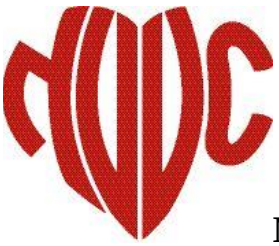
Dutch Guidelines For Competencies For Transcatheter Heart Valve Intervention

Nederlandse Vereniging voor Thoraxchirurgie



Nederlandse Vereniging voor Cardiologie

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NVT and NVVC (working group THI)

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Institutional, Team and Operator Competence Criteria

Inhoud

INTRODUCTION

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. The number of this complex cardiac intervention 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. In addition, the indication of patients suitable for THI is a rapid moving target and subject of clinical research. It is, therefore, mandatory that THI is performed by a specific and dedicated team of physicians who are adequately trained for THI and familiar with patient and treatment selection (medical, THI, surgery), work-up, execution and postoperative care. These physicians 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 present document 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 for competencies represent the expert opinion of representatives of both NVT and NVVC and have been submitted and approved by the board of NVT and NVVC.

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 an on-site Department of Cardio-Thoracic Surgery which is in accordance with the WBMV 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 specialized program for cardio-vascular imaging for THI (MSCT mandatory).
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 75 Transcatheter Aortic Valve Interventions per year, a volume that is or has to be established within 3 years after start of the program.
7. In case of Mitral valve interventions the institution performs at least 25 Transcatheter Mitral Valve Interventions. (TMVI) 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 on a regular basis.
9. THI board will evaluate on a yearly basis the status of volume and outcome based on data collected by BHN/NCDR.
10. This document will be yearly revised according to new (inter)national developments.

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 valve 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 from 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. Ability 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 and experience with ventricular assist devices.
6. Presence of a radiation protection program to comply with optimal radiation safety measures.
7. 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.
8. Written patient information concerning THI including the procedure.
9. Participation in a nationwide registration system of THI as agreed by the NVVC and NVT.

TEAM COMPETENCE CRITERIA

1. The 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 and medical practice - familiar with cardiac disease (pathophysiology, course, diagnosis), treatment options, treatment stratification, treatment planning and execution including postoperative care or prolonged medical care. In every performing THI-team, at least one of the cardiologists and/or cardiothoracic surgeons has completed radiation safety training at the acquired4A/M level.
3. The THI team has to be able to provide a patient-tailored TAVI approach with at least one alternative access route to transfemoral (e.g. transapical, subclavian or direct aortic).
4. During a five-year period an experienced operator, first or second operator, may perform less procedures but the total number of procedures during those five years should be at least 125.

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