Predictors of Long Term Outcomes in 11,441 Consecutive Patients Following Percutaneous Coronary Interventions

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Given the vicissitudes of percutaneous coronary intervention (PCI) technology, epidemiology, and mode of practice, the aim of this study was to define contemporary outcome predictors in a very large consecutive patient cohort. Data from 11,441 consecutive patients who underwent PCI at a tertiary medical center from April 2004 to September 2013 are presented. A comprehensive database was built using various data sources, with outcome end points defined as all-cause mortality and as a composite of death or nonfatal myocardial infarction during follow-up. Candidate variables to influence outcome were chosen a priori and were tested using multivariate time-dependent models to estimate each interaction. Mean follow-up was 5.5 years (range 3 months to 9.5 years). The cohort consisted of 75% men, 42% patients with diabetes, and 61% patients who underwent PCI in acute coronary syndrome settings and 7.8% for ST-elevation myocardial infarction. Drug-eluting stents were used in 43.4% of patients, bare-metal stents in 52%, and balloon angioplasty alone in 4.6%. In multivariate analysis, in addition to already well-recognized predictors of death or myocardial infarction such as advanced age (hazard ratio [HR] 1.031, p <0.001), female gender (HR 1.23, p <0.001), urgent setting (HR 1.23, p <0.001) and diabetes mellitus (HR 1.28, p <0.001), we particularly noted previous anemia (HR 1.55 p <0.001), previous chronic kidney injury (HR 1.93, p <0.001) and previous moderate to severe left ventricular dysfunction (HR 2.29, p <0.001). Drug-eluting stent placement was associated with better outcomes (HR 0.70, p <0.001). In conclusion, this analysis confirms the effect of some known predictors of PCI outcomes. However, the extent of their effect is modest, while other predictors may have a greater influence on outcomes. Risk stratification of PCI patients should take into account kidney injury, anemia, and left ventricular function. Drug-eluting stents provide sustained benefit. **(Am J Cardiol 2015;115:855−859)**

The treatment of atherosclerotic coronary artery disease with percutaneous coronary intervention (PCI) is ongoing, evolving, and improving.[1,2] Simultaneously, higher risk, more complicated procedures are being executed, extending the boundaries of the targeted population. Because different patients may be at widely varying risks for complications, risk stratification tools are essential to help physicians and their patients make informed clinical decisions. Only by integrating modernized, established prognostic variables, given the quantified prognostic influence of each, can precise risk/benefit ratio estimation be done. Over the years, numerous risk stratification tools have been developed on the basis of some of the notorious risk factors for adverse outcomes of PCI: advanced age, diabetes mellitus, elevated cardiac enzymes, ST-segment deviation, high Killip class, ongoing chest pain, multivessel disease, and so on.[3−8] It is unclear whether these characteristics still dictate the prognosis in the contemporary PCI era using novel stents, techniques, and adjunctive pharmacotherapy. Over the past few years, we have managed a comprehensive database including all patients who undergo PCI at our 2 hospitals' medical centers. We sought to define the matter of prognostic outcomes and outcome predictors in this very large, updated, consecutive patient cohort.

Methods

The study population comprised all consecutive patients (n = 11,441) who underwent PCI at our institution at the 2 hospitals of the Rabin Medical Center in Israel from April 2004 to September 2013. Data collection was approved by the hospital ethics committee in compliance with the Declaration of Helsinki. As we have previously reported,[9−12] all data regarding the index and subsequent procedures, as well as clinical and echocardiographic data, were extracted from the patients' electronic medical records. Demographic data and death dates were obtained from the medical centers' demographic information system, which is linked to the State of Israel Ministry of Interior data system and the Clalit Health Organization data warehouse. The accuracy of the mortality data were verified with the Israel Central Bureau of Statistics. All data regarding previous and subsequent hospitalizations, including all International Classification of Diseases, Ninth Revision, diagnoses, were retrieved from the

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Table 1
Patient's demographic, clinical and angiographic features at index percutaneous coronary intervention

Cohort characteristics	Num.
Age (years) (SD)	68 (±12)
Women	2,861 (25%)
Diabetes Mellitus	4,877 (43%)
Hypertension	8,468 (74%)
Cigarette smoker*	4,002 (35%)
Prior congestive heart failure	863 (8%)
Prior coronary bypass	1676 (15%)
Dementia	167 (1%)
Malignancy	923 (8%)
Hemoglobin [gr/dL] (SD)	13.3 (±2.1)
Prior anemia†	5,834 (51)
Creatinine [mg/dL] (SD)	1.07 (±0.4)
Prior chronic kidney injury‡	2,174 (19%)
Moderate to severe left ventricular dysfunction§	1,437 (13%)
Congestive Heart failure	2,345 (20.5%)
Urgent percutaneous coronary intervention¶	6,993 (61%)
Primary percutaneous coronary intervention	892 (8%)
Number of coronary artery narrowed	
1	2,588 (23%)
2	3,522 (31%)
3	5,188 (46%)
Proximal main vessel‖	5,025 (44%)
Proximal left-anterior-descending artery disease	2,208 (19%)
Mean complexity (SD)	1.34 (±0.57)
Balloon angioplasty alone	526 (4.5%)
Bare Metal Stents	5,949 (52%)
Drug eluting stents	4,962 (43.5%)

