CLINICAL STUDY

Predictors of Adverse Events After Percutaneous Transluminal Coronary Angioplasty in a Group of Hispanic Patients

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Objective. To identify predictors of adverse events after PTCA during hospitalization and after hospital discharge in a private hospital in Puerto Rico.

Background. A review of the literature shows limited information about predictors of adverse events associated to percutaneous transluminal coronary angioplasty (PTCA) in Hispanic patients.

Methods. This is a non-concurrent prospective study. Baseline variables were analyzed using multivariate logistic regression to identify predictors of adverse events. Data were collected from medical charts and telephone reports from referring physicians.

Results. Data from 197 subjects undergoing PTCA were analyzed for this study. Median age of patients was 65 years, and 62.9% of patients were male. Angiographic success rate was 81.6%. A total of 8.1% of patients had at least one in-hospital adverse event, and 39.8% had at least one adverse event after hospital discharge. After multivariate analysis, a statistically significant

association was found between the presence of at least one lesion with residual stenosis of 50% or greater and the risk of developing adverse events in-hospital (RO 11.75; 95% CI 4.32-31.97). A marginally significant association was found between family history of heart disease (RO 2.75; 95% CI 0.93-8.11) and the risk of adverse events during hospitalization. Family history of heart disease (RO 1.41; 95% CI 0.98-2.04) and the presence of at least one lesion with residual stenosis of 50% or greater (RO 2.87; 95% CI 0.82-10.01) showed marginally significant associations with increased risk for adverse events after discharge.

Conclusions. These findings suggest that the presence of at least one lesion with residual stenosis of 50% or greater and family history of heart disease may be risk factors for adverse events after PTCA during hospitalization and after discharge.

Key words: Angioplasty, Outcomes, Hispanics, PTCA.

oronary angioplasty was first described by Andreas Gruentzig in 1977 as an alternative form of revascularization in humans (1). Since then, there has been a significant acceptance in the use of percutaneous transluminal coronary angioplasty (PTCA). Approximately 369,000 procedures were performed in the United States in 1993 (2).

Despite the fact that balloon angioplasty has proved itself to be a successful means of achieving myocardial

revascularization, this procedure is not free of complications such as emergency coronary bypass surgery, myocardial infarction, or death (3-18). Moreover, coronary restenosis occurs in 20%-40% of patients after initial dilation, most commonly during the first six months after the procedure (5-11).

Several factors have been associated with an increased risk for complications during PTCA. These include advanced age, female gender, multilesion and multivessel disease, diabetes mellitus, reduced ejection fraction, congestive heart failure, unstable angina, hemodynamic instability, increasing lesion complexity, inadequate antiplatelet therapy and PTCA after thrombolytic therapy (4, 11, 12, 14, 16, 17). Other factors have been associated to restenosis after successful PTCA, including male gender, diabetes mellitus, absence of previous myocardial infarction, unstable angina, chronic total occlusion and post-angioplasty residual stenosis over 30%, among others (5-11, 13, 16).

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There is limited data on PTCA procedures performed in Hispanic populations (19-24). Most studies have been done in Mexico with small numbers of patients, showing outcomes similar to those in U.S. populations. However, a recent review of the literature shows no studies attempting to identify risk factors for adverse events among Hispanics. It is not clear whether ethnic or racial differences could affect previously identified risk factors for adverse events after PTCA. In one study using the National Heart, Lung, and Blood Institute (NHLBI) PTCA Registry, white and black patients were compared in terms of baseline characteristics and PTCA outcomes (25). This multicenter study found that black patients had a similar incidence of acute and long-term adverse events when compared to white patients despite a greater proportion of women and a higher prevalence of unstable angina, diabetes mellitus and multivessel disease. However, the study was limited by a small sample of black patients, most of which came from a single study site.

The purpose of this study was to identify predictors of adverse events after PTCA during hospitalization and after hospital discharge in a group of Hispanic patients who underwent the procedure in a private hospital in Puerto Rico.

