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Association of a Unique Cardiovascular Risk Profile with Outcomes in Hispanic Patients Referred for Percutaneous Coronary Intervention (From the NHLBI Dynamic Registry)

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Abstract

Although prior studies have demonstrated that Hispanic patients have a higher cardiovascular risk profile than Caucasians and present at an earlier age for percutaneous coronary intervention (PCI), limited studies exist examining the outcomes of Hispanics post PCI and potential explanations for differences noted. Utilizing patients from the National Heart, Lung, and Blood Institute Dynamic Registry Waves 1–5 (1997 to 2006), demographic features, angiographic data, and one year outcomes of Hispanic (n= 542) versus Caucasian patients (n=1357) undergoing PCI were evaluated. Compared with Caucasians, Hispanic patients were younger, and had more hypertension and diabetes mellitus, including more insulin treated diabetes mellitus. While the mean lesion length was longer in Hispanics (15.4 mm versus 14.1 mm, $p<0.001$), there were no differences in the number of significant lesions, or in the use of drug-eluting stents. At follow-up, Hispanics were more likely to report recent anginal symptoms, but had a similar incidence of one year hospitalizations for angina. Adjusted one year hazard ratios for adverse events for Hispanics versus Caucasians revealed lower rates of coronary artery bypass graft (CABG) surgery (HR 0.43, 0.22 – 0.85, $p=0.02$), and a trend toward lower rates of repeat revascularization (HR 0.76, CI 0.57 – 1.03, $p=0.08$). In conclusion, despite the presence of diabetes in almost 50% of Hispanic patients and longer lesion lengths than Caucasians, Hispanic patients were less likely to undergo CABG one year post PCI, and had a trend toward lower rates of repeat revascularization.

Keywords

Percutaneous Coronary Intervention; Hispanics; Restenosis

Introduction

Prior studies have demonstrated that Hispanic patients have a higher cardiovascular risk profile than Caucasians [1–5], and thus present at an earlier age for percutaneous coronary intervention (PCI) [2,4–5]. However, there are only a limited number of studies examining both in-hospital and long term outcomes of Hispanic patients following PCI [2,4, and 6], and none of these studies have explored further explanations of the differences described. Because Hispanic individuals account for one-half of the United States growth and will comprise approximately one-fourth of the nation's population by 2010 [7], studying the utilization and outcomes of Hispanics and revascularization is vital, as optimizing the care for this growing patient population could have a significant impact on the public health of our nation. Using the National Heart, Lung, and Blood Institute sponsored Dynamic Registry, we sought to investigate not only the cardiovascular profile and outcomes of Hispanic patients referred for PCI as compared to Caucasian patients, but also possible explanations of discrepancies in outcomes between the races.

Methods

The specific methodologies and characteristics of the National Heart, Lung, and Blood Institute Dynamic Registry have been reported previously [8]. In brief, data were collected on approximately 2,000 consecutive patients undergoing PCI during five recruitment 'waves' across 27 clinical centers (Wave 1: July 1997-February 1998; Wave 2: February-June 1999; Wave 3: October 2001-March 2002; Wave 4: February-May 2004; Wave 5: February-August 2006).

The Dynamic Registry is also designed to enroll an enriched sample of women and minority patients. In each wave, consecutive patients undergoing PCI are enrolled at each center until 120 Caucasian men are enrolled at that site or a total of 1,600 Caucasian patients are enrolled across all sites. Enrollment of Caucasian men ends, while consecutive women and minorities continue to be enrolled until a total of 2,000 patients are enrolled across the sites. Individual sites do not have a center-specific limit for minority patient enrollment.

Patients were contacted via telephone interview at one year by trained nurse coordinators to assess vital status, symptoms, coronary events or cardiac-related hospitalizations. Informed consent was obtained for all patients and the study protocol was approved by Institutional Review Boards at the respective clinical sites and at the University of Pittsburgh data coordinating center. Ethnicity (Hispanic or not regardless of race) and race (White, Black, Asian, or Other) were designated by the research coordinator at the individual sites. The present analysis includes Hispanic patients regardless of race and Caucasian patients, and is restricted to clinical centers where > 5% of patients were reported to be of Hispanic ethnicity.

