ORIGINAL ARTICLE

Efficacy of Olanzapine in Acute Bipolar Mania

A Double-blind, Placebo-Controlled Study

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Background: We compared the efficacy and safety of olanzapine vs placebo for the treatment of acute bipolar mania.

Methods: Four-week, randomized, double-blind, parallel study. A total of 115 patients with a *DSM-IV* diagnosis of bipolar disorder, manic or mixed, were randomized to olanzapine, 5 to 20 mg/d (n=55), or placebo (n=60). The primary efficacy measure was the Young–Mania Rating Scale (Y-MRS) total score. Response and euthymia were defined, a priori, as at least a 50% improvement from baseline to end point and as a score of no less than 12 at end point in the Y-MRS total score, respectively. Safety was assessed using adverse events, Extrapyramidal Symptom (EPS) rating scales, laboratory values, electrocardiograms, vital signs, and weight change.

Results: Olanzapine-treated patients demonstrated a statistically significant greater mean (± SD) improvement in Y-MRS total score than placebo-treated patients (–14.8±12.5 and –8.1±12.7, respectively; $P<.001$), which was evident at the first postbaseline observation 1 week after randomization and was maintained throughout the study (last observation carried forward). Olanzapine-treated patients demonstrated a higher rate of response (65% vs 43%, respectively; $P=.02$) and euthymia (61% vs 36%, respectively; $P=.01$) than placebo-treated patients. There were no statistically significant differences in EPSs between groups. However, olanzapine-treated patients had a statistically significant greater mean (± SD) weight gain than placebo-treated patients (2.1±2.8 vs 0.45±2.3 kg, respectively) and also experienced more treatment-emergent somnolence (21 patients [38.2%] vs 5 [8.3%], respectively).

Conclusion: Olanzapine demonstrated greater efficacy than placebo in the treatment of acute bipolar mania and was generally well tolerated.

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ALTHOUGH ADVANCES have been made in the treatment of bipolar disorder, existing therapies are not always effective or are accompanied by adverse effects that lead to noncompliance. The efficacy of lithium and valproate has been established by well-designed clinical trials[1-3]; however, side effects and treatment failures are present with both drugs.[1,4] Typical antipsychotics are also used for the treatment of acute mania, although their side effect profiles are far from ideal.[5]

Olanzapine has also been used for the treatment of bipolar disorder. A 21-day, double-blind, placebo-controlled study found olanzapine to be an effective and safe treatment in acute mania.[6,7] Limitations of that trial included separation of olanzapine from placebo at week 3 of treatment, rather than earlier, as occurred in other similarly designed modern trials of valproate and lithium in acute mania.[2,3] Possible reasons for the lack of a more robust separation between drug and placebo were hypothesized to include the following: (1) too slow an increase in olanzapine dosing (ie, acute mania may require more aggressive olanzapine dosing for optimal response); (2) too liberal use of adjunctive lorazepam; (3) inclusion of first-episode patients (who showed a disproportionately high rate of response to placebo); and (4) too short a treatment period. We therefore conducted a second double-blind, placebo-controlled study to further evaluate the efficacy and safety of olanzapine in the treatment of acute bipolar mania, with special attention to the potential methodological limitations of the first trial. Specifically, we conducted a 28-day study of 115 multiple-episode patients from December 1, 1997, through February 28, 1999, that used a more aggressive olanzapine-dosing schedule but permitted less concomitant lorazepam use.

PATIENTS AND METHODS

PATIENTS

Patients, aged 18 through 70 years, with a *DSM-IV*[8] diagnosis of bipolar disorder, manic or mixed, with or without psychotic features,were eligible to be enrolled in this study. Investigators recruited patients from private practices (13 sites), inpatient and outpatient services of university-affiliated centers (10 sites), and a Veterans Affairs facility. In addition, some sites recruited patients through colleague referral, and 6 sites advertised the study in local newspapers. Diagnosis was based on clinical assessment and confirmed by results of the Structured Clinical Interview for the *DSM-IV*, Patient Version (SCID-P), administered by trained clinicians (including principal and subinvestigators [all physicians] and study personnel with appropriate clinical degrees [PhD in psychology or MSW] and experience). After having the protocol explained to them, patients provided written informed consent to participate in the study. A minimum total score of at least 20 on the Young–Mania Rating Scale (Y-MRS)[9] was required at the screening visit and on the day of randomization (baseline). At baseline, patients displayed a clinically severe symptom profile, with a mean Y-MRS score of 29.10 (range, 14-49; 1 patient was enrolled with a baseline Y-MRS total score of 14). Patients were excluded with any of the following criteria: serious, unstable medical illness; *DSM-IV* substance dependence (except nicotine or caffeine) within the past 3 months; and serious suicidal risk.

