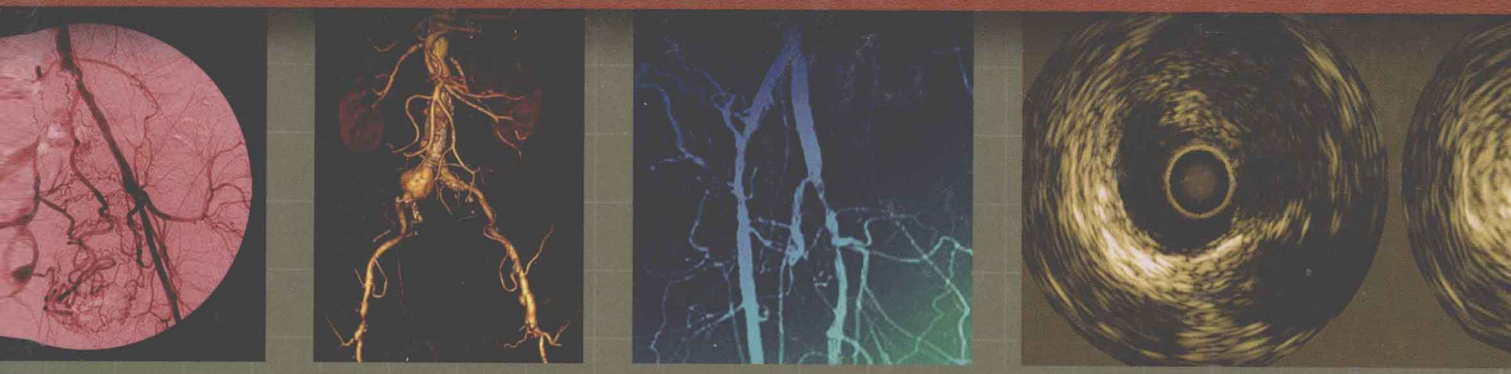
Practical Peripheral Vascular Intervention

SECOND EDITION



Ivan P. Casserly • Ravish Sachar • Jay S. Yadav

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PRACTICAL PERIPHERAL VASCULAR INTERVENTION

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To my parents and family, Sara Dahle and Huong Le (RIP), and all the patients who have entrusted me with their care.

Ivan P. Casserly

To my wife, Jignasa, for her immeasurable patience and for always being there. To my parents whose wisdom and guidance has made it all possible. And to my children, Nikhil and Natasha, who brighten up each day.

Ravish Sachar

To my wife (Marshalla) and my children (Nevin, Chethan, Priya, and Daven) for making every day a pleasure. To the many wonderful and courageous patients whom I have had the privilege of treating and who have contributed immeasurably to the development of better treatments for vascular disease.

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PREFACE

Over the past decade, the application of endovascular techniques to treat patients with peripheral artery disease, aneurysmal disease, and venous disorders has grown dramatically. Improvements in catheter, sheath, wire, balloon, and stent design, as well as the advent of distal emboli protection and other novel technologies, have collectively enabled the safe, efficacious, and durable treatment of obstructive and aneurysmal arterial disease and an array of venous disorders. These advances reflect the collective efforts of specialists from the fields of interventional cardiology, vascular surgery, and interventional radiology.

One of the major challenges in the field is the insufficient numbers of accredited fellowship positions dedicated solely to percutaneous peripheral vascular intervention. As a result, operators often finish fellowships with minimal specific training in peripheral vascular disease, and have to continue the learning process "on the job." Furthermore, for those who are already in practice, retraining in peripheral vascular intervention is often a difficult and haphazard process, consisting of didactic and "hands-on" training through short courses offered in various institutions. For those who are already trained, this rapidly evolving field mandates that physicians constantly keep abreast of newer developments.

This book seeks to address some of the above challenges. First and foremost, this is a *manual* of peripheral vascular intervention, with a firm emphasis on *how to perform* peripheral vascular interventions. For this reason, we purposefully invited authors with the greatest hands-on experience to write the chapters and provide their insights. Every effort has been made to graphically illustrate the techniques and provide real-life examples of these procedures. There is also an obligation for operators to have a sound understanding of the clinical and non-invasive evaluation of patients with peripheral vascular disease, and a working knowledge of the anatomy and biology of the vascular bed in which they intend to intervene. We have therefore provided this information in as succinct a manner as possible, for each vascular bed.

