The importance of infrarenal sealing zone assessment in endovascular aneurysm repair

Zuidema, Roy

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GENERAL INTRODUCTION

BACKGROUND

The abdominal aorta is the largest artery of the human body and runs from the hiatus of the diaphragm to its bifurcation in the lower abdomen.[1] The location of the renal arteries is used to clinically divide the abdominal aorta into the suprarenal aorta and the infrarenal aorta. The average diameter of the infrarenal aorta is between 1.7 and 2.2 cm in women and between 2.0 and 2.4 cm in men.[2] A segmental dilatation of ≥50% compared with the diameter of the healthy aorta is referred to as an abdominal aortic aneurysm (AAA).[2] This degenerative condition of the abdominal aortic wall has a multifactorial origin, with risk factors such as advanced age, male sex, smoking, hypertension, genetic predisposition, and atherosclerosis.[3,4] The estimated prevalence of AAAs is between 2% and 8%, most of which occur in the infrarenal aorta.[3,5] When left untreated, there is a significant rupture risk, which increases from 1% per year to >50% per year, based on the AAA diameter.[6] When a rupture occurs, the estimated mortality rate is between 65% and 85%, which is why preventive treatment is advised when the diameter of the AAA is >5.5 cm.[7,8]

AAA treatment

In 1948, Albert Einstein, the world-famous theoretical physicist, underwent an explorative laparotomy due to abdominal pain.[9] A large AAA was discovered during this procedure. At that time, wrapping the aneurysm with polyethene cellophane (i.e., plastic wrap) to reinforce the aortic wall was the only available treatment option.[10] Einstein initially recovered; however, in 1955, 7 years after the initial operation, he died of a ruptured aneurysm.[9] He refused resection of the aneurysm, which was at the time considered extremely experimental, saying, “I want to go when I want. It is tasteless to prolong life artificially. I have done my share, it is time to go. I will do it elegantly.”[11]

Since then, the (preventive) treatment of infrarenal AAAs has evolved and comprises open surgical repair or endovascular aneurysm repair (EVAR).[12] Open surgical repair generally consists of a laparotomy and lengthwise opening of the AAA, after which a synthetic graft is sewn into the healthy proximal and distal parts of the aorta. Lastly, the incision in the aneurysm sac and the abdominal incision are closed.[13]

The first EVAR procedure was performed in 1987 by Dr. Nikolay Volodos.[14] Since then, the use of EVAR has exponentially grown.[15] In general, during EVAR, a modular Y-shaped endograft is inserted through the common femoral artery and is deployed in the neck proximal of the aneurysm.[16] EVAR has a lower perioperative and early mortality risk compared with open repair; however, this difference disappears on the long-term, with increased reintervention and rupture rates after EVAR.[17–19] Currently, the guidelines of the European Society for Vascular Surgery (ESVS), the Society for Vascular Surgery (SVS), and the National Institute for Health and Care Excellence (NICE) recommend that the best treatment approach should be personalised for each patient, taking into account the patient's life expectancy, aortic anatomy, comorbidities, surgical history, anaesthetic risk, and level of frailty.[20–22]

Preoperative planning and sizing for EVAR

Assessment of aortic anatomy on a preoperative computed tomography angiography (CTA) using a three-dimensional vascular workstation with centreline reconstruction is essential to assess eligibility for EVAR.[23] Assessment of the proximal aortic neck includes neck length, diameter, infrarenal angulation, suprarenal angulation, shape, and the amount of thrombus and calcification.[24] In conjunction, these two-dimensional preoperative neck characteristics provide an estimate of the three-dimensional aortic neck. A neck length of ≥10 to 15 mm is generally required, according to the device instructions for use, with a neck diameter between 18 and 30 mm and infrarenal angulation ≤60°, depending on the device manufacturer.[21] For a successful EVAR procedure, the postoperative achieved sealing zone in the aortic neck should be ≥10 mm (i.e., circumferential contact of the endograft with the aortic wall) to exclude the AAA from the circulation and to prevent rupture.[25–27] However, due to the interrelationship of aortic neck characteristics, the presence of challenging aortic neck anatomy, and possible setbacks during the EVAR procedure, the achieved postoperative sealing zone length is often shorter than preoperative anticipated sealing zone.[28–30] This holds particularly true in patients with severe aortic neck angulation or a reverse tapered neck shape.[31] Even though assessment of the preoperative aortic neck is widely adopted, a definition of the preoperative sealing zone is lacking, and preoperative sealing zone assessment is not yet universally implemented. Another important factor during preoperative planning, to enhance the sealing zone and prevent complications after EVAR, is adequate sizing of the endograft. Too little or too much oversizing might have a negative influence on the postoperative sealing zone, and thus, the EVAR outcome.[32]

