Published in final edited form as:

J Cardiovasc Nurs. 2017 ; 32(6): 522–529. doi:10.1097/JCN.0000000000000387.

Can We Identify Minority Patients at Risk of Non-Adherence to Antiplatelet Medication at the time of Coronary Stent Placement?

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Abstract

Background—Lack of medication adherence is associated with significant morbidity and mortality, particularly among minorities. We aimed to identify predictors of non-adherence to antiplatelet medications at the time of percutaneous coronary intervention (PCI) with stent among African American and Hispanic subjects.

Methods—We used data collected for a randomized clinical trial that recruited 452 minority subjects from a large U.S. health insurance organization in 2010 post-PCI to compare phone-based motivational interviewing by trained nurses (MINT) to an educational video. The primary outcome was 12-month adherence to antiplatelet medications measured by the claims-based medication possession ratio (MPR). Adequate adherence was defined as $MPR \geq 0.80$.

Results—Over half of sample (age 69.52 ± 8.8 years) was male (57%) and Hispanic (57%). Majority (78%) had a median income below \$30,000 and 22% completed high school or higher. Univariate analyses revealed that symptoms of depression (<0.01) and not having a spouse ($p=0.03$) were associated with inadequate adherence. In multivariate analysis, baseline self-reported adherence (1.4; 95% confidence interval [CI] 1.05–1.89), depressive symptoms (0.49; 95% CI 0.7–0.90), comorbidity (0.89; 95% CI 0.80–0.98) and MINT (3.5; 95% CI 1.9–2.70) were associated with adherence.

Conclusions—Having multiple comorbidities, depression, suboptimal adherence to medications, and low English proficiency at the time of PCI increase the risk of poor 12-month adherence to antiplatelets among minorities. Identifying these risk factors can guide PCI therapy and the use of evidence-based strategies to improve long-term adherence.

Keywords

Medication Adherence; Minorities; Percutaneous Coronary Intervention; Motivational Interviewing

INTRODUCTION

Large scale clinical trials have shown that the appropriate use of thienopyridines after percutaneous coronary intervention (PCI) with stent placement reduces the rates of death and myocardial infarction by about 57%¹ and the risk of in stent thrombosis by 88%². Thus, current practice guidelines recommend that all patients undergoing PCI, over one million per year³, should be treated with thienopyridines for three to twelve months depending on the type of stent placed⁴ to prevent complications. Unfortunately, the translation of this finding to everyday practice has been limited and only 50 to 75% of PCI patients are adherent to thienopyridines post stent placement⁵⁻⁷. Inadequate adherence to medications is a pervasive healthcare problem that increases the risk of preventable hospitalizations⁸, morbidity and mortality⁹.

Minorities have even lower adherence to chronic medications^{10, 11}, a finding that might explain the increased risk of adverse outcomes observed among African American and Hispanic subjects after stent placement¹² as well as the decreased probability of receiving drug eluting stents¹³. Current guidelines recommend avoiding drug-eluting stents, a device with proven clinical superiority¹⁴ to bare metal stents, in the presence of financial or social barriers that might limit patient adherence¹⁵.

In this context, it is imperative to identify those at risk of antiplatelet medication non-adherence at the time of stent placement. Even though modifying health behaviors such as adherence remains challenging¹⁶, in recent years a few interventions have been successful in experimental design^{7, 17}. Some of the successful interventions are those using patient-centered, directive approaches such as motivational interviewing⁷. Motivational interviewing has been shown to be effective in improving medication adherence among African Americans¹⁸. Learning how to identify and target patients at risk of non-adherence at the time of coronary stent placement is important in order to use an informed approach to select appropriate therapy and disseminate successful preventive strategies that can improve medication adherence.

The current study is a secondary data analysis of data collected during the conduction of a randomized control trial. The parent trial evaluated the efficacy of phone-based motivational interviewing at improving adherence to antiplatelet medications among African American and Hispanic subjects who underwent PCI. The objective of the secondary analysis was twofold: 1) identify predictors of non-adherence to antiplatelet medications that can be measured at the time of PCI among African American and Hispanic patients; 2) evaluate if phone-based motivational interviewing, the intervention we previously reported to improve adherence in the RCT⁷, was equally effective among participants at higher risk of non-adherence.

