Coronary atherectomy

Background

Coronary atherectomy is a minimally invasive, catheter-based procedure that removes plaque that is blocking an artery and blood supply to the heart. It is a treatment option for patients with coronary artery disease.

There are three kinds of catheters approved for coronary atherectomy procedures: directional, rotational, and transluminal extraction. A directional coronary atherectomy (DCA) device slices the plaque, a rotational coronary atherectomy (RCA) device uses a high-speed rotating cutter to remove the plaque, and a transluminal extraction catheter (TEC) atherectomy device cuts away plaque using tiny rotating blades.

According to MedlinePlus, the consumer website for the National Institutes of Health, a surgeon injects a local anesthetic into the groin area and advances a diagnostic catheter into the blood vessel. The surgeon places the catheter in the opening of one of the coronary arteries, injects dye, and takes an x-ray. If the surgeon determines that the blockage is treatable, one of the specialized catheters is inserted through the blockage site.

During a DCA, the surgeon inflates a low-pressure balloon attached to a catheter that has a small blade at the end of it. The surgeon can deflate and re-inflate the balloon to cut the blockage in any direction. The pieces of the blockage are stored within the catheter and removed after the procedure.

During an RCA, a high-speed rotating shaver is used to grind up the plaque, which is naturally removed by the body’s circulatory system.

During a procedure using a TEC, tiny rotating blades cut away plaque and pull it into a tube using a vacuum.

The surgeon may place a stent within the coronary artery to keep the vessel open. The procedure ends with the surgeon injecting contrast media and taking an x-ray to check for any change in the arteries. The catheter is then removed, and the procedure is complete.
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Involved specialties

Cardiologists and interventional cardiologists

Positions of specialty boards

To become certified in cardiovascular disease, the American Board of Internal Medicine (ABIM) requires physicians to:

- Hold certification in internal medicine by the ABIM at the time of application
- Satisfactorily complete the requisite graduate medical education fellowship training
- Demonstrate clinical competence in the care of patients
- Meet licensure and procedural requirements
- Pass the Certification Exam in Cardiovascular Disease

To become certified in interventional cardiology, the ABIM requires physicians to:

- Hold certification in internal medicine by ABIM and maintain a valid underlying certificate in cardiovascular disease by ABIM
- Satisfactorily complete the requisite graduate medical education fellowship training
- Demonstrate clinical competence in the care of patients
- Meet the licensure and procedural requirements
- Pass the Certification Exam in Interventional Cardiology

Fellowship training taken before completing the requirements for the MD or DO degree may not be credited toward the requirements for subspecialty certification. Additionally, candidates must complete the required training in the subspecialty, including vacation time, by October 31 of the year of examination.

The clinical training pathway requires 12 months of satisfactory clinical fellowship training in interventional cardiology completed July 1, 1997, or after, in addition to the required three years of accredited cardiovascular disease training.

Interventional cardiology training undertaken July 1, 2002, and thereafter must be accredited by the Accreditation Council for Graduate Medical Education (ACGME). Interventional cardiology training undertaken prior to July 1, 2002, must be conducted within an accredited cardiovascular disease fellowship program.

Beginning with the November 2000 examination, candidates who have been out of formal training three or more years as of June 30 of the year of examination or who were admitted to the examination under the former Practice Pathways must
document post-training performance as primary operator of at least 150 therapeutic interventional cardiac procedures in the two years prior to application for examination.

During training in interventional cardiology, the fellow must have performed at least 250 therapeutic interventional cardiac procedures, documented in a case list and attested to by the training program director. In addition, the training program director must judge the clinical skill, judgment, and technical expertise of the fellow as satisfactory.

Additionally, ABIM requires candidates for recertification to submit a form verifying their performance as primary operator, co-operator, or supervisor of 150 percutaneous coronary interventional cases in the two years prior to expiration of their certificate.

If interventional cardiologists are unable to meet this requirement, they may provide a procedural log of 25 consecutive cases, including outcomes, in which they have served as primary operator.

The documentation period for certificates expiring December 31, 2010, may start no earlier than July 1, 2008, and end no later than October 1, 2010.

The American Osteopathic Board of Internal Medicine (AOBIM) offers a certificate of added qualification in interventional cardiology. To receive the certificate, candidates must:

➤ Hold certification by the AOBIM in cardiology.
➤ Satisfactorily complete 12 months of an American Osteopathic Association-approved training program in interventional cardiology. This training must follow 36 months of training in cardiology and must occur in 1997 or later.
➤ Participate in a total case volume of a minimum of 300 cardiac interventional procedures and serve as the primary operator in a minimum of 200 of these cases during training.

