# **ORIGINAL ARTICLE**

# CHARLES MAYNARD, PHD

Research Associate Professor

Health Services Research and Development

Department of Veterans Affairs

Investigator

Department of Health Services University of Washington

#### NATHAN R. EVERY, MD, MPH

Associate Professor

Department of Medicine University of Washington

Investigator

Health Services Research and Development Department of Veterans Affairs

## MICHAEL K. CHAPKO, PHD

Investigator

Health Services Research and Development Department of Veterans Affairs

Research Professor

Department of Health Services University of Washington

# JAMES L. RITCHIE, MD

Staff Physician

Department of Medicine Department of Veterans Affairs

Professor and Chairman

Division of Cardiology Department of Medicine University of Washington Seattle, Wash

Effective Clinical Practice. 1999;2:108–113.

Edited by John D. Birkmeyer, MD

# Institutional Volumes and Coronary Angioplasty Outcomes before and after the Introduction of Stenting

**CONTEXT.** An increasing number of patients undergoing percutaneous transluminal coronary angioplasty (PTCA) are receiving coronary stents.

**OBJECTIVES.** To assess whether the introduction of coronary stenting has changed hospital mortality or same-admission coronary artery bypass grafting (CABG) and whether the hospital's procedure volume affects these outcomes.

**DESIGN.** Observational study using hospital claims.

**SETTING.** Nonfederal hospitals that performed PTCA in California in 1993 and 1996.

**PATIENTS.** 35, 350 patients who underwent PTCA in 1993 (before the introduction of stenting) and 43,040 patients who had PTCA in 1996 (43% of whom received stents).

**MEASUREMENTS.** Hospital stenting volumes for 1996 were divided into terciles; total PTCA procedures per year were categorized as low (≤200), medium (201 to 400), or high (>400). Outcome variables included hospital death and coronary artery bypass grafting (CABG) performed during the same admission. Patients with a principal diagnosis of acute myocardial infarction (AMI) were analyzed separately from those without such a diagnosis.

**RESULTS.** From 1993 to 1996, the characteristics of patients undergoing PTCA did not change substantially. The use of same-admission CABG decreased by 13% (from 6.0% to 5.2%; P=0.008) in the AMI group and by 30% (from 3.7% to 2.6%; P<0.001) in the no-AMI group. Hospital mortality did not change significantly in either group. Procedure volume was not related to hospital mortality. However, rates of same-admission CABG were significantly lower at hospitals with high annual stenting volumes than at low-volume centers (1.3% vs. 2.3% among patients in the no-AMI group; P<0.001).

**conclusions.** Hospital mortality rates after PTCA have not changed considerably since the introduction and diffusion of coronary stenting. However, rates of same-admission CABG have decreased in recent years and are lowest at hospitals with high procedure volumes.

o reduce restenosis, percutaneous transluminal coronary angioplasty (PTCA) is increasingly being followed by introduction of a stent into the affected artery. Initially developed as a "bail-out" device for patients with complete occlusion (who would otherwise require emergency surgery), coronary stents were approved for general use in late 1994. In just a few short years, the use of stenting has dramatically increased and it is now a common method of nonsurgical myocardial revascularization.

The abstract of this paper is available at ecp.acponline.org.

Evidence clearly shows that patients undergoing PTCA in high-volume institutions have better outcomes than those who are treated in low-volume centers. <sup>1–9</sup> In addition, higher individual operator volumes seem to be associated with better outcomes in patients undergoing PTCA. <sup>6,8</sup> Treatment guidelines state that institutional volumes that exceed 200 cases per year be required to achieve acceptable patient outcomes. <sup>10</sup> How coronary artery stenting <sup>11–13</sup> affects the relation between volume and outcome is uncertain. Recent findings from Medicare Provider Analysis and Review files suggest that the volume outcome association for PTCA has not been changed by the introduction of coronary stenting. <sup>14</sup>

Continuing our work on PTCA outcomes in California, 1,2 we assessed whether coronary stenting has changed who undergoes PTCA and whether outcomes differ in these patients. We describe who received stents in 1996 and the distribution of stenting and total PTCA volumes across California hospitals. The final question we answer is whether stenting and total PTCA volumes affect outcomes, including hospital mortality and same-admission coronary artery bypass grafting (CABG).

