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Advances in Complex Endovascular Aortic Repair

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DEPARTMENT OF CLINICAL SCIENCES | FACULTY OF MEDICINE | LUND UNIVERSITY



Advances in Complex Endovascular Aortic Repair

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Angelos Karelis



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DOCTORAL DISSERTATION

Doctoral dissertation for the degree of Doctor of Philosophy (PhD) at the Faculty of Medicine at Lund University to be publicly defended on date 31 of month Mars 2023 at 09.00 in Aghardsalen, CRC, Department of Clinical Sciences, Jan Waldenströms gata 35, Malmö

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Abstract The specific aims of this thesis were: <ol style="list-style-type: none"> 1. To evaluate the feasibility and outcomes of IBDs use to preserve the IIA perfusion in emergent endovascular repair of ruptured aorto-iliac aneurysms. 2. To evaluate the outcomes of presenting the IIA with IBDs during acute endovascular repair or ruptured aortoiliac aneurysms. 3. To investigate the changes in supra and infra-renal aortic neck diameters before and after EVAR for rAAA and the possible association with endograft apposition. 4. To report the outcomes of redo fenestrated and/or branched endovascular aortic repair to rescue previous failed FEVAR. 5. To evaluate the feasibility and efficacy of a modified delivery system of the distal bifurcated FEVAR component where the dilator tip was shortened to prevent damage to the renovisceral bridging stents. 		
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Angelos Karelis



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MADE IN SWEDEN 

To my family, friends, and teachers

*“The life so short, the craft so long to learn.”
— Hippocrates*

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Abbreviations

AAA	Abdominal aortic aneurysm
BEVAR	Branched endovascular aortic repair
CBCT	Cone beam computed tomography
CIA	Common iliac artery
CMD	Custom made device
CT	Celiac trunk
CTA	Computed tomography angiogram
DSA	Digital subtraction angiography
DTA	Descending thoracic aneurysm
DUS	Doppler ultrasound
EL	Endoleak
EVAR	Endovascular aortic repair
ESVS	European Society of Vascular Surgery
FEVAR	Fenestrated endovascular aortic repair
FU	Follow-up
GFR	Glomerular filtration rate
IBD	Iliac branch device
IBE	Iliac branch endoprosthesis
ICU	Intensive care unit
IIA	Iliac internal artery
IMA	Inferior mesenteric artery
IV	Intravenous
IVUS	Intravascular ultrasound
jAAA	Juxtarenal abdominal aortic aneurysm
LSA	Left subclavian artery
OAR	Open aortic repair
OSR	Open surgical repair

OTS	Off-The-Shelf
rAAA	Ruptured abdominal aortic aneurysm
rCIA	Ruptured common iliac artery aneurysm
SCI	Spinal cord ischemia
SMA	Superior mesenteric artery
TAAA	Thoracoabdominal aortic aneurysm
TEVAR	Thoracic endovascular aortic repair
TV	Target vessel

Original Papers

This thesis is based on the following papers, referred to hereafter by their Roman numerals:

- I. **Karelis A**, Dijkstra ML, Singh B, Vaccarino R, Sonesson B, Dias NV. The Use of Iliac Branched Devices in the Acute Endovascular Repair of Ruptured Aortoiliac Aneurysms. *Ann Vasc Surg*. 2020 Aug; 67:171-177.
- II. **Karelis A**, Sonesson B, Gallitto E, Tsilimparis N, Forsell C, Leone N, Silingardi R, Mesnard T, Sobocinski J, Isernia G, Resch T, Gargiulo M, Dias NV. Iliac Branch Devices in the Repair of Ruptured Aorto-iliac Aneurysms: A Multicenter Study. *J Endovasc Ther*. 2023 Jan 22:15266028221149922.
- III. van der Riet C, Schuurmann RCL, **Karelis A**, Suludere MA, van Harten MJ, Sonesson B, Dias NV, de Vries JPM, Dijkstra ML. Supra- and Infra-Renal Aortic Neck Diameter Increase after Endovascular Repair of a Ruptured Abdominal Aortic Aneurysm. *J Clin Med*. 2022 Feb 23;11(5):1203.
- IV. **Karelis A**, Haulon S, Sonesson B, Adam D, Kölbel T, Oderich G, Cieri E, Mesnard T, Verhoeven E, Dias N; contributors. Editor's Choice - Multicentre Outcomes of Redo Fenestrated/Branched Endovascular Aneurysm Repair to Rescue Failed Fenestrated Endografts. *Eur J Vasc Endovasc Surg*. 2021 Nov;62(5):738-745.
- V. **Karelis A**, Dijkstra ML, Vaccarino R, Sonesson B, Dias NV. Editor's Choice - The use of a novel short dilator tip on the distal bifurcated component during fenestrated aortic repair to avoid reno-visceral bridging stents. *Int Angiol*. 2022 Oct;41(5):365-371.

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What this thesis adds

This thesis adds to the current knowledge of endovascular treatments for aortic diseases by exploring the feasibility and outcomes of various techniques, including iliac branched devices (IBDs), hypovolemic-induced hypotension, fenestrated and branched endovascular aneurysm repair (F/BEVAR), and the use of delivery systems with short dilator tips. The findings demonstrate the promise of these techniques, as well as the importance of strict patient selection, optimization of treatment plans, and ongoing research to improve outcomes and minimize complications. This thesis contributes to the ongoing efforts to develop and refine minimally invasive treatments for aortic diseases and highlights the need for further research and development in this field. In addition, those studies establish a baseline for comparison with other therapeutic options.

Introduction

*"Vascular surgery is the perfect blend of technology and humanity,
where we use our hands and our minds to heal."*

— Dr. Michael DeBakey

The aorta, the largest artery in the human body, originates from the heart and runs through the torso, supplying oxygenated blood to the rest of the body and sustaining life in all organs and body parts.

Aortic aneurysms are a serious condition that affects the aorta. An aneurysm is a weak or bulging area in the wall of the aorta that can rupture and cause severe internal bleeding and even death if left untreated. Approximately 150.000 – 200.000 deaths per year occur due to aortic aneurysms with higher prevalence in high income societies and affecting predominantly men (1). However, significant progress has been made in recent years in terms of diagnosis, treatment, and understanding of the underlying causes and risk factors associated with aneurysms.

Endovascular aortic repair (EVAR) (2, 3) is a minimally invasive technique that has been developed to treat aortic aneurysms and prevent the risk of rupture. The procedure involves the insertion of a stent-graft through a femoral artery, which is then guided to the aorta to repair the aneurysm. With the first cases to be performed in 1993 at Vascular Center, Malmö.

EVAR has become the preferred method of treatment for abdominal aortic aneurysms (AAA) due to its lower complication rates and faster recovery times compared to traditional open surgery (4-10). In recent years, advancements in EVAR have allowed for the treatment of more complex aortic aneurysms, including those involving the thoracic and juxtarenal aorta but even more proximal aneurysms such as aortic arch and ascending aneurysms (11-14). These cases were previously considered inoperable or required open surgery, but with the development of new devices and techniques, EVAR has become a viable option for these patients.

An EVAR procedure relies on achieving a seal above and below the aneurysm with consequent exclusion of the aneurysm from the circulation. A proximal seal achieves when proximal to the aneurysm a as much as possible healthy segment of aorta in chosen as the landing zone for the endograft. Usually on abdominal aortic aneurysms (AAA) this seal/landing zone refers to the segment of the aorta just

below the origin of renal arteries aiming to as much as possible seal in length in order to ensure the durability of the repair. This is also known as “AAA neck” and when this is not present there is the need to incorporate the renovisceral branches which technically increase the degree of repairs complexity.

In the early days of EVAR patients which inadequate AAA neck were classified as unsuitable for EVAR and treated with the traditional method of open surgery. Fortunately for our patients a major advancements in EVAR occurred in form of the development of fenestrated and branched stent-grafts (15, 16). These devices have the ability to exclude the aneurysm while preserving blood flow to the renal and visceral vessels. The key philosophy behind this is the preservation of normal anatomy whenever possible with fenestrated and branched stent-graft designs trying to mimic the normal human anatomy as much as possible, which was adopted from traditional open surgery techniques to the new era of endovascular surgery. Fenestrated and branched stent-grafts have shown to be effective in treating these cases with good outcomes and low complication rates (17-19).

Despite advancements in EVAR, there are still some challenges that need to be addressed for aortic aneurysms. One major challenge is the long-term durability of the repair, as the stent-grafts used in EVAR may have a limited lifespan although clinical data confirming that is still lacking in the literature. Additionally, there is a risk of endoleak, which occurs when blood continues to flow into the aneurysm sac and can lead to aneurysm growth or rupture. These challenges must be addressed in order to offer better therapy both short- and long-term to our patients.

In conclusion, the field of EVAR for aortic aneurysms has seen significant advancements in recent years, allowing for the treatment of more complex cases. With the development of new devices and techniques, EVAR has become a viable option for the treatment of almost all kinds of aortic aneurysms. However, there are still challenges that need to be addressed and future research is needed to improve the durability of the repair and reduce the risk of endoleak. Additionally, further research is needed to expand the indications for EVAR to include more complex aneurysms. With the continued advancement of EVAR technology and increasing clinical experience, this procedure has the potential to become the standard of care for aortic aneurysms, offering patients a safer and less invasive alternative to open surgery.

The goal of this thesis is to provide an overview of the current state of more complex EVAR for aortic aneurysms, and to explore the potential for future developments in this field.

Aortic aneurysm

*"The most rewarding aspect of being a vascular surgeon is the ability to make a dramatic and positive impact on a patient's quality of life."
— Dr. Thomas Fogarty*

A glimpse of History: Understanding the evolution of Aortic Aneurysm

Aortic aneurysm is defined as an enlargement of the aorta to greater than 1 ½ times its normal size (20, 21). Aortic aneurysms are a serious and potentially life-threatening condition that has been recognized for centuries. The earliest recorded description of an aortic aneurysm dates back to ancient Egypt, where it was described in the Edwin Smith Papyrus, an ancient medical text dating back to around 1600 BC, recommending, "Treat it with a knife and burn it with a fire so that it bleeds not too much" (22, 23). The ancient Egyptians recognized the dangers of aortic aneurysms and recognized the need for surgical intervention, Figure 1.

The next notable historical reference to aortic aneurysms comes from the Greek physician Galen in the 2nd century AD. Galen described the condition as "a swelling of the main vein," (24) and recognized the need for surgical intervention in some cases. However, it was not until the 17th century that the true nature of aortic aneurysms was understood and surgical techniques for their repair were developed.

In the 18th century, the famous French surgeon, Jean Louis Petit (the inventor of a screw-type tourniquet), performed the first recorded successful repair of an aortic aneurysm. Petit's surgical technique involved excision of the aneurysm and reconstruction of the aorta using a graft made from animal intestine (25). This marked the beginning of the modern era of aortic aneurysm surgery.

The 19th and 20th centuries saw significant advancements in the understanding and treatment of aortic aneurysms. Endoaneurysmorrhaphy, a technique for ligating the branches of an aneurysm from within the aneurysm sac, was first described by Rudolph Matas in 1888 (26). A few years later, Alexis Carrel received the Nobel Prize for his work on the feasibility of suture repair of arteries and the development of an anastomotic technique for joining two vessels. With these techniques in place,

an AAA could be repaired by connecting a synthetic conduit to the aorta, proximal and distal to the AAA, thereby preserving forward blood flow (27). Dubost was the first to combine these two techniques in 1952 and reported the first successful open AAA repair using a homograft replacement (28). While various conduit materials have been developed over time, open AAA repair has remained largely unchanged to this day (26).

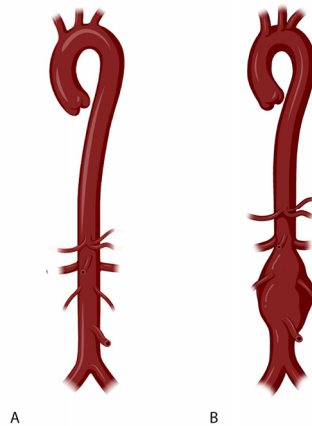


Figure 1: (A) normal aortic vessel, (B) abdominal aortic aneurysm.

The advent of x-ray imaging in the early 20th century allowed for more accurate diagnosis of the condition, and the development of synthetic materials in the mid-20th century led to the development of new surgical techniques, such as the use of synthetic grafts to repair aortic aneurysms. Some of the most notable synthetic materials used as vascular grafts include:

- Polyester grafts (with the most commonly used: Dacron®): a polyethylene terephthalate (PET) fabric that has been used since 1960s some of its characteristics are that it is strong, durable material with good resistance to infection and has been shown to have good long-term patency rates,
- PTFE (Polytetrafluoroethylene): also known as Teflon (accidentally discovered by Roy J. Plunkett in 1938) highly resistant to wear and tear. It has been used in vascular grafts since the 1970s and is known for its high durability and excellent patency rates.



Figure 2. Aortic aneurysm disease can affect virtually any part of the aorta – the ascending and arch, the descending thoracic, and the abdominal segments.

Today, the treatment of aortic aneurysms has advanced even further with the development of endovascular techniques, called endovascular aortic repair (EVAR), which allows for the repair of aortic aneurysms through small incisions in the groin. The first reported case of EVAR in English literature was by Parodi in 1991 (3) however, Volodos had already published this discovery in 1988 in Russian (2). Unfortunately, this discovery did not reach the Western medical community due to political, geographical, and linguistic barriers. Despite this, EVAR has greatly improved the recovery time and overall outcomes for patients with aortic aneurysms and was the most dramatic shift in the surgical management of AAA in the recent history of vascular surgery.

Despite these advancements, aortic aneurysms remain a serious and potentially life-threatening condition. Better understanding, early diagnosis and appropriate treatment are essential for the best outcomes.

Etiology of Aortic Aneurysm: Uncovering the Underlying Factors

Decades of research and efforts have been dedicated elucidating the pathophysiology of aortic aneurysm formation. It is a complex process that includes multiple components, such as inflammation, proteolysis, matrix injury, and dysfunction and necrosis of smooth muscle cells in the aortic wall, Figure 3 and more rarely in the setting of fundamental genetic abnormalities and syndromes (29). In a more simplified interpretation, a combination of genetic and environmental factors is assumed to be responsible for the formation of true aortic aneurysms.

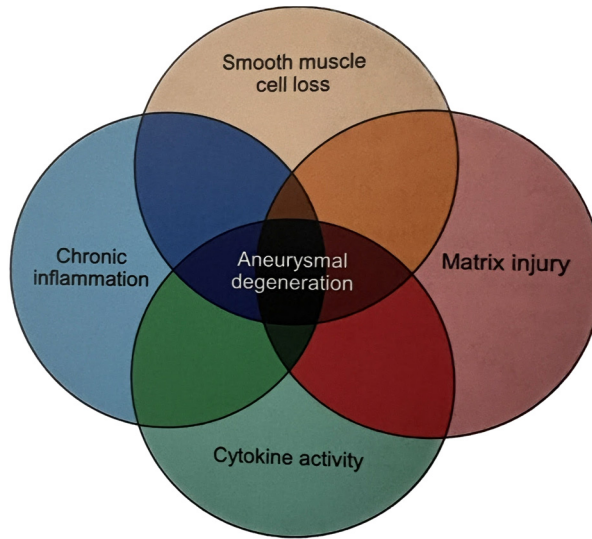


Figure 3. Illustration of multiple pathophysiological and overlapping components contributing to aortic aneurysm formation. By permission of Mayo Foundation and Springer Cham, Endovascular Aortic Repair, Gustavo S. Oderich, Chapter 2.

Degenerative AAAs that are the most common (30) with the presence of metalloproteinases in the media of aneurysm specimens to be associated with its presence. Highly associated with risk factors such as smoking (factor with the higher correlation), high blood pressure, and a family history of the condition. Other risk factors include age, male gender, atherosclerosis, and genetic predisposition to aortic aneurysm.

Other known factors are inflammatory, traumatic, infectious, development and congenital anomalies associated with arterial aneurysms and dissections.

Epidemiology of Aortic Aneurysm: Understanding the Prevalence and Distribution

It is estimated that AAAs affect approximately 2-8% of the population in developed countries (31). The condition is two to six times more common in men than women, and the incidence increases with age (32). Due to the fact of higher incidence among males most of the respective screening studies are predominantly including males with relatively stable prevalence of AAA among males 4% to 8% with a decreasing tendency the last years due to decreasing of smoking, healthier lifestyle approach and developments in medical treatments (33-36). In Sweden, screening studies have shown a prevalence of 1.5-2.6% in males at the age of 65 (37). Which is in line with

multicentric screening programs around the world with data from countries such as: Denmark, England, Finland, Italy, New Zealand, Norway, Scotland, Wales, Western Australia, USA, and Northern Ireland (38-40). Although newer studies tended to report lower rates of sub-aneurysmal (< 3.0 cm) men, showing a possible trend of lowering rates of sub-aneurysmal aortas (41).

