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EACTS/ESCVS best practice guidelines for reporting treatment results in the thoracic aorta

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Summary

Endovascular treatment of the thoracic aorta (TEVAR) is rapidly expanding, with new devices and techniques, combined with classical surgical approaches in hybrid procedures. The present guidelines provide a standard format for reporting results of treatment in the thoracic aorta, and to facilitate analysis of clinical results in various therapeutic approaches. These guidelines specify the essential information and definitions, which should be provided in each article about TEVAR:

- Definitions of disease conditions
- Extent of the disease
- Comorbidities
- Exact demographics of the patient material
- Description of the procedure performed
- Devices which were utilized
- Methods for reporting early and late mortality, and morbidity
- Reinterventions and additional procedures
- Statistical evaluation

It is hoped that strict adherence to these criteria will make the future publications about TEVAR more comparable, and will enable the readership to draw their own, scientifically validated conclusions about the reports.

Keywords: Thoracic aorta; Guidelines; Thoracic endovascular repair (TEVAR); Hybrid procedure; Early and late mortality; Reinterventions

1. Purpose

The purpose of these guidelines is to provide a standard format for reporting results of treatment in the thoracic aorta, and to facilitate analysis of clinical results in various therapeutic approaches, so that meaningful conclusions can be made and inferences drawn from investigations of medical, surgical, and percutaneous interventional treatment of patients with various diseases of the thoracic aorta [1,2].

2. Definition of disease conditions

Pathological entities that necessitate the treatment of the thoracic aorta are numerous, and clinical presentations are highly variable, reaching from asymptomatic dilatation of the aorta to the life-threatening acute rupture with severe hemodynamic compromise, necessitating an immediate

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intervention. Excellent overviews of the pathologic conditions can be found in the literature, and should be used [3]. Recently introduced term of 'acute aortic syndrome' [4] encompasses a series of pathological conditions leading to an acute presentation; nevertheless, for the purpose of exact analysis of treatment results, a specific patho-anatomical diagnosis should be given. Acuity of the disease process (acute, subacute, and chronic) must be specified.

The following major diseases are encountered in the descending aorta, and should be specified when reporting results:

- aortic dissection, according to Svensson's definition [5]
- degenerative aneurysm, chronic asymptomatic or symptomatic, as penetrating, ruptured, with or without compression symptoms
- intramural aortic hematoma
- aortic plaque, ruptured, embolizing, or asymptomatic
- Marfan and related connective tissue diseases (Ehlers-Danlos syndrome, etc.)
- coarctation
- mycotic aneurysm.
- traumatic aneurysm (acute and late post-traumatic)
- aneurysm resulting from previous interventions on the thoracic aorta (e.g. after coarctation repair, previous graft replacement or EVAR treatment.

For administrative purposes, e.g. when reporting a unit's activity, a single, encompassing diagnosis of thoracic 'aortic aneurysm' may be warranted. In scientific reports, individual results in each of disease categories must be provided to facilitate analysis of the results.

3. Extent of the disease

Many diseases of the thoracic aorta show a diffuse form, frequently extending from the ascending aorta through the aortic arch and descending thoracic aorta into the abdominal aorta, and even into its branches. Exact definition of the origin, extent and the termination of the dilatation should be given, and patients categorized according to the location of the disease process:

- ascending aorta (Stanford criteria can be used)
- aortic arch
- descending thoracic aorta. Crawford classification [6], being universally accepted, should be used
- thoracoabdominal aorta
- abdominal aorta:
  1. suprarenal
  2. juxtarenal
  3. infrarenal

Disease process can (and frequently does) encompass several locations in a single patient.

4. Clinical classification

Aneurysm should be classified according to its clinical presentation as symptomatic or asymptomatic. Symptomatic aneurysm is classified as acute (within 2 weeks after onset of symptoms) and chronic. Furthermore, the local complications of the aneurysm (compression or erosion of adjacent structures, thrombosis, embolization, contained or free rupture) should be mentioned. Hemodynamic condition at the presentation (stable, with or without preceding resuscitation; shock, unstable) must be noted.

