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Current options and recommendations for the use of thoracic endovascular aortic repair in acute and chronic thoracic aortic disease: an expert consensus document of the European Society for Cardiology (ESC) Working Group of Cardiovascular Surgery, the ESC Working Group on Aorta and Peripheral Vascular Diseases, the European Association of Percutaneous Cardiovascular Interventions (EAPCI) of the ESC and the European Association for Cardio-Thoracic Surgery (EACTS)

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Abstract

Since its clinical implementation in the late nineties, thoracic endovascular aortic repair (TEVAR) has become the standard treatment of several acute and chronic diseases of the thoracic aorta. While TEVAR has been embraced by many, this disruptive technology has also

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stimulated the continuing evolution of open surgery, which became even more important as late TEVAR failures do need open surgical correction justifying the need to unite both treatment options under one umbrella. This fact shows the importance of—in analogy to the heart team—aortic centre formation and centralization of care, which stimulates continuing development and improves outcome . The next frontier to be explored is the most proximal component of the aorta—the aortic root, in particular in acute type A aortic dissection—which remains the main challenge for the years to come. The aim of this document is to provide the reader with a synopsis of current evidence regarding the use or non-use of TEVAR in acute and chronic thoracic aortic disease, to share latest recommendations for a modified terminology and for reporting standards and finally to provide a glimpse into future developments.

Keywords: Expert consensus • Thoracic aortic endovascular repair • Aortic dissection • Intramural haematoma • Aortic aneurysm • Penetrating atherosclerotic ulcer

INTRODUCTION

Thoracic endovascular aortic repair (TEVAR) has become the standard treatment for several acute and chronic diseases of the thoracic aorta [1–3]. The aim of this document was to provide the reader with a synopsis of current evidence in acute and chronic thoracic aortic disease, to share the latest recommendations for a modified terminology and for reporting standards and finally to provide a glimpse into future developments in a field that mirrors the archetype of personalized medicine.

RECOMMENDATIONS FOR DEVELOPING A THORACIC ENDOVASCULAR AORTIC REPAIR PROGRAMME

Team approach

The same aortic team should be closely involved from diagnosis to treatment to follow-up. This team should include cardiac and/or vascular surgeons, as well as cardiologists, radiologists, anaesthesiologists, internal medicine specialists and, in selected cases, rheumatologists and geneticists [1, 4].

Availability 24/7

A key component of a successful programme is the availability of cardiac and vascular surgeons in their role as endovascular specialists on site to treat potential complications or to switch the surgical strategy if needed.

Intraoperative imaging

Intraprocedural imaging, including radiation protection for the physician and the patient, is important. Adequate imaging during the procedure is a key component of delivering reliable quality. Ideally, a hybrid room setting is available [5]. Radiation exposure should be minimized. Several measures to do so are available [6].

Aortic training and education perspective

There is growing evidence of a correlation between volume and outcome in aortic medicine [7].

Follow-up

Finally, the need for stringent surveillance of all patients either before they reach the criteria for treatment or after treatment cannot be overemphasized. One reason is quality control; another is the potential to develop aortic disease in non-treated upstream or downstream aortic segments. Magnetic resonance imaging can serve as a valuable adjunct or as a replacement for computed tomography angiography (CTA) under certain conditions.

INDICATIONS AND CONTRAINDICATIONS FOR THORACIC ENDOVASCULAR AORTIC REPAIR

Current recommendations for the treatment of thoracic aortic aneurysms have been formulated according to the available evidence [2, 3].

Type B aortic dissection

The use of TEVAR in acute complicated type B aortic dissection is established. The benefit of TEVAR in uncomplicated type B aortic dissection has been documented by the Investigation of Stent Grafts in Aortic Dissection (INSTEAD) XL trial [2, 8]. High-risk subgroups in uncomplicated acute type B aortic dissection have been defined by morphological features such as the location of the primary entry tear, the distance from the primary entry tear to the left subclavian artery (LSA), a primary entry tear of larger than 10 mm, false lumen diameters larger than 25 mm and, finally, initial total aortic diameters larger than 40 mm [9–12]. Figure 1 shows the recommended treatment algorithm for patients with acute type B aortic dissection.

