

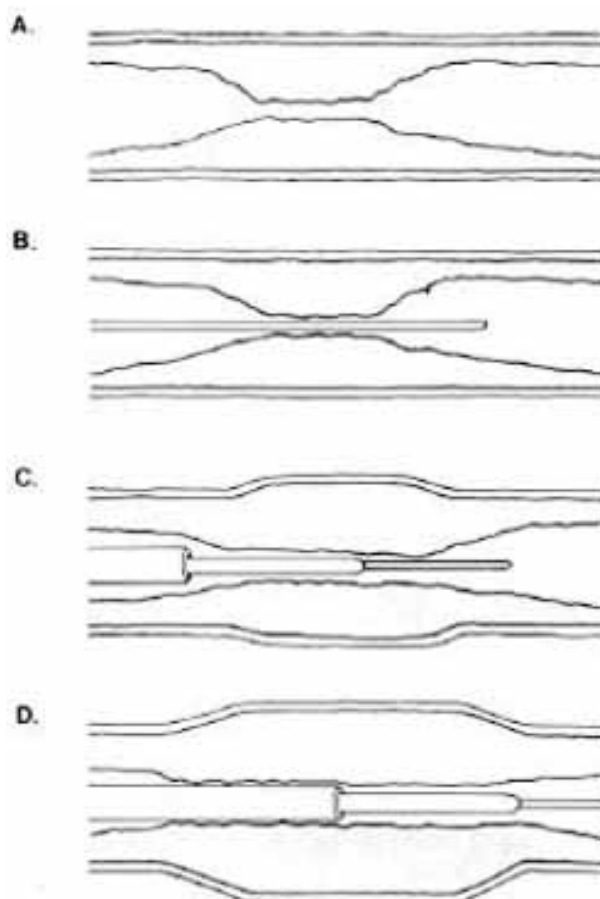
## PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY: CURRENT STATUS

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Percutaneous transluminal coronary angioplasty involves passage of a balloon-tipped catheter to the site of arterial narrowing and inflation of the balloon to relieve the obstruction. This nonoperative method of treatment of atherosclerotic lesions was first developed by Dotter and Judkins<sup>1</sup> in 1964. They used a percutaneously introduced coaxial catheter system to compress localized atherosclerotic lesions in the femoral artery (fig. 1). This technique later called transluminal angioplasty did not gain widespread acceptance because of the high incidence of local complications. This approach was modified by Grüntzig<sup>2</sup> who developed a double-lumen, balloon-tipped catheter that could be inflated and deflated to achieve a similar effect with a low complication rate and with short and long-term results comparable to those of surgical treatment. This early success with peripheral balloon angioplasty led to miniaturization of the balloon catheter.

Following successful tests in the animal laboratory, on cadaver hearts, and intraoperatively during coronary bypass surgery, Grüntzig performed percutaneous transluminal angioplasty on a coronary artery in a human<sup>3</sup>. Since its first application percutaneous transluminal coronary angioplasty (PTCA) has evolved from an exciting new method to a widely accepted alternative to coronary artery bypass graft surgery (CABG) in selected patients.

There are several reasons for the growing popularity of the procedure. Jang<sup>4</sup> reported that up to 170 million a year could be saved in the United States, if 17000 patients with 1 vessel coronary artery disease (CAD) who were potential surgical cases were treated instead by PTCA. Probably even more money could be saved, as this estimate does not take into account such factors as the amount of wages lost due to disability and funds expended for rehabilitation. Furthermore patients with successful PTCA return to Work significantly sooner when compared with patients who undergo to CABG<sup>5</sup>.



dilator required a substantial amount of contact or engagement between the catheter and stenosis during advancement. Dilatation occurred concurrently with introduction. A, severe arterial stenosis. B, guide wire is advanced through the stenosis. C, the No. 8 Fr and 12 Fr coaxial dilators are passed sequentially over the guide. D, passage of the fixed diameter dilator results in dilatation.

### TECHNIQUE

The technique of coronary angioplasty is based on the method originally described by Grüntzig<sup>6</sup>.

