

Original Research

The Decline in PCI Complication Rate: 2003-2006 Versus 1999-2002

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Introduction: Technical improvements permit the performance of percutaneous coronary interventions (PCI) reliably and safely. However, adverse events during such procedures have still not been eliminated. The purpose of this study was to assess the current rates of complications from PCI, as well as any changes from 1999 to 2006.

Methods: Prospectively collected Lenox Hill Hospital data were abstracted from the New York State PCI Report forms and a review of the Quality Improvement office database. The reported complications from 23,399 consecutive PCIs performed during an eight-year period (January 1999 to December 2006) were recorded. The one-month composite endpoint (CEP: death, myocardial infarction, stent thrombosis, stroke, or emergent cardiac surgery within one month of the PCI) and the one-month composite endpoint excluding stent thrombosis (CEPnoST) were evaluated.

Results: Complications occurred in 3.36% of PCIs. The following complication rates were found: one month death rate 0.6%, death in the catheterization suite 0.047%, stent thrombosis (one month) 0.53%, presumed stent thrombosis (one month) 0.82%, myocardial infarction (MI: either Q or non-Q wave) 0.74%, emergent cardiac surgery 0.15%, stroke 0.29%, cardiac perforation 0.29%, retroperitoneal bleeding 0.18%, acute renal failure 0.28%, need for hemodialysis 0.17%, CEP 1.8% and CEPnoST 1.58%. When the complication rates from the most recent period (2003-2006) were compared with those from the earlier period (1999-2002), a statistically significant difference was found in total complications, CEP, CEPnoST, stroke, MI, and vascular complications.

Conclusions: Current rates of PCI complications remain low. The overall PCI complication rate was lower during the last four years of the study.

Technical improvements permit the performance of coronary catheter interventions reliably and safely. However, adverse events during such procedures have not yet been eliminated. This may be related to the treatment of an increasingly aged population, including many with high-risk anatomy and/or clinical characteristics. In addition, technological and pharmacological advances have brought forth new complications.

Thus, although the overall incidence of acute complications has been reduced over the years,¹⁻⁵ the distribution of their causes has been markedly altered, reflecting the changes in percutaneous coronary

intervention (PCI) techniques, increased clinical and technical competence, use of new hardware-mechanical devices and evolution of adjunctive pharmacotherapy and other periprocedural treatment.⁶⁻¹⁵

Reported complication rates not only vary according to the definition applied, but also, almost universally, reflect the clinical trial literature which, given the inherent design of the randomized trials, does not offer information and guidance about the broad spectrum of patients treated in "real world" clinical practice.

Furthermore, the availability of a well structured and organized Quality Improvement (QI) program, along with the mandat-

ed New York State PCI reporting system, provides important information about the occurrence of complications and the safety profile of PCI procedures.

The objective of our study was to assess the current rates of complications from PCI in our center, as well as changes in the rates, if any, from 1999 to 2006.

Methods

Patient population

Prospectively collected hospital data were abstracted from the New York State PCI Report forms and a review of the QI office database. The reported complications from 23,399 consecutive PCIs performed during an eight-year period (January 1999 to December 2006) were recorded. In order to evaluate a possible change of the complication rates in recent years, the study data were arbitrarily divided into two groups, the first (early) and second (recent) groups, comprising the complications that occurred in the first four years (1999–2002) and the last four years of the study (2003–2006), respectively.

Data collection

Data were collected prospectively. A dedicated QI nurse followed each patient until discharge from the hospital and ensured completion of the New York State PCI Report form. As recommended by the ACC/AHA/

SCAI practice guidelines,¹⁶ in order to ensure valid quality assessment our institution's QI office maintained meticulous records of all complications occurring in each patient, including the demographic and clinical characteristics necessary to assess appropriateness. In addition to the complications reportable in the New York State PCI Report, the QI nurse recorded all complications occurring and entered them in a dedicated database. Monthly QI meetings were held for the discussion and review of these adverse events. A research nurse contacted each patient by telephone one month after cardiac catheterization and recorded any further procedure-related complications with special emphasis on stent thrombosis and death.

Definition of procedural complications

The definitions of the complications reportable to NY State, as well as the revisions and the changes in these definitions that occurred over the years, are given in Tables 1 and 2.

