

# The Impact of Diabetes

## On Clinical and Economic Outcomes of PCI in the Elderly

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## OVERVIEW

### Background:

- Diabetic patients have been shown to be at higher risk of coronary restenosis after percutaneous coronary intervention (PCI) in clinical trials and single-center series.
- However, this observation has not been investigated in unselected patients, and no data exist on the clinical or economic burden of restenosis in elderly diabetic patients in contemporary clinical practice.

### Objective:

- To examine the impact of diabetes mellitus (DM) on clinical and economic outcomes after PCI in an unselected population of elderly patients.

## METHODS

- Data were from the Medicare 5% sample Standard Analytic File for the years 1997, 1998, and 1999.
- Study population included all patients aged 65 and over undergoing “initial PCI” procedure in 1998 identified by having at least one of the following codes for coronary stenting (ICD-9 code 36.06 or CPT-4 codes 92980 and 92981) or PTCA (ICD-9 codes 36.01, 36.02, 36.05, 36.09 or CPT-4 codes 92982 and 92984).
- Patients who underwent a PCI procedure within 1 year prior to their 1998 procedure were excluded, along with patients who died within 30 days of the initial PCI.
- Patients with diabetes mellitus were identified by the presence of ICD-9 codes 250.x on any of their claims.
- Outcomes and costs were adjusted for 12 co-morbid conditions identified using groups of ICD-9 diagnosis codes as well as other demographic and procedural variables.
- Clinical events, resource use, and costs from 31 to 365 days after the initial PCI were identified. Events and resource utilization during the first 30 days of follow-up were excluded, as previous studies have demonstrated that repeat revascularization during the first 30 days is rarely due to restenosis and most likely relates to treatment of thrombotic complications or planned staging for multivessel disease.
- Clinical restenosis rates were estimated by multiplying the overall 1-year repeat revascularization rates by 0.85 on the basis of previous studies which have shown that approximately 85-90% of repeat revascularizations within 6 months after initial PCI represent target lesion revascularization (restenosis) (Kimmel SE et al., *AHJ* 2002;143(5):833-40).
- Costs were assessed from the Medicare payment perspective and included costs for hospital admissions, inpatient and outpatient procedures, and physician and supplier services.
- Analytic techniques included descriptive statistics, stepwise multivariable logistic regression, and multivariable linear regression.

## RESULTS

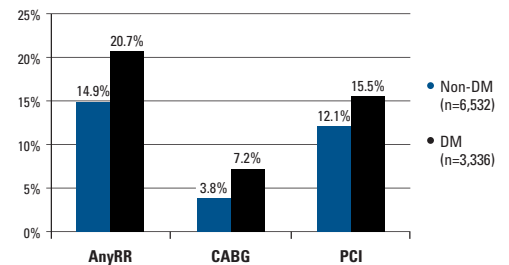
### Exhibit 1

#### Baseline Characteristics

	Non-DM (n=6,532, 66%)	DM (n=3,336, 34%)	P Value
Mean Age (± SD)	73.8 ± 6.0	72.8 ± 5.4	<0.001
Female (%)	41.7	44.9	0.002
Hypertension (%)	76.9	87.7	<0.001
Renal Disease (%)	3.4	9.6	<0.001
AMI as Principal Diagnosis (%)	29.0	26.8	0.023
Saphenous Vein Graft Disease (%)	4.8	5.5	0.120
Index Procedure Stent (%)	79.8	78.8	0.226
Mean Number of Co-morbid Conditions Excluding DM (± SD)	2.7 ± 1.5	3.2 ± 1.6	<0.001

### Exhibit 2

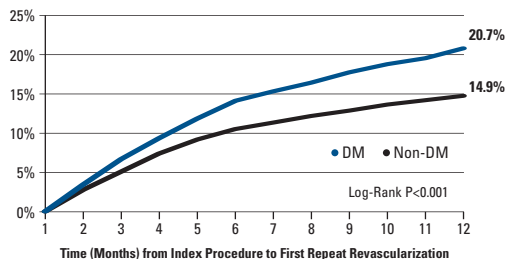
#### Repeat Revascularization Rates at 1 Year