STUDY DESIGN

We conducted a 4-week, randomized, double-blind, parallel study. All psychotropic medication therapy (except benzodiazepines) was tapered during the screening period and discontinued at least 1 day before randomization. Patients were randomized to olanzapine or placebo, in a 1:1 ratio. Computer-generated codes were used to create randomized blocks of clinical trial material kits before study start-up. Each block contained 2 olanzapine and 2 placebo kits. Each kit contained all clinical trial material used by a patient throughout the 4-week study. Personnel at the site assigned a patient the next available kit. Patients were required to be hospitalized for a minimum of 1 week after randomization and were allowed to leave the hospital after that time only if their Clinical Global Impressions–Bipolar Version of Severity of Illness (CGI-BP)[10] mania score was no greater than 3 (mild) and they had at least a 50% reduction in their Y-MRS score. Psychotherapy was permitted, but not controlled for, during the study.

The starting dose of olanzapine was 15 mg/d. After the first day of therapy, the daily dose could be adjusted upward or downward, as clinically indicated, by 5-mg increments or decrements within the allowed dose range of 5 to 20 mg/d. Modal dose was defined as the dose that the patient was prescribed for the most number of days. The mean (± SD) modal and median modal doses of olanzapine were 16.4±4.2 mg/d and 20 mg/d, respectively.

Concomitant use of lorazepam was allowed during double-blind therapy up to 2 mg/d for the first 4 days of treatment and thereafter by up to 1 mg/d for the next 6 days. Lorazepam was not permitted beyond the initial 10 days after randomization. Benztropine mesylate was permitted to treat extrapyramidal symptoms (EPSs) up to a maximum of 2 mg/d throughout the course of the study. However, the use of benztropine as prophylaxis was not allowed.

ASSESSMENT

Severity of illness and psychopathologic features were measured by the following rating scales: Y-MRS, Hamilton Psychiatric Rating Scale for Depression–21 Item (HAMD-21),[11] CGI-BP, and the Positive and Negative Syndrome Scale (PANSS).[12] Safety was monitored by assessing adverse events, including EPSs (parkinsonism as measured by the Simpson-

RESULTS

PATIENTS

A total of 115 patients were enrolled in the study. Mean age was 39 years; 80.0% were white, and 50.0% were men. Based on *DSM-IV* criteria using the SCID-P, 42.6% of the patients were in a mixed episode and 55.7% were experiencing psychotic features. Of those 64 patients with psychotic features, 47 (73.4%) were experiencing mood-congruent psychotic features. There were no statistically significant differences in any demographic or illness characteristics between treatment groups. Historical illness characteristics and previous medication use and response are presented in **Table 1**. A statistically significant greater number of patients randomized to the placebo-treated group had a history of previous response to valproate than in the olanzapine-treated group ($P=.02$, Fisher exact test). Frequency of recorded medication use at the beginning of the screening period included benzodiazepines and/or hypnotics (68.7%), anticonvulsants (23.5%), typical antipsychotics (16.5%), anticholinergics (14.8%), lithium (9.6%), atypical antipsychotics (7.8%), and antidepressants (4.3%). Study completion and discontinuation summary details are presented in **Table 2**. Frequency of study completion was significantly greater ($P=.04$; Fisher exact test) in the olanzapine group (61.8%) compared with the placebo group (41.7%). There were no significant differences between groups regarding reasons for discontinuation.

