UNIVERSITÀ DEGLI STUDI DI PADOVA

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TESI DI LAUREA

Outcomes of a novel off-the-shelf preloaded inner branch endograft for the treatment of complex aortic pathologies

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Riassunto

Presupposti dello studio: Il trattamento degli aneurismi aortici complessi (juxtarenali, pararenali, e toracoaddominali) è caratterizzato da una elevata difficoltà tecnica. L'introduzione delle tecniche endovascolari hanno permesso di ridurre l'invasività del trattamento, con conseguente riduzione di mortalità e complicanze perioperatorie rispetto al trattamento chirurgico convenzionale. Le endoprotesi a disposizione per il trattamento degli aneurismi aortici complessi possono essere custom-made (specifiche per il paziente) oppure "off-the-shelf"; queste ultime sono disponibili in misure standard in tempi rapidi, e non necessitano dei tempi di attesa di costruzione che hanno invece le endoprotesi specifiche per il paziente.

Scopo dello studio: Lo scopo di questo studio è di investigare gli outcome a breve (30 giorni) e medio (6 mesi) termine di una nuova endoprotesi off-the-shelf con inner branch pre-cannulati (E-nside Jotec Gmbh, Hechingen, Germania) per il trattamento di patologie aortiche complesse.

Metodi: I dati sono stati raccolti in un registro elettronico (REDCap) costituito su base volontaria da parte di diversi centri distribuiti sul territorio nazionale, includendo tutti i pazienti trattati con questo tipo di endoprotesi. L'endpoint primario è il successo tecnico a 30 giorni, definito come corretto posizionamento dell'endoprotesi, endoleak di tipo I o III, occlusione di un vaso viscerale o iliaco.
Gli endopoint secondari sono stati la comparsa di eventi avversi maggiori, l'assenza di complicanze dell'endoprotesi oltre che l'instabilità dei vasi target a 6 mesi, definita come comparsa di endoleak od occlusione.

Risultati: I dati di 104 pazienti sono stati raccolti da 26 centri italiani. L'età media è pari a 73 ± 8 anni e 70 (68%) sono uomini. Diverse patologie aortiche sono state trattate tra cui aneurismi degenerativi in 84 (82,4%) pazienti, dissezioni acute o subacute in 4 (3,9%), pseudoaneurismi in 6 (5,9%), ulcere aortiche penetranti in 3 (2,9%), ematomi intramurali in 1 (1%) e dissezioni croniche in 4 (3,9%). Il diametro medio degli aneurismi trattati è pari a 66,16 ± 16,51 mm.

Gli inner branch sono stati cannulati dall'alto in 81 (81%) casi, mentre la cannulazione utilizzando soltanto l'accesso femorale è stato scelto in 19 (19%) casi. Il tempo medio della procedura è pari a 258±120 min, con un volume medio di contrasto impiegato pari a 215±137 ml ed una esposizione alle radiazioni di 3189±5862 mGy*cm^2. In 36 (36%) pazienti è stato utilizzato un approccio multi-step.

Il successo tecnico è stato pari a 97,1% e la mortalità al 6%. Tra gli eventi avversi maggiori. 8 (8%) pazienti hanno presentato ischemia midollare, 4 (4%) ictus e 1 (1%) infarto del miocardio. In totale per 10 (2%) vasi target si è reso necessario un re-intervento entro 30 giorni.

Dal follow-up a 6 mesi, disponibile per 63 pazienti, si evince come la libertà da instabilità dei vasi target sia pari al 94% e la libertà da complicanze del corpo protesico pari al 100%.

Conclusione: Dai dati raccolti in questo registro si evince come E-nside sia stata usata per il trattamento di un largo spettro di patologie aortiche, inclusi scenari urgenti e anatomie complesse. I risultati mostrano un'eccellente sicurezza ed efficacia, oltre che soddisfacenti outcomes a 30 giorni. Ulteriori studi di follow-up saranno necessari per chiarire ulteriormente i risultati a lungo termine e il ruolo che questa nuova endoprotesi può ricoprire nel trattamento di patologie aortiche complesse.

Abstract

Background: The treatment of complex aortic aneurisms (juxtarenal, pararenal and thoracoabdominal) is characterized by an elevated technical difficulty.
New endovascular techniques allows to treat this condition, reducing operating time and complications if compared to open surgery. Endovascular stent grafts for the treatment of complex aortic aneurysms could be classified in custom made and off-the-shelf. The off-the-shelf ones are available in standard measures without having to wait the manufacturing time of custom made devices.

Objective: To investigate the early outcomes of a novel off-the-shelf preloaded inner branched endograft (E-nside Jotec Gmbh, Hechingen, Germany) in the treatment of complex aortic pathologies.

Methods: Data from a physician-initiated national multicenter registry were collected, including all consecutive patients treated with the E-nside endograft, an off-the-shelf inner branched endograft with preloaded catheters to facilitated branches cannulation. All data were stored in a dedicated electronic data capture system (REDCap). The primary endpoint was 30-days technical success, defined as successful introduction and deployment of the device in the absence of surgical conversion or mortality, type I or type III endoleak, branch occlusion, or graft limb obstruction. Secondary outcomes were the development major adverse events (MAE) and freedom from main endograft complications and target vessel instability at 6 months, defined as endoleak or occlusion.

Results: One-hundred-four consecutive patients from 26 Italian centers were collected. Mean age was 73 ± 8 years and 70 (68%) were male. Aortic pathologies included degenerative aneurysm in 84 (82,4%), acute or subacute dissection in 4 (3,9%), pseudoaneurysm in 6 (5,9%), penetrating aortic ulcer in 3 (2,9%), intramural hematoma in 1 (1%), chronic dissection in 4 (3,9%). Mean aneurysm diameter was 66,16 ± 16,51 mm.
The inner branches were cannulated from above in 81 (81%) cases, while cannulation and stenting using only the femoral accesses was performed in 19

(19%). Mean procedural time was 258±120 min, with a mean contrast volume of 215±137 ml and a radiation exposure of 3189±5862 mGy*cm^2. Staged procedures were performed in 36 (36%) patients.
Technical success was 97,1% and mortality was 6%. MAEs were spinal cord ischemia in 8 (8%), stroke in 4 (5%), and myocardial infarction in 1 (1%). There were 10 (2%) target vessel-related events needing reintervention. 6-months follow-up was available for 63 patients. Freedom from target vessel instability was 94% (19 stenosis/occlusion and 3 endoleaks) and freedom from main endograft complications was 100%.

Conclusion: In this real-life non-sponsored registry, the E-nside endograft was used for the treatment of a broad spectrum of aortic pathologies, including urgent and/or complex anatomy. Results shows excellent technical implantation safety and efficacy as also early outcomes; longer-term follow-up is needed to better define the clinical role of this novel endograft.

