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Collaborative care for depression symptoms in an outpatient cardiology setting: A randomized clinical trial☆,☆☆

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ABSTRACT

Background: Depression is a risk factor for morbidity and mortality in patients with coronary heart disease. Finding effective methods for identifying and treating depression in these patients is a high priority. The purpose of this study was to determine whether collaborative care (CC) for patients who screen positive for depression during an outpatient cardiology visit results in greater improvement in depression symptoms and better medical outcomes than seen in patients who screen positive for depression but receive only usual care (UC).

Methods: Two hundred-one patients seen in an outpatient cardiology clinic who screened positive for depression during an outpatient visit were randomized to receive either CC or UC. Recommendations for depression treatment and ongoing support and monitoring of depression symptoms were provided to CC patients and their primary care physicians (PCPs) for up to 6 months.

Results: There were no differences between the arms in mean Beck Depression Inventory-II scores(CC, 15.9; UC, 17.4; $p = .45$) or in depression remission rates(CC, 32.5%; UC, 26.2%; $p = 0.34$) after 6 months, or in the number of hospitalizations after 12 months ($p = 0.73$). There were fewer deaths among the CC (1/100) than UC patients (8/101) ($p = 0.03$).

Conclusions: This trial did not show that CC produces better depression outcomes than UC. Screening led to a higher rate of depression treatment than was expected in the UC group, and delays in obtaining depression treatment from PCPs may have reduced treatment effectiveness for the CC patients. A different strategy for depression treatment following screening in outpatient cardiology services is needed.

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1. Introduction

Depression and cardiovascular diseases are highly comorbid, and depression is a significant risk factor for psychosocial and medical morbidity and mortality in patients with coronary heart disease (CHD) [1,2]. A 2008 American Heart Association Science Advisory recommended that cardiologists routinely screen their patients for depression [3], and this statement was endorsed by the American Psychiatric Association. However, critics argued that this recommendation was premature due to insufficient evidence that depression screening improves either depression or cardiac outcomes in patients with CHD [4,5].

Both critics and supporters have generally agreed that in order for depression screening to improve depression, procedures must be in place to ensure that clinically appropriate actions are initiated when patients screen positive [6]. This concern is supported by a recent study of patients who were screened for depression following cardiac surgery without an organized response to a positive screen. The study found significant depression in many of these patients six months after the initial screening [7]. Collaborative care (CC), in which treatment is managed by a primary care physician (PCP) in consultation with a psychiatrist, is one of the best studied and most cost-effective models for depression management following routine depression screening in primary care and in some medical specialty settings [8–10]. At least 3 randomized controlled trials of CC for depression in cardiac care settings have been conducted since the publication of the AHA depression screening statement.

Rollman and his colleagues completed a study of depression screening and CC in patients recovering from coronary artery bypass surgery [11]. They compared UC provided by PCPs to an 8-month, nurse-delivered, telephone-based CC intervention for patients who screened

Abbreviations: BDI-II, Beck Depression Inventory-II; CM, case manager; CBT, cognitive behavior therapy; CC, collaborative care; DISH, Depression Interview and Structured Hamilton; PHQ-9, Patient Health Questionnaire; PCP, primary care physician; UC, usual care.

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positive for depression. The intervention included initiation or adjustment of antidepressants, watchful waiting, or referral to a mental health professional. CC participants received a median of 10 contacts of unreported duration. The CC patients had greater improvements in quality of life and depression symptoms than did those who received only UC. Forty-one percent of the patients were receiving antidepressants at baseline, and roughly half were receiving antidepressants by the end of the trial. The authors did not report the proportion of patients in each group who received antidepressants, but did indicate that the proportion was higher in the CC arm than in the UC arm.

In two separate trials [12,13], Huffman and colleagues enrolled patients who screened positive for depression and subsequently found to be clinically depressed during hospitalization for a cardiac event. In the first trial, patients were assigned to receive either UC or a CC intervention that included education about depression and its impact on heart disease, encouragement to plan pleasurable activities after discharge, and specific recommendations for treatment when appropriate (pharmacotherapy or referral for psychotherapy). The second trial (MOSIACS) enrolled patients with depression, an anxiety disorder, or both. Using a protocol otherwise similar to the one employed in the first trial, patients preferring psychotherapy over antidepressants were offered 50-minute sessions of cognitive behavior therapy (CBT) in-hospital and by telephone following hospital discharge for a minimum of 6 sessions. Most of the patients in the CC arm for whom antidepressants were recommended (approximately 80% in both studies) were prescribed the drug by their PCP or other physicians involved in their care, before hospital discharge. In the first trial, a study nurse acted as the care manager for patients randomized to the CC arm, whereas a social worker performed this function in the second trial. In both trials, patients in the CC arm received an average of 3 follow-up telephone calls after hospital discharge. Patients who received the intervention had significantly greater improvement in depressive symptoms and mental health quality-of-life at 6 and 12 weeks in the first trial, and after 24 weeks in the second trial.