EFFICACY

The primary efficacy measure was the change in Y-MRS score from baseline to end point (LOCF), after up to 4 weeks of acute double-blind treatment. The olanzapine group experienced a 6.65-point greater mean improvement in Y-MRS total score compared with the placebo group ($F_{1,86}=12.47$; $P<.001$). The impact of initial severity on LOCF change in Y-MRS score was not significantly different between the treatment groups

Angus scale[13] and akathisia as measured by the Barnes Akathisia scale[14]), laboratory values, electrocardiograms (ECGs), vital signs, and weight change. All adverse events reported by patients during the study were recorded and coded using the Clinical Symbol and Thesaurus for Adverse Event Terminology (COSTART) dictionary.

The primary efficacy variable, as defined by the protocol, was the reduction from baseline of the Y-MRS total score after 4 weeks of therapy. Response and euthymia were defined, a priori, as at least a 50% improvement from baseline to end point and as a score of no greater than 12 at end point in the Y-MRS total score, respectively. Interrater reliability assessments with the Y-MRS were conducted before study initiation by measuring the correlation of each rater with the groupwise median score of each item. Raters who did not achieve a correlation of at least 0.80 were not allowed to rate patients in this study.

To further investigate the effect of olanzapine on depressive symptoms, additional analyses were performed. The mean change from baseline to end point on the HAMD-21 score was calculated for all randomized patients and in a subset of patients who presented with moderate to severe depressive symptoms (HAMD-21 score, ≥20 at baseline). In addition, the proportion of patients experiencing a clinically detectable worsening in depressive symptoms at any time during acute therapy was assessed. A worsening of at least 3 points on the HAMD-21 score was used as a definition of clinically detectable worsening of depressive symptoms.

STATISTICAL METHODS

Patient data were analyzed on an intent-to-treat basis. For analysis of last observation carried forward (LOCF) mean change from baseline to end point, patients with a baseline and at least 1 postbaseline measurement were included in the analysis. Four placebo-treated patients and 1 olanzapine-treated patient did not have a postbaseline measure and were excluded from all efficacy analyses. Total scores from rating scales were derived from the individual items; if any single item was missing, the total score was treated as missing.

Continuous efficacy and safety parameters were evaluated using analysis of variance. The models generally included terms for the fixed effects of treatment, investigator, and treatment × investigator interaction. Investigators with fewer than 2 patients per treatment group were pooled as specified in the protocol. Analyses of subgroups included a term for treatment only, owing to sparse data. The LOCF change in the Y-MRS total score was also compared between treatment groups using the baseline Y-MRS score as a covariate to examine change in relation to initial severity; investigator was not included in this model. An examination of the effect of treatment over time was conducted on the Y-MRS total score using a likelihood-based repeated-measures analysis. The Y-MRS total score at each postbaseline visit was used as the response variable, and the baseline Y-MRS total score was used as a covariate. This analysis evaluated treatment and investigator effects along with the treatment × investigator and treatment × visit interactions using an unstructured covariance matrix for the within-patient error as specified in the protocol. In addition, an examination of the therapy difference stratified by treatment time for the Y-MRS total score was performed using a pattern-mixture analysis.[15] A mixed-effects model was used, including the main effects for therapy, visit, treatment time, investigator, and the interaction effects for therapy × investigator, therapy × treatment time, therapy × visit, investigator × visit, and therapy × treatment time × visit. Visit and dropout time were random effects; therapy and investigator were fixed effects in the model. The Kruskal-Wallis test was used to compare treatments for each of the individual items of the Y-MRS. The Fisher exact test was used to analyze treatment effects for categorical efficacy and safety parameters. All cited *P* values are 2-tailed, with a significance level of .05 as specified in the protocol. Unless otherwise indicated, data are given as mean±SD.

($F_{1,106}$=2.19; *P*=.14; **Figure 1**). In addition, olanzapine-treated patients demonstrated a statistically significant greater mean improvement on the CGI-BP severity of mania, CGI-BP severity of overall bipolar illness, and PANSS total and positive scores compared with placebo-treated patients (**Table 3**). Efficacy subgroup analyses were also performed based on the presence or absence of psychotic features and between patients in a manic or a mixed episode. Olanzapine-treated patients exhibited no statistically significant difference in the mean change in Y-MRS scores for any of these subtypes. For olanzapine-treated patients, the antimanic effect in patients with and without psychotic features was similar.