The most common type of aortic aneurysm is abdominal aortic aneurysm (AAA), Figure 4 which accounts for about 75-80% of all aortic aneurysms. Although up to 40 % of AAAs also involve the iliac arteries with isolated iliac artery aneurysms to be rare ($< 1\%$ of aortoiliac aneurysms) (42, 43). Thoracic aortic aneurysms (TAA) account for about 20-25% of all aortic aneurysms (44).

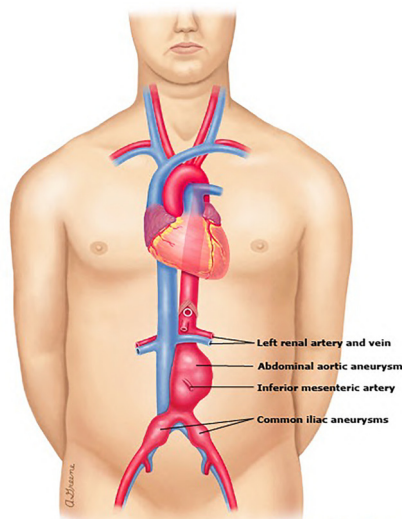


Figure 4: Illustration of the most common type of aortic aneurysm, abdominal aortic aneurysm (AAA)

Many of the same risk factors contribute to both the development and expansion/rupture of AAA, but the extent to which each factor affects these different stages may differ. Smoking is the most significant risk factor for the development of AAA, while being female, not white, having diabetes, and moderate alcohol consumption may lower the risk of developing AAA (45).

Aneurysmal disease is the cause of death in 0.13 % of males, compared with 0.07 % of females. The rates of rupture per 100,000 appear to be declining (1). Unfortunately, the mortality rates in cases on ruptured AAA (rAAA) remains high as 65-85% (46-49) despite all the surgical and technical advances in the recent years. The high mortality rates can partially justify due to the high pre-hospital deaths with several solutions to have been suggested such as pre-hospital aortic balloon occlusion (REBOA) (50, 51). This may suggest that can be still some space for more specialized screening.

Risk factors for AAA rupture

Baseline diameter is the most validated parameter associated with AAA rupture. Rupture risk at 12 months from randomized trials, stratified by baseline aortic diameter, are summarized below in Table 1 (52-56) with more modern studies showing declining of rupture rates than previously reported (57, 58), Table 2:

Table 1: Rupture risk of AAA in adherence to maximum AAA diameter.

Maximum AAA diameter (cm)	Rupture risk (%)
3.0 – 3.9	<1
4.0 – 4.9	Up to 1
5.0 – 5.9	1 - 11
6.0 – 6.9	10 - 22
>7.0	30 - 33

Table 2: Revised rupture risk of AAA in adherence to maximum AAA diameter, updated to 2019.

Maximum AAA diameter (cm)	Rupture risk (%)
< 5	<0.5
5 – 6	3.5
6 – 7	4.1
>7	6.3

Other known risk factors are: smoking (59, 60), hypertension (61), elevated peak aortic wall stress (62, 63), decreased forced expiratory volume (FEV1) (61, 64) and female sex (52, 53, 65, 66). Another risk factor which is correlated to rupture risk especially in women is the Aneurysm to Body index (66-68). There is also a few more possible factors though strong evidence regarding those are still missing some examples are: saccular aneurysm morphology (69) and the use of Fluoroquinolones (70, 71).

Diagnosing Aortic Aneurysm: Techniques and Methods

Most patients diagnosed with AAA present asymptotically. However, detection may occur during physical examination through the identification of a pulsatile mass (72), through other abdominal imaging studies, or through ultrasound screening programs (73). In instances where symptoms are present, patients may report abdominal, back, or flank pain (72). Additionally, though rarer thromboembolism, which can lead to symptoms of limb ischemia, may also be present. It is assumed that aneurysms that produce symptoms carry a higher risk of rupture, which is associated with high mortality rates but strong evidence regarding that is lacking.

A diagnosis of AAA generally requires imaging confirmation that an aneurysm is present, which is most often accomplished using abdominal ultrasound. Ultrasound is an excellent modality to primary assess and follow-up surveillance of AAA, as well as for screening purposes due to its low cost, easy reproducibility and excellent cost-effectiveness ratio. With its high sensitivity and almost perfect specificity, ultrasound wins the modality race of initial evaluation of AAA size and follow-up surveillance (74, 75). However, ultrasound comes with certain limitations as any other diagnostic modality, with operator- and equipment-dependent results (76, 77). Consensus has not been achieved still regarding the diameter measurement method with the currently prevailed methods to be, leading edge to leading edge, inner-to-inner and several others.

In overall any imaging study that demonstrates the focal dilation can be used to make a diagnosis, with ultrasound and computed tomography angiography (CTA) of the abdomen being the most useful in the everyday clinical praxis. Each modality is sensitive and specific for establishing a diagnosis of AAA (78-80) but recommended under differing clinical circumstances, with different decision-making algorithms to have been recommended over the years mainly depending upon the clinical presentation and the haemodynamic status of the patient.

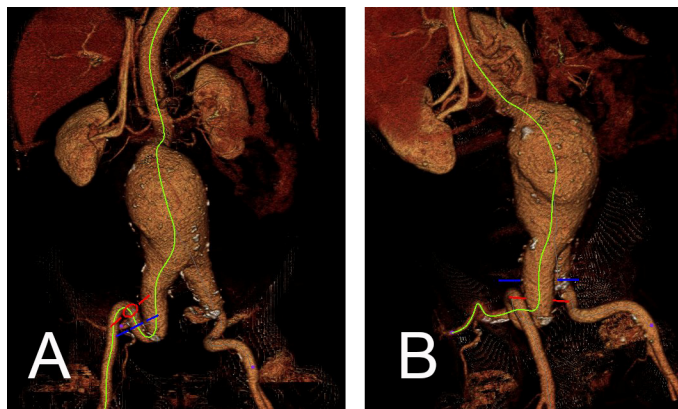


Figure 5: The patient with a ruptured abdominal aortic aneurysm and bilateral common iliac aneurysms with severe tortuosity in 3-D volume rendering reconstruction from the preoperative CTA. This reconstruction includes a centerline of flow to the external iliac (A) and internal iliac (B) artery. (Papper I)

As the size of an aneurysm increases to the point where treatment is necessary, CTA is often the preferred method for determining the size and structure of the aneurysm before surgery (81, 82). Although, comparative studies between anteroposterior (AP) ultrasound and CTA measurements have been showed a tendency to oversizing on the CTA from 3 to 6 mm (83-85) with may lead to potentially over-treating of AAA. Additionally, CTA has been proven to be effective in identifying and diagnosing ruptured abdominal aortic aneurysms (rAAA) (86). CTA involves the

use of intravenous (IV) contrast to highlight the vessel's lumen and allows for detailed mapping and measurement of the aneurysm's shape. These images can also be further analysed using specialized 3D computer software, Figure 5 to create a detailed centreline of the entire aorta, providing vital information for the surgeon in determining the best treatment plan (87).

While other imaging techniques such as magnetic resonance imaging (MRI) are not commonly used in the initial diagnosis of AAA, they may be used in specific situations, such as when a patient is unable to receive intravenous contrast (88, 89).

Classifying of Aortic Aneurysms: Understanding the Different Types

Ascending Aorta and Arch Aneurysms

Those aneurysms are commonly classified as supracoronary, annuloartec ectasia (also known as Marfanoid type) and tubular. On the other hand arch aneurysms can be isolated, proximal, or distal extension of ascending or thoracic aneurysms respectively.

Descending Thoracic Aneurysms

A classification scheme that has been proposed to describe the extent of descending thoracic aneurysms (DTA) includes three types:

- Type A: from left subclavian artery (LSA) to T6
- Type B: from T6 to the diaphragm
- Type C: from above T6 or LSA to the diaphragm

Thoracoabdominal Aortic Aneurysms

One of the first case report series of repair of descending and thoracoabdominal aortic aneurysms was from Cooley and DeBakey's published in 1954 (90).

In 1986, Crawford described the first TAAA classification scheme based on the anatomic extent of the aneurysms (91). Until today this is the accepted classification of TAAA after its final modification by Safi (92) which added a fifth type to describe disease starting below T6 and extending up to the renal arteries, Figure 6 (93). The Crawford TAAA classification should be renamed as it is a relatively open-ended classification in regard to the intercostal space and surgical dissection

required for each type of TAAA. This suggests that a more updated TAAA classification may be needed, which would take into account the specific modern endovascular requirements.

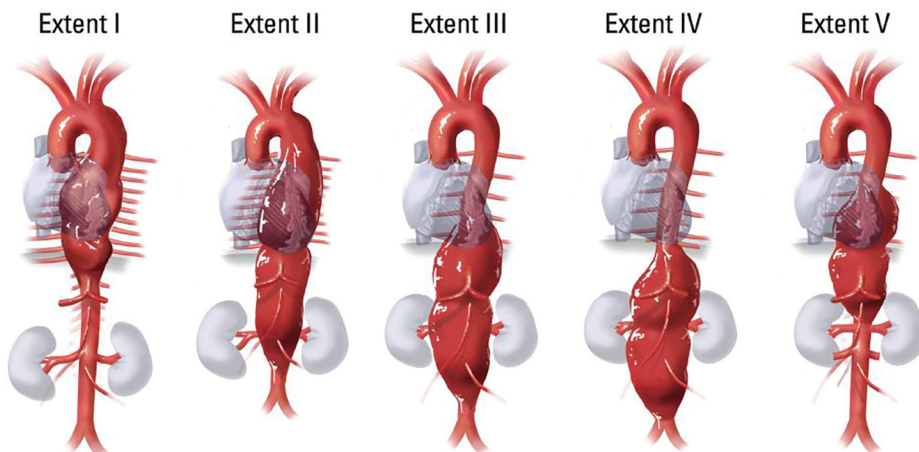


Figure 6: Schematic representation of the modified Crawford classification scheme for thoracoabdominal aortic aneurysm extents.

Abdominal Aortic Aneurysms

The vast majority of aortic aneurysms are located in the abdominal aorta, and it is estimated around 75-80 %. Of these, the most are infrarenal which imply adequate aortic neck during surgical repair either for an infrarenal clamping of aorta during open aortic repair or minimum proximal landing zone for EVAR of 10-15 mm.

Any other aneurysm that does not offer those conditions is assumed to be a complex abdominal aortic aneurysm. The anatomical classification of complex AAA includes short neck infrarenal (<10 mm infrarenal neck), juxtarenal aneurysms (0-4 mm infrarenal neck), and suprarenal aneurysms with a furthermore subdivision of the last one to pararenal aneurysms, up to superior mesenteric artery (SMA) and to paravisceral aneurysms, up to celiac trunk (CT) without involving its origin, Figure 7.

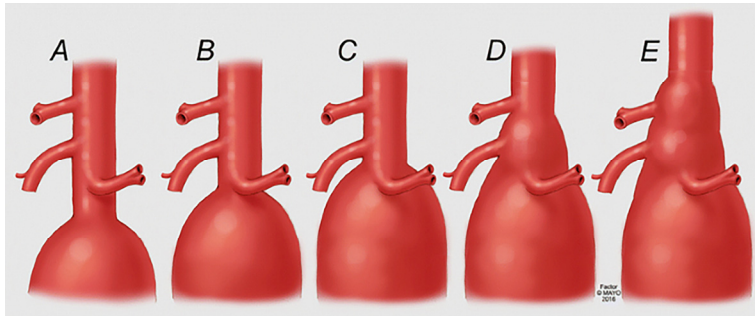


Figure 7: Classification of complex AAA: (A) short neck, (B) juxta-renal, (C) pararenal, (D) paravisceral, and (E) type IV TAAA. By permission of Mayo Foundation and Springer Cham, Endovascular Aortic Repair, Gustavo S. Oderich, Chapter 5.

Iliac Artery Aneurysms

Iliac artery aneurysms (IAA) can be isolated unilateral, isolated bilateral and aortoiliac with the last group to be the most common (94). Nowadays the more contemporary classification takes into account the modern endovascular techniques and present a classification of five types mainly based on feasibility of endovascular or open repair (95), Figure 8.

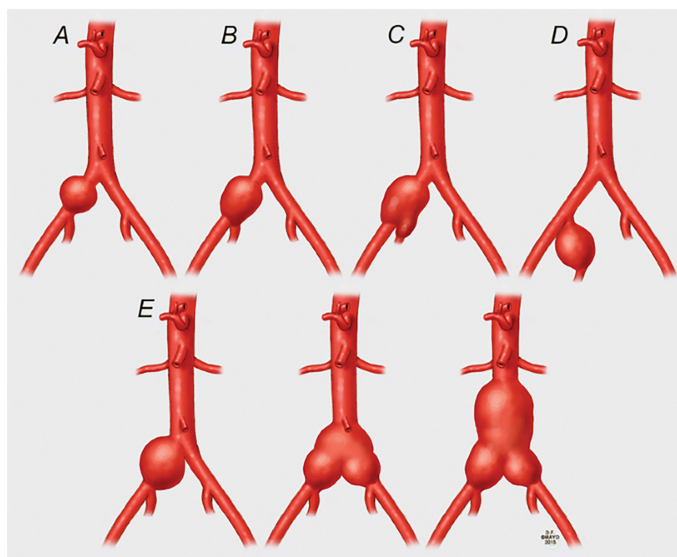


Figure 8: Classification of iliac artery aneurysms: (A) Isolated common iliac artery (CIA) aneurysm with proximal and distal neck adequate for open or endovascular repair, (B) Isolated CIA aneurysm with adequate proximal neck and aneurysmal disease extending to the common iliac bifurcation, (C) CIA aneurysm with adequate proximal neck and aneurysmal disease extending past the common iliac bifurcation to involve the internal iliac arteries, (D) Isolated internal iliac artery aneurysm and no aneurysmal involvement of the CIA, (E) CIA aneurysm with inadequate proximal neck or bilateral CIA aneurysms or combined CIA aneurysms and abdominal aortic aneurysm. By permission of Mayo Foundation and Springer Cham, Endovascular Aortic Repair, Gustavo S. Oderich, Chapter 5.

Treatment Options: A Short Review of Current Approaches

Treatment for aortic aneurysm depends on the size and location of the aneurysm, as well as the overall health of the patient. In all cases, medications should be used to manage the condition and prevent complications. It is worth to be named that there is a significant association between aortic diameter and cardiovascular mortality, excluding aneurysm-related deaths, suggesting that aneurysm diameter is an independent marker of cardiovascular disease risk (96). However, in most cases, surgery is required to repair or replace the affected section of the aorta.

Conservative management

Patients with small abdominal aortic aneurysms (AAA) under 5.5 cm in diameter should be managed conservatively, according to the results of randomized trials and meta-analysis (97-103). These patients should undergo regular evaluations to check for symptoms and monitor blood pressure, as well as the effectiveness of any risk reduction strategies (58). This is due to the fact that the natural progression of AAA is often one of expansion and potential rupture (104).

Guidelines from the European Society of Vascular Surgery (ESVS) likewise Society for Vascular Surgery (SVS) support longer surveillance intervals for small AAAs and suggest the following surveillance schedule (52, 105):

- AAA 3.0 to 3.9 cm, imaging at 3-year intervals
- AAA 4.0 to 4.9 cm, imaging at 12-month intervals
- AAA 5.0 to 5.4 cm, imaging at 6-month intervals

An interesting topic regarding surveillance of small AAA is the potential need for rescreening of patients with aortic aneurysms >2.5 cm but <3.0 cm, definition of sub-aneurysmal aortas, such there is currently a lack of high-quality evidence with some suggesting for those patients an ultrasound rescreening after 10 years.

Surgical repair

Elective repair of abdominal aortic aneurysm (AAA) is considered the most effective method for preventing rupture. Currently, two methods of repair are available: open aortic repair (OAR) and endovascular aneurysm repair (EVAR). The mortality rate for elective AAA repair is 3-6% for open surgery and 0.5-2% for EVAR (106-110). In determining the appropriate method of repair, it is essential to take into account the patient's expected survival, as well as their age and medical comorbidities.

Indications for AAA repair:

- Symptomatic or ruptured AAA – urgent or emergency repair, respectively
- Asymptomatic AAA ≥ 5.0 cm in females and ≥ 5.5 cm in males
- Rapidly expanding AAA

Open aortic repair

Open aneurysm repair is a surgical procedure that involves the replacement of the diseased aortic segment with a tube or bifurcated prosthetic graft, through a midline or transversal transperitoneal or left retroperitoneal incision (111). The technique demand a cross-clamping of aorta proximally and distally to the aortic aneurysm, then usually a synthetic graft is sutured with in-situ fashion, advisable with the proximal anastomosis as close as possible to the renal arteries to prevent later aneurysm development in the remaining infrarenal aortic segment (112, 113), to ensure a durable reconstruction of the diseased segment with patent online flow and alleviated risk of rupture, Figure 9.