Death was defined as all cause mortality. *Myocardial infarction* (MI) for waves 1 and 2 was defined as evidence of two or more of the following: (1) typical chest pain > 20 minutes duration not relieved by nitroglycerin, (2) serial electrocardiogram recordings showing changes from baseline or serially in ST-T and/or Q-waves in ≥ 2 contiguous leads, (3) serum enzyme elevation of creatinine kinase-myocardial band (CK-MB) > 5% (total creatinine kinase (CK) > 2X normal, lactate dehydrogenase (LDH) subtype 1 > LDH subtype 2, or troponin > 0.2 $\mu\text{g/ml}$), or (4) new wall motion abnormalities. For waves 3–5, an MI had to satisfy at least one of

the 2 following criteria: (1) evolutionary ST-segment elevation, development of new Q-waves in 2 or more contiguous electrocardiogram leads, or new or presumably new left bundle branch pattern on the electrocardiogram, (2) biochemical evidence of myocardial necrosis manifested as a) CK-MB ≥ 3 times the upper limit of normal, b) total CK ≥ 3 times the upper limit of normal (if CK-MB not available), or troponin level above the upper limit of normal.

Coronary artery bypass grafting (CABG) surgery was classified as elective when deferred for >24 hours, urgent when required within 24 hours, and emergency procedure when required immediately. Angiographic success was classified as either partial when some but not all attempted lesions were successfully treated or total when all attempted lesions were successfully treated. Procedural success was defined as either partial or total angiographic success without death, Q-wave myocardial infarction, or emergency CABG. A composite outcome of major adverse cardiac event rates was defined as a composite of death, MI and repeat revascularization.

Statistical comparisons were made between Hispanic and Caucasian patients. The chi-square test or Fisher's exact test were used for categorical data and the Wilcoxon rank-sum for continuous data. One-year event rates were calculated using the Kaplan-Meier method. Comparisons of survival curves were performed using the log-rank test. Patients who did not experience the outcome of interest were censored at the last known date of contact or at one year if contact extended beyond one year.

The association between 1-year adverse events for Hispanic patients as compared to Caucasian patients was performed with Cox proportional hazards methods. Covariate adjustment was performed such that demographic, clinical and angiographic variables were initially screened for univariate associations with outcomes of interest at $p \leq 0.30$. Identified variables were then assessed in a forward stepwise manner using a p value criterion of ≤ 0.05 . In instances when the variable indicating a patient's race/ethnicity did not 'step into a model', they were included in the model after entry of all other significant variables. Assumptions of proportionality was assessed and met for all models.

Consent to collect 1-year follow-up data were not obtained for 133 (7%) of the surviving 1879 patients. While follow-up contact was high, the rate was higher in surviving Caucasian than surviving Hispanic patients (96.9% versus 92.9%, $p < 0.001$).

Results

Five hundred and forty two Hispanic patients and 1357 Caucasian patients in the Dynamic Registry were analyzed. Compared with Caucasian patients, Hispanic patients were younger, more commonly female, and had more hypertension and diabetes mellitus, including insulin treated diabetes mellitus (Table 1).

Hispanic patients were more likely to be undergoing PCI secondary to an acute myocardial infarction; however, they had similar referrals for stable and unstable angina (Table 2). The angiographic results were reported as technically amenable to complete revascularization with CABG in 78.4% of Hispanic versus 81.2% of Caucasian patients ($p = 0.17$), while Hispanic patients had a higher likelihood of being technically amenable to complete revascularization with PCI than Caucasians (87.6% versus 83.9%, $p = 0.05$).

