Fenestrated and branched stent-grafts for treatment of complex aortoiliac aneurysms

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Ozan Yazar

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DISSERTATION

To obtain the degree of Doctor at Maastricht University, on the authority of the Rector Magnificus, Prof. dr. Pamela Habibović in accordance with the decision of the Board of Deans, to be defended in public on

Friday December 22nd 2023, at 16:00 hour

by

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born on May 3rd 1977, in Erzincan (Türkiye)

Cover & lay-out design
Maaike Disco - proefschriftopmaak.nl
Printed by
Ridderprint - ridderprint.nl
ISBN
978-94-6483-564-9

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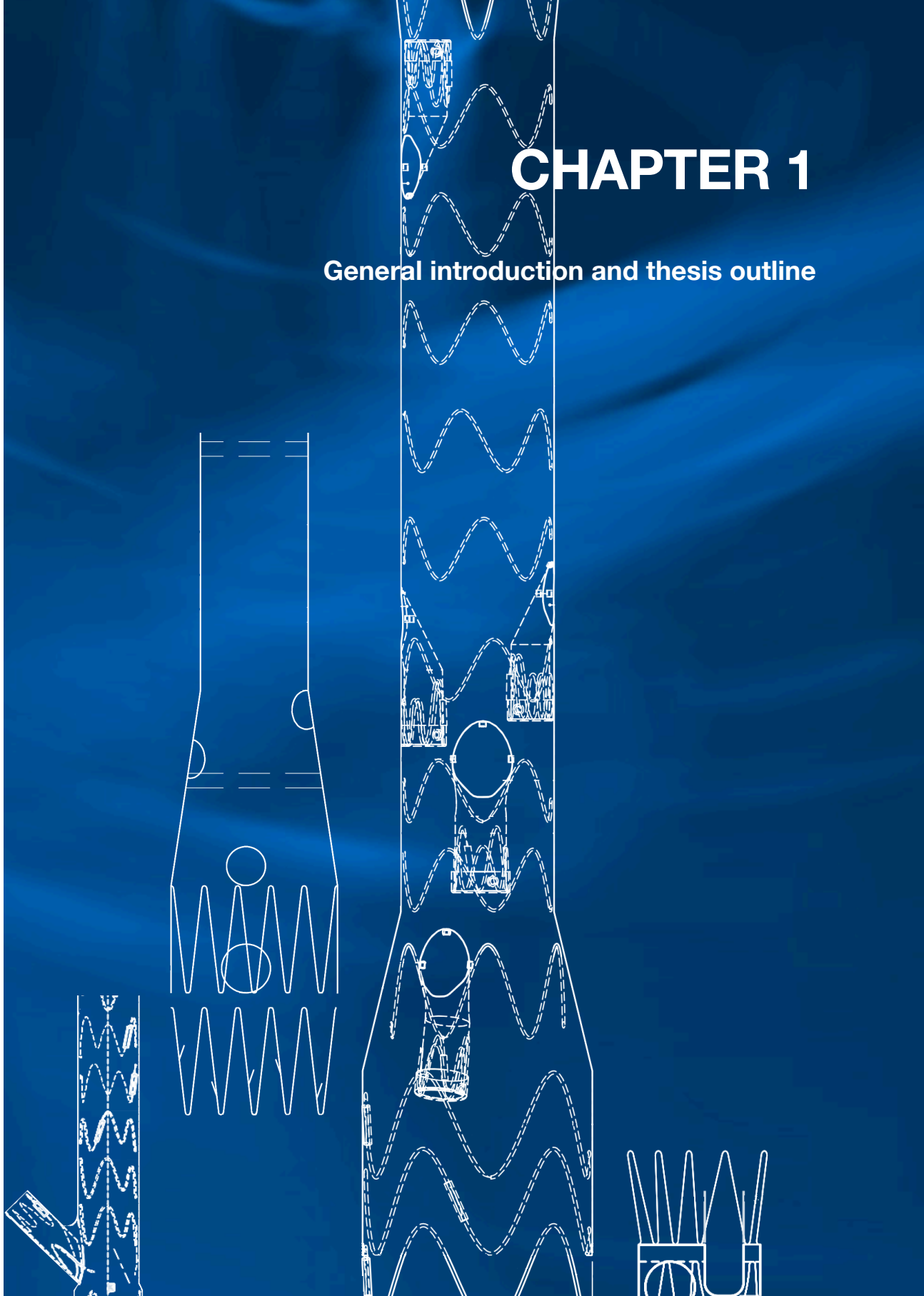
CHAPTER 1

General introduction and thesis outline



GENERAL INTRODUCTION

Aortic aneurysms have been already described in ancient Egyptian scrolls dating back to the time before Christ.[1] The word aneurysm derives from the Ancient Greek language ἀνεύρυσμα, which means “an opening” or “a widening” of an artery. The definition of an abdominal aortic aneurysm (AAA) is an abnormal permanent focal dilatation of the artery from a diameter of 3.0 cm or more than 150% compared to a normal adjoining diameter of the aorta (mostly suprarenal aorta). The involvement of the adjacent artery in infrarenal AAAs is common. In 20-40% there is an involvement of the iliac arteries and in 5-15% extension to the pararenal aorta has been reported. [2,3] The prevalence and incidence of AAA has decreased over the past decades. One of the important reasons is the decline in smoking. The prevalence in Western-Europe in 65-year-old men ranges from 1.3% to 3.3% and the annual incidence differs between 0.4% to 0.67%, in which age has an important impact on the incidence. [4,32,33] The mean growth rate for AAA is 2.3 mm/year, the growth rate increases by 0.5mm/year for each 0.5 cm expansion in AAA diameter. The mean growth rates are higher in smokers (by 0.35 mm/year) and lower by 0.51 mm a year in patients with diabetes.[4] The primary risk factor for AAA remains smoking and is even higher in women, who are smokers. Other risk factors are age, male sex, atherosclerosis, hypertension, ethnicity, and family history of AAA in first degree relative.[5,6] AAA gradually expand over a period, with various expansion rates. In general, lager aneurysms growth faster than smaller aneurysm. The rupture rate increases with the diameter of the aneurysm. Annual rupture rate is 3.5 % in AAA diameters between 5.5-6.0 cm, 4.1 % when the AAA diameter is between 6.1-7.0 cm and 6.3% in AAAs more than 7.0 cm.[34] The diameter threshold for considering an elective AAA repair varies between sexes. In men the recommendation is 5.5 cm (Class 1, Level A) or more and in women the threshold is ≥ 5.0 cm (Class 2b, Level C). Rapid aneurysm growth (>1 cm/year) and the shape (fusiform or saccular) of the aneurysm affects the threshold for an elective AAA repair.[4]

For centuries there were no lifesaving solutions for these lethal ruptures of aortic aneurysms. Long-term successful treatments did not emerge until modern periods of surgery. In the second half of the 20th century significant rapid advances were seen in the treatment of aortic aneurysms with proximal ligation or obliteration, wrapping, and open repair with autologous or synthetic grafts.[7-9] Pioneers in vascular surgery like Michael E. DeBakey, Denton A. Cooley and E. Stanley Crawford continued with development of techniques in the treatment of aortic aneurysms.[10-14] Open repair of aortic aneurysms became the gold standard.

In 1986, Balko et al. published the transfemoral placement of intraluminal polyurethane prosthesis for abdominal aortic aneurysm (AAA) in sheep and Lazarus invented an polyester graft fixed on the aortic wall with hooks, which you can introduce transfemoral.[15-16] Volodos performed the first endovascular aortic repair (EVAR) in 1987 for a post-traumatic aneurysm in the thoracic aorta.[17] In 1990, Parodi and Palmaz were the first who treated an infrarenal AAA in using a straight tubular polyester stent-graft with a Palmaz stent for proximal fixation.[18] After years’ experience with these stent-grafts EVAR continued to win territory and became the first option for the treatment of AAA in most countries. To extend the endovascular approach in patients with pararenal and thoraco-abdominal aneurysm (TAAA) fenestrated EVAR (FEVAR) was developed. In 1996 Park et al. published the first article on the use of a FEVAR.[19] Expanding the endovascular area distally in aortoiliac aneurysms or solitary iliac aneurysms, new configurations of stent-grafts with directional branches were produced. In 2001 Goodman performed the first iliac branch device (IBD) placement in a patient.[20] Chuter et al. published the first multibranched stent-graft for the visceral arteries in the treatment of a TAAA.[21] As the technology evolved further in these stent-grafts inner branch configurations were included. These inner branch stent-grafts were first used for the treatment of aortic arch pathology and afterwards for pararenal aortic aneurysms and TAAA. Due to these branches blood flow was preserved in the aortic arch side branches and visceral arteries, hereby creating a secure fixation of the stent-graft in healthy aorta with sufficient sealing zone.[22] Branched stent-grafts (BEVAR) are primarily used in TAAA with large diameter of the visceral aorta, resulting in a relatively great distance between the branch of the stent-graft and the origin of the target vessel. The advantages of BEVAR are long fixation and seal of the bridging stent for the target vessel, great compatibility with target vessels which are downward-facing orientated, and less precise positioning of the branch with respect to the target vessel. In outer branched stent-grafts (oBEVAR), the width of the visceral segment must be large enough to accommodate both the stent-graft and the branch. However, in pararenal aneurysms with narrow visceral aortic lumen, oBEVAR stent-graft is not suitable due to insufficient space between the outer branch and the aortic wall with risk of crushing the branch. In these relatively narrow aortic segments FEVAR stent-grafts are preferred. Another advantage of FEVAR is the limited coverage of the aorta compared to BEVAR. Furthermore, FEVAR stent-grafts are more suitable in horizontal or up facing orientated target vessels and type IIIc endoleaks remain low, despite the tenuous connection between the bridging stent and the fenestration.

Inner-branched stent-graft (iBEVAR) can be the solution in patients who are unsuitable for fenestrations or outer branches. This configuration has the feature to position the stent-graft in more narrow aortic segments and could result in less proximal aortic coverage compared to oBEVAR. The oval shape distal opening of the inner branches creates more space for cannulation of the target vessels compared to FEVAR. [23] Furthermore, several configurations of custom-made stent-grafts are available combining fenestrations, inner- or outer branches in the same stent-graft specifically designed to the aortic anatomy and the target vessels characteristics.

Type Ia (proximal) or type Ib (distal) endoleaks after EVAR occur due to inadequate seal of the stent-graft with the artery wall and are associated with significant risk for aneurysm rupture. The treatment of these endoleaks is highly recommended and should be done promptly following the ESVS guidelines.[4] The endovascular options to treat a type Ia endoleak include proximal compliant balloon dilatation, bare metal balloon expandable stents (e.g.,Palmaz stent), endo-anchors, embolization with coils or liquid (e.g. NBCA glue or Onyx), and proximal extension covered cuff. A more permanent treatment is needed if there is no more adequate infrarenal sealing zone. In these cases, a fenestrated or branched repair after EVAR procedure should be performed. This procedure has clearly less morbidity and mortality compared to an open conversion after EVAR, however technical endovascular difficulties have to be taken in consideration due to the pre-existing stent-graft. Nana et al. reported in their F/BEVAR after failed EVAR study a high technical success with low perioperative mortality.[24]

Up to 40% of AAA patients, have dilatation or aneurysm of the common iliac artery (CIA). Iliac artery aneurysm represents 0.4%-1.9% of all aneurysms. Regarding to the ESVS guidelines the threshold for elective repair of isolated iliac aneurysms may be considered from 3.5 cm. [4] Open surgical treatment is challenging due to deep location in the pelvis, large venous structures with excessive bleeding and risk of harm adjacent viscera and nerves. Endovascular techniques decreased the perioperative morbidity and mortality. [35] In both open surgery and endovascular it is important to preserve blood flow in the hypogastric artery. Potential complications of occlusion of the hypogastric artery include buttock claudication, erectile dysfunction, colon ischemia, perineal necrosis and spinal cord dysfunction. The risk for these complications increases in the situation of bilateral hypogastric occlusions.[25] Preserving blood flow to at least one internal iliac artery during the repair of iliac artery aneurysms is recommended.[4] IBDs allow preservation of these hypogastric arteries and can be used primarily for

the treatment of aortoiliac aneurysms or for a solitary iliac aneurysm. Moreover, they still can be performed after placement of an EVAR using brachial access or “up-and-over” transfemoral technique.[26] IBDs are relatively more expensive and technically more challenging than extending the repair over the hypogastric artery. However, they have a high technical success (96.2%) with minimal morbidity.[27]

An increasing number of elderly patients with AAA are presenting with a relatively good quality of life. The debate is still ongoing whether we should perform a F/BEVAR in these octogenarians. While some studies found similar outcomes for octogenarians, others found worse outcomes in this population.[28,29] Zil-E-Ali et al. conducted a retrospective analysis of 5507 patients, including 1156 octogenarians, who underwent a FEVAR procedure for juxtarenal AAA, which revealed a higher mortality rate and a higher risk of relocating the patient to a non-home location.[30] Whether or not to operate on patients of advanced age is primarily determined by their will and quality of life. However, the comorbidity will outweigh more than in younger patients.

With more complex stent-grafts, such as F/BEVAR, we require better technology to support these procedures with greater accuracy and intraoperative qualitative imaging than the standard mobile C-arm. This has led to the development of hybrid operating rooms (HOR), which allow for the use of tools like fluoroscopy image fusion guidance, intraoperative C-arm cone beam computed tomography, and operator-controlled imaging. These new imaging applications can aid in reducing peri- and postoperative complications due to more precise deployment of the stent-graft and the bridging stents with less contrast dose and shorter fluoroscopy and operation time. The advances are not only in the short-term outcomes but may also result in better long-term clinical outcomes.[31]

F/BEVAR for the treatment of more complex AAA is becoming increasingly popular. Initially, stent-graft configurations with only renal fenestrations (renal FEVAR) were used, allowing short-neck and juxtarenal AAA to be treated. The last decade more complex configurations (complex FEVAR) including visceral fenestrations were performed, hereby creating adequate proximal sealing zone in pararenal- and TAAA. Due to accumulating experience complex FEVAR has become a more standard intervention. In most studies an increased use of complex FEVAR vs. renal FEVAR has been seen during the study periods. [36,37] Mastracci et al described the use of more complex FEVAR over time to treat similar anatomy. Some studies show a decrease in type Ia endoleak by extending the sealing zone more proximal. [37] However, the complexity may result in higher morbidity and mortality. [38,39] Others showed no association of higher perioperative risk in the complex FEVAR compared to the renal FEVAR. [36,40]

AIMS AND THESIS OUTLINE

Endovascular solutions for treatment of AAA have been increasing in the past decades. More complex configurations of stent-grafts have been developed to extend the endovascular approach, especially with the more aging Western population. Complex stent-grafts with fenestrations or branches including the visceral arteries proximally or the hypogastric artery distally made it possible to treat these complex aortoiliac aneurysms.

High quality intraoperative imaging with advanced applications is needed to perform fenestrated or branched stent-grafts procedures. HOR has several advantages in these interventions. **Chapter 2** compared the use of a HOR versus a mobile C-arm in the treatment of pararenal AAA with FEVAR.

During the initial experience of fenestrated stent-grafts mostly renal FEVAR (fenestrations for renal arteries) were performed. The trend towards more complex FEVAR (fenestrations for the renal and mesenteric arteries) has evolved in the last decade. The idea of having an extended proximal sealing zone, may reduce the risk of type Ia endoleaks during follow-up. However, complex FEVAR is technically more challenging and may result in higher morbidity and mortality. In **Chapter 3** we compare renal FEVAR with complex FEVAR to assess the short- and mid-term outcomes of these stent-grafts.

In the absence of a systematic review of the literature comparing these two different configurations of stent-grafts (renal FEVAR vs. complex FEVAR), we performed a meta-analysis and a systematic review of the literature comparing the early- and mid-term results of stent-grafts, which you can find in **Chapter 4**.

Due to the increased life expectancy in the Western world, physicians have to deal with elderly patients. Deciding when to operate on patients of advanced age is more challenging than with younger patients. Should age on its own be the criterion whether to treat these octogenarians with highly complex AAAs or should other criterions be considered? **Chapter 5** analyses the outcomes of octogenarians treated with FEVAR and attempts to solve the prior rather difficult question.

Complications following complex endovascular treatment after previous standard EVAR is reported in **Chapter 6**. The advantages regarding perioperative morbidity/mortality and the elevated technical difficulties of these FEVAR after EVAR procedures are discussed.

In case of absence of a healthy sealing zone in the common iliac artery or in the event of type 1B endoleak following earlier endovascular aneurysm repair various techniques can be used to achieve seal. Preservations of flow to the hypogastric arteries is advised to avoid pelvic ischemic complications. IBDs are tube grafts with a branch for the hypogastric artery to secure this flow. The last decade these stent-grafts are used more often in complex aortoiliac aneurysms, combining (F/B) EVAR with IBD. Because not all major stent-graft companies manufacture IBDs, it is common practice to combine (F/B)EVAR with IBDs from different companies. In **Chapter 7** we present the compatibility of stent-graft components from two different manufacturers in the treatment of complex aortoiliac aneurysms.

Several IBDs from different manufacturers are on the market. Large single-center experience of the E-liac stent-graft from Artivion® are scarce. **Chapter 8** evaluates the mid-term outcomes of the E-liac stent-graft in the treatment of aortoiliac aneurysms.

Inner branch technology is progressively gaining popularity and may combine the advantages of oBEVAR and FEVAR. These benefits may be particularly advantageous in the case of a narrow visceral segment, such as in pararenal aortic aneurysms. **Chapter 9** describes our first experience with this inner branch technology in the treatment of pararenal AAA.

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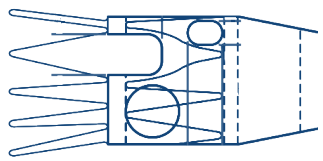
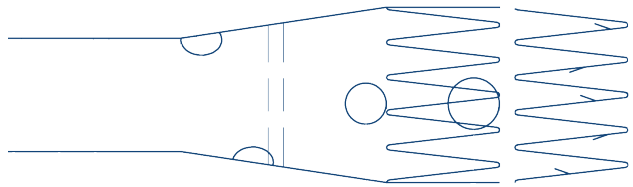
CHAPTER 2

Comparing mobile c-arm with a hybrid operating room for imaging in fenestrated stent-graft endovascular abdominal aortic aneurysm repair





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Annals of Vascular Surgery

2020 Oct;68:261-269

ABSTRACT

Background: To evaluate the advantages of a hybrid operating room (OR) (group 2) compared with a fluoroscopic mobile C-arm (group 1) during fenestrated stent-graft endovascular aneurysm repair (FEVAR).

Methods: This single-center study retrospectively analyzed prospectively collected data of consecutive patients treated with FEVAR for short-necked, juxtarenal, and suprarenal aortic aneurysms between January 2006 and July 2016. Primary end points were technical success and perioperative complications. Secondary end points included 30-day and 1-year mortality as well as target vessel patency.

Results: About 96 patients were treated (85 men; 74.1 ± 6.3 years); 46 patients (48%) belonging to group 1 and 50 (52%) patients belonging to group 2. Technical success was achieved in 92.7% of the procedures (group 1 91.3% vs. group 2 94%, P = .72). Significantly more complex interventions were performed in group 2 (n = 38 of 50) compared with group 1 (n = 14 of 46; P < .001), in which primarily renal FEVAR interventions were performed. In group 2, significantly less contrast was used (median 150 mL vs. 100 mL; P < .001). The 30-day mortality in group 1 was 9% and 2% in group 2 (P = .14), and 1-year survival was also not significantly different between both groups. Target visceral vessel primary patency was significantly higher in group 1 (87.6% vs. 85.5% [P = .006] and 83.8% vs. 78.3% [P = .03]) at 6 and 12 months, respectively). There was no significant difference in renal artery primary patency at 6 and 12 months.

Conclusions: Immediate and 1-year outcomes after FEVAR for abdominal aortic aneurysm were comparable using a hybrid OR compared with a mobile C-arm, despite the use of significantly more complex stent-grafts in the patients treated in the hybrid OR. The use of a hybrid OR may assist in achieving satisfying results in complex FEVAR.

INTRODUCTION

In the last 2 decades, treatment of abdominal aortic aneurysm (AAAs) has evolved from open to endovascular surgery, resulting in less perioperative and postoperative mortality and morbidity.[1] In the more challenging aortic aneurysms, fenestrated endovascular aneurysm repair (FEVAR) can provide a secure landing zone for the graft above or at the level of the renal and visceral arteries without compromising flow to these vital aortic side branches.

FEVAR is a technique requiring detailed intraprocedural imaging for optimal evaluation of vascular anatomy and precise procedural execution.[2,3] This need for better imaging has led to the introduction of the hybrid operating room (OR). In contrast to a regular OR with mobile C-arm, several extra modalities of these imaging systems may be combined in the hybrid OR, such as fluoroscopy image fusion guidance matched with preoperative computed tomography angiography (CTA), intraoperative C-arm cone beam computed tomography (CBCT), and operator-controlled imaging.[4-10]

To date, there are limited data on clinical outcomes in FEVAR procedures regarding usage of different intraoperative radiological equipment. New imaging applications should help in more precise placing of bridging stents, which could decrease the risk of target vessel complications, such as dissection, rupture, and occlusion. Furthermore, these applications should also reduce contrast medium injection, fluoroscopy, and operation time, which could diminish the risk for nephropathy, stochastic injuries, and ischemic limb complications.

The aim of this study was to determine the benefits in terms of clinical and technical outcomes a hybrid OR could offer in comparison with a mobile C-arm for the treatment of pararenal AAA with FEVAR.

MATERIALS AND METHODS

Patients

This study was conducted after approval by the institutional review board at our study center, and a waiver of consent was obtained. All consecutive patients who underwent FEVAR for short-necked (<10 mm), juxtarenal, and suprarenal aneurysms between January 2006 and July 2016 were entered in our database. The indication for treatment was elective primary AAA or repair of failing previous open or endovascular repair. All patients underwent preoperative imaging using contrast-enhanced CTA with 1 mm slices from the thoracoabdominal aorta. They underwent preoperative assessment by an anesthesiologist and when indicated by a cardiologist with echocardiography, treadmill, and/or coronary angiogram. Fenestrated stent-grafts were designed in all patients to match the specific anatomy of each patient using Aquarius Intuition software (TeraRecon Inc, Foster City, CA).

Materials

A variety of stent-grafts were used, including fenestrated composite grafts (consisting of a fenestrated proximal tube, a bifurcated graft distally, and iliac limbs), fenestrated bifurcated grafts, or fenestrated tube grafts. The scallops were consistently left unstented unless severe stenosis was present in the target vessels. Patients were classified into 2 consecutive groups. Group 1 consisted of patients treated in a regular OR using a mobile C-arm with 12-inch image intensifier (Ziehm Vision; Ziehm Imaging GmbH, Orlando, FL), between January 2006 and November 2012. Group 2 included patients who were treated in a hybrid OR with an Allura Xper FD20 X-ray system (Philips, Best, The Netherlands) with possibility for CBCT and 3-dimensional image fusion, between December 2012 and July 2016.

Data Collection and Follow-Up

Data were prospectively collected and retrospectively analyzed. Data collection included demographic characteristics, preoperative risk factors and comorbidities, clinical and diagnostic assess- ment, intraoperative data, and early and late follow-up outcomes.

Risk factors and comorbidities included arterial hypertension, cardiac disease, pulmonary disease, diabetes, hyperlipidemia, smoking, previous aortic surgery,

previous abdominal surgery, use of beta blocker, estimated glomerular filtration rate (eGFR) <60 mL/min/1.73 m^2, dialysis, and renal transplantation. Patients were grouped into 5 categories depending on their eGFR: (1) eGFR <15 mL/min/1.73 m^2; (2) eGFR 15-29 mL/min/ 1.73 m^2; (3) eGFR 30-44 mL/min/1.73 m^2; (4) eGFR 45-59 mL/min/1.73 m^2; and (5) eGFR ≥ 60 mL/min/1.73 m^2. We collected preoperative eGFR, postoperative lowest eGFR, eGFR at time of hospital discharge, and eGFR at the latest follow-up consultation. Acute kidney injury was defined as ≥ 26.4 mmol/L increase in serum creatinine within 48 hr, creatinine ≥ 50% above baseline within 7 days, or eGFR decrease more than 33.3%.[11]

Procedural information included the number of fenestrations, overall procedural time, radiation exposure, technical success, intraoperative complications, endoleak rate, and adjunctive procedures. Endoleaks were defined as described by Jain et al.[12] A distinction was made between renal and complex stent-grafts: the renal stent-grafts had fenestrations for the renal arteries only, whereas the complex stent-grafts also had fenestrations for the superior mesenteric artery and/or for the celiac artery. Primary technical success was defined as placement of both the main body graft and successful stenting of target vessels in an intent-to-treat manner, further defined by the absence of an endoleak type I or III or graft obstruction, the absence of the need to convert to open surgical repair, and survival >24 hr.[13] All patients were followed with a CTA 6 weeks after the operation, although alteration of this protocol was sometimes necessary because of clinical factors and features on the completion angiography. CTA was replaced by a combination of an abdominal (duplex) ultrasound and plain abdominal X-rays at 6 months and yearly thereafter, in case the first follow-up CTA showed no abnormalities and/or complications. In addition, annual serum creatinine and eGFR were determined. Date and cause of death were obtained from either chart review or family physicians. Analyzed outcome measures included 30-day and 1-year mortality, perioperative and postoperative complications, renal dysfunction, and reinterventions. Overall, primary end points were technical success and perioperative complications (intraoperative and 30-day postoperative period). Secondary end points included 30-day and 1-year mortality as well as target vessel patency.

Data Analysis

Data are presented as mean ± standard deviations (if normally distributed) or as median (if not normally distributed) with an interquartile range. Categorical variables are expressed as absolute numbers and percentages. When normal

distribution was present (as tested by means of the Shapiro-Wilk test), Student's t-test was applied for comparison of continuous variables. For abnormal distributed variables, the Mann-Whitney U-tests were used. Survival analysis was done using the Kaplan and Meier method. A P value below 0.05 was considered statis- tically significant. The analyses were performed using SPSS, version 23.0 (SPSS Inc, Chicago, IL

RESULTS

Patient Characteristics

Of 96 patients (85 men, mean age of 74.1 ± 6.3 years), 46 patients underwent the intervention before December 2012 (group 1), and 50 patients were treated afterward until July 2016 (group 2). Demographic data, cardiovascular risk factors, and preoperative comorbidities are presented in Table I. Patients in both groups had similar preoperative clinical and morphologic characteristics, except mean age (group 1, 75.7 years vs. group 2, 72.7 years; P = .02), hyperlipidemia (group 1, 27 of 46 [59%] patients vs. group 2, 39 of 50 [78%] patients; P = .04), American Society of Anesthesiologists score 3 or more (group 1, 36 of 46 [78%] patients vs. group 2, 28 of 50 [56%]; P = .02).

Aneurysm Characteristics and Stent-Graft Design

In terms of aneurysm type, group 1 included significant more short-necked aortic aneurysms (P < .001), and group 2 included significant more juxtarenal aneurysms (P < .045); however, there was no significant statistical difference in suprarenal aneurysms between the 2 groups (Table I). Group 2 contained significantly more FEVAR interventions after previous EVAR (group 1, n = 2 [4.3%] vs. group 2, n =13 [26%]; P = .004). In group 1, 2 patients needed an additional iliac branched device during the FEVAR intervention (group 1, n = 2 [4.3%) vs. group 2, n = 0 [0.0%]; P = .14). Significantly more complex custom-made FEVAR stent-grafts (3 fenestrations or more) were placed in group 2 (group 1, 14 of 46 [30%] vs. group 2, 38 of 50 [76%]; P < .001). Stent-graft design and target vessel stent features are tabulated in Table II.

Primary Outcomes

The primary technical success rate was 91% in group 1 and 94.2% in group 2 (P = .72). In group 1, technical failures occurred in 4 patients. In 1 patient, the left

renal artery (LRA) was cannulated and stented using a bare metal stent through the scallop for the superior mesenteric artery instead of through the fenestration, leading to a combined type Ia/IIIc endoleak. During follow-up, plug and coil embolization of the LRA and aneurysm sac was necessary to close the endoleak. Another patient had a proximal endoleak on the completion angiography from unclear origin. Initially, the endoleak was accepted, and 2 months later, additional stenting of the LRA with covered stents resolved this endoleak type Ic. In 1 patient, there was a rupture of the renal artery, which was treated with an Amplatz Vascular Plug (ST. Jude Medical, St. Paul, MN). The fourth patient had 2 technical complications. First, cannulating the LRA was unsuccessful, and it was left unstented. Second, after stenting the SMA, a distal occlusion because of a dissection was seen, which could not be salvaged by endovascular means. This patient subsequently underwent a laparotomy with local repair of the dissected distal SMA using a venous patch. In group 2, 3 technical failures were noted. One patient had a persistent type Ib endoleak via the left iliac limb despite multiple treatment attempts during the first intervention; the initial postoperative CTA still showed the endoleak, but this was not confirmed on subsequent investigations (CTA and ultrasound). Another patient showed type Ia endoleak on the completion angiography without explicit cause. This endoleak also disappeared on follow-up CTA. In the third patient, it proved impossible to cannulate the LRA because of severe significant stenosis resulting in an endoleak type IIIc. A second attempt was scheduled at 4 months postoperatively, but unfortunately, the angiography revealed an occlusion of the LRA, without any endoleak.

On completion angiography, in group 1, 1 type Ia, 1 type Ia/IIIc, and 3 type II endoleaks were observed. In group 2, 1 type Ia, 1 type Ib, 14 type II, and 1 type IIIc endoleaks were recorded. There was no significant statistical difference in endoleak type I (P = .93) and III (P = .95) between the 2 groups. None of the type II endoleaks required an addition intervention, as these either resolved spontaneously or persisted without causing aneurysm sac expansion during follow-up. There were no significant differences in intraoperative complications between the 2 groups (P = .46). There was no significant difference between both groups in spinal cord ischemia, bowel ischemia, cardiopulmonary complications, and lower limb complications (Table III). Acute renal injury was reported in 38 of 96 (39.6%) patients (group 1, 20 of 46 patients [44%] vs. group 2, 18 of 50 patients [36%]; P = .46). Twenty of these patients already showed renal function impairments preoperatively. Among these patients, there was 1 occlusion of a renal artery and 6 patients with covering of an accessory renal artery. Only 1 of these patients, who belongs to group 2, required temporary dialysis.

Secondary Outcomes

There was no significant difference between both groups in 30-day mortality (group 1, 4 of 46 [9%] patients vs. group 2, 1 of 50 [2%] patients; P = .14). In group 1, 2 patients suffered from intestinal ischemia and eventually died of multiorgan failure. One patient with a preexisting poor cardiac condition developed a major bleeding in the left renal region presumably because of guidewire perforation. He evolved rapidly into cardiogenic shock and died on the third postoperative day, without the opportunity for a reintervention. One patient died on the fourth postoperative day because of a myocardial infarction. In group 2, 1 patient died on the second postoperative day because of intestinal ischemia. The target vessel patency rate on completion angiography was 98.1% (105 of 107) in group 1 and 100% (136 of 136) in group 2 (P = .14).

Perioperative Results

The median length of hospital stay in group 1 (6 days [range, 5 - 10]) was significantly longer compared with group 2 (5 days [range, 3 - 9]) (P = .009). Analysis of the median fluoroscopy time and median radiation exposure showed no significant difference between the groups. The median contrast medium dose was statistically significant in favor of group 2; P < .001) (Table II).

One-Year Follow-Up Clinical Outcomes

The overall 1-year survival was 85% with no significant difference between both groups (group 1, 87% vs. group 2, 84%; P = .70) (Figure 1). Causes of mortality in both groups during follow-up (9 patients) were cardiac failure in 2 cases, cancer in 1, respiratory failure in 1, cerebral hemorrhage in 1, aneurysm related in 1, and unknown in 3. The patient with aneurysm-related death developed a stent-graft infection with type Ia endoleak and died 5 months postoperatively. The overall target visceral vessel primary patency rate was 86.4% and 80.7% at 6 and 12 months, respectively, and significantly different between groups (group 1, 87.6% and 83.8% vs. group 2, 85.5% and 78.3%; P = .006 and P = .031, respectively). There was no statistically significant difference between the 2 groups regarding primary patency of the renal arteries at 6 and 12 months (group 1, 86.8% and 83.5% vs. group 2, 86.6% and 81.4%; P = .906 and P = .763, respectively). Freedom from reintervention during the 1-year follow-up was 91.3% in group 1 and 88% in group 2 (P = .60). Timing, cause, type, and outcome of each reintervention are summarized in Table IV.

Table I. Demographics and comorbidities in patients of group 1 versus group 2.

Patient data	Group 1 (*n*=46)	Group 2 (*n*=50)	*P*
Demographics			
Age, y	75.7 (±6.33)	72.7 (±6.01)	*.02*
Men	41	44	.86
Comorbidities			
ASA ≥3	36	28	*.02*
Coronary artery disease	30	33	.94
Pulmonary disease	16	16	.77
Hypertension	31	40	.16
Diabetes	6	7	.89
Hyperlipidemia	27	39	*.04*
Renal[a]	58.5 (49-80)	64 (47-81)	.35
Previous aortic intervention	8	15	.15
Smokers	23	26	.11
Using beta blockers	28	26	.38
Aneurysm diameter, mm	65.39 (±8.77)	66.44 (±9.03)	.57
Juxtarenal aneurysms	20 (43.5)	32 (64)	*.045*
Short-necked aneurysms	21 (45.7)	3 (6)	*.001*
Suprarenal aneurysms	2 (4.3)	2 (4)	.93

Data are presented as mean ± standard deviation, median and interquartile range, or as number and percentage.
P < .05 was considered statistically significant and are given in italics.
ASA, American Society of Anesthesiologists.
[a]Preoperative eGFR (mL/min/1.73m^2).

Table II. Intraoperative details of FEVAR.

Patient data	Group 1 (*n*=46)	Group 2 (*n*=50)	*P*
Median intervention time (min)	173 (140-230)	176 (135-256)	.94
Median fluoroscopy time (min)	47 (37-67)	46 (27-75)	.66
Endoleak on completion angiography			
Type I	2	2	.93
Type II	3	14	*.006*
Type III	0	1	.95
Technical success	42 (91)	47 (94)	.61
Adjunctive procedure	8 (17)	3 (6)	*.082*
Median dose-area product (Gy.cm^2)	116 (74-174)	159 (86-244)	.16
Median contrast medium volume (mL)	150 (120-195)	100 (79-126)	*.001*
Intraoperative death	0 (0)	0 (0)	1.0
Intraoperative complications	8 (17)	6 (12)	.46
Target vessel dissection	3	3	
Target vessel stent crushed	0	2	
Target vessel stent migrated	1	0	
Rupture external iliac artery	2	0	
Occlusion hypogastric artery	1	0	
Malposition stent-graft	1	0	
Hemorrhage groin	0	1	
Stent-graft and target vessel stent configurations			
Iliac Branched Device	2 (4)	0 (0)	.14
Renal fenestrated stent-graft	32 (70)	12 (24)	*.001*
Complex fenestrated stent-graft	14 (30)	38 (76)	*.001*
Cook Zenith fenestrated stent-graft	45	48	
Anaconda fenestrated stent-graft	1	2	
Fenestrations	105	136	
0 fenestration	0	1[a]	
1 fenestration	2	2	
2 fenestrations	30	11	
3 fenestrations	13	32	
4 fenestrations	1	4	
Scallops	41	40	
Target vessel stent	110	140	
Atrium Advanta covered stent	102	137	
Balloon-expandable AVE stent	6	0	
Balloon-expandable Genesis stent	2	0	
BeGraft stent	0	2	
Scuba stent	0	1	

Data are presented as mean ± standard deviation, median and interquartile range, or as number and percentage.

