

Duloxetine Treatment for Role Functioning Improvement in Generalized Anxiety Disorder: Three Independent Studies

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Objective: Generalized anxiety disorder (GAD) is associated with impaired role functioning and diminished well-being. The present work examined the efficacy of duloxetine treatment for improving functional outcomes for patients with GAD in 3 independent clinical studies.

Method: Studies were randomized, double-blind, placebo-controlled multicenter trials conducted in adult outpatients with DSM-IV–defined GAD. One study compared 9-week fixed-dose treatment with duloxetine 60 or 120 mg (N = 168 and N = 170, respectively) with placebo (N = 175). The other 2 studies compared 10-week flexible-dose treatment with duloxetine 60–120 mg (study 2, N = 168; study 3, N = 162) with placebo (study 2, N = 159; study 3, N = 161). The main functional outcome measure for each study was the Sheehan Disability Scale (SDS). Additional measures were the Quality of Life Enjoyment and Satisfaction Questionnaire Short Form and the European Quality of Life 5 Dimensions. The 3 studies were conducted in the time period from June 2004 to November 2005.

Results: Duloxetine-treated patients improved significantly more than placebo-treated patients on SDS global functioning (study 1, $p \leq .001$; studies 2 and 3, $p \leq .01$) and SDS work, social life, and family/home responsibility scores (p values range from $\leq .05$ to $\leq .001$). At treatment endpoint, a greater percentage of duloxetine-treated patients had obtained SDS global functioning scores in the normative range than placebo-treated patients (p values range from $\leq .05$ to $\leq .001$). Duloxetine-treated patients also reported greater increases in quality of life, well-being, and health compared with the placebo group on the other functional measures (p values range from $\leq .05$ to $\leq .001$).

Conclusions: Duloxetine consistently reduced role functioning disabilities associated with GAD and enhanced patients' quality of life and well-being in 3 independent clinical studies.

Clinical Trials Registration: ClinicalTrials.gov identifiers NCT00122824 (study 1) and NCT00122850 (study 3). Study 2 was completed prior to the requirement to post trials at initiation and does not have a registration number.

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Although worry is a ubiquitous phenomenon, the process of worry becomes pathologic in the illness of generalized anxiety disorder (GAD), where excessive and uncontrollable worry results in multiple psychic and physical symptoms. Essential to the diagnosis of GAD, significant personal distress or role impairment also must be experienced by the person.¹ Recognizing these different aspects of the GAD illness, clinicians are increasingly concerned with the improvement of role functioning and quality of life along with the reduction of anxiety symptomatology as important treatment outcomes.²

In epidemiologic and clinical studies, GAD has been associated with various role functioning impairments, medical and psychiatric comorbidity, and diminished well-being. In the National Comorbidity Survey, Kessler et al.³ compared subjects who met criteria for GAD alone, those with major depressive disorder (MDD), and those with comorbid GAD and MDD using global ratings of mental health, social, and work role functioning. They found that the role impairment associated with GAD was equivalent to the impairment demonstrated by subjects with MDD, suggesting a greater need for recognition and treatment of GAD for the public health.⁴ In another epidemiologic study, when asked about the prior 30 days, patients with GAD reported a mean 28% of work days being

affected by their symptoms, compared with a mean of 7% of work loss days for respondents without a psychiatric illness.⁵ In primary care settings, patients with GAD also have been demonstrated to have lower functioning, impaired work productivity, and higher medical utilization either alone⁶ or in combination with depression.⁷

The concept of quality of life involves not only the absence of perceived functional impairment, but also the presence of positive well-being and subjective satisfaction with health and life. Using multiple quality of life measures, Cramer et al.⁸ found that subjects who had GAD reported less self-realization, less contact with friends, and greater dissatisfaction with their well-being compared with subjects without any other psychiatric disorder or with subjects with other anxiety disorders. Stein and Heimberg⁹ found that subjects with GAD were more dissatisfied with their main activity, family life, and overall well-being, even after controlling for depressive symptoms, than were other community residents in the Ontario Mental Health Survey.

