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Prospective Case-Control Comparison of Percutaneous Transluminal Coronary Revascularization in Patients With Multivessel Disease Treated in 1986–1987 Versus 1991: Improved In-Hospital and 12-Month Results

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Objectives. **This study sought to ascertain whether early and 12-month clinical outcomes after percutaneous coronary revascularization have improved between 1986–1987 and 1991.**

Background. **Since the mid-1980s, when the results of percutaneous revascularization were considered to be somewhat static, justifying large-scale clinical trials of percutaneous transluminal coronary angioplasty versus other modes of therapy, balloon technology has improved, and several new percutaneous revascularization techniques have become available. The clinical results of the current integrated approach to revascularization compared with those for coronary angioplasty alone in the late 1980s are not known.**

Methods. **In this prospective case-control study, 200 consecutively treated patients with multivessel disease in 1991 were studied prospectively and compared with 400 consecutive patients from the same centers during 1986–1987. Patients from 1991 were matched with earlier patients on the basis of four previously described prognostic determinants (left ventricular ejection fraction, presence of unstable angina, diabetes and target lesion morphology score) and the treating institution and were assessed for treatment outcome (completeness of revascularization, procedural success and event-free survival [freedom from death, myocardial infarction and further revascularization]).**

Results. **The 1991 cohort of patients was older (mean [±SD] age 62 ± 11 vs. 58 ± 11 years, $p < 0.001$) and tended to have slightly worse left ventricular function (ejection fraction 56 ± 10% vs. 58 ± 11%, $p = 0.009$) than the 1986–1987 cohort. Overall lesion morphology risk scores were similar. New devices (other than coronary angioplasty) were used in 26% of patients. The 1991 patient cohort had more frequent total revascularization (35% vs. 21%, $p = 0.003$), fewer emergency bypass operations (1.0% vs. 5.5%, $p = 0.006$) and an improved overall procedural success rate (90% vs. 84%, $p = 0.04$). In addition, at 12 months the event-free survival rate was superior in the 1991 cohort (73.3% vs. 63.6%, $p = 0.02$), although there was no difference in infarct-free survival rate (94.6% vs. 93.2%, p = NS).**

Conclusions. **Improved results with percutaneous revascularization in 1991 have important implications for patient care and interpretation of ongoing randomized trials enrolling patients in the late 1980s and intending to compare standard coronary angioplasty with other forms of therapy.**

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Recognition of the limitations of percutaneous transluminal coronary angioplasty—abrupt vessel closure in 4% to 10% of patients (1,2) and restenosis in 30% to 49% of lesions (3–7)—led in the mid-1980s to the development of several alternative or adjunctive means of percutaneous coronary revascularization. At the same time, the technique of coronary angioplasty was considered stable enough to warrant commitment to large-scale randomized trials designed to assess its appropriate role relative to other established therapies for coronary artery disease. Now, with many such trials reporting preliminary results (4,8–10), several new therapies (directional and rotational atherectomy, excimer laser, metallic stents) have become available for clinical application. To date, no study has examined whether these newer therapies, applied in an integrated manner with coronary angioplasty, or further refinements in the technique of coronary angioplasty, may have altered the outcome of percutaneous intervention relative to previous standards.

The Multivessel Angioplasty Prognosis Study (MAPS)

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group was formed to investigate predictors of outcome with coronary angioplasty as it was practiced in 1986–1987 in patients with multivessel disease. A comprehensive data base was established (11,12). The purpose of this prospective investigation was to determine whether, with the availability in 1991 of multiple new technologies at the five high volume interventional centers contributing to the 1986–1987 registry, either the type of patients or lesions being treated or the outcome of that treatment had changed.

Methods

Study overview. The present study was formulated in two parts: 1) an unmatched *treatment analysis* in which types of patients and lesions treated in 1986–1987 and 1991 were to be compared; and 2) a matched case-control *outcome analysis* in which clinical outcomes of patients treated in 1986–1987 and 1991 were compared after matching for several key variables.