METHODS

Study Design

The current study is a retrospective cohort study of the parent RCT data. We conducted secondary analysis of all the data collected for all participants of both arms of the RCT: 1) a telephone-based motivational interview delivered by trained nurses (MINT) or 2) a mailed educational DVD. The details of the RCT have been previously reported⁷. Participants of the RCT completed a baseline and final survey (12 months post PCI) that collected social determinants of health, self-reported adherence and barriers to adherence. The University of Miami Institutional Review Board approved all study procedures and materials

Study Subjects

For this cohort study, we included the 452 African American and Hispanic participants of the RCT. To be included in the RCT patients should have 1) been identified as African American or Hispanic, 2) been older than 18 years of age, 3) have received a coronary stent placement in the previous 90 days, and 4) have filled at least one prescription for Clopidogrel or Prasugrel within that timeframe. All the participants were recruited from a Humana Inc. administrative claims database of approximately 3.5 million members throughout the United States enrolled in a commercial health maintenance organization (HMO), preferred-provider organization (PPO) or Medicaid/Medicare plan.

Predictors of Adherence

During the baseline survey we collected a number of covariates considered social determinants of health, measurement variables derived from the concepts within theoretical frameworks or variables previously identified as predictors of adherence in other populations^{17, 21}. Specifically, the following was collected:

Demographic Variables—Age, gender, marital status, self-reported income, self-reported education level, and insurance type.

Race/Ethnicity—African American race and Hispanic ethnicity were identified using a validated 3-step algorithm based on 1) the 1990 Census Spanish Surname list to identify subjects of Hispanic origin, 2) the Medicare Race Code to identify African American or Hispanic subjects, and 3) geocoded census data on neighborhoods to assign individuals weighted probabilities of being minority. The positive predictive value of this method in identifying individual racial/ethnic minority participants among the overall sample was 93% (confidence interval [CI] 85–97). The positive predictive value to identify African American subjects was 91% (CI 80–96) and to identify Hispanic subjects 92% (CI 75–99)²⁰. Study staff verified self-reported race/ethnicity at the time of recruitment into the parent RCT.

English Proficiency—English proficiency was determined using the validated question “In general, what language(s) do you read and speak?” which had a multiple-choice format²². Health literacy was ascertained via validated questions on the Short Test of Functional Health Literacy in Adults²³ such as “How often do you have problems learning about medical conditions because of difficulty understanding written information?”.

Self-Reported Adherence—The 4-item Morisky Medication Adherence Scale (MMAS-4)²⁴ was used to collect self-reported medication adherence at baseline and at 12-months. The MMAS-4 is a 4-item scale that sums the scores (0=Yes and 1=No) to provide indication of medication adherence.

Co-morbidity Burden—A validated Charlson co-morbidity score^{25, 26} was derived from administrative data to measure burden of disease. In the parent RCT, we searched the 9 fields present in the Humana administrative medical file for the International Classification of Diseases, ninth revision (ICD-9) codes that inform the Charlson co-morbidity score.

Depressive Symptoms—We administered the PHQ-9 Depression Questionnaire²⁷ to determine the relationship between severity of depressive symptoms and medication adherence. The predictive ability of this instrument and of its first two questions, which constitutes a validated depression screening instrument (PHQ-2) was separately evaluated.

Randomized Arm—The randomized arm (MINT or DVD) was considered a possible predictor of medication adherence. Briefly, MINT is a patient centered strategy that was selected as the test intervention given its focus on self-determination and self-management as key mediators of successful behavior change¹⁹. The DVD arm of the trial was considered the control group and consisted of a one-time mailed educational DVD designed by the authors. The DVD featured a physician providing post-stent information and a patient modeling the desired behavior and discussing their experiences with the disease and stent procedure. All participants received care as usual from their health care providers that was independent of the RCT.

Other—Other domains we evaluated were access to care, beliefs regarding the medication, patient-physician communication, and trust.

Primary Outcome

The primary outcome of the original RCT and of this secondary analyses was adherence to antiplatelet medication measured through the Medication Possession Ratio (MPR) for clopidogrel or prasugrel. MPR is defined as the sum of the days' supply of medication divided by the number of days between the first fill and the last refill plus the days' supply of the last refill.

MPR was calculated as a continuous variable from real time Humana claims pharmacy data using the below validated formula²⁸.

$$MPR = \frac{\sum \text{Days' supply of medication}}{\sum \text{Number of days between the first fill and the last refill} + \text{Days' supply of the last refill}}$$

A MPR less than 1.0 is indicative of a lapse in prescription refilling/adherence. A more clinically meaningful interpretation of MPR is based on the dichotomized form which was defined as MPR $\geq$ 0.80 (adequate adherence or drug availability during 80% or more of the therapy time) and MPR $<$ 0.80 (non-adherence or drug availability during less than 80% of

the therapy time). Data regarding the dates of each Clopidogrel or Prasugrel prescription filled and the number of days supplied each time was captured six-months after subjects completed the study to calculate the MPR.