Chapter 1

Introduction

1.1 Definition and classification

Definition

The term aneurysm comes from an Ancient Greek word that means dilatation or widening of an artery, most commonly being in a fusiform shape. By definition, an aneurysm is permanent localized dilation of an artery having at least a 50% increase in diameter of the artery in question(1) Aortic Aneurysm (AA) is defined as a segmental, full-thickness dilatation of the abdominal aorta exceeding the normal vessel diameter by 50%, although an aneurysm diameter of 3.0 cm, which usually is more than 2 standard deviations above the mean diameter for men, is commonly considered as the threshold. (2,3) This second definition not seems to be fully appropriate in women and some Asian populations. That said, the 1.5 fold diameter increase provides a useful basis for the definition of AA in women and some specific populations. (4)

Classification

Aortic Aneurysms could be classified on the basis of the anatomical extent. The three main categories are defined by the location of the aneurysm in relation to the diaphragm. Thoracic Aortic Aneurysms (TAA) are extended only above the diaphragm, while Abdominal Aortic Aneurysm (AAA) only below. Thoracoabdominal Aneurysms (TAAA) involves the aorta both above and below the diaphragm. (5)

TAA are divided in 1) Ascending aorta Aneurysms, 2) Aortic arch Aneurysms and 3) descending aorta Aneurysms on the basis of the anatomical involvement of the three different segments of the thoracic aorta. On the other hand, AAA are classified referring to the position of the renal arteries: 1) Suprarenal, defined as an aneurysm that extends up to the superior mesenteric artery (SMA) involving one or both renal arteries to be repaired; 2) Juxtarenal or pararenal, is

defined as an aneurysm extending up but not involving the renal arteries; 3) Infrarenal, involving only the aorta below the renal arteries. (5–7)

The classification of aortic aneurysms is shown in figure 1. Juxtarenal, pararenal and thoracoabdominal aneurysm are classified as complex aortic disease.

Thoracoabdominal Aneurysms are classified referring to the Crawford classification: 1) Type I involves most of the descending thoracic aorta from the origin of the left subclavian artery to the suprarenal abdominal aorta; 2) Type II is the most extensive, extending from the subclavian artery to the aortoiliac bifurcation; 3) Type III involves the distal thoracic aorta to the aortoiliac bifurcation; 4) Type IV TAAAs are limited to the abdominal aorta below the diaphragm; Safi's group modified this scheme by adding Type V, which extends from the distal thoracic aorta including the celiac and superior mesenteric origins but not the renal arteries (6,8).

Other classifications are made on the basis of different criteria such as histopathological, morphological and etiological.

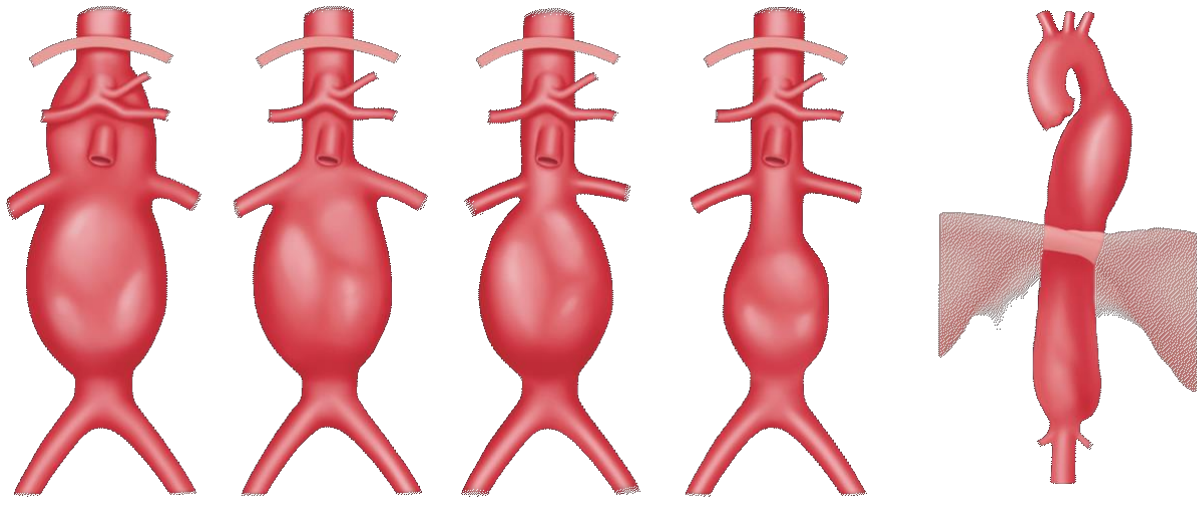

Figure 1: Classification of the aortic aneurysms

Other complex aortic disease

Besides thoracoabdominal, juxtarenal and pararenal aneurysm, other complex aortic disease deserving to be mentioned are:

Aortic Dissection: Aortic dissection is classified in acute and chronic. Acute aortic dissection (AD) is the most frequent and catastrophic manifestation of the so-called acute aortic syndrome. The incidence is said to be no less than 30 cases per million individuals per year. The initiating condition, in most cases, is an intimal tear resulting in tracking of the blood in a dissection plane within the media layer. This process could result in an aortic rupture in case of adventitial disruption or by a re-entering into the aortic lumen through a second intimal tear. The dissection can be either antegrade or retrograde. (9,10)

Aortic dissection is classified on the basis of the Stanford classification, which takes into account the extent of the dissection, rather than the location of the entry tear. Complications worthy to be mentioned are tamponade, aortic valve regurgitation, proximal or distal malperfusion syndromes in case of propagation of side branches. (9)

In its natural evolution, without treatment, acute type A aortic dissection reportedly has a mortality rate of about 1% per hour initially, with half of the patients expected to be dead by the 3rd day, and almost 80% by the end of the 2nd week. Death rates are lower but still significant in acute type B aortic dissection: 10% minimum at 30 days, and 70% or more in the highest-risk groups. (10) After the 2nd week the dissection is classified as chronic.

Penetrating Atherosclerotic Ulcer: Penetrating atherosclerotic ulcer (PAU) refers to an ulcerating atherosclerotic lesion that penetrates the elastic lamina. It is associated with an hematoma formation within the media of the aortic wall. Initially, atheromatous ulcers develop in patients with advanced atherosclerosis. At this stage, the lesions are usually asymptomatic and confined to the intimal layer. In the next stage, the lesion progresses to a deep atheromatous ulcer that penetrates through the elastic lamina and into the media. (11) The natural history of PAU is characterized by a progressive aortic enlargement and the development of saccular or fusiform aneurysm. The most common location of PAU is the middle and lower descending thoracic aorta. Less frequently, PAUs are

located in the aortic arch or abdominal aorta, while involvement of the ascending aorta is rare. (12–14)

Intramural Hematoma: Aortic Intramural Hematoma (IMH) is an entity in which a hematoma develops in the media of the aortic wall in the absence of a false lumen and an intimal tear. Pathognomonical findings of this lesions is the presence of an intramural collection of blood without identifiable intimal flap, tear or ulceration. Over the first 30 days after diagnosis, IMH can evolve into classic dissection, contained rupture or aneurysm, or reabsorb without further sequelae. (12–14)

1.2 Epidemiology of complex aortic disease

AAA global incidence and prevalence rates have decreased over the last 20 years. (15–17) Early studies describing the occurrence of AAs were based on findings at postmortem examination or on population-based clinical case-series, nowadays population-screening programs are used to describe the epidemiology. (18) Studies on postmortem examination reported a prevalence of 6% in selected populations (19), while population-screening reported that the prevalence of AAA was between 4% and 8%. (18) The prevalence in women, estimated around 0,7% from a systematic review of publications between 2000 and 2015 (20), is approximately six times less greater than in man, however evidence indicates that the prevalence of AAA among women could be slowly increasing. (21) This trend could be explained as a reflection of a temporal change in the prevalence of smoking among women, which increased between 1950 and 1970, several decades after the widespread of smoking among men. (22) The prevalence of AAAs is negligible before age 55-60 years while increases steadily with age. (17) In 1990, the global prevalence in 75-79 year old was 2423 per 100,000 population versus 2275 in 2010. (17)

