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Complex aortic aneurysm management: from technical outcomes to patient-centered insights

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COMPLEX AORTIC ANEURYSM MANAGEMENT

from technical outcomes to
patient-centered insights

W.C.M. Warmerdam

COMPLEX AORTIC ANEURYSM MANAGEMENT

from technical outcomes to
patient-centered insights

Wilhelmina Christina Maria Warmerdam

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**Complex Aortic Aneurysm Management;
from technical outcomes to patient-centered insights**

**Complexe aneurysmata van de aorta;
van technische uitkomsten tot het perspectief van de patiënt
(met een Nederlandse samenvatting)**

Proefschrift

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TABLE OF CONTENTS

Introduction and outline of this thesis		6
Part 1	Center-specific implementation and outcomes of complex endovascular aortic repair	22
Chapter 1	Learning curve analysis of complex endovascular aortic aneurysm repair	24
Chapter 2	Functional performance after complex endovascular aneurysm repair	42
Part 2	Preoperative considerations and patient selection	56
Chapter 3	A 15-year single-center experience treating complex aortic aneurysms; transitioning from open to complex endovascular repair	58
Chapter 4	The association between sarcopenia and adverse outcomes after complex endovascular aortic aneurysm repair	80
Part 3	Lessons learned from patient interviews and patient complaints regarding aortic aneurysm care	102
Chapter 5	Perspectives of patients and professionals on patient education in complex endovascular aortic repair	104
Chapter 6	Lessons learned from Dutch medical disciplinary law regarding aortic aneurysm and dissection care	132
General discussion and implications		158
Appendices		172
Summary		174
Dutch summary / Nederlandse samenvatting		179
Curriculum vitae of the author		184
List of publications		185
Acknowledgements / Dankwoord		186
Abbreviations		188

Introduction and o of this thesis

outline

1. COMPLEX AORTIC ANEURYSM CARE

1.1 Introduction

By the end of the 1980's, multiple teams across the world were simultaneously working on a new minimally invasive endovascular technique to treat abdominal aortic aneurysms. For several years, pioneers had been developing and testing stents, inspired by the catheterization innovations of dr. Charles Dotter. After playing a game of musical chairs with the ingenious Ukrainian cardiovascular surgeon Nicolai L. Volodos, who had already implanted an endovascular stent in a thoracic aneurysm, it was the Argentinian vascular surgeon Juan Parodi who, on September 6 1990, performed the first successful deployment of an endovascular stent treating an abdominal aortic aneurysm (**Figure 1**). Enthusiastically, he even attempted a second procedure that same day, which unfortunately resulted in conversion to open surgery. His first patient, however, would live on for nine years, before dying of an unrelated cause.¹⁻⁷ The work of Parodi and Volodos quickly spread across the world, and within just 15 years, endovascular aortic repair (EVAR) surpassed open surgical repair (OSR) as the main treatment modality for infrarenal aortic aneurysms in the United States. By that time, large trials had shown an early survival benefit for EVAR compared to open repair, although this was generally not maintained during long-term follow-up.⁸⁻¹²

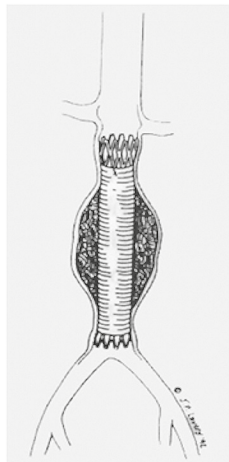


Figure 1: The first device

EVAR massively expanded treatment of abdominal aortic aneurysms and quickly became the preferred option for most patients. Application, however, was not possible for all. An aortic aneurysm that included or was narrowly adjacent to visceral side branches of the aorta could not be treated using conventional EVAR. Implanting a stent within these aneurysms would block the necessary blood flow to the end organs, for example the kidneys, resulting in lethal organ failure. And so, a new race for innovation started, to extend the benefits of endovascular repair to these more complex aneurysm patients

as well. Again, multiple teams simultaneously worked on similar innovations; in South-Korea, the United States, Australia, and Germany. Developments eventually led to the fabrication of devices, which were able to include the aortic side vessels by fenestrations (FEVAR, 1996-1999) or branches (BEVAR, 2001), resulting in complex endovascular aortic repair (complex EVAR, **Figure 2**).^{2,14} As the first results indicated a perioperative morbidity and mortality benefit for complex EVAR compared to complex OSR, it became a game changer in complex aortic aneurysm management. Frail patients who were considered unfit to undergo the large hemodynamic impact of OSR, and would previously not have been treated, could now be treated endovascularly.^{15,16} And although some guidelines still propose OSR as the golden standard, complex EVAR has become a widely adopted treatment modality.¹⁷

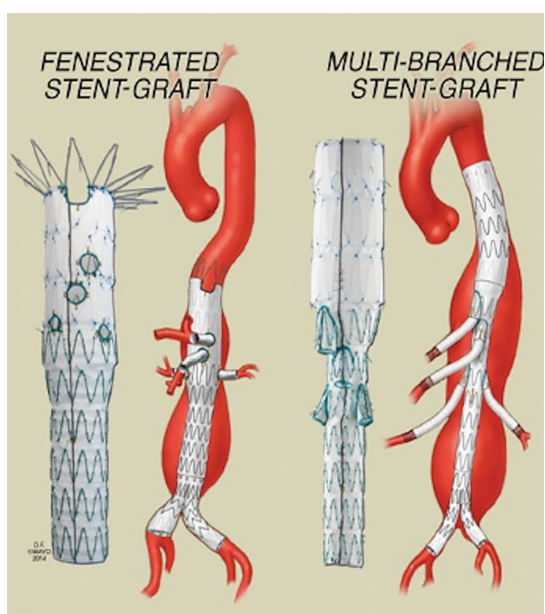


Figure 2¹³

These exponential technical developments, literally, come at a cost. Fenestrated and branched stents are usually custom-made for each patient to exactly align with the patient-specific anatomy. Fabrication is expensive and brings the total costs of complex EVAR to over 30.000 euros per patient; around double the price of OSR,^{18,19} although not all studies are in accordance.²⁰ In addition, it is hypothesized that with the introduction of complex EVAR, more (frail) patients are being treated, which would further contribute to increased total health care costs. Aside from monetary drawbacks, there are technical difficulties involved. Complex EVAR requires advanced technical appliances, a multidisciplinary treatment team, manufacturer contracts, and the ability to provide the necessary postoperative care and follow-up. Therefore, the implementation of complex EVAR is a demanding process and not possible in every treatment center.

Another important consideration when treatment options expand, is deciding which patients should be treated. This not only means deciding between complex EVAR and OSR, but also between conservative treatment of awaiting the natural course of the aneurysm for the frailest patients. Although less invasive compared to OSR, complex EVAR still comes with considerable perioperative risks and rehabilitation. The fact that treatment is technically possible does not necessarily mean that each patient will benefit from it. For some patients, complex EVAR might be a bridge too far.

As becomes clear, the implementation of new technical developments raises several important questions: How can complex EVAR successfully be implemented by a treatment center? How does a new treatment modality affect the treated complex aneurysm population? Which patients should be selected for treatment? How should patients be informed about this procedure and what do they find important when making a treatment decision? What can go wrong and how should we react when patient dissatisfaction occurs? This thesis will touch on most of these issues. It outlines complex EVAR treatment at a medium-volume tertiary referral center for aortic pathology in The Netherlands, since the introduction of this technique in 2013. Not all questions will be unequivocally answered; they will be examined in light of the available evidence. Most prior research originates from high-volume centers of excellence. This thesis provides additional insight into a smaller, but perhaps more 'real-world', patient population, addressing previously unexplored aspects. It aims to contribute to the ongoing quest for research into complex EVAR and will place the findings in a broader perspective of innovation in health care. In the remaining part of this introductory chapter, background information will be provided on aneurysm formation, anatomic configurations, current treatment guidelines, patient selection, and the introduction of complex EVAR within the Leiden University Medical Center (LUMC); the hospital of interest of this thesis. Lastly, this chapter will provide a thesis outline.

1.2 Aneurysm etiology and configuration

An aneurysm is defined as the enlargement of a vessel to at least 1.5 times its usual size. Therefore, the abdominal aorta is considered aneurysmatic once it reaches a size of ≥ 3 cm. The exact etiology of aneurysm formation is still being researched. It is mainly considered as a multifactorial degenerative disease, in which elastin and collagen decreases in the medial layer of the aortic wall due to proteolysis. The breakdown of elastin and collagen leads to an influx of inflammatory cytokines and leukocytes in the aneurysm wall, attributing to the cascade of degeneration. Upon losing its elastic properties, the aorta is no longer sufficient in managing pressure changes during cardiac contraction, causing increased stress on the damaged thinning aortic wall, which leads to aneurysm expansion. Risk factors of aneurysm development and growth are hypertension, aging, atherosclerosis, male gender, chronic obstructive pulmonary disease, family history, and smoking. Other causes are aortic infection, connective tissue disorders such as Ehlers-Danlos (type IV), Louis-Dietz, and Marfan, and non-syndromic genetic predisposition.²¹⁻²³

Aneurysms are usually asymptomatic and often go unnoticed until (imminent) rupture occurs, or once the aneurysm is of such an extent that it causes pressure on surrounding tissues and is noticed as a palpating mass in the abdomen. Some countries have introduced national screening programs for the diagnosis of aortic aneurysms. In the Netherlands, where such a program does not exist, aneurysms are usually diagnosed as an incidental finding during radiologic imaging for other purposes. The prevalence is estimated to be 1-3% among men above 65 years of age and around 1% in women.^{24,25} The risk of rupture increases with aneurysm growth (**Figure 3**).²⁶ A systematic review of aneurysm growth rates showed a pooled mean growth rate of 2.3-2.4 mm/year, with large heterogeneity among studies. The rate increases along with the aneurysm diameter and seems to be the same for complex thoracoabdominal aneurysms.²⁷⁻³⁰ Rapid expansion and smoking are among the risk factors for aneurysm rupture. Aortic aneurysm rupture is highly lethal. It is estimated that approximately 40% of patients are able to reach the hospital in time, of whom 50% can be operated successfully, leading to a mortality rate of 80%. In the Netherlands, it is estimated that 700-750 people experience aneurysm rupture each year.³¹

Abdominal aortic aneurysm size in cm	Cumulative rupture risk at 12 months	Cumulative rupture risk at 36 months
5.0-5.4 (women only)	2.1%	3.4%
5.5-6.0	1.3%	2.2%
6.1-7.0	4.5%	6.0%
>7.0	18.1%	18.4%

Figure 3: Rupture risk based on aneurysm size.

Aortic aneurysms can be classified based on their anatomy. A gross division exists between abdominal (AAA), thoracic (TAA), and thoraco-abdominal aortic aneurysms (TAAA). Abdominal aneurysms can be further divided into infrarenal (sealing zone below the renal arteries of ≥ 4 mm), juxtarenal (does not involve but approximates the renal arteries within < 4 mm), pararenal (involves at least one of the renal arteries but not the superior mesenteric artery (SMA)), and paravisceral aneurysms (involve the SMA but not the celiac axis). Thoraco-abdominal aneurysms can be further divided using the Crawford's classification system, ranging from type I to V, depending on the proximal and distal boarder of the aneurysm. Type I extends from just distal of the left subclavian artery to just above the renal arteries. Type II extends from the left subclavian artery to the aortic bifurcation. Type III starts at the descending thoracic aorta at the level of rib 6 and extends to the aortic bifurcation. Type IV starts at the diaphragm, extending to the aortic bifurcation. In some cases, an additional type V is recognized (Safi/modified Crawford classification), which starts at the level of rib 6 and extends to the paravisceral abdominal aorta, excluding the renal arteries (**Figure 4**).³²⁻³⁴

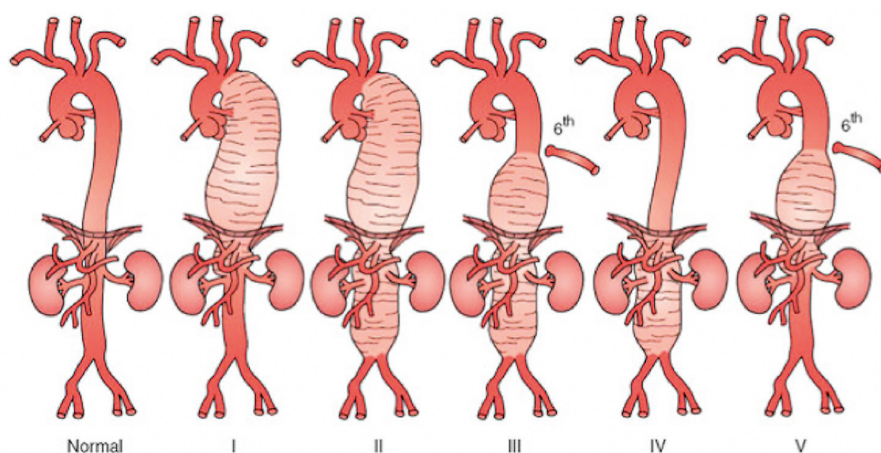


Figure 4³⁵

As stated in the introduction, a *complex* aneurysm is defined as an aneurysm which includes or is just adjacent to the renal or mesenteric aortic visceral side branches. If patent, these side vessels need to be incorporated in the stent in order to maintain visceral perfusion to the kidneys and intestines. Following this definition, complex aneurysms include all thoraco-abdominal aneurysms, as well as pararenal and paravisceral abdominal aneurysms. In addition, juxtarenal short neck aneurysms are classified as complex, since a short (<10-15 mm) or otherwise hostile neck is not suitable for regular EVAR implantation due to an insufficient landing zone for conventional stents. A somewhat separate category is formed by aortic arch aneurysms, which include the brachiocephalic truncus, left common carotid artery, and/or left subclavian artery.

1.3 Treatment options for complex aortic aneurysms

When an aneurysm is detected below the treatment threshold, surveillance is regularly performed by ultrasound or computed tomography (CT) imaging. The frequency depends on the aneurysm's diameter. During this period of surveillance, medical management is provided if necessary. Statins, blood pressure regulating drugs, and antiplatelets are often prescribed to lower cardiovascular risks. Smoking cessation is highly important. New ways of medical management, such as Doxycycline, Metformin, and ACE-inhibitors are being researched.^{36,37} Once the risk of rupture exceeds the risks of surgery, a treatment decision has to be made. Treatment is usually recommended once a complex aneurysm reaches a threshold of 6 cm. At that point, the estimated annual risk of rupture is considered around 10%. Due to the increased risk of serious complications, such as (partial) paralysis due to myelum ischemia or acute kidney insufficiency, the threshold is higher compared to conventional infrarenal abdominal aneurysms, which are treated from 5.5 cm in men and 5.0 cm in women. Another indication to treat is rapid expansion of the aneurysm of ≥ 0.5 cm in 6 months, or characteristics that might increase the risk of rupture, such as a saccular configuration or connective tissue disease.³⁸

Previously, open surgical repair (OSR) was the only available treatment option for complex aneurysms. During OSR, the aneurysm is exposed via the abdomen or retroperitoneal cavity. The aorta is clamped proximal and distal to the aneurysm, temporarily cutting of circulation to the side branches involved. The aneurysm is opened and a graft made of synthetic textile is inserted. Visceral arteries are re-implanted into the prosthesis or included by using a branched graft. The need for aortic clamping, single-lung ventilation, and long-lasting anesthesia exposes the patient to an immense hemodynamic impact.³⁹ The largest cohort study including 3309 patients that underwent OSR for a TAAA reported an in-hospital mortality of 7.5%, a paraplegia incidence of 2.9%, and renal failure needing dialysis in 7.6%. Mid-term outcomes are favorable, with a 1-year survival rate of 83.5%, survival at 5 years of 63.6%, and a low number of reinterventions during follow-up.^{40,41}

Building on experience in conventional aneurysm care, complex EVAR has been developed as a less invasive treatment option. Large abdominal incisions are no longer necessary. Instead, access is gained through both femoral arteries, sometimes accompanied by upper extremity access, to introduce and deploy an endovascular stent within the aneurysm. In order to maintain visceral perfusion, the aneurysm side vessels are included in the stent by using fenestrations (circumferential windows in the device) or branches. Stents are usually custom-made, in order to fit the patient-specific aortic anatomy, so that the branches and fenestrations perfectly align with their target vessels. Fenestrations are used in cases of relatively narrow (<35 mm) aortic segments with transverse or upgoing target arteries, most often the renal arteries. Branches can be used in wider (>35mm) aortic segments where the target artery is involved in the aneurysm and the distance between the stent and the target vessel needs to be bridged. Branches can also be used for down going or tortuous target arteries.⁴² Compared to OSR, complex EVAR requires negligible surgical incisions. In addition, it has a smaller hemodynamic impact and avoids aortic clamping. These advantages are counterbalanced by the need for lifelong surveillance, risk of spinal ischemia, and endoleaks as a complication specific to endovascular treatment. This entails circulation of blood into the aneurysm sac due to incomplete graft attachment (Type 1A and 1B), retrograde flow from side branches (Type 2), stent fabric tears or disconnection (Type 3), and graft wall porosity (Type 4).⁴³

Studies comparing OSR and complex EVAR have reported a lower 30-day mortality rate (although not always statistically significant) and a lower number of postoperative major adverse events in complex EVAR.^{15,16,44-49} However, complex EVAR is associated with a higher number of reinterventions during follow-up and higher costs.^{18,19} Guidelines on aneurysm care have not been in full agreement regarding their recommendation on the treatment of complex aneurysms. The 2020 National Institute for Health and Care Excellence (NICE) guideline for Abdominal Aortic Aneurysm (Diagnosis and Management) advises OSR over complex EVAR, whereas the European Society for Vascular Surgery

(ESVS) 2019 Clinical Practice Guidelines for the Management of Abdominal Aorto-iliac Aneurysms recommend to consider complex EVAR as the treatment modality of first choice, depending on patient-specific characteristics. The Society for Vascular Surgery practice guidelines on the care of patients with an abdominal aortic aneurysm (SVS) are more in accordance with the ESVS recommendations.^{36,17,37}

1.4 Patient selection and decision-making

Once the treatment threshold is reached, a decision on if and how a complex aneurysm should be treated has to be made. In case of a ruptured or symptomatic aneurysm, there is of course no time to wait for a custom-made stent, which takes at least 6 weeks. The same can be decided for very large aneurysms due to impending rupture.⁵⁰ In these cases, open repair is usually the only treatment option, although developments have been made in of-the-shelf (OTS) and physician-modified endografts (PMEGs).⁵¹⁻⁵⁵ In elective cases, several patient and aneurysm characteristics need to be taken into account to decide on the preferred method. First, the anatomy of the aneurysm needs to be considered. In order for complex EVAR to be possible, there needs to be an adequate proximal and distal landing zone for the stent in a segment of non-diseased aortic tissue of around 25 mm. In addition, the iliofemoral or brachial arteries need to provide sufficient access, and the visceral target vessels need to be suitable for in-stent incorporation. Major atherosclerosis, thrombus, early bifurcation of target vessels, and severe tortuosity, for example, may preclude complex EVAR. These characteristics can be assessed on a preoperative CT-scan.^{34,42} In addition, the etiology of the aneurysm is of importance. For aneurysms resulting from connective tissue disease, open repair is considered the treatment modality of first choice, due to concerns regarding the durability of a stent graft when implanted in a diseased aorta. However, in select patients, endovascular treatment of connective tissue aneurysms is performed.⁵⁶

Furthermore, patient characteristics have to be assessed. ESVES Guidelines do not recommend elective aneurysm repair for patients with a limited (2-3 years) life expectancy, for example due to malignancy or severe cardiac failure. It is usually accepted that for young, fit patients with a long life-expectancy (>10-15 years) open repair should be considered the treatment modality of first choice, as (complex) EVAR leads to a higher number of reinterventions during mid- and long-term follow-up. For frail patients considered unfit for open repair, complex EVAR could be proposed as a first-choice treatment modality. However, consensus has not yet been reached on how to define and identify frailty. Preoperative cardiac, pulmonary, geriatric, physiotherapeutic, and nutritional screening can provide valuable insights. Frailty scores such as the modified Frailty Index have been proposed as they appear to be able to predict postoperative mortality.⁵⁷ In recent years, low muscle quantity and/or quality have been identified as possible indicators of frailty and seem to be predictors of mortality and adverse events. Given the fact that muscle mass is partially modifiable, it could be optimized prior to treatment by nutritional and physiotherapeutic guidance.⁵⁸⁻⁶¹

However, a 'mortality and morbidity calculator', predicting postoperative outcomes for each individual patient, has yet to be developed. The treatment decision therefore partially remains an expert opinion, depending on the views, preferences, and experience of the treatment team.

Very important factors to take into account are, of course, the patient's preferences, especially if both treatment modalities are possible. Patients should be adequately informed on the risks of each procedure, as these can be interpreted differently depending on the patient's views and values. Some patients, for example, might be opposed to having to undergo a second procedure after complex EVAR, to finalize the stent. Other patients might dread the long rehabilitation period after open repair. It is paramount to investigate and understand these considerations during preoperative consultation.

2. THE INTRODUCTION OF COMPLEX ENDOVASCULAR AORTIC REPAIR IN THE LEIDEN UNIVERSITY MEDICAL CENTER

In July 2013, the first complex EVAR procedure was performed in the Leiden University Medical Center (LUMC); a tertiary referral center for aortic pathology in The Netherlands. To optimize the implementation of complex EVAR, a dedicated endovascular treatment team (ETT) was composed, consisting of vascular surgeons, interventional radiologists, thoracic surgeons, anesthesiologists, clinical neurophysiologists, radiology technicians, and scrub nurses. Great attention was paid to team composition; members were selected based on self-professed interest, capabilities, and time commitment. All interventional radiologists and vascular surgeons had previous experience with conventional EVAR.

Prior to surgery, most patients were seen by a geriatric specialist, a nutritionist, and physiotherapist. After this assessment, patients were discussed in a multidisciplinary meeting. When the decision was made to proceed with complex EVAR, the stent was designed based on CT-imaging by the interventional radiologists, vascular surgeons, and stent graft manufacturers. The first four procedures were proctored. Post-operative care was planned by consulting selected Intensive Care Unit (ICU) specialists and internal medicine doctors. After being discharged, patients were seen in the outpatient clinic by the vascular surgeon at 6 weeks, 6 months, 12 months, and yearly after that. CT-angiography and/or duplex ultrasonography was used to monitor aneurysm or stent graft related complications.

3. OUTLINE OF THIS THESIS

3.1 Part 1 – Chapter 1 and 2

Part 1 starts with the LUMC center-specific outcomes and findings regarding the introduction of complex EVAR. The first part consists of a learning curve analysis. It describes the quantitative changes that occurred when experience increased and the qualitative aspect that should be taken in mind when composing a new treatment team. Chapter 2 presents the first postoperative outcomes of the LUMC complex EVAR cohort. It not only provides morbidity and mortality numbers, but functional outcomes as well.

3.2 Part 2 – Chapter 3 and 4

Part 2 will discuss preoperative considerations and patient selection. Chapter 3 describes the changes in the treated complex aneurysm population within the LUMC over the last 15 years, during which complex EVAR was introduced. It gives insight into the considerations behind treatment decisions. Chapter 4 is a retrospective cohort study into the prevalence of sarcopenia among complex EVAR patients and its association with adverse outcomes. Defining which patients are most at risk for adverse outcomes, could aid in clinical decision-making and adequate preoperative consultation.

3.3 Part 3 – Chapter 5 and 6

Part 3 will present the lessons learned from patient interviews and patient complaints regarding aortic aneurysm care. Chapter 5 consists of a qualitative interview study, interviewing patients that underwent complex EVAR and health care workers involved in complex aneurysm care. It presents differences in perspectives of patients and professionals on patient education and visualizes the patient's journey. Chapter 6 is an explanatory review of 10 years of Dutch disciplinary law regarding aortic aneurysm care. Understandably, most doctors prefer to stay far away from disciplinary law. However, it provides valuable insight in the patient experience and the analytical framework of the courts.

3.4 Discussion

This thesis will conclude with a general discussion. It will combine the findings from previous chapters and discuss the limitations and implication for policy making, clinical care, and future research.

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PART 1

Center-specific im and outcomes of c endovascular aorti

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Learning curve ana endovascular aorti

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Analysis of complex endovascular aortic aneurysm repair

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ABSTRACT

Objectives

When introducing new techniques, attention must be paid to learning curve. Besides quantitative outcomes, qualitative factors of influence should be taken into consideration. This retrospective cohort study describes the quantitative learning curve of complex endovascular aortic repair (EVAR) in a non-high volume academic center and provides qualitative factors that were perceived as contributors to this learning curve. With these factors, we aim to aid in future implementation of new techniques.

Methods

All patients undergoing complex EVAR in the Leiden University Medical Center (LUMC) between July 2013 and April 2021 were included (n=90). Quantitative outcomes were: operating time, blood loss, volume of contrast, hospital stay, major adverse events (MAE), 30-day mortality, and complexity. Patients were divided into three temporal groups (n=30) for dichotomous outcomes. Regression plots were used for continuous outcomes. In 2017, the treatment team was interviewed by an external researcher. These interviews were re-analyzed for factors that contributed to successful implementation.

Results

Length of hospital stay ($p=0.008$) and operating time ($p=0.010$) decreased significantly over time. Fewer cardiac complications occurred in the third group (3: 0% vs. 2: 17% vs. 1: 17%, $p=0.042$). There was a trend of increasing complexity ($p=0.076$) and number of fenestrations ($p=0.060$). No significant changes occurred in MAE and 30-day mortality. Qualitative factors that, according to the interviewees, positively influenced the learning curve were: communication, mutual trust, a shared sense of responsibility and collective goals, clear authoritative structures, mutual learning, and team capabilities.

Conclusions

In addition to factors previously identified in the literature, new learning curve factors were found (mutual learning and shared goals in the OR), that should be taken into account when implementing new techniques.

INTRODUCTION

Originally introduced in aircraft manufacturing, learning curve studies addressed the variation in costs and labor time, when production quantity increased.¹ A learning curve can provide information on different levels: whether learning has taken place, at which rate, whether a desired level of performance has been reached, and whether learning has stopped or even regressed. A classic learning curve (Figure 1) is comprised of three phases; an initial gentle slope, followed by a phase of rapid learning, ending in a plateau phase when additional procedures no longer improve performance. Reaching the plateau phase can either mean learning has stopped and adjustments should be made in order to improve again, or that an expert plateau phase or target values have been reached. More recently, a period of regression or decline has been added as a potential fourth phase. Here, competence decreases due to an increase in challenging cases or due to 'unlearning'.²⁻⁴

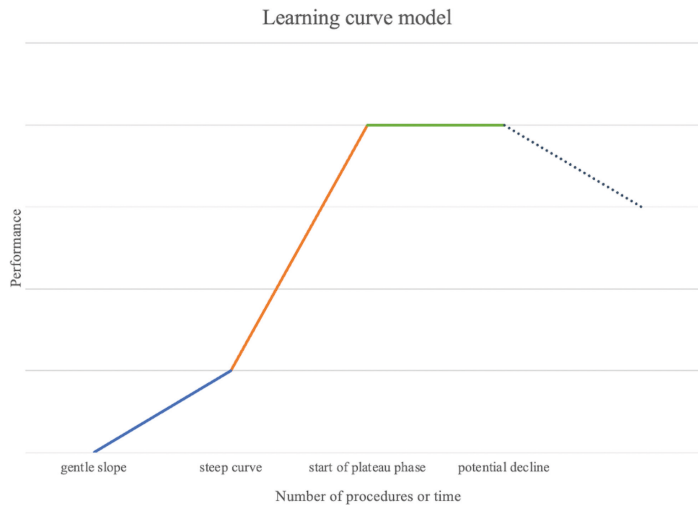


Figure 1: Learning curve model.

In order to optimize implementation of new surgical techniques, it is important to examine factors that contribute to a successful learning curve. Several technical factors have been established, such as a surgeon's manual dexterity and the experience of the supporting surgical team.^{2-3,5} Besides technical skills, deliberate team selection and a shared mental model of motivation are vital. In addition, a balance should be sought between authoritative leadership and a safe environment, in which all team members feel free to communicate their thoughts.⁶ Another important factor is team stability, which enhances relational competence; knowledge of individual team members' preferences, and the way team roles relate to each other. However, when procedures become too much of a routine, adapting to change becomes difficult. This can be addressed by performing trials of new routines, to prevent 'unlearning'.⁷

Establishing a learning curve is common practice in robotic and minimally invasive surgery. Switching from an established standard to a technically challenging new approach requires justification, and is therefore particularly suited for learning curve analyses.^{3,8-9} In the field of vascular surgery, complex endovascular aortic repair (complex EVAR) represents such a development. Complex aortic aneurysms extend up to or above the renal arteries, involving visceral and arch branches that need to be incorporated in the reconstruction. For decades, open reconstruction was the standard of treatment, albeit associated with significant morbidity and mortality.¹⁰⁻¹¹ Treatment options greatly expanded with fenestrated EVAR (FEVAR) and branched EVAR (BEVAR).¹² The application of this technique is expected to grow further, due to technical innovation.¹³ Complex EVAR is technically more demanding than conventional EVAR; stent grafts are tailor-made for each patient, implantation is supported by advanced imaging tools, high-end operating facilities are necessary, and it requires a treatment team to adopt new skills. These complex techniques were pioneered in high-volume aortic centers of excellence, and the most robust outcome data derives from their results.¹⁴⁻¹⁶

Previously, learning curves were established for branched-fenestrated EVAR implementation in the United States, for the experience of a single surgeon, and for the usage of a specific device.¹⁷⁻¹⁹ These studies focused on the quantitative aspect, as is often the case for surgical learning curves. The current study focuses on the qualitative aspect of implementing complex EVAR and presents quantitative outcomes in a non-high-volume hospital. By establishing factors that positively contributed to team-learning, we aim to support future implementation of new techniques; not just in endovascular surgery, but in other surgical fields as well.

METHODS

Complex EVAR implementation

In July 2013, the first complex EVAR procedure was performed in the Leiden University Medical Center (LUMC); a tertiary referral center for aortic pathology. To optimize the implementation of complex EVAR, a dedicated endovascular treatment team (ETT) was composed, consisting of vascular surgeons, interventional radiologists, thoracic surgeons, anesthesiologists, clinical neurophysiologists, radiology technicians, and scrub nurses. Great attention was paid to team composition; members were selected based on self-professed interest, capabilities, and time commitment. All interventional radiologists and vascular surgeons had previous experience with conventional EVAR.

Prior to surgery, each patient was discussed in a multidisciplinary consultation. Complex EVAR stents were designed for each individual patient based on CT-imaging by the interventional radiologists, vascular surgeons, and stent graft manufacturers. The

first four procedures were proctored. Postoperative care was planned by consulting selected ICU specialists and internal medicine doctors. Seven of the initial twenty members left the team due to job changes or retirement: a scrub nurse (2019), radiology assistant (2018), industry representative (2017), two thoracic surgeons (2019, 2018), anesthesiologist (2018), radiology product expert (2017). Eight members joined the team: a scrub nurse (2019), radiology assistant (2018), industry technician (2017), thoracic surgeon (2019), two anesthesiologists (2018, 2017), radiology product expert (2017), and a vascular surgeon (2020).

Data collection

A single-center retrospective study was performed. All patients who had undergone complex (thoraco-)abdominal EVAR in the LUMC between July 2013 and April 2021 were included. Solitary thoracic EVAR (TEVAR) procedures were excluded. Patients received standard of care follow-up, in accordance with our institution's protocol. They were seen in the outpatient clinic by the vascular surgeon at 6 weeks, 6 months, 12 months, and yearly after that. CT-angiography, duplex ultrasonography, and abdominal X-ray were used to monitor aneurysm or stent graft related complications. For the quantitative analysis, data were subtracted from patients' medical records, and stored in a secured computerized secure database. Data collection was approved by the institution's Medical Ethics Committee (METC).

In 2017, when 46 complex EVAR procedures had been performed, semi-structured face-to-face interviews were conducted with all 19 ETT members by an external interviewer, in order to monitor the implementation phase.²⁰ The main goal was to identify what every team member needed in order to adequately fulfil their task. These interviews were re-examined for the qualitative analysis of the current study. All interviews were conducted within an 11-day period during which no complex EVAR procedures were conducted, in order to avoid recency bias between the interviewees. Each interview lasted between 50 and 100 minutes. Questions are added in Appendix A. The interviews were transcribed and coded using Atlas.ti software. ETT members' reflections were captured in first order codes that closely followed the phrasing used by interviewees. Factors were considered to be vital to the procedure if they were mentioned at least ten times by at least five different interviewees. First order codes were subsequently grouped into second order codes by the external researcher. In a final step, the researcher aggregated the second order codes into three key dimensions: relational embedding, cognitive embedding, and team learning. Factors that influenced the learning curve according to interviewees were extracted from this data for the purpose of the current study. They were compared with factors derived from literature. Corresponding and supplementary factors are discussed in this paper.

Outcome measures

Surgical outcomes were initial technical success (achieved if all arteries were successfully treated as planned), operating time (minutes), blood loss (milliliters), fluoroscopy time (minutes), and volume of contrast (milliliters). Clinical patient outcomes were length of hospital stay (days), discharge to a rehabilitation center, 30-day mortality, major adverse events (MAE; complications with a Clavien-Dindo score of III-IV), the necessity of endoleak repair, and reinterventions due to complications.²¹ In order to monitor changes in complexity over the years, the ETT established a complexity coding scheme. Complexity levels were defined as 1 (least complex), 2, 3, and 4 (most complex). Level 1 included complex EVAR with 1 or 2 fenestrations. Level 2 included 3 or 4 fenestrated EVAR. Level 3 included all branched EVAR patients, and level 4 included branched-fenestrated EVAR combinations, arch EVAR, and emergency cases.²⁰ Scoring complexity based on the number of fenestrations is in accordance with previous research.²²⁻²³

Statistics

Patients were divided into three temporal groups: the first 30 patients (group 1), the second 30 patients (group 2), and the third 30 patients (group 3). These cut-off points are in accordance with previous research and were set before any analyses were made, in order to preclude bias resulting from data-dependent splitting.²⁴ Baseline characteristics and outcomes are presented as numbers and percentages for categorical data and as mean or median, with standard deviation or interquartile range respectively, for continuous data. Baseline characteristics were compared using the ANOVA F-test for continuous normally distributed data. The Fisher's exact test was used for dichotomous baseline data and categorical learning curve outcomes. In addition, Poisson regression analyses were made. The learning curve for continuous outcomes was established by calculating the regression coefficients, as this is the preferred statistical method.²⁴ A multivariate regression analysis was performed to determine the effect of complexity on these continuous outcomes. In all analyses, a p-value below .05 was considered to indicate a statistically significant difference. All analyses were conducted using IBM SPSS Statistics version 27.²⁵

RESULTS

Baseline characteristics

Between July 2013 and April 2021, 90 patients with complex aortic aneurysms were treated. Figure 2 shows how many patients were treated each year. A steady increase occurred in the first four years. Table 1 shows the baseline characteristics of these patients: 74 (82%) were male and mean age was 73.6 years (SD=6.3). Columns 3-6 of Table 1 show the baseline characteristics of the three temporal groups. The groups were comparable on all variables, including age, gender, BMI, comorbidities, risk factors, and ASA-score. No statistical differences were detected between baseline characteristics.

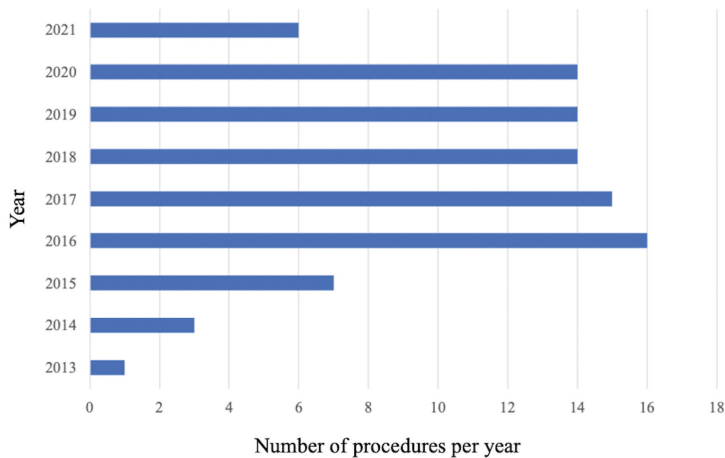


Figure 2: Number of complex EVAR procedures per year.

Qualitative assessment; factors influencing the learning curve

In 2017, after 46 procedures and four years of treatment, all ETT members were interviewed.²⁰ Factors were considered to be vital to the procedure if they were mentioned at least ten times by at least five different interviewees. They were divided into factors enabling relational embeddedness, cognitive embeddedness, and team learning. One factor enabling relational embedding was adequate *communication*. Communication should occur on a frequent basis, among all members of the ETT, and in formal as well as informal settings. In the preparatory phase, pre-case multidisciplinary briefings provided formal occasions of communication. During surgery, “thinking out loud” by the performing surgeons and interventional radiologists enabled involvement of all participating team members in the OR. In addition to communication during official meetings and in the OR, informal discussion and social gatherings provided occasions of valued interaction. Communication was supported by a culture of *mutual trust*; all team members felt free to openly share their opinions and raise concerns. This depended on the team environment, which was created over time.