Currently, the effect of TEVAR in patients with type B post-dissection aneurysmal formation is a theme of ongoing discussions. Condensed current evidence continues to favour open surgery in the majority [13]. Because there are no direct comparisons between methods, treatment recommendation remains a personalized one, taking patient-related, procedure-related and prognosis-related conditions into account [14].

Type non-A–non-B aortic dissection

Given the fundamentally different natural course of the disease process, whenever the aortic arch is affected, either by the location of the primary entry tear at the level of the aortic arch or by the retrograde extension of an intramural haematoma into the aortic arch from a primary type B aortic dissection, it should be classified as 'non-A–non-B aortic dissection' [4, 15, 16]. Figure 2 shows the different subtypes of aortic dissections.

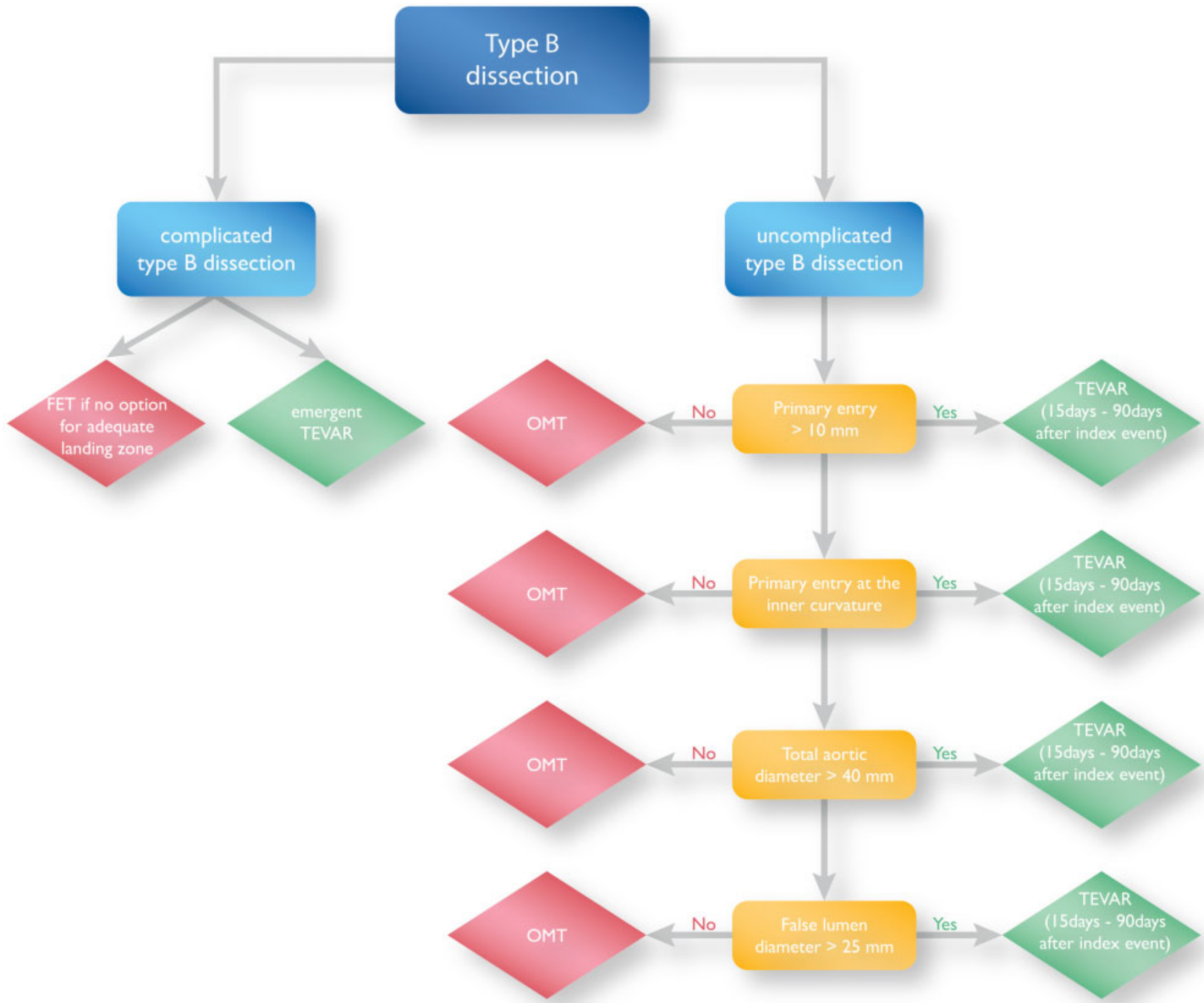

Figure 1: Treatment algorithm for patients with acute type B aortic dissection. FET: frozen elephant trunk; OMT: optimal medical therapy; TEVAR: thoracic endovascular aortic repair.

Intramural haematoma

The most important new knowledge is that many intramural haematomas (IMH) show intimal disruptions that can be visualized by advanced imaging techniques. Although tiny intimal disruptions, usually associated with artery branch ostia, have a good prognosis, focal intimal disruptions (>3 mm), also named ulcer-like projections, diagnosed in the acute phase, have a poor prognosis. However, those appearing in the subacute or chronic phase are more stable or evolve with slow aortic enlargement. The pathophysiological value is dependent mainly on the size and the developing phase [17]. These insights paved the way for a tear-oriented treatment approach [18, 19].

Penetrating atherosclerotic ulceration

