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Chapter 6

Endovascular Treatment of Descending Thoracic Aortic Aneurysms

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Additional information is available at the end of the chapter

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1. Introduction

The first series of patients treated with the endovascular technique for descending thoracic aortic aneurysm (DTAA) was published by Dake et al in 1994 [1]. Since then, the use of endografts has been affirmed as a valid alternative to traditional surgery, above all in elderly and high surgical risk patients. The progress of experience has evidenced advantageous immediate and mid term results, above all when compared with traditional surgery. However, this advantage has not been found in results at a distance.

The mobilization of the often extremely tortuous thoracic aorta, which is not supported by nearby internal organs and which extends into three spacial plains, are factors which determine through time an extreme strain on materials. This wear and tear can be responsible for stent rupture, and the evolution of complications such as stent migration and endoleak. Further, the anatomic contiguity of the bronchi and the esophagus, and the fragility of the diseased thoracic aortic wall, pose serious doubts on the development of catastrophic complications such as aorta-bronchial and aorta-esophageal fistula through time.

Aneurysms are distinguished as either true, where the aortic wall is constituted by all 3 layers (tunica intima, media and adventitia), or false, where only the adventitia and/or a perivascular connective tissue is present. They are classified according to either the pathogenesis: atherosclerotic (degenerative), post-traumatic, micotic, or inflammatory, or based on the morphology: sacciform or fusiform. The most frequent form of aneurysm is atherosclerotic, with an incidence of 10 cases per 10,000 adults, of which 30-40% are limited to the descending tract of the thoracic aorta. [2] The pathogenesis of the descending thoracic aorta is similar to the fre-

quent infra-renal aneurysm, and is due to the progressive degeneration of the media. Some authors indicate treatment for aneurysms of a diameter greater than 5.5 cm, but the universal indications specify a diameter of greater than or equal to 6 cm. The indications are based on the annual exponential risk of rupture [3], dissection or death associated with aneurysms greater than 6 cm reaching 16%. [4] True rupture or radiographic signals of imminent rupture with associated symptoms, also constitute an absolute indication for treatment.

2. Materials and methods

From May 1995 to July 2012, 170 consecutive patients presented at this centre with thoracic aortic pathologies which were subsequently treated with endovascular solutions. A total of 109 (64.1%) patients were treated in election, and 61 (35.9%) in emergency. The types of treated thoracic diseases in election included atherosclerotic aneurysms, chronic dissection and chronic post-traumatic. In emergency, pathologies included ruptured atherosclerotic aneurysm, acute dissection, aorto-esophageal fistula (AEF), aorto-bronchial fistula (ABF), acute pseudoaneurysm, acute post-traumatic and penetrating ulcer.

2.1. Patient selection

Patient selection for elective treatment at this centre includes rapid aneurysm expansion (> 10 mm in 1 year) or absolute size. For fusiform aneurysms, the minimum diameter was 5.5 cm, and for saccular aneurysms a protrusion of at least 2 cm from the disease free aortic wall or a total aortic size of 5 cm was considered an indication for treatment.

2.2. Emergency patient management

All patients treated in emergency are assisted by a vascular surgeon and an anaesthesiologist from their presentation through to the operating room. Permissive hypotension is practised with prudent fluid resuscitation to keep systolic blood pressure around 80 mm Hg, in order to avoid a recommencement of, or increase in bleeding. Patients are assessed by computed tomographic angiography (Angio-CT), 5 mm slices. Rupture is defined as visible spilling of blood outside the aneurysm as evident by Angio-CT images, and in some cases of extreme urgency, by intra-operative angiography and IVUS. During the Angio-CT scanning process, the operating room is prepared, in order to further reduce delay.

2.3. Pre-operative evaluation

The patients' anatomic suitability for emergency TEVAR is determined by Angio-CT. The maximum time taken to execute an Angio-CT in emergency is between 5 - 7 minutes at this centre (total time delay of 15 – 20 minutes). The diameter and length of the aneurysms are evaluated directly by the vascular surgeon from the screen. Transferred patients from other hospitals, with previously performed CT scans, are evaluated during patient transport, with images delivered via a diacom intranet system.