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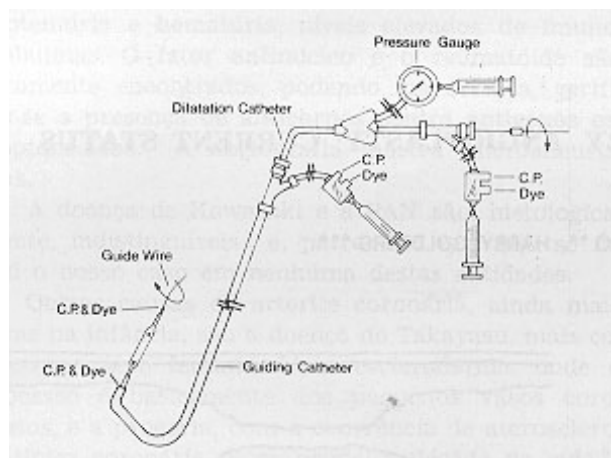


Fig. 2 - Schematic diagram of a steerable catheter system for PTCA. Cp, continuous pressure.

The preparation protocol is similar to that of standard cardiac catheterization, with certain modifications. The patient is brought to the catheterization laboratory without premedication; food and water are withheld overnight. During the evening before the procedure, the patient is given aspirin (1,0 gr) and started on nifedipine (10 mg q6 hrs). Blood is typed and cross-matched. A surgical and anesthesia teams are requested to see the patient on the day before and will be on standby during the procedure.

A peripheral intravenous (IV) line is inserted for administration of medication throughout the procedure. Intravenous diazepam is used for sedation during the procedure. Intravenous Dextran-40, at 100cc/hr is started and continued for 2 hours after the procedure to prevent platelet adhesion. A bipolar pacemaker catheter is inserted into the right ventricle through a femoral vein sheath. An 8Fr or 9Fr angioplasty guiding catheter is inserted in the femoral artery through a long percutaneous sheath. To prevent thrombus formation, 10,000 units of IV heparin is given. In addition 5 mg of isosorbide dinitrate and 10 mg of nifedipine are administered sublingually to prevent coronary spasm at the dilatation site.

The catheter-dilatation system consists of three parts: the guiding catheter, the dilatation catheter and the guiding wire (fig. 2). The guiding catheter can be inserted into the femoral artery percutaneously or into the brachial artery via an arteriotomy. Angiography is performed in the projection that best outlines the lesion to be dilated. Coronary angiography is repeated in the vessel to be dilated after the administration of 100 to 300 mcg of intracoronary nitroglycerin to decrease the possibility that coronary artery spasm is contributing to the stenotic lesion. The dilatation catheter is a double-lumen catheter that permits pressure monitoring or injection of contrast material from its distal part as well as inflation of the balloon. Once the catheter dilatation system is positioned at the ostium of the coronary artery to be cannulated the guide wire is advanced under fluoroscopy into the coronary artery and positioned distal to the lesion. Then the dilatation catheter is slid over guiding wire and positioned inside the

narrowed segment of the coronary to be dilated.

