Dutch Guidelines for Transcatheter Heart Valve Intervention

Institutional, team and operator competence criteria

On behalf of the

NVT and NVVC
Preamble

Transcatheter Heart valve Intervention (THI) entails a catheter-based intervention of heart valves with implantation of a device that is performed on the beating heart without direct vision of the target zone. It is a complex cardiac intervention that is rapidly growing and subject to many innovative changes in catheter (delivery) systems, frame and valve technology in addition to innovations in imaging modalities to guide the physicians performing THI. It is, therefore, mandatory that THI is performed by a specific and dedicated team of physicians who are not only adequately trained for THI but who are also familiar with patient and treatment selection (medical, THI, surgery), treatment preparation, treatment execution and postoperative care. These physicians, therefore, work in an environment that ensures maximum safety and comfort of patients who undergo THI or surgical intervention of cardiac valvular disease implying adequate infrastructure and organisation.

Upon request of the Ministry of Health (VWS) and the Inspection of Health care (IGZ), the present report concerns the Dutch Guidelines for THI summarizing the competence criteria of the institution, department and operator. The guidelines concerning training THI are not subject of this document but will be described in an addendum to these guidelines. The present guidelines only pertain to transcatheter intervention of aortic, mitral and tricuspid valve diseases but not pulmonary valve intervention and the treatment of paediatric valve disease. The Guidelines represent the expert opinion of representatives of both NVT and NVVC and have been accepted by the board of NVT and NVVC and will be yearly reviewed by the board of working group of THI (WTHI).

1. Institutional Competence Criteria

1. The institution has a Department of Cardiology with a subspeciality or unit of Interventional Cardiology which in accordance with the criteria of the Dutch Society of Cardiology (NVVC) and the criteria of the Wet Bijzondere Medische Verrichtingen (WBMV) is authorized to perform percutaneous coronary interventions (PCI).
2. The institution has a Department of Cardio-Thoracic Surgery which in accordance with the WBMV is authorized to perform open-heart surgery.
3. The institution has a Department of Surgery with subspeciality or unit of Vascular Surgery or eventually an independent Department of Vascular Surgery.
4. The Institution has a Department of Radiology in which at least one trained and dedicated radiologist performs catheter based treatment of atherosclerotic disease of the great arterial vessels on a regular basis.
5. The institution has an electronic data base system in which all relevant patient and procedure data are collected in addition to an electronic complication registration system
6. The institution performs at least one thousand (1000) PCI’s, at least 200 aortic- and/or mitral valve open-heart operations (stand alone or in combination with coronary artery bypass surgery)
7. The institution performs at least 50 Transcatheter Heart valve Interventions (aortic – mitral – tricuspid) per year.
8. The institution performs THI according to the indication documents, specified per valve – these are addenda to this document and will be updated yearly.

2. Competence criteria of The department of Cardiology and/or Cardio-Thoracic Surgery

1. The Department of Cardiology and the Department of Cardio-thoracic surgery have a dedicated daily or weekly heart team meeting in which all patients referred for catheter-based or surgical treatment of cardiac valvular disease are being presented and discussed with written or electronic documentation of the final treatment decision (medical, THI, surgery) and motivation,

2. Presence of protocols (written or electronic) in which all steps of the THI are described going screening (out-patient clinic) to postoperative care.

3. Presence of at least one cardiac catheterisation room (OR class II) and/or a hybrid OR (OR class II) equipped with dedicated digital high-quality radiographic cardiac imaging, with multi-angle rotation and multiple image manipulation supported by dedicated paramedical staff or technicians.

4. Availability to perform transthoracic and transesophageal echocardiography upon clinical indication in the cardiac catheterisation room and/or a hybrid OR to support and/or evaluate the procedure.

5. Presence of infection prevention class II (WIP) programme in the catheterisation room and (hybrid) OR

6. Presence of and experience with intra-aortic balloon pump and left ventricular assist devices

7. Presence of a radiation protection programme to comply with optimal radiation safety measures.

8. Availability of all necessary materials to perform THI such as guiding catheters, wires, balloons and for the swift handling of unexpected (bail out) situations (e.g. vascular complication) such as covered stents and temporary occlusive balloons

9. Written patient information concerning THI including the procedure

10. Availability upon indication of a vascular surgeon and interventional radiologist experienced in endovascular and conventional treatment of complications of vascular complications of accesses used for THI,

11. Participation in a nationwide registration system of THI, set up by the Board of The Committee Transcatheter Heart valve Interventions The Netherlands and agreed by the NVVC and NVT.

3. Team Competence Criteria

1. The team that performs THI (THI team) consists of at least three (3) dedicated physicians consisting of at least 1 (one) interventional cardiologist, 1 (one) cardiothoracic surgeon and 1 (one) cardiac-anaesthesiologist. Upon discretion of the THI team, the THI team may invite additional physicians to support the execution of THI such as a vascular surgeon and/or an interventional radiologist.

2. All THI team members are registered specialists and member of their respective clinical-scientific organization (NVVC, NVT,NVA) who are - by nature of their training
3. All cardiologists and/or cardiothoracic surgeons who are performing the THI have completed radiation safety training and acquired a 4A/M level.

4. The cardiologist and cardiac surgeon of the THI team participate in the daily or weekly dedicated heart team discussions in which patients referred for treatment of cardiac valvular disease are presented and discussed.

5. The THI team is supported by a dedicated paramedical staff that is trained to support THI.

6. The THI team performs at least 50 THI’s per year using more than one access for THI to provide a patient-tailored approach (transapical, transfemoral, subclavian, aorta direct,...). The THI team may decide to increase the number of THI team members in case the number of THI/year exceeds 50 by inviting another interventional cardiologist or cardiothoracic surgeon.

7. During a five-year period an experienced operator may perform less procedures but the total number of procedures during those five years should be at least 125.

Literature: