Our concepts of heart disease are based on the enormous reservoir of physiologic and anatomic knowledge derived from the past 80 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 Sanborn3 describe and cite references for experiments by Stephen Hales and others whose work antedates that of Claude Bernard. It is Stephen Hales who perhaps can be credited with the first invasive hemodynamic assessment, as he measured the blood pressure of a horse by inserting a brass rod in the femoral artery and observing the column of blood rising in a 9-foot glass tube connected to the brass rod. In further experiments, which he published in 1733, he proceeded toward identifying how much blood goes through the heart in one minute and determining the capacity of the left ventricle.4

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 and provided the inspiration for the future development of cardiac catheterization. In 1861, Chaveau and Marey published their work on the measurement of intracardiac pressure. They were able to determine that ventricular systole and apical beat are simultaneous, and they were able to perform the first simultaneous measurement of left ventricular (LV) and central aortic pressures. 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 is credited with performing the first cardiac catheterization of a living person—himself. At age 25, while receiving clinical instruction in surgery in Germany, he passed a 65 cm catheter 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 (Figure 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. 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 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.6

Others, however, appreciated the potential of using Forssmann’s technique as a diagnostic tool. In 1930, Klein 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. 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. 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. Subsequent studies from Dexter’s laboratory and by Werko 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, Lenègre and Maurice in Paris, and Warren, Stead, Bing, Dexter, Cournand, and others in the United States.

Further developments came rapidly in the 1950s and 1960s. Retrograde left heart catheterization was first reported by Zimmerman and others and Limon-Lason and Bouchard 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. Transeptal catheterization was first developed by Ross and Cope 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. Coronary angiography was modified for a percutaneous approach by Ricketts and Abrams in 1962 and Judkins in 1967. In 1970 Swan and Ganz introduced a practical balloon-tipped, flow-guided catheter technique enabling the application of catheterization outside the laboratory, and in 1977, Andreas Gruntzig introduced the technique of balloon angioplasty, generally known as percutaneous transluminal coronary angioplasty (PTCA), thus expanding the use of cardiac catheterization to therapeutic interventions and spearheading its future exponential growth.

INTERVENTIONAL CARDIOLOGY

The most significant change in the last 30 years has been the evolution of the therapeutic potential of the cardiac catheter. With rapidly 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. 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 28 through 31). 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 19, 34, and 37).

The evolution of PCI has also stimulated the development of other techniques for the treatment of structural heart disease (see Chapter 32). Catheter devices developed to close intracardiac shunts in pediatric patients have now been adapted to close adult congenital and acquired defects (see Chapter 35). Balloon valvuloplasty was developed in the mid-1980s and remains successful for the treatment of rheumatic mitral stenosis. Due to early recurrence, balloon aortic valvuloplasty is now used as a treatment for aortic stenosis only in patients who are not candidates for aortic valve replacement surgery or in preparation for percutaneous aortic valve replacement. Newer technologies for percutaneous aortic valve replacement and percutaneous reduction of mitral regurgitation are now available as alternative therapies to open heart surgery in selected patient populations (see Chapter 33).

In essence, these new procedures have made interventional cardiology a new field in cardiovascular medicine, whose history is well summarized by Spencer King, 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 (ACC) and the American Heart Association (AHA), and are available online at <http://www.cardiosource.org/>.