Statistical Analysis

Chi-square analyses were conducted to describe baseline characteristics such as gender, race/ethnicity, English language proficiency, marital status, self-reported income, self-reported education level, insurance type, low health literacy, positive screening of depressive symptoms (PHQ-2) or moderate to severe depressive symptoms (PHQ-9), presence of diabetes, previous myocardial infarction, and congestive heart failure. T-tests were conducted to compare age, the Charlson co-morbidity score, and the MMAS-4 score. Similar methodologies were used to compare groups according to race/ethnicity and gender. A p-value of less than or equal to 0.05 was considered statistically significant.

Univariate and multivariate linear and logistic regression models were developed to identify possible predictors of adherence using the continuous and the categorical MPR as dependent variables, respectively. Odds ratios and 95% confidence intervals (CI) were calculated for age, sex, race/ethnicity, MMAS-4 score, Charlson co-morbidity score, PHQ-2 and PHQ-9, health literacy, education, income, marital status, and randomization group. To assess if MINT modified adherence differentially among subjects at risk for non-adherence, an interaction term was included between the randomized arm and the variables predictive of adherence. If any interactions were found to be significant then the analyses were performed within the appropriate subgroups.

RESULTS

Sample Characteristics

The sample (N=452) comprised of 56% African American and 44% Hispanic subjects. The mean age was 69.5 +/- 9, 58% were males, 56% had an spouse or partner, 22% had an education of high school or above, 40% had low health literacy, 46% had diabetes, 16% had depressive symptoms and 13% presented with an acute myocardial infarction. Of the 452 participants, 227 received MINT and 225 the educational DVD. There were no statistically significant differences in the prevalence of baseline characteristics or predictors of adherence by randomization group with the exception of annual income. A lower proportion of subjects in the DVD group had an annual income less than \$30, 000 (74% vs 82%, p=0.04) (Table 1). When evaluating the baseline characteristics by gender and race/ethnicity groups, African American and Hispanic Females were more likely to have an annual income lower than \$30,000 and to have low health literacy. African American females were less likely to be married or have a domestic partner and Hispanic females were more likely to have a positive screening for depressive symptoms (Table 2).

Adherence to Antiplatelet Medication

When evaluating the prevalence of adequate and inadequate adherence to antiplatelet medications by baseline characteristics we found that, 57% of the entire sample were adequately adherent to their antiplatelet medication (64% among MINT versus 50% of

DVD, $p<0.01$). There were no differences in prevalence of adequate adherence based on gender (58% in both groups $p=0.78$) or race/ethnicity (Hispanic 58% versus African American 57%, $p=0.72$). The prevalence of adequate adherence was statistically higher among those with a domestic partner and those who received MINT ($p<0.05$). There was a higher prevalence of inadequate adherence among those with a positive screening for depression (56%) as well as among those participants with moderate to severe depressive symptoms (61%) ($p<0.01$) (Table 3).

Multivariate Predictors of Adherence

In multivariate analyses, subjects with adequate self-reported adherence at baseline had higher odds of adequate 12-month adherence to antiplatelet medications. Those who had depressive symptoms had half the odds (AOR: 0.48, 95% CI: 0.27–0.90; $p=0.02$) of their non-depressed counterparts to have adequate medication adherence (MPR 0.80). Those with a higher Charlson co-morbidity score had lower odds of adequate medication adherence when compared to subjects with a lower Charlson co-morbidity score (AOR: 0.89; 95% CI: 0.80–0.98; $p=0.03$). The more proficient a subject was in the English language, higher the odds of adequate medication adherence when compared to those with a lower proficiency in the English language (AOR: 1.9; 95% CI: 0.98–3.9; $p=0.05$). Subjects who had a spouse or domestic partner had higher odds than non-married subjects to present with adequate medication adherence (AOR: 1.5; 95% CI: 0.99–2.4; $p=0.05$). Subjects randomized to MINT had 3.5 higher odds of adequate medication adherence than those randomized to DVD (AOR: 3.5; 95% CI: 1.9–2.7; $p<0.01$) (Table 4). Health literacy did not significantly predict adequate medication adherence (AOR: 1.7; 95% CI: 0.93–3.1; $p=0.28$); however, in models that used the continuous MPR as an outcome, the less trouble subjects had understanding written information, the higher the odds of adequate adherence (AOR: 2.9; 95% C.I.: 1.3–6.3). Income, education, access to care, beliefs about the medication and patient-physician communication did not predict adherence in either type of adjusted models. In evaluating if the MINT intervention effect varied according to other co-variables associated with adherence we found that the interaction terms between each of the variables and the randomized arm were not significant (all p 's > 0.10) and in stratified analyses the OR for the MINT intervention were similar.

