Cardiac Catheterization 1

History and Current Practice Standards

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Our concepts of heart disease are based on the enormous reservoir of physiologic and anatomic knowledge derived from the past 70 years' of experience in the cardiac catheterization laboratory. As Andre Cournand remarked in his Nobel lecture of December 11, 1956, "the cardiac catheter was . . . the key in the lock." (1). By turning this key, Cournand and his colleagues led us into a new era in the understanding of normal and disordered cardiac function in humans.

According to Cournand (2), cardiac catheterization was first performed (and so named) by Claude Bernard in 1844. The subject was a horse, and both the right and left ventricles were entered by a retrograde approach from the jugular vein and carotid artery. In an excellent review of the history of cardiac catheterization, angiography, and interventional cardiology, Mueller and Sanborn (3) describe and cite references for experiments by Stephen Hales and others whose work antedates that of Claude Bernard. Although Claude Bernard may not have been the first to perform cardiac catheterization, his careful application of scientific method to the study of cardiac physiology using the cardiac catheter demonstrated the enormous value of this technical innovation. An era of investigation of cardiovascular physiology in animals then followed, resulting in the development of many important techniques and principles (pressure manometry, the Fick cardiac output method), which awaited direct application to the patient with heart disease.

Werner Forssmann usually is credited with performing the first cardiac catheterization of a living person—himself (4). At age 25, while receiving clinical instruction in surgery in Germany, he passed a catheter 65 cm through one of his left antecubital veins, guiding it by fluoroscopy until it entered his right atrium. He then walked to the radiology department (which was on a different level, requiring that he climb stairs), where the catheter position was documented by a chest roentgenogram (Fig. 1.1). During the next 2 years, Forssmann continued to perform catheterization studies, including six additional attempts to catheterize himself. Bitter criticism, based on an unsubstantiated belief in the danger of his experiments, caused Forssmann to turn his attention to other concerns, and he eventually pursued another catheter-related career as a urologist (5). Nevertheless, for his contribution and foresight he shared the Nobel Prize in Medicine with Andre Cournand and Dickinson Richards in 1956.

Forssmann's primary goal in his catheterization studies was to develop a therapeutic technique for the direct delivery of drugs into the heart. He wrote:

> If cardiac action ceases suddenly, as is seen in acute shock or in heart disease, or during anesthesia or poisoning, one is forced to deliver drugs locally. In such cases the intracardiac injection of drugs may be life saving. However, this may be a dangerous procedure because of many incidents of laceration of coronary arteries and their branches leading to cardiac tamponade, and death Because of such

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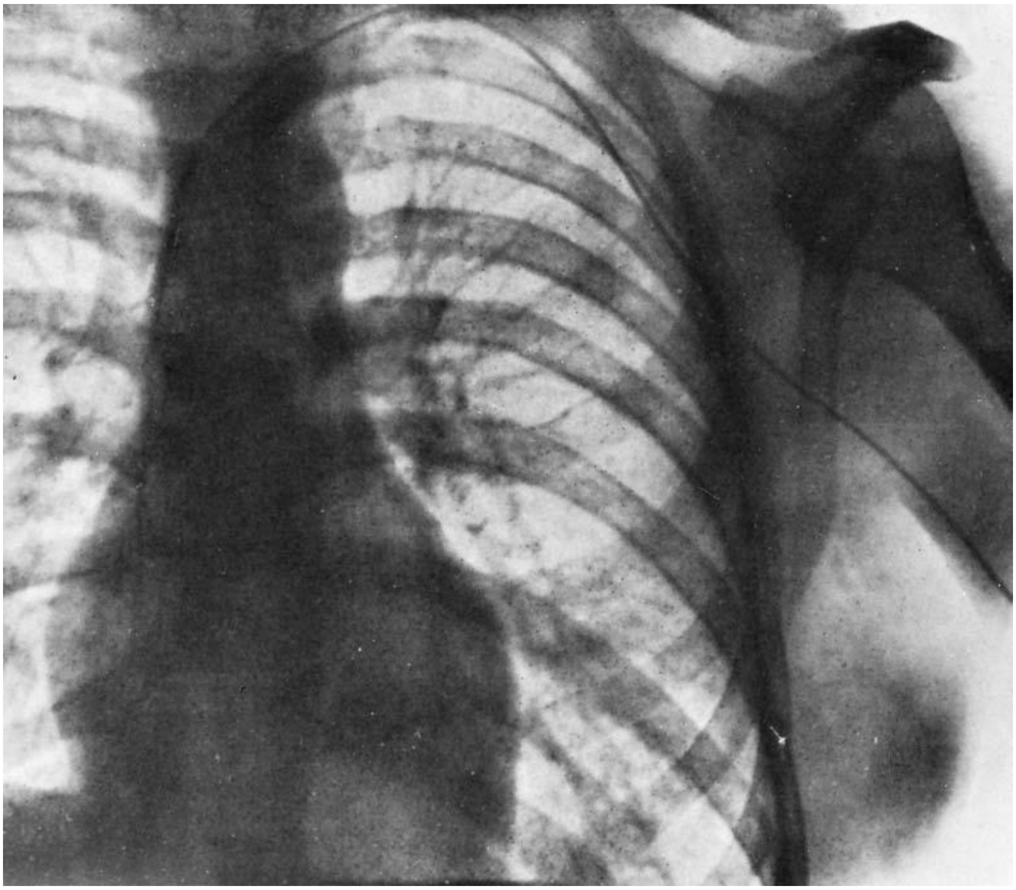