Despite, some technical advances in OAR peri- and post-operative complications associated with the procedure such as acute renal failure, distal embolization, wound infection, colonic ischemia, false aneurysm formation, aorto-duodenal fistula, graft infection, and perioperative bleeding remain significant issues especially in the acute setting of emergency OAR but even in elective cases. Those risks for peri-operative morbidity and mortality are significant increase in the case of complex AAA such as juxtarenal or pararenal AAA where it is generally needed a more proximal dissection and cross-clamping of the aorta involving some if not all of the reno-visceral vessels. This led to a temporary obstruction of the blow-flow to the viscera as well as the kidneys under the surgery which is associated with increased risk for renal function impairment and bowel ischemia (114). Long-term complications after open aortic repair are reported up to 20% with the most frequent to be hernias, small bowel obstructions and pseudoaneurysms among others (115, 116).

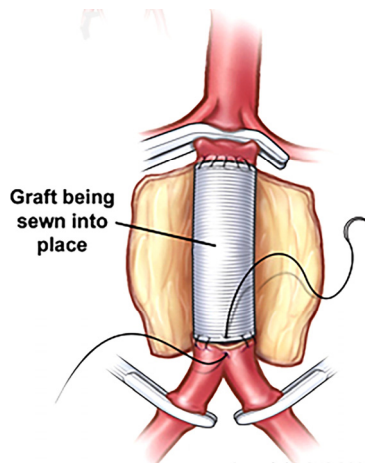


Figure 9: Illustration of open aortic repair with a tube synthetic graft.

Endovascular aortic repair

EVAR, on the other hand, involves the placement of modular graft components delivered via the iliac or femoral arteries to line the aorta and exclude the aneurysm sac from the circulation. Specific technical details will be presented on the next chapter both for standard EVAR and more complex repairs. However, EVAR requires specific anatomic criteria to be met, and up to 70% of patients are eligible for this method and even higher for complex AAA anatomies though with respectively more complex repairs such as fenestrated EVAR (FEVAR) and branched EVAR (BEVAR) (117-120). This percentage is expected to increase further with the approval of specialized endograft designs that will allow the treatment of more challenging aortic aneurysm anatomy and with the expansion of more complex EVAR procedures. Although EVAR is associated with lower perioperative mortality, late AAA rupture has been reported (121, 122) and that is why a post-operative imaging surveillance has been maintained (105).

Post-operative surveillance is crucial for patients who have undergone surgery for aortic aneurysm as it is explained before. This typically involves regular imaging tests to monitor the repair or replacement, as well as lifestyle changes such as quitting smoking and managing blood pressure. These steps are important to ensure the long-term success of the surgery and prevent complications or recurrence of the aneurysm with traditionally CTA to be the modality of choice for this purpose especially for complex AAAs treated with F/BEVAR (123-125). On the other hand, standard EVAR with good proximal and distal landing zones and absent of type I or III endoleaks (EL) on completion angiogram with uneventful perioperative Cone Beam CT (CBCT) could be followed up with DUS controls (126-130). There is no

consensus regarding the frequency of those controls with more liberal approach to even recommend DUS control every other year or even after three-years.

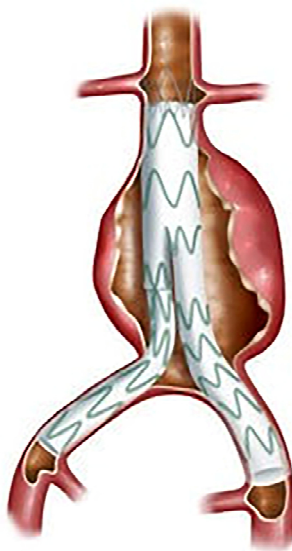


Figure 10: Illustration of standard EVAR components with a main body and limb extensions sealing the abdominal aortic aneurysm.

It's also crucial for patients to work closely with their healthcare providers to manage their condition and to make informed decisions about their treatment options. It's important for patients to understand the risks and benefits of each treatment option and to choose the one that is best for them (131-133).

In conclusion, aortic aneurysm is a serious and potentially life-threatening condition that requires prompt diagnosis and treatment. With advances in medical imaging and surgical techniques, the prognosis for patients with aortic aneurysm has improved significantly. However, ongoing surveillance and lifestyle changes are essential for ensuring the long-term success of the treatment and preventing complications. Early detection and treatment can greatly improve the outcome for patients with aortic aneurysm.

Complex endovascular aortic repairs

Complex endovascular aortic repair is defined as the reconstruction that incorporate aortic side branches and including the repair of aneurysms in the aortic arch, thoracoabdominal and iliac bifurcation. During the last decade, significant improvements and advances have been achieved in the field of endovascular technology. Those advances allow total endovascular repair using one of three well development methods of vessel incorporation: fenestrations, branches, and parallel grafts with the latter to tent to be used mainly as bailout solution on emergency or sub-emergency cases.

Those advancements have allowed the treatment of more complex cases, including those involving the arch, thoracic, thoracoabdominal and juxtarenal aorta. These cases were previously considered inoperable or required open surgery, but with the development of new devices and techniques, EVAR has become a viable option for these patients.

One of the major advancements in EVAR has been the development of fenestrated and branched stent-grafts, Figure 11. These devices have the ability to exclude the aneurysm while preserving blood flow to the renal and visceral vessels as well to the hypogastric arteries. This is particularly important in cases involving the juxtarenal aorta, where the renal vessels are in close proximity to the aneurysm, Figure 12. Fenestrated and branched stent-grafts have shown to be effective in treating these cases with good outcomes and low complication rates both on the elective but even on the acute setting (134-139). Even a technical demanded solution to rescue failing FEVAR is presented in this thesis (Paper IV), Figure 13.

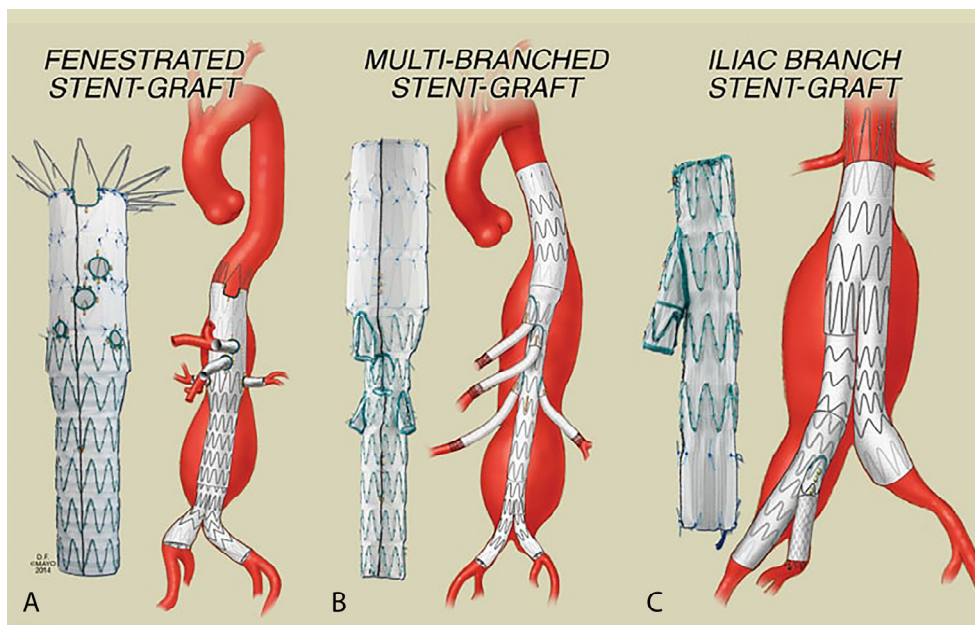


Figure 11: Endovascular options for complex aortic repairs with (A) fenestrated stent-grafts, (B) multibranched stent-grafts and (C) iliac branch devices for the preservation of iliac internal arteries. By permission of Mayo Foundation.

Additionally, it has to be highlighted that centres that are performing complex EVAR are required to have a robust endovascular inventory to deal with all variations in anatomy and unanticipated problems that can occur during procedures.

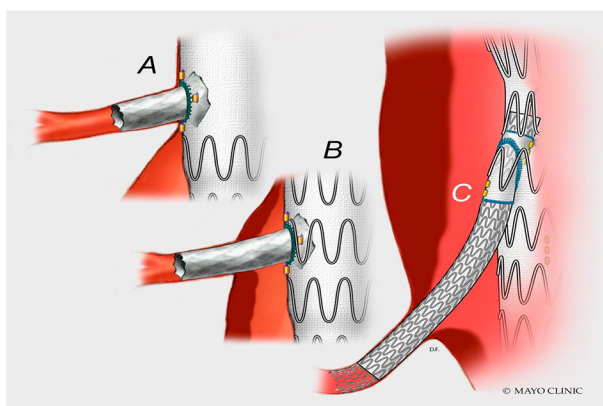


Figure 12: Technical solutions for bridging of target vessels during F/BEVAR. (A) Short balloon-expandable stent-graft for juxtarenal AAA treated with FEVAR; (B) long balloon-expandable stent-graft for suprarenal AAA treated with FEVAR (the gap between fenestration and inner aortic wall may lead to target vessel instability); (C) self-expanding stent-graft for TAAA treated with BEVAR and adjunctive distal relining with bare metal stent to accommodate smooth transition between edge of stent-graft and native artery in a tortuous segment. By permission of Mayo Foundation and Springer Cham, Endovascular Aortic Repair, Gustavo S. Oderich, Chapter 26.

Preoperative Evaluation and Clinical Risk Assessment

All endovascular procedures, in particular for the treatment of extensive aortic disease, should be preceded by a thorough evaluation of all major organ systems (including cardiac, pulmonary, and renal function), to outline the general health and physiological reserve of the patient. Indeed, most patients with aortic aneurysms may present with concomitant central and peripheral atherosclerotic lesions owing to the similar risk factors, such as hypertension, smoking and aging, amongst others (140). All these comorbidities may increase the surgical risk and may negatively impact long-term survival, which has been well documented for OSR (141).

Unlike for AAA, there are no validated specific protocols or risk prediction models for patient selection of F/BEVAR (142). However, routine cardiology consultations before the operation, is indicated and should preferably be performed non-invasively, for example with an echocardiogram, cardiac stress test, myocardial scintigraphy, or coronary computed tomography angiography.

The prevalence of internal carotid artery stenosis is high among patients with AAA, 8.8% in the SMART study (143). For this reason, a routine screening for asymptomatic carotid stenosis by DUS before aortic aneurysm repair is advisable but not recommended thus most of carotid stenosis are asymptomatic.

The use of frailty scoring tools by dedicated geriatric physicians may further complement the pre-operative evaluation of these patients, especially those of older age (especially with the continuing aging population) and/or with poor functional status. An interesting factor that has recently attracted the research interest is the presence of sarcopenia on the preoperative CTA by assessing the size and quality of psoas muscle. Sarcopenia seems to be linked to poorer short- and long-term outcomes in patients undergoing F/BEVAR (144, 145). However, sarcopenia alone is not sufficient to predict surgical and clinical outcomes and should be used in the context of other factors to balance the perceived risk of aneurysm rupture and expected complexity of the interventional procedure. These types of factors and even others should be thoroughly investigated, particularly in light of the growing elderly population and the increasing need for quantifiable frailty risk factors. Last, the importance of dedicated multidisciplinary teams for optimal assessment of patients' fitness for such complex procedures may not be overemphasized enough.

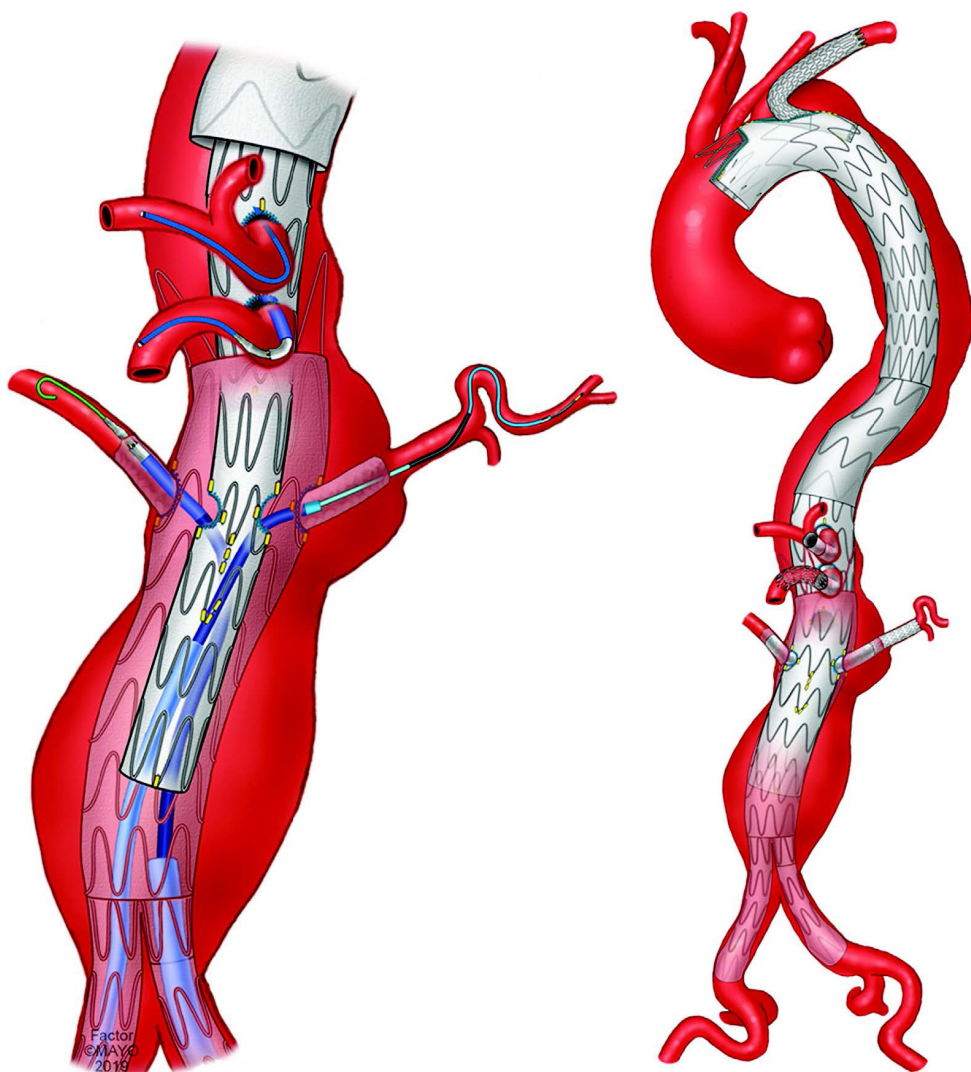


Figure 13: Failing fenestrated endovascular aneurysm repair (FEVAR) that required a new four fenestrated FEVAR (F/BEVAR in FEVAR) and a proximal extension up to the aortic arch. (Paper IV).

Imaging and radiation

Preoperative imaging studies must include thoraco-abdominal computed tomography angiography (CTA) from the neck to the groin, with multi-thin slice cuts of 1–3 mm. This is needed for planning and sizing of the endograft, as well as for the study of critical anatomic issues, such as angulation and diameter of the aorta and of the iliac vessels, calcifications or stenosis of the main aortic branches, suitability of the aortic arch in case upper extremity access, significant aortic mural thrombus, number of intercostal or lumbar arteries. With FEVAR to be usually considered in cases with narrower aortic lumens (<25 mm) and target vessels (TV) perpendicular to the aorta or tilted upwards. Conversely, BEVAR is usually preferred in patients with larger aortic lumens (>25 mm) and downward angled TV. Planning is usually easier in the case of an “off-the-shelf” multibranched device, making this approach more suitable for urgent or emergency settings. On the other hand, custom-made-devices (CMDs) for more accurate sizing and planning require more prolonged manufacturing and delivering times with the subsequent risk for complications which have to be taken into account (146, 147).

Radiation

With the exponential advance of Xray guided minimally invasive procedures in modern medicine practice among numerous specialties such as cardiology, vascular surgery, neurology etc. There is growing concern regarding the increasing radiation exposure to the patient, and to the whole team particularly on the endovascular teams working on complex cases (148). This need for radiation safety during endovascular procedures generated the recently published European Society for Vascular Surgery (ESVS) 2023 Clinical Practice Guidelines on Radiation Safety (149).

With the key concept in medical radiation protection is thus optimisation, for which is defined the ALARA principle: doses to operators and patients must be “as low as reasonably achievable” (150-152). Those principals, key principles according ICRP: justification, optimisation, and dose limits, protects both the patient and operator.

Towards to an optimal ALARA approach some technological advances have contributed to a significant radiation exposure decrease through imaging tools during performing and controlling complex EVAR with of them to be Fusion overlay technology, 3D navigation and intravascular ultrasound (IVUS).

Cone-Beam Computed Tomography (CBCT)

CBCT uses either a C-arm or X-ray CT scanner in the operating room. The X-ray scanner rotates 200° around the patient during a single breath-hold, Figure 14. The image acquisition can be performed with or without contrast administration and the acquired image set is automatically transferred to the corresponding post-process

workstation. CBCT is a powerful tool allowing intraoperative evaluation of the reconstruction and correction without further need for reintervention which can be analysed in the workstation and performed before the patient leaves the operating room (153).

