Treatment of Dysthymia and Minor Depression in Primary Care

A Randomized Trial in Patients Aged 18 to 59 Years

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■ OBJECTIVE We evaluated the effectiveness of paroxetine and Problem-Solving Treatment for Primary Care (PST-PC) for patients with minor depression or dysthymia.

■ STUDY DESIGN This was an 11-week randomized placebo-controlled trial conducted in primary care practices in 2 communities (Lebanon, NH, and Seattle, Wash). Paroxetine (n=80) or placebo (n=81) therapy was started at 10 mg per day and increased to a maximum 40 mg per day, or PST-PC was provided (n=80). There were 6 scheduled visits for all treatment conditions.

■ POPULATION We included a total of 241 primary care patients with minor depression (n=114) or dysthymia (n=127). Of these, 191 patients (79.3%) completed all treatment visits.

■ OUTCOMES We measured depressive symptoms using the 20-item Hopkins Depression Scale (HSCL-D-20). Remission was scored on the Hamilton Depression Rating Scale (HDRS) as less than or equal to 6 at 11 weeks. We measured functional status with the physical health component (PHC) and mental health component (MHC) of the 36-item Medical Outcomes Study Short Form.

■ RESULTS All treatment conditions showed a significant decline in depressive symptoms over the 11-week period. There were no significant differences between the interventions or by diagnosis. For dysthymia the remission rate for paroxetine (80%) and PST-PC (57%) was significantly higher than for placebo (44%, P=.008). The remission rate was high for minor depression (64%) and similar for each treatment group. For the MHC there were significant outcome differences related to baseline level for paroxetine compared with placebo. For the PHC there were no significant differences between the treatment groups.

see COMMENTARY *about this article by Donald E. Nease, Jr, MD,* **"Dysthymia in Primary Care: Who Needs Treatment and How Do We Know?"** ON PAGE 413

PRACTICE POINTS

- For patients with dysthymia, pharmacotherapy should be used as a first-line treatment.
- Also consider, for patients with dysthymia, Problem-Solving Treatment for Primary Care (PST-PC), if available, as a treatment alternative to medication, although further research with this treatment would be useful to better understand for which patients it is particularly effective.
- For patients with minor depression, use watchful waiting with regular face-to-face contact as the initial treatment of choice. Use an active treatment (eg, medication or a psychologic treatment such as PST-PC) for those patients with persistent symptoms or increasing severity of symptoms.

■ CONCLUSIONS For dysthymia, paroxetine and PST-PC improved remission compared with placebo plus nonspecific clinical management. Results varied for the other outcomes measured. For minor depression, the 3 interventions were equally effective; general clinical management (watchful waiting) is an appropriate treatment option.

■ KEY WORDS Depressive disorder; monor depression [non-MESH]; dysitymia [non-MESH]; paroxetine; behavioral treatment [non-MESH]. depression; behavioral treatment paroxetine. *(J Fam Pract 2001; 50:405-412)*

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Dysthymia and minor depression are common depressive disorders in patients in primary care settings.[1-5] Together with major depression, these 3 disorders account for the vast majority of depressive illness present in primary care. Although the level of depressive symptomatology for these patients is less than that for major depression, these disorders are accompanied by significant morbidity,[4-6] and their impact on the health delivery system is considerable.[1,7-9] However, there are relatively few controlled trials in primary care examining the effectiveness of recommended treatments for these disorders.[10-13] Studies in this area have typically involved small groups of patients, and generalizability was limited because of such factors as stringent entrance criteria that would exclude many primary care patients with these disorders. The need for treatment outcome data for the majority of these patients seen in primary care was a principal reason for our study.

Antidepressant medications, particularly the selective serotonin reuptake inhibitors, are commonly used for treatment of depression in primary care.[14,15] Support and watchful waiting make up another common method of treatment.[14] Psychologic treatments that customarily require referral to mental health providers have also been used, although stigma, fear of loss of confidentiality, increased cost, limited access in some localities, and local cultural preferences have limited their use as a treatment option. In part to address these issues a behaviorally based psychologic treatment—Problem-Solving Treatment for Primary Care (PST-PC)—was developed in the United Kingdom.[16] This treatment was relatively brief and could be applied in the primary care setting. In studies involving patients with major depression in the United Kingdom, the treatment had high patient acceptance and an effectiveness comparable with antidepressants,[17,18] making it an attractive alternative when patients did not want pharmacotherapy or if such treatment was contraindicated for medical reasons. For dysthymia and minor depression there are no studies specifically examining the effectiveness of PST-PC, but this treatment has potential utility for those conditions.