Figure 1.1 The first documented cardiac catheterization. At age 25, while receiving clinical instruction in surgery at Eberswalde, Werner Forssmann passed a catheter 65 cm through one of his left antecubital veins until its tip entered the right atrium. He then walked to the radiology department where this roentgenogram was taken. (*Klin Wochenschr* 1929;8:2085. Springer-Verlag, Berlin, Heidelberg, New York).

incidents, one often waits until the very last moment and valuable time is wasted. Therefore I started to look for a new way to approach the heart, and I catheterized the right side of the heart through the venous system" (4).

Others, however, appreciated the potential of using Forssmann's technique as a diagnostic tool. In 1930, Klein[6] reported 11 right heart catheterizations, including passage to the right ventricle and measurement of cardiac output using Fick's principle. In 1932, Padillo and coworkers reported right heart catheterization and measurement of cardiac output in two subjects (2). Except for these few early studies, application of cardiac catheterization to study the circulation in normal and disease states was fragmentary until the work of Andre Cournand and Dickinson Richards, who separately and in collaboration produced a remarkable series of investigations of right heart physiology in humans (7–9). In 1947, Dexter reported his studies on congenital heart disease and passed the catheter to the distal pulmonary artery, describing "the oxygen saturation and source of pulmonary capillary blood" obtained from the pulmonary artery "wedge" position (10). Subsequent studies from Dexter's laboratory (11) and by Werko (12) elaborated the use of this pulmonary artery wedge position and reported that the pressure measured at this position was a good estimate of pulmonary venous and left atrial pressure. During this exciting early period, catheterization was used to investigate problems in cardiovascular physiology by McMichael and Sharpey-Shafer in England (13), Lenègre and Maurice in Paris (14), and Warren, Stead, Bing, Dexter, Cournand, and others in the United States (15–23).

Further developments came rapidly in the 1950s and 1960s. Retrograde left heart catheterization was first reported by Zimmerman and others (24) and Limon-Lason and Bouchard (25) in 1950. The percutaneous (rather than cutdown) technique was developed by Seldinger in 1953 and was soon applied to cardiac catheterization of both the left and right heart chambers (26). Trans-septal catheterization was first developed by Ross (27) and Cope (28) in 1959 and quickly became accepted as a standard technique. Selective coronary arteriography was reported by Sones and others in 1959 and was perfected to a remarkable excellence over the ensuing years (29,30). Coronary angiography was modified for a percutaneous approach by Ricketts and Abrams (31) in

1962 and Judkins (32) in 1967. In 1970 Swan and Ganz introduced a practical balloon-tipped, flow-guided catheter technique enabling the application of catheterization outside the laboratory (33). Better radiographic imaging techniques and less toxic radiographic contrast agents have been developed progressively, as the number of diagnostic catheterizations has exceeded 2,000,000 per year.

INTERVENTIONAL CARDIOLOGY

The biggest change in the last 25 years has been the return to the therapeutic potential of the cardiac catheter. In 1977 Grüntzig and others introduced the technique of balloon angioplasty, generally known as percutaneous transluminal coronary angioplasty (PTCA) (34, 35). With rapid evolving technology and expanding indications, PTCA grew to equal stature with coronary artery bypass grafting (CABG) as the number of annual PTCA procedures grew to 300,000 by 1990 (see Chapter 22). Encouraged by the success of PTCA but challenged by its shortcomings, physician and engineer inventors have developed and introduced into clinical practice a panoply of new percutaneous interventional devices over the past decade. This includes various forms of catheter-based atherectomy, bare metallic stents, and drug-eluting stents, which together have largely solved earlier problems relating to elastic recoil, dissection, and restenosis of the treated segment (see Chapters 23 and 24). These newer techniques are usually subsumed (along with conventional balloon angioplasty) under the broader designation of percutaneous coronary intervention (PCI). Similar techniques have also developed in parallel for the treatment of peripheral arterial atherosclerotic disease, which is a common cause of morbidity and even mortality in patients with coexisting coronary disease (see Chapters 14 and 26).

The development of percutaneous coronary intervention has also stimulated the development of other techniques for the treatment of *structural heart disease.* Catheter devices developed to close intracardiac shunts in pediatric patients have now been adapted to close adult congenital and acquired defects (see Chapter 27). Balloon valvuloplasty was developed in the mid-1980s and remains successful for the treatment of rheumatic mitral stenosis, but because of early recurrence is now used as a treatment for aortic stenosis only in patients who are not candidates for aortic valve replacement surgery. Newer technologies for percutaneous aortic valve replacement and percutaneous reduction of mitral regurgitation are now entering clinical testing (see Chapter 25).

