Cardiac Admissions in Patients with Depression at an Urban Medical Center

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A. Study Purpose and Rationale

The purpose of this study is to investigate the association between depression and cardiac admissions in an economically disadvantaged minority patient population engaged in primary care at an urban medical center.

Cardiovascular disease remains the leading cause of death in the United States and is also associated with considerable patient morbidity (1). Depression, particularly major depressive disorder, has less of a direct effect on mortality but is still considered a leading cause of disability (2).

Given the prevalence of both disorders, as well as the consideration of depression as a potentially modifiable risk factor for cardiovascular disease, the relationship between the two has been of considerable research interest. Interestingly, a number of controlled observational studies have found that depression is a significant risk factor for new coronary events in patients with preexisting heart disease (3, 4, 5). Such studies have found an effect even when controlling for traditional risk factors such as age, smoking, hyperlipidemia, hypertension, diabetes, and obesity. In addition, research suggests that depression is a risk factor for the development of coronary disease in individuals without preexisting heart disease (6). While a definitive mechanism is unclear, depression may mediate such effects through inducing platelet activation (7), cytokine production (8), or variation in autonomic tone (9).

The concept of depression as an independent risk factor for heart disease is not universally accepted as some have argued that psychological distress influences known risk factors such as smoking, alcohol use, diet, and exercise (10). It should also be noted that some studies have failed to show an association between depression and increased cardiac morbidity and mortality (11, 12).

In addition, while the association between depression and cardiovascular disease is intriguing, intervention studies which address and treat depressive symptoms have not shown a reliable effect in reducing morbidity or mortality from heart disease (13). A recent study, the Sertraline Antidepressant Heart Attack Randomized Trial (SADHART), was the largest to date which analyzed use of an antidepressant for patients with heart disease (14). The study failed to show a significant reduction in MI or CHD death in patients treated with sertraline at 16 weeks after hospitalization for acute coronary syndrome, although the study was designed to evaluate safety rather than cardiovascular events.

Nonetheless, if present, the existence of a link between depression and heart disease is significant since it constitutes a potentially modifiable risk factor. Identifying and treating

depression in the primary care setting may delay the onset of cardiac events, and may reduce mortality in patients with established heart disease. While there appears to be a causal relationship between depression and poorer cardiovascular outcomes, investigators are still trying to elucidate both the underlying mechanisms and the potential ability to modify depression as a risk factor.

In addition to these questions, the relationship between depression and cardiovascular disease in particular sub-populations, particularly underserved and minority populations, remains largely unknown. It is becoming apparent that rates of depression vary by race (15) as well as socioeconomic status (16, 17), and in these populations depression is often both under-recognized and under-treated (16, 17, 18). Rates of cardiovascular disorders vary by race as well (1), and numerous studies have documented discrepancies between the identification, treatment, and outcome of both poor and minority patients with heart disease (19, 20, 21).

The proposed study will serve to address the relationship between depression and cardiovascular events in a primarily minority, Medicaid-insured patient population. Such data will be useful in identifying the degree to which depression plays a role as a risk factor for cardiac morbidity and mortality in these individuals.

B. Study Design and Statistical Analysis

This is a retrospective cohort study of patients who completed in the AIM Mental Health Survey, which was administered to a consecutive sample of patients waiting to see their primary care doctor in the AIM medical practice during 2001. A total of approximately two thousand patients completed the survey instrument over the study time period. Subjects were categorized as depressed based on responses to the PRIME-MD Patient Health Questionnaire (22). Based on responses to the survey instrument, the prevalence of depression was approximately twenty percent (16).

The primary endpoint will be all admissions for acute coronary syndrome (ICD-9 410.x and 411.x) during the five-year period between survey completion and the present time. The incidence of these admissions will be compared between patients classified as depressed by the AIM Mental Health Survey and patients classified as not depressed. We hypothesize that patients with depression will have a higher rate of admissions for acute coronary syndrome than patients without depression.

A multivariable logistic regression model will be used to identify the relationship between depression and cardiac admissions as identified by ICD-9 code. Covariates will include the presence pre-existing of CAD (as determined by chart review), self-reported cardiac risk factors (age, sex, smoking, DM, HTN), and chart-reviewed cardiac risk factors (LDL, BMI).

The prevalence of acute coronary syndrome (ACS) varies in the published literature. With regards to the general population, one study in Sweden found that the yearly incidence of acute chest pain admissions (including ACS and other causes of chest pain)

was 1.8% (23), while another study in Denmark found an annual incidence of ACS alone of 0.3% (24). Studies in the U.S. place the annual hospitalization rate for ACS at approximately 0.9% in individuals over the age of 20 (1). Another study in England found that chest pain itself was a common reason for presentation to the emergency room, accounting for 6% of all ED visits, with approximately half of these patients having clinical or electocardiographic evidence of ACS (25).

Among populations already seeking medical care (such as those attending regular doctor's visits), the incidence of admission for ACS is likely to be higher as such patients presumably have a number of comorbidities (such as hypertension and diabetes) that increase their likelihood of presentation to the emergency room. For the purposes of our study, we will use a conservative estimate of 2% for AIM patients presenting to the ER with ACS over a five-year period.