Patients and treatment. The baseline 1986–1987 patients have been described elsewhere (11). To that group an additional 50 patients meeting the same entrance criteria, consecutively treated beginning on January 1, 1986 at a fifth institution, were enrolled retrospectively in anticipation of the center's participation in the study reported herein.

The current 1991 phase of the MAPS study prospectively enrolled 200 consecutively treated patients meeting identical entrance criteria from the same institutions, with treatment beginning on January 1, 1991 (except at one center in which enrollment began on October 1, 1991 because of first availability of stents at that time). No patients receiving periprocedural anticoagulant agents other than aspirin, dipyridamole, heparin or dextran were included.

The choice of which device to use in any clinical situation was left to the individual operators, but experience with the devices had accrued such that the Rotablator was the most commonly used device for heavily calcified or ostial lesions, or both, and directional atherectomy was used frequently as the preferred device for proximal and eccentric lesions in large (≥3.0 mm) arteries. The techniques of device usage has been described elsewhere (13–17).

Clinical variables and follow-up. The following variables were assessed and recorded on dedicated case report forms by a physician or trained research nurse: age, Canadian Cardiovascular Society angina class, current smoking, diabetes mellitus, gender, previous myocardial infarction, previous restenosis and unstable angina. All definitions used have been previously published (11). Methods of follow-up have also been described (18).

Angiographic analysis. The cineangiograms were assessed at the Angiographic Core Laboratory using the same technique and supervisor as in the 1986–1987 study. Coding was performed by an experienced angiographer who had no knowledge at the time of the analysis of both the revascularization technique used (section taped over) and the clinical outcome. Variables coded included bifurcation stenosis, calcification, chronic total occlusion, eccentric stenosis, high grade stenosis, irregular contour, lesion length, modified American College of Cardiology/American Heart Association (ACC/AHA) score, ostial stenosis, proximal stenosis location (19), stenosis angle ≥45°, thrombus and tortuosity. Methodology for dimensional measurements (calipers) and definitions have been published elsewhere (11).

Definitions. *Complications* = myocardial infarction, emergency bypass surgery or death during index hospital stay. *Event-free survival* = freedom from death, myocardial infarction, bypass surgery or further percutaneous revascularization (other than intentionally staged procedures). *Myocardial infarction* = development of new pathologic Q waves or elevation of creatine kinase (CK) to three or more times the upper limit of normal for the laboratory, with CK MB fraction ≥4%. *Successful treatment* = reduction of diameter stenosis to <50% without complications. *Significant lesion* = any stenosis ≥50% in diameter in a coronary artery measuring >1.5 mm. *Target lesion* = a primary target stenosis (11) was identified prospectively on the basis of the severity and morphologic characteristics of the stenoses, their jeopardized territories, the presumed viability of the myocardium observed and available clinical data.

Matching. A matched case-control analysis is regarded as the most efficient and reliable method to study relatively rare events (20,21). Therefore, on the basis of previous work determining that left ventricular ejection fraction, presence of unstable angina, diabetes and target vessel morphology are key determinants of clinical outcome in patients with multivessel disease undergoing coronary angioplasty (8,9), a 2 × 2 × 2 × 4 matching matrix was generated, separating left ventricular ejection fraction into two groups (≤40% and >40%) and morphology into four groups based on the modified ACC/AHA criteria (11). For each patient in the 1991 cohort, matching patients in the 1986–1987 cohort were identified, and then a random number generator was used to select one of the patients to construct the 1986–1987 matched cohort. In a similar manner, but with 1:2 matching, lesions treated with new devices in the 1991 cohort were matched on the basis of lesion morphology (e.g., calcification [yes, no], length [≤9, 10 to 19, ≥20 mm] and location [vessel, proximal or nonproximal segment]) to determine the importance of new device usage on the procedural success for the types of lesions treated with new devices.

