium in New York in November, we were able to come together again with the sections of Vascular Surgery of the Yale University School of Medicine and the University Medical Center Utrecht. And in December, the Yale Section of Vascular Surgery came over to the Netherlands and we celebrated Frederik Jonker's PhD graduation in Utrecht.

Jasper made several trips during his stay in the USA with his Dutch friends and covered exciting destinations, such as New York City, upstate New York, the Catskill mountains, and Long Island. In addition, he went on two skiing trips in the New England mountains. Especially the last weeks, before his departure to Italy, he was living life to the highest degree. He traveled to Vermont for a ski trip and to Colorado for another ski trip and a vascular surgery symposium in the Rocky Mountains. He was looking forward to the arrival of his friend Jip Tolenaar in the summer, because he had some exciting plans for an American road trip with him.

Jasper enjoyed his life at Yale. He loved his friends, was always happy, optimistic and enthousiastic. Abraham Lincoln said: "And in the end, it's not the years in your life that count. It's the life in your years." Therefore, we will never forget Jasper at Yale.

IN MEMORIAM

Jasper van Keulen in Milan

The 3rd of February 2011 Jasper arrived in Milan, from the Yale University, to continue his research projects. At that time his main focus, was to study radiologic predictors of aortic growth in patients with type B dissection. Because of his prior research at Yale university, two papers, which focused on spiral versus straight dissections and the involvement of aortic side branches, were at a finalizing stage. We further reviewed these papers in order to have better manuscripts.

Based on these articles we planned for a universal article which included all radiologic predictors for aortic growth, including variables not considered previously, like presence of atherosclerosis, aortic arch diameter, origin of the dissection in the inner or outer aortic curve. Although this was his main project, in the meanwhile we developed ideas for other projects. Since it was in the same line of research, we projected clinical research projects using The International Registry of Acute Aortic Dissection (IRAD) to test our hypothesis on the importance of these radiologic predictors.

Like always, he was enthusiastic about all studies, but he was most excited about the study we developed to look at the bird-beak configuration in patients treated with TEVAR. On this topic, he reviewed several aortography and CT scan of patients treated at Policlinico San Donato IRCCS, with other radiologists. February 11, Friday, around 8.00 p.m. Jasper was still with me in the office, in the Hospital, to talk about his PhD tesis, our common projects and sending emails to USA and the Nederland to report his work and explaining new projects.

Regretfully, we never had the time to develop these ideas. February 12, at 1 a.m., I received a telephone call about the car accident.

During his short stay in Milan, Jasper had the opportunity to know people that immediately and naturally loved his simple and so nice personality. He participated at parties and went to the stadium to watch an Inter Milan soccer game. He loved soccer. We miss him, I miss him, a lot. He'll be a good friend of mine, forever.

Santi Trimarchi

CURRICULUM VITAE

CURRICULUM VITAE

Jasper Willem van Keulen was born on April 2nd, 1984 in 's-Gravenhage, the Netherlands. After completing Grammar School (Christelijk Gymnasium Sorghvliet, 's-Gravenhage) he entered the Utrecht University School of Medicine in 2002. During Medical School he combined his studies, with an active social live, travelling and additional studies. As part of an internship he spent three months in Tanzania, went on a five month cultural expedition through Asia and Australia and graduated with a Masters degree in Medical History at VU University, Amsterdam, The Netherlands. During this period he started conducting research for the department of Vascular Surgery under the supervision of Dr. Joost A. van Herwaarden and Prof. dr. Frans L. Moll. After obtaining his medical degree in 2009 he continued his PhD-training program on the dynamics of the aorta at the University of Utrecht, the Netherlands. In July 2010 he was invited by Dr. Bart E. Muhs to continue his research at the department of Vascular Surgery of the Yale University School of Medicine in New Haven, Connecticut, USA. His research focused on the radiologic predictors of aortic growth in medical treated type B dissection patients. The work in this thesis was presented at numerous (inter)national meetings. In February 2011, Jasper travelled to Milan to collaborate with Dr. Santi Trimarchi at Policlinico San Donato Milanese, Milan, Italy. On the night of February 11th – 12th, 2011 Jasper was involved in a car accident and suffered major brain injuries. These injuries proved too severe to overcome. Following his passing away, Jasper's vital organs were successfully donated according to his wishes.

Jasper was cremated on February 19th 2011 in 's-Gravenhage, the Netherlands. He was 26 years old.

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PUBLICATIONS

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