Size and symptoms guide in indicating treatment. Although the diameter of the access vessels for retrograde stent graft delivery is usually not a limiting component in any other thoracic aortic disease, it can be challenging in patients with penetrating atherosclerotic ulceration (PAU) because they frequently have associated peripheral vascular disease [20]. It should be stated that the transition between PAU and IMH may be a smooth one, and many PAUs do have an IMH component whereas many IMHs at least show intimal disruptions. Despite the fact that PAU, compared to all other thoracic aortic diseases, is an obliterative disease by nature and all others are dilatative, the connection of the pathophysiological spectrum should always be kept in mind. Finally, long-term outcome is always dependent on concomitant cardiovascular disease, which is by far more pronounced in PAUs (as to the obliterative nature of the disease) compared to all other thoracic aortic diseases, which are rarely accompanied by obliterative arteriopathy, irrespective of segment or end organ [21]

Connective tissue disease

Patients with connective tissue disease are living longer due to better provision of treatment of all organ systems involved. Even more disorders (actin alpha 2, myosin heavy chain 11) are

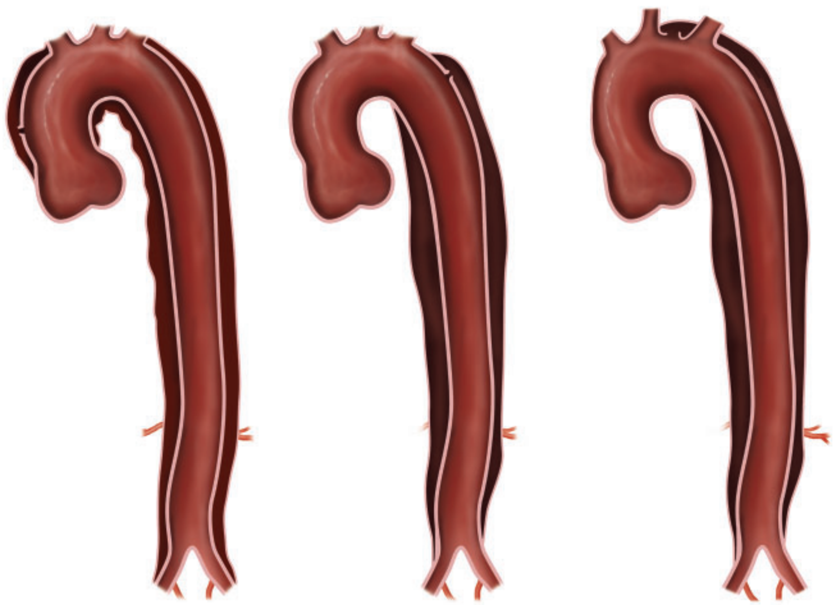

Figure 2: Aortic dissection types.

non-syndromic, and many remain unrecognized. Currently, open repair of thoraco-abdominal aneurysms is the gold standard in patients with genetic aortopathy [22]. At the time of this writing, TEVAR is not recommended for patients with genetic aortopathy except as a bail-out procedure or for patients with at least a proximal, alloplastic landing zone as well as in patients with thoracic segmental reattachment site aneurysms [23].

