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Change in Psychosocial Functioning and Quality of Life of Patients With Body Dysmorphic Disorder Treated With Fluoxetine: A Placebo-Controlled Study

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Abstract

In a 12-week placebo-controlled study of fluoxetine in the treatment of body dysmorphic disorder, the authors investigated change in psychosocial functioning and mental health-related quality of life in 60 subjects. The subjects were assessed with the LIFE-RIFT (a measure of impaired functioning), Social and Occupational Functioning Scale (SOFAS), and Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) before and after receiving fluoxetine or placebo. At baseline, the patients had impaired psychosocial functioning and markedly poor mental health-related quality of life. Compared to placebo, fluoxetine was associated with significantly greater improvement in LIFE-RIFT and SOFAS scores and with improvement on the mental health subscale of the SF-36 that approached significance. Decrease in the severity of body dysmorphic disorder, as measured by the Yale-Brown Obsessive Compulsive Scale Modified for Body Dysmorphic Disorder, was significantly correlated with improvement in functioning and quality of life.

Bphobia, consists of a distressing or impairing preocody dysmorphic disorder, also known as dysmorphocupation with a nonexistent or slight defect in appearance (e.g., “thinning” hair, a “large” nose, or “severe” acne). Body dysmorphic disorder is relatively common and is associated with significant impairment in social and occupational/academic functioning.[1–3] Patients with body dysmorphic disorder have high lifetime rates of psychiatric hospitalization (48%), suicidal ideation (45%–82%), and suicide attempts (22%–24%).[4,5] Death by suicide of patients with body dysmorphic disorder has been reported in both psychiatric[6] and dermatology[7,8] settings.

Although a majority of patients with body dysmorphic disorder receive surgery and other nonpsychiatric medical treatment (e.g., dermatologic treatment), such treatments usually appear to be ineffective and may even make body dysmorphic disorder symptoms worse.[4,9] In contrast, emerging research indicates that serotonin-reuptake inhibitors[10] and cognitive behavior therapy[11] are often effective for treatment of body dysmorphic disorder. However, most treatment research has focused on change in body dysmorphic disorder symptoms, and the important question of whether quality of life and psychosocial functioning improve with treatment has received little investigation. In a randomized, double-blind crossover trial (N = 29 patients), clomipramine was associated with significantly greater improvement on the Schneier Disability Profile, compared with desipramine.[12] In a small open-label study of

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citalopram in treatment of body dysmorphic disorder (N = 15), improvement was found in psychosocial functioning and quality of life, as assessed by the LIFE-RIFT (Range of Impaired Functioning Tool) and the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36).[13] To our knowledge, no other studies have investigated treatment-related change in psychosocial functioning and quality of life in body dysmorphic disorder.

Evaluating the effects of treatment on functioning and quality of life is increasingly considered to be as important as evaluation of symptom reduction.[14] We investigated medication treatment effects on functioning and quality of life in what is to our knowledge the only placebo-controlled study of patients with body dysmorphic disorder to date.[15] We hypothesized that, compared with placebo, fluoxetine would be associated with greater improvement in psychosocial functioning and mental health-related quality of life.

METHOD

The study's methods are described in detail elsewhere.[15] In brief, 67 outpatients with DSM-IV body dysmorphic disorder or its delusional variant (delusional disorder, somatic type) were randomly assigned to the placebo group or the fluoxetine group in a 12-week double-blind, parallel-group study. Psychosocial functioning and mental health-related quality of life (see definitions later in this section) were assessed at study baseline and endpoint. Results are presented for the 60 subjects for whom both baseline and endpoint data on functioning and quality of life were available (41 [68.3%] female patients; mean age = 32.2 years [SD = 10.5]).

