Dutch guidelines for interventional cardiology

Institutional and operator competence and requirements for training

Working Group of Interventional Cardiology

Interventional cardiology is an expanding field within cardiovascular medicine and today it is generally accepted that specific training, knowledge and skills are required by the cardiologists. Hospitals where coronary interventions are performed must be properly equipped and able to provide specialised care. Percutaneous coronary interventions are frequently used for coronary revascularisation. The public should have confidence in the uniformity of high quality care. Therefore such quality of care should be maintained by certification of the individual operators and general guidelines for institutional requirements and formal audits. The Netherlands Society of Cardiology (NVVC) will implement a new registration system for cardiologists with a sub-specialisation that will include registration for interventional cardiology. The NVVC asked the Working Group of Interventional Cardiology (WIC) to update the 1994 Dutch guidelines concerning operator and institutional competence, and requirements for training in interventional cardiology in order to incorporate them into the official directives.[1] The present guidelines represent the expert opinion of the Dutch interventional cardiology community and are in accordance with international regulations.[2-7]

1. Introduction

Dutch interventional cardiology is characterised by a limited number of high-volume intervention centres with experienced operators. In 2003 the average number of procedures per centre was more than 1500. In general, a high-volume load for operators and institutions is associated with better outcomes for procedures.[2-6] In the interventional community the Dutch situation is considered an ideal situation that serves as an example of how interventional cardiology should be organized. The recent expansion with new interventional centres (Alkmaar, Enschede, Leeuwarden, Rotterdam-Zuid, Den Haag and Arnhem) means that a rather complete geographical spread has been reached, which is especially important for rapid treatment of acute myocardial infarction. The present capacity should be sufficient for the next decennium, while assuring a high volume-load per centre. The purpose of these guidelines is to ensure and maintain a high quality in interventional cardiology in the Netherlands. Extensive discussions have been held within the WIC and with representatives of the NVVC about the numbers of procedures that need to be performed in the different sections mentioned in these guidelines. These numbers may deviate to some extent from guidelines in other countries, but guidelines are always adapted to local insights and expertise in a way that is practical and desirable in the specific situation. Included in the scope of interventional cardiology are techniques used for percutaneous coronary interventions, but also a broader group of percutaneous techniques for procedures involving the myocardium, cardiac valves, shunts, large thoracic vessels and peripheral vessels such as the carotid arteries. Specific expertise and a dedicated setting are often required for the latter group of percutaneous interventions. The majority of the interventions involve treatment of stenoses in the coronary system. Formerly known as percutaneous transluminal coronary angioplasty (PTCA), these procedures are now referred to by the more appropriate term percutaneous coronary interventions (PCI). These guidelines are based on scientific publications and expert opinion. Results of published studies may have a number of limitations for common practice because of selection and publication bias, differences in medical practice, patient characteristics and geographic factors. Moreover, conclusions and statements may become outdated due to rapid developments in interventional cardiology.[5,6] The strength of evidence in this paper is rated according to three levels, similar to guidelines of the European Society of Cardiology.[7]

Level of evidence A: Data derived from multiple randomized clinical trials or meta-analyses.
Level of evidence B: Data derived from a single randomized trial or non-randomized studies,
Level of evidence C: Consensus opinion of the experts.

Coronary interventional procedures are complex and technically demanding. Optimal performance requires an extensive knowledge and substantial technical skills. Complications of coronary interventions are becoming less frequent, but optimal outcome depends on proper recognition and management. The new developments in pharmacological therapy, technical improvements, novel techniques, medical approaches together with an increasing complexity of cases mean that individual operators need to undertake continuous education and invest time and interest in ensuring safe and appropriate patient care. Besides operator experience, institutional factors are important for the success of the procedures, such as the radiographic equipment, adequately trained and experienced nursing and technical staff, hospital facilities, patient logistics, patient load and adherence to protocols. Diagnosis and treatment of arrhythmias (electrophysiology) is a separate sub-specialisation within cardiology and is not included in these guidelines. Neither do the guidelines provide information about indications or performance of the procedures; these issues will be addressed in separate guidelines.

2. Training requirements for the interventional cardiologist

The results of PCI's in terms of success and complication rates are related to the operator's expertise, case selection, clinical judgement and technical skills. It is obvious that patients undergoing these procedures should be confident that the operator and nursing staff are skilled and well trained. During the training, an interventional cardiologist is required to perform a set minimum number of procedures as first operator to gain enough practical experience.