WEEKLY ANALYSIS

The olanzapine group consistently showed greater LOCF mean improvement on Y-MRS total score; HAMD-21 total score; CGI-BP mania, depression, and overall bipolar illness scores; and PANSS total, positive, and negative scores compared with the placebo group at each week. Olanzapine-treated patients demonstrated a statistically significant greater improvement in the mean change from baseline in the Y-MRS total score at the first postbaseline observation at week 1 ($F_{1,86}$=4.78; *P*=.03) (**Figure 2**). This statistically significant separation from the placebo group was maintained during the 4-week study. In addition, treatment differences were statistically significant at each week for CGI-BP severity of mania and overall bipolar illness scores and PANSS total and positive scores.

An examination of treatment effect over time using a repeated-measures analysis was conducted on the Y-MRS total score as specified in the protocol. Olanzapine demonstrated a statistically significant greater treatment effect compared with placebo ($F_{1,207}$=10.47; *P*=.002). The superior treatment effect of olanzapine was evident at week 1, and the superiority was maintained over time (**Table 4**).

A post hoc examination of the effect of dropout time on treatment result was performed. Patients who dropped

Table 1. Patient and Illness Characteristics

Characteristic	Placebo Group		Olanzapine Group		P
	Sample Size	Mean (SD)	Sample Size	Mean (SD)	
Age, y	60	39.0 (10.1)	55	38.3 (10.7)	.52*
Current episode, d	60	38.2 (21.1)	55	31.0 (28.0)	.74*
Age at onset of illness, y	59	21.1 (9.3)	55	23.2 (9.5)	.25*
No. of hospital admissions for bipolar I disorder	59	1.3 (1.8)	55	0.76 (1.0)	.07*
No. of previous episodes of mania, lifetime	49	19.9 (45.3)	44	16.1 (33.0)	.35*
No. of previous episodes of mania, previous 12 mo	60	3.2 (5.6)	55	2.3 (3.5)	.24*
No. of previous episodes of depression, lifetime	49	13.0 (24.8)	43	9.9 (13.6)	.08*
No. of previous episodes of depression, previous 12 mo	59	1.5 (2.4)	55	2.0 (3.0)	.43*
No. of previous mixed episodes, lifetime	49	9.8 (30.1)	43	7.5 (17.9)	.51*
No. of previous mixed episodes, previous 12 mo	59	1.8 (3.7)	54	2.7 (7.7)	.69*
	Placebo Group		Olanzapine Group		
	Sample Size	No. (%)	Sample Size	No. (%)	P
Male	60	30 (50.0)	55	27 (49.1)	>.99†
White	60	52 (86.7)	55	40 (72.7)	.10†
Psychotic	60	30 (50.0)	55	34 (61.8)	.26†
Current episode mixed state	60	25 (41.7)	55	24 (43.6)	.85†
Rapid cyclers‡	60	20 (33.3)	55	25 (45.5)	.25†
Lifetime diagnosis of substance abuse	60	37 (61.7)	55	30 (54.5)	.46†
Previous medication use					
Lithium	60	41 (68.3)	55	42 (76.4)	.41*
Valproate	60	31 (51.7)	55	32 (58.2)	.57*
Antipsychotic	60	35 (58.3)	55	39 (70.9)	.18*
Patients exposed to any of the above 3 medications	60	47 (78.3)	55	49 (89.1)	.14*
Patients exposed to all	60	21 (35.0)	55	22 (40.0)	.70*
Previous medication response§					
Lithium	41	22 (53.7)	42	18 (42.9)	.38
Valproate	31	21 (67.7)	32	11 (34.4)	.01
Antipsychotic	35	25 (71.4)	39	27 (69.2)	>.99
Patients exposed to any of the above 3 medications	47	36 (76.6)	49	35 (71.4)	.65

*Means were analyzed using a type III sum of squares analysis of variance.
†Frequencies were analyzed using Fisher exact test.
‡Defined as any patient with 4 or more manic, depressed, or mixed episodes in the previous year.
§Defined based on physician assessment.

