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Thoracic Endovascular Aortic Repair (TEVAR) for the treatment of aortic diseases: a position statement from the European Association for Cardio-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC), in collaboration with the European Association of Percutaneous Cardiovascular Interventions (EAPCI)†

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PREAMBLE

Thoracic endovascular aortic repair (TEVAR) is an emerging treatment modality, which has been rapidly embraced by clinicians treating thoracic aortic disease [1–4]. Fundamentally, it is a far less invasive approach than open surgery and its availability and relative ease of application has changed and extended management options in thoracic aortic disease, including in those patients deemed unfit or unsuitable for open surgery. In the operating room, this requires considerable perceptual, cognitive and psychomotor demands on the operators.

The dramatic expansion of TEVAR activity has necessarily prompted a requirement to systematically consider the indications, appropriateness, limitations and delivery of this treatment, which has been adopted by many specialties including cardiologists, cardiovascular surgeons, radiologists and vascular surgeons [5]. Our task has been to generate a multidisciplinary position statement that supports and advises all clinicians utilizing this technological advance. This document focuses on the main diagnoses—thoracic aortic aneurysm (TAA), thoracic aortic dissection (TAD) of the descending aorta (type B according to the Stanford classification) and thoracic aortic injury (TAI)—indications and applicability of TEVAR and includes information regarding its limitations and complications. It acts as a position statement for both societies that reflects current understanding of thoracic aortic endovascular therapy.

† This joint statement, which represents the views of the EACTS and the ESC, was arrived at after careful consideration of the available evidence at the time it was written. Health professionals are encouraged to take the joint statement fully into account when exercising their clinical judgement. The joint statement does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patients, in consultation with that patient, and where appropriate and necessary the patient's guardian or carer. It is also the health professional's responsibility to verify the rules and regulations applicable to drugs and devices at the time of prescription.

RECOMMENDATIONS FOR THE DEVELOPMENT OF A TEVAR PROGRAMME

Evaluation of symptoms and patient status

Symptoms in patients with TAA and chronic dissection are rare and non-specific [6, 7]. New onset of hoarseness or dysphagia may suggest a developing aneurysm in the distal aortic arch and proximal descending aorta. Most asymptomatic cases are discovered incidentally, while symptomatic patients have usually developed complications. Even in patients with acute aortic syndromes, chest pain, back pain and signs of malperfusion are often misinterpreted due to lack of awareness. In cases of clinical suspicion, a computed tomography (CT)-angiography is the diagnostic modality of first choice.

Multidisciplinary consultation

Patient selection should be performed on an individual basis according to anatomy, pathology, comorbidity and anticipated durability of any repair, using a multidisciplinary approach, ideally in an aortic centre. This concept offers the widest available opinion, an appropriate range of technical options and adequate infrastructure for endovascular therapy of thoracic aortic disease. The involvement of different specialties allows combining the best experience and expertise in medical, interventional and surgical therapy for tailoring an optimal treatment strategy for the individual patient.

Preoperative imaging

CT angiography (CTA) is the method of choice for diagnosis and planning treatment [8]. Magnetic resonance imaging (MRI) is not widely used in the acute setting, but may be useful in chronic disease and during follow-up [9]. Conventional angiography is no longer recommended as a routine diagnostic procedure. Positron emission tomography in combination with CTA may be used as an adjunct in specific situations (detection of signs of inflammation) but is not recommended for routine use [10, 11].

Intraprocedural imaging

High-quality imaging and appropriate facilities for open surgery during the endovascular procedure are of the utmost importance. Purpose-built, hybrid operating and imaging suites appear to be the optimal solution [12]. Transoesophageal echocardiography (TEE) is recommended as an adjunctive intraoperative imaging technique in complex aortic pathologies such as aortic dissection [13–15]. Intravascular ultrasound and phased-array intracardiac ultrasound could be useful as well in cases of dissection [16, 17].

Postprocedural imaging

CTA prior to discharge is advised to delineate complications undetected during the initial endovascular procedure and to form a reference for follow-up studies. To avoid radiation MRI may be more widely used in the future [8], but it lacks the visualization of metallic stent struts and is not compatible with stainless steel endografts [18].

Risk evaluation

To date, no TEVAR-specific risk stratification tool is available. Clearly, an individual risk stratification tool is required to predict endovascular outcomes and it will be the task of such working groups to establish a suitable tool in the near future. Until such risk stratification tools are available, individual patient's decisions will be made on the traditional basis of risk–benefit analysis [19].