#### **Methods**

# **Patient Population**

Our study examined discharge abstract data obtained from the California Office of Statewide Health Planning and Development for calendar years 1993 and 1996. Hospital discharges with International Classification of Diseases, ninth revision, clinical modification (ICD-9-CM) procedure codes 36.01, 36.02, 36.05, or 36.06 were selected. Stents were approved by the U.S. Food and Drug Administration in late 1994, but the ICD-9-CM code for stenting (36.06) was not implemented until October 1995.

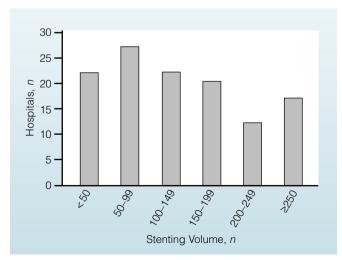


FIGURE 1. Distribution of stenting volumes in California hospitals in 1996.

Patients 18 years of age or older with at least one cardiac diagnosis (ICD-9-CM codes 390–429) were included in the analysis, as were institutions that performed more than five PTCA procedures per year. In 1993, 35, 350 patients were discharged after PTCA; in 1996, 43,040 patients were discharged after PTCA, of which 18,675 underwent stenting.

# **Study Variables**

Variables of interest, identified from earlier studies, included age, sex, ethnicity, diabetes mellitus, multivessel angioplasty (ICD-9-CM code 36.05), and length of stay.<sup>1,2</sup> The method of Deyo and colleagues<sup>15</sup> was used to define comorbid conditions that existed before hospital admission for PTCA and not such conditions as acute myocardial infarction (AMI) or congestive heart failure that could have developed in the hospital as a complication of the procedure. By means of an encrypted Social Security number, it was possible to link the PTCA admission with hospital admissions in the same year for a specific patient, thereby identifying patients who had more than one procedure in a given year.

Because outcomes in patients with AMI differ from those in patients with angina pectoris, patients were subdivided into two groups: those with a principal diagnosis of AMI (ICD-9-CM code 410.xx) and those without such a diagnosis. Outcome variables included hospital death or CABG performed during the same admission (ICD-9-CM procedure codes 36.11 to 36.19).

# **Hospital Procedure Volume**

For the volume–outcome analyses (1996 only), volumes of stenting and total PTCA were defined as low, medium, or high. Hospital stenting volume was divided into terciles

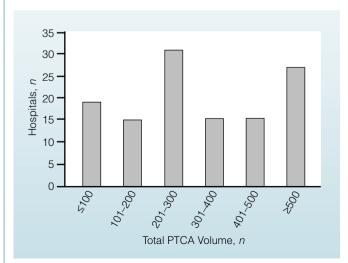


FIGURE 2. Distribution of total volumes of percutaneous transluminal coronary angioplasty (*PTCA*) in California hospitals in 1996.

TABLE 1
Comparison of Patients Undergoing
Percutaneous Transluminal Coronary
Angioplasty in California in 1993 and 1996

CHARACTERISTIC	1993	1996
Patients, n	35, 350	43, 040
Mean age ± SD, yr	64 ±12	65±12
Women, %	33	33
Nonwhite patients, %	18	22
Acute myocardial infarction, %	26	27
Diabetes mellitus, %	18	22
Multivessel angioplasty, %	14	13
Mean length of stay ± SD, d	$4.4 \pm 4.6$	3.8 ± 4.1
Patients receiving coronary stents, <i>n</i>	0	18, 675

<sup>\*</sup>All differences are statistically significant except the percentage of women undergoing angioplasty.

(< 85, 85 to 167, or >167 procedures per year). For total PTCA volume, low volume was defined as 200 or fewer procedures per year; this is the minimum volume established by the American College of Cardiology/American Heart Association guidelines for treatment of AMI. Medium volume was categorized as 201 to 400 procedures per year, and high volume was defined as more than 400 procedures per year; these criteria have been used by other investigators. 7,8

The mean annual stenting volume for the 120 hospitals that placed stents was 153 procedures; the median volume was 111, and the maximum caseload was 941. In two hospitals, either the stenting code was not used or no stents were implanted. In 1996, the mean total PTCA volume for 122 hospitals was 353 procedures, with a median volume of 287 and a maximum caseload of 1232. **Figures 1** and **2** show case distributions according to hospital procedure volume.