We have tried to address intervention in all of the vascular territories. Carotid angioplasty and stenting has become an alternative to surgery for patients with symptomatic and asymptomatic carotid disease. As such, we hope that the chapters on carotid intervention are especially useful. Other chapters, such as those on subclavian, aortoiliac, and infrapopliteal interventions, offer insights we hope will help even experienced operators. The section on the treatment of aneurysmal disease has been significantly expanded, as has the section on the treatment of venous disorders.

Peripheral vascular intervention is an exciting and challenging field. While this book is not meant to serve as a replacement for essential didactic and hands-on training, our hope is that both trainees and experienced operators in each of the disciplines involved in performing peripheral vascular intervention will find this a useful and practical guide.

Ivan P. Casserly, MD
Ravish Sachar, MD
Jay S. Yadav, MD

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Ivan P. Casserly
Ravish Sachar
Jay S. Yadav

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SECTION

Training and Credentialing

CHAPTER 1

Guidelines for Training and Credentialing in Peripheral Vascular Intervention

Christopher J. White

There are compelling reasons for interventional cardiologists to undertake percutaneous treatment of head to toe noncoronary atherosclerotic vascular diseases (1). Atherosclerosis is a "systemic" disease that often involves multiple vascular beds commonly causing coronary and noncoronary vascular problems in the same patient (2–4). There is general agreement that there is a shortage of trained health-care providers necessary to meet the rapidly increasing demand for percutaneous revascularization, particularly with regard to acute stroke and intracranial intervention. Interventional cardiologists possess the technical skills necessary to perform noncoronary vascular intervention but, in general, lack a comprehensive knowledge base regarding the specialty of vascular medicine. In recognition of the need for adult cardiovascular medicine trainees to gain broader expertise in vascular medicine and vascular intervention, a Core Cardiology Training Symposium (COCATS-11) has been developed (5,6).

Noncoronary vascular disease involving the extremities, visceral and renal organs, and brain is frequently an important aspect of the management of patients with heart disease. Renovascular hypertension is the most common cause of secondary hypertension in patients with atherosclerosis. Renovascular hypertension, causing resistant hypertension, negatively impacts the medical management of angina pectoris and congestive heart failure. Peripheral vascular symptoms, such as claudication, impair the effectiveness of cardiovascular rehabilitation programs. Coronary artery atherosclerosis is the most common cause of morbidity and mortality in patients with atherosclerotic peripheral vascular disease.

FEASIBILITY OF CARDIOLOGISTS PERFORMING NONCORONARY VASCULAR INTERVENTION

As experienced coronary interventionalists, we reported our initial experience in peripheral angioplasty in 164 consecutive patients over a 20-month period (7). Prior to performing angioplasty, we observed the performance of peripheral angioplasty in several angiographic laboratories performing high-volume peripheral angioplasty, we were proctored for our initial cases by a qualified outside operator, and our initial cases were reviewed and discussed with an experienced vascular surgeon.

Lower extremity percutaneous transluminal angioplasty (PTA) was performed in 116 patients, upper extremity PTA in 30 patients, and renal artery PTA in 18 patients. Successful results were obtained in 92% (191/208) of the lesions attempted, with a successful PTA in 99% (155/157) of stenoses versus 71% (36/51) of occlusions ($p < 0.01$). In no patient did a failed attempt result in worsening of the patient's clinical condition or the need for emergency surgery. The overall major complication rate of 4.3% (7/164) was similar to other studies published in the literature.

Our experience supported the hypothesis that experienced interventional cardiologists, working in partnership with vascular surgeons, possessed the necessary technical skills to perform peripheral vascular angioplasty in a safe and effective manner. We relied on our vascular surgery colleagues to provide guidance in patient and lesion selection, which compensated for our limited knowledge regarding vascular medicine. Our results did not demonstrate a learning curve. The percentage of patients with totally occluded vessels (25%) and the average lesion length (5.8 $\pm$ 8.0 cm) attests to the relatively difficult lesions we routinely accepted for treatment.