In essence, these new procedures have made interventional cardiology a new field in cardiovascular medicine, whose history is well summarized by Spencer King (36), and the interested reader is referred there for further historical details. But it is thus clear in the 21st century that interventional cardiology—by virtue of its new technologies, potent adjunctive drug therapies, expanding indications, and improving results—has blossomed. In many ways, these therapeutic modalities (rather than purely diagnostic techniques) have now become the centerpiece within the broad field of cardiac catheterization. *Although the emphasis thus lies appropriately on this dynamic field of catheter-based intervention, we can ill afford to lose sight of the basic principles of catheter insertion, hemodynamic measurement, high-quality angiography, and integration of catheterization findings with the overall clinical scenario as the foundations on which all current interventional techniques are built and from which future evolution of cardiac catheterization will proceed.*

INDICATIONS FOR CARDIAC CATHETERIZATION

As performed today, cardiac catheterization is a combined hemodynamic and angiographic procedure undertaken for diagnostic and often therapeutic purposes. As with any invasive procedure, the decision to perform cardiac catheterization must be based on a careful balance of the risk of the procedure against the anticipated benefit to the patient. Indications for the use of catheterization and coronary intervention in the management of stable angina, unstable angina, and ST-elevation myocardial infarction (MI) have been developed by the American College of Cardiology and the American Heart Association (37–39), and are available online at <http://www.acc.org/clinical/topic/topic.htm>. As an example, a summary of the indications for cardiac catheterization in patients with stable angina is given in Table 1.1.

The basic principle is that cardiac catheterization is recommended to confirm the presence of a clinically suspected condition, define its anatomic and physiologic severity, and determine the presence or absence of associated conditions when a therapeutic intervention is planned in a symptomatic patient. The most common indication for cardiac catheterization today thus consists of a patient with an acute coronary ischemic syndrome (unstable angina or acute myocardial infarction) in whom an invasive therapeutic intervention is contemplated. The goal of cardiac catheterization in such patients is to identify the culprit lesions and then to restore vessel patency via PCI. In a few such patients, the diagnostic portion of the catheterization procedure may reveal other features (e.g., complex multivessel or left main coronary disease, severe associated valvular disease), which provide critical information for the decision and planning of open heart surgery.

Although few would disagree that consideration of heart surgery is an adequate reason for the performance of catheterization, clinicians differ about whether *all* patients being considered for heart surgery should undergo preoperative cardiac catheterization. Many young patients with echo-proven valvular disease and no symptoms of myocardial ischemia are sometimes operated on using only noninvasive data, but the risks of catheterization in such

TABLE 1.1

INDICATIONS FOR CARDIAC CATHETERIZATION IN STABLE ANGINA

Class I

1. Patients with disabling (Canadian Cardiovascular Society [CCS] classes III and IV) chronic stable angina despite medical therapy. (Level of Evidence: B)
2. Patients with high-risk criteria on noninvasive testing [Table 23 in source] regardless of anginal severity. (Level of Evidence: B)
3. Patients with angina who have survived sudden cardiac death or serious ventricular arrhythmia. (Level of Evidence: B)
4. Patients with angina and symptoms and signs of CHF. (Level of Evidence: C)
5. Patients with clinical characteristics that indicate a high likelihood of severe CAD. (Level of Evidence: C)

Class IIa

1. Patients with significant LV dysfunction (ejection fraction less than 45%), CCS class I or II angina, and demonstrable ischemia but less than high-risk criteria on noninvasive testing. (Level of Evidence: C)
2. Patients with inadequate prognostic information after noninvasive testing. (Level of Evidence: C)

Class IIb

1. Patients with CCS class I or II angina, preserved LV function (ejection fraction greater than 45%), and less than high-risk criteria on noninvasive testing. (Level of Evidence: C)
2. Patients with CCS class III or IV angina, which with medical therapy improves to class I or II. (Level of Evidence: C)
3. Patients with CCS class I or II angina but intolerance (unacceptable side effects) to adequate medical therapy. (Level of Evidence: C)

Class III

1. Patients with CCS class I or II angina who respond to medical therapy and who have no evidence of ischemia on noninvasive testing. (Level of Evidence: C)
2. Patients who prefer to avoid revascularization. (Level of Evidence: C)

Class I: Conditions for which there is evidence or general agreement that a given procedure or treatment is useful and effective.
Class II: Conditions for which there is conflicting evidence or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.
Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.
Class IIb: Usefulness/efficacy is less well established by evidence/opinion.
Class III: Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful.
With permission from Gibbons RJ, Abrams J, Chatterjee K, et al. ACC/AHA 2002 guideline update for the management of patients with chronic stable angina. *J Am Coll Cardiol*. 2003;41:159–68.

patients are extremely small, particularly compared to the risk of embarking on cardiac surgery on a patient for whom an incorrect clinical diagnosis or the presence of an unsuspected additional condition greatly prolongs and complicates the planned surgical approach. By providing the surgical team with a precise and complete road map of the course ahead, cardiac catheterization can permit a carefully reasoned and maximally efficient operative procedure. Furthermore, information obtained by cardiac catheterization may be invaluable in the assessment of crucial determinants of prognosis, such as left ventricular function, status of the pulmonary vasculature, and the patency of the coronary arteries. For these reasons, we recommend cardiac catheterization (or at least coronary angiography) in nearly all patients for whom heart surgery is contemplated, even if the severity of valve disease and ventricular function have been determined by preoperative echocardiography.

