Treatment of Dysthymia and Minor Depression in Primary Care

A Randomized Controlled Trial in Older Adults

John W. Williams, Jr, MD, MHS
James Barrett, MD
Tom Oxman, MD
Ellen Frank, PhD
Wayne Katon, MD
Mark Sullivan, MD
John Cornell, PhD
Anjana Sengupta, PhD

Context Insufficient evidence exists for recommendation of specific effective treatments for older primary care patients with minor depression or dysthymia.

Objective To compare the effectiveness of pharmacotherapy and psychotherapy in primary care settings among older persons with minor depression or dysthymia.

Design Randomized, placebo-controlled trial (November 1995–August 1998).

Setting Four geographically and clinically diverse primary care practices.

Participants A total of 415 primary care patients (mean age, 71 years) with minor depression (n=204) or dysthymia (n=211) and a Hamilton Depression Rating Scale (HDRS) score of at least 10 were randomized; 311 (74.9%) completed all study visits.

Interventions Patients were randomly assigned to receive paroxetine (n=137) or placebo (n=140), starting at 10 mg/d and titrated to a maximum of 40 mg/d, or problem-solving treatment–primary care (PST-PC; n=138). For the paroxetine and placebo groups, the 6 visits over 11 weeks included general support and symptom and adverse effects monitoring; for the PST-PC group, visits were for psychotherapy.

Main Outcome Measures Depressive symptoms, by the 20-item Hopkins Symptom Checklist Depression Scale (HSCL-D-20) and the HDRS; and functional status, by the Medical Outcomes Study Short-Form 36 (SF-36) physical and mental components.

Results Paroxetine patients showed greater (difference in mean [SE] 11-week change in HSCL-D-20 scores, 0.21 [0.07]; $P=.004$) symptom resolution than placebo patients. Patients treated with PST-PC did not show more improvement than placebo (difference in mean [SE] change in HSCL-D-20 scores, 0.11 [0.13] ; $P=.13$), but their symptoms improved more rapidly than those of placebo patients during the latter treatment weeks ($P=.01$). For dysthymia, paroxetine improved mental health functioning vs placebo among patients whose baseline functioning was high (difference in mean [SE] change in SF-36 mental component scores, 5.8 [2.02]; $P=.01$) or intermediate (difference in mean [SE] change in SF-36 mental component scores, 4.4 [1.74]; $P=.03$). Mental health functioning in dysthymia patients was not significantly improved by PST-PC compared with placebo ($P\geq.12$ for low-, intermediate-, and high-functioning groups). For minor depression, both paroxetine and PST-PC improved mental health functioning in patients in the lowest tertile of baseline functioning (difference vs placebo in mean [SE] change in SF-36 mental component scores, 4.7 [2.03] for those taking paroxetine; 4.7 [1.96] for the PST-PC treatment; $P=.02$ vs placebo).

Conclusions Paroxetine showed moderate benefit for depressive symptoms and mental health function in elderly patients with dysthymia and more severely impaired elderly patients with minor depression. The benefits of PST-PC were smaller, had slower onset, and were more subject to site differences than those of paroxetine.

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ANTIDEPRESSANTS AND DEPRESSION-specific psychotherapies are clearly effective for major depression.[1] Treatments for major depression have been proved effective in both mental health specialty and primary care settings and in young and older adults.[2-5] However, the effectiveness of treatments for less severe depressive disorders, particularly in older primary care patients with coexisting medical illnesses, is less certain.[4] Recent literature syntheses concluded that there is insufficient evidence to recommend pharmacotherapy for minor depression. Evidence was also insufficient to recommend psychotherapy for either minor depression or dysthymia.[4,6,7] This knowledge gap is particularly problematic because the prevalence of less severe depressive disorders exceeds that of major depression, leaving primary care clinicians without evidence-based treatment recommendations for the majority of their depressed patients.[5,8,9]

See also p 1570 and Patient Page.

Author Affiliations and Financial Disclosure are listed at the end of this article.
Corresponding Author and Reprints: John W. Williams, Jr, MD, MHS, Ambulatory Care (11C-6), 7400 Merton Minter Blvd, San Antonio, TX 78284 (e-mail: jwilliam@verdict.uthscsa.edu).