According to the interviewees, a shared understanding of different team roles was vital to successful team performance. This contributed to cognitive embedding. Differences in hierarchical positions and the line of command between team members were accepted by all team members. Clear *authoritative structures* had to be present and unquestioned, while at the same time maintaining mutual trust. Another contributing factor to cognitive embedding was a strong sense of *shared responsibility and collective goals*. This included attendance of all pre-case and postoperative meetings. It also encompassed a realization of the interdependence between team members. Due to the necessity of each team member’s contribution, participants should be able to rely on each other, and therefore feel the obligation to enable the task execution of others. We found that the importance

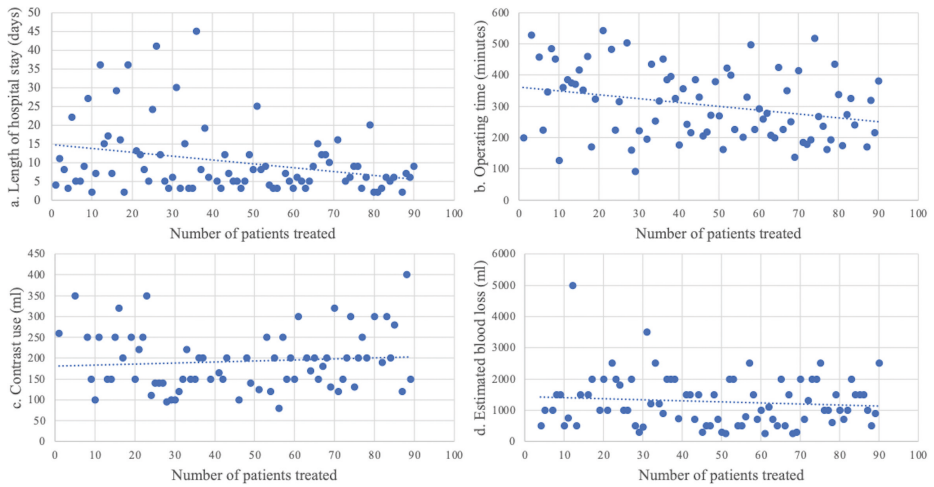
of this factor extended into the operating room (OR). During the procedure, it was expected that all conversations only concerned the treatment being performed and all members focused on their task, while being dedicated to the overall team performance. The feeling of responsibility exceeded planned working hours.

Three factors were identified to have contributed to team learning. Team members *shared their knowledge*, which meant that more information than strictly necessary to perform an assigned task was exchanged. Again, debriefing was important in this matter. In addition, acquired skills and experiences were shared for other team members to learn from, along with relevant developments in the different disciplines involved: *mutual learning*. Besides becoming familiar with the technical aspect of the procedures, team members also had to become acquainted with other members' way of work and preferences. Familiarity with each other's body language and specific preferences contributed to successful task performance and built *team capabilities*.

Quantitative assessment

Figures 3a-d show the quantitative learning curves for blood loss, operating time, length of hospital stay, and volume of contrast. Specifics are depicted in Table 2. It shows a statistically significant decline in operating time (Time (minutes) = $361.1 - 1.235 \times$ number of procedures, $p=.010$, CI: -2.17;-0.30) and length of hospital stay (Length of stay (days) = $14.7 - 0.102 \times$ number of procedures, $p=.008$, CI:-0.18;-0.03). No statistically significant trend was detected for blood loss (Blood loss (milliliters) = $1433.7 - 3.394 \times$ number of procedures, $p=.345$, CI:-10.50;3.71) or contrast use (Volume of contrast (milliliters) = $180.8 + 0.240 \times$ number of procedures, $p=.480$, CI:-0.43;0.91). No changes in statistical significance occurred after correction for complexity level. The adjusted regression coefficients were -1.344 (CI: -2.25;-0.44, $p=.004$) for operating time, -5.665 (CI: -12.43;1.10, $p=.100$) for blood loss, 0.365 (CI: -0.33; 1.06, $p=.300$) for volume of contrast, and -0.106 (CI: -0.17;-0.04, $p=.003$) for length of stay.

Table 2 shows that there was no significant difference between the three temporal groups in 30-day mortality (1: 3%, 2: 10%, 3: 7%, $p=.435$), MAE's (1: 17%, 2: 30%, 3: 27%, $p=.554$), initial technical success of the procedure (1: 93%, 2: 90%, 3: 83%, $p=.592$), endoleak repair-free survival (1: 50%, 2: 33%, 3: 77%, $p=.081$), or reintervention-free survival for stent graft or aneurysm complications (1: 67%, 2: 73%, 3: 53%, $p=.612$). The number of patients discharged to a rehabilitation center did not significantly differ between the groups of experience (1: 20% vs. 2: 20% vs. 3: 13%, $p=.964$). The Poisson regression coefficients were 0.009 for 30-day mortality ($p=0.572$), 0.006 for MAE's ($p=0.497$), -0.002 for initial technical success ($p=0.721$), -0.011 for endoleak repair ($p=0.257$), -0.021 for other reinterventions ($p=0.107$), and -0.001 for discharge to a rehabilitation center ($p=0.874$). This indicates, on a log scale, no statistically significant effect of patient volume on these outcomes.



Figures 3a-d: Regression plots showing a statistically significant decline in (a) length of hospital stay ($p=.008$) and (b) operating time ($p=.010$). No significant trends were detected for (c) contrast use ($p=.480$) or (d) blood loss ($p=.345$). ml = milliliters

Figures 4a-b show the trends in postoperative complications per temporal group, presented by the type of complications (figure 4a) and by Clavien-Dindo score (figure 4b). It shows a significant decrease in the percentage of patients with cardiac complications in group 3 vs. group 2 and 1 (3: 0%, 2: 17%, and 1: 17%, $p=.042$). In addition, it shows an increase in the percentage of patients with access complications, but this ascending trend was not statistically significant ($p=.322$). There were no significant changes in the severity of complications.

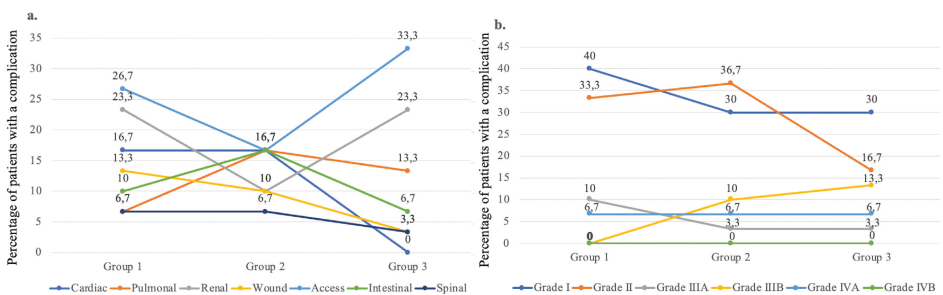


Figure 4a: Percentage of patients with one or more post-operative complications with a Clavien-Dindo score of I-IVB, presented per group of experience ($n=30$). The decline in cardiac complications was statistically significant ($p=.042$).

Figure 4b: Percentage of patients with one or more post-operative cardiac, renal, access, wound, pulmonal, intestinal, or spinal complications per group of experience, presented by Clavien-Dindo score. There were no significant differences between groups.

There was a trend towards an increase in complexity over the years. Table 1 shows that the number of procedures with a complexity score of 3 is larger in group 3 compared to group 1 (n=18 vs. n=8), which was mainly caused by an increase in FEVAR procedures with 4 fenestrations (n=10 vs. n=3). However, this trend did not present a statistically significant difference in overall complexity scores between groups (p=.076). There was also a trend towards an increase in the number of fenestrations per procedure, mainly caused by an increase in procedures with 3 fenestrations and a scallop, and procedures with 4 fenestrations. This trend was not statistically significant (p=.060).

DISCUSSION

Qualitative analysis

According to our interview data, factors thought by the interviewees to have positively influenced the learning curve were: communication, mutual trust, a shared sense of responsibility and collective goals, clear authoritative structures, knowledge sharing, mutual learning, and team capabilities. When implementing new techniques in the future, several of these factors can be encouraged from the start, for example by organizing team meetings in which experiences are shared, and mutual learning is supported.

Figure 5 (supplementary material) shows a comparison between our factors of influence and corresponding literature factors.^{6,7,26} The need for a shared sense of responsibility and collective goals resembles the "shared mental model" introduced by *Aveling et al.*: team members should be motivated, focused, and dedicated.⁶ Our analysis complements this factor by adding that this attitude should extend into the OR. *Parker et al.* discusses surgical leadership, which our factor of clear authoritative structures partially encompasses.²⁷ A contributing factor revealed by our analysis, but not discussed in the literature concerning learning curves, is mutual learning. Experiences and relevant developments in the different disciplines should be shared with other team members, even if this strictly extends beyond the scope of their assigned tasks. A factor mentioned in the literature that we did not identify in our data, is performing "trials of a new routine".⁷ This might be absent in our findings because additional techniques are introduced on a rolling basis in complex EVAR. Moreover, each procedure is adjusted to the specific configuration of the aneurysm that is being treated, which prevents complex EVAR from becoming routine surgery.

Quantitative analysis

Despite a trend of increased complexity, operating time declined, which indicates technical learning took place. An increase in complexity would be in line with existing literature that shows that with growing exposure, complex EVAR became technically more demanding.²⁸ Length of hospital stay, with a cluster of patients with a long length of stay in the earlier treatment stage (Figure 3a), significantly decreased as well.

Despite a slight trend of increased thirty-day mortality and major complications (mainly between groups 1 and 2), these results were not statistically significant, and adverse outcomes remained at comparable levels. In addition, the number of cardiac complications declined. Our 30-day mortality and MAE numbers can be compared to previous research with a higher number of patients, such as *Oderich et al.* (30-day mortality of 1.8-8.2%, MAE in 32-36%, depending on complexity) and *Tran et al.* (30-day mortality of 8.6%, MAE in 21.1-23.5%, depending on complexity).¹⁴⁻¹⁵

A decrease in operating time was also present in the learning curves of *Mirza et al.* (fenestrated-branched combinations) and *Starnes et al.* (FEVAR).¹⁷⁻¹⁸ In addition, *Mirza et al.* presented a decline in 30-day mortality and the incidence of MAE, although the incidence of MAE in our third group of experience (27%) resembles the incidence in the final group in *Mirza et al.* (29%). It should be noted that these studies described specific subgroups, whereas the current study included all types of complex EVAR. This impedes meaningful comparison of results.

Possible confounding factors

When interpreting a learning curve, confounders need to be taken into account. Procedural changes and adjustments in patient selection did occur during eight years of treatment. Although a change in patient characteristics was not identified, in our experience more complicated cases were taken on, based on combinations of case complexity and aneurysm configurations. Our complexity score was solely based on stent graft configuration, which does not include all aspects of a procedure's difficulty level. Factors that could be included for a more comprehensive complexity score are tortuosity, the way access was gained, and whether target vessel stenosis was present. Although consistency was aspired within the ETT, changes in team composition did occur over the years, as specified in the methods section. Another possible confounder is the fact that new innovations were introduced in the endovascular program, such as carbon dioxide flushing of thoracic stents to prevent cerebral air embolisms and branched and fenestrated arch-EVAR. The slight rise in access complications could be due to the introduction of percutaneous femoral access.

Strengths and limitations

The current study consecutively included all patients that underwent complex EVAR during eight years of treatment. Because treatment took place in a single center, inclusion was limited to 90 patients. This represents an unselected 'real world' complex EVAR population and provides insight in the outcome numbers of a medium-volume center. However, it does limit the extend of the analyses. If more patients were to be included, additional analyses could be performed, such as multivariate learning curve analysis corrected for confounding factors. With the current sample size, this could not be performed in a robust fashion. The temporal groups enabled us to determine whether learning took place. The regression plots depict the rate of learning and indicate that

learning has not stopped. Although widely used and accepted, our methods only partially describe the shape of the underlying learning curve (Figure 1). Future research aims to establish a mathematically more rigorous approach. This would provide a more thorough comparison of different learning curves and could enable treatment teams to determine what stage of learning they are in.^{4,24}

Another challenge is the fact that the qualitative data were gathered inductively, without ex ante referencing the medical learning curve literature. Suggestions regarding the interaction between qualitative and quantitative results thus depend on our interpretation. In future research, quantitative and qualitative data should preferably be examined prospectively. This enables researchers to investigate whether findings in the quantitative curves are reflected in the interviews, and vice versa. However, this fundamentally contradicts the inductive approach we took, which has as a core strength that interviewees dictate which factors are most important.

CONCLUSION

This study presented a quantitative as well as a qualitative analysis of the complex EVAR learning curve in a non-high-volume hospital. Despite a trend of increased complexity, operating time, length of hospital stay, and cardiac complications declined. Thirty-day mortality and MAE showed no statistically significant changes. We found that several learning curve factors that were previously identified in other fields, extend to the field of complex EVAR: adequate communication, a shared sense of responsibility, mutual trust, clear authoritative structures, and team capabilities. The factors mutual learning and shared goals during treatment in the OR were added by our research, and can aid in future implementation of new techniques. With complexity bound to increase, monitoring progress and striving for optimization of team learning will become even more relevant.

INTERIM SUMMARY

In this chapter, a learning curve analysis was presented regarding the implementation of complex EVAR in the Leiden University Medical Center, using the results of patients treated between July 2013 and April 2021 (n=90). A decrease in operating time and length of hospital stay implicate technical learning. In addition, qualitative factors experienced as a positive contributor to learning were presented. Most of these factors were recognized in literature regarding other fields. Mutual learning was added. Although the data did not support an increase in patient complexity in a statistically significant manner, the treatment team did experience such a change. This hypothesis will be further investigated in Part 2, describing changes in the treated complex aneurysm population with the introduction of complex EVAR.

TABLES AND SUPPLEMENTARY FIGURES

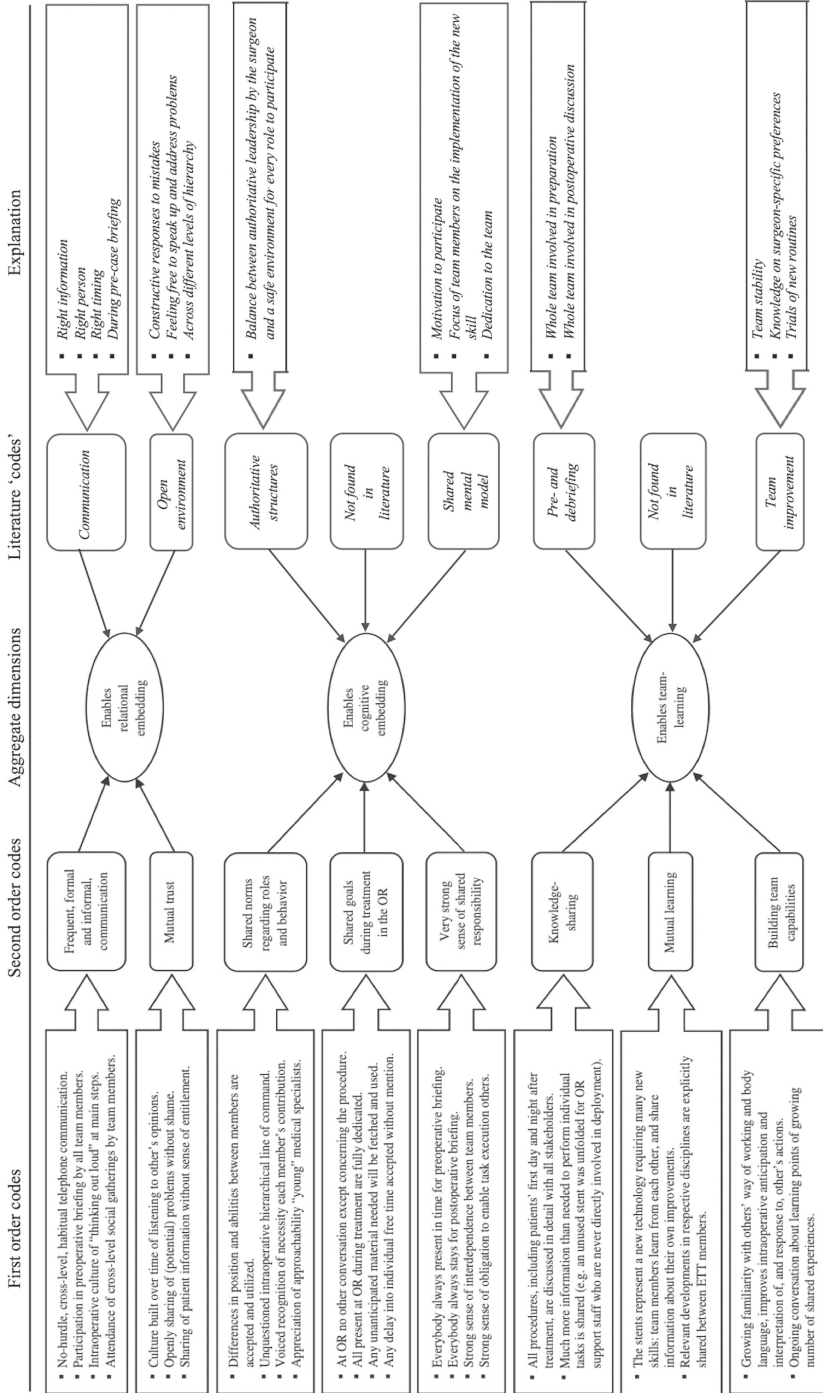


Figure 5: Factors influencing the learning curve identified in the interviews and corresponding factors deriving from literature (in cursive).^{6-7,20,26}

Table 1: Patient characteristics

Variable (unit)	All patients (n=90)	Group 1 (n=30)	Group 2 (n=30)	Group 3 (n=30)	p-value*
Age (years), mean (SD)	73.6 (6)	72.8 (6)	73.2 (7)	74.9 (6)	.379
Male, n (%)	74 (82)	24 (80)	25 (83)	25 (83)	.927
BMI (kg/m²), mean (SD)	26.6 (4)	26.4 (3)	27.1 (4)	26.1 (3)	.539
Aneurysm size (mm), mean (SD)	65.1 (11)	67.6 (15)	63.1 (7)	64.5 (9)	.255
Aneurysm configuration, n(%)					
Crawford 1	7 (8)	4 (13)	3 (10)	0	
Crawford 2	11 (12)	4 (13)	4 (13)	3 (10)	
Crawford 3	6 (7)	3 (10)	0	3 (10)	.078
Crawford 4	8 (9)	4 (13)	2 (7)	2 (7)	
Suprarenal	3 (3)	0	0	3 (10)	
Juxtarenal	52 (58)	15 (50)	18 (60)	19 (63)	
Aortic arch	3 (3)	0	3 (10)	0	
Procedure complexity, n (%)					
Level 1	12 (13)	7 (23)	3 (10)	2 (7)	
1 fenestration	2	2	0	0	
1 fenestration and scallop	3	2	1	0	
2 fenestrations and scallop	7	3	2	2	
Level 2	42 (47)	8 (27)	16 (53)	18 (60)	.076
3 fenestrations	9	2	5	2	
3 fenestrations and scallop	18	3	9	6	
4 fenestrations	15	3	2	10	
Level 3	29 (32)	13 (43)	7 (23)	9 (30)	
Level 4	7 (8)	2 (7)	4 (13)	1 (3)	
ASA-score ≥3, n (%)	54 (60)	15 (50)	18 (60)	21 (70)	.311
Comorbidities, n (%)					
MI/ACS	31 (34)	9 (30)	9 (30)	13 (43)	.490
AF or other cardiac comorbidities	35 (39)	15 (50)	11 (37)	9 (30)	.319
COPD	22 (24)	8 (27)	9 (30)	5 (17)	.554
Other pulmonary comorbidities	9 (10)	2 (7)	4 (13)	3 (10)	.905
eGFR <60 ml/min/1.73m ²	38 (42)	16 (53)	8 (27)	14 (47)	.096
CVA/TIA	23 (26)	8 (27)	7 (23)	8 (27)	1.000
Diabetes Mellitus type 2	11 (12)	6 (20)	3 (10)	2 (7)	.366
Risk factors, n (%)					
Currently smoking	26 (29)	6 (20)	12 (40)	8 (27)	.406
Hypercholesterolemia	29 (32)	9 (30)	10 (33)	10 (33)	1.000
Hypertension	65 (72)	22 (73)	21 (70)	22 (73)	1.000
Low tolerance of exercise (MET 1-4), n (%)					
	13 (14)	5 (17)	5 (17)	3 (10)	.919

Abbreviations: BMI = Body Mass Index, ASA = American Society of Anesthesiology, MI/ACS = myocardial infarction/acute coronary syndrome, AF = atrial fibrillation, COPD = chronic obstructive pulmonary disease, eGFR = estimated glomerular filtration rate, CVA/TIA = cerebral vascular accident/transient ischemic attack, MET = metabolic equivalent of task

*p-value of comparison between groups of experience

Complexity level 3: branched-EVAR, level 4: branched-fenestrated EVAR combinations, arch EVAR, and emergency cases.

Table 2: Outcome comparison between groups

Outcome	Group 1 (n=30)	Group 2 (n=30)	Group 3 (n=30)	p-value*
Continuous, median (Q1-Q3)				
Operating time (minutes)	360 (222-458)	304 (219-385)	245 (191-333)	.010
Blood loss (ml)	1000 (563-1950)	1200 (600-2000)	1000 (675-1625)	.345
Length of stay (days)	9 (5-20)	6 (3-11)	6 (5-9)	.008
Contrast use (ml)	150 (140-250)	150 (140-200)	200 (150-290)	.480
Fluoroscopy time (minutes)	69 (42-88)	86 (65-124)	82 (63-104)	†
Dichotomous, n (%)				p-value‡
30-day mortality	1 (3)	3 (10)	2 (7)	.435
Major Adverse Events	5 (17)	9 (30)	8 (27)	.554
Freedom from endoleak repair	15 (50)	10 (33)	23 (77)	.081
Freedom from reinterventions	20 (67)	22 (73)	16 (53)	.612
Initial technical success	28 (93)	27 (90)	25 (83)	.592
Discharge to a rehabilitation center	6 (20)	6 (20)	4 (13)	.964

*p-value of the regression analyses, †fluoroscopy time was not included in the regression analysis due to 22 missing values in group 1 (n=8), ‡p-value of the comparison between groups of experience. ml = milliliters

Appendix A available online via:

[https://www.annalsofvascularsurgery.com/article/S0890-5096\(23\)00057-2/fulltext](https://www.annalsofvascularsurgery.com/article/S0890-5096(23)00057-2/fulltext)

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Functional performance in patients with a complex endovascular aneurysm: results from a single-center retrospective cohort study

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Performance after Complex Endovascular Aortic Repair: A Single-Center Retrospective Cohort Study

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ABSTRACT

Background

Complex endovascular aortic repair (EVAR) procedures provide a treatment option for patients with aortic aneurysms involving visceral branches. Good technical results and short-term outcomes have been reported. Whether complex EVAR provides acceptable functional outcomes is not clear. The current study aims to describe postoperative functional outcomes in complex EVAR patients; an older and relatively frail patient group.

Methods

A single-center retrospective cohort study was performed, using data from a computerized database of consecutive patients who underwent complex EVAR in the Leiden University Medical Center (LUMC, The Netherlands) between July 2013 and September 2020. As of May 2017, patients scheduled for complex EVAR were referred to a geriatric care pathway to determine (Instrumental) Activities of Daily Living ((I) ADL) scores at baseline and, if informed consent was given, after 12 months. For the total patient group, adverse functional performance outcomes were: discharge to a nursing home and 12-month mortality. For the patients included in geriatric follow-up, the additional outcome was functional decline (defined by a ≥ 2 point increase in (I) ADL-score) at 12-months.

Results

Eighty-two patients underwent complex EVAR, of which 68 (82.9%) were male. Mean age was 73.3 years (SD=6.3). Within 30 days postsurgery, 6 patients (7.3%) died. Mortality within 12 months for the total patient group was 14.6% (n=12). After surgery, no patients had to be discharged to a nursing home. Fifteen patients (18.3%) were discharged to a rehabilitation center. Twenty-three patients gave informed consent and were included in geriatric follow-up. Five patients (21.7%) presented functional decline 12 months postsurgery and 4 patients had died (17.4%) by that time. This means that 39.1% of the patients in the care pathway suffered an adverse outcome.

Conclusion

To our knowledge, this is the only study that examined functional performance after complex EVAR, using a prospectively maintained database. No patients were newly discharged to a nursing home and functional performance results at 12 months were promising. Future multidisciplinary research could focus on determining which patients are most susceptible to functional decline, to facilitate preventative efforts and aid in patient selection.

INTRODUCTION

Endovascular aortic repair (EVAR) is well established in clinical practice for treating abdominal aortic aneurysms (AAA) located below the visceral arteries.^{1,2} Because of low immediate morbidity and mortality rates compared to open surgical repair (OSR), EVAR is often the procedure of choice.^{3,4} In recent years, endovascular techniques for aortic repair have developed extensively. Fenestrated EVAR (FEVAR) and branched EVAR (BEVAR) allow for endovascular treatment of complex aortic aneurysms, comprising segments of the entire aortoiliac tract, including the arch.⁵

These techniques have greatly expanded treatment options. Patients with complex aortic aneurysms who are considered too frail for OSR because of (cardiopulmonary) comorbidities, decreased physical performance, or other factors increasing the risk of adverse outcomes, can now also benefit from a less invasive endovascular approach. However, these complex EVAR procedures have a higher morbidity and mortality rate compared to conventional infrarenal EVAR. Thirty-day mortality rates ranging from 3.4% up to 8.6% have been reported in complex EVAR, compared with an average of 1.2% in conventional EVAR.⁶⁻⁹ In addition to morbidity and mortality, patients undergoing complex EVAR are at risk of decline in functional performance. Maintaining independent living and quality of life are highly valued outcomes, especially in older patients.¹⁰⁻¹² While high technical success rates are commonly reported, evidence on functional performance after complex EVAR is scarce.^{13,14}

Information on postoperative functional performance is important in order to properly inform patients about the consequences of treatment. We evaluated the functional outcomes of patients undergoing complex EVAR in a tertiary referral center. To our knowledge, this study is the only study that examined functional performance after complex EVAR, using a prospectively maintained database.

METHODS

Study design and setting

A single-center retrospective cohort study was performed, using data from a prospectively maintained secure computerized database of consecutive patients who underwent complex EVAR in the Leiden University Medical Center; a tertiary referral center (LUMC, The Netherlands). Patients were included since the introduction of complex EVAR in this hospital in July 2013, until September 2020. The database was approved by the LUMC Medical Ethics Committee (METC). Any information not provided by this database was subtracted from patients' medical records. As in the standard care pathway, all patients were seen at 6 weeks, 6 months, and 12 months postsurgery and yearly after that for outpatient-based follow-up. Additional appointments were made

if deemed necessary. Computed tomography angiography, duplex ultrasonography, and abdominal X-ray were used in follow-up. Given the retrospective character of the current study, the METC waived the necessity for informed consent.

As of May 2017, all patients scheduled for complex EVAR were referred to the LUMC geriatric department to undergo a comprehensive geriatric assessment. No selection based on patient demographics was made. Screening included (Instrumental) Activities of Daily Living Scores ((I)ADL), the 6-item Cognitive Impairment Test (6-CIT), and a Mini Nutritional Assessment (MNA). If the patient gave informed consent for follow-up, they were included in the Triage of Elderly Needing Treatment (TENT) study (ID number: NL53575.058.15).¹⁵ For these patients, geriatric scores were gathered again at 12 months postsurgery, by phone. In the current study, (I)ADL-scores were used to examine functional performance.

Patients and Procedures

Complex EVAR was defined as endovascular aortic surgery that entailed correction of an aneurysm including the visceral segment, with or without thoracic involvement. Baseline characteristics were described by demographics, living status, aneurysm characteristics, comorbidities, risk factors, and exercise tolerance by the estimated metabolic equivalent of task (MET) score.¹⁶ (I)ADL-scores were measured by the Katz Index of Independence in Activities of Daily Living (Katz ADL) and the Lawton Instrumental Activities of Daily Living Scale (Lawton IADL).^{17,18} The Katz ADL measures the (in)dependency of patients with regard to 6 daily life activities: bathing, getting dressed, toileting, transfers, continence, and feeding. For each activity, patients can score 0 (fully independent) to 2 (dependent). Patients are categorized on a hierarchic 0 to 12 scale, with 0 being independent and 12 being fully dependent in all 6 activities. The Lawton IADL measures the (in)dependency of patients with regard to 8 more complex activities: using the phone, shopping, preparing food, housekeeping, doing laundry, mode of transportation, responsibility for personal medication, and handling finances. Patients are categorized on a 0 to 24 scale, scoring 0 (fully independent) to 3 (not capable/has never performed) per category. The 6-CIT and MNA were used to examine cognitive impairment (score > 7) and malnutrition risk (score < 11), respectively.¹⁹⁻²¹ Both the Katz ADL and Lawton IADL are of sufficient validity when conducted by phone.^{22,23}

Outcomes

Adverse outcome measures for the total patient group were postoperative discharge to a nursing home and mortality at 12 months post-surgery. Clinical outcomes were: 30-day mortality, length of hospital stay, and major surgical complications defined as complications with a Clavien-Dindo score of III-IV.²⁴ For the 23 complex EVAR patients included in the TENT-study, the additional adverse outcome was functional decline at 12 months postsurgery. This was defined as an increase of at least 2 points on the Katz ADL and/or Lawton IADL scale. This entails the patient becoming (more) dependent in at least one category and is in line with definitions of functional decline used in other fields.²⁵⁻²⁷

Statistics

Baseline characteristics were expressed by number of patients and percentages, or as mean with the standard deviation (SD) in case of normal distribution. In case of skewed distribution, characteristics were presented as median with the interquartile range (Q1, Q3). Patients who gave informed consent for geriatric follow-up were compared with patients who did not consent, based on baseline characteristics. The independent t test was used for continuous normally distributed data, chi-square test for categorical data, and the Mann-Whitney U test for skewed data. All analyses were made using IBM SPSS Statistics version 26.

RESULTS

Patient characteristics

A total of 82 consecutive patients who underwent complex EVAR were included. Figure 1 shows a flowchart of patient inclusion. Table 1 shows the baseline characteristics of these patients; 68 (82.9%) were male, with a mean age of 73.3 years (SD=6.3). Mean aneurysm size was 65.1 mm (SD=11.1) and 17 patients (20.7%) had undergone previous aortic repair surgery (open or endovascular). Most patients (n=77, 93.9%) were hospitalized from home. Three patients (3.7%) were living in a nursing home, 1 patient (1.2%) lived in a homeless shelter and 1 patient (1.2%) had an unknown living situation at admission. The median ADL baseline score was 0.0 (IQR=0.0, 0.0) and the median IADL score was 1.0 (IQR=0.0, 3.75). Aneurysms were treated using FEVAR (59.8%), BEVAR (25.6%), FBEVAR (11.0%, using a graft with fenestrations and branches), and Arch-FEVAR (3.7%).

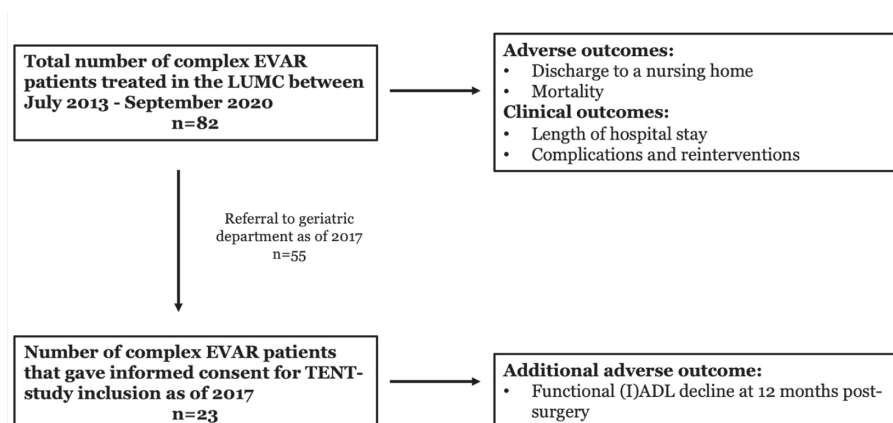


Figure 1: Patient inclusion and study outcomes. EVAR, endovascular aortic repair; (I)ADL, (Instrumental) Activities of Daily Living; LUMC, Leiden University Medical Center; TENT, Triage of Elderly Needing Treatment

Care dependency at discharge

Figure 2 shows the living status at admission and the destination of discharge after hospital stay. At discharge, 60 patients (73.2%) were able to return to their pre-admission living status, either with or without (additional) home care. Fifteen patients (18.3%) admitted from home, were discharged to a rehabilitation center, which was intended to be temporary. One patient (1.2%) previously living in a nursing home was discharged to a rehabilitation center. It is unknown whether this patient was more care dependent at discharge. No complex EVAR patients were newly admitted to a nursing home post-surgery.



Figure 2: Destinations of discharge with number of patients (%).

Functional performance

Twenty-three out of the 55 complex EVAR patients referred for geriatric assessment gave informed consent for follow-up and were included in the TENT-study for a functional performance analysis (Figure 1). There was no significant difference between the baseline geriatric scores of patients who did give informed consent for follow-up and patients who did not give consent. However, patients who did give informed consent were significantly older compared to patients who did not consent to follow-up (75.6 vs 71.8, $p=0.027$). Baseline geriatric scores of the 23 patients included in follow-up are depicted in Table 2. The median preoperative ADL score of these 23 patients was 0.0 (IQR=0.0, 1.0). The median preoperative IADL-score was 1.0 (IQR=0.0, 4.0). The MNA showed that 3 patients (13.0%) were at risk for malnutrition. Cognitive impairment, measured by the 6-CIT, was present in 1 out of 23 patients (4.3%). Functional outcomes are depicted in Figure 3. At 12 months, 5 patients presented with functional decline (21.7%), 3 patients with IADL decline only, and 2 patients with IADL as well as ADL decline. ADL decline was mainly caused by the need for assistance in bathing and getting dressed ($n=2$). IADL decline was mostly caused by needing assistance in shopping ($n=3$). Mortality at 12 months was 17.4% ($n=4$).

Medical records of the 5 patients who presented (I)ADL decline were searched for postoperative adverse events that could have caused their functional decline. In one patient, a pre-existent cognitive disorder worsened during follow-up. No potential other function-limiting complications were registered for this patient. In 2 patients, major complications following complex EVAR were reported: spinal ischaemia ($n=1$) and arterial occlusion of the lower limb ($n=1$). For two patients, no adverse events were registered during follow-up, while no function-limiting complications of complex EVAR were registered to have occurred.

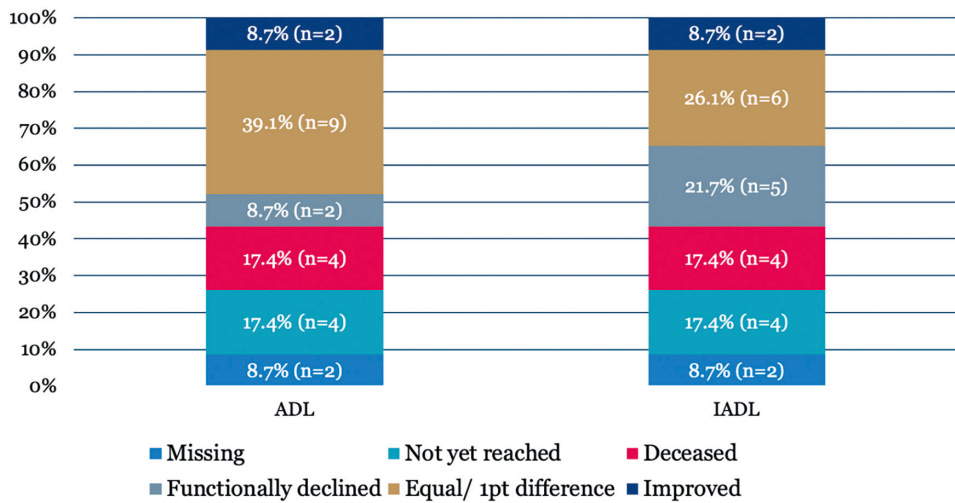


Figure 3: Incidence of functional decline (n(%)) in the 23 patients included in the TENT study at 12 months post-surgery. Functional decline was defined as an increase of at least 2 points in the Katz Activities of Daily Living scale or the Lawton Instrumental Activities of Daily Living Scale. (I)ADL, (Instrumental) Activities of Daily Living; TENT, Triage of Elderly Needing Treatment

Perioperative outcomes and complications

Perioperative outcomes are depicted in Table 3. Twenty-four complications with a Clavien-Dindo score of III-IV were registered, which meant that surgical, laparoscopic, or radiological intervention was necessary or a life-threatening complication took place during hospital stay. These 24 complications occurred in 19 patients (23.2%), including 2 out of the 5 patients who presented functional decline. Median length of hospital stay was 7.0 days (IQR=4.5, 12.5). Median length of follow-up was 21.5 months (IQR=4.1, 42.9). Complications that occurred during follow-up are presented in Table 4. Complications were detected in 33 patients (40.2%); the most common complication was aneurysm sac enlargement (n=19, 23.2%). In 11 patients (13.4%), 17 surgical reinterventions were necessary for complications during follow-up, including 1 out of the 5 patients that suffered functional decline. In addition, 12 patients (14.6%) needed endoleak repair.

Mortality

Mortality numbers are depicted in Table 4. Within 30 days post-surgery, 6 patients (7.3%) died. These patients were treated by FEVAR (n=3), arch-FEVAR (n=2), and BEVAR (n=1). Five deaths were procedure related and occurred in the hospital: intraoperative type A dissection (n=1), pneumonia (n=1), respiratory failure (n=2), and renal failure (n=1). Mortality within 12 months was 14.6% (12 patients). Total mortality during follow-up was 22.0% (18 patients), of which 7 deaths (38.9%) were surgery or aneurysm related.

DISCUSSION

No patients were discharged to a nursing home and mortality rates were 7.3% and 14.6% at 30 days and 12 months, respectively, for the total patient group. Major adverse events occurred in 23.2% of patients. Patients included in the TENT-study suffered functional decline at 12 months postsurgery in 21.7% (n=5) and 12-month mortality was 17.4%.

The value of these results is difficult to interpret because of the lack of data on functional performance after complex EVAR. We can however compare these results with functional performance after conventional EVAR and OSR. *Rectenwald et al*²⁸ showed that 79.5% of patients who underwent OSR for a thoracoabdominal aneurysm was discharged to their home or a rehabilitation facility (91.5% in our study), whereas 20.5% (0% in our study) was newly discharged to a nursing home. *Arko et al*²⁹ reported that 21% of EVAR patients and 25% of OSR patients were not able to shop/travel at the same level prior to surgery at 6-month follow-up. In addition, 4% of OSR patients lost the ability to independently bathe/eat as they were used to.²⁹ These results approximate the 21.7% of patients with functional decline at 12 months in our patient cohort. *Williamson et al*³⁰ studied patients who underwent OSR for an infrarenal aneurysm, and reported a decrease in 33% of patients in their functional abilities, including transportation and shopping at a mean follow-up of 34 months. *Blomaard et al*³¹ showed that 46.2% of patients acutely hospitalized for internal medicine were either deceased or showed functional decline 12 months later. For patients considered frail, this percentage was 67.0%.