Achieving a success rate of 92% for all lesions and a 99% success rate for stenoses suggested that coronary angioplasty skills are transferable to the treatment of noncoronary vascular lesions quite effectively. The fact that success rates were higher for non–total occlusions and lesions of shorter length were consistent with the reported outcomes for vascular intervention in the literature.

Because the risks of diagnostic aortic arch and cerebral angiography add to the risks of revascularization of the carotid artery, the most highly skilled angiographer, regardless of primary specialty, should perform these studies. We investigated the quality and risk of diagnostic cervical–cerebral angiography in the hands of experienced interventional cardiologists (8). We reviewed a total of 189 patients with 191 diagnostic catheter procedures over a 5-year period. There was only one neurologic complication (0.52%), which compares favorably to published results. There is good evidence that the catheter skills of experienced cardiologists compare well with those of other specialists for the safety and quality of noncoronary angiography.

FELLOWSHIP TRAINING IN NONCORONARY DIAGNOSTIC ANGIOGRAPHY

Cardiology fellows currently receive invasive training in both cardiac and noncardiac angiography (9). An example of this type of experience includes ascending, descending, and abdominal aortography. Additionally, angiographic studies may include selective angiography of the aortic arch vessels, mesenteric vessels, renal arteries, and iliofemoral arteries. Another example is the routine performance of selective angiography of the subclavian, internal mammary, and gastroepiploic arteries to determine patency of coronary bypass grafts. Screening renal

angiography is frequently done in patients at increased risk for renal artery stenosis with clinical indications for revascularization (10). Finally, routine imaging of the iliac and femoral arteries is commonly performed if there is difficulty advancing catheters or prior to placement of vascular closure devices.

Cardiologists performing noncardiac angiography are responsible for the accurate interpretation of the images they obtain. Physicians must accept the liability for errors or omissions in their interpretation of angiography studies, just as they do for coronary angiography. Physicians who feel insecure in their ability to interpret these films may ask for assistance or overreading of the films by a qualified physician. Peer review of angiographic studies, in a nonthreatening environment, leads to improved quality of peripheral angiographic studies and provides opportunities for less experienced angiographers to enhance their understanding of peripheral vascular anatomy, collateral circulations, and anatomic variations.

FELLOWSHIP TRAINING REQUIREMENTS FOR NONCORONARY VASCULAR INTERVENTION

The American College of Cardiology (ACC)'s COCATS document provides guidelines for training in catheter-based peripheral vascular interventions (5,6). For the cardiovascular trainee wishing to acquire competence as a peripheral vascular interventionalist, a minimum of 12 months of training is recommended (Table 1.1). This period is in addition to the required core cardiology training and a minimum of 8 months in diagnostic cardiac catheterization in an Accreditation Council for Graduate Medical Education (ACGME)–accredited fellowship program (9). The prerequisite for Level 3 training in peripheral vascular interventions includes Level 1 training in vascular medicine, and Level 1 and Level 2 training in diagnostic cardiac catheterization. Requirements for Level 3 training in peripheral vascular interventions can be fulfilled during fourth year of interventional training dedicated to peripheral vascular interventions or concurrently with coronary interventional training (6).

It is recommended that a cardiology fellow perform 300 coronary diagnostic procedures, including 200 with supervised primary responsibility before beginning interventional training (9). The trainee in an ACGME-accredited program should participate in a minimum of 100 diagnostic peripheral angiograms and 50 noncoronary vascular interventional cases during the interventional training period (11). The case mix should be evenly distributed among the different vascular beds. Cases of thrombus management for limb ischemia and/or venous thrombosis, utilizing percutaneous thrombolysis or catheter-based thrombectomy, should be included.

Advanced training in peripheral vascular intervention may be undertaken concurrently with fourth year of training for coronary interventions (6). Peripheral vascular interventional training should include experience on an inpatient vascular medicine consultation service, in a noninvasive vascular diagnostic laboratory, and experience in longitudinal care of outpatients with vascular disease. Comprehensive training in vascular medicine (Level 2) is not a prerequisite for noncoronary interventional training.

