SOP for the Endovascular Treatment of Thoracic Aortic Aneurysm and Type B Dissection

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Introduction

Thoracic endovascular aortic repair (TEVAR) represents a minimally invasive alternative to conventional open surgical reconstruction for the treatment of thoracic aortic pathologies. It is a valid therapeutic option for the treatment of thoracic aortic aneurysms and thoracic aortic dissections by virtue of its lower mortality, morbidity and paraplegia rates compared to open thoracic repair.

Rapid advances in endovascular technology and procedural breakthroughs have contributed to a dramatic transformation of the entire field of thoracic aortic surgery less than 15 years after the first report of on stent-graft repair of thoracic aortic aneurysms. (1) TEVAR procedures can be challenging and, at times, extraordinarily difficult. They require seasoned endovascular experience and refined skills. Of all endovascular procedures, meticulous assessment of anatomy and preoperative procedure planning are absolutely paramount to produce optimal outcomes.

These guidelines are intended for use in quality-improvement programs that assess the standard of care expected from all physicians who perform TEVAR procedures. The issues addressed by this document include

- disease/lesion definition, diagnosis and symptoms
- pre-treatment evaluation
- patient selection
- procedure and technical aspects
- follow-up
- outcomes: technical success, clinical results and complications based on the currently available data

Definition

Aneurysm: The permanent and irreversible dilation of an artery is called aneurysm. Conventionally, according to the definition of the Ad Hoc Committee on Reporting Standards of The Society for Vascular Surgery and the North American Chapter of the International Society for Cardiovascular Surgery, a transverse diameter exceeding at least 150% of the diameter of the remaining part of the artery can be judged “aneurysmatic” (2,3,4).
According to conventions proposed by these societies, thoracic aortic aneurysms can be divided into:

- Aneurysms that exist at the level of the ascending aorta, arch, descending aorta or involving all three of these segments (thoracic).
- Thoraco-abdominal aneurysms with involvement of both the descending aorta and the abdominal aorta.
- Based upon the extent of disease and in compliance with Crawford’s classification, these can be categorized further. (5):
  - Type 1 – involving the proximal half of the descending aorta with extension as far as the renal arteries;
  - Type 2 – stretching from the proximal half of the descending thoracic aorta to the intra-renal aorta;
  - Type 3 – extending from the distal half of the descending thoracic aorta to the abdominal aorta, and
  - Type 4 – affecting most of the abdominal aorta with proximal involvement above the renal arteries.

According to their shape, thoracic aneurysms can be divided into two types:

- Fusiform: these aneurysms typically involve all three layers of the aortic wall and thus, are usually true aneurysms. The abnormal dilation is often along an extended section of the aorta and involves the entire circumference of the aorta. Generally, the weakened portion appears as a symmetrical bulge.
- Saccular: these look like a small blister or bleb on the side of the aorta and are asymmetrical. Typically they are pseudoaneurysms caused either by trauma such as a car accident or as the result of a penetrating aortic ulcer.

Thoracic aorta aneurysms have a mean growth rate of 0.42 cm/year at the level of the descending aorta and of 0.56 cm/year at the level of the aortic arch(6,7).

The larger the diameter of a thoracic aortic aneurysm, the higher the annual rupture risk(8):
- > 4 cm – 0.3 %;
- > 5 cm – 1.7 %, and
- > 6 cm – 3.6 %.

A surgical or endovascular treatment is recommended when the diameter at the level of the ascending aorta exceeds 49 mm and when the calibre at the level of the arch and of the descending aorta the diameter is larger than 45 mm(10,11). Cambria(8) reported a 52% survival rate two years post-diagnosis and a 17% survival rate at five years in untreated patients. In patients diagnosed with the Marfan Syndrome, treatment is recommended if the aortic diameter is greater than 43 mm(12).

Idiopathic cystic medial degeneration, atherosclerosis, connective tissue disorders (Marfan Syndrome, Ehlers-Danlos Syndrome), trauma, infection of the aortic wall, and Takayasu’s arteritis are the principal aortic pathologies associated with thoracic aneurysm(10-13).
Dissection: Aortic dissection is caused by the formation of a false channel within the aortic wall consequent to a disruption of the intimal lining. A dissection plane that separates the intima from the surrounding adventitia is created within the media over a variable length of the aorta. This produces a false lumen or a double-barrelled aorta that can reduce blood flow to the major arteries arising from the aorta\(^{(14)}\).

If the dissection involves the pericardial space, cardiac tamponade may result.

The most common site for the initiation of dissection when the ascending aorta is involved, is within its first few centimetres. In fact, the entry tear for the process occurs within 10 cm of the aortic valve in 90% of cases. The second most frequent site for the initiating tear is just distal to the left subclavian artery (LSA)\(^{(15)}\).

The dissection can proceed for a variable distance, usually in an antegrade direction but sometimes retrograde from the site of the intimal tear. However in the majority of cases, the dissection affects the descending aorta with the primary entry tear located at the level of the origin of the left subclavian artery in 40%\(^{(16,17)}\).

Between 5% and 10% of dissections do not have an obvious intimal tear and are often attributed to rupture of the aortic vasa vasorum as first described by Krukenberg in 1920\(^{(16,17)}\).