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 MI) 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 and coronary angiography. According to the most recent update of the ACC/AHA 2006 Guidelines for the Management of Patients With Valvular Heart Disease, “Coronary angiography is not indicated in young patients undergoing nonemergency valve surgery when no further hemodynamic assessment by catheterization is deemed necessary and there are no coronary risk factors, no history of CAD, and no evidence of ischemia. (Level of Evidence: C)” Thus, many young patients with echo-proven valvular disease and no symptoms of myocardial ischemia are sometimes operated on using only noninvasive data. However, the risks of catheterization in such 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. Therefore, the current guidelines still recommend cardiac catheterization in patients who might be at higher risk of coronary artery disease independent of age, or in patients for whom additional information might be required. 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 LV 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 obstructive cardiomyopathy (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. 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, when there is confusion regarding the presence of obstructive coronary artery disease. Both management and prognosis of this difficult problem can be greatly simplified when it is known, for example, that the coronary arteries are widely patent. However, more recently CT angiography (CTA) has emerged as a new imaging modality and has been replacing invasive coronary angiography as a diagnostic tool to rule out coronary artery disease in this setting. 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 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 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 IRB (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 MI, cardiogenic shock, intractable 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 1.1 lists these relative contraindications. For example, hypertension increases predisposition to ischemia, pulmonary edema, or bleeding 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, active bleeding, digitalis toxicity, and hypokalemia. Unexplained increases in creatinine or worsening renal function are strong indications to postpone the procedure. Table 1.1 lists these relative contraindications. For example, hypertension increases predisposition to ischemia, pulmonary edema, or bleeding 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, active bleeding, digitalis toxicity, and hypokalemia. Unexplained increases in creatinine or worsening renal function are strong indications to postpone the procedure.

### Table 1.1 Relative Contraindications to Cardiac Catheterization and Angiography

<table>
<thead>
<tr>
<th>Condition</th>
<th>Increased Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperkalemia, Hypokalemia or digitalis toxicity</td>
<td>Arrhythmias</td>
</tr>
<tr>
<td>Uncontrolled Hypertension</td>
<td>Bleeding, hemorrhagic stroke following anticoagulation, heart failure and myocardial ischemia during angiography</td>
</tr>
<tr>
<td>Febrile illness</td>
<td>Infection</td>
</tr>
<tr>
<td>Ongoing anticoagulation with warfarin (INR &gt;1.5 commonly used as a cutoff)</td>
<td>Bleeding</td>
</tr>
<tr>
<td>Severe thrombocytopenia. The general consensus is that a platelet count of 40,000/mL to 50,000/mL is sufficient to perform major invasive procedures with safety, in the absence of associated coagulation abnormalities.</td>
<td>Bleeding</td>
</tr>
<tr>
<td>History of severe allergy to contrast media</td>
<td>Life-threatening anaphylactoid reactions</td>
</tr>
<tr>
<td>Decompensated heart failure</td>
<td>Pulmonary edema following contrast administration. Inability to lay flat during the procedure</td>
</tr>
<tr>
<td>Severe renal insufficiency and or anuria, unless dialysis is planned to remove fluid and as renal replacement therapy</td>
<td>Volume overload and pulmonary edema, nephropathy requiring dialysis</td>
</tr>
<tr>
<td>Worsening renal function: unexplained or following radiocontrast administration</td>
<td>Acute renal failure requiring dialysis</td>
</tr>
<tr>
<td>Active bleeding including gastrointestinal bleeding</td>
<td>Major bleeding secondary to administration of anti-platelets and antithrombotic agents</td>
</tr>
</tbody>
</table>

---

INR, international normalized ratio.
Premedication and use of low osmolar contrast agents can substantially reduce the risks of a major adverse reaction, as discussed in Chapters 2 and 4. 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 counter indication. Heparin (unfractionated or low molecular weight), direct thrombin inhibitors (bivalirudin), and antiplatelet agents such as aspirin, ADP receptor blockers, 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 coronary angiography, once felt to lower the incidence of thromboembolic complications during coronary angiography, is now uncommon except when the radial artery approach is used. These agents may be continued through and after the catheterization, particularly with the use of vascular closure devices, 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) that it is best to reverse the prolonged prothrombin time to an international normalized ratio (INR) of <2 (and in most labs to <1.5) 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., atrial fibrillation, a mechanical heart valve). If more rapid reversal of oral anticoagulation is required, fresh-frozen plasma (FFP) is commonly used. We reserve its use only to clinical conditions where urgent reversal is indicated, as administration of FFP requires a high volume load and it is associated with a low though not insignificant risk of infections and of transfusion-related acute lung injury (TRALI). More recently, prothrombin complex concentrates (PCC) have been introduced as a new option to reverse anticoagulation in patients receiving warfarin. They have the advantage of rapid reversal, no association with TRALI, and require administration of a significantly lower volume when compared with FFP. However, the major drawback with PCC has been the risk of thrombotic complications. Their use in reversing oral anticoagulation prior to cardiac catheterization has not been assessed.