Before the official training in interventional cardiology starts, the following requirements should be met:

a) Registration as a cardiologist and completion of a course on radiation safety with certification (level 4A).
b) Thorough knowledge of the anatomy and physiology of the large vessels and coronary circulation.
c) A minimum of 300 diagnostic cardiac catheterisations as first operator. (level of evidence C)[1,3]
d) The training has to be followed in a centre, certified for training in interventional cardiology (for requirements see 5.)
e) Literature study of interventional cardiology. Specific requirements will be formulated in the near future.
f) Positive attitude towards working together and sharing experiences with interventional and non-interventional colleagues, and the technical and nursing staff of the cardiac catheterisation laboratory.

During the training:

g) Attendance of at least one established international course in interventional cardiology (PCR or TCT).
h) Participation in a national course on interventional cardiology with an examination. (This course will be developed in the near future).

i) As in any surgical procedure, percutaneous coronary interventions require a high degree of dexterity to obtain vascular access and technical skills to manipulate and operate a variety of catheters and devices in the circulation. Most of these skills can only be acquired by training in actual procedures.
j) Knowledge of indications for PCI in different clinical conditions, in relation to conservative/medical treatment and surgical approaches.
k) Knowledge of all potential complications, including contrast reactions and bleeding complications and primary management of these complications.
l) Knowledge of the advantages and disadvantages of various arterial access sites and related techniques for haemostasis and the ability to perform diagnostic and interventional procedures via these access sites.
m) Knowledge of interventional techniques and features of various materials, such as balloons, wires and stents.
n) A wide case mix should be treated, including all types of coronary lesions and conditions, acute myocardial infarction and haemodynamically unstable patients.
o) Frequent participation in team discussions with the cardiac surgeons on evaluation of diagnostic procedures and on indications for intervention.
p) Knowledge and experience with intravascular ultrasound, intracoronary flow or intracoronary pressure measurements in at least 30 cases, as well as the interpretation of the findings. (level of evidence C)
q) Knowledge of PCI with different techniques such as rotablation, directional atherectomy, devices for thrombus removal, devices for prevention of distal embolisation, as well as the indications for these procedures.
r) Knowledge of special procedures, such as valvuloplasty, closure of ASDs, PFOs and ODBs, removal of foreign bodies and peripheral interventions.
s) Knowledge of comorbid conditions of the patient that increase the risk of the procedure, including measures which should be undertaken to reduce the complications in these specific situations.
t) Knowledge of advanced life support, pharmacological interventions, such as anticoagulants and antithrombotics, treatment of no-reflow phenomena and the different drugs used in this setting.
u) Knowledge of the indications for, and experience with, insertion of an intra-aortic balloon pump and alternative forms of haemodynamic support, as well as the potential complications.
v) Participation in on-call duties under close supervision.

During and at the end of the training:

w) Performing at least 300 interventions within one to two years, with 200 of these as first operator. (level of evidence C)
x) The duration of the training is one year full-time, or a two-year period with at least 50% of the time involved in interventional cardiology.
y) The training is formally evaluated at six monthly intervals.
z) After six months of training in interventional cardiology, an evaluation should be carried out by the programme director as to whether the trainee has made the required progress in technical skills and knowledge, and is suitable to continue training in interventional cardiology.

After 12 months the progress is evaluated and, in consultation with the trainee, the programme can be extended for up to two years to enable the trainee to fulfil all the

requirements. If the programme is being followed part-time, the duration of the training will be prolonged pro rata. In all cases, the training has to be completed within two years.

Qualification of the interventional cardiologist:

Oral and written endorsement from the director of the interventional cardiology training programme that the trainee has fulfilled all the requirements of the training. After fulfilling all the requirements of the training, a request for certification can be sent to the committee on interventional cardiology with representatives of the WIC and NVVC, which is to be installed. This committee has to be formalised by the Concilium Cardiologicum in the near future.

3. Continuing education and operator competence

Once qualified as an interventional cardiologist, it is important that the cardiologist continues to carry out PCIs on a regular basis for the maintenance of competence and technical skills. Several studies have identified procedural volume as a determining factor for rate of complications with PCI. (level of evidence B) Low volume operators in hospitals with an annual volume of <200 to 400 PCI cases per year have a greater incidence of complications in comparison to hospitals where more procedures are performed. [2,5,8,9] (level of evidence B) Improved outcomes were identified with a threshold value of 150-200 procedures per operator. However, procedural volume is only one of many factors contributing to the variability of measured outcomes.[10-12] Case selection is a potential pitfall in the evaluation of complication rates of coronary interventions.[13] Operators in hospitals without surgical backup on-site tend to perform less complicated interventional procedures. The success rates of coronary interventions over time have progressively improved despite an increase in procedural difficulty and more comorbid disease.[8] Part of this success is due to technical improvements in interventional devices, which often requires additional technical skills and knowledge. For that reason interventional procedures should be a substantial part of the duties of an interventional cardiologist. Operators should regularly seek the help and advice of other interventional cardiologists to guarantee optimal patient care. Sharing experiences with colleagues is an important issue within interventional centres, both formally and informally to optimise the process of learning new techniques and tackling new complications.[5,8] Requirements are derived from literature and adapted for the Dutch situation.[1-6,8]