In addition, the rates of the following complications were analyzed:

- Any vascular complication, including bleeding: blood loss at the site of arterial access requiring transfusion, or hematoma that was considered significant by the caring physician and/or prolonged the hospital stay, or entry vessel occlusion, pseudo-aneurysm or atrioventricular fistula diagnosed by ultrasonographic examination.

Table 1. New York State PCI Report form. Definitions, changes and revisions of major events reported following PCI for each year 1999–2006.

1999

Revisions from 1998:

Cardiac enzymes: One pre and two post measures. Troponin may be used.

Definitions of major post procedural events:

1. Stroke ≤ 24 hours: TIA or CVA intraop to 24 hours after procedure.
2. Stroke > 24 hours: TIA or CVA > 24 hours after procedure.
3. Transmural MI (New Q Waves): new Q waves and a rise in CPK at least 2.5 times the normal range, occurring within 24 hours after angioplasty.
4. Non-transmural MI (no new Q waves): utilize hospital's clinical guidelines to determine non-transmural MI occurring within 24 hours after angioplasty.
5. Acute occlusion at the site of angioplasty
6. Arterial or venous injury at catheter entry site, requiring surgery: any such injury, including those requiring femoral or brachial embolectomy, evacuation of a hematoma, repair of false aneurysm, or closure of arterio-venous fistula. Report of occlusions which occurred at other coronary arterial sites related to the angioplasty.
7. Renal failure, dialysis: contrast-induced nephropathy requiring dialysis.
8. Emergency bypass surgery, hemodynamically unstable: the patient is taken to the operating room on an emergency basis in an unstable condition, with ongoing chest pain, ECG changes, and hypotension.
9. Emergency bypass surgery, hemodynamically stable: the patient is taken to the operating room in a stable condition because of a complication of angioplasty.
10. Stent thrombosis: formation of clot in the stented segment of the artery and/or adjacent area. Stent thrombosis should be reported as a post procedural event even if it does not become apparent until after the patient is discharged from the hospital.

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2000

Revisions from 1999:

The term coronary angioplasty has been changed to coronary intervention.

The term PTCA has been changed to PCI

Deleted transmural and non-transmural MI

New: Periprocedural MI reported information:

-New abnormal wall motion

-New Q waves

-New LBBB

-New ST elevation

-New ST depression or T inversion

-TIMI ≤ 2

-Ischemic type chest pain

-Documentation of time from onset of chest pain to hospital admission

-Ongoing ischemia at time of procedure

2001

Revised CVA definition: only permanent CVA

2002

Cardiac enzymes: at least one set post PCI (but two sets post PCI recommended)

Can now report troponin with two decimal places

Stent thrombosis reported up to 6 months post PCI

Renal failure: creatinine > 2.5 mg/dl for more than 7 days post PCI or need for dialysis of any type

2003

New major events added:

-Transmural MI (new Q waves): new Q waves and a rise in CPK at least 2.5 times the normal range, occurring within 24 hours after PCI.

-Non-transmural MI (no new Q waves): utilize hospital's clinical guidelines to determine a non-transmural MI, occurring within 24 hours after PCI.

-Emergency return to the catheter lab for PCI: the patient is taken to the catheter lab on an emergency basis due to a complication of a previous PCI.

Acute occlusion at the site of intervention has been separated into two separate events:

-Acute occlusion in the targeted lesion and

-Acute occlusion in a significant side branch

Emergency cardiac surgery: is replacing two previously collected events (emergency bypass surgery hemodynamically stable and unstable).

This event is not separated out by hemodynamic stability and will include any cardiac surgery instead of being limited to bypass surgery.

2004

Renal failure: temporary or permanent renal dialysis of any type before hospital discharge. Elevated post-PCI creatinine is no longer reported as a major event.

2005

No revisions performed

2006

Transmural MI (new Q waves) is now referred to as "Q-wave MI"

The following data elements have been deleted from the PCI Report data collection system effective January 2006:

-Cardiac enzymes

-New abnormal wall motion

-New Q waves

-Ischemic type of pain

-Non-transmural MI (no new Q waves)

CVA – cerebrovascular accident; LBBB – left bundle branch block; MI – myocardial infarction; TIA – transient ischemic attack.

Table 2. Changes in the reporting of major events following PCI over the years 1999-2006.