Dysthymia is a chronic depressive disorder, characterized by functional impairment and at least 2 years of depressive symptoms.[10] Minor depression is a less chronic illness than dysthymia, with fewer symptoms than major depression, but it is associated with significant functional impairment and increased health care use.[11-14] Psychological treatments are a particularly attractive option in the elderly since many patients prefer such treatments, and they avoid drug interactions.[15] In addition, brief psychotherapies that can be delivered in primary care are needed because many older adults are unlikely to accept or follow-through on referrals to specialty mental health settings. Nevertheless, pharmacotherapy remains the most common treatment modality, in part because primary care clinicians are more comfortable treating with antidepressants than engaging in psychotherapy.[16] Since antidepressant medications are the number 1 or 2 pharmacy costs for many health plans, data that better define the patient groups in which they are useful would have important policy implications.

To address the lack of evidence on how to treat these disorders, we conducted an 11-week, multicenter, randomized controlled trial. We compared the effectiveness of placebo plus clinical management with paroxetine, a member of the most widely prescribed antidepressant drug class, and Problem-Solving Treatment–Primary Care (PST-PC), a behaviorally based psychotherapy designed specifically for primary care.[17-19] The study focuses on older primary care patients with dysthymia or minor depression and uses broad inclusion criteria to improve its applicability in primary care settings.

METHODS

Our methods have been described in detail elsewhere[19] and summarized briefly herein. The institutional review boards for each participating site approved the study. Patients gave written informed consent.

Patients and Setting

Patients aged 60 years or older were recruited through referral and screening at community, Veterans Affairs, and academic-affiliated primary care clinics. The 4 participating centers were chosen for geographic diversity and diversity of clinical populations. Eligible patients met *Diagnostic and Statistical Manual of Mental Disorders, Revised Third Edition* (*DSM-III-R*) criteria[10] for dysthymia or criteria for minor depression and scored 10 or higher on the 17-item Hamilton Depression Rating Scale (HDRS).[20,21] Criteria for minor depression were adapted from the *DSM-IV* research criteria. We required symptoms for at least 4 weeks rather than 2 weeks, and 3 or 4 symptoms, rather than 2 to 4 symptoms. A past history of major depression was not an exclusion criterion. Depression diagnoses were made by a research psychiatrist or psychologist using the Primary Care Evaluation of Mental Disorders (PRIME-MD), a diagnostic instrument designed for use in primary care.[21] Patients were excluded for: major depression, psychosis, schizophrenia or schizo-affective disorder, bipolar affective disorder, alcohol or other substance abuse within the past 6 months, antisocial personality disorder, borderline personality disorder, serious suicidal risk, moderate or severe cognitive impairment (Folstein Mini-Mental State Examination score ≤ 23[22]), and medical illness with a prognosis of less than 6 months to live. In addition, patients in current treatment were excluded, with an exception for patients willing to discontinue treatment who were taking 50 mg or less of amitriptyline or its equivalent.

Design

Patients were randomly assigned to placebo, paroxetine, or PST-PC. Randomization was blocked and stratified by site and diagnosis using a computer-generated random allocation table. The coordinating center created consecutively numbered envelopes containing concealed assignment codes that were assigned sequentially to eligible patients by a research associate. To preserve blinding, treatment assignments were held by the study statistician.

Treatment

All patients were scheduled for 6 treatment sessions over 11 weeks. Treatment sessions took place in the general medical setting. For patients assigned to receive medication, visits occurred at weeks 1, 2, 4, 6, 8, and 11. For patients assigned to receive PST-PC, the final treatment visit was at 10 weeks instead of 11 weeks to permit any effect of the last treatment session to be demonstrated at the final 11-week assessment. Medication therapists included general internists and psychiatrists; visits consisted of medication dose titration, symptom assessment, a review of adverse effects, and general support. Visits were designed to last approximately 15 minutes. Specific psychological treatments were prohibited. Identically appearing tablets containing paroxetine or placebo were given in a double-blind manner. Paroxetine was initiated at 10 mg/d and, if well tolerated, was increased at week 2 to the target dose of 20 mg/d. At week 4 or 6, the dose could be increased to 30 mg/d and at week 6 or 8 to 40 mg/d for patients who showed partial or no improvement. Placebo was titrated in an identical manner. At each visit, patients self-reported medication adherence.

The PST-PC therapists included 7 psychologists with doctorates of philosophy and 3 social workers and 2 counselors with a master's degree. All therapists received a treatment manual and training consisting of a short theoretical course, role playing in a clinical setting, and watching a training videotape. Subsequently, therapists treated at least 4 "practice" patients. Prior to seeing a study patient, therapists had to be certified as competent in the technique (Mark Hegel, PhD, unpublished data, 1999). The PST-PC technique is based on cognitive-behavioral principles and includes 3 main steps: (1) the patient's symptoms are linked with their problems in living; (2) the problems are defined and clarified; and (3) an attempt is made to solve the problems in a struc-

tured way.[18] Sessions lasted approximately 1 hour for the first visit, and 30 minutes for each subsequent visit. Antidepressant medication use was prohibited.