In 2007, the American College of Cardiology Foundation (ACCF), the American Heart Association (AHA), and the Society for Cardiovascular Angiography and Interventions (SCAI) published an “Update of the Clinical Competence Statement on Cardiac Interventional Procedures.”
The document states that atherectomy devices augment conventional balloon angioplasty and extend its capability; however, they all require specific training and mentoring by a previously experienced operator. In order to become competent, the organizations state that an operator must acquire the additional knowledge and technical skills specific to each device.

The statement advises that coronary interventionalists must also have a thorough knowledge of specialized equipment, techniques, and devices used to perform percutaneous coronary interventions, including catheters, guide wires, balloon catheters, intra-aortic balloon pumps, puncture site sealing devices, contrast agents, distal protection devices, and thrombus extraction devices.

In addition, most of the technical skills that are unique to coronary interventional procedures can only be acquired during training and by actual procedures under the direction of an experienced interventionalist.

These include the manipulation and operation of guide catheters, coronary angioplasty guide wires, coronary angioplasty balloon catheters, specialized atherectomy devices, stents, and intracoronary ultrasound catheters. Such training appropriately occurs in standardized training programs that are ACGME-approved and lead to eligibility for board certification.

According to the American Osteopathic Association (AOA), a subspecialty training program in interventional cardiology is 12 months in duration with 11 months spent in the interventional cardiology laboratory. One month can be used for discretionary vacation or elective time.

The AOA states that the training program must establish preparation and performance of interventional cardiology procedures, including balloon angioplasty, intracoronary stent deployment, and rotational atherectomy. The use of extraction atherectomy, DCA, balloon valvuloplasty, peripheral angioplasty, and intravascular ultrasound is not required.

However, the AOA states that the trainee should take part in the performance of these procedures if they are available at the institution. The program must also include training on the selection and use of vascular access devices, guiding catheters, guide wires, and balloon catheters.
CMS has no formal position concerning the delineation of privileges for coronary atherectomy. However, the CMS Conditions of Participation (CoP) define a requirement for a criteria-based privileging process in §482.22(c)(6), stating, “The bylaws must include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.”

§482.12(a)(6) states, “The governing body must assure that the medical staff bylaws describe the privileging process. The process articulated in the bylaws, rules or regulations must include criteria for determining the privileges that may be granted to individual practitioners and a procedure for applying the criteria to individual practitioners that considers:

➤ Individual character
➤ Individual competence
➤ Individual training
➤ Individual experience
➤ Individual judgment

The governing body must ensure that the hospital’s bylaws governing medical staff membership or the granting of privileges apply equally to all practitioners in each professional category of practitioners.”

Specific privileges must reflect activities that the majority of practitioners in that category can perform competently and that the hospital can support. Privileges are not granted for tasks, procedures, or activities that are not conducted within the hospital, regardless of the practitioner’s ability to perform them.

Each practitioner must be individually evaluated for requested privileges. It cannot be assumed that every practitioner can perform every task, activity, or privilege specific to a specialty, nor can it be assumed that the practitioner should be automatically granted the full range of privileges. The individual practitioner’s ability to perform each task, activity, or privilege must be individually assessed.

CMS also requires that the organization have a process to ensure that practitioners granted privileges are working within the scope of those privileges.

CMS’ CoPs include the need for a periodic appraisal of practitioners appointed to the medical staff/granted medical staff privileges (§482.22[a][1]). In the absence of a state law that
establishes a time frame for the periodic appraisal, CMS recommends that an appraisal be conducted at least every 24 months. The purpose of the periodic appraisal is to determine whether clinical privileges or membership should be continued, discontinued, revised, or otherwise changed.

The Joint Commission

The Joint Commission (formerly JCAHO) has no formal position concerning the delineation of privileges for coronary atherectomy. However, in its Comprehensive Accreditation Manual for Hospitals, The Joint Commission states, “The hospital collects information regarding each practitioner’s current license status, training, experience, competence, and ability to perform the requested privilege” (MS.06.01.03).

In the introduction for MS.06.01.03, The Joint Commission states that there must be a reliable and consistent system in place to process applications and verify credentials. The organized medical staff must then review and evaluate the data collected. The resultant privilege recommendations to the governing body are based on the assessment of the data.

The Joint Commission introduces MS.06.01.05 by stating, “The organized medical staff is responsible for planning and implementing a privileging process.” It goes on to state that this process typically includes:

- Developing and approving a procedures list
- Processing the application
- Evaluating applicant-specific information
- Submitting recommendations to the governing body for applicant-specific delineated privileges
- Notifying the applicant, relevant personnel, and, as required by law, external entities of the privileging decision
- Monitoring the use of privileges and quality-of-care issues

MS.06.01.05 further states, “The decision to grant or deny a privilege(s) and/or to renew an existing privilege(s) is an objective, evidence-based process.”