DISCUSSION

A number of easily measureable baseline characteristics were identified to predict 12-month adherence to antiplatelet medications among insured minority subjects who received a coronary stent. Among these were baseline self-reported adherence, positive screening for depressive symptoms, moderate to severe depressive symptoms, and burden of disease. Low English proficiency, not having domestic partner and health literacy might also influence adherence. The MINT intervention improved medication adherence similarly among subjects with and without these risk factors.

Others have also found that in spite of the importance of socioeconomic status and access to care as predictors of disparities on objective health outcomes, these factors alone have not predicted medication adherence^{29–32}. This suggests that the health behaviors related to

adherence with therapy are much more complex and involve multiple co-existing determinants that are difficult to tease apart^{9, 33}. This poses a challenge for improving adherence to any medication, a task that becomes pivotal for medications known to improve survival such as antiplatelet medications post PCI. Nevertheless, in recent years we have found that directive, patient-centered approaches such as motivational interviewing improve medication adherence to chronic medications⁷. Reasons for the improvement are not fully elucidated but may be related to motivational interviewing's focus on eliciting the desire for change from within each individual and improving their autonomy and problem solving skills^{34,35}. However, many of the medication adherence interventions shown effective in RCTs have been found to be non-sustainable in real world settings¹⁷. In this context, identifying replicable predictors of non-adherence can facilitate the dissemination of successful strategies. We identified a few clear predictors of adherence that have been previously linked to other outcomes. In particular, burden of disease and depression seem to be predictive of adverse events such as diabetes complications and mortality³⁶, as well as mortality for congestive heart failure³⁷, and coronary artery disease³⁸. However, the literature has been mixed regarding the association between adherence to medications and depressive symptoms and it seems to vary according to disease state. Nevertheless, depression has been a consistent predictor of adherence among diabetic patients³³ and more recently among subjects hospitalized with acute cardiac events³⁹.

The mechanisms by which subclinical and clinical depression influence outcomes are not fully understood but theories include poor self-management, hopelessness, as well as inflammatory mechanisms^{38,40-42}. However, studies have failed to demonstrate that reducing depressive symptoms improve clinical outcomes and recommend continuing the search for the mediating pathways^{36, 43}. Our study suggests that MINT can improve adherence among subjects with depressive symptoms without targeting depression per se but rather their self-management skills. In addition to the clinical risk factors, we found that early self-reported adherence measured by the 4-item Morisky score within 90 days of the stent placement is highly predictive of the 12-month medication possession ratio.

Low health literacy even though has been previously found to be a mediator of adverse outcomes⁴⁴ and of self-reported adherence³⁹ was not significant in multivariate models that used a categorical objective measure of adherence. This may suggest a confounding effect with the other factors or lack of discriminatory ability when using a dichotomized MPR, since the health literacy effect was significant when the continuous MPR measure was used. The evidence to date supports its measurement for screening purposes.

In light of these findings, we propose the development and testing of a targeting strategy to be deployed at the time of PCI. This targeting strategy should include patients with moderate or severe depressive symptoms, low English proficiency, low health literacy, more than two co-morbidities from the Charlson score, or those living alone. We could test adherence behaviors by collecting self-reported adherence (MMAS) for other cardiovascular medications at the time of PCI (e.g statin or hypertension). Patients who are experiencing lack of social support or poor self-management resources could benefit from phone-based, nurse-led MINT post-PCI as demonstrated by the original RCT and this study. Collecting self-reported adherence to the antiplatelet medication between 30- and 90-days post-PCI or

even later could be used to expand the identification of those at risk. Self-reported adherence correlates well to the objective MPR for antiplatelet medications among PCI recipients⁷. Given that changes in lifestyle related to having the PCI may affect mental health, we suggest retaking the PHQ-9 or the PHQ-2 during the follow-up visit or call between 30- and 90-days post-PCI. This is a more informed and equitable approach than selecting the use of a bare metal stent based on perceptions of potential barriers to adherence to antiplatelet medications such as insurance type⁴⁵, race¹³, or other subjective information.

There are several study limitations. First, the RCT included only African American and Hispanic subjects insured mostly through Medicare to one single U.S. health insurance organization. This may limit the generalizability of our results and of our proposed targeting strategy. Second, our population had a very low income and educational level, which may limit our ability to discern the impact of these socio-demographic variables.

Strengths include the prospective design, the low attrition rate at the end of the follow-up period, the use of an objective claims-based measure of adherence, the collection of self-reported instead of census based SES and educational variables, as well as the collection of many of the previously reported determinants of adherence.

