

IMPROVED CLINICAL OUTCOME AFTER WIDESPREAD USE OF  
CORONARY-ARTERY STENTING IN CANADA

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**ABSTRACT**

**Background** The introduction and refinement of coronary-artery stenting dramatically changed the practice of percutaneous coronary revascularization in the mid-1990s. We analyzed one-year follow-up data for all percutaneous coronary interventions performed in a large, unselected population in Canada to determine whether the use of coronary stenting has been associated with improved outcomes.

**Methods** Prospectively collected data on all percutaneous coronary interventions performed on residents of British Columbia, Canada, between April 1994 and June 1997 were linked to province-wide health care data bases to provide the date of the following end points: subsequent target-vessel revascularization, myocardial infarction, and death. Baseline characteristics and procedural variables were identified and Kaplan-Meier survival curves were generated for 9594 procedures divided into seven groups, one for each sequential half-year period.

**Results** The overall burden of coexisting illnesses remained stable throughout the study period. A large increase in the rate of coronary stenting (from 14.2 percent in the period from April to June 1994 to 58.7 percent in the period from January to June 1997) was associated with a significant reduction in the rate of adverse cardiac events at one year (from 28.8 percent to 22.8 percent; adjusted relative risk, 0.79; 95 percent confidence interval, 0.69 to 0.90;  $P < 0.001$ ). This reduction in adverse events was exclusively due to a large reduction in subsequent target-vessel revascularization (from 24.4 percent to 17.0 percent; adjusted relative risk, 0.72; 95 percent confidence interval, 0.62 to 0.83;  $P < 0.001$ ) without significant changes in the overall rates of myocardial infarction (5.4 percent,  $P = 0.28$ ) or death (3.9 percent,  $P = 0.65$ ).

**Conclusions** The need for target-vessel revascularization during one year of follow-up after percutaneous coronary intervention decreased during the mid-1990s. The reduction was coincident with the introduction and subsequent widespread use of coronary stenting. (N Engl J Med 1999;341:1957-65.)

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**T**HE technique of percutaneous revascularization for obstructive coronary disease has been evolving since it was pioneered by Grüntzig et al. in 1977.<sup>1</sup> The introduction<sup>2</sup> and refinement<sup>3-5</sup> of techniques for the implantation of coronary stents coupled with ongoing developments in stent, balloon, and catheter technology re-

sulted in dramatic changes in practice during the mid-1990s. The efficacy of stenting is supported by eight published randomized studies,<sup>6-13</sup> which directly compared elective stent implantation with balloon angioplasty in highly selected patients with predominantly simple coronary stenoses. Since only a minority of patients who are currently referred for percutaneous coronary intervention would have met the strict clinical and anatomical entry criteria of these studies, the generalizability of these results to the overall population of patients who are treated with percutaneous coronary intervention is uncertain. If current techniques are indeed broadly effective, then their implementation should be associated with improved outcomes among unselected patients.

To evaluate the one-year outcomes of percutaneous coronary intervention in unselected patients, we studied all percutaneous revascularization procedures performed during seven sequential half-year periods in residents of the province of British Columbia in Canada.

**METHODS****Data Linkage**

All residents of British Columbia undergoing percutaneous coronary interventions between April 1, 1994, and June 30, 1997, were eligible. No patients or procedures were excluded. The study was approved by the ethics committee of the University of British Columbia.

All data were collected from provincial health data bases. The age and sex of the patients and characteristics of the procedures were obtained for all 9686 eligible index procedures from the British Columbia Cardiac Registries, which have prospectively collected data on all cardiac surgical procedures performed in the province since 1991 and on all percutaneous coronary interventions performed since April 1994. The information from structured data sheets completed in the catheterization laboratory after each procedure is entered into a central data base maintained by a dedicated management team. The coronary segments that were treated are recorded according to the modified coronary-segment coding system of the Coronary Artery Surgery Study.<sup>14</sup>

Patients were linked to the British Columbia Patient Hospitalization Data Base with the use of a unique identifier. This data base records hospital-discharge data for all acute care hospital admissions in the province. Records for all 58,621 admissions of in-

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dex patients to hospitals in British Columbia between February 1992 and June 1998 were obtained. Each record contains up to 16 diagnoses coded according to the *International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM)*,<sup>15</sup> together with a code indicating whether the diagnosis was the primary reason for admission, a coexisting condition present before admission, a condition that arose during the admission, or a secondary diagnosis.