The EPs for standard MS.06.01.05 include several requirements as follows:

- The need for all licensed independent practitioners who provide care, treatment, and services to have a current license, certification, or registration, as required by law and regulation
- Established criteria as recommended by the organized medical staff and approved by the governing body with
specific evaluation of current licensure and/or certification, specific relevant training, evidence of physical ability, professional practice review data from the applicant’s current organization, peer and/or faculty recommendation, and a review of the practitioner’s performance within the hospital (for renewal of privileges)
➤ Consistent application of criteria
➤ A clearly defined (documented) procedure for processing clinical privilege requests that is approved by the organized medical staff
➤ Documentation and confirmation of the applicant’s statement that no health problems exist that would affect his or her ability to perform privileges requested
➤ A query of the NPDB for initial privileges, renewal of privileges, and when a new privilege is requested
➤ Written peer recommendations that address the practitioner’s current medical/clinical knowledge, technical and clinical skills, clinical judgment, interpersonal skills, communication skills, and professionalism
➤ A list of specific challenges or concerns that the organized medical staff must evaluate prior to recommending privileges (MS.06.01.05, EP 9)
➤ A process to determine whether there is sufficient clinical performance information to make a decision related to privileges
➤ A decision (action) on the completed application for privileges that occurs within the time period specified in the organization’s medical staff bylaws
➤ Information regarding any changes to practitioners’ clinical privileges are updated as they occur

The Joint Commission further states, “The organized medical staff reviews and analyzes information regarding each requesting practitioner’s current licensure status, training, experience, current competence, and ability to perform the requested privilege” (MS.06.01.07).

In the EPs for standard MS.06.01.07, The Joint Commission states that the information review and analysis process is clearly defined and that the decision process must be timely. The organization, based on recommendations by the organized medical staff and approval by the governing body, develops criteria that will be considered in the decision to grant, limit, or deny a request for privileges. The criteria must be consistently applied and directly
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relate to the quality of care, treatment, and services. Ultimately, the governing body or delegated governing body has the final authority for granting, renewing, or denying clinical privileges. Privileges may not be granted for a period beyond two years.

Criteria that determine a practitioner’s ability to provide patient care, treatment, and services within the scope of the privilege(s) requested are consistently evaluated.

The Joint Commission further states, “Ongoing professional practice evaluation information is factored into the decision to maintain existing privilege(s), to revise existing privileges, or to revoke an existing privilege prior to or at the time of renewal” (MS.08.01.03).

In the EPs for MS.08.01.03, The Joint Commission says there is a clearly defined process facilitating the evaluation of each practitioner’s professional practice, in which the type of information collected is determined by individual departments and approved by the organized medical staff. Information resulting from the ongoing professional practice evaluation is used to determine whether to continue, limit, or revoke any existing privilege.

HFAP

The Healthcare Facilities Accreditation Program (HFAP) has no formal position concerning the delineation of privileges for coronary atherectomy. The bylaws must include the criteria for determining the privileges to be granted to the individual practitioners and the procedure for applying the criteria to individuals requesting privileges (standard 03.01.09). Privileges are granted based on the medical staff’s review of an individual practitioner’s qualifications and its recommendation regarding that individual practitioner to the governing body.

It is also required that the organization have a process to ensure that practitioners granted privileges are working within the scope of those privileges.

Privileges must be granted within the capabilities of the facility. For example, if an organization is not capable of performing open-heart surgery, no physician should be granted that privilege.

In the explanation for standard 03.01.13 related to membership selection criteria, the HFAP states, “Basic criteria listed in the bylaws, or the credentials manual, include the items listed in this standard. (Emphasis is placed on training and competence in the requested privileges.) The bylaws also define the mechanisms by
which the clinical departments, if applicable, or the medical staff as a whole establish criteria for specific privilege delineation.”

Periodic appraisals of the suitability for membership and clinical privileges is required to determine whether the individual practitioner’s clinical privileges should be approved, continued, discontinued, revised, or otherwise changed (standard 03.00.04). The appraisals are to be conducted at least every 24 months.

The medical staff is accountable to the governing body for the quality of medical care provided, and quality assessment and performance improvement (standard 03.02.01) information must be used in the process of evaluating and acting on re-privileging and reappointment requests from members and other credentialed staff.

**DNV**

DNV has no formal position concerning the delineation of privileges for coronary atherectomy.

MS.12 Standard Requirement (SR) 1 states, “The medical staff bylaws shall include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to those individuals that request privileges.”

The governing body shall ensure that under no circumstances is medical staff membership or professional privileges in the organization dependent solely upon certification, fellowship, or membership in a specialty body or society.