According to the site of aortic involvement, aortic dissections can be divided into two groups (Stanford classification)\(^{(18)}\):

- **Type A**: The dissection involves the ascending aorta, and may extend distally to include the aortic arch and the descending aorta. The primary entry tear is typically located at the level of the ascending aorta or in the arch, but may be in the descending aortic segment and associated with retrograde propagation to affect the ascending aorta.
- **Type B**: The primary entry tear is typically after the origin of the left subclavian artery and the descending aorta and/or aortic arch are affected exclusively without involvement of the ascending aorta. Uncommonly, the entry tear may be located in the arch with or without extension to the descending segment, but not into the ascending aorta.

On the basis of the time from the onset of the initial symptoms, a dissection can be categorized as either acute (< 14 days) or chronic (> 14 days)\(^{(19)}\).

Moreover, Crawford divided chronic type B dissections into different categories\(^{(20)}\):

- **Type 1**: the dissection involves the descending aorta up to the origin of the renal arteries
- **Type 2**: the descending aorta is dissected over its entire length and the abdominal aorta up to the iliac arteries is involved.
- **Type 3**: the dissection starts at the level of the mid-third of the descending aorta and involves the entire abdominal aorta.
- **Type 4**: the whole abdominal aorta, below the diaphragm, is involved.

The main causes of dissection are cystic medial necrosis, atherosclerosis (occlusion of the vasa vasorum), connective tissue disorders (Marfan Syndrome, Ehlers-Danlos Syndrome), hypertension, metabolic disorders, pregnancy, crack cocaine use, and iatrogenic (arterial catheterization)\(^{(21)}\).

Dissection can be also divided into uncomplicated and complicated disease. Complicated dissection consists of one or more if the following manifestations: rupture, imminent rupture, branch vessel involvement with malperfusion syndrome or persistent or worsening thoracic pain, drug-resistant hypertension and false lumen aneurysm formation.
Symptoms

Aneurysm: when carotid or coronary pathology does not co-exist, thoracic aorta aneurysms are generally silent and diagnosed by sheer chance. But if the maximum diameter of aneurysm exceeds 70 mm, symptoms that correlate with the compression of adjacent organs may be reported(7,8,22).

- Ascending aortic aneurysms: often provoke aortic root dilation and leakage of the aortic valve with consequent shortness of breath and even heart failure when the incompetence is severe. A dull sub-sternal pain that may radiate to the upper back can also be present.
- Aortic arch aneurysms: may be associated with upper chest or interscapular back pain. When aortic arch aneurysms are large, both the esophagus and the airway can be compressed. Difficulty swallowing and/or hoarseness are the initial symptoms.
- Descending thoracic aneurysms: mostly asymptomatic, they can occasionally cause back pain.

Dissection: When the initial tear and dissection occurs, the symptoms are severe with an abrupt onset of pain(24). The sudden pain is generally located at the mid-sternum for dissection of the ascending aorta and in the interscapular region for descending thoracic aortic dissection. “Migratory pain” should be regarded suspiciously as a sign of dissection extension in an antegrade or retrograde direction(25).

Painless dissection has been described and usually occurs in the presence of an existing aneurysm where the pain of a new dissection may not be differentiated from chronic aneurysm pain(26).

Depending on the evolution of the dissection process, symptoms can be complicated by hypotension, bradycardia, abdominal pain, intestinal or inferior limbs ischemia(26). However, a differential diagnosis for chest pain should be considered with myocardial ischemia, aortic aneurysm, acute aortic regurgitation, pericarditis, musculoskeletal pain and pulmonary embolus entertained(27,28).

Diagnosis

Both thoracic aortic aneurysm and dissection are diagnosed by the same spectrum of imaging evaluations: plain chest radiography, CT-Angiography (CTA), MR-angiography (MRA), conventional digital subtraction angiography (DSA) and transesophageal echocardiography (TEE)(29-31).

X-ray: abnormal findings are evident in 88% of cases and include:
- widened mediastinum (25% of cases): differential diagnosis is tumor, adenophaty, lymphoma, and enlarged thyroid.
- abnormal aortic knob contour (66% of cases)
- tracheal or esophageal deviation
- ring sign (dissection) with displacement of the aortic margin >5cm beyond the calcified aortic intima.

CTA: the best non-invasive alternative to DSA, it is considered the gold standard and primary diagnostic modality today. With a single breath-hold acquisition, after contrast media injection, it can evaluate the thoracic and abdominal aorta, the supra-aortic vessels, abdominal branches, and the iliac-femoral axis. Images can be studied in the standard axial format and after post-
processing, multiplanar reconstructions using different algorithms (Volume Rendering-VR, Maximum Intensity Projection-MIP, Multiplanar Reformation-MPR, Shaded Surface Display-SSD, etc.) provide three-dimensional characterizations.

CTA evaluations can provide:
- diameter and morphology of the aorta
- diameter and length of the proximal and distal necks
- intimal flap anatomy, extent of the dissection, true and false lumen morphologies
- site of the primary entry tear
- re-entry site(s)
- presence of thrombus or calcifications
- patency of the abdominal branches
- size, tortuosity, disease status of iliac and femoral arteries

Recently a new imaging modality, electrocardiogram (ECG)-gated CTA, has been introduced. The 3-D volumetric datasets allow rotation of the aorta while viewing it in different phases of the cardiac cycle. This may improve diagnostic accuracy as motion artefacts, often the cause of false-positive findings of a thoracic dissection, all minimal(32,33).