Traumatic aortic injury

TEVAR is regarded as the therapy of choice for traumatic aortic lesions, provided that the anatomy is suitable, which depends mainly on access vessel size in young patients, proximity to the LSA warranting left common carotid artery-LSA bypass in some patients and the fact that the majority of arches in this predominantly young patient group are type I aortic arches with small aortic diameters, which impacts the choice of device because of the potential for the known 'bird-beak' phenomenon on the inner curvature. The successful use of iliac extensions in very small aortas has been reported. Finally, when determining the size of the stent graft, the intravasal volume status should be taken into consideration [24, 25].

Contraindications for thoracic endovascular repair

Although infective aortic disease is a contraindication for TEVAR, it can serve as a bridge to decision in selected cases such as organ fistulas. [26].

The role of the frozen elephant trunk technique

The frozen elephant trunk (FET) technique combines a stent graft with a Dacron prosthesis for more extensive initial application of the FET technique in patients with complex anatomies that provides an ideal platform (landing zone) for secondary endovascular or open surgical distal extension [27]. Figure 3A and B shows the scheme for treating a thoracic aortic aneurysm where (Figure 3A) the FET technique is the first step and (Figure 3B) secondary TEVAR completes the exclusion of the aneurysm from the bloodstream.

TERMINOLOGY AND REPORTING STANDARDS

Because of the need to speak a common language, the STORAGE guidelines (STandards Of Reporting in open And endovascular aortic surGEry) and the European Association for Cardio-Thoracic Surgery/European Society for Vascular Surgery (EACTS/ESVS) expert consensus on the treatment of thoracic aortic diseases involving the aortic arch [4, 28] were recently published.

The EACTS/ESVS guidelines recommended the use of the Ishimaru zones as a reference for the extent of repair in both open and endovascular surgery [4] (Fig. 4). The frequently used term 'multiple entries and re-entries' should be avoided. The term 'communications between lumina' is preferred because the main focus is always on the primary entry tear, and the 'multiple entries and re-entries' term distracts from the main focus. With respect to the terminology related to the timing of the event, 'acute dissection' is defined as a dissection identified within 14 days of symptom onset, whereas 'subacute' and 'chronic' characterize events diagnosed between 15 and 90 days and thereafter, respectively [2, 4].

A new classification system for acute aortic dissection has been proposed—the TEM (type/entry location/malperfusion) system. The idea is analogous to that of the tumour/node/metastasis system in oncology. In the TEM system, 'type' refers to either type A, type B or type non-A–non-B aortic dissection; 'entry location' refers to E0 (no entry visible), E1 (entry located in the aortic root or in the ascending aorta), E2 (entry located within the aortic

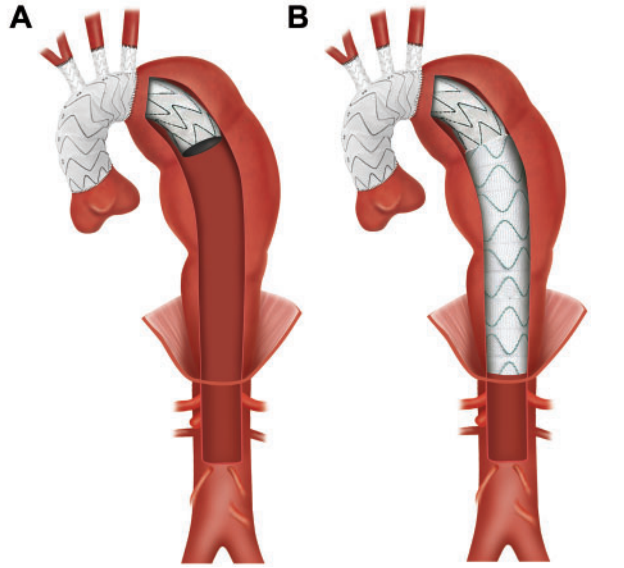

Figure 3: Thoracic aortic aneurysm starting at the level of the left subclavian artery and extending down to the thoraco-abdominal transition (**A**) treated initially by frozen elephant trunk and (**B**) completed secondarily by thoracic endovascular aortic repair.