Methods

This is a non-concurrent prospective study. Subjects were defined as all Hispanic patients with no previous coronary artery bypass graft who underwent their first PTCA between October 1991 and July 1996 in a cardiology practice at a private hospital in Puerto Rico. PTCA's were performed by balloon dilation without placement of coronary stents. Patients who underwent a PTCA in the acute stage of myocardial infarction and those with missing baseline or follow-up information were excluded from the study.

Baseline data collected from the medical record included age, gender, height and weight; family history of heart disease; history of arterial hypertension, hypercholesterolemia, diabetes mellitus, congestive heart failure, decreased left ventricular ejection fraction (LVEF), chronic renal insufficiency, and cigarette smoking, admission diagnosis for PTCA of stable angina, unstable angina or myocardial infarction, and number of coronary lesions. Patients were followed up to the time of their last cardiology clinic visit.

A coronary lesion was defined as an initial stenosis of 70% or more previous to the PTCA. Angiographic success was defined as a residual stenosis less than 50%, and restenosis was defined as a recurrent stenosis greater than or equal to 50% occuring after an initial successful dilation.

Adverse in-hospital events after PTCA were defined as

need for coronary artery bypass graft (CABG), acute myocardial infarction (MI), recurrent angina or cardiac-related death occurring after PTCA during hospitalization for the procedure. Adverse events after hospital discharge were defined as stable angina, unstable angina, positive angiography for restenosis, repeat PTCA, CABG, acute MI, or cardiac-related death occurring after discharge from the hospital following the PTCA.

All data were collected from the medical charts as it was documented by the cardiology group and from telephone interviews with referring physicians. Frequency distributions, medians and proportions were used to describe baseline characteristics.

Median time of follow-up was determined. Cumulative incidence and unadjusted relative odds using bivariate analysis for adverse events during hospitalization and after hospital discharge were calculated. No evidence of effect modification (interaction) was identified after stratified analysis. Logistic regression was used to determine adjusted relative odds and 95% confidence intervals for the occurrence of at least one adverse event in hospital and after hospital discharge (26). In order to facilitate data analysis, only data from patients without in-hospital adverse events were used to calculate relative odds for adverse events after hospital discharge.

Results

Originally, 218 patients were included in the study. Six patients were excluded due to prior CABG, six were excluded due to PTCA in the acute stage of myocardial infarction and nine were excluded due to incomplete follow-up information. The following results are based on the information obtained from the remaining 197 patients (90%). Baseline characteristics are listed in Table 1. The median age of our study population was 65 years (range 42 to 89), and the majority of patients were male (62.9%). The median body-mass index (BMI) was 26.5 kg/m². There was a high prevalence of stable angina (86.3%), family history of heart disease (64.3%), history of arterial hypertension (62.4%), hypercholeste-rolemia (59.7%), cigarette smoking (43.7%), and diabetes mellitus (43.1%). There were only eight patients (4%) with history of congestive heart failure, four patients (2%) with LVEF < 40% and three patients (1.5%) with history of chronic renal insufficiency (data not shown). Most patients had an admission diagnosis of stable angina (70.6%) and one coronary lesion present (72.1%). Angiographic success rate was 81.6% (191 lesions dilated out of 234 attempted).

Table 2 shows the incidence of different types of adverse in-hospital events after PTCA. Coronary artery bypass surgery was the most common event with an incidence of

Table 1. Baseline Characteristics of Patients who Underwent PTCA at San Pablo Hospital between October 1991 and July 1996 (n=197)

Characteristic	n	%
n	197	
Median age (range)	(42-89)	65 yrs
Median body-mass index (range)	(16-42)	26.5 Kg/m ²
Male sex	124	62.9
Family history of heart disease	126	64.3
History of high blood pressure	123	62.4
History of hypercholesterolemia	117	59.7
History of cigarette smoking	86	43.7
History of diabetes mellitus	85	43.1
Admission diagnosis		
Stable angina	139	70.6
Unstable angina	45	22.8
Myocardial infarction	13	6.6
Number of coronary lesions		
One	142	72.1
Two	47	23.9
Three	8	4.1

PTCA=Percutaneous transluminal coronary angioplasty.