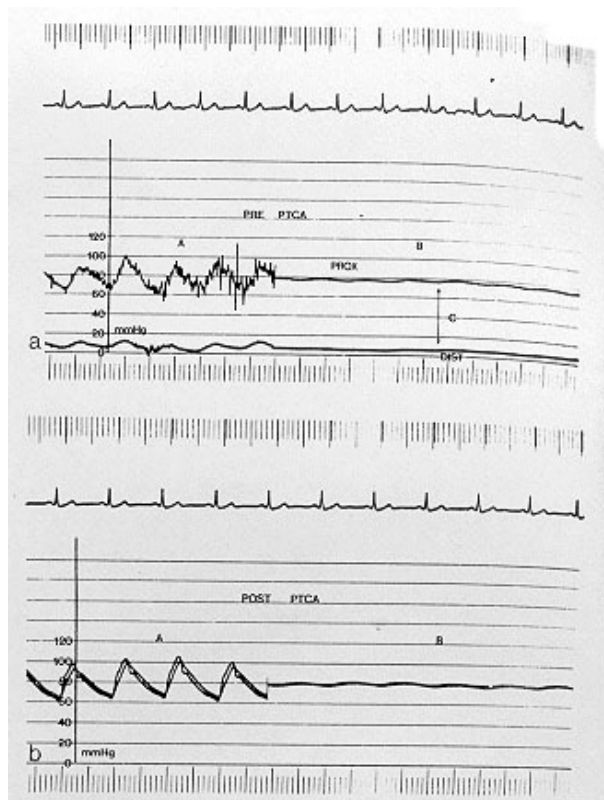


Fig. 3 - Pressure tracings simultaneously recorded from the guide and balloon catheters. A, phasic pressure. B, mean pressure. C, gradient across the stenosis. Prox, proximal. Dis, distal. A, pre PTCA. B, post PTCA.

Pressures are constantly monitored during positioning of the dilatation catheter. The guiding catheter monitors proximal coronary artery pressure while the dilatation catheter measures distal pressure. As the dilatation catheter passes through the lesion, the distal pressure falls, reflecting the pressure gradient across the stenosis. The angioplasty balloon, which has been filled with a solution of saline and contrast material, is then inflated for 10-30 seconds to 4-10 atmospheres of pressure. Successive inflations are then made. When injections of contrast medium through the guiding catheter show satisfactory reduction of stenosis and when the pressure gradient across the coronary narrowing is below 20 mm Hg, the balloon catheter is withdrawn and a control coronary angiogram is performed (Fig. 3 and 4). The guiding wire is left inside the dilated coronary artery for 10-15 minutes in the event that sudden reclosure or coronary spasm occurs. Then the angioplasty catheter system is withdrawn leaving the femoral artery sheath. The temporary pacemaker wire is also removed.

The patient is then moved to a telemetry bed in an intermediate care nursing unit. Dextran-40 is continued for about 2 hours. Nifedipine and nitrates given to prevent coronary spasm. The sheaths are

removed 2 hours after the procedure. In some cases heparin is given by continuous infusion for 24 hours and activated partial thromboplastin time 2-3 times the control and then the sheaths are removed. If the physician is concerned about the success of angioplasty or if the patient experiences pain or arrhythmias, monitoring is carried out in the coronary care unit.

If chest pain or ECG changes occur following PTCA, the patient is brought back to the catheterization laboratory, and resting angiograms are obtained via the original sheaths to document the angiographic situation. Chest pain following PTCA is usually due to sudden reclosure and/or coronary spasm and is treated with intracoronary nitroglycerin administration. If chest pain persists, repeat PTCA may be attempted, based on the likelihood of successful recrossing and dilatation. Sudden, persistent reclosure unresponsive to nitrates and calcium blockers, may necessitate emergency coronary bypass surgery. Some authors have used intracoronary infusion of streptokinase for coronary thrombosis in the course of PTCA. Reopening was described as being achieved successfully and surgery performed soon after the PTCA was carried out without bleeding complications<sup>7</sup>.

Patients who have undergone successful PTCA are usually discharged on aspirin and dipyridamole. Although there is no conclusive proof, it is thought that these drugs, through their platelet inhibitory properties may prevent vascular reocclusion of the dilated vessel.

#### PATIENT SELECTION

PTCA is not invariably successful (Fig. 5). It also has to be considered a major intervention. PTCA was introduced as an alternative to coronary surgery primarily in patients who had single-vessel disease<sup>6</sup>. Careful selection of PTCA candidates is important in order to minimize complications and maximize the success rate.

Several factors should be considered in patient selection: all patients referred for PTCA should be candidates for coronary bypass surgery. Because some PTCA patients may go on to have either emergency or elective surgery, PTCA candidates should be prepared for surgery before PTCA is attempted. Patients who refuse surgery are not candidate for the procedure. Patients should have objective evidence of myocardial ischemia by treadmill electrocardiogram with or without scintigraphy. Such studies allow noninvasive evaluation of the functional success of the PTCA. Ideally patients should have single-vessel disease, although indications have presently been expanded to include selected cases of multi vessel disease with an acceptable complication rate<sup>8</sup>.