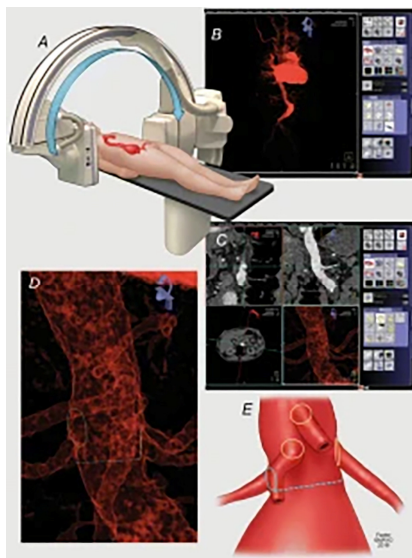


Figure 14: Fusion imaging using the Siemens Zee system is depicted in the illustration. The Cram is rotated (a) to allow creating a template for intraoperative guidance. The CT scans are automatically processed (b) using PR reconstructions (c) to outline the branches which are marked with rings (d, e). By permission of Mayo Foundation and Springer Cham, Endovascular Aortic Repair, Gustavo S. Oderich, Chapter 8.

Fusion imaging

Involves four steps to achieve optimal intraoperative guidance: processing of preoperative CTA, intraoperative volume acquisition (nowadays only with two 2D registrations of bony landmarks such as the pelvis), registration of preoperative CTA, and CBCT plus intraoperative adjustments. Some advantages of this technology are the decreased radiation during the procedure as well the use of contrast, Figure 15.

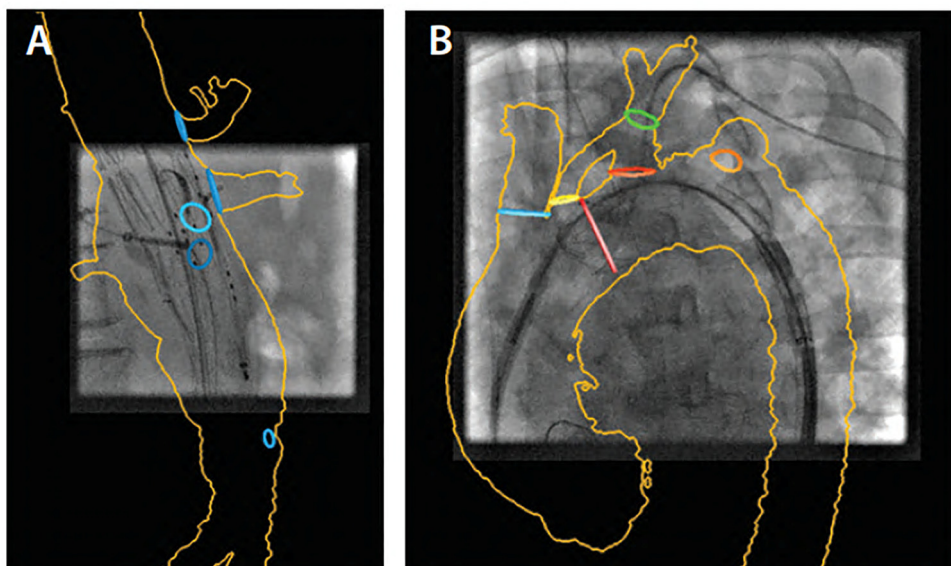


Figure 15: EVAR guided by image fusion (Discovery IGS 740 HOR equipped with EVAR Assist, GE Healthcare). The 3D model associates the aortic silhouette with the landmarks positioned by the operator. Graft landing zone and target visceral (A) and supra-aortic (B) vessel ostia are identified with planning circles, with optimal gantry angulations for their selection stored during planning and recalled from tableside for guidance. Several rendering modes and opacity options are available to display landmarks without obscuring live fluoroscopic visibility. Image fusion also allows gantry and table positioning without the use of x-ray, further reducing radiation exposure. By permission of Mayo Foundation and Springer Cham, Endovascular Aortic Repair, Gustavo S. Oderich, Chapter 8.

3D navigation

3D navigation of endovascular devices inside the body is new technology allowing notable reduction in radiation dose. Two of these technologies, electromagnetic (EM) tracking and Fiber Optic Real Shape (FORS) have shown potential in pre-clinical studies (154, 155) with the later one to have been even evaluated in small clinical trials (156-158).

The FORS technology platform consists of equipment that sends laser light through a multicore optical fibre which is incorporated in endovascular guidewires and catheters. By analysing the reflected light, it is possible to reconstruct the 3D shape of the full length of the optical fibre and thus of the endovascular devices.

Intravascular Ultrasound

Intravascular ultrasound (IVUS) is a catheter-based imaging modality that provides high-resolution cross-sectional images of vessels. Initially used on the assessment of the coronary arteries and eventually utilized on all endovascular procedures and even FEVAR. IVUS allows a real-time imaging of the vessel and is ideally suited for aortic interventions especially for cases of aortic dissections (159-161). This modality provides accurate imaging to assess access, and distances between branch

vessels, vessel size for endograft sizing, particular useful on aortic dissections allowing the safe navigation between the true and false lumen which in overall facilitates complex aortic endovascular procedures. Additionally, the use of IVUS reduces the need of contrast and radiation doses in those procedures (162).

Sealing zones and endoleaks

Sealing zones

The cornerstone of endovascular aortic repair is the successful exclusion of the aneurysm sac from the circulation. This is achieved with absolute wall apposition of the stentgraft to the respective vessel accomplishing a sealing zone both proximally and distally to the aneurysm itself. As adequate sealing zone defines as a healthy segment of aorta proximally, more often >15 mm (though minimum sealing zones length varies between different manufactures IFU) and at least >10 mm distally, more often in the iliacs level. On more complex reconstructions with implantations above zone 7, ideally segments of normal aorta are selected for placement of endografts with minimum of 20 mm length of normal parallel aortic wall without excessive thrombus or atherosclerotic debris. During planning adequate overlapping between all conjoined components has to be considered to avoid endoleaks mainly type III, (detailed classification of all endoleak types follows). The established reported classification of implantation zones are the Ishimura classification, which have been incorporated in the SVS reporting standards (163), Figure 16.

An interesting topic regarding the proximal sealing zone is the oversizing model that should be followed especially considering the known aortic neck dilatation which pose a risk for the durability on the repair. It is generally accepted that a more liberal oversizing is advisable on ruptured cases then the haemodynamic status is compromised, and severe hypovolemia is usually present. On the other hand, aggressive oversizing on elective cases on euvolemic cohort patients has been associated with high risk for infolding and building of big gutters with the consequent risk for type Ia endoleaks as well with risk for aortic neck dilatation driven by the endografts oversizing and the radial force especially of stentgrafts with suprarenal fixation (164, 165). Aortic neck dilatation has even been found on thoracic endovascular aortic repairs (166) and it is something that should be monitored on the follow-ups.

With similar fashion the durability of a FEVAR repair can be impaired by failure of the proximal sealing zone. Beside the proximal dilatation the actually design of FEVAR has to be mentioned. FEVAR's current design, which is modular, consists of a proximal tubular stent-grafts with the customised fenestrations in regards of clock position, depth, and size/diameter and a distal bifurcated component in order to achieve as much as possible overlap between components and avoid type 3

endoleaks and unilateral or bilateral iliac limb extensions. Fenestrations divide into three basic types: small (6x6 mm), big (6x8 mm) and scallops. This design has some advantages as well some limitations. An advantage of this modular design is that gives higher flexibility to adapt on more challenging anatomies as well that utilizes a limited number of distal components that do not need to be customised necessary. Another crucial advantage is that the risk for distal migration can be attenuated by the sufficient overlap with the tubular component. That way, it protects the fenestrated component from a distal migration. One of the potential limitations on the other hand is that the fenestrated component requires the bridging stents of all TV to protrude into the usually narrow aortic lumen in order to ensure sealing. Those bridging stents are exposed to substantial risk for conflict with the distal component long dilator tip which often have to cross the renovisceral segment.

Equal value importance has the distal sealing zone. Usually when the anatomy is favourable the distal segment of CIA is chosen as landing zone in order to preserve the pelvic circulation. In cases where the anatomy is more challenging with aneurysmatic CIA and sometimes even IIA the origin of hypogastric artery has to be incorporated in the reconstruction in order to avoid pelvic ischemic complications such as buttock claudicatio, bowel ischemia, sexual dysfunctions, spinal ischemia and even more rarely gluteal or skin necrosis. Incidence of those complications varies in the literature with reports to demonstrate complications up to 45% of the patients during unilateral IIA embolization and even higher during bilateral (167, 168). The respective reported incidence of ischemic pelvic complications after use of iliac branch devices are significant lower (2%) and mainly concerned the most frequent ischemic complication of buttock claudicatio (168).

The Achilles' heel of endovascular aortic repair remains the need for re-interventions especially after more complex repairs such as FEVAR. Re-interventions after FEVAR may be needed within three to five years, mostly related to the target vessels (5%-15%) or endoleaks (4%-10%) (169-171) with inadequate sealing zones to be the most common cause of persistent endoleaks leading to sac growth or rupture (172).

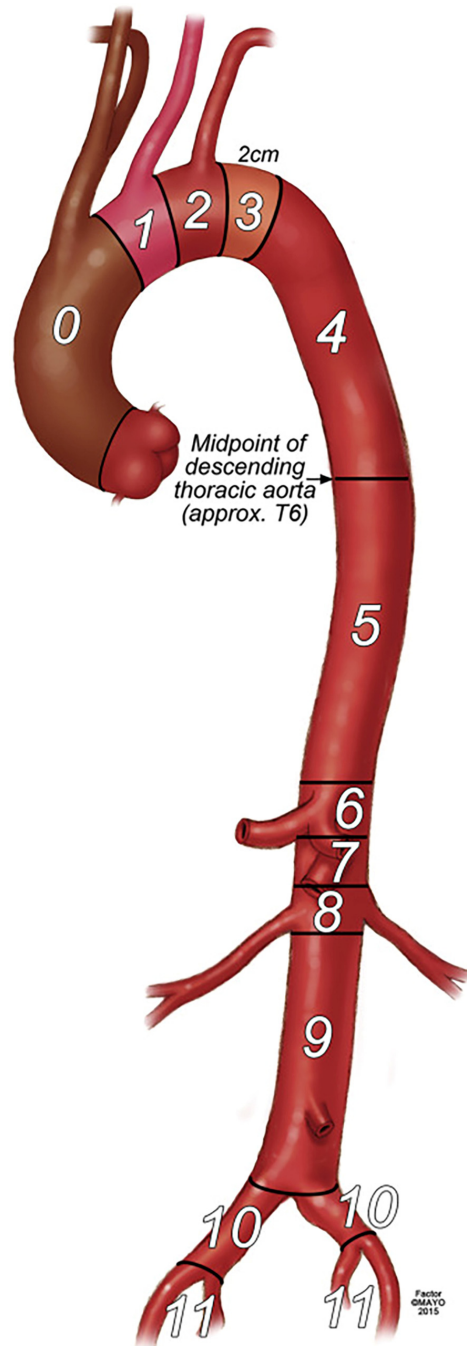


Figure 16: Zones of implantation. The proposed classification includes zones 0 to 3 (ascending aorta to distal aortic arch), 4 to 5 (proximal to distal thoracic aorta), 6 to 8 (visceral aorta), 9 (infrarenal aorta), and 10 to 11 (iliac arteries). By permission of Mayo Foundation and Springer Cham, Endovascular Aortic Repair, Gustavo S. Oderich, Chapter 5.

Classifications of endoleaks

The development of new technology requires an updated classification system to account for the potential failure modes associated with modular devices that feature fenestrations, directional branches, or parallel stent-grafts. The revised classification system is summarized in Figure 17 according to the recently updated reporting standards from the Society for Vascular Surgery. (173).

Endoleaks should be classified as primary endoleaks if present on initial completion angiography or at the first cross-sectional imaging evaluation using either CTA or MRA. Secondary endoleaks are described as development of a new endoleak detected by CTA after the original procedure and after the first follow-up CTA or MRA has demonstrated absence of an endoleak. The reappearance of an endoleak after spontaneous resolution or successful intervention is termed a recurrent endoleak. Additionally, according to the latest reporting standard endoleaks that are detected intraoperative but disappear on the one-month CTA do not classify as endoleaks anymore. Further categorization of endoleaks requires precise information about the course of blood flow into the aneurysm sac.

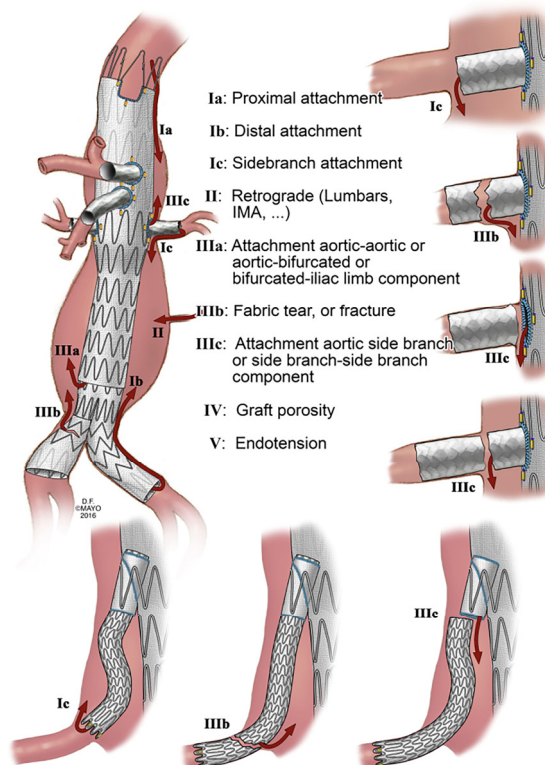


Figure 17: Classification of endoleaks. IMA, Inferior mesenteric artery. By permission of Mayo Foundation.

Two peculiar forms of endoleaks are the *indeterminate endoleaks*, defined as endoleaks that are visualized on imaging studies without a defined source and *endotension*, defined as aneurysm sac enlargement >5 mm with no imaging evidence of an endoleak. This may represent an endoleak that may not be evident because of inadequate imaging or limitations of currently available imaging modalities (174).

Target vessel instability

The fenestrated and branched nature of these devices, used to treat complex aortic aneurysms, can result in increased susceptibility to endoleaks, device migration, and limb occlusions, leading to target vessel (TA) instability as defined by Mastracci et al. (175). This can cause significant morbidity and mortality and may require further intervention. One of the most correlated risk factors of TA instability has been found to be the gap distance between fenestration and aortic wall on target artery with a threshold of fenestration gap $\geq 5\text{mm}$ to be associated with increased risk (176). Therefore, careful patient selection, appropriate device selection, precise implantation technique, and vigilant follow-up are crucial to minimize the risk of target vessel instability in EVAR procedures with fenestrated and branched devices.

In conclusion, the field of endovascular aortic repair has seen significant advancements in recent years, allowing for the treatment of more complex cases. With the development of new devices and techniques, EVAR has become a viable option for the treatment of thoracic, thoracoabdominal and juxtarenal aortic aneurysms and dissections. However, there are still challenges that need to be addressed, and future research is needed to improve the durability of the repair and reduce the risk of endoleak. The potential for further expansion of the indications for EVAR is high, and it is likely that EVAR will continue to play an increasingly important role in the treatment of aortic diseases.

Aims

The specific aims of this thesis were:

1. To evaluate the feasibility and outcomes of IBDs use to preserve the IIA perfusion in emergent endovascular repair of ruptured aorto-iliac aneurysms.
2. To validate the results of presenting the IIA with IBDs during acute endovascular repair or ruptured aortoiliac aneurysms in a multicentric study, and to examine any possible disparities compared to sacrificing the IIA.
3. To investigate the changes in supra and infra-renal aortic ~~neck~~ diameters before and after EVAR for rAAA and the possible association with endograft apposition.
4. To report the outcomes of redo fenestrated and/or branched endovascular aortic repair to rescue previous failed FEVAR.
5. To evaluate the feasibility and efficacy of a delivery system with a shortened dilator tip on the distal FEVAR component in preventing compression of the renovisceral bridging stents.

Material and methods

Patient population and rationale

Patients in the studies included in this thesis were treated at the Vascular Center in Malmö for complex aortic diseases. These were completed with other patients undergoing similar treatment in other national and international hospitals in three studies where multicentre series are reported.

Paper I

This was a retrospective cohort study that included consecutive patients who were treated endovascularly with IBD on the acute setting of ruptured aortoiliac aneurysms. All patients were treated at the Vascular Center in Malmö between 2012 and 2017. Previously, a ruptured aneurysm extending into the iliac arteries implied necessarily sacrifice of the internal iliac artery. However, this, already in the elective setting can be associated with the risks of pelvic malperfusion discussed above. It is unclear if these risks are increased further in the acute setting of a rupture.

Paper II

This was a collaborative work between eight European Aortic Centres. All consecutive patients who received IBD during endovascular repair of ruptured aortoiliac aneurysms between 2012 and 2020 were included. The inclusion period differed in the different sites depending on when their experience started. A control group from the same study period was included in the analysis. These underwent treatment at the initiating centre, the Vascular Center in Malmö, where the internal iliac artery was sacrificed during the EVAR of the ruptured aneurysm instead of being preserved with an IBD.