The study inclusion and exclusion criteria were standard for a pharmacotherapy efficacy trial and are reported in detail elsewhere.[15] In brief, inclusion criteria were the presence of DSM-IV body dysmorphic disorder or its delusional variant currently and for at least 6 months, age 18–65 years, score of ≥24 on the Yale-Brown Obsessive Compulsive Scale Modified for Body Dysmorphic Disorder (BDD-YBOCS),[16] and a score of at least moderate on the Clinical Global Impression Scale for body dysmorphic disorder. Exclusion criteria included current or lifetime bipolar disorder or psychotic disorder (other than delusional body dysmorphic disorder), alcohol or other substance dependence or abuse in the past 6 months, a recent suicide attempt or clinically significant suicidal ideation, use of psychoactive medication within 2 weeks of the 1-week placebo lead-in period or initiation of psychotherapy within 4 months of placebo lead-in, and significant or unstable medical illness. An institutional review board approved the study and the informed consent documents. After a thorough description of the study, voluntary written informed consent was obtained from the patients.

Subjects received fluoxetine or pill placebo equivalent for 12 weeks starting at 20 mg/day and reaching a maximum dose of 80 mg/day if tolerated. The mean fluoxetine dose at study endpoint was 77.7 mg/day (SD = 8.0, range = 40–80); the fluoxetine equivalent in the placebo group was 76.0 mg/day (SD = 13.1, range = 20–80). No other psychotropic medications were taken except 0.5–2.0 gm/day of chloral hydrate up to three times a week, if needed, for insomnia. Psychotherapy of any type was not initiated during the study. The primary outcome measure was the BDD-YBOCS, a reliable and valid 12-item, semi-structured, clinician-rated measure of current severity of body dysmorphic disorder.[16] The 17-item Hamilton Depression Rating Scale[17] was used to assess current severity of depressive symptoms. Psychosocial functioning and quality of life were assessed at baseline and endpoint with the following scales:

1. Social and Occupational Functioning Scale (SOFAS),[18] a global clinician-rated measure of functioning. Scores range from 0 to 100, with lower scores denoting poorer functioning.
2. LIFE-RIFT (Range of Impaired Functioning Tool),[19] a reliable and valid semistructured clinician-rated measure of functional impairment. The LIFE-RIFT

consists of items from the Longitudinal Interval Follow-up Evaluation (LIFE).[20, 21] The LIFE-RIFT has a total score and individual domain scores for the following areas of functioning: household duties, work, recreation, relationships with family, relationships with friends, schoolwork, and global life satisfaction (the satisfaction item is patient rated). Scores in each domain range from 1 to 6, with higher scores indicating poorer functioning; scores ≥2 reflect impaired functioning. We report results for the total score, which is based on all individual domain scores, and for each individual domain except school functioning (because only 13 subjects were in school). Ratings were done for the average level of functioning during the previous 2 weeks.

3. SF-36,[22] a reliable, valid, and widely used self-report measure of mental and physical health-related quality of life. The subscales that best assess mental health-related quality of life are: 1) mental health (a measure of psychological distress and well-being that is the most valid SF-36 measure of mental health-related quality of life), 2) social functioning, and 3) role (e.g., work) limitations due to emotional problems. The mental health subscale primarily assesses subjective sense of well-being, whereas the social functioning and role limitations subscales primarily assess disability and reflect the World Health Organization definition of disability.[23] Subscale scores range from 0 to 100; lower scores indicate poorer quality of life. Baseline SF-36 data for the first 42 subjects were previously reported.[24]

All data were double entered to ensure accuracy. Published norms for the SF-36 are available for the general U.S. population (N = 2,474) and for patients with major depression and/or dysthymia (i.e., patients meeting NIMH Diagnostic Interview Schedule criteria for major depression and/or dysthymia [N = 502]).[22] The mean scores of the body dysmorphic disorder patients in this study were compared to these norms. To determine by how many standard deviation units scores for the body dysmorphic disorder patients differed from these norms, norm means were subtracted from the mean body dysmorphic disorder score and divided by the standard deviation of the norm.

All tests of differences in outcome variables between the fluoxetine group and the placebo group used an intention-to-treat analysis plan that included all patients randomly assigned to the treatment groups, with the last observation carried forward for dropouts. Analyses of group differences were performed by using analysis of covariance (ANCOVA), with baseline scores as the covariate. Based on the ANCOVA, effect sizes (Cohen's d) were also calculated. For the individual functioning domains, only effect sizes were calculated to minimize type I error. A d of 0.20 is considered small, 0.50 is medium, and 0.80 is large.[25] Pearson's product-moment correlation was used to examine correlations between variables. All tests were two-tailed; an alpha level of 0.05 was used to determine statistical significance.