Catheterization data can also inform other nonsurgical therapeutic considerations. For example, the decision for pharmacologic intervention with heparin and/or a thrombolytic agent in suspected acute pulmonary embolism, the use of high-dose beta-blocker and/or calcium antagonists in suspected hypertrophic subaortic stenosis (versus catheter-based alcohol septal ablation) might well be considered of sufficient magnitude to warrant confirmation of the diagnoses by angiographic and hemodynamic investigation prior to the initiation of therapy. Although a clinical diagnosis of primary pulmonary hypertension can often be made by echocardiography, cardiac catheterization is usually required (a) to confirm the diagnosis and (b) to assess potential responsiveness to pharmacologic agents, such as epoprostenol (40). Catheterization can also be used to optimize pharmacologic therapy for advanced congestive heart failure.

Another broad indication for performing cardiac catheterization is to aid in the diagnosis of obscure or confusing problems, even when a major therapeutic decision is not imminent. A common instance of this indication is presented by the patient with chest pain of uncertain cause, about whom there is confusion regarding the presence of obstructive coronary artery disease. Both management and prognosis of this difficult problem are greatly simplified when it is known, for example, that the coronary arteries are widely patent. Another example within this category is the symptomatic patient with a suspected diagnosis of cardiomyopathy. Although some may feel satisfied with a clinical diagnosis of this condition, the implications of such a diagnosis in terms of prognosis and therapy (such as long-term bed rest or chronic anticoagulant therapy) are so important that we feel it worthwhile to be aggressive in ruling out potentially correctable conditions (e.g., hemochromatosis, pericardial effusive-constrictive disease) with certainty, even though the likelihood of their presence may appear remote on clinical grounds.

Research

On occasion, cardiac catheterization is performed primarily as a research procedure. Although research is conducted to some degree in many of the diagnostic and therapeutic studies performed at major medical centers, it usually relates to the evaluation of new therapeutic devices (e.g., new stent designs) in patients who would be undergoing diagnostic and therapeutic catheterization in any event. All such studies (41) require prior approval of the Food and Drug Administration (FDA) in the form of an Investigational Device Exemption, of the local Committee on Human Research at the institution (Institutional Review Board, or IRB), and attainment of informed consent after the details of the risks and potential benefits of the procedure and its alternatives have been thoroughly explained. Doing such research also requires meticulous attention to protocol details, inclusion/exclusion criteria, data collection, and prompt reporting of any complications.

Even so, this is quite different from a catheterization that is performed solely for the purpose of a research investigation (as a 6-month follow-up angiogram after a new stent might be). Such studies should be carried out only by or under the direct supervision of an experienced investigator who is expert in cardiac catheterization, using a protocol that has been carefully scrutinized and approved by the Institutional Review Board (Human Use Committee) at the investigator's institution.

Contraindications

Although it is important to carefully consider the indications for cardiac catheterization in each patient, it is equally important to discover any contraindications. Over the years, our concepts of contraindications have been modified by the fact that patients with acute myocardial infarction, cardiogenic shock, intractable ventricular tachycardia, and other extreme conditions now tolerate cardiac catheterization and coronary angiography surprisingly well.

At present, the only *absolute* contraindication to cardiac catheterization is the refusal of a mentally competent patient to consent to the procedure. But a long list of relative contraindications must be kept in mind, including all intercurrent conditions that can be corrected and whose correction would improve the safety of the procedure. Table 1.2 lists these relative contraindications. For example, ventricular irritability can increase the risk and difficulty of left heart catheterization and can greatly interfere with interpretation of ventriculography; therefore, it should be suppressed if possible prior to or during catheterization. Hypertension increases predisposition to ischemia and/or pulmonary edema and should be controlled before and during catheterization. Other conditions that should be controlled before elective catheterization include intercurrent febrile illness, decompensated left heart failure, correctable anemia, digitalis toxicity, and hypokalemia. Allergy to radiographic contrast agent is a relative contraindication to cardiac angiography, but proper premedication and use of a newer nonionic low osmolar contrast agent can substantially reduce the risks of a major adverse reaction, as discussed in Chapter 2. Even so, severe allergic reactions or even anaphylaxis can occur, and the operator and catheterization laboratory staff should be well versed in managing the procedure.

Anticoagulant therapy is more controversial as a contraindication. Heparin (unfractionated or low molecular weight), direct thrombin inhibitors (bivalirudin), and antiplatelet agents such as aspirin, clopidogrel, or the platelet glycoprotein IIb/IIIa receptor blockers are widely used in the precatheterization management of acute coronary syndromes and are part and parcel of any coronary intervention. But the use of heparin for simple diagnostic