In 1995 the MacArthur Foundation and the Hartford Foundation provided funding for a comparative treatment trial. The project's development and methodology have been outlined in an earlier report.[19] Four sites recruited patients 60 years and older; the results of that study have been reported elsewhere.[20] Two sites recruited patients aged 18 to 59 years. We present outcome data for this younger group.

METHODS

Patients aged 18 to 59 years were recruited from primary care settings at 2 participating sites (Lebanon, New Hampshire, and Seattle, Washington). To be eligible, patients had to meet *Diagnostic and Statistical Manual of Mental Disorders, third edition, revised* (*DSM-III-R*) criteria for dysthymia,[21] or specified criteria for minor depression and score 10 or higher on the 17-item Hamilton Depression Rating Scale (HDRS).[22] To receive a diagnosis of minor depression, 3 of the 9 *DSM-III-R* symptoms for major depression (1 of these had to be depressed mood or anhedonia) had to be present for at least 4 weeks. Depression diagnoses were made by a research psychiatrist using the Primary Care Evaluation of Mental Disorders (PRIME-MD), a diagnostic instrument designed for use in primary care.[23]

Design

Patients who met the entrance criteria and consented to the study were randomly assigned to paroxetine, placebo, or PST-PC using a computer-generated random allocation table. Randomization was blocked and stratified by site and by diagnosis. Treatment assignments were held by a local pharmacist and were available to study personnel only in the event of a medical emergency.

Treatment

Patients were scheduled for 6 treatment sessions occurring over 11 weeks. The treatment sessions took place in the general medical setting. Medication visits were 10 to 15 minutes each, were conducted by psychiatrists or psychiatric residents, and consisted of medication dose titration, symptom assessment, a review of adverse effects, and general support. Specific psychologic treatments or counseling were prohibited. Paroxetine and placebo were given in a double-blind fashion. Paroxetine was initiated at 10 mg per day and increased at week 2 to the target dose of 20 mg. At week 4 or 6, the dose could be further increased to 30 mg per day and at week 6 or 8 to 40 mg if there had been limited clinical improvement. Placebo was titrated in an identical fashion.

The PST-PC therapists were PhD psychologists. All therapists received training in PST-PC. The patients received 6 PST-PC sessions, lasting approximately 1 hour for the first visit and 30 minutes for each subsequent visit. Antidepressant medication was prohibited for the PST-PC group.

Assessments

Sociodemographic and clinical information was collected at baseline. Coexisting medical illness was evaluated by chart review using the Duke Severity of Illness Checklist.[25] Outcome measurements included self-report and interviewer rated instruments; the latter were completed blind to the patient's treatment assignment. There were 3 principal outcome measures. One was the 20-item Hopkins Depression self-report scale[26] (HSCL-D-20) consisting of the 13-item depression scale and 7 additional depression-related items added to increase responsiveness.[27] The HSCL-D-20 score was obtained at baseline and at each

treatment visit. The other principal outcome measures were a 17-item Hamilton Depression Rating Scale (HDRS), used to determine remission status, and the 36-item Medical Outcomes Study Short Form (SF-36), that provided 2 functional status measures—a mental health component (MHC) and a physical health component (PHC).[28,29] Both these measures were obtained at baseline and at 6 and 11 weeks.

Data Analysis

For continuous demographic and clinical data, we used parametric and nonparametric analysis of variance 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. For all analyses, design variables (specified in advance) included diagnosis, treatment provided, and site.

We analyzed the HSCL-D-20 using a nonlinear piece-wise random coefficient model with 2 random intercepts and a random slope fit to the individual patient data.[30] Random intercepts were defined at baseline and at week 2. The 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 week 2 through week 11. Restricted maximum likelihood estimation was used to fit the random coefficient model to the data.[31] The Tukey-Kramer multiple comparison procedure[32] was used to adjust P values for multiple comparisons. For the HSCL-D-20, analyses were performed both on an intention-to-treat group (full sample) and on an adequate treatment exposure subgroup defined as patients who completed at least 4 treatment sessions.