By including all 82 consecutive patients that underwent complex EVAR, it was attempted to present an unselected “real-world” patient group, commensurate with patients seen in a daily clinical practice. The 30-day mortality rate found in the current study (7.3%) is higher compared with the mortality rate found by *Van Calster et al*³² (4.9%) and lower compared with the 30-day mortality rates mentioned by *Oderich et al*⁶ (8.2%) and *Tran et al*⁷ (8.6%). The difference with *Van Calster et al*³² could be explained by different procedures being included. A relatively low percentage of patients was treated for extensive aneurysms using BEVAR (9.2% vs. 25.6% in our study) and no patients were treated using Arch-FEVAR (3.7% in the current study). The use of differing definitions of “complex” EVAR should be kept in mind when interpreting results in the available literature.

This study has several limitations. The number of patients that could be included in the (I) ADL analysis (n=23) was small. However, to our knowledge, this study is the only study that examined functional performance after complex EVAR, using a prospectively maintained database.³³ Another limitation is formed by potential confounders for functional decline during follow-up, such as adverse events not related to the complex EVAR procedure and aging. Although a fixed (I)ADL decline per year of aging is not established in the available literature, we cannot ignore that with increasing age, functional performance declines.^{34,35} By confining follow-up to 12 months, we attempted to limit the influence of aging as a

confounding factor. Possible confounding adverse events were reported descriptively for the functionally declined patients. Surprisingly, some patients improved in function (Figure 3). Given the fact that patients electively treated for aortic aneurysms are usually asymptomatic prior to surgery, this is remarkable. One explanation could be that follow-up (I)ADL scores were self-reported, which could lead to an overestimation bias.^{36,37} It could also be that with treatment of the aneurysm other function-limiting conditions, such as claudication caused by iliac stenosis, improved. In addition, medication use, nutrition, or postoperative home care might have been optimized during hospital stay. This was not further examined in the current study. When comparing functional performance after conventional EVAR, OSR, and hospitalized older patients in other fields, complex EVAR results are promising. Even more so considering the general frailty of complex EVAR patients, which makes this group often not suitable for OSR. However, for some patients, the prospect of losing independence or not being able to return home after surgery is unacceptable and can be reason to renounce treatment.¹⁰⁻¹² Therefore, multidisciplinary efforts should be directed toward preventing postoperative functional decline and care dependency.

CONCLUSION

The results found in this study give insight in functional performance after complex EVAR. No patients were newly discharged to a nursing home and functional performance results at 12 months were promising. To our knowledge, this is the only study examining functional performance after complex EVAR, by providing data from a prospectively maintained database. Future multidisciplinary research should focus on determining which patients are most susceptible to functional decline, to facilitate preventative efforts and aid in patient selection.

INTERIM SUMMARY

This chapter presented postoperative outcomes of complex EVAR in the Leiden University Medical Center, examining 82 patients. The 30-day and 1 year mortality rate was 7.3% and 14.6% respectively. Most patients were able to return home; 18.3% of patients were discharged to a rehabilitation center, intended as a temporary stay. No patients were newly discharged to a nursing home. A subgroup was included in functional performance analysis, which showed that 5 out of 23 patients presented with functional decline at 12 months follow-up. Compared with functional outcomes in other fields, complex EVAR results seem to be promising. It would be interesting to be able to predict which patients are most prone to adverse outcomes, in order to adequately inform patients preoperatively and to support decision-making. In Part 2, sarcopenia will be examined as a potential preoperative marker for adverse events after complex EVAR.

TABLES

Table 1: Baseline characteristics

Variable (unit)	Total patient group (n=82)
Age (years), mean (SD)	73.3 (6.3)
Male, n (%)	68 (82.9)
BMI (kg/m ²), mean (SD)	26.7 (3.6)
Aneurysm size (mm), mean (SD)	65.1 (11.1)
Procedure type, n (%)	
FEVAR	49 (59.8)
BEVAR	21 (25.6)
FBEVAR	9 (11.0)
Arch-FEVAR	3 (3.7)
ASA-score ≥ 3 , n (%)	48 (58.5)
Comorbidities, n (%)	
Cardiac	53 (64.6)
Pulmonary	27 (32.9)
eGFR <60 ml/min/1.73m ² , n (%)	33 (40.2)
CVA/TIA	20 (24.4)
Peripheral vascular disease	16 (19.5)
Diabetes Mellitus type 2	11 (13.4)
Malignancy	
Active	3 (3.7)
Cured	20 (24.4)
Other comorbidities	26 (31.7)
Risk factors, n (%)	
Currently smoking	25 (30.5)
Hypercholesterolemia	26 (31.7)
Hypertension	59 (72.0)
Previous aortic repair, n (%)	17 (20.7)
Low tolerance of exercise (MET 1-4), n (%)	12 (14.6)
Living status, n (%)	
Home	77 (93.9)
Nursing home	3 (3.7)
Other/unknown	2 (2.4)
Baseline (I)ADL-scores	n=40
ADL, median (IQR)	0.0 (0.0, 0.0)
IADL, median (IQR)	1.0 (0.0, 3.75)

AAA: Abdominal Aortic Aneurysm, ACS: Acute Coronary Syndrome, ASA: American Society of Anesthesiologists Classification, COPD: Chronic Obstructive Pulmonary Disease, CVA: Cerebrovascular Accident, eGFR: estimated Glomerular Filtration Rate in ml/min/1,73 m², IQR: Interquartile Range (Q1, Q3), MET: Metabolic Equivalent of Task, MI: Myocardial Infarction, TIA: Transient Ischemic Attack

Table 2: Geriatric scores and functional performance of patients included in the TENT-study (n=23)

Geriatric domain	Scores
ADL, median (IQR)	0.0 (0.0, 1.0)
IADL, median (IQR)	1.0 (0.0, 4.0)
Cognitive impaired (6CIT>7), n (%)	1 (4.3)
At risk for malnutrition (MNA<11), n (%)	3 (13.0)
Patients with functional decline at 12 months	Number of patients (%)
Total	5 (21.7)
IADL decline only	3 (13.0)
IADL and ADL decline	2 (8.7)
Deceased	4 (17.4)

ADL: Activities of Daily Living, IADL: Instrumental Activities of Daily Living, IQR: Interquartile Range (Q1, Q3), MNA: Mini Nutritional Assessment, 6CIT: Six item Cognitive Impairment Test

Table 3: Perioperative outcomes and surgical complications

Variable (unit)	
Surgical complications Clavien-Dindo III-IV	24
Number of patients, n (%)	19 (23.2)
Length of hospital stay in days, median (IQR)	7.0 (4.5, 12.5)
Preadmission living status and destination of discharge, n (%)	
Home to home	58 (70.7)
Home to rehabilitation center	15 (18.3)
Nursing home to nursing home	2 (2.4)
Other/Unknown	2 (2.4)
Deceased in hospital	5 (6.1)
Newly admitted to a nursing home	0 (0.0)

IQR: Interquartile Range (Q1, Q3)

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PART 2

Preoperative cons and patient selecti

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on

A 15-year single-centre treating complex aortic aneurysms transitioning from complex endovascular to open surgery

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Center experience treating complex aortic aneurysms; transitioning from open to endovascular repair

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ABSTRACT

Introduction

This is a descriptive study analyzing all surgically treated complex aneurysm patients in a tertiary referral center, during a 15-year time period in which complex endovascular aortic repair (complex EVAR) was introduced alongside open surgical repair (OSR). The goal was to present the real-world clinical profiles and surgical outcomes of complex (thoraco-)abdominal aneurysm patients, based on the current decision-making process.

Methods

Patients undergoing OSR and complex EVAR between January 2008 and August 2023 were retrospectively included. The reasoning behind each treatment decision was analyzed. Both groups were described in terms of baseline characteristics and outcomes. A subanalysis was made for the frailest complex EVAR patients, considered unfit for OSR.

Results

As of 2008, 112 patients underwent OSR, whereas 119 patients underwent complex EVAR since 2013. When both modalities were considered opportune, the patient's preference toward complex EVAR was often decisive in shared decision-making. Based on the current selection process, 47 patients were considered too frail for OSR. Complex EVAR patients had a higher Charlson Comorbidity Index (3.0 [IQR: 2.0, 4.0] vs 4.0 [3.0, 5.0], $p=0.002$). More complications occurred after OSR (31.3% vs 18.5%, $p=0.027$), while reinterventions were more common after complex EVAR (20.2% vs 8.0%, $p=0.008$). The 47 frailest complex EVAR patients had a lower median survival time and high 1-year mortality of 23.8%.

Conclusion

Although less invasive compared to OSR regarding complications, complex EVAR still comes with considerable risks. For some frailest patients, complex EVAR might be a bridge too far. Specific insights in patient selection are warranted.

INTRODUCTION

Aortic aneurysms that comprise segments of the aorta including visceral side branches are classified as complex. Such aneurysms can be treated by open surgical repair (OSR) or by endovascular aortic repair (complex EVAR), using fenestrated (FEVAR) or branched (BEVAR) stents. Evidence suggests that complex EVAR provides favorable perioperative outcomes compared to OSR. These advantages are counterbalanced by a higher number of reinterventions and the need for lifelong surveillance. Moreover, it appears that the short-term survival benefit is not maintained during longer-term follow-up.¹⁻⁴ Guidelines have therefore been somewhat cautious in their advice on the implementation of complex EVAR, primarily recommending it for patients considered frail or unfit for OSR.⁵⁻⁹

In practice, complex EVAR has become more and more conventional, extending beyond a treatment modality only for the frailest patients. Implementation of this technique is limited by the need for advanced materials, patient exposure, and related costs.^{10,11} In addition, the introduction of new techniques necessitates adequate patient selection and information provision. For future planning and policy making, it is essential to understand how the introduction of complex EVAR has shaped real-world treatment patterns and outcomes.

This descriptive study provides a detailed overview of how complex (thoraco-)abdominal aneurysm patients were selected and treated in a tertiary referral center for aortic pathology in the Netherlands, in a 15-year time period during which complex EVAR was introduced. The goal was to analyze the clinical profiles and surgical outcomes of complex aneurysm patients, based on the current decision-making process. A sub analysis was made of patients deemed unfit for OSR; the initial target group, intended to benefit the most from complex EVAR. We aspire to contribute real-world data to the ongoing research on complex EVAR, to better understand the changing landscape of complex aneurysm repair.

METHODS

Study design

The current study is a descriptive single-center retrospective cohort study, within a tertiary referral center for aortic pathology in the Netherlands; Leiden University Medical Center (LUMC). This study was not designed to evaluate treatment efficacy, but to provide a detailed overview of how complex (thoraco-)abdominal aneurysm patients were selected and treated in current practice. As is required by Dutch law, approval was issued by the LUMC Medical Ethics Committee (METC, registration number 2024-010). Due to the merely retrospective character of our study, the anonymized use of data,

and the fact that there was no interference in the standard care pathway, explicit patient consent was not obtained. All data were subtracted from patients' medical records and archived in an online secured computerized database (Castor).¹²

Decision-making

In this study, a complex aneurysm was defined as a (thoraco-)abdominal aneurysm that includes or is narrowly adjacent to segments of the aorta with visceral side branches, to which perfusion needs to be maintained when surgery is performed. Prior to the introduction of complex EVAR, open repair was the sole treatment option for complex aneurysms. Complex EVAR was introduced in the LUMC in July 2013, when an endovascular treatment team (ETT) was formed, consisting of vascular surgeons, cardiothoracic surgeons, interventional radiologists, anesthesiologists, dedicated operating room (OR) staff, and radiology technicians. The main stent graft manufacturer was COOK Medical, using the Zenith.

When a complex aneurysm is discovered, imaging follow-up is initiated until the treatment threshold of 6 cm is reached, and a treatment decision has to be made. Patients are usually referred to an anesthesiologist, geriatric specialist, dietician, and physiotherapist, in order to examine the patient's physical and cognitive condition, all using their own indicators, such as cardiopulmonary fitness tests, American Society of Anesthesiologists score, hand grip strength, Mini Nutritional Assessment, and (Instrumental) Activities of Daily Living scores. Other specialists can be consulted if comorbidities require so, for example, a pulmonologist when concerns arise regarding pulmonary function. Complex EVAR, OSR, and conservative non-surgical management are discussed within the multidisciplinary treatment team. The ETT forms an advice in a multidisciplinary meeting, taking into account preoperative screening, the aneurysm's anatomy, and the patient's preferences. This advice is discussed with the patient and, preferably, its relatives. Usually, there is a reflection period of at least 2 weeks before the final treatment decision has to be made.

After complex EVAR, patients are seen at 6 weeks, 6 months, and 12 months post-surgery and yearly after that for lifelong follow-up. Additional appointments are made if deemed necessary. Computed tomography angiography and Duplex ultrasonography are used for detection of complications such as stent migration, aneurysm sac enlargement, and endoleaks. After OSR, patients are seen at 6 weeks, 6 months, and after 1, 3, and 5 years. Duplex ultrasonography is usually applied within year 1 and after 3 to 5 years.

Patient inclusion

All patients electively treated for a complex aneurysm between January 2008 and August 2023 were included. January 2008 was chosen as the starting point of inclusion, because by that time rigorous registration had started within the currently still accessible electronic patient file software (ChipSoft HiX). Inclusion ended by August 2023, in order

to reach a minimum follow-up period of 6 months when retrospective data collection started in January 2024. This means we were able to include patients treated during 5 years before complex EVAR was introduced (2008–2012) and during approximately 10 years in which both treatment modalities were available (July 2013–August 2023). As of 2021, patients with a thoraco-abdominal aneurysm undergoing OSR were treated in collaboration with a surgical team of the Amsterdam University Medical Center (AUMC).

The endovascular cohort consisted of all patients that underwent fenestrated EVAR (FEVAR), branched EVAR (BEVAR), or a combination (F/B-EVAR). The open repair group included patients that underwent a Crawford procedure for thoraco-abdominal aneurysms and patients that underwent open reconstruction for suprarenal, pararenal, or juxtarenal aneurysms. Juxtarenal aneurysms were considered complex if they were unsuitable for regular EVAR (within instructions for use) due to hostile neck anatomy, based on a combination of criteria: aortic length (<10 mm), excessive aortic neck angulation, aortic neck diameter (>30 mm), conical neck, and presence of circumferential calcification or thrombus. Reasons for exclusion were: (semi-)emergent repair of ruptured and symptomatic complex aortic aneurysms, explantation of an infected or otherwise failing EVAR-stent with conversion to open repair. In addition, patients who underwent both complex EVAR and open repair were excluded. Arch-EVAR patients were excluded, due to small patient numbers and to comply with inclusion criteria of previous research, as including these cases would impede meaningful comparison.

Outcomes of interest

The nature of this study was descriptive, aiming to analyze changes in the number of patients being treated, differences in patient characteristics between OSR and complex EVAR, and the reason for choosing either treatment modality. For these primary outcomes, the following baseline and surgical characteristics were gathered: age at the time of surgery, sex, body mass index (BMI), American Society of Anesthesiologists (ASA) score, comorbidities, type and size of the aneurysm, treatment modality, and the documented reasoning behind the treatment decision between open and endovascular repair as of July 2013. Baseline characteristics were used to determine the Charlson Comorbidity Index, in order to measure and compare the burden of comorbid disease, ranging from 0 to 37. The modified 5-Item Frailty Index (mFI-5) was calculated as an indicator of the patient's frailty, ranging from 0 to 5.^{13,14}

The secondary aim was to analyze the postoperative outcomes, resulting from the current selection process. Outcomes of interest were: (modified) technical success, Major Adverse Events (MAE), length of hospital stay, reinterventions, 30-day mortality, 1-year mortality, and all-cause mortality during follow-up. The definition of modified technical success was based on reporting standards for complex EVAR and adapted to apply to OSR as well; a procedure needing an alteration of the preoperative plan, but resulting in the successful employment of a stent or implantation of a graft.¹⁵ A subgroup

analysis was made regarding complex EVAR patients deemed unfit for OSR by the ETT, due to comorbidities, physical condition, and/or age. The goal was to examine the baseline characteristics and outcomes of these frailest patients, compared to patients eligible for both treatment modalities.

Statistics

Categorical patient characteristics were expressed by number of patients and percentages. Continuous variables were tested for normal distribution using histograms, assessing skewness. Normally distributed data were expressed as mean with the standard deviation (SD). Median with the interquartile range (Q1–Q3) was used in case of skewed distribution. The independent t-test (2 groups) or 1-way ANOVA test (3 groups) were used to compare continuous normally distributed data, Chi-square test for categorical data, and the Mann-Whitney U test (2 groups) and Kruskal-Wallis (3 groups) for skewed data. When less than 5 events occurred, the Fisher's exact test was used instead of chi-square. Post-hoc testing was performed using Dunn's test after Kruskal-Wallis analysis. All-cause mortality was tested by Kaplan-Meier with log-rank testing. Data were terminated when less than 10 patients were at risk in any of the groups and/or when the standard error reached below 10%. The study design was descriptive, aiming to present real-world data based on clinical practice and the current decision-making process. Therefore, propensity score methods to artificially balance the (sub)groups, were not applied, in order to prevent the loss of selection effects. P-values are presented to indicate observed trends in both treatment groups, in the context of their known baseline characteristics. They do not aim to indicate treatment efficacy or superiority. All analyses were made using IBM SPSS Statistics version 27.

RESULTS

Patient numbers

A total of 231 elective complex aneurysm patients were included (Figure 1). From 2008 until August 2023, 112 patients underwent open complex aneurysm repair, whereas 119 patients underwent complex EVAR between July 2013 and August 2023. Figure 2 depicts a distribution of the number of treated patients over the years, showing an increase in the total number of complex aortic aneurysms being treated and a rise in endovascular procedures. By 2016, complex EVAR exceeded open repair as the preferred treatment modality, except for the year 2017.

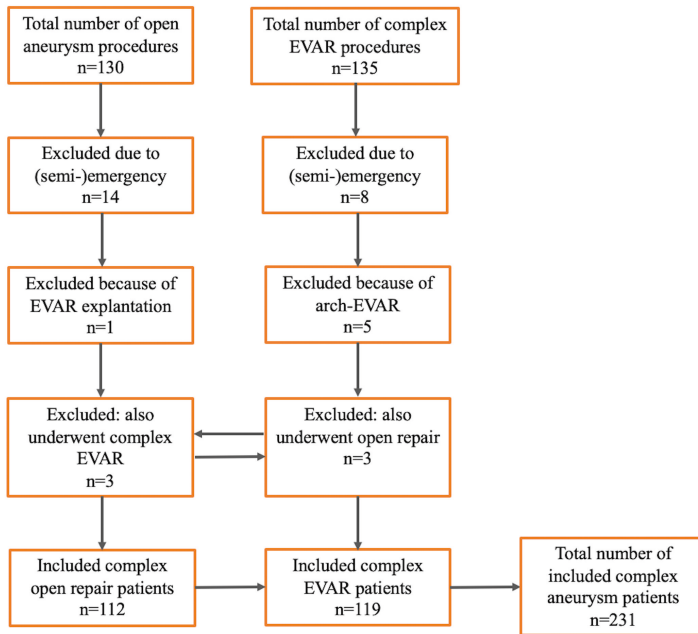


Figure 1: Inclusion flow-chart.

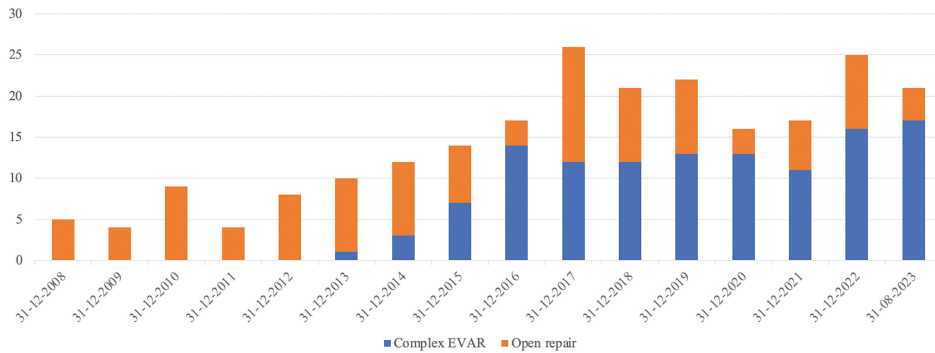


Figure 2: Number of complex aneurysm patients treated in the Leiden University Medical Center from 2008 until August 2023.

Reasoning behind treatment decisions

Table 1 outlines the considerations underlying the decision between OSR and complex EVAR. Figure 3 depicts a flow-chart. This analysis included patients treated as of 2013 (n=201), when both complex EVAR and OSR were practiced in the LUMC. It indicates the number of patients for whom each consideration was relevant. For some patients, multiple reasons were registered. The main reason for the treatment team to prefer open repair (n=82) in this era was based on the aneurysm’s configuration (n=27, 32.9%), for example, due to doubts regarding stent sealing or the need for extended aortic coverage. In addition, factors complicating femoral access (n=9) and the etiology of the aneurysm (connective tissue disease, infectious) could favor open repair (n=9). Young age (n=12, ranging from 43 to 77 years old) and good physical condition (n=5) were patient-specific characteristics leading to a preference for OSR. In 8 cases, the patient’s own preference toward OSR was one of the decisive reasons in shared decision-making.

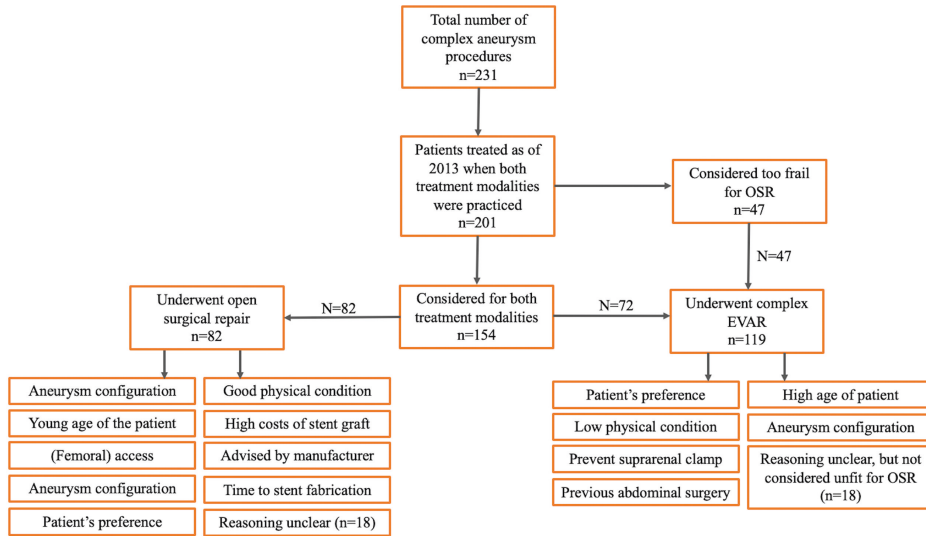


Figure 3: Flow-chart of decision-making when both open surgical repair (OSR) and complex endovascular aortic repair (complex EVAR) were practiced.

In the same era, 119 patients underwent complex EVAR. In 47 cases (39.5%), the ETT decided that the patient was too frail for OSR, based on physical condition, preoperative screening, and/or age. When both modalities were considered possible, the patient’s preference toward endovascular repair was often decisive in shared decision-making (n=49, 41.2%). Other considerations for choosing complex EVAR over OSR were: wanting to prevent the need for suprarenal clamping (n=4), adhesions after previous abdominal surgery (n=3), and the aneurysm’s configuration being regarded as less compatible with OSR (n=2). In 18 patients, the reason for choosing complex EVAR did not become clear from their medical record, although they did not seem to be considered unfit for OSR.

Patient characteristics

Table 2 includes the patient characteristics, comparing patients treated by OSR versus complex EVAR. Following the current patient selection process, patients selected for complex EVAR turn out to be more often male (69.6% vs 85.7%, $p=0.003$), older (67.9 [SD: 9.6] vs 74.1 [SD: 6.5] years, $p<0.001$), with a higher median Charlson Comorbidity Index (3.0 [IQR: 2.0, 4.0] vs 4.0 [IQR: 3.0, 5.0], $p=0.002$), and more often a Modified 5-Item Frailty scale of 2 or higher (16.1% vs 26.9%, $p=0.046$). This is indicative of a heavier burden of comorbid disease and more frail patients among the complex EVAR group.

A sub analysis (Table 2) was made comparing complex EVAR patients considered unfit for OSR ($n=47$), with patients that were considered fit for both modalities. Patients considered unfit for OSR had a higher Charlson Comorbidity Index compared to fit complex EVAR and OSR patients, while there was no statistically significance in this score between fit complex EVAR versus OSR patients (4.0 [IQR: 4.0, 5.0] vs 4.0 [IQR: 3.0, 4.0] and 3.0 [IQR: 2.0, 4.0] respectively). In addition, the frailest complex EVAR patients more often had an ASA score of 3 or higher and a mFI-5 of 2 or above, while these numbers were not statistically different between fit complex EVAR patients and patients that underwent OSR. In addition, the frailest complex EVAR patients were more often diagnosed with an eGFR below 60 mL/min and COPD.

Perioperative outcomes and reinterventions during follow-up

The modified technical success rate in the OSR group was 100%, with 11 cases (9.8%) needing a perioperative alteration from the preoperative procedure plan, such as a splenectomy for capsule tear or a bypass for encountered artery occlusion. In the complex EVAR group, the modified technical success rate was 96.6% ($p=0.125$), with 13 patients (10.9%) needing a perioperative alteration in order to reach technical success, such as an unplanned iliac extension due to type 1B endoleak or intentionally leaving a branch open due to stent rotation. Table 3 shows the Major Adverse Events (MAE). In total 35 (31.3%) patients experienced 58 MAE in the open repair group versus 22 (18.5%) patients with a total of 31 MAE in the complex EVAR group ($p=0.027$). In the open repair group, a significantly higher number of patients experienced respiratory failure (15.2% vs 4.2%, $p=0.006$), as well as renal function decline (16.1% vs 7.6%, $p=0.047$).

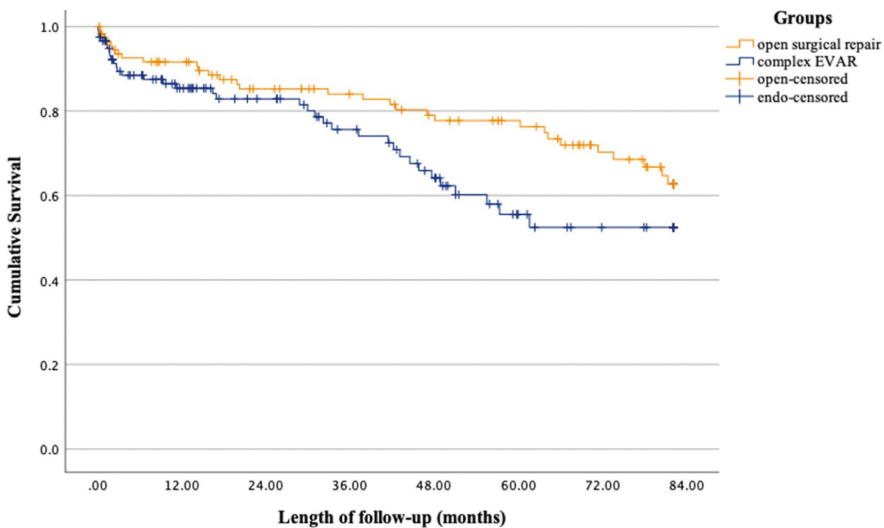
Thirty-day mortality was comparable: 2.7% ($n=3$) in the open repair group and 3.4% ($n=4$) in the complex EVAR group ($p=1.000$). The causes of these deaths are indicated in Appendix A. Median length of hospital stay in the OSR group was 11.0 (IQR: 8, 20) days versus 6.0 (IQR: 3, 11) days after complex EVAR ($p<0.001$).

During follow-up, 17 complex EVAR patients (14.3%) needed a reintervention for one or more endoleaks (8 type 1 endoleaks, 6 type 3 endoleaks, and 6 other endoleaks). In addition, there were 9 patients (7.6%) in this group that had to undergo a reintervention for other aneurysm-related complications. In total, 24 complex EVAR patients (20.2%) needed

any aneurysm or procedure-related reintervention during follow-up versus 8 patients (7.1%) in the OSR group ($p=0.004$). The types of reinterventions are included in Appendix B.

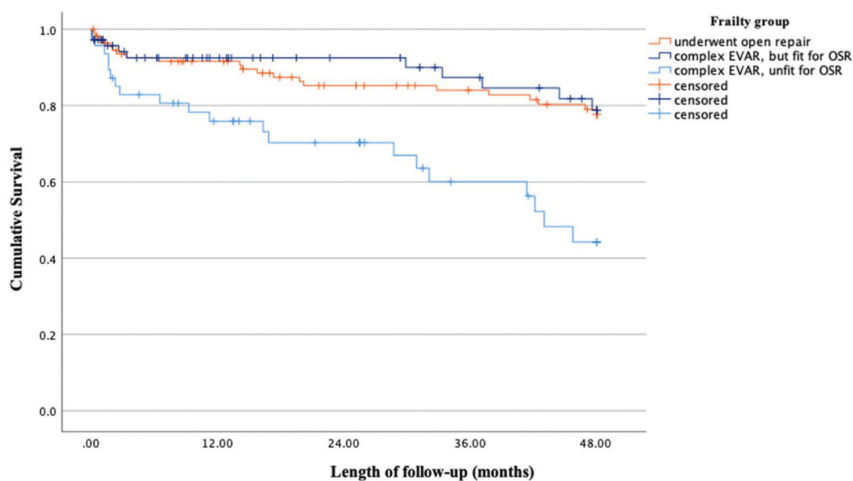
One-year and all-cause mortality

There was no statistically significant difference in 1-year mortality between all complex EVAR versus OSR patients (15.8% vs 8.9% respectively, $p=0.142$). However, there was a significant difference when analyzing the 1-year mortality between the frailest complex EVAR patients (23.8%), compared to fit complex EVAR patients (9.4%), and OSR (8.9%), $p=0.047$. The overall survival curve (Figure 4) showed a trend toward lower estimated mean survival time for complex EVAR patients (57.7 months, CI: 51.3–64.1), compared with patients treated by open repair (66.7 months, CI: 61.4–72.1), $p=0.048$. Data were censored after 82 months, when less than 10 patients remained at risk in the complex EVAR group. A sub analysis showed that the frailest complex EVAR patients had a significantly lower mean survival time (33.0 months, CI: 27.5–38.6), compared to fit complex EVAR patients (43.3 months, CI: 40.2–46.5) and patients that underwent OSR (41.8 months, CI: 39.0–44.5), with $p<0.001$ (Figure 5). The apparent lower survival in the OSR group, compared to the analysis above, is not due to worse survival, but is caused by the fact that data were truncated earlier in this analysis, at 48 months, when less than 10 frail complex EVAR patients remained at risk.



Survival Table / months	0	12	24	36	48	60	72	82
OSR (SE)	112	91 (2.7)	75 (3.5)	68 (3.7)	61 (4.2)	55 (4.4)	41 (5.1)	31 (5.8)
Complex EVAR (SE)	119	78 (3.4)	62 (3.7)	49 (4.6)	37 (5.6)	19 (6.3)	13 (6.7)	11 (6.7)

Figure 4: Kaplan Meier survival curve of patients treated by complex endovascular aortic repair (EVAR) and open surgical repair (OSR). Standard Error (SE) is provided in %. Data is censored beyond 82.2 months, when less than 10 patients remained in the complex EVAR group.



Survival Table	0 months	12 months	24 months	36 months	48 months
OSR (SE)	112	91 (2.7)	75 (3.5)	68 (3.7)	61 (4.2)
Fit complex EVAR (SE)	72	47 (3.2)	38 (3.2)	33 (4.0)	26 (6.3)
Frail complex EVAR (SE)	47	31 (6.4)	24 (7.0)	16 (8.1)	11 (9.1)

Figure 5: Kaplan Meier survival curve with a sub analysis of frail complex endovascular aortic repair (EVAR) patients. Standard Error (SE) is provided in %. Data is censored beyond 48.1 months, when less than 10 patients remained in the frail complex EVAR group.

DISCUSSION

An analysis of 15 years of complex aneurysm management in our tertiary referral center showed a steady increase in the number of complex aneurysm procedures being performed, with a temporary decrease during the Covid pandemic (2020–2021). Complex EVAR became the preferred treatment method soon after its introduction, which should be anticipated when deciding to introduce this technique. Over one third of complex EVAR patients was deemed too frail for open repair by the ETT. These patients would likely not have been treated in the pre-EVAR era. When both modalities were considered opportune, the patient’s preference toward complex EVAR was often decisive in shared decision-making.

Our decision-making process is currently based on the professional opinion and expertise of the multidisciplinary treatment team, including patient preferences in shared decision-making. Preoperative screening is often performed, using several indicators of a patient’s physical and cognitive condition. This practice-based approach resulted in the fact that complex EVAR patients were more likely to be frail, with a higher burden of comorbid disease. These differences were mainly caused by the frailest complex EVAR patients, considered unfit for OSR.

The reason for complex EVAR being the preferred treatment option for frail patients is the fact that studies have shown a lower perioperative risk of morbidity compared to OSR and a trend toward lower perioperative mortality.^{1,2,4} In addition, studies have shown that complex EVAR can safely be performed in carefully selected octogenarians.¹⁶ In our real-world cohort, there was indeed a lower number of MAE after complex EVAR, while 30-day mortality was comparable. The frailest complex EVAR patients, considered unfit for OSR, had a high 1-year mortality (23.8%) and an estimated median survival time of about 33 months.

A notable proportion of complex EVAR patients had to undergo reinterventions during follow-up. However, it is possible that due to the extensive surveillance after complex EVAR more minor complications are detected and treated, in addition to the fact that reinterventions after complex EVAR are usually less intensive compared to reinterventions after OSR. In addition, center-specific practices can be of importance when interpreting MAE results. In our hospital, for example, epidural anesthetics are usually applied and early extubation is pursued. In open repair, renal preservation techniques are usually not applied. However, the application of such techniques can vary over time. Given the relatively small patient cohort, meaningful trend analyses are currently not feasible.

Although it is not clear whether the survival differences are entirely attributable to frailty, as the difference in endovascular procedures type (BEVAR vs FEVAR) could for example also play a role, it is debatable whether all these frailest patients have ultimately benefit from undergoing surgery. Especially when considering prolonged recovery and possible decline in physical functioning. The current selection process seems effective in recognizing the frailest patients and assigning them to complex EVAR, as guidelines propose. However, it might not yet be able to select those who would benefit more from conservative non-surgical management.

Being able to predict which patients are most at risk for an unfavorable outcome after surgery, would contribute to patient information and selection.¹⁷ In our cohort, unfit patients who experienced more unfavorable outcomes, were more likely to have cardiovascular disease, COPD, and renal function insufficiency. Efforts are being taken to investigate such potential predicting factors, not just regarding comorbidities, but including a patient's physical and daily functioning, nutritional status, and quality of life as well. Some indicators might be modifiable, like malnutrition and low muscle mass and could be optimized by prehabilitation.^{18,19} In addition, survival time does not provide information on quality of life after surgery. Patients decide to get treated with expectations and hopes regarding their life after surgery, with a certain level of functional performance in mind that they wish to uphold.²⁰ Being able to provide more information on this aspect of postoperative outcomes, by performing more research into functional performance after complex aneurysm repair, would further aid in preoperative counseling.²¹

For some patients, complex EVAR is a bridge too far. Their life expectancy is limited more or equally by their level of comorbid disease, than by the risk of aneurysm rupture. This is supported in guidelines stating that elective aneurysm repair is not suitable for patients with a limited life expectancy of 2 to 3 years.⁶ Previous research has shown, however, that conservative management is often not regarded as a realistic treatment option by patients.²⁰ We hypothesize that this is due to the fear of aneurysm rupture; the feeling of “living with a time bomb”. In this perspective, patients might overestimate the chance of aneurysm rupture, while underestimating their frailty and surgical risks. Treating the patient’s fear should not be the main reason for complex aneurysm surgery. The reality of this fear, compared to the risks of surgery, should be addressed during preoperative counseling. Professional psychological counseling could be offered, addressing the concerns that might arise when a conservative treatment decision is made.

Limitations

Inclusion was limited to the number of patients treated in the center of interest, which resulted in a relatively small patients cohort compared to multicenter studies or studies within high-volume centers. This impeded meaningful subgroup analyses regarding the different surgical subtypes, which were therefore not performed. The external validity of the results is confined by restricted generalizability. However, this approach fitted our goal of reporting on the patient population and outcomes within this specific center.

This study was constructed retrospectively. Analyses were therefore limited by the data available in patients’ medical records. Gathering data prospectively might lead to more data being available and more thorough research, especially regarding the analysis into the reasoning behind the treatment decisions. In 18 of the complex EVAR (15%) and 18 of the OSR patients (22%), the reason for choosing their treatment modality did not become clear. However, for these complex EVAR patients, OSR was considered as well, leading to the conclusion that they were not considered frail. In addition, complex aneurysm patients that ended up not being treated were not systematically registered and could therefore not be included in our study. Including these patients could shine a broader light on the decision-making process, baseline characteristics, and outcomes of all complex aneurysm patients presented in our hospital.

The study design was descriptive, aiming to present real-world data based on clinical practice and the current decision-making process. Propensity score methods to artificially balance (sub)groups were not applied.^{22,23} Confounders are therefore inherently present. However, this reflects the complexity of clinical decision-making in a real-world setting. Instead of eliminating these factors, we chose to present the variation that occurred based on our routine clinical practice. The indicators of frailty (modified 5-Item Frailty Index and Charlson Comorbidity Score) have not yet been verified as indicators of frailty for complex aneurysm patients specifically, but have been for a number of other patient cohorts.^{24,25}

CONCLUSIONS

An analysis of 15 years of complex aneurysm management showed that complex EVAR became the preferred treatment method soon after its introduction. The current selection process seems effective in recognizing the frailest patients and assigning them to complex EVAR, as guidelines propose. Although less invasive compared to OSR when focusing on major complications, complex EVAR still comes with considerable perioperative risks, mortality, and reintervention rates. For some frailest patients, complex EVAR might be a bridge too far. Specific insights in patient selection are warranted, identifying potential indicators of unfavorable outcomes or targets for preoperative optimization. In addition, we propose to include postoperative functioning into analyses regarding surgical outcomes.