**MRA:** Limiting exposure to ionizing radiation and forgoing the use of non-iodinated contrast media are preferable in those cases where multiple follow-up examinations are required and in patients with iodinated contrast allergies. MRA was once considered ideal for patients with renal failure but after the discovery of nephrogenic systemic fibrosis in patients with renal dysfunction receiving intravenous gadolinium, the initial enthusiasm drastically decreased. MRA gives the same information that can be achieved using CTA. The introduction of axial images, acquired with “black-blood” sequences, allows a better evaluation of the aortic wall and of any dissection, ulcer or thrombus accumulation. This sequence takes advantage of the lack of signal from blood flowing perpendicular to the imaging plane.

MRA does have some limits, it gives no information about the presence of calcium in the aorta or conduit arteries and cannot be performed in patients with old cardiac valve prostheses or pacemakers(31,34).

**DSA:** It is still considered the definitive diagnostic test for thoracic pathology, but it clearly displays limitations when compared to more modern CTA and MRA. Principally, this is because of the complications associated with an invasive procedure not encountered with non-invasive imaging tests and its inability to evaluate the thrombus quantity, when present, along the aortic wall. DSA is usually performed before any interventional procedure and when CTA and MRA can’t answer all diagnostic doubts.

DSA is mandatory when patients exhibit ischemic problems with mesenteric, renal or lower extremity malperfusion, because it provides the final diagnostic data that contributes to the determination of whether a therapeutic intervention is required and feasible. It also provides vital morphological and hemodynamic data to guide any endovascular treatment.

**TEE:** This test can be quickly performed at the patient’s bed side in no more than 20 minutes. It has a diagnostic sensitivity ranging from 98 to 100 % for dissection and a technical suitability for patient application that ranges from 90 to 100 %³⁵. Moreover, it can be performed more than once, its cost is limited, it is useful during the follow-up of patients who have undergone surgery and patients treated with medical therapy. The limitations of TEE include that it can be performed only in selected medical centers, it requires a specialized operator, and it cannot provide information about the false lumen extension at the level of the abdominal aorta or about the involvement of abdominal aortic branch vessels³⁵,³⁶.
Natural History

Aneurysm: The natural history of a thoracic aneurysm is expansion, rupture and death, with the greatest risk of rupture in larger aneurysms(2). Factors affecting aneurysm expansion are increasing age, smoking, chronic obstructive pulmonary disease and hypertension. The larger the aortic diameter, the greater the rate of aneurysm expansion and in fact, an aneurysm over 50 mm expands faster than a smaller one. Also the location of an aneurysm is crucial. Aneurysms located in the proximal descending aorta expand more rapidly than those located in the distal descending aorta(3,4).

Dissection: Thoracic aortic type B dissection presents a severe prognosis in the acute phase; without any treatment it has a mortality rate of 33% at 24 hours, 50% at 48 hours and 75% at 2 weeks(16).
After the acute phase, uncomplicated type B dissection, that does not require interventional treatment, has a survival rate of 91% at 1 month and 89% at 1 year(37).
After 40 to 50 months, a thoracic aortic aneurysm develops in 20% to 30% of cases. This requires interventional management to prevent aortic rupture in 18%(38).
However, those patients who survive the acute phase have a good prognosis. Thus, any strategy that recommends intervention for all chronic stable type B dissections must insure that the majority of survivors have an acceptable long-term outcome(39).

Inclusion Criteria

Aneurysm: In patients with a thoracic aneurysm that is ≤ 50 mm in diameter, no treatment is usually recommended, but regular interval imaging follow-up must be performed (every 6 months). In these patients, moreover, close clinical surveillance is necessary, especially in order to monitor and maintain blood pressure at recommended values (systolic BAP level ≤ 110 mmHg).
Repair of a thoracic aortic aneurysm should be considered when patients present with one of the following symptoms: chest discomfort, symptoms of surrounding organ compression (dyspnea, dysphagia, SOB, hemoptysis, etc.) and/or an aortic diameter exceeding 55 mm(8).

Treatment is also indicated when the aneurysm diameter increases by more than 1 cm per year or when signs of aneurysm rupture are evident.
Surgical therapy of descending aortic aneurysm with prosthetic graft repair is associated with a perioperative mortality rate ranging from 5% to 20%, depending on the clinical conditions of the patient and the aneurysm diameter(13).
Aneurysms of the ascending aorta are generally treated with surgical reconstruction while aneurysms of the descending aorta are addressed by using either surgery or endovascular techniques.

The endovascular treatment, based on the insertion of an endograft, represents a valid alternative to the conventional open repair with lower early morbidity and mortality rates. It is associated with a 30-day mortality rate ranging from 0 to 20% and a periprocedural stroke rate from 0 to 7%(21,22).

