Percutaneous transluminal coronary angioplasty, a 1985 perspective

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AS WITH MOST chronic progressive diseases, cure of ischemic heart disease is not expected by any current therapy. The objective in management is to achieve maximum cardiac function for an increased period of time. Coronary bypass is now generally accepted as a useful method in many patients for accomplishing this palliation. It is also recognized as temporizing in most instances. Complementary interventions are therefore attractive as a means to extend the period of palliation. Percutaneous transluminal coronary angioplasty (PTCA) is one such technique.

Percutaneous angioplasty of peripheral vessels was demonstrated as feasible by Dotter and Judkins in 1964. This application has increased slowly but steadily and served as a background experience for Gruentzig et al. before their use of the technique in the coronary circulation.

In the five years since that first clinical report, interest in PTCA has steadily increased and there are now hundreds of centers in this country that perform the procedure. This review is an attempt to present one observer’s appraisal of the current place of the procedure in clinical medicine.

Of concern to many is the lack of a precisely defined process by which dilatation increases luminal diameter and coronary flow. The proposition that there results a compression of atheromatous material, or even an extrusion of material, has not been excluded as a mechanism but has not been verified in most preparations or in postmortem examinations. In the atherosclerotic rabbit, investigators have not observed compression, even though in this preparation foam cells are a much more prominent component than in human atherosclerosis. Instead, in most animals there is splitting of the atheromatous plaques out to the adventitia. There is, in addition, desquamation of most endothelial cells in the dilated area, with exposure of subendothelial microfibrils and subsequent deposition of platelets and fibrin. In a very few instances the plaques do not split and an increased narrowing results.

Portmortem studies in human vessels have yielded similar findings. Dilatation of vessels with eccentric plaques results in enlargement of luminal cross-sectional area by separation of the plaque from the underlying tunica media and stretching and thinning of the media with frequent medial rupture. The integrity of the vessel is maintained by the adventitia. In vessels with circumferential plaques there is rupture of the plaque with extensive separation of the plaque and deep cleft formation between the plaque and the tunica media. Current wisdom has it that the splitting of the intima and aneurysm formation, rather than compression, are the mechanisms of increased luminal diameter resulting from transluminal angioplasty.

Regardless of mechanism, it is clear that a meaningful number of patients are demonstrated to have improved flow and are symptomatically improved after PTCA. Evidence of improvement after PTCA, other than symptomatic relief and angiographic appearance, has been presented by several investigators. The result of 38 successful dilatations in 59 patients reported by Kent was improvement in luminal diameter reflected by a reduction in average stenosis from 71% to 31%. This was associated with a change in ejection fraction at exercise from 51% to 61%. Improvement in diastolic filling has been observed after PTCA in the presence of pretreatment normal resting systolic function.

Although several centers have reported short-term results after PTCA, the most comprehensive information is available from the NHLBI Registry established in 1979. That registry accessed 3248 patients who had a total of 3567 procedures through September 30, 1982. The major emphasis of the registry centers around the courses of 3079 patients undergoing 3390 procedures performed at 105 sites. In nearly 25% it was not possible to pass the dilatation catheter through the lesion. In another 8% dilatation could not be ac-

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complished. Serious complications, defined as the need for emergency bypass, death, or myocardial infarction, occurred in 9%. The overall complication rate was 21% and the mortality rate was 0.9%. The recent experience of several large centers is somewhat more favorable than this and the registry itself indicates that larger experiences are associated with a higher incidence of success and fewer complications. There is also a learning curve indicating increasing success with increasing experience. Considering, however, that the registry is heavily weighted toward larger experiences, it is reasonable to believe that the results from the registry are not less favorable than those generally experienced. It is clear that both success and complications are a matter not only of technical expertise, but also of patient selection. The current overall immediate success rate can be considered to be close to 70% when based on an estimated improvement in luminal diameter of 20%. In some larger experiences, this success rate approaches 85%.