The characteristics of the attempted lesions in Hispanic patients compared to Caucasian patients demonstrated a longer mean lesion length, higher moderate/severe tortuosity, and a higher rate of American Heart Association/American College of Cardiology Class C lesions. Angiographic success was similar between Hispanic and Caucasian patients (96.2% versus 98.0%, $p = 0.48$).

Peri-procedural outcomes were similar or better in Hispanic patients compared to Caucasian patients. Major dissection was seen in 3.2% versus 4.9% ($p=0.05$) of attempted lesions in Hispanic versus Caucasian patients, embolization in 0.5% versus 0.8% ($p=0.47$), side branch occlusion in 2.4% versus 1.4% ($p=0.06$), but persistent flow reduction in 0.1% versus 1.3% ($p=0.005$).

There were no differences in in-hospital outcomes between Hispanic and Caucasian patients, including death (0.9% versus 1.1%, $p=0.72$), MI (1.5% versus 2.0%, $p=0.28$), stroke (0.2% versus 0.4%, $p=0.40$), bleeding (1.4% versus 2.2%, $p=0.28$), or CABG (0.4% versus 0.2%, $p=0.57$). Procedural success rates were also similar at 97.0% versus 96.0% ($p=0.29$). Hispanic patients had a longer mean length of stay and at discharge were less likely to be prescribed a thienopyridine and calcium channel blockers, but were more likely to be prescribed long acting nitrates as compared to Caucasians (Table 3).

Despite a similar incidence in 1-year hospitalizations for angina (15.0% versus 12.1%, $p=0.12$), Hispanic patients were significantly more likely than Caucasians to report anginal symptoms within the past six weeks (29.0% versus 16.3%, $p<0.001$). Furthermore, the frequency of revascularization procedures during follow-up in the subset of patients re-hospitalized for angina or angina and/or MI differed by ethnicity (Figure 1). In both clinical scenarios, there was significantly less use of CABG and revascularization procedures in Hispanic compared to Caucasian patients. The frequency of PCI was numerically lower in Hispanic patients but did not reach statistical significance. Alternatively, the percent of patients undergoing revascularization via CABG or PCI during follow-up among patients not experiencing angina was identical for Hispanic and Caucasian patients.

Adjusted analyses of one year outcomes revealed that Hispanic patients had similar rates of death and MI as Caucasian patients, but were less likely to undergo CABG (HR 0.43, 95% CI 0.22 – 0.85, $p=0.02$), and had a trend toward lower rates of revascularization (HR 0.76, 95% CI 0.57 – 1.03, $p=0.08$) (Figure 2).

Discussion

Utilizing the National Heart, Lung, and Blood Institute Dynamic Registry, we examined the risk profile and outcomes of Hispanic patients referred for PCI. We confirmed that Hispanic patients referred for PCI not only have a higher risk cardiovascular profile as compared to Caucasians including higher rates of hypertension, diabetes mellitus, and insulin treated diabetes mellitus, but also presented at a younger age than Caucasian patients. We found no differences in in-hospital outcomes for Hispanic patients post PCI, as reported by others [2,4,6]. We did, however, at one year find lower rates of CABG in Hispanic patients as compared to Caucasians.

Given the findings of this study, we must consider the causality and clinical implications of these data. Diabetes mellitus and longer lesion lengths are well-described predictors of in-stent restenosis in patients undergoing PCI [9–12], resulting in higher rates of repeat revascularization. Surprisingly, although Hispanic patients had more diabetes mellitus and longer lesions lengths than Caucasians in our study, they had no difference in repeat PCI at one year, lower rates of CABG, and a trend toward lower rates of repeat revascularization. There are several possible explanations for this disparity.

