



**TURUN
YLIOPISTO**
UNIVERSITY
OF TURKU

COMPLEX AORTIC ENDOVASCULAR PROCEDURES

Outcomes and safety

Vaiva Dabravolskaite



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To my grandmother, Adèle

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VAIVA DABRAVOLSKAITE: Complex Endovascular Aortic Procedures:

outcomes and safety

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ABSTRACT

Endovascular aortic treatment involving all aortic segments has replaced open surgery in most patients during the last three decades. Although the endovascular techniques have significantly decreased invasiveness, preoperative mortality, and morbidity, the risk of spinal cord ischemia (SCI) and stroke remains the main concern after complex endovascular aortic repair. Moreover, ensuring adequate patient selection for endovascular aortic repair and challenges related to visceral stent patency after branched endovascular aneurysm repair (BEVAR) are addressed in this thesis too.

This thesis comprises four parts. The first consisted of all patients from two high-level aortic centers who were treated with custom-made devices (CMDs) for different aortic arch pathology, with stroke as the primary endpoint. In the second part, we analyzed the safety and outcome after preoperative coil embolization of segmental arteries prior to open or endovascular aortic repair concerning the risk for SCI in a single-center observational study and a part of a meta-analysis. The third part was a multicentre international study analyzing the risks for bridging stent occlusion after BEVAR regarding the characteristics of the target vessel and bridging stents. In the fourth part, an international multicentre study tested a previously established prognostic survival model of patients treated with EVAR, using age, estimated glomerular filtration rate (eGFR), and chronic obstructive pulmonary disease (COPD) as independent predictors for survival for abdominal aortic aneurysm (AAA).

Endovascular treatment of different pathology in all aortic segments requires meticulous planning and treatment, especially in the aortic arch. The latest technical developments have made this safe. However, these expensive methods should be offered to patients with fair outcomes. Therefore, predictive models for decision-making are essential.

KEYWORDS: complex aortic pathology, MIS2ACE, branched vessel occlusion, EVAR survival

TURUN YLIOPISTO

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TIIVISTELMÄ

Viimeisten kolmen vuosikymmenen aikana aortan sairauksien hoitomenetelmät ovat muuttuneet. Perinteisen avokirurgian osuus on hyvin pieni ja aortan sairauksia hoidetaan nykyaikana pääosin suonensisäisin menetelmin. Muutos invasiivisesta avokirurgiasta vähemmän invasiiviseen suonensisäiseen hoitoon on muuttanut hoitotoimenpiteet potilaalle kevyemmiksi, vähentänyt hoitoon liittyviä ongelmia ja kuolleisuutta. Vaikka avokirurgian hoitoon liittyvät merkittävät komplikaatiot, kuten aivoinfarkti ja selkäytimen verenkiertohäiriö ovat vähentyneet, nämä komplikaatiot ovat haasteita myös suonensisäisessä aortan hoidossa.

Väitöskirja koostuu neljästä osatyöstä. Ensimmäinen osatyö selvittää aorttan-kaaren sairauksien hoitoon suunnitellun custom-made devise (CMD) hoitotuloksia. Toinen osatyö selvitti kaksivaiheisen hoidon etua potilaita, joilla oli korkea riski selkäytimen iskeemisille komplikaatioille. Tutkimus pohjautui potilasaineistoon, ja kirjallisuudesta tehtyyn meta-analyysiin. Kolmannessa osatyössä selvitettiin sivuhaarallisten stenttigrافتien (BEVAR) liittyvän lääkehoidon merkitystä hoitotulokseen. Neljännessä osatyössä validoitiin ennusteellinen malli munuaisvaltimotason alapuoleisen aorttan stenttigrافتilla hoidetuille potilaille (endovascular aortic repair, EVAR). Ennusteellisissa mallissa ennusteeseen vaikuttavat parametrit olivat ikä, arvioitu munuaiskerästen suodatus aika (GRF), krooninen ahtauttava keuhkotauti (COPD). Viimeaikaiset teknologian kehitykset ovat mahdollistaneet myös aorttan-kaaren turvallisen suonensisäisen hoidon. Suonensisäisiin hoitoihin tarvittavat lääkkinnälliset laitteet ja stenttigrافتit ovat kalliita ja sen vuoksi näiden hoitojen kohdentaminen riittävän hyvän ennusteen potilaisiin on tärkeää. Potilaiden ennustemallien kehitys on keskeinen osa näiden uusien, kalliiden hoitomuotojen kehittymistä. Tunnistamisen kannalta mahdollisimman yksinkertaiset, hyvän ennustearvon mallit ovat helpoiten implementoitavissa kliiniseen käytäntöön.

Väitöskirjatutkimus vahvistaa näkemystä, että aorttan sairauksien hoito suonensisäisillä menetelmillä on turvallista ja hoitoon liittyy vähemmän sairastuvuutta ja kuolleisuutta kuin perinteiseen avokirurgiaan. Turvallinen suonensisäinen hoito edellyttää tarkkaa hoidon suunnittelua ja herkkiä, erityisosaamista vaatia tekniikoita.

AVAINSANAT: aorttan patologia, MIS2ACE, haarautuneen verisuonen tukos, EVAR jälkeinen elinikäisyys.

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Abbreviations

AA	Aortic Arch
AAA	Abdominal aortic aneurysm
AD	Aortic dissection
AKA	A. radicularis magna or Adamkiewicz artery
ASA	American Society of Anesthesiology
BCT	Brachiocephalic trunk
BMI	Body mass index
BEVAR	Branched endovascular aortic repair
bTEVAR	branched thoracic endovascular aortic repair
CA	Celiac artery
CAD	Coronary Artery Disease
CFA	Common femoral artery
CH-EVAR	Chimney/snorkel endovascular aneurysm repair
CI	Confidence Interval
CKD	Chronic kidney disease
COPD	Chronic obstructive pulmonary disease
CT	Computed Tomography
CTA	Computed Tomographic Angiography
DAPT	Dual antiplatelet therapy
DFA	Deep femoral artery
DSA	Digital Subtraction Angiography
DUS	Duplex Ultrasonography
eGFR	Estimated Glomerular Filtration Rate
EJVES	European Journal of Vascular and Endovascular Surgery
EL	Endoleak
ESVS	European Society for Vascular Surgery
EVAR	Endovascular aneurysm repair
FEV1	Forced Expiratory Volume in one second
FEVAR	Fenestrated endovascular aneurysm repair
Fr	French
fTEVAR	Fenestrated thoracic endovascular aortic repair

FVC	Forced Vital Capacity
GFR	Glomerular filtration rate
HR	Hazard ratio
IA	Innominate artery
IFU	Instructions for use
IMA	Inferior mesenteric artery
IMH	Intramural Haematoma
ITI	Inner to Inner
JRAAA	Juxtarenal Abdominal Aortic Aneurysm
LCCA	Left common carotid artery
LRA	Left renal artery
LSA	Left subclavian artery
LZ	Landing zone
MAE	Major adverse event
MEP	Motor evoked potentials
MIS2ACE	Minimally invasive segmental artery coil-embolisation
MRI	Magnetic resonance imaging
SMA	Superior mesenteric artery
OR	Odds ratio
OSR	Open Surgical Repair
PAOD	Peripheral Artery Disease
PAU	Penetrating Aortic Ulcer
rAAA	Ruptured of abdominal aortic aneurysm
RCT	Randomized controlled trial
RCCA	Right common carotid artery
RIFLE	Risk, Injury, Failure, Loss of kidney function, and Endstage kidney disease
RRA	Right Renal artery
RSA	Right subclavian artery
SA	Segmental arteries
SCI	Spinal cord ischemia
SFA	Superficial femoral artery
SRAAA	Suprarenal Abdominal Aortic Aneurysm
SVS	Society for Vascular Surgery
TAAA	Thoracoabdominal aortic aneurysm
TEVAR	Thoracic endovascular aortic repair

List of Original Publications

This dissertation is based on the following original publications, which are referred to in the text by their Roman numerals:

- I Dabravolskaite V, Makaloski V, Hakovirta H, Kotelis D, Schoenhoff F, Lescan M. Evaluation of custom-made Relay ® ® stent-grafts for aortic arch stent-grafts for aortic arch landing zones 0 and I: experience from two high-volume aortic centres. *Eur J Cardiothorac Surg*, 2024; 2024 Jul 1;66(1):ezae241. doi: 10.1093/ejcts/ezae241. Online ahead of print.
- II Dabravolskaite V, Xourgia E, Kotelis D, Makaloski V. The safety and outcome of minimally invasive staged segmental artery coil embolization (MIS²ACE) prior thoracoabdominal aortic aneurysm repair: a single-center study, systematic review and meta-analysis. *Journal of Clinical Medicine*, 2024 Feb 29;13(5):1408. doi: 10.3390/jcm13051408. Online ahead of print
- III Dabravolskaite V, Meuli L, Yazar O, Bouwmann L, Mufty H, Maleux G, Aho P, Hakovirta H, Venermo M, Makaloski V. Antithrombotic Therapy and Freedom From Bridging Stent Occlusion After Elective Branched Endovascular Repair: A Multicenter International Cohort Study. *J Endovasc Ther*, 26:15266028241253133. doi: 10.1177/15266028241253133. Online ahead of print
- IV Dabravolskaite V, Aweys M, Venermo M, Hakovirta H, Mufty H, Zimmermann A, Makaloski V, Meuli L. Editor's Choice - External Validation of a Prognostic Model for Survival of Patients With Abdominal Aortic Aneurysms Treated by Endovascular Aneurysm Repair. *Eur J Vasc Endovasc Surg*, 2024; 67(5):718–725

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1 Introduction

Since the introduction of EVAR in the early 1990s, endovascular aortic repair has become the gold standard in treating abdominal aortic aneurysms. The use of bifurcated stent-grafts for AAA significantly improved short-term morbidity and mortality compared with open aortic repair. (Patel et al., 2016) Patients recognize and accept this, too, and prefer EVAR to open repair. (Reise et al., 2010) Still, diseased aortas might further dilate over time, and even a primarily successful EVAR can end as a failed treatment after 10 or 15 years. (Isselbacher et al., 2022; Wanhainen et al., 2024) Proper patient selection can improve overall survival, especially considering the patient's comorbidities. Impaired lung and renal function, as well as advanced age over 80 years, may significantly reduce the life expectancy after EVAR. (Meuli, Zimmermann, et al., 2022) Identifying the patients who will benefit from EVAR remains essential. With the help of a predictive model, one could justify the use of EVAR to differentiate patients with good life expectancy from elective repair in patients for whom elective EVAR is not appropriate at the current diameter threshold.

After being introduced to the infrarenal aorta, the endovascular treatment of the thoracoabdominal aortic segment brought further challenges. Completing such repair results in the discontinuation of the segmental artery perfusion. As a result, it may lead to devastating consequences for patients such as paraplegia/paraparesis. In an experimental setting, coil embolization of the segmental arteries prior to total endovascular thoracoabdominal aneurysm repair (TAAA) reduced the risk of postoperative paraplegia. (von Aspern et al., 2019) The very first application of this spinal cord circulation preconditioning revealed promising perioperative results. However, this approach has yet to be proved in a larger setting.

Parallel to the risk of spinal cord ischemia, complex repair with BEVAR may cause additional challenges related to the covered bridging stents in the renovisceral arteries. The bridging stent occlusion rate might vary depending on the target vessel and bridging stent features. (Mezzetto et al., 2021) Next to the diameter and the length of the bridging stents, several mechanical factors, like respiratory-induced end-stent bending, could influence the bridging stent occlusion rate. (Cheng et al., 2023) Analyzing the vessel dynamics distal to the bridging stents gives valid

information about the hemodynamics in the target vessel and bridging stent fracture risk. Bridging stent patency depends not only on the mechanical features but also on the established antithrombotic regime after complex endovascular aortic repair. The PRINCE²SS recommendations suggest an aggressive lifelong DAPT if multiple or long bridging stents are used. (D'Oria et al., 2022) However, these recommendations are based only on a highly successful and experienced group of experts' opinions and have to be proved on a bigger patient cohort. The bleeding risk was not taken into consideration in these recommendations and may influence an overall patient's outcome at follow-up.

The aortic arch is the last segment of the whole aorta addressed by the endovascular repair. This is due to its proximity to the heart and the aortic valve, as well as the special mechanical features of the ascending aorta and the supra-aortic. Not every available aortic arch stent-graft can match these anatomical needs. (Smorenburg et al., 2020) Specialized custom-made manufacturing could be the solution to this problem, especially if it combines different stent-graft features like fenestration, branches, and scallops.

This thesis comprises four parts. The first consisted of all patients from two high-level aortic centers who were treated with custom-made devices (CMDs) for different aortic arch pathology, with stroke as the primary endpoint. In the second part, we analyzed the safety and outcome after preoperative coil embolization of segmental arteries prior to open or endovascular aortic repair concerning the risk for SCI in a single-center observational study and a part of a meta-analysis. The third part was a multicentre international study analyzing the risks for bridging stent occlusion after BEVAR regarding the characteristics of the target vessel and bridging stents. In the fourth part, an international multicentre study tested a previously established prognostic survival model of patients treated with EVAR, using age, estimated glomerular filtration rate (eGFR), and chronic obstructive pulmonary disease (COPD) as independent predictors for survival for abdominal aortic aneurysm (AAA).

2 Review of the Literature

2.1 Aortic diseases

2.1.1 Anatomy of the aorta

The aorta is the 'largest artery, through which oxygenated blood is delivered from the left ventricle to end organs with each cardiac cycle. It is divided into four parts:

The ascending aorta arises from the aortic orifice in the heart's left ventricle and ascends for around five centimeters to become the aortic arch. Its branches include the left and right aortic sinuses at the aortic valve level.

The aortic arch is a continuation of the ascending aorta. It begins roughly at the second sternocostal joint and ends at the level of the thoracic fourth vertebrae. The main arteries to the brain and upper extremities arise from the aortic arch. (Figure 1) The literature reports a number of AA variations. (Natsis et al., 2009)

The thoracic (descending) aorta is a continuation of an aortic arch. It lies between the thoracic vertebrae 4 and 12. Side branches from the descending thoracic aorta feed organs in the esophagus, bronchi, lungs, pericardium, and diaphragm. (Figure 1)

The abdominal aorta is between the T12 vertebrae and the L4 vertebra. It ends by bifurcating into the left and right iliac arteries. Renovisceral and lumbar arteries are the most important side branches of the abdominal aorta. (Figure 1) (Dagenais, 2011; di Gioia et al., 2023; Loukas et al., 2014; White et al., 2024)

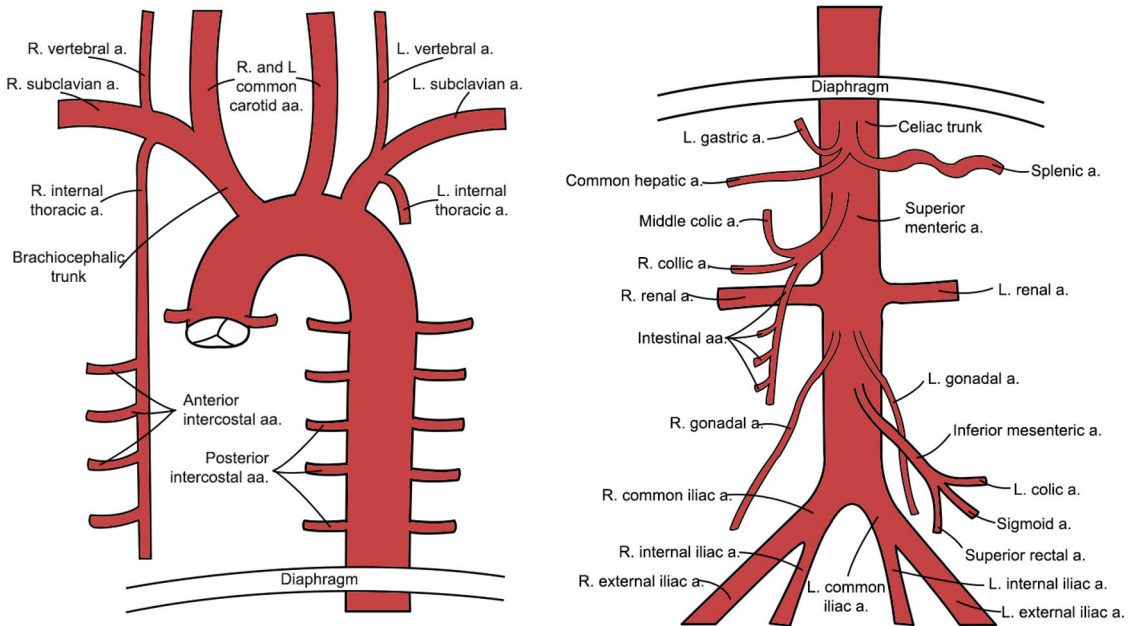


Figure 1. Anatomy of the aorta and its branches. Adapted from Clement T. et al.