For the purpose of identifying coexisting conditions that were present before the procedure, we examined index admissions and all admissions in the two years before each index admission for selected conditions using the diagnostic codes and previously described ICD-9-CM definitions.<sup>16</sup> We used these data to calculate a clinical index of coexisting conditions that is predictive of one-year mortality in patients who have undergone coronary bypass surgery.<sup>17</sup>

### Definitions of End Points

For each index coronary intervention, the date of the first subsequent target-vessel revascularization was obtained from the British Columbia Cardiac Registries. The occurrence of myocardial infarction at any time after an index procedure was identified with use of the British Columbia Patient Hospitalization Data Base. Clinically diagnosed periprocedural or post-procedural infarctions were included, though post-procedural serum cardiac-enzyme levels were not measured routinely at all centers. Deaths were identified from the Deaths Registry of the British Columbia Vital Statistics Agency with the use of probabilistic record linkage. A major adverse cardiac event was defined as the first occurrence of target-vessel revascularization, myocardial infarction, or death from any cause according to the above definitions.

### Percutaneous Coronary Intervention

The procedures were performed at one of four centers by 14 experienced operators (each of whom performed between 165 and 351 procedures per year) with the use of contemporary techniques according to the operator's preference. Variation in the rate of stent implantation over time reflects primarily changing operator thresholds for elective and provisional stenting. The use of first-generation stents predominated in 1994 and 1995. Second-generation tubular slotted stents were introduced in 1996, and their use predominated in 1997. A transition from warfarin-based regimens of anticoagulation after stenting to antiplatelet therapy with ticlopidine and aspirin occurred during the second half of 1995. Abciximab was introduced in 1996 and used in 2 percent of cases in the second half of that year and in 7 percent of cases in the first half of 1997. Intracoronary ultrasonography was used infrequently and largely for research purposes rather than as a clinical tool.

### Statistical Analysis

All analyses are reported on a per-procedure basis. To examine changing outcomes over time, we divided the procedures into seven cohorts, one cohort for each sequential half-year period, based on the calendar year, beginning in 1994. Since the study period began on April 1, 1994, the first cohort included only procedures performed in April, May, or June of that year. The rates of stenting for each period were calculated as the percentage of all procedures in which at least one stent was implanted. Temporal trends in base-line variables were examined with Mantel-Haenszel chi-square statistics for binary and ordinal variables, Spearman's rank correlation for continuous variables, and the Kruskal-Wallis test for nominal variables.

The end points were estimated by the Kaplan-Meier method for each of the seven periods. Patients who underwent multiple procedures during the study period were included for each intervention. To avoid double counting of patient-specific events in patients who underwent multiple index procedures, we censored follow-up times for death, myocardial infarction, and composite end

points at the time of a subsequent index coronary intervention. This method attributes events to the most recent procedure. Target-vessel revascularization was considered a vessel-specific outcome and was not censored at the time of a subsequent procedure not involving the target vessel. Follow-up times for myocardial infarction and revascularization were censored at the time of death.

For each end point, we used Cox proportional-hazards analysis to estimate the aggregate relative risk for all seven periods on the basis of the entire data set ( $e^{\beta}$ , where  $\beta$  is the coefficient indicating the log relative risk for the comparison of two consecutive periods). We computed relative risks, 95 percent confidence intervals, and significance levels with and without adjustment for significant base-line variables. We identified statistically significant base-line variables for each end point by forward stepwise selection of variables with a P value of less than 0.1. We also used Cox proportional-hazard analysis to examine the effects of interactions between the cohort period of the index procedure and the following variables: age ( $\geq 65$  years vs.  $< 65$ ), sex, diabetes status, target vessel (left anterior descending coronary artery vs. other vessels), the number of vessels involved (one vs. two or more), clinical status (stable or unstable), and whether the procedure was the first or a subsequent intervention.

## RESULTS

Between April 1, 1994, and June 30, 1997, a total of 9686 percutaneous coronary interventions were performed in residents of British Columbia. Ninety-two procedures with poorly defined target segments were excluded. The analysis was based on the remaining 9594 procedures (99 percent), which involved the treatment of 14,511 lesions in 10,994 vessels in 7880 patients. The number of procedures performed during each period is shown in Tables 1 and 2. Eleven months of follow-up data were available in 100 percent of cases, and 12 months of data were available in 97 percent.

Base-line characteristics are shown in Table 1. During the study period, the mean age of the patients increased, from 61 years in the period from April to June 1994 to 63 years in the period from January to June 1997 ( $P=0.009$ ). The proportion with a recent history (within two weeks) of an acute coronary syndrome also increased (from 38.6 percent to 46.4 percent,  $P<0.001$ ), as did the prevalence of hypertension (from 31.3 percent to 34.1 percent,  $P<0.001$ ) and cerebral vascular disease (from 2.7 percent to 3.8 percent,  $P=0.03$ ). The prevalence of previous myocardial infarction (overall prevalence, 48.3 percent), prior unstable angina (40.3 percent), congestive heart failure (9.6 percent), and diabetes (15.2 percent) remained stable, as did the overall burden of coexisting conditions, as indicated by the clinical comorbidity index.