INTERIM SUMMARY

This chapter gave insight into the treatment decision-making process and showed that for some frailest patients, complex EVAR might be a bridge too far. It stated that research into patient selection is warranted. The next chapter will investigate whether sarcopenia could be an indicator of frailty and a predictive factor for adverse outcomes.

TABLES

Table 1: Main reasoning behind the treatment decision between open repair (n=82) and complex EVAR (n=119) in the era that both procedures were being performed in [anonymized, institution name] (2013-2023). For some patients, multiple considerations were decisive.

Reasoning behind treatment decisions	Number of patients for whom this reason was decisive	Examples
When choosing open repair (n=82)		
Aneurysm configuration less compatible with endovascular repair	27	Difficult proximal or distal seal, steep arcus, shaggy aorta, excessive thrombus, large size, fear of kidney function loss
Young age of the patient	12	These patients were 43-77 years old.
Etiology less compatible with endovascular repair	9	Mycotic aneurysm, connective tissue disease, infection.
Access less compatible with endovascular repair	9	Tortuous access arteries, extensive atherosclerosis
Patient's preference	8	Open repair seen as a more long-term solution, fear of endovascular related reintervention
ETT preferring not to wait for stent graft fabrication	6	Due to dissection, fast growth
Good physical condition of the patient	5	Small burden of comorbid disease, high exercise tolerance, active lifestyle, still working
Advised against complex EVAR by stent graft manufacturer	2	
High costs of stent graft	1	
Reasoning unknown/unclear	18	
When choosing complex EVAR (n=119)		
Patient's preference	49	Hoping for shorter recovery after complex EVAR.
Low physical condition of the patient	47	Low pulmonary function, decreased cardiac function, recent malignancy treatment, recent surgery.
Wanting to prevent suprarenal clamping	4	
Previous abdominal procedures	3	Expected scar tissue
High age of the patient	3	These patients were 78 and 88 years old.
Aneurysm configuration less compatible with OSR	3	
Reasoning unknown/unclear	18	

Abbreviations: complex EVAR: complex endovascular aortic repair; ETT: endovascular treatment team; OSR: open surgical repair

Table 2: Baseline characteristics of complex aneurysm patients, treated by complex EVAR vs. open surgical repair.

Variable	Patients treated by open repair (n = 112)	Patients treated by complex EVAR (n = 119)	P-value	Fit complex EVAR patients (n = 72)	Complex EVAR patients unfit for OSR (n = 47)	P-value*
Age (years)	69 (62-75)	75 (70-79)	<0.001	74 (70-78)	75 (71-79)	<0.001
Male	78 (69.6)	102 (85.7)	0.003	64 (88.9)	38 (80.9)	0.008
BMI	25.0 (23.5-27.7)	25.7 (23.9-28.6)	0.081	25.8 (24.3-28.7)	25.3 (23.2-28.1)	0.194
ASA ≥ 3	61 (54.5)	75 (63.0)	0.186	37 (51.4)	38 (80.9)	0.003
MI/ACS	39 (34.8)	37 (31.1)	0.547	22 (30.6)	15 (31.9)	0.824
AF	12 (10.7)	18 (15.1)	0.319	7 (9.7)	11 (23.4)	0.058
Other cardiovascular disease	18 (16.1)	37 (31.1)	0.007	17 (23.6)	20 (42.6)	0.002
COPD	19 (17.0)	27 (22.7)	0.276	11 (15.3)	16 (34.0)	0.024
eGFR below 60	25 (22.3)	49 (41.2)	0.005	21 (29.2)	28 (59.6)	<0.001
Diabetes	12 (10.7)	14 (11.8)	0.801	6 (8.3)	8 (17.0)	0.331
Peripheral vascular disease	9 (8.0)	25 (21.0)	0.005	15 (20.8)	10 (21.3)	0.021
Cerebrovascular disease	14 (12.5)	22 (18.5)	0.210	12 (16.7)	10 (21.3)	0.362
Malignancy						
Active	6 (5.4)	7 (5.9)	0.214	3 (4.2)	4 (8.5)	0.316
Past	18 (16.1)	30 (25.2)		20 (27.8)	10 (21.3)	
Hypertension	71 (63.4)	94 (79.0)	0.009	55 (76.4)	39 (83.0)	0.024
Hypercholesterolemia	26 (23.2)	42 (35.3)	0.044	27 (37.5)	15 (31.9)	0.106
Charlson Comorbidity Index	3.0 (2.0-4.0)	4.0 (3.0-5.0)	0.002	4.0 (3.0-4.0)	4.0 (4.0-5.0)	<0.001
Modified 5-Item Frailty Index ≥ 2	18 (16.1)	32 (26.9)	0.046	13 (18.1)	19 (40.4)	0.002
Aneurysm size	61.0 (56.0-68.0)	63.8 (59.0-69.0)	0.066	60.0 (57.0-68.0)	67.0 (61.0-70.0)	0.005

Table 2: Baseline characteristics of complex aneurysm patients, treated by complex EVAR vs. open surgical repair. (continued)

Variable	Patients treated by open repair (n = 112)	Patients treated by complex EVAR (n = 119)	P-value	Fit complex EVAR patients (n = 72)	Complex EVAR patients unfit for OSR (n = 47)	P-value*
Aneurysm type						
Crawford 1	9 (8.0)	10 (8.4)		3 (4.2)	7 (14.9)	
Crawford 2	16 (14.3)	9 (7.6)		5 (6.9)	4 (8.5)	
Crawford 3	4 (3.6)	6 (5.0)	0.343	1 (1.4)	5 (10.6)	0.071
Crawford 4	4 (3.6)	6 (5.0)		4 (5.6)	2 (4.3)	
Crawford 5	2 (1.8)	2 (1.7)		1 (1.4)	1 (2.1)	
Juxtarenal	77 (68.8)	82 (68.9)		55 (76.4)	27 (57.4)	
Suprarenal	-	4 (3.4)		3 (4.2)	1 (2.1)	
Procedure type						
Juxtarenal open	77 (68.8)	-		-	-	
Suprarenal open	13 (11.6)	-		-	-	
Crawford open	22 (19.6)	-	<0.001	-	-	<0.001
FEVAR	-	81 (68.1)		55 (76.4)	26 (55.3)	
F/B-EVAR	-	13 (10.9)		6 (8.3)	7 (14.9)	
BEVAR	-	25 (21.0)		11 (15.3)	14 (29.8)	

Abbreviations: AF: atrial fibrillations; ASA: American Society of Anesthesiologists; BEVAR: branched endovascular aortic repair; BMI: Body Mass Index; COPD: chronic obstructive pulmonary disease; eGFR: estimated Glomerular Filtration Rate; FEVAR: fenestrated endovascular aortic repair; MI/ACS: myocardial infarction/acute coronary syndrome

Categorical data is presented as number (%). Numerical data is presented as median (interquartile range). *P-value of a comparison between complex EVAR patients considered unfit for open repair vs. patients that underwent OSR, and patients that underwent complex EVAR, but were considered fit for OSR.

Dunn's post-hoc test after Kruskal Wallis test showed:

- Age: Significant difference between fit and unfit complex EVAR patients vs. OSR.
- Charlson Comorbidity Index: Significant difference between unfit complex EVAR patients vs. OSR and fit complex EVAR patients.
- Aneurysm size: Significant difference between unfit complex EVAR patients vs. OSR and fit complex EVAR patients.

Table 3: The number of Major Adverse Events (MAE) compared between patients treated by open surgical repair and complex endovascular aortic repair (complex EVAR).

Major Adverse Events	Patients treated by open repair	Patients treated by complex EVAR	P-value
30-day mortality	3 (2.7)	4 (3.4)	1.000
Myocardial infarction	5 (4.5)	3 (2.5)	0.490
Respiratory failure requiring prolonged ventilation or reintubation	17 (15.2)	5 (4.2)	0.004
Renal function decline of $\geq 50\%$ or new-onset dialysis	18 (16.1)	9 (7.6)	0.047
Bowel ischemia requiring surgical intervention or not resolving with medical therapy	5 (4.5)	3 (2.5)	0.490
Major stroke	5 (4.5)	1 (0.8)	0.112
Paraplegia grade 3 or higher	3 (2.7)	4 (3.4)	1.000
Total number of patients with any MAE	35 (31.3)	22 (18.5)	0.027

Appendix A: The number and causes of deaths among patients treated by open surgical repair and complex endovascular aortic repair (complex EVAR), with in-hospital deaths depicted separately.

	Open surgical repair	Complex EVAR
Deceased within 30-days and in-hospital deaths beyond 30-days	Total: 5 Of which procedure related: 5 - Pneumosepsis - Respiratory failure due to pneumonia - Multi-organ failure due to hypovolemia - Sepsis - Respiratory failure	Total: 6 Of which procedure related: 6 - Pneumosepsis - Respiratory failure - Paraplegia with organ failure - Aspiration leading to cardiac arrest - Respiratory failure due to pneumonia - Mesenteric ischemia
Other deaths	Total: 32 Of which procedure related: 1 - Sepsis after ischemia due to adhesion ileus	Total: 29 Of which procedure related: 3 - Mesenteric ischemia (n=2) - Stent-graft infection
Total number of deaths during follow-up	N = 37	N = 35

Appendix B: Type of aneurysm or procedure-related reinterventions during follow-up after open surgical repair and complex endovascular aortic repair (EVAR), with the time after surgery indicated.

Reinterventions after open surgical repair	Time after surgery
Aortic arch replacement due to growth at prosthesis juncture	18 months
Incisional hernia correction (n = 5)	12 months (n=3) 24 months 4 years
Abscess drainage	6 months
Extension with infrarenal aortic replacement	6 years
Open bifurcation prosthesis and EVAR due to abdominal segment growth	3 months
TEVAR for contained rupture at proximal sealing zone	4 years
Reinterventions after complex EVAR	Time after surgery
Bypass due to limb thrombosis	6 months
Partial bowel resection due to ischemia due to SMA occlusion	3 months
Partial revision due to mycotic blow-out in the groin	4 years
Percutaneous transluminal angioplasty for iliac extension stenosis	1 year
Reintervention for limb thrombosis	1 month
Stenting of side vessels	1 year
Thrombectomy for renal artery occlusion	2 years
Thrombolysis for iliac extension occlusion (n=2)	3 years 2.5 months

Abbreviations: SMA; superior mesenteric artery

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The association between endovascular aortic repair and adverse outcomes

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Association between sarcopenia and adverse outcomes after complex endovascular aortic aneurysm repair

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ABSTRACT

Background

Sarcopenia is identified as a predictive factor for adverse outcomes after complex endovascular aortic repair (complex EVAR). Consensus on preferred parameters for sarcopenia has not yet been reached. The current study compares three CT-assessed parameters for their association with adverse outcomes after complex EVAR.

Methods

This was a single-center retrospective cohort study. Psoas muscle index (PMI), skeletal muscle index (SMI), and lean psoas muscle area (LPMA) were examined by CT-segmentation. PMI, SMI, and LPMA were analyzed as continuous variables. In addition, cut-off values from previous research were used to diagnose patients as sarcopenic or non-sarcopenic. Outcomes were: all-cause mortality, Major Adverse Events (MAE), length of hospital stay, and non-home discharge. A sub-analysis was made for severely sarcopenic patients; sarcopenia based on any of the parameters, combined with low physical performance (based on gait speed, Timed Up and Go test, and/or Metabolic Equivalent of Task-score).

Results

We included 101 patients. A higher PMI (HR:0.590, CI:0.374-0.930, $p=0.023$), SMI (HR:0.453, CI:0.267-0.768, $p=0.003$), and LPMA (HR:0.559, CI:0.333-0.944, $p=0.029$) were associated with a lower risk of mortality. Being identified as sarcopenic based on cut-off values for PMI and LPMA was not significantly associated with survival. Sarcopenia based on SMI did present a higher mortality risk ($p=0.017$). A sub-analysis showed that severely sarcopenic patients were at even higher risk of mortality ($p=0.036$). None of the parameters were significantly associated with the other outcomes.

Conclusion

SMI had a slightly stronger association with mortality compared to PMI and LPMA. High-risk patients were selected by adding physical performance scores. Future research could focus on complex EVAR-specific PMI and LPMA cut-off values.

BACKGROUND

Complex endovascular aortic repair (complex EVAR), including fenestrated EVAR (FEVAR) and branched EVAR (BEVAR), provides a less invasive treatment option compared to open repair for patients with juxtarenal and suprarenal aortic aneurysms.¹⁻² Although complex EVAR provides better early postoperative outcomes compared to open repair, it is an extensive surgical procedure with considerable morbidity and mortality.³⁻⁵ This necessitates evidence-based patient risk assessment and selection. A systematic review on risk factors for mortality after aortic aneurysm repair, including FEVAR, defined oxygen-dependent chronic obstructive pulmonary disease (COPD) and dialysis as the greatest risk factors. In addition, female gender, diabetes, age, and ASA-score were negatively associated with survival.⁶

In other surgical fields, especially oncologic surgery, sarcopenia has been established as a predictive factor for adverse outcomes.⁷⁻⁸ According to the European Working Group on Sarcopenia in Older People (EWGSOP), sarcopenia is defined as a progressive skeletal muscle disease. It is of multifactorial cause; age, malnutrition, physical inactivity, and systemic disease can play a role, among other factors. Sarcopenia is suspected when a patient has low muscle strength and is confirmed by low muscle quantity or quality. It is considered severe if combined with low physical performance.⁹⁻¹⁰ For muscle quantity, CT-assessed muscle area is an often-used parameter.¹¹⁻¹² However, definitive consensus on the preferred method and cut-off points is not yet reached.¹³

Recently, studies have focused on sarcopenia in complex EVAR patients and have shown that sarcopenia based on CT-assessed low psoas muscle mass is a predictor for adverse outcomes.¹⁴⁻¹⁷ Due to time-effectiveness, psoas muscle area is often used to identify muscle quantity. However, measuring whole skeletal muscle area (SMA) at the level of lumbar 3 has been proposed as a more accurate method.¹⁸⁻²⁰ The current study reports on sarcopenia in complex EVAR patients by using three parameters based on CT-assessed psoas muscle, as well as total skeletal muscle. Our aim is to compare the different parameters on their association with adverse outcomes, and to identify whether CT-assessed sarcopenia combined with physical performance scores can assess the highest-risk complex EVAR patients. Not only could it serve as a tool for patient selection, it could also provide a target for prehabilitation, as sarcopenia is partially modifiable.²¹

METHODS

Patient inclusion and data collection

All patients that underwent complex EVAR between July 2013 and June 2022 in the Leiden University Medical Center (LUMC) were consecutively included based on their date of surgery. Complex EVAR included FEVAR, BEVAR, and branched or fenestrated arch-

EVAR. A decision to treat is usually made when the aneurysm reaches a diameter of 6 cm. Data on patient characteristics and complications during follow-up were subtracted from patients' medical records and entered into a computerized secure database. A certificate of no objection was issued by the LUMC Medical Ethics Committee (METC), as is required in our institution (registration number: 2022-034, July 5, 2022). Due to the merely retrospective character of our study and the fact that there was no interference in the standard care pathway, explicit patient consent was not obtained.

Identifying sarcopenia

All patients routinely underwent a preoperative CT-scan. A cross-sectional slice of 5 mm thickness at the level of L3 was identified and examined in the arterial contrast-phase. A slice was selected on which the lateral tips of both transverse processes were visible. If multiple slices at L3 met this criterion, the most cranial one was used. Slices were analyzed using SliceOmatic (Tomovision, Montreal, QC, Canada); a software tool, clinically available and widely used for this purpose.²²⁻²³ Muscle (including m. rectus abdominis, m. obliquus internus and externus, m. transversus, m. psoas major and minor, m. erector spinae, and m. quadratus lumborum) was identified by using a Hounsfield unit threshold of -29 to +150 (figure 1).²⁴⁻²⁶ Based on visual evaluation of the segmented contours, adjustments were made if necessary. For each scan, segmentation time was registered (seconds).

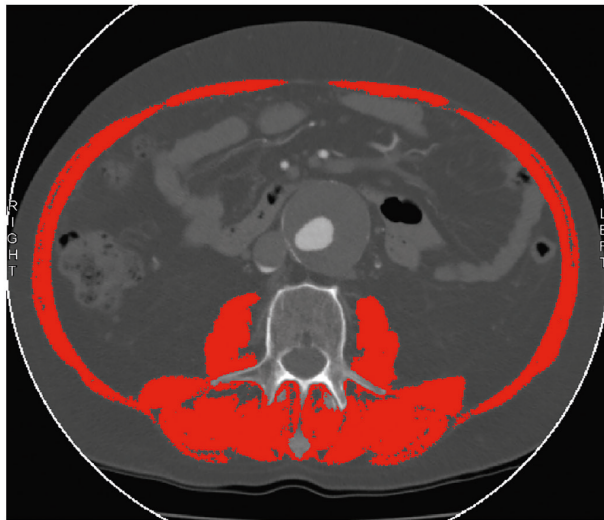


Figure 1: Example of a segmented scan at L3 for total skeletal muscle area.

Because muscle area is related to total body muscle mass, SMA and PMA were corrected for height into the Skeletal Muscle Index (SMI) and Psoas Muscle Index (PMI, cm^2/m^2). LPMA ($\text{cm}^2 \times \text{HU}$) was calculated as $((\text{PMA right} + \text{PMA left}) / 2) \times \text{mean psoas muscle density (HU)}$. Definitive consensus on cut-off values for sarcopenia is not yet reached. In order to

place our results in existing literature, the values used in this paper are based on previous research. SMI values were 52.4 cm²/m² for men and 38.5 cm²/m² for women.²⁴ For PMI, these values were 5.40 cm²/m² and 3.56 cm²/m² for men and women respectively.²⁷ For LPMA, sarcopenia was considered present if LPMA was <350 cm²xHU.¹⁵

Outcomes of interest

Baseline patient characteristics were: demographics, comorbidities, American Society of Anesthesiologists (ASA)-score, body mass index (BMI, kg/m²), procedure complexity, PMI, SMI, and LPMA. It was assessed whether the presence of sarcopenia based on PMI, SMI, and LPMA was associated with adverse outcomes. These parameters were also analyzed as continuous variables. The primary outcome was all-cause mortality. Secondary outcomes were: increased length of hospital stay, discharge to a rehabilitation center, and Major Adverse Events (MAE). MAE were defined as complications with a Clavien-Dindo score of ≥3. This included all complications needing a (minor or major) radiological, surgical, or laparoscopic intervention, as well as organ failure leading to ICU admission (including spinal ischemia), and death.²⁸

As of 2017, complex EVAR patients were routinely referred for preoperative geriatric, physiotherapeutic, and dietetic screening. Timed Up and Go-test (TUG) and gait speed were performed. Metabolic Equivalent of Task-score was assessed during preoperative anesthetic screening.²⁹ A sub-analysis for the primary outcome and MAE was made for severely sarcopenic patients. This was considered to be the case if a sarcopenic patient (based on either PMI, SMI, or LPMA) had a low physical performance based on low MET-score (1-4), slow gait speed (≤0.8 m/s), and/or high TUG-score (≥20 sec).^{30-31,10}

Statistics

To compare baseline characteristics, patients were divided into six groups: patients with and without sarcopenia based on PMI (group 1a and 1b), patients with and without sarcopenia based on SMI (group 2a and 2b), and patients with and without sarcopenia based on LPMA (group 3a and 3b). Categorical patient characteristics were expressed by number of patients and percentages. Continuous variables were tested for normal distribution using histograms, Q-Q plots, and the Shapiro-Wilk test. Normally distributed data were expressed as mean with the standard deviation (SD). Median with the interquartile range (Q1-Q3) was used in case of skewed distribution. Groups 1a vs. 1b, 2a vs. 2b, and 3a vs. 3b were compared on baseline characteristics using the independent t-test for continuous normally distributed data, chi-square test for categorical data, and the Mann-Whitney U-test for skewed data. When less than 5 events occurred, the Fisher's exact test was used instead of chi-square.

All-cause mortality in group 1a vs. group 1b, group 2a vs. 2b, and group 3a vs. 3b was tested by Kaplan-Meier with log-rank testing. Cox regression was used for a multivariate analysis of survival, corrected for variables that were associated with survival in univariate

analysis. The association of PMI, SMI, and LPMA with adverse outcomes was also tested with these parameters as continuous variables. PMI, SMI, and LPMA were adjusted by dividing them by their standard deviations, in order to compare hazard ratios. To compare secondary outcomes in the different groups, the same tests were used as for the baseline characteristic analyses. With PMI, SMI, and LPMA as continuous outcomes, logistic regression analysis was used to assess the categorical secondary outcomes and linear regression analysis for continuous secondary outcomes. All analyses were made using IBM SPSS Statistics version 27.

RESULTS

Selection of CT-scans

Figure 2 shows a flow-chart of patient inclusion. Between 2013 and June 2022, 104 patients underwent complex EVAR in the Leiden University Medical Center (LUMC). In three patients, the preoperative CT-scan was not suitable for muscle segmentation, either because it did not extend to the level of L3 (n=2), or because the correct level could not be determined due to extreme scoliosis (n=1). This left 101 patients to be included in the analysis. In 7 patients, the scan was suitable for segmentation of the psoas muscles but not for whole skeletal muscle. This was either due to anatomic aberrations, or due to the scan being cut off on both sides, impeding segmentation of the abdominal wall muscles. In four patients the arterial phase was not suitable for segmentation, and the non-contrast scan was used. Median time between the scan and surgery was 140.0 days (IQR: 110.0-175.8).

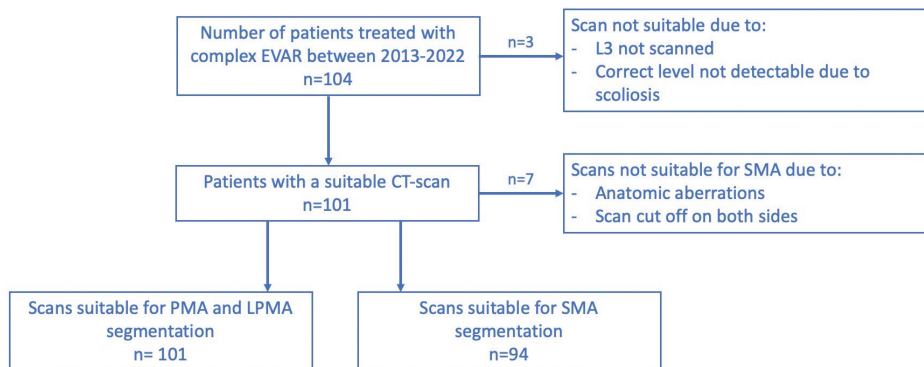


Figure 2: Flow-chart of patient inclusion.

Patient characteristics

Eighty-four of 101 patients (83%) were male, and mean age was 73.8 (SD: 6.1) years. Based on PMI cut-off values, 24 patients (24%) were sarcopenic. Using LPMA, 53% was considered sarcopenic. Of the 94 patients included in skeletal muscle segmentation, 64 (68%) were

considered sarcopenic. Median segmentation time was 41.1 seconds (IQR: 34.6-51.6) for the psoas muscles and 163.1 seconds (IQR: 133.9-193.7) for total skeletal muscle.

A comparison of sarcopenic versus non-sarcopenic patients (Table 1) based on PMI showed that a higher number of patients in the sarcopenic group had undergone previous AAA repair (38% vs. 13%, $p=0.014$). A comparison of the groups based on LPMA showed that there were significantly more women in the sarcopenic group (17 (40%) vs. 0, $p < 0.001$) and more patients with cardiovascular comorbidities other than AF or MI/ACS (22 (42%) vs. 10 (21%), $p=0.033$). The same analysis based on SMI showed that sarcopenic patients in this subgroup had a significantly lower mean BMI (25.5, SD: 3.5 vs. 28.3, SD: 3.6, $p < 0.001$).

Association between sarcopenia and mortality

Median follow-up time was 26.0 months (IQR: 4.0-47.9). All-cause mortality during follow-up was 28% ($n=28$). Based on PMI, estimated mean survival in months was 38.3 (95% CI: 27.2-49.4) and 65.9 (95% CI: 57.0-74.9) for sarcopenic and non-sarcopenic patients respectively ($p=0.049$). Using LPMA cut-off values, mean survival was 45.3 (95% CI: 33.0-57.6) in the sarcopenic group, and 71.1 (95% CI: 62.3-79.9) in the non-sarcopenic group ($p < 0.001$). Based on SMI, estimated mean survival was 52.1 (95% CI: 43.2-61.0) and 74.6 (95% CI: 62.0-87.1) for sarcopenic and non-sarcopenic patients respectively ($p=0.064$). Figure 3 depicts the survival curves.

Table 2 shows that female gender, AF, other cardiovascular disease, $ASA \geq 3$, higher procedure complexity, and previous AAA repair were associated with a higher chance of mortality. A multivariate analysis for sarcopenia based on PMI cut-off values (HR: 1.574, 95% CI: 0.591-4.190, $p=0.364$) no longer showed a statistically significant association with mortality. The same accounted for LPMA (HR: 2.534, 95% CI: 0.940-6.829, $p=0.066$), whereas the association between sarcopenia based on SMI became statistically significant after adjustment (HR: 3.624, 95% CI: 1.263-10.398, $p=0.017$).

PMI, SMI, and LPMA were also analyzed as continuous variables. They were adjusted by dividing them by their SD (1.5, 7.7, and 146.5 respectively), in order to be able to compare hazard ratios (HR). Univariate analysis showed that a higher PMI (HR: 0.434 per 1 standard deviation, 95% CI: 0.287-0.656, $p < 0.001$), SMI (HR: 0.496, 95% CI: 0.334-0.736, $p < 0.001$), and LPMA (HR: 0.361, 95% CI: 0.222-0.589, $p < 0.001$) were associated with a lower mortality risk. In a multivariate cox regression analysis, the statistically significant negative association remained present for PMI (HR: 0.590, 95% CI: 0.374-0.930, $p=0.023$), SMI (HR: 0.453, 95% CI: 0.267-0.768, $p=0.003$), and LPMA (HR: 0.559, 95% CI: 0.333-0.944, $p=0.029$). Table 3 shows an overview of these results. No multicollinearity was shown between SMI, PMI, and LPMA and the factors in the multivariate analyses, as well as possible other factors causing collinearity in our dataset (COPD, BMI, Diabetes Mellitus); all variance inflation factors were below 2, and tolerance was above 0.1.

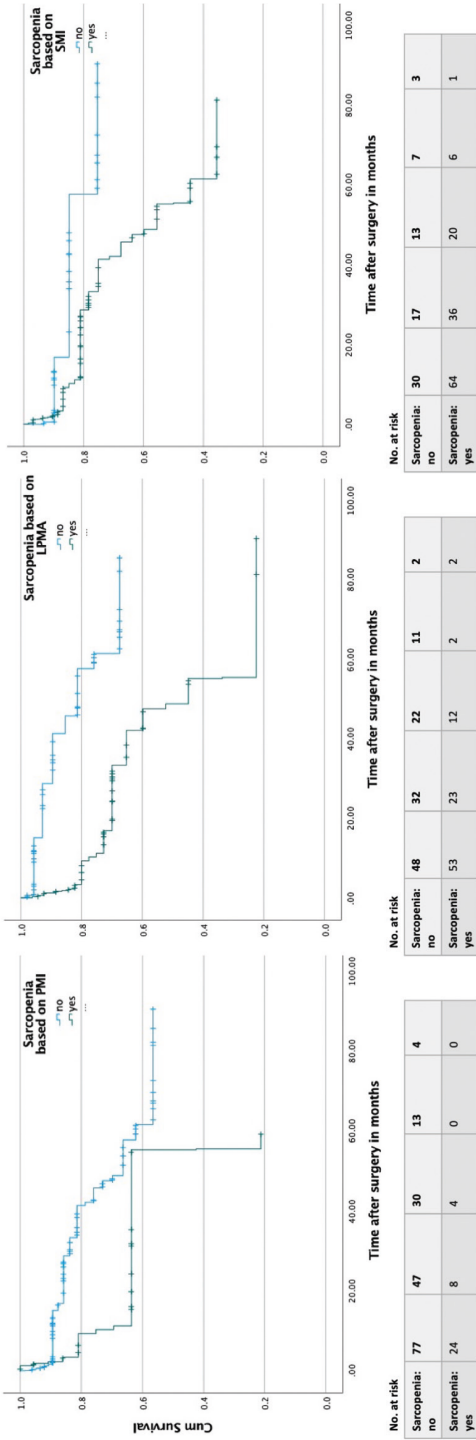


Figure 3: Kaplan-Meier curves for PMI (38.3, 95% CI: 27.2-49.4 vs. 65.9, 95% CI: 57.0-74.9, $p=0.049$), for LPMA (45.3, 95% CI: 33.0-57.6 vs. 71.1, 95% CI: 62.3-79.9, $p<0.001$), and SMI (52.1, 95% CI: 43.2-61.0 vs. 74.6, 95% CI: 62.0-87.1, $p=0.064$), for sarcopenic and non-sarcopenic patients respectively.

Association between sarcopenia and secondary adverse outcomes

The secondary outcomes were MAE (a composite endpoint of complications with a Clavien-Dindo score of ≥ 3 , including death by surgical complications), non-home discharge, and length of hospital stay. These outcomes were compared between patients with and without sarcopenia based on SMI, PMI, and LPMA. In addition, these parameters were analyzed as continuous variables (Table 4a-b). None of the outcomes were statistically significant, which is presented in further detail below.

In the total patient group, 32 patients (32%) suffered a MAE, of whom 7 died (7%). There was no statistical difference in the number of patients with a MAE when comparing patients with and without sarcopenia based on PMI (8 (33%) vs. 24 (31%), $p=1.000$), based on SMI (19 (30%) vs. 12 (40%), $p=0.353$), and based on LPMA (20 (38%) vs. 12 (25%), $p=0.202$). Logistic regression also showed no statistically significant association between the different parameters and MAE (Table 4a-b).

For PMI, 5 patients (23%) in the sarcopenic group and 14 patient (19%) in the non-sarcopenic group were discharged to a rehabilitation center or nursing home ($p=0.765$). For SMI, this was 14 (23%) vs. 4 (15%) for sarcopenic and non-sarcopenic patients respectively ($p=0.568$), and for LPMA 12 (26%) sarcopenic vs. 7 (15%) non-sarcopenic patients ($p=0.304$). Logistic regression also showed no significant association for PMI and LPMA (Table 4a-b). However, logistic regression did show a negative association between SMI and non-home discharge. Corrected for male gender (OR: 0.233, 95% CI: 0.068-0.800, $p=0.021$) and COPD (OR: 3.000, 95% CI: 1.033-8.708, $p=0.043$), which were identified as being associated with non-home discharge, this was no longer significant (Table 4a).

A comparison of the length of hospital stay showed no statistically significant differences between sarcopenic and non-sarcopenic patients, based on PMI (median: 5.0, IQR: 3.0-10.0 vs. median: 6.5, IQR: 5.0-12.0, $p=0.300$), LPMA (median 6.0, IQR: 5.0-13.0 vs. median: 6.0, IQR: 3.0-9.0, $p=0.172$), and SMI (median: 6.0, IQR: 5.0-12.8 vs. median: 7.0, IQR: 4.0-12.0, $p=0.828$). A linear regression analysis also showed no statistically significant association for these parameters as continuous variables (Table 4a).

Association of severe sarcopenia with mortality and MAE

Physical performance based on gait speed, TUG-score, and/or MET-score was assessed in 90 of 101 patients (89%). In this subgroup, 17 patients were considered severely sarcopenic (17%), 55 patients (55%) were sarcopenic but not severe, and 18 patients (18%) did not have sarcopenia based on either PMI, SMI, or LPMA. There were two patients with a low physical performance score, without having sarcopenia. Kaplan Meier survival analysis (Figure 4) showed a statistically significant difference in mortality risk between severely sarcopenic (33.6 months, 95% CI: 21.1-46.1) and sarcopenic patients (63.9 months, 95% CI: 52.6-75.3, $p=0.012$), and between severely sarcopenic and non-

sarcopenic patients (80.0 months, 95% CI: 70.3-89.8, $p < 0.001$). A multivariate cox-regression analysis, adjusted for the previously identified confounders also showed a statistically significant association between severe sarcopenia and mortality (HR: 10.525 95% CI: 1.163-95.239, coefficient 2.354, $p = 0.036$), compared to non-sarcopenic patients in this subgroup. There was no significant difference in the number of MAE's in severely sarcopenic ($n = 8$, 47%), sarcopenic ($n = 17$, 31%), and non-sarcopenic patients ($n = 4$, 22%, $p = 0.286$).

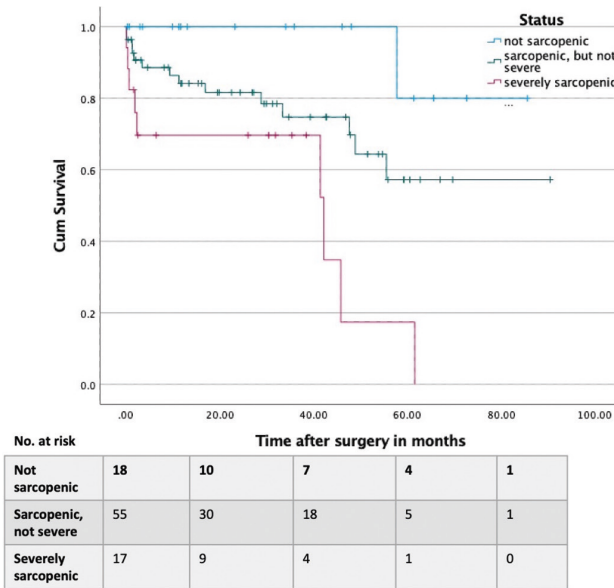


Figure 4: Kaplan-Meier curves for severely sarcopenic patients (33.6 months, 95% CI: 21.1-46.1), compared to non-sarcopenic (80.0 months, 95% CI: 70.3-89.8, $p < 0.001$), and sarcopenic patients (63.9 months 95% CI: 52.6-75.3, $p = 0.012$), in the sub-group analysis.

DISCUSSION

Association of PMI, SMI, and LPMA with adverse outcomes

After adjustment for confounding factors, a lower PMI, SMI, and LPMA were all associated with a higher risk of mortality, with a slightly stronger association for SMI. Sarcopenia based on cut-off values for PMI and LPMA was not significantly associated with survival, whereas sarcopenia based on SMI did lead to a significantly higher mortality risk. A sub-analysis based on physical performance parameters showed that severely sarcopenic patients were at even higher risk of mortality. None of the parameters were significantly associated with secondary adverse outcomes. The fact that psoas muscle measurements take less time, in addition to more scans being appropriate for psoas segmentation, would favor PMI and LPMA over SMI in clinical application.

The discrepancy between the significant association of PMI and LPMA with mortality as continuous variables and the non-association of these variables based on cut-off values could indicate that the cut-off values did not fit our population. Cut-off points depend on various characteristics, such as age and height, and therefore vary between different countries and patient cohorts. The number of patients in our cohort impedes the identification of robust cut-off points. A recent study by *Bradley et al.* defined cut-off points for SMI and PMI in a cohort of patients undergoing EVAR (n=674), including fenestrated- and branched-EVAR (n=133).³² When comparing their cut-off points with the values used in our study, *Bradley et al.* defines slightly lower cut-off values for SMI and slightly higher for PMI. This could indicate an underestimation of the number of sarcopenic patient in our cohort based on PMI and an overestimation based on SMI, although these cut-off points were identified for conventional and complex EVAR patients combined. Future studies on complex EVAR patients could focus on validating these cut-off points by *Bradley et al.*, in order for these parameters to be applied in clinical practice.

Results in context

Previous research based on PMA by *Alenezi et al.* reported an increased all-cause mortality risk for lower PMA. Although a different parameter was used, this is in accordance with our findings that a higher psoas muscle quantity, whether it be adjusted for height into PMI or for density into LPMA, is associated with a lower mortality risk.¹⁶ *Kärkkäinen 2020 et al.* reported a comparable hazard ratio for LPMA and all-cause mortality (0.59, 95% CI: 0.40-0.87, p=0.008), compared to our hazard ratio (0.56, 95% CI: 0.33-0.94, p=0.029).¹⁵ Using their LPMA cut-off values, we were able to detect a difference in all-cause mortality between sarcopenic and non-sarcopenic patients. However, after adjustment for confounders this was no longer significant (p=0.066).

Alenezi et al. (PMA) and *Kärkkäinen 2021 et al.* (LPMA) found that their parameters were predictive for MAE, while this was not supported by our results, even when analyzing severely sarcopenic patients. Although these discrepancies might be due to the fact that both studies included substantially larger patient cohorts of 257 and 504 patients respectively, it is an interesting finding which might indicate that in our cohort sarcopenic patients were fit enough to undergo surgery, but were more likely to die of other causes on a longer-term compared to non-sarcopenic patients.^{14,16}

The EWGSOP-criteria propose that physical performance status can be used to identify severely sarcopenic patients at an even higher risk for adverse outcomes.¹⁰ This was supported by our results, by using TUG, gait speed, and MET-score as indicators of physical performance. In *Kärkkäinen 2021 et al.*, ASA-score was used for risk stratification of extremely high-risk patients. Future research could focus on identifying preferred physical performance parameters.

Clinical application

The decision if and when an aneurysm should be treated, is mainly based on weighing the risk of rupture against the short-term and long-term risks of surgery.³³⁻³⁴ Being at higher risk of mortality due to individual characteristics could be taken into this equation. Sarcopenia combined with physical performance parameters is proposed as such a characteristic, although regarding short term mortality due to surgery-related complications this is not supported by our results.

As opposed to other risk factors for adverse outcomes, such as COPD and age, sarcopenia is partially modifiable. Malnutrition and physical inactivity, two contributors to sarcopenia, have been targeted for optimization in prehabilitation programs.²¹ Given the fact that complex EVAR is generally elective surgery, time during surveillance or time between the decision to treat and the actual procedure could be used to optimize patients. A meta-analysis on prehabilitation programs for patients undergoing major abdominal surgery concluded that pulmonary morbidity can be reduced by prehabilitation.³⁵ Another review on prehabilitation prior to intra-abdominal surgery stated that pulmonary and all-cause complications can be reduced by prehabilitation, but was inconclusive on the ability to decrease mortality.³⁶ A review on prehabilitation in open and endovascular aortic repair concluded that exercise therapy might reduce cardiac and renal complications.³⁷

However, all reviews stated that more research is necessary to validate these findings. Furthermore, these studies investigated whether prehabilitation improved physical function, and did not comment on post-prehabilitation changes in sarcopenia. A randomized controlled trial showed a significant increase in SMI in community-dwelling healthy elderly, who underwent a resistance-exercise intervention program.³⁸ A study among elderly nursing-home residents reported a decrease in the prevalence of sarcopenia after three months of resistance-exercise training, but found no significant decrease in SMI.³⁹ To our knowledge, the safety of such programs and their effect on muscle mass has not yet been studied among *complex* aneurysm patients.