# **Statistical Methods**

Patient characteristics for 1993 and 1996 were compared by using the chi-square statistic for categorical variables and the *t*-test for continuous variables. Analyses were conducted separately for patients with and without the principal diagnosis of AMI. To adjust for patient differences across the three volume categories, multivariate logistic regression was used to examine the association between volume and outcome. At the first stage of the

model, age, sex, ethnicity, diabetes status, and multivessel PTCA were added to the model; at the final stage, volume category was incorporated to determine its association with outcome. A similar approach was used to adjust for patient differences when comparing outcomes between 1993 and 1996.

#### **Results**

# Patient Characteristics and Outcomes before and after the Introduction of Stenting

In 1996, 43,040 PTCAs were performed, reflecting an increase of 22% from 35,350 in 1993 (Table 1). The proportion of nonwhite patients and patients with diabetes mellitus increased from 1993 to 1996. Although statistically significant changes were seen in age and the use of multivessel PTCA, these differences were minimal. It should be recognized that large sample sizes in both years produced highly statistically significant differences for relatively small changes. Also of note was a significant decrease in length of stay from 1993 to 1996.

Hospital mortality was similar in 1993 and 1996 in both the AMI group (3.6%) and the no-AMI group (0.9% in 1993 and 0.8% in 1996). Overall, use of same-admission CABG from 1993 to 1996 decreased by 13% (from 6.0% to 5.2%) in the AMI group and by 30% (from 3.7% to 2.6%) in the no-AMI group (**Figure 3**). In 1996, more than one half of PTCAs were performed on the same day as hospital admission, and about one third of same-admission CABGs were done on the day of hospital admission in the AMI group.

In 1996, 43% of PTCAs involved stent placement. Patients who received stents were most often white men

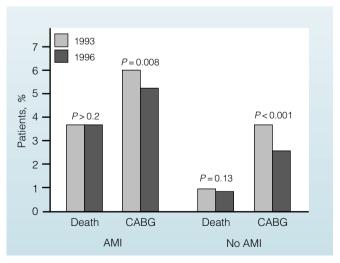


FIGURE 3. Rates of hospital mortality and same-admission coronary artery bypass grafting (*CABG*) in 1993 and 1996 among patients who had acute myocardial infarction (*AMI*) and those who did not. *P* values are adjusted for age, sex, ethnicity, diabetes mellitus, and multivessel angioplasty.

TABLE 2
Characteristics of Patients Undergoing
Percutaneous Transluminal Coronary
Angioplasty with and without Stenting in 1996\*

CHARACTERISTIC	STENTING	NO STENTING
Patients, n	18, 675	24, 365
Mean age ± SD, y	64±12	65±12
Women, %	30	35
Nonwhite patients, %	19	23
Acute myocardial infarction, %	23	30
Diabetes mellitus, %	20	24
Multivessel angioplasty, %	13	13
Mean length of stay ± SD, d	$3.8 \pm 3.7$	3.8 ± 4.3

<sup>\*</sup>All differences are statistically significant except multivessel angioplasty and mean length of stay.

without a diagnosis of AMI (**Table 2**). Length of stay did not differ between the two groups.

# **Hospital Procedure Volume and Outcomes after** the Introduction of Stenting

To determine whether the introduction of stenting changed the association between volume and outcome, we compared outcomes across categories of stent volume among patients who received stents (n=18,675). After being adjusted for covariates, hospital mortality

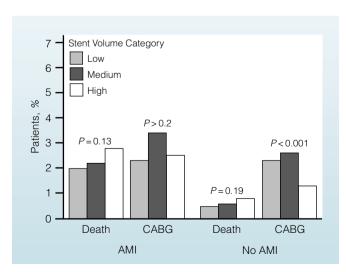


FIGURE 4. Hospital mortality and same-admission coronary artery bypass grafting (CABG) among patients who received stents (n = 18, 675), by stenting volume terciles. P values are adjusted for age, sex, ethnicity, diabetes mellitus, and multivessel angioplasty. AMI = acute myocardial infarction.

was similar across low (n=444), medium (n=1246), and high stenting volumes (n=2650) in the AMI group (**Figure 4**). There was also no association between same-admission CABG and stenting volume; CABG was done most often in the medium-volume category. In the no-AMI group, hospital mortality was similar across categories of stenting volume; the highest mortality was seen in the high-volume group (**Figure 4**). The association between same-admission CABG and stenting volume in the no-AMI group was statistically significant; the rate of same-admission CABG was 2.3% in the low-volume category (n=1183), 2.6% in the medium-volume group (n=3559), and 1.3% in the high-volume category (n=9553).