Paper III

It was a collaboration between two academic aortic centres in Europe. In this retrospective cohort study patients treated with emergency EVAR for rAAA and sufficient image quality between 2010 and 2019 were included. The hypotension caused by the ruptured may lead to a decreased size of the aorta when the preoperative CTA is done, which can have several implications. It can potentially influence the sizing of the endograft, which may compromise the seal. It may also

influence the dynamic of any potential subsequent postoperative dilatation of the sealing zone.

Paper IV

It was a collaboration between eight European Aortic Centres, with all consecutive patients who received F/BEVAR-in-FEVAR being included. This was initially shown in a series from our centre that it was a potentially good solution to rescue a previously failed FEVAR. In the current study we aimed at validating the findings of that initial report that preceded this thesis. This retrospective review included patients between 2006 and 2016. Once again, the inclusion period differed in-between the different sites.

Paper V

All consecutive patients from Vascular Center in Malmö that underwent a FEVAR with a custom delivery system of the distal bifurcated endograft with a short tip between 2017 and 2019 were retrospectively analysed. This was aiming at analysing if this adaptation could minimize the risk of the introduction of the distal component can avoid the risk of compressing the section of the bridging stents of the fenestrations that protrude into the lumen of the proximal tubular component.

Definitions and Reporting standards

The outcomes were defined as early or late if occurring within 30 days or more from surgery, respectively. The definitions for the study were primarily based on the reporting standards for endovascular aortic repair established by Oderich et al (173), with the exception of the definition endoleaks. For studies I and IV, endoleaks were considered present until 30 days, as they preceded the publication of the reporting standards by Oderich et al. Outcomes were analysed according to the reporting standards of Society for Vascular Surgery and the American Association for Vascular Surgery reporting standards (177, 178) with the exception of Paper IV where technical success was not precluded by intentional endoleaks deriving from procedure staging. On clinical success, it was directly assumed and reported as secondary clinical success any kind of reintervention needed to re-establish success of treatment without reporting the primary assisted.

Branch related instability was defined according to a previously proposed classification by Mastracci et al. (175) Aneurysm expansion or shrinkage were assumed whenever the diameter increased or decreased > 10 mm respectively (105) with the exception of the first study (Paper I) where aneurysm sac enlargement referred to diameter changes > 5 mm.

Spinal cord ischaemia (SCI) was defined as any new lower limb neurological deficit not attributable to other pathology. SCI was further classified as paraplegia (complete inability to move the lower limbs) and paraparesis or lower limb weakness (required assistance to stand or to walk). (179) The duration of SCI was considered transient if the neurological deficit resolved within 30 days post-operatively and persistent if it persisted for more than 30 days after the procedure.

Early morbidity was defined as occurring within the first 30 post-operative days. All-cause mortality encompasses both early and late mortality in our centre, with the collaborating sites having discretion in their interpretation. It would be valuable to supplement this the use of national death registries and medical records to better understand mortality rates.

Data Collection and CTA Measurements

Data was collected retrospectively from electronic medical records and from local prospective databases according to an anonymized pre-established dedicated protocol with the respective specifications for each study. In the multicentric studies, Paper II and IV involving multicentre registries only the primary investigators had and will have access to the dataset with the specification of that only study-personal have access to the data and in a pseudoanonymized form. Upon completion of the project, each centre has ownership of its own data. Any future need to re-use or transfer the data must be approved by all contributing centres.

Patient characteristics, clinical details, and CTA measurements were retrospectively collected in RED-Cap 10.0.23 (Vanderbilt University, Nashville, TN, USA) from electronic patient records and re-measurement of the CTA in Paper III.

The arterial phase imaging of the contrast-enhanced CT angiography (CTA) was used for preoperative measurements in all the studies. Aneurysm and arterial diameters were measured on axial imaging perpendicular to the largest diameter to avoid overestimation from tortuosity. In Papers II, III and IV pre- and postoperative follow-up CTA were done according to each centre's routine. Particularly in Paper III the preoperative and first postoperative CTA scans were assessed in a 3mensio 10.2 vascular workstation (Pie Medical Imaging BV, Maastricht, the Netherlands) following a predefined measurement protocol (180). The planned pre- and the effective post-EVAR endograft oversizing were calculated from the nominal endograft diameter and the pre- and post-EVAR neck diameter at the lowest renal artery baseline, respectively, as shown in Formulas (1) and (2):

$$\left(\frac{\text{nominal endograft diameter}}{\text{preoperative neck diameter}} - 1 \right) \times 100\% \quad (1)$$

$$\left(\frac{\text{nominal endograft diameter}}{\text{postoperative neck diameter}} - 1 \right) \times 100\% \quad (2)$$

Subsequently, the shortest apposition length was calculated using vascular image analysis (VIA) prototype software (Endovascular Diagnostics BV, Utrecht, The Netherlands), according to previously published methods (181). The measurements were performed by one experienced observer, to avoid inter-observer variability. Measurements were randomly verified, and outliers were checked for correctness by a second experienced observer.

Iliac tortuosity index, which was calculated in Papers I and II as the ratio between the distance along the central lumen line from the aortic bifurcation to the common femoral artery and the shortest distance between the same anatomical landmarks (182). In our centre iNtuition (TeraRecon, San Mateo, CA) was used, whereas in the multicentre study each centre used their local 3-D software. All imaging in the multicentre studies was reviewed at each centre by experienced observers according to local routines. No consolidated diagnostic laboratory was used such as core-lab.

Statistics

Categorical data are presented as absolute number and percentages and analysed using the χ^2 test or Fisher exact test in Paper II. Continuous variables were tested for normal distribution by the Kolmogorov-Smirnov test and expressed as median (interquartile range; quartile 1 to quartile 3) and mean \pm standard deviation according to the normality of the distribution. In a similar way, 2-sample t test or Mann-Whitney U test, were used according to the data distribution. In Paper III correlations between the increase in aortic diameter, the preoperative aortic diameter, and the intended oversizing with the systolic blood pressure were tested with the Pearson correlation coefficient (R). Correlations between the increase in infra-renal aortic diameter and the shortest apposition length were tested with the Spearman correlation.

Time-dependent outcomes were reported using Kaplan-Meier estimates, with respective numbers at risk, standard error (with an exception for Paper I) and differences determined by the log-rank test. Statistical analysis in all Papers was conducted using SPSS software (IBM Corp, Armonk, New York, NY, USA).

An important statistical tool is the statistical power calculation, which is commonly employed for determining the sample size required for a study and is carried out

during the planning stage. Particular useful in prospective random control studies to estimate the ability of a study to detect a meaningful effect or difference in a population based on a specified level of statistical significance, sample size, and variability. The use of power calculations helps to ensure that a study is adequately powered to detect the effects being studied, which can increase the chances of obtaining reliable and meaningful results. However, power calculations are not always necessary in medical research and depend on the specific design and objectives of the study. In some cases, the sample size may be determined based on practical or logistical considerations, and power calculations may not be necessary or feasible. In this thesis, only Study II had two or more comparing groups and did not conduct a priori analysis due to the limitation of the lack of pre-existing reference literature on the subject. However, a retrospective power analysis was conducted by the given data set, known as a “post hoc power analyses”, which showed a power of 98.4% (generally considered sufficient a power for any test > 80%). Despite the small sample size, the expected discrepancy in outcomes was anticipated due to the main difference between the groups in terms of their haemodynamic stability.

A probability (p) value < 0.05 was considered indicative of statistical significance (183).

Ethical considerations

All of the studies were conducted in accordance with the declaration of Helsinki for medical research involving human subjects and complied with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for cohort studies (184).

Ethical approval was obtained for all studies by the initiating centre and locally whenever required. Local and national requirements for the informed consent were followed. Currently, in Sweden, this is waived for retrospective data analysis following a decision from the national central ethical committee board.

All patients had already given the informed consent to the procedures according to the local routines.

Results

Paper I

Six male patients with a median age of 65 (42-80) years were included. Six patients who had CIA aneurysms >25 mm with 4 of them having an AAA with concomitant unilateral (n = 2) or bilateral (n = 2) CIA aneurysms were included. Indications for use of IBD in the current series was rupture of the abdominal aortic aneurysm with concomitant CIA aneurysm (n = 3) and rupture of iliac artery aneurysms (n = 3). Full patient demographics and anatomical characteristics are presented in Table 3. Technical success achieved in all cases with procedural details presented in Table 4. The median follow-up time was 34 months (range 19 - 78 months).

Table 3: Patient's demographical and anatomical characteristics.

Patient characteristics	Median (IQR)	N
Age, y	65 (42-80)	
Male		6
Diabetes mellitus		0
Hypertension		4
Hyperlipidemia		2
Cardiac disease ^a		2
Renal failure ^b		0
GFR (mL/min/1.73 m ²)	68 (43-118)	1
COPD		1
Smoking, current	27 (22-30)	0
Buttock claudication		6
BMI	48 (22-104)	6
Circulatory stable	51 (25-65)	
ASA classification ≥4		
AAA (mm)		
CIAA (mm)		

Circulatory stability was assumed as systolic blood pressure >90 mm Hg and conscious patient. COPD, chronic obstructive pulmonary disease; BMI, body mass index.

^aDefined as current angina pectoris, previous myocardial infarction, CABG operation or PCI, current or previous arrhythmia, or heart failure.

^bDefined as a serum creatinine level >130 mmol/L.

Primary clinical success was achieved in 6 (75%) of the 8 IBDs (2 patients with bilateral aneurysms). During surveillance, 4 secondary interventions were performed in 2 patients, both who had bilateral IBDs. The overall primary and primary assisted clinical success rates at 24 months postoperatively were 75% and

100%, respectively. The primary and assisted IIA patency at the same time point were 75% and 100%, respectively, whereas the secondary intervention-free survival estimate was 75%. No other major complications occurred during the follow-up, and there were no deaths, Figure 18.

Table 4: Procedural details.

	Median (IQR)
Total procedure time, min	188 (114-350)
Procedure time per IBD, min	28 (14-55)
Contrast volume, ml	139 (57-260)
Procedural radiation, Gy.cm2	87.1 (67.9-181)
Fluoroscopy time, min	33 (20-76)



Figure 18: 3-D reconstruction of CTA image on the first month of follow-up showing successful exclusion of the ruptured aortoiliac aneurysm and patent IIA with the use of IBDs bilateral.

Paper II

48 patients were included in this study. 24 patients received unilateral (20 patients) or bilateral IBDs (4 patients). 24 consecutive patients with at least 1 IIA intentionally occluded during the repair of a ruptured aneurysm were identified as controls (14 unilateral and 10 bilateral). There were no differences in demographics,

preoperative characteristics, and aneurysm extent (including anatomical and morphological characteristics of the aneurysms) between groups, except for a higher tortuosity index of the right iliac artery on the embolization group. Baseline demographics and clinical characteristics of the 2 groups are reported in detail in Table 5 while anatomical characteristics and clinical indication for treatment are reported in Table 6.

Table 5: Demographics and Clinical Characteristics of 48 Patients treated with preservation or occlusion of the IIA in the acute repair of Ruptured Aortoiliac Aneurysms.

	IIA preservation (N=24)	IIA occlusion (N=24)	p Value
Age, years	71±12	76±9	0.89
Male sex	22 (92)	22 (92)	
BMI, kg/m ²	27±4	26±4	0.59
Smoking, current	6 (25)	2 (8)	0.12
Smoking, prior	10 (42)	13 (54)	0.39
Hypertension	17 (71)	15 (63)	0.76
Hyperlipidaemia	9 (38)	11 (52)	0.33
Coronary artery disease	5 (21)	10 (42)	0.66
Congestive heart failure	2 (8)	6 (25)	0.12
COPD	6 (25)	8 (33)	0.53
Peripheral artery disease	0	1 (4)	0.31
Diabetes mellitus	1 (4)	2 (8)	0.55
Stroke or TIA	1 (4)	2 (8)	0.55
Chronic kidney disease			
Stage III-V	11 (46)	12 (50)	0.77
Loss of consciousness	3 (13)	5 (21)	0.44
Haemodynamic instability	4 (17)	10 (42)	0.23
Ischemic changes on ECG	2 (8)	1 (4)	0.55
Haemoglobin, g/L	114±22	114±27	0.93
Creatinine, µmol/L	130±60	127±80	0.89
eGFR, mL/min/1.73 m ²	62±27	55±21	0.24

Table 6. Anatomic Characteristics and Indications for Repair of 48 Patients Treated With Intentional Occlusion of IIA or IBD with Preservation of IIA on Acute Setting of Ruptured Aortoiliac Aneurysms.

	IIA preservation (N=24)	IIA occlusion (N=24)	p Value
Prior aortic repair			
OAR	2 (8)	0	0.15
EVAR	3 (13)	1 (4)	0.30
F/BEVAR	1 (4)	0	0.31
TEVAR	2 (8)	0	0.15
Ascending/arch	2 (8)	0	0.15
Aneurysm morphology, mm			
Abdominal aortic diameter	62±31	71±27	0.26
CIA left	31±16	33±21	0.89
CIA right	35±17	33±20	0.35
IIA left	18±18	13±7	0.43
IIA right	19±18	12±7	0.43
Iliac tortuosity left	0.83±0.59	1.61±0.75	0.16
Iliac tortuosity right	0.89±0.55	1.36±0.27	0.004
Preoperative status of hypogastric arteries			
Both patent	22 (92)	22 (92)	
One occluded	2 (8)	2 (8)	
Indication for treatment			
rAAA	8 (33)	18 (75)	0.004
rTAAA	2 (8)	0	0.15
PAU	3 (13)	0	0.07
rCIA right	4 (17)	2 (8)	0.38
rCIA left	5 (21)	4 (17)	0.71
rIIA right	2 (8)	0	0.15
rIIA left	1 (4)	0	0.31

Categorical variables are presented as number (%). Continuous variables are presented as mean±standard deviation. Boldface entries indicate statistical significance.

Abbreviations: CIA, common iliac artery; EVAR, endovascular aortic repair; F/BEVAR, fenestrated/branched EVAR; IBD, iliac branched devices; IIA, internal iliac artery; OAR, open aortic repair; PAU, penetrating atherosclerotic ulcer; rAAA, ruptured abdominal aortic aneurysm; rCIA, ruptured common iliac artery; rIIA, ruptured internal iliac artery; TEVAR, thoracic EVAR.

Table 7. Procedural Details and Device Design of 48 Patients Treated With Intentional Occlusion of IIA or IBD With Preservation of IIA on the Acute Setting of Ruptured Aortoiliac Aneurysms.

	IIA preservation (N=24)	IIA occlusion (N=24)	p Value
Anaesthesia			
Local	4 (17)	6 (25)	0.48
Regional	0	2 (8)	0.15
General	12 (50)	14 (58)	0.56
Local converted into general	8 (33)	2 (8)	0.033
Upper extremity approach			
Right side	1 (4)	1 (4)	
Left side	0	5 (21)	0.018
Both sides	1 (4)	1 (4)	
Percutaneous femoral access	22 (92)	18 (75)	0.13
Open femoral access	2 (8)	9 (37)	0.016
Type of aortic repair			
EVAR	20 (83)	23 (96)	0.16
F/BEVAR	1 (4)	0	0.31
Isolated IBD	3 (13)	0	0.07
Side of procedure			
Right	10 (42)	7 (29)	0.37
Left	10 (42)	10 (42)	
Bilateral	4 (17)	7 (29)	0.31
Device (EVAR)			
Cook	23 (96)	15 (63)	0.004
Gore	1 (4)	0	0.31
Medtronic	0	9 (37)	0.001
Total procedure time, minutes	224±151	176±70	0.45
Procedure time per IBD, minutes	70±90	—	
Contrast volume, mL	139±86	163±62	0.13
Fluoroscopy time, minutes	58±75	49±20	0.11
Procedural radiation, mGy/cm ²	8887±9170	10430±16486	0.81
Completion cone beam CT, yes	7 (29)	5 (21)	0.51
Haemodynamic instability (intraoperative)	4 (17)	12 (50)	0.014
Use of occlusion balloon, yes	2 (8)	11 (46)	0.003
Vessel target			
IIA right			
IBD	14 (58)	0	
Embolization	3 (13)	13 (54)	
Intentional coverage	1 (4)*	1 (4)	
IIA left			
IBD	14 (58)	0	
Embolization	0	12 (50)	
Intentional coverage	0	4 (17)	
Technical success per vessel	28 (100)	30 (100)	
Estimated blood loss, mL	986±1278	2933±4460	0.043
Hospital stays, days	12±8	22±22	0.33
Intensive care unit stay, days	2±2	8±16	0.043

Categorical variables are presented as number (%). Continuous variables are presented as mean±standard deviation. Boldface entries indicate statistical significance.

Abbreviations: CT, computed tomography; EVAR, endovascular aortic repair; F/BEVAR, fenestrated/branched EVAR; IBD, iliac branched devices; IIA, Internal iliac artery.

*this patient was treated with IBD on one side and intentional occlusion on the other (right).

Procedural Details and Device Design are demonstrated in detail in Table 7.