Statistical analysis. All data were entered into the MAPS Databank at the Data Coordinating Center. Data are expressed as mean value ± 1 SD, unless otherwise noted. Intraobserver variability for core angiographic laboratory assessment of morphologic variables was assessed from observations made >6 months apart, using kappa statistics for discrete variables and explained variance (r^2) for continuous variables on a subset of 30 randomly chosen stenoses (one stenosis per patient; 15 patients from each time period). The comparative incidences of procedural success, complications and total revascularization (the primary end points) were assessed using sign-test analysis on a per-patient basis, and procedural success was assessed on a per-lesion basis. Multivariate logistic regression analysis was performed to assess the influence of lesion

Table 1. Comparison of Baseline Patient and Lesion Characteristics

	Entire 1986–1987 Cohort	1991 Cohort	Matched 1986–1987 Cohort
Patients			
No. of patients	400	200	200
Age (yr)	58 ± 11	62 ± 11*	58 ± 10
Current smoking (%)	50.5	50.6	48.5
Diabetes (%)	18.8	25.0	25.0
Gender (% male)	71.5	70.5	72.0
LVEF (%)	58 ± 11	56 ± 10*	58 ± 11
Previous MI (%)	45.6	52.8	44.2
Three-vessel disease (%)	30.0	26.5	30.5
Unstable angina (%)	47.8	51.5	51.5
Lesions			
Total no. of lesions	1,235	590	642
No. of lesions treated	773	406	393
Angulated ≥45 (%)	20.8	16.4	21.1
Bifurcation (%)	22.8	14.7*	17.6
Calcified (%)	8.1	13.6†	9.9
Chronic total occlusion (%)	4.3	6.2	5.1
Eccentric (%)	29.0	46.3*	33.1
High grade (≥80%) (%)	24.2	26.9	24.9
Lesion ≥10 mm (%)	11.2	13.8	11.9
Modified ACC/AHA score			
A	29.2	32.5	32.8
B1	35.1	33.2	33.1
B2	24.2	21.7	22.9
C	11.5	14.5	11.2
Ostial (%)	3.9	3.0	3.6
Irregular contour (%)	27.2	16.1*	21.9
Restenosis lesion (%)	5.4	4.7	5.1
Thrombus (%)	4.2	3.8	4.1
Tortuosity (%)	14.1	14.6	14.0

*$p < 0.001$ (or $p \leq 0.05$ for a primary or secondary end point) versus the entire 1986–1987 cohort. †$p \leq 0.05$ versus the entire 1986–1987 cohort. Data presented are mean value ± SD, unless otherwise indicated. ACC/AHA = American College of Cardiology/American Heart Association; LVEF = left ventricular ejection fraction; MI = myocardial infarction.

morphology on treatment used and outcome. Analysis of covariance was used to examine possible heterogeneity of treatment effect by hospital site. Kaplan-Meier survival curves were generated to describe freedom from long-term events, and Cox analyses were performed to assess differences in long-term outcome between the study groups. For primary and secondary end points, $p \leq 0.05$ was considered significant. For other comparisons, to lessen the risk of a type II statistical error, $p \leq 0.001$ was regarded as definitely significant and $0.002 \leq p \leq 0.05$ as possibly significant. All analyses were performed using SYSTAT software (System for Statistics, Systat version 5.03 and Survival version 1.0).

Results

Comparison of overall 1986–1987 cohort and 1991 cohort. During the period of patient recruitment in early 1991, 1,265 patients underwent percutaneous revascularization at the five centers (the study cohort represents 16% of all treated patients). Data are not available as to how many of the 1,265 patients had previous bypass surgery and hence were excluded from recruitment.

The study cohort of 200 patients consecutively treated in 1991 were older ($p < 0.001$) and had a somewhat lower left ventricular ejection fraction ($p = 0.009$) than the 400 patients treated earlier (Table 1). There were 590 significant lesions (2.95 ± 1.08/patient) and 406 lesions with attempted treatment (68.8% of the significant lesions) in the 1991 cohort, and 1,235 lesions (3.09 ± 1.10/patient) and 773 lesions with attempted treatment (62.6%) in the 1986–1987 cohort (difference between percent of lesions with attempted treatment, $p = 0.01$). There was no difference in overall stenosis complexity (modified ACC/AHA score) between the groups.