**Factors Influencing Choice of Approach**

Certain approaches to cardiac catheterization have only historical interest (transbronchial approach, posterior transthoracic left atrial puncture, suprasternal puncture of the left atrium). In this book, we discuss in detail catheterization by percutaneous approach from various sites (including femoral or radial arteries, femoral or internal jugular veins, transseptal catheterization of the left heart, and apical puncture of the left ventricular apex; Chapter 6). Although it has largely been supplanted by the percutaneous approach, we also discuss catheterization by direct surgical exposure of the brachial artery and vein (the so-called Sones technique, Chapter 8). In addition, the need for using larger catheters for percutaneous valve replacement or endovascular aortic stenting is leading to a resurgence of the femoral artery and subclavian/axillary artery surgical exposure technique, and a shift of the paradigm toward a multidisciplinary team approach including interventional cardiologists, vascular surgeons, and cardiac surgeons (Chapter 8).

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). More recently, the radial artery approach has become the preferred approach of many operators (Chapter 7). It appears to have a lower complication rate when compared to femoral artery access and allows early ambulation. In general, the radial artery is our preferred approach in any setting that might increase the risk of bleeding, including, among others, morbid obesity or the need to resume anticoagulation following a diagnostic or therapeutic procedure.

**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 sync 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),
Chapter 1 Cardiac Catheterization History and Current Practice Standards

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 11) 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 LV 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 to 5 mL/kg divided by the serum creatinine). In a patient with an elevated creatinine in whom coronary intervention is anticipated, the LV 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.

The Checklist
Checklists are commonly used (and are often a necessity) in several industries and professions. They allow a detailed breakdown of the process in each individual component and prevent skipping key steps, which could result in an adverse outcome. More recently, there has been an enhanced interest in the application of checklists to medicine and particularly to surgical procedures. It has been shown that routine use by hospitals of surgical checklists can result in improved survival and lower complications rates. The field of interventional cardiology, with its evolution toward the execution of more complex procedures requiring the expertise and interaction of multiple subspecialties, is an ideal area for the effective use of checklists. Figures 1.2 and 1.3 illustrate two simple checklists currently in use in our institution for all patients referred for invasive procedures and for patients referred for transcatheter aortic valve implantation.

Informed Consent
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. The consent process should be viewed as an opportunity to set expectations and as a tool to manage risk. In general, adequate informed consent discussions should include a description of the proposed procedure and alternatives, including risks and benefits. In addition, 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.

In general, the expectation is that the physician performing the procedure or proposing the therapy has the duty to provide informed consent and that such duty is “nondelegable.” The consent process should be documented in a standardized consent form and in a contemporary note in the patient's chart. The note in the patient's chart should document that a discussion on risks, benefits, and alternatives to the procedures has occurred between the physician performing the procedure and the patient. A study of psychological preparation for cardiac catheterization found that patients who received careful psychological preparation had lower levels of autonomic arousal both during and after cardiac catheterization than did control subjects. A more recent study has also shown that the use of visual aids enhances the patient's understanding of the procedure and future retention of the information provided.

Preparation and Premedication of the Patient
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. The guidelines by the American Society of Anesthesiologists currently recommend a minimum of 2 hours fasting period after clear liquids, and 6 hours after a light meal. 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 antibiotic prophylaxis should be considered if there have been any breaks in sterile technique, in immunocompromised patients, or if a vascular closure device is being used in a patient with diabetes mellitus. Antibiotic prophylaxis is also commonly used prior to implantation of certain devices, such as atrial septal or ventricular septal defect occluders and percutaneous aortic valves. A single dose of a cephalosporin administered 30 to 60 minutes prior to the procedure is adequate in providing suitable tissue concentrations for several hours. As an alternative, vancomycin can be used although the recommendation is that it should be given 120 minutes prior to the procedure. For a comprehensive review on infection control in the cardiac catheterization
### PRE - PROCEDURE CHECKLIST