About the incidence, studies reported a decline in both developed and developing countries. The mean annual incidence of new AAA diagnoses in Western population is 0,4-0,67%. (23–25) The incidence is lower in Asian population by a factor of 10. (26) The Swedish Screening Programme reported a a prevalence of 1,7% in 65 years old men with an additional 0.5% with an already

known AAA. (15) The UK National Screening Programme reported an incidence of 1,3% (27,28)while the Danish screening program targeting men aged 65-74 years reported an incidence of 3,3%. (29) In contrast, a programme in the USA which only offers screening to smokers reports a prevalence of over 5%. (30)

For what concerns the incidence of TAAAs multiple factors, including the relative rarity, the broad enactment area of the tertiary centers treating this disease, and delayed diagnosis, impair assessment of the actual incidence of TAAAs. While the exact epidemiology of TAAA remains unknown, it can be estimated based on larger studies of TAAs, of which TAAAs comprise approximately 6%.(31) An early study on a Midwestern community in the United States calculated an age and sex adjusted incidence of 5.9 thoracic aneurysms per 100,000 person-years. (32) Later, Clouse et al found the incidence of thoracic aneurysms to be 10.4 per 100,000. (33)

1.3 Pathophysiology and risk factors

Pathophysiology

Aneurysmal disease are considered a dynamic process rather than a static pathological problem. Proteolysis, inflammation and smooth muscle cell apoptosis are considered the main pathological drivers of the aneurismatic process. (18) The factors that initiate the aneurysmal degeneration and those that drive the transition from minimally dilated aorta to clinically relevant AA is critical but still not fully understood. (18)The predisposition to AA formation could have an embryological origin; placental dysfunction or abnormalities in micronutrients could lead to an impairment in the elastin synthesis in the aorta or in the fetal elastogenesis, leading likely to long term effects. (34) Signaling pathways during embryogenesis dictate smooth muscle cell phenotype and their future responses to factors currently implicated in AA pathogenesis, such as transforming growth factor β. (34)

Advanced atherosclerosis has been considered for year the main driver in the formation of AAs. (35) This conventional theory has been challenged by the evidence that people with AAs have abnormalities in the entire vascular tree. (36) Atherosclerosis in AA is considered an epiphenomenon of the altered luminal flow, rather than an initiating factor in the development of the lesion. (37) Furthermore,

if atherosclerosis was a the dominant feature in AA development, then the severity of aortic atherosclerosis would correlate with AA development, but there is no evidence to support this correlation. (38) All layers of the arterial wall are dilated in AAs as a result of loss of elastin, smooth muscle cell apoptosis, and compensatory collagen deposition. (39,40) There is evidence that this alterations are not only present in the aneurism wall but rather in the different arteries and veins, suggesting a systemic nature of the aneurysmal process. Inflammation, matrix degradation as well as the presence of reactive oxygen and nitrogen species are crucial in the progressive cell and tissue damage characteristics of oxidative stress that is implicit in AA pathogenesis. (39,40)

Even if the dilating diathesis is considerable ad systemic, the aorta is the most involved vessel. (41) The abdominal aorta, as a matter of fact, is exposed to unique hemodynamic forces as it is located proximal to the first major branching of the vessel and is constrained by the renal arteries and the iliac arteries.

Risk factors

Risk factors can be associated with the development, expansion and rupture of AA, based on large scale, cross-sectional studies. Out of all the risk factors that seems to be associated with AA, only smoking is considered a modifiable one. (42)

Age: The incidence of AA increases with advancing age. The age specific prevalence of AA is six times greater in men than in women and the risk factors increases by 40% every 5 years after the age of 65 years. (43)

Sex: Man are way more inclined than women to develop AA even if the reason is still unclear. Different hypothesis were made, such as different function of hormonal factors, genetic susceptibility, and different risk factors exposure. (44)

Family history: Family history is considered as an established risk factor for the development of AA. (45) Population studies have found that a positive history of AA is associated with an approximately doubled risk of AA compared with those without a family history. (46–48)

Smoking: Smoking is one of the most accepted risk factors for the development of AAAs, not only based on an epidemiological point of view, but also there is a clear evidence behind the mechanisms that leads to the formation of AAs. (49) Smoking increases the RR of AA 7,6-fold and considering men that smoke 25 cigarettes per day, those have a 15-fold increase risk of AA compared

with men who have never smoked. (50,51) Not only the number of cigarettes per day but also the duration of smoking is relevant. Smoking is not only associated with the development of AA, but also a more rapid AA expansion. (52,53)

Hypertension: Even if hypertension is one of the commonly cited risk factor for the development of AA, any association seems weak. (54,55) Interestingly enough, hypertension is associated with AA risk but only in women. On the other hand, elevated blood pressure is associated with and increased risk of aneurysm rupture in man and women, reflecting the hemodynamic burden on the aortic wall, contributing to wall weakness. (56,57)

Obesity: Central obesity is independently associated with AA. In the prospective Health in Men study, specific anthropometric measures, particularly waist circumference (OR 1,14, 95% CI 1,06–1,22) and waist–hip ratio (OR 1,22, 95% CI 1,09–1,37), were independently associated with AA in a cohort of 12.203 screened men. (58)

Lipid levels: The association between plasma lipid levels and AA is not fully understood. Iribarren *et al.* reported that elevated serum cholesterol (>240 mg/dl) was associated with an OR of 2,82 for AA (95% CI 2,13–3,72).(59) However, a similar retrospective epidemiological study failed to reproduce this finding. (60)

1.4 Diagnosis

Clinical signs

AAs are in the majority of cases clinically silent. The sensitivity of abdominal palpation is less than 50% for detecting an AAA, and decreases in patients with abdominal girth more than 100 cm. (3,61,62) Physical examination and abdominal palpation are not considered reliable methods for detecting AAs. Symptoms as well are not reliable, and often vague. Relevant symptoms, instead, are often related to complications such as compression of nearby organs, distal embolism or in case of rupture. (63)

Imaging techniques

Ultrasonography: Abdominal Ultrasound (US) is considered highly sensitive and specific in detecting AAs, therefore US is recommended for the first line diagnosis and surveillance of small abdominal aortic aneurysms. (64,65) There

are some limitations in its use such as obesity, excess bowel gas or the variation of aortic diameters with the cardiac cycle. (54)

Computed tomography angiography: Computed tomography (CT) angiography (CTA) plays a key role in assessing the extent of disease and therapeutic decision making and planning. (66) Many of the same issues concerning measurement by US apply to CT measurement, for example axial versus orthogonal centerline diameters, changes with the cardiac cycle and details of calliper placement. (67,68) Study shows that even applying predefined methodologies, intra-observer reproducibility falls in the clinically accepted range (+/- 5 mm) in 90% AA measurements, but the intra-observer reproducibility is poor, with 87% comparisons being outside +/- 5 mm. This variability is of particularly high clinical significance, since the number of patients considered for AA repair, based on a diameter threshold, may significatively vary. (67)

Considered this limitations, CTA is still the gold standard for diagnosis and therapeutic decision making in patients with abdominal aortic aneurysms, as for the diagnosis of aortic rupture. (63)

Magnetic resonance imaging: Magnetic resonance imaging (MRI) is well known for its advantages such as not requiring the use of iodinated contrast agents, finding its role in when AA management requires repeated images. On the other hand, MRI is less way available that CTA, having also some contraindications such as claustrophobia and some metal implants. (63,69)