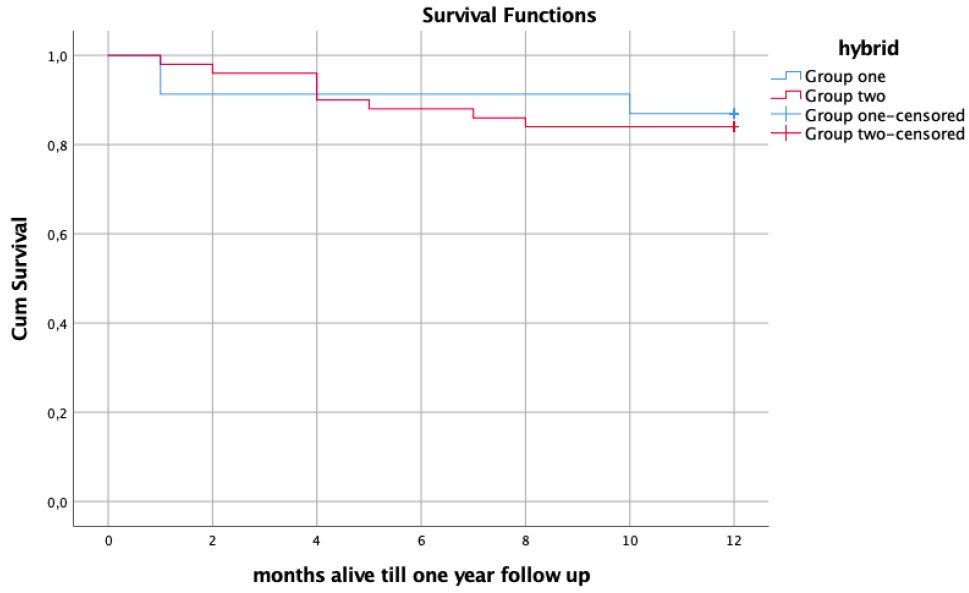
P < .05 was considered statistically significant and are given in italics.

[a]Patient without fenestrations but had 2 scallops.

Table III. Early results after FEVAR.

Variable	Group 1 (*n*=46)	Group 2 (*n*=50)	*P*
30-d mortality	4 (9)	1 (2)	.14
Cardiopulmonary complications	10 (22)	7 (14)	.46
Bowel ischemia	2 (4)	1 (2)	.51
Lower limb complications	1 (2)	4 (8)	.20
Cerebral spinal ischemia	2 (4)	4 (8)	.46
eGFR decrease ≥ 1 category	21 (46)	19 (38)	.40
Acute kidney injury	20 (44)	18 (36)	.46

Data are presented as mean ± standard deviation, median and interquartile range, or as number and percentage.



No. at risk

Group							
One	46	42	42	42	42	40	40
Two	50	48	45	44	42	42	42

Figure 1. Kaplan-Meier curve of survival after FEVAR in group 1 and group 2 (Log-rank test, P = .70), by the type of X-ray system. At risk: group 1 (n = 46, 42, 42, 42, 42, 40, and 40, respectively) and group 2 (50, 48, 45, 44, 42, 42, and 42, respectively).

Table IV. Reinterventions occurred from discharge of the hospital till 1-year follow-up: timing, treatment and outcome.

Case	Cause	Time[a]	Group	Procedure	Results
1	Type Ic endoleak	3	1	RA stent relining	Solved
2	RA occlusion	7	1	Recanalized and relining	Solved
3	Type IIIa endoleak	12	1	Covered stent relining	Solved
4	Type Ia/IIIc endoleak	6	1	Coiling and thrombin	Solved
5	Stenosis Iliac artery	2	2	Self-expandable stent	Solved
6	Crushed RA	3	2	PTA relining	Solved
7	Stenosis CFA	3	2	Endarterectomy	Solved
7	Occlusion CT	11	2	Conservative	[b]
8	Type B dissection & SMA occlusion	3	2	Recanalized and relining & TEVAR and CSB	Death[c]
9	Stenosis SMA	9	2	PTA relining	Solved
10	Migration SMA stent	10	2	Stent relining	Solved

RA, renal artery; PTA, percutaneous transluminal angioplasty; CFA, common femoral artery; CT, celiac trunc; SMA, superior mesenteric artery; TEVAR, thoracic endovascular aortic repair; CSB, carotid subclavian bypass.

[a] Time (months).

[b] Parenchyma loss of the spleen without further clinical or biochemical consequences.

[c] Death because of subdural hematoma.

DISCUSSION

In our experience, clinical and technical outcomes of FEVAR for AAA were satisfactory using either a fluoroscopic mobile C-arm or a hybrid OR. In terms of primary outcomes, the technical success rate and perioperative complications were similar between both groups, despite the significant higher number of more complex fenestrated stent-grafts and secondary revisions of previously placed EVAR in group 2. One of the reasons for these results could be better image quality and the use of advanced imaging applications in the hybrid OR. These complex procedures are technically more demanding and associated with the valid concern that more fenestrations may increase the risk of complications and radiation exposure.[14,15] Verhoeven et al.[16] reported that more extensive repairs had longer operative and fluoroscopy time, but no difference in mortality, morbidity, and patient survival (n = 333). Furthermore, Sveinsson et al.[17] described a significantly higher number of targeted vessels, with similar procedure time, but less fluoroscopy time and contrast use, and identical mortality rate (n = 288).

In terms of secondary outcomes, both our 30-day mortality of 5.2% (group 1, 9% vs. group 2, 2%; P = .14) and overall 1-year survival of 85% (group 1, 87% vs. group 2, 84%; P = .70) are comparable with reports in the literature, in which FEVAR is described as a feasible treatment with low mortality both on the short term and long term.[2,18] In a study comparing 3 generations of hybrid rooms in a patient group consisting of both pararenal aortic aneurysms and thoraco-AAAs, Tenorio et al.[19] described a decrease in the first 30 days in mortality, major adverse events, and secondary interventions in the patients who had intraoperative CBCT. Although the X-ray systems we compared are technically further apart than the systems in the study by Tenorio et al., we could not find these differences in outcome. The number of patients in our study could be a factor; however, the differences between the studies in type of aneurysms, design of stent-grafts, and complexity of the procedures could explain these differences.

An interesting finding was that the target vessel primary patency at 12 months of follow-up in group 1 was significantly higher compared with group 2, although there was no significant difference regarding primary patency of only the renal arteries. One explanation for differences in target vessel patency in FEVAR could be a difference in used bridging stent type and technique. Different studies compared the use of covered stents versus uncovered stents used as bridging stent during FEVAR.[20-23] Mohabbat et al.[24] showed that covered stents are feasible over uncovered stents because they are associated with a lower occlusion rate (2.5%) versus uncovered stents (10%). In our study, most bridging stents were V12 Atrium Advanta (Atrium Medical Corporation, Merrimack, New Hampshire, USA) covered stents, and this was not different between both groups. According to our results, the significant difference in primary patency in this study cannot be explained by the use of bridging stent type. In our opinion, the target vessel patency difference might be rather explained by the more complex fenestrated stent-grafts applied in group 2. The complexity is associated with a higher number of target vessels, which perioperatively may undergo bleeding, dissection, and kinking during cannulation and stent deployment, with the subsequent potential necessity for adjunctive maneuvers and leading to a lower patency.[25] On the other hand, Motta et al.[26] showed that the extension of the repair, with superior mesentery artery or celiac artery incorporation with stents during fenestrated-branched EVAR, did not affect the patency outcomes.

As demonstrated by previous studies, placement of FEVAR with a mobile C-arm requires significant more volume of iodinated contrast medium and is also associated with longer operating times and fluoroscopy time. Tenorio et

al.[19] described significant lower radiation exposure and operator effective dose with the evolution of fenestrated-branched EVAR experience and the use of advanced imaging applications such as onlay fusion and CBCT. In our study, we also analyzed radiation exposure and contrast dose in both groups, trying to reproduce previous results for EVAR. Unexpectedly, only for the median contrast volume ($P < .001$), we noticed a significant reduction in group 2, whereas the study showed no advantage for the hybrid OR in operation and fluoroscopy time. The latter might be explained by the learning curve of the team working in a hybrid OR and at the same time because of the more complex procedures that were performed in the hybrid OR. Because of the higher image quality of the hybrid OR, we detected significantly more type II endoleaks in group 2. However, this had no relevant influence on the clinical outcomes because none of the type II endoleaks in both groups needed additional intervention.

The length of hospital stay in group 1 of 5 days was actually significantly shorter compared with group 1 where hospitalization lasted 6 days ($P = .009$). We postulate the latter can be explained by discharging these patients earlier than in the past according to our recent department regulations. We detected significantly more type II endoleaks in group 2, which could be explained by the higher image quality of the hybrid OR. However, type II endoleak had no relevant influence on the clinical outcomes because none needed additional intervention.

Reinterventions after FEVAR are sometimes necessary to maintain aneurysm exclusion as well as stent-graft and target vessel patency and are potentially associated with important morbidity and mortality. In both groups, there was no significant difference in freedom from reintervention during follow-up. The underlying cause of the reintervention varied, and most reinterventions were necessary in group 2 (group 1, 4 of 46 vs. group 2, 7 of 50). Three of the 7 reinterventions in group 2 were related to the superior mesenteric artery or celiac artery showing more complex stent-grafts can elevate the risk of reinterventions.

Study Limitations

Interpretation of the results of our data has its limitations. An important confounder in this study is the factor time. During the study period, the interventional team went through a learning curve in performing FEVAR procedures and accepted more complex stent-graft procedures in the later stage of the inclusion period with increased challenging aortic anatomy in the hybrid OR group. In the same perspective, switching from an established routine intervention using a C-arm to working in the hybrid OR was also associated with a learning curve and could have influenced the results. Other limitations are the 1-year follow-up period,

which only represents short-term findings, as well as the relatively small study population and the single-center setting. Finally, this study is a retrospective analysis of a prospectively maintained database and is thus exposed to selection bias.

CONCLUSION

In this study, we report our immediate and 1-year results of FEVAR using a mobile fluoroscopic C-arm or a hybrid OR. There were no significant differences in technical success, perioperative complications, or mortality, despite the fact that in the hybrid OR group, significantly more complex stent-grafts were used. In the hybrid OR group with more complex stent-grafts, there was a significantly lower target vessel primary patency at 1-year follow-up. We conclude that the use of a hybrid OR may assist in achieving satisfying results in complex FEVAR. Additional studies and advancements in imaging and endovascular techniques will further improve outcomes for patients and safety for both patients and health care staff.

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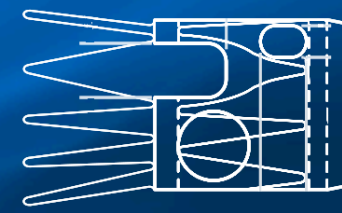
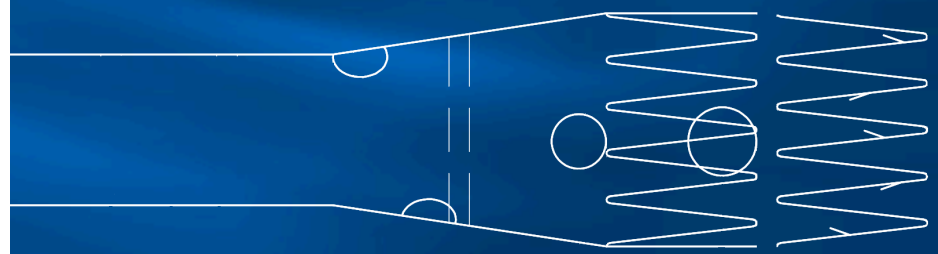
CHAPTER 3

Impact of stent-graft complexity on mid-term results in fenestrated endovascular aortic repair of juxtarenal and suprarenal abdominal aortic aneurysms





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The Journal of Cardiovascular Surgery

2023 Jun;64(3):268-278

ABSTRACT

Background: The impact of stent-graft complexity on clinical outcome after fenestrated endovascular aortic aneurysm repair (FEVAR) has been conflicting in the literature. The objective of this study was to compare mid-term results of stent-grafts with renal fenestrations alone with more complex stent-grafts including mesenteric fenestrations.

Methods: A single-center retrospective study was conducted on 154 patients, who underwent FEVAR from 2006 to 2020 at our institution.

Results: There were 54 (35.1%) patients in the renal FEVAR group and 100 (64.9%) patients in the complex FEVAR group. Median follow-up of the total group was 25 months (IQR 7-45). There were no significant differences in technical success and perioperative mortality. Intra- operative complications (4% *vs*. 18%, P = .001), operative time (145 min *vs*. 191 min, P = .001), radiation dose (119372 mgy*cm^2 *vs*. 159573 mgy*cm^2, P = .004) and fluoroscopy time (39 min *vs*. 54 min, P = .007) were significantly lower in the renal FEVAR group. During follow-up target vessel instability, endoleaks and reinterventions were not significantly different between the two groups.

Conclusions: In this single-center retrospective study, renal FEVAR was a safe and effective treatment for patients with juxtarenal AAA demonstrating fewer intraoperative complications and similar mid-term outcomes as complex FEVAR. If the anatomy is compatible for renal FEVAR, it might be unnecessary to expose patients to potentially more complications by choosing a complex FEVAR strategy.

INTRODUCTION

Since 1999, fenestrated endovascular aneurysm repair (FEVAR) has made endovascular treatment of more challenging abdominal aortic aneurysms possible.[1, 2] Fenestrated stent-grafts provide a secure landing zone for the graft at or above the level of the renal and mesenteric arteries without compromising flow to these vital aortic side branches. During the initial experience mostly renal FEVAR (fenestrations only for renal arteries) stent-grafts were used. In the past decade a trend has evolved towards more complex FEVAR (fenestrations for the renal and mesenteric arteries). Complex FEVAR secures a more proximal seal in the aorta reducing the risk of future proximal endoleaks which is thought to make the fevar technique more reliable.[3] More experience has been gained with complex fenestrated stent-grafts throughout the years, which has lowered the threshold to use such designs, even in cases which were previously treated with renal FEVAR.

However, a more proximal seal carries additional risks because of the supplemental fenestrations and scallops. Several studies have been published on stent-graft complexity and their outcomes. Manning *et al.* described longer procedures and greater early morbidity and mortality for a complex fenestrated group, however the number of treated patients was small (n=20).[4] Patel *et al.* showed that mortality, operative duration, blood loss, and hospital stay all significantly increased as the proximal sealing zone of the aneurysm repair ascended.[5] On the contrary, the results of FEVAR in 14 experienced institutions in the United Kingdom revealed no significant outcome differences between renal FEVAR and complex FEVAR.[6] Furthermore, other authors have shown there was no difference in morbidity nor mortality between complex and renal FEVAR.[3, 7-9] Relative few studies have been focusing on the mid-term results of renal FEVAR and their durability in time. Our hypothesis was that if patient anatomy is suitable for FEVAR with only renal fenestrations this treatment would have comparable results to a more complex FEVAR including mesenteric fenestrations. The aim of this retrospective analytical study was to compare the short and mid-term outcome of FEVAR with only renal fenestrations with FEVAR including mesenteric fenestrations.

MATERIALS AND METHODS

Study population

This study was conducted following approval by the institutional review Board of our hospital and a waiver of consent was obtained. The collected information did not pose a potential risk for the integrity of the patients. We followed the strengthening the reporting of observational studies in epidemiology (STROBE) statement guidelines for observational studies.[10] Data of all patients who underwent FEVAR from January 2006 through August 2020 for AAA were collected. Renal fenestrated stent-grafts (renal FEVAR) contain fenestrations only for renal arteries with or without a scallop for the superior mesenteric artery (SMA). More complex fenestrated stent-grafts (complex FEVAR) include fenestrations for the renal and mesenteric arteries, or fenestrations for the renal (with or without scallop for the mesenteric artery) and stenting of the mesenteric artery due to stenosis. The indications for treatment were juxta- and suprarenal AAA, both primary and after previous aneurysm repair. The design of the custom-made stent-grafts was performed by the treating vascular surgeon. Juxtarenal AAA with a minimum of 20 mm total used seal zone were treated with renal fenestrated stent-grafts. If this minimum seal zone could not be obtained, complex fenestrated stent-grafts were used. In all patients with suprarenal AAA complex fenestrated stent-grafts were implanted. The total effective seal zone and total used seal zone were defined as described by Oderich *et al.*[11]

Data collection and follow-up

Medical documentation of all interventions was prospectively collected from our hospital's centralized patient history system and retrospectively analyzed. Data collection included demographic characteristics, preoperative risk factors, clinical and diagnostic assessment, intraoperative features, 30-day and mid-term follow-up outcomes. Acute kidney injury (AKI) was defined as ≥ 26.4 μmol/L increase in serum creatinine within 48 hours, ≥ 50% above baseline within 7 days, or eGFR decrease more than 33.3%.[12] Date and cause of death were obtained from chart review or general practitioners. Primary end points were technical success, perioperative complications (intraoperative and 30-day postoperative period), and reinterventions during follow-up. Secondary end points included 30-day mortality, and endoleak and target vessel instability during follow-up. Endoleaks were defined as described by Jain *et al.*[13] Primary technical success was defined as placement of both the main-body stent-graft and successful

stenting of target vessels in an intent-to-treat manner, further defined by the absence of an endoleak type I and III, absence of graft obstruction, absence of the need to convert to open surgical repair, and survival >24 hours.[14] Target vessel instability was defined as any side-branch-related complication, including branch occlusion or stenosis, kink, disconnection, branch related-growth of the aneurysm, device migration effecting a branch, or the need for any secondary intervention related to the target vessel.[15] Follow-up was done clinically, including CTA (in case of impaired renal function an ultrasound was performed instead of a CTA) and blood investigations. We had 2 patients lost to follow-up. When follow-up was performed in another center, the responsible vascular surgeons were contacted for data collection.

Statistical analysis

Continuous data were expressed as mean ± standard deviations (if normally distributed) or as median (if not normally distributed) with an interquartile range (IQR). Categorical variables were expressed as absolute numbers and percentages. When normal distribution was present (as tested by means of the shapiro-Wilk Test), student's *t*-test was applied for comparison of continuous variables. For abnormally distributed variables, the Mann-Whitney U Test was used. Categorical variables were analyzed through cross tabulation using Fisher's Exact test or Pearson's Chi-squared test when appropriate. The comparison of the learning curve for operation time and fluoroscopy time between the two groups was done using ANOVA linear regression analysis. Data on survival and target vessel instability were analyzed performing Kaplan-Meier curves and the log-rank P value to compare the two groups. Statistical significance was assigned at 2-sided P values less than 0.05. All statistical analyses were performed with statistical Package for the social sciences (SPSS V26.0, Inc., Chicago, IL, USA).

RESULTS

Demographics

Table I reports the baseline characteristics for a total of 154 patients (135 men) with a mean age of 73.2±5.9 years. Renal FEVAR was performed in 54 (35.1%) patients and complex FEVAR in 100 (64.9%) patients. We observed significantly more arterial hypertension (87% *vs.* 65%; P = .04) and more previous aortic interventions (28% *vs*. 6%; P = .015) in the complex FEVAR group.

Table I. Baseline characteristics of the patients with renal FEVAR versus complex FEVAR.

	Renal FEVAR (N.=54) N. (%)	Complex FEVAR (N.=100) N. (%)	P value
Age, y (mean [SD])	73.2 [±6.0]	73.1 [±5.8]	.89
Men	50 (93)	85 (85)	.17
ASA≥3	37 (69)	63 (63)	.50
Arterial hypertension	35 (65)	87 (87)	.04
Coronary artery disease	32 (59)	58 (58)	.60
Pulmonary disease	13 (24)	31 (31)	.20
Diabetes	11 (20)	13 (13)	.24
Hyperlipidemia	40 (74)	77 (77)	.85
Smokers/ex-smokers	33 (61)	57 (57)	.76
Preoperative eGFR* (median [IQR])	60 [49-74]	62 [47-74]	.35
Previous aortic intervention	6 (11)	28 (28)	.015
Previous EVAR	3	22	
Open aortic repair	3	5	
Previous TEVAR**	0	1	
Aneurysm diameter, mm (median [IQR])	61 [58-66]	64 [59-71]	.13
Short-neck aneurysm	26 (48)	7 (7)	.001
Juxtarenal aneurysm	23 (43)	67 (67)	.003
Suprarenal aneurysm	1 (2)	5 (5)	.34
Type Ia endoleak after EVAR	3 (6)	20 (20)	.017
Paraanastomic aneurysm	1 (2)	0	.17

Operative data and technical success

All operations were elective, except for one patient with a type Ia endoleak after EVAR, who was on the waiting list for FEVAR. He presented with a rupture of his AAA needing an acute intervention, while his fenestrated stent-graft was delivered only days before his presentation. From the start of the study period in January 2006 the patients were treated in a regular operating room (OR) using a mobile C-arm with 12-inch image intensifier (Ziehm Vision, Ziehm imaging GmbH, Orlando, FL, USA). After December 2012 we performed all interventions in a hybrid operating room with fixed angiography system (Allura Xper FD20 X-ray system, Philips, Best, the Netherlands). Figure 1 shows a bar graph of the numbers of renal FEVAR *versus* complex FEVAR over the study period. Significantly more patients in the complex FEVAR group compared to the renal FEVAR group were treated in the hybrid operating room (P < .001). We observed that more complex FEVAR were performed in the last period of the study. By dividing the complex FEVARs into two groups, with the first complex FEVAR group between 2006 - 2015 and the second complex FEVAR group between 2016 - 2020, we revealed a significant higher total effective seal zone in the second complex FEVAR group, respectively P = .019 (mean 42.8 mm first group *vs.* 56.6mm second group).

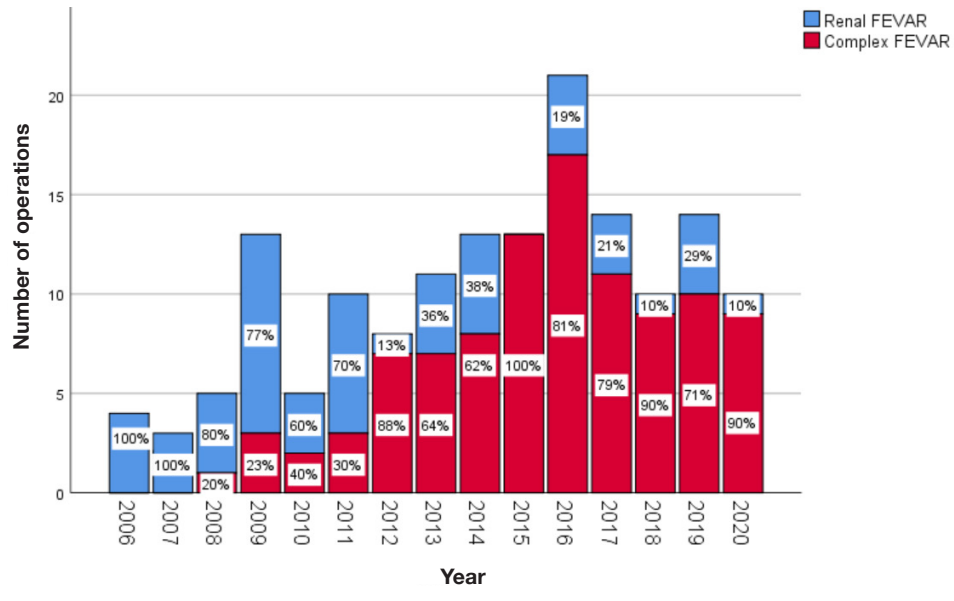


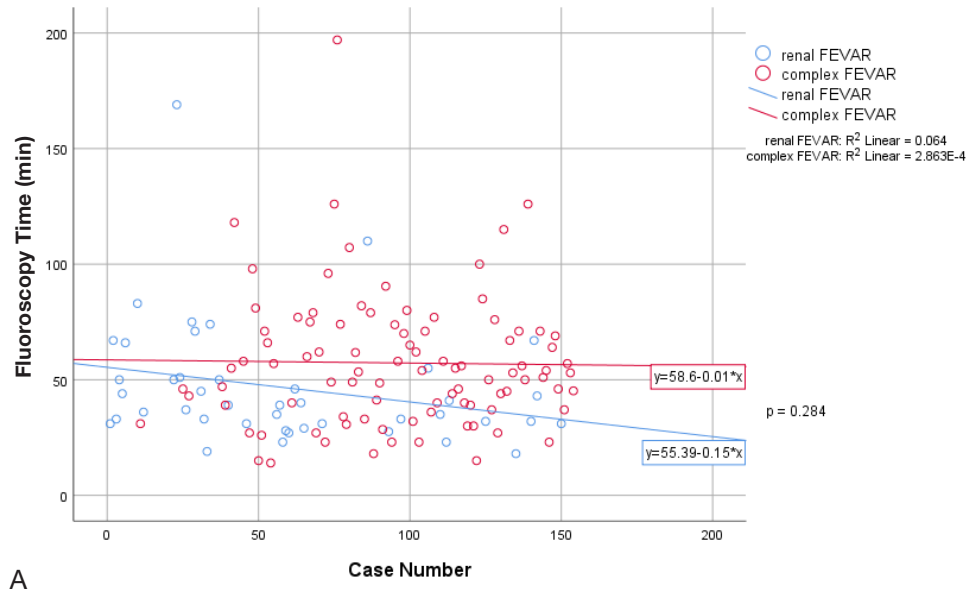
Figure 1. Bar graph of the numbers of renal FEVAR *versus* complex FEVAR from 2006 until 2020.

From this preceding result we most likely can assume that we performed more four fenestrations instead of three fenestrations with scallop in the last period of the complex FEVAR group, resulting in significant higher total effective seal zone. The mean total effective seal zone of the renal FEVAR group remains basically the same (mean 27.1 mm first group *vs*. 28.8 mm second group, P = .27). This presumably means that we only performed renal FEVAR interventions in patients who were anatomically compatible for renal FEVARs. We also noted an evident increase in FEVAR after EVAR procedures in the last years, eleven in the first period *vs*. fourteen in the last period. There were significant differences between the renal FEVAR *vs.* the complex FEVAR group regarding median operative time (145 min *vs.* 191 min; P = .001), median fluoroscopic time (39 min *vs.* 54 min; P = .007), median radiation exposure (119372 mgy*cm^2 *vs.* 159573 mgy*cm^2; P = .004) and median contrast dose (120 ml *vs.* 70 ml; P = .001). The learning curve for operative time and fluoroscopic time is shown in Figure 2. There was no significant difference in the learning curve for operative time or fluoroscopic time between the renal FEVAR and complex FEVAR groups (P = .589, P = .284, respectively). Furthermore, intraoperative complications occurred significantly more in the complex FEVAR group (P = .001). The complications were mainly related to target vessels, iliac artery ruptures or occlusions and access site hemorrhage. The χ^2 test demonstrated a statistically significant difference in access method between the renal FEVAR and complex FEVAR group (χ (3) = 19.910; P < .001). Subsequent post-hoc analyses through Fisher's exact test showed that surgical exposure was more frequently performed in the renal FEVAR group (P < .001), while a percutaneous approach was significantly more often selected in the complex FEVAR group (P < .001). Overall technical success was 144 of 154 (93.5%) patients. Technical success was comparable between the renal FEVAR group and the complex FEVAR group (94.4% *vs.* 93%; P = .73). Outcomes are presented in Table II.

Thirty-day mortality, clinical success, and morbidity

The overall 30-day mortality was 3.9% (3 patients of the renal FEVAR group, 3 patients of the complex FEVAR group [P = .44]) in the renal FEVAR group one patient died from myocardial infarction and another from renal bleeding with hypovolemic and cardiogenic shock. Four patients died due to bowel ischemia, three in the complex FEVAR group and one in the renal FEVAR group

There were no differences in cardiopulmonary complications, acute kidney injury, visceral ischemia, spinal cord ischemia, lower limb complications or



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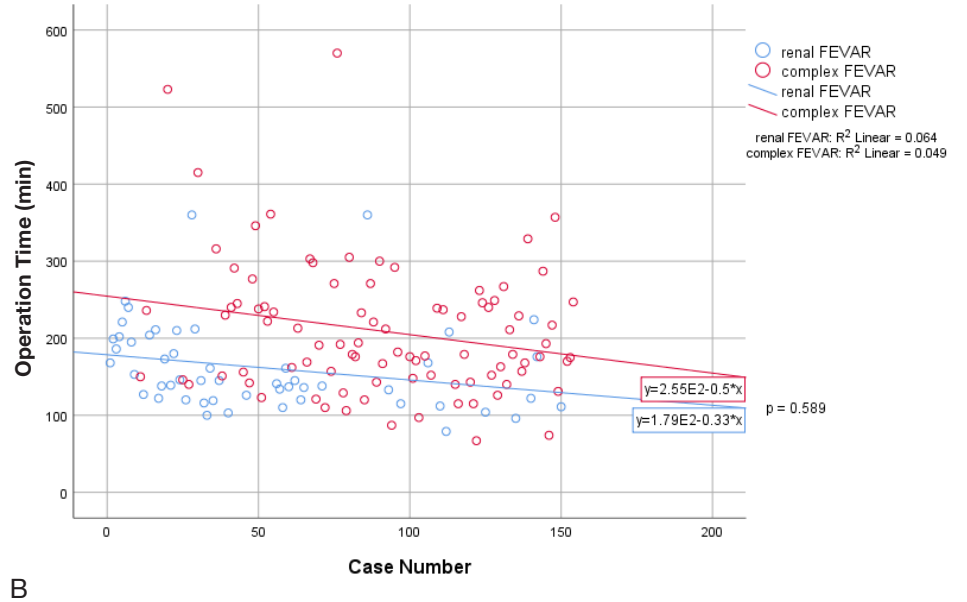


B

Figure 2. Learning curve for operative time (A) and fluoroscopic time (B).

Table II. Operative data, morbidity and mortality.

	Renal FEVAR (N.=54) N. (%)	Complex FEVAR (N.=100) N. (%)	P value
Intraoperative mortality	0	0	1.0
Technical success	51 (94.4)	93 (93)	.73
Intraoperative complications	2 (4)	18 (18)	.001
Target vessel dissection	0	6	
Target vessel stent crushed	0	2	
Target vessel stent migrated	1	0	
Rupture external iliac artery (eia)	0	2	
Occlusion hypogastric artery	0	2	
Malposition stent-graft	0	1	
Stent-graft tear	1	0	
Thrombectomy	0	1	
Fasciotomy	0	1	
Hemorrhage groin	0	3	
Contrast, ml (median [IQR])	120 [80-150]	70 [50-120]	.001
Radiation dose* (median [IQR])	119372 [74541-197711]	159573 [114788-245408]	.004
Fluoro time, min (median [IQR])	39 [31-51]	54 [39–71]	.007
Operative time, min (median [IQR])	145 [120-198]	191 [150-246]	0.001
Access			
Open exposure both CFA	42	41	.001
Percutaneous access both CFA	12	53	.001
Open right CFA+ percutaneous left CFA	0	4	.30
Open left CFA+ percutaneous right CFA	0	2	.54
Aneurysm rupture	0	0	1.0
Hybrid OR	22 (41)	86 (86)	.001
Stent-graft configuration			
Cook Zenith**	54	93	
Anaconda***	0	7	
No fenestration + one scallop	1****	0	
No fenestration + two scallops	1****	0	
One fenestration + no scallop	3	0	
One fenestration + one scallop	2	0	
One fenestration + two scallops	1	0	
Two fenestrations + no scallop	2	2	
Two fenestrations + one scallop	42	9	
Two fenestrations + two scallops	1	0	
Three fenestrations + no scallop	1	11	
Three fenestrations + one scallop	0	56	
Four fenestrations + no scallop	0	21	
Four fenestrations + one scallop	0	1	
Number of stents into target vessels	103	313	

Data are presented as mean ±SD, median and interquartile range or as number and percentage.
*(mGy*cm2), **Cook Zenith fenestrated stent-graft (William A. Cook Australia Pty Ltd, Brisbane, Australia)
***Anaconda fenestrated stent-graft (Vascutek/Terumo Aortic; Inchinnan, Scotland, United Kingdom),
**** Patients without fenestrations, but have 1 or 2 scallops.

reinterventions within 30 days between the two groups (Table III, IV). The mean total effective seal zone (27.5 mm [± 12.4] *vs.* 38.6 mm [± 13.4], P < .001) and the mean total used seal zone (37.2 mm [± 11.4] *vs.* 48.8 mm [± 10.6], P < .001) was significantly more in the complex FEVAR group compared with the renal FEVAR group (Table III).

Midterm results

Median follow-up of the total group was 25 months (IQR 8-45), 34 months (IQR 7-68) in the renal FEVAR group and 23 months (IQR 7-42) in the complex FEVAR group, P = .14. shrinkage of the aneurysm or stable aortic aneurysm size was significantly more common in the renal FEVAR group (91.1%) in comparison to the complex FEVAR group (77.6%, P = .017). during follow-up the aortic aneurysm diameter had a significant reduction of 19.7% (12 mm reduction, median diameter 49 mm [IQr, 39-62]) in the renal FEVAR group and 7.8% (5 mm reduction, median diameter 59 mm [IQR, 48-66]) in the complex group (P = .032).

Table III. Postoperative data, 30-day morbidity and mortality.

	Renal FEVAR N. (%)	Complex FEVAR N. (%)	P value
Hospital stay, days (median [IQR])	[3.8-6.3]	5.5 [3-9]	.45
30-day mortality	(5.6)	(3)	.44
Reintervention	(7.4)	(11)	.48
Acute kidney injury	(29.6)	(34)	.58
Cardiac (AF, infarction, endocarditis)	(9.3)	(3)	.08
Pulmonary sequelae	(3.7)	(7)	.40
Spinal cord ischemia	(1.9)	(5)	.34
Irreversible visceral ischemia	(1.9)	(2)	.95
Lower limb complications	(0)	(6)	.07
Total effective seal zone, mm (mean [SD])	27.5 [±12.4]	38.6 [±13.4]	.001
Total used seal zone, mm (mean [SD])	37.2 [±11.4]	48.8 [±10.6]	.001

Reinterventions during follow-up

A total of 47 reinterventions were done of which 15 in the renal FEVAR group and 32 in the complex FEVAR group, Table V. Thirteen patients (24%) required reinterventions in the renal FEVAR group and sixteen (16%) in the complex FEVAR group (P = .28). In the renal FEVAR group two patients required two interventions. in the complex FEVAR group one patient required four reinterventions, five patients required three reinterventions and three patients required two reinterventions. There was an average of 0.278 and 0.320 reinterventions per patient in the renal and complex FEVAR groups, respectively (P = .59).

Reinterventions during follow-up included 56 aortic procedures and 2 non-aortic procedures. Aortic reinterventions took place for the treatment of endoleaks, target vessel instability, stent-graft patency or disconnection, iliac or femoral artery complications and in one patient for a type B aortic dissection. Non-aortic reinterventions included incision and drainage for an abscess at the femoral access site.

Table IV. Reinterventions within 30 days.