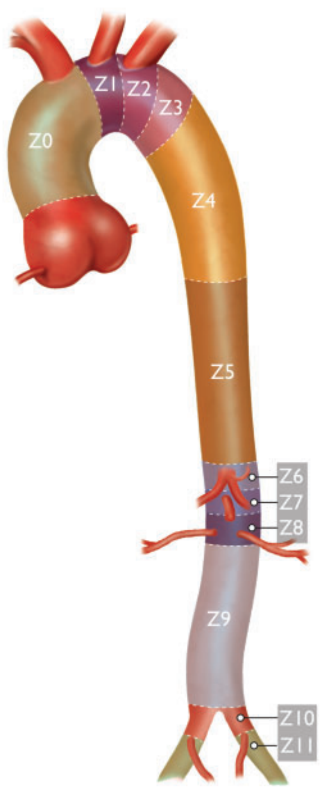

Figure 4: Ishimaru aortic zones. Z: zone.

arch) or E3 (entry located in the descending aorta); 'malperfusion' refers to M0 (no malperfusion) or M1 (malperfusion related to coronary arteries), M2 (malperfusion related to the supra-aortic vessels) or M3 (malperfusion related to visceral/renal/limb malperfusion or a combination of these) with a further categorization in 'M-', irrespective of segment, for patients without clinical signs of malperfusion but, e.g. true lumen collapse and 'M+' for those

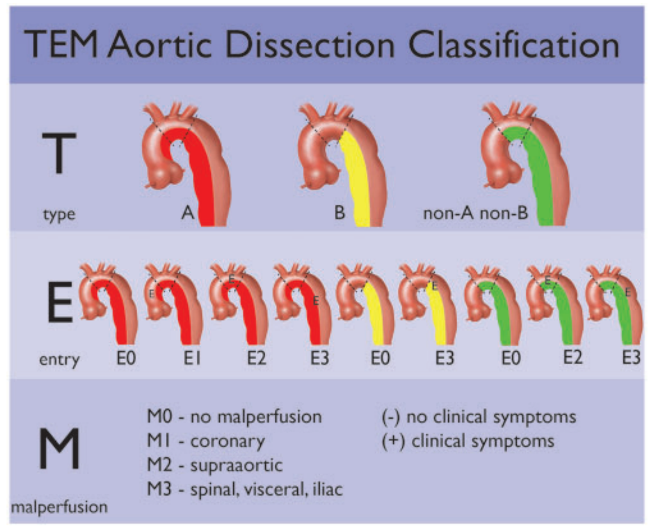

Figure 5: TEM aortic dissection classification system. TEM: type/entry location/malperfusion.

with additional clinical signs of malperfusion in the respective segment (Fig. 5) [29].

Several proposals have recently been made for modifying currently used classification systems where each of them has its value but for one reason or another is either too complex for the acute scenario like the DISSECT classification or misses important details such as the newly proposed STS classification [30, 31]. Recently, investigators from the International Registry of Acute Aortic Dissections suggested a differentiation between arch A and arch B groups in patients who had a primary entry tear in the aortic arch based on the type of propagation (retro-A or antegrade-B), which supports this writing committee's recommendation to regard the latter (arch B group) as a separate entity [32].

LANDING ZONE PREREQUISITES AND EXTENSIONS, COMBINED PROCEDURES

Adequate landing zone length is a prerequisite for success [1–4]. Proximal and distal landing zones of at least 2.5 cm each are considered adequate. Overlap between prostheses (in case 2 or more stent grafts are needed) should be at least 5 cm.