A reduction in GAD symptom severity is associated with improvements in functioning and perceived well-being; however, the 2 outcomes are only modestly related.¹⁰ Researchers have therefore recommended including quality of life measures as a separate objective in clinical research studies.^{11,12} Current treatment guidelines for GAD recommend pharmacologic interventions with serotonergic reuptake inhibitors (e.g., escitalopram, paroxetine) or serotonergic noradrenergic reuptake inhibitors (SNRIs, e.g., venlafaxine).¹³ Duloxetine is an SNRI that has previously demonstrated efficacy for major depression and diabetic peripheral neuropathic pain.^{14,15}

Recently, 3 placebo-controlled clinical trials were completed that investigated the efficacy of duloxetine for the treatment of GAD in adults. Consistent with the above recommendations, the clinical studies of duloxetine also included measures for role functioning, subjective well being, and perceived health as secondary study objectives. Two flexible-dose trials and 1 fixed-dose study were conducted independently using double-blind, placebo-controlled designs; however, the patient selection criteria, symptom severity, and functional measures used in each study were similar enough to allow side-by-side evaluation. The results of duloxetine treatment for reducing the severity of symptoms associated with GAD have been reported previously^{16–18}; the objective of the present work is to report the efficacy of duloxetine in reducing role impairments and in enhancing well-being in patients with GAD from each of the 3 studies.

METHOD

Study Designs

All 3 studies were randomized, double-blind, placebo-controlled multicenter trials. Study 1 consisted of a

1-week single-blind placebo lead-in, a 9-week double-blind acute therapy phase, and a 2-week discontinuation period. Patients were randomly assigned to receive treatment with duloxetine 60 mg/day (60 mg), duloxetine 120 mg/day (120 mg), or placebo. For the duloxetine treatment, the initial dose was 60 mg, which temporarily could be lowered to 30 mg if tolerability concerns arose, but all patients were required to be at their randomized dose by week 2. Study 1 was conducted from June 2004 to September 2005.

Study 2 consisted of a 1-week single-blind placebo lead-in phase, a 10-week double-blind acute therapy phase, and a 2-week discontinuation phase. Patients were randomly assigned to receive either duloxetine 60–120 mg/day (60–120 mg) or placebo. For the duloxetine treatment, the initial dose was 60 mg, which temporarily could be lowered to 30 mg if tolerability concerns arose, but patients had to be taking 60 mg by week 2. After titration to 60 mg/day, flexible dosing was allowed in weekly increments of 30 mg/day up to a maximum dose of 120 mg/day. Study 2 was conducted from August 2004 to June 2005.

Study 3 consisted of a 10-week acute therapy phase, followed by a 2-week discontinuation phase. Patients were randomly assigned in a 1:1:1 ratio to duloxetine 60–120 mg/day (60–120 mg), venlafaxine (75–225 mg once daily), or placebo. Duloxetine treatment was initiated at 30 mg/day for 1 week, followed by an increase to 60 mg/day. After titration to 60 mg/day, flexible dosing was allowed in weekly increments of 30 mg/day up to a maximum dose of 120 mg/day. Study 3 was conducted from October 2004 to November 2005.

For studies 2 and 3, dose increases to maximize efficacy were allowed based on investigator judgment; however, the protocol required that the dose be increased if a patient's Clinical Global Impressions-Improvement scale¹⁹ score was 3 or higher (minimal improvement, no change, or worse) during the first 4 weeks of treatment unless the patient was unable to tolerate an increased dose. A total of 2 downward dose adjustments for tolerability concerns were allowed, with a minimum allowable dose of 60 mg/day duloxetine (studies 2 and 3) or 75 mg/day venlafaxine (study 3). In accordance with the objective of this study, results from the venlafaxine treatment arm will not be reported here.