An examination of the temporal trends (Table 2) revealed the increasing urgency of the procedures, with the proportion of urgent procedures increasing from 48.6 percent in the period from April to June 1994 to 61.7 percent in the period from January to June 1997 ( $P<0.001$ ) and the proportion of elective and semiurgent procedures decreasing. There was also a change in the indications for procedures over time ( $P<0.001$ ), with unstable angina increasing as

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TABLE 1. TEMPORAL TRENDS IN THE BASE-LINE CHARACTERISTICS OF THE PATIENTS.

CHARACTERISTIC	APRIL 1, 1994– JUNE 30, 1997	APRIL–JUNE 1994	JULY–DEC. 1994	JAN.–JUNE 1995	JULY–DEC. 1995	JAN.–JUNE 1996	JULY–DEC. 1996	JAN.–JUNE 1997	P VALUE FOR TREND
No. of procedures	9594	591	1234	1480	1421	1558	1587	1723	<0.001
Mean age (yr)	63	61	63	63	63	63	63	63	0.009
Female sex (%)	27.6	25.4	26.7	28.0	27.0	28.0	27.8	28.8	0.12
Cardiac conditions (%)									
Previous myocardial infarction	48.3	51.4	44.8	48.5	47.8	48.6	48.3	50.3	0.10
Admission for unstable angina ≤2 yr before procedure	40.3	42.0	39.6	39.5	40.9	41.8	40.5	39.1	0.12
Acute coronary syndrome ≤2 wk before procedure	45.0	38.6	40.4	43.5	47.2	45.1	49.0	46.4	<0.001
Congestive heart failure	9.6	8.0	11.4	8.8	9.3	10.3	9.1	9.3	0.15
Coexisting conditions (%)									
Diabetes mellitus	15.2	16.8	16.4	13.8	14.8	15.3	14.2	15.9	0.74
Hypertension	32.5	31.3	30.8	27.1	38.6	32.9	36.1	34.1	<0.001
Cerebral vascular disease	3.3	2.7	1.9	3.2	3.6	3.8	3.5	3.8	0.03
Chronic renal disease	1.9	1.9	2.2	1.5	2.0	2.1	2.1	1.9	0.43
Peripheral vascular disease	4.2	5.8	5.2	3.8	4.6	4.2	3.5	3.7	0.01
Chronic obstructive pulmonary disease	6.2	6.3	5.4	5.7	6.9	6.6	6.4	6.7	0.13
Mean comorbidity index*	0.95	0.89	1.02	0.90	0.94	0.99	0.94	0.95	0.67

\*The clinical comorbidity index<sup>17</sup> was calculated with use of the following formula: 1 × (recent myocardial infarction) + 1 × (cerebral vascular disease) + 2 × (peripheral vascular disease) + 3 × (renal disease) + 4 × (congestive heart failure).

TABLE 2. TEMPORAL TRENDS IN THE CHARACTERISTICS OF THE PROCEDURES.