	1999	2000	2001	2002	2003	2004	2005	2006
Stroke ≤24 hours	*	As of 1999	Only CVA	As of 2001	As of 2001	As of 2001	As of 2001	As of 2001
Stroke >24 hours	*	As of 1999	Only CVA	As of 2001	As of 2001	As of 2001	As of 2001	As of 2001
Transmural MI	*	Periprocedural MI [†]	As of 2000	As of 2000	Transmural MI	As of 2003	As of 2003	Q-wave MI
Non-transmural MI	*				Non-transmural MI	As of 2003	As of 2003	Non-Q wave MI
Acute occlusion	*	As of 1999	As of 1999	As of 1999	Revised	As of 2003	As of 2003	As of 2003
Vascular injury	*	As of 1999	As of 1999	As of 1999	As of 1999	As of 1999	As of 1999	As of 1999
Renal failure	*	As of 1999	As of 1999	Revised	As of 2002	Revised	As of 2004	As of 2004
Emergency CABG, hemodynamically unstable	*	As of 1999	As of 1999	As of 1999	Revised	As of 2003	As of 2003	As of 2003
Emergency CABG stable	*	As of 1999	As of 1999	As of 1999				
Stent thrombosis	Reported any time occurred	As of 1999	As of 1999	Up to 6 mo	As of 2002	As of 2002	As of 2002	As of 2002
Emergency return to the cath. lab for PCI	NA	NA	NA	NA	New	As of 2003	As of 2003	As of 2003

*See 1999 definitions of major post procedural events (Table 1). [†]See 2000 reported information for peri-procedural MI (Table 1). CABG – coronary artery bypass graft; NA – not available. Other abbreviations as in Table 1.

- Presumed stent thrombosis: angiographically documented stent thrombosis, or Q-wave myocardial infarction (MI), or sudden cardiac death one month post PCI.
- One month composite endpoint (CEP): death (including sudden cardiac death), MI, stent thrombosis, stroke, or emergent cardiac surgery within one month of the PCI.
- One month composite endpoint excluding stent thrombosis (CEPnoST): death (including sudden cardiac death), MI, stroke, or emergent cardiac surgery within one month of the PCI.

Statistical analysis

The complication rate was calculated for each of the two time periods. As mentioned, each period consisted of four years. The first one covered the time period from January 1999 to December 2002 and the second from January 2003 to December 2006. The rates of each complication, between the two groups, were compared using the Z-test for two proportions. Complications in the same patient during different hospital admissions, were recorded as separate event entities. A p-value <0.05 was considered *a priori* to indicate statistical significance. GO.COM (McGraw-Hill, Inc., 1988) and SPSS (version 14, Chicago IL) statistical programs were utilized for the statistical analysis.

Results

Complications occurred in 787 of the 23,399 PCIs performed (3.36%). Ten patients experienced complications in more than one hospital admission. Death from any cause, in one month following the PCI, occurred in 0.6% of the patients. Most of the patients who died in the hospital had the following complications: stent thrombosis, Q or non-Q wave MI, cardiac perforation, stroke, need for emergent cardiac surgery, bleeding or vascular complication, renal failure, multiorgan failure.

There were 11 deaths that occurred in the catheterization suite, after PCI, giving a rate of 0.047%. The rate did not change significantly during the study period. The average age of the patients who died in the catheterization suite was 75 ± 14 years. Thrombus was noted in 8 (73%) of these 11 patients. Eight patients died because of cardiogenic shock and coronary thrombosis. Two patients died because of arrhythmias — pulseless electrical activity and cardiac arrest — and another experienced cardiac tamponade and shock due to presumed myocardial rupture after an MI.

Stent thrombosis in the month following the inter-

vention occurred in 0.53% of cases. Presumed stent thrombosis occurred in 0.82% of patients. MI (either Q or non-Q wave) was recorded in 0.74% of procedures. Emergent cardiac surgery was required in 36 patients (0.15%). Stroke occurred in 0.29% of patients. The one-month CEP was recorded in 1.8% of PCIs and the one-month CEPnoST in 1.58%.

Twenty-one PCIs (0.087%) were complicated by left main artery dissection. Four patients experienced aortic dissection. Cardiac perforation occurred in 68 patients (0.29%). Retroperitoneal bleeding was noted in 0.18% of the procedures. Acute renal failure was noted in 0.28% of patients and hemodialysis was required in 39 patients (0.17%). Vascular complications, including bleeding, were reported in 0.79% of cases. Eight patients developed groin infection. Three patients experienced significant air embolism. Eight patients, under treatment with glycoprotein IIb/IIIa inhibitors, had pulmonary hemorrhage. Three patients developed severe anaphylactoid reactions to the contrast medium, none of which resulted in death. The 8-year PCI complication rate is shown in Table 3.