	Early complication (<30 days)	N.	Treatment
Renal FEVAR	Bowel ischemia	1	Aorto-SMA bypass
	Endoleak type Ia/IIIc	1	Plug and coil embolization of the left renal artery and aneurysm sac
	Postoperative paraplegia	1	Cerebral spinal fluid drainage and revascularization of the hypogastric artery
	Endocarditis with dislocation of prosthetic aortic valve	1	Valve replacement
Complex FEVAR	Bowel ischemia	1	Relaparotomy showed trans mural ischemia of small bowel and the sigmoid colon, without any therapeutic options
		1	Colon resection
	Endoleak type IIIc	1	Additional atrium stent in the LRA
	Acute compartment syndrome of the leg	2	Fasciotomy
	Occlusion of the CFA	1	Revascularization
	Occlusion of the CFA, EIA and the stent-graft limb	2	Revascularization
	Stenosis SMA stent	1	Percutaneous transluminal angioplasty (PTA)
	Occlusion SMA + occlusion left limb of the stent-graft (1)	1	Recanalization and stenting of the SMA + thrombectomy left limb of the stent-graft and CFA endarterectomy with patch

Table V. Reinterventions after 30 days per patient in renal and complex FEVAR groups.

Reinterventions	Renal (N.=54) N. (%)	Complex (N.=100) N. (%)	P value
AORTIC			
Endoleak	6(11)	5(5)	.52
Type Ib	1(2)	2(2)	
Type Ic	1(2)	0(0)	
Type II	1(2)	2(2)	
Type IIIa	1(2)	0(0)	
Type IIIc	2(4)	2(2)	
Total reinterventions for endoleaks	6	6	
Target vessel	N.=99	N.=311	
Stenosis	2(2)	9(3)	
Occlusion	0(0)	3(1)	
Malposition	0(0)	1(0)	
Migration	0(0)	2(1)	
fracture	0(0)	2(1)	
Crushed	1(1)	0(0)	
Total target vessel reinterventions	3(3)	17(5)	.43
Iliac and femoral reinterventions			
Iliac limb			
Stenosis	1(2)	1(1)	
Migration	1(2)	1(1)	
Threatened disconnection and loss of seal	0(0)	1(1)	
Contained rupture	1(1)	0(0)	
CIA, EIA, CFA and/or SFA			
Stenosis	0(0)	2(2)	
Occlusion	2(4)	2(2)	
Dissection	1(2)	0(0)	
Total iliac and femoral reinterventions	6	7	.52
Type B aortic dissection	0(0)	1(1)	.65
NON-AORTIC			
abscess groin	0(0)	1(1)	.65
Total number of reinterventions	15	32	.59
Total patients requiring reintervention	13(24)	16(16)	.28

Endoleaks

No late type 1a endoleaks were seen in both groups. eleven patients, of which 6 in the renal FEVAR group and 5 in the complex FEVAR group, needed a re-intervention for any endoleak during follow-up. In the renal group one patient

needed graft extension to the EIA with embolization of the hypogastric artery for a type Ib endoleak. Another patient was treated for a type Ic endoleak through placement of an additional Advanta V12® covered balloon-expandable stent (Atrium Medical, Hudson, NH) in the left renal artery (LRA). Embolization of the inferior mesenteric artery was performed in one patient to treat aneurysm sac enlargement. One patient had a type IIIa endoleak, which was treated with a Covered CP stent ® (NuMed, Inc.) to cover the gap between the fenestrated Cook cuff and the Talent stent-graft, and additionally, an Advanta V12® was placed at the level of the left limb for suspect of also an endoleak type IIIa between the body and the left limb.Two patients had a type IIIc endoleak, which was treated in one patient by placement of an additional Advanta V12® stent in the right renal artery (RRA) and required embolization of the LRA to occlude the endoleak completely in the other patient.

In the complex group two patients with type Ib endoleaks were treated with a graft extension to the EIA, one patient with embolization of the hypogastric artery and one patient without. In two patients with type II endoleaks, which were responsible for aneurysm sac enlargement, embolization of the lumbar arteries was performed. Two patients had a type IIIc endoleak, one patient was treated by placement of an additional Advanta V12® stent in the LRA and the other patient needed an embolization of the RRA.

Target vessel instability

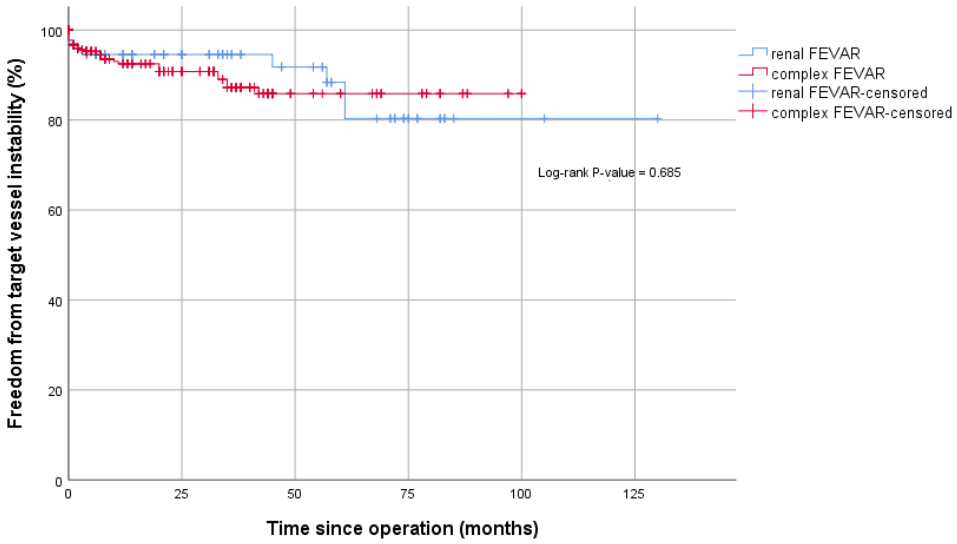
During follow-up we performed reinterventions in 20 target vessels (3 renal FEVAR *vs.* 17 complex FEVAR; P = .33). Eleven target vessels had a stenosis requiring reintervention (2 renal FEVAR *vs.* 9 complex FEVAR). Three vessels in the complex FEVAR group, two SMAs and one RRA, had an occlusion requiring reintervention while no target vessel occlusions were observed in the renal FEVAR group. Other target vessel complications requiring reintervention were a crushed mating stent in the renal FEVAR group and two stent fractures, two migrations, one in the celiac artery (CA) and the other in the LRA, and one malposition in the SMA in the complex FEVAR group. All reinterventions for target vessel instability were performed by percutaneous transluminal angioplasty (PTA) with or without placement of a stent.

In total, there were 37 cases of target vessel instability in 410 target arteries. In the renal group target vessel instability was detected in 8 LRA and 1 RRA. In the complex group, 6 LRA, 6 RRA, 10 SMA and 6 CA were diagnosed with

target vessel instability. The Kaplan-Meier estimate for freedom from target vessel instability was 91.0% overall, 90.9% for renal FEVAR group, and 91% for complex FEVAR group (log-rank P = .685; Figure 3).

Mortality

During median follow-up of 45 months (IQR 16-75), 71 patients died (34 renal FEVAR patients *vs*. 37 complex FEVAR patients). Five of these deaths were

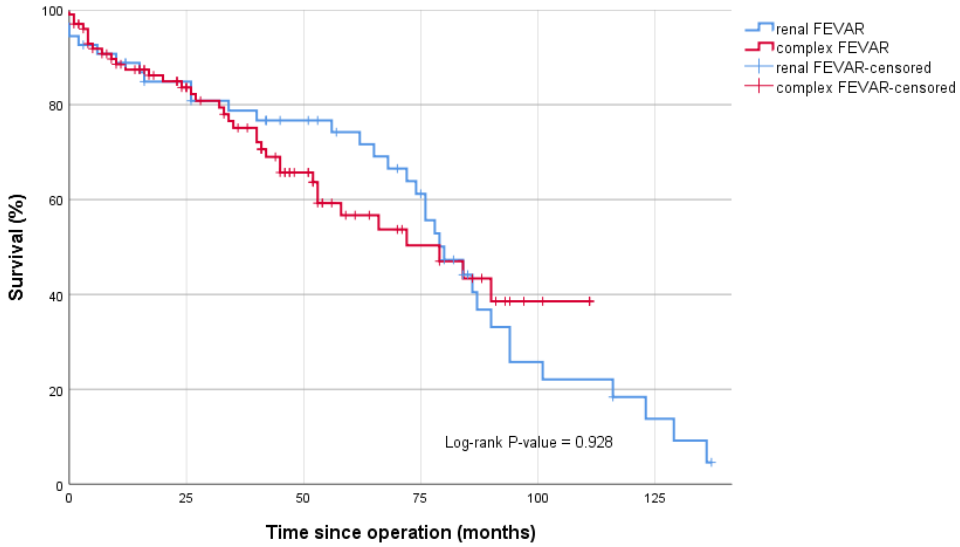


Time since operation, months		0	25	50	75	100	125
Target vessels at risk	Renal	99	48	31	9	2	1
	SE, %	2.5	3.5	7.2	7.2	7.2	7.2
	Complex	311	125	34	19	0	0
	SE, %	2.0	2.9	2.9	2.9	-	-

SE = standard error

Figure 3. Kaplan-Meier curve for freedom from target vessel instability comparing renal FEVAR group with complex FEVAR group. no difference in freedom from target vessel instability is noted (P = .685).

aneurysm related (1 renal FEVAR and 4 complex FEVAR; P = .660). One patient in the renal FEVAR and 2 patients in the complex FEVAR group died due to a ruptured aneurysm without any clear evidence of endoleak in the follow-up. Two patients in the complex FEVAR group developed a stent-graft infection with rupture of the aneurysm, one died 5 months and the other 3 years after FEVAR. For 32 patients the cause of death was unknown. Survival by Kaplan-Meier analysis of mid-term mortality showed no significant difference between the renal FEVAR group and complex FEVAR group (log-rank P = .928; Figure 4).



Time since operation, months		0	25	50	75	100	125
N at risk	Renal, n	54	42	33	22	6	3
	SE, %	5.0	6.1	7.3	7.6	6.9	4.1
	Complex, n	100	60	34	15	4	0
	SE, %	4.0	5.6	6.7	8.4	8.4	-

SE = standard error

Figure 4. Kaplan-Meier survival curve comparing renal FEVAR group with complex FEVAR group. No difference in survival is noted (p = .928).

DISCUSSION

Our study shows satisfactory mid-term results in terms of reintervention, endoleak and mortality during follow-up of stent-grafts with only renal fenestrations in the treatment of juxtarenal abdominal aortic aneurysms. Although there is a tendency in the literature to incorporate more visceral vessels in the proximal sealing area of a fenestrated graft, our results suggest that if there is an adequate seal with only renal fenestrations, renal FEVAR can results in the same mid-term outcome as more complex FEVAR.

In our cohort of complex FEVAR procedures, the intra-operative complications, median operative time, radiation dose and fluoro time were significantly higher (P = .001; P = .001; P = .004; P = .007, respectively). One possible reason for these findings could be a more complex anatomy of suprarenal aortic aneurysms. Another reason could be the higher incidence of previous aortic interventions in the complex FEVAR group (P = .015). Several studies observed more technical difficulties during FEVAR after EVAR, due to the presence of a previous stent-graft.[16-18]

Contrast medium volume was surprisingly higher in the renal FEVAR group with a median contrast dose of 120 ml in the renal group *versus* 70 ml in the complex group (P = .001). One possible explanation for this could be the limited experience of the vascular team in the early stage when the majority of the renal FEVAR group were performed. Another reason could be that we used diluted contrast medium and vessel navigator system in the hybrid operating room period which included most of the complex FEVAR group procedures. Additionally, we observed a decreasing trend in operative time throughout the course of the study with no significant difference between the two groups, however fluoroscopy time remained stable throughout the study period (Figure 2). Starnes *et al.* observed a reduction of both operative and fluoroscopy time during the learning curve of a single surgeon performing fevar procedures.[19] Furthermore, due to the better imaging system in the hybrid operating room, we could perform fevar interventions with more diluted contrast medium.

In our study, the number of reinterventions during follow-up was not significantly different between the renal FEVAR group (24%) and the complex FEVAR group (16%). Other studies report similar rates of reinterventions during follow-up for renal FEVAR.[5,7] Despite a significantly lower total effective seal zone and total used seal zone in the renal FEVAR group compared with the complex FEVAR group,

we observed no late type Ia endoleaks in the renal FEVAR group during follow-up, which shows an evident stability of the proximal sealing zone. In a retrospective cohort study of fenestrated endovascular aneurysm repair, comparing outcomes of two fenestrations *versus* more than two, Katsargyris *et al.* showed that only one of the 199 patients in the renal group needed a reintervention for type Ia endoleak during 3-years follow-up. They reported no increased sealing complication in their renal group.[3] Oikonomou *et al.* performed 24.4% reinterventions in the renal group and 15.6% in the complex group at 3 years follow-up. In the complex group no patients had an endoleak type Ia during follow-up, in contrast to the renal group 4% (2 of 45 patients) needed a reintervention for type Ia endoleak.[8] Roy *et al.* reported a significant lower number of type I or type III endoleaks in the renal group during follow-up compared to the complex FEVAR group and reported an overall secondary intervention rate of 22%.[20] In contrast, Mastracci *et al.* documented an increased rate of proximal type I endoleak over time in the renal FEVAR group (10.4% for renal FEVAR *vs.* 1.9% for complex FEVAR; P < .01). However, in this study the majority of the renal fenestration stent-grafts were included in the early phase, similar as in our study, thus including a learning curve with the device and a significantly longer follow-up.[21]

We report a 30-day mortality of 3.9%. similar results were obtained by other authors, reporting 30-day mortality rates between 2%-5.2%. In some studies, the 30-day mortality appeared higher when more complex stent-grafts were used, especially when it incorporated the coeliac trunk.[4, 5, 22-29] In our study we observed no statistically significant differences in 30-day mortality between the renal FEVAR and the complex FEVAR group. This could be due to the relatively small numbers of patients, however, other studies with similar or less numbers of patients revealed a significant difference in mortality.[4, 5, 20]

There has been an increasing trend towards the use of FEVARs of higher complexity as surgeons became more familiar with the technique. The theory behind this trend is that pushing the sealing zone higher in the aorta by using complex stent-grafts results in a more durable proximal seal in healthier aorta. In our study group we also performed more complex FEVAR procedures over time. One of the possible reasons may have been that our threshold to perform a complex FEVAR became lower as we got more skilled in this technique. We revealed a significant higher total effective seal zone in the complex FEVAR group, which was performed in the last period of the study. This may imply that we shifted too early towards complex FEVAR procedures in patients whose anatomy may be suitable for a renal FEVAR. Another possible reason could have been that

our referring centers have embarked on renal FEVAR procedures in their own center and are currently referring only patients with more complex juxtarenal AAA to our tertiary hospital. Finally, we noted an evident increase in FEVAR after EVAR procedures in the last years and it is uncommon to be able to achieve a sufficient sealing with renal FEVAR to correct a failing EVAR. However, higher stent-graft complexity is more likely to cause intraoperative complications and secondary reinterventions during follow-up. Indeed, Kärkkäinen *et al.* reported a higher risk of primary target vessel endoleaks in patients with four incorporated target vessels.[30] Roy *et al.* showed significantly higher rates of graft-related endoleak ($P < .001$) when more complex stent-grafts were used.[20] Furthermore, Mastracci *et al.* described an increased rate of reinterventions in more complex stent-grafts and more likely celiac occlusion over time in patients with celiac fenestrations ($P < .01$).[21] In contrast, our study revealed only significant higher intraoperative complications in the complex FEVAR group, but early and reinterventions during follow-up showed no difference between the two groups. Furthermore, in our study we did not observe significantly more spinal cord ischemia by pushing the sealing zone higher in the aorta.

Limitations of the study

Several limitations of this study need to be addressed. It is a single-center retrospective study with a relatively small number of treated patients. Another limiting factor may be the use of different intraprocedural imaging, since significantly more of the complex FEVARs were performed in the hybrid room. Furthermore, throughout the years the intervention team became more experienced with FEVAR. Consequently, the team accepted more complex stent-graft procedures in the later stage of the inclusion period with increased challenging aortic anatomy. Additionally, the median follow-up period of the study of 25-months may have been insufficient to observe complications related to proximal sealing in renal FEVAR group. From previous reports such complications seem to occur after longer follow-up, thus, different results could be expected when expanding the follow-up period.[8, 21] However, the mean follow-up of our renal FEVAR group, which could be most at risk for proximal failure, was 34 months and in the whole cohort of 54 patients we observed no proximal failures.

CONCLUSIONS

Our single-center retrospective study shows that renal FEVAR is a safe and effective treatment option in juxtarenal abdominal aneurysm. Renal FEVAR performed equally satisfactory as complex FEVAR with regards to perioperative mortality and technical success. However, there was a significant increase in intraoperative complications, median operative time, radiation dose and fluoroscopy time in the complex FEVAR group. Finally, we observed no significant difference in survival, reintervention, endoleaks, and target vessel instability after renal FEVAR compared to complex FEVAR. Therefore, if the anatomy is compatible for renal FEVAR, it might be unnecessary to expose patients to potentially more complications by choosing a complex FEVAR strategy.

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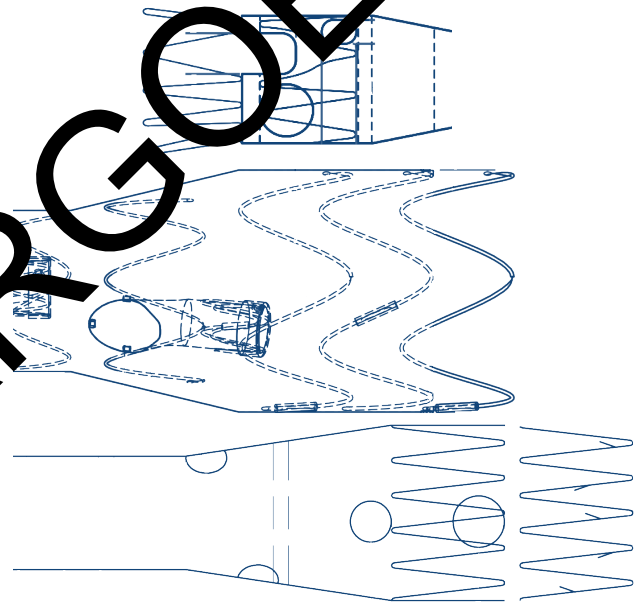
CHAPTER 4

Impact of stent-graft complexity on the outcome of complex abdominal aortic aneurysms repair: a systematic review and meta-analysis



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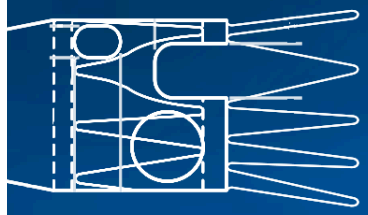
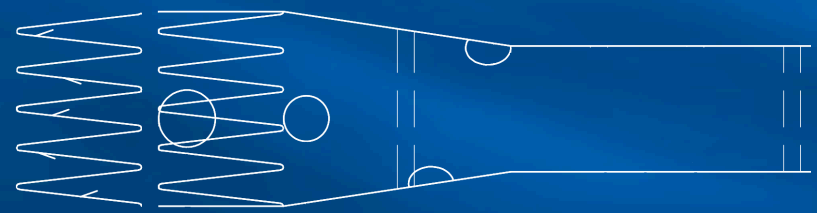
Submitted

CHAPTER 5

Outcome of fenestrated endovascular aneurysm repair in octogenarians: a retrospective multicentre analysis





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European Journal of Vascular and Endovascular Surgery

2020 Jan;59(1):24-30

ABSTRACT

Objective: An ageing population leads to more age related diseases, such as complex abdominal aortic aneurysms (AAA). Patients with complex AAAs and multiple comorbidities benefit from fenestrated endovascular aneurysm repair (FEVAR), but for the elderly this benefit is not completely clear.

Methods: Between 2001 and 2016 all patients treated for complex AAA by FEVAR at two tertiary referral centres were screened for inclusion. Group 1 consisted of patients aged 80 years and older and group 2 of patients younger than 80 years of age. The groups were compared for peri-operative outcome, as well as patient and re-intervention free survival, and target vessel patency during follow up.

Results: Group 1 consisted of 42 patients (median age 82 years; interquartile range [IQR] 81-83 years) and group 2 of 230 patients (median age 72 years; IQR 67-77 years). No differences were seen in pre-operative comorbidities, except for age and renal function. Renal function was 61.4 mL/min/1.73 m^2 vs.74.5 mL/min/ 1.73 m^2 ($p < .01$). No differences were seen between procedures, except for a slightly longer operation time in group two. Median follow up was 26 and 32 months, respectively. No difference was seen between the groups for estimated cumulative overall survival ($p = .08$) at one, three, and five years, being 95%, 58%, and 42% for group 1, and 88%, 75%, and 61% for group 2, respectively. There was no difference seen between groups for the estimated cumulative re-intervention free survival ($p = .95$) at one, three, and five years, being 84%, 84%, and 84% in group 1, respectively, and 88%, 84%, and 82% in group 2, respectively. Ultimately, no difference was seen between groups for the estimated cumulative target vessel patency ($p = .56$) at one, three, and five years, being 100%, 100%, and 90% for group 1, and 96%, 93% and 92% for group 2, respectively.

Conclusion: Age itself is not a reason to withhold FEVAR in the elderly, and choice of treatment should be based on the patient's comorbidities and preferences.

INTRODUCTION

Abdominal aortic aneurysm (AAA) is an age related and potentially life threatening disease, due to the risk of rupture.[1,2] The life expectancy of the Western population has increased and, consequently, more octogenarians will need treatment for an AAA.[2-5] The elderly are often considered to be unfit for open surgical AAA repair.[6]

Endovascular aortic repair (EVAR) has increasingly replaced open repair for the treatment of an AAA.[5,7] EVAR in octogenarians is associated with less morbidity and mortality than open repair.[8] However, the 30 day mortality after EVAR is higher than in patients younger than 80 years and varies from 2.6% to 7.0%.[8-10]

Fenestrated EVAR (FEVAR) is used to treat complex aneurysms, including short neck infrarenal or juxtarenal AAAs.[11] FEVAR is a feasible alternative to open repair, with a 30 day mortality varying from 2.0% to 5.8%.[12,13] With the introduction of FEVAR elderly patients, who are too frail for open surgery but who have a complex AAA unsuitable for EVAR and in whom watchful waiting is not an option, got a new opportunity to get treatment.[14] A recent study by Locham et al. showed the 30 day mortality rate in octogenarians with complex AAA who were treated by either open repair or FEVAR.[15] The octogenarians undergoing open repair had a higher 30 day mortality rate than patients treated by FEVAR (8.5% vs. 4.1%).[15] A few other studies with small sample sizes on the outcomes of FEVAR in octogenarians have been published recently.[7,16] Their findings suggest that octogenarians might not benefit from treatment by FEVAR, but the results are ambiguous. Knowledge of the results of FEVAR in octogenarians remains sparse. Most studies focus on peri-operative mortality and short term survival.[15,16] Information about other outcomes, such as re-interventions and survival in the longer term, is limited. To the authors' knowledge only the studies by Hertault et al. and Roy et al. presented data on mid term results; consequently, more results will enable assessment of FEVAR in the elderly.[7,17]

This study aimed to evaluate the results of FEVAR in octogenarians related to patient survival, complications, and number of re-interventions, and target vessel patency in the mid term.

MATERIALS AND METHODS

Study design

This retrospective cohort study included patients with a short neck infrarenal or pararenal AAA. The patients were treated primarily or after previous aneurysm repair with type I endoleak or para-anastomotic aneurysm. One urgent treatment of a contained ruptured aneurysm after EVAR was also included as the fenestrated stent-graft was already in the authors' possession. Patients with thoraco-abdominal aortic aneurysm were excluded. The custom made fenestrated endografts used were the Zenith Fenestrated endografts (Cook Medical, Bloomington, IN, USA) or the Fenestrated Anaconda endograft (Terumo Aortic, Inchinnan, UK). Data were collected from two tertiary referral centres for patients treated between 2001 and 2016. The study was approved by the institutional review board (METC-2017- 540). Retrospective patient file research does not fall under the scope of the Dutch Act on Medical Scientific Research involving Human Beings. Therefore, informed patient consent was not required and not obtained. Patient related data were analysed anonymously.

Data collection and definitions

Data collection included demographics and comorbidities, including cardiovascular and pulmonary disease, renal failure, dialysis, and diabetes mellitus. Procedural information included type of fenestrated endograft, number of fenestrations, operating time, adjunctive procedures, and (assisted) primary technical success. Patients treated with a fenestrated endograft including only scallops were excluded.

Cases were assigned to two groups: patients aged 80 years and older were assigned to group 1 (octogenarian group), and patients younger than 80 years were assigned to group 2 (non-octogenarian group). Both groups were divided into quartiles (≤ 2006, 2007-2009, 2010-2012, and ≥ 2013) to check for change in median age at the time of surgery.

The primary technical success was defined as the successful introduction and deployment of the device and the absence of surgical conversion or mortality, type I or III endoleaks, or graft limb obstruction, extending into the first 24 h post-operatively. When successful unplanned endovascular procedures were done within 24 h, they were defined as assisted primary technical success.[1] Endoleaks were defined as described by Jain et al.[18] Post-operative information about re-

intervention and 30 day mortality was also registered. Follow up information included patient survival rate, re-intervention free survival rate, and target vessel patency.

Statistical analysis

Chi square tests were used for differences between groups with categorical variables. Distribution normality was tested with the ShapiroeWilk test. Results are presented as mean standard deviation (SD) for normally distributed data, and as median (interquartile range [IQR]) for skewed data. Differences between groups with continuous variables were analysed with the Student's t test (normal distribution), or with the ManneWhitney U test (skewed distribution). Differences in continuous data between multiple groups were tested with the KruskaleWallis test. For paired data, the Wilcoxon signed rank test was used. Kaplan-Meier analysis and log rank test were used for patient survival, re-intervention free survival, and target vessel patency. P values < .05 were considered statistically significant. SPSS version 24.0 (IBM, Armonk, NY, USA) was used for analysis.

RESULTS

Characteristics

A total of 272 patients (236 men) were included. Baseline characteristics are shown in Tables 1 and 2. Group 1 consisted of 42 (15.4%) cases (median age 82 years, range 80-91 years) and group 2 of 230 (84.6%) cases (median age 72 years, range 50-79 years). The median age in the four time periods did not change (p = .79 in group 1; p = .98 in group 2), nor was there a difference seen in the relative number of cases in group 1 vs. group 2 (p = .09). Two hundred and fifty five patients were treated with the Zenith fenestrated graft (41 in group 1 and 214 in group 2), while 17 patients were treated with a Fenestrated Anaconda (one in group 1 and 16 in group 2; p = .26). A total of 89 fenestrations (mean 2.1 (SD± .74)) were incorporated in group 1 and 527 fenestrations 2.3 (SD±.80) in group 2 (p = .20).

Intra-operative results

On completion angiogram, in group 1, two type Ia (4.8%), one type Ia/IIIc (2.4%), one type Ic (2.4%), and eight type II (19.0%) endoleaks were observed. During follow up, the two type Ia endoleaks resolved spontaneously, the type Ia/ IIIc

Table 1. Baseline characteristics of 272 patients undergoing fenestrated endovascular aneurysm repair (FEVAR), stratified by age.

	Octogenarians (n = 42)	Non-octogenarians (n =230)	P value
Mean age ± SD (range) - y	82.3 ± 2.5 (80-91)	71.4 ± 6.1 (50-79)	< .01
Men	37 (88)	199 (87)	.78
ASA ≥ 3	29 (69)	165 (72)	.73
Diabetes mellitus	3 (7)	37 (16)	.14
Hyperlipidaemia	21 (50)	159 (69)	.01
Arterial hypertension	28 (67)	183 (80)	.98
Coronary artery disease	29 (69)	137 (60)	.24
Pulmonary disease	10 (24)	82 (36)	.15
Mean renal function ± SD (range) - mL/min/ 1.73 m2 (eGFR)	61.4 ± 17.4 (29-96)	74.5 ± 22.1 (25-132)	< .01

Data are n (%) unless otherwise stated.
SD = standard deviation; ASA = American Society of Anaesthesiologists' score; eGFR = estimated glomerular filtration rate.

endoleak needed Amplatzer vascular plug embolisation of the left renal artery (LRA) and coiling with thrombin in-jection of the aneurysm sac, and the type Ic endoleak was treated by relining of the LRA. In group 2, eight type Ia (3.5%), one type Ib (.4%), one type Ic (.4%), 43 type II (18.7%), one type IIIa (0.4%), and one type IIIc (0.4%) endoleaks were recorded (Table 3). All the type I endoleaks resolved spontaneously during follow up, expect for one type Ia endoleak. The follow up computed tomography angiography (CTA) revealed a type IIIc instead of a type Ia endoleak, which was treated by relining of the target vessels. No significant difference was noted between the two groups regarding primary technical success or primary assisted technical success (p = .84 and p = .56, respectively).

Table 2. Aneurysm specific baseline characteristics of 272 patients undergoing fenestrated endovascular aneurysm repair (FEVAR), stratified by age.

	Octogenarians (n = 42)	Non-octogenarians (n =230)	P value
Mean aneurysm diameter ± SD (range) - mm	65.3 ± 8.4 (54-89)	63.3 ± 8.6 (42-92)	.17
Proximal aneurysm location			
Short neck aneurysm	20 (48)	91 (40)	.95
Juxtarenal aneurysm	22 (52)	126 (55)	.77
Suprarenal aneurysm	0 (0)	13 (6)	.12
Type Ia endoleak	3 (7)	12 (5)	.62
Para-anastomotic aneurysm	0	1 (0.4)	.67

Data are n (%) unless otherwise stated. SD = standard deviation.

Early outcome

Thirty day morbidity and mortality for the two groups are presented in Table 4. The 30 day mortality was 2.4% in group 1. In one patient, a renal artery was presumably punctured by a guidewire, leading to bleeding and development of a haematoma in the left kidney. This patient, with an already poor cardiac condition, evolved rapidly into cardiogenic shock and death, without the opportunity for re-intervention. The 30 day mortality was 3.0% (seven patients) in group 2. Five patients died of gastrointestinal ischaemia. Four had a superior mesenteric artery (SMA) and/or coeliac artery (CA) occlusion. Although laparotomy was performed, these occlusions led to multi-organ failure and death at 2, 2, 4, and 11 days, respectively. In the last patient there was a SMA dissection which, despite open surgical patch plasty, eventually led to death 23 days post-operatively. Two patients died of myocardial infarction, both on post-operative day four.

In group 1, three patients underwent a re-intervention within 30 days (7.1%). In the first, a post-operative groin bleed was sutured on the evening of initial surgery.

Table 3. Procedural outcomes of fenestrated endovascular aneurysm repair (FEVAR) in 272 patients, stratified by age.

	Octogenarians (*n* = 42)	Non-octogenarians (*n* =230)	P value
Intra-operative mortality	0 (0)	0 (0)	1.00
Primary technical success	33 (79)	179 (78)	.84
Assisted primary technical success	38 (90)	214 (93)	.56
Endoleak on completion angiography	12 (29)	55 (24)	.35
Iliac branched device	1 (2)	1 (0.4)	.18
Adjunctive procedure	9 (21)	59 (26)	.56
Median contrast volume (IQR) - mL	150 (100-183)	170 130-210)	.07
Median procedure time (IQR) - min	171 (145-235)	200 (160-267)	.048

Data are n (%) unless otherwise stated. IQR = interquartile range.

In the second, there was dissection of the external iliac and common femoral arteries, and an endarterectomy was performed, including placement of an iliac stent four days post-operatively. In the last patient the LRA stent disconnected during operation, and could not be bridged. On day seven coil embolisation of the LRA was performed because of persistent endoleak.

In group 2, 13 patients needed a re-intervention within 30 days (5.6%). The five patients undergoing laparotomy were mentioned above. Three patients had an iliac artery occlusion followed by a bypass (day 0) in one and stent placement in two (both day 15). In two patients additional stenting was performed: one on day six to the right renal artery (RRA) due to stent fracture and another on day 15 to a LRA, resolving a type III endoleak. In one patient the SMA stent showed a stenosis and additional percutaneous transluminal angioplasty was performed on day five. In two patients a compartment syndrome, with ischaemia of the lower leg, was noted on the day of operation and a fasciotomy of the lower leg was performed.

Table 4. Early outcomes after fenestrated endovascular aneuryms repair (FEVAR) in 272 patients, stratified by age.

	Octogenarians (*n* = 42)	Non-octogenarians (*n* =230)	P value
Mean ICU length of stay ± SD (range) - d	0.2 ± 0.6 (0-3)	0.9 ± 4.6 (0-62)	.39
Mean lenght of hospital stay ± SD - d	5.8 ± 3.4 (1-18)	6.9 ± 10.8 (1-120)	.54
Mean postoperative renal function ± SD (range) - mL/min/1.73 m2 (eGFR)	61.0 ± 22.7 (8-117)	72.5 ± 26.5 (13-154)	.01
Spinal cord ischaemia	0 (0)	5 (2)	.34
Visceral ischaemia	1 (2)	9 (4)	.63
Lower limb ischaemia	2 (5)	15 (7)	.67
30 day mortality	1 (2)	7 (3)	.82

Data are n (%) unless otherwise stated.
SD = standard deviation; eGFR = estimated glomerular filtration rate; ICU = intensive care unit.

In patients with signs of spinal cord ischaemia, a spinal drain was used to lower spinal pressure. This was only done in group 2 patients (five cases [2.2%]). One patient was paraplegic post-operatively due to thalamic ischaemia possibly combined with spinal ischaemia. After spinal drainage and rehabilitation a paresis of the left leg persisted. In the other four cases the patient had paresis of both lower limbs, which disappeared fully after spinal drainage.

Mid term outcome

Patient survival. Median follow up in group 1 was 26 months (IQR 12-58 months) and in group 2 it was 32 (IQR 9-58 months) (p = .72). In 16 cases follow up after 30 days was available, of whom eight died (one in group 1 and seven in group 2), and in eight cases (one in group 1 and seven in group 2) no follow up was available. In those last cases the follow up took place at the primary referral centre.

No difference was seen between groups for estimated cumulative patient survival (p = .08) at 1, 3, and 5 years, being 95% 4%, 58% 9%, and 42% 10%, respectively for group 1, and 88% 2%, 75% 3%, and 61% 4%, respectively for group 2 (Figure 1).