The initial recommendation of limiting the procedure to cases with proximal, short, smooth, non-calcified and concentric narrowing have been widened to include distal, calcified and eccentric lesions, al-

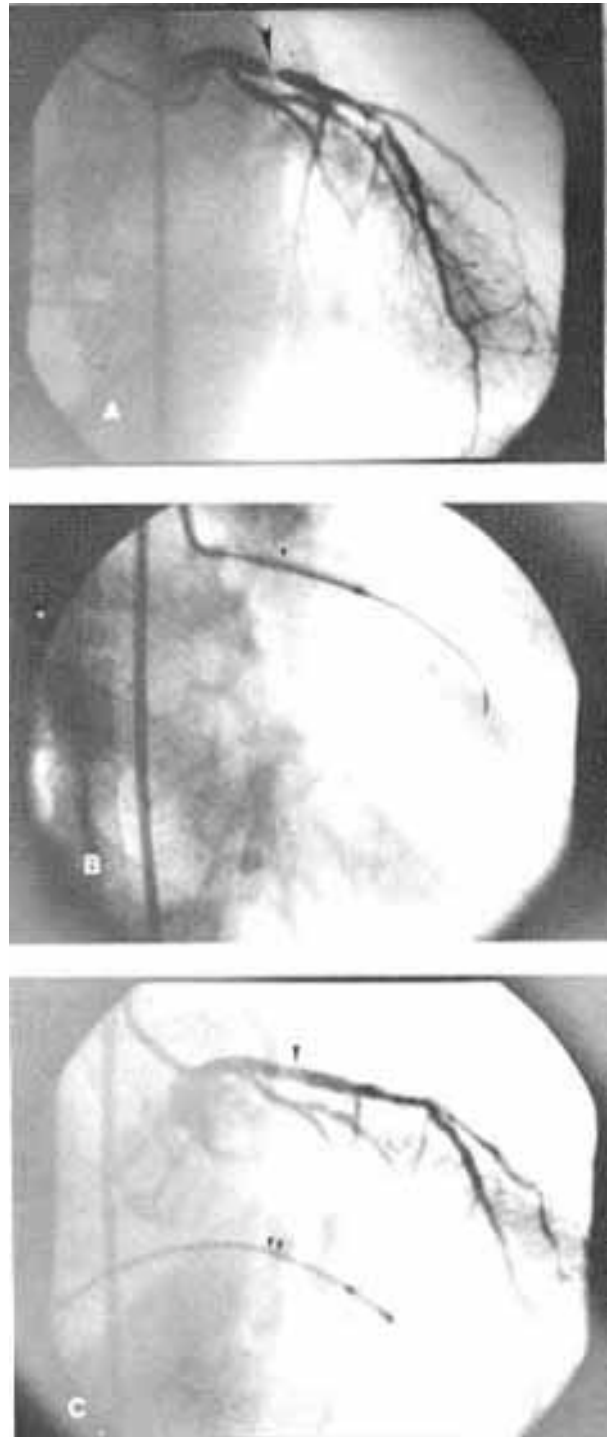


Fig. 4 - A, severe stenosis in the left anterior descending coronary artery (arrow). B, balloon catheter being inflated inside the stenosis (arrow). C, post PTCA coronary arteriography revealing minimal luminal irregularity (single arrow). Pacemaker catheter (double arrow).

though the success rate may be reduced. Patients with a short duration of symptoms have a higher chance of success, since recent onset of symptoms correlates with distensibility of the lesion. The lesion should be in a suitable anatomic location, away from branching points, through this has been broad-