1.5 Indication to treatment

Indications to treatment are made on the base of the aortic diameter. Different factors are kept in mind, first of all the balance between the risk of aneurysm rupture and the risk of operative mortality for aneurysm repair. (63) Large multicentered randomized controlled trials reached the consensus that aneurysms <5,5 cm in diameter should be managed conservatively. That said, in men, the threshold for considering elective abdominal aortic aneurysm repair is recommended to be ≥5,5 cm diameter. (70) On the other hand, in women with acceptable surgical risk the threshold for considering elective abdominal aortic aneurysm repair may be considered to be ≥5,0 cm diameter. (56,71–74)

In both sex, there is evidence that rapid aneurysm growth (>1cm/year) is associated with higher risk of rupture. If such growth is observed, fast track referral to a vascular surgeon should be considered. (75,76)

Different repair techniques are available, such as open surgical repair (OSR) versus the endovascular approach. Large population based registry studies have compared the risks, mortality and morbidity of the two different approaches, showing that the increasing utilization of endovascular treatment carries a continued decrease in mortality and morbidity, despite the older and more comorbid populations treated. (63)

1.6 Open repair of complex aortic disease

For open repair, an abdominal or a flank incision is required. Vessels above and below the aneurysm are isolated and clamped, the aneurysm sac is opened and a synthetic graft is placed. The upper anastomosis is made with an end-to-end fashion and the distal anastomosis is located on the aortic bifurcation, the iliac bifurcations, or the common femoral arteries depending on the extent of aneurysmal transformation and the patency of the external iliac arteries. Attention is pay to preserve at least one of the internal iliac arteries. Several prosthetic grafts are available for aortic replacement: knitted or woven Dacron, impregnated with collagen, albumin, or gelatin if needed, and polytetrafluoroethylene (PTFE). All materials show excellent patency and long-term results, so that the surgeon's preference and the costs determine the aortic graft choice. (7) Prager *et al*. found a comparable long-term patency for PTFE and Dacron, but PTFE had a higher incidence of early graft failure and graft infection.(77)

1.7 Endovascular repair of complex aortic disease

The choice of EVAR allows a minimally invasive treatment of complex aortic disease based on the use of a stent graft, usually deployed inside the aneurysm through femoral access to exclude the AA sac from the circulation. EVAR requires adequate aortic and iliac fixation sites for effective sealing and fixation. Multiple types of endograft are available with different characteristics and indications. (7)

Fenestrated EVAR

New endovascular techniques and technical improvements in endovascular surgery lead to the possibility to extend the proximal lading zone for stent grafts by incorporating the renal and visceral arteries in the graft, allowing endovascular repair of juxta- and suprarenal aneurysms. In fenestrated EVAR (fEVAR) fenestrations in the fabric that allows for the insertion of stent grafts as side branches. (63)

Branched EVAR

Branched EVAR (bEVAR) is a similar technique, if compared to fEVAR, with extra branches woven onto the fabric of the stent graft through which an extra stent graft can be entered into the renal and/or visceral arteries. bEVAR could be classified on the basis of the technical aspects of implant in inner and outer branch; Another classification is made on the basis of the facture in custom-made and off-the-shelf. (63)

Custom-made and off-the-shelf bEVAR: bEVAR could be divided in the more traditional custom-made types, and the innovative off-the-shelf (OTS) ones. The more traditional custom-made devices (CMD) require a long time (10-12 weeks) necessary for the device creation. (78) This period is associated to a non-negligible aneurysm rupture rate during the manufacturing period ranging from 1,7% to 3,8%. (79–81) New types of devices, the so called OTS, allows a ready to use availability of the device also in urgent settings. The number of OTS devices, previously limited to the Zenith t-Branch (Cook Medical, Bloomington, Ind) has recently expanded by two new investigational multi-branched endografts: the Gore Excluder thoracoabdominal branch endoprosthesis (TAMBE; W. L. Gore & Associates, Flagstaff, Ariz) and the E-nside multibranch stent graft system (Jotec GmbH, Hechingen, Germany). (78,82)

1.8 Off-the-shelf device with preloaded inner branches

The E-nside multibranch stent graft system it is the first and only off-the-shelf precannulated thoracoabdominal stent graft with inner branches. The device is a self-expanding stent graft with individual nitinol springs permanently sewn into a textile tube that is preloaded in a delivery system. In figure 2 are shown the main features of the E-nside stent graft. The E-nside stent graft can be supplied in four different versions with proximal diameters of 38 and 33 mm and distal diameters of 30 and 26 mm. The middle portion has a constant diameter of 24 mm. The 24F delivery system comes with a non-hydrophilic atraumatic tip and a hydrophilic outer sheath. The stent graft is released by a so-called "squeeze to release mechanism", where each click corresponds to a 4 mm step. Several radiopaque markers placed into the graft are used for better localization. Different radiopaque markers are used for identification. A total of 5 tubular markers were used for the proximal and 3 ring markers for covering the distal end of stent graft. The inlet of each inner branch is marked with 1 ring marker, while the outlet is marked with 3 tubular markers. A total of 2 "E" markers display the maximum and minimum overlap for the proximal landing zone and provide rotational orientation. The distal overlapping line is marked with an "8".

The four different inner branches have an anterograde orientation and a constant length of 20 mm. The diameter is 8 mm for the celiac trunk (CT) and the superior mesenteric artery (SMA), while 6 mm for both the renal arteries. All 4 branches present an enlarged and oval-shaped outlets in order to allow for a great variability of the bridging stents.

The branches are pre-cannulated with polyimide tubes with a length of 1465 mm which extends to the proximal end of the stent graft. The inner diameter is 0,5 mm (0,018in) and the outer diameter is 0,7mm (0,035in). All tubes are loaded with a 0.018in disposable transportation wire that has to be removed to use the pre-cannulation tubes. (83)

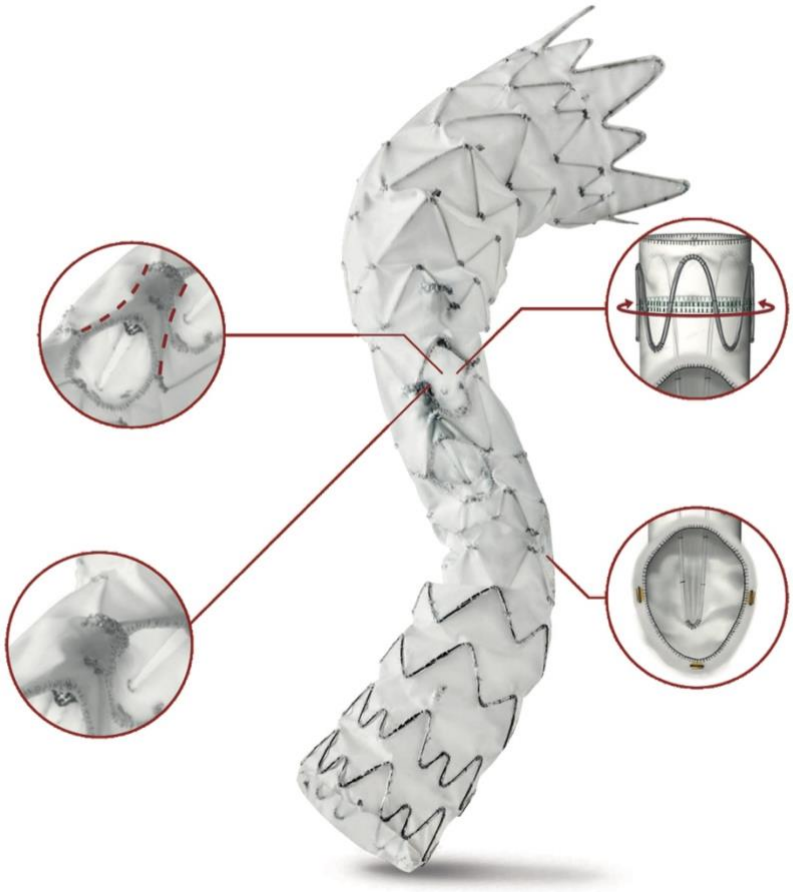

Figure 2: main features of the E-nside stent graft

Chapter 2

Aim of the study

The aim of the present study is to investigate the early outcomes of a novel off-the-shelf preloaded inner branched endograft (E-nside Jotec Gmbh, Hechingen, Germany) in the treatment of complex aortic pathologies.