Patient Selection

Men and women ≥ 18 years of age who met criteria for GAD (diagnosed using *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition [DSM-IV]) were recruited from outpatient centers. Diagnoses were determined using the Mini International Neuropsychiatric Interview (MINI)²⁰ for the DSM-IV; interviews were conducted by either research personnel or the principal investigator. All diagnoses had to be confirmed by the

study psychiatrist through an individual psychiatric examination. Study 1 involved 42 treatment centers in 7 countries (Finland, France, Germany, South Africa, Spain, Sweden, and United States). Studies 2 and 3 were conducted independently at outpatient centers (comprising 62 separate sites) in the United States. The inclusion criteria required a GAD illness of moderate severity as defined by a Hospital Anxiety and Depression Scale²¹ anxiety subscale score ≥ 10 and a rating of ≥ 4 on the Clinical Global Impressions-Severity of Illness scale¹⁹ at both baseline and randomization. Although a diagnosis of MDD was an exclusion criterion, patients with GAD often experience secondary dysthymia. Therefore, to ensure that anxiety symptoms predominated, patients were required to have a Covi Anxiety Scale²² score ≥ 9 and no item in the Raskin Depression Scale²³ scored > 3 at baseline. The Covi Anxiety Scale score had to be greater than the Raskin Depression Scale score at visit 1.

In all 3 studies, patients were excluded for diagnostic reasons if they had any primary DSM-IV Axis I diagnosis other than GAD (including MDD) within the past 6 months; panic disorder, posttraumatic stress disorder, or an eating disorder within the past year; obsessive-compulsive disorder, bipolar disorder, psychosis, factitious disorder, or somatoform disorders during their lifetime; or a DSM-IV-defined history of alcohol or any psychoactive substance abuse/dependence within the prior 6 months. Additional key exclusion criteria were benzodiazepine use in the 2 weeks prior to randomization; serious suicide risk or Axis II pathology as assessed by a clinician; previous treatment with duloxetine; any medical illness that would contradict the use of duloxetine or venlafaxine; initiation of psychotherapy, change in intensity of psychotherapy, or other nondrug therapies from within 6 weeks prior to enrollment to study completion; treatment with a monoamine oxidase inhibitor or fluoxetine within 30 days of randomization; or uncontrolled narrow-angle glaucoma. Patients also were ineligible if their current episode of GAD had not previously responded to 2 or more adequate trials of antidepressants, benzodiazepines, or other anxiolytics.

Functional Outcome Measures

In all 3 studies, the primary functional outcome measure was the Sheehan Disability Scale (SDS).²⁴ The SDS consists of 3 domain items (work, social life, and family/home responsibility) that are rated on a 0-to-10 scale where 0 = "not at all" and 10 = "extremely" (Appendix 1). The 3 items were summed into a global functioning score to indicate overall impairment; for patients who were neither working nor in school, the mean value from the other 2 domains was imputed for the work score. The SDS was originally developed for use with anxiety patients and has been reported to have moderate to good internal reliability.²⁵ In a validation study of the SDS using primary care

patients, SDS global functioning scores ≥ 5 were associated with role impairment due to psychiatric illness.²⁶

Well-being and quality of life were assessed using the Quality of Life Enjoyment and Satisfaction Questionnaire Short Form (Q-LES-Q-SF)²⁷ and the European Quality of Life 5 Dimensions (EQ-5D).²⁸ The Q-LES-Q-SF was used in all 3 studies, but the EQ-5D was administered only in studies 1 and 2. The Q-LES-Q-SF is a 16-item questionnaire that assesses subjective enjoyment and satisfaction with various life areas, such as physical health, leisure, sexual drive, economic status, and living arrangements. Items are rated on a 5-point scale where 1 = "very poor" and 5 = "very good," and the first 14 items are summed to provide the total score, which is also converted into a percentage of the maximum possible score (70). Higher totals or percentages indicate greater enjoyment and satisfaction. Community adult normative values for the Q-LES-Q-SF have been reported as a mean total score of 58.1 or a mean percentage of the maximum score of 83%.¹⁰