RESULTS

Patients' mean scores on the SOFAS, LIFE-RIFT, and SF-36 before treatment reflected impaired functioning in all domains and very poor mental health-related quality of life (See Table 1). On the SF-36, body dysmorphic disorder patients' mean baseline scores were markedly poorer than those for the general U.S. population: −2.1 standard deviation units poorer on the mental health subscale, −2.0 standard deviation units poorer on social functioning, and −1.6 standard deviation units poorer on role limitations due to emotional health. Body dysmorphic disorder patients' mean baseline SF-36 scores were also poorer than the norms for patients with major depression and/or dysthymia: −0.44 standard deviation units poorer for mental health, −0.73 standard deviation units poorer for social functioning, and −0.23 standard deviation units poorer for role limitations. At baseline, more severe body dysmorphic disorder symptoms, as measured by the BDD-YBOCS, were significantly

correlated with poorer scores on the SF-36 mental health ($r = -0.60$, $df = 57$, $p<0.001$) and social functioning ($r = -0.58$, $df = 57$, $p<0.001$) subscales, as well as the SOFAS ($r = -0.57$, $df = 58$, $p<0.001$) and LIFE-RIFT total score ($r = 0.51$, $df = 58$, $p<0.001$).

Fluoxetine was more effective than placebo in reducing body dysmorphic disorder symptoms as assessed by the BDD-YBOCS (from 31.5 [SD = 5.6] to 21.0 [SD = 9.8] in the fluoxetine group versus 30.8 [SD = 5.8] to 26.9 [SD = 9.5] in the placebo group; $F = 16.5$, $df = 1, 64$, $p<0.001$), as previously reported.[15] In addition, as previously reported,[15] Hamilton depression scale scores improved significantly more with fluoxetine than with placebo (from 19.8 [SD = 8.3] to 12.5 [SD = 10.1] in the fluoxetine group versus 21.5 [SD = 8.1] to 19.5 [SD = 10.5] in the placebo group; $F = 7.5$, $df = 1, 64$, $p<0.01$). The effect of fluoxetine on body dysmorphic disorder symptoms was significant even after covarying for the main and interactive effects of baseline depressive symptoms ($F = 5.4$, $df = 1, 64$, $p = 0.02$).

Regarding change in psychosocial functioning with treatment (see Table 1), fluoxetine was associated with significantly greater improvement than placebo on the SOFAS and LIFE-RIFT total score. For individual LIFE-RIFT domains, effect sizes ranged from small for relationships with friends to medium-large for work, with many effect sizes in the medium range. On the SF-36 mental health subscale, fluoxetine was associated with greater improvement than placebo, but the difference only approached significance. There were no significant group differences on the other two SF-36 subscales. In a post hoc analysis, however, fluoxetine responders improved significantly more than fluoxetine nonresponders on both the SF-36 mental health subscale ($F = 4.6$, $df = 1, 26$, $p = 0.04$) and the SF-36 social functioning subscale ($F = 8.6$, $df = 1, 26$, $p = 0.007$). Fluoxetine responders improved more than fluoxetine nonresponders on the SF-36 role limitations subscale, but the difference only approached significance ($F = 3.9$, $df = 1, 25$, $p = 0.06$).

For all 60 subjects, decrease in severity of body dysmorphic disorder was significantly correlated with improvement on all measures of functioning and quality of life (SOFAS: $r = -0.39$, $df = 58$, $p = 0.002$; LIFE-RIFT total score: $r = 0.73$, $df = 58$, $p<0.001$; SF-36 mental health subscale: $r = -0.33$, $df = 57$, $p = 0.01$; SF-36 social functioning subscale: $r = -0.48$, $df = 57$, $p<0.001$; and SF-36 role limitations subscale: $r = -0.44$, $df = 55$, $p = 0.001$).