For the HDRS data, patients were classified as remitted (HDRS ≤6) or as nonremitters[33] at week 11 on the basis of previously reported normative data. The analytic method we used was a generalized linear model with binomial response and logit link function; adjustment of P values for multiple comparisons was by the Sidak procedure.[32] Six-week assessment scores were carried forward for patients for whom HDRS data were unavailable at the 11-week follow-up. The analysis reported was based on the adequate treatment exposure patient sample. This analysis gives clinicians an estimate of treatment effects for patients who actually received the treatment.

For the SF-36 data, analyses were performed both on the intention-to-treat group and the adequate exposure subgroup. The analytic method used was a mixed model analysis of covariance. Baseline SF-36 MHC and PHC component scores served as covariates in each respective analysis.

RESULTS

Patient Enrollment and Characteristics

Of the 407 patients who received a study assessment, 241 (59%) were eligible and were randomized. Of those patients assessed but not randomized, 22 were eligible but refused participation, and 144 were ineligible (Figure 1). The most common reasons for ineligibility were major depression (n=77), depression with an HDRS score of less than 10 (n=26), and no depression diagnosis (n=21).

Patients were randomized to paroxetine (n=80), PST-PC (n=80), and placebo (n=81). Sociodemographic and clinical characteristics were similar for the 3 treatment groups (Table 1). Comorbid anxiety disorders assessed by the PRIME-MD at baseline were present in approximately 25% of the