2.1.2 Aortic diseases: definitions and classifications

Aortic diseases encounter a broad spectrum of pathologies, including aortic aneurysms, acute aortic syndromes, traumatic aortic lesions, pseudoaneurysms, and congenital anomalies of the aorta. Due to the complexity of aortic pathologies, their classification is multifactorial, and they may be classified based on the underlying causes, location, shape, and size of the aorta. Cardiovascular specialists rely on various diagnostic tools and clinical evaluations to classify aortic diseases. (Table 1) (Bossone & Eagle, 2021; Czerny, Schmidli, Adler, van den Berg, Bertoglio, Carrel, Chiesa, Clough, Eberle, Etz, Grabenwöger, Haulon, Jakob, Kari, Mestres, Pacini, Resch, Rylski, Schoenhoff, Shrestha, von Tengg-Kobligk, Tsagakis, & Wyss, 2019; Gouveia et al., 2022; Oderich et al., 2021; Wanhainen et al., 2019)

Table 1. Classification of aortic diseases based on different factors. (Bossone & Eagle, 2021; Czerny, Schmidli, Adler, van den Berg, Bertoglio, Carrel, Chiesa, Clough, Eberle, Etz, Grabenwöger, Haulon, Jakob, Kari, Mestres, Pacini, Resch, Rylski, Schoenhoff, Shrestha, von Tengg-Kobligk, Tsagakis, & Wyss, 2019; Gouveia et al., 2022; Oderich et al., 2021; Wanhainen et al., 2019)

Factors		Definition
Anatomical Location	Ascending aorta	
	Aortic arch	
	Thoracic (descending) aorta	
	Abdominal aorta	
Underlying pathology	Aortic aneurysm	
	Acute aortic syndromes	
Etiology	Atherosclerotic	A buildup of plaque in the aorta, leading to stenosis and weakening of the aortic wall with time.
	Inflammatory	Various conditions causing an inflammation in the aortic wall and the damage of it as a result. Those conditions may include giant cell arteritis, vasculitis, and Takayasu arteritis.
	Genetic predisposition	Some conditions are associated with gene mutations, such as Ehlers-Danlos syndrome and Marfan syndrome.
	Traumatic injuries	A direct injury of the aortic wall.
Extent of disease and size	Extent of disease	May be defined based on the extent and involvement of branch arteries
	Size	May be defined as requiring intervention or still under surveillance

2.1.2.1 Aortic aneurysm

An aortic aneurysm is defined as a pathological dilation of the aorta, more than 50% of the normal diameter. Aneurysms tend to progress gradually, often leading to rupture and death if untreated. (Erbel et al., 2014; Wanhainen et al., 2019) Aneurysms may be divided into four parts based on their anatomical location: ascending aortic aneurysms, which are located between the root of the aorta, and the take-off of the innominate artery. An aortic arch aneurysm is an aneurysm dilatation of the aorta between the ascending and the descending, including the area with the take-off from the supra-aortic vessels.-A descending thoracic aorta aneurysm is in a segment between the LSA and the diaphragm. Thoracoabdominal aneurysms (TAAA) are defined as aneurysms that originate proximally to the Th6 vertebra. They involve the thoracic aorta and extend distally to the level of the renal arteries and below. (Powell & Wanhainen, 2020; Riambau et al., 2017)

Classification of thoracoabdominal aortic aneurysm

Thoracoabdominal aortic aneurysms (TAAA) are classified using the Crawford classification developed by Dr. E. Stanley Crawford. (Wanhainen et al., 2019) Classification is based on the anatomical extent and location of the aneurysm and its involvement in various aortic segments. The Crawford classification divides TAAA into five main types: Type I, Type II, Type III, Type IV, and Type V. (Table 2)

Table 2. Thoracoabdominal aortic aneurysm Crawford classification. (Wanhainen et al., 2019)

Type	Definition
I	Distal of the left subclavian artery to the visceral aorta (suprarenal)
II	Distal of the left subclavian artery to the infrarenal aorta
III	From the mid-thoracic aorta (below T6) to the infrarenal aorta
IV	From the diaphragm (T12) to the infrarenal aorta
V	From the mid-thoracic aorta (below T6) to the visceral aorta (suprarenal)

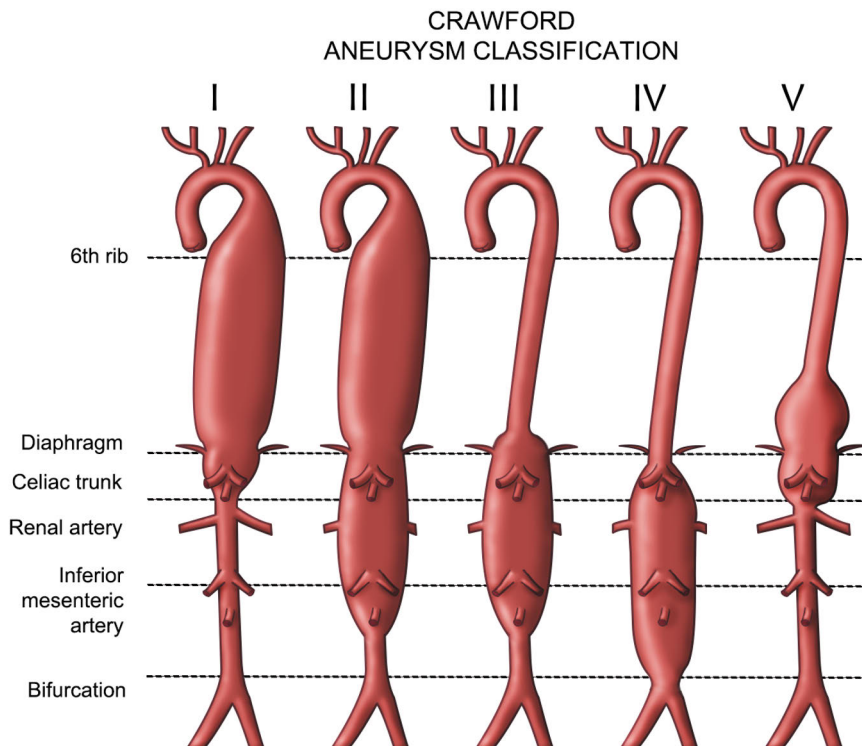


Figure 2. Crawford classification of the thoracoabdominal aneurysm. Adapted from (Wanhainen et al., 2019).

Classification of abdominal aortic aneurysm

An abdominal aneurysm is defined as the diameter of an abdominal aortic aneurysm larger than ≥ 3.0 centimeters. AAA may be further classified based on the involvement of branches (Figure 3):

Suprarenal – an abdominal aneurysm that involves the SMA but does not extend until the celiac trunk.

Pararenal – an abdominal aneurysm with the involvement of at least one of the renal arteries, without the involvement of visceral arteries.

Juxtarenal – an abdominal aneurysm with a minimal sealing zone of < 4 mm

Infrarenal – an abdominal aneurysm with a minimal sealing zone with respect to renal arteries of ≥ 4 mm. (Wanhainen et al., 2019)

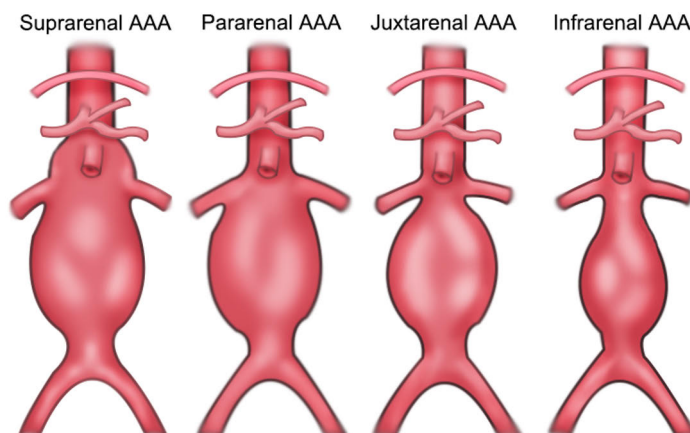


Figure 3. Classification of abdominal aortic aneurysm. AAA; abdominal aortic aneurysm; Adapted from (Wanhainen et al., 2019).

2.1.2.2 Acute aortic syndromes

2.1.2.2.1 Aortic dissection

Aortic dissection is a condition defined by a tear or separation in the aortic wall layers – intimal flap, creating a true and false lumen in the aorta. The classification of aortic dissection is vital for determining appropriate treatment and management. Aortic dissections are typically classified into two major categories based on the location of the tear and the extent of involvement. It's important to note that just like aortic aneurysms, aortic dissections are complex and can vary in their presentation and anatomy. (Czerny, Schmidli, Adler, van den Berg, Bertoglio, Carrel, Chiesa, Clough, Eberle, Etz, Grabenwöger, Haulon, Jakob, Kari, Mestres, Pacini, Resch,

Rylski, Schoenhoff, Shrestha, von Tengg-Kobligk, Tsagakis, & Wyss, 2019; Lombardi et al., 2020; Powell & Wanhainen, 2020; Rimbau et al., 2017) The severity of aortic dissection can be defined as uncomplicated and complicated. Patients with uncomplicated aortic dissection have stable hemodynamics, controlled pain, and no evidence of malperfusion. These patients usually do not need immediate intervention. Complicated aortic dissections lead to malperfusion and end-organ ischemia, present with rupture or impending rupture. Therefore, it is a medical emergency and requires immediate surgical intervention. (Kamman et al., 2017; Reutersberg et al., 2018; van Bogerijen et al., 2014)

Historically, there have been different classifications for aortic dissection:

Stanford anatomical classification divides the aorta into two parts:

- Type A involves the ascending aorta, 2/3 (the most common). It requires emergency surgical intervention due to their proximity to the heart and the risk of life-threatening complications.
- Type B – that begins from distal to L subclavian, 1/3. While it is a serious condition that often requires medical management and sometimes endovascular interventions, it does not typically require emergency surgical repair. (Levy et al., 2023)

This classification is often used to quickly assess and determine the urgency of treatment, especially in emergencies. Type A dissections are considered surgical emergencies, while Type B dissections are generally managed medically, with endovascular repair reserved for specific cases. (Czerny, Schmidli, Adler, van den Berg, Bertoglio, Carrel, Chiesa, Clough, Eberle, Etz, Grabenwöger, Haulon, Jakob, Kari, Mestres, Pacini, Resch, Rylski, Schoenhoff, Shrestha, von Tengg-Kobligk, Tsagakis, Wyss, et al., 2019; Levy et al., 2023)

DeBakey classification provides a more detailed classification of aortic dissections, considering the extent of the dissection. It includes three categories:

Type A

1 – It involves ascending and extending towards the descending aorta.

2 – it is confined only to ascending aorta.

Type B – distal or at the LSCA.

3a – Descending aorta above the diaphragm

3b – Descending aorta above and below the diaphragm (Levy et al., 2023)

The Debakey classification provides a more detailed description of the anatomical extent of the dissection, which can be helpful for surgical planning and management decisions. (Czerny, Schmidli, Adler, van den Berg, Bertoglio, Carrel, Chiesa, Clough, Eberle, Etz, Grabenwöger, Haulon, Jakob, Kari, Mestres, Pacini, Resch, Rylski, Schoenhoff, Shrestha, von Tengg-Kobligk, Tsagakis, Wyss, et al., 2019)

Society of Vascular Surgery (SVS – society of Thoracic Surgery (STS) classification, published in 2020 (Lombardi et al., 2020) This new classification not only defines the location of the entry tear but also the location of the proximal and distal extent of the dissection. (Figure 4)

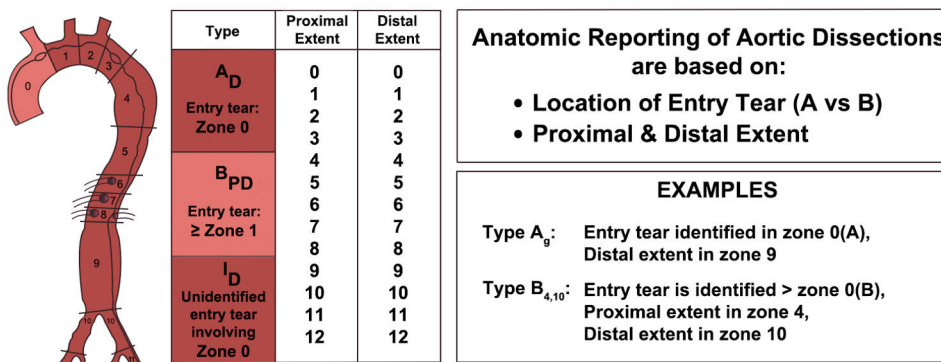


Figure 4. SVS-STS classification of aortic dissection. Adapted from (Lombardi et al., 2020).

2.1.2.2.2 Penetrative Aortic Ulcer (PAU)

The penetrating aortic ulcer is a vascular condition that affects the aorta, the largest artery in the body. PAU is characterized by a focal defect or ulceration in the inner lining of the aortic wall, which can extend into the deeper layers of the aorta. (Lombardi et al., 2020)

2.1.2.2.3 Intramural Hematoma (IMH)

An intramural hematoma is characterized by the accumulation of blood within the layers of the aortic wall, specifically between the inner and middle layers of the aortic wall (the intima and media). IMH is a type of aortic syndrome closely related to aortic dissection, but it differs in certain aspects. IMH occurs when blood accumulates within the aortic wall without a true tear or dissection flap. The blood collects within the layers of the aortic wall, leading to the separation of the layers and the formation of a hematoma. IMH is sometimes classified based on its location within the aorta (e.g., ascending aorta, descending aorta) and its extent (e.g., localized or extensive). (Lombardi et al., 2020)

Treatment indications

Treatment indications of the above-described pathologies are classified based on the type of pathology, its size and severity (Czerny, Schmidli, Adler, van den Berg,

Bertoglio, Carrel, Chiesa, Clough, Eberle, Etz, Grabenwöger, Haulon, Jakob, Kari, Mestres, Pacini, Resch, Rylski, Schoenhoff, Shrestha, von Tengg-Kobligk, Tsagakis, & Wyss, 2019; Erbel et al., 2014; Lombardi et al., 2020; Powell & Wanhainen, 2020; Riambau et al., 2017; Wanhainen et al., 2019) and are listed in Table 3.