TABLE 1.2

RELATIVE CONTRAINDICATIONS TO CARDIAC CATHETERIZATION AND ANGIOGRAPHY

1. Uncontrolled ventricular irritability: the risk of ventricular tachycardia/fibrillation during catheterization is increased if ventricular irritability is uncontrolled
2. Uncorrected hypokalemia or digitalis toxicity
3. Uncorrected hypertension: predisposes to myocardial ischemia and/or heart failure during angiography
4. Intercurrent febrile illness
5. Decompensated heart failure: especially acute pulmonary edema, unless catheterization can be done with the patient sitting up
6. Anticoagulated state: prothrombin time >18 seconds
7. Severe allergy to radiographic contrast agent
8. Severe renal insufficiency and/or anuria: unless dialysis is planned to remove fluid and radiographic contrast load

coronary angiography, once felt to lower the incidence of thromboembolic complications during coronary angiography (42), is now uncommon (43). These agents may be continued through and after the catheterization, particularly with the use of groin puncture closure technology, with only a small increase in the risk of local bleeding. If a complication arises, these agents can often be reversed (protamine, platelet transfusion) or allowed to wear off. But the view regarding oral anticoagulants (e.g., warfarin) is that it is best to reverse the prolonged prothrombin time to a prothrombin time of < 18 seconds or an international normalized ratio (INR) of <2 before cardiac catheterization represents a more complex problem. This is best done by withholding warfarin for 3 to 5 days before the procedure, potentially switching to subcutaneous low–molecular-weight heparin or intravenous heparin for a strong anticoagulant indication (e.g., a mechanical heart valve). If more rapid reversal of oral anticoagulation is required, we favor administration of fresh-frozen plasma rather than vitamin K, which can occasionally trigger a hypercoagulable state with thrombosis of prosthetic valves or thrombus formation within cardiac chambers, arteries, or veins.

Factors Influencing Choice of Approach

Of the various approaches to cardiac catheterization, certain ones have only historical interest (transbronchial approach, posterior transthoracic left atrial puncture, suprasternal puncture of the left atrium). In this book, we will discuss in detail catheterization by percutaneous approach from various sites (including femoral or radial arteries, femoral internal or jugular veins, trans-septal catheterization of the left heart, and apical puncture of the left ventricular puncture; Chapter 4). Although it has largely been supplanted by the percutaneous approach, we will also discuss catheterization by direct surgical exposure of the brachial artery and vein (the so-called Sones technique, Chapter 5).

The great vessels and all cardiac chambers can be entered in nearly all cases by any of these approaches; thus the choice depends on patient issues (aortic occlusion, morbid obesity), procedural issues (need for use of larger bore catheters), and patient/operator preference. Ideally, the physician performing cardiac catheterization should be well versed in several of these methods (at least one upper extremity approach as well as the femoral approach).

DESIGN OF THE CATHETERIZATION PROTOCOL

Every cardiac catheterization should have a protocol, that is, a carefully reasoned sequential plan designed specifically for the individual patient. This protocol may be so common (e.g., left heart catheterization with coronary angiography, annual transplant evaluation) that the operator and support staff are already in synch with the plan. If anything beyond this approach is planned, it is helpful to map this out, even preparing and posting a written protocol in the catheterization suite so that all personnel in the laboratory understand exactly what is planned and anticipate the needs of the operator.

Certain general principles should be considered in the design of a protocol if it includes hemodynamic measurements. First, hemodynamic measurements should generally precede angiographic studies, so that crucial pressure and flow measurements may be made as close as possible to the basal state. Second, pressures and selected oxygen saturations should be measured and recorded in each chamber "on the way in," that is immediately after the catheter enters and before it is directed toward the next chamber. If a problem should develop during the later stages of a catheterization procedure (atrial fibrillation or other arrhythmia, pyrogen reaction, hypotension, or reaction to contrast material), it will be beneficial to have the pressures and saturations already measured in advance, rather than waiting until the time of catheter pullback. Third, measurements of pressure and cardiac output (using true Fick, Fick with estimated oxygen consumption, or thermodilution, Chapter 8) should be made as simultaneously as possible.

Beyond these general guidelines, the protocol will reflect differences from patient to patient and factor in changes when unexpected findings are encountered (e.g., finding an unexpected marked elevation of left ventricular end diastolic pressure may cause addition of a right heart catheterization to the protocol). It is important to be selective about the inclusion of angiographic studies beyond the coronaries to limit total contrast volume for the study (the upper limit is 3 mL/kg divided by the serum creatinine). In a patient with an elevated creatinine in whom coronary intervention is anticipated, the left ventricular angiogram should be replaced by a noninvasive evaluation of ventricular function and even the number of baseline coronary injections should be limited. With regard to angiography, it is important to keep Sutton's law in mind (When asked why he robbed banks, Willie Sutton is reported to have replied, "because that's where the money is."), and limit contrast injections to the most important diagnostic considerations in a given patient.

Preparation and Premedication of the Patient

It goes without saying that both the medical and the emotional preparation of the patient for cardiac catheterization are the responsibility of the operator. This includes a full explanation of the proposed procedure in such terms that the patient can give truly informed consent. This should include a candid but general discussion of the potential risks, particularly if the patient's condition or the nature of the procedure increases them above the boilerplate information in the preprinted consent form: "There is a less than 1% risk of serious complications (stroke, heart attack, or death) and a similar risk of other complications including bruising or bleeding at the catheter site, plus less than 1 in 1,000 risk of a complication requiring emergency surgery." Otherwise, it is not necessary to go into intricate detail of each of the component risks unless the patient and family indicate a desire for more information. We try to accurately state the moderate amount of discomfort involved, the duration of the procedure, and the postprocedure recovery—failure to do so risks one's credibility. A study of psychologic preparation for cardiac catheterization (44) found that patients who received careful psychologic preparation had lower levels of autonomic arousal both during and after cardiac catheterization than did control subjects.