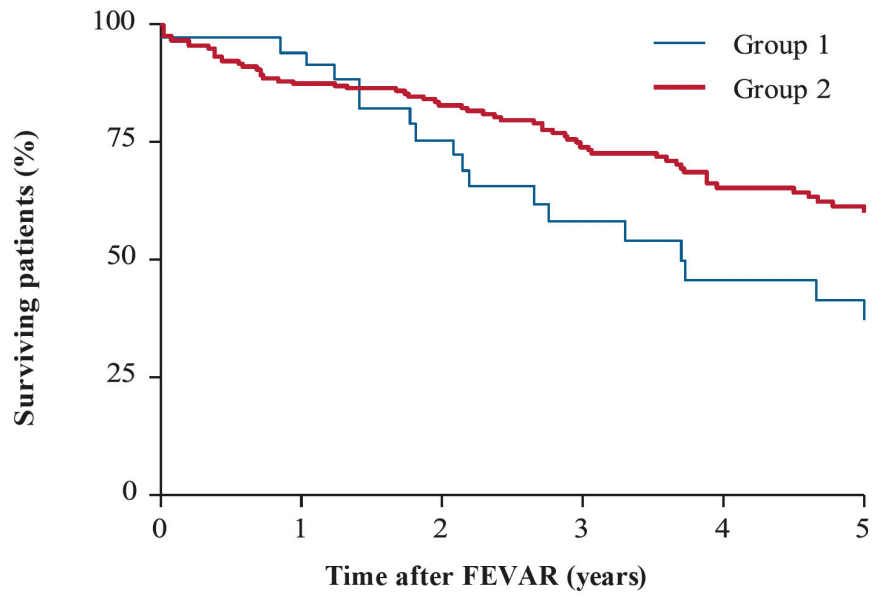
In group 1, the causes of death were cardiac failure in three, respiratory failure in one, a cerebrovascular event in one, and malignancy in three. In three cases the deaths were considered aneurysm related. One patient had a type Ib endoleak and aneurysm growth, but refused further treatment, subsequently leading to rupture 45 months post-operatively. A second patient was admitted 17 months after surgery with a mycotic aneurysm, subsequently developing abdominal pain and instability during admission. On suspicion of aneurysm rupture conservative care was chosen with subsequent death. The cause of death was unknown in 12 cases.

In group 2, causes of death were cardiac failure in 16, respiratory failure in three, cerebrovascular events in six, and malignancy in 12. Another five cases were considered aneurysm related. In one patient, a laparotomy was performed four months after surgery because of an endograft infection. At 44 months the SMA occluded in this patient, resulting in death. In another case occlusion of both renal arteries led to death 100 months post-operatively. In three cases there was an infected endograft, of which one combined with a type Ia endoleak led to rupture and death five months post-operatively. The two other cases were managed conservatively, and both died 33 months post-operatively. The cause of death was unknown in 38 cases.

Complications and re-intervention free survival.

After the 30 day post-operative period, 23 patients needed a re-intervention. Three patients had a re-intervention in group 1. In the first patient a persistent type Ic endoleak was treated by an additional LRA stent at 2.4 months. In the second patient a stent was placed because of a sharp iliac angle at 11 months, and in the third patient an uncovered stent was placed for a type IIIa endoleak to push two aortic endograft components together at 12.1 months.

Twenty patients underwent a re-intervention in group 2. One patient had an uneventful index procedure and a normal post-operative CTA. However, 2.9 months later the patient presented at the emergency room with chest pain and lower limb ischaemia. CTA detected a type B retrograde thoraco-abdominal aortic dissection from the left subclavian artery to just above the fenestrated



No. at risk (SE in %)

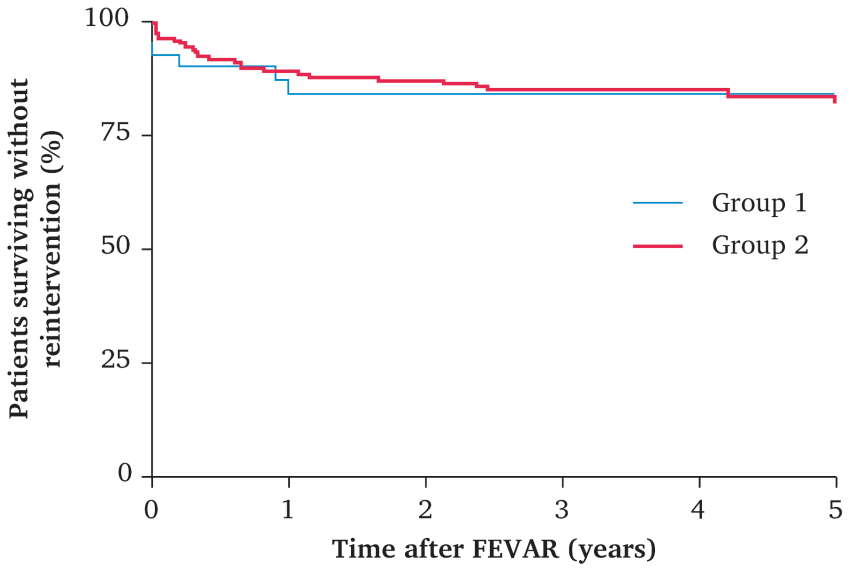
Group 1:	42 (0)	32 (4)	23 (8)	15 (9)	11 (10)	10 (10)
Group 2:	230 (0)	166 (2)	136 (3)	103 (3)	76 (4)	54 (4)

Figure 1. Cumulative Kaplan Meier estimates of patient survival after fenestrated endovascular aneurysm repair (FEVAR), stratified by age. Group 1 consists of octogenarians; group 2 consists of non-octogenarians. SE = standard error.

endograft, with occlusion of the SMA and thrombosis of a popliteal aneurysm. Initially, a stent was placed in the SMA to preserve patency and a femoropopliteal bypass was performed. Three weeks later a second intervention was performed with a carotidesubclavian bypass, stenting of the CA, and thoracic stent-graft. In one, a laparotomy was performed after four months for endograft infection as mentioned above, and in another groin re exploration for a groin abscess at eight months. In one patient a severely stenotic LRA prevented cannulation and stenting, and was therefore left unstented. A second cannulation attempt was performed at 3.8 months to treat the type IIIc endoleak and the deterioration in renal function. However, the digital subtraction angiography (DSA) images showed total occlusion of the artery, after which the attempt was abandoned. With repeated DSA imaging, the LRA appeared to be occluded. Only a small niche filled with contrast and there was insufficient space to occlude the

fenestration with an Amplatzer plug. In the fifth case the CA occluded and thrombolysis with urokinase was tried at 11 months, without effect, and no further clinical consequences. In the sixth case, at 14 months thrombin injection of a false aneurysm of the femoral artery was performed. A lumbar artery was coiled for a type II endoleak at 65 months in the seventh case. Re-intervention of the iliac or femoral artery was performed for occlusion in four cases by stent (2.4 months), thrombectomy (3.5 months), ilio-femoral (4.0 months), and ilio-iliac crossover bypass (5.0 months). Relining of visceral arteries was performed for a fractured stent (20 and 29 months), a stenosis or occlusion (7.3, 13.0, 15.0 and 62.0 months), a displaced stent (6.0 months), a type Ib endoleak (31.6 months), or a type III endoleak (30.0 months).

No difference was seen between the groups for estimated cumulative re-intervention free survival (p = .95) at 1, 3, and 5years, being 84% ± 6%, 84% ± 6%, and 84% ± 6%, respectively for group 1, and 88% ± 2%, 84% ± 3%, and 82% ± 3%, respectively for group 2 (Figure 2).



No. at risk (SE in %)

Group 1:	42 (0)	28 (6)	19 (6)	12 (6)	8 (6)	7 (6)
Group 2:	230 (0)	150 (2)	123 (3)	93 (3)	69 (3)	51 (3)

Figure 2. Cumulative Kaplan Meier estimates of reintervention free survival after fenestrated endovascular aneurysm repair (FEVAR), stratified by age. Group 1 consists of octogenarians; group 2 consists of non-octogenarians. SE = standard error.

Target vessel patency and renal function. At last follow-up there had been three one target vessel occlusions (3.4%) in group one (one in the LRA and two in the RRA), and 29 occlusions (5.4%) in group 2 (two in the CA, 9 in the SMA, 9 in the LRA, and 9 in the RRA [p = .44]). All necessary interventions are mentioned above. The estimated target vessel patency at 1, 3, and 5 years were 100% ± 0%, 100% ± 0%, and 90% ± 7% in group 1, respectively, and 96% ± 1%, 93% ± 1%, and 92% ± 2% in group 2, respectively (p= .56; Figure 3).

In group 1 the pre-operative mean estimated glomerular filtration rate (eGFR; 61.417 mL/min/1.73 m^2) remained stable *vs.* a post-operative eGFR of 61.023 mL/min/1.73 m^2 (p = .47) and the last follow up eGFR (61.124 mL/min/1.73 m^2) (p = .06). In group 2, the mean pre-operative eGFR changed from 74.5 ± 22 mL/min/1.73 m^2 to 72.5 ± 26 mL/ min/1.73 m^2 post-operatively (p = .77), and declined further to 60 ± 20 mL/min/1.73 m^2 at the last follow up (p < .001). There was no statistically significant difference between the two groups regarding eGFR decline at the last follow up (p = .91). No post-operative dialysis dependence was observed in group 1 but occurred in five patients in group 2 (p = .34).

Endoleaks.

After implantation, 15 endoleaks were noted in 15 patients (35.7%) in group 1 and 52 endoleaks in 50 patients in group 2 (22.0%) (p = .06).

In group 1, one type Ia/IIIc endoleak, one type Ib, one type Ic, 10 type II, one type IIIa, and one type IIIb endoleaks were found. A re-intervention was performed in two cases, as mentioned above.

In group 2, two type Ia endoleaks, one type Ib, one type Ic, 43 type II, and four type IIIc were found, and one patient had a type Ib, type II, and type IIIc endoleak. Re-intervention was performed in six patients. The patient with the three endoleaks had relining of an iliac artery for the type Ib endoleak, coiling of a lumbar artery for the type II endoleak, and the type IIIc endoleak was treated by watchful waiting. Relining of one or more visceral arteries was performed for a type III endoleak in four patients. One patient needed coiling of a lumbar artery for a type II endoleak due to growing aneurysm sac. All other endoleaks disappeared spontaneously or were followed by watchful waiting.

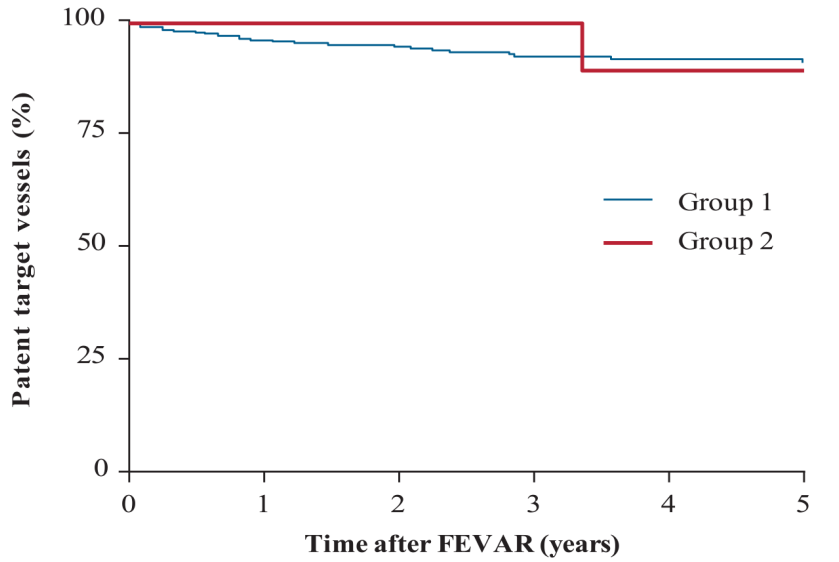


Figure 3. Cumulative Kaplan Meier estimates of target vessel patency after fenestrated endovascular aneurysm repair (FEVAR), stratified by age. Group 1 consists of octogenarians; group 2 consists of non-octogenarians. SE = standard error.

DISCUSSION

This multicentre retrospective cohort study shows no statistically significant difference in survival and re- intervention free survival benefit of FEVAR in the treatment of complex AAA in octogenarians and in younger patients.

Pre-operative patient characteristics were comparable in both groups. Obviously, pre-operative age was different, probably also resulting in lower pre-operative renal function in the octogenarian group. The other similarities might be the result of a selection of healthier elderly people, which might result in a selection bias for the octogenarian group. It could be argued that despite the absence of statistical significance, a slight difference in aneurysm diameter between groups was observed (65 mm in group 1 vs. 63 mm in group 2), and maybe this is the consequence of withholding treatment in cases with multiple comorbidities and a borderline AAA diameter.

The assisted primary technical success in the present study is similar to earlier work by Hertault et al. and Timaran et al.[7,16] The 30 day mortality in the octogenarian group, however, is different than found by Hertault et al. and Timaran et al. In the study by Timaran et al.,[16] octogenarians with a mean age of 84 years (n = 18) treated by FEVAR for complex AAA were compared with patients with a mean age of 71years (n = 67), and there was a 30day survival of 100% in both groups.[16] Additionally, there was no difference between groups for estimated survival at 20 months. The larger study by Hertault et al. included a group with a mean age of 82years (n = 33) and a group with a mean age of 70 years (n = 255).[7] They observed a slightly higher 30 day mortality rate in the elderly group of 9% vs.1.9% in the younger group after FEVAR.[7] These findings suggest that octogenarians might not benefit from treatment by FEVAR.

The explanation of the discrepancy between those two studies and the present one is not completely clear, but the 30 day mortality in the current study is comparable to other studies not differentiating in age, suggesting age is not a limiting factor for the technical success of FEVAR.[12,19,20]

In the general population, overall survival is expected to be lower in octogenarians simply due to age. The estimated overall survival rate at five years in this study did not differ statistically from the non-octogenarian group (42% vs. 62%), but it seems the octogenarian group has lower long term cumulative survival than the non-octogenarian group and a reported five year survival of 59.4%.[17] Although a difference can be seen, the lack of statistical significance in this fairly large cohort suggests the difference is not as clear as that described by Hertault et al.[7]

No difference was seen between groups for re-intervention free survival. Timaran et al. found a re-intervention free survival of 90% in octogenarians at 20 months, but a 43% rate in the non-octogenarian group.[16] This difference is remarkable although, due to a small sample size, not statistically significant. Comparing this with the estimated re-intervention free survival and available literature, it seems more plausible that age does not influence AAA or endograft related re-intervention rate during follow up.[21]

Target vessel patency related to age is not well described. Besides a higher chance of cardiovascular disease with older age, the elderly tend to have larger AAAs and more angulation. It could be said that this makes them more difficult to treat and therefore more at risk of stent occlusion than younger patients.[22] However, the present study showed good estimated target vessel patency rates at five years (Figure 3).

One interesting issue in this study is the lower post-operative renal function in the octogenarian group (Table 3). The pre-operative renal function was lower in the octogenarian group (Table 1), probably related to older age. During follow up renal function remained stable in the octogenarian group, while there was a decline in renal function in the younger group. It is possible that the small sample size led to a type II statistical error or a lower pre-operative renal function made clinicians initiate a more active treatment of renal function or use more protective measures. Altered renal function did not lead to dialysis dependency in this study. A decline in renal function often happens after FEVAR and age is an independent risk factor of long term decline in renal function after FEVAR. Special care should be taken in those with already borderline renal function.[12,23,24]

A relatively higher (non-significant) number of endoleaks was seen in the octogenarian group. As higher age involves greater peri-operative risk, it is possible that the treatment of octogenarian patients was done preferably with an endovascular approach over open surgical repair, despite more challenging anatomy, consequently leading to a slightly higher number of type I endoleaks. It seems that there is no other clear reason why there were more endoleaks in the octogenarian group.

CONCLUSIONS AND RELEVANCE

The treatment of patients with a complex abdominal aortic aneurysm will include more elderly people owing to the increasing longevity of the population. In the elderly particularly, survival rates after treatment with fenestrated endografts will remain part of the discussion, but age itself is not a reason to refuse treatment. The choice of treatment should be weighed by all comorbidities and the preference of the patient.

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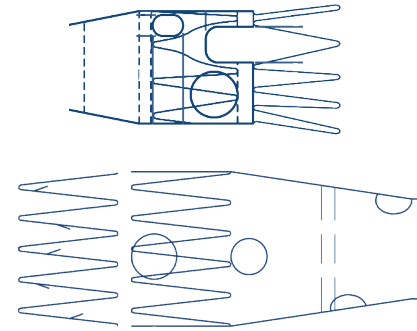
CHAPTER 6

Fenestrated stent-grafts for salvage of prior endovascular abdominal aortic aneurysm repair



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European Journal of Vascular and Endovascular Surgery

2013 Jul;46(1):49-56

ABSTRACT

Objectives: To review our experience with fenestrated endovascular aneurysm repair (FEVAR) to treat complications after previous standard infrarenal endovascular aneurysm repair (EVAR).

Methods: A prospectively maintained database including all consecutive patients with juxtarenal abdominal aortic aneurysm that were treated with FEVAR after failed previous EVAR within the period March 2002 to November 2012 at the University Medical Center of Groningen, Netherlands (up to October 2009), and the Klinikum Nürnberg Süd, Germany (from November 2009) was analyzed. Evaluated outcomes included initial technical success, operative mortality and morbidity, and late procedure-related events with regard to survival, target vessel patency, endoleak, renal function, and reintervention.

Results: A total of 26 patients (24 male, mean age 73.2 ± 6.5 years) were treated. All patients had proximal anatomies precluding endovascular reintervention with standard techniques. In 23 patients a fenestrated proximal cuff was used, and in three patients a bifurcated fenestrated stent-graft. Technical success was achieved in 24 (92.3%) patients. One patient required on-table open conversion because of impossibility to retrieve the top cap as a result of twist of the ipsilateral limb. In the second patient the right kidney was lost due to inadvertent stenting in a smaller branch of the renal artery. Catheterization difficulties, all related to the passage through the limbs or struts of the previous stent-graft, were encountered in 11 (42.3%) cases, including five (19.2%) patients with iliac access problems and six (23.1%) with challenging renal catheterization. Operative target vessel perfusion success rate was 94.6% (70/74). Operative mortality was 0%. Mean follow-up was 26.8 ± 28.5 months. No proximal type I endoleak was present on first postoperative CTA. The mean aneurysm maximal diameter decreased from 73 ± 20 mm to 66.7 ± 21 mm ($p < .05$). There were six late deaths, one of them aneurysm related. Estimated survival rates at 1 and 2 years were 94.1 ± 5.7% and 87.4 ± 8.4%, respectively. Patency during follow-up for the target vessels treated successfully with a fenestrated stent-graft was 100% (70/70). Reintervention was required in four cases, including one acute conversion due to rupture, one for iliac limb occlusion and two for type Ib and II endoleak. Renal function deterioration was observed solely in the two cases of primary technical failure.

Conclusions: FEVAR represents a feasible option for the repair of juxtarenal abdominal aortic aneurysm after prior EVAR failure. It is advantageous in terms of mortality and less morbid than open surgery, but is associated with increased technical challenges because of the previously placed stent-graft. Outcome seems related to initial technical success.

INTRODUCTION

Proximal type I endoleak is the most feared complication after standard endovascular aneurysm repair (EVAR) during follow-up. Inadequate proximal sealing may result from poor indication or planning (too short neck, undersized stent-graft, low deployment of stent-graft), postoperative stent-graft migration, and extension of aneurysmal degeneration during follow-up. Proximal type I endoleak is associated with an increased risk for aneurysm rupture, thus treatment is strongly advocated.[1,2] In the presence of a suitable infrarenal neck an additional proximal endovascular stent-graft (i.e., cuff) can be used. In unfavorable anatomy, other options such as extensive coiling or conversion to open repair have been used.[3] Reports of coiling for proximal type I endoleak are scarce and indicate suboptimal efficacy.[4] Conversion to open surgery is invasive and often technically challenging, resulting in higher mortality and morbidity.[5]

Fenestrated endovascular aneurysm repair (FEVAR) is now an established technique for treatment of short-necked and pararenal aneurysms, with excellent early and mid-term outcomes.[6-8] FEVAR has also been used to repair type I endoleak after previous EVAR, with initial experience published.[9] However, no larger series or follow-up reports have been published. In the present paper, we report the mid-term outcomes of FEVAR after failed standard EVAR in 26 consecutive patients.

PATIENTS AND METHODS

All consecutive patients with juxtarenal abdominal aortic aneurysm (AAA) treated with FEVAR after failed previous EVAR within the period March 2002 to November 2012 under the supervision of the senior author were included in this study. Data were prospectively collected. The study was approved by our institution's ethical committee and all patients provided their informed consent.

Aneurysm morphology was assessed by thin cut (≤ 1.5 mm) spiral computerized tomography angiography (CTA) with axial and coronal reconstructions. Digital subtraction angiography (DSA) was also performed preoperatively when deemed necessary. Infrarenal neck length (H1) was defined as the distance between the lowest renal artery (regardless of supra- or infrarenal fixation), to the beginning of diseased, dilated aorta. The physical status of all patients was assessed preoperatively with the American Society of Anesthesiologists (ASA) score.

Fenestrated stent-grafts were customized based on the Cook Zenith system (William A. Cook Australia, Ltd., Brisbane, Australia) according to preoperative measurements to fit fenestrations and/or scallops for the visceral vessels. Stent-grafts were oversized by 10-15%. Three types of fenestrated stentgrafts were used depending on the aortic anatomy. A fenestrated cuff was utilized if distal sealing could be achieved within the body of the pre-existing stent- graft. In cases where distal landing in the iliac arteries was deemed necessary, a bifurcated fenestrated graft (with a contralateral iliac limb) was initially used, and thereafter a composite stent-graft (fenestrated tube + bifurcated graft with contralateral limb) that became later available.

The procedures were performed either in the operating theatre using a mobile C-arm (OEM 9800, General Electric Medical Systems, Salt Lake City, UT, USA, and Arcadis Avantic, Siemens AG, Forchheim, Germany) or (later) in a hybrid operating room (OR) with a fixed C-arm system (Artis Zeego, Siemens AG, Forchheim, Germany). The operation was carried out under general, epidural, or local anesthesia according to surgeon, anesthesiologist, and patient preferences.[7,8] The stent-graft deployment technique has been previously described in detail.[8] Technical success was defined as an endovascularly completed procedure with absence of type I or III endoleak and patent target vessels.

Postoperatively, patients were evaluated with clinical and laboratory examination prior to discharge along with CTA at 1 month, 1 year, and annually thereafter. Upon suspicion of endoleak or branch vessel malperfusion, additional DSA for further evaluation and possible reintervention was carried out. Pre- and postoperative renal function was monitored by serum creatinine and estimated glomerular filtration rate (eGFR) measurement.

Data analysis

SPSS for Windows (version 17.0; SPSS Inc, Chicago, IL, USA) was used for statistical analysis. Variables are presented as mean standard deviation (SD) in case of normal distri- bution, and median plus range if data had a skewed dis- tribution. Statistical significance was taken at $p < .05$. Analyzed outcomes included technical success, operative mortality and morbidity, and late-procedure-related events with regard to target vessel patency, endoleak, renal func- tion, and reintervention. Survival and reinterventions during follow-up were subjected to Kaplan-Meier analysis.

RESULTS

Patients

A total of 26 patients (24 male, two female; mean age mean age 73.2 6.5 years) were treated with FEVAR after previous failed EVAR. Eighteen (69.2%) patients were classified as ASA III and eight (30.8%) patients as ASA II. Mean pre-operative eGFR was 60.3 ± 17.9 mL/min/1.73 m^2, with nine (34.6%) patients having an eGFR<60 mL/min/1.73 m^2. Mean preoperative serum creatinine was 112.3 ± 36 mmol/ L. Patient comorbidities and risk factors are listed in Table 1.

Table 1. Preoperative patient characteristics.

Comorbidity risk factor	Patients, n (%)
CAD	19 (73)
Hypertension	19 (73)
COPD	7 (27)
Smoking (current or past)	15 (58)
Diabetes mellitus	5 (19)
Hypercholesterolemia	18 (69)
Serum creatinine>100 µmol/L	12 (46)
Previous stroke/TIA	3 (11.5)
Hostile abdomen	6 (23)
ASA III	18 (69)

CAD = coronary artery disease; COPD = chronic obstructive pulmonary disease; TIA = transient ischemic attack; ASA = American Society of Anesthesiologists.

Previous stent-grafts and current aneurysm characteristics

Median time interval from previous EVAR to FEVAR was 41 months (range, 3-152 months). Ten (38.5%) patients had their previous EVAR in the centers of this study and 16 (61.5%) patients were referred from elsewhere. All initially implanted stent-grafts were bifurcated. Nine (34.6%) patients were previously treated with a Zenith stent-graft (Cook Inc, Bloomington, IN, USA), seven (26.9%) with a Powerlink stent-graft (Endologix, Irvine, CA, USA), five (19.2%) with a Talent (Medtronic World Medical, Sunrise, FL, USA), two (7.7%) with an Anaconda (Vascutek, Inchinnan, UK), two (7.7%) with an Excluder (W.L. Gore & Associates, Flagstaff, AZ, USA), and one (3.8%) with a Vanguard stent-graft (Boston Scientific,

St Quentin-en- Yvelines Cedex, France). Mean maximal AAA diameter was 73 ± 20 mm. Mean infrarenal aortic neck length (H1) before current FEVAR procedure was 4.3 ± 4.1 mm, ranging from 0 mm to 10 mm. Mean proximal neck diameter was increased from 24.3 ± 3.2 mm before the initial EVAR to 26.2 ± 3.7 mm before the current FEVAR procedure ($p < .05$). Twenty-five patients had a proximal type I endoleak and/or migration. One patient had aneurysm growth without manifest endoleak (endotension) but only a minimal sealing zone length. Table 2 shows the postulated causes for initial EVAR failure.

Table 2. Possible causes for endovascular aortic aneurysm repair (EVAR) failure in the 26 patients.

Reason for EVAR failure	*n*	%
Low initial stent-graft placement	7	27
Stent-graft migration	6	23
Extension of disease	6	23
Short initial necka	5	19
Undersized initial stent-graft	2	8

[a] Refers to the neck length before the first EVAR procedure and was defined as length <10 mm.

Devices

In 23 (88.5%) patients a fenestrated proximal cuff was used, in two (7.7%) patients a bifurcated fenestrated stent-graft and in one (3.8%) patient a composite bifurcated configuration. The two bifurcated stent-grafts featured a bifurcation with an internal limb (i.e., limb inside the tube, Figure 1) to accommodate the shorter "working" length inside the main body of the pre-existing stent-graft.[9] The total number of fenestrations/scallops was 74, including 49 renal artery, 21 superior mesenteric artery (SMA), and four celiac artery (CA) fenestrations (Table 3). In 18 (69.2%) patients a stent-graft targeting renal arteries and the SMA was used, with the most common combination (16 patients) being two small fenestrations for the renal arteries and a scallop for the SMA. A four-fenestration device with three small fenestrations for the renal arteries and the SMA, and a scallop for the CA was implanted in three (11.5%) patients. A two-fenestration stent-graft was used in three (11.5%) patients and a stent-graft with one fenestration in two (7.7%) patients. Target vessels were secured with balloon expandable Advanta V12 covered stents (Atrium Europe, Manchester, UK) in 24

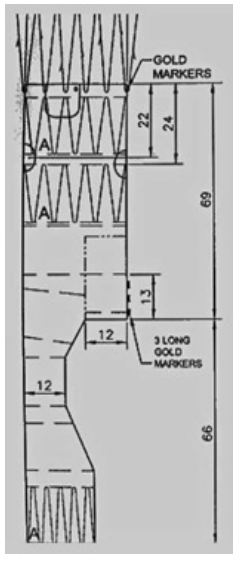


Figure 1. Bifurcated fenestrated stent-graft featuring an internal limb in order to be accommodated in the limited working length within the pre-existing stent-graft.

Table 3. Fenestration type and target vessel distribution incorporated in the fenestrated stent-graft.

Target vessel	Fenestration type		Total
	Small fenestration	Scallop	
Right renal artery	20	4	24
Left renal artery	23	2	25
SMA	4	17	21
CA	0	4	4
Total	47	27	74

SMA = superior mesenteric artery; CA = celiac artery.

patients, Genesis balloon expandable stents (Cordis Corporation, Miami Lakes, FL, USA), and Bridge renal bare stents (Medtronic AVE Inc., Santa Rosa, CA, USA) in one patient each.

Operative details

All procedures were performed through bilateral femoral access. Target vessels were catheterized from below with the standard technique, through separate 5F sheaths inserted in the valve leafs of a large 20F sheath via contralateral femoral

access. In 23 patients (88.5%) the procedure was performed under general anesthesia, in two (7.7%) patients under epidural anesthesia, and in one (3.8%) patient under local anesthesia. Median operative time was 150 min (range, 85-540 min) and median estimated blood loss (EBL) was 200 mL (range, 90-3000 mL). Median fluoroscopy time was 30 min (range, 5-85 min) and mean iodinated contrast volume used 149.4 ± 33 mL. Thirteen (50%) procedures were performed with a mobile C-arm and 13 (50%) in a hybrid OR with a fixed C-arm system.

Technical success and intraoperative technical issues

Technical success was achieved in 24 (92.3%) patients. In two patients the procedure was not successful. One patient underwent intraoperative open conversion. Repositioning maneuvers to reorient the bifurcated fenestrated stent-graft caused twisting of the ipsilateral limb, which made it impossible to retrieve the top cap. Additional manipulations to retrieve the top cap resulted in crushing of both renal stents, which prompted acute conversion. In the second patient, the right renal artery was not correctly catheterized, resulting in deployment of the covered stent in a branch of the main renal artery with kidney loss. Operative target vessel perfusion success rate was 94.6% (70/74).

In 11 (42.3%) patients, iliac and renal artery access proved difficult. In five (19.2%) patients iliac access through the previous stent-graft was tedious and caused some dislodgment of the pre-existing stent-graft and alterations in the available working length. In one of these patients the iliac limb of the previous stent-graft (Vanguard) was dislocated during the insertion of the contralateral limb of the bifurcated fenestrated stent-graft and was repaired with a bridging stent-graft. In a second patient previous stent-graft dislodgment resulted in inadequate overlap between the body of the pre-existing stent-graft and the fenestrated cuff, which led to the use of an extra aortic cuff (Zenith TX2 TAA, ESBE-30-80-T endovascular graft distal extension [William A. Cook Europe, Bjaeverskov, Denmark]). In six (23.1%) patients renal artery access was tedious. In five (19.2%) patients renal artery wire catheterization was initially feasible, but subsequently the catheter and/or the guiding sheath could not be advanced over the wire because of interference with a suprarenal stent-strut of the previous stent-graft. Therefore the wire was retrieved and a new catheterization attempted aiming to find another entry hole, which finally allowed the catheter and guiding sheath to follow the wire. In the sixth patient with a Powerlink stent-graft and two additional suprarenal proximal cuffs and two Palmaz stents (Cordis Corporation, Bridgewater, NJ, USA), both renal arteries were catheterized and the Palmaz stent struts dilated in a separate procedure in order to ensure subsequent catheterization of the renal arteries, as

reported earlier.[10]

Postoperative mortality and morbidity

There was no surgical mortality. Major complications occurred in two (7.7%) patients. The patient that had undergone open conversion developed respiratory insufficiency and renal function deterioration requiring an intensive care unit stay for 8 days and prolonged hospital stay. He was finally discharged in good condition but with impaired renal function (20% eGFR decrease), which returned to preoperative levels 6 months later. The patient in whom we lost the right kidney due to a technical error required permanent dialysis 1 month after the procedure as the left kidney preoperatively had a diminished function. Four (15.4%) patients suffered minor complications, including one retroperitoneal hematoma (conservative treatment), one bilateral renal hematoma, and two cases of urinary

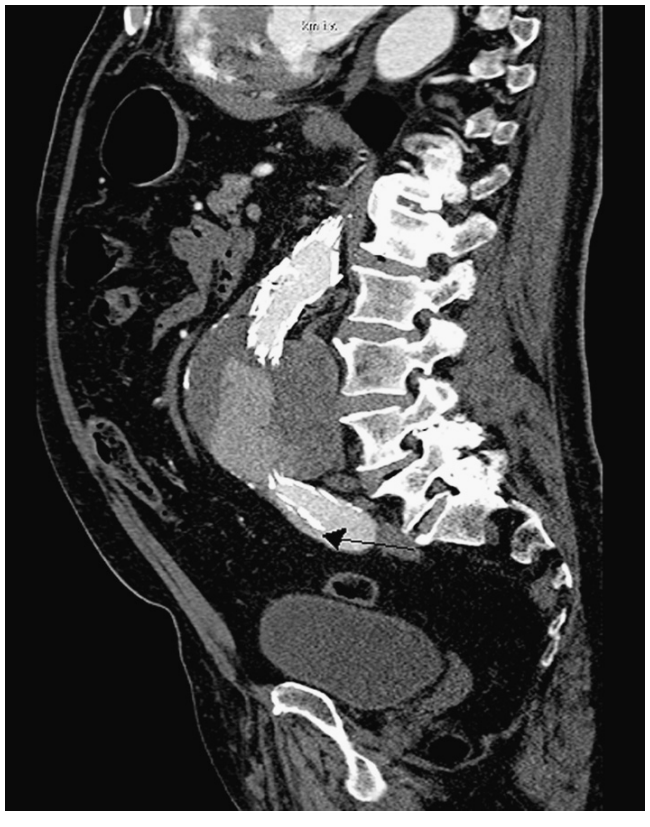
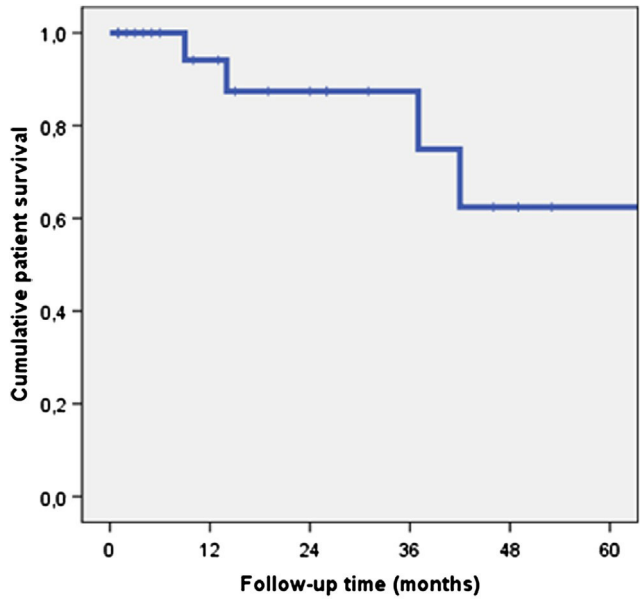


Figure 2. Computed tomography angiography demonstrating type Ib endoleak due to inadequate iliac graft limb wall apposition. This patient suffered a contained rupture and underwent acute conversion.

retention. Median hospital stay was 6 days (range, 3-22 days).

Follow-up

Mean follow-up was 26.8 ± 28.5 months. One patient was lost to follow-up after 18 months due to old age and poor general condition. All-cause late mortality was six patients, five of them aneurysm unrelated. One patient died after open conversion for contained aneurysm rupture 9 months after the FEVAR procedure. This 86-year-old patient had an unremarkable imaging follow-up, up to 7 months after the procedure, but was admitted to another hospital with a symptomatic aneurysm and a large type Ib endoleak (Figure 2). The patient collapsed 3 hours after admission and was treated urgently with open conversion, but died from complications 3 days after the procedure. Figure 3 demonstrates the cumulative survival curve as estimated with Kaplan-Meier analysis. Estimated survival rates were 94.1 ± 5.7 and 87.4 ± 8.4% at 1 and 2 years, respectively. Target vessel patency for the branches treated successfully with a fenestrated stent-graft was

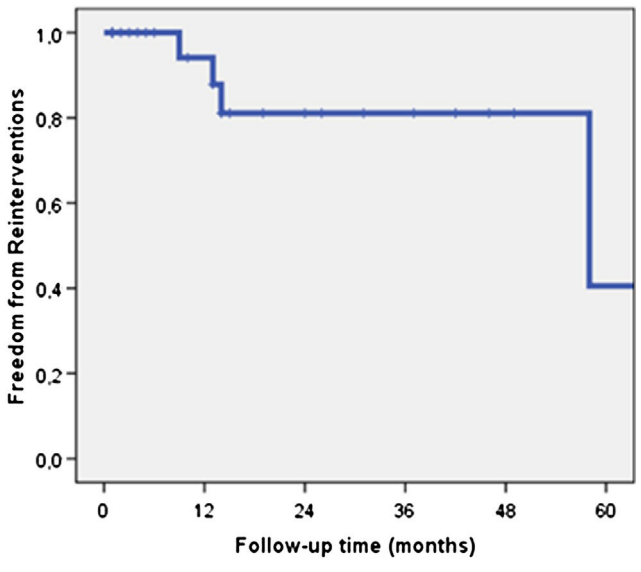


Time (months)	12	24	36	48	60
Number at risk	15	11	7	4	2
Standard Error	0.057	0.084	0.084	0.16	0.16

Figure 3. Kaplan-Meier estimate of the cumulative overall patient survival for all-cause mortality during follow-up.

