**Working Group Report**

**Recommendations for qualification of centres implanting and following defibrillators**

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**Introduction**

Sudden cardiac death is a major public health problem in Western countries. Its prevalence is estimated to be 400,000 deaths/year in the U.S.A. and 150,000 deaths/year in Western Europe. Several therapeutic strategies are currently available for the treatment of manifest malignant arrhythmias (ventricular tachycardia or ventricular fibrillation) and prevention of sudden death including pharmacological therapy, tachycardia surgery, catheter ablation, heart transplantation and the implantable cardioverter defibrillator.

Since the first implantation in man in 1980, implantable cardioverter defibrillator technology has greatly improved. Non-thoracotomy lead systems and biphasic shocks are now the approach of choice, offering an almost 100% success rate. Modern implantable cardioverter defibrillators can prevent bradycardia and tachycardia, and can cardiovert (low energy) and defibrillate the heart. The device has a memory which can document arrhythmic events, permitting validation of its efficacy to terminate ventricular tachyarrhythmias and its potential to reduce sudden cardiac death.

The number of devices implanted (35,000 up to 1992) has increased considerably in recent years. In 1994 the number of implantable cardioverter defibrillators implanted were: U.S.A. 16,000, Germany 1200, France 200, Spain 150, Italy 225, Netherlands 200, Belgium 134, United Kingdom 220. The small number of devices implanted in Europe compared to the U.S.A. is partly explained by financial limitations. Various aspects of implantable cardioverter defibrillator therapy have been addressed by previous guidelines but the qualification of the implanting centre itself has not been defined.

The clinical and technical demands of implantable cardioverter defibrillator therapy (indications, implantation and follow-up) and its high cost dictate that implantation be restricted to centers appropriately equipped and staffed.

These recommendations set out the desirable criteria for a centre to be accredited for implantable cardioverter defibrillator implantation and for the training of implantable cardioverter defibrillator implantation. Some European and other countries have addressed this problem, but the Working Groups on Arrhythmias and Cardiac Pacing of the European Society of Cardiology believe there is a need for uniform European criteria. Criteria for implantable cardioverter defibrillator implanting centres which have been proposed in France have served as a framework for these guidelines.

**Criteria for an implantable cardioverter defibrillator implanting centre**

A centre accredited for implantation and follow-up of implantable cardioverter defibrillators should be part of a cardiac department which has access to diagnostic and therapeutic techniques pertinent to the management of malignant ventricular arrhythmias including: invasive electrophysiology, haemodynamic and angiographic evaluation, cardiac pacing, an intensive care unit for pre- and postoperative monitoring.

The near 100% efficacy of the non-thoracotomy approach has greatly reduced the need for cardiac surgical back-up. Ideally, implantable cardioverter defibrillator implantation should be undertaken in a sterile operating theatre. Recent reports have, however, suggested that implantable cardioverter defibrillators can be safely implanted in a well equipped and staffed electrophysiological laboratory if requirements of sterility are met.

The radiological equipment should include an adequate image intensifier and a radiotransparent and...
mobile table. As the patient and the team are exposed to X-rays, the radioprotection of the operating room should satisfy the safety requirements of a given country.

The equipment for electrocardiographic recordings should fulfill the requirements for diagnostic electrophysiology. There should be a minimum of three surface ECG channels and one or more channels for endocavitary uni- or bipolar recordings, which should also be displayed on a multi-channel recorder. In addition, equipment for invasive and non-invasive haemodynamic monitoring has to be available. An ECG machine for recording a 12-lead ECG should be readily available.

**Equipment essential for an implantable cardioverter defibrillator implanting centre**

The following equipment should be in situ: an external programmable stimulator for induction of ventricular tachycardia (VT); an AC generator for induction of ventricular fibrillation (VF); an automatic external device with the diagnostic and therapeutic functions of the device to be implanted, including the capability of delivering up to 40 joule shocks; a pacing system analyser; the external programmer appropriate for the device to be implanted; equipment for general anaesthesia, resuscitation and emergency care, including instruments for pericardiocentesis. Echocardiographic equipment should be readily available to assist diagnosis when cardiac perforation is suspected, and an external defibrillator for termination of VT-VF in case the implantable device and the external counterpart should malfunction. This device should be capable of operating through adhesive electrodes attached to the thorax.

**Equipment essential for the follow-up of implantable cardioverter-defibrillators**

These include: a multichannel ECG recorder; an external defibrillator (tested daily); equipment for the emergency management of cardiopulmonary arrest; external programmers for all the devices implanted; a database for retrieval of patient data and storage of follow-up data; a magnet.