Assessments

Sociodemographic and clinical information was collected at baseline. Coexisting medical illness was evaluated by physician chart review using the Duke Severity of Illness Index.[23] This index ranges from 0 to 100 with higher scores indicating greater morbidity. In addition, chronic medical conditions were categorized by organ systems using *International Classification of Diseases, Ninth Revision (ICD-9)* classification (eg, respiratory, endocrine, cardiovascular, etc).[10,24]

Outcome measurements included self-report and interviewer-rated instruments. Raters who were blinded to the patient's treatment assignment and not involved in patient assignments or treatment scored the latter instruments. The primary outcome measure was a 20-item self-report scale consisting of the 13 items from the Hopkins Symptom Checklist Depression Scale (HSCL-D-20) and 7 additional depression-related items added to increase responsiveness.[25,26] Items were averaged, yielding a continuous score ranging from 0 to 4 with higher scores indicating more severe symptoms. The HSCL-D-20 was administered at baseline and at each follow-up visit. In addition, the 17-item HDRS (a measure of severity) and the Medical Outcomes Study Short-Form 36 (SF-36) (a measure of functional status) were rated at baseline and at 6 and 11 weeks.[20,27-29]

Data Analysis

For continuous demographic and clinical data, parametric and nonparametric analysis of variance was used to analyze baseline differences across site, diagnostic group, and treatment assignment. Stratified contingency table analyses were used to analyze baseline differences in categorical patient variables.

Treatment efficacy was based on an assessment of 4 outcome measures: HSCL-D-20 depression scale, the HDRS, and the SF-36 mental and physical component scores. Analyses were performed using an intent-to-treat principle that included all randomized patients and using an adequate treatment exposure subgroup, defined as completing at least 4 treatment sessions. The adequate exposure analysis was performed to give clinicians a better estimate of treatment effects for patients who receive an adequate course of treatment. Both HSCL-D-20 and SF-36 measures were treated as continuous response measures. For the HDRS, patients were classified as remitters (score <7) or nonremitters at week 11.[30]

The HSCL-D-20 was analyzed using a nonlinear piecewise random coefficient model with 2 random intercepts and a random slope fit to the individual patient data.[31,32] Random intercepts were defined at baseline and week 2. The second random intercept at week 2 enabled us to model a nonlinear response to treatment. Treatment effects were evaluated by comparing the slopes of the fitted function from weeks 2 through 11. Restricted maximum likelihood estimation was used to fit the random coefficients model to the data.[33] Subgroup analyses were performed for each diagnostic group. A generalized linear model with binomial response and logit link function was used to analyze the HDRS remission data. Six-week assessments were used for patients who discontinued treatment and were unavailable at the 11-week follow-up; complete data were available for 323 subjects (95.6%). Mixed-model analysis of covariance was used to analyze the SF-36 mental and physical component scores. Baseline SF-36 mental and physical component scores served as covariates in each respective analysis. Because baseline mental component scores interacted significantly with treatment assignment and diagnosis, these results are presented by tertiles of baseline functioning.

RESULTS

Patient Enrollment and Characteristics

Of the 629 patients who were assessed, 415 (66.0%) were eligible and randomized. Among the 214 patients assessed but not randomized, 17 (7.9%) were eligible but refused participation and 197 (92.1%) were ineligible (FIGURE 1). The most common reasons for ineligibility were no depression diagnosis (n=59), major depression (n=58), and depression with an HDRS score of less than 10 (n=43). No patients were excluded because of severe coexisting medical illness with limited life expectancy.