It is our practice to have the patient fasting (except for oral medications) after midnight, but some laboratories allow a light tea and toast breakfast without ill effects. Complete vital signs should be recorded before the patient leaves the floor (for inpatients), or shortly after arriving at the Ambulatory Center (for outpatients), so that the procedure may be reconsidered if a change has occurred in the patient's condition since he or she was last seen.

Once the question of indications and contraindications has been dealt with and the patient's consent obtained, attention can be directed toward the matter of premedications. We do not administer antibiotics prophylactically before cardiac catheterization, and we know of no controlled studies to support their use, but we may give a dose of intravenous cephalosporin (plus two follow-up doses 8 and 16 hours later) if there have been any breaks in sterile technique or if a groin closure device is being used (particularly in a patient with diabetes mellitus). Various sedatives have been used for premedication. We no longer routinely order premedication to be given before the patient is sent to the Catheterization Laboratory, but instead assess the patient's state of alertness and need for sedation once he or she is on the catheterization table. Per conscious sedation guidelines, we usually administer small repeated doses of midazolam (Versed) 0.5 to 1 mg intravenously and/or fentanyl 25 to 50 mg intravenously to maintain a comfortable but arousable state. With appropriate prior counseling, good local anesthesia, and a reassuring presence by the operator and team throughout, a cardiac catheterization should be an easily tolerated procedure.

THE CARDIAC CATHETERIZATION FACILITY

A modern cardiac catheterization laboratory requires an area of 500 to 700 ft^2, within which will be housed a conglomeration of highly sophisticated electronic and radiographic equipment. Reports of the Inter-Society Commission for Heart Disease Resources on optimal resources for cardiac catheterization facilities have appeared in 1971, 1976, 1983, and 1991 (45). The American College of Cardiology (ACC) and the Society of Cardiac Angiography and Interventions published a clinical consensus document of cardiac catheterization laboratory standards in 2001 (43). These reports deal with issues regarding lab construction, staffing, quality assurance, and more controversial topics such as the following:

1. Traditional versus nontraditional settings for a cardiac catheterization laboratory; location within a hospital versus freestanding
2. Ambulatory cardiac catheterization: indications and contraindications
3. Ethical issues related to self-ownership of laboratories, self-referral of patients, and advertising
4. Optimal annual caseload for physicians and for the laboratory
5. Safety issues during conduct of the procedure (sterile technique, heparin)
6. Physical arrangements and space requirement
7. Radiation safety and radiologic techniques

Certain points, however, are worth discussing here.

Location Within a Hospital Versus Freestanding

The issue of whether cardiac catheterization laboratories should be hospital based, freestanding, or mobile has been the subject of much debate (45–47). Performance of catheterization in a freestanding or mobile unit should be limited to diagnostic procedures in low-risk patients. In its 1991 report, the ACC/AHA (American Heart Association) Task Force "generally found that in freestanding catheterization laboratories, access to emergency hospitalization may be delayed, and appropriate oversight may be lacking. Additionally, opportunities for self-referral may be fostered and the perception of commercialism and entrepreneurial excess in practice created" (45). Immediately available cardiac surgical backup is particularly critical for laboratories that perform diagnostic catheterization on unstable or high-risk patients, as well as for those that perform coronary angioplasty, endomyocardial biopsy, or trans-septal catheterization. Some states, however, have recently allowed performance of acute MI and even elective coronary intervention in hospitals without on-site cardiac surgery as long as it is performed by operators active at other sites and with a formal plan (e.g., an ambulance standing by, and an agreement with a nearby surgical facility to provide timely backup if needed).

Outpatient Cardiac Catheterization

Outpatient cardiac catheterization has been demonstrated by a variety of groups to be safe, practical, and highly cost efficient, and is now widely practiced throughout the world. Outpatient catheterization can be accomplished by the radial, brachial, or femoral approaches, which allow the patient to be ambulatory within minutes of the completion of the catheterization study (48–51). For femoral procedures, hemostasis can be obtained by manual compression for 10 minutes over the femoral artery, followed by a pressure dressing and bed rest for 2 to 4 hours, or use of a femoral closure device (see Chapter 5) with 1 to 2 hours of bed rest before discharge.

TRAINING STANDARDS

Training in the performance and interpretation of hemodynamic and angiographic derived from cardiac catheterization is an important part of fellowship training in Cardiovascular Disease. The current Accreditation Council for Graduate Medical Education (ACGME) training guidelines call for a minimum of 4 months of diagnostic catheterization experience (100 cases), with an additional 4 months of catheterization experience (100 additional cases) for individuals wishing to perform *diagnostic catheterization* in practice, within the basic 3-year Cardiovascular Disease fellowship (52). Although many cardiologists in the past were jacks-of-all-trades performing office evaluation, noninvasive imaging, pacemaker implantation, and diagnostic cardiac catheterization, the current trends toward ad hoc coronary intervention as an adjunct to diagnostic catheterization (see Chapter 22) make it less likely that new practitioners will be seeking to establish practices that are limited to diagnostic cardiac catheterization.