Requirements for interventional cardiologists:

a) Performing at least 150 cases a year as first operator. (level of evidence C)
b) Participation in on-call duties on a regular basis.
c) The operator should perform a minimum of 30 cases of primary PCI for acute myocardial infarction annually. (level of evidence B)[5]
d) During a five-year period an experienced operator (> 1000 PCI) may perform less procedures for one or two years, but the total number of procedures during those five years should be at least 500. (level of evidence C)[3]
e) Participation in a team with the cardiac surgeons to discuss indications for intervention on a regular basis, at least 25 times a year.
f) Registration of all procedures with respect to the baseline features of the patient, procedure time (from the first puncture to removal of the guiding catheter), fluoroscopy times, material used, outcome and complications of the procedure in a certified format.

g) Participation in meetings on interventional complications within the institution, four times a year, to discuss complications of PCI, new developments and technologies within interventional cardiology.
h) It is strongly recommended to follow formal education (courses and seminars) in interventional cardiology for at least 30 hours, every 2 years.[3]
i) Operators should keep up to date with the literature, with technical improvements, novel techniques, and adjunctive pharmacology in interventional cardiology.
j) The requirements apply equally to cardiologists that are mainly employed in a non-interventional centre and who are performing interventional cases in the interventional centre ("guest" interventional cardiologists).
k) Each operator should personally file all the above requirements and recommendations for his personal audit.
l) Once every five years, or sooner depending on the duration of the licence, a visitating committee including two interventional cardiologists and one cardiologist from the quality board of the NVVC will conduct a formal audit on site, to maintain the registration.

4. Institutional requirements

Prerequisites:

Interventional cardiology procedures are associated with potentially life-threatening or disabling complications that in general are inversely related to the operator's and the institution's volume of patients. Significantly fewer complications occurred in cardiac catheterisation laboratories performing ≥ 400 PCI procedures per year. (level of evidence B)[5] Conversely, low-volume hospitals were associated with higher rates of emergency coronary artery bypass surgery and death. The American guidelines strongly discourage small surgical coronary bypass programmes to support angioplasty programmes or starting new angioplasty facilities near to well-equipped, high-volume angioplasty centres.[5,6]
Close cooperation with the cardiac surgeons is essential for a balanced assessment of the patient's options. Elective or acute interventional procedures should continuously be compared with standards of cardiac surgery. Appropriate use of new technology is recommended to keep up to date with more difficult procedures. Covered stents, drug-eluting stents, intracoronary pressure measurements, intracoronary ultrasound and distal protection have been proven to be of benefit in certain sub-populations of patients. These devices and technology should be readily available.
All procedures should be registered in a database, which should at least contain the following: indication for the procedure, the technique performed and materials used, radiation exposure time, procedure time (from the first puncture to removal of the guiding catheter), the result of the procedure in different vessels, complications in the catheterisation laboratory, coronary bypass surgery and mortality. Preferably there should be information at hospital discharge. The requirements are listed below and when necessary discussed per issue.

Emergency PCI for acute myocardial infarction:

PCI in the acute phase of myocardial infarction with its specific complications is more complex and requires even more skills and experience than routine PCI in the haemodynamically stable patient. An experienced PCI team (operators, assisting physicians and nurses in a dedicated setting is required for an optimal result in these acutely ill patients. As a consequence primary PCI for myocardial infarction should only be performed in centres

with a full time interventional cardiology schedule. If these conditions are not fulfilled, transfer to an interventional centre that routinely performs complete PCI is indicated (level of evidence B)[7,15] Regional logistics should be improved to enable the direct transport from the patient's home to the interventional centre to decrease the delay between onset of symptoms and PCI. In addition, transport of patients with acute myocardial infarction for primary PCI over large distances has been proven effective in comparison to thrombolysis. (level of evidence A)[16,17] As the delay in time to primary PCI is relevant, the transport time by ambulance to an intervention centre should ideally be less than 30-45 minutes. Availability of primary PCI within a reasonable time and the specific geographical situation may favour the discussion of the start-up of a new PCI centre. However, a strategy of prehospital thrombolysis in acute myocardial infarction with early rescue PCI may have comparable results to primary PCI. (level of evidence B)[18]