100% (70/70). Mean aneurysm maximal diameter decreased from 73 ± 20 to 66.7 ± 21 mm ($p < .05$). Renal function during follow-up remained unchanged in 24 patients (92.3%). The two patients with renal function problems have been described above.

During follow-up, major complications occurred in five (19.2%) patients and reintervention was required in four (15.4%) cases. The case of rupture requiring acute conversion has been described above. Two patients had an iliac limb occlusion. One iliac limb occlusion was diagnosed 3 years postoperatively in the patient with the intra-operatively dislocated Vanguard limb and was left untreated since it was asymptomatic. The second iliac limb occlusion was diagnosed in conjunction with a disconnected left iliac limb 6 years after the FEVAR procedure and was treated with an aorto-uni-iliac stent-graft and a femoro-femoral bypass graft. A fourth patient developed a type Ib endoleak, which was treated with internal iliac artery embolization and limb graft extension to the external iliac artery. Finally, one more patient required reintervention due to persistent type II endoleak. Figure 4 demonstrates the estimated cumulative freedom from reinterventions during follow-up.



Time (months)	12	24	36	48	60
Number at risk	15	9	6	3	1
Standard Error	0.057	0.09	0.09	0.1	0.3

Figure 4. Kaplan-Meier estimate of freedom from reinterventions during follow-up.

DISCUSSION

Open surgical repair of short necked and pararenal AAA is challenging and often requires suprarenal clamping and renal artery revascularization, which can increase mortality and morbidity rates.[11,12] The presence of a stent-graft, especially if with suprarenal fixation, poses additional surgical difficulties and leads to significant increase in perioperative mortality and morbidity because of the risk of visceral aortic segment damage during stent-graft explantation.[5,13-15] In a recent series, operative mortality and morbidity of elective open conversion after EVAR reached 8.8% and 65%, respectively.[13] Whereas distal complications after previous EVAR can easily be treated with endovascular techniques, a complication at the proximal sealing site is more tedious to repair, especially if a proximal neck is missing. In such cases FEVAR could be the best option. The present series suggests that FEVAR can indeed offer a safe and effective alternative treatment to open conversion after failed EVAR. Despite the high-risk profile of our patient cohort, operative mortality was zero. Perioperative morbidity in the patients treated successfully was low, allowing for short hospital stay and prompt return to normal activity. Target vessel patency remained high during follow-up and so was the freedom from reintervention. This is the largest study in the literature reporting FEVAR for prior EVAR salvage in patients with juxtarenal AAA. Apart from our earlier report,[9] there is one additional paper, describing successful FEVAR following EVAR in three patients.[16]

As shown in Table 2, the reasons for failure of the initial EVAR procedure were related to poor indication, or too low positioning of the stent-graft to start with, or due to migration or extension of disease at a later stage. Short proximal neck (<10 mm) in particular and extension of disease in relatively short necks (10-15 mm) was the main reason of EVAR failure in our patients. Treating short neck AAA with standard EVAR will achieve initial sealing in most cases, as reported in the literature. However, longer term data are often poor and underreported. In addition, most articles that report good results of EVAR in short necks do include limited patient cohorts with mixed adverse neck characteristics. Moreover, there are multiple reports that underline the higher perioperative mortality and morbidity and increased proximal endoleak rates of standard EVAR in short-neck AAA.[17] Theoretically, many of our patients would have been better treated initially with FEVAR; however, this was commonly unavailable at the time (late 1990s) at the center of initial EVAR operation.

Migration accounted for 23% of prior EVAR failures. Interestingly, 62% of the pre-existing stent-grafts in our patients had a design that is expected to diminish the risk of migration, either by suprarenal fixation (e.g., Zenith), or by enabling device accommodation on the aortic bifurcation (e.g., Powerlink). These data, however, more likely represent a selection bias and do not necessarily reflect the performance of the different stent-graft types with regard to migration resistance. Migration resistance has been previously studied and is beyond the scope of the present paper.[18]

Despite the high technical success and target vessel preservation rates observed in this series, a number of technical difficulties should be reported and taken into account before attempting this technique. One case required acute conversion, since we were unable to retrieve the top cap due to twisting of the iliac limb. This occurred in a bifurcated fenestrated stent-graft after extensive reorientation. By paying more attention to the deployment of the limb we could have untwisted the limb and probably avoided the conversion. The potential problem of a twisted limb was quickly addressed by the company in changing towards a composite system consisting of a fenestrated tube, followed by a bifurcated graft and a contralateral limb. In case of FEVAR after EVAR, however, a composite system is usually not applicable because of shorter “working” length within the body of the previous stent-graft. This often prompted us to use a fenestrated tube (i.e., cuff) only (Figure 5). A fenestrated cuff only seems to be a reasonable option in these cases although one could argue that more stability would be achieved with a complete relining (cuff + bifurcated + contralateral limb). In the current series, fenestrated cuffs only were used in 88.5% of the cases. No migration or disconnection was noticed during follow-up. Additional surveillance is needed in order to prove long-term durability of such a configuration.

Access difficulties have also to be expected due to the presence of an earlier stent-graft. Although technical tricks including buddy wires, manual compression or stabilization of the stent-graft with a balloon can be helpful, and all were used when needed, the risk of dislodging a stent-graft component is inherent.

Changing the position of the previous stent-graft can result either in inadequate overlap between the pre-existing and the current fenestrated stent-graft, or in a shorter than estimated working length. In the latter case one can attempt to pull the previous stent-graft down again using a compliant balloon through the contra-lateral limb. A particular problem occurs in patients previously treated with a Powerlink stent-graft. This graft features the stent on the inside of the

Figure 5. Computed tomography angiography with three-dimensional volume rendering technique demonstrating a fenestrated cuff with two small fenestrations (renal arteries) and a scallop (superior mesenteric artery) deployed within the pre-existing Powerlink stent-graft (Endologix, Irvine, CA, USA).

graft, without complete attachment. This allows enough room for a guidewire to be trapped between the graft and the struts, which can cause serious problems with wire access, especially in angulated anatomy. To make sure that the wire is not trapped behind a strut we routinely pass an inflated angioplasty balloon over the guide wire before inserting and deploying the device.

Renal artery catheterization can similarly be more demanding when performed within already implanted stent-grafts. Poorer image quality and visualization of the fenestrations due to overlapping stent-grafts, and restrictions during catheter and guiding sheaths movements have to be expected due to interference with the already placed stent-grafts. The struts of the suprarenal uncovered part of the initial stent-graft that crosses the renal arteries can also cause problems. In five (19%) cases we had to recatheterize the artery until we found the best entry (i.e., the biggest gap between wall and a crossing strut). In one patient initially treated with a Powerlink stent-graft, with two proximal cuffs with suprarenal fixation and two Palmaz stents placed over the renal arteries, we decided to first catheterize and dilate the Palmaz stent struts across the renal orifices in order to ensure renal catheterization during the FEVAR procedure.[10] All these additional technical challenges make the procedure more difficult than standard FEVAR in a native aorta.

Highest possible image quality is of utmost importance in such cases, to enable visualization of the radiopaque markers inside the previous stent-graft and allow for cath- eterization of the fenestrations and target vessels. Exact positioning of the bridging stent-grafts with correct pro-trusion into the main stent-graft also requires the highest quality of fluoroscopy. In our experience a hybrid suite with a fixed C-arm system is indispensable to address such complex cases. Not only the better image quality, but also the ease of use in terms of ergonomics and three-dimensional fusion options helps achieve success in these cases.

During follow-up, one aneurysm-related death occurred. This 86-year-old patient was treated with a fenestrated cuff 12 years after the initial EVAR because of proximal extension of disease. Seven months after the procedure the patient was admitted with a symptomatic aneurysm due to a large distal type Ib endoleak (Figure 2). Unfortunately, rupture occurred within 3 hours, resulting in an acute open conversion. In retrospect, it would have been better to extend the iliac graft limb to seal the massive endoleak. Overall, late complications during follow-up occurred in 19.2%, delineating the need for close long-term surveillance of these patients.

An alternative endovascular treatment for selected patients with proximal type I endoleak could potentially be the stabilization of the previous stent-graft with endoanchors (HeliFX, Aptus Endosystems Inc., Sunnyvale, CA, USA). The latter have already been used successfully, most commonly combined with implantation of a proximal cuff in patients with adequate infrarenal neck length.[19] Our patient cohort, however, was not appropriate for such a combined procedure (proximal cuff + endostapling) because of very short or no proximal neck.

This study has some limitations and its outcomes should be carefully interpreted. The presented results originate from selected patients and do not represent outcomes on consecutive patients with failed EVAR. During the study period, we also treated a number of patients with open conversion and standard cuffs when a sufficient neck was still present. The referral bias should be also noted, as we do get the patients referred from other hospitals when a standard option (cuff or conversion) is not considered anymore. Finally, this study reflects the outcomes of two high-volume referral centers for FEVAR. Thus, reproducibility of similar good results in a wider scale including less experienced institutions may be questionable.

CONCLUSION

Our results indicate that FEVAR should be considered to treat patients with proximal complications after EVAR when an adequate infrarenal neck is not present anymore. If technically successful, FEVAR after EVAR clearly represents a less morbid alternative to open conversion. However, increased technical difficulties due to the pre-existing stent-graft have to be expected, both with planning and execution of the procedure. Technical failure leads to worse outcome.

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CHAPTER 7

Treatment of aortoiliac aneurysms: compatibility of the E-liac stent-graft (Artivion®, Iliac Branch Device) with Endurant II or IIs (Medtronic®, EVAR)

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CardioVascular and Interventional Radiology

2023 Feb;46(2):187-193

ABSTRACT

Purpose: Iliac branch devices (IBD) are widely used to treat aortoiliac aneurysms with an unfit distal landing zone for standard endovascular aneurysm repair (EVAR). The aim of this retrospective study was to examine the treatment of aortoiliac aneurysms with the combination of the Endurant II(s) stent-graft system (Medtronic®) and the E-liac stent-graft (Artivion®).

Materials and Methods: Data of all patients who underwent an EVAR combined with unilateral or bilateral IBD between January 2015 and January 2020 were analyzed. Primary outcomes were technical success at implantation (successful EVAR with IBD extension placement and patency of the grafts without type 1 or type 3 endoleak), and type 1b/3 endoleak, hypogastric artery patency and IBD-related reinterventions during follow-up. Secondary outcomes were all type 1 endoleak, all reinterventions, rupture, and mortality during follow-up.

Results: A total of 38 patients were treated with a combination of EVAR with IBD. Technical success was 94.7% (n = 36/38). The 30-day survival was 100%. Median follow-up time was 31 months (range 8–56). During follow- up, no patients developed type 1b or type 3 endoleak and all hypogastric arteries at the side of IBD remained patent. The overall reintervention rate at 12 months follow-up was 5.3% (n = 2/38) and the IBD-related reintervention rate was 2.6% (n = 1/38).

Conclusion: The combination of the Endurant II(s) and the E-liac stent-graft system is an effective and safe procedure for patients with an aortoiliac aneurysm. We confirm the high hypogastric artery patency rate using IBD. Furthermore, these devices have a high technical success rate even when it is combined with an Endurant II(s) EVAR main body.

INTRODUCTION

In patients with an abdominal aortic aneurysm (AAA), concomitant common iliac artery (CIA) dilatation or aneurysm is present in 20–40% of cases.[1] The treatment of aortoiliac aneurysms remains challenging using conventional endovascular aneurysm repair (EVAR) to achieve effective distal sealing. Various successful techniques are described in the literature to deal with this unfit distal landing zone.

One of the proposed solutions for sufficient distal sealing in an aneurysmal CIA is the use of flared limbs, also known as the bellbottom technique.[2] An important disadvantage of using bellbottom technique is the risk of type 1b endoleak (EL). Higher iliac limb reintervention rates have been reported with the use of flared iliac limbs.[3]

Another option includes endovascular coiling of the hypogastric artery with extension of the endoprosthesis into the external iliac artery (EIA).[4] Although this may seem a relatively simple solution, it increases the risk of pelvic ischemic complications including primarily buttock claudication and erectile dysfunction up to respectively 27% and 10%. [4, 5] In more severe cases, occluding the internal iliac artery can result in colon ischemia, perineal necrosis and spinal cord dysfunction.[6] The European Society of Vascular Surgery (ESVS) guidelines recommend preserving blood flow to at least one internal iliac artery during the repair of iliac artery aneurysms to reduce this risk of these pelvic ischemic complications.[7]

Since recent years, the endovascular repair of aortoiliac aneurysms has evolved to the use of iliac branch devices (IBD) to have a suitable distal landing site while main- taining patency of the hypogastric artery with high clinical and technical success rates.[8] One of these devices is the E-liac stent-graft System (Artivion® GmbH, Hechingen, Germany) that has received CE approval in 2014 for the treatment of iliac artery aneurysms. This system showed promising results at 12 months follow-up of the PLIANT study with a device-related reintervention rate of 5% and primary hypogastric artery patency rate of 98%.[9]

In our center we routinely use the Endurant II(s) stent-graft system (Medtronic® Vascular, Inc, Minneapolis, Minnesota, USA) in conventional EVAR for its reliability, trackability and flexibility. The Endurant II(s) is one of the most widely used commercially available endoprosthesis due to its clinical experience and

excellent clinical outcomes.[10] When looking for solutions for the distal sealing zone in dilated iliac arteries, we chose to hold on to the experience we had with Endurant II(s) and combine it with the E-liac stent-graft in patients with aortoiliac aneurysms. The aim of this study was to assess the compatibility between the widely used Endurant II(s) stent-graft system and the E-liac stent-graft in patients with aortoiliac aneurysms.

MATERIALS AND METHODS

Study Design and Patients

A single-center retrospective cohort study was conducted. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013) and was approved by the local Medical Ethics Review Committee Individual consent for this retrospective analysis was waived. We followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement guidelines for observational studies.[11] Clinical data was retrospectively analyzed of all patients with aortoiliac aneurysms who underwent an EVAR (Endurant II(s), Medtronic®) combined with unilateral or bilateral IBD (E-liac, Artivion®) between January 2015 and January 2020. EVAR with IBD extension was indicated for male patients with AAA 55 mm in diameter and female patients with AAA ≥ 50 mm who had unilateral/bilateral CIA of ≥ 25 mm in diameter; or patients with unilateral/bilateral CIA of ≥ 35mm in diameter in the absence of a proximal CIA sealing zone. Patients were excluded if they received an IBD extension after open repair or EVAR in the past, only an isolated IBD was implanted, or if they had symptomatic or ruptured aneurysms.

The following data was extracted from the electronic patient records: (1) demographic characteristics including age, gender, BMI and comorbidities (i.e., ASA grade, history of ischemic heart disease, diabetes and chronic lung or kidney disease), (2) aneurysm characteristics (diameters measured on preoperative CT), (3) procedure-related characteristics, and (4) postoperative complications including endoleak, patency, reintervention, rupture and mortality.

Technical success was defined as EVAR with IBD extension placement and patency of the grafts without type 1 or type 3 endoleak at implantation, within 24 h after the procedure. Primary outcome measures were technical success, type 1b and 3 endoleak, IBD-related reinterventions and patency of the stent-grafts. Secondary outcomes were all type 1 endoleak, all reinterventions, rupture and mortality during follow-up.

Surgical Procedure/Intervention

Before surgery, all patients had their pre-operative planning based on contrast-enhanced CT. All procedures were performed under general anesthesia and under fluoroscopic guidance. At the end of the procedure, a completion angiography was performed to confirm the patency of the stent-grafts and successful exclusion of the aneurysm without type 1 or type 3 endoleak (Figure 1).

Postoperative Care and Management

Clinical evaluation and aortoiliac contrast-enhanced CT imaging was obtained at 6 weeks follow-up. After 6 months and 12 months clinical evaluation and imaging was repeated, where the choice of imaging (duplex ultrasound or CT) was at the physician's discretion. When the duplex ultrasound exam was inconclusive or showed progression of the diameter of the aneurysm sac, a contrast-enhanced CT imaging was repeated. There were no patients lost to follow-up.

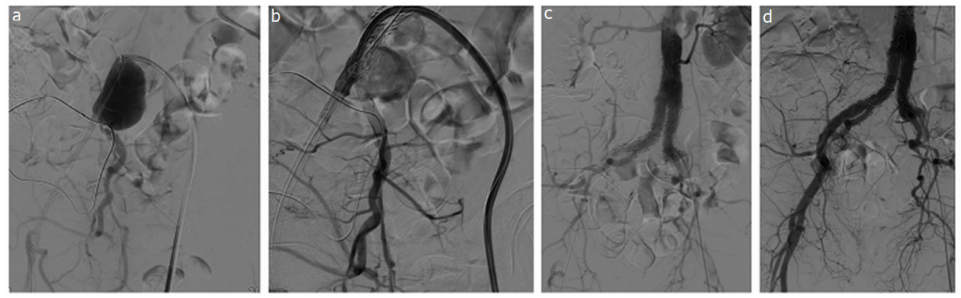

Figure 1. Treatment of aortoiliac aneurysm with the use of endovascular aneurysm repair and iliac branch device (IBD) with no endoleaks on the completion angiogram. **a** Preoperative angiography showing a large right common iliac artery aneurysm. **b** Placement of iliac branched device in the right iliac bifurcation. **c** and **d** Angiography at the end of the procedure (EVAR with right IBD) with successful exclusion of the aneurysm, patent bilateral hypogastric artery and no signs of endoleak.

Symptoms of hypogastric artery occlusion (e.g., intermittent buttock claudication or new onset erectile dysfunction) were reported in the patient electronic record. The diameter of the aneurysm sac, the patency of the hypogastric artery and the presence of endoleak type 1 or type 3 were determined based on the imaging results.

Statistical Analysis

Categorical variables were presented as frequency and percentage. Continuous variables were presented as mean and standard deviation or as median and interquartile range in the presence of skewness. Normality was evaluated by the Shapiro–Wilk test in conjunction with visual assessment of normal-probability plots. Missing data was reported as such. The Kaplan–Meier method was used to calculate freedom from reintervention. Statistical analyses were performed using SPSS (SPSS for Windows version 27.0, SPSS Inc, Chicago, Illinois, USA)

RESULTS

Preoperative Characteristics

Table 1 reports the baseline characteristics for a total of 38 patients, who were treated with an EVAR-IBD procedure for their aortoiliac aneurysms. Patients had a mean age of 69 years (± 7 SD), 37 patients were male (97.4%) and the mean BMI was 28.1 kg/m^2 (± 4.3 SD). Regarding comorbidities, history of ischemic heart disease, chronic lung disease and chronic kidney disease (GFR < 60 mL/min) was present in respectively 10 (26.3%), 13 (34.2%) and 3 patients (7.9%). Additionally, 6 patients (15.8%) had diabetes mellitus type 2, and 16 patients (42.1%) were active smokers or had quit less than a month before the procedure.

Of all patients, 11 patients were diagnosed with an aortoiliac aneurysm with AAA diameter ≥ 50 mm and CIA diameter ≥ 35 mm. Seventeen patients had an abdominal aortic aneurysm ≥ 50 mm in diameter with an unfit distal landing zone (CIA diameter ≥ 25 mm). Ten patients had an isolated CIA aneurysm (diameter ≥ 35 mm) in which a suitable proximal CIA sealing zone was absent. The median AAA diameter was 55 mm (IQR 43, 59). The median diameters of the CIA, EIA and hypogastric artery at the side of the implanted IBD were respectively 34 mm (IQR 26, 38), 10 mm (IQR 9, 12) and 9 mm (IQR 8, 10).

Procedure-Related Characteristics

Table 2 presents the surgery characteristics. A total of 50 hypogastric arteries were treated with an IBD. Bilateral IBDs were implanted in 12 patients, 26 patients received an unilateral IBD: eleven patients on the right side and 15 patients on the left side. The E-Ventus BX stent-graft (Artivion®) was used as extension in the hypogastric artery in 47 IBDs. In 3 cases the Advanta V12 Balloon Expandable Covered Stent (Getinge®) was used. As bridging stent an Endurant limb (Medtronic®) was implanted to connect to 49 IBDs. One patient received a bridging stent of Artivion®.

Table 1. Baseline characteristics.

Characteristics	N	
Age (years)[a]	38	69 ± 7 (53–82)
Male gender	38	37 (97.4%)
BMI (kg/m2)[a]	38	28.1 ± 4.3 (17.6–37.3)
ASA grade	38	
2		19 (50.0%)
3		19 (50.0%)
Active smoker or<1 month ago	38	16 (42.1%)
Comorbidities	38	
Diabetes mellitus type 2		6 (15.8%)
Ischemic heart disease		10 (26.3%)
Chronic lung disease (asthma, COPD)		13 (34.2%)
Chronic kidney disease (GFR<60 mL/min)		3 (7.9%)
Aneurysm characteristics		
AAA diameter (mm)[b]	38	55 ± 17 (24–71)
CIA diameter at side of IBD (mm)[b]	50	34 ± 12 (23–65)
EIA diameter at side of IBD (mm)[b]	50	10 ± 3 (8–31)
Hypogastric artery diameter at side of IBD (mm)[b]	50	9 ± 2 (6–27)

Data are N (%) unless specified otherwise.
ASA=American Society of Anesthesiologists Physical Status Classification score; BMI=body mass index; COPD=chronic obstructive pulmonary disease; GFR=glomerular filtration rate. AAA=abdominal aortic artery; CIA=common iliac artery; EIA=external iliac artery, IBD=iliac branch device.
[a] Mean ± SD (Min-Max); [b] Median ± IQR (Min-Max).

The median procedure time was 143 min (IQR 116,208), median fluoroscopy time was 37 min (IQR 28, 49) and median fluoroscopy dose was 307 Gy/cm^2 (IQR 183, 456). In 36 patients (94.7%) the aneurysms were successfully excluded showing no signs of endoleak or hypogastric occlusion on the side of the IBD.

The completion angiogram at the end of surgery showed a type 3 endoleak in 2 patients (5.3%) and kinking of the EIA stent-graft in a single patient (2.6%) (Table 3). One type 3 endoleak was a type 3b at the bifurcation of IBD. This patient had an iliac aneurysm of 65 mm in maximal diameter. Because of this large diameter

Table 2. Procedure related characteristics.

Characteristics	N = 38
Procedure time (min)b	143 ± 88 (71–266)
Fluoroscopy time (min)b	37 ± 21 (17–85)
Fluoroscopy dose (Gy/cm2)b	307 ± 273 (64–1278)
Side of IBD	**N = 38**
Bilateral	12
Left	15
Right	11

Data are N (%) unless specified otherwise. [b] Median ± IQR (Min-Max).

and the risk of short term rupture, we decided to perform a relining of the CIA limb onto the EIA with selective coiling of the hypogastric artery. In another patient, a type 3a endoleak was visible between the bridging stent of Medtronic (diameter 16 mm) and the IBD (proximal size of 14 mm). There was a sufficient overlap zone of 40 mm between these components. It was treated expectantly and was not visible on imaging during follow-up. One patient had kinking of the EIA limb and received a relining stent. Forty-nine of the 50 hypogastric arteries (98.0%) were patent at the end of the procedure.

Table 3. Findings on completion angiogram at the end of the procedure.

Procedure	Completion angiogram	Intervention
EVAR + IBD R	Kinking EIA limb R	Relining stent EIA
EVAR + IBD L	EL type 3 at IBD bifurcation	Relining stent CIA to EIA with occluding the hypogastric artery
EVAR + IBD L	EL type 3 at bridging stent-IBD	No intervention: no endoleak on imaging during follow up

CIA=common iliac artery; EIA=external iliac artery; EVAR= endovascular aneurysm repair; EL=endoleak; IBD=iliac branch device; L=left side; R=right side.

Postoperative Results

As shown in Table 4, the median length of hospitalization was 2 days (IQR 2, 4). Neither reinterventions were required during hospitalization, nor pelvic ischemic complications were reported. Median follow-up time was 31 months (range 8–56). The 30-day survival was 100%. Survival at 12 months was 94.7%. Two patients died within the year after the procedure. Cause of death was stage IV cancer in

Table 4. Postoperative characteristics.

Postoperative characteristics	N	
Length of hospitalization (days)b	38	2 ± 2 (1–8)
30-day survival	38	38 (100%)
1 year survival	38	36 (94.7%)
Reintervention during hospitalization	38	0 (0%)
Reintervention rate (1 year)	38	2 (5.3%)
IBD-specific reintervention rate (1 year)	38	1 (2.6%)
Endoleak type 1b or 3 during follow up	38	0 (0.0%)
Hypogastric artery patency during follow up	50	49 (98.0%)
Rupture	38	0 (0.0%)

Data are N (%) unless specified otherwise. [b] Median ± IQR (Min-Max). IBD=iliac branch device.

both patients. There was no IBD-related mortality or aneurysm-related mortality. Regarding endoleaks, no patients developed type 1b or 3 endoleak. One type 1a endoleak was treated with embolization. Hypogastric arteries at the side of IBD remained patent during follow-up. Buttock claudication or new onset erectile dysfunction was not reported. The overall reintervention rate at 12 months and during follow-up was 5.3% (n = 2) and 10.5% (n = 4), respectively. IBD-related reintervention rate at 12 months was 2.6% (n = 1) and remained 2.6% (n = 1) during follow-up. One patient showed kinking of the EIA limb at 6 weeks with no signs of significant arteriosclerosis or severe iliac tortuosity. This was successfully treated with a relining stent from Medtronic®. The same patient showed at 36 months asymptomatic stenosis in the bridging stent between the main body and the IBD, which was diagnosed on contrast-enhanced CT as a nonocclusive thrombotic instent plaque in absence of other kinking or outflow stenosis. It was

treated again with a relining stent from Medtronic®. Two patients developed an asymptomatic stenosis in the CIA limb, contralateral to the implanted IBD, which was also diagnosed on contrast-enhanced CT. One stenosis was a thrombotic instent plaque and was treated with a relining stent, while the other stenosis was not visible on catheter angiography (Table 5). The estimated freedom from all intervention and IBD-related intervention rates at 48 months were respectively 82.5% and 97.4%. (Figure 2).

Table 5. Reinterventions during follow-up.

Initial procedure	Problem on CT imaging	Timing	Reintervention
EVAR + IBD BILATERAL	Kinking EIA limb R	6 weeks FU	Relining stent
EVAR + IBD L	Stenosis CIA limb R	6 months FU	Catheter angiography
EVAR + IBD L	Stenosis CIA limb R	18 months FU	Relining stent
EVAR + IBD BILATERAL	Stenosis bridging stent R	36 months FU	Relining stent
EVAR + IBD R	Type 1a EL	42 months FU	Embolization

CIA=common iliac artery, EIA=external iliac artery, EVAR=endovascular aneurysm repair, EL=endoleak, FU=follow-up, IBD=Iliac branch device, L=left side, R=right side.

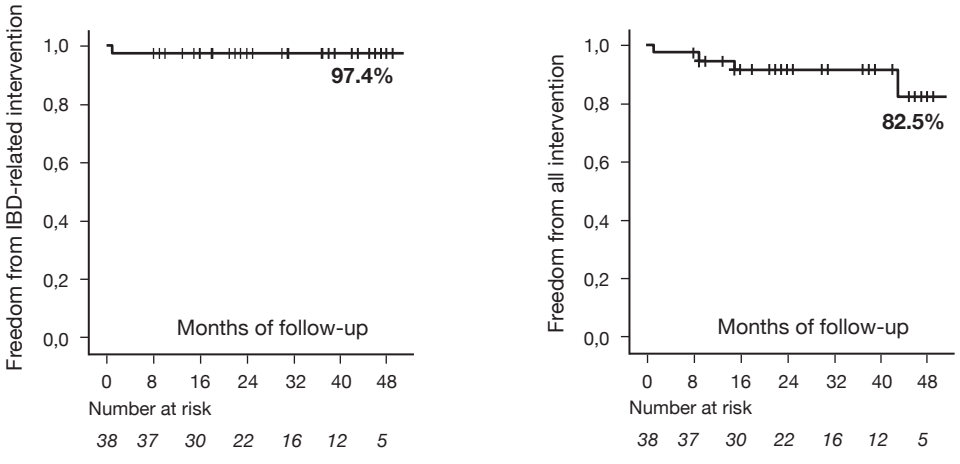

Figure 2. Kaplan Meier curves of the freedom from all reinterventions and iliac branch device (IBD)-related reinterventions.

DISCUSSION

The combination of the Endurant II(s) (EVAR) and E-liac (IBD) stent-grafts for the treatment of aortoiliac aneurysms showed excellent compatibility. In 94.7% of our patients, we achieved technical success. Only one patient had a type 3b endoleak at the IBD bifurcation which was treated by relining the CIA limb onto the EIA with selective embolization of the hypogastric artery. Type 3b endoleak is a very rare complication and, to our knowledge, it has not been reported before in the use of the E-liac stent-graft. We consider this an atypical complication. Another type 3a endoleak between the bridging stent and the IBD was observed. However, no endoleak was seen on the postoperative CT at 6 weeks. The adequate sizing and overlap, with the resolution of the endoleak on postoperative imaging, implies that this cannot be explained by an incompatibility between the stent-grafts.

Our study showed similar findings in terms of a successful patency compared to the PLIANT study in which patients were also treated with the E-liac stent-graft system. The PLIANT study reported successful aneurysm exclusion with primary hypogastric patency of 90% at 12 months follow-up; and only 5% of their patients had an IBD-related reintervention.[9] While our retrospective cohort showed a 1-year all reintervention rate of 5.3% and an even lower reintervention rate for the IBD-specific reinterventions (2.6%).

Direct comparison with other available iliac branch devices remains difficult, given the different technical features and the instructions for use (IFU) for each device. Giosdekos et al. performed a subgroup meta-analysis by type of endograft. They compared the Zenith Branch Iliac Endovascular Graft (Cook®), the Excluder Iliac Branch Endoprosthesis (Gore®) and the E-liac stent-graft (Artivion®), which all had similar high technical success and patency rates between 95 and 100%, and a low IBD-related reintervention rate between 2 and 8%.[12]

In our cohort, all revascularized hypogastric arteries at the side of IBD remained patent during follow-up and we had no reports of intermittent buttock claudication, new onset of erectile dysfunction or colon ischemia. The high patency rates and low rates of pelvic ischemic complications advocate for the preservation of the hypogastric artery when possible. In comparison, in a large literature review of Lin et al. [13] intermittent buttock claudication had an incidence of 28% after unilateral coiling of the hypogastric artery and erectile dysfunction appeared in 19%. In their systematic review, Cao et al.[14] confirmed significantly lower rates of buttock claudication in patients with bilateral IBD (0.7%) compared with unilateral (7.9%) and bilateral hypogastric artery embolization (33.8%).

The objective of successful aneurysm repair should be total exclusion of the pathologically dilated artery. Expansion of iliac arteries after conventional EVAR has been researched and seems proportional to their initial size at time of diagnosis.[15] Dube et al.[16] investigated the diameter progression of common iliac artery after EVAR for AAA. Aneurysmal iliac arteries (> 20 mm) showed a diameter expansion of 2.7 mm during a follow-up of 39 to 60 months. Dhanji et al.[17] reported similar findings with a mean CIA aneurysm growth of 1.5 mm/year. Henceforth, the bell-bottom technique had been linked with higher incidence of type 1b endoleak in late follow-up when compared with standard EVAR technique.[18, 19] Gray et al.[17] showed a fivefold higher risk of late type Ib endoleak in iliac limbs ≥ 20 mm compared with patients with iliac limbs < 20 mm. Furthermore, higher iliac limb reintervention rates are associated with placement of bell- bottom limbs outside manufacturer's instructions for use or in larger and tortuous CIA. [20, 21]

The use of an IBD extension allows to treat aortoiliac aneurysms with a healthy-to-healthy vessel technique that completely excludes the dilated arteries and lowers the reintervention rates. We had no type 1b endoleak during median follow-up time of 31 months and our 30-day and 1-year survival rate was respectively 100% and 94.7%. There were no reports of aneurysm-related death.

However, not all patients are suitable for use of an IBD, based on anatomical restrictions.[22] As we await more long term data on different iliac branch devices, the choice of stent-graft and the combination of different manufacturers can broaden the available options for endovascular repair of aortoiliac aneurysms, especially in patients with atypical anatomy. The aspect of the iliac artery, the choice to preserve the hypogastric artery and the patient's comorbidities are all important factors in choosing the optimal approach.

This study was limited by the small number of patients, relative short follow-up and its retrospective design. Furthermore, no standard questionnaires were used during the clinical follow-up for the assessment of erectile dysfunction or buttock claudication. Due to underreporting, data of these pelvic ischemic complications may be missing.

CONCLUSION

This retrospective study showed that the combination of the Endurant II or IIs and the E-liac stent-graft system is an effective and safe procedure for patients with an aortoiliac aneurysm. We confirm the high hypogastric artery patency rates and lower risk of pelvic ischemic complications using IBD in patients with aortoiliac aneurysms. Furthermore, these devices have a high technical success rate even when it is combined with a different manufacturer of the EVAR main body.

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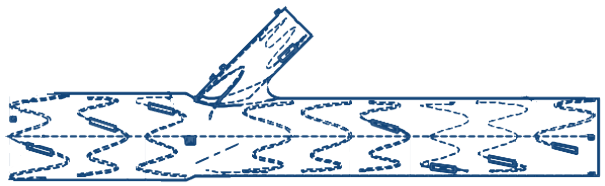
CHAPTER 8

Single-center mid-term experience with E-liac branched device from Artivion®



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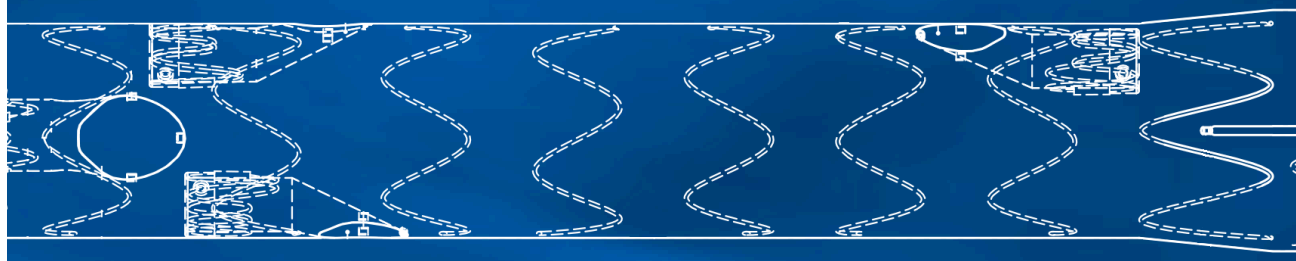
*are joint first authors and contributed equally.

