



# A six-year evolution of percutaneous transluminal coronary angioplasty

The Cleveland Clinic experience, 1981–1986

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■ Percutaneous transluminal coronary angioplasty (PTCA) was initially introduced as an alternative to coronary bypass surgery for patients with single-vessel disease, and its use has expanded over the years to include patients with acute myocardial infarction and multivessel disease, as well as those who have previously undergone coronary bypass surgery. Distribution, indications, and results are analyzed on a year-to-year basis from a cohort of 3,973 patients treated by PTCA at the Cleveland Clinic from 1981 through 1986.

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**S**INCE the release by the Food and Drug Administration of the Grüntzig balloon catheter for general marketing in March 1980, percutaneous transluminal coronary angioplasty (PTCA) has evolved into an accepted method to treat selected patients with coronary artery disease. In approximately seven years of clinical application, advances in equipment design have led to improved results, and indications for its use have expanded rapidly. The objective of this report is to evaluate the changing practice of PTCA over the past six years.

## MATERIALS AND METHODS

The study group consisted of all patients undergoing PTCA at the Cleveland Clinic between January 1981 and December 1986. To allow evaluation of patients in groups of 1,000, we extended the analysis into 1987 to

achieve a total of 4,000 patients.

Primary success was defined as a stenosis reduction of more than 20%, with a residual stenosis diameter of less than 50% and no major complications. We define multivessel PTCA as angioplasty of at least two of the following: left anterior descending artery, left circumflex artery, right coronary artery, or coronary artery bypass graft. In patients with multivessel dilatation, primary success was defined as dilation of all treated lesions. Mortality was defined as cardiac-related death before hospital discharge. Myocardial infarction (MI) complicating PTCA was based on the appearance of new Q waves.

## RESULTS

### Clinical characteristics

From 1981 through 1986, 3,973 patients underwent PTCA at the Cleveland Clinic. *Table 1* shows the patient volume and sex distribution on a year-to-year basis. The volume increased from 39 procedures in 1981 to more

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**TABLE 1**  
TOTAL NUMBER OF PATIENTS AND SEX DISTRIBUTION

|           | 1981 | 1982 | 1983 | 1984 | 1985 | 1986 |
|-----------|------|------|------|------|------|------|
| Total     | 39   | 100  | 490  | 930  | 1209 | 1205 |
| Men (%)   | 82   | 81   | 77   | 71   | 74   | 73   |
| Women (%) | 18   | 19   | 23   | 29   | 26   | 27   |

**TABLE 2**  
MEAN AGE AND PROPORTION OF PATIENTS (70 YEARS OR OLDER) UNDERGOING PTCA

|                   | 1981     | 1982   | 1983      | 1984      | 1985        | 1986        |
|-------------------|----------|--------|-----------|-----------|-------------|-------------|
| Mean age (years)  | 55.0     | 57.5   | 57.9      | 57.7      | 58.3        | 58.6        |
| 70 years or older | 2 (5.1%) | 6 (6%) | 40 (8.2%) | 102 (11%) | 137 (11.3%) | 143 (11.9%) |

**TABLE 3**  
PATIENTS UNDERGOING MULTIVESSEL PTCA AND PATIENTS WITH PREVIOUS CORONARY BYPASS SURGERY

|                               | 1981      | 1982     | 1983      | 1984        | 1985        | 1986        |
|-------------------------------|-----------|----------|-----------|-------------|-------------|-------------|
| Multivessel PTCA              | 0 (0%)    | 3 (3%)   | 31 (6.3%) | 78 (8.4%)   | 154 (12.7%) | 207 (17.1%) |
| After coronary bypass surgery | 6 (15.3%) | 20 (20%) | 59 (14%)  | 114 (12.2%) | 154 (12.7%) | 177 (14.6%) |