Limitations

This study presented a real-world complex EVAR patient group in a non-high-volume university hospital. Consequently, the sample size was relatively small. This limits the analyses that can be performed, and could confine the external validity. However, a comparison with larger sized studies showed comparable results for the main outcome.

Several baseline characteristics were analyzed as possible confounders or factors of multicollinearity. For example, physical inactivity can cause sarcopenia, which is likely to be present in patients suffering from COPD. COPD could therefore correlate with sarcopenia in a predictive model for mortality. In our data however, no significant collinearity was shown and we adjusted for confounding factors in our multivariate

analyses. However, it is possible that we did not examine all relevant variables. Due to the restricted sample size, the number of variables in multivariate analysis is limited. As mentioned in the introduction, sarcopenia is a disease of multifactorial cause. It could also be argued whether, in a way, sarcopenia is already partially adjusted for these confounding factors, and whether including these confounding factors in multivariate analyses will have the desired effect.

CONCLUSION

As continuous variables, PMI, SMI, and LPMA were all associated with mortality, with SMI as a slightly stronger predictor. When using cut-off values for PMI, SMI, and LPMA, only sarcopenia based on SMI was associated with mortality after adjustment for confounders. In our cohort, none of the factors were associated with MAE, including surgery-related death. Psoas segmentation took less time, was possible in a higher number of scans, and therefore has practical advantages compared to total skeletal muscle segmentation. Future research, preferably with a higher number of patients, could be conducted to determine optimal PMI and LPMA cut-off values for complex EVAR patients. Furthermore, the highest-risk patients were identified by adding physical parameters. Selecting high risk patients can aid in clinical decision-making and identifies a group that might benefit from prehabilitation strategies.

INTERIM SUMMARY

In this chapter, sarcopenia was examined as a predictor of adverse outcomes after complex EVAR. All parameters on a continuous scale showed to be associated with mortality. However, based on cut-off values from previous research, only sarcopenia based on SMI was associated with a lower estimated mortality in Kaplan Meier analysis. This might indicate that PMI and LPMA cut-off values are not yet optimized for the complex EVAR patient cohort. As it appears to be partially modifiable, sarcopenia could be a target for preoperative prehabilitation strategies during the watchful waiting period before the treatment threshold has been reached or while waiting for the custom-made stent. Additionally, identifying sarcopenic patients who are at risk for adverse outcomes, can improve clinical decision-making and patient counseling. Understanding what patients perceive as important and what they expect from treatment, is essential in this matter. The next part of this thesis attributes to patient involvement and counseling by analyzing patient preferences and by reviewing Dutch disciplinary law in order to identify factors underlying patient dissatisfaction.

TABLES

Table 1: Comparison of patient characteristics

Variable	Sarcopenic PMI n= 24	Not sarcopenic PMI n= 77	p-value	Sarcopenic SMI n=64
Male gender	22 (92)	62 (81)	0.348	55 (86)
Age	75.3 (6.0)	73.4 (6.1)	0.199	74.83 (6.5)
BMI	25.4 (4.4)	26.7 (3.3)	0.115	25.5 (3.5)
ASA-score				
2	7 (29)	31 (40)	0.219	26 (41)
3	15 (63)	44 (57)		36 (56)
4	2 (8)	2 (3)		2 (3)
Aneurysm size	62.0 (59.0-74.3)	65.0 (58.5-70.0)	0.867	64.5 (60.0-69.0)
Procedure complexity*				
Grade 1	5 (21)	9 (12)	0.709	9 (14)
Grade 2	10 (42)	34 (44)		32 (50)
Grade 3	7 (29)	27 (35)		18 (28)
Grade 4	2 (8)	7 (9)		5 (8)
MI/ACS	9 (38)	26 (34)	0.808	21 (33)
AF	4 (17)	11 (14)	0.750	7 (11)
Other cardiovascular disease	11 (46)	21 (27)	0.130	21 (33)
COPD	6 (25)	17 (22)	0.784	19 (30)
Diabetes type 2	3 (13)	11(14)	1.000	6 (9)
Previous AAA repair**	9 (38)	10 (13)	0.014	11 (17)
PVD	4 (17)	13 (17)	1.000	10 (16)
Stroke	3 (13)	20 (26)	0.265	14 (22)
Malignancy				
Active	1 (4)	4 (5)	0.501	2 (3)
Past	8 (33)	17 (22)		16 (25)
Smoking				(n=63)
Active	7 (29)	22 (29)	0.706	15 (24)
Past	11 (46)	41(53)		33 (52)
Hypertension	15 (63)	61 (79)	0.111	48 (75)
Hypercholesterolemia	6 (25)	29 (38)	0.329	23 (36)
MET-score	(n=20)	(n=69)		(n=56)
Low (1-4)	5 (25)	11 (16)		11 (20)
Average (4-7)	14 (70)	56 (81)	0.349	42 (75)
High (7-10)	1 (5)	2 (3)		3 (5)
PMI	4.8 (4.2-5.2)	6.3 (5.8-7.3)	<0.001	5.6 (1.2)
SMI	40.6 (5.411)	48.0 (7.5)	<0.001	44.3 (38.6-48.1)
LPMA	226.5 (160.9-331.2)	379.5 (305.4-478.2)	<0.001	328.0 (110.3)

Abbreviations: SD: standard deviation, IQR: interquartile range (Q1-Q3), BMI: Body Mass Index (kg/m²), ASA: American Association of Anesthesiologists, MI/ACS: myocardial infarction/acute coronary syndrome, AF: atrial fibrillation, COPD: chronic obstructive pulmonary disease, AAA: aortic aneurysm repair, PVD: peripheral vascular disease, MET: Metabolic Equivalent of Task, PMI: Psoas Muscle Index, SMI: Skeletal Muscle Index

Not sarcopenic SMI n=30	p-value	Sarcopenic LPMA n=53	Not Sarcopenic LPMA n=48	p-value
22 (73)	0.158	36 (68)	48 (100)	<0.001
72.6 (5.1)	0.076	74.3 (6.2)	73.3 (6.1)	0.394
28.3 (3.6)	<0.001	26.2 (4.2)	26.7 (3.0)	0.518
9 (30)	0.507	18 (34)	20 (42)	0.822
19 (63)		33 (62)	26 (54)	
2 (7)		2 (4)	2 (4)	
66.0 (58.0-76.0)	0.403	64.0 (60.0-69.5)	65.5 (58.0-74.8)	
4 (13)	0.597	4 (8)	10 (21)	0.169
11 (37)		22 (42)	22 (46)	
12 (40)		21 (39)	13 (27)	
3 (10)		6 (11)	3 (6)	
12 (40)	0.643	15 (28)	20 (42)	0.209
6 (20)	0.336	8 (15)	7 (15)	1.000
8 (27)	0.636	22 (42)	10 (21)	0.033
4 (13)	0.122	14 (26)	9 (19)	0.477
7 (23)	0.106	6 (11)	8 (17)	0.567
4 (13)	0.768	11 (21)	9 (19)	0.622
7 (23)	0.397	9 (17)	8 (17)	1.000
8 (27)	0.794	8 (15)	15 (31)	0.061
3 (10)	0.419	3 (6)	2 (4)	0.593
6 (20)		11 (21)	14 (29)	
		(n=52)		
10 (33)	0.264	12 (23)	17 (35)	0.382
17 (57)		30 (58)	22 (46)	
23 (77)	1.000	42 (79)	34 (71)	0.363
10 (33)	0.822	17 (32)	18 (38)	0.676
(n=26)		(n=44)	(n=45)	
4 (15)		10	6 (13)	
22 (8)	0.638	32	38 (84)	0.408
0		2	1 (2)	
7.2 (1.5)	<0.001	5.2 (4.7-6.1)	6.9 (6.1-7.8)	<0.001
55.5 (52.5-57.9)	<0.001	42.4 (6.6)	51.0 (6.3)	<0.001
451.0 (177.1)	0.001	289.3 (229.8-318.0)	457.3 (385.5-531.4)	<0.001

* Grade 1: 1 or 2 fenestrations. Grade 2: 3 or 4 fenestrated EVAR. Grade 3: branched-EVAR. Grade 4: branched-fenestrated EVAR combinations, arch EVAR, and emergency cases.

**either open or endovascular

Table 2: Univariable analyses for all-cause mortality

Variable	HR	95% CI	Coefficient	p-value
Gender (male)	0.318	0.144-0.705	-1.145	0.005*
Age	0.974	0.917-1.035	-0.026	0.392
BMI	0.936	0.831-1.055	00.066	0.280
ASA of ≥ 3	2.524	1.063-5.995	0.926	0.036*
Hypertension	1.367	0.553-3.377	0.313	0.498
Smoking				
Past	0.983	0.388-2.494	-0.017	0.972
Active	0.859	0.311-2.374	-0.152	0.770
Diabetes	1.021	0.627-1.662	0.021	0.933
Hypercholesterolemia	0.625	0.275-1.423	-0.470	0.263
MI/ACS	0.506	0.215-1.191	-0.682	0.119
AF	2.469	1.039-5.864	0.904	0.041*
Other cardiovascular disease	4.625	2.135-10.020	1.532	<0.001*
Stroke	0.687	0.276-1.708	-0.376	0.419
COPD	1.572	0.690-3.582	0.453	0.281
PVD	1.237	0.500-3.061	0.212	0.646
Previous AAA repair	2.757	1.237-6.142	1.014	0.013*
Malignancy				
Past	1.067	0.430-2.651	0.065	0.889
Active	0.738	0.099-5.510	-0.304	0.738
Procedure complexity**				
Grade 2	1.241	0.332-4.780	0.216	0.754
Grade 3	2.039	0.527-7.270	0.712	0.272
Grade 4	4.389	1.032-18.670	1.479	0.044*
PMI	0.573	0.435-0.755	-0.556	<0.001*
SMI	0.913	0.868-0.961	-0.091	<0.001*
LPMA	0.993	0.990-0.996	-0.007	<0.001*

Abbreviations: BMI: Body Mass Index (kg/m²), ASA: American Association of Anesthesiologists, MI/ACS: myocardial infarction/acute coronary syndrome, AF: atrial fibrillation, COPD: chronic obstructive pulmonary disease, PVD: peripheral vascular disease, AAA: abdominal aortic aneurysm, PMI: psoas muscle index, SMI: skeletal muscle index, LPMA: lean psoas muscle area

* Statistically significant association, based on a p-value cut-off of <0.05.

** Procedure complexity: Grade 2: 3 or 4 fenestrated EVAR. Grade 3: branched-EVAR. Grade 4: branched-fenestrated EVAR combinations, arch EVAR, and emergency cases.

Table 3: Multivariate analysis of all-cause mortality adjusted for gender, ASA-score, AF, other cardiovascular disease, previous AAA repair, and procedure complexity

Variable	HR	95% CI	Coefficient	p-value
Unadjusted PMI	0.704	0.520-0.953	-0.351	0.023**
Unadjusted SMI	0.902	0.843-0.966	-0.103	0.003**
Unadjusted LPMA	0.996	0.992-1.000	-0.004	0.029**
Adjusted* PMI	0.590	0.374-0.930	-0.528	0.023**
Adjusted* SMI	0.453	0.267-0.768	-0.528	0.003**

Table 3: Multivariate analysis of all-cause mortality adjusted for gender, ASA-score, AF, other cardiovascular disease, previous AAA repair, and procedure complexity (*continued*)

Variable	HR	95% CI	Coefficient	p-value
Adjusted* LPMA	0.559	0.333-0.944	-0.581	0.029**
Sarcopenia based on PMI cut-off	1.574	0.591-4.190	0.453	0.364
Sarcopenia based on SMI cut-off	3.624	1.263-10.398	1.288	0.017**
Sarcopenia based on LPMA cut-off	2.534	0.940-6.829	0.930	0.066

Abbreviations: ASA: American Association of Anesthesiologists, AF: atrial fibrillation, AAA: abdominal aortic aneurysm, PMI: Psoas Muscle Index, SMI: Skeletal Muscle Index, LPMA: Lean Psoas Muscle Area

*PMI, SMI, and LPMA were divided by their standard deviation in order to enable interpretation of hazard ratios.

**Statistically significant association based on a p-value cut-off of <0.05.

Table 4a: Comparison of secondary outcomes between patients with and without sarcopenia based on SMI, PMI, and LPMA.

Outcome	Variable	OR	95% CI	P-value
MAE	SMI	0.970	0.917-1.027	0.296
	PMI	0.960	0.724-1.272	0.774
	LPMA	0.998	0.995-1.002	0.329
Non-home discharge	SMI	0.931	0.867-0.999	0.048*
	SMI corrected	0.964	0.890-1.044	0.370
	PMI	0.763	0.535-1.087	0.134
	LPMA	0.996	0.992-1.000	0.072
Length of stay	SMI	-0.135	-0.372-0.102	0.261
	PMI	-0.004	-1.159-1.151	0.994
	LPMA	-0.001	-0.130-0.110	0.873

Abbreviations: MAE: Major Adverse Events, SMI: Skeletal Muscle Index, PMI: Psoas Muscle Index, LPMA: Lean Psoas Muscle Area

*Statistically significant association based on a p-value cut-off of <0.05.

Table 4b: Odds ratios of SMI, PMI, and LPMA as continuous variables for the secondary outcomes.

Outcome	Variable	Sarcopenia		P-value
		Yes	No	
MAE (n, %)	SMI	19 (30)	12 (40)	0.353
	PMI	8 (33)	24 (31)	1.000
	LPMA	20 (38)	12 (25)	0.202
Non-home discharge (n, %)	SMI	14 (23)	4 (15)	0.568
	PMI	5 (23)	14 (19)	0.765
	LPMA	12 (26)	7 (15)	0.304
Length of stay (median, IQR)	SMI	6.0 (5.0-12.8)	7.0 (4.0-12.0)	0.828
	PMI	5.0 (3.0-10.0)	6.5 (5.0-12.0)	0.300
	LPMA	6.0 (5.0-13.0)	6.0 (3.0-09.0)	0.172

Abbreviations: MAE: Major Adverse Events, SMI: Skeletal Muscle Index, PMI: Psoas Muscle Index, LPMA: Lean Psoas Muscle Area, IQR: Interquartile Range

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PART 3

Lessons learned fr interviews and pat regarding aortic a

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Perspectives of patient professionals on patient complex endovascular

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Patients and Professional Perspectives on Patient Education in Complex Endovascular Aortic Repair

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ABSTRACT

Objectives

Misinterpretation of patient preferences in perioperative education can lead to an undesired treatment decision. This explorative interview study presents differences in perspectives of patients and professionals on patient education in complex endovascular aortic aneurysm management.

Methods

Using convenience sampling, a cross-sectional interview study was performed among patients who were in various stages of the decision-making process for complex endovascular aortic repair. Five physicians were interviewed, representing the main providers of clinical information. Interviews were transcribed verbatim and analyzed inductively.

Results

Twelve patients (mean age 76.6 (SD: 6.4), 83% male) were interviewed. Ten (83%) felt like they had no other realistic option besides undergoing surgery, whereas all professionals (5/5) stressed the importance of delicate patient selection. Five patients out of 10 (50%) who commented on their preferred decisional role, considered the professional's advice as decisive. All but one patient (11/12) reported that the information was easy to understand, whereas four out of five professionals (80%) doubted whether patients could fully comprehend everything. Patients experienced a lack of information on the recovery process, although professionals stated that this was addressed during consultation.

Conclusions

Several differences were found in the perspective of patients and professionals on information provision in complex aortic aneurysm management. In order to optimize patient involvement in decision-making, professionals should be aware of these possible discrepancies and address them during consultation. Future research could focus on these differences in more detail, by including more patients in different treatment- and decision stages.

INTRODUCTION

Since the publication of *Charles et al.*, shared decision-making has been embraced as the preferred model of decision-making in healthcare.¹ Involving the patient in decision-making and discussing patient-specific treatment preferences minimizes the risk of a so-called 'preference misdiagnosis', which can potentially lead to an undesired treatment decision.²⁻³ This is particularly important when there are multiple treatment options, each with their pros and cons, without one necessarily being superior.⁴

In vascular surgery, complex aortic aneurysm management is such a subject par excellence.⁵ Complex aneurysms contain visceral side branches that need to be preserved during treatment, in order to maintain blood flow to their target organs. Although cut-off points vary, the yearly risk of rupture is generally considered to exceed the risk of non-emergent surgery once a complex aneurysm reaches 6.0 cm.⁶ Previously, open repair (OR) was the only modality of treatment, which is often ill suited for frail patients. Building on experience in conventional aneurysm management, complex endovascular aortic repair (complex EVAR) was developed as a less invasive treatment option.⁷ This requires far smaller incisions, has less hemodynamic impact, and lower short-term mortality. Nonetheless, it is still associated with considerable risks, requires life-long surveillance, and carries higher surgical risks compared to conventional EVAR.⁸⁻¹⁴ A third option would be not to treat the aneurysm and choose a conservative approach.

The introduction of complex EVAR not only provides surgical challenges, but challenges in patient education as well. Frailer patients for whom different considerations might be relevant are considered for surgery, and this highly technical procedure needs to be explained in an understandable manner. Previous research has highlighted challenges that may arise during patient-involvement in decision-making for conventional aortic aneurysm surgery, such as the lack of feeling involved (*Santema et al.*), or an inadequate understanding of complications after surgery (*De Mik et al.*, *Jones et al.*).¹⁵⁻¹⁷ Our explorative interview study aims to present potential differences in perspectives of patients and professionals on patient education in *complex* endovascular aortic aneurysm management. In addition, we aim to visualize the care pathway of complex EVAR patients in our institution by constructing a patient journey.¹⁸ The aim is to improve medical professionals' understanding of the decisional process the patient goes through. Recommendations will be provided, aiming to improve the perioperative information provision and patient satisfaction.

METHODS

Design

This is a cross-sectional explorative interview study, performed at the department of vascular surgery in the Leiden University Medical Center (LUMC). Ethical approval was obtained from the local medical ethics committee (protocol number: N20.174), and written informed consent was obtained from all interviewees.

Current information provision

Currently at the LUMC, when patients are diagnosed with a (non-emergent) complex aortic aneurysm, they are referred to a vascular surgeon. Depending on aneurysm size, a surveillance plan is drafted. Once the aneurysm reaches or approximates the treatment threshold of 6.0 cm, the treatment modalities are discussed in further detail. As of 2017, complex aneurysm patients are routinely referred for geriatric, physical, and dietetic screening. The goal is to disclose possible indicators of frailty and to identify targets for (p)rehabilitation. Thereafter, the patient is discussed in a multidisciplinary meeting, in which a patient-specific provisional treatment plan is drafted. Participants in this meeting are vascular surgeons, interventional radiologists, thoracic surgeons, and anesthesiologists. The outcome of this meeting is discussed with the patient, and the patient is given approximately two weeks to deliberate. Additional appointments are made at the patient's request, and each patient is provided with a printed informational folder.

Study population

Patients for whom complex EVAR was considered and patients who had already undergone complex EVAR were invited to participate in the study. Patients were selected using convenience sampling. This often-used method is a form of non-probability sampling, which consists of including patients that are easily accessible in the clinical setting.¹⁹ To determine sample size, thematic saturation was aspired. At the start of our study, it was not clear how many patients would need to be included. The initially envisioned patient sample size consisted of fifteen patients, based on previous research.²⁰ Inclusion came to a halt when coding of the interview transcripts showed that no new thematic insights arose, which meant that including more patients was not expected to provide additional information on the subjects of interest. Saturation was reached after interviewing twelve patients and inclusion was ended.

The character of our study is explorative. Therefore, we included patients in different stages of the treatment- and decision-making process in order to create a broad view. To explore the professional's view on patient education and information provision, five medical professionals were interviewed. They represent the main stakeholders of complex EVAR education in our institution: three vascular surgeons (working at the LUMC and the affiliated HagaZiekenhuis hospital), one interventional radiologist, and

one geriatrician. Because of the limited number of professionals involved in information provision on complex aneurysm management, saturation was not aspired.

Interviews

Semi structured interviews were conducted by author FO. Semi structured means that a framework of questions (Appendix A and B) was used, but interviewees themselves eventually directed the topics that were discussed. Due to the leading role of the interviewee and our inductive approach, not every question was featured in each interview. Prior to the interview, patients received an introductory booklet via (e-) mail, to provide a better understanding of what the interview would entail. Baseline characteristics such as age, gender and comorbidities were obtained from patients' medical records. It was estimated that interviews would last approximately 60 minutes, but no time limit was set in advance. All interviews were recorded using a recording device provided by the LUMC. Data were stored using a secured server in the LUMC.

Coding and analysis

Audio recordings were transcribed verbatim. To ensure anonymity of the interviewees, authors that were involved in patient care did not listen to the audio tapes, nor did they read the interview transcripts, except for the (translated) anonymous quotes included in this manuscript. Transcriptions were coded inductively, using Atlas.ti as supporting software. Codes were analyzed into groups, which were divided into themes. Subsequently, themes were categorized. This was performed based on consensus agreement between two researchers (WW and FO).²¹⁻²³ Our coding focused on the interviewees' perspectives on three main themes in the interview framework, but was not limited to these subjects.

Patient journey

To visualize the care pathway of complex EVAR patients in our institution, a patient journey was constructed. Patient journey mapping is a commonly used method in human-centered design engineering (customer journey), but is relatively new in health care.²⁴ It combines several methods in order to best understand the patient experience. Our patient journey was created based on the interviews, combined with additional observations during visits at the outpatient clinic, and the standard elements of the complex aortic aneurysm care pathway. Data were analyzed using the process mapping approach, in which these elements are combined to depict the patient experience in consecutive steps of events. It includes the key informants, channels of information, considerations of patients and professionals, and emotions involved.²⁵⁻²⁶

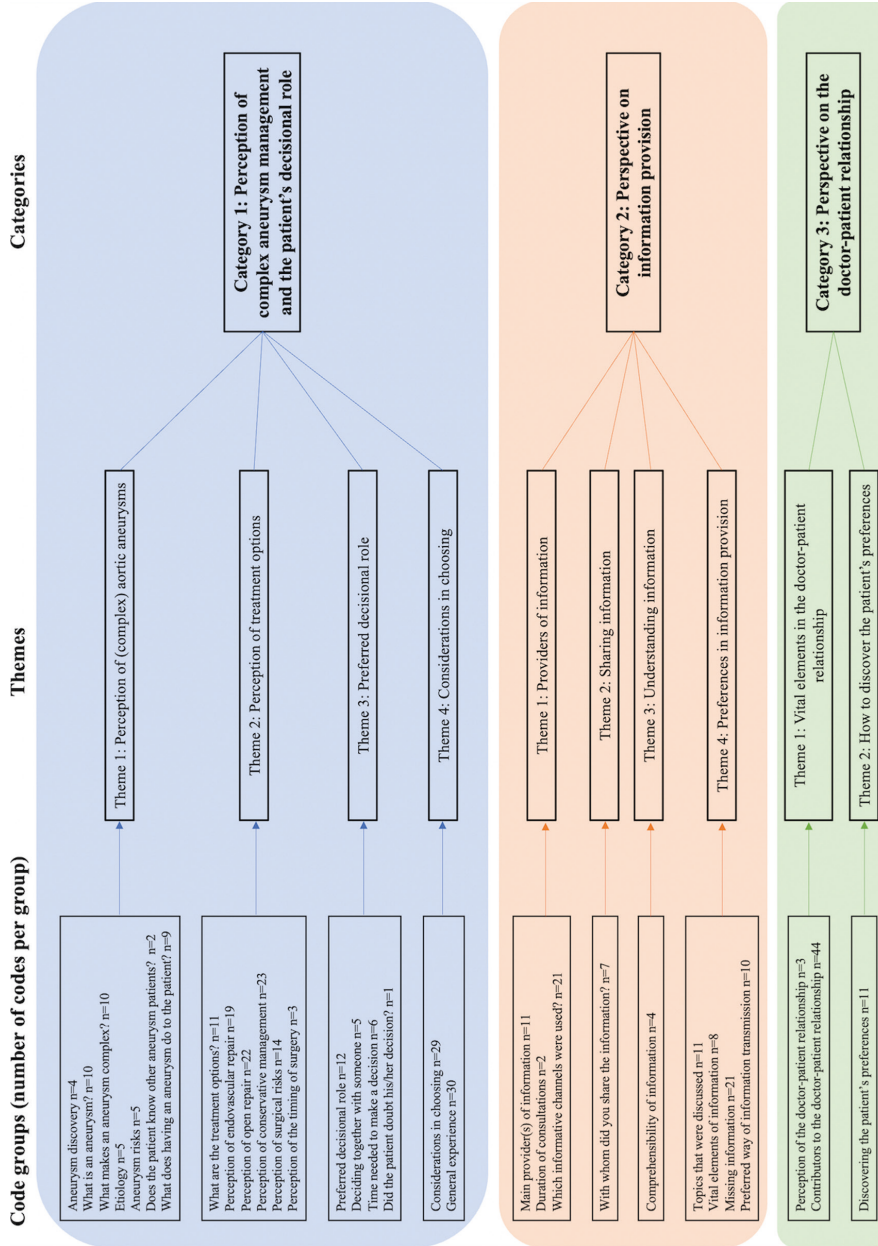


Figure 1: Coding tree of the patient-centered interviews.

RESULTS

Demographics and coding

Table 1a and 1b show the patient-specific and baseline characteristics of the twelve patients, including timing of the interview. Mean age was 76.6 (SD: 6.4), and 83% of participants was male. At the time of the interview, four patients were still scheduled to undergo complex EVAR, and for one patient the treatment modality had not yet been decided. One patient chose conservative management. Patient interviews lasted between 32 and 77 minutes, with a mean duration of 55 minutes (SD: 13.2). One patient interview was conducted by phone, all other interviews were performed face-to-face. One interview was performed in English, all other interviews in Dutch. Six patients were accompanied by their partner, one by his son, and one patient brought a friend. For the patient interviews, 366 codes were analyzed into 31 code groups, which were divided into ten themes. Subsequently, themes were categorized into three categories. Figure 1 shows the coding tree for the patient interviews.

The patient perspective

Category 1: Perception of complex aortic aneurysms and management

Theme 1: Perception of complex aneurysms

When asked to define an aneurysm, patients described a ‘broadening’, ‘enlargement’, ‘widening’, and ‘bulging’ of the aorta or ‘the body’s main artery’. Five participants (42%) knew other aortic aneurysm patients. Patients commented on the complex configuration of their aneurysm by mentioning that the surgeon had to make side branches to the kidneys and the intestines, and by stating that the stent had to be custom-made. When asked about the potential causes of an aneurysm, patients considered hypertension, hypercholesterolemia, ‘calcification’, and smoking as contributors. In eight out of the ten non-emergent patients, the diagnosis caused (great) feelings of fear, due to the potential risk of rupture (*Quote 1, Table 2*). Two patients mentioned that it felt like living with a ‘time bomb’ which could go off at any time.

Theme 2: Perception of treatment options

One patient chose not to undergo surgery. Only one other patient considered the option of not undergoing surgery and awaiting the natural course of the aneurysm. All other patients (10/12, 83%) did not consider the conservative approach as a realistic option.

All patients considered the open procedure as more invasive compared to endovascular repair. Three patients regarded open repair as an old-fashioned procedure (*Quote 2*), and one partner thought that open repair was always the secondary choice of treatment (*Quote 3*). Patients perceived various disadvantages of open repair compared to endovascular surgery: longer hospital stay, extensive recovery time, a larger wound, and a higher risk of complications. Patients mentioned cardiac complications, pneumonia, infection, ending up in a wheel chair, brain damage due to embolisms, and ‘leg

problems'. One patient considered it an advantage of open repair that doctors are more experienced with this procedure. Although all patients considered the endovascular procedure to be less invasive, they did mention several surgical risks: kidney failure, spinal cord injury, paralysis, and 'scars inside the body' instead of a large skin incision. Four patients added that the risks of such complications were small (*Quote 4*).

Theme 3: Preferred decisional role

Ten patients commented on their preferred decisional role in the decision-making process. Five patients (50%) wanted the doctor or the medical team to make the treatment decision regarding when and how to treat the complex aneurysm (*Quote 5*). One of these patients wanted to be involved, but considered the decision of the vascular surgeon as decisive. Four patients appreciated that they were able to decide together with their doctor (40%). Two of these patients added that they felt relieved when the surgeon seemed to agree with their decision to undergo complex EVAR. One patient (10%) presented with the decision between surgical or conservative treatment claimed that patients need to decide for themselves, because a doctor cannot be burdened with this responsibility (*Quote 6*).

Theme 4: Considerations when choosing

The patient who chose conservative management considered himself unfit for surgery. For other patients, the main reasons for not considering conservative treatment were the will to live (n=6, *Quote 7*) and not wanting to live with the fear of possible rupture (n=7). One patient described that he felt like he could take control over the situation by deciding to undergo surgery, even though the outcome could be bad (*Quote 8*). When presented with the fact that complex aneurysm surgery can lead to serious complications, six patients put this into perspective by stating that any surgical procedure carries risks. In addition, for five patients the feeling of being fit enough to successfully undergo a surgical procedure played a role. Main concerns with undergoing surgery were: not wanting to end up in a nursing home, not wanting to become disabled, and being scared of losing independence.

Category 2: Perspective on information provision

Theme 1 and 2: Providing and sharing information

Table 3 shows by whom information was provided and with whom information was shared.

Theme 3: Understanding information

Only one patient mentioned that he did not understand all information (*Quote 9*), without further explaining why. For all other patients (11/12, 92%), the information on complex aneurysm management shared by the medical professional was easy to understand. However, two patients remarked that doctors should avoid using medical jargon (*Quote*

10). All nine patients that commented on the length of the consultations were satisfied with the duration of the conversations and felt no rush during appointments.

Theme 4: Preferences in information provision

The main subjects of interest for patients were the potential surgical risks, although four patients stressed that they did not want to know every detail. Other subjects of interest were: the aneurysm growth rate, length of hospital stay, necessary medication, and the success rate of the procedure. Two participants emphasized that doctors are inclined to inform the patient about possible complications, in order to avoid accusations or legal claims. When asked about preferred channels of information provision, in addition to the consultations with their doctor, seven patients commented that the informational folder was a positive contribution. Seven patients thought that a drawing they received, clarified their understanding of the aneurysm.

Patients were asked whether any information was lacking during or after the decision-making process. Four patients would have wanted to receive more information about the recovery process. They encountered unexpected complaints such as skin numbness, muscle weakness, and long-lasting fatigue. One patient mentioned he would have liked an additional appointment between making the decision to treat and the surgery itself, to discuss possible insecurities that might arise during this time. Additional subjects patients wanted to receive more information about were: updates about the planned date of surgery, what to expect after deciding not to undergo surgery, and information about parking facilities and route directions at the hospital.

Category 3: Perspective on the doctor-patient relationship

Theme 1: Vital elements in the doctor-patient relationship

All patients were satisfied with the doctor-patient relationship (12/12, 100%). Patients and their accompaniment mentioned 44 elements that, in their experience, contributed or could contribute to a successful doctor-patient relationship. Codes that were mentioned twice or more are included in Table 4, with corresponding quotations.

Theme 2: How to discover the patient's perspective

Eight participants commented on exploring the patient perspective. One patient thought it was not possible for a doctor to investigate patient preferences and felt like this was a subject for the field of psychology (*Quote 11*). Three participants thought it was the patient's responsibility to talk openly about his/her preferences. Three patients commented that doctors should actively ask about the patient's lifestyle, in order to explore his/her preferences (*Quote 12*). One participant believed that doctors need 'people skills' in order to adequately support a patient in the decision-making process (*Quote 13*).

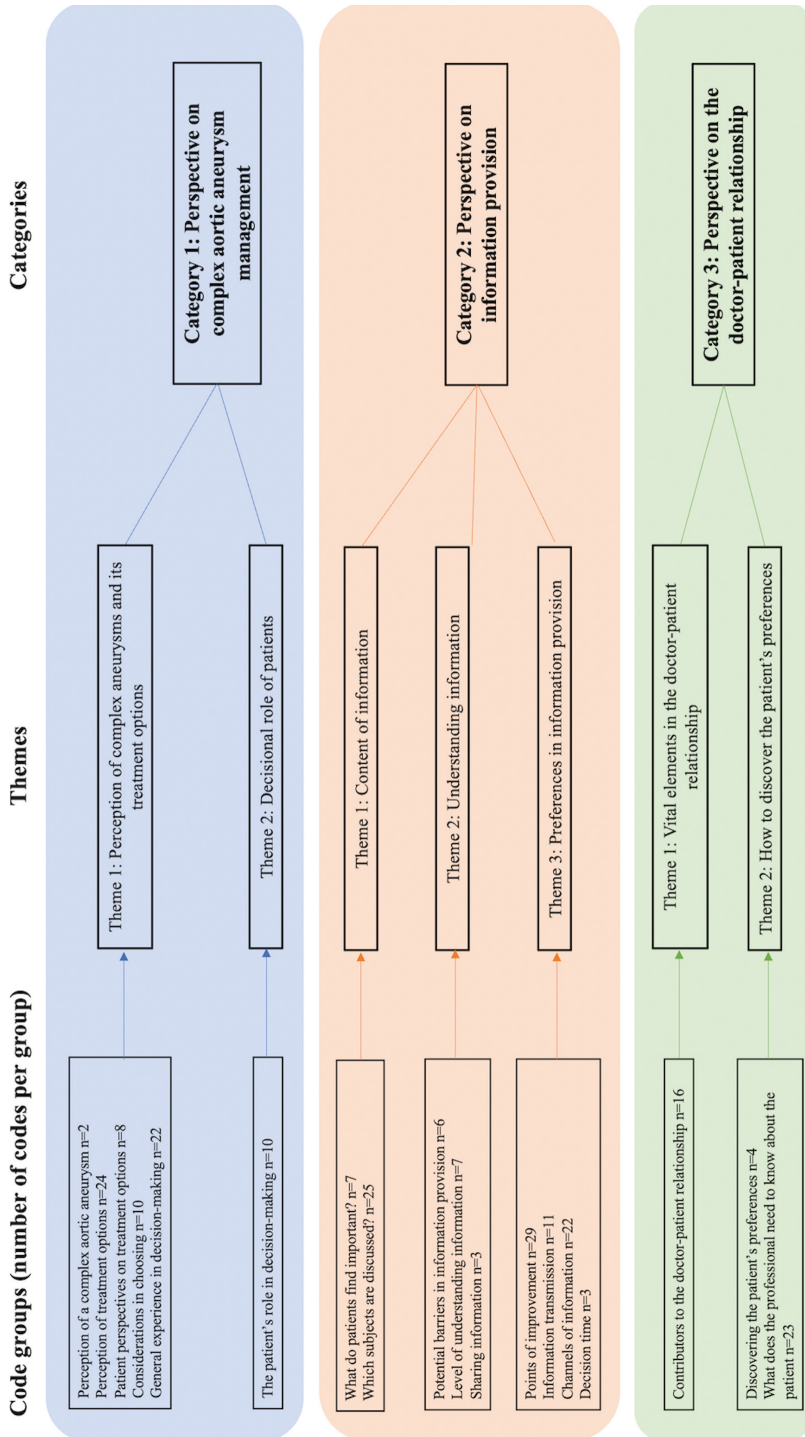


Figure 2: Coding tree of the professional-centered interviews.

The professional's perspective

The interviews with professionals were all conducted in person and lasted between 34 and 75 minutes. From these interviews, 232 codes were analyzed into 18 code groups, which were divided into 7 themes. Subsequently, themes were categorized into three categories. Figure 2 shows the coding tree for the interviews with professionals.

Category 1: Perspective on complex aortic aneurysm management

Theme 1: Perception of complex aneurysms and its treatment options

Two professionals commented that an aneurysm itself usually does not cause physical complaints. Therefore, they believed that treating an aneurysm essentially entails treating the threat or fear of potential rupture in the future. When asked about complex aneurysm treatment options, all professionals mentioned the option of complex EVAR and open repair, as well as conservative management. All professionals (5/5, 100%) commented that the decision to treat a complex aneurysm, either via open or endovascular repair, should be made carefully. Especially in older or frail patients, the option of conservative management should be discussed (*Quote 14, Table 5*). Three professionals addressed the high costs of custom-made stents in this equation.

Perceived disadvantages of open repair compared to complex EVAR were: bigger scars, a longer duration of recovery, and a higher rate of complications. One participant highlighted the long-term advantages of open repair for younger patients. A perceived downside of endovascular repair was the fact that the long-term outcomes are less known.

Theme 2: Decisional role of patients

Each professional believed that the patient should be involved in the decision-making process. The extent to which they thought patients should be able to make a treatment decision slightly differed among the interviewees. Four out of the five professionals (80%) commented that the decision whether to treat endovascularly or using open repair was mainly up to the medical team, and that patient involvement played a role in deciding whether to undergo surgery or to choose conservative management. In addition, three of these professionals (3/4, 75%) saw a guiding role for the doctor if, from a medical point of view, they thought the patient was too frail to undergo surgery. However, all participants (5/5, 100%) believed patients should be informed in-depth about the medical team's considerations in choosing between open or endovascular repair. One professional (1/5, 20%) thought the treatment decision should ultimately be left up to the patient, unless there is a definite contraindication (*Quote 15*).

Category 2: Perspective on information provision

Theme 1: Content of information

All professionals mentioned that patients should be informed about the surgical risks and possible consequences. Examples were: spinal ischemia causing paralysis, endoleaks

needing reintervention, kidney failure, and pulmonary complications. Other subjects of information were: the definition of an aneurysm, aneurysm size, the risk of rupture, risk factors (hypertension, smoking, diabetes, hyperlipidemia), technicalities of the procedure, hospital admission, medication, duration of recovery, and the possibility of necessary reinterventions.