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Elective patients are evaluated for TEVAR suitability according to the most appropriate modality:

- Computed tomographic angiography (Angio-CT)

The volumetric angio-CT (Angio-CTV) is currently considered the best diagnostic tool for the evaluation of the aorta and its branches. [5-6] The Angio-CTV is non invasive, has a high spatial resolution and densitometry, which allows the study of the vessels on any spatial plain (the submillimeter isotropic voxels of the recent Angio-CTV consents the elaboration of the oblique images to a quality equal to that obtained at axial images).

In endovascular treatment of the DTAA, the Angio-CTV correlated with adequate multi-plain reconstruction, allows an accurate evaluation of aortic caliber and length, essential information for the choice of endograft, and the presence of tortuosity, thrombosis and atherosclerotic lesions. The evaluation of the condition of the accesses is also of fundamental importance.

The limits of the Angio-CTV are common to all imaging methods which utilize ionizing radiation and iodized contrast mediums:

- exposure to elevated doses of radiation, especially for patients with a long life expectancy who will require programmed check-ups. Compared to the annual level of natural radiation a person is exposed to (2 mSv), a single thoracic Angio-CT delivers a dosage equivalent to that absorbed in 3.6 years (8mSv), which increases to an equivalent of 4.5 years (10 mSv) if the exam is extended to include the abdomen and the pelvis.
- the risk of allergic reactions to iodized compounds (which is less frequent since the introduction of non-ionic contrasts)
- nephrotoxicity from iodized contrast, partly resolvable by reducing the toxic chemical compounds (non ionic iso-osmolar) and the quantity of contrast injected.
- Magnetic resonance angiography (Angio-MR)

Compared with the Angio-CT, the Angio-MR has the advantage of not requiring ionizing radiation and iodized contrast medium. It therefore represents an alternative for patients with allergies to contrast mediums and those affected by renal insufficiency. However, the Angio-MR has an inferior spatial resolution and a reduced capacity to highlight the presence of calcification compared with Angio-CT. The evaluation of aortic neck and aneurysmal sac diameters are often less precise, caused by the difficult visualization of the extreme limit of the aortic wall.

Further, this diagnostic examination cannot be performed in patients with iron magnetic devices (pace-maker, metallic acoustic devices, vascular ocular clips. etc...), and is contra-indicated for patients with grave renal insufficiency (GFR <30 ml/min/1.73m^2) due to the risk of systemic nephrogenic fibrosis onset associated with the administration of gadolinium. Compared to the Angio-CT, this examination methodology is less common, more costly and more time consuming, and therefore is less accessible to patients.

2.4. The TEVAR procedure

All TEVAR procedures are performed in a dedicated vascular operating room equipped with mobile C-Arm (OEC 9800, GE Medical System, Salt Lake City, UT, USA), IVUS (Volcano s5, Rancho Cordova, CA, USA) and eco-duplex scanner (Esaote AU 5, Genova, Italy). Our TEVAR team includes 3 vascular surgeons (at least 2 endovascular experts), an anaesthesiologist, an endovascular trained operating room nurse and a radiological technician.

CSF drainage is applied selectively in patients with previous or contemporary AAA treatment, programmed long coverage of the aortic tract (≥20cm), and coverage of the distal tract beyond T10-T12. In the case of a short or absent proximal neck which would require the coverage of the left subclavian artery, reimplantation (the preferred technique) or a bypass is performed pre-operatively. A preventive retrograde re-vascularization of the visceral vessels (i.e. tripode or mesenteric or renal arteries) is performed in cases of short distal neck to ensure adequate distal sealing.

In most cases, arterial access is obtained through the surgical exposure of both femoral or omeral arteries. Intra-operative angiography is performed manually through an introducer sheath inserted from the contro-lateral artery to the side chosen for the deployment of the endograft. The angiography outlines exactly the position of the supra-aortic vessels, which are then marked directly by the vascular surgeon on the C-Arm screen.

Following the insertion of a super-stiff guide wire, the endograft is deployed. Completion angiography confirms adequate proximal and distal fixation and identifies any endoleak. When required, a post-dilation is executed with a compliant balloon.

2.5. Endograft selection

The increasing frequency of DTAA has generated an intensification in endograft manufacturers interest, determining a technological breakthrough in the presentation of increasingly refined and better performing devices, each with an individual peculiarity. Nevertheless, the ideal endograft still does not exist and a single endograft has not demonstrated a clear superiority over another.