TABLE 1.1 Recommended Fellowship Training Requirements for Cardiovascular Physicians

• Duration of training*—12 months
• Diagnostic coronary angiograms†—300 cases (200 as the primary operator)
• Diagnostic peripheral angiograms—100 cases (50 as primary operator)
• Peripheral interventional cases‡—50 cases (25 as primary operator)

*After completing core cardiovascular training with at least 8 months of cardiac catheterization.
†Coronary catheterization procedures should be completed before beginning interventional training.
‡The case mix should be evenly distributed among the different vascular beds. Supervised cases of thrombus management for limb ischemia and venous thrombosis, utilizing percutaneous thrombolysis or thrombectomy, should be included.

ALTERNATIVE TRAINING PATHWAYS FOR PVD INTERVENTION

Many physicians with specialty training and board certification in interventional cardiology are currently performing peripheral vascular (noncoronary) interventional procedures. These physicians have received either formal training in accredited programs or on-the-job training. Unfortunately, there currently exists little or no cooperation between the specialty training programs with regard to peripheral vascular interventional training.

An ongoing "turf-war" over the provision of these services between competing subspecialties in many hospitals is not in the best interest of patients. Several professional societies including the ACC, the American Heart Association, the American Society of Cardiovascular Interventionists, the Society of Cardiovascular Interventional Radiologists, the Society of Vascular Surgery, and the Society for Cardiovascular Angiography and Interventions (SCAI) have published disparate guidelines for the performance of peripheral angioplasty (12–17).

The realization that there is a need for cardiologists to provide noncoronary vascular care to patients with concomitant peripheral vascular disease has prompted revision of prior guidelines that were not "cardiology" specific (11,18). This was done in order to provide a more focused view of the role of the cardiologist, specifically the interventional cardiologist, in the management of these patients. Cardiologists with widely varying backgrounds and clinical experience are currently performing peripheral vascular intervention. Competency to perform peripheral vascular percutaneous interventions can be broken down into three categories or skill sets (Table 1.2).

Unrestricted Certification

Completion of at least 100 diagnostic peripheral angiograms, with a minimum of 50 peripheral interventional procedures, has been recommended for unrestricted certification

TABLE 1.2 Skills for Optimal Endovascular Intervention

- **Cognitive:** The fund of knowledge required is derived from the specialties of vascular medicine and angiology. It includes the knowledge of the natural history of the disease, the anatomy and physiology of the affected organ systems, interpretation of noninvasive tests, and an understanding of the indications for treatment and expected outcomes (risks and benefits) of the treatment options.
- **Procedural:** These skills involve the full range of invasive percutaneous cardiovascular techniques including gaining vascular access, performing diagnostic angiography, performing angioplasty and intervention, administering thrombolytic agents, and recognizing and managing complications of these procedures.
- **Clinical:** This category encompasses the skills necessary to manage inpatients and outpatients with noncardiac vascular diseases. It includes the ability to admit patients to the hospital and provide daily care. The ability to perform a complete history and physical examination, and to integrate the patient's history, physical examination, and noninvasive laboratory data to make accurate diagnoses is required. Finally, it requires establishing a doctor–patient relationship and continuity of care in order to provide long-term care for this chronic disease.

TABLE 1.3 Suggested Alternative Pathways for Achieving Competency in Peripheral Vascular Intervention

Unrestricted Certification

- Diagnostic angiograms—100 cases (50 as primary operator)
- Peripheral interventions—50 cases (25 as primary operator)
  - Aortoiliac, brachiocephalic arteries, and extracranial carotid arteries
  - Abdominal and visceral (renal and mesenteric) arteries
  - Infrainguinal arteries
  - Thrombolysis/thrombectomy

Restricted Certification

- Diagnostic angiograms—30 cases per specific vascular territory (15 as primary operator)
- Peripheral interventions
  - Aortoiliac and brachiocephalic—15 cases (8 as primary operator)
  - Abdominal and visceral (mesenteric and renal)—15 cases (8 as primary operator)
  - Infrainguinal—15 cases (8 as primary operator)

(Table 1.3) (11). The physician should have been the supervised primary operator for one half of the procedures. These procedures should be performed under the guidance of a credentialed noncoronary vascular interventionalist.

