Clinical competency statement: Training pathways for implantation of cardioverter defibrillators and cardiac resynchronization devices

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Implantable cardioverter defibrillators (ICDs) are widely used for the management of patients with life-threatening ventricular arrhythmias.[1] The indications for ICD therapy are expanding as the results of clinical trials for primary prevention of sudden cardiac death have shown that survival is improved in patients with serious heart disease when ICDs are implanted prophylactically, i.e. before a patient has had a potentially lethal arrhythmia.[2–4] The results of these clinical trials will continue to be incorporated into the current and upcoming American College of Cardiology/American Heart Association/North American Society of Pacing and Electrophysiology Guidelines for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices.[5]

Another important recent development in cardiac pacing has been resynchronization therapy. It has been found that ventricular dyssynchrony, a common finding in patients with heart failure, can be corrected by pacing the left ventricle via a branch of the coronary sinus simultaneously or near-simultaneously with standard right ventricular pacing. Clinical trials of cardiac resynchronization therapy (CRT) have demonstrated improvements in quality of life, New York Heart Association class, and exercise capacity when compared to standard medical therapy in patients with heart failure and intra- and interventricular conduction delays.[6,7]

As increasing numbers of patients receive these devices, it is necessary that physicians involved in the care of these patients have knowledge and expertise in the indications, techniques for implantation, complications, programming and follow-up of these devices. Completion of a fellowship in clinical cardiac electrophysiology is clear evidence of such training. However, there has been increasing interest in training pathways for ICD implantation and CRT by non-electrophysiologists in order to accommodate the large number of patients who could potentially benefit from these devices based on recent clinical trial results.

If physicians other than electrophysiologists are to engage in ICD and CRT device implantation, there is a need to develop a clinical competency statement relating to these modalities to help guide the training of such individuals. With this in mind, the Heart Rhythm Society (HRS) Board of Trustees commissioned a task force that included HRS members, representatives from the Heart Failure Society of America and industry. The purpose of the task force was to develop a training pathway for ICD implantation for prophylactic indications and CRT for cardiologists who are already experienced in pacemaker implantation.

The task force developed initial recommendations that were presented to the HRS Board of Trustees. A subgroup of the Board of Trustees then developed the final document that was presented to the Board of Trustees for approval. The HRS Board of Trustees approved the document on May 18, 2004.

Physicians currently in cardiovascular training programs

Guidelines already exist for physicians in training who want to be credentialed to implant pacemakers, ICDs, and cardiac resynchronization devices at the end of fellowship training. Nothing in this document is intended to replace the requirements that have already been published for physicians in

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training. The COCATS guidelines for training in adult cardiology have recently been revised.[10] As described in that document, training in device implantation that is applicable to level 2 or level 3 training includes, in addition to didactic training, 50 primary pacemaker implantations, 20 pacemaker system revisions or replacements, 100 pacemaker follow-up visits, 25 primary ICD implantations, 10 ICD revisions or replacements, and a minimum of 50 ICD follow-up visits. These recommendations are concordant with those in the NASPE Policy Statement: Training Requirements for Cardiac Implantable Electronic Devices: Selection, Implantation, and Follow-up[11] and the NASPE Clinical Competency Statement for ICD Implantation and Follow-up.[12] For CRT, the recommended number of supervised implants during training is 15.[11]

Table 1 Curriculum content for training in ICD and CRT implantation

- Review of current, basic knowledge required for previous NASPE definition of a Level I and Level II trained physician
- Indications for ICD therapy
- Indications for CRT
- Review of implant techniques, including coronary sinus lead placement
- Defibrillation threshold testing (DFT)
- Review of external defibrillation techniques
- ICD sensing
- Basics of programming
- ICD emergencies
- Hands-on programmer workshop
- Assessment of biventricular and univentricular pacing thresholds
- Programming CRT devices
- ICD troubleshooting

Alternate training track for ICD and CRT implantation for non-electrophysiologists

It is acknowledged that there are physicians in practice who are already experienced pacemaker implanters yet who have not completed formal training in clinical cardiac electrophysiology. There can be a variety of reasons why such physicians would want to implant ICDs or cardiac resynchronization devices, such as the increasing demand for implantation of ICDs based on recent clinical trial data or the lack of availability of a formally trained electrophysiologist in the area. For such physicians, adding the technical skills required to implant ICDs or coronary sinus leads may not be exceptionally difficult, yet technical skill for implantation alone is clearly insufficient to be credentialed to implant ICD or CRT devices. In particular, implantation of ICDs with no formal didactic education or technical training is not optimal for patient safety or optimal outcomes, no matter how many pacemakers a physician implants.