First, there may be a referral bias for Hispanic patients needing revascularization procedures. Prior studies have revealed that Hispanic patients are less likely to undergo angiography, PCI (both angioplasty and stents), and bypass surgery [4,13–15], however the data is not consistent. Other studies have shown no differences in rates of CABG between Hispanic and Caucasian patients [16]. We investigated this specifically in our study and our 1-year data demonstrate

lower rates of CABG and revascularization in Hispanic versus Caucasian patients that were re-admitted for angina or angina and/or MI. Given that this population of patients had previously agreed to PCI during the index procedure, it is more likely in our study that this represents a referral bias.

Second, there may be more difficulty with access to health care for Hispanic patients as compared to Caucasians. Language barriers appear to be an important contribution. DuBard et al recently examined access to health care between Spanish-speaking and English-speaking Hispanics [17]. Whereas both groups had similar employment rates, Spanish-speaking Hispanics were more likely to lack health insurance and less likely to have a primary care physician. Although our study did not discriminate between primary language spoken for our Hispanic patients, Hispanic patients were more likely to have public aid and less likely to have private methods of payment as compared to Caucasian patients. These differences in payment method may lead to hesitancy in undergoing costly procedures such as PCI or CABG. While it is not possible to measure rates of declined procedures in our data, differences in clinical follow-up were potentially a mediating factor in our study with follow up rates for Hispanics and Caucasians of 92.9% and 96.9%, respectively, $p < 0.001$.

An alternate explanation for the lower rates of CABG in Hispanic patients may be related to the possibility of an ethnicity related component to inflammation and restenosis. Bild et al reported that despite similar cardiovascular risk factors, diabetic Hispanic patients had less coronary artery calcification and abdominal aortic calcification as compared to Caucasian diabetic patients [18], and they questioned whether environmental or genetic differences exist in Hispanic patients that may protect them from atherosclerosis and calcification. In our study, despite longer lesion lengths and more insulin treated diabetes mellitus, Hispanic patients had equivalent rates of repeat PCI and were less likely to undergo CABG compared to Caucasian patients. Whether or not Hispanic patients possess any intrinsic or lifestyle factors that could be protective toward restenosis remain to be determined.

Limitations to our study include our reduced sample size given the restriction of analysis to centers with more than 5% of patients reported to be Hispanic. Also, the rates of medication adherence following hospital discharge were not followed to allow association with outcomes. Additionally, the Dynamic Registry does not collect data regarding the above-mentioned barriers that individual patients may have to access medical care.

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Figure 1. Frequency of Revascularization Procedures in Patients Re-Hospitalized for Angina or Angina and/or MI*

MI=Myocardial Infarction, CABG=Coronary Artery Bypass Grafting, PCI=Percutaneous Coronary Intervention, Revasc=Revascularization

*Angina hospitalizations: n=146 Caucasians, n=65 Hispanics

Angina or MI hospitalizations: n=166 Caucasians, n=75 Hispanics

Figure 2. Adjusted One Year Hazard Ratios and Confidence Intervals for Hispanic versus Caucasian Patients

CABG=Coronary Artery Bypass Grafting, MI=Myocardial Infarction, PCI=Percutaneous Coronary Intervention, MACE=Major Adverse Cardiac Events (Death/MI/Repeat Revascularization)

Table 1**Patient Demographics for Hispanic versus Caucasian Patients**

Variable	Hispanic (N=542)	Caucasian (N=1357)	P Value
Mean age (years)	61.9	64.9	< 0.0001
Female	36.0%	31.4%	0.05
Mean Body Mass Index (kg/m ²)	29.0	29.1	0.66
Prior percutaneous coronary intervention	27.9%	34.4%	0.006
Prior coronary artery bypass graft	12.9%	16.4%	0.055
Prior myocardial infarction	25.8%	30.9%	0.03
Diabetes mellitus	49.2%	27.8%	<0.001
Insulin treated diabetes mellitus	15.0%	7.4%	<0.001
Hypertension*	80.4%	72.3%	0.001
Heart failure	9.6%	10.9%	0.41
Hypercholesterolemia**	70.6%	73.8%	0.17
Severe non-cardiac concomitant disease	24.6%	34.0%	<0.001
Cerebrovascular disease	4.1%	6.5%	0.04
Pulmonary disease	6.3%	9.4%	0.03
Renal disease	4.9%	5.3%	0.71
Peripheral vascular disease	5.6%	10.3%	0.001
Smoking	57.1%	69.1%	<0.001