The need for landing zone extensions to reach the required 2.5 cm length is frequent. The left common carotid to subclavian artery bypass prior to TEVAR is an excellent method for creating a sufficient proximal landing zone. In patients in whom the proximal landing zone remains inadequate, the concept of double-vessel transposition (left common carotid artery and LSA) should be considered. Total aortic arch rerouting, defined as transposition of all 3 head and neck vessels, is not routinely recommended due to a high incidence of retrograde type A aortic dissection [1–4]. In patients with such complex pathologies, the FET procedure is preferred. Any kind of parallel graft (chimneys, periscopes and snorkels) is not recommended routinely because of poor long-term outcome.

Distal landing zone extensions by open surgery are rarely performed because these are major operations with questionable efficacy; fenestrated and branched endografts are clearly preferred treatment options if technically feasible. Finally, open thoraco-abdominal replacement remains an excellent method.

HOW TO PLAN THE PROCEDURE

CTA studies are critical. The patency of the circle of Willis should be evaluated in patients in whom the proximal landing zone is intended to be in zones 0–2 and is not mandatory when zone 3 or further downstream zones are targeted. CTA should extend to the level of the common femoral arteries to allow visualization of the underlying aortic disease, to estimate aortic wall quality and to assess parietal thrombus load (and thereby risk of detachment and embolization during wire manipulation). This procedure is completed by evaluating the coronary status to rule out associated coronary artery disease using echocardiography and duplex ultrasound scanning of the supra-aortic vessels [4]. These recommendations refer to the elective setting in which, in acute aortic syndromes requiring immediate treatment, further diagnostics are usually omitted.

The choice of the prosthesis is based on the anatomy and the design of its proximal configuration. Non-bare stent designs have become popular [33]. Angulation-corrected images on CTA form the basis for the determination of the prosthetic diameter required. The length of the prosthesis is estimated based on measurements of the outer curvature of the respective aortic segment whereas the length of the landing zone is always measured at the inner curvature. The sizes of the delivery sheath for TEVAR prostheses range between 18 and 25 Fr, corresponding to a minimum vessel diameter required at the level of the common femoral/external iliac arteries of 6 mm.

As a general principle, the more proximal a stent graft is deployed, the more accurate the deployment mechanism of the device and the deployment technique should be. This goal is best achieved by a tip capture in combination with profound arterial hypotension that can be achieved by rapid pacing via a temporary right ventricular pacemaker wire or venous inflow occlusion or pharmacologically by adenosine [34].

CURRENT TECHNIQUES FOR ENDOVASCULAR REPAIR OF ANEURYSMS AND DISSECTIONS

Stent grafts have been developed for thoracic aortic aneurysms. Dissection-specific devices are warranted because this underlying disease has unique components.

The fact that the distal end of the prosthesis in aortic dissection lands in dissected tissue is a great challenge. The broad availability of tapered stent grafts has led to a substantial improvement in the reduction in distal stent graft-induced new entries (dSINE) and to better conformability to the disease process.

Finally, the dynamic dissection process evolves gradually over time to a chronic aneurysm-like state. It remains unpredictable when the membrane is stiffened to an extent for which TEVAR has no more effect on positive remodelling and open surgical strategy is indicated. Several surrogates for positive remodelling are available [12].

ACCESS VESSEL OPTIONS

Common femoral artery surgical cut-down has traditionally been the standard access for TEVAR. Recently, fully percutaneous access with preclosure strategies—analogous to those used in transcatheter aortic valve implantation—has entered the arena and is now frequently used. In case of inadequate vessel diameters, the option to get access via the common iliac artery, via the infrarenal aorta or, in highly selected cases, via the apex of the left ventricle should be considered [4].

INTRAOPERATIVE MANAGEMENT AND DEFINITION OF TREATMENT SUCCESS AND OF ENDOLEAKS AND AORTIC REMODELLING

Standard monitoring during TEVAR should be performed using unilateral invasive arterial blood pressure measurement by any adequate means for inducing profound arterial hypotension [4].

Treatment success is defined as the absence of type IA, type IB and type III endoleaks. Table 1 provides an overview of the current definitions of endoleaks. Persisting or newly developing type II endoleaks are not associated with worse outcomes and do not require specific treatment in the absence of aortic diameter increase. Type IV and type V endoleaks are merely historical and have not been observed with newer generation devices.