**TABLE 4**  
PTCA FOR ACUTE MI AND PATIENTS UNDERGOING REPEAT PTCA

|                   | 1981   | 1982   | 1983      | 1984      | 1985      | 1986        |
|-------------------|--------|--------|-----------|-----------|-----------|-------------|
| PTCA for acute MI | 0 (0%) | 0 (0%) | 8 (1.6%)  | 24 (2.6%) | 29 (2.3%) | 54 (4.5%)   |
| Repeat PTCA       | 0 (0%) | 3 (3%) | 37 (7.3%) | 85 (9.1%) | 145 (12%) | 143 (11.9%) |

than 1,200 in 1985 and again in 1986. The male-to-female ratio was 4:1 during the first two years and has remained at 3:1 since 1983.

The mean age increased from 55 to 58.6 years. Encouraged by favorable results, the percent of patients 70 years or older increased from 5.1% to 11.9% (Table 2). For the entire group, the clinical indications were: angina despite medical treatment (83%), large amount of myocardium at risk (7.5%), and acute MI (3%). This did not change significantly during the study period.

Of the 3,973 patients, 3,500 (88%) underwent single-vessel dilatation. The number of patients treated by multivessel PTCA gradually increased to 17.1% in 1986. Table 3 also shows the distribution of patients with previous coronary bypass graft surgery. Of these, 79%

underwent PTCA of native vessels at a mean interval of 62 months after the surgery and 21% had PTCA of a bypass graft at a mean interval of 47 months after the surgery. The primary success rate of PTCA in patients with previous coronary artery bypass surgery was 93.2%.

Table 4 shows the distribution of patients undergoing PTCA for acute MI and the percent of patients undergoing repeat PTCA. The distribution of different subsets of patients undergoing PTCA in subgroups of 1,000 patients is shown (Table 5). Except for a nearly constant rate of patients who have previously undergone coronary artery bypass surgery, percentages have increased.

### Complications

The primary success rate was 61.5% in 1981, increas-

**TABLE 5**  
DISTRIBUTION OF PATIENT SUBSETS BY GROUPS OF 1000 PATIENTS

|                                             | 1st<br>1000 | 2nd<br>1000 | 3rd<br>1000 | 4th<br>1000 |
|---------------------------------------------|-------------|-------------|-------------|-------------|
| 70 years or older (%)                       | 8.9         | 10.0        | 12.1        | 13.5        |
| Previous coronary artery bypass surgery (%) | 13.8        | 13.0        | 13.7        | 14.0        |
| Multivessel PTCA                            | 5.8         | 10.1        | 14.7        | 16.9        |
| PTCA for acute MI (%)                       | 1.7         | 2.5         | 4.1         | 4.8         |
| Repeat PTCA (%)                             | 7.9         | 9.7         | 11.4        | 13.0        |

**TABLE 6**  
PRIMARY SUCCESS AND COMPLICATIONS

|                                          | 1981       | 1982     | 1983        | 1984        | 1985         | 1986         |
|------------------------------------------|------------|----------|-------------|-------------|--------------|--------------|
| Primary success                          | 24 (61.5%) | 72 (72%) | 450 (91.8%) | 885 (95.2%) | 1135 (93.9%) | 1137 (94.4%) |
| Emergency coronary artery bypass surgery | 3 (7.7%)   | 5 (5.0%) | 29 (5.9%)   | 29 (3.1%)   | 22 (1.8%)    | 29 (2.4%)    |
| Acute MI                                 | 1 (2.5%)   | 1 (1.0%) | 10 (2.0%)   | 15 (1.6%)   | 6 (0.4%)     | 14 (1.2%)    |
| Mortality                                | 0 (0%)     | 2 (2.0%) | 3 (0.6%)    | 6 (0.6%)    | 4 (0.3%)     | 11 (1.0%)    |