CONCLUSION

In conclusion, our study suggests that there are predictors that can be measured at the time of stent placement to inform PCI therapy and deployment of services to support medication adherence. Motivational interviewing was effective at improving adherence among subjects with the identified risk factors. The cost-effectiveness of using this predictive model as a screening tool for risk of non-adherence to antiplatelet medications at the time of coronary stent placement needs to be evaluated among diverse populations in real world settings.

Acknowledgments

Funding: The study was sponsored by National Center on Minority Health and Health Disparities NCMHD under Recovery Act (ARRA) grant RC1 MD004327.

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TABLE 1

Baseline Characteristics by Intervention Group

Characteristic	Total N=452	MI n=227	DVD n=225	p-value
Mean Age, SD	69.52 ± 8.83	69.1 ± 8.6	69.9 ± 9.0	0.83
Male, %	58	56	60	0.29
Hispanics, %	45	45	44	0.99
Income <30,000, %	78	82	74	0.05
Completed High School, %	22	23	22	0.80
Mean Charlson Score, SD	1.83 ± 2.08	1.78 ± 1.9	1.96 ± 2.2	0.35
Low Health Literacy, %	40	43	38	0.38
Married or partner, %	56	57	56	0.84
Positive Screening for Depressive Symptoms (PHQ-2), %	16	15	16	0.89
Moderate to Severe Depressive Symptoms (PHQ-9), %	13	13	14	0.78
Mean MMAS-4, SD	3.64 ± 0.70	3.64 ± 0.71	3.64 ± 0.69	0.98
Current Smoker, %	45	19	26	0.15
Diabetes, %	46	44	47	0.52
Myocardial Infarction, %	13	13	12	0.88
Congestive Heart Failure, %	13	13	13	0.99

TABLE 2

Baseline Characteristics by Race/Ethnicity and Gender

	Black Females n=120	Black Males n=131	Hispanic Females n=70	Hispanic Males n=131	p-value
Age	70± 8.4	69± 9	72± 9.4	68± 8.4	
Income <30,000, %	84	77	85	70	0.04
Completed High School, %	19	21	26	25	0.52
Mean Charlson Score, SD	1.89 ±1.97	2.01±2.3	1.96±1.95	1.68±2.07	
Low Health Literacy, %	47	38	50	32	0.03
Married or partner, %	35	58	52	74	0.01
Positive screening for depressive symptoms (PHQ-2), %	13	14	27	13	0.03
Moderate to Severe Depressive Symptoms (PHQ-9), %	12	12	23	12	0.08
Mean MMAS-4, SD	3.57±0.57	3.66±0.64	3.48±0.83	3.59±0.76	
Current Smoker, %	11	16	9	10	0.48
Diabetes, %	49	46	45	43	0.88
Myocardial Infarction, %	14	13	12	12	0.91
Congestive Heart Failure, %	15	14	15	11	0.76

TABLE 3

Prevalence of Adequate Medication Adherence among Predictors

Predictor	MPR ≥ 0.80 n (%)	MPR < 0.80 n (%)	p-value
Male	138 (58)	105 (42)	0.78
Female	104(58)	75(42%)	0.78
Hispanic	109 (58)	78 (42)	0.73
African American	133 (57)	102 (43)	0.73
Believe medication improves future health	230 (58)	164 (42)	0.10
Sometimes forget to take medication	26 (44)	33 (56)	0.01
Adequate Health Literacy	146 (58)	107 (42)	0.91
Positive Screening for Depressive Symptoms (PHQ-2)	29 (43)	38 (56)	0.01
Moderate to Severe Depressive Symptoms (PHQ-9)	22 (39)	34 (61)	0.003
Having a Domestic Partner	137 (63)	80 (37)	0.03
English Proficiency	41 (68)	19 (32)	0.05
Motivational Interviewing Group	137 (64)	76 (36)	0.003

TABLE 4

Adjusted Odds of Medication Adherence by Predictor

Predictor	Odds Ratio (95% CI)	p-value
Adequate Baseline Adherence (MMAS-4)	1.4 (1.05–1.89)	0.02
Adequate Health Literacy	1.7 (0.93–3.1)	0.28
Moderate to Severe Depressive Symptoms (PHQ-9)	0.49 (0.27–0.90)	0.02
Married or with a Domestic Partner	1.5 (0.99–2.4)	0.05
Charlson Score	0.89 (0.80–0.98)	0.03
English Proficiency	1.9 (0.98–3.9)	0.05
Motivational Interviewing Group	3.5 (1.9–2.7)	<0.01