5.1%. The overall incidence of adverse in-hospital events was 8.1%. A total of 176 patients (89%) who had at least one successfully dilated lesion and no adverse in-hospital event were followed for the occurrence of adverse events after hospital discharge (Table 3). The median time for follow-up was 398 days. The overall incidence of at least one adverse event after hospital discharge was 39.8%. The two most common adverse events were development of stable angina and positive angiography for restenosis, with incidences of 25.6% and 22.2%, respectively.

Table 4 shows unadjusted relative odds for adverse inhospital events after PTCA. The presence of at least one lesion with residual stenosis of 50% or greater

Table 2. Incidence of Adverse In-Hospital Events After PTCA (n=197)

110/1 (11-177)		
Adverse event	n	%
CABG	10	5.1
Acute MI	5	2.5
Recurrent angina	4	2.0
Cardiac-related death	2	1.0
At least one of the above	16	8.1

MI: Myocardial infarction

PTCA: Percutaneous transluminal coronary angioplasty; CABG: Coronay artery bypass graft.

(RO 87.89; 95% CI 16.76-903.01) showed a statistically significant association with adverse in-hospital events after PTCA. History of diabetes mellitus (RO 2.5; 95% CI 0.72-10.00), unstable angina on admission (RO 2.5; 95% CI 0.67-8.81) and family history of heart disease (RO 2.14; CI 0.54-12.50) showed a moderate, though not statistically significant, association with an increased risk for the occurrence of adverse in-hospital events.

Table 3. Incidence of Adverse Events After Hospital Discharge Among Patients Without In-Hospital Complications (n=176)

Adverse event	n	%
Stable angina	45	25.6
Positive angiography	39	22.2
Unstable angina	20	11.4
Repeat PTCA	19	10.8
CABG	18	10.2
Acute MI	4	2.3
Cardiac-related death	1	0.6
At least one of the above	70	39.8

Median time for follow-up was 398 days. Abbreviations as in table 2.

Table 5 shows unadjusted relative odds for adverse events after hospital discharge among patients without in-hospital complications. Results suggest that the presence of at least one lesion with residual stenosis of 50% or greater (RO 4.78; 95% CI 0.37-255.27) might be an

Table 4. Unadjusted Relative Odds (RO) for Adverse Inhospital Events After PTCA (n = 197)

Characteristic	RO	95% CI
At least one lesion with residual stenosis of 50% or greater	87.89	16.76-903.01
History of diabetes mellitus	2.50	0.72-10.00
Unstable angina on admission	2.50	0.67-8.81
History of arterial hypertension	0.79	0.23-2.86
History of hypercholesterolemia	1.23	0.35-4.76
Family history of heart disease	2.14	0.54-12.50
Past or present history of smoking	1.79	0.52-6.53
Single vs. multilesion disease	1.47	0.37-5.19
Body mass index $\leq 25 \text{ Kg/m}^2$	1.38	0.39-4.80
Male gender	1.06	0.31-4.21
Age 60 years or older	1.60	0.44-7.24

PTCA= Percutaneous transluminal coronary angioplasty; RO=Relative odds; Cl=Confidence interval.

important factor in the development of adverse events after hospital discharge, though this association was not statistically significant.

Table 5. Unadjusted Relative Odds for Adverse Events After Hospital Discharge Among Patients Without In-Hospital Complications and at Least One Lesion Successfully Dilated.

Characteristic	RO	95 % CI
At least one lesion with residual stenosis of 50% or greater	4.78	0.37-255.27
History of diabetes mellitus	1.04	0.53-2.00
Unstable angina on admission	1.57	0.50-1.87
History of arterial hypertension	1.49	0.76-2.94
History of hypercholesterolemia	1.54	0.79-3.03
Family history of heart disease	1.92	0.96-4.00
Past or present history of smoking	1.17	0.60-2.25
Single vs. multilesion disease	1.66	0.81-3.40
Body mass index ≤ 25 Kg/ m ²	1.21	0.63-2.34
Male gender	0.81	0.41-1.58
Age 60 years or older	0.73	0.37-1.42

PTCA=Percutaneous transluminal coronary angioplasty; RO=Relative odds; Cl=Confidence interval