The case mix should be evenly distributed, so as to ensure exposure to diagnosis and intervention in a variety of different vascular beds. Experience that is heavily weighted toward treatment of one specific site (e.g., renal) to the exclusion of other vascular distributions (e.g., infrainguinal) may not provide adequate expertise or preparation for the latter. To achieve the balanced experience required for unrestricted competence, the following three broadly defined vascular territories should be evenly represented: (1) aortoiliac and brachiocephalic arteries (i.e., subclavian and axillary); (2) abdominal visceral arteries (i.e., renal and mesenteric arteries); and (3) infrainguinal arteries (i.e., femoral, popliteal, tibial, and peroneal arteries). In addition, unrestricted competence requires separate supervised cases of thrombus management for limb ischemia or venous thrombosis, utilizing catheter-based thrombolysis or thrombectomy, in a nonspecified vascular bed. Familiarity with thrombolytic agents and their use is also required. Facility with other devices and technologies (e.g., mechanical thrombectomy) available for thrombus management is also desirable (11).

Obtaining competence in the performance of procedures and interventions in the cervical (i.e., subclavian, carotid, and vertebral arteries) and intracranial cerebral vessels poses unique challenges associated with gaining vascular access to the carotid and vertebral arteries and performing interventions in these circulatory beds. There are special concerns related to the morbidity and mortality associated with this vascular territory, which allows for very narrow safety margins. For physicians performing neurovascular interventional procedures, suggested requirements for achievement of competence include mastery of the cognitive and clinical skills pertaining specifically to this vascular bed and these procedures. This includes, as with other sites, an understanding of the anatomic and pathologic characteristics unique to this vascular bed and the ability to interpret relevant angiographic images. To achieve competence, additional diagnostic cerebrovascular angiograms and interventions should be performed, with appropriate documentation, follow-up, and outcomes assessment. As with procedures in other regional vascular venues, it is anticipated that for some physicians to achieve competence, supervising faculty will recommend additional cases beyond the minimum number.

Restricted Certification

Achievement of competence to perform peripheral vascular intervention need not be an all-or-none phenomenon. Rather, levels of competence in specific procedures or regional vascular territories can be achieved, particularly for those established physicians who have already completed formal training in coronary intervention or vascular surgery. A physician might become competent to perform interventions only in some regional circulations, but not in others. This is termed restricted certification. For example, one might acquire the skills to perform percutaneous renal, iliac, and subclavian intervention, yet

not have adequate background or expertise to perform infrapopliteal or carotid intervention. Competence in one area may be partly or wholly transferable to another, depending upon the degree of overlap or similarity between the vascular bed, the disease state, and the knowledge and skill sets involved. For example, the technical skills required to perform iliac artery intervention are partly transferable to subclavian artery intervention, since the size of these vessels is comparable, and the therapeutic procedures are similar. In contrast, expertise in iliac artery revascularization does not confer comparable ability to perform carotid stenting, tibioperoneal angioplasty, or catheter-based thrombolysis because of the dissimilarity of these interventions and their associated vascular territories.

Restricted certification can be achieved for each of the three major vascular territories defined previously (aortoiliac and brachiocephalic vessels, abdominal visceral arteries, and infrainguinal arteries), in which competence is sought and supervised performance of a minimum of diagnostic angiograms and interventions is required (Table 1.3). One half of the diagnostic angiograms and one half of the interventions in the specific territory must have been performed as the supervised primary operator. The cognitive and clinical skills pertaining to the particular territory should also have been mastered. Utilizing a restricted certification approach, a practicing physician possessing the requisite catheter skills can initially achieve competence in one or more selected territories and, subsequently, can elect to progress in a stepwise fashion to gain unrestricted certification.

BOARD CERTIFICATION FOR ENDOVASCULAR THERAPY

The American Board of Vascular Medicine (ABVM) was formed with sponsorship from the ACC, the Society of Vascular Medicine (SVM), and the SCAI and held its first certifying examination for cardiovascular specialists in both vascular medicine and endovascular medicine in 2005 (19). The eligibility criteria for sitting for the endovascular examination are listed in Table 1.4. ABVM certification is intended to demonstrate that a candidate has the knowledge, skills, and commitment to provide quality patient care in vascular medicine. Formal board certification is intended to establish a consistent benchmark of expertise in the field of vascular medicine.