It should be emphasized that the guidelines outlined below do not pertain to physicians in practice with no device implant experience, but rather only to "experienced implanters," as defined below. A specific example would be the heart failure specialist in practice without any prior training or experience in device implantation. This individual would still need to fulfill the basic requirements for device implantation as outlined in the section above entitled, "Physicians Currently in Cardiovascular Training Programs."

Definition of experienced implanter

For any invasive or surgical procedure, larger volumes performed by an individual physician are usually associated with a lower complication rate and may be correlated with a better outcome for the patient. In limited studies, there is clear cut evidence that pacemaker complications become much more common among physicians who implant <12 pacemakers/year.[13–18] While implantation rates over 12/year may be associated with acceptable complication rates, it has also been shown that more experienced implanters (≥ 30 pacemakers/year) are more likely to use advanced programming features in devices and require less support from industry.[17] ICD and CRT systems are clearly more sophisticated devices than standard pacemakers and the consequences of inadvisable programming or device malfunction are potentially dire for the patient, e.g., lethal arrhythmias that are inadequately treated by the ICD, or inappropriate patient shocks that lead to substantial morbidity. Based on the data, the Board of Trustees of the Heart Rhythm Society defines an experienced pacemaker implanter as one who implants a minimum of 35 pacemakers a year, with a minimum of 100 implants over the preceding three years.

In addition to having current privileges to implant permanent pacemakers and having the minimum volume of procedures stated above, the physician must have a documented systematic approach to follow-up of pacemaker patients, either by following them personally or by making arrangements for each patient to have follow-up in some other appropriate manner.

Training pathway for ICD implantation by experienced pacemaker implanters

This training pathway should be considered for pacemaker implanters who wish to implant ICDs for prophylactic indications exclusively, i.e. for patients who are at high risk for a life-threatening ventricular arrhythmia but who have not yet experienced an event. For patients who have had sustained ventricular tachycardia or fibrillation, management can be quite challenging, and such patients should be cared for by an experienced clinical cardiac electrophysiologist.

There are a number of important considerations involved in designing these recommended requirements for training

for ICD implantation to maximize patient safety and optimize outcome. There is proper patient selection and device selection, surgical aspects of device implantation, management of problems and emergencies during implantation, and follow-up, including programming and troubleshooting. Some of these items can be dealt with in didactic courses, but others require hands-on experience with implantation. In addition, it is important not only that the physician be competent in ICD implantation, but also that all the technical and nursing staff be competent to handle ICD implantations. Required skills include, among others, conscious sedation and management of emergencies such as inability to defibrillate a patient using the ICD.

Current ACLS certification is strongly recommended but not required. Didactic course work, including CME certification, is required. Such course work cannot be provided directly by industry. Some of the content required as part of a didactic course on ICD implantation is outlined in Table 1. The course must have a formal assessment as part of the course, either during the course or to be submitted after the course that tests the individual on the course content. A CME certificate should not be provided until the assessment is passed successfully. The didactic course as well as the assessment examination should be sponsored or endorsed by the Heart Rhythm Society. Alternatively, successful passing of the NASPExAM, which tests knowledge in pacemakers and defibrillators, would provide evidence that the physician has the knowledge base for ICD implantation and follow-up.

While satisfactory completion of didactic course work is necessary in order to have the knowledge to properly select, implant, and follow ICDs, course work alone is not sufficient to be credentialed to implant ICDs. The experienced pacemaker implanter who wants to implant ICDs must be proctored for a minimum number of implants prior to proceeding independently. While physicians in cardiovascular training programs are required to participate in a minimum of 25 new ICD implantations and 10 revisions, these requirements were set in the context of physicians who have no prior device implantation experience. The Board of Trustees of the Heart Rhythm Society believes that physicians who meet the definition of an experienced pacemaker implanter as defined in this document already have extensive experience in most relevant surgical aspects of ICD implantation, such as venous access, formation of a pocket, placement of standard pacing leads, and interpretation of electrical measurements. Therefore, the additional skills required for placement of an ICD lead and defibrillation threshold testing do not require performance of a full 25 implantations to perform the procedure safely. Thus, experienced pacemaker implanters should be proctored by a physician experienced in ICD/CRT implantation for a minimum of 10 ICD implants, with at least 2 of those implantations being performed at the hospital where the physician will be performing the ICD implantations, in order to assure that the technical staff has the requisite skills as well. Since there are unique issues in ICD revisions compared to pacemaker revisions, such as the need to test defibrillation thresholds (DFTs) and evaluation of sensing problems, it is recommended that a minimum of 5 ICD revisions be done in a proctored setting as well. Monitoring of patient outcomes, operator complications, and the ability to complete the procedure in a safe and timely fashion is essential as well. These requirements for documentation of training and competence are summarized in Table 2. A physician experienced in ICD/CRT implantation who qualifies as a proctor should have graduated from an ACGME certified training program that meets the COCATS guidelines in electrophysiology and/or device implantation, be at least two years out of training, currently implanting a minimum of 25 ICDs a year and following a minimum of 50 ICD patients a year personally.