Dissection: For Type A dissection, surgery is still the treatment of choice. The surgical procedure should be performed emergently due to the possibility of serious ensuing complications related to rupture and/or involvement of the coronary arteries by the intimal flap.
In case of Type B dissection three different treatment options should be considered:
- medical
- surgical
- endovascular
Selection is based on the specific characteristics of the dissection and the clinical status of the patient.

**Medical therapy:** β-blockers and ACE-inhibitors in combination are considered the current treatment of choice in case of uncomplicated type B dissection, but in complicated cases with lower extremity malperfusion, visceral ischemia and/or renal failure, an immediate interventional treatment is necessary. Medical therapy provides good early-term results in uncomplicated dissection with 85% of patients surviving the initial acute phase. The 30-day mortality rate is 10% for uncomplicated patients versus 30% for those with complicated dissection\(^{(39)}\).

Long-term results are poor however, with a 50% mortality at five years and high incidence of aneurysm formation (25%) at 4 years\(^{(40)}\).

In cases of complicated Type B dissection (renal or abdominal ischemia) or unstable conditions (shock, severe uncontrollable hypertension) an invasive treatment should be considered.

**Surgery:** Open operative repair represents a valid therapeutic option in cases of acute type B dissection complicated by retrograde extension into the ascending aorta, Marfan syndrome, rupture or involvement of vital organs. However, similar to the existing operative management considerations for thoracic aneurysms, surgery in the setting of complicated dissection is associated with a high incidence of paraplegia, prolonged hospital stay, and pulmonary complications.

**Endovascular treatment:** Endograft placement is the new frontier for the treatment of type B dissection. The first report of endografting for an acute dissection was by Dake in 1994\(^{(1)}\). The rationale for endovascular therapy is to obliterate the false lumen and restore normal thoracic aortic anatomy. Stent-graft therapy will promote thrombosis of the false lumen and in so doing, mitigate aneurysm development.

Compared to open surgical repair, reports of this technique detail lower morbidity and mortality rates, especially for complications correlated to spinal cord ischemia\(^{(41)}\).

Indications are:

- Acute type B dissection in unstable patients when medical therapy cannot guarantee blood pressure is controlled at a recommended low level (systolic BAP ≤ 120 mmHg).
- Complicated acute type B dissection when the dissection involves an abdominal branch or the peripheral arteries with consequent ischemia.
- Chronic type B dissection to avoid progressive dilatation of the aorta with aneurysm formation and progressive risk of rupture.
- Chronic Type A dissection after a surgical repair of the ascending aorta when the descending aortic false lumen is still patent and a progressive increase in its size/volume is observed during follow-up.

Endovascular treatment is also recommended to solve ischemic branch complications correlated to the dissection.

A 30-day mortality rate of 10% is reported for uncomplicated type B dissection, while in cases of complicated dissection, mortality rates are higher: 20% at 2 days and 25% at 30 days.\(^{(39)}\)

Early results from different clinical series of stent-graft management in patients with acute and chronic type B dissection are encouraging\(^{(39,42)}\). The obliteration of flow across the entry tear into the false lumen is achieved in more than 90% of cases, with complete thrombosis of the proximal thoracic aortic false lumen over the length of the device in 80% to 95%\(^{(38)}\).
Endovascular Procedure

Endovascular treatment of the thoracic aorta should be performed either in an operating room or in an angio-suite, in a sterile configuration and with all the equipment necessary in case a surgical conversion is necessary. As the procedure requires angiograms to be performed in severe and/or compound oblique views in order to optionally evaluate the landing zones, it is crucial to use a state-of-the-art fluoroscopy machine or dedicated new-generation C-arm.

Procedures can be performed with patients under local, epidural or general anaesthesia depending upon the patient's clinical conditions. General anesthesia should be selected, especially in unstable patients, to maintain appropriately low blood pressure levels. The large diameter of the stent-graft device (22 Fr to 25 Fr.) requires a surgical cut-down to expose the common femoral artery, but recently TEVAR can also be performed with a completely percutaneous access with the use of percutaneous access closure devices. Avoidance of surgical femoral exposure may also result in shorter procedure times, consequent fewer local and systemic complications and increased patient comfort. The technique is well tolerated by patients with almost none of the post-operative discomfort typical of groin incision and rapid return to normal activities\(^{(43)}\).

A graduated marker pig-tail catheter (4-5Fr - 110 cm long) is introduced via the contralateral femoral site through a small introducer (4-5Fr – 11 cm long). The stent-graft device is then advanced over a stiff guidewire in order to have enough support throughout the femoral and iliac systems. Through the pig-tail catheter, several automated injections of contrast media are performed to correctly evaluate the morphology of the aorta. Then the device is advanced up to the desired position using fluoroscopy.

If the stent-graft is deployed at the level of the aortic arch, the final aortogram should be performed with the device in its final position because the presence of a large and stiff device can modify a shift the arch morphology. During the entire procedure, it is important to insure that the blood pressure never exceeds 100 mmHg to avoid stent-graft misplacement.

