

Procedure

Clinical Privilege White Paper

Cardiac Stereotaxis

Background

Cardiac stereotaxis involves using a magnetic navigation system during catheter-based diagnostic or interventional cardiac procedures for the treatment of coronary artery disease and arrhythmias. Computer-controlled, externally applied magnetic fields govern the motion of the working tip of the catheter or guidewire, resulting in improved navigation, shorter procedure time and reduced x-ray exposure. The system enables electrophysiologists to complete more complex procedures by providing direct digitally guided delivery of catheters and guidewires through the blood vessels and chambers of the heart to treatment sites.

A physician performing a cardiac stereotaxis procedure is not in the room with the patient. The procedure is conducted remotely, at a control panel, which allows the physician to view a three dimensional image of the patient's heart during the procedure without being exposed to radiation. The physician uses a joystick or other steering device to maneuver two magnets alongside the patient's body, creating a magnetic field which draws the magnet-tipped guidewire or catheter through the patient's vessels. This magnetic method of directing movement permits the guidewire or catheter to make sharp turns, as the movement of the device is not limited by physician dexterity.

Manually guided catheter based diagnostic or interventional procedures require the physician to directly feed the guidewire into the patient's heart. If the patient has an atypical anatomy or severe disease—such as narrow vessels, curving arteries or complete occlusions—the manually guided procedure will require more time and greater skill to perform, and the risk of complications increases. The physician may not be able to complete the procedure through minimally invasive means, and the patient's only remaining option may be open heart surgery. Use of the NIOBE magnetic navigation system preserves the minimally invasive surgical option for patients with severe occlusion or atypical anatomy. In addition, cardiac stereotaxis procedures are generally less lengthy than procedures performed manually, and so efficiency in the cardiac catheterization lab is increased.

Stereotaxis Inc, of St. Louis MO, developed the first magnetic navigation system, NIOBE. The NIOBE system received initial FDA approval in 2003. The NIOBE system has been ordered by, or is in use at, over 80 medical centers around the world. Hansen Medical Inc. of Mountain View Ca received FDA permission to market its Hansen Medical Catheter Control System in March, 2007. The Hansan system is robotically controlled catheter guidance.

Involved specialties

Cardiac electrophysiology

Positions of societies and academies

ACC

The American College of Cardiology is a professional medical organization devoted to the field of cardiology. The mission of the American College of Cardiology is to advocate for quality cardiovascular care—through education, research promotion, development and application of standards and guidelines—and to influence health care policy. Members of ACC are physicians with special education, training and interest in the practice of cardiology.

ACC offers no specific guidance regarding training in the use of stereotaxis technology in the performance of cardiac procedures. However, the procedures that may be performed using stereotaxis technology require a specific understanding of, and competency in, principles of cardiac electrophysiology. In its Clinical Competence Statement on Invasive Electrophysiology Studies, Catheter Ablation, and Cardioversion, written in conjunction with the American Heart Association, the ACC set forth recommended training and competency standards for electrophysiologists. ACC recommends:

- a minimum of 1 year of specialized training in electrophysiology studies to acquire the cognitive and technical skills required to become expert in clinical cardiac electrophysiology, in addition to time spent during general cardiology fellowship training learning to diagnose and manage arrhythmias.
- during the specialized training year, each trainee should be a primary operator and analyze 100 to 150 initial diagnostic studies. At least 50 of these procedures should involve patients with supraventricular arrhythmias.
- the trainee should also have been a primary operator during ≥ 25 electrophysiological evaluations of implantable antiarrhythmic devices.
- the trainee's experience should be documented in writing and confirmed by the laboratory supervisor. For each procedure during the training period, the following facts should be documented: date, patient identification number, patient age, indication, type of procedure, findings, and complications.

Furthermore, the publication addresses the issue of obtaining and maintaining competency in emerging technologies, such as magnetic navigation through stereotaxis. It notes that “the majority of clinical electrophysiologists will first be exposed to, and begin using, emerging techniques and technologies outside of their training experience. As such, the skills required to record, compile, synthesize, integrate, render, interpret, and apply the resulting data will be acquired through alternative educational pathways.” Specifically, the ACC publication points out that the training required for proficiency in the application of new technologies and techniques will depend on the technology and procedures under consideration, and advises that developments in technology may require changes to formal training programs as the specific technology becomes more readily available.

