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ACC POLICY STATEMENT

Recommendations for Peripheral Transluminal Angioplasty: Training and Facilities

AMERICAN COLLEGE OF CARDIOLOGY PERIPHERAL VASCULAR DISEASE COMMITTEE

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Introduction

The strong national commitment to excellence in health care requires resources and personnel that far exceed those that are available. Therefore, numerous decisions must be made regarding priorities and resource utilization. The medical profession must participate in these determinations, including the examination of the impact of developing technology on the practice and cost of medical care. Such analyses, carefully conducted, could potentially influence the expenditures and the effectiveness of medical care.

The following information provides a guide to the physician qualifications needed to perform peripheral vascular interventions, particularly angioplasty, with attention directed toward physician skill development (during training or postgraduate study), the radiologic facilities required to perform interventional procedures and the establishment of a hospital-based registry to permit peer review.

To this end, the American College of Cardiology as well as other organizations such as the American Heart Association, the Society for Cardiac Angiography and Intervention and the Society of Cardiovascular and Interventional Radiology established, in 1989, subcommittees on peripheral vascular disease and peripheral vascular interventions to address some of these concerns.

Training and Credentialing

Cardiovascular interventional techniques require specialized skills and training in diagnostic angiographic as well as diagnostic and therapeutic cardiovascular medicine. Although the majority of individuals currently performing angioplasty learned the technique by observing experts, participating in individual tutorials and attending "how-to" seminars, the complexity of the procedures and the recognized need for hands-on experience dictate that formal training programs in peripheral angioplasty and other vascular interventions become the standard means of learning. Entrance requirements to such programs should require the completion of a structured cardiovascular (cardiology) or radiology fellowship program. Alternatively, formal training should be part of a vascular surgery residence program entered after board certification in general surgery, or a vascular medicine fellowship program entered after board certification in internal medicine.

A growing consensus within the cardiovascular medicine community suggests that the performance of peripheral angioplasty requires the individual to take additional instruction that includes the natural history of and the anatomic changes occurring with vascular disease, noninvasive patient assessment, the indications for and risks and benefits of different therapeutic modalities (including conservative measures, angioplasty, surgical techniques, other interventional techniques and the indications for the use of and management of thrombolytic agents).

A desirable experience for a single physician to demonstrate and maintain competence and proficiency is estimated to be about one case/week with continued performance dependent on the success and complication rates compiled by a hospital data registry and compared biannually with expected standards. Regular attendance at postgraduate seminars would provide continuing education in new endovascular techniques and equipment.

Responsible leadership of health care institutions offering peripheral angioplasty as part of their health care program should insist on the documentation of accredited training and maintenance of physician skills. The practice of peripheral angioplasty by the untrained physician should be avoided; it is risky and contrary to patient welfare and good medical practice.

A training program chief's written assurance that a physician has learned a procedure during the training phase

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provides the requisite information for the credentialing committee to grant the appropriate type of privileges (i.e., probational, temporary and, subsequently, regular [renewable] full privileges), a situation that differs for a new procedure once a physician has completed his or her formal training. As various specialties merge, and as different modalities of diagnosis or therapy develop, individual physicians must be able to study and utilize these new modalities for better patient care. Therefore, there should be multiple tracks to enable physicians to obtain these privileges at various stages in their career.

Suggested guidelines for the performance of percutaneous transluminal angioplasty and related interventional procedures are:

I. Physician Qualifications.
   1. Physicians should have accomplished the following to obtain peripheral angioplasty privileges:
      a. The physician-in-training (in a formal fellowship program) should provide the hospital with a list of patients, including the total number of cases he or she attended and/or served as primary operator, the sites (lesions) treated and the complications encountered. This information should be accompanied by a letter from the program director stating that the physician was adequately trained and should be capable of performing peripheral angioplasty independently. A physician who does not meet these requirements should enter the postgraduate section (1, 1b)
         i. Angiographic experience: A desired number of 100 diagnostic peripheral angiograms and 50 peripheral angioplasty procedures should have been performed under the supervision of an experienced peripheral interventionist (with >50% performed as primary operator). The physician should also have had experiences in 10 cases of peripheral thrombolytic therapy and management.
      b. Postgraduate physicians with or without prior peripheral angiographic experience and without previous peripheral angioplasty experience should have:
         i. Attended at least two peripheral angioplasty seminars, including one with live case demonstrations; learned the nature of and anatomy of peripheral vascular disease and its natural history, the indications for and risks and benefits of alternative therapies; learned to perform noninvasive patient evaluation; visited a laboratory in which peripheral angioplasty was actively being performed by experienced personnel; and observed at least 10 peripheral angioplasty procedures.
         ii. Angiographic experience: A desired number of 100 diagnostic peripheral angiograms and 50 peripheral angioplasty procedures should have been performed under the supervision of an experienced peripheral interventionist (with >50% performed as primary operator). The physician should also have had experience in 10 cases of peripheral thrombolytic therapy management.