Technical Aspects

*Landing Zone:* Thoracic aortic repair by endovascular stent-graft placement requires suitable proximal and distal landing zones for stable fixation and complete sealing of the endoprosthesis to the aortic wall. As the majority of the proximal fixation targets will be adjacent or within the aortic arch, this can be considered the Achilles’ heel of TEVAR. The reasons are multiple and related mainly to the anatomy. In terms of endograft conformation to the underlying aortic wall, the arch is geometrically challenging and it contains critical branches. The knuckle of the arch refers to the area of the distal arch where the descending aorta takes its origin. This point represents a potential problem spot because presently available devices are unable to conform to such abruptly angled geometry, especially along the lesser curve and/or a lack of fixation in this area can lead to a fatal disaster.

A problem arises when there is a short distance (<20 mm) between the origin of the left subclavian artery (LSA) and an adjacent distal arch aneurysm or the primary entry tear of a type B dissection. Several options have been proposed to overcome this problem such as, prophylactic transposition of the LSA to the left common carotid artery (LCCA) or creation of a by-pass graft between the left LCCA and LSA in order to provide sufficient blood flow to the arm\(^{(44)}\).
Intentional occlusion of the LSA by thoracic stent-graft represents a valid alternative to the surgical procedures, especially in those patients with critical or emergent clinical conditions. In this case if symptoms, ischemic or neurological, develop, subsequent surgical revascularization of the LSA can be easily performed. Total arch debranching is also possible, but it requires the need for a sternotomy with ascending aorta-based bypass grafts to all of the arch branches, followed by retrograde or antegrade endograft placement across the entire arch. Alternatively, there are no easy management strategies to deal with a short distal neck above the celiac trunk. Intentional coverage of the celiac is not an innocuous procedure even in cases a coexisting normal superior mesenteric artery capable of supporting an apparently normal network of collateral flow.

Some authors report that pre-treatment embolization of the celiac trunk is a reasonably safe alternative to create a longer landing zone at the level of the superior mesenteric artery (SMA). However, an accurate pre-treatment evaluation is mandatory to evaluate the collateral flow at the level of the gastro-duodenal artery. In these cases, to guarantee patency of the SMA, a 4-5 Fr angiographic catheter is frequently placed within the SMA to serve as a reference marker during the thoracic device deployment.

Device insertion: Patients undergoing TEVAR often have concomitant peripheral vascular disease involving the femoral and iliac arteries. Because the currently available devices employ relatively large delivery systems, their insertion can be challenging. Several techniques have been described to facilitate safe introduction of these device. If a focal iliac lesion exists, a simple method to increase arterial caliber is to perform a PTA of the stenotic segment. However, dilation should be done very carefully, especially when the artery is calcified.

In cases where the femoral arteries are too small or where disease exists at the level of the external iliac arteries, the stent-graft device can be inserted through a common iliac artery exposed via a right or left lower-quadrant oblique incision. The device can be inserted either after direct arteriotomy or alternatively, after anastomosing a vascular graft to the common iliac artery and creating a temporary conduit. Alternatively, a right brachial approach can be used to insert the device if no other peripheral access is available, but this approach may be associated correlated with neurological complications related to crossing the origin of the innominate trunk. A rare, but possible access that may be required in very unusual conditions is the common carotid artery.

Generally speaking, the right side provides a better angle for the insertion and delivery of the stent-graft device. It is advisable however to perform an accurate evaluation of the intracranial circulation to confirm the presence of adequate collateral flow via the anterior or posterior communicating arteries to avoid cerebral ischemia. Alternatively, the most direct approach for device introduction is to insert the delivery system via the abdominal aorta.

Stent-graft dilation: In cases of aortic aneurysm, gentle dilation of the stent-graft is performed at the level of the proximal and distal attachment sites to secure optimal wall apposition of the stent-graft. Dilation should be performed in a particular way with a rapid deflation of the balloon because balloon expansion is similar to aortic clamping and provokes a marked increase in blood pressure. Stent-graft dilation should be avoided in cases of dissection. A stent-graft’s radial force is generally sufficient to obtain good aortic wall apposition and expansion of the true lumen. In fact, in these cases dilation may be associated with a progression of the dissection or rupture of the intimal flap. When more than one stent-graft device is implanted, dilation of the overlap zone between pieces is mandatory to insure circumferential sealing between the different elements.
Stent-Graft Selection

Selection of the stent-graft (type, diameter and length) is performed before the procedure after accurate analysis of the diagnostic images.

The correct selection of the right diameter of the stent-graft can be difficult in dissection cases because the true lumen is only a fraction of the overall transaortic diameter and rarely cylindrical in shape. Thus, several measurements should be performed along the dissected aorta with a special attention to the diameter of the non-dissected aorta immediately proximal to the entry tear. Stent-graft selection is based on the evaluation of the diameter of the healthy aorta just before the dissection. Treatment of acute aortic dissections should be performed with minimal (<2 mm) or no oversizing using the non-dissected mid aortic arch as the target segment for measurement. In cases of an aortic aneurysm, the stent-graft diameter is calculated on the basis of the proximal and distal neck diameters. In aneurysm cases, a device oversize factor, ranging between 20% to 30%, is applied to select the most correct diameter of the endoprosthesis and to ensure a secure anchoring and a tight circumferential seal.

In cases of aortic dissection, another critical factor to decide is the length of the aorta to cover in order to completely exclude the false lumen. Devices that are longer than the entry tear are often used with resultant rapid formation of thrombi within the false lumen over the length of the device. The total length of the implant however, must be weighed against the risk of spinal cord ischemia, which is increased with more extensive aortic coverage.