5. Comorbidities

Scientific analysis of the results necessitates an exact definition of patient characteristics. Diseases of the thoracic aorta are, for the most part, encountered in patients of advanced age with multiple comorbidities, which often dictate the choice of treatment. The preoperative presence of these conditions should be identified according to standard definitions: renal insufficiency, renal failure (dialysis dependent, acute preoperative or chronic), COPD, peripheral vascular disease, neurovascular involvement, diabetes (insulin dependent or non-insulin dependent), previous neurological events (stroke, TIA, spinal chord ischemia, etc.), coronary artery disease, previous surgical interventions (e.g. CABG, AAA) etc. Use of standard risk assessment scores (e.g. additive EuroSCORE) is suggested to permit comparison between various studies.

6. Demographics

Exact definition of patient cohort should be given: age (mean $\pm$ SD), gender, previous surgeries or interventions, time since diagnosis, comorbidities (see above). Selection of patients for a particular modality of treatment, i.e. conservative versus open versus endovascular, exerts the major influence on the results. In all series, the statement about the total cohort from which a particular patient population was being selected should be given (including the total number of patients from whom this selected patient population was drawn, along with the year horizon over which the patients were chosen) to assess the magnitude of pretreatment selection. Delineation of patient selection criteria, and how the criteria have changed over time should be provided. Furthermore, the patient series should be consecutive, i.e. include all patients which have been subjected to a particular treatment method within the specified time frame. In all reports, the results must be analyzed with 'intention to treat' method, which should be documented at the start of the trial ('time zero'). Later crossovers should be documented, with the reason for abandoning originally chosen treatment, and their eventual clinical outcome.

The study design and methodology must be explicitly defined in the study or report. Duplicated studies reporting different outcomes but with the same patient groups must be clarified. This is important for cumulative evidence to be properly assessed for systematic review and meta-analysis in RCT, nRCT and case series for practice guidelines recommendations [7,8].

7. Late follow-up

Some pathological conditions of the descending aorta display very slow progression, and the extended follow-up (at least 1–2 years) is essential when comparing various treatment modalities to the conservative management (medical therapy or 'watch and wait'). Patient's condition at the time of follow-up with respect to the aneurysm (survival; complication-free and rupture-free survival; freedom from expansion or endoleak; additional interventions) should be mentioned. Exact method of follow-up must be specified (letter to the patient, telephone contact, information from the attending physician, access to the national death registry or information from major insurance carriers such as Medicare, etc. Furthermore, imaging modalities (CT, MRI, echo, angiography, etc.) should be described. The mode of follow-up should be included, whether prospective *anniversary* contact (although periodic follow-up may be at intervals shorter or longer than one year); or *cross-sectional* (at a common closing date), whereby an entire group of patients is followed more-or-less at the same calendar time, despite their index procedures occurring at widely disparate times. Prospective follow-up is preferred to retrospective follow-up. The extent of follow-up should be reported, and should be at least 95% complete. Extent of loss to follow-up must be clearly delineated so that the denominator is known at all reported time points. Ascertainment of complete data for losses to follow-up should be applied with just as much effort for prospective analyses as for retrospective analyses, since the latter are particularly prone to survivor bias (i.e., selective follow-up of survivors or those who are able to present for follow-up clinical will lead to a bias toward reporting on the healthiest cohort, and will preferentially ignore those who have died or are too severely incapacitated for follow-up clinics).

Cumulative event rates should be reported rather than event rates within discrete intervals. Ideally, time to event will be reported over the duration of follow-up, as well as proportion of patients with an event at discrete endpoints (specifying the numerator and denominator).

The number of patients experiencing an outcome once or more should be reported, even for events that may occur repeatedly within the same patient (such as stroke, endoleak, need for reintervention). If the author also wishes to provide the total number of events (i.e., allowing for more than one event per patient to be counted), the rate per patient-years may be provided.