In selecting an endograft, some fundamental principles apply which should always be respected.

- An oversizing of more than 10 - 15% should not be performed. This is most important in order to reduce the risk of aorto-esophageal and aorto-bronchial fistulas. However, to date there are no studies which have demonstrated that the adoption of oversizing greater than 15% to be correlated with the above mentioned complications.
- In the case of a measurement discrepancy of greater than 10% between the proximal and distal necks, the selection of a tapered endograft is advised.
- For necks with diameters inferior to 20 mm, the use of an endograft with an uncovered proximal or distal end with the positioning of the device either at the emergence of the epiaortic or the celiac-mesenteric vessels, according to the case.

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- Where possible, the use of a single segment is preferred to the "telescopic technique" in order to avoid type III endoleak from segment disconnection. In the case of multiple segments being utilized, the overlapping should be at least 5 cm.

The first generation of endografts were Stentor (Min Tec, La Ciotat, France), Vanguard (Boston Scientific Corp., Natick, MA), Aneurx (Medtronic Vascular, Santa Rosa, CA, USA). The endografts recently used in the study were commercially available, supplied by Talent (Medtronic Vascular, Santa Rosa, CA, USA), Excluder and TAG device (W.L. Gore and Associates, Inc., Flagstaff, AZ, USA), Zenith TX2 (Cook, Inc., Bloomington, IN, USA), Endofit (Endomed, Phoenix, AZ, USA) and Relay (Bolton Medical Inc., Sunrise, FL, USA).

2.6. Data collection

Patients' clinical information is collected prospectively in a dedicated database, and were retrospectively evaluated for this study.

2.7. Follow-up protocol

The post-discharge TEVAR follow-up scheme at this centre consists of routine Angio-CT at 3, 6 and 12 months, and annually thereafter in the absence of symptoms. Plain radiographs are performed at 6 months, and annually thereafter.

3. Results

From May 1995 to July 2012, 170 consecutive patients with various thoracic aortic pathologies were treated with endovascular solutions at this centre. A total of 109 (64.1%) patients were treated in election for DTA diseases, and 61 (35.9%) in emergency (Table 1). Patient mean age was 73.78 yrs old.

CSF drainage was used in 16 (9.4%) patients. A reimplantation or bypass of the left subclavian artery was performed pre-operatively for a total of 31 (18.2%) patients. In 5 (2.9%) cases, a preventive retrograde re-vascularization of the visceral vessels was performed.

Complications following treatment are outlined in Table 2. The most common intra-operative complications were access associated (15.9%). Neurological complications were observed in 7%. 30 day mortality was reported at 14.1%, with the majority of the deaths occurring among the patients treated in emergency (29.5%).

Late complications included a rate of endoleak of 20% (24 patients of the 34 cases had recurrent endoleak), rupture in 3.5%, 2 aorto-esophageal fistulas (AEF) and single cases of aorto-bronchial fistula and infection.

Reinterventions were required in 21.1%. Most were treated with endovascular solutions (91.7%). Table 3 outlines the complications for which a reintervention was required and the modality of intervention.

4. Discussion

Various studies which compare thoracic endovascular aortic aneurysm repair (TEVAR) to traditional surgery for DTAA in literature report superior results for endovascular treatment, most importantly in terms of post-operative complication rates and length of hospital stay.

A meta-analysis published in 2010 [7] including 38 comparative studies and 4 registries (5,888 patients) revealed a significant reduction in mortality for TEVAR (5.8% vs 13.8%, $p<0.00001$, OR=0.44), neurological, renal, respiratory and cardiological complications (41.4% vs 69.3%, $p<0.001$, OR=0.19) and length of hospital stay (7 days less for TEVAR).

A meta-analysis comparing the two techniques by Walsh et al. [8] including 17 published series, with a total of 1,109 patients, also concluded a significant reduction in mortality ($p=0.005$, OR=0.25) and neurological complications ($p=0.0013$, OR=0.28) for TEVAR.

A study published in 2010 [9] compared data extracted from the NIS (National Inpatient Sample) database with data of 11,669 patients. This study found that the mortality rates were identical for both TEVAR and traditional surgery (2.3%), even though the mean age of TEVAR patients was significantly higher (69.5 vs 60.2 yrs, $p<0.001$). Significant reductions were also found for TEVAR in terms of post-operative complications (60%, $p<0.001$, OR=0.39) and length of hospital stay ($p<0.001$).

