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Roentgen stereophotogrammetric analysis to study dynamics and migration of stent grafts
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Citation
Koning, O. H. J. (2009, June 25). *Roentgen stereophotogrammetric analysis to study dynamics and migration of stent grafts*. Retrieved from https://hdl.handle.net/1887/13870

Version:	Corrected Publisher's Version
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Downloaded from:	https://hdl.handle.net/1887/13870

Note: To cite this publication please use the final published version (if applicable).

CHAPTER 1

General Introduction

Abdominal Aortic Aneurysm

An aneurysm of the aorta is defined as a permanent dilatation of the artery, exceeding 1.5 times the normal diameter.[1] In clinical practice, the definition of an abdominal aortic aneurysm (AAA) is set at 3-3.5cm.[2,3] The prevalence of AAA in The Netherlands is 2.1% in the population over 55 years of age, and occurs approximately 6 times more frequent in men.[4] A large Veterans Administration study (USA) in 1997 demonstrated a prevalence of 4.6% in 73.000 patients aged 50 to 79 years.[5] In specific subgroups, the percentage can be much higher, demonstrated by the study of Akkersdijk showing a prevalence of 11.4% in men over 60 years of age.[6] With a growing proportion of elderly people in the population, the incidence of aortic aneurysms is expected to increase in the future and could therefore constitute a major health risk.[7-9]

The main risk of this usually asymptomatic disease is rupture and subsequent death. Mortality rates have been reported to be as high as 75 - 90% in patients suffering from a ruptured aneurysm.[10,11] Therefore, the aim of treatment of the aneurysm is to reduce or preferably eliminate this risk of death due to rupture. Since the nature of the disease is one of gradual growth, much research has been undertaken to study the effect of lifestyle and medical therapy on the growth rate of AAA's. Cessation of smoking seems to be most effective to diminish the risk of AAA rupture.[12] The effects of statins, doxycyclin and other drugs to influence AAA growth rate, i.e. by altering the activity of inflammation and lytic enzymes look promising but this is still experimental.[13-17]

Treatment

The current consensus is to keep patients with a known AAA under surveillance until the AAA diameter reaches 5.5 cm.[18] An AAA size smaller than 5.5 cm constitutes only a low risk of rupture: 0.6-1% per year in AAA's of 4.0 - 5.4 cm.[19,20] If the AAA size is 5.5 – 5.9 cm, the annual risk of rupture increases to 9.4% in one year.[21] As aneurysm size increases further, the rupture rate rises dramatically up to 25% in 6 months for aneurysms larger than 8cm.[21]

Until 1991, the only option for treatment of an AAA was open surgical repair. This procedure has excellent long term results but is followed by considerable morbidity and mortality in the post operative phase. In 1991, the first clinical experience of endovascular aneurysm repair (EVAR) was reported in literature.[22,23] The major advantage of this technique is that the procedure is less invasive than open aneurysm repair. The initial outcome after surgery compares favorably to open repair with a lower complication and mortality rate.[24-26] In the years that followed the introduction of EVAR, stent-graft design and materials have improved significantly and the success rate of EVAR both in the shorter and longer term have increased. EVAR has now been embedded in standard clinical practice in most of the western world and yearly thousands of aneurysm patients are treated by endovascular repair. Despite the attractive concept of less invasive surgery and the high initial success rate, EVAR remains a relatively new technique and durability problems such as kinking, thrombosis, endoleak, stent-graft disintegration and stent-graft migration have arisen. Most of these complications were unheard of after open aneurysm repair. These adverse events have been analyzed and have lead to the withdrawal of earlier types of stent-grafts, adjustments in stent-graft design and development of completely new, more durable, devices.