CHARACTERISTIC	APRIL 1, 1994– JUNE 30, 1997 (N=9594)	APRIL–JUNE 1994 (N=591)	JULY–DEC. 1994 (N=1234)	JAN.–JUNE 1995 (N=1480)	JULY–DEC. 1995 (N=1421)	JAN.–JUNE 1996 (N=1558)	JULY–DEC. 1996 (N=1587)	JAN.–JUNE 1997 (N=1723)	P VALUE FOR TREND
Urgency of coronary intervention (%)									<0.001
Elective	21.0	25.2	28.8	25.9	18.0	21.4	16.0	16.6	
Semiurgent	16.4	17.0	19.6	15.8	17.1	18.9	12.1	15.5	
Urgent	54.1	48.6	43.8	51.0	53.9	49.8	63.1	61.7	
Emergency	8.5	9.2	7.8	7.3	11.0	9.9	6.3	6.2	
Coronary intervention at diagnostic angiography (%)	19.8	11.9	13.0	13.3	14.9	18.8	26.5	33.0	<0.001
Indication (%)									<0.001
Stable angina	35.6	40.1	45.3	40.2	33.0	39.1	27.6	30.1	
Unstable angina	44.5	39.6	36.7	43.0	45.6	38.7	49.3	52.9	
Myocardial infarction (direct PCI)*	3.1	3.9	3.1	2.2	2.9	3.5	3.9	2.6	
Myocardial infarction (failed thrombolysis)	3.0	2.5	1.9	3.6	4.2	3.2	2.8	2.6	
Ischemia after myocardial infarction	12.6	12.1	11.8	9.9	13.6	14.2	15.4	10.6	
Other	1.2	1.8	1.2	1.1	0.7	1.3	1.0	1.2	
Vessels involved (%)									
Left main coronary artery	0.9	0.3	0.5	1.0	1.8	0.6	0.9	0.9	0.51
Left anterior descending coronary artery	43.6	42.8	44.1	43.5	44.7	43.4	43.2	43.5	0.79
Ramus intermedius	1.6	1.5	1.5	1.8	1.2	1.1	2.1	1.7	0.41
Left circumflex artery	23.3	23.9	24.8	23.8	22.3	23.2	22.9	23.2	0.32
Right coronary artery	35.0	38.2	36.6	38.5	38.5	38.0	36.9	38.0	0.61
Saphenous-vein graft	6.1	5.6	5.6	6.0	6.1	6.7	5.2	6.7	0.47
Internal-thoracic-artery graft	0.5	0.5	0.6	0.4	0.4	0.2	0.7	0.6	0.56
Total occlusion (%)	18.6	19.3	17.6	20.1	16.2	20.7	19.4	17.0	0.61
Mean no. of lesions treated/procedure	1.51	1.47	1.44	1.54	1.58	1.49	1.52	1.57	0.001
Mean no. of vessels treated/procedure	1.15	1.13	1.14	1.15	1.15	1.14	1.14	1.15	0.20
≥2 Vessels involved (%)	14.4	13.9	14.1	14.9	14.4	13.8	13.3	16.1	0.40
Use of atherectomy or stent implantation (%)									
Directional atherectomy	0.4	1.9	0.8	0.9	0.4	0.3	0.0	0.1	<0.001
Rotational atherectomy	0.8	2.4	1.2	1.1	1.1	0.4	0.2	0.2	<0.001
Stent implantation	34.8	14.2	14.7	20.0	30.0	37.9	47.4	58.7	<0.001

\*PCI denotes percutaneous coronary intervention.

**TABLE 3. KAPLAN-MEIER ESTIMATES OF THE RATES OF EVENTS SOON AFTER THE PROCEDURE AND AT ONE YEAR.\***

EVENT	percentage of procedures												P VALUE FOR TREND	ADJUSTED RELATIVE RISK (95% CI)†	P VALUE FOR TREND	
	APRIL 1, 1994-JUNE 30, 1997 (N=9594)	APRIL-JUNE 1994 (N=591)	JULY-DEC. 1994 (N=1234)	JAN.-JUNE 1995 (N=1480)	JULY-DEC. 1995 (N=1421)	JAN.-JUNE 1996 (N=1558)	JULY-DEC. 1996 (N=1587)	JAN.-JUNE 1997 (N=1723)	UNADJUSTED RELATIVE RISK (95% CI)	P VALUE FOR TREND	ADJUSTED RELATIVE RISK (95% CI)†	P VALUE FOR TREND				
<b>Early outcome</b>																
Emergency CABG on day 1	0.9	0.7	1.5	0.5	1.2	0.8	0.7	1.0	0.91 (0.46-1.79)	0.78	0.83 (0.42-1.68)	0.62				
Target-vessel revascularization by day 7	3.8	3.9	4.1	3.8	4.5	4.0	2.7	3.7	0.81 (0.58-1.12)	0.20	0.78 (0.55-1.09)	0.14				
<b>Outcome at 1 year</b>																
Target-vessel revascularization	20.6	24.4	22.0	22.3	21.7	19.8	19.9	17.0	0.72 (0.62-0.83)	<0.001	0.72 (0.62-0.83)	<0.001				
Myocardial infarction	5.4	4.5	5.6	4.8	5.0	5.8	6.0	5.6	1.23 (0.92-1.63)	0.15	1.17 (0.88-1.57)	0.28				
Death	3.9	3.5	3.4	4.2	4.1	4.0	3.6	4.4	1.14 (0.81-1.60)	0.44	1.08 (0.76-1.54)	0.65				
Death or target-vessel revascularization	23.8	27.4	24.9	25.9	25.1	23.2	22.9	20.6	0.76 (0.66-0.86)	<0.001	0.74 (0.65-0.85)	<0.001				
Death or myocardial infarction	8.6	7.1	8.5	8.2	8.5	9.3	8.8	9.1	1.19 (0.95-1.50)	0.12	1.08 (0.85-1.36)	0.52				
Major adverse cardiac event	26.1	28.8	27.4	27.7	26.9	25.8	25.4	22.8	0.80 (0.70-0.91)	<0.001	0.79 (0.69-0.90)	<0.001				

\*CI denotes confidence interval, and CABG coronary-artery bypass grafting.