Adjunctive diagnostic modalities

It is recommended that a transthoracic echocardiogram be performed as part of the diagnostic work-up in the elective setting in order to exclude valvular and structural heart disease. Further imaging should include a duplex ultrasound of the supraaortic vessels. A stress test to exclude coronary artery disease is not necessary in asymptomatic patients [20, 21]. Cardiac catheterization is suggested in patients with proven signs and symptoms of ischaemia or suspicion of coronary artery disease.

Planning of TEVAR–TAA

A sufficient proximal and distal landing zone of at least 2 cm is necessary for the safe deployment and durable fixation of TEVAR [22, 23]. If landing zones are shorter or significantly angulated, prior transposition or bypass surgery/re-routing of the involved aortic branch may be considered. Evaluation of access vessels (sizing, calcification, tortuosity) is of major importance. An access vessel of at least 8 mm in diameter is necessary for a standard 24 French delivery device. Alternative access sites are the iliac arteries, the infrarenal aorta or even the ascending aorta.

Planning of TEVAR–type B TAD

Planning of TEVAR includes clinical examination, laboratory tests and imaging to classify the type of dissection (classical dissection, intramural haematoma (IMH), penetrating atherosclerotic ulcer, traumatic dissection), its duration and potential complications. Localization of all tears, with emphasis on identifying the primary entry tear, is important. The next step is to define the extension of dissection and possible static, dynamic or complex involvement of supraaortic, visceral and pelvic vessels resulting in malperfusion [8]. Perfusion of side branch vessels through the false lumen does not automatically exclude patients from TEVAR, as a distal communication is often present or the visceral vessel may receive a contribution from both lumina.

INDICATIONS AND CONTRAINDICATIONS FOR TEVAR

TEVAR for TAA

In asymptomatic TAA patients TEVAR is indicated (by consensus) when the maximum diameter of the aneurysm exceeds 5.5 cm

or if rapid expansion (>5 mm in 6 months) occurs [24, 25]. In certain morphologic situations which are considered prone to rupture, e.g. saccular aneurysms, TEVAR may be justified at a diameter of less the above referenced 5.5 cm. Comorbidities and age of the patient have to be considered [26], and it may be appropriate to set a larger aortic diameter threshold in patients with increased operative risk.

TEVAR for type B aortic dissection

TEVAR is the treatment modality of choice in complicated acute type B aortic dissections [3, 27–29]. The term 'complicated' means persisting or recurrent pain, uncontrolled hypertension despite full medication, early aortic expansion, malperfusion and signs of rupture (haematothorax, increasing periaortic and mediastinal haematoma) [28]. Further subgroups benefiting from immediate TEVAR are being defined. In an uncomplicated type B dissection, a primary conservative approach with close surveillance seems to be justified until complications arise [30]. The treatment of aneurysms on the basis of chronic type B dissections should be discussed in a multidisciplinary team approach, considering TEVAR versus open surgery [31].

In cases of penetrating aortic ulcer, treatment may be recommended, when patients are symptomatic, or the ulcer demonstrates expansion and IMH [32]. In patients with IMH, intimal lesions/laceration can often be found in the inner curvature of the aortic arch by careful CTA analysis. This may be an aim for stent-graft implantation in patients with a progressive/complicated IMH [32].

TEVAR for traumatic aortic injury

Immediate endovascular treatment is indicated in patients with complete transsection of the aortic wall and free bleeding into the mediastinum or pseudocoarctation syndrome, whereas delayed treatment can be suggested when limited disruption of the aorta is present but media and adventitia are intact [33–35].

Connective tissue disease

TEVAR is not recommended in patients with connective tissue disease except as a bail-out procedure or bridge to definitive open surgical therapy, or as a procedure following prior aortic repair when both landing zones lie within previously sited prosthetic grafts (e.g. intercostal patch aneurysm after Marfan's TAA repair) [36, 37].

ENDOLEAKS

Definition of endoleak after TEVAR for TAA

Type I (proximal and/or distal reperfusion of the aneurysmal sac) and type III endoleaks (endograft/endograft disconnection leaks) are regarded as treatment failures and warrant further treatment to prevent the continuing risk of rupture [38]. Type II endoleaks (retrograde perfusion via branch vessels) are managed primarily conservatively by a 'wait and watch' strategy to detect aneurysmal expansion, except for supraaortic arteries. In these patients coil embolization, plug occlusion or surgical ligation should be performed during or early after the TEVAR procedure. Type IV (endograft porosity) and type V (endotension) endoleaks are historical phenomena and are no longer observed with more recent technology [39].