The EQ-5D is a patient-rated questionnaire that consists of 5 items—mobility, self-care, usual activities, pain/discomfort, and mood—that are rated as being associated with "no, some, or extreme problems." Scores on each item are combined into a profile that is converted into an overall index reflective of health status; higher index scores indicate greater health and well-being, with 0 = "death" and 1 = "perfect health." A separate EQ-5D visual analog scale (VAS) (0–100) also was included for rating patients' perception of their global health satisfaction; higher ratings indicate greater perceived health. Community adult normative values for the EQ-5D have been reported as a mean index score of 0.86 and a mean VAS health score of 79.3.^{29,30}

Procedures

Written informed consent was obtained from each patient prior to any study procedures. Each treatment center's institutional review board approved the conduct of the study, which was developed in accordance with the ethical standards of Good Clinical Practice and the Declaration of Helsinki as revised in 2000.³¹

During baseline and screening phases, patients underwent diagnostic and clinical evaluations, a physical examination, laboratory chemistries, and an electrocardiogram. Study 1 visits were conducted at 1, 2, 4, 6, and 9 weeks of double-blind treatment. For studies 2 and 3, visits occurred at 1, 2, 4, 7, and 10 weeks of double-blind treatment. In each study, the functional outcome measures were given at baseline and at the end of the acute treatment phases or at early discontinuation visit if necessary.

Statistical Methods

Each study was designed and powered to determine treatment group differences based on the primary outcome measure of mean change from baseline to endpoint

Table 1. Patient Demographics and Clinical Characteristics at Baseline in Each Generalized Anxiety Disorder Study

Characteristic	Study 1			Study 2		Study 3	
	Duloxetine 60 mg (N = 168)	Duloxetine 120 mg (N = 170)	Placebo (N = 175)	Duloxetine 60–120 mg (N = 168)	Placebo (N = 159)	Duloxetine 60–120 mg (N = 162)	Placebo (N = 161)
Age, mean, y	43.1	44.1	44.1	42.2	41.0	40.4	41.9
Ethnicity, N							
Caucasian	163	169	173	134	124	108	113
Hispanic	0	0	1	7	12	14	19
African	1	1	1	20	21	34	25
Asian	4	0	0	7	2	5	3
Gender, N							
Female	108	123	117	103	99	104	99
Male	60	47	58	65	60	58	62
HAM-A total	25.0	25.2	25.8	22.6	23.5	25.6	25.0
SDS							
Global functioning	15.1	15.0	15.0	14.3	14.6	17.4	17.5
Work/school	4.9	5.0	4.9	4.6	4.5	5.4	5.7
Social life	5.3	5.1	5.1	4.8	5.0	6.1	5.9
Family/home responsibility	4.9	5.0	5.0	4.8	5.1	5.9	5.8
Q-LES-Q-SF							
Total score	40.6	40.7	40.6	43.8	42.4	41.1	41.2
Percent of maximum score	47.4	47.7	47.6	53.3	50.8	48.4	48.5
EQ-5D ^a							
Index	0.59	0.61	0.59	0.62	0.61		
VAS health score	55.8	59.3	55.6	69.5	64.5		

^aAdministered only in studies 1 and 2.

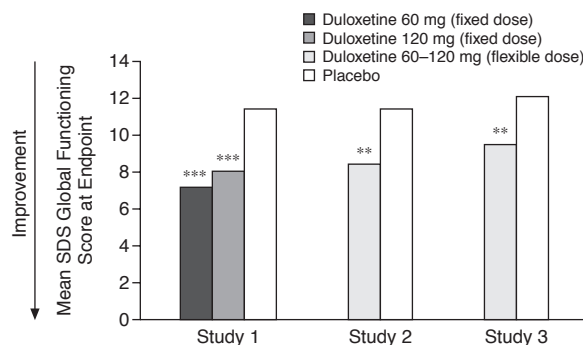
Abbreviations: EQ-5D = European Quality of Life 5 Dimensions, HAM-A = Hamilton Rating Scale for Anxiety, Q-LES-Q-SF = Quality of Life Enjoyment and Satisfaction Questionnaire Short Form, SDS = Sheehan Disability Scale, VAS = visual analog scale.

in Hamilton Rating Scale for Anxiety³² total scores. The functional outcome measures were considered secondary objectives within the trials and were therefore not the basis for the power analyses. For the functional outcome results, we analyzed each study independently using the intent-to-treat sample, which consisted of all randomized patients with at least 1 baseline and 1 post-randomization observation. Baseline was defined as the last nonmissing measurement prior to treatment randomization. Endpoint was defined as the last nonmissing postbaseline measurement (last observation carried forward).