<table>
<thead>
<tr>
<th>Completed</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Arrival to Holding Area / 7-S. Time: ______</td>
<td></td>
</tr>
<tr>
<td>Time-out Done (Correct info/identifiers/orders)</td>
<td></td>
</tr>
<tr>
<td>Physician Pre-procedure Orders Completed/Done</td>
<td></td>
</tr>
<tr>
<td>Procedure Consent Signed and in Chart</td>
<td></td>
</tr>
<tr>
<td>H&amp;P Completed</td>
<td></td>
</tr>
<tr>
<td>Nursing Assessment Done</td>
<td></td>
</tr>
<tr>
<td>Nursing Notes Sheet in Chart</td>
<td></td>
</tr>
<tr>
<td>Pre-Sedation Assessment Form Completed</td>
<td></td>
</tr>
<tr>
<td>Medication Reconciliation Completed</td>
<td></td>
</tr>
<tr>
<td>IV Access Started / Checked / Patent / IVF Infusing</td>
<td></td>
</tr>
<tr>
<td>Patient Clipped / Preped</td>
<td></td>
</tr>
<tr>
<td>Pre Cath/ EPS/ Pacer / AICD Orders Completed</td>
<td></td>
</tr>
<tr>
<td>Post Cath/ EPS/ Pacer/ AICD Orders in Chart</td>
<td></td>
</tr>
<tr>
<td>Post PTCA Orders in Chart</td>
<td></td>
</tr>
<tr>
<td>Anesthesia Consent in Chart</td>
<td></td>
</tr>
<tr>
<td>Blood Refusal Consent in Chart</td>
<td></td>
</tr>
<tr>
<td>Labs (BP7/CBC/PT/PTT/Type &amp; Screen) Done, Results in Chart</td>
<td></td>
</tr>
<tr>
<td>EKG Done and in Chart</td>
<td></td>
</tr>
<tr>
<td>Physician Post Procedure Orders Forms in Chart</td>
<td></td>
</tr>
<tr>
<td>Observation Orders for Outpatients in Chart</td>
<td></td>
</tr>
<tr>
<td>Printed Physician Progress Notes in Chart</td>
<td></td>
</tr>
<tr>
<td>Sensis Documentation Completed and in Chart</td>
<td></td>
</tr>
<tr>
<td>PACU Report Form in Chart/Post Gen. Anesthesia</td>
<td></td>
</tr>
<tr>
<td>Physician Preliminary Report Form in Chart</td>
<td></td>
</tr>
<tr>
<td>Procedures Charges Sheet in Chart</td>
<td></td>
</tr>
<tr>
<td>Report given to Procedure RN. Time: ________</td>
<td></td>
</tr>
<tr>
<td>Checklist/Chart Reviewed by both RNs</td>
<td></td>
</tr>
<tr>
<td>Holding Area/7-S RN Signature: ________________________________</td>
<td></td>
</tr>
<tr>
<td>Receiving CCL RN Signature: ________________________________</td>
<td></td>
</tr>
</tbody>
</table>

---

**Figure 1.2** Example of a simple nursing checklist for patients referred for cardiac catheterization or any other invasive procedure. The checklist can be easily included in the workflow when using either paper charts or a full electronic medical record (courtesy of the University of Miami).

---

laboratory, the reader is referred to the guidelines of the Society for Cardiovascular Angiography and Interventions.55 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 1.0 mg intravenously and/or fentanyl 25 to 50 mg intravenously to maintain a comfortable but arousable state. Premedication of patients with prior history of allergic reactions to contrast media is listed in Chapter 4. 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**