* Hypertension = blood pressure $\geq$ 140 systolic or $\geq$ 90 diastolic on two occasions or if the patient is currently on antihypertensive medications

** Hypercholesterolemia = repeated values for serum cholesterol greater than 240mg/100ml or if a physician has medically treated the participant for high cholesterol

Table 2**Angiographic and Procedural Characteristics for Hispanic versus Caucasian Patients**

	Hispanic (N=542)	Caucasian (N=1357)	P Value
Patient Level			
Revascularization Reason			
Stable Angina Pectoris	20.0%	20.1%	0.93
Unstable Angina Pectoris	46.6%	44.8%	0.47
Acute Myocardial Infarction	24.2%	18.0%	0.002
Cardiogenic shock	1.8%	0.6%	0.01
Thrombolytic therapy	5.4%	3.2%	0.03
Circumstances of Procedure			<0.001
Elective	57.4%	47.6%	
Urgent	31.0%	43.7%	
Emergent	11.6%	8.7%	
Mean left ventricular ejection fraction	53.2%	52.9%	0.89
Mean Significant lesions	3.0%	2.9%	0.43
Coronary Luminal Irregularities			
None	44.4%	55.3%	<0.001
Two Arteries	11.6%	10.1%	0.33
Three Arteries	15.3%	7.6%	<0.001
Medications used <24hrs, prior to, or during procedure			
Aspirin	90.0%	93.3%	0.02
Clopidogrel and/or Ticlopidine	65.9%	57.4%	< 0.001
IIb/IIIa Receptor Antagonists	27.9%	35.7%	0.001
Mean number of lesions attempted	1.4%	1.4%	0.87
	Hispanic (N=542)	Caucasian (N=1357)	P Value
Lesion Level			
Mean reference vessel size (mm)	2.9	2.9	0.25
Mean lesion length (mm)	15.5	14.1	<0.001
Total occlusion	12.3%	10.6%	0.21
Mean diameter % stenosis	84.6	84.5	0.87
Evidence of thrombus	12.7%	14.1%	0.35
Calcified	21.4%	23.0%	0.39
Bifurcation	11.4%	9.1%	0.08
Ostial lesion	11.3%	8.3%	0.02
Lesion tortuosity			< 0.001
None/Mild	73.7%	79.8%	
Moderate/Severe	26.3%	20.2%	
American College of Cardiology/American Heart Association Class			0.055
A	11.8%	13.4%	
B1	35.4%	37.0%	
B2	34.9%	35.8%	
C	17.9%	13.8%	
Stent use overall	75.1%	77.9%	0.12
Drug eluting stent use *	29.1%	29.8%	0.72

* Limited to patients in waves 4 and 5

Table 3

Discharge Data for Hispanic versus Caucasian Patients

Variable	Hispanic (N=542)	Caucasian (N=1357)	P Value
Number of catheterization lab visits during hospitalization			0.02
1	95.6%	97.6%	
≥2	4.4%	2.4%	
Mean length of stay (days)	2.5	2.2	0.01
Discharge Medications			
Aspirin	95.3%	95.5%	0.86
Clopidogrel and/or Ticlopidine	79.9%	84.6%	0.01
Beta blocker	75.7%	76.0%	0.92
Ace-Inhibitor	46.8%	36.7%	<0.001
Statin	58.4%	61.3%	0.24
Nitrate	23.9%	18.4%	0.008
Calcium channel blocker	20.3%	31.1%	<0.001
Method of payment			<0.001
Medicare	36.7%	37.3%	
Public	33.5%	11.3%	
Private	22.7%	46.9%	
Self	7.2%	4.4%	