The main functional outcome measure of interest was the mean change from baseline to endpoint on SDS global and specific domain scores; additional functional outcome measures were mean change on Q-LES-Q-SF total and maximum percent scores and on the EQ-5D index and VAS scores. Treatment group differences were examined using an analysis of covariance model with treatment and investigator as main effects and the baseline score as the covariate.

Treatment-group comparisons of baseline clinical and demographic variables were examined using χ^2 statistics for categorical variables and analysis of variance (with treatment and study as terms in the model) for continuous variables. All means referred to in the article are least-square means, which is the model-adjusted mean for the respective analysis. Statistical comparisons were based on a 2-sided significance level of .05.

Figure 1. Sheehan Disability Scale (SDS) Global Functioning Score at Endpoint by Treatment Group in 3 Placebo-Controlled Studies of Duloxetine for the Treatment of Generalized Anxiety Disorder



** $p \leq .01$, duloxetine vs. placebo.

*** $p \leq .001$, duloxetine vs. placebo.

RESULTS

Patient Characteristics

Patient demographics and illness characteristics are reported by study since each study was analyzed separately (Table 1). The majority of the patients were female with moderate to severe GAD. No significant baseline differences between the active treatment and placebo groups were observed in any of the studies. The numbers

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Table 2. Mean Changes (improvements) in Functional Outcome Measures From Baseline to Endpoint in ITT Samples From 3 Placebo-Controlled Studies of Duloxetine for Treatment of Generalized Anxiety Disorder

Measure	Study 1			Study 2		Study 3	
	Duloxetine 60 mg (N = 168)	Duloxetine 120 mg (N = 170)	Placebo (N = 175)	Duloxetine 60–120 mg (N = 168)	Placebo (N = 159)	Duloxetine 60–120 mg (N = 162)	Placebo (N = 161)
SDS							
Global functioning	−7.8***	−7.0***	−3.8	−5.8**	−3.1	−8.0**	−5.4
Work/school	−2.6***	−2.4***	−1.1	−1.8*	−1.0	−2.8**	−1.5
Social life	−2.5***	−2.4***	−1.3	−2.0**	−1.0	−2.8**	−1.8
Family/home responsibility	−2.6***	−2.3***	−1.2	−1.9*	−1.3	−2.8*	−2.0
Q-LES-Q-SF							
Total	9.0***	8.5***	4.7	5.7	4.2	9.1***	5.3
Percent of maximum score	16.2***	15.1***	8.3	10.2	7.4	16.3***	9.6
EQ-5D ^a							
Index	0.19***	0.17*	0.11	0.10	0.05		
VAS health score	16.7***	15.0**	8.8	8.0	5.4		

^aAdministered only in studies 1 and 2.

* $p \leq .05$, duloxetine compared with placebo.

** $p \leq .01$, duloxetine compared with placebo.

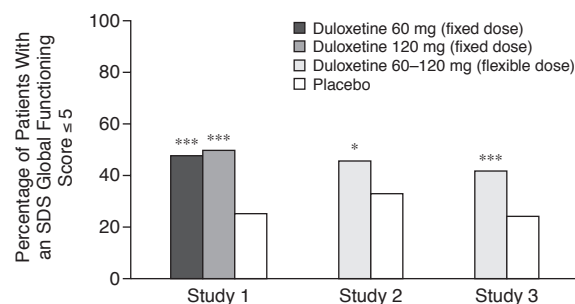
*** $p \leq .001$, duloxetine compared with placebo.