FIGURE 1

PARTICIPANT FLOW AND TREATMENT VISITS COMPLETED: PATIENTS AGED 18 TO 59 YEARS

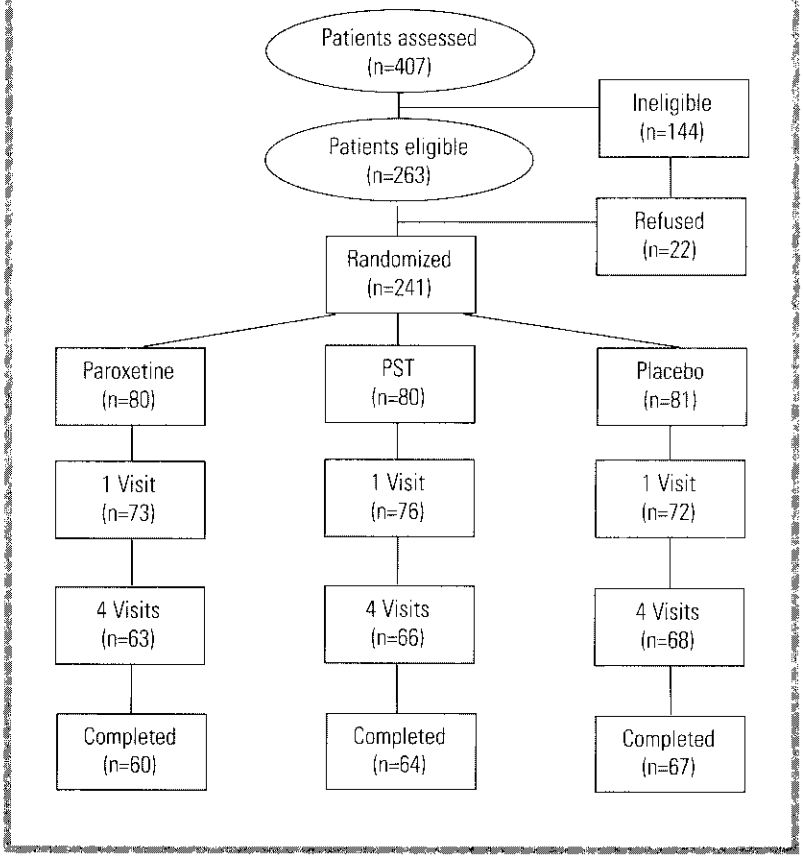


TABLE 1

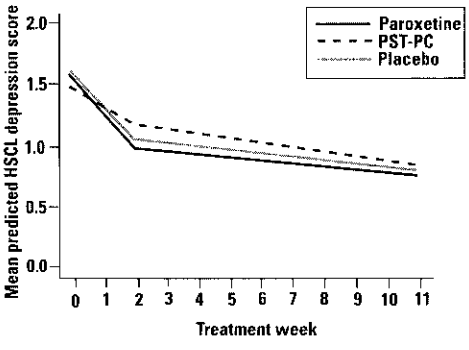
SOCIODEMOGRAPHIC AND CLINICAL CHARACTERISTICS, PATIENTS AGED 18-59 YEARS

	Total Sample (n=241)	Paroxetine (n=80)	PST-PC (n=80)	Placebo (n=81)	*P*
DEMOGRAPHICS					
Age, mean	44.1	45.2	44.5	42.6	.26
Women, %	63.9	57.5	67.5	66.7	.34
Ethnic background, %					
Non-Hispanic white	90	90	90	89	
Asian Pacific	3	3	4	2	
African American	3	5	1	4	
Native American	3	1	4	4	
Hispanic	<1	1	0	1	
Marital status, % married	53.1	46.3	56.3	56.8	.32
Employment status, %					
Full time	61.3	57.5	67.5	58.8	
Part time	18.3	20.0	16.3	18.8	
Median income, dollars	25,000-35,000	25,000-35,000	25,000-35,000	25,000-35,000	.32
Median years education	14	14	14	14	.88
CLINICAL CHARACTERISTICS					
Depression diagnosis, %					
Minor depression	47.3	47.5	46.3	48.1	
Dysthymia	52.7	52.5	53.8	51.9	
Comorbid anxiety disorder, %					
Panic disorder	7.1	10.0	6.3	4.9	.43
General anxiety disorder	23.2	21.3	22.5	25.9	.77
Anxiety NOS	14.9	10.0	20.0	14.8	.21
HSCL 20, mean	1.6	1.6	1.5	1.6	.63
HDRS, mean	14.2	13.9	14.4	14.3	.55
SF-36 MHC, mean	33.7	34.3	34.6	32.1	.24
SF-36 PHC, mean	47.1	45.3	48.4	47.7	.25
Duke Severity of Illness, mean	13.3	14.3	13.5	12.3	.63
Chronic medical conditions, mean	2.1	1.9	2.1	2.2	.41

PST PC denotes Problem Solving Treatment for Primary Care; NOS, not otherwise specified; HSCL, the 20-item Hopkins Depression Scale; HDRS, the Hamilton Depression Rating Scale; SF-36 MHC, the mental health component of the 36-item Medical Outcome Study Short Form; SF-36 PHC, the physical health component of the 36-item Medical Outcome Study Short Form.

FIGURE 2

PREDICTED MEAN OF HOPKINS DEPRESSION SCALE SCORES, BY TREATMENT ASSIGNMENT FOR PATIENTS 18 TO 59 YEARS (N=241)



PST PC denotes Problem Solving Treatment for Primary Care.

patients but with no significant difference in prevalence across the 3 treatment groups. Depression severity was mild to moderate as reflected by a mean HDRS of 14.2 (standard deviation [SD]=3.33) and mean HSCL-D-20 of 1.6 (SD=0.65). On the SF-36, mental health functioning was more impaired (MHC mean=33.7; SD=10.2) than physical health functioning (PHC mean=47.1; SD=12.1). At baseline, there were no significant differences between patients with dysthymia and those with minor depression on any of these 4 outcome measure scales.

Treatment Received and Follow-Up

Of the 241 patients randomized, 197 (81.7%) attended at least 4 treatment sessions (Figure 1); 191 (79.3%) completed all scheduled treatment sessions. Twenty patients (8.3%) did not attend any treatment sessions; they dropped out after randomization. Of these 20 patients, 16 (80%) were assigned to paroxetine or placebo; 4 (20%) were assigned to PST-PC. Subsequently, 6 patients (2.4%) discontinued treat-

ment for adverse effects; all of these were in the paroxetine group. One patient also in the paroxetine group discontinued because of medical illness. Twenty-three patients (9.5%) with at least 1 treatment visit discontinued for a variety of other reasons, such as relocation, self-medication, or because they felt they were not getting better.

Adherence to paroxetine and placebo was high. By the second treatment visit, 85% of patients initiating treatment achieved the target dose of 20 mg (2 pills) per day (81% of those receiving paroxetine, 89% receiving placebo). By study end, 94% had achieved the target dose or higher. Of patients who came for at least 1 visit, more patients randomized to placebo were increased to 40 mg per day (21/72, 29.2%) than those randomized to paroxetine (10/73, 13.7%; P=.023). For patients randomized to PST-PC, treatment attendance was high. Of those beginning treatment, 84.2% (64/76) completed all 6 treatment sessions.