TABLE 1.4 ABVM Endovascular Examination: Eligibility Requirements

A. Must possess a valid, unrestricted license to practice medicine in the jurisdiction of practice.
B. Hold primary board certification (ABIM, ABOIM, ABS, ABR) or specialty board certification in Cardiology, Cardiothoracic Surgery, Interventional Radiology, Vascular Surgery, or Vascular Medicine (ABVM General Examination).
C. Meet the training requirements for peripheral intervention through either the practice pathway or fellowship training pathway as outlined below.
D. Attestation of privileges or fellowship training statement as outlined below.
E. Pay the required examination (ABVM Endovascular Examination) fee.
Certification Process to Attain Status as Diplomate of ABVM
A. Meet all of the eligibility requirements.
B. Pass the computer-based endovascular examination.
Training Requirements
A. Practice Pathway 1. Active hospital privileges for diagnostic and interventional peripheral procedures. 2. Performance of peripheral interventional procedures for at least 12 months before application. 3. Performance of at least 100 diagnostic peripheral arteriograms with at least 50 as the primary operator at the attending physician level (cases performed as a trainee are not counted toward this total) in the hospital where the applicant holds privileges. All qualifying procedures must have been performed within 2 years of application. 4. Performance of at least 50 therapeutic peripheral interventional procedures, at least 25 as the primary operator at the attending physician level (cases performed as a trainee are not counted toward this total) in the hospital where the applicant holds privileges. All qualifying procedures must have been performed within 2 years of application. (OR)
B. Fellowship Training Pathway 1. Successful completion of a formal ABIM-accredited fellowship that includes training in peripheral interventional procedures. 2. Performance of the requisite number of diagnostic (100) and therapeutic (50) peripheral interventional procedures, at least half as primary operator. 3. Written attestation of acceptable performance of peripheral procedures by the fellowship program director. 4. Counting of cases and procedures follow the guidelines outlined in the Clinical Competence document of the ACC (http://www.vascularboard.org/cert_reqs.cfm).

PTA, percutaneous transluminal angioplasty; ABIM, American Board of Internal Medicine; ABS, American Board of Surgery; ABR, American Board of Radiology.

MAINTAINING CLINICAL COMPETENCY

Maintaining one's skill level in catheter-based peripheral vascular (noncoronary) interventions is an ongoing and continuing process. The physician's cognitive knowledge base in peripheral vascular disease management and techniques must remain up to date. The physician must commit to ongoing education and lifelong learning through documented attendance at continuing medical education seminars in the field of vascular diseases. Technical skills should be maintained via performance of a minimum of at least 25 peripheral vascular intervention cases annually with documentation of success and complication rates. Continuing appropriate board certification in his or her specific medical specialty or subspecialty as well as appropriate recertification is necessary.

CONCLUSION

There is evidence that the technical skills necessary to perform coronary intervention are transferable to the peripheral vasculature. However, an understanding of the natural history of peripheral disease, patient and lesion selection criteria, and the knowledge of other treatment alternatives are essential elements required to perform these procedures safely and effectively. For interventional cardiologists who are inexperienced in the treatment of peripheral vascular disease, appropriate preparation and training with a team approach that includes an experienced vascular surgeon are both desirable and necessary before attempting percutaneous peripheral angioplasty.

Clearly, patients with peripheral vascular disease are being underdiagnosed and undertreated. Patient care will benefit by increasing the number of physicians who can provide this needed care with either a restricted or unrestricted certification. Criticisms that the "standards" are being lowered may be countered by the implementation of ongoing quality assurance program.

There are inherent advantages for patients when the interventionalist performing the procedure is also the clinician responsible for the pre- and postprocedure care, analogous to the vascular surgeon who cares for patients before and after surgical procedures. Judgments regarding the indications, timing, and risk-to-benefit ratio of procedures are enhanced by a long-term relationship between physician and patient. Finally, in view of the increased incidence of coronary artery disease in patients with atherosclerotic peripheral vascular disease, the participation of a cardiologist in their care is appropriate.

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SECTION II

Noninvasive Evaluation and Management of Peripheral Artery Disease