Prompt operative revascularization is required in 3% to 5% of instances in which acute ischemia is induced. The data from the NHLBI registry indicate that 6.6% of the 3079 patients required emergency revascularization. In a recent large single-center study, this percentage was 3.7% of 866 patients undergoing 963 attempts. In the registry the emergency operations were associated with a 4.4% mortality. The absence of mortality in 32 patients undergoing emergency operations recently reported from Emory can perhaps be attributed in part to immediate initiation of intra-aortic balloon counter pulsation and prompt initiation of cardiopulmonary bypass. Patients suffering acute myocardial infarction as a complication of emergency operations experienced an 8.4% mortality. It is generally accepted that the complications of acute ischemia induced by PTCA are best treated by prompt revascularization. This can at times be accomplished by further manipulations of the intravascular catheter, but surgery remains a final resort. The availability of operative capability is taken to be an essential component of the system when PTCA is undertaken. It is not unreasonable to expect a response time of less than an hour from the onset of ischemia to the initiation of extracorporeal circulation. The onset of ischemia, as manifested by pain or electrocardiographic changes during or immediately after PTCA, should trigger vigorous evaluation and treatment. Results of coronary arteriography are important in defining the anatomic basis of the complication and deciding on the method of treatment. There are no well-established guidelines for deciding, once a complication occurs, between operative and nonoperative therapy. A large extent of myocardium at risk would seem to be a crucial factor in deciding for operation. Thrombolysis has been frequently employed, but should not delay operation if a major vascular bed is compromised. Comprehensive monitoring, rhythm control, pharmacologic support, and perhaps even intra-aortic balloon pump support, are useful preoperative adjuncts while progressing to the operating room.

Complications other than acute ischemia that necessitate surgery are consequential: ventricular tachycardia and fibrillation, hypotension, bradycardia, coronary occlusion without infarction, blood loss, and vascular lesions at the puncture site. In a well-controlled setting these can be managed with an overall mortality rate of 1%, with essentially all of the risk residing with those patients who have acute infarction and who require emergency operative intervention. In spite of what seems to be an array of threatening complications, it is important to emphasize that the average registry hospital stay was only 3 days.

Long-term results of PTCA remain unknown. Although there was a very early plea for systematic evaluation by clinical trials, such studies have not been initiated. The feasibility of prospective randomized trials has been an agenda item at the three workshops convened by the NHLBI (in 1979, 1982, and 1983). A host of factors, including changing equipment and technique, unstandardized ancillary treatments, unwillingness of practitioners to randomize, softness of end points, changing indications and patient selectivity, and patterns of referral and follow-up, all have mitigated against organization of such a study. Meaningful prospective long-term (3 to 5 year) results are yet to be reported. The NHLBI registry does have some limited follow-up data. At 1 year, of the 1418 patients followed, 37 (2.7%) had died, 8.5% had undergone repeat PTCA, and 33.3% had been treated operatively. Overall 62.7% were symptom free and had not experienced myocardial infarction. If only those not treated by operation are considered, only 36.5% were symptom free and had not sustained infarction. Initial successful dilatation was followed by restenosis in 34% within 6 months. The number followed to 3 years has been small (248). Thirty-six percent of those remained symptom free. Seven percent of those not successfully dilated and not operated upon were, however, also symptom free at 3 years.

This latter information suggests that although it is generally stated that candidates for PTCA should be in a clinical category indicating the need for bypass, some patients are being selected for PTCA that truly do
not have operative indications. It is an impression that as indications for operation have become more restrictive in patients with mild angina, PTCA is being applied more frequently as an alternative to drug therapy rather than as an alternative to operation. Comparison of risks of operation are therefore somewhat strained as the more symptomatic patients are generally those with more significant disease with more myocardium at risk and at greater risk at operation.

Although originally advocated for patients with single-vessel disease, use of PTCA has quickly been extended to patients with double- or triple-vessel disease with dilatation of one or, at times, more lesions at the same procedure. There is a belief that patients might be converted from the risk category of double-vessel disease to that of single-vessel disease if one vessel is dilatated. Reported experiences with single or multiple dilatation in patients with multiple-vessel disease would indicate that the immediate risk remains low and that successful dilatations can be expected 60% or 70% of the time. The effect of this on longevity and the duration of benefit has not yet been determined.

Intraoperative dilatation of stenotic lesions in conjunction with bypass operation has had a small but generally favorable application. The most usual application has been the dilatation of a narrowing distal to an anastomosis, where the vessel beyond the stenosis is not of a size or location favorable for grafting. Although the follow-up has been short and incomplete, the results suggest that this will be an increasingly employed adjunct to surgery as the instrumentation and technique become better defined.