Submitted

CHAPTER 9

Single-center experience with inner-branched endograft for the treatment of pararenal abdominal aortic aneurysms



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Journal of Endovascular Therapy

2023 Oct 16:online ahead of print

ABSTRACT

Purpose: To report a single-center result of patients with pararenal aneurysms treated with inner-branched endograft.

Materials and Methods: This retrospective study analyzed prospectively collected data of patients treated with elective inner-branched endovascular aneurysm repair (iBEVAR) using an Artivion® E-xtra custom-made endograft. Primary endpoints were clinical and technical success after iBEVAR. Secondary endpoints were overall survival, target vessel patency during follow-up, aneurysm-related mortality, and freedom from reintervention.

Results: Over a 56-month period, a total of 23 patients (19 men; 72.3 ± 7.2 years) were treated with iBEVAR with a mean follow-up of 15 months. Technical success was achieved in 96% of procedures, incorporating 87 inner branches. Two (8.3%) intraoperative complications (target vessel dissection) were reported, without additional reinterventions needed. Two (8.3%) patients died within 30 days after initial procedure. One due respiratory failure and the other from an ischemic stroke. During follow-up, three patients (13%) required reintervention, either to repair a type I or III endoleak (n=2) or to place an iliac branched device, that did not succeed during the initial iBEVAR procedure (n=1). Primary target vessel patency and freedom from reintervention during follow-up was respectively 98.9% and 87%. We revealed no aneurysm related mortality. Overall survival was 78.3%.

Conclusion: The present study confirms previous findings that iBEVAR on the Artivion® E-xtra design platform is an effective and safe procedure achieving high technical success rate in the treatment of pararenal abdominal aortic aneurysms.

INTRODUCTION

Custom-made endografts with fenestrations or branches have become standard of care in the endovascular treatment of pararenal abdominal aortic aneurysm (PAAA) or thoracoabdominal aortic aneurysms (TAAA) type IV as they show lower mortality and morbidity compared with open surgery.[1–5] Fenestrated endovascular aneurysm repair (FEVAR) and branched endovascular aneurysm repair (BEVAR) or a combination of both have been extensively investigated. Each of these techniques has specific advantages and drawbacks. Fenestrated grafts have the advantage that less aortic coverage is required, preserving spinal perfusion. On the other hand, meticulous placement is required to prevent misalignment. Furthermore, catheterization ofthe target vessel can be challenging and there is no real sealing zone of bridging stents within the graft main body.

Usage of outer-branched grafts is only possible in cases where a wide aortic lumen is present. As opposed to FEVAR, longer aortic coverage is required since narrowing of the endograft at the level of the visceral vessels is necessary to provide enough space for the outer branches of the endograft. Advantages of directional side branches include more forgiving placement in the main body of the endograft and easier catheterization of target vessels.[6]

Recently, custom-made endografts with inner branches (iBEVAR) have been developed for the treatment of aortic arch pathologies.[7,8] These branches consist of a cylindrical branch inside the main graft with an external fish-mouth–like opening fixed to the endograft fabric. It has been argued that the use of iBEVAR combines the advantages of both FEVAR and outer-branched EVAR (oBEVAR). Incorporation of inner branches in custom-made endografts for the treatment of TAAA is slowly gaining popularity. However, due to limited availability, only few selected centers are able to provide data and are able to assess the outcome of these devices.[9–12] The aim of this study is to present our single-center experience with the use of iBEVAR for the treatment of PAAA and assess the safety, technical success rate, and short-term to mid-term outcome.

MATERIALS AND METHODS

Study design and patients

A single-center retrospective review of all patients who underwent elective iBEVAR between April 2018 and November 2022 at our secondary referral vascular center was performed after approval from the institutional ethics review board (approval number: 20220120). The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). We respected the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement guidelines for observational studies. [13] All patients were treated using the Artivion® E-xtra design platform (Artivion®, Hechingen, Germany). The patient demographics, cardiovascular risk factors, morphology of aortic aneurysm and target vessels, perioperative morbidity and mortality, and reintervention rates were recorded. All patients received a preoperative thin-slice (1 mm) computed tomography angiography (CTA) of the aorta. All patients were evaluated in our multidisciplinary aortic team, including vascular surgeons, interventional radiologist, and vascular internist. The iBEVAR repair was offered as an alternative to open surgical repair to patients that were fit for surgery with a life expectancy greater than 2 years and had suitable anatomy. Anatomic requirements were suprarenal aortic diameter ≥22 mm, thrombus-free proximal sealing zone of ≥30 mm and renal arteries should be at least 4 mm. The endograft design and characteristics were based on reconstruction of the CTA images using EndoSize software (Therenva, Rennes, France) and confirmed after consultation with the Artivion® engineering department. Only patients receiving at least 1 inner branch in their final endograft design were included in the study population.

End points

The primary study outcomes were clinical and technical success after iBEVAR. Technical success was defined as complete deployment of the endograft, cannulation, and stenting of all inner branches with patent target vessel, and the absence of either type I or type III endoleak at completion of the procedure.[14] Secondary outcomes were overall survival, target vessel patency during follow-up, aneurysmrelated mortality, and freedom from reintervention.

Endograft design

Endografts were custom-made using the E-xtra design platform loaded on a 24 French delivery system. The inner branches all consisted of a 6 to 8 mm diameter internal opening pointed upward inside the lumen of the main graft. Although

design of retrograde inner branches is possible, all endografts in the present study were designed with antegrade branches. The internal part of the branch ranged from 17 to 19 mm in length and is supported by compression springs with a ring-shaped radiopaque marker at the inlet. At the branch outlet, there are 3 radiopaque dot markers positioned to allow for easy visualization of the outlet and catheterization of the target vessel.

Surgical procedure

Procedures were performed under general anesthesia in a hybrid operating room with a fixed imaging system and usage of image fusion guidance. Percutaneous femoral access was bilaterally obtained using ultrasound guidance to introduce the endograft and its components. If necessary, the left axillary or brachial artery was exposed with surgical cutdown at the level of the proximal arm. Cerebrospinal fluid (CSF) drainage was not used routinely but was available to use in the event of spinal cord ischemia. Hypotension during the operation was avoided. After heparinization (5000 international units [IU], after 1.5-hour procedure time, 2500 IU additional heparin was administered), the main endograft was positioned within the thoracoabdominal aorta with the outlet markers positioned 5 to 10 mm above the target vessel ostium. After appropriate orientation, the main endograft was then fully deployed. Left upper brachial access was then used to cannulate all the branches with a coaxial introducer sheath. First, a 12F 64 cm Sentrant sheath (Medtronic, Minneapolis, MN, USA) was introduced into the proximal part of the main aortic endograft. Then, an 8F Cook Flexor sheath (Bloomington, IN, USA) was coaxially passed in the larger sheath, sequentially positioned in the desired inner branch and advanced inside the target vessel after successful cannulation using a 0.035 inch hydrophilic guidewire. In 1 case, the cannulation of the branches was carried out completely from the femoral entry using a Tour Guide steerable guiding sheath 8.5F 55 cm (Medtronic, Inc., Santa Rosa, CA, USA) and looping a 0.018 inch hydrophilic guidewire through this sheath. Finally, a balloon expandable E-Ventus BX stent-graft (Artivion®) or Advanta V12 Balloon Expandable Covered Stent (Getinge®) was positioned with at least 15 mm of overlap in the target vessel and deployed. The choice of the bridging stent depends on the operator preference. The Advanta V12 may have more radial force and was preferable used in BEVAR after EVAR cases for extra support through the struts of the suprarenal stent. When necessary, we added additional short balloon expandable stent-grafts to acquire sufficient proximal and distal sealing. Selfexpandable bridging stent-grafts were not used and were not necessary for smoothing the transition zone between the stent and

the target artery in cases of a kink. After completion of the main endograft with all the inner branches, the additional components (bifurcated grafts and limbs) of the endovascular repair were placed followed by a completion angiogram. Both common femoral arteries were closed (if needed a classic surgical cutdown was performed) using closure devices (MANTA device [Teleflex, PA, USA] or Perclose ProGlide™ system (Abbott Vascular, CA, USA)), while the primary sutures were used to close the surgical cutdown of the left brachial artery.

Postoperative Care and Management

Patients were postoperatively monitored on the intensive care unit until the day after the procedure, after which they were transferred to the regular surgical nursing unit. Neurologic assessment was done every 2 hours during the first 8 hours, then every 4 till 6 hours during 48 hours postoperatively. A mean arterial pressure of at least 80 mmHg was preserved and anemia was avoided. Dual antiplatelet therapy consisting Clopidogrel 75 mg once daily and aspirin 100 mg once daily was initiated in all patients except those who previously had been receiving anticoagulation therapy. In these patients, aspirin 100 mg once daily was added. Follow-up consisted of a CTA 6 weeks after the procedure to assess aneurysm sac diameter, positioning of the endograft, branches, and endoleaks. In the absence of a significant endoleak or other complications, a yearly CTA was subsequently carried out.

Statistical Analysis

Categorical variables were presented as frequency and percentage. Continuous data with a normal distribution were presented as mean±standard deviation or if not normally distributed as median and interquartile range in the presence of skewness. Normality was evaluated by the Shapiro-Wilk test in conjunction with visual assessment of normal-probability plots. Missing data were reported as such. The Kaplan-Meier method was used to calculate the survival. Statistical analyses were performed using SPSS (SPSS for Windows version 28.0, SPSS Inc., Chicago, Illinois, USA) .

RESULTS

Patient Characteristics

A total of 23 patients (19 men) received elective iBEVAR repair using an E-xtra custom-made endograft during the study period. The mean patient age at the time of the procedure was 72.6±7.1 years, and the mean maximal aortic diameter on preoperative CTA was 58.7±9.1 mm. Eight patients had undergone previous aortic surgery and suffered from proximal progressive aneurysmal disease or anastomotic aneurysm requiring endovascular repair. Of these 8 patients, 7 were treated with previous standard infrarenal endovascular repair using bifurcated endografts and developed a type Ia endoleak during follow-up. One patient had undergone open aortic tube interposition, but during followup, aneurysm formation was seen at the proximal anastomosis. The median diameter of the visceral aorta was 25 mm (IQR=23–27) and the mean proximal covered length of the aorta above the aneurysm was 74±8.4 mm and above the celiac artery was 56.3±8.9 mm. Demographic data, preoperative comorbidities, and aneurysm characteristics are presented in Table 1.

Intra-operative data and technical success

The median procedural time was 254 minutes (IQR=180–309). The median contrast volume used was 210 ml (IQR=150–290) with a median fluoroscopy time of 64 minutes (IQR=45–96) and median hospital stay of 4 days (IQR=3–5). Four branches (in 1 patient) were cannulated from a femoral access, while the others were approached from above using a surgical cutdown of the axillary artery. All but 4 patients were treated with 4 inner branches. Two of them had previous nephrectomy, the other had an nonfunctional left kidney and the renal artery was embolized during procedure, and the fourth patient had an endograft configurations of 2 fenestrations and 2 branches.

Technical success was achieved in 95.6% of procedures with all endografts successfully positioned and deployed, incorporating 87 inner branches. In 5 vessels (2 left renal arteries, 1 superior mesentery artery, and 2 celiac arteries), further stenting with a balloon expandable covered stent-graft was necessary to achieve adequate distal seal. Procedural data are presented in Table 2. A sufficient aneurysm seal was observed in all cases on completion angiogram with no type Ia, type Ib, or type III endoleak present. A type II endoleak was visualized in 9 patients, none deemed significant enough to require intervention during the index procedure. Three patients received a concomitant iliac-branched endograft, one of which had to be postponed to a second procedure 12 months later due to technical difficulties in positioning and cannulation of the iliac device. Even though in this case deployment of the main endograft, all inner branches and sufficient distal seal of the aortic aneurysm and iliac-branched device (IBD) on the right side was achieved, we did not label this case as a technical success as the 36 mm left iliac aneurysm was not excluded during the index procedure as a left-sided IBD

Table 1. Baseline characteristics of the 23 iBEVAR patients.

Characteristics	N=23
Age (years)	72.6 ± 7.1
Male gender	19 (82.6%)
ASA grade	
2	8 (34.8%)
3	15 (65.2%)
Active smoker or < 1 month ago	18 (78.3%)
Comorbidities	
Diabetes mellitus type 2	4 (17.4%)
Ischemic heart disease	12 (52.2%)
Chronic lung disease (asthma, COPD)	11 (47.8%)
Chronic kidney disease (GFR<60 mL/min)	5 (21.7%)
Hyperlipidemia	5 (21.7%)
Aneurysm characteristics	
AAA diameter (mm)	58.7 ± 9.1mm
Previous EVAR intervention with type Ia endoleak	7 (30.4%)
Previous Open Abdominal Aortic Repair	1 (4.4%)
Juxtarenal AAA	12 (52%)
Suprarenal AAA	11 (48%)

Data are N (%) unless specified otherwise. Mean±SD; median and IQR.Abbreviations: AAA, abdominal aortic artery; ASA, American Society of Anesthesiologists Physical Status Classification score; COPD, chronic obstructive pulmonary disease; GFR, glomerular filtration rate; iBEVAR, inner-branched endovascular aneurysm repair; IQR, interquartile range.

was also originally planned. In 3 patients, a planned embolization of an internal iliac artery (2), inferior mesenteric artery (1), or accessory renal artery (1) was carried out during the index procedure. Two (8.3%) intraoperative complications were reported. After stent placement in the target vessel, a dissection was seen in 2 patients, localized to the celiac artery in 1 patient and to the left renal artery in the other. Since both dissections were not flow-limiting, further stenting was not carried out. Both inner branches, bridging stent-grafts and target vessels were patent on follow-up CTA. In the 3 most recently placed iBEVAR cases, we had a lower mean operating time (147 minutes), total contrast volume (167 ml), and fluoroscopy time (32.29 minutes) compared with the initial procedures.

Perioperative mortality and morbidity

Two patients died within 30 days after initial procedure. The first died of respiratory failure, possibly COVID related, 17 days after discharge. The second suffered a cerebellar stroke on the right side 7 days after hospital discharge while on dual antiplatelet therapy and developed hemorrhaging secondary to thrombolysis. This patient already had a medical history of recurrent ischemic stroke with 2 neurologic events within the last 2 years, without clear reason. The axillary access site was on the left side, so we do not believe that it was due to intraoperative manipulations of the sheaths or guidewires. Other complications that were observed in the perioperative period included hospitalacquired pneumonia (n=1), groin hematoma (n=1), and brachial hematoma (n=8), all of which were treated conservatively. There were no cases of spinal cord ischemia. No aortic reinterventions were carried out in the first 30 days after the index procedure.

Reinterventions and mortality during follow-up

No patients were lost to follow-up. Mean follow-up time was 15 months (range=1–50 months). During follow-up, 3 patients (13%) required reintervention, either to repair a type I or type III endoleak (n=2) or to exclude the iliac aneurysm by coiling the left internal iliac artery and placement of covered stent-graft from the common to the external iliac artery (n=1) (Table 3). The latter patient was

Table 2. Procedure-Related characteristics.

Characteristics	N=23
Procedure time (min)	254 (180-309)
Fluoroscopy time (min)	64 (45-96)
Contrast dose (ml)	210 (150-290)
Technical success	96%
Inner branches (n)	87
Intraoperative death (n)	0
Endoleak on completion angiography	
Type I (n)	0
Type II (n)	9
Type III (n)	0

Data are presented as mean±standard deviation, median IQR, or as number and percentage. Abbreviation: IQR, interquartile range.

described earlier, the left iliac aneurysm was left untreated due to technical difficulties during the index procedure. The first patient had a type Ia endoleak on control CT at 6 weeks requiring proximal aortic extension 2 months after index procedure. The second patient had a type IIIc endoleak originating at the left

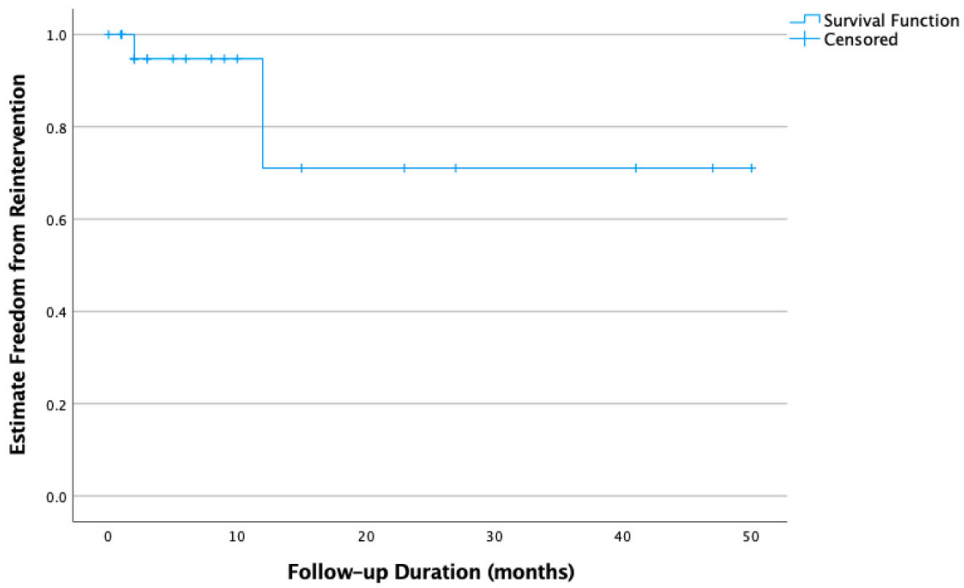

Figure 1. Kaplan-Meier estimate of freedom from reinterventions.

renal artery that was repaired by relining the bridging stent with another balloon expandable covered stent-graft after 12 months. Finally, 1 patient developed a type Ia endoleak on CTA after 6 months but refused further treatment. After 41 months of follow-up, this patient is having persistent sac growth on duplex ultrasound, however, he continued to decline an intervention. Furthermore, 2 more patients are currently awaiting angiography and if needed a reintervention as their postoperative CTA at 6 weeks showed a possible type II or type III endoleak. Only 1 branch occlusion was observed during follow-up (renal), where recanalization was not deemed desirable. Primary target vessel patency was 98.9%. No patient required explantation of the endograft (Figure 1). We revealed no aneurysm-related mortality during follow-up. Five patients died during follow-up; 3 patients due to cardiac reasons, 1 patient died of a COVID infection, and the fifth patient died of multi-organ failure following sepsis. The overall survival was 78.3% (Figure 2).

Table 3. Reinterventions during follow-up: timing, treatment and outcome.

Case	Cause	Time (months)	Intervention	Result
1	Type Ia endoleak	2	TEVAR	Solved
2	Type Ic endoleak	10	Covered stent relining LRA	Solved
3	Type IIIc endoleak	12	Covered stent relining LRA	Solved

Abbreviations: LRA, left renal artery; TEVAR, thoracic endovascular aortic repair.

DISCUSSION

The use of FEVAR and BEVAR has evolved over the past decade from treatment in patients unfit for open surgery to a first-line option for complex TAAA as its safety and efficacy have been well proven. While fenestrations and outer branches are considered standard, inner branches are emerging as a valid alternative as they seem to offer the advantages of both established solutions without their known drawbacks. Currently, fenestrations can be positioned in places where apposition of the endograft with the aortic wall is to be expected and they can be accessed through the femoral arteries, thus avoiding the need for upper limb access. They do, however, require very precise placement directly across the ostium of the target vessel to make cannulation of the visceral artery possible. In addition, the sealing zone between the stent-graft and the fenestration is subjected to significant force and is therefore prone to failure resulting in target vessel instability leading to endoleak or branch occlusion. On the other side, outer branches offer a longer overlap zone between the main endograft and the bridging stent, theoretically leading to less instability. Their placement above the ostium of the target vessel allows for a more forgiving positioning of the endograft and possibly easier stenting of the target vessel, but usually requires axillary or brachial artery access to facilitate cannulation of the downward facing branches. Furthermore, sufficient space between aortic wall and endograft (25–30 mm) is required for the outer branches to deploy. Inner branches, in contrast, can be considered a third option offering most of the benefits of both fenestrations and outer branches. They can be positioned in smaller aortic diameters when compared with outer branches, thereby possibly shortening the proximal aortic coverage required to achieve sufficient seal and thus lowering the risk of spinal cord ischemia. Furthermore, they offer the same stability and freedom in placement as outer branches without compromising on the overlap between

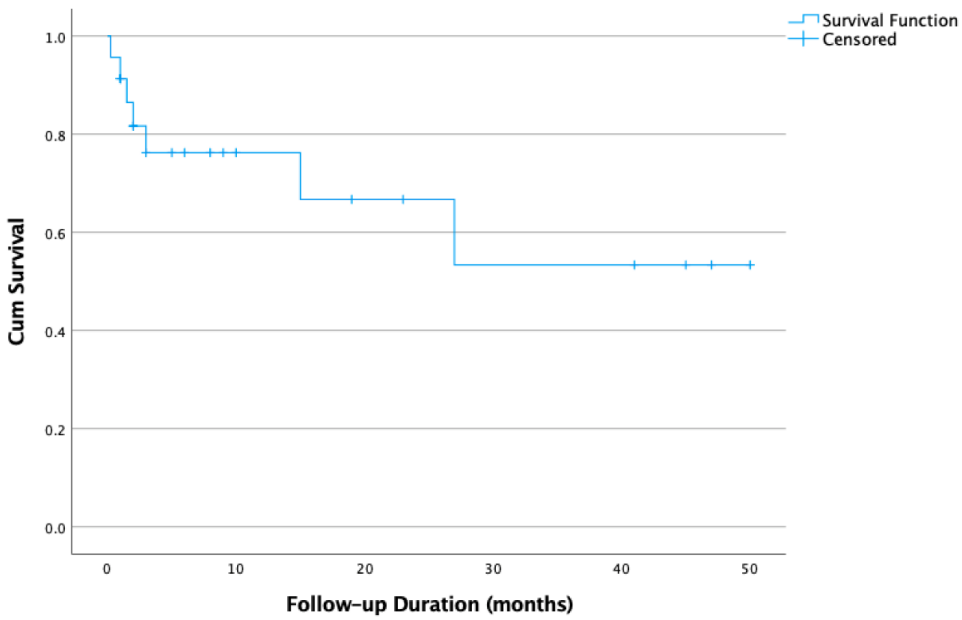

Figure 2. Kaplan-Meier curve of survival during follow-up after iBEVAR procedure.

main endograft and bridging stent-graft. There are numerous studies reporting on the outcome of FEVAR that manage to show a very high technical success rate, usually bordering 100%, and low perioperative mortality and morbidity.[15–17] Ou et al[18] showed in a systematic review that FEVAR is a safe treatment in juxtarenal aneurysm. The Zenith FEVAR stent-graft (Cook Medical, Bloomington, IN, USA) is one of the first fenestrated stent-grafts that was available for the treatment of (T)AAA and has one of the longest follow-up clinical outcomes. Enhancement of this stent-graft has results in better outcomes. Some believe that it serves as benchmark to compare it with other fenestrated stent-grafts.[19] In symptomatic (T)AAA, custom-made stent-grafts are not available due to the duration of the production, in these cases, off-the-shelf (OTS) multibranched stent-grafts can be the solution. Currently, there are 3 stent-grafts commercially available: the E-nside Multibranch stent-graft System (Artivion, Kennesaw, GA, USA), the Zenith t-Branch (Cook Medical, Bloomington, IN, USA), and the Gore Excluder thoracoabdominal branch endoprosthesis (TAMBE; W.L. Gore & Associates, Flagstaff, AZ, USA). One of the major disadvantages of these stent-grafts is the length of supravisceral aorta coverage resulting in higher risk of spinal ischemia. The overall feasibility of these devices varied from 33% to 94%. Bilman et al[20]

demonstrated in a systematic review a good suitability of OTS stent-grafts in the treatment of aneurysms.

The available literature for iBEVAR in thoracoabdominal aneurysm repair is limited but shows promising results. Initially, inner branches were selectively proposed in cases where either the target vessel was unsuitable for FEVAR/ BEVAR or in cases where proximal reduction of the aortic coverage compared with BEVAR could be achieved. [9,10,21,22]

In 2018, Youssef et al reported a multicenter experience with a variety of Artivion® endograft configurations with upward inner branches being used in case of thrombus-free aortic lumen ranging from 24 to 28 mm. As outer branches were used when the thrombus-free lumen of the aorta exceeded 28 mm, only 11.9% (46/384) target vessels incorporated an inner-branch design.[21] Comparably, Lucatelli et al[22] opted for an inner-branch Artivion® design in cases where the aortic anatomy was too dilated for FEVAR, but not dilated enough for BEVAR, resulting in inner branches accounting for 14% (22/156) of the target vessels treated. Both studies showed encouraging results. In their retrospective series using the Cook Zenith design platform, Katsargyris et al[9] advocate the use of combined inner branches and fenestrations, as the endograft with inner branches only was deemed more challenging to correctly rotate and to cannulate the target vessels due to difficult visualization of the radiopaque markers. Subsequent studies using the Artivion® E-xtra design platform do not share this sentiment, however, as the E-markers on the endograft seem to provide a reliable and safe orientation reference for positioning and deployment of the endograft. [10,12] Both Silverberg et al[11] and Simonte et al[12] argue that once familiarity with the device characteristics is achieved, a complete inner-branch design can be used as a primary choice of device, thus not selectively reserving it for cases where FEVAR or BEVAR are not suitable. This study and its authors concur that once the learning curve had been overcome an inner-branch–only design can quickly become the preferred primary treatment option as operating time, total contrast volume used, and fluoroscopy time in the 3 most recently placed iBEVAR cases was lower compared with the initial procedures. Furthermore, we recently changed our operating procedure to completely implant the endograft and its branches from a transfemoral approach, thereby no longer needing upper limb access. We achieved this by looping a 0.018 inch hydrophilic guidewire through the femoral access sheath and then advancing a 8.5F 55 cm Tour Guide Steerable Sheath (Medtronic, Inc., Santa Rosa, CA, USA) over one end of the wire, maintaining control of both wire ends in a through and through fashion. This provides a stable

downward facing platform through which the inner branch can be cannulated and the bridging stent-graft advanced, as already described by Abisi et al.[10]

Differences in both patency, endoleak, and reintervention rate between fenestrations and outer branches are difficult to assess, as most studies reporting on FEVAR and BEVAR do not make a distinction between the 2 designs.[23,24] Kärkkäinen et al[25] demonstrated that while outer branches suffered from more primary endoleaks, they showed more spontaneous disappearance of it compared with endoleaks at fenestration level. We observed a significant number of reinterventions and endoleaks, which is in concurrence with the literature with regards to FEVAR and BEVAR.[2,26] While 2 of the 4 reinterventions were carried out due to a type III endoleak, both stent-grafts in these target vessels had to be distally extended as there was no endoleak visible at the overlap zone between inner branch and bridging stent-graft.

Limitations

The present study is limited by single-center design and the number of patients is small to support strong conclusions. Furthermore, the median follow-up was short (15 months) and may have been insufficient to identify complications related to inner-branch stent-grafts. Another limitation could be that we did not perform a CTA immediate postoperative to confirm technical success.

CONCLUSION

Overall, the present study confirms previous findings that iBEVAR on the Artivion® E-xtra design platform is safe, effective, achieves high technical success rate.[10–12] We therefore believe that incorporating an inner-branch–only device or a combined design of fenestrations or outer branches and inner branches seems to be a valid choice of treatment modality for complex endovascular thoracoabdominal aneurysm repair. As with any new surgical technology, further multicentric studies are required to assess the long-term validity of these results and a cautious follow-up of patients treated with iBEVAR seems justified.

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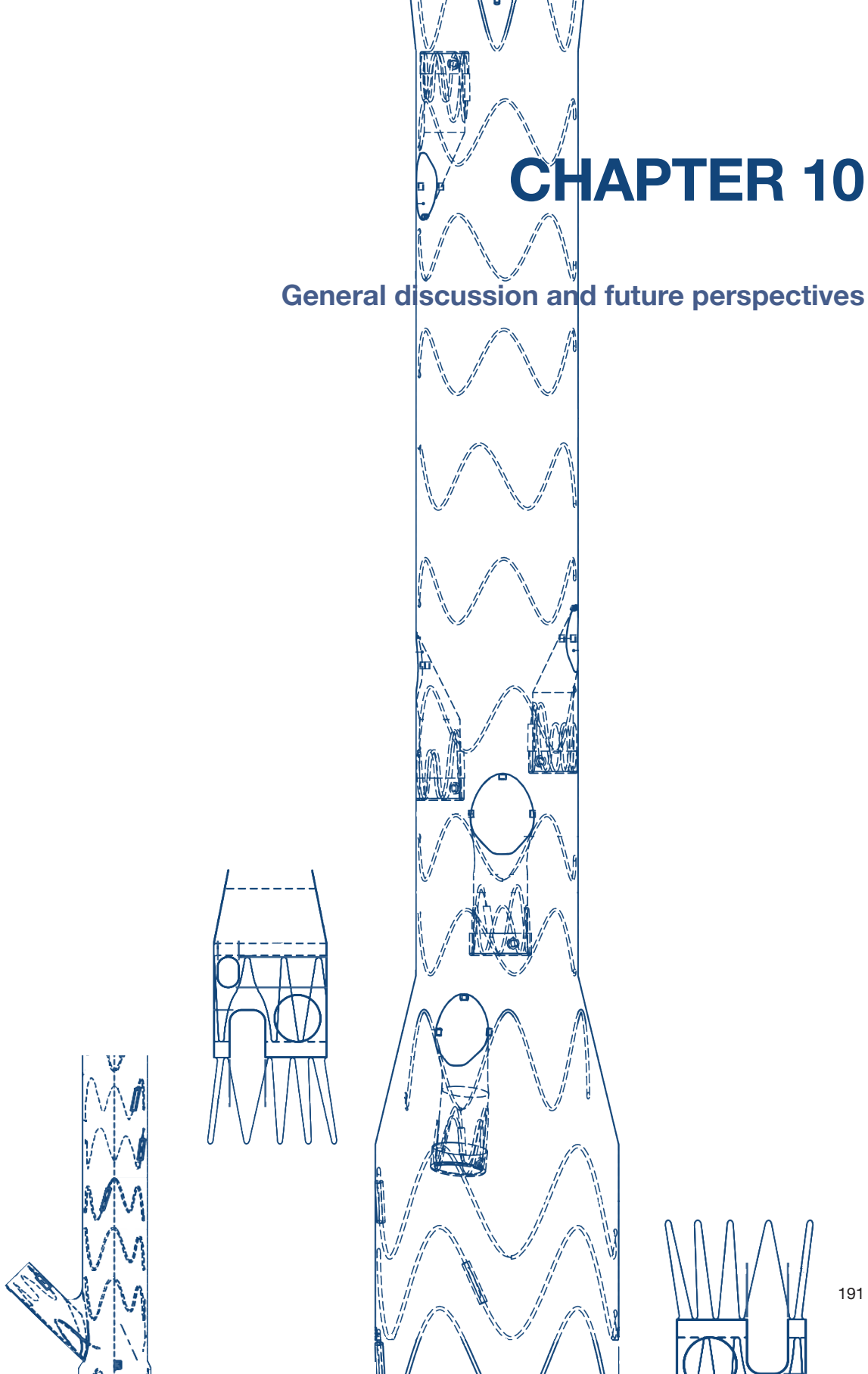
CHAPTER 10

General discussion and future perspectives



GENERAL DISCUSSION

In the previous decade, there has been a significant increase in the number of endovascular techniques, stent-graft designs, and manufacturers of these complex stent-grafts for the treatment of aortoiliac aneurysms. There is a constant need for evidence regarding all new aspects of endovascular treatment of aortic aneurysms, such as complex stent-graft configuration and intraoperative imaging, as well as for extended treatment indications, such as complex aortic aneurysms in octogenarians or after failure of previous endovascular treatment. This thesis investigates the technical challenges, outcomes and risks associated with several of these factors.

Aortoiliac aneurysms are associated with rupture, that occurs when the wall stress exceeds the wall strength. It's a life-threatening situation with mortality up to 85%.[1] The goal is to treat the aneurysm before it ruptures. The indications for preventive treatment of aortoiliac aneurysms are maximum diameter, growth rate and aneurysm shape (fusiform or saccular). Initially, open aortic repair was the only choice for treatment of AAA. However, after introducing stent-grafts for the treatment of AAA, the management of these aneurysms shifted profoundly towards endovascular techniques. These minimal invasive techniques have the advantage of decreasing the morbidity and mortality compared to open surgery.[2,3] Due to the continuous developments of stent-grafts and growing experience of physicians in these techniques, ESVS guidelines recommend endovascular as the first line treatment for aortoiliac aneurysms.[4] IBD is one of the solutions for treatment of an iliac aneurysm with preservation of the hypogastric artery. FEVAR is the preferred elective endovascular treatment in juxtarenal AAA. Based on aortic anatomic features, preferred sealing zone length, local routines and team experience, FEVAR or BEVAR or a combination of these configurations can be selected for the treatment of suprarenal aneurysms or TAAA.

Increasing complexity of endovascular procedures require better and more sophisticated intraoperative imaging. Because of the increased need for improved imaging, hybrid operating rooms featuring advanced imaging applications such as fusion technology and intraoperative contrast-enhanced cone beam computed tomography (CBCT) have been constructed.[5-7] CBCT and fusion are associated with decrease operator effective dose and radiation exposure. Moreover, CBCT avoids early reinterventions due to intraoperative assessment with immediate revision if necessary.[8] Even in standard EVAR the use of a hybrid operating room may be associated with less contrast usage, a lower patient radiation dose, and shorter operative time than performing EVAR with a mobile C-arm. [7] In

Chapter 2 we demonstrated that the use of hybrid operating room may assist in achieving satisfying results in complex FEVAR. New approaches are described using electromagnetic guidance or Fiber Optic RealShape guidance in F/BEVAR procedures. These innovative options will reduce radiation exposure for the patient and healthcare team. [9,10]

The trend towards performing more complex FEVAR has been seen in the last decade due to more familiarity with the fenestrated- and branched stent-grafts. Currently, it is generally accepted that extending the sealing zone higher in a healthier aorta may result in a more durable sealing zone. However, theoretically a higher number of fenestrations and branches increases the complexity of the intervention and may result in a higher risk of complications. There is no consensus in the literature whether these complex FEVAR have worse clinical outcomes compared with renal FEVAR or whether renal FEVAR have more reinterventions due to type Ia endoleaks due to progression of disease. There have been reports showing increased risk of stent-graft related endoleaks in complex FEVARs.[11,12] The complex FEVAR group in **Chapter 3** showed significant more intraoperative complications. Mastracci et al. revealed a greater risk of spinal cord ischemia and overall branch reintervention in patients with coverage of the supraceliac zone. However, significant higher type Ia endoleak was seen in the renal FEVAR group with a mean follow-up of 8 years. The authors suggest three fenestrations and a wide scallop may be desirable for juxtarenal aneurysms for a more durable result on long-term.[13] We believe if the anatomy is compatible for only renal FEVAR, it might be unnecessary to perform a complex FEVAR procedure with potentially more complications, as we report no significant higher type Ia endoleak rate in the renal group during follow-up. In contrast to our findings, other studies demonstrated no higher perioperative morbidity or mortality in complex FEVAR comparing to renal FEVAR and suggest a longer proximal sealing zone whenever needed.[14,15] Moreover, in the systematic review and meta-analysis in **Chapter 4** we found no significant differences in mortality, reinterventions or comorbidity between the complex F/BEVAR and the renal FEVAR. In addition, the renal FEVAR group showed no higher risk on type Ia endoleak. More experienced centers tend to shift mainly towards complex F/BEVAR, in particular when they are mastered their learning curve. However, these skilled centers demonstrate no better clinical outcomes with complex F/BEVAR compared to renal FEVAR performed in the early learning curve period or by less experienced centers.