Use and results of balloon angioplasty and newer techniques in the 1991 cohort. Balloon angioplasty was used as primary treatment in 335 of the 406 lesions treated (82.5%). Success was achieved in 292 lesions (87.2%), and complications occurred during treatment of 4 lesions (1.2%). New devices were used most commonly in ostial, calcified, lengthy or thrombus-containing lesions. Rotablator treatment (n = 33)

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Table 2. Comparison of 1986–1987 and 1991 Procedural Outcomes (matched analysis)

	1986–1987	1991	p Value
Procedural success (%)	83.5	90.0	0.04
Complications (%)	8.0	3.5	0.06
Bypass surgery	5.5	1.0	0.006
Myocardial infarction	2.0	1.5	NS
Death	1.0	1.0	NS
Total revascularization (%)	21.5	35.0	0.003

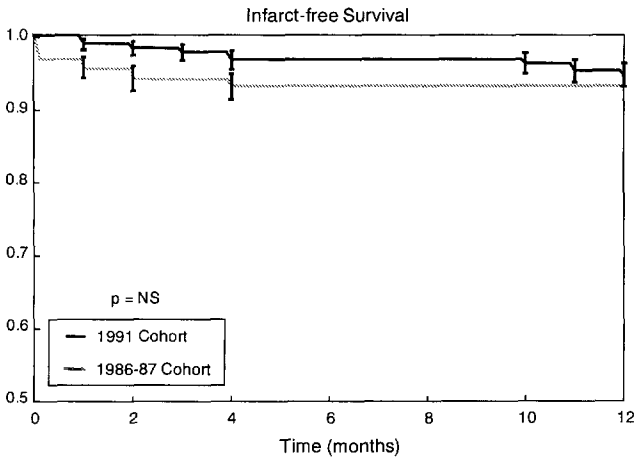

Figure 1. Kaplan-Meier product-limit estimates (±SE) for infarct-free survival for the two cohorts.

was used significantly more often for calcified ($p < 0.001$) and ostial ($p = 0.001$) lesions and somewhat more often for bifurcation ($p = 0.03$) and high grade lesions ($p = 0.05$) than for treatment of lesions with other morphologies. Success was achieved in 32 of (97%) 33 lesions, and complications occurred in 1 of (3%) 33. Directional atherectomy ($n = 25$) was used more commonly for irregularly contoured ($p = 0.02$) or proximal lesions ($p = 0.02$). Success was achieved in 22 of (88%) 25 of lesions, and complications occurred in 2 of (8%) 25 of lesions. Stent placement for abrupt closure ($n = 6$) and excimer laser treatment ($n = 3$) were used less frequently. In this group no stent was placed prophylactically in an attempt to prevent restenosis. Procedural success continued to be highly correlated with modified ACC/AHA lesion classification (11): *type A* = 127 of (94.8%) 134; *type B1* = 125 of (93.3%) 134; *type B2* = 63 of (78.8%) 80; and *type C* = 42 of (72.4%) 58, $p < 0.001$. There was no significant heterogeneity of treatment effect by hospital site.

Comparison of paired 1986–1987 and 1991 patient and lesion outcomes. Composite clinical outcome was superior in the 1991 group, primarily because of more complete revascularization ($p = 0.003$), less frequent need for emergency bypass surgery ($p = 0.006$) and a higher rate of procedural success ($p = 0.04$) (Table 2). Results of the paired lesion analysis are shown in Table 3 and demonstrate superior outcome for the 1991 cohort in terms of procedural success ($p = 0.004$) and final diameter of stenosis ($p < 0.001$). In the 1991 cohort, multivariate logistic regression found lesion failure to be associated most closely with long-term total occlusion (success 64.0%, $p \leq 0.001$), lesion length ≥10 mm (success 81.4%, $p = 0.022$) and angle ≥45° (success 83.6%, $p = 0.030$). When none of these characteristics was present, success was obtained in 92.6%. When the modified ACC/AHA lesion classification was entered first in the stepwise regression, no other variable achieved statistical significance as a predictor of success.