* Current or past.
† Hemoglobin concentration [gr/dL] <13g/dL in males and <12g/dL in females.
‡ Chronic kidney injury: CrCl ≤60 mL/min.
§ Left ventricular dysfunction defined in echocardiography.
¶ Urgent: percutaneous coronary intervention for acute/recent MI or acute coronary syndrome.
‖ Proximal main vessel: left anterior descending, circumflex or right coronary artery (left main artery not included).

Table 2
Univariable analysis - association with Death or Myocardial infarction during follow-up

Variable	Hazard-ratio	95% CI	p Value
Age years	1.05	1.05-1.06	<0.001
Women	1.44	1.31-1.58	<0.001
Diabetes-mellitus	1.64	1.51-1.79	<0.001
Hypertension	2.04	1.82 -2.31	<0.001
Cigarette smoking*	1.45	1.32-1.59	<0.001
Moderate-severe left ventricular dysfunction	3.09	2.80-3.40	<0.001
Prior coronary artery bypass surgery	1.76	1.59 -1.95	<0.001
Proximal main vessel¶	1.27	1.17 -1.39	<0.001
Proximal left-anterior-descending	1.13	1.02 -1.26	.021
Coronary artery disease complexity	1.01	0.94-1.09	0.726
Urgent percutaneous coronary intervention†	1.16	1.06- 1.27	0.001
ST-elevation myocardial infarction	1.01	0.87-1.17	0.906
Chronic kidney injury‡	3.20	2.94-3.49	<0.001
Anemia§	2.20	2.01-2.41	<0.001
Drug eluting stent	0.63	0.57-0.69	<0.001

* Current or past. Proximal main vessel: left anterior descending, circumflex or right coronary artery (left main artery not included).
† Urgent: coronary intervention for acute or recent coronary syndrome.
‡ Chronic kidney injury: CrCl ≤60 mL/min.
§ Anemia: hemoglobin <13g/dL in males and <12g/dL in females.
¶ Main vessel: left anterior descending, circumflex or right coronary artery (left main artery not included).

medical centers' data warehouse. Laboratory data were retrieved from the medical centers' central laboratory database. Definitions regarding ST-elevation myocardial infarction (STEMI) were obtained from the Rabin Medical Center interventional cardiology database, which records detailed data regarding all patients with STEMIs. All follow-up data were collected up to September 30, 2013.

An initial list of candidate variables to influence outcome was chosen a priori, selected and based on relevance, as identified in previous research, or by the researchers' clinical experience. Baseline demographic, clinical and angiographic parameters were then examined by univariate logistic regression analysis for their relation to the study outcome of interest: death or myocardial infarction (MI) during follow-up.

On the basis of previous studies, the left ventricular ejection fraction, creatinine clearance (CrCl), and hemoglobin level were all dichotomized and treated as binary variables.[3,13,14] All patients with moderate or worse left ventricular dysfunction (LVD) defined in the echocardiographic record were flagged as "moderate to severe LVD." All PCIs for acute/recent MI or acute coronary syndromes, defined according to the indication as noted on the electronic record, were flagged as "urgent PCI." Primary PCI for STEMI was defined by the prerequisites for inclusion in the STEMI registry: within 12 hours of symptoms, without previous thrombolysis. All patients who arrived at the PCI laboratory after resuscitation or with cardiogenic shock were flagged as "critical state." Chronic kidney injury (CKI), based on the Kidney Disease Outcomes Quality Initiative criteria,[15] was defined as estimated CrCl ≤60 ml/min (calculated using the Modification of Diet in Renal Disease [MDRD] equation). Anemia, based on World Health Organization criteria, was defined as baseline hemoglobin concentration <13 g/dl in men and <12 g/dl in women.[16] To assess coronary artery disease complexity, the number of vessels with coronary disease was determined by analyzing the diagnostic catheterization report. Significant disease was considered when >50% stenosis was noted. Treated territories were defined by analyzing the angioplasty report. For each territory, PCI sites were counted (e.g., proximal and mid left anterior descending coronary artery, first or second diagonal branch) and a simple score of sites and territories, termed "complexity," was defined, which reflects the number of discrete lesions treated per territory. Whenever treatment involved ≥1 ostial or proximal main vessel (left anterior descending, circumflex, or right coronary artery) or the left main coronary artery, the procedure was flagged as "proximal main vessel." Total stent length was calculated and filed for each procedure. All patients with any drug-eluting stent (DES) implanted in the index PCI were included in the DES group regardless of use of any additional bare-metal stent.

Univariate analysis was used to identify which of the candidate variables had a statistical association with the composite end point of death or MI during follow-up and