Table 3. Aortic diseases and their indications for repair. (Czerny, Schmidli, Adler, van den Berg, Bertoglio, Carrel, Chiesa, Clough, Eberle, Etz, Grabenwöger, Haulon, Jakob, Kari, Mestres, Pacini, Resch, Rylski, Schoenhoff, Shrestha, von Tengg-Kobligk, Tsagakis, & Wyss, 2019; Erbel et al., 2014; Lombardi et al., 2020; Powell & Wanhainen, 2020; Riambau et al., 2017; Wanhainen et al., 2019)

Aortic pathology	Indication for treatment*
Aortic aneurysms	
Ascending aorta	Maximum diameter ≥ 55 mm, or ≥ 50 mm in patients with CTD.
Aortic arch	Maximum diameter ≥ 55 -60mm.
Descending thoracic aorta	Maximum diameter ≥ 55 -60mm or >50 -55mm in females or patients with CTD
Thoracoabdominal aorta	Maximum diameter ≥ 60 mm.
Abdominal aorta	Maximum diameter ≥ 55 or ≥ 50 mm in females
Acute aortic syndromes	
Aortic dissection	
Type A	Indication for immediate intervention
Type B	Complicated AD, uncontrolled pain, malperfusion
IMH	Complicated IMH, uncontrolled pain, expansion of IMH, intima disruption, peri-aortic hematoma
PAU	Complicated PAU, uncontrolled pain, initial diameter >20 mm or >10 mm in depth, progression of total aortic diameter

CTD = connective tissue disease; AD = aortic dissection; IMH = intramural hematoma; PAU = penetrative aortic ulcer. *The threshold in some segments in some settings (i.e. ascending aorta, in the CTD setting) may have been adjusted downwards.

2.2 Aortic arch repair

The aortic arch is the most challenging segment of the aorta, not only because of its different anatomical characteristics and pathological presentations but, above all, because of the need for continuous perfusion of all its supra-aortic branches as well as the rest of the body distally while repairing it. The risk of interrupting the perfusion to the supra-aortic branches might result in a massive stroke, both in the anterior or posterior brain circulation and with death consecutively. Since the introduction of extracorporeal circulation, it took a while until the first open aortic arch repair was done by Borst in 1964. (Borst et al., 1964) Such aortic arch repair requires hypothermic circulatory arrest, cautious manipulation of the cannulas, and excellent surgical skills.

After the introduction of thoracic endovascular aortic repair (TEVAR) in the late 1990s (Mitchell et al., 1996), this approach became more and more interesting for many different specialties having connecting points with the aortic arch, like vascular surgery. However, extending the landing zone of the thoracic stent-graft from the descending aorta in the aortic arch didn't develop quickly. Creating an appropriate stent-graft for the corresponding, challenging aortic arch anatomy is still demanding. With the introduction of the "frozen elephant trunk" technique, open and endovascular approaches found a common denominator to facilitate total aortic arch repair. (Kato et al., 1996)

Open aortic arch repair is still a treatment choice in younger patients, especially those with connective tissue disease. (Erbel et al., 2014)

2.2.1 Open aortic arch repair

Although the first open aortic arch repairs were performed in the sixties, the real breakthrough in the open aortic arch repair came in the nineties. (De Bakey et al., 1966; Rokkas & Kouchoukos, 1999) This was, above all, caused by the plodding evolution steps concerning the surgical adjuncts like deep or moderate hypothermia, the use of circulatory arrest during the performance of the anastomoses, arterial and venous cannulation sites, the selective ante- or retrograde cerebral perfusion, the distal aortic perfusion, and the CSF drainage. Moreover, the surgeons were confronted with the type of surgical technique they had to choose complete or partial replacement of the diseased arch, separate or "en-bloc" re-implantation of the supra-aortic vessel, the use of two vs. one aortic graft, performing additional cardiac procedures like aortic valve replacement or bypass, etc. All these difficulties challenge the treating surgeon, thus making open surgery of the aortic arch difficult and unpredictable.

The most devastating postoperative complication after an open aortic arch repair is the neurological injury. This can vary between 0 and 7% and depends entirely on the protecting brain strategy: the type of cerebral perfusion, ante- vs. retrograde perfusion, uni- vs. bilateral perfusion, and the expected perfusion time. (Malvindi et al., 2008) However, some imaging studies combined with neurocognitive testing demonstrated significantly higher rates of stroke or change on the CTs/MRIs of up to 15%, followed by a neurocognitive decline of 18% after 3–4 months postoperatively. (Svensson et al., 2015) The circulatory arrest duration significantly influences the total procedure's outcome. The duration of the circulatory arrest, which is less than 40 minutes, is safe and associated with a lower rate of postoperative complications. (Damberg et al., 2017)

2.2.2 Endovascular aortic arch repair

2.2.2.1 Hybrid approach

This technique was mainly reserved for high-risk patients and was unsuitable for total open aortic arch repair. Principally, with this approach, the diseased aortic arch will not be replaced but treated by an endovascular means with a thoracic stent graft. The word “hybrid” denotes the surgically created landing zone in the aortic arch, including the origins closure and debranching of the supra-aortic arteries. The debranching part is done via open surgical access, while the endovascular part is performed typically via percutaneous femoral access. Both parts can be done simultaneously or separately. (Koullias & Wheatley, 2010). The Ishimaru classification is used to define the proximal landing zone (LZ) of the graft. (Figure 5) It divides the proximal part of the aorta into four zones, which are used as land markers during the endovascular treatment of the proximal part of the aorta with TEVAR. (Chiesa et al., 2011) Depending on the required landing zone (LZ), different debranching can be performed via cervical approach (i.e., LZ 2) or via sternotomy and partial cross-clamping of the ascending aorta (landing zone 0). The most common debranching is the extra-anatomic bypass from the LCCA to the LSA, usually done via the left supra-clavicular approach and followed by a TEVAR landing in zone 2. Debranching requiring sternotomy and landing in the proximal aortic arch (zone 0) is more demanding and associated with higher rates of morbidity (21%) and mortality (9%). (Antoniou et al., 2010; Czerny et al., 2012)

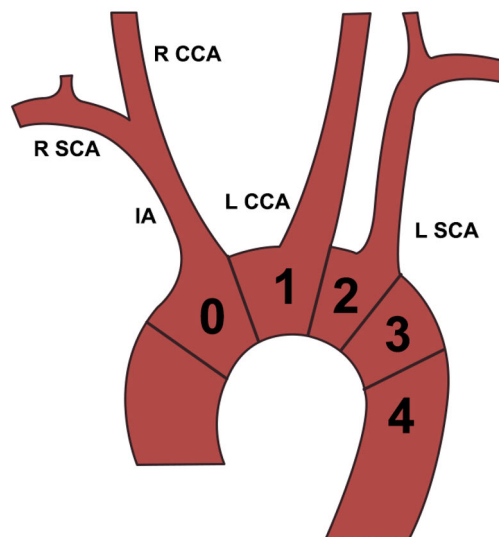


Figure 5. Ishimaru's classification of landing zones. Adapted from (Chiesa et al., 2011).

2.2.2.2 Chimney stents

The first experiences with this technique were at the level of the renovisceral aorta as a “bail-out” option, meant to preserve or rescue unintentionally covered vessels by an abdominal aortic stent-graft. Following this success, the technique was widely applied in treating different aortic arch pathologies to preserve the (un)intentionally covered LSA. However, this technique can be used only in the proximal aortic arch. This technique is based on implanting several parallel covered stents and stent-grafts. A recent meta-analysis demonstrated a high rate of technical success (95.8%) but also a high rate of type Ia endoleak (9.3%). (Liu et al., 2023) This can be explained by the so-called gutters, which represent the space between the chimney stents and the stent-grafts. Although a low rate of cerebral events (2.2%) can be anticipated, the high rate of type Ia endoleak is the major drawback of this technique, making it feasible only as a treatment option for emergency cases.

2.2.2.3 In-situ fenestration

This technique was initially used as a rescue technique in emergencies. However, in-situ fenestration has also gained popularity within the vascular surgery community in the endovascular treatment of elective aortic arch cases. (Tsilimparis et al., 2016) The in-situ fenestration can be performed either in an ante- or retrograde fashion in an already deployed thoracic stent-graft with the help of a catheter-driven needle, laser, or radiofrequency. The first experience focused on preserving the LSA in an emergency with good results. Redlinger et al. analyzed 22 patients undergoing in-situ laser fenestration of the LSA after emergency TEVAR for different pathologies, intentionally covering the LSA origin. They reported no fenestration-associated morbidity, no stroke, and an in-hospital mortality of 4%. (Redlinger et al., 2013) Recent systematic review and meta-analysis reported excellent short-term primary branch patency of 96.6%, low rates of endoleak of 4.8%, and stroke of 2.0%, respectively. (Tish et al., 2023) There seems to be no difference in the technique of creating fenestration currently. The needle puncture creates almost circular holes, whereas those made by laser are more square or elliptical with ragged edges and burned fibers. (Zeng et al., 2021) Moreover, the laser can create fabric debris and toxic particles due to the burning of the material. If the fenestration is planned for the BCT or the LCCA, the debris might cause brain emboli.

2.2.2.4 Total endovascular aortic repair

Since the fenestrated and branched stent-grafts were introduced, the total endovascular aortic arch repair appeared more applicable. (Chuter et al., 2003; Inoue et al., 1999) Although multiple vessel access (bilateral femoral, bilateral carotid, or brachial artery

access) might be necessary, the minimally invasive approach for total endovascular arch repair without sternotomy and extracorporeal circulation gains popularity.

However, this repair is technically demanding and requires meticulous planning and surgical expertise. Continuous perfusion of all supra-aortic arteries, without prolonged cerebral ischemia, is mandatory. Sufficient anticoagulation with unfractionated heparin reduces the risk of intraoperative embolization. Nevertheless, manipulating the endovascular tools in the arch or air emboli may lead to cerebral embolization. (Kölbel et al., 2016)

The fenestrated, branched, or scallop design is the most frequently used and is custom-made and tailored to the patient's anatomy. The biggest disadvantage for all custom-made devices are the waiting period, which can last up to 3 months. Currently, there is no available off-the-shelf treatment option with one or two big fenestrations for the supra-aortic arteries. An off-the-shelf arch branch stent-graft is challenging to produce, mostly because of anatomical diversities. Total arch repair with a physician modified TEVAR containing two fenestrations was reported recently with low rates of mortality and stroke. However, this method remains an off-label treatment option with good results in limited centers with a lot of experience with physician-modified stent-grafts. (Canaud et al., 2024) The center's experience in aortic arch repair affects the outcome. Total endovascular arch repair, conducted in experienced centers, has a high technical success rate of >95% for custom-made devices, with cerebrovascular event rates ranging up to 10% and 3% 30-day mortality. (Nana et al., 2022)

2.2.3 Technical challenges

Total open or endovascular aortic arch repair is technically very demanding. Independent of the preferred surgical technique, keeping simultaneous perfusion of all supra-aortic arteries without longer cerebral ischemia time and at the same time trying to avoid any cerebral embolization labels the total aortic arch repair with the highest level of surgical expertise and technical difficulty. The endovascular armamentarium in the aortic arch can lead to different complications: cerebral embolization, acute arm ischemia, and/or paraplegia. (Czerny et al., 2024)

The main challenge of endovascular repair is an adequate proximal sealing. (Kursch & Doukas, 2023) Concerning challenges related to chimney technique remains gutter-related type Ia endoleaks, which may lead to further interventions (Dueppers et al., 2022) Even though in situ technique demonstrated lower endoleak rates in comparison with chimney technique, maintaining cerebral perfusion during bilateral common carotid artery cannulation remains a concern.(Y. Li et al., 2021) Lastly, the main limitations for the use of fenestrated and branched aortic arch endografts are: the distance between distal coronary artery or aortocoronary bypass

and innominate artery (>50mm), the maximum diameter of the ascending aorta (≤ 38 mm), and the angulation between the aortic arch and the ascending aorta, which should not exceed more than 70°. (Stana et al., 2021)

Cut-down and retrograde stent-graft deployment in case of branched aortic arch repair may further influence the outcome of this complex procedure. Sufficient anticoagulation with heparin is mandatory. Any stent-graft dislocation might end with partial or complete coverage of the supra-aortic vessels and consecutive brain or arm ischemia. On the other hand, these stent-grafts have to bring special mechanical features with them because of the landing zone's proximity to the left ventricle and high systolic blood pressure. Furthermore, relevant wind socking, potential material fatigue, or stent fracture, as well as graft migration or collapse, can occur. (Hauck et al., 2022) These stent-grafts need to adapt to the curvature of the aortic arch at the same, thus allowing complete wall apposition, aneurysm sealing and avoiding endoleak. Therefore, independently of the above described techniques those procedures should be performed in high-volume centres. (Kursch & Doukas, 2023)

2.3 Thoracoabdominal aortic repair

The surgical repair of the thoracoabdominal aorta started more than 65 years ago with the pioneering work of Dr. M. De Bakey, Dr. D. Cooley, and Dr. S. Crawford in Houston, USA. (*Debakey et al., 1956*) This team has advanced the surgical technique over the decades, especially focusing on strategies to protect the spinal cord and reduce the risk of paraplegia, as well as improve the general outcome after these challenging operations. (Marcondes et al., 2023) Nevertheless, the repair of the thoracoabdominal aorta remains the most difficult area of the whole vascular surgery, still facing considerable perioperative challenges, especially with the treatment of elderly and comorbid patients. The ongoing need to improve these somewhat unsatisfying results and the introduction of the endovascular approach led to a treatment switch from the total open repair to a hybrid approach first and then towards a total endovascular thoracoabdominal aortic repair. The hybrid approach combines the endovascular exclusion of the aneurysmatic aorta following a previous open surgical debranching of all renovisceral arteries. After the introduction of custom-made devices with directional branches and fenestrations for the renovisceral arteries, total endovascular aortic repair gained popularity due to its better outcome compared with open repair. (Verhoeven et al., 2015)

With the increasing treatment options, especially with the endovascular approach, the number of patients who might benefit from a thoracoabdominal aortic treatment will also grow. Patients whose advanced age and comorbidities would have been considered as a risk factor or even contraindication for a treatment a decade ago are now receiving total endovascular aortic treatment with lower

mortality and better outcomes. Regardless of the chosen operative treatment, good preoperative imaging and patient workup are required. (Marcondes et al., 2023)

2.3.1 Open aortic repair

The first successful open repair of a thoracoabdominal aorta took place in the USA in 1955. (Etheredge et al., 1955) Since then, this operation evolved enormously, but it is still a great team effort involving many specialties. The anesthesiologic preparation time can take a couple of hours for the induction of anesthesia with the insertion of a double-lumen endotracheal tube. Additional central access and a pulmonary artery catheter are obtained for hemodynamic monitoring. Proximal and distal perfusion during aortic clamping is observed via arterial lines in both the upper and lower extremities. CSFD is used routinely, maintaining an intrathecal pressure at ≤ 10 mmHg. In case MEPs are used, special anesthetic induction is mandatory because the use of neuromuscular blocking agents can confound monitoring. (Oostveen et al., 2020) All open TAAA repairs are performed with the help of the ECC in the form of a left heart bypass (LHB). The latter is used for the distal perfusion of the abdominal viscera, spinal cord, and lower extremities when the proximal aorta is clamped. LHB is established with cannulation of the inferior pulmonary vein and any site distal to the aortic clamp site, most frequently via the left external iliac or left common femoral artery. (Green et al., 2021)

The open repair of the thoracoabdominal aorta should be done in a high-volume center with large expertise in this type of surgery. Best results can be achieved only through a dedicated team approach and improvement of the perioperative strategy. The lowest mortality and complications rate after open TAAA repair was published by the group of Coselli et al. (Coselli et al., 2016) After a total of 3300 open TAAA repairs, Coselli et al. were able to lower the early mortality to 7%, SCI to 5%, acute kidney injury down to 6%, and the stroke rate to 2%. However, even if the early results are very promising, this cohort of patients has limited life expectancy, with 10- and 20-year survival rates of 37% and 10%, respectively. (Coselli et al., 2016)

Open surgical repair has evolved significantly over the last decades, but the technical challenge and the morbidity and mortality rates are still significant, especially in patients with extensive aneurysms. (Coselli et al., 2016)

2.3.2 Hybrid approach

The total open repair bears some challenges with it, particularly in organ protection strategies. In order to lower the organ ischemia time and avoid the use of the ECC, the hybrid approach was introduced. (Chiesa et al., 2011) With this technique, a visceral branch re-routing or debranching is performed through a midline laparotomy

and transperitoneal access. The inflow site has to be chosen considering the extent of the underlying aortic pathology, and it is limited either to the infrarenal aorta or the common iliac artery. (Antoniou et al., 2010) With this approach, all four major reno visceral arteries can be addressed one after the other, thus reducing the specific organ ischemia time. Usually, in a second step, over femoral access, the whole underlying aortic pathology will be excluded with several thoracic aortic stent grafts. (Di Bartolomeo et al., 2016; Pellenc et al., 2021)

The hybrid approach has some advantages versus total open repair. By avoiding the thoracotomy, a significant reduction of pulmonary complications can be achieved. Additionally, there is no need for the ECC, as the infrarenal aorta is not going to be clamped at all, or the clamping time is short. Therefore, there is no relevant lower limb ischemia during the abdominal re-routing. However, the abdominal debranching itself is a long procedure with wide dissection of almost all parts of the abdomen, increasing the risk of collateral damage, like pancreatitis. The risk of re-stenosis or visceral graft occlusion must be carefully assessed, and these patients undergo life-long controls. (Pacini et al., 2013)

2.3.3 Total endovascular aortic repair

Since the introduction of endovascular aortic repair in the 1990s, stent-grafts and their technical features have constantly improved. (Veith et al., 2005) After the introduction of the abdominal bifurcated and thoracic tube grafts, the last addressed segment of the aorta was at the level of the renovisceral arteries. Creating a solution to preserve the flow in the renovisceral artery while excluding the aortic aneurysm led to the creation of two different but similar endovascular techniques for addressing this issue: the fenestrated and the branched repair. (Chuter et al., 2001)

Both approaches are widely accepted as an alternative to open repair for the treatment of complex endovascular aortic procedures.