Abbreviations: EQ-5D = European Quality of Life 5 Dimensions, HAM-A = Hamilton Rating Scale for Anxiety, ITT = intent to treat, Q-LES-Q-SF = Quality of Life Enjoyment and Satisfaction Questionnaire Short Form, SDS = Sheehan Disability Scale, VAS = visual analog scale.

of patients randomized per treatment per study were as follows, with the subset numbers of patients who completed the acute therapy phase in parentheses: study 1 (fixed-dose): 60 mg duloxetine N = 168 (N = 135), 120 mg duloxetine N = 170 (N = 124), placebo N = 175 (N = 130); study 2 (flexible-dose): 60–120 mg duloxetine N = 168 (N = 93), placebo N = 159 (N = 109); and study 3 (flexible-dose): 60–120 mg duloxetine N = 162 (N = 88), placebo N = 161 (N = 99).

Role Functioning Outcomes: Sheehan Disability Scale

Mean baseline global functional impairment and specific domain scores indicated moderate role functioning impairment. In each study, duloxetine-treated patients improved significantly more in their role functioning compared with placebo-treated patients on the SDS global functioning score. The mean SDS global functioning score at endpoint for duloxetine-treated patients ranged from 7.4 to 9.5 (mild severity) compared with 11.4 to 12.1 (moderate severity) for placebo-treated patients (Figure 1). These endpoint scores represented a mean change from baseline on the SDS global functioning score of −5.8 to −8.0 for the duloxetine groups compared with −3.1 to −5.4 for the placebo groups. Similarly, in each study, patients in the duloxetine group demonstrated significantly greater improvements than patients in the placebo group across the domains of work, social life, and family/home responsibility (p values from $\leq .05$ to $\leq .001$, Table 2). At treatment endpoint, duloxetine patients were more likely to obtain an SDS global functioning score ≤ 5 , which is indicative of the normative range on the SDS for nonpsychiatric primary care patients (Figure 2). Across the studies, approximately 47%

Figure 2. Percentage of Patients With a Sheehan Disability Scale (SDS) Global Functioning Score ≤ 5 at Endpoint (normative value in nonpsychiatric primary care patients) in Each Study

* $p \leq .05$, duloxetine vs. placebo.

*** $p \leq .001$, duloxetine vs. placebo.

of duloxetine-treated patients and 28% of placebo-treated patients achieved this outcome.

Quality of Life and Well-Being

Duloxetine-treated patients reported greater improvements in their satisfaction and well-being in multiple life areas as indicated by the Q-LES-Q-SF total score in 2 of the studies (Table 2, $p \leq .001$). The mean Q-LES-Q-SF percent of maximum score at endpoint for duloxetine-treated patients ranged from 65.9% to 67.9% compared with a range of 58.5% to 60.9% for placebo-treated patients. Improvement in perceived health status was also demonstrated by the EQ-5D index and VAS health scores (Table 2). Duloxetine treatment groups experienced significantly greater improvement in index scores and VAS

health scores compared with the placebo group in study 1 ($p \leq .001$), but the difference between treatment groups was not significant in study 2 (Table 2).

DISCUSSION

The efficacy of duloxetine treatment for improving patient-reported functional outcomes for patients with GAD was independently replicated in all 3 studies. At baseline, patients with GAD were significantly impaired, as their mean baseline scores on the role functioning and quality of life measures were substantially below community norms. The consistency of these impairments across studies indicates the pervasiveness of the impact of GAD on both role functioning and life satisfaction, and these findings complement other research as well.³³ After treatment, the mean global functioning score for the duloxetine groups had fallen to mild severity, whereas the mean endpoint scores for the placebo groups remained in the moderate severity range. The improvement on the SDS global score was not only statistically significant, but also clinically meaningful. Patients treated with duloxetine were more likely to attain a global functioning score of ≤ 5 at study endpoint, and this value represents the cutoff score that differentiated impairment due to emotional problems between nonpsychiatric and psychiatric primary care patients.²⁶

Duloxetine treatment not only improved patients' abilities to carry out their roles and responsibilities, but also resulted in increased enjoyment and greater engagement with the positive attributes of well-being, such as satisfaction with social life, physical health, and self-fulfillment. In 2 of the 3 studies, duloxetine-treated patients reported greater increases in their total and percent of maximum Q-LES-Q-SF score satisfaction ratings than placebo-treated patients. At treatment endpoint, patients' scores had increased an average of almost 50% from baseline. Given that only one third of psychiatric patients score within 10% of community norms on the Q-LES-Q-SF,¹⁰ an improvement in this area is particularly encouraging.