Chapter 3

Materials and Methods

3.1 Study design

We performed a multicentric, prospective cohort study. All data was collected prospectively in a physician-initiated national multicenter registry. Thirty-three different Italian centers of vascular surgery were involved in the study, contributing to the data collection.

3.2 Patients selection

Patients were included in the registry if they had undergone E-nside implantation for a TAAA, AAA, or other complex aortic pathologies. Procedures, as well as the device selection, were planned using the findings from high-resolution computed tomography angiography (CTA). The type and the measure of endograft was selected in accordance with the patient's anatomy.

3.3 Data collection

The electronic data capture system used is the Research Electronic Data Capture (REDCap™), a secure web application for building and managing online surveys and databases.

Patient demographic, risk factors, aortic history as well as preoperative clinical and anatomical data were collected and recorded. Particularly, for each patient, age, sex, BMI, risk factors and comorbidities were reported. Data concerning previous aortic history was collected, including aortic dissection, prior aortic repair either open or endovascular, the presence of cervical debranching or a permanent iliac conduit. Preoperative CTA measures were collected with the use of a medical imaging software (Aquarius APS, TeraRecon, Foster City, Calif), including aortic largest diameter, status and details about the aneurysm, status as dimeters of the visceral vessels. Procedural data (i.e. total operating room time, total contrast and total radiation dose) and early (30-days) medical and surgical complications and outcomes were collected as well. In a different section of the

registry the follow-up data was collected as well, recording any complications after 30-days.

3.4 Primary and secondary endpoints

The primary endpoint was 30-days technical success (successful introduction and deployment of the device in the absence of surgical conversion or mortality, type I or type III endoleak, branch occlusion, or graft limb obstruction). Secondary outcomes were procedural metrics and major adverse events (MAE) freedom from main endograft complications and target vessel instability at 6 months.

3.5 Follow-up

All the patients were followed up with serial imaging studies in accordance with a standardized protocol. The patients underwent CTA at 1 and 6 months and annually thereafter. The 6 months follow-up was collected and recorded in the electronic data capture system.

3.6 Statistical analysis

Descriptive statistics were used in order to summarize patient characteristics and demographics, operative characteristics and perioperative outcomes. Continuous covariates are summarized as mean with standard deviation, categorical covariates as absolute and percentage frequencies.

3.7 Implantation technique

Multi-step implantation has to be considered while planning this procedure. Is thoracic aorta stent graft is required, it should be performed first in order to ensure an adequate proximal landing zone. Due to the length of the covered aorta, a two stage procedure must be considered in order to reduce the risk of spinal ischemia, adopting the so called “temporary aneurysm sac perfusion” technique.

Systemic heparization is performed according to body weight, with a target activated clotting time of 250-300 seconds. Common femoral arteries are identified as access vessels via a surgical cut-down or percutaneously. For the delivery of the device only one femoral site is need, the contralateral one is used if intravascular ultrasound (IVUS) is performed during the procedure. In order to cannulate the

inner branches either a brachial or a femoral access could be used, even if the first one is preferred.

In the case of a previously implanted thoracic aortic stent graft, it is important to verify that its distal end is compatible in diameter (for at least 30 mm in length for overlap) with the proximal diameter of the selected E-nside stent graft. The graft must be positioned 20 mm (or more, according to the expected final position of the E-nside stent graft) proximal to the ostium of the CT.

The E-nside delivery system is advanced in anterior-posterior (A/P) projection with an extra stiff 0.035 in guidewire through the access vessel into the abdominal aorta. Tactile elevation of the gray handpiece of the delivery system must always point toward 12:00 and ensure correct alignment of the stent graft when it is advanced into the thoracoabdominal aorta. The 2 proximal “E” markers are used for fluoroscopic verification of the correct rotation of the stent graft. Angiography or IVUS is used to visualize the renovisceral segment. Still in A/P projection, alignment of the prosthesis in relation to the renal arteries is now performed under fluoroscopy/IVUS control.

After the precise alignment with the visceral arteries and the correct orientation, the deployment of the stent graft can be started the “squeeze to release” mechanism. After deployment of the first few centimeters of the proximal stent graft portion, gentle adjustment of the stent graft position by slowly rotating the outer sheath and the black knurled cap with both hands can be performed if necessary until the intended orientation is confirmed once again. Proceed with the “squeeze to release” mechanism until the whole stent graft is deployed. To fully deploy and detach the stent graft from the delivery system, proximal tip capture must be released by rotating and pushing the knot at the distal end of the delivery system. Some of the main features of the E-nside delivery mechanism are shown in figure 3.

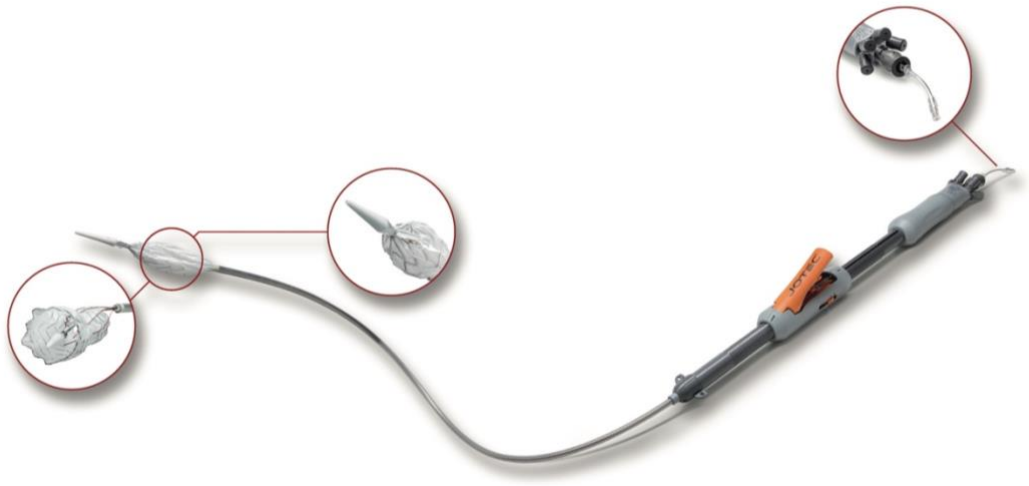

Figure 3: Some of the main features of the E-nside delivery mechanism

After full deployment, the cannulation process of the inner branches can be started. The sequence in the cannulation of the branches may vary based on the preference of the surgeon, but the suggestion is to start with le lower renal arteries in case of transbrachial cannulation in order to avoid compromising the already completed branches. After selecting the intended inner branch, the corresponding safe transportation wire must be removed. The polyimide tube has to be flushed with heparin–saline solution before a 0.018in nonhydrophilic wire can be advanced. The wire can now be snared in the area of the thoracic aorta either via femoral or brachial access. After the through and through wire is established, the polyimide tube must be removed to ensure smooth advancement of the sheath. Depending on the desired bridging stent graft, a 7 F (0.035 in through and through wire) or 8 F (0.018in through and through wire) target sheath can be introduced via this shuttle sheath to probe the inner branches using the through and through 0.018 in wire. If a shuttle sheath is not desired, a 10 F sheath is inserted via transbrachial access and placed in the descending aorta. Either a flexible or a steerable 10F sheath can be used from the femoral access site. A snare is inserted through the sheath, and the pre-cannulated inner branch wire is captured. After removal of the polyimide tube, the sheath is advanced into the inner branch via established through and through wire. Parallel to the through and through wire, a probing catheter can now be inserted into the sheath, and the target vessel is addressed. Before releasing the selected bridging stent graft, the through and through wire must be removed.