Patients were randomized to receive paroxetine (n=137), PST-PC (n=138), or placebo (n=140). Sociodemographic and clinical characteristics were similar for the 3 treatment groups (TABLE 1). The average age of participants was 71 years (range, 60-93 years), 172 (41.5%) were women, and 90 (21.8%) were from minority ethnic groups. Patients averaged 3.4 chronic medical conditions and scored a mean (SD) of 24.4 (12.8) on the Duke Severity of Illness Scale. The most common systems affected by illness were cardiovascular in 294 patients (70.8%), endocrine in 239 (57.6%), musculoskeletal in 194 (46.8%), and gastrointestinal in 123 (29.6%). Comorbid anxiety disorders were present in 121 participants (29.2%). Of the 415 subjects, 211 (51%) met criteria for dysthymia with the remaining 204 (49%) meeting criteria for minor depression. At baseline, depression severity was mild to moderate as shown by a median HDRS score of 13 (interquartile range, 12-15) and an HSCL-D-20 score of 1.4 (interquartile range, 0.9-1.9). Mental health functioning (median, 38.9; interquartile range, 32.4-45.1) and physical functioning (median, 37.4; interquartile range, 29.3-47.5) were markedly impaired. At baseline, patients with dysthymia and minor depression had similar levels of impairment on all scales.

Treatment Received and Follow-up

Of 415 patients randomized, 338 (81.4%) attended at least 4 treatment sessions, the minimum number considered to be an adequate test of treatment efficacy (Figure 1). A total of 311 (74.9%) completed all scheduled treat-

ment sessions. Patients discontinued treatment for the following reasons: adverse effects (n=20, 4.8%) and medical illness (n=8, 1.9%); 33 patients (7.7%) dropped out after randomization and did not attend any treatment sessions. Drop-out rates and reasons for discontinuation did not differ significantly between treatment groups.

Adherence to paroxetine and placebo was high. Patients reported taking 96% of scheduled doses. By the second treatment visit, 194 (77.0%) of 252 patients initiating treatment achieved the target dose of 20 mg/d, and by study end 228 (90.5%) had achieved the target dose. Seventy-three patients (55.3%) randomized to receive placebo were increased to tablets equivalent to 30 mg/d or more vs 43 (35.8%) who were taking paroxetine ($P<.01$). Treatment attendance was high among those assigned to the PST-PC therapy. Of those beginning treatment, 108 (83.1%) of 130 patients completed all 6 treatment sessions.

Outcomes: Intent to Treat

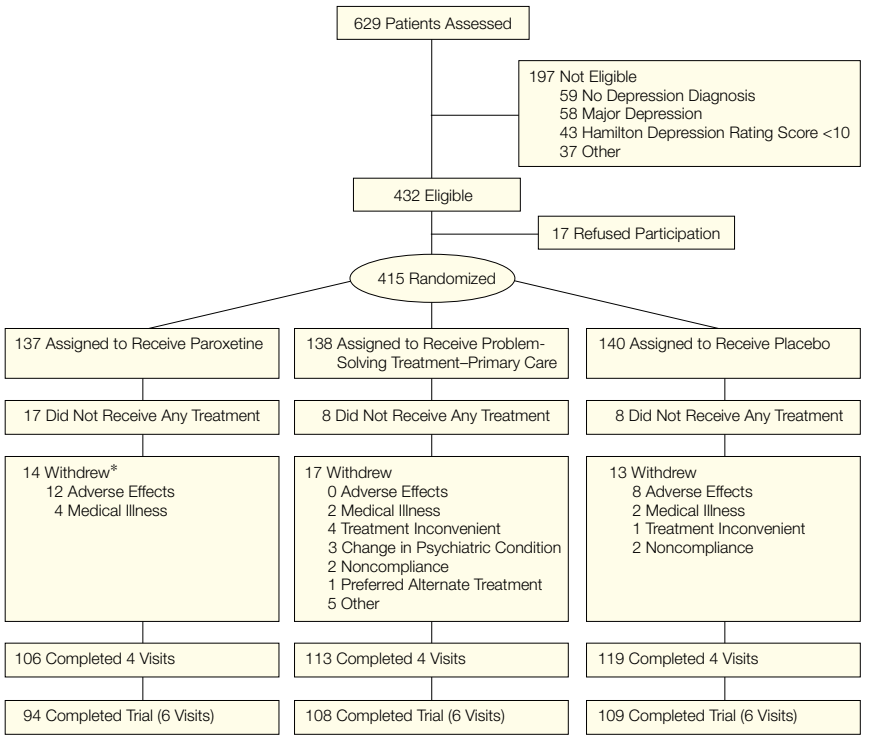
The primary outcome measure, specified a priori, was the change in depressive symptoms on the HSCL-D-20 score. All groups showed improvement over the 11-week treatment period, with mean (SE) HSCL-D-20 scores decreasing by an average of 0.61 (0.05) points for patients taking paroxetine, 0.52 (0.05) for those receiving PST-PC, and 0.40 (0.05) for those taking placebo and receiving clinical management. In the intent-to-treat analysis, paroxetine was more effective than placebo (difference in mean (SE) change at 11 weeks, 0.21 [0.07]; $P=.004$). Those in the PST-PC therapy did not differ significantly from placebo (difference in mean [SE] change in scores, 0.11 [0.13]; $P=.13$) or from paroxetine (difference in mean [SE] change in score, 0.09 [0.07]; $P=.17$). The rate of symptom resolution was similar and rapid during the first 2 weeks of treatment, slowing and diverging during weeks 2 through 11 (FIGURE 2). Compared with placebo, paroxetine showed a greater rate of symptom resolution during weeks 2 through 11. Although the overall mean improvement in symptoms for PST-PC did not differ from placebo, those in the PST-PC therapy showed more rapid symptom resolution during weeks 2 through 11 ($P=.01$). Depression diagnosis did not interact with treatment ($P=.36$), indicating a similar effect for dysthymia and minor depression (FIGURE 3 and FIGURE 4). The interaction term for clinical site and treatment was not significant, indicating similar effects across sites ($P=.25$).