Although the stent-grafts were submitted to extensive preclinical laboratory and animal testing, newly introduced or redesigned stent-grafts showed varying defects during post-EVAR surveillance. These defects are caused by the hostile and demanding biomechanical environment of the aorta. Repetitive forces of the cardiac and respiratory cycle induce strain to the graft material leading to migration and fatigue. Currently, it is impossible to quantify the nature and extent of these three-dimensional dynamics of the stent-graft inside the aorta. Therefore, preclinical biomechanical modeling is difficult and has shown to have been insufficient in the past. This has lead to design shortcomings in stent-grafts that only became apparent after clinical introduction despite extensive but, in retrospect, insufficient pre-clinical testing. Reversed engineering of the circumstances to reproduce these types of stent-graft failure have led to improved understanding of previously unknown motion of the aorta, like torsion / rotation of the thoracic aorta. Increased knowledge of stent-graft dynamics after EVAR is essential to improve preclinical testing of new devices and to help detect deficiency of this type of testing early after initial clinical introduction of new stent-grafts.

Migration of the graft can result in disconnection between the stent-graft and the "landing zone", the relatively healthy part of the artery in which the stent-graft is positioned before bridging the aneurysm. This disconnection may lead to reestablishment of flow and / or repressurization of the aneurysm sac. Stent-graft migration has been reported to occur in over 50% in certain first generation devices.[27] Migration can have detrimental effects on patient safety.[28-30] Despite design changes like adding hooks and barbs to the graft to increase fixation to the aortic wall,[31] stent-graft migration is still reported in currently marketed abdominal and thoracic devices between 1 and up to 66% and detailed analysis seems to reveal more cases of migration.[32-50]

Material fatigue can lead to stent fracture and / or stent-graft disintegration. Stent fracture can be harmless, but can also lead to perforation of the fabric or the aortic wall, with graft infection, bleeding or repressurization of the aneurysm as a result.[32,46,47] Disintegration of the graft, due to detachment of the fabric and the stents can also lead to repressurization of the AAA sac.[48] These forms of failure can ultimately lead to death of the patient.[39] The reported late aneurysm related mortality after EVAR is 1-2% per year and is largely explained by migration, endoleak and material fatigue.[28,30,33,35,37,51-53]

Surveillance after EVAR

Surveillance after EVAR aims at early detection of the described adverse events. In contrast to open repair, rigorous follow-up is required because long term results of the available stent-grafts are unknown and new or redesigned grafts are constantly introduced in clinical practice. Current surveillance protocols vary slightly but in general consist of intravascular contrast enhanced CT-scan investigation and plain radiography combined with duplex ultra-sound. To date, intravascular contrast enhanced CT-scan is the clinical gold standard to detect stent-graft migration and AAA size.[54] The major disadvantages of this surveillance program are poor patient compliance, intravascular contrast requirement, logistical burden and healthcare cost.[30,55,56,57] Another disadvantage is the high cumulative radiation dose that results from frequent CT scanning.[58]

Patient compliance with the current follow-up regime is poor and this may explain part of the incidence of late rupture after EVAR.[30,57] A possible explanation for this incompliance is the cumbersome amount and intensity of investigations for an asymptomatic disease.[57] A less intensive surveillance schedule might increase patient compliance. This is an additional argument in favor of a more patient friendly alternative to CT surveillance in selected patients. The risk of limiting the intensity of surveillance is that adverse effects are identified too late. Therefore, it is paramount that alternative surveillance strategies are not only more patient friendly but also at least as accurate as current clinical strategies.

Optimal imaging using CT requires intravascular contrast enhancement. The major disad-vantage of intravascular contrast use is its nephrotoxic side effect. This is especially relevant considering the fact that reported rates of renal function impairment vary from 23% up to 83% in patients eligible for EVAR.[59-61]

Cost effectiveness of EVAR as compared to open aneurysm repair is mainly limited by the cost of the stent-graft, post EVAR surveillance and secondary interventions.[56] The introduction of a safe and accurate lower cost alternative to CT for surveillance in selected cases could therefore significantly improve this cost effectiveness balance.