Twelve-month outcome. Clinical follow-up was available in 394 of (98.5%) 400 of patients. Infarct-free and event-free survival is shown in Figures 1 and 2. Event-free survival was superior in the 1991 cohort ($p = 0.02$) largely because of better early outcome, but there was no difference in either survival or infarct-free survival. Bypass surgery was used in 13.4% versus 8.1% ($p = 0.07$) and repeat revascularization by percutaneous intervention alone in 16.2% versus 13.2% (p = NS) of the 1986–1987 and 1991 cohorts, respectively.

Reproducibility of assessment of lesion morphology. The following kappa values were obtained in the reproducibility evaluation: angulation 0.65, bifurcation 0.67, calcification 0.71, chronic total occlusion 1.00, irregular contour 0.66, modified ACC/AHA classification 0.64, ostial 0.92, tortuosity 0.81 and thrombus 0.87 (all $p < 0.001$). Correlation between readings of lesion length (LL) was good ($LL_1 = 1.18LL_2 - 0.64$ [mm], $r^2 = 0.98$, $p < 0.001$).

Table 3. Comparison of Outcomes for Types of Lesions Treated With New Devices in 1991 (matched analysis)

	1986–1987	1991	p Value
No. of patients	98	50	
No. of lesions	130	65	
Age (yr)	60 ± 10	61 ± 12	NS
Gender (% male)	66.9	63.1	NS
Angina class	3.0 ± 1.2	3.4 ± 0.9	0.008
Pretreatment % stenosis	71 ± 15	69 ± 16	NS
Posttreatment % stenosis	40 ± 19	27 ± 15	< 0.001
Procedural success (%)	80.0	92.3	0.004
Procedural complication (%)	6.2	4.6	NS

Data presented are mean value ± SD, unless otherwise indicated.

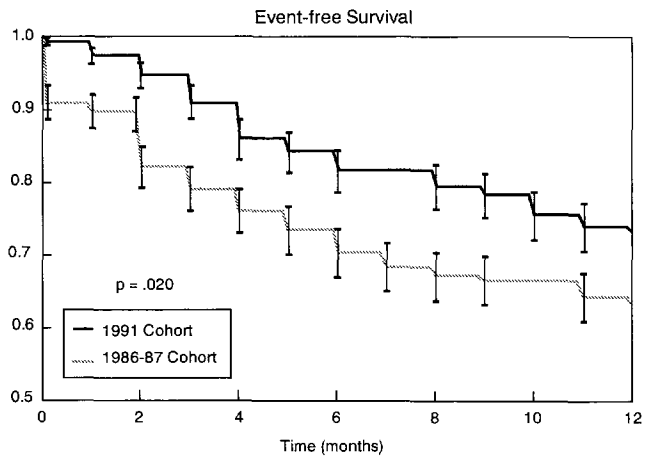

Figure 2. Kaplan-Meier product-limit estimates (±SE) for event-free survival (freedom from death, infarction, bypass surgery and repeat percutaneous intervention) for the two cohorts.

Discussion

Status of percutaneous coronary intervention. In 1994, >410,000 coronary angioplasties and directional atherectomies were performed in the United States (USCI Division of C. R. Bard, Billerica, Massachusetts, unpublished data); yet to date, despite several ongoing randomized trials comparing coronary angioplasty with other forms of therapy, only a few early comparative trial results have been reported (8–10,22). These showed modest benefit of coronary angioplasty compared with medical therapy in patients with single-vessel disease and mixed results of coronary angioplasty compared with bypass surgery in more extensive disease.