Treatment effects on mental health functioning were complex, varying by diagnosis and baseline functioning (TABLE 2). For patients with dysthymia, mental health functioning improved by a mean (SE) of 5.8 (2.02) points more among those taking paroxetine than those taking placebo ($P=.01$) in patients at the highest tertile of baseline functioning, and by a mean (SE) score of 4.4 (1.74) points ($P=.03$) in those with intermediate baseline functioning. A 5-point difference on this scale is considered clinically significant.[34] For dysthymia patients treated with PST-PC, mental health function did not improve significantly more than those receiving placebo. Both paroxetine and PST-PC benefited mental health functioning in patients with minor depression in the lowest tertile of baseline functioning by a mean (SE) score of 4.7 (1.96) points for those treated with PST-PC and 4.7 (2.03) for those taking paroxetine compared with those taking placebo ($P=.02$). Compared with placebo, treatment with paroxetine or PST-PC did not affect physical functioning ($P=.65$).

Outcomes: Adequate Treatment

To give clinicians a better estimate of treatment effects for patients who receive an adequate course of treatment, we report results based on individuals completing at least 4 treatment sessions. The pattern and magnitude of improvement in self-reported symptoms on the HSCL-D-20 were similar to the intent-to-treat analysis. Patients treated

Figure 1. Participant Flow and Treatment Visits Completed



Asterisk indicates that 2 patients gave medical illness and adverse effects equal weight as reasons for withdrawal.

with paroxetine showed greater improvement than those taking placebo. Those treated with PST-PC did not differ overall from placebo plus clinical management or paroxetine but showed more rapid symptom resolution than those taking placebo during weeks 2 through 11.

Next, we compared the proportion of patients achieving remission using an HDRS of less than 7. Treatment effects varied significantly across the 4 sites and by diagnostic group, differences that were only slightly attenuated after adjustment for sex, severity of medical illness, and education. A test for the more complex interaction of site, treatment, and diagnosis was not significant ($P=.42$). For descriptive purposes, we report these results separately for each diagnosis and site (TABLE 3). Several points deserve comment. First, patients randomized to receive placebo had relatively high remission rates, 25 (40.3%) of 62 with dysthymia and 28 (49.1%) of 57 with minor depression. Second, 113 (51.6%) of 219 subjects did not remit with either depression-specific treatment. Third, PST-PC showed the greatest variability in remission rates across sites, ranging from 33.3% to 80% for dysthymia and 26.7% to 100% for patients with minor depression. Compared with placebo plus clinical management, PST-PC was highly effective at one site (Lebanon, Pa) for both dysthymia ($P<.001$) and minor depression ($P=.03$), but less effective at other sites on an absolute basis and relative to placebo treatment.

COMMENT

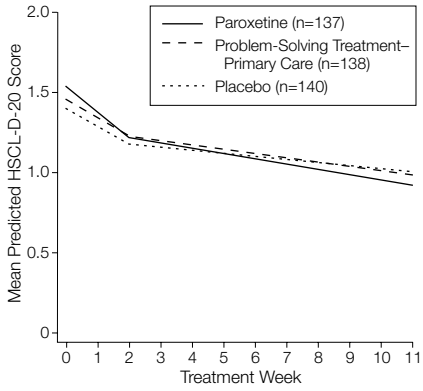
Evidence-based guidelines are available to direct primary care physicians in treating major depression. When implemented well, these guidelines improve patient outcomes.[26,35,36] For minor depression and dysthymia, evidence-based guidelines are unavailable because the evidence base is insufficient to develop recommendations. Furthermore, since existing trials typically have been conducted in relatively healthy, younger adults, treatment outcomes may differ substantially for older,