Given that the subject enrollment has been completed with 2000 patients, 400 (20%) of whom have been identified with depression, Chi square analysis for effect size is as follows (with alpha set at 0.05 and power set at 80%): N for group 1 (non-depressed) = 1600; N for group 2 (depressed) = 400; group 1 proportion (patients with ACS) = 2%; group 2:1 ratio = 0.25; therefore the smallest detectable proportion for group 2 is $p<.0047$, and the largest is $p>.055$. Thus in order to detect a significant effect (to $P = 0.05$), given a 2% 5-year prevalence of ACS in the control population, depressed patients will need to have a true event rate greater than 5.5%.

Secondary outcomes for the study will include all ED visits for chest pain (ACS plus all other causes), ED visits for acute stroke, and total ED visits.

C. Study Procedure

The proposed study will utilize patient data previously obtained through the AIM Mental Health Survey, as well as ICD-9 codes between survey administration and the current time. The administration of the survey has been previously described (17) and is briefly summarized below.

Patients were screened from the Associates in Internal Medicine (AIM) practice, which is the resident and faculty group practice of Columbia University Medical Center. The patient population is primarily poor, Medicaid-insured, and minority (predominantly Hispanic). A consecutive sample of patients who were waiting for an appointment with their primary care doctor (PMD) were approached by a research assistant about filling out the survey. Patients were required to have been to the AIM clinic at least one time prior, and were required to have a face-to-face appointment with their PMD. Patients had to be between 18 and 70 years of age. Surveys were administered in either English or Spanish.

Patients were excluded from the study if their health status prevented them from filling out the surveys. In addition, if they were determined to be suicidal based on the survey instrument, they were referred to the ED for appropriate emergency care.

The survey recorded demographics, current and past medical problems, self-perceived health score, mental disorders (via the PRIME-MD instrument), and social adjustment. More details on this survey are provided in section F.

The original instrument was administered in 2001. A sub-sample was subsequently re-surveyed to evaluate change in mental health status. Data from the additional survey instrument will not be used for purposes of the current study. In addition, no patients from the original sample will be re-assessed for the current investigation; rather, data will be obtained through existing databases, chart review, and hospital admission records.

D. Study Drugs

N/A

E. Medical Devices

N/A

F. Study Questionnaires

The study will utilize data from the AIM Mental Health Survey, which contains the following general information:

1. Demographic information (age, country of origin, years in U.S., race/ethnicity, education, income, insurance status, employment)
2. Current and past medical problems
3. 5-point self-perceived overall health measure (excellent, very good, good, fair, poor)
4. PRIME-MD patient health questionnaire sections:
    a. Current MDD
    b. Current PD
    c. Current GAD
    d. Past-year probable alcohol abuse/dependence
    e. Suicidal ideation
5. Social adjustment scale for getting along with family members (very well, well, poorly, very poorly)

G. Study Subjects

The study population consists of patients in the Associates in Internal Medicine (AIM) practice, which is the resident and faculty group practice of Columbia University Medical Center. The patient population is primarily poor, Medicaid-insured, and minority (predominantly Hispanic). The original screening required that patients be between 18 and 75 years of age. No other restrictions were placed.

H. Recruitment of Subjects

The original patient sample consisted of a group of adult primary care patients with scheduled appointments awaiting an appointment with their primary physician in the AIM clinic. Patients had to have had at least one prior appointment with their doctor in the same clinic. Patients were excluded from the study if their health status prohibited completion of the questionnaire, or if they were deemed actively suicidal (in which case they were referred for emergency care).

I. Confidentiality of Study Data

Each patient is provided with a unique study number and unique identifiers are not used for coding. Data is stored so that only study investigators are able to access such information.

J. Potential Conflict of Interest

None.

K. Location of the Study

The study instrument is administered in the waiting room of the AIM practice, which is a routine clinical care area.

L. Potential Risks

Patients involved in the study volunteer a portion of their time to complete the questionnaire. There is no significant medical risk to patients that is foreseen. There is no potential for a subject's condition to worsen as a result of the study.

M. Potential Benefits

Individual patients may benefit through the identification of previously undiagnosed mental health disorders which can subsequently be addressed. Suicidal patients are screened and referred for appropriate emergency care. In terms of larger (i.e. societal) benefits, the study will help to identify whether, in this sub-population, depressive symptoms are associated with increased cardiovascular resource utilization. Such results will help address whether future patients should be more aggressively screened and treated for depression, as this may prevent admissions for acute cardiac syndromes.

N. Alternative Therapies

N/A

O. Compensation to Subjects

There is no compensation to subjects who fill out the questionnaire.

P. Costs to Subjects

There are no costs to subjects who fill out the questionnaire.

Q. Minors as Research Subjects

N/A

R. Radiation or Radioactive Substances

N/A

S. References

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ICD-9 Codes
Acute MI 410
Angina 411 or 413
Cardiovascular dz NOS 429.2
“other chest pain" 786.5

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