Requirements for the institutions:

a) At least two fully equipped cardiac catheterisation labs with sophisticated digital high-quality radiographic cardiac imaging, with multi-angle rotation and multiple image manipulation. Two cardiac catheterisation labs are required to ensure a continuing service in the case of breakdown or during servicing. (level of evidence C). Furthermore this will allow faster access to the cathlab for emergency patients.
b) Full facilities for cardiopulmonary support and procedures under general anaesthesia.
c) Intra-aortic balloon pump should be readily available. (level of evidence B)
d) State of the art intravascular ultrasound has to be on hand.
e) Physiological measurement systems and instruments for intracoronary pressure or flow measurements by wire technology. (level of evidence B)
f) Radiation protection programme to comply with optimal radiation safety measures.
g) Extensive stock and choice of guiding catheters, balloons, stents, wires and special devices.
h) Adequate adjunctive medication, such as IIb/IIIa inhibitors, must be readily available.
i) On-call service available 24 hours a day, 7 days a week.
j) During procedures during on-call hours, an interventional cardiologist and two additional members of the cardiac catheterisation staff (two trained nurses, or one trained nurse in combination with one radiology assistant or technical assistant) should be present.
k) All centres should have the catheterisation laboratory operational within 30 minutes after notification for acute procedures.
l) Each centre should have at least four certified operators to ensure continuity of service and also because of the on-call demands. (level of evidence C)
m) The minimum number of procedures in the specific Dutch situation should not be less than 600 per year (see also "Requirements for starting interventional centres").
n) For emergency PCI, external communication and in-hospital logistics are important for fast and dedicated care. In patients with acute myocardial infarction, efforts should be made to accomplish a "door-to-balloon time" of no more than 30 minutes in patients who are transferred and no more than 60 minutes in patients primarily seen at the centre's own emergency care department. (level of evidence B)[7,19,20]
o) Surgical on-site backup is a heavily debated subject.[21,22] Emergency coronary bypass surgery has been reduced to less than 1.5% of the procedures by the use of stents. In patients submitted for PCI in the acute phase of myocardial infarction, emergency surgery is needed sometimes because of life-threatening anatomy or suboptimal results of PCI. Because the interval to surgical revascularisation may take some time (on basis of first available operation room), it is essential to undertake high-risk PCI in close contact with

the cardiac surgeon. Although worldwide, a number of centres provide angioplasty without on-site surgical backup, it should be considered as a sub-optimal choice, but sometimes acceptable given the geographical considerations.[5] Therefore, the preferred and recommended Dutch situation is to have cardiac surgery on-site, although this is no longer a prerequisite. Immediate discussions with the cardiac surgeons in the cardiac catheterisation lab are possible on a 24 hour, 7 days a week basis. This issue can be accomplished by phone and in the future by immediate image transmission by secured internet communication.

p) Regular meetings with the cardiac surgeons to discuss indications for interventional cardiology, cardiac surgery or medical therapy to reach a formal written therapeutic decision are necessary for all non-acute patients, with a copy to the referring cardiologist.
q) Organisation of written and/or oral information about the interventional procedure to the patient, including clear and comprehensive information about the advantages and disadvantages and possible alternates for this procedure. This should also include the presence of surgical coverage.
r) Post-procedural care is an important part of the PCI procedure. Patient selection for early discharge versus close electrocardiographic and haemodynamic monitoring is important. There should be protocols for sheath removal, mobilisation, post-procedural medication and how to manage bleeding complications. General instructions should be given on risk-factor modification and the medication for secondary prevention should be checked.
s) Participation in a nationwide registration system of PCI set up by the government in cooperation with the NVVC, NVT and NHS.

Requirements for starting interventional centres:

Institutions with or without cardiac surgery on-site that want to start a PCI programme must fulfil all the requirements mentioned above within a three year period.