As the field continues to evolve, it is thus increasingly likely that an *invasive cardiologist* (one who performs cardiac catheterization) will also be an *interventional cardiologist* (one who performs percutaneous coronary intervention). In the first 20 years of coronary intervention (1977–1997), one's designation as an interventional cardiologist was at first based on an expressed interest in the field and attendance at one or more informal training symposia. Subsequently, most interventional cardiologists completed a 1-year fellowship at a center that performed interventional procedures (53).

In 1999, however, the ACGME established the structural, content, and faculty requirements for creating an accredited fellowship in interventional cardiology, requiring an additional 12 months beyond the 3-year general cardiovascular training period, during which at least 250 interventional procedures should be performed (52,54). As of 2005, there were 116 accredited interventional programs with 231 positions (compared with 169 accredited general cardiovascular disease programs with 2,117 positions).

In parallel, the American Board of Internal Medicine (ABIM) recognized the body of knowledge subsumed by interventional cardiology by offering a voluntary one-day proctored examination to individuals who met certain eligibility requirements—documented prior performance of 500 coronary interventions (the practice pathway, no

TABLE 1.3

SAMPLE TOPICS THAT MAY BE INCLUDED IN THE INTERVENTIONAL BOARD EXAM

Case selection and management
Choice of intervention or surgery in patient with chronic ischemic disease
Intervention in acute myocardial infarction and acute ischemic syndromes
Drug and device management of hemodynamic compromise
Selection of patients for percutaneous versus surgical valve therapy
Management of adult congenital heart disease
Diagnosis and selection of therapy for peripheral vascular disease
Procedural techniques
Planning and execution of an interventional plan and backup plans
Selection and use of guiding catheters, balloons, stents, etc.
Knowledge of catheter techniques and risks
Use of antithrombotic agents in interventional procedures
Management of procedural complications
Basic Science
Vascular biology of plaque formation, vascular healing, reperfusion
Platelet function and the clotting cascade, including drug effects
Coronary anatomy and physiology (flow dynamics, collaterals, perfusion)
Pharmacology
Biologic effects and use of drugs (vasoactive, sedatives, antiarrhythmics, etc)
Biologic effects of contrast agents
Imaging
Use of angiography and ultrasonography (intravascular and intracardiac)
Radiation physics and radiation safety
Miscellaneous
Ethical issues and risks of diagnostic and therapeutic techniques
Statistics, epidemiology, and economic issues of intervention

TABLE 1.4

ACC/AHA TASK FORCE GUIDELINES FOR CATHETERIZATION LABORATORY AND PHYSICIAN CASELOADS

Category	Cases Per Year
Adult catheterization laboratories	300
Pediatric catheterization laboratories	150
Physician caseload*	
Adult diagnostic catheterizations	Š150 but Š1,000
Adult PTCA procedures	75
Pediatric catheterizations	50
Electrophysiology procedures	100

* The report indicates that physicians with extensive experience (e.g., more than 1,000 independently performed catheterizations) can perform fewer catheterizations to maintain their skill levels.

Pepine CJ, Allen HD, Bashore TM, et al. ACC/AHA Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories. American College of Cardiology/American Heart Association Ad Hoc Task Force on Cardiac Catheterization. *Circulation.* 1991;84: 2213, 2247, and updated in 2001 (see reference 45).

longer open after 2003), or completion of an ACGME-approved interventional fellowship (the fellowship pathway). Candidates able to pass this examination receive Board Certification via a Certificate of Additional Qualification in Interventional Cardiology. An example of the type of content tested in this exam is given in Table 1.3. At this writing, more than 4,000 interventional cardiologists have received the Certificate of Additional Qualification in interventional cardiology, which may soon include the performance of computer-simulated procedures for both training and certification. On the other hand, several thousand individuals continue to perform interventional procedures without the benefit of such certification.

As the field of interventional cardiology expands, it is increasingly recognized that knowledge and skill in coronary intervention does not necessarily confer the ability to safely perform *peripheral* vascular intervention. Some content relating to peripheral vascular procedures is tested in the interventional exam, but individuals interested in performing complex lower extremity or carotid intervention are increasingly undertaking an additional training period after their interventional fellowship to gain the necessary skills and experience (55,56). This training usually includes some degree of training in vascular medicine and noninvasive testing for peripheral vascular disease. At this time, additional board certification has been discussed but not implemented.

As is evident from the range of topics discussed in the remainder of this text, the knowledge and experience base that is now required to perform invasive and interventional cardiology procedures is quite extensive and changes continuously with the serial introduction of new devices and procedures. Staying current in this field thus requires more than completion of a training program and demonstrating an adequate fund of knowledge at one point in time, but rather it requires an ongoing involvement with a sufficient number of procedures (see below) and serial exposure to new procedures and didactic content through review of new clinical trial literature, attendance at one or more lecture and live-case demonstration courses each year, and participation in FDA-mandated industry training programs on significantly novel interventional devices. *We hope that this text will also be an important part of the effort to stay current in this clinically important field!*

Physician and Laboratory Caseload

Use levels and optimal physician caseload are important issues in invasive cardiology. Earlier reports have recommended 300 diagnostic catheterization cases per year for the laboratory and 150 cases per year for each operator to maintain cost-effectiveness, skills, and favorable outcome (Table 1.4) (45,53). At the same time, a cardiologist should not have such an excessive caseload that it interferes with proper precatheterization evaluation of the patient and adequate postcatheterization interpretation of the data, report preparation, patient follow-up, and continuing medical education. More recent guidelines, however, have pointed out the exceptionally low incidence of complications from diagnostic catheterization and questioned the need for minimum individual operator volumes as long as outcome data collection and quality assurance programs are in place (see below) (43).