†Each outcome was adjusted independently for predictive base-line variables, including age, sex, cardiac conditions, coexisting conditions, urgency of and indication for percutaneous coronary intervention, and vessels treated.

an indication (from 39.6 percent to 52.9 percent) and stable angina decreasing (from 40.1 percent to 30.1 percent). There was also an increase in the proportion of procedures performed at the time of diagnostic angiography (from 11.9 percent in the period from April to June 1994 to 33.0 percent in the period from January to June 1997,  $P < 0.001$ ). There were no significant changes in the types of vessels treated or in the proportion of acutely or chronically occluded arteries that were treated (overall prevalence, 18.6 percent). The mean number of lesions treated per procedure increased (from 1.5 in the period from April to June 1994 to 1.6 in the period from January to June 1997,  $P = 0.001$ ), whereas the proportion of multivessel procedures remained stable (overall prevalence, 14.4 percent). There was also a large increase in the rate of use of stents (from 14.2 percent in the period from April to June 1994 to 58.7 percent in the period from January to June 1997,  $P < 0.001$ ) and a decrease in the rates of atherectomy (from 4.3 percent to 0.3 percent,  $P < 0.001$ ).

Kaplan-Meier estimates of the rates of events soon after the procedure and at one year for each period are shown in Table 3. Between 1994 and 1997, the overall rates of emergency coronary-artery bypass surgery one day after percutaneous revascularization (0.9 percent,  $P = 0.62$ ) and of target-vessel revascularization within seven days after the procedure (3.8 percent,  $P = 0.14$ ) remained stable. During the same period, there was a significant stepwise reduction in the rates of adverse cardiac events at one year (from 28.8 percent in the period from April to June 1994 to 22.8 percent in the period from January to June 1997,  $P < 0.001$ ), due exclusively to declining rates of target-vessel revascularization (from 24.4 percent to 17.0 percent,  $P < 0.001$ ). Overall, the one-year rates of myocardial infarction (5.4 percent,  $P = 0.28$ ) and death from any cause (3.9 percent,  $P = 0.65$ ) remained stable. Unadjusted Kaplan-Meier estimates of the likelihood of freedom from target-vessel revascularization, death or target-vessel revascularization, and major adverse cardiac events after percutaneous coronary intervention are shown in Figure 1. Analysis of the procedures according to various clinical characteristics revealed no interactions between these variables and the cohort period of the procedure (Fig. 2).

The Cox proportional-hazards model for the risk of target-vessel revascularization at one year demonstrated that the use of stents (relative risk, 0.79; 95 percent confidence interval, 0.71 to 0.88) and the time of the procedure (relative risk for the comparison of consecutive periods, 0.97; 95 percent confidence interval, 0.94 to 0.99) were both independent predictors of improved outcome. Among the 1011 procedures that involved stenting during the period from January to June 1997, the rate of target-vessel revascularization was 12.1 percent at one year. Similarly, the use of stents (relative risk, 0.86; 95 per-

cent confidence interval, 0.79 to 0.94) and the cohort period of the procedure (relative risk for the comparison of consecutive periods, 0.98; 95 percent confidence interval, 0.95 to 0.998) were independent predictors of a reduction in the risk of major adverse cardiac events at one year.

We repeated our end-point analysis on a per-patient basis, including only the 7413 first procedures, and on a per-procedure basis for all 9594 procedures, using competing-risks analysis.<sup>18</sup> The competing-risks analysis was adjusted for possible correlation effects resulting from the repeated inclusion of 2181 patients who had undergone multiple procedures. Neither analysis resulted in an appreciable difference in event rates, temporal trends, or significance levels from our primary analysis.

### DISCUSSION

Rapid changes in the practice of interventional cardiology with respect to the selection of patients, devices used, and adjunctive drug treatment have occurred in the past decade. Dominated by recent marked increases in the use of stents, these myriad changes have been based on extrapolation of the results of studies of selected populations. Such extrapolation may be inappropriate,<sup>19</sup> given the diverse and often complex characteristics of real patients treated with percutaneous coronary interventions. The absence of confirmed effectiveness in unselected populations has had clear implications for clinical practice, clinical research, and cost effectiveness.

Our population-based study provides documentation of one-year event rates after percutaneous coronary intervention within a large geographic region. Between 1994 and 1997, we observed sequential, incremental improvements in outcome, with a 21 percent adjusted reduction in the composite end point of adverse cardiac events that was due entirely to a 28 percent adjusted reduction in the rate of target-vessel revascularization. Event rates declined despite increases in the mean age of the patients and the prevalence of a recent history of acute coronary syndromes and a stable rate of coexisting conditions at base line. This reduction was consistent among key demographic and clinical subgroups, demonstrating the broad effectiveness of evolving techniques of percutaneous coronary revascularization during the mid-1990s.