TABLE 2

REMISSION RATES (HDRS ≤6) FOR PATIENTS ATTENDING 4 OR MORE TREATMENT SESSIONS, BY DIAGNOSIS AND SITE

Diagnosis and Site	Paroxetine No. (%)	PST-PC No. (%)	Placebo No. (%)	P
DYSTHYMIA (n=108)				
Lebanon, NH	17/17 (100.0)	8/16 (50.0)	10/18 (55.6)	.003
Seattle, Wash	11/18 (61.1)	13/21 (61.9)	6/18 (33.3)	.143
Overall	28/35 (80.0)	21/37 (56.8)	16/36 (44.4)	.008
MINOR DEPRESSION (n=89)				
Lebanon, NH	10/15 (66.7)	8/13 (61.5)	13/18 (72.2)	.820
Seattle, Wash	7/13 (53.9)	11/16 (68.8)	8/14 (57.1)	.683
Overall	17/28 (60.7)	19/29 (65.5)	21/32 (65.6)	.906

HDRS denotes Hamilton Depression Rating Scale; PST-PC, Problem-Solving Treatment for Primary Care; NH, New Hampshire; Wash, Washington.

Outcomes

HSCL-D-20

One principal outcome measure was change in depression level on the HSCL-D-20 scale. In the intention-to-treat analysis, all treatment groups showed significant improvement over the 11-weeks (P <.001; Figure 2). The average mean change was 0.88 (SE=0.08) for paroxetine, 0.79 (0.09) for PST-PC, and 0.85 (0.09) for placebo. For paroxetine and for placebo, the rate of symptom resolution was similar and rapid during the first 2 weeks of treatment: 0.60 (.06) and 0.56 (.06), respectively; from week 2 to week 11 it slowed and remained similar: paroxetine, 0.28 (.06); placebo, 0.29 (.07). For PST-PC in the first 2 weeks, the rate of symptom resolution was slower 0.36 (.06) compared with paroxetine or placebo, but it was more rapid from week 2 through week 11; 0.43 (.07).

In this overall analysis, from baseline to 2 weeks there were significant differences in outcome by site (P=.006) and by treatment group (P=.007) but not by diagnosis (P=.497). For this time period the site by treatment group interaction was marginal (P=.101). Lebanon accounted for the majority of these treatment differences. At that site, from baseline to week 2 the improvement was significantly more rapid for paroxetine (P=.003) and for placebo (P=.016) compared with PST-PC. When outcome was examined from week 2 to week 11, there were no significant differences at the .05 level, although there was a trend toward the earlier pattern of differences by site (P=.104) and by treatment group (P=.190), with PST-PC marginally better than paroxetine (P=.090) and placebo (P=.149; Figure 2). On this measure diagnostic group again showed no relationship to outcome (P=.718). When the overall outcome (baseline

TABLE 3

EFFECTS ON MENTAL HEALTH FUNCTIONING: CHANGES IN SF-36 MENTAL COMPONENT SCORES OVER TIME FOR 3 INTERVENTION GROUPS (INTENTION-TO-TREAT SAMPLE)

Baseline Mental Health Function*	Paroxetine Mean Change (SE)†	P‡	PST-PC Mean Change (SE)†	P	Placebo Mean Change (SE)†	P
High	+1.59 (1.31)	.832	+3.24 (1.45)	.249	+1.98 (1.47)	.761
Intermediate	+4.25 (1.13)	<.003	+3.16 (1.34)	.174	+1.44 (1.15)	.810
Low	+7.36 (1.50)	<.001	+3.06 (1.63)	.416	+0.81 (1.36)	.991

SF-36 denotes 36-item Medical Outcomes Study Short Form; PST-PC denotes Problem Solving Treatment for Primary Care.
*Baseline SF-36 mental component for high = ≥40; intermediate=28-39; low = ≤27.
†Change in mental health functioning score week 6 to 11 controlled for baseline mental health functioning level. Increase in score means improved function.
‡Student t test, corrected for multiple comparisons using Tukey-Kramer procedure.

to week 11) was examined, there were no significant differences between the 3 intervention groups.

When these analyses were repeated on the adequate treatment exposure group of patients, the results were essentially similar. There was significant reduction in symptomatology for all 3 treatment groups, but from baseline to week 11 there were essentially no differences in the amount of this reduction between the 3 treatment groups.