Definition of endoleak after TEVAR for TAD

The only important types of endoleaks in TAD are type Ia (antegrade perfusion of the false lumen) and type II (perfusion of the false lumen via the overstented left subclavian artery). Retrograde flow from distal entry tears must not be considered as endoleaks.

DEFINITION OF TREATMENT SUCCESS

TAA

Procedural 'technical' success is achieved when the endograft is deployed accurately and the aneurysm is excluded from the circulation (i.e. absence of type I or III endoleak). Evaluation of clinical success requires follow-up examinations of the patient demonstrating complete thrombosis and shrinkage of the aneurysm sac, and in the absence of complications.

TAD

Procedural 'technical' success is defined as closure of the primary entry tear (i.e. absence of type Ia endoleak) and induction of false lumen thrombosis. The aim of endovascular treatment is to overcome or resolve complications of aortic dissection including malperfusion, imminent rupture and bleeding. This does not imply complete immediate thrombosis of the false lumen, as further thrombosis and remodelling processes are a matter of time.

CURRENT TECHNIQUES FOR TAAS AND TADS

Available endovascular systems

It is beyond the scope of this statement to address all manufacturers as well as their advantages and drawbacks. The aim of this section is to briefly discuss the different concepts regarding design and mode of deployment. Regarding design, devices with or without proximal uncovered struts are available. The aim of proximal uncovered struts is to enhance proximal fixation of the prosthesis, and ensure adequate alignment of the endograft. However, adverse events potentially associated with bare stents including retrograde type A dissection have been reported [40, 41]. Whether these observations are causal or not remains undefined. In terms of deployment, there is a choice between devices with and without a tip-capture system [42, 43]. It would appear that the availability of a tip capture may increase safety, as blood pressure or anatomy-dependent migration or displacement of the prosthesis during deployment is reduced. A tip-capture system is recommended in patients, where proximal stent-graft deployment is needed (cranial ascending aorta, arch).

Specifics of TEVAR for TAA

Detailed attention has to be paid to the length of the landing zone, sufficient overlapping if more than one prosthesis is being

used, as well as angulation in the aorta and iliac arteries. The stent-graft diameter should exceed the diameter of the landing zones by at least 10–15% of the reference aortic diameter. Anatomic constraints in the infrarenal aorta or the thoracoabdominal transition with excessive tortuosity may lead to a loss of pushability and may preclude advancement of the prosthesis into the area of interest. These difficult situations may be overcome using, in addition to a superstiff guidewire, a second protected stiff buddy wire or a pull-through procedure via the brachial artery.

Specifics of TEVAR for TAD

The focus is the occlusion of the primary entry tear. The size of the selected stent graft should be based on the diameter of the aorta proximal to the dissected segment, applying almost no oversizing. The technical challenge, especially in complicated type B dissections, may be to cannulate the narrowed, sometimes collapsed true lumen. To assure access to the true lumen, TEE may often be necessary [44]. Procedure-related difficulties may be overcome by an antegrade approach via the brachial artery with the guidewire being snared in the aorta. After deployment, ballooning is not recommended, even if the stent graft is not fully expanded, because of the self-expanding nature of the stent and the time required for the remodelling process of the aorta. Retrograde dissection and rupture of the dissection membrane has been reported due to ballooning.

INTRAPROCEDURAL MONITORING AND BLOOD PRESSURE CONTROL

Invasive blood pressure monitoring is required on a routine basis. Cardiovascular anaesthesiologists trained in endovascular procedures are desirable. Pharmacological lowering of blood pressure <80 mmHg systolic during stent-graft deployment may be sufficient in many cases to avoid displacement of the device. If further blood pressure lowering is required in proximal aortic procedures, then rapid pacing is the method of choice [45].

VASCULAR ACCESS

Surgical cut-down is traditionally regarded as the safest way to fully control access vessels. Percutaneous approaches are increasingly used with a wide variety of techniques. At present, the diameter and calcification of the vessel represent major limitations of these devices [46]. Further reduction in the profile of stent-graft delivery device will expand the indication for percutaneous approaches.