Table 1. Sociodemographic and Clinical Characteristics*

Characteristics	Paroxetine (n = 137)	Problem-Solving Therapy–Primary Care (n = 138)	Placebo (n = 140)	*P* Value
Age, mean (SD), y	71 (6.8)	71 (7.0)	71 (7.2)	.66
Female, No. (%)	53 (39)	56 (41)	63 (45)	.55
Ethnic background, No. (%)†				
Non-Hispanic white	113 (82.5)	104 (75.4)	106 (75.7)	.55
Latino	15 (11.0)	17 (12.3)	17 (12.1)	
Black	8 (6.0)	16 (11.6)	14 (10.0)	
Other	1 (1.0)	1 (1.0)	1 (1.0)	
Married, No. (%)	(52)	(52)	(54)	.95
Employed, No. (%)				
Full-time	(7)	(6)	(9)	.84
Part-time	(7)	(8)	(7)	
Median income, range, US $	15 000-20 000	15 000-20 000	15 000-20 000	.76
Median education, y	12	12	13	.89
Clinical characteristics				
Depression diagnosis, No. (%)				
Minor depression	(50)	(48)	(50)	.93
Dysthymia	(50)	(52)	(50)	
Hopkins Symptom Checklist-20 score, mean (SD)	1.4 (0.64)	1.4 (0.72)	1.4 (0.67)	.50
Hamilton Depression Scale score, mean (SD)	13.8 (3.04)	13.3 (2.56)	13.2 (2.44)	.19
Anxiety disorder, No. (%)				
Panic disorder	5 (3.7)	1 (0.7)	6 (4.3)	.21
Generalized anxiety disorder	18 (13.1)	24 (17.4)	24 (17.1)	.57
Anxiety not otherwise specified	12 (8.8)	14 (10.1)	17 (12.1)	.65
Duke severity of illness, mean (SD)	26.2 (13.13)	22.7 (12.57)	24.3 (12.48)	.08
Chronic medical conditions, mean (SD)	3.3 (1.44)	3.4 (1.39)	3.4 (1.38)	.59

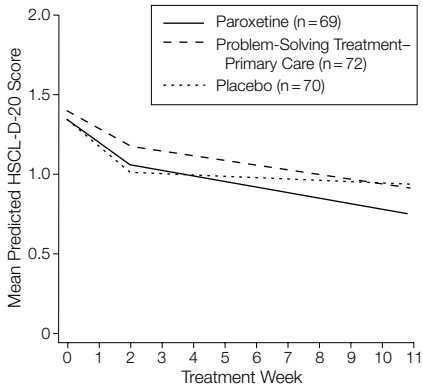
*Percentages may not add to 100 due to rounding.
†Ethnic background is missing for 2 patients.

Figure 2. Mean Hopkins Symptom Checklist Depression Scale (HSCL-D-20) Scores by Treatment Assignment



Estimated from random regression model.

Figure 3. Mean Hopkins Symptom Checklist Depression Scale (HSCL-D-20) Scores of Patients With Dysthymia

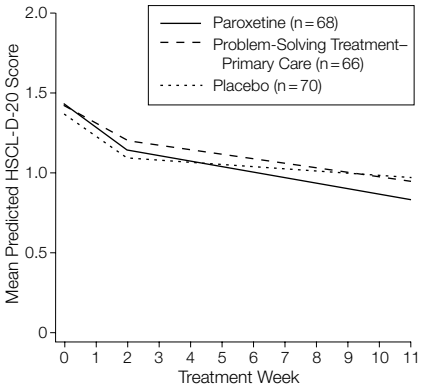


Estimated from random regression model.

more physically ill primary care patients. This primary care based study, with broad inclusion criteria to increase generalizability, sought to address this gap.