No observational study allows the clear establishment of causal relations. Simple observations of superior outcomes among patients selected for new therapies are particularly prone to bias, even after adjustment for known prognostic factors. However, the demonstration of a change in the overall outcome during the gradual adoption of a new therapy in a stable, population-based cohort is less subject to bias. The finding that the observed improvement in outcomes after coronary intervention coincided with the increasing use of stents in the absence of a decrease

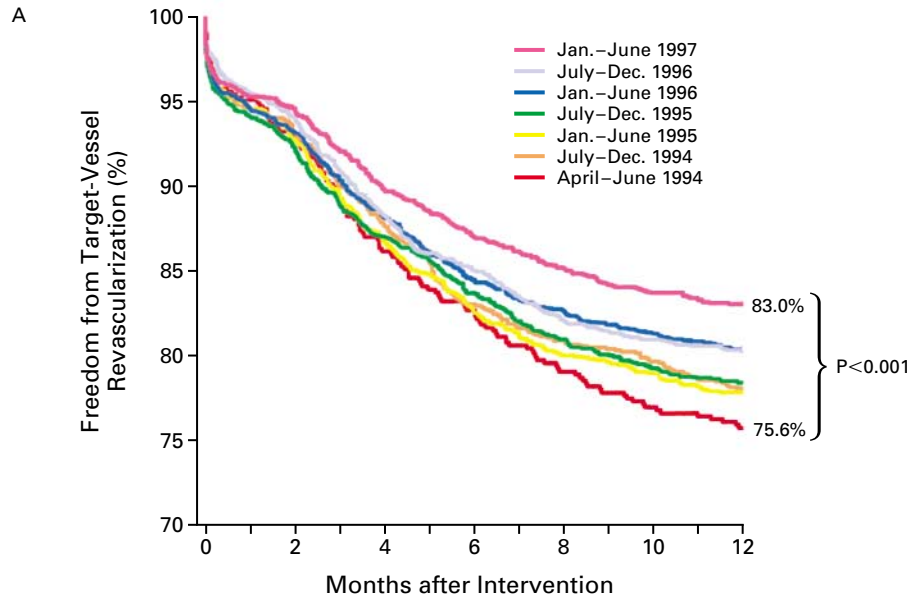
in the complexity of the cases suggests that the effect is attributable to the use of stents.

Our results are concordant with the results of prior randomized stent trials.<sup>6-13</sup> In the original Benestent trial, for example, randomization to stent implantation (with a rate of implantation of 94.6 percent) was associated with a 28 percent reduction (23 percent vs. 32 percent) in the rate of adverse events at one year.<sup>20</sup> This finding is similar to our finding of a 21 percent decrease in the rate of adverse cardiac events, which was associated with an increase in the rate of use of stents (from 14.2 percent to 58.7 percent).

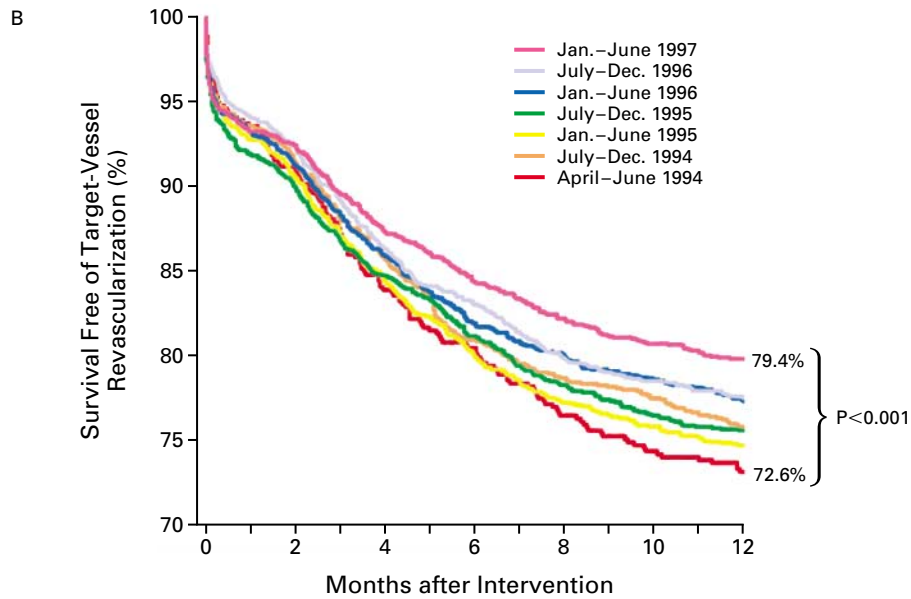
Recently, the original comparisons of stenting and balloon angioplasty<sup>6-13</sup> have been criticized for having insufficient statistical power to detect small increases in the risk of death or myocardial infarction with stenting.<sup>19</sup> In our much larger cohort of patients, despite the infrequent use of abciximab, increasing rates of stenting were not associated with significant increases in the rates of myocardial infarction at one year. Although the methods we used may have been insensitive to the occurrence of asymptomatic periprocedural myocardial infarctions, we consider the fact that there was no significant change in one-year mortality particularly important. Conversely, the absence of such a change is not unexpected, since most of the revascularization procedures in our study involved single vessels.