FEVAR and BEVAR stent-grafts use different methods for target vessel revascularization and each approach have its pros and cons.

If comparing FEVAR to BEVAR in pararenal aortic aneurysms, FEVAR can have a more distal seal in the aorta, which can be an advantage considering the risk of spinal cord ischemia. The placement of the stent-graft should more accurate in FEVAR to ensure correct alignment with the target vessel. Especially in angulated anatomy, the BEVAR is more forgiving in its placement. Canulation of the target vessels in FEVAR is usually done from the groin. In case of down facing target vessels either steerable sheath from the groin of antegrade brachial access can be used, as has been standard in BEVAR. Sealing of the covered stent on the stent-graft is more reliable because of the longer sealing zone in BEVAR compared to the narrow ring in FEVAR.

If comparing iBEVAR to oBEVAR in pararenal aortic aneurysms, iBEVAR can be used in a narrower visceral aortic segment without compression of the branch outside the stent-graft. Because the proximal end of an inner branch can sit at the level of the proximal sealing stent of the BEVAR, the aortic coverage can theoretically be less than in oBEVAR, reducing the change of spinal cord ischemia. The current diamond shape of the distal end of inner branch allows for less accurate alignment with and eases cannulation of the target vessel.

Multiple studies confirm this high technical success and the use of BEVAR in different indications including type I-V TAAA repair, pararenal AAA and type Ia endoleaks after previous EVAR.[16-18] Inner branch technology could be seen as the solution to overcome the limits of FEVAR without the intrinsic constraints of oBEVAR. In **Chapter 9** we demonstrated high technical success rates with the iBEVAR stent-graft in the treatment of pararenal AAA or type Ia endoleak after failed EVAR. However, the benefits and drawbacks of converting a pararenal aortic aneurysm treatment into a thoracoabdominal treatment by covering the distal thoracic aorta with the risk of paraplegia and the requirement to stent all the visceral arteries must be carefully considered for each patient. When the visceral section of the aorta is not healthy and parallel, when severe angulation is present in the suprarenal region, or when the target vascular configuration is not appropriate for fenestrations, iBEVAR may be justified in pararenal aneurysms. Several studies have demonstrated the benefits of BEVAR in the treatment of pararenal aneurysms with endoleak type Ia after failed EVAR.[19,20] Literature about iBEVAR after failed EVAR are scarce. [21,22] The configuration of the stent-graft (FEVAR or (i)/(o)BEVAR or combination) for the treatment of type Ia endoleak after previous EVAR in pararenal aneurysms must be carefully considered for each patient. In juxtarenal aneurysms with healthy suprarenal aorta less overlap between the initial device and the rescue stent-graft is needed as there is lower

risk of migration between the stent-grafts compared to suprarenal aneurysms. Moreover, in short body length of the initial device results in combining the rescue F/BEVAR with a bifurcated stent-graft. [23] Juszczak et al. reported more reinterventions in F/BEVAR cuff compared to full relining of the initial device in patients with aneurysmal degeneration with or without type Ia endoleak after prior open repair or EVAR. [24] Endovascular interventions are more technically challenging in patients with previous aortic operations. After standard EVAR, more than 20% of patients need a reintervention during follow-up, which is associated with decrease of survival. Especially type I endoleaks are life-threatening with high risk of rupture. [25] Treatment of an inadequate proximal sealing zone after EVAR is complex, because of the presence of a stent-graft, particularly with suprarenal hooks in the top stents. Open surgery results in significant elevated perioperative morbidity and mortality due to the surgical difficulties of removing the stent-graft and clamping the aorta. Although technical unsuccessful FEVAR intervention leads to worse outcomes, the initial attempt to treat the type Ia endoleak after failed EVAR should be endovascular. [26,27] However, a systematic review analyzing 10 studies (total of 423 patients) of FEVAR reintervention after failed previous EVAR revealed a high technical success rate of 94.9% and a low 30-day mortality rate of 2.4%. FEVAR after failed EVAR is a feasible treatment option to prevent AAA rupture.[28] In **Chapter 6** we reported comparable technical success (92.3%) of FEVAR for the repair of juxtarenal AAA after prior EVAR failure. Failure of the distal sealing zone results in a type Ib endoleak with high risk for rupture. Various successful techniques are described to treat these endoleaks including Iliac Branch Device (IBD). [29] IBDs are also indicated in the treatment of solitary iliac aneurysms or aortoiliac aneurysms with preservation of the flow in the hypogastric artery through a branch in the tube graft. IBD has been widely used as a first treatment option when deciding to preserve the hypogastric artery to maintain perfusion of the pelvic region. Cao et al. performed a systematic review and meta-analysis of IBDs in the treatment of aortoiliac or solitary iliac aneurysms. They concluded that the treatment of aortoiliac aneurysms with IBD was associated with high technical success and low rate of pelvic ischemia.[30] **Chapter 8** revealed the mid-term results of the E-liac stent-graft in the treatment of aortoiliac- or solitary iliac aneurysms. Compared to the literature, we confirm a high technical success and low rate of endoleak and reinterventions of the E-liac stent-graft. Publications of combinations of stent-grafts from different manufactures are scarce. Shahverdyan et al. showed the technical feasibility of the combination of Vascutek Anaconda custom-made FEVAR with the Cook Zenith IBD. [31] In vitro pullout force testing on stent-grafts from the same (non-

hybrid stent-graft) or different manufactures (hybrid stent-graft) showed that the combination of stent-grafts from different manufactures performed the same or better than the non-hybrid group.[32] A multicenter study combining Cook Zenith body with Endurant limb reports favorable results and advice the use of hybrid stent-grafts in patients with unsuitable anatomy for a single type of stent-graft.[33] The Zenith limb may have a higher risk of kinking and thrombosis with a maximum Zenith iliac limb of 24mm, whereas the Endurant limb can be used in high tortuosity arteries with larger limbs up to 28mm.[34-36] Bos et al. combined the Cook Zenith body with the Gore Excluder limb, no adverse effects or type III endoleaks were seen at midterm follow-up.[37] **Chapter 7** describes the combination of the Endurant II(s) and the E-liac branch device with excellent compatibility in the treatment of aortoiliac aneurysms. Using stent-grafts from the same manufacturer creates a safe feeling; nevertheless, if a different stent-graft has better features for a specific anatomy, it might be beneficial to combine these stent-grafts.

As the population ages, an increasing number of octogenarians present with a AAA. In this fragile population, EVAR showed decreased morbidity and mortality rates compared with open repair.[38] FEVAR in octogenarians emerges also with lower morbidity and mortality compared with open aortic repair. F/BEVAR is a safe technique in octogenarians and has the same postoperative morbidity and mortality compared to non-octogenarians. [39,40] In their study, Motta et al. concluded that F/BEVAR is a safe and effective treatment option in octogenarians with AAA in experienced aortic centers.[41] Especially in complex endovascular interventions, advanced age remains a significant risk factor. Zil-E-Ali et al. reported an increased mortality and higher incidence of nonhome discharges in octogenarians who underwent a FEVAR intervention.[42] Chronic renal failure, lean psoas muscle area and American Society of Anesthesiologists class III to V are independent risk determinants for late mortality in octogenarians after F/BEVAR. [41,43,44] Because octogenarians usually have larger AAA diameter, size above 75mm is another independent risk factor for late mortality.[45,46] The expanding literature of F/BEVAR procedures in octogenarians, on the other hand, demonstrates that these complex procedures are safe, with no significant difference in morbidity and mortality. [39-41,46] In **Chapter 5** we found no significant difference in technical success, reinterventions or mortality between octogenarians and non-octogenarians. Multidisciplinary approach involving a geriatrician may be the best method to make decisions in these vulnerable patients.

FUTURE PERSPECTIVES

Early- and long-term results of endovascular repair of complex aortoiliac aneurysms have been investigated accurately. Future research in these complex stent-grafts is critical. Hybrid operating rooms with highly sophisticated imaging applications created a more optimal environment in performing these complex procedures. Continuous development of the hybrid operating room supports better assessment, which may reduce intraoperative complications and better outcome. Last generations of applications are cloud-computing and artificial intelligence image fusion systems. These systems can update real-time vessel anatomy during the procedure, after placement of stiff guidewires which causes frequent displacements of the arteries and their origins. Significant reductions in contrast use, radiation exposure and decrease of procedure time during FEVAR has been revealed.[47] Furthermore, electromagnetic guidance or Fiber Optic RealShape guidance needs to prove his spot in F/BEVAR procedures. In the last decade more complex FEVAR has been performed compared to renal FEVAR, in particular by accumulated experience in these procedures. Further research is needed with longer follow-up time to collect more evidence on the long-term effect of renal FEVAR and risk on endoleak type Ia. Moreover, data should also be gained in low-volume hospitals performing complex FEVAR reflecting the complexity of these procedures. Complex FEVAR is more demanding regarding the vascular team and adjoining medical specialists such as anesthetists and intensivist. Spinal cord ischemia prevention and rescue protocol should be well known by all involved specialist, especially in BEVAR procedures with more coverage of the thoracic aorta. Few manufacturers are developing semi-branches for the renal arteries and SMA, with a scallop for the celiac trunc, as a result having the advantages of the branches without extensive proximal coverage of the aortic wall. Continuous development of configurations in these stent-grafts will perhaps develop mini-inner branches with scallops, which could be used in smaller suprarenal aortic diameters and still have the advantage of overlap zones with bridging stents. Branched stent-grafts have other advantages than fenestrations. Combining inner-branch technology with outer branch or fenestrations in the same stent-grafts seems to be the best options. Manufacturers should provide these technologies and create the best possible stent-graft configurations for specific anatomies. Inner branch technology has shown its benefits in iBEVAR. Further studies and data over these inner-branch technology is needed to have more knowledge of the indication and which bridging stents are more suitable in these grafts. Iliac fenestrated stent-grafts (IFSG) have been developed as a

different technology to overcome these iliac aneurysms with preservation of the hypogastric artery. These IFSG require other anatomic features which could be the solution for specific patients with aortoiliac aneurysms. Future perspectives are development in manufacturing iliac inner-branch devices, creating the same advantages as fenestrated, but having overlap zones with the bridging stent. To obtain the most suitable stent-graft for the right anatomy it's sometimes necessary to combine stent-grafts from different manufactures. The available data shows favorable results, without high risk for type III endoleak. Further research is needed as more manufactures of stent-grafts entering the aortic platform which in turn results in different combination of these stent-grafts.

Reintervention rates after endovascular repair increased due to placements of EVAR outer IFU in the earlier periods, longer follow-up of older generation stent-grafts. Treatment of the proximal sealing zone after EVAR will probably decrease due the trend of declining use of EVAR outer IFU, new generations EVAR stent-grafts and other more sustainable solutions like renal FEVAR or complex F/BEVAR stent-grafts. However, due to progression of disease in the proximal sealing zone the need for endovascular experience in fenestrated/branched stent-grafts is necessary. Centralization of aneurysm treatment may be the solution for providing the total endovascular package of treatment options. In the Netherlands we already have created a document with minimum requirements for treating patients with (T)AAA, resulting in a decrease of low volume centers.

Octogenarians remain a fragile increasing population. In many fields of medicine, we don't have a cut-off age limit to stop offering any treatment. Further research by a systematic review and meta-analysis of F/BEVAR procedures in octogenarians should be performed. We rather look at quality of life, life expectancy, comorbidity, and desire of the patient. We believe each case should be seen separately, even in rupture cases some octogenarians may still have an acceptable survival after an intervention. Extensive preoperative work-up, multidisciplinary approach and clear discussion with the patient and family about severe complications and expectations is mandatory. The World Health Organization describes that the number of octogenarians is anticipated to increase threefold between 2020 and 2050 and to reach 426 million in the world, which makes it more important to investigate these elderly patients and try to create an algorithm to decide whether to offer an operation or not.

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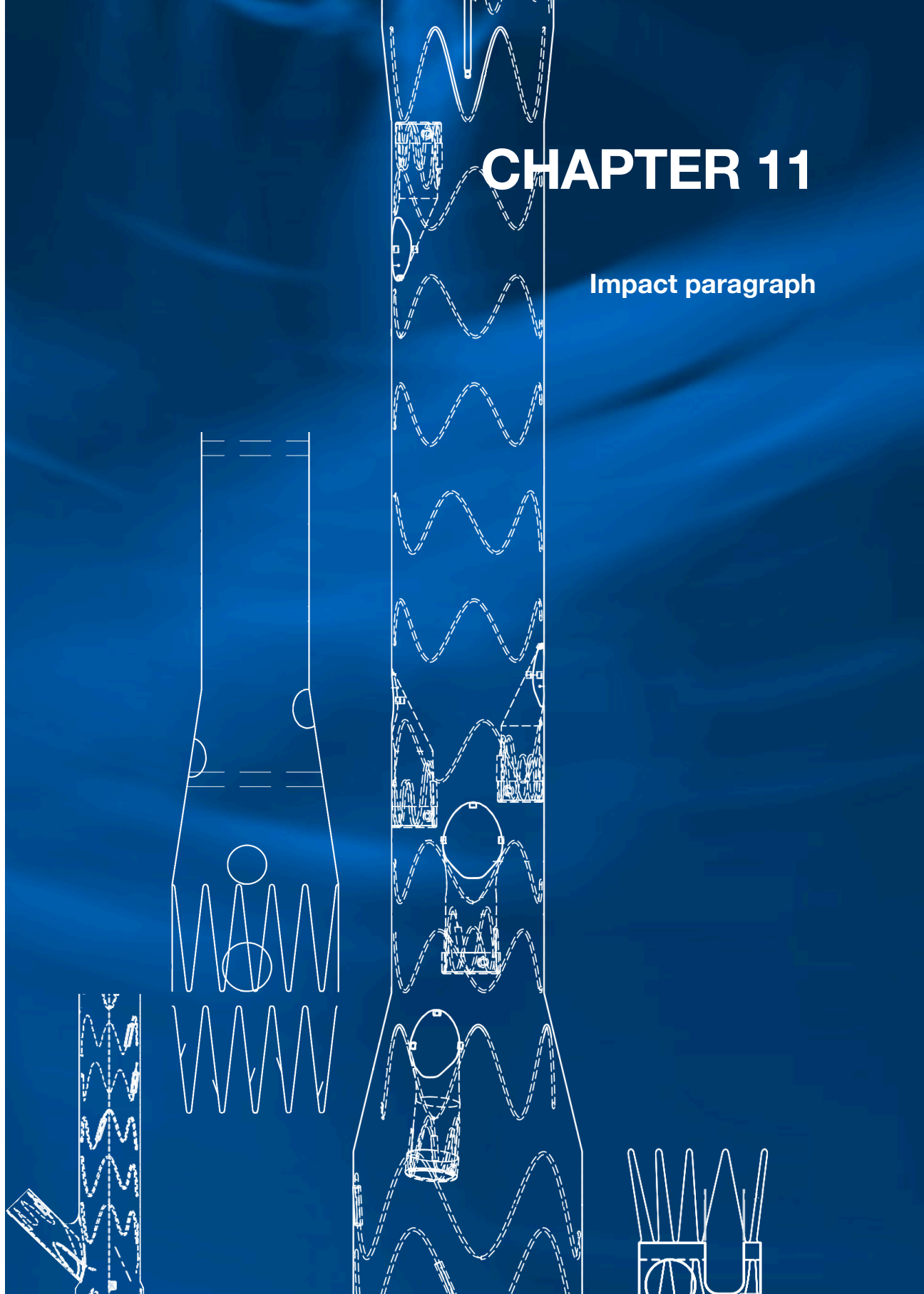
CHAPTER 11

Impact paragraph



IMPACT PARAGRAPH

The main objective of this thesis is to show the impact and results of endovascular treatment in complex aortoiliac aneurysms. These complex stent-grafts have a workload on the overall organisation of the hospital. Twenty-four hours of dedicated vascular teams is necessary and close collaboration with several departments such as cardiology, anaesthesiology, and intensive care unit. The hospital's infrastructure must also be permitted with building a hybrid room and the financial availability of providing this structure. The research shows that hybrid operating room may assist in achieving favorable results especially in complex F/BEVAR. Currently nearly every vascular unit, which is treating complex aneurysm, has a hybrid room. Especially last generation hybrid operating room with highly sophisticated applications show their real benefits in operation time, radiation dose, contrast use, and even in long term clinical outcomes.

The thesis gives an insight in decision making between renal FEVAR or more complex F/BEVAR. The results advise a more liberal approach in choosing complex F/BEVAR stent-grafts if needed. However, liberal use of complex F/BEVAR in centers with less experience should remain cautious. Renal FEVAR in juxta-renal aneurysms remains a safe and effective treatment option in the borders of instruction of use with no higher risk on type Ia endoleak during follow-up compared to complex F/BEVAR.

One of the socioeconomics impacts of this thesis is revealing satisfactory results in the treatment of complex aneurysms within the elderly population. It shows that age alone is not an acceptable reason to deny a F/BEVAR intervention. Whether we should operate on these octogenarians or not, depends on the comorbidity, quality of life and patient's preference. In light of the more ageing population, it is recommended for further investigation about this topic. Hospitals and health care takers should prepare themselves for these challenging and ethical choices in the treatment of octogenarians. Endovascular treatment comes with a financial higher cost especially in complex aneurysms. The custom-made stent-grafts are even more expensive. However, endovascular treatments have shown their benefits in increasing mortality and morbidity. We have shown similar results with high technical intraoperative success and successfully exclusion of aneurysms for preventing rupture during follow-up. Even in endovascular reinterventions like FEVAR after EVAR we have presented high technical success of treatment of the aneurysm. Expanding the field of endovascular treatment, IBD studies have shown a safe and effective solution in the treatment of solitary iliac aneurysms or complex aortoiliac aneurysms. Moreover, it showed that stent-grafts from

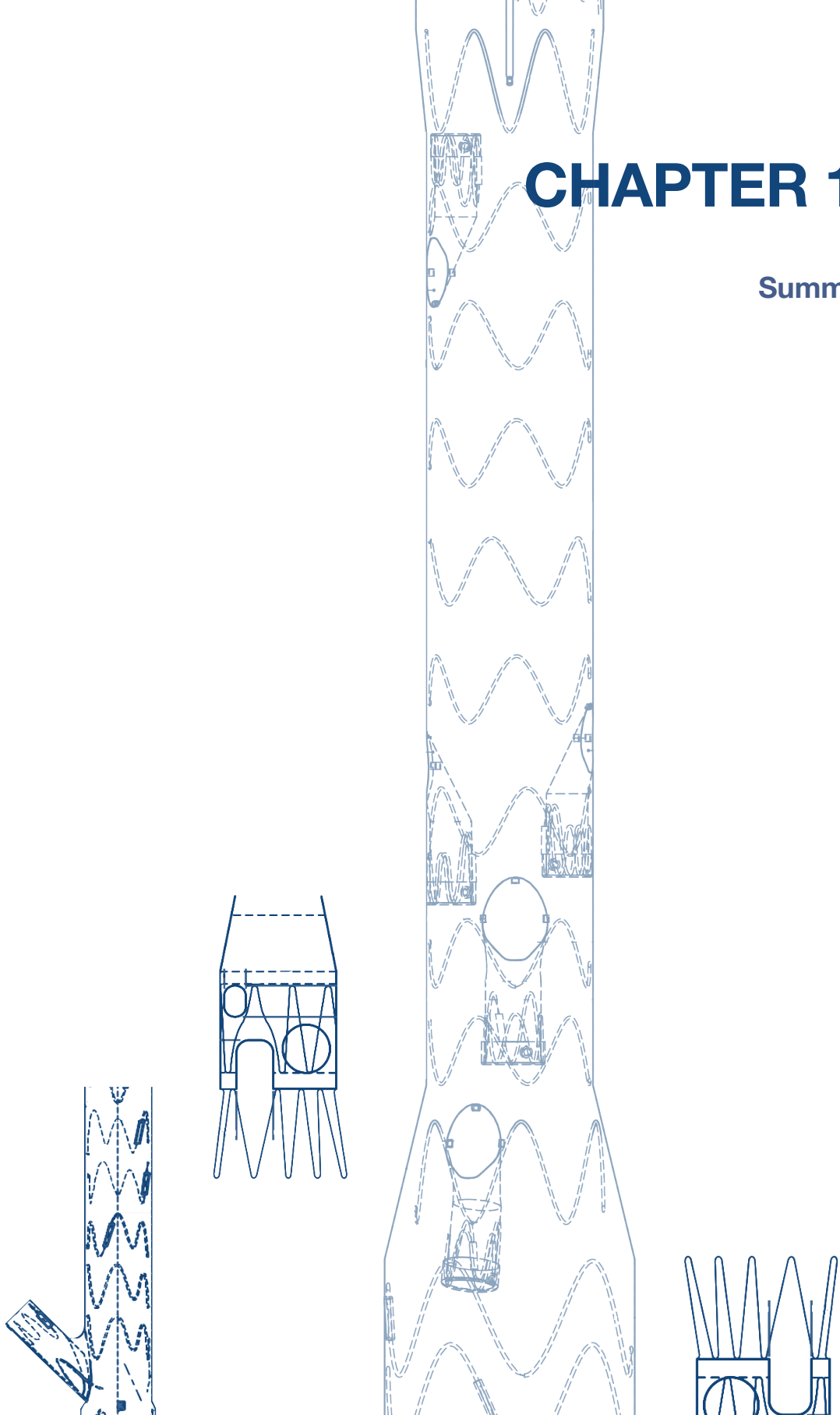
different manufacturers could be combined. It can support physicians in specific situations, for example patients who already have a Medtronic® EVAR and have an indication to be treated with an IBD. Considering Medtronic doesn't have an IBD system yet, an Artivion® E-liac branch device could be used. The study also shows that not every manufacturer has to provide all stent-graft configurations, because it's justified to combine stent-grafts from different brands. The iBEVAR study shows the continuous development of technology creating stent-grafts, which can be implemented in different anatomies to expand the indications of endovascular treatment options. Combination of different configurations in the same stent-graft (inner-branch, outer-branch and fenestrations) will support expanding endovascular options.

The target group of this thesis is mainly for vascular surgeons and interventional radiologists and all healthcare workers who are involved in the treatment of complex aortoiliac aneurysms. These target groups can be informed via published studies from this thesis in international journals and via presentations on (inter) national congresses.

Further research is needed in different configurations (inner-branch, outer-branch and fenestrations) of these stent-grafts. Furthermore, in the iliac branch devices the options of branches or fenestrations are still a domain that needs extended examination. Establishing randomised controlled trials comparing fenestrated stent-grafts with branched stent-grafts in the treatment of aortoiliac aneurysm will provide value data. This data will influence the direction for further development of these stent-grafts and their applicability.

CHAPTER 12

Summary



SUMMARY

This thesis investigates the technical challenges, outcomes, and risks of endovascular treatment of complex aortoiliac aneurysm. It suggests that hybrid operating rooms may assist in achieving satisfying results in complex FEVAR. However, complex FEVAR might unnecessarily expose the patients to higher risk of complications in the treatment of juxtarenal AAA, which are suitable for renal FEVAR. We have shown that renal FEVAR is a safe and effective treatment option with fewer intraoperative complications and similar mid-term outcomes compared with complex FEVAR. In the last decade a trend has evolved towards more complex FEVAR. The systematic review revealed that renal FEVAR remains a safe and effective treatment option in the borders of instruction of use with no higher risk on type Ia endoleak or reinterventions during follow-up compared to complex F/BEVAR. The indications for endovascular interventions increase due to the less invasive character and getting more applicable even in the elderly high-risk population. This thesis showed that age itself is not a reason to withhold FEVAR in the elderly, and choice of treatment should be based on the patient's comorbidities and preferences. Furthermore, the thesis support FEVAR as a feasible option for the repair of juxtarenal AAA after prior failed EVAR, but it is associated with increased technical challenges due to the previous placed stent-graft.

Chapter 2 evaluates the benefits of a hybrid operating room (group 2) compared with a mobile C-arm (group 1) in the treatment of AAA with FEVAR. We analysed 96 patients, of whom 46 patients were treated with a mobile C-arm and 50 patients in a hybrid operating room. In our hospital the hybrid operating room was active from December 2012, and we had the possibility to use CBCT and 3-D image fusion. The technical success and intraoperative complications were not significantly different (respectively, 91.3% group 1 vs. 94% group 2, p = .72 and 17% group 1 vs. 12% group 2, p = .46). In group 2 significantly less contrast was utilized compared to group 1 (group 1 median 150ml vs group 2 median 100mL, p< .001). Fluoroscopy- and intervention time were not significantly different. The 30-day mortality in group 1 was 9% and 2% in group 2 (p = .14), and 1-year survival was also not significantly different between both groups. Target vessel patency was significantly higher in group 1 (87.6% vs. 85.5% [p = .006] and 83.8% vs. 78.3% [p = .03]) at 6 and 12 months, respectively). However, this could be explained due to the significant (p< .001) more complex FEVAR (including SMA or/and celiac trunc) that were performed in group 2 compared to group 1. Regarding the primary patency in the renal arteries there was no significant

difference between the two groups. Freedom from reintervention during the 1-year follow-up was 91.3% in group 1 and 88% in group 2 (p = .60). This study showed satisfactory clinical and technical results using mobile C-arm or hybrid operating room in FEVAR interventions. In terms of mortality (30-day and 1-year), technical success, perioperative complications, reinterventions, and perioperative complications were similar between both groups, despite the significantly higher number of more complex FEVAR and secondary revisions of previously placed EVAR in group 2. The similar results in both groups could be explained due to better image quality and the use of advanced imaging applications in the hybrid operating room.

The impact of stent-graft configurations in FEVAR on clinical outcome has been investigated in **Chapter 3**. The aim of this study was to compare mid-term outcomes of fenestrated stent-grafts with only renal fenestration (renal FEVAR group) with stent-grafts including the SMA and celiac trunk (complex FEVAR group). We studied 154 patients (54 renal FEVAR vs. 100 complex FEVAR), who underwent FEVAR for the treatment of AAA. Median follow-up was 25 months (IQR 7-45). We revealed no significant differences in technical success and perioperative mortality. Intraoperative complications (4% vs. 18%, p = .001), operative time (145 min vs. 191 min, p = .001), radiation dose (119372 mGy*cm^2 vs. 159573 mGy*cm^2, p = .004) and fluoroscopy time (39 min vs. 54 min, p = .007) were significantly lower in the renal FEVAR group. During follow-up target vessel instability, endoleaks and reinterventions (renal FEVAR 24% vs. complex FEVAR 16%) were not significantly different between the two groups. The study showed that renal FEVAR is a safe and effective treatment for juxtarenal AAA. When we compared the renal FEVAR group to the complex FEVAR we describe fewer intraoperative complications with similar mid-term outcomes. We advise to choose for renal FEVAR stent-graft configuration if the anatomy is suitable for it. The renal FEVAR group had a significantly lower total effective seal zone and total used seal zone compared with the complex FEVAR group. However, during follow-up no late type Ia endoleaks in the renal FEVAR group was detected, which shows a secure proximal sealing zone.

The aim of **Chapter 4** is to demonstrate if there is a relationship between increased stent-graft complexity and clinical outcomes. After screening 7149 articles, 11 matched the inclusion criteria with a total of 2167 patients. Patients of any race, sex and age who presented with a PAA or TAAA (only Crawford type IV) and underwent elective endovascular repair were eligible for inclusion. Studies that compared renal (double) with complex (triple or quadruple) fenestrated

(FEVAR) and/or branched endovascular aneurysm repair (BEVAR) were eligible for inclusion. The systematic review showed no significant difference in technical success and all-cause mortality rate during hospital stay or within 30 days, however the latter was twice as high for the complex group. No significant difference was revealed between the two groups regarding reinterventions or the other secondary outcomes. In conclusion juxtarenal aneurysms renal FEVAR remains a safe and effective treatment option depending on the anatomy of the aneurysm and staying within the instruction of use. No significant higher risk on type Ia endoleak was reported in the renal FEVAR group, suggesting that whenever the anatomy is indicated for two fenestrations and a scallop for the SMA you can choose for this configuration, without elevated risk for reinterventions in the proximal sealing zone. However, complex FEVAR in this study showed no increase significant risk for target vessel occlusion, perioperative complications, mortality or reinterventions compared to renal FEVAR, so a liberal approach of complex FEVAR might be justified. On the other hand, we should be prudent with interpreting the data, as the large portion of the complex FEVAR was performed in the last period of several studies with accumulated experience and some of the studies were performed by high volume centres with extensive experience in FEVAR.

In **Chapter 5** we evaluate the mid-term results of FEVAR in octogenarians from two tertiary referral centers. We investigated 272 patients, which were divided in group 1 octogenarians (n 42) and group 2 non-octogenarians. The median age was respectively, 82 years and 72 years old. In our study there was no statistically significant difference in technical success, survival, and reintervention of FEVAR between the two groups. Moreover, no difference was seen between groups for the estimated cumulative target vessel patency. In conclusion, age itself should not be a reason to refuse FEVAR in the treatment of complex AAA. The choice of treatment in octogenarians should be weighed by patients' preference and comorbidities.

In **Chapter 6** we present results of one of the endovascular solutions after failed previous EVAR for the treatment of AAA. A total of 26 patients were treated with FEVAR (25 had a type Ia endoleak and one patient with endotension after EVAR). Twenty-three patients were treated with a fenestrated cuff and 3 patients with a bifurcated fenestrated stent-graft. The previous EVARs were from various manufacturers, but the fenestrated stent-grafts were all customized based on the Cook Zenith system (William A. Cook Australia, Ltd., Brisbane, Australia). Technical success was 92.3% and there was no postoperative mortality. Two

major complications occurred: one patient needed an open conversion because of impossibility to retrieve the top cap as a result of twist of the ipsilateral limb and another patient required permanent dialysis due to loss of the right kidney. In the patients who underwent a successful FEVAR interventions, target vessel patency was 100%. Our results suggest that FEVAR after EVAR is technical feasible, and that the outcome is related to the initial technical success. It is advantageous in terms of mortality and less morbid than open surgery but is associated with increased technical challenges because of the previously placed stent-graft.

Chapter 7 focusses on the use of an iliac branch device in the treatment of aortoiliac aneurysms and assesses the compatibility of the combination of two stent-grafts (EVAR Medtronic® (Vascular, Inc, Minneapolis, Minnesota, USA) and E-liac stent-graft System (Artivion® GmbH, Hechingen, Germany)) from different manufacturers. The study included 38 patients with a total of 50 hypogastric arteries which were treated with an IBD. Only balloon expandable stents (94% E-Ventus BX stent, 6% Advanta V12) were used as extension in the hypogastric artery. The aneurysm was successfully excluded in 94.7%. During follow-up, type Ib or type III endoleak wasn't detected and all stented hypogastric arteries remained patent. We conclude that the combination of these stent-grafts (EVAR+IBD) from different manufacturers are an effective and safe procedure for the treatment of aortoiliac aneurysms. Moreover, we confirm the high hypogastric artery patency rate using IBD.

Chapter 8 describes the mid-term outcomes of the E-liac stent-graft in the treatment of aortoiliac aneurysms. The clinical data regarding the E-liac stent-graft from Artivion®, however, are scarce. We included sixty-three patients (60 male, median age 70 years (IQR 66-;76) in our study, who were treated with 82 E-liac stent-grafts with a median follow-up of 38 months (IQR 22-51). This study showed a technical success rate of 95% and the internal iliac artery stayed patent during follow-up in 97.6%. No patients died or needed reinterventions within 30-days. During follow-up, we revealed in one patient an endoleak type Ib of both hypogastric arteries, however the patient refused additional interventions. One other patient had a contained rupture due to a type II endoleak. The patient had severe comorbidities and based on these findings the patient was rejected of any interventional treatment. Furthermore, only one (1.6%) IBD-related reintervention was needed with relining of the stent-graft. The primary patency of the hypogastric branch was 95.1% and the mortality was 25.4% during follow-up. In conclusion our study showed a high technical success rate for the E-liac stent-graft, with corresponding good mid-term outcomes. The E-liac stent-graft is a feasible, safe

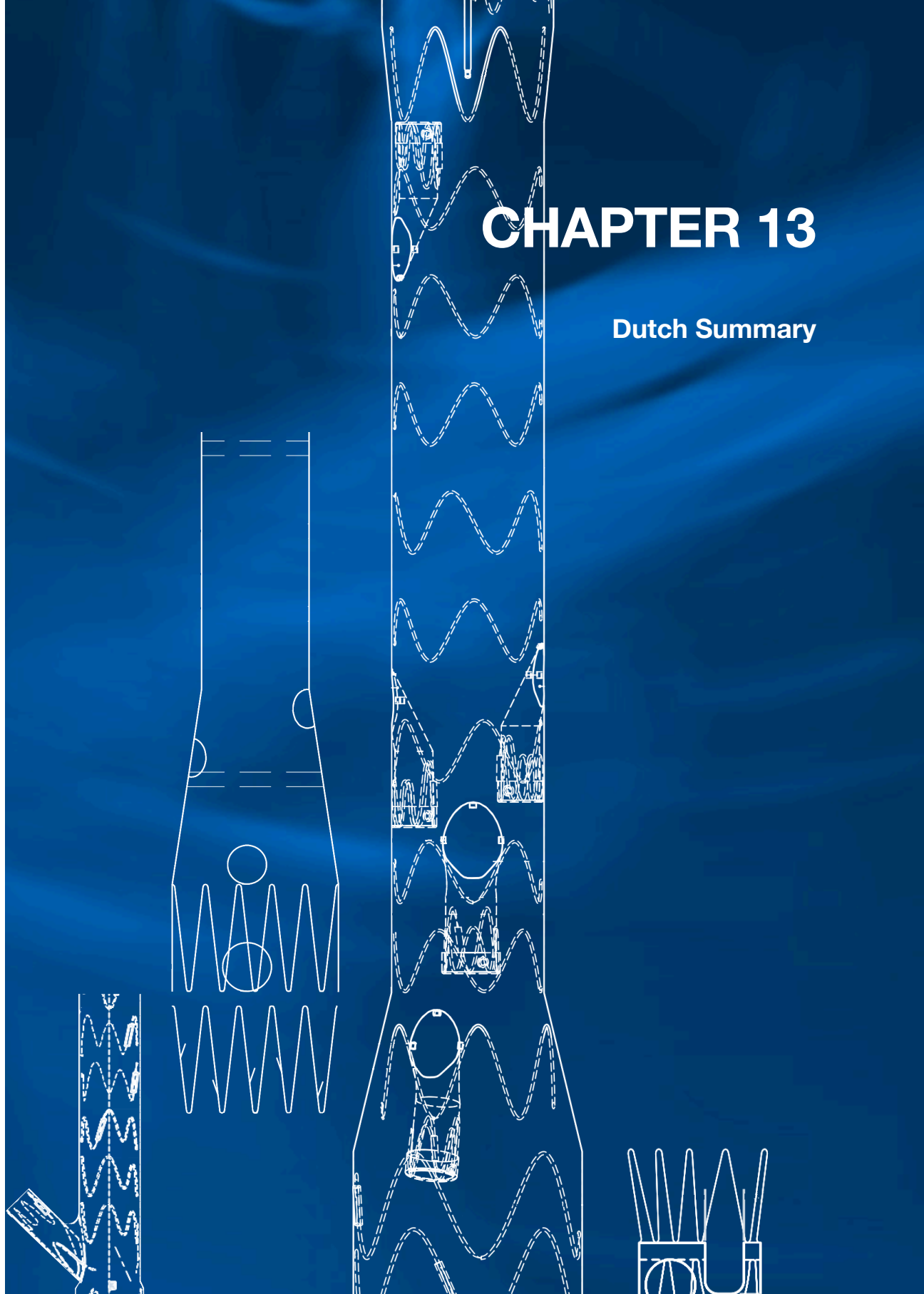
and effective stent-graft in the treatment of aortoiliac aneurysms.