Three interviewees mentioned that they got the impression most patients do not want to know every detail (*Quote 16*). According to the professionals, subjects that matter most to patients are: the surgical risks, the chances of success, postoperative functioning and rehabilitation, and the potential heredity of aneurysms. Subjects the interviewees considered to be underexposed during consultation were: the option of conservative treatment, the fact that an aneurysm might not rupture during the patient's lifetime, and erectile dysfunction as a surgical complication.

Theme 2: Understanding information

Four professionals commented on the patients' understanding of information; they all thought that patients are not able to understand all information that is offered, or that they cannot fully comprehend the situation they are in. These professionals therefore suggested that the patient is accompanied by someone to each consultation. Three professionals believed that patients needed the provided multiple consultations in order to make a decision. Two interviewees thought that patients needed several weeks to decide after the initial consultation in which the treatment options are presented (*Quote 17*). Although professionals did not often experience difficulties in transferring information themselves, they did mention potential barriers doctors might encounter: a different cultural or religious background, cognitive impairment, language barriers, a different educational background, and memory problems.

Theme 3: Preferences in information provision

Interviewees were asked to come up with additional ideas that might improve current decision-making and information provision. Suggestions consisted of: improving the inter-professional communication, establishing predictive tools in order to improve patient selection, hiring a physician assistant to support patients, a combined consultation with a vascular surgeon, interventional radiologist and geriatrician, implementing a supportive decision-tool, providing online additional information for patients who wish to receive more details, and visualizing the patient journey.

Category 3: Perspective on the doctor-patient relationship

Theme 1: Vital elements in the doctor-patient relationship

Table 4 shows which elements of the doctor-patient relationship were mentioned by both professionals and patients. All elements mentioned by professionals were also reported by patients. However, there were various additional elements mentioned by patients, which were not expressed by the medical professionals.

Theme 2: How to discover the patient's preferences?

In order to support a patient in the decision-making process, professionals wanted to know about objective characteristics such as: comorbidities, living status, physical functioning, cognitive functioning, the patient's support network, and his/her level of independence. These parameters could be questioned during consultation or tested via geriatric, physiotherapeutic, and dietetic screening. In addition, professionals were interested in more subjective characteristics, such as: the patient's vision on life (*Quote 18*), a patient's general mood, his/her quality of life and understanding of the disease, and the impact of having an aneurysm on the patient's quality of life (*Quote 19*). Two interviewees commented that they sometimes find it hard to objectify patient preferences. Three professionals mentioned that they explicitly ask patients about their preferences.

Patient journey

Figure 3 (supplementary material) depicts the patient journey that was construed based on the interview data. It shows the phases patients go through between receiving the diagnosis and their treatment (decision). The professionals in the patient journey correspond with the professionals included in this interview study. In addition, the dietician, anesthesiologist and physiotherapist are included in the patient journey. The emotional curve shows an initial decline in mental well-being due to receiving the diagnosis. Because of satisfaction with the doctor-patient relationship, the emotional curve rises during the consultation process. During the waiting period and directly after surgery it drops again, due to feelings of uncertainty and physical recovery with sometimes unexpected symptoms respectively.

DISCUSSION

In this interview study the greatest majority of patients felt like they had no other choice than to undergo surgery, either in order to stay alive, or because they could not live with the threat of aneurysm rupture. However, all professionals stressed the importance of adequate patient selection for surgery. Patients and professionals grossly agreed on the most important topics of information. In addition, most patients agreed with a leading role of the professional in decision-making. However, several important differences were detected between the patient and professional's perspective, which will be discussed below, including recommendations to avoid miscommunication.

Perception of a complex aneurysm and its treatment options

The finding that most patients considered surgery as the only realistic option is in accordance with *Berman et al.*, who reported that conventional aortic aneurysm patients considered surgery as their only option.²⁷ Here, there seems to be a discrepancy with the professional's perspective. All professionals believed that conservative management

should be discussed and considered, especially in older and frail patients. They emphasized that in some cases the risks of surgery might not weigh against its potential survival gain, and that for some patients other health conditions are more likely to lead to the death of the patient before aneurysm rupture.

The difference in the patient and professional's perspective could indicate that the professional's considerations on conservative management do not come across during consultations. It is important to address possible misperceptions of the risks of aneurysm rupture and the risks of surgery, as several patients considered the chances of surgical complications as minor, whereas they thought the aneurysm would definitely rupture. It is also possible that professionals underestimate the impact of living with an aneurysm on a patient's quality of life, and therefore perceive the option of conservative management as more realistic compared to most patients.

The information provision and the exploration of individual considerations on this subject could be improved in consultations by addressing these differences when informing patients. In addition, more attention could be paid to the guidance of patients with respect to the psychological impact of living with an aneurysm, for example by consulting a medical psychologist during preoperative screening or following the decision not to treat, and by gaining advice from a geriatric specialist. The patient journey supports these improvements by providing insight, to professionals as well as patients, in the needs and emotions of patients during the decision-making process.

Perception of the patient's role in decision-making

Unlike *Santema et al.*, we did not find that patients prefer a more active role in decision-making.¹⁵ Most patients preferred the professional to have a leading role, whereas professionals were convinced patients should have a leading role in deciding whether to undergo surgery or not. Professionals estimated that patients needed multiple appointments or several weeks to come to a decision. Patients stated that they were able to make this decision either directly after consultation, or within a few days. Adhering to these shorter terms could limit the lead time between diagnosis and treatment.

Perception of information provision

Patients stated that they wanted to receive more information about the period of recovery. The informational folder, which most patients found useful, does address the fact that surgery has a considerable effect on the patient's physical condition and mentions that total recovery might take up to 6 months after complex EVAR. In addition, professionals mentioned the duration of recovery as one of the topics they discussed during consultation. This discrepancy might be caused by a bias towards short-term thinking.^{16,28} Interestingly, *Faggioli et al.* found that the recovery time was considered significantly important by treated patients, but not by untreated patients prior to surgery.²⁹ To prevent dissatisfaction regarding the provided information, professionals

could emphasize this subject during pre-surgical consultation and could mention the expected period of recovery again prior to hospital discharge. In addition, a patient expert could provide patients with information on their own experience with the postoperative period.

All but one patient stated that the information was easy to understand, whereas professionals felt like patients were not able to comprehend all information. Based on our data, it is not possible to define the level of understanding among patients. However, previous research has established the Dunning-Kruger Effect, due to which people tend to overestimate their medical knowledge. It is important to be aware of this phenomenon, because of its potential negative impact on decision-making.³⁰

Perception of the doctor-patient relationship

The subject of 'contributors to the doctor-patient relationship' received the highest number of codes. Contributors mentioned by professionals were in accordance with codes mentioned by patients. However, several additional important elements were mentioned by patients, which professionals should take into consideration when caring for their patients (Table 4).

Limitations

The character of our study is explorative. Therefore, we included various professionals and patients in different stages of the treatment- and decision-making process by convenience sampling. This causes heterogeneity and can limit the external validity.¹⁹ In addition, the type of health care system might be of influence on the complex aneurysm pathway, which could limit the generalization of our results with regards to other countries. However, this approach best fitted our aim of exploring different visions of patients and caregivers involved. An additional study could be performed, in which patients are divided into different groups based on the decision-making phase they are in, in order to investigate their needs in greater detail.

An inductive approach was used to analyze interview data, which meant that the interviewees directed the extent to which topics were discussed. Therefore, not every question was featured in each interview. In order to quantify results, a questionnaire study could be performed, although these are limited in their in-depth analysis. In addition, quantified observations during consultation could be added in order to objectify results.

CONCLUSIONS

Several important differences were detected between the patient and professional's perspective. Patients felt like they had no other choice than to undergo surgery, whereas all professionals stressed the importance of adequate patient selection for surgery. Secondly, patients experienced a lack of information on the postoperative recovery period, although this was addressed in the informational folder and, according to professionals, mentioned during consultations. Professionals should be aware of these discrepancies and address them during consultations, in order to optimize patient involvement and satisfaction with information provision on complex aneurysm management. Future research could focus on further detailing the needs of patients in different phases of the decision-making process by including a larger patient cohort and by adding additional quantifying methods.

INTERIM SUMMARY

This chapter showed that patients and professionals have a different understanding of the possibility of conservative management. Professionals stress the importance of addressing this option, whereas patients do not seem to regard it as a realistic treatment option, mainly due to their fear of aneurysm rupture. Patients experienced a lack of information on the recovery period, although the professionals stated this is something they address during consultation, and it is mentioned in the informational flyer. This could be due to a bias towards short-term thinking. The fact that patients were very prone to talk about their (positive) experience of the doctor-patient relationship indicates that this is something they perceive as highly important. In the current chapter, overall, patients seemed to be satisfied with information provision and the doctor-patient relationship. However, patient dissatisfaction does occur. In the next chapter we will identify factors underlying patient dissatisfaction, by analyzing Dutch medical disciplinary complaints.

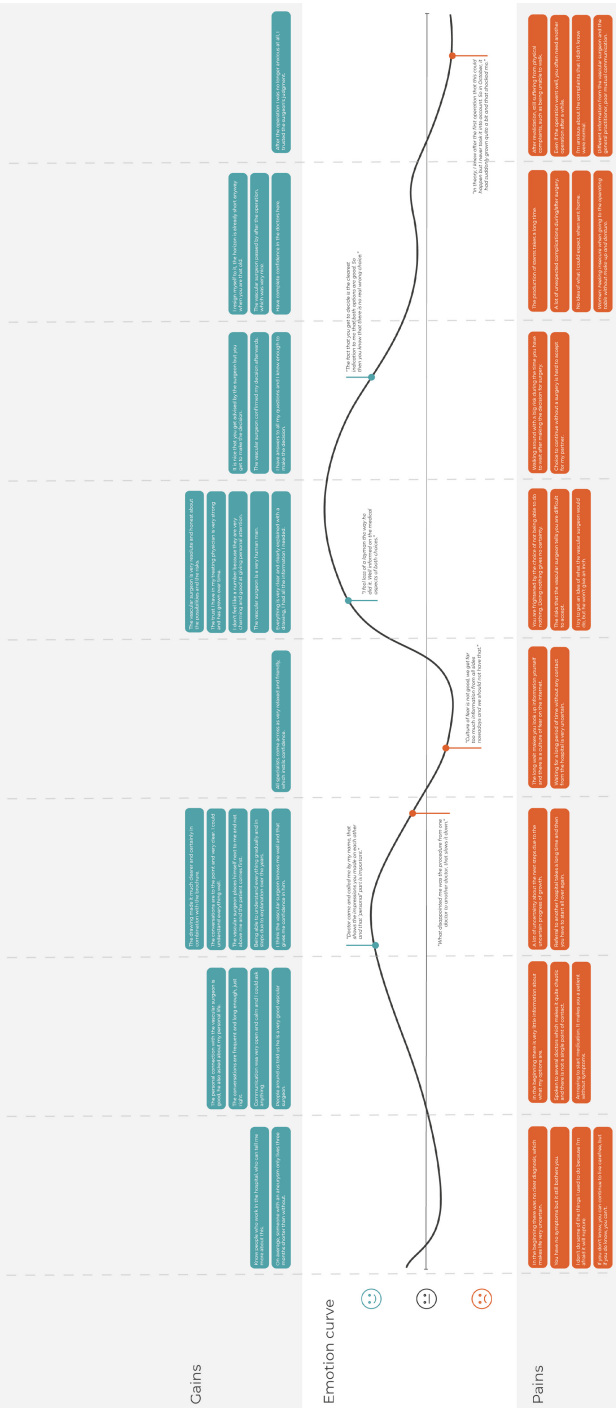


Figure 3: The patient journey of complex aortic aneurysm patients in the Leiden University Medical Center. Available online: [https://www.annalsofvascularsurgery.com/article/S0890-5096\(23\)00327-8/fulltext](https://www.annalsofvascularsurgery.com/article/S0890-5096(23)00327-8/fulltext)

Table 1a: Patient-specific characteristics

Patient	Age	Gender	Treatment	Timing of interview
1.	77	male	not yet decided	weeks after diagnosis
2.	84	male	FEVAR	pre-surgery
3.	74	male	BEVAR	pre-surgery
4.	81	male	BEVAR	pre-surgery
5.	84	male	Arch-EVAR	pre-surgery
6.	77	female	FEVAR	months post-surgery
7.	72	female	emergency BEVAR	months post-surgery
8.	85	male	FEVAR	1 year post-surgery
9.	87	male	FEVAR	1 year post-surgery
10.	71	male	emergency BEVAR	5 years post-surgery
11.	74	male	FEVAR	5 years post-surgery
12.	75	male	conservative treatment	months after decision

FEVAR; fenestrated endovascular aortic repair, BEVAR; branched endovascular aortic repair

Table 1b: Baseline characteristics

Variable	
Age, mean (SD)	76.6 (6.4)
Male gender, n (%)	10 (83%)
Aneurysm size in mm, mean (SD)	68.9 (12.6)
ASA-score	
2	3 (25%)
3	8 (67%)
4	1 (8%)
Comorbidities, n (%)	
Hypertension	10 (83%)
Hyperlipidemia	3 (25%)
Type 2 diabetes	2 (17%)
MI/ACS	2 (17%)
AF	1 (8%)
Other cardiac comorbidities	6 (50%)
COPD/other pulmonary comorbidities	3 (25%)
Previous AAA repair	5 (42%)

SD: standard deviation, ASA-score: American Society of Anesthesiologists-score, MI/ACS: Myocardial Infarction/Acute Coronary Syndrome, AF: atrial fibrillation, COPD: Chronic Obstructive Pulmonary Disease, AAA: abdominal aortic aneurysm

Table 2: Quotes of patients

Quote number	Category	Theme	Quote
1	1	1	<i>You're happy that you're still walking around, but you start to wonder; How much longer will I be around? How much risk do I have?</i>
2	1	2	<i>The first conversation was with an older doctor, who would soon retire. He still performed that old-fashioned treatment, which was a horrible procedure.</i>
3	1	2	<i>If they think that it's possible via the groin, they will choose to do so. If there really is no other way, then they will...I don't think they're jumping up and down to perform an open [procedure].</i>
4	1	2	<i>There is always a risk, but it's only small percentages.</i>
5	1	3	<i>I found it quite surprising [that the doctor didn't want to decide for me]. It feels a bit like theoretically implemented democracy in health care. Back in the day, the patient was silenced; 'This is what we're going to do sir, shut up.' Of course, that wasn't good either, but now it's a bit overdone. As long as it's nuanced, then it's ok.</i>
6	1	3	<i>You can't expect the doctor to decide for you; he's not going to take that responsibility. So, it's very simple: you just need to make your own decision.</i>
7	1	4	<i>'It can also go wrong, so yeah... What do you want?', [the doctor asked]. Because some people do not want to undergo surgery. I said: 'I still want to live for a while. I'm not that old yet.'</i>
8	1	4	<i>If you decide to do nothing, then [aneurysm rupture] will happen. You just don't know when. But it will happen, and you have no power over it. I really don't like that idea. It's better to know where you stand, don't you think?</i>
9	2	3	<i>I think a lot of it just went over my head. I heard what was being said, but I didn't understand it.</i>
10	2	3	<i>In the online patient portal, you can read a lot about what's going on. But in order to understand it, you would have to know Latin. That was disappointing. So many things are in Latin, which is impossible to understand.</i>
11	3	2	<i>I think [discovering the patient's perspective] is a subject for the field of psychology. There are so many factors that can play a role (...) You would have to dig into someone's existence: Are you married? Do you have children? Are you still having fun? (...) What are your hobbies? (...) But they see so many patients each year.</i>
12	3	2	<i>They should get to know the patient a little bit, to guide them in the right direction (...) [They should know about] someone's vision on life, if you're still active... If you only stay at home looking outside the window, that's a very different life compared to when you're still active, going on a holiday...</i>
13	3	2	<i>The more they get to know the patient, the better [doctors] are able decide what to do. One doctor will have more people skills than the other; there are people who are very interested in others, and people who are absolutely not. The latter should not become a doctor, right? [laughing]</i>

Category 1: Perception of complex aortic aneurysms and management

Theme 1: Perception of complex aneurysms as an anatomic entity

Theme 2: Perception of treatment options

Theme 3: Preferred decisional role

Theme 4: Considerations when choosing

Category 2: Perspective on information provision

Theme 3: Understanding information

Category 3: Perspective on the doctor-patient relationship

Theme 2: How to discover the patient's perspective

Table 3: Providing and sharing information

Information provided by	Mentioned by number of patients
Vascular surgeon	12
The internet	5
Befriended medical specialist	2
Home care nurse	1
Online hospital portal	1
Family member	1
Acquaintance	1
Information shared with	Mentioned by number of patients
Child(ren)	8
Friends/family	5
Partner	3
General practitioner	2
Home care nurse	1

Table 4: Quotes and codes of patients and professionals regarding the doctor-patient relationship.

Code	Mentioned by number of patients	Quotes of patients	Mentioned by professional(s)	Quotes of professionals
The doctor and other hospital staff were kind.	9	<i>There was also a very kind medical receptionist behind the counter. That really helps.</i>		
Personal aspect in the doctor-patient relationship.	8	Interviewer: <i>What is your overall opinion of the conversations with your doctor?</i> Patient: <i>Well, good, useful, efficient. Uhm...he is also engaged personally.</i> Interviewer: <i>How can you tell?</i> Patient: <i>By his demeanor, his way of talking (...), like he is interested.</i>	yes	<i>Why should it be impersonal? You don't go to the doctor to receive something impersonal.</i>
Doctor was not authoritative.	6	<i>He was not like; you're the patient and I'm the doctor, so shut up. I'm saying it a bit black-and-white. No that was really not the case.</i>	yes	<i>Doctors used to be placed on a pedestal. People were like 'yes if you say so doctor'. That's very different now, and I think that's a good thing.</i>
Doctor should be available to ask questions.	6	<i>I picked up the phone and got an appointment in no time. He took care of that. That makes me think; this is someone I can trust.</i>		
The patient felt like the doctor was trust-worthy.	5	<i>Feeling that you are in good hands, that's most important. (...) And I fully trusted him.</i>	yes	<i>You have to build trust.</i>
Doctor took the necessary time for consultations.	5	<i>No as I said, the character of people that seem to be working here... uhm you never got the sense of well let's get this over with very quickly (...) There was no rush to get out.</i>	yes	<i>In my experience, patients appreciate (...) a doctor taking the time to explain the treatment options.</i>
It is important that the patient can see the same doctor.	3	Interviewer: <i>Was it nice to see the same doctor?</i> Patient: <i>Well, there's no guarantee because it's an academic hospital, so these people have to go somewhere else sometimes. (...) That is something I find unfortunate, but that's the way it is.</i>	yes	<i>It would be best if there was continuity in [the professional that] patients get to see.</i>
A doctor should keep his promises.	3	<i>He does what he says, that's important.</i>		

Table 4: Quotes and codes of patients and professionals regarding the doctor-patient relationship. (continued)

Code	Mentioned by number of patients	Quotes of patients	Mentioned by professional(s)	Quotes of professionals
Doctor came across as confident.	2	<i>He came across as very confident. That's important.</i>		
Doctor should treat you as a human being, not just as a patient.	2	<i>(...) They treat you as a person, not just as a patient.</i>		
Doctor needs to be honest.	2	<i>He was honest and explained it all very well.</i>	yes	<i>You need to tell it like it is.</i>
Doctor should reassure the patient.	2	<i>What the doctor tells you and how he responds, is very important. To a patient, that is very important and reassuring.</i>	yes	<i>(...) I will try to reassure them (...)</i>
The surgeon that provides the information should perform the surgery himself.	2	<i>(...) I wanted to be absolutely sure that [name doctor] would perform the surgery himself, and not a doctor in training (...)</i>		
The doctor showed compassion.	2	<i>(...) if someone shows interest and compassion.</i>	yes	<i>It's about the way you engage with someone; showing compassion.</i>
The surgeon was a modern doctor.	2	<i>A modern doctor, I must say.</i>		
The doctor used humor.	2	<i>He used a bit of humor as well. I liked that.</i>		
The surgeon personally called family members after surgery.	2	<i>Well, I found it very pleasant that [name doctor] called [my husband by name]. That is something I really appreciate. I didn't expect that. Everything is so impersonal nowadays.</i>		

Table 5: Quotes of professionals

Quote number	Category	Theme	Quote
14	1	1	<i>(...) We do suggest [conservative management] if we think the remedy might be worse than the disease. In older patients, or someone with a lot of comorbidities, you should wonder if you should still perform surgery. But with a relatively healthy 65-year-old patient, I usually don't discuss the option of doing nothing.</i>
15	1	2	<i>Eventually, it is not up to us to decide what a patient wants. (...) Of course, it's a different scenario if the surgeon says 'if I perform the surgery, then I will kill the patient'. That's a medical contra-indication. Then the patient can bend over backwards, but the surgery won't happen. That doesn't happen a lot.</i>
16	2	1	<i>(...) [Patients] say; 'That may be the case doctor, but [the surgery] has to happen anyway'. So, they react quite dismissive towards detailed information.</i>
17	2	2	<i>That process takes several weeks, and I think patients need that time.</i>
18	3	2	<i>(...) And also a patient's vision on life; how long do you want to live, and with what quality of life?</i>
19	3	2	<i>In deciding whether to perform surgery or not, especially in older patients, it is very important to know (...) whether someone can handle the idea of not treating something that might cause a problem in the future.</i>

Category 1: Perspective on complex aortic aneurysm management

Theme 1: Perception of complex aneurysms and its treatment options

Theme 2: Decisional role of patients

Category 2: Perspective on information provision

Theme 2: Understanding information

Category 3: Perspective on the doctor-patient relationship

Theme 2: How to discover the patient's perspective?

Appendix A and B available online via:

[https://www.annalsofvascularsurgery.com/article/S0890-5096\(23\)00327-8/fulltext](https://www.annalsofvascularsurgery.com/article/S0890-5096(23)00327-8/fulltext)

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CHAPTER 6

Lessons learned from disciplinary law re aneurysm and dissection

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om Dutch medical garding aortic ection care

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ABSTRACT

Objectives

The current study is an explanatory analysis of Dutch disciplinary law regarding aortic aneurysm and aortic dissection care. We aim to give insight in the way disciplinary judges rule on quality of care and to extract the lessons to be learned.

Methods

The online open-access governmental database, which includes all disciplinary rulings since 2010, was searched using search terms related to aortic aneurysm and dissection care. First, abstracts were screened for relevance. Thereafter, the full text of all remaining cases was read. Cases related to the diagnosis, treatment, or the postoperative phase of an aortic aneurysm or aortic dissection were included. Characteristics were registered and analyzed for quantitative assessment. Each case was summarized and coded for qualitative analysis.

Results

Forty-eight first-instance cases were included, of which 19 (40%) were founded. Reprimands (n=9) and warnings (n=7) were the prevailing measures. Seven out of 8 appeal cases filed by plaintiffs were unfounded. Six out of 9 appeals filed by defendants were adjudged and led to a less severe measure. Most cases concerned the subject of 'wrong treatment/wrong diagnosis' (75%). Whether not recognizing an aneurysm or dissection led to disciplinary culpability depended on case-specific circumstances, and much importance was attached to adequate documentation. In many complaints, an element of inadequate communication was recognized.

Conclusions

Patient-involvement, clear communication, and implementing changes after a mistake could increase patient satisfaction, avert complaints, and prevent time-consuming trials. Maintaining adequate documentation and having knowledge on the analytical framework of the court is beneficial when confronted with a complaint.

INTRODUCTION

In general, health care workers aim to provide the best care for their patients. Unfortunately, medical errors and patient-dissatisfaction do occur, which can be very much unsettling for all parties involved. In the Netherlands, the medical-legal system provides multiple pathways for patients to raise their concerns (Figure 1). A somewhat unique form of legislation is medical disciplinary law. Patients and other ‘parties with a direct interest’ can file a complaint against health care professionals with one of three regional disciplinary courts, consisting of medical professionals and legal members.¹ The goal is to guard and improve the quality of individual health care and to protect patients against incompetence or carelessness.² Although this is an admirable objective, research has shown that procedures are often experienced by health care workers as to incriminate, and can lead to stress, insecurity, and elements of defensive medicine.³⁻⁶ Although disciplinary law differs among countries, international research has shown comparable results. For example, malpractice lawsuits have been associated with burn-out among vascular surgeons.⁷⁻¹⁰

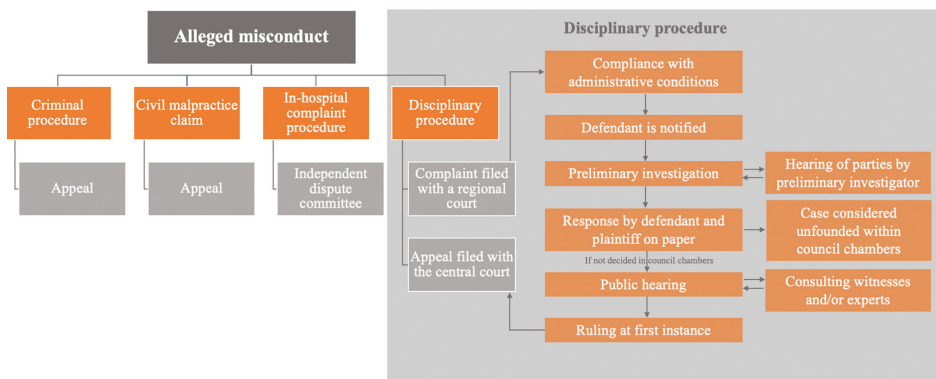


Figure 1: An overview of possibilities to file a complaint following alleged misconduct by health care workers in the Netherlands.

These negative consequences might partially be due to little knowledge of disciplinary rulings among medical professionals, prior to receiving a complaint.^{5,11} Understandably, most doctors prefer to stay far away from disciplinary law. However, disciplinary cases provide valuable information, as they give insight in the patients’ experience and the analytical framework of the courts regarding quality of care. In this review, disciplinary law on aortic aneurysm and dissection care will be discussed, aligning with the increasing thematic approach of subspecialties within vascular surgery. Previous research has focused on malpractice claims and litigation regarding vascular surgery in the United States and United Kingdom. The available evidence in these studies did not provide the opportunity to perform a qualitative in-depth analysis of the incidents leading to

these claims.¹²⁻¹⁴ The Dutch registry does provide this information. We aim to extract the lessons to be learned, in order to contribute to the ongoing search for optimal patient care in this part of vascular surgery. However, we believe that the principles underlying these cases can be of value when caring for patients in other fields of medicine as well.

METHODS

Set-up

The current study is an explanatory analysis of Dutch disciplinary law regarding aortic aneurysm and aortic dissection care. Since 2010, all disciplinary rulings are published in an online open-access governmental database.¹⁵ This database was used for data collection. Since cases are anonymized and available to all, we did not seek approval from the Medical Ethics Committee of our institution, nor of parties involved in the disciplinary cases.

Context of Dutch disciplinary law¹⁶

As mentioned in the introduction, ‘parties with a direct interest’ can file a complaint with one of the regional courts. Apart from patients themselves, these can be patients’ family members, friends, or partners. In addition, complaints can be filed by employers, colleagues, and the Dutch Health and Youth Care Inspectorate (IGJ). Complaints can only be filed against health care workers of professions registered under the Healthcare Professionals Act (BIG Act), including but not limited to all doctors (including residents), dentists, pharmacists, and nurses. Registration is mandatory for these professions. Complaints can be filed up to 10 years after the accused act.

First, the accused is notified and asked to reply. If a complaint is manifestly unfounded or clearly carries insufficient weight, the case can be ruled unfounded within council chambers. Otherwise, a public hearing will be held with the full disciplinary committee, consisting of three medical professionals (preferably of the same profession as the defendant) and two legal specialists. Both parties are invited to appear. Assistance by a lawyer or legal expert is possible, but not mandatory. The regional court rules within two months. Disciplinary assessment does not aim to investigate whether the accused could have done better, but to determine whether the defendant stayed within the boundaries of reasonable competence.

Non-occupation-restrictive measures are a warning, reprimand, and fine (maximum of 4500 euros). The more severe occupation-restrictive measures consist of a (provisory) suspension during a maximum of 1 year, withdrawal of the right to provide certain treatment or imposing special conditions to continue one’s profession, and permanent revocation of a professional’s medical license. All occupation-restrictive measures are published in the public register for health care professions. In the case of a reprimand

or fine, publication is a discretionary power of the court. Warnings are never published. Within six weeks after the ruling, both parties can appeal to the Central Medical Disciplinary Court. Its decision is final.

Search

Our search was performed in August 2023 and therefore included cases published since the founding of the database in 2010, until August 2023. The online database can only be searched using individual search terms. We consecutively entered terms related to aneurysm care, including the Dutch translations of 'aneurysm', 'vascular surgeon', 'vascular surgery', 'EVAR', and 'aorta'. An additional search using the Dutch translation of 'dissection' was added. Cases regarding veterinarians or lawyers, which are published in the same database, were excluded and duplicates were removed. First, abstracts were screened for relevance regarding aortic aneurysm and dissection care. If no abstract was available, the full text was screened. After this initial assessment, the full text of all remaining cases was read. Cases sufficiently related to the diagnosis, treatment, or the postoperative phase of an aortic aneurysm or aortic dissection were included. If, for example, an aortic aneurysm was merely mentioned in the patient's medical history, without the case being related to this pathology, the verdict was not included. The same applied to cases regarding intracranial aneurysms or carotid dissections.

Statistics and data assessment

For each included verdict, the following characteristics were registered: profession of the defendant, position of the plaintiff, whether a lawyer/legal expert was consulted, time between the accused act and the filing and ruling of the case, the decision, and whether appeal was filed. In addition, the topic was registered. Cases are classified by the courts in fixed topics, for example: 'providing no or insufficient care', 'unacceptable behavior', 'wrong treatment/wrong diagnosis', 'insufficient documentation', and 'violating professional secrecy'. For cases classified as 'wrong treatment/wrong diagnosis', the authors additionally examined whether it was mainly a complaint of wrong treatment or of a wrong/missed diagnosis. This data were analyzed for the quantitative results, using 'Descriptives', 'Frequencies', and 'Explore' in SPSS Statistics version 27. Normally distributed data were expressed as mean with the standard deviation (SD). Median with the interquartile range (Q1-Q3) was used in case of skewed distribution. In addition, each case was read in-depth for qualitative analysis, in order to extract learning points. A summary of each case was made, including the filed complaints and the essence of the ruling (Online Supplementary Table S1). These summaries were coded for relevant considerations leading to the court's decision. Similar codes were bundled into themes, and themes were divided into categories.^{17,18}

RESULTS

Quantitative results

General numbers

Each year, the disciplinary courts publish their figures. Between 2013 and 2022, 14.657 cases were handled by the regional disciplinary courts. In addition, 4472 decisions in appeal were made. In the last few years, the number of cases per year has shown a decreasing trend with currently, on average, a thousand complaints per year being filed at first instance. In about 65%, the defendant is a doctor.¹⁹ Surgeons, psychiatrists, and urologists top the list of most often accused specialities.¹¹ In 16% of first-instance complaints, the case is considered founded. If a measure is imposed, it is most often a warning (50%), followed by a reprimand (25%), (provisional) suspension (10%), and revocation of a medical license (1.5%). In some cases (13%), the complaint is considered founded, but no measure is imposed. In the past few years, no fines were issued.^{19,20}

Search and inclusion

Figure 2 depicts an inclusion flow-chart. Our search regarding aortic aneurysm care yielded 542 cases in total. After removing duplicates, 339 cases remained for abstract screening, which resulted in 105 cases seemingly related to aneurysm or dissection care and eligible for full-text screening. A search using the Dutch term for ‘dissection’ yielded 77 results. After removing duplicates and abstract screening, two cases remained. In total, 107 full-text verdicts were examined in the second stage of inclusion by full-text evaluation. This resulted in 48 first-instance cases and 17 related appeal cases being included, which regarded the diagnosis, treatment, and/or the postoperative phase of an aortic aneurysm or aortic dissection. Figure 3 shows the distribution of verdicts per year from 2010-August 2023.

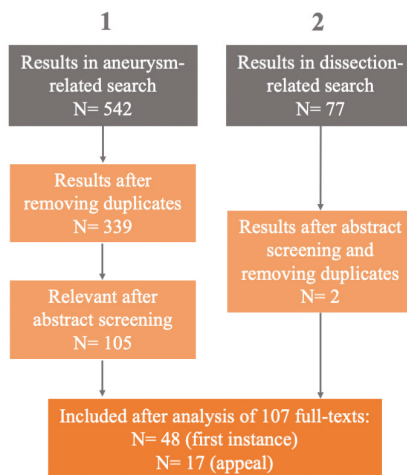


Figure 2: Inclusion flow-chart.

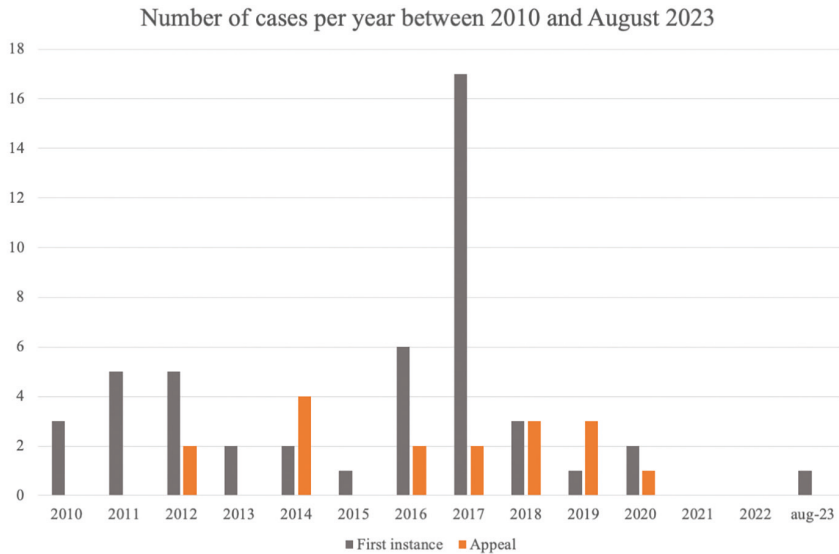


Figure 3: The number of cases per year between 2010 and August 2023.

First instance ruling

Table 1 shows the descriptives of the 48 cases at first instance. These cases were filed by 30 separate plaintiffs. Eleven plaintiffs filed complaints against multiple health care workers (ranging from two to four) regarding the same or related events. Most cases concerned the subject of ‘wrong treatment/wrong diagnosis’ (75%), of which 67% were accusations of a wrong (or missed) diagnosis. In 19%, the complaint concerned ‘providing no or insufficient care’. Defendants were most often surgeons (25%), family doctors (23%), internal medicine doctors (13%), or residents (15%). Plaintiffs were most often the child(ren) or partner of a patient that was treated by the defendant (33%). In 17%, the case was filed by the patient themselves. Almost all defendants were assisted by a lawyer (92%), compared to 23% of plaintiffs.

The median time between the accused act and filing of the complaint was just over a year; 387 days (IQR: 161-948). Median time between filing of the case and ruling by the court was 312 days (IQR: 234-363). In the majority of cases (60%), the complaint was ruled unfounded. In 9 instances (19%), the defendant received a reprimand, and in 7 cases (15%) a warning was issued. In one instance, defendant was denied the authority to ever perform surgery again.

Appeal

Appeal was filed in 17 out of 48 cases (35%).²¹ Descriptives can be found in Table 2. In 7 out of 8 cases filed by plaintiffs, the appeal was unfounded. In one case, a warning was issued, whereas the case was considered unfounded at first instance. In 6 out of 9

cases filed by defendants, appeal was adjudged. These decisions led to revocation of a reprimand (n=3), conversion of a reprimand into a warning (n=2), and changing a non-provisional suspension into a provisional suspension (n=1).

Qualitative results

All cases were examined for potential considerations leading to the court's decision. Given the fact that each case can serve as jurisprudence in following verdicts, the decision in a single case can be of value. Codes (n=72) were bundled into 17 themes, which were divided into three categories. This qualitative analysis is displayed in Table 3. Summaries of all cases, which were used for coding, are included in the Supplementary Table S1.

Considerations regarding diagnosis, treatment, and patient care

The courts were unanimous in their consideration that missing a diagnosis in itself does not necessarily lead to disciplinary culpability. In each case, the court examined whether presented symptoms should have raised the suspicion of a (symptomatic) aortic aneurysm or dissection, which only appeared to be required if symptoms were characteristic (Case 2018/504, 138/2016), or if other possible diagnoses were ruled out and symptoms were not yet explained (Case 021/2015, 119/2009, G2013/05). According to the courts, characteristic symptoms of aortic dissection were a non-excitabile 'tearing' pain high in the chest, extending to the back, sometimes accompanied by sweating, nausea and/or vomiting, and disparity between interarm blood pressure (Case 021/2015, 118/2009, 2015-324a, 09168). The rareness of the diagnosis was taken into account (Case 2016-214a, G2013/05). The courts emphasized that once an aneurysm or dissection is considered likely, immediate radiologic imaging should be performed (Case 2016/034, 2013-104: '(...) *the doctor (...) should have ordered an ultrasound that same evening/night to exclude an aneurysm.*').

If something was not written down in the patient's file, the courts assumed that it did not take place. This led the court in two possible directions. In some cases, missing information transferred the burden of proof to the defendant, who, according to the court, insufficiently documented the case. This was the court's reasoning if something that should have been performed (e.g., physical examination or reaching informed consent) was not documented (Case 11112a, 09168: '*Given the obligation to document the results of [an interarm blood pressure test] (...) and the fact that [documentation] did not take place (...), the court has to assume that this exam was not performed.*'). In other cases of missing information, the court decided that it could therefore not be established whether defendant acted unjust. This was the court's reasoning if something that should not have happened (e.g., improper behavior, acting unpleasant) did not become apparent from the available documentation (Case 056/2011, 057/2011: '*Neither from the documentation, nor from what was discussed during trial, did it become apparent that defendant made improper comments against the patient or his family.*').

In many cases, an accusation of inadequate communication played a part in the complaint (Case 307/2020, 2018/504, 181/2017, 263/2016, 16164, all other complaints depicted in bold in the Supplementary Table S1), although these complaints did not directly lead to the measures being imposed (Case 118/2009: *'The court identifies the remark [that the patient must be an important man] as a bit unlucky (...), but it does not justify any disciplinary action.'*).