After all intended renovisceral bridging stents were delivered in the target vessels the entire delivery system can then be removed. Final angiography is performed to assess the correct position of the stent prostheses and bridging stent grafts. (83) Periprocedural images are shown in figure 4.

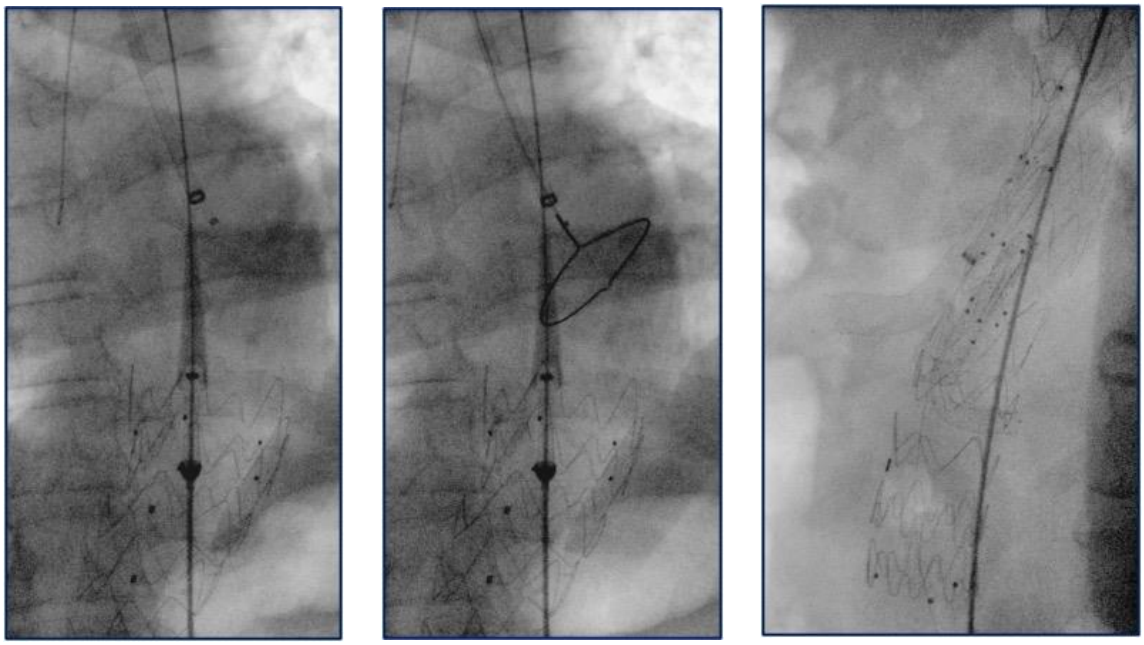

Figure 4: Implantation procedure at angiography

Chapter 4

Results

4.1 Patient demographics and characteristics

Overall, 104 patients from 26 Italian vascular surgery centers were collected between 2021 and 2022. Patients' demographic, risk factors and comorbidities are summarized in table I. Mean age was 73,14 ± 8,16 years and 70 (68,0%) were male, mean BMI was 27,1 ± 4,08Kg/m^2. Different risk factors were considered, showing that hypertension (90,3%), hypercholesterolemia (65,0%) and tobacco use (55,4%) are the most diffused.

Aortic history was collected and summarized in table II. Twenty-nine patients (28,2%) had a prior aortic repair either open (72,4%) or endovascular (1,9%).

Patients presented different aortic pathologies including degenerative aneurysm in 84 (82,4%) patients, acute or subacute dissection in 4 (3,9%), pseudoaneurysm in 6 (5,9%), penetrating aortic ulcer in 3 (2,9%), intramural hematoma in 1 (1%), chronic dissection in 4 (3,9%). Mean aneurysm diameter was 66,16 ± 16,51 mm; aneurysm extent was classified as I-III in 49 patients (49,4%), type IV in 19 (19,2%), pararenal in 26 (26,3%), and juxtarenal in 5 (5,1%).

Complete preoperative aortic measurements are reported in table III.

4.2 Graft implantation procedure

In the majority of patients a bilateral femoral access was preferred in 58 cases (56,9%), as well as the left brachial or axillary access in 66 (74,2%). Prophylactic spinal drainage (37, 36,6%) and neuromonitoring (26, 26,2%) were not commonly used during the procedure. The inner branches were cannulated from above in 81 cases (81,0%), while cannulation and stenting using only the femoral accesses was performed in 19 (19,0%); the use of preloaded channels was used by the vast majority of centers in 62 cases (87,3%).

For celiac artery a balloon expandable bridging stent was preferred in 69 cases (75,8%) while self-expandable in 19 (19,8%). In 6 patients (6,6%) an adjunctive bare metal stent was used. The mean time for celiac artery stenting was 21,68 ± 30,18 minutes.

For the superior mesenteric artery, similarly to CT artery, a balloon expandable bridging stent was preferred in 77 cases (76,2%) while self-expandable in 24 (23,8%). In 11 (11,1%) patients an adjunctive bare metal stent was used. The mean time for SMA stenting is 18,50 ± 19,80 minutes.

Considering the two renal arteries, balloon expandable bridging stent was preferred in 70 (72,9%) cases for LRA and 66 (68,7%) cases for RRA while self-expandable in 25 (26,1%) for LRA and 26 (27,1%) for RRA. In 15 (15,6%) patients for LRA and 13 (14,3%) for RRA, an adjunctive bare metal stent was used. The mean time for LRA stenting is 21,37 ± 26,11 minutes and 24,58 ± 37,74 for RRA.

Mean procedural time was 258,53 ± 120,58 minutes, with a mean contrast volume of 215,29 ± 137,08 ml and a radiation exposure of 3189 ± 5862 mGy*cm^2.

Staged procedures were performed in 34 (34%) patients, with a mean time interval between stages of 22,50 ± 36,43 days. Technical success was achieved in 97,1% of cases.

All data concerning the graft implantation procedure was collected and reported in table IV.

4.3 Early outcomes at ≤30 days

At 30 days mortality was 6%. MAEs were spinal cord ischemia in 8 patients with a clinical presentation of sensory deficit in 3 patients and motor deficit not able to ambulate in other 5 cases. Stroke or TIA presented in 4 patients, myocardial infarction in 1, while AKI in 9 patients. Other complications were negligible in incidence.

The main surgical complications were endoleaks and other target vessel-related events in 10 patients (9,9%) needing reintervention. There were 8 occlusions, and 1 type IC endoleak and 1 stenosis or kinking needing reintervention. The most involved target vessel needing reintervention was celiac artery (5 cases,

50% of reinterventions). Freedom from aortic rupture and main endograft complication was 99%.