Table 6 shows adjusted relative odds for adverse inhospital events after PTCA. After logistic regression analysis, the presence of at least one lesion with residual stenosis of 50 % or greater (RO 11.75; 95% CI 4.32-31.97) showed a strong and statistically significant

Table 6. Adjusted Relative Odds for Adverse In-Hospital Events After PTCA

Characteristic	RO	95%CI
At least one lesion with residual stenosis of 50% or greater	11.75	4.32-31.97
History of diabetes mellitus	1.64	0.69-3.91
Unstable angina on admission	1.75	0.68-4.53
History of arterial hypertension	0.83	0.35-1.97
History of hypercholesterolemia	0.80	0.34-1.88
Family history of heart disease	2.75	0.93-8.11
Past or present history of smoking	1.13	0.48-2.67
Single vs. multilesion disease	1.08	0.45-2.59
Body mass index $\leq 25 \text{ Kg/m}^2$	0.72	0.28-1.83
Male gender	0.83	0.31-2.21
Age 60 years or older	1.77	0.61-5.10

PTCA=Percutaneous transluminal coronary; RO=Relative odds; CI=Confidence interval.

association with adverse in-hospital events. Family history of heart disease (RO 2.75; 95% CI 0.93-8.11) showed a moderate but marginally significant association.

Table 7 shows adjusted relative odds for adverse events after hospital discharge among patients without in-

Table 7. Adjusted Relative Odds for Adverse Events After Hospital Discharge, Among Patients Without In-Hospital Complications.

Charasteristic	RO	95% CI
At least one lesion with residual stenosis of 50% or greater	2.87	0.82-10.01
History of diabetes mellitus	0.92	0.65-1.30
Unstable angina on admission	1.32	0.89-1.97
History of arterial hypertension	1.12	0.78-1.61
History of hypercholesterolemia	1.20	0.83-1.73
Family history of premature coronary heart disease	1.41	0.98-2.04
Past or present history of smoking	1.03	0.71-1.50
Single vs. multilesion disease	1.15	0.79-1.68
Body mass index ≤ 25 Kg/m ²	0.83	0.58-1.17
Male gender	1.00	0.69-1.44
Age 60 years or older	0.85	0.59-1.22

PTCA= Percutaneous transluminal coronary angioplasty; RO=Relative odds; CI= confidence interval.

hospital complications. Multivariate adjustment shows a moderate association between the presence of at least one lesion with residual stenosis of 50% or greater (RO 2.87; 95% CI 0.82-10.01) and events after hospital discharge. Family history of heart disease (RO 1.41; 95% CI 0.98-2.04) shows a weak association with events after discharge. Both associations were marginally significant.

Discussion

In our study population, the prevalence of diabetes mellitus and single lesion disease was higher than in other studies (9-10, 13-16). This may reflect the higher prevalence of diabetes mellitus in Hispanic populations, selection criteria for the performance of PTCA at the hospital, and inclusion criteria for this study.

Angiographic success was 81.6%. Success between 85% and 93% have been reported in the literature (12-14,16,18-24). The incidence for adverse in-hospital events (8.1%) was in the range between 6% and 18% reported in other studies (11, 14, 16, 19, 23, 29). Similarly, the incidence of adverse events after hospital discharge (39.8%) was in the range between 30% and 47% reported in other studies

(5-7, 11, 14, 16, 19, 24). The incidence of adverse events for Hispanic patients seems to be similar to those found in non-Hispanic populations.

This study found that having at least one lesion with residual stenosis of 50% or greater (RO 11.75; 95% CI 4.32-31.97) had a strong and statistically significant association with adverse in-hospital events after PTCA. A small sample size may account for the wide confidence interval of the relative odds. The instability of the atherosclerotic plaque with subsequent predisposition for platelet aggregation can explain the increased risk associated with the presence of lesions with residual stenosis of 50% or greater (6,7).

The presence of at least one lesion with a residual stenosis of 50% or greater (RO 2.87; 95% CI 0.82-10.01) showed a moderate but marginally statistically significant association with increased risk for adverse events after hospital discharge. A high-grade post-angioplasty stenosis has been previously associated with poor long-term outcomes (7).