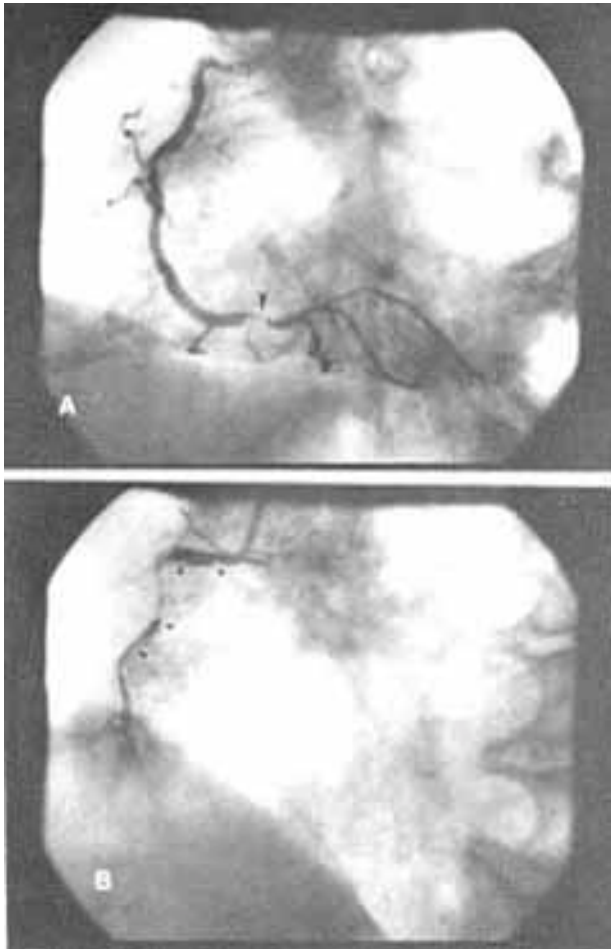


Fig. 5 - Severe stenosis of the distal right coronary artery prior attempt to PTCA. B, severe dissection (arrow) occurring during PTCA requiring emergency coronary artery bypass surgery.

ed with the new generation of steerable guiding wires that permit easier access into the coronary circulation.

Because of the large amount of myocardium at risk in case of vessel occlusion, left main coronary stenosis is considered a relative contraindication for PTCA, although selected patients with isolated left main disease may be suitable candidates<sup>9</sup>.

The beginner should be careful in selecting his patients, taking in consideration factors mentioned: as the location and length of the lesion, its eccentricity, calcification, number of vessels involved and the duration of the patient's symptoms. Although the indications for PTCA have been widened, caution is a must in having good results and growing personal confidence in selecting future cases.

#### SHORT AND LONG-TERM RESULTS

Since 1979 institutions in North America and western Europe have collaborated in acquiring data on the immediate and long-term effects for all patients in whom PTCA was attempted. This project sponsored by the National Heart, Lung, and Blood Institute (NHLBI), represents the most comprehen-

sive data base available for analysis of the patients outcome. Proficiency in the performance of coronary angioplasty requires considerable practical skill and careful patient selection for the procedure. As with all sophisticated techniques, operators who perform PTCA show a learning curve<sup>10</sup>. It can best be visualized by observing changes in success rate with growing numbers of patients. The initial steep upslope of the learning curve is mainly caused by the increasing skill of the particular operator. The later, flatter part appears to represent improvements in technical equipment.

Before the advent of steerable balloon catheters about 66% of the failures of PTCA were the result of an inability to reach (18%) or cross (48%) the stenosis<sup>12</sup>. The steerable catheters<sup>11,12</sup> changed this picture, mainly by reducing the number of lesions that could not be reached. The most recent PTCA Registry report from NHLBI contained a total of 3079 cases from 105 centers<sup>13</sup>. Accordingly the angiographic success rate has been 72% with inability to pass the obstruction in 27%. The right coronary artery subgroup also had a larger proportion of cases in which the lesion could not be passed. Patients with circumflex artery disease had the highest number of risk factors<sup>13</sup>. The low success rate presented by the Registry may not reflect the real present success rate since the cases were collected prior to the use of new technology such as special guiding catheter shapes and form, steerable dilating catheters and No. 8Fr guiding catheters.