In the past, the cardiac catheterization suite required ~ 500 square feet of space. With the advent of multimodality imaging and the growth of interventions for structural heart disease, interventional procedures today require the contribution and presence of multiple subspecialties, as well as the presence in the cardiac catheterization suite of additional equipment ranging from anesthesia equipment to echocardiographic consoles and LV assist devices. Thus, the modern cardiac catheterization laboratory has been evolving toward the new concept of the “hybrid suite” and today requires an area ranging from 850 to 1,000 square feet, within which will be housed a conglomeration of highly sophisticated
Chapter 1 Cardiac Catheterization History and Current Practice Standards

Reports of the Inter-Society Commission for Heart Disease Resources on optimal resources for cardiac catheterization facilities have appeared in 1971, 1976, 1983, and 1991.56 The American College of Cardiology (ACC) and the Society of Cardiac Angiography and Interventions have published clinical consensus documents of cardiac catheterization laboratory standards in 2001 and in 2012.43,57 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, self-reporting, unnecessary services 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

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.36,38 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. 

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 transseptal 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 for transfer within 1 hour to a facility with cardiac surgery on site (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.

For femoral procedures, hemostasis can be obtained by manual compression for 10 minutes over the femoral artery, followed by bed rest for 2 to 4 hours, or use of a femoral closure device (see Chapter 6) with 1 to 2 hours of bed rest before discharge. More recently, it has been suggested that outpatient PCI with same day discharge might be both feasible and safe in selected patients.

**Figure 1.4** Modern cardiac catheterization suite. Multimodality imaging hybrid room that can be transformed into an operating room and used for procedures requiring an open access approach such as the transapical approach for transcatheter aortic valve implantation (courtesy of the University of Miami).

**TRAINING STANDARDS**

Training in the performance and interpretation of hemodynamic and angiographic data 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, Level 1), with an additional 8 months of catheterization experience (200 additional cases, Level 2) for individuals wishing to perform diagnostic catheterization in practice, within the basic 3-year Cardiovascular Disease fellowship. Level 3 advanced training in interventional cardiac catheterization requires 12 months of additional training and the performance of 250 PCI as primary operator. 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 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 PCI). 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.

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.63,64 As of 2005, there were 116 accredited interventional programs with 231 positions. By 2011, the number of ACGME-accredited training programs had grown to 137 with 300 active positions.65

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 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 1.2. At this writing, 5,337 interventional cardiologists held a valid Certificate of Additional Qualification in Interventional Cardiology,63 which now also includes the performance of computer-simulated procedures for both training and certification.66 On the other hand, several thousand individuals continue to perform interventional procedures without the benefit of such certification, or do not recertify after expiration of the initial certification. However, many hospitals today require active certification for renewal of privileges.

As the field of interventional cardiology expands, it is increasingly recognized that knowledge and skill in coronary intervention do 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.67,69 As outlined in Table 1.3, this training should occur under the proctorship of a formally trained vascular interventionalist and includes some degree of training in vascular medicine and noninvasive testing for peripheral vascular disease.68 Certifications by a general examination in vascular medicine and an endovascular specialty examination are available through the American Board of Vascular Medicine. Details on eligibility criteria and the examinations can be found at: http://www.vascularboard.org/cert_reqs.cfm. (access date: May, 16, 2013).

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.
### Section I: General Principles