Family history of heart disease (RO 2.75; 95% CI 0.93-8.11) showed a moderate but marginally significant association with in-hospital adverse events. However, this factor showed only a weak, but marginally significant association with adverse events after hospital discharge (RO 1.41; 95% CI 0.98-2.04). Although a known risk factor for cardiovascular disease, we did not find any previous study associating positive family history of heart disease with adverse PTCA events during hospitalization or after hospital discharge. Two studies have reported an increased risk of operative complications and late mortality after coronary bypass surgery in patients with a family history of coronary artery disease (27, 28). However, a study of patients who underwent CABG at the Cardiovascular Center of Puerto Rico and the Caribbean did not find an association between family history of premature coronary artery disease and the occurrence of early postoperative complications (31).

Factors such as old age, male sex, multiple lesions, no prior myocardial infarction, smoking, decreased ejection fraction, history of congestive heart failure and others that have been identified to increase risk for poor inhospital and long-term outcomes after PTCA (5-17) were not associated with an increased risk in our study. A review of the current literature shows a lack of consistency in risk factors identified in different studies. This is due in part to the fact that different studies use different definitions for their baseline variables and outcomes. Also, the type endpoints varies among studies. Some measure only clinical outcomes while other follow angiographic evidence of restenosis. The use of standard definitions for baseline variables and end-points in future studies will help clarify

these inconsistencies. Standard definitions proposed by the American College of Cardiology are an important step in this direction (11).

This study has important limitations. In the first place, this is a non-concurrent prospective study based on data collected from medical records. We followed clinical adverse events, but we made no attempt to determine if the events were caused by the lesion that underwent the PTCA. No additional sources of information, such as the National Death Index, death certificates or health insurance records, were used to track patients more thoroughly. Secondly, sample size is not large, and may not be optimal to achieve statistical significance, especially for multivariate analysis. Also, our sample represents a selected population due to the absence of prior PTCA, CABG, or performance of the procedure in the acute stage of myocardial infarction, and by the low prevalence of CHF. The incidence of adverse events after hospital discharge was 39.8%. This high incidence makes the relative odds a less accurate estimate of the relative risk. Finally, and in spite of its limitations, this study represents an initial attempt to identify predictors of adverse PTCA events among Hispanic patients.

Resumen

El propósito de este estudio prospectivo no concurrente fue identificar predictores de eventos adversos durante hospitalización y posterior al alta en pacientes sometidos a angioplastía percutánea transluminal coronaria (APTC) en un hospital de Puerto Rico. Las variables independientes fueron analizadas mediante regresión logística para identificar los predictores de eventos adversos. Los datos fueron recopilados de expedientes médicos y reportes por vía telefónica de los médicos que refirieron a los pacientes para el procedimiento. La mediana de la edad de los pacientes fue 65 años, y 62.9% pertenecían all sexo masculino. El 8.1% de los pacientes experimentó por lo menos un evento adverso durante la admisión para el procedimiento, y 39.8% tuvo por lo menos un evento adverso luego del alta. Luego del análisis de regresión logística, se encontró una asociación estadística entre la presencia de por lo menos una lesión con estenosis residual de 50% o más y el riesgo de desarrollar eventos adversos durante la admisión (RO 11.75; 95% CI 4.32-31.97). Se encontró una asociación marginalmente significativa entre el historial familiar de enfermedad cardíaca y el riesgo de eventos adversos durante la hospitalización (RO 2.75; 95% CI 0.93-8.11). El historial familiar de enfermedad cardíaca (RO 1.41; 95% CI 0.98-2.04) y la presencia de por lo menos una lesión con estenosis residual de 50% o mayor (RO 2.87; 95% CI 0.8210.01) mostraron asociaciones marginalmente significativas con el riesgo de eventos adversos luego del alta. Estos hallazgos sugieren que la presencia de lesiones con estenosis residual sobre 50% y un historial familiar de enfermedad cardíaca pueden ser factores de riesgo para eventos adversos luego de APTC durante la hospitalización y luego del alta.

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