The overall complication rate was lower during the last four years of the study. When the complication rates in the most recent period (2003-2006) were compared with those from the earlier period (1999-2002) (Figure 1), a statistically significant difference was found for the total number of complications, CEP, CEPnoST, stroke, any MI (Q or non-Q), and vascular complications, but not for the rate of death (one month), need for emergent cardiac surgery, car-

Table 3. Eight-year PCI complication rates (1999-2006).

Complication	Rate
Death one month post PCI	0.6%
Death in the cath. lab suite	0.047%
Stroke	0.29%
Cardiac perforation	0.29%
Any myocardial infarction	0.74%
Emergent surgery	0.15%
Stent thrombosis in one month	0.53%
Presumed stent thrombosis	0.82%
Renal failure	0.28%
Hemodialysis	0.17%
Retroperitoneal bleeding	0.18%
Vascular complication and bleeding	0.79%
CEP	1.8%
CEPnoST	1.58%
Any complication	3.36%

CEP – one-month composite endpoint; CEPnoST – one-month composite endpoint excluding stent thrombosis.

diac perforation, tamponade, stent thrombosis and presumed stent thrombosis (Table 4).

Discussion

We report the PCI-related complication rate from our institution, over an eight year period (January 1999 to December 2006). Our study shows that the overall complication rate remained low. More importantly, the overall complication rate was lower during the last four years of the study compared with the first four.

It is worth reviewing the significant changes that have occurred in the complication rates since the initial reports. In the 1984 NHLBI PTCA Registry report, the overall hospital mortality rate was 0.9% and major adverse coronary events occurred in 13.6% of patients. Major MI occurred in 5.5% of patients and bypass surgery was required in 6.6%.¹⁷⁻¹⁸ In a more recent report, outcomes of 1559 consecutive patients in the 1997-1998 Dynamic Registry were compared with 2431 patients in the 1985-1986 National Heart, Lung, and Blood Institute Registry. The rate of combined in-hospital death, MI, and emergency coronary artery bypass grafting (CABG) was lower in the 1997-1998 Dynamic Registry than in the 1985-1986 Registry (4.9% versus 7.9%; $p=0.001$), despite the fact that substantially more complex lesions were attempted.¹⁰ Also, in a report of the Registry for the Society for Cardiac Angiography and Interventions, where a total of 19,510 consecutive coronary interventional procedures were recorded from June 1966 through December 1998, decreased rates of in-hospital death and CABG were reported, compared to prior reports from the registry.¹⁹ Additionally, a study of 34,752 procedures performed in northern New England between 1990 and 1997 showed that the rate

of emergency CABG after PCI fell from a peak of 2.3% to 1.3%, while mortality rates decreased slightly from 1.2% to 1.1%.²⁰ Another recent analysis from data collected between January 1998 and September 2000 for the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR) indicated that the frequencies of in-hospital Q-wave MI, CABG and death were 0.4%, 1.9% and 1.4%, respectively.²¹ Mortality varied by hospital from a low of 0% to a high of 4.2%. Also, in a recent report, the RIVIERA registry study (2002-2005) investigators reported an in-hospital death rate of 0.3% and an MI rate of 1%.²²

Our results are consistent with these reports and show a one-month death rate 0.6%, rate of any MI 0.74%, rate of the one-month CEP 1.8% and CEPnoST 1.58%. Furthermore, in our study, the total number of complications, and the incidence of CEP, CEPnoST, stroke, MI and vascular complication were significantly lower during the last four-year period (2003-2006) when compared with the earlier four years (1999-2002) (Figure 1). Additionally, the low complication rates reported in the present study were recorded up to one month post intervention, covering a greater period compared to the usually reported in-hospital complication rates.

Possible explanations for the decreased rates of complications in our study may include improvement of devices, periprocedural adjunctive pharmacologic therapy and techniques, improvement of overall post-procedural care, and individual operators' characteristics. Of interest is the fact that, although the actual rates of death in one month and need for emergent cardiac surgery decreased in recent years, they were not statistically different between the two studied periods (1999-2002 vs. 2003-2006).

Our overall rate of 0.15% for need of emergent cardiac surgery is consistent with the recent report by Yang

Table 4. PCI complication rates. Early (1999-2002) vs. recent period (2003-2006).