Many factors influence the success of the total endovascular aortic repair but may be divided into three groups: preoperative planning, intraoperative implementation, and postoperative follow-up. (Wanhainen et al., 2024) The preoperative planning of complex procedures relies profoundly on static imaging. Current research efforts are artificial intelligence assisting in more precise planning, integrating simulation training on stent-graft's performance, which may help avoid postoperative treatment failure. (Lareyre et al., 2023) The equipment used intraoperatively is developed for totally different settings and needs to be further improved, specifically for these complex treatments. Specially designed sheaths, guidewires, and bridging stents could improve the procedure and the outcome.

In patients receiving a total endovascular TAAA repair life-long follow-up is necessary. These controls are planned at regular intervals to ensure that the stent

graft doesn't migrate, that the aneurysm remains excluded, and that all components used still have adequate overlap as originally placed. Postoperative follow-up currently relies on cross-sectional imaging techniques like CT or MRI. For this purpose, radiation and contrast mediums are required, which might have a negative effect on the patient. Some patients may not benefit from routine imaging. We need to identify which patients need more frequent imaging follow-ups. Some noninvasive techniques, such as ultrasound, could be used to evaluate the end-organ function and reduce the burden of follow-up and unnecessary radiation exposure. (Modarai et al., 2023; Riambau et al., 2017; Wanhainen et al., 2024)

2.3.3.1 The fenestrated endovascular aortic repair (FEVAR)

The fenestrated endovascular aortic repair (FEVAR) was developed in the late '90s and is the foremost example of preservation of normal anatomy that incorporates blood flow to the branch vessel. (Browne et al., 1999) Within the stent-graft, the fenestrations are placed at the level of the renovisceral artery origins and connected with balloon-expandable bridging stents.

Generally, FEVAR is applied for supra-, juxtarenal, or infrarenal aneurysms with short or inadequate neck and where the target reno visceral arteries arise from normal aortic diameter (<30mm). (Wanhainen et al., 2024) This technique allows for the continuation of blood flow to the reno visceral arteries through holes (fenestrations) in the stent graft fabric. The holes are intended to match the ostium of the renovisceral arteries. Depending on the native vessel ostium, the fenestrations vary between 6–8 mm, and their location will be customized to fit the patient's anatomy. If the device doesn't meet these needs and the alignment to the native vessels is not accurate, the catheterization of the renovisceral vessels might be very challenging, or the total procedure may fail. Ideally, there should be no gap between the fenestration and the target vessel or a very short one (2–3mm). (Cross et al., 2012) Balloon-expandable alignment (bridging) covered stents are used to seal the fenestration on one side and to prevent vessel occlusion on the other side. (Mezzetto et al., 2021)

2.3.3.2 Branched endovascular aortic repair (BEVAR)

Continuing the fenestrated design development, the stent-grafts with directional branches followed. The rationale for developing the directional branches was the treatment of thoracoabdominal aortic aneurysms with large lumen, where the gaps between the fenestration and native origins were too long. With the creation of the branched stent-grafts, these gaps can be shortened and connected with the native vessel with balloon- or self-expandable bridging covered stents. (Armstrong et al., 2014) The first branched stent graft was implanted in 2001 by Dr. Chuter and

introduced the beginning of a new era in the total endovascular repair of thoracoabdominal aneurysms. (Chuter et al., 2001)

BEVAR is used when the renovisceral branches arise from the aneurysm sac and there is a gap between the main aortic stent graft and the wall of the aneurysm. These branches can be straight or helical, oriented downwards or upwards, and external or internal. (Armstrong et al., 2014) Covered stents are then brought in these branches and in the native vessels, to anchor the stent-graft, prevent a potential migration, secure the perfusion of the renovisceral arteries, and avoid endoleak. In some patients with anatomy a combination of one or more branches and one or more fenestrations might be needed. This is technically feasible and is usually made on a custom-made basis. (Nana et al., 2023)

2.3.4 Technical challenges

Many complications can occur during and after total endovascular TAAA repair: visceral and/or lower limb embolization, target vessel injury (perforation or dissection), spinal cord injury, acute kidney injury, bridging stent-related dislocation, stenosis or occlusion, postoperative bleeding due to aggressive antithrombotic therapy, etc. (Abisi et al., 2021; D'Oria et al., 2022; Katsargyris et al., 2023; Nana et al., 2023; Piazza et al., 2021; Torsello et al., 2021; Tsilimparis et al., 2019) All these potential complications reflect the difficulty of these procedures and their meticulous planning and refined execution with attention to detail to have the best possible outcome. (Kouvelos et al., 2024) Within the next chapters, major challenges will be described in depth.

2.3.4.1 The risk of spinal cord ischemia during an open repair of descending or thoracoabdominal aortic repair

The open or endovascular treatment of descending or thoracoabdominal aorta (TAAA) remains to be the most difficult and complex procedure of all aortic segments. Many complications like pulmonary, renal, or intestinal malfunction can occur, but the most feared one is still spinal cord ischemia (SCI). (Doering et al., 2024) This can be permanent (paraplegia) or temporary (paraparesis). In the early nineties, the reported rates of SCI was up to 16%. (Svensson et al., 2015) The highest risk for paraplegia in those days was longer cross-clamping time and the extent of aneurysm resection. Since then, many adjuncts like left-heart bypass with systemic cooling and intraoperative control of the motor evoked potentials (MEPs) have been established in the open repair. (Coselli et al., 2023) A recent meta-analysis of >22,000 patients demonstrated an overall incidence of 7.0% SCI for open TAAA repair. Regardless of the reduction in complication rate after TAAA repair, the risk of SCI remains, with the highest for

Crawford extent II and lowest for extent IV (extent I, 4%; Extent II, 15%; Extent III, 7%; Extent IV, 2%; and Extent V, 7%). (Gaudino et al., 2022)

The introduction of endovascular treatment started a new era in this domain, significantly reducing the rate of perioperative SCI, especially the introduction of staged procedures and temporary aneurysm sac perfusion. (Kasprzak et al., 2014)

2.3.4.2 Spinal cord circulation and the significance of segmental arteries

Although SCI is a rare complication, accounting for 0.26% of all thoracic aneurysm repairs (Coselli et al., 2016), it is the most devastating one, “warranting” a poor outcome with limited life expectancy, independently of the type of procedure: 63% one-year survival after open and 64% after endovascular TAAA treatment, respectively. (Gialdini et al., 2017) Despite improving the outcomes after TAAA repair in the last decades, the principle is still identical: the more aortic segments from the descending and abdominal aorta we remove (open repair) or cover (endovascular repair), the higher the number of excluded segmental arteries (SA). Above the diaphragm, these are called intercostal, and below the diaphragm, lumbar arteries. However, the SA is only one part responsible for the spinal cord circulation. Dr. Albert Adamkiewicz described the oldest concept in 1881, who reported that one artery originating from T8-L1 (known as A. radicularis magna or Adamkiewicz artery, AKA) is the responsible vessel for the perfusion of lower thoracic, lumbar, and sacral portions of the spinal cord. (Griep et al., 1996) Relying on this theory, identification and reimplantation of the AKA would reduce the rate of SCI during TAAA repair. Many research groups were looking intensively to identify the AKA on preoperative images like CTA or MRI and were able to find it in 97.6%. (H. Tanaka et al., 2016) However, the SCI was still present postoperatively, even in patients where the AKA was reimplanted. In these patients, even delayed paraplegia (after the first 48 hours postoperatively) occurred, which somehow doesn't correlate with this pathophysiology. One revolutionary proposal was the idea of an extensive collateral network that supports spinal cord perfusion. Dr. Griep et al suggested that the collateral network includes a complex of vessels in the intraspinal, paraspinous, and epidural space, including all SAs, both subclavian and hypogastric arteries. (Griep et al., 1996) The maintenance of sufficient pressure in this collateral network perioperatively is essential for preventing SCI in open and endovascular descending or TAAA repair.

2.3.4.3 Current approaches to spinal cord protection and neuromonitoring during descending or thoracoabdominal repair

The current approaches differ depending on the planned treatment, open or endovascular. Independent of the chosen approach, a multi-disciplinary team with

expertise in both treatment modalities is necessary to reduce the mortality rate and severe complications. The most common denominator for both strategies is the use of prophylactic CSFD. (Chen et al., 2023) Additionally, for endovascular treatment, a staged approach, lower limb perfusion, and temporary aneurysm sac perfusion have proven to be of enormous value for spinal cord protection. (Tenorio et al., 2022)

These three management steps have the goal of enhancing the spinal cord perfusion under perioperative circumstances and between different steps of treatment while reducing the metabolic and oxygen demands. (Figure 8) Perioperatively, temporary permissive hypertension can also be applied to increase the spinal cord collateral network perfusion pressure. As previously mentioned, the use of CSFD remains debatable as recently published. (Leone et al., 2024) Many centers use it on a regular base, whereas some use it only as a therapeutic measure after symptoms occur. (Marcondes et al., 2023) The current European and American guidelines recommend the selective use of CSFD based on practice in large-volume centers. (Riambau et al., 2017; Upchurch et al., 2021) Recently, intraoperative neuromonitoring with MEPs during endovascular TAAA treatment was demonstrated to have beneficial outcomes, but this still is to be proved in a larger series. (Banga et al., 2016) This neuromonitoring has a higher impact on outcome during an open thoracoabdominal aortic repair compared to an endovascular approach. A recent meta-analysis reported that MEPs have a summary sensitivity of

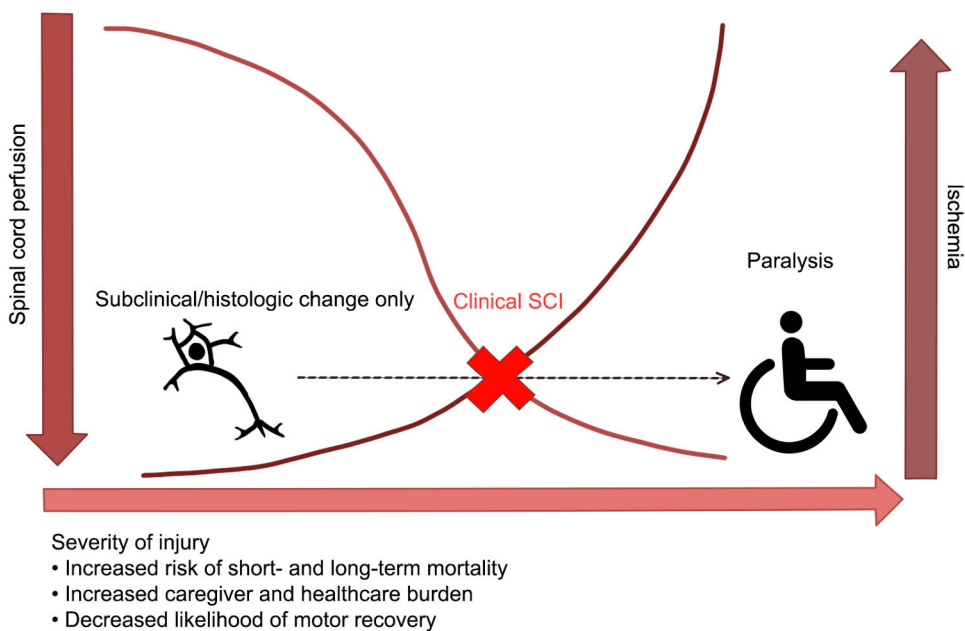


Figure 6. Association between spinal cord perfusion and spinal cord ischemia. Adapted from (Marcondes et al., 2023).

89.1% and summary specificity of 99.3% for the detection of SCI during open TAAA repair. (Y. Tanaka et al., 2016) In general, no change in MEPs during an open aortic repair ensures a good postoperative outcome, whereas failure of MEPs to return perioperatively to their index value has an odds ratio of 15.87 for developing immediate CSI. Although MEPs and neuromonitoring, in general, play a great role in perioperative SCI detection, there is still a relevant risk of delayed SCI of up to 20%, without any intraoperative MEP abnormalities, thus leaving some space for criticism and the reliability of the intraoperative neuromonitoring role. (Tanaka et al., 2023) Intraoperative neuromonitoring requires a huge team effort from the anesthetist, neurophysiologist, and surgeons, and it's time- and resource-consuming. However, it is a very useful adjunct for the recognition of intraoperative SCI and allows for immediate reaction if necessary.

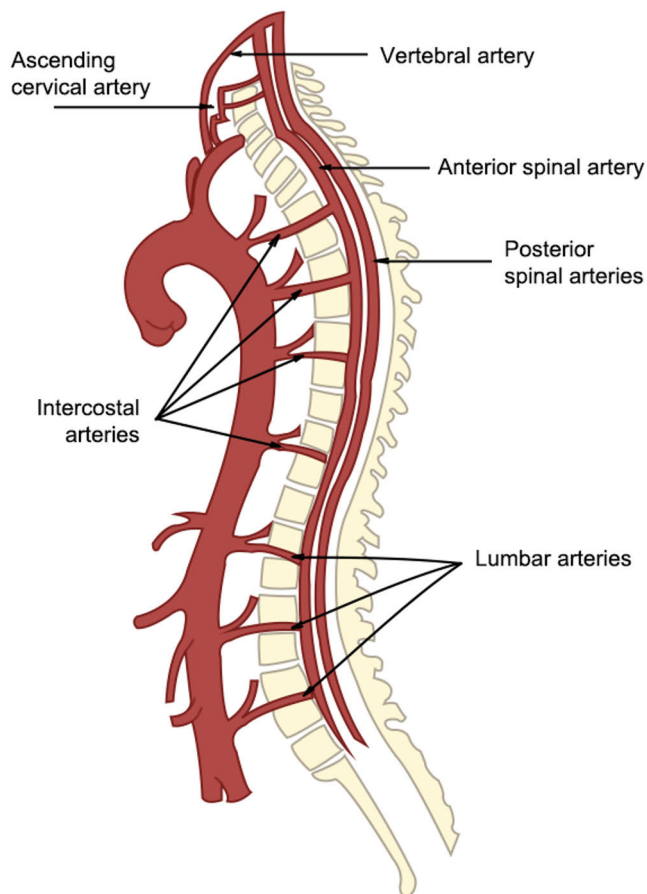


Figure 7. Spinal cord circulation. Adapted from (Marcondes et al., 2023).