Postcoronary bypass dilatation of the native vasculature and of graft stenosis has also had limited applications. Mortality for those patients having native lesions dilated at some time after surgery has been unusually high, although the group observed has been small and the nature of the disease incompletely detailed. It is suspicious that this group had more extensive disease than those first undergoing dilatation. It is quite likely that graft stenosis is considerably different in morphology and mechanism than native vessel disease and the place of dilatation in this setting awaits definition.

In that the risk of mortality with PTCA is principally a concern in those patients requiring prompt operative intervention, and considering that the technical problems of operating in the setting of a previous operation can induce considerable delay and risk in both establishing extracorporeal circulation and revascularization, careful attention should be given to patient selection when choosing PTCA after bypass operation. Elective surgery likely offers greater safety to most such patients.

The results of coronary artery bypass are now well known. Two prospective randomized trials comparing surgery with drug therapy, a well-documented registry of patients undergoing and those not undergoing surgery, and numerous reports of immediate and long-term results allow for reasonably accurate statements as to risks and anticipated benefits. These risks and benefits have been detailed relative to a goodly number of disease stratifications.

The lack of a comparative experience with PTCA and coronary bypass makes it difficult to draw comparisons. It has been contended that operation in a group of patients who had undergone PTCA would result in no greater, or even less, mortality and incidence of myocardial infarction. Reports of current operative experiences clearly confirm this. The persistence of beneficial effects, according to reported results, appear to be considerably better with operation. Surgery clearly is disabling for a longer period of time and as a single event more costly. Total cost comparisons are hampered at this time by insufficient information as to the incidence of repeat dilatations and good cost figures under those circumstances in which there is PTCA failure and concurrent or subsequent operation. There is clearly some reason to believe that there are some savings in the short-term by PTCA.

In the absence of trials identifying the differences in outcome between PTCA and operations, or between PTCA and drug therapy, therapeutic decisions have to be made by best judgment based on current reported results.

There is, then, an obligation for detailed reporting of basic information and of immediate and long-term results. Although obviously quite inferior to the data that would be generated by prospective randomized clinical trials, information from well-described and rigorously followed patient groups should allow for more informed decisions as to therapeutic approaches for categories of diseases and for individual patients.

Studies of coronary artery bypass surgery have adequately demonstrated that the relief of symptoms and improvement of life expectancy after the procedure result from amelioration of localized mechanical obstructions in the coronary system. It is only reasonable that methods would be sought to accomplish relief of this mechanical obstruction by simpler methods. PTCA, although somewhat immature and incompletely evaluated, is such a method compared with the open heart operation of coronary bypass. Its current adoles-
cience, limited applicability, and relatively temporary effect will certainly prompt investigation of altered techniques and ancillary measures to extend its use and improve results. This will clearly come about by increasing clinical application under low-risk circumstances in which there is reasonable promise of advantage to the individual patient. There will certainly also be vigorous efforts to develop other methods of relieving the obstructions by intraluminal manipulations.

Percutaneous angioplasty and operation should not be viewed as competitive procedures. For many patients both will be employed over the total course of their treatment, each being employed at a time when there is promise of ameliorating the disease process for some period of time. Both procedures are temporizing. Both procedures are being repeated in individual patients. Dilatation at a time before operation will, in many patients, delay but not contradict operation and in some instances will be a useful adjunct at the time of operation or in treating postoperative progression of disease or graft narrowing. In the individual patient it is of greatest importance to choose the procedure that, at the lowest risk, will offer an opportunity for improved function and preservation of myocardium without foreclosing the possibility of use of an alternate procedure at a later time.

The objective is to palliate and to protect, as much as possible, the patient with coronary restrictive lesions. In the absence of a cure, all choices for amelioration are only temporizing. It is not unreasonable to expect that in individual patients the appropriate choice of any one procedure, or the sequencing of procedures, lacks absolute definition. Bypass operation has come to have well-recognized advantages and risks. It is imperative that comparable information be developed for PTCA so that, insofar as possible, practitioners can help patients make informed choices.

References
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