DISCUSSION

This study found that patients with body dysmorphic disorder have pervasive impairment in functioning and poor mental health-related quality of life and that these patients improved significantly more with fluoxetine than placebo in these areas, as measured by the SOFAS and LIFE-RIFT, although not by the SF-36. However, fluoxetine responders improved significantly more than fluoxetine nonresponders on two mental health SF-36 subscales and showed more improvement than fluoxetine nonresponders on a third mental health subscale, although the difference only approached significance. In addition, improvement in functioning and quality of life was highly correlated with improvement in body dysmorphic disorder symptoms on all scales.

At baseline, the mean SOFAS score indicated moderate difficulty in psychosocial functioning,[18] and the LIFE-RIFT mean scores were in the impaired range in all functioning domains. The SF-36 mental health subscales indicated that patients had notably high levels of distress, very poor social functioning, and marked curtailment of role performance by emotional problems.

It is notable that psychosocial functioning as assessed by the SOFAS and LIFE-RIFT improved significantly more with fluoxetine than placebo after only 12 weeks of treatment. This finding is similar to results from acute pharmacotherapy studies of other disorders, such as depression.[26] After 12 weeks of treatment, the mean LIFE-RIFT scores in the fluoxetine group were

generally in the range of satisfactory functioning to mildly impaired functioning. The mean SOFAS score in the fluoxetine group at study endpoint (mean = 71.1 [SD = 17.8]) approached the low end of the normal range. These improvements were similar to those in a small open-label study of citalopram in body dysmorphic disorder.[13] On the other hand, despite this significant improvement, patients on average were not functioning at a high or very high level. (Similarly, core body dysmorphic disorder symptoms usually improve only partly with treatment.[10,15]) Because some improvements in functioning—such as getting a job, beginning to date, or starting school—can take time to accomplish after symptoms improve, functioning may have improved further in a longer-term treatment study.

On the SF-36, improvement was less marked. Although fluoxetine responders improved significantly more than fluoxetine nonresponders on two SF-36 subscales, fluoxetine was differentiated from placebo only on the mental health subscale at a level approaching significance. However, the effect size obtained on this subscale was close to medium. Thus, subjective well-being (assessed by the mental health subscale) improved more than disability (assessed by the other two subscales). A possible explanation for the lack of statistically significant differences between the fluoxetine and placebo groups is the small number of subjects, which limited power. To detect a substantial difference between intervention and control treatments on quality of life measures such as the SF-36, larger sample sizes are generally needed.[27] Furthermore, the SF-36 was designed as a survey instrument rather than a measure of treatment-related change in quality of life, and it may be relatively insensitive to treatment effects (M.H. Rapaport, personal communication, 2003). In addition, more than 12 weeks may be needed for significant improvements to occur in mental health-related quality of life. On all three SF-36 subscales, the fluoxetine-treated patients, although improved compared with baseline measures, were still impaired after 12 weeks of treatment, with scores that ranged from 1.0 to 1.3 standard deviation units poorer than scores for the general U.S. population. Compared to published SF-36 norms for patients with major depression and/or dysthymia,[22] the posttreatment scores of the body dysmorphic disorder patients who received fluoxetine ranged from 0.5 standard deviation units better (on mental health) to −0.09 standard deviation units poorer (on social functioning). The mean posttreatment SF-36 mental health sub-scale scores of the fluoxetine group were also poorer than posttreatment scores on that instrument in other 12-week pharmacotherapy trials, including studies of treatment of double depression or chronic major depression,[26] depression in a primary care setting,[28] and posttraumatic stress disorder.[29]

This study has several strengths, including the fact that it is, to our knowledge, the only placebo-controlled study of medication treatment for body dysmorphic disorder and the largest treatment study of body dysmorphic disorder to date. Patients were carefully assessed with standard assessments of functioning and quality of life. In addition, only one small previous study of body dysmorphic disorder has reported on multiple functioning domains by using a standard measure or on change in these domains and in quality of life with treatment.[13]

The study also has several limitations. Functioning and quality of life were assessed in an acute treatment study and might have improved further with longer-term treatment, as in some pharmacotherapy studies of disorders such as depression[30] and posttraumatic stress disorder.[29] In addition, change in functioning and quality of life was assessed only at the end of treatment, so we could not determine the time course of improvement and its temporal relationship to body dysmorphic disorder symptom improvement. Furthermore, the number of subjects was relatively small, which limited power to detect differences between treatment groups.