4.1. Complications associated with endovascular treatment

4.1.1. Access complications

Carpenter et al. [10] reported that inadequate accesses are responsible for roughly 50% of the cases of ineligibility for TEVAR treatment.

Damage of access vessels continues to the greatest cause of grave comorbidities and even death, correlated to endovascular treatment of thoracic aorta pathologies. [11-12] It has been estimated that access related problems occur in around 28% of cases. [13-14] This is principally due to three reasons. The first reasons is that thoracic endografts generally require introducers with large calibers (20-25 Fr.), with external diameters between 22 and 27 Fr. Secondly, unlike the aneurysmatic pathology in the abdominal aorta, over 30% of the population with DTAA is female who generally present with vessels of smaller diameters. [15] The third reason is that the often advanced aged patients present with atherosclerotic steno-obstructive lesions and accentuated tortuosity, above all at the iliac axes.

In cases of small caliber vessels, the phase of the removal of the introducer is particularly crucial, which can provoke rupture and in some cases the complete detachment of the iliac artery. [16]

The preoperative examination is therefore of fundamental importance in order to plan the best access site and to be ready during the intervention for alternative operative strategies if necessary. The femoral access is suitable in 70-85% of cases, [11, 17] although in doubtful cases,

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the selection of a more proximal access site (iliac or aortic in extreme cases), also with the assitance of another graft, is recommended to avoid potential grave complications.

Another useful strategy includes the use of a Coons dilator (Cook Medical, Bloomington, IN) with progressively increasing diameters, incrementing 2 Fr at a time. The dilator enables both the testing of a possible passage and the progressive dilation of the artery to a diameter which adequately allows the passage of the endograft. It must also be underlined that, in cases of difficult accesses, an angiographic evaluation of the iliac arteries is absolutely necessary.

4.1.2. Neurological complications

Paraplegia and stroke represent the most devastating complications associated with the treatment of thoracic aorta pathologies.

Compared to traditional surgery, endovascular treatment appears to have significantly reduced the global incidence of paraplegia. This advantage is of particular relevance in the treatment of acute Stanford type B dissections, where the incidence associated with traditional surgery is between 14 - 19% [18-19]. Conversely, for the treatment of isolated descending thoracic aneurysms, the two treatment techniques have a comparable incidence of paraplegia, reported to be between 0-4% [20] and 2.5% [21] respectively.

The mechanisms which provoke paraplegia following TEVAR have not been fully identified. Simultaneous and previous traditional surgery of the abdominal aorta has been associated with increased risk of paraplegia. [21-23] The medullary vascularization from the lumbar and hypogastric arteries are important contributors in the risk of paraplegia. [24] Given this information, it is therefore advised by various authors [22,25] to perform eventual treatment of the abdominal and thoracic aorta in different interventions, so that a gradual establishment of a collateral medullary vascular circuit can be established. At this centre, in cases where a long segment of the thoracic aorta is planned to be covered and the hypogastric circulation is compromised, a preventive treatment is routinely performed. Embolization into major intercostal arteries due to the manipulation of the device in the aortic lumen has also been nominated as another potential risk factor. Extended coverage of the thoracic aorta has also been proven [22,26-28] to augment the risk of medullary ischemia. This risk rises further when coverage includes the region distal to T10. [22, 25, 29]

The EUROSTAR [21] study reported a significantly increased incidence of paraplegia when three or more endograft segments were used (OR, 3.5; P =.043).

A debated argument is that of the necessity to perform left subclavian revascularization when the placement of the endograft requires the coverage of the left subclavian artery. The EUROSTAR [21] study demonstrated the contribution of the subclavian/left vertebral arteries to the anterior spinal artery, and that the coverage of which determines an almost 4 times increased risk of paraplegia (OR, 3.9; P =.027). At this centre, with the exception of emergency cases, a preventative transposition of the subclavian artery is performed in all cases where treatment would require it to be covered.

Chiesa et al. [25] highlighted the importance of arterial pressure in the post-operative period: medium pressure values of 70 mmHg are associated with an increased risk of medullary ischemia. Other correlated factors include the female gender and renal insufficiency.