Table 2 Summary of requirements for alternate training pathway for ICD and CRT implantations

- Documentation of current experience: 35 pacemaker implantations per year and 100 implantations over the prior 3 years
- Proctored ICD implantation experience
  - 10 Implantations
  - 5 Revisions
- Proctored CRT implantation experience: 5 implantations
- Completion of didactic course and/or NASPExAM
- Monitoring of patient outcomes and complication rates
- Established patient follow-up
- Maintenance of competence
  - 10 ICD and CRT procedures per year
  - 20 patients per year in follow-up

Requirements for CRT implantation

With respect to CRT, the majority of patients eligible for such devices will also be candidates for prophylactic ICDs, and the requirements above hold for physicians desiring to implant resynchronization ICDs. For experienced pacemaker implanters who want to implant left ventricular leads for resynchronization therapy, it is recommended in addition that at least 2 procedures be observed and that the physician perform at least 5 coronary sinus lead placements in a proctored setting, as recommended previously.[11] If an experienced pacemaker implanter is proctored for a resynchronization ICD, that proctored implant may count toward both the numbers needed for ICD implants as well as for CRT devices. Monitoring of patient outcomes and success rates for adequate coronary sinus lead implantation is essential. A didactic course in CRT that meets CME criteria must also be completed.

ICD programming and follow-up

ICD programming prior to discharge of a post-procedure patient from the hospital should be limited to bradycardia

parameters and defibrillation therapy only. It is recognized that antitachycardia pacing (ATP) therapy, when programmed empirically, can result in better patient acceptance of therapy through avoidance of shocks.[19] However, ATP can also result in acceleration of ventricular tachycardia with syncope and hemodynamic compromise. Therefore, ATP should be prescribed only in consultation with the electrophysiologist who will be involved in the follow-up care of the patient.

Requirements for follow-up of patients after hospital discharge

ICD follow-up for each patient must be established prior to leaving the hospital. Routine follow-up for patients who have had no serious events can be accomplished by an experienced pacemaker implanter with proper education. Such follow-up includes device interrogation and reprogramming, including evaluation of pacing thresholds, lead impedances, sensing, and rate cut-offs for defibrillation therapy. Establishment of a relationship with an electrophysiologist in the area willing to assume follow-up care of these individuals is also essential for any patient problems that may develop. Once defibrillator discharge has occurred, the patient should be referred for follow-up to a fully trained electrophysiologist. In addition, patients with CRT devices whose heart failure symptoms do not improve or appear to worsen at follow-up should be referred to a fully trained electrophysiologist and consultation with a heart failure specialist should be considered as well.

Documentation of successful completion of training requirements

Fulfillment of the guidelines will be demonstrated prior to commencement of unsupervised ICD and/or CRT implants and will require submission of the following to the hospital credentialing body:

- Letter and documentation of current experience and privileges
- Certificate from endorsed CME program that the individual has completed the course and associated testing and/or successful passing of NASPExAM
- Letter from an appropriate proctor documenting successful completion of the required number of proctored implants
- Letter documenting the follow-up plan and a corresponding or co-signed letter from the electrophysiologist with whom the individual will be collaborating

Maintenance of competence

A minimum of 10 ICD procedures and 10 CRT devices per year is necessary in order to maintain competency in these procedures. Physicians who fall below the numbers of implants required to maintain competence should retrain with an appropriate proctor for a minimum of five implants. Physicians should follow a minimum of 20 patients per year each with ICDs and CRT devices in order to maintain proficiency in device programming and follow-up. Continuing medical education is also essential in order to keep abreast of new devices, technologies, and programming features to maximize patient benefit. A minimum of two hours of CME per year should be obtained in ICD and CRT devices in order to maintain the knowledge base necessary for optimal patient outcomes.

Summary

ICDs are complicated devices that provide life-saving therapy for patients with a documented history of ventricular arrhythmias or for prophylaxis against sudden cardiac death in patients with serious structural heart disease. CRT devices improve symptoms and quality of life in patients with heart failure. Both modalities require special expertise not only in the techniques of implantation, but also a core of knowledge in the indications for the devices as well as programming and proper follow-up. These guidelines are intended to provide a pathway for non-electrophysiologists already experienced in pacemaker implantations to obtain the skills and knowledge to implant ICD and CRT devices safely and to provide effective therapy to patients in follow-up.

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