Complications after EVAR

A multitude of complications can occur after an EVAR procedure, of which endoleaks and endograft migration pose the biggest challenges during follow-up.[33] An endoleak is defined as persistent blood flow in the aneurysm sac, due to failure to exclude the aneurysm, and occurs after ~30% of EVAR procedures (of which three-fourths are type 2 endoleaks).[34] The most important endoleaks can be classified as follows:[33,35,36]

Type 1: leakage at the proximal (1a) or distal (1b) attachment site of the endograft
Type 2: leakage through branch vessel(s) of the aneurysm
Type 3: leakage caused by a defect in the endograft or between modular components

Accordingly, type 1a endoleak and migration occur in the infrarenal aortic neck. Type 1a endoleaks that occur later during follow-up are particularly hazardous because they are difficult to detect and can result in unforeseen aneurysm rupture.[37] The incidence of these late type 1a endoleak is estimated at ~3%; however, this is probably underestimated because of underdiagnosis of endoleaks and patients who are lost to follow-up.[17,38–40]

Post-EVAR imaging

To detect and treat complications after EVAR, the ESVS, SVS, and NICE guidelines advise life-long imaging surveillance.[20–22] In most cases, this is done by duplex ultrasound (DUS) or CTA.[36] DUS has a slightly lower detection rate for endoleaks, although the missed endoleaks are considered less clinically relevant.[36,41,42] Historically, a CTA was made at 1 month, 6 months, and annually thereafter.[43] Recent evidence suggests that a more liberal regimen might be sufficient after a 1-month CTA without endoleaks and with an adequate postoperatively achieved sealing zone.[25,26,44–46] In any case, each follow-up CTA should be carefully and systematically assessed to detect postoperative complications. This was emphasised by Andersson et al., who retrospectively investigated 51 patients with a ruptured AAA after EVAR. They found that a large portion of patients with a rupture had precursors (e.g., proximal neck dilatation, migration, or inadequate sealing zone) that were missed during regular CTA follow-up.[47] These precursors could be detected by implementing a structured CTA analysis protocol, including assessment of the postoperatively achieved sealing zone.[47]

Postoperative assessment of the sealing zone

Long-term durability after EVAR mainly depends on the sealing zone (i.e., apposition) of the endograft, and multiple studies have demonstrated that the length of the postoperative proximal sealing zone is associated with neck-related complications, such as type 1a endoleak and migration.[25,26,48–50] A sealing zone length of <10 mm poses an especially high risk for these complications.[25,26] Despite these results, the findings by Andersson et al., and the current guidelines, assessment of the postoperative sealing zone is not yet a common practice.[21,47] In addition, several methods are available to assess the postoperative sealing zone, and no clear consensus exists.[51] For each of these methods, a dedicated vascular workstation is required. In short, it is possible to measure the sealing zone length over (1) the centreline between to orthogonal planes, (2) the aortic wall between two three-dimensional coordinates, (3) or to measure the total surface area between the endograft and the aortic wall.[25,26,48,51–53] The first method might under- or overestimate the actual sealing zone, especially in patients with angulated aortic neck anatomy.[51] In 2016, Schuurmann et al. developed postprocessing software to measure the sealing zone over the aortic wall, which was subsequently validated.[52,54,55] Figure 1 shows an overview of the workflow for this method.