However, the current definitions of endoleaks for aortic dissection need modification [35]. The type IB endoleak definition needs clarification: According to current standards of reporting, each type B aortic dissection after TEVAR has a type IB endoleak. However, this is not the case nor does the definition *per se* address the pathophysiology in an adequate manner. Retrograde false lumen perfusion should be addressed descriptively to the level of the contrast medium detectable such as 'retrograde false lumen perfusion to the level of the distal end of the stent graft'. Endoleaks due to retrograde flow via the LSA (e.g. after overstenting, which should remain the exception) present an issue of ongoing discussion but should be named type II.

A frequently used term to describe the morphological changes after TEVAR is 'aortic remodelling'. Analogous to 'left ventricular remodelling, the term would describe an unfavourable course. In aortic medicine, however, the term has a positive connotation, which makes sense and is supported by this writing committee but with the suffix 'positive' or 'negative', referring to diameter decrease (positive) or increase (negative), respectively.

TECHNIQUES FOR NON-SURGICAL SIDE-BRANCH ACCESS AND MEMBRANE STABILIZATION

Within the aortic arch, branched (2 branches) endovascular repair has been established with good mid-term results [4]. Single-branch devices also are already available for the brachiocephalic trunk (BCT) and are currently being evaluated in clinical trials involving the LSA [36–38].

This approach has also gained popularity in the thoraco-abdominal segment. In dissections, true and false lumen vessel offspring play a major role during the planning process. It should be stated that false lumen major side-branch offspring does not primarily exclude these patients from a fenestrated approach. Because these approaches are primarily meant for patients with a chronic condition, it may be necessary to enhance membrane stabilization in the acute setting on top of TEVAR, e.g. a patient has acute complicated type B aortic dissection with true lumen collapse at the level of the visceral arteries and radiological as well as clinical signs of malperfusion (according to the new classification types B, E3 and M3+) and TEVAR does not reverse true lumen collapse, then implantation of a non-covered stent will

Table 1: Endoleak types

Type I: persisting or recurring reperfusion of lesion[a] IA—from proximal IB—from distal
Type II: persisting or recurring perfusion of lesion[a] by thoracic segmental arteries or by the left subclavian artery IIA—single vessel IIB—more than 1 vessel
Type III: persisting or recurring perfusion of lesion[a] by IIIA—separation of modular components (i.e. 2 or more endografts) or IIIB—by fabric defect
Type IV (now historical): graft porosity (not seen after the first endograft generation)
Type V (now historical): endotension (not seen after the first endograft generation)

[a]Lesion comprises aneurysm, penetrating atherosclerotic ulceration, dissection, intramural haematomas and pseudoaneurysm.

serve well. This approach is also known as the PETTICOAT concept (Provisional Extension To Induce Complete Attachment Technique) [39]. PETTICOAT offers good short- and mid-term results. To fully eliminate false lumen perfusion, more aggressive approaches to create a single-channel aorta for the prevention of aneurysm formation in the subacute setting (STABILISE) have been suggested [40]. The presented short-term results are good. However, further evidence is needed to support the concept on a broader basis or to put it into perspective.

BRAIN AND SPINAL CORD ISCHAEMIA AND ITS PREVENTION

The incidence of procedure-induced stroke after TEVAR varies [1–4]. The underlying disease seems to be a major driver of the process, which is why a critical assessment by CTA is so important. This assessment frequently leads to a change in strategy because open surgery with peripheral cannulation for cardiopulmonary bypass, systemic cooling and touching the diseased tissue solely during the phase of lower body hypothermic circulatory arrest might be a better option than endografting [27]. The risk of air embolization appears to be related to the type of device used, but most of the remaining air can be removed either by extensive saline or CO_2 flushing [41].

Preserving major side-branch inflow is extremely important. The 'four-stage concept' aids in anticipating the remaining risk of symptomatic spinal cord injury (SCI) [42]. The principle lies in the fact that the spinal cord has 4 major inflow sources, namely the subclavian/vertebral arteries forming the anterior spinal artery, the thoracic segmental arteries, the lumbar segmental arteries and finally the hypogastric arteries. If 1 major source is lost (e.g. by TEVAR), this circumstance alone is less likely to cause symptomatic SCI. However, if 2 major inflow sources are occluded simultaneously (e.g. TEVAR and LSA overstenting without prior revascularization), the risk substantially increases. Importantly, prior infrarenal aortic replacement and infrarenal endovascular aortic repair do not increase the risk of SCI.