Medical complications at 30 days are summarized in table V while surgical complications are available in table VI.

4.4 Outcomes at six-months follow-up

Follow-up at 6-months is available for 63 patients. Mortality at follow-up is 4,8% (3 cases, only 2 classified as aortic related). Freedom from target vessel instability was 95% (11 stenosis/occlusion and 2 endoleaks). The most involved target vessel in complications was the right renal artery. Only in 5 cases these complications needed reintervention.

Complete data about 6-months follow-up can be found in table VII.

Table I: Patients' demographic, risk factors and comorbidities

Variables		N (%) or Mean ± StDev
Age	Years	73,14 ± 8.16
Gender	Male	70 (68,0%)
BMI	Kg/m^2	27,1 ± 4,08
Coronary artery disease		29 (28,2%)
Chronic heart failure		7 (6,8%)
Hypertension		93 (90,3%)
Hypercholesterolemia		67 (65,0%)
Tobacco Use		56 (55,4%)
Chronic obstructive pulmonary disease		46 (44,7%)
Peripheral artery disease		15 (14,9%)
Diabetes		11 (10,7%)
Chronic kidney disease		19 (18,4%)
Stroke or TIA		12 (11,8%)

Table II: Patients' aortic history

Variables		N (%) or Mean ± StDev
Aortic dissection		9 (8,7%)
Genetically triggered aortic disease		2 (1,9%)
Prior open aortic repair		29 (28,2%)
Type of prior open aortic repair	None	74 (71,8%)
	Ascending/arch	12 (41,4%)
	Thoracic	1 (3,4%)
	Abdominal	15 (51,7%)
	Thoracoabdominal	1 (3,4%)
Prior endovascular aortic repair		25 (24,3%)
Type of prior endovascular aortic repair	None	78 (75,7%)
	EVAR	10 (40,0%)
	TEVAR	14 (56,0%)
	EVAR + TEVAR	1 (4,0%)
Prior staged aortic repair	None	74 (71,8%)
	Endovascular	27 (26,2%)
	Open	2 (1,9%)
Cervical debranching	None	92 (89,3%)
	Carotid-subclavian	9 (8,7%)
	Carotid-Carotid-Subclavian	2 (1,9%)
Permanent iliac conduit		3 (2,9%)

Table III: Patients' anatomical characteristics

Variables		N (%) or Mean ± StDev
Aortic pathology	Degenerative aneurysm	84 (82,4%)
	Acute or subacute	4 (3,9%)
	dissection	4 (3,9%)
	Chronic dissection	6 (5,9%)
	Pseudoaneurysm	3 (2,9%)
	PAU	1 (1,0%)
	IMH	
Largest aortic diameter	mm	66,16 ± 16,51
Aortic diameter at	CT level, mm	39,55 ± 11,77
	SMA level, mm	37,64 ± 13,35
	RRA level, mm	38,17 ± 16,13
	LRA level, mm	39,16 ± 16,37
Status of aneurysm	Non ruptured	77 (77,0%)
	asymptomatic	
	Non ruptured	21 (21,0%)
	symptomatic	
	Contained rupture	2 (2,0%)
Aneurysm anatomical	Extent I	13 (13,1%)
classification	Extent II	22 (22,2%)
	Extent III	14 (14,1%)
	Extent IV	19 (19,2%)
	Pararenal	26 (26,3%)
	Juxtarenal	5 (5,1%)
Chronic dissection		5 (4,9%)
Celiac artery:		
Diameter	mm	7,70 ± 1,46
Stenosis		23 (23%)
Angle	degrees	40,00 ± 26,13
Superior mesenteric		
artery:	mm	7,51 ± 1,35

Diameter		10 (10%)
Stenosis	degrees	32,84 ± 24,49
Angle		
Right renal artery:		
Diameter	mm	5,71 ± 1,09
Stenosis		18 (17,8%)
Angle	degrees	46,99 ± 27,65
Left renal artery:		
Diameter	mm	5,91 ± 1,46
Stenosis		11 (11,1%)
Angle	degrees	66,79 ± 34,01
Aortic infrarenal angle	degrees	34,71 ± 22,90
Aortic pararenal angle	degrees	27,51 ± 28,56
Aortic supraceliac angle	degrees	34,57 ± 26,02
Aortic thrombus		56 (56%)

Table IV: Periprocedural data

Variables		N (%) or Mean ± StDev
Percutaneous femoral access	No	30 (29,4%)
	Unilateral	14 (13,7%)
	Bilateral	58 (56,9%)
Femoral conduit		5 (4,9%)
Iliac Conduit		5 (4,9%)
Brachial or axillary access	Left	66 (74,2%)
	Right	23 (25,8%)
E-NSIDE dimeter		
Proximal	33 mm	27 (35,1%)
	38 mm	50 (64,9%)
Distal	26 mm	62 (81,6%)
	30 mm	14 (18,4%)
Prophylactic spinal drainage		37 (36,6%)
Neuromonitoring		26 (26,3%)
Celiac artery:		
Main bridging stent	Baloon-Expandable	69 (75,8%)
	Self-Expandable	19 (19,8%)
Stent diameter	mm, mode	8
Stent length	mm, median	59
Adjunctive bare metal stent		6 (6,6%)
Time from cannulation to stenting	Minutes	21,68 ± 30,18
Superior mesenteric artery:		
Main bridging stent	Baloon-Expandable	77 (76,2%)
	Self-Expandable	24 (23,8%)
Stent diameter	mm, mode	8
Stent length	mm, median	60
		11 (11,1%)

Adjunctive bare metal stent Time from cannulation to stenting	Minutes	18,50 ± 19,80
Right renal artery:		
Main bridging stent	Baloon-Expandable	70 (72,9%)
	Self-Expandable	25 (26,1%)
Stent diameter	mm, mode	6
Stent length	mm, median	59
Adjunctive bare metal stent Time from cannulation to stenting	Minutes	15 (15,6%) 21,37 ± 26,11
Left renal artery:		
Main bridging stent	Baloon-Expandable	66 (68,7%)
	Self-Expandable	26 (27,1%)
Stent diameter	mm, mode	6
Stent length	mm, median	59
Adjunctive bare metal stent Time from cannulation to stenting	Minutes	13 (14,3%) 24,58 ± 37,74
Any target vessel cannulated from below		19 (19,0%)
Use of preloaded channels		62 (87,3%)
Staged procedure:	Single step	64 (64%)
	Two step	34 (34%)
	Three steps	2 (2,0%)
Time interval between stages	Days	22,50 ± 36,43
Technical success		99 (97,1%)
Imaging at completion	Angiography	91 (91,9%)
	Contrast CBCT	9 (9,1%)

	Non-Contrast CBCT	3 (3,0%)
	IVUS	14 (14,1%)
Endoleak at final angiography		22 (22,2%)
Endoleak type	Type 1A	1 (5,3%)
	Type 1B	3 (15,8%)
	Type 1C	0
	Type 2	9 (47,4%)
	Type 3	6 (31,6%)
Total operating room time	Minutes	258,53 ± 120,58
Total contrast	ml	215,29 ± 137,08
Total fluoroscopy time	Minutes	99,73 ± 46,03
Total radiation dose	Gy/cm^2	3189 ± 5862
Intraprocedural complications		24 (23,8%)

Table V: Medical complications (30 days)