The complete exclusion of the aneurysm sac is based on the implantation of an endoprosthesis, at least 2 cm above and below the lesion. If more than one endoprosthesis is implanted, the overlap between two elements should be greater than 5 cm to avoid separation of the elements during the follow-up, especially in cases with very tortuous anatomy.

In the presence of a mismatch between the proximal and distal landing zone diameters that exceeds 4 mm, the procedure should be completed using either a tapered stent-graft or using two endoprostheses of different diameters. The small endoprosthesis should be deployed first, and the larger device should be inserted into the smaller to facilitate good sealing. Selection of the ideal endograft for a particular ease should be made on the basis of the morphological characteristics of the aorta in order to promote easy and accurate deployment, permanent fixation, and long durability.

Endograft parameters that should be considered when making the choice are: stent configuration, graft material, fixation mechanism, sizes, delivery system, tapered design, and radial force.

Currently, different stent-grafts are commercially available on the European market:
- Gore TAG (WL Gore & Associates, Flagstaff, AZ, USA)
- Valiant (Medtronic, Minneapolis, MN, USA)
- Zenith TX 2 (Cook Inc, Bloomington, IN, USA)
- Relay (Bolton Medical, Sunrise, FL, USA)
- EndoFit (LeMaitre Vascular, Burlington, MA, USA)
- E-vita (Jotec, Hechingen, Germany)

TAG: is formed from a nitinol stent skeleton lined by ePTFE (expanded-polytetrafluoroethylene) reinforced with a layer of ePTFE/fluorinated ethylene propylene (FEP). Both proximal and distal ends of the stent-graft have scalloped flares to facilitate conformity of the endograft to tortuous anatomy. A gold radiopaque marker at each end is located at the base of the
flares. The TAG stent-graft is released from its middle portion towards each end simultaneously to reduce the deployment time. This is very important to avoid stent-graft misplacement that can occur as a consequence of strong aortic flow forces that may distort and displace a partially deployed endograft. The stent-graft is inserted via an introducer sheath that ranges from 20 to 24 Fr in accordance with the stent-graft diameter. The TAG device is available in diameters ranging from 26 to 45 mm and in lengths of 10, 15 and 20 cm.

**Valiant**: represents the latest evolution of the Talent stent-graft. It is made of a nitinol stent covered by polyester fabric. To improve deployment accuracy and technical ease, the long connecting bar of the Talent device has been removed while columnar support has been optimised through stent spacing and the skeleton design. The proximal portion of the stent-graft is bare (free-flow) while the distal end is covered. The metallic structure is supported by different rings of nitinol Z-stents connected to the grafts material with multiple polypropylene sutures. Stent-graft diameters range from 22 to 46 mm with different lengths: 10, 15, 22 cm and with a delivery system of 22-25 Fr. The Valiant is available both in straight and tapered designs. The use of a special releasing system, Xcelerant technology, allows a deployment that is more precise, stable and easier than that of the old Talent, even in cases of severe angulation of the aortic arch.

**Zenith TX2**: is designed as a two-piece modular system with one proximal and one distal component; although the implantation of a single piece may be sufficient for focal lesions. It is composed of a stainless-steel Gianturco modified Z-stents covered with polyester (Dacron). At the ends of the endograft the stents are sewn inside the fabric, however in the mid-portion they lie outside it. This design promotes fabric apposition to the aortic wall and fabric to fabric interstent junctions. The proximal element presents a proximal bare end with protruding barbs with distal angulation to secure a better fixation to the aortic wall. The distal end of the proximal component is fully covered. The distal component presents a covered proximal portion and a distal bare stent with barbs.

Zenith endograft diameters range between 22 mm and 42 mm for the proximal component and from 28 mm to 42 mm for the distal element. Lengths range from 108 mm to 206 mm for the proximal element and from 127 mm to 207 mm for the distal one. The delivery system (20 Fr to 22 Fr) is covered with a hydrophilic coating and is very flexible. Recently, a new component was introduced on the market: the Zenith Dissection Endovascular Stent (TXD). It is a completely bare stent that is used to treat aortic dissection in conjunction with the TX2 proximal element in order to increase the true lumen diameter and reduce the risk of spinal cord ischemia.

**Relay**: is composed of a polyester vascular graft fabric supported by a Nitinol stent and a spiral Nitinol wire that provides longitudinal stability. The stent-graft provides different levels of radial force over its length in order to create optimal wall apposition: the higher radial force is applied at both ends, while in the middle portion the radial force is less. A bare stent (free-flow) is present at the proximal end of the endoprosthesis to better orient the angle of the proximal graft margin. The stent-graft is constrained within a flexible secondary sheath that is further constrained within an outer primary sheath. Once the device is advanced into the abdominal aorta, the secondary sheath is pushed out of the primary sheath. The flexibility of the secondary sheath allows an easier navigation into the aortic arch and reduces friction during stent-graft deployment. The delivery system ranges from 22 Fr to 26 Fr according to the diameter. The Relay is available both in straight and tapered designs, with diameters ranging from 22 mm to 46 mm and lengths up to 25 cm.
**EndoFit:** is composed of an encapsulated body with two layers of laminated expanded polytetrafluoroethylene graft with Nitinol Z-stent rings in between. Two different proximal end designs are available with or without a bare stent. The deployment system is based on a traditional pull-back mechanism consists of a 22 Fr to 24 Fr device. EndoFit graft diameters range from 34 mm to 42 mm with lengths up to 20 cm.