Table 2. Patient Disposition

Variable	Treatment Group, No. (%)		P*
	Placebo (n = 60)	Olanzapine (n = 55)	
Completed	25 (41.7)	34 (61.8)	.04
Discontinued	35 (58.3)	21 (38.2)	
Adverse event	1 (1.7)	2 (3.6)	.61
Lack of efficacy	23 (38.3)	15 (27.3)	.24
Unavailable for follow-up	3 (5.0)	1 (1.8)	.62
Patient decision	5 (8.3)	3 (5.5)	.72
Physician decision	3 (5.0)	0	.25

*Frequencies analyzed using Fisher exact test.

out at week 1 had a similar response regardless of therapy. Placebo-treated patients who dropped out at weeks 2 or 3 had minimal response. On the other hand, olanzapine-treated patients who dropped out at week 2 or 3 did have some improvement (**Table 5**). To estimate the therapy difference stratified by treatment time, a pattern-mixture analysis[15] was performed. The results of this analysis were similar to the results of the LOCF and repeated-measures visitwise analyses. The main difference was that in this analysis, there was no statistical separation at week 1 (**Table 6**).

In the analysis of the individual items of the Y-MRS, olanzapine-treated patients exhibited a statistically significant greater mean improvement than placebo-treated patients on the following items: elevated mood (χ^2_1=9.11; P=.003), sleep (χ^2_1=12.33; P<.001), language-thought disorder (χ^2_1=4.66; P=.03), content (χ^2_1=8.48; P=.004), and disruptive-aggressive behavior (χ^2_1=6.64; P=.01).

RESPONSE AND EUTHYMIA

Responders were classified as patients with an improvement of 50% or more in Y-MRS total score from baseline to end point (LOCF). The olanzapine group demonstrated a significantly greater response rate compared with the placebo group (64.8% vs 42.9%, respectively; Fisher exact test, P=.02). Patients achieving a Y-MRS total score of at least 12 at the final visit of the acute phase were considered to be euthymic. A statistically significant greater number of olanzapine- than placebo-treated patients met the euthymia criterion for mania (61.1% vs 35.7%, respectively; Fisher exact test, P=.01).

IMPROVEMENT IN DEPRESSIVE SYMPTOMS AND LACK OF DEPRESSOGENIC EFFECTS

The analysis of change in HAMD-21 score from baseline to end point for all randomized patients showed a similar improvement in olanzapine- and placebo-treated patients (–7.83±7.79 vs –4.45±6.95, respectively; $F_{1,86}=2.91$; $P=.09$). In patients who presented with moderate to severe depressive symptoms (HAMD-21 score, ≥20 at baseline), a statistically significant greater improvement in olanzapine- compared with placebo-treated patients was observed on the change in HAMD-21 score from baseline to end point (–12.29±8.79 vs –6.81±8.43, respectively; $F_{1,40}=4.24$; $P=.05$) (**Figure 3**). Using a 6-item subscale score of the HAMD-21 to reflect a core mood factor[16,17] (items 1, 2, and 7-10,), there was no significant difference in change from baseline to end point when comparing all olanzapine- and placebo-treated patients (–3.06±4.24 vs –2.04±3.69, respectively; $F_{1,86}=0.30$; $P=.59$), or in the subset of patients who presented with moderate to severe depressive symptoms at baseline (–5.52±4.72 vs –3.19±4.34, respectively; $F_{1,40}=2.78$; $P=.10$).

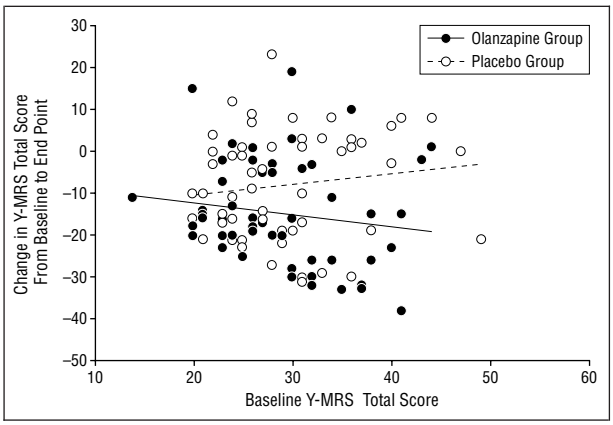

Figure 1. *Scatterplot of Young–Mania Rating Scale (Y-MRS) last observation carried forward (LOCF) change from baseline vs baseline severity. Analysis of covariance using baseline Y-MRS score as a covariate indicated no significant difference between olanzapine (n=54) and placebo (n=56) groups in the impact of initial severity on baseline to end point LOCF change in the Y-MRS ($F_{1,106}=2.19$; P=.14; baseline× therapy interaction). Solid and dotted lines indicate regression trend lines.*