Variables		N (%) or Mean ± StDev
Death		6 (6,0%)
Estimated blood loss < 1000 ml		4 (4,5%)
Myocardial infarction		1 (1,0%)
Congestive heart failure		1 (1,0%)
Respiratory failure		4 (4,1)
Pneumonia		0
Postoperative stroke or TIA		4 (4,1%)
Spinal cord ischemia	Sensory deficit	3 (3,1%)
	Motor not able to ambulate	5 (5,1%)
Acute kidney injury		9 (9,2%)
Gastro-intestinal complications		1 (1,0%)
Length of hospitalization after procedure	Days	11,6 ± 8,18
Dismissal medical therapy	Aspirin	82 (89,1%)
	Clopidogrel	64 (69,6%)
	Novel anticoagulant	6 (6,5%)
	Warfarin	11 (12,0%)
	Other antiplatelt	5 (5,4%)
Platelet count pre-procedure	Plt/ul	225873 ± 77383
Platelet count post-procedure	Plt/ul	174302 ± 105131

Table VI: Surgical complications (30 days)

Variables		N (%) or Mean ± StDev
Aortic rupture		1 (1,0%)
Main endograft complications		2 (2,0%)
Type of main endograft complications	Type 1a endoleak	1 (100%)
Target vessel complication		11 (10,9%)
Site of target vessel complication	Celiac Artery	5 (50%)
	Superior mesenteric artery	1 (10,0%)
	Right renal artery	3 (30,0%)
	Left renal artery	1 (10,0%)
Type of target vessel complication	Type 1c endoleak	1 (10,0%)
	Occlusion	8 (80,0%)
	Stenosis or kinking requiring intervention	1 (10,0%)
Early reintervention		10 (2%)
Reason early reintervention	Main graft complication	1 (11,1%)
	Branch complication	3 (33,3%)
	Access site complication	5 (55,6%)

Table VII: Follow-up (6 months)

Variables	N (%) or Mean ± StDev
Death	3 (4,8%)
Aortic related death	2 (66,6%)
Celiac artery	
Endoleak	0
Loss of patency	2 (3,6%)
Reintervention	0
Superior mesenteric	
artery	1 (1,7%)
Endoleak	0
Loss of patency	1 (1,7%)
Reintervention	
Right renal artery	
Endoleak	0
Loss of patency	6 (10,5%)
Reintervention	2 (3,4%)
Left renal artery	
Endoleak	1 (1,7%)
Loss of patency	3 (5,1%)
Reintervention	2 (3,3%)

Chapter 5

Discussion

To date, few data is available regarding the outcomes and follow-up of this novel off-the-shelf device. This study is the largest series of elective and urgent patients available treated with this endograft.

Technical success in this study was encouraging (97,1%). Overall mortality ≤30 days (6%) was comparable to other published series dedicated to similar devices (range, 0%-6%). (84,85)Also, this outcome was lower when compared to other CMDs cohorts (range, 7%-11.6%).(86–89) At follow-up (mean time 6,80 ± 4,87 months) available on sixty-three patients, three (4,8%) additional deaths were reported. Only two deaths were classified as aortic related, but due to the limited amount of data no associations with independent factors predictive of mortality was made. Mortality at 1 year follow-up is still not available, therefore not comparable with other studies.

The 30-days reintervention rate was 9,9% (10 patients), but in half of the cases (5 patients) the reason of reintervention was an access site complication, excluding technical failure of the main graft or the branch grafts.

The data collected in this study is encouraging and in line with the other available OTS endograft (Zenith t-Branch, Cook Medical, Bloomington, Ind) as well as the CMDs, emphasizing their major disadvantage of the manufacturing delay.(84,85,90,91) In 2009, the first results assessing patient eligibility for the use of standardized multi-branched endografts were reported. (92) These endografts were then used in one half of the TAAA patients, and the results were comparable to those observed for patients treated with CMDs but without the manufacturing delay. (93) The anatomical applicability limitation is well addressed by the Jotec E-nside, studies reported an overall feasibility of 43% scoring the highest if compared to other OTS devices (33-39%). (78,94)

In emergency situations as well, E-nside offers a good alternative to open surgery, even if an increased risk of paraplegia would have to be accepted due to the increased aortic coverage. (95) Although the inner branch design would offer the chance of reducing the supraceliac coverage of the aorta and thus the risk of

spinal ischemia, a comparison with the Zenith t-branch shows a similarly long distance from the beginning of the covering to the outlet of the CT branch (E-nside: 93mm vs Zenith t-branch: 99mm) because the E-nside is principally designed as a thoracoabdominal stent graft. However, the different proximal diameters of the stent graft, 33 and 38 mm, allow a wider range of thoracic aortas to serve as native landing zones, thus avoiding the need for an additional thoracic stent graft in some cases. (83)

Promising results were published about thoracoabdominal stent prosthesis with an inner branch design. Katsargyris et al. reported that inner branch design was particularly favorable for patients with complex/narrow aortas, postdissection TAAA, failed previous FEVAR cases, and for all those cases with difficult origin of the visceral vessels therefore unsuitable for fenestrations or outer branches. (96) It was found that inner branches that were not pre-cannulated were often difficult to cannulate. This is not the case with E-nside, where all inner branches are pre-cannulated. Due to pre-cannulation, the delivery system of the E-nside stent graft, similar to fenestrated stent grafts, must remain in the vessel until all branches and target arteries are completed. This may increase the risk of peripheral ischemia or even spinal cord ischemia. The collected data shows that eight (8,2%) patients developed either sensory or motor deficits as manifestation of spinal cord ischemia. This result is comparable to other OTS devices (range, 5%-8,8%) or CMDs (4%). (97,98)

That said, we have to keep in mind that the high variability, pre-cannulation and low susceptibility to kinking of the inner branches, the time to cannulation of the target vessel can usually be kept very short. Safety data on E-nside are encouraging as well, the mean operating room time is 258 ± 120 minutes, which is significantly lower if compared to other OTS device implantation procedure reported by the mbEVAR group (331 ± 126 minutes), or by Bosiers and collegues (369 ± 128 minutes). Fluoroscopy time, radiation dose and contrast volume do not show significant differences when compared to other OTS and CMDs endografts. (97,98)

Another technical aspect of the E-nside endograft worth to be mentioned, is the transbrachial cannulation of the target vessels. This is the standard procedure as it was intended from the manufacturer. In the vast majority of cases (81%), the transbrachial approach was preferred. On the other hand, in nineteen patients, the

cannulation from below approach was used. This may carry some advantages, such as the avoidance of the brachial access, the manipulation of the aortic arch as well as the fully opening of the main graft before the cannulation of the visceral vessels. At the same time, some limitations are carried by this approach, indeed this could result in a more difficult procedure, obliging the surgeon to choose a steerable guide wire as well as a balloon expandable stent graft.

The present study has some limitations, starting from its partially retrospective, nonrandomized design. The most important limitation is the incomplete follow-up data of some patients, both due to the inability of retrieving it, as well as the time frame. These limitations could have contributed to a bias regarding the mortality and morbidity rate, as well as the complications due to the main graft as well as the branches. More complete data will be published as soon as it becomes available.

Chapter 6

Conclusions

This novel off-the-shelf inner branch endograft appears safe, with good 30-days and 6-months mortality and morbidity. The rates of MAEs and reintervention appears similar to those reported for others CMDs and OTS devices. The lack of waiting time is a great advantage for this prothesis, keeping an acceptable anatomical feasibility rate, in both elective and urgent cases.

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