In the domain of physical health, patients also reported an increase in their own perception of their health quality as evidenced by the EQ-5D. Within a validation study of the EQ-5D, a mean change of 0.07 on the index score was found to be the smallest value that patients reported as reflecting a true change in their health status for either better or worse.³⁴ In the duloxetine studies, this value of 0.07 was exceeded, which suggested that the differences between duloxetine and placebo treatments not only were statistically significant, but also represented a genuine increase in subjective well-being. Longer-term treatment is typically needed to maximize functional outcome for chronic illnesses, such as GAD³⁵; therefore, it is impressive that such consistent improvements in role

functioning and well-being were achieved in these acute trials.

The strength of this study is the independent replication of duloxetine intervention for improvement of role functioning and well-being in patients with GAD. Across the 3 studies, the response of over 1100 patients with primary GAD was investigated with both disease-specific functional impairment and general quality of life measures. Thus, the multiple measures used in these studies allowed separate examination of the therapeutic response for reduction of disease impact and for the enhancement of perceived health and life satisfaction.

One limitation of this current work is that the trials were of short-term duration (9–10 weeks of treatment). While functional impairments can improve and remit in acute treatment, studies with longer follow-up treatment are needed to determine the persistence of these gains. Another limitation of the study is that the patients had a primary GAD diagnosis without significant comorbidity of either depressive disorders or other anxiety disorders. Given that comorbidity is often associated with greater severity of illness, the efficacy of duloxetine on functional outcomes may differ in patients with various comorbid conditions. Effectiveness studies are needed to examine the impact of duloxetine in patient populations with multiple psychiatric and medical conditions comorbid with GAD.

In summary, GAD has been demonstrated to be an illness that is characterized not only by severity of anxiety symptoms, but also by diminished role functioning and life enjoyment. The challenge for treatment providers is not only to attend to the response of symptoms to pharmacologic interventions, but also to monitor patients' role functioning and well-being. The consistency of duloxetine's efficacy in improving role functioning across 3 short-term independent trials demonstrates its ability to impact these essential patient outcomes associated with the symptoms of GAD.

Drug names: duloxetine (Cymbalta), escitalopram (Lexapro and others), fluoxetine (Prozac and others), paroxetine (Paxil and others), venlafaxine (Effexor and others).

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Appendix 1. Clinical Report Form for the Sheehan Disability Scale^a

SHEEHAN DISABILITY SCALE

INFORMATION NOT OBTAINED ☐ 93

On each scale below, circle one number that best describes your situation now.

WORK*/SCHOOL The symptoms have disrupted your work/school work: <div style="display: flex; justify-content: space-between; margin-top: 5px;"> 012345678910 </div> <div style="display: flex; justify-content: space-between; margin-top: 5px;"> Not at AllMildlyModeratelyMarkedlyExtremely </div>	
<input type="checkbox"/> 96 I have not worked/studied at all during the past week for reasons unrelated to the disorder. <small>*Work includes paid, unpaid volunteer work or training</small>	
SOCIAL LIFE The symptoms have disrupted your social life/leisure activities: <div style="display: flex; justify-content: space-between; margin-top: 5px;"> 012345678910 </div> <div style="display: flex; justify-content: space-between; margin-top: 5px;"> Not at AllMildlyModeratelyMarkedlyExtremely </div>	
FAMILY LIFE/HOME RESPONSIBILITIES The symptoms have disrupted your family life/home responsibilities: <div style="display: flex; justify-content: space-between; margin-top: 5px;"> 012345678910 </div> <div style="display: flex; justify-content: space-between; margin-top: 5px;"> Not at AllMildlyModeratelyMarkedlyExtremely </div>	

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