Positions of other interested parties

ACGME

The Accreditation Council for Graduate Medical Education has no specific guidelines regarding the use of stereotaxis technology in cardiac procedures. However, in its *Program Requirements for Fellowship Education in Clinical Cardiac Electrophysiology*, the ACGME states that a subspecialty program in cardiac electrophysiology must function as an integral component of an accredited subspecialty fellowship in cardiovascular disease and must be organized to provide training and supervised clinical experience at

a level sufficient for the fellow to acquire the competency of a specialist in the field, and must be of one year duration.

Clinical experience

Fellows must have formal instruction, clinical experience and demonstrate competence in the prevention, evaluation, and management of both inpatients and outpatients with

- disorders of the cardiac rhythm, including sinus node dysfunction; atrioventricular and intraventricular block; and supraventricular and ventricular tachyarrhythmias
- unexplained syncope
- aborted sudden cardiac death
- palpitations
- Wolff-Parkinson-White syndrome
- Prolonged QT syndrome.

Fellows must have formal instruction, clinical experience and demonstrate competence in:

- Consultation to physicians in other disciplines
- Care of patients in the cardiac care unit, emergency room, or other intensive care settings
- Care of patients before and after an electrophysiologic procedure
- Care of patients with post-operative arrhythmias
- Outpatient follow-up of patients treated with drugs, devices or surgery
- Electrocardiography, proficiency in the interpretation of of standard 12-lead ECG, stress testing, ambulatory ECG recording, signal-average ECG, and telephone-transmitted ECGs
- Care of patients with temporary and permanent pacemakers
- Care of patients with ICDs.,

Technical and other skills

Fellows must have formal instruction, clinical experience and demonstrate competence in:

- Non-invasive testing relevant to arrhythmia diagnosis and treatment;
- Invasive electrophysiologic testing, including an average of three or more electrophysiology invasive diagnostic/interventional catheter procedures per week as the primary operator, or as an assistant closely involved with data collection and analysis; 150 intracardiac procedures,

which must include at least 75 studies related to supraventricular arrhythmia during these procedures

- Therapeutic catheter ablation procedures, a minimum of 75 procedures, that must include a mix of AV nodal reentrant tachycardia and accessory pathway modification, atrial tachycardia and atrial flutter, AV junctional ablation and modification, and ventricular tachycardia ablation.
- Implantation of cardioverters/defibrillators and pacemakers, a minimum of 25 initial ICD and 50 pacemaker procedures, plus device programming (minimum 100 interrogations), non-invasive program stimulation, defibrillation threshold testing, final prescription of anti-tachycardia pacing and defibrillation therapies.

ABIM

In addition to the primary certification in Internal Medicine, the American Board of Internal Medicine (ABIM) grants a certificate in the subspecialty of cardiac electrophysiology. To be awarded a certificate in cardiac electrophysiology, physicians must satisfy the following requirements:

- Have been previously certified in internal medicine by ABIM
- Maintain a current underlying certificate cardiovascular disease by ABIM
- Have satisfactorily completed the requisite training
- Demonstrated clinical competence in the care of patients
- Met the licensure and procedural requirements
- Passed the secure exam for that discipline

The ABIM requires three years of cardiovascular disease fellowship training, including 24 months of clinical training, in programs accredited by the Accreditation Council for Graduate Medical Education (ACGME) and one additional year of acceptable training in clinical cardiac electrophysiology completed July 1, 1992 or after.

To satisfy ABIM's certification requirements in electrophysiology, the applicant must demonstrate, in each year since completion of training, a commitment of at least 50% of professional time and effort to clinical cardiac electrophysiology, including balanced experience in a variety of clinical settings.

The clinical cardiac electrophysiology training must be conducted in a program that is accredited for training in cardiovascular disease by the ACGME. Training in clinical cardiac electrophysiology must include clinical activity either as the primary physician or as a consultant for/to patients with cardiac arrhythmias. The training must be supervised by a qualified electrophysiologist. The training should provide a balanced experience in a variety of clinical settings, including but not limited to the electrophysiology laboratory, emergency department, coronary care unit, operating room, and the follow-up clinic.

The program must be structured to permit the development of requisite procedural and technical skills, which are the learned manual skills and the associated technical aspects necessary to perform diagnostic and therapeutic procedures. Successful mastery of these essential skills also includes an understanding of the indications for electrophysiologic study, contraindications and complications, and the ability to monitor and interpret the results

Within the four years of training required for certification in both cardiovascular disease and clinical cardiac electrophysiology, three years must be clinical, of which 12 months must be in electrophysiology.

AOA

The American Osteopathic Association is a professional organization representing 59,000 osteopathic physicians (D.O.s). The AOA serves as the primary certifying body for D.O.s, and is the accrediting agency for all osteopathic medical colleges and health care facilities. The AOA's mission is to advance the philosophy and practice of osteopathic medicine by promoting excellence in education, research, and the delivery of quality, cost-effective healthcare within a distinct, unified profession.