IBD group. The median follow-up time was 17 months (2–39). Six (25%) patients needed a total of 8 late reinterventions, with 5 of them being IBD-related. Three (11%) IBD occlusions occurred 11, 15, and 23 months after the index surgery; the occlusions were of the entire IBD, the IIA branch, and the CIA, respectively. The first 2 were successfully dealt by endovascular means, while the latter was treated with a femoral-femoral crossover bypass, which revascularized the lower limb but not the IIA. No patient developed buttock claudication. The overall primary patency of the IIA branch at 3 years was $60\pm 14\%$, and primary-assisted and secondary patency was $92\pm 8\%$ (Figure 19). The overall survival at 12 and 36 months was $85\pm 8\%$ and $76\pm 11\%$, respectively. No aneurysm-related death occurred, but there were 4 late non-aneurysm-related deaths after 35 (11–47) months (Figure 20).

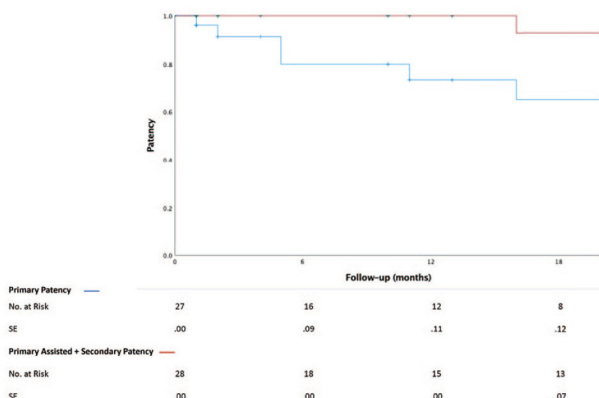


Figure 19: Cumulative Kaplan-Meier estimate for primary patency and primary-assisted and secondary patency of 28 internal iliac artery branches after the use of iliac branch devices on ruptured aortoiliac aneurysms. Estimates up to 18 months. SE, standard error.

IIA occlusion group. The median follow-up time was 27 (13–63) months. One secondary intervention was performed with extension to the external iliac artery due to CIA aneurysm on the contralateral side. Twenty-five (83%) hypogastric arteries were embolized, and 5 (17%) were intentionally covered with stent grafts without embolization. Of the 25 embolizations, 21 (84%) were performed with a liquid embolic agent (Onyx; Medtronic, Minneapolis, MN, USA), 4 (16%) with Amplatzer vascular plugs (Abbott, Chicago, IL, USA), and 1 case with a combination of liquid embolic agent and coils. No late endoleaks from the IIA were noted. The overall survival at 12 and 36 months was $48\pm 11\%$ and $38\pm 10\%$, respectively (Figure 12), which was significantly lower than that after IBD ($p=0.022$). However, this difference disappeared when the first 90 days were censored ($p=0.142$).

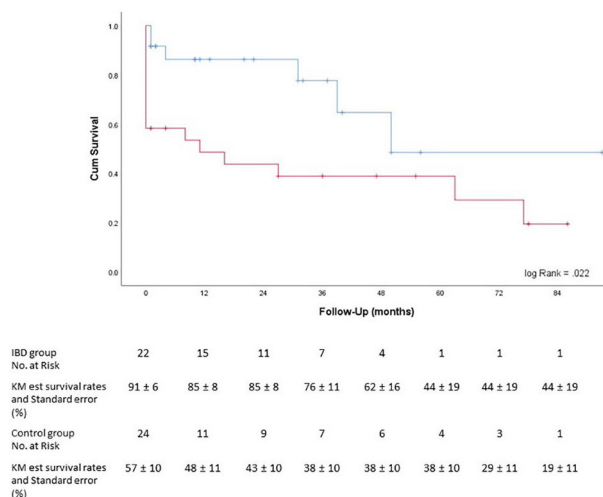


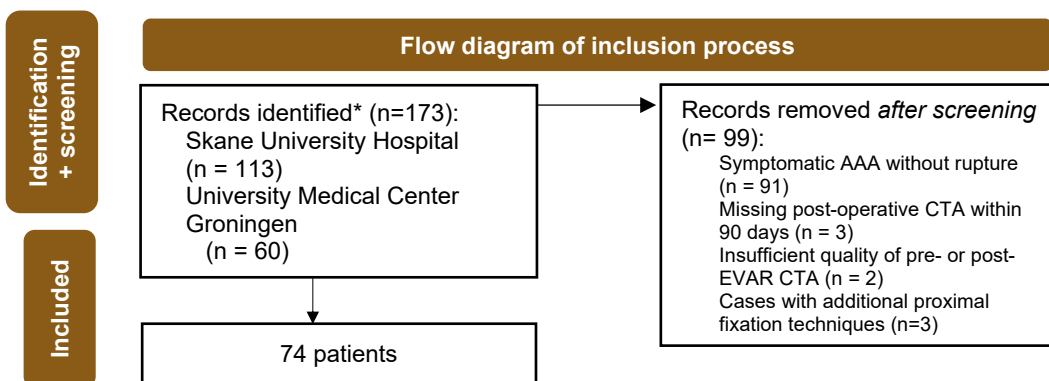
Figure 20: Cumulative Kaplan-Meier (KM) estimate for 48 patients' survival after the use of iliac branch devices or internal iliac artery intentional occlusion on ruptured aortoiliac aneurysms. IBD, iliac branched devices.

Paper III

Inclusion criteria were a CTA-confirmed rupture of the AAA and endovascular treatment with a standard infra-renal bifurcated endograft. An rAAA was defined as a visible retroperitoneal hematoma on CTA confirmed by an experienced vascular surgeon or radiologist. A flow diagram, Table 8 shows the inclusion process that has been followed.

Table 8: Flow diagram of inclusion process.

*Patients with acute or emergency endovascular repair of abdominal aortic aneurysm.



The baseline characteristics of the 74 included patients are reported in Table 9, and their haemodynamic and renal parameters are shown in Table 10. The pre- and postoperative systolic blood pressure was available for 63 patients and was significantly lower pre-EVAR compared to post-EVAR ($p < 0.001$), and 23 of these patients (33%) were in hypovolemic shock, defined as preoperative systolic blood pressure of <90 mmHg.

The aortic endografts that were used were: Cook Zenith (72%), Gore Excluder (21%), and Medtronic Endurant (7%). The aortic diameter was significantly larger postoperative compared with preoperative at all aortic levels, Tables 11 and 12, in all tables “+” means cranial orientation and “-” “caudal.

Tabel 9. Baseline total patient characteristics.

Variable	Value (%)
Age (years)	74 \pm 7
Male sex	64 (87)
BMI (kg/m ²)	26 \pm 5
ASA Physical Status >II	42 (58)
Hypertension (Systolic blood pressure > 140 mmHg)	39 (53)
Diabetes mellitus	11 (15)
Heart disease	7 (10)
COPD	13 (18)
Smoking:	
Current	18 (25)
Former	16 (22)
Never smoked	4 (5)
Unknown	36 (49)

Categorical data are presented as n (%); continuous data are presented as mean \pm SD; ASA = American Society of Anesthesiologists physical status classification; BMI = body mass index; COPD = chronic obstructive pulmonary disease.

Table 10. Haemodynamic and renal parameters upon presentation at emergency department and post-EVAR.

Variable	Pre-EVAR (Mean \pm SD)	Post-EVAR (Mean \pm SD)	p-Value
Systolic blood pressure (mmHg)	106 \pm 32	133 \pm 24	<0.001
Heart rate (bpm)	81 \pm 19	84 \pm 22	0.497
eGFR (mL/min/1.73 m ²)	57 \pm 16	66 \pm 21	0.002
Creatinine (μ mol/L)	110 \pm 33	95 \pm 36	0.001

eGFR = estimated glomerular filtration rate.

Table 11. Aortic neck diameters and oversizing measured on the preoperative and first postoperative computed tomography scans.

Level Relative to Lowest Renal Artery	Preoperative Diameter (mm)	Post-Operative Diameter (mm)	p-Value	Planned Pre-EVAR Oversizing (%)	Achieved Post-EVAR Oversizing (%)	p-Value
+40 mm	24.9 ± 2.7	26.3 ± 2.6	<0.001			
+ 10 mm	22.9 ± 2.8	24.9 ± 2.8	<0.001			
Baseline	22.0 ± 3.2	25.4 ± 3.7	<0.001	31 (22-40)	20 (10-26)	<0.001
-10 mm	22.7 ± 3.9	25.4 ± 3.7	<0.001	27 (19-36)	14 (7-23)	<0.001
- 20 mm	24.4 ± 6.0	27.7 ± 6.3	<0.001	22 (11-28)	10 (1-16)	<0.001

The aortic diameter increases at 40 mm proximal to the baseline correlated with the preoperative systolic blood pressure ($R = -0.368$ [$p = 0.003$]; Table 12). The supra-renal diameter increased 2.2 ± 1.4 mm in patients with hypovolemic-induced hypotension, and 1.3 ± 1.0 mm in patients without hypovolemic-induced hypotension. The diameter increases at 40 mm proximal to the renal artery baseline in patients with hypovolemic-induced hypotension is 69% higher than in patients without hypovolemic-induced hypotension.

Table 12. Correlation between preoperative systolic blood pressure and aortic diameter increase post-EVAR.

Level Relative to Lowest Renal Artery	Diameter Increase (mm)	Correlation with Systolic Blood Pressure (R)	p-Value
+40 mm	1.5 ± 1.8	-0.368	0.003
+ 10 mm	2.1 ± 1.5	-0.338	0.007
Baseline	2.2 ± 1.5	-0.204	0.108
-10 mm	2.7 ± 1.9	-0.387	0.002
- 20 mm	3.4 ± 4.3	-0.115	0.371

Paper IV

18 male patients (76 years old; range 69-78 years) underwent F/BEVAR in FEVAR to salvage a FEVAR with a failing proximal sealing zone. During the same period 2805 FEVAR were done at the eight institutions (0.64% receiving F/BEVAR in FEVAR). The median time from the initial repair to diagnosis of the failure was 46 (25-95) months while the F/BEVAR in FEVAR was done 53 (29-103) months post-operatively. One open conversion of failed FEVAR was done during the study period due to graft infection. Patient characteristics are presented in Table 13.

Table 13. Clinical characteristics of 18 patients undergoing redo fenestrated/branched endovascular aneurysm repair (F/BEVAR) to rescue failed fenestrated endografts. Data are presented as n or median (interquartile range).

Patient characteristics		Patients (n=18)
	Male gender	18
	Age at the time of re-F/BEVAR - y	76 (69-78)
	Aneurysm diameter - mm	63 (56-69)
Comorbidity	Heart disease	3
	Diabetes mellitus	1
	COPD	9
	Renal insufficiency	4
	Hypertension	14
	Stroke	3
	Coronary artery disease	11

COPD: chronic obstructive pulmonary disease.

The vast majority of the initial FEVARs incorporated the distal part of the renovisceral segment (13 patients, 72%) with a graft with two fenestrations and one scallop being the most common configuration (12 patients, Figure 21). Indication for F/BEVAR in FEVAR was as a type Ia endoleak in eight cases, a type Ia endoleak combined with graft migration in eight cases, one graft migration without endoleak and one migration with significant proximal aortic expansion.

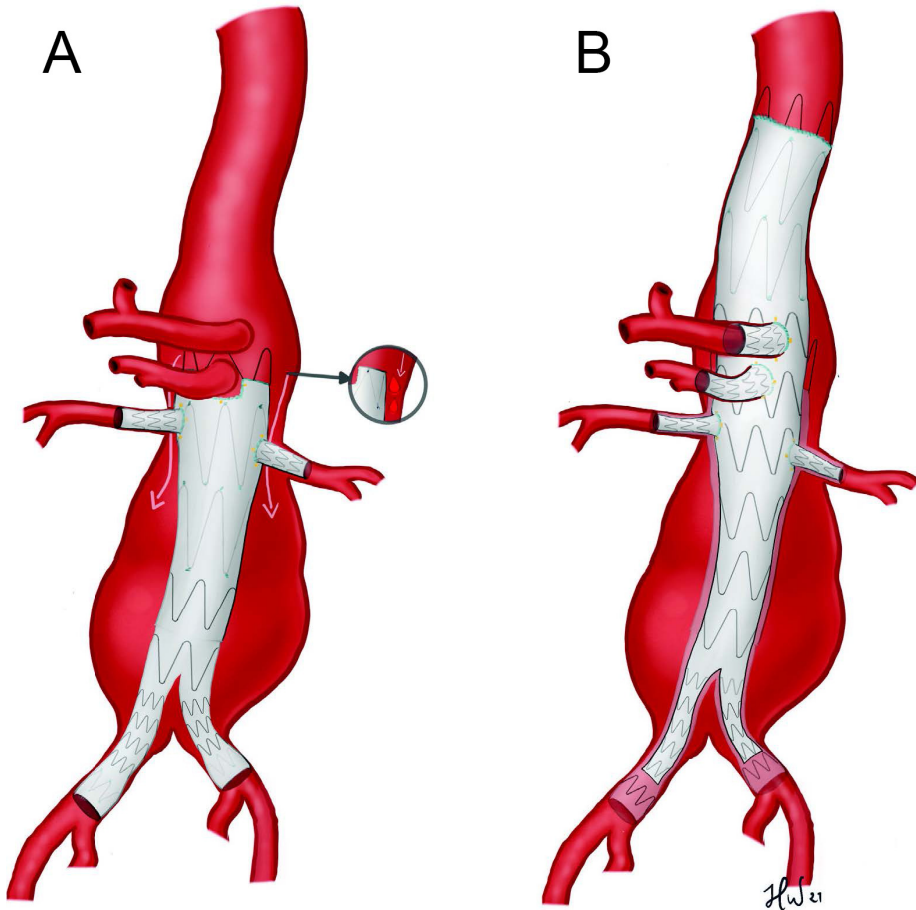


Figure 21: (A) Type 1a endoleak after a fenestrated endovascular aneurysm repair (FEVAR) with fenestrations for the renal arteries and a scallop for the superior mesenteric artery which was the most common configuration in the initial FEVARs. (B) A new four fenestration FEVAR (F/BEVAR in FEVAR) successfully implanted.

Details regarding the procedures can be found in Table 14. Median CT follow up was 18 (2 - 39) months. 13 (72%) patients had primary clinical success throughout follow up. Three (17%) patients required late reinterventions with the exception of three intentional staged procedures. In one patient it was not possible to bridge a branch cuff to the left renal artery intra-operatively and a later reintervention was needed which performed successfully through an open retrograde access. In another case a renal artery branch had been embolised despite the aneurysm being well excluded as mentioned above. Lastly, one patient repeatedly refused treatment of a type Ib endoleak that re-required an intra-operative common iliac extension.

Primary clinical success at 12 and 24 months were $58 \pm 16\%$ and $58 \pm 16\%$ while the corresponding secondary clinical success was $84 \pm 11\%$ and $84 \pm 11\%$. Clinical follow

up duration was 27 (7 - 39) months, with an overall survival at 12 and 24 months of $82\pm 9\%$ and $70\pm 11\%$, respectively. No aneurysm related death occurred but there were seven late non-aneurysm related deaths after 25 (7 - 45) months.

Table 14. Details for the fenestrated/branched endovascular aneurysm repair (F/BEVAR) in FEVAR procedure in 18 patients.

	Patients (n=18)
Technical success	15 (83%)
Operation time - min	238 (204-344)
Fluoroscopy time - min	97 (63-131)
Dose area product - Gy.cm2	591.5 (141.2-2679.5)
Contrast volume - mL	110 (84-133)
FEVAR configuration	
4 fenestrations	3
3 fenestrations	2
3 fenestrations/1 branch	2
2 fenestrations/2 branches	6
1 fenestration/3 branches	3
T branch	2
Proximal component/TEVAR	10
Proximal landing zone	
Zone 3	2
Zone 4	6
Zone 5	10
Distal component	14
Tubular straight extension graft	3
Regular distal unibody	1
CMD bifurcated with inverted limb	

Data are presented as n or median (interquartile range).

Paper V

A total of 25 patients, not consecutive were treated using a delivery system with a short tip for the distal bifurcated device between November 2017 and July 2019 were included in the study. The majority of patients were male (N.=21, 91.3%), with a mean age of 72.8 ± 7.0 years. Full patient baseline characteristics are shown in Table 15.

Table 15. Baseline characteristics of the 23 included patients who underwent fenestrated endovascular aneurysm repair with short dilator tip of the distal bifurcated component. Data are presented as mean±standard deviation or N. (%).

		Patients (n=23)
Demographics		
	Age	72.8±7.0
	Female sex	2 (8.6)
Comorbidities		
	BMI>30	27.1±4.2
	IHD	9 (39.1)
	Hypertension	15 (65.2)
	Hypercholesterolemia	16 (69.5)
	COPD	4 (17.3)
	DM	6 (26.0)
	CDK stage >3 (eGFR<60)	13 (56.5)
	Previous stroke/TIA	3 (13.0)
Smoking		
	Never	4 (17.4)
	Previous	11 (47.8)
	Current	8 (34.8)
ASA class > 3		0

BMI: Body Mass Index; IHD: ischemic heart disease; CHF: congestive heart failure; CKD: chronic kidney disease; COPD: chronic obstructive pulmonary disease; DM: diabetes mellitus; eGFR: estimated glomerular filtration rate; EVAR: endovascular aneurysm repair; OAR: open aortic repair.