Before the start:

a) For the acceptance of new centres, the need from a geographical standpoint (spread of interventional cardiology centres in the Netherlands) has to be substantiated.
b) There has to be a formal cooperation agreement with one of the existing interventional centres (cardiology and cardiac surgery) for the purposes of supervision, support, back-up, and training in the initial phase. There has to be agreement about indications for emergency referral, procedures in high-risk cases requiring surgical back up on-site, organisation of meetings for discussions on indications for PCI and joint meetings on complications. These procedures have to be described in protocols. The supervising centre has cardiac surgery on site and is performing at least 800 PCIs per year for at least 5 years. The supervising centre should be able to continue with a patient load of more then 800 patients per year after full development of the new PCI centre. The supervising centre should be located no further away than 30-45 min. transport time by ambulance in case of referral for emergency PCI or emergency surgery.
c) The centre has to demonstrate that a number of 400 PCIs can be reached within two years and the number of 600 PCIs within three to five years on the basis of the number of PCIs that are generated by the centre itself, added to the number of PCIs that will be referred from other centres. The willingness and extent of cooperation of those referring centres with the new centre has to obtained in writing.
d) Based on a national population of 16.000.000 and a total of 20 interventional centres, the average adherent population at present is calculated as 800.000 people. Correcting for a

growth of the number of centres the minimum adherent population for a centre is set at 600.000 people.

At the start:

e) At least two experienced and certified operators are employed by the institution.
f) At least two fully equipped cardiac catheterisation labs with sophisticated digital high-quality radiographic cardiac imaging, with multi-angle rotation and multiple image manipulation.
g) Full facilities for cardiopulmonary support and procedures under general anaesthesia.
h) Intra-aortic balloon pump.
i) State of the art intravascular ultrasound system has to be on stand-by.
j) Physiological measurement systems and instrumentation for intracoronary pressure or flow measurements by wire technology.
k) Radiation protection programme to comply with optimal radiation safety measures.
l) Adequate stock and sufficient choice of guiding catheters, balloons, stents, wires and special devices.
m) Adequate adjunctive medication, such as IIb/IIIa inhibitors, must be readily available.

During the establishment of a centre:

n) On-call service available 24 hours a day, 7 days a week should be organised and effective within two years from the start. Until that time a program during office hours is acceptable. For urgent procedures outside office hours patients will be transported to the supervising centre.
o) The centre should have the catheterisation laboratory operational within 30 minutes after notification of an acute procedure.
p) Number of operators: minimally three at the end of year two and minimally four at the end of year three.
q) Number of procedures: for centres that are starting an interventional programme the number might be as low as 400 cases a year after two years. (level of evidence B)[5,15]

5. Requirements of interventional centres for training

Centres that provide a formal training in interventional cardiology have to meet additional demands:[4,7]

a) The director of the educational programme, who is the official supervisor, should be an interventional cardiologist who has performed the required number of procedures and has at least five years experience. This individual should also have demonstrated skills in teaching and have experience in research, demonstrated by a thesis in the cardiovascular field.
b) The institution provides full level A education in cardiology and preferably also in cardiac surgery.
c) Interventional cardiology is organised in a state-of-the-art manner according to the guidelines described here.
d) Active scientific research in interventional cardiology is possible and will be stimulated.
e) The centre has at least four cardiologists who participate in the interventional procedures as the predominant task.
f) Cardiac surgery and interventional radiology are on-site.
g) The institution performs at least 800 interventional procedures a year.
h) The technical and nursing staff of the cardiac catheterisation laboratory are very experienced and there must be a good ‘learning’ atmosphere.

i) Registration facilities are a necessary prerequisite to allow personal and institutional audits.
j) Training centres in interventional cardiology will have the same visitation procedures as full level A centres with training programmes in cardiology.

6. Certification, personal and institutional audits

To maintain a high quality of care, standards for training and performing interventional cardiology procedures will be implemented. A visiting committee within the quality control board of the NVVC will be established with professionals in the field of interventional cardiology together with a member of that board to provide the institutional and individual audit on a time base similar to current visitation of training centres in cardiology. The committee will also review outcomes of the procedures in relation to indications for the procedure. Further, the committee will examine whether the individual operator and the institution fulfil minimal requirements as formulated in the guidelines for interventional cardiology and whether there are shortcomings in patient care. The committee may suggest changes in care to the local interventional group and to the management of the institution, or advice on matters that have not been introduced or implemented for various reasons. Also, this new committee will be qualified to certify trainees in interventional cardiology, training institutions and may have a role in approving institutions for interventional cardiology. Current institutions and operators in interventional cardiology will have a retrograde certification for the next five years. Not only are the local hospital factors important but also regional factors must have an important impact in approval of institutional competence for interventional cardiology to ensure adequate patient load and logistics on a regional basis. For patients with heart disease in the Netherlands, regulation of certification is one of the guarantees for appropriate interventional care by properly trained and educated interventional cardiologists. Formal regulation is awaited.

7. References

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