In our study, the cohort period of the procedure was an independent predictor of improved outcome after adjustment for the use of stents, confirming that changes other than increasing use of stents contributed. Although we can only speculate on their relative importance, such changes include refined techniques of stent deployment; improved stent designs; evolving catheter, balloon, and imaging technology; improved antithrombotic therapy; and increasing operator experience. In addition, we cannot exclude possible effects related to increasingly early treatment in patients with unstable coronary syndromes or to improvements in general medical therapy.

The absence of population-based data on the outcome after percutaneous coronary intervention has limited the interpretation of the results of randomized clinical trials and data from registries. Understanding the degree to which study populations reflect real patients and their outcomes is vital in determining the degree to which results may be generalized. By showing that the outcome continually improved between 1994 and 1997, our study suggests that much of the existing data comparing percutaneous coronary intervention with other therapies is dated. This applies to trials comparing percutaneous revascularization (in which the use of stents was infrequent) to medical<sup>21,22</sup> and surgical<sup>23-28</sup> therapies and has implications for studies of early angiography and intervention in patients with acute coronary syndromes.<sup>29-31</sup> In the most recent period that we studied — January

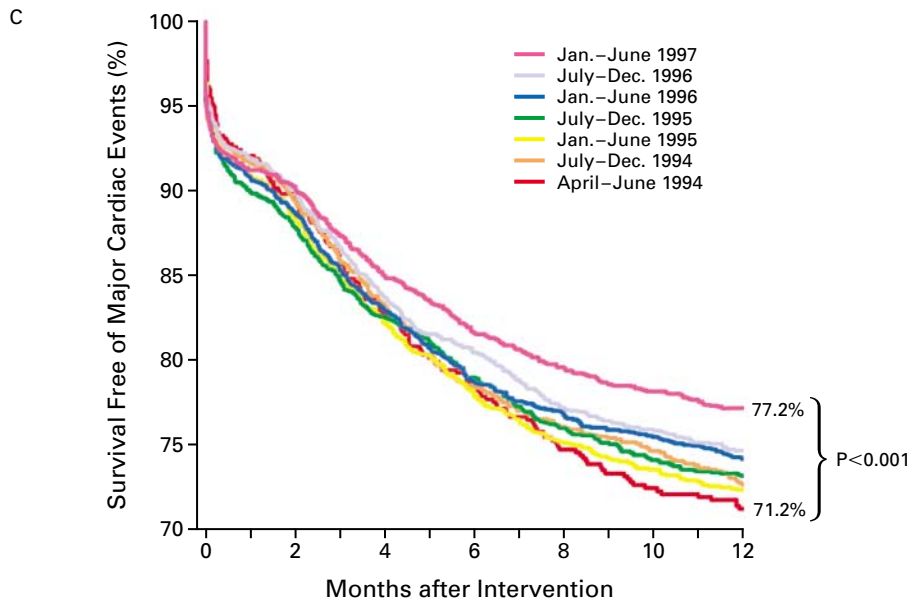


No. AT RISK	0	2	4	6	8	10	12
April-June 1994	591	538	496	475	452	440	432
Jan.-June 1997	1723	1592	1503	1452	1414	1387	1134
April 1, 1994- June 30, 1997	9594	8761	8208	7844	7950	7442	7090