COMBINED PROCEDURES

Combined surgical and endovascular techniques—so-called hybrid procedures—have become popularized during the last decade. Staged conventional surgical repair is associated with significant morbidity and mortality, due to the summation of possible complications between first operation, waiting period and second surgical intervention [47].

In principle, two different approaches to extensive disease of the aortic arch and proximal descending aorta were developed: First, the 'frozen elephant trunk' technique involves conventional surgical repair of the ascending aorta and the aortic arch combined with open antegrade stent grafting of the descending aorta in the period of circulatory arrest [48–50]. Second, re-routing of supraaortic branches by transposition or bypass enables endovascular treatment of the arch and proximal descending aorta without need for cardiopulmonary bypass and hypothermic circulatory arrest [23, 51]. Visceral and renal transpositions cannot be recommended as standard procedures for thoraco-abdominal aneurysms as the early results of these procedures have revealed high mortality rates [52]. Clearly, further larger series need to be awaited.

TECHNIQUES FOR NON-SURGICAL SIDE BRANCH ACCESS

Aortic pathologies involving major side branches are a complex challenge for endovascular repair. Implantation of a stent-graft may result in critical ischaemia and organ dysfunction. Recently, there has been increasing interest in the development of catheter-based non-surgical techniques to address this issue. Approaches include: (1) development of dedicated stent-graft prostheses with fenestrations or branches for direct side branch access, and (2) modification of readily available interventional techniques to establish extra-anatomic side branch perfusion (e.g. 'Chimney', 'Sandwich' technique etc.). All these techniques are still investigational as sufficient follow-up is not yet available; such procedures are not endorsed and should be limited to clinical trials in centres of excellence or with a particular interest until broader knowledge supports the technique [53].

PROCEDURE-RELATED COMPLICATIONS

Any vascular injury or vessel-associated injury (thrombosis, bleeding, retrograde type A dissection, stroke) during TEVAR and within 24 h, as well as cardiac complications (perforation of a superstiff guidewire, myocardial injury of any kind) should be reported as procedure-related [54].

STENT GRAFT RELATED COMPLICATIONS

The most significant complication is retrograde type A dissection [40, 41]. Associated factors may include radial force of uncovered struts, diagnosis of TAD, extensive oversizing and ballooning. Erosion of the oesophagus or the left main bronchus is an extremely rare complication and potentially more related to the underlying disease than to the stent graft [55, 56]. Finally, in TAD, membrane rupture at the distal end of the stent graft may occur. This rare event is likely to be related rather to the underlying disease, than to the size of the stent graft itself.

OUTCOME PARAMETERS

TEVAR for TAA

The main outcome parameters are survival and aortic-related survival [22, 57]. Other clinically significant outcome parameters

would include rate of persisting or newly developing endoleakage, freedom from reintervention or secondary surgical conversion. Summarizing the available literature, outcomes are encouraging, but seem to be predominantly determined by age and co-morbidities [22, 26, 58].

TEVAR for TAD

Measures of outcome are identical to those of TAA. However, additional information needs to encompass the fate of the distal aorta involved in the dissection. The closure rate of the primary entry tear and thrombosis of the false lumen of the stented segment of the thoracic aorta is high in most series, but needs to be reported in the long term [54]. It seems reasonable to accept continued perfusion of the false lumen in the abdomen distal from the stent-graft site as long as aortic dilatation does not occur [59, 60].

EVALUATION OF RESULTS

Follow-up after TEVAR

Lifelong clinical and morphological surveillance is mandatory after TEVAR as late treatment failure may develop even years after the initial treatment [61]. Currently CTA is recommended prior to discharge. Further follow-ups at 6 and 12 months is based on CTA, thereafter MRI/CTA in addition to annual clinical follow-up should be implemented. The imaging algorithm in case of detectable endoleaks cannot be generalized and remains according to the individual discretion of the treating physician.

PENDING QUESTIONS

Malperfusion

TEVAR has proved to be the modality of choice in the treatment of malperfusion from dynamic true lumen compression. Additional branch vessel stenting may be necessary in order to resolve malperfusion related to static obstruction (false lumen thrombosis). Interventional or surgical fenestration of the dissecting membrane is not considered as first line therapy [28]. So far, the value of extending the stented aortic segment into the abdominal aorta for persisting malperfusion after TEVAR by implantation of additional uncovered stents distally (PETTICOAT concept) requires further data collection and evaluation [62].