Considerations regarding collegiate responsibility

When working with inexperienced residents, main culpability was assigned to the supervising physician (Case 057/2011, 056/2011, 180/2017). Doubting the decision of a supervisor could only be expected from experienced residents (Case 2016/307: *'Defendant, as a resident, was not very experienced and did not have to doubt her supervisor's decision.'*). However, this did not exclude a resident from culpability when acting independently (Case 2017/030).

Another element of collegiate involvement that the courts regarded as important, was that concerns of a referring doctor had to be taken seriously (Case 2016/018, 2017/030: *'(...) defendant should have understood that the [referring] general practitioner was worried. There was a feeling that something was off, which defendant should have investigated further.'*). In addition, close contact between involved colleagues was necessary, especially in acute situations (Case 10192b, 2016/306). Being the primary care taker did not come with sole responsibility for the patient's care, nor did it lead to disciplinary responsibility regarding actions that were taken by other consulted health care professionals (Case 2016-214c, 2016/033, 10115, G2013/06, 2011-069a: *'The responsibility of the primary care taker is limited in the fact that he does not carry responsibility for actions taken by other specialists (...) outside the area of expertise of the primary care taker.'*).

Circumstances taken into account

In deciding whether a complaint was founded and, if so, which measure should be imposed, several circumstances were taken into account by the courts. Along with being a first-time offender (Case 2016/018, 263/2016, 2016/034, 012/2015, G2011/22), the way defendants acted after receiving a complaint and during trial was important. Being open to feedback, acknowledging mistakes, showing empathy, and implementing changes were appreciated (Case 139/2016, 2016/306, 10192a, 2016/018: *'In deciding which measure should be imposed, it should (...) be taken into account that (...) defendant offered his regrets and apologized multiple times (...). Defendant clearly took lessons from this tragic event.'*). Although in the case of serious misconduct, such a demeanor could no longer lead to a less severe measure (Case 2013/227). In addition, a high workload did not excuse defendants of providing optimal care (Case 10192a, 10192b: *'Defendant cannot invoke the fact that he was busy caring for other patients with a life-threatening condition (...).'*).

DISCUSSION

Quantitative analysis

Sixty-five disciplinary cases regarding the diagnosis, treatment, and care of aortic aneurysms and dissections were initiated by 30 separate plaintiffs. The majority of cases involved a complaint of not recognizing an aortic aneurysm or aortic dissection, which led to complications or death. Misdiagnosis or treatment delay has previously been proven to be one of the most common reasons for litigation claims regarding vascular surgery in the United Kingdom and the United States.¹²⁻¹⁴ In the Netherlands, there is no national screening program for aortic aneurysms, like there exists in Sweden²² and the United Kingdom,²³ and is recommended in the United States.²⁴ An aneurysm is therefore usually diagnosed as an incidental finding when performing imaging for other purposes, or once symptoms occur due to (imminent) rupture. In our country, a general practitioner is usually the first point of contact for patients. This clarifies the number of family doctors among the defendants.

Our findings are in accordance with the decreasing number of complaints that are being filed each year. However, a substantially higher percentage of complaints was founded (40%), compared to the general data (16%). It is difficult to compare our results with other health care topics, in order to differentiate the extent of aortic aneurysm and dissection care among disciplinary cases. Previous research has mainly focused on the number of verdicts per profession, instead of per subject of care.²⁵⁻²⁸ When looking at the total number of complaints that were handled between 2013 and 2022 (n=14.657), cases regarding aneurysm and dissection care seem to be a modest contributor. Research into vascular surgery liability claims in Spain drew the same conclusion, although a shift toward an increase in endovascular cases has been seen in the United States.^{13, 29} However, whether we characterize the number of complaints as small or large, they are best avoided given the negative effects on plaintiffs as well as defendants. It is therefore important to recognize the possible pitfalls leading to complaints and measures, which are presented by our qualitative analysis below.

Qualitative analysis

Considerations regarding diagnosis, treatment, and patient care

The courts attached great importance to the obligation of adequate documentation.³⁰ Overall, information noted in the patient's file is considered true, unless it is plausible that it contains an incorrect delineation of the truth. It can therefore be difficult for patients to contest something that is noted in their file or to prove something which is not described in the doctor's documentation. This is not because the courts attach less credibility to plaintiffs compared to defendants, but is understandable given the fact that patient files are often the only source of information available to the courts. This explains why the courts strongly condemn inadequate documentation by health care professionals.

In many cases, an accusation of inadequate patient communication played a part in the complaint. While in our results these complaints did not directly lead to the measures being imposed, seemingly due to evidential difficulties, it does indicate that patients often experience a lack of effort on this front.⁵ Although this might not always lead to disciplinary culpability, it is very much undesirable. Clear communication, patient-involvement in (the reasoning behind) decision-making, and providing sufficient information could increase patient satisfaction, avert complaints, and prevent time-consuming trials.

Considerations regarding collegiate responsibility

Not only adequate patient communication played a part; communication between health care workers was also a subject of discussion. Concerns of a referring doctor should be taken seriously, and close contact should be kept between professionals involved, especially in emergency cases. Special attention was paid to the relationship between a resident and his/her supervisor. Residents are always working under the supervision of a medical specialist, but the degree and type of supervision differs, depending on what type of action is performed and on the resident's experience. Usually, clear agreements are made regarding if and when a supervisor should be consulted. Residents are personally responsible for their own actions. In each individual case, the disciplinary court rules whether the resident stayed within the boundaries of competent professional practice, which can be expected of a resident with the same level of experience in the same situation. In practice, the courts usually hold a resident responsible if they went outside of their competence, by not consulting their supervisor when guidance should have been asked for (Case 2017/030). Once a supervisor is contacted and the resident and supervisor are working together, both parties can be held responsible. When working with inexperienced residents, main culpability and great responsibility is assigned to the supervising physician (Case 180/2017, 2016/307). This indicates that the ratio gently changes into fully shared responsibility while the resident's experience increases.

Circumstances taken into account

Being open to feedback, acknowledging mistakes, showing empathy, and implementing changes seemed to lead to less severe measures. Understandably though, it can be difficult to acknowledge a mistake if you, as a defendant, are convinced you did nothing wrong. Especially if this is confirmed later on in appeal (Case 181/2017). Many doctors might recognize that a high workload can lead to suboptimal performance, but this did not excuse defendants from providing optimal care. Although this statement is understandable, it might encounter some critique given the high work load and staff shortage in many health care systems.³¹ However, this criticism might better be directed to the actual cause of these organizational problems, rather than the patient complaints that arise subsequently.

Criticism

Several points of critique have been expressed against Dutch disciplinary law. One considers so-called futility cases; cases that lack importance and cause an unnecessary burden on defendants. This critique is based on the small percentage of complaints that are eventually founded.^{5,32-33} Another matter is the negative effect that disciplinary procedures can have on defendants.³⁻¹⁰ Two thirds of 294 warned or reprimanded health care professionals experienced the procedure as very or extremely burdensome. Furthermore, 1.9% of warned and 12.7% of reprimanded professionals left their profession due to the procedure, while 37.6% had considered to quit.⁶ Another study questioning 210 disciplined or reprimanded doctors, showed that they felt criminalized and powerless.³ In the cases included in the current study, detailed information regarding the personal impact of the complaints on the defendant, was not provided in the available data. Some feeling of guilt or increased cautiousness is not necessarily problematic, but psychological and work-related problems are unwanted consequences. After all, this goes against the quality improvement goal of disciplinary law.

On the other hand, research has shown that knowledge on disciplinary law among health care workers leaves something to be desired. Many doctors are not aware of the way disciplinary law is organized, and 65% of Dutch doctors (almost) never reads a disciplinary case.^{5,11} Verdicts provide valuable insight in the analytical framework of the courts. Knowledge on the trial process and seeking legal assistance could diminish the feeling of being powerless. If these feelings do occur, professional or peer-support could be helpful. Positive effects after receiving a disciplinary measure have also been reported, such as making more accurate notes, discussing possible improvements with colleagues, and earlier signaling of patient discomfort.³ Reading disciplinary cases could elicit these positive effects, without having to undergo a procedure.

International perspective

Several elements of Dutch disciplinary law can be recognized within the legal systems of other countries. The aim is often to ensure the quality and safety of care, and measures are comparable. The responsible authority differs (Table 4). In France, each disciplinary procedure starts with mediation. If this does not lead to a satisfactory outcome, the case moves on to the disciplinary court. In some countries, there is no separate medical disciplinary law; complaints are either filed within the hospital or with the general judicial court (Estonia, Finland, Hungary). Quantitative data on disciplinary law is scarce, and due to divergent demographics, difficult to compare.³⁴⁻⁴⁰ Within the European Union, an international warning system has been implemented, which obligates countries to report occupation-restrictive measures. The goal of this arrangement is to prevent doctors from continuing their profession abroad after severe misconduct (Directive 2013/55/EG and Directive 2005/36/EG).

Limitations

Complaints that are handled by in-hospital complaint officers or independent dispute committees are not published and were therefore not included in our review. Furthermore, we did not search for cases within criminal or civil law, as these systems are fundamentally different compared to disciplinary law. Although we included as much search terms as considered relevant until no new cases arose, it is possible that we missed search terms that would have led to the inclusion of more cases. However, given the fact that elements of saturation already occurred, this would not necessarily have yielded additional insights.

Most verdicts are concise, and the courts are clear in their considerations leading to a decision. However, it is possible that the qualitative assessment of our study is influenced by the authors' interpretation, and other readers might come to different conclusions.

CONCLUSION

Disciplinary complaints regarding aortic aneurysm and dissection care most often involved an accusation of a missed diagnosis. The cases taught us that characteristic symptoms need to be recognized, concerns of a referring doctor need to be taken seriously, and immediate radiologic imaging should be performed if these diagnoses are suspected. In addition, close contact between professionals could avert mistakes, and adequate documentation can support truth-finding during trial. As is true for many things; prevention is better than cure. Patient-involvement in all phases of treatment could avert patient dissatisfaction. But even while taking this in mind, complaints can arise. Knowledge on the trial process and the analytical framework of the court is therefore advised. Although our research focused on aortic aneurysm and dissection care, we believe that the qualitative findings can be of value in many health care fields, due to the universality of the underlying principles.

INTERIM SUMMARY

This chapter showed that disciplinary complaints regarding aortic aneurysm and dissection care most often involved an accusation of a missed diagnosis. This is understandable given the serious consequences of not recognizing an aneurysm or dissection. In addition, many complaints contained an accusation of inadequate communication by the health care professional involved, which again stresses the importance of adequate patient communication. The next part of this thesis consists of the general discussion on the main findings of this thesis, their clinical implications and importance for future research.

TABLES AND SUPPLEMENTARY MATERIAL

Table 1: Descriptives of cases at first instance.

Variable	Cases at first instance
Number of cases	48
Time between accused act and ruling (days)	
Median	703
IQR (Q1-Q3)	469-1289
Minimum, maximum	244, 2879
Time between accused act and filing (days)	
Median	387
IQR (Q1-Q3)	161-948
Minimum, maximum	45-2608
Time between filing and ruling (days)	
Median	312
IQR (Q1-Q3)	234-362
Minimum, maximum	85, 700
Plaintiff (n=30)	
Child(ren) of patient	10
Partner of patient	10
Patient	5
Inspection	2
Patient and partner	1
Partner and child	1
Parents and sibling	1
Defendant	
Surgeon	12
Family doctor	11
Resident (in training and not in training)	7
Internal medicine doctor	6
Cardiologist	5
Radiologist	3
Emergency doctor	2
Anesthesiologist	1
Nurse	1
Subject	
Wrong treatment/wrong diagnosis	36
<i>Of which wrong diagnosis</i>	24
Providing no or insufficient care	9
Providing insufficient information	1
Not showing up or being too late	1
Not referring a patient or referring too late	1

Table 1: Descriptives of cases at first instance. (continued)

Variable	Cases at first instance
Decision	
Complaint unfounded	29
<i>Of which manifestly unfounded</i>	2
Reprimand	9
Warning	7
Complaint founded, no measure	1
(Non-provisional) suspension	1
Partial revocation/special conditions to continue profession	1

Abbreviations: IQR: interquartile range, Q: quartile

Table 2: Descriptives of appeal case.

Variable	Appeal cases
Number of cases	17
<i>Filed by defendant</i>	9
<i>Filed by plaintiff</i>	8
Time between accused act and ruling (days)	
Median	1409
IQR (Q1-Q3)	947-1750
Minimum, maximum	708, 3548
Time between first instance ruling and ruling in appeal (days)	
Median	384
IQR (Q1-Q3)	284-476
Minimum, maximum	130, 786
Plaintiff (n=16)	
Partner of patient	7
Child(ren) of patient	3
Patient	3
Inspection	2
Partner and child	1
Defendant	
Surgeon	6
Internal medicine doctor	3
Emergency doctor	2
Family doctor	2
Resident (in training and not in training)	2
Cardiologist	1
Radiologist	1
Subject	
Wrong treatment/wrong diagnosis	15
<i>Of which wrong diagnosis</i>	5
Providing no or insufficient care	2

Table 2: Descriptives of appeal case. (continued)

Variable	Appeal cases
Decision	
Appeal of plaintiff rejected; decision remains	7
Appeal plaintiff founded; decision changed <i>Unfounded changed to founded with warning</i>	1
Appeal defendant founded; decision changed	6
<i>Unfounded, reprimand revoked</i>	3
<i>Reprimand changed to warning</i>	2
<i>Non-provisional suspension changed to provisional</i>	1
Appeal defendant rejected, decision remains	2
Appeal revoked by defendant	1

Abbreviations: IQR: interquartile range, Q: quartile

Table 3: An overview of considerations of the courts, in order of the number of relevant cases per consideration.

Lessons learned	Relevant cases
Considerations regarding diagnosis, treatment, and patient care	
In many cases, an accusation of inadequate communication played a part in the plaintiff's complaint, but miscommunication does not always lead to culpability.	<p>Case 317/2017: Plaintiff requested a second opinion. She was invited to discuss her wishes and was told to arrange a second opinion herself. Although this approach did not lead to disciplinary culpability, more attention could have been paid to communication.</p> <p>Case 118/2009: A remark made by defendant was described by the court as 'unlucky', but did not lead to disciplinary culpability.</p> <p>Case 16164: Although it would have been decent if defendant contacted patient after hospital admission, not doing so does not lead to disciplinary culpability.</p> <p>Cases: 307/2020, 2018/504, 181/2017, 263/2016, 2016/018, 2016/034, 2016-214c, 012/2015, 11112a, 11112b, Z2022/4413, 057/2011, 056/2011, 165/2015, 2013-104</p>
Missing the diagnosis of an aortic aneurysm or dissection does not necessarily lead to disciplinary culpability.	<p>Case 138/2016 and Case 2016/139: Defendants did not recognize that patient suffered from an abdominal aneurysm. Patient died due to aneurysm rupture. Given the unconventional symptoms (hematuria, fever, stomach pain, diarrhea, involuntary leg movements), it is not culpable that this diagnosis was missed.</p> <p>Cases: 2016/034, 021/2015, 10115, 118/2009, 119/2009, 2015-324a, 2015-324b, 2015-324c, 2015-324d, G2013/05, 057/2011, 2018/504</p>

Table 3: An overview of considerations of the courts, in order of the number of relevant cases per consideration. (*continued*)

Lessons learned	Relevant cases
Maintaining adequate administration and documentation is important and facilitates truth-finding by the courts.	<p>Case 012/2015: The mere mentioning of an aneurysm in a discharge letter does not contain a clear assignment to a general practitioner to arrange necessary follow-up.</p> <p>Case 11112a: Defendant did not note whether preoperative consultation took place. The burden of proof therefore lied with defendant to show that this conversation took place, which he was not able to.</p> <p>Case 09168: In the absence of adequate notations in the patient's file, it is plausible that defendant did not perform a complete physical examination.</p> <p>Cases: 263/2016, 2018/504, 2011-069a, 307/2020</p>
When a (symptomatic) aortic aneurysm or aortic dissection is considered likely, imaging should be performed immediately.	<p>Case 2013-104: Patient was admitted to the emergency department with stomach pain. Defendant decided that the patient should be admitted, with a differential diagnosis of an aneurysm or obstipation. The next day, an ultrasound was performed, which showed an AAA of 8 cm, which was confirmed by a CT-scan a day later. Patient (successfully) underwent emergency surgery. A warning was issued; imaging should have been performed immediately, given the fact that an aneurysm was suspected.</p> <p>Case 119/2009: Given the presented symptoms, it was understandable that acute coronary syndrome (ACS) was considered more likely than the eventual diagnosis of aortic dissection. It was therefore understandable that a CT-scan was not performed immediately, but 19 hours after admission when ACS was ruled out.</p> <p>Case: 2016/036, 2016/034</p>
The rareness of a disease makes it less culpable to not recognize it as a diagnosis.	<p>Case 2016-214a: An internal medicine doctor was accused of missing the diagnosis of compression of the left main bronchus due to soft tissue swelling after TEVAR, causing dyspnea. On an initial CT-scan, this was not recognized. Especially given the rareness of this pathology, defendant could trust the radiologist in his/her initial diagnosis regarding the first CT-scan.</p> <p>Case G2013/05: A GP initially missed the diagnosis of an aortic dissection, by being too focused on possible symptoms of stress, and by not examining the patient after she calmed down. However, due to the rarity of the pathology and the non-specific symptoms of the patient, the court did not impose a measure.</p>
Guidelines and instructions for use need to be followed if applicable.	<p>Case 17258: Patient was treated for an aneurysm before the guideline's treatment threshold was reached. In addition, instructions for use regarding the stent were not followed. A reprimand was imposed.</p> <p>Case 181/2017</p>
When confronted with a frail patient, questioning and physical examination should be even more thorough.	<p>Case 16164: A frail patient presented with hematuria. Defendant diagnosed a urinary tract infection. Later, an aortic aneurysm was diagnosed and surgery was performed. In appeal, a warning was issued; given the frailness of the patient, even more cautious care should have been provided, in order to come to the correct diagnosis.</p>

Table 3: An overview of considerations of the courts, in order of the number of relevant cases per consideration. (*continued*)

Lessons learned	Relevant cases
Considerations regarding collegiate responsibility	
When working with inexperienced residents, disciplinary culpability mainly lies with the supervisor. While gaining experience, disciplinary culpability of a resident increases.	<p>Case 180/2017: Given the experience of the resident (year 2 out of 6 years of training), according to accepted jurisprudence, main disciplinary culpability in such a complicated vascular surgery case lies with the supervising surgeon.</p> <p>Case 2016/307: A resident in training performed an ultrasound together with a supervising radiologist. An aortic dilation and iliac artery aneurysm were diagnosed. As agreed with her supervisor, the resident advised the GP to make an appointment with a vascular surgeon, instead of directly calling a vascular surgeon herself. That night, aneurysm rupture occurred and emergency surgery was necessary. Given the experience of the resident (first year), culpability mainly lies with the supervising radiologist, and it cannot be expected that defendant doubted the supervisor's decision to call the GP instead of a vascular surgeon.</p> <p>Case 056/2011: Given the inexperience of the resident (3 months), defendant should have examined the patient, presenting with acute symptoms, himself.</p> <p>Case 057/2011</p>
The primary care taker is not necessarily responsible for the actions of other (consulted) practitioners involved.	<p>Case 2011-069a: Patient developed back pain after a Crawford procedure. This was caused by spinal deterioration and a chronically infected aortic prosthesis, for which patient was treated with medication by defendant. Defendant consulted a rehabilitation specialist, who prescribed a Hewitt brace, which patient wore for about 3 years, instead of the necessary 3 months. The court decided that defendant was not responsible regarding the actions of the rehabilitation specialist, although consulted by defendant.</p> <p>Cases: 2016/033, 10115, G2013/06</p>
Concerns of a referring doctor need to be taken seriously.	<p>Case 2016/018: A patient was referred to the hospital by a GP because of heavy backpain. The GP suspected an aortic aneurysm. Defendant (emergency care specialist) diagnosed the pain as myalgia. Patient died a few days later. Aneurysm rupture was suspected to be the cause of death. At first instance, a reprimand was issued; defendant should have been more thorough in his examination, especially given the concern of the referring GP. In appeal, the measure was changed to a warning.</p> <p>Case 2017/030</p>
Close contact between health care workers involved is necessary, especially in acute situation with imminent danger for the patient.	<p>Case 10192b: A radiologist diagnosed a type A dissection of the ascending aorta. At first instance, a reprimand was issued because the radiologist should have contacted the treating doctor directly, either in person or by phone, given the imminent danger for the patient. In appeal, the reprimand was revoked, because the radiologist was able to prove that direct contact indeed took place.</p> <p>Case 2016/306</p>
Providing information within your own area of expertise is sufficient.	<p>Case 2016-214c: It suited his role as an ICU-specialist to limit information provision to the reason for ICU-admission (dyspnea), and to not go outside his area of expertise by commenting on areas that should be covered by his colleagues (TEVAR complications).</p>

Table 3: An overview of considerations of the courts, in order of the number of relevant cases per consideration. (*continued*)

Lessons learned	Relevant cases
Circumstances taken into account	
Presenting yourself open to feedback is appreciated by the courts and plays a role in deciding on the appropriate measure.	Case 2017/030: A resident decided, without contacting a supervisor, that a patient with a dilated aortic bifurcation and a large iliac aneurysm did not have to be seen the same day. Rupture occurred the next day, necessitating emergency surgery. A warning was issued. However, the court appreciated the fact that defendant presented himself open to feedback.
	Case 149/2014: Defendant showed serious malpractice when performing surgery on patients with a ruptured aortic aneurysm. The court prohibited defendant to perform any form of surgery again. The fact that defendant showed little understanding of his wrongdoing was frowned upon by the court.
	Case G2011/22: It was noted that defendant showed insufficient self-reflection and little sense of responsibility.
	Cases: 10192b, 10192a, 2016/306, 2016/018, 2016/034, 012/2015, 181/2017
Implemented improvements by defendants after receiving a complaint are taken into account when judging a case.	Case 139/2016: The court appreciated that the emergency GP-post altered their reporting system to improve adequate documentation.
	Case 2016/306: A radiologist diagnosed an aortic and iliac dilation. Given the size of the iliac aneurysm (51mm), defendant should have directly contacted a vascular surgeon, instead of referring patient back to her GP. A warning was issued. However, the court took into account that defendant had altered the in-hospital guidelines following this case and was open to feedback.
	Case 2013/227: Defendant implemented improvements into his way of work. However, the misconduct was of such gravity that a less severe measure did not suffice. A reprimand was imposed.
	Cases: 2017/030, 2016/018, 2016/034, 181/2017
Being a 'first time offender' is of relevance and can lead to a less severe measure.	Cases: 263/2016, 2016/018, 2016/034, 012/2015, G2011/22
Expressing regret and offering an apology after a culpable act is appreciated.	Cases: 2016/018, 10192a
A high workload does not excuse defendants of providing optimal care.	Case 10192a: Defendant failed to read a CT-scan report the same day the scan was made, and once he read the report, he overlooked the notation of an aortic dissection twice. Patient was sent home and died. As defendant recognizes himself, a heavy workload does not justify this error.
	Case 10192b

Abbreviations: AAA: abdominal aortic aneurysm, CT: computed tomography, GP: general practitioner, ICU: intensive care unit, TEVAR: thoracic endovascular aortic repair

Table 4: A simplified overview of the organization of medical disciplinary law in other (Western) countries.

Country	Responsible authority	(Main) plaintiffs
Belgium	Provincial board of the professional association of doctors	Doctors and 'third parties'
France	Professional association's disciplinary board	Patients, medical professionals, public organizations
Germany	Chamber of Physicians (under the professional code)	Patients, relatives
Greece	Disciplinary Boards of the regional medical chambers	Patients
Italy	Provincial associations	Patients or a magistrate, The Ministry of Health, and associations themselves
Poland	Medical Courts (inquiry by the Screener for Professional Liability)	Patients, any other party that provides credible information pertaining to an offence
Spain	Provincial college of the Doctor's Association	Patients, doctors, the courts
The Netherlands	Disciplinary courts	Parties with a direct interest
United Kingdom	General Medical Council, Fitness to Practice Panel	Patients, medical professionals
United States	State medical boards	General members of the public, physicians, hospitals/entities

Supplementary Table S1: Available online:
[https://www.annalsofvascularsurgery.com/article/S0890-5096\(24\)00393-5/fulltext](https://www.annalsofvascularsurgery.com/article/S0890-5096(24)00393-5/fulltext)

Measures	Goal	Specialties
Warning, censorship, reprimand, suspension, license revocation	To protect the collective interest and quality of health care.	Reconciliation and mediation are more and more strived for.
Warning, reprimand, (provisional) suspension of max. 3 years, license revocation	Upholding the necessary principles of honesty, competence, and morality.	Each procedure starts with an attempt to mediation by the mediation board.
Warning, admonition, fine, statement of unworthiness	Monitoring the compliance to professional standards.	Other options are: procedures under federal law and out-of-court arbitration procedures on liability.
Admonition, fine, suspension, withdrawal of license	To judge in cases of misconduct by members.	Disciplinary Boards consist of medical professionals.
Warning, admonition, suspension up to 6 months, removal from the register (request of re-registration possible after 5 years of impeccable behavior)	To judge violations of the rules of good conduct and of the standards established in the Code of Ethics.	Hearings are not open to the public and legal representation is not possible for defendants.
Admonition, reprimand, suspension up to 3 years, ban from practicing without the right to reregister	To assess whether defendants acted according to the code of ethics and regulations pertaining to the doctor's profession.	Members of the professional liability bodies are doctors chosen by medical conventions for a 4-year term.
Agreement between parties through mediation, suspension, removal of registration, transferal to a court of law	To assess fitness to practice.	Many cases are handled in court by a court of law.
Warning, reprimand, fine, (provisional) suspension, partial interdict, license revocation	To guard and improve the quality of individual health care.	No monetary compensation possible within disciplinary law.
Warning, conditions on the doctor's registration, suspension, license revocation	Protecting patients and the wider public interest against unfit doctors.	A panel consists of professionals and laymen.
Advisory letter, reprimand, fine, mandatory education/treatment, probation, license restrictions, license revocation	To protect medical consumers from potential harm.	Monetary compensation possible in civil procedures.

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General discussion implications

and

1. MAIN GOALS AND CORRESPONDING FINDINGS

The main goals and corresponding findings of this thesis were:

1. Analyzing the introduction of complex EVAR within the Leiden University Medical Center; a medium-volume tertiary referral center (Part 1).

In **Chapter 1**, a learning curve analysis of the introduction of complex EVAR in the LUMC was presented, based on the first 90 patients that were treated. A decrease in operating time and length of hospital stay implicated that technical learning took place. No significant changes occurred between the three consecutive treatment groups regarding major adverse events (MAE) and 30-day mortality, although fewer cardiac complications occurred in the thirty most recently treated patients. Due to the set-up of this study and the available data, the shape of the underlying learning curve could not be provided. This chapter identified qualitative factors experienced by the endovascular treatment team (ETT) as a positive contributor to the learning process. Interviews with ETT members in 2017 were researched for these factors and compared to contributive elements known from literature. Adequate communication, mutual trust, and a clear authoritative structure were among the contributive factors found in our results and in literature. The element of 'mutual learning' was added; sharing knowledge beyond what is strictly necessary among team members, such as lessons learned during conferences. Some of these findings might seem obvious. 'Of course, team members should adequately communicate', readers might think. The interviewees, however, offered practical tools for implementation. For example: 'thinking out loud' within the operating room. The fact that these factors were explicitly mentioned, indicates that such behavior is not always self-evident. Interviewees tend to highlight things that stood out or surprised them, rather than stating what is considered obvious.

Descriptives on the number of fenestrations and the complexity scores seemed to imply that complexity increased over time. This was also experienced as such by the members of the treatment team. However, this trend did not reach statistical significance. The discrepancy between the feeling of increased complexity among the ETT and this non-significant trend might be caused by the fact that the complexity score was solely based on stent graft configuration and did not include other factors that might increase complexity, such as treating increasingly frail patients and taking on aneurysms with challenging anatomy. It was hypothesized that with the introduction of complex EVAR, more (frail) patients were treated compared to the open surgical treatment era; a hypothesis that was further investigated in Chapter 3, and will be discussed below.

In **Chapter 2** postoperative outcomes of 82 complex EVAR procedures were presented, with a focus on functional outcomes; a critically important yet underexposed outcome. In the total cohort, almost all patients were able to return home. A subgroup analysis of 23

patients included in functional performance follow-up at 12 months showed that 5 of them suffered functional decline, mainly by losing independence in bathing, getting dressed, and shopping. Studies on conventional EVAR and OSR showed comparable numbers of functional decline and higher numbers of non-home discharge. Functional decline following complex EVAR is definitely not negligible in an absolute sense, especially when mortality is taken into account, yet these results remain relatively promising compared to other research. Of course, the subgroup included in functional analysis is very small. The discharge destinations perhaps provide more useful information in this cohort, as this was registered for almost all patients.

2. Identifying changes in the treated complex aneurysm population and analyzing whether sarcopenia could serve as a predictor of adverse outcomes in patient-selection (Part 2).

In **Chapter 3**, the perceived changes in the treated complex aneurysm patient population were further investigated by performing a descriptive analysis of complex aneurysm patients that were treated using either open or endovascular repair between 2008 and 2023. This analysis showed a steady increase in the number of complex aneurysm procedures. The current practice-based decision-making process seems to be able to select the frailest patients, for whom complex EVAR was preferred. Some of these patients would likely not have been treated in the pre-complex EVAR era. Although less invasive compared to OSR in the early postoperative stage when focusing on the number of major complications, 30-day mortality did not significantly differ between both groups. The frailest complex EVAR patients had a low estimated median survival time of about 3 years. When informing patients about the different treatment options, complex EVAR should not be pictured as non-invasive surgery, as the considerable perioperative risks cannot be ignored. The fact that treatment is technically possible does not necessarily mean that each patient will benefit from it. This is supported in guidelines stating that elective aneurysm repair is not suitable for patients with a limited life expectancy of 2-3 years.¹ Conservative management might have been a better option for some of our frailest patients.

It would be interesting to be able to predict which patients are most prone to adverse outcomes, in order to adequately inform patients and to support decision-making. In **Chapter 4**, three CT-assessed parameters of sarcopenia were examined regarding their association with adverse outcomes after complex EVAR. Results showed that PMI, SMI, and LPMA were all associated with mortality. When labeling patients as sarcopenic vs. non-sarcopenic, only sarcopenia based on SMI was associated with mortality. This could indicate that the cut-off values for PMI and LPMA were not suitable for complex EVAR patients. By adding physical performance parameters, a subgroup of severely sarcopenic patients was identified, who had a lower estimated survival. However, this subgroup was considered sarcopenic based on any of the parameters and therefore might be an

overestimation. In addition, analyzing a subgroup within a larger cohort could lead to false positive findings, although the subgroup was defined prior to data analysis and not selected by trial and error. Future research could validate sarcopenia cut-off values for complex EVAR patients. Being able to select high risk patients aids in clinical decision-making and identifies a group that might benefit from prehabilitation strategies.

3. Identifying pitfalls and discrepancies between the patient and professional perspective on patient information regarding complex aortic aneurysm care (Part 3).

Chapter 5 consisted of an exploratory interview study, interviewing 12 patients in different stages of the treatment process and 5 professionals involved in complex aneurysm care. Although the professionals, like the treatment guidelines, emphasized the appropriateness of conservative management for the frailest patients, most patients did not perceive this as a viable option. We hypothesized that this is due to the fear of aneurysm rupture; the feeling of 'living with a time bomb'. In this perspective, patients might overestimate the chance of aneurysm rupture, while underestimating their frailty and surgical risks. Treating the patient's fear should not be the main reason for complex aneurysm surgery. The reality of this fear, compared to the risks of surgery, should be addressed during preoperative counseling. Professional psychological counseling could be offered, addressing the concerns that might arise when a conservative treatment decision is made.

All but one of the interviewees underwent surgery, introducing selection bias. Including more patients who opted against surgery could nuance these patient perspectives. However, the decision not to treat is usually initiated by the treatment team, rather than the patient themselves. Patients' main concerns regarding surgery were not wanting to end up in a nursing home and the fear of losing independence. This is consistent with the literature findings in Chapter 2 on functional performance and emphasizes, again, the importance of research into functional outcomes.

Patients experienced a lack of information on the duration and symptoms of postoperative recovery, even though this is mentioned in the informational folder, and the interviewed professionals claimed to discuss this during their consultations. This may reflect a bias towards short-term thinking, with individuals focusing on what they perceive as immediate risks, such as aneurysm rupture and surgical risks, rather than postoperative recovery. It is important to be aware of this phenomenon, as it might lead to dissatisfaction regarding information provision. A patient journey was provided, which is a relatively new concept in health care. It provides insight in the path from diagnosis to treatment and could be used by professionals to identify the needs of patients and to inform patients on what to expect after receiving a complex aneurysm diagnosis. Of course, this patient journey is center-specific; not every step will be the same for each hospital and it should therefore be adjusted according to the center-specific care pathway. A simplified version of the patient journey could then be provided to the patient.

The interviews in Chapter 5 seemed to imply that, overall, patients were satisfied. However, patient dissatisfaction is not rare. In **Chapter 6**, patient complaints were researched, by analyzing ten years of Dutch medical disciplinary law on aortic aneurysm care. Forty-eight first instance and 19 appeal cases were included. Most cases concerned an accusation of a missed diagnosis. As this can have devastating outcomes, it is understandable that it causes distraught among patients and their relatives. You could wonder whether a national screening program would diminish these cases by early detection of aneurysms. Trials have shown a positive effect of screening programs on aneurysm related mortality, and screening has been proposed in the ESVS 2019 guideline.^{2,3} However, evaluation of screening programs in other countries showed mixed results. A study in Sweden indicated that the reduced mortality was more likely due to smoking cessation. In addition, screening could lead to overdiagnosis and avoidable surgery.^{4,5} The Dutch Health Council seems to tend more towards these negative findings by advising the Ministry of Health, Welfare and Sports against implementing a screening program.⁶

Courts attach great importance to the obligation of adequate documentation. Overall, information noted in the patient's file is considered accurate, unless there are plausible grounds to question its reliability. This is not because the courts favor medical professionals over plaintiffs, but is understandable given the fact that medical records are often the only source of information available to the courts. Although time consuming, documentation should be thorough. Another main finding of Chapter 6 is that inadequate communication often contributed to the complaint. This indicates that patients often experience a lack of effort on this front. Although this might not always lead to disciplinary culpability, it is very much undesirable. Clear communication, patient-involvement in (the reasoning behind) decision-making, and providing sufficient information could increase patient satisfaction, avert complaints, and prevent time-consuming trials. Chapter 5 aids in this matter, as it offers valuable insights in the patient perspective.

Several points of critique have been expressed against Dutch disciplinary law, one being its potential negative effect on defendants. Disciplinary trials cause stress, self-doubt, and the feeling of being criminalized and powerless.^{7,8} Some feeling of guilt or increased cautiousness is not necessarily problematic, but psychological and work-related problems are unwanted consequences. After all, this goes against the quality improvement goal of disciplinary law. On the other hand, research has shown that knowledge on disciplinary law among health care workers leaves something to be desired. Verdicts provide valuable insight in the analytical framework of the courts. Knowledge on the trial process and seeking legal assistance could diminish the feeling of being powerless.

2. RECENT LITERATURE

During the years it took to write this thesis, new insights on the main interests emerged. This shows that complex EVAR is a topical issue, but it can diminish the completeness of the chapters that were written before these insights were published. Therefore, this paragraph will briefly discuss the most recent findings in complex EVAR, relevant to this thesis.

2.1 Recent literature on Part 1

Mesnard 2023 et al. performed a learning curve analysis of a single early-career vascular surgeon and compared his outcomes to an experienced colleague within the same high-volume treatment center. The early-career operator had prior independent (T)EVAR experience in about 250 procedures, took part in over 50 complex EVAR procedures as a resident, and performed 24 procedures under direct supervision of his experienced colleague. A cumulative sum analysis showed that the individual performances of both surgeons regarding morbidity and mortality, were equal. In addition, there was no clear initial learning curve effect for the early-career surgeon, as outcomes were favorable from the start and remained stable thereafter. This indicates that complex EVAR can be safely adopted by early-career surgeons with previous experience and training in (complex) aneurysm care. It should be noted, however, that these results are surgeon-specific and that the early-career surgeon in this study had quite a lot of experience already.⁹

Borzák 2022 et al. provided a complex EVAR learning curve of a treatment team experienced in conventional EVAR, in a small-volume hospital. The first 20 FBEVAR procedures, performed over the course of two years, were analyzed. Thirty-day mortality (5%) was comparable to higher-volume centers, although the initial technical success of 65% was lower. The authors decided that complex EVAR can be safely adopted by a (low-volume) treatment center experienced in conventional EVAR. However, a Dutch nationwide study on hospital volume associated mortality after complex EVAR, showed that an annual volume of 13 or greater was associated with less perioperative mortality compared to hospitals with a volume of less than 9 cases per year.¹⁰ A study among 15 centers performing complex EVAR in the United States showed no difference in outcomes between low (1-3 cases/year) and high-volume (4-6 cases/year), although it could be argued whether a center performing 6 cases per year can be determined as high-volume.¹¹

2.2 Recent literature on Part 2

In 2021, a nationwide cohort study was announced in the United Kingdom, comparing clinical and cost-effectiveness of open repair vs. complex EVAR (UK-COMPASS).¹² Patients undergoing conservative management are included to perform a quality-of-life comparison between surgically treated and medically managed patients. One of the goals was to establish the clinical and cost utility of FEVAR in patients considered unfit for OSR, and to compare this against non-surgical management. Early findings have

been presented during the Vascular Society of Great Britain and Ireland annual scientific meeting. These results indicate that on the long term, all-cause mortality was lower for OSR compared to FEVAR, although FEVAR does appear to be equivalent to OSR in case of short-neck aneurysms. In addition, FEVAR presented with significantly more mid-term reinterventions compared to conventional EVAR. Based on these preliminary results, it was posited that patients who survive surgery might not gain the survival benefit treatment teams hope for, which emphasizes the need for adequate patient selection.^{13,14}

2.3 Recent literature on Part 3

Efforts are being made to incorporate patient preferences into the decision-making process in vascular surgery. The OVIDIUS trial (Operative Vascular Intervention Decision Making Improvement Using SDM tools) investigated whether decision support tools, such as apps and consultation cards, would aid in this matter. These tools significantly improved the level of shared decision-making and knowledge of vascular surgery patients, although in a subgroup analysis of AAA patients this was not significant. It did show, however, an increase in the number of AAA patients choosing non-surgical treatment choices when using such tools (21.4% vs. 28.8%), without being associated with a lower quality of life or greater decisional conflict. This further supports our findings that conservative management is an underexposed topic in current decision-making practice.¹⁵

3. GENERAL LIMITATIONS

Study-specific limitations have been discussed in each of the previous chapters and in paragraph 1 of the current chapter. Below, the remaining general limitations of this thesis will be presented.