II. Suggested Recommendations for Peripheral Vascular Intervention Patient Registry (Quality Assurance).

Maintenance of peripheral angioplasty privileges could be dependent on the physician's active participation in a Joint Commission on Accreditation of Health Care Organizations–mandated quality assurance program.

A hospital peripheral angioplasty and vascular intervention data registry, its costs borne by the hospital, should be established to:

1. Enroll all patients who undergo peripheral angioplasty and other peripheral interventions.
2. Compile statistics from a data base form including data on clinical characteristics, pertinent medical and surgical history and appropriate medical examination findings.
3. Record angioplasty data including information on angioplasty site, angiographic and clinical success, transstenotic/occlusion, pressure measurements and procedural complications (e.g., renal failure, stroke, bleeding problems, entry site repair, emergency bypass surgery, death).
4. Obtain clinical follow-up (by telephone, letter, interview, office visit) after hospital discharge at 1 week, 3 months and 1 year.
5. All cases must be entered into the peripheral angioplasty vascular intervention data registry and the data reviewed on an annual or biannual basis by a peer review panel. This panel should forward its observations to the section, department or hospital committee. These data should be reviewed, with physicians listed by a code known only to the director of the registry. If the results are acceptable, then credentials and privileges should be reviewed and renewed on a biannual basis.

III. Minimal Requirements for Radiologic Facilities for Peripheral Angioplasty.

The resources for cardiac catheterization and radiographic facilities have been detailed in Fries-

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inger GC. et al. "Optimal Resources for Examination of The Heart and Lungs: Cardiac Catheterization and Radiographic Facilities" (*Circulation* 1983;68:893A–930A), which presented guidelines for administration, space, equipment, personnel and working arrangements for diagnostic cardiovascular laboratories. These recommendations apply to any laboratory planning to perform peripheral angioplasty procedures.

In addition, a laboratory performing peripheral angioplasty should have available the following:

1. An ample inventory of balloon dilation catheters, calibrated balloon inflation devices and a complete range of existing guide wires of variable flexibility and steerability.
2. A high resolution fluoroscopic system and an optimal television chain that allows ready visualization of a 0.014-in. (0.036 cm) guide wire and in which still frames or "road map images" can be displayed simultaneously with the real time fluoroscopic image.
3. Preferably, an angulating X-ray tube image intensifier arm that allows ready three-dimensional determination of the anatomic position of a guide wire or balloon catheter.
4. A physiologic recording system, a high resolution fluoroscope, cineangiographic and/or digital (subtraction or acquisition) angiographic and/or cut film (analog) angiographic equipment, a complete set of emergency resuscitation instruments and a full complement of drugs.
5. Radiation exposure control systems including such items as an X-ray beam with automatic collimation, a carbon fiber scattered radiation grid, carbon fiber tabletop and a correct tube filter. Further reduction of radiation exposure to personnel can be achieved by gap filling during cinematography, using a reference monitor for pathfinding and video disks for automatic storage and replay. All personnel should be further protected from radiation exposure by the use of appropriate lead aprons, eyeglasses, thyroid protection and additional shielding of the X-ray tube
6. *Diagnostic imaging fine resolution:* Diagnostic imaging ideally should be obtained by using contrast material and imaging of the entire vascular distribution in question using conventional analog film changers or adequate field digital or analogies imaging systems. For example, peripheral angiography of vessels should image the vessels of both lower limbs from the distal abdominal aorta down to the distal leg. The use of video fluoroscopy alone is not sufficient to perform diagnostic peripheral angiographic studies. This procedure may be performed on an outpatient or inpatient basis.
7. The specific requisite space, equipment, personnel and administration of an appropriate vascular surgery operating suite falls outside these recommendations but should include a surgical operating suite that is equipped to provide general anesthesia, a full complement of instruments for peripheral vascular surgery, as well as drugs for management of the cardiovascular patient.

Appendix: Definitions

1. Angiographic success = <30% residual diameter stenoses.
2. Clinical success = angiographic success of culprit lesion or lesions and clinical improvement.