We found that treatment with paroxetine improved depressive symptoms to a greater degree and more rapidly than placebo plus clinical management. The positive effects of paroxetine on depressive symptoms were moderate and similar for dysthymia and minor depression. The similar effect may reflect our requirement that patients have 3 to 4 *DSM-IV* symptoms for at least 4 weeks and a Hamilton Depression score of at least 10 to meet minor depression criteria. In addition, diagnostic distinctions between minor depression and dysthymia may be less certain in primary care than those portrayed in the *DSM-IV* diagnostic manual. Although the difference in symptom improvement was relatively small, the more rapid symptom resolution was associated with a clinically and statistically significant improvement in mental health functioning for the majority of patients with dysthymia and for the most functionally impaired patients with minor depression. Considering effects on depressive symptoms and function, the positive effects of paroxetine were somewhat more consistent and stronger for dysthymia than minor depression. Overall, patients treated with PST-PC did not have significantly greater improvement but did show more rapid late-course resolution of symptoms than did patients treated with placebo plus clinical management. The PST-PC treatment approach led to functional improvement for fewer patients than paroxetine and showed significant variability across sites when comparing remission rates.

Figure 4. Mean Hopkins Symptom Checklist Depression Scale (HSCL-D-20) Scores of Patients With Minor Depression



Estimated from random regression model.

These results are particularly important because they are derived from an ethnically and socioeconomically diverse sample of older patients with multiple chronic coexisting medical illnesses, a group for which there is little treatment data. How do these findings fit with the extant literature? Two recent literature syntheses examined the efficacy of pharmacotherapy for dysthymia.[4,7,37] Overall, 26 trials compared an antidepressant with placebo. In aggregate, these trials found that antidepressant treatment is efficacious, increasing response rates significantly from 37% with placebo to 59% with active treatment. These response rates are greater than what was seen in our study. However, only 2 studies focused on dysthymia in older adults and only 2 included primary care settings. Compared with the current study, prior studies had significantly higher depressive symptoms at baseline and frequently excluded patients with chronic medical illness.[38-40] These differences are important because other studies have shown less definitive treatment effects in patients with milder symptoms and in patients with chronic medical illness. In the largest study of younger adults with similar baseline depression severity (HDRS ≈ 13), sertraline-treated patients showed improvements on the 13-item Hopkins Symptom Checklist Depression Subscale that were comparable with the improvements patients taking paroxetine in our study experienced.[41]

Controlled trials of psychological treatments for dysthymia are sparse. This is

Table 2. Effects on Mental Health Functioning: Mean Differences in Medical Outcomes Study Short-Form 36 (SF-36) Mental Component Scores at 11 Weeks

	Dysthymia		Minor Depression	
Baseline Mental Health Function†	Paroxetine vs Placebo	PST-PC vs Placebo	Paroxetine vs Placebo	PST-PC vs Placebo
High	5.8 (2.02)‡	3.6 (1.76)	0.2 (1.96)	1.4 (1.84)
Intermediate	4.4 (1.74)§	2.2 (1.59)	2.3 (1.65)	2.9 (1.60)
Low	2.7 (2.17)	0.4 (2.04)	4.7 (2.03)‡	4.7 (1.96)‡

*PST-PC indicates Problem-Solving Treatment–Primary Care. Data are mean (SE).
†The baseline SF-36 mental component high score is 45 or more; intermediate, 33 to 44; and low, 32 or less.
‡$P<.05$.
§$P<.005$.

Table 3. Remission Rates for Patients Attending 4 or More Treatment Sessions by Diagnosis and Site*

	Dysthymia (n = 182), No. (%)			Minor Depression (n = 156), No. (%)		
Site	Paroxetine	PST-PC	Placebo	Paroxetine	PST-PC	Placebo
Lebanon, Pa	8/12 (66.7)†	8/10 (80.0)†	3/10 (30.0)	5/10 (50.0)	8/8 (100)†	7/12 (58.3)
Pittsburgh, Pa	7/13 (53.8)	5/13 (38.5)	5/11 (45.5)	7/10 (70.0)	5/14 (35.7)	11/17 (64.7)
San Antonio, Tex	8/21 (38.1)	7/21 (33.3)	10/27 (37.0)	8/14 (57.1)	5/13 (38.5)	5/14 (35.7)
Seattle, Wash	3/11 (27.3)	12/19 (63.2)	7/14 (50.0)	6/15 (40.0)	4/15 (26.7)	5/14 (35.7)
All sites	26/57 (45.6)	32/63 (50.8)	25/62 (40.3)	26/49 (53.1)	22/50 (44.0)	28/57 (49.1)

*Remission was defined as a Hamilton Depression Rating Scale score of less than 7. PST-PC indicates Problem-Solving Treatment–Primary Care.
†$P<.05$ compared with placebo.