Complication	Absolute difference*	Z value	p-value	95% CI
Death one month	0.002	1.49	0.13	-0.000 to 0.004
Stroke	0.002	3.34	0.000	0.001 to 0.004
Cardiac perforation	0.001	1.86	0.06	0.000 to 0.003
Tamponade	0.000	0.55	0.58	-0.001 to 0.000
Emergent surgery	0.001	1.19	0.23	-0.000 to 0.002
Any myocardial infarction	0.005	4.84	<0.001	0.003 to 0.008
Stent thrombosis (ST)	0.001	0.85	0.39	-0.003 to 0.001
Presumed ST	0.002	1.64	0.1	-0.000 to 0.004
Vascular complication	0.004	3.52	<0.0001	0.002 to 0.006
CEP	0.007	4.26	<0.0001	0.004 to 0.011
CEPnoST	0.009	5.41	<0.0001	0.006 to 0.012
Any complication	0.013	5.48	<0.0001	0.008 to 0.018

*Absolute difference = Early group (1999-2002) - Recent group (2003-2006) complication rate. Abbreviations as in Table 3.

et al in 2005, which showed a significant decrease in the incidence of emergency CABG from 2.9% to 0.3% in the “current stent era”.²³ As these authors report, fewer patients in the current stent era – 2000 to 2003 – had coronary artery dissections and abrupt vessel closure requiring emergency CABG, while despite the increase in high-risk patients undergoing PCI, there has been a marked decrease in the incidence of patients requiring emergency CABG. This fact reaffirms the established role of PCI as a safe and successful revascularization procedure for the treatment of CAD, being less dependable, in the current era, on the on-site presence of cardiac surgery.

Unfortunately, we do not have data on the patients’ clinical characteristics in order to be able to characterize the studied population accurately, but we have no reason to believe that our patients’ clinical profile was less “high risk” compared to other studies. Our population probably represents the practice of any large volume referral center in the country.

Rates of periprocedural MI in our study have declined in recent years. In previous studies, periprocedural MI rates ranged from 0.4% to 4.9%.¹⁶ Post-procedural cardiac enzyme determination (CPK) is routine in our institution. The reported rates in our study include both Q and non-Q wave MI and differences in the rates between studies may reflect different methodologies.

The rate of stroke has also declined significantly in recent years (from 0.4% in the early period to 0.16% in the recent period). Recently, Fuchs et al²⁴ reviewed a total of 12,407 PCIs between January 1990 and July 1999 and reported an overall stroke rate of 0.38%, while Kawamura et al²⁵ found that the rate of stroke in patients with acute MI (NSTEMI and STEMI) undergoing PCI was 0.88%. Increased experience and familiarity of the interventional cardiology community with peripheral and carotid procedures might have contributed to the decreased incidence of stroke. The rate of cardiac perforation was 0.29%, slightly lower than the rate of 0.48% reported in previous studies.²⁶ Retroperitoneal bleeding was noted in 0.18% of the procedures, consistent with the rate of 0.27% reported in a recent study²⁷ and possibly reflecting the routine fluoroscopy of the anatomic landmarks prior to vascular access, as well as the increasing number of procedures performed via the transradial vascular approach. Of note is the fact that, in the last years of the study, PCIs were performed routinely under at least dual anti-platelet therapy and use of bivalirudin. The overall vascular complication rate, including bleeding, was low. During the period 2003-2006 the overall rate of vascular complications was 0.57%, compared with 0.99% for the period 1999-2002 (p=0.000, Figure 1B).