Remission over 11 Weeks as Measured by HDRS

The proportion of patients achieving remission status (HDRS score ≤6) was examined using the 197 patients with adequate treatment exposure (4 or more visits). This group was compared with the 44 patients with less than 4 visits on baseline variables. There were no significant differences except for education: 54.5% of those with fewer than 4 visits had 13 or more years of education compared with 75.6% of those with 4 or more visits (P=.005).

In the generalized linear model used to analyze the HDRS remission data, diagnostic group, treatment group, site, and all the interactions (diagnosis by treatment, site by treatment, site by diagnosis, and site by diagnosis by treatment) were entered into the analysis. There was a significant site by treatment group interaction (P=.001) and a significant diagnostic group by treatment group interaction (P=.005). To understand these interaction terms, results were examined separated by diagnosis and by site. For dysthymia at the Lebanon site, there were 2 significant effects: paroxetine had a better outcome than placebo (P <.001) or PST-PC (P<.001). For dysthymia at the Seattle site, both paroxetine and PST-PC had marginally better outcomes than placebo (P=.093 and P=.073, respectively). To display these findings, bivariate analyses were carried out for each diagnosis by site (Table 2). Table 2 also shows the remission rates when patients with each diagnosis were combined across sites. For dysthymia, the remission rates were 80% for paroxetine, 56.8% for PST-PC, and 44.4% for placebo (P=.008). For minor depression, the overall remission rate was high (64.0%), and it was similar for each treatment group: 60.7% for paroxetine, 65.5% for PST-PC, and 65.6% for placebo (P=.906).

SF-36 Mental Health Component and Physical Health Component Scales

For the SF-36 MHC, on the intention-to-treat sample there was a significant baseline level by treatment group by time interaction (P=.006). Baseline MHC was then used as a covariate by dividing patient groups into tertiles on the basis of the baseline scores (Table 3). Change from week 6 to week 11 was examined after controlling for baseline MHC within each group. With paroxetine there was significant improvement for the more impaired MHC group, +7.4 (SE=1.5), P <.001; and for the intermediate group, +4.3 (1.1), P <.003. For PST-PC, the absolute change for each MHC group was essentially similar: +3.1 (1.6) for the low group, +3.2 (1.3) for the intermediate group, and +3.2 (1.5) for the high group. These changes were not significant at the .05 level. For placebo, the amount of change was lower than that for the 2 active interventions; none of those changes approached statistical significance.

Results using the adequate exposure sample for the SF-36 MHC were similar overall to those obtained on the intention-to-treat analysis.

For the SF-36 PHC analyses there were no significant differences between any of the treatment groups.

DISCUSSION

The findings from this study provide information about treatment response for these 2 diagnostic conditions, dysthymia and minor depression, in primary care patients. There are few data from other studies with which to compare these results; most treatment outcome results for these disorders come from patients treated in psychiatric settings. One study that does provide such data used a similar design and methodology on older patients (60 years and older) and was done in parallel with this study.[20] In that study, the patients showed improvement on all the interventions for the measures examined. However, whether outcome with the active treatments showed a significant difference over placebo plus nonspecific clinical management is clearly of interest. For this question, the results are more complex, with variations in outcome by site, diagnosis, and treatment for both age groups, depending on the measure used. The most easily interpreted results are the remission results obtained using the HDRS. These are also the reported results when all individuals received an adequate exposure to the treatment (4 or more visits). For dysthymia in the patients aged 18 to 59, there was an overall gradient with the highest recovery rate obtained for paroxetine, the next highest for PST-PC, and the lowest for placebo. The same pattern was evident for dysthymia in the patients aged 60 years and older; higher remission rates were obtained for both paroxetine and PST-PC than placebo.

When change was measured by decline over the 11-week trial on the HSCL-D-20 as the outcome variable, in the patients 60 years or older, those taking paroxetine had a significantly greater decline compared with those taking placebo at 11 weeks and a greater rate of decline from week 2 to 11. Patients receiving PST-PC did not show a significantly greater symptom reduction than those on placebo at 11 weeks, but they did show a significantly more rapid symptom reduction in weeks 2 to 11. For patients aged 18 to 59 years, there were no significant differences between the active treatments and placebo on this measure.