The effect of olanzapine on induction of depressive symptoms was also investigated. A worsening in the HAMD-21 score of at least 3 points was used as a definition of a clinically detectable worsening. The percentage of olanzapine-treated patients who experienced a clinically detectable worsening in depressive symptoms at any time during double-blind therapy was similar to that seen in placebo-treated patients (11.1% vs 17.9%, respectively; $P=.42$, Fisher exact test).

BENZODIAZEPINE USE

The categorical rates of patients who received at least 1 dose of benzodiazepine were 36 (65.5%) of 55 patients and 44 (73.3%) of 60 patients in the olanzapine and placebo groups, respectively. The between-treatment group difference in categorical use was not statistically significant $P=.42$, Fisher exact test). Of those patients treated with a benzodiazepine, placebo-treated patients had a higher mean daily dose (0.74 mg/d) compared with olanzapine-treated patients (0.55 mg/d) ($F_{1,55}=1.06$; $P=.31$).

SAFETY

Adverse Events

Adverse events that originally occurred or worsened in severity during double-blind therapy were considered treatment emergent. One patient in the placebo group (agitation) and 2 patients in the olanzapine group (unintended pregnancy and rash) discontinued treatment because of an adverse event. The only treatment-emergent event with a statistically significant more frequent occurrence in the olanzapine group compared with the placebo group was somnolence ($P<.001$, Fisher exact test) (**Table 7**). The only treatment-emergent event with a statistically significant more frequent occurrence in the placebo group was agitation ($P=.03$, Fisher exact test).

Table 3. Change in the Severity-of-Illness Scores From Baseline to End Point*

	Placebo Group (n = 56)		Olanzapine Group (n = 54)			
Measure	Baseline	Change From Baseline	Baseline	Change From Baseline	$F_{1,86}$	*P*†
Y-MRS total	29.43 (6.77)	–8.13 (12.72)	28.76 (6.72)	–14.78 (12.49)	12.47	<.001
HAMD-21 total	16.16 (9.49)	–4.45 (6.95)	17.33 (9.24)	–7.83 (7.79)	2.91	.09
PANSS total	72.61 (21.68)	–7.43 (19.73)	76.74 (25.72)	–21.19 (23.73)	13.25	<.001
PANSS positive	20.54 (6.38)	–2.96 (6.61)	21.72 (6.91)	–7.76 (7.89)	15.94	<.001
PANSS negative	13.29 (6.15)	–0.63 (4.41)	14.46 (7.32)	–2.78 (6.50)	3.21	.08
CGI-BP severity of mania	4.80 (0.82)	–0.88 (1.54)	4.78 (0.77)	–1.83 (1.45)	15.02	<.001
CGI-BP severity of depression	2.61 (1.57)	–0.45 (1.26)	2.89 (1.53)	–0.74 (1.32)	0.82	.37
CGI severity of overall bipolar illness	4.77 (0.89)	–0.73 (1.43)	4.78 (0.77)	–1.72 (1.46)	16.20	<.001

**A total of 4 placebo-treated patients and 1 olanzapine-treated patient had no postbaseline scores for any of the efficacy measures and were excluded from all efficacy analyses. No statistically significant differences were observed between baseline values for any measure. Y-MRS indicates Young–Mania Rating Scale; HAMD-21, Hamilton Psychiatric Rating Scale for Depression–21 Item; PANSS, Positive and Negative Symptoms Scale; and CGI-BP, Clinical Global Impressions–Bipolar Version of Severity of Illness. Data are given as mean (SD).*

†Change from baseline to end point means were analyzed using an F test from analysis of variance model, which included terms for treatment, investigator, and interaction.

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