Endoleaks

The majority of endoleaks can be avoided by careful selection particularly with regard to important morphological details such as the length of the landing zone, use of multiple stents, length of overlapping segments as well as severe angulation and massive aortic calcification (porcelain aorta) [61].

TEVAR induced neurologic injury: brain

Brain injury after TEVAR is a major complication and most often associated with the underlying pathology, excessive device manipulation within the arch or intended or inadvertent overstenting of one or more of the great vessels. Further reduction in the stroke rate will be feasible by aggressively maintaining antegrade cerebral perfusion through prior vascular transposition [23]. Overstenting of the left subclavian artery is permissible in the emergency setting (e.g. traumatic aortic injury), but is inadvisable in elective cases due to a heightened risk of stroke and spinal cord injury. Therefore, detailed information on cerebral blood supply is required in elective situations [63, 64].

TEVAR induced neurologic injury: spinal cord

Spinal cord injury can occur immediately after TEVAR or be delayed, requiring clinical and neurological surveillance. The risk may be increased with extended lengths of the covered thoracic aortic segments [65]. Recent reports underline the importance of maintaining collateral blood supply via the left subclavian artery, lumbar arteries as well as hypogastric arteries. Special attention has to be paid to patients with previous treatment of AAA and intended coverage of subclavian artery by TEVAR. In such cases pre-deployment subclavian transposition would appear mandatory. In high-risk patients, preventive cerebrospinal fluid (CSF) drainage, which has proven efficacy in spinal cord protection during open thoraco-abdominal aneurysm surgery, is strongly recommended [66].

Reversal of paraplegia can be achieved by the immediate initiation of CSF drainage and pharmacological elevation of blood pressure (>90 mmHg mean arterial pressure). Hypotensive episodes during the procedure should be avoided. Neurological outcomes seem to be better with delayed occurrence of paraplegia than with immediate paraplegia after TEVAR [67]. Finally, a highly normal serum haemoglobin as well as precise attent to oxygenation will serve to both, prevention and reversal.

Vascular complications

Vascular complications are rare when anatomy is respected. Furthermore, the introduction of hydrophilic delivery sheaths has substantially facilitated the introduction of devices in relatively small access vessels. In calcified vessels, open surgical cut-down is preferred [46].

Retrograde aortic dissection

Retrograde aortic dissection may occur after TEVAR. However, it is seen more frequently in acute aortic dissection and procedures where the aortic arch or the ascending aorta is involved. The role of bare proximal stents in retrograde type A dissection remains undefined [40, 41].

Aorto-oesophageal or aorto-bronchial fistulation

Fistulation after TEVAR is rare and more frequently seen after acute aortic syndromes than after elective procedures. The final common pathway in development may be local inflammation in the posterior mediastinum [55, 56]. The treatment of choice is radical oesophageal resection comparable to treatment of oesophageal cancer.

PERSPECTIVES

Progress of device development

Challenges in endograft design are the development of branched endografts and of pathology-specific endografts [68–70]. However, the unique composition of the proximal thoracic aorta as well as the associated mechanical properties have to be taken into account and make this effort by far more complex than initially expected. There is a need for reducing the dimension (outer diameter) of the stent-graft devices, increasing the conformability and trackability.

Pressure sensors

Despite the convincing concept, there are no data showing that pressure sensors are superior to conventional imaging in order to detect or prevent aortic-related adverse events [71]. Development of so-called 'smart' stents has to be expected.

Progress of imaging

Recently, there has been increasing interest in functional imaging (assessment of flow patterns, membrane dynamics, diameters during the cardiac cycle, wall stress), which will help to improve our understanding of aortic diseases and may be able to predict future events [72]. This may be complemented by molecular imaging of the aortic wall metabolism, which will provide important insights into the pathogenesis and healing process [10].

SYNOPSIS AND OUTLOOK

TEVAR has changed aortic medicine, enhancing the armamentarium of the aortic specialist in treating acute and chronic thoracic aortic disease. TEVAR offers a valid treatment option for the elderly patients deemed at excessive risk for open surgery, but also for fit patients with suitable anatomies. Particularly, in patients with traumatic aortic injury and acute complicated TAD, TEVAR is considered the treatment of choice. A prerequisite is a multidisciplinary team approach in centres with a dedicated interest in aortic diseases. Therefore, the foundation of specialized aortic centres providing the full range of diagnostic and treatment options is strongly recommended.

Conflict of interest: none declared.

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