Current evidence also supports the routine use of cerebral spinal fluid drainage to prevent SCI [5] in the majority of patients in whom the mechanism can best be described as 'fasciotomy of the spinal cord'. However, insertion of cerebral spinal fluid is a prophylactic step that is not without risk. Should symptomatic SCI still occur after TEVAR, the measures to be taken include elevating the arterial blood pressure, assuring an adequate haemoglobin level, preventing supraventricular arrhythmias and applying prednisone systemically [5]. Intraoperative monitoring of motor-evoked and/or somatosensory-evoked potentials is a useful adjunct for immediate diagnosis of SCI and should be used.

Recently, the Minimally Invasive Segmental Artery Coil Embolization concept, designed to precondition the spinal cord to ischaemic injury, has gained popularity. Initial results have been very promising [43–45]. A large prospective randomized trial is currently recruiting patients to explore the effect of this approach [46].

STENT GRAFT-RELATED COMPLICATIONS AND RARE COMPLICATIONS AFTER THORACIC ENDOVASCULAR AORTIC REPAIR

Endoleaks, bird-beak phenomena (detachment of the prosthesis from the aortic wall at the inner curvature of the aortic arch), side-branch occlusion, dSINE or retrograde type A dissection (RTAD) should be mentioned [33, 47]. Both dSINE and RTAD share pathophysiological components. RTAD is more dangerous than dSINE and requires open surgical repair, which is very similar to classical type A aortic dissection. The reported incidence of dSINE is higher than that of RTAD, and it is usually treated via an endovascular approach. Organ fistulation is a rare complication after TEVAR and is more frequently seen after acute aortic syndromes and more closely related to the underlying disease than to the stent graft [48]. The only durable approach to curing the disease is a radical one with orthotopic aortic reconstruction, preferentially with biological material such as neoaorta from bovine pericardium [49].

PENDING QUESTIONS

The underlying thoracic aortic disease process is progressive and, despite good initial results with endografting, long-term failures occur that warrant open surgery for final correction. Conversely, in some situations, endografting is a useful tool for treating surgical failures. Therefore, when discussing the best approach, the long-term durability of TEVAR versus surgery is a major factor that should be considered together with other factors.

SYNOPSIS AND OUTLOOK

TEVAR has broadened our armamentarium for treating acute and chronic thoracic aortic diseases and has developed as the strategy of first choice for many of them. A better understanding of the natural course of the disease and of the importance of applying the right strategies in the right patients has impressively contributed to improve outcomes. Finally, aortic centres and the aortic team, which is analogous to the heart team and encompasses the entire spectrum of treatment options under one umbrella, will be instrumental in moving aortic medicine to the next level (Table 2).

Table 2: Ten points summarizing current options and recommendations for the use of TEVAR in acute and chronic thoracic aortic disease

• Aortic medicine is the archetype of personalized medicine
• Centralization of aortic care is needed; 24/7 service provision is a prerequisite
• Visualization and understanding of the aortic disease process are key: treatment should be planned on that basis
• TEVAR and open surgery should be regarded as complementary rather than competing
• New classification systems (such as TEM) add clarity, allow risk assessment and help in planning treatment
• Having adequate landing zones and respecting anatomy are the prerequisites for long-term success in TEVAR
• The FET procedure provides an excellent platform for downstream endovascular or open repair
• Neurological complications remain an issue, and every effort must be made to keep them to a minimum
• Type I and type III endoleaks have to be seen as treatment failures and have to be corrected
• Aortic outpatient clinics are mandatory for long-term surveillance

FET: frozen elephant trunk; TEM: type/entry location/malperfusion; TEVAR: thoracic endovascular aortic repair.

Conflict of interest: Martin Czerny: Consultant for Terumo Aortic, Medtronic and Cryolife, speaking fees from Bentley, shareholder of TEVAR Ltd. Bartosz Rylski: Consultant for Terumo Aortic. Eugenio Stabile: Consultant for Cardionovum.

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