Similar analyses were done for all PTCA patients by using total PTCA volume (n=43,040) (**Figure 5**). In the AMI group, no association was seen between volume and hospital mortality, as indicated by the adjusted P value. A barely statistically significant association was found for same-admission CABG; it was 5.3% in the low-volume category (n=1086), 6.0% in the medium-volume category (n=4099), and 4.8% in the high-volume category (n=6470). In the no-AMI group, hospital mortality was similar across volume categories. However, there was a distinct decrease in the use of same-admission CABG; the rates were 3.5% in the low-volume category (n=8993), and 2.2% in the high-volume category (n=20,221).

# **Discussion**

In this study, neither stenting volumes nor total PTCA volumes were associated with hospital mortality. How-

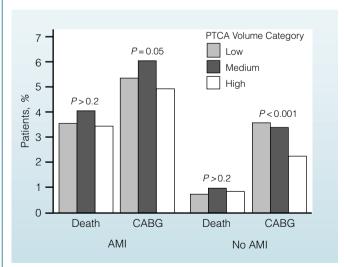


FIGURE 5. Hospital mortality and same-admission coronary artery bypass grafting (CABG) among all patients who underwent percutaneous transluminal coronary angioplasty (PTCA) (n = 43,040), by total procedure volume categories. P values are adjusted for age, sex, ethnicity, diabetes mellitus, and multivessel PTCA. AMI = acute myocardial infarction.

ever, in patients with no AMI, rates of same-admission CABG were lower in the high-volume categories for both stenting and total PTCA volumes. In patients with AMI, the higher total PTCA volumes and lower same-admission CABG rates had marginal statistical significance; this finding was not evident for stenting volume. Of note, in the stenting group, rates of mortality and same-admission CABG were low across volume categories.

The overall volume–outcome association for mortality has been established in various settings in which PTCA is performed.<sup>1–9</sup> In our study, this association was not apparent. However, the finding of reduced rates of same-admission CABG in high-volume centers was sustained. These findings do not support the suggestion that stents, by their ability to "bail out" threatened closure, negate the effects of institutional volume on the use of same-admission CABG.

In California from 1989 to 1996, the proportion of hospitals performing more than 200 PTCAs per year increased significantly, as did the proportion of patients treated in those centers. In 1996, over 72% of hospitals had volumes exceeding 200 procedures per year, whereas in 1989, only 42% of hospitals exceeded the minimum standard. In 1996, California was the most populous state, with 31.9 million people, more than 500 hospitals, and 3.6 million hospitalizations. That year, each of 122 hospitals performed at least 6 PTCAs compared with 110 hospitals in 1989. In comparison, in 1994, PTCA was performed in only 31 centers in New York, which had a population of 18.2 million people that year; 13 of those hospitals had volumes that exceeded 600 cases per year.<sup>3</sup> In 1996, 21 hospitals in California had centers whose annual caseloads exceeded 600 per year. Despite the rapidly growing population of older persons, the number of facilities performing PTCA increased by only about 1% per year from 1989 to 1996. The net result in California was that the proportion of hospitals classified as performing more than 200 procedures per year increased by more than 50% during that 8-year period. There are numerous explanations for this occurrence, including the implementation of practice guidelines, economies of scale, and competition among hospitals.

Our results are subject to the limitations of administrative or hospital discharge abstract data. One advantage is that these data allow complete assessment of PTCA utilization in a large state with many hospitals. A disadvantage is that clinical variables were not available for multivariate adjustment. The lack of clinical detail, such as extent of coronary disease, vessel characteristics, history of myocardial infarction, or whether primary PTCA was performed, is a limitation of administrative data. Some of these factors—for example, the extent of

disease and morphologic characteristics of the vessel—may help to explain why some patients receive stents and others do not. Other shortcomings include the absence of long-term follow-up and data on individual operator volumes.

An encouraging finding of this study was that in 1996, more patients were treated in high-volume centers—where outcomes were generally better—than in 1989.¹ Another result was that in 1996, rates of same-admission CABG were lower in patients who received stents. However, mortality in 1993 (before stenting was generally used) did not differ substantially from that in 1996 (when stenting was widely used). In addition, mortality and use of same-admission CABG were low across volume categories for patients who received stents, although the use of same-admission CABG was lower in centers with high stenting volumes. It will be interesting to see whether these results hold in the years to come as experience with stenting increases.