8. Procedure performed

In diseases of thoracic aorta, there is a choice between conservative and invasive treatment. This latter group involves classical open surgical repair (OPEN), endovascular mode (EVAR, or better TEVAR), and a combination thereof, often referred to as hybrid procedure. The treatment modalities should be clearly stated in the 'Methods' section of the report; any crossovers should be mentioned, with their respective timing (which procedure first). 'Intention-to-treat' description should be applied, and all deviations and the reasons for the abandonment of the original intention should be given.

9. Devices used

There is already a large choice of endovascular devices, especially outside of the U.S., and new techniques and endografts are expected to appear in near future. It is essential to describe in detail the devices and grafts which have been used in the report, along with the manufacturer's name and address, and indicate if the device is available for general use, or if it is only an experimental model.

As access is an essential element of most endovascular and some open procedures it is important to describe the type and diameter of access sheaths, cannulae that were used and which artery was accessed and its diameter e.g. common femoral/iliac/axillary, 9, 10, 12 mm.

It is also necessary to describe the number and length of devices used as well as the size/diameter of the device and its ratio to the aortic wall diameter. The landing zone, its length, and any major arterial branch that is covered as well as any extra-anatomic bypass performed.

10. Early mortality and morbidity (endpoints of the study)

All-cause mortality should be reported, rather than only vascular or cardiac mortality; although, causes of death may also be specified. Early mortality will be reported as all-cause mortality at 30 and 90 days. Preferably, longer term follow-up should also be provided at 6 months, 1 year, 2 years, 5 years, and 10 years and should be depicted by actuarial estimates (with number remaining at risk and confidence intervals) or as simple percentages, regardless the patient's location, be it home or in a healthcare facility. Mortality should always be reported as the cumulative mortality (i.e., all deaths occurring in hospital should be included within the reported 30-day mortality, and all 30-day deaths should be accumulated within the 1 year mortality, etc.). All complications of the chosen treatment will be documented at the same time interval, and categorized as:

- disease related
- procedure related
- device related
- others (e.g. atrial fibrillation, etc.)

Reporting should be mandatory, and the complication and/or lack thereof, always mentioned for:

- access complication (report separately for complications during initial access attempt, and complications post-operatively such as significant bleeding, hematoma, wound infection)
- ischemic complications (peripheral and visceral), reported in aggregate, and individually for all types observed, such as gut ischemia, limb ischemia
- stroke and neurological morbidity [9]; define CVA, TIA, paraplegia, etc.
- renal failure (defined as new onset need for renal replacement therapy)
- renal dysfunction (serum creatinin increase of $>$50% of baseline)

- myocardial infarction (define diagnostic technique: elevated cardiac enzyme, new Q wave, etc.)
- reoperations or repeat procedures
- patients transfused
- major blood loss, defined as any episode of major internal or external bleeding that causes death, hospitalization or permanent injury or necessitates transfusion)
- duration of intubation
- length of ICU and hospital stay
- infection (specify pneumonia, wound, sepsis)
- endoleak, classified as type I—IV, according to accepted criteria [10]
- endocarditis; furthermore, imaging modalities (CT, MRI, echo, angiography, etc.) should be described.
- arrhythmias

11. Hybrid procedures

If a hybrid procedure is used, this method of treatment should be described in detail. In particular, the type of the procedures (surgical and endovascular); the sequence of interventions; time between two (or more) interventions; the vessels approached; the imagining before, during and after the intervention; drug regimen in the interval, should be described.

12. Reinterventions and additional procedures

Need for aortic reintervention should be reported, and defined as any surgical or percutaneous interventional catheter procedure that repairs, otherwise alters or adjusts, or replaces a previously implanted prosthesis or repaired aorta. In addition to surgical reoperations, balloon dilatation, interventional manipulation, embolization, repositioning, or retrieval, and other catheter-based interventions for prosthesis-related complications are also considered reinterventions. Need for access site reintervention should also be reported. Indications for reintervention must be reported. Open surgical and percutaneous catheter reinterventions should be listed separately.

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