Technical success was in all cases. Full anatomical and procedural details are shown in Table 16.

Table 17 shows an overview of the intra-operative fenestration adverse events detected by the cone beam CT and the relation to the crossing of the fenestrations, which was graded as “not crossing,” “partial crossing” and “complete crossing” relative to the lowermost fenestration (Figure 22). Partial crossing was defined as crossing of the lowermost fenestration with $\geq 50\%$ of the introducer tip, complete crossing was defined as crossing of the lowermost fenestration with the complete introducer tip.

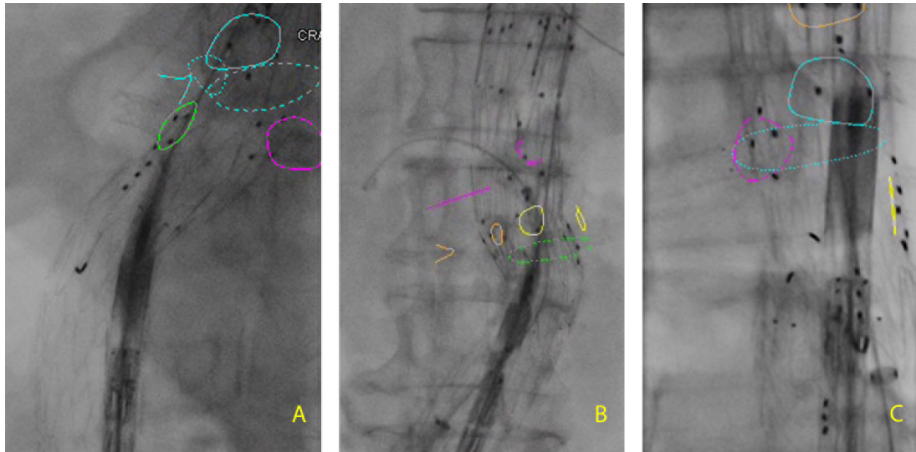


Figure 22: Degree of crossing of the fenestration mating stent-grafts, graded as A: not crossing, B: partial crossing and C: complete crossing relative to the lowermost placed fenestration.

The fenestration compression was corrected intra-operatively by doing a repeat PTA in 5 patients. All fenestrated stent-grafts were on a preloaded delivery systems with the distal components to be especially designed with short bodies. In another patient it was impossible to gain access to the lumen of the original compressed bridging stentgraft and a second stent-graft was placed in the LRA alongside the first. All these intra-operative re-interventions were done with good effect.

Table 16. Aneurysmal, procedural and device characteristics for the 23 included patients who underwent fenestrated endovascular aneurysm repair with short dilator tip of the distal bifurcated component. Data are presented as mean±standard deviation, median (with interquartile range) or N. (%).

Variables	Patients (n=23)
Prior EVAR	4 (17.3)
Anatomical details	
Juxtarenal	21 (91)
Type IV TAAA	2 (9)
Largest AAA diameter (mm)	61.9±7.5
Supra renal angulation (°)	15 (5-42)
Infra renal angulation (°)	31 (20-43)
Inner vessel diameter*	24.0±4.2
Device details	
N of fenestrations	4 (3-4)
Graft diameter proximal (mm)	32.8±3.3
Lowest fenestration	
Right renal artery	11 (47.8)
Left renal artery	12 (52.2)
Graft diameter lower fen	26.7±4.8
Procedure details	
Total operation time (min)	363.0±97.5
Total fluoroscopy time (min)	101.1±42.3
Contrast volume (mL)	83.1±35.5
Cone beam CT	23 (100)

*At the level of lowest fenestration.

During follow-up, 4 (17.3%) patients underwent reintervention due to fenestration target vessel adverse events. All these procedures were done immediately postoperatively due to symptoms or following findings on the 1-month postoperative CTA. One patient had a dissection in the SMA distal to the stented segment with thrombosis. This was only identified on postoperative day 2 and a secondary intervention was performed using the Angiojet pharmacomechanical system with thrombolysis with power pulse spray (Boston Scientific, Marlborough, MA, USA). The vessel was stented with good effect and afterwards an ileocecal bowel resection was performed. In this case, there had been no crossing of the fenestrations with the short dilator tip. Two patients had signs of a type Ic endoleak, originating from the renal artery, which were diagnosed on the 1-month post-operative CTA, not detectable with CBCT. A secondary intervention was done in both cases with re-PTA and stenting with good result and without complications. The last patient had signs of thrombus in the RRA stent-graft on the first post-operative CTA, although there was still perfusion of the kidney and no change in the creatinine. Retrospective evaluation of the intraoperative cone beam flat panel CT showed already the compression of the RRA stent-graft, but this had been interpreted as artifacts from the gold markers of the fenestration.

Median follow-up was 34 (27-38) months. Two patients died during the study period both non-aneurysm related. Fenestration related overall secondary intervention rate in this cohort was therefore 13.0% meanwhile the estimated primary patency during follow-up was 96±4% at one year and 91±6% at 2, 3 and 4 years with 100% primary assisted patency.

Table 17. Overview of fenestration related adverse events peri-operatively, as diagnosed by cone beam CT on 23 patients treated with short dilator tip of distal bifurcated component during FEVAR. Events occurred in 6 (26%) patients, of which one had both SMA and LRA compression.

Compression of mating stentgraft	Side of introduction ¹	Crossing of lowermost fenestration	Lowest fenestration
CT (n=1)	Right	Partial	LRA
SMA (n=1)	Right	No	RRA
RRA (n=1)			
RRA	Right	Partial	RRA
LRA (n=4)			
LRA	Right	No	LRA
LRA	Right	Partial	LRA
LRA	Right	No	RRA
LRA	Right	Partial	LRA

¹= Side of introduction of the bifurcated device. CT = coeliac trunk, SMA = superior mesenteric artery, RRA = right renal artery, LRA = left renal artery

Discussion

Endovascular aortic surgery, with its minimalistic nature and limited repercussions on the patient has gained popularity in both elective and acute settings, especially for the challenging cases of complex aortic aneurysms. One of the major challenges is the long-term durability of the repair though. Previous concerns regarding the lifespan of the stent-grafts seem to have settled down as the devices often outlive the patients. The continuing progress of this degenerative disease on the other hand worsens the clinical outcomes regardless the surgical techniques and method that is applied and future reinterventions may be needed (185). Additionally, on the endovascular treatments there is a risk of endoleaks. Especially complex AAAs or ruptured cases, particular those outside the IFU for treatment with standard component, pose considerable challenges for the endovascular repair. The constant struggle of a modern vascular surgeon remains the accomplishment of adequate proximal, and distal sealing without causing impairment of spinal cord perfusion (186, 187) with a well excluded aneurysm. A < 5 cm threshold of aortic coverage above the celiac trunk seems sufficient in regards of avoidance spinal cord ischemia (188).

Iliac branch devices on ruptures

In the case of ruptured aortoiliac aneurysm, which is a very challenging clinical scenario, iliac branched devices (IBDs) have been found to be a feasible option with high technical success rates and satisfactory midterm outcomes. However, strict patient selection is necessary, with a focus on haemodynamic stability, and reintervention rates are still considerable, particularly for bilateral procedures (Paper I and II)(189, 190). Even if reinterventions may be needed later on, the risk for pelvic complications such as buttock claudication, sexual dysfunction, colon ischemia and spinal ischemia (167, 191, 192) is anticipated to be decreased due to the perfusion maintenance of pelvic circulation during the most critical and hazardous period of the acute setting with an ongoing rupture. Moreover, the use of IBD can also be an indirect way of staging the repair of the complex anatomies often found in ruptures. Standard infrarenal solutions are commonly used in poor proximal sealing zones on those occasions, as discussed further down. This may risk the need for proximal extensions in the future which can in itself compromise the spinal cord if the IIA collateral bed has been sacrificed before. This decision needs to take into account the haemodynamic stability. Particularly, one important technical remark has to be made regarding the scenario of patient becoming

haemodynamically unstable intraoperative. In that case it is advisable to abort the IBD stage of the procedure and proceed with immediate exclusion of the aneurysm with the intended EVAR. In case that IBD is already partially deployed, endoclamping (193) in the branch can applied, proceed with EVAR and as soon aneurysm is excluded the patient should be reassessed in regard to haemodynamic status and final decision can be taken depended on the status for either embolization of the branch or bridging and completion of the repair. The potentially increased time until exclusion may also lead to more severe repercussion such as increased blood loss and even increased risk of abdominal compartment syndrome development. All of these factors have to be taken into consideration prior the decision for use of IBD on an acute setting. The importance of strict patient selection cannot therefore be overstated.

Another interesting topic is the choice of embolization agents when it is decided to proceed with embolization of IIA for clinical reasons. The current available options are vascular plugs with most commonly used Amplatzer Vascular Plug (AVP; St Jude Medical, Saint Paul, MN, USA) (194), coils (195, 196), and liquid embolic agents (Onyx; Medtronic, Minneapolis, MN, USA) (197). High technical success is reported for all these agents though vascular plugs are associated with reduction of procedure time and radiation exposure. An important technical remark during embolization of IIA is the following:

- When is necessary the embolization of IIA it should be performed as proximal as possible to prevent interference with pelvic collateral circulation (198).
- On the other hand, and particular on the acute setting of rAAA the use of Onyx allows the exclusion of the aneurysm and leaving the retrograde flow embolization to the last step, through a parallel catheter, which may help in stabilizing the patients (197). The decision on those cases has to be personalized.

There are some limitations particular to Paper II that have to be addressed especially in regard to the comparison between the two groups. First, it was a retrospective analysis of real-world data on an, until then, rare procedure at experienced centres. Consequently, it encompasses a long period where the experiences started at different times and have also evolved. The more frequent and liberal use of IBD outside the IFU guidelines on ruptures seems to follow the operators learning curve with this branched device, similar to what had happened to the main aortic infrarenal devices. Moreover, the value of a control group was limited by using a cohort from a single centre and not from all participating centres, which would have improved the assessment of patient selection and feasibility. The results of the comparison with patients whose IIA was sacrificed was naturally severely hampered not only by patient selection but also by the differences in haemodynamic stability which was the most critical confounder factor. The latter is certainly influencing the

survival differences and possibly the colonic ischemia incidence. Another approach could have been to aim on a more “matched” analysis to overcome some of those limitations such as a propensity matched analysis. This would have been also unrealistic due to the high patients’ number that would have been required (> 200 patients in the control group). Despite those limitations these results are still very valuable as a well-designed randomized control trial between different treatments would be unrealistic given the difficulties faced in EVAR for ruptured AAA (195).

- Paper I and II, show that ruptured aortoiliac aneurysms do not necessarily require mandatory occlusion of hypogastric arteries in the era of widely available iliac branch devices (189, 190).

Aortic neck dilatation post EVAR in rAAA

The results of hypovolemic-induced hypotension on aortic diameter in patients with ruptured abdominal aortic aneurysms (rAAA) show that a decrease in aortic diameter is significant, and the subsequent increase in neck diameter correlates with preoperative hypotension (Paper III)(199). These results are in line with previous studies in hypovolemic abdominal and thoracic aortic repair and porcine aortic models (200-202).

An important aspect of these types of studies is the value of intra- and inter-observer validation, which can be potentially improved through the use of a core laboratory that processes and analyses all data and imaging following standardized protocols. This was the strategy that was used in this study, where all the markings and measurements conducted by one person. This approach was also used in the single-centre studies, but it was unfeasible in the multi-centric ones.

Insufficient oversizing or even undersizing increases the risk of a type Ia endoleak, possibly affecting outcomes after EVAR of ruptured AAA. To achieve 10% to 20% effective oversizing, the endograft should be oversized by 30% to 40% compared with the pre-EVAR measured infra-renal neck and depending on the haemodynamic status with even more liberal oversizing on cases with signs of haemodynamic instability. This is in accordance with the ESVS guidelines, which advises 30% oversizing for rAAA patients (105). This recommendation is, however, based on a single case study (203) and needs to be balanced with the haemodynamic status at the time of the CT as suggested by our study. Too much effective oversizing (>30%) should be avoided as it has been associated with increased risk of endograft migration and AAA expansion and may also result in infolding of the endograft with associated type IA endoleaks.

- The achieved oversizing in hypotensive patients with ruptured cases seems to be less than would otherwise be achieved. This together with the poor anatomies that often met in ruptures makes the risk of failure of the proximal sealing higher in the future. This stresses the need for a close

postoperative follow up in these cases and the likely increased risk for more complex reinterventions in the future.

In those cases, with failure of the proximal sealing zone, the distances from the aortic bifurcation to the renal arteries will be decreased from the previous graft which will increase the risk of compression of the fenestrations with the new distal component's dilator tip. This is particularly the case if there are very angulated anatomies in the original acute phase repair and the use of grafts with longer distances to the flow divider, such as the Zenith platform, is not the most suitable. In those situations, survival is the top priority, and the most adequate graft should be chosen leaving the eventual problems with a re-do repair to be dealt with in the future. In those occasions, a one-piece bifurcated-FEVAR with integrated bifurcation of the fenestrated component (204) has also proven useful. More complex solutions may also be considered in the acute setting. One such is an off-the-shelf fenestrated graft as the Cook Zenith p-Branch (William A. Cook Australia, Brisbane, Queensland, Australia). This is still not commercially available but was shown to have a high anatomical feasibility in ruptures and good clinical outcomes, but it also needs haemodynamically stable patients (205-208). Finally, antegrade in situ laser fenestration techniques can be also applied in order to ensure an appropriate sealing (209), but their long-term results are still uncertain. Independently of the technique, the potential impact of the haemodynamic situation at the time of the preoperative CTA needs to be better understood.

- Studies such as ours help to optimize the sizing of endografts on those challenging cases of ruptures (199). Future studies are needed to investigate the long-term clinical impact of this phenomenon and could eventually focus even on more complex anatomies such as AAAs with conical and short aortic necks to determine adequate and safe oversizing's pattern.

Failing F/BEVAR, is it a lost cause?

Inadequate proximal sealing may potentially constitute a risk for the durability also of complex repairs such as F/BEVARs. The pooled data of the late type Ia endoleak after FEVAR were reported to be around 2-3% (170, 210, 211) with no guidelines or consensus regarding the approach to solve this complication. One therapeutic option is to extend the reconstruction proximally using a redo F/BEVAR. At this stage, the majority of the patients who require reintervention are not eligible or suitable due to frailty for major open thoracoabdominal repairs, and to the best of my knowledge, there are no published series on this topic besides ours. There is data on previous failed infrarenal repairs treated with redo EVAR (212-216) showing that is preferable to have a new bifurcated distal component in the redo reconstruction in order to avoid occult or impending type III endoleaks. The same applies to F/BEVAR in F/BEVAR since the difficulties to identify them in regular EVARs becomes even higher in FEVARs due to the excess of markers from all the devices.

- This has a practical implication during planning and designing the distal component on redo FEVARs where short tip dilator tip can also be included on the plan in order to avoid further complications and conflicts with the bridging stents of renovisceral target vessels.

In this very challenging scenario of failed FEVAR with need for fenestrated or branched endovascular aneurysm repair (F/BEVAR) to rescue the repair, the results are promising from a small cohort thus from eight high volume aortic centres (Paper IV)(217). Those low inclusion numbers shows that this is a very rare scenario due to combination of several factors and despite the technical demanding repair those cases are not beyond the therapeutic spectrum. Although it is advisable that such rare cases to be treated or referred on centres with high experience on complex endovascular aortic repairs. Efforts must be made to minimise serious complications, optimise patient selection, and reduce the need for re-interventions.

- It would be interesting to conduct a comparative study investigating the outcomes of these complex repairs with the ones from the elective setting. The aim would be to find the ideal balance on adequate sealing and complexity of the repair to the expected survival of the patient. As the ultimate repair's goal is just to outlive the patient.

It has to be highlighted the collective efforts which are critical in addressing rare diseases such as this. The value of collective efforts lies in the ability to generate a higher level of evidence, to make a greater impact than individual efforts alone and confirms the repeatability of these studies as well. Multicentred collaborations are essential to get the numbers of patients needed to gain a better understanding of the disease, improve diagnostic tools, and generate more effective treatments. A good example consists of the American, US F/BEVAR Aortic Research Consortium (US-ARC) from across 10 sites in the United States. Similar initiatives would be beneficial also in our continent.

Short dilatator tip: a technical advancement towards fewer reinterventions on FEVAR

A potential technical advance towards fewer re-interventions during complex endovascular aortic treatments could be for example the use of novel delivery systems with short dilator tips as it is already mentioned on the distal bifurcated devices especially during FEVAR. This has been found to reduce the need to cross fenestration bridging stent-grafts and subsequently potentially reducing fenestration-related adverse events (Paper V)(218). Although it has to be highlighted the potential confounding factor of the compression of the mating stents from the iliac extensions which are loaded into standard delivery systems with long dilators.

- A similar technology for the limb's extension dilator would be most probably beneficial with a similar fashion.