**TABLE 7**  
PRIMARY SUCCESS AND COMPLICATION RATE BY GROUPS OF 1000 PATIENTS

|                                              | 1st<br>1000 | 2nd<br>1000 | 3rd<br>1000 | 4th<br>1000 |
|----------------------------------------------|-------------|-------------|-------------|-------------|
| Primary success (%)                          | 89.4        | 95.2        | 93.8        | 94.4        |
| Emergency coronary artery bypass surgery (%) | 5.4         | 1.8         | 2.6         | 1.6         |
| Acute MI (%)                                 | 1.6         | 1.4         | 1.3         | 1.6         |
| Mortality (%)                                | 0.7         | 0.5         | 0.6         | 0.8         |

ing to 91.9% in 1983, and remaining above 90% since then. Table 6 shows the incidence of complications over the years. The same information divided by groups of 1,000 patients is displayed in Table 7 and reveals an increase in the primary success rate and a reduction in the need for emergency coronary artery bypass surgery.

#### DISCUSSION

PTCA was performed approximately 3,500 times in 1982. This number increased to more than 100,000 by 1985. Our experience reflects the rapid growth of PTCA seen worldwide, which has been stimulated by advances in equipment design<sup>1</sup> and operator experience.<sup>2</sup> The National Heart, Lung and Blood Institute data show that when performing PTCA with nonsteerable catheters, the primary success rate is 59%.<sup>3</sup>

Although indications for PTCA have rapidly expanded, the best candidates for the procedure are symptomatic patients with single-vessel disease. Consequently, by 1986, almost 83% of our patients underwent single-vessel dilatation.

#### Patients with previous coronary artery bypass surgery

Graft failure or progression of disease in the native coronary arteries occurs in a significant number of patients after coronary artery bypass surgery. Since morbidity and mortality are high when a second operation is performed,<sup>4</sup> PTCA is sometimes undertaken instead. During our six-year experience, 12%–20% of patients undergoing PTCA had previously undergone coronary artery bypass surgery. Results and risks involving these patients appear to be similar to those in patients who have not undergone the surgery.<sup>5</sup> If dilatation of native vessels or anastomotic sites has occurred within the first

year after surgery, PTCA is particularly effective.

### Elderly patients

Patients older than 65 have an increased mortality rate relating to coronary artery bypass surgery.<sup>6</sup> They can undergo PTCA, however, with excellent results, low risk, and a recovery time of only three to four days.<sup>7</sup> In our own practice, the proportion of patients older than 70 years increased from 5.1% in 1981 to 11.9% in 1986.

### Multivessel PTCA

Roubin and Gruntzig<sup>8</sup> reported an increased risk of MI, emergency coronary artery bypass surgery, and death after multivessel PTCA. Hollman et al<sup>9</sup> have also reported a higher restenosis rate. We have restricted multivessel PTCA to patients with "ideal" lesions in two or three vessels. Despite this conservative approach, the performance of multivessel PTCA had increased by 17.1% by 1986. The long-term merits of this approach remain unclear.

### PTCA in MI

The performance of PTCA has resulted in high reperfusion rates in patients with acute MI. Preliminary results suggest preservation of left ventricular function due to this approach.<sup>10</sup> Since establishing an acute intervention program in May 1986, the proportion of patients undergoing PTCA because of an acute MI has steadily increased.

### Primary success and complications

The low primary success rate during the first two years

was due to the inability to "cross" lesions. Since the over-the-wire system was described,<sup>1</sup> the primary success rate has been consistently above 90%. Despite the increasing complexity of cases, rates of emergency surgery, MI, and mortality have remained low. Centers following a more aggressive approach, particularly when dealing with a higher proportion of patients with multivessel dilatation and PTCA for acute infarction, have reported higher mortality rates.<sup>11</sup>

### SUMMARY

Technological advances and operator experience have contributed to the rapid growth of PTCA. The procedure can be applied with higher success rates and lower risk in patients with single-vessel disease. Its role in selected patients with acute MI appears promising and will most likely expand in the future.

Encouraged by the good results related to single-vessel disease, we are seeing PTCA performed for multivessel disease with increasing frequency. Ongoing studies will determine if this approach is justified.

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