For interventional cardiology, the guidelines call for the laboratory to perform a minimum of 200 procedures (more than 400 being ideal), and each operator to perform a minimum of 75 cases per year, to remain proficient (43,53). In actuality, these numbers are generally not enforced except at the level of hospital privileging (compliance with minimal volumes is required in some states, however), and a segment of the interventional community still performs as few as 25 to 50 interventions per year. Outcomes data suggest that higher-volume operators working in higher-volume interventional centers do have greater procedural success and fewer adverse complications. But contradictory data suggest that lower-volume operators can still practice safely, at least if they work side-by-side with more-experienced operators in high-volume centers and if they limit the complexity of the procedures they attempt. With the current very low rate of major complications associated with interventional procedures and the difficulties in accurately adjusting outcomes for differences in case complexity, it would be very difficult to draw statistically valid conclusions about this issue. But as in other areas of procedural medicine, there is a compelling truth to the adage that "practice makes perfect."

The Catheterization Laboratory Director and Quality Assurance

An important check on the appropriateness of procedural indications, the safety of procedural outcomes, and the

quality of cath lab report documentation, is the existence of a qualified director in each functioning catheterization laboratory. There are some published general guidelines (43), but my (DSB) comments below are also drawn from more than 20 years of experience in this role.

The director should have at least 5 years of postfellowship experience in procedural performance and should ideally be board certified in both Cardiology and Interventional Cardiology (i.e., the Certificate of Additional Qualification as described above). Important roles of the director include selection and upkeep scheduling of all equipment, over- sight of device ordering systems and procedural policies, training supervision of ancillary personnel (nurses, cardio- vascular technicians, and radiographic technicians), and development of an equitable case scheduling methodology. The director usually also has fiduciary responsibilities to the hospital for the safe and efficient use of catheterization lab time, personnel, and supplies, as well as oversight of the hospital billing activity for catheterization procedures. In exchange, the director often receives partial salary support from the hospital to cover time taken away from remunera- tive clinical practice.

But one of the most important roles of the catheteriza-
tion laboratory director is the systematic collection of outcomes data (using a home-grown database, or increas- ingly, one of several commercial software packages) and periodic (at least annual) reporting of laboratory vol- umes, procedure mix, and major adverse outcomes (43). This usually includes periprocedural death, myocardial infarction (usually using the definition of total creatine kinase [CK] greater than twice the upper limit of normal), emergency cardiac surgery, stroke, local vascular compli- cations, and renal failure (see Chapter 3). These are best presented to the clinical cardiology and cardiac surgery staffs in a joint conference, during which laboratory-wide solutions to certain problems can be introduced and their effectiveness monitored in subsequent conferences (so- called Continuous Quality Improvement methodology). The director should also organize didactic conferences for the fellows and faculty as well as a periodic "cath confer- ence" in which interesting cases, complications, and cases performed with new technologies are presented. In short, the director is responsible for overseeing the safe, effec- tive, and up-to-date operation of the laboratory, with the commitment to provide the best patient care.

PERFORMING THE PROCEDURE

Having carefully considered indications and contraindi- cations, chosen a method of approach, designed the catheterization protocol, and prepared the patient, the next step is to perform the cardiac catheterization itself and thereby gain the anatomic and physiologic informa- tion needed in the individual case. Benchmarking from 82,548 procedures across 53 catheterization laboratories in 1997–1998 (57) showed that the average left heart catheterization took 64 minutes of lab time, including 25 minutes of procedure time. Adding a right heart catheteri- zation increased lab time to 84 minutes and procedure time to 32 minutes. Interventional procedures averaged 117 minutes, with a procedure time of roughly 70 min- utes. Of course, the actual procedure time varies with operator experience and patient complexity, but these data serve as useful benchmarks.

In individual cardiac catheterization procedures, the choice of procedure components will draw selectively on the techniques that are described throughout this text. Detailed descriptions of catheter insertion and hemodynamic mea- surements are contained in Section II (Chapters 4 through 6) and Section III (Chapters 7 through 10), with description of angiographic and interventional techniques in Section IV (Chapters 11 through 14) and Section VII (Chapters 22 through 27). Methods for evaluation of cardiac function and special catheter techniques used only in selected situa- tions are described in Section V (Chapters 15 through 17) and VI (Chapters 18 through 21). Interventional techniques are described in Section VII (Chapters 22 through 27).

Our readers should note that the techniques that are described throughout this text are not proposed as the only cor- rect approaches to cardiac catheterization (many laboratories and operators take different approaches, and still obtain excel- lent results). Rather, they are the methods that have consis- tently been found to be safe, successful, and practical. Moreover, their strengths and weaknesses are well charac- terized, and they therefore constitute an excellent point of reference as one's personal practice continues to evolve based on new clinical trial data and individual preference.