unfortunate since many patients, particularly in certain ethnic groups, prefer psychological treatments for depression.[15] Psychological treatments are particularly appealing in older individuals because they avoid adverse drug-drug and drug-disease interactions. Despite its inherent appeal, a review of the International Cochrane Collaboration's trials registry showed no controlled trials with appropriate controls.[42] A small, 16-week trial[43] comparing cognitive behavioral treatment with fluoxetine showed no difference between treatments. Our study is the first test, that we know of, to evaluate the effects of PST-PC on patients with dysthymia. The PST-PC approach has been proved efficacious for major depression and has several potential advantages in primary care.[17] These advantages include relatively few, brief sessions, compared with the typical 12 to 16 used for cognitive or interpersonal psychotherapy. In addition, PST-PC has been efficacious when used by nonphysicians, including nurses, which could increase its applicability in primary care.[18,44,45] How did it work for older adults with milder forms of depression? When results are combined across all sites, PST-PC was not consistently better than placebo plus clinical management. However, the response to PST-PC was highly variable with particularly strong effects at 1 of the 4 sites. Although a variety of factors may explain site variability, the most plausible is varying experience and skill among the therapists. At the site with the best response, the primary therapist was a behavioral therapist with a doctorate in philosophy who had a such an affinity for this therapy that he has become a trainer of other therapists.

The evidence base for treating minor depression is more limited than for dysthymia. Only 2 studies have compared antidepressants with placebo: one study showed no effect for amitriptyline[38]; the other study showed small but significant effects for minaprine in geriatric patients with "prolonged depressive reaction."[46]Two studies comparing multifaceted interventions (including pharmacotherapy) to usual primary care for depression showed important positive effects for the subgroup with major depression but not for minor depression.[26,47] Both the multimodal intervention and usual-care treatments produced very high, 65% to 70% response rates, for patients with minor depression. In addition, 2 trials[44,48] evaluated psychosocial interventions. Miranda and Munoz[48] evaluated 8 sessions of cognitive behavioral therapy in an ethnically diverse, urban, primary care population. At 4 months' postintervention in the subgroup with minor depression, cognitive behavior therapy showed a delayed positive effect that persisted to the 12-month follow-up visit.[48] An underpowered trial in family practice showed positive but statistically insignificant effects of a telephone-based problem solving treatment.[44] In our study, PST-PC showed inconsistent effects for minor depression with a 100% remission rate at 1 site but poor efficacy at the other 3 sites. The more rapid symptom improvement during weeks 2 through 11 was encouraging, and it will be interesting to see if patients with minor depression show a delayed treatment effect similar to that observed by Miranda and Munoz.

Our study has potential treatment implications for primary care clinicians. Although depression-specific psychotherapies are proved effective for major depression, we cannot yet recommend PST-PC for older persons with minor depression or dysthymia because of our weak, inconsistent positive effects on outcomes and the lack of other convincing studies. Consistent with trials in younger and more symptomatic patients, pharmacotherapy with a serotonin reuptake inhibitor was effective for older patients with dysthymia, improving both depressive symptoms and function. We recommend pharmacotherapy as first-line treatment but caution that the benefits may be more modest in older persons with relatively low symptom severity.

Because treatment effects were less consistent for minor depression, our data suggest that clinicians should consider antidepressant treatment only for those with more severe functional impairment and a 4- to 6-week trial of watchful waiting for all others. This is not a recommendation to do nothing. We underscore the fact that placebo-treated participants received face-to-face attention of a physician who was focusing on their depressive symptoms 6 times over an 11-week period, as well as the attention of their clinical evaluator and of other clinic personnel. Clinicians should support, educate, and reevaluate all patients, probably in several face-to-face contacts before concluding either that the depression is resolved or there is a need for further intervention. For individuals who worsen or have persistent symptoms and increasing functional impairment, a trial of antidepressant treatment should be considered. Finally, these findings reinforce the importance of a careful diagnostic assessment that evaluates the severity of depressive symptoms and the degree of functional impairment when making treatment decisions for older primary care patients.

Author Affiliations: The South Texas Veterans Affairs Health Care System, Audie Murphy Division and Divisions of General Internal Medicine (Drs Williams and Cornell) and Geriatrics (Dr Cornell), University of Texas Health Science Center at San Antonio; Departments of Community and Family Medicine (Drs Barrett, Oxman, and Sengupta) and Psychiatry (Dr Oxman), Dartmouth Medical School, Hanover, NH; Department of Psychiatry, Western Psychiatric Institute and Clinic, University of Pittsburgh, Pittsburgh, Pa (Dr Frank); and Department of Psychiatry and Behavioral Sciences, University of Washington, Seattle (Drs Katon and Sullivan).

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