- DM patients were more likely to undergo one or more PCI (OR 1.34, 95% CI: 1.19 - 1.51, P<0.001) and CABG (OR 1.96, 95% CI: 1.63 - 2.35, P<0.001) procedure to 1 year than non-DM patients after adjustment for baseline differences.
- The mean number of repeat procedures following the initial procedure were 1.4 for DM and 1.3 for non-DM patients with a repeat procedure (P=0.003), with repeat PCIs being 1.0 among DM and 1.0 among non-DM patients.
- Of DM and non-DM patients incurring repeat revascularization, 34.6% and 25.4% of patients underwent CABG (P<0.001).

### Exhibit 3

#### Repeat Revascularization >30 Days After Initial PCI in Diabetics and Non-Diabetics



- After adjusting 1-year repeat revascularization rates by 0.85 to exclude repeat procedures to non-target lesions, the estimates of “clinical restenosis” were 17.6% and 12.7% for patients with and without diabetes, respectively.

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### SUMMARY

- During the first year after PCI in an unselected group of elderly patients, the rate of restenosis rates was 39% higher among diabetic than non-diabetic patients (20.7% vs. 14.9%,  $P < 0.001$ ).
- After adjusting by 0.85, the clinical restenosis rates were estimated to be 17.6% and 12.7% for diabetic and non-diabetic patients, respectively.
- In addition to the higher rate of repeat revascularization, the unadjusted 1-year medical costs also were higher among diabetic patients compared with non-diabetic patients with a repeat revascularization (\$30,111 vs. \$23,408,  $P < 0.001$ ).
- Adjusting for demographic, clinical, and procedural characteristics, the independent attributable costs per DM and non-DM restenosis patient were \$21,450 (95% CI 20,451-22,448) and \$17,508 (95% CI 16,697-18,320), respectively.
- Thus, the 1-year economic burden of clinical restenosis for each patient undergoing initial PCI was ~\$1,551 higher for diabetic than non-diabetic patients (\$3,775 vs. \$2,224).
- Extrapolation to the full population of PCI patients in the Medicare Program in 1998 ( $n \approx 266,220$ ) suggests that the direct medical care costs for treatment of restenosis are ~\$342 million for DM patients and ~\$391 million for non-DM patients, giving a total cost of restenosis of \$732 million.

### CONCLUSIONS

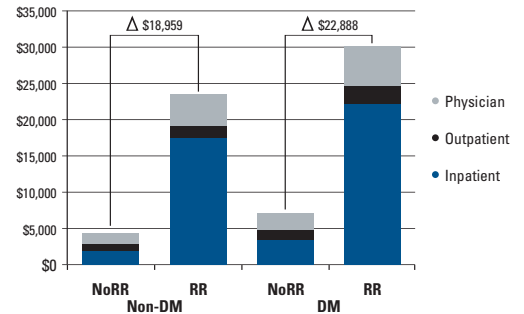
- Among unselected, elderly patients undergoing PCI, diabetes is associated with both an increased risk of restenosis and higher costs for treatment of restenosis.
- Assuming similar levels of effectiveness, technologies such as drug-eluting stents that may reduce repeat procedure rates after PCI are likely to have a more favorable economic profile among diabetic patients.

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### RESULTS

#### Exhibit 4 Mean Cost of Care (Unadjusted) per Patient With and Without Repeat Revascularization (RR)



- After adjustment for baseline differences, the need for a repeat procedure increased follow-up medical care costs by \$21,450 for DM patients and by \$17,508 for non-DM patients ( $P < 0.001$ ); the risk-adjusted difference in repeat revascularization costs was \$4,275 per patient ( $P < 0.001$  by interaction test).
- A similar result was found when examining cardiovascular costs only at \$20,742 for DM patients and \$17,337 for non-DM patients ( $P < 0.001$ ).
- The 1-year economic burden of restenosis to the healthcare system was \$3,775 and \$2,224 per initial PCI procedure for DM and non-DM patients, respectively.