2.3.4.4 Minimally invasive staged segmental artery coil embolization (MIS²ACE) for spinal cord protection

MIS²ACE is a recently introduced technique of spinal cord preconditioning to avoid any perioperative SCI. By preoperative occlusion of all SA, which will be covered during the aortic repair, a strong paraspinal collateral network and especially its capacity to develop new vessels (arteriogenesis) can be induced. This technique was first presented in 2014, and afterward, in some larger human series ((Etz et al., 2015; Luehr et al., 2014)). Preoperative planning is of utmost importance and is based on the underlying aortic pathology and excellent preoperative imaging (contrast-enhanced CTA with 1mm slices). High-resolution MRI can be used as an alternative imaging modality in case of CTA counter indication. All potentially covered SA during the aortic repair has to be identified, their diameter measured, and the access to them clearly identified. This might be challenging in patients with residual type A or chronic type B dissection cases with chronic postdissection aneurysms. The SA occlusion should be performed with local anesthesia via transfemoral access so that any potential neurological deterioration can be recognized and treated immediately. This technique was not used in our published study. However, it has been used in our clinic. A 6 F sheath can be used in combination with different macro- and microcatheters. Either coils or microvascular plugs are used for SA occlusion. (Branzan et al., 2018) In case of back pain or any paraparesis/paraplegia signs, the procedure has to be stopped immediately, and all necessary steps for spinal cord protection are induced.

The effects of MIS²ACE are currently investigated by the ongoing PAPAartis trial (multicenter, international, randomized-controlled). (Haunschild et al., 2023; Petroff et al., 2019) Until now, more than 150 MIS²ACE procedures have been performed safely without any severe peri-interventional adverse effects. The SA occlusion primes the paravertebral collateral network prior to aortic repair but also reduces the amount of back-bleeding during open repair and the incidence of type II EL after endovascular repair. Although there is some convincing evidence about its effect, MIS²ACE still needs to be established as a systematic preoperative approach in preconditioning spinal cord perfusion. (Branzan et al., 2018; Luehr et al., 2014)

2.3.4.5 The risk of bridging stent occlusion after BEVAR

This is a very serious and most severe early and late complication after complex endovascular treatment. It is still unclear if the risk for bridging stent occlusion is higher for the self- or balloon-expandable bridging stents. However, many data demonstrated a higher bridging stent occlusion rate in BEVAR vs. FEVAR and for the renal vs. visceral arteries. (Martin-Gonzalez et al., 2016) Next to the bridging stent used, the role of the hemodynamic/pathophysiological changes in the target

vessel, might reveal more understanding of the unknown area of the higher bridging stent occlusion rate in BEVAR. Recent analysis of some mechanical components with 3D geometric models showed that reduction in respiratory-induced deformation of branch take-off angle from pre- to post-BEVAR should reduce the risk of device disengagement and endoleak. (Cheng et al., 2023) There is still a debate about the bridging stent length, which might lead to an occlusion. Piazza et al. recommended that the total branch length covered by self-expandible bridging stents, including branch overlap and target vessel landing zone in BEVAR for TAAA, should be between 60 and 100 mm. (Marcondes et al., 2023) Shorter and longer total branch lengths were associated with branch instability. Opposite to this, the PRINCE²SS Delphi Consensus recommends avoiding the use of longer covered bridging stents, or they have to be treated life-long with DAPT or anticoagulation therapy to avoid any occlusion. (D'Oria et al., 2022) The characteristics of covered vs non-covered stents is described in detail in the next chapter.

2.3.4.6 Self- or balloon-expandable bridging stents

There is no ideal bridging stent available in the market. Ideally, the stent would have a combination of the balloon- and self-expandable stent characteristics, with a variety in diameter (4–12mm), length (20–100mm), and acquiring 6French (Fr) or 7Fr sheath introducer. Many clinical situations require the use of multiple stents per fenestration or branch to achieve the best possible result, thus resulting in extra costs. Generally seen, balloon-expandable bridging stents are preferred for the fenestrations and self-expanding bridging stents for the branches. (Nana et al., 2023) After the introduction of BEVAR, most of the bridging stents implanted as branch extensions in BEVAR were balloon-expandable covered stents. These stents had a single layer ePTFE membrane with a bare stent core, which led to many stent fractures, even occlusions, requiring re-intervention with their relining. A recent meta-analysis of current retrospective studies suggests lower overall target vessel instability and re-intervention rates favour the self-expanding bridging stents. (Nana et al., 2023) One of the most frequently used covered stents in FEVAR and BEVAR is the Advanta V12 covered stent. A recent study demonstrated excellent bridging stent patency of 98% in FEVAR and 87% in BEVAR after eight years. (Katsargyris et al., 2023) Currently, thanks to the introduction of newly designed, flexible balloon-expandable stents (double core stent with double-layered ePTFE membrane, Bentley, BeGraft Plus and the new Viabahn Balloon Expandable Covered Stent (VBX)) there is a clear trend towards standard use of balloon-expandable bridging stent in BEVAR too. With their broader use in BEVAR, there was a significant reduction of bridging stents re-intervention and occlusion. (Abisi et al., 2021)

2.3.4.7 Antithrombotic therapy after complex endovascular aortic treatment and the risk of postoperative bleeding

Currently, there is no clear recommendation on postoperative antithrombotic therapy in patients undergoing FEVAR or BEVAR. The recent European clinical practice guidelines on antithrombotic therapy for vascular disease did not address the issue of the postoperative therapy after complex endovascular treatment. (Twine et al., 2023) After post-revascularisation for atherosclerotic renal or mesenteric disease, only one month of DAPT is recommended. The PRINCE²SS International Expert-Based Delphi Consensus suggests a lifelong DAPT antithrombotic therapy, depending on the target vessels' anatomical and bridging stent characteristics: vessel diameter <6 mm, tortuosity >60° within 30 mm from the origin of the target vessel, use of multiple stents and total stent's length used >50 mm. (D'Oria et al., 2022) However, this recommendation did not take into account the potential risk of a bleeding event, and this should not be underestimated. Three recent RCTs showed a higher risk of spontaneous bleeding of up to 5%/y in patients >65 years and undergoing coronary stenting. (Urban et al., 2019) The vast majority of the patients undergoing FEVAR and BEVAR are older than 65 years, meaning that this risk of bleeding will increase with age and longer follow-up in a fragile population set on a lifelong DAPT. Moreover, the study by Kontopodis et al., reported that anticoagulated patients were found to have increased mortality, endoleak, and reintervention rates after EVAR compared to their non-anticoagulated counterparts. (Kontopodis et al., 2023)

2.4 Open and endovascular abdominal aortic repair

2.4.1 Open aortic repair

In 1951, the famous French colorectal surgeon Charles Dubost, who later became a cardiovascular surgeon, performed the first open abdominal aortic repair in Paris using a homograft from a 20-year-old woman. (Dubost et al., 1952) This operation was performed via a left-sided extraperitoneal, thoracoabdominal approach with resection of the 11th rib. The aorta was clamped below the renal arteries; the homograft anastomosed about 2cm below the renal arteries with 5/5 Silk 0 and distally to the origin of the right common iliac artery, with the left one being reimplemented afterward in the homograft. Interestingly, the aneurysm sac was completely dissected and resected. In the next years, this technique was implemented in many cardiovascular surgical centres as a regular open abdominal aortic repair procedure.

Consequently, the removal of the total aneurysm sac caused severe collateral damage until Oscar Creech suggested in 1966 in Houston to leave the sack and do endo-aneurysmorrhaphy as a protection to the graft. (Creech, 1966) Since the late 1960, the replacement of the abdominal aorta with the inlay technique, followed by a sac reduction and endo-aneurysmorrhaphy, has been widely accepted as a gold standard. The only dilemma remains whether access should be transperitoneal or retroperitoneal. Recent Cochrane Database Analysis demonstrated no difference between both approaches concerning mortality, complications including hematoma, abdominal wall hernia, and chronic pain. (Mei et al., 2021) However, patients who had a retroperitoneal approach had shorter intensive care unit (ICU) and hospital stays, accompanied by a reduction in blood loss, however, that was not found to be statistically relevant.

One of the biggest disadvantages after an open abdominal aortic repair is the higher rate of early morbidity and mortality compared with EVAR. Two RCTs, the EVAR-1 trial and the DREAM trial, demonstrated higher early mortality, 4.2% after open repair vs. 1.8% after EVAR (for the EVAR-1 trial), with a clear early benefit after EVAR. (Greenhalgh et al., 2010; van Schaik et al., 2017)

However, this benefit was lost after two years. Furthermore, the long-term results of the EVAR-1 trial demonstrated lower mortality after open repair vs. EVAR after 15 years and the higher rate of re-interventions after EVAR, showing that there is still some place for the open repair in the treatment of AAA, especially in patients with longer life expectancy. (Patel et al., 2016)

The current ESVS guidelines didn't recommend open abdominal aortic repair as a first treatment choice in younger and fitter patients, but this should be discussed with the patient based on the current data and the patient's and surgeon's preferences. (Wanhainen et al., 2024)

2.4.2 Endovascular aneurysm repair

After the introduction of EVAR in 1986 by Volodos and in 1990 by Parodi, the endovascular technique continued to develop. (Volodos et al., 1986) From the 1st generation with large sheets, stainless steel, and inflexible stents, it offers currently low-profile introducing sheets with flexible nitinol stent-grafts, better trackability, and availability to accommodate different anatomies while staying within the IFUs. The undisputable benefit of the minimally invasive, endovascular approach is the very low early mortality rate and quick recovery compared with open repair. However, this survival advantage decreases after one year and equals the mortality after open repair at three years. (Schermerhorn et al., 2015) Additionally, the patients undergoing EVAR had a higher rate of secondary rupture during follow-up. After 15 years, EVAR showed an inferior survival compared with an open aortic repair. (Patel

et al., 2016) With longer follow-up duration, the risk of re-intervention increases up to 25% after eight years, and the total treatment becomes more costly. (Greenhalgh et al., 2010) In order to achieve good long-term outcomes and avoid re-interventions during the follow-up, the index procedure has to be planned and performed immaculately for each patient. As a result, potential device failure and disease progression can be decreased or avoided over time. (Dias et al., 2018)

2.4.3 Technical challenges

Even though EVAR is the preferred option for AAA repair and has many advantages over open repair, some of EVAR procedures may fail over time. (Dias et al., 2018; Wanhainen et al., 2024) These failures have multimodal causes, either related to the device or to disease progression, especially if the treatment for a particular stent-graft is outside its IFUs. (Hahl et al., 2022) It is unclear which percentage of the radial force of the stent-grafts, especially the excessive oversizing for the proximal sealing, is responsible for the disease progression. Short, wide, and angulated aneurysm necks are prone to type Ia EL and have to be properly addressed prior to index treatment and eventually treated initially with fenestrated or branched stent grafts to allow for sealing in a healthy pararenal aorta. Proximal sealing in a longer, parallel aortic segment warrants a better long-term outcome because it optimizes the stent-graft apposition with the aortic wall. (Bryce et al., 2018; Pitros et al., 2022)

One of the remaining technical challenges is the size of the delivery system and its applicability in patients with atherosclerotic, diseased iliac vessels. By reducing the profile, stent-grafts can be used in different anatomies, especially in women with small access vessels per se. On the other hand, the reduction of the profile means thinner stents and fabric, which should not endanger potential stent fracture or fabric tear in the long term. (O'Donnell et al., 2021)

The overall success after EVAR depends also on the persistence of type II EL during follow-up. Current ESVS guidelines don't recommend the routine occlusion of the lumbar arteries or IMA, but persistent type II EL means a limited chance for sac shrinkage and a clear tendency for sac expansion. Coil embolization of the lumbar arteries prior to EVAR might reduce the rate of type II EL, but it also increases the risk of the intervention; it's time-consuming and costly. (Hatzl et al., 2023)

Continuous collaboration between the industry and physicians has been essential in the last decades and has led to significant technological improvement. This partnership allows for further innovation and promises better long-term outcome.

2.4.4 The influence of the co-morbidities on the survival rate

Pre-existing co-morbidities can determine late survival after AAA repair rather than the repair method chosen. A meta-analysis that included four RCTs comparing open repair vs. EVAR demonstrated that the treatment modality chosen for AAA repair does not influence survival at 4 years (OR 0.92, 95% CI 0.75–1.12) (Paravastu et al., 2014) This conclusion did not change after adding the results in the meta-analysis from further three propensity score matched studies (HR 0.97, 95% CI 0.9–1.04). (Takagi & Umemoto, 2014)

Multiple studies reported poor late survival following AAA repair after analyzing demographic and preoperative clinical variables. A recent meta-analysis showed that the age at index AAA repair plays a role in the expected survival but is not a contraindication for treatment per se. (Khashram et al., 2016) If the reference category is the age of <65 years, patients with age up to 75 and above (>75 years old) had estimated pooled HRs of 1.77 (95% CI 1.36–2.30), $I^2 = 77\%$ and 2.32 (95% CI 1.93–2.80), $I^2 = 37\%$ respectively. (Khashram et al., 2016) Similarly, gender was analyzed and showed worse overall survival for females than males with HR 1.15 (95% CI 1.07–1.27), $I^2 = 45\%$. (Khashram et al., 2016)

Literature has shown that ischemic heart disease and heart failure influence patient survival; however, reports lack consistency regarding postoperative outcomes. If an ischemic heart disease is mainly reported in the form of a previous myocardial infarction, with an increased HR of around 1.5 (CI 1.32-1.73) (De Martino et al., 2013; Saratzis et al., 2013) If the ischemic heart disease is specifically defined as the presence of relevant coronary atherosclerotic lesions with or without previous myocardial infarction, the HR of 1.29 (95% CI 1.18–1.48), is still slightly increased but without wider impact on the overall survival. The impact of cardiac failure is variably defined and is based on a mixture of clinical, radiological, and echocardiographic criteria. Independent of the definition, previously known heart failure seriously diminishes the overall survival with a HR of 1.91 (95% CI 1.58–2.30). (Khashram et al., 2016)

COPD is well known as a relevant preoperative co-morbidity, severely influencing the overall survival after AAA repair. (Mastracci et al., 2010) If only analyzed by the presence of a preoperative COPD, the HR is increased by 1.53 (95% CI 1.37–1.70), but preoperative supplementary oxygen therapy significantly influences the outcome with a pooled HR of 3.05 (95% CI 1.93–4.80). (Xiong et al., 2016)

Preoperative renal function impairment is widely but inconsistently reported, mainly due to the various definitions of impairment and the units of measurement used. Unifying units of measure may diminish the differences: converting creatinine units in mg/dL into $\mu\text{mol/L}$ or vice versa. Creatinine values are differently reported, either as categorical data or kept in a continuous form. However, severe renal

function impairment with ESRD and/or dialysis has a massive impact on overall survival, with an HR of 3.15 (95% CI 2.45–4.04). (Khashram et al., 2016) Peripheral arterial disease (PAD) and diabetes can influence the outcome, too. However, this statement lacks high-level evidence. (Matsumura et al., 2009) It seems that diagnosis of PAD and diabetes prior to AAA repair has a limited impact on the overall survival with HR of 1.36 (95% CI 1.18–1.58) and 1.34 (95% CI 1.20–1.49), respectively. (Matsumura et al., 2009)

2.4.5 Prognostic model for survival of patients treated for AAA with EVAR

Although the number of ruptured AAA is decreasing, this pathology remains one of the leading death causes in elderly men. (Nordon et al., 2011) In order to lower rAAA-caused mortality, surveillance and an elective repair may assist in preventing the rupture. (Sakalihan et al., 2018) The last three ESVS treatment guidelines still recommend the same aneurysm size (≥ 5.5 cm in men; ≥ 5 cm in women) as an indication for treatment (Wanhainen et al., 2024; Wanhainen et al., 2019). Throughout the years, a number of different prediction models were published, with different limitations and shortcomings, which are summarized in Table 4. (Baas et al., 2008; Barnes et al., 2008; Carlisle, 2015; DeMartino et al., 2018; Grant et al., 2015; Lijftogt et al., 2017; Mastracci et al., 2010) The minimally invasive treatment using EVAR is the preferred treatment method, especially in the elderly. (Patel et al., 2018) It is still debatable whether elderly or frail patients should be treated with EVAR or not treated at all. (Sweeting et al., 2017) The EVAR-2 trial, in which patients unfit for open repair were randomized in conservative treatment vs. EVAR, demonstrated no survival benefit in patients treated with EVAR. Of the patients randomized for conservative treatment, 20% were still alive after eight years. Paradoxically, these patients were probably the fittest of the whole randomized cohort and were exposed to the risk of AAA rupture for a long period of time. (Sweeting et al., 2017) Nowadays, an elective EVAR is a very safe procedure and can be performed with a very low mortality of $< 1\%$. (Meuli, Menges, et al., 2022).