According to the Registry among 3070 patients a total of 1180 complications were reported in 21% of patients<sup>14</sup>. Prolonged angina was the most frequent event with 236 episodes in 211 patients. Myocardial infarction occurred in 170 patients, coronary occlusion in 151, dissection in 135, spasm in 130, coronary embolism in 5, coronary perforation in 2 and coronary rupture in 1. Death occurred in 29 patients (0.9%); nonfatal myocardial infarction in 154 (5%); and emergency CABG without death or infarction in 106 (3.4%). Myocardial infarction was more often seen within 24 hours after PTCA. Myocardial infarction occurred in 45% of patients who had emergency CABG, 3.6% in those who had elective CABG and 2.6% in those who did not have CABG. Myocardial infarction and prolonged angina pectoris were more often seen in patients with unstable angina and severe stenosis<sup>14</sup>. The incidence of fatal complication with PTCA is not negligible, with an overall mortality of 0.9%. The mortality rate is adversely affected by female gender, the presence of previous CABG, the presence of left main CAD, attempting to dilate a vein graft stenosis, the duration of angina and patients older than 60 years<sup>15</sup>.

Emergency CABG for complication that occur with PTCA was necessary in 6.6% of patients enrolled in the NHLBI PTCA Registry. Surgery was performed in these patients for severe myocardial ischemia during or after PTCA. The most frequent

indication was coronary dissection with deterioration of flow or progression to occlusion, which occurred in nearly 50% of these patients. Occlusion or spasm was the primary complication in approximately 30%, and prolonged angina or myocardial infarction in 20%<sup>15</sup>. Emergency operation was performed most often in patients in whom dilatation could not be achieved because of inability to reach or transverse the lesion and in patients in whom the lesion failed to dilate with balloon inflation. More than one-fourth of the patients who required emergency surgery had initially successful dilatation with angiographic improvement, followed by abrupt reclosure of the dilated vessel. Although this usually occurred during or immediately after the procedure and in nearly all patients within 24 hours after PTCA, several patients required emergency operation beyond the initial 24 hours after angioplasty<sup>16</sup>.

The success of percutaneous transluminal angioplasty may be judged angiographically (reduction in stenosis), hemodynamically (decrease in trans-stenotic pressure gradient), functionally (increase in left ventricular function and exercise tolerance), and symptomatically (decrease in frequency and severity of ischemic episodes)<sup>17</sup>. Most data are limited to angiographic measures of success. A significant decrease in trans-stenotic pressure gradients, functional improvement (an increase in ejection fraction during exercise), and symptomatic improvement all correlate with measures of angiographic success. However, hemodynamic and symptomatic improvement appear to be lower than the frequency of angiographic success; only 80% to 85% of patients with successful angiographic results after PTCA exhibit such improvement<sup>18</sup>.

Among those patients who had an initially successful procedure about half were event-free and symptom-free whether the PTCA had been performed 1, 2, 3 or 4 years previously<sup>19</sup>. Because almost three fourths of the patients were classified as having severe or unstable angina before PTCA, the procedure must be considered effective in ameliorating symptoms and signs of myocardial ischemia in approximately half of those symptomatic patients.

Restenosis occurs in 25% to 35% of patients usually within the first 6 months after the procedure and it is commonly associated with recurrence of angina pectoris<sup>17</sup>. CABG was performed in 12% of the patients during the first year. The cumulative percentage increase to 14, 16 and 18% in the second, third and fourth years respectively after the initial PTCA<sup>19</sup>. Almost all repeat PTCAs were performed in the first year after the initial procedure. The success rate of repeat PTCA was high and exceeds that in a larger population of patients who underwent on initial or a single PTCA<sup>20</sup>.

#### MECHANISM OF PTCA

Experimental studies performed on post-mortem hearts with coronary atherosclerosis showed that co-

ronary stenosis could be reduced in severity by coronary angioplasty<sup>21</sup>. In rabbits coronary arteries sectioned after angioplasty showed that the atherosclerotic plaque was split, frequently down to the internal elastic membrane<sup>22</sup>. Histologic sections of human arteries that were studied after successful angioplasty done *in vivo* have shown similar changes to those seen in experimental models and in human postmortem coronary specimens.

The constant finding in all of these studies was splitting of the atheromatous plaque<sup>23</sup>. As the balloon inflates the intima splits at its weakest point, where the atherosclerotic plaque is thinnest<sup>24</sup>. The split may extend down to the internal elastic membrane. Splitting of the plaque may also "release" the cicatrizing effect of the plaque allowing the media to assume its more normal diameter and hence return luminal size toward normal.