Another limitation is that the study was a standard treatment efficacy study: patients had to agree to participate in a medication study, and they met strict inclusion and exclusion criteria.

For example, they had to be relatively physically healthy and could not have bipolar disorder or current substance dependence or abuse. Patients who were highly suicidal or needed inpatient treatment were excluded, as were those with relatively mild body dysmorphic disorder. Thus, it is unclear how representative the patients were of the larger population of treatment-seeking individuals with body dysmorphic disorder. A previous study of axis I comorbidity in 293 individuals with body dysmorphic disorder (which included patients who participated in the present study) found that pharmacotherapy study participants were somewhat less impaired than non-participants who had a clinical consultation.[31] Thus, participants in the present study may have had somewhat better functioning and quality of life than treatment-seeking patients with body dysmorphic disorder who have not participated in a placebo-controlled medication study. On the other hand, because the patients in the present study were seeking treatment, their functioning and quality of life may be poorer than that of nonclinical samples, although this question has not been studied.

Because functioning and quality of life are critically important components of treatment efficacy, further studies are needed to confirm our findings and to determine how generalizable our results are to other body dysmorphic disorder patients. Studies that use other measures of functioning and quality of life are also needed. It would be beneficial for both pharmacotherapy and psychosocial treatment studies to focus on treatment-related change in functioning and quality of life; to date, they have assessed primarily symptom change. Finally, the finding of residual impairment after treatment in this study underscores the importance of developing more effective treatments for body dysmorphic disorder.

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TABLE 1

Scores on Measures of Psychosocial Functioning and Quality of Life of Patients With Body Dysmorphic Disorder at Baseline and Endpoint in a 12-Week Placebo-Controlled Trial of Fluoxetine

	Baseline				Endpoint							
	Fluoxetine Group (N = 31)		Placebo Group (N = 29)		Fluoxetine Group (N = 31)		Placebo Group (N = 29)		Analysis			
Measure	Mean	SD	Mean	SD	Mean	SD	Mean	SD	F	df	p	Effect Size[a]
Social and Occupational Functioning												
Scale score[b]	56.4	9.1	55.8	9.2	71.1	17.8	60.0	15.1	8.5	1, 57	.005	.37
LIFE-RIFT score[c]												
Total	12.7	2.5	13.6	2.7	9.6	3.6	12.6	3.3	9.4	1, 57	.003	.42
Household duties	3.1	0.9	3.4	1.3	2.3	1.0	3.2	1.3				.38
Work	3.5	1.1	3.7	1.2	2.2	0.9	3.3	1.3				.63
Recreation	2.9	1.0	3.0	1.1	2.2	1.2	3.1	1.2				.49
Relationships with family	2.6	0.9	2.8	1.0	1.9	0.7	2.7	1.1				.40
Relationships with friends	2.7	1.2	2.5	1.2	2.3	1.2	2.5	1.2				.19
Satisfaction	3.3	0.7	3.6	0.7	2.4	1.1	3.2	1.1				.33
Medical Outcomes Study 36-Item Short-Form Health Survey subscale score												
Mental health	36.8	16.5	37.2	16.0	56.6	21.2	47.5	21.3	3.9	1, 56	.06	.40
Social functioning	39.2	24.9	35.0	21.9	54.7	31.8	52.1	27.1	0.0	1, 56	.98	.01
Role limits-emotional	25.0	29.6	33.3	41.8	44.8	43.0	43.7	39.9	0.1	1, 54	.79	.09

[a] Effect size of .20 is small, .50 is medium, and .80 is large.

[b] A score of 50–60 reflects moderate impairment in functioning (e.g., few friends, conflicts with peers or coworkers).

[c] Total score is based on all individual items; individual item scores range from 1 to 6, with a score of ≥2 indicating impairment.