#### Table 1.2: Medical Content, Sample Topics, and Relative Percentage Included in the Interventional Board Exam

<table>
<thead>
<tr>
<th>Case Selection and Management</th>
<th>25%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Topics:</strong> Chronic ischemic heart disease and acute coronary syndromes: catheter-based interventions (angioplasty, stent, IVUS, other devices, pressure wire/FFR assessment, thrombectomy; treatment modality (interventional, surgical, medical); recognition, and management of hemodynamic compromise: pharmacologic agents, devices, and procedures (balloon counterpulsation, emergency pacing, pericardiocentesis, stent placement, and therapeutic hypothermia); catheter-based management in valvular disorders (mitral, aortic, and pulmonary) and in hypertrophic cardiomyopathy, including clinical, invasive, and noninvasive findings that differentiate patients who require surgical versus percutaneous approaches. Catheter-based management of adult congenital heart disease and interventional approaches to peripheral vascular disease, focusing primarily on diagnosis and patient selection.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Procedural Techniques</th>
<th>25%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Topics:</strong> Planning and execution of interventional procedures, selection and use of equipment (guiding catheters, guidewires, balloon catheters, coronary stents, atherectomy, thrombectomy, embolic protection devices, ventricular support devices), antithrombotic agents, complications.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Basic Science</th>
<th>15%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Topics:</strong> Vascular biology, including plaque formation, vascular injury, vasoreactivity, vascular healing, restenosis, reperfusion injury, microvascular angina, clotting cascade, platelet function, thrombolysis, coronary and peripheral anatomy, coronary physiology and myocardial function, alterations in coronary flow, assessment and effect of flow dynamics on myocardial perfusion, function of collateral circulation, arterial spasm or microembolization on coronary flow, left ventricular function, including stunning and hibernation, arterial pressure evaluation, right ventricular infarction, and shunt quantification.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pharmacology</th>
<th>15%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Topics:</strong> Effects and appropriate use of vasoactive drugs, antiplatelet agents, thrombolytics, anticoagulants, antiarrhythmics, lipid-lowering agents, sedating agents, DES compounds, device-related pharmacology, local anesthetic agents, angiographic contrast agents.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Imaging</th>
<th>15%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Topics:</strong> Applications of imaging to interventional cardiology, including identification of anatomic features; visualization of lesion morphology by angiography and by intravascular and intracardiac ultrasonography; structural cardiac and peripheral vascular imaging (including echocardiography, MRI, and OCT), radiation physics, radiation risks and injury, and radiation safety, methods to control radiation exposure for patients, physicians, and technicians, equipment operation and imaging techniques.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Miscellaneous</th>
<th>5%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ethical and legal issues, as well as risks associated with diagnostic and therapeutic techniques. Patient consent and patient safety, statistics, epidemiologic data, and economic issues related to interventional procedures.</strong></td>
<td></td>
</tr>
</tbody>
</table>

FFR, fractional flow reserve; IVUS, intravascular ultrasound; MRI, magnetic resonance imaging; DES, drug eluting stents; OTC, optical coherence tomography; Adapted from American Board of Internal Medicine: Interventional Cardiology Certification Examination Blue Print. At: http://www.abim.org/pdf/blueprint/card_cert.pdf

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. 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 lectures 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. While there are no data supporting these minimum volume standards, it is generally accepted that high-volume laboratories tend to have better outcomes. In addition, low-volume laboratories might be associated with the risk of inadequate equipment and staffing due to financial limitations. At the same time, a cardiologist...
Written curriculum with goals and objectives

Consultation settings

Regular written evaluations by proctor

Supervised experience in inpatient and outpatient vascular

Supervised experience in a noninvasive vascular laboratory

Documentation of procedures and outcomes

Peripheral interventions—50 cases (25 as primary operator)

Must include aortoiliac arteries as initial area of competency

Percutaneous thrombolysis/thrombectomy—5 cases

Peripheral interventions per area—15 cases (8 as primary operator)

Alternative Route to Achieve Competence in Peripheral Catheter-Based Interventions

No fewer than 20 diagnostic/10 interventional cases in each area,

Diagnostic peripheral angiograms per area—30 cases (15 as primary operator)

Completion of required training within 24-month period

Training under proctorship of formally trained vascular interventional-

Written curriculum with goals and objectives

Regular written evaluations by proctor

Supervised experience in inpatient and outpatient vascular

Consultation settings

Supervised experience in a noninvasive vascular laboratory

Diagnostic peripheral angiograms—100 cases (50 as primary operator)

Peripheral interventions—50 cases (25 as primary operator)

No fewer than 20 diagnostic/10 interventional cases in each area,

Extracranial cerebral (carotid/vertebral) arteries—30 diagnostic (15 as primary operator), 25 interventional (13 as primary operator)

Percutaneous thrombolysis/thrombectomy—5 cases

Table 1.3 Alternative Route to Achieve Competence in Peripheral Catheter-Based Interventions

Common requirements

Procedural requirements for competency in all areas

Requirements for competency in subset of areas (up to 3, excluding carotid/vertebral arteries)

*The fulfillment of requirements via an alternative pathway is only appropriate if the candidate physician has the cognitive and technical skills and is competent to perform either coronary intervention, interventional radiology, or vascular surgery.