Alternative to current surveillance modalities

Because surveillance aims at early detection of adverse events, the methods used need to be accurate enough to reliably detect abnormalities. The items that need to be identified are:

- Correct position and integrity of the stent-graft
- Exclusion of the AAA sac from the circulation

CT, duplex ultrasound and plain radiography, alone or in various combinations are currently used. The correct position and integrity of the stentgraft are currently assessed with CT and / or plain radiography. Both aim at identifying stent fractures, configuration changes and (pending) disconnection of components. The accuracy of both methods to determine stent-graft migration is not known but considered clinically adequate. An important factor in the accuracy of CT and plain radiography is the fact that the images have to be analyzed by hand. The clinical significance of the impact of human error on the accuracy of this kind of analysis is unknown. Furthermore, plain radiography produces a two dimensional image of a three dimensional situation. This may lead to projection errors due to the divergence of the X-ray beam (parallax). Most clinicians agree that technical problems may arise with reproducibility of plain radiographic imaging. CT is, next to the disadvantages of intravenous contrast requirement, high radiation dose and cost, a still image reconstructed from a relatively long exposure of a dynamic situation and therefore incorporates artefacts of varying degree.

Plain abdominal radiography is widely used as a method to detect stent-graft migration [62-64] and has been proposed to replace CT as a more cost effective and patient friendly method. The main difference between these modalities is that plain radiography uses the vertebral column as the point of reference to determine stent-graft position, whereas CT analysis uses the, more appropriate, branches of the aorta to detect changes in position of the graft.

Over the last years, the accepted length of the proximal landing zone in EVAR, the aneurysm neck, is continuously reported to be shorter.[65] Currently a length as short as 5mm is accepted in selected patients. With this ever decreasing neck length, the accuracy and precision of migration detection becomes increasingly important.

To ensure exclusion of the AAA sac from the systemic circulation, several strategies can be followed. AAA sac diameter or volume can be measured with CT and, in case of growth, additional diagnostics can be performed to determine and treat the cause of the sac growth. In case of significant (over 5mm) sac diameter shrinkage after EVAR, this change can be reliably detected and followed by ultrasound. Ultrasound seems inappropriate to accurately detect changes smaller than 5mm due to the inter- and intra-observer variability.[66] Alternatively, sac pressure measurement could be performed to determine trends in pressure changes.[67-73] The latter method is still under investigation and has considerable pitfalls.[74-77]

A significant reduction of aneurysm sac size is reported to occur in 50-73% after EVAR and appears to be a strong indicator for succes.[78-84] If this reduction is found after EVAR, it can be deduced that the pressure in the AAA sac, has been reduced.[85] In this case the only remaining issues of interest are stent-graft position and integrity. If a method can be developed to accurately determine these items at low cost in terms of logistics and healthcare budget, the indications for CT could be reduced and therefore the cost effectiveness and patient friendliness of EVAR could increase. In theory, Roentgen Stereophotogrammetric Analysis (RSA) may be the ideal tool to perform the surveillance of stent-graft position and integrity. The technique is described in further detail below. If RSA can be used for the purpose of surveillance of stent-grafts, follow-up intensity after EVAR in patients with a decreased AAA sac size could be reduced to ultrasound and RSA imaging without the risk of loss (or possibly even increase) of accuracy. This would result in significant reduction of cost, burden to hospital and patient and required doses of radiation and intravascular contrast.

Roentgen stereophotogrammetric analysis

Roentgen stereophotogrammetric analysis is a method that has been used in orthopedic surgery for many years.[86-88] It enables highly accurate detection of the position of joint prosthesis components relative to the bony structures. The technique is based on computer aided analysis of calibrated stereo images to determine the relative position of markers in space. The markers are placed on the prosthesis and reference markers are attached to the bone.

In endovascular surgery, the stent-graft markers that are used to position the graft during endovascular aneurysm repair can be used as graft markers. Additional markers need to be attached to the aortic wall to function as reference markers and enable detection of change of position of the graft. This means an additional procedure has to be performed during EVAR. Major assets of RSA are the fact that no intravascular contrast is required, its low cost and low burden to hospital logistics and its low radiation dose. Moreover, it may be a more accurate method than CT and plain radiography. There are several questions that need to be answered before RSA can be introduced into clinical practice. In short, they concern the accuracy and feasibility of RSA to detect stent-graft migration and the extent to which these are influenced by physiological motion due to the cardiac cycle. Furthermore, the nature and the number of aortic reference markers required for accurate analysis needs to be clarified.