# **Take-Home Points**

- An increasing proportion of patients undergoing PTCA receive coronary stents.
- Overall rates of in-hospital mortality with PTCA did not change from 1993 (before introduction of coronary stenting) to 1996 (when almost half of patients undergoing PTCA received stents).
- Rates of same-admission CABG, which is sometimes needed after PTCA, decreased after introduction of coronary stenting.
- Although hospital procedure volume was not associated with mortality after coronary stenting, high-volume hospitals had lower rates of sameadmission CABG did than low-volume centers.

#### References

- Ritchie JL, Phillips KA, Luft HS. Coronary angioplasty. Statewide experience in California. Circulation. 1993;88:2735-43.
- 2. Phillips KA, Luft HS, Ritchie JL. The association of hospital volumes of percutaneous transluminal coronary angioplasty with adverse outcomes, length of stay, and charges in California. Med Care. 1995;33:502-14.
- 3. Hannan EL, Racz M, Ryan TJ, et al. Coronary angioplasty volume-outcome relationships for hospitals and cardiologists. JAMA. 1997;277:892-8.
- Malenka DJ. Indications, practice, and procedural outcomes of percutaneous transluminal coronary angioplasty in northern New England in the early 1990s. The Northern New England Cardiovascular Disease Study Group. Am J Cardiol. 1996;78:260-5.
- Kimmel SE, Berlin JA, Laskey WK. The relationship between coronary angioplasty procedure volume and major complications. JAMA. 1995:274:1137-42.

- Ellis SG, Weintraub W, Holmes D, Shaw R, Block PC, King SB 3d. Relation of operator volume and experience to procedural outcome of percutaneous coronary revascularization at hospitals with high interventional volumes. Circulation. 1997;95:2479-84.
- Jollis JG, Peterson ED, DeLong ER, et al. The relations between the volume of coronary angioplasty procedures at hospitals treating Medicare beneficiaries and short-term mortality. N Engl J Med. 1994;331:1625-9.
- 8. Jollis JG, Peterson ED, Nelson CL, et al. Relationship between physician and hospital coronary angioplasty volume and outcome in elderly patients. Circulation. 1997;95:2485-91.
- Ritchie JL, Maynard C, Chapko MK, Every NR, Martin DC. Association between percutaneous transluminal coronary angioplasty volumes and outcomes in the Healthcare Cost and Utilization Project, 1993-1994. Am J Cardiol. 1999; 83:493-7.
- Ryan TJ, Anderson JL, Antman EM, et al. ACC/AHA guidelines for the management of patients with acute myocardial infarction. A report of the American College of Cardiology/ American Heart Association Task Force on Practice Guidelines (Committee on Management of Acute Myocardial Infarction). J Am Coll Cardiol. 1996;28:1328-428.
- 11. Fishman DL, Leon MB, Baim DS, et al. A randomized comparison of coronary-stent placement and balloon angioplasty

- in the treatment of coronary artery disease. Stent Restenosis Study Investigators. N Engl J Med. 1994;331:496-501.
- Cohen DJ, Krumholz HM, Sukin CA, et al. In-hospital and oneyear economic outcomes after coronary stenting or balloon angioplasty. Results from a randomized clinical trial. Stent Restenosis Study Investigators. Circulation. 1995;92:2480-7.
- 13. Versaci F, Gaspardone A, Tomai F, Crea F, Chiariello L, Gioffre PA. A comparison of coronary-artery stenting with angioplasty for isolated stenosis of the proximal left anterior descending coronary artery. N Engl J Med. 1996;334:561-6.
- 14. Ritchie JL, Maynard C, Every NR, Chapko MK. Coronary artery stent outcomes in a Medicare population: less emergency bypass surgery and lower mortality in stent patients. Am Heart J. [In press.]
- 15. Deyo RA, Cherkin DC, Ciol MA. Adapting a clinical comorbidity index for use with ICD-9-CM administrative databases. J Clin Epidemiol. 1992;45:613-9.

## **Grant Support**

Supported by the Department of Veterans Affairs Health Services Research and Development Service grant 99-044.

# Correspondence

James L. Ritchie, MD, Division of Cardiology, Box 356422, University of Washington, Seattle, WA 98195; phone: 206-543-8584; fax: 206-616-4847; e-mail: ritchie@u.washington.edu.