**E-vita:** is basically a Nitinol stent covered with polyester graft. An innovative release system for the graft provides full control and deployment accuracy even in cases with tortuous anatomy. Different proximal and distal configurations are available.
- The Straight Open design allows precise and safe positioning in the aortic arch.
- The Twin stent design features maximum radial force and an optimal sealing surface.
- The Straight Cut design features a circular distal terminus designed especially for type B dissections, whereas the Free Wire design allows a safe and secure anchoring mechanism while ensuring blood flow into the existing branch vessels.
Diameters range from 24 mm to 44 mm with varying lengths up to 23 cm. The size of the delivery system ranges from 20 Fr to 24 Fr.

**Follow-up**

As the procedure is still considered relatively “new”, the adoption of a general protocol for accurate follow-up is necessary in order to critically evaluate any post stent-graft evolution of aortic morphology and the structure of the device.

CTA is the current imaging method of choice because it provides all the critical information required to evaluate the aorta, its branches, the aneurysm sac morphology, and the presence of any endoleak. DSA is performed only in equivocal cases with ambiguous CT findings or when a complication occurs and conventional DSA is employed immediately prior to an endovascular reintervention.

A CTA follow-up exam is usually performed before the patient’s discharge (3 to 5 days after the procedure), after 6 to 12 months and thereafter, yearly. Overall, aortic size, flow in the true and false lumens, diameter of the two lumens, endoleak and characteristics of the stent-grafts are evaluated in each patient.

A post-implantation syndrome consisting of fever, mild leukocytosis and elevated C-reactive protein was reported by Won in 23 patients within ten days of stent-graft placement for thoracic aortic dissections or aneurysms\(^{(50)}\). The initiation of false lumen thrombosis by sealing the primary entry tear induces both consolidation of the false lumen and remodelling of the aortic wall. Aortic stability results from both thrombosis of the false lumen and the endoprosthesis itself. Aortic remodelling consists of an active component (expansion of the true lumen) and a passive component (thrombus retraction in the false lumen) and mimics a natural healing process because a thrombosed false lumen is associated with a lower risk for future adverse events and better survival, than a partially thrombosed or patent false channel.

**Left Subclavian Artery (LSA):** Typically, the use of commercially available stent-grafts requires a proximal neck length of at least 20 mm in the proximal descending aorta to achieve secure fixation and a tight seal between the graft and the aortic wall. If intentional occlusion of the LSA is planned to create a sufficiently long landing zone, an accurate pre-stenting evaluation of both vertebral arteries with duplex ultrasound, DSA, CTA or MRA is necessary to analyze their anatomy, patency and continuity with the basilar artery.
In addition, the potential for ischemia of the left arm after the procedure may be predicted before stent-graft deployment by performing a 20-minute test balloon occlusion of the proximal left subclavian artery. During the period of balloon occlusion, clinical monitoring of left arm symptoms is performed to assess the status of the collateral circulation. However, if there is documented normal flow in both vertebral arteries and intact anatomical connections to the basilar artery, a pre-interventional balloon occlusion test may be avoided.

Several papers document the safety of intentional occlusion of the LSA by an aortic stent-graft without prophylactic surgical transposition\((44,49)\). Alternatively, it is possible to limit any ischemic complication associated with LSA exclusion by adjunctive operative strategies of surgical transposition of LSA to the left common carotid artery or left common carotid artery to LSA surgical by-pass. These interventions must be performed prior to stent-graft coverage of the LSA in those patients with a documented incomplete circle of Willis that compromises collateral flow, critical stenosis of the vertebral arteries, anatomical variant of the right subclavian artery (lusorian subclavian artery), compromised collateral circulation to the left arm from variant anatomy such as an independent left vertebral artery origin from the arch or a previous aorto-coronary bypass performed with the left internal mammary artery.

Recently, a new strategy to manage the LSA has been introduced with the development of a branched stent-graft designed to maintain the normal antegrade flow into the LSA\((51,52)\).

**Complications**

Endovascular treatment of the thoracic aortic pathologies has been firmly established as a valid alternative to surgery. As this treatment becomes more and more widespread, procedural-related complications are more widely recognized, although the majority of these treatment-related problems can be managed with catheter-based interventions. Only critical conditions, such as stent-graft infection or migration, may ultimately require endograft removal followed by conventional open surgery repair.

**Spinal Cord Ischemia:** One major problem related to type-B dissection repair is spinal cord ischemia, especially after surgery\((23)\). The effect of endoluminal repair on the spinal cord is still uncertain but the absence of aortic clamping, which may cause left-sided heart failure and spinal cord ischemia, may reduce the incidence of paraplegia \((in many series it is less than 3\%)\) relative to open surgery\((17,57)\).