The causes of late onset paraplegia are more difficult to identify. A possible cause could be the onset of a secondary medullary edema due to damage such as reperfusion ischemia, which could in some cases reduce the medullary perfusion. Another possible cause could also be linked to long periods of post-operative hypotension.

The principal prevention method of medullary ischemia is cerebral spinal fluid (CSF) drainage. The use of this method however, should be weighted against the risk of complications associated with this procedure, which above all include subdural hematoma and infection. For this reason, and as suggested by other authors, the procedure is reserved for selected cases only in which a long tract of thoracic aorta is programmed to be covered (>20 cm) or in cases in which previous traditional surgery or endovascular treatment of the abdominal aorta is evidenced. Other methods utilized in the surgical environment includes medullary cooling [30] in order to reduce metabolic activity and increase the tolerance of the medulla to ischemia and the use of corticosteroids [31] with the aim of reducing edema from revascularization. This method has not found a use in TEVAR.

The incidence of stroke was reported in a literature review published in 2006 by Sullivan et al. [32] to be a mean of 2.2%. The EUROSTAR [21] study reported a 3.1% incidence of stroke in 606 patients treated with endografts for all pathologies of the thoracic aorta. It is commonly accepted that the cause of stroke during TEVAR is related to embolization caused by the manipulation of catheters and guide wires in the "dirty" aortic arch, rather than a base of hypoperfusion. [33-34]

The EUROSTAR [21] identified two significant risk factors for stroke: the duration of the procedure > 2.6 hours and female gender. Whilst the duration of the procedure is obviously connected to a greater manipulation of the guide wire and catheters in the aortic arch, the reasons explaining as to why females are more likely to develop a stroke is more difficult to understand. An hypothesized explanation is that in female patients the atherosclerotic pathology is often more advanced.

It can be deduced that the most effective mode of stroke prevention is an accurate pre-operative evaluation of the aortic arch, a careful manipulation of the catheters and guide wires attempting to limit maneuvers to those of absolute necessity, and an extensive operative strategy plan devised to reduce to a minimum the operative time.

4.1.3. Endoleak

Endoleak is the most frequent motive for reintervention following TEVAR. [35]

The rates of endoleak reported in literature vary and depend upon the type of pathology treated, and the length of the follow-up. Parmer et al. [36] reported an endoleak incidence of 29% at an average follow-up of 17 months, Ellozy et al. [37] published an incidence of 18% at roughly 15 months, and the Gore-TAG trial [38] reported only 10.6% at 5 years.

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The EUROSTAR study [35] declared a 6.5% rate of need for secondary intervention due to endoleak at 2 years. Beyond single experiences, the reasoning behind this frequent complication can be explained by two fundamental factors: the prominent mobility and the frequent tortuosity of the thoracic aorta. Both of these factors force the endograft, and can provoke migration through time, disconnection and even rupture.

Parmer et al. [36] also evidenced some factors which are combined with the development of endoleak: male gender, larger diameter aneurysms, coverage of a long portion of the thoracic aorta and the usage of multiple endograft segments.

Among the various types of endoleak, the most frequent is type I proximal, reported as having an incidence in literature ranging between 0 and 44%. [39-41] The extreme variation in range can be explained by the different anatomical complexities in the aneurysms treated and therefore in the selection criteria. It is noted that the treatment of an isolated relatively small aneurysm situated in the rectilinear descending thoracic aorta, is relatively simple to treat and the development of a complication is relatively rare. Conversely, the treatment of an aneurysm which includes a part of the aortic arch is more complex and the results are less convincing. We believe that in the circumstances of complex anatomies including the aortic arch, it is necessary to construct a straight neck of at least 2 cm, which may include a by-pass or a transposition of the epi-aortic branches, in the hope of achieving aneurysm exclusion which will endure through time.

Type II endoleak are less common in the thoracic aorta compared to the incidence observed in the abdominal aortic region. In some cases, post-deployment angiography can evidence the patency of bronchial and intercostal arteries, but these arteries generally develop spontaneous thrombosis and do not require treatment.