A critical preoperative assessment of the risk profile of patients presumed physically unfit prior to treatment is essential. The fittest patients with larger AAA can benefit from open repair or EVAR, thus reducing the overall mortality significantly. (Powell & Wanhainen, 2020) On the other hand, relevant costs could be avoided by not treating the patients with the highest risk profile and smaller AAA. The UK NICE guidelines recommended in 2020 that in patients with AAA who meet the treatment indication but have medical comorbidities that contraindicate open surgical repair, either EVAR or conservative management should be considered.

(Spanos et al., 2020; Sultan et al., 2020) With this statement, the role of EVAR as a treatment option in these patients is more than questionable.

The success of an AAA treatment strategy and its overall mortality depends on three factors: the impending risk of aneurysm rupture, the risk of elective repair, and the life expectancy. (Figure 8)

A recent study of more than 3000 patients with asymptomatic, untreated AAA showed a low annual rupture rate of 2.2% for AAA with diameters 5.5–6.0. (Lancaster et al., 2022) However, the annual rupture rates for AAA with diameters 6.1–7.0 cm and > 7 cm were higher, at 6.0% and 18.4%, respectively. (Elshikhawoda et al., 2023; Malas et al., 2014; Wanhainen et al., 2024) Currently, an elective AAA repair carries a low perioperative risk of mortality between 0.9% and 5%.

Several RCTs and large registry data on patients who were treated for their AAA delivered information concerning the life expectancy of patients with AAA. (De Bruin et al., 2010; Johal et al., 2019; Patel et al., 2016) The median survival in the EVAR-1 trial was around 8.5 years, with 40% of the patients living at 10 years after index treatment. (Patel et al., 2016) On the contrary, the median survival in the EVAR-2 trial was lower, with only 3 years. (Sweeting et al., 2017) Several comorbidities like advanced age, CKD, COPD, or heart failure can influence the life expectancy after EVAR and have to be considered in decision-making prior to EVAR. (Marques-Rios et al., 2018)

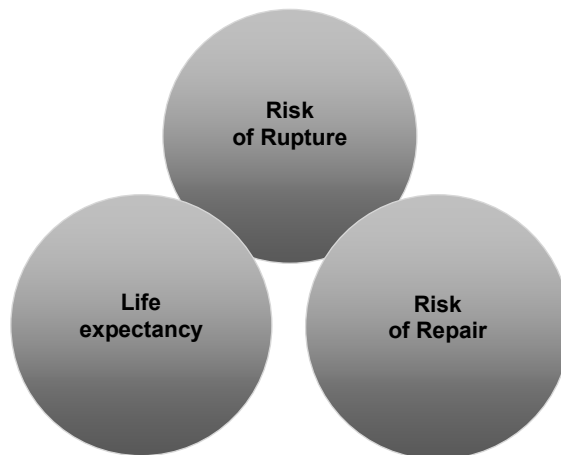


Figure 8. Factors contributing to AAA treatment strategy.

Table 4. Existing prediction tools in the literature.

First author	Year of publication	Patients (n)	Type of repair	Study period	Model type / design	Data inputs	Model output	Model performance	Notes
Barnes (Barnes et al., 2008)	2008	961	EVAR	1999–2001	Regression	Derivation cohort-patient risk factors and AAA anatomical features	Early, 3- and 5y death, early and mid-term endoleak, graft re-interventions, and complications	Externally validated with 4 datasets-variable performance	Inconsistent validation results among different data sets
Baas (Baas et al., 2008)	2008	345	EVAR and OAR	2000–03	Regression coefficient	GAS	30-d and 2-y mortality	c-statistic at 2-y 0.74 (OAR) and 0.78 (EVAR)	DREAM trial cohort
Mastracci (Mastracci et al., 2010)	2010	697	EVAR	1998–2005	Nomogram	Demographics and comorbidities from derivation cohort	2-, 4-, and 8-y survival	c-statistic 0.68 at 4 years	No further external validation
Carlisle (Carlisle, 2015)	2015	1096	EVAR and OAR	Variable, depending on centre (>5-y period)	Regression / calculator	Demographics, comorbidities, and CPX variables	Simulated survival rates for repair and nonrepaired	c-statistic (1–5 y) 0.73, 0.71, 0.68, 0.67, 0.66	Available online (free)
Grant (Grant et al., 2015)	2015	NA	EVAR and OAR	NA	Discrete event simulation	Inputs from the British aneurysm repair score	Life expectancy, survival, and costs	Not validated	No external validation
DeMartino (DeMartino et al., 2018)	2018	1038	EVAR and OAR	2002–11	Regression coefficient	VSGNE risk prediction	5 y survival, three risk categories	c-statistic at 5 years 0.66	Only <6.5 cm included
Khashram (Khashram et al., 2018)	2018	683	EVAR, OAR, and small AAA	Repairs 2010 Small AAA surveillance 2006–11	Discrete event simulation	Systematic review	Simulated life expectancy, survival of repaired and nonrepaired	c-statistic (30 day, 2–5 y) 0.87, 0.67, 0.69, 0.69, and 0.71	Requires further testing

Note: EVAR = endovascular aneurysm repair; AAA = abdominal aortic aneurysm; OAR = open AAA repair; GAS = Glasgow Aneurysm Score; CPX = cardiopulmonary exercise; NA = not applicable; VSGNE = Vascular Study Group of New England.

3 Aims

This thesis aims to provide information regarding outcomes and safety of the endovascular treatment of complex aortic pathologies, specifically:

1. To evaluate the safety and outcome of custom-made devices used for the treatment of aortic arch pathologies.
2. To evaluate the safety and outcome of preoperative coil embolization of the segmental arteries prior to thoracoabdominal aortic repair.
3. To analyze long term patency of the bridging stents after branch endovascular aneurysm repair and the impact of antithrombotic medication to the patency.
4. To validate prognostic model for the survival of patients after endovascular aortic repair.

4 Materials and Methods

This thesis consists of four heterogeneous papers. All studies included patients from high-level aortic centres, and three out of four papers were multicenter. All data was collected prospectively from each hospital's electronic databases. Furthermore, it was retrospectively analyzed. Studies were approved by each country's Ethics Committees. As the studies were retrospective, patient consent was not required.

4.1 Paper I

4.1.1 Patient cohort and study design

The patient cohort consisted of all patients treated for various aortic arch pathologies: aneurysms, PAUs, and dissections, using the Relay® stent-graft custom-made platform with three different designs (Figure 9) at University Hospital Bern, Switzerland, and University Medical Center Tübingen, Germany, between July 2016 and July 2023. This cohort included patients with above mentioned conditions, who were deemed unfit for open repair by a multidisciplinary team. Thereafter patients underwent either elective or urgent endovascular aortic arch repair.

We collected all patients' baseline characteristics, as well as all pre' and perioperative and follow-up data as per 1st of December 2023. The patients had follow-up control CT scans at 3, 6 and 12 months and yearly thereafter.

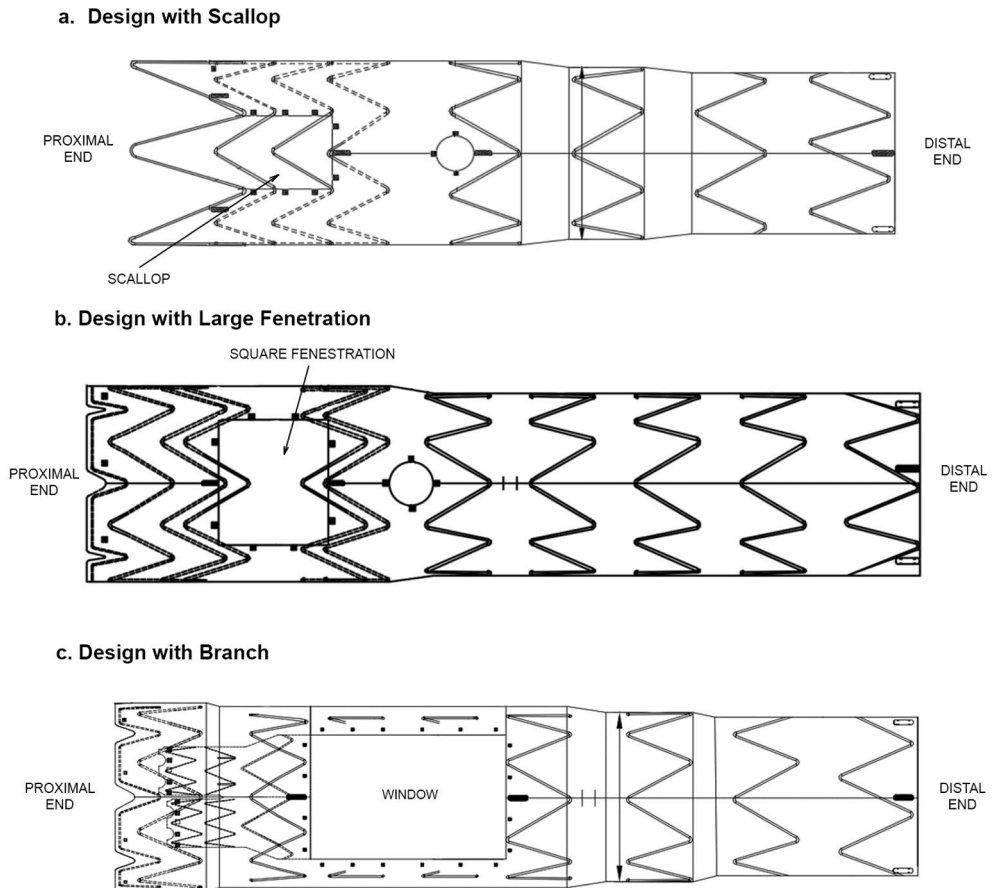


Figure 9. (a-c). Technical drawing of three different designs from the Relay® stent-graft custom-made platform.

4.1.2 Outcomes

The endpoints of the study were: technical success, perioperative stroke, death, and the need for re-intervention. Technical success was defined as complete deployment of the main body and all bridging stents with complete exclusion of treated underlying aortic pathology at final angiogram. Perioperative stroke was defined as either hemorrhagic or ischemic stroke which appeared within 30-days after the initial procedure. Diagnosis was confirmed based on correlation between clinical and radiological findings. The need for re-intervention was defined based on either clinical representations or radiological findings indicating the need of intervention.

4.1.3 Statistical analysis

Statistical analyses were performed using SPSS software 22.0 (IBM, Armonk, NY, USA) and followed the European Journal of Cardio-Thoracic Surgery standards. Continuous Variables were summarized using medians and quartiles (Q1, Q3). Categorical variables were presented as numbers and percentages. This study adhered to the reporting guidelines outlined in the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement.

4.2 Paper II

4.2.1 Patient cohort and study design

This study consisted of two parts: a systematic review and an observational single-center study; the latter consisted of all consecutive patients undergoing MIS2ACE as preparation for either open or endovascular thoracoabdominal aortic aneurysm (TAAA) repair with a high risk of SCI at University Hospital Bern, Switzerland between January 2021, and September 2023. The multidisciplinary team evaluated patients' suitability for the procedure. To ensure patient's neurological function the procedure was performed under local anesthesia in either an angio suite or a hybrid operating theatre. Postoperative monitoring was achieved in an intermediate care unit for at least 48 hours.

After summarizing our cohort's data, we conducted a systematic review and meta-analysis of relevant studies per the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement. We prespecified search strategy, data extraction, and outcomes in a protocol registered with PROSPERO (CRD42023477411) and available online.

4.2.2 Outcomes

The primary endpoint of the study was spinal cord ischemia within 48 h after MIS2ACE. Secondary endpoints were spinal cord ischemia at seven days, technical success of MIS2ACE, perioperative major bleeding, acute renal failure at 30 days, and all-cause mortality at 30 days.

The primarily endpoint of the systematic review was spinal cord ischemia after MIS2ACE.

4.2.3 Statistical analysis

For the observational study, we used SPSS software 22.0 (IBM, Armonk, NY, USA). Continuous variables were presented as the median and interquartile range (IQR), and categorical variables as the number of patients (percentage). For the single-arm meta-analysis of proportions, the metafor package of R was used. We performed the pooling of proportions with a random effects model using the DerSimonian and Laird methods and presented results as proportions with 95% confidence intervals.

4.3 Paper III

4.3.1 Patient cohort and study design

The study was an international multicenter retrospective analysis, which consisted of patients treated at four European tertiary vascular units: Inselspital, University of Bern in Bern, Switzerland; Turku University Hospital in Turku, Finland, University Hospital Zurich in Zürich, Switzerland; Leuven University Hospital in Leuven, Belgium between January 2014 to December 2022. The patient cohort consisted of all patients who underwent elective Branched Endovascular Aortic Repair for one of the following conditions: pararenal aortic aneurysms, type Ia endoleaks after previous EVAR, and thoracoabdominal aortic aneurysms.

We collected all patients' baseline characteristics, as well as all pre- and postoperative and follow-up data as of 31 December 2022, with a specific focus on survival, antithrombotic therapy, and bridging stent patency.

4.3.2 Outcomes

The primary endpoint was freedom from bridging stent occlusion and its correlation with postoperative antithrombotic therapy. Secondary outcomes were overall survival and identifying target vessel and bridging stent characteristics that might be associated with a higher risk of stent occlusion.

4.3.3 Statistical analysis

Statistical analyses were performed using R Studio version 4.2.3. Continuous Variables were summarized using medians and quartiles (Q1, Q3) and Kruskal – Wallis Rank Test was used for comparison calculations. Categorical variables were presented as numbers and percentages and Chi-square Test was used to compare those variables between group. Time- to – event analysis was calculated using cumulative incidence function and Gray's test. For data analysis on relationship

between various factors and bridging stent occlusion Cox Proportional Hazard Model was used. Competing Risk Analysis was used to identify the incidence of stent occlusion. This study adhered to the reporting guidelines outlined in the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement.