One of the main goals of this thesis was to analyze the implementation and outcomes of complex EVAR within the LUMC. Inclusion was therefore limited to the number of patients being treated in this center, which results in a relatively small patients cohort compared to multi-center studies or studies within high-volume centers. The external validity of the results is therefore confined by restricted generalizability. Words like 'might', 'could', 'potentially', and 'possibly' are often added to the statements presented. A second limitation is the fact that the idea of analyzing the implementation and outcomes of complex EVAR arose several years after its introduction. Data were gathered retrospectively, and analyses were therefore limited to the data that were present in patient files.

The qualitative data in Chapter 1, 5, and 6 is analyzed and, in a way, constructed by the researchers. It is therefore prone to bias due to interpretation. Discussing the results between multiple authors with different professions aimed to limit this bias by inviting different views. Information on the authors' roles and perceptions is of interest and will

be provided here. Data analysis in Chapter 5 was performed in collaboration with an interventional radiologist, vascular surgeons, and authors trained in the field of inter-professional teamwork and patient participation. Chapter 6 was written by the author of this thesis, trained in medicine and health law, and by three vascular surgeons, one being a member of a Regional Disciplinary Court. The qualitative results were subject to interpretation, albeit by multiple authors with different views, who reached consensus.

Advancing perceptions and newly published research on complex EVAR led to new insights regarding the way outcomes are best presented. Not only did the endovascular treatment team undergo a learning curve, but, as is common over the course of PhD-research, so did the author of this thesis. The outcomes in Chapter 3 are therefore presented slightly different than in Part 1 of this thesis. For example, technical success was no longer defined in the strict way of 'all arteries treated successfully as planned', according to which each aberration of the preoperative plan would be classified as non-technical success, even if this resulted in a functioning endograft. Instead, a more commonly used definition was used, based on the definition provided by authorities on complex EVAR in the *Journal of Vascular Surgery*.¹⁶ Furthermore, in contrast with Part 1, emergency and Arch-EVAR cases were excluded in Chapter 3 as is done in most other studies. The perioperative outcomes of these patients are significantly worse compared to elective complex EVAR. Including these cases would impede meaningful comparison. It is important to note these changes, as not recognizing them might cause confusion when interpreting the results in the different chapters.

The three different parts of this thesis consisted of quite broad subjects. Although a bit of a platitude, each topic could serve as a thesis subject on its own.¹⁷ It is acknowledged that the results presented in this thesis do not answer all questions that arise. From the start, this has not been the goal of this thesis, as it aimed to provide an overview of the implementation of complex EVAR in the LUMC and to give insight in patient preferences regarding complex aneurysm management. More rigorous analyses could definitely be performed, should more patients be included. This will be further stated in the paragraph on implications for future research below.

4. IMPLICATIONS

4.1 Implications for policy-making

Over the last decade, the quality of aortic aneurysm and dissection care has been a topic of discussion in the Netherlands, with an emphasis on procedure volume and experience of treatment teams. Since 2013, all aortic aneurysms procedures are registered in the Dutch Surgical Aneurysm Audit (DSAA), to monitor surgical outcomes and provide hospitals with feedback on their performances.¹⁸ In 2023, the Ministry of Health, Welfare and Sports introduced a plan to centralize (complex) vascular surgery. According to the

ministry, only high-volume centres of excellence (50-100 surgeries per year) should be allowed to perform certain complicated procedures. The idea is to improve the quality of care by centralizing knowledge and experience.^{19,20}

Although this is an admirable objective and centralization of knowledge, experience and resources has proven to raise performance in the past, the results in this thesis showed that a lower-volume hospital (<20 complex EVAR cases per year) can reach comparable mortality and morbidity outcomes to higher-volume centres, as well as acceptable functional outcomes and patient satisfaction. In addition, we addressed the organizational challenges that come with the introduction of complex EVAR; the need for a dedicated multidisciplinary treatment team, manufacturer contracts, and the ability to be able to adapt to a growing and frailer patient cohort, with complex EVAR becoming the preferred treatment modality soon after its introduction. These challenges should be considered when rearranging the distribution of care.

4.2 Clinical implications

When complex EVAR is implemented in a hospital, attention should be paid to team learning, focussing on the positive learning curve factors proposed in this thesis. In addition, it is important to identify and address patient preferences. For example, the fact that most patients fear functional decline or discharge to a nursing home, could be addressed during consultation by providing data on center-specific postoperative outcomes. Health care professionals should realize that there is a difference in the perception of conservative management between patients and doctors. Most patients regard conservative management as a non-realistic treatment option. The fear of aneurysm rupture seems to be greater than the fear of postoperative complications. For some patients, having to live with the fear of rupture seems like no life at all. They are anxious to undertake activities that provide them joy. The reality of this fear, compared to the risks of surgery, should be addressed during preoperative counseling. Professional psychological counseling could be offered, addressing the concerns that might arise when a conservative treatment decision is made.

Patients experienced a lack of information on what to expect during postoperative recovery. Whether this was really not discussed or a result of bias towards short-term thinking, it is an issue that warrants attention in order to prevent patient dissatisfaction. By repeating information on the recovery period during pre-surgery consultation, at hospital discharge, and during postoperative follow-up, unpleasant surprises can be prevented. In addition, providing this information via a patient expert could have a stronger impact, as a personal story might appeal more to the imagination.

Patients were adamant to talk about the doctor-patient relationship. They appreciated a kind and non-authoritative doctor, who was available to answer questions and allowed for a personal aspect in the doctor-patient relationship. Of course, each doctor's way

of work is different. Independent of one's style, however, it is important to realize that the doctor-patient relationship very much impacts the way patients experience the provided care. This is supported by the fact that miscommunication was often at the root of disciplinary complaints. Clear communication and some level of personal engagement with patients seems important to maintain a satisfactory doctor-patient relationship and to avoid complaints. Several decision support tools (DSTs) have been and are being researched to aid in determining patient preferences. In addition, once a decision to treat is made, a patient journey as presented in this thesis could be used to provide patients insight in the road to come. Once a disciplinary complaint is filed, courts attach great importance to adequate documentation. Overall, information noted in the patient's file is considered accurate, unless there are plausible grounds to question its reliability. Although time consuming, documentation should be thorough.

4.3 Future research

Future research into complex EVAR should include functional performance outcomes. Preserving independence and being able to live at home are factors that complex aneurysm patients find most important. By gathering data on functional performance in a prospective standardized way, sufficient patient numbers can be reached to perform adequate analyses. Preferably, research should individualize the different types of complex EVAR, in order to analyze FEVAR, BEVAR, and Arch-EVAR separately.

In addition, more research should be performed into baseline characteristics that are associated with adverse outcomes after complex EVAR. This would help in decision-making and, if modifiable, could be a target of prehabilitation. Frailty scores and cut-off factors for sarcopenia could be researched in a larger cohort of complex EVAR patients, to compose predictive factors that can be used for complex EVAR patients in general. In addition, effort could be made to construct a complex EVAR complexity score. The complexity score that was used in this thesis, based on stent graft configuration, was not able to depict the perceived increased complexity of the procedures over the years.

With more results on postoperative morbidity, mortality, and functional performance coming to light, we get a better idea of life after complex aneurysm surgery. It shows that a certain frail patient group might not benefit as much from surgery as we had hoped. At the same time, new research suggest that annual aneurysm rupture rates might be lower than previously reported.^{21,22} Treatment is considered opportune if the risk of rupture exceeds the surgical risks. Based on previous research, the treatment threshold for complex aneurysms was established at around 6 cm. However, when rupture and surgical risks change, a new equation must be made. The frailest patients in **Chapter 3**, with a mean aneurysm size of 6.7 cm, had a 1-year mortality of 23.8%, while their cumulative rupture rate at 12 months would have been about 4.5% based on these newest numbers. It might be time to perform research into potentially raising the treatment threshold, as some patients would benefit more from (a longer period of) conservative management.

With the exception of one interviewee in Chapter 5, no complex aneurysm patients that ended up not having surgery were included. Incorporating complex aneurysm patients that received conservative management, would be a valuable contribution to complex EVAR research.²³ Long-term follow-up of these patients can offer insights into the rationale behind opting for non-surgical management, their functional performance, life expectancy, causes of death, and psychological well-being. Such findings are crucial for well-informed decision-making. A patient's fear of aneurysm rupture should not be the sole reason for surgical treatment. However, this fear often serves as a barrier for the discussion all treatment options. Recognizing and addressing a patient's fears and concerns contributes to treatment decisions genuinely reflecting a patient's preferences and quality of life considerations.

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Summary

Dutch summary

Curriculum vitae

List of publications

Acknowledgements

Abbreviations

of the author

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SUMMARY

Introduction

An aortic aneurysm is a dilation of the body's greatest artery to at least 1.5 times its usual size. The aorta has multiple side branches to vital organs, such as the kidneys. An aneurysm can arise in each part of the aorta. When it includes or is located close to side vessels, it is called a *complex* aneurysm. Aneurysms are asymptomatic and therefore usually go unnoticed until (imminent) rupture occurs. Aortic aneurysm rupture is highly lethal, with the risk of rupture increasing as the aneurysm enlarges. Once the risk of rupture exceeds the risks of surgery, a treatment decision has to be made. Treatment is usually recommended once a complex aneurysm reaches a diameter of 6 cm.

Previously, open surgical repair (OSR) was the only available treatment option for complex aortic aneurysms. During OSR, the aneurysm is reached by opening the abdomen or retroperitoneal cavity. The 'diseased' part of the aorta is replaced by a graft. The need for aortic clamping, single-lung ventilation, and long-lasting anesthesia exposes the patient to an immense hemodynamic impact. Building on experience in conventional aneurysm care, *complex endovascular aortic repair* (complex EVAR) has been developed as a less invasive treatment option. Large abdominal incisions are no longer necessary. Instead, access is gained via the groin, to deploy a stent within the aneurysm. The aneurysm sac remains, but the blood circulation into this diseased part of the aorta is cut off and now flows through the stent. In order to maintain visceral perfusion, the aneurysm's side vessels are included in the stent by using fenestrations (circumferential windows in the device) or branches. It was mainly introduced as a treatment option for frail patients, considered unfit for OSR.

This exponential technical development, literally, comes at a cost. Fenestrated and branched stents are usually custom-made for each patient to exactly align with the patient-specific anatomy. In addition, it is hypothesized that with the introduction of complex EVAR, more (frail) patients are being treated, which further contributes to health care costs. Aside from monetary drawbacks, there are technical difficulties involved. Complex EVAR requires advanced technical appliances, a multidisciplinary treatment team, manufacturer contracts, and the ability to provide the necessary postoperative care and follow-up. Therefore, the implementation of complex EVAR is a demanding process, not possible in every treatment center. Another important consideration when treatment options expand, is deciding which patients should be treated. This not only means deciding between complex EVAR and OSR, but also between conservative treatment of awaiting the natural course of the aneurysm for the frailest patients. Although less invasive compared to OSR, complex EVAR still comes with considerable perioperative risks and rehabilitation. The fact that treatment is technically possible, does not necessarily mean that each patient will benefit from it. For some patients, complex EVAR might be a bridge too far.

This thesis examines how complex EVAR was implemented in a tertiary referral center in the Netherlands; the Leiden University Medical Center (LUMC). It presents the first postoperative outcomes, with a focus on postoperative functioning. It discusses the learning curve and the qualitative aspects that are important when implementing a new technique. In addition, it focuses on patient selection; what changed with the introduction of complex EVAR, and which factors might be associated with negative postoperative outcomes? The final part focuses on perioperative information provision and lessons learned from complaint procedures regarding aortic aneurysm care.

Main goals and corresponding findings

1. Analyzing the introduction of complex EVAR within the Leiden University Medical Center; a medium-volume tertiary referral center (Part I).

A learning curve analysis of complex EVAR in the LUMC was presented based on the first 90 patients that were treated. A decrease in operating time and length of hospital stay implicated that technical learning took place. Fewer cardiac complications occurred in the thirty most recently treated patients and procedure complexity seemed to increase, while no significant changes occurred between the three consecutive treatment groups regarding other major adverse events (MAE) and 30-day mortality. Interviews with the endovascular treatment team (ETT) members identified factors experienced as positive contributors to the learning process. Adequate communication, mutual trust, and a shared sense of responsibility were among the contributive factors found in our results and in literature. The element of 'mutual learning' was added; sharing knowledge beyond what is strictly necessary among team members. Some of these findings might seem a bit obvious. 'Of course, team members should adequately communicate', readers might think. The fact that these factors were explicitly mentioned, however, indicates that such behavior is not always self-evident. Interviewees tend to highlight things that stood out or surprised them, rather than stating what is considered obvious.

Postoperative outcomes of 82 complex EVAR procedures performed between 2013 and 2020, showed that almost all patients were able to return home. Fifteen patients (18.3%) were temporarily admitted to a rehabilitation center. A subgroup analysis of 23 patients included in functional performance follow-up at 12 months, showed that 5 of them suffered functional decline, mainly by losing independence in bathing, getting dressed, and shopping. Four patients of this subgroup were deceased at 12 months post-surgery. Studies on conventional EVAR and OSR showed comparable numbers of functional decline and higher numbers of non-home discharge. Functional decline following complex EVAR is definitely not negligible in an absolute sense, especially when mortality is taken into account, yet these results remain relatively promising compared to other research, given the frailty of this group.

2. Identifying changes in the treated complex aneurysm population and analyzing whether sarcopenia could serve as a predictor of adverse outcomes in patient-selection (Part 2).

In 2024, the perceived changes in the treated complex aneurysm patient population were investigated by performing a descriptive analysis of complex aneurysm patients that were treated using either open or endovascular repair between 2008 and 2023. Between 2008 and 2023, 122 open procedures were performed, while 119 complex endovascular procedures were performed between 2013 and 2023. When the ETT preferred OSR over complex EVAR, it was mainly based on the aneurysm's anatomy. An important reason for choosing complex EVAR was either the patient's preference (n=49), or the fact that the ETT considered the patient unfit for OSR (n=47). The current practice-based decision-making process seems to be able to select the frailest patients, for whom complex EVAR was preferred. Some of these patients would likely not have been treated in the pre-complex EVAR era. Although less invasive compared to OSR in the early postoperative stage when focusing on complications, 30-day mortality did not significantly differ between both groups. The frailest complex EVAR patients had a low estimated median survival time of about 3 years, with a 1-year mortality of 23.8%.

The fact that treatment is technically possible does not necessarily mean that each patient will benefit from it. This is supported in guidelines stating that elective aneurysm repair is not suitable for patients with a limited life expectancy of 2-3 years. Conservative management might have been a better option for some of our frailest patients. It would be interesting to be able to predict which patients are most prone to adverse outcomes. Some predictive factors might be optimized prior to surgery, such as sarcopenia. Three CT-assessed parameters of sarcopenia were examined regarding their association with adverse outcomes after complex EVAR. Results showed that low muscle mass was associated with higher mortality. However, adequate cut-off values labeling patients as sarcopenic vs. non-sarcopenic have yet to be developed for complex EVAR patients.

3. Identifying pitfalls and discrepancies between the patient and professional perspective in patient information regarding complex aneurysm care (Part 3).

Once the treatment threshold is reached, a decision has to be made. It is important to consider patient preferences. An explorative interview study was performed, interviewing 12 patients in different stages of the treatment process and 5 professionals involved in complex aneurysm care. Although the professionals, like treatment guidelines, stress the possibility of conservative management for the frailest patients, most patients did not regard conservative management as a realistic option. We hypothesized that this is due to the fear of aneurysm rupture; the feeling of 'living with a time bomb'. In this perspective, patients might overestimate the chance of aneurysm rupture, while underestimating their

frailty and surgical risks. The reality of this fear, compared to the risks of surgery, should be addressed during preoperative counseling.

Patients experienced a lack of information on the duration and symptoms of postoperative recovery, even though this is mentioned in the informational folder, and the interviewed professionals claimed to discuss this during consultations. This may reflect a bias towards short-term thinking, with individuals focusing on what they perceive as immediate risks, such as aneurysm rupture and surgical risks, rather than postoperative recovery. It is important to be aware of this phenomenon, as it might lead to dissatisfaction regarding information provision. All patients were adamant to talk about their (positive) experience with the doctor-patient relationship, expressing that this element of the treatment process requires sufficient care and consideration.

Although the interviewees were satisfied with the information provision, it is important to be aware of factors that might cause patient dissatisfaction, or even official complaints. A literature study, analyzing Dutch medical disciplinary law on aortic aneurysm care, showed that most cases concerned an accusation of a missed diagnosis. In essence, inadequate communication often contributed to the complaint. This indicates that patients often experience a lack of effort on this front. Courts attach great importance to the obligation of adequate documentation. Clear communication, patient-involvement in (the reasoning behind) decision-making, and providing sufficient information could increase patient satisfaction, avert complaints, and prevent time-consuming trials.

Conclusion and implications

The introduction of a new technique such as complex EVAR requires a dedicated multidisciplinary treatment team and available resources. Team member should realize that communication, mutual trust, a shared sense of responsibility, and mutual learning contribute to a successful learning curve. In the era in which complex EVAR was introduced in the Leiden University Medical Center, the number of treated complex aneurysms increased, and complex EVAR became the preferred treatment method soon after its introduction. Patient frailty increased, while postoperative morbidity and mortality remained comparable over time and in relation to other treatment centers.

However, the frailest complex EVAR patients, considered unfit for OSR, had a limited survival time. This is the cohort that would likely not have been treated in the pre-complex EVAR era. While professionals involved in complex EVAR care consider conservative management as an appropriate option in select cases, patients often perceive it as an unrealistic choice. Aneurysm rupture is a great fear. At the same time, patients seem to underestimate the surgical risks and have a bias towards short term thinking. This causes some discontent regarding the preoperative information provision. As dissatisfaction regarding communication is a main cause of patient complaints, it is a topic that requires great attention.

Summary

A first initiative was made regarding research into postoperative functioning after complex EVAR. Remaining independent and returning home is one of the main patient preferences in deciding whether to undergo treatment. Prospective research in larger patient cohorts could be a next step. To further optimize patient information provision, future research should include complex aneurysm patients that underwent conservative management. Results on their quality and duration of life would be valuable information to add to the decision-making process. A patient's fear of aneurysm rupture should not be the sole reason for surgical treatment. However, this fear often serves as a barrier for discussing all treatment options. Recognizing and addressing a patient's fears and concerns contributes to treatment decisions genuinely reflecting a patient's preferences and quality of life considerations.

DUTCH SUMMARY (NEDERLANDSE SAMENVATTING)

Inleiding

Een aneurysma van de aorta is een verwijding van de grootste lichaamsslagader tot ten minste 1.5x de normale diameter. De aorta heeft meerdere zijtakken naar vitale organen, zoals de nieren. In elk gedeelte van de aorta kan een aneurysma ontstaan. Wanneer een aneurysma gelokaliseerd is ter hoogte van de zijtakken naar de buikorganen, wordt het een *complex* aneurysma genoemd. Het grote risico van een aneurysma is een ruptuur. Aangezien de aorta de grootste slagader van het lichaam is, treedt bij een ruptuur snel massaal bloedverlies op, met een grote kans op overlijden. Hoe groter het aneurysma, des te groter de ruptuurkans. Het is dus van belang om een aneurysma op tijd te behandelen. Wanneer het risico op een ruptuur groter is dan het risico op operatieve complicaties, moet een behandelbeslissing worden genomen. Over het algemeen wordt een behandelgrens van 6 cm in diameter aangehouden voor complexe aneurysmata.

Voorheen konden complexe aneurysmata enkel behandeld worden middels een open operatie, waarbij de buik van de patiënt middels een grote incisie geopend wordt, de aorta boven en onder de verwijding wordt afgeklemd en het 'zieke' stuk van de arterie wordt vervangen. Voor fragiele patiënten kan deze ingreep een brug te ver zijn. Er werd daarom gezocht naar minder invasieve endovasculaire behandelvormen, zoals voor niet-complexe aneurysmata reeds mogelijk was in de vorm van *endovascular aortic aneurysm repair* (EVAR). Hierbij wordt een stent via de lies van de patiënt in het aneurysma gebracht, zodat de bloedcirculatie voortaan door de stent stroomt en niet langer druk uitoefent op de verzwakte vaatwand van het aneurysma. Uiteindelijk werd zo'n 20 jaar geleden *complex EVAR* ontwikkeld, waarbij de aftakkingen van het aneurysma door fenestraties (FEVAR) of zijtakken (*branches*, BEVAR) worden geïncorporeerd in de stent. Bij deze procedure is geen grote incisie nodig, is het bloedverlies beduidend minder en de hemodynamische impact kleiner. Wel is levenslange follow-up voor eventuele stent gerelateerde complicaties nodig; denk aan lekkage, migratie, en infectie. Het werd daarom met name geïntroduceerd als een optie voor fragiele patiënten, voor wie een open procedure niet geschikt was.

Deze technische ontwikkeling komt echter wel met enkele kanttekeningen. Zo moet elke stent op maat gemaakt worden voor de patiënt, wat kostbaar is qua tijd en geld. Het gaat gepaard met technische en organisatorische uitdagingen, die niet elk ziekenhuis zal kunnen implementeren. Bovendien zou het behandelen van meer zwakke patiënten kunnen leiden tot hogere gezondheidszorgkosten. Met de komst van nieuwe behandel mogelijkheden, breidt ook de patiëntselectie en patiëntinformatie uit. Het feit dat behandeling mogelijk is, betekent niet dat elke patiënt geschikt is en daarvan zal profiteren. Hoewel minder invasief dan open herstel, heeft ook complex EVAR niet te verwaarlozen perioperatieve risico's en een postoperatief herstel. Voor sommige patiënten is ook deze behandeling misschien een brug te ver.

Dit proefschrift onderzoekt de implementatie van complex EVAR in het Leids Universitair Medisch Centrum (LUMC), een tertiair verwijscentrum voor aneurysmata in Nederland. Het behandelt de eerste postoperatieve uitkomsten, met een focus op postoperatief functioneren. Het bespreekt de leercurve in het LUMC en de kwalitatieve aspecten die bij de implementatie van een nieuwe techniek en een nieuw team komen kijken. Ook wordt gekeken naar de patiëntselectie; wat is er veranderd met de introductie van complex EVAR en welke factoren kunnen als voorspeller van mogelijk negatieve uitkomsten fungeren? Het laatste deel richt zich op de preoperatieve informatievoorziening en welke lessen er te leren zijn uit tuchtklachten met betrekking tot aneurysmazorg.

Hoofddoelen en de bijbehorende bevindingen

1. Het analyseren van de introductie van complex EVAR in het Leids Universitair Medisch Centrum (LUMC) (deel I).

De leercurve van de introductie van complex EVAR in het LUMC tussen juli 2013 en april 2021 (na 90 behandelde patiënten) toonde een afname in operatietijd en een verkorting van de opnameduur. Ook nam het aantal cardiale complicaties af, terwijl de complexiteit van de procedures leek toe te nemen. De 30-dagen mortaliteit en andere ernstige complicaties bleven gelijk. Uit interviews met het behandelteam kwamen factoren naar voren die bijdragen aan een succesvolle leercurve, zoals communicatie, onderling vertrouwen en een gedeeld verantwoordelijkheidsgevoel. Het begrip 'gezamenlijk leren' (*mutual learning*) werd toegevoegd aan reeds bestaande literatuur, wat inhoudt dat het onderling delen van opgedane kennis, ervaring en nieuwe ontwikkelingen van positieve invloed is, ook wanneer dit niet strikt noodzakelijk is voor de uitvoering van ieders taak. Deze bevindingen lijken wellicht vanzelfsprekend; 'Natuurlijk moeten teamleden goed communiceren', denkt de lezer wellicht. De teamleden gaven echter concrete voorbeelden, die als handvat gebruikt kunnen worden bij het implementeren van deze begrippen, bijvoorbeeld: hardop denken in de operatiekamer. Bovendien wijst het feit dat deze begrippen in de interviews benadrukt worden erop, dat dit niet altijd vanzelfsprekend is. Geïnterviewden zullen eerder geneigd zijn factoren te benoemen die opvallend of verassend waren of nadere aandacht behoeven.

Een onderzoek naar de postoperatieve uitkomsten van complex EVAR patiënten tussen juli 2013 en september 2020 (n=82) toonde dat vrijwel alle patiënten postoperatief met ontslag naar huis konden. Vijftien patiënten (18.3%) werden tijdelijk opgenomen in een revalidatiecentrum. Er werden geen patiënten opgenomen in een verpleeghuis. Van 23 patiënten konden de preoperatieve en postoperatieve functionele scores (ADL en IADL) worden geanalyseerd. Deze analyse toonde dat vijf patiënten (21.7%) functionele achteruitgang rapporteerden 12 maanden postoperatief, met name door verlies in zelfstandigheid bij het wassen, aankleden en boodschappen doen. Vier patiënten waren overleden bij 12 maanden follow-up. Vergelijkbare studies naar conventionele EVAR patiënten toonden soortgelijke uitkomsten t.a.v. functionele achteruitgang, waarbij een

hoger aantal patiënten in een verpleeghuis werd opgenomen. Functionele verslechtering na complex EVAR is zeker niet te verwaarlozen, met name wanneer mortaliteitscijfers worden meegenomen, maar in vergelijking met ander onderzoek zijn deze resultaten voorzichtig positief gezien de kwetsbaarheid van deze groep.

2. Het beschrijven van veranderingen in de behandelde patiëntengroep met de invoering van complex EVAR en de associatie tussen sarcopenie en negatieve uitkomsten.

In 2024 werd een analyse verricht naar alle patiënten die sinds 2008 voor een complex aneurysma in het LUMC waren behandeld, zowel middels een open operatie als complex EVAR. Het doel was te achterhalen welke veranderingen er waren opgetreden in patiëntaantallen, de reden om voor een van beide behandelopties te kiezen en de mate van kwetsbaarheid van de patiënten. Tussen 2008 en 2023 kregen 112 patiënten een open procedure, terwijl tussen 2013 en 2023 119 patiënten complex EVAR ondergingen. Het aantal behandelingen per jaar steeg en complex EVAR was vanaf 2016, 3 jaar na de introductie, de behandeling van voorkeur. Wanneer het behandelteam voor een open procedure koos, was dit meestal vanwege een ongunstige anatomie voor complex EVAR. Een reden om voor complex EVAR te kiezen, was vaak de voorkeur van de patiënt (n=49) en wanneer een patiënt te kwetsbaar werd geacht voor open herstel (n=47).

Dit leidde tot meer comorbiditeit en een hogere kwetsbaarheidsscore onder de complexe EVAR patiënten. Het aantal postoperatieve serieuze complicaties was hoger na open herstel, maar het aantal heringrepen gedurende follow-up was hoger na complexe EVAR. Mortaliteitscijfers waren vergelijkbaar, hoewel de 47 patiënten die te kwetsbaar voor open herstel werden geacht een relatief korte overleving hadden van rond de 3 jaar, met een 1-jaarsmortaliteit van 23.8%. Wanneer patiënten geïnformeerd worden over de verschillende behandelopties is het van belang dat er een realistisch verwachtingspatroon t.a.v. de postoperatieve uitkomsten van complex EVAR wordt geschetst, aan de hand van de conditie van de patiënt. Het feit dat behandeling technisch mogelijk is, betekent niet dat elke patiënt gebaat is bij chirurgie. Deze opvatting wordt ondersteund door het feit dat richtlijnen electieve aortachirurgie afraden voor patiënten met een beperkte levensverwachting van 2-3 jaar. Niet opereren zou voor sommige van de meest kwetsbare patiënten wellicht een betere optie zijn geweest.

Het zou bijdragend zijn om vooraf te kunnen bepalen welke patiënten wel en welke patiënten geen baat zullen hebben van een complexe EVAR operatie. Sommige voorspellers van een slechte uitkomst kunnen preoperatief wellicht geoptimaliseerd worden, zoals een slechte voedingsstatus. Er werd daarom onderzocht of een lage spiermassa een voorspeller is van negatieve postoperatieve uitkomsten en hoe dit het beste gediagnostiseerd kan worden. Spiermassa werd berekend door het meten van de spieroppervlakte op een doorsnede van een CT scan, ter hoogte van de derde lumbale

wervel. Een lagere spiermassa was geassocieerd met een hogere mortaliteit. Er zijn echter nog geen duidelijke afkapwaardes voor een (te) lage spiermassa, oftewel sarcopenie, in de complex EVAR patiëntengroep.

3. Het identificeren van het patiënt perspectief en mogelijke valkuilen en discrepanties in perioperatieve informatievoorziening tussen zorgverleners en patiënten.

Wanneer de behandelgrens van een complex aneurysma wordt bereikt, moet een behandelbeslissing genomen worden. Het behandelteam, de patiënt en eventueel naasten moeten besluiten of er geopereerd gaat worden, en zo ja, op welke manier. Het is belangrijk om te weten wat patiënten van belang vinden bij het maken van zo'n beslissing. Een interviewstudie toonde dat patiënten en behandelaren anders denken over de optie van een afwachtend conservatief beleid bij een complex aneurysma. Leden van het behandelteam benadrukten in interviews dat dit soms een goede keuze kan zijn, terwijl patiënten dit niet als een reële optie zagen, voornamelijk door angst voor een ruptuur. Patiënten lijken het risico op een ruptuur te overschatten, terwijl de chirurgische risico's en hun kwetsbaarheid wordt onderschat. In hoeverre hun angst reëel is, in vergelijking tot de operatieve risico's, moet besproken worden in het preoperatieve proces om een realistisch beeld te scheppen.

Patiënten gaven aan dat er te weinig informatie werd verschaft over de postoperatieve herstelperiode, hoewel behandelaren aangaven dit wel te bespreken. Mogelijk is bij patiënten sprake van '*bias towards short term thinking*'; een focus op de korte termijn, gericht op de operatie en niet zozeer het traject daarna. Alle deelnemende patiënten spraken uitgebreid over hun (positieve) ervaring met de arts-patiëntrelatie. Dit geeft aan dat dit als een belangrijk onderdeel van de zorg wordt ervaren en voldoende aandacht behoeft.

Hoewel patiënten in de interviewstudie over het algemeen tevreden waren over de informatievoorziening, is het goed om beducht te zijn op mogelijk oorzaken van patiëntontevredenheid of zelfs klachten. We verrichtten daarom een literatuurstudie waarin alle tuchtrechtzaken met betrekking tot aneurysmazorg in Nederland sinds 2010 werden geanalyseerd. De meeste klachten bleken gericht op een, volgens de klager, gemiste diagnose. Veel van de klachten draaiden in essentie om communicatie. Dit geeft opnieuw aan hoe belangrijk het is om als zorgverlener de patiënt te betrekken in het zorgen besluitvormingsproces, waarbij de bevindingen uit de interviewstudie gebruikt kunnen worden om een inschatting te maken van wat patiënten het meest van belang achten.

Conclusie en aanbevelingen

De introductie van een nieuwe techniek als complex EVAR vereist een gemotiveerd multidisciplinair behandelteam en beschikbare technische en financiële middelen. Het besef dat communicatie, onderling vertrouwen, een gedeeld verantwoordelijk-

heidsgevoel en 'gezamenlijk leren' (*mutual learning*) bijdragen aan een succesvolle leercurve, is van belang bij het vormen van een team. In het tijdsbestek waarin complex EVAR werd geïntroduceerd in het Leids Universitair Medisch Centrum, is het aantal operaties voor complexe aneurysmata per jaar gestegen, werd complex EVAR binnen 3 jaar de behandeling van voorkeur en werden kwetsbaardere patiënten geopereerd. Direct postoperatieve morbiditeit en mortaliteit bleven grotendeels vergelijkbaar, ook met grotere centra elders in de wereld. De meest kwetsbare complex EVAR patiënten, die niet fit genoeg werden geacht voor open herstel, bleken een relatief korte overleving te hebben. Dit betreft de groep die in het pre-complex EVAR tijdperk waarschijnlijk niet chirurgisch zou zijn behandeld. Een conservatieve behandeling is voor deze groep het alternatief. Waar zorgverleners dit voor een selecte groep patiënten als een goede optie zien, lijken patiënten dit niet snel te overwegen. De angst voor een ruptuur is groot. Tegelijkertijd lijken patiënten de operationele risico's te onderschatten en is er een '*bias towards short term thinking*'. Dit zorgt voor enige ontevredenheid over de informatievoorziening. Uit de literatuur weten we dat ontevredenheid omtrent communicatie kan leiden tot officiële klachten, wat des te meer benadrukt dat dit aandacht blijft behoeven.

Dit proefschrift deed een eerste voorzet voor het doen van onderzoek naar functionele uitkomstmaten na complex EVAR. Het behoud van onafhankelijkheid en thuis kunnen blijven wonen, zijn belangrijke waardes voor de oudere patiënt. Prospectief onderzoek naar functionele uitkomsten met grotere patiëntaantallen zou een goede vervolgstap zijn. Om de informatievoorziening verder te optimaliseren, zou toekomstig onderzoek complexe aneurysma patiënten kunnen includeren die uiteindelijk geen chirurgische behandeling hebben ondergaan. Informatie over hun kwaliteit van leven en levensverwachting is waardevol voor het besluitvormingsproces. De angst van een patiënt voor een ruptuur moet niet de enige reden zijn om een aneurysma te opereren. Deze angst is echter wel de reden dat patiënten huiverig zijn om over een conservatieve behandeling te praten. Het erkennen en bespreken van deze zorgen draagt bij aan een behandelbeslissing die de voorkeuren en overwegingen omtrent kwaliteit van leven van patiënten daadwerkelijk weerspiegelt.

CURRICULUM VITAE OF THE AUTHOR

Britt Warmerdam was born in the hospital of interest of this thesis; Leiden University Medical Center (LUMC). She grew up in Noordwijkerhout and Wassenaar in a *'gezellige'* family with her parents Piet and Guda, although the tranquility often got disturbed by her two brothers. As a child, she wanted to become a farmer. During high school, however, she became interested in writing and policy making, which led her to study Law instead of Agriculturalism. In her second year, she realized that something was missing. She finished her Bachelor in Law and started studying Medicine at the LUMC, while finishing a Master's degree in Health Law to combine her two interests.



In the first year of her medical internships, Britt decided she wanted to perform research in the field of Surgery. Referred by her class mentor at the time, she came into contact with drs. Jan van Schaik, dr. Joost van der Vorst, and professor Hamming. What started as a research internship, resulted in a PhD trajectory, very much supported by the outstanding guidance of the above-mentioned supervisors, and their willingness to let Britt include her own interests and ideas into the process. During this trajectory, Britt was able to attend conferences, lectures, and a course in statistics by the Leiden University. In addition, she enjoyed sparring with professionals within different fields related to her research.

Although Britt very much enjoyed her research time in vascular surgery, it could not convince her to become a general surgeon. During a rotation in Otorhinolaryngology in Haaglanden Medical Center (HMC), she decided she wanted to become an Ear, Nose, Throat (ENT) specialist. Upon graduating Medicine, she started as an ENT resident in the University Hospital of Antwerp, Belgium. After finishing this residency, having seen virtually nothing of the Antwerp city life but having gained a lot of experience, she returned to the HMC to work as a resident for 5 more months, before being accepted into the ENT program at the LUMC, where she is currently in her second year of training.

Britt lives in Utrecht and likes to spend her spare time windsurfing and learning to play the saxophone. She aspires to incorporate her interests in health law, policy making, and patient communication in her future career as an ENT doctor.

LIST OF PUBLICATIONS

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ABBREVIATIONS

AAA	abdominal aortic aneurysm
ACE-inhibitor	angio converting enzyme inhibitor
ACS	acute coronary syndrome
ADL	Activities of Daily Living
AF	atrial fibrillation
ASA-score	American Society of Anesthesiology score
AUMC	Amsterdam University Medical Centre
BEVAR	branched endovascular aortic repair
BMI	Body Mass Index
CI	confidence interval
cm	centimeter
complex EVAR	complex endovascular aortic repair
COPD	chronic obstructive pulmonary disease
CT	Computed Tomography
CVA	cerebral vascular accident
eGFR	estimated glomerular filtration rate
Endo	endovascular
ESVS	European Society for Vascular Surgery
ETT	endovascular treatment team
EVAR	endovascular aortic repair
EWGSOP	European Working Group on Sarcopenia in Older People
FBEVAR	fenestrated/branched EVAR
FEVAR	fenestrated endovascular aortic repair
GP	general practitioner
HU	Hounsfield Unit
IADL	Instrumental Activities of Daily Living
ICU	Intensive Care Unit
IQR	interquartile range
LPMA	Lean Psoas Muscle Area
LUMC	Leiden University Medical Center
m	meter
MAE	Major Adverse Events
MET	metabolic equivalent of task
METC	Medical Ethics Committee
mFI-5	modified 5-Item Frailty Index
MI	myocardial infarction
ml	milliliters
MNA	Mini Nutritional Assessment
n	number
NICE	National Institute for Health and Care Excellence

OR	open repair
OR	operating room
OSR	open surgical repair
OTS	Of-The-Shelf Endografts
PMA	Psoas Muscle Area
PMEG	Physician Modified Endo Graft
PMI	Psoas Muscle Index
PVD	peripheral vascular disease
Q	quartile
SD	standard deviation
SE	standard error
SMA	skeletal muscle area
SMA	superior mesenteric artery
SMI	Skeletal Muscle Index
SVS	Society for Vascular Surgery
TAA	thoracic aortic aneurysm
TAAA	thoraco-abdominal aortic aneurysm
TENT-study	Triage of Elderly Needing Treatment study
TEVAR	thoracic endovascular aortic repair
TIA	transient ischemic attack
TUG	Timed Up and Go-test
WMO-act	Medical Research Involving Human Subjects Act
6-CIT	6-item Cognitive Impairment Test

