Guidelines for the Performance of Percutaneous Transluminal Coronary Angioplasty

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SUMMARY Percutaneous transluminal coronary angioplasty is a complex procedure that requires special training of the physician who performs it and appropriate laboratory facilities and surgical support. The guidelines in this report represent the optimal conditions for the safe performance of percutaneous transluminal coronary angioplasty.

PERCUTANEOUS transluminal coronary angioplasty (PTCA) is a new, innovative, nonoperative technique for treating selected patients with coronary artery disease.1 Data from the PTCA Registry of the National Heart, Lung, and Blood Institute indicate that PTCA can reduce the extent of coronary artery stenosis.2 Successful PTCA can relieve angina pectoris and improve objective signs of myocardial ischemia.1,3-5 In selected patients, these benefits can be obtained with a combined mortality and morbidity rate less than or similar to that associated with coronary artery bypass surgery.6,7

Although PTCA is performed in the cardiac catheterization laboratory with patients fully conscious and with techniques similar to those used in routine diagnostic catheterization and angiography, it is far more complex, requiring skills and knowledge beyond those necessary for usual diagnostic procedures. Serious complications, including death, have occurred as a result of PTCA, and the possibility of such complications is far greater than expected from diagnostic cardiac catheterization. The knowledge and experience gained by the developer and initial investigators of this technique and data contributed to the NHLBI Registry indicate that both the incidence of serious complications and of successful PTCA procedures may be related to patient selection and to performance characteristics and experience of the physician, the laboratory facility and the standby surgical team involved in the PTCA procedure.6 From an analysis of these data, we have formulated guidelines for the optimal performance of PTCA. These guidelines are intended for physicians, hospital administrators and health planners who contemplate the initiation of or continued performance of PTCA in an institution.

The Physician
The physician who performs PTCA should be thoroughly competent at performing routine diagnostic cardiac catheterization and angiographic procedures. He should satisfy previously published criteria for performing catheterization, which may include: (1) training and certification or qualification for certification in internal medicine, pediatrics or radiology, and preferably their respective cardiovascular subspecialty board; and (2) 1 or 2 years of specialized training in cardiovascular laboratory procedures.8,9 Furthermore, the physician should have substantial experience (usually 3-4 years) in performing cardiac catheterization without supervision; demonstrate a complication rate within previously established guidelines;10 and be competent in the diagnosis and management of the serious cardiovascular complications that can occur during catheterization and PTCA, particularly ventricular fibrillation, heart block and cardiogenic shock.

In addition, performance of PTCA requires specialized training beyond that necessary for routine diagnostic cardiac catheterization and angiography. This requirement would be best satisfied by completion of a formal training program dedicated to training physicians in PTCA. Since the availability of such programs is limited, the following alternative recommendations are offered. First, the physician considering initiating a PTCA program should observe the procedure at a demonstration course or an established center. This preliminary contact with PTCA permits the physician to judge the appropriateness of his own and his institution’s suitability to establish a new PTCA program. Second, if suitable patients are identified by the physician trainee and they wish to undergo the procedure, the procedure could be carried out at the established PTCA site with the physician in attendance and participating. At this time the physician would obtain additional in-laboratory training. This activity could be repeated until the physician gains sufficient skill and knowledge to perform PTCA independently. This format would also allow the physician to determine if his

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laboratory would generate an adequate volume of suitable PTCA candidates to warrant the initiation of PTCA at his facility. Third, when performing the initial PTCA procedure in his own laboratory, the physician may benefit from on-site guidance by a physician already skilled in performing PTCA.

A physician performing PTCA should carry out an adequate number of procedures to maximize patient safety and the efficiency of the laboratory. A minimum case load for a single physician is estimated to be about one case per week after 1–2 years of initial experience. Because the incidence of PTCA candidates is currently about 5% of patients undergoing cardiac catheterization with coronary artery disease, those institutions capable of drawing upon a substantial case volume are logical sites to consider undertaking PTCA. Given these considerations, PTCA is a procedure most appropriately performed on a regional basis with a central laboratory offering this service for laboratories of other local institutions.

Continued performance of PTCA should be dependent upon the demonstration of success and complication rates that meet the national standard. The incidence of serious, nonfatal complications (i.e., emergency cardiac surgery, myocardial infarction) should be less than 10% in a facility’s first 50 cases and less thereafter. Mortality should not exceed that of coronary artery bypass surgery for matched patients. The success rate should be at least 60%. If a physician cannot perform PTCA within these guidelines, he should review his protocol with a more experienced practitioner of PTCA or consider referring his patients to a physician with acceptable results.

Since the PTCA technique continues to be modified and refined, practitioners should participate in a program of continuing education to maintain and further enhance their skills.

Laboratory

The angiographic information required to assess a patient’s suitability for PTCA or to perform the procedure is substantially greater than that required for routine diagnostic cardiac catheterization. Thus, radiologic equipment suitable or even optimal for performing routine diagnostic catheterization procedures may be suboptimal or even inadequate for a PTCA facility. In addition to satisfying specifications already enumerated, an ideal facility for the optimal performance of PTCA should include the following radiologic capabilities: (1) an x-ray tube-image intensifier configuration capable of multangular projections, including cranial and caudal views, with the ability to change projections expeditiously; (2) a high-resolution image intensifier and television chain providing high definition with broad latitude; (3) biplane imaging capability; and (4) multimode image intensification, including 15–17-cm (6–7-inch) and 10–12-cm (4–5-inch) modes.

These recommendations are optimal and do not represent the minimal requirements. Not all of these radiologic features are available in most laboratories. Moreover, the expense of upgrading existing equipment to this level may be prohibitive, and facilities available in a given community may be duplicated. Nevertheless, every laboratory in which PTCA is performed should satisfy the minimal requirements of readily obtainable multangular views and demonstrated high-quality video imaging that permits distinct visualization of the guidewire (0.018-inch diameter) at the tip of the dilating catheter when positioned in a coronary artery.

Surgical Support

Performance of PTCA requires the standby support of a surgical team that can perform immediate coronary artery revascularization. PTCA can result in abrupt coronary arterial occlusion. Thus, certain patients undergoing the procedure may develop acute myocardial ischemia and possibly infarction. Experience to date indicates that immediate coronary artery bypass surgery with an elapsed time from occlusion to restoration of flow of approximately 90–120 minutes, will usually avert progression from ischemia to infarction. Thus, PTCA should be performed only when a skilled surgical team is immediately available. The surgical team should be capable of successfully operating on unstable, acute ischemic patients in an emergency setting.

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