These findings are very encouraging. However, there have not been any studies of routine screening and CC for depression in outpatient cardiology settings. Inpatient and outpatient settings pose different challenges for implementation of collaborative depression care. The purpose of this study was to determine the effectiveness of CC vs. UC in reducing depression symptoms in an outpatient cardiology setting.

2. Methods

2.1. Screening/Enrollment

Participants were recruited from the outpatient cardiology services at the Washington University Center for Advanced Medicine in St. Louis, Missouri and its suburban satellite facility. Both facilities are administered and staffed by the Division of Cardiovascular Medicine at the Washington University School of Medicine. Patients seen at these facilities represent a cross-section of residents of the City of St. Louis and the surrounding suburbs, as well as from rural areas and small towns in eastern Missouri and western Illinois.

In accordance with the AHA recommendation [3], routine screening for depression with the Patient Health Questionnaire (PHQ-9) [14] was instituted by the outpatient cardiology service just prior to the start-up of this study. Patients with CHD who were being seen for their first outpatient cardiology appointment were asked by the receptionist to complete the PHQ-9 upon arrival at the clinic. Patients who received ongoing care at the clinic were rescreened annually. The cardiologists were notified if their patient screened positive for depression (PHQ-9 ≥ 10), and this information was also entered in the patient's electronic medical record.

Clinic patients who had documented CHD (angiographic findings of ≥50% stenosis in one or more major coronary artery, or a history of either coronary revascularization or hospitalization for ACS), and who screened positive for depression (PHQ-9 ≥ 10) between November, 2011 to January, 2015 were evaluated for study eligibility. Patients who were receiving an antidepressant at baseline were included if they had been taking a standard recommended dose of the prescribed agent for at least 4 weeks and met all other study criteria.

Patients were excluded from study participation for any of the following: 1) significant suicidal ideation or behavior; 2) significant cognitive impairment or inability to read or speak English; 3) schizophrenia, bipolar disorder, active substance abuse or alcoholism, or other severe Axis I comorbidities; 4) medical conditions including a recent (within the past 3 months) acute coronary syndrome (ACS) or coronary artery bypass graft (CABG) surgery, severe valvular heart disease according to standard echocardiographic criteria, severe heart failure (NYHA class IV), malignancy, or physical limitations that would interfere with participation in the study protocol; 5) exemption by the patient's cardiologist or primary care physician; 6) participation in a competing research protocol; or 7) refusal to participate or to sign an informed consent form.

With the permission of their cardiologist, eligible patients were contacted by telephone after their clinic visit by a research nurse to discuss study participation. Those who wished to participate were asked to provide written informed consent as approved by the Human Research Protection Office at Washington University School of Medicine conforming to the guidelines of the 1975 Declaration of Helsinki. An appointment for the patient to visit the Washington University Behavioral Medicine Center was scheduled to complete the baseline assessments. If an appointment could not be scheduled within one week, the informed consent and baseline questionnaires were mailed to the patient and the recruiting nurse again contacted the patient to review the consent form and answer questions. The first 201 patients meeting all study criteria who provided informed consent and completed baseline forms were randomly assigned to receive either UC or up to 6 months of a CC intervention in a 1:1 allocation ratio. Participants were randomized in permuted blocks, and randomization was stratified by antidepressant use at baseline. Treatment assignments were concealed in sequentially numbered, opaque envelopes (one set per stratum) and opened by the study coordinator after the baseline evaluation.

2.2. Treatment groups

2.2.1. Collaborative care (CC)

The CC intervention was designed to be both feasible and cost-effective for a nurse or social worker trained as a case manager (CM) to implement in cardiology outpatient practice settings. The CM was responsible for assessing the patient's depression, treatment needs, and treatment preferences; meeting with a study psychiatrist (EHR) and psychologist (RMC) to establish a treatment plan; and encouraging the patient's PCP (or cardiologist if the patient did not have a PCP) to prescribe an antidepressant or facilitate a referral for other appropriate treatments. A nurse assumed the role of CM for half of the CC participants, and a social worker functioned in that role for the other half.

A clinical interview was conducted by the CM to determine whether a provisional diagnosis of major depressive disorder could be made. The CM assessed depression treatment history, current medications, comorbid medical illnesses, and the patient's treatment preferences, and these data were provided to the consulting psychiatrist and psychologist for review. Potential treatment recommendations included specific antidepressants or psychotherapy. For patients with mild depression, the options included exercise (if medically appropriate), support groups, pleasant activity scheduling, or watchful waiting with ongoing support and monitoring from the CM for patients who declined treatment. The patient was asked to rank order his/her treatment preferences during the initial contact with the CM. Selective serotonin reuptake inhibitors (SSRIs) such as sertraline or citalopram, which have generally been found to be safe in cardiac patients, were usually recommended unless contraindicated by treatment history, potential drug–drug interactions,

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