4.4 Paper IV

4.4.2 Patient cohort and study design

The study was an international multicenter retrospective analysis, which consisted of patients treated with standard EVAR for asymptomatic AAAs at four different European aortic referral centers: University Hospital of Zurich, Switzerland (2003–2020), University Hospitals of Turku and Helsinki, Finland (2010–2021 and 2002–2016, respectively), and University Hospital of Leuven, Belgium (2001–2019). Patients who had complex EVAR procedures (e.g., fenestrated, branched, or parallel grafts) or symptomatic or ruptured aneurysms or other conditions like penetrating aortic ulcers were excluded from this study.

Patients' data on demographics, comorbidities, treatment indications, and outcomes were collected from local databases. Information on survival was obtained from hospital databases, and where necessary, patients were contacted via telephone for additional follow-up data.

4.4.3 Outcomes

The primary outcome was to test model's performance measured by discrimination and calibration for overall survival in the validation cohort.

4.4.4 Statistical analysis

Statistical analyses were performed using R Studio version 4.2.3. Continuous Variables were summarized using medians and quartiles (Q1, Q3) and Kruskal – Wallis Rank Test was used for comparison calculations. Categorical variables were presented as numbers and percentages and Chi-square Test was used to compare those variables between group. The original model's variables were selected based on a literature review and refined using a machine learning method (the beta coefficients of a Cox model). Model's performance was assessed by discrimination (Harrell's concordance statistic, C) and calibration (comparison of predicted vs. observed survival at 5 and 10 years). Additional analyses included comparing survival across different risk groups and examining the cohort's characteristics over time.

5 Results

Paper I consists of thirty-five patients who were treated with custom-made devices from the Relay (Terumo Aortic) platform for different aortic arch pathologies between 2016–2023. Two patients (5.7%) had a perioperative stroke, and there was no early death. Mean follow-up was 36 at± 27 months, and six patients (16%) died during follow-up, none of them aortic-related. One patient required relining of the bridging stent in the left common carotid artery, three required distal extension with thoracic stent-graft, and one needed additional plugging of the left subclavian artery.

Paper II is a systematic review, meta-analysis and the single-center observational study. Seven patients underwent 12 coil embolization sessions of the segmental arteries in the observational study. The median number of embolised arteries was 4 (IQR 1,4), and eleven sessions (92%) were successful. All sessions went uneventfully. For the meta-analysis, two of the 432 initially retrieved articles were included. The prevalence of SCI in the patients receiving preoperative segmental artery coil embolization was 1.9% (95% CI -0.028 to 0.066, $p=0.279$; 3 studies; 81 patients, 127 coiling sessions).

Paper III is a multicentre retrospective international study, which included 120 patients treated with previous BEVAR. In total, 416 target vessel and their bridging stents were analyzed. During follow-up, 24 (5.8%) primary bridging stent occlusions (LRA =10, RRA= 7, SMA= 3, TC = 4) were identified. The risk of renal bridging stent occlusion was significantly higher compared with visceral bridging stent, $p=.013$. The occlusion rate was 7.8% for renal branches and 1.5% for visceral branches at one year and 10.6% and 3.7% at five years, respectively. The multivariable Cox proportional hazard model on bridging stent occlusion showed no significant difference between the antithrombotic strategies.

Paper IV is an external validation of the previously established prognostic survival model after EVAR for AAA. Study included 1500 patients from four international European centers. During 65 months of follow-up, 54.6% of the patients died. A high-risk subgroup of patients with impaired survival rates was identified: octogenarians with $eGFR < 60$ OR COPD, septuagenarians with $eGFR < 30$, and septuagenarians with $eGFR < 60$ and COPD having limited survival rates of only 55.2% and 15.5% at five and ten years, respectively.

5.1 Paper I

The study included 35 patients, 31 males (89%) and 4 females (11%). The median age was 72 years (IQR 68;79). Fourteen patients (40%) had a PAU, 11 patients (31%) had an aneurysm, including 3 patients with post-dissection aneurysms (2 after residual type A dissection and 1 after chronic type B dissection), 10 patients (28.6%) had an aortic dissection, including 6 with persistent re-entry in the aortic arch after previous open repair and 4 with chronic type B dissection. Aortic Arch Type: 13 patients (37%) had a type I aortic arch, 8 patients (23%) had a type II, and 14 patients (40%) had a type III aortic arch. Ten patients (29%) had a common origin of the brachiocephalic trunk (BCT) and left common carotid artery (LCCA).

All custom-made stent-grafts were successfully implanted as intended without any occurrences of type I or III endoleaks or retrograde type A dissections during the procedure, reporting a 100% success rate.

Two patients (5.7%) experienced a stroke postoperatively, both of which were ischemic. However, both patients fully recovered without any disabling deficits 30 days after specialized neurorehabilitation. There were no deaths within the first 30 days postoperatively.

No major perioperative complications were reported; one case of pneumonia (2.9%) and two wound infections (5.7%) were registered. No type I or III endoleaks or retrograde type A dissections occurred during the procedure. One case of ventricular tachycardia during rapid pacing (2.9%), which required defibrillation, and one case of external iliac artery dissection requiring additional stenting (2.9%).

The mean follow-up period was 35 ± 26 months. Six patients (17.1%) died during the follow-up period, none of which were related to aortic complications. One patient required reinforcement of the bridging stent in the left common carotid artery (LCCA) due to a suspected stent fracture. Three patients required distal extensions due to new aortic entries or type Ib endoleaks. Five patients had type II endoleaks via the left subclavian artery (LSA) after previous plugging, with one case being hemodynamically significant and requiring an additional vascular plug.

5.2 Paper II

Observational Study Results. Seven patients (5 males, 71%) with a median age of 57 years (IQR 55–69 years). Six patients (86%) underwent previous aortic surgery. Five patients (71%) had extent II thoracoabdominal aortic aneurysms (TAAA), two patients (29%) had extent III TAAA, and five patients (71%) had post-dissection TAAA.

There were no events of spinal cord ischemia within 48 hours after MIS2ACE. There were no reports of spinal cord ischemia at seven days postoperatively. Technical success of MIS2ACE was achieved in 11 out of 12 sessions (92%). The

median procedural time was 153 minutes (IQR 116–192 minutes), and the median number of embolized arteries was 4 (IQR 1–4). There were no periprocedural complications and no reports of major bleeding postoperatively or acute renal failure within 30 days post-MIS2ACE. One patient (14%) died 36 hours after combined thoracic and fenestrated endovascular aortic repair due to complications unrelated to SCI.

The meta-analysis included two additional studies alongside the observational study cohort described above, resulting in 81 patients and 127 coiling sessions. The pooled prevalence of postoperative spinal cord ischemia among MIS2ACE patients was 1.9% (95% CI: -0.028 to 0.066). The SCI prevalence following MIS2ACE was significantly lower than previously reported rates of SCI in TAAA repairs without preconditioning, suggesting the effectiveness of MIS2ACE in reducing SCI risk.

5.3 Paper III

The primary outcomes focused on antithrombotic therapy influence on target vessel's patency and freedom from bridging stent occlusion. Out of 416 target vessels treated, there were 24 (5.8%) primary bridging stent occlusion. Renal arteries had a significantly higher occlusion rate compared to visceral arteries. (Figure 10). The occlusion rate was 7.8% for renal branches at 1 year and 10.6% at 5 years, compared to 1.5% for visceral branches at 1 year and 3.7% at 5 years.

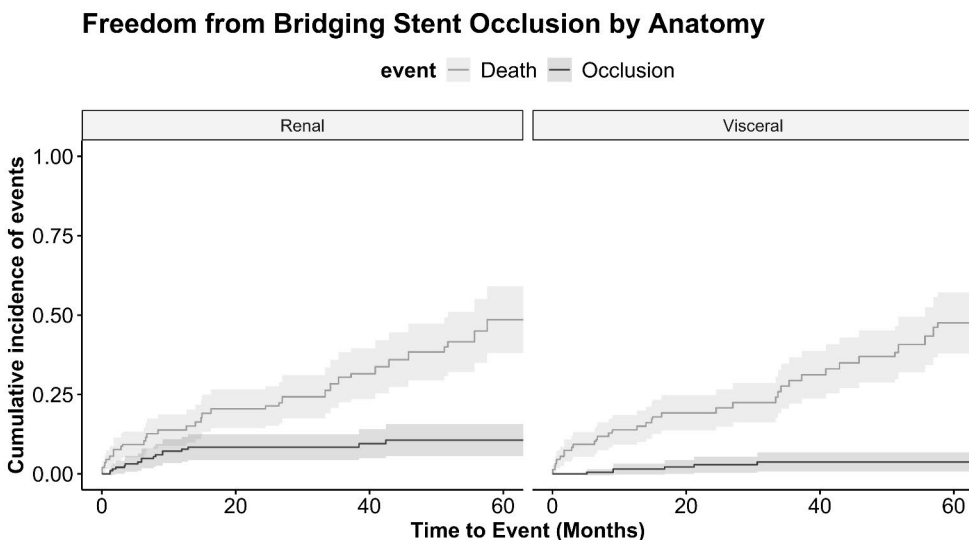


Figure 10. Freedom from bridging stent occlusion: renal arteries vs visceral arteries.

The multivariable Cox proportional hazard model showed that patients without antithrombotic therapy had an almost 11-fold increased risk of stent occlusion (HR = 10.7, 95% CI = 1.12–102, p = 0.039). The other antithrombotic therapies, including aspirin monotherapy, clopidogrel, dual antiplatelet therapy, and oral anticoagulation, did not significantly impact the target vessel’s patency.

Secondary Outcomes focused on overall survival reintervention rate and target vessel characteristics. The estimated overall survival was 85% at 1 year and 48% at 5 years. The study reported an in-hospital mortality rate of 3.4%. A total of 12 patent bridging stents (2.9%) required reintervention due to issues like stent fracture, kinking, or in-stent stenosis. The study found that certain characteristics, such as smaller vessel diameter (<6 mm), higher vessel tortuosity (>60°), and longer stent length, were associated with a higher risk of stent occlusion. Specifically, the total stent length was significantly associated with stent occlusion (HR = 1.03, 95% CI = 1.01–1.06, p = 0.015).

5.4 Paper IV

Study included 1,500 patients, 91.3% male (1,370 patients). The median age was 75.2 years (IQR 69.3;80.0). 31.3% (470 patients) had COPD diagnosis, median estimated glomerular filtration rate (eGFR): 77.8 mL/min/1.73 m² (IQR 63.0;87.5 mL/min/1.73 m²) and median creatinine level: 93 µmol/L (IQR 80;112 µmol/L). 17.2% (252 patients) had diabetes, 60.6% (855 patients) had a history of smoking. Median BMI: 26.1 kg/m² (IQR 24.0;29.2 kg/m²). The median aortic aneurysm diameter was 58.0 mm (IQR 55.0;65.0 mm).

Our study group developed a predictive model for survival in 2021 at a single center in the University Hospital of Bern, Switzerland. A temporal validation was performed using patients treated later at the same institution. (Figure 11)

Table 5. Development of the prediction model.

Original data (Meuli et al., 2021)	Internal validation (Meuli, Zimmermann, et al., 2022)	External validation (Dabravolskaitė et al., 2024)
Single Centre	Single Centre	Multicentre
2001–2012	2013–2020	2002–2021
Age, COPD, eGFR	Model updated	Discrimination
		Calibration

The current study is a multicentre external validation study testing the calibration and discrimination of this model. The predictive model’s discrimination ability, measured by Harrell’s C-statistic, was 0.62 (95% CI 0.60–0.65) in the validation

cohort, indicating a moderate ability to distinguish between patients with different survival outcomes. This was lower than the original cohort's C-statistic of 0.70 (95% CI 0.66–0.75), suggesting a slightly decreased discrimination in the validation cohort.

The model showed excellent calibration, with the predicted survival rates closely matching the observed survival rates at 5 years (Predicted 69.5%, Observed 70.3%) and 10 years (Predicted 37.0%, Observed 38.3%). (Figure 10)

Overall Survival at 30-Day was 98.9%, which was similar to the original cohort (98.7%). 5-Year Survival was 70.8%, and it matched the original cohort. Lastly, the 10-year survival rate was 38.7%, comparable to 39.2% in the original cohort. Furthermore, the study categorized patients into four risk groups based on the predictive model (Figure 12); we assessed the survival by risk groups separately.

- Low Risk: 5-year survival was 86.2%; 10-year survival was 61.2%.
- Low to Moderate Risk: 5-year survival was 74.0%; 10-year survival was 43.2%.
- Moderate to High Risk: 5-year survival was 61.8%; 10-year survival was 24.6%.
- High Risk: 5-year survival was 55.2%; 10-year survival was 15.5%.

Survival in the high-risk group was better in the validation cohort compared to the original cohort, indicating that the model might have slightly overestimated the mortality risk for these patients.

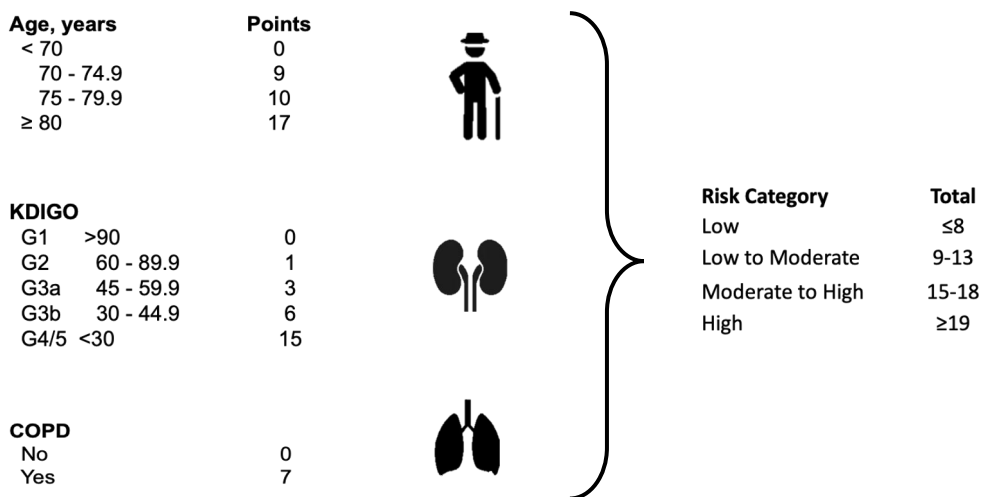


Figure 12. Four risk groups are based on the predictive model.

6 Discussion

The thesis consists of four papers addressing different challenges in the endovascular treatment of complex aortic pathologies. To a certain extent, it captures themes of innovation and evaluation in endovascular treatment approaches for complex aortic conditions, highlighting the efforts to refine and validate techniques and tools to improve patient outcomes.

The first study evaluated using custom-made Relay® stent-grafts for the treatment of aortic arch pathologies in high-risk patients deemed unfit for an open repair. CMD grafts proved to be a less invasive, safe, and effective alternative to open aortic surgery, ensuring a precise and individualized adaptation to complex arch anatomies. Moreover, our study demonstrated a low incidence of stroke (5.7%) and no mortality perioperatively. (Dabravolskaite, Makaloski, et al., 2024)

The second study focused on the safety and outcomes of MIS2ACE prior to thoracoabdominal aortic aneurysm repair. The procedure aims to reduce the risk of perioperative spinal cord ischemia, a devastating complication of TAAA repair. After analyzing our experience, we performed a meta-analysis of the available data, including our observational study. The prevalence of pooled SCI was 1.9%, lower than any other previous reports. (Dabravolskaite, Xourgia, et al., 2024)

The third study addressed the risk of bridging stent occlusion after branched endovascular aortic repair, with an occlusion rate of 7.8% for renal branches and 1.5% for visceral branches at 1 year and 10.6% and 3.7% at 5 years, respectively. Different postoperative antithrombotic regimes led to similar outcomes, thus leaving us questioning the influence of antithrombotic therapy on an occlusion rate. (Dabravolskaite, Meuli, et al., 2024)

The fourth study focused on external validation of a prognostic model for predicting survival outcomes in patients undergoing endovascular aneurysm repair for abdominal aortic aneurysms. (Meuli et al., 2021)The model proved to be robust and applicable in various clinical settings. (Dabravolskaité et al., 2024)

6.1 Paper I

Total endovascular repair of the aortic arch remains the most complex of all aortic segments due to the risk of stroke and retrograde type A dissection. Custom-made

devices are preferred because of this aortic segment's diversity and anatomical specificity. The Relay Branch system showed good preliminary technical success, but limited data is available. (Czerny et al., 2021; van der Weijde et al., 2020) These studies reported a higher rate of strokes, with the disabling one leading to a lethal outcome. According to their findings, a high stroke rate can be expected in the case of PAU, as underlying aortic pathology, and if there is excessive endovascular manipulation in the arch. Highly atherosclerotic supra-aortic vessels can increase the risk of stroke, too. We report in our study a low rate of perioperative stroke with complete recovery at 30 days in two patients, both having PAU as an underlying aortic pathology and highly atherosclerotic supra-aortic vessels.