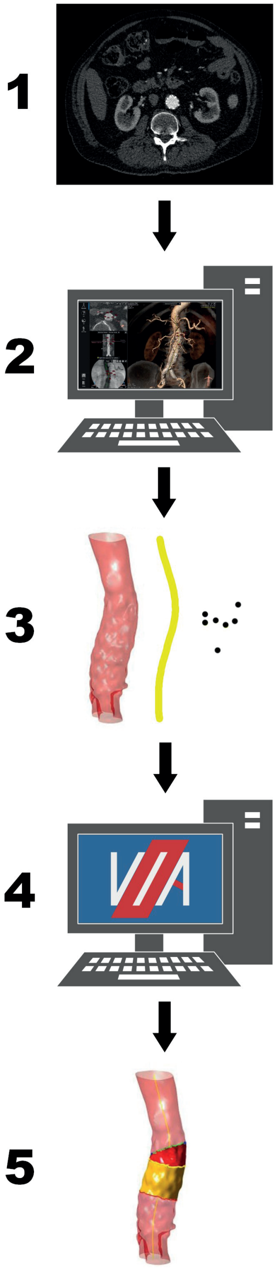

Figure 1. Workflow of sealing zone assessment according to the method by Schuurmann et al. A regular CTA is used as input (1) and preprocessed using a vascular workstation (2), by generating a three-dimensional mesh of the aortic lumen, the aortic centreline and key-coordinates of the renal arteries, endograft fabric and the end of circumferential apposition (3). These are used as input for the Vascular Image Analysis (VIA) software (4), which calculates the position and apposition dimensions (5). The yellow surface area indicates the achieved endograft apposition.[52,54,55]

The workflow in Figure 1 presents a multitude of variables that describe the position and apposition of the endograft, of which the shortest apposition length (SAL) and shortest fabric distance (SFD) are particularly interesting. Figure 2 shows a schematic representation of the SAL and SFD. The SAL is the shortest length of circumferential sealing between the endograft and the aortic wall and indicates the weakest point of the postoperatively achieved sealing zone in the aortic neck. The SFD is the distance between the lowest renal artery and the endograft and is a measure of endograft placement accuracy.

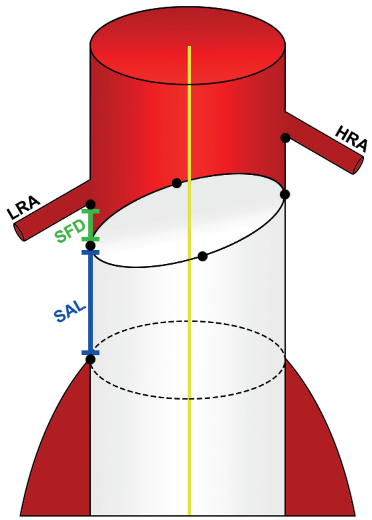

Figure 2. Schematic overview of the shortest apposition length (SAL) and the shortest fabric distance (SFD), as calculated with Vascular Image Analysis (VIA) software.[56]

By using this method, it is possible to detect subtle changes in the dimensions of endograft apposition and position during follow-up after EVAR, which could be used to determine patients at risk for type 1a endoleak and migration.[49] Furthermore, several studies have adopted this method to quantify the adequacy of endograft placement after EVAR.[57,58]

Aim of this thesis

The general aims of this thesis are to provide consensus on the definition and measurement of the infrarenal preoperative and postoperative sealing zone, further evaluate its ability to determine the risk for type 1a endoleak and migration after EVAR, and ultimately encourage implementation of structured apposition analysis in regular EVAR follow-up. In addition, the apposition and position of a new conformable endograft are assessed.

OUTLINE OF THIS THESIS

This thesis is divided into three parts. The first part addresses the definitions of the preoperative and postoperative sealing zone in the infrarenal neck and defines risk factors for inadequate sealing zone after EVAR. **Chapter 2** reports the results of a European expert group of vascular surgeons who were gathered to propose a consensus definition of the infrarenal sealing zone and to provide a decision algorithm for the use of sealing zone assessment during follow-up after EVAR. **Chapter 3** is a systematic review that provides an overview and summary of the currently available literature regarding the infrarenal neck and the infrarenal sealing zone and their association with type 1a endoleak and migration after EVAR.

Part II addresses the ability of endograft apposition to discriminate between patients with a low or high risk for type 1a endoleak and migration during follow-up. In **Chapter 4,** apposition at the initial post-EVAR (1-month) CTA was analysed in patients with and without a late type 1a endoleak. The goal was to determine whether it would be possible to identify patients with an increased risk for type 1a endoleak during subsequent follow-up. In **Chapter 5**, follow-up CTAs of these patients were assessed to determine whether a decline in apposition during follow-up would precede a type 1a endoleak.

Part III describes the assessment of apposition and position of a new conformable endograft that was specifically developed to treat challenging aortic neck anatomy. **Chapter 6** describes the short-term apposition, as well as clinical and geometrical results, of EVAR with the Gore Excluder Conformable Endoprosthesis with active control system in a single-centre study. In addition, the 1-year geometrical results of this endograft were analysed in a prospective multicentre registry in **Chapter 7**.

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PART I

DEFINING THE INFRARENAL SEALING ZONE