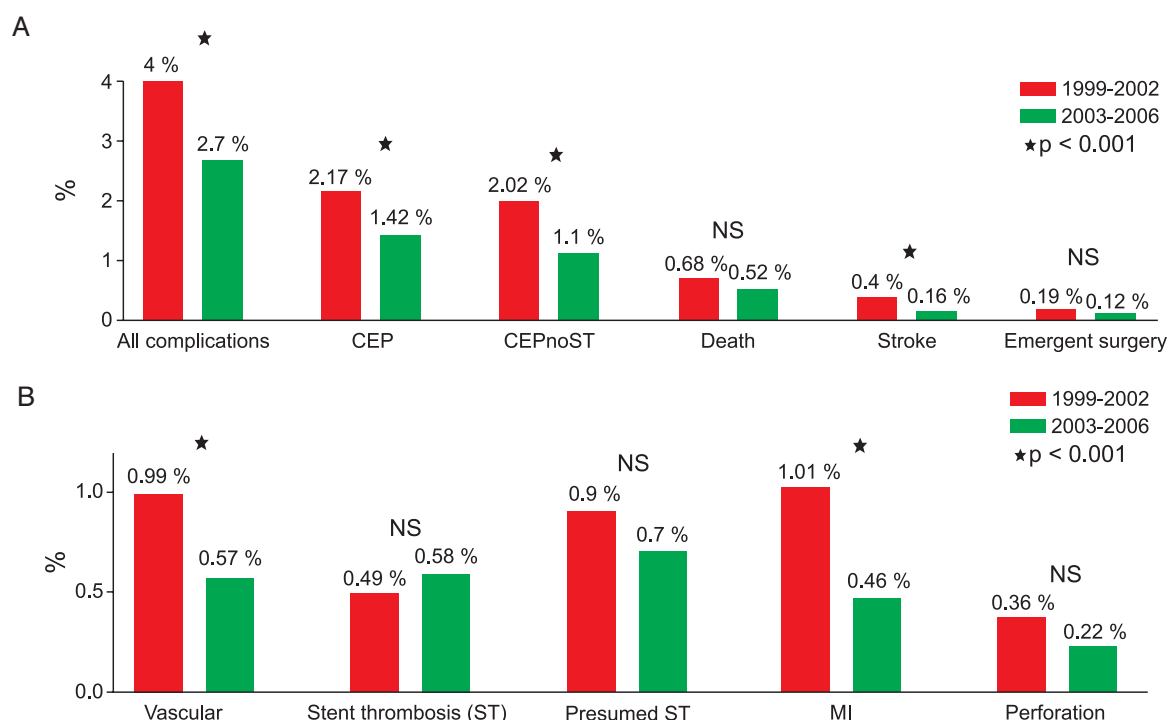


Figure 1. PCI complication rates. Early (1999-2002) vs. recent period (2003-2006). CEP – one-month composite endpoint; CEPnoST – one-month composite endpoint excluding stent thrombosis; MI – myocardial infarction.

Finally, the one-month rate of presumed stent thrombosis was 0.82%, while the rate of angiographically documented stent thrombosis was 0.53%. Similar results were indicated in a recent meta-analysis of 10 randomized studies, involving 5030 patients, comparing drug eluting stents (DES) and bare metal stents (BMS), in which the thrombosis rate was 0.58% for DES and 0.54% for BMS.²⁸ Also of interest is our observation that the rate of stent thrombosis did not differ statistically between the years 1999-2002, when BMS predominated, compared to the recent years 2003-2006 since DES approval by FDA and their widespread utilization. In our hospital DES were also used during the 1999-2002 period. Our data add to the current evidence from other registries that there does not appear to be an increased incidence of early thrombosis with DES.

Study limitations and caveats

The limitations of our study are due to the observational quality of the data, which implies potential incompleteness, such as under-reporting of complications. Nevertheless our data correlate with the reported data from other studies and registries^{29,30} and the information provided becomes even more important today, now that the applications of interventional cardiology have significantly expanded.³¹ Furthermore, an observational study like ours provides information about the complication rate over a sufficiently large period of 8 years, involves a large number of patients and is not limited – as randomized studies are – by exclusion criteria. Whether our improved outcomes, especially in the last few years, may be extrapolated to the remainder of the USA remains to be seen, as hospital-specific characteristics may be present.

Additionally, the present study did not analyze the impact of various clinical and procedural factors on complication rates and we can only speculate about the actual risk profile of the patients and the lesions. Still, as mentioned earlier we have no reason to believe that our patients' clinical profile was less "high risk" compared to other studies.

Conclusions

We report the PCI related complications rate from our institution over an eight year period (January 1999 to December 2006). Our study shows that the overall complication rate remains low. More importantly, the overall complication rate was lower during the last years of the study, and a statistically sig-

nificant difference was observed for the total number of complications, CEP, CEPnoST, CVA, MI and vascular complications. Additionally, no statistically significant difference was found in the rate of death, need for emergent cardiac surgery or stent thrombosis.

Despite the study's limitations it is hoped that these data provide a point of reference toward a better, accurate and updated knowledge of PCI complication rates in the current era.

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