Regarding the Medical Staff Standards related to clinical privileges (MS.12), DNV requires specific provisions within the medical staff bylaws for:

- The consideration of automatic suspension of clinical privileges in the following circumstances: revocation/restriction of licensure; revocation, suspension, probation of a DEA registration; failure to maintain professional liability insurance as specified; and noncompliance with written medical record delinquency/deficiency requirements
- Immediate and automatic suspension of clinical privileges due to the termination or revocation of the practitioner’s Medicare/Medicaid status
- Fair hearing and appeal

The Interpretive Guidelines also state that core privileges for general surgery and surgical subspecialties are acceptable as long as the core is properly defined.
DNV also requires a mechanism (outlined in the bylaws) to ensure that all individuals provide services only within the scope of privileges granted (MS.12, SR.4).

Clinical privileges (and appointments or reappointments) are for a period as defined by state law or, if permitted by state law, not to exceed three years (MS.12, SR.2).

Individual practitioner performance data must be measured, utilized, and evaluated as a part of the decision-making for appointment and reappointment. Although not specifically stated, this would apply to the individual practitioner’s respective delineation of privilege requests.

Suresh Mulukutla, MD, is an assistant professor of medicine at the University of Pittsburgh Division of Cardiology. His clinical interests are in the areas of interventional cardiology with a focus on percutaneous coronary interventions.

Mulukutla says that although manufacturers developed coronary atherectomy devices to debulk lesions and remove plaque, surgeons now use the devices to help pass equipment.

According to Mulukutla, DCA is a procedure that is no longer widely used. He reports that DCA procedures became popular in the 1990s.

Although the initial studies were positive, they were later found to be flawed because the procedure proved to have an increase in complications associated with it. As a result, he says DCA was used in “niche circumstances” for specific types of plaque and angiographic findings.

“This was an angioplasty-only era for treating coronary disease,” Mulukutla states. “Because of the limitations of chest balloon angioplasty, a number of different techniques—one of them DCA—were developed.”

As a result, he states that there used to be DCA training courses, but he isn’t aware of any that currently exist since the procedure’s usefulness has greatly diminished.

According to Mulukutla, interventional cardiologists use RCA procedures more than DCA procedures. “When you have some-
one who has a really calcified blockage, it’s somewhat difficult to pass the equipment down,” he says. “We tend to use RCA in those situations because that helps to score the lesion to allow you to pass the stent equipment down.”

In regards to RCA, a course is sponsored yearly by a variety of manufacturers that provide training on how the device works, Mulukutla says. After training, physicians need experience in the catheterization laboratory, he adds.

“We have our fellows perform between 10 and 15 rotational atherectomy procedures every year,” he says. “Whenever someone happens to have a patient who needs a rotational atherectomy, the fellow will come in and help do the procedure.”

In order to initially become proficient with coronary atherectomy, Mulukutla says that a fellow should complete 10–20 procedures per year during training. However, it takes more than that to become adept at applying the devices to the right scenarios. To maintain proficiency, a physician should perform two to four procedures per year, he says.

“Once you get comfortable with how the device works, it’s relatively straightforward in terms of how to set it up and how to proceed from there,” Mulukutla states. “The main issue is how to deal with complications that may occur.”

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 coronary atherectomy. The core privileges and accompanying procedure list are not meant to be all-encompassing. They define the types of activities, procedures, and privileges that the majority of practitioners in this specialty perform. Additionally, it cannot be expected or required that practitioners perform every procedure listed. Instruct practitioners that they may strike through or delete any procedures they do not wish to request.

Basic education: MD or DO.

Minimal formal training: The applicant must demonstrate successful completion of an ACGME- or AOA-accredited internal medicine residency program followed by completion of a training program in cardiology. Interventional cardiologists must successfully complete a fellowship program in interventional cardiology.

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Required current experience: Demonstrated current competence and evidence of the performance of at least four coronary atherectomy procedures during the previous 12 months or completion of training in the past 12 months.

References

If the applicant is recently trained, a letter of reference should come from the director of the applicant’s training program. Alternatively, a letter of reference may come from the applicable department chair and/or clinical service chief at the facility where the applicant most recently practiced.

Reappointment

Reappointment: Reappointment should be based on unbiased, objective results of care according to a hospital’s quality assurance mechanism.

Applicants must be able to demonstrate that they have maintained competence by documenting that they have successfully performed at least four coronary atherectomy procedures annually over the reappointment cycle.

In addition, continuing education related to coronary atherectomy should be required.

For more information

For more information regarding this procedure, contact:

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American Osteopathic Association
142 East Ontario Street
Chicago, IL 60611
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Website: www.osteopathic.org
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American Osteopathic Board of Internal Medicine
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Centers for Medicare & Medicaid Services
7500 Security Boulevard
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Healthcare Facilities Accreditation Program
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The Joint Commission
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