Results obtained using the SF-36 MHC are difficult to compare between the age groups because diagnosis showed a significant improvement in the patients 60 years and older but not in the patients aged 18 to 59 years. Dysthymic patients taking paroxetine who were 60 years and older with higher baseline MHC (less impaired) did significantly better at 11 weeks compared with those taking placebo; those receiving PST-PC did better but not significantly so. Patients with minor depression and low baseline MHC (more impaired) improved significantly more on both paroxetine and PST-PC compared with placebo. The patients aged 18 to 59 years showed a different pattern with diagnosis not relating to outcome, but all patients with low or intermediate baseline MHC improved significantly on paroxetine. Improvement amount on PST-PC fell between paroxetine and placebo, but was not significant. These results are difficult to interpret except to note that paroxetine did have a beneficial but modest effect in both age groups for some patients.

Taking an overview of the findings from both studies, it is worth noting that there are some consistent patterns of outcome related to treatment across the 2 age groups. In general, those patients taking paroxetine showed a greater improvement compared with placebo on one or more of the measures used. Similarly for PST-PC, on some measures there was a significant difference compared with placebo, although these results were more variable than those obtained with paroxetine. The greatest PST-PC versus placebo differences were present on the remission analyses; for both age groups, diagnosis was an important predictor with the best remission results obtained for patients with dysthymia. In both age groups, for those with minor depression there was a higher placebo response and almost no significant differences between either active treatment and placebo.

Strengths and Limitations

Our study has several strengths. It is focused on those depressive disorders, dysthymia and minor depression, that are common in primary care and are treated most often in that setting. The inclusion criteria were broad, permitting results to be generalizable to the majority of patients with these disorders presenting in primary care. The treatments were provided in the primary care setting, emphasizing their potential practicality for primary care practice. For the medication intervention, this placebo-controlled trial contributes to the scientific knowledge base concerning treatments in primary care. There are relatively few such controlled trials for dysthymia and even fewer for minor depression.

This is the first treatment trial outside of the United Kingdom in which the behavioral treatment PST-PC was used. As in the United Kingdom, PST-PC had a high patient acceptance rate; 80% of the patients assigned to it completed all 6 visits and 87% of those coming for one visit completed 4. On some outcome measures, it had effectiveness similar to paroxetine and greater than placebo plus clinical management, although it showed greater variability by site than paroxetine. In this trial, PST-PC therapists varied on the level of previous experience with behavioral therapy treatment, overall experience, and number of patients treated with PST-PC, all variables that may have related to their skill in delivering the treatment. Analyses are in progress to examine the effects of these and other variables on PST-PC outcome. The results reported here indicate PST-PC has promise but cannot be considered an established treatment alternative to antidepressants in depressed primary care patients, as it is in the United Kingdom.

Our study also has shortcomings. The placebo-controlled condition involved contact with a clinician for 6 visits over the 11-week trial, considerably more than usually takes place in primary care. Whether this nonspecific clinician contact related to the relatively high improvement (remission rates) for placebo, particularly for those with minor depression, cannot be assessed in our study. In retrospect, including a true "treatment as usual" group making 2 to 3 in-person visits over 11 weeks would have clarified these results. Also, the clinical significance of the amount of symptom reduction observed in the scale analyses (SF-36-MHC, HSCL-D-20) is difficult to establish. The amounts of those reductions were modest, even when statistically significant. For clinical significance, one must rely primarily on the remission analyses that were based on those patients receiving adequate exposure to the treatments, not an intention-to-treat group.

Further Research

Variation in outcome by site was a problem in this data, as it was in the group of patients 60 years and older. Further analyses have taken place, to be reported in separate publications,[35,36] in an attempt to examine the effect of other variables, such as demographics, level of medical comorbidity, or personality variables such as neuroticism. The findings we reported on patients aged 18 to 59 years and those reported elsewhere for the patients 60 years and older are examining only the effects of diagnosis, treatment received, and site. The effect, if any, of various moderator variables was not examined but will be in these later reports.

CONCLUSIONS

Evidence-based guidelines are available to direct primary care physicians' treatment for major depression, and when implemented well, they improve patient outcomes.[37,38,57] For the treatment of minor depression and dysthymia, evidence-based guidelines are unavailable, because the evidence base is

insufficient to develop recommendations.

Our results showed that paroxetine andto a lesser degree PST-PC improved remission of dysthymia more than the use of placebo plus nonspecific clinical management. Results varied for the other outcomes measured. For minor depression, the 3 interventions (paroxetine, PST-PC, and placebo) were equally effective, so general clinical management is an appropriate treatment option.

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