The stent-graft design directly influences the amount of manipulation in the aortic arch. Branched stent-grafts require additional manipulation to catheterize the branches and implant the bridging stents. On the other hand, implanting a stent-graft with fenestration or scallops requires only angiography and a single manipulation in the arch - while deploying the main stent-graft. We tend to use different combinations of all three possible designs, varying from one big scallop for the LSA or LCCA up to triple-branch devices with separate access from all supra-aortic vessels. All combinations were planned to seal in landing zone 1 or 0, with limited manipulation in the arch and all supra-aortic branches. Recent studies proved that limited involvement of the supra-aortic arteries results in a higher technical success rate and lower risk of stroke. (X. Li et al., 2021; Nana et al., 2022, 2024) Following previously published recommendations, both centers have the same strategy to extensively flush all stent grafts with 100ml of saline. (Rylski et al., 2020) This step influences the amount of air released during deployment of the main graft and reduces the risk of air embolism. Concerning the release of air during deployment, the Relay® stent-graft has another special feature: it has a rigid outer and softer inner sheath, with the latter one being responsible for the reduced amount of trapped air within the stent-graft. Immediate removal of the stent-graft after its deployment also minimizes the presence of endo-tools in the arch.

The patients treated in our series with proximal scallop or one big fenestration had limited manipulation in the arch and significantly shorter operating time than those with branched components. Fernandez-Alonso et al. reported a similar experience with an excellent technical success rate after an arch repair with a proximal scalloped and fenestrated stent graft. (Fernández-Alonso et al., 2020) However, using a scallop design might increase the risk for type Ia endoleak. The same group reported two type Ia ELs in patients treated with proximal scallop and landing in zone 1. We have a similar duration of follow-up but didn't find any type of late I EL. Proximal scallop design without additional bridging stent, either in the LSA or the LCCA, is a good solution mainly for aortic pathologies localized in the distal aortic arch and along the lesser curvature.

The type of underlying aortic pathology and its location, either along the greater or the lesser curvature, can influence the kind of stent-graft design. In both centers, there is a tendency towards a fenestrated design for aortic pathology along a lesser curvature. Tsilimparis et al. reported a similar approach with the fenestrated COOK stent-graft. (Tsilimparis et al., 2020) Although the fenestrated stent-graft has clear perioperative advantages, it may bear a higher risk of type I and type III EL during follow-up. A four-fold higher risk for type I and III EL in fenestrated vs. branched arch repair was reported by a recent meta-analysis. (Spath et al., 2023) During follow-up we found no difference in outcome for fenestrated vs. branched repair.

Strengths and limitations

The aortic arch pathology is rare; therefore, we report a limited number of patients here. The novelty of using custom-made devices for total endovascular arch repair with different design options in two centers is a potential confounding factor. However, we report in this study all custom-made designs from the Relay platform for treating aortic arch. There is a well-organized outpatient clinic in both centers with close monitoring of all patients, which results in an excellent follow-up and detailed history of every patient.

6.2 Paper II

In this work, we first analyzed our series of patients undergoing segmental artery occlusion with coil embolization prior to open or endovascular aortic repair. We did not observe any side effects after the coil embolization, especially when no SCI occurred. No SCI was observed after the aortic repair either. All patients had standardized treatment and post-interventional observation at the intermediate care unit for at least 24 hours. This allows close neurological surveillance and, if necessary, immediate intervention in case of any neurological deterioration.

One patient died after the aortic repair, undergoing a very complex endovascular treatment followed by severe acute bilateral leg ischemia and consequent multiorgan failure. Low early postoperative mortality rates were reported: 5% (3/57) by Branzan et al. and 6% (1/17) by Addas et al. This patient died after suffering early postoperative paraplegia. (Addas et al., 2022; Branzan et al., 2018) Neither series reported any peri- or post-interventional complications after MIS²ACE.

After thoroughly researching the literature, we identified only two other studies to complete the meta-analysis. This could demonstrate that MIS²ACE is a safe procedure with very low morbidity and mortality. A well-planned, staged, multiple-session approach can be used as a supplementary tool to the preoperative strategy in preventing or reducing the risks for perioperative SCI in complex open or

endovascular aortic treatment. We found a pooled peri- and postoperative SCI prevalence of 1.9% in all patients undergoing preoperative MIS²ACE. Our research shows this is significantly lower than any previously reported SCI risk. (Coselli et al., 2016; Katsargyris et al., 2023) Spinal cord ischemia after endovascular repair of thoracoabdominal aortic aneurysms with fenestrated and branched stent grafts. (Verhoeven et al., 2015)

This low rate of postoperative SCI prevalence has even more value, considering that most of the patients in this meta-analysis had type II or III TAAA.

It is unclear what role the time interval between the coil embolization and the aortic repair plays. The centers included in this meta-analysis had different treatment approaches and, therefore, different time intervals, between 37 days in Bern, 51 days in Toronto, and 83 days in Leipzig. (Addas et al., 2022; Branzan et al., 2018) Independently of the different time intervals between the operations, the low risk of perioperative SCI after the aortic repair remained the same in all centers. This differs, of course, on the numbers of treated segmental arteries and the planned MIS²ACE sessions. Branzan et al. planned and performed two sessions in most of the patients, occluding in a median of five segmental arteries per session, whereas in Bern and Toronto, there was one session per patient with a median of four and three segmental arteries per session, respectively. This more frequent number of sessions could explain the longer time interval in one center than the other. A detailed approach with defined protocol points like the number of sessions planned, the number of segmental arteries per session, performing it in local anesthesia, structured neurological observation afterward, etc., could help standardize this technique.

The current literature research demonstrated the scarce reports about the MIS²ACE technique. The PAPAartis trial, a multicenter, multinational, randomized controlled trial, started in 2019 and intended to answer all the above questions. Experiencing some recruitment difficulties, the trial is not finished yet and the results are eagerly awaited. (Haunschild et al., 2023)

Strengths and limitations

Even though the treatment of TAAA has been growing in numbers, especially in the expense of endovascular treatment, MISA²CE is a technically demanding procedure requiring high skills from the performing physician; as a result, it has not been applicable in most cardiothoracic units, and in both observational studies and meta-analyses, we report a limited number of patients. However, it does show promising results, and this is the first meta-analysis of such scope.

6.3 Paper III

The background of this paper was the publication of the PRINCE2SS recommendation. A group of international experts recently published a summary of recommendations based on their personal experience. (D'Oria et al., 2022) These recommendations advise a longer DAPT if multiple or longer bridging stents were used, or the target vessel diameter is <6mm and highly tortuous. Currently, there is limited evidence data to support any specific antithrombotic treatment regime after BEVAR. This work looked at the freedom of bridging stent occlusion after elective BEVAR in a multicenter international database, correlating with the postoperative antithrombotic regimens. As previously reported, we found a very low overall bridging stent occlusion rate and a higher rate of occluded renal vs visceral bridging stents. (Katsargyris et al., 2023; Martin-Gonzalez et al., 2016; Mezzetto et al., 2021)

In most cases, the occlusion happened during the first year of follow-up and was independent of the antithrombotic regimens. Some patients were even on DAPT or OAC when the occlusion occurred. Unfortunately, due to the limited number of events in our series, we were not able to identify any correlation with the postoperative antithrombotic regimens. The percentage of occluded balloon-expandable stents 5.2% vs 8.6% for self-expandable stents did not differ in our series. However, a recent meta-analysis suggests lower overall target vessel instability and re-intervention rates when using self-expanding bridging stents. (Nana et al., 2023)

The analysis of our series's 24 occluded bridging stents showed various characteristics of target vessel/bridging stents. The diameters varied from 4.7 mm of a renal artery up to 11 mm diameter of a celiac trunk, using multiple stents in only 11 out of 24 occluded bridging stents. The total length of the occluded bridging stents varied between 34 and 115 mm. Therefore, considering the PRINCE2SS recommendations, most occluded vessels and their mating bridging stents in our series were not at risk for occlusions. Furthermore, most of these patients had an extensive antithrombotic treatment when the occlusion occurred. It remains unclear what role the antithrombotic treatment plays in these occlusions and the role of the mechanical component. The movement of the diaphragm during inspiration and expiration influences the form, position, and potential fatigue of the bridging stents. (Cheng et al., 2023)

These authors recommend using longer bridging stents in BEVAR to enable smoother paths and a lower bridging stent occlusion rate, which is completely opposite from the PRINCE2SS recommendations.

The in-hospital mortality in our series was very low (3%). However, during a median follow-up of 21 months, 42 patients died, resulting in an estimated 5-year survival rate of 46%. Of the 42 patients, 31 had previous open and/or endovascular TAAA repair. Previously treated type I to III TAAA is recognized as a significant independent risk factor for late mortality. (Van Calster et al., 2019) Van Calster et al.

analyzed a bigger series with 468 patients over a longer period (2004–2016). They reported an estimated survival rate of 59.6% after 5 years and a median follow-up of 29 months. Oderich et al. reported an estimated survival rate of 57.5% at five years in a cohort of 185 patients after a mean follow-up of 22 ± 20 months. (Oderich et al., 2017) In both these studies, the median age was 72 years, like in our series. We presume that the patients with TAAA in our series were already severely diseased prior to BEVAR, thus leading to a relatively lower estimated survival rate after 5 years compared with other studies.

Strengths and Limitations

The most severe limitation while analyzing antithrombotic regimens is patients' compliance. It is not easy to prove this retrospectively. Additionally, different antithrombotic regimens can influence the stent's patency and increase the risk of antithrombotic-induced bleeding as well. These were not proven during follow-up due to limited data availability. During the study period, some centers observed a clear shift from self-expandable to balloon-expandable stents, thus resulting in a difference in follow-up time, as self-expandable stents had a longer follow-up.

In all centers, we were able to follow-up on all patients after BEVAR, resulting in a complete follow-up index of 1.0. Additionally, we had a detailed outcome for every patient, which included the exact timing of branch occlusion, the antithrombotic therapy regime at the moment of occlusion, and the bridging stent patency.

6.4 Paper IV

We validated the original predictive model for the survival of patients with AAA treated by EVAR, both internally and externally. Both validations showed excellent model calibration and a modest reduction in the discriminatory ability. For the external validation international, a multicentre database was analyzed and compared with the original cohort. The model identified a high-risk subgroup of patients with a 5- and 10-year survival rate of only 55% and 16%, respectively. These are octogenarians with $eGFR < 60$ or COPD, septuagenarians with $eGFR < 30$, and septuagenarians with both an $eGFR < 60$ and COPD. With this limited life expectancy, the benefit of EVAR in these high-risk patients must be highly questioned, provided that the aneurysm does not carry a relevant risk of rupture. Furthermore, a detailed analysis of the high-risk patients revealed that 50% had AAA diameters < 60 mm and approximately 25% had AAA diameters < 55 mm. Considering the historical and recently published data, accounting for the risk of AAA rupture with $< 6\%$ for diameter < 7 cm gives somewhat space for discussion if

the majority of these high-risk patients should have been treated at all. (Lancaster et al., 2022; Lederle et al., 2002)

After its introduction 30 years ago, the postoperative EVAR mortality rate dropped to as low as 1% in asymptomatic patients. (Patel et al., 2016) Even if the early mortality is very low, our cohort shows, similar to other studies, that patients treated electively for an AAA have a poor long-term survival of about 40% after 10 years. (Johal et al., 2019; Lederle et al., 2012)

Taking this into consideration, a significant part of all patients treated in this validation cohort would not have felt the advantages of this preventive treatment but would have died earlier due to non-aortic-related causes. Either strict adherence to the current diameter threshold of 55 mm or even increasing it to maybe 60mm and above would enhance the quality of patient care in these high-risk patients. This would mean they don't have to undergo any EVAR with an AAA size <6cm at presentation if their 5-year life expectancy is lower than 50%—a positive association between initially larger AAA diameter and poor survival after elective EVAR has already been described. (Marques-Rios et al., 2018) In our model, we had to eliminate the AAA diameter in the variable selection process cause its magnitude was not strong enough; still, its association was confirmed in the multivariable analysis of this cohort, HR 1.01 per millimeter AAA diameter increase (95% CI 1.00–1.02, $p < .001$). (Meuli et al., 2021; Meuli, Zimmermann, et al., 2022) Additionally, in our cohort, the AAA diameters were significantly larger in high-risk patients compared with the other risk groups ($p < .001$). This study provides a risk stratification to support and improve such decisions in the future.

The question of whether one patient would benefit from EVAR in case he/she is not fit for an open repair was addressed previously. (Sweeting et al., 2017) The EVAR 2 trial showed no increase in overall life expectancy for the EVAR group vs. the non-treated group. Of the 404 originally included patients in the EVAR 2 trial, only 17% (69/404) survived more than eight years. (Sweeting et al., 2017) These patients were younger during study enrolment and had higher body mass index, better renal (higher eGFR), and pulmonary function (better forced expiratory volume in one second). So, the decision to do a preventive treatment for an asymptomatic AAA in high-risk patients remains challenging and needs to be met on an individual base.

The initial application of EVAR was meant for patients unfit for an open repair. Meanwhile, EVAR is even performed in relatively healthier and younger patients. It is very debatable whether EVAR should be used in low-risk patients (< 70 years with eGFR \geq 60, independent of COPD) for better life expectancy. Most of these patients will still be alive after 10 years and unnecessarily exposed to late complications. The use of EVAR in this group of younger and healthier patients should be more restrictive. (Patel et al., 2016)

Strengths and limitations

We validated the model's performance and confirmed robust discrimination ability and excellent calibration in identifying a subset of high-risk patients for impaired long-term survival. The retrospective extraction of routinely collected data is probably the main limitation of this international multicentre external validation study, which inherently carries a risk of bias. None of the centers did a routine preoperative measurement of forced expiratory volume in one second, and the COPD diagnosis was only coded based on the preoperative diagnosis lists. The model overestimated the mortality in the high-risk group and slightly underestimated it in the low-risk group; this is probably caused by some degree of model overfitting or underfitting. Additional model validation in different case mix cohorts (i.e., lower or higher degrees of comorbidities) might help better understand the model calibration.

7 Summary/Conclusions

1. The custom-made design of the devices used to treat aortic arch pathologies is safe and effective, allowing for a low rate of perioperative complications.
2. The preoperative segmental artery coil embolization is safe and reduces the risk of perioperative SCI after complex treatment of thoracoabdominal aortic pathologies.
3. No antithrombotic therapy was significantly associated with bridging stent occlusion after BEVAR, whereas no evidence for the superiority of any other antithrombotic therapy was found.
4. Not all patients will benefit from EVAR, and an individualized treatment recommendation should consider life expectancy.

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Vaiva Dabravolskaite

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