Type III endoleak are the second most common form of endoleak. The extreme mobility of the thoracic aorta and its frequent tortuosity, especially found in large caliber aneurysms, can invoke through time the disconnection of the endograft segments and in some cases wear and tear which can lead to graft rupture. Experience has enabled the reduction in the incidence of type III endoleak, through increasing the length of device overlap in the case of multiple segments, which at this centre we believe should not be less than 5 cm, and using longer endografts rather than multiple shorter segments.

4.1.4. Aneurysm rupture

Avoiding aneurysm rupture is the ultimate objective of endovascular treatment. The percentage of rupture following endovascular treatment of abdominal aortic aneurysms (AAA) has been estimated to be around 1%.

The Stanford University group [42] reported their experience of TEVAR with a "custom-made" endograft claiming a rate of rupture at a distance of 10.7%, and a mortality rate of 91% at an average follow-up of 54 months. The EUROSTAR study [35] reported 2 cases of rupture at a distance of 12 months in 443 patients (0.5%). Other smaller experiences in literature with follow-ups ranging from 15 - 40 months presented a percentage of rupture at a distance between 1.6% and 6%. [37,43,44]

4.1.5. Aorto-Esophageal Fistula (AEF) and Aorto-Bronchial Fistula (ABF)

The AEF and the ABF are grave complications, which are almost always fatal and whose incidence is yet to be clearly defined. The Stanford University study [42], published in 2004, revealed a rate of AEF/ABF of 3%. Eggebrecht [45] also reported in 2004 an incidence equal to 5%, which were fatal in 100% of cases. Other cases of AEF/ABF following TEVAR have also been reported in more recent experiences. [38,43,46-47]

The anatomical proximity of the bronchi and the esophagus to the aorta is a factor which influences the incidence of this disastrous complication through time, due to the associated mechanical stress exercised by the endograft on the diseased aortic wall.

The use of restricted oversizing (about 10%) to reduce the mechanical stress on the aortic wall may theoretically reduce the incidence of these complications. However, this theory has not yet been proven.

4.2. Emergency treatment for ruptured thoracic aortic aneurysms

The annual incidence of rupture of the thoracic aortic aneurysm has been estimated to be at 5 cases per 100,000 inhabitants. [48-49] Around 30% of all the ruptured thoracic aortic aneurysms are localized in the descending aorta (rDTAA), with the remaining 70 % involving the arch and the ascending thoracic aorta. RDTAA represents a catastrophic event with a global mortality rate estimated to be up to 97%. [48]

In the few patients who arrive to the emergency department alive, traditional surgery has an ulterior mortality rate of 45% and a rate of systemic complications of around 50%. [50]

Endovascular treatment for rDTAA requires an endovascular emergency service with dedicated technical and nursing personnel combined with a surgical, anesthesiological and radiological team with knowledge and experience of endovascular materials. This preparation also demands the availability of advanced radiological equipment (eg. Angio CT) and an endovascular team 24hr/24hr for adequate diagnosis and treatment. The endovascular team must also be competent in traditional surgical techniques, so as to be able to treat different cases with the most appropriate surgical method. The operation room must also be equipped for an endovascular procedure, with high quality radiological and ultrasonographic machines (such as a portable C-Arm angiography and intravascular ultrasound (IVUS) and must have a large warehouse of basic endovascular materials available.

A meta-analysis [51] comparing traditional surgery and TEVAR for rDTAA included 859 patients and revealed significantly reduced mortality and paraplegia rates in favour of TEVAR. Mortality rates (11.4% vs 26.5%, p=0.13) favoring endovascular treatment were also reported by Patel et al. [52] in a comparative study.

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5. Conclusion

Various studies have demonstrated a reduction in intra-operative mortality and neurological complications associated with endovascular treatment for DTAA pathologies compared to traditional surgery.

Technical improvements in catheters, specifically in terms of flexibility, have enabled the reduction in access related complications and the extension of the patient population to include those with more complex anatomies in terms of tortuosity. Mid and long term complications are still frequent, but are often able to be treated with ulterior endovascular procedures. A substantial rate of complications, such as rupture and AEF/ABF, are frequently fatal and often underestimated, especially in the case of fistulas.

At this centre however, endovascular treatment is considered the first choice treatment in emergency for rDTAA and in elderly patients and/or patients at high surgical risk. For patients with a long life expectancy, traditional surgery is currently our preferred treatment.

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