TEVAR is generally associated with 3% to 6% frequency of spinal cord ischemia secondary to the interruption of multiple branch vessels that provide spinal cord perfusion. Sacrificing critical intercostals can lead to immediate paraplegia but the multiple collateral pathways between the aorta and the spinal cord allow maintenance of good perfusion in many cases, even if some intercostals are sacrificed.

Factors that influence the development of spinal cord ischemia include prior abdominal aortic repair, length of thoracic aortic coverage, hypogastric artery interruption, subclavian artery coverage, emergency repair, and hypotension.

To reduce the risk of spinal cord ischemia during surgical procedures, several interventions have been suggested, such as, cerebrospinal fluid (CSF) drainage, intercostal artery reimplantation, maintenance of normotension and hypothermia.

CSF drainage via a lumbar drain can be easily performed and is used to maintain the pressure of the cerebrospinal fluid at \(\leq 15\) mmHg, in concert with keeping the mean arterial blood pressure at \(\geq 90\) mmHg. Initial results suggest this policy is applicable to patients treated with endovascular
therapy, particularly for patients who have undergone a previous abdominal aortic procedure or in whom a long stent-graft must be implanted.

Greipp reported that no single intercostal arterial pair at any vertebral level is absolutely necessary for spinal cord integrity. Moreover, he noted the risk of paraplegia increases if more than ten intercostal pairs are sacrificed\(^\text{53}\).

**Endoleak:** Endoleak represents the most common complication following the endovascular treatment of aortic pathologies with a rate ranging from 4% to 24%\(^\text{48}\). Leakage is classified according to the site of its origin at the proximal, distal or mid graft. Proximal or distal endoleak is due to incomplete fixation of the stent-graft to the aortic wall neck(s) (type I), while a leak at the mid-graft level is consequent to retrograde blood flow via an aortic branch (type II) or graft defects (type IV). Endoleaks can also originate from an incompetent overlap seal between stent-grafts (type III) when multiple devices are implanted\(^\text{40,41}\).

The prognosis for type I endoleak is generally poor and aggressive treatment is mandatory. Endovascular or surgical intervention is recommended when a type I endoleak is documented more than 2-4 weeks after stent-graft implantation. Type I endoleak at the level of the proximal neck represents a very dangerous event with continuous direct arterial pressurization of the false lumen. In these cases an immediate intervention is mandatory with the deployment of one or more endograft cuffs.

Type II endoleak is associated with residual blood flow into the aneurysmatic sac or the false lumen from patent intercostals arteries, bronchial arteries or patent LSA.

In cases of TAA, if no documented enlargement of the sac is observed, regular interval follow-up imaging surveillance is the most prudent course of action. In case of sac enlargement or persistent patency of the false lumen, percutaneous treatment with selective catheter embolization is suggested and easily performed.

Type III endoleak, secondary to the disconnection of different stent-graft elements, requires immediate treatment to avoid severe complications due to continuous flow within the aneurysm or the false lumen. In these cases, endovascular therapy can be performed with the insertion of a new endoprosthesis inside the previous ones. In more complex cases, surgical explantation is the best solution.

Type IV is related to the porosity or damage of the graft material.

**Retrograde Aortic Dissection:** represents a catastrophic sequelae more evident during treatment of type B dissection. This complication is associated with the use of an especially stiff device, especially in cases where there is a severe angle of the aortic arch. In fact, if insufficient support is provided by the guidewire during advancement, the device can be pushed against the greater curvature of the aortic arch, increasing the risk of wall damage.

Retrograde aortic dissection, involving the aortic arch and the ascending aorta, can also be caused by an endograft with excessive radial force that may cause an intimal tear within the proximal landing zone. Sometimes, the aggressive or inappropriate manipulation of catheters and wires can be responsible for a new intimal tear that facilitates a retrograde dissection.

Several studies have reported retrograde dissection involving the aortic arch and ascending aorta after stent-graft deployment\(^\text{54}\). In these cases, the new intimal tear can be managed either with deployment of an additional stent-graft over it or with surgery.
Neurological Injury: The etiology of intracranial injuries associated with endograft placement is multifactorial. Different authors indicate neurological complications secondary to LSA exclusion, as well as, stent-graft and wire manipulations at the level of the arch\(^{(55)}\). This condition seems to be more frequent in patients with atherosclerotic aneurysms. Moreover, Freezor reported that 56% of individuals with stroke during TEVAR had documented intraoperative hypotension with a systolic blood pressure less than 80 mmHg\(^{(55)}\).

Conclusions

Endovascular treatment of a variety of aortic pathologies is considered a valid alternative to open surgery with reduced rates of morbidity and mortality relative to conventional operative repair. This less-invasive method for treating these potentially catastrophic aortic lesions has created great enthusiasm however, careful and sound considerations regarding an individual patient’s anatomic suitability, clinical appropriateness as well as institutional experience should always be carefully judged.

An important debate regarding the long-term effectiveness of thoracic aortic stent-grafting is ongoing among researchers interested in defining the legitimate role of this therapy in the management of thoracic aortic pathologies.

As technology and available devices improve day by day, the number of patients undergoing endovascular repair will certainly increase. At the same time, it is anticipated that the limitations associated with this technology will decrease as delivery systems become smaller in size, and interventionists gain more experience determining optimal patient selection.
References


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