Advances in percutaneous revascularization since 1986–1987. The technique of coronary angioplasty has not remained static since 1986. Improvements in guide catheter structure and internal dimension have led to improved balloon support and coronary visualization. For instance, the internal dimensions of 8F guide catheters were typically 0.079 in. (0.20 cm) in the 1991 cohort and 0.072 in. (0.18 cm) in the 1986–1987 cohort studied (23). Deflated balloon profile has decreased, leading to an expected improved ease of stenosis crossing. In 1991, a 3.0-mm over-the-wire balloon typically had a 0.034-in. (0.86 cm) crossing profile, compared with 0.037- to 0.039-in. (0.094 to 0.099 cm) in 1986–1987 (23). Improvements in trackability and pushability were also made but are more difficult to quantify. A wide variety of coronary stents, atherectomy devices and lasers have been available since the time of the first MAPS registry. Although reports of moderate size, single-device experiences have been published (15–17,24–28), the results with an integrated application of a wide variety of such devices, as is currently practiced, are not known.

1991 results. Balloon angioplasty was used as the only technique in 75% of patients in this series from five centers with a wide array of technologies for treatment. Rotational atherectomy was used in 12% of patients and directional atherectomy in another 12%, whereas other devices were used infrequently. Advances in balloon technology and availability of new devices led to a somewhat higher proportion of lesions with attempted treatment ($p = 0.01$) and to a higher incidence of eccentric ($p < 0.001$) and calcified ($p = 0.008$) lesions within the case mix. Furthermore, after matching for major prognostic indices, overall clinical outcome was clearly improved in the 1991 cohort compared with that in the 1986–1987 cohort (Table 2, Fig. 2). This occurred because of more frequent total revascularization ($p = 0.003$), less emergency bypass surgery ($p = 0.006$), more frequent procedural success ($p = 0.04$) and improved 12-month event-free survival ($p = 0.02$). Improvement in 12-month event-free survival appears to have occurred during the index hospital stay, and the later curves are essentially parallel.

Clinical implications. If verified by other studies, the present results suggest that the indications for percutaneous revascularization, relative to medical treatment or bypass surgery, should be broadened. Thus, the proscription of new device use in studies such as the Bypass Angioplasty Revascularization Investigation may represent a very important limitation to the application of their results to patient care in the 1990s.

Study limitations. The results of the present study should be interpreted with the recognition of several limitations. First, the numbers of patients and lesions studied were relatively modest, although not so for this type of analysis requiring attention to complex angiographic detail. The results, although demonstrating an overall improvement between 1986–1987 and 1991, will thus require confirmation. Nonetheless, the likelihood of finding some of these differences by chance alone—especially freedom from emergency bypass surgery and achievement of total revascularization—is diminishingly small. Second, although the patients of the two time cohorts were matched for key prognostic variables and appeared similar for other recorded variables, it is possible that they differed in other important ways. Third, the reproducibility of coronary morphologic analysis is somewhat imprecise, and the treated lesions in the two groups may have differed more than is suggested in Table 1. Nonetheless, the reproducibility of results from this core angiographic laboratory are as good as or better than those from other, albeit limited, reports (29). Fourth, it is not possible to ascertain exactly how much of the improvement in procedural outcome in 1991 was due to the availability of new techniques and how much was due to advances in old ones (coronary angioplasty), although both factors appear to have played a role. The frequency of new device usage during this study is similar to contemporary use in the United States now that these devices are widely available (30). Finally, the procedural success rates in the present study may appear to be low but in fact are commensurate with those from other current studies in which objective measures of stenosis dimension were used (31).

Conclusions. Procedural results of percutaneous coronary revascularization at high volume interventional centers with access to techniques in addition to coronary angioplasty, as well as extensive experience with coronary angioplasty,

appeared to have improved considerably between 1986–1987 and 1991. This has important implications for patient care and for the interpretation of randomized trials enrolling patients in the late 1980s and intending to define the proper role of percutaneous revascularization relative to other forms of therapy.

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Appendix

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