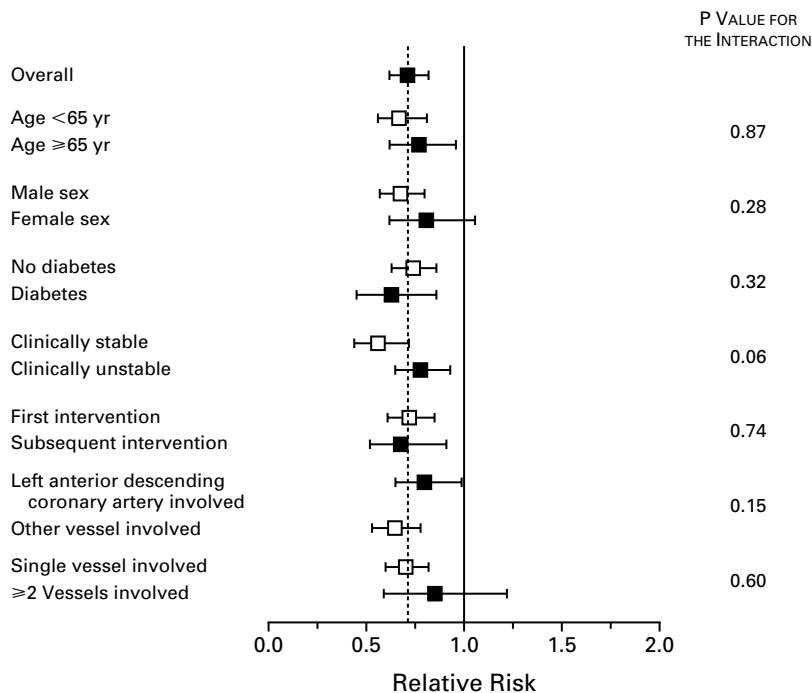


No. AT RISK	0	2	4	6	8	10	12
April-June 1994	591	526	483	461	438	423	416
Jan.-June 1997	1723	1574	1481	1424	1377	1351	1102
April 1, 1994- June 30, 1997	9594	8617	8022	7622	7340	7179	6821

**Figure 1.** Unadjusted Kaplan-Meier Estimates of the Likelihood of Freedom from Target-Vessel Revascularization (Panel A), Death or Target-Vessel Revascularization (Panel B), and Major Adverse Cardiac Events (Panel C) after Percutaneous Coronary Intervention.



NO. AT RISK							
April-June 1994	591	517	476	452	429	413	403
Jan.-June 1997	1723	1538	1442	1380	1335	1310	1066
April 1, 1994- June 30, 1997	9594	8414	7807	7402	7121	6959	6602



**Figure 2.** Adjusted Relative Risk of Target-Vessel Revascularization during the Entire Study Period, Overall and According to Various Clinical Characteristics.

No significant interaction was identified between the cohort period of the procedure and the variables examined, indicating consistency with the overall results. I bars indicate 95 percent confidence intervals. A dotted reference line for the overall adjusted relative risk of target-vessel revascularization is shown.

to June 1997 — the rates of target-vessel revascularization were just 12.1 percent at one year among the 1011 procedures (59 percent) that involved stenting. These contemporary data on outcome must be considered in any determination of appropriate and cost-effective applications of new therapies and forms of technology.<sup>32</sup>

Several limitations regarding our data should be considered. We did not compare the data sheets filled out in the catheterization laboratories with patients' records; therefore, the data may contain errors or bias. We have attempted to minimize the extent to which this may have influenced our results by limiting the use of operator-reported data for coding of the coronary segments. Our end point of target-vessel revascularization relied only on the correct identification of the target vessel and is thus unlikely to have been affected by minor errors or bias in the coding of target segments. Periprocedural myocardial infarction may have been underreported, because cardiac enzymes were not measured routinely after the procedure at all centers during the study period.

We derived data on coexisting conditions and myocardial infarction from an administrative data base. The accuracy of clinical data in administrative data bases has been criticized.<sup>33</sup> In contrast to many insurance-based data bases in the United States, Canadian health data bases are population-based and administered by the government, and each record contains up to 16 diagnoses linked to codes defining the timing and importance of each diagnosis. They are not linked to reimbursement or risk-adjusted hospital report cards rating outcomes, both of which are potential sources of bias. The accuracy and suitability of Canadian health data bases for use in clinical studies have been reviewed,<sup>34</sup> and we validated our own methods of data extraction by comparing them with a chart review in 817 patients at a single hospital (kappa, 0.52 to 0.83). Both our own validation study and a previous study<sup>35</sup> demonstrate that hospital-discharge data are suitable for risk adjustment in research on outcomes.

Our methods may have underestimated the effect of the use of coronary stenting, since the rate of use in the earliest period of the study — April to June 1994 — was 14.2 percent. Those considered at highest risk for acute closure or early restenosis were already receiving stents. This point may explain the lack of a reduction in the number of early, repeated revascularization procedures and may have attenuated the improvement in cumulative one-year outcomes.

In the absence of data on late symptoms, the proportion of patients with recurrent symptoms that were managed medically rather than by repeated revascularization remains unknown. We therefore cannot exclude the possibility that an increasing reluctance to intervene surgically after stenting has been associated with changing interventional techniques and contrib-

uted to the reduction in the rate of target-vessel revascularization. Finally, because our findings reflect the practice of interventional cardiology in British Columbia in the mid-1990s, we cannot state with certainty the extent to which these data can be extrapolated to other populations in other regions with other health systems.

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