One note is that to take full advantage of the modification the graft planning needs to be adapted. The optimal planning should take into consideration the technical specifics mentioned earlier in order to overcome the potential hazardous manoeuvre of crossing the bridging stents.

- A practical guide would be to plan for approximate 45 mm of space for the dilator tip from the most distal fenestration. The use of inverted limb technology (219) on the distal bifurcated component, as necessary, can help ensure sufficient overlap with the proximal component and the deployment of contralateral gate at least gate 10 mm above the aortic bifurcation.

Another interesting fact was that the contralateral fenestrations to the introduction side were apparently influenced, with one exception where it was the lowest. A possible explanation would be that this may occur due to the positioning of the wires and the proximal angulations. It's important to note that this is just one possible explanation and further research would be necessary to determine the exact cause of these results taking into consideration factors such as neck angulation, iliac tortuosity, and others.

To maximize the durability and minimize the need for reinterventions of the repair, beside the technical consideration of the endograft's design, it is crucial to intraoperative assess and recognize technical complications. If these complications are not recognized, they can lead to loss of target vessels or significant morbidity and mortality (220).

- The utilizations of Cone Beam CT (CBCT) intraoperative, when available, is an essential tool for this purpose.

CBCT has been found to reliably detected positive findings that require immediate revisions in nearly one out of five patients, with the highest rates being among patients undergoing fenestrated-branched endovascular aneurysm repair (221, 222). Digital subtraction angiography alone may fail to detect positive findings that require secondary interventions.

In conclusion, advances in complex endovascular aortic techniques have revolutionized the way aortic aneurysms and other related conditions are treated. The development of new endograft designs and the integration of advanced imaging technologies have improved the accuracy and reliability of these procedures, resulting in increased durability and reduced need for reinterventions. With the continued development and refinement of these techniques, patients with aortic aneurysms and other related conditions have more options for treatment, with improved outcomes and reduced risk of complications. However, further research and refinement of these techniques is necessary to fully exploit their potential and ensure the best outcomes for patients.

Conclusions

- I. The IBDs are a feasible option to exclude ruptured aortoiliac aneurysms while maintaining the pelvic circulation. The reintervention rate is considerable, especially for the bilateral procedures, but the midterm primary assisted patency rates are very good.
- II. Iliac branched devices allow the exclusion of ruptured aortoiliac aneurysms while maintaining the pelvic perfusion with high technical success and satisfactory midterm outcomes. Strict patient selection is necessary, with a focus on haemodynamic stability and having an a priori bailout solution planned in case of perioperative instability signs.
- III. Hypovolemic-induced hypotension correlates negatively with the decrease of the aortic diameter in patients presenting with an rAAA. This may have implications on the sizing of the grafts and the long-term implications are still unknown.
- IV. F/BEVAR in FEVAR is rarely needed but, when it is, it is technically demanding. The results are promising though improvements are needed to minimize serious complications and the need for re-interventions. Proper preoperative planning of the original FEVARs may minimize the need of this very complex procedure.
- V. The use of delivery systems with short dilator tip on the bifurcated device reduces the need to cross the fenestration bridging stent-grafts during FEVAR and thereby potentially avoids the fenestration related adverse events.

Future perspectives

Future prospects for endovascular treatments of aortic diseases include the continued development of minimally invasive techniques and devices, as well as advancements in imaging and diagnostic technologies. This will likely lead to improved patient selection, better outcomes, and reduced complications. Additionally, there may be a growing emphasis on personalized medicine in the field, with treatments tailored to the specific needs and anatomy of each patient. As we are beyond the era of “one size fits them all” mentality and that is a big advancement of our field.

The latest advances include new bidirectional design of inner branches for increased flexibility of inner branch endografting (currently commercial available on limited centres by Cook Medical, Bloomington, Ind) (223). New platforms of inner-branched endografts (Jotec GmbH, Hechingen, Germany) in complex endovascular aortic aneurysm repair with good early outcomes beside the established platform of CMD from Cook Medical (224). Another new preloaded endograft, the TAMBE (thoracoabdominal branched endoprosthesis; W.L. Gore, Tempe, Ariz) is under investigation in the United States and Europe (139). Likewise new aortic stent-grafts devices (Kardiozis, Affluent Medical SA, Paris, France) with incorporated thrombogenic fibers (225) on the external surface to prevent endoleaks and possibly led to increased aneurysm sac shrinkage (in clinical development). Another area of potential growth is the use of artificial intelligence and machine learning to assist in decision making and device placement during procedures. This technology may also be used to improve patient outcomes by predicting complications and optimizing treatment plans based on individual patient data. Despite these advances, room for further refinement and improvement remains, including the techniques and the devices with a new generation of stent and stentgrafts to seem necessary in the near future.

In summary, the future prospects for endovascular treatments of aortic diseases are bright, with a focus on continued technological advancements and improved patient outcomes. This field will likely see continued growth and evolution in the coming years, leading to improved patient care and better outcomes for those affected by aortic diseases.

Populärvetenskaplig sammanfattning

Bukaortaaneurysm är ett tillstånd där kroppens stora blodkärl i buken vidgas. Tillståndet förekommer hos upp till 1,5 – 2,6 % av den svenska befolkningen vid 65 års ålder och drabbar främst män. Orsakerna till bukaortaaneurysm är flera, men det finns en stark korrelation mellan aneurysmbildning och rökning, ärftliga faktorer, högt blodtryck, ålder och manligt kön. Ju större aneurysm, desto större är risken att kärlet brister med katastrofala konsekvenser för patienten. En bristning, även kallat ruptur, orsakar en betydande inre blödning som ofta leder till döden. Tidigare forskning har visat att risken för bristning överstiger de risker som finns i samband med förebyggande kirurgiska ingrepp när kärldvidningen når 5,5 cm i diameter för män och 5,0 cm i diameter för kvinnor. Därför är det rekommenderat enligt nuvarande internationella riktlinjer att behandla i förebyggande syfte.

För att behandla bukaortaaneurysm används främst två olika behandlingsmetoder:

- Öppen kirurgi då den drabbade delen av aorta byts ut mot en insydd tub av tyg via ett stort snitt på buken.
- Endovaskulär kirurgi som innebär att en metallförstärkt protes av tyg förs in med hjälp av röntgen via punktion, oftast i ljumskpulsåderna och fodrar kärlets vägg. Denna minimalinvasiva metod kallas för EVAR (Endovascular Aortic Repair) som de senaste åren har utvecklats i rask takt till att även användas för komplexa bukaortaaneurysm, vilket innefattar kärllavgångar till viktiga bukorgan som lever, tarmar och njurar. Då kallas ingreppet F/BEVAR (fenestrerad/branched EVAR). Protesen är då försedd med hål i tyget (fenestreringar) eller inbyggda sidogrenar (branches) så att blod ska rinna ohindrat till de olika bukorganen. Proteserna har individuell design beroende på aneurysmets anatomi, varför dessa proteser kallas för custom made devices (CMD).

Behandling med F/BEVAR innebär ett flertal tekniska utmaningar. Protesen måste läggas med stor precision avseende höjd och rotation så att fenestreringarna ska hitta sina respektive kärllavgångar, som i sin tur även förses med mindre, tubulära proteser för att förhindra läckage. Noggrann planering med hjälp av kontrastförstärkt datortomografi krävs före ingreppet, och uppföljning av behandlingen sker regelbundet med årliga kontroller. Flera studier har visat att FEVAR ger bra resultat, åtminstone på kort sikt. Som med alla andra operativa behandlingar kommer dessvärre även F/BEVAR med vissa risker, både i samband med operation men även

efteråt under uppföljning. En av den mest vanliga är behovet av någon form av re-intervention för att säkerställa god och långsiktig funktion av ingreppet.

Slutgiltigt syfte med samtliga operativa tekniker är att exkludera aneurysmet från blodcirkulationen och på så sätt förhindra ett potentiellt livshotande tillstånd, såsom aortaruptur.

Syftet med denna avhandling var att utvärdera nya tekniker under de mest krävande kliniska omständigheter? såsom vid aortaruptur, men även utforska utfall av nya tekniker och metoder under operationer av komplexa bukaortaaneurysm avseende patientsäkerhet och protesernas hållbarhet. Avhandlingen består av fem olika delarbeten (I-V).

Studiernas specifika syfte var att:

- I. Utvärdera genomförbarheten och resultaten av IBD:s användning för att bevara IIA-perfusionen vid akut endovaskulär reparation av brustna aortoiliakala aneurysm.
- II. Utvärdera resultaten av att preservera cirkulation till IIA med IBD under akut endovaskulär reparation av brustna aortoiliakala aneurysm.
- III. Undersöka förändringarna i supra- och infrarenala aortahalsdiametrar före och efter EVAR för rAAA och det möjliga sambandet med endograft apposition.
- IV. Rapportera resultaten av att göra om fenestrerad och/eller grenad endovaskulär aortareparation för att rädda tidigare misslyckad FEVAR.
- V. Utvärdera genomförbarheten och effektiviteten av ett modifierat tillförselsystem av den distala bifurkerade FEVAR-komponenten där dilatatorspetsen förkortades för att förhindra skador på de renoviscerala överbryggande stentarna.

Slutsatserna av denna avhandling är att IBD i selekterade fall med rupturerade aortoiliakala aneurysm verkar ha god effekt i förhållande till överlevnaden. Misslyckad FEVAR är inte bortom räddning och bättre förståelse av fysiologin vid rupturer samt nya designer av stentgrafter kommer att förbättra de kliniska resultaten efter endovaskulär aortakirurgi ytterligare.

Περίληψη στα ελληνικά

Το ανεύρυσμα κοιλιακής αορτής είναι μια κατάσταση όπου τα μεγάλα αιμοφόρα αγγεία του σώματος στην κοιλιακή χώρα διαστέλλονται. Η πάθηση επηρεάζει έως και 1,5–2,6% του σουηδικού πληθυσμού στην ηλικία των 65 ετών και αφορά κυρίως άνδρες. Οι λόγοι για αυτό είναι αρκετοί, αλλά υπάρχει μια κύρια συσχέτιση μεταξύ του σχηματισμού ανευρύσματος και του καπνίσματος, των κληρονομικών παραγόντων, της υψηλής αρτηριακής πίεσης, της ηλικίας και του ανδρικού φύλου. Όσο μεγαλύτερο είναι το ανεύρυσμα, τόσο μεγαλύτερος είναι ο κίνδυνος ρήξης του αγγείου με καταστροφικές συνέπειες για τον ασθενή. Αυτό οδηγεί σε σημαντική εσωτερική αιμορραγία που συχνά οδηγεί σε θάνατο. Προηγούμενες έρευνες έχουν δείξει ότι ο κίνδυνος ρήξης ξεπερνά τον κίνδυνο της προληπτικής χειρουργικής επέμβασης όταν η διαστολή φτάνει τα 5,5 cm σε διάμετρο για τους άνδρες και τα 5,0 cm για τις γυναίκες. Επομένως, σύμφωνα με τις τρέχουσες διεθνείς κατευθυντήριες γραμμές, συνιστάται να αντιμετωπίζεται εκ των προτέρων με προληπτικό σκοπό.

Για την αντιμετώπιση αυτού, χρησιμοποιούνται κυρίως δύο διαφορετικές μέθοδοι θεραπείας:

- Ανοιχτή χειρουργική επέμβαση όπου το προσβεβλημένο τμήμα της αορτής αντικαθίσταται με ένα σωληνωτό μόσχευμα ραμμένο μέσα από μια μεγάλη τομή στην κοιλιά,
- Ενδοαγγειακή χειρουργική όπου με μια ελάχιστη επεμβατική μέθοδο, μια ενδοπρόθεση από ύφασμα ενισχυμένο με μέταλλο πραγματοποιείται υπό ακτινολογικής καθοδήγησης μέσω παρακέντησης, συνήθως στις μηριαίες αρτηρίες και έτσι ενισχύεται το τοίχωμα του αγγείου. Η μέθοδος που αναφέρθηκε τελευταία ονομάζεται EVAR και ανακαλύφθηκε και αναπτύχθηκε πρόσφατα με γρήγορο ρυθμό για να χρησιμοποιείται επίσης σε πολύπλοκα ανατομικά ανευρύσματα κοιλιακής αορτής που περιλαμβάνουν αγγεία τα οποία τροφοδοτούν σημαντικά κοιλιακά όργανα όπως το ήπαρ, τα έντερα και τα νεφρά. Τότε η διαδικασία ονομάζεται F/BEVAR (fenestrated/branched EVAR). Οι ενδοπροθέσεις αυτές έχουν ξεχωριστό σχέδιο ανάλογα με την ανατομία του ανευρύσματος, και για αυτό το λόγο ονομάζονται custom made devices (CMD).

Η θεραπεία με F/BEVAR περιλαμβάνει αρκετές τεχνικές προκλήσεις. Η ενδοπρόθεση πρέπει να τοποθετηθεί με μεγάλη ακρίβεια ως προς το ύψος και την

περιστροφή, έτσι ώστε οι σπές να βρουν τις αντίστοιχες εξόδους των αγγείων τους, οι οποίες με τη σειρά τους διαθέτουν επίσης μικρότερες, σωληνοειδείς προθέσεις για την αποφυγή διαρροής. Απαιτείται προσεκτικός σχεδιασμός με χρήση αξονικής τομογραφίας με σκιαγραφικό πριν από τη διαδικασία και η παρακολούθηση μετά τη θεραπεία να γίνεται ετησίως με τακτικούς ελέγχους. Αρκετές μελέτες έχουν δείξει ότι το FEVAR δίνει καλά αποτελέσματα, τουλάχιστον βραχυπρόθεσμα. Αλλά δυστυχώς, όπως και με όλες τις άλλες χειρουργικές θεραπείες με τον ίδιο τρόπο, το F/BEVAR ενέχει ορισμένους κινδύνους κατά τη διάρκεια της επέμβασης καθώς επίσης και μετά από αυτό κατά τη διάρκεια της παρακολούθησης. Ένα από τα πιο συνηθισμένα είναι η ανάγκη για κάποια μορφή εκ νέου παρέμβασης για να διασφαλιστεί η καλή και μακροπρόθεσμη λειτουργία της επέμβασης. Ο απώτερος στόχος όλων των χειρουργικών τεχνικών είναι να αποκλειστεί το ανεύρυσμα από την κυκλοφορία, αποτρέποντας έτσι μια δυνητικά απειλητική για τη ζωή κατάσταση όπως η ρήξη της αορτής.

Σκοπός της παρούσας διπλωματικής εργασίας ήταν η αξιολόγηση νέων τεχνικών στις πιο απαιτητικές κλινικές προκλήσεις, όπως η ρήξη αορτής, αλλά και η διερεύνηση της έκβασης νέων τεχνικών και μεθόδων κατά τη διάρκεια πολύπλοκων επεμβάσεων ανευρύσματος κοιλιακής αορτής σχετικά με την ασφάλεια του ασθενούς και την ανθεκτικότητα των προθέσεων. Αποτελείται από πέντε διαφορετικά μέρη (I-V).

Ο ειδικός σκοπός των μελετών ήταν:

I. Αξιολόγηση της χρήσης IBD για τη διατήρηση της αιμάτωσης της υπογάστρια αρτηρίας στην οξεία ενδοαγγειακή αποκατάσταση των ρήξεων αορτολαγόνιου ανευρύσματος.

II. Αξιολόγηση των αποτελεσμάτων της διατήρησης της κυκλοφορίας της υπογάστρια αρτηρίας με IBD κατά τη διάρκεια της οξείας ενδοαγγειακής αποκατάστασης ρήξης αορτολαγόνιου ανευρύσματος.

III. Διερεύνηση των αλλαγών στη διάμετρο του αυχένα της υπο- και υπέρ-νεφρικής αορτής πριν και μετά το EVAR για iAAA και την πιθανή σχέση με την τοποθέτηση του ενδομοσχεύματος.

IV. Αναφορά κλινικών αποτελεσμάτων της επανάληψης της επισκευής του FEVAR που είχε αποτύχει στο παρελθόν.

V. Αξιολόγηση της σκοπιμότητας και της αποτελεσματικότητας ενός τροποποιημένου συστήματος χορήγησης του περιφερικού διακλαδισμένου εξαρτήματος FEVAR όπου το άκρο του διαστολέα είχε βραχύνει για να αποφευχθεί η βλάβη στα μοσχεύματα των νεφροσπλαχνικών γεφυρώσεων.

Τα συμπεράσματα αυτής της διατριβής είναι ότι η χρήση IBD σε επιλεγμένες περιπτώσεις με ρήξη αορτολαγόνιου ανευρύσματος φαίνεται να έχει καλή επίδραση στην επιβίωση. Το αποτυχημένο FEVAR δεν είναι πέρα από τη διάσωση και η

καλύτερη κατανόηση της φυσιολογίας κατά τη διάρκεια των ρήξεων, καθώς και τα νέα σχέδια ενδομοσχευμάτων θα βελτιώσουν περαιτέρω τα κλινικά αποτελέσματα μετά από ενδοαγγειακή χειρουργική επέμβαση αορτής.

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About the author



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