**The medical staff**

These should include: a minimum of one but preferably two or more cardiologists competent (see later) in the implantation and follow-up of implantable cardioverter defibrillators. The implanting centre or the arrhythmias' section should be under the direction of a cardiologist specialized in clinical electrophysiology and competent in cardiac pacing. The presence of a cardiac or thoracic surgeon is necessary if an epicardial approach is to be used. Transvenous electrode placement may be performed by either an experienced surgeon and a cardiologist/electrophysiologist, or an adequately trained cardiologist; an anaesthetist: since the implantation is performed under general anaesthesia, an anaesthetist is required during the entire procedure. Even if a transvenous implantation can be performed under local anaesthesia, an anaesthetist is necessary to anaesthetize the patient for device testing. (Depending on local or national regulations, this role could be taken by a physician with approved experience of short-term anaesthesia); a nurse specialized and trained in cardiac pacing and defibrillation, should be present during the procedure. The nurse ideally should also be present at the follow-up visit clinic.

**Technical assistance**

During the implantation, technical assistance may be provided by a trained assistant (technician, nurse or clinical electrophysiologist).

**Criteria for a training centre**

The training of physicians who implant implantable cardioverter defibrillators should take place in designated cardiology departments. These may be in university or non-university hospitals. The training centre should ideally be accredited for this purpose by the relevant national authorities (e.g. a National Cardiology Society, national working groups on arrhythmias and/or cardiac pacing, a medical council or any organisation that holds the right to supervise training).

The minimum number of implantable cardioverter defibrillator implantations required for training should be 15 per year including reimplants. This number should be reevaluated according to the evolution of the indications and techniques.

A teaching centre should have facilities to perform all relevant diagnostic and therapeutic techniques in the assessment and management of cardiac arrhythmias; it should also have a theoretical and technical training programme.

**Requirements for physician competence in the use of implantable cardioverter defibrillators**

Physicians competent to prescribe and implant implantable cardioverter defibrillators should have been fully trained with regard to indications, implantation and follow-up in arrhythmia diagnosis and management. They should be aware of the indications for implantation, be competent in the technique of implantation, have had experience of complications and how they should be managed and should have extensive experience of implantable cardioverter defibrillator follow-up.
Indications

The indications for implantable cardioverter defibrillators should be decided by a cardiologist trained in clinical electrophysiology and arrhythmia management and who is familiar with all treatment modalities for malignant ventricular arrhythmias.

Implantation

Non-thoracotomy implantation should be performed by a cardiologist trained in clinical electrophysiology and competent in the field of permanent pacing. Alternatively, the implantation could be performed by a (cardiac) surgeon adequately trained. A trainee in an approved training environment should be supervised by a cardiologist.

Follow-up

The surveillance of patients after implantable cardioverter defibrillator implantation requires detailed knowledge of the programming of the device. Management of patients with automatic antitachycardia devices should be restricted to cardiologists trained in clinical electrophysiology and cardiac pacing and who have had additional training in the specific problems of implantable cardioverter defibrillators.

Training requires a period of at least one year in a full-time position in a centre fulfilling the requirements for a training centre. During this period, the trainee should participate him/herself in the implantation of 20 or more implantable cardioverter defibrillators and the follow-up of at least 20 patients with implantable cardioverter defibrillators. A record of the training should be signed by the programme director and should detail the practical and theoretical teaching received by the trainee.

Audit of the activity of the implanting centre

A centre involved in the use of implantable cardioverter defibrillators should record the clinical data and investigations on which the implantation decision was based, and should have detailed records of the device types, the lead configuration and reference and the parameters initially programmed. After the implantation, a follow-up card should be given to the patient. It should identify the implanting centre, the operator, relevant clinical data in a coded form if necessary and the parameters programmed or recorded during the follow-up. This would be ideally fulfilled by a European Card for implantable cardioverter defibrillator patients.

A system for 'defibrillation vigilance' should be developed at the same time, as in the case of cardiac pacing. The ability to detect a device or lead failures as early as possible constitutes an additional factor of patient safety. Some of these failures may be isolated but others may be serial and require (if confirmed) recall by manufacturers and the intervention of the warranty. Participation of the implanting centre in the European Registry on implantable cardioverter defibrillator (EURID) should be regarded as mandatory.

References


Appendix

These guidelines, first drafted by Samuel Lévy, Richard Hauer and Antonio Ravielle, underwent extensive review by the Writing Committee. They were then submitted to the members of the Study Group and to the chairman.

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Presidents of National Societies were asked to provide details of existing guidelines and regulations in the different European countries. The manuscript underwent the usual reviewing process of the European Heart Journal. Its contents represent the opinion of the study group and does not necessarily represent the official opinion of the European Society of Cardiology.

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