Plaque splitting alone, however, cannot account for all of the changes seen physiologically during successful angioplasty. Compression and extrusion of material out of the atherosclerotic plaque during balloon inflation may also be a factor of vessel dilatation. Despite the controlled injury to the atheromatous area of the artery that angioplasty produces, embolization of atheromatous material has not been documented experimentally and has not been clinically important in coronary angioplasty<sup>25</sup>.

#### PERSPECTIVE

Percutaneous transluminal coronary angioplasty is a relatively new procedure; its technology and application are still evolving and experience with it is increasing rapidly. Our opinion is that percutaneous transluminal coronary angioplasty is a truly remarkable clinical advance for a significant proportion of patients with symptomatic coronary artery disease. An impressive eagerness to share clinical data and skills has characterized the efforts of the physicians engaged in PTCA. This has facilitated the rapid development of the procedure so that even at this early stage of its development, much is known about its potential clinical usefulness.

As the morbidity, mortality, and long-term patency of single-vessel disease are comparable for both PTCA and CABG<sup>26</sup>, percutaneous transluminal coronary angioplasty is probably the therapy of choice for a patient whose refractory ischemic symptoms can be ascribed to a single proximal stenosis. PTCA can effectively dilate highly stenotic coronary vessels and improve coronary perfusion, both in stable and unstable angina with salutary results<sup>6,27,28</sup>. In some selected cases, depending upon the experience and skills of the angiographer, PTCA may be performed in patients with isolated stenoses in two separate vessels.

A recent review<sup>29</sup> indicated that the percentage of patients who underwent CABG that could be treated by angioplasty is about 2.8%. This conservative figure represents the most ideal subjects for PTCA;

that is, those with isolated, discrete lesions located in the most proximal segments of the main right, left anterior descending coronary arteries and with no significant lesions in any distal segments of the respective vessel. However with increasing in the angiographer experience and technological improvements, candidates for CABG who could be treated by angioplasty may reach figures of approximately 15-20%<sup>30</sup>. Immediate success may be anticipated to be as high as 80% of cases in experienced hands. An equal percentage of patients will report continued symptomatic relief at least one year. The procedure can be done with a mortality rate of less than 1%. For patients with a previous successful angioplasty, a second angioplasty at the same vessel site carries a greater success rate. The complication rate should decrease and success rate should rise with further experience and the availability of improved catheters (Fig. 6).

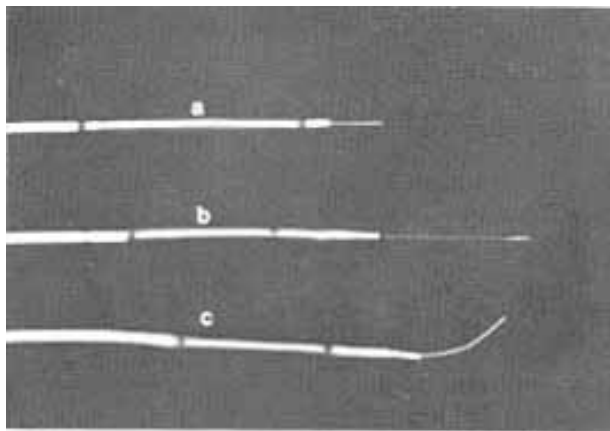


Fig. 6 - Presently available dilatation catheters for coronary angioplasty. A, DG catheter with a fixed guide wire. B, standard catheter with a movable but non steerable guide wire. C, low profile catheter with steerable guide wire.

The natural progression of coronary atherosclerosis will continue in both types of the diseases in treated as well as untreated vessels. The use of PTCA may effectively postpone the time of bypass graft surgery. Experience now being acquired should enable a more clear definition of the role of PTCA in multi-vessel disease and other anatomic situations in the relatively near future. Technologic improvements in the equipment used for coronary dilatation can be expected to contribute to expanded indication and improved success rate.

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