Chapter 9 reports our first experience with inner-branched stent-grafts (iBEVAR) for the treatment of pararenal AAA. Twenty-three patients were treated with a mean follow-up of 15 months. Technical success was achieved in 96% of procedures, incorporating 87 inner branches. Two (8.3%) intraoperative complications (target vessel dissection) were reported, without additional reinterventions needed. Two (8.3%) patients died within 30 days after initial procedure. One due to respiratory failure and the other from an ischemic stroke. During follow-up, two patients (8.7%) required reintervention. The first patient had a type IIIc endoleak at the left renal artery that was treated by religning the bridging stent with another balloon expandable covered stent-graft after 12 months. The second patient needed an IBD intervention that was not successful during the initial iBEVAR procedure. Primary target vessel patency and freedom from reintervention during follow-up was respectively 98.9% and 87%. We detected no aneurysm-related mortality during follow-up. Overall survival was 69.6%. This study showed that iBEVAR was a safe and effective intervention achieving high technical success rate in the treatment of pararenal AAA.

In conclusion, this thesis describes the results of endovascular treatment of aortoiliac aneurysms. It provides evidence on the impact of stent-graft configurations (renal FEVAR, complex FEVAR, BEVAR) and compatibility of different manufactured stent-grafts for the management of aortoiliac aneurysms. Moreover, the high technical success and patency of IBDs was reconfirmed. Furthermore, it showed that after previous failed EVAR, endovascular solution with FEVAR is in terms of mortality and morbidity less than in open surgery. These complex interventions should not be abstained from octogenarians and should be performed with high sophisticated intra operative imaging. Further research on endovascular solutions for the treatment of aortoiliac aneurysms are crucial, as failed treatment leads to rupture and death of these patients.

CHAPTER 13

Dutch Summary



SAMENVATTING

Dit proefschrift onderzoekt de technische uitdagingen, resultaten en risico's die gepaard gaan met de endovasculaire behandeling van complexe aortoiliacale aneurysmata.

Hoofdstuk 2 evalueert de voordelen van het gebruik van een hybride operatiekamer (groep 2) in vergelijking met een mobiele C-boog (groep 1) voor de behandeling van abdominaal aorta aneurysma (AAA) met een gefenestreerde endoprothese (FEVAR). We analyseerden in totaal 96 patiënten, waarvan 46 patiënten werden behandeld met het gebruik van een mobiele C-boog en 50 patiënten in een hybride operatiekamer. In ons ziekenhuis werd de hybride operatiekamer operationeel vanaf december 2012, waardoor we de mogelijkheid hadden om CBCT (Cone Beam Computer Tomografie) en 3-D beeldfusie te gebruiken. Het technisch succes en de intra-operatieve complicaties waren niet significant verschillend tussen de twee groepen (respectievelijk 91,3% groep 1 vs. 94% groep 2, p = .72 en 17% groep 1 vs. 12% groep 2, p = .46). Bovendien vertoonden doorlichtingstijd en interventietijd ook geen significante verschillen. Niettemin werd in groep 2 significant minder contrast gebruikt vergeleken met groep 1 (groep 1 mediaan 150 ml vs. groep 2 mediaan 100 ml, p< .001). De mortaliteit binnen 30 dagen was 9% in groep 1 en 2% in groep 2 (P = .14), en de overleving na 1 jaar liet eveneens geen significant verschil zien tussen beide groepen. De 'target vessel patency' was significant hoger in groep 1 in vergelijking met groep 2 (87,6% vs. 85,5% [P = .006] en 83,8% vs. 78,3% [P = .03]) na respectievelijk 6 en 12 maanden). Dit kan deels worden toegeschreven aan het feit dat er significant (p< .001) meer complexe FEVAR (inclusief AMS (arteria mesenterica superior) en/of truncus coeliacus (TC)) werden uitgevoerd in groep 2. Wat betreft de 'primaire patency' van de nierarteriën was er geen significant verschil tussen de twee groepen. Na een follow-up van 1 jaar was er geen re-interventie nodig in 91,3% van de patiënten in groep 1 en 88% in groep 2 (p = .60). Dit onderzoek toonde positieve klinische en technische resultaten bij het gebruik van een mobiele C-boog of hybride operatiekamer voor FEVAR-interventies. Wat betreft mortaliteit (zowel op 30 dagen als op 1 jaar), technisch succes, peri-operatieve complicaties en re-interventies vertoonden beide groepen vergelijkbaar resultaten, ondanks het significant hogere aantal complexere FEVAR en secundaire revisies van eerder uitgevoerde EVAR in groep 2. De vergelijkbare resultaten in beide groepen zouden kunnen worden toegeschreven aan de verbeterde beeldkwaliteit en het gebruik van geavanceerde beeldvormingstoepassingen in de hybride operatiekamer.

In **hoofdstuk 3** hebben we geanalyseerd wat de invloed van de configuratie van de FEVAR endoprothese is op de klinische uitkomst. Het doel van deze studie was om de tussentijdse uitkomsten van endoprotheses met fenestraties voor alleen de nierarteriën (renale FEVAR groep) te vergelijken met endoprotheses met inbegrip van de AMS en/of de TC (complexe FEVAR groep). We bestudeerden 154 patiënten (54 renale FEVAR vs. 100 complexe FEVAR), die een FEVAR procedure ondergingen voor de behandeling van AAA. De mediane follow-up was 25 maanden (IQR 7-45). We vonden geen significante verschillen wat betreft technisch succes en peri-operatieve mortaliteit. Intra-operatieve complicaties (4% vs. 18%, p = .001), operatietijd (145 min. vs. 191 min., p = .001), stralingsdosis (119372 mGy*cm2 vs. 159573 mGy*cm2, p = .004) en doorlichtingstijd (39 min. vs. 54 min., p = .007) waren significant lager in de renale FEVAR groep in vergelijking met de complexe FEVAR groep. Tijdens follow-up waren er geen significante verschillen tussen de twee groepen wat betreft 'target vessel instability', endolekkage en re-interventies (renale FEVAR 24% vs. complexe FEVAR 16%). Het onderzoek toonde aan dat renale FEVAR een veilige en effectieve behandeling is voor juxtarenaal AAA. Beide groepen hebben vergelijkbare resultaten op middellange termijn, maar er waren minder intra-operatieve complicaties in de renale groep. Wij adviseren, indien de anatomie dit toelaat, te opteren voor een renale configuratie van de FEVAR endoprothese. Zowel de 'total effective sealing zone' als de 'total used sealing zone' waren significant lager in de renale FEVAR groep. Echter, gedurende de follow-up periode werden geen type Ia endolekkage vastgesteld in de renale FEVAR groep, wat duidt op een veilige proximale 'sealing zone'.

Het doel van de systematic review in **hoofdstuk 4** is om te onderzoeken of er een correlatie bestaat tussen een grotere complexiteit van gefenestreerde endoprotheses en de klinische resultaten. Na het screenen van 7149 artikelen, voldeden er 11 aan de inclusiecriteria, wat resulteerde in een totaal van 2167 patiënten. De inclusiecriteria omvatten patiënten van elk ras, geslacht en leeftijd die zich presenteerden met een para-renaal aorta aneurysma (PAA) of thoraco-adominaal aneurysma aorta (TAAA) (alleen Crawford type IV) en die een electief endovasculair herstel ondergingen. Alleen studies die renale FEVAR met complexere FEVAR en/of BEVAR vergeleken, werden geïncludeerd. De systematic review toonde geen significant verschil in technisch succes en mortaliteit tijdens ziekenhuisopname of binnen de 30 dagen. Ook werden er geen significant verschil gevonden tussen de twee groepen met betrekking tot re-interventies of andere secundaire uitkomsten. Concluderend blijft renale FEVAR een veilige en effectieve behandelingsoptie voor juxtarenale aneurysmata, op

voorwaarde dat de anatomie van het aneurysma dit toelaat en men zich houdt aan de gebruiksinstructies. Er werd geen verhoogd risico op re-interventies in de proximale 'sealing zone' vastgesteld in de renale FEVAR groep, wat suggereert dat deze endoprothese configuratie veilig is als de anatomie geschikt is voor twee renale fenestraties en een scallop voor de AMS. Dit onderzoek toonde echter geen significant verhoogd risico op 'target vessel' occlusie, peri-operatieve complicaties, mortaliteit of re-interventies voor complexe FEVAR in vergelijking met renale FEVAR. Daarom zou een ruimere toepassing van complexe FEVAR gerechtvaardigd kunnen worden. We moeten echter voorzichtig zijn bij het interpreteren van de gegevens, aangezien een groot deel van de complexe FEVAR werd uitgevoerd in de latere periodes van verschillende studies, waardoor men meer ervaring had opgebouwd in FEVAR ingrepen. En in deze studies waren het voornamelijk centra met een groot volume van dergelijke ingrepen, wat resulteerde in een aanzienlijke expertise in FEVAR procedures.

In **hoofdstuk 5** evalueren we de middellange termijn resultaten van FEVAR bij patiënten van 80 jaar en ouder in twee tertiaire referentiecentra. De studie omvatte 272 patiënten, verdeeld in twee groepen: groep 1 (80-plus groep (n=42) en groep 2 (overige patiënten). De mediane leeftijd was respectievelijk 82 jaar en 72 jaar. Onze studie toonde geen statistisch significant verschil in technisch succes, overleving en re-interventie van FEVAR tussen de twee groepen. Bovendien werden er geen verschillen gezien tussen de groepen met betrekking tot de 'estimated cumulative target vessel patency'. In conclusie kan worden gesteld dat leeftijd op zichzelf geen reden mag zijn om FEVAR te weigeren als behandelingsoptie voor complexe AAA. De keuze voor behandeling bij tachtigjarigen moet worden overgewogen op basis van de voorkeur van de patiënt en hun comorbiditeiten.

In **hoofdstuk 6** presenteren we de resultaten van een endovasculaire behandeling van een AAA na het falen van eerder geplaatste EVAR. In totaal werden 26 patiënten behandeld met FEVAR, waarvan 25 patiënten een type Ia endolekkage hadden en één patiënt ontwikkelde endotension na eerdere EVAR. Van deze totale groep werden drieëntwintig patiënten behandeld met een gefenestreerde cuff en 3 patiënten met een gefenestreerde bifurcatie-endoprothese. De eerdere EVAR's waren van verschillende fabrikanten, maar de gefenestreerde endoprotheses waren allemaal op maat gemaakte Cook Zenith (William A. Cook Australia, Ltd., Brisbane, Australië). Het technische succes bedroeg 92,3%, zonder postoperatieve mortaliteit. Er deden zich twee belangrijke complicaties voor: één patiënt vereiste een open conversie vanwege het niet kunnen verwijderen van

het inbreng systeem als gevolg van verdraaiing van het ipsilaterale poot, en een andere patiënt had permanente dialyse nodig vanwege het verlies van de rechter nier. Bij de patiënten die een succesvolle FEVAR-procedure ondergingen, was de 'target vessel patency' 100%. Onze bevindingen suggereren dat FEVAR na EVAR technisch haalbaar is en dat het resultaat gerelateerd is aan het initiële technische succes van de procedure. Deze aanpak is gunstig wat betreft mortaliteit en is minder invasief dan open chirurgie, maar gaat gepaard met meer technische uitdagingen vanwege de eerder geplaatste endoprothese.

Hoofdstuk 7 richt zich op de behandeling van aortoiliacale aneurysmata door middel van EVAR met een 'iliac branch endoprothese' (IBD). Dit hoofdstuk beoordeelt de compatibiliteit van de combinatie van deze twee endoprotheses van verschillende fabrikanten, namelijk de EVAR van Medtronic® (Vascular, Inc, Minneapolis, Minnesota, VS) en het E-liac endoprothese systeem van Artivion® (GmbH, Hechingen, Duitsland). In dit onderzoek werden 38 patiënten met in totaal 50 iliacale trajecten behandeld met een IBD. Uitsluitend ballon-expandeerbare stents (94% E-Ventus BX stent, 6% Advanta V12) werden gebruikt als extensie in de arteria iliaca interna (AII). Het aneurysma werd succesvol behandeld in 94,7% van de gevallen. Tijdens de follow-up periode werden geen gevallen van endolekkage type Ib of type III gedetecteerd en alle gestente AIIs bleven doorgankelijk. Op basis van onze bevindingen concluderen we dat de combinatie van deze endoprotheses (EVAR+IBD) van verschillende fabrikanten een effectieve en veilige procedure is voor de behandeling van aortoiliacale aneurysmata. Bovendien bevestigen we de hoge mate van doorgankelijkheid van de AII bij het gebruik van een IBD.

Hoofdstuk 8 beschrijft de resultaten op middellange termijn van het gebruik van de E-liac endoprothese (Artivion® GmbH, Hechingen, Duitsland) bij de behandeling van aortoiliacale aneurysmata. In de literatuur zijn er beperkte klinische resultaten beschikbaar met betrekking tot de E-liac endoprothese. In onze studie hebben we 63 patiënten geincludeerd (60 mannen, mediane leeftijd 70 jaar (IQR 66-;76)), die in totaal 82 E-liac endoprotheses kregen. De mediane follow-up periode bedroeg 38 maanden (IQR 22-51). Onze bevindingen tonen aan dat het technisch succespercentage van de E-liac endoprothese 95% bedraagt en dat de AII in 97,6% van de gevallen doorgankelijk bleef tijdens de follow-up periode. Binnen de 30 dagen deed zich geen enkel overlijden voor, noch was er een re-interventie nodig. Tijdens de follow-up constateerden we bij één patiënt een endolekkage type Ib van de beide AIIs, maar de patiënt weigerde verdere ingrepen. Een andere patiënt ontwikkelde een gedekte ruptuur als gevolg

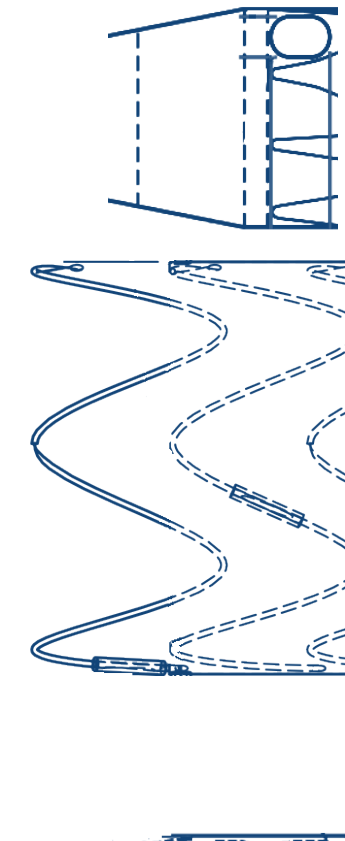
van een type II endolekkage. Deze specifieke patiënt had echter ook ernstige co-morbiditeiten, waardoor er werd afgezien van een re-interventie. Verder was er slechts één (1,6%) re-interventie gerelateerd aan de IBD, waarbij een 'relining' van de endoprothese werd uitgevoerd. De 'primary patency' van de AII bedroeg 95,1% en de mortaliteit tijdens de follow-up was 25,4%. Samenvattend toonde ons onderzoek aan dat het gebruik van de E-liac endoprothese een hoog technisch succespercentage heeft en goede uitkomsten op middellange termijn oplevert. De E-liac endoprothese blijkt een haalbare, veilige en effectieve behandelingsoptie te zijn voor aortoiliacale aneurysmata.

Hoofdstuk 9 geeft een overzicht van onze initiële ervaring met een 'inner-branched' endoprothese (iBEVAR; Artivion® GmbH, Hechingen, Duitsland) voor de behandeling van para-renale AAA. In totaal ondergingen 23 patiënten deze procedure, met een gemiddelde follow-up van 15 maanden. Technisch succes werd behaald in 96% van de procedures, waarbij 87 'inner branches' werden geplaatst. Er deden zich twee (8,3%) intra-operatieve complicaties ('target vessel dissection') voor, echter zonder dat aanvullende reinterventies nodig waren. Binnen de 30 dagen na de initiële procedure overleden twee (8,3%) patiënten, één als gevolg van respiratoir falen en de andere door een ischemische beroerte. Gedurende de follow-up ondergingen twee patiënten (8,7%) een reinterventie. De eerste patiënt kreeg te maken met een endolekkage type IIIc ter hoogte van de linker nierarterie, dat na 12 maanden werd behandeld met een extra 'balloon expandable covered stent'. Bij de tweede patiënt werd een IBD-procedure uitgevoerd, omdat deze niet was ingebracht tijdens de langdurige initiële iBEVAR-procedure. Primaire 'target vessel patency' en percentage patiënten zonder reinterventie tijdens follow-up bedroegen respectievelijk 98,9% en 87%. Er was geen sprake van aneurysma gerelateerde mortaliteit tijdens de follow-up, en de totale overleving was 69,6%. Dit onderzoek bevestigt dat iBEVAR een veilige en effectieve ingreep is, gekenmerkt met een hoog technisch succespercentage bij de behandeling van para-renale AAA.

In conclusie, dit proefschrift beschrijft de resultaten van complexe endovasculaire behandeling van aortoiliacale aneurysmata. De diverse onderzoeken tonen het belang aan van de gebruikte radiologische apparatuur en de variatie in endoprothese configuratie in de resultaten van de behandeling. Ook wordt er aangetoond dat deze complexe ingrepen niet mogen worden onthouden aan tachtigjarigen alleen op basis van leeftijd. Verder onderzoek naar endovasculaire oplossingen voor de behandeling van aortoiliacale aneurysmata blijft van cruciaal belang, aangezien een gefaalde behandeling leidt tot ruptuur en overlijden van deze patiënten.

CHAPTER 14

Acknowledgements - Dankwoord
List of publications
Curriculum Vitae



ACKNOWLEDGEMENTS – DANKWOORD

Tot slot wil ik mijn oprechte dank uitspreken aan iedereen die op welke manier dan ook heeft bijgedragen aan de totstandkoming van dit proefschrift. Mijn diepste waardering gaat in de eerste plaats uit naar alle patiënten, wiens bijdrage het mogelijk heeft gemaakt om dit proefschrift te realiseren. Daarnaast wil ik een aantal mensen in het bijzonder noemen.

Prof. dr. G.W.H. Schurink, beste Geert Willem, mijn diepe erkenning voor je belangrijke bijdrage als promotor. Ik herinner me nog levendig dat je me telefonisch vroeg of het niet iets voor mij zou zijn om een proefschrift te schrijven. Zonder enige aarzeling antwoordde ik met volle overtuiging 'JA'. Ik ben je dankbaar dat je destijds die cruciale vraag hebt gesteld en voor je voortdurende steun en begeleiding gedurende dit proces. Het vermogen om helder het overzicht te behouden en de moeilijke discussiepunten in de literatuur niet te vermijden, maar juist bij te dragen aan de wetenschappelijke dialoog, zijn enkele van jouw sterke eigenschappen. Dankzij jouw wetenschappelijke begeleiding, toewijding en expertise heeft dit proefschrift een succesvol eindresultaat behaald. Ik kijk uit naar verdere wetenschappelijke onderzoeken, die we samen in onze regio kunnen uitvoeren.

Dr. B.M.E. Mees, beste Barend, mijn oprechte dank voor de bereidheid om de rol van co-promotor op je te nemen. Je bent later in mijn PhD traject toegetreden, maar ik ben bijzonder verheugd dat je het alsnog hebt gedaan. Je kritische evaluatie van de manuscripten heeft een onmiskenbare bijdrage geleverd aan de wetenschappelijke waarde en niveau. Samen hebben we intensief gereflecteerd over de te volgen koers voor deze manuscripten, en uiteindelijk kwamen we altijd tot een overeenstemming, wat heeft geresulteerd in aanzienlijke kwaliteitsverbeteringen. Dank voor je voortdurende bereikbaarheid voor uitgebreide discussies en in het bijzonder voor je waardevolle respons op mijn vragen.

Voorzitter en de leden van de beoordelingscommissie, prof. dr. A.W.J. Hof, van 't (voorzitter), dr. E. Bidar, prof. dr. I. Fourneau, prof. dr. J.A. van Herwaarden en prof. dr. J.E. Wildberger, mijn hoge achting voor de tijd en inspanningen die jullie hebben besteed aan het lezen en kritisch beoordelen van mijn proefschrift, ondanks dat dit in de zomerperiode viel.

Prof. dr. P. Broos, beste Paul, het genoegen van onze kennismaking ontstond tijdens een hoorcollege. Een bijeenkomst die ik niet snel zal vergeten vanwege de opvallende aanwezigheid van mede-studenten. Na een buitengewoon boeiende

en intrigerende les begreep ik al snel waarom de zaal zo goed gevuld was. Jouw onvermoeibare ondersteuning vanaf het begin van mijn opleiding tot chirurg is iets wat ik ten zeerste waardeer. Bovendien ben ik bijzonder trots dat ik behoorde tot de laatste groep assistenten die jij hebt begeleid. Het is zelfs een eer geweest om jou te mogen assisteren bij een van de laatste operaties, en ik vermoed zelfs dat dit de laatste operatie in jouw carrière is geweest vóór je welverdiende pensioen. Mijn dank gaat uit naar jou voor de solide en uiterst hoogwaardige opleiding die je hebt verzorgd op het gebied van de chirurgie.

Prof. dr. I. Fourneau, beste Inge, het fundament voor mijn chirurgische carrière is op een solide wijze gelegd door de Leuvense School. Gedurende mijn opleiding heb ik het voorrecht gehad te mogen ervaren hoe jij met een onuitputtelijke passie en onvoorwaardelijke toewijding hebt bijgedragen aan het succesvolle traject van vele jonge vaatchirurgen (de Leuvense telgen) uit Leuven. Het heeft mij altijd een gevoel van trots gegeven om als vervangend staflid zij aan zij met jou te mogen werken in UZ Leuven. Ik ben blij dat mijn huidige functie mij nog steeds in staat stelt om assistenten chirurgie te verwelkomen uit Leuven, waardoor ik een blijvende band met Leuven behoud. Verder wil ik je bedanken voor je adviezen op de meest cruciale momenten in mijn carrière, die van onschatbare waarde zijn gebleken. Ik zie vol verwachting uit naar de mogelijkheid om samen te werken aan wetenschappelijke projecten in de toekomst. We hebben reeds een veelbelovende start gemaakt.

Prof. Dr. E. Verhoeven, beste Eric, de Duitse taal was voor mij geen grote drempel. Het was voor mij verbazingwekkend hoe snel ik me in Nürnberg thuis voelde. Deze vlotte aanpassing was grotendeels te danken aan jouw begeleiding en ondersteuning. Je kennis, je professionaliteit, je passie voor vaatchirurgie en sociale omgang in het team hebben me enorm aangetrokken. De waardevolle ervaring die ik heb opgedaan in complexe aorta chirurgie heeft een blijvende invloed gehad op mijn carrière en heeft me in staat gesteld me verder te specialiseren in dit vakgebied. Het legde tevens de basis voor mijn huidige proefschrift.

Prof. dr. L. Bouwman, dr. CY Wong, drs. P. Salemans, beste Lee, ChunYu, Pieter, beste vaatmaten, ik wil mijn dankbaarheid en erkenning uitspreken voor de sterke band en hechte samenwerking die we hebben ontwikkeld als vaatmaten. Samen hebben we door uitdagende situaties genavigeerd en ervoor gezorgd dat we als een geolied team tevoorschijn kwamen, wat een onschatbare waarde heeft in mijn professionele reis. De kracht van ons team schuilt niet alleen in onze constante beschikbaarheid voor elkaar, maar ook in onze bereidheid om elk

onderwerp openlijk te bespreken, aanpassingen te maken en gezamenlijk sterker te worden. We hebben niet alleen binnen de klinische setting hard gewerkt, maar ook op wetenschappelijk vlak. Mijn dank gaat uit naar ieder van jullie voor jullie waardevolle bijdragen aan de verschillende manuscripten.

MHZL, beste vakgroep chirurgie Zuyderland MC, beste collegae, ik wil graag mijn grote respect uitspreken voor het privilege om deel uit te maken van onze vakgroep. Ik ben trots op onze samenwerking en het gezamenlijke streven naar uitmuntendheid in ons vakgebied. Bij mijn overgang van België naar Nederland ben ik warm en hartelijk ontvangen door elk van jullie. Deze warme ontvangst heeft me meteen thuis doen voelen en mijn integratie in de groep vergemakkelijkt. Ik ben jullie allen dankbaar voor de geboden steun en vertrouwen.

Beste collega's van Zuyderland MC, beste vaat-operatieassistenten, angioteam, poli medewerksters, verpleegkundig specialisten, physician assistants, OK-planners, wondverpleegkundigen, afdeling 11 en KNF. Ik wil mijn waardering uitspreken voor jullie toewijding en inzet die de basis vormen voor een goede patiëntenzorg. De sterke teamgeest die hier heerst, sluit mooi aan bij mijn persoonlijke waarden. De afgelopen jaren hebben we vooral op het gebied van multidisciplinaire samenwerking mooie resultaten geboekt. Onze gezamenlijke passie om de patiënten 'de zorg van je leven' te bieden, blijft de drijfveer.

Europa Ziekenhuizen, vakgroep chirurgie St. Elisabeth, beste collegae, met grote vreugde kijk ik terug op mijn vijf jaar werkervaring in Brussel. Samen hebben we belangrijke vooruitgang geboekt, zowel op het gebied van vaatchirurgie als in multidisciplinaire samenwerking, waarbij we talloze uitdagingen succesvol hebben overwonnen. Dank voor jullie steun in mijn persoonlijke groei om de Franse taal te leren en in het bijzonder de secretaressen. Ik zal deze periode in de Europa Ziekenhuizen altijd met warme gevoelens blijven herinneren.

Beste medeauteurs, bedankt voor de vruchtbare samenwerking. Onze gezamenlijke inspanningen om elkaar te stimuleren, moeilijkheden te overwinnen, onze krachten te bundelen en onvermoeibaar door te werken hebben geleid tot dit proefschrift. Jullie steun en betrokkenheid zijn van wezenlijk waarde geweest.

Paranimf, Roel Nollen. Nollen, bedankt voor je bereidwilligheid om deze belangrijke rol als paranimf op je te nemen. Onze 34 jaar durende vriendschap en broederschap hebben geleid tot de vanzelfsprekendheid dat jij naast mij zou staan tijdens deze cruciale verdediging. Je bent altijd aanwezig geweest, zowel in de hoogte- als dieptepunten in mijn leven. Jouw onschatbare steun en unieke perspectieven hebben mij veel geleerd. Onze capaciteit om elkaar uit te dagen en vooral de waarheid te vertellen, zijn de fundamenten van onze vriendschap.

Paranimf, Rik de Jongh, onze vriendschap heeft een solide basis gevonden tijdens onze periode als assistenten in opleiding. Kort daarna besloten we om samen een reis te maken, wat voor mij een bijzondere leuke ervaring was. In de jaren die volgden, zijn we in nauw contact gebleven en heeft onze band zich alleen maar verdiept en versterkt. Het was een eer om je getuige te zijn op je bruiloft, een moment waarvan ik echt heb genoten. Ik vind het ook een eer dat jij bereid bent om de rol van mijn paranimf op je te nemen.

Muzaffer † (vader) & Zöhre (moeder), jullie onuitputtelijke liefde is het warmste geschenk dat ik ooit in mijn leven heb gekregen. Jullie liefde heeft me gevormd tot de persoon die ik vandaag ben. Het heeft me laten voelen dat je in het leven alles kunt bereiken, zolang je maar volhoudt. Zelfs als ik soms tekortschoot, wist ik jullie steun altijd te vinden. Opleiding heeft altijd een prominente plaats ingenomen in jullie leven, en dit heeft mij aangemoedigd om mijn nieuwsgierigheid verder te ontwikkelen. Dank dat jullie voor mij een warm nest hebben gecreëerd, gevuld met prachtige waarden en sterke normen. Het onvoorwaardelijk vertrouwen en altijd klaar staan om je medemens te helpen heb ik van jullie geleerd.

Hülya (zus), zonder jou was ik niet zo ver gekomen. Je bent altijd een compas geweest in mijn leven, als ik het even niet wist dan kon ik bij jou terecht voor richtinggevend advies. Door je zusterliefde en onvoorwaardelijke beschikbaarheid heb ik de ongrijpbare doelen bereikt in mijn leven. Met de jaren ben ik steeds meer gaan inzien hoe waardevol onze relatie is geworden. Dank dat je me altijd bijstond tijdens het schrijven van dit proefschrift. En dank dat je me hebt laten zien wat de echte betekenis van een zus is. Het is nu tijd voor je broertje om in de rol van de oudere broer te stappen, want na verloop van tijd hoef je niet meer voor de jongste te zorgen.

Özgür (broer), je bent één van de meest belangrijkste personen in mijn leven. Je hebt talloze rollen op je genomen om mijn leven gemakkelijker te maken. Je was niet alleen mijn grote broer, altijd klaar om op te steunen, maar ook een vader, vriend, mentor en soulmate. Samen zochten we naar een kamer in Leuven, werkten we in de horeca, deelden we je fonkelnieuwe auto, gingen we vaker op vakantie, brachten elk weekend samen door, sportten we samen, en zo kan ik nog wel even doorgaan. We hebben zoveel plezier gehad. Bedankt dat je mijn broer bent.

Onze familie, de familie Yazar, en vooral Serpil, heeft iets bijzonders: we doen veel dingen samen als een team. We begrepen al snel dat we in het leven verder kunnen komen als we samenwerken dan wanneer we alleen handelen. Ieder van jullie heeft zijn of haar eigen speciale talenten, en op die manier vullen we

elkaar aan en kunnen we elkaar op verschillende manieren ondersteunen. We mogen dan wel niet groot zijn als familie, maar we zijn zeker hecht. Ik wil jullie bedanken voor jullie voortdurende steun. Ik hoop dat ik een voorbeeld voor jullie heb kunnen zijn, maar jullie zijn zeker een voorbeeld voor mij geweest, van de jongste tot de oudste generatie. De talloze zomervakanties die we samen hebben doorgebracht, hebben een bijzondere plek in mijn hart veroverd. Ze zijn rijk aan vreugdevolle en humorvolle herinneringen die me altijd zullen bijblijven. Laten we niet vergeten: 'Wij zijn de Yazarlar,' een trotse herinnering wat we al samen hebben gedeeld.

Vreugdevolle Axel Kaan (zoon), een godsgeschenk dat ben jij. Jouw vreugde, jouw stem, jouw glimlach en vooral jouw liefde hebben me altijd de energie gegeven om door te gaan, wat er ook op mijn pad kwam. Je kwam vaak op mijn schoot zitten, terwijl we samen naar het grote scherm keken, waar nog onafgemaakte manuscripten op wachtten. Wie weet, misschien was dat het begin voor jou, en zul je op een dag ook een proefschrift schrijven. Als dat moment komt, zal ik naast je zitten en samen met jou naar dat grote scherm kijken.

Liefdevolle Sinem (echtgenote), dank je wel dat je in mijn leven bent verschenen. Als ik nu terugkijk op wat je voor me hebt betekend tijdens het schrijven van dit proefschrift, schieten woorden tekort om mijn dankbaarheid te uiten. Het delen van dit levenspad met jou is een van de meest kostbare geschenken die ik ooit heb ontvangen. Dank je wel voor het altijd vasthouden van mijn hand, voor het telkens weer optillen van mijn geest, en voor je onvoorwaardelijke liefde. Zonder jouw voortdurende steun zou ik dit proefschrift nooit hebben kunnen voltooien. Jouw geduld, jouw belangstelling, en bovenal jouw liefde, hebben me de kracht gegeven om door te gaan. Jouw nieuwsgierigheid tijdens mijn diensten was als een onuitputtelijke bron van nachtelijke vragen, zelfs wanneer de hele wereld sliep. Je nachtelijke vragen over het wel of niet opereren van een patiënt, waren een bron van amusement, die ik nooit zou willen missen. Seni seviyorum "Mon Cœur".

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This Thesis

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CURRICULUM VITAE

Ozan Yazar was born on May 3rd, 1977, in Erzincan, Türkiye. At the age of two, he moved with his parents, older sister Hülya and brother Özgür to Maastricht, the Netherlands. After graduation from high school in Maastricht, he started his medical education in Belgium. In 2000 he received his Bachelor of Medicine at the University Hasselt. Afterwards, he completed his medical education at the Catholic University Leuven (KU Leuven) and received his Master of Medicine in 2004.

In that same year he started his general surgical training under the guidance of prof. dr. P. Broos, the University Hospitals Leuven. During his traineeship he worked in several Belgium Hospitals (Dodoens Hospitals in Mechelen, Virga Jesse Hospital in Hasselt, Imelda Hospital in Bonheiden). In his fourth year of surgical training, he worked in Maxima Medical Center (MMC) in Veldhoven, the Netherlands. Between 2008 and 2010 he played an active role as a board member in the Belgian Association of Surgical Trainees (BAST) and fulfilled the position of president in the last period.

In 2010 he became a general surgeon and started his two years of specialization in vascular surgery under guidance of prof. dr. I. Fourneau and prof. dr. B. Meyns. The first year he worked at the Hospital East-Limburg (ZOL) in Genk under supervision of dr. H. Schroë. In his second year he moved to Germany and started working in Klinikum Nuremberg. He mastered the latest techniques in aortic surgery including fenestrated endovascular aortic repair (FEVAR), under supervision of prof. dr. E. Verhoeven.

In 2012/2013 he was appointed a deputy staff member in the University Hospitals Leuven and did an additional fellowship in MMC becoming a certified vascular and endovascular surgeon in the Netherlands. In 2014 he filled the position as staff member vascular and endovascular surgeon in the Europe Hospitals in Brussels for a period of 5 years. After taking extensive French classes he mastered a fifth language, as most of his patients were French speaking in the South of Brussels.

Moreover, he continued his work focusing on the endovascular treatment of aneurysms and the arteries below the knee. In 2018 he started his PhD program on Fenestrated and Branched Stent-Grafts for Treatment of Complex Aortoiliac Aneurysms under supervision of prof. dr. GW. Schurink and dr. B. Mees at the Maastricht University Medical Center+ (MUMC). In 2019 he joined the vascular team at the Zuyderland Medical Center (ZMC) in Heerlen, the Netherlands. Together with his vascular colleagues prof. dr. L. Bouwman, dr. CY. Wong and drs. P. Salemans, he expanded his endovascular expertise by treating aneurysms with branched EVAR (BEVAR) and iliac branch stent-grafts. Currently, studies have been initiated with Optical Coherence Tomography and Fractional Flow Reserve in the arteries below the knee. Furthermore, he established decisive care pathways (aneurysm, carotid and diabetic foot) and launched a multidisciplinary diabetic foot clinic in the ZMC. He currently works there and lives together with his wife Sinem Yazar Uslu in Lanaken, Belgium. They have one son, Axel Kaan Yazar (2021).