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). 87,88

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. 87,88 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. Outcome data suggest that higher-volume operators working in higher-volume interventional centers do have greater procedural success and fewer adverse complications. However, other data suggest that while the trend between operator and outcomes continues to exist with contemporary PCI, some lower-volume operators can still practice safely (Figure 1.6), 71 and particularly 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. All that said, 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 catheterization lab report documentation, is the existence of a qualified director in each functioning catheterization laboratory.

The director should have at least 5 years of post fellowship experience in procedural performance and should 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, oversight of device ordering systems and procedural policies, training supervision of ancillary personnel (nurses, cardiovascular 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 remunerative clinical practice.
Section I General Principles

One of the most important roles (if not the most important) of the catheterization laboratory director is the systematic collection of outcomes data and a fair assessment of the quality of care provided by individual operators. In addition to clinical outcomes, data collection should include comorbidities and procedure variables. This can be achieved by participation in a regional or national registry, or through the use of homegrown databases. Participation in a regional registry (Northern New England, Michigan BMC2, New York State, Massachusetts, Washington State, and other regional registries), or in the national American College of Cardiology CathPCI registry provides the added value of comparative risk-adjusted data that can be used for benchmarking and for quality improvement. Outcome data of interest usually include periprocedural death, MI, stroke, emergency CABG, peripheral vascular/access site complications (pseudoaneurysm, arteriovenous (AV) fistula, loss of pulse, need for vascular surgery, or significant hematoma), pericardial tamponade, the occurrence of contrast-induced nephropathy, and blood transfusion.

These are best presented to the clinical cardiology and cardiac surgery staff in a joint conference, during which laboratory-wide solutions to certain problems can be introduced and their effectiveness monitored in subsequent conferences (Continuous Quality Improvement methodology). The director should also organize didactic conferences for the fellows and faculty as well as a periodic “cath conference” in which interesting cases, complications, and cases performed with new technologies are presented. In addition, an assessment of the appropriateness of procedure performed according to available guidelines should be included in the quality assurance program. In short, the director is responsible for overseeing the safe, effective, and up-to-date operation of the laboratory, with the commitment to provide the best and most appropriate patient care.

PERFORMING THE PROCEDURE

Having carefully considered indications and contraindications, 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 information needed in the individual case. Benchmarking from procedures across 53 catheterization laboratories in 1997–1998 showed that the average left heart catheterization took 64 minutes of lab time, including 25 minutes of procedure time. Adding a right heart catheterization increased lab time to 84 minutes and procedure time to 32 minutes. Interventional procedures averaged 117 minutes, with a procedure time of roughly 70 minutes. 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 draws selectively on the techniques that are described throughout this text. Detailed descriptions of catheter insertion and hemodynamic measurements are contained in Section II (Chapters 6 through 8) and Section III (Chapters 10 through 14), with description of angiographic and interventional techniques in Section IV (Chapters 15 through 19) and Section VII (Chapters 28 through 39). Methods for evaluation of cardiac function and special catheter techniques used only in selected situations are described in Section V (Chapters 20 through 23) and VI (Chapters 24 through 27). Our readers should note that the techniques that are described throughout this text are not proposed as the only correct approaches to cardiac catheterization (many laboratories and operators take different approaches, and still obtain excellent results). Rather, they are the methods that...
have consistently been found to be safe, successful, and practical. Moreover, their strengths and weaknesses are well characterized, 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.

REFERENCES
4. Hales S. Statical Essays: Containing Haematastics: Or, an Account of Some Hydraulic and Hydrostatical Experiments Made on the Blood and Blood-vessels of Animals. To which is added, an appendix, with an index to both vols II, 3rd ed., v 2 of 2. (Reduction of original writings available through: Gale Eighteenth Century Collection Online Print Editions).
Section I General Principles