The AOA has no specific recommendations regarding the use of stereotaxis technology in cardiac procedures, but it does specify education and training standards for fellowship programs training specialists in electrophysiology. In its publication "Program Requirements for Fellowship Education in Clinical Cardiac Electrophysiology," the AOA sets forth the following requirements for AOA-accredited residency programs in electrophysiology:

- the subspecialty educational program must function as an integral component of an accredited subspecialty fellowship in cardiovascular disease and must be organized to provide training and supervised clinical experience at a level sufficient for the fellow to acquire the competency of a specialist in the field
- All applicants to the subspecialty program must have completed a cardiovascular disease program accredited by the ACGME

Clinical requirements

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Krannert Institute of Cardiology

According to John M. Miller, MD, Director of Clinical Cardiac Electrophysiology at the Krannert Institute of Cardiology, part of the Indiana University Department of Medicine, cardiac stereotaxis technology is “another tool to help us do the things we do better, easier, safer.” He notes that for most procedures which may use stereotaxis—such as cardiac ablation for arrhythmias—standard training in arrhythmia ablation is essential. Specialists in electrophysiology and interventional cardiology have the requisite training in manually performed arrhythmia ablation.

With regard to specialized training in the NIOBE magnetic navigation system, Stereotaxis, Inc. provides training in the operation of the system. The training involves observation of live cases, and practice using models or phantoms, in which physicians are taught set up, principles of function, interface with computers, and actual operation of the controls. The company also provides a physician proctor to oversee the first few cases using the system.

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“Use of stereotaxis is limited to highly technical procedures, such as cardiac ablation,” Miller explains. “The bulk of what the operator needs to know in performing the procedure safely and effectively is gained during regular fellowship training, with the stereo action a relatively mild add-on.”

Miller believes that it is necessary to perform 20-30 cases using the stereotaxis system to acquire competence and comfort in using it. He suggests that “a couple of cases per month, ideally more” are required to maintain competence, confidence and skills.

Swedish Heart and Vascular Institute

Dr. Adam Zivin, an electrophysiologist at Swedish Medical Center in Seattle Washington, reports that his training in stereotaxis consisted of practice on a plastic phantom heart, and proctoring by a physician experienced with the system. He notes that “there is a fairly steep and long learning curve for the system because it is a different and unfamiliar way of manipulating the tools you are used to using.”

In Zivin’s experience, half a dozen procedures were necessary before he felt comfortable with the system. He suggests that physicians ought to be able to maintain their level of comfort and competence with the system if they perform procedures with it 2-3 times per month; but he cautions that “it’s too new a technology to have any sort of perspective” about how frequently the physician must use the system to maintain an appropriate skill level.

CRC draft criteria

The following draft criteria are intended to serve solely as a starting point for the development of an institution’s policy regarding this procedure.

Minimum threshold criteria for requesting special privileges in electrophysiology

Cardiac Stereotaxis

Basic Education: MD or DO

Minimum formal training: Applicants must be able to demonstrate successful completion of an ACGME or American Osteopathic Association approved residency program and certification by the American Board of Medical Specialties or the American Board of Osteopathic Internists in Internal Medicine. This must be followed by completion of a three year formal fellowship program in cardiology, and an additional one year sub-speciality training in electrophysiology.

Required previous experience: The successful applicant must be able to demonstrate that he or she has performed cardiac ablation procedures on at least 30 patients, at least 24 over the preceding twelve months .

References

A letter of reference should come from a representative of the Stereotaxis Inc. NIOBE training program. If the applicant completed electrophysiology fellowship training at an institution that offers cardiac stereotaxis training, a letter from the Director of the program verifying the applicant’s training and number of procedures performed using the NIOBE system should be obtained. If the applicant performed procedures using the NIOBE system at another institution, a letter from the

cardiac catheterization laboratory director verifying the applicant's competence and experience in the use of the system should be obtained.

Special privileges in cardiac stereotaxis

Privileges include being able to treat patients presenting with diseases or injuries of the heart and its vessels, using magnetic navigation system to place catheters.

Reappointment

Reappointment should be based on unbiased, objective results of care according to the organization's quality assurance mechanisms.

Applicants must be able to demonstrate that they have maintained competence by documenting that they have successfully performed cardiac stereotaxis procedures on at least 24 patients annually over the reappointment cycle.

In addition, continuing education related to electrophysiology and use of the cardiac stereotaxis system should be required.

For more information

For more information regarding this practice area contact:

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