Imaging of stent-graft motion in vivo using FRSA

As previously described, the forces of the cardiac cycle can have a detrimental effect on a stent-graft. To analyze these forces and enable accurate laboratory fatigue and biocompatibility modeling, detailed knowledge of stent-graft motion is mandatory. With current imaging techniques such as CT, MRI motion analysis is possible using cinematographic reconstruction with the help of "ECG-gating".[89-91] These methods have specific disadvantages to the patient in terms of intravascular contrast requirement, radiation dose (for CT) and limitation in analysis of stainless steel stent-grafts (MRI). Furthermore, there are technical difficulties in ECG gated analysis.

ECG gating is a technique that reconstructs a series of still images acquired over a short period of time according to the recorded ECG phase in which the image was acquired. The images are all reconstructed in the same plane respective to the position of the patient on the couch. This means that the cinematographic loop that is produced with this kind of imaging is actually a reconstruction that sequences images that are not acquired consecutively. The image loop is therefore a representation of a series of motions, not an exact image. Cardiac arrythmias can hinder this kind of image reconstruction.

The main disadvantage of cine-CT and cine-MRI is that reconstruction of images is limited to one single plane at a time. Therefore, quantification of out-of-plane motion is impossible with the current techniques.

In other words, cine-CT and cine-MRI can only quantify two-dimensional motion. The accuracy of this type of measurement is not validated. Out of plane motion can only be visualized. Complex, three-dimensional motion cannot be measured with current techniques.

With the knowledge of RSA available at our institution and the arrival of new, digital bi-plane fluoroscopy equipment, we will develop and validate Fluoroscopic Roentgen Stereophotogrammetric Analysis, FRSA. FRSA uses the same three-dimensional reconstruction technique as RSA, but a different method of calibration is required. Redesigning the available software and testing for accuracy will be required before introduction into clinical practice can take place.

Patient risk of radiation exposure due to imaging in EVAR

As mentioned above, there is considerable exposure of the patient to ionizing radiation due to different imaging modalities.[58] There is concern with regard to patient safety, since this type of radiation can induce malignancy. However, EVAR candidates are afflicted with other forms of systemic disease. This co-morbidity results in significant long term mortality.[92-95] There is no literature on the risk of radiation induced death due to imaging for (surveillance of) EVAR.

Aims of this research:

- To develop, test for feasibility and validate roentgen stereophotogrammetric analysis to assess stent-graft migration in long-term surveillance studies, as an alternative to plain abdominal radiography and CT, the current clinical gold standard.

- To develop, validate and clinically introduce fluoroscopic roentgen stereophotogrammetric analysis, a noninvasive tool that can be applied to assess real time three-dimensional stent-graft dynamics due to the cardiac and respiratory cycle.

Outline

The technique of RSA to determine stent-graft migration and FRSA to study stent-graft dynamics are explained in further detail in **CHAPTER 2**. **CHAPTER 3 and 4** concern the accuracy and feasibility of RSA to detect stent-graft migration in a static model and in a model with pulsatile motion. The results are compared to CT, the current clinical gold standard. RSA requires an aortic reference marker to detect stent-graft migration. A possible aortic reference marker is studied in **CHAPTER 4 and 5**. In **CHAPTER 5**, the feasibility of RSA in vivo is described. Furthermore, the position and the number of aortic reference markers required for accurate analysis needs to be clarified. These issues are discussed in **CHAPTERS 5 and 6**.

Plain abdominal radiography is widely used as a low cost method to determine stent-graft migration. In **CHAPTER 7,** a study on the accuracy and, therefore, clinical applicability of plain abdominal radiography to detect stent-graft migration is described.

In **CHAPTER 8** the feasibility of FRSA is studied in a model and the method is validated for accuracy and precision. In **CHAPTER 9**, the first clinical introduction of this technique is reported. To conclude this thesis, the risk of radiation due to imaging for EVAR is evaluated in **CHAPTER 10.**

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